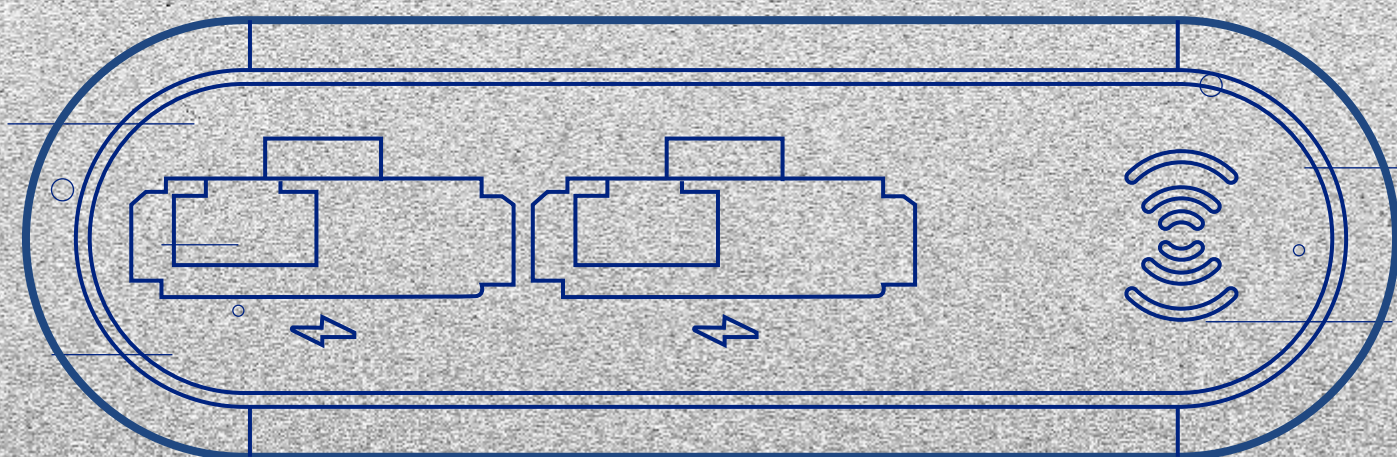




Intraoral Digital Sensor

LELA 5600

User Manual



Version 2.5
Date xxxx

Dear Users,

LELA thanks you for purchasing and using the LELA 5600 System. We will provide our best support to ensure your full satisfaction when you use the system.

The LELA 5600 System includes acquisition software designed to optimize the use of the LELA digital sensor. Therefore, we highly recommend the combined use of the LELA 5600 Sensor and LELA 5600 Acquisition Software to achieve the best image quality and the highest processing quality.

To ensure your safety and the efficient use of our LELA 5600 Intraoral Digital Sensor, please read this manual carefully prior to using the LELA 5600 System.

Best regards

LELA

NOTICE

The user manual for the LELA 5600 system contains comprehensive information about the device, including its installation and operation guidelines by OTELELA Medical Technology Development Co., Ltd. LELA reserves the right at any time to revise this manual, and the product described herein and assumes no obligation to notify any person or entity of such revisions.

To ensure optimal use of the system and full utilization of all its features in your practice, we strongly recommend reviewing this manual thoroughly.

The LELA 5600 system is designed for healthcare professionals and veterinarians to generate images of the dent maxillofacial region in human or animal anatomy.



Please note that the information in this manual is subject to change without prior notice or explanation.

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Manufacturer

OPTIMA LELA, INC
Room 402, No. 1915 North Sichuan Road, Hongkou, Shanghai, 200081, China

Authorized Representative:



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1

CONVENTIONS IN THIS GUIDE

The following messages emphasize information or indicate potential risk to personnel or equipment.



WARNING: Warns you to avoid injury to yourself or others by following.



CAUTION: Alerts you to a condition that might cause serious damage.



Important: Alerts you to a condition that might cause problems.



Note: Emphasizes important information.

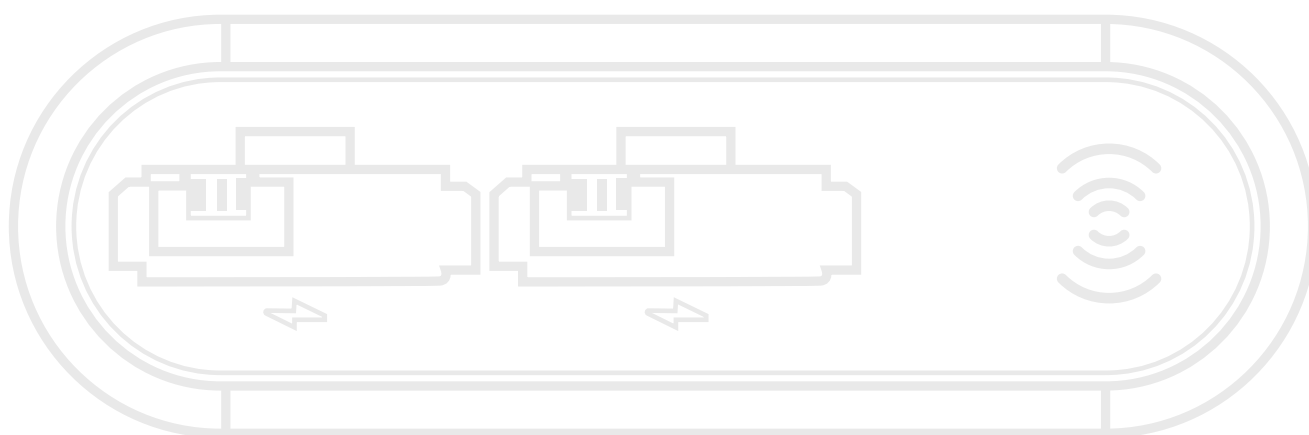


Tip: Provides extra information and hints.

2

LELA 5600 INTRAORAL DIGITAL SENSOR

LELA 5600 is a wireless intraoral sensor system which is based on Wi-Fi 5 communication standards for stable and high-speed transmission of radiographic images.



The LELA 5600 Intraoral Digital Sensor System mainly includes the CC Handpiece, the CC Dock, and Acquisition Software.

