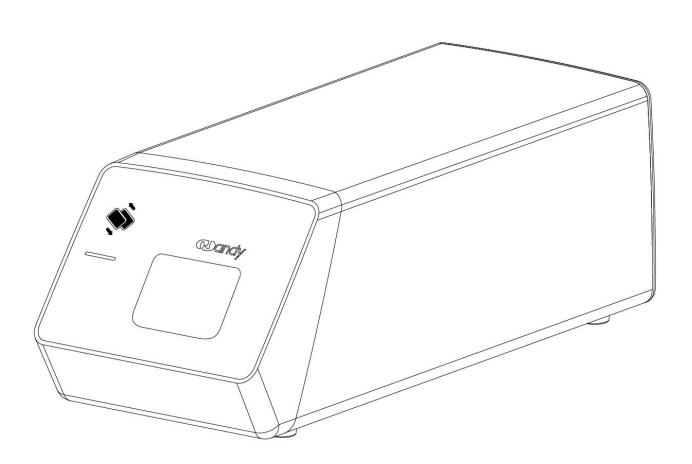


# HDS-500

# Digital Imaging Plate Scanner User Manual



# **Preface**

#### Dear Users:

Thank you for using Handy brand HDS-500 Digital Imaging Plate Scanner and trust us on the product, we are deeply honored by your choice, and will provide our best to ensure your satisfaction with HDS-500.

HDS-500 is performed in equipped HandyDentist imaging software, which is designed to take full advantage of the scanner performance. To get the optimal image and higher processing quality, the use of HandyDentist imaging software in combination is necessary.

To ensure your safety and efficient use of HDS-500 scanner, please follow this manual carefully, Handy Medical company will not be held responsible for any failure or accidental damage caused by improper operation against the instructions in the manual.

This manual contains proprietary information protected by copyright laws, including but not limited to technical secrets, patent information and other business secrets. Users have the obligation of confidentiality, any content in this manual shall not be disclosed to an irrelevant third-party / shall not be copied without explicit permission from Handy Medical company.

Modification and update of this manual, as well as the right of final explanation belong to Handy Medical company.

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# 1. Product Overview

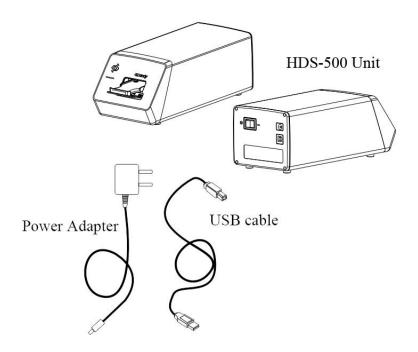
This product consists of imaging plate scan unit, power adapter, USB cable and HandyDentist dental image management software.

The unit should work with a imaging plate (IP is equipped by the user own self, not be provided together with the product). When the IP is exposed to X-rays, the phosphor layer in the plate stores the image. As the IP being read by the scanner, a focused laser releases the stored image in the form of visible light photons. These photons are collected and amplified by the scanner, converted to a digital signal and then transferred to a computer for processing and display.

The unit is powered by power adapter, instead of batteries or any charging system.

The computer and other external devices(like monitor, printer, etc.) that work with this product are equipped by the user own self. For the suggested computer configuration, please refer to '3.2 Computer Configuration Requirements'.

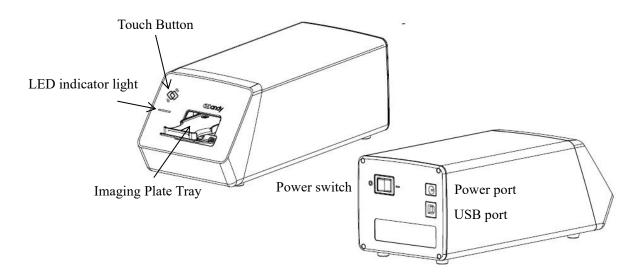
#### 1.1 Appearance



#### 1.2 HDS-500 Unit Description

The unit is used to read out the latent image on the IP by stimulating it with a laser beam, to collect information and convert into digital data, and then transferred to a computer for processing and display.





Name	Description
Touch Button	Open/Close the door
LED indicator light	Status of be powered and work mode
IP tray	Hold the imaging plate
Power switch	Main switch of the unit
Power port	DC12V power port
USB port	USB data transmission port

#### 1.3 Classification, Parameters and Warnings of a Laser Product

The unit is a class I laser product.

Items	Value
wavelength	660nm
Horizontal irradiation angle	38°
Vertical irradiation angle	45°
Laser type	Continuous CW
Maximum output power	<40mW
Maximum allowable avecause	cornea 10 w/m²(duration time 10³~3×10⁴)
Maximum allowable exposure	skin 2000 w/m²(duration time 10³~3×10⁴)

# Warning 1:

- This product is defined as class I laser product during normal use.
- Keep your eyes away from closely look inside the plate tray during normal use.
- When disassembled, the unit is a class III B laser product. Do not take the unit apart by non-professionals around, contact your dealer or the manufacturer to carry out repair of the unit.



