

iTero Element™ 2 iTero Element™ Flex iTero Element™ 2 Plus intraoral scanners

User manual



it starts with **iTero™**

Copyright

© 2026 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

PN 218501 Rev. E
Updated April 2026

Patents

www.aligntech.com/patents

Trademarks

Align, Invisalign, ClinCheck, iTero and iTero Lumina 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.

Global headquarters**Align Technology, Inc.**

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

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

Align Technology Ltd.

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

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

**Align Technology B.V.**

Herikerbergweg 312
1101 CT, Amsterdam
The Netherlands

Compliance

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.

Class 1 laser compliance

This device complies with 21 CFR 1040.10 and IEC 60825-1.



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.

RCM and R-NZ compliance

This device complies with Australian RCM and New Zealand Radio Label requirements.



Safety compliance

This device complies with the following safety standards:

- IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
- IEC 80601-2-60: Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- IEC 60825-1: Safety of laser products – Part 1: Equipment classification, requirements and user's guide
- IEC 62471: Photobiological safety of lamps and lamp systems

ANATEL compliance

This device complies with ANATEL resolution nº 242/2000 under the number ANATEL 02563-15-06534.

CSA compliance

This device complies with CSA standards.

This marking means that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.



CE compliance

This device complies with Council Regulations (EU) 2017/745 for Medical Devices.



Contraindications

For persons who have been diagnosed with Epilepsy, there is a risk of epileptic seizure from the flashing light of the iTero scanner.

Nature of emitted scanner radiation

- **Electromagnetic radiation (EMR)** - When used as directed, the iTero scanner's level of electromagnetic radiation is similar to that of a personal computer and complies with International Standard IEC 60601-1-2.
- **Laser and LED radiation** - When used as directed, the iTero scanner's level of Laser and LED radiation is incapable of producing damage to eyes or other human tissue and complies with International standards IEC 62471 and IEC 60825-1.

Symbols

The following symbols may appear on iTero Element 2 and iTero Element 2 Plus hardware components and may appear within this document and other iTero Element literature.

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read before using this device.	ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs.	M002
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.	IEC 60417 Graphical symbols for use on equipment.	5840
	Do not re-use	Indicates a medical device that is intended for one single use only.	EN/ISO 15223-1*	5.4.2
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN/ISO 15223-1*	5.1.5

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Waste electrical and electronic equipment (WEEE)	Separate collection of electrical waste and electronic equipment is required. In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE), do not dispose of this product in domestic or municipal waste. This device contains WEEE materials. Please contact the EARN service. Link for the online request form: http://b2btool.earn-service.com/aligntech/select	EN 50419 Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE).	N/A
	Caution	Wherever this symbol appears on the device, it is mandatory to refer to safety-related information in this document.	EN/ISO 15223-1*	5.4.4
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	EN/ISO 15223-1*	5.3.9
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	EN/ISO 15223-1*	5.3.8
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	EN/ISO 15223-1*	5.3.1

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	This way up	To indicate correct upright position of the transport package.	ISO 7000 Graphical symbols for use on equipment Registered symbols	0623
	Direct current	To indicate on the rating plate that the equipment is suitable for direct current (DC) only.	IEC 60417 Graphical symbols for use on equipment.	5031
	Wand	Scanning unit.	N/A	N/A
	Unique device identifier	Indicates a carrier that contains unique device identifier information.	EN/ISO 15223-1*	5.7.10
	Country of manufacture (including date of manufacture)	To identify the country of manufacture of products. The date of manufacture is located adjacent to the symbol.	EN/ISO 15223-1*	5.1.11
	Prescription device	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 trained dental healthcare providers only.	21 CFR 801.15(c) (1)(i)F	Labeling - Medical devices; prominence of required label statements; use of symbols in labeling.

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Manufacturer	Indicates the medical device manufacturer.	EN/ISO 15223-1*	5.1.1
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN/ISO 15223-1*	5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	EN/ISO 15223-1*	5.1.7
	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current (AC) only.	IEC 60417 Graphical symbols for use on equipment.	5032
	Keep dry	Indicates a medical device that needs to be protected from moisture.	EN/ISO 15223-1*	5.3.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN/ISO 15223-1*	5.3.7
	Medical device	Indicates the item is a medical device.	EN/ISO 15223-1*	5.7.7
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	EN/ISO 15223-1*	5.4.3

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Universal Serial Bus (USB), port/plug	To identify a USB port.	ISO 7000 Graphical symbols for use on equipment - Registered symbols.	3650
	Battery	To identify the location of the panel PC battery.	N/A	N/A
	Stand-by	To identify the power on/standby push button.	IEC 60417 Graphical symbols for use on equipment.	5009
	Swiss authorized representative	Indicates the authorized representative in Switzerland.	MU600_00_016 version 5.0 Obligations Economic Operators CH.	N/A
	RoHS compliant for China	Indicates the electrical product contains certain hazardous substances and can be used safely during the environmental protection use period of 10 years and should be recycled after its environmental protection use period comes to an end.	SJ/T 11364 Marking for the restriction of the use of hazardous substances in electrical and electronic products.	N/A
	CE marking/CE marking of conformity	Indicates that a device is in conformity with the applicable requirements set out in EU MDR 2017/745 regulation and other applicable Union harmonisation legislation providing for its affixing.	Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices.	Annex V of EU MDR 2017/745

