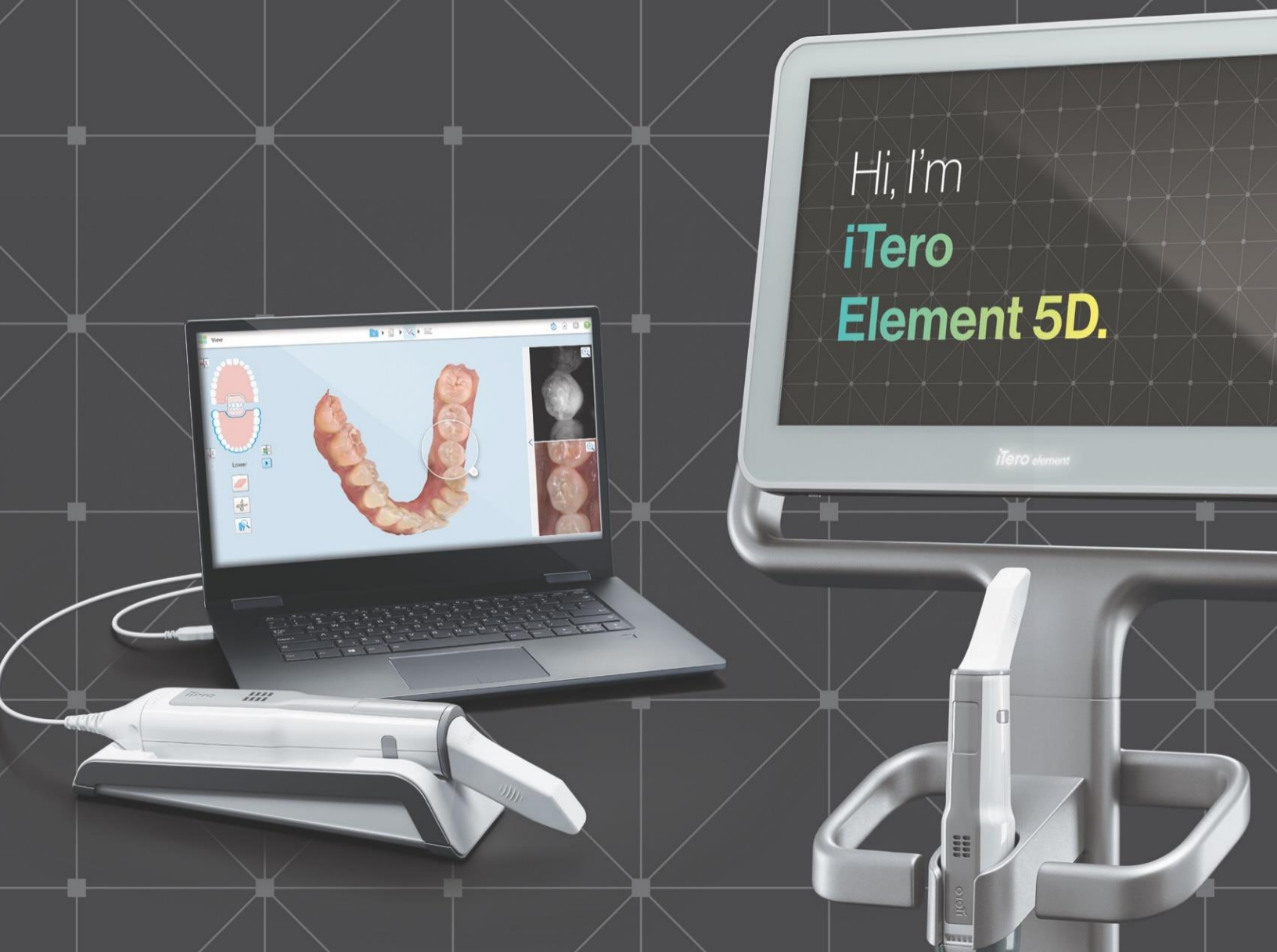
iTero Element 5D User Manual



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Contraindications

For persons who have been diagnosed with Epilepsy, there is a risk of epileptic shock from the flashing light of the iTero scanner. These persons should refrain from any eye contact with the flashing light associated with the system during operation.

Compliance

Class 1 laser compliance

This device complies with “21 CFR 1040.10” and “EN 60825-1”.

CSA compliance

This device complies with the following CSA standard for Canada and the USA: “UL Std. No. 60601-1 – Medical Electrical Equipment Part 1: General Requirements for Safety”.

C US

Safety compliance

This device complies with the following safety standard:

“IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”.

FCC compliance

This device complies with Part 15 of FCC Rules and its operation is subject to the following two conditions:

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

FCC warning

Modifications to the device that are not expressly approved by the manufacturer may void your authority to operate the device under FCC Rules.

EMC compliance

This device complies with the following EMC standard:

“IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic phenomena - Requirements and tests”.

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Symbols

The following symbols may appear on iTero Element 5D hardware components and may appear within this document and other iTero Element 5D literature.

Wherever this symbol appears on the device, it is recommended to refer to this document for information on the proper usage of the device.

Applied part type BF. Any component on which this symbol appears is electric isolation type BF.

Separate collection of electrical waste and electronic equipment is required. In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE), do not dispose of this product in domestic or municipal waste. This device contains WEEE materials.

Please contact the EARN service.

Link for the online request form: http://b2btool.earn-service.com/aligntech/select.

Attention! This symbol is used to highlight the fact that there are specific warnings or precautions associated with the device. Wherever this symbol appears on the device, it is mandatory to refer to safety-related information in this document.

Parts or accessories on which this symbol occurs should not be reused.

"Rx only"

CAUTION: US Federal Law restricts this device to sale by or on the order of a licensed Dentist, Orthodontist, or Dental Professional. The system serves as a prescription medical device and should be operated by qualified health-care providers only.

Medical device manufacturer.

Order number.

Serial number.

Alternating current.

Indicates a medical device that needs to be protected from moisture.

Indicates the temperature limits to which the medical device can be safely exposed.

Indicates the need for the user to consult the instructions for use.

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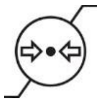
Manufacturer’s batch code.



Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Indicates the range of humidity to which the medical device can be safely exposed.

Fragile, handle with care.

This side should be up.

IEC 60417-5031: Direct current.

Wand (scanning unit).

USB socket.

Electric battery.

IEC 60417-5009: STAND-BY.

Use-by date. This symbol is accompanied by a date to indicate that the iTero Element 5D wand barrier sleeves should not be used after the end of the year, month, or day shown.

CAUTION: Do not step on the iTero Element 5D laptop configuration hub.

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Safety instructions

Before beginning to work with the system, all users are required to read these safety instructions.

Power supply

Power is supplied to the system via an internal medical-grade power supply.

Battery power

Wheel stand configuration only:

- Charging – the scanner battery will be fully charged after being plugged into a power source for 2 hours.
- With a fully-charged battery, you can scan up to 30 minutes.
- WARNING The scanner is provided with a Li-ion rechargeable battery pack. Never replace the battery with a battery that is not recommended by the manufacturer. There is a danger of explosion if the battery is incorrectly replaced. Discard used batteries according to the manufacturer's instructions.

Electric warnings

- Do not remove external panels and covers, in order to avoid electrical shock. There are no user-serviceable parts inside.
- Do not connect the scanner to a mains supply without protective grounding, in order to avoid the risk of electrical shock.

Laptop configuration only:

- The iTero Element 5D laptop configuration is provided with a hub containing the power supply for the wand. Do not place the system on a wet surface or step on it, in order to avoid risk of system damage and electrical shock.
- Never connect the hub to a laptop that is not approved according to IEC60950 and to UL60950-1. The laptop and all its accessories should be located at least 1.5m away from the patient. Do not scan a patient and touch the laptop or any of its accessories at the same time. Not following these instructions may lead to electrical shock.

Electric precautions

- Do not connect a non-Align-approved web camera to the USB sockets on the rear of the touch screen, in order to avoid the risk of electrical shock.
- Do not connect anything besides the iTero wand and an approved laptop to the USB sockets on the hub.
- Do not connect a power cable that is not approved by Align Technology to the system, in order to avoid electrical shock.

Wireless LAN

The system comes equipped with a wireless LAN unit.

Safety classifications

- Type of protection against electrical shock: Class 1.
- Degree of protection against electrical shock: Type BF.
- Degree of protection against harmful ingress of water: Ordinary.
- Equipment not suitable for use in the presence of flammable anesthetic mixtures.
- Mode of operation: Continuous.

Prescription health device

The system serves as a prescription medical device and should be operated by qualified health-care providers only.

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Scanner precautions

- The wand emits red laser light (680nm Class 1), as well as white LED emissions and 850nm LED emissions. Normal usage of the wand does not present any danger to the human eye. Avoid shining the wand directly into the patient's eyes.
- Avoid twisting, knotting, pulling, and stepping on the cable.
- When the system is not in use, the wand should be placed in the cradle with the probe facing the touch screen, in order to avoid eye contact with the laser beam, flickering white LED emission, and 850nm LED emission. Eye contact could cause damage to the eyes.
- Avoid activating the wand while the tip of the wand is outside the patient's mouth, in order to prevent eye damage.
- Avoid placing the wand in the cradle while the scanning operation is still active, in order to prevent eye damage.
- Do not use the equipment if a scanner malfunction occurs or if physical damage is observed, in order to avoid electrical shock. Call Customer Support.

Cleaning & disinfection

- To avoid cross-contamination, it is mandatory to:
  - Clean and disinfect the wand, as described in section 10.2, and replace the wand barrier sleeve, as described in section 4.1, before each patient session.
  - Remove and replace gloves after each patient session.
  - Discard torn, contaminated, or removed gloves.
- Dispose of wand barrier sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Unpacking & installing

The system should be unpacked and installed following Align Technology's instructions, described in section 2.1.

Work environment

- The system should be moved between rooms with utmost care to avoid damage.
- Do not block the air vents on the wand and the screen.
- The system is intended for indoor use only. It should not be exposed to direct sunlight, excessive heat, or humidity.
- Laptop configuration only: If the iTero Element 5D laptop configuration has just been brought into the office from a hot, cold, or humid environment, it should be set aside until it has adjusted to the room temperature, to avoid internal condensation.

Electromagnetic interference precaution

This device has been tested and found to comply with the requirements for medical devices according to standard IEC60601-1-2. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation.

Avoid placing this device near frequency transmitting equipment or other sources of electrical and electromagnetic interference (e.g. cellular phones, mobile two-way radios, electrical appliances, RFID). High levels of such interference, due to close proximity or strength of the source, may result in disruption of performance of this device. In this case, the device can be returned to operation mode after user intervention or by
auto-recovery.

General

Notes:

- Do not make any modifications to this equipment.
- Wheel stand configuration only: Do not remove the touch screen from the stand after assembly.

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1 Introduction

The iTero Element 5D intra-oral scanner is Align Technology's latest-generation integrated hardware (scanner) and software system.

This all-in-one system is available on a monitor with a fully interactive, touch-screen display and an easy-to-use wand. The topography of a patient's teeth can be viewed on the screen as they are being scanned, and determining the degree of occlusion of the bite can be analyzed when the scan is completed.

The iTero Element 5D system combines:

- **3D scanning:** Recording and visualization of topographic 3D data and 2D imaging with an intra-oral camera.
- **NIRI technology:** Capturing data, to be used as a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions. For more information on NIRI, see section 1.5.

The iTero software also includes administrative capabilities, which enable the user to:

- Fill in a new prescription
- Place a new order for an existing patient or new patient
- View orders in progress
- Review and/or track past orders

1.1 Intended use

The iTero Element 5D is an intra-oral scanner with the following features and intended use:

- The optical impression (CAD/CAM) feature of iTero Element 5D is intended/indicated for use to record the topographical images of teeth and oral tissue. Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories.
- iTero Element 5D software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. The software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.
- The iTero Element 5D NIRI functionality is a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions.

1.2 Benefits

The iTero Element 5D system provides important advantages over existing crown-production methods, including powder-free scanning, greater crown-production accuracy, and immediate feedback during the scanning process.

Refer to our website http://www.itero.com to learn how the iTero Service can enhance your business by increasing patient satisfaction, improving clinical outcomes, and enhancing office efficiency.

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1.3 iTero Element 5D hardware

The iTero Element 5D scanner is available in two models:

- iTero Element 5D wheel stand configuration
- iTero Element 5D laptop configuration

Note: The laptop must meet the requirements listed in section 15.

1.3.1 Wheel stand configuration

Front view of the system

A Touch screen
B Power switch
C Power LED
D Wand
E Cradle
F Wheel base

Figure 1: Front view of the iTero Element 5D wheel stand configuration

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Rear view of the system

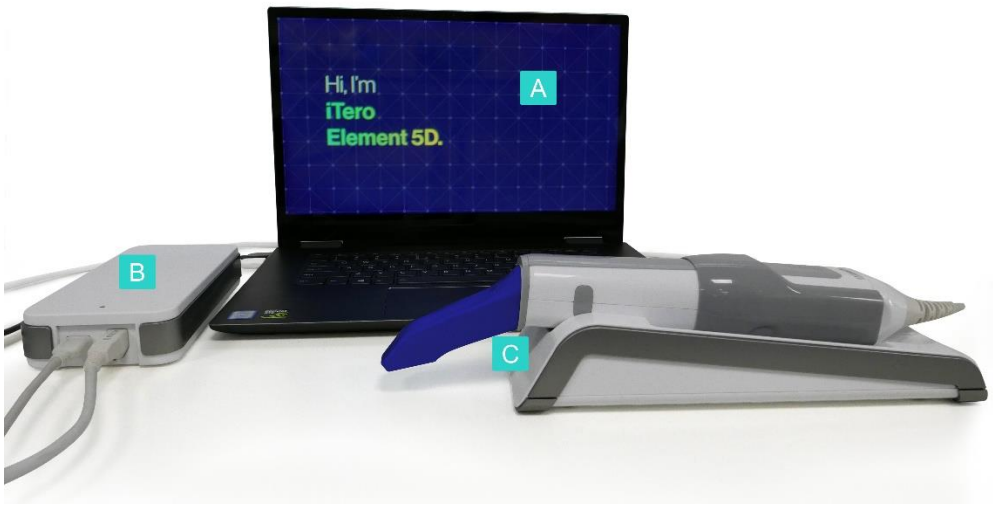
A Wand connector

B Wand cable

C Screen power cable

Figure 2: Rear view of the iTero Element 5D wheel stand configuration

1.3.2 iTero Element 5D laptop configuration



A Laptop touch screen

B iTero Element 5D hub

C Wand and cradle

Figure 3: iTero Element 5D laptop configuration

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1.3.2.1 Transporting the system

To ensure maximum system protection, it is recommended to follow the instructions below when transporting the system:

1. Attach the blue protective sleeve onto the wand.
2. Place all items in the supplied carrying case to move the system between offices.

Figure 4: iTero Element 5D laptop configuration in the supplied carrying case

3. Make sure the case is kept dry to protect the system components from humidity.

1.3.3 iTero Element 5D wand

A Protective sleeve

B Touchpad

C Side buttons: Scan, on/off, touchpad activation

D Vent cover

E Air vents

F Detachable wand cable with USB connector

Figure 5: iTero Element 5D wand

Note: In order to protect the wand cable if too much pulling force is applied, the cable cap is designed to detach from the wand. If this happens, gently reattach it.

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1.3.4 iTero Element 5D protective sleeves and wand barrier sleeves

The following accessories must be used with the iTero Element 5D wand:

- **Protective sleeve:** When the scanner is not in use, use the protective sleeve to protect the optical surface of the wand.
- **Wand barrier sleeve:** Before scanning a patient, attach a new wand barrier sleeve, as described in section 4.1.

Figure 6: Protective sleeve

A Rigid section of the wand barrier sleeve

B Transparent sheath

Figure 7: Wand barrier sleeve

1.4 iTero Element 5D software

The iTero Element 5D system contains the following exclusive software features:

- Confirmation that a new wand barrier sleeve is used before scanning, described in section 4.3.2
- Toggling the 3D and viewfinder display while scanning, described in section 4.4.4
- Toggling the color mode and NIRI mode in the viewfinder while scanning, described in section 4.4.5
- Viewing an area of interest after scanning using the Review tool, described in section 4.5.6

New iTero Element 5D wheel-stand systems come with the software installed. To install the software on iTero Element 5D laptop configurations, see section 2.2.

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1.5 Working with near infra-red imaging (NIRI)

NIRI is a method of spectroscopy that uses the near-infrared region of the electromagnetic spectrum (850nm).

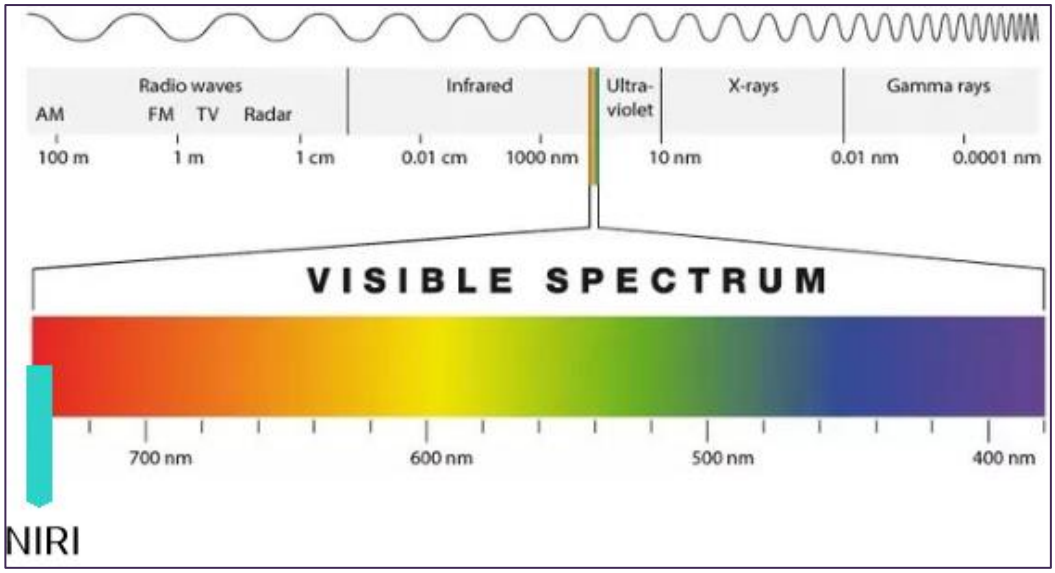
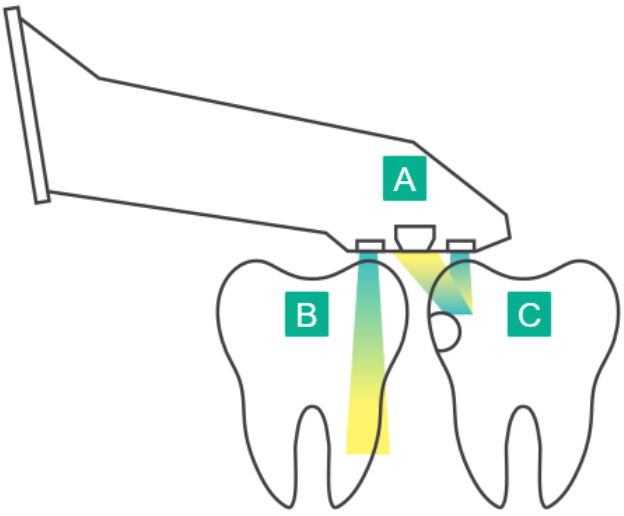


Figure 8: Visible light spectrum showing NIRI on the 850nm wavelength

When the wand is positioned above the tooth, NIR images will be captured.

The translucency of the structure translates to the brightness level in the NIRI image – the higher the translucency, the darker the object, and vice versa. Tooth enamel is translucent to NIRI and will appear dark. Dentin and any interference in the enamel, e.g. caries, are reflective and cause the light to scatter, and therefore will appear brighter and opaque.



A Wand positioned on the tooth surface

B Tooth enamel is translucent

C Dentin and caries are reflective

Figure 9: Reflective concept – healthy enamel is translucent while dentin and caries are reflective

NIR images are captured automatically and seamlessly during the scan, from every angle used for the 3D scanning, and all collected information can then be reviewed using the iTero Element 5D Review tool.

Note: NIR images should be used in conjunction with the current standard of care for caries detection, and do not replace it.

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The resulting NIRI grayscale image shows structures with varying translucency as different levels of brightness. The lower the translucency, the higher the reflection of the infrared light and the brighter the structure. Using this technology, it is possible to make out the following structures:

	Appears	Translucency
Enamel	Dark	High
Interproximal caries	Bright	Low
Dentin	Bright	Low

The differentiation between carious lesions and dentin is based upon the location of the bright feature. Dentin is located in the center of a tooth, whereas interproximal carious lesions appear on the interproximal or distal mesial region, where healthy enamel is expected.

As such, dentin and interproximal carious lesions appear as bright features, with a dark enamel ring around the dentin structure, as shown in the figure below, which provides an occlusal view of a carious lesion.

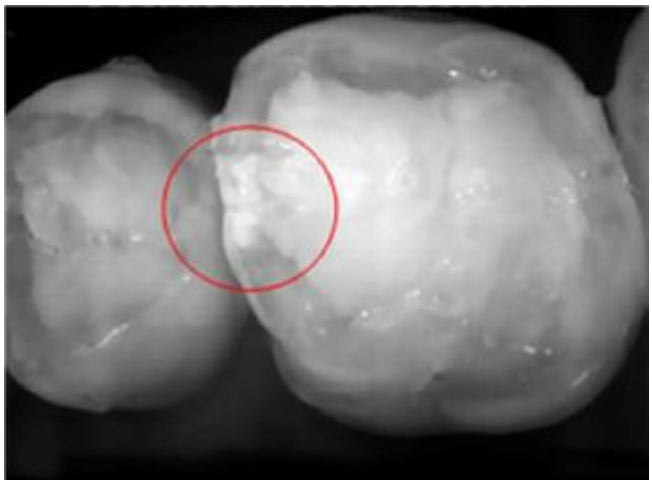

Figure 10: Interproximal carious lesion

1.5.1 Limitations

NIRI has the following limitations:

- NIRI cannot detect caries below the gingiva, for example, to view caries in the roots of the teeth.
- NIRI cannot detect the progression of caries beyond the dentin-enamel junction (DEJ), which is the boundary between the enamel and the underlying dentin that forms the solid architecture of a tooth.
- Some restorations, e.g. crowns and amalgam fillings, are not translucent and may mask carious lesions below them.
- Highly opaque teeth have low translucency of the enamel making them appear brighter. This may cause difficulty in understanding the internal tooth structure, and differentiating between enamel and dentin, thereby affecting the ability to detect proximal caries.

For more information on using NIRI and the clinical benefits, please refer to the *iTero Element 5D Clinical Guide*.

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1.6 About this document

This document provides general information and an overview of the iTero Element 5D application. In addition, it describes how to assemble the system, install the software on iTero Element 5D laptop configurations, start and shut down the system, how to handle the wand and cable, how to clean and disinfect the wand, and how to replace the wand barrier sleeves between patients.

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2 Getting started

2.1 Assembly instructions

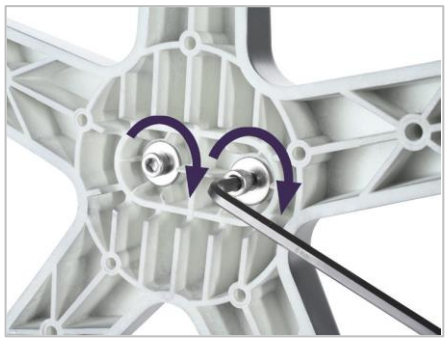
2.1.1 Assembling the iTero Element 5D wheel stand configuration scanner

Follow the instructions below to assemble the iTero Element 5D wheel stand scanner.

A Wheel stand
B Wand with cable
C Wand cradle
D HD touch screen
E External battery
F Power cable

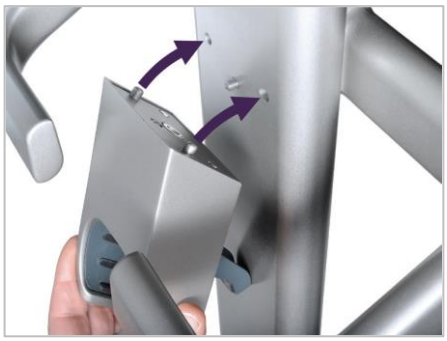
1. Check the contents of the boxes.

2. Connect the post to the wheel base.



3. Tighten the two Allen screws using the larger Allen key.

4. Remove the cover from the back of the handle.



5. Attach the wand cradle to the front of the wheel stand.

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6. Hold the cradle.

7. Tighten the back of the wand cradle with the Allen screw using the smaller Allen key.

8. Reattach the cover behind the handle.

9. Remove the magnetic cover from the back of the wheel stand frame.

10. Loosen the thumbscrews and remove the battery cover.

11. Slide the battery into the battery slot and tighten the thumbscrews.

12. Lift the touch screen to mount it.

13. Turn the scanner around and tighten the thumbscrew to secure the screen.

14. Connect the power cable to the port labeled DC, as shown in the next image.

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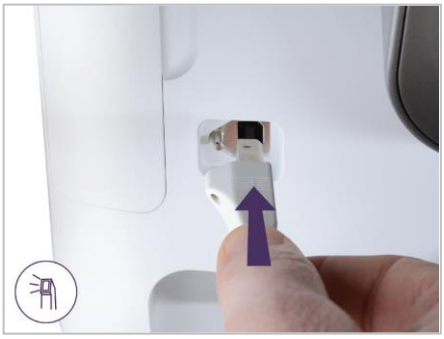
Power cable inserted.

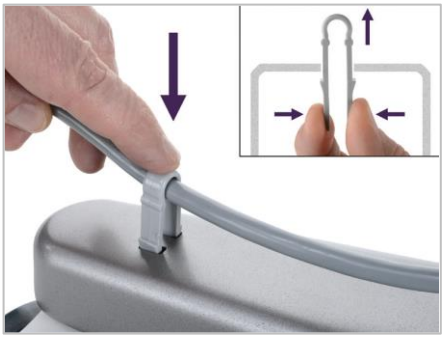
15. Attach the magnetic back cover.

16. Place the wand in the cradle.



17. Connect the wand cable to the back of the touch screen.

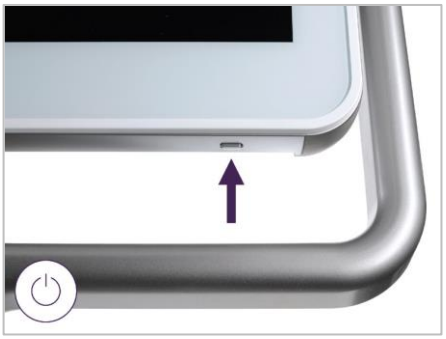
18. Connect the power cable on the bottom of the wheel stand.



19. Secure the cable to the bottom of the wheel stand with the clip.

20. Position the webcam on the touch screen for remote training or support sessions.

21. Connect the webcam to the USB port at the bottom of the touch screen.



22. Plug the power cable into the AC power outlet and then press the Power button to switch on the scanner.

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2.1.2 Assembling the iTero Element 5D laptop configuration scanner

Follow the instructions below to assemble the iTero Element 5D laptop configuration scanner.

A Hub and hub power cable
B Cradle
C Wand and wand cable
D USB cable to connect laptop and hub

1. Place the wand in the cradle

2. Connect the hub power cable to the hub.

3. Connect the USB cable to the hub.

4. Connect the USB cable to the laptop.

5. Connect the wand cable to the hub.

6. Plug the hub power cable into the AC power outlet.

Notes:

- The hub must be connected to an AC wall outlet at all times
- The laptop should be connected to an AC wall outlet during intraoral scanning.

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2.2 Installing the iTero Element 5D software – laptop configuration

New iTero Element 5D wheel-stand systems come with the software installed, but the user must install the software on iTero Element 5D laptop-configuration systems.

Note: Before installing the iTero Element 5D Laptop-configuration software, please install all available Windows updates. New Windows computers should apply the updates automatically.

For proper software installation and configuration of your iTero Element 5D Laptop-configuration system, please ensure the following:

- The wand is secure in the cradle and connected to the hub
- The hub is connected to the laptop
- The laptop is plugged into the AC wall socket during the entire software installation

To install the iTero Element 5D software on an iTero Element 5D laptop configuration:

1. Install all available Windows updates.
   a. To check for Windows Updates, open the *Windows Settings* window (Winkey + I) and click **Update & Security**.
   b. Click Windows Update.
   c. Click **Check for updates** to see whether there are new updates available.
2. In the registered email Inbox, look for the email “Your iTero was shipped”, which includes the download instructions.
3. Click the link to access the software download page or browse to http://download.itero5D.com.
4. On the website, click the **Get Started** button. The **FirstTimeInstaller.exe** file will be downloaded.
5. Run the downloaded installation file and follow the instructions on the screen to complete the iTero software installation.

   The *Welcome* screen is displayed. Proceed as described in section 2.3, below.

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2.3 Logging in to the iTero Element 5D scanner for the first time

When you turn on the iTero Element 5D for the first time, the *Welcome* screen is displayed:

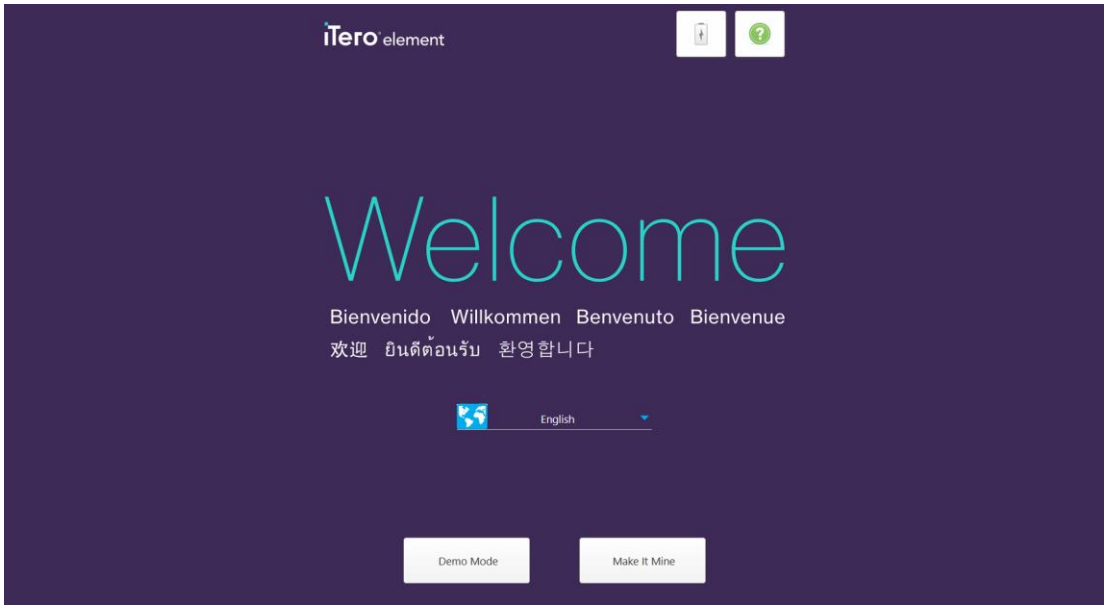

Figure 11: Welcome screen

Select the required language and one of the following modes:

- **Demo Mode:** Enables you to familiarize yourself with the scanner's features and perform practice scans without submitting the scans. For more information, see section 2.4.
- **Make It Mine:** Enables you to register the scanner. For more information, see section 2.5.

Note: If you select the Demo Mode option before the Make It Mine option, you will have to restart the scanner to access the Make It Mine option.

2.4 Working in Demo Mode

Demo Mode is designed for training new staff members and for practicing scanning. Demo Mode is available anytime for dental practices to train on an iTero Element 5D device, for scanning techniques, how-to guidelines for prescription forms, case types, and to familiarize themselves with the iTero interface. Demo Mode features all the aspects of the scanning process and includes a wide variety of sample cases, such as clinical cases, Invisalign cases, and restorative cases. In addition, demo cases that can be used for demonstration and training purposes of the iTero Element 5D Review tool and clinical indications shown by NIRI, are displayed.

When Demo Mode is in use for practice scanning, a lightly striped background and red tag in the upper left-hand corner will indicate that Demo Mode is currently running. Demo Mode is available from the *Welcome* screen when logging in for the first time, or at any point by tapping the iTero logo on the home screen.

Note: Scans captured in Demo Mode cannot be saved or submitted for patient treatment.

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To enter Demo Mode after logging in:

1. Tap the **iTero Element** logo at the top of the scanner screen.

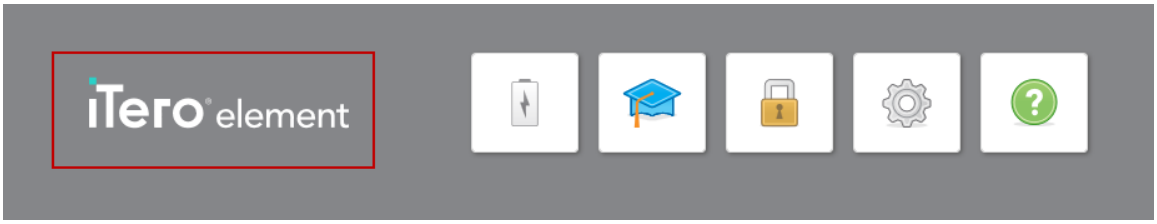

Figure 12: iTero Element logo

2. Tap Demo Mode.

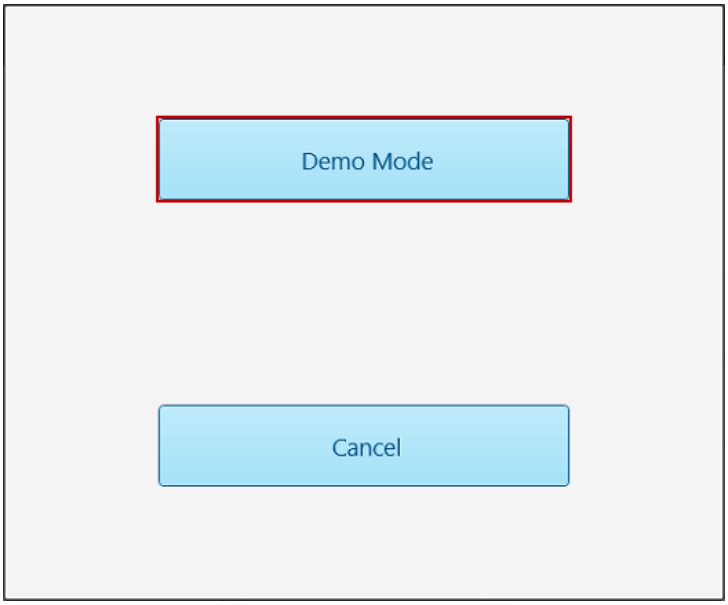

Figure 13: Demo Mode option

The *Login* window is displayed, enabling you to select the demo user.

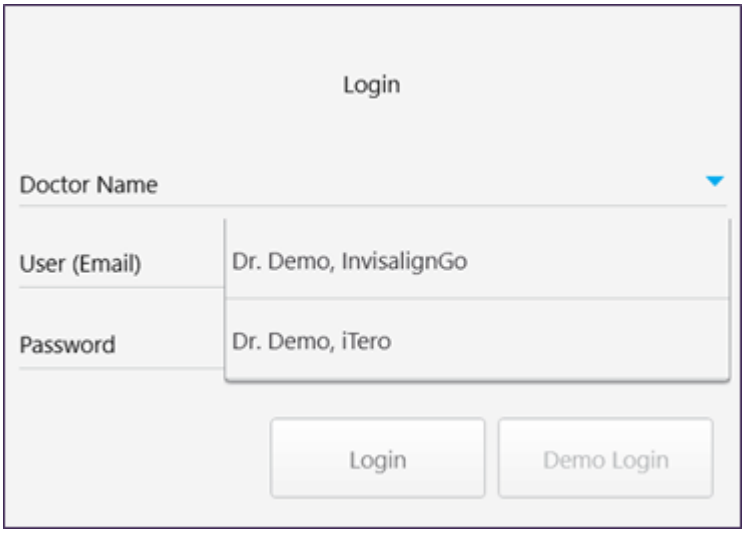

Figure 14: Login window with a list of demo users

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3. To view iTero Element 5D cases, select the **Dr. Demo, iTero** user from the **Doctor Name** drop-down list.

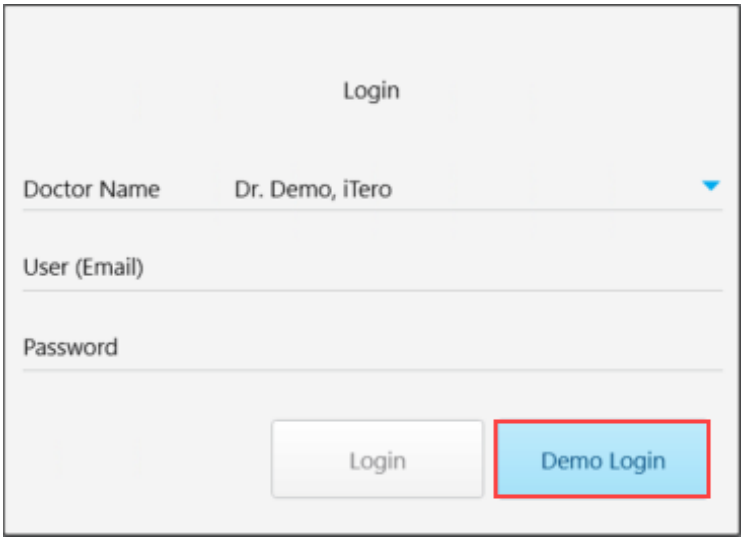

Figure 15: Demo Login button

4. Tap **Demo Login**.

The Demo Mode home screen is displayed, with **Demo Mode** shown on the top left of the window.

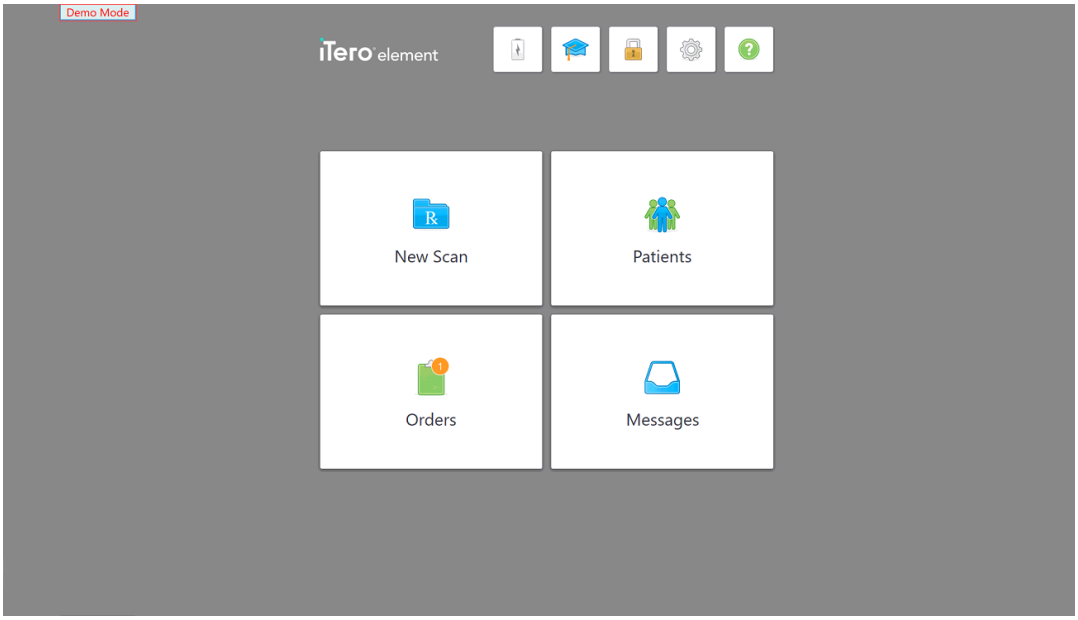

Figure 16: Demo Mode home screen

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5. To view the demo cases, tap **Orders** to display a list of orders that are currently in progress as well as a list of the past orders.

   In addition to the examples of restorative and orthodontic scan types, the following iTero Element 5D demo cases are displayed in the list of **Past Orders**:

   - Demo, 5D NIRI
   - Demo, 5D proximal caries
   - Demo, 5D with restorations

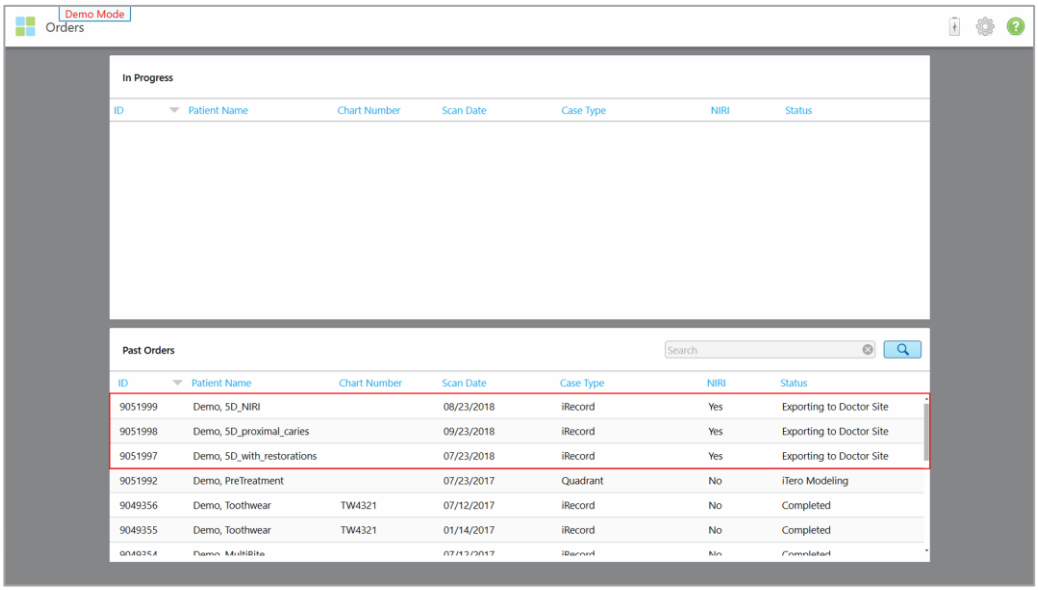

Figure 17: iTero Element 5D demo cases displayed in the list of past orders

6. Tap the required demo case.

   The selected case is expanded to show the following options:

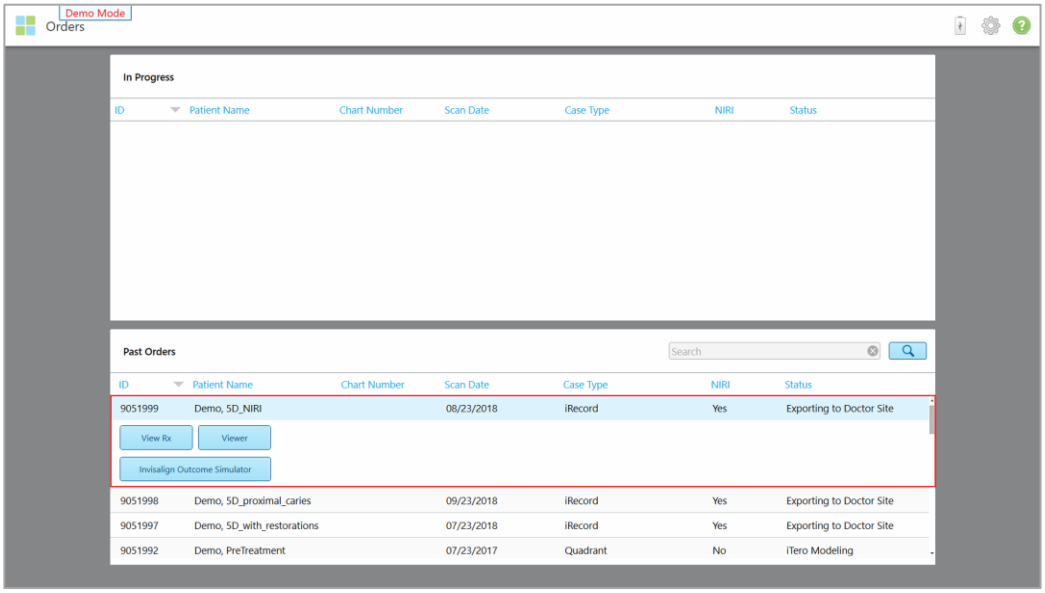

Figure 18: Past Orders pane – options

For more information on working with orders, see section 6.

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2.4.1 Exiting Demo Mode

To exit Demo mode:

- Tap the iTero Element logo and then tap **Exit Demo** to exit the demo mode.

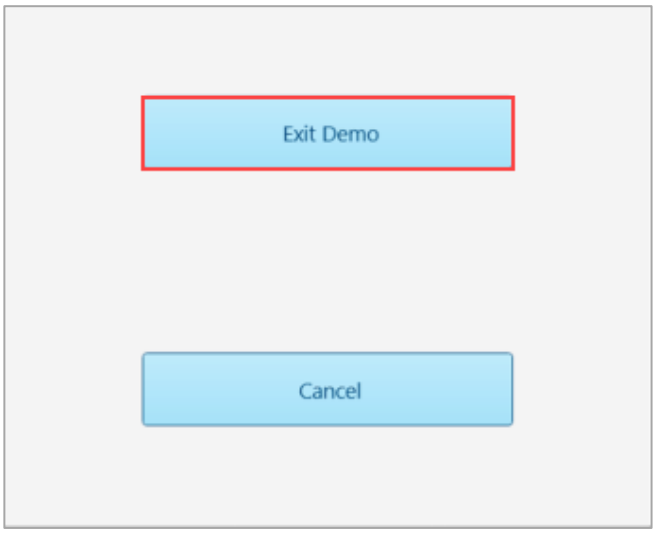

Figure 19: Exiting Demo mode

2.5 Registering the scanner – Make It Mine process

When registering the scanner, you need the following to complete the registration process:

- User Name
- User Password
- Company ID

You will receive an email from an iTero representative with login credentials and detailed information on how to proceed with the **Make It Mine** process.

Note: If you accessed the Demo Mode from the *Welcome* page before registering the scanner, you will have to restart the scanner to access the **Make It Mine** option.

To register the scanner:

1. In the *Welcome* page, select the required language.
2. Tap **Make It Mine**.

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The *Connect* page is displayed.

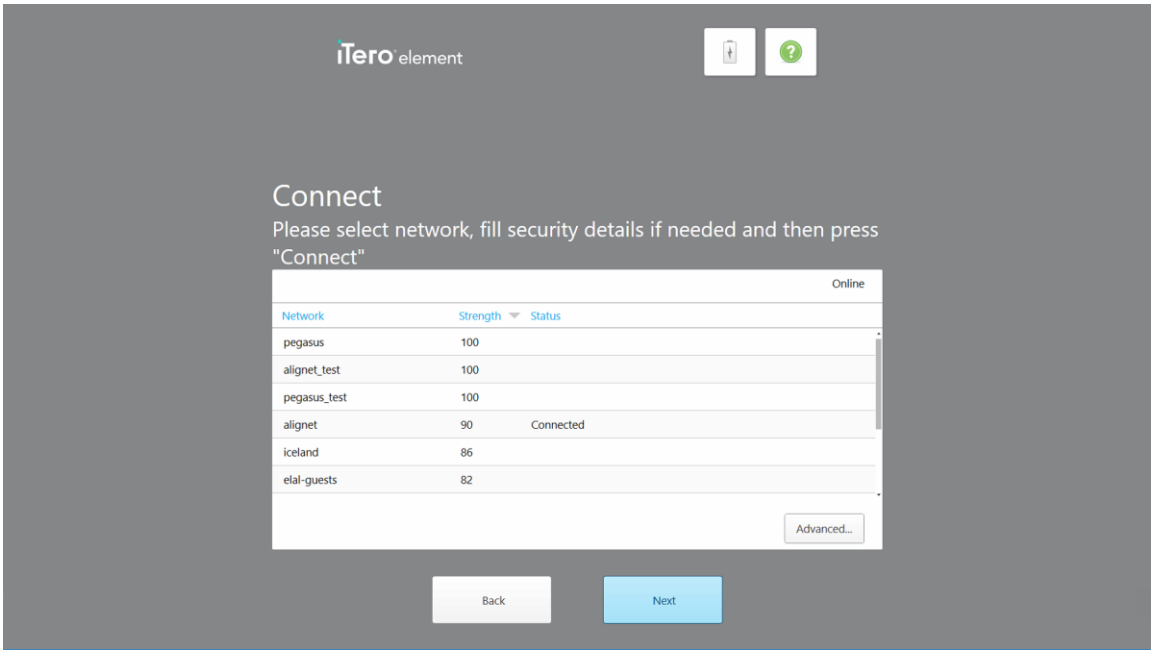

Figure 20: Selecting the network

3. Select the required network connection and then tap **Next**.

   The communication with Align is verified.

