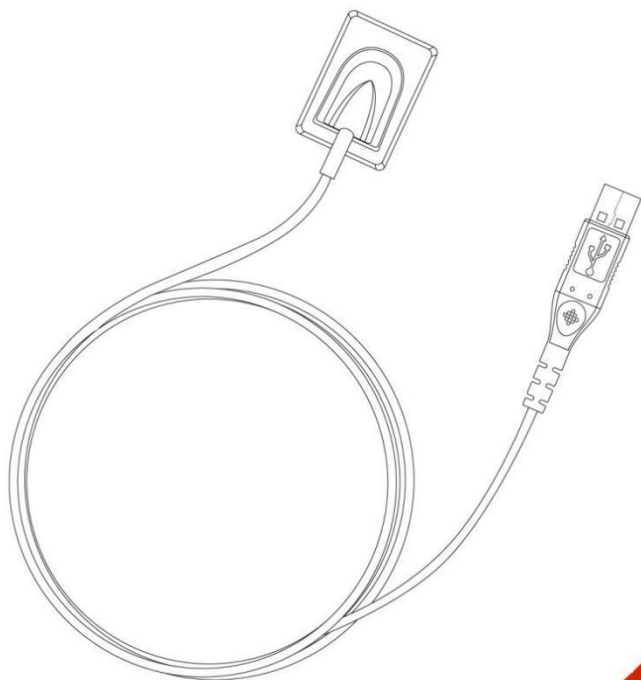


HDR-360/460

Digital Dental X-ray Imaging System

User Manual



Preface

Dear Users:

Thank you for using Handy brand HDR-360/460 Digital Dental X-ray Imaging Sensor and trust us on the product, we are deeply honored by your choice, and will provide our best to ensure your satisfaction with HDR-360/460.

HDR-360/460 is performed in equipped HandyDentist imaging software, which is designed to take full advantage of the image sensor 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 HDR-360/460, 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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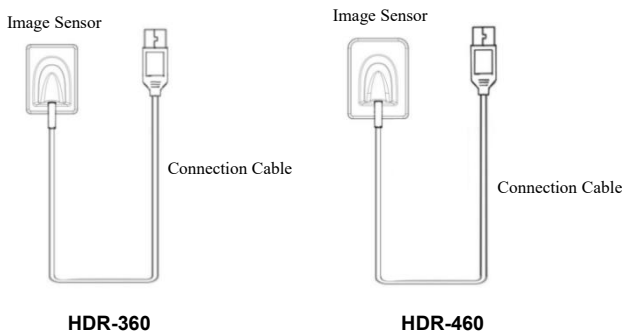
1 Product Description

This product consists of image sensor, connection cable and HandyDentist dental image management software.

Image sensor applies to collect x-ray photons for photoelectric conversion, digital data collection / conversion / transmission. Digital data is sent to computer via USB cable. The sensor is powered by the USB hub, instead of batteries or a charging system, but need to work with software..

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 HDR-360/460 Appearance



1.2 Image Sensor Description

Image sensor is used to collect x-ray photons for photoelectric conversion, digital data collection / conversion / transmission.

Image sensor (see below) applies to peripapical and posterior crown surgery.

HDR-360		HDR-460	
			
Nonsensitive side	Sensitive side	Nonsensitive side	Sensitive side

1.3 Intended Use

The product connected with an appropriate computer is intended for medical institutions to convert the X-ray photons emitted from the dental X-ray generator into X-ray images, which is for dental clinical reading, saving or transferring for clinical diagnosis. This product does not include X-ray generator, nor the computer and monitor for imaging.






2 Safety Instruction






This chapter provides important safety information for the use of Digital Dental X-ray Imaging System.

