

iTero Element[®]

User manual

For new and certified pre-owned scanners



it starts with iTero[®]

Copyright

© 2022 Align Technology, Inc. All rights reserved.

The information contained in this manual is subject to change without notice.

The hardware and software described in this manual are supplied under a Sales and Services Agreement and may be used only in accordance with the terms of that agreement.

No part of this manual may be reproduced, photocopied, stored in a retrieval system, or transmitted in any manner (electronic or mechanical) for any purpose other than the customer's normal usage, without the prior written permission of Align Technology.

English language version
P/N: 213218 Rev. B
Updated January 2022

USA office

Corporate Headquarters
Align Technology, Inc.

410 North Scottsdale Road,
Suite 1300, Tempe,
Arizona 85281

www.aligntech.com

Tel: +1 (408) 470-1000
Fax: +1 (408) 470-1010

Customer Support

Tel: +1 (800) 577-8767
E-mail: iterosupport@aligntech.com

Patents

www.aligntech.com/patents

Trademarks

Align, Invisalign, ClinCheck and iTero among others, are trademarks and/or service marks of Align Technology, Inc. or one of its subsidiaries or affiliated companies and may be registered in the U.S. and/or other countries.

Any other trademarks or registered trademarks appearing in this manual are the property of their respective owners.



Align Technology Ltd.

1 Yitzhak Rabin Rd.,
Petach Tikva, 4925110,
Israel

Tel: +972 (3) 634-1441
Fax: +972 (3) 634-1440

Contraindications

For persons who have been diagnosed with Epilepsy, there is a risk of epileptic shock from the flashing light of the iTerro 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 IEC 60825-1.



CSA compliance

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



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.

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.

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.

Symbols

The following symbols may appear on iTero Element hardware components and may appear within this document and other iTero Element 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 B. Any component on which this symbol appears is electric isolation type B.



Separate collection of electrical waste and electronic equipment is required.



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.



Batch code.

"Rx only"

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



Medical device manufacturer.



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



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



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



IEC 60417-5009: STAND-BY.



Fragile, handle with care.



This side should be up.



Indicates the date the medical device was manufactured.

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 a medical-grade power supply.
Electric warnings	<ul style="list-style-type: none"> • Do not remove external in order to avoid electrical shock. There are no user-serviceable parts inside. • Do not connect the scanner to a mains supply without protective grounding, in order to avoid the risk of electrical shock.
Electric precautions	<ul style="list-style-type: none"> • Do not connect a non-Align-approved web camera to the USB sockets on the rear of the touch screen, in order to avoid the risk of electrical shock. • Do not connect anything besides the iTero wand to the USB sockets on the hub. • Do not connect a power cable that is not approved by Align Technology to the system, in order to avoid electrical shock.
Wireless LAN	The system comes equipped with a wireless LAN unit.
Safety classifications	<ul style="list-style-type: none"> • Type of protection against electrical shock: Class 1. • Degree of protection against electrical shock: Type B. • 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 precautions	<ul style="list-style-type: none"> • The wand emits red laser light (680nm Class 1), as well as white LED emissions. Normal usage of the wand does not present any danger to the human eye. Avoid shining the wand directly into the patient's eyes. • Avoid twisting, knotting, pulling, and stepping on the wand cable and the power cable. • When the system is not in use, the wand should be placed in the cradle with the probe facing the touch screen, in order to avoid eye contact with the laser beam or the flickering white LED emission. Eye contact could cause damage to the eyes. • Avoid activating the wand while the tip of the wand is outside the patient's mouth, in order to prevent eye damage. • Avoid placing the wand in the cradle while the scanning operation is still active, in order to prevent eye damage. • Do not use the equipment if a scanner malfunction occurs or if physical damage is observed, in order to avoid electrical shock or physical injury. Call Customer Support.

Cleaning & disinfection

- To avoid cross-contamination, it is mandatory to:
 - Clean and disinfect the wand, as described in section 10.2, and replace the wand sleeve, as described in section 4.1, before each patient session.
 - Remove and replace gloves after each patient session.
 - Discard torn, contaminated, or removed gloves.
 - Dispose of wand 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. For more information, refer to the *iTerro Element Wheel Stand Quick Assembly Guide*.

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.
- If the system has just been brought into the office from a hot, cold, or humid environment, it should be set aside until it has adjusted to the room temperature, to avoid internal condensation.

Electromagnetic interference precaution

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

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

General**Notes:**

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

Incident notification

Any serious incidents related to the iTerro device should be reported to Align Technology Ltd. and the competent authority of the Member State in which the user and patient are established.

Table of contents

1	Introduction	1
1.1	Intended use	1
1.2	Benefits	1
1.3	iTero Element hardware	2
1.3.1	iTero Element wand	4
1.4	About this manual	4
2	Getting started	5
2.1	Logging in to the scanner for the first time	5
2.2	Registering the scanner – Make It Mine process	5
2.3	Working in Demo Mode	11
2.3.1	Exiting Demo Mode	16
3	Working with the iTero Element scanner	17
3.1	Logging in to the scanner	17
3.1.1	Resetting your password	21
3.1.2	Installing Windows security updates	23
3.2	Logging out of the scanner	24
3.3	Shutting down the scanner	24
3.4	Moving the scanner	25
3.5	User interface	26
3.5.1	Scanner toolbar	28
3.5.2	Touch-screen gestures	30
3.6	Defining the scanner settings	31
3.6.1	Defining the Computer settings	32
3.6.2	Defining the User settings	36
3.6.3	Defining the System settings	42
4	Starting a new scan	49
4.1	Applying a wand sleeve	49
4.2	Starting the scan	49
4.3	Patient management	51
4.3.1	Adding new patients	52
4.3.2	Searching for existing patients	55
4.3.3	Editing the patient details	58

4.3.4	Clearing the patient details from the New Scan window	60
4.4	Filling in the Rx	60
4.4.1	Working with restorative scan types	63
4.5	Scanning the patient	66
4.5.1	Scanning guidance	67
4.5.2	Scanning best practices	68
4.5.3	Scan options	68
4.5.4	Editing a scan	71
4.6	Viewing the scan	72
4.6.1	Missing scan segment notifications	73
4.6.2	Using the scan timer	74
4.7	Sending the scan	74
4.8	Working with the Viewer	75
4.9	Removing the wand sleeve	79
5	Working with patients	81
5.1	Searching for patients	82
5.2	Viewing the patient details	83
5.3	Creating a new scan for a specific patient	84
5.4	Viewing the Rx	86
5.5	Viewing previous scans in the Viewer	87
6	Working with orders	89
6.1	Working with returned orders	92
7	Viewing messages	95
8	Working with MyiTero	97
9	iTero scanner features and tools	99
9.1	Comparing previous scans using iTero TimeLapse technology	99
9.2	Invisalign Go system	102
9.3	Invisalign Outcome Simulator	103
9.4	Invisalign Progress Assessment	103
9.5	Editing tools	104
9.5.1	Deleting a segment	105
9.5.2	Deleting a selection	106
9.5.3	Filling in missing anatomy	108
9.5.4	Disabling A.I. cleanup	109
9.6	Working with the Eraser tool	111

9.7	Working with the Occlusal Clearance tool	113
9.8	Working with the Edge Trimming tool	117
9.9	Working with the Die Separation tool	119
9.10	Working with the Margin Line tool	123
9.10.1	Automatically defining the margin line	123
9.10.2	Manually defining the margin line	125
9.11	Working with the Snapshot tool	126
10	Care and maintenance	133
10.1	Handling the wand and cable	133
10.2	Cleaning and disinfecting the wand	133
10.2.1	Preparation before cleaning and disinfection	134
10.2.2	Wand cleaning and disinfection	135
10.2.3	Drying – wand body	136
10.2.4	Storage and maintenance	136
10.3	Cleaning and disinfecting the cradle	137
10.3.1	Preparation before cleaning and disinfection	137
10.3.2	Cradle cleaning and disinfection	138
10.3.3	Drying – cradle	139
10.3.4	Storage and maintenance	139
10.4	Cleaning and disinfecting the scanner touch screen	139
10.5	General cleaning	139
10.6	Approved cleaning and disinfecting materials	140
A	Clinic LAN network guidelines	141
A.1	Introduction	141
A.2	Preparations	141
A.3	Router guidelines	142
A.4	Internet connection guidelines	142
A.5	Firewall	142
A.6	Wi-Fi tips	142
A.7	Align hostname recommendations	143
B	EMC declaration	145
C	iTero Element product security whitepaper	149
D	System specifications	153
E	Checking and replacing main fuses	155

Table of figures

Figure 1: Front view of the iTero Element	2
Figure 2: Rear view of the iTero Element	3
Figure 3: iTero Element wand	4
Figure 4: Protective sleeve	4
Figure 5: Disposable sleeve	4
Figure 6: Welcome screen	5
Figure 7: Connect page listing the available networks	6
Figure 8: Entering the security key	7
Figure 9: Scanner is connected to the Internet and online	7
Figure 10: Verifying the communication with Align	8
Figure 11: Selecting the time zone	8
Figure 12: Registering the system to customize the setup	9
Figure 13: iTero subscription package	9
Figure 14: License agreement	10
Figure 15: Checking for updates	10
Figure 16: System is registered and ready	11
Figure 17: iTero Element logo	12
Figure 18: Demo Mode option	12
Figure 19: Login window with a list of demo users	13
Figure 20: Demo Login button	13
Figure 21: Demo Mode home screen	14
Figure 22: Past Orders pane – options	15
Figure 23: Exiting Demo mode	16
Figure 24: Login window	17
Figure 25: Unexpected shutdown notification	18
Figure 26: Password is masked	19
Figure 27: iTero home screen	20
Figure 28: Forgot Password button	21
Figure 29: Email field for forgotten password	21
Figure 30: Security answer field	22
Figure 31: Login window with notification about Windows security updates	23
Figure 32: Home screen with notification about Windows security updates	24

Figure 33: iTero home screen26

Figure 34: Help overlay27

Figure 35: Scanner toolbar28

Figure 36: Help overlay29

Figure 37: Settings window31

Figure 38: Brightness settings32

Figure 39: Volume settings32

Figure 40: List of nearby Wi-Fi networks33

Figure 41: Connecting to the clinic Wi-Fi network34

Figure 42: Forgetting or Disconnecting from the network34

Figure 43: Time zone settings35

Figure 44: Scan Settings window36

Figure 45: Only scanning range is highlighted38

Figure 46: Rx Settings window39

Figure 47: Signature Settings window41

Figure 48: Language Settings window42

Figure 49: Login Settings window43

Figure 50: Diagnostics window44

Figure 51: Licensing Information window45

Figure 52: System Information window46

Figure 53: Export Settings window – deleting exported files47

Figure 54: Gently slide the new sleeve into place49

Figure 55: New Scan window showing an empty Rx and the progress toolbar at the top of the window50

Figure 56: New Scan window – adding a new patient52

Figure 57: New Patient window53

Figure 58: Adding the new patient53

Figure 59: Message notifying that a patient with the same details exists54

Figure 60: Confirmation message regarding an existing patient54

Figure 61: New Scan window – searching for an existing patient55

Figure 62: Search Patient window with search field56

Figure 63: Search criteria in the search field and list of matching patients56

Figure 64: Selecting the required patient57

Figure 65: Selected patient displayed in the New Scan window57

Figure 66: New Scan window – editing a patient58

Figure 67: Edit Patient window and Update button59

Figure 68: Message that a patient with the same details already exists	59
Figure 69: Clear patient data button	60
Figure 70: Selecting the required case type	61
Figure 71: New Scan window – iRecord case type	62
Figure 72: New Scan window – Restorative case type with a tooth chart	63
Figure 73: List of restorative treatment options	64
Figure 74: Defining the restoration properties	65
Figure 75: Treatment Information area	66
Figure 76: Recommended scanning sequence – lower jaw	67
Figure 77: Wand guidance	68
Figure 78: Areas with missing anatomy shown with and without additional scan feedback – monochrome	69
Figure 79: Areas with missing anatomy shown with and without additional scan feedback – color mode	69
Figure 80: Model displayed in color and monochrome mode	70
Figure 81: Tap the opposite arch or tap the arrows to select it	71
Figure 82: Editing tools	72
Figure 83: Missing scan message and missing segments highlighted in red	73
Figure 84: Scan timer button on the toolbar and scan time	74
Figure 85: Sending the scan	75
Figure 86: Viewer option in the Past Orders pane in the Orders page	75
Figure 87: Viewer option in patient's profile page	76
Figure 88: Model in a 1-window view	77
Figure 89: Model in a 2-window view	77
Figure 90: Model in a 5-window view	78
Figure 91: Removing a wand sleeve	79
Figure 92: Optical surface of the wand	79
Figure 93: Gently slide the new sleeve into place	80
Figure 94: Patients page	81
Figure 95: Searching for a patient	82
Figure 96: Patients matching the search criteria are displayed	82
Figure 97: Patient's profile page	83
Figure 98: Patient's profile page – New Scan option	84
Figure 99: New Scan window with patient's details already filled in	85
Figure 100: Patient's profile page – View Rx option	86
Figure 101: Rx Details window	87
Figure 102: Patient's profile page – Viewer option	88

Figure 103: Scan displayed in the Viewer	88
Figure 104: Orders page	90
Figure 105: In Progress pane – options	91
Figure 106: Past Orders pane – options	91
Figure 107: Orders button notifying a returned order	92
Figure 108: Returned order in the In Progress pane	93
Figure 109: Messages page	95
Figure 110: iTero TimeLapse – selecting the scans to compare	100
Figure 111: iTero TimeLapse window showing the highlighted changes between the scans	100
Figure 112: Area of interest from the first scan displayed in the animation window	101
Figure 113: Area of interest from the second scan displayed in the animation window	101
Figure 114: iTero TimeLapse scale options	102
Figure 115: Progress Assessment window	103
Figure 116: Editing tools	104
Figure 117: Delete Segment tool	105
Figure 118: Delete Selection tool	106
Figure 119: Expanded Delete Selection tool	107
Figure 120: Selected area of the anatomy is deleted	107
Figure 121: Fill tool	108
Figure 122: Areas that require scanning are highlighted in red – Fill tool	109
Figure 123: Disable A.I. Cleanup tool	110
Figure 124: Scan displayed with excess material showing	110
Figure 125: Eraser tool	111
Figure 126: Eraser tool options	111
Figure 127: Mark the area to be modified	112
Figure 128: Selected area removed and scan tool enabled	112
Figure 129: Deleted area marked in red	113
Figure 130: Occlusal clearance between the opposing teeth	114
Figure 131: Occlusal Clearance range options	115
Figure 132: Occlusal Clearance tool and legend displayed in the Viewer	116
Figure 133: Edge trimming tool	117
Figure 134: Edge trimming tool options	117
Figure 135: Mark the area to be trimmed away	118
Figure 136: Selected area is highlighted and the confirmation icon is enabled	118
Figure 137: Selected area has been removed	119

Figure 138: Green hint point centered on the prepped tooth	120
Figure 139: Die separation is displayed in high resolution	120
Figure 140: Die Separation tool options	121
Figure 141: Scan is displayed in low resolution	121
Figure 142: Before selecting the die separation	122
Figure 143: Prepped tooth is displayed in high resolution	123
Figure 144: Model display moves to the occlusal view, and zooms in on the prepped tooth	124
Figure 145: Margin Line tool options	124
Figure 146: Margin line is marked on the prepped tooth	125
Figure 147: Margin Line tool options	126
Figure 148: View mode – with Snapshot tool	127
Figure 149: Screen capture thumbnail is displayed after taking a screen capture	127
Figure 150: Screenshot with an annotations toolbar	128
Figure 151: Annotations toolbar	128
Figure 152: Adding text to the screenshot	129
Figure 153: Screenshot with annotations	129
Figure 154: Notification that the screenshots and annotations will be uploaded to MyiTero	130
Figure 155: Confirmation about the annotations being discarded	130
Figure 156: Notification that the screenshots will be uploaded to MyiTero	131
Figure 157: Option to download screenshots from the Orders page in MyiTero	131
Figure 158: Wand without a sleeve	134
Figure 159: Remove gross contaminants using CaviWipes1	135
Figure 160: Remove marks and stains using a soft bristle brush	135
Figure 161: Wipe the optical surface of the wand with IPA	136
Figure 162: Remove gross contaminants on the cradle using CaviWipes1	138
Figure 163: Remove remaining marks and stains on the cradle using the soft bristle brush	138

1 Introduction

1.1 Intended use

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

- The optical impression (CAD/CAM) feature of the scanner 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 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.

iTero Element scanners may be used on patients classified as Preadolescent, Adolescent, and Adult.

1.2 Benefits

The iTero Element systems provide 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 hardware

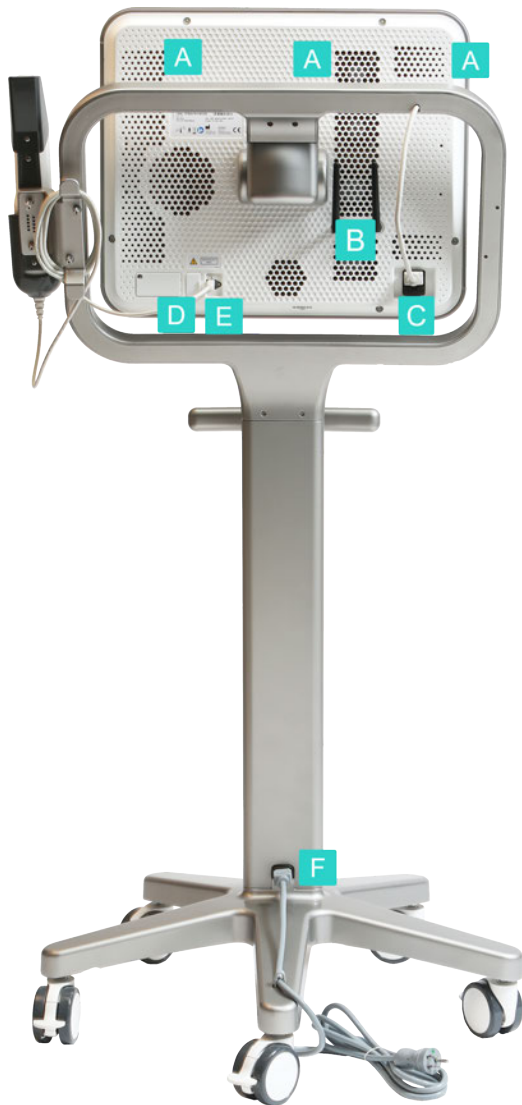
Front view of the system



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

Figure 1: Front view of the iTero Element

Rear view of the system



- A Air vents
- B Wi-Fi antennas
- C Power inlet and fuse holder
- D USB socket for approved webcam
- E Wand connector
- F Power cable connection

Figure 2: Rear view of the iTero Element

1.3.1 iTero Element wand



Figure 3: iTero Element wand

1.3.1.1 Wand sleeves

There are two 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, as described in section 4.1.



Figure 4: Protective sleeve



Figure 5: Disposable sleeve

1.4 About this manual

This manual provides general information and an overview of the iTero Element scanners and software.

In addition, this manual describes how to assemble the system, start and shut down the system, clean and disinfect the system, and how to replace the wand sleeves between patients.

2 Getting started

2.1 Logging in to the scanner for the first time

When you turn on the scanner for the first time, the *Welcome* screen is displayed:

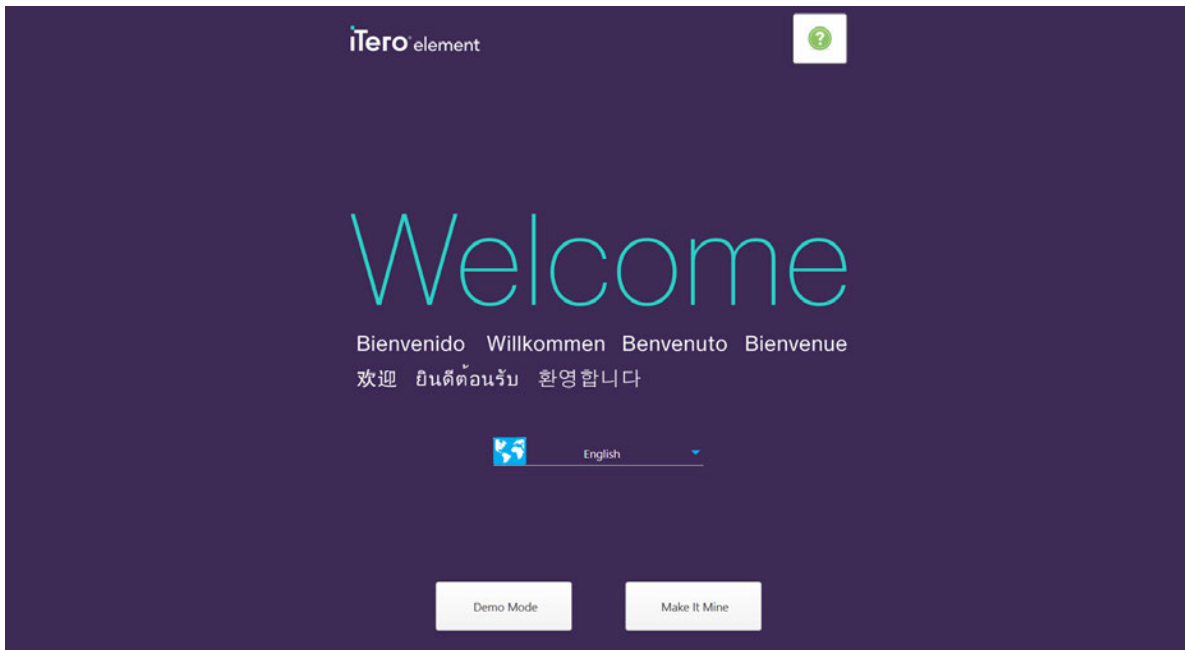


Figure 6: Welcome screen

Select the required language and one of the following modes:

- **Make It Mine:** Enables you to register the scanner. For more information, see section 2.2, below.
- **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 2.3.

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.

2.2 Registering the scanner – Make It Mine process

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

- User Name
- User Password
- Company ID

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

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

To register the scanner:

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

The *Connect* page is displayed, showing a list of available networks.

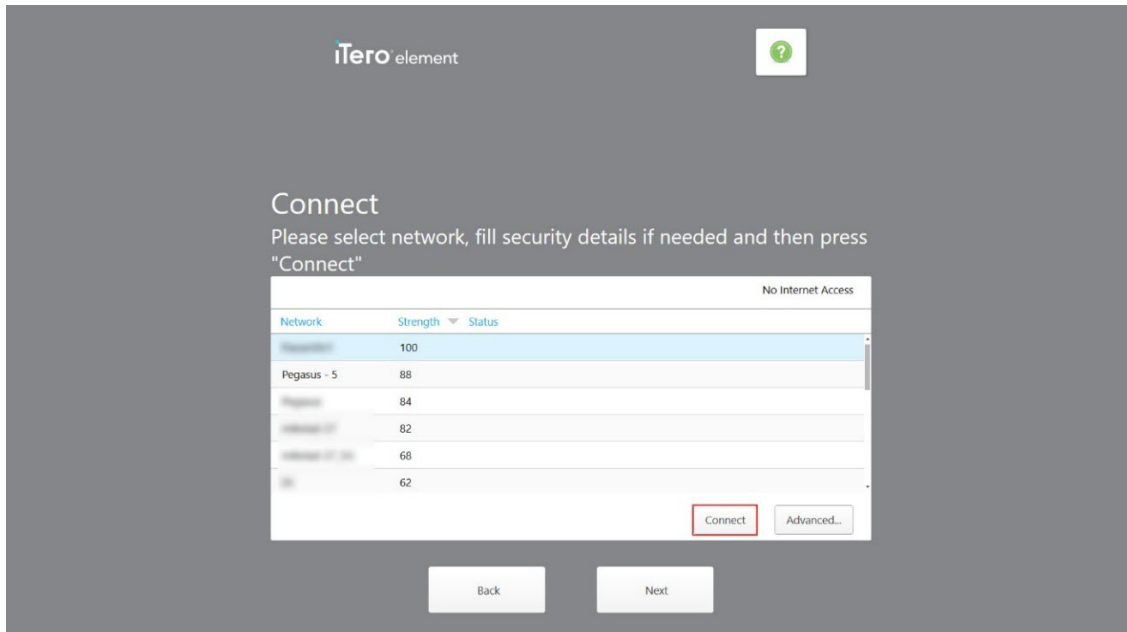


Figure 7: Connect page listing the available networks

3. Select the clinic network from the list and then tap **Connect**.

You are prompted to enter the network security key.

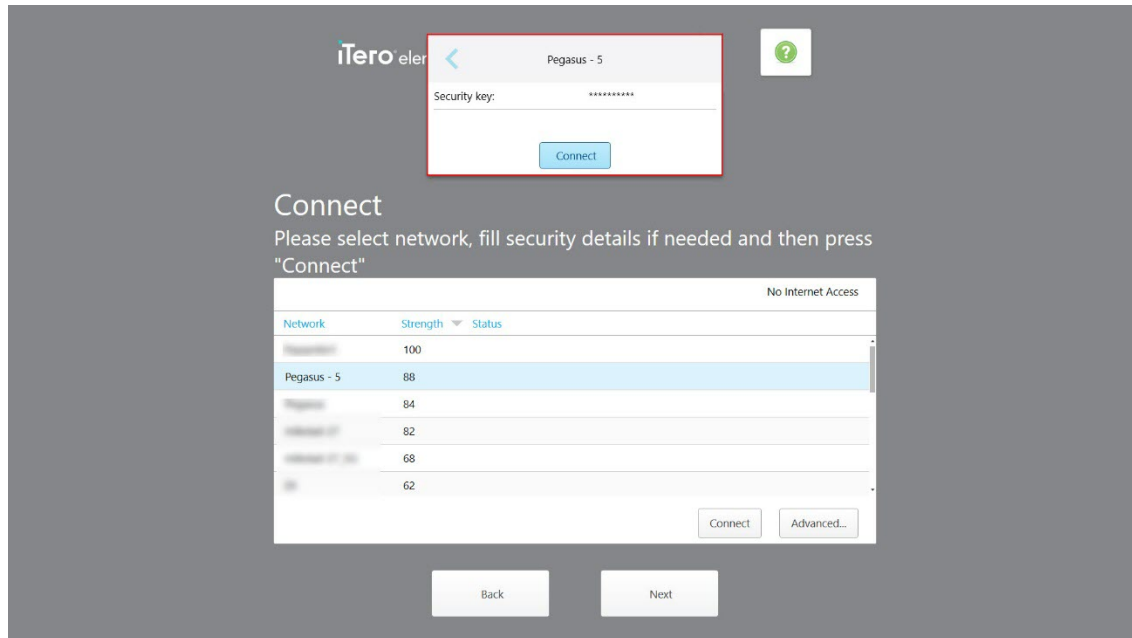


Figure 8: Entering the security key

4. Enter the security key and then tap **Connect**.

The scanner is now connected to the Internet and online.

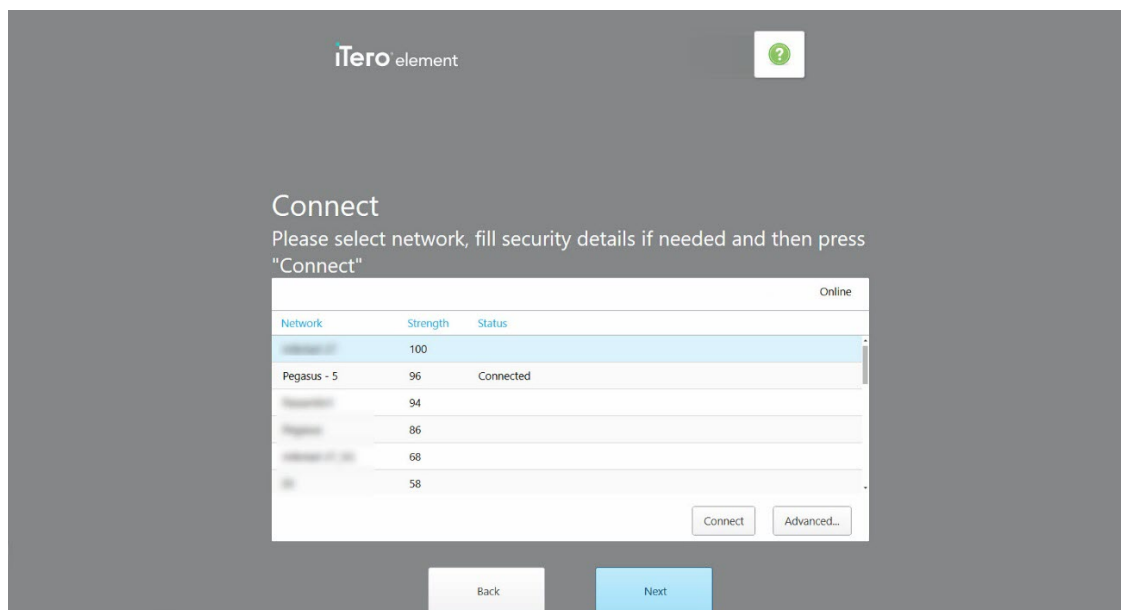


Figure 9: Scanner is connected to the Internet and online

5. Tap **Next**.

The communication with Align is verified.



Figure 10: Verifying the communication with Align

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

The *Time Zone* page is displayed.

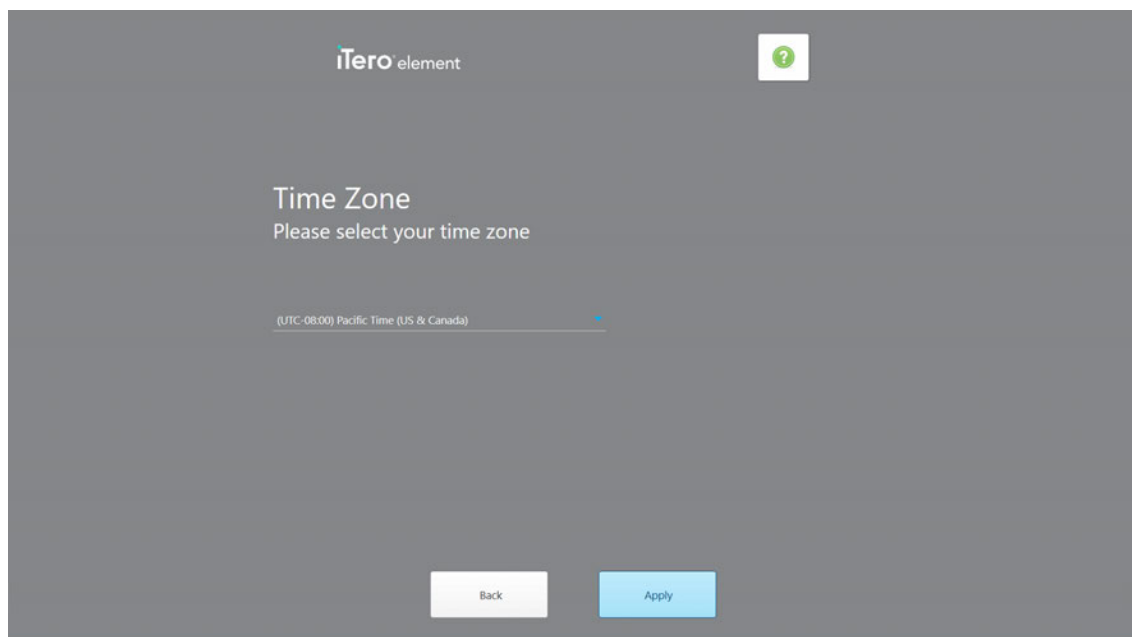


Figure 11: Selecting the time zone

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

The *Register System* page is displayed.

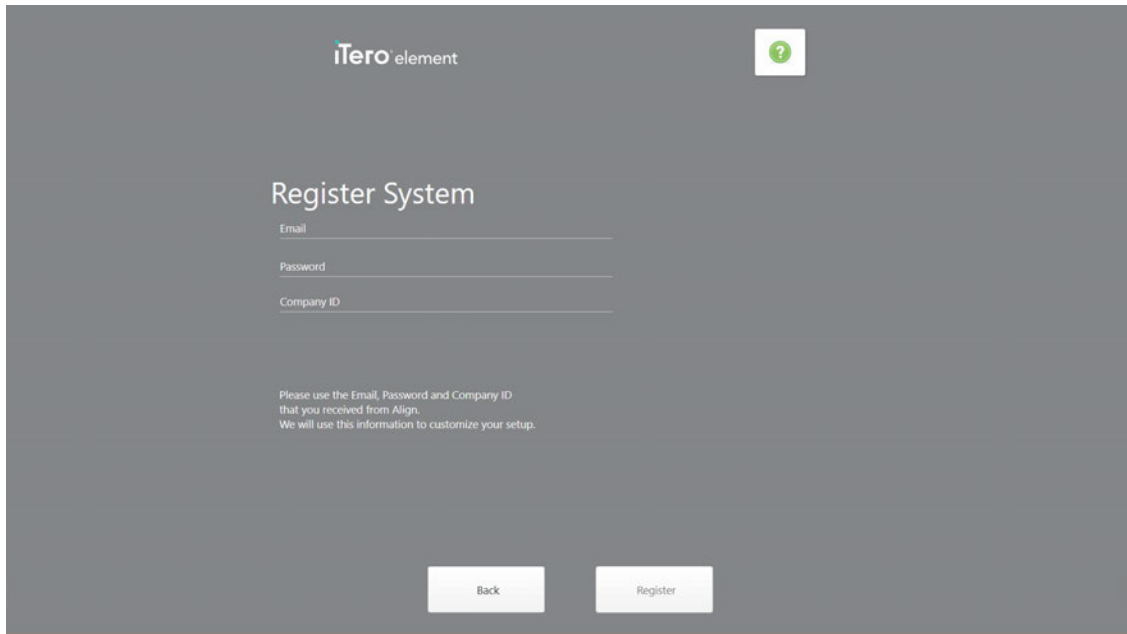


Figure 12: Registering the system to customize the setup

8. 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.

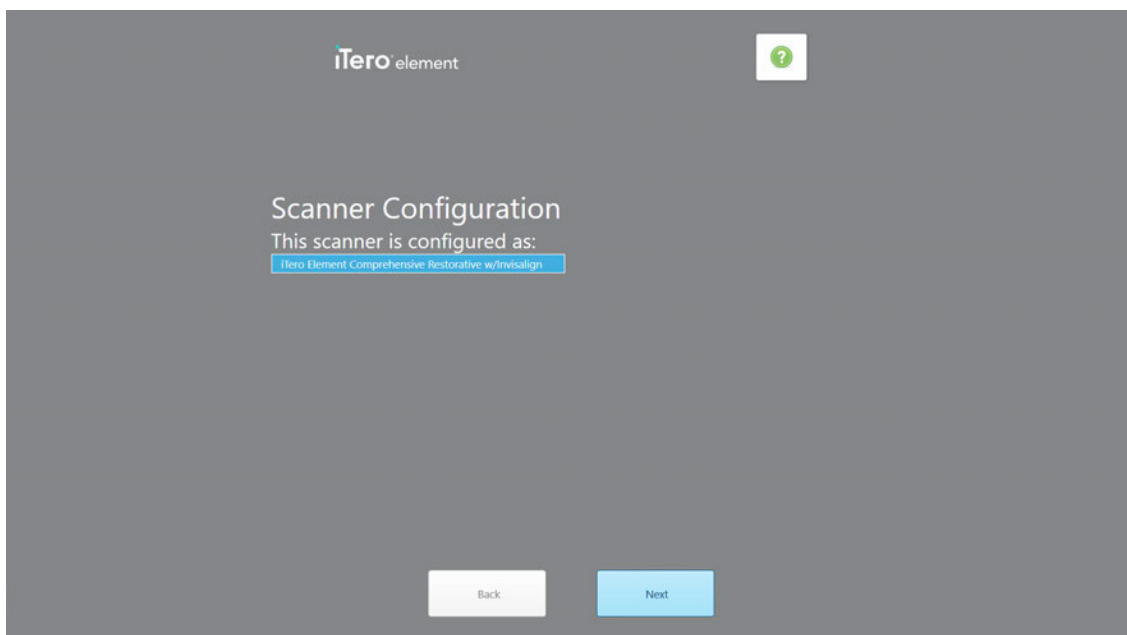


Figure 13: iTero subscription package

9. Tap **Next**.

The *License Agreement* page is displayed.

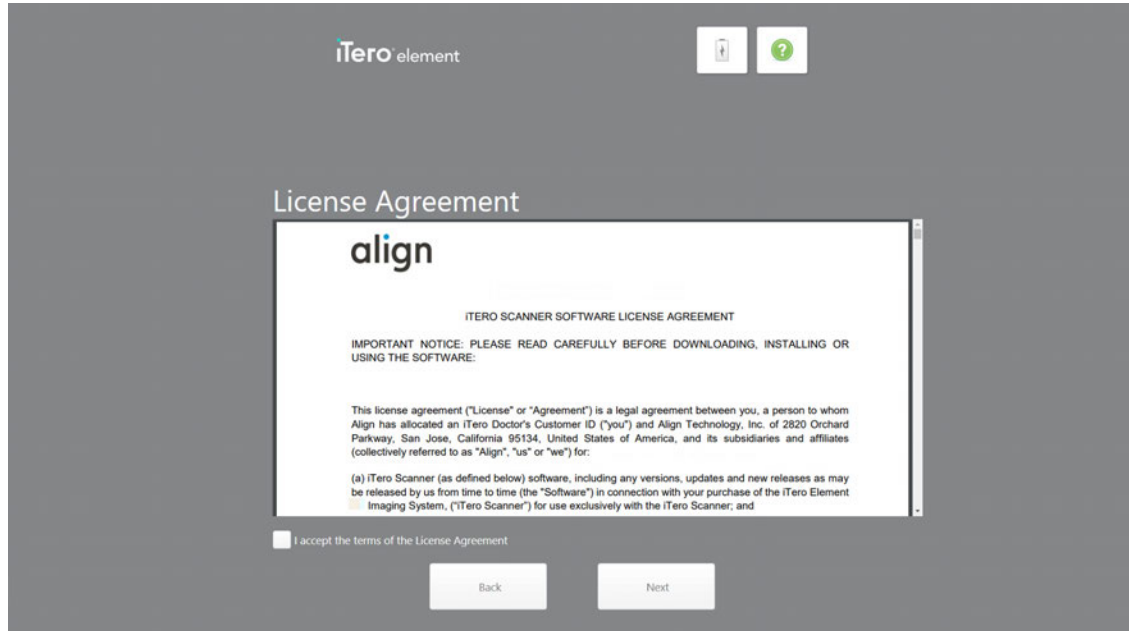


Figure 14: License agreement

10. 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 is upgraded to the latest version, if relevant.

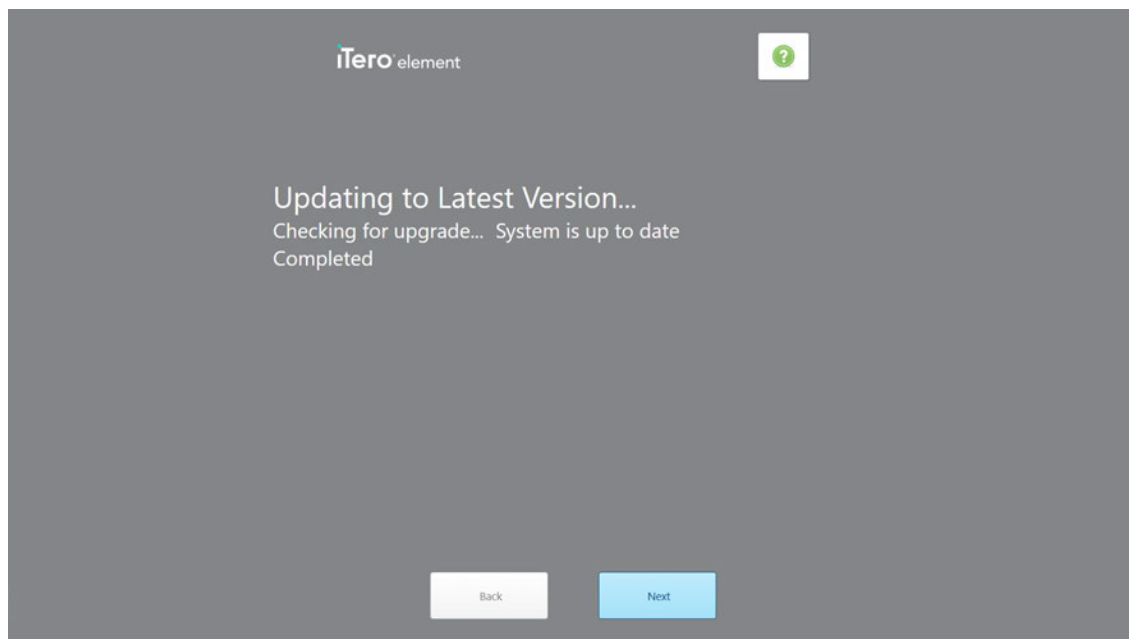


Figure 15: Checking for updates

11. Tap **Next**.

The system has been registered and is ready.



Figure 16: System is registered and ready

12. Tap **Login to iTero Element** to log in to the system.

The *Login* window is displayed. For more details on logging in to the system, see section 3.1.

2.3 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 scanner, 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.