# 1.4 Principles of Image Processing

1	Stimulated by red light on sensitive side	
2	Emit blue light from the plate to release the stored X-ray info	
3	The emitted blue light perform optical collection pixel by pixel (light by light), and measured with an extremely sensitive light detector	
4	A digital image is formed according to the changes of measured optical density	Y20190546

#### 1.5 Intended Use

Work with dental X-ray generator, to achieve the purpose of digital image viewing / saving / transferring.

# 1.6 Scope of application

Used to read latent image information saved on imaging plate and then convert to digital image, for viewing / saving / transferring.



# 2. Safety Instruction

This chapter provides important safety information for the use of digital imaging plate scanner.

# 2.1 Product Safety Classification

Tpye of Protection Against Electric Shock: Class II		
Degree of Protection Against Electric Shock: Type B		
Laser Safety Classification: Class I laser products GB7247.1-2012		
Operation Mode: Continuous Operation		
Waterproofing Grade:IPX0		
Rated Voltage:AC220V/50Hz		
Working Voltage:DC12V 1A		
Input Power:12W		
Non-AP type equipment: Non-APG type equipment		
No application for protection against defibrillation discharge effect		
Non-permanent installation equipment		

# 2.2 Symbols Description

Symbol	Description
$\triangle$	Caution, refer to accompanying documentation
[]i	Refer to the user manual
2	Do not reuse
	Class II Device
<u> </u>	Laser radiation
SN	Manufacturer serial number
	Fragile
Ţ	Contests of the transport package are fragile Therefore it shall be
	handled with care
l tt	This way up
ш	Indicates correct upright position of the transport package.
*	Keep away from rain
J	Transport package shall be kept away from rain.
	Antiroll
X	Temperature limit
<b>2</b>	Humidity limit
<b>∳••</b>	Air pressure limit
	Manufacturer
	Name and address of the manufacturer



#### 2.3 Warnings and Precautions

#### 2.3.1 Cautions

- Check whether the scanner surface is with visible physical damage before each usage, the surface should be smooth, without any crack or damage. Please contact our after-sales team once any damage occurred
- As with other electronic equipment, the scanner is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low humidity environments. During cable moved, when scanner contacts are exposed, it is especially important to protect the device from potential ESD damage. Touching a metal surface prior to moving the cable will reduce the risk of components damage caused by accidental static discharge. The use of anti-static floor mats or floor treatments will also help eliminate static build-up in your office.
- When the scanner is in use, avoid touching exposed connectors on non-medical electrical equipment (like computer peripherals) and the patient at the same time. The human body is capable of conducting electrical current and may cause a shock hazard to patients if appropriate safety practices are not observed.
- The scanner has been determined to be in accordance with international safety standards and is deemed suitable for use within 5ft (1.5m) away from the patient. To comply with these standards, do not operate non-standard equipment within the patient area. Within the patient area, the presence of approved medical grade equipment and Listed / Approved / GB9706.1(IEC60601-1), YY0505(IEC60601-1-2) certified computer equipment is acceptable. Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / GB4943(IEC60950) certified computer equipment is acceptable. The whole medical electrical system should compliant with medical system requirements GB9706.15(IEC60601-1-2). The person connect the product to the host computer shall ensure its compliance. Also, to keep optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not impact imaging applications after installation
- If the power cable of the system is lost or damaged, please use the one specified by our company and compliance with local standards.
- Portable and mobile radio frequency communication equipment may affect medical electrical equipment performance.
- To avoid damaging the product and degrading the image quality, please don't use it in the following environments:



1	Environment with direct sunlight and strong lamp light	
2	Environment with drastic temperature changes	
3	Environment with full of dusty	
4	Near the heat source	
5	High Humidity environment	

#### 2.3.2 Warnings

- Non-following the user manual probably endanger the patient. The manufacture of the product bear no compensation liability for any damage caused by improper operation.
- Only installers authorized by the manufacturer are allowed to install this product. Do
  not turn on the power supply until all cables are correctly installed and confirmed.
- The product must be used by a trained personnel in accordance with the user manual carefully.
- The unit is a class I laser product. Non-following the user manual may result in hazardous laser radiation exposure or other accidents.
- No waterproofing on this product. Do not position the product where it could be splashed with liquids.
- Power off at once when malfunction occurred, and contact us or the authorized dealer.
- Do not move or knock the device while in working state.
- This product is not used for treatment, all images are for doctor's reference only.
- Only professional technician / trained staff can operate this product.
- Only the manufacturer's authorized service personnel are authorized to carry out maintenance and repair of the unit.
- Use with caution in epilepsy / psychosis patients and children.
- Do not work with or approach toward other equipment. If must to work with or approach toward other equipment, please observe and verify that it can work normally under the existing configuration.
- All connecting cables of the product are sold as spare parts. The use of unspecified cables may result in an increase in the x-ray emission or a reduction in the disturbance immunity of this product.
- Portable and mobile radio frequency communication equipment probably impact the use of this product. Do not cross the recommended isolation distance to close to any part of the product.



