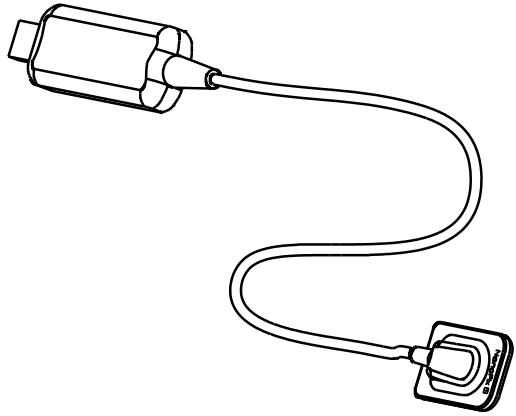
Eighteeth



Intraoral Digital Imaging Sensor

USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd.

Version: S01
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Size: 130x184mm

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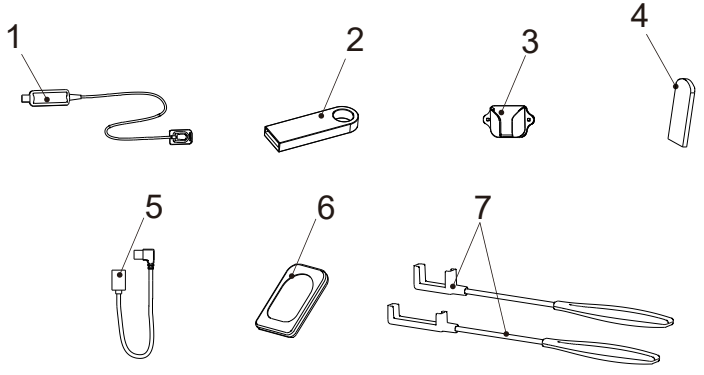
1. Scope of Sensor

1. Sensor
2. USB Flash Driver
3. Sensor Mounting Bracket
4. Disposable Sleeve
5. USB Extension Cable
6. Silicone Protective Cover
7. Handheld Bracket (Optional).



2. Symbols

	If the instructions are not followed properly, the operation may lead to hazards for the product or the user/patient.
	Additional information, explanation of operation, and performance.
	Serial number
	Catalogue number
	Manufacturer
	Country of manufacture+ Date of manufacture
	Lot of manufacture
	Type BF applied part
	Dispose of in accordance with the WEEE directive
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer's LOGO
	Follow instructions for use
	Do not reuse
IP68	Protection against liquid and particular matter
IPX8	Protection against liquid
	Medical device
	Washer-disinfector for thermal disinfection

	Sterilizable in a steam sterilizer (autoclave) at the temperature specified

3. Introduction

3.1 Scope of Application

The NanoPix-M series intraoral digital imaging sensors (model: NanoPix-M1, NanoPix-M1.5, NanoPix-M2) are intended to produce an image of the dental area at the direction of dentists, oral surgeons and orthodontists for X-ray imaging of the dento-maxillofacial area for pediatric and adult patients.

3.2 Contraindications

There are no contra-indications identified for the NanoPix series intraoral digital imaging sensors. When operating the devices, observe the warning and safety instructions in the user manual.

3.3 Safety Instructions

1. Please read this manual before use.
2. The safety regulations and guidelines of NanoPix must be installed and used following the purposes specified in the manual.
3. Do not use the device when the sensor is damaged.
4. Avoiding liquid entering the device, which could cause short circuit or corrosion.
5. This device must be disconnected from the power supply before cleaning or disinfection.
6. To avoid the cross-infection of patients, a disposable sleeve must be used before placing the sensor in the mouth, and the sleeve must be discarded after use on each patient.
7. This device must be used in a professional healthcare facility environment.

WARNING

Please read the following warning carefully before using:

1. This device can only be used by people with relevant qualifications and

technical approval.

2. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.

3. Do not expose the device to direct or indirect heat sources. Never use the device in conjunction with oxygen-rich environment. The device must be operated and stored in a safe environment.

4. The device requires special precautions concerning electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near the active HF Surgical Equipment in the hospital. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NanoPix, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5. Do not operate or store at high temperatures.

6. If irregularities occur in the device during treatment, switch it off. Contact the agency.

7. Never open or repair the device yourself, otherwise, void the warranty.

8. Please use original accessories and install original software.

3.4 Summary of use specification

1. Intended medical indication

X-ray imaging of the dento-maxillofacial area.

2. Intended patient population and intended part of the body or type of tissue applied to or interacted with

Dento-maxillofacial area of pediatric and adult patients.

3. Intended user profile

Dentists, oral surgeons and orthodontists for X-ray imaging of the dento-maxillofacial area.

The required qualifications are as shown below：

Considerations	Requirement Description
Education	A licensed dentists, oral surgeons, orthodontists, and graduates of relevant bachelor's degree (national qualifications)
Knowledge	The operator must have understood: 1. Treatment and diagnosis of dental disease; 2.Terms and guidance of diagnostic medical radiation devices; 3.Device connection, installation and operating conditions.
Language understanding	The operator must have understood:the English manuals.
Experience	The operator must have understood: 1. Objectives and effects of treatment and diagnosis of dental disease using diagnostic medical radiation devices; 2.Normal operation of diagnostic medical radiation devices; 3.The contents of the user manual.

4. Intended use environment

- The device is intended to be used in a professional healthcare facility environment, such as hospital or clinic. It is not suitable to be operated in oxygen rich and/or explosive environments. The operating conditions are as follows:

  Use in enclosed spaces

  Ambient temperature: 10°C ~ 35 °C

  Relative humidity: 20% ~ 90%

  Operating altitude < 3000m above sea level

- The device can be easily moved from one dental chair to another. Once disconnected from the USB port of the computer, the device can be positioned near a second dental chair and connected to a USB port present nearby.
- The device is intended to be used with a dental X-ray generator. Appropriate precautions should be taken during X-ray operation. Always observe the safety guidelines and precautions supplied with the X-ray generator and by local regulatory authorities.
- Use frequency: 3 cases per day.

5. Operating principle

The sensor plate is direct-deposited with CsI scintillator to achieve the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by diode capacitor array within CMOS panel, which are composed and processed by connecting to scanning and readout electronics, consequently to form a panel image by transmitting to PC through the user interface.

3.5 Clinical benefit

Acquire diagnostic digital intraoral X-ray images of the dento-maxillofacial area to help diagnosis of oral diseases.

3.6 Potential clinical side-effects

Increase the chance of image retakes and patient discomfort as direct digital sensors can be more difficult to position intraorally due to their bulky nature compared with conventional films and PSPs.

4. Product Installing

4.1 Installation Environment Requirements

Since this product is not equipped with a computer, during the installation of this product, customers need to provide an additional laptop or desktop computer. The specific performance requirements of the computer are as follows:

1. Hardware requirements

CPU	≥ 1.0GHz
Memory	≥ 2GB
Hard Disk	≥ 64GB
Display Resolution	1024*768 or above
USB ports	USB2.0 ≥ 1

2. Operating system requirements

- Microsoft Windows 7/8/10 32-bit/64-bit

4.2 Cybersecurity

1. No Network: NanoPix do not need to connect to the network during use. Please make sure that the NanoPix installation environment is not connected to the network to avoid dangers related to cybersecurity.

2. Data Interface and Transfer Protocol: USB2.0

3. Data Format: JPG、PNG、BMP、DICOM

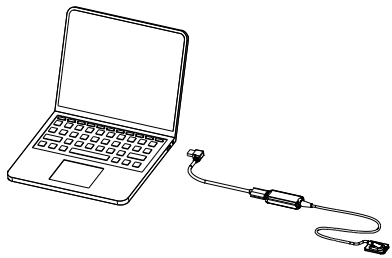
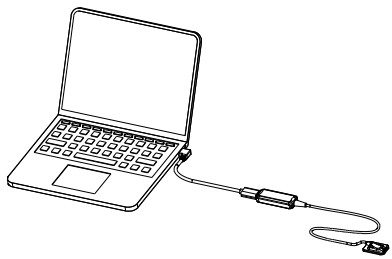
4. User Access Control:

Account Setting: NanoPix software adopts account settings when starting, and users can open the software only after entering the correct user name and password.