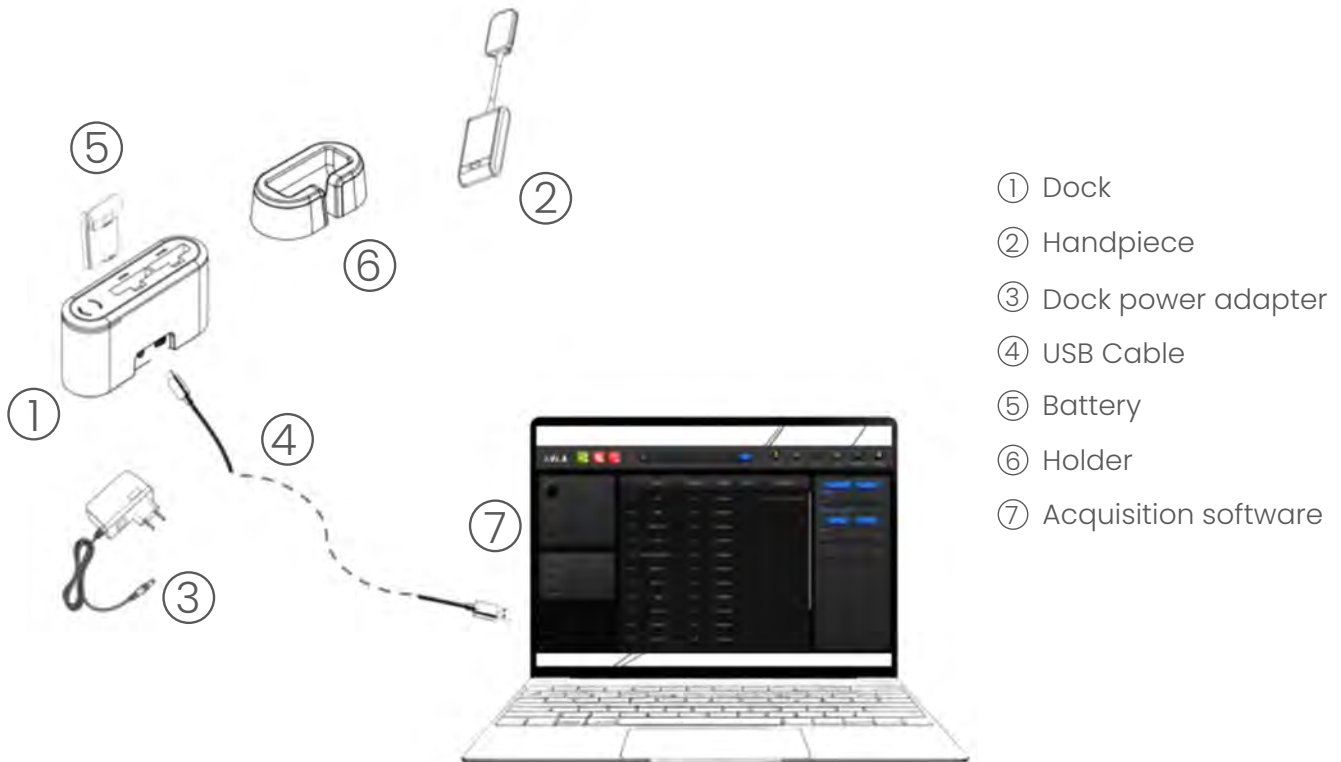


Figure 1 LELA 5600 Intraoral Digital Sensor System Overview

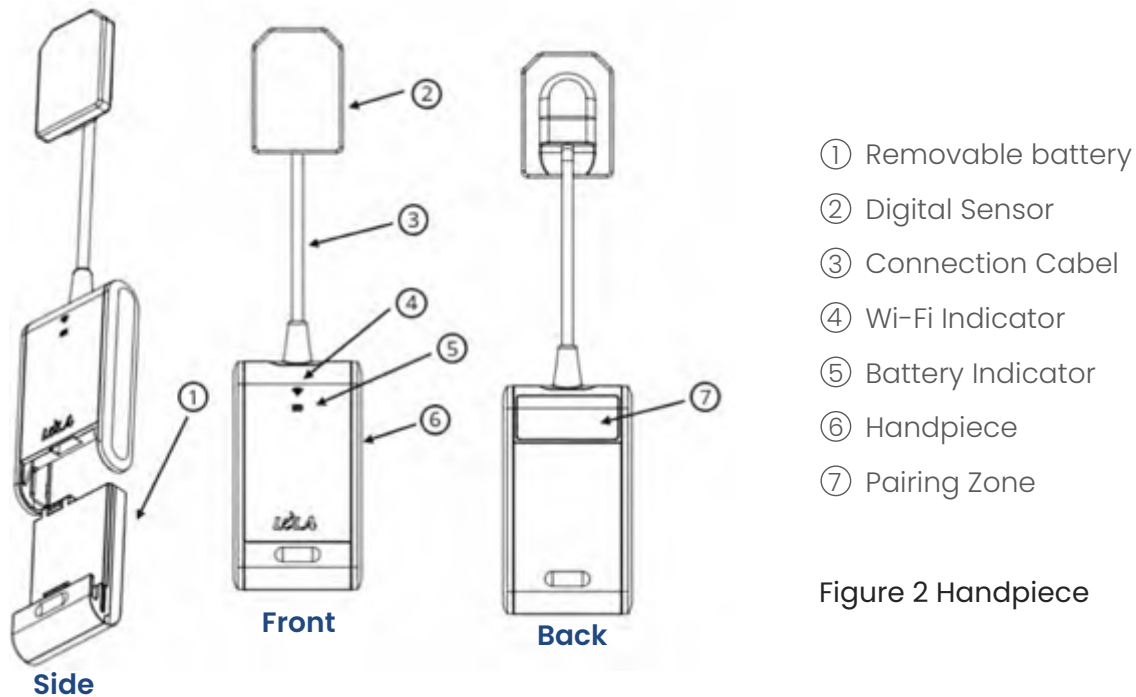
LELA 5600 system mainly contains the following:

- The CC handpiece is designed for intraoral imaging and wireless transmission of images, with its integrated battery powering the digital sensor.
- The CC Dock serves as the primary interface for image acquisition, data transfer, and battery charging.
- The acquisition software enables comprehensive patient management, real-time image acquisition, post-processing adjustments, and system configuration.

It provides the following advantages:

- Easily capturing dental intraoral x-ray images,
- Direct transmission of the images to docking station via Wi-Fi
- High storage capacity
- Easily removable battery
- Dedicated and friendly-to-use imaging software

2.1 Handpiece



- The digital sensor is based on CMOS technology which has been specifically designed for dental applications. The sensor is available in one format: size 2, (26X34 mm active area).
- Temporary memory storage in the connector enables x-ray images from the sensor stored.
- The handpiece has built-in RFID (radio frequency identification) module for pairing with Dock.
- X-ray images are transmitted wirelessly to the Dock depending on built-in Wi-Fi module.
- Removable battery design ensures the handpiece and digital sensor with consistent and reliable power supply. It is especially useful for those who capture x-ray images frequently. With a removable battery, you can swap a drained battery for a fully charged one, thus significantly extending handpiece's uptime.

Handpiece indicator lights (Table 1)

The sensor indicator lights located at the front of the handpiece

	Color	Function	Indication
●	Orange	Wi-Fi: Steady on	System initialized, but handpiece not connected
●	Green	Wi-Fi: Flash	Establishing connection with Handpiece
●	Green	Wi-Fi: Steady on	handpiece successfully connected
●	Blue	Wi-Fi: Steady on	Handpiece ready for X-ray Exposure
●	Blue	Battery: Steady on	Battery level sufficient for X-ray exposure

2.2 Dock

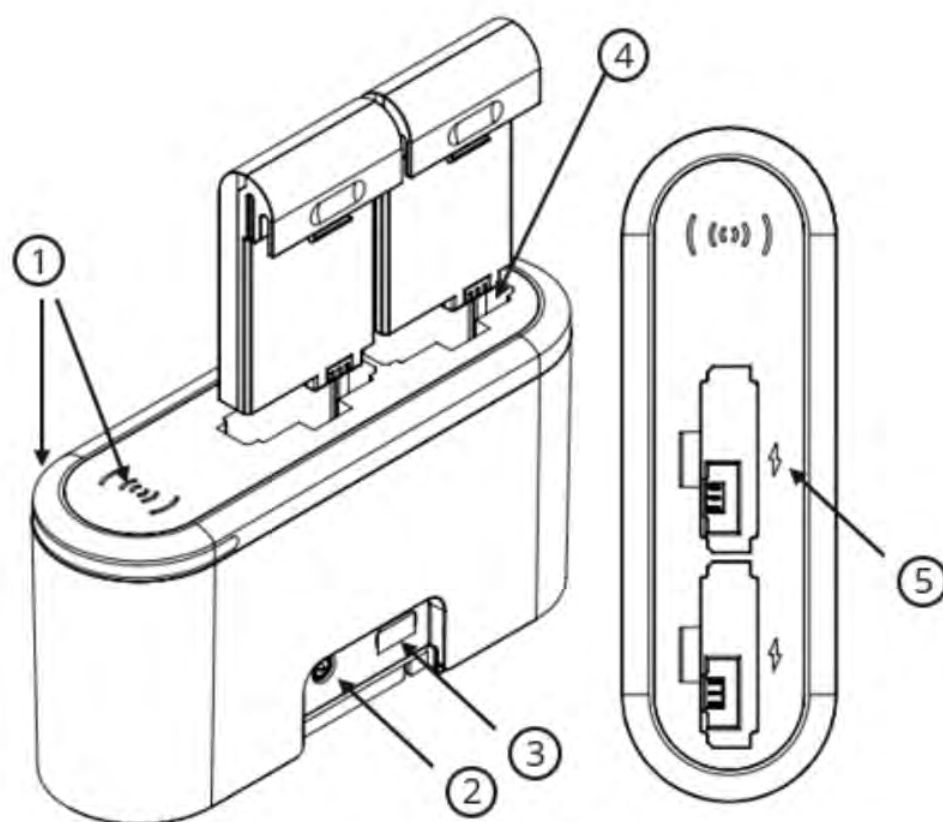


Figure 3: Side and Top view of the Dock.

