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”.

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”.

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

CE compliance

This device complies with Council Directive 93/42/EEC for Medical Devices.

CE
0344

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”.

Contre-indications

Pour les personnes ayant un diagnostic d'épilepsie, la lumière clignotante du ITero Scanner peut engendrer un risque de choc épileptique. Ces personnes doivent éviter tout contact visuel avec la lumière clignotante inhérente au système pendant le fonctionnement.

Conformité

Conformité laser de classe 1

Cet appareil est conforme aux normes "21 CFR 1040.10" et "EN 60825-1".

Conformité aux normes de sécurité

Cet appareil est conforme à la norme de sécurité suivante:

"IEC 60601-1 Appareils électriques médicaux – Section 1: Règles générales sur la sécurité de base et les performances essentielles".

Conformité CSA

Cet appareil est conforme à la norme CSA suivante pour le Canada et les États-Unis: «UL Std No. 60601-1 - Appareils électromédicaux, partie 1: Règles générales de sécurité».

C US

Conformité CE

Cet appareil est conforme à la directive du Conseil Européen 93/42/EEC relative aux dispositifs médicaux.

CE
0344

Conformité FCC

Cet équipement est conforme à la section 15 des règles la FCC. Son fonctionnement est soumis aux deux conditions suivantes :

1. Cet appareil ne doit causer aucune interférence nuisible.
2. Cet appareil doit accepter toute interférence reçue, y compris des interférences pouvant provoquer un fonctionnement non désiré.

FC

Avertissement de la FCC

Les modifications apportées à l'appareil qui ne sont pas expressément approuvées par le fabricant peuvent révoquer votre droit d'utiliser l'appareil en vertu des règles de la FCC.

Conformité CEM

Cet appareil est conforme à la norme CEM suivante:

"IEC 60601-1-2 Equipement médical électrique - Section 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Electromagnétisme - Exigences et essais".

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.

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.

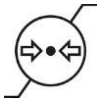
Alternating current.

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.

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.

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

Indicates the Authorized representative in the European Community.

Indicates that the device is RoHS compliant for China.

Symboles

Les symboles suivants peuvent apparaître sur les composants matériels de l'iTero Element 5D, ainsi que dans ce document et dans d'autres documents relatifs à l'iTero Element 5D.

Partout où ce symbole apparaît sur l'appareil, il est recommandé de consulter ce document pour obtenir des informations sur sa bonne utilisation.

Partie appliquée de type BF. Tout composant sur lequel ce symbole apparaît contient une isolation électrique électrique de type BF.

Une collecte séparée des déchets électriques et des équipements électroniques est requise. Conformément à la directive européenne sur les déchets d'équipements électriques et électroniques (DEEE), ne jetez pas ce produit avec les déchets ménagers ou urbains. Cet appareil contient des matériaux DEEE.

Veuillez contacter le service EARN.

Lien vers le formulaire de demande en ligne: http://b2btool.earn-service.com/aligntech/select

Attention! Ce symbole est utilisé pour souligner le fait que des avertissements ou des précautions spécifiques sont associés à l'appareil. Partout où ce symbole apparaît sur l'appareil, il est obligatoire de se référer aux informations relatives à la sécurité contenues dans ce document.

Les pièces ou accessoires sur lesquels ce symbole apparaît ne doivent pas être réutilisés.

"Rx only"

MISE EN GARDE: La loi fédérale américaine limite la vente de cet appareil par ou pour le compte d'un dentiste, d'un orthodontiste ou d'un professionnel dentaire agréé. Le système constitue un dispositif médical sur ordonnance et ne doit être manipulé que par des prestataires de soins qualifiés.

Fabricant de dispositif médical.

Numéro de commande.

Numéro de série.

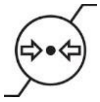
Courant alternatif.

Indique un dispositif médical qui doit être protégé de l'humidité.

Indique les limites de température auxquelles le dispositif médical peut être exposé en toute sécurité.

Indique le besoin pour l'utilisateur de consulter les instructions d'utilisation.

Numéro de lot de fabrication.



Indique la plage de pression atmosphérique à laquelle le dispositif médical peut être exposé en toute sécurité.

Indique la plage d'humidité à laquelle le dispositif médical peut être exposé en toute sécurité.

Fragile, à manipuler avec soin.

Ce côté doit être placé vers le haut.

IEC 60417-5031: Courant continu.

Tige (unité de numérisation).

Prise USB.

Batterie électrique.

IEC 60417-5009: EN ATTENTE.

ATTENTION: Ne marchez pas sur le hub de configuration pour ordinateur portable iTero Element 5D.

Indique le représentant agréé dans la communauté européenne.

Indique que l'appareil est conforme à la norme RoHS pour la Chine.

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. There is a danger of explosion if the battery is incorrectly replaced. Replace only with the same type recommended by the manufacturer. Discard used batteries according to the manufacturer's instructions.

Electric warnings

- **Electric shock hazard!!** Only authorized Align Technology technicians can remove external panels and covers. There are no user-serviceable parts inside.
- To avoid the risk of electric shock, the scanner must be connected only to a mains supply with protective grounding.
- Only an Align Technology approved web camera or disk on key should be connected to the USB sockets on the rear of the touch screen.

Laptop configuration only:

- The iTero Element 5D laptop configuration is provided with a hub containing the power supply for the wand. The hub must be kept dry and be protected against breakage.
- Connect the hub only to a laptop that is 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.
- Only the iTero wand and the approved laptop should be connected to the USB sockets on the hub.
- Only the Align Technology approved power cable should be used to connect the hub to the AC outlet.

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.

Scanner warnings

- 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. However, you should refrain from 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, so there will be no eye contact with the laser beam, flickering white LED emission, and 850nm LED emission.
- Activate the wand only while the tip of the wand is in the patient's mouth.
- Avoid placing the wand in the cradle while the scanning operation is still active.
- If a scanner malfunction occurs or if physical damage is observed, stop scanning and 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 disposable sleeve, as described in section 1.3.3.1.1, after each patient session.
  - Remove and replace gloves after each patient session.
  - Discard torn, contaminated, or removed gloves.
- Dispose of scanner 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

WARNING: 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. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical and electromagnetic interference in the healthcare environments (e.g., cellular phones, mobile two-way radios, electrical appliances, RFID), it is possible that high levels of such interference due to close proximity or strength of 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

WARNINGS:

- No modification of this equipment is allowed.
- Wheel stand configuration only: The touch screen must always be attached to the stand after assembly.

Consignes de sécurité

Avant de commencer à travailler avec le système, tous les utilisateurs doivent prendre connaissance de ces consignes de sécurité.

Alimentation électrique

Le système est alimenté via une batterie interne de qualité médicale.

Puissance de la batterie

Configuration support de roue uniquement:

- Chargement en cours - La batterie du scanner sera complètement chargée après avoir été branchée à une source d'alimentation pendant 2 heures.
- Avec une batterie complètement chargée, vous pouvez numériser jusqu'à 30 minutes.
- **Avertissement:** Le scanner est fourni avec une batterie rechargeable Li-ion. Il y a un risque d'explosion si la batterie est remplacée de manière incorrecte. Remplacez-la uniquement par une batterie identique recommandée par le fabricant. Jetez les batteries usagées conformément aux instructions du fabricant.

Avertissements électriques

- **Risque de décharge électrique!!** Seuls les techniciens agréés par Align Technology peuvent retirer les panneaux et les capots externes. L'appareil ne contient aucune pièce réparable par l'utilisateur.
- Pour éviter tout risque de choc électrique, le scanner doit être branché uniquement sur une prise de terre.
- Seule une caméra Web ou une clé USB approuvées par Align Technology peuvent être connectées aux prises USB à l'arrière de l'écran tactile.

Configuration portable uniquement:

- La configuration pour ordinateur portable iTero Element 5D est fournie avec un concentrateur contenant l’alimentation électrique de la tige. Le hub Flex doit être gardé au sec et protégé contre les chocs.
- Connectez le hub Flex uniquement à un ordinateur portable respectant les normes IEC60950 et UL60950-1. L'ordinateur portable et tous ses accessoires doivent être situés à au moins 1,5 m du patient. Ne scannez pas un patient et ne touchez pas l'ordinateur portable ou l'un de ses accessoires en même temps.
- Seuls la tige iTero et l'ordinateur portable approuvés doivent être connectés aux prises USB du hub Flex.
- Seul le câble d'alimentation approuvé par Align Technology doit être utilisé pour connecter le hub Flex à la prise de courant.

Réseau local sans fil

Le système est équipé d'une unité de réseau local sans fil.

Classifications de sécurité

- Type de protection contre les chocs électriques: Classe 1.
- Degré de protection contre les chocs électriques: Type BF.
- Degré de protection contre les infiltrations d’eau dangereuses: Ordinaire.
- L'équipement ne convient pas à une utilisation en présence de mélanges anesthésiques inflammables.
- Mode de fonctionnement: En continu.

Dispositif médical sur ordonnance

Le système constitue un dispositif médical sur ordonnance et ne doit être manipulé que par des prestataires de soins qualifiés.

Avertissements relatifs au scanner

- Le scanner émet une lumière laser rouge (680nm de classe 1), ainsi que des émissions à LED blanches et des émissions à LED de 850 nm. L'utilisation normale du scanner ne présente aucun danger pour l'œil humain. Cependant, les médecins doivent éviter de placer le scanner directement dans les yeux du patient.
- Évitez de tordre, de nouer, de tirer ou de marcher sur le câble.
- Lorsque le système n'est pas utilisé, placez la tige dans le socle avec la sonde face à l'écran tactile afin d'éviter tout contact visuel avec le faisceau laser ou l'émission de LED blanche vacillante et l'émission de LED 850nm.
- N'activez la tige que lorsque son extrémité est dans la bouche du patient.
- Évitez de placer la tige dans le socle tant que l'opération de numérisation est toujours active.
- Si un dysfonctionnement du scanner se produit ou si des dommages physiques sont observés, arrêtez la numérisation et appelez le support client.

Nettoyage & désinfection

- Pour éviter la contamination croisée, il est obligatoire de:
  - Nettoyer et désinfecter la tige comme décrit dans la section 10.2 et remplacer le manchon jetable de la tige comme décrit dans la section1.3.3.1.1, après chaque session patient.
  - Enlevez et remplacez les gants après chaque session patient.
  - Jetez les gants déchirés, contaminés ou déjà enlevés.
- Jetez les manchons du scanner conformément aux procédures d'utilisation standard ou aux réglementations locales relatives à l'élimination des déchets médicaux contaminés.

Déballage & installation

Le système doit être déballé et installé conformément aux instructions fournies par Align Technology, décrites dans cette section2.1.

Environnement de travail

- Le système doit être déplacé d'une pièce à l'autre avec le plus grand soin pour ne pas l'endommager.
- Ne bloquez pas les bouches d'aération de la tige et de l'écran.
- Le système est conçu pour une utilisation en intérieur uniquement. Il ne doit pas être exposé directement à la lumière du soleil, à une chaleur excessive ou à l'humidité.
- Configuration ordinateur portable uniquement: Si la configuration pour ordinateur portable iTero Element 5D vient juste d'être amenée dans le bureau en provenance d'un environnement chaud, froid ou humide, laissez le matériel s'adapter à la température de la pièce pour éviter la condensation interne.

Interférence électromagnétique

AVERTISSEMENT: Cet appareil a été testé et approuvé conforme aux exigences des dispositifs médicaux selon la norme IEC60601-1-2.

Cette norme est conçue pour fournir une protection raisonnable contre les interférences dangereuses dans une installation médicale classique. Cependant, en raison de la prolifération des équipements de transmission sur fréquence radio et d'autres sources d'interférence électrique et électromagnétique dans les environnements de soins de santé (par exemple, téléphones portables, radios mobiles bidirectionnelles, appareils électriques), il est possible que des niveaux élevés d'interférences dûs à la proximité ou à la force d'une source puissent entraîner des perturbations du fonctionnement de cet appareil. Dans ce cas, l'appareil peut être remis en mode de fonctionnement après une intervention de l'utilisateur ou par une récupération automatique.

Informations générales

AVERTISSEMENTS:

- Aucune modification de cet équipement n'est autorisée.
- Configuration du support de roue uniquement: l'écran tactile doit toujours être fixé au support après l'assemblage.

Table of contents

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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 the data beneath the tooth surface without harmful radiation, 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.

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 (available in selected countries only)
  Refer to http://www.itero.com/en/products/itero_element_5d for the minimum system requirements.

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

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

1.3.2.1 Transporting the iTero Element 5D laptop configuration

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 Disposable sleeve

B Touchpad

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

D Air vents

E 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.

1.3.3.1 Wand sleeves

There are 2 types of wand sleeves:

- **Protective sleeve:** When the scanner is not in use, use the blue protective sleeve to protect the optical surface of the wand.
- **Disposable sleeve:** Before scanning a patient, attach a new disposable sleeve.

Figure 6: Protective sleeve

Figure 7: Disposable sleeve

1.3.3.1.1 Replacing the wand sleeves between patients

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

Before scanning a patient, you will be prompted to confirm that a new sleeve is attached to the wand, as described in section 4.1.2.

CAUTION: Dispose of used sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

To replace the wand sleeve:

1. Pressing lightly on the center of the sleeve, pull the sleeve slowly off the wand and discard.

Figure 8: Removing a wand sleeve

WARNING: OPTICAL SURFACE!

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

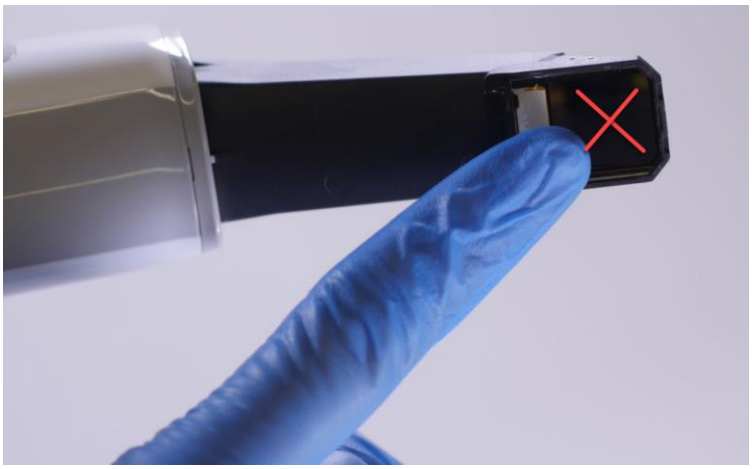


Figure 9: Optical surface of the wand

2. Clean and disinfect the wand, as described in section 10.2.
3. Gently slide a new sleeve onto the tip of the wand until it clicks into place.

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

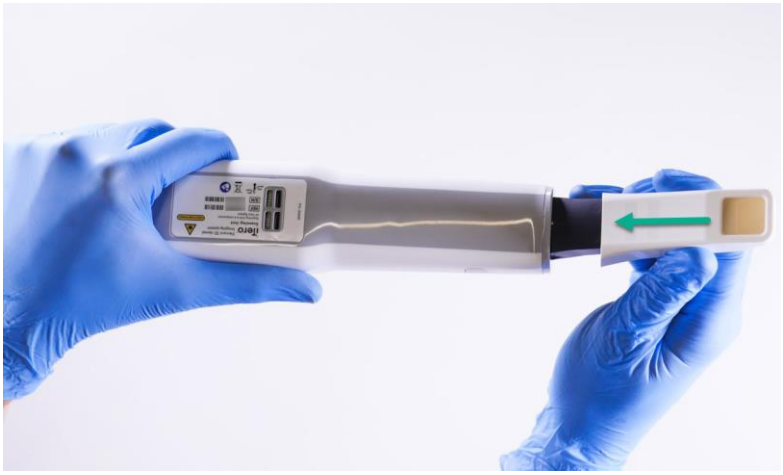


Figure 10: Gently slide the new sleeve into place

1.4 iTero Element 5D software

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

- Confirmation that a new wand sleeve is used before scanning, described in section 4.1.2
- Toggling the 3D and viewfinder display while scanning, described in section 4.2.4
- Toggling the color mode and NIRI mode in the viewfinder while scanning, described in section 4.2.5
- Viewing an area of interest after scanning using the Review tool, described in section 4.3.6

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

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) to provide imaging of the area beneath the tooth surface.

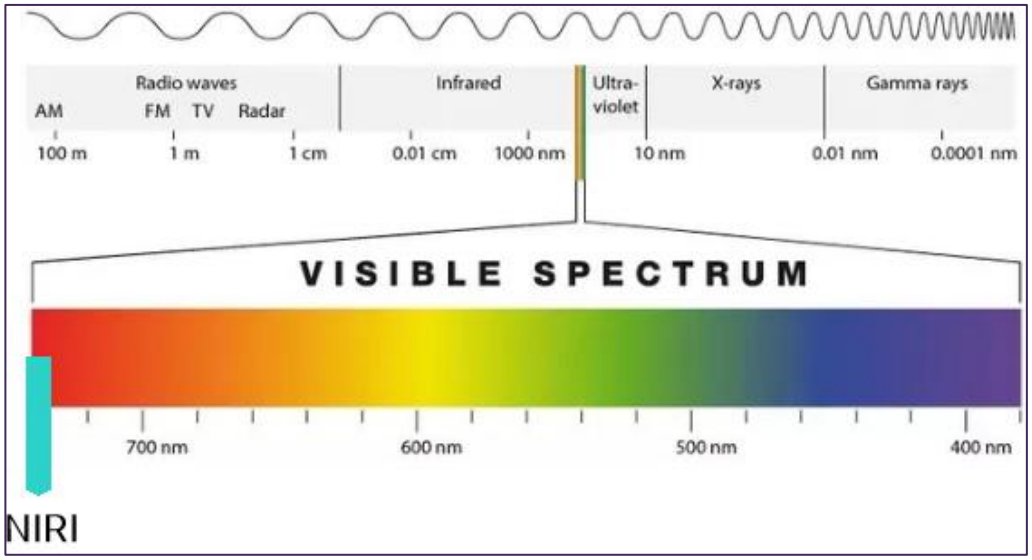
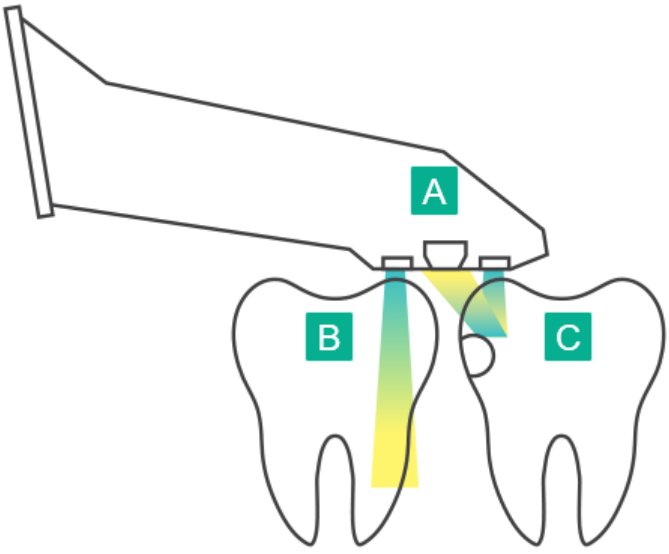


Figure 11: Visible light spectrum showing NIRI on the 850nm wavelength

When the wand is positioned above the tooth, NIRI will provide imaging of the area beneath the tooth surface.

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 bright.



A Wand positioned on the tooth surface

B Tooth enamel is translucent

C Dentin and caries are reflective

Figure 12: Reflective concept – healthy enamel is translucent while dentin and caries are reflective

Note: The NIRI image should be used in conjunction with the current standard of care for caries detection, and does not replace it.

For more information on using NIRI and the clinical benefits, please refer to http://storagy-itero-production-eu.s3.amazonaws.com/download/en/iTero-Element-5D-Clinical-Guide.pdf

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 sleeves between patients.

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.


AC power


Battery


Click

DC power


Power button

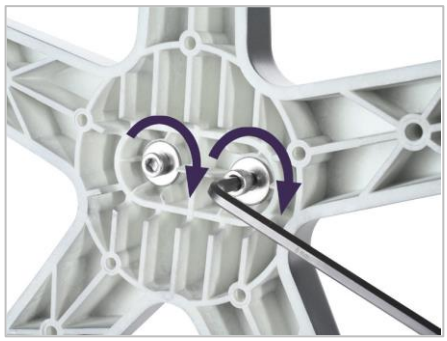

Wand


2 people are required for installation

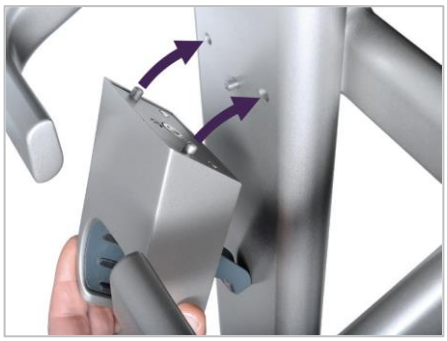
A Wheel stand
B Wand with cable
C Wand cradle
D HD touch screen
E External battery
F Power cable

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.

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.

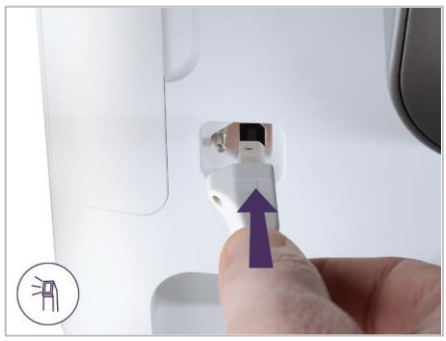
13. Turn the scanner around and tighten the thumbscrew to secure the screen.

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

Power cable inserted.

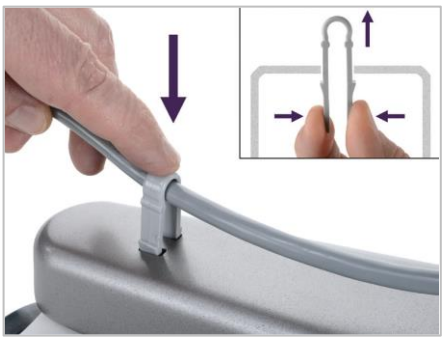
15. Attach the magnetic back cover.

16. Place the wand in the cradle.



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

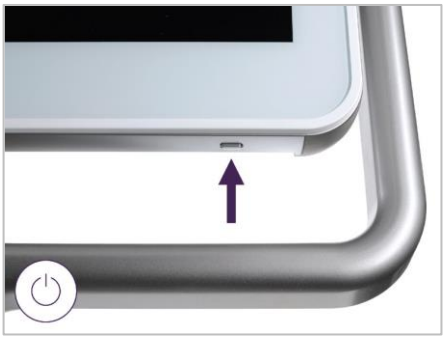
18. Connect the power cable on the bottom of the wheel stand.



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.

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.

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.

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:

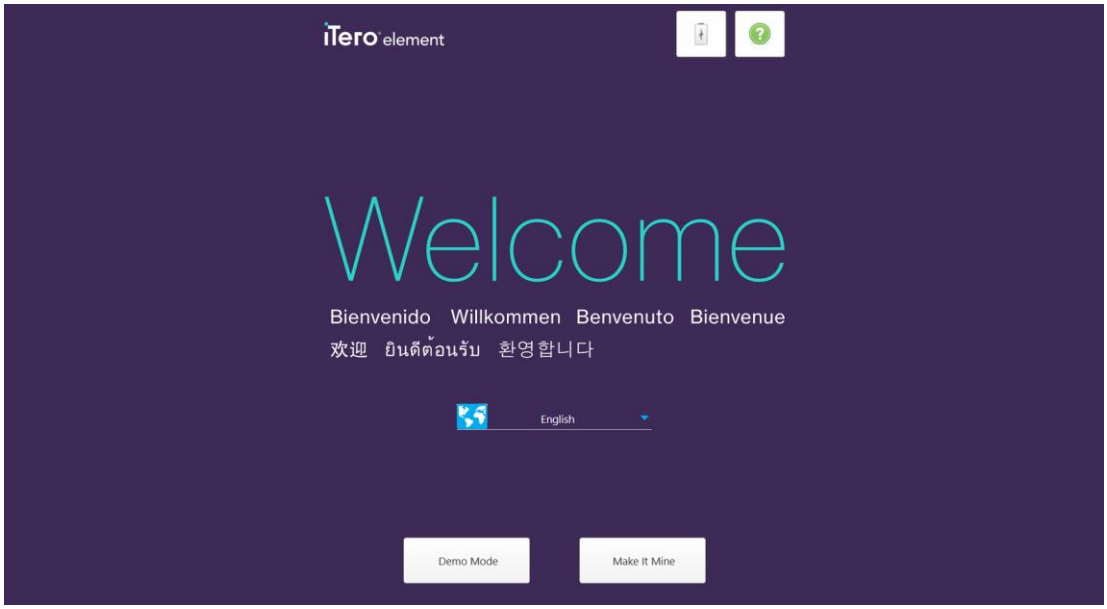


Figure 13: Welcome screen

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.

To enter Demo Mode after logging in:

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

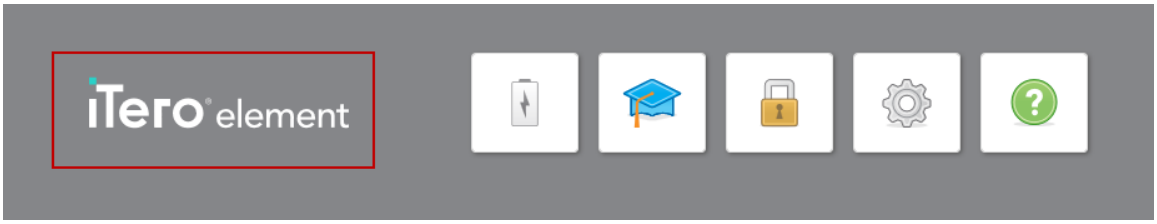


Figure 14: iTero Element logo

2. Tap **Demo Mode**.

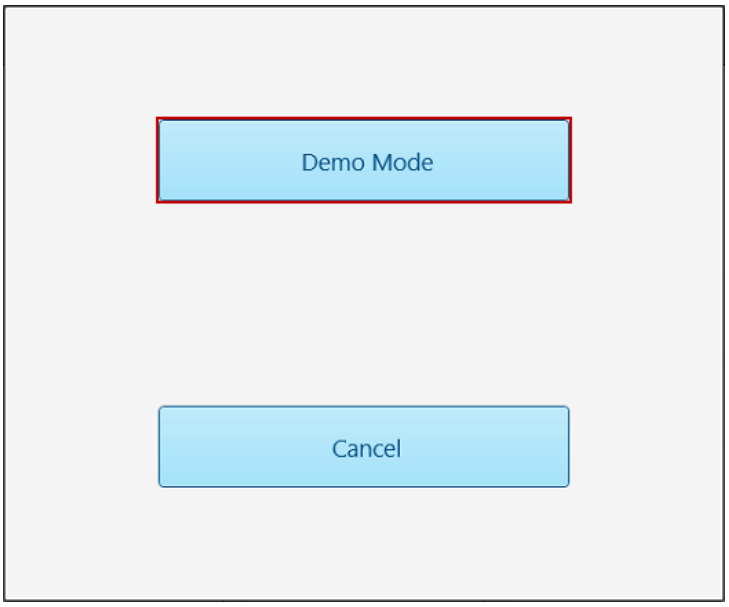


Figure 15: Demo Mode option

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

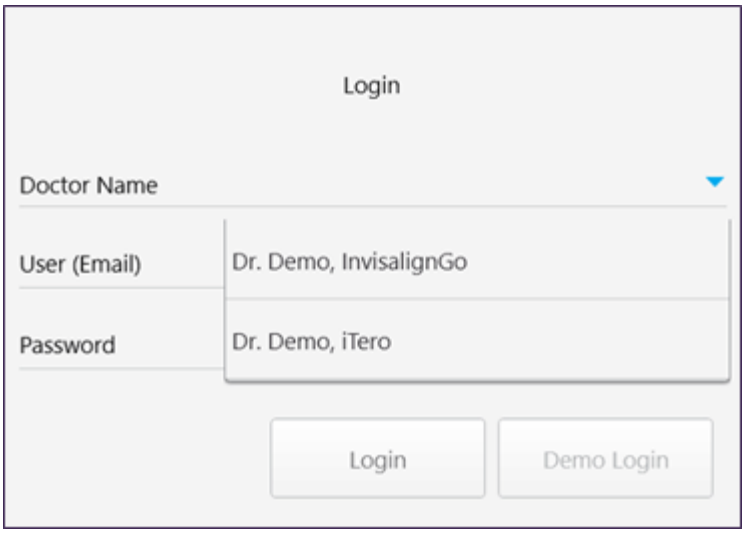


Figure 16: Login window with a list of demo users

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

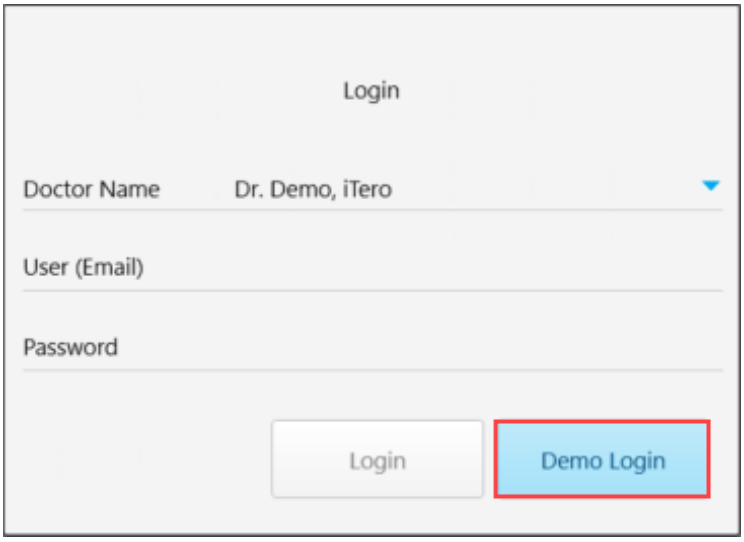


Figure 17: Demo Login button

4. Tap **Demo Login**.

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

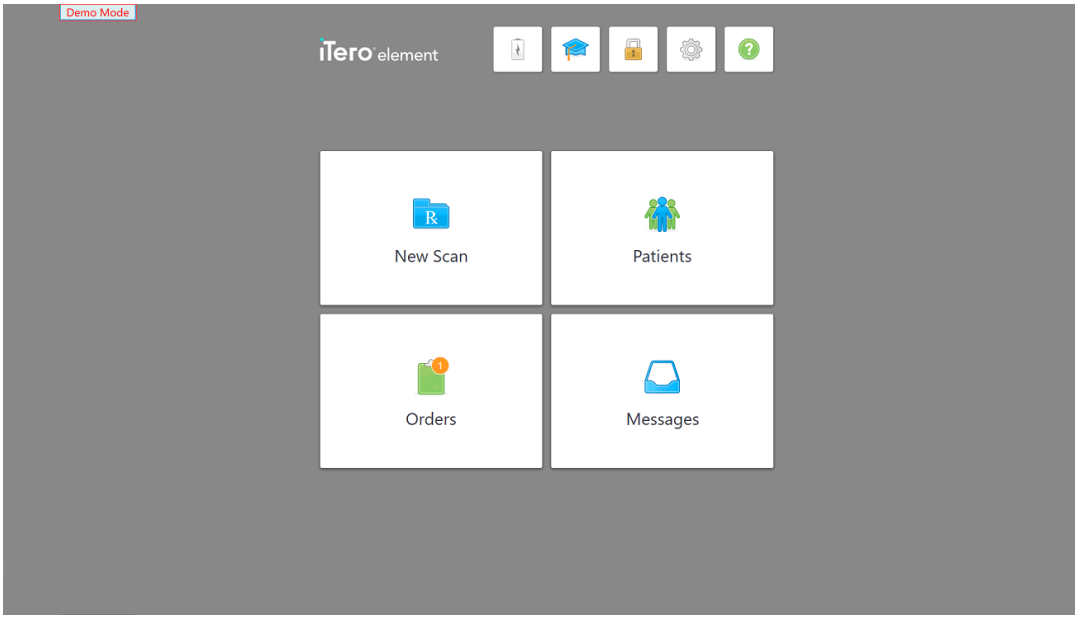


Figure 18: Demo Mode home screen

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

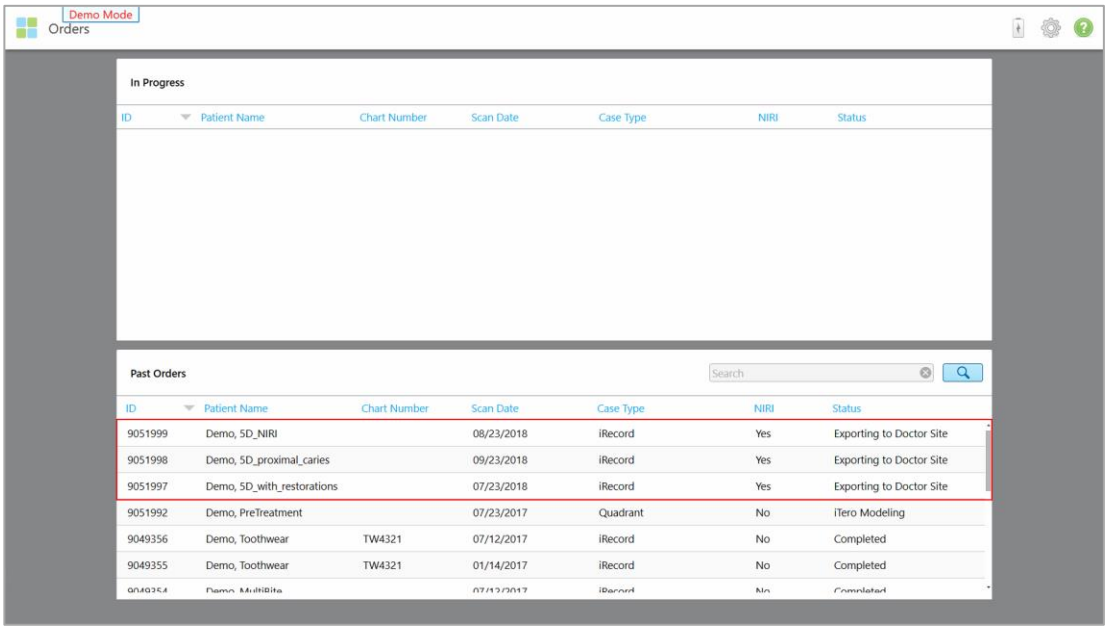


Figure 19: iTero Element 5D demo cases displayed in the list of past orders

6. Tap the required demo case.

   The selected case is expanded to show the following options:

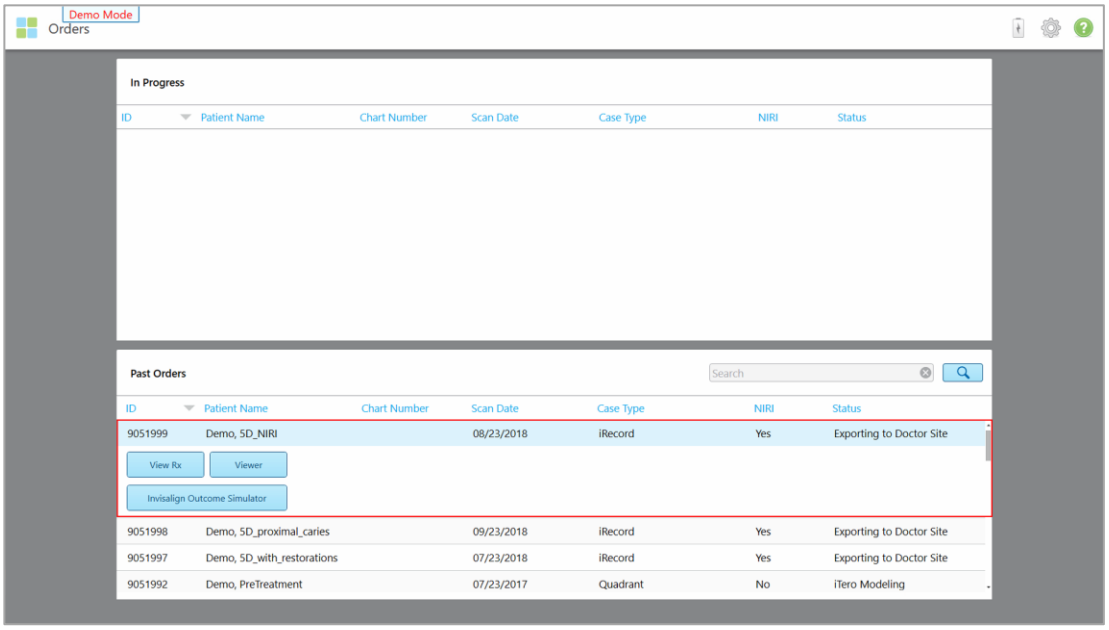


Figure 20: Past Orders pane – options

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

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 21: 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. Select the required language.
2. Tap **Make It Mine**.

