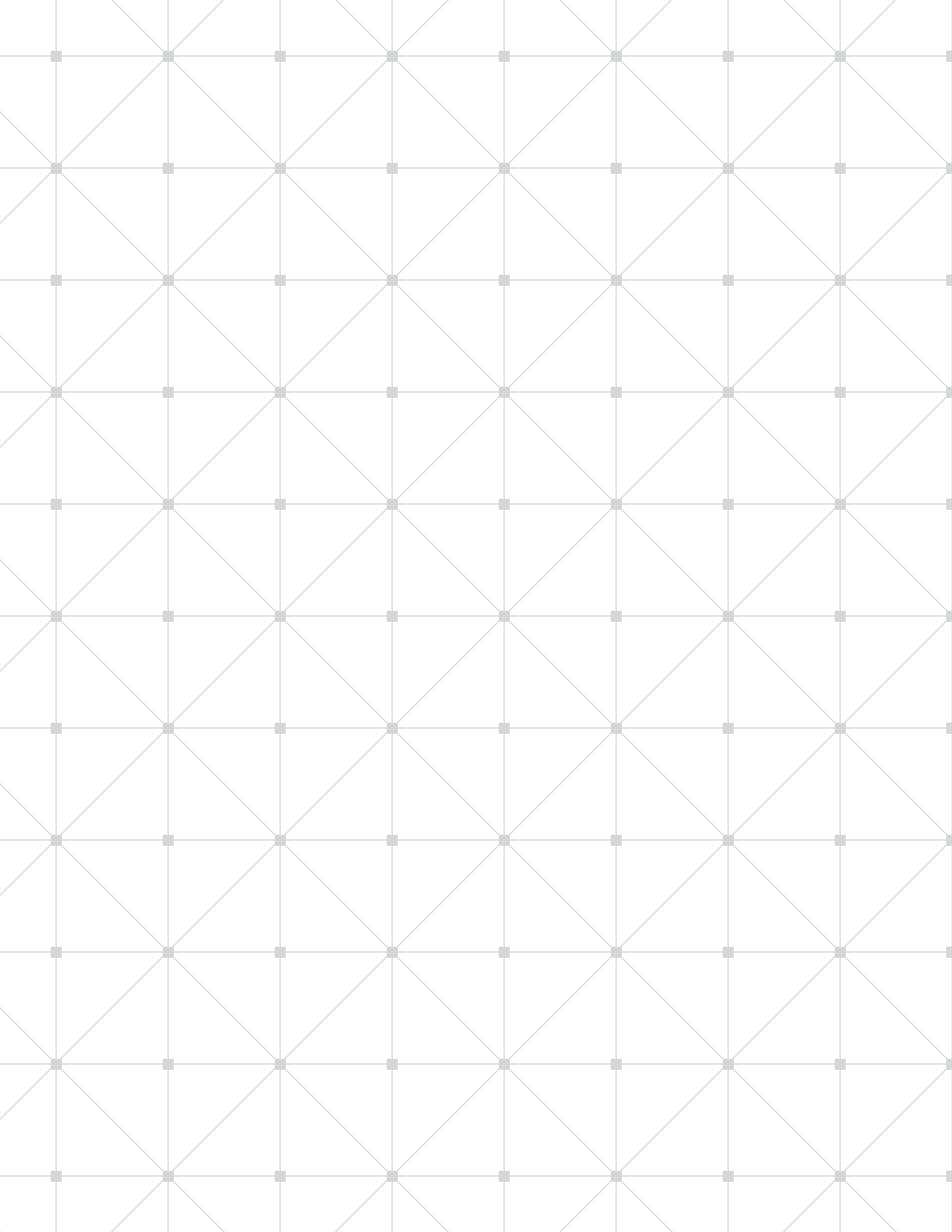


Imaging system **instructions** **for use**



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This document describes the iTero® Element 5D Optical Impression Device. English language version. Updated in November 2019.

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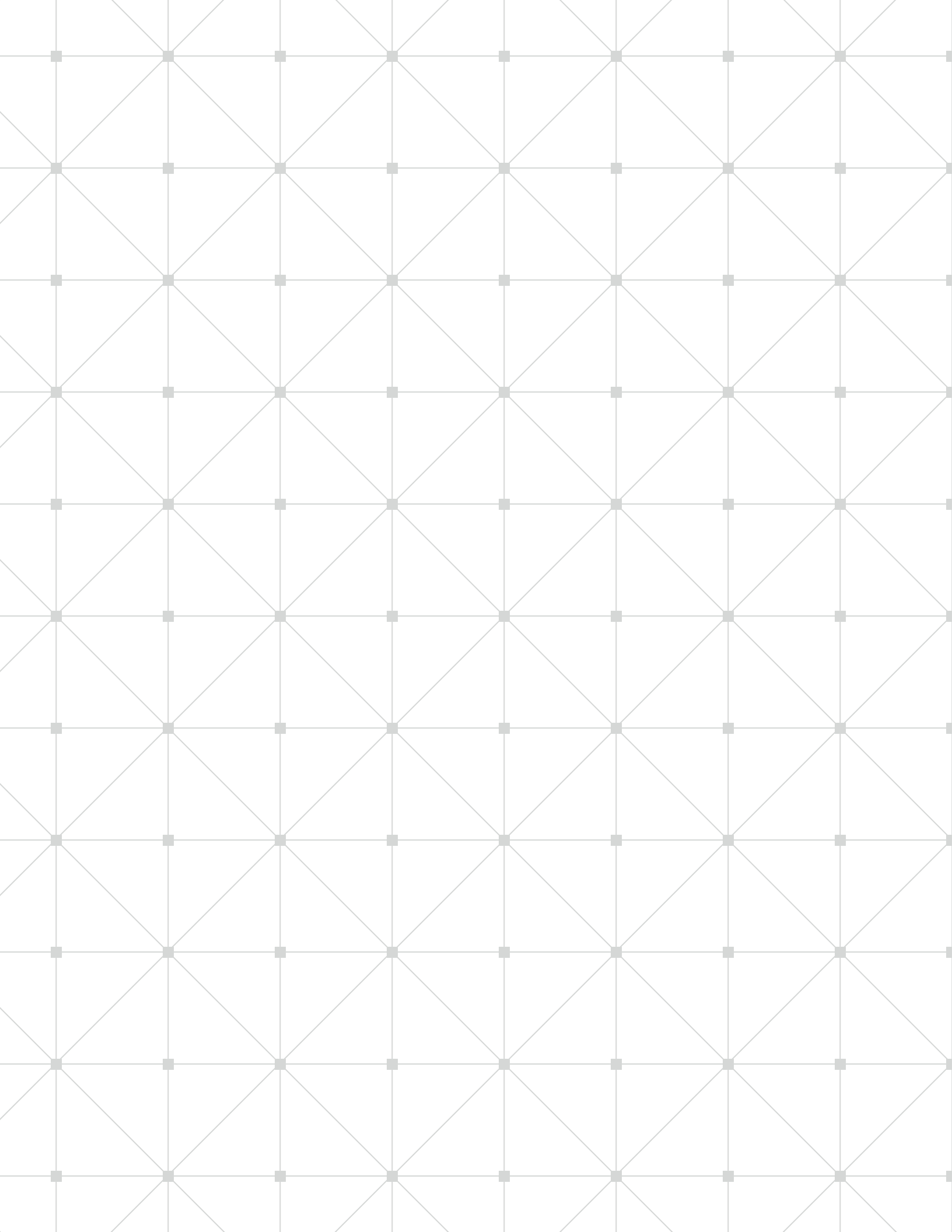


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Introduction

The iTero Element 5D intra-oral scanner is Align Technology's latest generation integrated scanner and software system. It enables doctors to take 3D digital scans of patients' teeth and bite, make adjustments of the scan in real time and transmit the results wirelessly.

This user guide provides general information and an overview of the application.

Intended use

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

1. The optical impression (CAD/CAM) feature of iTero Element 5D is intended/indicated for use to record the topographical images of teeth and oral tissue. Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories.
2. iTero Element 5D software is used with the iTero Element 5D scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. iTero 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.
3. The iTero Element 5D NIRI functionality, is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.

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

the scan is completed.

In conjunction with the scanner, the application facilitates the following tasks by:

- Capturing 3D digital impressions of teeth, oral soft tissue and structures as they are being scanned.
- Enabling real-time viewing of the visual bite relationship once the scan is completed.
- Managing the processing of the data.
- Sending the data wirelessly to designated providers for the fabrication of dental restorations, orthodontic devices, abutments, and accessories, etc.
- Using the data for simulation purposes.