- ① Wi-Fi Indicator
- ② Power supply port
- ③ USB Type-C port
- ④ Battery recharging port
- ⑤ Battery recharging Indicator

The LELA 5600 Dock has three important functions:

- Connect the handpiece to the PC through RFID pairing step
- Acquire the x-intraoral images from the handpiece to PC via USB cable
- Charge the battery in two dedicated ports

CC Dock indicator lights (Table 2)

Color	Function	Indication
● Orange	Wi-Fi: Steady on	System initialized, but handpiece not connected
● Green	Wi-Fi: Flash	Establishing connection with Handpiece
● Green	Wi-Fi: Steady on	handpiece successfully connected
● Blue	Wi-Fi: Steady on	Handpiece ready for X-ray Exposure
● Blue	Battery Recharging Port: Steady on	Battery is fully charged
● Blue	Battery Recharging port: Flash	Battery is in charging process



Tip: Dock could be placed on the table or mounted on the wall

2.3 Holder

The Clipper is designed for easy access to and storage of the Handpiece. It can be attached to a wall or other suitable bonding surface via Velcro adhesive.

When installing the Clipper, choose a location that ensures easy access and clear visibility during patient examinations.

3

LELA ACQUISITION SOFTWARE

Minimum Computer System requirements

Item	Requirement
Hardware/ Workstation	Processor: Intel Core i5 or equivalent.
	RAM: 8 GB
	Graphics card: Any
	Hard disk: 4 GB free space (image repository not included).
	Display: 1920 x 1080 minimum screen resolution
Operation	Windows 10, 64-bit,
System	Windows 11, 64-bit,

LELA Acquisition Software provides the customer with advanced features for acquisition, display, storage, and Patient management. It also provides software interface between LELA 5600 hardware and the computer. The specific panel was developed in LELA Acquisition Software to assist Intraoral Digital Sensor LELA 5600 configuration, monitoring, upgrade and diagnosis. Its function will be detailed in the installation and Operation chapters.

3.1 Patient module



1. Hardware status Bar

Status	Battery	Dock	Handpiece	Tips
Unconnected	N.A.			Both Dock and Handpiece are not connected to the Acquisition software
Paired				Both Dock and Handpiece are connected to the Acquisition software
Sleeping				The Handpiece is in the sleeping mode
Battery Low				The battery of the Handpiece is low and requires replacement; additionally, the removed battery should be charged promptly

2. Panel switch

- Patient: Patient list display and register new patient and study
- X-ray: Tooth position or FMS template selection and x-ray images acquisition
- View: Images review and postprocessing
- Export: Images exportation
- Comparison: Images comparison
- Setting: User/ sensor management, calibration and selection language etc.

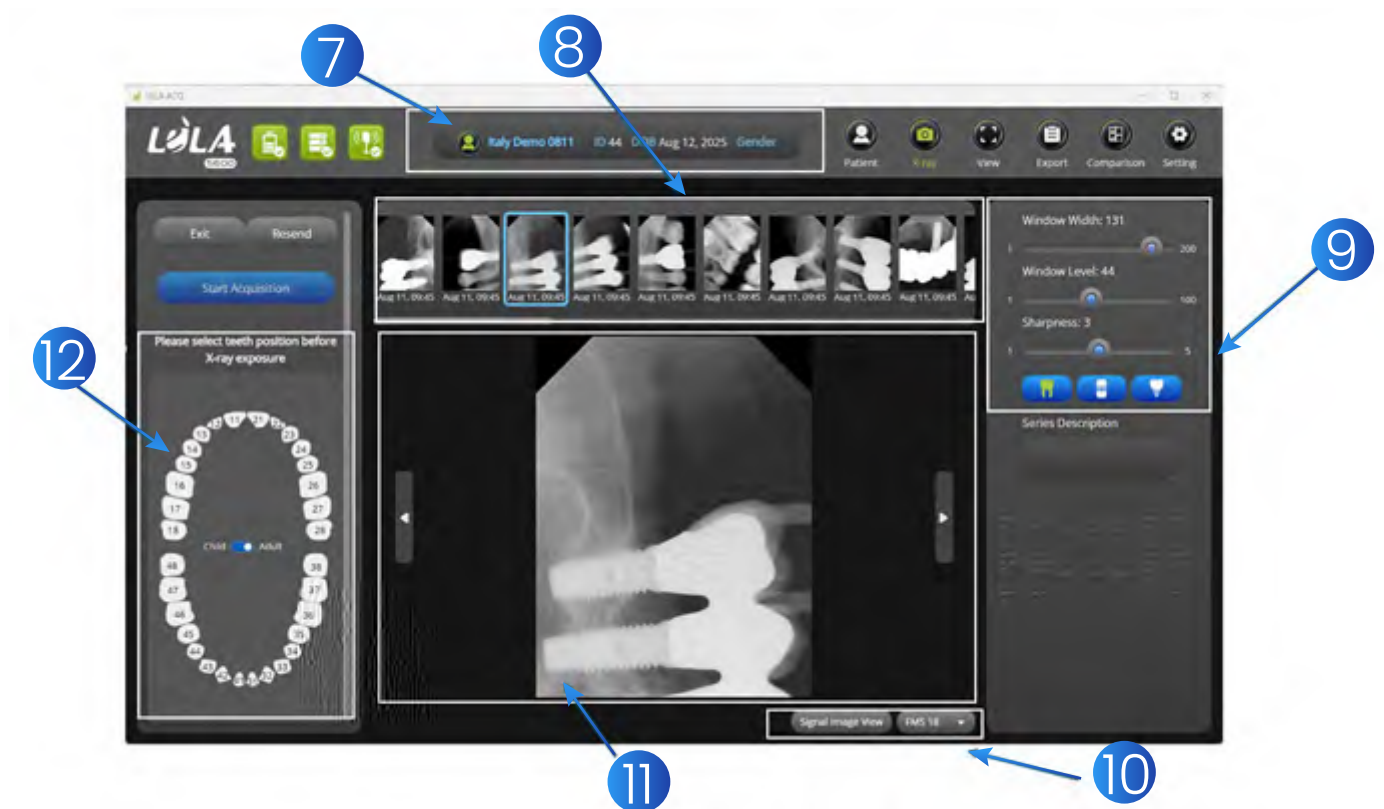
3. Patient information

4. Patient list filter

5. Thumbnail for the selected study in the patient

6. Patient list

3.2 X-ray Module



7.The information of the patient undergoing x-ray exposure

8.Images acquired in the current study

9.Images contrast adjustment with window width(WW) and window level(WL)



Default: WW/WL Optimization



Reduction: WW/WL improvement in over exposure



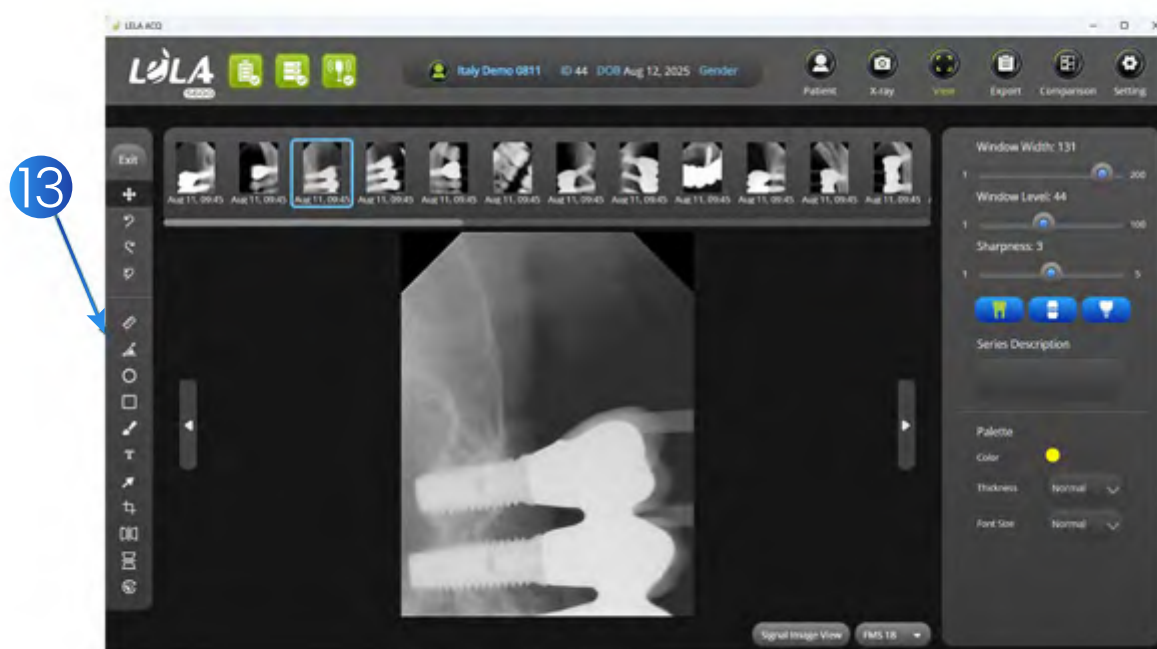
Metal: Imaging protocol for implant enhancement