   The *Connect* page is displayed.

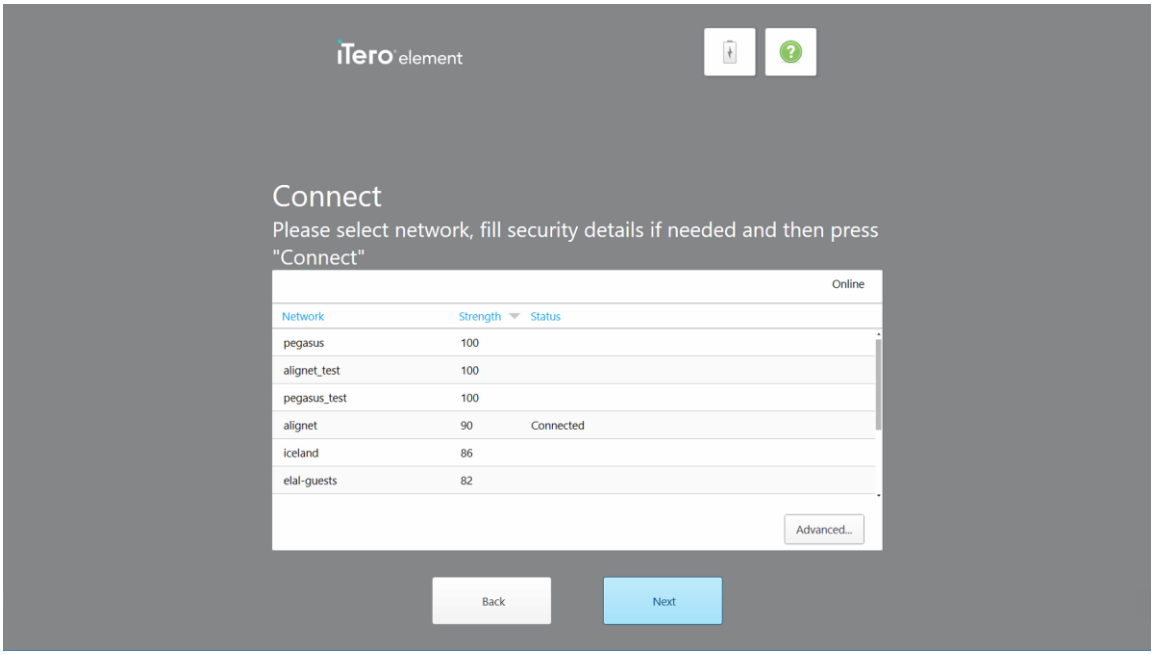


Figure 22: Selecting the network

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

   The communication with Align is verified.

Figure 23: Verifying the communication with Align

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

   The *Time Zone* page is displayed.

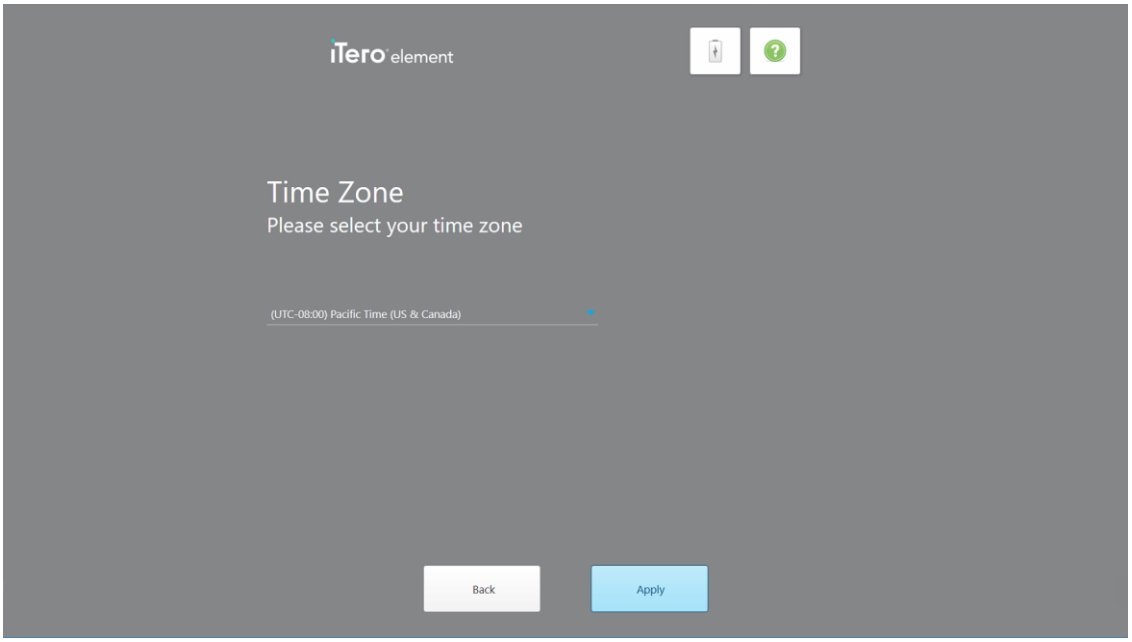


Figure 24: Selecting your time zone

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.

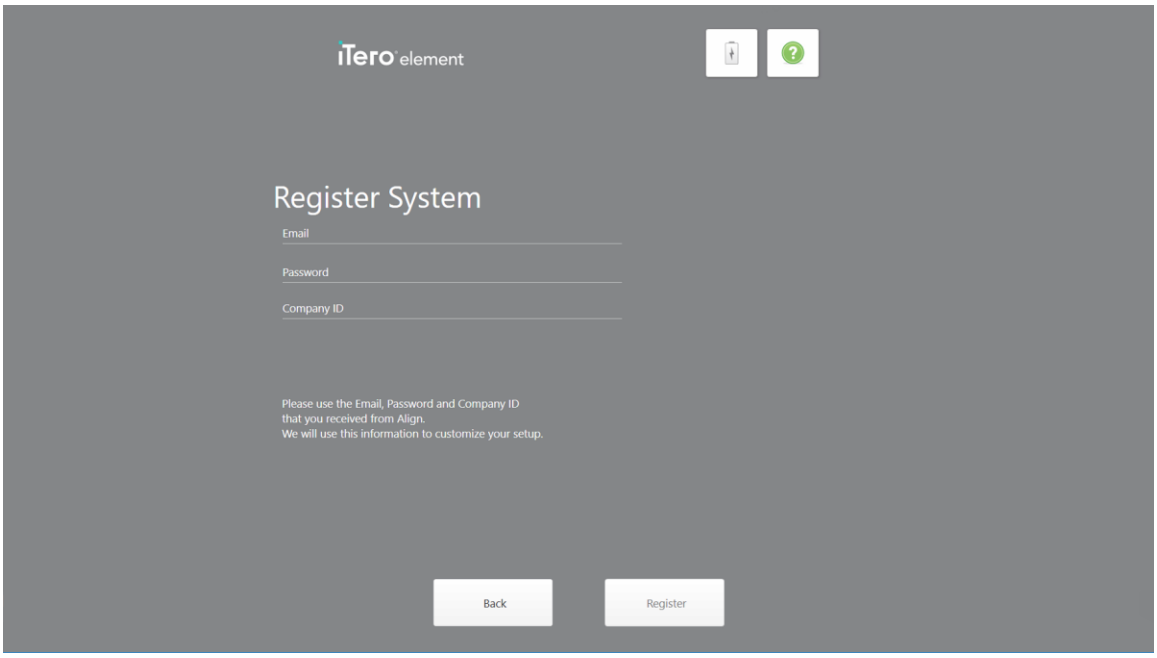


Figure 25: Registering the system to customize the setup

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.

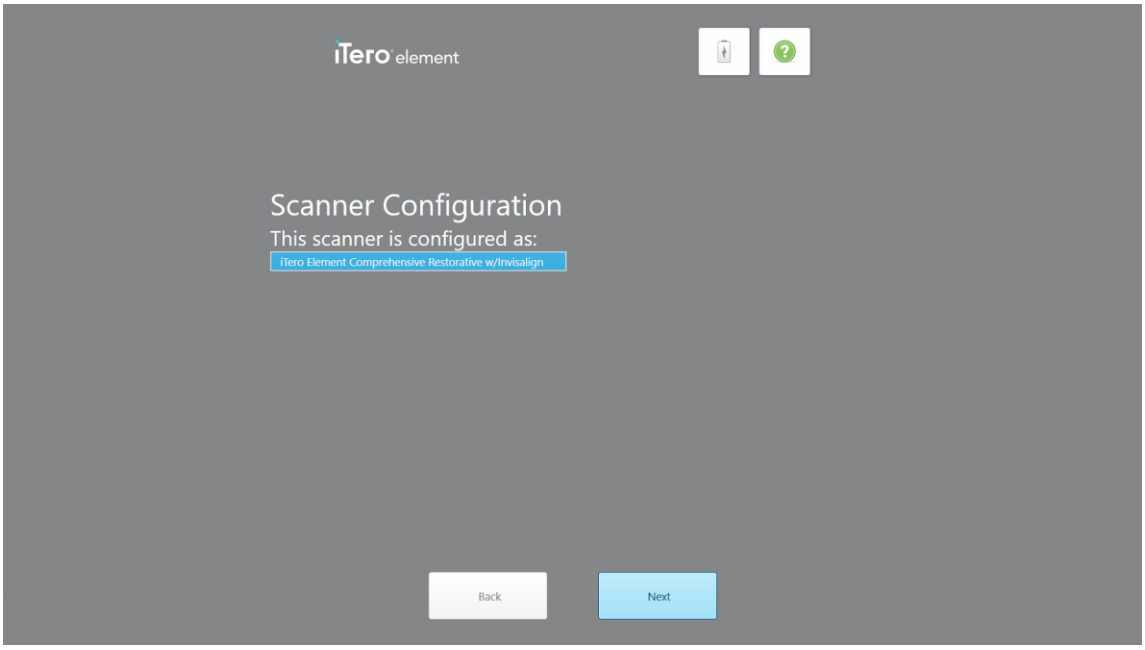


Figure 26: iTero subscription package

7. Tap **Next**.

   The *License Agreement* page is displayed.

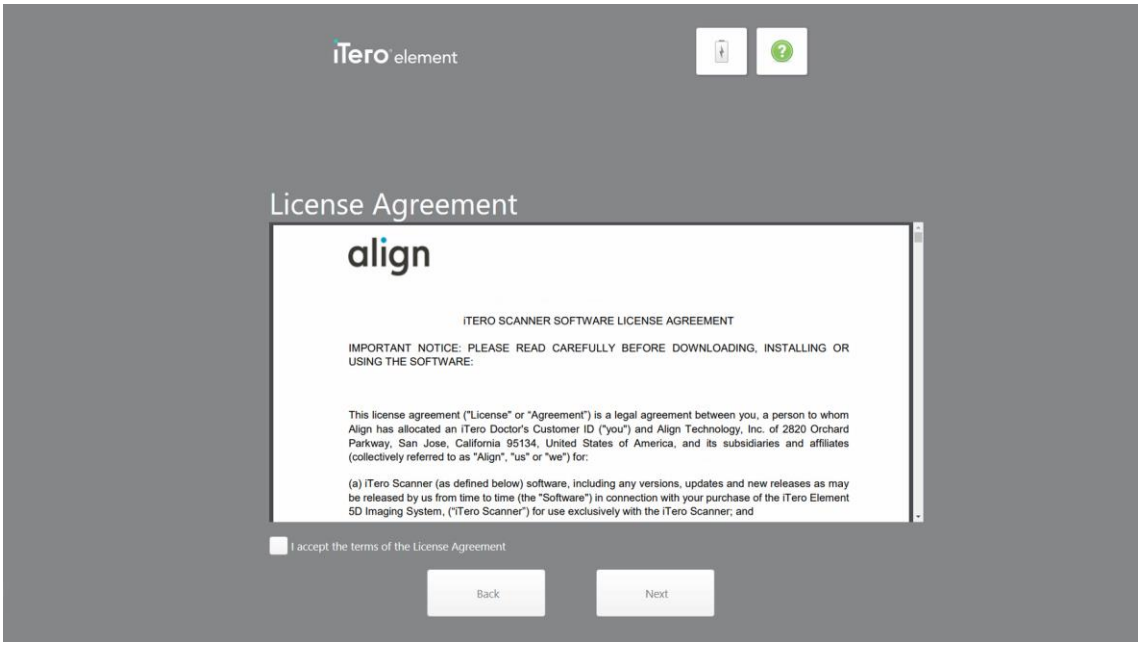


Figure 27: License agreement

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.

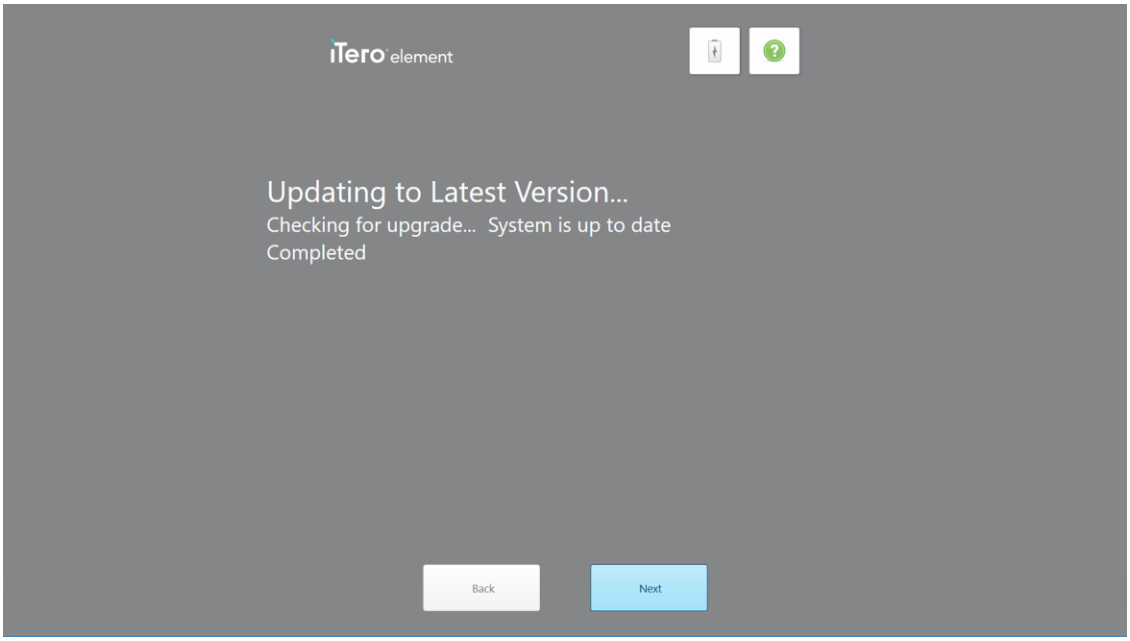


Figure 28: Checking for updates

9. Tap **Next**.

   The system has been registered and is ready.

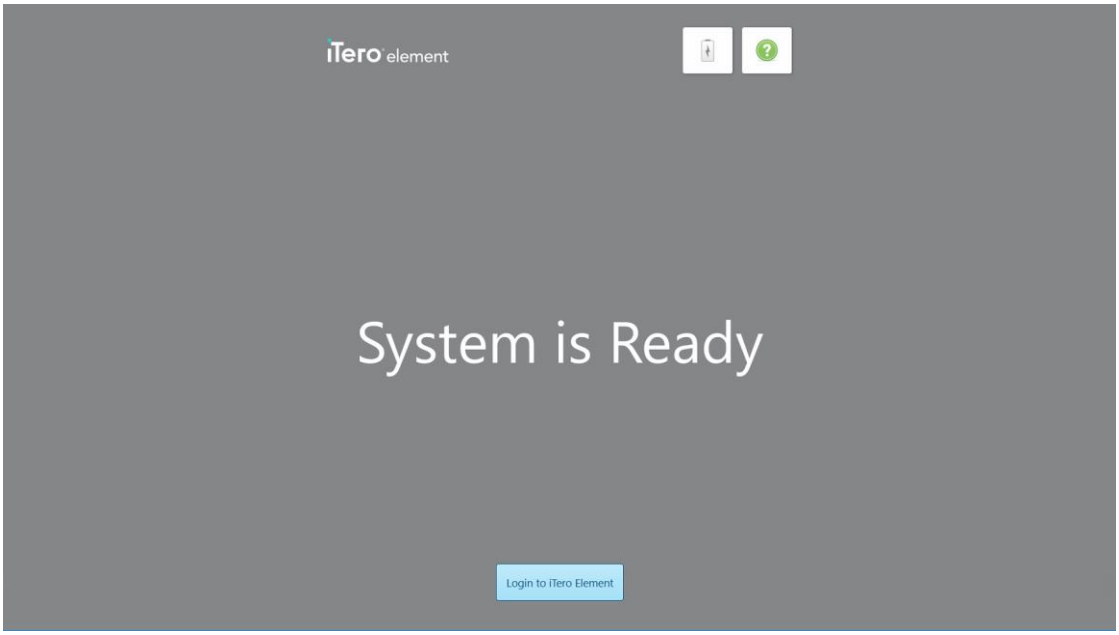


Figure 29: System is registered and ready

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

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.

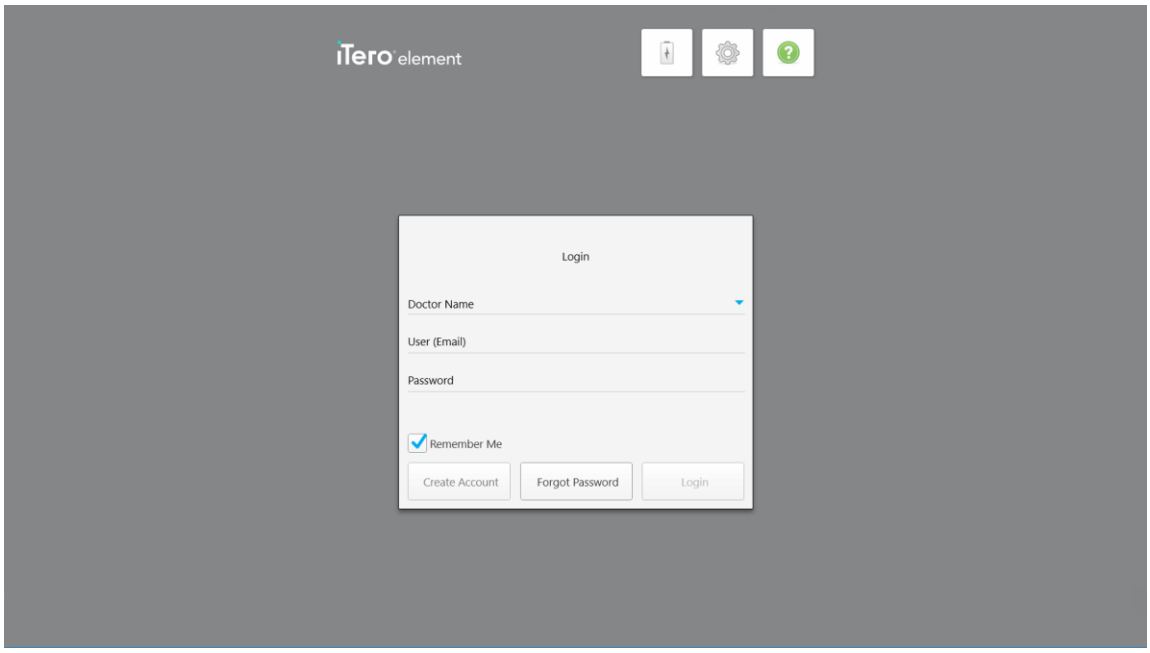


Figure 30: Login window

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 is 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, you can 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.
5. Click **Login**.

The iTero Element 5D home screen is displayed.

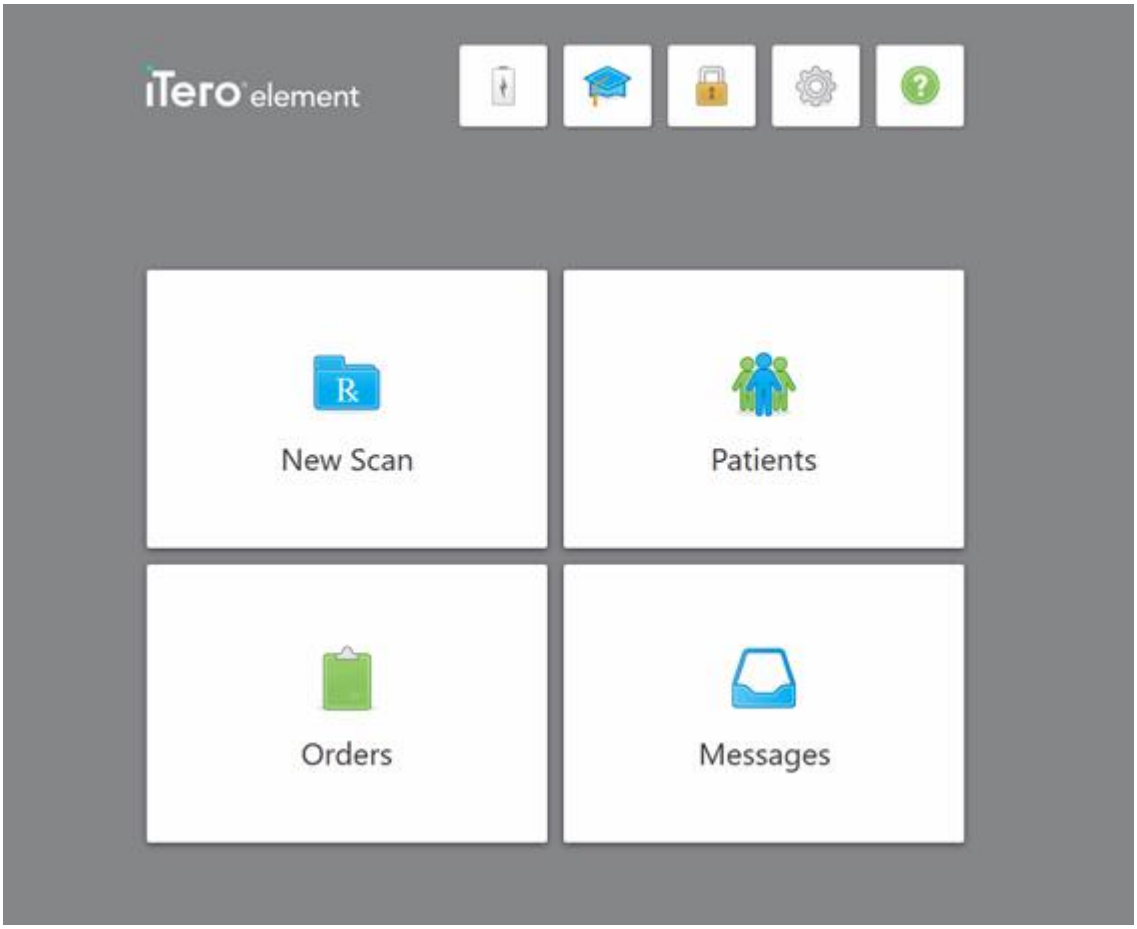


Figure 31: iTero Element 5D home screen

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**.

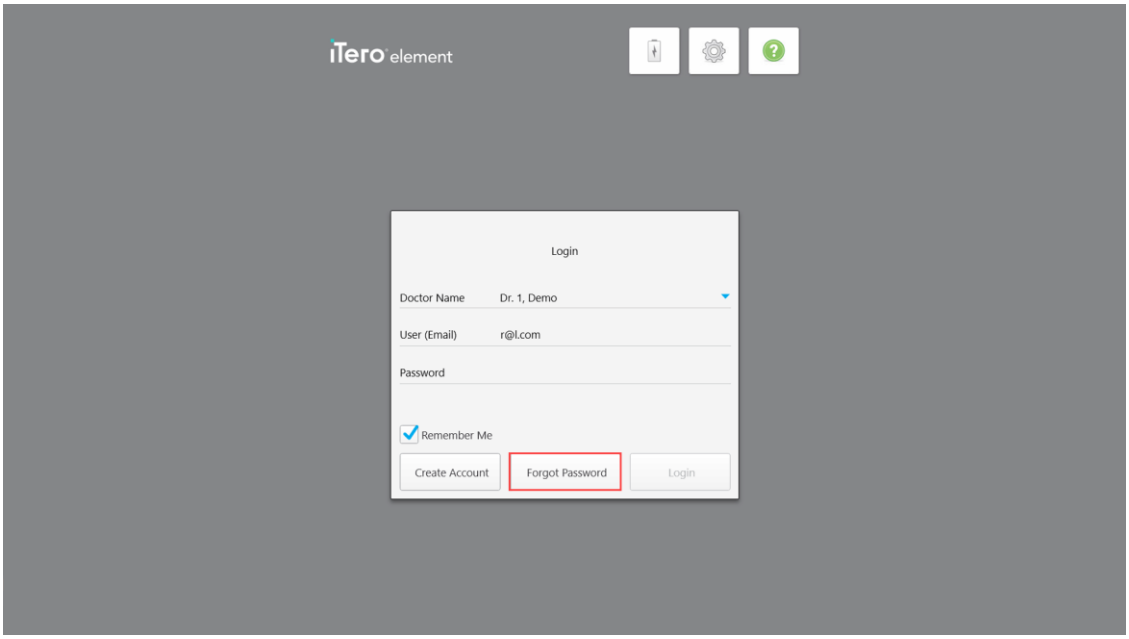


Figure 32: Forgot Password button

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

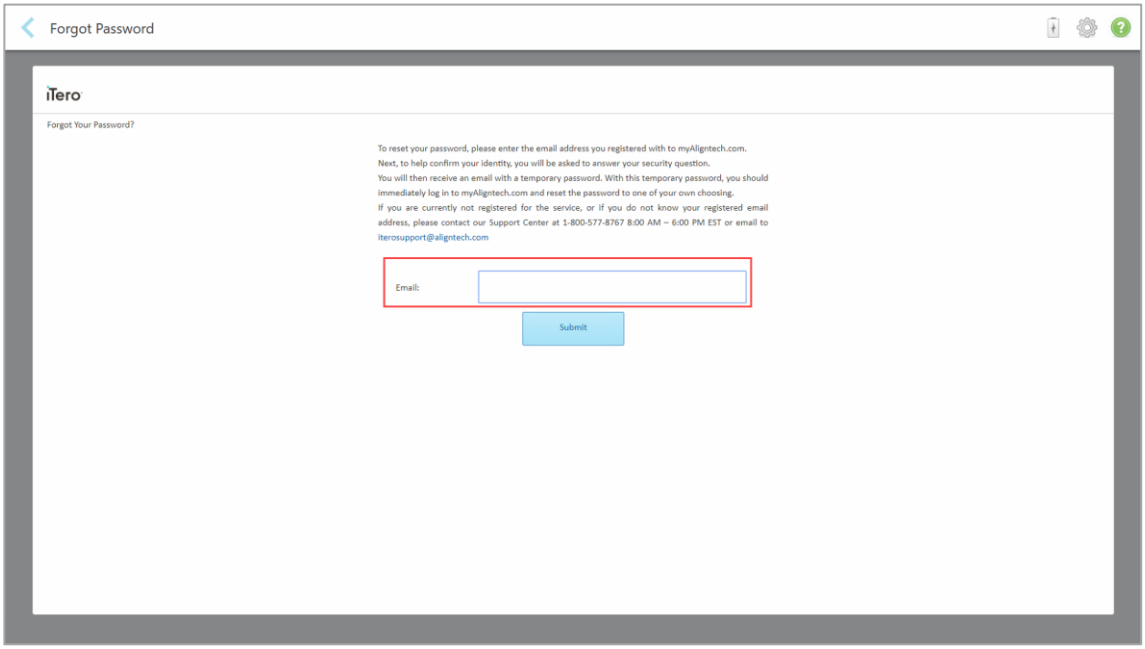


Figure 33: Email field for forgotten password

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

3. Click **Submit**.

   Your predetermined security question is displayed.

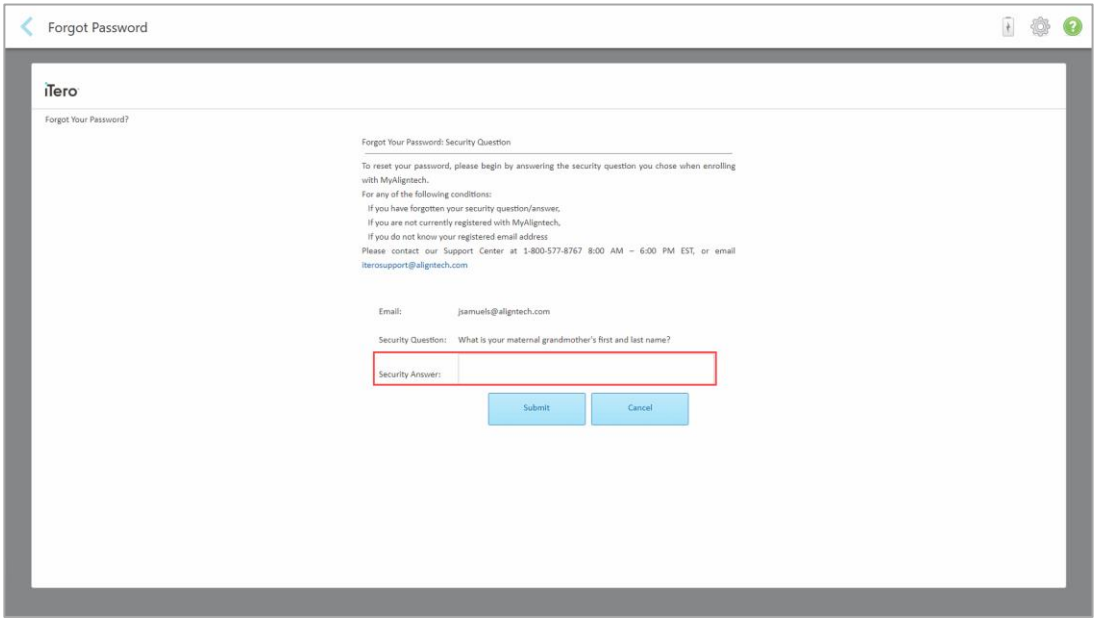


Figure 34: Security answer field

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.

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.

   Warning: Holding the button for more than 4 seconds 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.

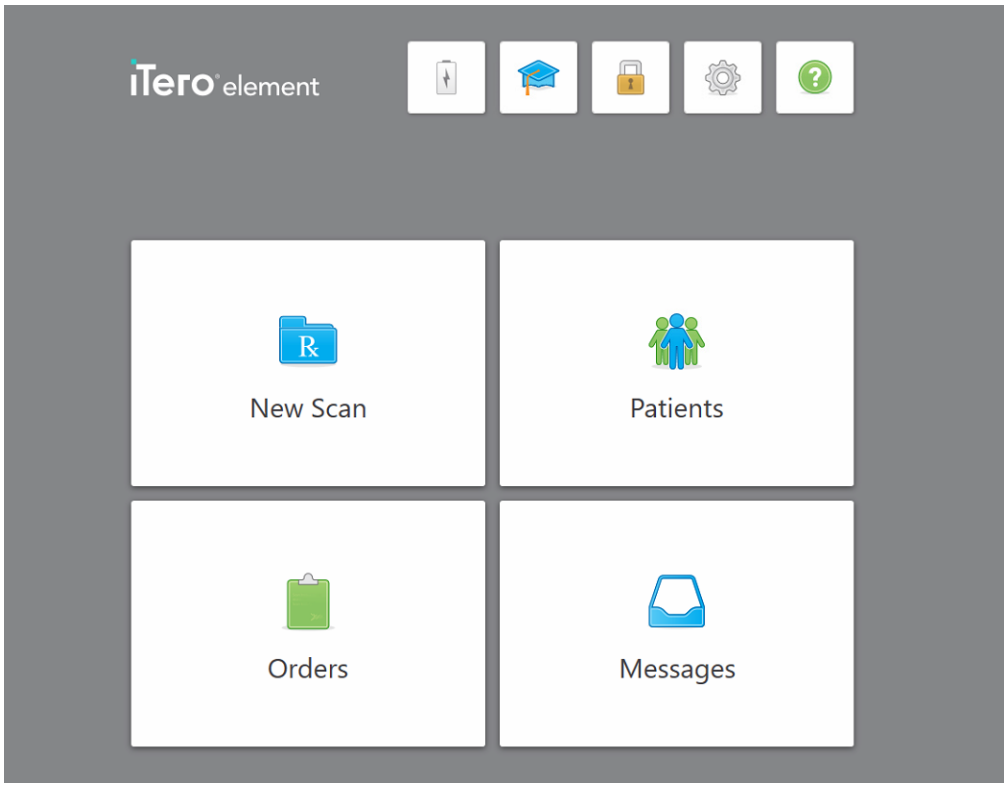


Figure 35: iTero Element 5D home screen

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.

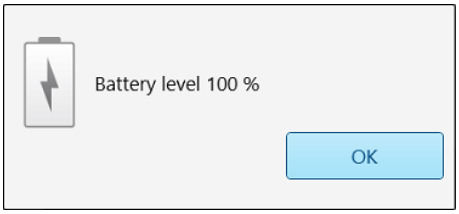


Figure 36: Remaining battery charge

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.

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

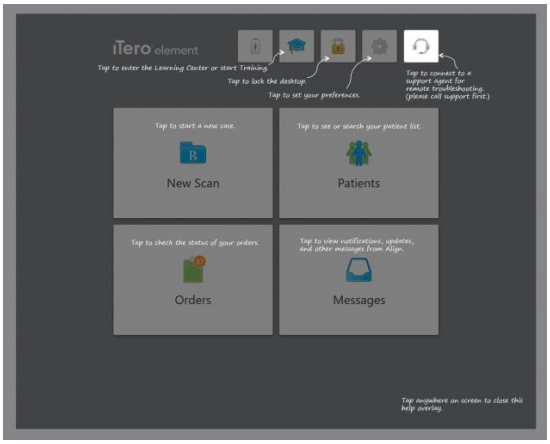
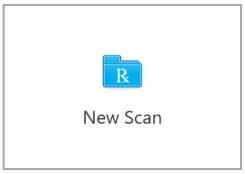


Figure 37: Help overlay

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

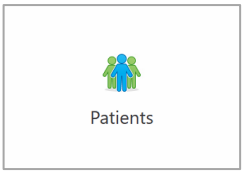
Note: Please call Customer Support before trying to connect remotely.