When Demo Mode is in use for practice scanning, a lightly striped background and red tag in the upper left-hand corner indicates 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 17: iTero Element logo

2. Tap **Demo Mode**.

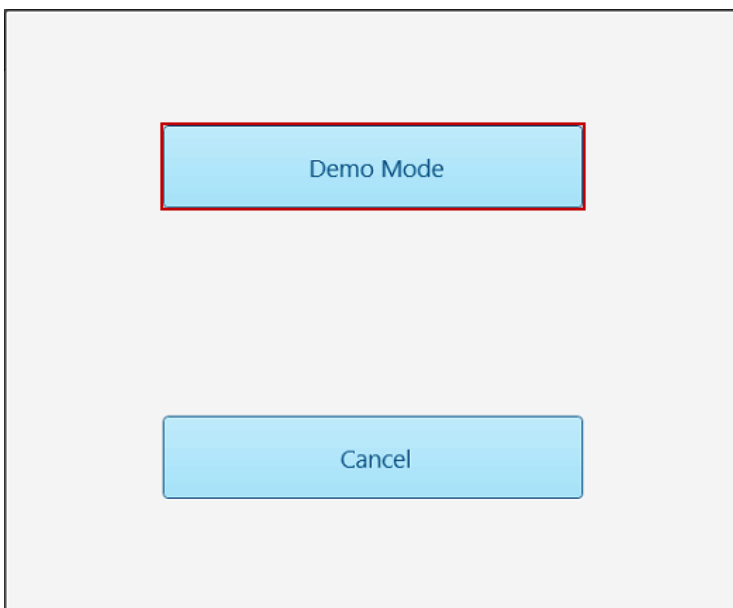
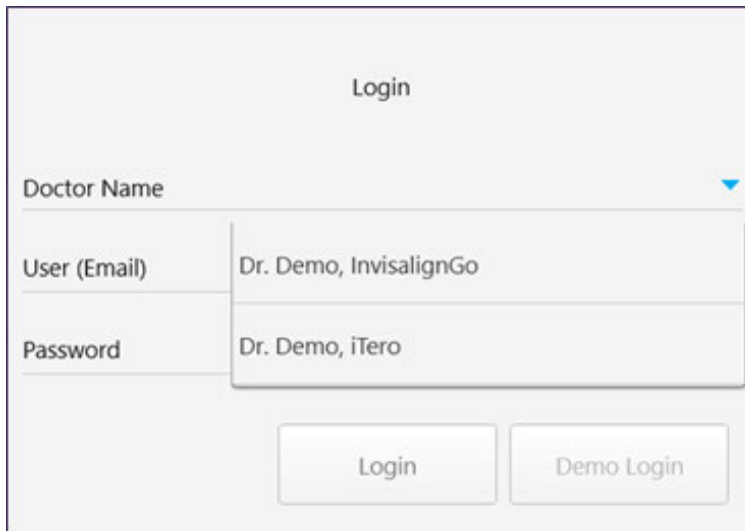


Figure 18: Demo Mode option

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

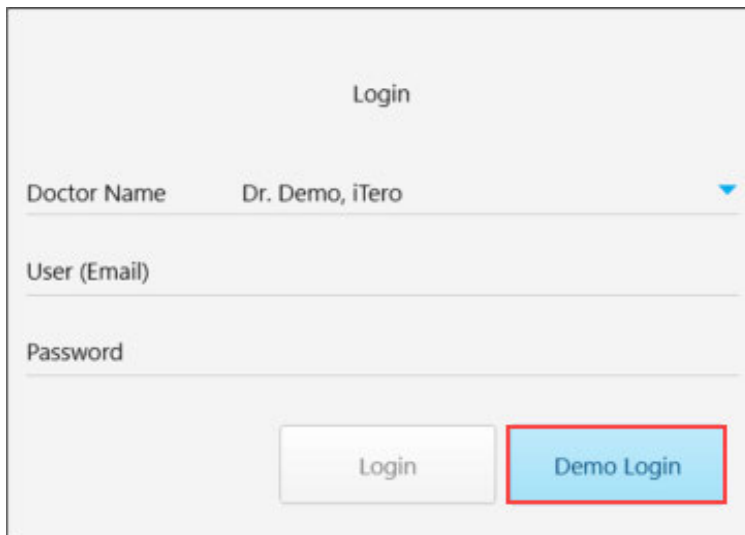


The screenshot shows a 'Login' window with the following fields and buttons:

- Doctor Name:** A dropdown menu with a blue downward arrow, currently displaying 'Dr. Demo, InvisalignGo'.
- User (Email):** A text input field containing 'Dr. Demo, InvisalignGo'.
- Password:** A text input field containing 'Dr. Demo, iTero'.
- Login:** A light gray button.
- Demo Login:** A light gray button.

Figure 19: Login window with a list of demo users

- To view iTero restorative cases, select the **Dr. Demo, iTero** user from the **Doctor Name** drop-down list.



The screenshot shows the 'Login' window with the following fields and buttons:

- Doctor Name:** A dropdown menu with a blue downward arrow, displaying 'Dr. Demo, iTero'.
- User (Email):** An empty text input field.
- Password:** An empty text input field.
- Login:** A light gray button.
- Demo Login:** A light blue button with a red border, indicating it is the selected option.

Figure 20: 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.

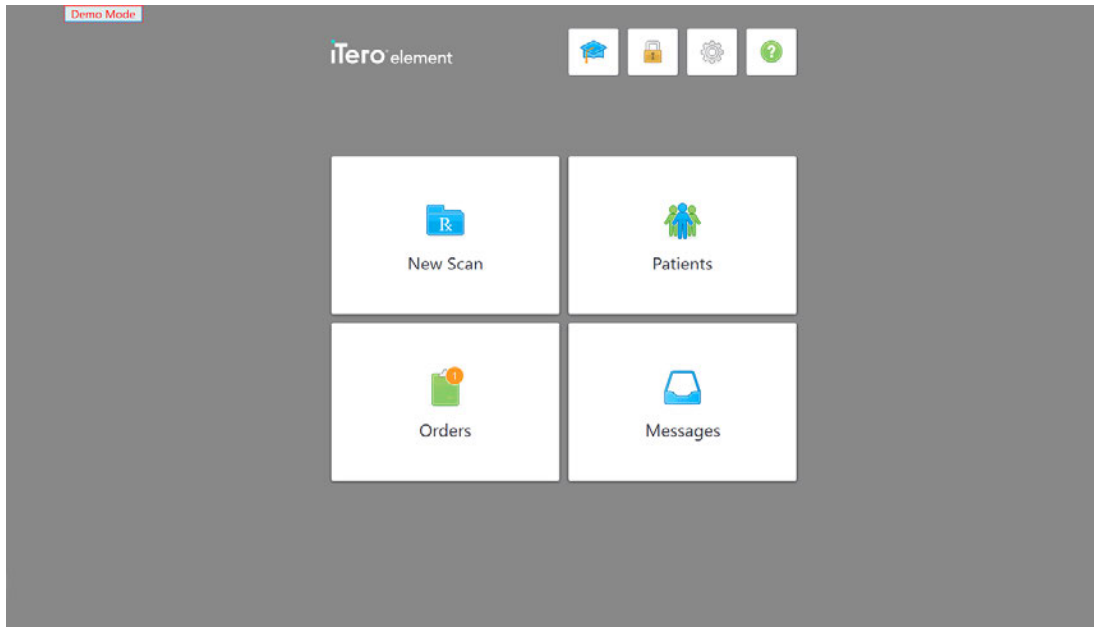


Figure 21: Demo Mode home screen

5. To view the demo cases, tap **Orders**.

A list of demo cases is displayed in the **Past Orders** pane.

6. Tap the required demo case.

The selected case is expanded to show the following options:

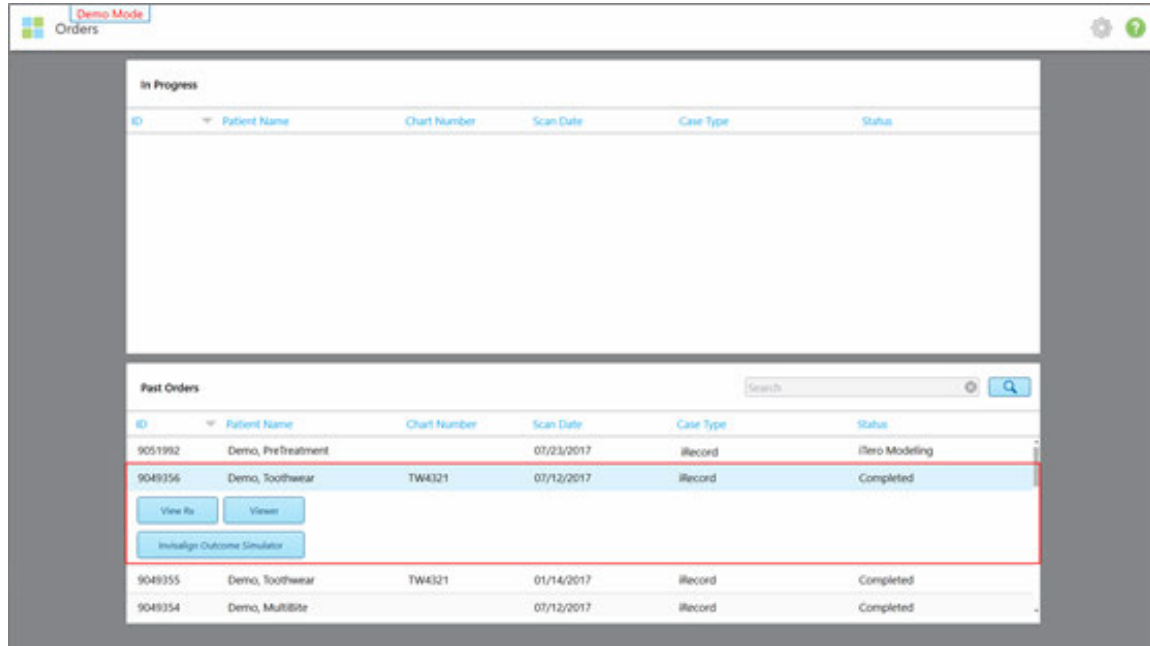


Figure 22: Past Orders pane – options

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

2.3.1 Exiting Demo Mode

To exit Demo mode:

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

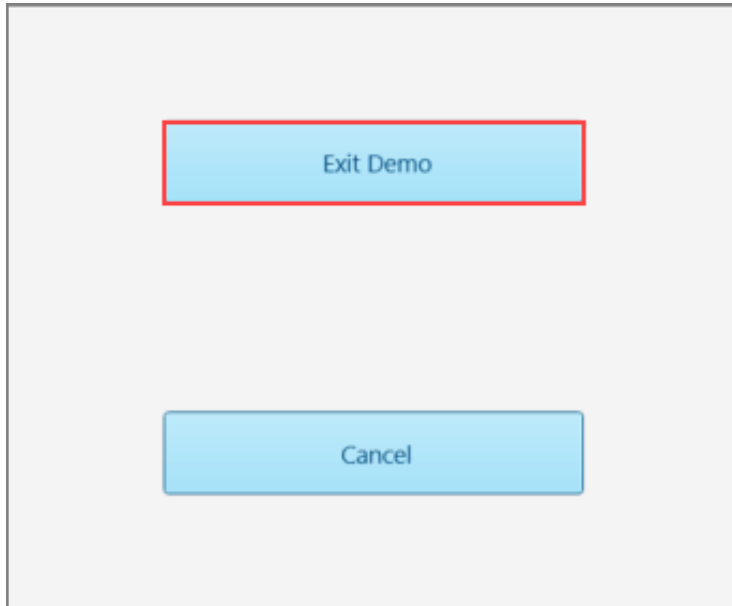


Figure 23: Exiting Demo mode

3 Working with the iTero Element scanner

3.1 Logging in to the scanner

When the scanner is powered on, the *Login* window is displayed.

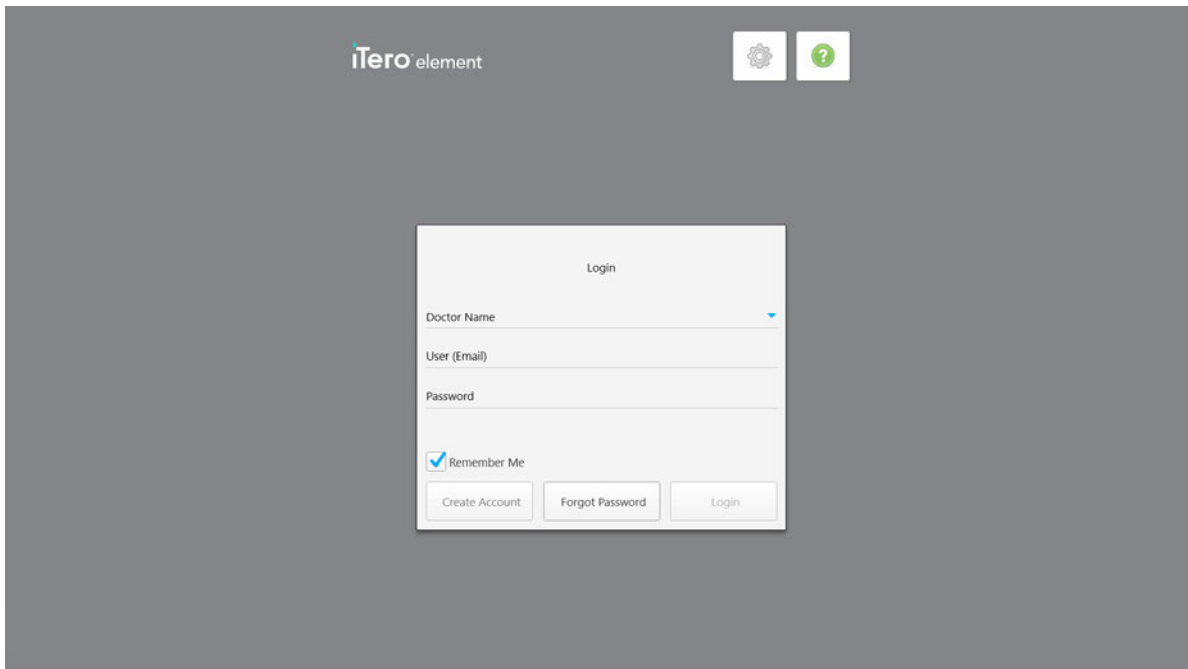


Figure 24: Login window

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

Notes:

- In order to ensure that all Windows security patches are up-to-date, a notification will be displayed at the bottom of the Login window and the home screen as soon as security updates are available to be installed. For more information on installing security updates, see section 3.1.2.

- If you did not shut down the scanner correctly previously, a message will be displayed notifying you of this and will remain until you acknowledge the message by tapping **I UNDERSTAND**. For more information on shutting down the scanner, see section 3.3.

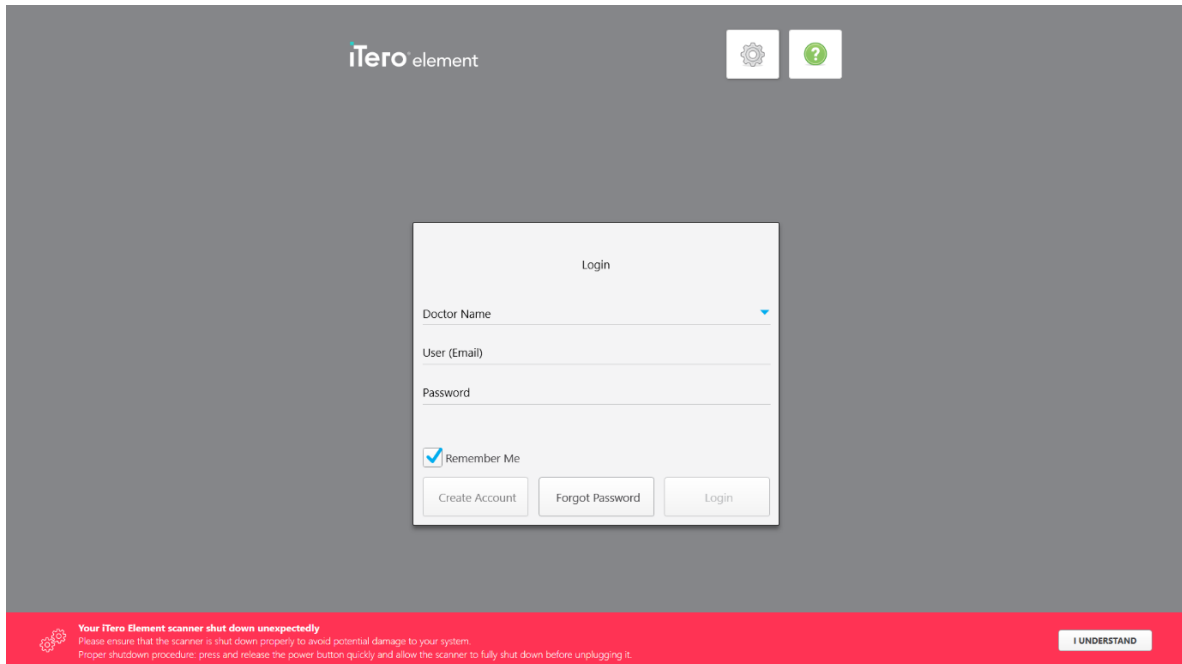
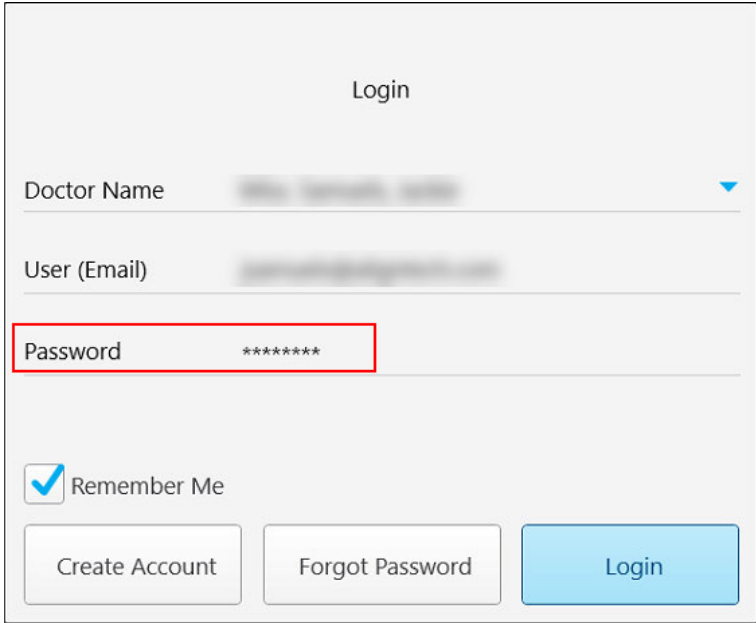


Figure 25: Unexpected shutdown notification

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 displayed automatically if you selected the **Remember Me** check box in a previous login session.
3. Enter your password.

The text is masked as asterisks.



The screenshot shows a login form titled "Login". It contains three input fields: "Doctor Name" with a dropdown arrow, "User (Email)", and "Password". The "Password" field is highlighted with a red border and contains seven asterisks. Below the fields is a "Remember Me" checkbox which is checked. At the bottom are three buttons: "Create Account", "Forgot Password", and "Login".

Figure 26: Password is masked

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. Tap **Login**.

The iTero home screen is displayed.

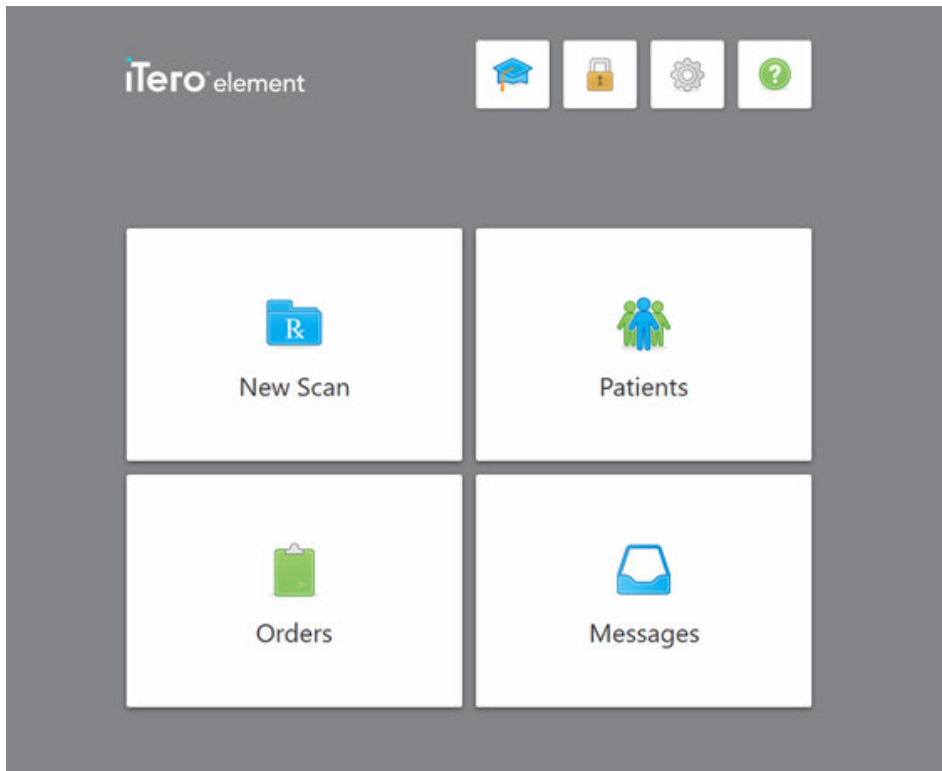


Figure 27: iTero home screen

Note: In order to ensure that all Windows security patches are up-to-date, you will see a notification at the bottom of the Login window and home screen as soon as security updates are available. For more information on installing security updates, see section 3.1.2.

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**.

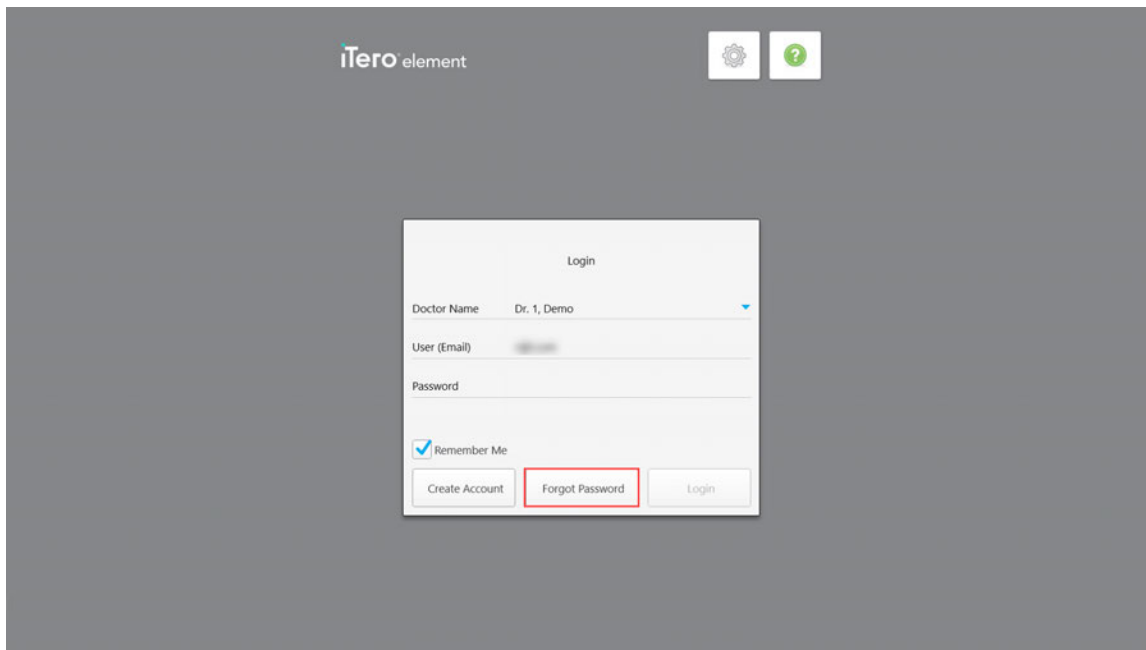


Figure 28: Forgot Password button

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

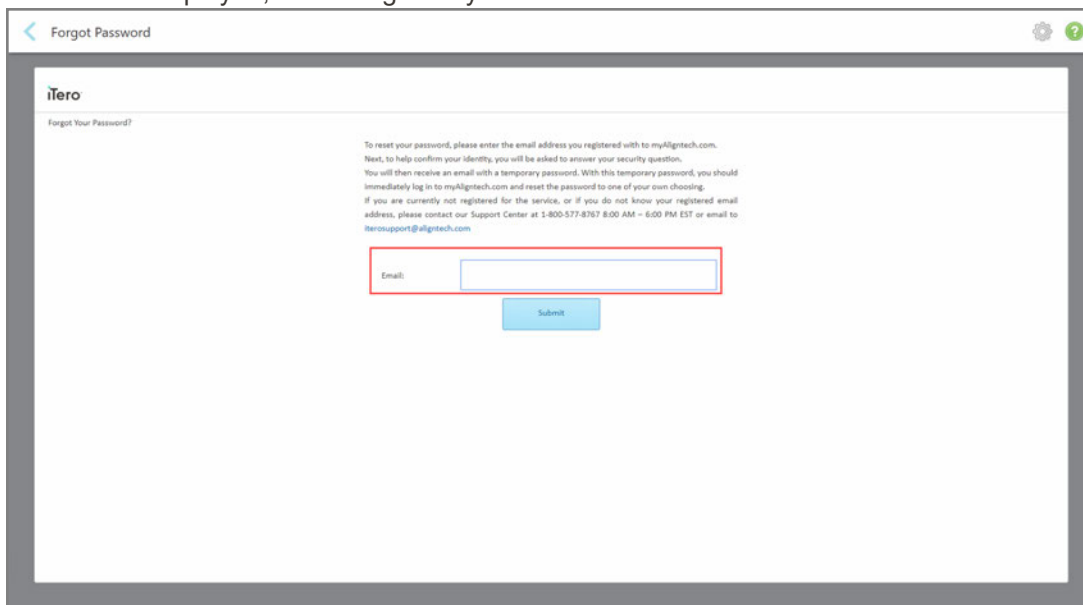


Figure 29: Email field for forgotten password

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

Your predetermined security question is displayed.

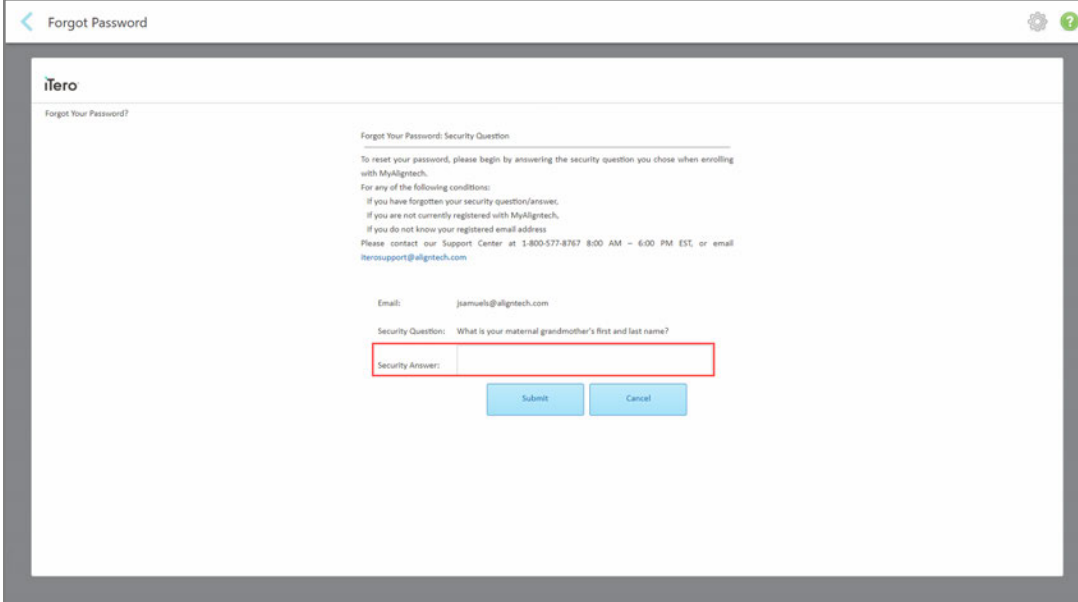
The screenshot shows a mobile application interface for a password reset. At the top, there is a navigation bar with a back arrow and the text 'Forgot Password'. Below this, the iTerO logo is displayed. The main content area is titled 'Forgot Your Password?' and contains the following text: 'Forgot Your Password: Security Question', 'To reset your password, please begin by answering the security question you chose when enrolling with MyAlignTech.', 'For any of the following conditions:', 'If you have forgotten your security question/answer, if you are not currently registered with MyAlignTech, if you do not know your registered email address. Please contact our Support Center at 1-800-577-8767 8:00 AM - 6:00 PM EST, or email iterosupport@aligntech.com'. Below the text, the user's email is listed as 'Email: jiamueh@aligntech.com'. The security question is 'Security Question: What is your maternal grandmother's first and last name?'. A text input field for the 'Security Answer:' is highlighted with a red border. At the bottom, there are two buttons: 'Submit' and 'Cancel'.

Figure 30: Security answer field

4. Enter the answer to the 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, according to the iTerO password policy described in section 3.1.1.1.
6. If you do not know your registered email address, contact iTerO Customer Support.

3.1.1.1 iTerO password policy

When changing your password, ensure that your new password meets the following criteria:

- At least eight characters in length
- No spaces
- At least one upper case letter
- At least one lower case letter
- At least one number
- Optional: Passwords may include special characters (for example: !, #, \$, %, ^)

3.1.2 Installing Windows security updates

In order to ensure that the scanner is compliant with all cyber-security standards, whenever the iTero software is upgraded, the relevant Windows security updates will be downloaded on the scanner and be available for installation.

You will receive a notification on the *Login* window and the home screen when these Windows security updates have been downloaded and are available to be installed.

Installing the updates should take about half an hour, during which time the scanner cannot be used. Therefore, it is recommended to install them at a time that is convenient for you.

Note: If you ignore the message and do not install the updates, they will be installed automatically the next time the scanner is restarted.

To install the security updates:

1. In the *Login* window or the home screen, tap **INSTALL NOW**.

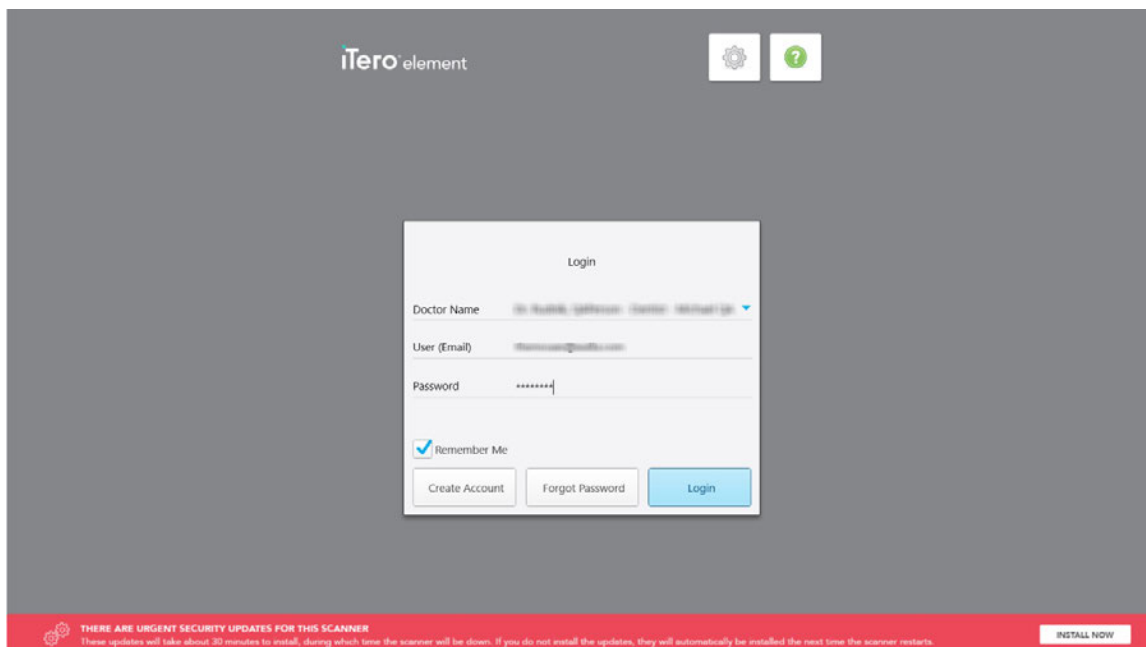


Figure 31: Login window with notification about Windows security updates

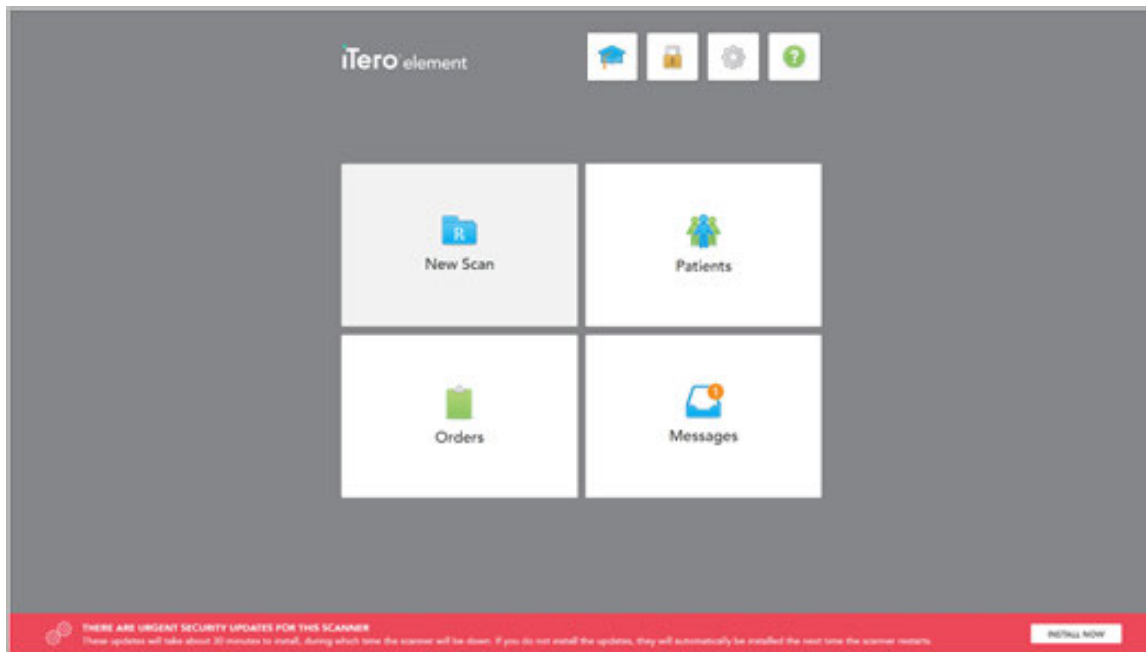


Figure 32: Home screen with notification about Windows security updates


A Windows progress bar is displayed during the installation. Once the updates have been installed, the scanner restarts and the *Login* page is displayed.


3.2 Logging out of the scanner

In order to protect the 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.

Note: If you do not shut down the scanner correctly, the next time you log on, a message will be displayed notifying you of this and will remain until you acknowledge it. Incorrect shutdown can be caused by pressing the Power button for longer than 4 seconds.

To shut down the scanner:

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

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

3.4 Moving the scanner

The scanner can be moved between rooms within the office.

Note: To ensure maximum system protection, it is recommended to have 2 people move the scanner.

To move the scanner between rooms:

1. Ensure that the wand is firmly positioned in the cradle.
2. Press and release the power button at the bottom of the touch screen to shut down the system.
3. Unplug the system from the wall outlet.
4. Move the system to its new location and plug it into a wall outlet.

3.5 User interface

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

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

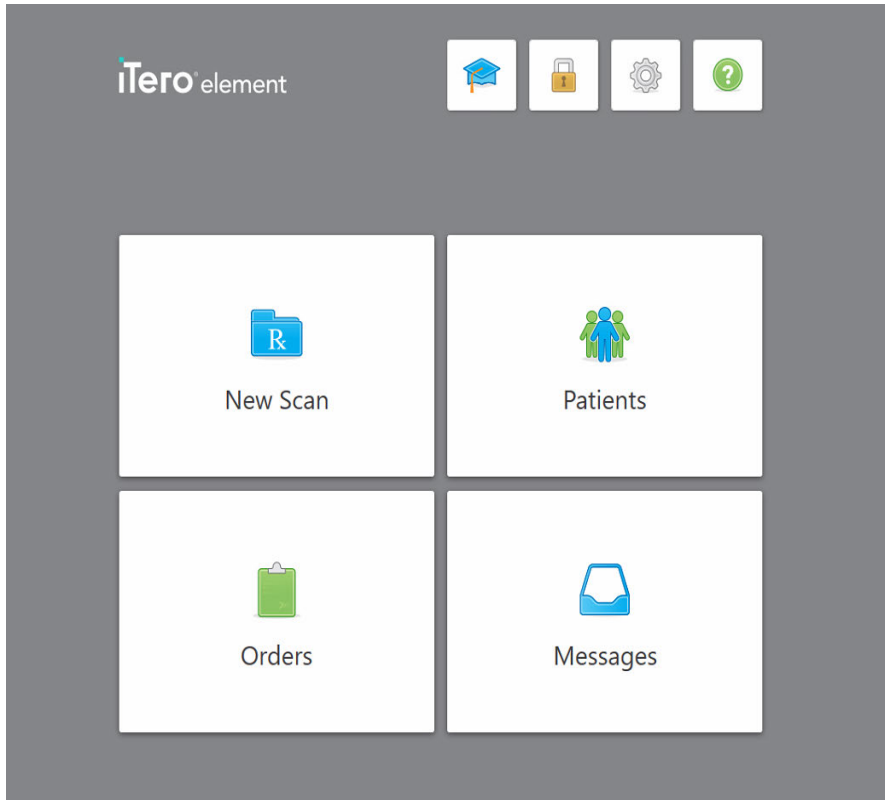
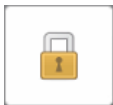


Figure 33: iTeror home screen

The following buttons are displayed on the home screen:



Learning Center: Tap to access training materials and educational videos for the iTeror scanner.



Lock: Tap to log out of your account whenever the scanner is not in use, as described in section 3.2. This helps 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 scanner preferences, 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.

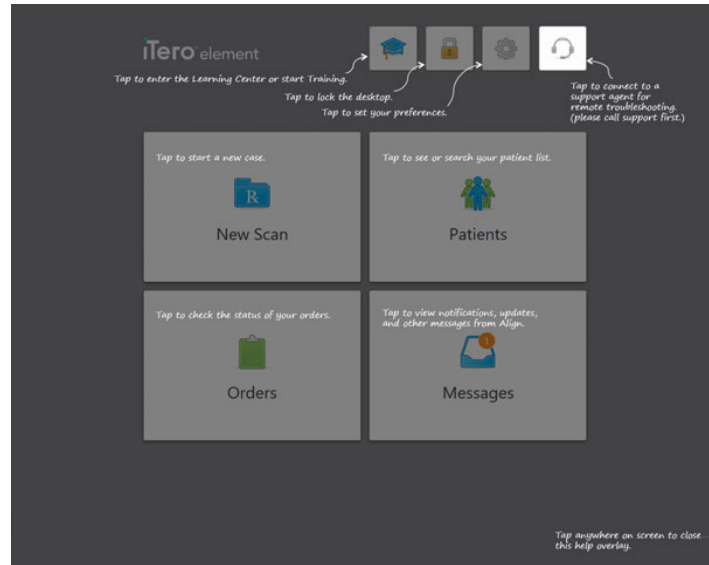



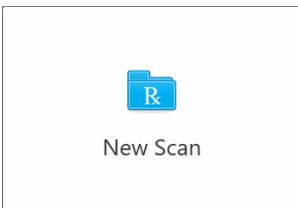
Figure 34: Help overlay



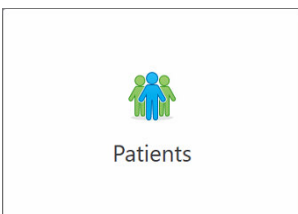
In this view, the button changes to . Tap the button for remote assistance from Customer Support. Customer Support is available from every Help overlay.

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

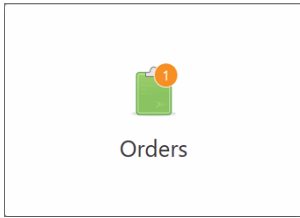
Tap anywhere to close the Help overlay and return to the relevant screen.



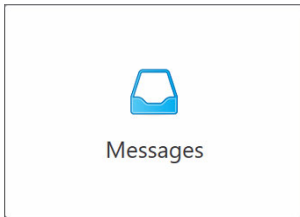
New Scan: Tap to open the *New Scan* window to fill in the Rx before starting a new scan. For more information, see section 4.



Patients: Tap to view the *Patients* page with a list of all your patients, their chart number, and the date of their last scan. 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 the messages from Align Technology. For more information, see section 7.

The **Settings** button is 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:



Figure 35: Scanner toolbar

The 4 center buttons indicate the current status of the scan process. Tap the buttons to navigate through the scan flow.



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 4.4.



Tap to move to Scan mode to scan the patient, described in section 4.5.



Tap to move to View mode to view the scanned model, described in section 4.6.



Tap to send the scanned model to the lab, described in section 4.7.



Tap to create a screenshot of the scanned model, described in section 9.11.

Note: This button is displayed in View mode only.



Tap to adjust the scanner preferences, 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 36: 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 software supports touch-screen (also known as multi-touch) gestures. These gestures are predefined motions used to interact with multi-touch devices.

Examples of common touch-screen gestures:



Tap



Double tap



Long press



Scroll



Rotate



Swipe



Pan



Zoom out



Zoom in

3.6 Defining the scanner settings

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

To define the scanner settings:

1. Tap the  button.

The *Settings* window is displayed.

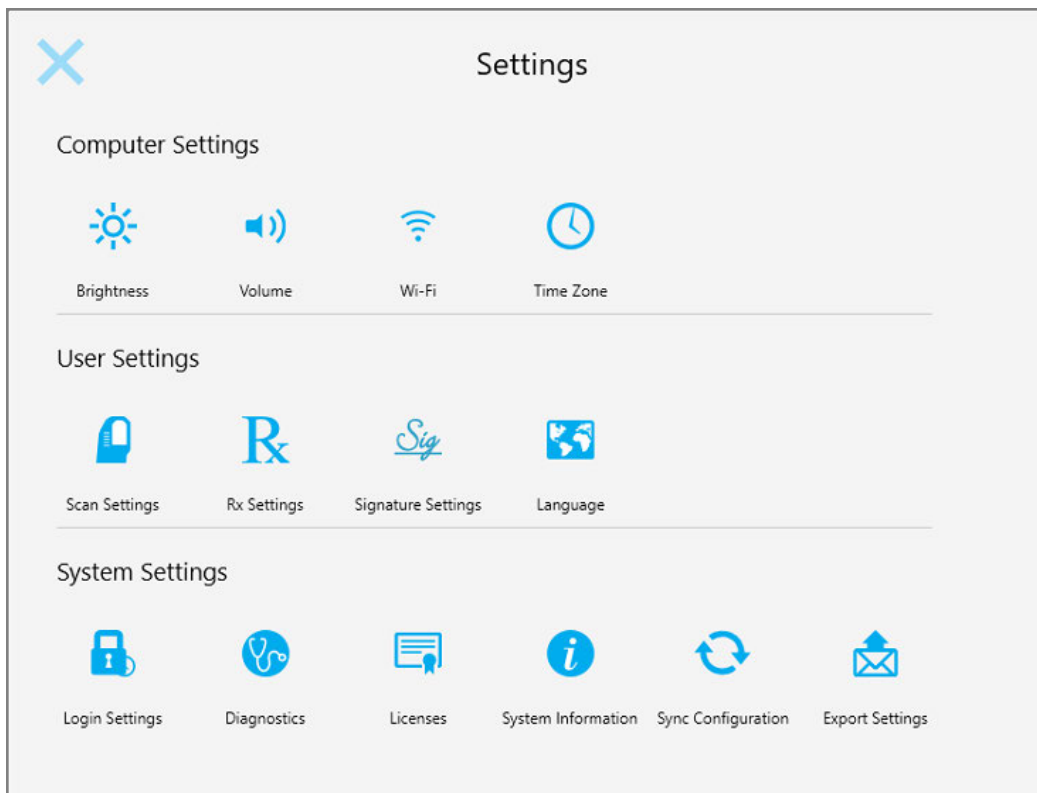


Figure 37: Settings window

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 required changes and then tap  to save the 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 slider to the required brightness level, and then tap  to save the changes and return to the *Settings* window.



Figure 38: 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 the changes and return to the *Settings* window.



Figure 39: 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 the scanner to the clinic's Wi-Fi network, you will need to add the 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.