2.1 Product Safety Classification

Type of Protection Against Electric Shock: Class II
Degree of Protection Against Electric Shock: Type BF
Operation Mode: Continuous Operation
Grade of Water Proof: IPX7(only applicable for the sensor head part)
Power Supply(through USB port): DC5V
Input Power: 1W
Non AP equipment; Non APG equipment
No application for protection against defibrillation discharge effect
Non-permanent installation equipment

2.2 Symbols Description

Symbol	Description
	Caution, refer to accompanying documentation
	Operating instructions
	Type BF applied part
	Manufacturer serial number
	Fragile Contents of the transport package are fragile Therefore it shall be

	handled with care
	This way up Indicates correct upright position of the transport package
	Keep away from rain Transport package shall be kept away from rain
	Antiroll
	Temperature limit
	Manufacturer Name and address of the manufacturer
IPX7	Degrees of protection provided by enclosures

2.3 Warnings and Precautions

2.3.1 Cautions

- Check whether the image sensor 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, image sensor 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 image sensor 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 image sensor is in use, do not touch 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.
- HDR image sensor 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 configuration of the medical electrical system shall be in accordance with GB9706.15(IEC60601-1-2). The person connect the product to the host computer shall ensure its compliance. 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
- Portable and mobile radio frequency communication equipment probably impact on medical electrical equipment.

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.
- As a precision electronic product, avoid falling on the floor, pulling and long-time disinfectant soaking.
- The product must be used by a trained personnel in accordance with the user manual carefully.
- Cover a disposable hygienic sheath before each usage to avoid cross infection and allergy.

- Do not bite on sensor to avoid damage to the disposable hygienic sheath and the image sensor.
- Stop using once the product is malfunction, contact our company or authorized dealer immediately.
- 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 dentist / qualified technician 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℃～35℃
Relative Humidity	30%～85%
Air Pressure	700hPa～1060hPa

2.4.2 Transportation and Storage Conditions

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

3 Specifications

3.1 Digital Dental X-ray Imaging System Specifications

Model	HDR-360	HDR-460
Chip Type	APS CMOS	
Dimension (mm)	39×28.5×6	44.5×33.0×6
Active Pixel Array (pixels)	1200×1600	1402×1888
Voltage (through USB connection)	DC5V	
Electricity Current (through USB connection)	200mA	
Power	1W	
Digitization	14bit	
Spatial Resolution	≥14 Lp/mm	
Connection	USB	
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
USB	At least 2 available USB2.0/USB3.0 ports (If used desktop computer, 2 available USB ports must be have at the back of computer)
Operating System	Win7/Win10 (32bit&64bit)
Backup Medium	USB flash drive / Mobile disk (use mobile disk to avoid loss of patient data, some case like PC disk is corrupt / full, PC is attacked by

	virus,etc.)
--	-------------

Note  :

- 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).

Note  :

- 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 / Firewall
<p>Note </p> <p>When use 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.</p>	

3.4 Exposure Requirements of Dental X-ray Generator


Note  : **Dental X-ray generator is equipped by the user own self.**

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.

Recommended exposure time:

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

Lower premolar	0.18
Lower molar	0.25

Note  :

- 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

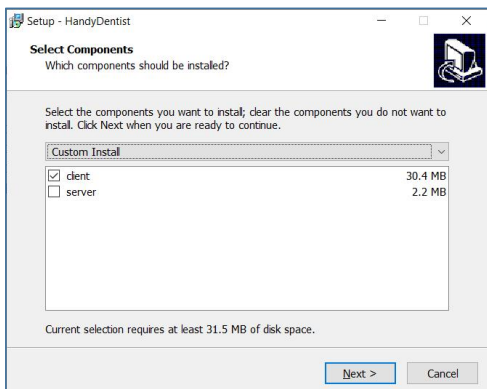
4.1 Driver Installation

We provide a USB flash drive together with the product in package. Open the 'Driver' folder on the USB flash drive, double click the Driver icon 'HDR Sensor Driver 2.x.x.x(xxxxxxxxxx).exe' to complete the installation by following install-shield wizard. (The Driver name might change with update version, please refer to the actual using name)