Encryption and Binding: NanoPix is encrypted and bound with Intraoral Digital

Imaging Sensor. Only when the license file and sensor calibration file are included, the user can use the software normally.

4.3 Connecting the Sensor to the Computer Terminal.

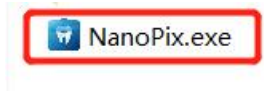
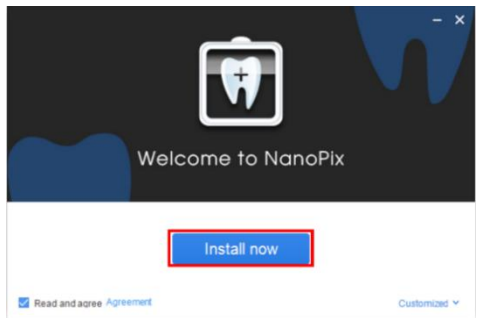
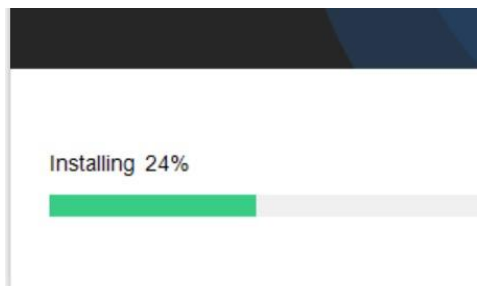
Step	Graphic Example	Description
1		Connect the USB extension cable and the sensor, and then insert the other end of the USB extension cable into USB sockets on the computer.
2		Check and ensure the connection between the computer and the sensor is reliable.

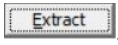
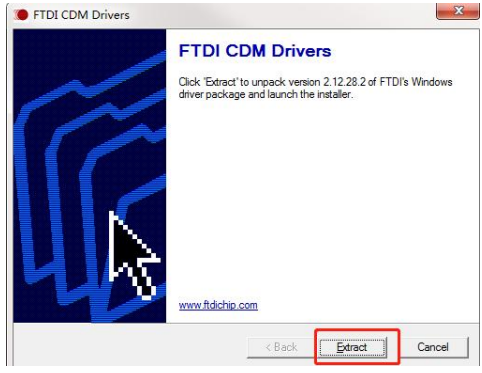
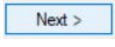
NOTE

All IT components electrically connected to the NanoPix must confirm to **IEC 62368-1.**

4.4 Software Installing

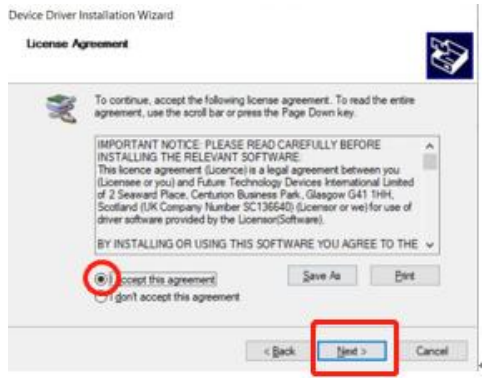
Make sure the sensor is connected to the computer terminal before installing the software.

Step 1: Connect the USB flash driver to the computer and open it.	
Step 2: double click **.exe** file, and then click Install now.	
Step 3: Enter the software installation, wait for the software to pop up the driver installation dialog box.	

Step 4: The software pops up the driver installation dialog box, and click  .	
Step 5: Click 	

Step 6:

Accept the agreement to continue to the next step.

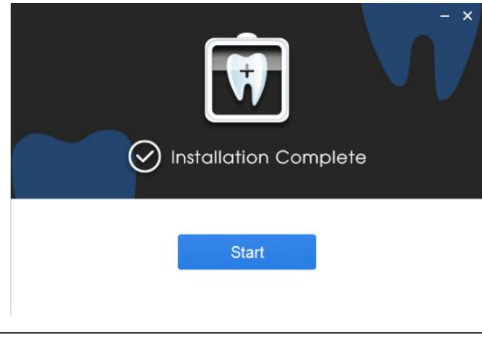


Step 7:

The software pops up a dialog box on the right, click Finish , to indicate successful driver installation.

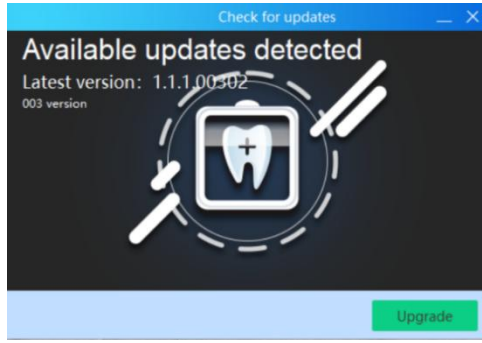
Step 8:

In the last step, the software installation successful dialog box pops up, you can click Start or close it.



4.5 Software Update

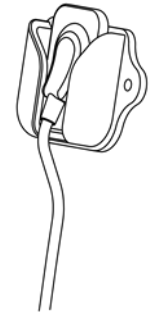
If there is an update of NanoPix software, we (Sifary) will notify local distributors (agents) and provide free installation U disk, and the distributor (agents) will upgrade the software for everyone.



4.6 Sensor Mounting

It is recommended to use the sensor mounting bracket to place the sensor. The installation method is as follows:

1. Use screws and vias to fix the sensor mounting bracket to the wall.	

2. Place unused sensors in the mounting bracket.	

4.7 Sensor Protection

When the sensor is not in use, it can be wrapped with a silicone protective cover, which has reduced scratches or wears on the sensor receiving board. The sensor silicone protective cover is used as follows:

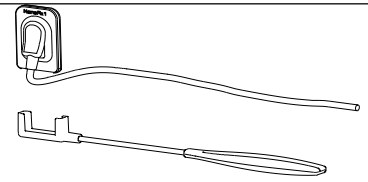
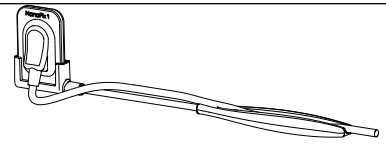
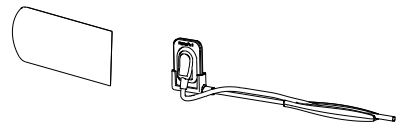
1. Prepare the sensor and the silicone protective cover	
2. Gently put the silicone protective cover on the sensor receiving board	

4.8 Use of Handheld Bracket

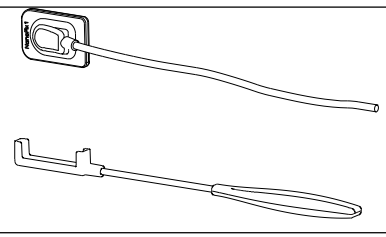
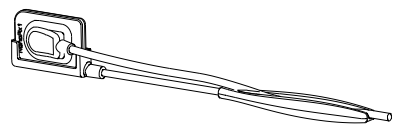
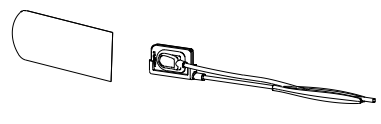
Apply the same rules for positioning the NanoPix sensor in the mouth that you use in classic radiology. When using the Intraoral Digital Imaging Sensor system for intraoral imaging, it is recommended to use the sensor with the handheld bracket.

The handheld bracket has **2** types for each model, **A** and **B**.

The use of **handheld bracket A**:

1. Prepare the sensor and the handheld bracket A.	
2. Insert the long side of the sensor into the handheld bracket A in the vertical direction and fix the wire.	
3. Use a Disposable Sleeve to cover the sensor and handheld bracket A and then place it in the mouth for imaging.	