#### 2.4 Work Environment

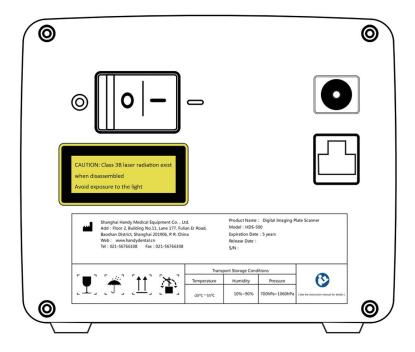
# 2.4.1 Operating Conditions

Environment Temperature	10℃~40℃
Relative Humidity	30%~75%
Air Pressure	700hPa $∼$ 1060hPa

# 2.4.2 Transportation and Storage Conditions

Environment Temperature	-20°C∼+55°C
Relative humidity	10%~90%
Air pressure	700hPa∼1060hPa

#### 2.5 Label and Laser Label Position



# 3. Specifications

# 3.1 Scanner Specifications

Product Name	Digital Imaging Plate Scanner
Model	HDS-500
Rated voltage	AC220V/50Hz
Working voltage	DC12V
Working current	≤1.0A
Power	≤12W



consumption	
Pixel size	35um
Bit depth	14 位
Resolution	≥7lp/mm
Connection	USB port
Firmware version	1.00 or higher
Software	HandyDentist Dental Image Management software
Software version	3

#### 3.2 Computer Configuration Requirements

Note : Suggested minimum configuration for the computer, it's equipped by the user own self.

Table of Minimum Computer Configuration Requirements:

Items	Minimum Requirements	
PC processor	Intel 1.5GHz chip or above	
Memory	Above 4G	
Hard disk	Above 40G (1GB for software installation,40GB for software operation)	
Video card	32M or above	
Display	Resolution 1024 × 768 (15") or above 32-bit color mode	
At least 2 available USB2.0/USB3.0 ports  (If used desktop computer, 2 available USB ports makes at the back of computer)		
Operating System	Win7/Win10 (32bit&64bit)	
Backup Medium	USB flash drive / Mobile disk (using mobile disk to avoid loss of patient data, some case like PC disk is corrupt/full, PC is attacked by virus,etc.)	

# Note 1:

- Computers and external devices (like monitors/printers, etc.) must meet the GB4943 (or IEC60950) standard and approved with 3C ( or CE ).
- The computer and other external devices (like monitor, printer, etc.) are equipped by the user own self.
- The requirement form above is the suggested minimum configuration for the



computer, and the product performance might be affected if those above are not reached.

- Prohibit the use of computer non-comply with GB4943(or IEC60950), like some kind of unauthorized assembly computer may incur potential safety hazards.
- Prohibit the use of computer unapproved with 3C(or CE).

#### 3.3 Network Security

Enable to link several computers via LAN to have the database sharing.

- Connect the computer to the local area network (Router/Switch) with an ethernet cable.
- Consult a network administrator to set up a LAN if needed.
- The computer can automatically obtain an IP address (DHCP) or set it manually (static IP).



- Select one computer as a database server carrier.
- Make sure HandyDentist software is installed on all computers.
- Keep the Server installed computer always running, when sub-computer is in use.

Network requirements			
Network connection setting	Ethernet TCP/IP protocol		
Security software	Anti-virus software		
Security software	Firewall		



When used multiple users version, images will unable to be saved to the Server if disconnect from the net during transferring. In this case, repair the network, when the network back to normal, re-transmit.



#### 3.4 Exposure Requirements of Dental X-ray Generator



As with traditional radiology equipment, the exposure time depends on the performance of the generator, the shape of the patient and the tooth being irradiated. The recommended exposure time of x-ray generator for reference under the value of 70kV/7mA showed in below table. Reset a special value according to your practical experience to make the radiograph more clear.

Tooth Position	Recommended Exposure Time(Unit:s)
Upper	0.18
incisor/canine	
Upper premolar	0.24
Upper molar	0.35~0.45
Lower	0.12
incisor/canine	
Lower premolar	0.18
Lower molar	0.25



- Dental X-ray generator tube voltage range should be: 60~70kV.
- The X-ray generator is with DC power supply, if it with AC power supply, please increase the exposure time by 10~30%.