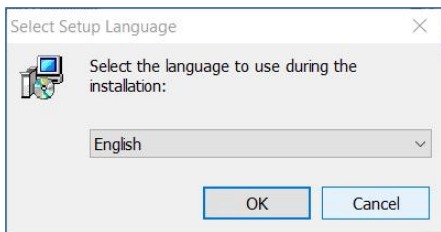
4.2 Software Installation

4.2.1 Single user version

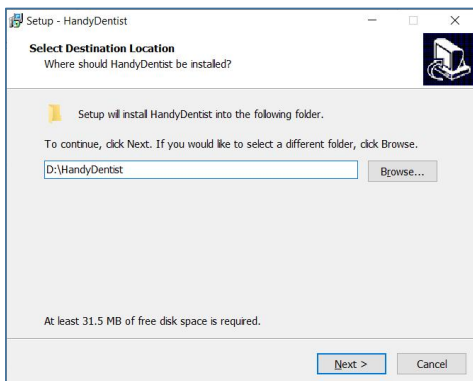
Double click the Software icon "HandyDentist_3.xx.xx(xxxxxxxxxx).exe" to launch the installer. (The Software name might change with update version, please refer to the actual using name)



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

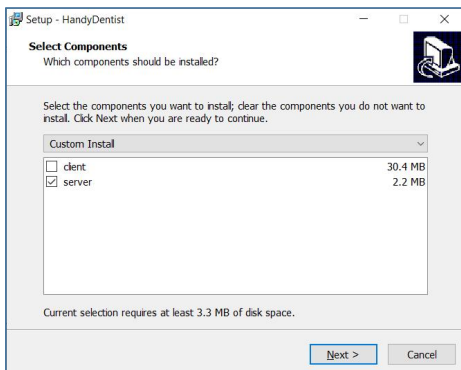



4. Click 'Next' , and then complete the installation by following install-shield wizard.

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:



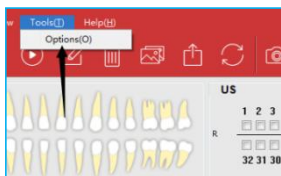
1. Choose the 'server' option at the step of 4.2.1
2. Click 'Next', and then complete the installation by following install-shield wizard. Double click the icon  to run the program, work window is as below:

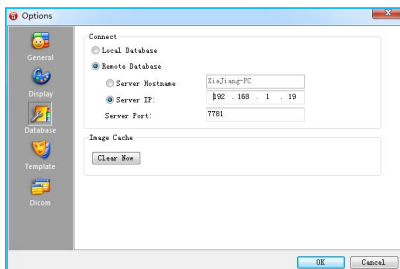


1. Reset the 'Database connect' in each HandyDentist Software on each computer:

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

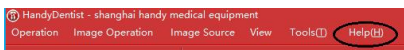
All copyright, trademark, patent, trade secret and other intellectual property rights of the software are protected by the P.R.China laws and rules, as well as the corresponding international treaties. It's restricted to use as any other form without permission, otherwise he will be investigated for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

4.3.1 HandyDentist Software Registry

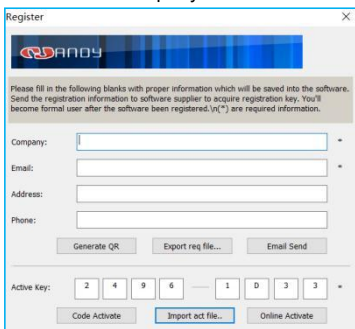
(Note: For HandyDentist Software operation, please check Chapter 5)


After 30 days since the date of software installed, the trial version will be locked, and ask for an activation code, 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  ;



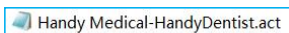
2) Fill in the blank of the user information: Company/Email/Address/Phone, in which the Company and Email information is required;

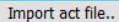


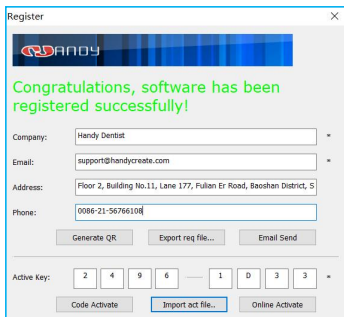
3) Click  button after the user information is finished, save it on your computer desktop, a file suffixed with '.req' will be generated, then send this request file to your local distributor or directly to our after-sales support: support@handycreate.com;