The use of **handheld bracket B**:

1. Prepare the sensor and the handheld bracket B.	
2. Insert the short side of the sensor into the handheld bracket B in the vertical direction and fix the wire.	
3. Use a Disposable Sleeve to cover the sensor and handheld bracket B and then place it in the mouth for imaging.	

4.9 Positioning sensor operation

A dental model is used to visually display how to position the sensor properly for optimal imaging.

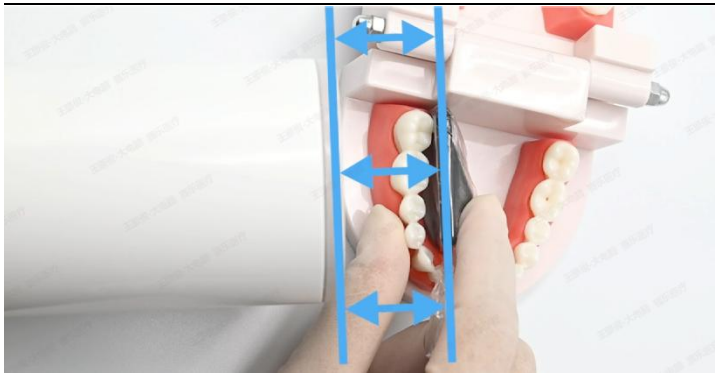
1) Cover the Sensor with the disposable sleeve.

2) Insert the Sensor into the patient's mouth, close to the lingual side of the teeth.

3) Ensure that the patient's tooth is positioned at the center of the Sensor.

4) Tightly press the Sensor against the tooth surface.

5) Ensure that the emitting surface of the X-ray unit is parallel to the receiving surface of the Sensor during the exposure.



NOTE

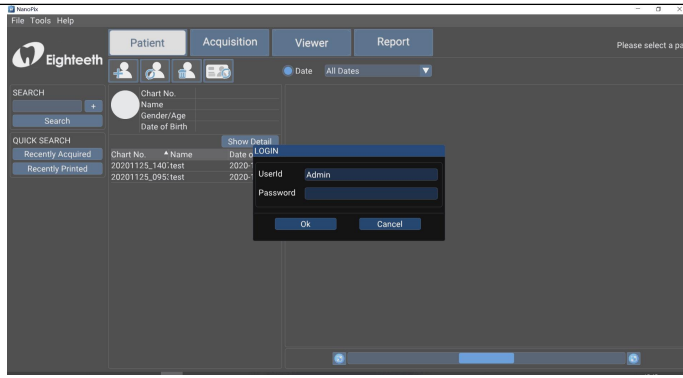
1. The training video on how to position the Senso is provided on the company's website(https://www.eighteeth.com/Digital-Sensor/1.html#08).Make sure to watch the training video before use to better understand how to position the Sensor properly.

5. Software Introduction

5.1 Login

Click the icon 

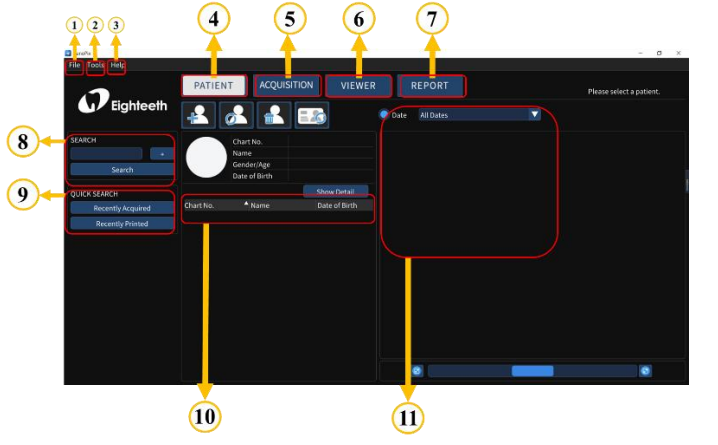
on the desktop to start the software, and its startup interface is as shown in the figure below:



UserId	Admin(Default)
Password	123456(Default)

5.2 Software Interface Introduction

After completing the user login, the software enters the home page interface:

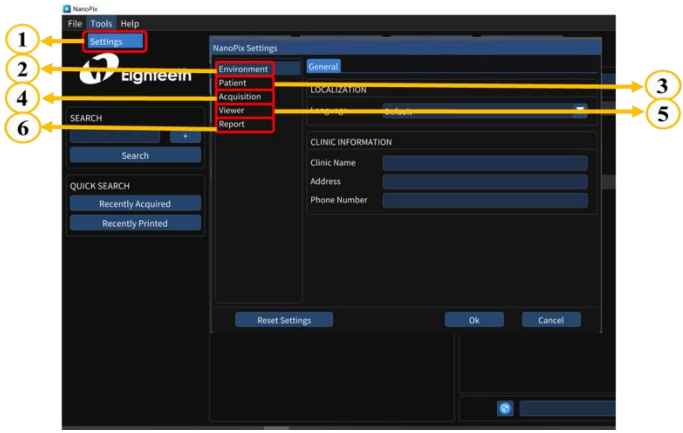


1	**File**: Use to exit.
2	**Tools**: Use for the basic setting of the software.
3	**Help**: User guides.
4	**PATIENT**: Patient Medical Record Menu.
5	**ACQUISITION**: Oral X-ray Image Acquisition Menu.
6	**VIEWER**: Oral X-ray Image View Menu.
7	**REPORT**: Oral Diagnostic Report Menu.
8	**SEARCH**: Use for searching for the diagnostic data in the software database. When the content of the search box is empty, clicking the search button could display all the diagnostic data in the database.

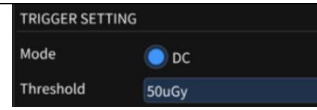
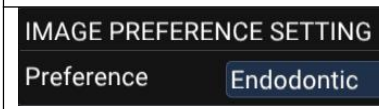
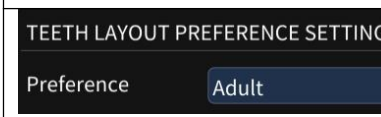
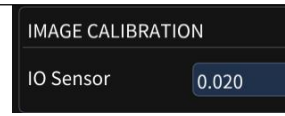
9	**QUICK SEARCH**: Use for searching for the recently acquired or recently viewed diagnostic data.
10	Medical record list display area.
11	Use for filtering medical records by date.

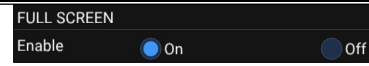
5.3 The Menu of Tools

The menu of Tools is used for the basic setting of the software



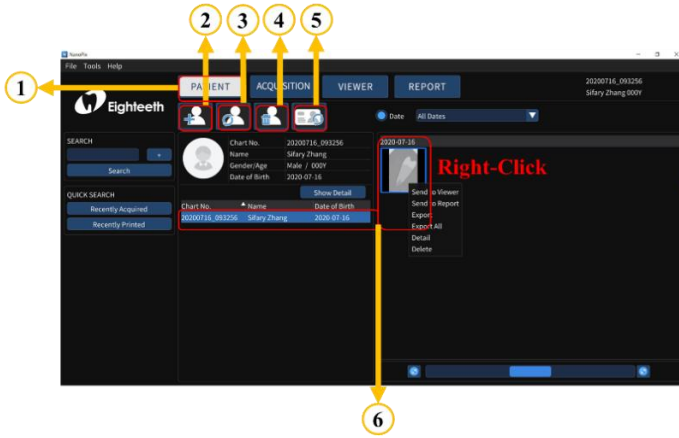
1	**Setting**: Use for basic setting of the software.	
2	**Environment** Setting	Language **Language** setting.
		USER STYLE Icon Size Small Medium Big **User Style** Setting.
		Clinic Name **Clinic Name** setting.

