

**CE** <sub>0344</sub>



# Intraoral Digital X-ray Imaging System USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd

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# 1. Scope of Sensor

- 1. Sensor
- 2. USB Flash Driver
- 3. Sensor Mounting Bracket
- 4. Disposable Sleeve
- 5. Computer Terminal (Pad and its support, optional)



# 2. Symbols

WARNING	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.		
ΝΟΤΕ	Additional information, explanation of operation and performance.		
SN	Serial number		
REF	Catalogue number		
	Manufacturer		
$\sim$	Date of manufacture		
LOT	Lot of manufacture		
	Class II		
×	BF type device		
X	WEEE directive marking		
Ť	Keep dry		
-20'C	Temperature limitation		
20%	Humidity limitation		
70kPa	At mospheric pressure limitation		
<b>Eighteeth</b>	Manufacturer's LOGO		
<b>CE</b> 0344	CE marking		
ECREP	Authorized Representative in the European Community		
8	Follow instructions for use		

# **3. Introduction**

## 3.1 Scope of Application

NanoPix1-P is used in combination with a dental X-ray transmitter for medical units to perform dental X-ray photography.

This device must only be used in hospital environments, clinics, or dental offices by qualified dental personnel.

## **3.2 Contraindications**

Patients and operators of cardiac pacemakers should use it with caution. Pregnant women are prohibited from using it.

## **3.3 Safety Instructions**

1. Please read this manual before use.

2. The safety regulations and guidelines of NanoPix 1-P 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.



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. 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 NanoPix1-P, 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. The dental team should not rely on a single precautionary strategy. When using the NanoPix 1-P, the following universal precautions should be followed routinely for adequate protection.

- Universal barrier precautions (such as masks, gloves and eye protection) should be followed;

- A preprocedural rinse should be used before treatment;

- A rubber dam should be used where possible.

## 4.1 Connecting the Sensor to the Computer Terminal.

Step	Graphic Example	Description
1		Insert the USB plug of the sensor into USB sockets on the Pad support.
2		Insert the Pad into the support, pay attention to the installation direction, and ensure the connection between the Pad and the support is reliable.



The picture of the connection between the sensor and the computer terminal.

## 4.2 Software Installing

- 1. Operating system requirements
- Microsoft Windows 7/8/10 32/64 位
- 2. Hardware requirements

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

3. Installing the driver







#### 4. Dependency library installation Hicrosoft Visual C++ 2013 Redistributable (x86) - 12... — × Step 1: Microsoft Visual C++ 2013 Open USB Redistributable (x86) - 12.0.30501 flash driver. ^ MICROSOFT SOFTWARE LICENSE TERMS double click MICROSOFT VISUAL C++ REDISTRIBUTABLE FOR VISUAL STUDIO 2013 These license terms are an agreement between Microsoft Corporation (or haced on where you live one of its affiliates) and you. Please read them I agree to the license terms and conditions vcredist\_x86.ex Install <u>Close</u> Step 2: Click 🙀 Microsoft Visual C++ 2013 Redistributable (x86) - 12... — $\times$ 💎 Install Microsoft Visual C++ 2013 When the Redistributable (x86) - 12.0.30501 software pops Setup Progress up a prompt Processing: Microsoft Visual C++ 2013 x86 Minimum Runtime - 12.0.21005 click box. Yes and wait for Cancel the installation to complete

#### 4 Product Installing

Step 3: Click	Microsoft Visual C++ 2013 Redistributable (x86) - 12 – – × Microsoft Visual C++ 2013 Redistributable (x86) - 12.0.30501
<u>C</u> lose	Setup Successful
, Software	
installed	
successfully	
	Close

## 5. Intraoral Digital X-ray Imaging System soft installing: NanoPix



Step 2:	Pin to taskbar	
<b>\</b>	Restore previous versions	
Right-click Xe xe xe in the folder to create a desktop shortcut.	Send to > Cut Copy Create shortcut Delete Bename	Bluetooth device     Compressed (zipped) folder     Desktop (create shortcut)     Documents     Fax recipient     Mail recipient
Step 3:		
find on the computer desktop, double-click the NanoPix shortcut to run the software.	NanoPix Short	Lexe - cut

## 4.3 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.



# 5. Software Introduction

## 5.1 Software Interface Introduction



Click the icon on the desktop to start the software, and its home page

interface is as shown in the figure below:





#### 5 Software Introduction

	5 Software Introduction or recently viewed diagnostic data.
10	Medical record list display area.
(11)	Use for filtering medical records by date.

