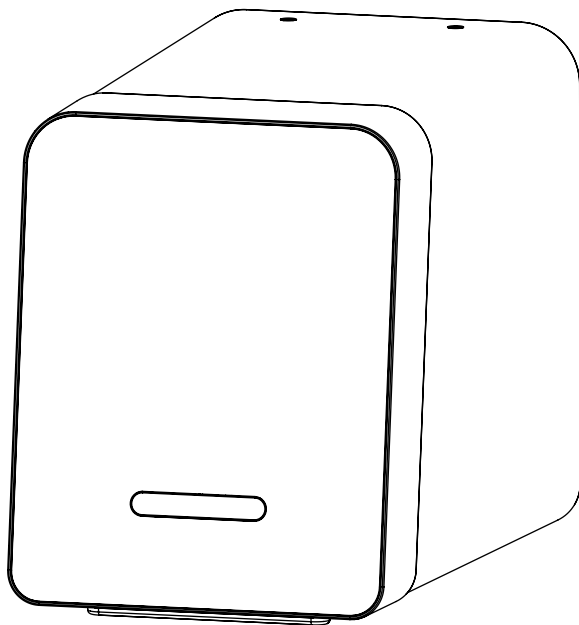


CE



Free Scan Dental Imaging Plate Scanner Operation Instruction

Please read the instruction carefully before operating the instrument

Guilin Woodpecker Medical Instrument Co., Ltd.

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Preface

Thank you for purchasing the dental imaging plate scanner produced by Guilin Woodpecker Medical Instrument Co., Ltd., a high-tech enterprise, integrating research and development, production, sales of dental products, with a perfect quality assurance system. To ensure the safe operation of instrument in the right way, please read the whole instruction carefully before starting operation.

1 Product Introduction

1.1 Introduction

Features of the instrument:

- 1) Ultra-high image resolution provides physicians with clearer diagnostic images;
- 2) High quality user interface makes shooting and reading easier;
- 3) High fidelity image storage and transmission, easy to refer to and follow-up diagnosis;
- 4) Fast reliable scanning processing provides excellent user experience.

1.2 Model

Free Scan

1.3 Configurations

See the packing list for detailed instrument configurations.

1.4 Software title and version

PC software: Ai-Dental V1

Embedded software: Free Scan V1

1.5 Structure and composition

The product consists of host unit, IP imaging plates, power adapters, disposable protective bags and protection cards for IP imaging plates, and image management software, etc.

1.6 Applicable scope

This product is used to scan latent image information of IP imaging plate to form digital dental X-ray images, and to browse, process and read images.

1.7 Contraindication

Use with caution in pregnant women and children

1.8 Safety classification of instrument

1. Classified by operation mode: Intermittent loading and

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continuous operation.

2. Classified by anti-electric shock proof type: It belongs to Class II.

3. Classified by anti-electric shock proof degree: None application.

4. Degree of protection against liquid intake: Common device (IP21)

5. Safety degree when used with flammable anesthetic gas mixed with air or with oxygen or nitrous oxide: It should not be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide

1.9 Main technical parameters

1.9.1 Grid power input: 100-240Vac, 50/60HZ,1.1A

1.9.2 Main unit power input: DC 15V 3.2A

1.9.3 Model of IP imaging plate: 0、1、2、3

1.9.4 Threshold contrast: It can distinguish all four holes of 1.0mm, 1.5mm, 2.0mm and 2.5mm

1.9.5 Image uniformity < 2%

1.9.6 Effective imaging area

Specification	Maximum size (mm)	
	X direction	Y direction
0	21	32
1	23	39
2	30	40
3	26	53

1.9.7 Class 1 laser product, in accordance with GB 7247.1-2012/ICE 60825-1:2007, in accordance with EU Regulations on Medical Devices 2017/745 EU.

1.9.8 Specification: 280*165*210mm

1.9.9 Weight : 5.2KG

1.10 Operating environment

Ambient temperature: 5°C ~ 40°C

Relative humidity: 30% ~ 75%

Atmospheric pressure: 70kPa ~ 106kPa

2 Product installation and function description

2.1 Diagram of complete instrument

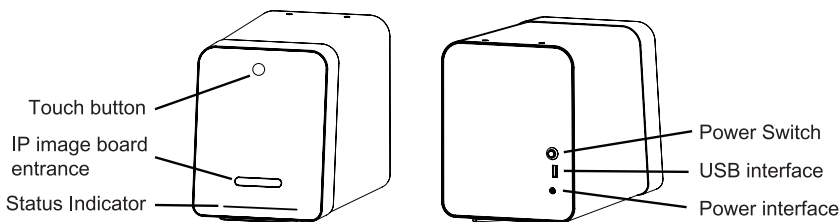


Figure 1 Diagram of dental imaging plate scanner (The left is front, the right is back)

2.2 Fitting installation

2.2.1 Installation area.

Remove all components from the packing box, as shown in Table 1, see packing list for details. Be careful not to drop or damage instrument.

Table 1

Sequence No.	Name	Quantity
1	Power adapter	1 pc
2	IP imaging plate	4 pcs
3	IP imaging plate protective bag	1 box
4	IP imaging plate protection card	4 boxes
5	Power line	1 pc
6	USB cable	1 pc

2.2.2 Installation of power adapter

Take out the power adapter and power lines from the package box and connect them as shown in Figure 2.

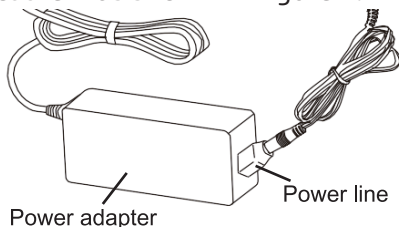


Figure 2

- [Note] 1. Use only the power adapter and power lines delivered with the device.
 2. The power adapter is provided by Dongguan Shilong Fuhua Electronics Co., Ltd., the model is UES48.

2.3 ON/OFF

2.3.1 ON/OFF the Imaging Plate Scanner

1. Turn on the machine: connect the power adapter to the device, press the power button for 1 second to turn the device on, and then the touch button and progress indicator on the device panel will light up.

2. Turn off the machine: press the power switch to turn the device off, and then the touch button and progress indicator on the device panel will be off. If the device is not operated for a long time, disconnect the power adapter from the device.