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);

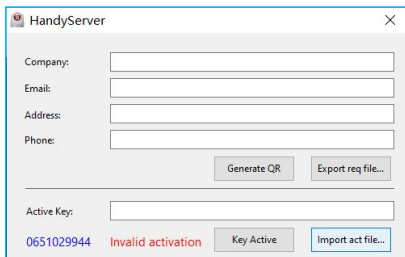
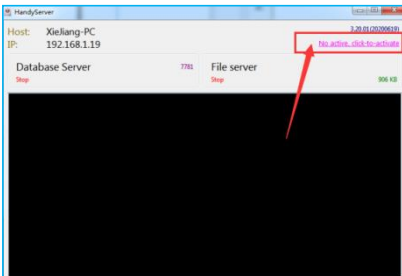


5) Click  button to import the activation file you received;
 6) Successful registration information will appear to remind you your software has been activated;




4.3.2 HandyServer Registry

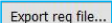
Double click the icon  to run the program



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


1) Click  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 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;

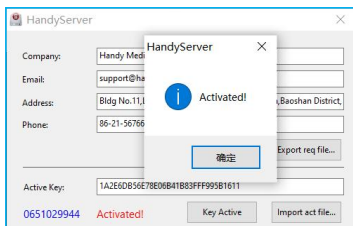
 0651029944-HandyServer.req

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  button to import the activation file you received;

6) Successful registration information will appear to remind you your software has been activated;



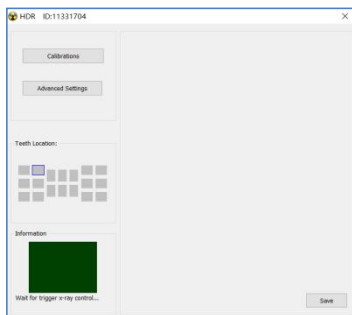
4.4 Calibration File Installation

Installation by manual

Open 'Calibration file' folder on USB flash drive, copy those three files and then paste into 'Sensor' file folder in software installation path. (refer to your actual sensor 8 digit numbers), see samples as below:

 11901528_Gain Image	2019/5/30 15:23	文件	3,750 KB
 11901528_Offset Image	2019/5/30 15:23	文件	3,750 KB
 11901528_Pixel Map	2019/5/30 15:24	文件	3 KB

The prompt box will be closed or the warning message in title bar will be removed after calibration file installed successfully.

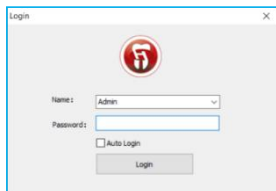


NOTE: Refer to chapter 5 'Software Operation' on how to bring up the shooting window.

5 Software Operation

5.1 Login

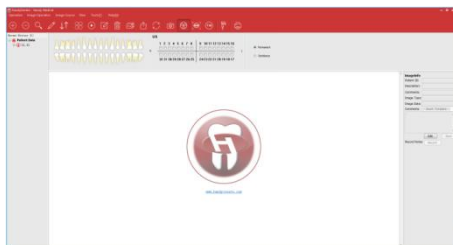
Double click the icon  to run the software



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: <ul style="list-style-type: none"> ● 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
Basic Operations	New patient		Create a new patient or a new case

	Delete patient		Delete a patient or a case
	Search patient		Search a patient
	Edit patient		Edit patient name or patient No.
	Refresh image		Refresh the cases shared by net
Image Operations	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		All images will be played one by one in a loop

		<p>Edit Image</p> 	<p>Edit images as required</p>
<p>Edi t</p>	<p>Tool Bar</p>	<p>Reload</p> 	<p>Click to bring back original image</p>
		<p>Undo</p> 	<p>Click to withdraw the previous operation</p>
		<p>Redo</p> 	<p>Click to repeat previous operation</p>
		<p>Partition</p> 	<p>Click to choose the display mode you want,drag a image from left list into black square for comparison</p>
		<p>Relocation</p> 	<p>Click to rotate image</p>
		<p>Magnifier</p> 	<p>Click to zoom up part of the image</p>
		<p>Draw</p> 	<p>Click to mark the image</p>

