



DIGISMILE
Digital Intraoral Scanner System



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This manual is only applicable to **DIGISMILE digital intraoral scanner system.**

Declaration

This manual is a reference material for the operation, maintenance and repair of the product. The user must use the product in strict accordance with the manual. NEW LIFE RADIOLOGY assumes no legal responsibility for any breakdowns or accidents caused by non-compliance with this manual.

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Manual Application

This manual describes functions and operations of the digital intraoral scanner system.

Readers

This manual is intended for clinic staff and other authorized users.

Legend and designation

Any legend provided in this manual is used for illustrative and descriptive purposes only. Any legend and designation given as an example in this manual is virtual and any similarity is coincidence.

Terminology



Warning

- Indicates operations or circumstances that can cause personal injury or death.



Attention

- Indicates operations or circumstances that can cause equipment damage, data errors, or process errors.

Note

- Indicates any important information to understand.

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Chapter 1 Safety Guide

This section presents important safety information on the operation of the product.

1.1 Intended purpose

This product can be used in medical institutions to perform oral scanning, images of teeth and other tissues, making a 3D digital model for CAD/CAM for prosthetic design and processing, which can be used for restoration system and other applications.

1.2 Contraindications

This product should be used with caution in the presence of patients with moderately or severely limited mouth.

1.3 Equipment

This product consists of a handpiece, tip, holder, power supply and its Euclide software.

1.4 Operating conditions

Environmental conditions :

a) Ambient temperature: 10 °C ~ 30 °C.

b) Relative humidity: <80%. Atmospheric pressure: 70kPa ~ 110kPa.

A computer system (including monitor) that meets the requirements.

Item	Recommended	Minimum
CPU	Intel i7-7700HQ, Quad core CPU, 2.8 GHz	Intel i7-4700QM, Quad core CPU, 2.4 GHz
RAM	16 GB RAM	16 GB RAM
Monitor	Standard CRT / LCD with screen resolution of 1920 x 1080	Standard CRT / LCD with screen resolution of 1440 x 900
Operating system	Windows 10 Professional (64-bit)	Windows 10 Professional (64-bit)

Video Card	NVIDIA GeForce GTX 1050 Ti	NVIDIA GeForce GTX 960M
USB port	USB 3.0 high speed port	USB 3.0 high speed port

Table 1-1 Computer Configuration

1.5 Warnings and Notes

For safe and effective use of the system and to avoid system failures, the user should first be familiar with the operations in the Windows system, read this manual carefully and be familiar with the Euclide Software and its applications. Users should pay particular attention to the following warnings and precautions during operation.

Note

The System is not suitable for home use.

The images and screenshots provided in this manual are for reference only.

1.5.1 Safety warning



Warning

- Indicates operations or circumstances that can cause personal injury or death.
- Failure to operate the instrument and system in accordance with the safety instructions can endanger the operator. The manufacturer assumes no liability for any injury resulting from improper operation.
- The system must be installed by a qualified technician.
- Before using this system, the user must be professionally trained and carefully read this manual.
- This system must not be used for treatment.
- This system must not be used for family purposes.
- Diagnosis and examination with this system should be combined with clinical patient research and the diagnostic result should be used as a reference for the physician only.
- Explosion Hazard: This equipment should not be used in

environments exposed to a mixture of flammable anesthetic gases and air or oxygen or nitrous oxygen.

- This system is not equipped with a waterproof device and therefore should not be used in places exposed to moisture or water.
- Do not spray liquids on or inside this equipment, otherwise there is a risk of electric shock.
- Do not spray any detergent on the product, in order to avoid damage to the electronics and internal components by organic solvents.
- In the event of a fault, shut down the equipment immediately and contact us or our authorized representative.
- Risk of electric shock - Do not touch the power component with wet hands. Be sure to touch the power cord with clean and dry hands.
- Make sure to use any non-medical device (eg external printer) at least 1.5m away from the patient.
- This system can only be connected to accessories supplied or recommended by the manufacturer.
- Pay attention and prevent any ESD and EMI of any other instrument.
- Using this instrument near any strong EMI source, such as surgical electrical equipment or magnetic resonance imaging, can cause adverse effects.