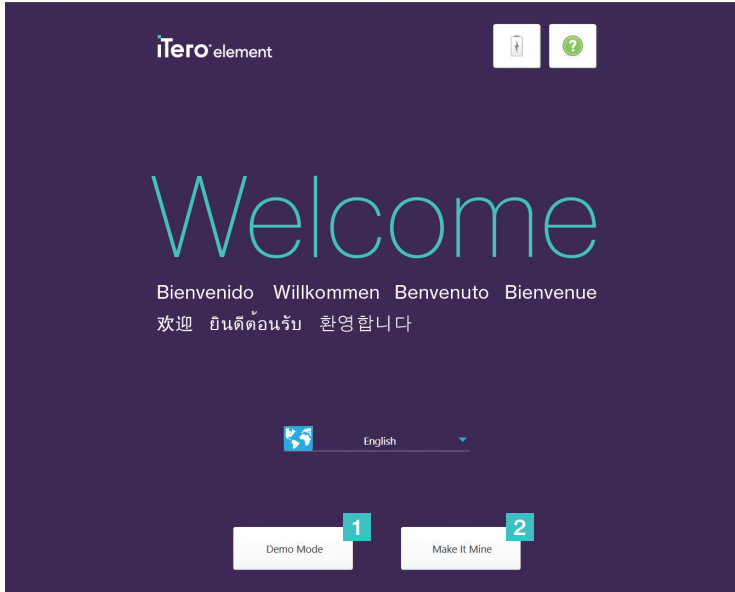
The application also includes administrative capabilities which enable the user to:

- Start a new scan.
- Place a new order for an existing patient or new patient.
- View orders in progress.

Review and/or track past orders.

Chapter 1:

System registration



- 1 Demo Mode
- 2 Make it Mine

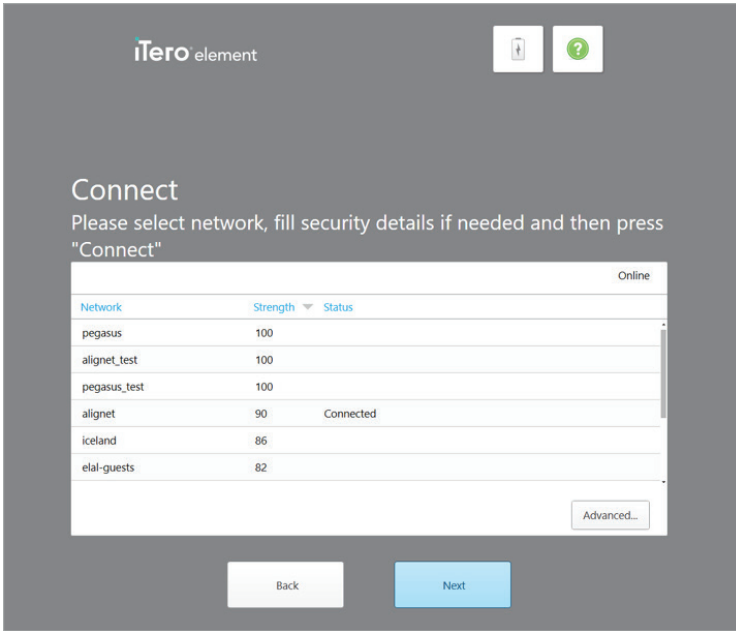
Demo Mode

Press Demo Mode to familiarize yourself with the scanner's features and perform practice scans without submitting the scans. Demo Mode is designed for training new staff members and practice. Demo Mode is available anytime for dental practices to train on an iTero Element 5D device, for scanning techniques, how-to guidelines for prescription forms, case types, and to familiarize with the iTero interface. Demo Mode will feature all the aspects of the scanning process and include a wide variety of cases. Sample cases offered will include clinical cases, Invisalign cases, and restorative cases for your convenience.

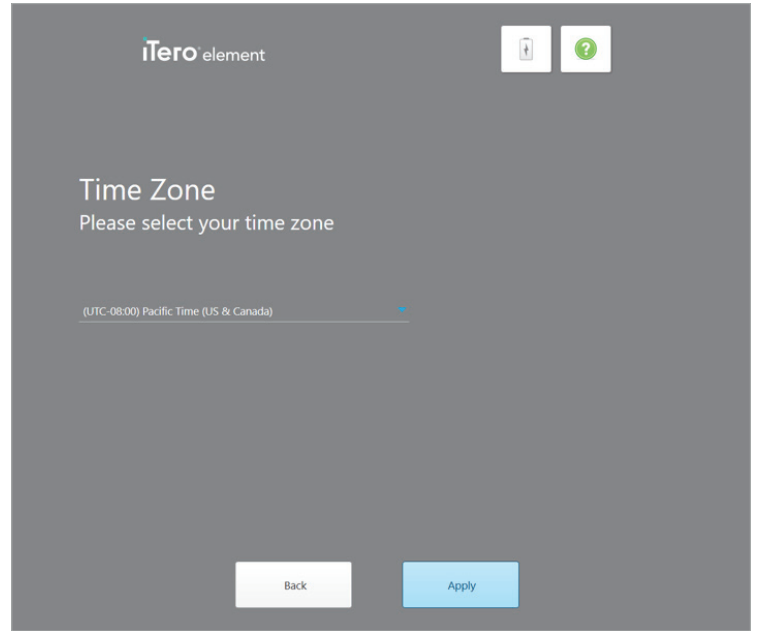
When Demo Mode is in use for practice scanning, a lightly striped background and red tag in the upper left-hand corner will indicate Demo Mode. **Any scans captured in Demo Mode cannot be saved or submitted for patient treatment.** Demo Mode is available to access on the Welcome screen or at any point by pressing the iTero Element logo button on the home screen.

Make it Mine

Press Make It Mine to register your scanner. Please have your User Name, User Password, and Company ID ready to complete the registration process. You will receive an email from an iTero representative with login credentials and detailed information on the how to Make it Mine procedure.



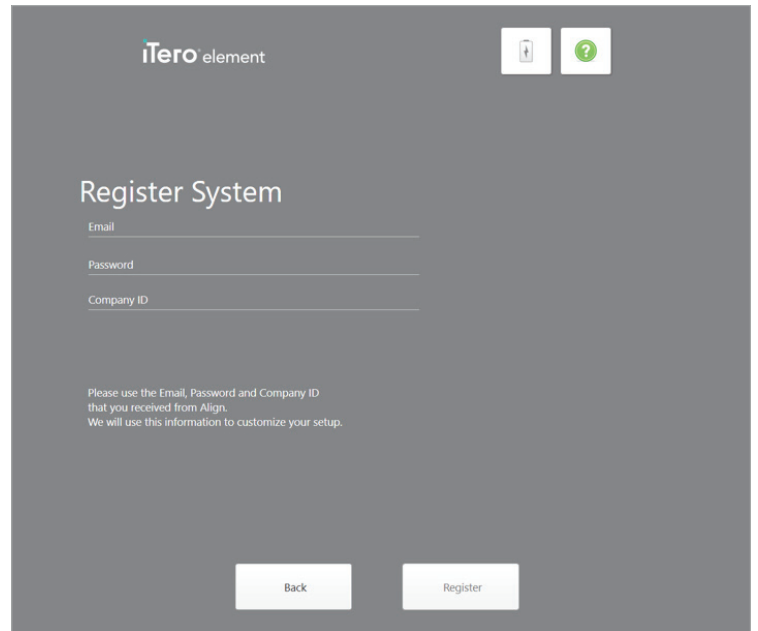
1. Select the appropriate Network Connection