2.3.2 ON/OFF the computer

1. Turn on the computer: Press the computer's power switch to turn the computer on.

2. Turn off the computer: close the Ai-Dental software after saving the data and "select the turn off the computer" option in the Start menu

2.4 Installation

2.4.1 PC configuration requirements

When using a dental imaging plate scanner, you must ensure that the computer and its peripherals are free of any use restrictions that might cause any personal injuries. Besides, the computer system must meet the following configuration requirements:

Windows®:	Recommended configuration
Operating system	Windows® 7 , Windows® 8 , Windows® 10
Processor	Main frequency 3.0GHz , 4 cores
Memory	8 GB or above
Hard disk	500GB or above
USB port	4 high-speed USB 2.0 ports
Display panel	NVIDIA GT710
USB chip	Intel or NEC® /RENESAS®
Display resolution	1920*1080 or above

2.4.2 Compatibility with dental X-ray radiation devices

The dental imaging plate scanner is compatible with dental X-ray radiation devices that meet the regulatory standards on the market.

2.4.3 Software installation

1. The software installation package is in the USB flash drive. Insert the USB flash drive into the computer interface and double-click to run the installation program, as shown in Figure 3.

Ai-Dental-woodpecker-V1.0.10-setup.exe

Figure 3

2. Select the installation language, as shown in Figure 4.

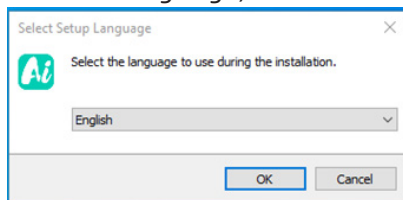


Figure 4

3. After the installation program is started, click the "Browse" button and select the installation path. After the path is selected, click the "Next" button, as shown in Figure 5:

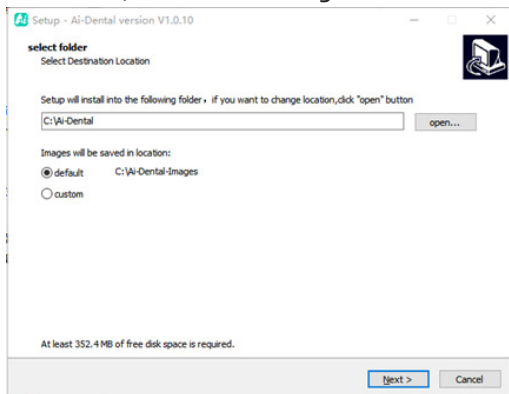


Figure 5

4. Read the software license agreement and click "I agree to this agreement", click "Next" to continue the installation, if you do not agree to this agreement, click "Cancel" to exit the installation program, as shown in Figure 6.



Figure 6

5. Select components: The user checks the checkboxes of corresponding components as required. After selecting the components, click "Next" button, as shown in Figure 7:

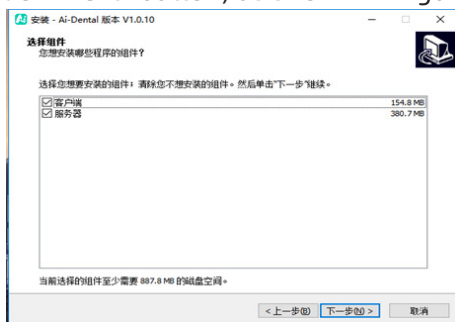


Figure 7

6. Set whether to create a shortcut and boot, and click "Next" button after completion, as shown in Figure 8:

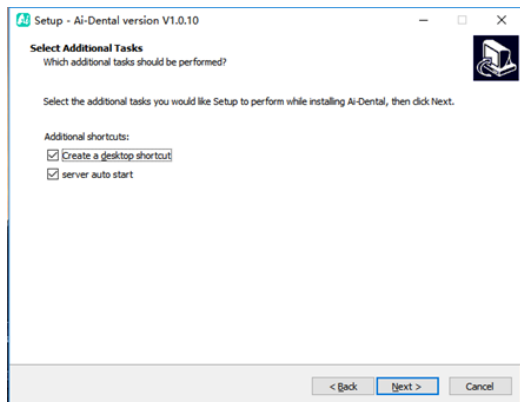


Figure 8

7. Click "Install" button, as shown in Figure 9:

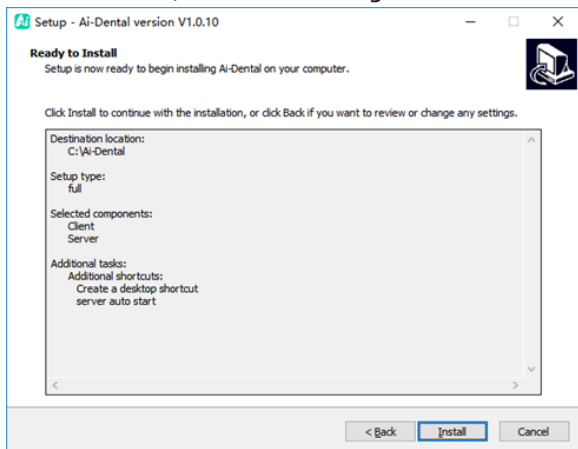


Figure 9

8. The program starts automatic installation, and then the user can wait till the installation is complete, as shown in Figure 10:

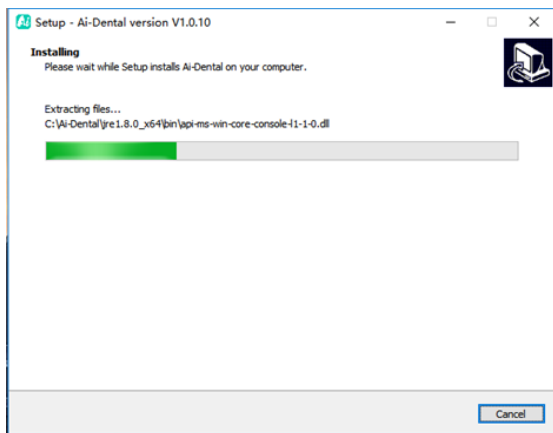


Figure 10

9. After software installation is complete, click "Finish", as shown in Figure 11:

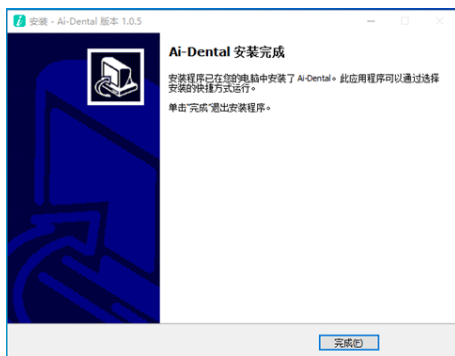


Figure 11

2.5 Communication Connection

Computer is connected to main unit of device by USB connection to carry out data transmission and processing.