# 4. Software Installation Instructions

#### 4.1 Driver Installation

We provide a USB flash drive together with the scanner in package. Open the 'Driver folder' on the USB flash drive, double click the file named 'HDS Scanner Driver 2.x.x.x(xxxxxxxxxx)' to complete the installation by following install-shield wizard. (The

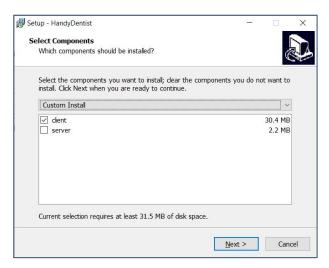


Driver name might change with update version, please refer to the actual using name)

#### 4.2 Software Installation

#### 4.2.1 Single user version

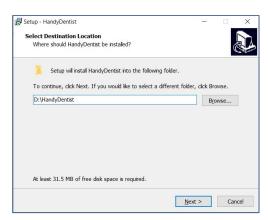
Open Software folder on USB drive, double click the file "HandyDentist\_3.xx.xx(xxxxxxxxxx)" to launch the installer. (The Software name might change with update version, please refer to the actual using name)



1. Choose the 'client' option, click 'Next'



- 2. Chose your language, click 'OK'
- 3. Select the installation path you want: default path is 'D:\HandyDentist', or change it by click 'Browse' button



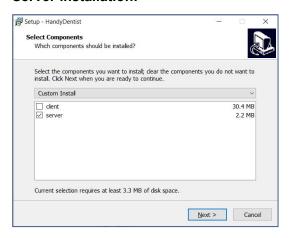


4. Click 'Next', and then complete the installation by following install-shield wizard.

#### 4.2.2 Multiple users version

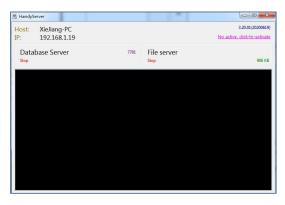
To satisfy the needs of data sharing among several computers run under the same LAN, a Server program is required to be installed in one of them. (Note: Server program needs to be purchased separately, please consult your sales if needed)

#### Server installation:



- 1. Choose the 'server' option at the step of 4.2.1
- 2. Click 'Next', and then complete the installation by following install-shield wizard.

Double click the icon to run the program, work window is as below:



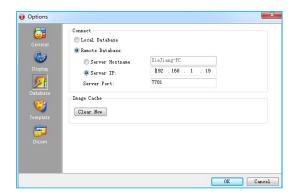
3. Reset the 'Database connect' in each HandyDentist Software on each computer:

Click 'Tools' - 'Options' - 'Databases' to open the setting window.

(Note: For HandyDentist Software operation, please check Chapter 5)







Fill in the correct Server Host Name or Server IP, the same as be showed in Server program work window (Host: Xiejiang-PC; IP:192.168.1.19)

#### 4.3 Registry & Activation

All copyright, trademark, patent, trade secret and other intellectual property rights of the software are protected by the P.R.China laws and rules, as well as the corresponding international treaties. It's restricted to use as any other form without permission, otherwise he will be investigated for legal responsibility according to law. To protect your legitimate rights and interests, please activate the software as required.

#### 4.3.1 HandyDentist Software Registry

(Note: For HandyDentist Software operation, please check Chapter 5)

After 30 days since the date of software installed, the trial version will be locked, and ask for an activation code, as well the registration window will be showed automatically for your side to proceed with register. (To avoid software be locked, please activate in advance by following the instructions)

If the registration window disappear, please follow the below steps:

1) Run the software, click button in menu bar, and select Register(R)



2) Fill in the blank of the user information: Company/Email/Address/Phone, in which the Company and Email information is required;





3) Click Export req file... button after the user information is be finished, save it on your computer desktop, a file suffixed with '.req' will be generated, then send this request file to your local distributor or directly to our after-sales support: support@handycreate.com;.



4) We will reply you an activation file suffixed with '.act', to activate your software by import this file into registration window directly (No need to open this file);



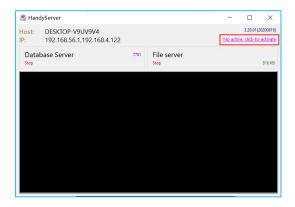
- 5) Click Import act file.. button to import the activation file you received;
- 6) Successful registration information will appear to remind you your software has been activated;

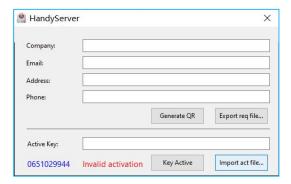


#### 4.3.2 HandyServer Registry

Double click the icon to run the program



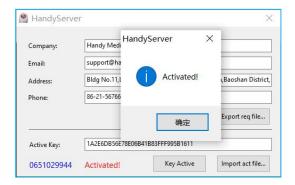




There is a 30days trial period, please activate your program within 30days by following the below steps:

- 1) Click No active, click-to-activate button;
- 2) Fill in the blank of the user information: Company/Email/Address/Phone,in which the Company and Email information is required;
- 3) Click button after the user information is be finished, save it on your computer desktop, a file suffixed with 'HandyServer.req' will be generated, then send this request file to your local distributor or directly to our after-sales support: support@handycreate.com;
- 0651029944-HandyServer.req
- 4) We will reply you an activation file suffixed with '.act', to activate your software by import this file into registration window directly (No need to open this file);
- 0651029944-HandyServer.dat
- 5) Click Import act file.. button to import the activation file you received;
- 6) Successful registration information will appear to remind you your software has been activated:

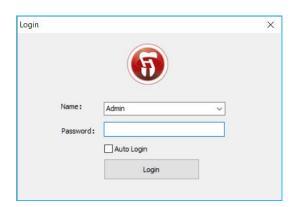




# 5 Software Operation

# 5.1 Login

Double click the icon to run the software



Default name: Admin

Password: NULL (no password by default, click 'Login' directly)

#### Home screen





Generate your password or correct the name in the setting window (click the 'Menu bar' - 'Tools' - 'Options' - 'General').

#### **User Access Control:**

Admin	All menu function be available		
Guest	Access Denied:		
	● Tool — Option - Database		
	● Help — Registry		
	Basic Operation — Delete Patient		
	● Image Processing — — Delete		
	Images		

# 5.2 Functions Introducing



Home Screen	Functions
1. Title Bar	Remind of unregistered or be registered state
2. Menu Bar	All operation functions included
3. Tool Bar	Visible operation button
4. Teeth Location	Display the teeth location
5. Case List	Display recent history
6. Target Frame	Display teeth images when the patient be selected
7. Image Information	Information for a single image



Main Menu	Functions			Icon	Description
	New patient			+	Create a new patient or a new case
	Delete patient				Delete a patient or a case
Basic Operation s	Searc	ch patient		Q	Search a patient
5	Edit p	Edit patient			Edit patient name or patient No.
	Refre	sh image		$\downarrow \uparrow$	Refresh the cases shared by net
Tile		Tile			Press and hold down "Ctrl" key, left-click to select several pictures at the same time (the maximum quantity is 6), then release "Ctrl" key, click this icon to pave together
	Play	Play			All images will be played one by one in a loop
	Edit I	Edit Image			Edit images as required
		Tool Bar	Reload	S	Click to bring back original image
			Undo	•	Click to withdraw the previous operation
Image			Redo	*	Click to repeat previous operation
Operation s			Partition		Click to choose the display mode you want,drag a image from left list into black square for comparison
	Edit		Relocation	C	Click to rotate image
			Magnifier	Q	Click to zoom up part of the image
			Draw		Click to mark the image
			Scale	1	Click to do measurement
			Save		Click to save the edited image
		Functio n	Color Adjust	1	Move the slider to adjust color



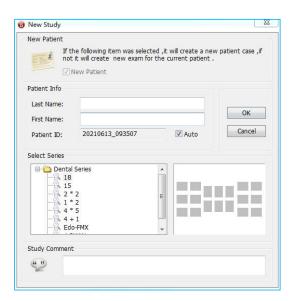
Main Menu	Functions		Icon	Description	
		Area	Bright/Contras t	1	Move the slider to adjust brightnes / contrast
			Image Process	1	Smart contrast, Smart sharpen, Negative, Colorize, Embossment, Normalize, Denoise, Soft
			Simulation Diagnosis	1	Saprodontia, Root canal, Periodontal, Crown, Diagnosis
	Delet	e Image			Delete image
	File ii	mport			Import an image
	Expo	rt image			Export an image
	Сору	,		1	Copy an image
	Paste	e		1	Paste an image
	Refre	esh image		$\mathcal{C}$	Refresh the images on the home page
	Print	Image			Print image
	Oper	ı image path	1	/	Open the image location
	Pre-p	orocessing		1	Only apply to the class I product (Intraoral Camera)
	Prese	et Image edi	tor	/	Preset parameters for some algorithms in image editing
	Intrad	oral Camera			Only apply to the class I product (Intraoral Camera)
	Digital Der Xray Imag System		Calibration		Includes dark field calibration, flat field calibration, bad spot bad line repair
Image Sources			Advanced Settings		Pre-process the image
	_	al Imaging Scanner	Advanced Settings		Pre-process the image
	(TW	/AIN)		τw	Use with a device that supports the Twain protocol



Main Menu	Function		Description	
	Tool bar		Show/Hide toolbar	
	Status bar		Show/Hide the status bar	
View	Show information		Show/Hide image information	
	Show Tee	eth location	Show/Hide tooth position	
	Reset view		Restore the default window layout	
		General	General settings for user login,etc	
Tools	Options	Display	Multilingual, name display, teeth location, print font	
		Database	Select single user or multiple users version	
		Template	Template of image annotation	
Halp	Registry		Software registration	
Help	About		About the software version info	

#### 5.3 Create new patient

Click the icon to create a new patient before image acquisition at the first time of visit.