1.5.2 Attention



Caution

- Before using this product, the user must inspect the main unit and any accessories to avoid any damage that could endanger the operator or compromise the performance of the instrument. It is recommended to inspect the equipment weekly or more frequently. If there is any obvious damage, replace the damaged part before using this product.
- In case the power cord is missing, damaged or unavailable, choose an alternative power cord that meets the original specifications and local codes.

- Any device or accessory used must be disposed of in accordance with local laws and regulations or returned to the manufacturer or dealer for proper disposal.
- Select a power cord with adequate rating to minimize the risk.
- No part of the system is user manageable, so any maintenance must be done by our service personnel.






1.5.3 Note









Note

To avoid damage to the system, do not use the product in the following environment:

- Exposed to direct sunlight;
- Exposed to strong temperature variations;
- Exposed to dense dust;
- Exposed to high humidity.

1.6 Description of symbols

	Note
	Refer to the operation manual
	Recyclable
P/N	Part number
	Serial number
	Date of production

	Information about the manufacturer
	This side up
	Fragile
	Protect from the rain
	Maximum storage levels
	Temperature limits
	Relative humidity limit (non-condensing)
	Atmospheric pressure limit

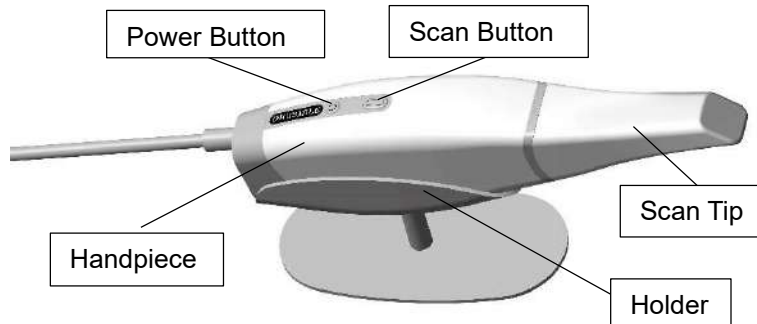
Chapter 2 Product overview

2.1 Product overview

The device is designed to acquire 3D images in the following ways:

- Lower jaw
- Upper jaw
- Occlusal relation

The image below shows the main components of the device.



- Scan tip: is reusable and must be cleaned and sterilized before use.
- Power Button: Long press the button to turn on/off the device.
- Scan Button: Press the button to start/pause scanning; long press to stop scanning.
- Holder: Place the device on the holder when not in use.

Chapter 3 Installation and Connection

Chapter 5 Euclide Software Operation Guide

5.1 Overview

Euclide is the software of the NEW LIFE RADIOLOGY Digital Intraoral Scanner. It contains three modules, including case creation, scanning and image editing. Helps to acquire intraoral scan data in "restorations", "orthodontics" and "implants".

5.1.1 System functions

Euclid consists of three modules, each with its specific functions.

- Case creation form: add patients, dentists, indications and processing scheme. And above all about focusing on and managing patient information.
- Scanning Module: Activate the camera to collect intraoral data such as maxilla, mandible and occlusal relation.
- Image Editing Module: Edit the scanned image, convert data to STL / PLY format for archiving or sending and exporting video.

5.1.2 Operating conditions

Please refer to Table1-1 for more details

5.2 Basic exams

This section mainly describes how to examine a patient with Euclide. Make sure the device is well connected to the computer and adapter before proceeding to the basic exams.

5.2.1 Logging in

Note

Before turning on the computer, make sure that the device is turned on and well connected to the computer.

Press the power button on the computer to display the startup information on the monitor. A few minutes later, the computer turns on.

When the computer turns on, the login window appears. Enter a correct username and password for login. (For various system settings, the password may not be required to log in.)