2.6 Description of Network Security

2.6.1 Operating environment

(1) Recommended hardware and software configuration

Configure hardware and software based on 2.3.1 PC Configuration Requirements.

(2) Network conditions

Network environment: With a LAN, the client and server are on the same LAN.

Network type: 100 MB or above wireless LAN or Ethernet.

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2.6.2 Security Software

AI-Dental software supports common security software, such as 360 Security Guard. There is no limit to the software version, as long as it keeps the computer system secure.

2.6.3 Data and device (system) interface

Communication Protocol: USB2.0 interface serial port communication

Storage format: Images can be stored in DCM, PNG, JPG, JPEG , BMP.

2.6.4 User Access Control Mechanism

When the software enables login, the user must be identified and authenticated (at least the user name and password must be verified) to obtain different permissions. The permissions are divided into permissions of the administrator and common users. The administrator has the permission to add users, and all users have the permission to add, modify, and access patient data, etc.

2.6.5 Relevant requirements on software environment and security software update

The security of AI-Dental will not be affected when the software environment and security software are being updated.

3 Operating instruction

3.1 Preparation for X-ray photography

1 Start the image management software on the image workstation to create a new patient file or open an existing patient file.

2 Take out the IP imaging plate of the required size from the storage box.

Caution: natural or scattered x-rays may have IP imaging plates exposed before their normal use.

Warning: Risk of cross infection. Ensure that you always pay attention to the necessary health protection measures when handling IP imaging plates, protection cards and disposable protective bags of IP imaging plates to reduce the potential risk of cross infection.

3 Insert the IP imaging plate into the hard protection card in the disposable protective bag. The black side of the IP imaging plate marked with the logo must correspond to the white side printed with the logo on the protection card. More importantly, the blue side of the IP image board must correspond to the black side of

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the disposable protective bag of IP image plate.

4 Remove the covering strip from the sealing tape and press the adhesive tape with your thumb and forefinger to ensure that the disposable protective bag of IP imaging plate is fully sealed.

3.2 Get an X-ray image

Caution: ① Before entering the patient's mouth, please use a disinfecting towel or a cotton lint free cloth sprayed with disinfectant to disinfect the disposable protective bag of IP imaging plate.

② Wear protective gloves when placing the disposable protective bag of IP imaging plate into patient's mouth.

1 A sealed protective bag containing an IP imaging plate is placed in the patient's mouth parallel to the longitudinal axis of the teeth. The back of protective bag (black side) must face the X-ray radiation device.

2 Select an appropriate exposure value for the dental X-ray radiation device.

3 Move the dental X-ray device toward the mouth of patient. Ensure that the light cone of dental X-ray radiation device is perpendicular to the IP imaging plate.

4 After image acquisition, remove the sealed protective bag containing IP imaging plate from the patient's mouth.

Caution: Risk of infection. Wear protective gloves when removing the sealed protective bag from the patient's mouth.

Warning: Risk of infection. Clean and disinfect protective bags before opening them. Clean and disinfect protective bags with a disinfectant towel or lint free cloth sprayed with disinfectant. Then remove the protective gloves. Disinfect and wash hands.

5 Remove the adhesive tape and open the disposable protective bag of IP imaging plate.

6 Take out the hard protective card containing IP imaging plate from the protective bag.

7 Keep the IP imaging plate in the hard protective card until it is ready to be inserted into the scanning device. Pay special attention not to touch the IP imaging plate or expose it to ambient light.

Caution: The disposable protective bag and protective card of IP imaging plate are disposable consumables which should not be reused. Any reuse of disposable medical consumables can lead to the risk of iatrogenic infection of pathogenic microorganisms

and accidents related to the safety supervision of medical devices.

3.3 Read IP imaging plate

1. Operate the computer and click the scan button on Ai-Dental software, and the device automatically pushes out the tray for placing IP imaging plate.

2. Place the IP imaging plate on the tray and click the touch button of the device.

3. After scanning, the image will be displayed on the computer, and the device will automatically push out the tray.

4. Take out the IP imaging plate from the tray and put it into the storage box.

Note: When pushing in or out the tray of dental imaging plate scanner, do not put your fingers on the tray to avoid squeezing your fingers.

3.4 Erase IP imaging plate

After being read, the IP imaging plate is automatically erased before falling into the storage bin of dental imaging plate scanner. However, it is necessary to erase the imaging plate for the following cases, including that the IP imaging plate is being used for the first time or has been stored for more than 24 hours or has been stored in a dark room, or the data of image fault has not been erased from the dental imaging plate scanner.

3.5 Software operation instruction

3.5.1 Login system

Double-click Ai-Dental-Server to start the server. Then the server is successfully started, as shown in Figure 13.

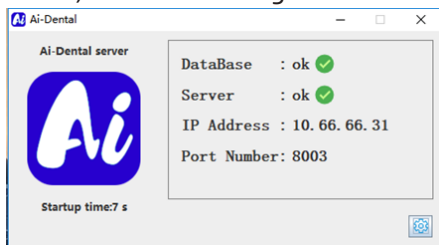


Figure 13

2. Double-click Ai-Dental-Client to start the software and enter the software login interface, as shown in Figure 14.

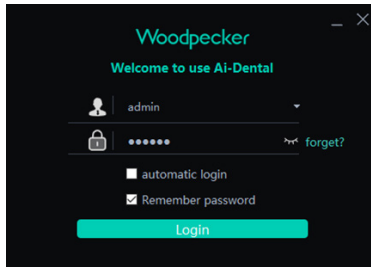


Figure 14

3. Enter the user name and password and click the login button to log in to the main interface, as shown in Figure 15.

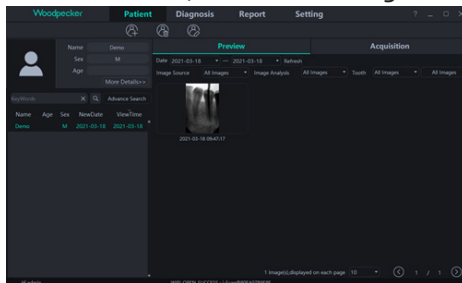


Figure 15

1. When using the software for the first time, you will not be provided with user name or password, as shown in Figure 16. Click "Free registration" to register the administrator.