## 5.2 Patient Medical Record Menu



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

## 5 Software Introduction

## 5.3 Oral X-ray Image Acquisition Menu



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1	ACQUISITION: Click it and enter the oral X-ray Image
	Acquisition Menu interface.
2	: Use to rotate image 90° counterclockwise.
3	: Use to rotate image 90° counter-clock.
4	: Use to make image mirror left and right.
5	: Use to make image mirror up and down.
	<b>NEW STUDY</b> : represents the data source.
6	<b>IO</b> Sensor: data comes from the sensor;
	<b>Import</b> : data comes from local.
	IMAGE PREFERENCE: use to process the acquired image data
()	and contains 4 processing algorithms.
8	TEETH LAYOUT: use to determine the age group: adult or child
	Ready: indicate that the experiment preparation is completed and
(9)	can be measured.
	Save to DB: save data to the database.
10	Examples of different teeth layout.
11	The display area of the oral X-ray image.

### 5 Software Introduction

# 5.4 Oral X-ray Image View Menu





#### 5 Software Introduction

	5 Software Introduction
	X-ray image list: Double-click the X-ray image in the list to display
(17)	it in the display area.
(10)	
	The display area of the oral X-ray image.

## 5.5 Oral Diagnostic Report Menu



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5	Add image box
6	Add text box
7	Print
8	Print Setting
9	Fit horizontal
10	Fit vertical
11	<b>TEMPLATE:</b> Use to select a template for generating a medical record report.
12	<b>REPORTHISTORY</b> : Use to save the generated report and import the existing report.
13	X-ray image list
14	The display area of the report.

## 5 Software Introduction

# 6. Operating Instructions

## 6.1 Acquiring oral X-ray image

1. Open NanoPix software.



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

record.



#### 6 Operating Instructions



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to pop up the exposure prompt box.

	NanoPix		- 0 ×
	File Tools Help		
		PATIENT ACQUISITION VIEWER REPORT 2020 120	0713_152715 00Y
	Eighteeth		
	SEARCH		
		CAPTURE IMAGE	
01	Search		
0	NEW STUDY	Wating for exposure	
	IO Sensor		
		Cancel	
	General	18 17 17 1 24 20 25 26 26 26 26 26 26 26 26 26 26 26 26 26	
			1
	TEETH LAYOUT		10
7	Adult 🔽		
	Pearly		
	Save to DR		
		0 0 0 0 0 0 0 0 0 0 0 0	

6. 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. Save X-ray images to the database.



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. Before step 5, make sure that the X-ray transmitter is turned on and the sensor USB terminal is connected to the display(computer terminal).

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

4. Make sure to save the X-ray image to the database after finishing step 6. In other words, make sure to do step 7.

## 6.2 Importing existing oral X-ray images

1. Open NanoPix software.

PATIENT



2. Click

, create a new medical record or select an existing medical

record.

#### 6 Operating Instructions



4. Make sure that the **NEW STUDY** is **Import**, and click

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

NEW STUDY

#### 6 Operating Instructions

File Taols Help					
<b>3</b>	PATIENT ACQUISITION	VIEWER REPORT			28280714_185248 1.2.0009
Lighteen		5			
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		2 28 / /			
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		No.			
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Adult	<u> </u>	Condition of K			
6		211 Figs (2020103,140123,0001.4cm	<ul> <li>Exage Dec Gog</li> </ul>	ávelote ×	
Save to DB			8mg	NO4	
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			M 10 10 10 10 10 10 10 10 10 10 10 10 10		

5. Save X-ray images to the database.

	C Newsfie		- в ж
	The Tools Help		
		PATIENT ACQUISITION VIEWER REPORT	20200714_385248 1.2.0009
	Eighteeth		
8	SEARCH Search New Stater Import MAGE PREFERENCE General TEETE LANOUT Jakat Pale Import	Ŵ	V
		ter inn an a	



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 brightness, contrast, sharpening, super sharpening, smoothing, and inversion. The

user can optimize the acquired X-ray image in the **VIEW** interface.