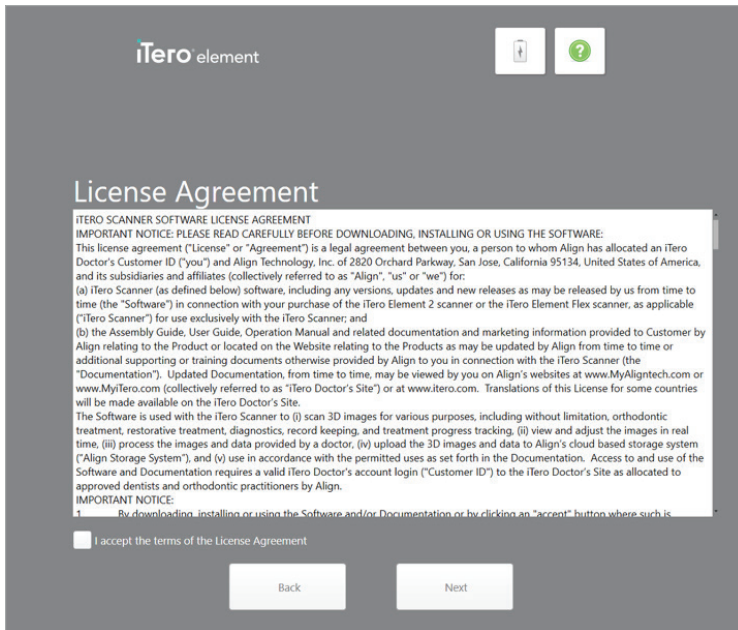
3. Register the system



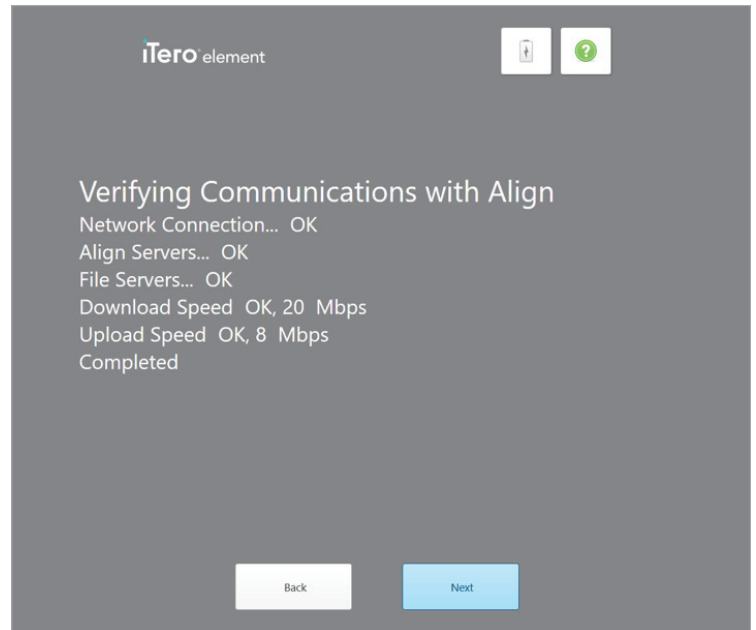
2. Network connection verification



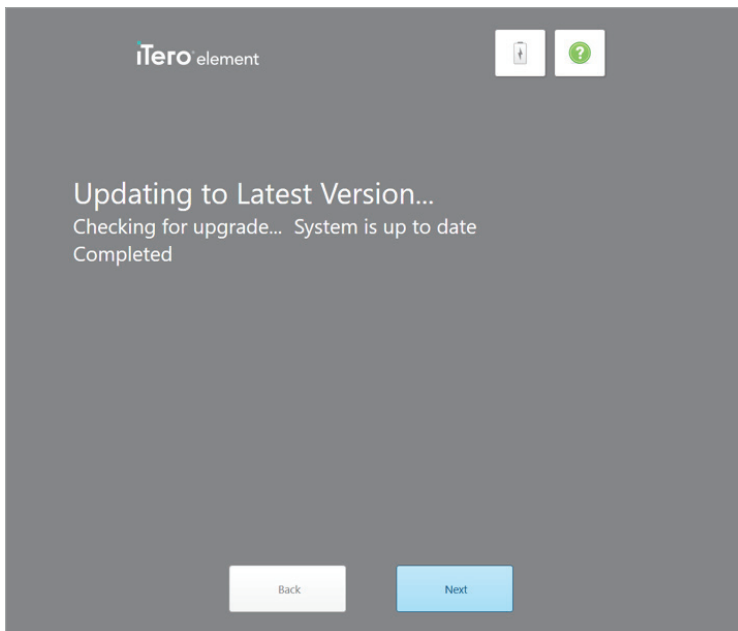
4. System is registered



5. Accept the License Agreement



7. System is now ready



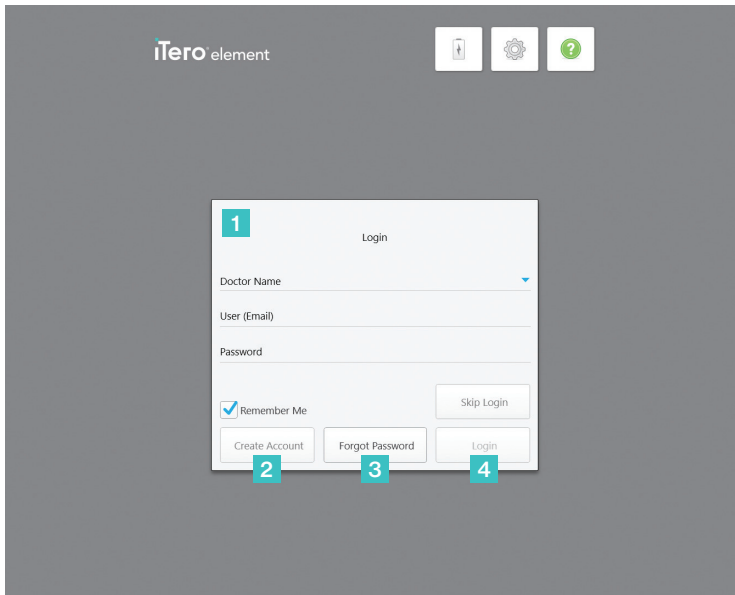
6. Updating SW to the latest version

Chapter 2:

Logging in to the scanner application

Login

When the scanner is powered on, the login screen for the iTerO Element 5D will appear.



- 1 User information
- 2 Create Account
- 3 Forgot Password
- 4 Login

Please have your MyiTero account information ready when logging in to the iTerO Scanner. You will need your name, account email, and password. Fill out all the necessary fields and click the Login button.

Create account

To create an account, please press the bottom button labeled Create Account. Enter an email and create an account to use on the iTerO Scanner and MyiTero.com.

Forgot password

If you forgot your password, press the lower button labeled Forgot Password. Enter your registered account email and a temporary password will be sent to your email. Alternatively, answer your predetermined security question and gain access to the account from the scanner.

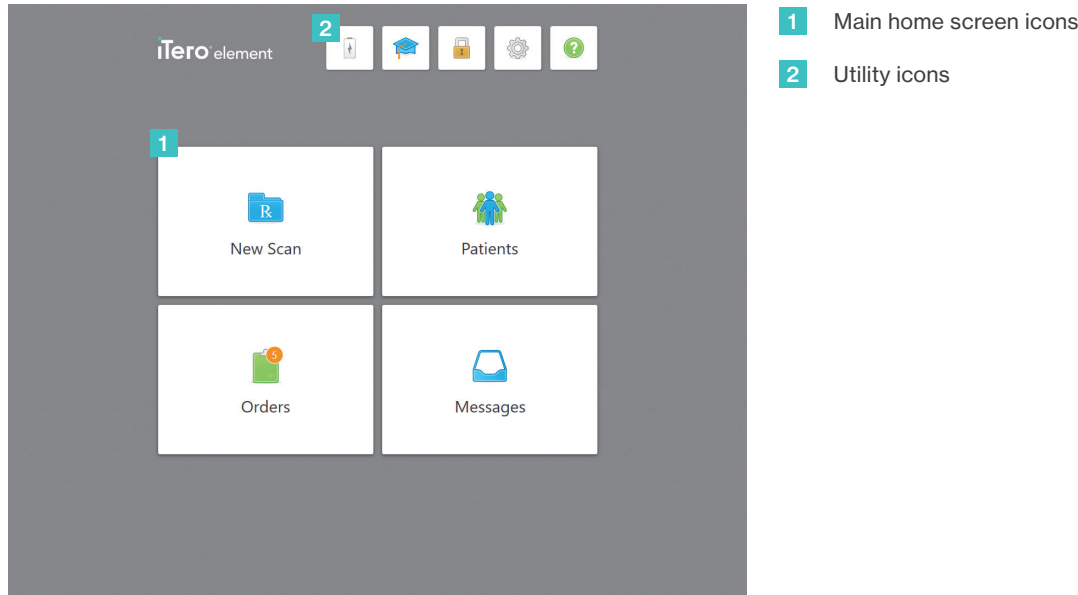
Chapter 3:

iTero Element 5D main features

Home screen

The iTero Element 5D home screen provides access to all the main features of the iTero software.

Below is an image of the iTero Element 5D application's home screen.



Main desktop icons

There are four main home screen icons for the iTero Element 5D software.

New Scan: To begin a new scan for a patient, select the New Scan icon. This home screen icon navigates to the iTero Rx form to fill out the prescription form for a patient and begin scanning.

Patients: To look up any patient on your system, select the Patients icon. This home screen icon navigates to the Patients page. Search for a specific patient, scroll through recently scanned patients, review scans, access iTero TimeLapse, view patient history, add new scans, or add a treatment plan.

Orders: To view the status of your orders, select the Orders icon. This home screen icon navigates to a list of orders in progress or past orders.

Messages: To read messages, select the Messages icon. This home screen icon navigates to the message inbox, where you may read on the latest notifications from the Align team regarding new updates, improved features, enhanced tools, and latest developments.