5.3 Software operations

5.3.1 Access to Euclide software

1. Double-click Euclide's shortcut icons on your computer desktop to open it and access the login screen, as shown below

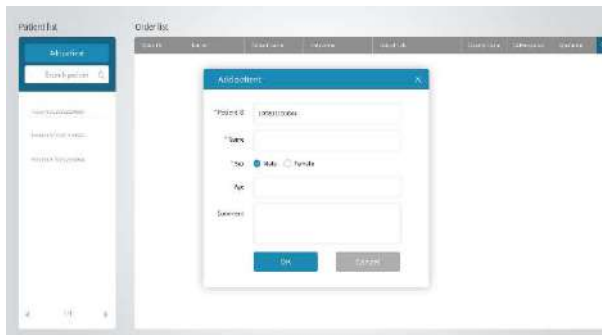


2. Choose an account to access the main software screen



5.3.2 Adding Patient Information



1. Select Add Patient on the home screen to display a window as below.




2. Add Patient ID, Name, Gender, Age and Annotations in the window and click OK to add a new patient.

Note: Patient ID, Name and Genders are required fields.

3. The patient's name will be displayed in the patient list

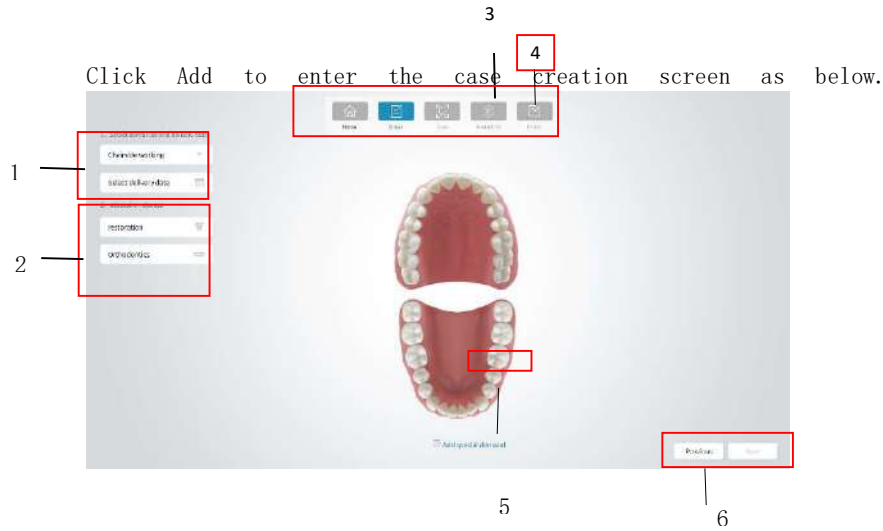
4. Click  on the right side of the patient name to edit patient information again and click O K to confirm the information; or click  > **OK** to delete the patient.

5. Click  up in the upper right corner of the screen to enter keywords to search for in the patient list.

6. Click on a patient name in the patient list to enter the patient screen as below.



5.3.3 Adding new cases



5.3.4 Indications of choice

Indications of choice

1. Choose a dental laboratory and a delivery date.
2. Choose the desired exam items from the Patient Indication List.

Indications	Items for exam
Restoration	Complete crown, veneer, inlay/onlay, missing teeth
Orthodontics	Invisible appliance, stationary, jaw, PAN

Select the exam items from the restorations list then select the material, color, restorations methods or bridge type accordingly.



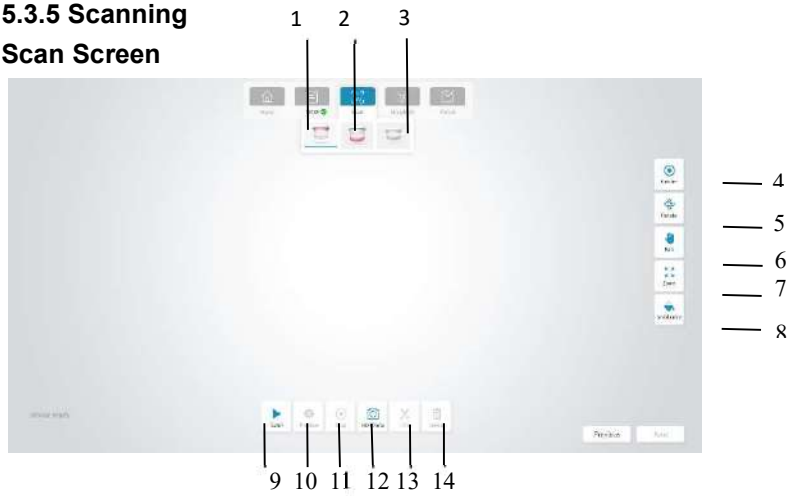
3. Select the teeth that need restoration on the dentition. Information about the process will appear on the right of the screen.