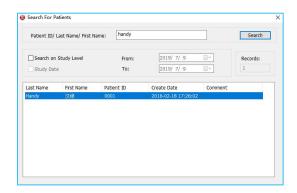


Fill in the patient name, select picture series you'd like, write study comment in the bottom side blank, and then click 'Ok' button to go back to home screen automatically, meanwhile the new patient will be displayed in 'Recent History' area with the state of being selected.



#### 5.4 Search patient

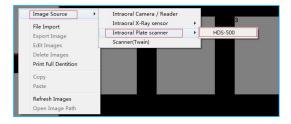
Click the icon to bring up searching window



Search for the registry patient by use his case No. or the name. An accurate searching is based on the exam date. Double click the target patient, searching window will be closed and go back to home screen automatically, the patient will be displayed in 'Recent History' area with the state of being selected.

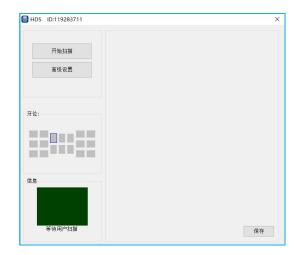
#### 5.5 Image Acquisition

1. Directly click the icon select 'Image Source'/ 'Intraoral Plate Scanner'/ 'HDS-500' in drop-down menu by right-click a null frame, to bring up the scanning window. On the second time use, simply double-click a null frame to quickly bring up.

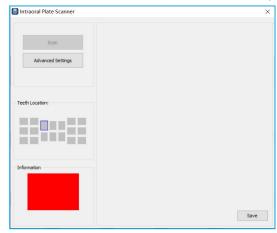


Working box with green blinking means the scanner connection is normal and waiting for acquiring x-ray, at the same time its IP tray will be pop out.



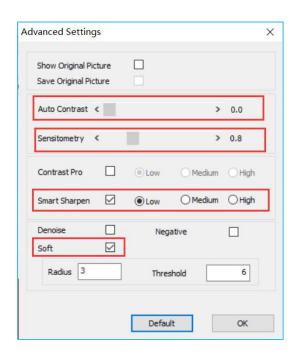


Red color means an abnormal connection, the scanner is unable to be detected:



Click the 'Advanced Settings', show below:



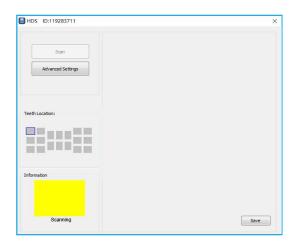


The function is used to preset parameters for some algorithms in image editing.

Function	Description
Display the original	Display the original image and the preprocessed image at the same
image at the same time	time after exposure
Save the original image	Select this function when only the original picture is confirmed to be
by default	saved
Contrast	Adjust the image contrast, same as the contrast function in 'Image Edit'
Sensitometry	Correct the sensitometry value of the image, same as the brightness function in 'Image Edit'
Contrast Pro	Select 'Low', 'Medium' and 'High' for different levels of contrast enhancement
Smart Sharpen	Select 'Low', 'Medium' and 'High'for different levels of sharpen
Negative	Negative processing
Denoise	Image denoise processing
Soft	Soften the image
Radius	Set the radius for soft processing
Threshold	Set a threshold for soft processing

- 2. Taking an exposure ( see 'Operation Guidelines' for the details)
- 3. Position the exposed imaging plate in the scanner tray, sensitive side face up, non-sensitive side face down. Click 'Scan' button to start scanning, the working box color turn to yellow. See below:

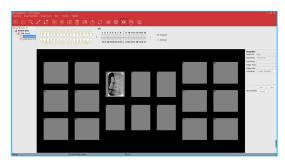




4. After scanning completed, the acquired image will appear on the right side, the IP tray will pop out automatically, and then pick up the imaging plate.



5. Close the scanning window directly after complete image acquisition, the image will be loaded into corresponding image frame automatically.



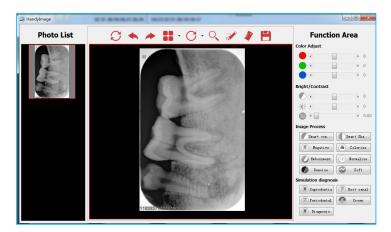


 Close the scanning window when not in use, the IP tray will be retracted automatically.



#### 5.6 Image Editing

Double click a image required to edit, or directly click the icon , to bring up the edit window



Three parts of the image editing

1. Photo list: Display all the images required to edit.

#### 2. Tool bar:

- Reload: Click to bring back original image.
- Undo: Click to withdraw the previous operation.
- Redo: Click to repeat previous operation.
- Partition: Click to choose the display mode you want, drag a image from left list into black square for comparison.
- Relocation: Click to rotate image.
- Magnifier: Click to zoom up part of the image.
- Draw: Click to mark the image.
- Scale: Click to do measurement.
- Save: Click to save a edited image.