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



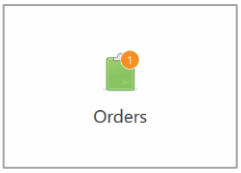
New Scan: Tap to open the *New Scan* window to fill in the Rx before starting a new scan.

For more information, see section 4.



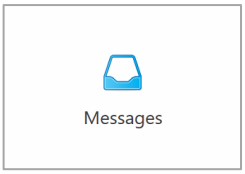
Patients: Tap to view the *Patients* page with a list of all your patients, their chart number, and last scan date.

For more information, see section 5.



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 4 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 4.1.

Tap to move to Scan mode to scan the patient, described in section 4.2.

Tap to move to View mode to view the scanned model, described in section 4.3.

Tap to send the scanned model to the lab, described in section 4.4.

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.

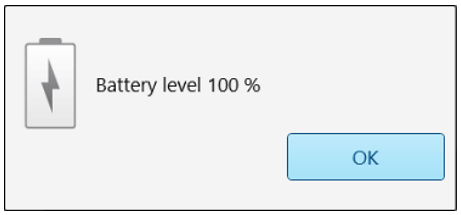


Figure 38: Remaining battery charge

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.

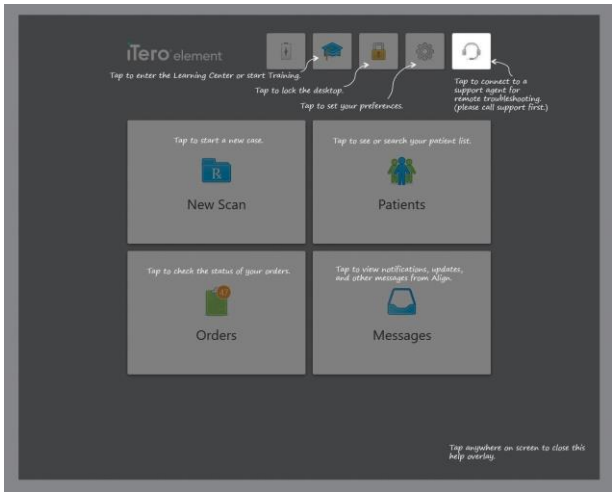


Figure 39: Help overlay

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.

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:

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. Click the button.

   The *Settings* window is displayed.

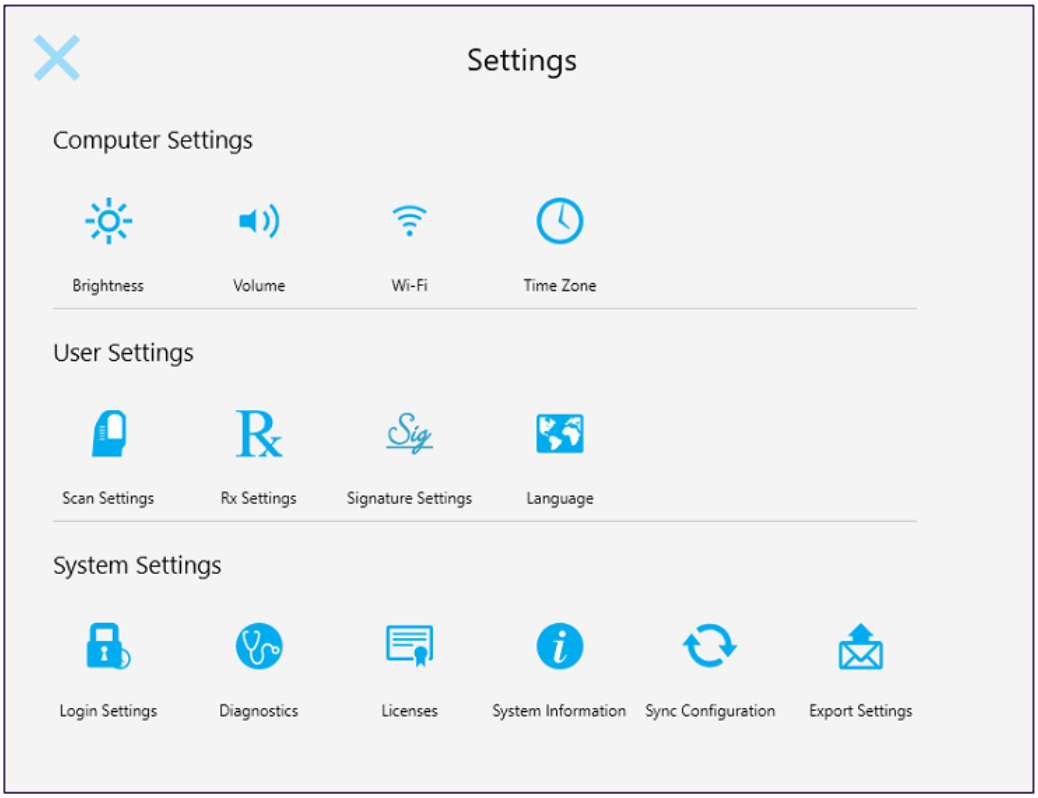


Figure 40: Settings window

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.

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.

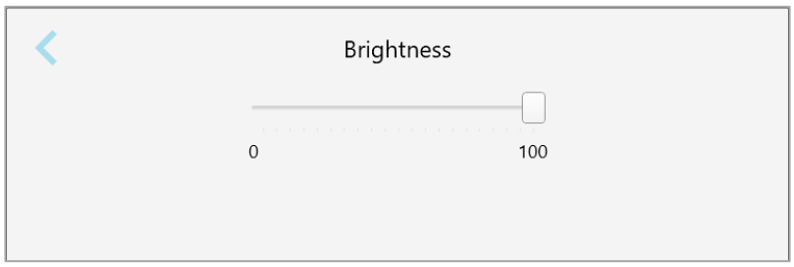


Figure 41: Brightness settings

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.

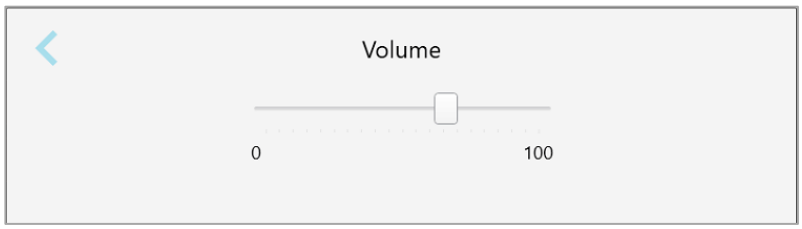


Figure 42: Volume settings

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

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.

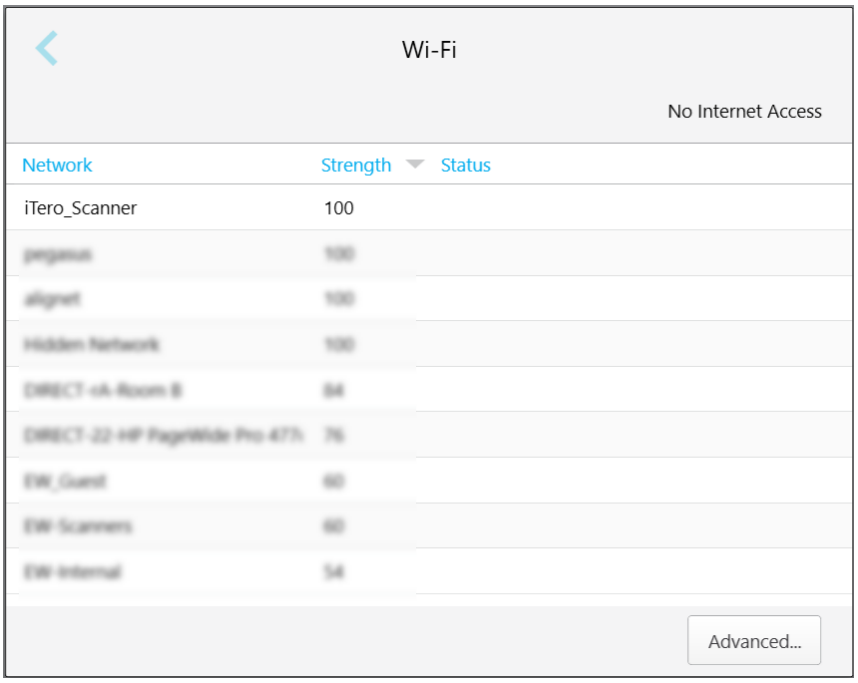


Figure 43: List of nearby Wi-Fi networks

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

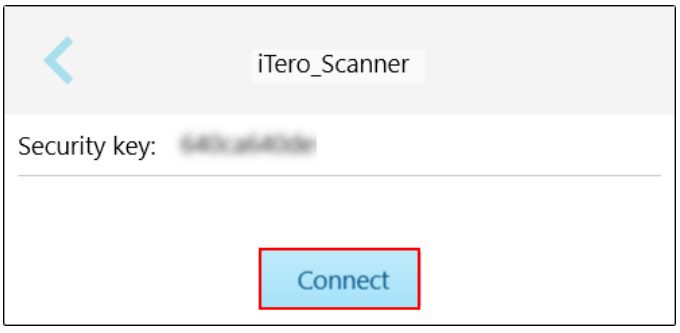


Figure 44: Connecting to the clinic Wi-Fi network

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

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.

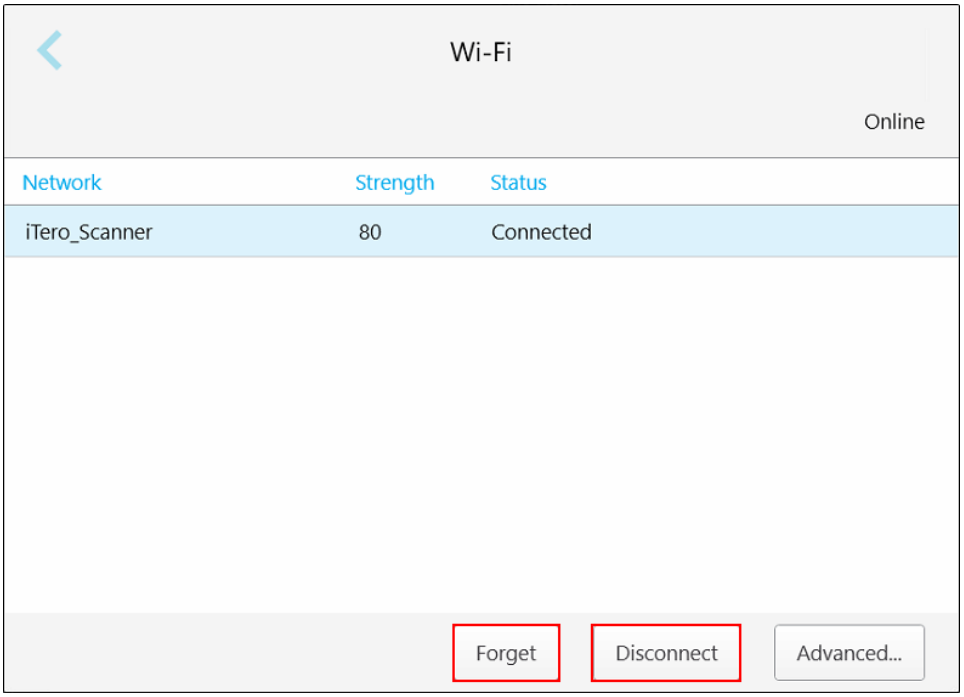


Figure 45: Forgetting or Disconnecting from the network

5. To disconnect from the network, click **Disconnect**.
6. Tap to save your settings and return to the *Settings* window.

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.

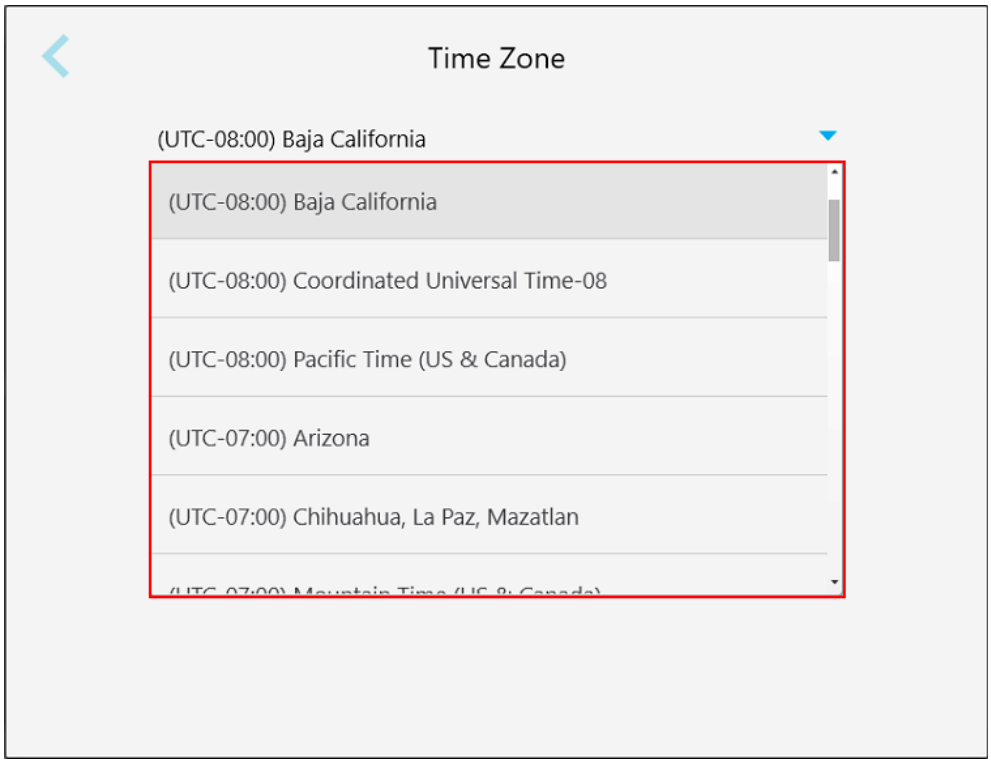


Figure 46: Time zone settings

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

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.

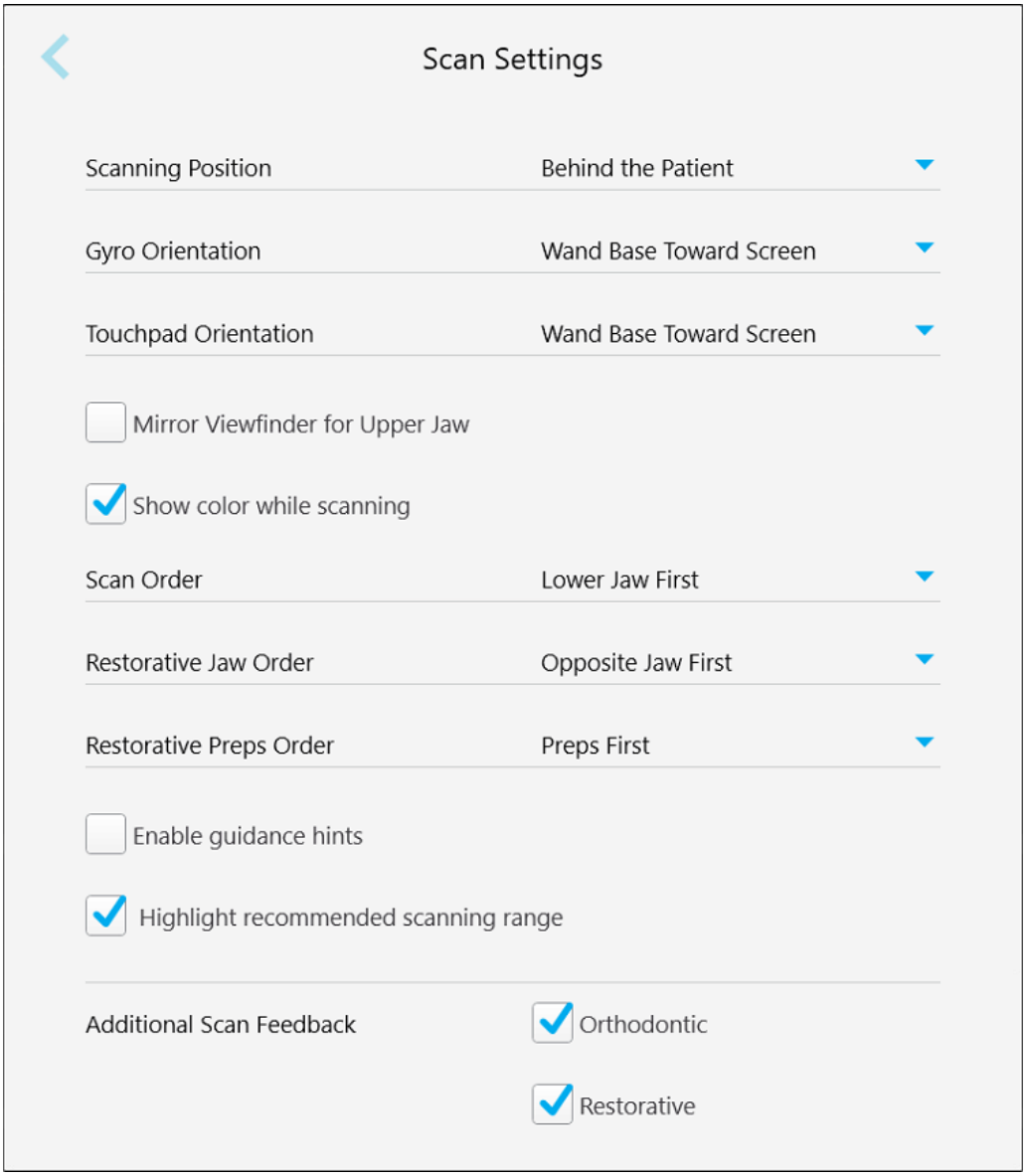


Figure 47: Scan Settings window

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 4.2.1.

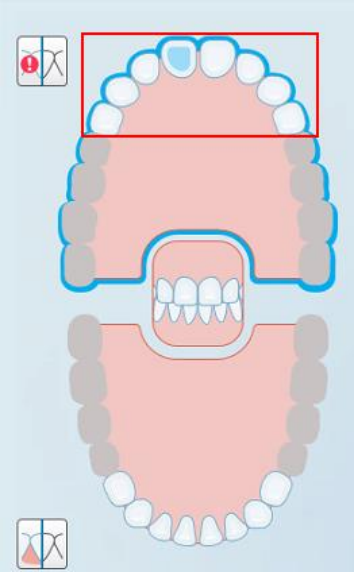
Scan setting	Scan options
Highlight recommended scanning range check box	Select this check box to highlight only the scanning range on the navigation controls. 
Additional Scan Feedback	Select the relevant check boxes to display areas of missing anatomy while scanning, as described in section 4.2.3.1. • Orthodontic • Restorative

Figure 48: Only scanning range is highlighted

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

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.

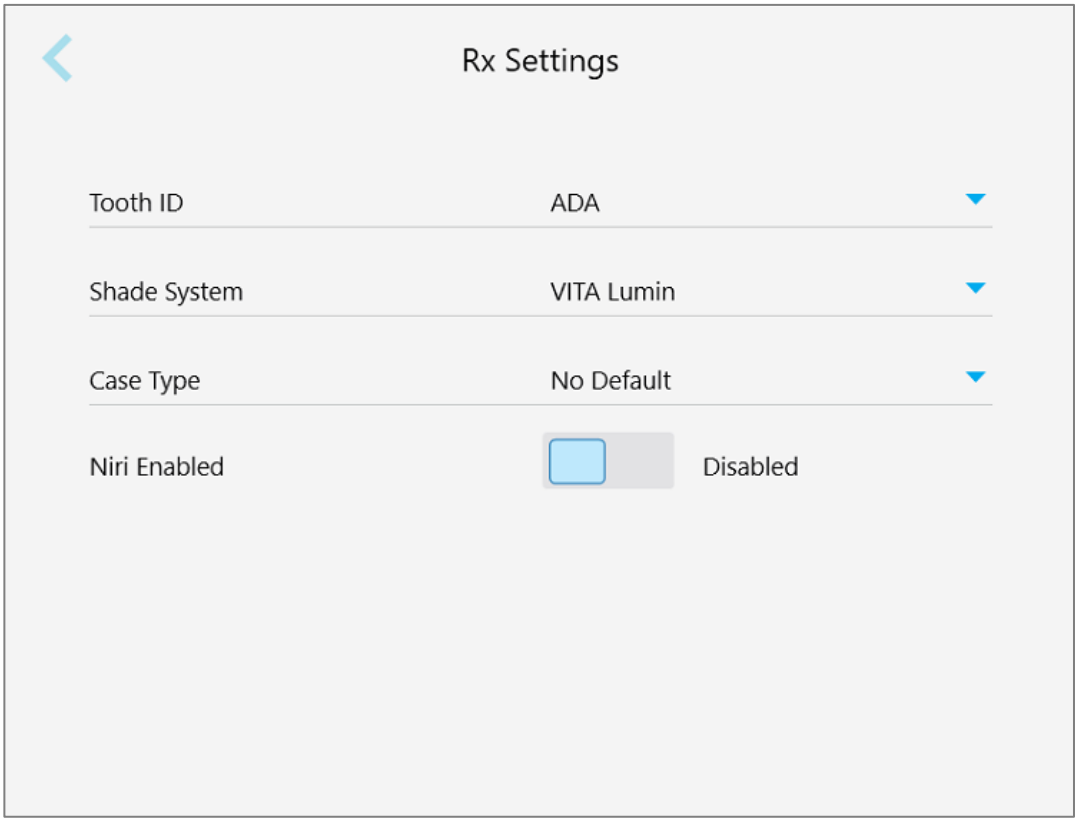


Figure 49: Rx Settings window

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

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 50: Signature Settings window

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.

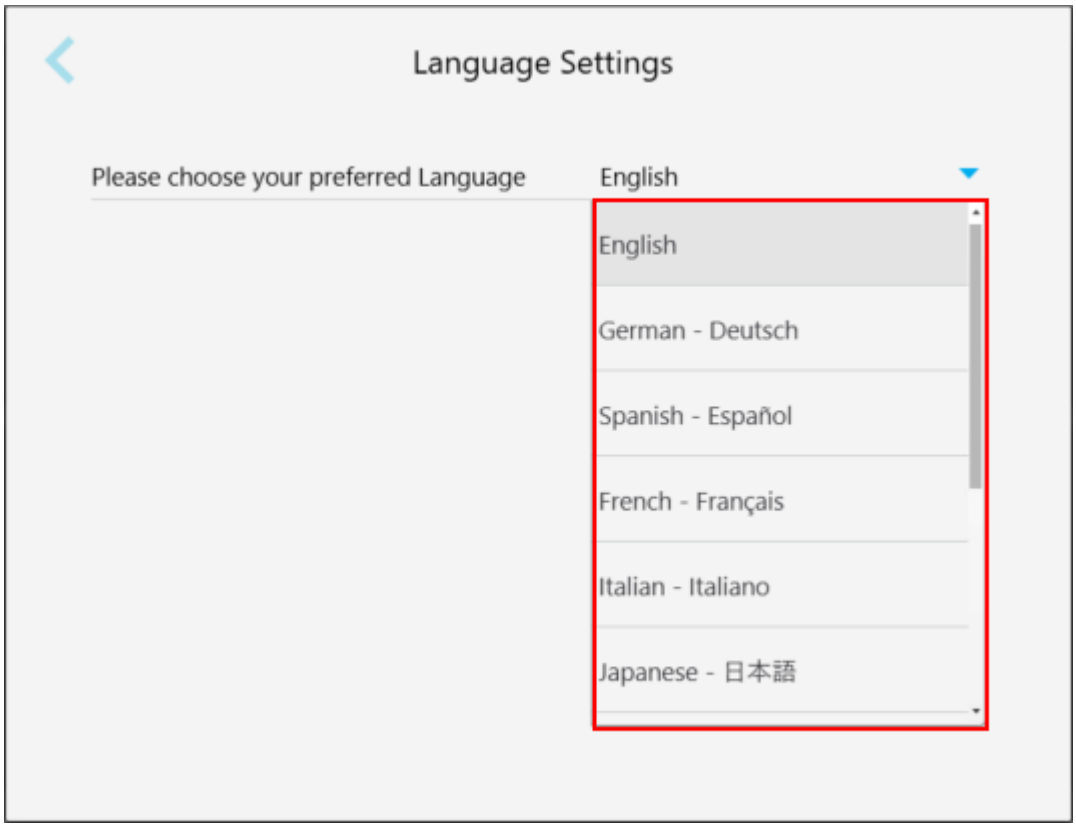


Figure 51: Language Settings window

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, sync 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. Click the **Login Settings** button.

   The *Login Settings* window is displayed.

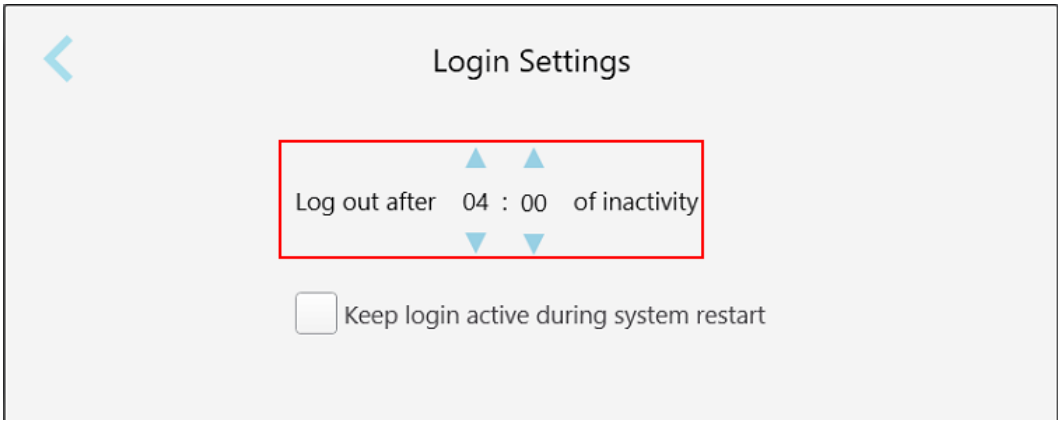


Figure 52: Login Settings window

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.

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.

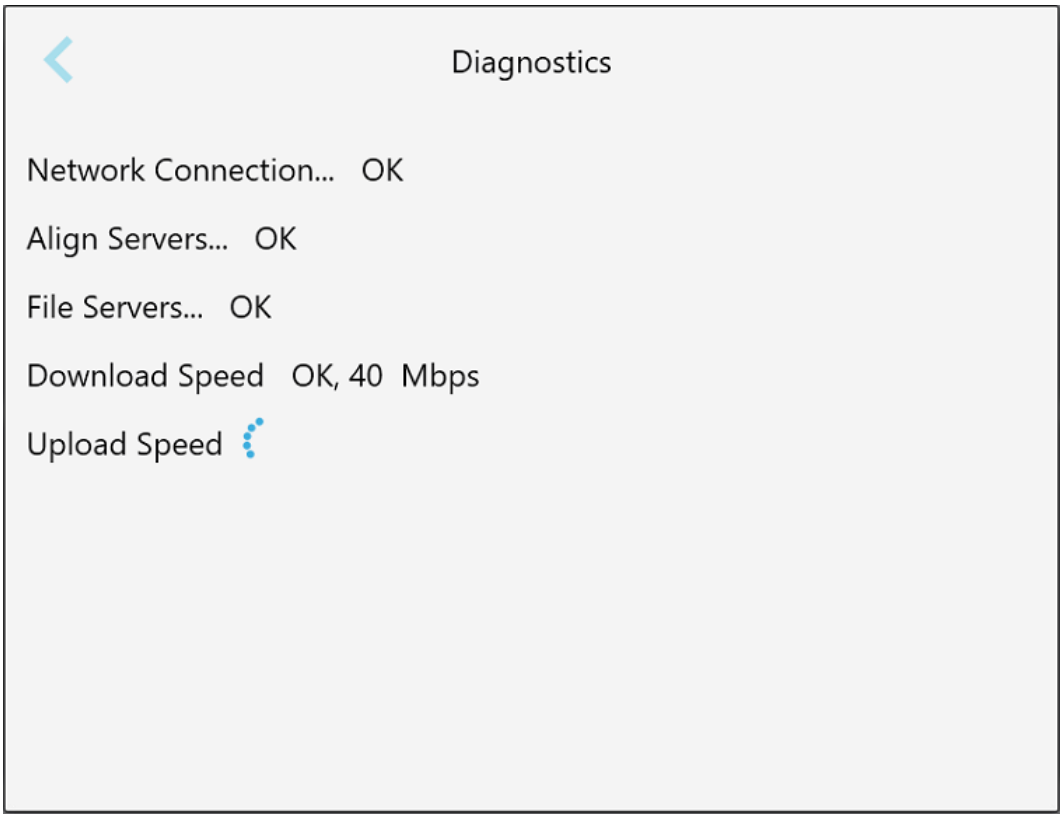


Figure 53: Diagnostics window

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

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 54: Licensing Information window

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.

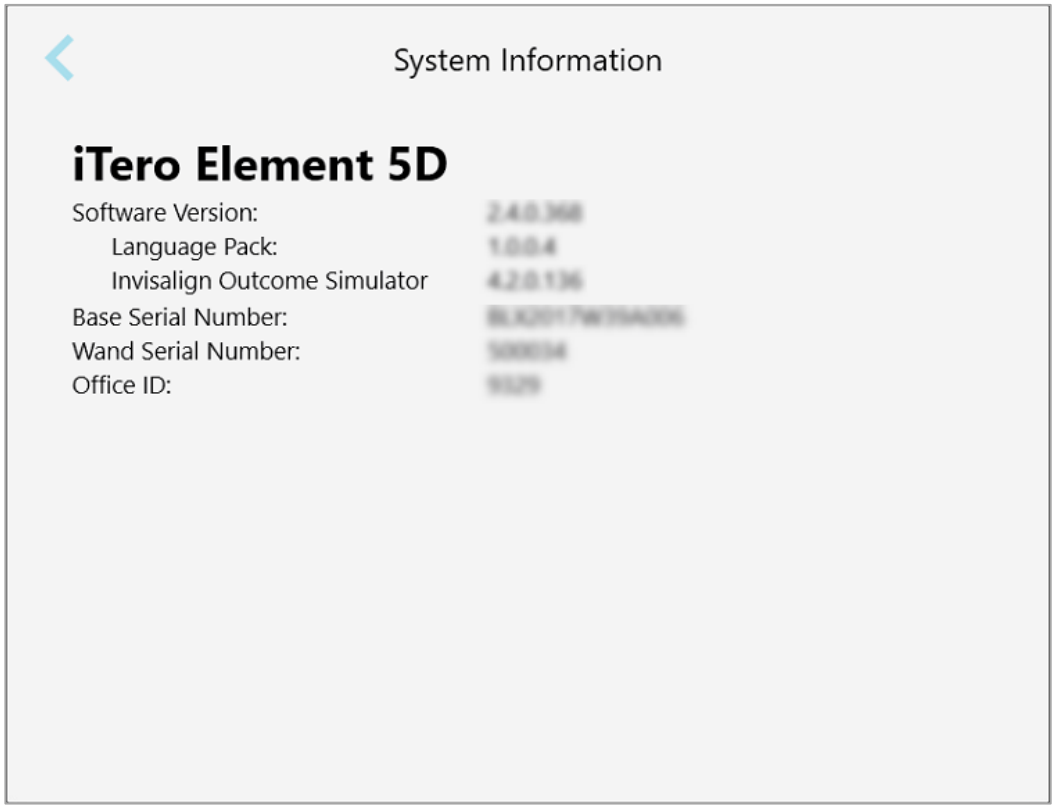


Figure 55: System Information window

3.6.3.5 Sync configuration

Tap the **Sync Configuration** button to sync any new updates from the server, for example, new software options.

Tap to return to the *Settings* window.

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.

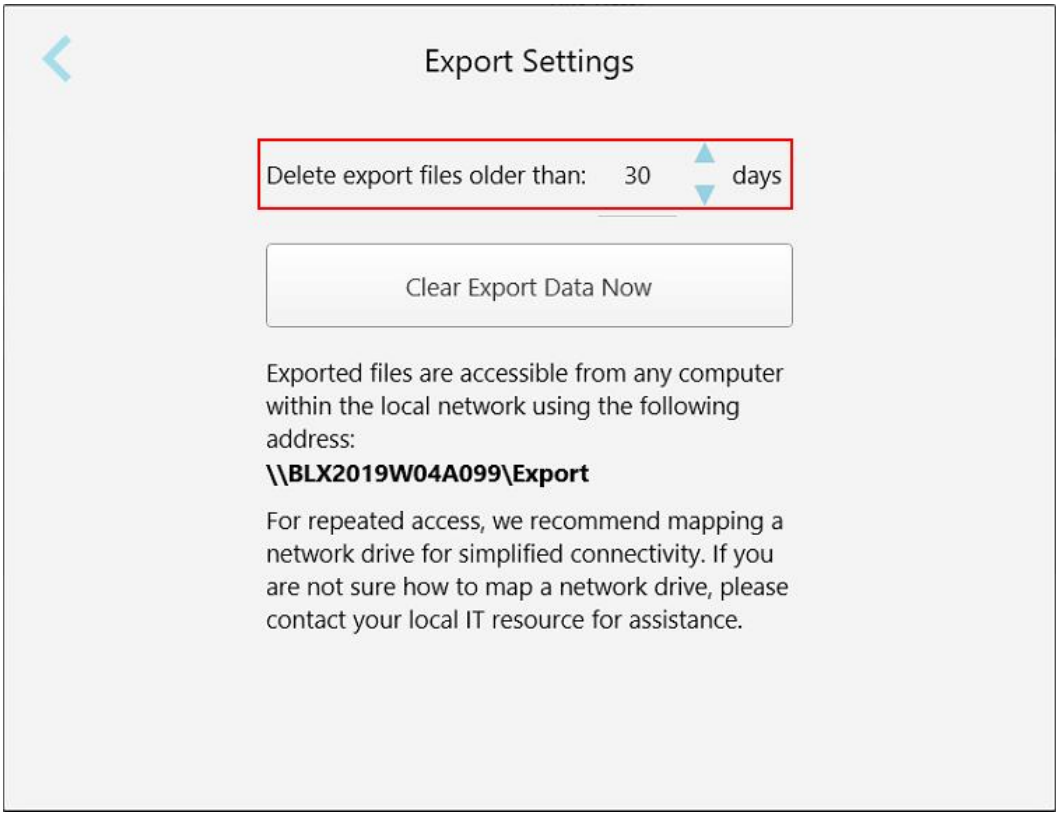
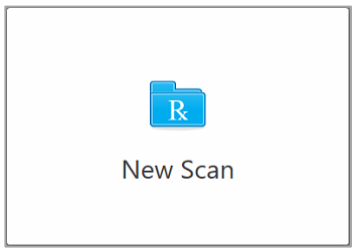


Figure 56: Export Settings window – deleting exported files

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

4 Starting a new 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.

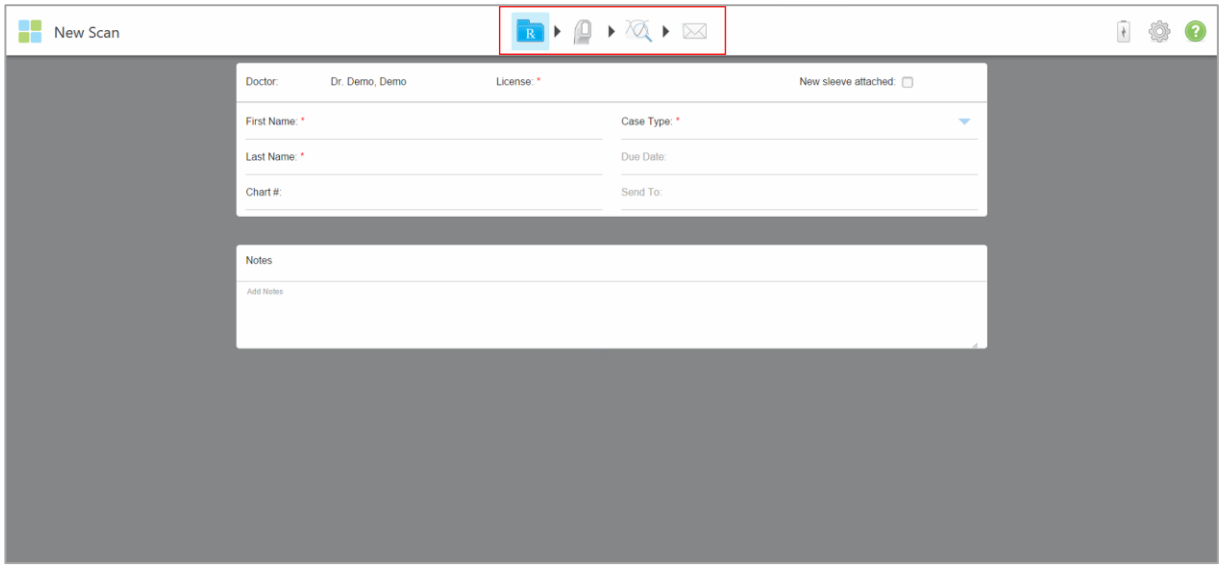


Figure 57: New Scan window showing an empty Rx and the progress toolbar at the top of the window

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

Filling in the Rx, described in section 4.1

Scanning the patient, described in section 4.2

Viewing the scan, described in section 4.3

Sending the scan to the lab, described in section 4.3.7

Your current progress is highlighted on the toolbar.