4. Click Add Special Question at the bottom of the screen, enter your question and click OK in the pop-up dialog box. The request will be displayed below.

5. Click Next to enter the scan screen.

5.3.5 Scanning Scan Screen



N	Poi	Descrizione
1	Scan of the upper jaw	Scan the patient's teeth on the upper jaw.
2	Lower jaw scan	Scan the patient's teeth on the lower jaw.
3	Scan of occlusal relation	Scan the patient's teeth for the occlusal relation.
4	Center	The image returns to the center of the screen.
5	Rotate	Disable image pan and zoom, enable image rotation.
6	PAN	Disable image rotation and zoom, enable image panning.
7	Zoom	Disable image rotation and pan, enable image zoom.
8	Full color	Exchange between full color and solid color.

9	Scanning	Click the icon to start scanning.
10	Preview	Preview the scanned image.
11	Stop	Stop scanning to get final data.
12	HD Photo	Click HD photos to take oral photos.
13	Trim	Adjust the 3D image and eliminate the extra parts.
14	Delete	Delete the current image.

5.3.5.1 Scanning

Note: Since saliva on the tooth surface reflects light and affects the accuracy of the scan, the teeth must be dry and subjected to moisture isolation treatment prior to scanning.

Make sure the edge of the tooth is clearly exposed. If not, use a gingival retraction cord to move the gums backward before scanning.

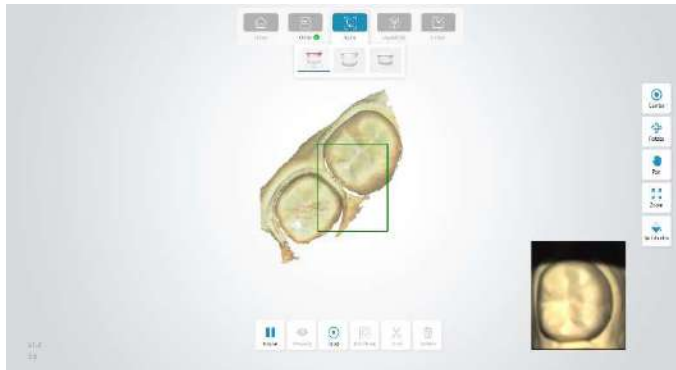
The scanning tip must be warmed up before scanning. Refer to Chapter 4 for details.

1. Click or in the scan screen.





Note: The image capture screen will show the upper jaw, lower jaw and occlusal relation scan icons by default. The upper jaw and lower jaw preset icons will only appear on the image capture screen when they are checked in the newly added indication screen.

2. Press the scan button on the device or click on the screen to start scanning. A live dynamic window will appear on the bottom right of the screen.

3. Let the scanning mirror of the scanning tip point towards the teeth to be scanned. When scanning starts, the scanned image will be displayed on the screen as below.



Note

When scanning starts, the scan icon on the screen changes to  . Click  to pause scanning. If the image is incomplete, click  to continue scanning. If the image is well formed, click  to stop scanning and generate a 3D image.

You can also press the scan icon on the device to pause scanning or long press the scan icon to stop scanning.

The scanned area will be displayed with a green frame.

- 4. After the scan is complete, a 3D image will be generated, as below.



5. Follow steps 1-4 above to complete the scans of the upper jaw, lower jaw, and occlusal relation.

Note

If the upper jaw scan and the lower jaw scan are performed, the occlusal relation scan is required to proceed.


6. When the 3D image is generated, hold down the right mouse button and drag the image to rotate it with the mouse; or hold down the left and right mouse buttons at the same time to drag it; or scroll the mouse wheel up and down to enlarge it accordingly.

5.3.6 Image Editing


Select at the bottom of the screen to change the image.




5.3.7 Deleting images

If the scanned image is not needed, select  at the bottom of the screen to delete it.