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
QTY	Quantity	Indicates the number of items in the package.	NA	NA
 / 	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community/European Union.	EN/ISO 15223-1*	5.1.2
	Stepping prohibited	Indicates no stepping on the surface.	ISO 7010:2020	P019
	Regulatory Compliance Mark (RCM)	Australian RCM label	AS/NZS 4417.1:2012 Regulatory Compliance Mark For Electrical And Electronic Equipment	N/A
	R-NZ mark	New Zealand Radio label	Radiocommunications (Compliance) Notice 2020	N/A

***Glossary References:** EN/ISO 15223-1 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements.

Safety instructions

Before using the system, all users are required to read and understand these safety instructions.

The terms below indicate the different levels of safety information:

- **Warning:** Indicates a potential hazard that could result in serious injury if not avoided.
- **Caution:** Indicates a potential hazard that could result in minor or moderate injury if not avoided.
- **Note:** Important information that is not a warning/caution but must be strictly followed.

Power supply	Power is supplied to the system via a medical-grade power supply. In iTero Element 2 Plus cart-configuration scanners, the power supply is enclosed in the base of the wheel stand. In iTero Element 2 Plus mobile-configuration scanners, the power supply is external.
Battery power	• Charging – the scanner battery will be fully charged after being plugged into a power source for 2 hours (iTero Element 2) or 2.5 hours (iTero Element 2 Plus). • With a fully-charged battery, you can scan for up to 30 minutes using the wheel-stand or cart-configuration scanner, or 10 minutes using the mobile-configuration scanner. Warning: The cart-configuration scanners are provided with two Li-ion rechargeable battery packs and the wheel-stand configuration and mobile-configuration scanners are provided with one battery pack. There is a danger of battery explosion if the screen is damaged. Do not use the scanner if dropped or any damage is noticed. Contact Customer Support. • Use only the original AC/DC adaptor connected to the system to charge the batteries. • Warning: A failing Li-ion battery begins to hiss, bulge, and leak electrolytes. The electrolytes consist of lithium salt in an organic solvent (lithium hexafluorophosphate), which is highly flammable. Burning electrolytes can ignite combustible materials in close proximity. Please note, there is a risk of burns associated with this situation. • The screen should be stored and operated following the environmental conditions that appear in this manual. Do not expose the scanner to extreme heat sources, such as radiators and fireplaces. • Never operate the device without batteries! Do not use the batteries for any purpose other than the intended use of the product. Discard used batteries according to the manufacturer's instructions and local requirements. • Replace the batteries only with the same battery type supplied by Align.
Electric warnings	• Do not remove external panels and covers in order to avoid electrical shock. There are no user-serviceable parts inside. In iTero Element 2 Plus scanners, you can open the cover of the diagnostics panel in case of system failure, only when required by Customer Support. • Do not connect the scanner to a mains supply without protective grounding, in order to avoid the risk of electrical shock.

iTero Element Flex:

Electric precautions

- The iTero Element Flex scanner is provided with a hub containing the power supply for the wand. Do not place the system on a wet surface or step on it, in order to avoid the risk of system damage and electrical shock.
- Never connect the hub to a laptop that is not approved according to IEC 60950-1 or IEC 62368-1, as applicable. The laptop and all its accessories should be located at least 1.5m away from the patient. Do not scan a patient and touch the laptop or any of its accessories at the same time. Not following these instructions may lead to electrical shock.
- Do not connect a non-Align-approved web camera to the USB sockets on the rear of the touchscreen, 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 supplied by Align Technology to the system, in order to avoid electrical shock.

Wireless LAN

- The system comes equipped with a wireless LAN unit.
- When using the product, maintain a separation distance of at least 20cm between the computing unit and all persons' bodies to ensure compliance with RF exposure requirements.

Safety classifications

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

Prescription health device

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

Scanner precautions

- 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 optical surface facing the cradle, 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.
- **CAUTION:** Keep the wand 2 inches (5 cm) away from magnetically susceptible medical devices, for example, cochlear implants, neurostimulators, stents, and shunts.

Cleaning & disinfection

To avoid cross-contamination, it is mandatory to adhere to the following:

- [Clean and disinfect](#) the wand, cradle, and other system components according to the instructions provided, and [replace the wand sleeve](#) before each patient session.
- Remove and replace gloves after each patient session.
- Discard torn, contaminated, or removed gloves.
- Replace the iTero Element 2 sleeve between each patient. Failing to replace the wand sleeve between patients may cause the inadvertent transfer of microorganisms and other contaminants from one patient to another.
- **CAUTION:** Dispose of iTero Element 2 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.

Note: Contact Customer Support if the scanner box is damaged.