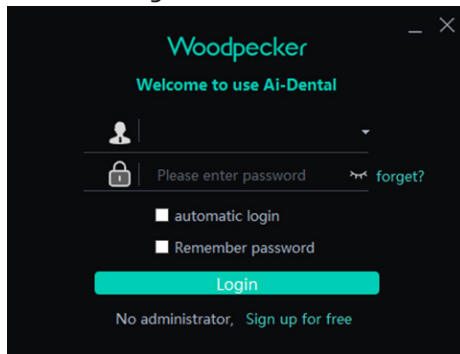


Figure 16

5. As shown in Figure 17, enter the user name, password, and confirm password and other information, and click "Add" to register successfully. Enter the user name and password on the login interface to log in to the main interface of the software.

Note: Items marked with "*" are mandatory.

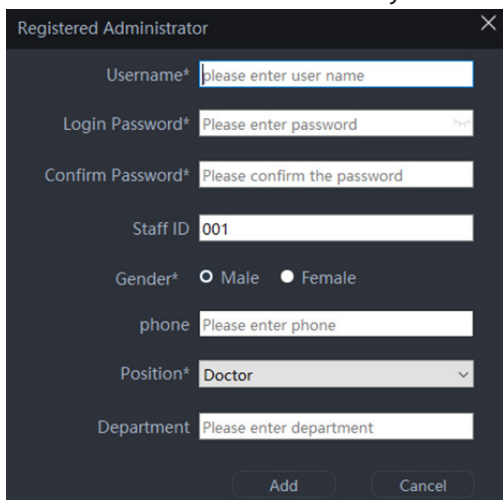


Figure 17

The administrator account provides user management functions that common users do not have, such as creating, deleting, modifying, and searching users, etc.

3.5.2 Patient module

1 Add, delete and modify patient information

(1) As shown in figure 18 patient interface, from left to right are buttons to add, delete and modify patients. Click the button of "Add patient", enter information, and click OK to add a patient. If the patient information needs to be modified, click the button of "Modify patient" to make modification of patient information, click OK to complete the modification. If the patient information needs to be deleted, click the button of "Delete patient", wait for 3 seconds, and click OK to complete deletion.



Figure 18

2 Patient information interface

(1) Select the patient from the patient list, as shown in Figure 19, the patient information is displayed in the patient information interface. Click "More details" to view the patient details.

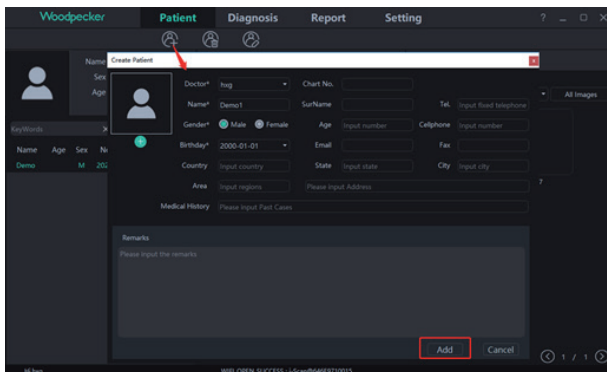


Figure 19

(2) Patient search interface

Enter the patient information in the search bar, click “Advanced search”, enter or select the creation time, age range, gender, doctor and other information, click the search button, you can query the specified patient. To view only the patients created by the current user, select current user from doctor’s options, as shown in Figure 20.

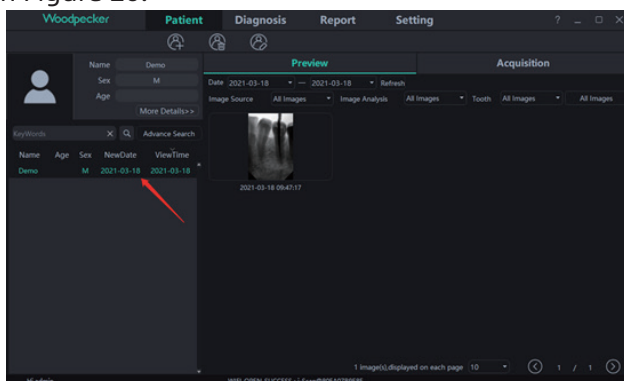


Figure 20

3. Patient information acquisition

(1) Click the acquisition button to enter the image acquisition interface. Connect the Free Scan device to the computer USB interface, select the type of “Free Scan” device. After the Free Scan device is successfully connected, the device name will be displayed in the drop-down box below. Click to open and the device will be ready to and begin to collect images. At this time, a dynamic picture is displayed on the lower part of the software, as

shown in Figure 21. After completing image collection, the device transfers them to the software to save them, and the device returns to no load status.

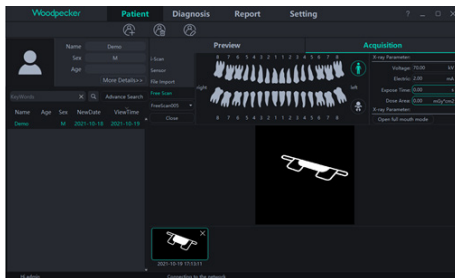


Figure 21

(2) After entering the patient interface of the software, click the collection button, select the device type of "File import", and click "Import" to enter the interface for selecting images. PNG, JPG, JPEG, BMP, DCM and other formats can be imported into the software, as shown in Figure 22. After selecting images, click "OK" to enter the interface for importing images, as shown in FIG. 23. The target patient and shooting time can be selected for each image, and click "OK" to save the image for the specified patient.

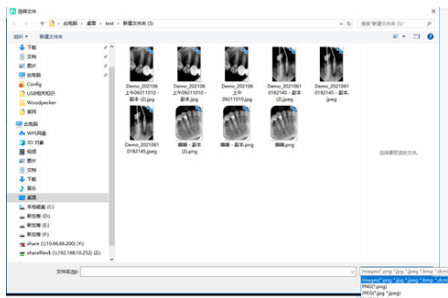


Figure 22

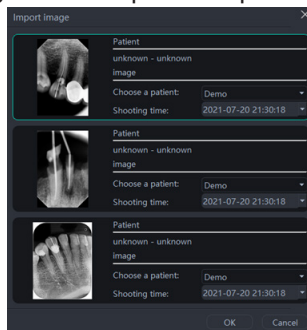


Figure 23

In the process of image collection, failures might occur in saving images. In this case, there is a symbol indicating failure in saving image in the lower right corner of the image, and the image can be exported to local and saved again by right-clicking, as shown in Figures 24 and 25