5.3.8 HD photos

1. Click on  to complete the scan and acquire a 3D image on the scan screen.

2. Click on  at the bottom of the screen to access the photo screen.

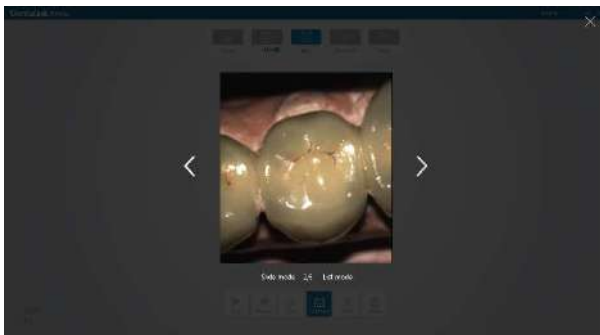
3. Place the scan tip on the teeth of interest. The scanned teeth will be displayed in the central live window. Users can adjust the brightness of the scanned image by adjusting the slider bar on the window. Once the brightness is set, the device will keep it next scan.



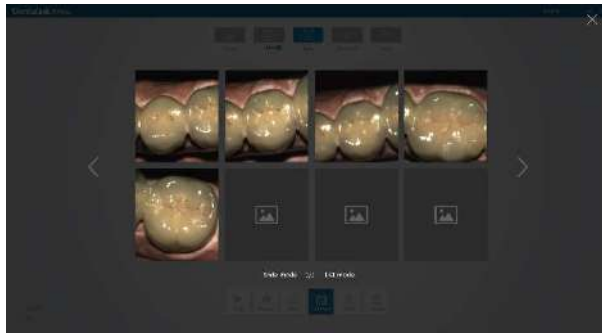
4. Press the scan button on the device or click  Capture in the center of the screen to take photos, as below.




4. Click the photo in the center to enter the photo list screen to view the photos.



5. There are two photo preview modes, slide mode and list mode, which can be changed by clicking the corresponding mode, as shown in the following figure.




6. Click on  in the upper right corner of a photo to delete an extra photo.

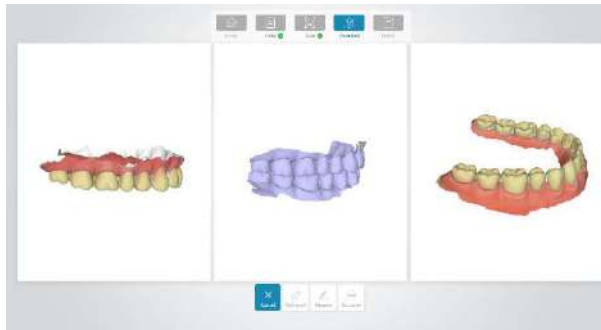
5.3.9 Editing the image

When a 3D image is captured, click Next at the bottom right of the screen to enter the image editing screen as below.



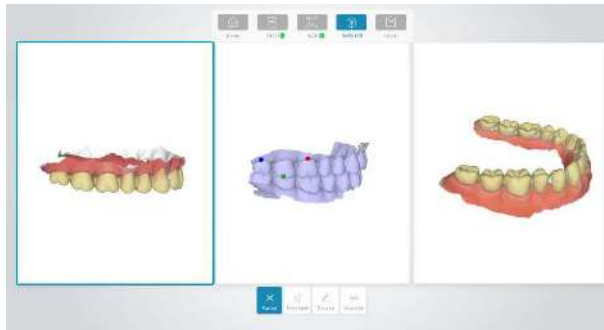
5.3.9.1 Occlusal image - split joint

If an occlusal relation image is captured, the icon  will be accessible in the image editing screen  to access the split image joint screen, as below. The left side of the screen is an image of the upper jaw, the right side is an image of the lower jaw, and the center is the occlusal image.



The stages of the split joint of the occlusal image are as follows.

1. Hold down the right mouse button and move it to rotate the occlusal image to an easily aligned angle. Rotate the images of the upper and lower jaws to the same angle as the occlusal image in the same way as in the figure above.
2. Mark three points on the upper jaw of the occlusal image, which will be displayed as red, green and blue in order. Mark three points on the same position of the left image in succession, as below.