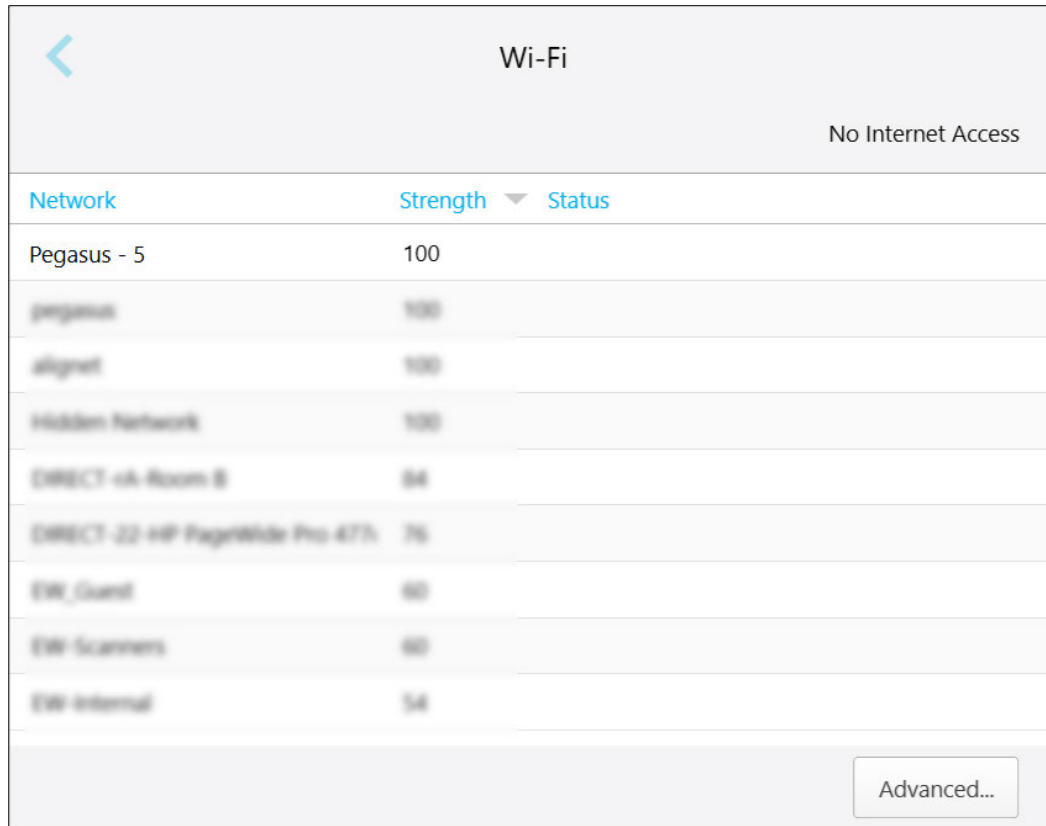


Figure 40: List of nearby Wi-Fi networks

2. Select the clinic network, for example, Pegasus - 5, and then tap **Connect**.

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

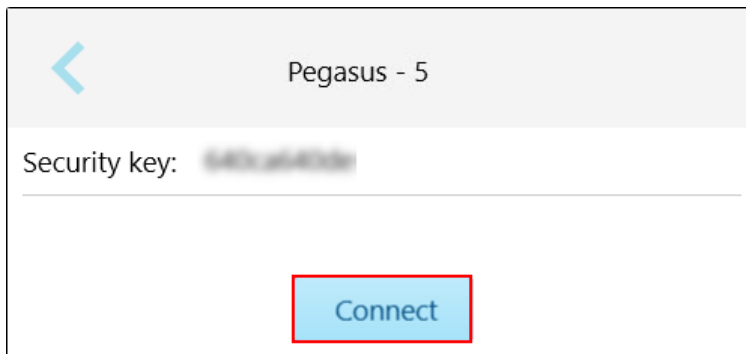


Figure 41: Connecting to the clinic Wi-Fi network

The scanner connects 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.

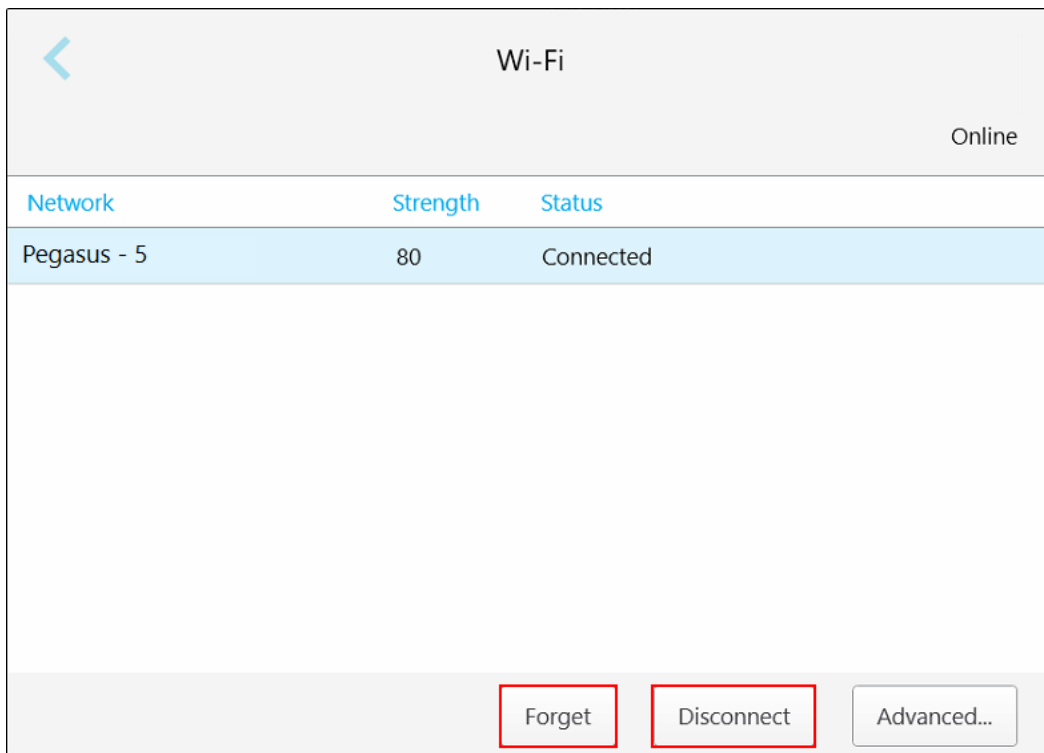




Figure 42: Forgetting or Disconnecting from the network

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

3.6.1.4 Defining the time zone

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

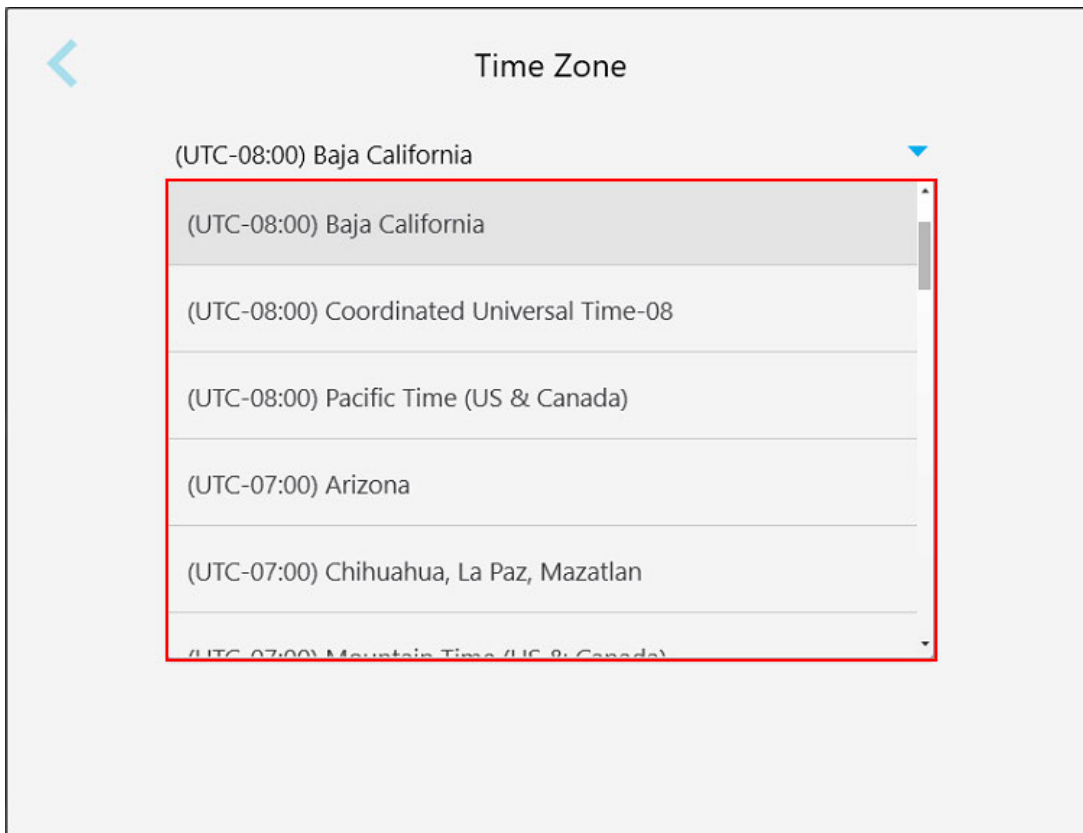


Figure 43: Time zone settings

Note: The time zone settings can be accessed only when you are logged in 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.

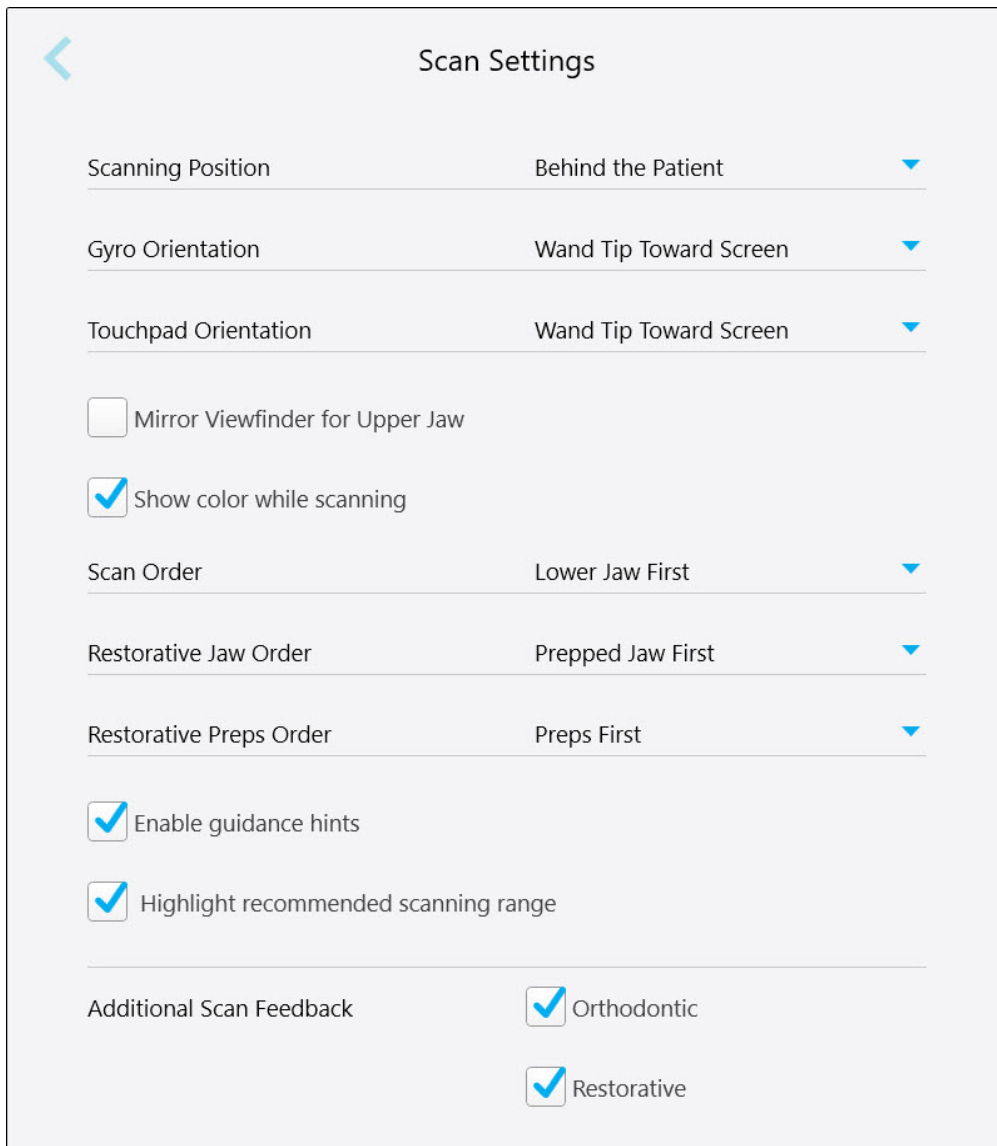


Figure 44: Scan Settings window

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

Scan setting	Scan options
Scanning Position	Select your position while scanning the patient: <ul style="list-style-type: none"> • Behind the patient • In front of the patient
Gyro Orientation	Select the default gyro orientation: <ul style="list-style-type: none"> • Wand Tip Toward Screen • Wand Base Toward Screen
Touchpad Orientation	Select the default touchpad orientation: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Upper Jaw First • Lower Jaw First
Restorative Jaw Order	Select the order in which to scan the jaws for restorative case types: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Preps First • Arch First • No Guidance
Enable guidance hints check box	Select this check box to display guidance when scanning, as described in section 4.5.1.

Scan setting**Highlight recommended scanning range** check box**Scan options**

Select this check box to highlight only the scanning range on the navigation controls.

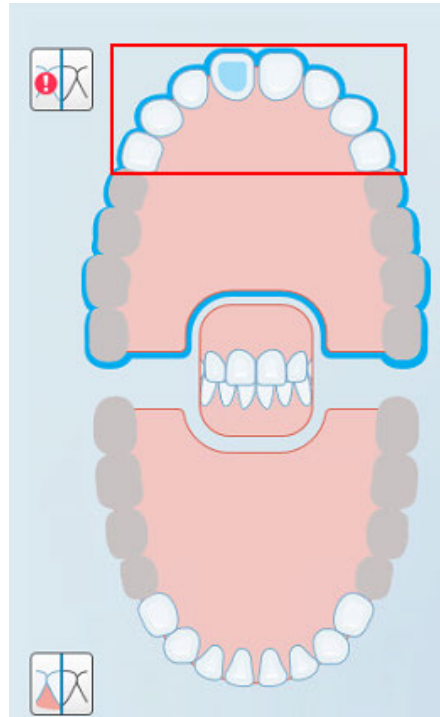



Figure 45: Only scanning range is highlighted

Additional Scan Feedback

Select the relevant check boxes to display areas of missing anatomy while scanning, as described in section 4.5.3.1.

- Orthodontic
- Restorative

3. Tap  to save the 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.

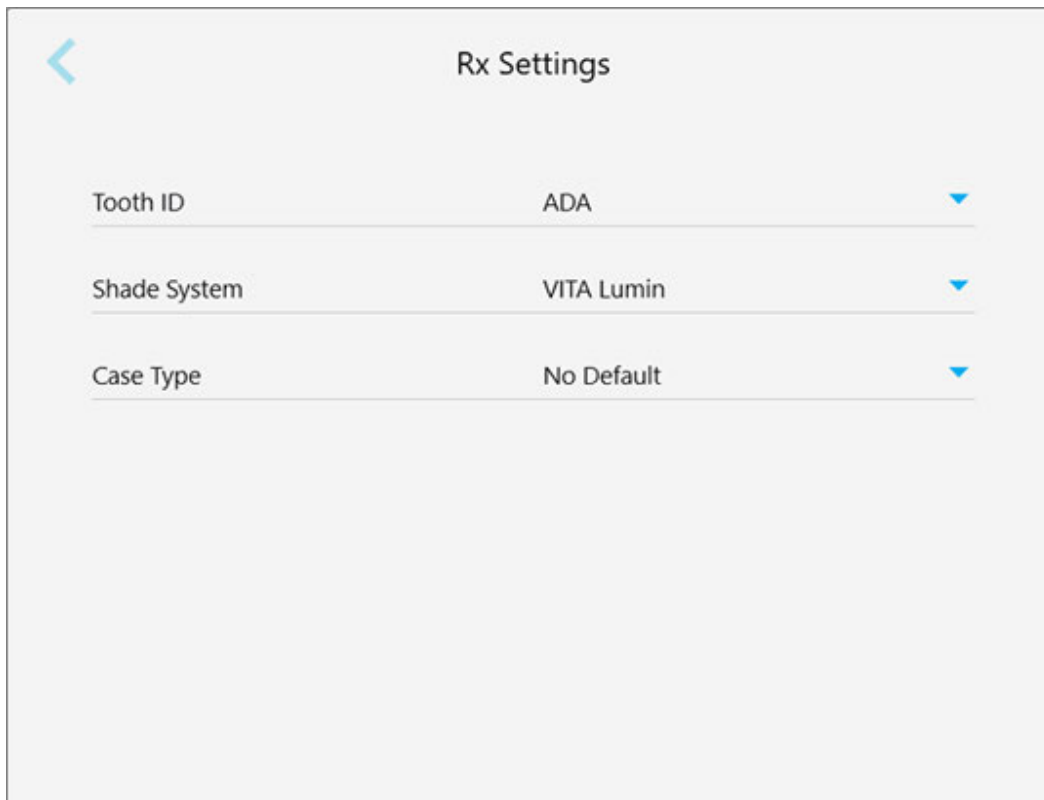



Figure 46: Rx Settings window

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

Rx setting	Rx options
Tooth ID	Select the default tooth ID system: <ul style="list-style-type: none"> • FDI • ADA • Quadrant
Shade System	Select the default shade system: <ul style="list-style-type: none"> • VITA Lumin • VITApan 3D Master • Other
Case Type	Select the default case type: <ul style="list-style-type: none"> • No Default • Invisalign • iCast • iRecord • Chair Side Milling • Invisalign + iRecord • Vivera • Vivera Pre-Debond • Restorative <p>Note: The list of available options changes according to the subscription package.</p>

3. Tap  to save the 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 47: Signature Settings window

2. Define the 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: <ul style="list-style-type: none"> • 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 the changes and return to the *Settings* window.

3.6.2.4 Defining the language settings

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

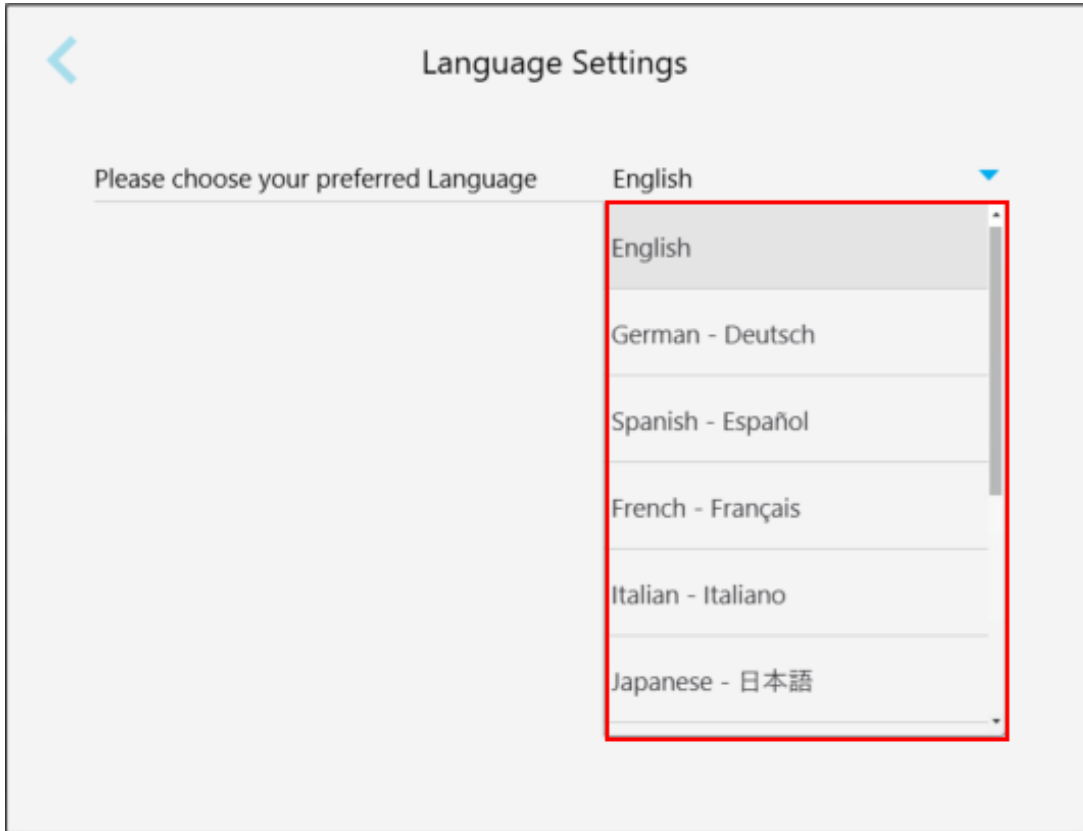


Figure 48: Language Settings window

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, synchronize new updates from the server, 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 1 hour, but you can change it if required.

Notes:

- To ensure patient privacy, it is recommended to not increase the inactivity period to more than the default 1 hour.
- You will not be logged out of the scanner while the scanner is in Scan mode.

To define the period of inactivity:

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

The *Login Settings* window is displayed.

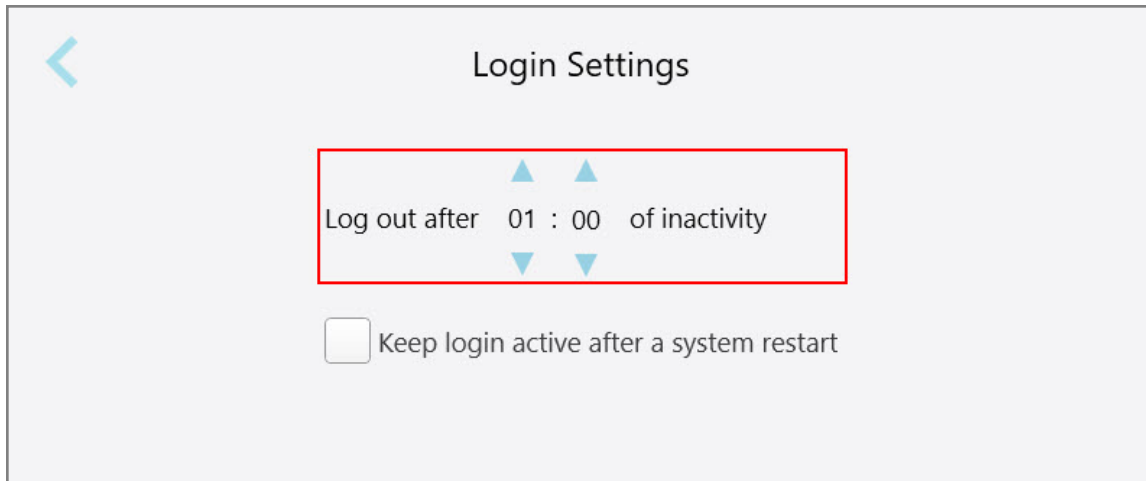



Figure 49: Login Settings window

2. Select the period of inactivity after which the user will be logged out of the scanner. (Min time: 10 minutes, Max time: 8 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 the 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.

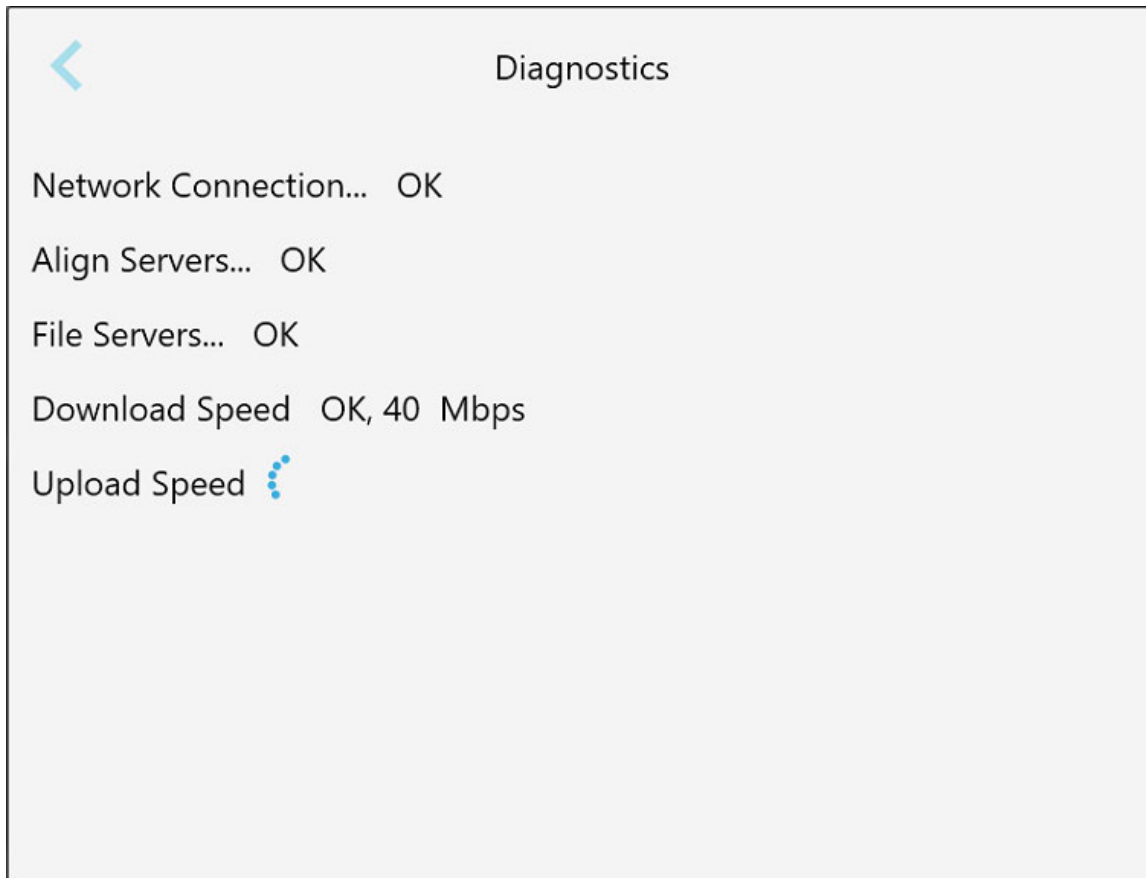




Figure 50: Diagnostics window

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.

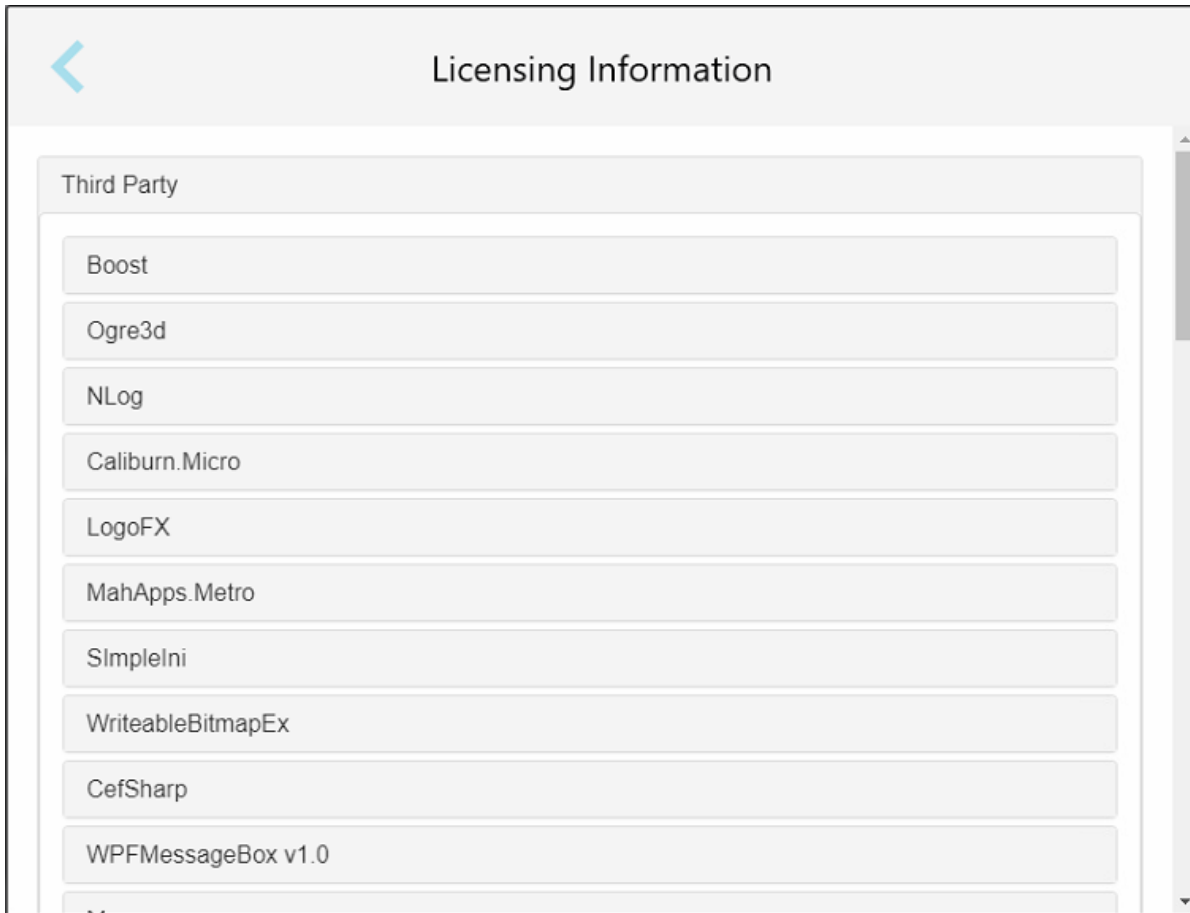



Figure 51: Licensing Information window

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.

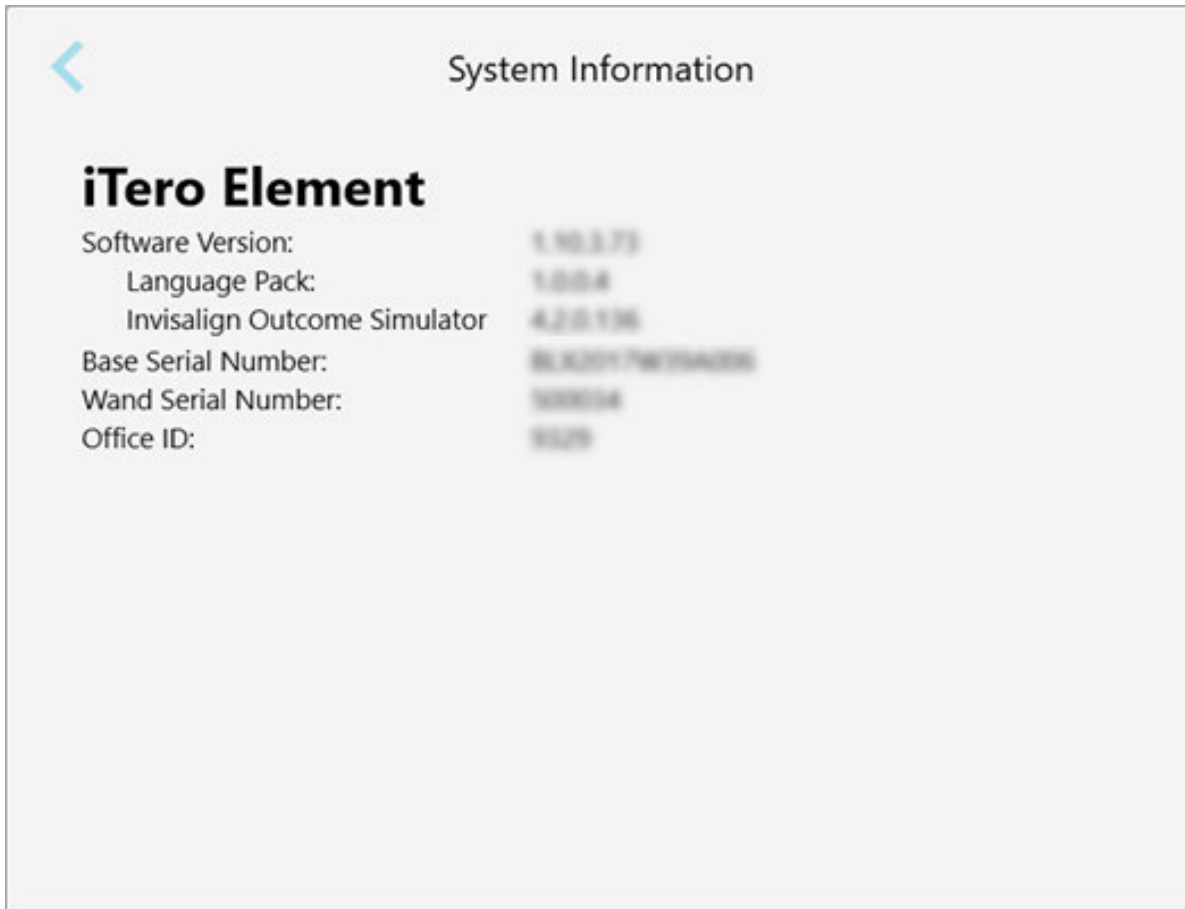


Figure 52: System Information window

3.6.3.5 Sync configuration

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

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 53: Export Settings window – deleting exported files

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

4 Starting a new scan

Before starting a new scan, you must:

- Add a new patient, as described in section 4.3.1 or search for an existing patient, described in section 4.3.2.
- Check whether there are any particles on the wand. If so, use a CaviWipe1 to remove them.
- Apply a new wand sleeve, as described below.

4.1 Applying a wand sleeve

To apply a wand sleeve:

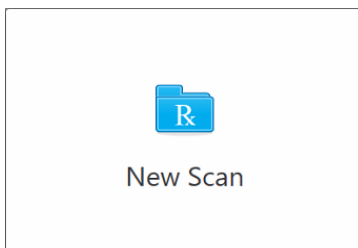
1. Gently remove the blue protective sleeve from the wand.
2. Gently slide a new sleeve onto the tip of the wand until it clicks into place.



Figure 54: Gently slide the new sleeve into place

4.2 Starting the scan

On the home screen, 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.

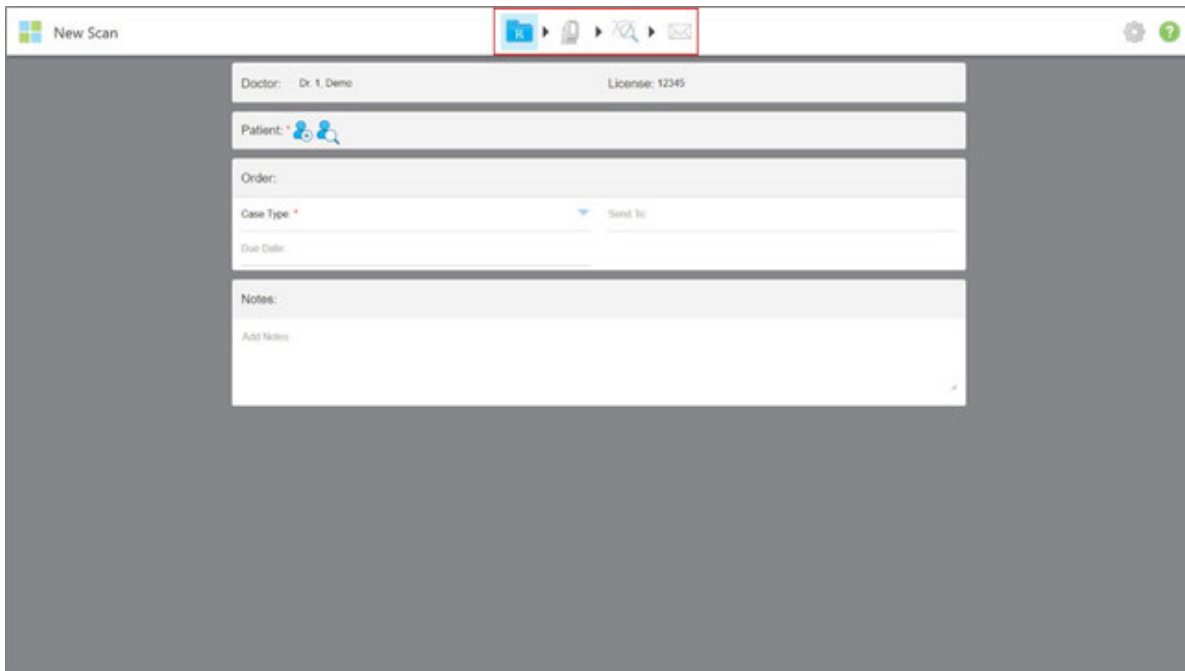


Figure 55: New Scan window showing an empty Rx and the progress toolbar at the top of the window

The *New Scan* window is made up of the following areas:

- **Doctor:** Displays the doctor's name and license number.
- **Patient:** Enables you to display the name of the patient for which the treatment is prescribed, by adding a new patient or by searching for an existing patient. If required, once the patient's data is displayed, you can edit it, or clear it from the *New Scan* window. For more information, see section 4.3
- **Order:** Enables you to define the details of the required treatment, for example, the case type.
- **Notes:** Enables you to make specific notes regarding the patient's treatment.

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



Filling in the Rx, described in section 4.4



Scanning the patient, described in section 4.5



Viewing the scan, described in section 4.6



Sending the scan to the lab, described in section 4.6.2

Your current progress is highlighted on the toolbar.

4.3 Patient management


You control the patient's data-management process from the **Patient** area in the *New Scan* window.

- Add a new patient, as described in section 4.3.1
- Search for an existing patient, as described in section 4.3.2
- Edit a patient's details, as described in section 4.3.3
- Clear the patient data from the *New Scan* window, as described in section 4.3.4

4.3.1 Adding new patients

You can add a new patient while filling in the Rx or at any time before.

To add a new patient:

1. In the *New Scan* window, in the **Patient** area, tap .

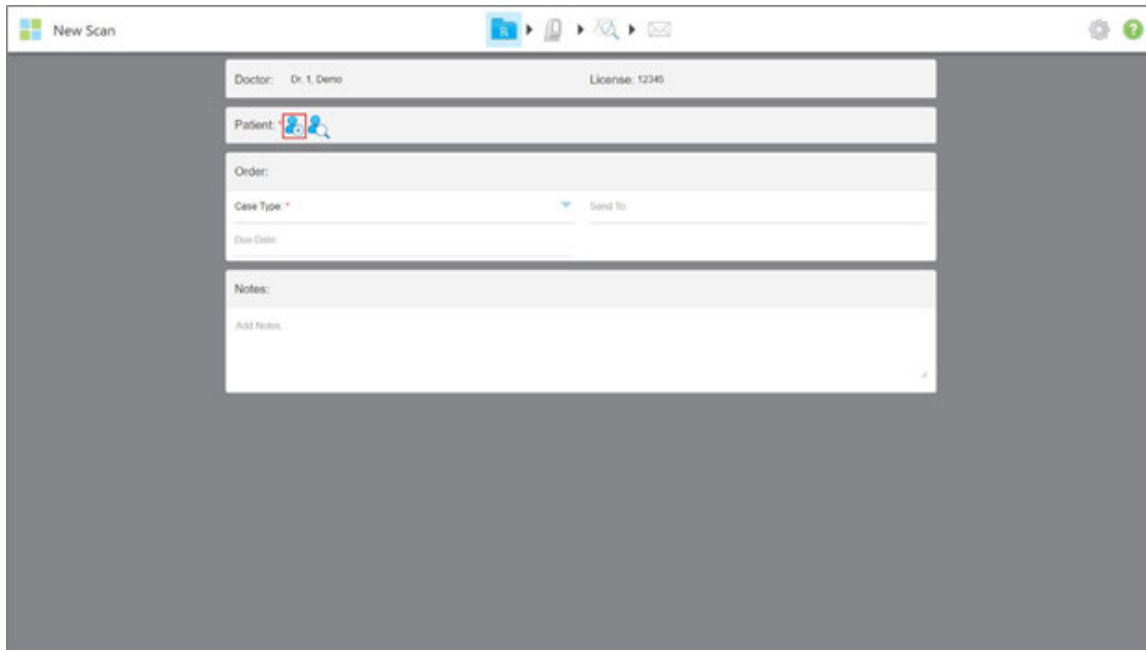


Figure 56: New Scan window – adding a new patient

The *New Patient* window is displayed.

Figure 57: New Patient window

2. Enter the patient's first name and last name.
3. If required, enter a chart number.
4. Tap **Add** to add the new patient.

The new patient's name and chart number, if relevant, are displayed in the *New Scan* window.

Figure 58: Adding the new patient

Note: If you try adding a patient who already exists, a message is displayed notifying you that a patient with the same details exists.

The screenshot shows a 'New Patient' form with the following fields: 'First Name: *' containing 'Patient 1', 'Last Name: *' containing 'Demo', and 'Chart Number:'. Below the form, a yellow error message box states: 'A patient with the same details already exists: Demo, Patient 1'. At the bottom of the form are 'Cancel' and 'Add' buttons.

Figure 59: Message notifying that a patient with the same details exists

- a. If this is the same person, tap **Add**.

You are prompted to confirm whether the new patient is the same patient as the existing patient.

The screenshot shows the 'New Patient' form with a confirmation dialog box overlaid. The dialog box has a question mark icon and contains the text: 'A patient with the same details already exists: Demo, Patient 1' and 'Is this the same patient?'. There are 'No' and 'Yes' buttons in the dialog. The 'Add' button from the form is visible at the bottom right.

Figure 60: Confirmation message regarding an existing patient

- b. Tap **Yes** to combine the patient data.


The patient is displayed in the *New Scan* window.

4.3.2 Searching for existing patients

When searching for an existing patient, you have to enter at least 3 characters of the patient's name in the search field to see a list of patients who match the search criteria.

In addition, you can search for a patient from the **Patients** page, described in section 5.1.

To search for an existing patient:

1. In the **Patient** area, tap .

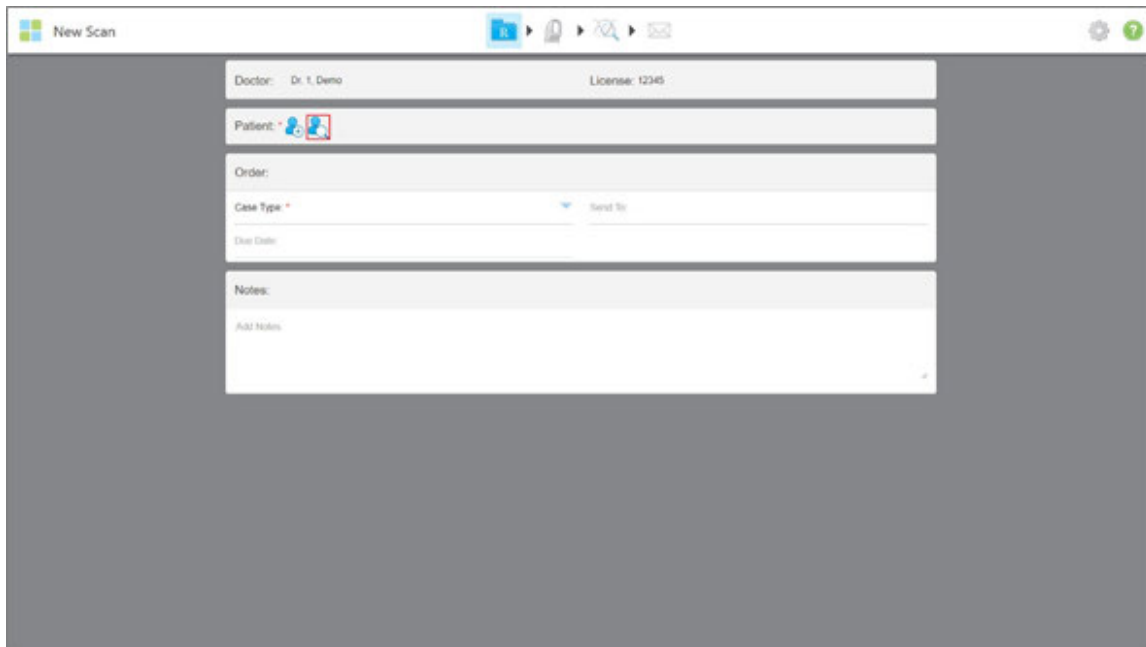


Figure 61: New Scan window – searching for an existing patient

The *Search Patient* window is displayed.