Figure 21: Verifying the communication with Align

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4. When the verification is complete, tap **Next**.

   The *Time Zone* page is displayed.

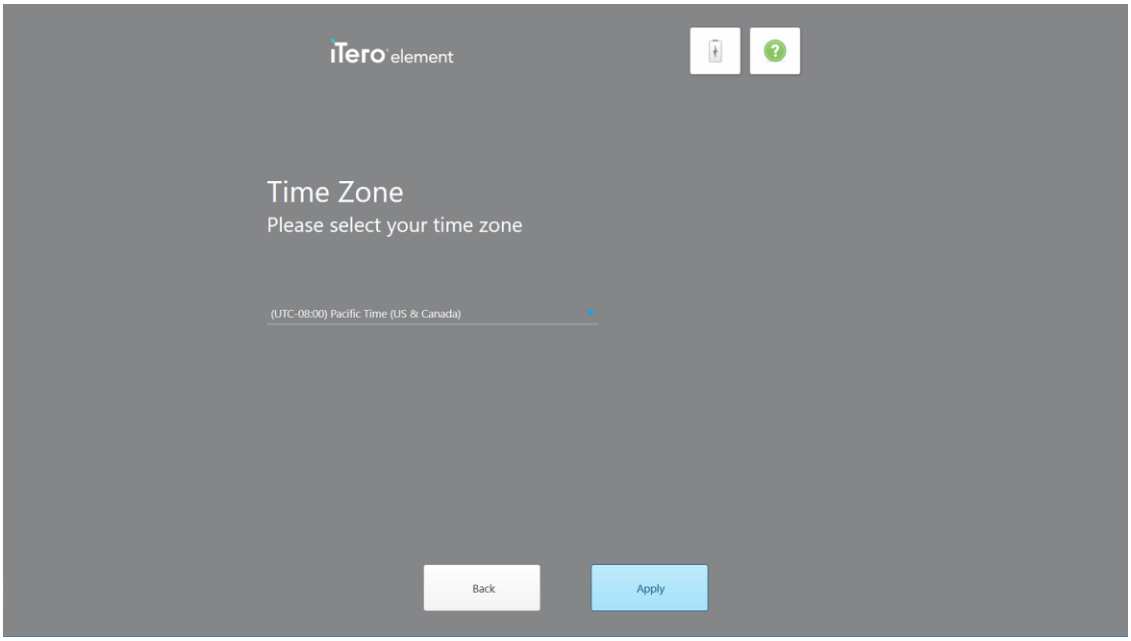

Figure 22: Selecting your time zone

5. Tap **Next** if the default time zone is correct or select your time zone from the drop-down list and then tap **Apply**.

   The *Register System* page is displayed.

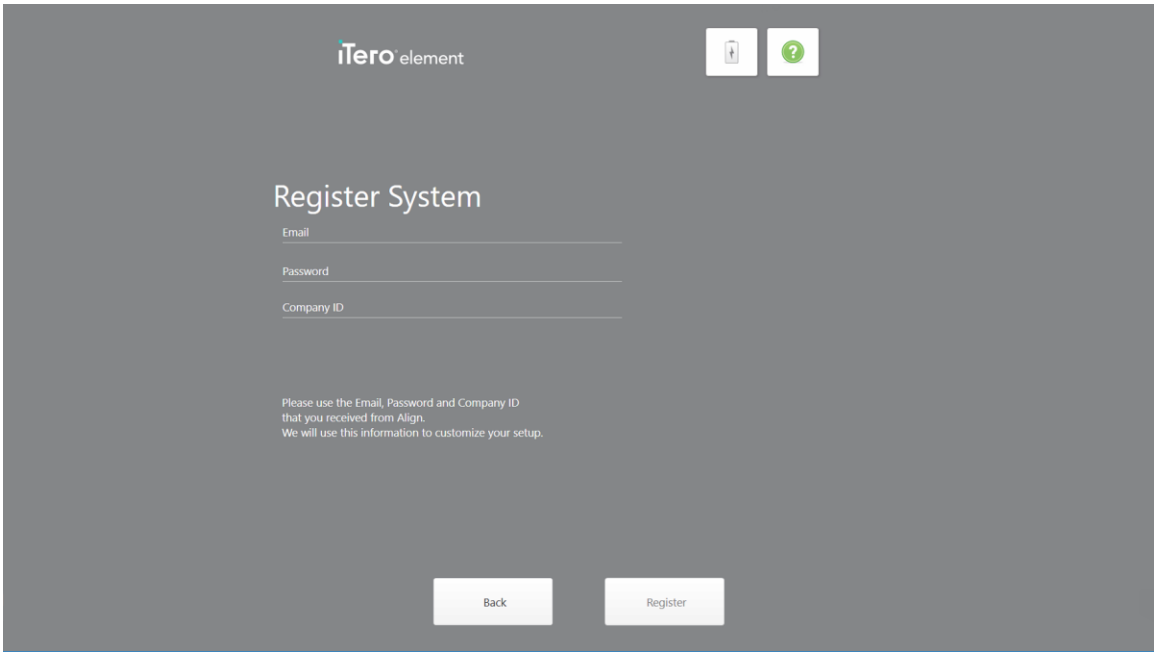

Figure 23: Registering the system to customize the setup

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6. Enter your email, password, and company ID in the fields provided, and then tap **Register**.
   The *Scanner Configuration* page is displayed, showing your iTero subscription package.

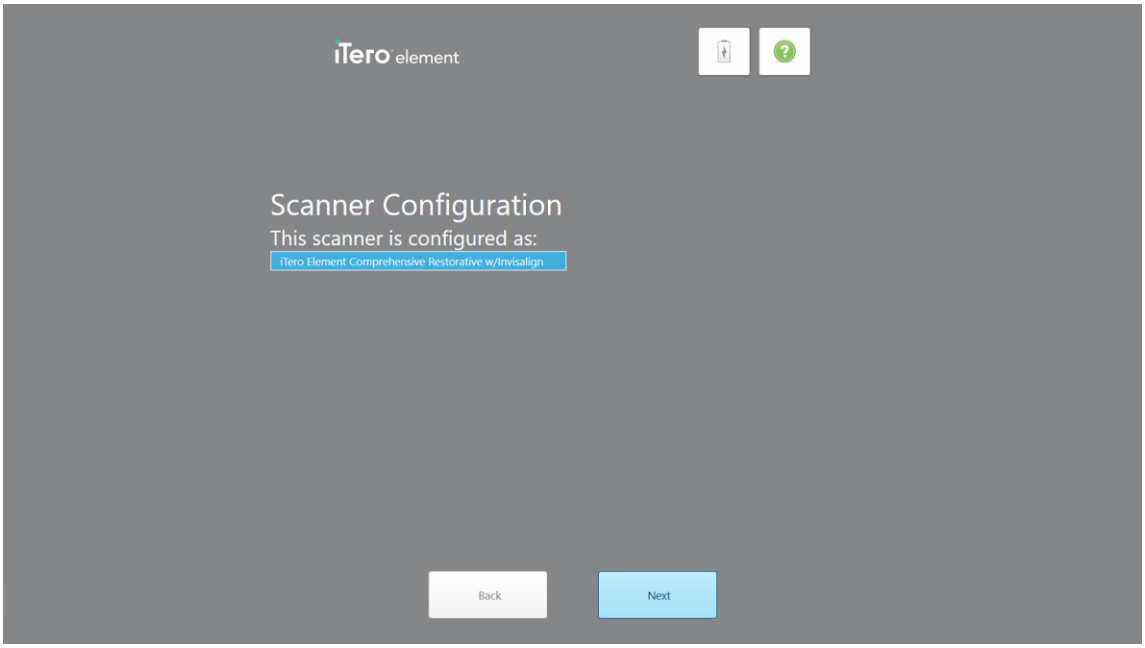

Figure 24: iTero subscription package

7. Tap **Next**.
   The *License Agreement* page is displayed.

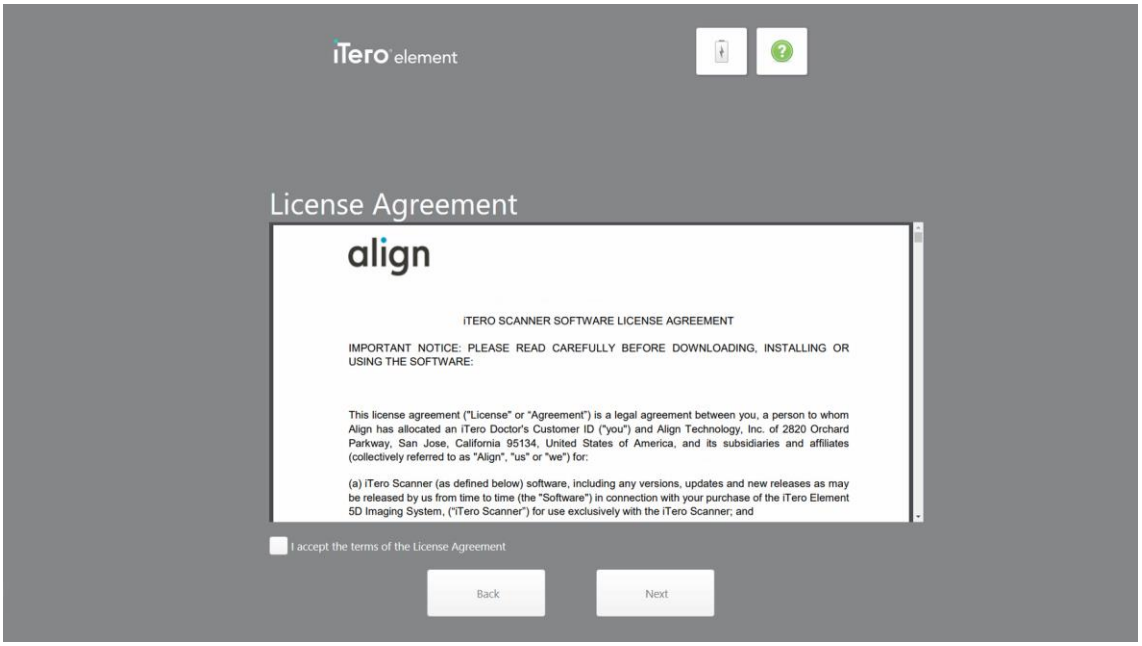

Figure 25: License agreement

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8. After reviewing the license agreement, select the check box to accept the terms of the agreement and then tap **Next**.

   The system checks for an upgrade and will be upgraded to the latest version, if relevant.

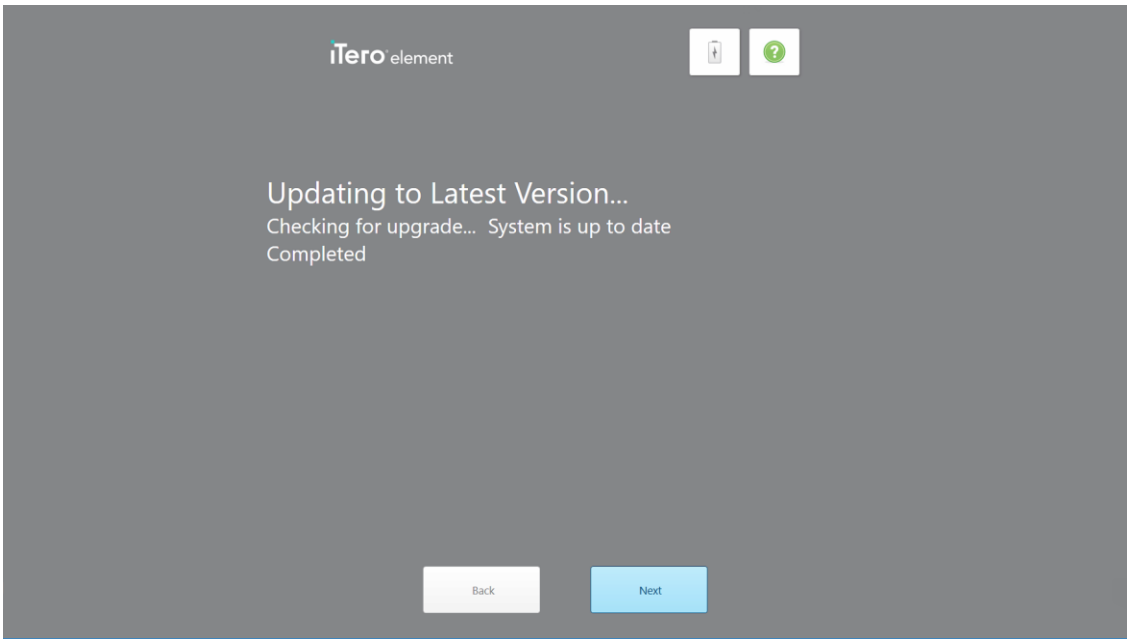

Figure 26: Checking for updates

9. Tap **Next**.

   The system has been registered and is ready.

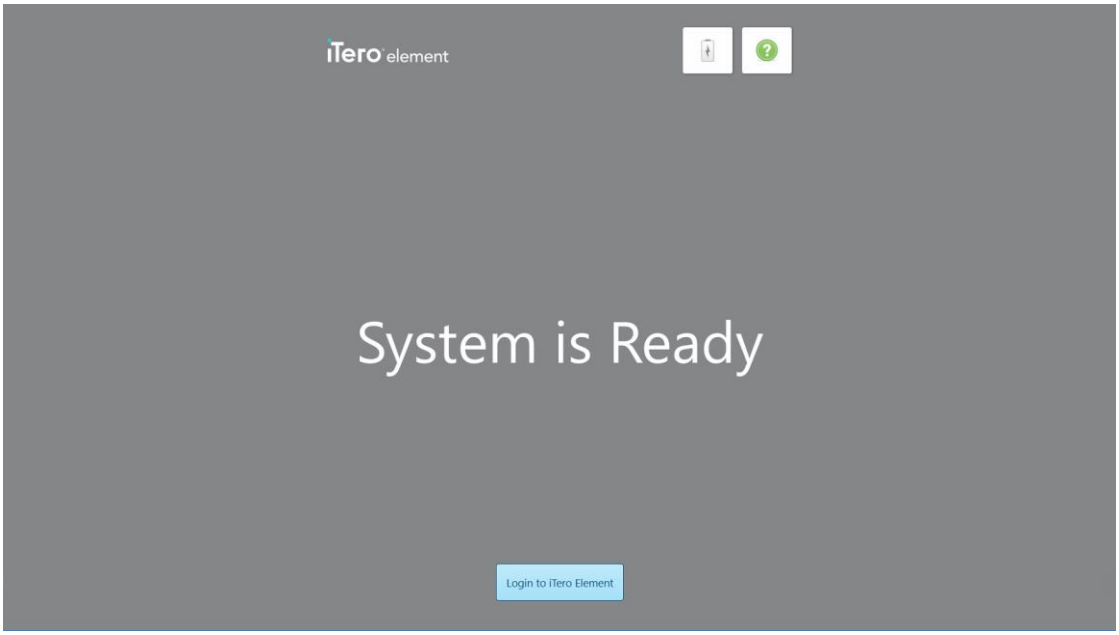

Figure 27: System is registered and ready

10. Tap **Login to iTero Element** to log in to the system, as described in the following section.

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3 Working with the iTero Element 5D scanner

3.1 Logging in to the scanner

When the scanner is powered on, the *Login* window will appear.

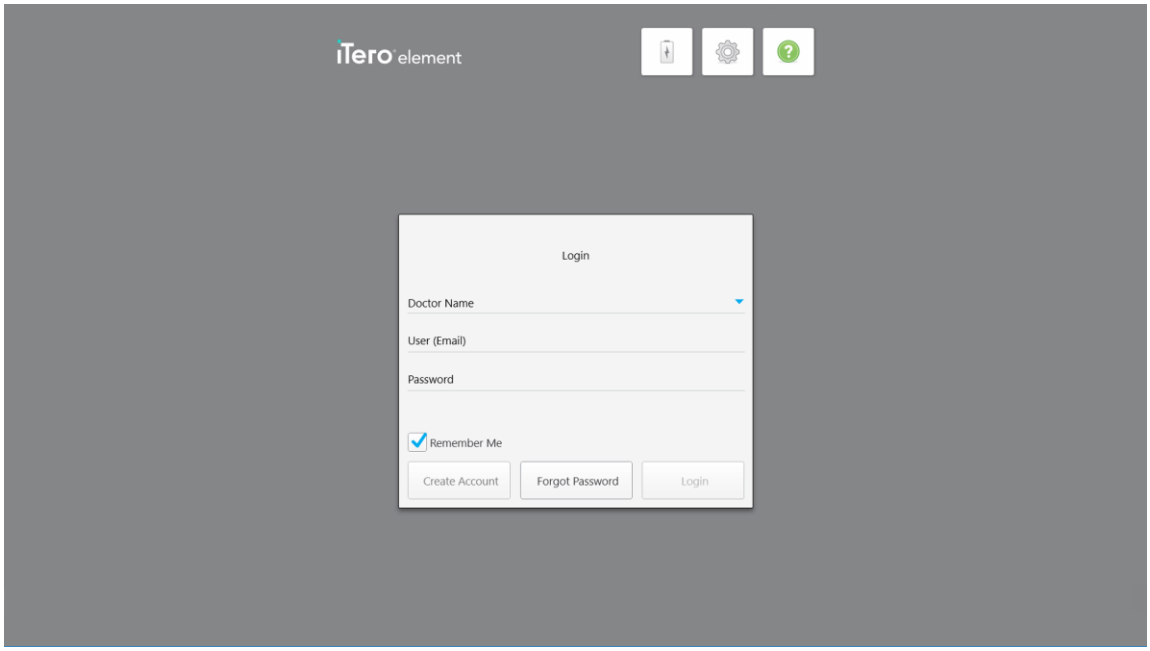

Figure 28: Login window

Make sure you have your MyAligntech account information ready when logging in to the iTero scanner. You will need your name, account email, and password. Fill in all the necessary fields and then tap the **Login** button.

To log in to the scanner:

1. Select your user name from the **Doctor Name** drop-down list.
2. Enter the email address you used when registering with myaligntech.com. Your email address will be displayed automatically if you selected the **Remember Me** check box in a previous login session.
3. Enter your password. If you have forgotten your password, reset it as described in section 3.1.1.
4. Select the **Remember Me** check box for the system to remember your email address in future sessions. You will still need to enter your password in order to access the scanner.

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5. Tap **Login**.

   The iTero Element 5D home screen is displayed.

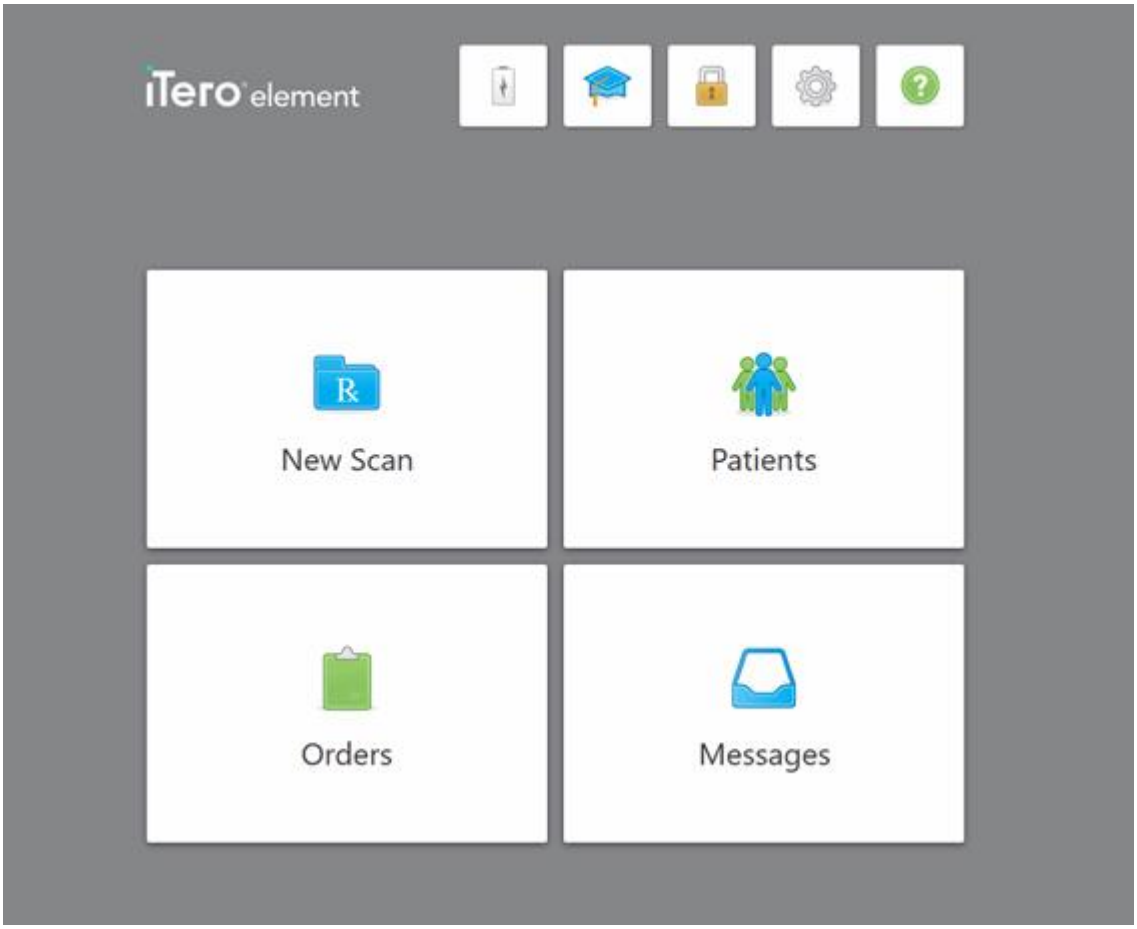

Figure 29: iTero Element 5D home screen

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3.1.1 Resetting your password

You can reset your password, if required.

To reset your password:

1. In the *Login* window, tap **Forgot Password**.

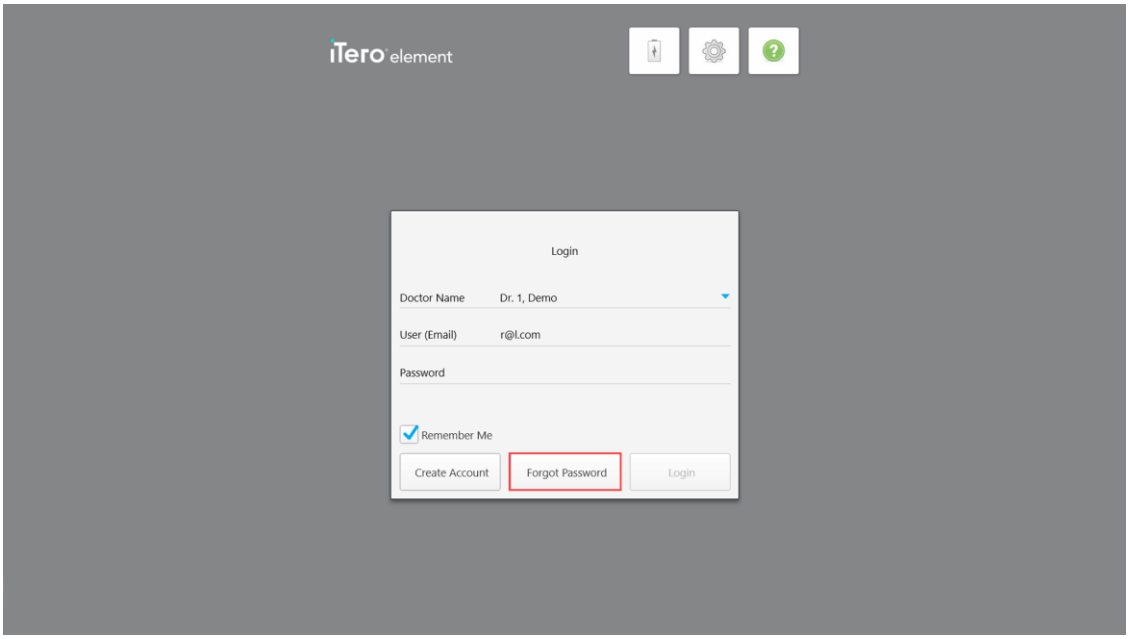

Figure 30: Forgot Password button

A window is displayed, describing what you should do next.

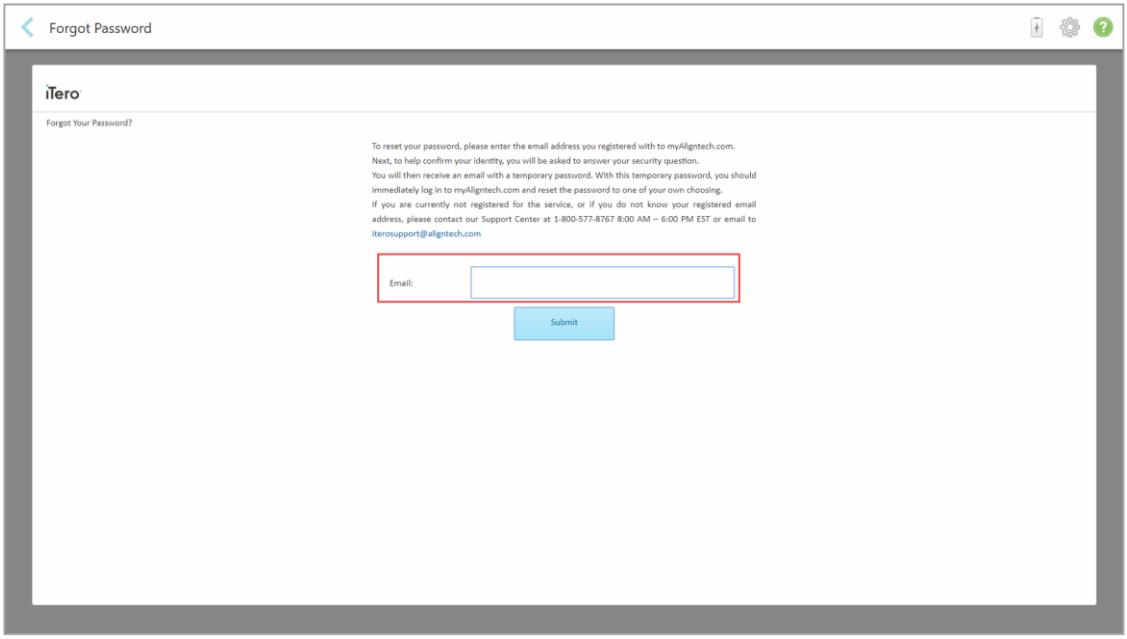

Figure 31: Email field for forgotten password

2. In the **Email** field, enter the email address you used to register to myaligntech.com.

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3. Tap **Submit**.

   Your predetermined security question is displayed.

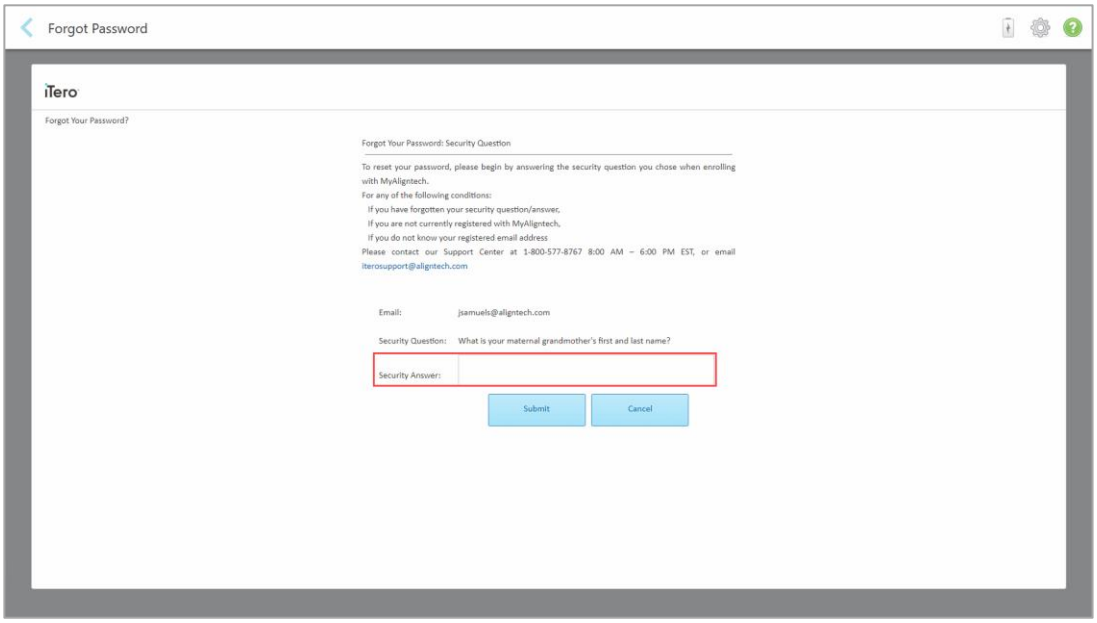

Figure 32: Security answer field

4. Enter the answer to your security question.

   A temporary password will be sent to you.

5. Use the temporary password to log in to myaligntech.com and then reset your password.
6. If you do not know your registered email address, contact iTero Customer Support.

3.2 Logging out of the scanner

In order to protect your patient information, you should log out of the scanner when it is not in use.

By default, you will be logged out after a predefined period of inactivity, which can be defined in the Login settings, described in section 3.6.3.1.

To log out of the scanner:

1. Tap to return to the home screen.
2. Tap to log out of the system.

   The *Login* window is displayed, ready for the next user to log in to the system.

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3.3 Shutting down the scanner

It is recommended to shut down the system at the end of each day to allow software updates to be installed.

To shut down the scanner:

1. Close all files and applications.
2. Press and release the power button, located at the bottom right of the screen, to shut down the system.

   CAUTION: Never press the power button for more than 4 seconds. This activates a hard reset, which can cause problems such as gray and blue screens.

3.4 Moving the scanner within the office

The iTero Element 5D scanner can be moved within the office.

To move the scanner:

1. Ensure that the wand is firmly positioned in the cradle.
2. Unplug the system from the wall outlet.
3. Place the system at its new location and plug it into a wall outlet.

3.5 User interface

The iTero Element 5D system provides an intuitive user interface for performing digital scans for Restorative or Orthodontic use. The touch screen and wand buttons are used to respond to screen instructions during the scanning process.

For a list of the touch-screen gestures that can be used, see section 3.5.2.

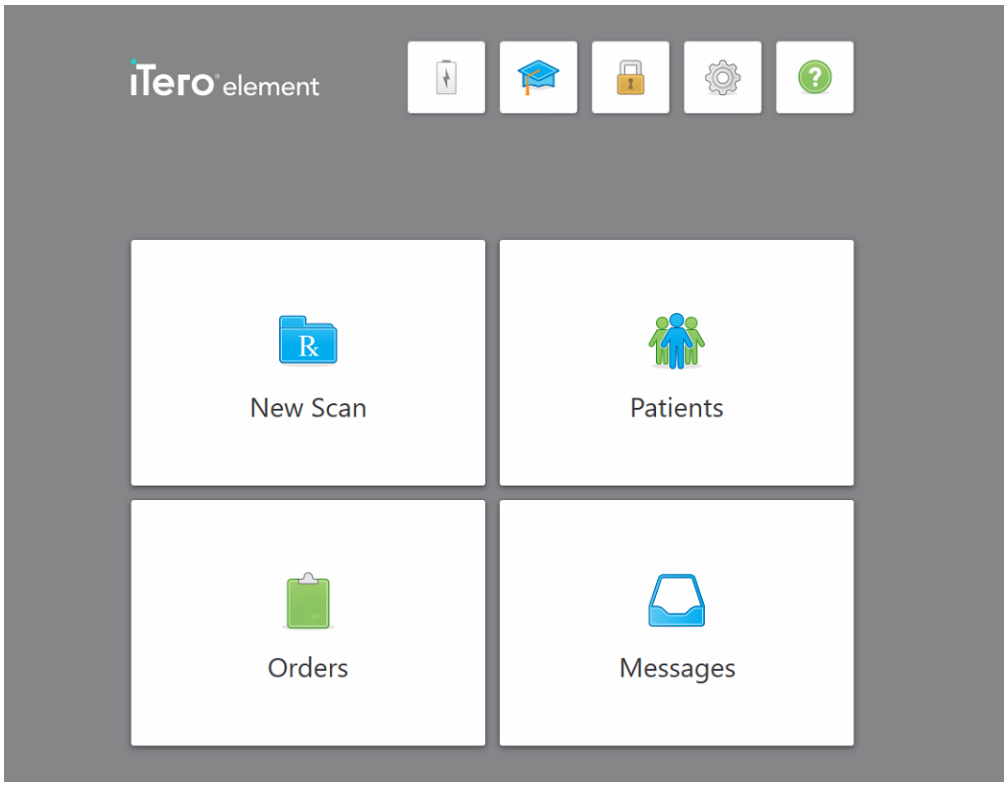

Figure 33: iTero Element 5D home screen

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The following buttons are displayed on the home screen:

Battery: Tap to view the remaining charge on the iTero external battery.

A battery indicator will appear, showing the percentage of battery charge remaining. When the battery icon displays a lightning bolt symbol, the battery is charging.

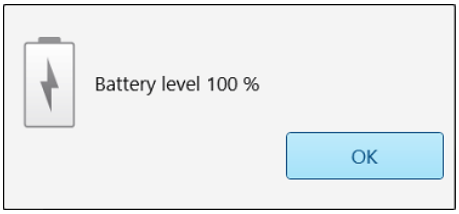

Figure 34: Remaining battery charge

Learning Center: Tap to access training materials and educational videos for your iTero Element 5D scanner.

Lock: Tap to log out of your account whenever the iTero Element 5D is not in use, as described in section 3.2. This will help ensure that the dental practice is HIPAA compliant and that all medical information is secure.

Tip: You should lock the system while cleaning it, in order to avoid unintended entries.

Settings: Tap to adjust the preferences for your iTero Element 5D, for example, for wand configuration, localization, user settings, and more.

For more information, see section 3.6.

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Help: Tap to display a translucent Help overlay with hints to aid in the navigation of features and tools.

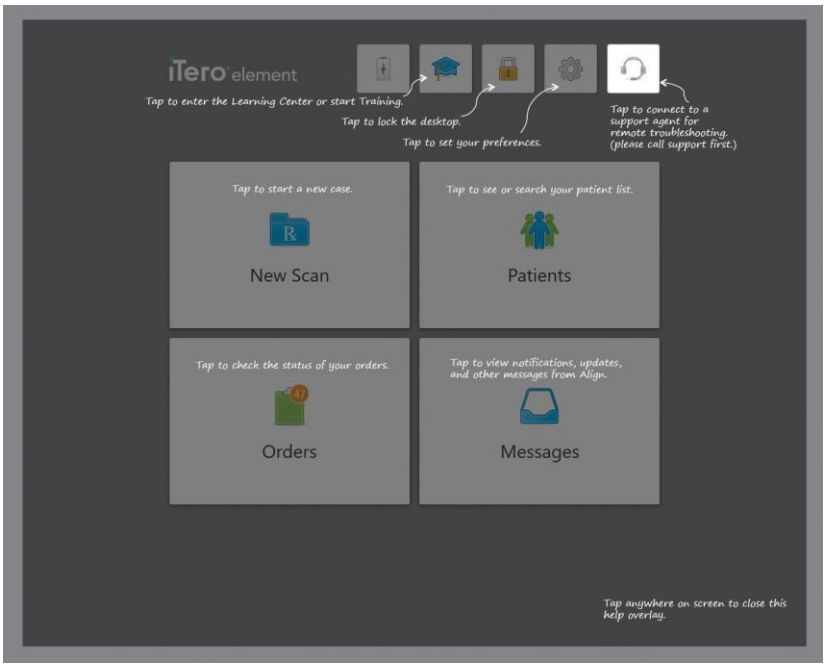
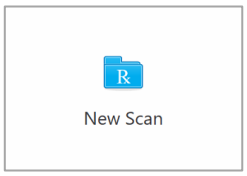


Figure 35: Help overlay

In this view, the button changes to . Tap the button for remote assistance from Customer Support. Customer Support is available from every Help overlay.

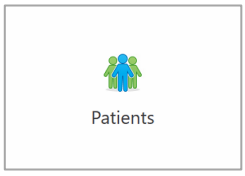
Note: Please call Customer Support before trying to connect remotely.

Tap anywhere to close the Help overlay and return to the relevant screen.



New Scan: Tap to open the *New Scan* window to fill in the Rx before starting a new scan.

For more information, see section 4.



Patients: Tap to view the *Patients* page with a list of all your patients, their chart number, and last scan date.

For more information, see section 5.

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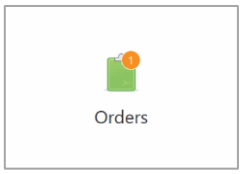
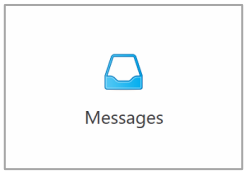


Orders: Tap to display a list of all your orders.

For more information, see section 6.



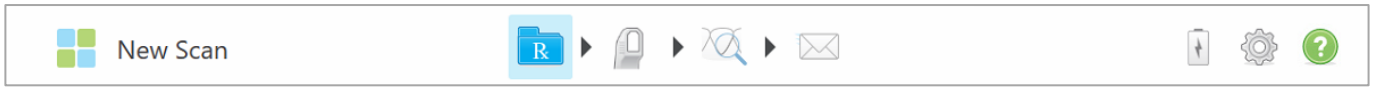
Messages: Tap to view your messages from Align Technology.

For more information, see section 7.

The **Battery** and **Settings** buttons are displayed on each of the scanner windows as well, as described in section 3.5.1.

3.5.1 Scanner toolbar

The following toolbar is displayed on the top of each of the scanner windows:



The four center buttons indicate the current status of the scan process.

Tap to return to the home screen.

New Scan

Displays the current stage in the scanning process, also indicated by the relevant highlighted button in the toolbar.

Tap to return to the *New Scan* window to view the Rx, as described in section 4.3.

Tap to move to Scan mode to scan the patient, described in section 4.4.

Tap to move to View mode to view the scanned model, described in section 4.5

Tap to send the scanned model to the lab, described in section 4.5.7

Tap to view the remaining charge on the iTero external battery.

A battery indicator will appear, showing the percentage of battery charge remaining. When the battery icon displays a lightning bolt symbol, the battery is charging.

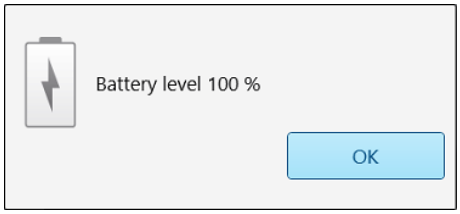


Figure 36: Remaining battery charge

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Tap to adjust the preferences for your iTero Element 5D, for example, for wand configuration, localization, user settings, and more.

For more information on the Settings preferences, see section 3.6.

Tap to display a translucent Help overlay with hints to aid in the navigation of features and tools.

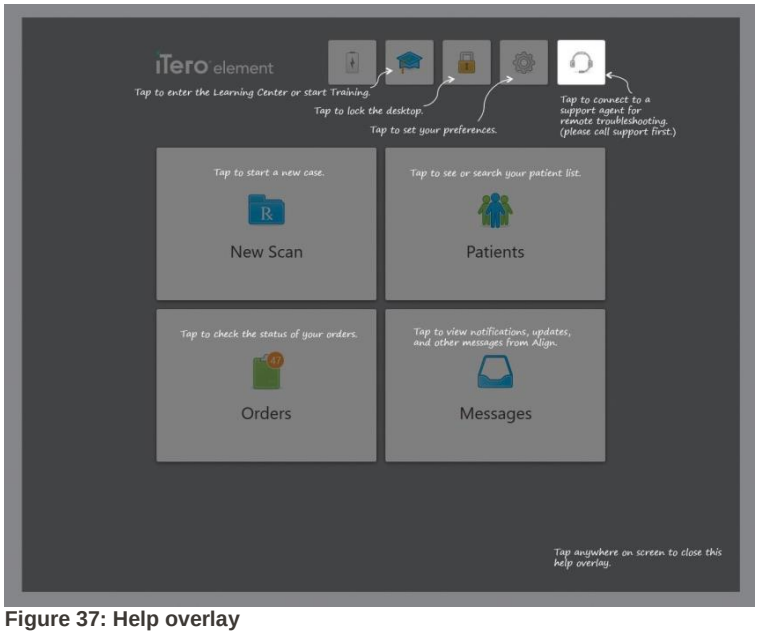

Figure 37: Help overlay

In this view, the button changes to . Tap the button for remote assistance from Customer Support. Customer Support is available from every Help overlay.

Tap anywhere to close the Help screen and return to the relevant screen.

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3.5.2 Touch-screen gestures

The iTero Element 5D application supports touch-screen (also known as multi-touch) gestures. These gestures are predefined motions used to interact with multi-touch devices.

Examples of common touch-screen gestures:

Tap

Double tap

Long press

Scroll

Rotate

Swipe

2 finger tap

Zoom in/pinch

Zoom out

Pan

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3.6 Defining the scanner settings

The scanner settings enable you to define your preferences and the settings that are displayed by default when you use the scanner.

To define the scanner settings:

1. Tap the button.

   The *Settings* window is displayed.

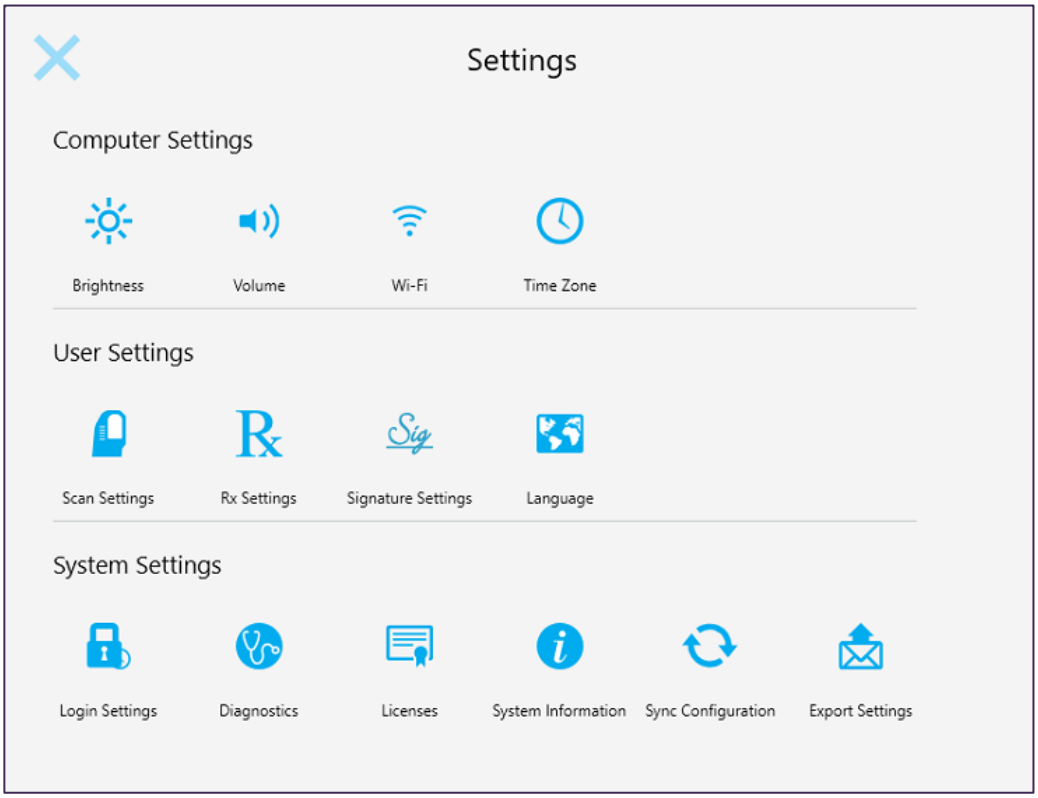

Figure 38: Settings window

2. Tap the settings you would like to define.
   - Computer settings, described in section 3.6.1
   - User settings, defined in section 3.6.2
   - System settings, defined in section 3.6.3

   The relevant window opens.

3. Make your changes and then tap to save your changes and return to the *Settings* window.

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3.6.1 Defining the Computer settings

The Computer settings enable you to define the brightness, volume, Wi-Fi, and time-zone settings for the scanner.

3.6.1.1 Defining the default brightness setting

To define the default brightness setting, tap the **Brightness** button, move the lever to the required brightness level, and then tap to save your changes and return to the *Settings* window.

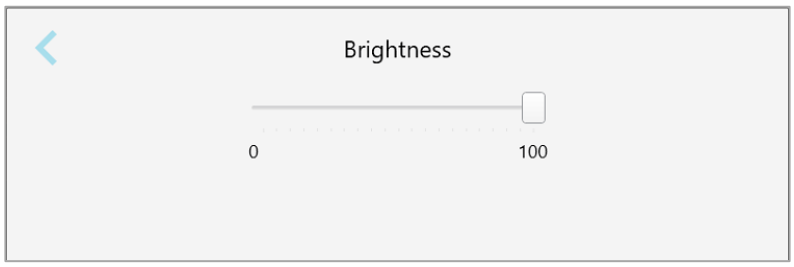

Figure 39: Brightness settings

3.6.1.2 Defining the default volume setting

To define the default system volume, tap the **Volume** button, move the slider to the required volume level, and then tap to save your changes and return to the *Settings* window.

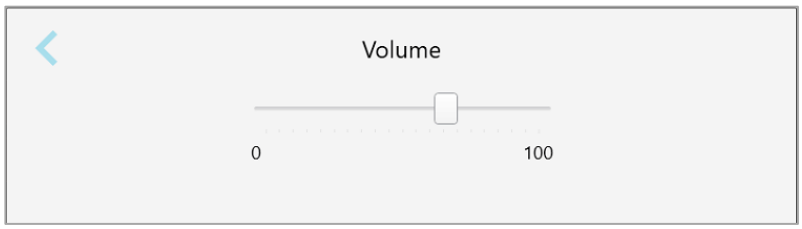

Figure 40: Volume settings

In addition to the system sounds, the volume settings define the volume for the content from the Learning Center .

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3.6.1.3 Defining the Wi-Fi settings

The first time you connect your scanner to the clinic's Wi-Fi network, you will need to add your password. After that, by default, the scanner will connect automatically.

To connect to the Wi-Fi network:

1. Tap the **Wi-Fi** button.

   A list of nearby Wi-Fi networks is displayed.