#### 3. Function Area

- Color Adjust: Move the slider to adjust color.
- Bright/Contrast: Move the slider to adjust brightnes / contrast
- Sensitometry: Correct the sensitometry value to adjust brightnes / contrast
- Image Process: Smart contrast, Smart sharpen, Negative, Colorize, Embossment, Normalize, Denoise, Soft
- Simulation Diagnosis: Saprodontia, Root canal, Periodontal, Crown, Diagnosis





- All the function buttons change the characteristics of the images instead of itself. The doctor must make a diagnosis based on the actual clinical situation.
- Since the X-ray image is a two-dimensional image of a three-dimensional object, the measurement results will have an error of ±0.1mm. This function is just as an assistant tool for doctor.

Backup and recovery the software: Copy the whole HandyDentist folder by manual to backup and recovery the software (default path: 'D:\HandyDentist').

# 6. Digital Imaging Plate Scanner Operation Guidelines

#### 6.1 Working Sketch Map



1	x-ray source
2	Tooth
3	Place the exposed imaging plate in the scanner tray
4	Scanning
5	Digital image transferred to computer via USB cable
6	Image acquisition in software



# **6.2 Scanner Operation Guidelines**

No.	Decription	Picture
1	Plug in the power, turn on power switch	・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・ ・
2	Connect the scanner to the computer via a USB cable	也需要口 USB接口
3	Bring up the scanning window and make sure that the IP tray pop out	
4	Insert the IP (IP is not provided together with the unit, please purchase the approved IP separately) with the protective cover and disposable sheath into patient's mouth, like using a dental film.	
5	Select appropriate exposure values	



No.	Decription	Picture
6	Position the X-ray generator and then take shooting	
7	Peel off the disposable sheath and remove the protective plate	
8	Place the exposed IP in the scanner tray, and gently touch the button to close the door	
9	Click the 'Scan' button to start scanning	Tourney  Tourney
10	Refer to section 5.5 and 5.6 for details of image acquisition	200 0 011002711 × 30000





- Do not position the scanner in directly sunlight or lamp light, etc. Avoid exposure to the UV-C light.
- Do not position and use the scanner in dusty area.
- Do not use the scanner near the strong magnetic equipment.
- Do not operate with wet hands.

# 7. Cleaning and Disinfection

Do not keep immersing this product in any liquids, avoid disinfecting with liquids. Wipe the scanner surfaces with a little bit ethanol to do regularly clean, other disinfectants may cause damage to the scanner.

#### 8. Care and Maintenance

As with all kinds of electronic equipment, this product requires not only proper operation, but also visual inspection and routine check at regular intervals. These precautions can ensure the product with accurate, safe and high-efficient running.

Before each usage, the operator should check for whether there is any physical damage or malfunction. Contact our after-sales team for more guidance if happened.

#### 8.1 Scanner Care and Maintenance

Position the scanner on a dry and well-ventilated place, avoid placing on a dusty and damp place. Check the below items prior each usage:

- The labels are with intact, readable, and adhere well on the surface.
- No damage on the unit cable.



- No damage on the product surface which could incur safely issue.
- The indicator lights and software both are in normal status after installed by following the user manual correctly.

#### 8.2 Damaged or Nonfunctional Scanner

Stop using and contact your local dealer immediately once the scanner occur visible physical damage or abnormal working state.

Do not disassemble the scanner to take repair without permission.

Please consult the manufacture for more technical information if needed.

# 9. Troubleshooting

#### 9.1 Faulty Image

Faulty image	Causes and Solution
White lines or ripples on the images	·Check whether the X-ray exposure conditions are met; ·Check whether the imaging plate is scratched; ·There may be dust inside, contact after-sales team for support.
Images are too pale with grainy	·Refer to section 3.4 'Suggested Exposure Time' to reset x-ray exposure values; ·Under the chosen X-ray dose, generator is too far away from the patient, please position closer; ·Check your monitor brightness/contrast setting, make sure there is no reflects light on the screen; ·The X-ray generator tube voltage is too low, inspect the X-ray generator; · Remove dust on IP sensitive side.
Images are too dark	·Excessive of exposure time, please decline exposure time;



Images are blurred	·The patient moved at the moment of x-ray exposure; ·X-ray generator work state is unstable; ·Increase the Contrast Pro value in scanning window 'Advanced Setting';				
Incomplete image	·Check whether the X-ray generator is completely aligned with the IP; ·Make sure the X-ray generator can generate X-rays; ·Restart the scanner by following the user manual;				