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 computing unit.
- The system is intended for indoor use only. It should not be exposed to direct sunlight, excessive heat, or humidity.
- iTero Element Flex only: 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 room temperature, to avoid internal condensation.

Electromagnetic interference precautions

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 computing unit from the stand after assembly.

Incident notification

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

Conformité – French

Conformité EMC

Cet appareil est conforme à la norme CEM suivante :

CEI 60601-1-2 : Appareils électriques médicaux —
Section 1-2 : Exigences générales pour la sécurité de
base et les performances essentielles — Norme
collatérale : Phénomènes électromagnétiques —
Exigences et essais.

Conformité du laser de classe 1

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



Conformité FCC

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

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



Avertissement de la FCC

Les modifications apportées à l'appareil qui ne sont pas
explicitement approuvées par le fabricant peuvent
révoquer votre droit d'utilisation de l'appareil en vertu du
règlement de la FCC.

Conformité RCM et R-NZ

Cet appareil est conforme aux exigences du RCM
australien et du marquage radio néo-zélandais.



Conformité aux normes de sécurité

Cet appareil est conforme aux normes de sécurité
suivantes :

- CEI 60601-1 : Appareils électriques médicaux —
Exigences générales de sécurité
- CEI 60601-1-6 : Appareils électriques médicaux —
Section 1-6 : Exigences générales de sécurité —
Norme collatérale : Aptitude à l'utilisation
- CEI 80601-2-60 : Appareils électriques médicaux —
Section 2-60 : Exigences particulières pour la
sécurité de base et les performances essentielles
des équipements dentaires
- CEI 60825-1 : Sécurité des produits laser — Section
1 : Classification des équipements, exigences et
guide de l'utilisateur
- CEI 62471 : Sécurité photobiologique des lampes et
des systèmes de lampes

Conformité ANATEL

Cet appareil est conforme à la résolution ANATEL
n° 242/2000 sous le numéro ANATEL 02563-15-06534.

Conformité CSA

Cet appareil est conforme aux normes CSA.

Ce marquage signifie que le produit est homologué
pour les marchés des États-Unis et du Canada, selon
les normes étasuniennes et canadiennes applicables.



Conformité CE

Cet appareil est conforme aux règlements du Conseil
(UE) 2017/745 pour les dispositifs médicaux.



Contre-indications

Pour les personnes souffrant d'épilepsie, la lumière clignotante du scanner iTero peut engendrer un risque de choc épileptique.

Nature du rayonnement émis par le scanner

- **Rayonnement électromagnétique (REM)** — Lorsqu'il est utilisé comme indiqué, le niveau de rayonnement électromagnétique du scanner iTero est similaire à celui d'un ordinateur personnel et respecte la norme internationale CEI 60601-1-2.
- **Rayonnement laser et DEL** — Lorsqu'il est utilisé comme indiqué, le niveau de rayonnement laser et DEL du scanner iTero est incapable de produire des dommages aux yeux ou à d'autres tissus humains et est conforme aux normes internationales CEI 62471 et CEI 60825-1.

Symboles

Les symboles suivants peuvent apparaître sur les composants matériels iTero Element 2 et iTero Element 2 Plus peuvent apparaître dans ce document et dans d'autres documents du iTero Element.

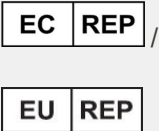
Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Consulter le manuel/la brochure d'utilisation	Pour signifier que le manuel d'instructions/livret doit être lu avant d'utiliser cet appareil.	ISO 7010 Symboles graphiques — Couleurs de sécurité et signaux de sécurité — Signaux de sécurité enregistrés.	M002
	Partie appliquée de type BF	Pour identifier une pièce appliquée de type BF conforme à la CEI 60601-1.	CEI 60417 Symboles graphiques à utiliser sur l'équipement.	5840
	Ne pas réutiliser	Indique un dispositif médical destiné à un usage unique.	EN/ISO 15223-1*	5.4.2

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Code du lot	Indique le code du lot du fabricant, afin que le lot ou l'expédition de produits puisse être identifié.	EN/ISO 15223-1*	5.1.5
	Déchets d'équipements électriques et électroniques (DEEE)	Une collecte séparée des déchets électriques et des équipements électroniques est requise. Conformément à la directive européenne sur les déchets d'équipements électriques et électroniques (DEEE), ne jetez pas ce produit avec les déchets ménagers ou urbains. Cet appareil contient des matériaux DEEE. Veuillez contacter le service EARN. Lien pour le formulaire de demande en ligne : http://b2btool.earn-service.com/aligntech/select	EN 50419 Marquage des équipements électriques et électroniques (EEE) en ce qui concerne la collecte séparée des déchets d'EEE (DEEE).	S.O.
	Attention	Chaque fois que ce symbole apparaît sur l'appareil, il est obligatoire de se référer aux informations relatives à la sécurité dans ce document.	EN/ISO 15223-1*	5.4.4
	Limitation de pression atmosphérique	Indique la plage de pression atmosphérique à laquelle le dispositif médical peut être exposé en toute sécurité.	EN/ISO 15223-1*	5.3.9
	Limitation d'humidité	Indique la plage d'humidité à laquelle le dispositif médical peut être exposé en toute sécurité.	EN/ISO 15223-1*	5.3.8