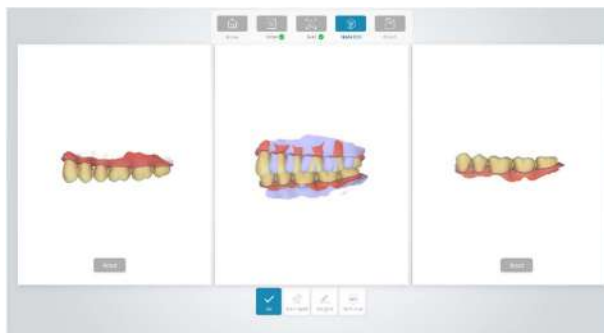
Note

When you mark the third point on the image of the upper jaw, the data of the upper jaw will immediately match that of the occlusal data, as below.

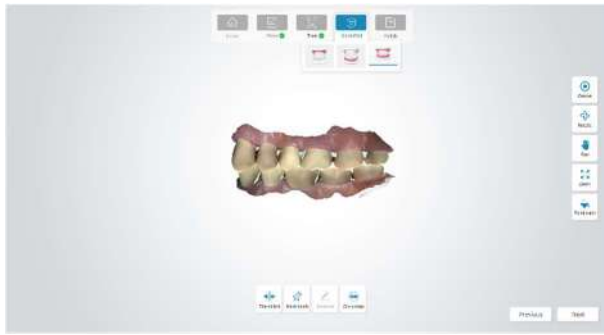


3. Mark three points on the lower jaw image and the lower jaw of the occlusal image separately according to the method of step 2. If the alignment result is not satisfactory, click Reset to start the mark again.

4. Exams with both sides scanned need to proceed with two occlusal images - split joint. After finishing the occlusal image of a split joint, click on Bite 2 and finish its split joint according to the methods of step 2-3.

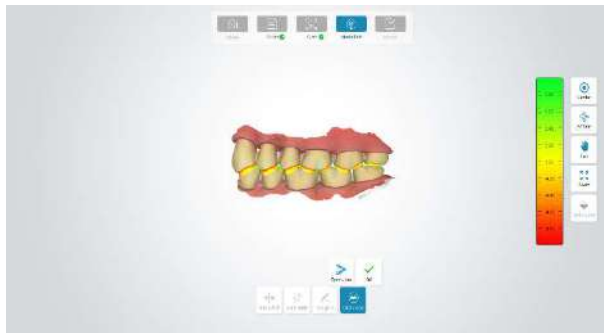


5. Click OK to view the joint split result of the occlusal image, just like below.



5.3.9.2 Occlusal relation

1. Click Occlusion at the bottom of the screen to view the occlusal relation as below.



2. Click Open Jaw / Close Jaw to view images.

3. Click OK to exit the view.

5.3.9.3 Marking of teeth

Mark the positions of the teeth for the teeth in the patient case information in order from the upper jaw to the lower jaw and from left to right. The examples will be based on the positions of the teeth in # 26, # 28, # 37.

1. Click Mark Teeth. Tooth position information will be displayed on the lower left of the screen. The outward blue dot indicates the position of the tooth that needs to be marked. Left click on the corresponding tooth of the central image to view it, as below.



2. Select and drag the blue point with the left mouse button to adjust the position of the point on the tooth.

3. When all the necessary teeth are marked, click OK at the bottom to complete the tooth marking.



5.3.10 Sending an order

When you finish editing the image, click Next to enter the order confirmation screen as below.



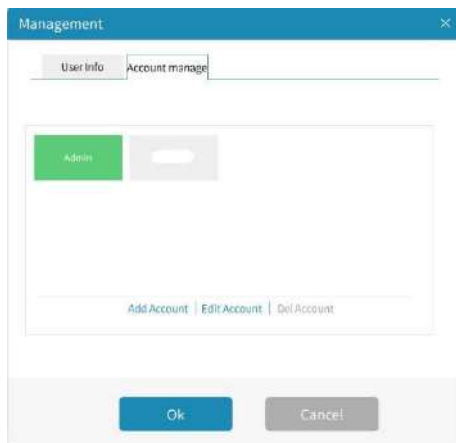
Click Submit at the bottom of the screen to display a confirmation dialog. Click OK to store all scanned images in the database, which can be viewed in the order list on the home screen by clicking View Details.