4.1 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 click  to move to Scan mode and scan the patient, as described in section 4.2.

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.

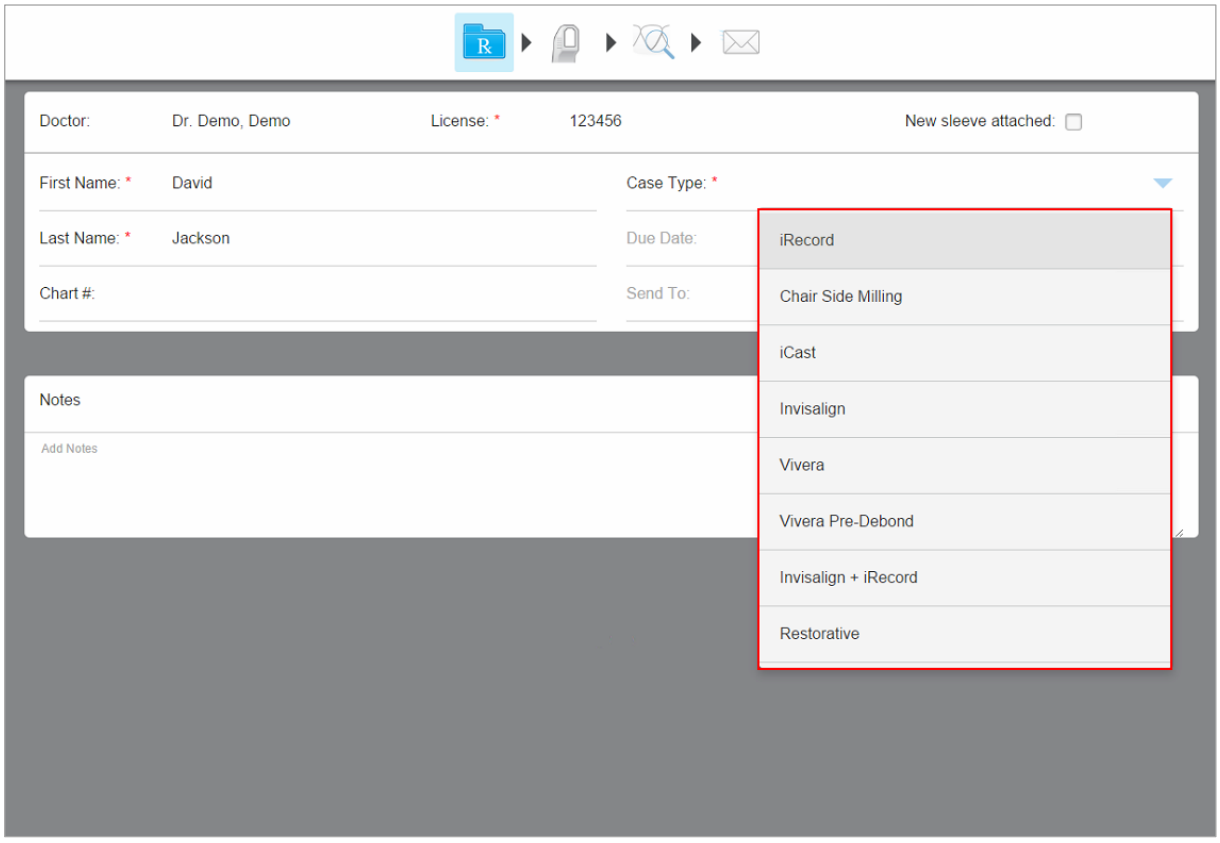


Figure 58: Selecting the required case type

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.
- **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.

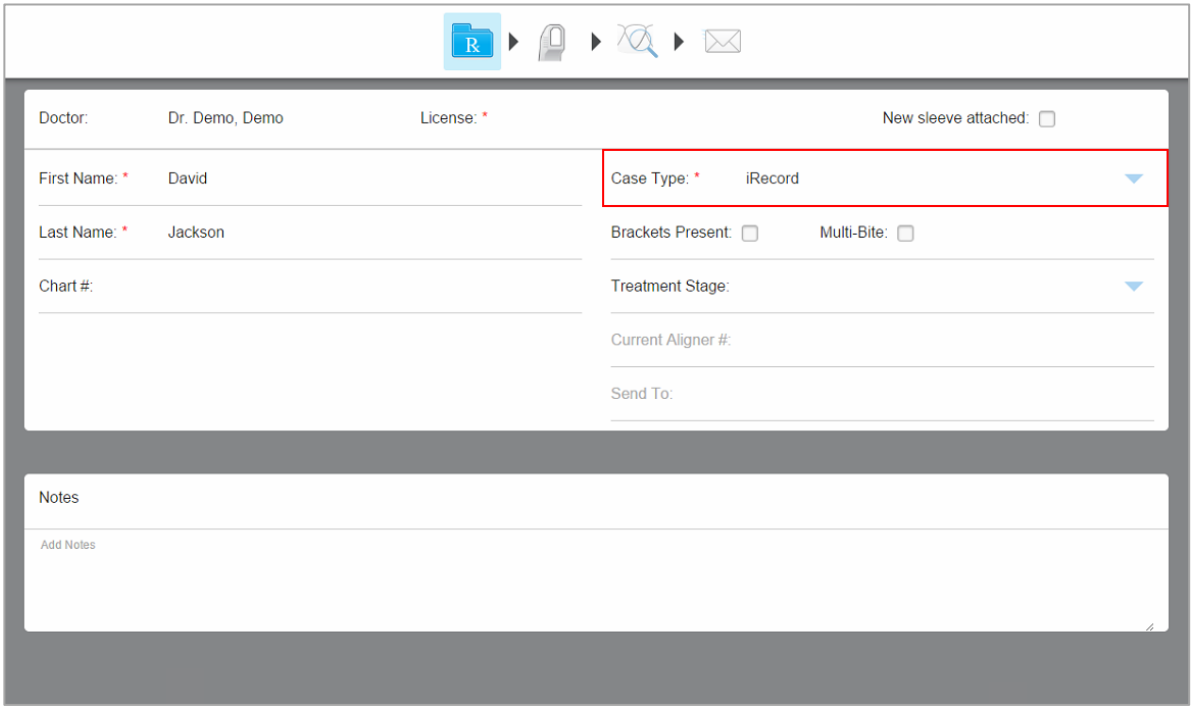


Figure 59: New Scan window – iRecord case type

3. Depending on the case type selected, fill in the relevant details.
   - **Restorative** and **Chair Side Milling** case types, see section 4.1.1.
   - **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.

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 sleeve has been attached to the wand. For more information, see section 4.1.2.

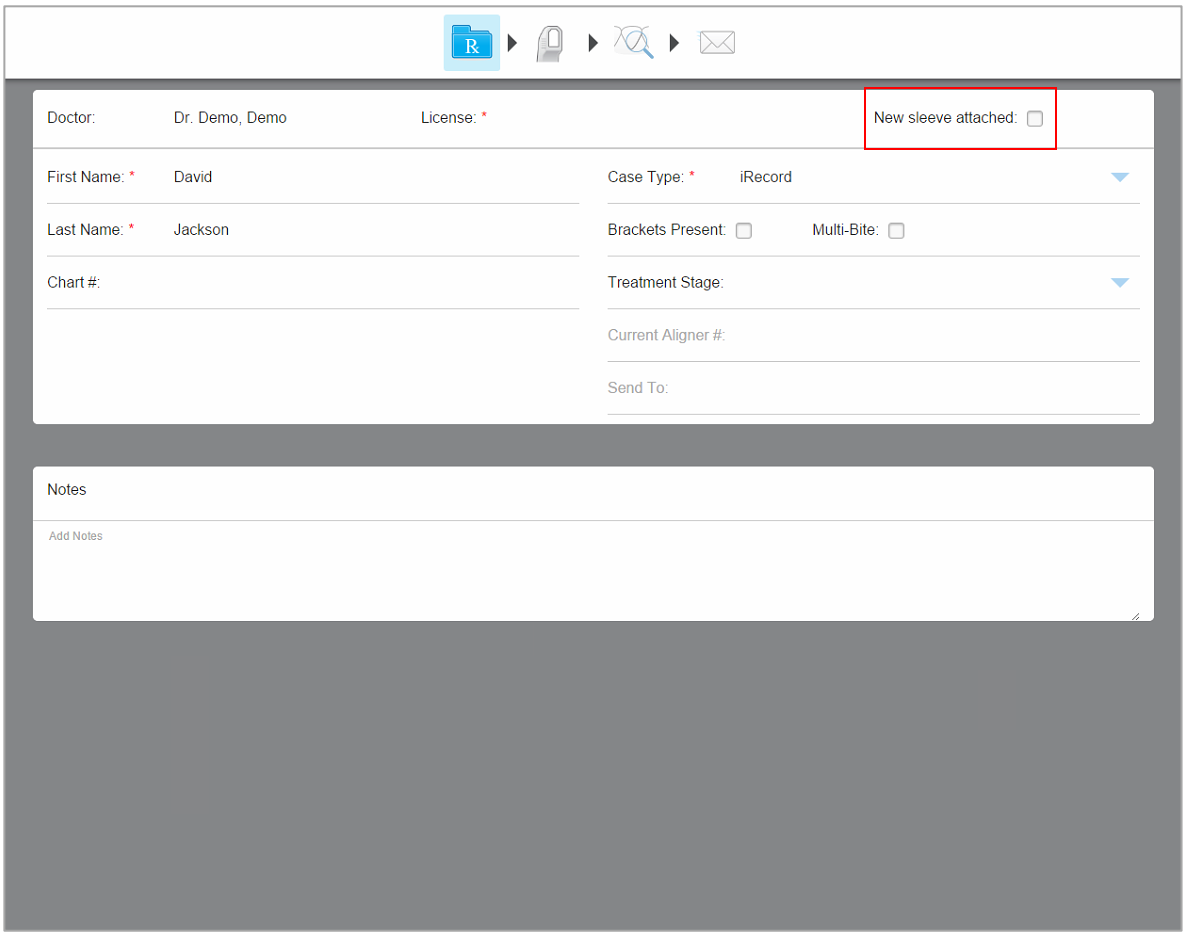


Figure 60: New sleeve attached check box

6. Tap  on the toolbar to move to Scan mode, as described in section 4.2.

4.1.1 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.

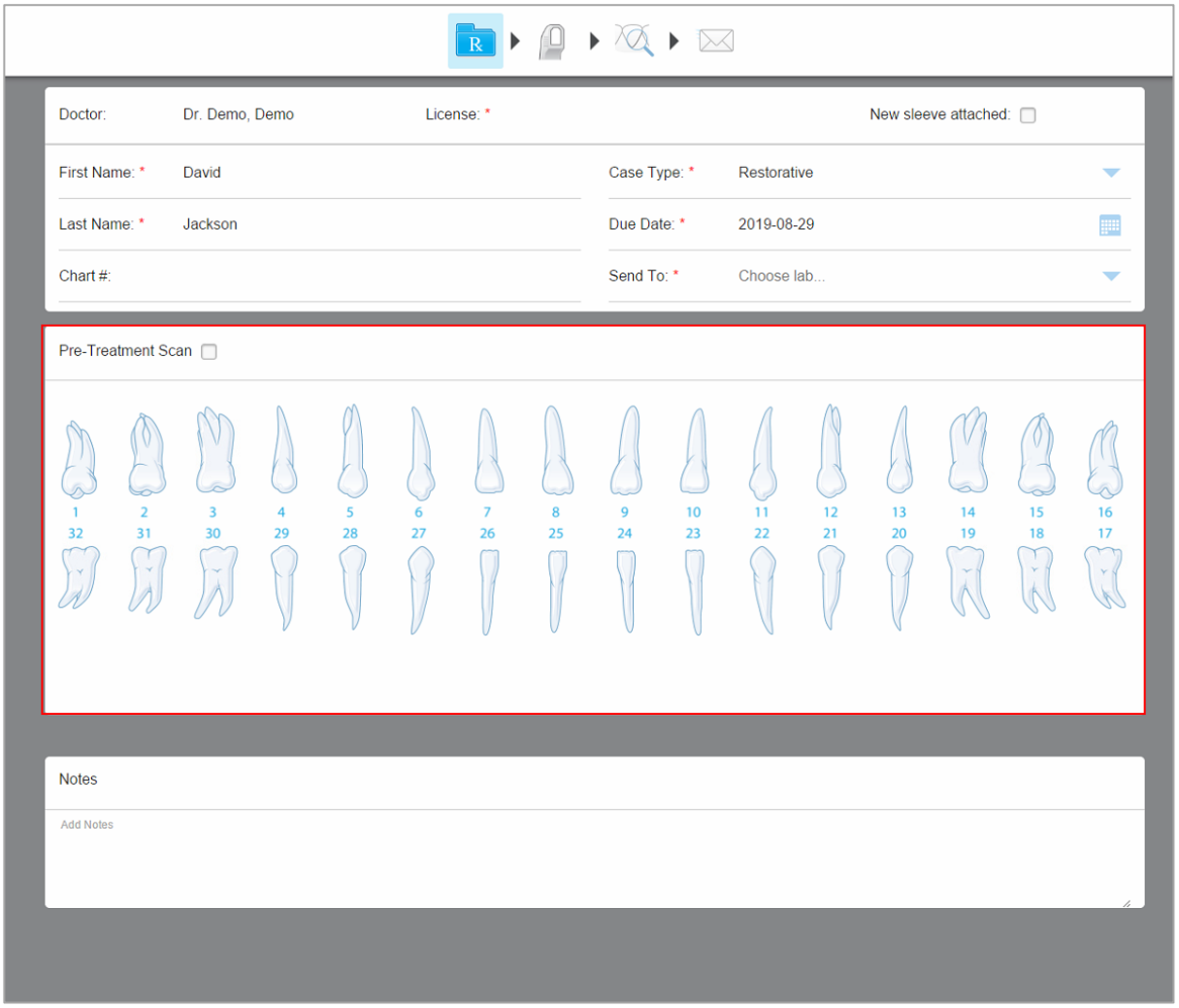


Figure 61: New Scan window – Restorative case type with a tooth chart

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.

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

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

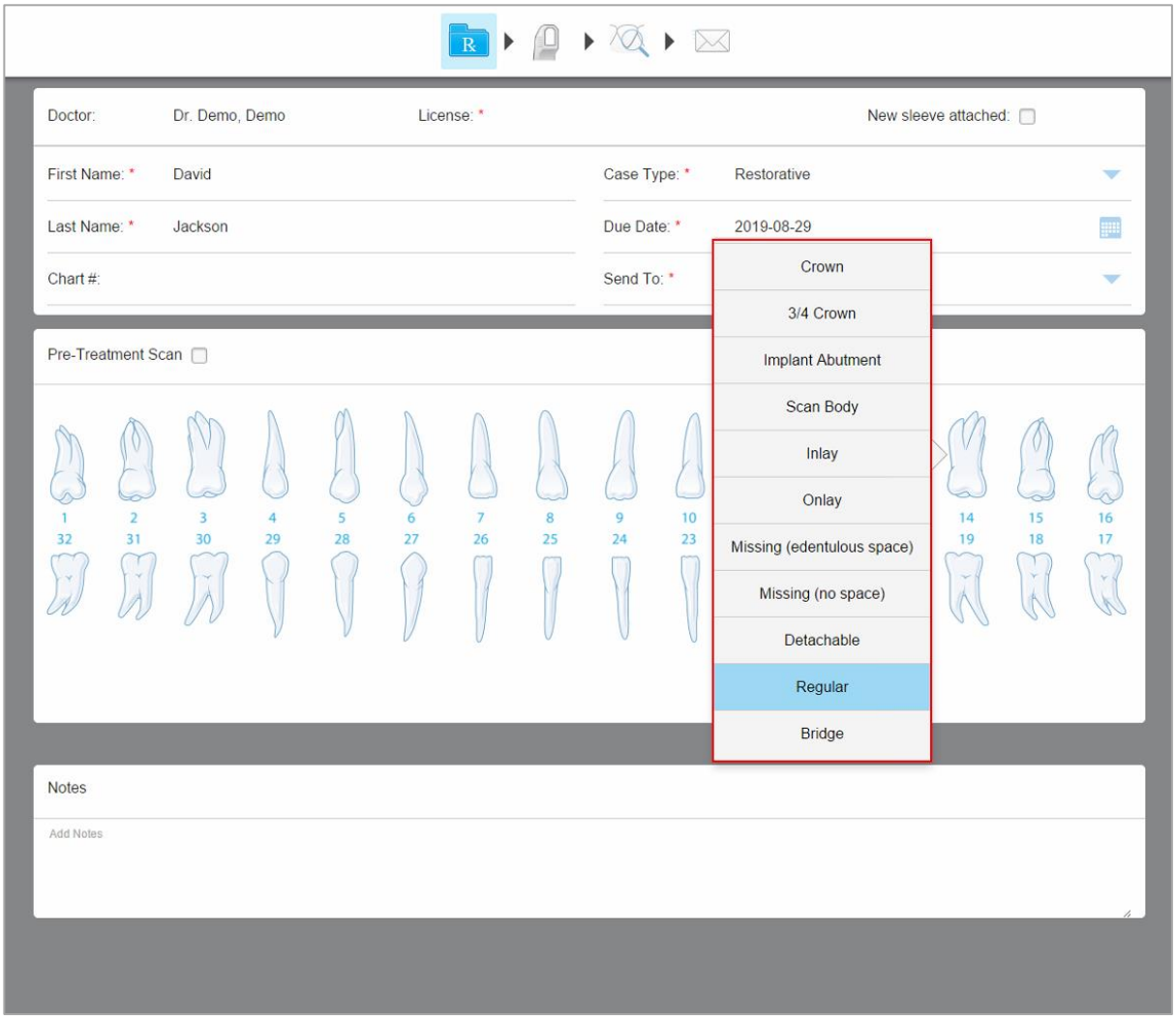


Figure 62: List of restorative treatment options

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

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

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

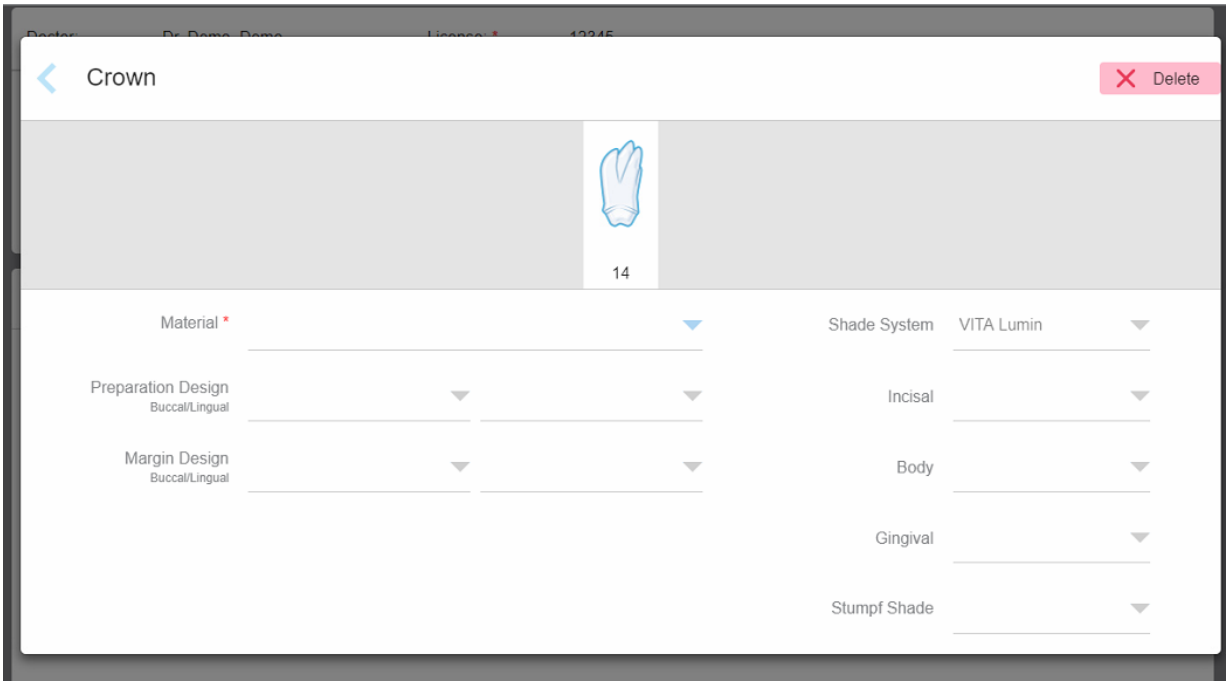


Figure 63: Defining the restoration properties

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.

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

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

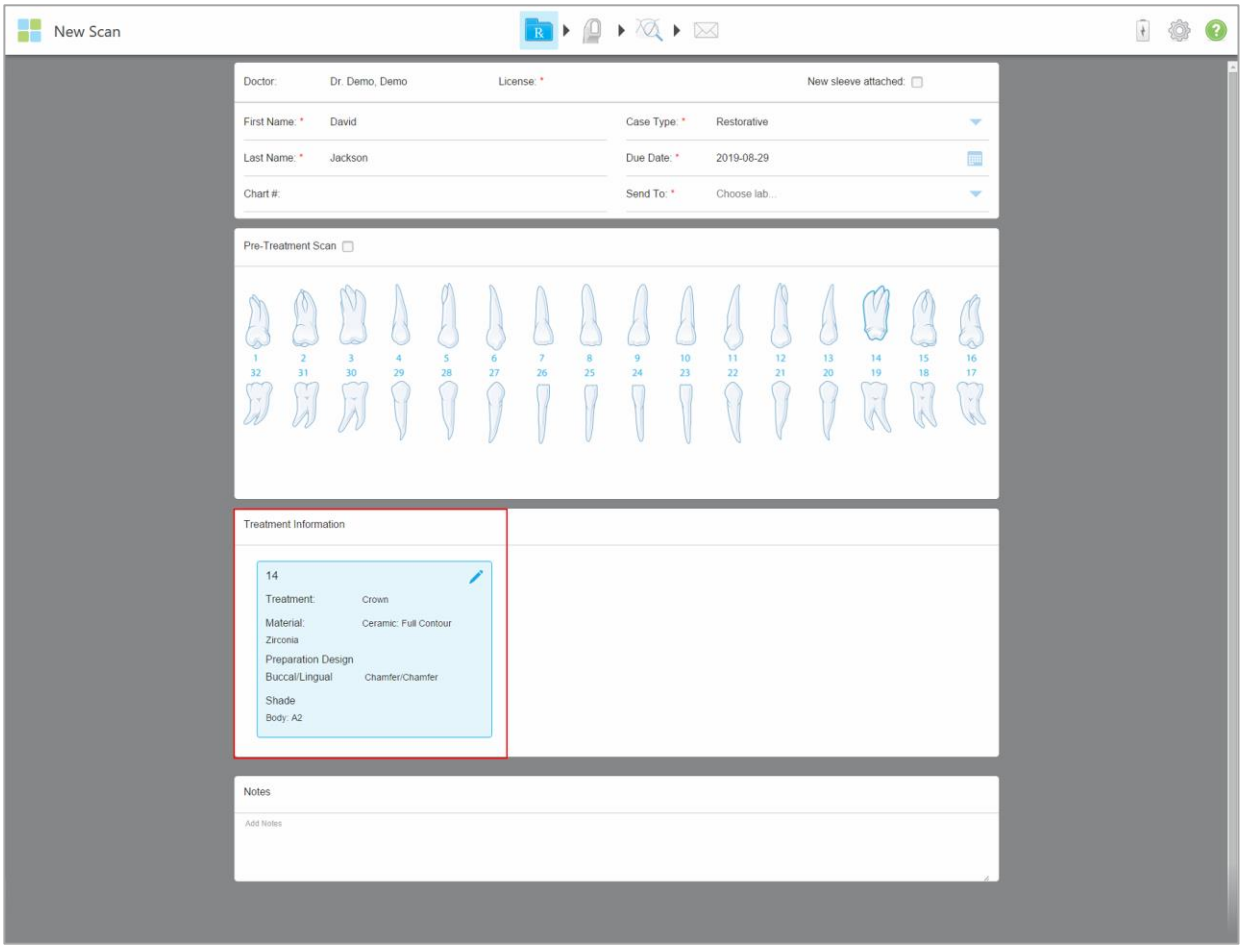


Figure 64: Treatment Information area

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

4.1.2 Confirming a new wand sleeve between patients

In order to prevent cross-contamination, you must confirm that a new wand sleeve is used for each patient. You can confirm the new sleeve using one of the following options:

- Selecting the **New sleeve attached** check box when filling in a new Rx, as described in section 4.1.2.1. This method is minimally intrusive and will not alarm the patient.
- Clicking either of the wand buttons or tapping **OK** when prompted, when trying to access Scan mode as described in section 4.1.2.2.

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

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

4.1.2.1 Confirming the new sleeve when filling in the Rx

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

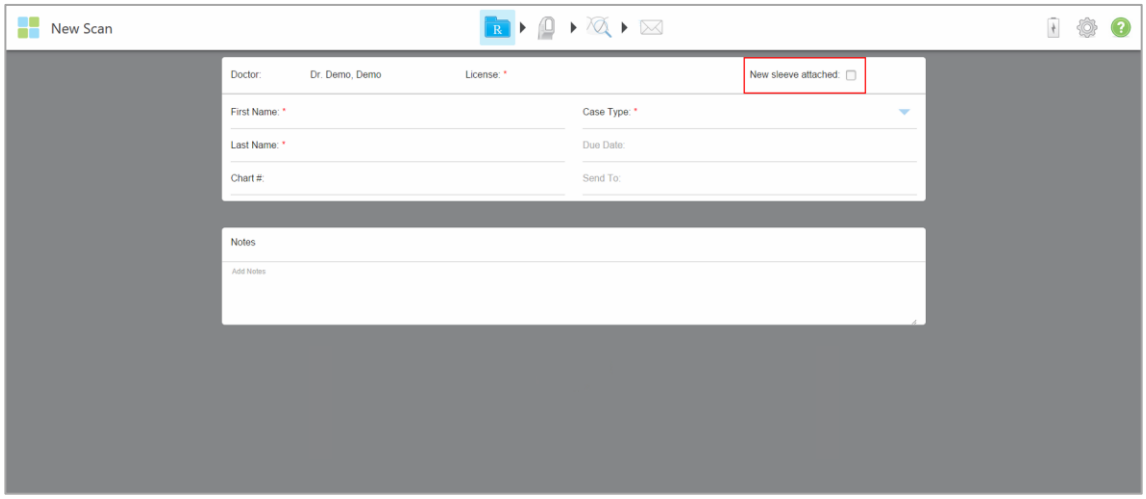


Figure 65: Check box confirming a new sleeve

- 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 sleeve, as described in the following section.

4.1.2.2 Confirming the new 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  .

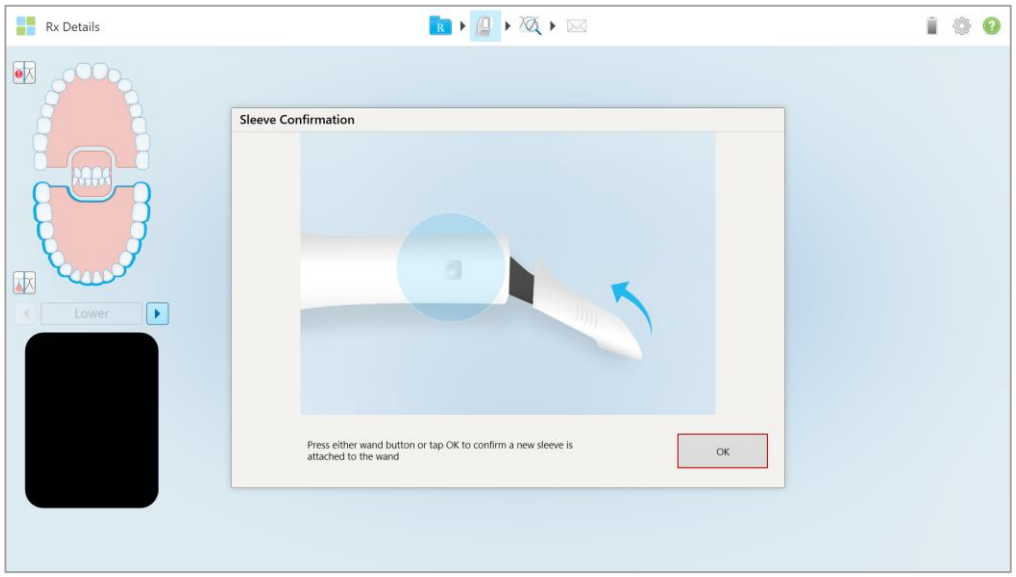


Figure 66: Popup confirmation message before scanning

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

4.2 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.

While scanning, you can perform the following actions:

- View additional scan feedback, described in section 4.2.3.1
- Toggle between color and monochrome mode, described in section 4.2.3.2
- Toggle the 3D and viewfinder display, described in section 4.2.4, below
- Toggle between color mode and NIRI mode, described in section 4.2.5

After scanning, you can edit the scan by:

- Deleting a segment, as described in section 4.2.6.1
- Deleting a selected area, as described in section 4.2.6.2
- Capturing areas with missing anatomy, as described in section 4.2.6.3

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 4.3.

4.2.1 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.

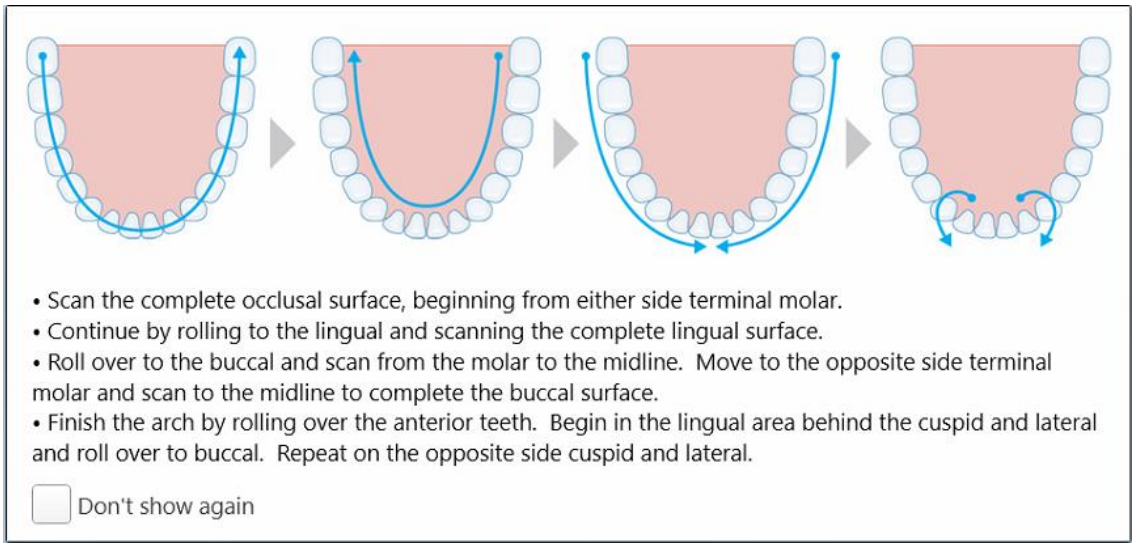


Figure 67: Recommended scanning sequence – lower jaw

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.

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

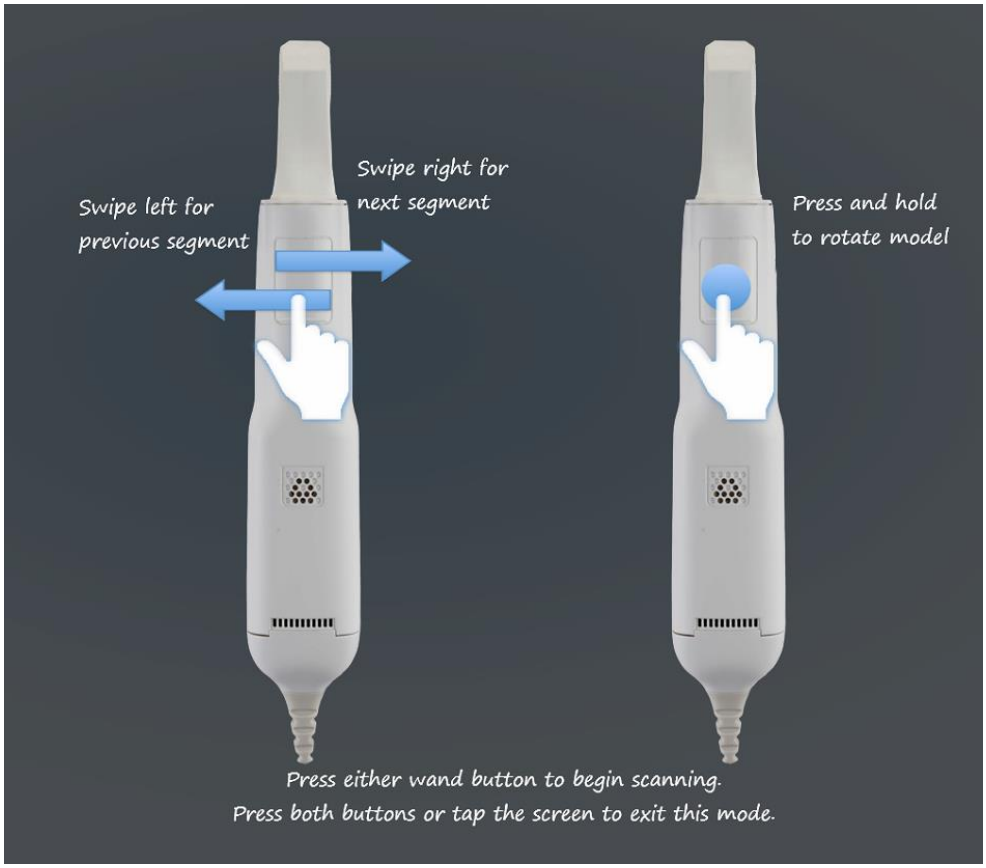


Figure 68: Wand guidance

4.2.2 Scanning best practices

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.