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Fragile, à manipuler avec précaution	Indique un dispositif médical qui peut être cassé ou endommagé s'il n'est pas manipulé avec précaution.	EN/ISO 15223-1*	5.3.1
	Vers le haut	Pour indiquer la position verticale correcte de l'emballage de transport.	ISO 7000 Symboles graphiques à utiliser sur l'équipement Symboles enregistrés	0623
	Courant continu	Pour indiquer sur la plaque signalétique que l'équipement est adapté au courant continu (CC) uniquement.	CEI 60417 Symboles graphiques à utiliser sur l'équipement.	5031
	Tige	Unité de scan.	S.O.	S.O.
	Identifiant unique de l'appareil	Indique un opérateur qui contient l'information de l'identifiant d'appareil unique.	EN/ISO 15223-1*	5.7.10
	Pays de fabrication (y compris la date de fabrication).	Identifier le pays de fabrication des produits. La date de fabrication est située à côté du symbole.	EN/ISO 15223-1*	5.1.11

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Dispositif sur ordonnance	ATTENTION : La loi fédérale américaine limite la vente de cet appareil par ou pour le compte d'un dentiste, d'un orthodontiste ou d'un professionnel dentaire agréé. Le système constitue un dispositif médical sur ordonnance et ne doit être manipulé que par des professionnels de santé dentaire qualifiés.	21 CFR 801.15(c) (1)(i)F	Étiquetage — Dispositifs médicaux ; importance des mentions d'étiquetage requises ; utilisation de symboles dans l'étiquetage.
	Fabricant	Indique le fabricant du dispositif médical.	EN/ISO 15223-1*	5.1.1
	Numéro de catalogue	Indique le numéro de catalogue du fabricant, afin que le dispositif médical puisse être identifié.	EN/ISO 15223-1*	5.1.6
	Numéro de série	Indique le numéro de série fourni par le fabricant permettant l'identification de chaque dispositif médical spécifique.	EN/ISO 15223-1*	5.1.7
	Courant alternatif	Pour indiquer sur la plaque signalétique que l'équipement est adapté au courant alternatif (CA) uniquement.	CEI 60417 Symboles graphiques à utiliser sur l'équipement.	5032
	Garder au sec	Indique un dispositif médical qui doit être protégé de l'humidité.	EN/ISO 15223-1*	5.3.4
	Limite de température	Indique les limites de température auxquelles le dispositif médical peut être exposé en toute sécurité.	EN/ISO 15223-1*	5.3.7

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Dispositif médical	Indique que l'article est un appareil médical.	EN/ISO 15223-1*	5.7.7
	Consulter les instructions d'utilisation ou consulter les instructions électroniques d'utilisation.	Indique la nécessité pour l'utilisateur de consulter les instructions d'utilisation.	EN/ISO 15223-1*	5.4.3
	Bus série universel (USB), port/prise	Pour identifier un port USB.	ISO 7000 Symboles graphiques à utiliser sur l'équipement — Symboles enregistrés	3650
	Batterie	Pour identifier l'emplacement de la batterie du Panel PC	S.O.	S.O.
	Veille	Pour identifier le bouton-poussoir de mise sous tension/veille.	CEI 60417 Symboles graphiques à utiliser sur l'équipement.	5009
	Représentant agréé suisse	Indique le représentant autorisé en Suisse.	MU600_00_016 version 5.0 Obligations Opérateurs économiques CH.	S.O.

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Conforme RoHS pour la Chine.	Indique que le produit électrique contient certaines substances dangereuses et peut être utilisé en toute sécurité pendant la période d'utilisation de protection de l'environnement de 10 ans et doit être recyclé après la fin de sa période d'utilisation de protection de l'environnement.	SJ/T 11364 Marquage pour la limitation de l'utilisation de substances dangereuses dans les produits électriques et électroniques.	S.O.
	Marquage CE/marquage CE de conformité	Indique qu'un dispositif est conforme aux exigences applicables énoncées dans le règlement UE MDR 2017/745 et toute autre législation d'harmonisation de l'Union applicable prévoyant son apposition.	RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL du 5 avril 2017 relatif aux dispositifs médicaux	Annexe V du RDM UE 2017/745
QTY	Quantité	Indique le nombre d'articles dans l'emballage.	S.O.	S.O.
	Représentant autorisé dans la Communauté européenne/l'Union européenne	Représentant autorisé dans la Communauté européenne/Union européenne	EN/ISO 15223-1*	5.1.2
	Il est interdit de monter sur l'appareil.	Indique qu'il ne faut pas monter sur la surface.	ISO 7010:2020	P019
	Marque de conformité réglementaire (RCM)	Marquage RCM australien	AS/NZS 4417.1:2012 Marque de conformité réglementaire pour les appareils électriques et électroniques	S.O.

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Marque R-NZ	Marquage radio néo-zélandais	Radiocommunications (Conformité) Avis 2020	S.O.