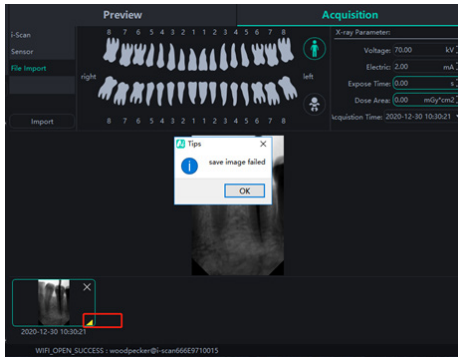


Figure 24

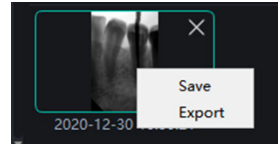


Figure 25

4. Image preview

Click the preview button to view the collected image, select an image, click the right mouse button, and select "Export" to export the image to the local, select "Information" to view the image information. Select "Delete", and confirm to delete, the image will be deleted. Double-click the image to enter the diagnostic interface. For deleting or exporting several images, you can click the "Multiple selection" button to select the images you want to process, and then export or delete them, as shown in Figures 26 and 27

Image preview interface has the function of screening images by time, source, analysis, tooth shape, and all images, etc. Click the "Refresh" button, and the software will synchronize and display the latest image data of patients in the image list. Below the image list, the following contents will be displayed, including the current number of patient images, the number of images displayed on each page, the sequence number of current page and the total number of pages, etc. Select the drop-down box option to select the number of images displayed on each page, and view images on different pages by selecting the upper or lower pages.

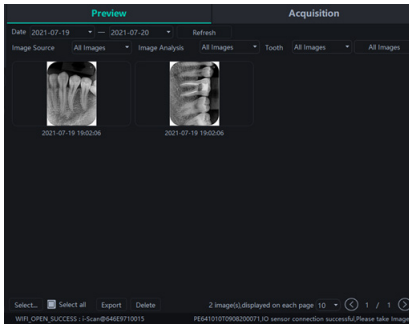


Figure 26

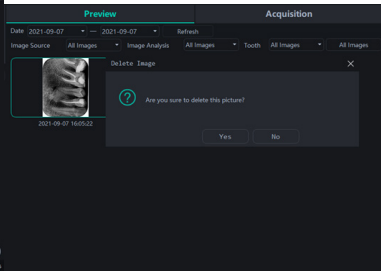


Figure 27

3.5.3 Diagnosis module

Click the diagnostic button to enter the diagnostic module.

Click the "Image" on the left to select an image to be processed. There are image processing tools on the right part of the diagnostic interface, such as display, image correction, measurement, view, enhancement, sharpening, bar chart, annotation, etc. Hover the mouse over the image processing tool to display the corresponding function. Select the image processing tool and adjust the image to a result with satisfactory quality. In the enhancement class, click the High Definition (HD) button, the image will be enhanced; click again, the enhancement will be cancelled.

Use image processing tools to adjust image quality. Click the "Add temporary state button" to save the image quality at this point. Select the temporary state in the drop-down box to reproduce the image.

Above the processed image, there are some icons with functions of deleting, exporting image information, which are similar to corresponding functions of the patient module. When multiple images are selected for processing, click the "Clear" button to close all.

Mouse wheel scroll up and down to achieve image zoom; hold the right mouse button to move up to increase contrast, down to reduce contrast, left to reduce brightness, right to increase brightness.

Select an image, click the linear measurement (Angle measurement) in the measurement class, click the start point by the left mouse button, move the mouse, click the end point by the left mouse button, and click the right mouse button to end the

measurement. The measurement line will be displayed on the image, and the corresponding annotation of the measurement line will be displayed in the annotation class, as shown in figure 28. The accuracy of straight line measurement is 0.1mm, and the accuracy of angle measurement is 0.1° .

The measured values may be inaccurate if the image is collected using file import or TWAIN. But the measured values can be calibrated by the measurement calibration function. Select the measurement line, enter its actual length in the measurement type input box, and click the modify button to conduct calibration.

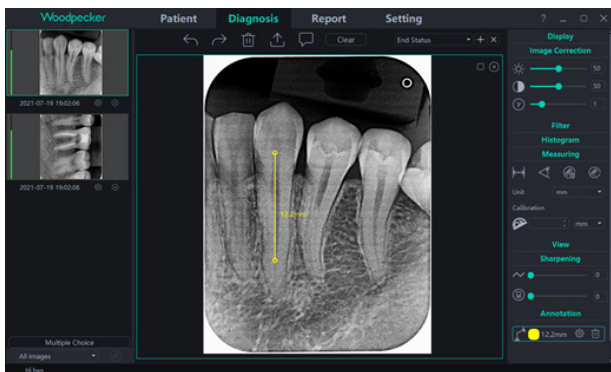


Figure 28

3.5.4 Report module

Click the report button to enter the report module, as shown in Figure 29

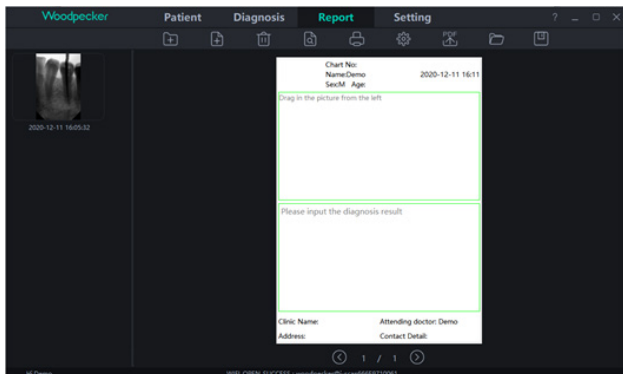


Figure 29

(1) Click the "New Report" button to create a new report

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template, drag an image to the image box from the left, enter the diagnosis result in the text box, etc. If more pages are needed, click "Add Page" to add a page to the report.

(2) After finishing report writing, click the "Save to server" button to save it to the server. Whenever you want to view the report, click "Open the report", select the report you want to view, and click to open and view it. Click the "Export to PDF" button to export the report locally.

3.5.5 Module Setup

Click the "Setup" button to enter the setup module.

1 Basic setup

Click the "Basic Setup" button to enter the basic setup page, click the log out button to return to the login interface. Click the language drop-down box to select the software language, click the tooth shape drop-down box to select the tooth shape code, as shown in Figure 30.