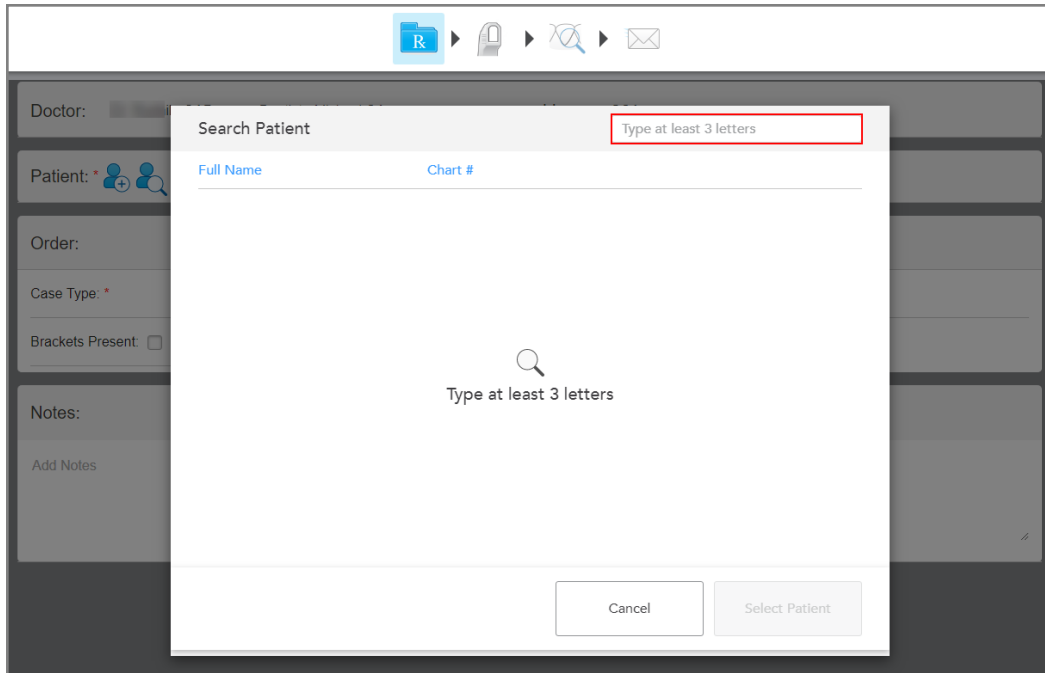


Figure 62: Search Patient window with search field

2. In the *Search Patient* window, enter at least three letters in the search field to display a list of patients matching the search criteria.

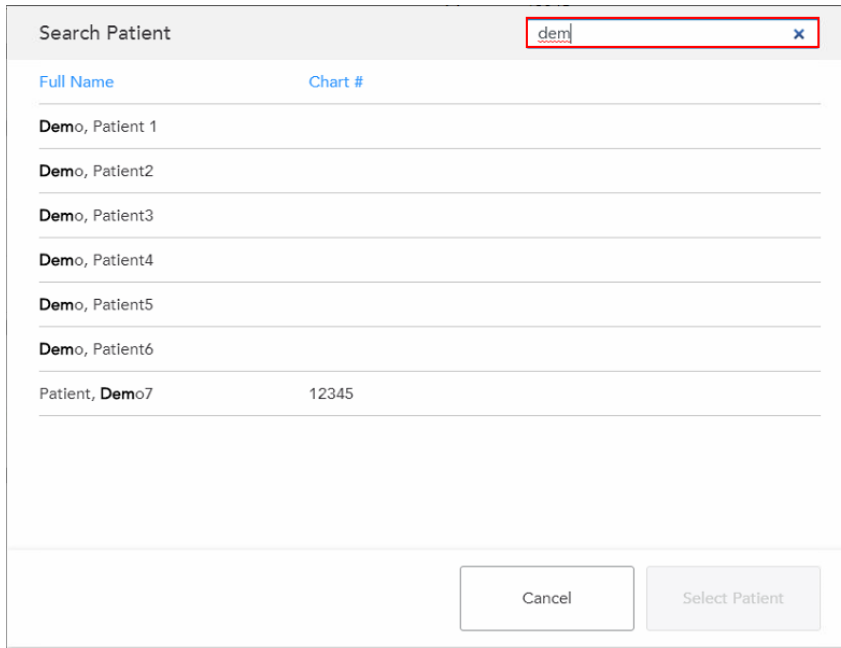
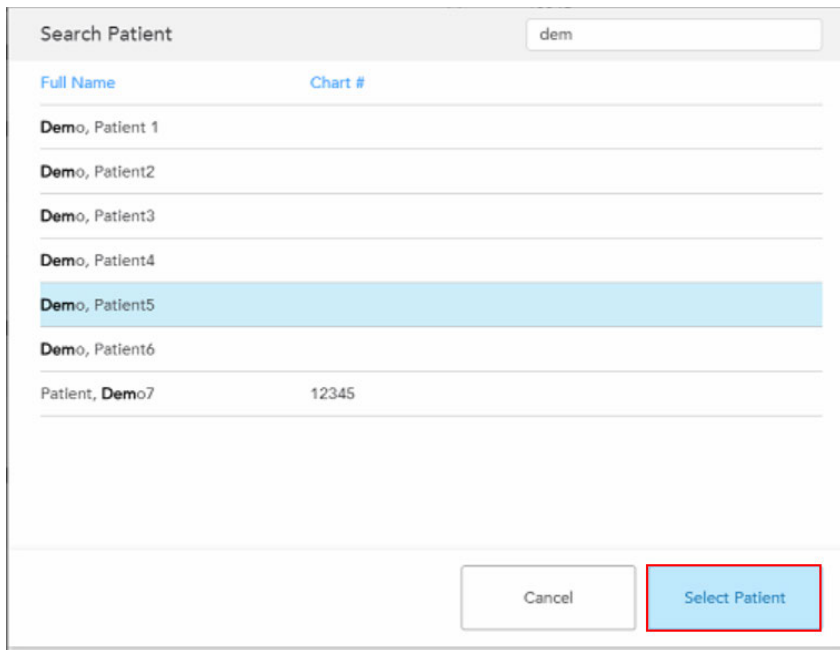


Figure 63: Search criteria in the search field and list of matching patients

3. Select the required patient, and then tap **Select Patient**.

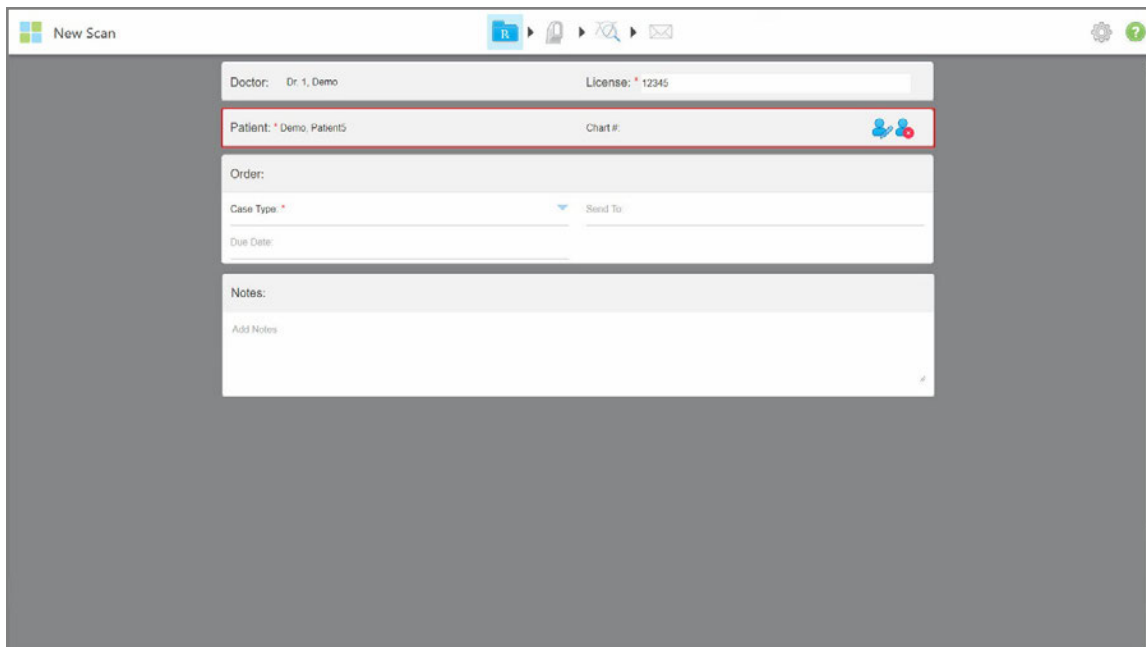


Search Patient

Full Name	Chart #
Demo, Patient 1	
Demo, Patient2	
Demo, Patient3	
Demo, Patient4	
Demo, Patient5	
Demo, Patient6	
Patient, Demo7	12345

Figure 64: Selecting the required patient

The selected patient is displayed in the *New Scan* window.



New Scan

Doctor: Dr. 1, Demo License: # 12345

Patient: Demo, Patient5 Chart #:

Order:

Case Type: * Send To:

Due Date:

Notes:

Add Notes

Figure 65: Selected patient displayed in the New Scan window

4.3.3 Editing the patient details


After you have searched for and selected a patient, or after you have added a new patient, you can edit the patient's details.

In addition, you can edit the patient's details when opening the Rx from the patient's profile page, as described in section 5.4.

To edit a patient's details:

1. Search for an existing patient, as described in section 4.3.2.

The patient is displayed in the *New Scan* window.

2. In the **Patient** area, tap .

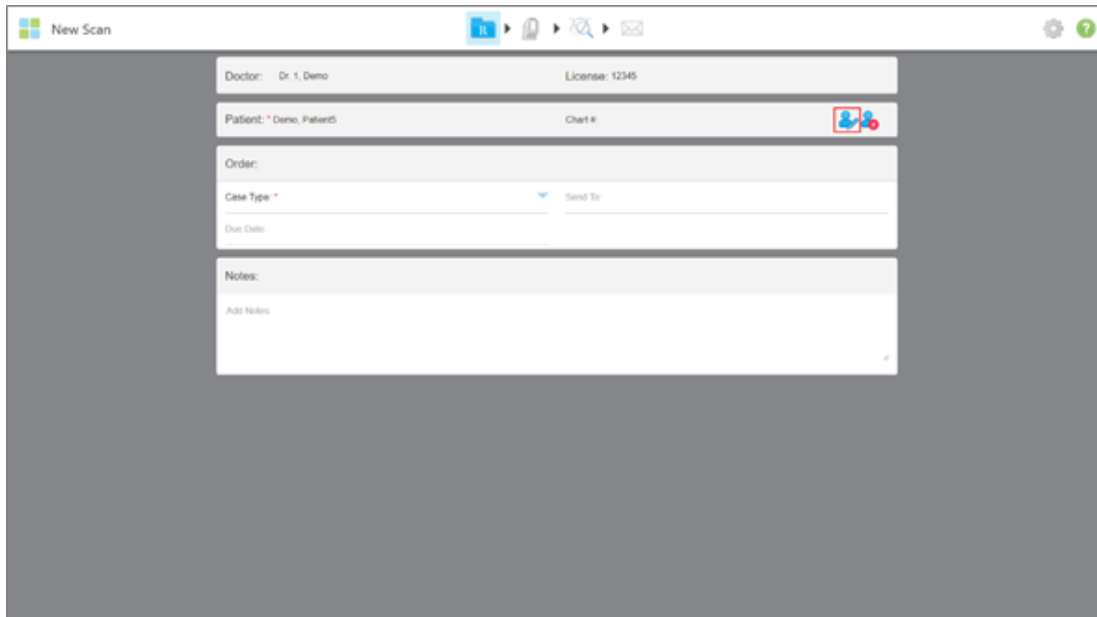


Figure 66: New Scan window – editing a patient

The *Edit Patient* window is displayed.

3. Edit the patient's details as required and then tap **Update**.

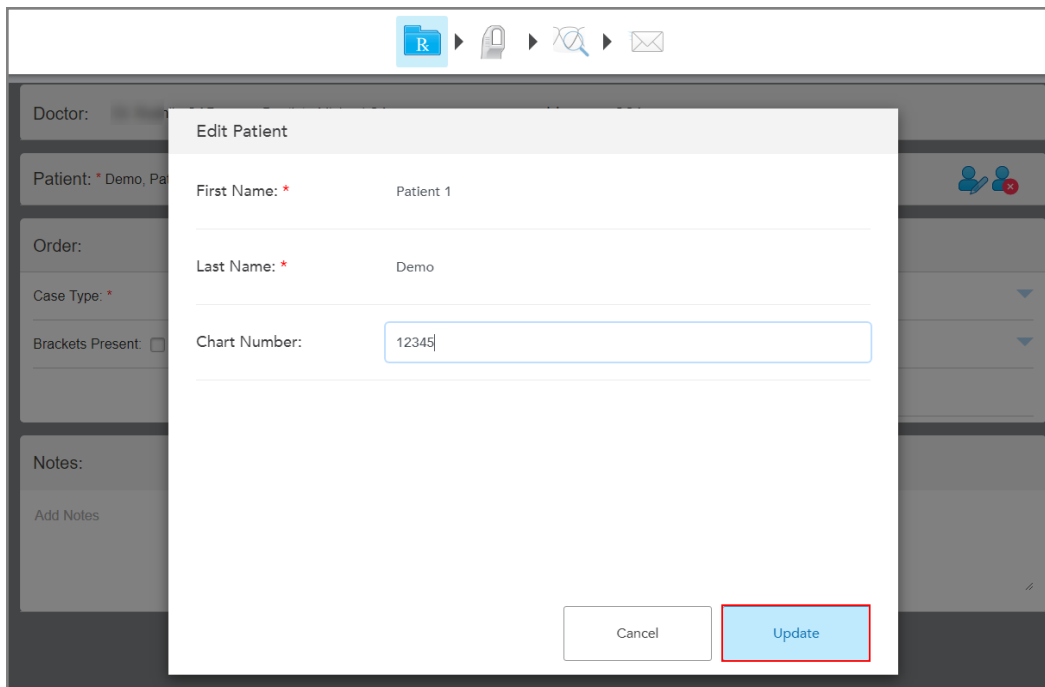


Figure 67: Edit Patient window and Update button

If, while editing the patient's name, you enter the same details as an existing patient, a message is displayed notifying you of such.

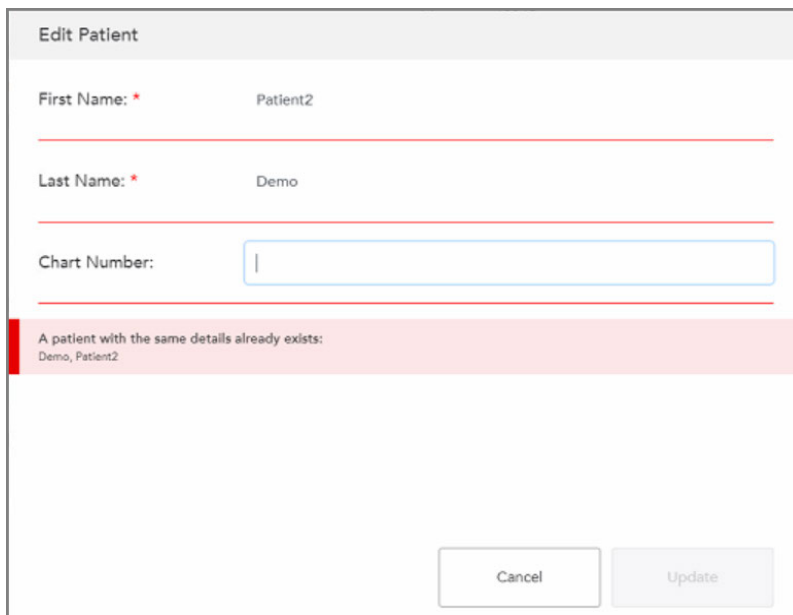


Figure 68: Message that a patient with the same details already exists

To differentiate between patients with the same details, use a chart number.

4.3.4 Clearing the patient details from the New Scan window

If required, you can remove the currently-displayed patient's details from the *New Scan* window.

To clear the patient details from the *New Scan* window:

- In the **Patient** area, tap  .

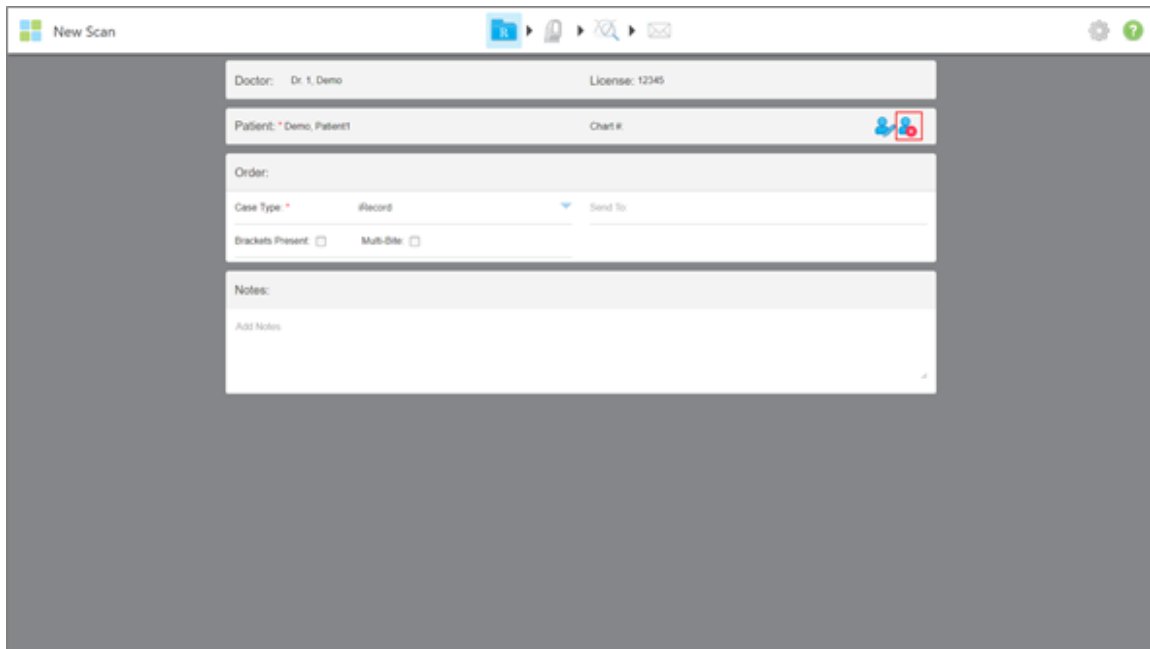



Figure 69: Clear patient data button


All data is cleared from the *New Scan* window, and you can now add a new user or search for an existing user, if required.

4.4 Filling in the Rx


The first step in the scanning process is filling in the Rx (prescription). The *New Scan* window enables you to create a new patient or search for an existing patient. It also enables you to enter the details about the case type, as well as add notes about the case. Fields marked with a red asterisk are mandatory.

After you have filled in the Rx, tap  to move to Scan mode and scan the patient, as described in section 4.5.

To fill in the Rx:

1. In the **Patient** area, tap  to create a new patient, as described in section 4.3.1.

Or

Tap  to search for an existing patient, as described in section 4.3.2.

2. In the **Order** area, from the **Case Type** drop-down list, select the required case type.

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

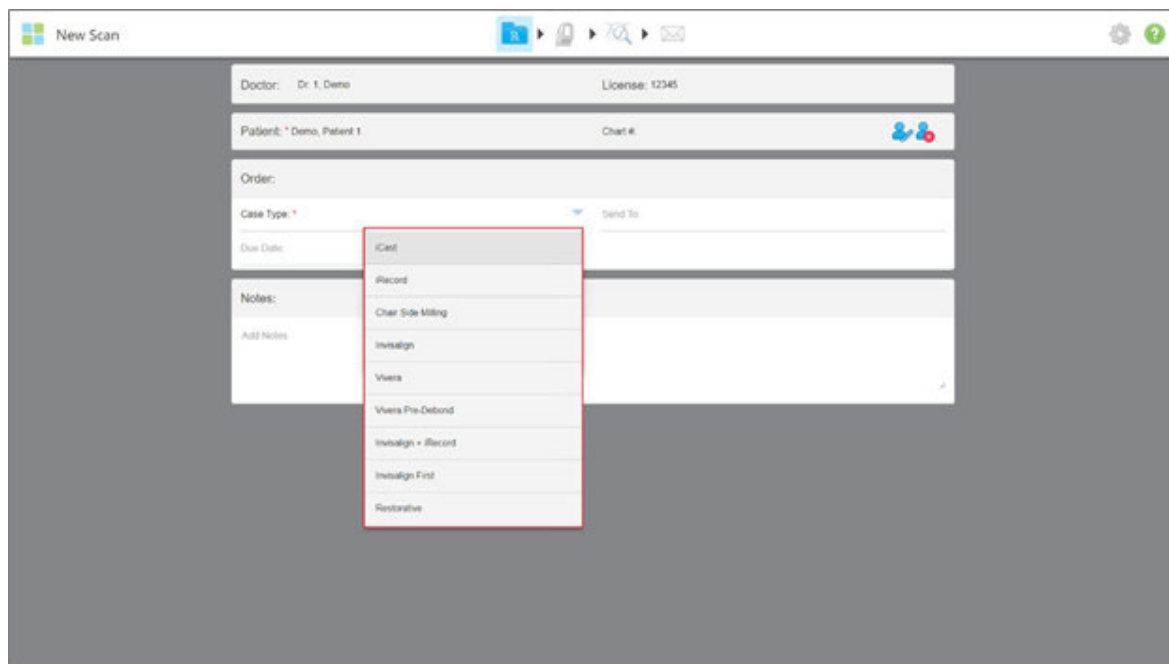


Figure 70: Selecting the required case type

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 or orthodontic 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.

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

Figure 71: New Scan window – iRecord case type

- Depending on the case type selected, fill in the relevant details.
 - **Restorative** and **Chair Side Milling** case types, see section 4.4.1.
 - **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 enables you to preserve the 2-bite relation based on your needs, and delivers precise bite information to the lab for appliance fabrication, for example, sleep apnea appliances.
 - If your subscription package includes the **Final Records** option, you are able to select the treatment stage. For more information, refer to the Invisalign documentation.

- If relevant, from the **Send To** drop-down list, select the lab to which the scan should be sent.
- Tap  on the toolbar to move to Scan mode, as described in section 4.5.

4.4.1 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.

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

A tooth chart is displayed in the window.

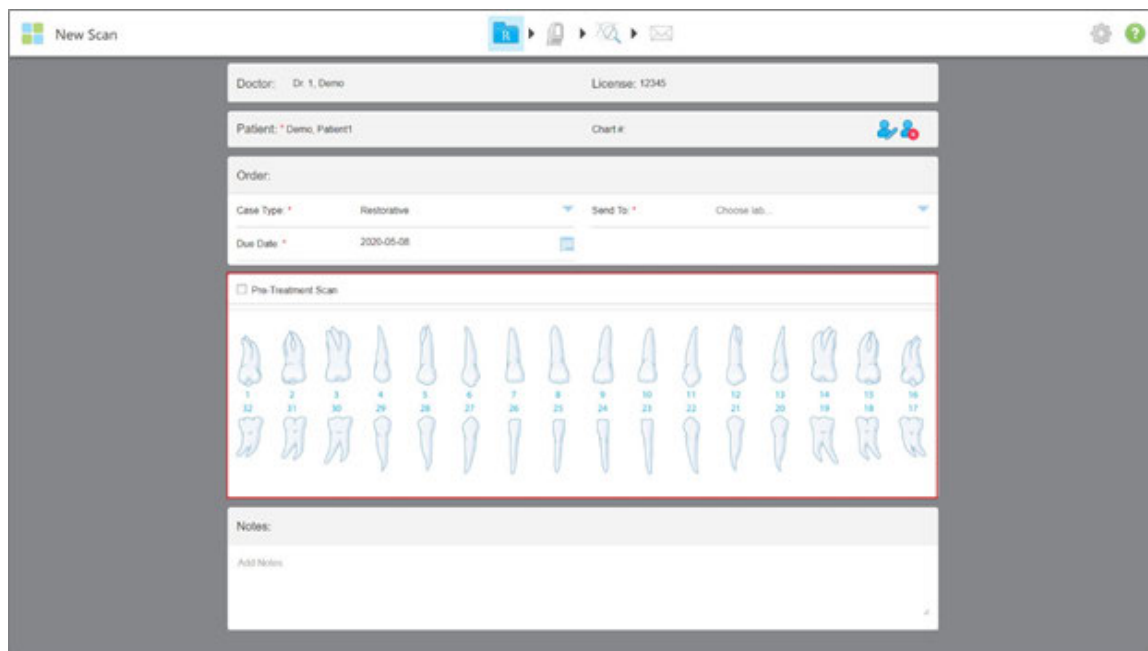


Figure 72: New Scan window – Restorative case type with a tooth chart

- 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.

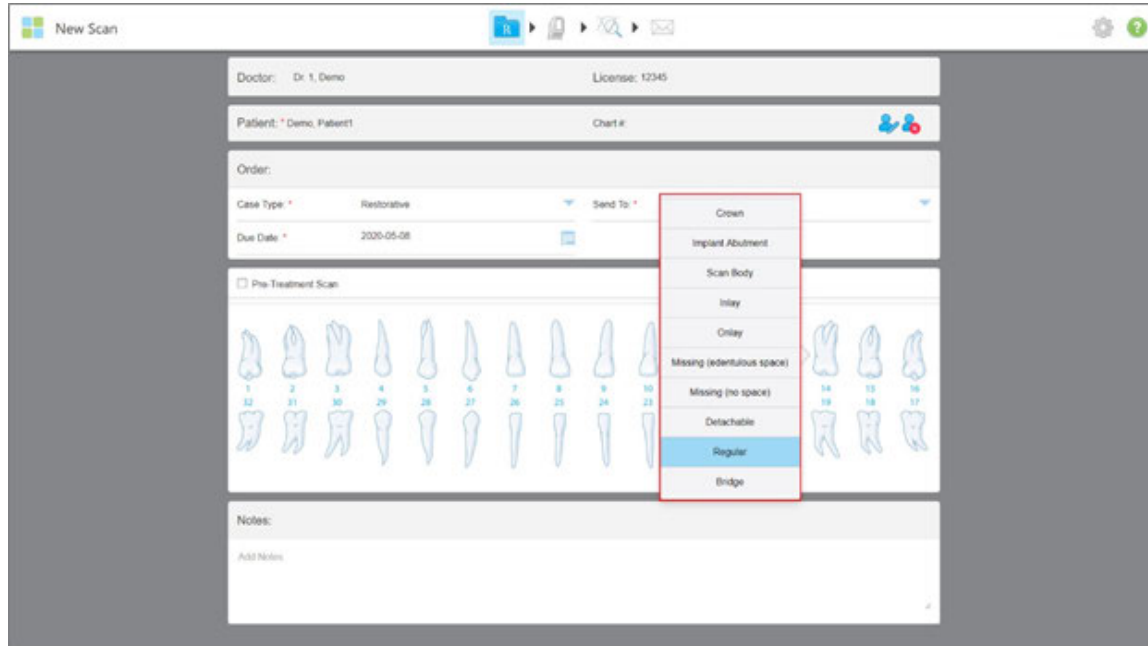


Figure 73: List of restorative treatment options

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 are prompted to select the settings for the selected treatment option.

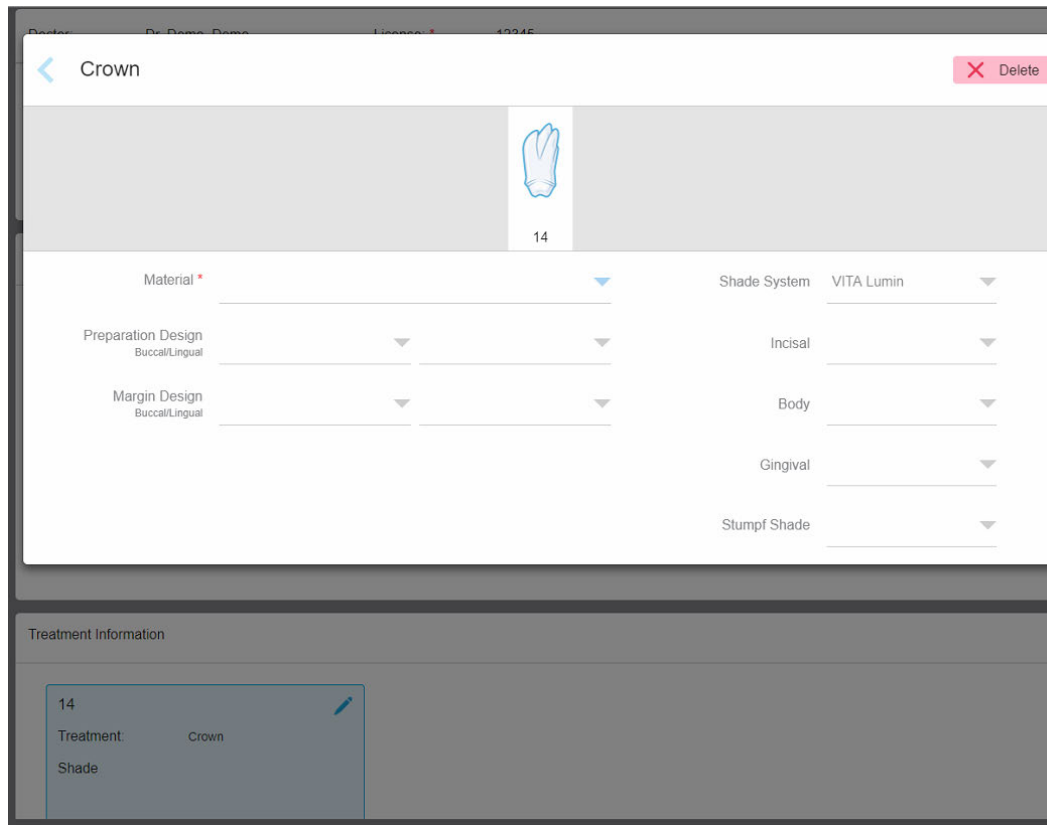



Figure 74: Defining the restoration properties

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 restoration should be fabricated.
 - **Preparation Design:** The shape of the finishing line (margin line) created by the user during the preparation. You can 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 restoration.
 - **Incisal:** The shade for the incisal area of the restoration.
 - **Body:** The shade for the body area of the restoration.
 - **Gingival:** The shade for the gingival area of the restoration.
 - **Stumpf Shade:** The shade of the prepped tooth.

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

The selected treatment options are displayed in the **Treatment Information** area.

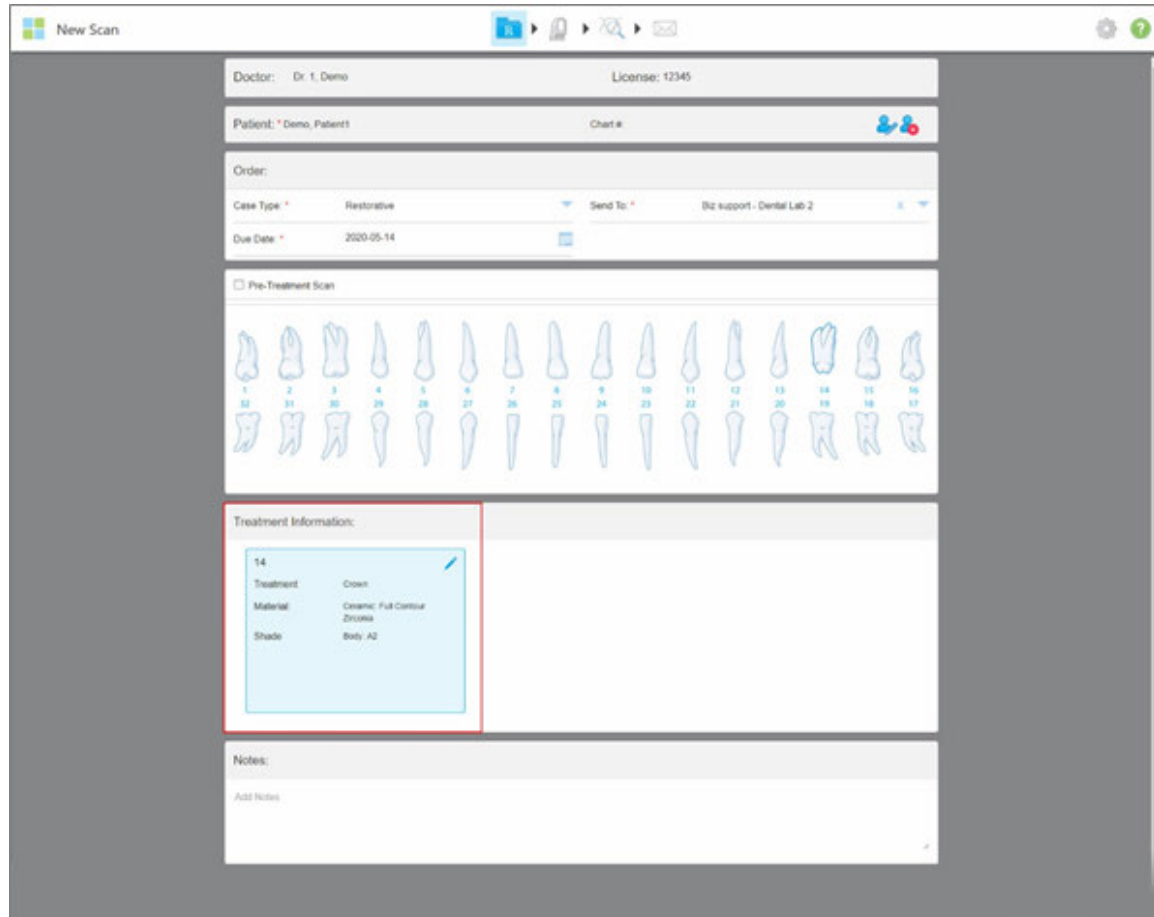




Figure 75: Treatment Information area

You can change the selected treatment options at any time before sending the scan by tapping .

4.5 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 4.5.3.1
- Toggle between color and monochrome mode, described in section 4.5.3.2

After scanning, you can edit the scan by:

- Deleting a segment, as described in section 9.5.1
- Deleting a selected area, as described in section 9.5.2
- Capturing areas with missing anatomy, as described in section 9.5.3
- Displaying the excess tissue around the edges of the 3D model, as described in section 9.5.4



When you have finished scanning the patient, tap  on the toolbar to move to **View** mode, where you can ensure that the scan is complete before sending it to the lab or storage, as described in section 4.6.

4.5.1 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.

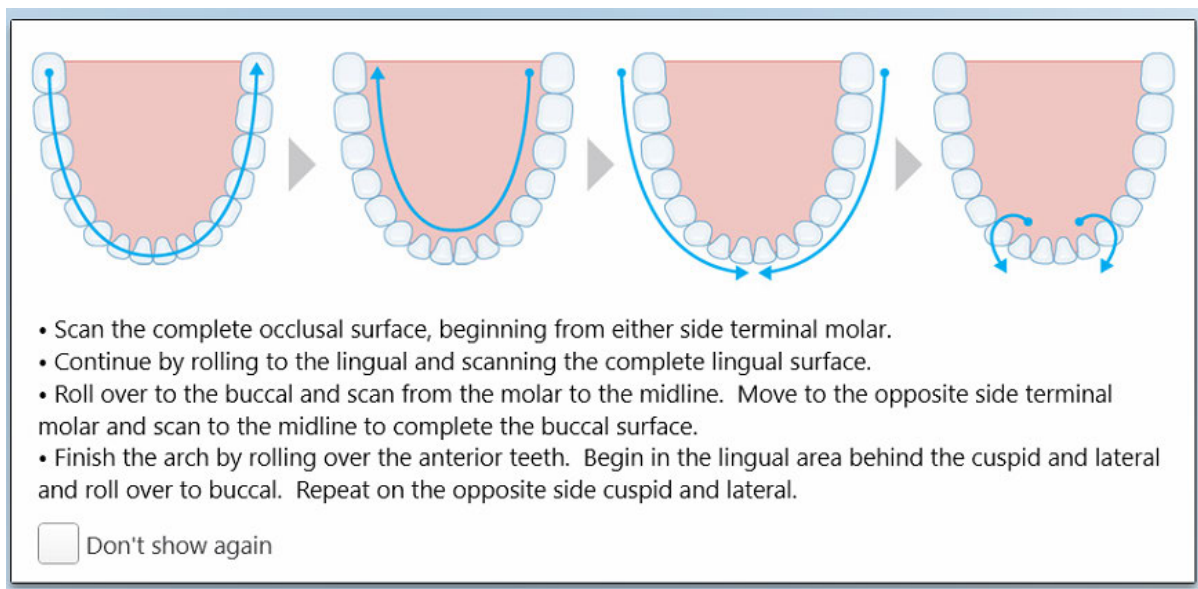


Figure 76: Recommended scanning sequence – lower jaw

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 press both wand buttons simultaneously, the following guidance is displayed:

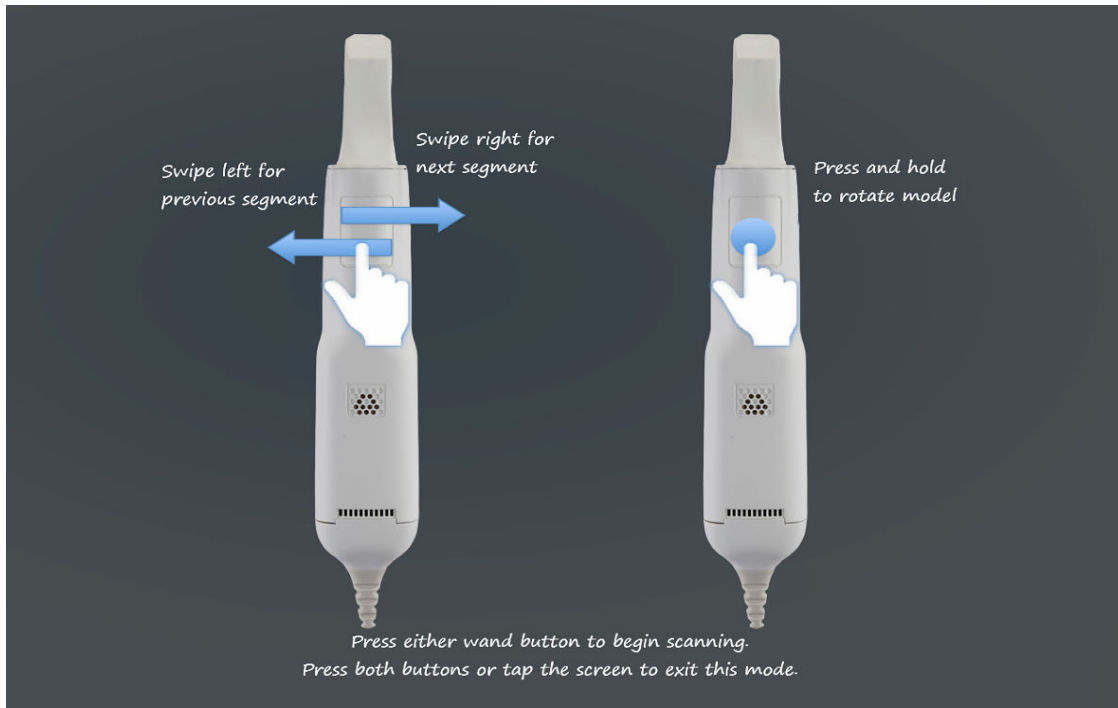


Figure 77: Wand guidance

For a detailed description on how to scan restorative cases, refer to the *iTerO Element Restorative eGuidebook* on the iTerO website: <http://www.itero.com/en/training/literature>

For a detailed description on how to scan orthodontic cases, refer to the *iTerO Element Orthodontic eGuidebook* on the iTerO website: <http://www.itero.com/en/training/literature>

4.5.2 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.

4.5.3 Scan options


In Scan mode, you can select the following options:

- Additional scan feedback, described in section 4.5.3.1
- Toggle color/monochrome, described in section 4.5.3.2

- Edit the scan:
 - Delete a segment, described in section 9.5.1
 - Delete a selection, described in section 9.5.2
 - Fill in missing anatomy, described in section 9.5.3
 - Disable A.I cleanup, described in section 9.5.4

4.5.3.1 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.

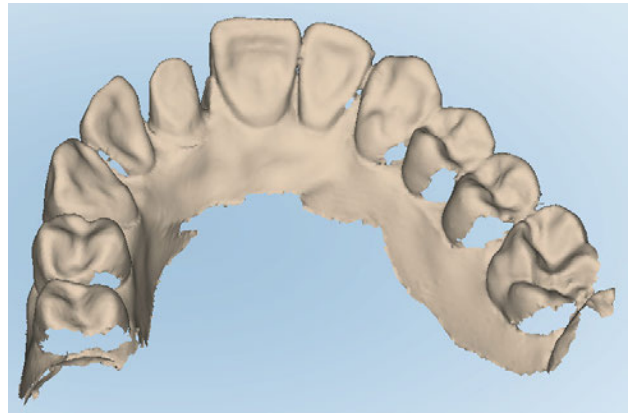
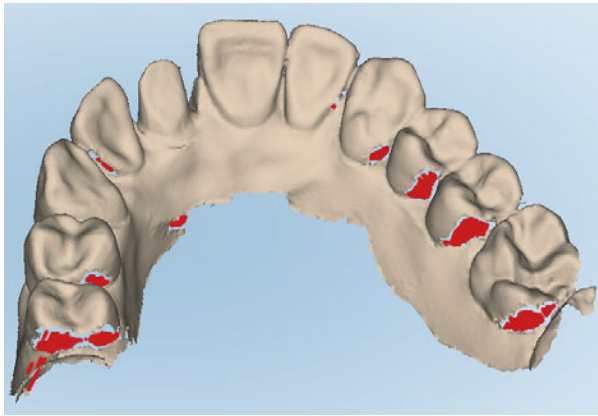


Figure 78: Areas with missing anatomy shown with and without additional scan feedback – monochrome

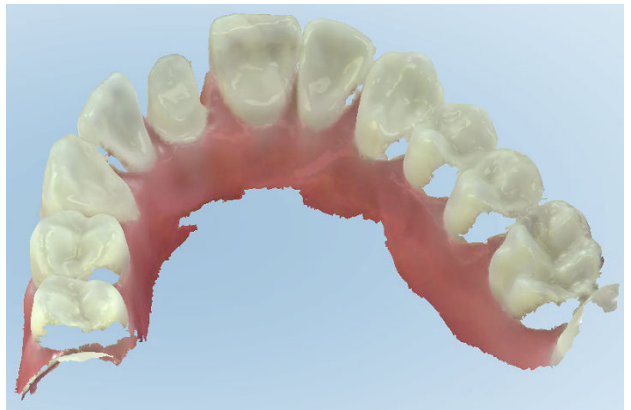
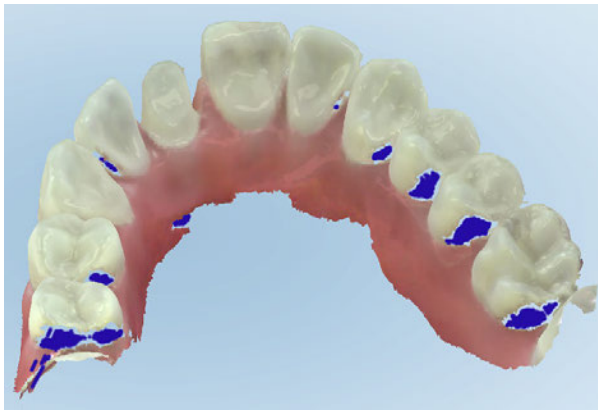




Figure 79: Areas with missing anatomy shown with and without additional scan feedback – color mode

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

4.5.3.2 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.