4.2.3 Scan options

In Scan mode, you can select the following options:

- Additional scan feedback, described in section 4.2.3.1
- Toggle color/monochrome, described in section 4.2.3.2
- Toggle between the 3D and the viewfinder display, described in section 4.2.4
- Toggle between color mode and NIRI mode in the viewfinder, as described in section 4.2.5
- Edit the scan:
  - Delete a segment, described in section 4.2.6.1
  - Delete a selection, described in section 4.2.6.2
  - Fill in missing anatomy, described in section 4.2.6.3

4.2.3.1 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.

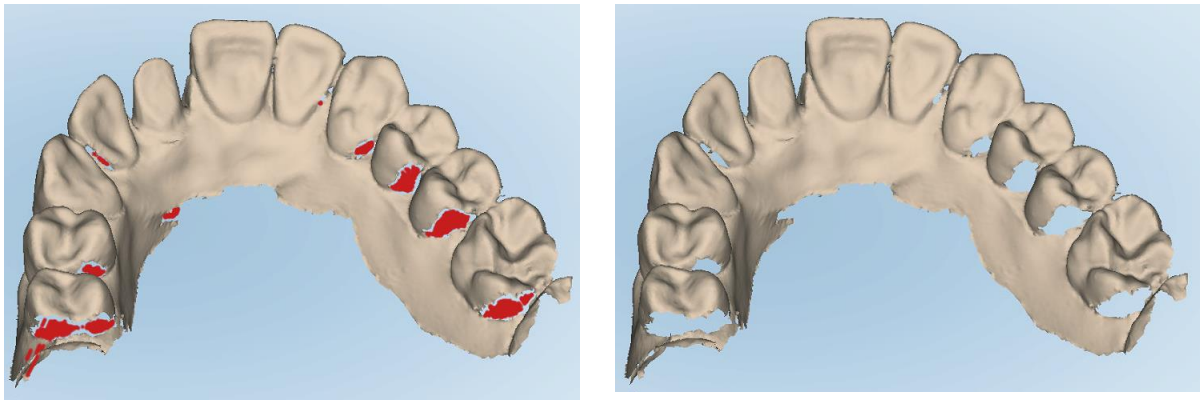


Figure 69: Areas with missing anatomy shown with and without additional scan feedback – monochrome

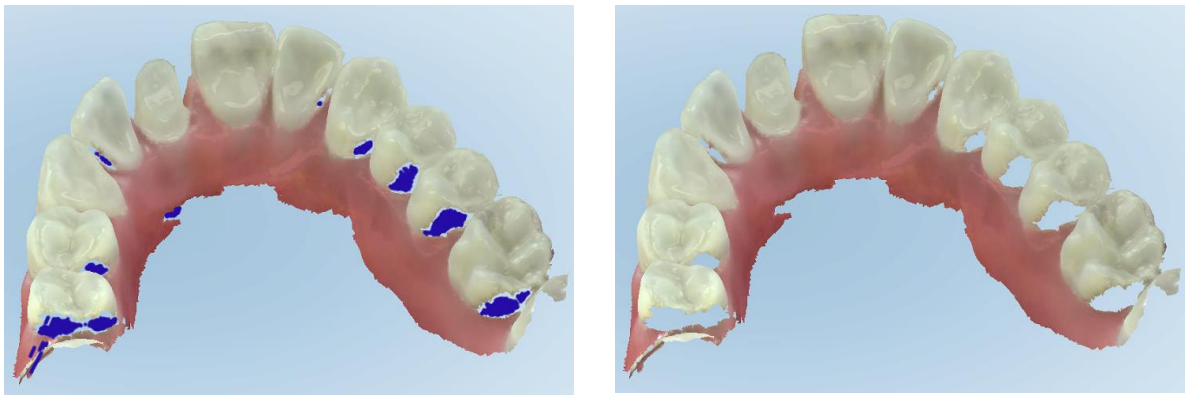


Figure 70: Areas with missing anatomy shown with and without additional scan feedback – color mode

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

4.2.3.2 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.

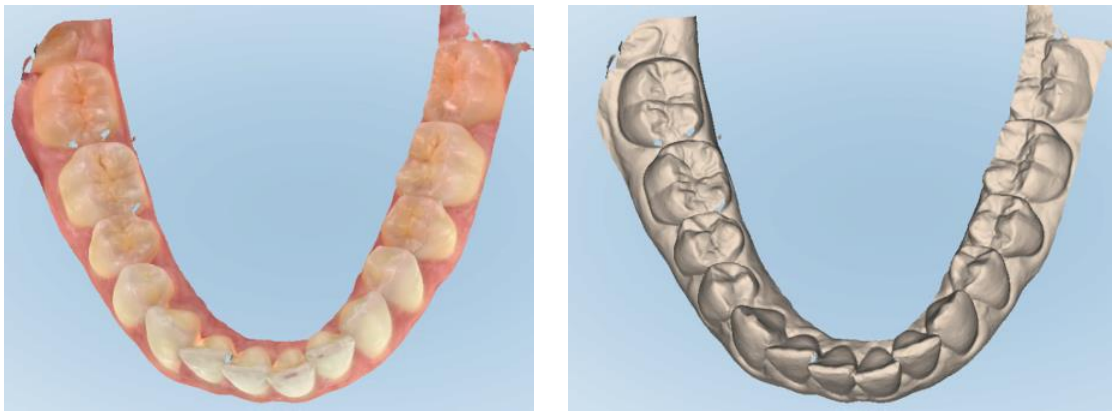


Figure 71: Model displayed in color and monochrome mode

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

4.2.3.3 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, prep, or bite segment
- Tapping the arrows

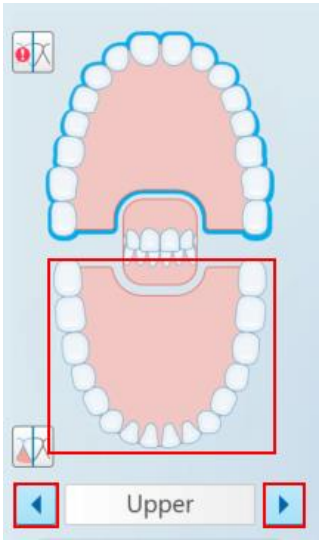


Figure 72: Tap the opposite arch or tap the arrows to select it

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

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

4.2.4 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.

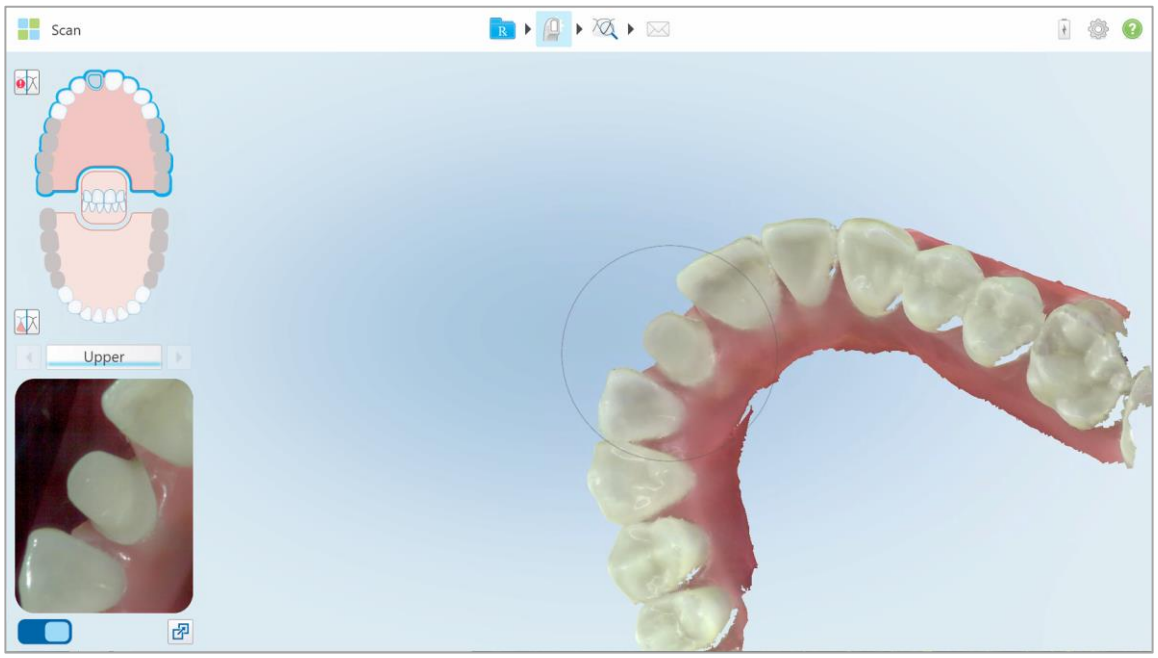


Figure 73: Default view – 3D scan in the center of the window and viewfinder on the left

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

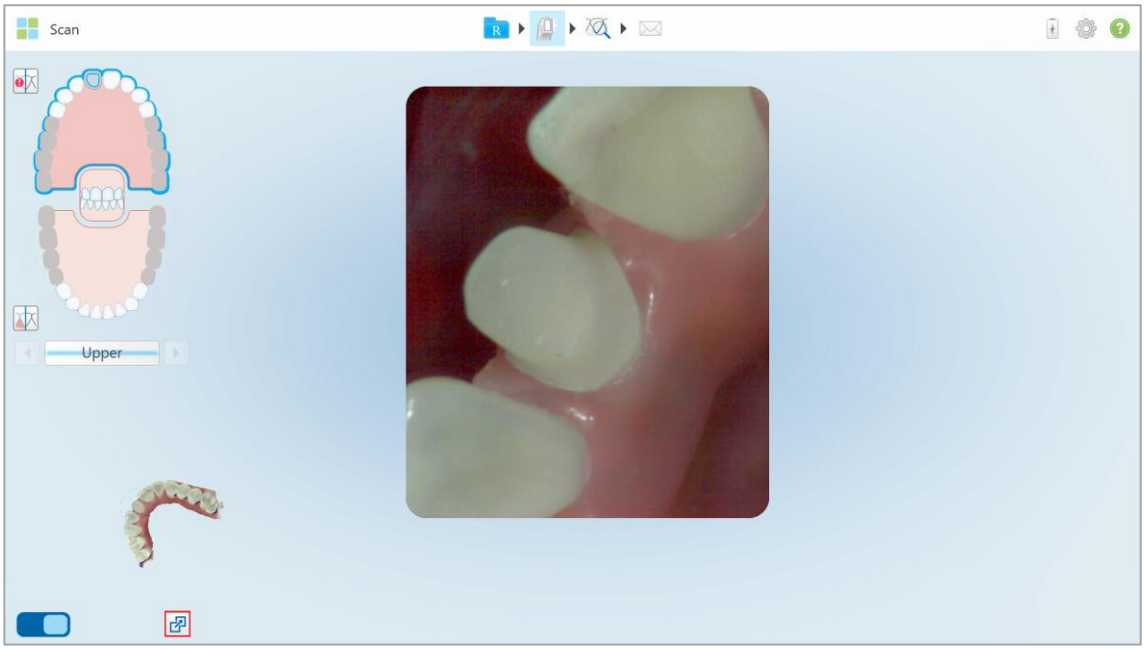


Figure 74: Large viewfinder in the center of the screen and 3D image on the left

4.2.5 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.

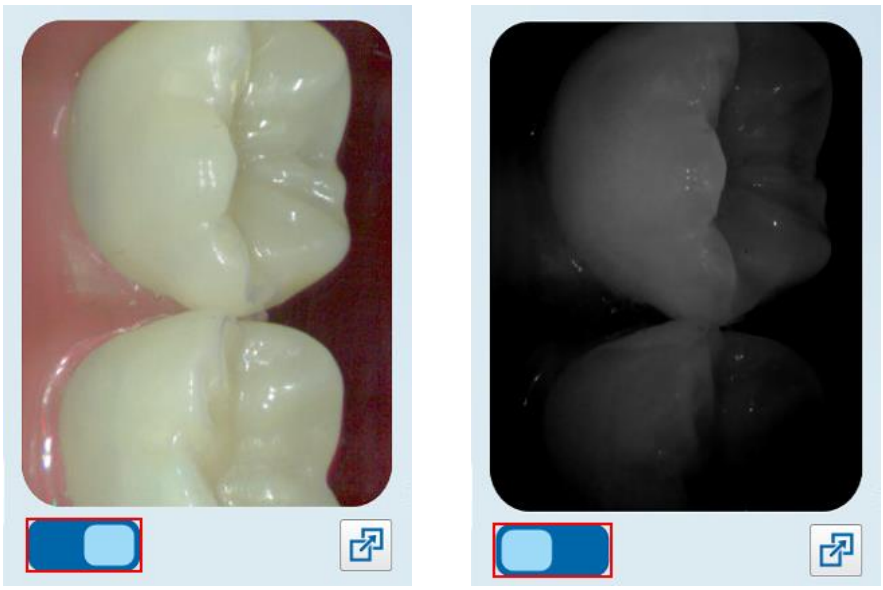


Figure 75: Viewfinder displaying a color image (left) or a NIRI image (right)

4.2.6 Editing a scan

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

- Delete Segment tool, described in section 4.2.6.1
- Delete Selection tool, described in section 4.2.6.2
- Fill tool, described in section 4.2.6.3

The editing tools are accessed by pressing on the screen.

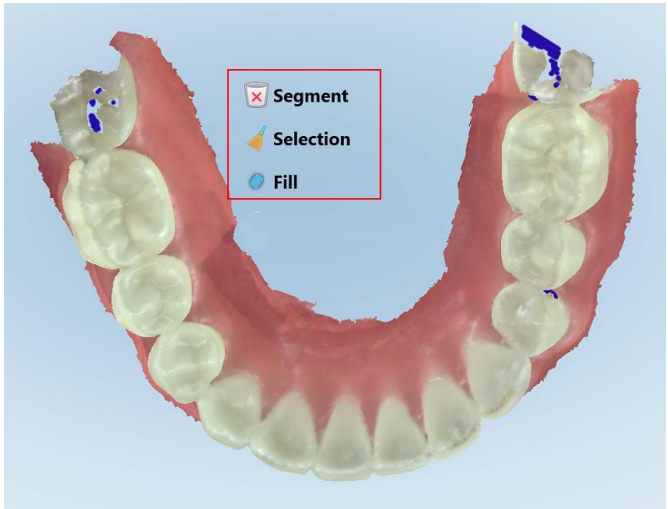


Figure 76: Editing tools

4.2.6.1 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  .

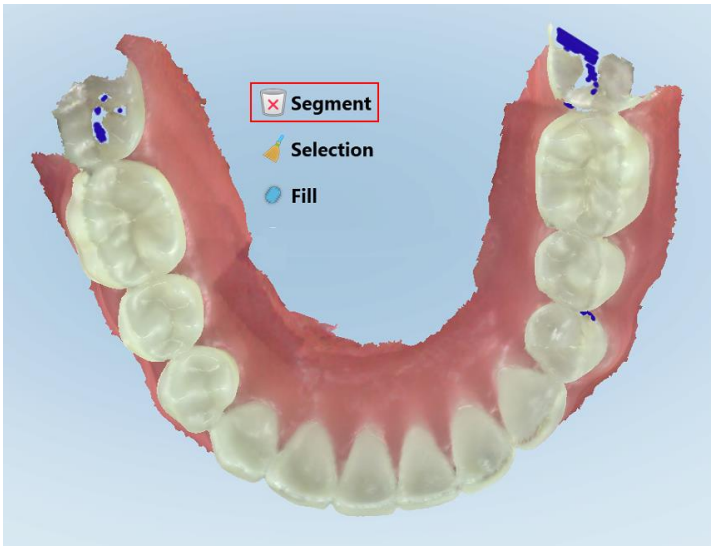


Figure 77: Delete Segment tool

A confirmation message is displayed.

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

   The entire scanned segment is deleted.

4.2.6.2 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 .

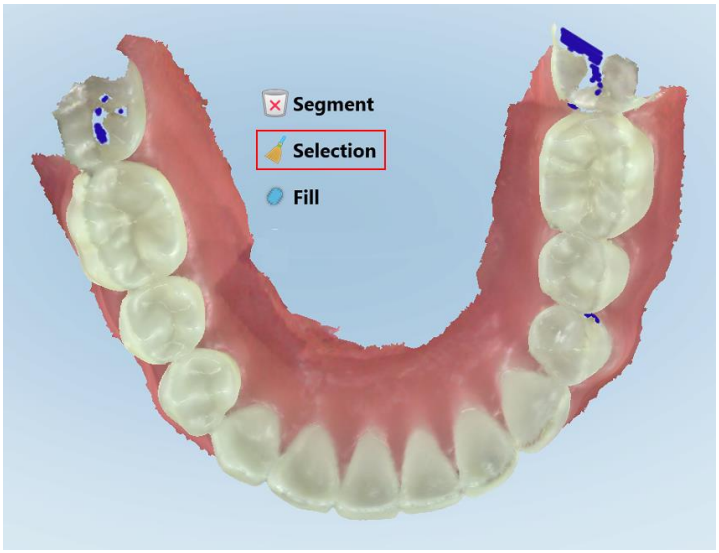


Figure 78: Delete Selection tool

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

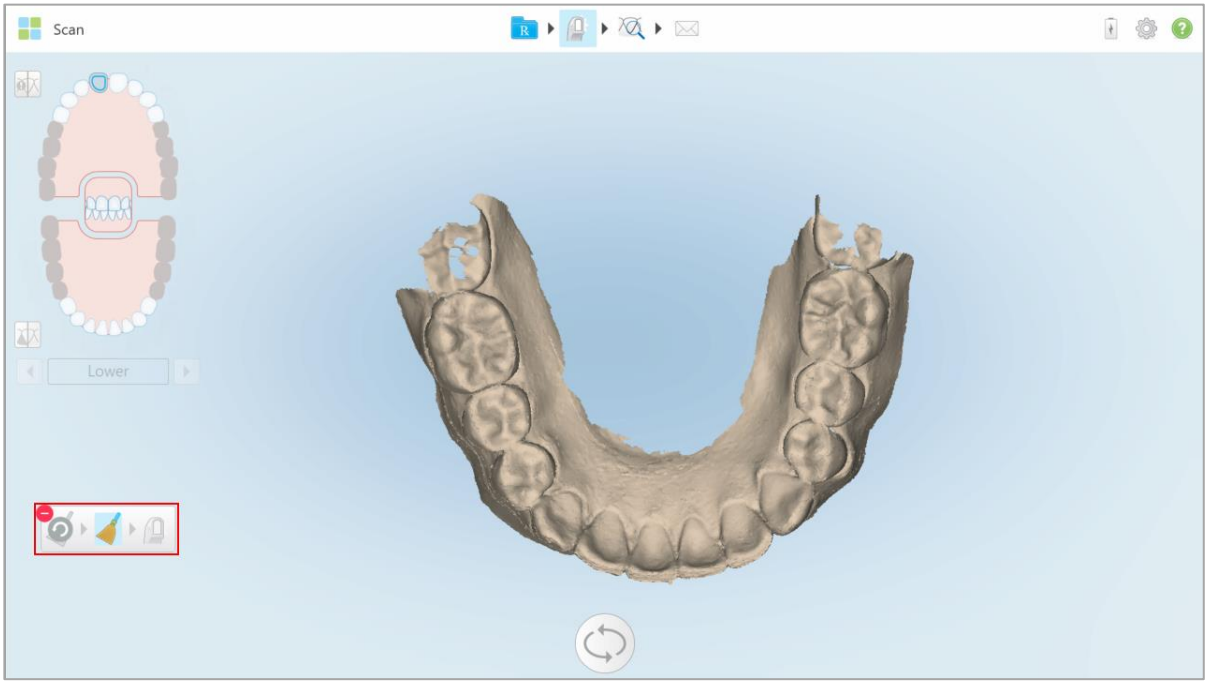


Figure 79: Expanded Delete Selection tool

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

   The selection is removed.

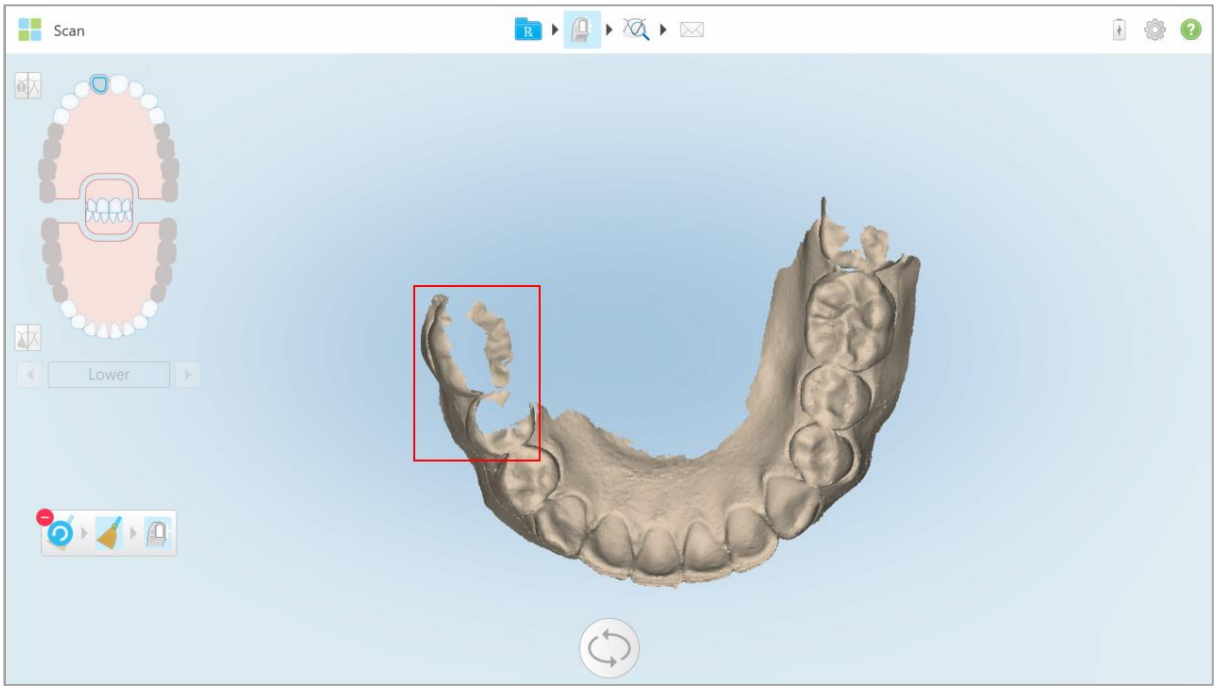


Figure 80: Selected area of the anatomy is deleted

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

4.2.6.3 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.

To use the Fill tool:

1. Press the screen to display the editing tools.

2. Tap the Fill tool .

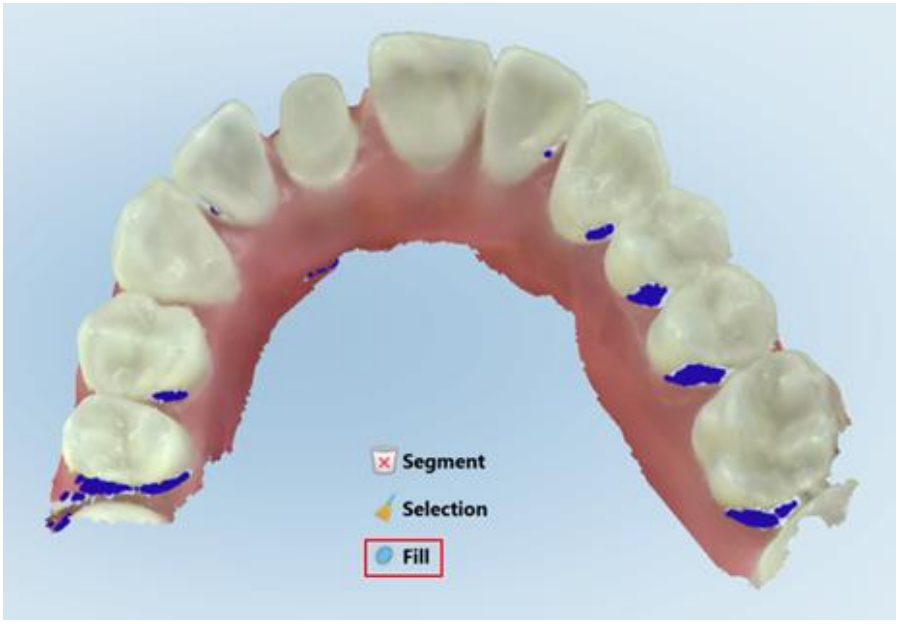


Figure 81: Fill tool

Areas that require scanning are highlighted in red.

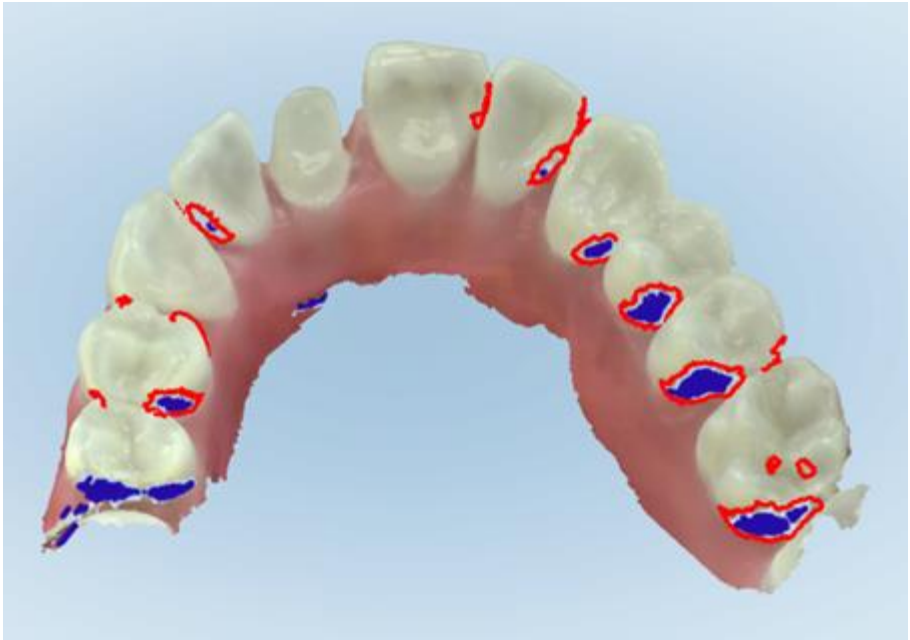


Figure 82: Areas that require scanning are highlighted in red – Fill tool

4.3 Viewing the scan

After scanning the patient, click  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 4.3.1.

While viewing the scan, you can:

- Delete selected areas of a scan, as described in section 4.3.2
- Trim excess tissues from the scan, as described in 4.3.4
- 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 4.3.5
- View an area of interest, as described in section 4.3.6

After you have reviewed the scan, tap  on the toolbar to send the scan to the lab or to storage, as described in section 4.4.

4.3.1 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.

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.

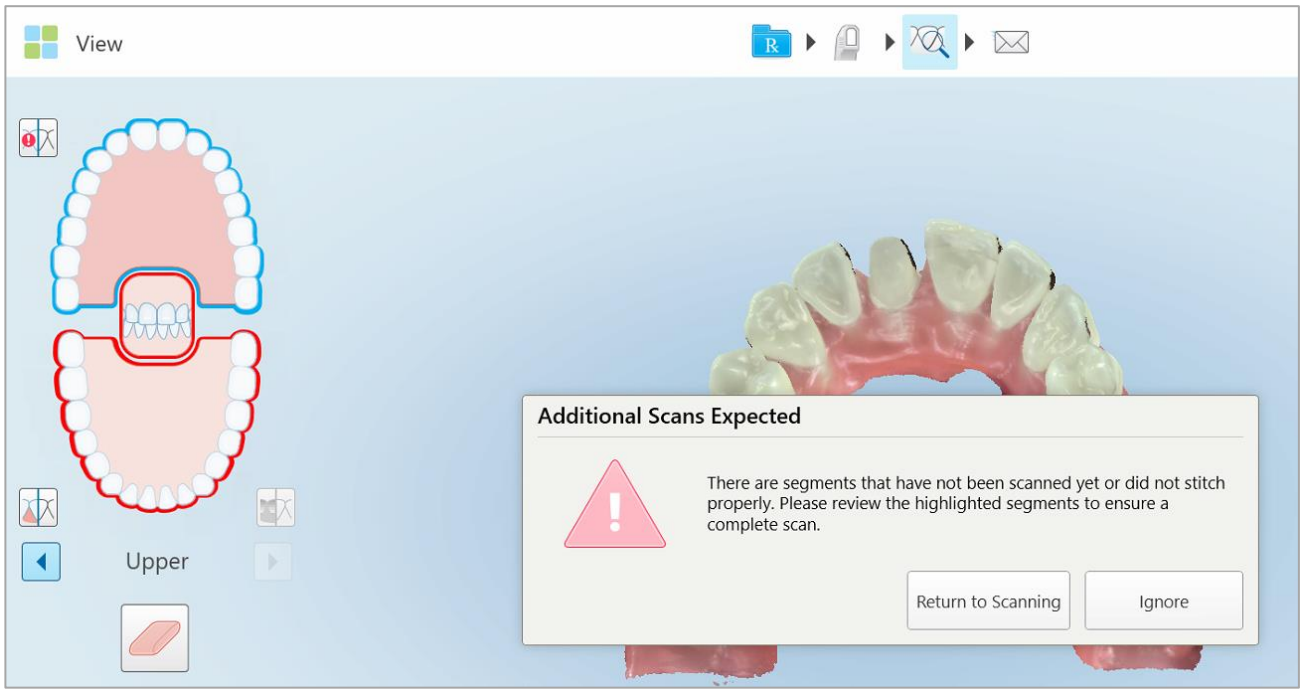


Figure 83: Missing scan message and missing segments highlighted in red

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.

4.3.2 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.

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  .

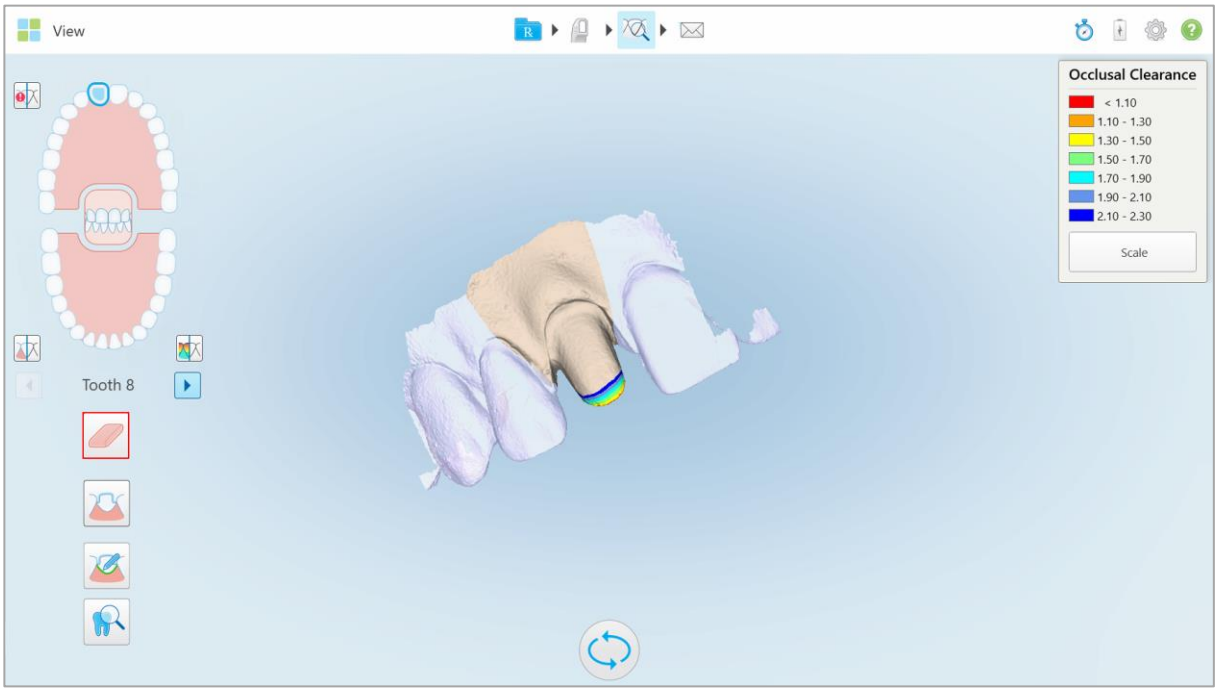


Figure 84: Eraser tool

The Eraser tool expands to show the following options:

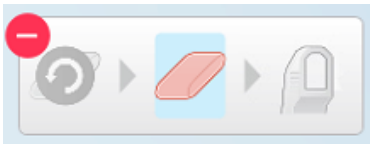


Figure 85: Eraser tool options

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

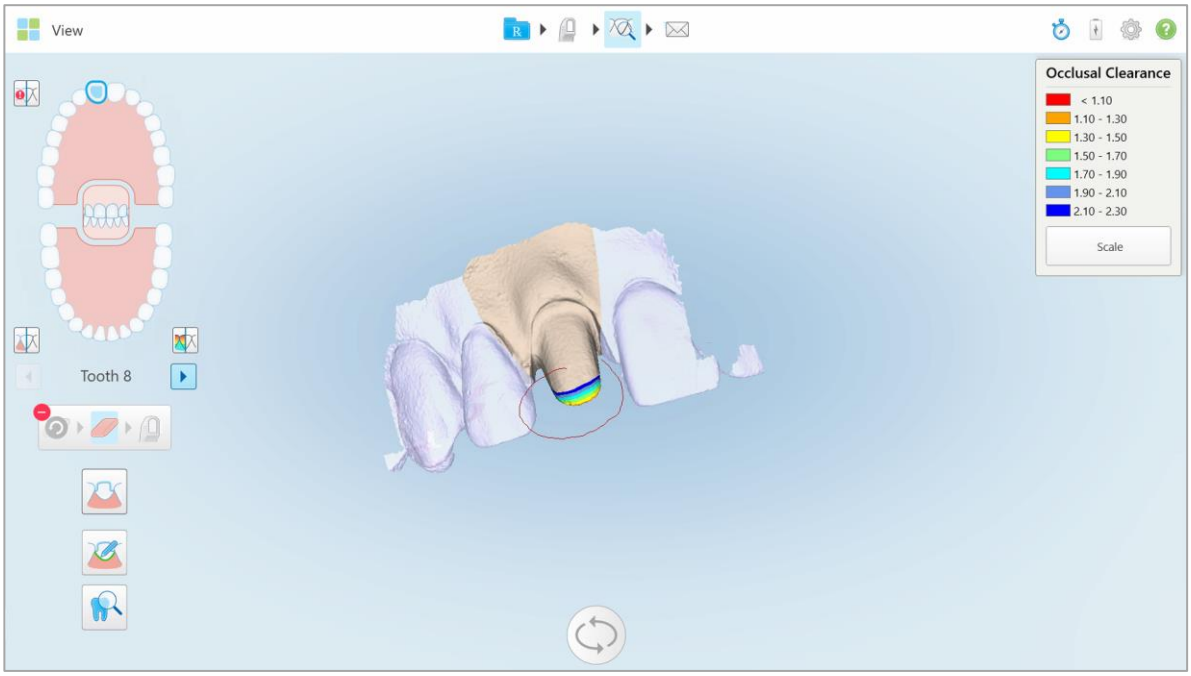


Figure 86: Area to be modified

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

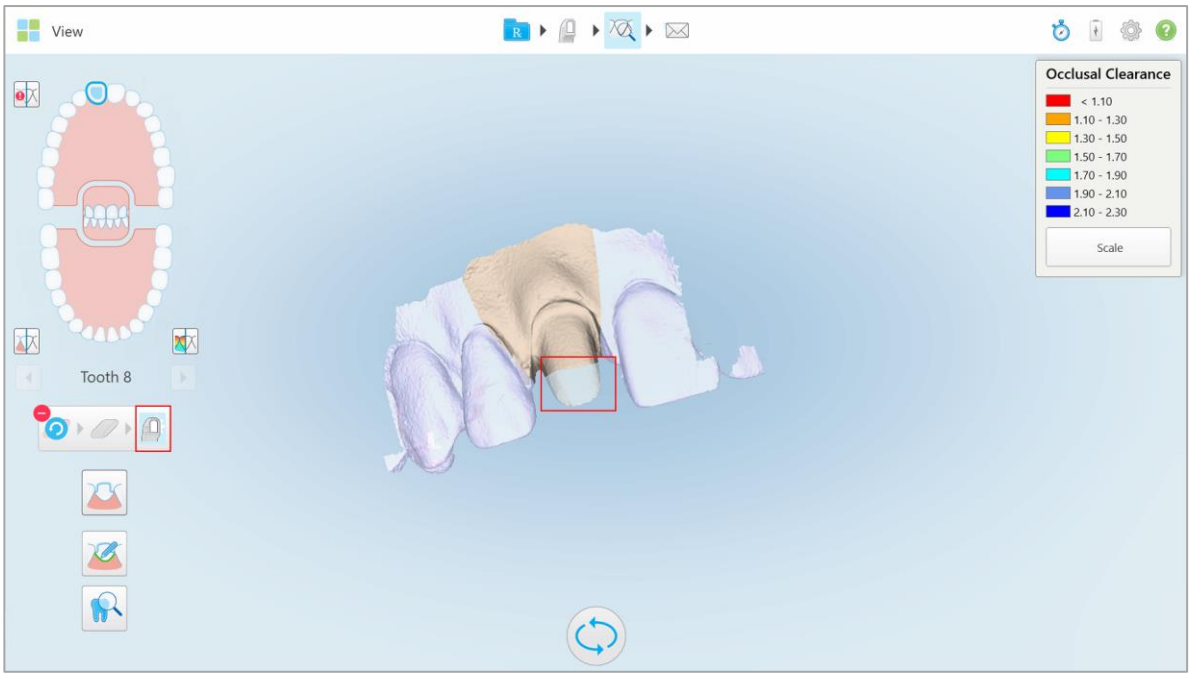


Figure 87: Selected area removed and scan tool enabled

3. If required, click  to undo the deletion.

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.