Utility icons

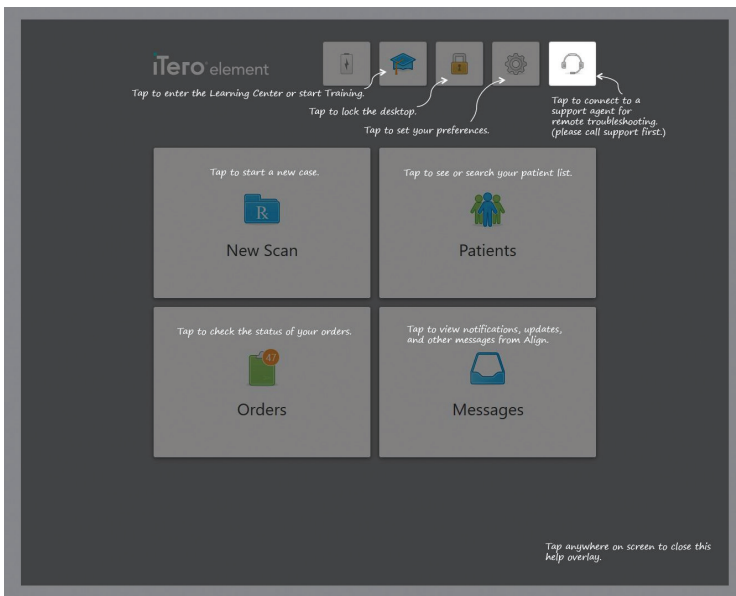
Battery: To view the charge on the iTero external battery, press the Battery icon. A battery indicator will appear and specify how long the battery has until the iTero Element 5D may need to be charged again. When the battery icon displays a lightning bolt symbol, the battery is charging. Note: this feature only appears in supported iTero Element 5D scanners.

Learning Center: To access training materials and educational videos for your iTero Element 5D, press the Learning Center icon.

Lock: To log out of an account whenever the iTero Element 5D is not in use, press the Lock icon. This will help ensure that the dental practice is HIPAA compliant and that all medical information is secure.

Settings: To adjust preferences for your iTero Element 5D like wand configuration, localization, user settings, and more, press the Settings icon.

Help: To navigate icons for home screen and helpful hints, press the Help icon. A transparent Help overlay appears over the screen to aid in navigation of features and tools. At any time, tap the Help icon for assistance. Tap anywhere to close the Help screen and return to the relevant screen. Customer support is available on every Help overlay.



Touch screen gestures

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

Examples of common touch screen gestures:



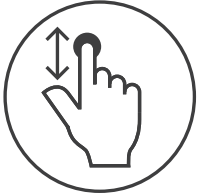
Tap



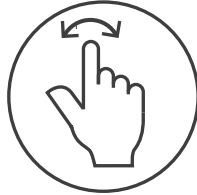
Double tap



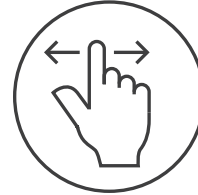
Long press



Scroll



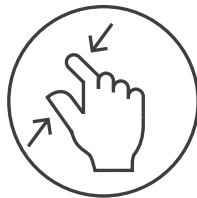
Rotate



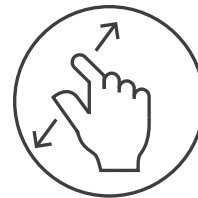
Swipe



2 finger tap



Zoom in/pinch



Zoom out



Pan

Wand controls



- 1** Side buttons
- 2** Touchpad

Side buttons: Press and release either of the side buttons on the wand to start or stop the scanning process. Press the buttons simultaneously to activate the touchpad.

Touchpad: Once activated, swipe left or right on the touchpad to navigate between scan segments. Press and hold the touchpad will enable the gyro function to rotate the model on the screen.

Demo Mode

To access demo mode, press the iTero Element logo on the upper left side of the home screen. A menu will appear to press Demo Mode or to cancel and return to the home screen. Demo Mode will appear with all the same functionality as when taking a normal scan. No data will be permanently saved.

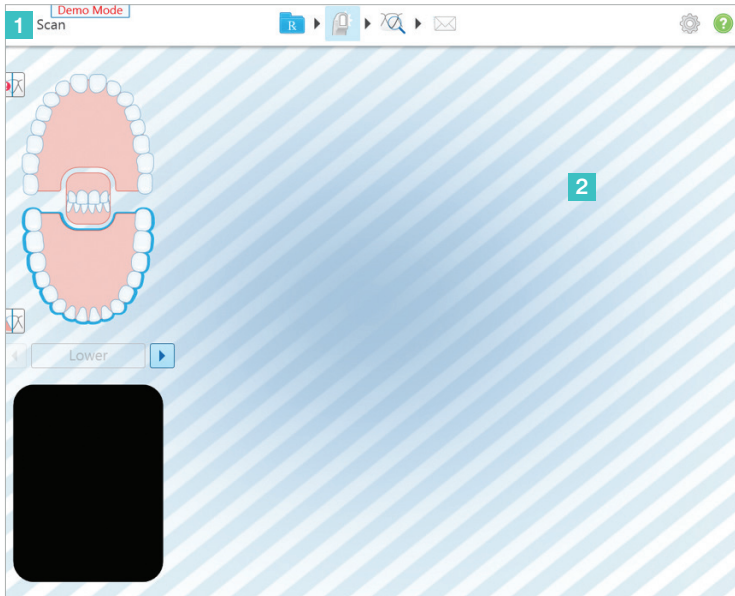


- 1** Demo Mode
- 2** Exit to Windows
- 3** Cancel

Demo Mode: Initiate Demo Mode for practice without saving any data.

Exit to Windows: To Exit the iTero interface and return to Windows. Note: Only available on iTero laptop configuration devices.

Cancel: To exit from the screen and return to normal use.



- 1 Demo Mode tag
- 2 Striped background

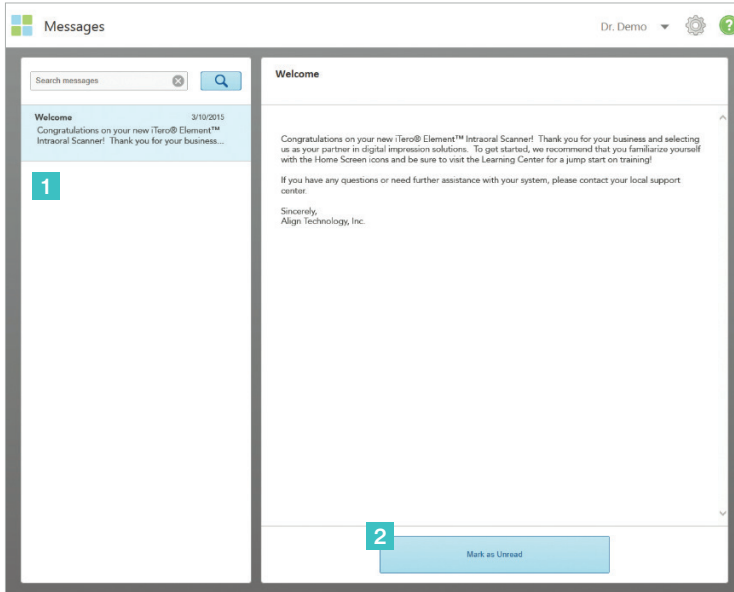
Demo Mode tag: The red tag indicator when using Demo Mode.

Striped background: A striped background will appear while scanning. It is designed to prevent scanning real patients in Demo Mode.

Practice any portion of the patient experience. **Any scans taken during Demo Mode cannot be submitted for treatment.** To exit Demo Mode, please go back to the home screen and press the iTero Element logo. The menu for Demo Mode will appear in order to exit Demo Mode.

Chapter 4:

Messages



1 Inbox

2 Mark as Unread

Press the Messages icon from the home screen to view notifications, updates and other messages from Align Technology. On the left side of the page, search for specific messages by subject title quickly or, press on the right side of the screen and scroll down the page to search and find a specific message. To mark any message as unread, press Mark as Unread.

Chapter 5:

Orders

Tap on the Orders icon to view or review In Progress or Past Orders.

The screenshot shows the iTero Orders interface for Dr. Sarah Smith. It is divided into two main sections: 'In Progress' and 'Past Orders'.

In Progress (1): This section contains a table with the following data:

ID	Patient Name	Chart Number	Scan Date	Case Type	Status
	Jane White			Restorative	Rx Created
	Anne Miller		03/30/2017 15:10:10	Restorative	Scanning
	Joe Johnson			iRecord	Rx Created
	James Doe		03/27/2017 10:47:47	iRecord	Scanning
	Joe Smith			iRecord	Rx Created
	Bill Williams			iRecord	Rx Created
	Sarah Jones		03/27/2017 10:30:47	iRecord	Scanning

Past Orders (2): This section features a search bar and a table with the following data:

ID	Patient Name	Chart Number	Scan Date	Case Type	Status
11358871	Jane Doe		03/27/2017	iRecord	Completed

Below the 'Past Orders' table, there are several action buttons: 'View Rx', 'Viewer', 'Add Rx', 'Invisalign Outcome Simulator', and 'Progress Assessment'.