			Scale		Click to do measurement
			Save		Click to save the edited image
		Function Area	Color Adjust	/	Move the slider to adjust color
			Bright/Contrast	/	Move the slider to adjust brightness / contrast
			Image Process	/	Smart contrast, Smart sharpen, Negative, Colorize, Embossment, Normalize, Denoise, Soft
			Simulation Diagnosis	/	Saprodontia, Root canal, Periodontal, Crown, Diagnosis
			Delete Image		Delete image
		File import		Import an image	


	Export image		Export an image
	Copy	/	Copy an image
	Paste	/	Paste an image
	Refresh image		Refresh the images on the home page
	Print Image		Print image
	Open image path	/	Open the image location
	Pre-processing	/	Only apply to the class I product (Intraoral Camera)
	Preset Image editor	/	Preset parameters for some algorithms in image editing
Image Sources	Intraoral Camera		Only apply to the class I product (Intraoral Camera)

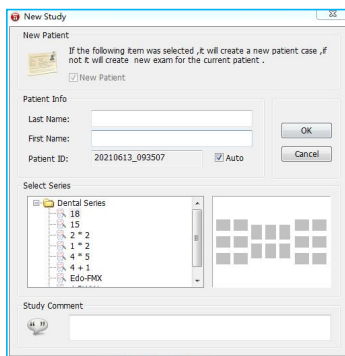
	Digital Dental Xray Imaging System	Calibration		Includes dark field calibration, flat field calibration, bad spot bad line repair
		Advanced Settings		Pre-process the image
	Digital Imaging Plate Scanner	Advanced Settings		Pre-process the image
	(TWAIN)			Use with a device that supports the Twain protocol

Main Menu	Function	Description	
View	Tool bar	Show/Hide toolbar	
	Status bar	Show/Hide the status bar	
	Show information	Show/Hide image information	
	Show Teeth location	Show/Hide tooth position	
	Reset view	Restore the default window layout	
Tools	Options	General	General settings for user login,etc
		Display	Multilingual, name display, teeth location, print font

		Database	Select single user or multiple users version
		Template	Template of image annotation
Help	Registry		Software registration
	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.



New Study

New Patient
 New Patient
If the following item was selected, it will create a new patient case, if not it will create new exam for the current patient.

Patient Info
 Last Name:
 First Name:
 Patient ID: 20210613_093507 Auto


Select Series
 Dental Series
 18
 15
 2 * 2
 1 * 2
 4 * 5
 4 + 1
 Edo-FMX

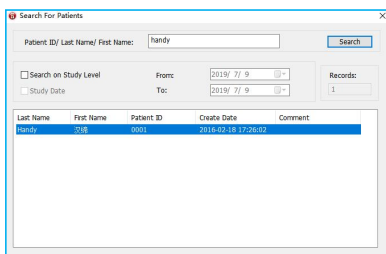
Study Comment

OK Cancel

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

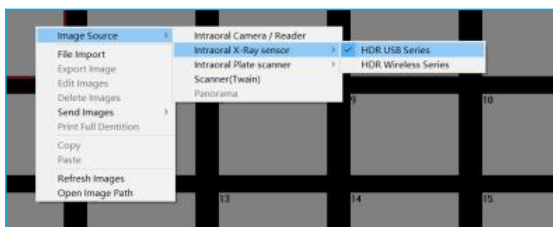
Click the icon  to bring up searching window



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.