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.

#### 6 Operating Instructions



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



3. Click the **report REPORT** to enter the oral diagnostic report interface, select the report **template 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.



# 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-	No filter				
ray Unit		Approximate exposure time(second)			
Incisor	300~500	0.12~0.2	0.1~0.2	0.18~0.28	
&					
Canine					
Molar	400~600	0.16~0.25	0.15~0.25	0.24~0.34	

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



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%.



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.

# 8. Maintenance



#### 8 Maintenance



avoid being placed in a dust y or humid environment.

# 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-	Check whether the connection between the sensor and the computer terminal is normal.	
displayed	Check if the sensor's X-ray receiver is facing the X-ray generator.	
	Exposure time is too short, increase exposure time.	
	The selected acquisition mode does not correspond to the X-ray dose.	
The X-ray image is	The voltage of the high voltage generator is too low (less than 60kVrms), check the high voltage generator.	
dim and textured	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 terminal to ensure that there is no problem with the screen display.	
	The exposure time is too long, shorten the exposure time.	
The X-ray image is	The selected acquisition mode does not correspond to an X-ray dose.	
too dark	Check the contrast and brightness settings of the computer terminal to ensure that there is no problem with the screen display.	
The X-ray image is blurred	The patient moves during exposure 。	

## 9 Troubleshooting

	The head of the generator is unstable.	
	The receiver of the sensor is not in the X-ray direction.	
The image is white	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	NanoPix1-P		
Dimensions	29.0cm x 20.9cm x 8.0cm±1cm(Package)		
Weight	$1.5$ kg $\pm$ 10%		
Effective imaging area	20x30mm <sup>2</sup>		
Power	1.5W Max		
Sensor technology	CMOS CsI		
Pixel size	20um		
Theoretical resolution	25pl/mm		
X-ray energy range	55~100kV		
Data interface	USB2.0		
Electrical safety class	Class II		
Operating conditions	Use: in enclosed spaces Ambient temperature: 5°C ~ 40 °C Relative humidity: < 80% Operating altitude < 3000m above sea level		
Transport and storage conditions	Ambient temperature: -10 °C ~ 60 °C Relative humidity: <95% Atmospheric pressure: 70kPa~106kPa		

# 11. EMC Tables

#### Guidance and manufacturer's declaration - electromagnetic emissions

The NanoPix1-P is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoPix1-P should assure that it is used in such an environment.

<b>Emissions test</b>	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The <b>NanoPix1-P</b> 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 CISPR 11	Class B	The NanoPix1-P is suitable for use in	
Harmonic emissions IEC61000-3-2	Class A	all establishments, including domes establishments and those direc	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

Guidance and manufacturer's declaration – electromagnetic immunity				
The <b>NanoPix1-P</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>NanoPix1-P</b> should assure that it is used in such an environment.				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	