10.Image acquisition mode selection with single image view and FMS template

11.Image view area for the selected

12.Tooth position selection and review

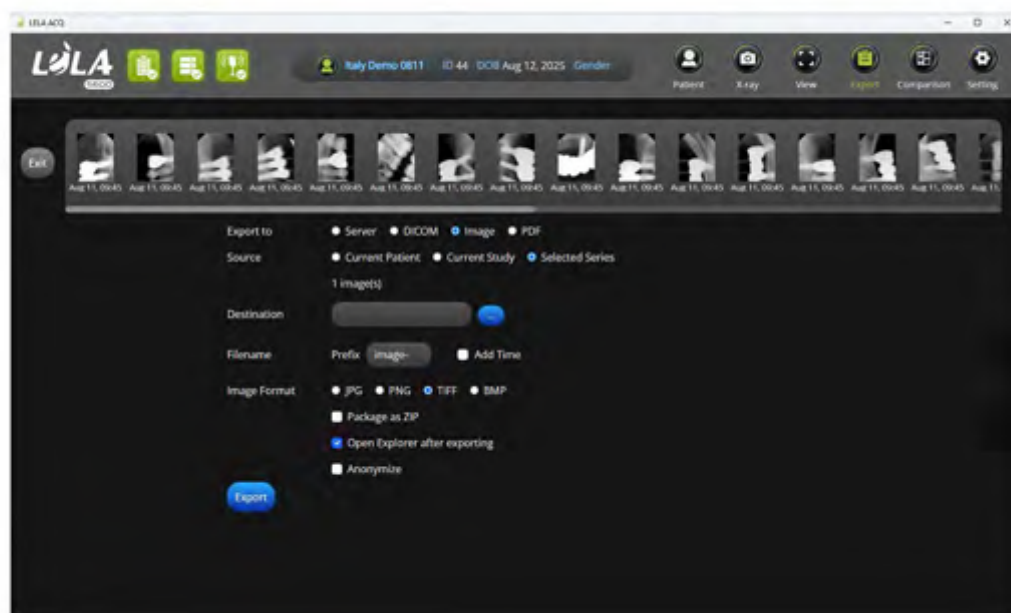
3.3 View Module



13. Image postprocessing tool bar

Zoom/Move/Undo/Redo/Reset/Measure Distance/Angle, Draw Circle/Square, Paintbrush, Text etc

3.4 Export Module

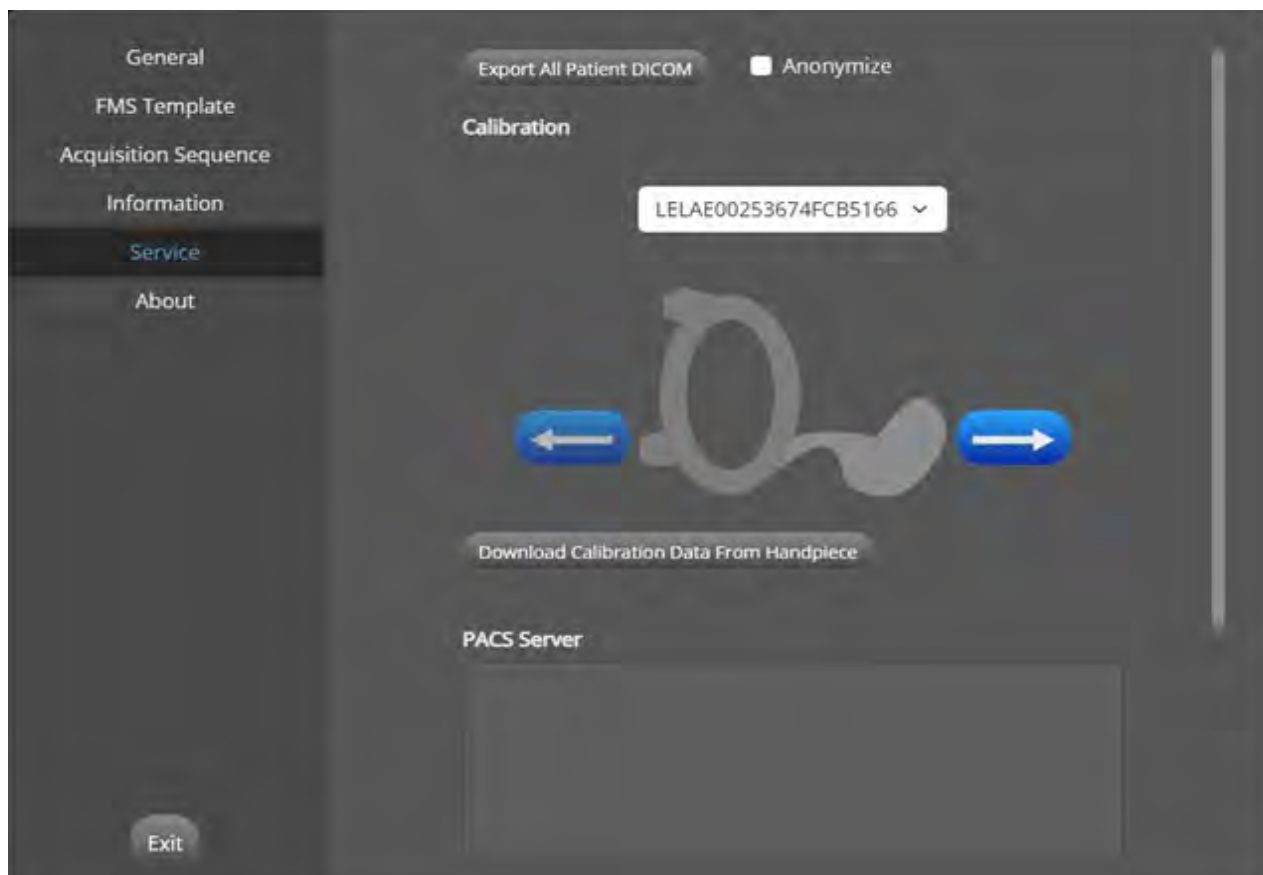


3.5 Comparison Module



Compare two images by dragging their thumbnails into the image browsing interface.

3.6 Setting Module



- General: Change Tooth Chart Naming, Language, and Storage Location etc..
- FMS Template: Add, Delete and Edit the FMS Template
- Acquisition Sequence: Edit the Acquisition Sequence for Single image view mode
- Information: Add, Delete and Edit Sensor
- Service: Download calibration data Perform recalibration, and Set up the PACS server
- About: Basic information and Software version

4 INSTALLATION

4.1 Acquisition software Installation

Install LELA Acquisition Software on the target computer in accordance with the following installation guide.

- 1 Before starting the installation, check that the computer meets the minimum system requirements listed above. It is recommended to close any running applications.
- 2 Check your computer documentation for details of your current hardware and display specifications.

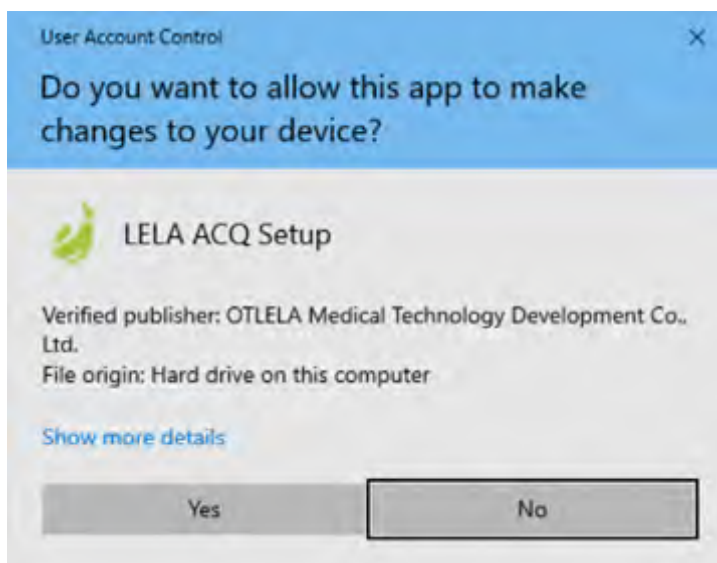


Warning: You are required to make a backup copy of your image database, as well as your other database files when the operation system is reinstalled or restored, so that you can recover stored images. LELA is not responsible for backing up your data. Make sure the latest security patches are automatically downloaded and installed to help keep your device safe and protect it from attacks.