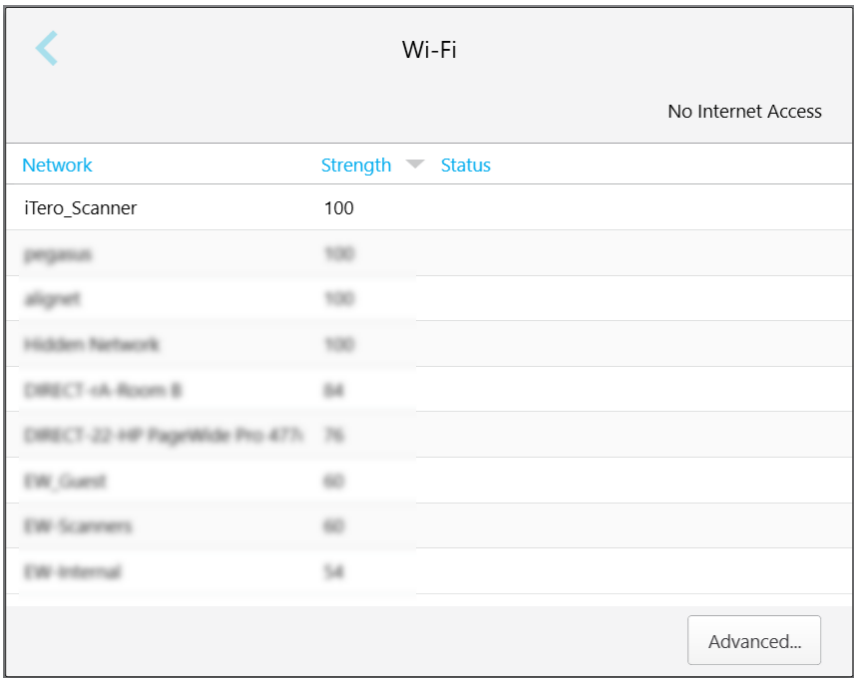

Figure 41: List of nearby Wi-Fi networks

2. Select your clinic network and tap **Connect**.
3. Enter your network security key (password) in the window that opens and then tap **Connect**.

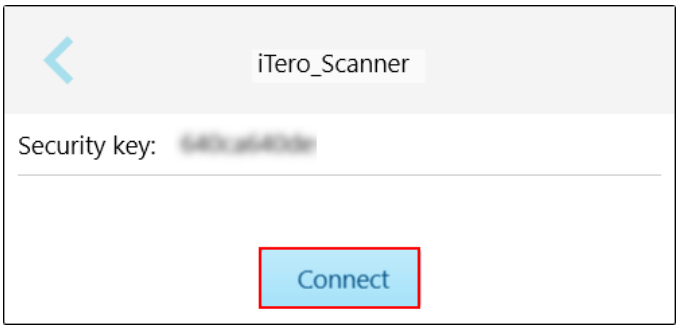

Figure 42: Connecting to the clinic Wi-Fi network

The scanner will connect to the Wi-Fi network, and the status changes to **Connected**.

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4. If you do not want to connect to the network automatically, tap the network you are connected to and then tap **Forget**.

   You will need to select the required network and enter the Wi-Fi password the next time you want to connect.

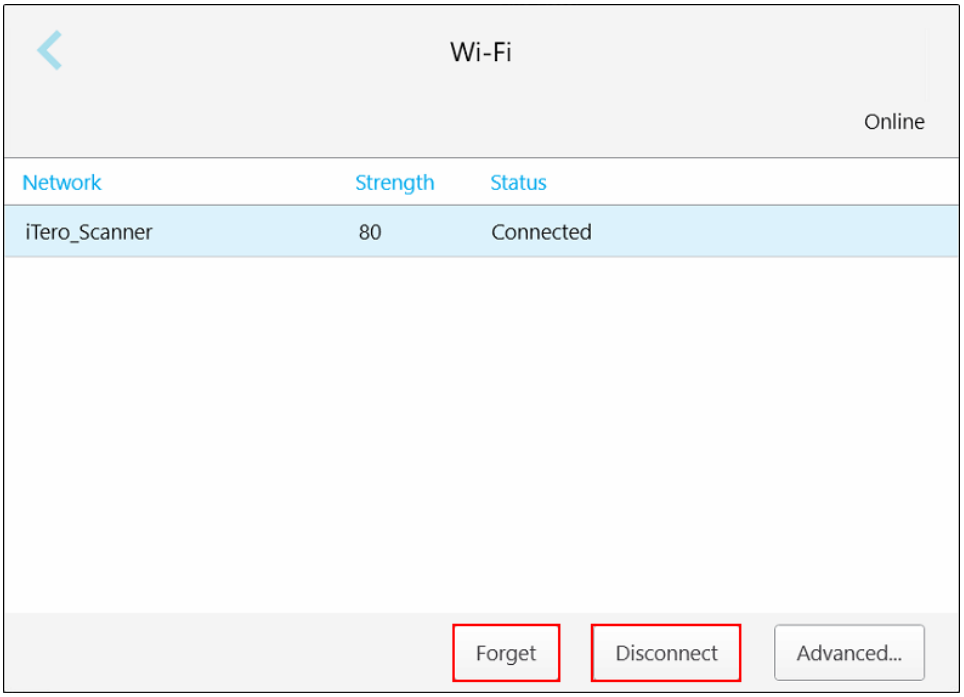

Figure 43: Forgetting or disconnecting from the network

5. To disconnect from the network, tap **Disconnect**.

6. Tap to save your settings and return to the *Settings* window.

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3.6.1.4 Defining your time zone

To define your time zone, tap the **Time Zone** button, select your time zone from the drop-down list, and then tap to save your changes, and return to the *Settings* window.

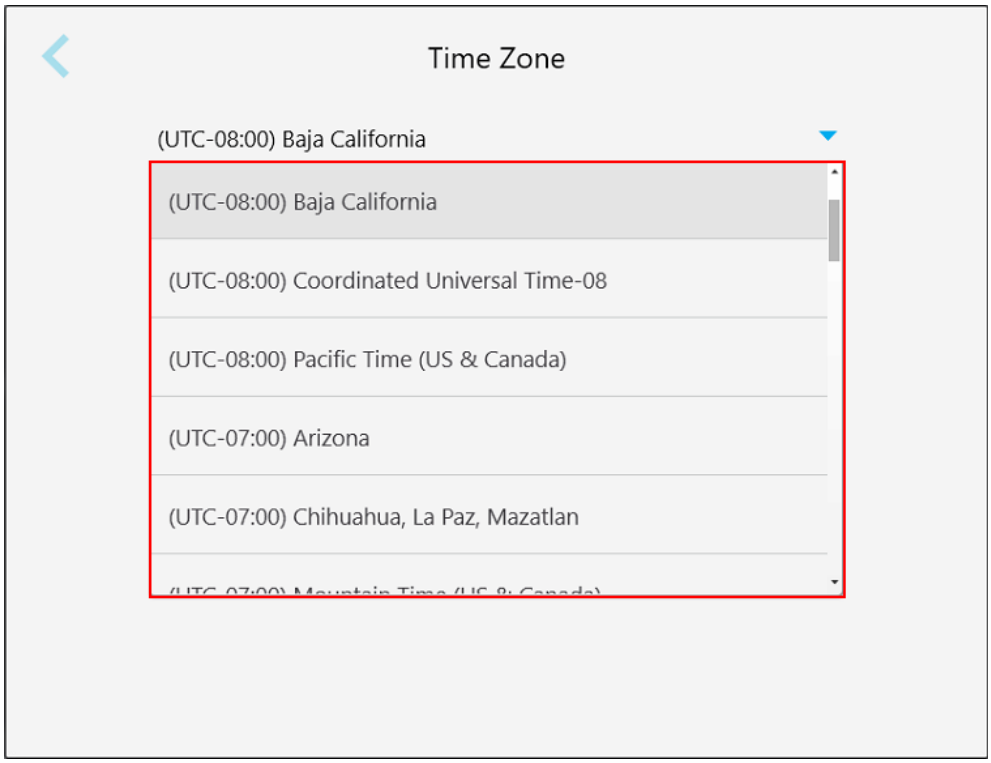

Figure 44: Time zone settings

Note: The time zone settings can be accessed only when you are logged on to the scanner.

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3.6.2 Defining the User settings

The User settings enable each user to define the settings that are displayed by default when the specific user logs in to the scanner.

3.6.2.1 Defining the scan settings

You can define the default settings that are taken into account when scanning a patient.

To define the scan settings:

1. Tap the **Scan Settings** button.

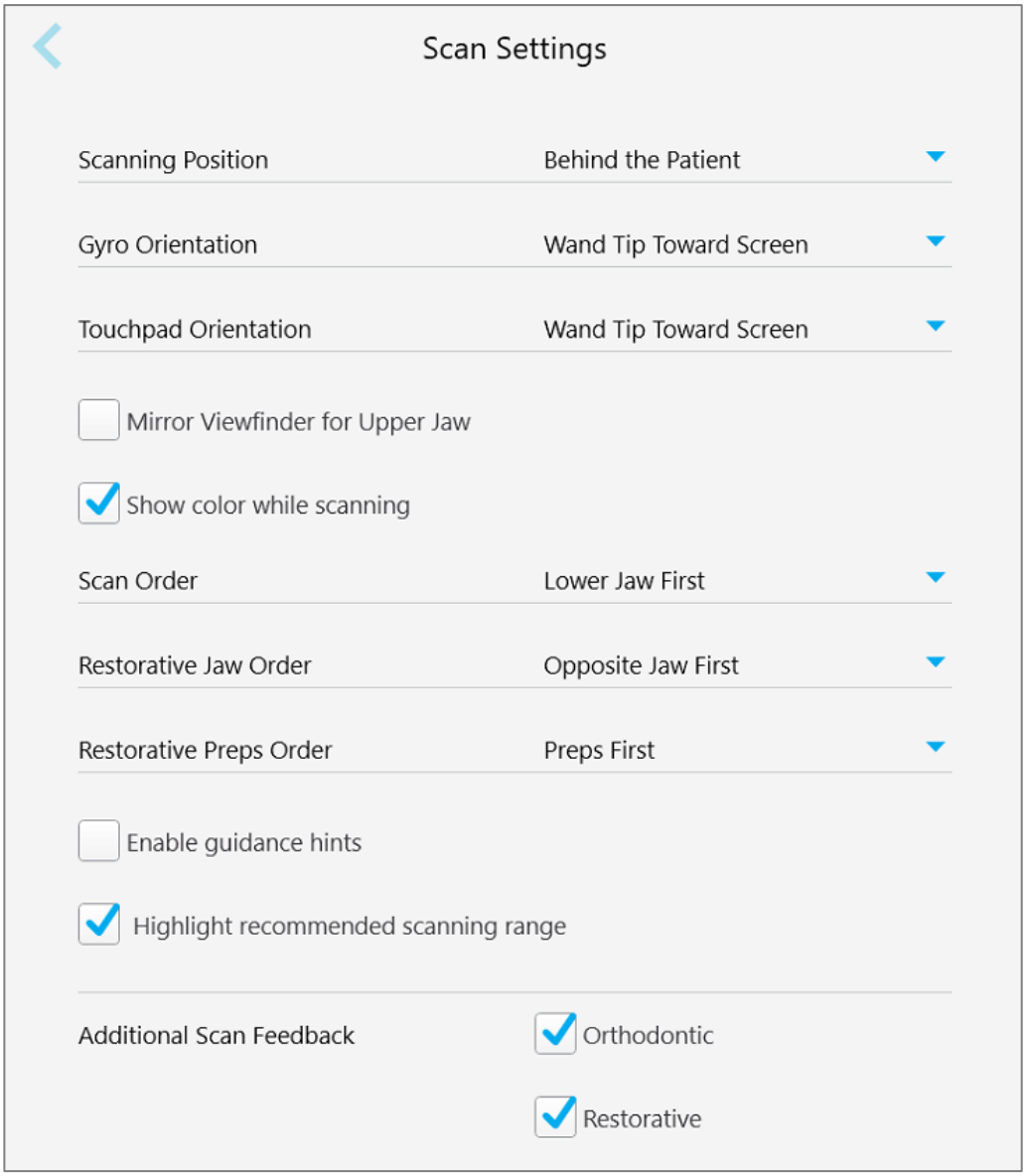

Figure 45: Scan Settings window

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2. Select your default scanning preferences from the *Scan Settings* window.

Scan setting	Scan options
Scanning Position	Select your position while scanning the patient: • Behind the patient • In front of the patient
Gyro Orientation	Select the default gyro orientation: • Wand Tip Toward Screen • Wand Base Toward Screen
Touchpad Orientation	Select the default touchpad orientation: • Wand Tip Toward Screen • Wand Base Toward Screen
Mirror Viewfinder for Upper Jaw check box	Select this check box to define the orientation of the viewfinder when scanning the upper jaw.
Show color while scanning check box	Select this check box to scan in color, by default.
Scan Order	Select the order in which to scan the jaws: • Upper Jaw First • Lower Jaw First
Restorative Jaw Order	Select the order in which to scan the jaws for restorative case types: • Opposite Jaw First • Prepped Jaw First
Restorative Preps Order	Select the order in which to scan the prepped teeth and the arches in restorative case types: • Preps First • Arch First • No Guidance
Enable guidance hints check box	Select this check box to display guidance when scanning, as described in section 4.4.1.

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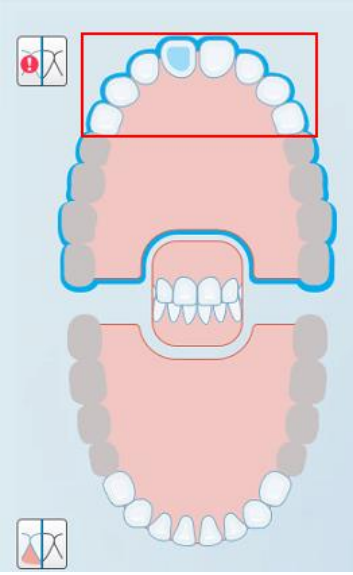
Scan setting	Scan options
Highlight recommended scanning range check box	Select this check box to highlight only the scanning range on the navigation controls. 
Additional Scan Feedback	Select the relevant check boxes to display areas of missing anatomy while scanning, as described in section 4.4.3.1. • Orthodontic • Restorative

Figure 46: Only scanning range is highlighted

3. Tap to save your changes, and return to the *Settings* window.

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3.6.2.2 Defining the Rx settings

You can define the settings that are displayed by default when you open the *Scan Details* window to fill in a new Rx.

To define the Rx settings:

1. Tap the **Rx Settings** button.

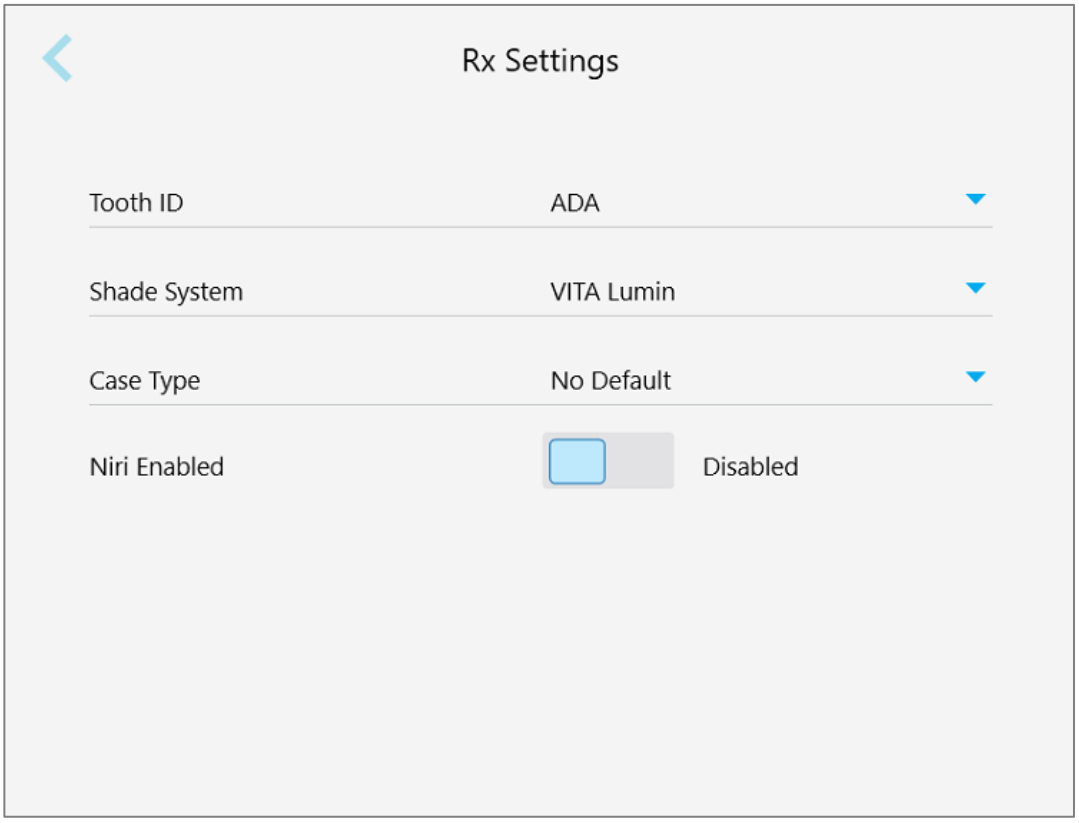

Figure 47: Rx Settings window

2. Select your default Rx preferences from the *Rx Settings* window.

Rx setting	Rx options
Tooth ID	Select the default tooth ID system: • FDI • ADA • Quadrant
Shade System	Select the default shade system: • VITA Lumin • VITApan 3D Master • Other

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Rx setting	Rx options
Case Type	Select the default case type: • No Default • Invisalign • iCast • iRecord • Chair Side Milling • Invisalign + iRecord • Vivera • Vivera Pre-Debond • Restorative **Note:** The list of available options changes according to your subscription package.

3. Tap to save your changes, and return to the *Settings* window.

3.6.2.3 Defining the signature settings

You can define the default settings that are displayed when sending an order to the lab.

To define the signatures settings:

1. Tap the **Signature Settings** button.

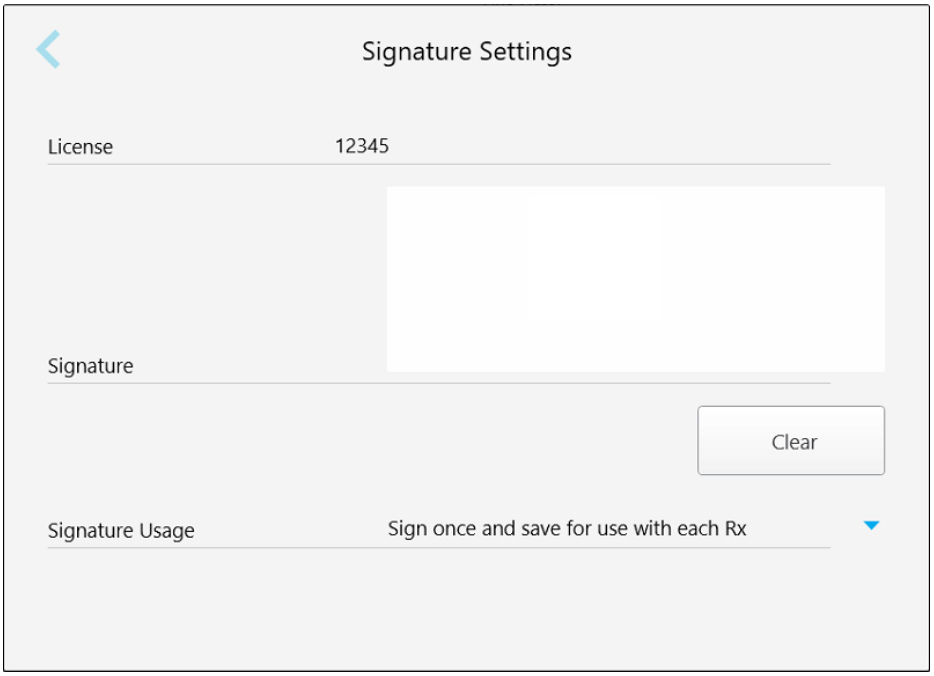

Figure 48: Signature Settings window

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2. Define your default signature settings.

Signature setting	Signature options
License	Add your license number.
Signature	Add your signature.
Signature Usage	Select one of the following signature options: • Sign once and save for use with each Rx • Do not save my signature (requires a signature for each Rx) • Disable this function (for this user only)

3. Tap to save your changes, and return to the *Settings* window.

3.6.2.4 Defining the language settings

Tap the **Language** button, select your required language from the drop-down list, and then tap to save your changes and return to the *Settings* window.

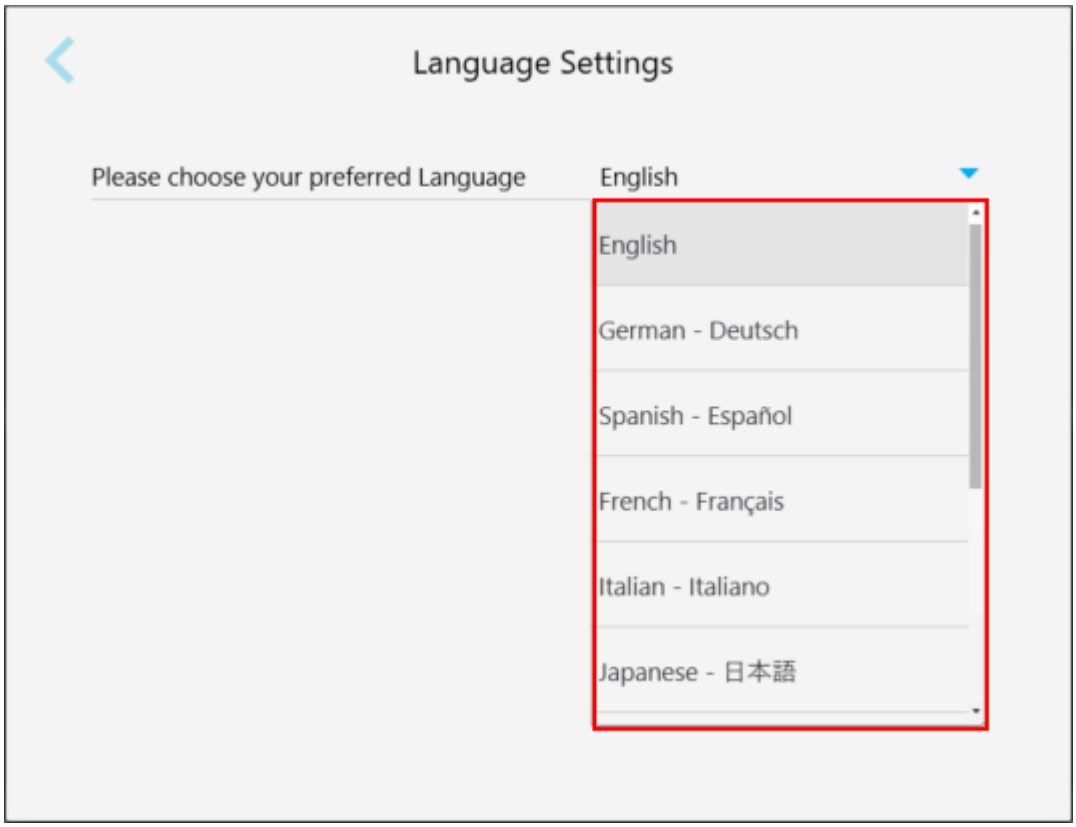

Figure 49: Language Settings window

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3.6.3 Defining the System settings

The System settings enable you to set the login settings, run diagnostics, view the licenses, view the system information, synchronize the configuration, and define the export settings.

3.6.3.1 Defining the login settings

In order to comply with privacy and security regulations, you will be logged out of the scanner after a predefined period of inactivity. By default, this time is set to 4 hours, but you can change it if required.

To define the period of inactivity:

1. Tap the **Login Settings** button.

   The *Login Settings* window is displayed.

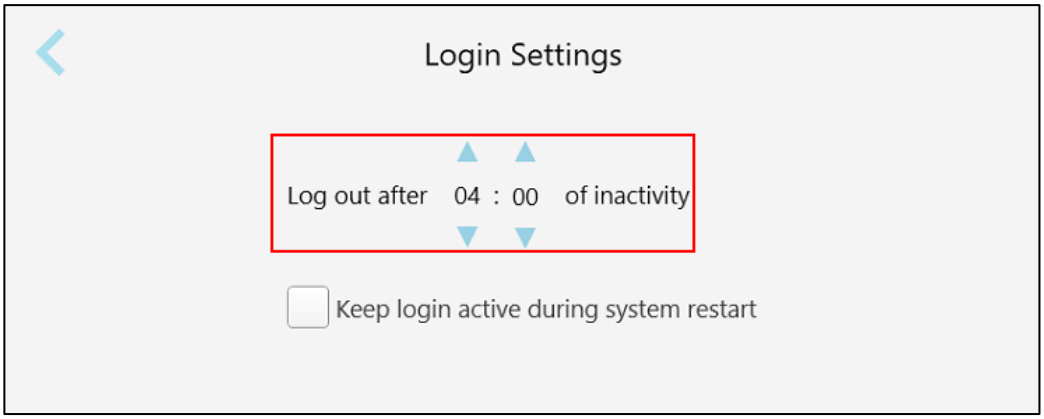

Figure 50: Login Settings window

2. Select the period of inactivity after which the user will be logged out of the scanner. (Min time: 10 minutes, Max time: 10 hours)
3. Select the **Keep login active during system restart** check box to remember the user's password if the system restarts before the inactivity logout period has elapsed.
4. Tap to save your changes and return to the *Settings* window.

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3.6.3.2 Running diagnostics

Tap the **Diagnostics** button to check the network connection and speed.

To run system diagnostics:

1. Tap the **Diagnostics** button.

   The network connection and speed are checked.

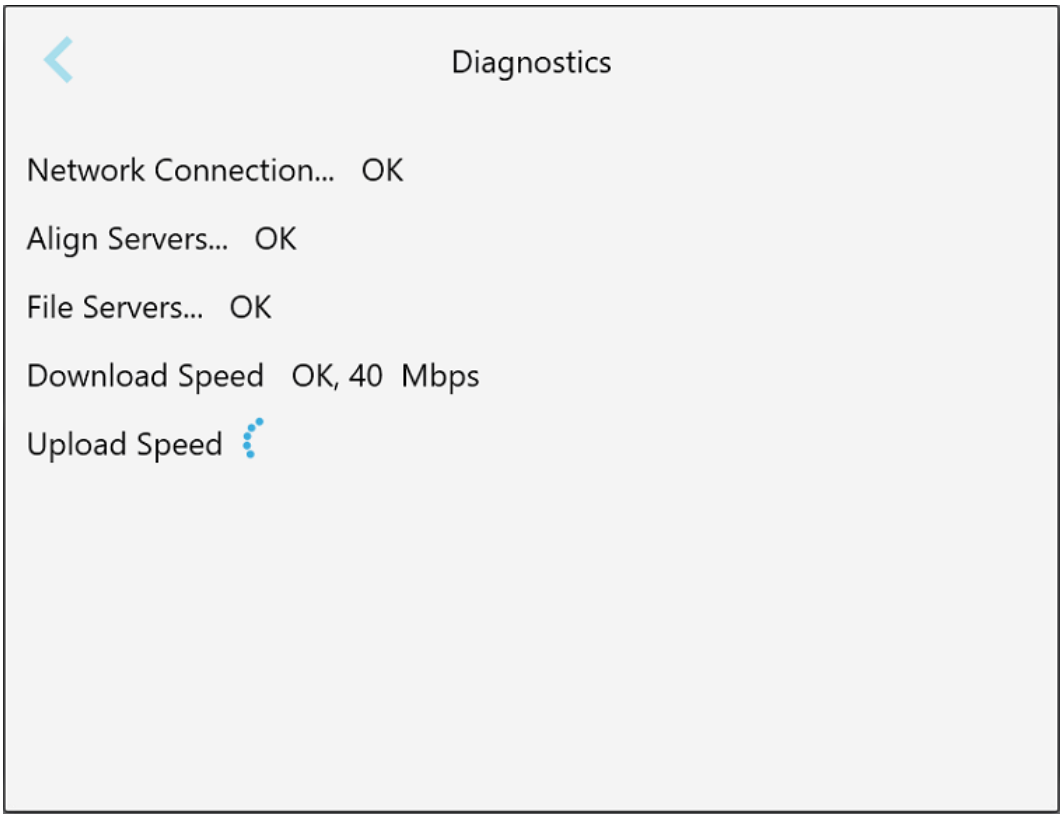

Figure 51: Diagnostics window

2. Tap to return to the *Settings* window.

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3.6.3.3 Licenses

Tap the **Licenses** button to view a list of third-party software components installed on the scanner and then tap to return to the *Settings* window.

Figure 52: Licensing Information window

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3.6.3.4 System information

Tap the **System Information** button to view details about the software versions currently installed and the hardware serial numbers and ID, and then tap to return to the *Settings* window.

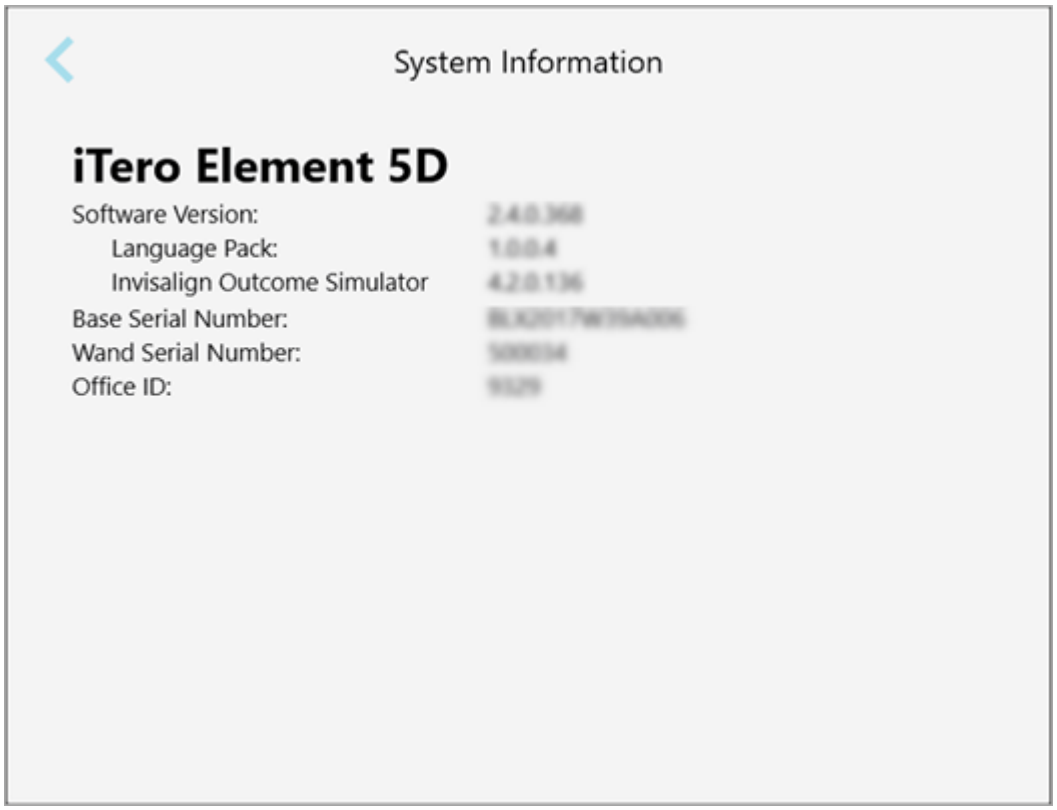

Figure 53: System Information window

3.6.3.5 Sync configuration

Tap the **Sync Configuration** button to synchronize any new updates from the server, for example, new software options, and then tap to return to the *Settings* window.

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3.6.3.6 Export settings

You can define how long exported files should be kept before being deleted. In addition, you can view the local network address of the exported files, in boldface letters (starting with "\\"). This address is accessible from any computer within the local network.

Note: If required, you can export the files at any time from MyiTero.

To edit the export settings:

1. Tap the **Export Settings** button.
2. Select the number of days after which exported files should be deleted. By default, this is set at 30 days.

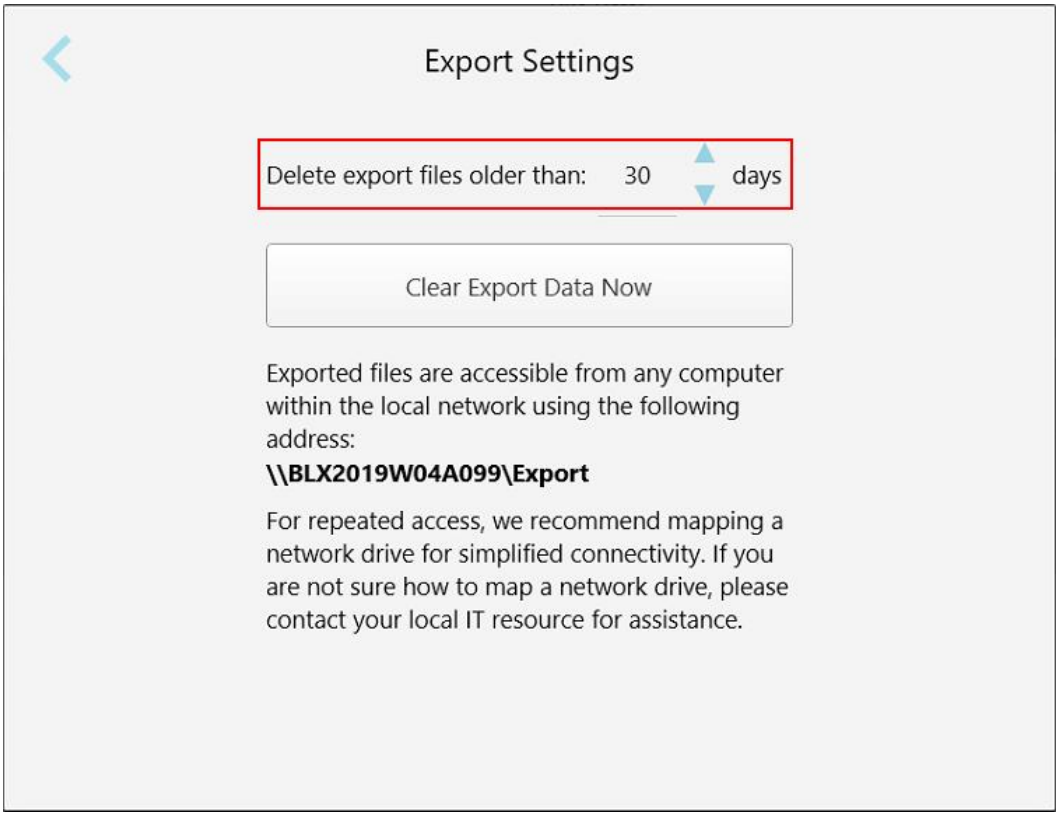

Figure 54: Export Settings window – deleting exported files

3. If required, tap **Clear Export Data Now** to delete the exported files immediately.
4. Tap to return to the *Settings* window.

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4 Starting a new scan

Before starting a new scan, you must:

- Check whether there are any particles on the wand. If so, use a CaviWipe1 to remove them.
- Ensure that the vent cover is securely attached and does not move. If the vent cover does not fit securely or is damaged, replace it as described in section 10.2.5.1.
- Apply a new wand barrier sleeve, as described below.

4.1 Applying a wand barrier sleeve

To apply a wand barrier sleeve:

1. Place a new wand barrier sleeve in its original packaging near the iTero Element 5D wand.

   Note: Inspect the packaging to verify that there is no visible damage. Replace it if any damage is observed.

2. Gently remove the protective sleeve from the wand.

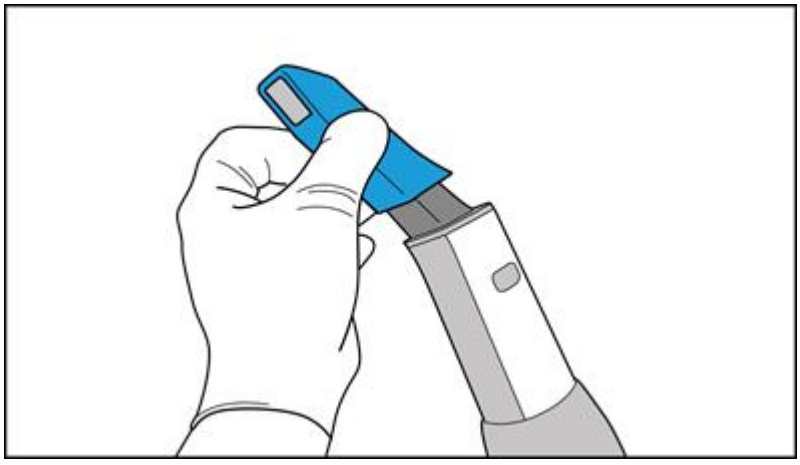

Figure 55: Remove the protective sleeve

3. Wearing gloves, remove the wand barrier sleeve from its packaging, making sure to keep the transparent sheath folded.

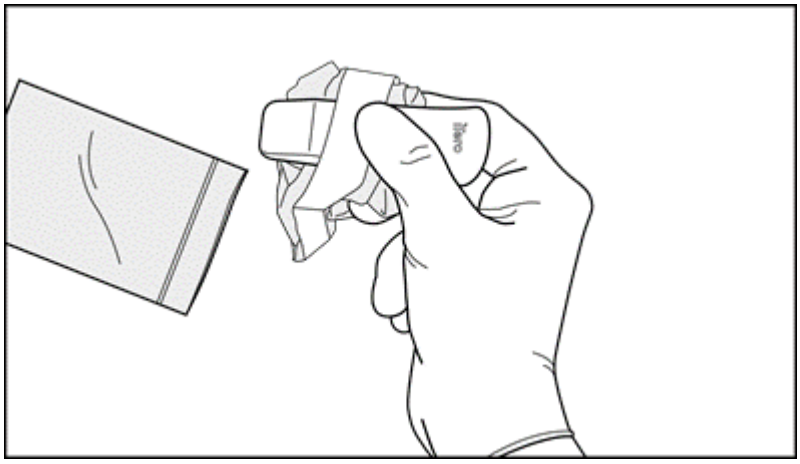

Figure 56: Remove the wand barrier sleeve from its packaging

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4. Slide the rigid section of the wand barrier sleeve onto the optical tip of the wand until you feel a “click”, making sure that the transparent sheath is not pinched between the rigid section of the wand barrier sleeve and the wand.

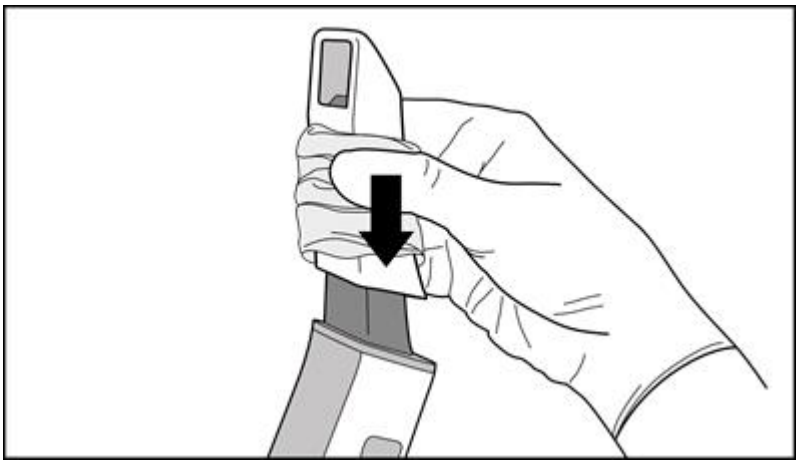

Figure 57: Slide the rigid section of the wand barrier sleeve into place

5. Gently pull the transparent sheath to cover the entire wand.

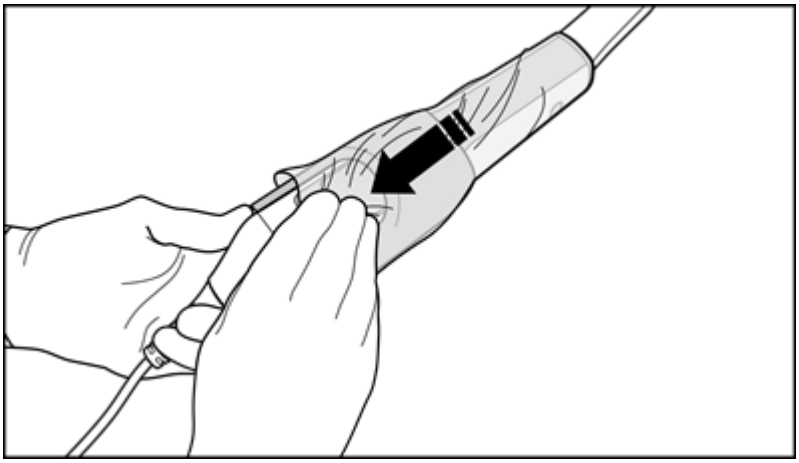

Figure 58: Gently pull the transparent sheath to cover the entire wand

Note: The white tape on the transparent sheath is for manufacturing purposes only, and should be ignored.

6. Visually inspect the wand barrier sleeve for any noticeable damage, for example, cracks, scratches, and holes.

   Replace the wand barrier sleeve in case of noticeable damage.

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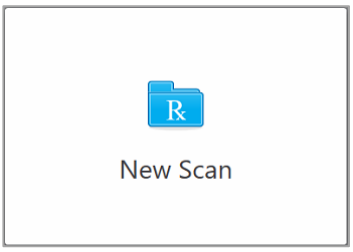
4.2 Starting the scan

Tap the **New Scan** button to start the scanning process.



The *New Scan* window is displayed, as well as a toolbar that shows your progress throughout the scanning process.

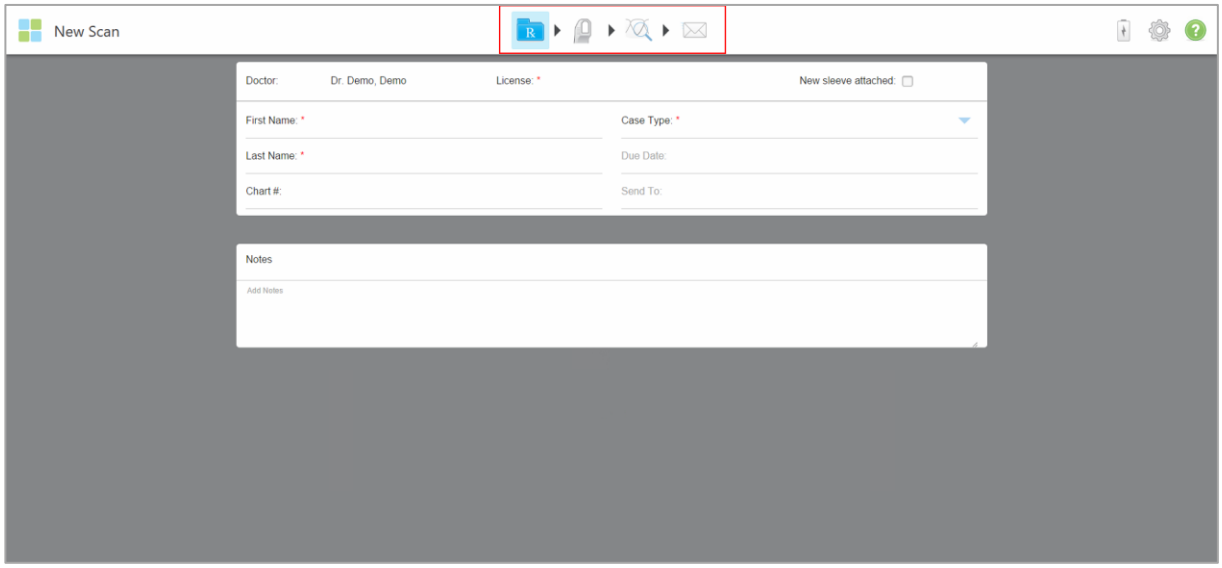


Figure 59: New Scan window showing an empty Rx and the progress toolbar at the top of the window

The scanning process requires the following steps, which are displayed on the toolbar:

Filling in the Rx, described in section 4.3

Scanning the patient, described in section 4.4

Viewing the scan, described in section 4.5

Sending the scan to the lab, described in section 4.5.7

Your current progress is highlighted on the toolbar.

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4.3 Filling in the Rx

The first step in the scanning process is filling in the Rx (prescription). The *New Scan* window enables you to enter the patient's details as well as details about the case type. Fields marked with a red asterisk are mandatory.

After you have filled in the Rx, you can tap to move to Scan mode and scan the patient, as described in section 4.4.

To fill in the Rx:

1. Enter the patient's first name and last name in the fields provided.
2. From the **Case Type** drop-down list, select the required case type.

   Note: The list of case types displayed depends on your subscription package.

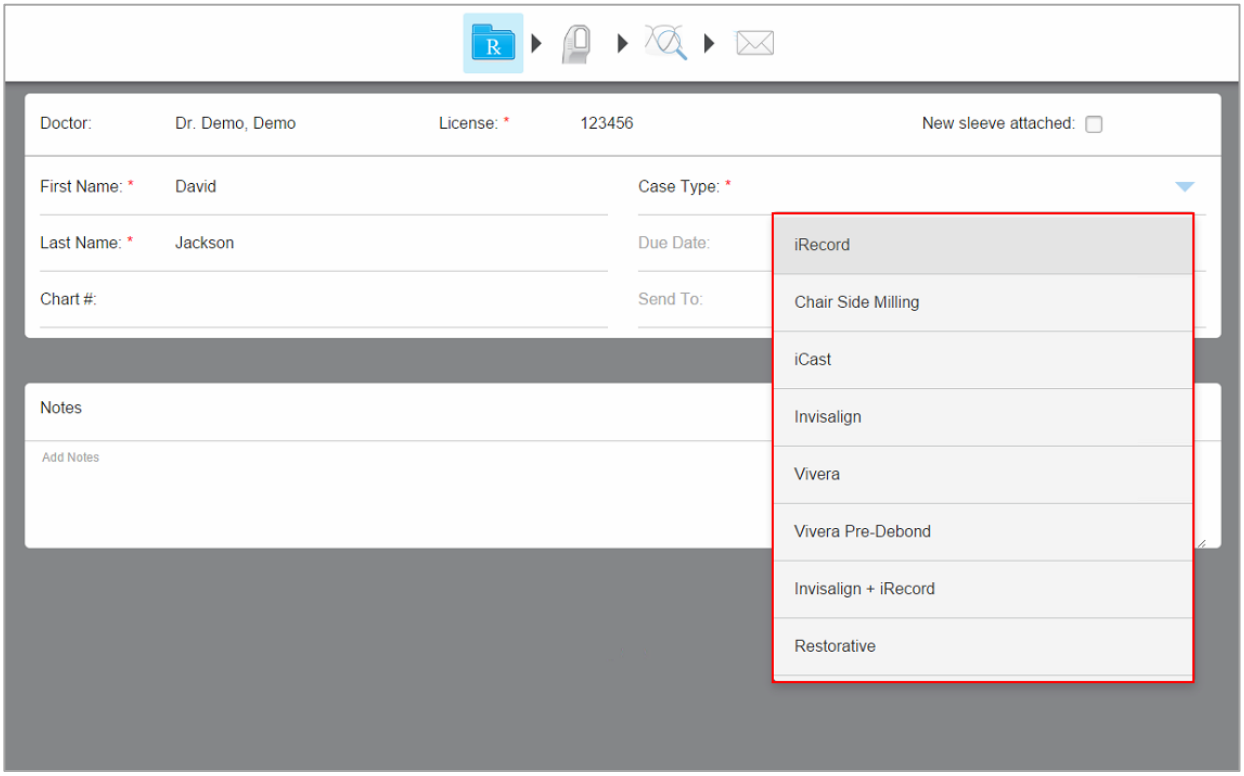

Figure 60: Selecting the required case type

The following case types are available by default, depending on whether you have a Restorative or Orthodontic subscription package:

- **iRecord:** A simple scan with no additional modification, mainly used for referencing and instead of storing the plaster model, as required by law. (This case type can later be changed to iCast or Invisalign, if required.)
- **Chair Side Milling:** A restorative scan without the need to send the scan to a laboratory for modeling and milling.
- **iCast:** The same as iRecord, but showing the ABO model and a modeling step that can remove unused data and adjust the bite if needed. (This case type can later be changed to Invisalign, if required.)
- **Invisalign:** The basic scan for Invisalign treatment. The model must be scanned without any holes to ensure that the aligners are a perfect fit with the patient's teeth.