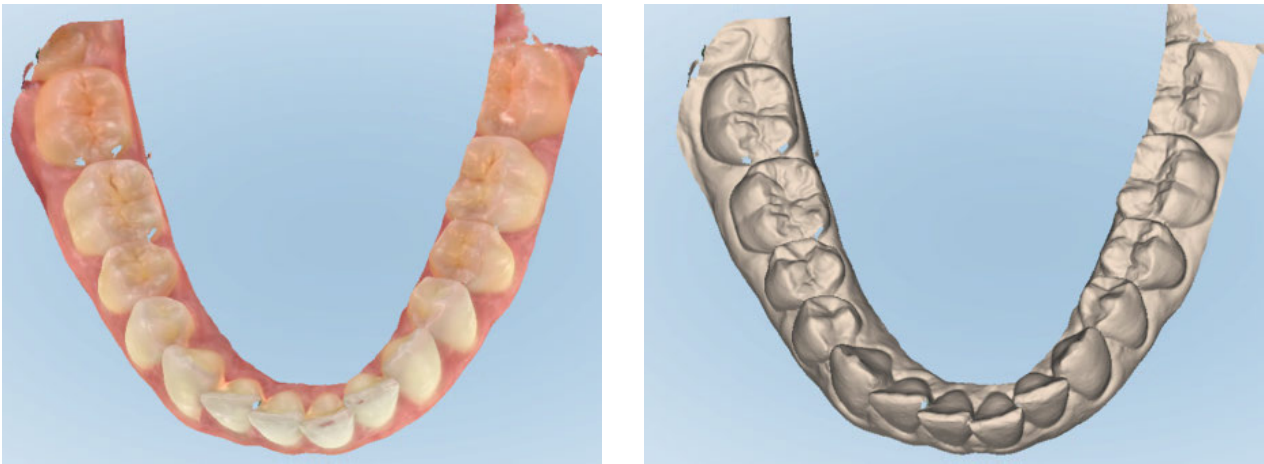



Figure 80: Model displayed in color and monochrome mode

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

4.5.3.3 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.

Note: Before moving to the next segment, press either of the wand buttons to stop the wand from scanning.

You can move to the next segment by:

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

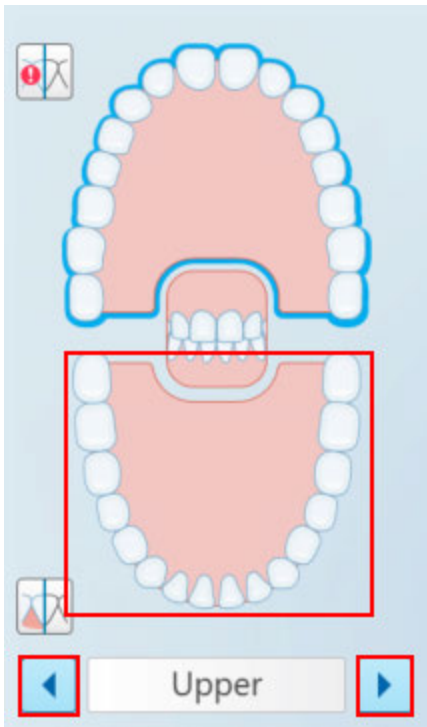


Figure 81: Tap the opposite arch or tap the arrows to select it

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

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

4.5.4 Editing a scan

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

- Delete Segment tool, described in section 9.5.1
- Delete Selection tool, described in section 9.5.2
- Fill tool, described in section 9.5.3
- Disable A.I. Cleanup tool, described in section 9.5.4

The editing tools are accessed by pressing on the screen.

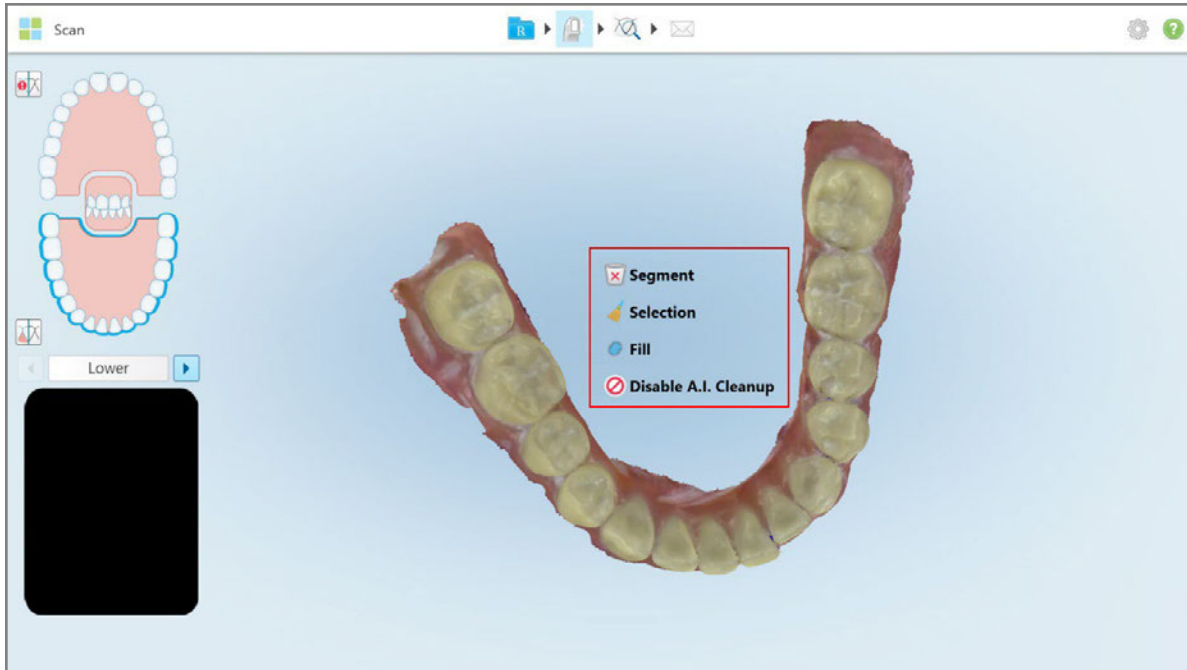



Figure 82: Editing tools


4.6 Viewing the scan

After scanning the patient, tap  to move to View mode to inspect the model and ensure that sufficient occlusal and buccal anatomy have 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 4.6.1.

While viewing the scan, you can:

- Delete selected areas of a scan, as described in section 9.6
- Trim excess tissues from the scan, as described in 9.8
- 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 9.9
- Capture a screenshot of the model, as described in section 9.11

After you have reviewed the scan, tap  on the toolbar to send the scan to the lab or to storage, as described in section 4.7.

4.6.1 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 are 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 is 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 may be warned that the case may be returned from the lab if you do not fix the issues.

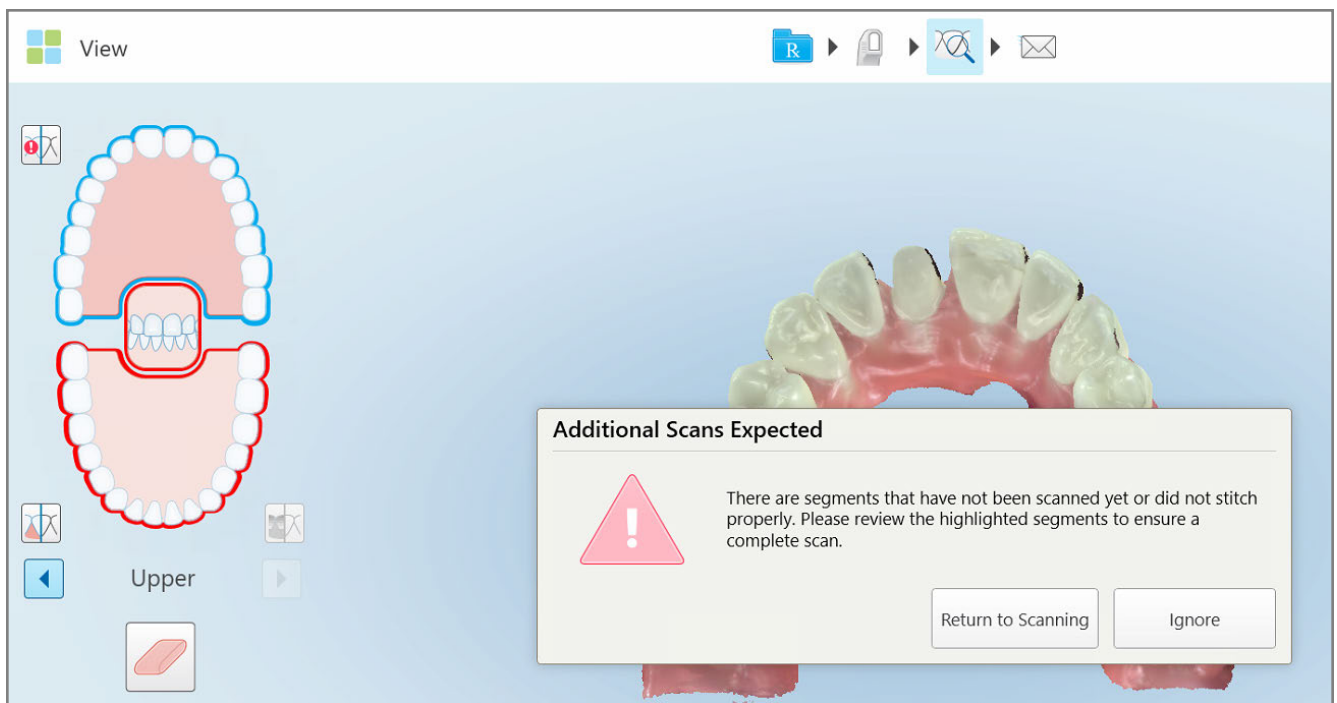



Figure 83: Missing scan message and missing segments highlighted in red

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.

4.6.2 Using the scan timer

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

To view the scan time:

1. On the toolbar, tap the  button.

The scan time is displayed.

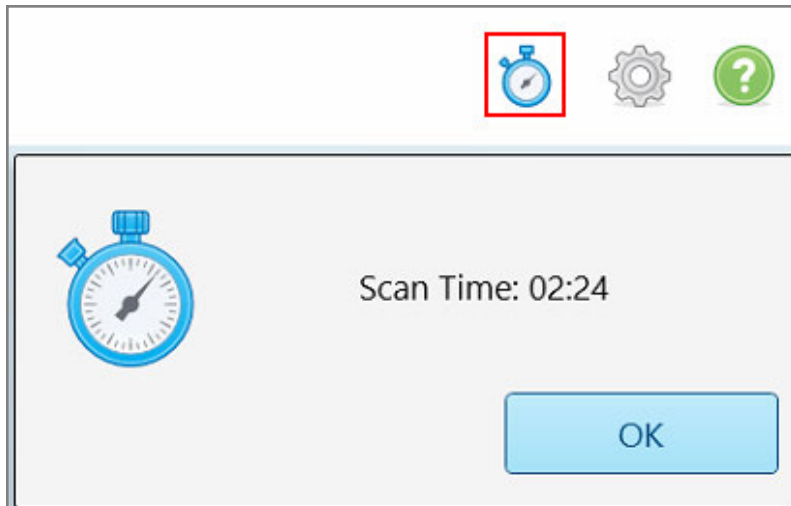



Figure 84: Scan timer button on the toolbar and scan time

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

4.7 Sending the scan

After you have scanned the patient and reviewed 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 85: 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.

4.8 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.

Past Orders						Search
ID	Patient Name	Chart Number	Scan Date	Case Type	Status	
34047499	[REDACTED]	123	07/19/2020	iCast	Ortho Modeling	
						View Rx Viewer
34046655	[REDACTED]		07/15/2020	iCast	Ortho Modeling	
34046475	[REDACTED]		07/14/2020	Invisalign	Completed	
34028466	[REDACTED]		05/13/2020	Restorative	Completed	
34028462	[REDACTED]		05/13/2020	Restorative	Completed	

Figure 86: Viewer option in the Past Orders pane in the Orders page

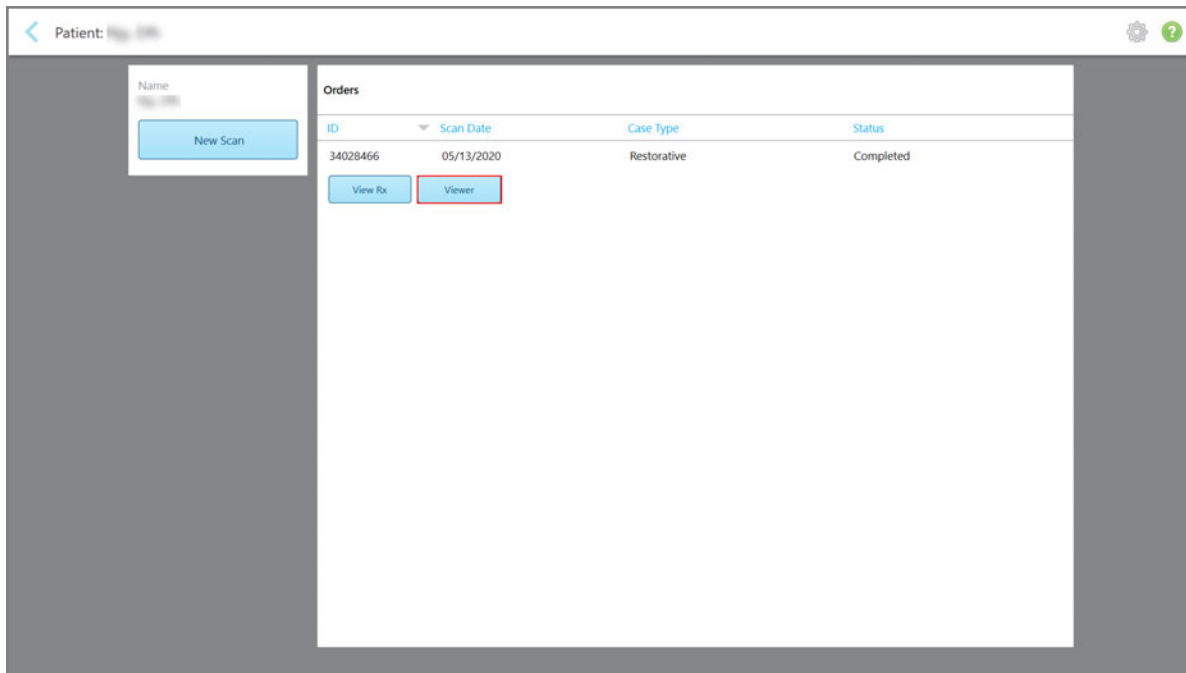
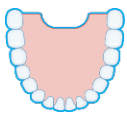


Figure 87: Viewer option in patient's profile page

In the Viewer, you can tap the following to:



Show/hide the upper jaw



Show/hide the lower jaw



Show both jaws



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



Figure 88: 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 89: 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.

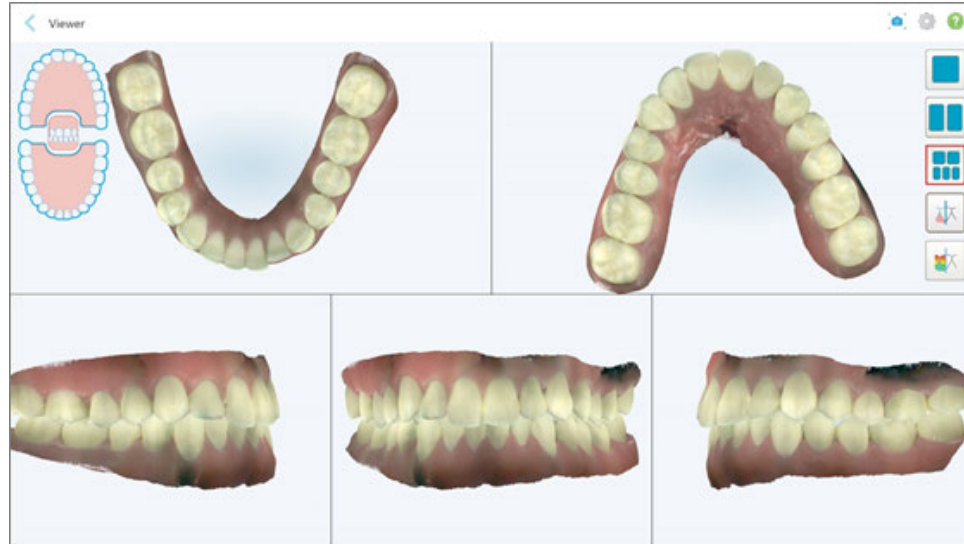


Figure 90: Model in a 5-window view

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. This will be enabled in the Viewer only after the modeling phase.

Relevant for Restorative case types only.



Toggle between viewing the model in color or in monochrome.



Show/hide the occlusal clearance between the opposing teeth, as described in section 9.7.

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 appear in color on the model and the tools are displayed in color, indicating that they are active.

4.9 Removing the wand sleeve

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.

To remove the wand sleeve:

1. Once the scan is complete, or if the scan has been interrupted, press lightly on the center of the sleeve, pull the sleeve slowly off the wand, and discard.



Figure 91: Removing a wand sleeve



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

CAUTION: OPTICAL SURFACE!

DO NOT touch the optical surface of the wand. Contact may cause damage. If additional cleaning, besides that listed in section 10.2.2 is necessary, use the anti-static cloth found inside the sleeve box. For more information, refer to the instructions in the box.



Figure 92: 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.

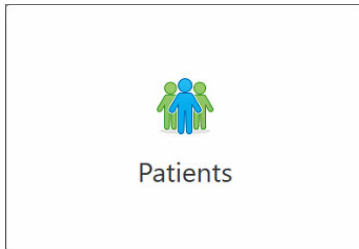
Note: If the scanner will not be used immediately after cleaning and disinfection, attach the blue protective sleeve.



Figure 93: Gently slide the new sleeve into place

5 Working with patients

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



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

Patient Name	Chart Number	Last Scan Date
John Doe		06/30/2019
Jessica Smith		06/24/2019
Michael Jones	1	06/10/2019
Alice Brown		06/10/2019
David White		06/10/2019
Christopher Lee		06/05/2019
Andrew Davis		05/29/2019
Kimberly Wilson		05/15/2019
James Miller		05/06/2019
Michelle Garcia		04/23/2019
Matthew Rodriguez	2019011801	03/18/2019
Stephanie Taylor		03/10/2019
Eric Anderson		02/21/2019
Michelle Green		01/14/2019
Michelle Green		01/14/2019
Michelle Green		01/14/2019
Michelle Green		01/14/2019
Michelle Green		01/14/2019


Figure 94: 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 field and then tap the search button .

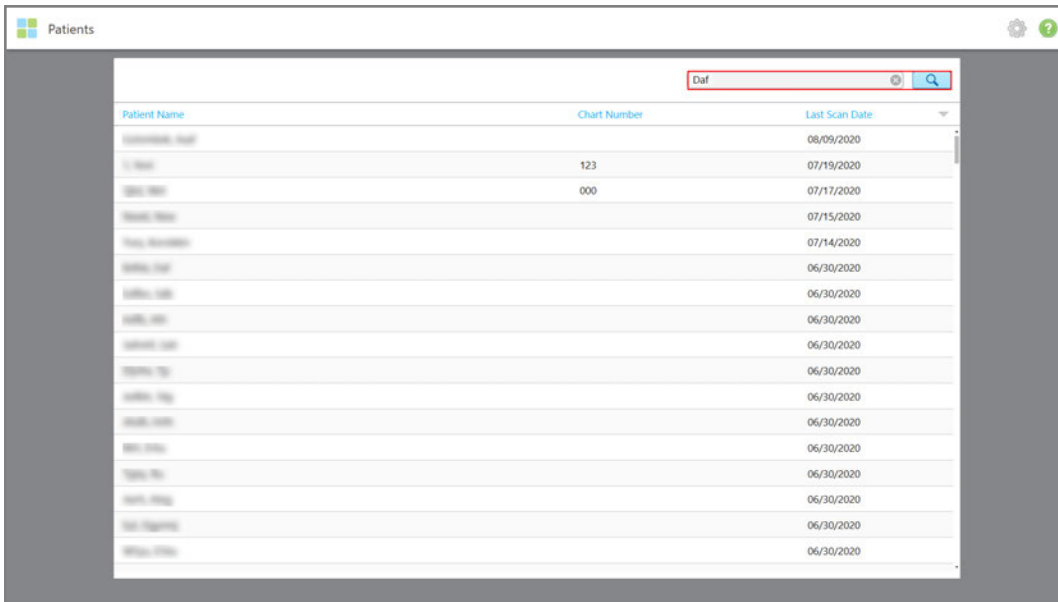


Figure 95: Searching for a patient

The patients that match the search criteria are displayed.

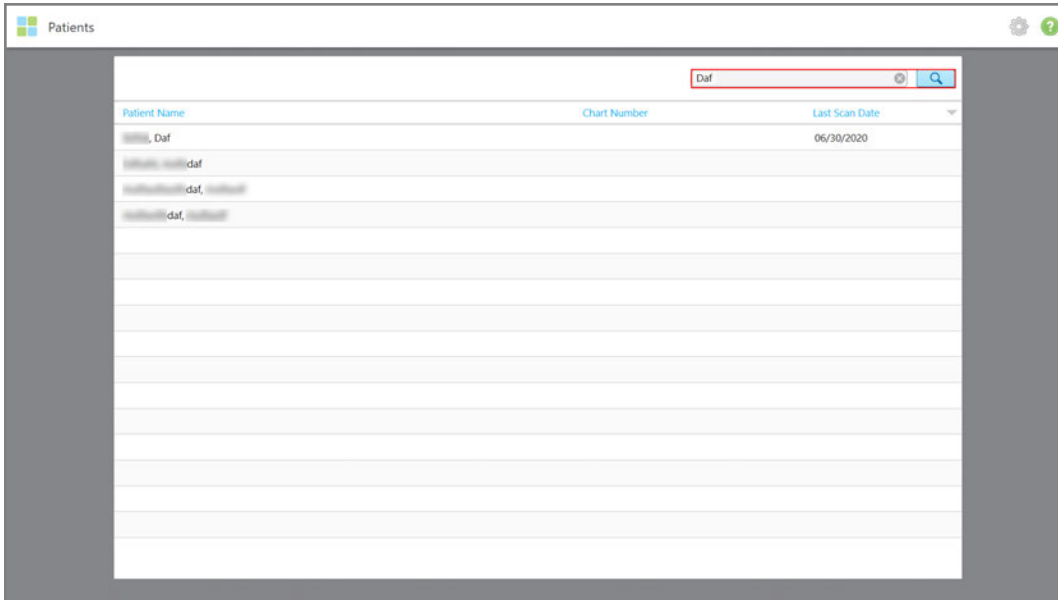


Figure 96: Patients matching the search criteria are displayed

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 patients, their chart number, and the date of their last scan.

2. Select the required patient in the list.

The selected patient's profile page is displayed:

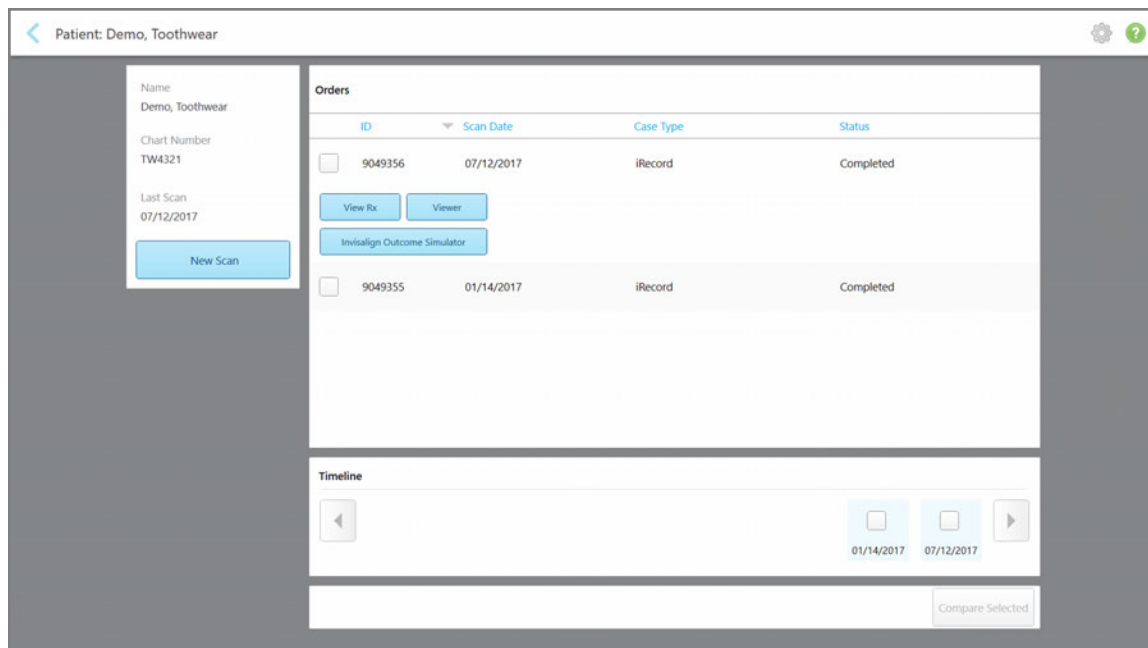


Figure 97: Patient's profile page

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 and edit the patient's details, described in section 5.4
- View the patient's previous scans in the Viewer, described in section 5.5
- Compare 2 previous scans using iTero TimeLapse technology, described in section 9.1
- 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 opens 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**.

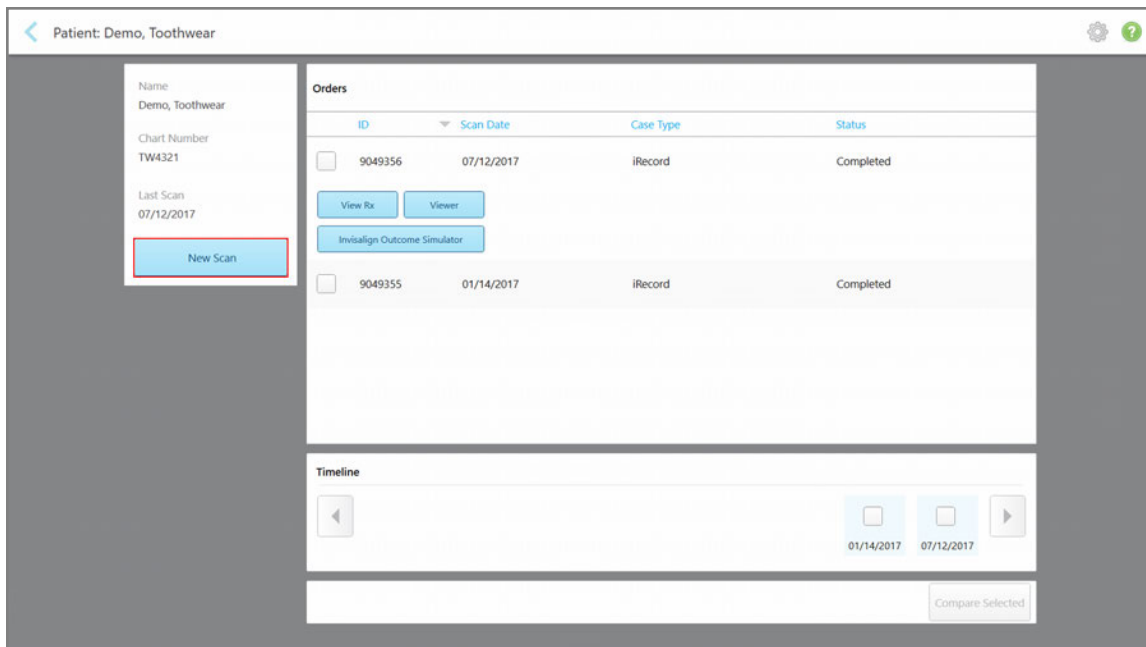
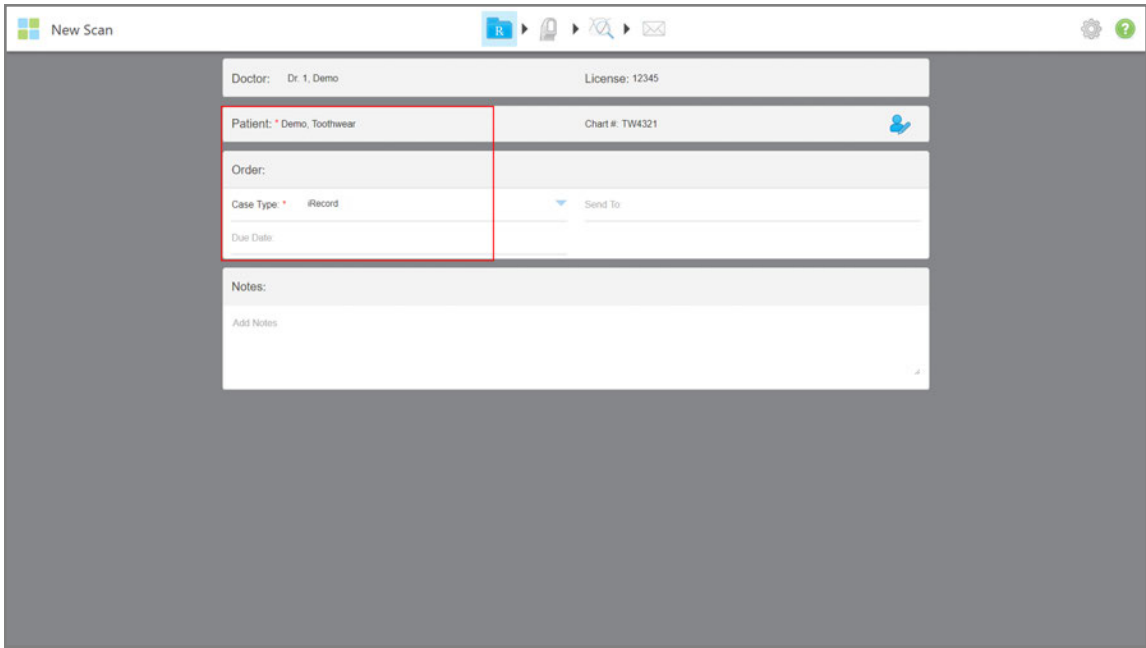


Figure 98: Patient's profile page – New Scan option

The *New Scan* window is displayed, with the patients details already filled in.



The screenshot shows the 'New Scan' window with the following details:

- Doctor: Dr. 1, Demo
- License: 12345
- Patient: Demo, Toothwear (highlighted with a red box)
- Chart #: TW4321
- Order:
- Case Type: #Record
- Send To:
- Due Date:
- Notes: Add Notes

Figure 99: 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 tap **View Rx**.

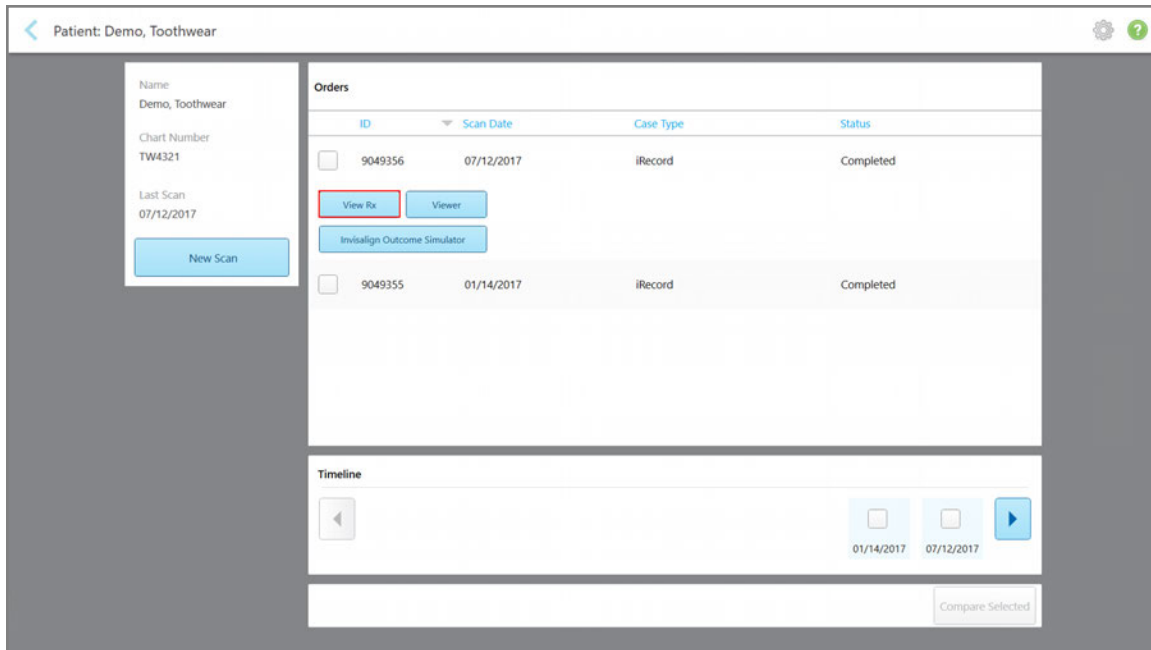


Figure 100: Patient's profile page – View Rx option

The *Rx Details* window is displayed.

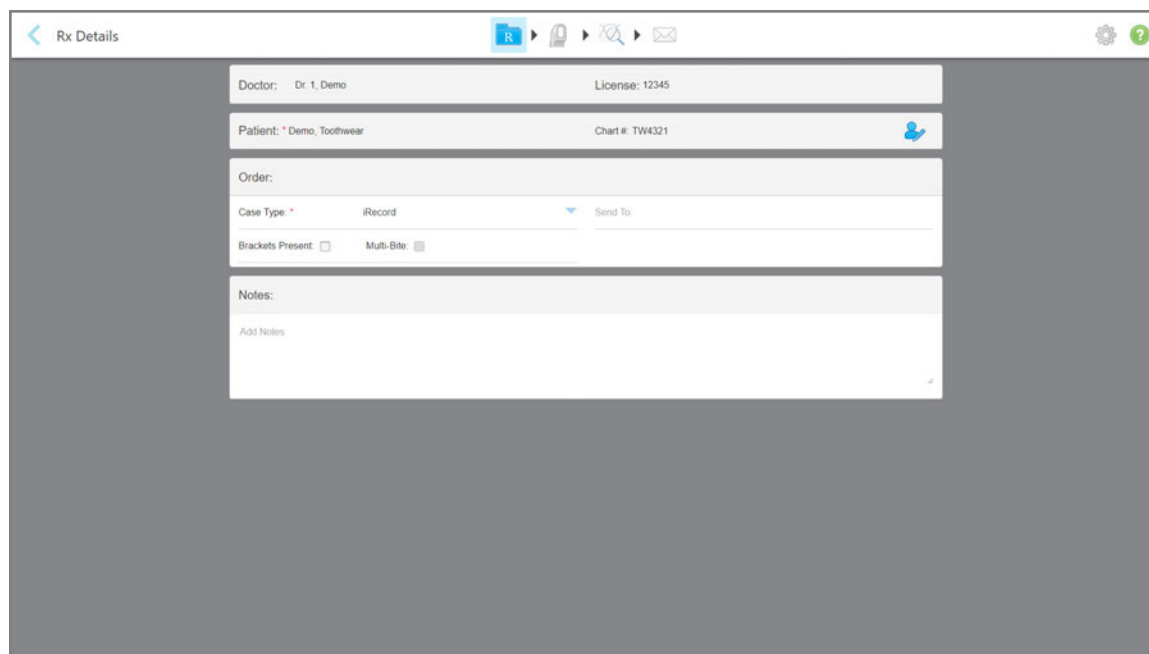



Figure 101: Rx Details window

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 tap **Viewer**.

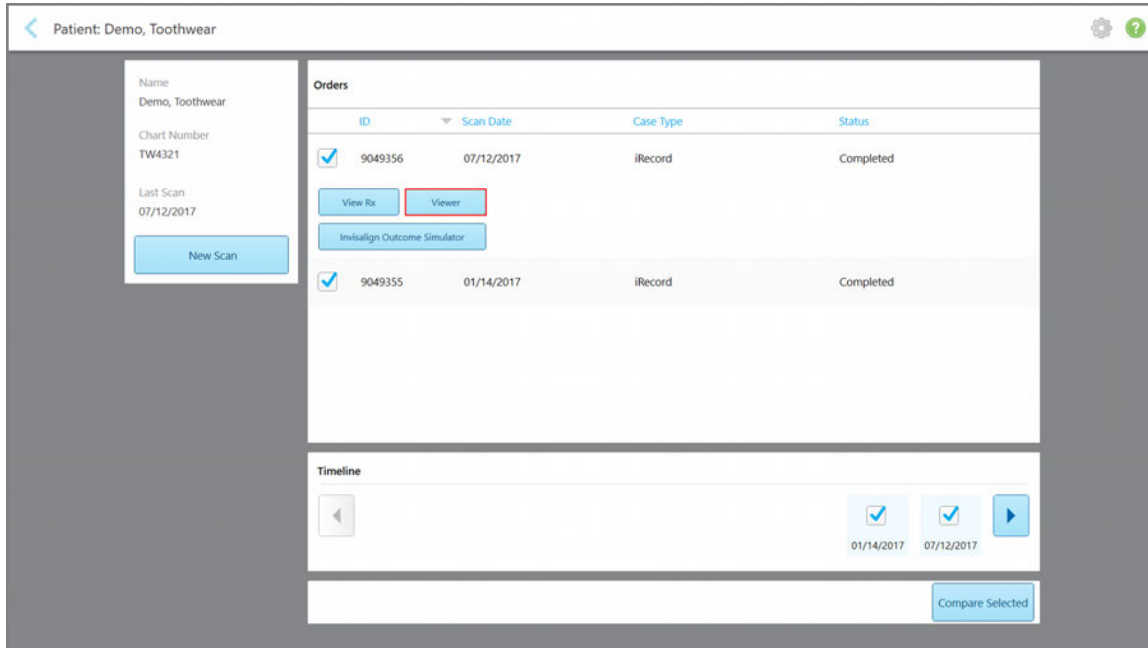


Figure 102: Patient's profile page – Viewer option

The scan is displayed in the Viewer.

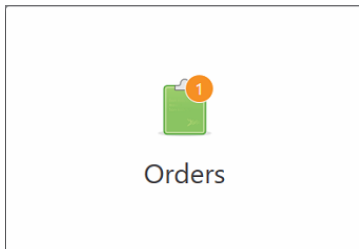


Figure 103: Scan displayed in the Viewer

For more information on working with the Viewer, see section 4.8.

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.



If an order has been returned from the lab, the button is displayed in red, with an alarm icon badge, as described in section 6.1

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, chart number, 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
- **Returned:** The order was rejected by the lab and has been sent back for rescanning or other adjustments, as described in section 1.1
- **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

The screenshot shows the 'Orders' page in the iTerro application. It features two main sections: 'In Progress' and 'Past Orders'. The 'In Progress' section contains a table with columns for ID, Patient Name, Chart Number, Scan Date, Case Type, and Status. The 'Past Orders' section also has a similar table but includes a search bar at the top right.

In Progress					
ID	Patient Name	Chart Number	Scan Date	Case Type	Status
				iCast	Rx Created
				Restorative	Rx Created
				Restorative	Rx Created
				Restorative	Rx Created
				Restorative	Rx Created
				Invisalign	Rx Created
				Invisalign	Rx Created
				Invisalign	Rx Created

Past Orders					
ID	Patient Name	Chart Number	Scan Date	Case Type	Status
34047499		123	07/19/2020	iCast	Ortho Modeling
34046655			07/15/2020	iCast	Ortho Modeling
34046475			07/14/2020	Invisalign	Completed
34028466			05/13/2020	Restorative	Completed
34028462			05/13/2020	Restorative	Completed
34028460			05/13/2020	Restorative	Completed

Figure 104: 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:

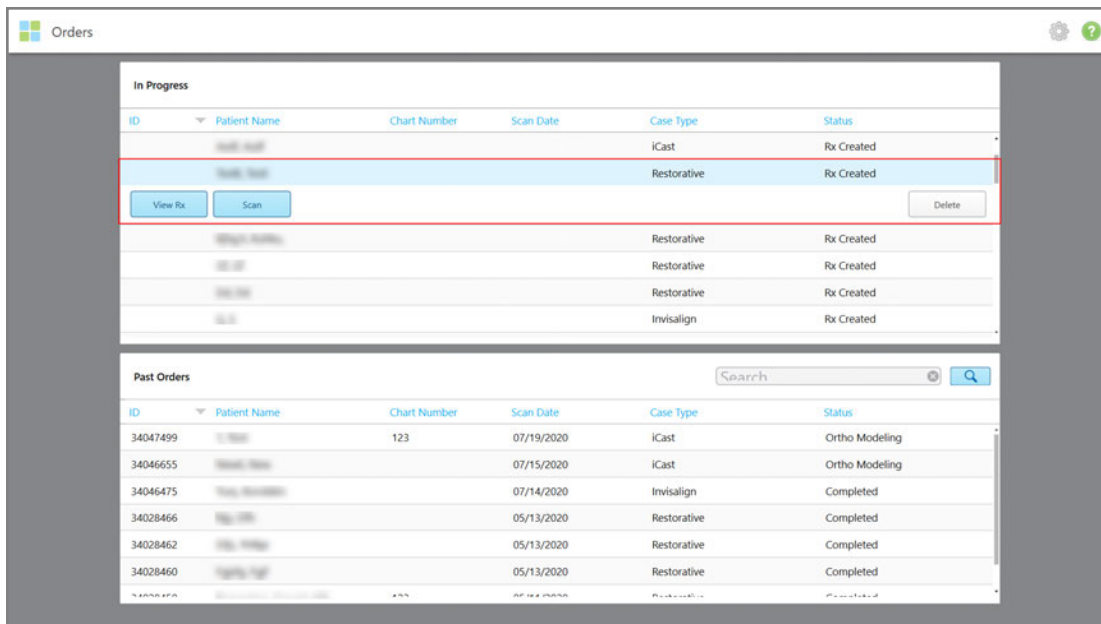


Figure 105: In Progress pane – options

- **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:

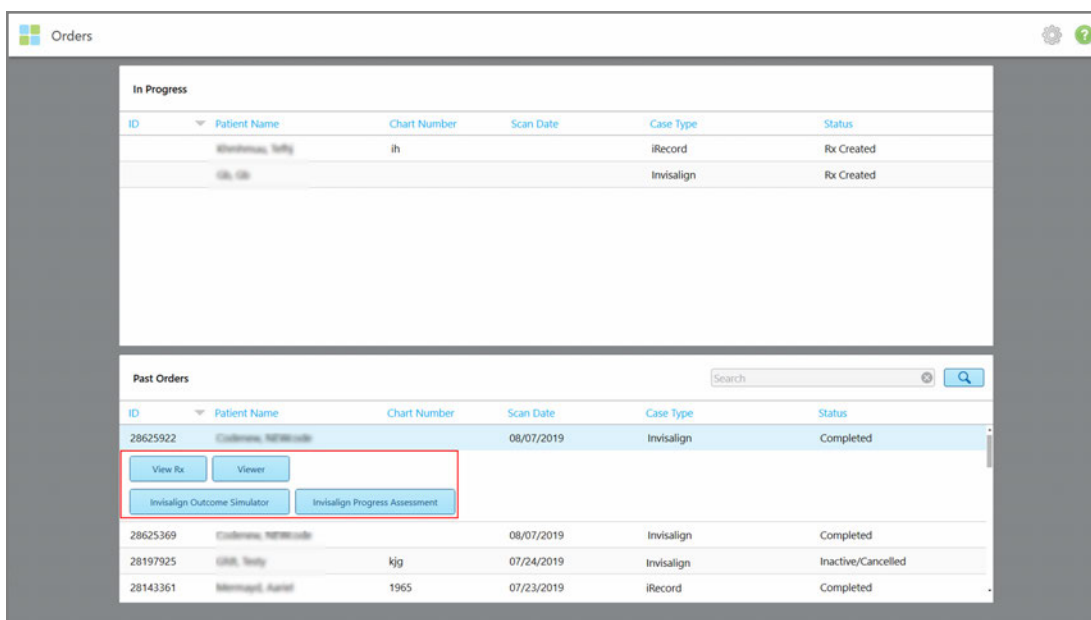


Figure 106: Past Orders pane – options

- **View Rx:** Opens the *Rx Details* window, enabling you to view the prescription for this order.
- **Viewer:** Opens the *Viewer* window, enabling you to view and manipulate the model. For more information on working with the Viewer, see section 4.8.
- **Add Rx:** Opens the *New Scan* window and enables you to add a prescription for this order.
Note: This is applicable for Orthodontic orders only, and available for up to 21 days after the scan.
- Invisalign users can also select the following Invisalign features:
 - Invisalign Go Outcome Simulator
 - Invisalign Go Case Assessment
 - Invisalign Outcome Simulator
 - Invisalign Progress Assessment

6.1 Working with returned orders

If the lab returns an order, for example, if the scan is incomplete and needs to be rescanned, or if there are missing scans, bite issues, or if the margin line is not clear, the **Orders** button is highlighted in red with an alarm icon badge.