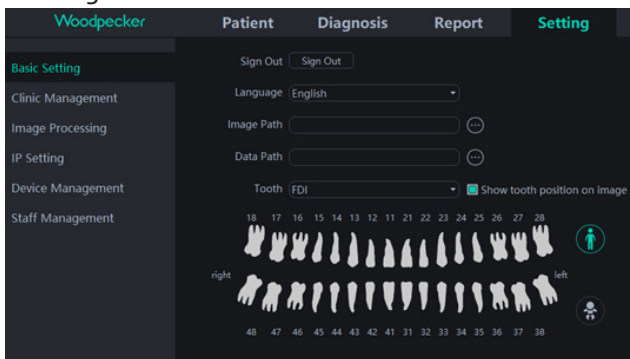


Figure 30

2 Clinic management

Click "Clinic management" to enter the clinic management interface where you can enter the related clinic information, as shown in Figure 31.

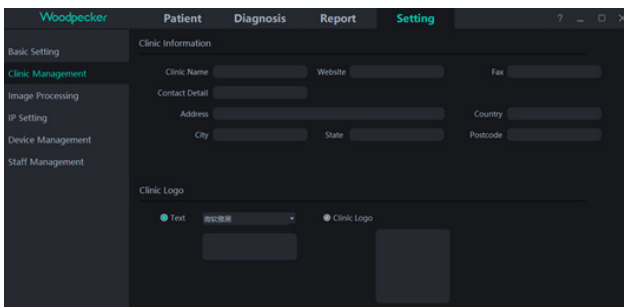


Figure 31

3 Image processing

Click the image processing button to enter the image processing interface, check HD, select in-port HD, and the collected image will be automatically initialized and HD processed; select in-port refinement, the collected image will be automatically initialized and refined.

Click the “Set up” button to set the initial color of measurement line in the diagnostic module, as shown in Figure 32.

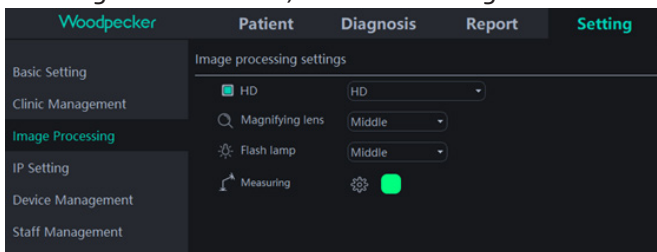


Figure 32

4 IP setting

Click the IP setting button, enter the IP setting interface, enter the IP address, port number, and click “Connect to test” to view the test result; click “Modify”, you can switch the connected server, it needs to restart the software at this time, as shown in Figure 33.

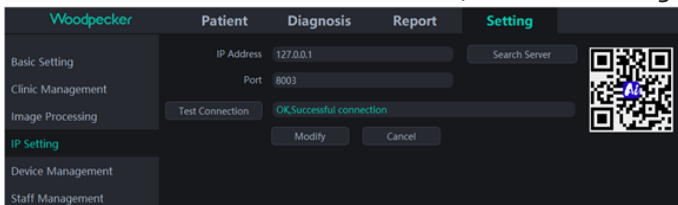


Figure 33

5 Staff management

Only log in the administrator account of software, and the "Staff Management" button will appear in the setting module. Click the "Staff Management" button to enter the staff management interface, as shown in Figure 34.

The staff management interface has functions of adding, deleting, modifying and querying users. Click "Add user", enter user name, password, confirm password and other information to complete addition, as shown in Figure 35. Enter a user name in the search bar to search for a specified user. Double-click the staff information bar to query the details of user.

When the administrator forgets the login password, open the server interface and click "Set" button -> Password -> check "Show Password" to view the administrator password, as shown in Figure 36. If an ordinary user forgets the login password, double-click the staff information bar and the staff information interface will pop up. Hold down the password view button, the password input box will display the employee's password, as shown in Figure 37. The issue of forgetting the password can also be solved by changing the employee's password.

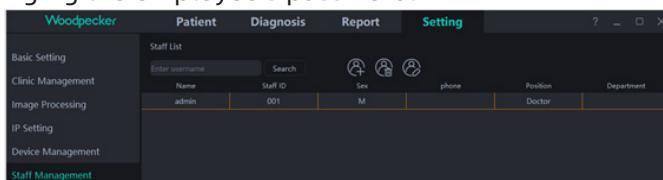
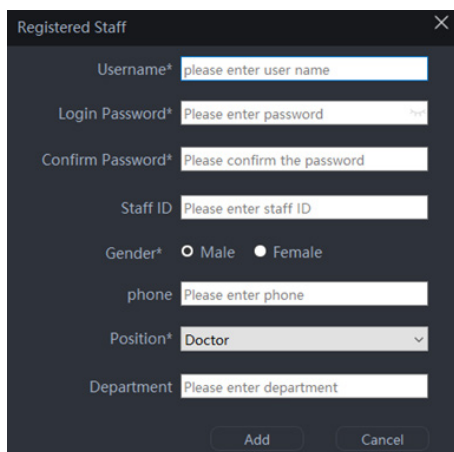


Figure 34



Registered Staff

Username*

Login Password*

Confirm Password*

Staff ID

Gender* Male Female

phone

Position*

Department

Figure 35

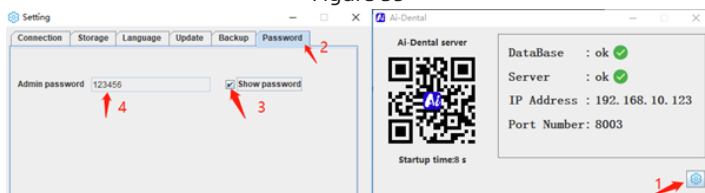
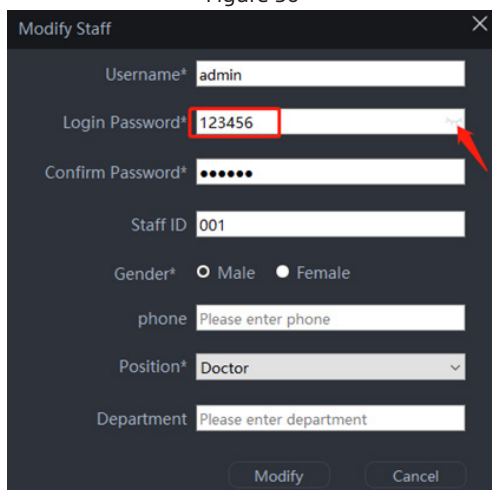


Figure 36



Modify Staff

Username*

Login Password*

Confirm Password*

Staff ID

Gender* Male Female

phone

Position*

Department

Figure 37

3.5.6 Help document

<https://stomshop.pro/>

Log in to the main screen of the software and click "? " in the upper right corner. There are Ai-Dental instructions, AI-Dental App instructions, operating instructions for i-Scan dental imaging plates, solutions for frequently asked questions and other online help documents. In addition, click "About Ai-Dental" to view the software version, as shown in Figure 38



图 38

3.5.7 Software upgrading

The software is with the function of automatic updating. If the computer is installed with the Ai - Dental server, when the software becomes upgradeable, the computer will pop up whether to upgrade. Click "Yes" to start upgrading, as shown in figure 39, and click "Finish" after the upgrading, as shown in Figure 40. Connect all clients to the server, a 10s countdown will be received after starting, and the software will shut down automatically after 10s, then the software will start the upgrading. Click "No", the software is not upgraded temporarily.