1 In Progress

2 Past Orders

In Progress: Scans that have not been submitted.

Past Orders: Orders that have been submitted. Press on any order to check the status of the scan.

Clicking on a past order shows the following options, depending on the case type.

View Rx: View the prescription for this order.

Viewer: View the scans for this order.

Add Rx: Add a prescription for this order (only applicable for Orthodontic orders and available up to 21 days after a scan).

Invisalign doctors may also select Invisalign features such as Invisalign Outcome Simulator.

Chapter 6:

Scan

Start a new scan

To start a new scan, press the New Scan icon from the home screen or press the new scan button from the Patient page.

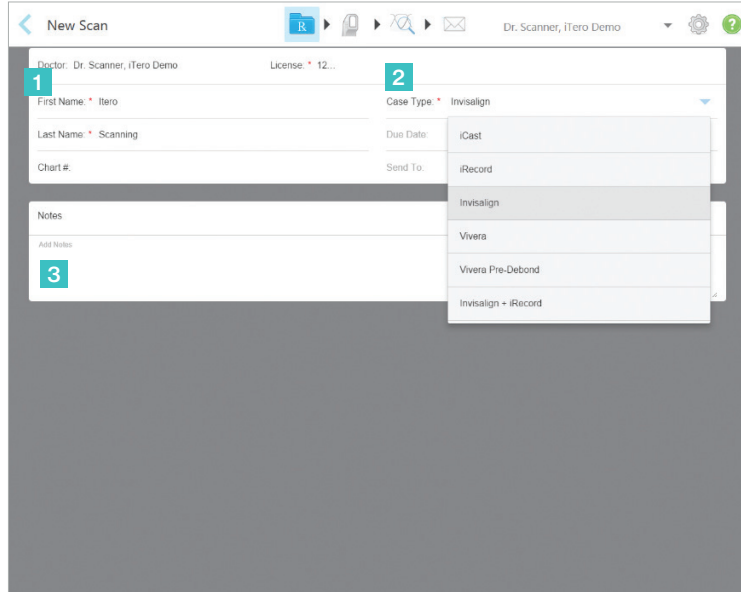


Prescription icon: The first step in the New Scan workflow. Fill out the prescription form with patient information, case type, and any notes to include.

Scan icon: The second step in the New Scan workflow. Scan the patient for a new scan to be captured.

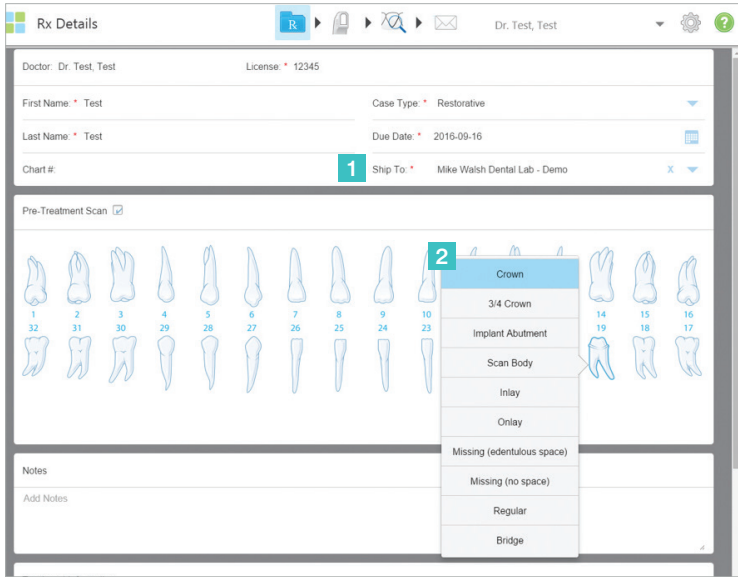
View and Review icon: The third step in the New Scan workflow. Inspect the scan and examine that all adequate data has been captured.

Send Case icon: The final step in the New Scan workflow. Sign the confirmation form and send the case to its destination for storage or additional work needed.



- 1 Patient information
- 2 Case Type
- 3 Notes

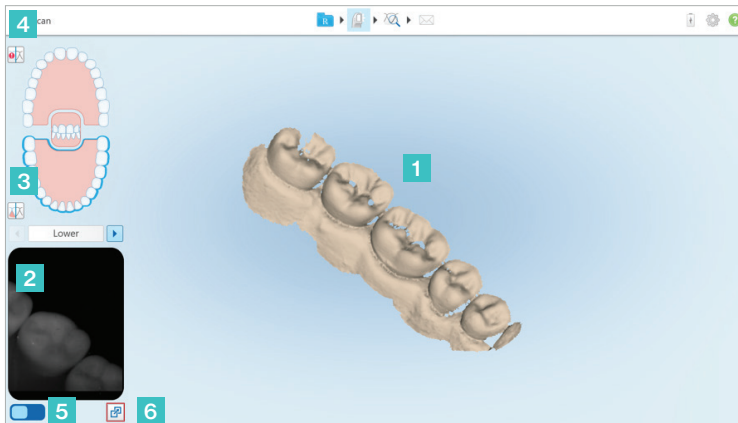
For Restorative cases, select the case type and restoration needs for the appropriate indication. For Orthodontic cases, such as Invisalign or iRecord, select the case type and enter in patient information.



- 1 Select a lab to send the case
- 2 Select the restoration type from the dropdown

After selecting the case type for a patient, please begin scanning.

To start a scan, tap the scan icon.



- 1 Real time modeling
- 2 View finder
- 3 Color
- 4 Scan feedback
- 5 Toggle view
- 6 Enlarge view

Scan feedback: To view any missing tooth, soft tissue, or oral structure during the scan.

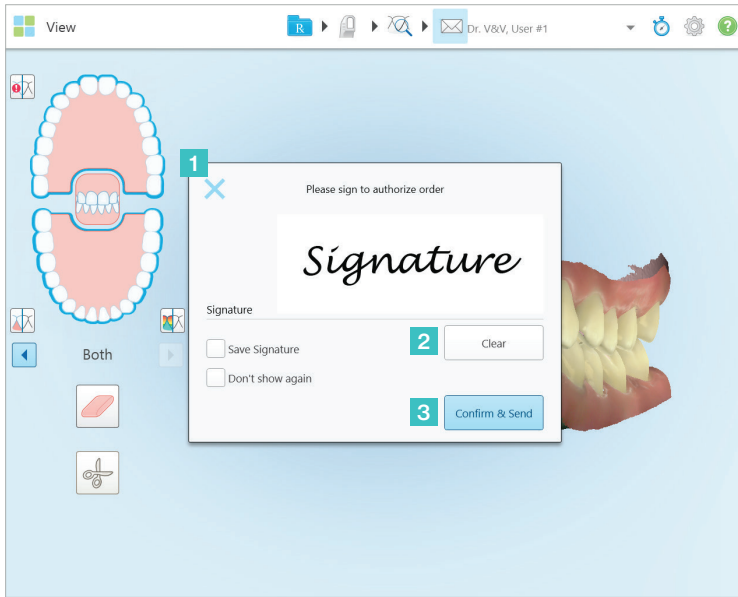
Color: To switch from scan to color view.

View finder: View the wand's current positioning.

Toggle View: Toggle between displaying a color image or a NIRI image in the viewfinder

Enlarge View: Switch to a large viewfinder in the middle of the screen

After reviewing the scan, sign the Rx form and send the scan to complete the case.



- 1 Signature box
- 2 Clear
- 3 Confirm & Send

Signature box: Sign your signature here with a finger. Check "Save Signature" to store a signature away for future ease and use. Check "Don't show again" to eliminate this step.

Clear: To clear a signature from the signature box.

Confirm & Send: Confirm scan has been reviewed and send the scan to a lab or iTero storage.