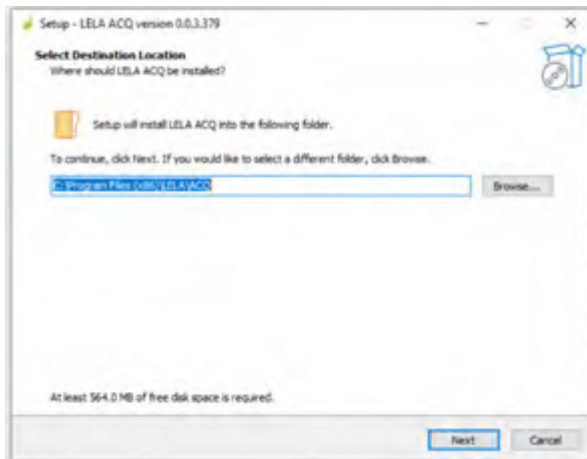
- 3 Connect the Dock to your computer using the USB cable provided. Locate and run the file named LELA_ACQ_XXXXX_setup.exe from the Dock's USB drive.

Name	Date modified	Type	Size
 LELA_ACQ_0.1.1.392_Windows-AMD64_241102_Setup	11/7/2024 10:30 AM	Application	261,985 KB

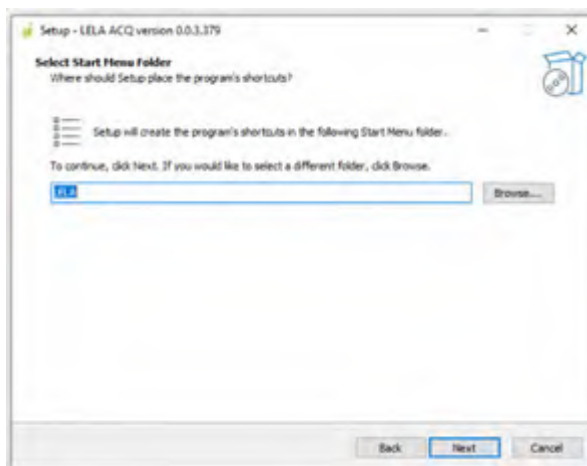
- 4 Click Yes if UAC (User Account Control) pops up.



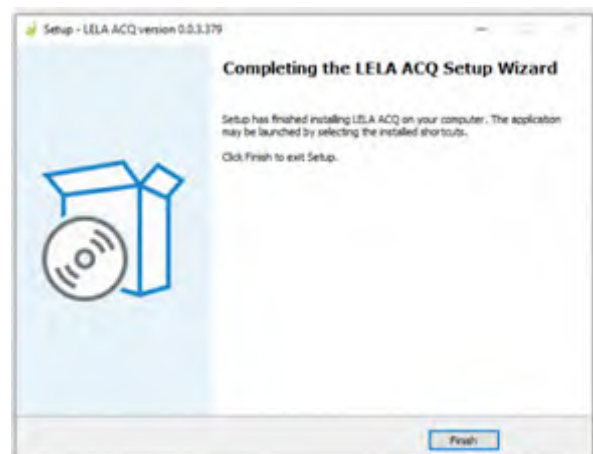
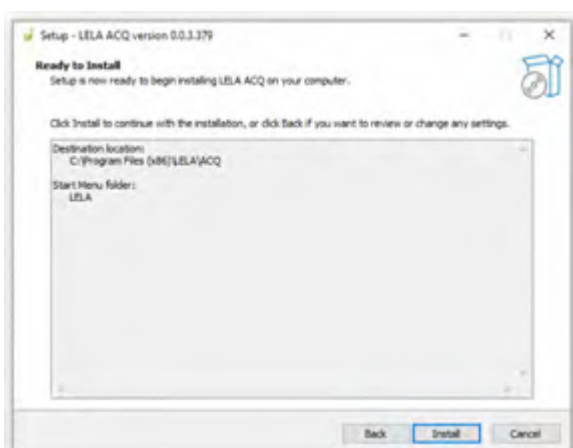
- 5 Select a folder for LELA Acquisition Software and click Next.



- 6 Select a folder for Start Menu shortcuts and click Next.



- 7 Confirm install folder and click Install and Finish.

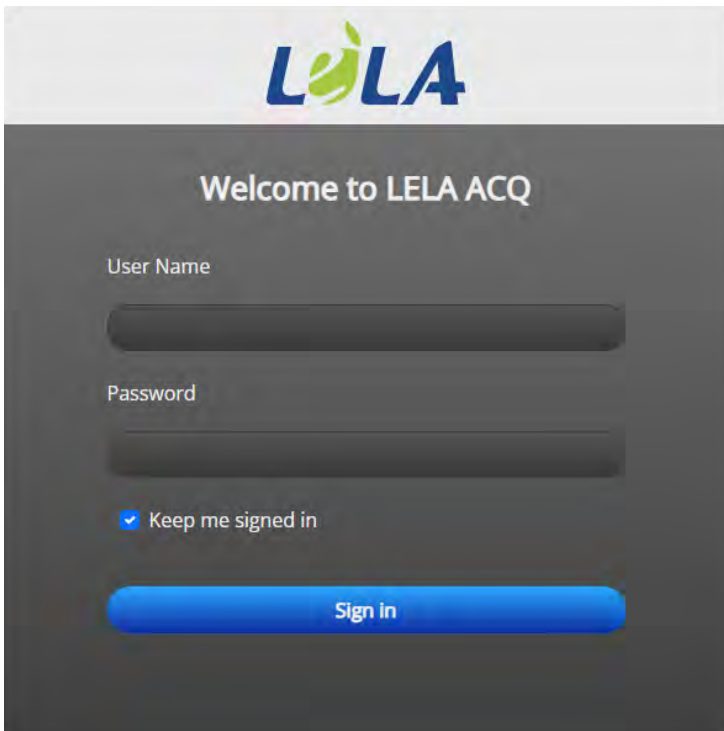


- 8 Enter the SN of the CC Dock you wish to connect to; The SN is then sent to LELA's official website for verification. Once validated, Acquisition Software receives the returned result and proceeds to activate itself. Acquisition Software can then be opened normally and navigate to the standard login screen.

- 9 Login using the following information to login in the LELA Acquisition Software.

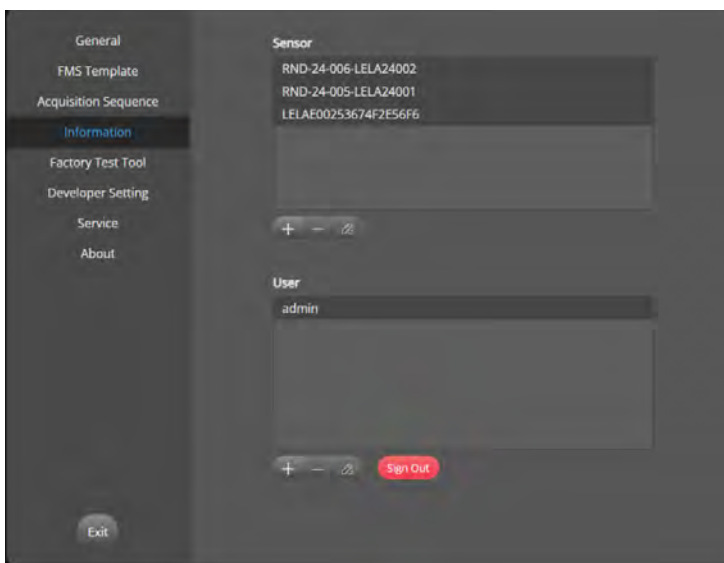
Username: LELA

Default Password: LELA



The image shows the LELA ACQ login interface. At the top is the LELA logo. Below it, the text "Welcome to LELA ACQ" is displayed. There are two input fields: "User Name" and "Password". Below the password field is a checkbox labeled "Keep me signed in" which is checked. At the bottom is a blue "Sign in" button.