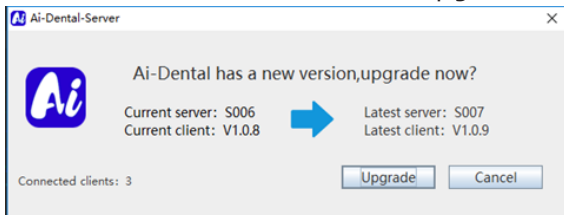


图 39

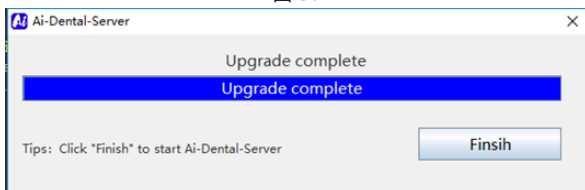


图 40

4 Notes

Other safety information can be found in each chapter of this instruction manual. Please read the whole manual carefully to familiarize yourself with the operation of the dental imaging plate scanner. Pay more attention to the following precautions during

operation.

4.1 The device must be used in accordance with the manufacturer's instructions, otherwise the device may be damaged and the patient's safety may be endangered. The manufacturer bears no responsibility for hazards caused by improper use.

4.2 The device should be operated and installed by a trained doctor or technician in a position where the device can be easily disconnected from power supply.

4.3 The device should be placed out of the reach of children to avoid electrical injuries caused by the power cord and to avoid swallowing tiny parts that could cause suffocation.

4.4 The imaging plate scanner shall never be used in the presence of flammable anesthetic gas, pure oxygen or nitrogen oxide to avoid any risk of explosion.

4.5 The imaging plate scanner is a CLASS 1 LASER PRODUCT and turns CLASS 3B after the cover is removed. Make sure to avoid exposure to laser rays to prevent the risk of injury to the eyes.

4.6 The imaging plate scanner and its accessories, especially the IP imaging plate, protection card and protective bag, have been designed and developed to ensure the highest safety and performance. The use of accessories not provided by the original manufacturer may cause risks to patients, users or the equipment itself. Do not use IP imaging plates, protection cards and protective bags provided by other manufacturers to avoid any risk of contamination or malfunction of imaging plate scanner.

4.7 In the handling of IP imaging plate, protection card and protective bag, necessary health protection measures must be taken to avoid the risk of cross infection.

4.8 The imaging plate scanner complies with the IEC 60601-1 standard. Only peripheral equipment conforming to IEC 60950-1 can be connected to the imaging plate scanner to avoid any risk of failure of the scanner.

4.9 Our company is specialized in the production of medical devices. We are responsible for the safety of the device only when the maintenance, repair and modification of the machine are carried out by Woodpecker or by our authorized dealers. If product information such as circuit diagrams and parts lists are required, the manufacturer can provide them.

4.10 The parts to be used for maintenance, repair and alteration

of the device shall be our Woodpecker brand parts and shall be operated in accordance with the instruction manual.

4.11 In order to ensure safe and correct operation and the use of the imaging plate scanner, it is very important to use the power cord coming with the scanner. The power cord of the imaging plate scanner system must only be replaced by the same type of cord.

4.12 Due to the electromagnetic compatibility, the dental imaging plate scanner in operation might affect ambient devices, resulting in abnormal function of nearby devices.

4.13 Due to the electromagnetic compatibility, the use of other devices may interfere with the dental imaging plate scanner.

4.14 When the IP imaging plate is overused or artificially damaged, which affects the imaging quality, it should be replaced in time.

5 Fault clearance

Fault	Reason	Solution
"Connection timed out" is displayed on the software interface	The USB driver is not installed	Reinstall the USB driver
	The USB driver is incorrectly installed	Reinstall the USB driver
	The USB port is improperly inserted	Make the USB port reinserted
	The USB cable is damaged	Contact local distributors

If the fault cannot be cleared by the above measures, contact the dealer to return the device to the manufacturer. Do not attempt to open the shell of the device to repair by yourself.

6 Cleaning, disinfection and sterilization

Complete disinfection procedures must be followed before the first use of the device. It should be thoroughly disinfected before use after each repair or maintenance.

6.1 Cleaning and disinfection of IP imaging plates

a) Clean the IP imaging plate with the attached soft, lint-free dry microfiber cloth;

b) Wipe the IP imaging plate with disposable disinfected cleaning wipes;

c) Use the attached soft, lint-free dry microfiber cloth to dry the imaging plate

6.2 Cleaning, disinfection, sterilization of IP imaging plate storage box

a) The storage box of IP imaging plate can be cleaned with non-abrasive cloth dipped with recommended detergent, such as cold water, warm water, soapy water and medical ethanol; make sure the parts are completely dry before cleaning.

b) The storage box can be wiped and disinfected with recommended disinfection solution, aldehyde free disinfectant; make sure the parts are completely dry before cleaning.

Note: Do not adopt the following disinfection methods

a) Do not adopt organic solvents or corrosive cleaning products to clean the dental imaging plate scanner and IP imaging plates;

b) Do not spray detergent directly on the dental imaging plate scanner;

c) Do not use organic solvents or corrosive disinfectants to disinfect the dental imaging plate scanner and IP imaging plates;

d) Do not spray disinfectant directly on the dental imaging plate scanner;

7 Storage, maintenance and transportation

7.1 Storage/maintenance

1) The device should be placed with care, away from vibration sources, and should be installed or stored in a cool, dry and ventilated place.

2) Do not mix it with toxic, corrosive, flammable and explosive items when stored.

3) When the device will not be used for a long time, the power switch should be turned off, the power plug should be unplugged, and the IP imaging plate should be put into the storage box;

4) The product should be stored in an environment with the relative humidity of 10% ~ 93%, atmospheric pressure of 70kPa ~ 106kPa, temperature of -20°C ~ +55°C .

5) After each image reading, clean the fingerprints, stain, dirt or dust on the IP imaging plate, and check for scratches, wear and other mechanical abrasion or damage.