***Références du glossaire** : EN/ISO 15223-1 Dispositifs médicaux — Symboles à utiliser avec les étiquettes de dispositifs médicaux, étiquetage et informations à fournir — Partie 1 : Exigences générales

Consignes de sécurité

Avant d'utiliser le système, tous les utilisateurs sont tenus de lire et de comprendre ces consignes de sécurité.

Les termes ci-dessous indiquent les différents niveaux d'information sur la sécurité :

- **Avertissement** : Indique un danger potentiel pouvant entraîner des blessures graves s'il n'est pas évité.
- **Attention** : Indique un danger potentiel pouvant entraîner des blessures mineures ou modérées si elles ne sont pas évitées.
- **Remarque** : Information importante qui n'est pas un avertissement/une mise en garde, mais qui doit être strictement respectée.

Alimentation électrique

Le système est alimenté par une batterie interne de qualité médicale. Dans les scanners de configuration de chariot iTero Element 2 Plus, l'alimentation électrique est enfermée dans la base du support de roue. Dans les scanners de configuration mobile iTero Element 2 Plus, l'alimentation électrique est externe.

Alimentation par batterie

- **Charge** — La batterie du scanner sera entièrement chargée après avoir été branchée dans une source d'alimentation pendant 2 heures (iTero Element 2) ou 2,5 heures (iTero Element 2 Plus).
- Avec une batterie entièrement chargée, vous pouvez scanner jusqu'à 30 minutes à l'aide du scanner de configuration de support de roue ou de chariot, ou 10 minutes à l'aide du scanner de configuration mobile.

Avertissement : Les scanners de configuration de chariot sont fournis avec deux blocs-batteries rechargeables Li-ion et les scanners de configuration de support de roue et de configuration mobile sont fournis avec un bloc-batterie. Il y a un risque d'explosion de la batterie si l'écran est endommagé. Ne pas utiliser l'écran du scanner si vous des dommages sont constatés. Contacter le service client.

- Utiliser uniquement l'adaptateur CA/CC d'origine connecté au système pour charger les batteries.

**Avertissements
électriques**

- **Avertissement** : une batterie Li-ion défectueuse commence à siffler, à gonfler et à fuir des électrolytes. Les électrolytes sont constitués de sel de lithium dans un solvant organique (hexafluorophosphate de lithium), très inflammable. La combustion d'électrolytes peut enflammer des matériaux combustibles à proximité.

Remarque : il existe un risque de brûlures associé à cette situation.

- L'écran doit être stocké et utilisé en respectant les conditions environnementales qui apparaissent dans ce manuel. Ne pas exposer le scanner à des sources de chaleur extrêmes, telles que des radiateurs et des foyers.
- Ne jamais utiliser l'appareil sans batteries ! Ne pas utiliser les batteries à d'autres fins que l'utilisation prévue du produit. Mettez au rebut les batteries usagées conformément aux instructions du fabricant et aux exigences locales.
- Remplacer les batteries uniquement par le même type de pile fourni par Align.
- Ne pas enlever les panneaux externes et les couvercles afin d'éviter un choc électrique. L'appareil ne contient aucune pièce remplaçable par l'utilisateur. Dans les scanners iTero Element 2 Plus, vous pouvez ouvrir le couvercle du panneau de diagnostic en cas de défaillance du système, uniquement lorsque le SAV l'exige.
- Ne connectez pas le scanner à une alimentation principale sans prise terre, afin d'éviter tout choc électrique.

iTero Element Flex:

- Le scanner iTero Element Flex est fourni avec un concentrateur contenant l'alimentation électrique de la baguette. Ne pas placer le système sur une surface humide ou ne pas marcher dessus, afin d'éviter tout risque d'endommagement du système et de choc électrique.
- Ne jamais connecter le concentrateur à un ordinateur portable qui n'est pas approuvé conformément à la norme CEI 60950-1 ou CEI 62368-1, selon le cas. Avertissement : L'ordinateur portable et tous ses accessoires doivent être placés à une distance d'au moins 1,5 m du patient. Ne pas scanner un patient en touchant l'ordinateur portable ou l'un de ses accessoires en même temps. Le non-respect de ces instructions peut entraîner un choc électrique.

**Précautions
électriques**

- Ne pas connecter une webcam non approuvée par Align sur les ports USB à l'arrière de l'écran tactile, afin d'éviter le risque de choc électrique.
- Ne connecter rien d'autre que la tige iTero aux prises USB du concentrateur.
- Ne pas connecter au système un câble d'alimentation qui n'est pas fourni par la Align Technology afin d'éviter les chocs électriques.

**Réseau local sans
fil**

- Le système fourni est équipé d'une unité de réseau local sans fil.
- Lors de l'utilisation du produit, maintenir une distance de séparation d'au moins 20 cm entre l'unité informatique et le corps de toutes les personnes afin d'assurer la conformité aux exigences concernant l'exposition aux RF.