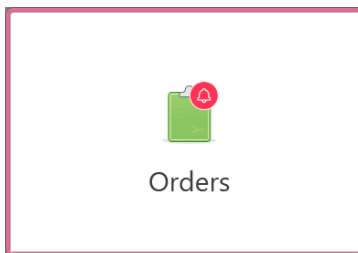
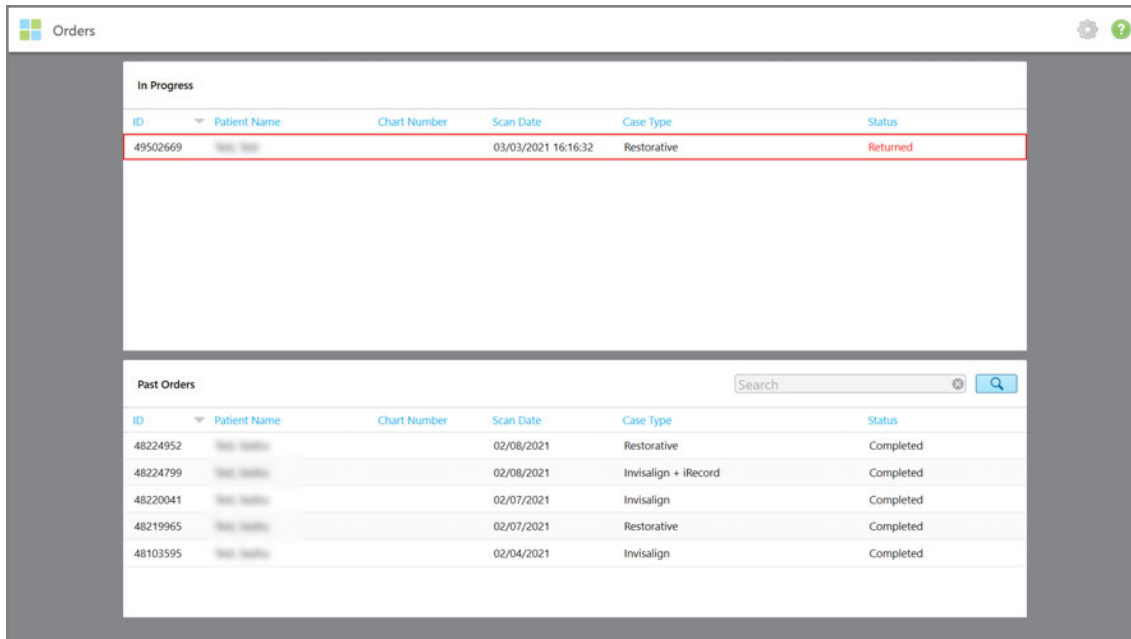


Figure 107: Orders button notifying a returned order

The returned order is displayed at the top of the **In Progress** pane, with the status **Returned**, in red.



Orders						
In Progress						
ID	Patient Name	Chart Number	Scan Date	Case Type	Status	
49502669	[REDACTED]	[REDACTED]	03/03/2021 16:16:32	Restorative	Returned	

Past Orders						
ID	Patient Name	Chart Number	Scan Date	Case Type	Status	
48224952	[REDACTED]	[REDACTED]	02/08/2021	Restorative	Completed	
48224799	[REDACTED]	[REDACTED]	02/08/2021	Invisalign + iRecord	Completed	
48220041	[REDACTED]	[REDACTED]	02/07/2021	Invisalign	Completed	
48219965	[REDACTED]	[REDACTED]	02/07/2021	Restorative	Completed	
48103595	[REDACTED]	[REDACTED]	02/04/2021	Invisalign	Completed	

Figure 108: Returned order in the In Progress pane

To fix a returned case:

1. Open the returned order and fix the scan according to the lab's instruction in the **Notes** area of the Rx.
2. Return the order to the lab.

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.

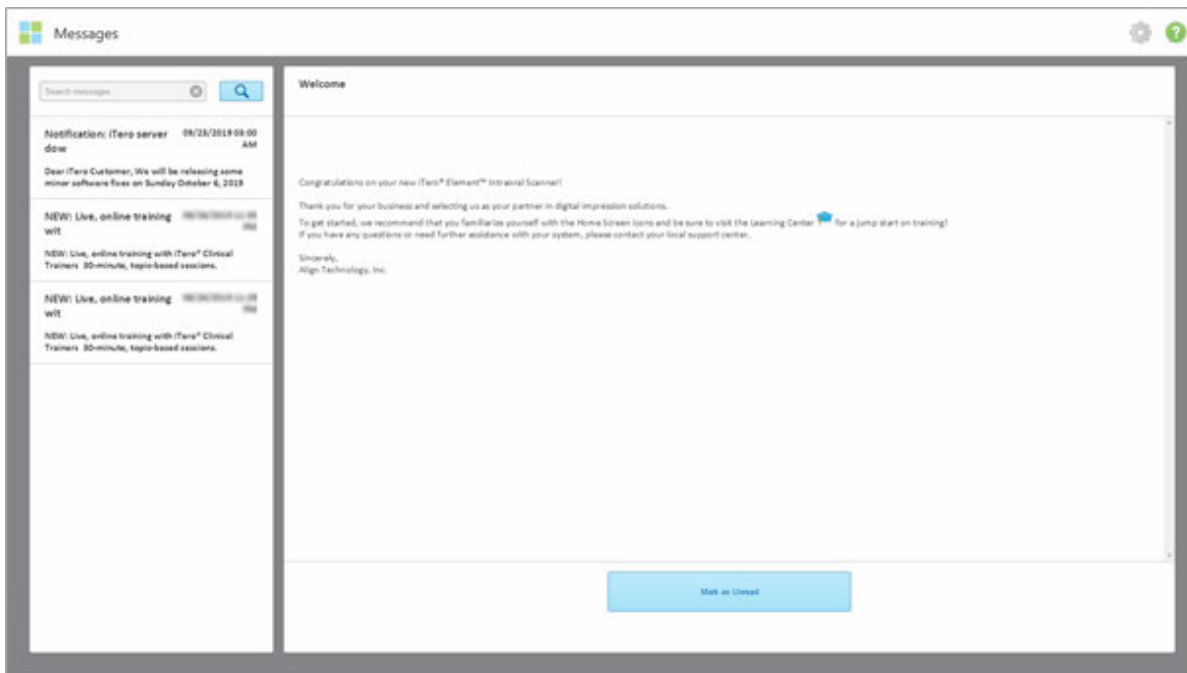
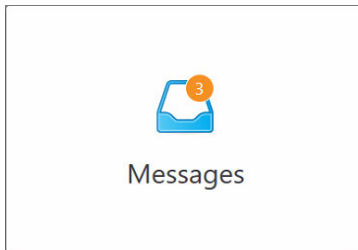


Figure 109: Messages page

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 software. It enables users to carry out administrative tasks such as filling in a new Rx on any supported device, for example, a PC or a tablet, without using valuable scanner time. In addition, it enables viewing 3D models after they have been created by the scanner, and tracking orders.

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

9 iTero scanner features and tools

This section describes the following iTero scanner features and tools:

- Comparing previous scans using iTero TimeLapse technology, described in section 9.1
- Invisalign Go system, described in section 9.2
- Invisalign Outcome Simulator, described in section 9.3
- Invisalign Progress Assessment, described in section 9.4
- Editing tools, described in section 9.5
- Scan tools:
 - Eraser tool, described in section 9.6
 - Occlusal clearance tool, described in section 9.7
 - Edge trimming tool, described in section 9.8
 - Die separation tool, described in section 9.9
 - Margin line tool, described in section 9.10
 - Snapshot tool, described in section 9.11

9.1 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.

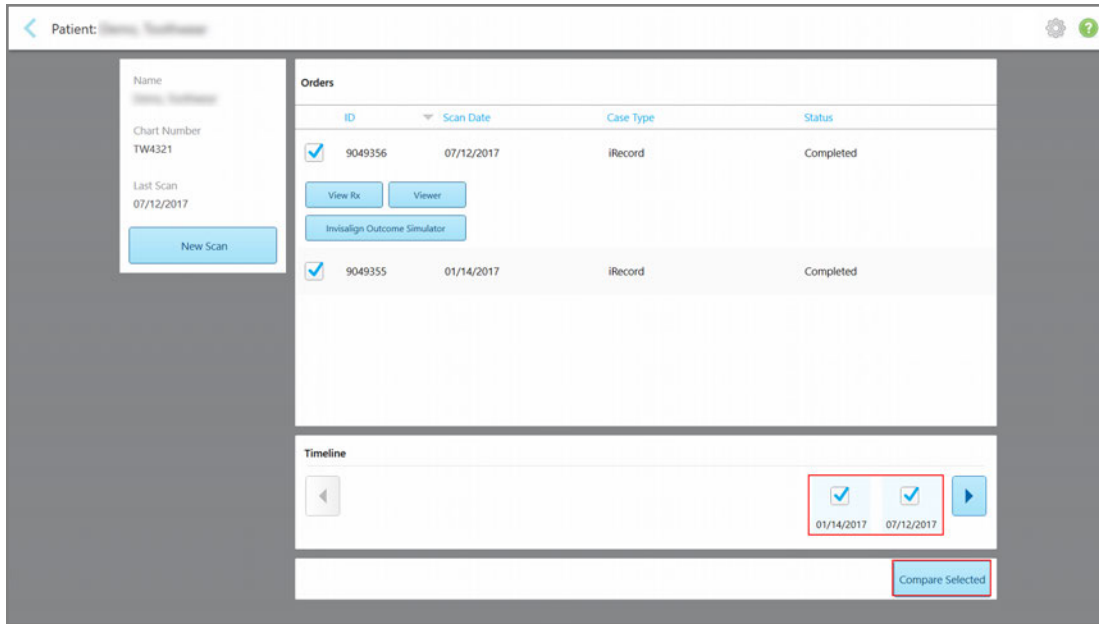


Figure 110: iTero TimeLapse – selecting the scans to compare

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.

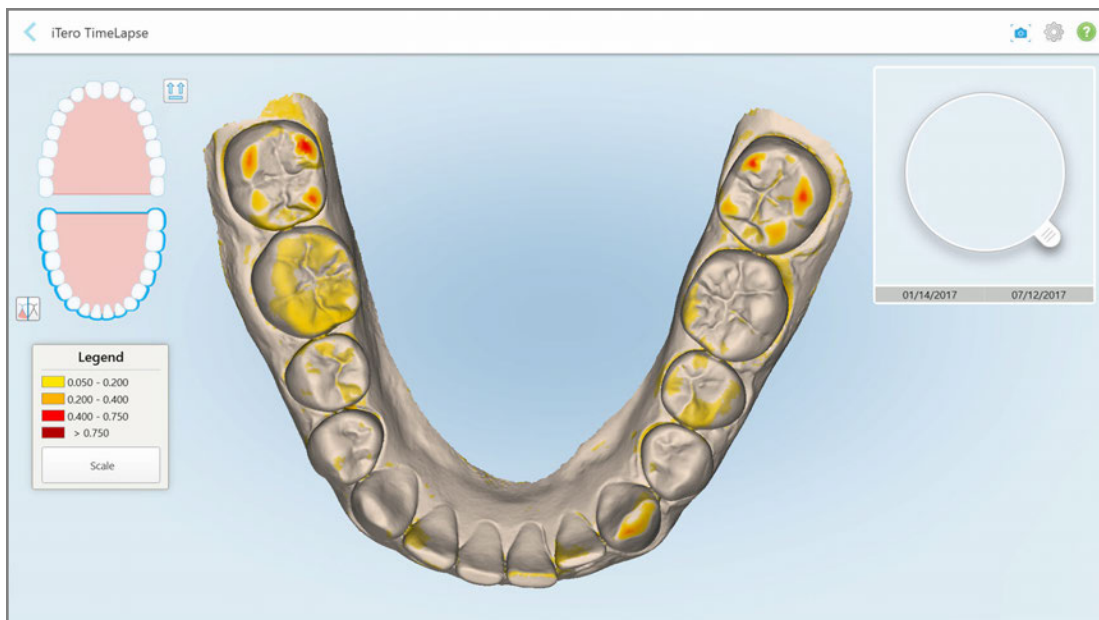



Figure 111: iTero TimeLapse window showing the highlighted changes between the scans

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

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

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.

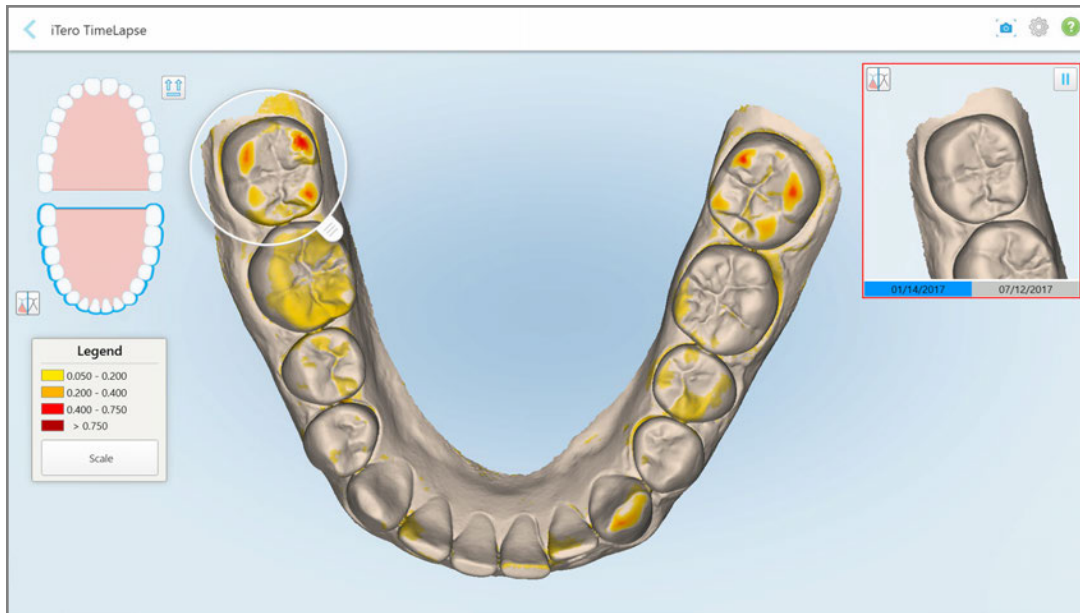


Figure 112: Area of interest from the first scan displayed in the animation window

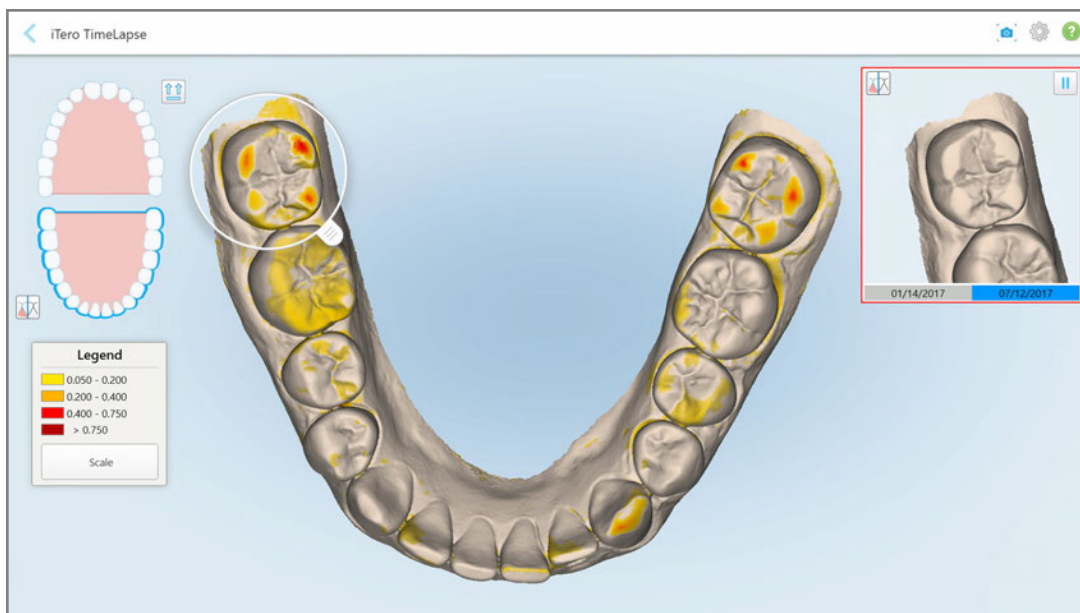


Figure 113: Area of interest from the second scan displayed in the animation window

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, tap **Scale**.

The legend is expanded to display a list of ranges:

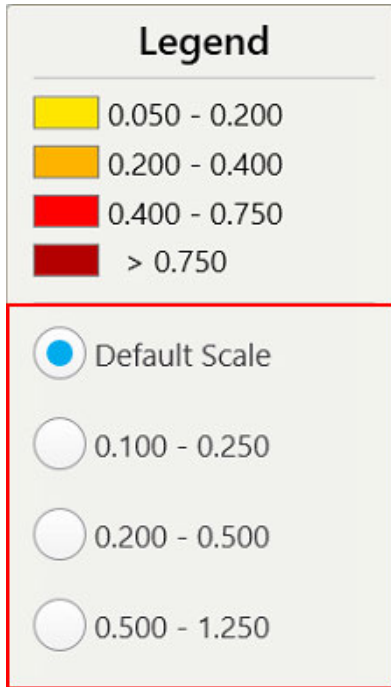



Figure 114: iTerro TimeLapse scale options

- b. Select the required scale.

The changes are displayed according to the new scale.

5. If required, tap the Snapshot tool  to capture a screenshot of the images. For more information, refer to section 9.11.

9.2 Invisalign Go system

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

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

9.3 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 provides additional information for the patient in their decision to accept treatment.

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

9.4 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 115: 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.

9.5 Editing tools

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

- Delete Segment tool, described in section 9.5.1
- Delete Selection tool, described in section 9.5.2
- Fill tool, described in section 9.5.3
- Disable A.I Cleanup tool, described in section 9.5.4

The editing tools are accessed by pressing on the screen.

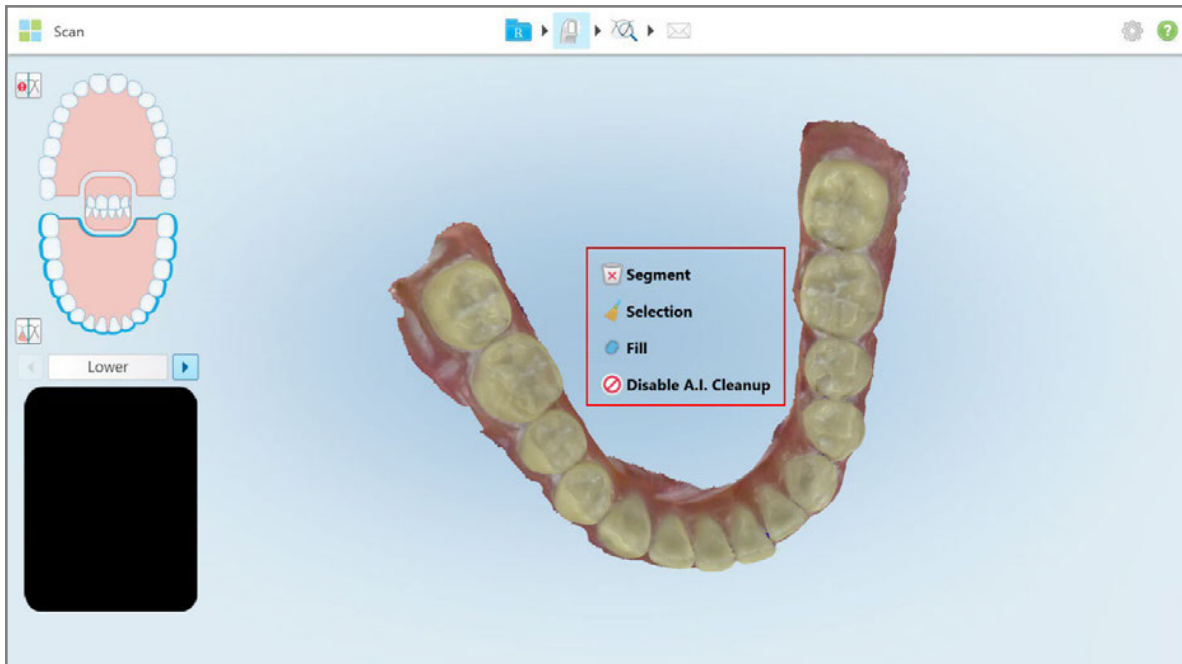


Figure 116: Editing tools

9.5.1 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 .

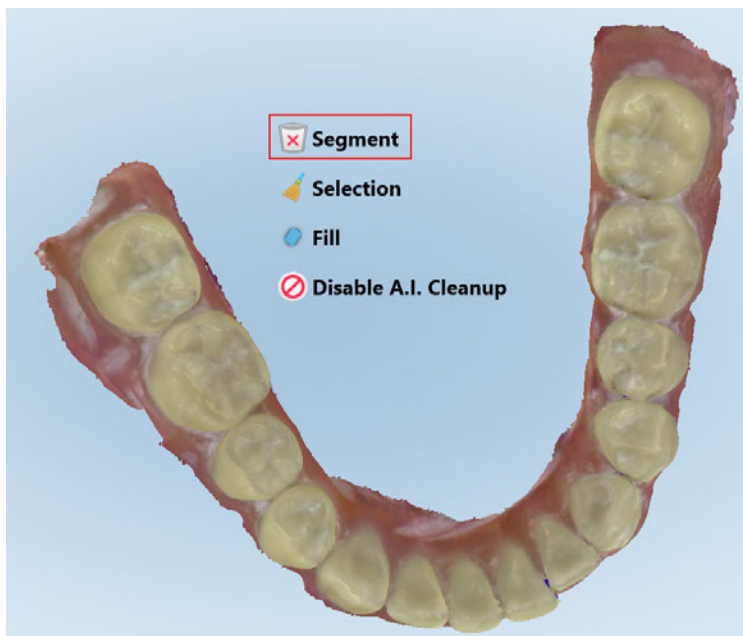



Figure 117: Delete Segment tool

A confirmation message is displayed.


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

The entire scanned segment is deleted.

9.5.2 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 .

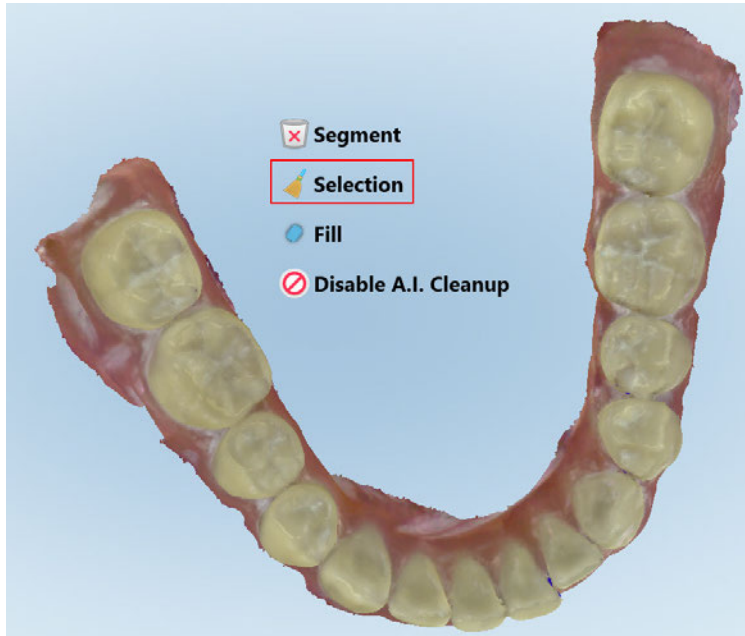


Figure 118: Delete Selection tool

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

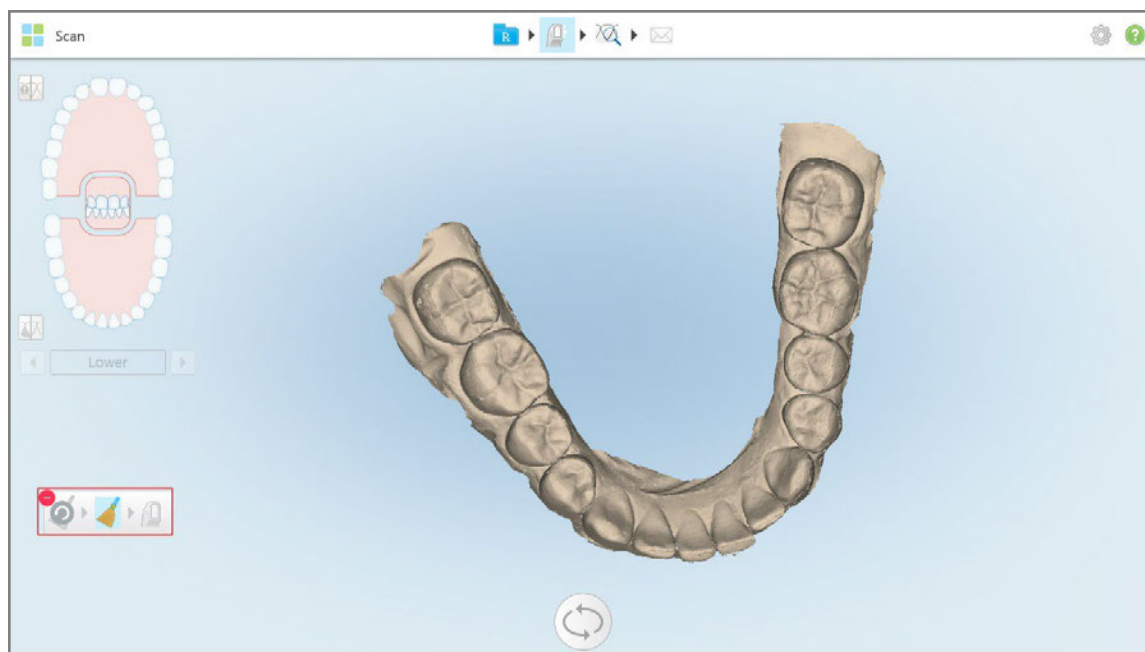


Figure 119: Expanded Delete Selection tool

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

The selection is removed.

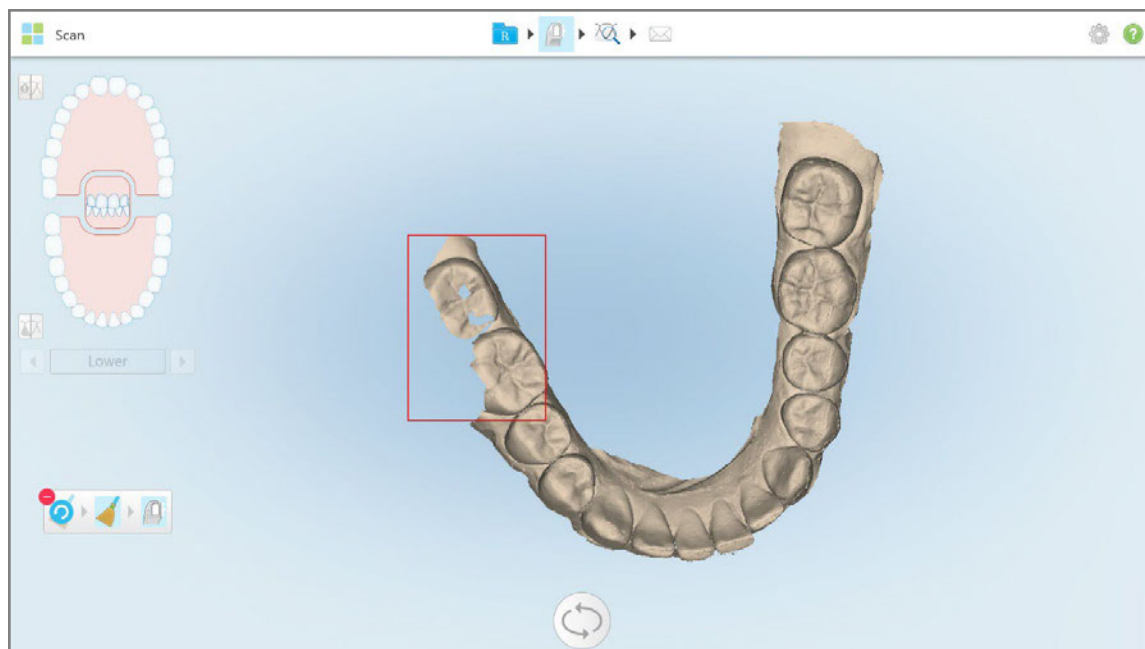





Figure 120: Selected area of the anatomy is deleted


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

9.5.3 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 .

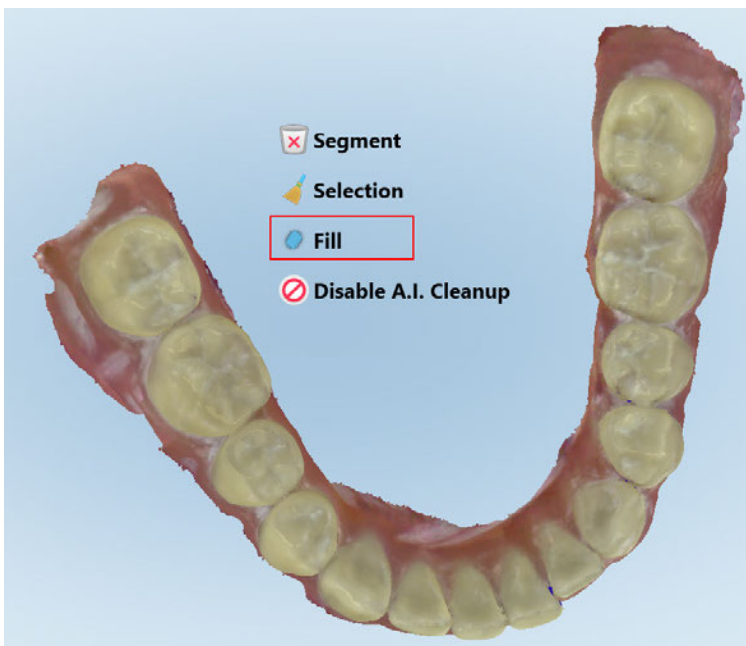


Figure 121: Fill tool

Areas that require scanning are highlighted in red.



Figure 122: Areas that require scanning are highlighted in red – Fill tool

3. Rescan the patient.

In order to prevent over scanning, only the highlighted areas are scanned and the voids are filled.

9.5.4 Disabling A.I. cleanup

By default, excess tissue is removed from around the edges of the 3D model during scanning. If required, you can turn off this functionality for the current case.

Notes:

- This tool is not supported for edentulous gums.
- Disabling the A.I. cleanup is relevant for the current case only. Excess material will be removed by default in the next scan.

To disable the A.I. cleanup:

1. Press the screen to display the editing tools.

2. Tap the **Disable A.I. Cleanup** tool.

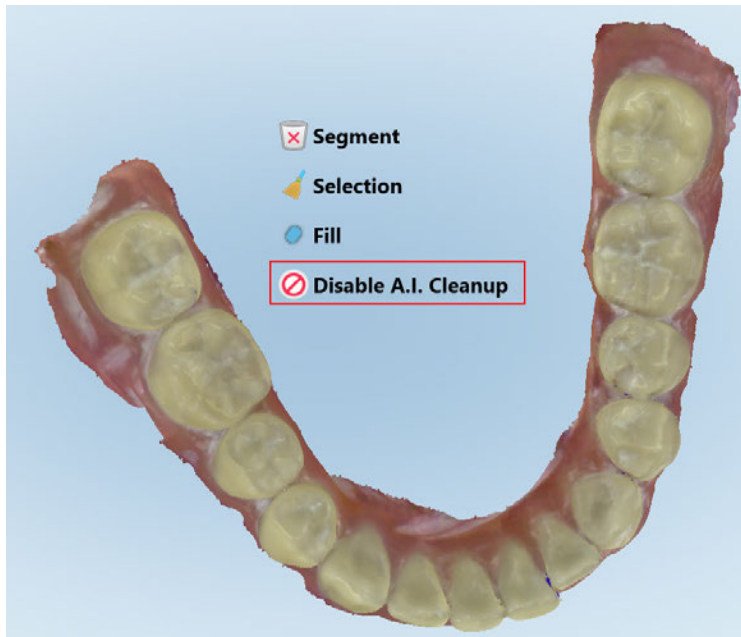


Figure 123: Disable A.I. Cleanup tool

The scan is displayed with the excess material showing.



Figure 124: Scan displayed with excess material showing

3. To return the excess tissue, press the screen to display the editing options and then tap **Enable A.I. Cleanup**.

9.6 Working with the Eraser tool



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

For example:

- You can remove moisture and artifacts, such as blood or saliva, that are covering the margin.
- 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 on the relevant section to be erased, and then tap the Eraser tool

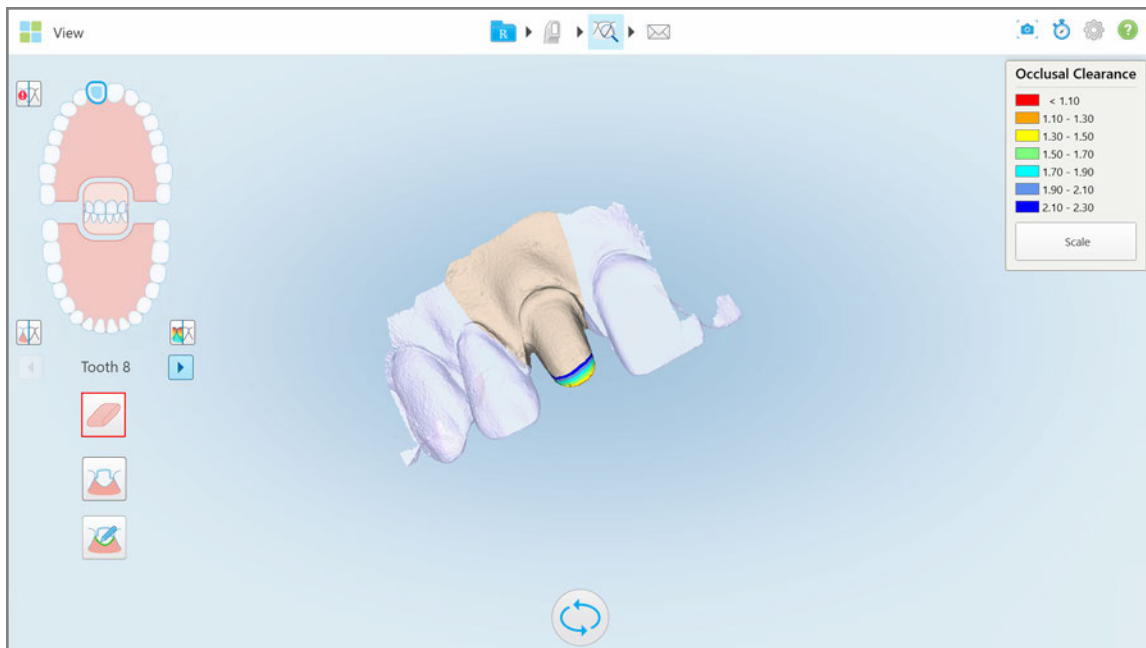


Figure 125: Eraser tool

The Eraser tool expands to show the following options:



Figure 126: Eraser tool options

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

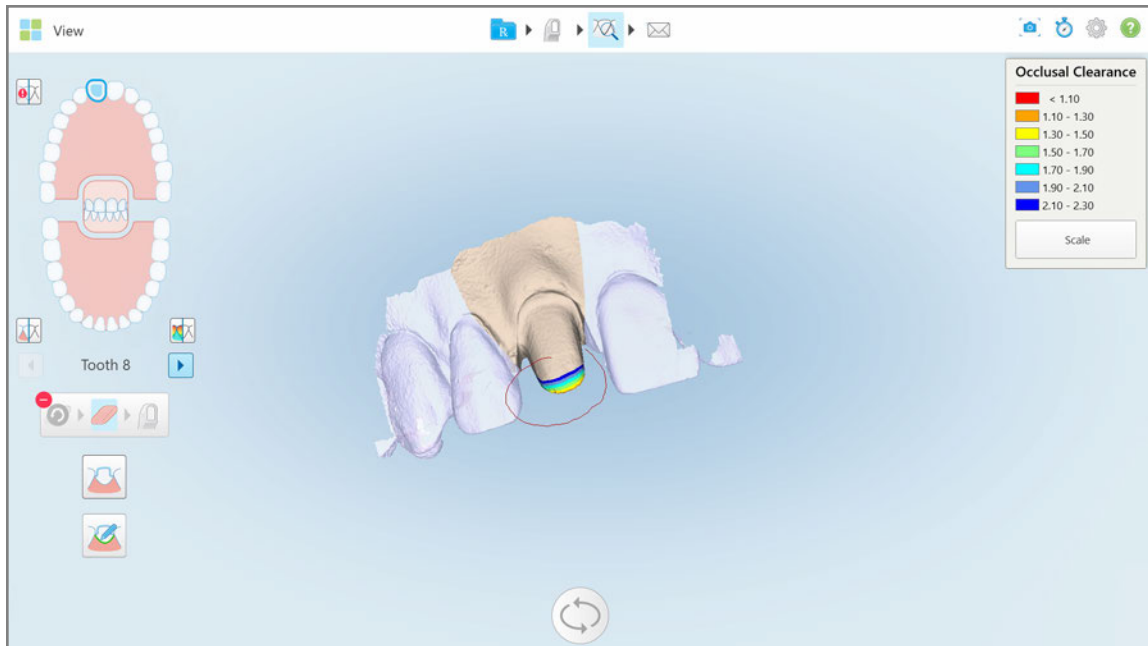



Figure 127: Mark the area to be modified

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

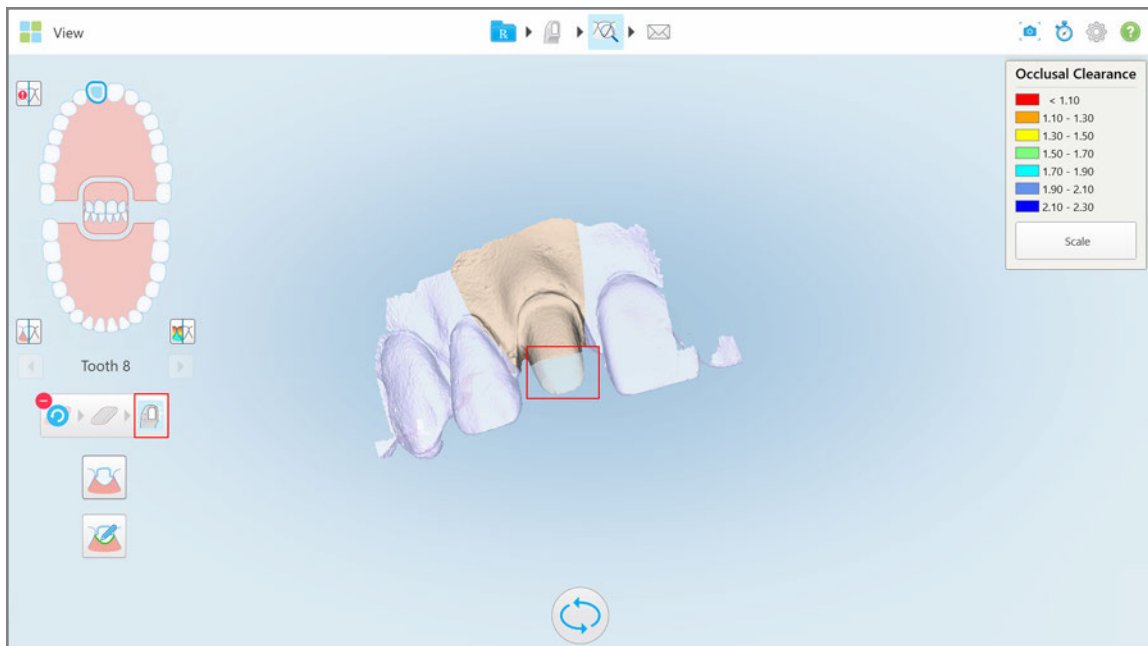




Figure 128: Selected area removed and scan tool enabled

- If required, tap  to undo the deletion.
- 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.