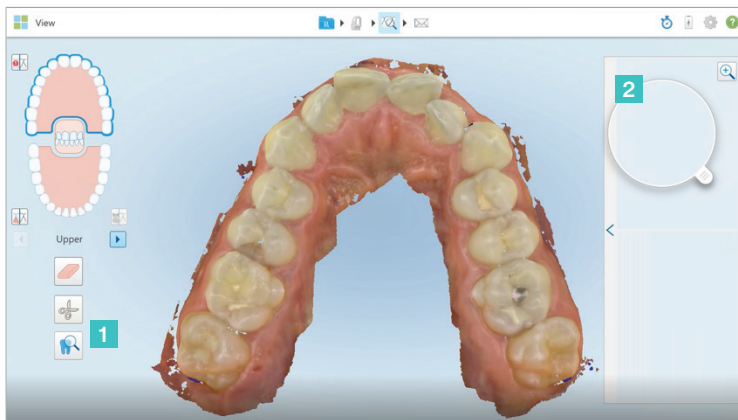
Chapter 7:

iTero Element 5D screens

In addition to scanning, the iTero Element 5D scanner provides a Near Infra-Red Imaging (NIRI) mode. The NIRI and ViewFinder color images are captured during the scan, and can be reviewed, once scanning has completed.

Review tool for iTero Element 5D imaging systems

After scan is completed, go to View and Review icon, inspect the scan and examine that all adequate data has been captured, including NIRI and color images, on specific locations in the mouth.

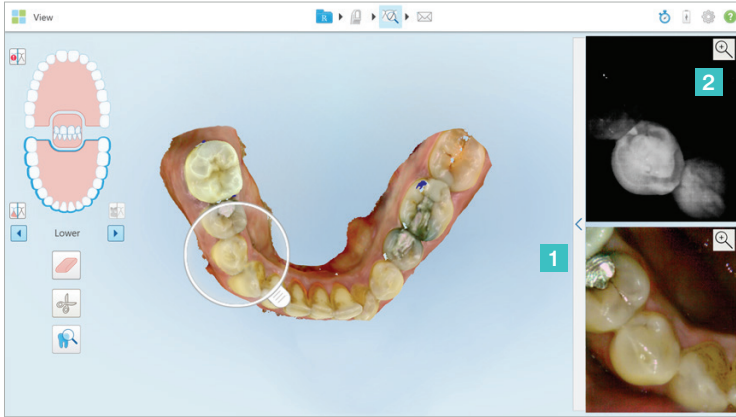


1 Review tool

2 Loupe

Review tool: Displays the Color and NIRI images captured during scan

Loupe: When loupe is dragged to the scan, the Color and NIRI images are displayed according to the specific location of the loupe on the scan



- 1 Zoom in button
- 2 Brightness and contrast toolbar

Zoom in button: Viewfinder window will be enlarged and only the specific image will be displayed in the viewfinder.

Brightness and contrast toolbar: Opens the brightness and contrast adjustment toolbar.

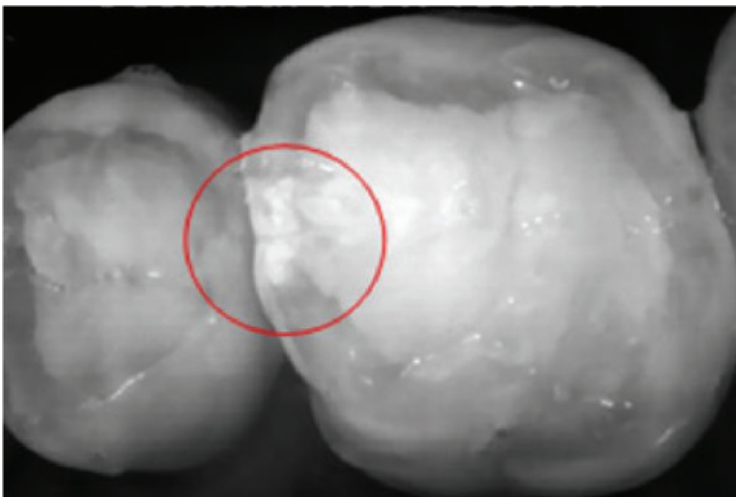
After review and confirmation that the scan has been captured with sufficient data, the following features can be used to view the scan in color or monochrome, edit the scan, remove any extra scanned artifacts, and erase additional scanned materials.

Using NIRI

NIRI provides imaging of the internal tooth structure.

Structure translucency translates in the NIRI image to brightness level; the darker the object the higher is its translucency and vice versa.

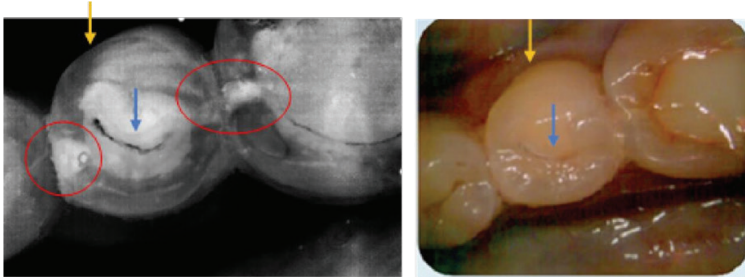
Healthy enamel appears dark, translucent, while dentin or caries are less translucent and appear brighter.



Proximal lesion will appear as bright stripe/wedge-like features as in the image above, in this case proximal lesion reaching all the way to the dentin.

Changing viewing angle around such area may provide more information regarding its depth, while using the color image may help differentiate the diagnosis as well as the lesions severity.

In addition to the NIRI, the color images are also provided to give more information regarding the tooth's health, and help with the diagnosis.



The NIRI above demonstrates two proximal lesions circled in red, reaching all the way to the dentin, while the color image helps determine that the lesions are proximal and not occlusal, as no white/brown spots appear in the correlating areas of the occlusal surface in the color image. The dark lines marked by the blue arrows indicate occlusal fissures.

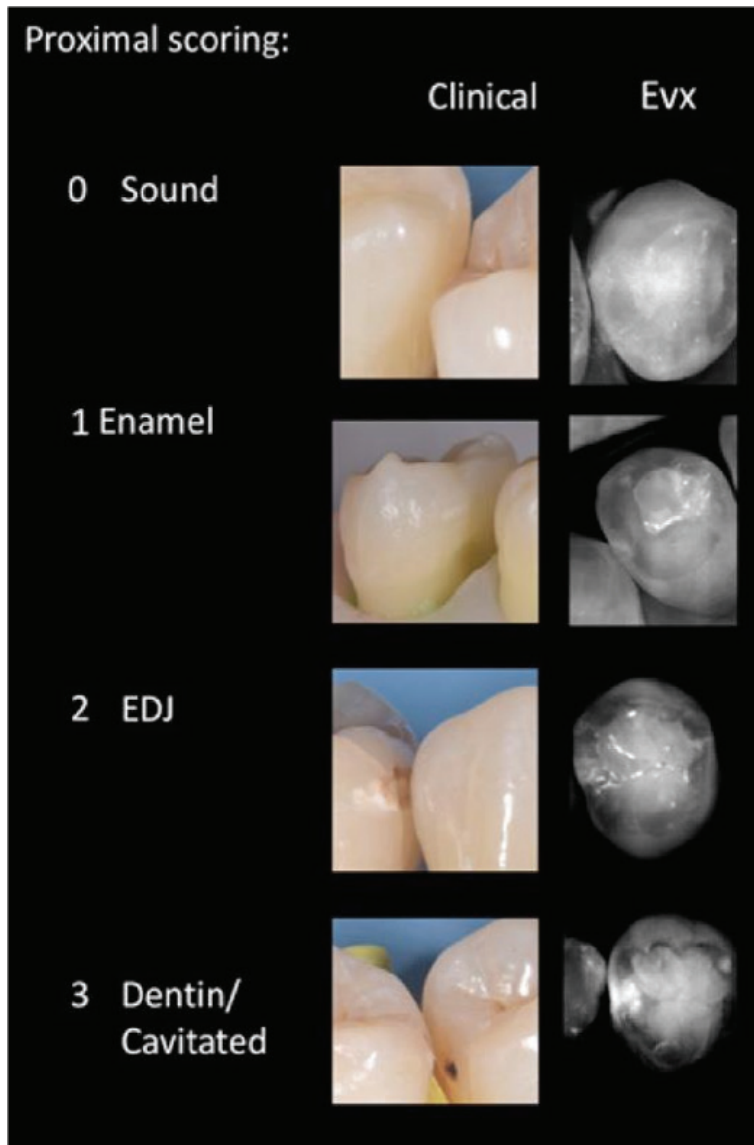
Note: Highly opaque teeth will have low translucency of the enamel making it appear brighter, this may cause difficulty in understanding internal tooth's structures, and differentiating between enamel and dentin, thus affecting the ability to detect proximal caries. In addition, several dental restorations such as amalgam fillings are not translucent for the NIRI, meaning they may mask lesions underneath them.

NIRI along with the color images can assist in the detection of proximal caries.