# 9.2 Fault State Information

Fault	Causes and Solution			
Working box color is red instead of green blinking	·Correct image Source option 'Intraoral Plate Scanner'/ 'HDS-500'; ·Check the connection state with the computer, make sure they are well connected; ·Re-install the Driver; ·Switch to the case back side USB port, make sure USB interface is 2.0 or above. If a laptop is used, please connect to power supply, avoid selecting energy saving mode which may result in USB port voltage unstable;			
Working box turn to red color during scanning	·Check whether the USB connection is loose; ·Check whether the power adapter is connected or the main switch is turned on; ·Restart the scanner by following the user manual;			
No images acquired after X-ray emission	·Make sure the scanning windows is launched, normal working state with green blinking; ·Make sure the X-ray generator faces to the sensitive side of IP; .Make sure the IP is not be exposed to strong light or UV-C; ·Make sure the X-ray generator exposure values are correct; ·Re-install the Driver and switch to the case back side USB port, make sure USB interface is 2.0 or above, and increase the exposure time appropriately;			

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Unable to open scanning window	·Close the antivirus program and reinstall the software;
The scanner makes an abnormal noise	·Check if the startup sequence is wrong; ·Restart the scanner by following the user manual;
Click the software, the scanner does not respond	·Check whether the power adapter is connected and the main switch is turned on; ·Restart the scanner by following the user manual;
Unable to use the software after 30 days trial, remind of registration	·Refer to section 4.3 Registry & Activation;



- Try the above solutions if the same failure occurs.;
- Please contact our after-sales team for support on the condition of failure persists or even more serious.

# 10. Warranty

We guarantee that the product functions are correct and that there is no failure in raw materials and workmanship within 12 months starting from the release date. Please contact your local distributor in case of malfunction occurred, by according to the below condition:

We would responsible for free of the maintenance charge against the product's abnormal working state due to quality problem within 12 months start from the date of delivery.

If any of the following situation happened, maintenance charge would be attracted:

- Damage caused by improper operation / maintenance / storage against the instructions in
  - the manual or by user's carelessness;
- Damage caused by unauthorized disassembly;
- Damage caused by irresistible factors;
- The warranty period has expired;

Regarding a reasonable complain about the product failure or delivery, we would provide replacement or maintenance. We reserve the right to take repair, include some kind of natural or special damage, which is only under the compliance with legal provisions to avoid default/ malfeasance / wilful misconduct.



Please contact your local distributor for the maintenance executed by our company in case of malfunction occurred. Please do not disassemble the product without permission, and we will not be held responsible for any damage due to unauthorized disassemble by customer or a third-party.

If the scanner is operated under normal conditions, the expectant lifetime of the product is 5 years. Calculation method is as below:

The	number	of	the	usage	calculated based on an average of 10000 scans
scans			time		•
50000			5 ye	ars	per year.

# 11. Product Components

NO.	Name	Qty
1	HDS-500 unit	1pc
2	Power Adapter	1pc
3	USB cable	1pc
4	HandyDentist Dental Image Management Software (U Disk)	1pc
5	User Manual	1pc
6	Product warranty and certificate	1pc

# Annex A. EMC table

The following tables provide HDS-500 compliance information of electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) standards. To ensure conformance, the user must operate HDS-500 in environments that are consistent with these standards.

Table 1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions HDS-500 is intended for use in the electromagnetic environment specified below. The purchaser or the user of HDS-500 must ensure that it is used in such an environment:



Emissions Test	Compliance	Guidance
RF emissions CISPR11	Group 1	HDS-500 uses 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 equipment.
RF emissions CISPR11	Class A	
Harmonic emissions IEC 61000-3-2	N/A	HDS-500 is suitable for use in all establishments, including domestic and those directly connected to
Voltage fluctuations/flicker emissions EN 61000-3-3	N/A	the public low voltage power supply network which supplies buildings used for domestic purposes.

Table 2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity HDS-500 is intended for use in the electromagnetic environment specified below. The purchaser or the user of HDS-500 must ensure that it is used in such an environment:

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±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 EN 610004-4	±2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.



Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0 % UT; 0.5 cycle At 0°,45°,90°,135°, 180°,225°,270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of HDS-500 requires continued operation during power mains interruptions, it is recommended that HDS-500 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic fields EN 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.



Conducted RF EN 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V	communication equipment should not be used close to any part of HDS-500 within the recommended separation distance, including its cables. This separation distance is calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ $80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P}$ $800 \text{ MHz} \sim 2.5 \text{ GHz}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol.  ((***)*)
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		I	
Radiated RF	10 V/m 80 MHz to 2.7	10 V/m 80	
EN 61000-4-3	GHz	MHz to 2.7	
		GHz	

NOTE 1: At 80 MHz and 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

<sup>a</sup> 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 HDS-500 is used exceeds the applicable RF compliance above, HDS-500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating HDS-500.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m

Table 3. Recommended Separation Distance between Portable and Mobile RF Communications Equipment and HDS-500

PLEASE NOTE: HDS-500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The purchaser or the user of HDS-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable, mobile RF communications equipment (transmitters) and HDS-500 as recommended below, according to the maximum output power of the communications equipment.



Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)			
	150 kHz to 800 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$	
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 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

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