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- **Vivera:** A simple scan with no additional modification, for the creation of a clear retainer that is similar to a single Invisalign aligner, which maintains the position of the teeth after treatment.
- **Vivera Pre-Debond:** A scan used on patients while their brackets are still attached. The Vivera retainers are then provided at the debonding appointment.
- **Invisalign + iRecord:** Records the file (iRecord) and uploads an Invisalign scan to the IDS portal. Saves two different scans, as may be requested for insurance-refund purposes.
- **Restorative:** A scan that you need to send to a laboratory for modeling or milling.
  - Expanded – 6 teeth are scanned
  - Quadrant – 4-6 teeth are scanned for a single crown
  - Full arch – all the teeth are scanned
  - Reference – no prepped tooth or restoration was selected

The *New Scan* window is displayed, according to the case type selected.

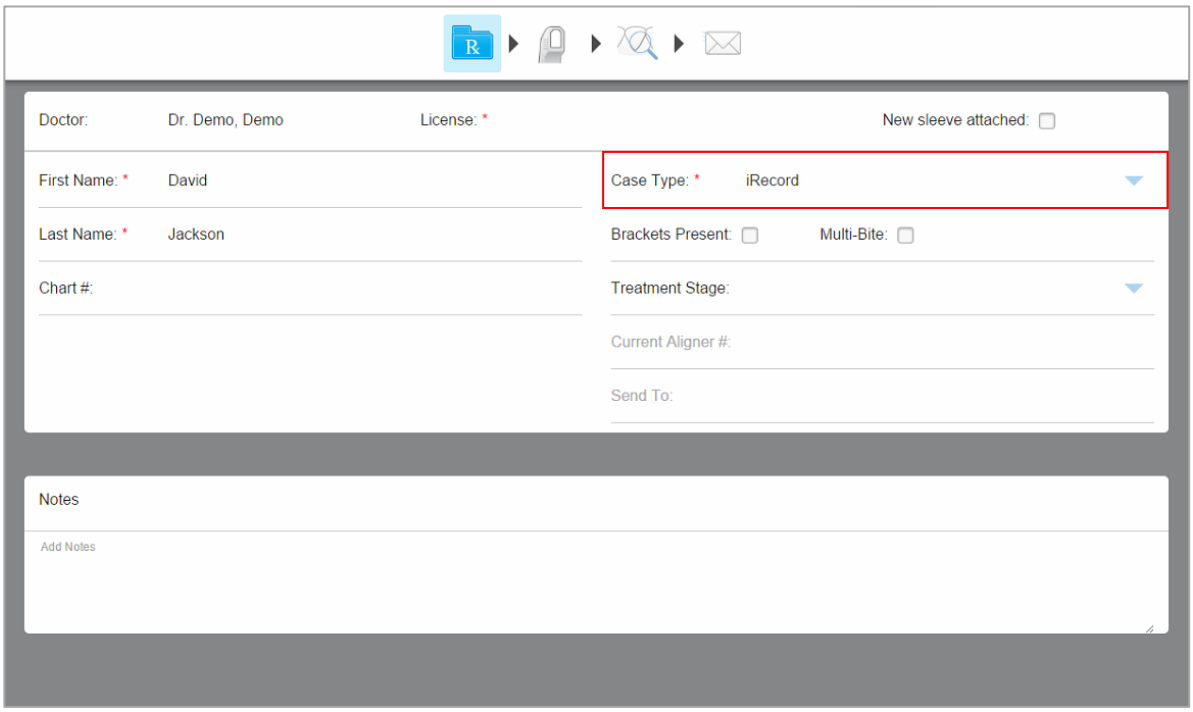

Figure 61: New Scan window – iRecord case type

3. Depending on the case type selected, fill in the relevant details.
   - **Restorative** and **Chair Side Milling** case types, see section 4.3.1.
   - **iCast**: Select the **Brackets Present** check box if there are brackets on the patient's teeth.
   - **iRecord:**
     - Select the **Brackets Present** check box if there are brackets on the patient's teeth.
     - Select the **Multi-Bite** check box if a multi-bite scan is required. This will enable you to preserve the 2-bite relation based on your needs, and will deliver precise bite information to the lab for appliance fabrication, for example, sleep apnea appliances.

     If your subscription package includes the **Final Records** option, you will be able to select the treatment stage. For more information, refer to the Invisalign documentation.

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4. If relevant, from the **Send To** drop-down list, select the lab to which the scan should be sent.
5. Select the **New sleeve attached** check box to confirm that a new wand barrier sleeve has been attached to the wand. For more information, see section 4.3.2.

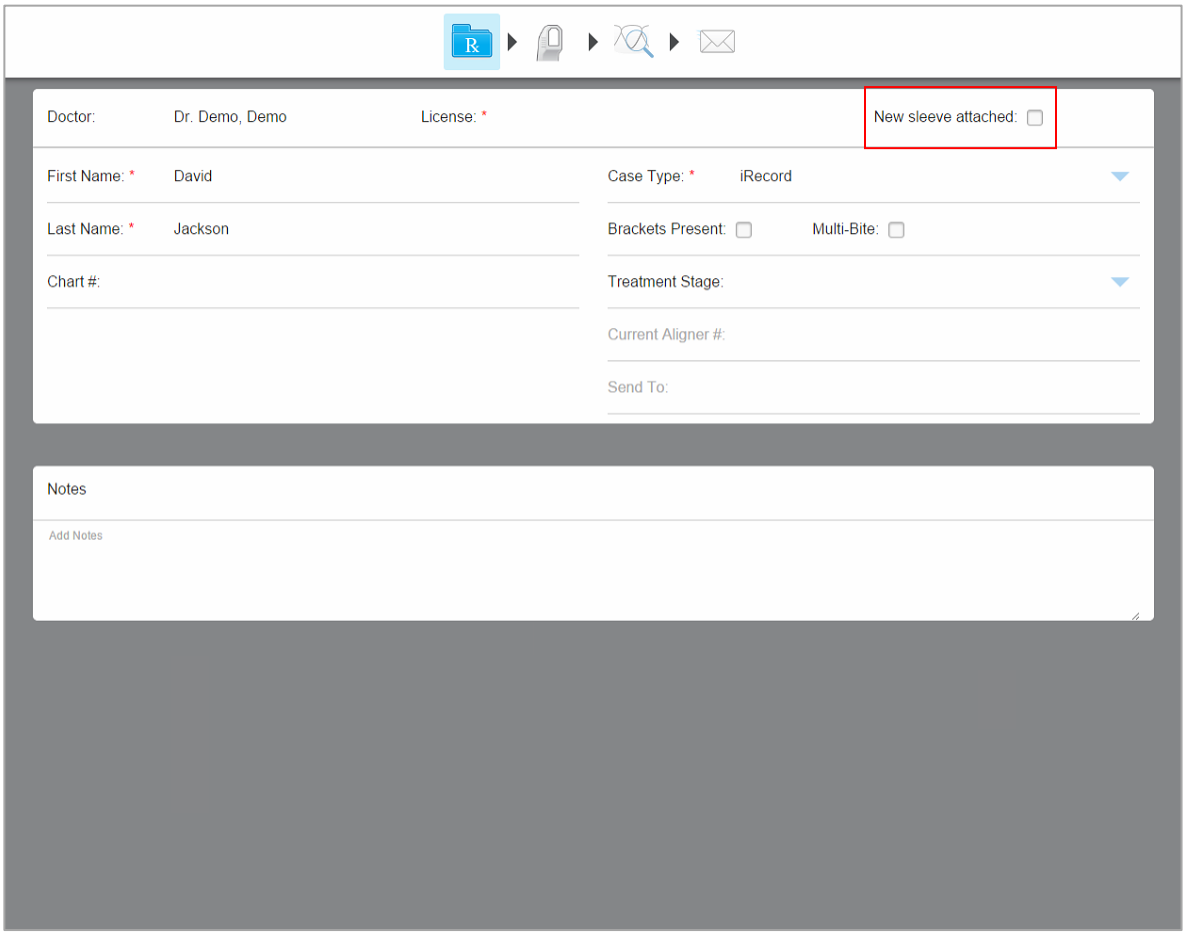

Figure 62: New sleeve attached check box

6. Tap on the toolbar to move to Scan mode, as described in section 4.4.

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4.3.1 Working with Restorative scan types

When selecting restorative case types, you need to select the tooth that needs to be restored, the type of restoration required, as well as the material, shade, etc. of the restoration.

To scan a restorative or chairside milling case.

1. From the **Case Type** drop-down list, select **Restorative**.

   A tooth chart is displayed in the window.

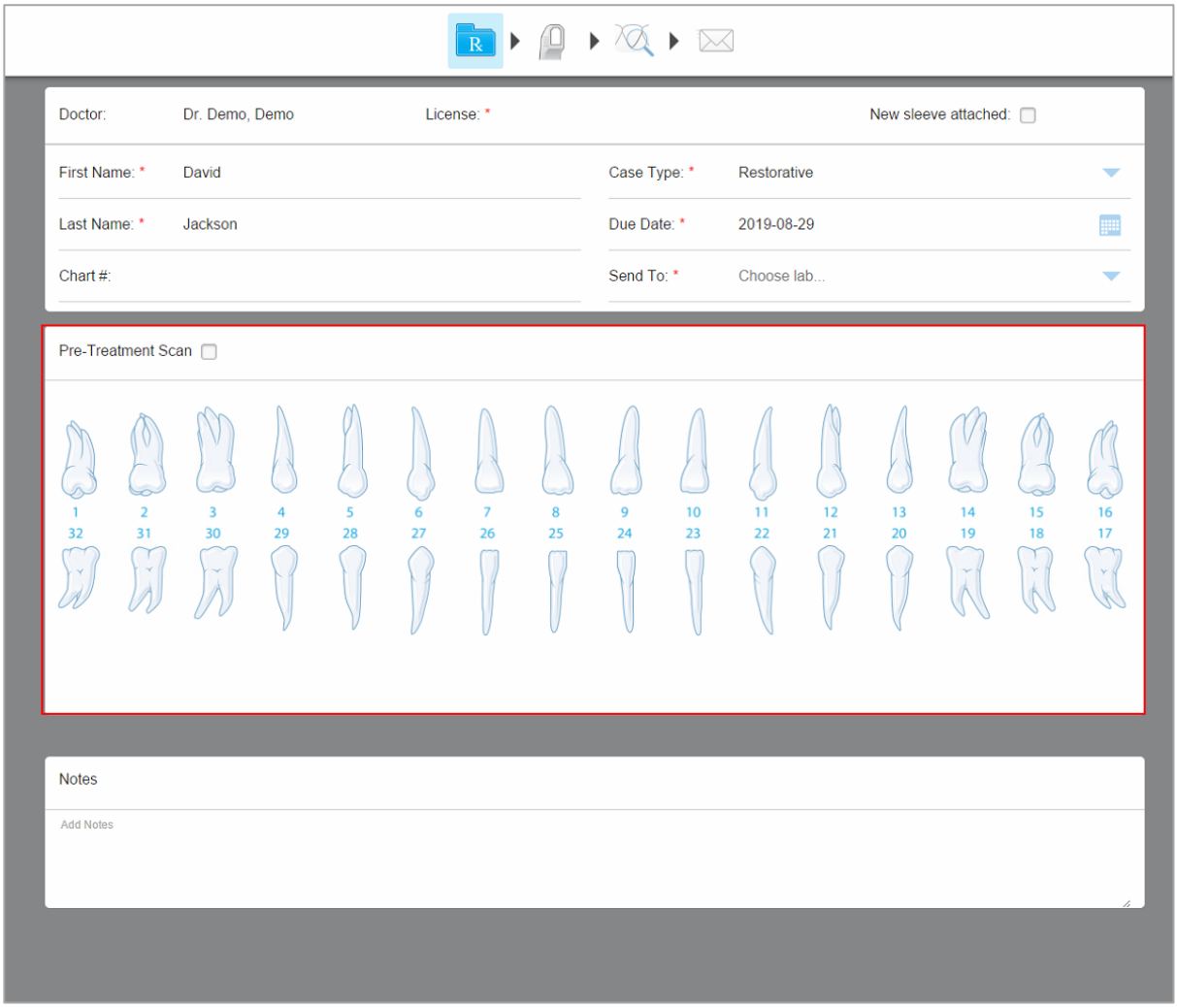

Figure 63: New Scan window – Restorative case type with a tooth chart

2. Select the **Pre-Treatment Scan** check box if you would like to scan the patient before prepping the relevant tooth. In this case, the patient must be scanned twice – before and after the tooth has been prepped.

   The pre-treatment scan enables the lab to copy the original anatomy to the new restoration.

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3. In the tooth chart, tap on the tooth to be restored.

   A list of available treatment options for the selected tooth is displayed.

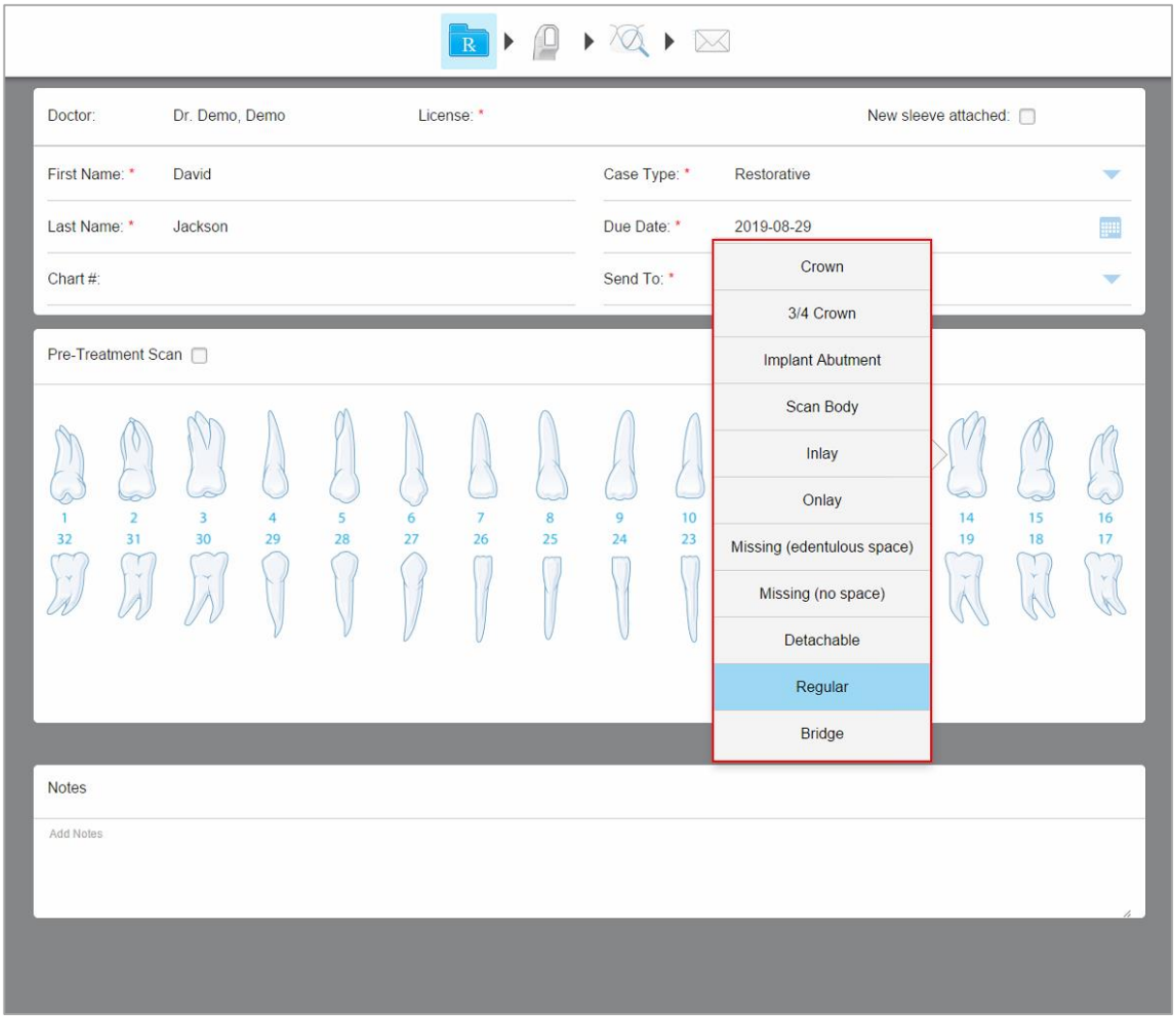

Figure 64: List of restorative treatment options

The list of treatment options is the same for all teeth, except for the following:

- **Inlay** and **Onlay**: Relevant only for the molars and premolars
- **Veneer**: Relevant only for the incisors and the premolars

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4. Select the required treatment option, for example, Crown.

   You will be prompted to select the relevant treatment options for your selected dental order.

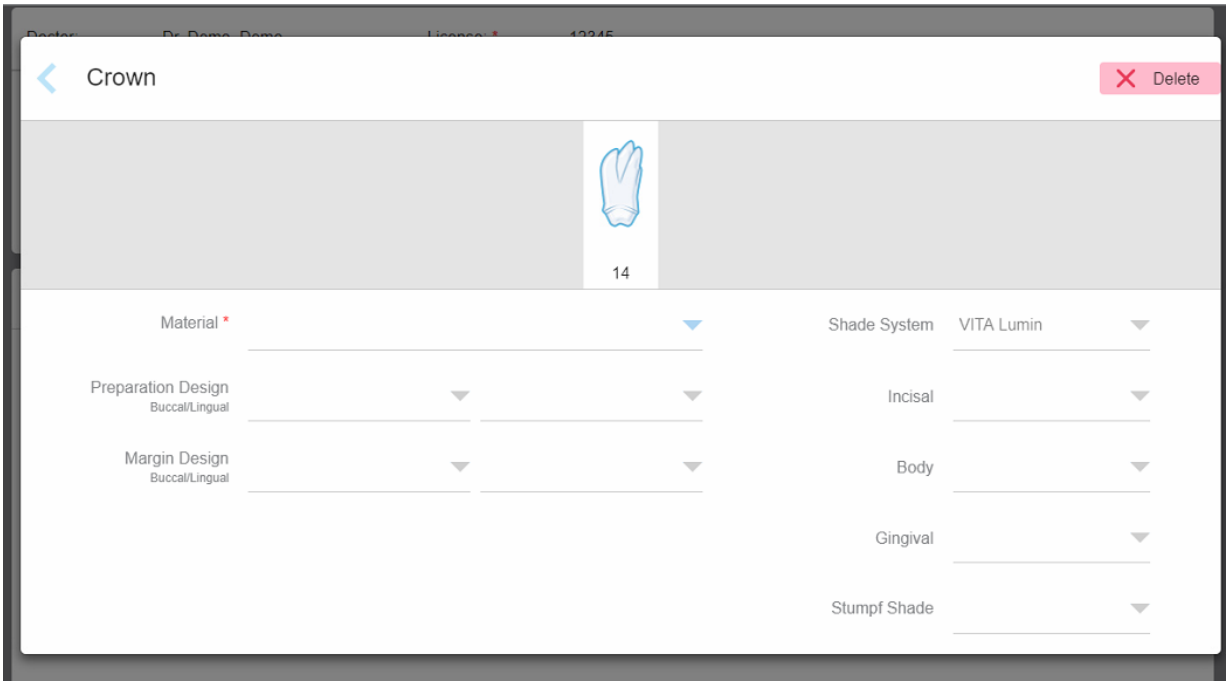

Figure 65: Defining the restoration properties

5. Select the following settings from the relevant drop-down lists. Settings marked with an asterisk are mandatory. Initially, only the material selection is mandatory, but once the material has been selected, other settings become mandatory depending on the material selected. In addition, the options in each setting change according to the material selected.
   - **Material:** The material from which the dental order will be fabricated.
   - **Preparation Design:** The shape of the finishing line (margin line) created by the user during the preparation. You must choose this for both the buccal and the lingual.
   - **Margin Design:** The type of ceramic-metal border relationship required for the selected metal-based crown. You must choose this for both the buccal and the lingual. This is relevant only for metal dental work.
   - **Shade System:** The system used for choosing the shade of the crown.
     - **Incisal:** The shade for the incisal area of the crown.
     - **Body:** The shade for the body area of the crown.
     - **Gingival:** The shade for the gingival area of the crown.
   - **Stumpf Shade:** The shade of the prepped tooth.

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6. Tap to save your selection and return to the *New Scan* window.

   Your preferences are displayed in the **Treatment Information** area.

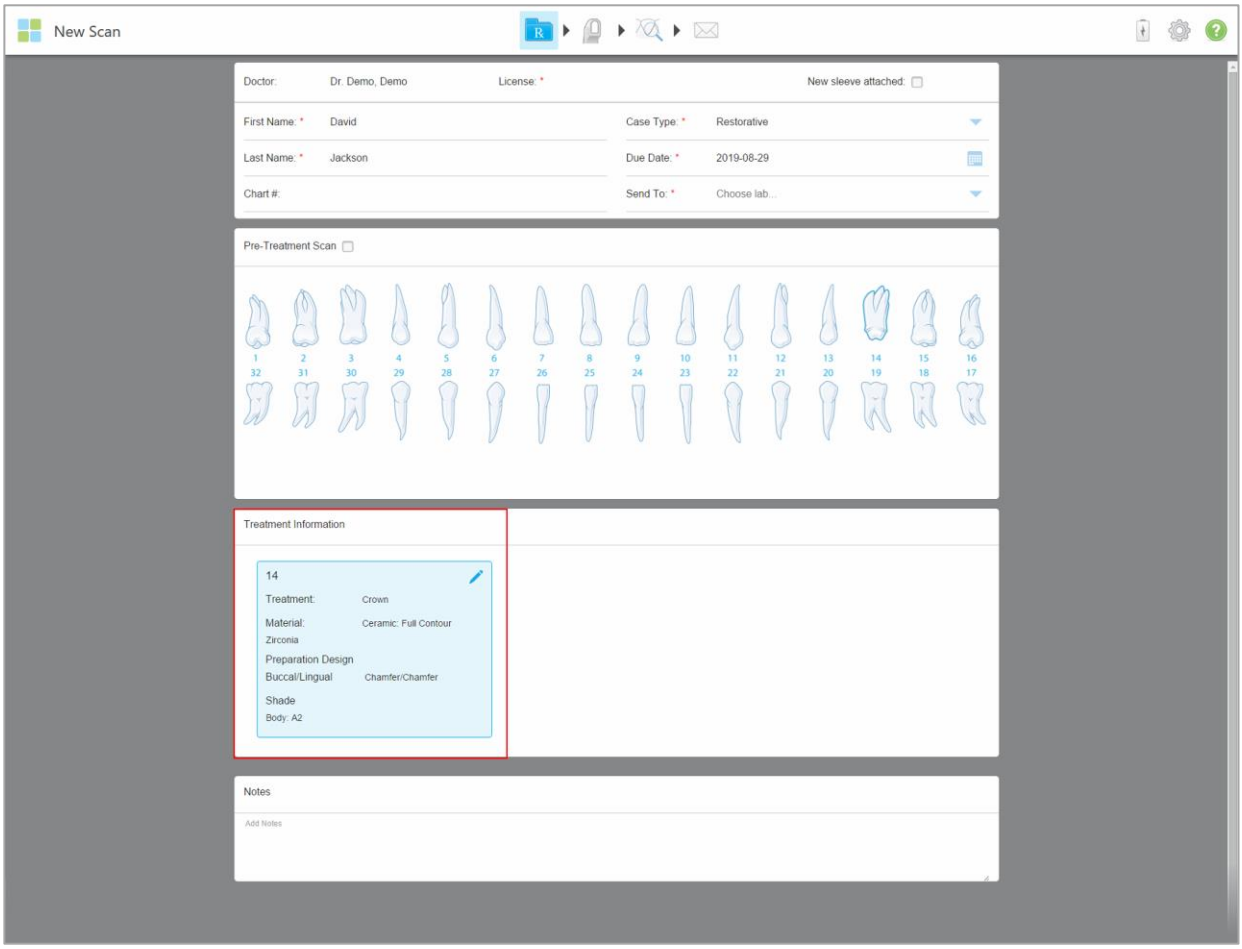

Figure 66: Treatment Information area

You can edit your preferences at any time before sending the scan by tapping .

4.3.2 Confirming a new wand barrier sleeve between patients

In order to prevent cross-contamination, you must confirm that a new wand barrier sleeve is used for each patient. See the scanning best practices, described in section 4.4.2 for more details.

You can confirm the new wand barrier sleeve using one of the following options:

- Selecting the **New sleeve attached** check box when filling in a new Rx, as described in section 4.3.2.1. This method is minimally intrusive and will not alarm the patient.
- Pressing either of the wand buttons or tapping **OK** when prompted, when trying to access Scan mode , as described in section 4.3.2.2.

Failure to confirm a new wand barrier sleeve will block you from starting a new scan.

Both methods of barrier sleeve confirmation are documented in the log file, which contains the name of the user who confirmed the new wand barrier sleeve, as well as the timestamp.

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4.3.2.1 Confirming the new wand barrier sleeve when filling in the Rx

In the *New Scan* window, select the **New sleeve attached** check box to confirm that a new wand barrier sleeve is attached to the wand.

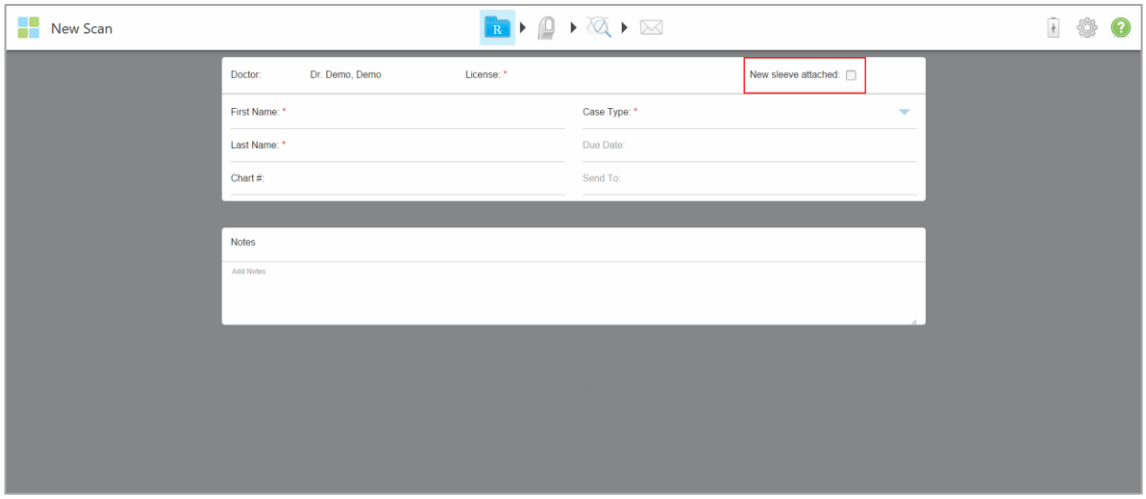

Figure 67: Check box confirming a new wand barrier sleeve

- If the check box is selected, you will not see any further messages and will be able to scan upon entry to Scan mode.
- If the check box is not selected, you will be blocked from accessing Scan mode and will have to confirm the new wand barrier sleeve, as described in the following section.

4.3.2.2 Confirming the new wand barrier sleeve when accessing Scan mode

If you did not select the **New sleeve attached** check box when filling in the new Rx, the following popup message is displayed when tapping the Scan tool .

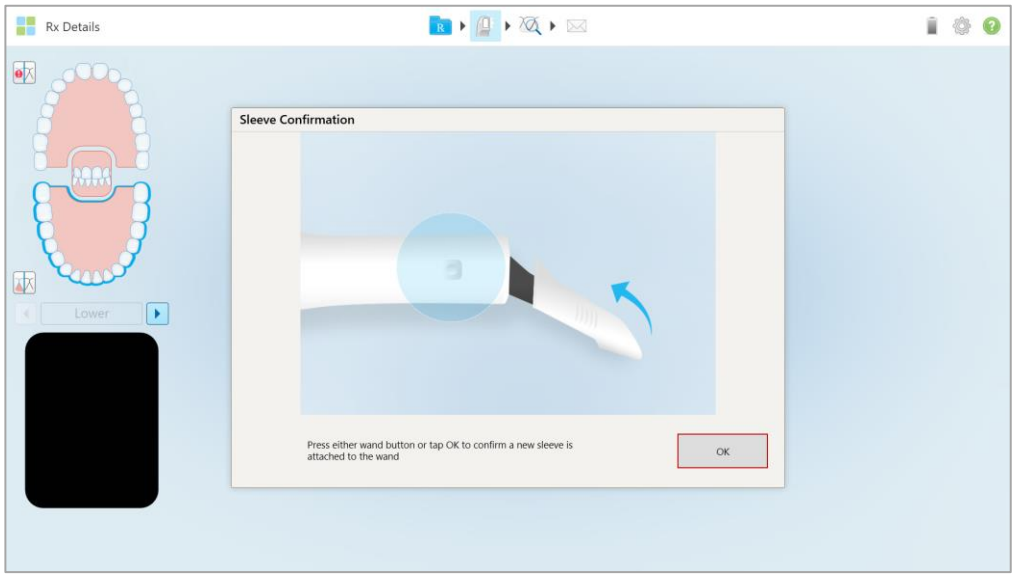

Figure 68: Popup confirmation message before scanning

You will be blocked from scanning until you tap **OK** on the screen or press either of the wand buttons.

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4.4 Scanning the patient

After you have filled in the Rx, tap on the toolbar to enter Scan mode. The *Scan* window is displayed, enabling you to start scanning the patient.

The iTero Element 5D scanner provides simultaneous capture and display of NIRI, 2D color images, and 3D intraoral optical impression data.

While scanning, you can perform the following actions:

- View additional scan feedback, described in section 4.4.3.1
- Toggle between color and monochrome mode, described in section 4.4.3.2
- Toggle the 3D and viewfinder display, described in section 4.4.4, below
- Toggle between color mode and NIRI mode, described in section 4.4.5

After scanning, you can edit the scan by:

- Deleting a segment, as described in section 4.4.6.1
- Deleting a selected area, as described in section 4.4.6.2
- Capturing areas with missing anatomy, as described in section 4.4.6.3

When you have finished scanning the patient, tap on the toolbar to move to **View** mode, where you can ensure that your scan is complete before sending it to the lab or storage, as described in section 4.5.

4.4.1 Scanning guidance

As soon as you move to Scan mode, the recommended scanning sequence for the selected scan segment is displayed in the center of the scanner window. It will automatically disappear after a short while, or you can tap anywhere on the screen to hide it.

iTero recommends you follow the scanning sequence for best results.

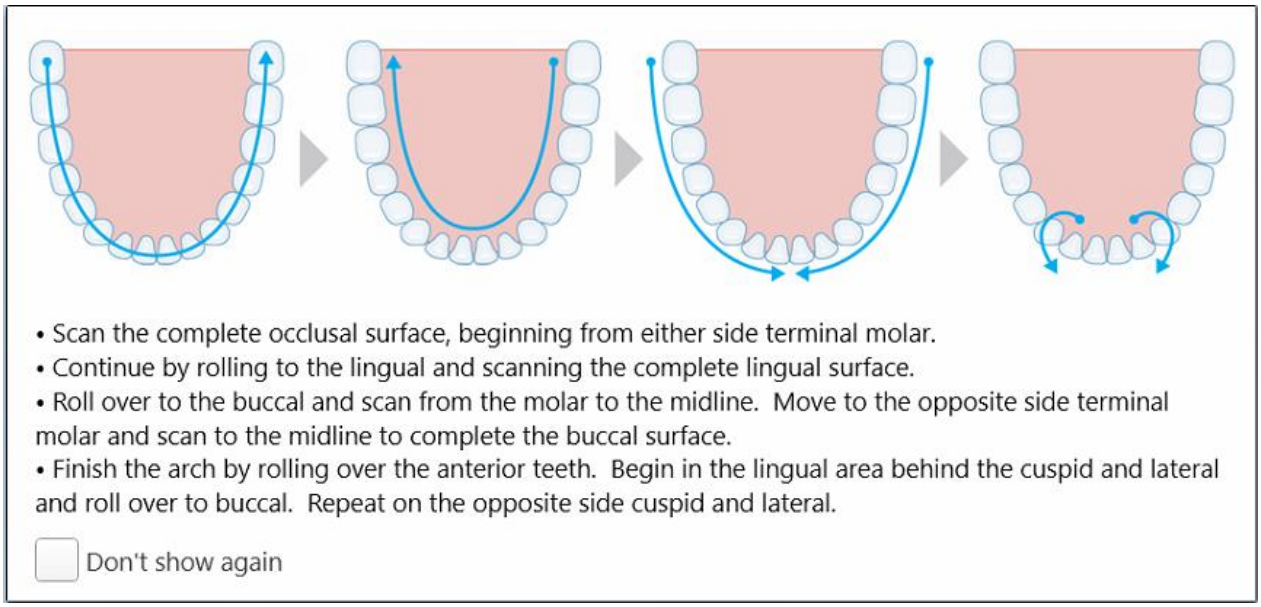

Figure 69: Recommended scanning sequence – lower jaw

Note: If you select the **Don't show again** check box, this guidance will not be displayed in future scans. You can return the guidance by enabling it in the **Scan** settings, as described in section 3.6.2.1.

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In addition, if you press both wand buttons simultaneously, the following guidance is displayed:

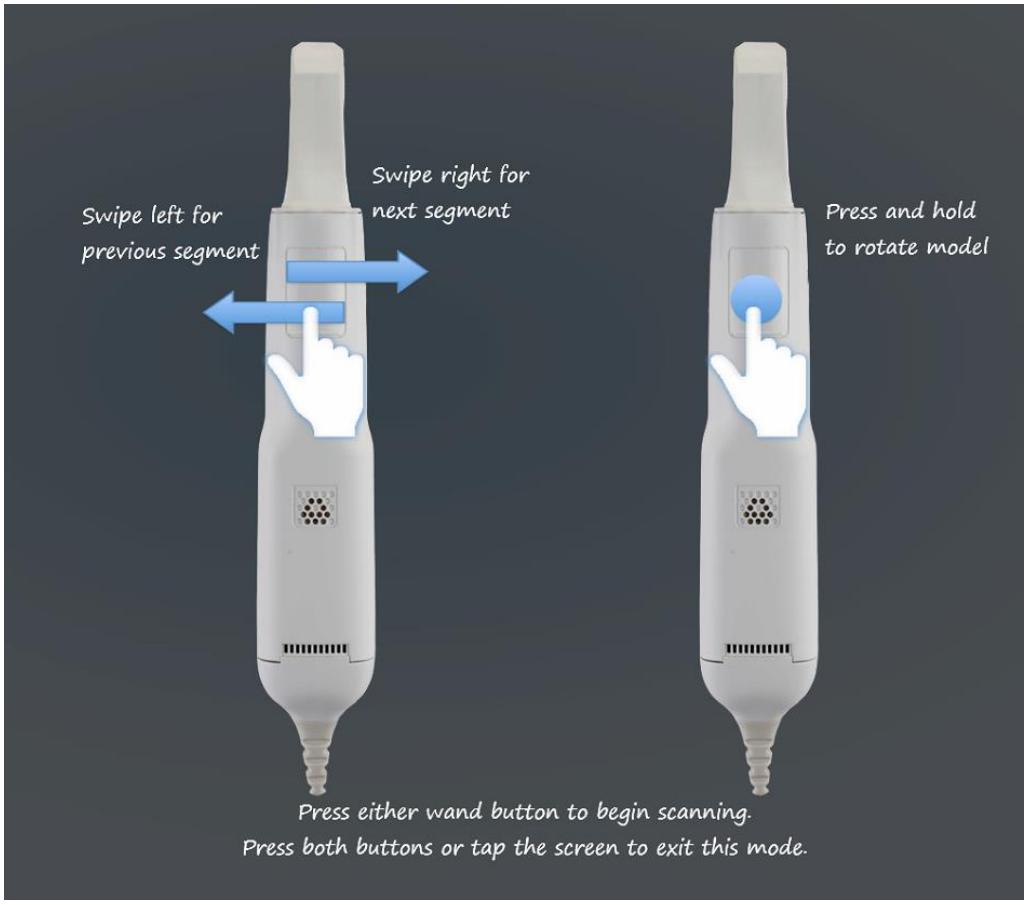

Figure 70: Wand guidance

To allow optimal capturing of the NIR images, the wand should be held 0-3 mm above the patient's teeth.

For a detailed description of how to scan restorative cases, refer to the *iTero Element Restorative eGuidebook*
http://storagy-itero-production-eu.s3.amazonaws.com/download/en/iTero-Element-Restorative-Guidebook.pdf.

For a detailed description on how to scan orthodontic cases, refer to the *iTero Element Orthodontic eGuidebook*
http://storagy-itero-production-eu.s3.amazonaws.com/download/en/iTero-Element-Ortho-Guidebook.pdf.

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4.4.2 Scanning best practices

iTero recommends the following best practices for use of the scanner and accessories:

- Ensure that the wand barrier sleeves remain in the labeled box until the point of use.
- Inspection of the wand barrier sleeve should take place before the application of the barrier sleeve on the wand and after the scan.
- **CAUTION:** If the patient bites down on the wand barrier sleeve, stop the procedure and inspect the wand barrier sleeve for visible damage.
    - If damage is observed, remove the wand barrier sleeve and visually inspect the optical tip of the wand.
        - If cracks are observed on either the optical surface or the tip of the wand, do not use the wand and contact iTero Support.
    - If no damage to the wand is observed, replace the wand barrier sleeve and continue the scan.

iTero recommends the following best practices for scanning restorative cases:

- Ensure that the prepped tooth and the surrounding area is free of debris, saliva, and blood contamination.
- The prepped tooth should be dry and the margin line should be clear of tissue.
- You should be familiar with proper scanning techniques and avoid over scanning.

4.4.3 Scan options

In Scan mode, you can select the following options:

- Additional scan feedback, described in section 4.4.3.1
- Toggle color/monochrome, described in section 4.4.3.2
- Toggle between the 3D and the viewfinder display, described in section 4.4.4
- Toggle between color mode and NIRI mode in the viewfinder, as described in section 4.4.5
- Edit the scan:
    - Delete a segment, described in section 4.4.6.1
    - Delete a selection, described in section 4.4.6.2
    - Fill in missing anatomy, described in section 4.4.6.3

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4.4.3.1 Additional scan feedback

You can activate the additional scan feedback mode to alert you to the areas that need additional scanning, to ensure that critical areas that could compromise the whole model are not missed.

Areas with missing anatomy are highlighted in red when scanning in monochromatic mode, and purple when scanning in color mode.

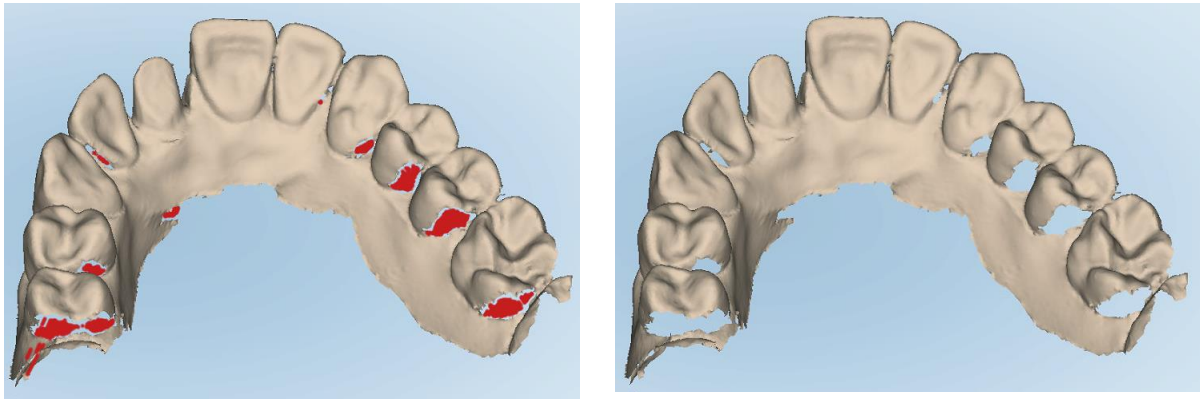

Figure 71: Areas with missing anatomy shown with and without additional scan feedback – monochrome

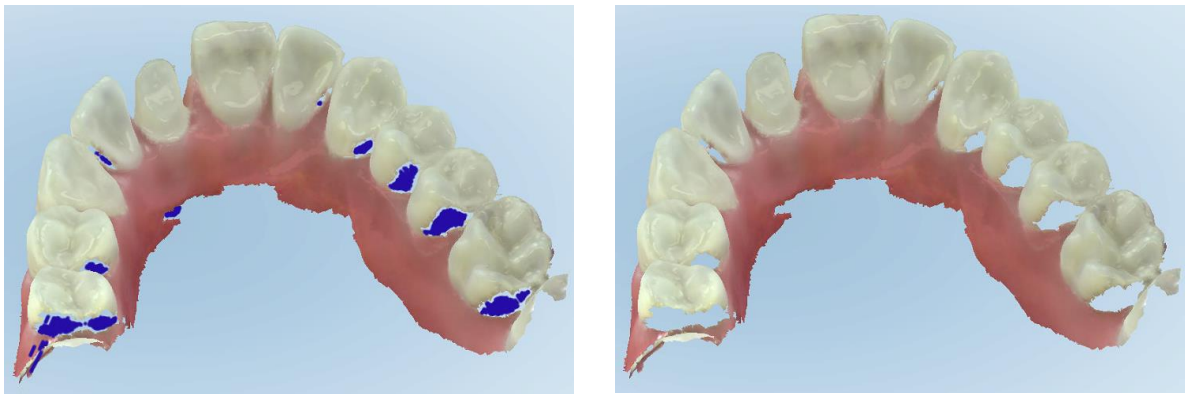

Figure 72: Areas with missing anatomy shown with and without additional scan feedback – color mode

By default, this mode is enabled, but it can be disabled per case by tapping or by default in the Scan settings, as described in section 3.6.2.1.

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4.4.3.2 Scan color toggle

The color toggle button allows you to toggle between color and monochromatic modes. This applies to both scanning and viewing all case types.

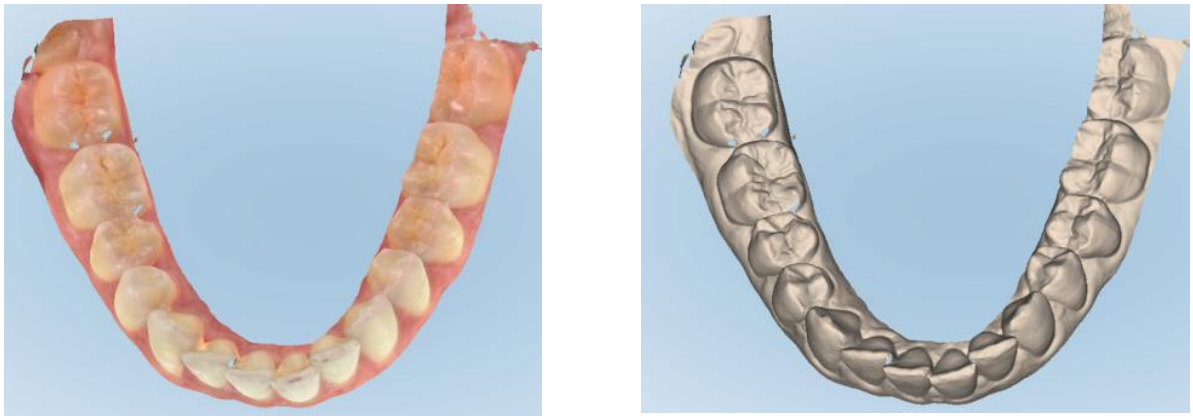

Figure 73: Model displayed in color and monochrome mode

By default, models are scanned in color, but you can toggle the display per case by tapping or by default in the Scan settings, as described in section 3.6.2.1.

4.4.3.3 Switching to the next scan segment

During scanning, the current segment is highlighted in blue in the navigation controls, and also displayed in the segment indicator box, between the arrows.

You can move to the next segment by:

- Tapping on the relevant arch, prepped tooth, or bite segment
- Tapping the arrows

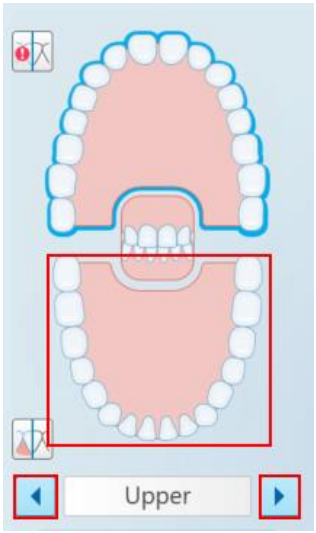

Figure 74: Tap the opposite arch or tap the arrows to select it

- Swipe to the left or the right on the wand touchpad.

  Note: To enable the wand touchpad, press and release both wand buttons simultaneously.

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4.4.4 Toggling the 3D and viewfinder display

By default, when scanning the patient's teeth, a large 3D image of the scan is displayed in the center of the screen and the area currently being scanned is displayed in the viewfinder on the bottom left of the window.

In order to facilitate exploring a specific area of interest, you can switch the display to show an enlarged viewfinder in the center of the window, and a smaller 3D image displayed on the side of the window.

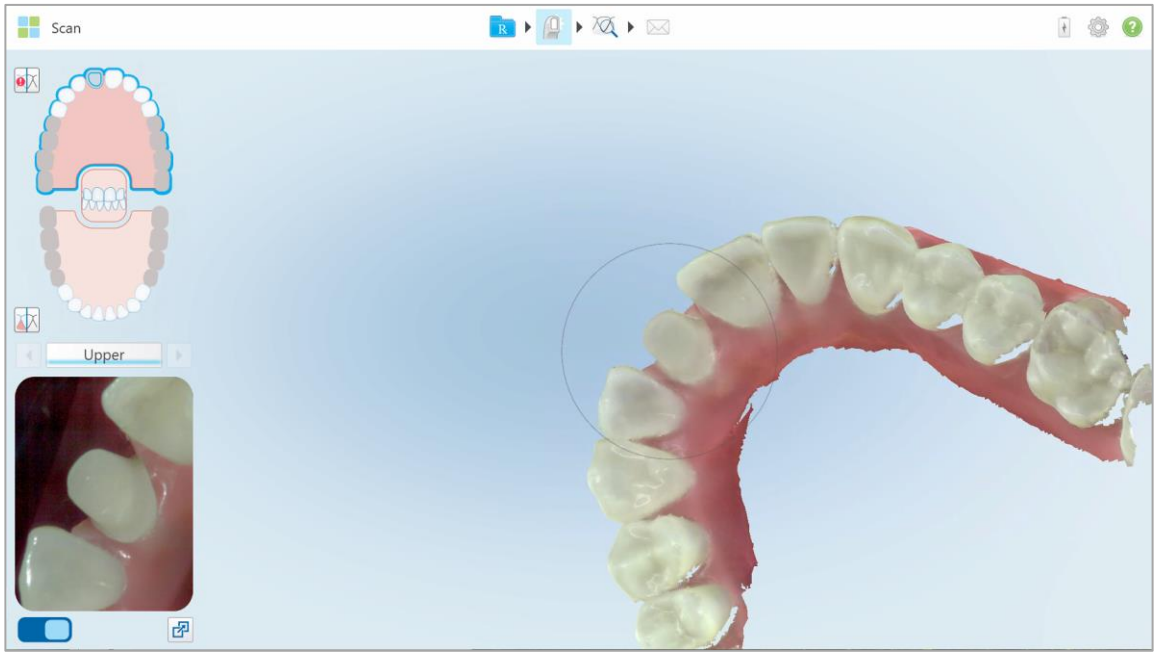

Figure 75: Default view – 3D scan in the center of the window and viewfinder on the left

- To switch to a large viewfinder in the center of the screen, tap the button.