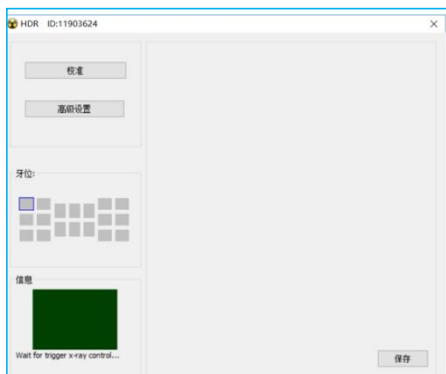
5.5 Image Acquisition

1. Connect the product to your computer via USB cable, the power light will be on under normal connection, the working light will flicker after 2 seconds.
2. Directly click the icon  or select 'Image Source'/ 'Intraoral Sensor'/ 'HDR USB Series' in drop-down menu by right-click a null frame, to bring up the shooting window. On the second time use, simply double-click a null frame to quickly bring up.

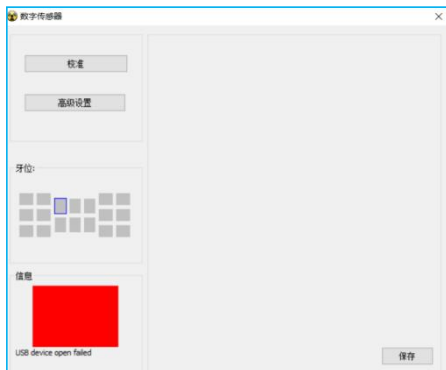


- (1) Working box with green blinking means the sensor connection is normal

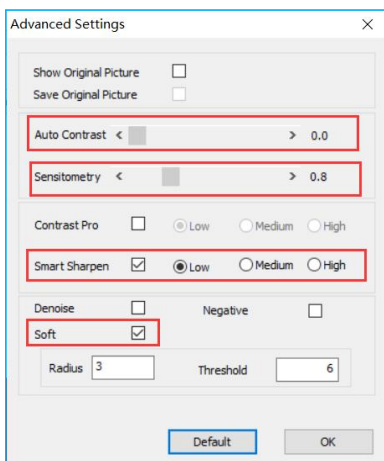
and waiting for acquiring x-ray.



(2) Red color means an abnormal connection, the sensor is unable to be detected:



3. Click the 'Advanced Settings', show below:

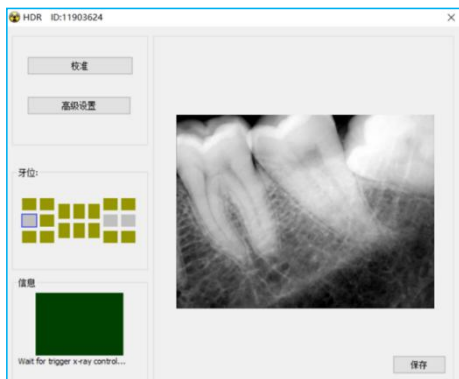


The function is used to preset parameters for some algorithms in image editing after shooting and before image come out.

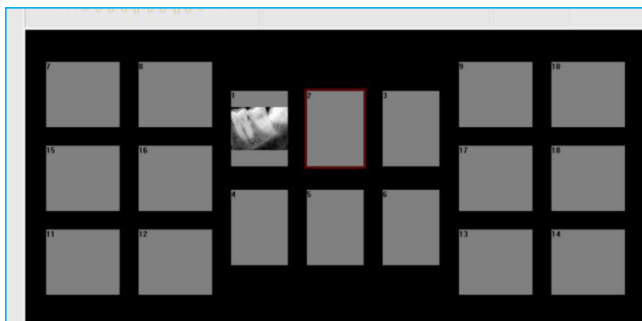
Function	Description
Display the original image at the same time	Display the original image and the preprocessed image at the same time after exposure
Save the original image by default	Select this function when only the original picture is confirmed to be saved
Contrast	Adjust the image contrast, same 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

4. Select X-ray generator exposure value.
5. Cover the sensor head with a disposable hygienic sheath, then insert into patient mouth, post it appropriately, bring the x-ray generator tube head close to the target area. After exposure, the software will show that image is in transferring.
6. After transmission completed, the acquired image will appear on the right side.



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




CAUTION:

- Face the sensor sensitive side to x-ray generator tube while take shooting.
- Disconnect the sensor from compute when not in use to prevent LED lights from over heat.