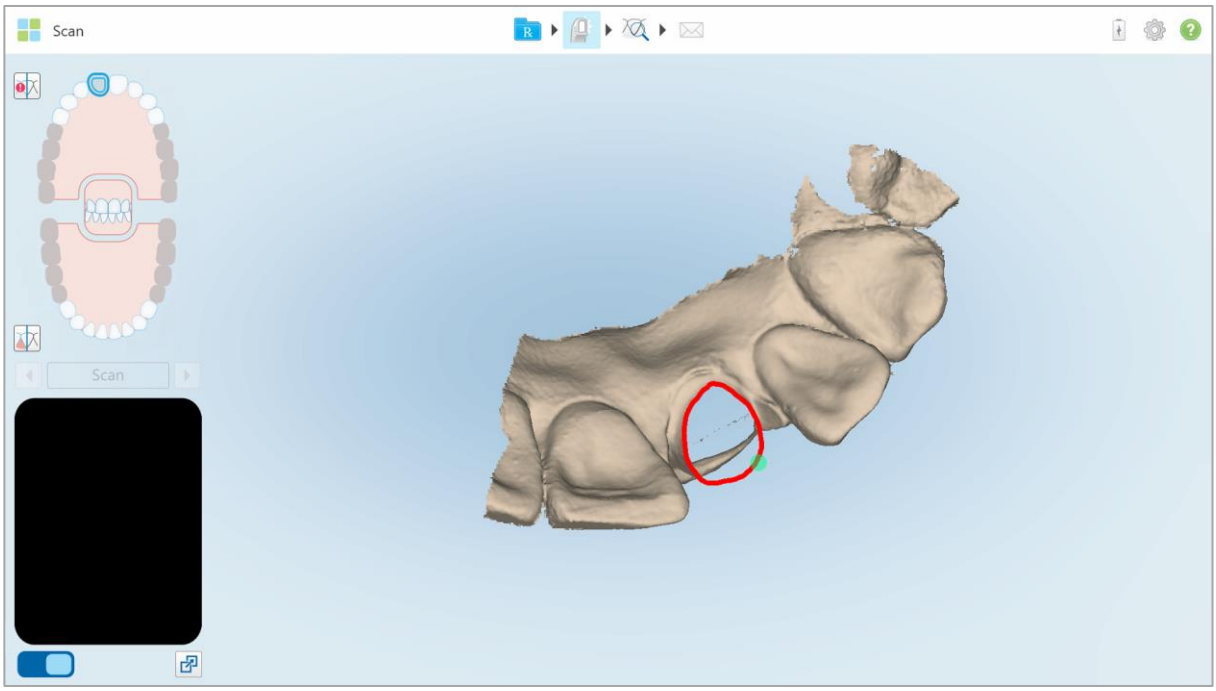


Figure 88: Deleted area marked in red

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

4.3.3 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  .
   The occlusal clearance between the opposing teeth is displayed.

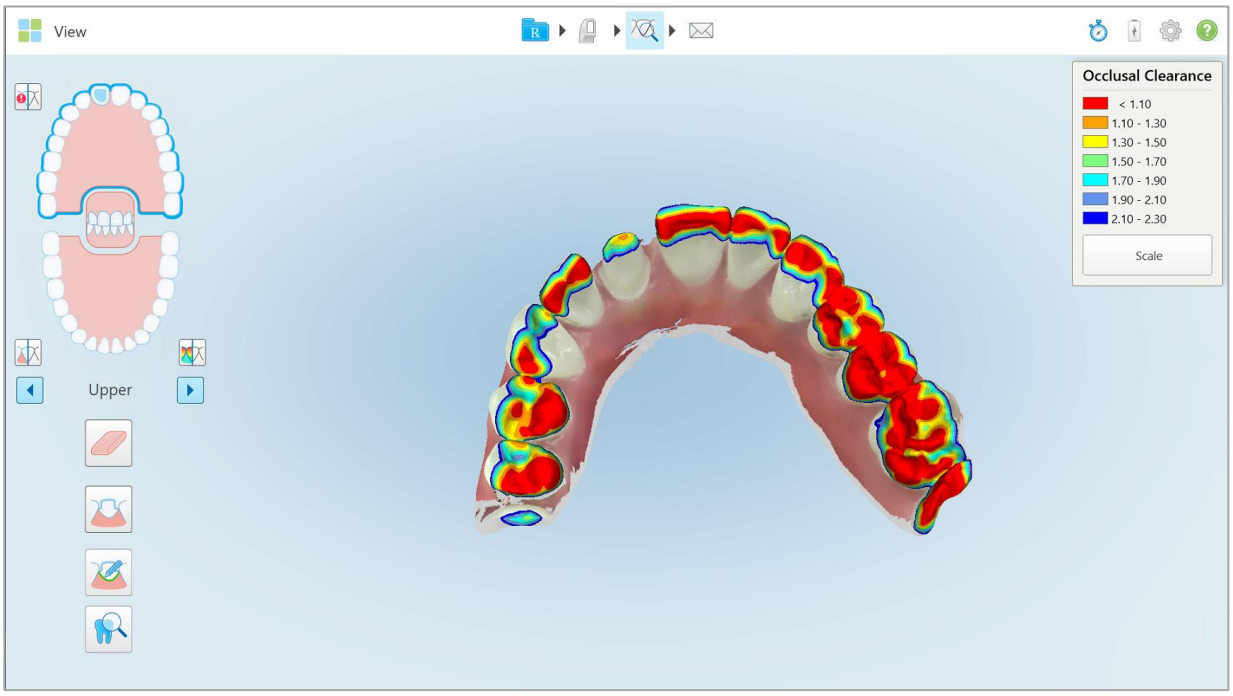


Figure 89: Occlusal clearance between the opposing teeth

2. If necessary, reduce the prepped tooth and rescan the area, as described in section 4.3.2, above.
3. If required, you can change the occlusal values displayed on the opposing teeth.

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

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

Figure 90: Occlusal Clearance range options

b. Select the required scale.

The occlusal clearance is displayed according to the new scale.

4.3.4 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  .

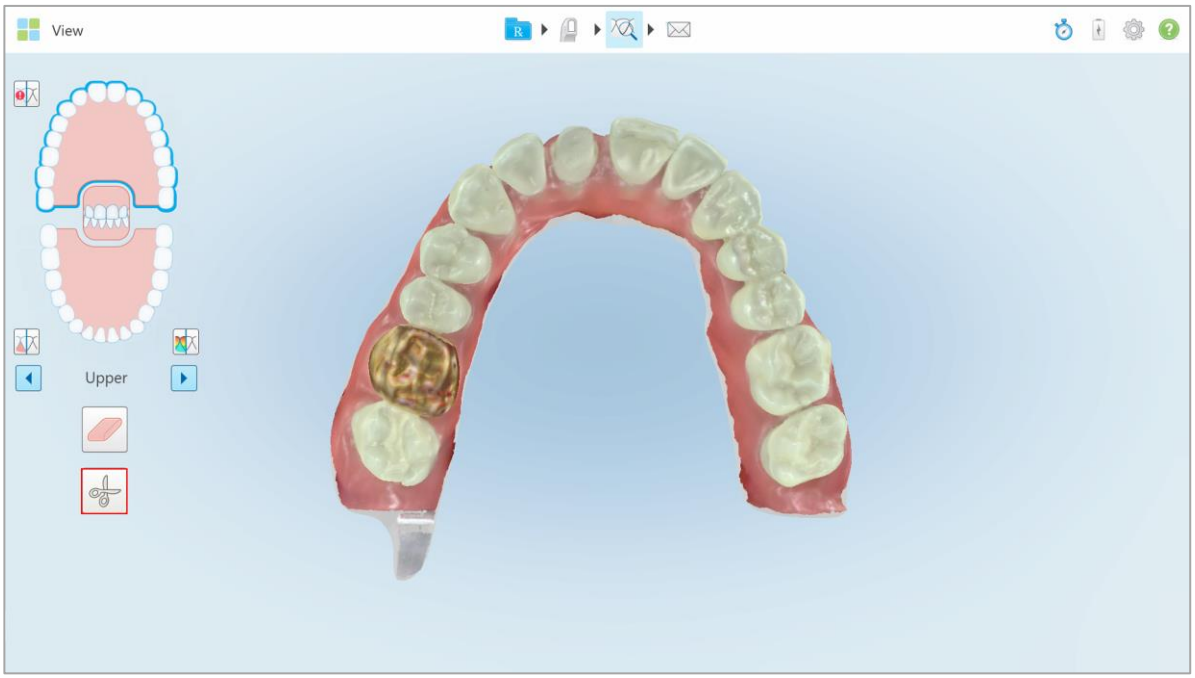


Figure 91: Edge trimming tool

The Edge Trimming tool expands to show the following options:

Figure 92: Edge trimming tool options

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

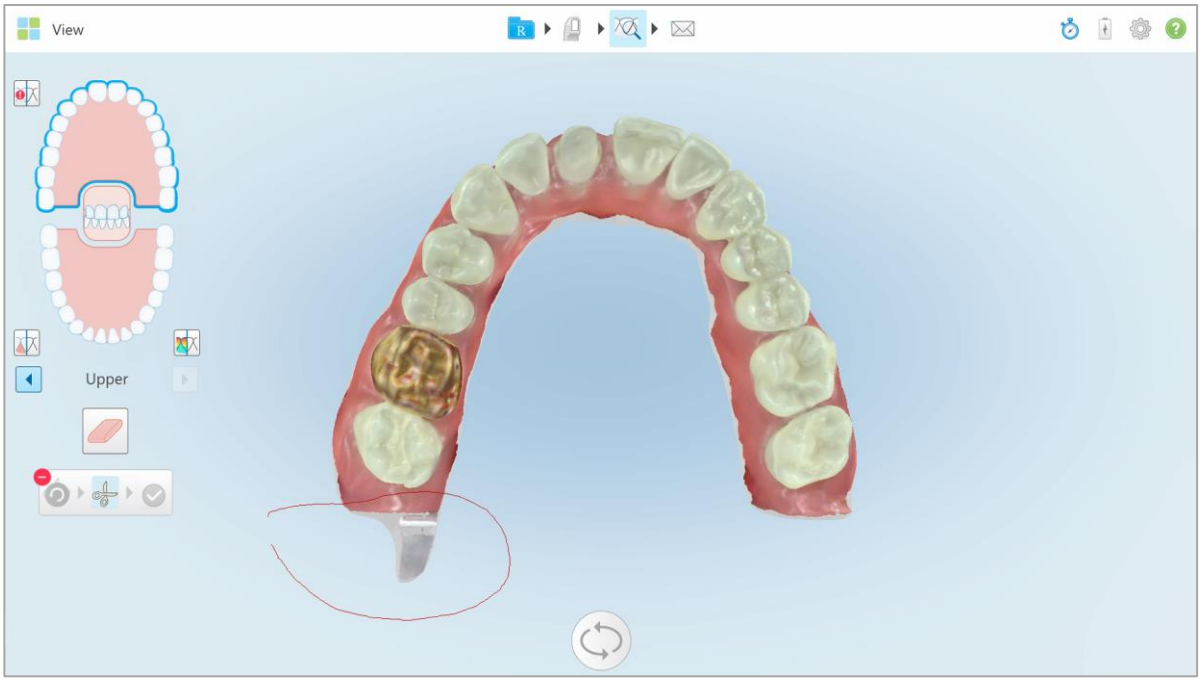


Figure 93: Marking the area to be trimmed away

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

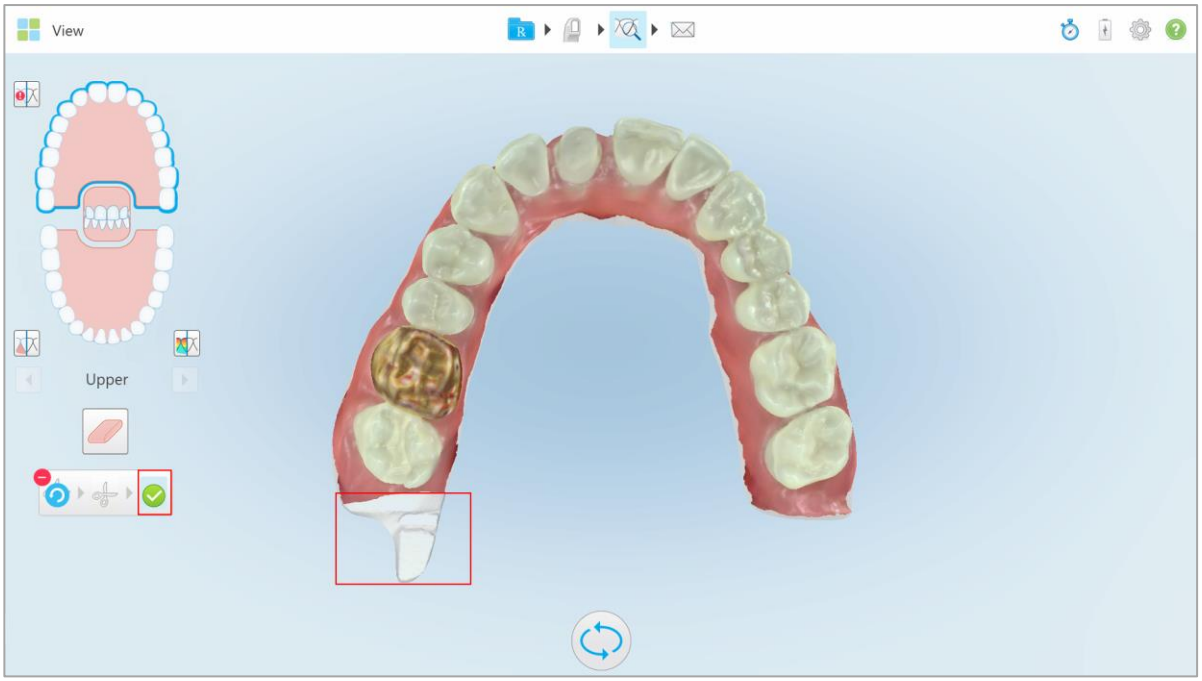


Figure 94: Selected area is highlighted and the confirmation icon is enabled

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

4. Tap  to confirm the trimming.

   The selected area is removed.

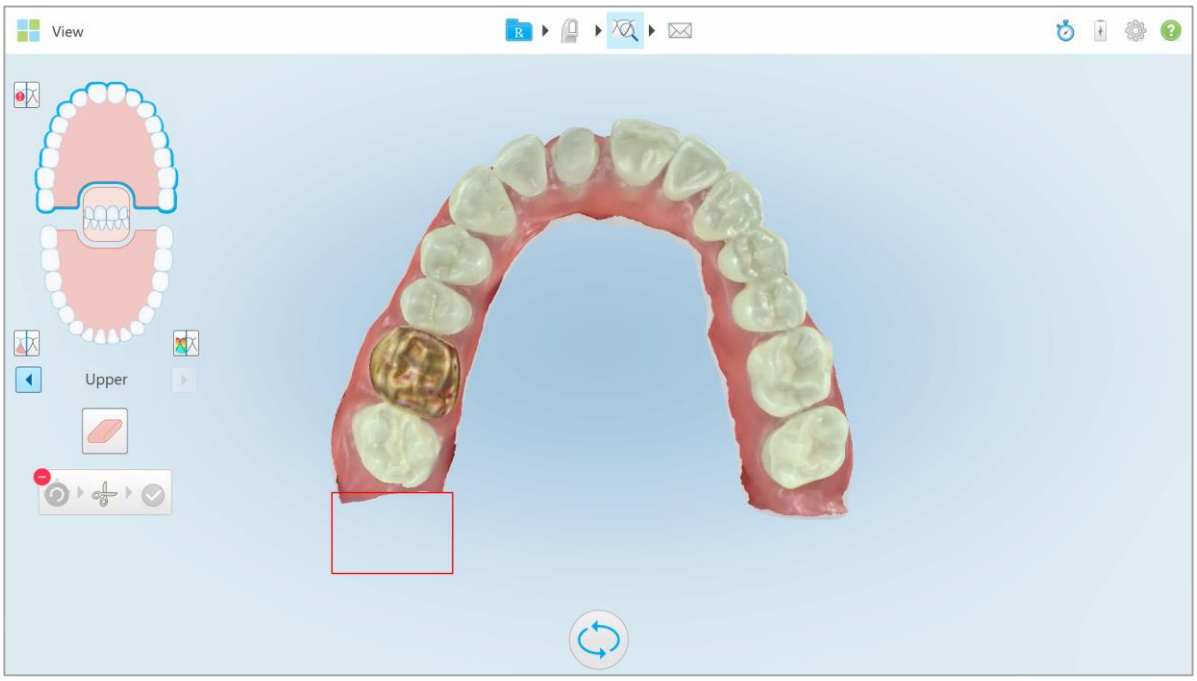


Figure 95: Selected area has been removed

4.3.5 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.

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.

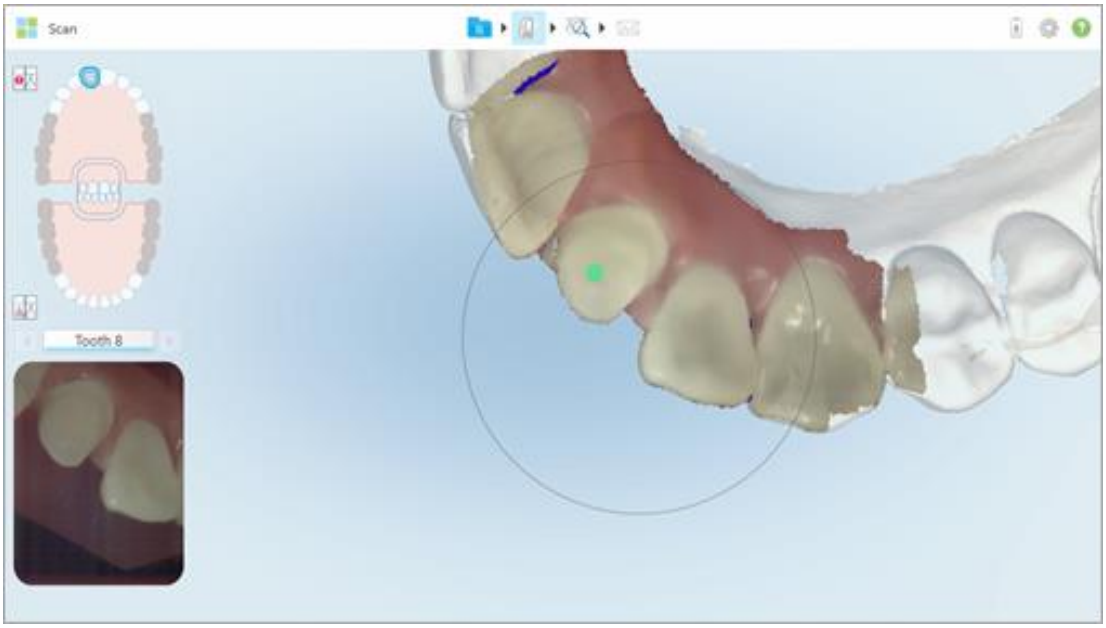


Figure 96: Green hint point centered on the prepped tooth

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.

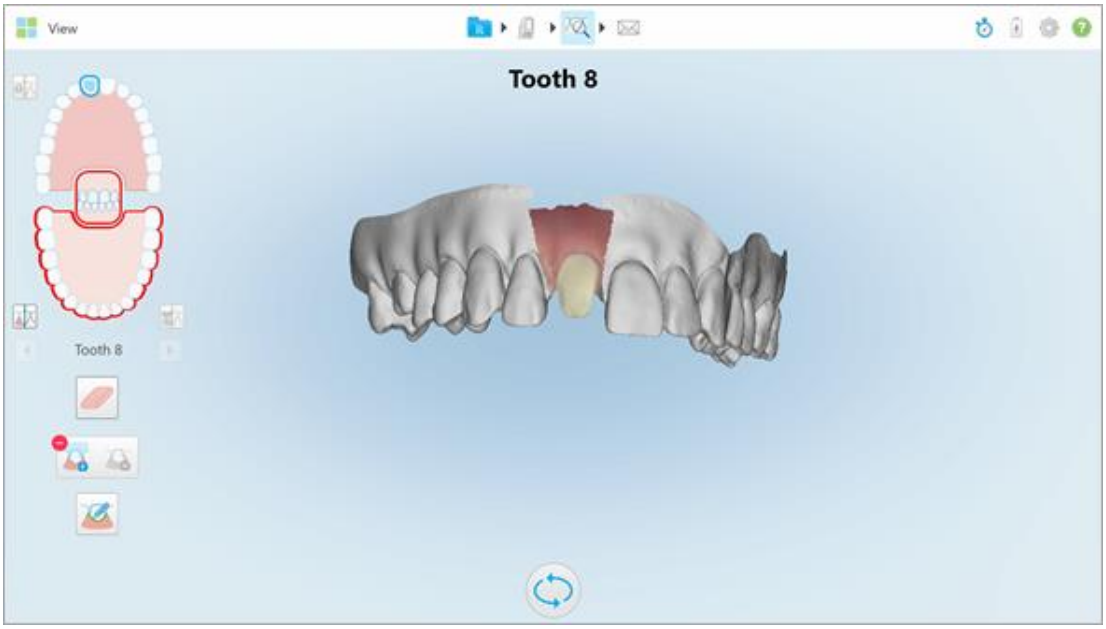


Figure 97: Die separation is displayed in high resolution

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 98: Die Separation tool options

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

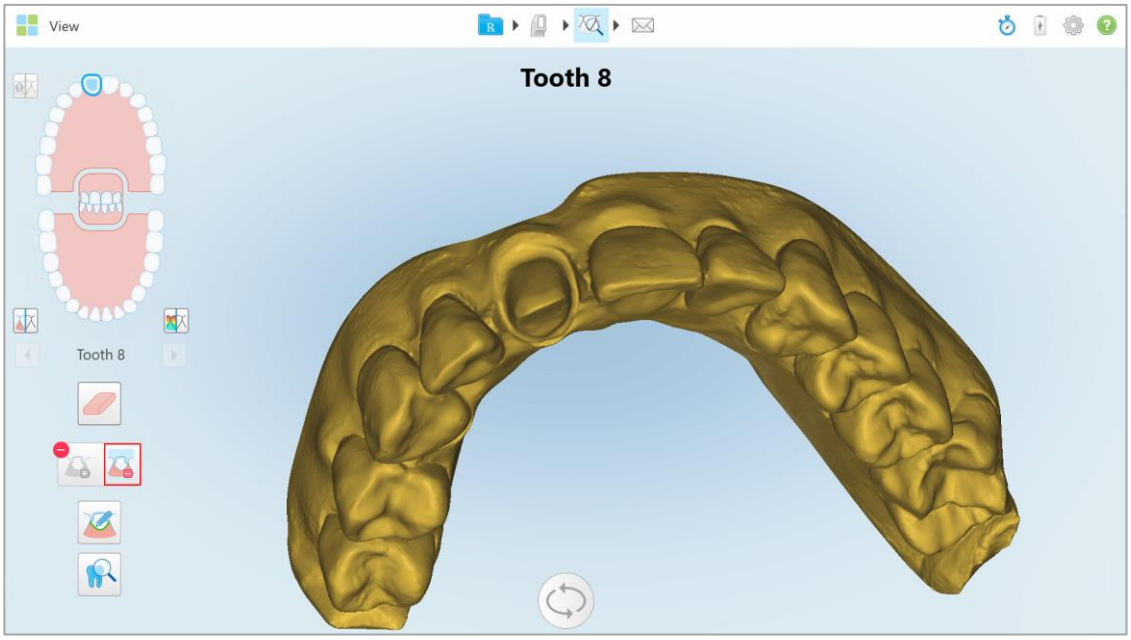


Figure 99: Scan is displayed in low resolution

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

   The model is displayed as follows:

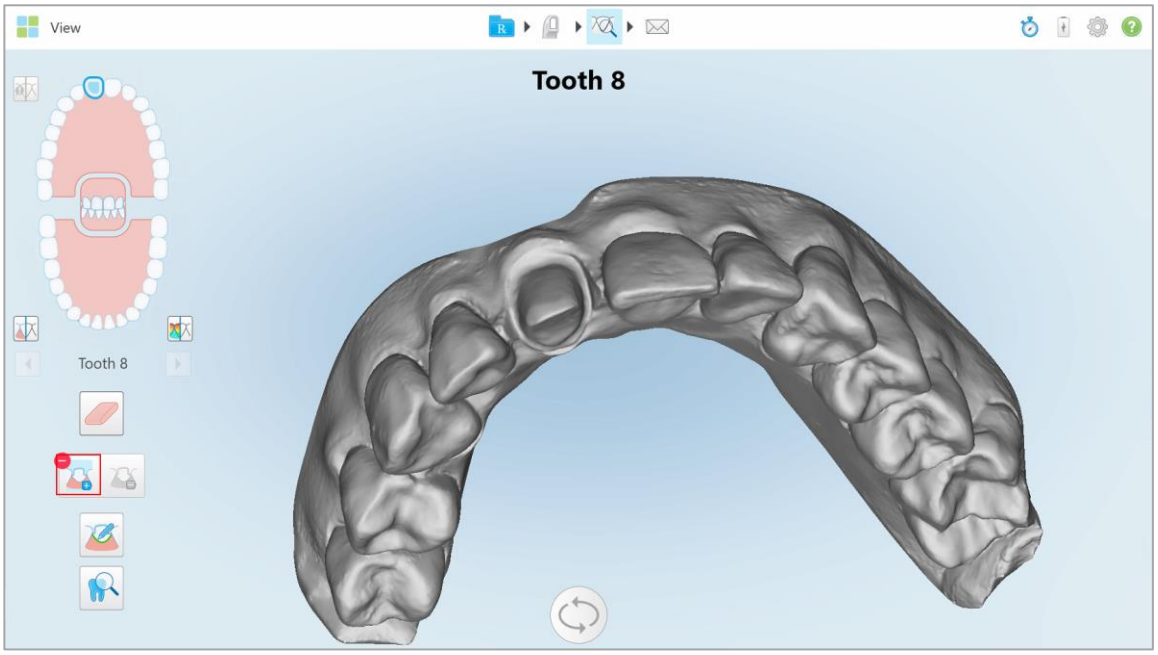


Figure 100: Before selecting the die separation

4. Draw the area for the die separation.

   The selected area is displayed in high resolution.

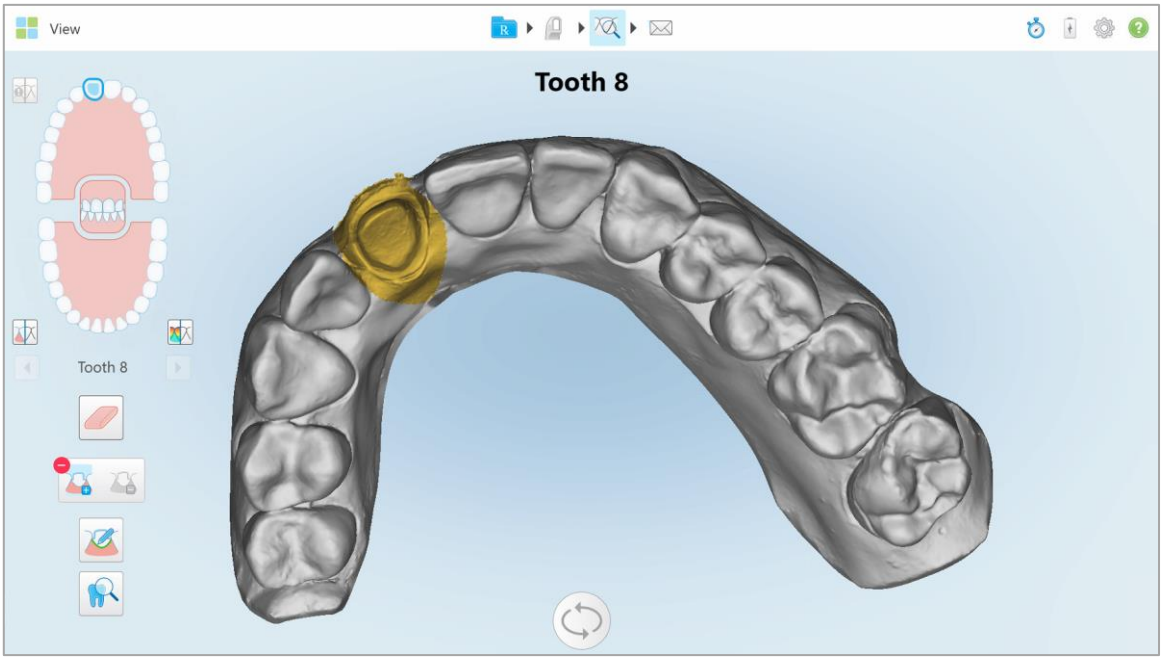


Figure 101: Prepped tooth is displayed in high resolution

4.3.6 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 4.3.6.1
- Adjust the brightness and contrast of images in the viewfinder, as described in section 4.3.6.2
- Capture images, as described in section 4.3.6.3

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.

To activate the Review tool:

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

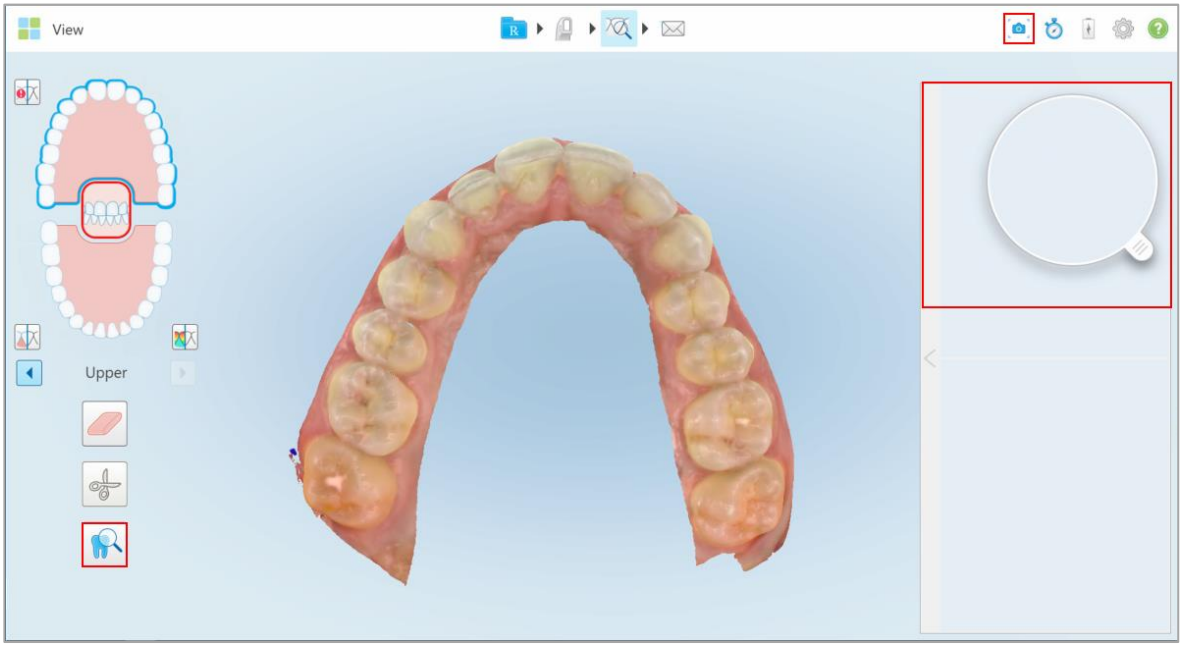


Figure 102: Review tool with the capture tool on the toolbar and the loupe in the right pane

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

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.