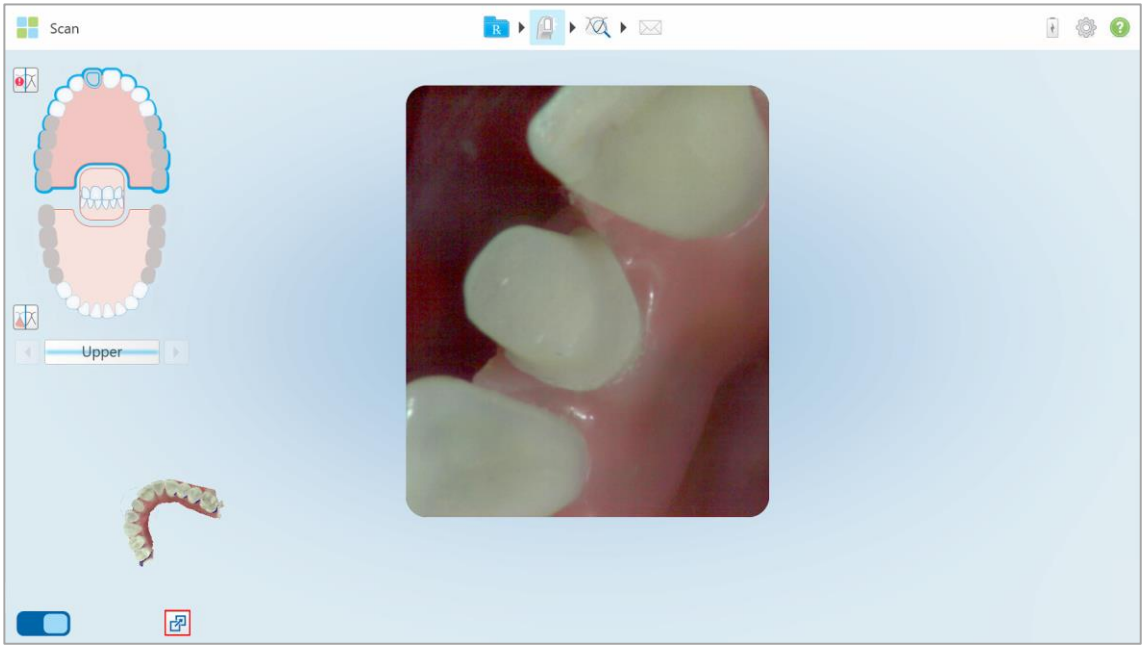

Figure 76: Large viewfinder in the center of the screen and 3D image on the left

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4.4.5 Toggling between color mode and NIRI mode in the viewfinder

In addition to moving the viewfinder, you can toggle the display to show the viewfinder image in color or in NIRI mode.

- Tap to toggle between displaying a color image or a NIRI image in the viewfinder.

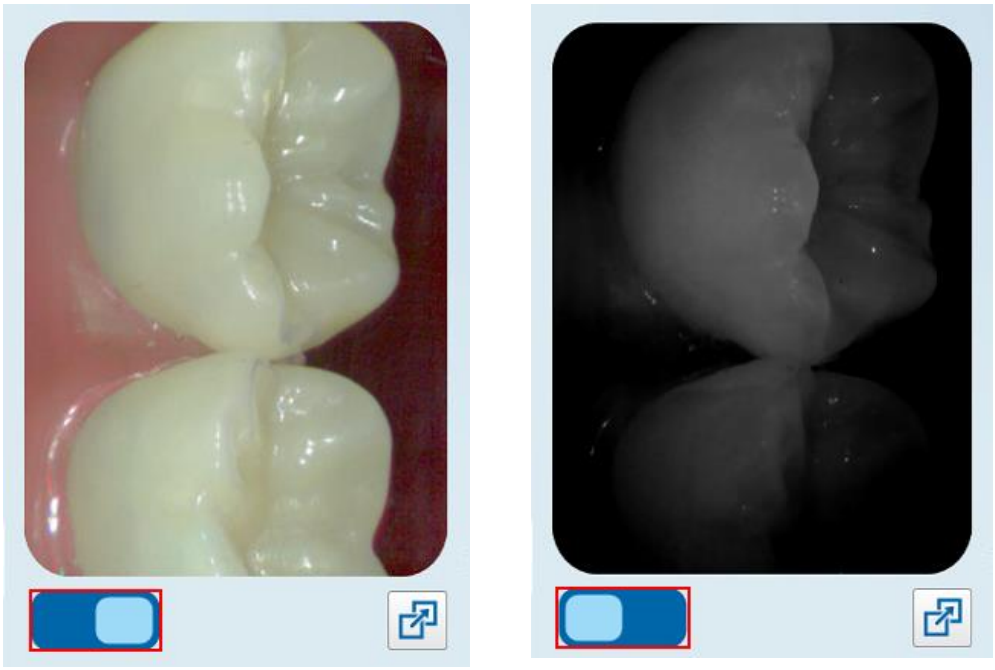

Figure 77: Viewfinder displaying a color image (left) or a NIRI image (right)

4.4.6 Editing a scan

After you have scanned the model, you can edit it using the following tools:

- Delete Segment tool, described in section 4.4.6.1
- Delete Selection tool, described in section 4.4.6.2
- Fill tool, described in section 4.4.6.3

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The editing tools are accessed by pressing on the screen.

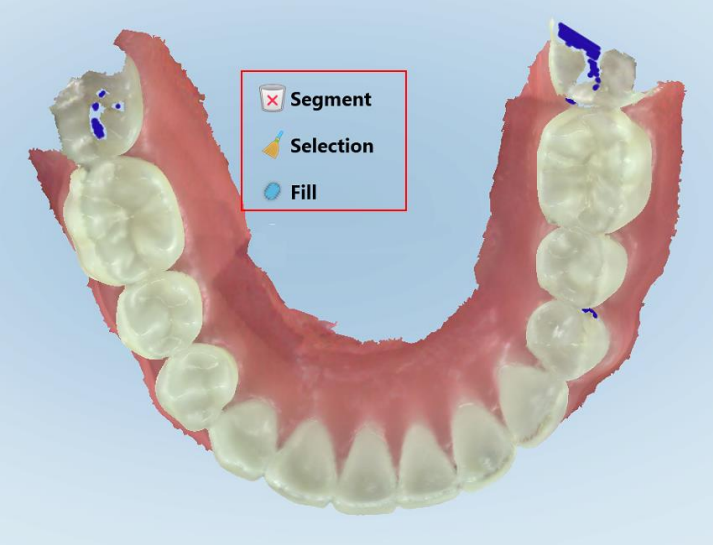

Figure 78: Editing tools

4.4.6.1 Deleting a segment

The Delete Segment tool enables you to delete the entire scanned segment.

To delete the segment:

1. Press the screen to display the editing tools.
2. Tap the Delete Segment tool .

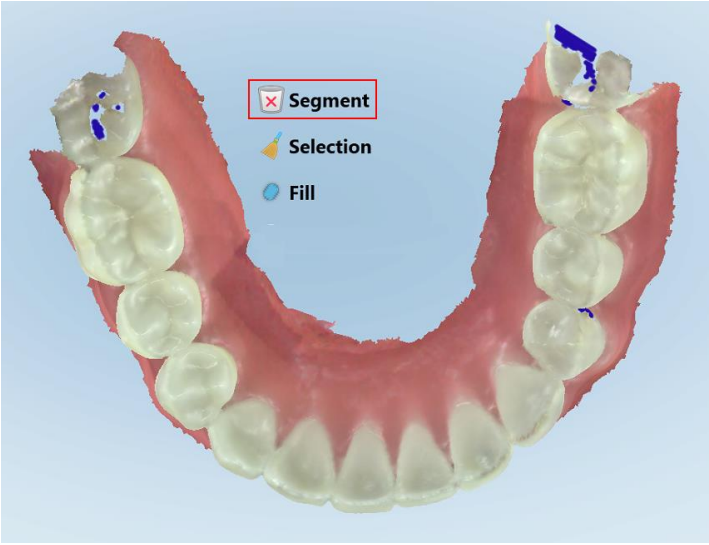

Figure 79: Delete Segment tool

A confirmation message is displayed.

3. Tap **OK** to confirm the deletion.

The entire scanned segment is deleted.

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4.4.6.2 Deleting a selection

The Delete Selection tool enables you to delete a section of the scan so that it can be rescanned.

To delete a selection:

1. Press the screen to display the editing tools.
2. Tap the Delete Selection tool .

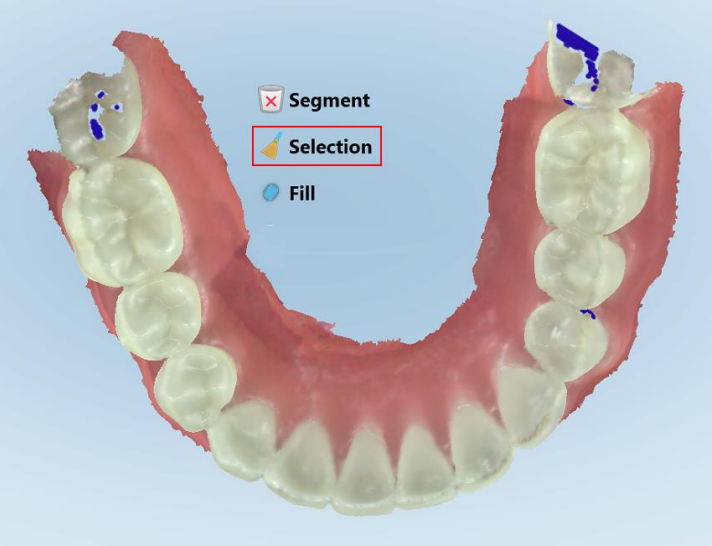

Figure 80: Delete Selection tool

The Delete Selection tool expands and the model is displayed in monochrome:

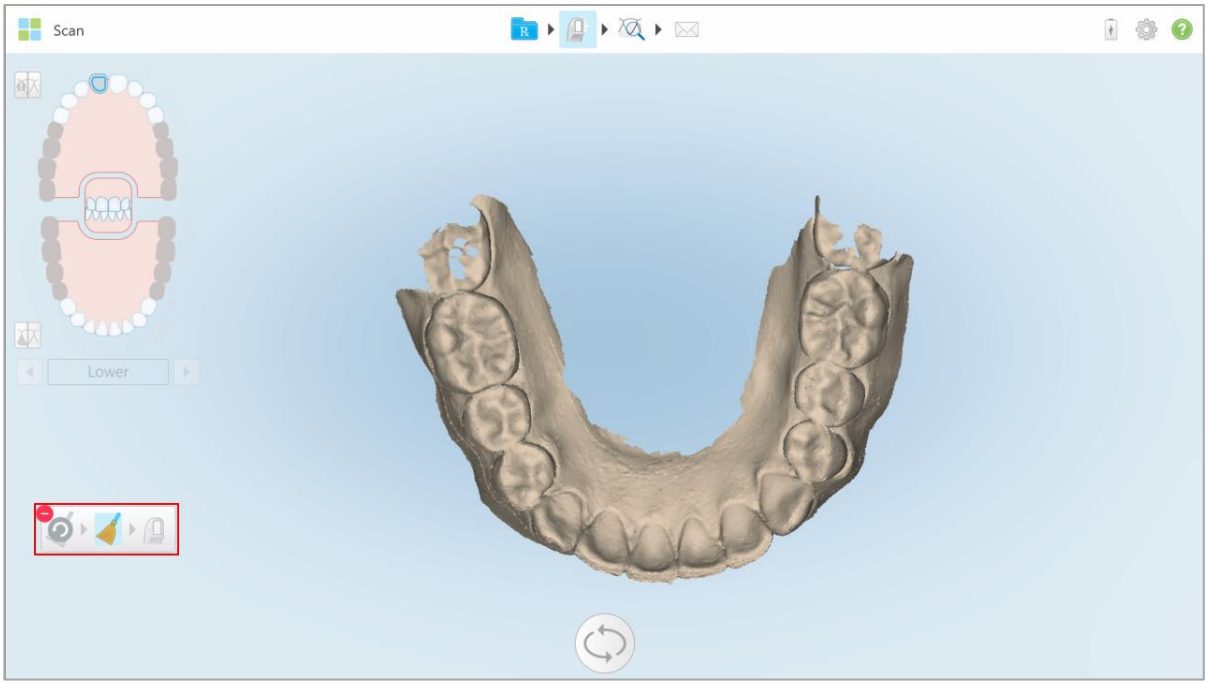

Figure 81: Expanded Delete Selection tool

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3. Touch the area of the anatomy you want to delete.

   The selection is removed.

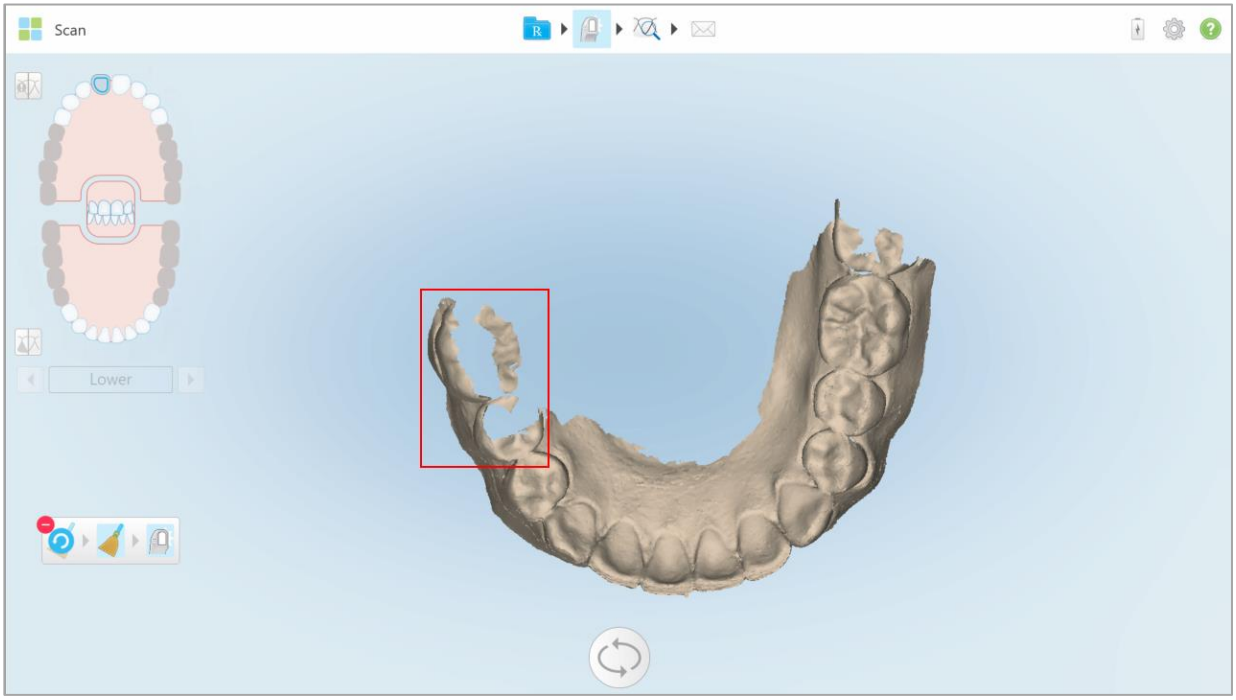

Figure 82: Selected area of the anatomy is deleted

4. If required, tap to undo your changes.
5. Tap to rescan the deleted anatomy.

4.4.6.3 Filling in missing anatomy

Occasionally there are areas with missing anatomy that are not filled even after trying to scan the area numerous times. These areas may be caused by the interference of anatomy (lips, cheeks, and tongue) or moisture in the scanning segment.

The Fill tool highlights these areas and then scans only the highlighted areas, in order to prevent over scanning.

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To use the Fill tool:

1. Press the screen to display the editing tools.
2. Tap the Fill tool .

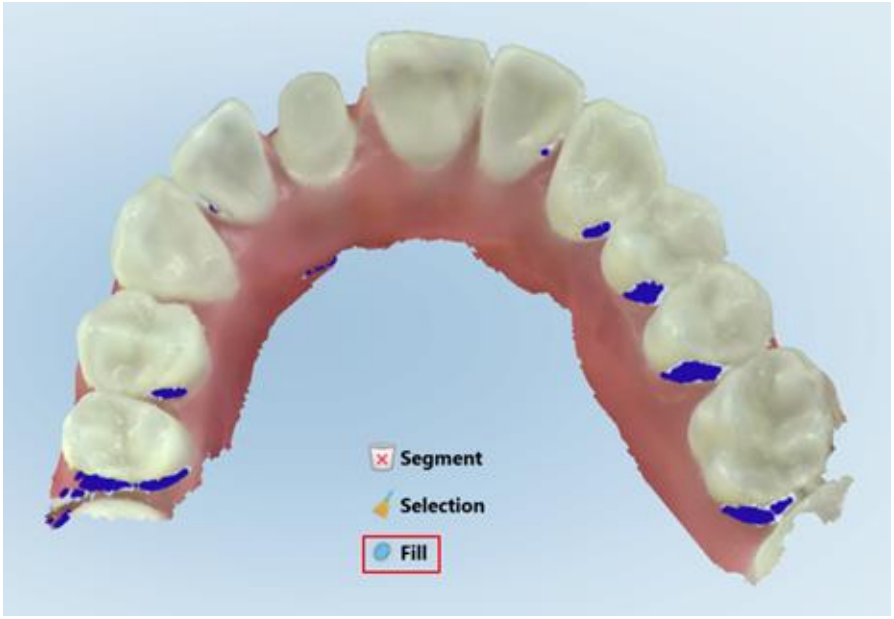

Figure 83: Fill tool

Areas that require scanning are highlighted in red.

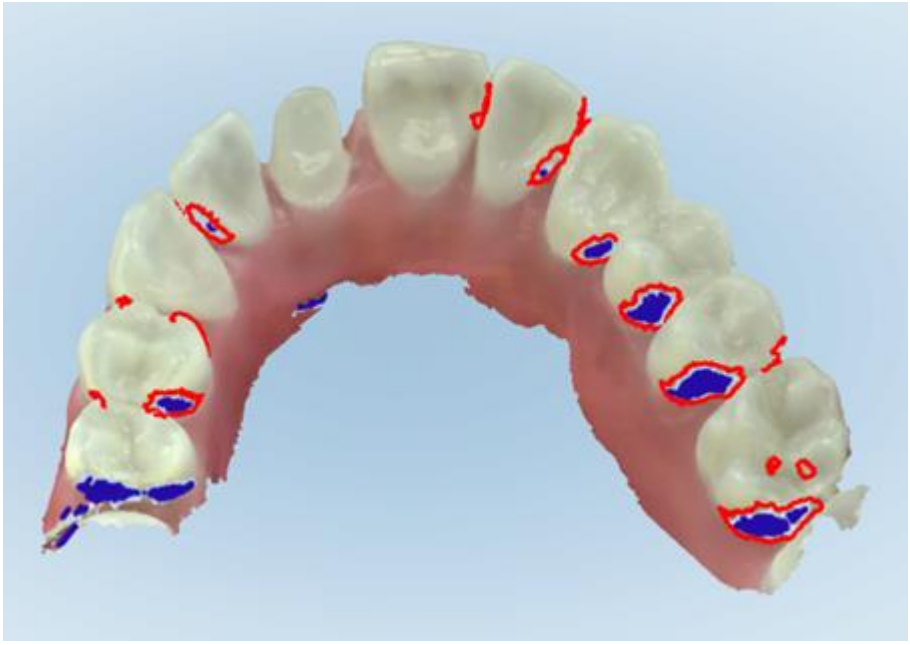

Figure 84: Areas that require scanning are highlighted in red – Fill tool

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4.5 Viewing the scan

After scanning the patient, tap to move to View mode to inspect the model and ensure that sufficient occlusal and buccal anatomy has been captured, and that the model is accurate and complete.

If there are missing scan segments or missing bites, a message will be displayed at the beginning of the post-processing stage notifying you of this and enabling you to go back and fix the scan. For more information, see section 4.5.1.

While viewing the scan, you can:

- Delete selected areas of a scan, as described in section 4.5.2
- Trim excess tissues from the scan, as described in 4.5.4
- Manually create the die separation if the green hint point was not on the center of the prepped tooth during scanning, as described in section 4.5.5
- View an area of interest, as described in section 0

After you have reviewed the scan, tap on the toolbar to send the scan to the lab or to storage, as described in section 4.6.

4.5.1 Missing scan segment notifications

If there are missing scan segments or bite scans when you tap the button, you will be notified at the beginning of the post-processing stage, and you will be able to go back and fix the scan, in order to reduce manual intervention later on.

Notifications will be displayed in the following cases:

- Missing prep or arch – segments were not scanned or not stitched together properly
- Bite issues:
  - Missing bite
  - Bite scanned from one side only
  - Discrepancy between the left and the right bite scans

  In addition, the bite section in the navigation controls will be highlighted in red.

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The message may be generic, or very specific to the issue including guidance on how to correct the issue. In some cases, you will be warned that the case may be returned from the lab if you do not fix the issues.

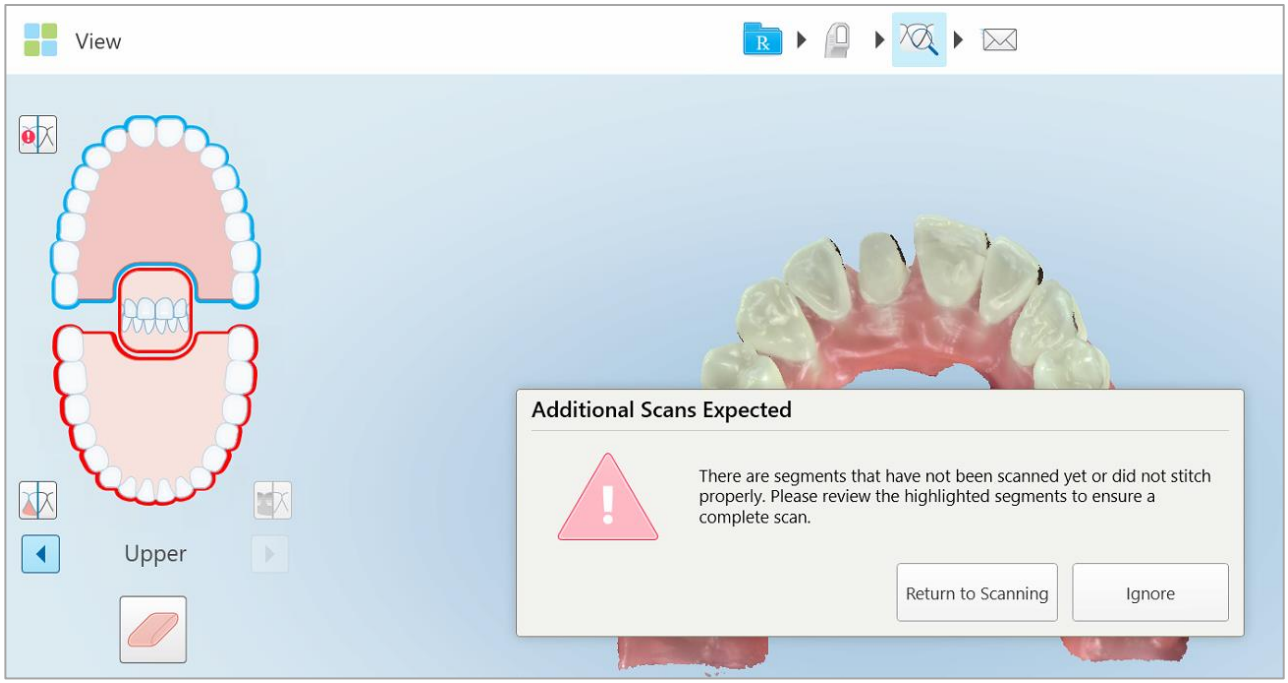

Figure 85: Missing scan message and missing segments highlighted in red

You can tap **Return to Scanning** to go back to Scan mode and rescan the missing segments, which are highlighted in red in the navigation controls.

4.5.2 Working with the Eraser tool

The Eraser tool enables you to erase a selected area of the scanned model and then rescan it.

For example:

- You can remove moisture and artifacts at the margin level, such as blood or saliva
- If the prepped tooth shows areas of red on the Occlusal Clearance legend, you can reduce the prepped tooth, erase the area on the model, and then rescan it, as described below.

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To erase part of the scan:

1. In the *View* window, ensure you are in Buccal view and on the relevant section to be erased, and then tap the Eraser tool .

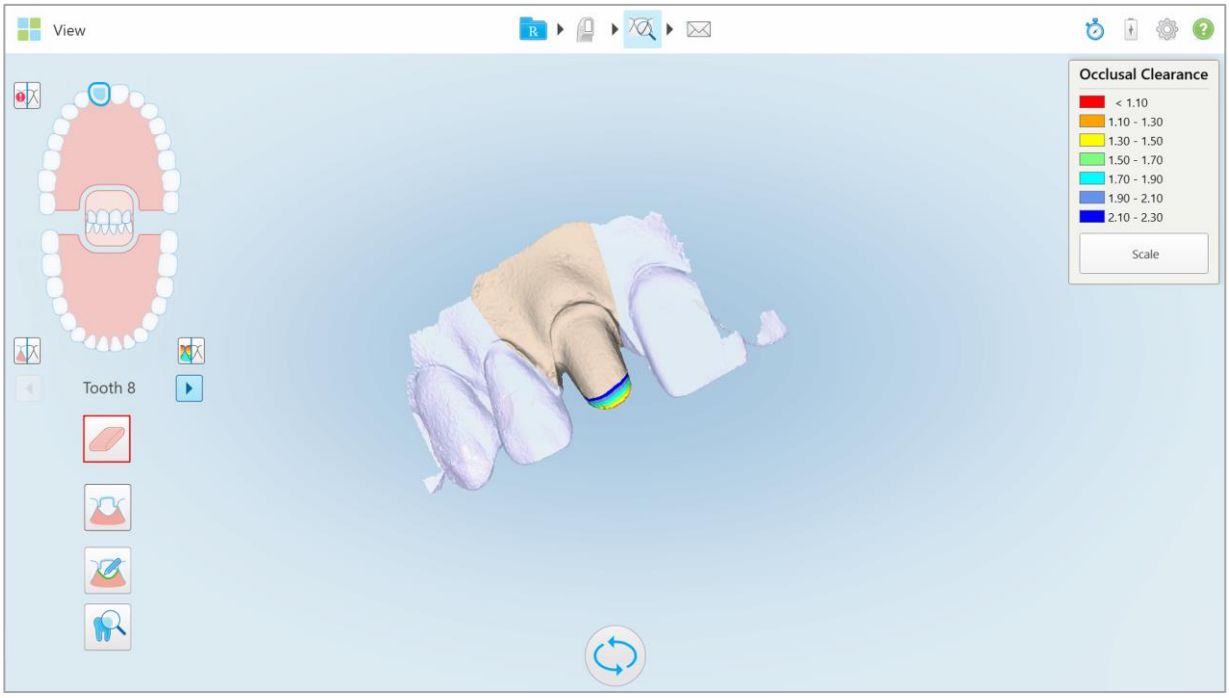

Figure 86: Eraser tool

The Eraser tool expands to show the following options:

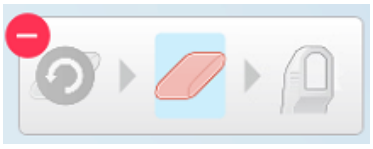

Figure 87: Eraser tool options

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2. With your finger, mark the area to be modified.

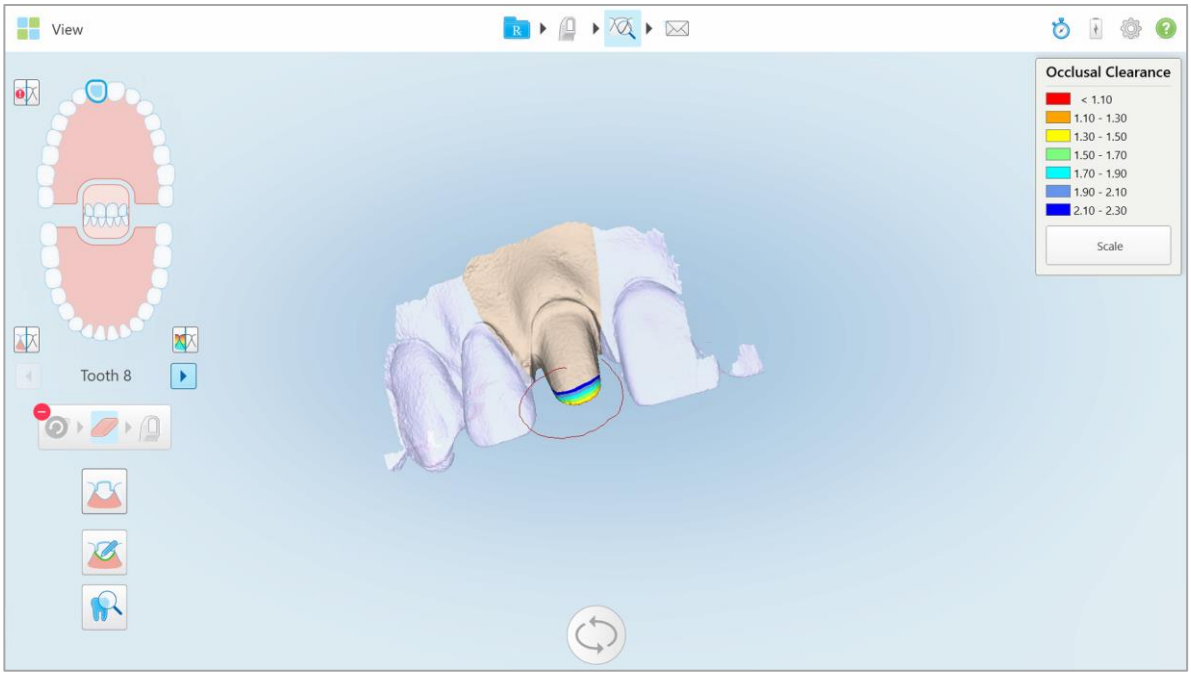

Figure 88: Area to be modified

As soon as you lift your finger, the selected area is removed and the scan tool is enabled.

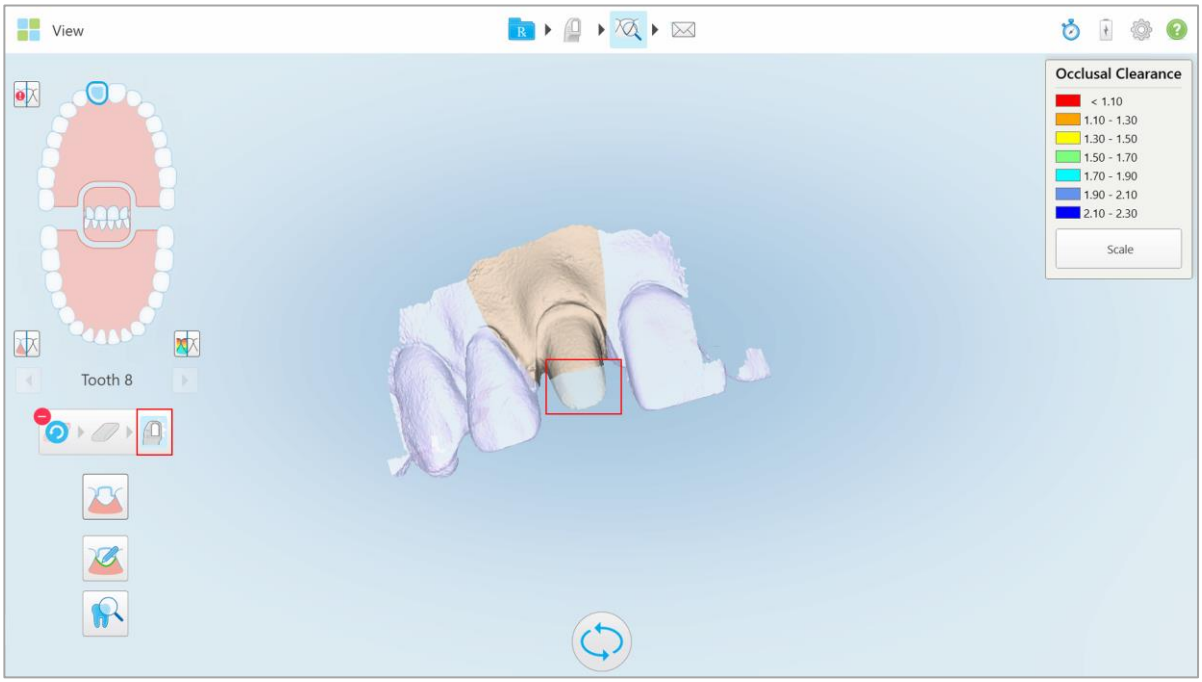

Figure 89: Selected area removed and scan tool enabled

3. If required, tap to undo the deletion.

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4. After adjusting the clearance on the patient's tooth, tap to return to Scan mode and rescan the deleted area, which is marked in red.

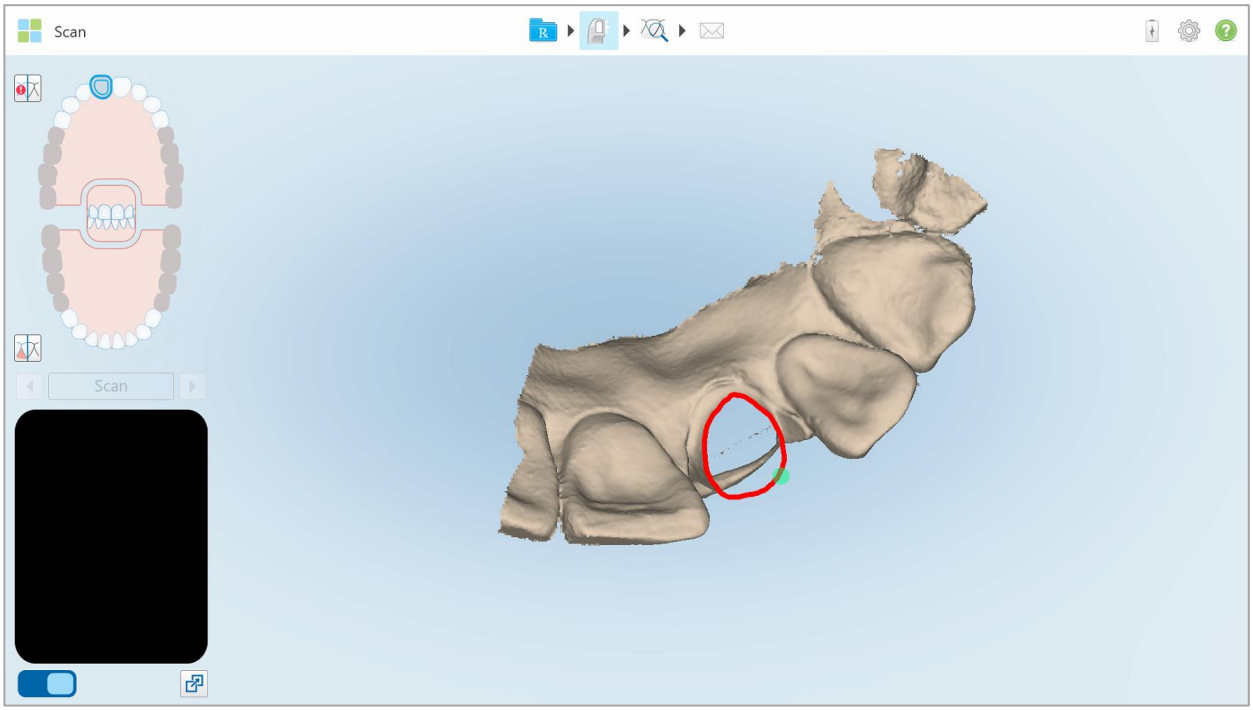

Figure 90: Deleted area marked in red

5. Tap the Clearance tool to confirm that the prepped tooth was sufficiently reduced.

4.5.3 Working with the Clearance tool

The Clearance tool enables you to view the contact and distance between the opposing teeth, to ensure that the prepped tooth has sufficient reduction for the material chosen in the Rx.

The Clearance tool can be accessed from the View mode and from the Viewer, as described in section 4.7.1.

Note: The Clearance tool is displayed only after you have scanned the upper and lower jaws, and the bite.

To display the occlusal clearance:

1. In the *View* window, tap the Clearance tool .

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The occlusal clearance between the opposing teeth is displayed.

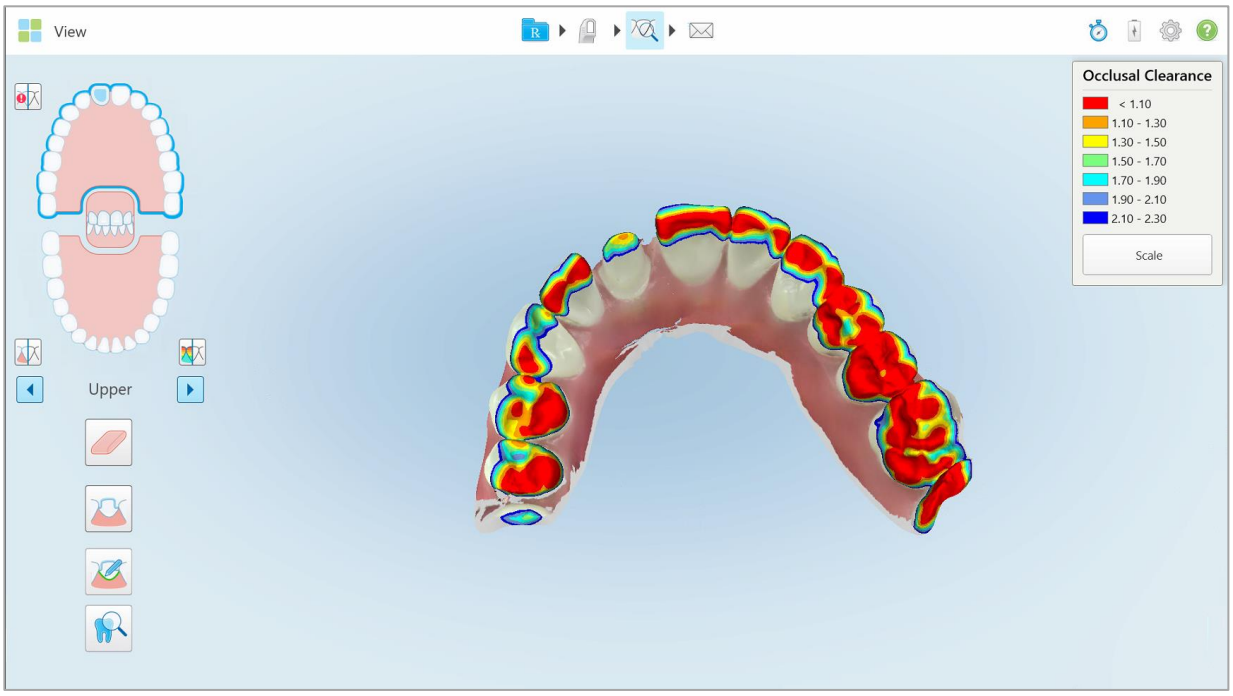

Figure 91: Occlusal clearance between the opposing teeth

2. If necessary, reduce the prepped tooth and rescan the area, as described in section 4.5.2, above.
3. If required, you can change the occlusal values displayed on the opposing teeth.
   a. On the legend, tap **Scale**.

      The legend is expanded to display a list of range options, in millimeters.

Figure 92: Occlusal Clearance range options

   b. Select the required scale.

      The occlusal clearance is displayed according to the new scale.

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4.5.4 Working with the Edge Trimming tool

The **Edge Trimming** tool enables you to trim away excess soft tissue such as cheek or lip artifacts from the scan. This tool is available for all case types, except Restorative case types.

To trim the excess material:

1. In the *View* window, tap the Edge Trimming tool .

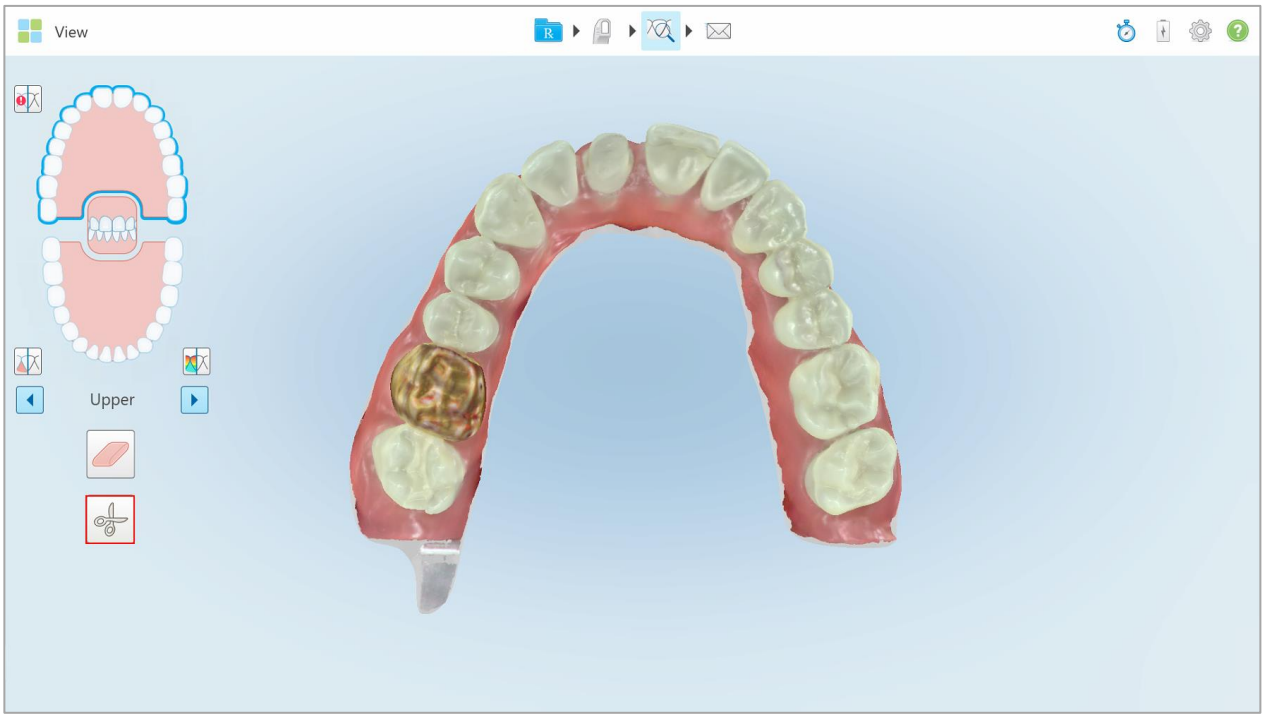

Figure 93: Edge trimming tool

The Edge Trimming tool expands to show the following options:

Figure 94: Edge trimming tool options

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2. With your finger, mark the area you would like to trim away.

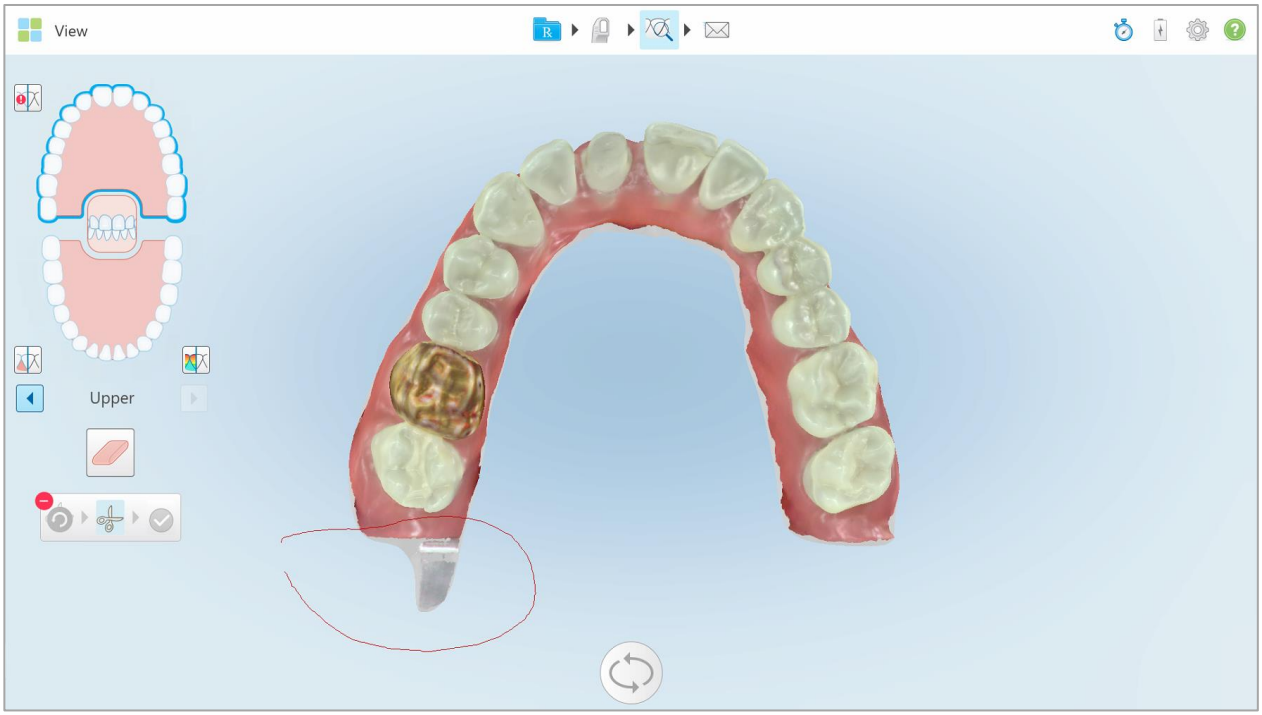

Figure 95: Marking the area to be trimmed away

The area to be trimmed away is highlighted and the confirmation icon is enabled.

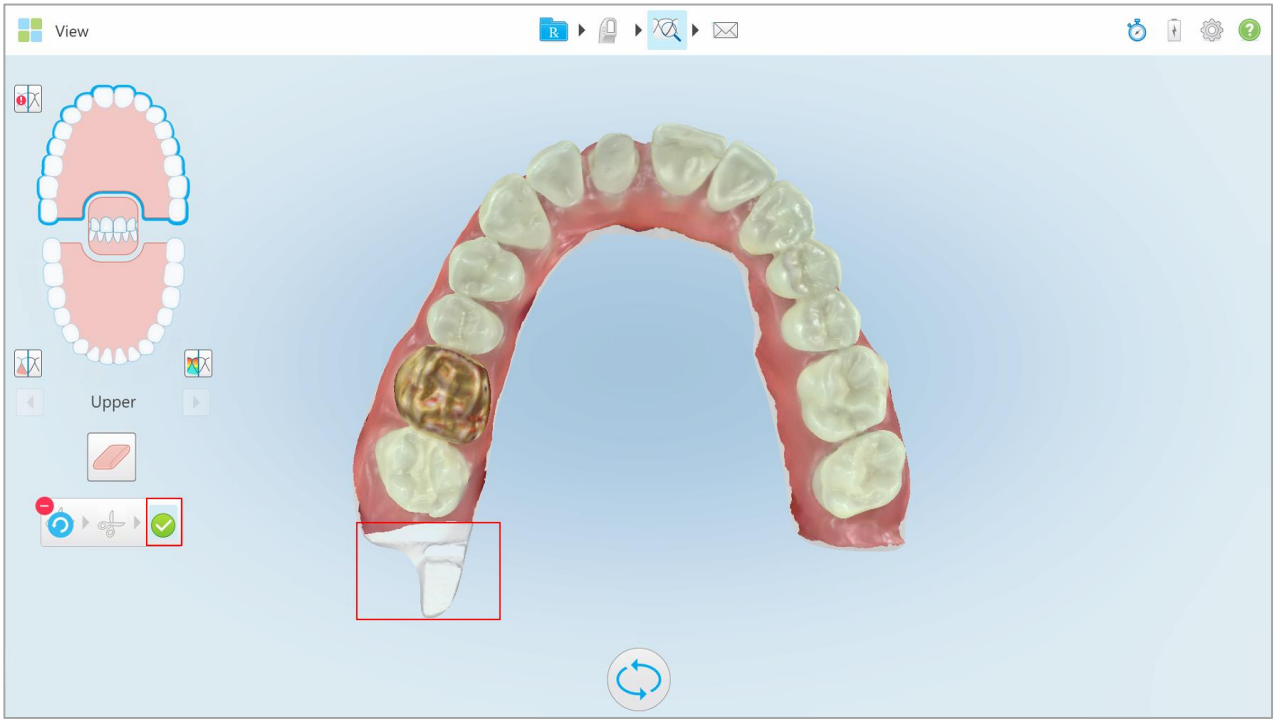

Figure 96: Selected area is highlighted and the confirmation icon is enabled

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3. If required, you can tap to undo the trimming.