		Address	**Address** setting.
		Phone Number	**Phone Number** setting
3	**Patient** Setting	CHART NUMBER SETTING	**Chart Number** setting
		PATIENT NAME OPTION	**Patient Name Option**
		QUICK SEARCH	**Quick Search** setting.
4	**Acquisition** Setting	General	 **Trigger Mode** and **Threshold** settings **Threshold**: 50uGy, 100uGy, 200uGy
			 **Image Preference:** **Endodontic**; **Periodontic**;**Restorative**.
			 **Teeth Layout**: **Adult** and **Child.**
		Image	 **Image Calibration**: Use for the image resolution while displaying, keep **the default value.**
			 **Image Storage** path

5	**Viewer** Setting	General	 Full Screen setting: **On** and **Off**.
			 Image Lauout Preference Setting: **1x1, 1x2, 2x1** and **2x2**.
		Tools	 Includes **Magnifier size** 、 **Capture Border Color** and **Grid** settings.
		Mesur-a ment	 Includes **Length** and **Angle** settings.
		Annot-at ion	 Includes **Draw** 、 **Line** 、 **Rectangle** and **Ellipse** settings.
		Memo	 Includes **Memo Style** and **Text Preset** settings.
6	**Report** Setting	General	 Includes **Border Style** and **Text Box Style** setting.
		Print	 Includes **Paper** 、 **Header** and **Footer Preference** settings.

5.4 Patient Medical Record Menu

The main page of Patient Medical Record Menu

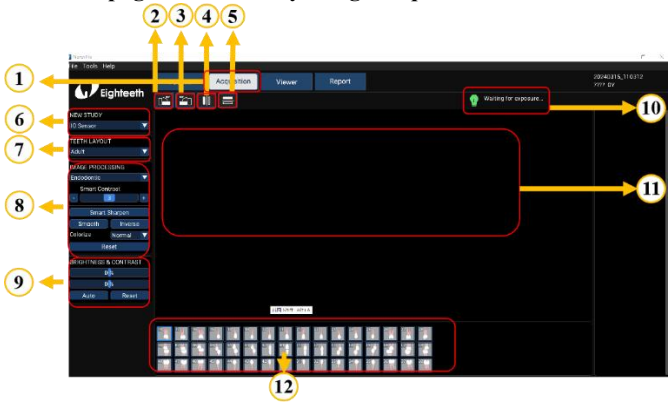


1	**PATIENT**: Click it and enter the Patient Medical Record interface.
2	 : Use to create a new medical record.
3	 : Use to edit a medical record.
4	 : Use to delete a medical record.
5	 : Use to clear the medical record list.

6	**Patient list and thumbnails of selected patients**: **Right-click** the selected thumbnail to quickly execute: **1. Send to the Viewer;** **2. Send to Report;** **3. Export;** **4. Export All;** **5. Detail;** **6. Delete.**

5.5 Oral X-ray Image Acquisition Menu

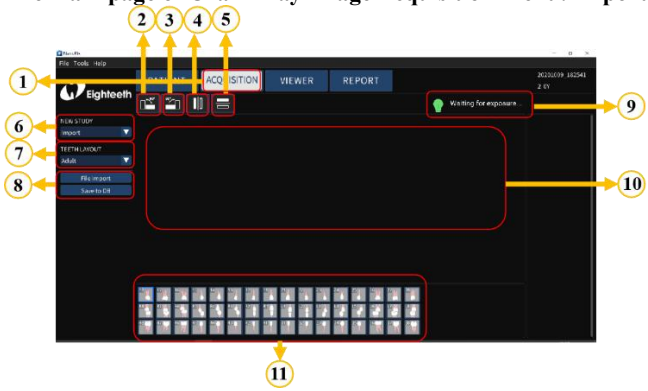
The main page of Oral X-ray Image Acquisition Menu：IO Sensor



1	**ACQUISITION**: Click it and enter the oral X-ray Image Acquisition Menu interface.
2	 **90CCW**: Use to rotate image 90° counterclockwise.
3	 **90CW**: Use to rotate image 90° clockwise.
4	 **Flip Horizontal**: Use to make image mirror left and right.
5	 **Flip Vertival**: Use to make image mirror up and down.
6	**NEW STUDY**: represents the data source. **IO Sensor**: data comes from the sensor; Import: data comes from local.
7	**TEETH LAYOUT**: use to determine the age group: adult or child.
8	**IMAGE PROCESSING**: use to process the acquired image data,

	include **Endodontic**, **Periodontic**, **Restorative**, **Smart Contrast**, **Smart Sharpen**, **Smooth**, **Inverse**, **Colorize**, and **Reset**.
9	**BRIGHTNESS & CONTRAST**: Manual, **Auto** and **Reset**.
10	Sensor Indicator: "**Waitting for exposure**": Indicate that the sensor is connected successfully and can be exposed. "**Offline**": Sensor is not connected.
11	The display area of the oral X-ray image.
12	Examples of different teeth layout.

The main page of Oral X-ray Image Acquisition Menu: Import

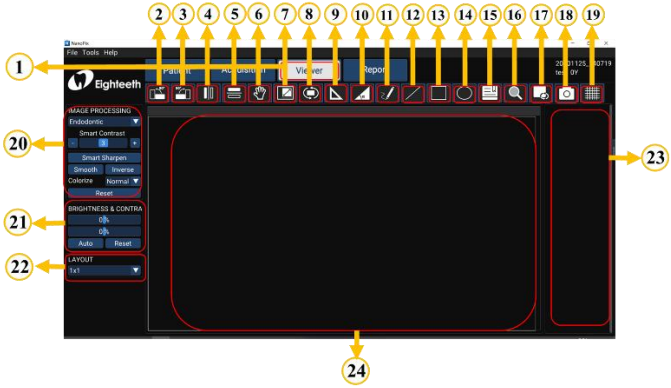


1	**ACQUISITION**: Click it and enter the oral X-ray Image Acquisition Menu interface.
2	 **90CCW**: Use to rotate image 90° counterclockwise.
3	 **90CW**: Use to rotate image 90° clockwise.

4	 **Flip Horizontal**: Use to make image mirror left and right.
5	 **Flip Vertival**: Use to make image mirror up and down.
6	**NEW STUDY**: represents the data source. IO Sensor: data comes from the sensor; **Import**: data comes from local.
7	**TEETH LAYOUT**: use to determine the age group: adult or child.
8	**File Import:** import image data from local. **Save to DB:** save image data to the database.
9	/ (No need to care).
10	The display area of the oral X-ray image.
11	Examples of different teeth layout.

5.6 Oral X-ray Image View Menu

The main page of Oral X-ray Image View Menu



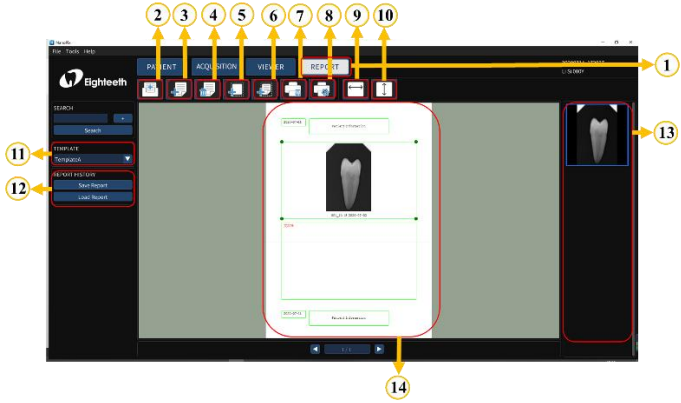
1	**VIEWER**: Click it and enter the Oral X-ray image View Menu interface.
2	**90CCW**: Use to rotate image 90° counterclockwise.
3	**90CW**: Use to rotate image 90° clockwise.
4	**Flip Horizontal**: Use to make image mirror left and right.
5	**Flip Vertival**: Use to make image mirror up and down.
6	**Pan**: Drag images
7	**Zoom**: Combine the mouse wheel to zoom in/out the

	image.
8	 **Reset.**
9	 **Length**: Measure length.
10	 **Angle**: Measure angle.
11	 **Draw**: Draw a curve.
12	 **Line**: Draw a straight line.
13	 **Rectangle**: Place rectangle.
14	 **Ellipse**: Place ellipse.
15	 **Memo**: Make a memo.
16	 **Magnify**: Local zoom
17	 **Clear Overlayers**
18	 **Capture**: Screenshot
19	 **Grid.**

20	**IMAGE PROCESSING**: use to process the acquired image data, include **Endodontic**, **Periodontic**, **Restorative**, **Smart Contrast**, **Smart Sharpen**, **Smooth**, **Inverse**, **Colorize**, and **Reset**.
21	**BRIGHTNESS & CONTRAST**: Manual, **Auto** and **Reset**.
22	**LAYOUT**: image layout, use to configure the image display.
23	**X-ray image list**: Double-click the X-ray image in the list to display it in the display area.
24	The display area of the oral X-ray image.