- Cover the sensor head with a disposable hygienic sheath prior to be put into patient's mouth. Use a new disposable sheath for each usage.
- Disposable hygienic sheath should comply with GB/T16886 bio-compatibility requirements: with no cytotoxicity / no delayed-type hypersensitivity / no irritation / no endothelial reaction.
- Disposing of the used disposable hygienic sheath should be executed by medical and health facilities according to Regulation on the Administration of Medical Treatment Wastes.

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

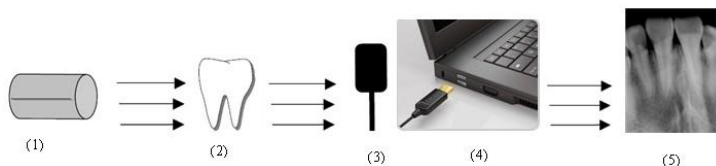
Note  :

- 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 $\pm 0.1\text{mm}$. 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 Dental X-ray Imaging Sensor Operation Guidelines


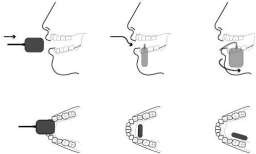
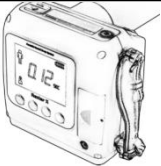

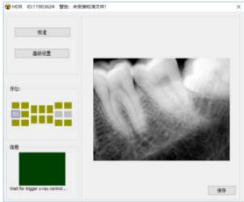
6.1 Working Sketch Map



1	X-ray source
2	Tooth
3	X-ray collection and conversion
4	Digital image transferred to computer via USB cable
5	Image acquisition in software

6.2 Digital Dental X-ray Imaging System Operation Guidelines

No	Description	Picture
1	Insert HDR sensor	
2	Create or search for a registered patient to bring up the shooting window	

<p>3</p>	<p>Cover a disposable sheath on the sensor head</p>	
<p>4</p>	<p>Position the sensor in patient's mouth just like conventional film</p>	
<p>5</p>	<p>Select X-ray generator exposure values</p>	
<p>6</p>	<p>Position the X-ray generator appropriately and then take shooting</p>	
<p>7</p>	<p>Refer to section 5.5, 5.6 for the image acquisition and viewing</p>	

WARNING:

- Connect the sensor into back side of the computer case USB port (about the computer configuration, please refer to section 3.2).
- Use a disposable sheath.
- Avoid biting the image sensor and its accessories.
- The recommended exposure conditions for X-ray generator, please refer to section 3.4 'Exposure Requirement of X-ray Generator'.

7. Cleaning and Disinfection

Do not keep immersing this product in liquids for a long time, please try to avoid disinfecting with any liquids. Cover a disposable sheath before each usage to avoid cross infection (Disposable sheath is not provided in this product package, please purchase with alone, the sheath should be registered by Food and Drug Administration, compliant with GB/T16886 biocompatibility requirements: with no cytotoxicity / no delayed-type hypersensitivity / no irritation / no endothelial reaction). Use soft cloth with a little bit ethanol to clean the sensor surface. Any other disinfectants may cause damage to CMOS sensor, that is regarded as against the usage guideline in intended application. Manufacture will not held responsible for any damage caused by unauthorized disassembled or improper operation.

WARNING:

- Do not sterilize the sensor by heating/autoclave.
- Do not put the sensor in an ultrasonic bath for cleaning or disinfecting.
- Keep the sensor away from disinfecting spray.
- Remove dirt before clean, wipe the sensor with a soft cloth gently.

Manufacture will not be held responsible for any damage caused by non-following the users manual to proceed with cleaning or disinfection, all risks should be born by the user.

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 Periodic Care and Maintenance

Periodic maintenance is performed as needed, but at least once a month, include the below inspection items, which should be executed by the user or a qualified technician.

- The labels are with intact, readable, and adhere well on the surface.
- No damage on sensor cable.
- No damage on the product surface which could incur safety issue.

8.2 Damaged or Nonfunctional Image Sensor

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

Do not disassemble the sensor to take repair without permission.