4. Tap to confirm the trimming.

   The selected area is removed.

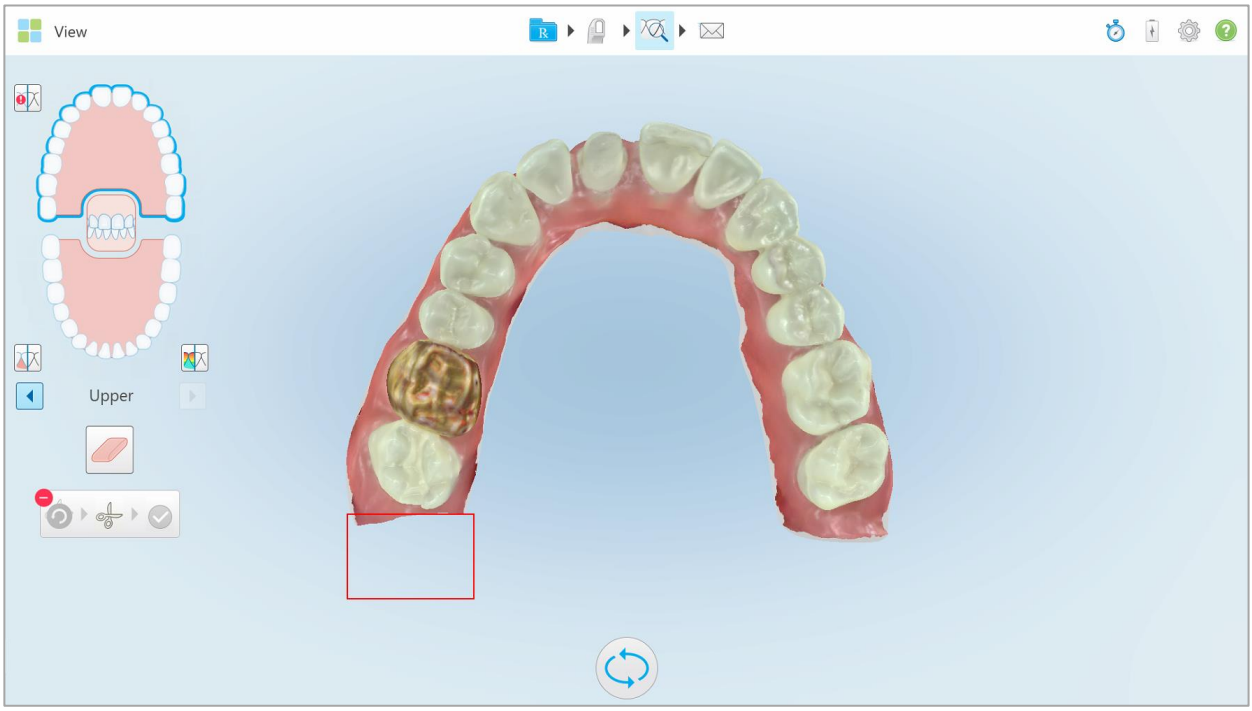

Figure 97: Selected area has been removed

4.5.5 Working with the Die Separation tool

The die separation is created automatically, according to the position of the green hint point, which must be located on the center of the prepped tooth after scanning.

If required, the die separation area can be edited or created manually.

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To display the die separation:

1. After scanning the prepped tooth, ensure that the green hint point is centered on the prepped tooth. Move it manually, if required.

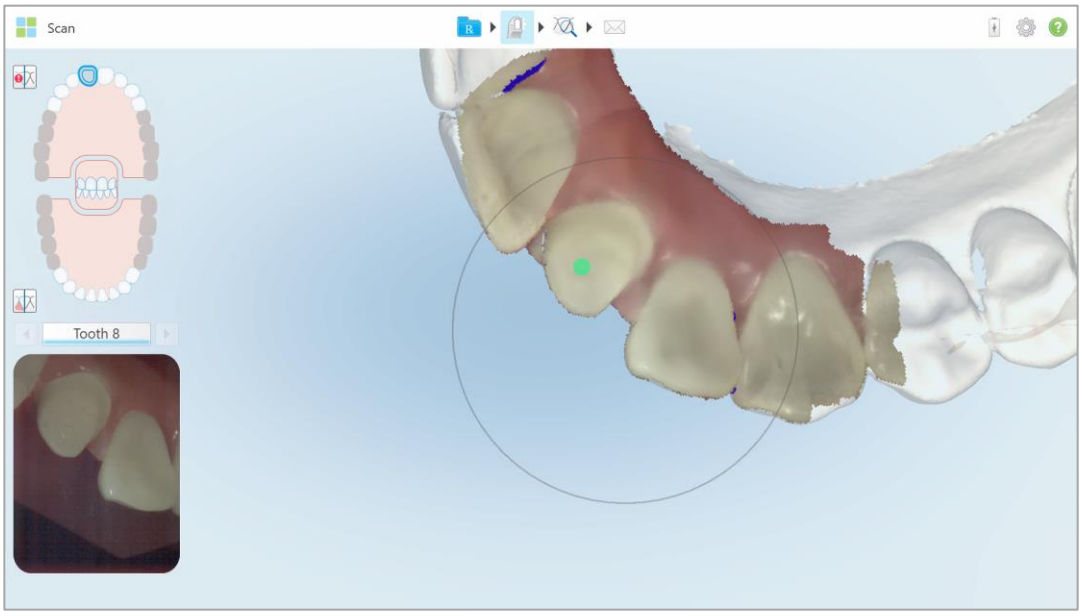

Figure 98: Green hint point centered on the prepped tooth

2. Tap on the toolbar to move to **View** mode.

3. In the *View* window, tap the Die Separation tool .

   The die separation is displayed in high resolution.

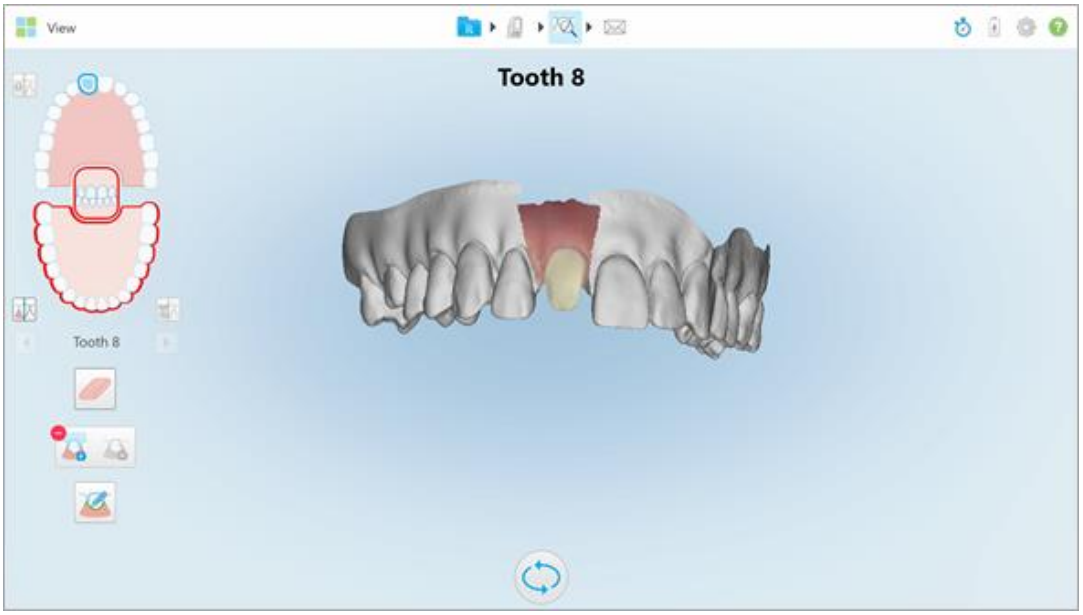

Figure 99: Die separation is displayed in high resolution

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To create the die separation manually:

1. In the *View* window, tap the Die Separation tool .
   The tool expands to show the following options:

Figure 100: Die Separation tool options

2. Tap and mark the whole segment with your finger.
   The scan is displayed in low resolution.

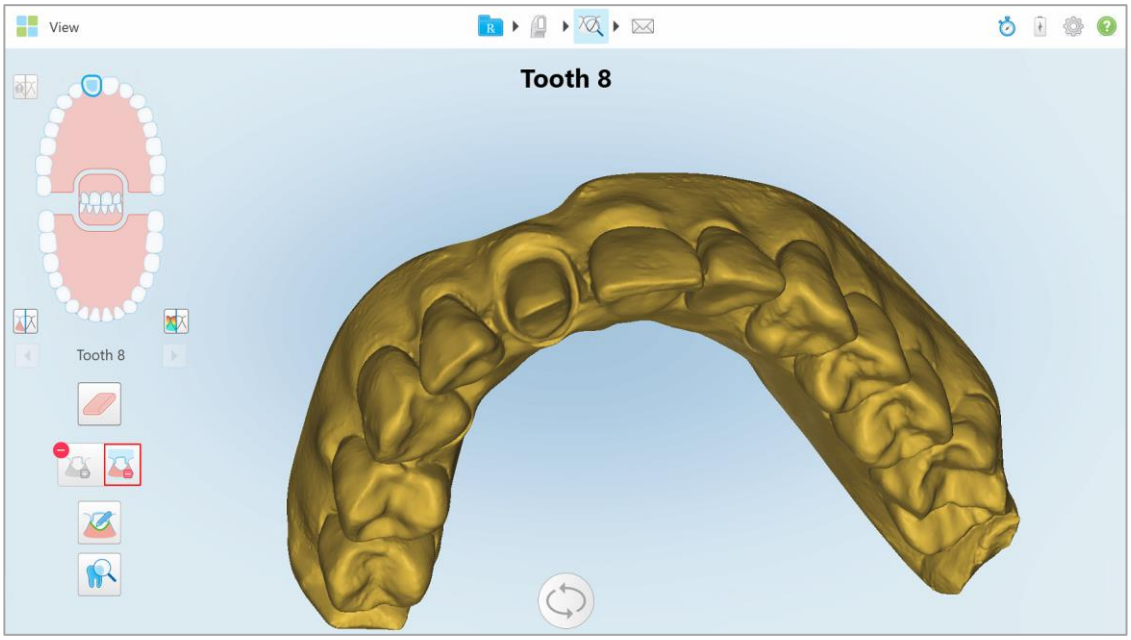

Figure 101: Scan is displayed in low resolution

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3. Tap to mark the prepped tooth in high resolution.

   The model is displayed as follows:

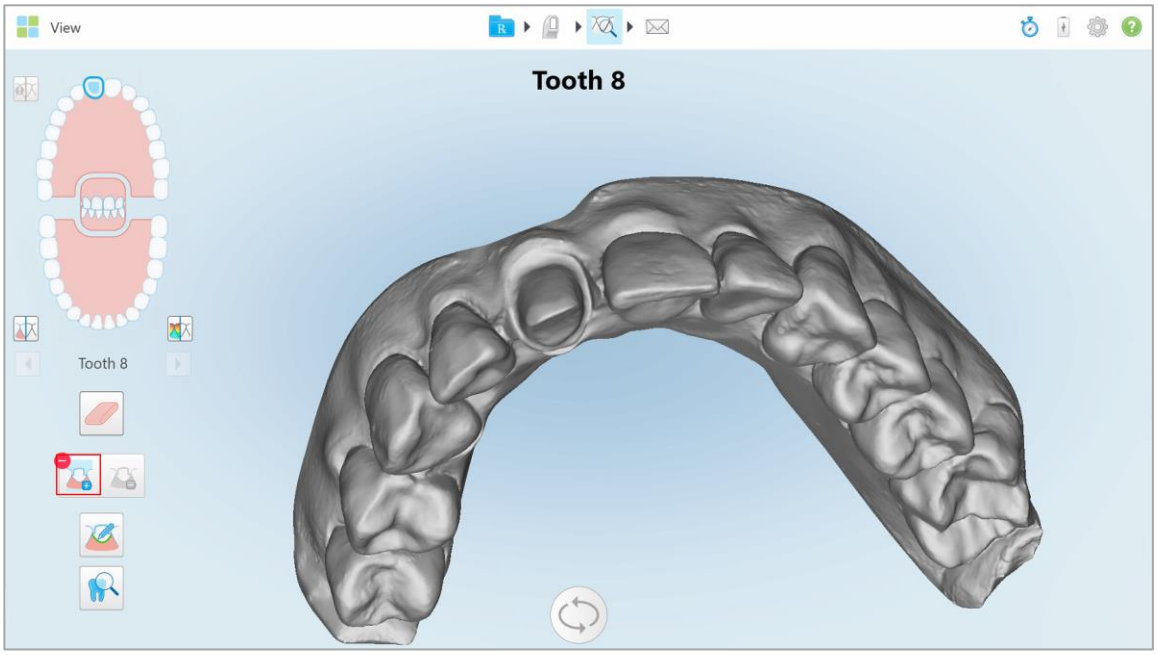

Figure 102: Before selecting the die separation

4. Draw the area for the die separation.

   The selected area is displayed in high resolution.

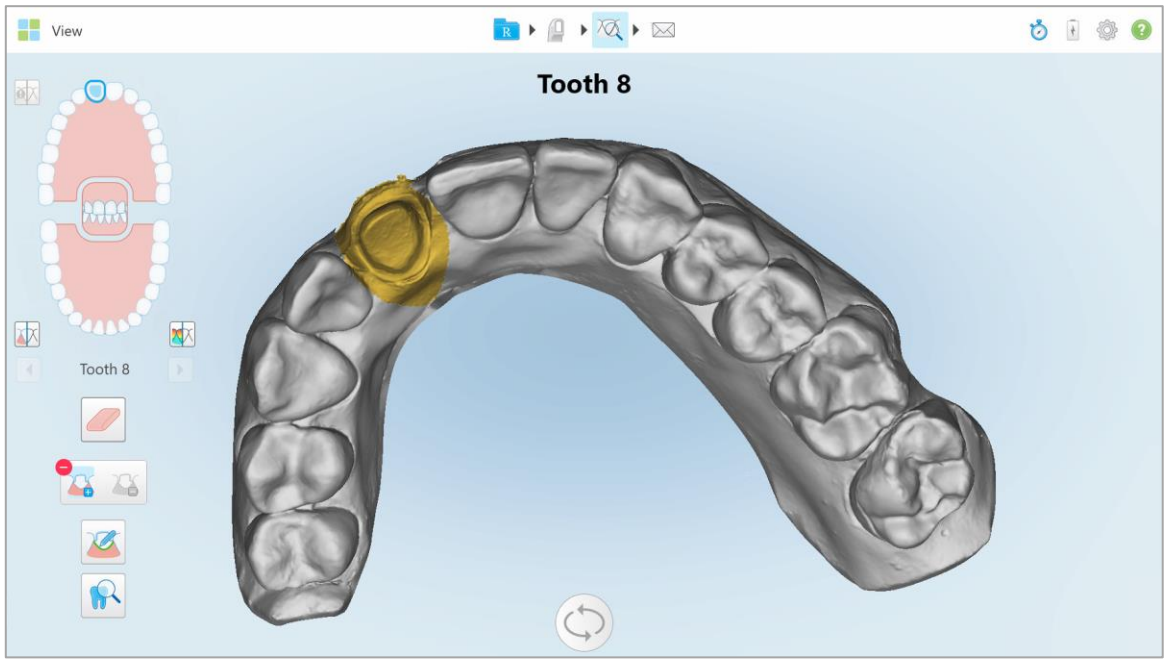

Figure 103: Prepped tooth is displayed in high resolution

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4.5.6 Working with the Review tool

The View mode includes a **Review tool** that enables you to view an area of interest in both NIRI and color modes, one below the other.

In addition, you can:

- Zoom in and out of images in the viewfinder, as described in section 4.5.6.1
- Adjust the brightness and contrast of images in the viewfinder, as described in section 4.5.6.2
- Capture images, as described in section 4.5.6.3

When reviewing the 3D model in NIRI mode, the upper and lower jaw orientation has been set to look as if you are looking into the patient's mouth.

Note: If you notice an issue with a NIRI image, please contact Customer Support.

To activate the Review tool:

- In the *View* window, tap and then drag the loupe from the right pane over the area of interest.

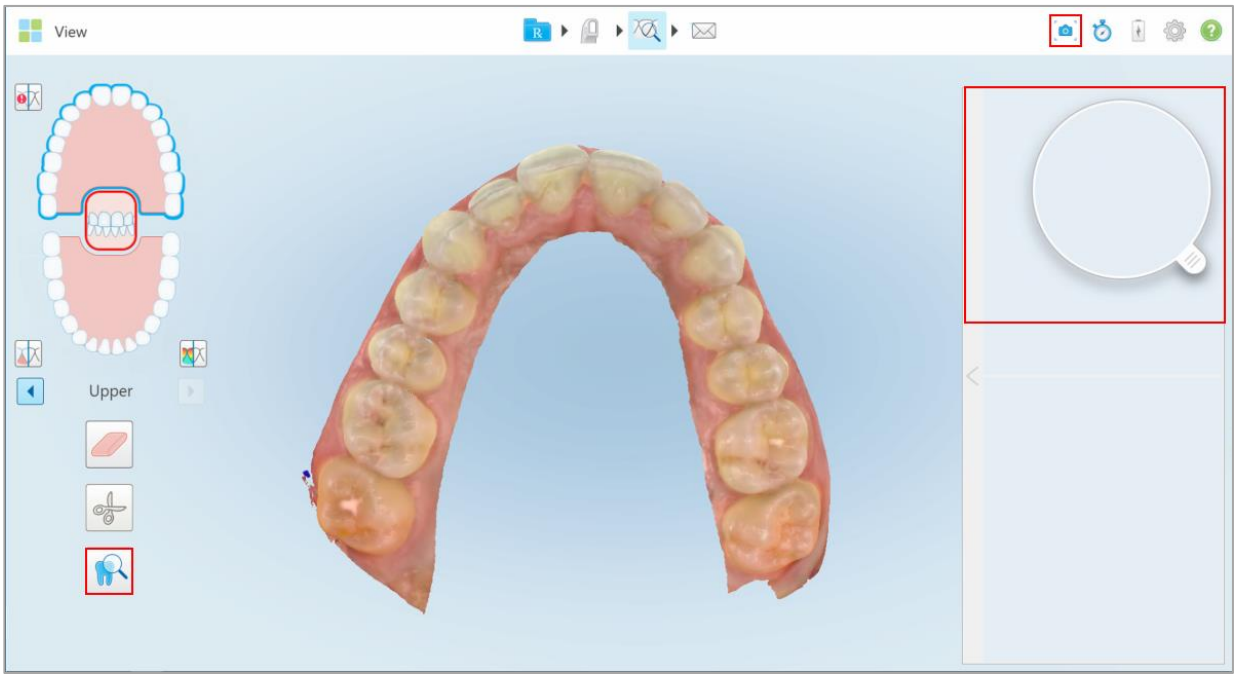

Figure 104: Review tool with the capture tool on the toolbar and the loupe in the right pane

The area within the loupe is displayed in the viewfinder. The display in the viewfinder changes according to the position of the loupe.

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A NIRI and color image are displayed one below the other in the viewfinder on the right. The color and NIRI mode images in the viewfinder match the direction of the loupe and are updated simultaneously while moving the loupe over the 3D display.

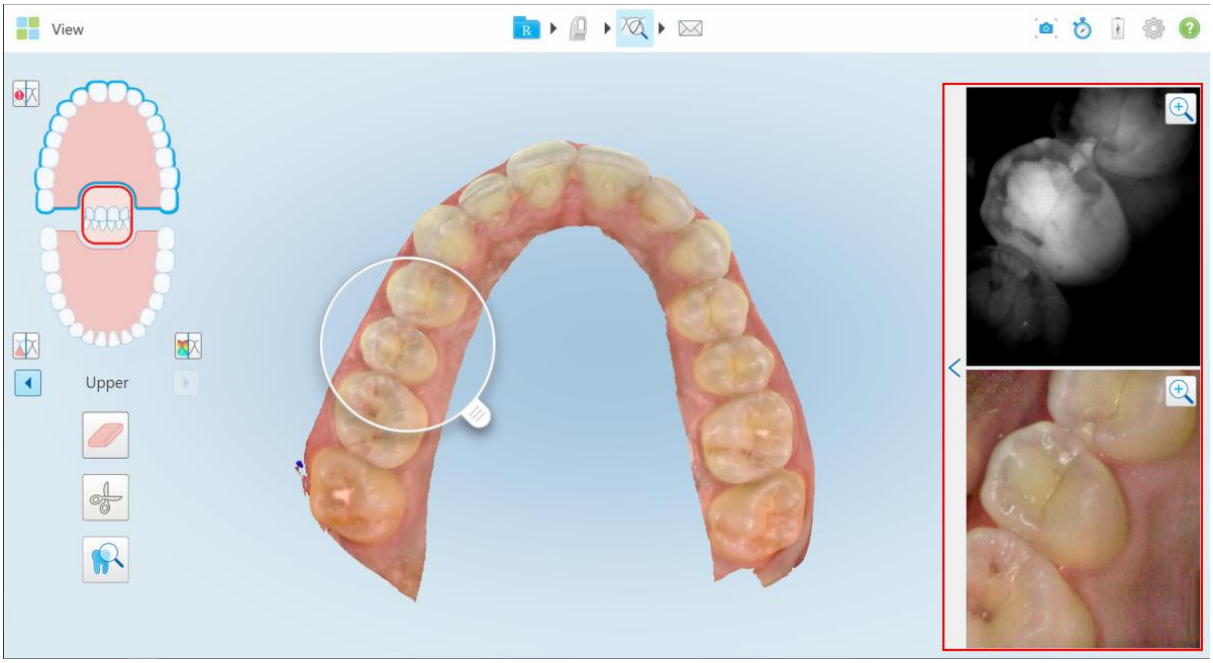

Figure 105: Viewfinder on the right showing the area in the loupe in both NIRI and color modes

4.5.6.1 Zooming in to and out of images in the viewfinder

In order to better evaluate the scanned images in the viewfinder, you can zoom in to and out of the images, as well as adjust the contrast and brightness of each image.

You can zoom in to or out of the selected area of the images displayed in the viewfinder using the following methods:

- Using a spreading or pinching gesture on one of the images displayed in the viewfinder
- Double-tapping an image in the viewfinder to toggle zoom in/zoom out
- Tapping the zoom button displayed on the required image

Zooming in or out using the first two methods will enlarge or decrease the size of both viewfinder images simultaneously, but keep the viewfinder window the same size.

Zooming in using the zoom tool will enlarge and display only the relevant image.

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To zoom in or out using the zoom button:

1. Tap on either the color or the NIRI image to zoom in to that view.

Figure 106: Zoom-in buttons on both images in the viewfinder

The viewfinder window will be enlarged and only the specific image is displayed in the viewfinder.

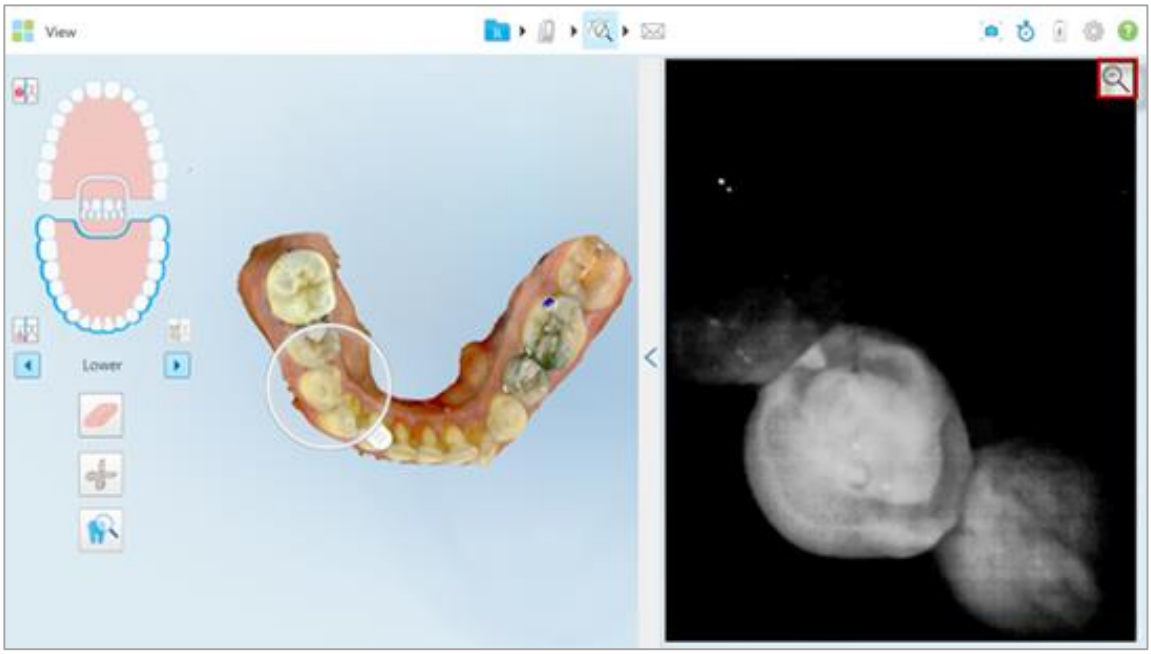

Figure 107: Only the zoomed-in image is displayed in the enlarged viewfinder

2. Tap on the enlarged 2D image to return the image to the default size.

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4.5.6.2 Adjusting the brightness and contrast of images in the viewfinder

You can set the brightness and contrast of each of the images displayed in the viewfinder by adjusting the relevant sliders in the brightness and contrast toolbar.

- **Brightness** refers to the overall lightness or darkness of an image. Increasing the brightness makes every pixel in the image lighter, and vice versa.
- **Contrast** is the difference in **brightness** between objects in an image. Increasing the contrast makes light areas lighter and dark areas darker, and vice versa.

By default, the brightness and contrast toolbar is collapsed.

Note: The color and brightness controls are displayed only when images are displayed in the viewfinder, and not when the loupe is in its default position in the right pane.

The contrast and brightness image controls are reset to their default values when selecting a different jaw, pushing the loupe back to its default position, or when exiting the tool.

To adjust the brightness and contrast of images in the viewfinder:

1. Tap on the left edge of the viewfinder to display the brightness and contrast adjustment toolbar.

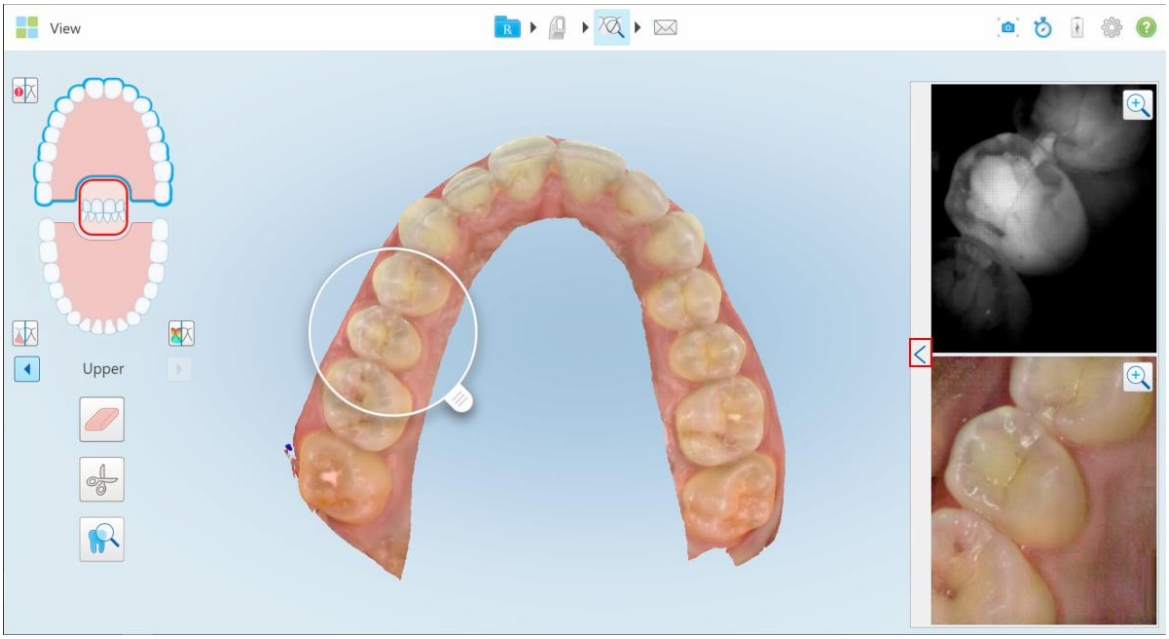

Figure 108: Brightness and contrast toolbar is collapsed

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A brightness and contrast adjustment toolbar is displayed on each of the windows in the viewfinder. By default, the brightness level is set to the lowest position and the contrast is set to the middle position.

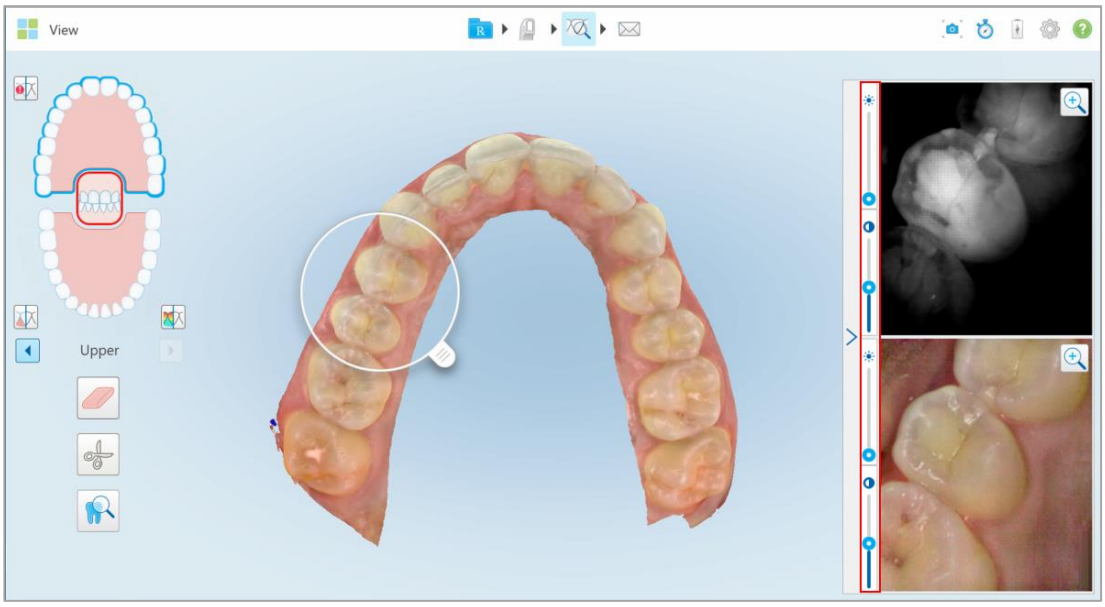

Figure 109: Brightness and contrast toolbars

2. Move the slider up or down to adjust the brightness or contrast .
   Tip: You can tap anywhere in the slider area and drag up or down to adjust the settings.
3. Tap to collapse the toolbar.

4.5.6.3 Capturing the Review tool images

If required, you can capture the images displayed when using the Review tool. These images become part of the patient's export package, and can later be downloaded from MyiTero.

By default, each time you tap the Capture tool, the following images are captured and saved in a separate folder, whose name includes the Order ID and date and time of the screenshots:

- Entire Review tool window, including 3D image, and 2D NIRI and color viewfinder images.
- 3D image
- 2D NIRI viewfinder image (if the loupe has been dragged onto the 3D image)
- 2D color viewfinder image (if the loupe has been dragged onto the 3D image)

Each set of screenshots is saved in a separate folder and saved in a folder with the patient's name, which can be downloaded from MyiTero as a zipped file.

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To capture Review tool images:

1. In the Review tool window, drag the loupe to the required location on the 3D model and then tap on the toolbar. (If required, you can capture the image before dragging the loupe onto the model.)

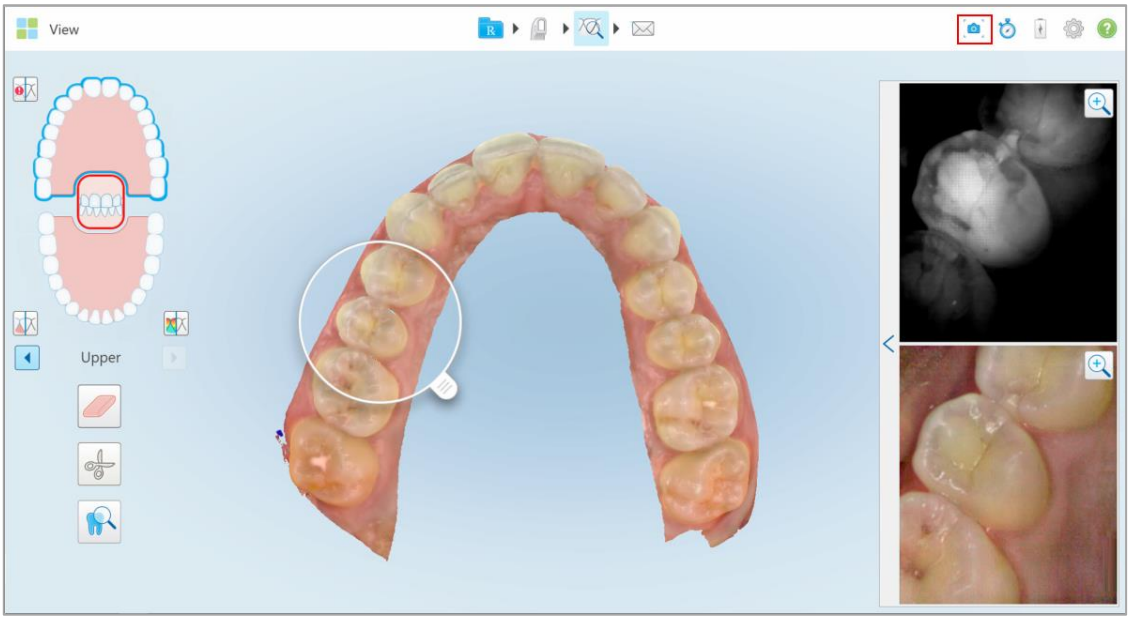

Figure 110: Capturing an area of interest

The screen flashes, indicating that the screenshot was captured.

2. Repeat, as required, for each set of images you would like to capture.

The screenshots will be sent to the lab, together with the scan.

After a short while, the screenshots can be downloaded from MyiTero from the *Orders* page or the Viewer.

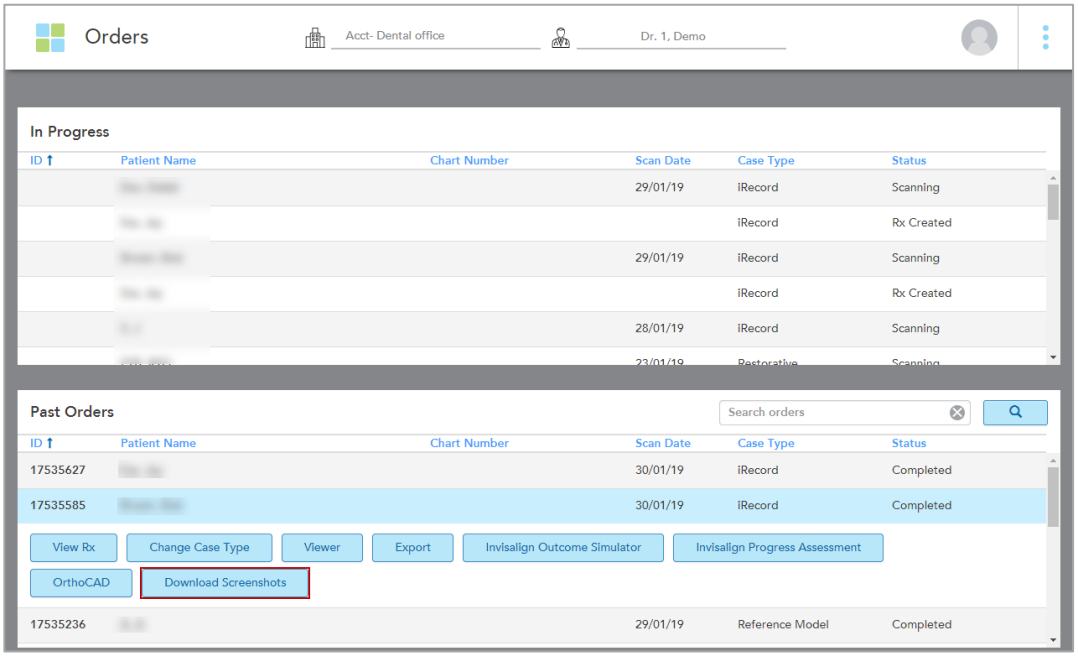

Figure 111: Option to download screenshots from the Orders page in MyiTero

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4.5.7 Using the scan timer

The scan timer enables you to see how long it took to scan the model.

To view the scan time:

1. On the toolbar, tap the button.

   The scan time is displayed.

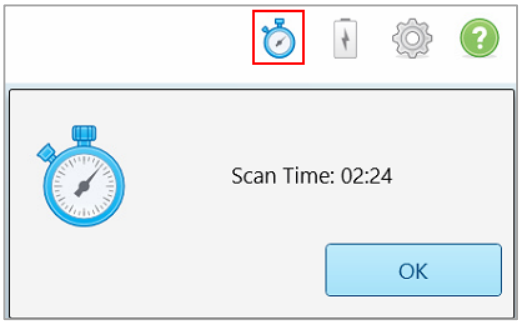

Figure 112: Scan timer button on the toolbar and scan time

2. Tap **OK** to close the window.

4.6 Sending the scan

After you have scanned the patient and viewed the case to ensure that no data is missing, you can send the scan to the lab or to storage, depending on the case type.

To send the scan:

1. Tap on the toolbar to send the case, including the screenshots if any.
2. Add your signature to authorize the order and then tap **Confirm and Send**.

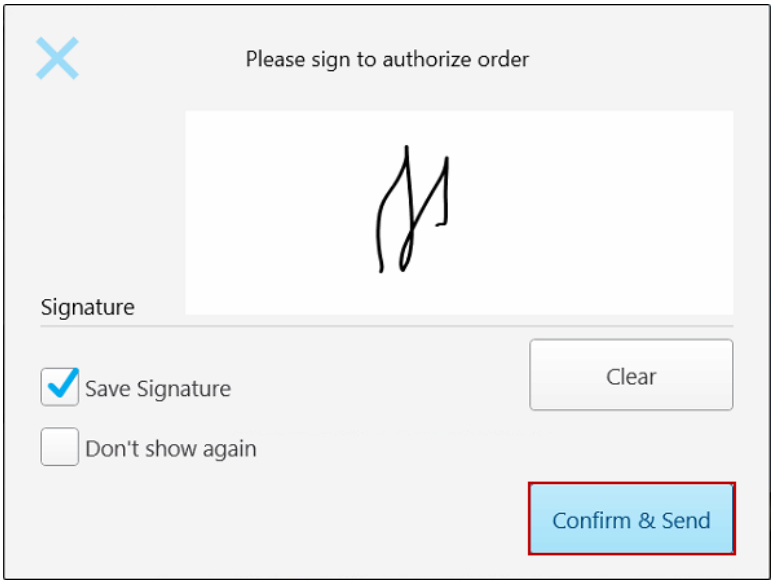

Figure 113: Sending the scan

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3. If required, select the **Save Signature** check box to save your signature for authorizing future cases.
4. If required, select the **Don't show again** check box to skip the authorization stage.

   To return the authorization stage, define the signature settings, as described in section 3.6.2.3.

   A notification message is displayed that the model is being sent and then the patient's profile page is displayed showing the status of the order.

4.7 Working with the Viewer

The Viewer is a tool that enables you to view and manipulate the digital model for case presentations. Only cases that have already been sent can be viewed in the Viewer.

The Viewer can be accessed from Past Orders in the *Orders* page, or from a specific patient's profile page.

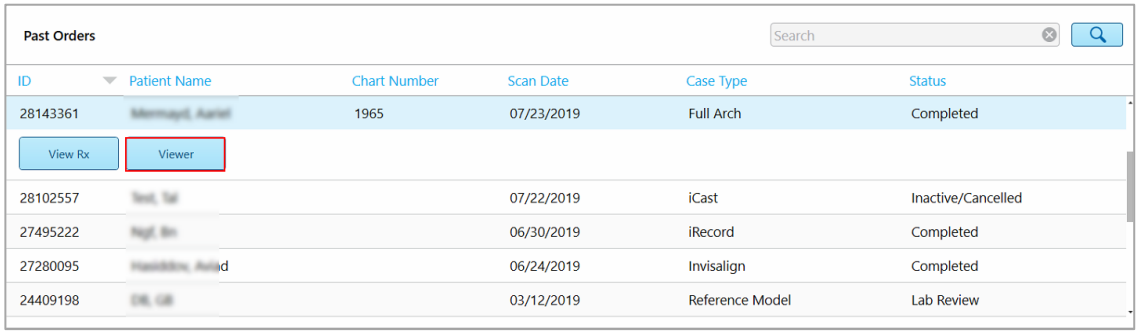

Figure 114: Viewer option in the Past Orders pane in the Orders page

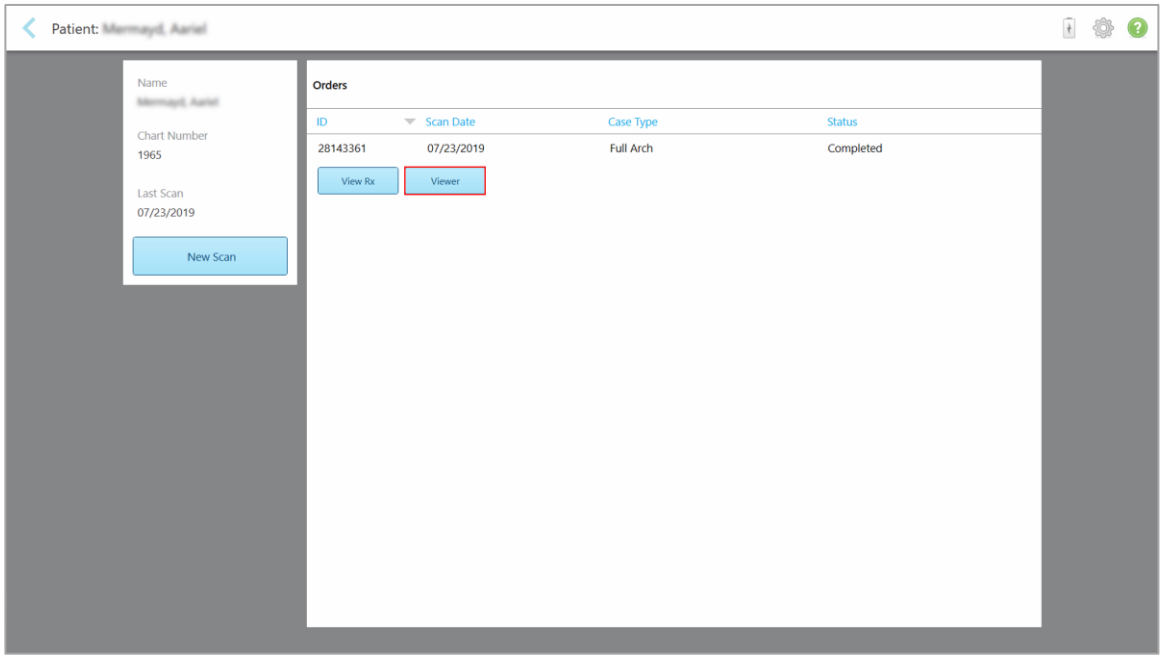

Figure 115: Viewer option in patient's profile page

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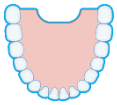
In the Viewer, you can tap the following to:

Show/hide the upper jaw



Show/hide the lower jaw

Show both jaws

Open the Review tool to view an area of interest in both NIRI and color modes, one below the other, as described in section 4.5.6.

Display the model in a 1-window view, with the upper and lower jaws in the same window (Frontal view).

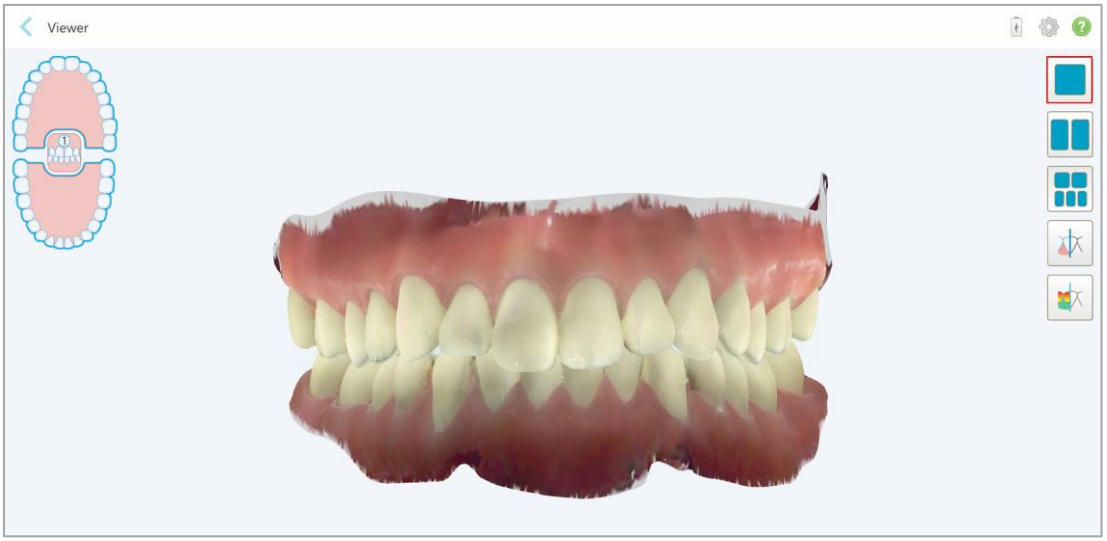


Figure 116: Model in a 1-window view

Relevant for Orthodontic case types only.

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Display the model in a 2-window view, with the upper and lower jaws in separate windows (Occlusal view). Each model can be controlled separately, for better evaluation.

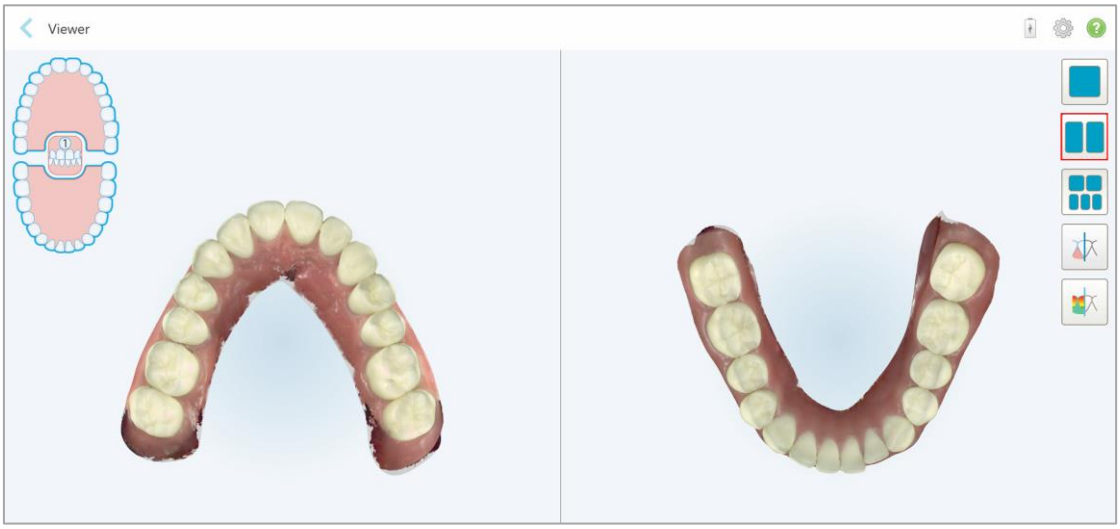

Figure 117: Model in a 2-window view

Relevant for Orthodontic case types only.