Classifications de sécurité

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

Dispositif médical sur ordonnance

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

Précautions avec le scanner

- La tige émet une lumière laser rouge (680 nm classe 1) ainsi que des émissions de DEL blanches. L'utilisation normale de la tige ne présente aucun danger pour l'œil humain. Éviter de diriger la lumière de la tige directement dans les yeux du patient.
- Éviter de tordre, de nouer, de tirer et marcher sur le câble de la tige et le câble d'alimentation.
- Lorsque le système n'est pas utilisé, la tige doit être placée dans le socle avec la surface optique tournée vers le socle, afin d'éviter tout contact visuel avec le faisceau laser ou l'émission de DEL blanche vacillante. Le contact avec les yeux peut les endommager.
- Éviter d'activer la tige lorsque la pointe de la tige est hors de la bouche du patient, afin d'éviter des dommages oculaires.
- Éviter de placer la tige dans le socle pendant que l'opération de scan est encore active, afin d'éviter des dommages oculaires.
- Ne pas utiliser l'équipement en cas de dysfonctionnement du scanner ou si des dommages physiques sont constatés, afin d'éviter tout choc électrique ou blessure physique. Appeler l'assistance client.
- **ATTENTION** : Garder la tige et à 5 cm des dispositifs médicaux sensibles aux champs magnétiques tels que les implants cochléaires, les neurostimulateurs, les stents et les shunts.

Nettoyage & désinfection

Pour éviter contamination croisée, il est obligatoire de respecter ce qui suit :

- [Nettoyer et désinfecter](#) la tige, le socle et les autres composants du système conformément aux instructions fournies, et [remplacer le manchon](#) avant chaque patient.
- Ôter les gants et les changer après chaque séance avec un patient.
- Jeter tous gants déchirés, contaminés ou ôtés.
- Remplacer le manchon iTero Element 2 entre chaque patient. Ne pas changer le manchon entre les patients peut entraîner le transfert de micro-organismes et d'autres contaminants d'un patient à un autre par inadvertance.
- **ATTENTION** : Jeter les iTero Element 2 manchons conformément aux procédures d'utilisation standard ou à la réglementation locale relative à la mise au rebut des déchets médicaux contaminés.

Déballage et installation

Le système doit être [déballé et installé](#) conformément aux instructions fournies par Align Technology.

Remarque : Contactez l'assistance client si le boîtier du scanner est endommagé.

Environnement de travail

- Le système doit être déplacé d'une pièce à une autre avec le plus grand soin pour éviter de l'endommager.
- Ne pas bloquer les bouches d'aération sur la tige et l'unité informatique.
- Le système est destiné à être utilisé à l'intérieur uniquement. Il ne doit pas être exposé directement à la lumière du soleil, à une chaleur excessive ou à l'humidité.
- iTero Element Flex uniquement: Si le système vient juste d'être déplacé dans un endroit en provenance d'un environnement chaud, froid ou humide, laissez le matériel s'adapter à la température ambiante pour éviter la condensation interne.

Précautions contre les interférences électromagnétiques

Cet appareil a été testé et jugé conforme aux exigences relatives aux dispositifs médicaux selon la norme CEI 60601-1-2. Cette norme est conçue pour fournir une protection raisonnable contre les électromagnétiques dangereuses dans une installation médicale classique.

Éviter de placer cet appareil à proximité d'équipements de transmission de fréquence ou d'autres sources d'interférences électriques et électromagnétiques (par exemple, téléphones portables, radios mobiles bidirectionnelles, appareils électriques, RFID). Des niveaux élevés de telles interférences, en raison de la proximité ou de la force de la source, peuvent entraîner une perturbation des performances de cet appareil. Dans ce cas, l'appareil peut être remis en mode de fonctionnement après une intervention de l'utilisateur ou par une récupération automatique.

Informations générales**Remarques :**

- N'apportez aucune modification à cet équipement.
- Ne pas retirer l'unité informatique du support après l'assemblage.

Notification d'incident

Tout incident grave lié à l'appareil iTero doit être signalé à Align Technology Ltd. et à l'autorité compétente du pays dans lequel l'utilisateur et le patient sont établis.

Table of contents

Compliance	ii
Contraindications	iii
Nature of emitted scanner radiation	iii
Symbols	iii
Safety instructions	ix
Conformité – French	xii
Contre-indications	xiii
Nature du rayonnement émis par le scanner	xiii
Symboles	xiii
Consignes de sécurité	xix
1 Introduction to iTero Element™ 2, iTero Element™ Flex, and iTero Element™ 2 Plus intraoral scanners	1
1.1 Intended purpose/Intended use	2
1.2 Indications for use	2
1.3 Contraindications	2
1.4 Intended patient population	2
1.5 Intended users	2
1.6 Use environment	2
1.7 Clinical benefits	2
1.8 iTero Element 2 and iTero Element 2 Plus hardware	3
1.8.1 iTero Element 2 wheel-stand configuration	3
1.8.2 iTero Element Flex	4
1.8.3 iTero Element 2 Plus cart configuration	5
1.8.4 iTero Element 2 Plus mobile configuration	6
1.8.5 iTero Element wand	7
1.9 About this manual	8
2 Assembly instructions	9
2.1 Assembling the iTero Element 2 scanner	10
2.2 Assembling the iTero Element Flex scanner	14
2.2.1 Installing the iTero Element Flex software	14
2.3 Assembling the iTero Element 2 Plus scanner – cart configuration	16
2.4 Assembling the iTero Element 2 Plus scanner – mobile configuration	21
2.4.1 Initial assembly	22