You could change the password and add new accounts in the setting>>> Information



The image shows the LELA ACQ settings interface. On the left is a sidebar menu with options: General, FMS Template, Acquisition Sequence, Information (highlighted), Factory Test Tool, Developer Setting, Service, and About. The main area is divided into two sections: "Sensor" and "User". The "Sensor" section lists three sensors: RND-24-006-LELA24002, RND-24-005-LELA24001, and LELAE00253674F2E56F6. Below this is a button with a plus sign, a minus sign, and a refresh icon. The "User" section shows a list with "admin" and a large empty input field below it. At the bottom of the user section are buttons with a plus sign, a minus sign, a refresh icon, and a red "Sign Out" button. An "Exit" button is located at the bottom left of the sidebar.

4.2 Dock Activation

If it is the first time to use the Dock on this computer, the computer needs to be connected to the internet for Dock.

1. Basic Preparation

Verify network connection and ensure the computer is connected to the internet via Wi-Fi or a wired network. For unstable networks, prioritize a wired connection.

2. Hardware Connection

Insert one end of the USB cable into the USB Type-C standard port on the Dock, then plug the other end into your PC's USB Type-C port. The power adapter is properly connected to the Dock and can supply power to it normally.

3. Validation

Acquisition Software can recognize the Dock SN and its inactivated status. It then verifies the Dock's validity via the official LELA website and returns the result to Acquisition Software. Once validated, the Dock will be recognized by the Acquisition Software and exhibit normal functionality for handpiece pairing, connection, and image transmission.

4.3 Handpiece Activation

If it is the first time to use the Handpiece on this computer, the computer needs to be connected to the internet for Handpiece Activation.

1. Basic Preparation

Verify network connection and ensure the computer is connected to the internet via Wi-Fi or a wired network. For unstable networks, prioritize a wired connection.

Dock Connection

The Dock is properly activated and connected to the Acquisition Software as required above.

Handpiece Pairing

Bring the pairing zone of the Handpiece into contact with the WiFi Indicator of the Dock to initiate pairing. Once you hear a beep sound, move the two apart. When you observe that the WiFi Indicator Lights of both the Dock and the Handpiece change from orange to green, this indicates that the Handpiece has been successfully paired with the Dock.

2. Validation

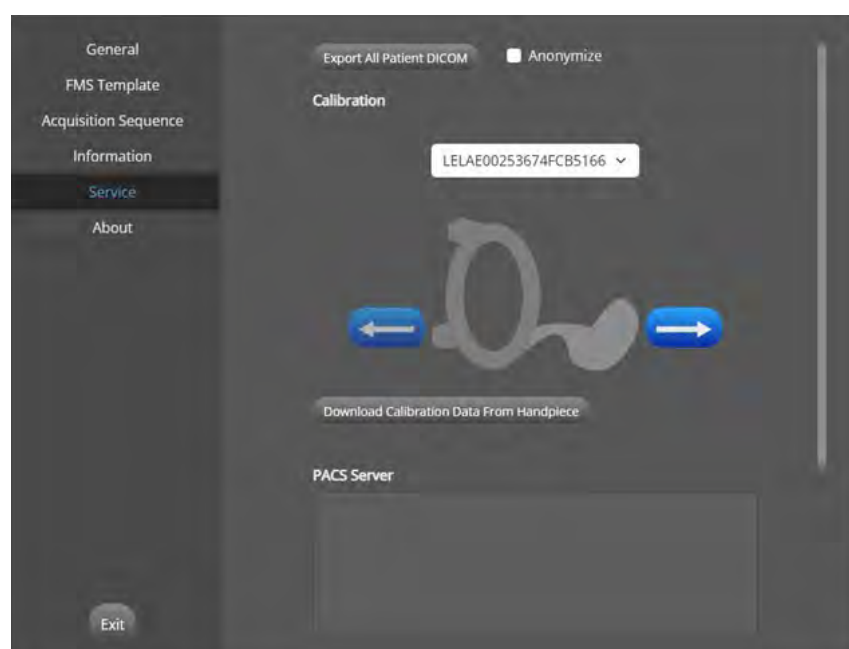
Acquisition Software can recognize the Handpiece's SN. It then verifies its validity via the official LELA website and returns the result to Acquisition Software. Once validated, the Handpiece can be recognized by the Acquisition Software. After clicking 'Start Acquisition', it will display a normal functional status for X-ray exposure.

4.4 Download Calibration data from Handpiece

Each LELA 5600 sensor's calibration data is automatically stored in the handpiece's internal memory in the factory during the manufacturing process.

Download Procedure:

- Pair the handpiece with the Dock (ensure the Dock is connected to the Acquisition Software).
- Navigate to Settings > Service > Download Calibration data from HP in the software interface to
- transfer data to the Acquisition software.



- Or Switch to X-ray Module > Download Calibration data.



5 OPERATION

5.1 Images Acquisition

1 Check hardware status, and connect handpiece and Dock

Unconnected



Connected



Connect Dock station and Handpiece to PC if unavailable

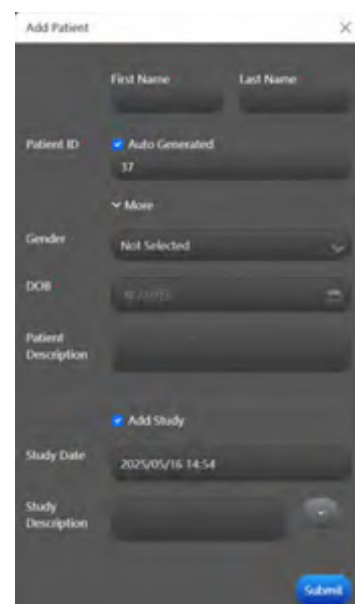
- Connect Dock station to PC with USB cable
- Pair handpiece to Dock with RFID

2 Register patient if it is a new patient

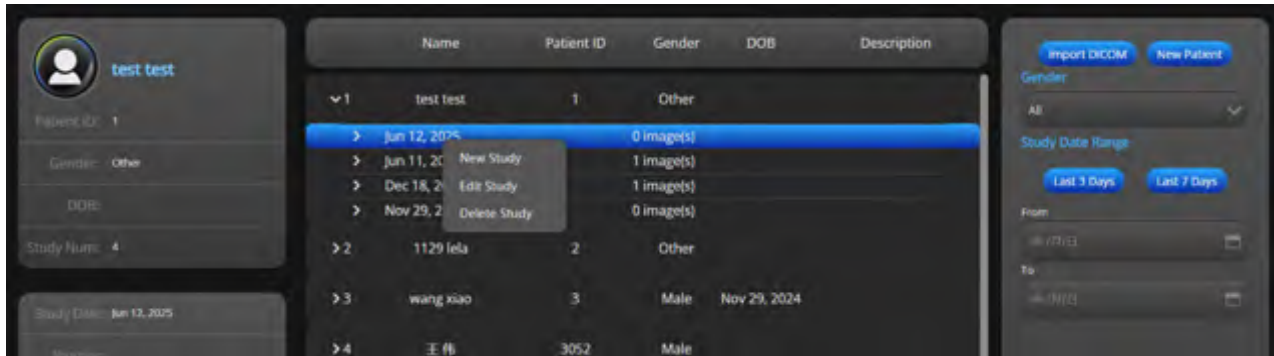
1.Switch to 'Patient' panel and Select 'new patient'