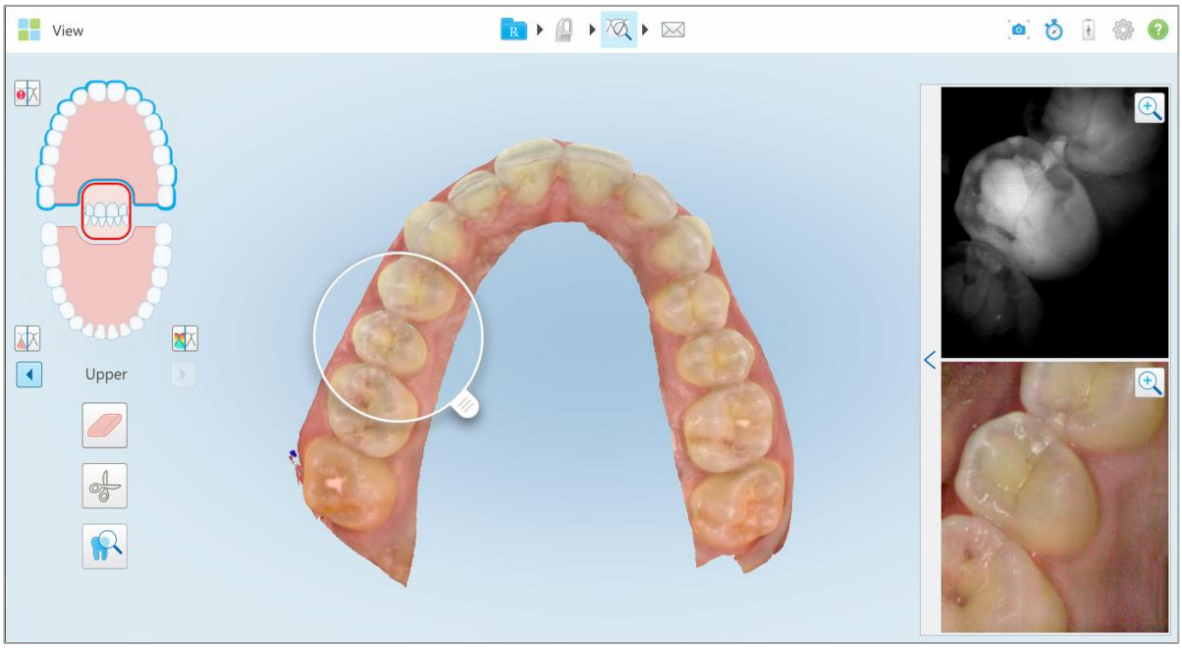


Figure 103: Viewfinder on the right showing the area in the loupe in both NIRI and color modes

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

4.3.6.1 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.

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 104: 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.

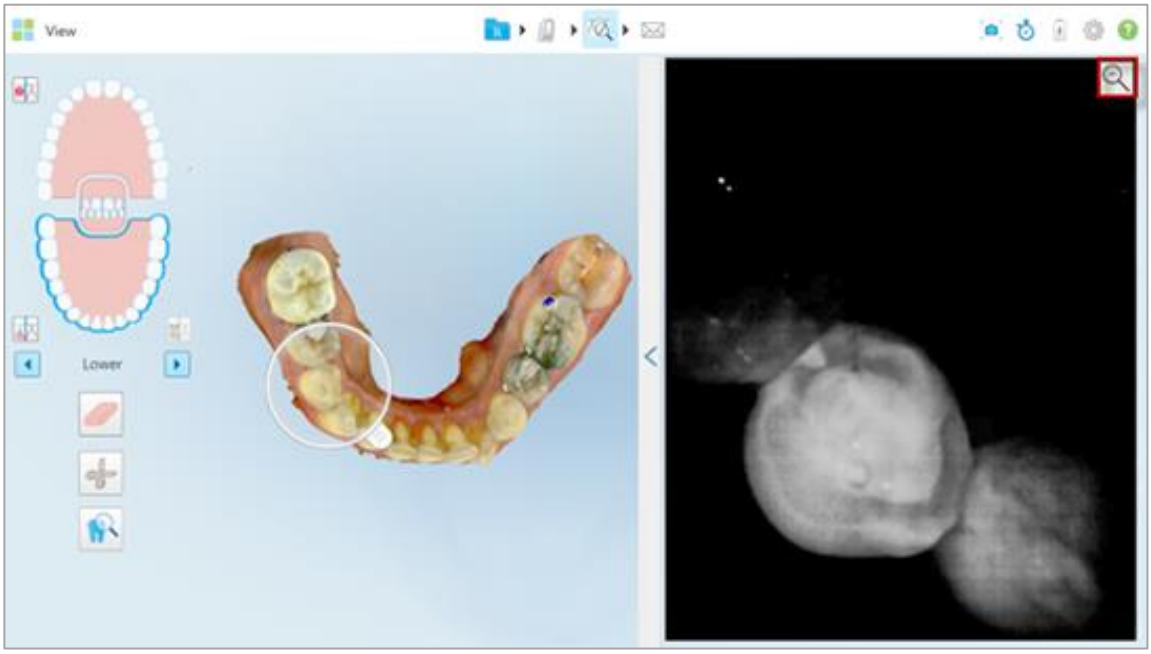


Figure 105: Only the zoomed-in image is displayed in the enlarged viewfinder

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

4.3.6.2 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.

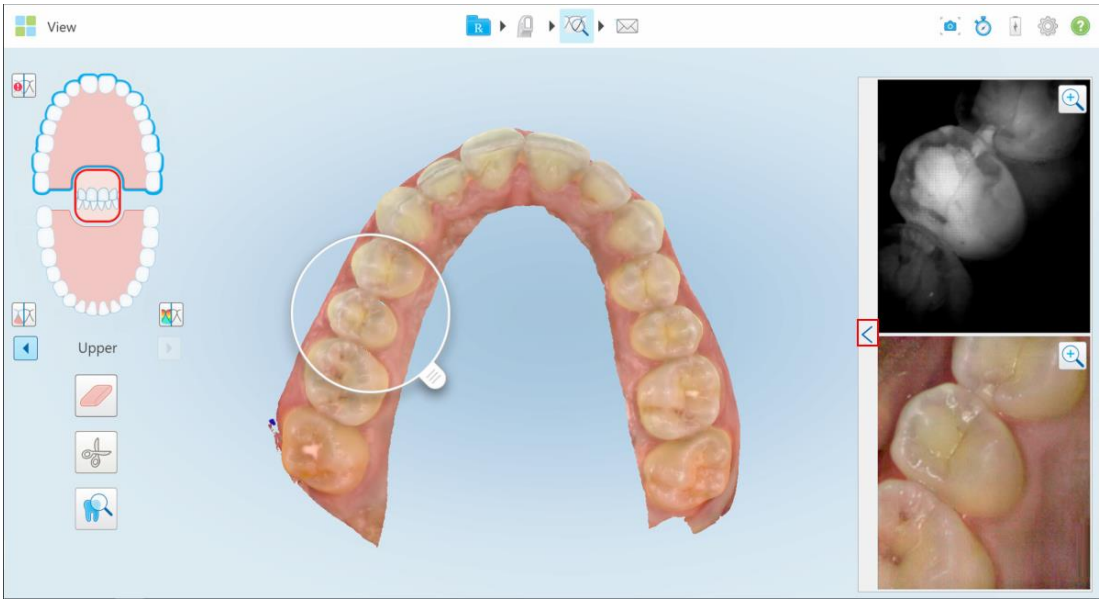


Figure 106: Brightness and contrast toolbar is collapsed

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.

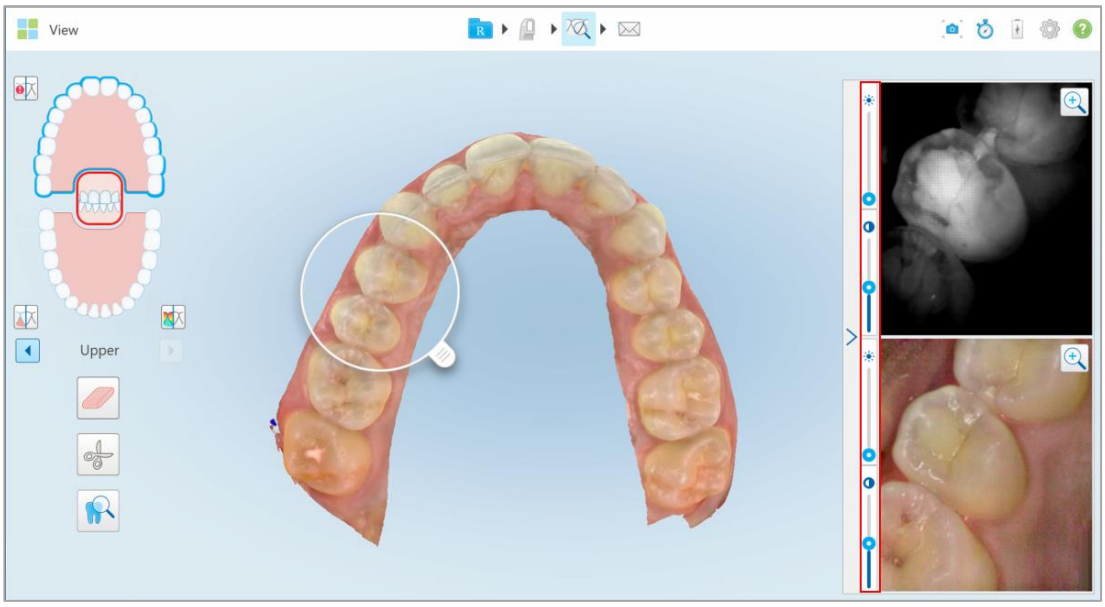


Figure 107: Brightness and contrast toolbars

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.

4.3.6.3 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.

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.)

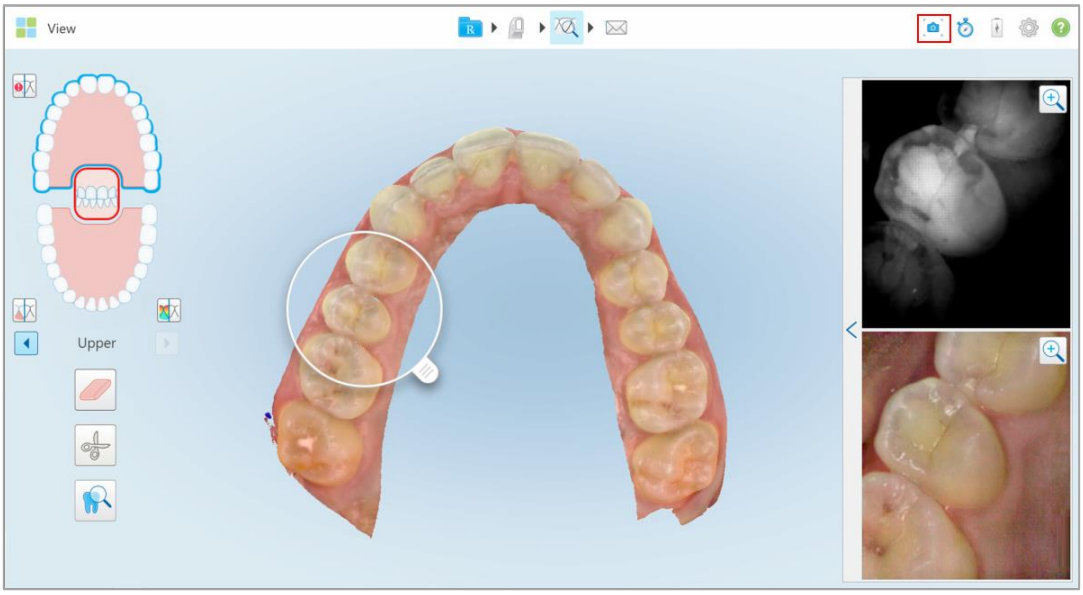


Figure 108: Capturing an area of interest

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, and can then be downloaded from MyiTero, from the *Orders* page or the Viewer.

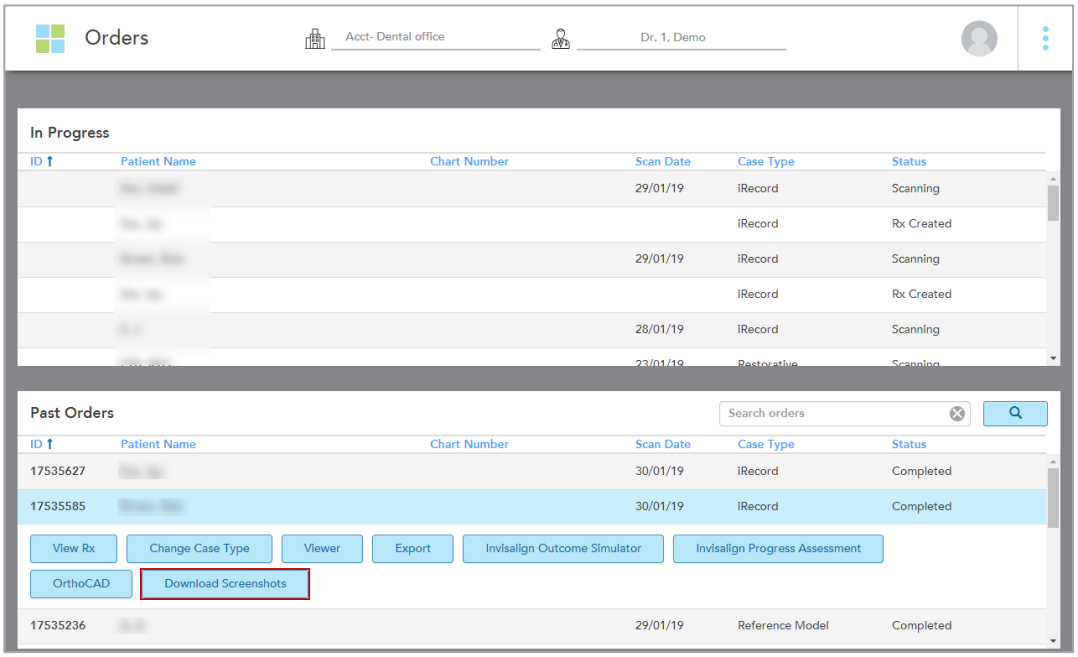


Figure 109: Option to download screenshots from the Orders page in MyiTero

4.3.7 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, click the  button.

   The scan time is displayed.

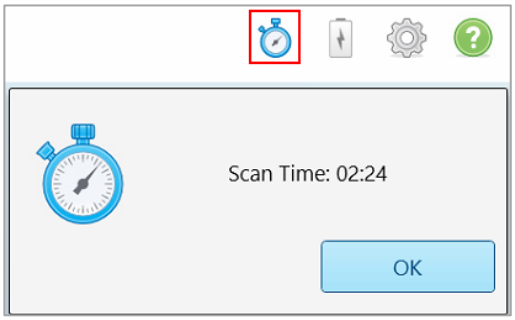


Figure 110: Scan timer button on the toolbar and scan time

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

4.4 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**.

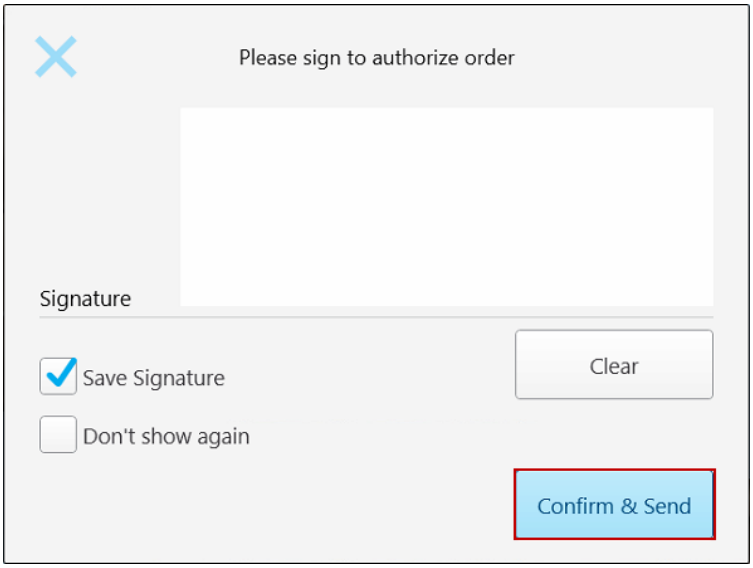


Figure 111: Sending the scan

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.

4.5 Restorative scanning basics

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

4.6 Orthodontic scanning basics

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

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.

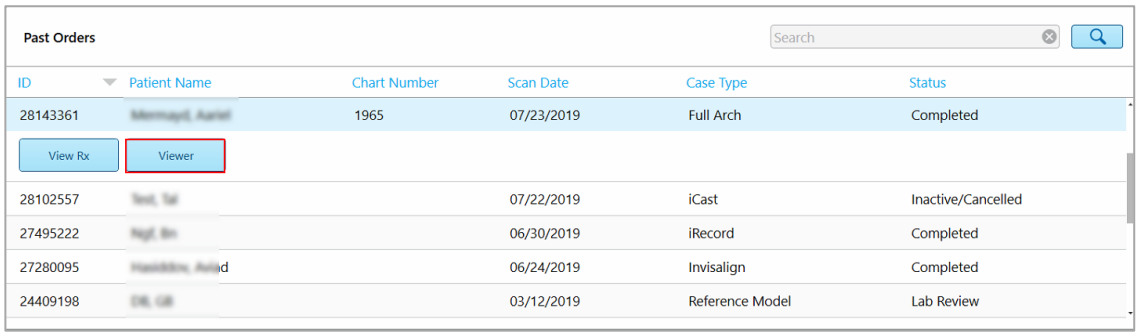


Figure 112: Viewer option in the Past Orders pane in the Orders page

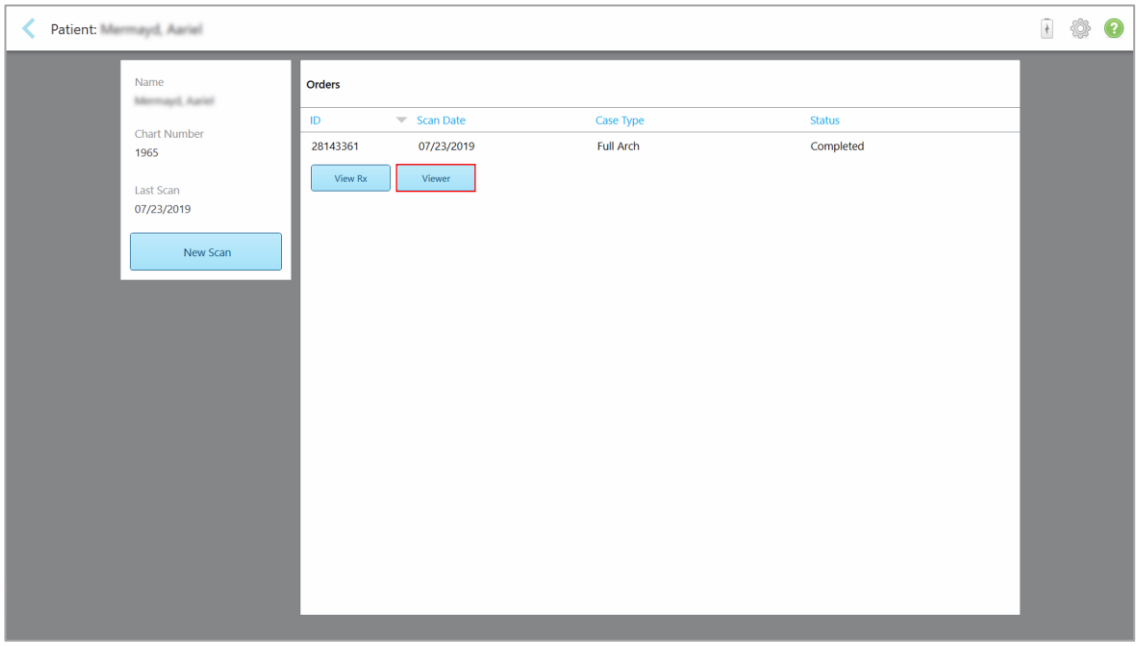
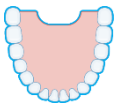


Figure 113: Viewer option in patient's profile page

In the Viewer, you can click 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 4.3.6

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

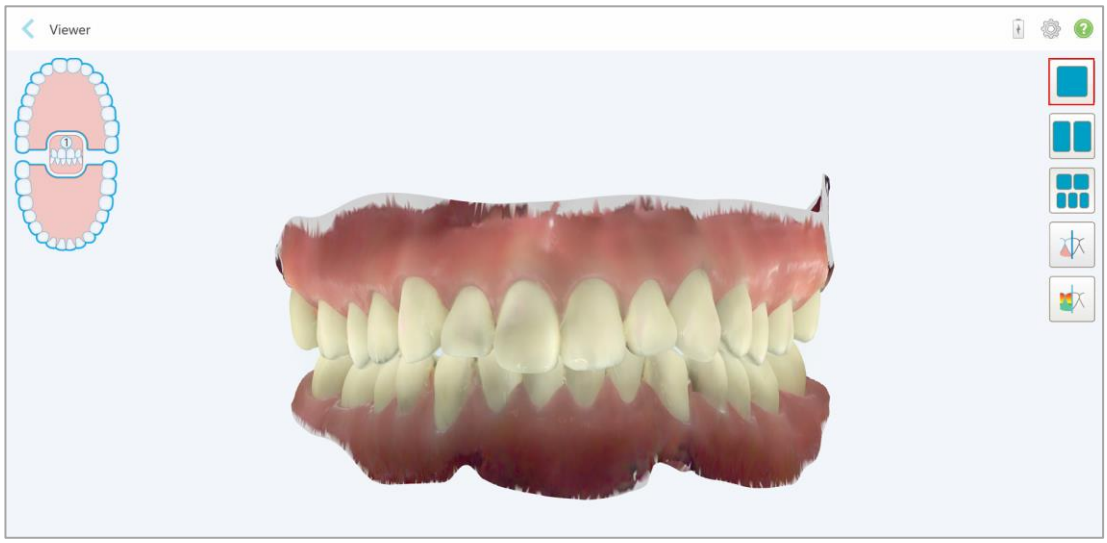


Figure 114: Model in a 1-window view

Relevant for Orthodontic case types only.

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.

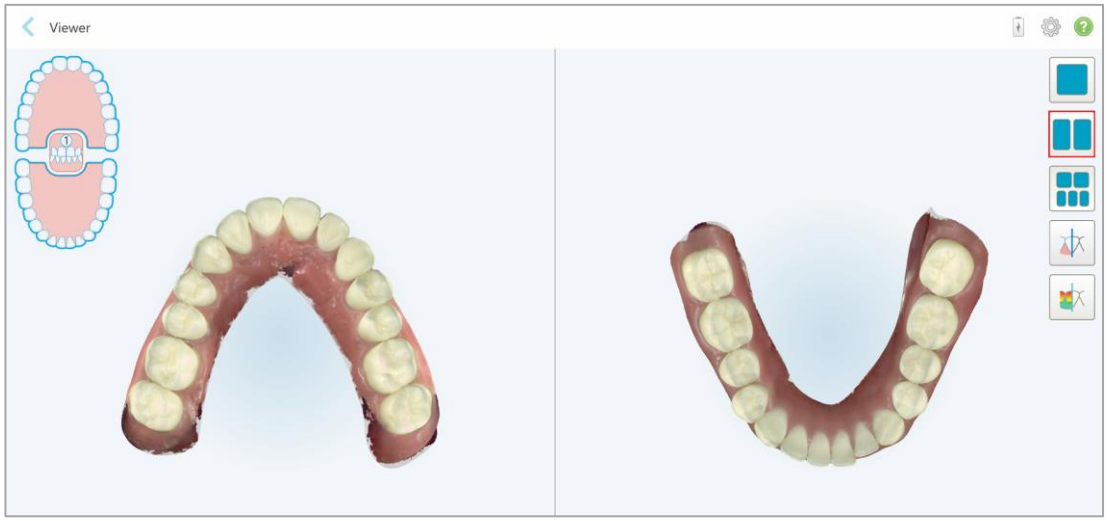


Figure 115: Model in a 2-window view

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.

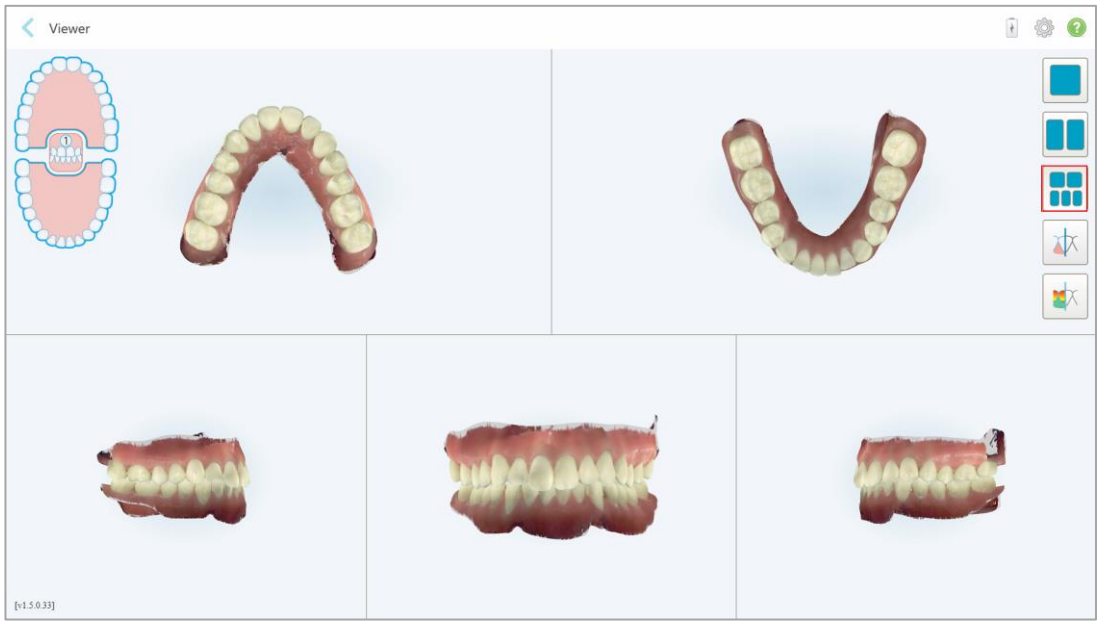


Figure 116: Model in a 5-window view

Relevant for Orthodontic case types only.

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.

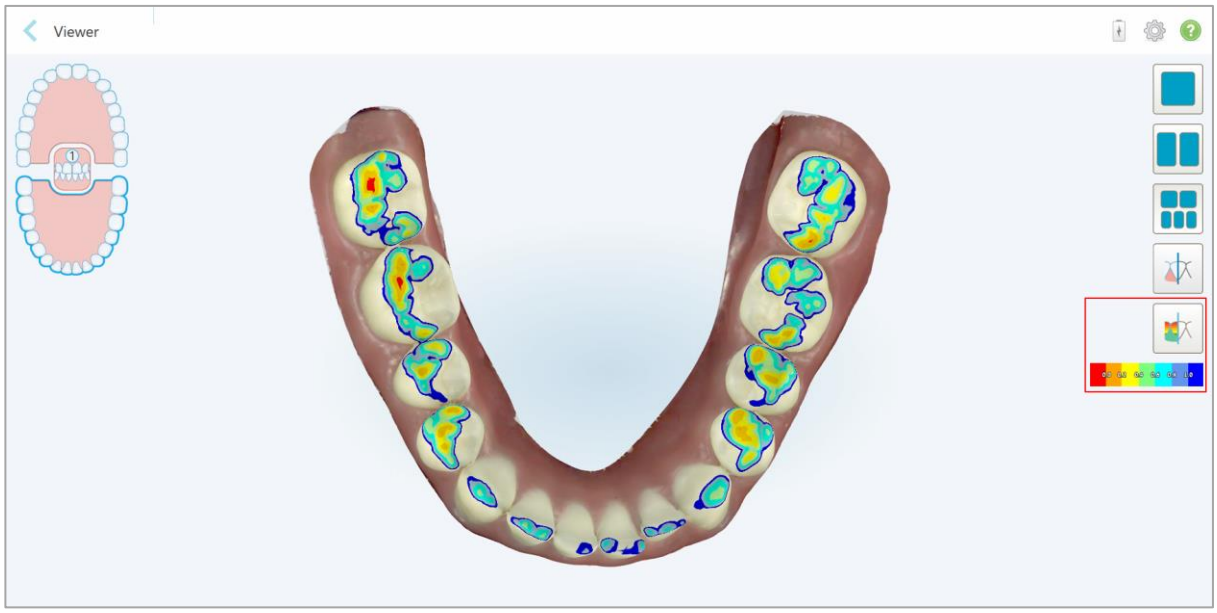
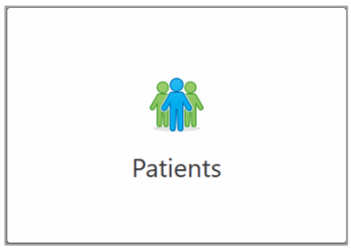


Figure 117: Clearance tool and legend displayed in the Viewer

The occlusal clearance can also be viewed from View mode while scanning the patient, as described in section 4.3.3.

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 last scan date.

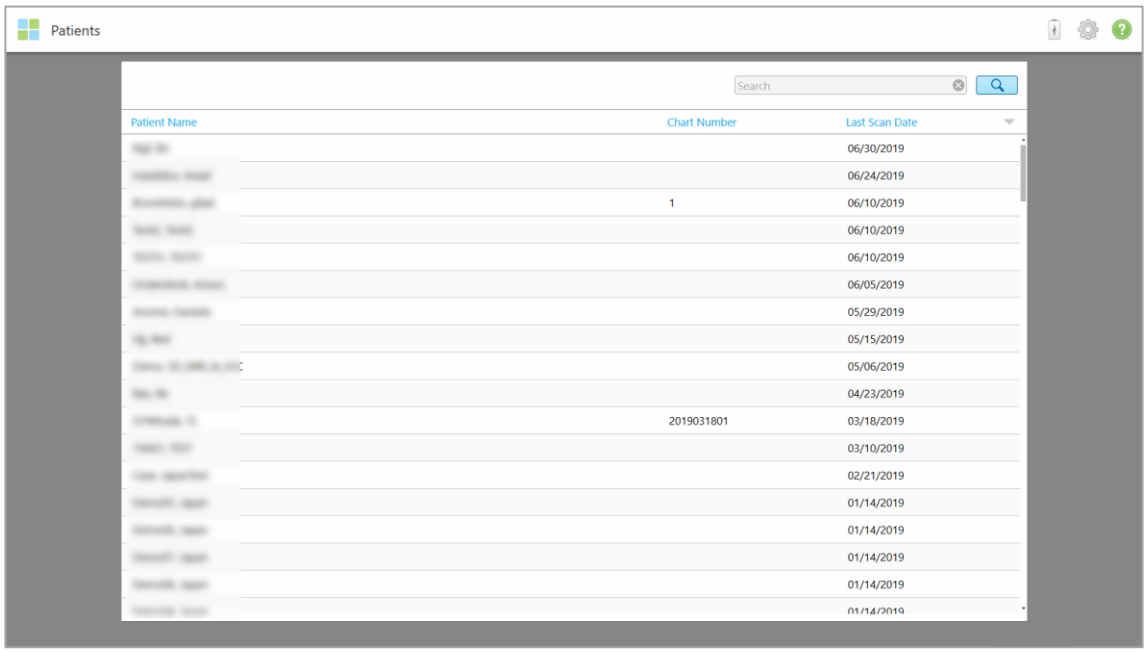


Figure 118: Patients page

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

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  .

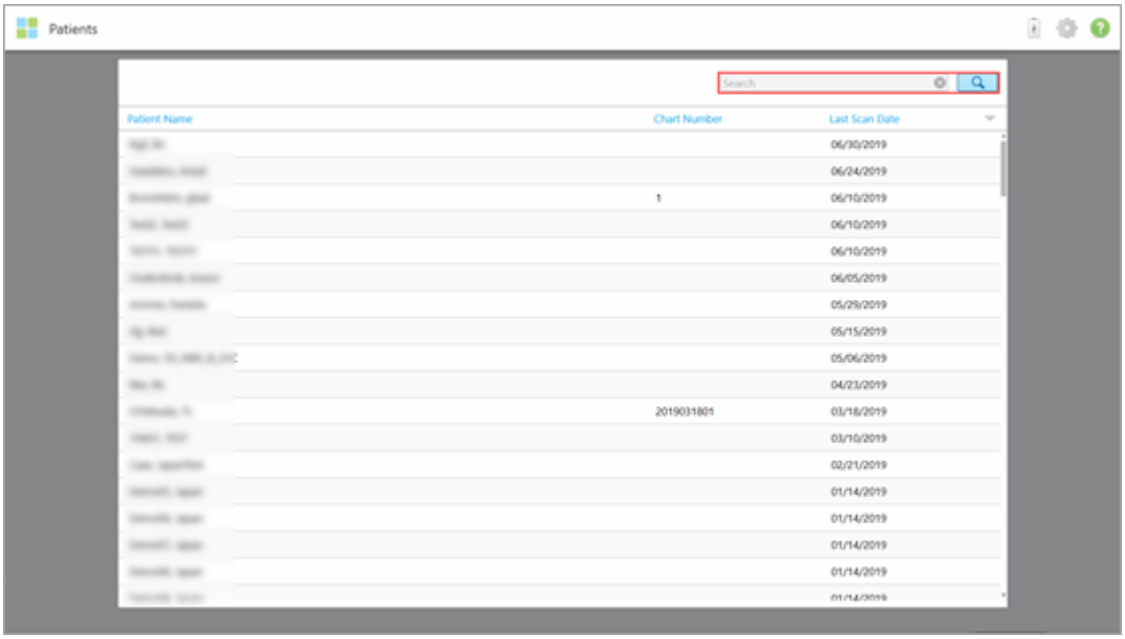


Figure 119: Searching for a patient

The patients that match your search criteria are displayed.

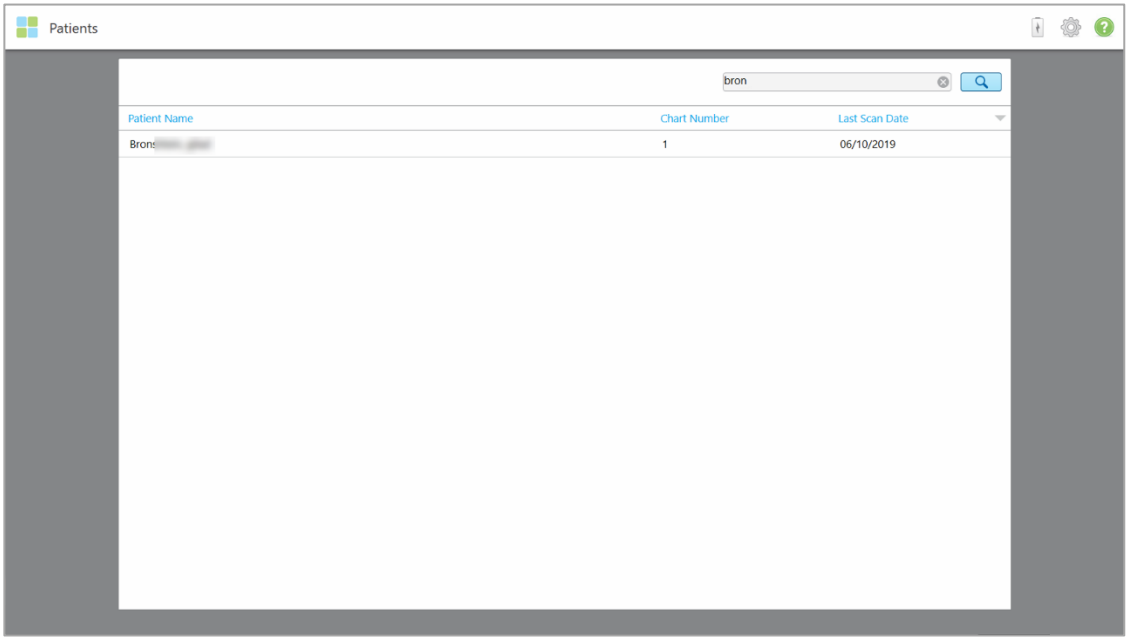


Figure 120: Patients matching the search criteria are displayed

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 from the list.