5.7 Oral Diagnostic Report Menu

The main page of Oral Diagnostic Report Menu



1	**Report**: Click it and enter the Oral Diagnostic Report Menu interface.
2	 New report
3	 Add page
4	 Delete page
5	 Add image box
6	 Add text box
7	 Print

8	 Print Setting
9	 Fit horizontal
10	 Fit vertical
11	**TEMPLATE**: Use to select a template for generating a medical record report.
12	**REPORT HISTORY**: Use to save the generated report and import the existing report.
13	X-ray image list
14	The display area of the report.

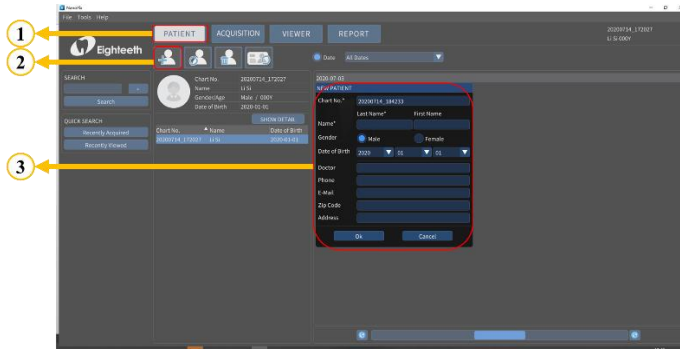
6. Operating Instructions

6.1 Acquiring Oral X-ray Image

1. Open NanoPix software.

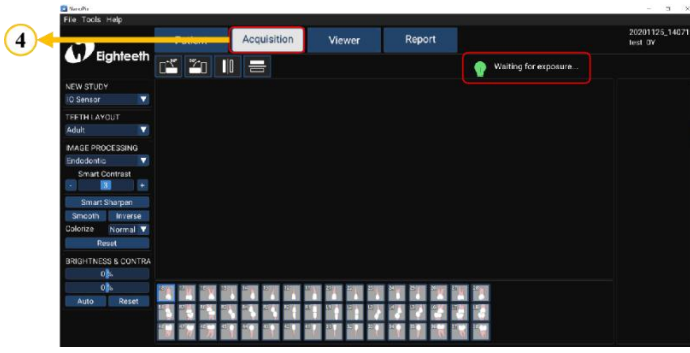
2. Click 

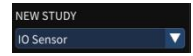
, create a new medical record or select an existing medical record.



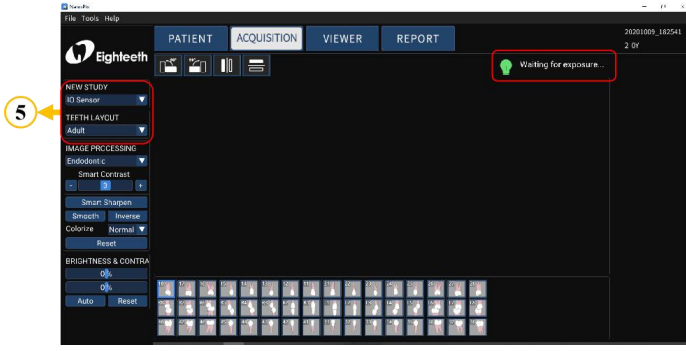
3. Click 

, enter the oral X-ray image acquisition interface, and make sure the sensor is connected successfully (the  is ready).



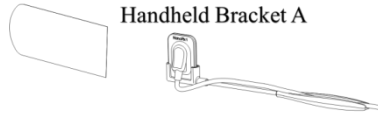
4. Make sure that the **NEW STUDY** is **IO Sensor** 

, and determine the patient's **TEETH LAYOUT** 



5. Use the handheld bracket to fix the sensor and a Disposable Sleeve to cover the sensor and handheld bracket and then place it in the mouth for imaging. For

specific operations, please refer to **Chapter 4.8**.



6. Click 

(**Optional**), place the transmitter of the X-ray generator directly on the receiving surface of the sensor (ensure the receptor of the sensor can efficiently receive X-rays) and Press the exposure button to complete the collection, the interface displays the acquired X-ray image **(Figure A is only for illustration, this product does not include this part).**

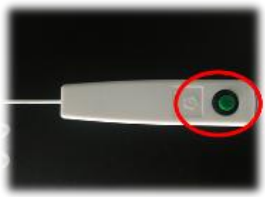
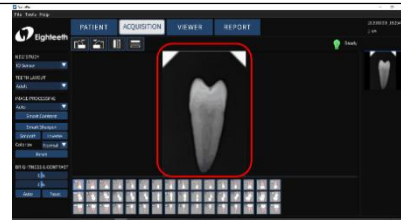
	

Figure A	Figure B

7. Checks the image quality, if it is not good, adjust the X-ray generator parameters (refer to chapter 7), repeat step 5-6.

WARNING

Please read the following warning carefully before using:

1. Before starting the experiment, please keep the sensor receiving board clean and wrap it with a disposable sleeve before putting it in the patient's mouth.

2. Patients should wear disposable gloves during use.

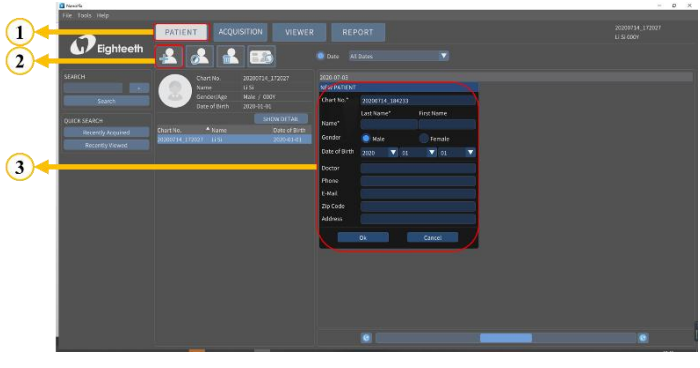
3. Before step 6, make sure that the X-ray generator is turned on and the sensor USB terminal is connected to the computer.

4. Before step 6, set the exposure time of the X-ray generator according to the actual needs.

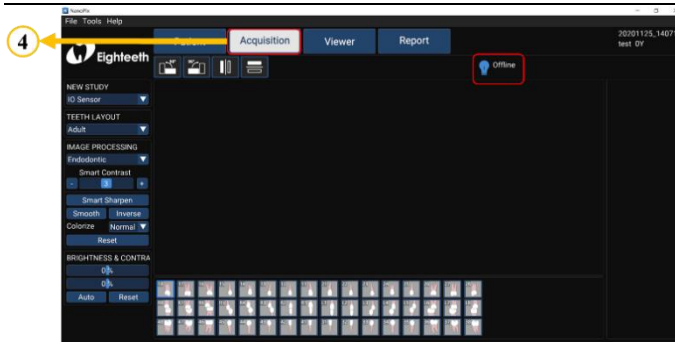
6.2 Importing Existing Oral X-ray Images

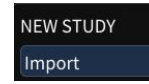
1. Open NanoPix software.