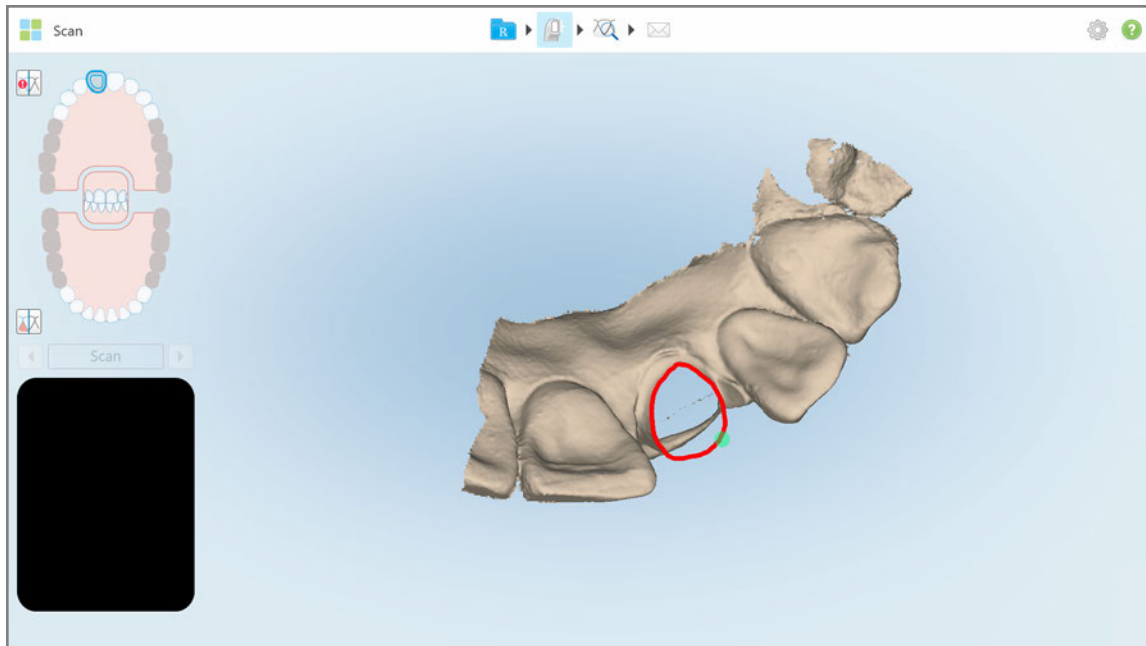




Figure 129: Deleted area marked in red

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


9.7 Working with the Occlusal Clearance tool

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

The Occlusal Clearance tool can be accessed while in View mode and from the Viewer.

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

To display the occlusal clearance while in View mode:

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

The occlusal clearance between the opposing teeth is displayed.

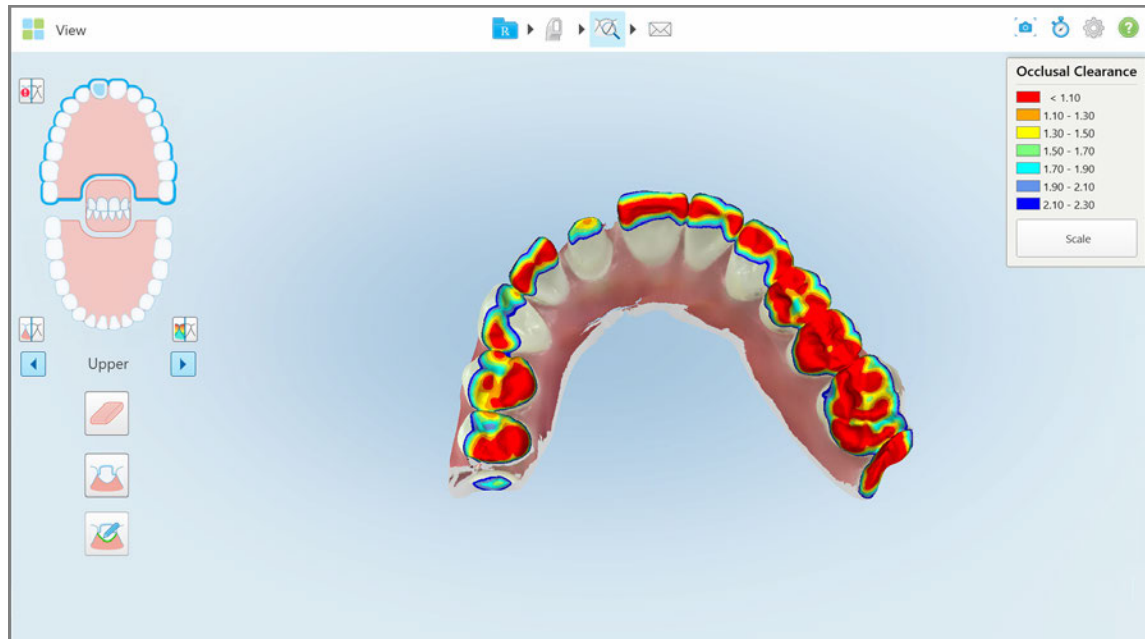


Figure 130: Occlusal clearance between the opposing teeth

2. If necessary, reduce the prepped tooth and rescan the area, as described in section 9.6, above.
3. If required, you can change the occlusal values displayed on the opposing teeth.

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

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

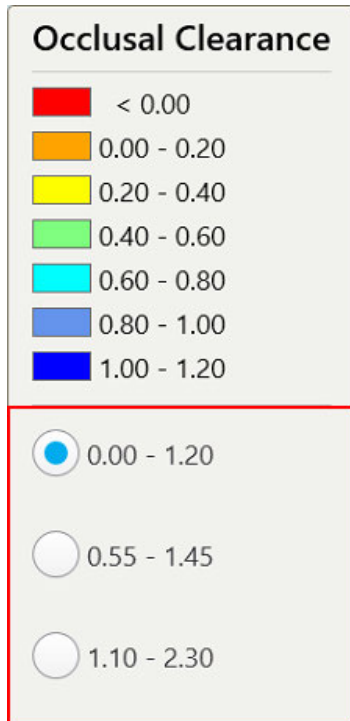



Figure 131: Occlusal Clearance range options

- b. Select the required scale.
- c. The occlusal clearance is displayed according to the new scale.
4. If required, tap  to take a screenshot of the occlusal clearance. For more information on capturing screenshots and adding annotations, see section 9.11.

To display the occlusal clearance from the Viewer:

1. In the Viewer, tap .
2. Select the arch for which to display the occlusal clearance.

The clearance between the opposing teeth is displayed, as well as a legend displaying the scale.

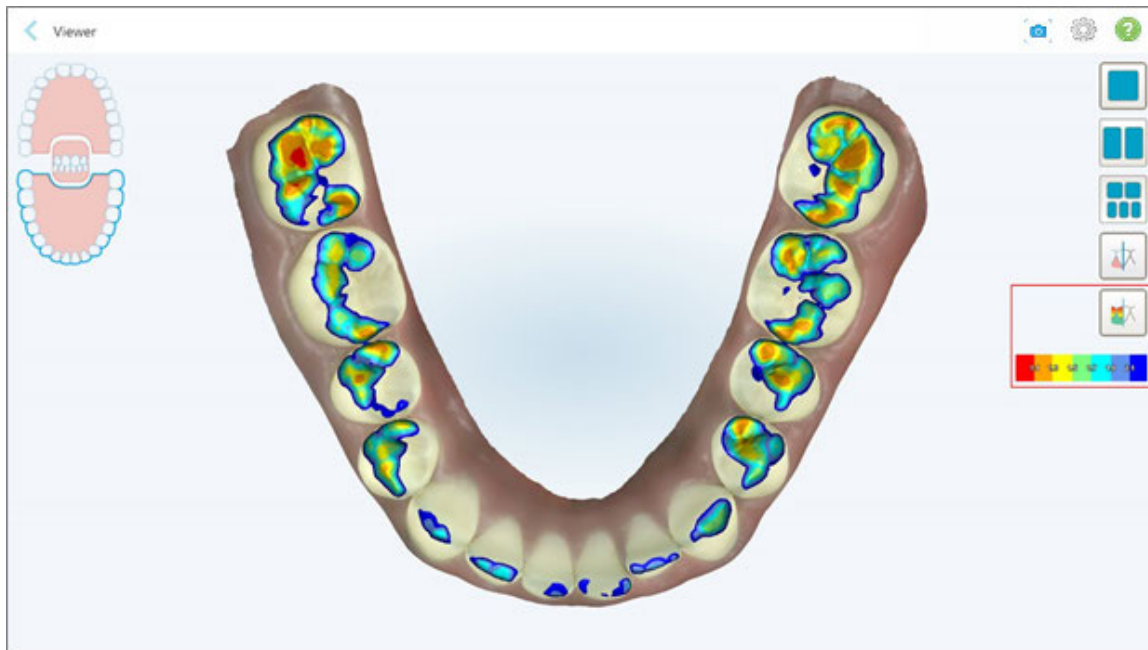





Figure 132: Occlusal Clearance tool and legend displayed in the Viewer

3. If required, tap  to take a screenshot of the occlusal clearance. For more information on capturing screenshots and adding annotations, see section 9.11.

9.8 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 .

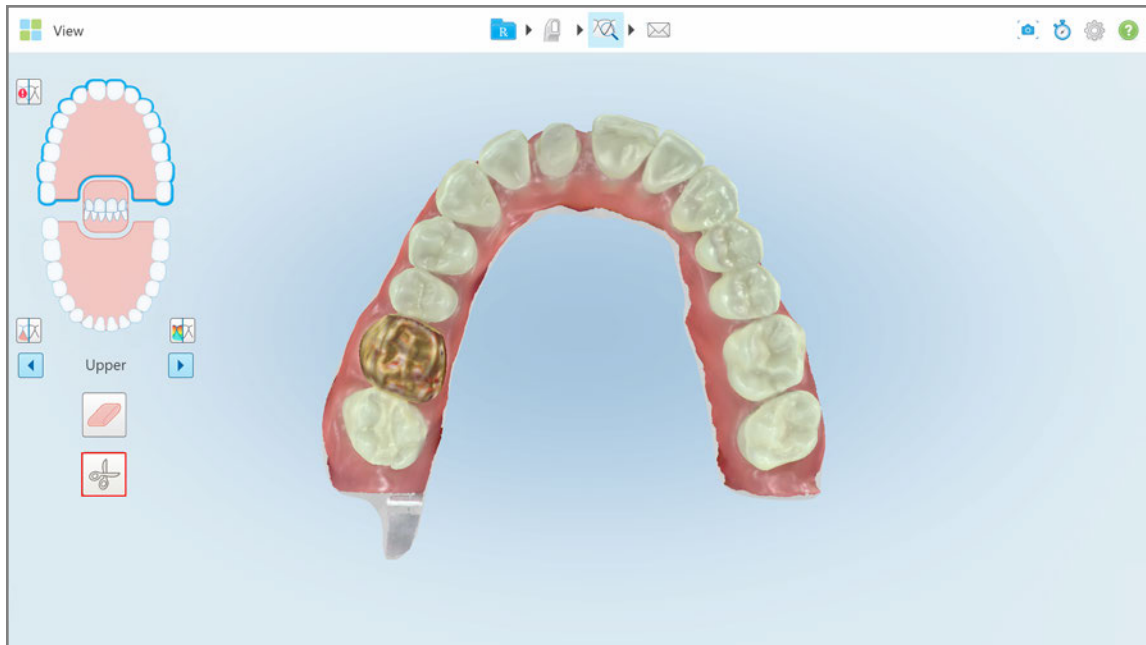


Figure 133: Edge trimming tool

The Edge Trimming tool expands to show the following options:



Figure 134: Edge trimming tool options

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

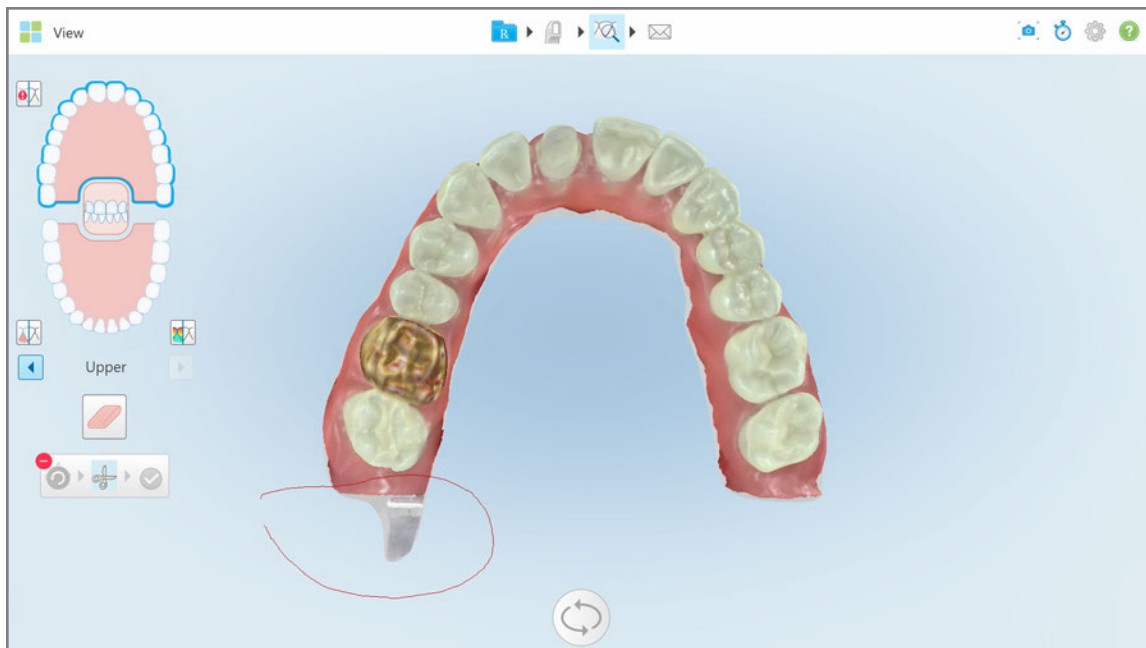


Figure 135: Mark the area to be trimmed away

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

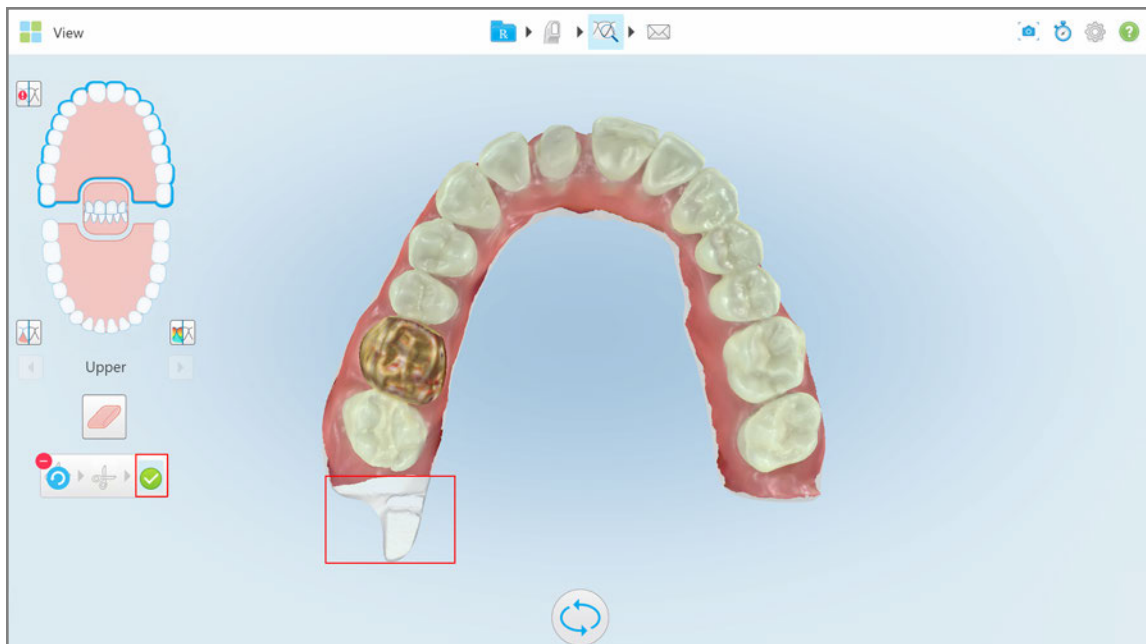



Figure 136: Selected area is highlighted and the confirmation icon is enabled

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

4. Tap  to confirm the trimming.

The selected area is removed.

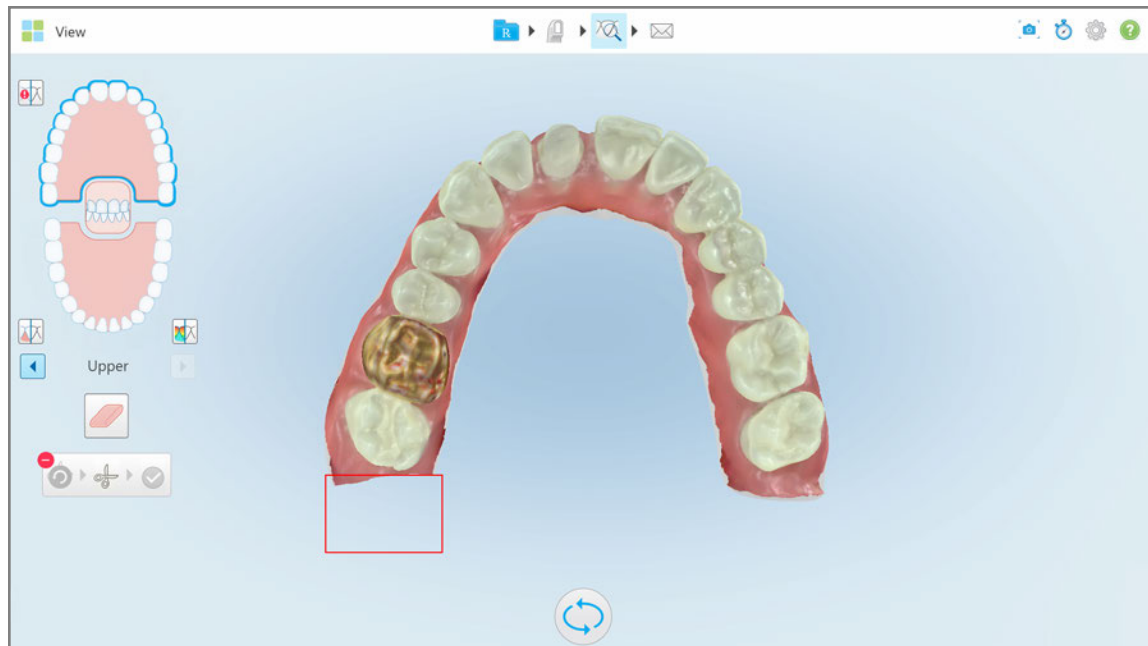


Figure 137: Selected area has been removed

9.9 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.

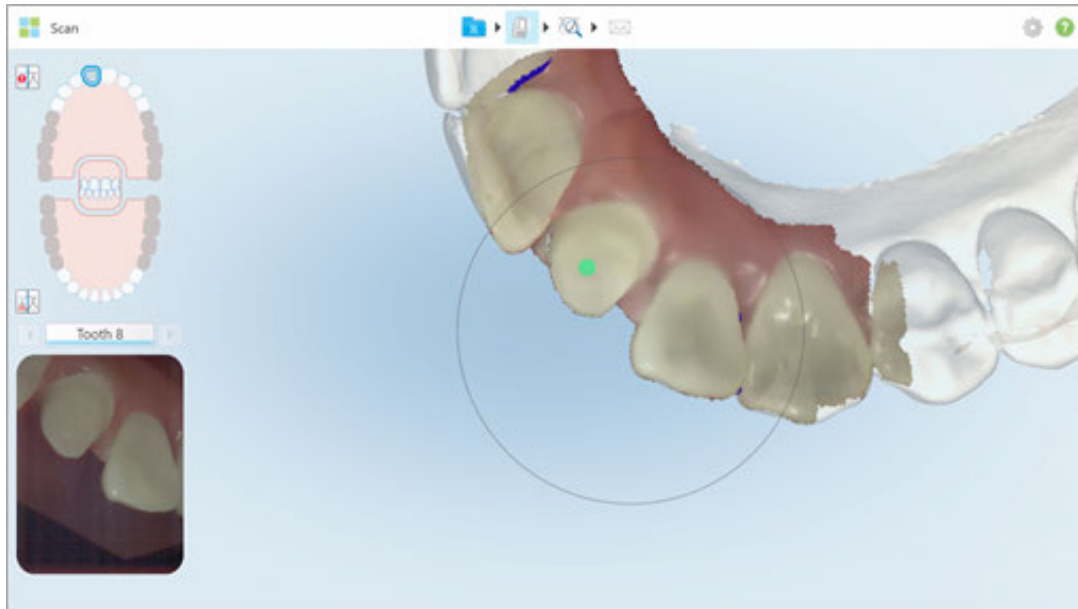




Figure 138: Green hint point centered on the prepped tooth

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.

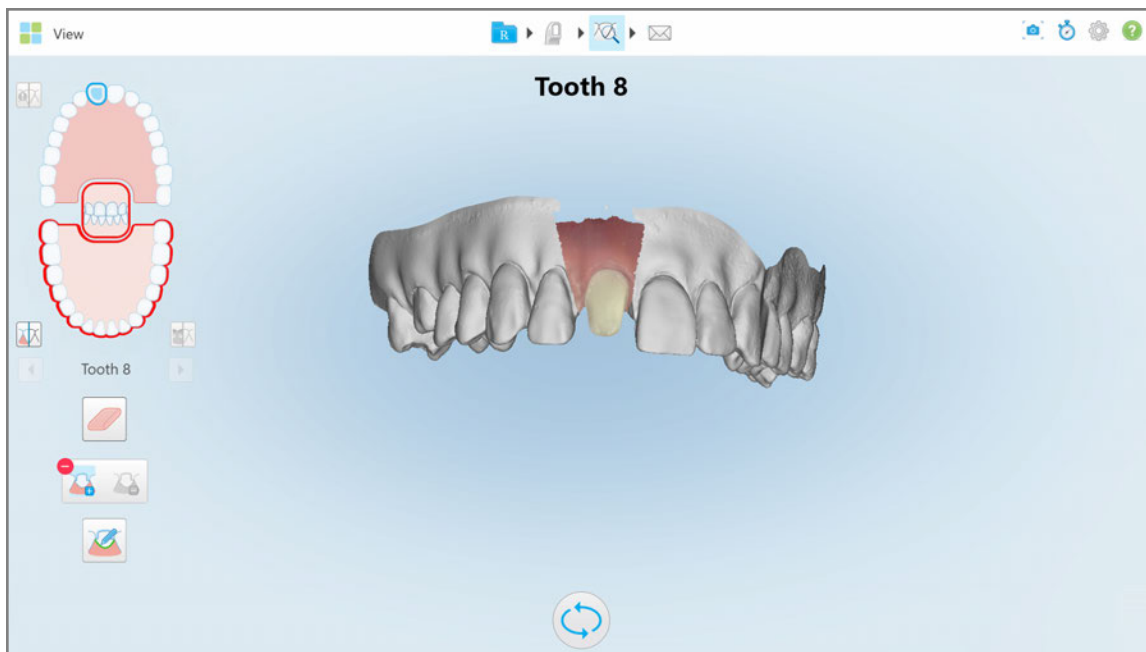



Figure 139: Die separation is displayed in high resolution


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 140: Die Separation tool options

2. Tap  and mark the whole segment with your finger.

The scan is displayed in low resolution.

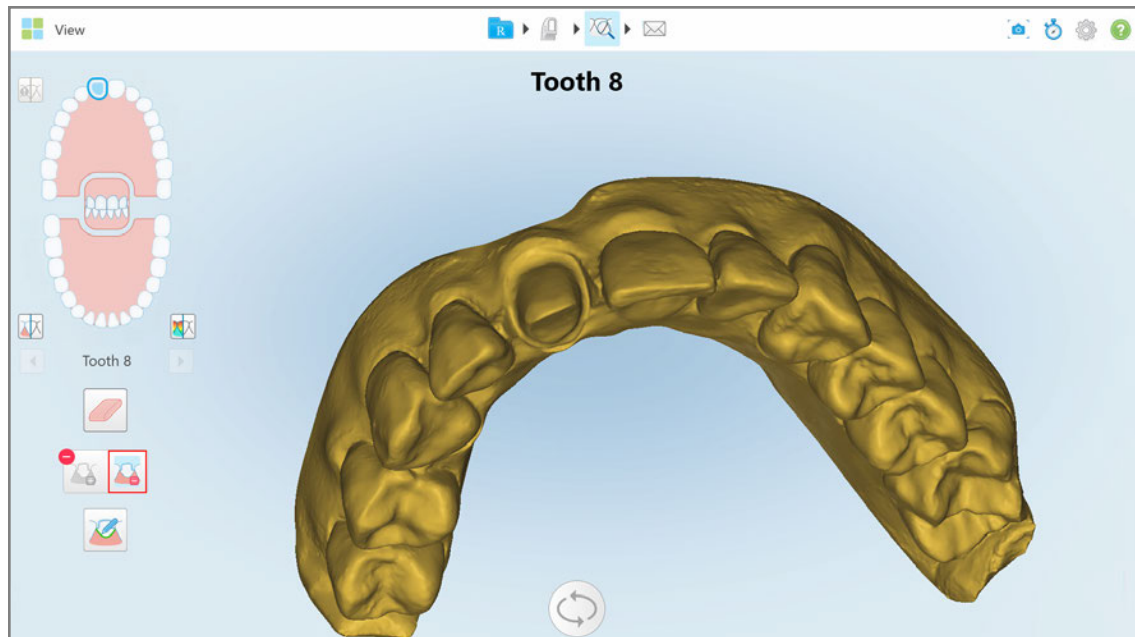



Figure 141: Scan is displayed in low resolution

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

The model is displayed as follows:

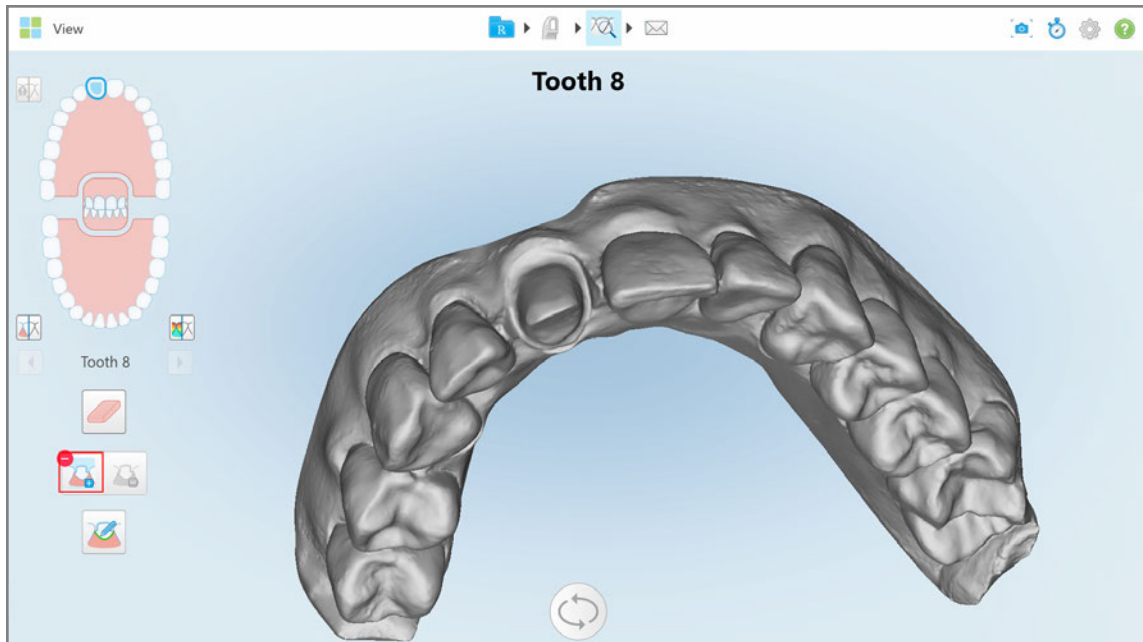


Figure 142: Before selecting the die separation

4. Draw the area for the die separation.

The selected area is displayed in high resolution.

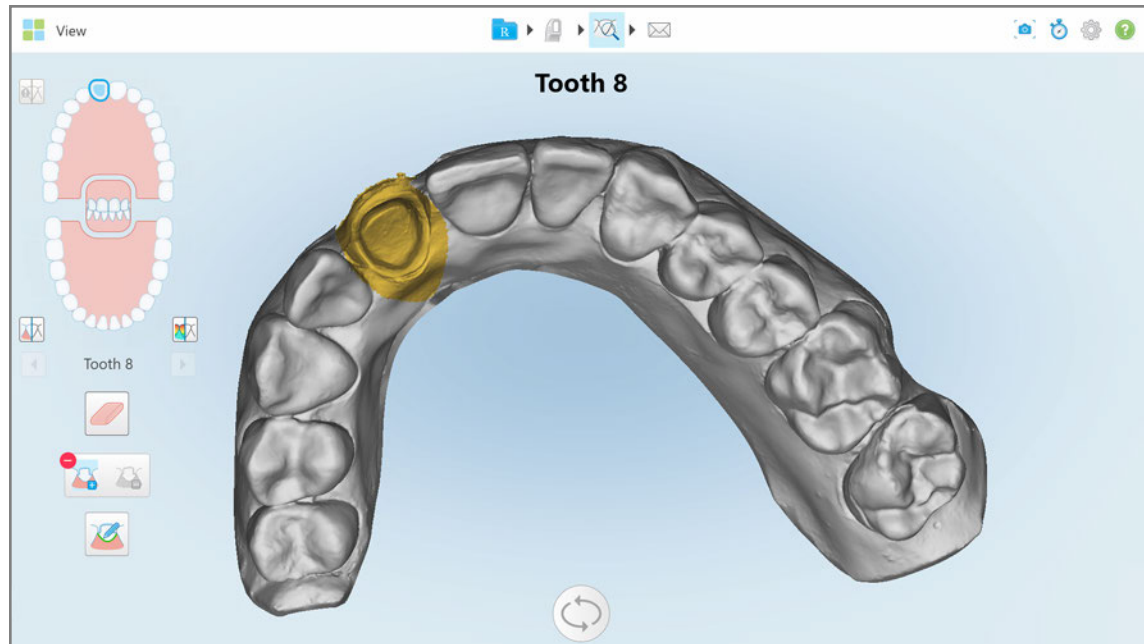


Figure 143: Prepped tooth is displayed in high resolution

9.10 Working with the Margin Line tool



The Margin Line tool automatically detects and marks the margin line on restorative case types that require crowns. If required, it can be marked manually for other indications. Once the margin line has been created, you can tweak it or recreate it if it has been deleted.

9.10.1 Automatically defining the margin line

The Margin Line tool automatically detects and marks the margin line on restorative case types (crowns only).

Note: The margin line may not be created automatically if:

- The prepped tooth was not scanned properly.
- The wrong die separation was used – the green dot was not centered on the prepped tooth while scanning – therefore part of the scan is not within the die separation area.

If the margin line cannot be created automatically, you will receive a message notifying you of this, and you can manually define the margin line, as described in section 9.10.2.

To define the margin line automatically:

1. In the *View* window, tap the prepped tooth in the navigation controls.

The 3D model display moves to the occlusal view, and zooms in on the prepped tooth.

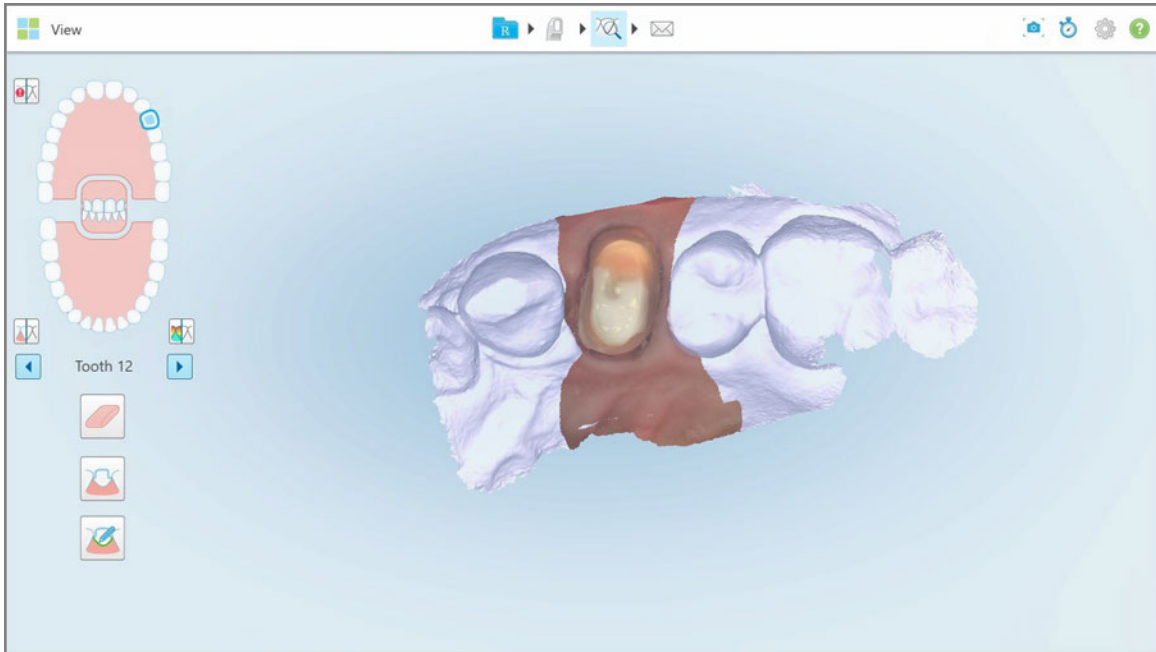



Figure 144: Model display moves to the occlusal view, and zooms in on the prepped tooth

2. Tap the Margin Line tool .

The Margin Line tool expands to show the following options:



Figure 145: Margin Line tool options

A message is displayed prompting you to wait while the automatic AI-based margin line is being detected. After a few seconds, the margin line is automatically marked on the prepped tooth. The teeth adjacent to the prepped tooth appear transparent, enabling you to see the edges of the margin line.

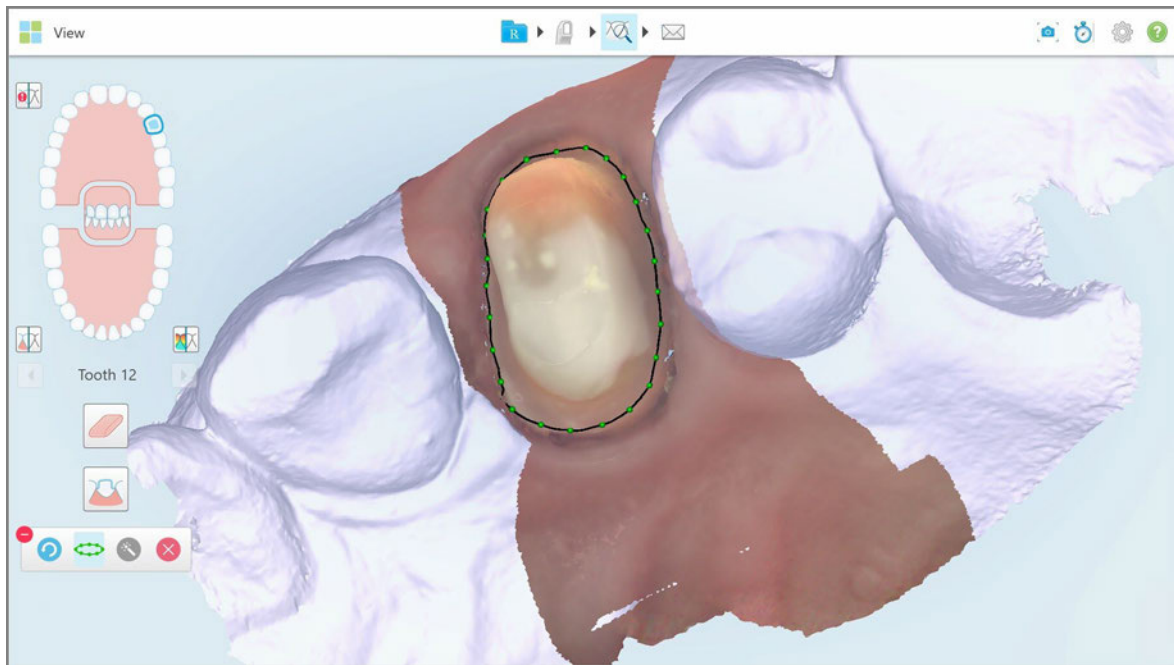





Figure 146: Margin line is marked on the prepped tooth

3. Tweak the margin line if required, by dragging any of the green control points.

4. If required, click  to undo the last action. You can click the button to undo the last 50 actions.

5. If required, click  to delete the margin line.

6. If required, click  to redisplay the deleted margin line.

9.10.2 Manually defining the margin line

If the margin line cannot be defined automatically, you can define it manually.

To define the margin line manually:

1. In the *View* window, tap the prepped tooth in the navigation controls.


The 3D model display moves to the occlusal view, and zooms in on the prepped tooth.

2. Tap the Margin Line tool .

The Margin Line tool expands to show the following options:



Figure 147: Margin Line tool options

3. Tap  and then tap around the prepped tooth to draw a point-by-point line of at least 6–8 points.

Note: Make sure to close the margin line. If you do not complete the margin line and try sending the case, you will receive a notification that the partial margin line will be deleted. You can go back and complete the margin line.

9.11 Working with the Snapshot tool


The Snapshot tool enables you to capture screenshots of the scanned model. These screenshots become part of the patient's export package, and can later be downloaded from MyiTero. In addition, these screenshots can be added to the iTero Scan Report, which is created in MyiTero. For more information on the iTero Scan Report, refer to the *MyiTero User Guide*.

Once the image has been captured, you can add annotations, if required.


By default, each time you tap the Snapshot 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 View window
- 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.

Screenshots can be captured from any window that includes the Snapshot tool  on the toolbar.

To capture a screenshot of a scanned image:

1. In **View** mode, tap the Snapshot tool  on the toolbar.

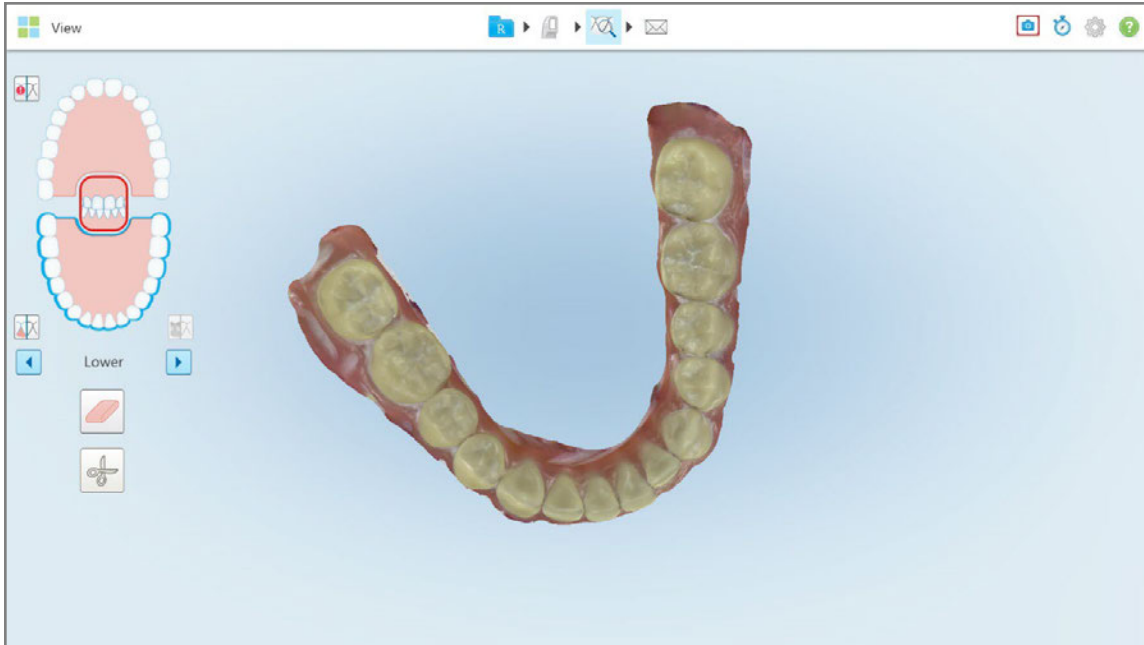


Figure 148: View mode – with Snapshot tool

The screen flashes, indicating that the screenshot was captured. A thumbnail of the screenshot is displayed on the bottom left of the window and remains for 7 seconds.

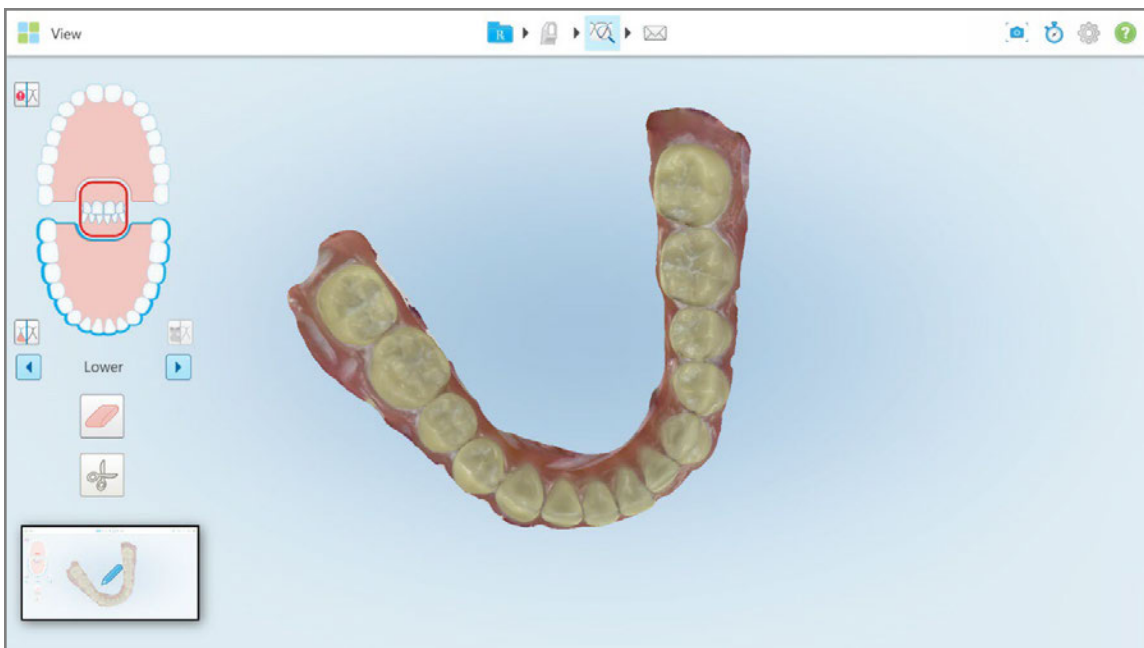


Figure 149: Screen capture thumbnail is displayed after taking a screen capture

2. Tap the thumbnail if you would like to add annotations to the screenshot.

The *Draw* window is displayed, showing a screenshot of the entire window, with an annotations toolbar on the top.