Proximal caries

Scoring provided according to ICDAS-II standard

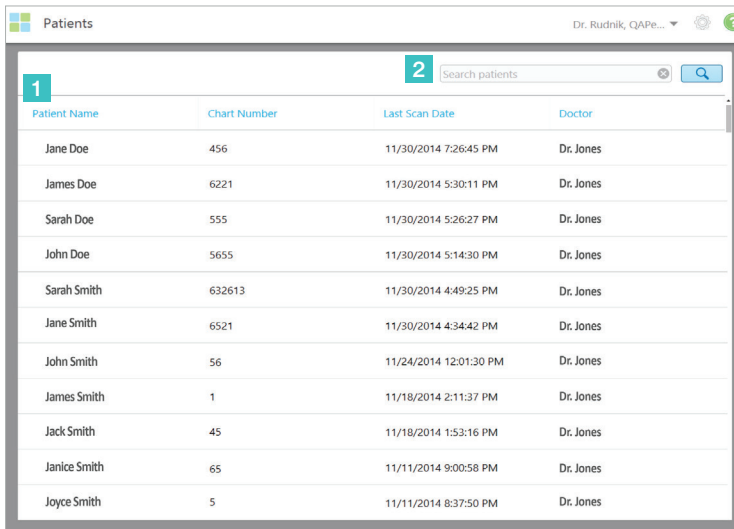
- Sound enamel, will appear without any noticeable bright spots, meaning it will resemble a dark ring circling a bright inner circle representing the dentin.
- Enamel caries appear as a bright spot, which is not reaching the dentin.
- Caries reaching EDJ will appear as bright spot in the enamel dark ring, which connects, to the bright dentin.
- Bright spot in the enamel which is connecting significantly to the bright dentin, may indicate a dentinal/cavitated caries.



Chapter 8:

Patients

On the home screen, press the icon labeled Patients to locate a patient and their scans. Press on a patient to add a new scan or view previous scans.



The screenshot shows the 'Patients' page in the iTero application. The page title is 'Patients' and the user is 'Dr. Rudnik, QAPE...'. A search bar is located at the top right of the patient list area. The patient list is a table with the following data:

Patient Name	Chart Number	Last Scan Date	Doctor
Jane Doe	456	11/30/2014 7:26:45 PM	Dr. Jones
James Doe	6221	11/30/2014 5:30:11 PM	Dr. Jones
Sarah Doe	555	11/30/2014 5:26:27 PM	Dr. Jones
John Doe	5655	11/30/2014 5:14:30 PM	Dr. Jones
Sarah Smith	632613	11/30/2014 4:49:25 PM	Dr. Jones
Jane Smith	6521	11/30/2014 4:34:42 PM	Dr. Jones
John Smith	56	11/24/2014 12:01:30 PM	Dr. Jones
James Smith	1	11/18/2014 2:11:37 PM	Dr. Jones
Jack Smith	45	11/18/2014 1:53:16 PM	Dr. Jones
Janice Smith	65	11/11/2014 9:00:58 PM	Dr. Jones
Joyce Smith	5	11/11/2014 8:37:50 PM	Dr. Jones

1 Patient page

2 Search bar

Patient page: View any patients, see historical scans associated with the patient, access iTero TimeLapse, or add a new scan.

Search bar: Search for specific patients using their names or chart numbers.

Chapter 9:

iTerro TimeLapse

iTerro TimeLapse compares previously captured patient's 3D scans to allow a clinician to visualize changes of a patient's teeth, tooth structures, and oral soft tissues.

Patients scanned on a regular basis can be analyzed using the iTerro TimeLapse tool.

In the patient's profile, select two scans from the timeline at the bottom of the screen. Once two scans are selected, press the Compare Selected button to analyze the scans.

The screenshot shows the iTerro TimeLapse interface for a patient named "Demo, Toothwear". The interface includes a sidebar with patient information (Name, Chart Number, Last Scan) and a "New Scan" button. The main area displays a table of orders with columns for ID, Scan Date, Case Type, and Status. Two orders are listed, both with checkboxes selected. Below the table is a "Timeline" section with a left arrow, two checkboxes (both selected), and a right arrow. The dates 01/14/2017 and 07/12/2017 are shown under the checkboxes. A "Compare Selected" button is located at the bottom right of the timeline.

ID	Scan Date	Case Type	Status
<input checked="" type="checkbox"/> 9049356	07/12/2017	iRecord	Completed
<input checked="" type="checkbox"/> 9049355	01/14/2017	iRecord	Completed

Timeline: 01/14/2017 07/12/2017

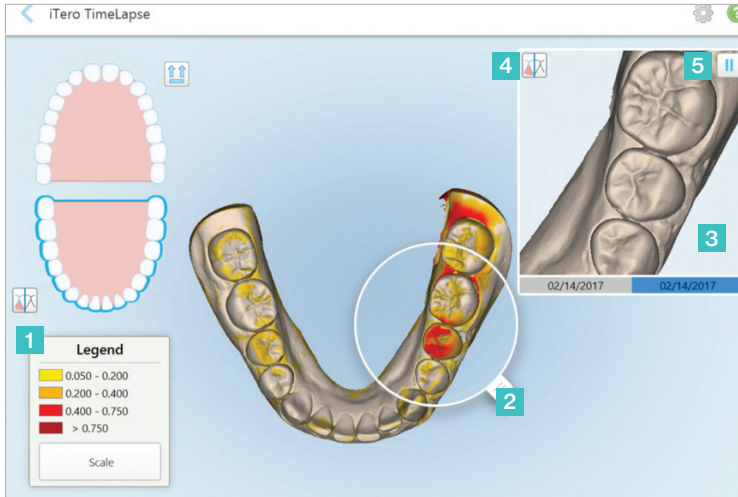
Compare Selected

- 1 Timeline
- 2 Scan selection checkboxes
- 3 Compare selected

Timeline: Scans taken over time of the patient.

Scan selection checkboxes: Selected scans to compare and visualize in iTerro TimeLapse.

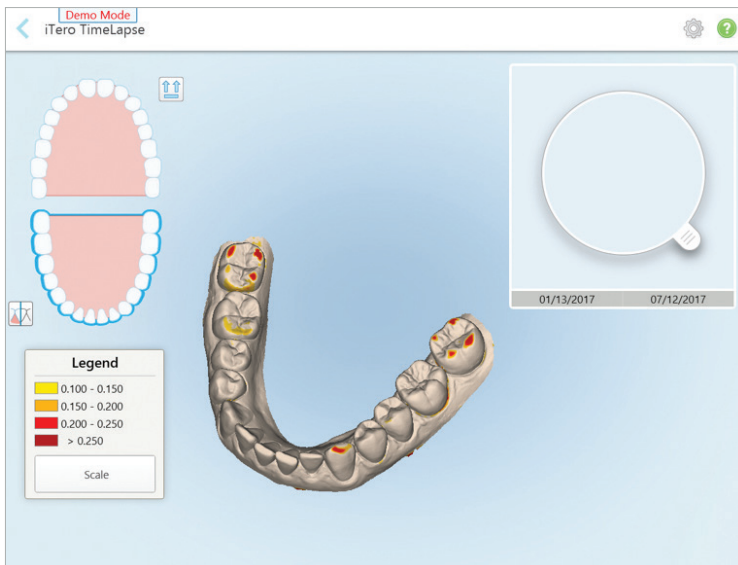
Compare selected: Analyze scans using iTerro TimeLapse.



- 1 Color Legend
- 2 Loupe
- 3 Animation window
- 4 Color visibility
- 5 Play/pause

Color Legend: Highlighted areas with the most changes between scans with rich color. Scale measurements are in millimeters.

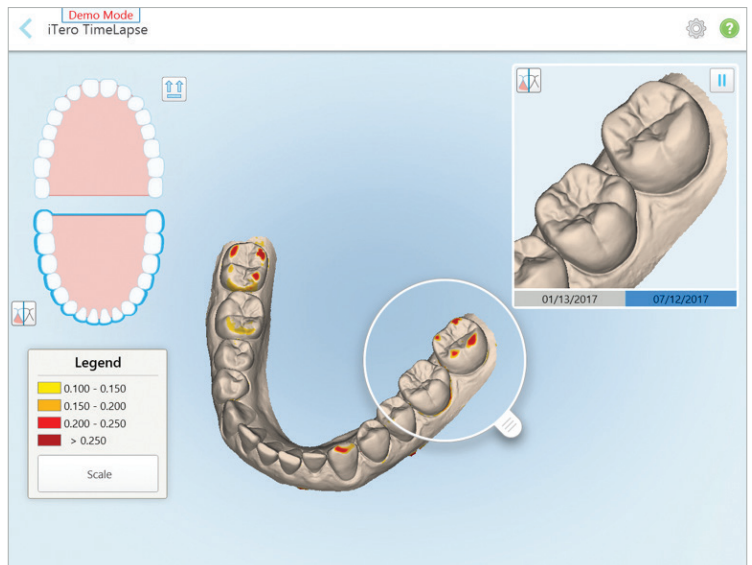
Loupe: To view areas in detail and visualize points of interest in the Animation Window. Drag the loupe from the animation window to the area of interest in order to magnify potential treatment spots. The areas in which appear in the loupe will be magnified within the animation window.