Electrostatic discharge	+/- 8 kV	+/- 8 kV	Floors should be wood,
(ESD) IEC 61000-4-2	contact	contact	concrete or ceramic tile.
			If floors are covered
	+/- 2 kV, +/- 4	+/- 2 kV, +/- 4	with synthetic material,
	kV, +/- 8 kV,	kV, +/- 8 kV,	the relative humidity
	+/- 15 kV air	+/- 15 kV air	should be at least 30 %.
Electrical fast	±2kV	$\pm 2kV$	Mains power quality
transients/bursts	100kHz	100kHz	should be that of a
IEC 61000-4-4	repetition	repetition	typical commercial or
	frequency	frequency	hospital environment.
Surge	Line to line:	Line to line:	Mains power quality
IEC 61000-4-5	$\pm 0.5 kV$ , $\pm 1 kV$	±0.5kV,	should be that of a
		$\pm 1 kV$	typical commercial or
	Line to earth:		hospital environment.
	±0.5kV,	Line to earth:	
	$\pm 1 kV$ , $\pm 2 kV$	±0.5kV,	
		$\pm 1 kV$ , $\pm 2 kV$	
Voltage dips	0% UT; 0.5	0% UT; 0.5	Mains power quality
IEC 61000-4-11	cycle	cycle	should be that of a
	at 0°, 45°, 90°,	at 0°, 45°,	typical commercial or
	135°, 180°,	90°, 135°,	hospital environment. If
	225°, 270°,	180°, 225°,	the user of devices
	and 315°	$270^{\circ}$ , and	require continued
		315°	operation during power
	0% UT; 1		mains interruptions, it is
	cycle and 70%	0% UT; 1	recommended that
	UT; 25/30	cycle and	devices be powered
	cycles	70% UT;	form an uninterruptible
	sine phase at	25/30 cycles	power supply or a
	0°	sine phase at	battery
		0°	
Voltage interruptions	0% UT;	0% UT;	

11 EMC Tables

IEC 61000-4-11	250/300 cycle	250/300 cycle		
Pated Power frequency	30 A/m	30 A/m	Power frequency	
magnetic field IEC 61000	50Hz or 60Hz	50 Hz or 60 Hz	mognotic field should be	
	30112 01 00112	30 HZ 01 00 HZ		
4-8			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				

## 11 EMC Tables

Guidance and manufacturer's declaration – electromagnetic immunity			
The NanoPix1-P is intended for use in the electromagnetic environment specified below.			
The customer or the user of the NanoPix1-P should assure that it is used in such an			
environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted dis-turbances	3 V	3 V	Portable and mobile RF
induced by RF fields	0.15 MHz - 80		communications
IEC 61000-4-6	MHz, 6 V in		equipment should be used
	ISM bands be-		no closer to any part of the
	tween 0.15		NanoPix1-P, including
	MHz and 80		cables, than the
	MHz, 80 % AM		recommended separation
	at 1 kHz		distance calculated from
			the equation applicable to
			the frequency of the
			transmitter.
		23.1/	
Radiated RF EM fields	3 V/m, 80 MHz	3 V/m	Recommended
IEC 61000-4-3	– 2,7 GHz,		minimum separation
	80 % AM at 1		distances
	kHz		See the RF wireless
			communication
			equipment table in
			"Recommended
			minimum separation
			distances"
Provimity fields from PE	See the RF	Complies	
viralass communication	wireless	Complies	
equipment	communication		
$EC \in 1000 \ 4.2$	equipment table		
IEC 01000-4-5	in		
	"Recommended		
	minimum		
	separation		
	distances"		

11 EMC Tables

#### 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 **NanoPix1-P** 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 **NanoPix1-P** as recommended below.

Test freq uenc y (MH	B and (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380- 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430- 470	G MRS 460 FRS 460	FM ± 5 kHzdeviation 1 kHzsine	2	0.3	28
710 745 780	704- 787	LTE Band 13,17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE B and 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700- 1990	G SM 1800; CDMA 1900; G SM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,	Pulse modulation 217Hz	2	0.3	28

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11 EMC Tables

		LTE Band 7				
5240		MUL A NI				
5500	5100- 5800	802.11	Pulse modulation	0.2	0.3	9
5785	2000	a/n	21,112			



1. Use of accessories and cables other than those specified or provided by the manufacturer of **NanoPix1-P** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **NanoPix1-P** and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Power Cord	3	No	/

2. Use of **NanoPix1-P** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **NanoPix1-P** and the other equipment should be observed to verify that they are operating normally.

# 12. Statement

#### Service Life

The service life of Sensor series products is 24 months.

#### 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 regulation s.

## Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.

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## EC REP

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