5.4 System configuration

5.4.1 User management

1. Enter a password on the login screen to access the main screen.
2. Click Administrator > Management in the upper right corner of the screen to display the system configuration dialog as below.

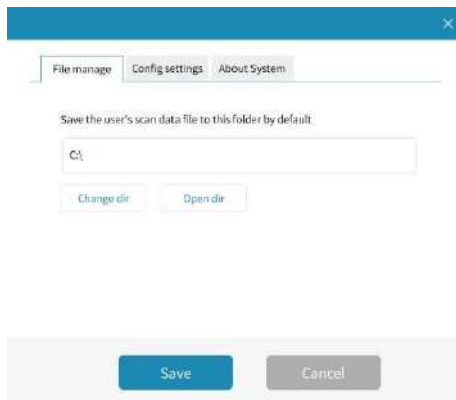
3. Click Account Management on the system setup screen.
4. Click Add Account, enter the required account information and click Save to add a new account.



5. Select an account to delete in the user list, click Delete account to delete it.

5.4.2 System settings

1. Enter a password on the login screen to access the main screen.
2. Click Administrator> Settings in the upper right corner of the home screen to display the system settings dialog as below.




3. Click Configuration Settings, select an item that needs to be changed, such as Scan Audio and Record Video, and change it.
4. Click System Information to view system information.

Note

When the audio scan is activated, the device beeps each time it starts or stops scanning.

5.5 Closing the software

1. Click **Admin > Log Out** in the upper right corner of the main screen.
2. Click **OK** to log out of the current account.
3. Click  > **OK** to close the software

Chapter 6 Cleaning**Warning**

1. Follow the applicable safety protection provisions.
2. Carefully read the material safety data list of each detergent.
3. Carefully read the operating and maintenance instructions for all sterilization equipment.
4. Do not allow liquid to splash on the device when cleaning.

Notes:

1. Clean the equipment as needed before using it for the first time. See cleaning methods in this chapter.
2. To avoid equipment damage, refer to the manufacturer's information if you have any questions about the detergent.
3. Do not use organic, halogenated or petroleum based solvents, glass cleaners, acetone or other irrational cleaners.
4. Do not use abrasive cleaners (eg steel wool, silver polish or detergent).
5. Keep liquid away from electronic components.
6. Prevent liquid from entering the shell of the equipment.
7. The pH value of the detergent must be between 7.0 and 10.5.
8. Turn off the power before cleaning.
9. Wear gloves to clean and sterilize the device.

6.1 Cleaning the device

1. Keep your device clean.
2. If necessary, clean with 75% medical alcohol.

6.2 Changing and sterilization of scan tips

Replacement and sterilization of scan tips

1. A sterilized scan tip must be installed before re-scanning.
2. Hold the main part of the device to pull out the scanning tip.
3. Install a sterilized scan tip on the device.

Warning

- A scan tip must be sterilized before use.
- A scan tip can be sterilized at high temperatures up to 20 times. After 20 times, it is recommended that the scan tip be discarded if there is any sign of deterioration.
- Eliminate scan tips according to relevant local regulations or hospital (or clinic) waste handling regulations.

6.2.1 Sterilization Methods

It is recommended to sterilize the scanning tips at a high temperature with disinfectant o-benzaldehyde (0.5% -0.6% o-benzaldehyde).

1) high temperature sterilization

Clean a scanning tip with clean water or soapy water. Check its scanning mirror and make sure it has no spots or milky mist. Dry the scanning tip with an air gun.

b. Place the scan tip in a sterilization pouch, then seal the sterilization pouch.

c. Put wrapped scan tips into sterilizer, select sterilization process 121 to sterilize at 121 ° C for at least 45 minutes.

d. After sterilization, remove the scan tips from the sterilizer for storage.

2) O-benzaldehyde disinfectant

Clean the scanning tip with clean water or soapy water. Check its scan mirror and make sure it has no spots or milky fog. Dry the mirror with clean tissues.

b. Use an o-benzaldehyde disinfectant to sterilize the scan tip for at

least 20 minutes. For details, refer to the o-benzaldehyde disinfectant user manual.

c. Remove the scanning tip from the o-benzaldehyde disinfectant and clean it with clean water. For details, refer to the user manual of the o-benzaldehyde disinfectant.

d. Dry the scanning tip. Use a sterile, non-abrasive cloth or tissue to dry the scanning tip.