Please consult the manufacture for more technical information if needed.

9 Troubleshooting

The following table shows some solutions for common troubles. If the problem persists, please contact your local distributor or our after-sales team.

9.1 Fault State Information

Fault	Causes and Solutions
<p>Working box color is red instead of green blinking</p>	<ul style="list-style-type: none"> ·Correct image Source option 'Image Sensor/HDR USB Series'; ·Check whether the sensor is well connected to the computer; ·Re-install the sensor 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;
<p>No images acquired after X-ray emission</p>	<ul style="list-style-type: none"> ·Make sure the shooting windows is launched, normal working state is with green blinking. ·Make sure the X-ray generator faces to the sensor sensitive side. ·Make sure the X-ray generator exposure values are correct. ·Re-install the sensor 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.
<p>Unable to opening shooting window</p>	<ul style="list-style-type: none"> ·Close anti-virus program and re-install HandyDentist software

Remind of calibration file absence	·Please refer to section 4.4'Calibration File Installation'
Unable to use the software after 30 days trial, remind of registration	·Please refer to section 4.3'Software Registration'

9.2 Faulty Images

Faulty Images	Causes and Solutions
White lines or ripples on the images	·Lack of calibration file: Please refer to section 4.4 'Calibration File Installation';
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 object under test, please position closer; ·Check your monitor brightness/contrast setting, make sure there is no reflects light on the screen; ·The X-ray generator voltage is too low, check your generator;
Images are too dark	·Excessive of exposure time, please decline exposure time; ·The X-ray generator voltage is too high, check your generator.
Images are blurred	·The patient moved at the moment of x-ray

	<p>exposure;</p> <ul style="list-style-type: none"> ·X-ray generator work state is unstable; ·Increase the Contrast Pro value under Advanced Setting in shooting window;
Images are too light	<ul style="list-style-type: none"> ·Exposure values(Kv/mA/s) are too low; ·Make sure your X-ray generator is able to generate X-rays, consult with a certified technician to inspect this generator;

CAUTION  :

- 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 24 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 24 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 sensor is operated under normal conditions, the expectant lifetime of the product is 5 years. Calculation method is as below:

The number of exposures	Lifetime(The calculation is based on the average of 10000 times shooting per year)
50000	5 years

11 Product Components

NO.	Name	Qty
1	Digital Dental X-ray Imaging System	1pc
2	HandyDentist Dental Image Management Software (U Disk)	1pc
3	Sensor Holder	1pc
4	User Manual	1pc

5	Product warranty and certificate	1pc
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Annex A. EMC table

The following tables provide HDR compliance information to electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) standards. To ensure conformance, the customer or user must use the HDR in environments that are consistent with these standards. USB cables used with HDR Interfaces must also comply with the same standards.

Table 1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: HDR is intended for use in the electromagnetic environment specified below. The customer or user of HDR must ensure that it is used in such an environment.

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

Table 2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	EN 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 61000-4-4	±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.

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 HDR requires continued operation during power mains interruptions, it is recommended that the HDR be powered from an uninterruptible power supply or a battery.
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PLEASE NOTE: HDR is intended for use in the electromagnetic environment specified below. The customer or user of HDR must ensure that it is used in such an environment.

Power frequency (50/60 Hz) magnetic field 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.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Electromagnetic Immunity 2

Guidance and manufacturer's declaration - Electromagnetic immunity

The Equipemnt is intended for use in the electromagnetic environment specified below .The customer or the user of the Equipemnt should assure that it is used in such an 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	Portable and mobile RF communication equipment should be used no closer to any part of HDR, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{f_1} \right] \sqrt{P}$
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Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ for 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation 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. 
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			
<p>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.</p> <p>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 HDR is used exceeds the applicable RF compliance above, HDR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HDR.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m</p>			

Table 4. Recommended Separation Distance between Portable and Mobile RF Communications Equipment and HDR

PLEASE NOTE: HDR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of HDR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and HDR 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	80MHz to 800MHz	800 MHz to 2.7 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