Animation window: Visualize fine details of changes for the scans selected.

Color visibility: Toggle between monochrome and color in the Animation Window.

Play/pause: To play or pause the Animation Window.



Chapter 10:

iTero Element 5D Operational manual

The iTero Element 5D system is delivered as a proprietary, PC-based workstation for performing intra-oral scans in the doctor's office. This document describes how to start and shut down the system, how to correctly handle the Scanning Unit/Wand and cable, and how to clean the Scanning Unit and replace its sleeves between patients.

This section is referenced from the iTero Element 5D operational manual 206519

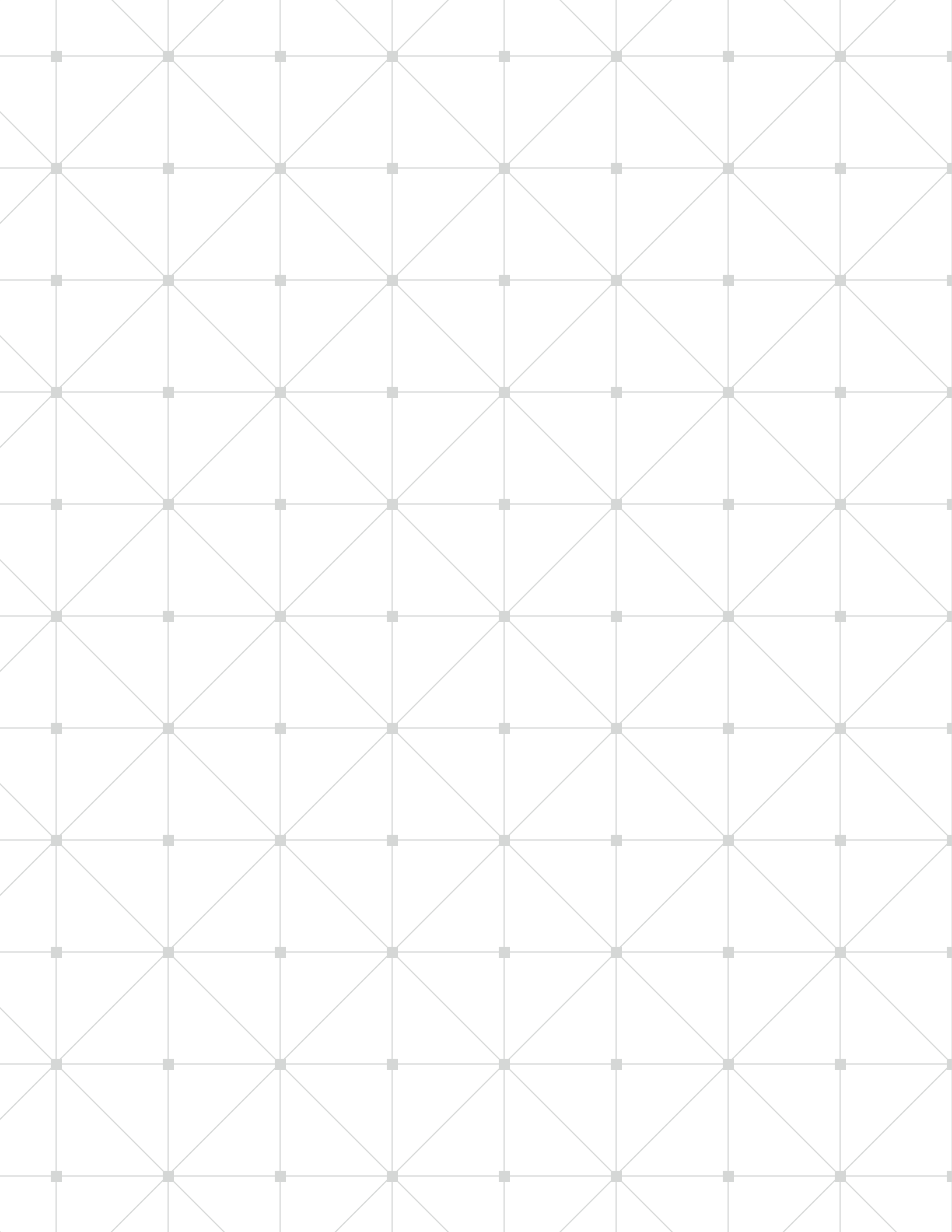
Chapter 11:

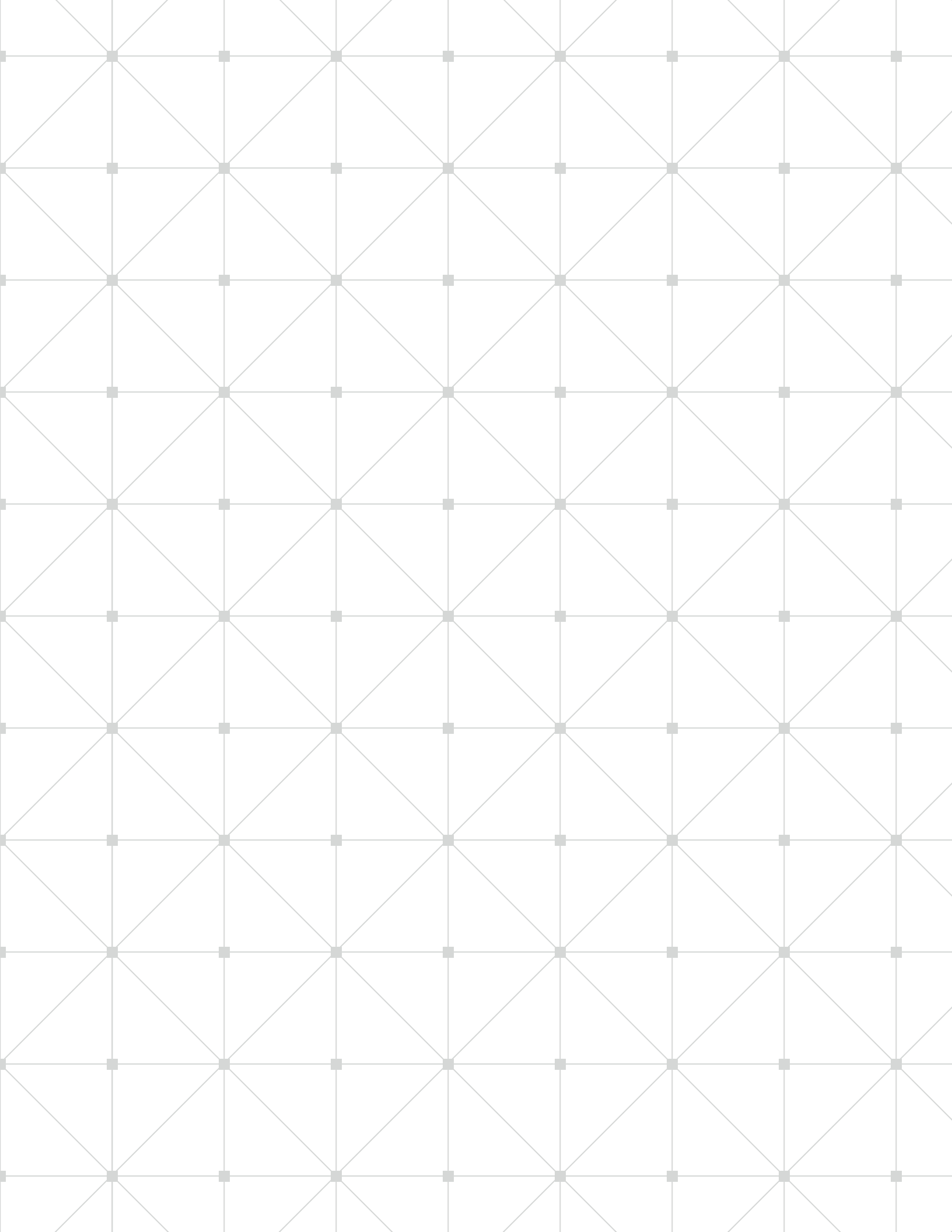
iTero Element 5D laptop configuration Operational manual

The iTero Element 5D laptop configuration system is delivered as a proprietary, laptop based workstation for performing intra-oral scans in the doctor's office. This document describes how to start and shut down the system, how to correctly handle the Scanning Unit/Wand and cable, and how to clean the Scanning Unit and replace its sleeves between patients.

This section is referenced from the iTero Element 5D laptop configuration operational manual 206520

Notes:





iTero element 5D

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