2. Click PATIENT, create a new medical record or select an existing medical record.



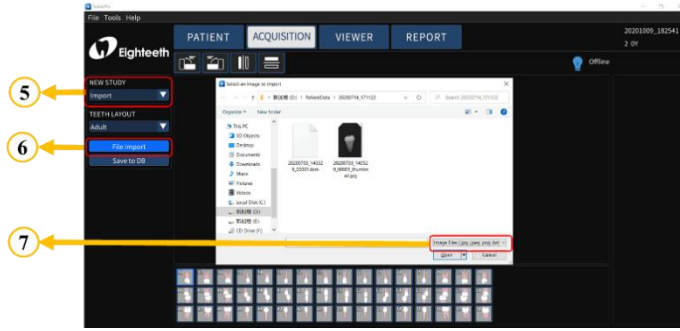
3. Click ACQUISITION, enter the oral X-ray image acquisition interface.



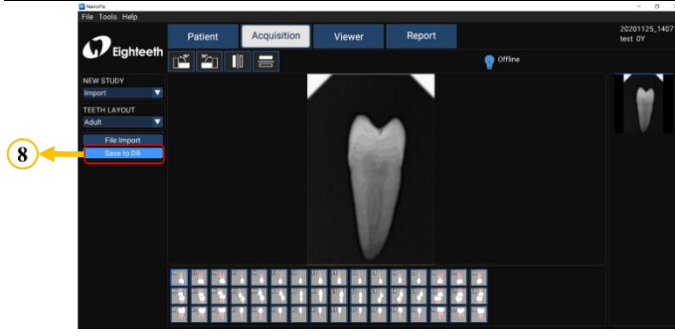
4. Make sure that the **NEW STUDY** is **Import** 

, and click 

to import existing X-ray images (***jpeg***, ***png***, ***bmp***, ***jpg***, and ***dcm*** file).



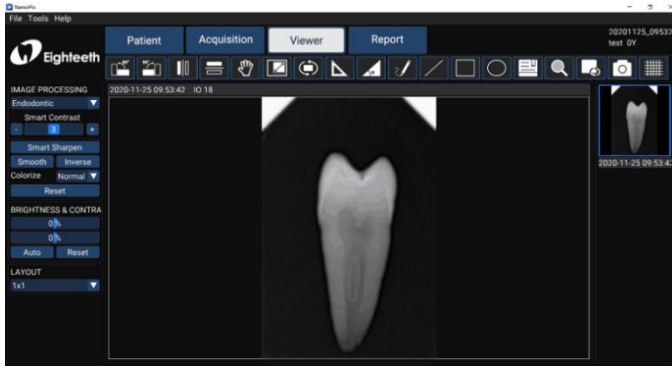
5. Save X-ray images to the database.



WARNING

Please read the following warning carefully before using:

Make sure to save the X-ray image to the database after finishing step 4. In other words, make sure to do step 5.



6.3 Image Quality Optimization

The image quality optimization currently supported by **NanoPix** includes **IMAGE PROCESSING**(Endodontic, Periodontic, Restorative),**Smart Sharpen**, **Smooth**,

Inverse, **Colorize**, **Reset**, **BRIGHTNESS&CONTRA**(Manual, Auto, Reset). The user can optimize the acquired X-ray image in the **VIEW** 

interface.

WARNING

Please read the following warning carefully before using:

Besides the optimization of the software, the image quality is also related to the **Dose** / **Exposure** time. The user can manually adjust the corresponding parameters according to experience or reference manual.

6.4 Report Generation

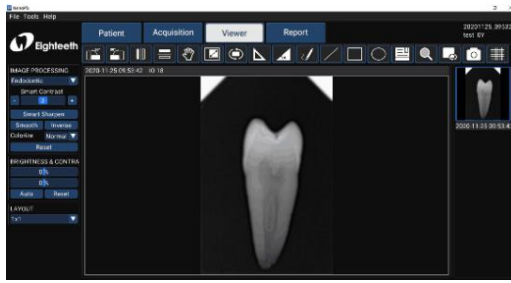
1. Obtain oral X-ray image data according to Section 6.1 or Section 6.2, and save the X-ray image to the database.

IO Sensor

Or

File Import

2. Optimize the acquired X-ray images according to section 6.3 (optional).

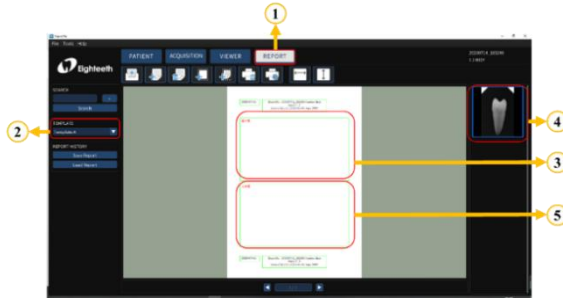


3. Click the **report** 

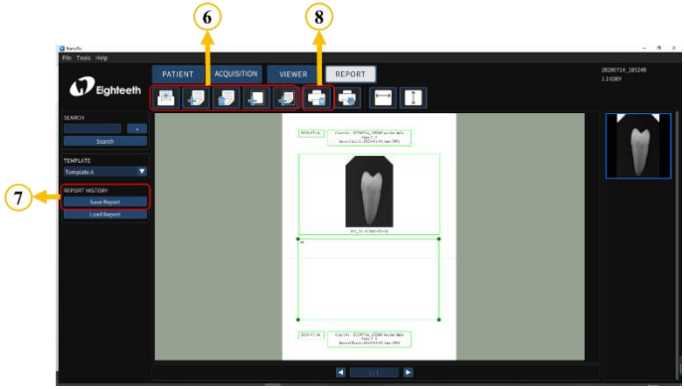
to enter the oral diagnostic report interface,

select the report **template** 

; Select the picture frame and double-click the right X-ray image to fill the image box; Double-click the text box and input the patient's diagnosis results.



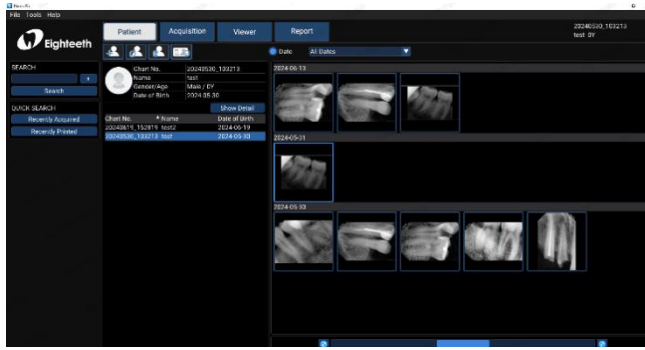
4. According to the actual needs, use the upper toolbar to edit the report, including creating a new report, adding a page, deleting a page, adding an image box, adding text box (optional); Finally, save and print the report.



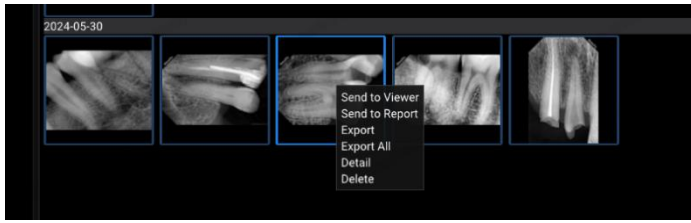
6.5 Export Oral X-ray Images

1. Open NanoPix software.

2. Click PATIENT, Select a patient and then select an oral X-ray Image.



3. Right-click the oral X-ray Image. and select Export.



4. Select the image type,and click Ok to export X-ray images (**jpg, png**, **bmp** and **dicom** file).


Eighteeth
Patient
Acquisition
Viewer
Report
SEARCH
Search
QUICK SEARCH
Recently Acquired
Recently Printed
Chart No.
Name
Gender/Age
Date of Birth
Show Detail
Chart No
Name
Date of Birth
2024-05-13
2024-05-31
EXPORT IMAGE
EXPORT FORMAT SETTING
Image Type
dicom
jpg
png
bmp
Ok
Cancel

7. Recommended X-ray Source Parameters and Exposure Time

exposure time	**Dose (μGy)**	**60kVp 6mA**	**60kVp 2mA**	**65kVp 5mA**
Patient		Adult	Adult	Adult
SID		**28cm**	**28cm**	**28cm**
Intra Oral X-ray Unit	No filter			
		Approximate exposure time(second)		
Incisor & Canine	300~500	0.12~0.2	0.1~0.2	0.18~0.28
Molar	400~600	0.16~0.25	0.15~0.25	0.24~0.34

*SID: Source to X-ray imaging sensor receptor distance.