2.Input the essential patient information

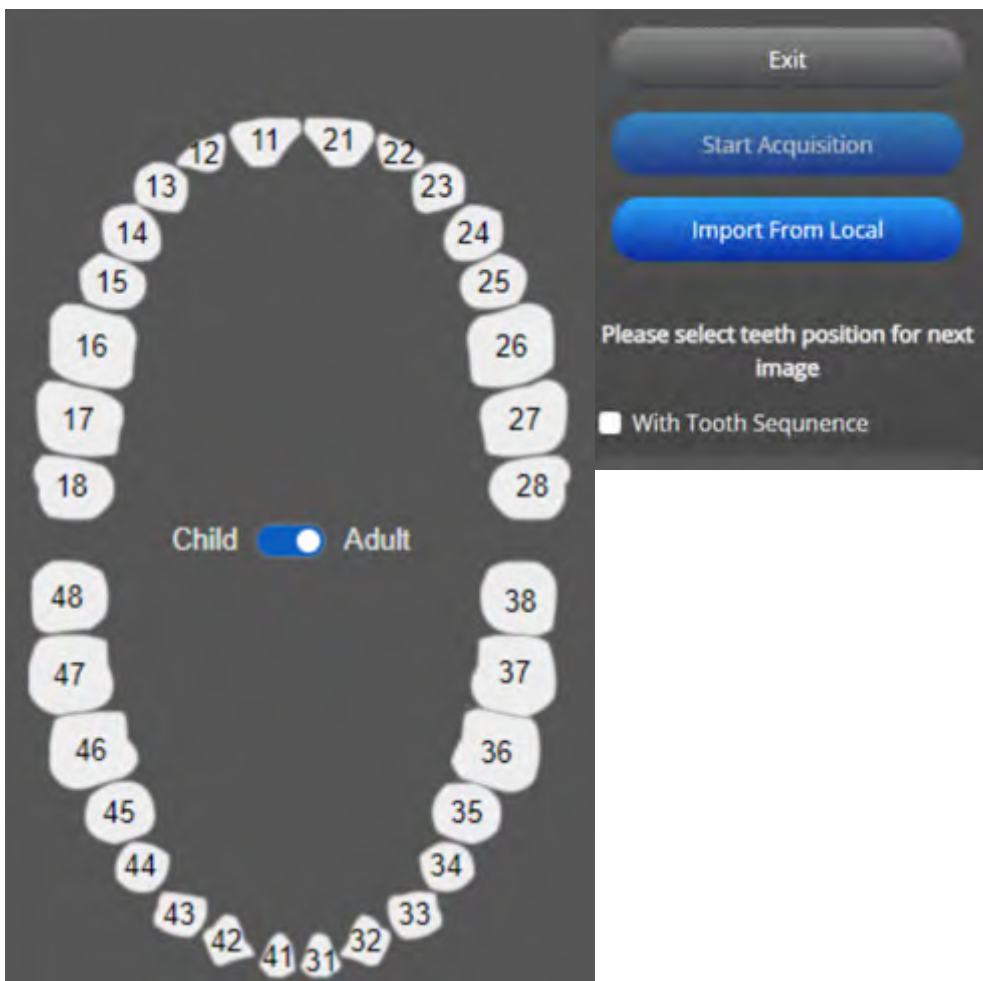


③ New Study if patient information already exists in the system



④ Then, it automatically Switch to 'X-ray' panel

1. Select tooth position and Start Acquisition



2.If the user wants to adopt the FMS template for image acquisition, Click the small triangle icon in the image above, select the desired template, and choose the tooth position and click the 'Start Acquisition' button.

You can also select 'Single Image View' to switch to single image capture.



⑤ Position the sensor and adjust the exposure parameters,

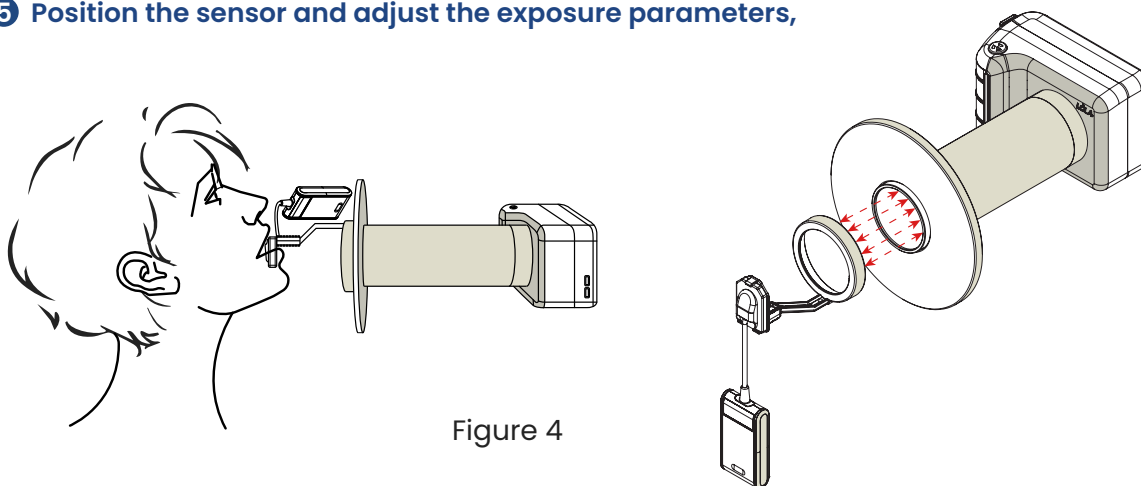


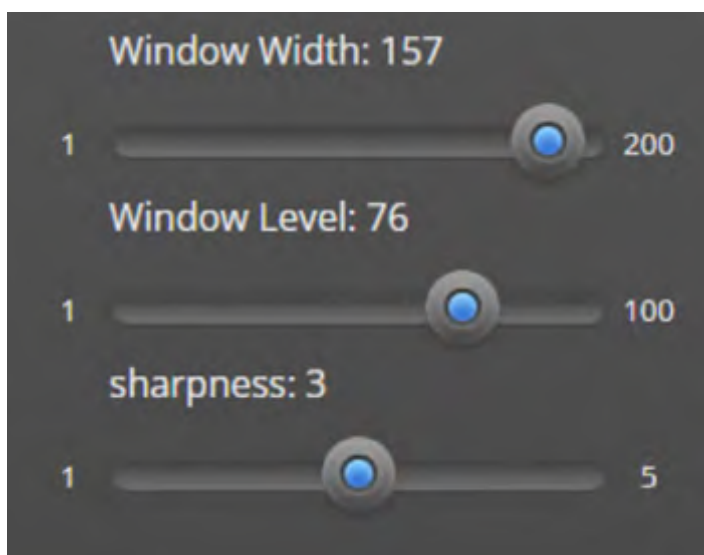
Figure 4



Tip: We recommend that when positioning the sensor, it is advisable to use the Holder to assist with positioning. LELA has designed a dedicated Holder for the CC Handpiece; for further information, please contact LELA if needed.

⑥ Shoot the x-ray, and intraoral x-ray image will be acquired and displayed.

- 7 Switch to the "View" Panel and manually modify the display parameters.



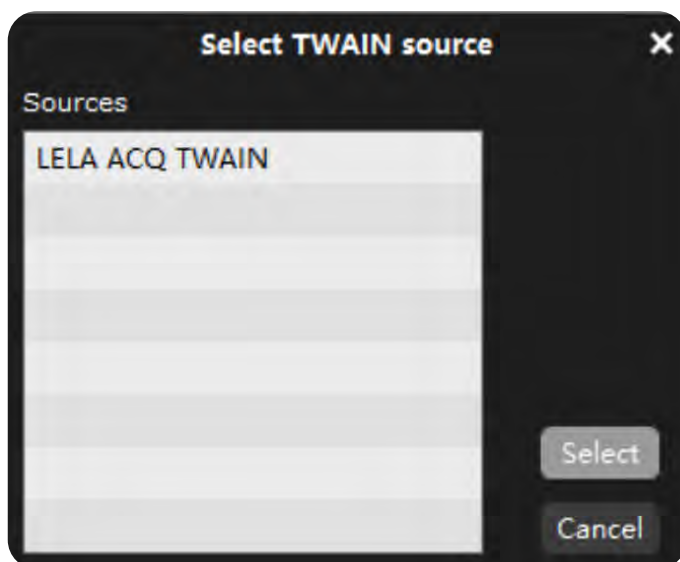
- 8 Adaptive adjust WW/WL level.