6.3 Maintenance

Before using this system, the user should read this manual carefully and become familiar with all the operations on the system.

Only simple maintenance is required for the operation of this equipment, while only adequate operations on it can ensure its long-term stable operation. Therefore, you must fully adhere to the manufacturer's instructions and recommendations.

6.3.1 Device Maintenance

The main unit and monitor should be placed in a dry place with good ventilation and not exposed to thick dust or moisture. The air duct cooling system must be kept well ventilated.

6.3.2. Computer data protection

The database must be backed up to any reusable high-capacity storage media, such as magnetic tape, ZIP disk, DAT digital audio tape.

Keep any copies of the data in a safe place in accordance with the recommendations of the computer vendor.

Chapter 7 Accessories

Warning

Only accessories supplied by the manufacturer may be used, otherwise the performance of the equipment may not be guaranteed.

The company will not be responsible for any serious consequences caused by the use of accessories not approved by the manufacturer.

Accessory	Type	Quantity
Adaptor	HPU63A-10 5	1
Handpiece	DIGISMILE-10	1
Tips	DIGISMILE-20	5
Holder/base	DIGISMILE-30	1

Table 7 – 1 standars accessories list

The digital intraoral scanner system and its accessories can be purchased from the manufacturer or local dealer.

Chapter 8 Troubleshooting

This section lists some basic troubleshooting steps you can use to fix common problems with your device.

1. The scanning speed is slow.

Update your computer configuration to the recommended requirements.

2. The margin line is unclear.

Adjust the toe position to get a clear view on the margin line, then re-acquire.

3. Mesh is not smooth and spikes are present in some areas.

Delete the acquired data and reacquire.

4. Some meshes have the shape of a stripe.

Clean the tip mirror and reacquire.

5. There is fog on the mirror inside the tip.

Delete the scanned data, restart the device, wait 2-3 minutes and reacquire.

Note: For more troubleshooting information, please contact NEW LIFE RADIOLOGY for technical support.

Chapter 9 Specifications and parameters

Product Specifications :

Component	Parameter
Sensor	CMOS da 1 / 3,6 "
Lighting	LED : Red, Green, Blue
Scanning Mode	-2~12 mm
Anti-fog Technology	Actively heated tip
Cable	2 m
Digital connection	USB3.0
Dimensions of the front of the toe	20mm * 20 mm * 19.2mm
Nominal voltage	100-240VCA
Input current	1,62A-0,72A
Software Version	V1.0.0

ENVIRONMENT CONDITIONS :

Room temperature	+10-30° C
Relative humidity	<80% Relative humidity
Atmospheric Pressure	70 Kpa -110Kpa

Chapter 10 After Sales Service

NEW LIFE RADIOLOGY guarantees that all products supplied meet the specifications shown on the label and do not have defects in material or workmanship within the warranty period. The warranty period extends to 2 years from the date of the sales invoice.

The warranty will no longer be valid in any of the following cases:

- a) damage caused during shipment;
- b) damage caused by improper use or maintenance;
- c) damage caused by modifications or repairs by personnel other than those authorized by NEW LIFE RADIOLOGY;
- d) accidental damage;
- e) the label indicating the serial number or the manufacturer is replaced or removed.

Contact information

If you have any questions or problems with maintenance, technical specifications or equipment failures, please contact your dealer or our after-sales service.

E-mail: info@newliferadiology.it

Manufacturer's address: 10095 - Grugliasco (TO) - Italy. Corso Giuseppe Canonico Allamano 13/15 INT.G

Phone: + 39 011 / 78.19.94

Appendix 1 Manufacturer Information

Manufacturer: NEW LIFE RADIOLOGY SRL

Product Name: Digital Intraoral Scanner

Product models: DIGISMILE

Manufacturer's address: 10095 - Grugliasco (TO) - Italy. Corso
Giuseppe Canonico Allamano 13/15 INT.G

Production date: see the label for details

Product life cycle: 5 years

Issued in: May 2021