*Make sure your exposure source is **DC**.

*If your exposure source cannot trigger the sensor, you can modify the exposure trigger threshold through software: **Tools → Settings → Acquisition → Trigger setting**. The operation steps could refer to chapter 5.3. In our test, the exposure source parameter used is **60kV 1mA**, and its corresponding threshold is **50uGy**; if the exposure source you use is **higher** than this parameter, you can set the threshold to **100uGy** or **200uGy** to give it a try; if the exposure source used is **lower** than this parameter, you can set the threshold to **20uGy or 5uGy**. The advantage of this operation is that it can Improve image quality.

NOTE

For larger body types: increase the exposure time (or Source current) by 25%

For children (5~21age): reduce the exposure time (or Source current) by 20%

For edentulous patients: reduce the exposure time (or Source current) by 20%.

WARNING

1. Since the X-ray exposure condition can be changed depending on the age,

gender, and bone density of the patient, in the case of Pediatric, X-ray exposure condition can be changed by the expert's judgment.

2. For X-ray protection: All X-ray equipment for Dental Intra-oral Radiography used with NanoPix must conform to IEC 60601-2-65. The rules for dental radiography still apply to digital X-ray systems. Please continue to use protection for your patients. As a clinician, clear the immediate area when exposing the sensor.

3. This device is not compatible with AC exposure sources.

4. The device is not suitable for pregnant women.

8. Maintenance

8.1 Foreword

For hygiene and sanitary safety purpose, the Sensor, USB Extension Cable, and Sensor Mounting Bracket must be cleaned and disinfected even if the Disposable Sleeve is used. The Silicone Protective Cover and Handheld Bracket can be steam sterilized, and they should be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Reprocessing procedures have only limited implications to this dental device. The Sensor, USB Extension Cable, and Sensor Mounting Bracket have been verified to withstand 5500 times cycles of reprocessing using the method specified in chapter 8.3 of this manual. The expected service life of the device is 5 years. For the critical sensor, the maximum verified reprocessing cycle or the expected service life, whichever comes first shall prevail.

The Silicone Protective Cover and Handheld Bracket (optional) are verified to be able to withstand 250 times reprocessing cycles. Please contact the local distributor to request for repair or exchange in case of damage of the two parts during the claimed service life.

In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

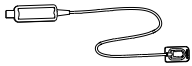
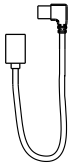
8.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty device, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.

- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Thoroughly clean and wash the sterilizable components before autoclaving.
- Do not use bleach or chloride disinfectant materials.

8.3 Disinfection devices

Disinfection devices

Sensor	USB Extension Cable	Sensor Mounting Bracket
		

WARNING

Before first use, after each use and whenever there is a risk of contamination, disinfect the above devices.
Do not sterilize the Sensor, USB Extension Cable and Sensor Mounting Bracket by heating, autoclaving or UV.

Reprocessing Instructions

Preparation before cleaning:

Immediately after using, remove the used disposable sleeve. Disconnect all plug connections. Put the Sensor, USB Extension Cable in container for transportation.

WARNING

Make sure that used disposable sleeves are disposed of as infected waste which is potentially biologically hazardous.

Transportation:

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

Cleaning:

Wet the clean soft cloth completely with 70% isopropyl alcohol, and wipe the Sensor, USB Extension Cable and Sensor Mounting Bracket surface

thoroughly for 5 times. Wipe for at least 30 s each time, until there are no visible stains.

Disinfection:

Wet the clean soft cloth completely with 70% isopropyl alcohol, and wipe the Sensor, USB Extension Cable and Sensor Mounting Bracket surface to disinfect them completely and thoroughly for 5 times. Wipe for at least 2 min each time.

Then wet the clean soft cloth completely with sterile water, wipe the Sensor, USB Extension Cable and Sensor Mounting Bracket surface thoroughly for 5 times. Wipe for at least 1 min each time, to remove the residual disinfectant on the surface.

NOTE

1. Do not use disinfectants other than isopropyl alcohol (70%) for disinfection.
2. Make sure no liquid penetrates the sensor through the USB cable or connectors, otherwise, it will damage the internal parts.
3. When cleaning the cable, hold the sensor with one hand and wipe with the other hand from the sensor receiving board to the sensor USB connector. Do not pull on the insulation of the cable.

WARNING

1. Do not disinfect the sensor in an autoclave or other sterilization container.
2. Do not immerse the sensor in disinfectants or any other chemicals.

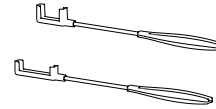
Drying:

Use a dry lint free sterile cloth to wipe off the residual water on the devices thoroughly for 3 times. Wipe for at least 30 s each time, until no water stains remain.

Storage:

Storage of disinfected devices in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

8.4 Autoclavable accessories

Silicone Protective Cover	Handheld Bracket (purchased separately)
	

WARNING

1. Only the above devices can be automated cleaning, disinfection and sterilization.

2. The silicone protective cover and handheld bracket are not mandatory but recommended to be used. They should be cleaned, disinfected and sterilized for the first use and whenever they are used between patients. The silicone protective cover and handheld bracket are verified to be able to withstand 250 times reprocessing cycles. Please contact the local distributor to request for repair or exchange in case of damage of the two parts during the claimed service life.

3. Before first use and after each use, clean, disinfect and sterilize the above devices.

Reprocessing Instructions

Preparation at the Point of Use:

1. Disconnect the silicone protective cover and handheld bracket before cleaning. Remove gross contaminations from the devices with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

2. Store the devices in a humid surrounding.

WARNING

Do not submerge the devices or wipe them with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the devices.

Transportation:

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

Preparation for Decontamination:

The devices must be reprocessed in a disassembled state.

WARNING

Observe suitable personal protective measures.

Pre-Cleaning:

Do a manual pre-cleaning, until the devices are visually clean. Submerge the devices in a clean water. Clean the surfaces with a soft bristol brush.

Cleaning:

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

Automated Cleaning:

Carefully put the devices into the washer-disinfector on a tray and set the parameters as follows, then start the program:

- 4 min pre-washing with cold water (<40°C);
- emptying
- 5 min washing with a mild alkaline cleaner at 55°C;
- emptying
- 3 min neutralising with warm water (≥40°C);
- emptying
- 5 min intermediate rinsing with warm water (≥40°C);
- emptying

The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert) cleaning agent and Rapid-M-320 Washer-disinfector from SHINVA.

Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it

prior to use.

WARNING

1. Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly.

2. Follow instructions and observe concentrations given by the manufacturer (see general recommendations).

Disinfection:

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883).

A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.

Drying:

Automated Drying:

Dry the devices according to the drying program of the washer/disinfector by setting parameter to 120 °C, 15 min.

If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.

Packaging:

Pack the devices in an appropriate packaging material for sterilization.

WARNING

1 Check the validity period of pouch given by the manufacturer to determine the shelf life.

2 Use pouches which resist to a temperature up to 141℃ and in accordance with EN ISO 11607.

Sterilization:

Sterilization of devices by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

Sterilization parameters: 134℃, 5 minutes, dry 8 minutes.