Display the model in a 5-window view, with the upper and lower jaws separately, and both jaws from the left, center, and right (Gallery view). Each model can be controlled separately, for better evaluation.

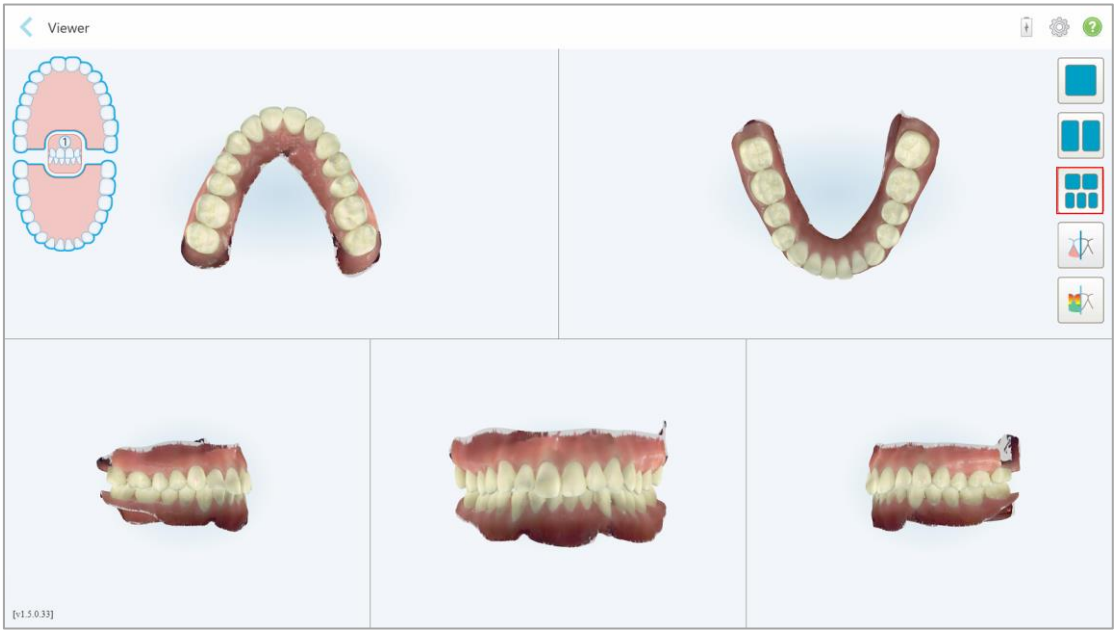

Figure 118: Model in a 5-window view

Relevant for Orthodontic case types only.

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Display/hide the margin line of the prepped tooth.

Relevant for Restorative case types only.

Show/hide the ditch created by the Modeling team.

Relevant for Restorative case types only.

Toggle between viewing the model in color or in monochrome.

Show/hide the clearance between the opposing teeth, as described in section 4.7.1.

Note: When the case status is **iTero Modeling**, it is in the early stages of modeling and the margin line and die tools are disabled.

When the modeling process is completed and the die and margin line have been edited, the changes will appear in color on the model and the tools will be displayed in color, indicating that they are active.

4.7.1 Clearance tool

You can view the occlusal clearance between opposing teeth in the Viewer.

In the Viewer, tap .

The clearance between the opposing teeth is displayed.

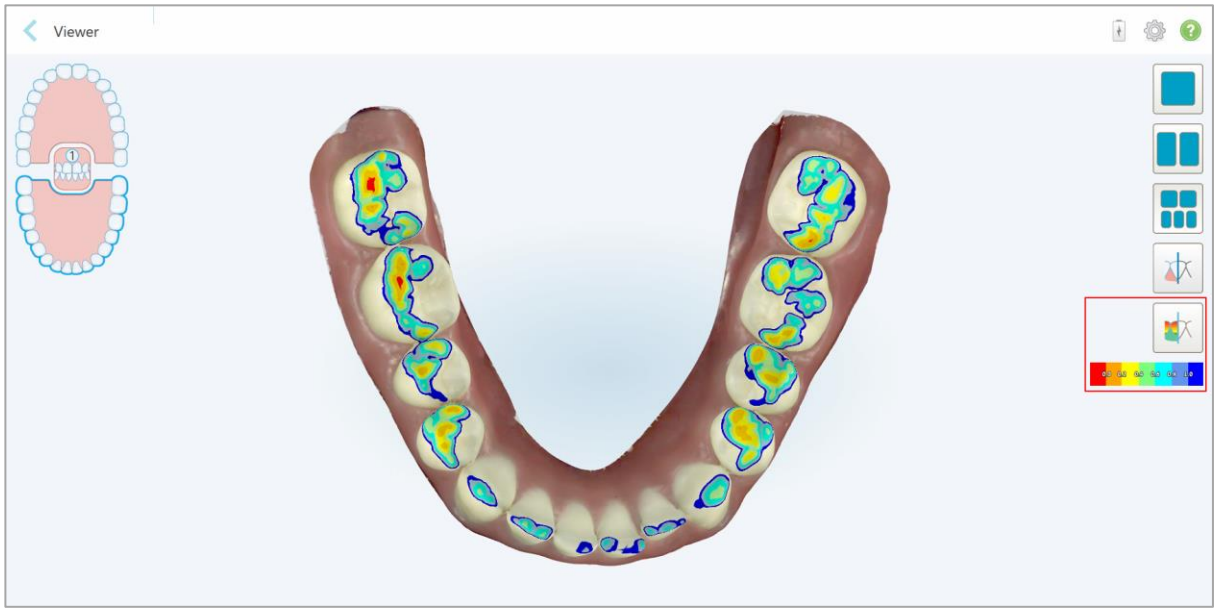

Figure 119: Clearance tool and legend displayed in the Viewer

The occlusal clearance can also be viewed from View mode while scanning the patient, as described in section 4.5.3

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4.8 Removing the wand barrier sleeve

The wand barrier sleeves are intended for single-patient use and must be disposed of and replaced after each patient in order to avoid cross-contamination.

To remove the wand barrier sleeve:

1. Once the scan is complete, or if the scan has to be interrupted, wearing gloves, scrunch the transparent sheath halfway toward the wand tip.

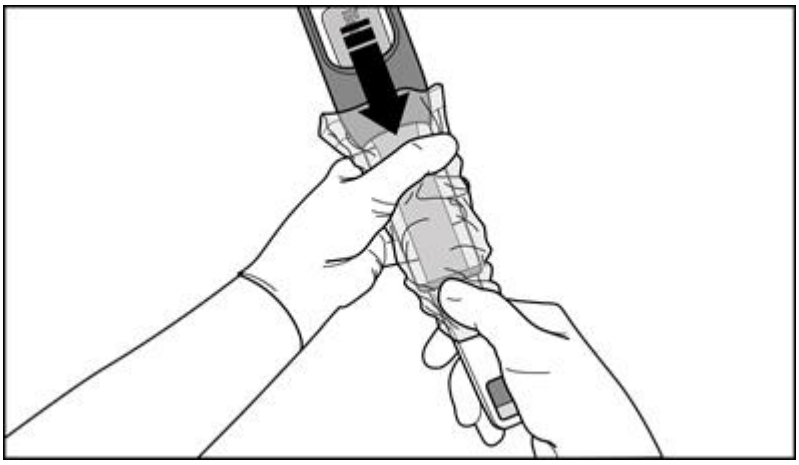

Figure 120: Scrunch the transparent sheath halfway towards the tip

2. Holding the wand by the scrunched transparent sheath, slightly release the rigid section of the barrier sleeve from the wand tip using the other hand.

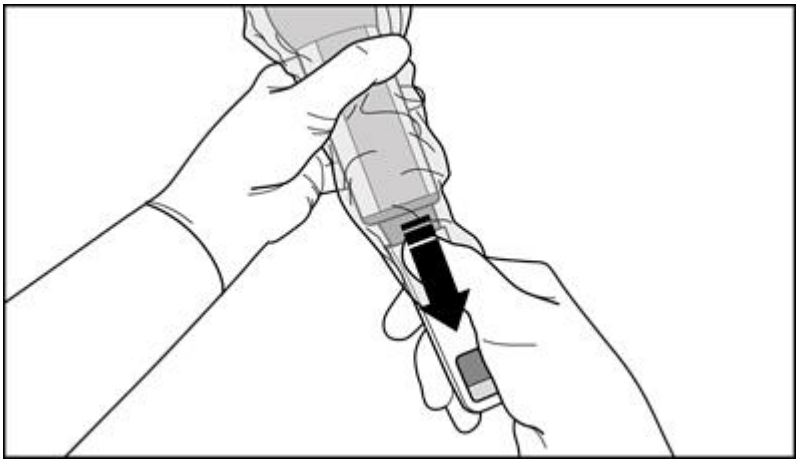

Figure 121: Slightly release the rigid section of the wand barrier sleeve from the tip of the wand

3. Holding the wand by the scrunched transparent sheath, place the wand in the cradle.

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4. Pull the rigid section of the barrier sleeve to remove it from the wand.

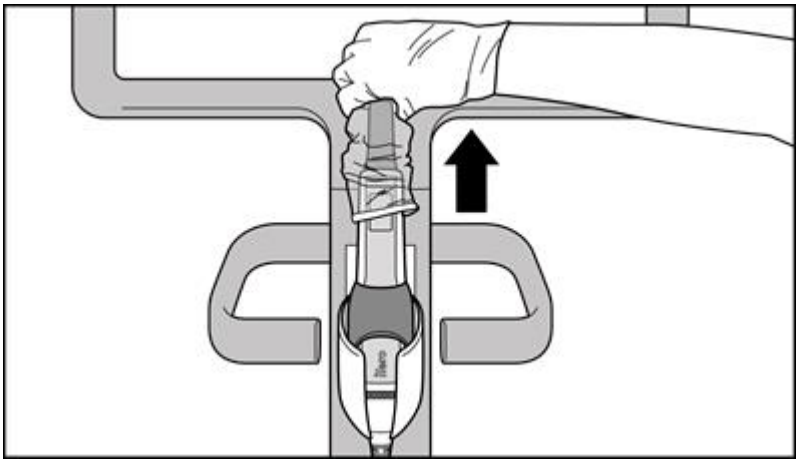

Figure 122: Remove the wand barrier sleeve

CAUTION: Do not dispose of used wand barrier sleeves other than according to standard, operating procedures or local regulations for the disposal of contaminated medical waste.

CAUTION: OPTICAL SURFACE!

DO NOT touch the optical surface of the wand. Contact may cause damage. If cleaning is necessary, use the anti-static cloth found inside the wand barrier sleeve box. For more details, refer to the instructions in the box.

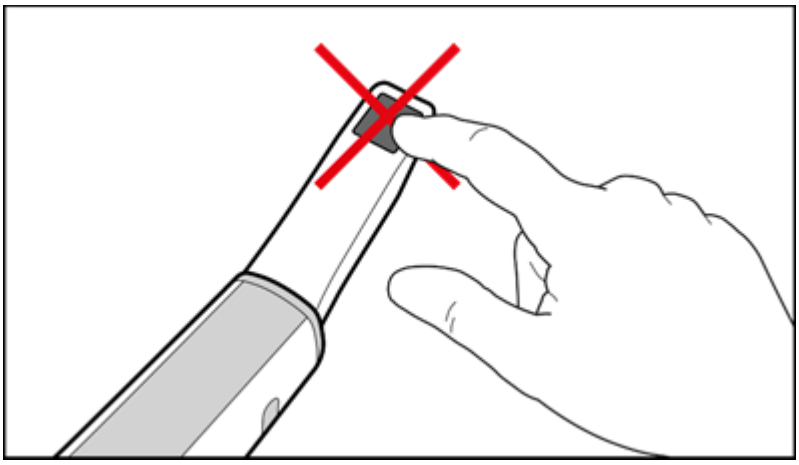

Figure 123: Optical surface of the wand

The iTero Element 5D wand and cradle must be cleaned and disinfected in between patients to avoid cross-contamination, as described in sections 10.2 and 10.3. A new wand barrier sleeve may be applied to the wand after cleaning and disinfection have been performed.

Note: If the scanner will not be used immediately cleaning and disinfection, attach the blue protective sleeve.

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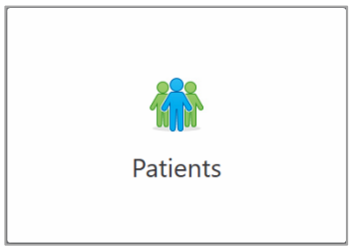
5 Working with patients

On the home screen, tap the **Patients** button to display the *Patients* page.



The *Patients* page displays a list of all your patients, their chart number, and the last scan date.

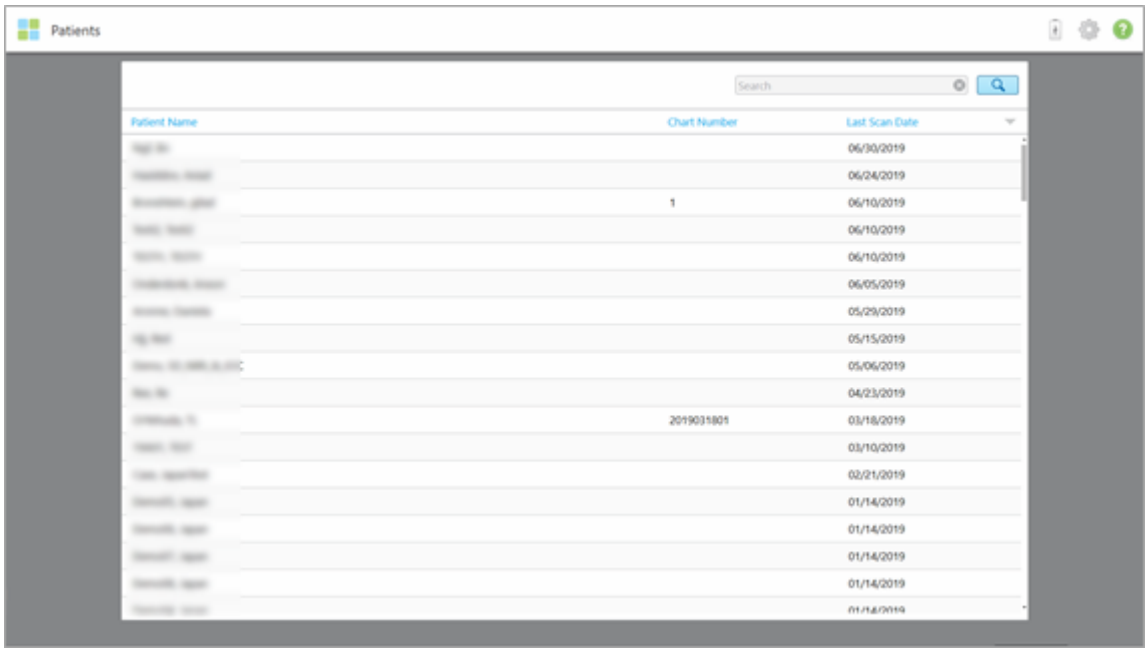


Figure 124: Patients page

Once you have selected a patient, you can view the patient's profile page with the patient's data.

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5.1 Searching for patients

If required, you can search for patients in the iTero database using their names or chart numbers.

To search for a patient:

- In the *Patients* page, enter the patient's name or chart number (or part thereof) in the search bar and then tap the search button .

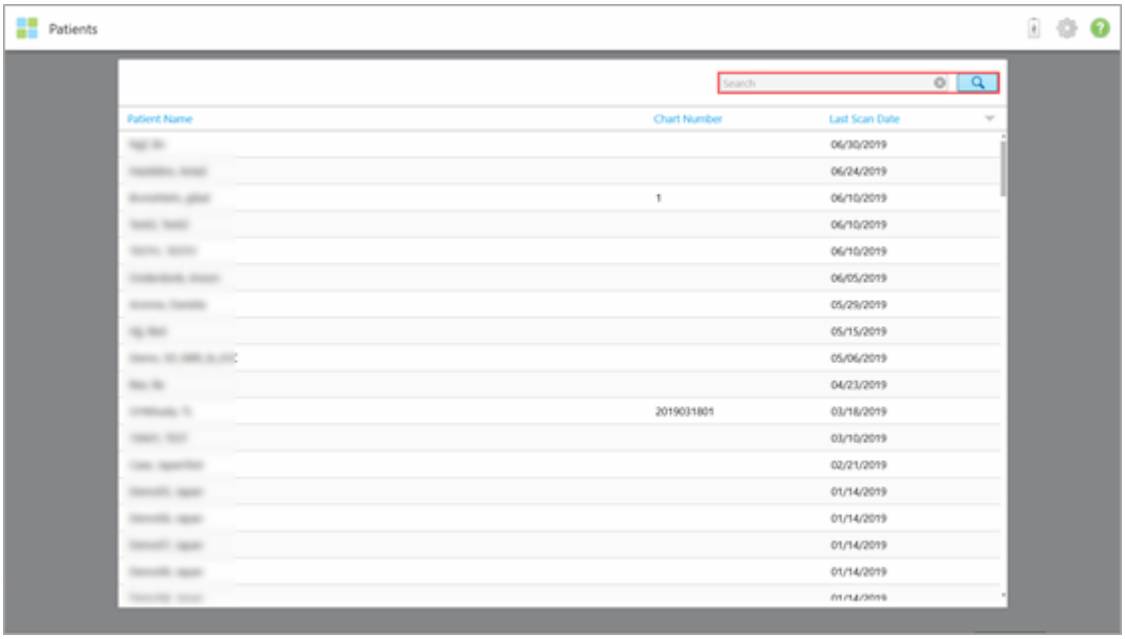

Figure 125: Searching for a patient

The patients that match your search criteria are displayed.

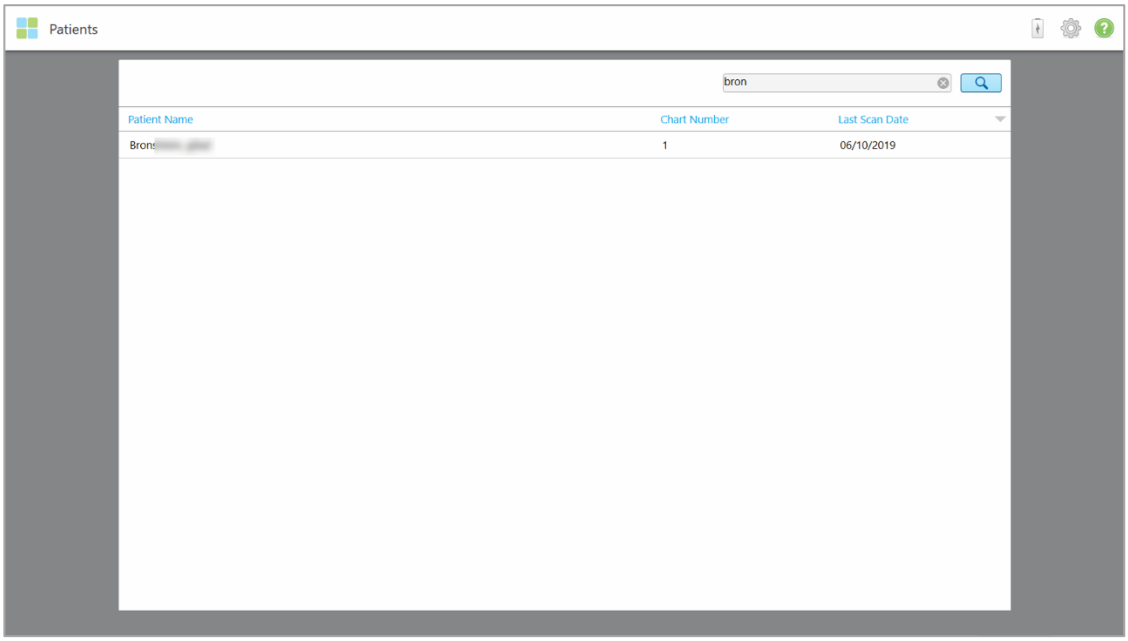

Figure 126: Patients matching the search criteria are displayed

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5.2 Viewing the patient details

You can view the patient's details, including all the patient's previous scans, in the patient's profile page.

To view the patient details:

1. Tap the **Patients** button on the home screen.

   The *Patients* page is displayed, showing a list of your patients, their chart number, and the date of their last scan.

2. Select the required patient in the list.

   The selected patient's profile page is displayed:

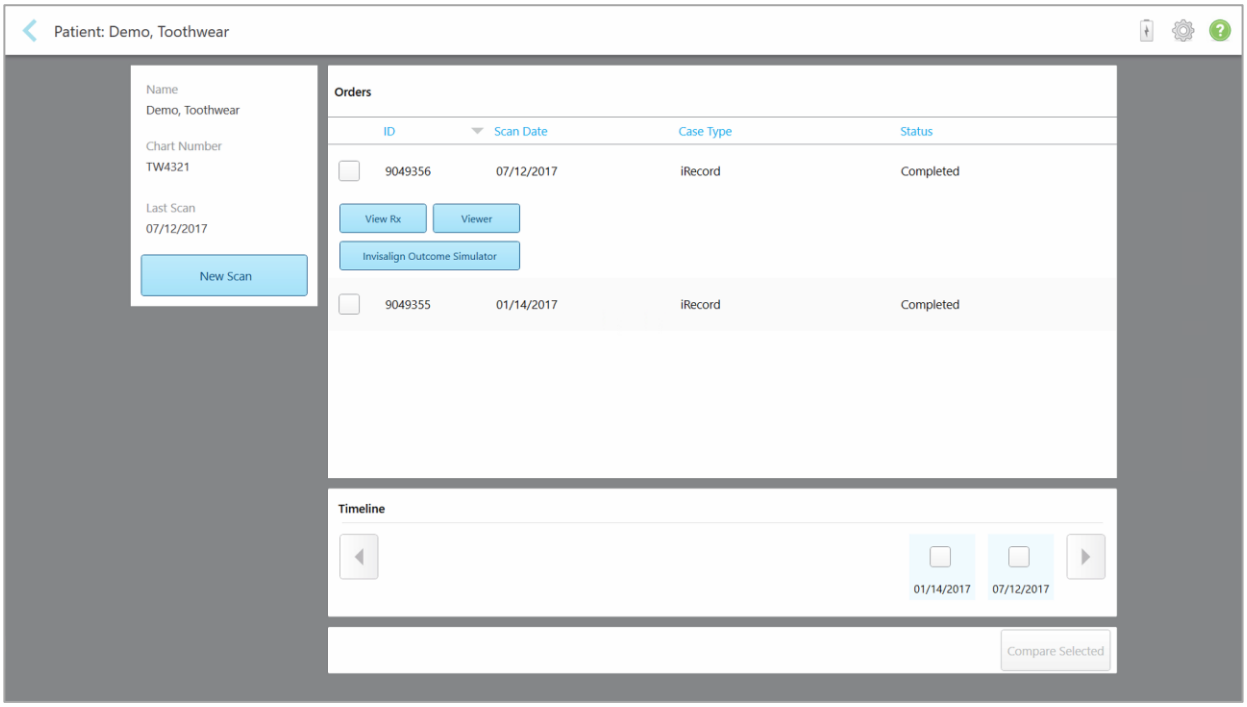

Figure 127: Patient's profile page

From the patient's profile page, you can:

- Create a new scan for the specific patient, described in section 5.3
- View the Rx details, described in section 5.4
- View the patient's previous scans in the Viewer, as described in section 5.5
- Compare 2 previous scans using iTero TimeLapse technology, described in section 5.5.1
- View any Invisalign-related processes

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5.3 Creating a new scan for a specific patient

If required, you can create a new scan for a specific patient. The Rx will be opened with the patient's details already filled in.

To create a new scan for a specific patient:

1. In the patient's profile page, tap **New Scan**.

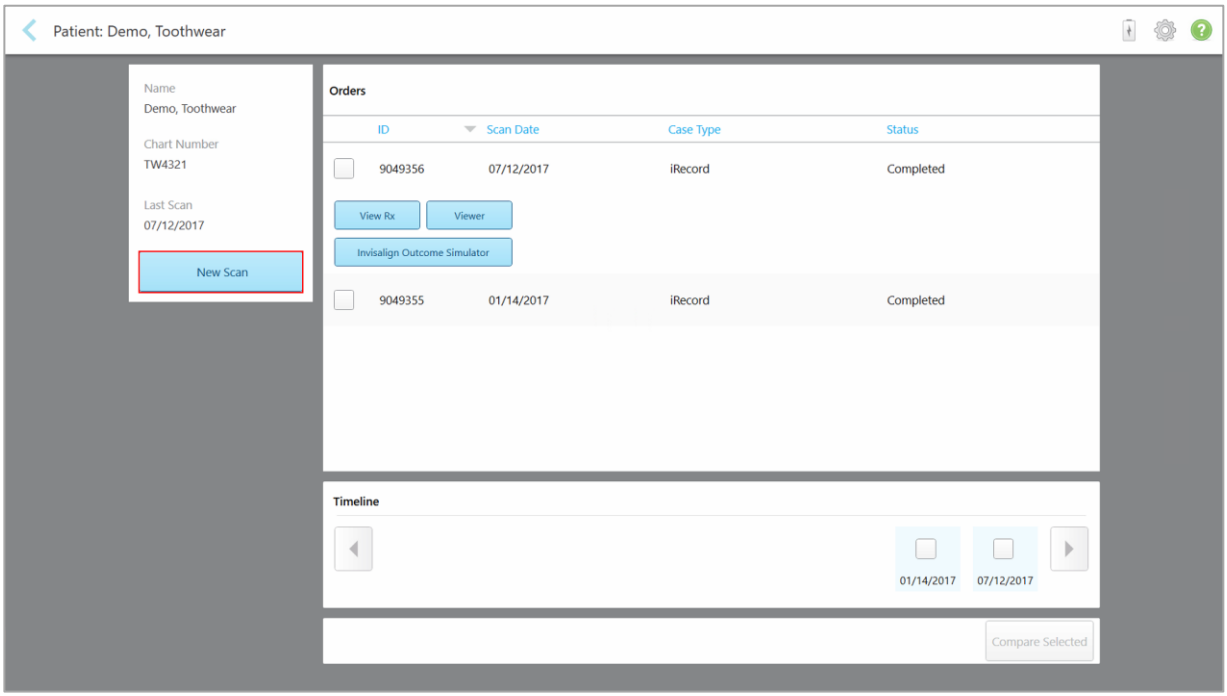

Figure 128: Patient's profile page – New Scan option

The *New Scan* window is displayed.

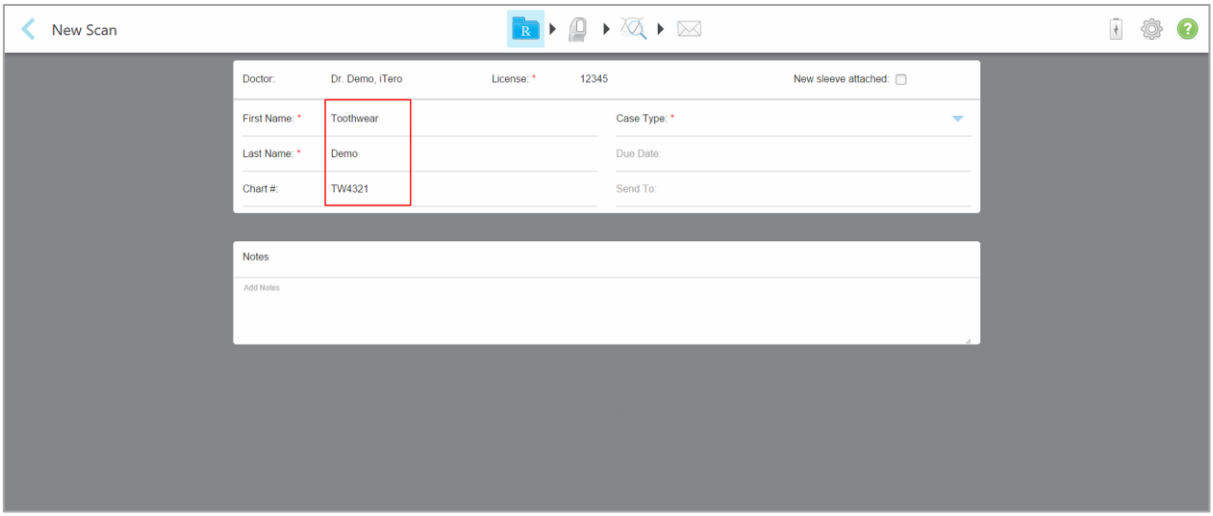

Figure 129: New Scan window with patient's details already filled in

2. Fill in the rest of the Rx details according to the new requirements.

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5.4 Viewing the Rx

If required, you can view the Rx of a previous order.

To view the Rx of a previous order:

1. In the patient's profile page, select the order for which to view the Rx and then tap **View Rx**.

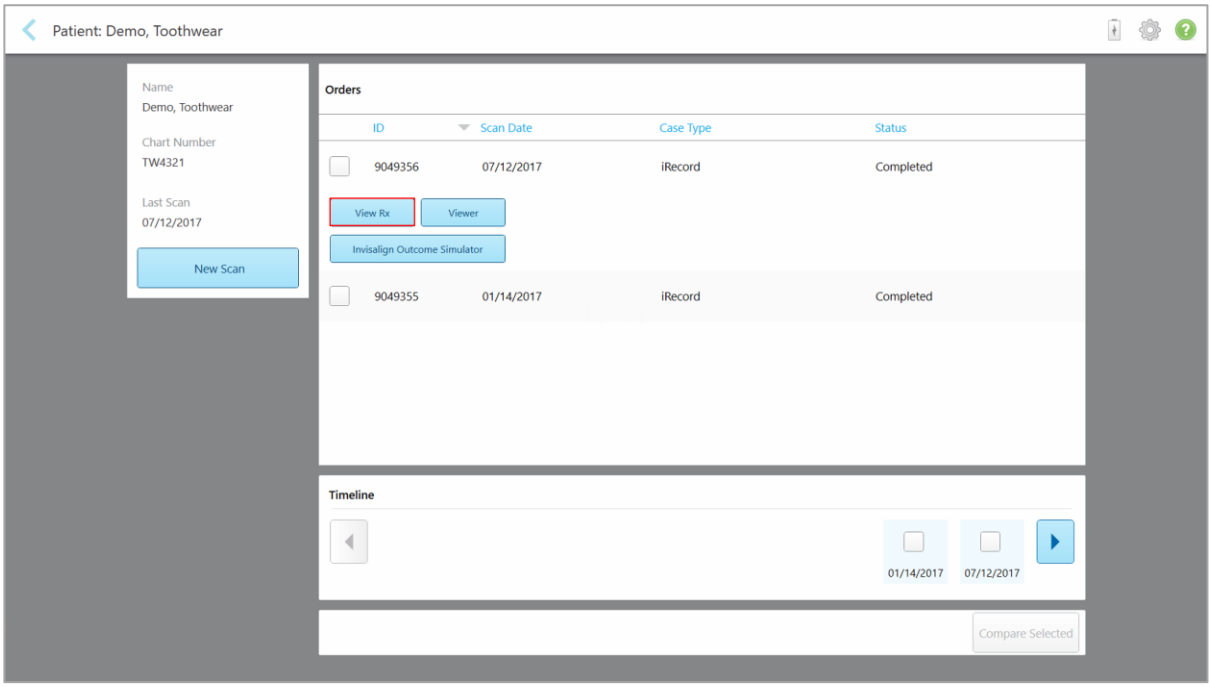

Figure 130: Patient's profile page – View Rx option

The *Rx Details* window is displayed.

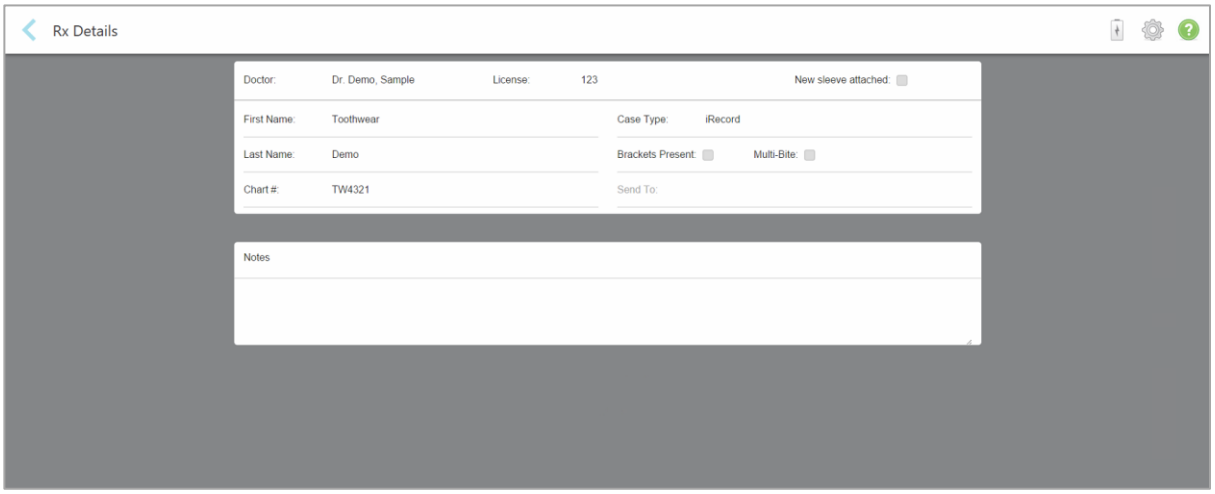

Figure 131: Rx Details window

2. Tap to return to the patient's profile page.

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5.5 Viewing previous scans in the Viewer

If required, you can display previous scans in the Viewer.

To view a previous scan in the Viewer:

1. In the patient's profile page, tap the scan you want to display in the Viewer and then tap **Viewer**.

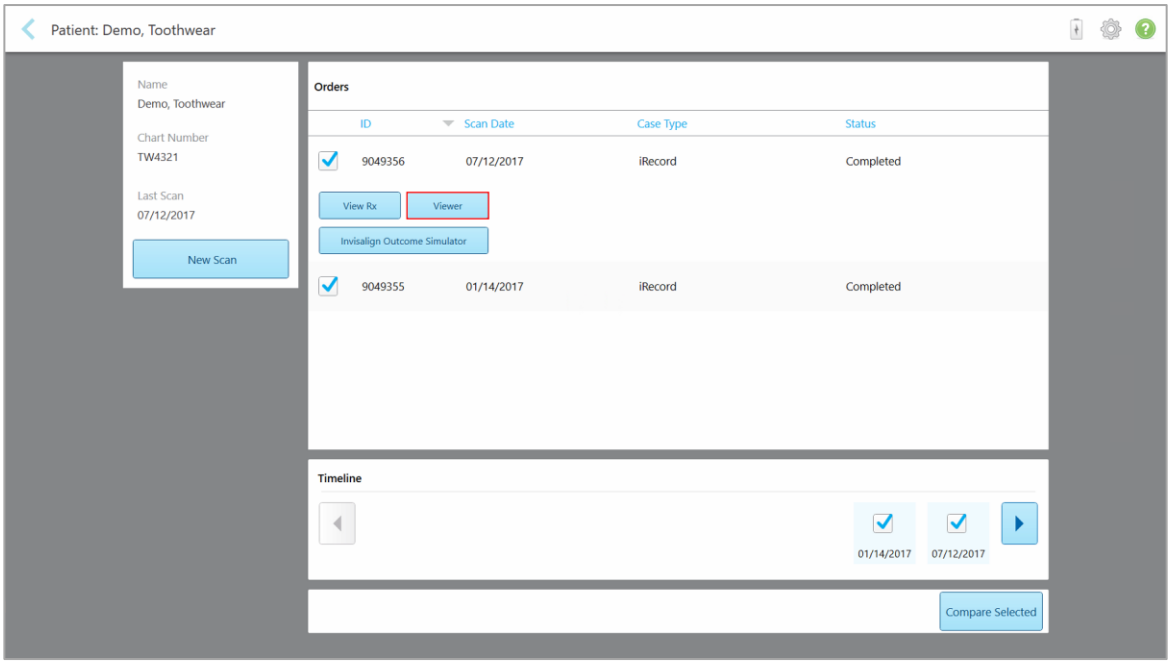

Figure 132: Patient's profile page – Viewer option

The scan is displayed in the Viewer.

Figure 133: Scan displayed in the Viewer

For more information on working with the Viewer, see section 4.7.

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5.5.1 Comparing previous scans using iTero TimeLapse technology

Patients who are scanned on a regular basis can have their scans analyzed using iTero TimeLapse technology.

iTero TimeLapse technology compares 2 of the patient's previously captured 3D scans to allow visualization of the changes of the patient's teeth, tooth structure, and oral soft tissues over the period between the scans. For example, iTero TimeLapse technology can display tooth wear, gingival recession, and tooth movement over the relevant period.

Note: iTero TimeLapse technology is available for iRecord and orthodontic case types only.

To use iTero TimeLapse technology:

1. Select the patient for whom to create an iTero TimeLapse visualization.
2. In the patient's profile page, select two scans to compare. You can select the scans by selecting the check boxes next to the relevant orders, or by selecting the check boxes in the **Timeline** area at the bottom of the page.

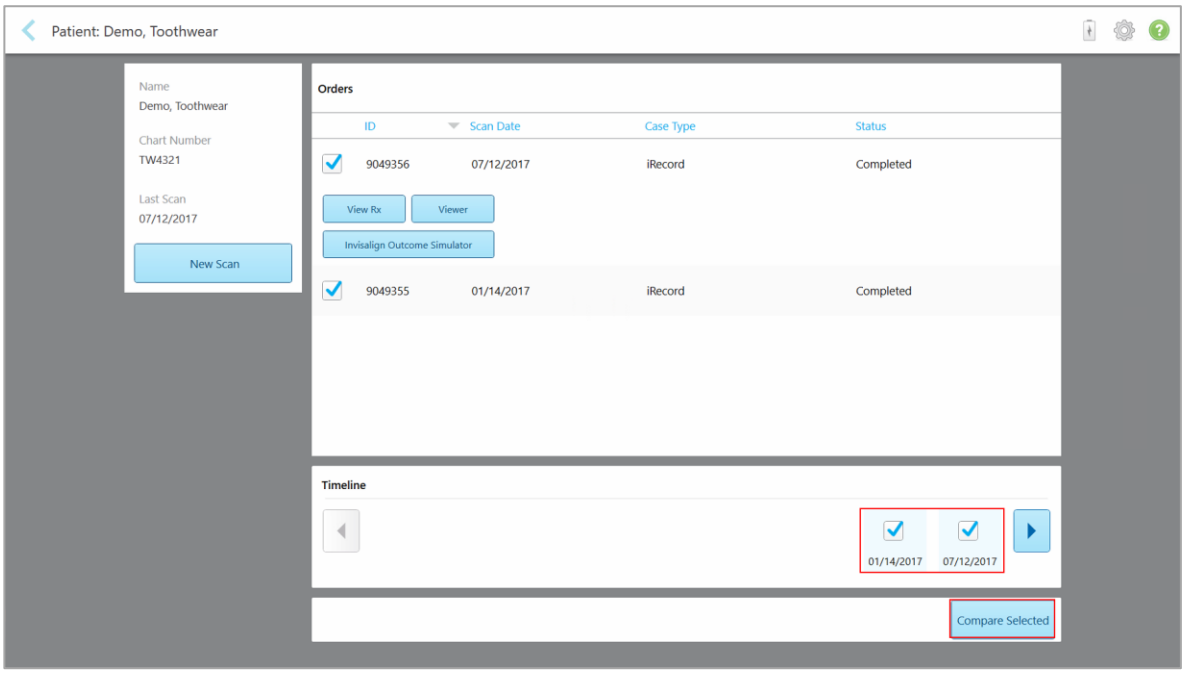

Figure 134: iTero TimeLapse – selecting the scans to compare

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3. Tap the **Compare Selected** button to compare and analyze the scans.

   The *iTero TimeLapse window* is displayed, highlighting the areas with changes between the scans. The darker the color, the bigger the change between the scans, as displayed in the legend (scale measurements are in millimeters).

Figure 135: iTero TimeLapse window showing the highlighted changes between the scans

Note: Changes are highlighted only when the scans are displayed in monochrome mode.

If required, tap to move the scan to the default occlusal view – lower arch with anterior teeth at the bottom and upper arch with anterior teeth at the top and both arches in a frontal view like the iRecord default view.

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4. Drag the loupe onto the model to view areas of interest and potential treatment areas in the animation window.

   An animation is displayed, comparing the state of the teeth in the current area of interest on the selected scan dates.

Figure 136: Area of interest from the first scan displayed in the animation window

Figure 137: Area of interest from the second scan displayed in the animation window

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You can zoom in to the image in the animation window or tap the pause button to pause the animation.

If required, you can change the scale of the changes displayed.

a. On the legend, tap **Scale**.

The legend is expanded to display a list of ranges, in millimeters:

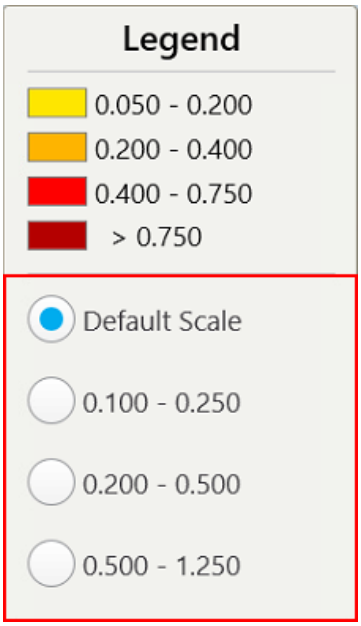

Figure 138: iTero TimeLapse scale options

b. Select the required scale.

The changes are displayed according to the new scale.

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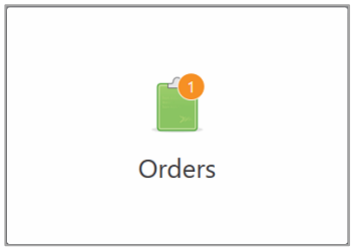
6 Working with orders

Tap the **Orders** button to display a list of all your orders. The button may contain a badge that indicates the number of orders that have not been submitted yet.



The *Orders* page is made up of two panes listing the orders that are still in progress and the ones that have already been submitted.

You can view the following details for each order: the patient's name, the scan date, case type, and the status of the order.

The order could have one of the following statuses, depending on the case type:

- **Rx Created:** The Rx has been filled in, but the patient has not been scanned yet.
- **Scanning:** The scan process is in progress
- **Sending:** The scan is in the process of being sent
- **Sent:** The case has been sent
- **iTero Modeling:** The order has been sent to iTero Modeling
- **Lab Review:** The order has been sent to the lab for review
- **Align Production:** The case is undergoing an internal process
- **Exporting to Doctor Site:** The case is on the way to the IDS portal
- **Completed:** The flow is completed

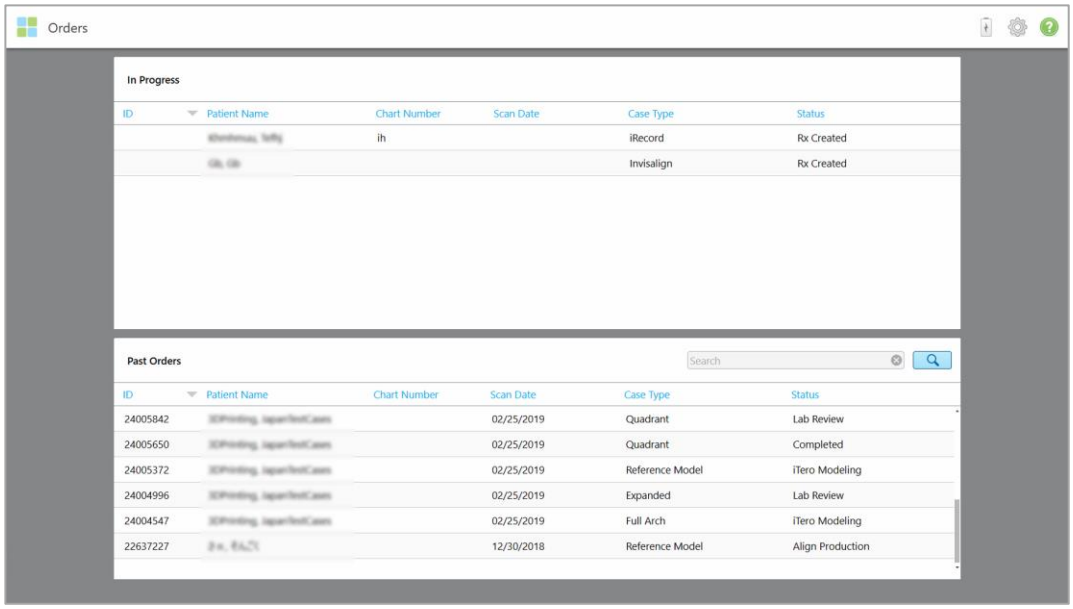


Figure 139: Orders page

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To view or review orders:

1. Tap the **Orders** button on the home screen.

   The *Orders* page is displayed, showing two panes – **In Progress** orders and **Past Orders**.

   - **In Progress:** Scans have not yet been submitted.
   - **Past Orders:** Scans have already been submitted.

2. Tap on an order in the **In Progress** pane to view the following options:

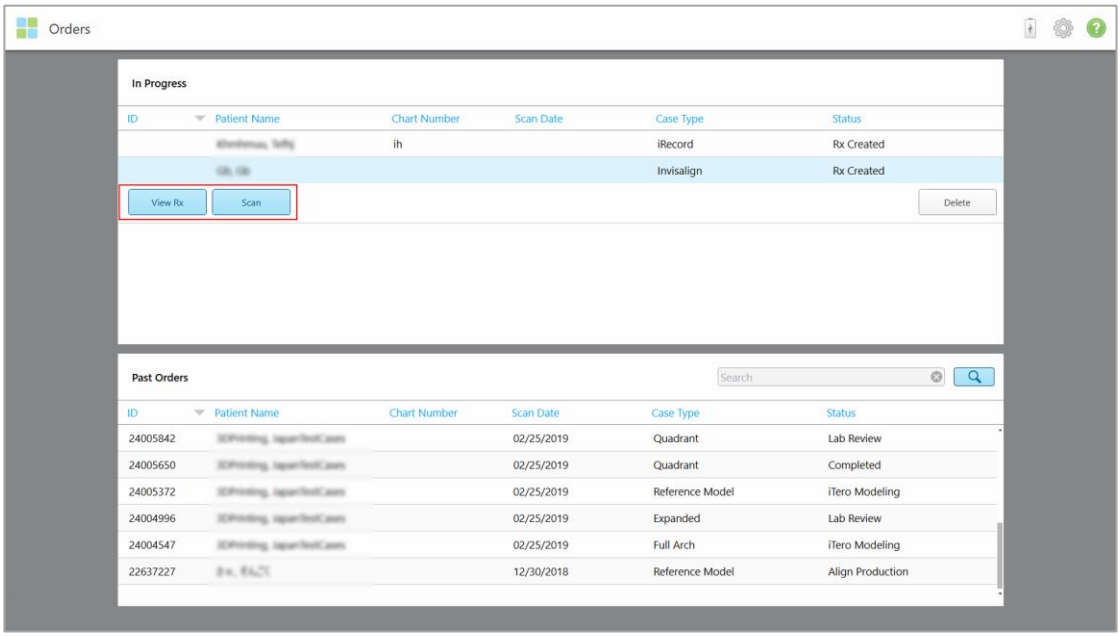

Figure 140: In Progress pane – options

- **View Rx:** Opens the *Rx Details* window, enabling you to view the prescription for this order.
- **Scan:** Opens the *Scan* window, enabling you to create a new scan or continue scanning the patient.
- **View Scans:** Opens the *View* window, enabling you to review the current scan.