2.4.2	Moving the scanner within the clinic	24
2.4.3	Using the trolley for transportation	24
2.4.4	Optional protective trolley cover	27
2.4.5	VESA mounting	27
3	Getting started	30
3.1	Logging in to the scanner for the first time	30
3.2	Registering the scanner – Make It Mine process	30
3.3	Working in Demo Mode	41
3.3.1	Align Oral Health Suite	44
3.3.2	Exiting Demo Mode	45
4	Working with the scanner	46
4.1	Logging in to the scanner	46
4.1.1	Resetting your password	50
4.1.2	Logging in with a PIN	51
4.1.3	Updating the scanner software and security	53
4.2	Logging out of the scanner	59
4.3	Shutting down the scanner	60
4.4	Moving the scanner	60
4.4.1	Moving the iTero Element 2 wheel-stand configuration scanner	60
4.4.2	Transporting the iTero Element Flex intraoral scanner	60
4.4.3	Moving the iTero Element 2 Plus cart-configuration scanner	61
4.4.4	Carrying the iTero Element 2 Plus mobile-configuration scanner within the clinic	62
4.4.5	Transporting the iTero Element 2 Plus mobile-configuration scanner between clinics	63
4.5	User interface	64
4.5.1	Scanner toolbar	67
4.5.2	Touchscreen gestures	70
4.6	Defining the scanner settings	71
4.6.1	Defining the Device settings	72
4.6.2	Defining the User settings	76
4.6.3	Defining the System settings	84
5	Starting a new scan	88
5.1	Applying a wand sleeve	88
5.2	Starting the scanning process	88
5.3	Filling in the Rx	90
5.3.1	Filling in the Rx for Study Model/iRecord procedures	93

5.3.2	Filling in the Rx for Invisalign Viverra procedures	94
5.3.3	Filling in the Rx for Fixed Restorative procedures	96
5.3.4	Filling in the Rx for Implant Planning procedures	109
5.3.5	Filling in the Rx for Denture/Removable procedures	112
5.3.6	Filling in the Rx for Appliance procedures	117
5.3.7	Saving list items as favorites	118
5.4	Patient management	120
5.4.1	Adding new patients	120
5.4.2	Searching for existing patients	121
5.4.3	Editing the patient details	123
5.4.4	Clearing the patient details from the New Scan window	125
5.5	Scanning the patient	126
5.5.1	Scanning guidance	126
5.5.2	Scanning best practices	128
5.5.3	Scan options	128
5.5.4	Editing a scan	131
5.6	Viewing the scan	132
5.6.1	Missing scan segment notifications	133
5.6.2	Using the scan timer	134
5.7	Sending the scan	134
5.8	Working with the Viewer	138
5.9	Removing the wand sleeve	141
6	Working with patients	143
6.1	Searching for patients	143
6.2	Viewing the patient details	145
6.3	Creating a new scan for a specific patient	146
6.4	Viewing the Rx	148
6.5	Viewing previous scans in the Viewer	149
7	Working with orders	151
7.1	Working with returned orders	154
8	Viewing messages	155
9	Working with MyiTero	156
10	iTero scanner features and tools	157
10.1	Comparing previous scans using iTero TimeLapse technology	157
10.2	Invisalign Outcome Simulator Pro	160

10.3	Invisalign Outcome Simulator	161
10.4	Invisalign Progress Assessment	161
10.5	Invisalign Go system	162
10.6	Editing tools	162
10.6.1	Deleting a segment	163
10.6.2	Deleting a selection	165
10.6.3	Filling in missing anatomy	167
10.6.4	Disabling auto-cleanup	168
10.7	Working with the Eraser tool	170
10.8	Working with the Occlusal Clearance tool	172
10.9	Working with the Edge Trimming tool	176
10.10	Working with the Die Separation tool	178
10.11	Working with the Margin Line tool	182
10.11.1	Automatically defining the margin line	182
10.11.2	Manually defining the margin line	184
10.12	Working with the Snapshot tool	184
10.12.1	Working with the Annotation Tool	186
10.13	Working with the Patient Gallery	188
10.14	Working with the Align Oral Health Report	189
11	Care and maintenance	194
11.1	Handling the wand and cable	194
11.2	Cleaning and disinfecting the wand	195
11.2.1	Preparation before cleaning and disinfection	195
11.2.2	Wand cleaning and disinfection	196
11.2.3	Drying – wand body	198
11.2.4	Storage and maintenance	198
11.3	Cleaning and disinfecting the cradle	199
11.3.1	Preparation before cleaning and disinfection	199
11.3.2	Cradle cleaning and disinfection	200
11.3.3	Drying – cradle	201
11.3.4	Storage and maintenance	202
11.4	Cleaning and disinfecting the scanner touchscreen and the wheel-stand handle or main handle	202
11.5	General cleaning and disinfection comments	202
11.6	Approved cleaning and disinfecting materials	203
11.6.1	Approved cleaning and disinfection materials (not relevant for Australia)	203