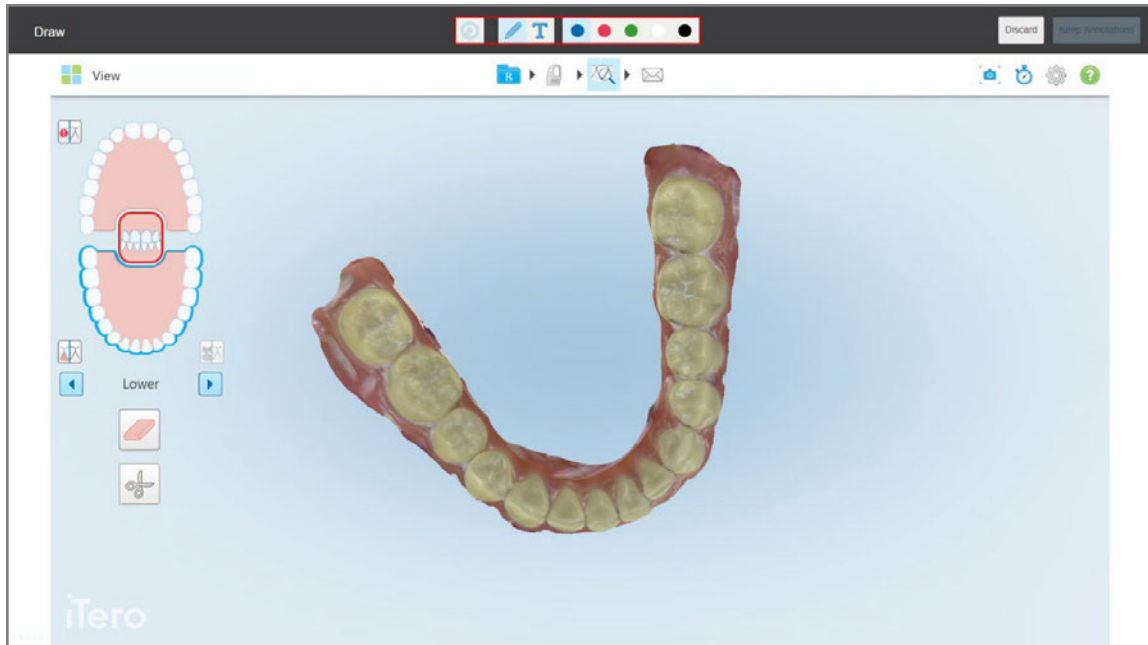



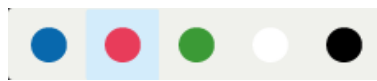



Figure 150: Screenshot with an annotations toolbar




Figure 151: Annotations toolbar

The annotations toolbar contains the following buttons:

- | | |
|---|---|
|  | Tap to undo previous annotations. |
|  | Tap to draw on the screenshot. |
|  | Tap to enter text on the screenshot. |
|  | Tap the color for the drawing and text. By default, these will be the same color. |

3. Tap the required tool and color and then add your annotations. After adding text, tap  to save the text in the color selected.

Note: If you do not tap  after entering text, the color of the text will be changed if you select a different color for the next annotation.

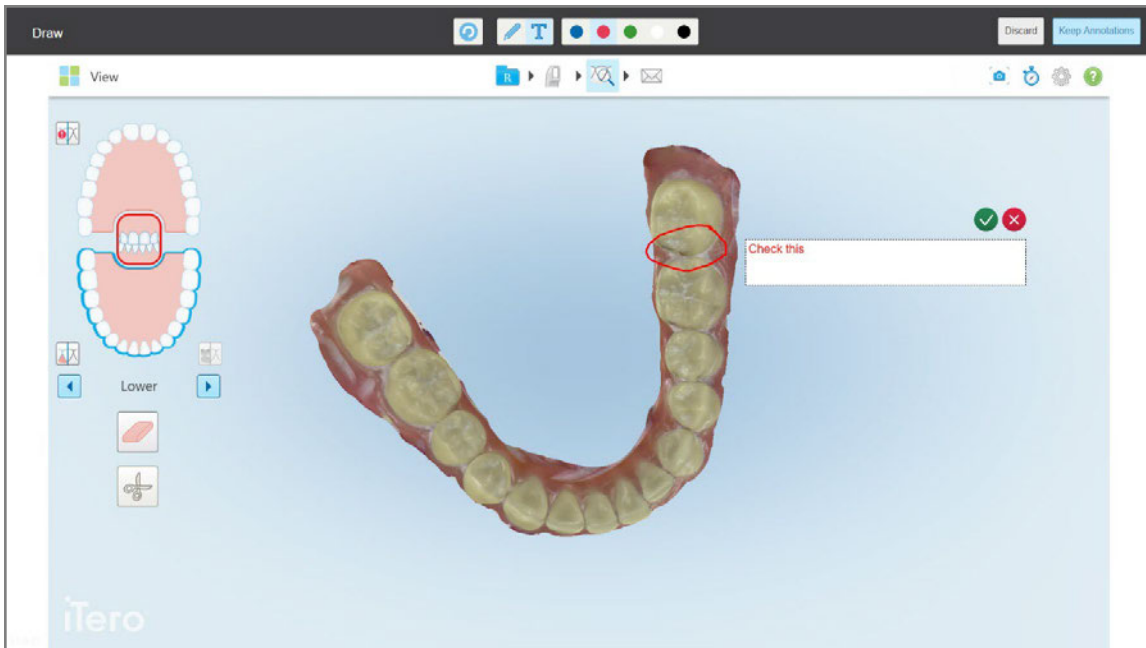


Figure 152: Adding text to the screenshot

4. To save the screenshot with the annotations, tap **Keep Annotations**.

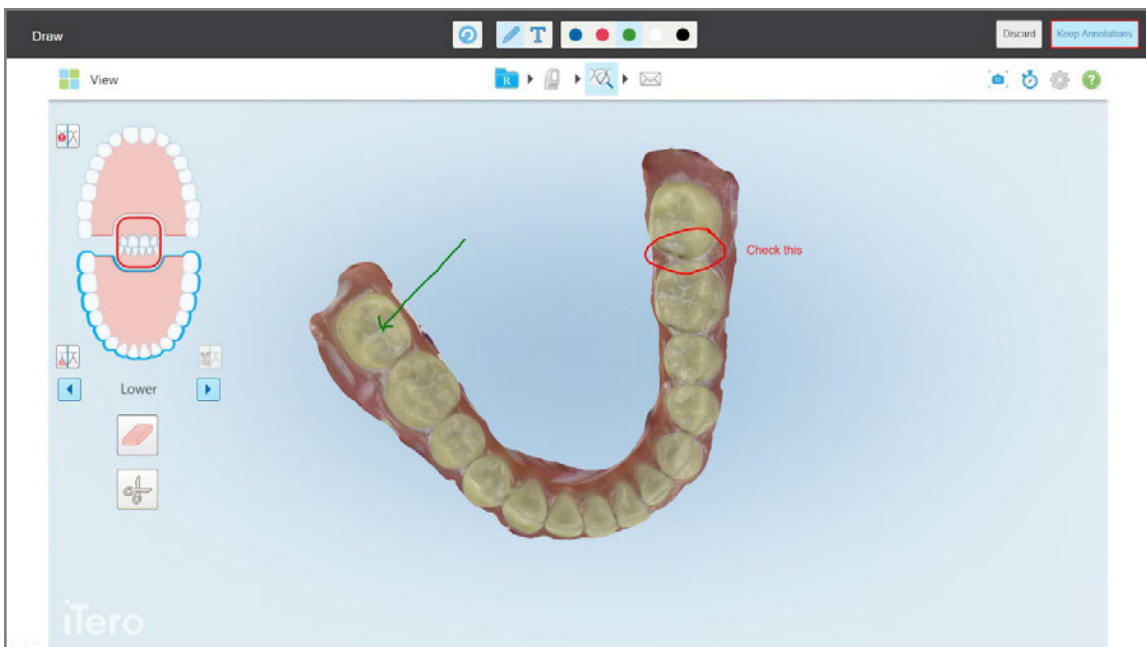


Figure 153: Screenshot with annotations

A pop-up message is displayed at the bottom of the screen, notifying that the screenshots and annotations will be uploaded to MyiTero, where you can access them.

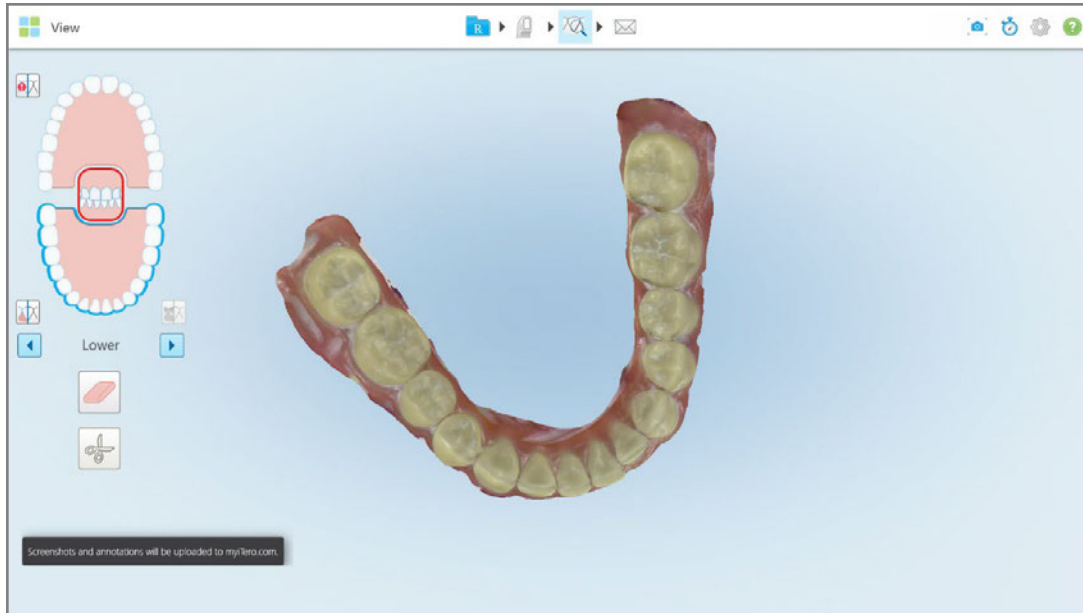


Figure 154: Notification that the screenshots and annotations will be uploaded to MyiTero

5. To save only the screenshots without the annotations, tap **Discard**.

A confirmation message is displayed.

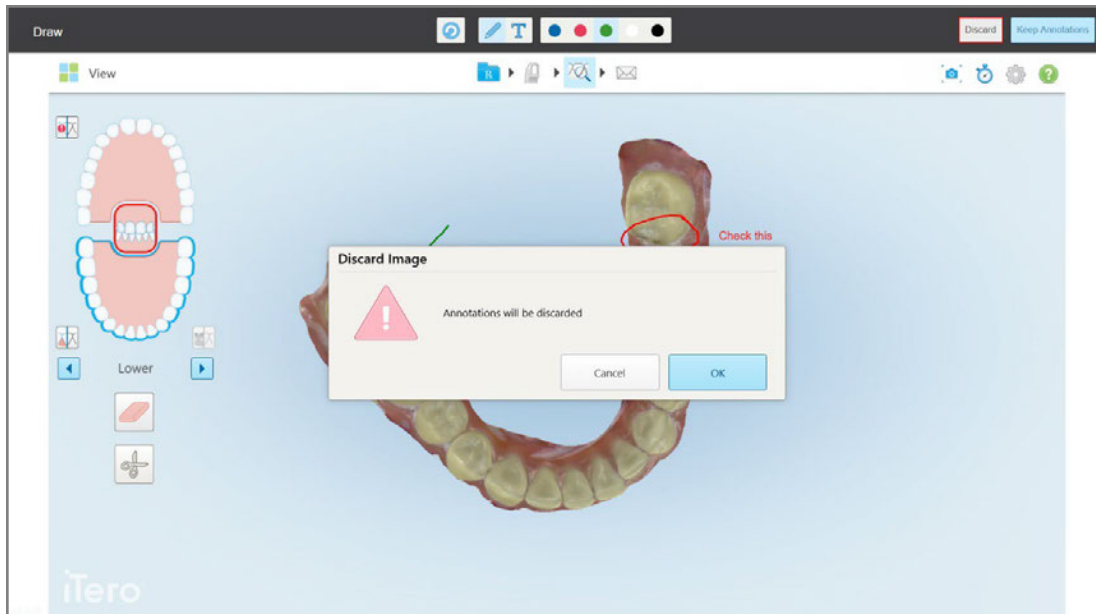


Figure 155: Confirmation about the annotations being discarded

a. Tap **OK** to proceed.

A pop-up message is displayed notifying that the screenshots will be uploaded to MyiTero.

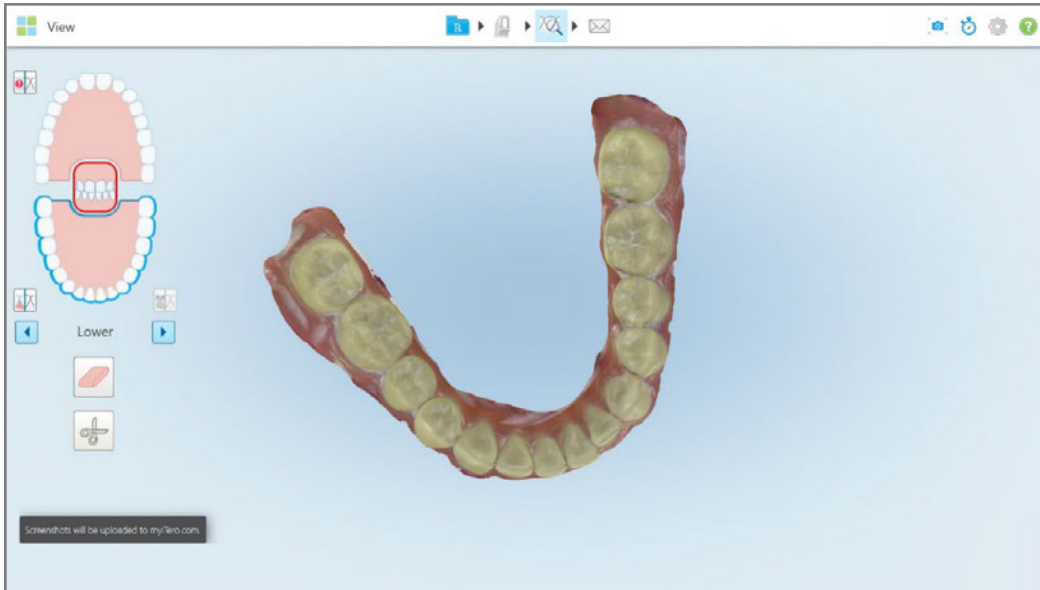


Figure 156: Notification that the screenshots will be uploaded to MyiTero

The screenshots can now be downloaded from MyiTero, from the *Orders* page or the Viewer.

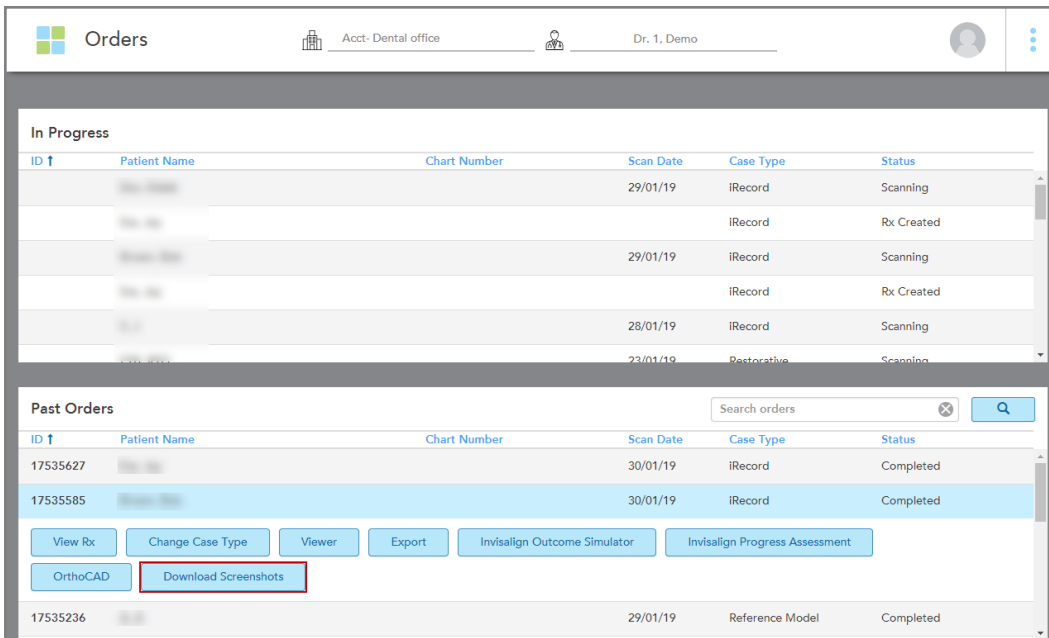


Figure 157: Option to download screenshots from the Orders page in MyiTero

10 Care and maintenance

If you are performing any sanitation procedures in the office that involve fogging or spraying, make sure that the iTero scanner is not in the room.

To avoid cross-contamination, it is mandatory to:

- Clean and disinfect the wand, cradle, touch screen, as described in the following sections.
- Replace the wand sleeve before each patient session, as described in section 4.1.
- Dispose of wand sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
- Remove and replace gloves after each patient procedure.
- Discard torn, contaminated, or removed gloves.

10.1 Handling the wand and cable

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

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.

10.2 Cleaning and disinfecting the wand

The iTero wand requires the procedures in the following sections for cleaning and disinfection.

These procedures must be carried out:

- After the scanner assembly, before first-time use
- Between patients

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

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

10.2.1 Preparation before cleaning and disinfection

1. To avoid false activation of the wand during the cleaning and disinfection procedures, make sure to exit a scan completely by sending the case or by going back to the home screen.
2. Remove the wand sleeve, making sure not to touch the optical surface of the wand.

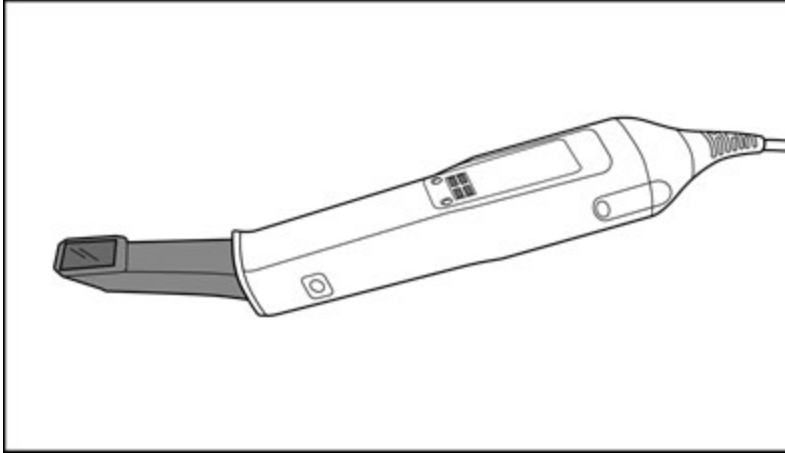


Figure 158: Wand without a sleeve

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

WARNING

Do not clean, disinfect, or use the wand if any damage is found. Please contact iTerro Customer Support for further instructions.

4. Prepare the following:
 - Required cleaning and disinfecting materials:
 - CaviWipes1 (or, for a list of alternative materials and the required contact time, see section 10.6)
 - 70% isopropyl alcohol (IPA)
 - Dry lint-free wipes
 - Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter, Cat # 3770 or equivalent)
 - Personal Protective Equipment (PPE) and work environment
 - Please follow the cleaning and disinfection material manufacturers' instructions

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

Before starting the cleaning and disinfection procedure, put on your PPE.

10.2.2 Wand cleaning and disinfection

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

Cleaning

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

Note: If you are using an alternative disinfectant, please refer to section 10.6 for the required contact time.

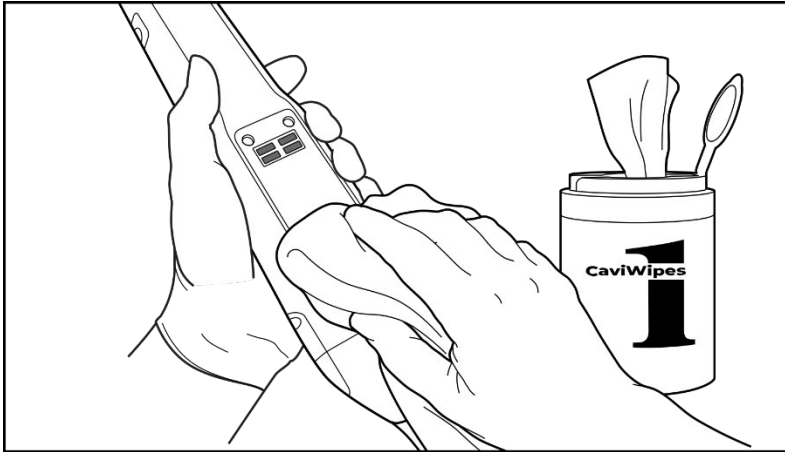


Figure 159: Remove gross contaminants using CaviWipes¹

2. Using the soft bristle brush, remove any remaining marks and stains on the wand body and wand tip, paying special attention to the grooves, indents, joints, vents, etc. Brush until visibly clean.

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

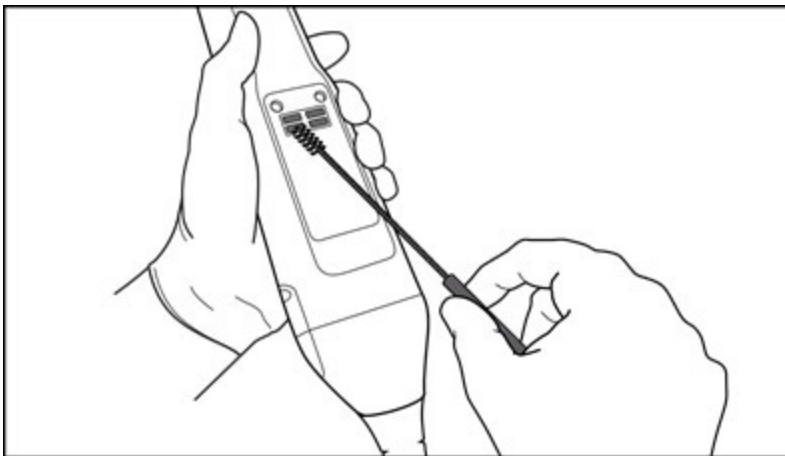


Figure 160: Remove marks and stains using a soft bristle brush

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

Disinfection

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

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

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

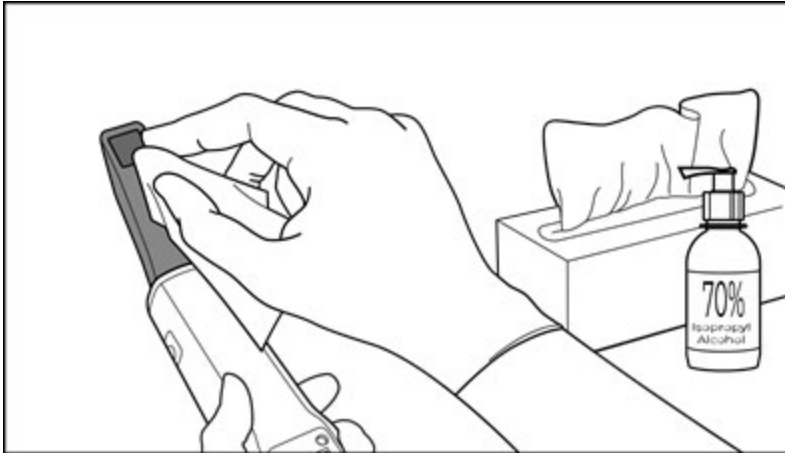


Figure 161: Wipe the optical surface of the wand with IPA

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

10.2.3 Drying – wand body

Air-dry the disinfected wand at room temperature.

10.2.4 Storage and maintenance

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

WARNING

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

2. Place the blue protective sleeve on the wand tip.
3. Place the wand in the cleaned and disinfected cradle, as described in section 10.3, below.

10.3 Cleaning and disinfecting the cradle

The wand cradle requires the procedures in the following sections for cleaning and disinfection.

These procedures must be carried out:

- After the scanner assembly, before first-time use
- Between patients

WARNING

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

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

10.3.1 Preparation before cleaning and disinfection

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

CAUTION: Do not clean, disinfect, or use the cradle if any damage is detected. Please contact iTero Customer Support for further instructions.

2. Prepare the following:
 - Required cleaning and disinfecting materials:
 - CaviWipes1 (or, for a list of alternative materials and the required contact time, see section 10.6)
 - Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter, Cat # 3770 or equivalent)
 - PPE and work environment
 - Please follow the cleaning and disinfecting material manufacturers' instructions.

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

Before starting the cleaning and disinfection procedure, put on your PPE.

10.3.2 Cradle cleaning and disinfection

Cleaning

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

Note: If you are using an alternative disinfectant, please refer to section 10.6 for the required contact time.

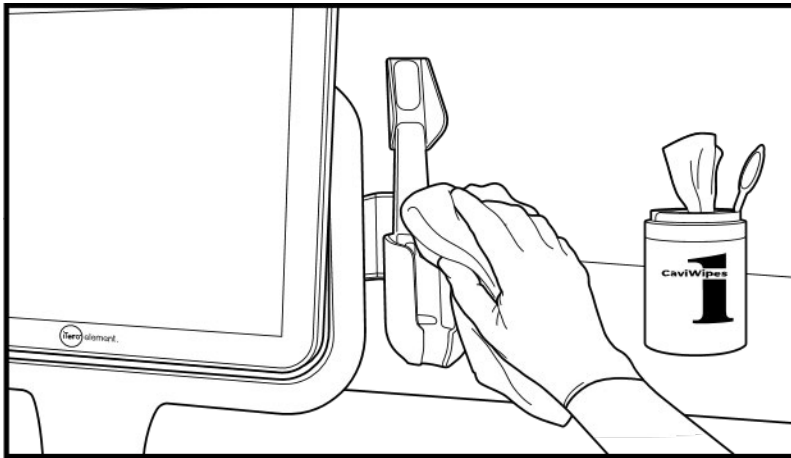


Figure 162: Remove gross contaminants on the cradle using CaviWipes1

2. Using the soft bristle brush, remove any remaining marks and stains on the cradle, paying special attention to the grooves, indents, joints, etc.

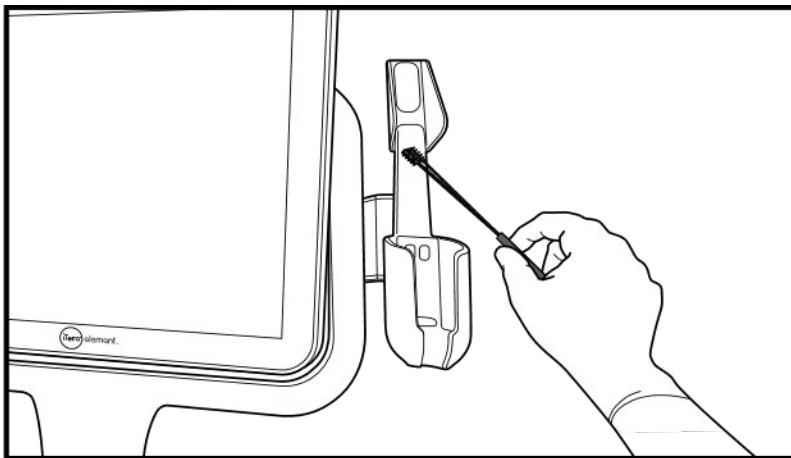


Figure 163: Remove remaining marks and stains on the cradle using the soft bristle brush

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

Disinfection

- Using CaviWipes¹, thoroughly dampen all external surfaces of the cradle and ensure they remain wet for a minimum of one (1) minute.

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

10.3.3 Drying – cradle

Air-dry the disinfected cradle at room temperature.

10.3.4 Storage and maintenance

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

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

10.4 Cleaning and disinfecting the scanner touch screen

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

1. Clean all outer surfaces using approved disinfectant wipes, or approved disinfectant liquid with a clean lint-free wipe, and follow the manufacturer's instructions. For a list of approved materials, see section 10.6.
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, or solvents

10.5 General cleaning

All scanner parts and accessories not outlined above should be cleaned according to standard operating procedures or local regulations.

10.6 Approved cleaning and disinfecting materials

The following table lists the Align-recommended cleaning and disinfecting materials, as well as the minimum contact time required.

If you are using liquid disinfectant, soak a clean, sterile, lint-free wipe in the liquid and squeeze until moist, and then follow the cleaning and disinfection instructions described in this document.

Material	Active Ingredient	Contact time (minutes)
CaviWipes1/CaviCide1	Quats-alcohol	1
CaviWipes/CaviCide	Quats-alcohol	3
Clorox HP Wipes	1.4% Hydrogen Peroxide	5
Oxivir® 1 Wipes	AHP Hydrogen Peroxide	1
Clinell Universal Range Wipes	≤50% Peracetic Acid	2

Note: If the recommended alternative disinfectants are not available in your region, consult your local supplier of disinfecting materials for equivalent products in your region. Equivalent products must meet local regulatory requirements, have the same active ingredients, and in addition, must be able to disinfect against at least Hepatitis and Tuberculosis.

A Clinic LAN network guidelines

A.1 Introduction

The 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

>-50 dBm



Good

-50 to -60 dBm



Fair

-60 to -70 dBm



Weak

<-70 dBm

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

WARNING

Never connect the LAN cable to the scanner, in order to prevent electrical shock.

A.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 the 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 A.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.

A.3 Router guidelines

Minimum standards: 802.11N / 802.11AC

A.4 Internet connection guidelines

In order to achieve the best performance of your iTero scanner, ensure that the 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.

A.5 Firewall

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

- 443 - HTTPS - TCP

A.6 Wi-Fi tips

Wi-Fi routers allow you to access the 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 the 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 the wireless signal.
- Keep the scanner 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), the 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 any other wireless devices as far as possible from the 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.

A.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 hostname recommendation:

Hostname	Port
Mycadent.com	443
Myaligntech.com	443
Export.mycadent.com	443
Cbserver.mycadent.com	443
Matstore.invisalign.com	443
Matstore2.invisalign.com	443
Matstore3.invisalign.com	443
Matstore4.invisalign.com	443
Matstoresg.invisalign.com	443
Matstorechn.invisalign.com.cn	443
AWS IP range - Amazon global CDN service - IP address range varies depending on the location of the scanner.	443
cloud.myitero.com	443
https://itero-scanner-speed-test-prd.s3-accelerate.amazonaws.com/	443
alignapi.aligntech.com	443
http://www.google.com	443
http://www.microsoft.com	443
http://www.yahoo.com	443
iterosec.aligntech.com	443
storage.cloud.aligntech.com	443

B EMC declaration

IEC 60601-1-2 Edition 4.0 (2014)	Medical electrical equipment; Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - 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	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
Environment for intended use	Professional Healthcare and Home Healthcare Facility Environment

The iTero Element intraoral scanner essential performances are:

- Display viewfinder and 3D imaging without interference on the touch screen.
- Stored scan data is accessible and can be displayed.

Note: 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 scanners:

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

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) ms	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0, 6.0 VRMS 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

Emission (per ETSI EN 301 489-1, ETSI EN 301 489-17)

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)			
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) ms	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

C iTero Element product security whitepaper

This whitepaper applies to the iTero Element Family of products. Depending on the version of the product you have procured, there may be differences in the features of the product. In addition, as this whitepaper 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 Management Program: Align Technology conducted the program on the iTero Element Family of products. The methodology included planning and information gathering, scoping product ecosystem, performing a product security risk assessment, analyzing threats and vulnerabilities, assessing applicable security controls, and calculating the residual risk rating of any identified gaps. Security and privacy risks and controls considered as part of the assessment leverage industry leading practice security risk frameworks including, but not limited to, AAMI TIR57, NIST CSF, IEC/TR 80001-2-2, and the FDA's Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.



Security and privacy features of the product.

We aim to protect your data and patients through the design and maintenance of our products. As a result of our security- and privacy-by-design approach to product development, we have implemented the following non-exhaustive security controls in the iTerO Element Family of products.

- **Data-at-rest is encrypted:** The scanners store Personally Identifiable Information (PII) in an encrypted database using AES-256 and intraoral scan images in an encrypted folder using Microsoft Encrypting File System (EFS). These encryption technologies help to prevent an attacker from capturing patient information stored on the scanner.

Applicable to iTerO Element, iTerO Element 2, iTerO Element Flex, iTerO Element 5D, and iTerO Element 5D Laptop Configuration, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **Data-in-transit is encrypted:** PII and intraoral scan images that are backed up to Align servers is transmitted over transport layer security (TLS) 1.2 encryption using trusted certificates. This helps to prevent an attacker from capturing patient information while in transit.

Applicable to iTerO Element, iTerO Element 2, iTerO Element Flex, iTerO Element 5D, and iTerO Element 5D Laptop Configuration, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **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.

Applicable to iTerO Element, iTerO Element 2, iTerO Element 5D, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **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.

Applicable to iTerO Element, iTerO Element 2, iTerO Element Flex, iTerO Element 5D, and iTerO Element 5D Laptop Configuration, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **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.

Applicable to iTerO Element, iTerO Element 2, iTerO Element 5D, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **User access management controls are enforced:** A user account and password is required to utilize the scanners. This helps protect access to the scanner and protects against unauthorized use.

Applicable to iTerO Element, iTerO Element 2, iTerO Element Flex, iTerO Element 5D, and iTerO Element 5D Laptop Configuration, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

- **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.

Applicable to iTerO Element, iTerO Element 2, iTerO Element Flex, iTerO Element 5D, and iTerO Element 5D Laptop Configuration, iTerO Element 2 Plus, iTerO Element 5D Plus, iTerO Element 5D Plus Lite

Security and privacy responsibilities of the customer.

As part of our assessments, we have identified risks that are dependent on how the product is used. The securing of the products we provide to our customers is a shared responsibility among all stakeholders. Based on the assessment conducted on the iTero® Element™ optical impression system series, we expect that you will take the following security steps to protect the product:

- **Physically secure the product and its operating environment:** It is the customer's responsibility to protect the physical security of the product and operate it in a secure manner. For the iTero® Element™ Flex system, control and monitor physical access to the platform hosting the application through the use of mechanisms such as security cameras and security badges. In addition, shut down physical ports of network equipment that is not in use to prevent unauthorized access to the application.

Applicable to iTero Element, iTero Element 2, iTero Element Flex, iTero Element 5D, and iTero Element 5D Laptop Configuration, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite

- **Securely operate and protect your network:** It is the customer's responsibility to secure your network through the use of network intrusion detection and prevention mechanisms, using adequately hardened network/application firewalls, and network segmentation, especially if exposed to public Internet. Additionally, dispose of data in an appropriate manner, complying with all local laws and regulations.

Applicable to iTero Element, iTero Element 2, iTero Element Flex, iTero Element 5D, and iTero Element 5D Laptop Configuration, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite

- **Detect malicious and mobile code:** It is the customer's responsibility to select and implement anti-virus/anti-malware protection for the iTero® Element™ Flex host machine. Additional CPU and memory resources should be provided, if necessary, in order to prevent any degradation in performance caused by the execution of this software.

Applicable to iTero Element Flex and iTero Element 5D Laptop Configuration

- **Create strong passwords and protect login credentials:** It is the customer's responsibility to set strong passwords with to access scanners and Align systems. The more characters it has with special characters, the stronger it is. Using a passphrase without personal information is one of the simplest ways to ensure that you have a strong password along with changing it every 90 days. Protect your username and password login credentials granting you access to scanners and Align systems by not sharing with anyone and working in a secure environment.

Applicable to iTero Element, iTero Element 2, iTero Element Flex, iTero Element 5D, and iTero Element 5D Laptop Configuration, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite

- **Apply segregation of duties and timely remove staff accounts when no longer needed:** If customer has multiple user accounts with access to the scanner, it is the customer's responsibility to register those multiple user accounts with the appropriate role of Doctor, Assistant, or Support Technician. This helps ensure the ability to track activities performed by individual users better protecting the device. Additionally, it is the customer's responsibility to remove user accounts when staff no longer require the access to the scanner.

Applicable to iTero Element, iTero Element 2, iTero Element Flex, iTero Element 5D, and iTero Element 5D Laptop Configuration, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite

- **Ensure current data backup and maintain latest software version:** It is the customer's responsibility to ensure scanners remain connected to Align systems to backup PII and intraoral scan images to Align servers and are being restarted as requested to ensure latest scanner updates are being applied.

Applicable to iTero Element, iTero Element 2, iTero Element Flex, iTero Element 5D, and iTero Element 5D Laptop Configuration, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite

- **Exported data not encrypted:** It is the customer's responsibility to protect exported data, such as intraoral images, by using mechanisms such as digital signatures or encrypting removable media.

Applicable to iTero Element Flex and iTero Element 5D Laptop Configuration

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.

D System specifications

Monitor	19" touch screen								
Wand	<ul style="list-style-type: none"> The wand emits red laser light (680nm Class 1) as well as white LED emissions. Wand operating power: 15VDC 								
Wireless LAN	A LAN card provides local network communications with wireless connectivity								
Mains Fuses	T3. 15AL (3.15A, slow-blow) 250V glass tube fuses (5x20 mm)								
Security	See the product security whitepaper in appendix C.								
Operating Power	100-240 VAC- 50/60 Hz- 350200 VA (max)								
Operating Temperature	18°C to 26°C / 64.4°F to 78.8°F								
Storage/Transportation Temperature	-5°C to 50°C / 23°F to 122°F								
Operating Pressure and Altitude	Pressure: 520 mmHg to 760 mmHg (69.3 kPa to 101.3 kPa) Altitude: 0 feet to 10,000 feet								
Storage/Transportation Pressure and 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	<table> <tr> <td>iTero touch-screen base unit:</td> <td>Wheel stand:</td> </tr> <tr> <td> <ul style="list-style-type: none"> Height: 389 mm (~15 in) Width: 459 mm (~18 in) Depth: 123 mm (~5 in) </td> <td> <ul style="list-style-type: none"> Height: 1280 mm (~50 in) Width: Depth: 625 mm (~24.5 in) </td> </tr> <tr> <td colspan="2">Wand:</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> Length: 338.5 mm (~13 in) Width: 53.5 mm (~2 in) Depth: 69.8 mm (~3 in) </td> </tr> </table>	iTero touch-screen base unit:	Wheel stand:	<ul style="list-style-type: none"> Height: 389 mm (~15 in) Width: 459 mm (~18 in) Depth: 123 mm (~5 in) 	<ul style="list-style-type: none"> Height: 1280 mm (~50 in) Width: Depth: 625 mm (~24.5 in) 	Wand:		<ul style="list-style-type: none"> Length: 338.5 mm (~13 in) Width: 53.5 mm (~2 in) Depth: 69.8 mm (~3 in) 	
iTero touch-screen base unit:	Wheel stand:								
<ul style="list-style-type: none"> Height: 389 mm (~15 in) Width: 459 mm (~18 in) Depth: 123 mm (~5 in) 	<ul style="list-style-type: none"> Height: 1280 mm (~50 in) Width: Depth: 625 mm (~24.5 in) 								
Wand:									
<ul style="list-style-type: none"> Length: 338.5 mm (~13 in) Width: 53.5 mm (~2 in) Depth: 69.8 mm (~3 in) 									
Net Weight	<p>Base unit: 11 kg (~24.0 lbs.)</p> <p>Wand: 0.47 kg (~1.0 lbs.) without the cable</p> <p>Wheel stand: ~10 kg (~22 lbs.)</p>								

E Checking and replacing main fuses

Follow the instructions below to check and replace the main fuses of the iTero Element scanner.



1. Unplug the power cord from the wall socket.



2. Move the system to gain easy access to the power cord and fuse tray.



3. Unplug the power cord from the back of the computing unit.



The fuse tray is located below the power socket.



4. Release the fuse tray by pushing down on the small plastic part, and then pull out the fuse tray.



5. Carefully remove each of the fuses from the tray. Check the fuses visually and with a tester, if available.



6. If either fuse is blown or suspect, replace both fuses. See section D for the fuse specifications.



7. Close the fuse tray and firmly insert the power cable.

Index

A

- Adding patients 52
- Additional scan feedback 69

B

- Barrier
 - Removing 79
- Benefits 1
- Best practices 68
- Brightness
 - Settings 32

C

- Care and maintenance 133
- Cleaning and disinfecting
 - Cradle 137
 - Handle 139
 - Touch screen 139
 - Wand 133
- Clearance tool 113
- Clearing patient data 60
- Color toggle 70
- Comparing scans 99
- Compliance ii
- Computer settings 32
- Contraindications ii

D

- Delete Segment tool 105
- Delete Selection tool 106
- Demo mode 11
 - Exit 16
- Diagnostics 44
- Die Separation tool 119
- Disabling A.I. Cleanup tool 109

E

- Edge Trimming tool 117
- Editing
 - Patient details 58
- Editing scan 71
- Editing tools 104
- EMC declaration 145
- Eraser tool 111
- Export settings 46

F

- Fill tool 108
- Filling in Rx 60
- Firewall 142
- Fuses
 - Checking and replacing 155

G

- Guidance 67

H

Hardware 2
Hostname recommendations 143

I

Installing security updates 23
Intended use 1
Internet connection guidelines 142
Introduction 1
Invisalign Go system 102
Invisalign Progress Assessment 103
iTerro TimeLapse technology 99

L

LAN network guidelines 141
 Firewall 142
 hostname recommendations 143
 Internet connection 142
 Router 142
 WiFi tips 142
Language settings 42
Licenses 45
Logging in 17
 First time 5
Logging out 24
Login settings 42

M

Maintenance 133
Make It Mine 5

Margin Line tool 123
Messages 95
Missing scan segment notifications 73
Moving the scanner 25
Moving to next segment 70
MyiTerro 97

N

New Scan 49
New Scan window
 Clearing 60
Notifications
 Missing scan segment 73

O

Orders 89

P

Password
 Resetting 21
Password policy 22
Patient management 51
Patients 81
 Adding 52
 Clearing details 60
 Comparing scans 99
 Details 83
 Editing 58
 New 52
 New scan 84

Searching 82
Searching for 55
View Rx 86
Viewing scans 87

R

Registering the scanner 5
Restorative scan types 63
Router guidelines 142
Rx
 New 60
 View Rx 86
Rx details 86
Rx settings 39

S

Safety instructions v
Scan
 Sending 74
 Starting 49
 Timing 74
 Viewing 72
Scan color toggle 70
Scan editing 71
Scan options 68
Scan settings 36
Scan timer 74
Scan types
 Restorative 63
Scanner settings 31
Scanning best practices 68

Scanning guidance 67
Scanning the patient 66
Searching for patients 55, 82
Security updates
 Installing 23
Security whitepaper 149
Sending the scan 74
Settings
 Brightness 32
 Computer 32
 Diagnostics 44
 Export 46
 Language 42
 Licenses 45
 Login 42
 Rx 39
 Scan 36
 Signature 41
 Sync configuration 46
 System 42
 System information 46
 Time zone 35
 User 36
 Volume 32
 Wi-Fi 33
Shutting down 24
Signature settings 41
Sleeves 4
Snapshot tool 126
Symbols iii
Sync Configuration 46

System information 46
System settings 42
System specifications 153

T

Time zone settings 35
TimeLapse technology 99
Toolbar 28
Tools
Delete Segment 105
Delete Selection 106
Die Separation 119
Disable A.I Cleanup 109
Edge Trimming 117
Eraser 111
Fill 108
Margin Line 123
Occlusal Clearance 113
Snapshot 126
Touch screen
Gestures 30

U

User interface 26
User settings 36

V

Viewer 75
Viewing the scan 72
Volume settings 32

W

Wand 4
Handling 133
Whitepaper 149
Wi-Fi settings 33
Wi-Fi tips 142

align

Align Technology, Inc.
410 North Scottsdale Road
Suite 1300, Tempe,
Arizona 85281
USA

©2022 Align Technology, Inc. All rights reserved. Align, Invisalign, iTero Element, among others, are trademarks and/or service marks of Align Technology, Inc., or one of its subsidiaries or affiliated companies and may be registered in the U.S. and/or other countries. 213218 Rev. B