   The selected patient's profile page is displayed:

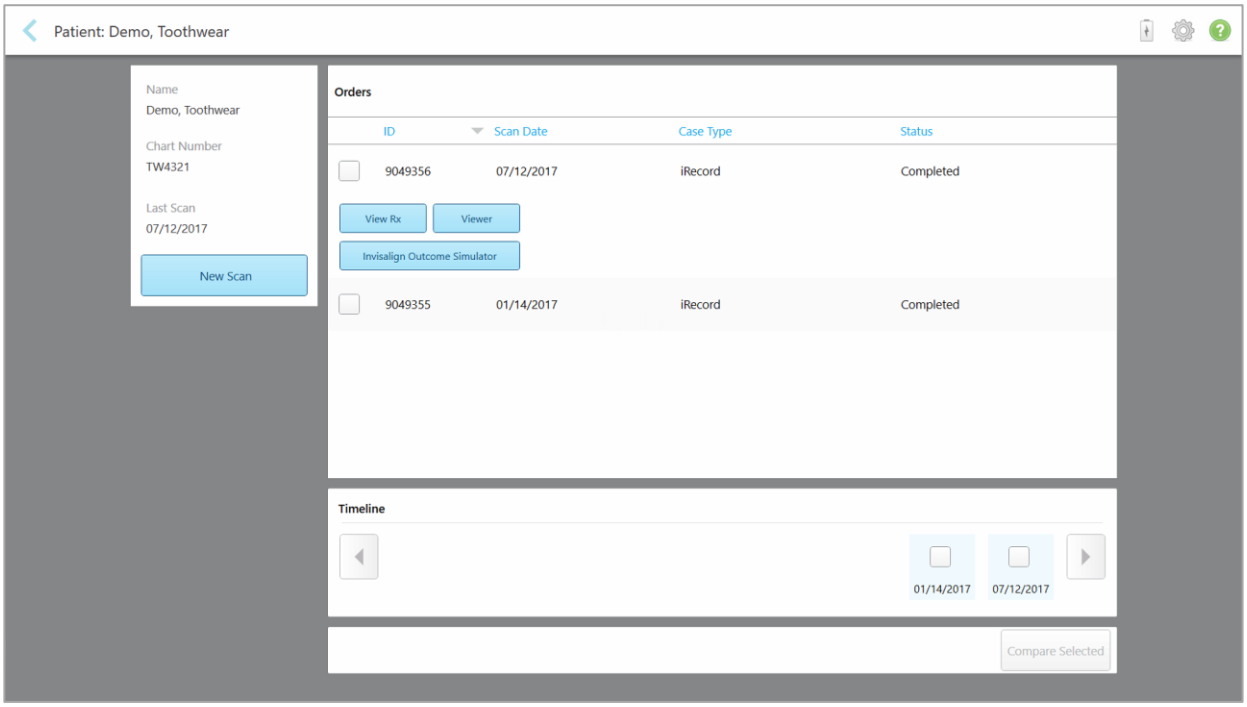


Figure 121: Patient's profile page

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

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**.

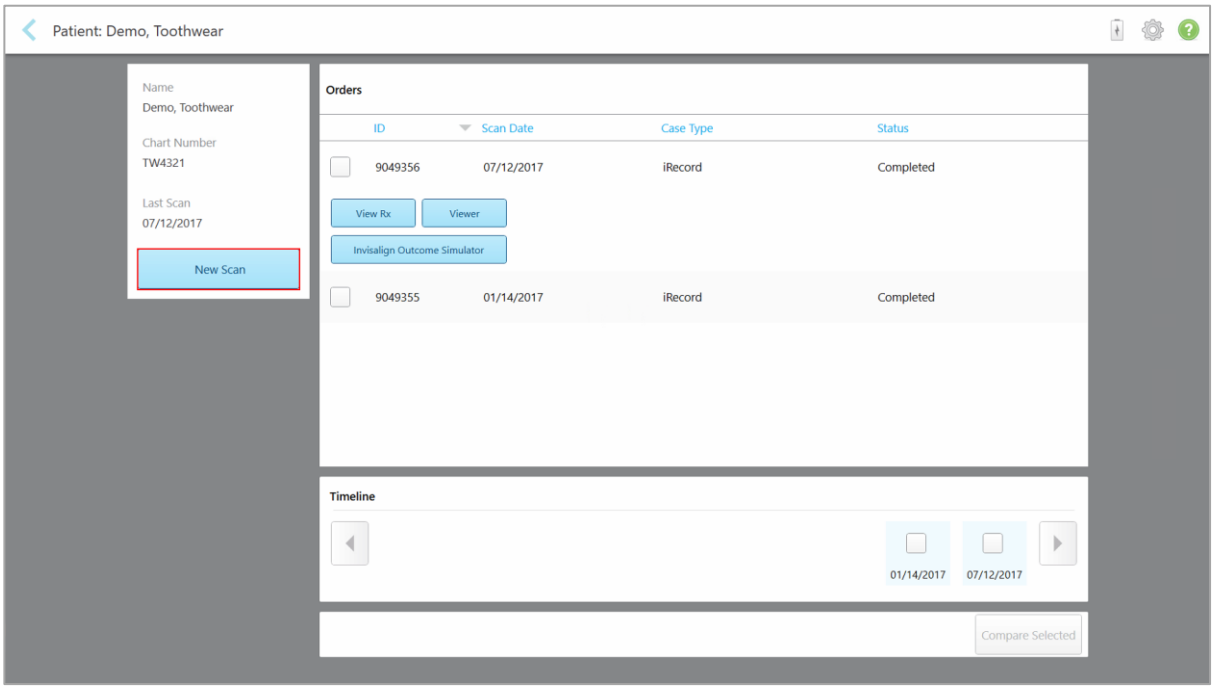


Figure 122: Patient's profile page – New Scan option

The *New Scan* window is displayed.

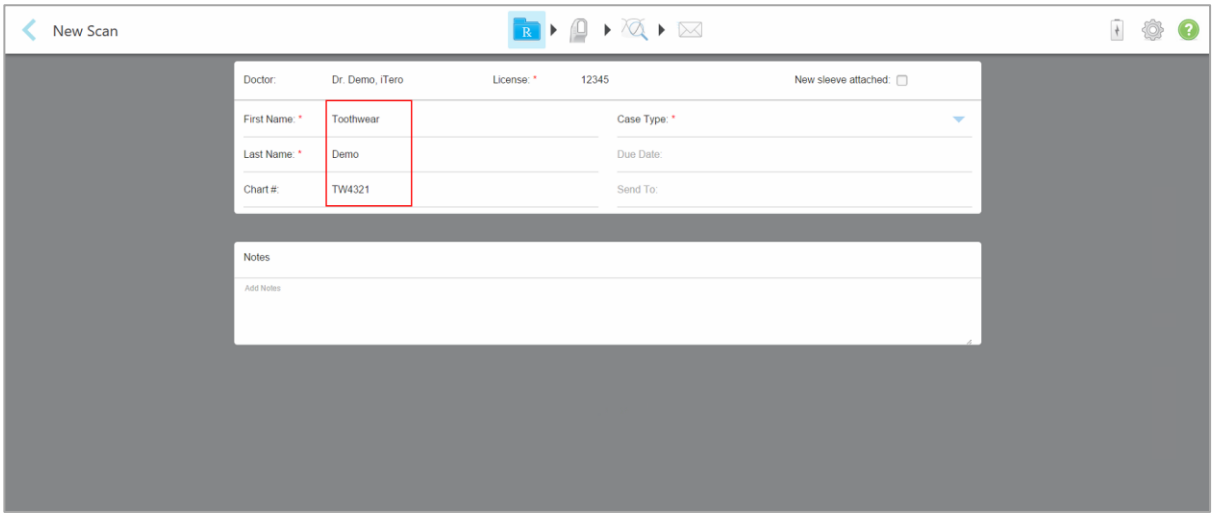


Figure 123: New Scan window with patient's details already filled in

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

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 click **View Rx**.

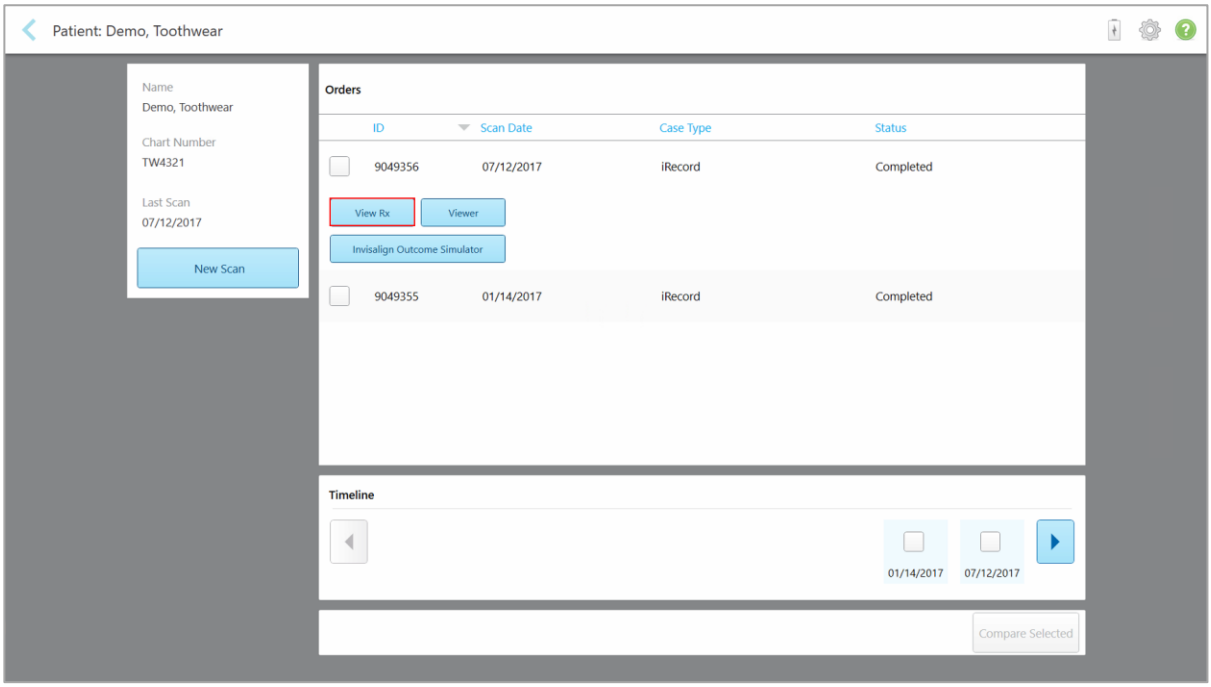


Figure 124: Patient's profile page – View Rx option

The *Rx Details* window is displayed.

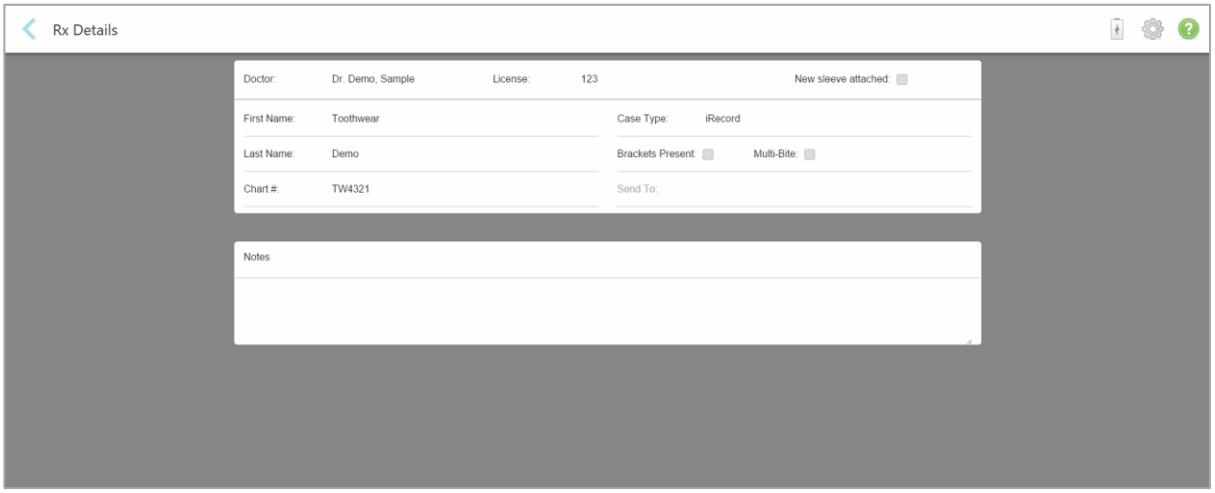


Figure 125: Rx Details window

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

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 click **Viewer**.

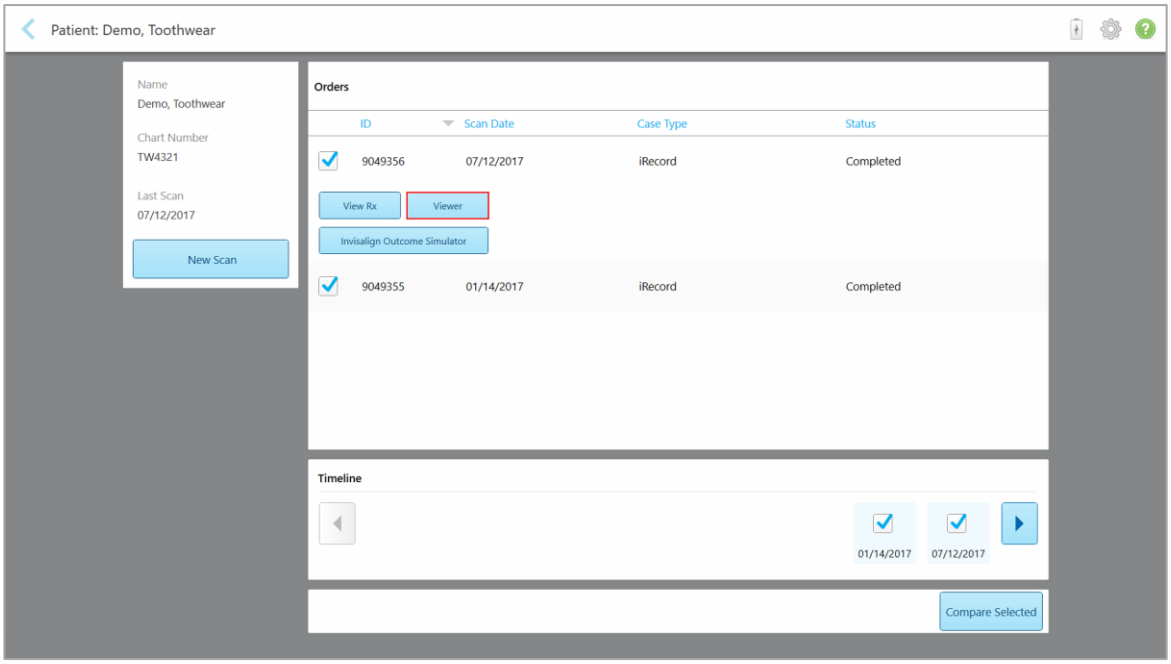


Figure 126: Patient's profile page – Viewer option

The scan is displayed in the Viewer.

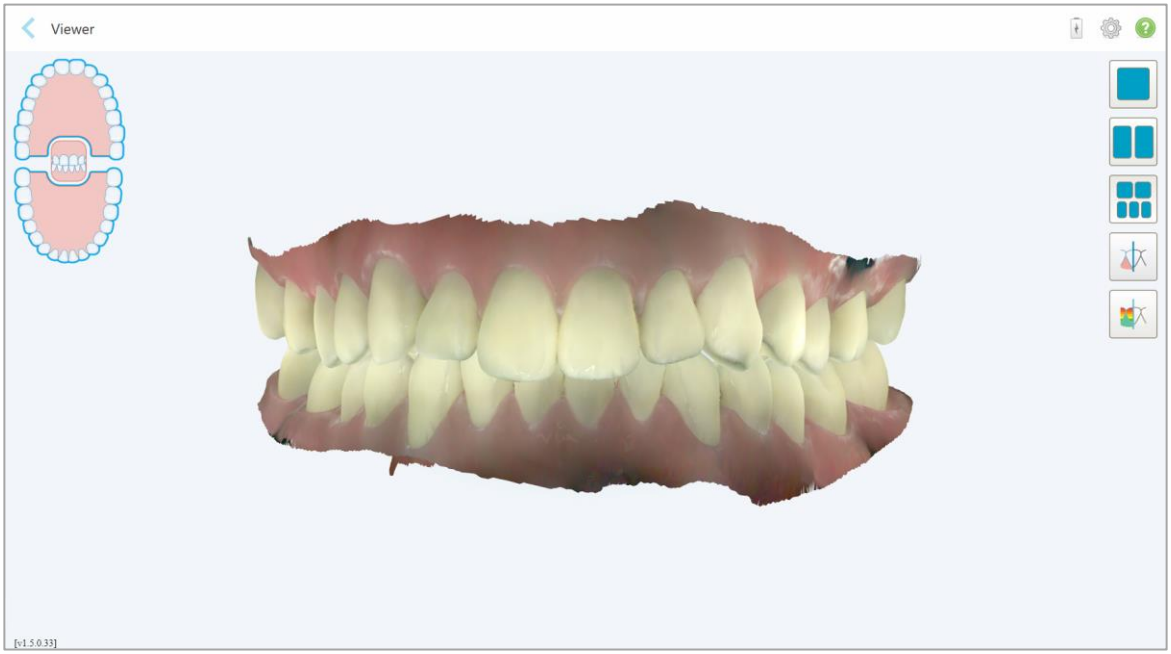


Figure 127: Scan displayed in the Viewer

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

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.

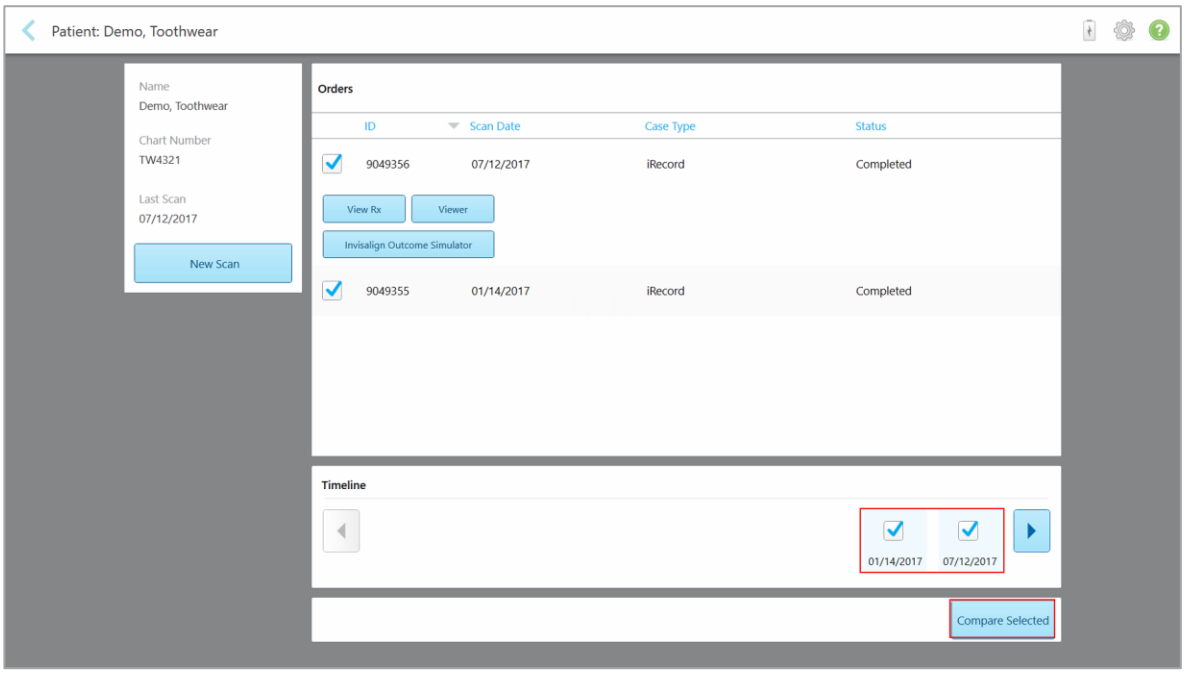


Figure 128: iTero TimeLapse – selecting the scans to compare

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 129: 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, click  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.

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

Figure 131: Area of interest from the second scan displayed in the animation window

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, click **Scale**.

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

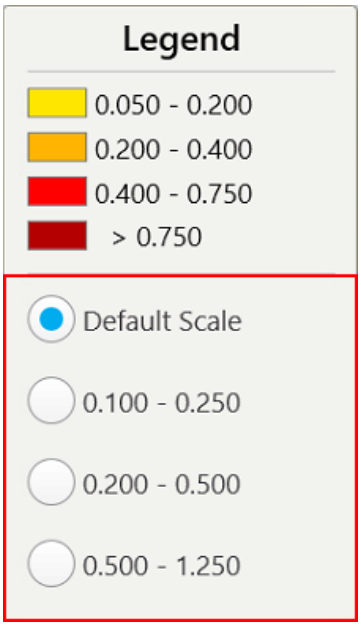


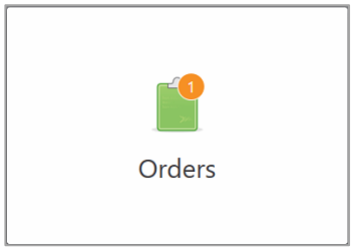
Figure 132: iTero TimeLapse scale options

b. Select the required scale.

The changes are displayed according to the new scale.

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

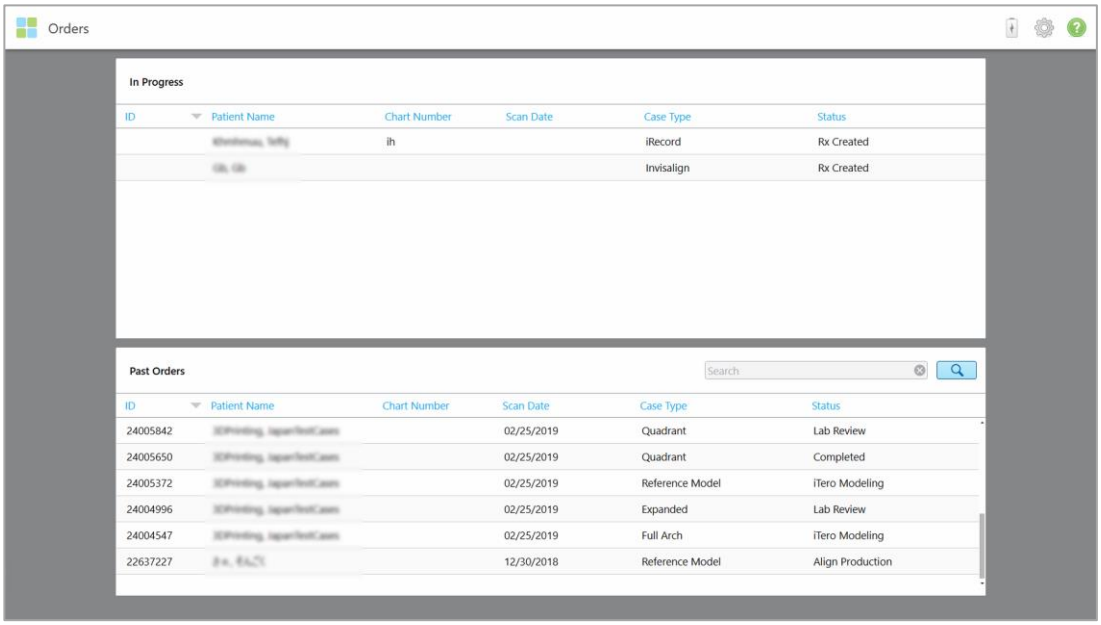


Figure 133: Orders page

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:

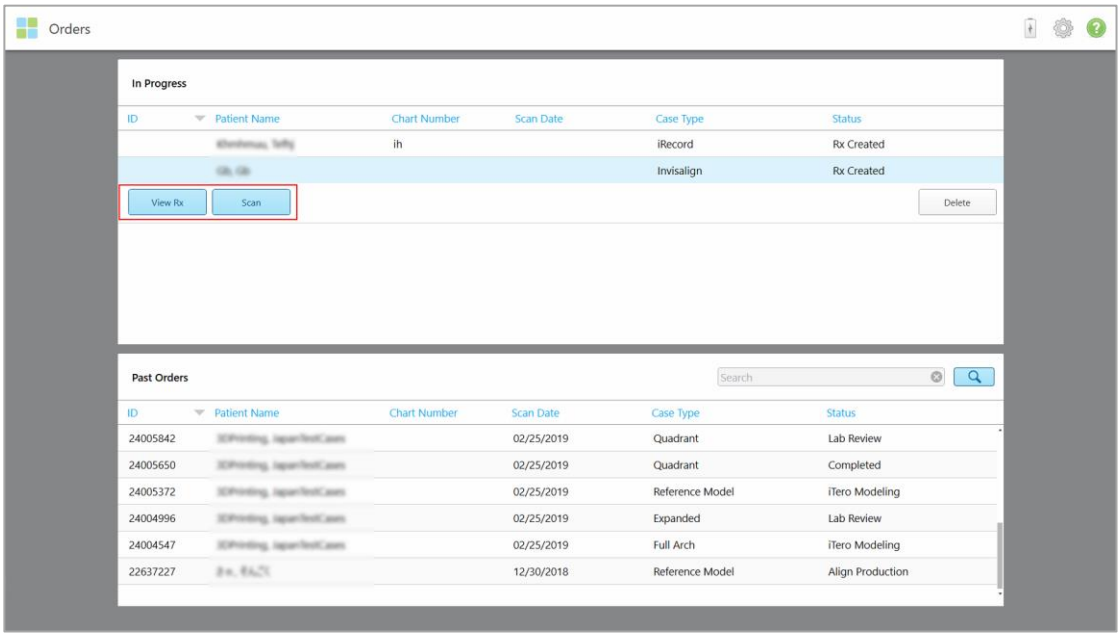


Figure 134: In Progress pane – options

- **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.

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

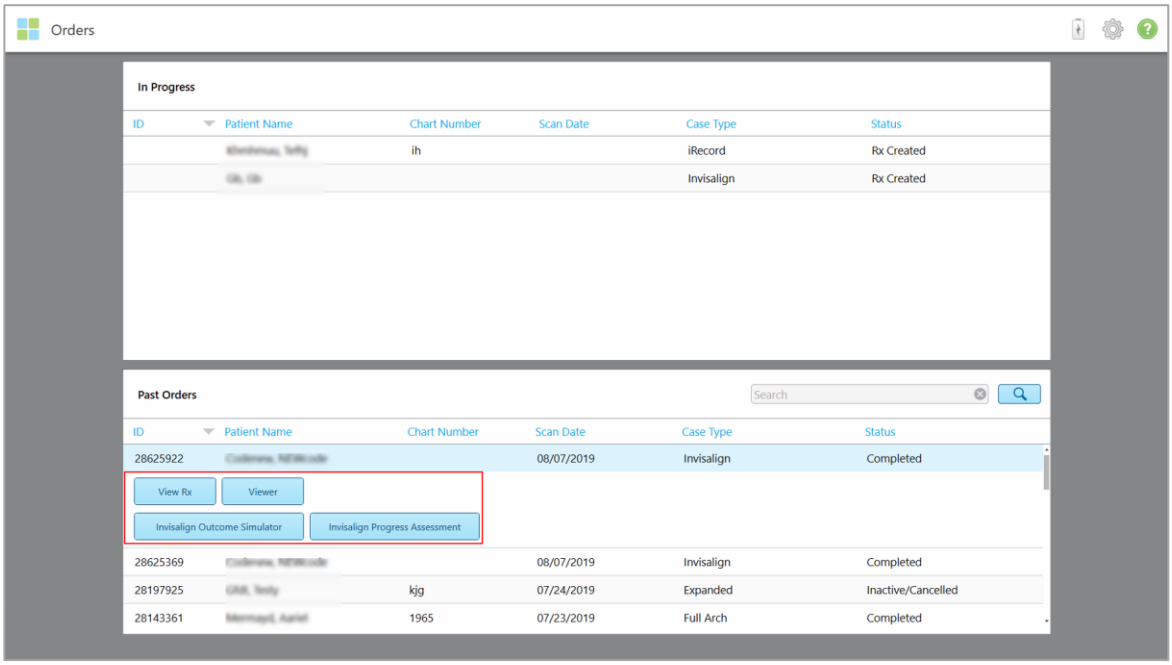


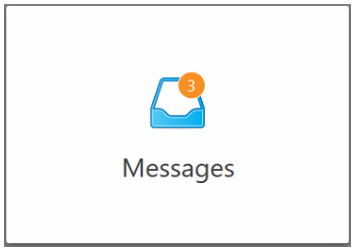
Figure 135: Past Orders pane – options

- **View Rx:** Opens the *Rx Details* window, enabling you to view the prescription for this order.
- **Viewer:** Opens the V*iewer* 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

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.



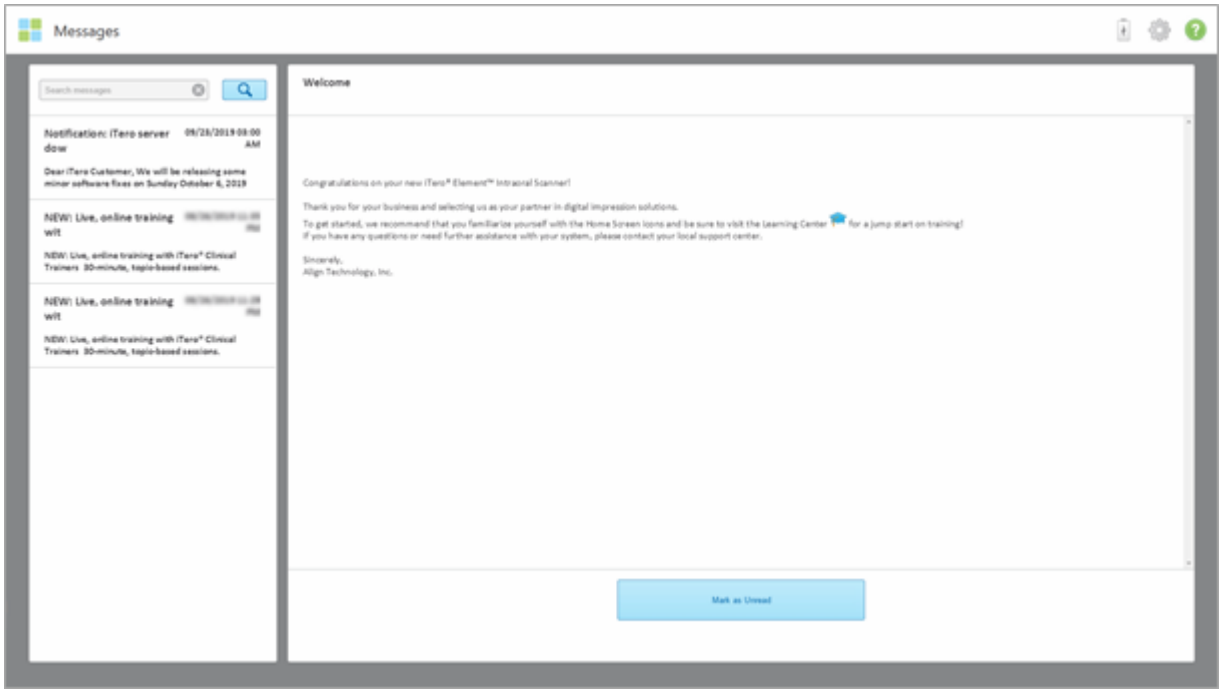


Figure 136: Messages page

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**.

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.

MyiTero is targeted at orthodontists and general-practice dentists, and their staff (assistants, office admin, etc.).

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

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 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.

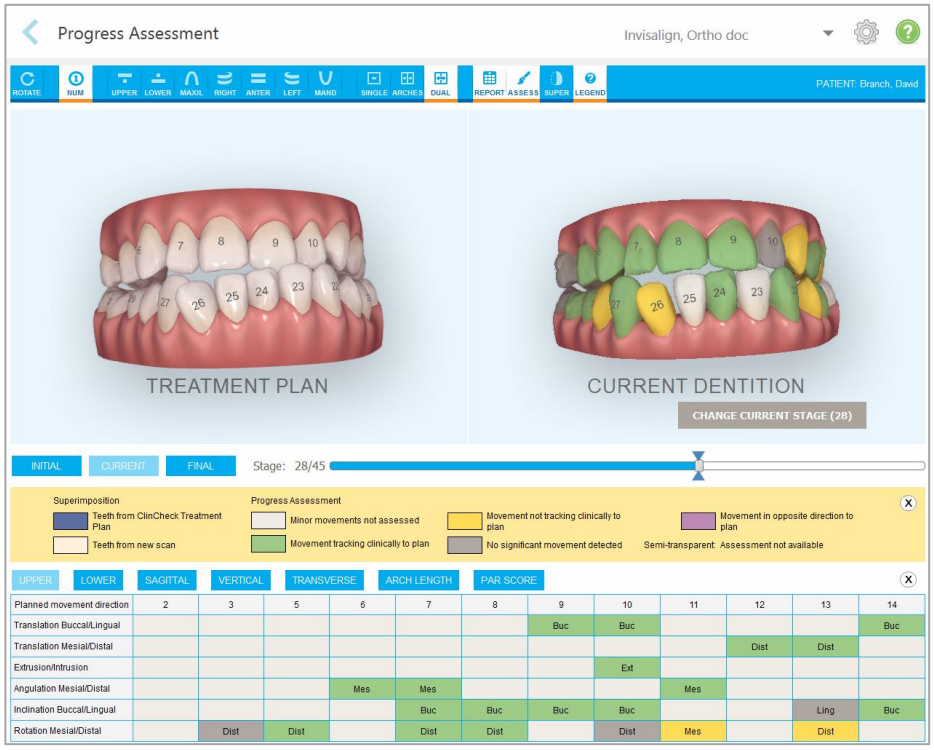


Figure 137: Progress Assessment window

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.

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 requires proper cleaning and disinfection before the first use and between each additional use, and no later than 30 minutes after the last scan. For more information on cleaning and disinfecting the wand, see section 10.2, below.

10.2 Cleaning and disinfecting the wand

The wand should be cleaned and disinfected as follows:

1. Soak a lint-free cloth in ready-to-use CaviCide 1, and then squeeze out the cloth until it is moist.
2. Wipe the wand thoroughly to remove the gross debris.

   The entire device needs to be visually inspected to ensure that no residual debris remains prior to continuing to the next step.
3. Soak two additional lint-free cloths in CaviCide 1, and squeeze until the cloths are moist.
4. Wipe the device thoroughly for at least 2 minutes, ensuring that all surfaces, including all edges and slots, are covered.
5. Wet lint-free cloths with distilled water and wipe all surfaces for at least 15-30 seconds.
6. Dry the surfaces using lint-free cloths.

10.3 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.

10.4 Webcam Maintenance

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

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.

CAUTION: Ensure that a LAN cable is **not** connected to the iTero Element 5D when scanning a patient – this is forbidden due to safety-hazard reasons.

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

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.

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

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 wheel stand configurations 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

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

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 VRMS; 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

13 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.

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.

14 System specifications

14.1 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 13.
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.)

14.2 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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