WARNING

1 Use only approved autoclave devices according to EN 13060 or EN 285.

2 Use a validated sterilization procedure according to EN ISO 17665.

3 Respect the maintenance procedure of the autoclave device given by the manufacturer.

4 Use only this recommended sterilization procedure.

5 Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters).

6 Wait for cooling before touching.

Functional Testing, Maintenance:
Visual inspection for cleanliness of the devices and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until device is visibly clean.

Packaging:
Pack the devices in an appropriate packaging material for storage.

Storage:

Storage of sterilized devices in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

Reprocessing validation study information:

The above-mentioned reprocessing process (cleaning, disinfection and sterilization) has been successfully validated.

NOTE

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

8.5 Inspection

Before each operation, please routinely check the following contents to ensure that

the device can operate correctly, safely and effectively:

Check the sensor and its cable, and the USB extension cable for any damage or ab normal condition. Do not use if there is any damage or abnormal condition.

Check the PC and software to ensure that they work properly. The software can log in normally.

9. Troubleshooting

When a problem or malfunction occurs, please check the machine with the table below before contacting the dealer to quickly eliminate common problems or malfunctions. If the problem or malfunction is not solved, please contact the dealer.

Problem or malfunction	Reasons & Solutions
After triggering X-ray, no image is displayed	Check whether the connection between the sensor and the computer is normal.
	Check if the sensor's X-ray receiver is facing the X-ray generator.
	In the software setting interface, try to set other exposure thresholds, the operation could refer to section 5.3.
	Close and reopen the software.
	Unplug the sensor and plug it in again.
The X-ray image is dim and textured	Exposure time is too short, increase exposure time.
	The selected acquisition mode does not correspond to the X-ray dose.
	The voltage of the high voltage generator is too low (less than 60kVrms), check the high voltage generator.
	The distance between the high voltage generator and the patient is too far to match the selected dose.
	Check the contrast and brightness settings of the computer to ensure that there is no problem with the screen display.
The X-ray image is too dark	The exposure time is too long, shorten the exposure time.
	The selected acquisition mode does not correspond to an X-ray dose.
	Check the contrast and brightness settings of the computer to ensure that there is no problem with the screen display.

The X-ray image is blurred	The patient moves during exposure.
	The head of the generator is unstable.
The image is white	The receiver of the sensor is not in the X-ray direction.
	Insufficient X-ray dose.
	The sensor is not connected or improperly connected.
	Check the high-voltage generator to ensure that it emits X-rays.

10. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	NanoPix-M1 / NanoPix-M1.5 / NanoPix-M2
Dimensions	19.6cm x 14.4cm x 3.4cm±1cm(Package)
Weight	0.4kg ± 10%
Effective imaging area	NanoPix-M1: 20x30mm^2
	NanoPix-M1.5: 24x33mm^2
	NanoPix-M2: 26x36mm^2
Power	2W Max
Sensor technology	CMOS CsI
Pixel size	20um
Gray scale	65536 grey levels (16 bits)
Resolution	Theoretical: 25 lp/mm
	Measured: ≥12 lp/mm
AED trigger threshold	5 μGy, 20 μGy, 50 μGy, 100 μGy, 150 μGy, 200 μGy
Low contrast resolution	Background gray-scale value（ADC）: 0-65535
	Minimum aperture: 0.1 mm
	Minimum hole depth: 0.8 mm
Maximum linear dose	≥300 μGy
Imaging time	＜6 s
X-ray energy range	60~70kV
Data interface	USB2.0
Electrical safety class	Depend on the computer terminal that the sensor is connected to.
Protection against liquid / particular matter	IP68 (Intraoral part of sensor)
	IPX8 (USB cables)
Anti-defibrillation application part	No

AP/APG type equipment	Non-AP/APG type equipment
Operating conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 35 °C Relative humidity: 20% ~ 90% Operating altitude < 3000m above sea level
Transport and storage conditions	Ambient temperature: -20 °C ~ 55 °C Relative humidity: 20% ~ 80%, no condensation Atmospheric pressure: 70kPa~106kPa

11. EMC Tables

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The NanoPix is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoPix should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The NanoPix 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The NanoPix is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>NA(*)</td></tr>
<tr><td colspan="3">(*)NanoPix is not intended to connect to the PUBLIC MAINS NETWORK, and this test is not applicable in this environment. Computers used with the NanoPix sensor must meet this rating.</td></tr>
</table>

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The NanoPix is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoPix should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
</table>

Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 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 transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11 Voltage interruptions IEC 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 sine phase at 0° 0% UT; 250/300 cycle	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 sine phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery

Rated Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **NanoPix** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NanoPix** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted dis-turbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the **NanoPix**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended minimum separation distances**

Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	See the RF wireless communication equipment table in "Recommended minimum separation distances"
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	

Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **NanoPix** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **NanoPix** as recommended below.

Test frequency (Mz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation	1.8	0.3	27

			18Hz			
450	**430-470**	**GMRS 460 FRS 460**	**FM ± 5 kHz deviation 1 kHz sine**	**2**	**0.3**	**28**
710	**704-787**	**LTE Band 13, 17**	**Pulse modulation 217Hz**	**0.2**	**0.3**	**9**
745						
780						
810	**800-960**	**GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5**	**Pulse modulation 18Hz**	**2**	**0.3**	**28**
870						
930						
1720	**1700-1990**	**GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
1845						
1970						
2450	**2400-2570**	**Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
5240	**5100-5800**	**WLAN 802.11 a/n**	**Pulse modulation 217Hz**	**0.2**	**0.3**	**9**
5500						
5785						

WARNING

1. Use of accessories and cables other than those specified or provided by the manufacturer of **NanoPix** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **NanoPix** and result in improper operation.

Cable information:

Cable Name	Cable Length(m)	Shielded or not	Remark
Communication line	2.80	Yes	/
USB extension cable	0.13	Yes	/

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

12. Operator Training Test

10 points per question, only those who score above 80 on the exam can use the device

1) Which of the following device can be sterilized ?
A Sensor
B USB Extension Cable
C Silicone Protective Cover

2) What disinfectant should be used to reprocess devices that cannot be sterilised?
A 70% Xylene
B 70% Ethanol
C 70% Isopropyl alcohol

3) What color does the Sensor Indicator show when the sensor is connected successfully and can be exposed?
A Red
B Green
C Yellow

4) Which of the following icons is used to edit a medical record?

A 

B 

C 

5) NanoPix is compatible with AC exposure sources
A True
B False

6) NanoPix require a network connection for use
A True
B False

7) NanoPix is compatible with any type of computer
A True
B False

8) Different tooth positions can use the same exposure conditions..
A True

B False

9) The sensor can be placed directly into the patient's mouth
A True
B False

10) Please describe the disinfection process of the sensor

13. Operator Training Test Answers

1). C
2). C
3). B
4). B
5). B
6). B
7). B
8). A
9). B
10). Wet the clean soft cloth completely with 70% isopropyl alcohol, and wipe the Sensor surface to disinfect them completely and thoroughly for 5 times. Wipe for at least 2 min each time.

Then wet the clean soft cloth completely with sterile water, wipe the Sensor, surface thoroughly for 5 times. Wipe for at least 1 min each time, to remove the residual disinfectant on the surface.

14. Statement

Expected Service Life

The expected service life of ***NanoPix*** series products is **5** years.

Warranty

MANUFACTURER hereby warrants ***NanoPix*** series products against defects in material and the workmanship under normal usage and service for a period of **24** months from the date of installation.

If the Buyer promptly notifies MANUFACTURER or the Seller regarding any parts that fail to perform as specified under normal usage during the Warranty Period and MANUFACTURER determines that such failure resulted from a defect in materials or workmanship during the Warranty Period, then MANUFACTURER, at its option, shall repair, rebuild or adjust the affected parts.

Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Please deal with them according to the local environmental protection laws and regulations.

Rights

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NOTE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.