7.2 Transportation

1) Excessive impact and vibration should be prevented during

transportation. Handle with care and avoid upside down;

2) It should not be mixed with hazardous articles during transportation;

3) Avoid exposure to sun and keep away from rain and snow during transportation;

8 Environmental protection

This device can not be disposed as household waste. Therefore, it should be placed in a special recycling area for wasted electronic medical devices. For more information on device disposal and recycling, contact the dental device dealer.

	Parts	Power adaptor	Main unit	IP imaging plate	Mechanical components, including screws, nuts, washers, etc
Toxic or harmful substance or elements	Lead(Pb)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Mercury (Hg)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Cadmium(Cd)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Hexavalent chromium(Cr6+)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Polybrominated biphenyls(PBB)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Polybrominated diphenyl ethers(PBDE)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Diisobutyl phthalate; phthalic acid diisobutyl ester (DIBP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	(DEHP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Butyl benzyl phthalate (BBP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dibutyl phthalate (DBP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

○: indicate that the content of toxic substance in all homogeneous material of the component is below the limit requirements specified in SJ/T-11363-2006 "Limit requirements for toxic and harmful substances in electronic information products".

×: indicate that the content of toxic substance in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/ T-11363-2006.

(This product meets the EU RoHS environmental protection requirements; At present, there is no mature technology to replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys. Please abide by the safety precautions of the product, in accordance with the "Management measures for limiting the use of hazardous substances in electrical and electronic products", "Management regulations for recycling and treatment of wasted electrical and electronic products" and relevant standards and recycle or discard the product in an appropriate manner, according to local laws and regulations after use.

9 After-sales service

If the device cannot work normally due to quality problems since the date of sale, our company shall be responsible for maintenance against the warranty card. Refer to the product warranty card for the warranty period and scope. This product does not contain any spare parts for self repair. The repair should be carried out by designated professionals or special repair shop.

10 Electromagnetic compatibility

Special precautions regarding electromagnetic compatibility (EMC) must be taken for the device, and the device must be installed and operated in accordance with the EMC information specified in the manual. Both portable and mobile radio frequency communication devices may affect the device. The following cables must be used to meet electromagnetic emission and interference resistance requirements:

Name	Cable length	Shielding	Remark
power cable	1.2m	No	/

Direct current cable	1.5m	No	/
USB cable	1m	No	/

Except for cables (transducers) sold as spare parts for internal components, the application of non-specified accessories and cables (transducers) may result in increased electromagnetic emission or decreased electromagnetic immunity of the device or system.

The device or system should not be used in close proximity to or in combination with other devices. If such proximity or combination is necessary, the device or system should be observed to verify that it works properly in the configuration in which it is used.

Basic performance: Under electromagnetic interference, the product can read images but is with stripes on the display, which can be restored itself. Occasionally, the self-test fails after startup, which will be restored after restarting.

10.1 Guidance and manufacturer's statement - electromagnetic emission

Guidance and manufacturer's declaration - electromagnetic emissions		
The dental imaging plate scanner is intended for being used in the electromagnetic environment specified below. The customers or users of the dental imaging plate scanner should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The dental imaging plate scanner use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
RF emissions CISPR 11	Class B	The dental imaging plate scanner is suitable for being used in professional healthcare facility environment. Requirements for domestic establishment is applied as it may be used in establishments that is directly connected to a low voltage power supply network which is for domestic power supply.
Harmonic emissions IEC 61000-3-2	Class A	
IEC 61000-3-2	Compliance	

10.2 Guidance and manufacturer's declaration - electromagnetic

immunity


Guidance & Declaration — electromagnetic immunity			
The model dental imaging plate scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the model dental imaging plate scanner should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 , ± 4 , ± 8 , ± 15 kV air	± 8 kV contact ± 2 , ± 4 , ± 8 , ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for Input/ output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV line to ground	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models The dental imaging plate scanner requires continued operation during power mains interruptions, it is recommended that the models The dental imaging plate scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE UT is the a.c. mains voltage prior to application of the test level.

10.3 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance & Declaration - Electromagnetic immunity			
The dental imaging plate scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the dental imaging plate scanner should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

<p>Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz</p>	<p>3V 6V 3V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the dental imaging plate scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \times P^{1/2}$ $d=2 \times P^{1/2}$ $d=1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d=2.3 \times P^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur In the vicinity of equipment marked with the following symbol: </p>
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NOTE 1 At 80 MHz end 800 MHz. 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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the dental imaging plate scanner is used exceeds the applicable RF compliance level above, the dental imaging plate scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the dental imaging plate scanner.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

10.4 Recommended distance between RF communication devices and the dental imaging plate scanner

Recommended separation distance between portable and mobile RF communications equipment and the dental imaging plate scanner

The dental imaging plate scanner is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the dental imaging plate scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the dental imaging plate scanner as recommended below.

Maximum rated power output of transmitter/ W	Separation distance according to frequency of transmitter/m		
	150kHz ~ 80MHz	80MHz ~ 800MHz	800MHz ~ 2.5GHz
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) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all solutions.

Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.

⚠ Warning:





WARNING: Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance.










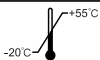



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of adapter or USB cable other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Electronic Stimulator for Pain Relief, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

11 Symbol

	Manufacturer		Production date
	Serial number		CE production sign

	Power identification		Non-reusable
	Laser beam		High Voltage
	Avoid direct sunlight		Class II device
	Reference No. of product		Follow the operating instruction
	Product complies with WEEE directive		
	Storage condition, a temperature range of -20°C ~ +55°C		
	Storage condition, an atmospheric range of 70kPa ~ 106kPa		
	Storage condition, a humidity range of 10% ~ 93%		
	Authorized Representative in the EUROPEAN COMMUNITY		

12 Special instruction

1. Please refer to the product packaging label for the production date. The service life of the product is 8 years, and the frequency of use of the IP imaging plate is limited to 2000 times.

2. If the product label cannot be clearly identified at a distance of 1m, a distance of 30cm is recommended.

3. The Dental Imaging Plate Scanner and its accessories shall be recycled and treated according to local regulations, or returned to the manufacturer or dealer for processing.

4. Do not modify this equipment without authorization of the manufacturer.

For assistance, if needed, in setting up, using or maintaining the ME. EQUIPMENT or ME SYSTEM; or to report unexpected operation or events.



Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, Guilin National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196
Http://www.glwoodpecker.com
E-mail: woodpecker@glwoodpecker.com

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany
ZMN-SM-475 V1.1- 20220309

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