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3. Tap an order in the **Past Orders** pane to view the following options, depending on the case type:

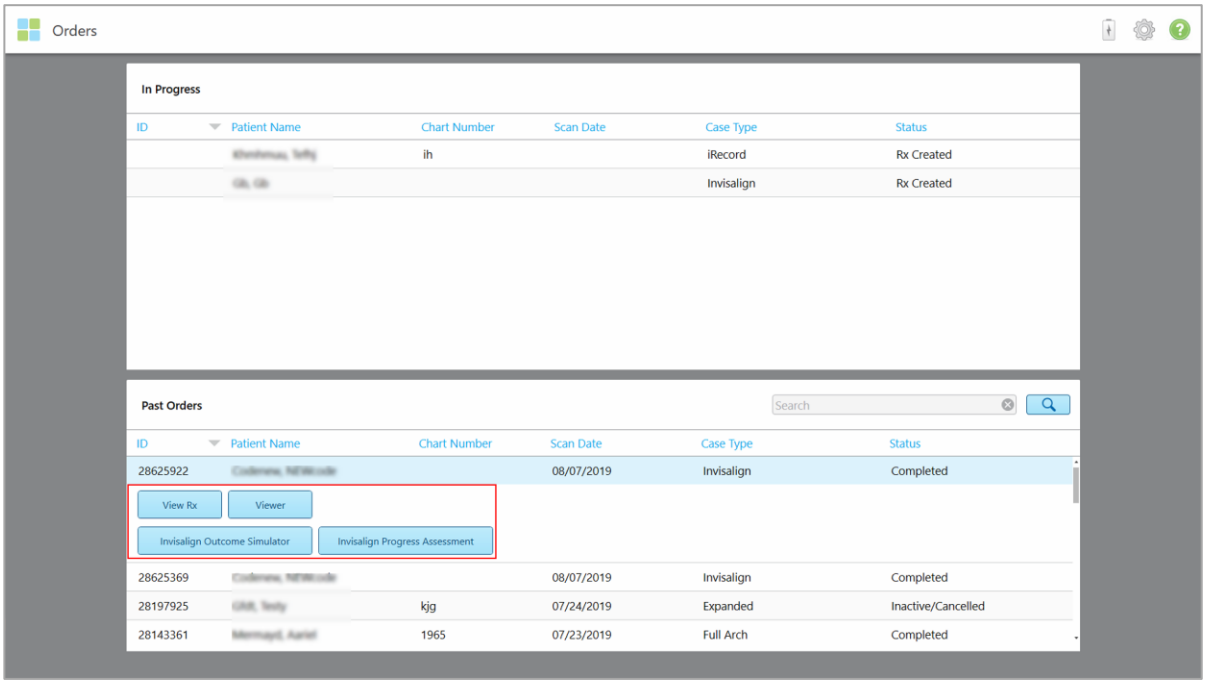

Figure 141: Past Orders pane – options

- **View Rx:** Opens the *Rx Details* window, enabling you to view the prescription for this order.
- **Viewer:** Opens the *Viewer* window, enabling you to view and manipulate the model.
- **Add Rx:** Opens the *New Scan* window and enables you to add a prescription for this order (only applicable for Orthodontic orders and available for up to 21 days after a scan).
- Invisalign users can also select the following Invisalign features:
  - Invisalign Go Outcome Simulator
  - Invisalign Go Case Assessment
  - Invisalign Outcome Simulator
  - Invisalign Progress Assessment

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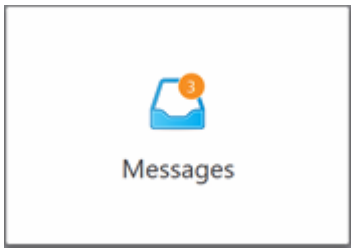
7 Viewing messages

The *Messages* page displays notifications, updates, and other system messages from Align Technology, for example, product updates, upcoming educational sessions, or internet connectivity issues.

If relevant, you can view the number of new or unread messages on the badge on the **Messages** button.



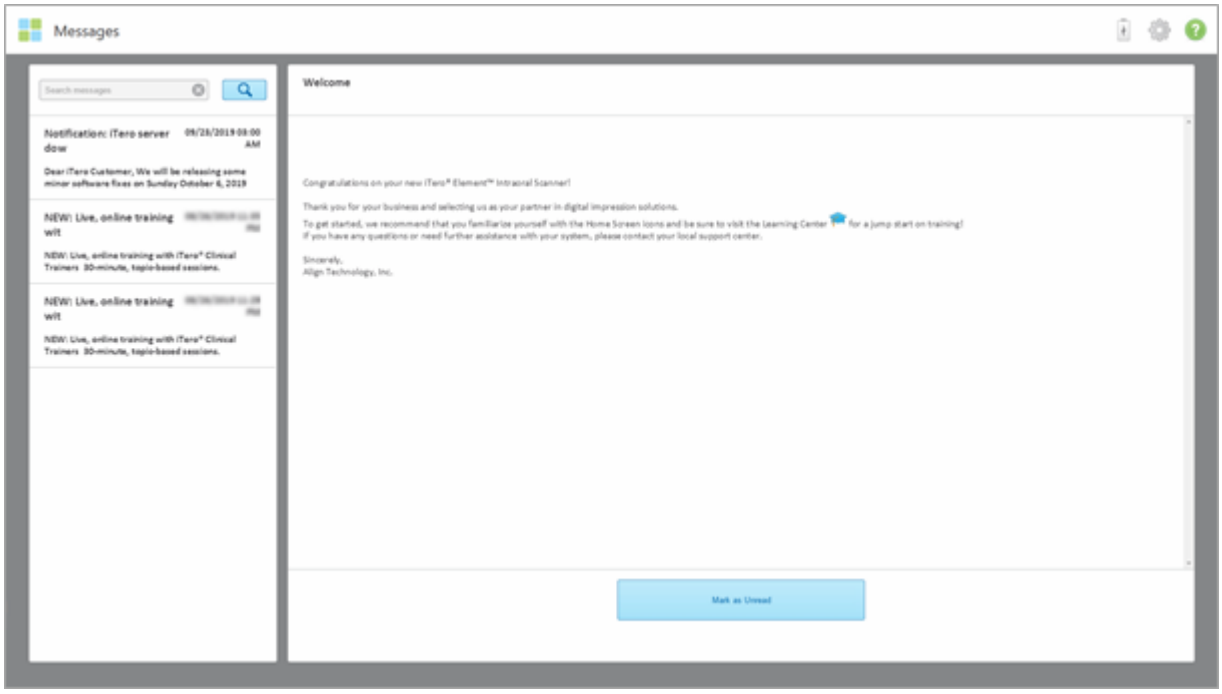


Figure 142: Messages page

To view the messages:

1. Tap the **Messages** button on the home screen.

   A list of notifications, updates, and other messages from Align Technology is displayed.

2. In the left pane, quickly search for a specific message by subject title or scroll down the pane to find a specific message.

3. To mark any message as unread, tap **Mark as Unread**.

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8 Working with MyiTero

MyiTero is a web-based portal, with the same look-and-feel as the iTero Element 5D software. It enables users to carry out administrative tasks such as filling in a new Rx on any supported device, for example, a PC or a tablet, without using valuable scanner time. In addition, it enables viewing 3D models after they have been created by the scanner, and tracking orders.

For more information on working with MyiTero, please refer to the *MyiTero User Manual*.

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9 iTero Invisalign features

9.1 Invisalign Outcome Simulator

The Invisalign Outcome Simulator is a software tool that enables you to show the patients the simulated outcome of their Invisalign treatment.

You can make real-time adjustments to the simulated outcome while showing the patient. This tool will provide additional information for the patient in their decision to accept treatment.

For more information on the Invisalign Outcome Simulator, refer to the *Invisalign Outcome Simulator User Guide* http://storagy-itero-production-us.s3.amazonaws.com/download/en-us/iOSim_User_Guide.pdf.

9.2 Invisalign Progress Assessment

The Progress Assessment tool includes a report that is a color-coded tooth movement table to assist the user in making treatment decisions to track the patient's progress in their ClinCheck treatment plan.

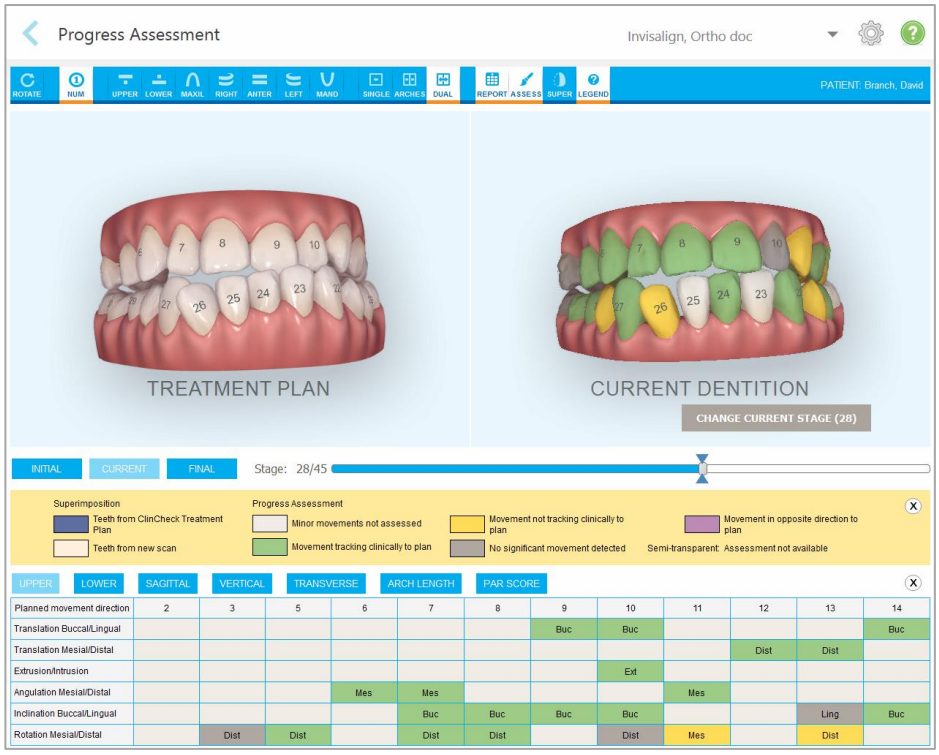

Figure 143: Progress Assessment window

For more information regarding the Invisalign Progress Assessment tool, refer to the **Progress Assessment** section in the *Invisalign Outcome Simulator User Guide* http://storagy-itero-production-us.s3.amazonaws.com/download/en-us/iOSim_User_Guide.pdf.

9.3 Invisalign Go system

Invisalign Go is a low-stage aligner product that helps you assess and treat your patients in just a few clicks, with guidance every step of the way.

For more information regarding the Invisalign Go System, refer to the Invisalign documentation.

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10 Care and maintenance

10.1 Handling the wand and cable

The wand contains delicate components and should be handled with care.

When not in use, the wand should be kept in its cradle, with the blue protective sleeve attached. If you have an iTero Element 5D laptop configuration, the wand should be stored in the supplied carry case when the system is not in use.

Between patients, undo any twists and knots in the wand cable in order to relieve all tension. If the cable cap detaches from the wand, gently reattach it.

The wand and cradle must be cleaned and disinfected before the first use and after each use, between patients. For more information on cleaning and disinfecting the wand and cradle, see sections 10.2 and 10.3, below.

10.2 Cleaning and disinfecting the wand

The iTero Element 5D wand requires the following procedures for cleaning and disinfection.

These procedures must be carried out:

- Before the first-time use
- After each use, between patients

WARNING Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials to prevent biological hazard.

You should follow all the cleaning and disinfecting steps below to ensure that the wand is properly reprocessed and ready for use.

10.2.1 Handling

1. Ensure all working surfaces used throughout this process are cleaned and disinfected per internal clinic procedures.
2. Disconnect the wand from the screen, and place it on a clean and clutter-free surface with the optical window facing upwards.
3. Remove the protective sleeve or wand barrier sleeve, making sure not to touch the optical surface of the wand.

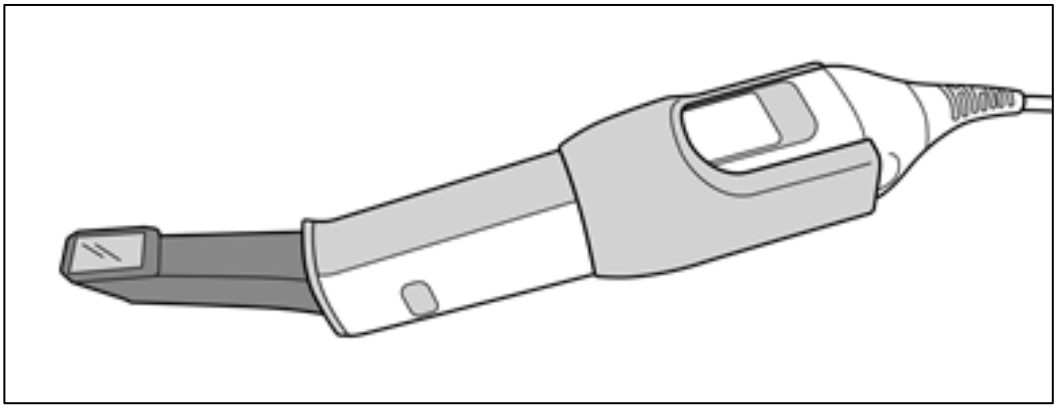

Figure 144: Wand without a sleeve

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10.2.2 Preparation before cleaning and disinfection

1. Visually inspect the wand for any noticeable damage, for example, deterioration such as corrosion, discoloration, cracks.

   WARNING Do not use the wand if any damage is found. Please contact iTero Customer Support for further instructions.

2. Prepare the following:
   - Required cleaning and disinfecting materials:
     - CaviWipes1
     - 70% isopropyl alcohol (IPA)
     - Dry lint-free wipes
     - Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter. Cat # 3770 or equivalent)
   - Protective clothing and work environment
     - Please follow the cleaning and disinfection material manufacturers' instructions

     Note: Replace cleaning and disinfection materials (brushes/wipes) if visibly damaged or soiled.

Before starting the cleaning and disinfection procedure, put on the protective clothing.

10.2.3 Cleaning and disinfection – Wand

Before cleaning and disinfecting the wand, ensure that the protective sleeve or barrier sleeve has been removed.

Note: The vent cover should not be removed.

Cleaning

1. Using CaviWipes1, remove any gross contaminants on the wand body and wand tip for a minimum of one (1) minute.

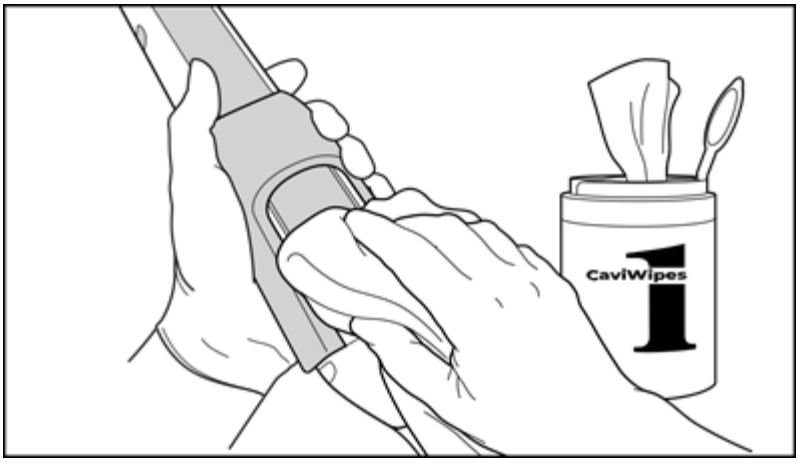

Figure 145: Remove gross contaminants using CaviWipes1

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2. Using the soft bristle brush, remove any remaining marks and stains on the wand body and wand tip, paying close attention to the cracks and crevices. Brush until visibly clean.

   CAUTION: Do not use the brush on the optical surface to prevent damage to the wand.

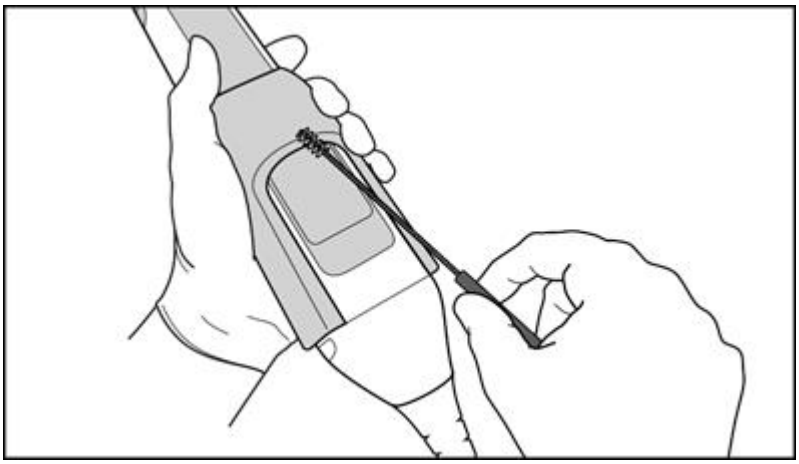

Figure 146: Remove marks and stains using a soft bristle brush

3. Using CaviWipes1, remove any remaining contaminants on the wand body and wand tip.
4. Visually inspect the device in a well-lit area to ensure all surfaces are visibly clean.

Disinfection

1. Using CaviWipes1, thoroughly dampen all external surfaces of the wand body and wand tip, including the optical surface and ensure they remain wet for a minimum of one (1) minute.

   Note: Use multiple wipes, as necessary, to keep the wand surfaces wet for the full one (1) minute contact time.

2. Using lint-free wipe(s) wetted (but not dripping) with 70% Isopropyl Alcohol (IPA), thoroughly wipe the optical surface of the wand one (1) time and until visibly clean.

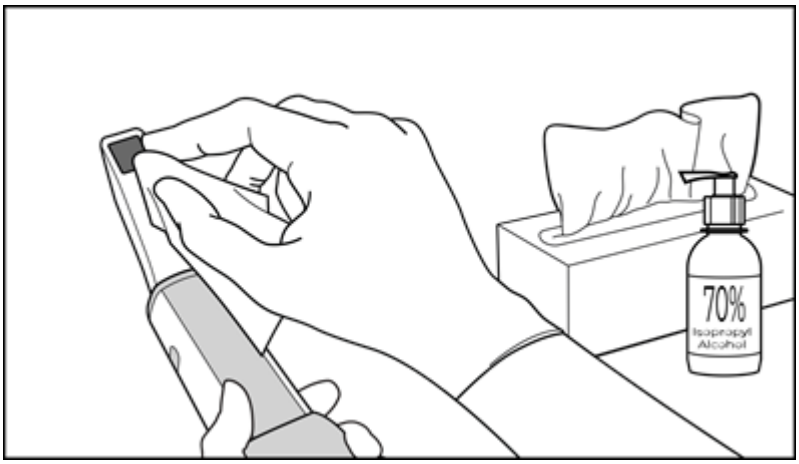

Figure 147: Wipe the optical surface of the wand with IPA

3. Wait until the optical surface dries (approximately 5–10 seconds).
4. Remove any residue from the optical surface using a dry lint-free wipe.

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10.2.4 Drying – wand body

Air-dry the disinfected wand at room temperature.

10.2.5 Storage

1. Visually inspect the wand for any noticeable damage, for example, deterioration such as corrosion, discoloration, pitting, and cracks. Pay special attention to the optical surface, making sure it remains clean.

   WARNING Do not use the wand if any damage is found. Please contact iTero Support for further instructions.

2. Inspect the vent cover for noticeable damage, and check that it fits securely on the wand. If the vent cover is damaged or you are unable to secure it in place, replace it with one of the spare vent covers that were shipped with the system. For more information on replacing the vent cover, see section 10.2.5.1 below.

   Note: When you replace the vent cover, please order an additional vent cover to ensure that you have a spare if needed.

3. Assemble the blue protective sleeve on the wand tip.
4. Reconnect the wand to the back of the screen, and place inside the cleaned and disinfected cradle, as described in section 10.3.

The iTero Element 5D laptop configuration wand should be stored in the carrying case when not in use.

10.2.5.1 Removing and replacing the wand vent cover

1. Remove the protective sleeve from the wand.
2. Press both dimples on the wand vent cover to release the locking snaps, and then pull the vent cover towards the tip of the wand and gently remove it.

Figure 148: Release and remove the vent cover

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3. Gently insert the tip of the wand into a new vent cover, making sure that the vent cover dimples are aligned towards the top of the wand.

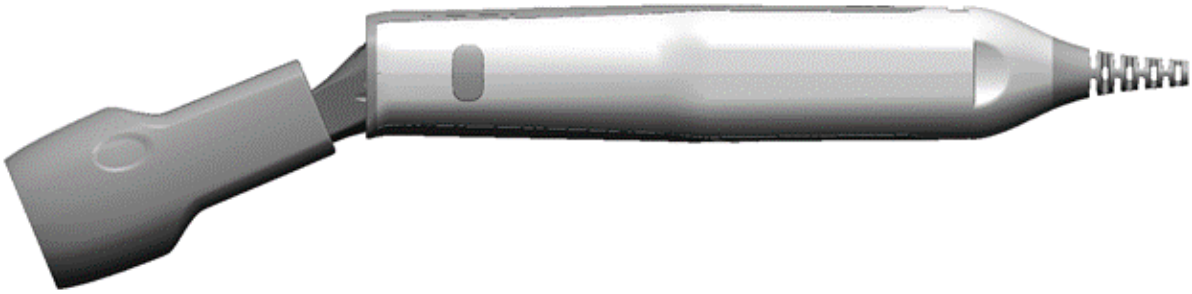

Figure 149: Insert the tip of the wand into the new vent cover

4. Pull on the vent cover until it locks into place.

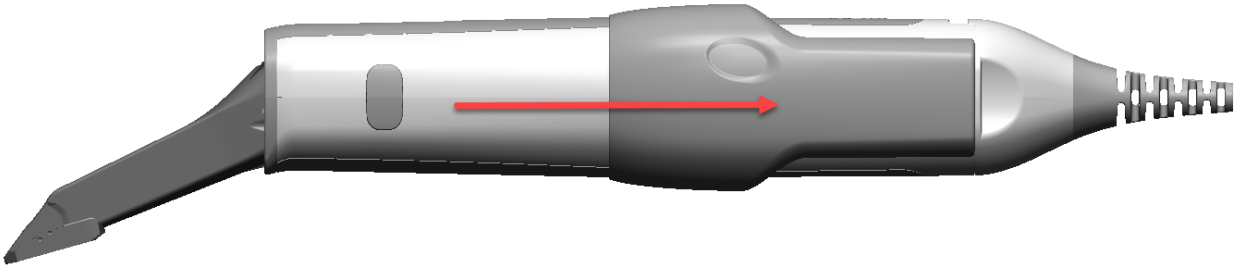

Figure 150: Pull on the vent cover until it locks into place

5. Ensure that the vent cover is placed properly on the wand by checking that the rear end of the vent cover reaches the cable cap, as shown by the red line below.

Figure 151: Check that the rear end of the vent cover reaches the cable cap

6. Replace the protective sleeve and place the wand in the cradle.

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10.3 Cleaning and disinfecting the cradle

The iTero Element 5D cradle requires the following procedures for cleaning and disinfection.

These procedures must be carried out:

- Before the first-time use
- After each use, between patients

WARNING Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials to prevent biological hazard.

You should follow all the cleaning and disinfecting steps below to ensure that the cradle is properly reprocessed and ready for use.

10.3.1 Handling

Ensure that all surface areas used throughout this process are cleaned and disinfected per internal clinic procedures.

- If relevant, disconnect the wand and place it on a clean and clutter-free surface with the optical window facing upwards.

10.3.2 Preparation before cleaning and disinfection

1. Visually inspect the cradle for any noticeable damage, for example, deterioration such as discoloration, pitting, and cracks.

   CAUTION: Do not use the cradle if any damage is found. Please contact iTero Customer Support for further instructions.

2. Prepare the following:
   - Required cleaning and disinfecting materials:
     - CaviWipes1
     - Soft bristle brush (e.g. Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter. Cat # 3770 or equivalent))
   - Protective clothing and environment
     - Please follow the cleaning and disinfecting material manufacturers' instructions

   Note: Replace cleaning and disinfection materials (brushes/wipes) if visibly damaged or soiled.

Before starting the cleaning and disinfection procedure, put on the protective clothing.

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10.3.3 Cleaning and disinfection – cradle

Cleaning

1. Using CaviWipes1, remove any gross contaminants on the cradle for a minimum of one (1) minute.

Figure 152: Remove gross contaminants on the cradle using CaviWipes1

2. Using the soft bristle brush, remove any remaining marks and stains on the cradle, paying close attention to the cracks and crevices.

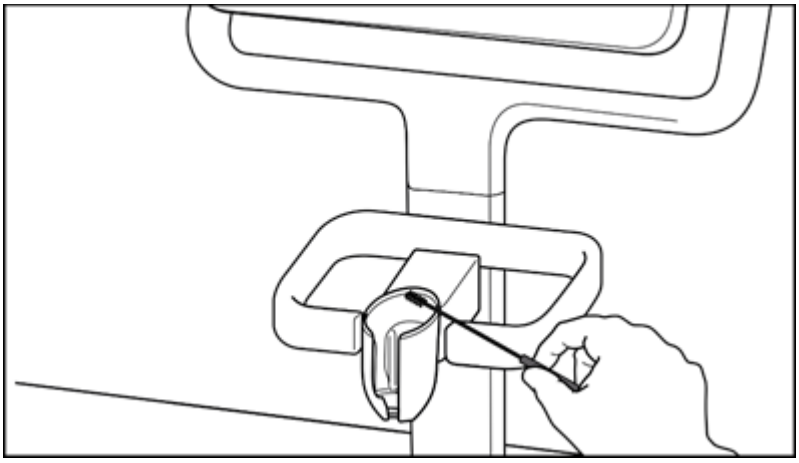

Figure 153: Remove remaining marks and stains on the cradle using the soft bristle brush

3. Using CaviWipes1, remove any remaining contaminants on the cradle.
4. Visually inspect the cradle in a well-lit area to ensure all surfaces are visibly clean.

Disinfection

- Using CaviWipes 1, thoroughly dampen all external surfaces of the cradle and ensure they remain wet for a minimum of one (1) minute.
- **Note:** Use multiple wipes, as necessary, to keep the cradle surfaces wet for the full one (1) minute contact time.

10.3.4 Drying – cradle

Air-dry the disinfected cradle at room temperature.

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10.3.5 Storage

Visually inspect the cradle for any noticeable damage, for example, deterioration such as discoloration, pitting, and cracks.

WARNING Do not use the cradle if any damage is found. Please contact iTero Customer Support for further instructions.

The iTero Element 5D laptop configuration cradle should be stored in the carrying case when not in use.

10.4 Cleaning the scanner touch screen

The scanner touch screen must be cleaned between patients, as follows:

1. Clean all outer surfaces of the system using approved disinfectant wipes, or spray disinfectant on a clean lint-free wipe and follow the manufacturer's instructions.
2. Remove any residual liquid disinfectant with a clean lint-free wipe.

Note: Do not use abrasive cleaners and/or corrosive cleaning agents or disinfectants with acids, bases, oxidizing agents, and solvents.

10.5 Webcam maintenance

The supplied webcam is maintenance-free and can be cleaned with a lint-free wipe if required.

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11 Clinic LAN network guidelines

11.1 Introduction

The iTero Element 5D scanner uses Wi-Fi to send and retrieve scans to and from the iTero cloud.

Below are some helpful guidelines for the best Wi-Fi connection.

Levels of Wi-Fi Internet Connectivity

Excellent	Good	Fair	Weak
>-50 dBm	-50 to -60 dBm	-60 to -70 dBm	<-70 dBm

IMPORTANT: In order to achieve the best performance of your iTero Element 5D scanner, ensure that the Wi-Fi signal strength is Excellent or at least Good.

WARNING Never connect the LAN cable to the iTero Element 5D, in order to prevent electrical shock.

11.2 Preparations

- The required modem/router should be configured with the WPA2 security standard, including a password.
- Ensure that your IT professional staff will be available when the scanner installation is planned to take place.
- Make sure that your Wi-Fi SSID credentials are available: Login & password.
- The minimum Wi-Fi strength signal for the system should display at least two lines, as shown above.
- Following are some suggestions for the office IT personnel, regarding what should be considered in order to prevent issues such as access or connectivity to/with the iTero scanner:
  - Hostname recommendations related to Align services listening to ports 80 and 443, as described in section 11.7.
  - Do not prevent FTP communication since the scanner sends specific file types (.3ds and.3dc/.3dm).
  - Disable any proxy clients for data communication through TCP/IP.
  - Do not add the scanner to any domain group.
  - Do not run any group policy on the scanner as it may disrupt its proper functioning.

11.3 Router guidelines

Minimum standards: 802.11N / 802.11AC

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11.4 Internet connection guidelines

In order to achieve the best performance of your iTero Element 5D scanner, ensure that your internet connection upload speed is at least 1Mbps per scanner. Also, note that any additional devices connected to the internet in parallel to the scanner may affect the scanner's performance.

11.5 Firewall

Open the following ports (in case of a firewall):

- 80 - HTTP - TCP
- 443 - HTTPS - TCP

11.6 Wi-Fi tips

Wi-Fi routers allow you to access your internet system using a Wi-Fi connection from essentially any place within the functional range of the wireless network. Nevertheless, the number, depth, and position of walls, ceilings, or additional partitions that the wireless signals must travel through may limit the range and strength of the signal. Normal signals vary, depending on the material types and background RF (radio frequency) noise in your home or business.

- Be sure to have a minimal number of walls and ceilings between the router and other network devices. Each barrier can reduce your adapter's range by 1-3 meters (3-9 feet).
- Be sure to have a straight line, free of any partition, between network devices. Even a wall that seems rather thin can block a signal of 1 meter (3 feet) if the wall angle is shifted by only 2 degrees. To achieve the best reception, place all the devices so that the Wi-Fi signal travels straight through a wall or partition (instead of at an angle).
- Construction materials make a difference. A solid metal door, or aluminum nails, can be very dense and may have an adverse effect on a Wi-Fi signal. Try to position access points, wireless routers, and computers so that the signal travels through drywalls or open doorways. Materials and objects such as glass, steel, metal, walls with insulation, water tanks (aquariums), mirrors, file cabinets, brick, and concrete may reduce your wireless signal.
- Keep your iTero product away (at least 3-6 feet or 1-2 meters) from electrical devices or appliances that generate RF noise.
- If you are using 2.4GHz cordless phones or X-10 (wireless products such as ceiling fans, remote lights, and home security systems), your wireless connection may be severely degraded or entirely drop. The base of many wireless devices transmits an RF signal, even if the device is not in use. Position your other wireless devices as far as possible from your scanner and router.
- In your area, there may be more than one active wireless network. Each network uses one or more channels. If the channel is near your system channels, the communication may gradually decline. Ask your IT department to check this, and if required, change the channel numbers used by your network.

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11.7 Align hostname recommendations

Align constantly improves its products and services, and can therefore commit to a Hostname, rather than a specific IP address.

The following list of hostnames was created to provide Align's scanners the proper operation functions, in order to be able to utilize all the advanced capabilities of the scanner performance.

Align hostnames recommendation:

Hostname	Port
Mycadent.com	80, 443
Myaligntech.com	80, 443
Export.mycadent.com	80, 443
Cboserver.mycadent.com	80, 443
Matstore.invisalign.com	80, 443
Matstore2.invisalign.com	80, 443
Matstore3.invisalign.com	80, 443
Matstore4.invisalign.com	80, 443
Matstoresg.invisalign.com	80, 443
Matstorechn.invisalign.com.cn	80, 443
AWS IP range - Amazon global CDN service - IP address range varies depending on the location of the scanner.	80, 443
cloud.myitero.com	443
speedtest.tele2.net	80
alignapi.aligntech.com	80, 443
http://www.google.com	80, 443
http://www.microsoft.com	80, 443
http://www.yahoo.com	80, 443
iterosec.aligntech.com	80, 443
storage.cloud.aligntech.com	443

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12 EMC declaration

IEC 60601-1-2 Edition 4.0 (2014)	Medical electrical equipment; Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests
CFR 47 FCC	Rules and Regulations: Part 15. Radio frequency devices. Subpart B: Unintentional radiators (2015)
ETSI EN 301 489-1, ETSI EN 301 489-17 (relevant for iTero Element 5D wheel stand only)	Electromagnetic Compatibility (EMC) standard for radio equipment and services
Environment for intended use	Professional Healthcare and Home Healthcare Facility Environment

The iTero Element 5D intraoral scanner essential performances are:

- Display near-infrared imaging without interference on the iTero Element 5D touch screen as part of the caries-detection solution.
- Stored scan data is accessible and can be displayed.

Due to electromagnetic disturbance, in some cases, the image may disappear and a non-communication message will appear on the touch screen. The scanner will return to operation mode after user intervention or auto-recovery.

The following is a summary of the EMC test results for iTero Element 5D scanners:

Test	Standard	Severity level/lines	Test results
Emission (IEC 60601-1-2 section 7)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B on 230, 220, 120 & 100 VAC mains @ 50 Hz; 220 VAC mains @ 60 Hz	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	230 VAC mains @ 50 Hz & 220 V @ 50 Hz & 60 Hz	Complies
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	230 VAC mains @ 50 Hz & 220 VAC mains @ 50 Hz	Complies

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Test	Standard	Severity level/lines	Test results
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on 230 VAC @ 50 Hz; & 220 VAC mains @ 60 Hz; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±2.0 CM / ±1.0 kV DM on 230 VAC mains @ 50 Hz; & 220 VAC mains @ 60 Hz; Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0, 6.0 V_{RMS} on 230 VAC mains @ 50 Hz & 220 VAC mains @ 60 Hz & Wand cable; 0.15÷ 80 MHz, 80% AM @ 1 kHz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 VAC & 100 VAC mains @ 50 Hz: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles; on 220 VAC mains @ 60 Hz: 0 % - 0.5 cycle & 1 cycle; 70% - 30 cycles; 0% - 300 cycles	Complies

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Test	Standard	Severity level/lines	Test results
Emission (per ETSI EN 301 489-1, ETSI EN 301 489-17) **Relevant for iTero Element 5D wheel stand configuration only**			
Conducted emissions on mains terminals in freq. range 150 kHz - 30 MHz	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 55032	Group 1 Class B 230 VAC mains	Complies
Radiated emissions in freq. range 30 - 6000 MHz	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 55032	Class B	Complies
Harmonic current test	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 61000-3-2	230 VAC mains	Complies
Flicker tests	ETSI EN 301 489-1 / EN 61000-3-3	230 VAC mains	Complies
Immunity (per ETSI EN 301 489-1, ETSI EN 301 489-17) **Relevant for iTero Element 5D wheel stand configuration only**			
Immunity from Electrostatic discharge (ESD)	EN 61000-4-2	4 kV contact discharge 8 kV air discharge	Complies
Immunity from radiated electromagnetic fields	EN 61000-4-3	3.0 V/m, 80 MHz ÷ 6.0 GHz, 80% AM, 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	EN 61000-4-4	AC mains: ± 1.0 kV; Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	EN 61000-4-5	AC mains: ± 1.0 kV DM / ± 2.0 kV CM, Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	EN 61000-4-6	AC mains: 3.0 V_{RMS}; 0.15÷80 MHz, 80% AM @ 1 kHz	Complies
Immunity from Voltage interruptions	EN 61000-4-11	AC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

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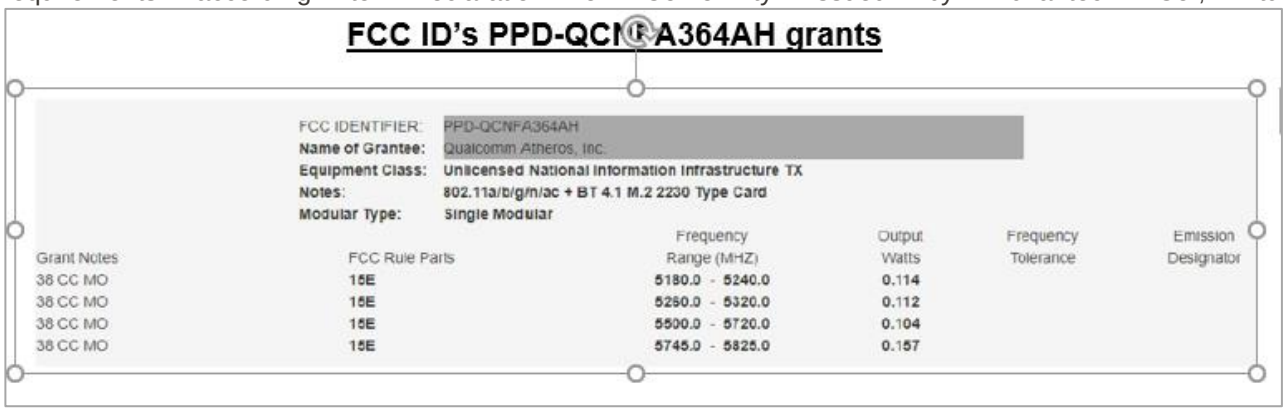
13 FCC compliance information statement (SDoC)

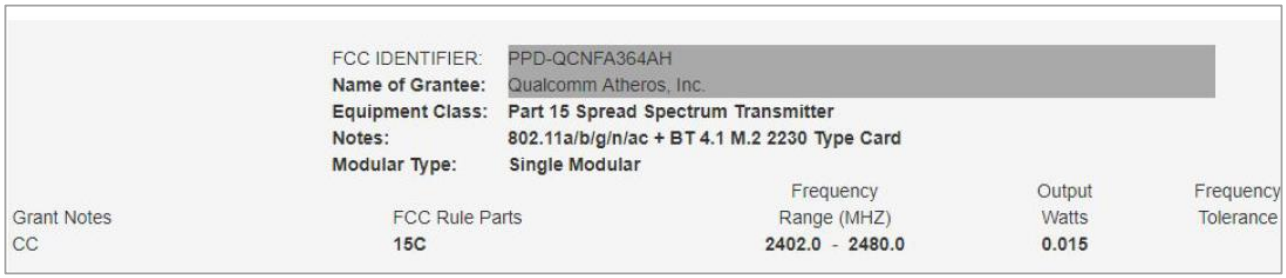
We Align Technology Ltd. declare:

Type of equipment: The iTero Element 5D is an integrated intraoral imaging system capable of intraoral optical impression for CAD/CAM of dental devices which also captures 2D color images, and Near Infrared (NIR) images.

Brand name or trademark: iTero Element 5D

Modular component used: Qualcomm Atheros, FCC ID PPD-QCNFA364AH complies with FCC requirements according to Declaration of Conformity issued by Advantech Co., Ltd.





Country of origin: Israel

Manufacturer: Align Technology Ltd.

Responsible Party name (IN USA): Align Technology, Inc.

Address: 2820 Orchard Parkway San Jose, California 95134 USA

Telephone: +1 (408) 470-1000

Internet E-Mail: iterosupport@aligntech.com

Standards applied:

- FCC Part 15B - For Unintentional radiators, performed by Align & Advantech
- FCC Part 15C for 2.4GHz band based on Qualcomm Atheros FCC ID PPD- QCNFA364AH, performed by Qualcomm Atheros
- FCC Part 15E for the 5GHz bands based on Qualcomm Atheros
- FCC ID PPD-QCNFA364AH, performed by Qualcomm Atheros

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Test reports/ certificates issued by:

- FCC Part15B - Test report number 9812320398 by SII & T171020D04-A-D by Compliance Certification Services Inc.
- FCC Part15 C&E - Test report number RF150107E07B-1 by Bureau Veritas Consumer Product Service (H.K) Ltd.

Declaration of Conformity as issued by Advantech Co., Ltd. for panel PC model POC-ALG, which declares compliance with FCC requirements

As manufacturer we declare under our sole of responsibility that the equipment follows the provisions of FCC Equipment Authorization Procedures under CERTIFICATION (47 CFR Section 2.907) and/or SUPPLIER'S DECLARATION OF CONFORMITY (47 CFR Section 2.906) as stated above.

Thus, is placed on the product

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14 iTero Element product security whitepaper

This whitepaper applies to the iTero® Element™ optical impression system series. Depending on the version of the product you have procured, there may be differences in the features of the product. In addition, as this artifact was created at a point-in-time, changes may have occurred in Align Technology's product security practices to address evolution and maturation in the product security ecosystem.

We understand the life sciences and healthcare industry and are addressing security across the organization.

The threat of cyber-attacks to life sciences and healthcare products is constantly evolving. With this in mind, we proactively established a product security program that is focused on minimizing the security risk associated with our products, enabling us to be vigilant when facing emerging threats and to continuously improve our products.

We recognized the importance of incorporating security and privacy considerations by design and throughout our product lifecycle. To accomplish this, we established a cross-functional product security team, including representatives from engineering/software development, security, legal/privacy, information technology, and quality.

We identify security risks using robust risk management processes.

Align Technology is committed to addressing and minimizing security and privacy risks in the products that we design, develop, and maintain. We conduct in-depth assessments of our products so that we can implement appropriate risk mitigation measures at the outset of product development. Based on the risk level of the product, as well as the functionality of the product, the below methodology is applied.

Product Security Risk Assessment (PSRA): Align Technology conducted a PSRA on the iTero® Element™ optical impression system series. The assessment methodology included planning and information gathering, identifying applicable product profiles, developing a component register, performing a controls analysis, identifying vulnerabilities, calculating the risk rating of the vulnerability, identifying appropriated mitigating controls, and calculating the residual risk rating. Security and privacy risks considered as part of the assessment leverage industry leading practice security risk frameworks including, but not limited to, NIST 800-53, NIST CSF, UL 2900-2-1, ISO 80001, and the FDA's Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

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Security and privacy features of the product.

The following non-exhaustive security controls are implemented in the iTero® Element™ optical impression system series:

- **PII data-at-rest is encrypted:** Personally Identifiable Information (PII) is stored in an encrypted database. This helps to prevent an attacker from capturing patient and customer information stored on the scanner.
- **Data-in-transit is encrypted:** The scan data that is backed up to Align servers is transmitted over transport layer security (TLS) encryption using trusted certificates. This helps to prevent an attacker from capturing patient and customer information while in transit.
- **Anti-malware protections are in place:** The scanners come with pre-installed Trend Micro anti-virus software that checks for malicious files on the system. The anti-virus software definitions are updated frequently and scans are scheduled to run daily on the devices.
- **Remote maintenance is not possible without permission:** The devices use TeamViewer for establishing a remote session. The TeamViewer software requires a User ID and password that must be supplied from the customer to the Align service personnel before the connection can take place.
- **Changes to the operating system and software are restricted:** The scanners implement a kiosk mode that prevents the user from making any unwanted changes to the operating system and software components.
- **User access management controls are enforced:** A user account and password are required to utilize the scanners. This helps protect access to the scanner and protects against unauthorized use.
- **Segregation of duties is applied:** The scanners offer the ability to register multiple user accounts with different roles to one scanner. There are roles for Doctor, Assistant, and Support Technician. This helps ensure the ability to track activities performed by individual users better protecting the device.

If you have any questions or concerns about the risks as they are described, please do not hesitate to contact TRM@aligntech.com or privacy@aligntech.com.

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15 System specifications

15.1 System specifications – iTero Element 5D wheel stand configuration

Monitor	21.5” HD touch screen
Wand	The wand emits red laser light (680nm Class 1), as well as white LED emissions and 850nm LED emissions.
Wireless LAN	A LAN card provides local network communications with wireless connectivity.
Security	Please see the product security whitepaper in section 14.
Operating Power	100-240VAC- 50/60 Hz – 200VA (max)
Operating Temperature	18°C to 26°C / 64.4°F to 78.8°F **Note:** The system will operate with degraded performance – without scanning ability – when subjected to temperatures of 10°C to 17°C (50°F to 62.6°F) and 27°C to 40°C (80.60°F to 104°F)
Storage/Transportation Temperature	-5°C to 50°C / 23°F to 122°F
Operating Pressure & Altitude	Pressure: 520 mmHg to 771 mmHg (-69 kPa to -103 kPa) Altitude: -400 feet to 10,000 feet
Storage/Transportation Pressure & Altitude	Pressure: 430 mmHg to 760 mmHg (~57 kPa to ~101 kPa) Altitude: 0 feet to 15,000 feet
Relative Humidity	Operating: 40% to 70% Storage: 30% to 90%
Dimensions	**iTero HD touch screen:** • Height: 356 mm (~14 in) • Width: 552 mm (~21.7 in) • Depth: 65 mm (~2.5 in) **Wand:** • Length: 346 mm (13.3 in) • Width: 50 mm (2.0 in) • Depth: 68 mm (2.7 in) **Wheel stand:** • Height: 1280 mm (~50 in) • Width: 645 mm (~25 in) • Depth: 625 mm (~24.5 in)
Net Weight	iTero HD touch screen: 8.3 kg (~18.3 lbs.) Wand: 0.47 kg (~1 lbs.), without the cable Wheel stand: 13.6 kg (~30 lbs.)
Shipping Weight	~37.5 kg (~83 lbs.)

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15.2 System specifications – iTero Element 5D laptop configuration

Monitor	Laptop touch screen
Wand	The wand emits red laser light (680nm Class 1), as well as white LED emissions and 850nm LED emissions.
Security	Align Technology takes the responsibility of securing the data of our customers and their patients very seriously. All patient data is transmitted via an encrypted TLS channel, and communications and information are securely stored, enabling our customers to take reasonable measures to protect their patient data.
Operating power	100-240VAC- 50/60 Hz – 40VA (max)
Operating temperature	18°C to 26°C / 64.4°F to 78.8°F
Storage/Transportation temperature	-5°to 50°C / 23° to 122°F
Operating pressure & altitude	Pressure: 520 mmHg to 760 mmHg (~69 kPa to ~101 kPa) Altitude: 0 feet to 10,000 feet
Storage/Transportation pressure & altitude	Pressure: 430 mmHg to 760 mmHg (~57 kPa to ~101 kPa) Altitude: 0 feet to 15,000 feet
Relative humidity	Operating: 40% to 70% Storage: 30% to 90%
Dimensions	iTero Element 5D laptop configuration hub: • Length: 206 mm (~8 in) • Width: 94 mm (~3.7 in) • Depth: 36.5 mm (~1.4 in) iTero Element 5D wand: • Length: 346 mm (~13.3 in) • Width: 50 mm (~2.0 in) • Depth: 68 mm (~2.7 in) Cradle: • Length: 262 mm (~10 in) • Width: 89 mm (~3.5 in) • Depth: 52 mm (~2 in) Carrying case: • Height: 326.5 mm (~13 in) • Width: 455 mm (~18 in) • Depth: 184 mm (~7 in)
Net weight	iTero Element 5D laptop configuration hub: ~0.5 kg (~1 lbs.) iTero Element 5D wand: 0.47 kg (~1 lbs.) Empty carrying case: ~2 kg (~4.5 lbs.)
Shipping weight	~8 kg (~17.6 lbs.)

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16 Laptop requirements

The iTero Element 5D software can be installed on any laptop that meets the following requirements:

Components		Requirements
Intel CPU	9th Gen Intel	Recommended: Intel® Core™ i5-9400H Intel® Core™ i5-9300H Intel® Core™ i7-9850H Intel® Core™ i7-9750HF Intel® Core™ i7-9750H Intel® Core™ i9-9980HK Intel® Core™ i9-9880H
Intel CPU	8th Gen Quad-core / Hexa-core Intel	Recommended: 6-Core i9: i9-8950HK 6-Core i7: i7-8850H / i7-8750H / i7-8700B Minimum: 4-Core i7: i7-8809G / i7-8709G / i7-8706G / i7-8705G
Intel CPU	7th Gen Quad-core Intel	Minimum: 4-Core i7: i7-7920HQ / i7-7820HQ / i7-7820HK / i7-7820EQ / i7-7700HQ
Memory	RAM	Recommended: 16 GB Minimum: 8 GB
Hard Drive	Solid State Drive (SSD)	Minimum: 256 GB
Display	Touch screen	Minimum resolution: 1920 x 1080 (Full HD) Dual touch screen laptops are not approved for use
Ports	USB	At least one USB A port
Windows	Windows 10 Pro Edition	-

In addition, the laptop must have one of the following compatible antivirus programs installed: Norton, McAfee, or ESET

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