-  Default: WW/WL Optimization
-  Reduction: WW/WL improvement in over exposure
-  Implant: Imaging display protocol for implant enhancement

5.2 LELA Acquisition Software TWAIN Application

- 1 Launch third party Image Management Software (IMS e.g. CS Imaging), Please ensure your IMS is configured to interface with a TWAIN source.
- 2 New Patient Registration
- 3 Select the following Twain Source 'LELA ACQ TWAIN' to launch LELA Acquisition Software TWAIN



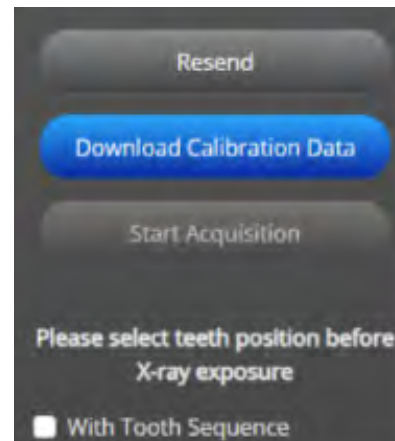
- 4 Application Software switches to LELA Acquisition Software TWAIN



- 5 Check the Hardware connection status. Connect Dock and Handpiece to PC if not connected.
- 6 Position the sensor, select tooth position and Start Acquisition
- 7 Shoot the X-ray
- 8 The Intraoral X-ray image is acquired and confirmed, then sent to the third-party IMS for further review.

5.3 Resend Function

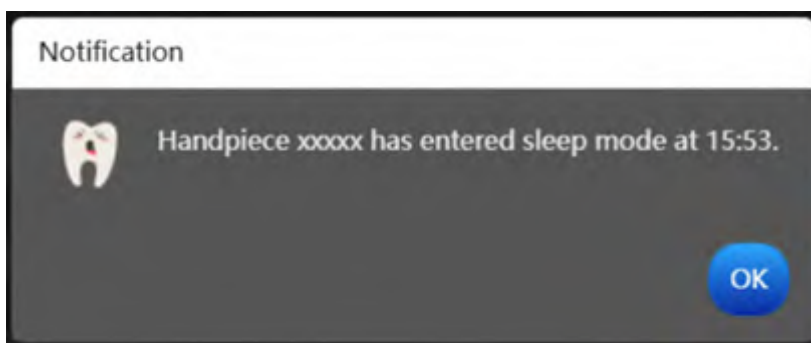
After launching 'Start Acquisition', the indicator lights of the Handpiece and Dock turn blue. During the period from the exposure preparation phase (including position adjustment, exposure parameter settings, and other operations) to the completion of exposure, if Wi-Fi disconnection occurs due to signal interference or the Handpiece going beyond the signal coverage of the Dock, the exposure can still proceed normally. After the Handpiece re-establishes a normal connection, the user can obtain the image via the Resend function.



5.4 Sleeping Mode

The Handpiece can detect its own movement. If not in use for more than 5 minutes, it will automatically enter sleep mode, with the following indications:

- **The ACQ interface displays a prompt message.**



- **The CC Handpiece's indicator lights extinguish.**

Sleeping



6 TROUBLE SHOOTING

This section supplies information in the event the user experiences the malfunction with the product.

After shooting the x-rays, Images should be acquired.

1.The image is too dark, or 'Over Exposure' message is pop up

- Lower the exposure time if it is too high.
- Lower the milliampere if it is more than 2mA.
- Check the contrast and brightness setting.

2.The image is pale and grainy

- Increase the exposure time if it is too short.
- Increase the generator voltage if it is too low.
- The x-ray generator is too far from the patient regarding the selected dose.
- Check the contrast and brightness setting

3.After shooting the X-rays, no image is displayed.

- Make sure the hardware is ready for image acquisition, The indicator lights of both CC Dock and CC handpiece were blue.
- Patient record is open, tooth position is selected, and 'Start Acquisition' is clicked.
- Check x-ray exposure settings and ensure the x-rays were correctly emitted.

4.The image is blurred.

- Patient moved during exposure
- Calibration data was not available
- X-ray generator head was not stable

7

MAINTENANCE

LELA 5600 does not need any special maintenance other than cleaning and disinfection.



CAUTION: After each patient examination, the sheath covering the sensor must be removed.

7.1 Sheath

Disposable sanitary sheaths should be stored in a clean, dry location and not exposed to sunlight or UV rays. Used sheaths must be disposed of as infected waste, as they are potentially biologically hazardous. Disinfect the image sensor before first use and whenever there is a risk of contamination.



Tip: LELA has designed a dedicated Sheath for the CC Handpiece. For further information, please contact LELA if needed.

7.2 Handpiece

For disinfection, LELA recommends the following:

- CaviWipes (Metrex Research, USA)
- Dürr FD 322 (Dürr Dental AG, Orochemie GmbH)
- Dürr FD 333 (Dürr Dental AG, Orochemie GmbH)
- Cidex Opa (Johnson & Johnson)

All recommended disinfectants have been tested and confirmed to be non-harmful to surfaces.

Surfaces

Surface can be cleaned with a soft cloth dampened in a mild cleaning solution. For disinfection, stronger cleaning agents may be used; we recommend Dürr FD 333 or an equivalent disinfecting solution.

Handpiece



CAUTION: Autoclaving the sensor is strictly prohibited, as it will cause permanent damage to the handpiece. The handpiece can only be disinfected by wiping.

For infection control, decontamination of the handpiece must follow CDC guidelines. Wiping the handpiece with one of the cleaning agents listed above is recommended.

Sensors and Cables

LELA 5600 sensors support enhanced infection control in clinical settings. Due to their hermetically sealed casing, the sensors can be immersed in disinfectant solution.



CAUTION: Always use appropriate instruments when cleaning the sensors.



CAUTION: It is mandatory to strictly follow these cleaning and disinfection recommendations to avoid damaging the sensors.



CAUTION: Sensors must not be sterilized in an autoclave or UV oven.

Wipe the sensor surface with a soft cloth dampened in disinfectant solution. Sensors can be soaked in disinfectant solution provided there are no nicks in the cable.

Recommended disinfectant solutions include Dürr System Hygiene FD 322, FD 333, or equivalent products. The immersion time for Dürr disinfectants is 2 minutes.

If more effective disinfection or cold sterilization is preferred, use Johnson & Johnson's Cidex Opa high-level disinfectant at a minimum temperature of 20°C, with a maximum immersion time of 8 minutes and a reuse period not exceeding 14 days.



CAUTION: Adhere to the specified immersion times and recommended disinfectant solutions. Do not leave the sensor in disinfectant overnight.

Carefully wipe the sensor surface with a soft, lint-free cloth dampened in disinfectant.

7.3 Dock

The dock can be cleaned with a soft cloth dampened in a mild cleaning solution.



CAUTION: Switch off the unit before cleaning.

Do not disinfect the unit.

In a clinical environment, healthcare providers should wear disposable protective gloves and cover the sensor with a hygienic barrier. Before first using the sensor and before each new patient, follow this protocol:

- 1 Remove and discard all protective hygienic barriers and/or sheaths from the sensor before removing disposable gloves.
- 2 Place the sensor on a tray covered with a disposable liner, or in a receptacle that can be thoroughly disinfected.
- 3 Remove and discard gloves.
- 4 Wash hands and put on a new pair of disposable gloves.
- 5 If the sensor or cable is visibly soiled (e.g., with blood or saliva), clean each with a soapy cloth or paper towel, then dry with a clean, lint-free cloth or paper towel.
- 6 Thoroughly wipe the sensor, cable, and handpiece with one of the recommended disinfectant products. Do not expose the sensor cable connectors or handpiece to any liquid.
- 7 Repeat step 6. After spraying or wiping the sensor twice, proceed to the following steps.
- 8 Remove any potential chemical residue from the sensor by wiping it with a sterile lap sponge saturated with deionized water.
- 9 Use a sterile, dry lap sponge to dry the sensor or cable as needed.
- 10 Place the sensor in a clean environment, ready for use.
Remove and discard gloves.

7.4 Handling

The whole kit is supplied in protective packaging against physical impacts and antistatic packaging.

It should be handled under the following requirements:

Environmental condition	Humidity	Air Pressure	Ambient temperature
Operation	30%RH to 85%RH	700 - 1060hPa	+5°C ~ 30°C
Transportation and Storage	5%RH to 95%RH		-10°C ~ +50°C

8

ACCESSORIES



1.Holder



2.Battery



3.Adaptor



4.Type C USB cable

Notice: Thank you for taking the time to read this User Manual carefully. We hope our Lela 5600 System will meet your needs and assist you with your daily work.

Should you have any questions or comments, please do not hesitate to contact your local vendor or distributor.



User manual of Intraoral Digital Sensor LELA 5600 System

Manual Name: User manual of LELA 5600 Intraoral Digital Sensor System

Document code:

Revision Number: 01

Issued: 2025.07

Copyright: Trademark

➤ FCC Statement

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Following statement is only for Dock:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.