11.6.2	Approved cleaning and disinfection materials (Australia only)	203
Appendix A:	Clinic LAN network guidelines	205
A.1	Introduction	205
A.2	Preparations	205
A.3	Router guidelines	206
A.4	Internet connection guidelines	206
A.5	Firewall	206
A.6	Wi-Fi tips	206
A.7	Align hostname recommendations	207
A.7.1	Align hostname recommendations – China	208
Appendix B:	EMC declarations	209
B.1	EMC declaration – iTero Element 2 and iTero Element Flex	209
B.2	EMC declaration – iTero Element 2 Plus	212
Appendix C:	iTero Element™ Family product security whitepaper	216
Appendix D:	System specifications	218
D.1	iTero Element 2 system specifications	219
D.2	iTero Element Flex system specifications	220
D.3	iTero Element 2 Plus system specifications	222
Appendix E:	Scanner labels	225
E.1	Package labels	225
E.1.1	Package label - iTero Element 2	225
E.1.2	Package label - iTero Element Flex	226
E.1.3	Package label - iTero Element Flex (Certified pre-owned)	226
E.1.4	Package labels - iTero Element 2 Plus cart and iTero Element 2 Plus mobile	227
E.2	Computing unit labels	228
E.2.1	Computing unit - iTero Element E2	228
E.3	Wheelstand labels	228
E.3.1	Wheelstand labels - iTero Element 2	228
E.4	Wand labels	229
E.4.1	Wand label - iTero Element 2	229
E.4.2	Wand label - iTero Element 2 Plus	229
E.5	Hub labels	230
E.5.1	Hub label - iTero Element Flex	230
E.5.2	Hub label - iTero Element Flex (Certified pre-owned)	230

Table of figures

Figure 1: Front view of the iTero Element 2 intraoral scanner	3
Figure 2: Rear view of the iTero Element 2 intraoral scanner	4
Figure 3: iTero Element Flex intraoral scanner	4
Figure 4: Front view of the iTero Element 2 Plus cart-configuration intraoral scanner	5
Figure 5: Rear view of the iTero Element 2 Plus cart-configuration intraoral scanner	6
Figure 6: Front view of the iTero Element 2 Plus mobile-configuration intraoral scanner	6
Figure 7: Rear view of the iTero Element 2 Plus mobile-configuration intraoral scanner	7
Figure 8: iTero Element wand	7
Figure 9: Protective sleeve	8
Figure 10: Disposable sleeve	8
Figure 11: Removing the wand from the cradle	20
Figure 12: Moving the scanner	20
Figure 13: Do not lift the scanner using the main handle	20
Figure 14: Do not allow the power pack to dangle in the air	29
Figure 15: Never tilt the screen more than 45 degrees	29
Figure 16: Welcome screen	30
Figure 17: Connect page listing the available networks	31
Figure 18: Entering the security key	31
Figure 19: Scanner is connected to the Internet and online	32
Figure 20: Verifying the communication with Align	32
Figure 21: Selecting the time zone	33
Figure 22: Registering the system to customize the setup	33
Figure 23: Welcome popup screen	34
Figure 24: Example of an iTero subscription package	34
Figure 25: License agreement	35
Figure 26: New software update available – installation options	36
Figure 27: Downloading the latest version	37
Figure 28: System is registered and ready for use	38
Figure 29: Welcome screen – enter email address	39
Figure 30: Welcome screen – enter password	39
Figure 31: Set PIN screen	40
Figure 32: PIN confirmation screen	40

Figure 33: iTero Element logo	41
Figure 34: Demo Mode option	41
Figure 35: Login window with a list of demo users	42
Figure 36: Demo Login button	42
Figure 37: Demo Mode home screen	43
Figure 38: Past Orders pane – options	43
Figure 39: Align Oral Health Suite home screen	44
Figure 40: iTero Element logo	45
Figure 41: Exiting Demo mode	45
Figure 42: Welcome window	46
Figure 43: Unexpected shutdown notification	47
Figure 44: Password is masked	48
Figure 45: Set PIN window	48
Figure 46: PIN set confirmation window	49
Figure 47: iTero home screen	49
Figure 48: Forgot Password link	50
Figure 49: Forgot password window	50
Figure 50: Check your email notification	51
Figure 51: Welcome window - Enter PIN	52
Figure 52: Set PIN window	53
Figure 53: Software updates available window – scheduling options	54
Figure 54: Connect the scanner to the AC power	55
Figure 55: Installation in progress	55
Figure 56: Installation completed successfully	56
Figure 57: Security updates – number of days until the updates must be installed	56
Figure 58: Security updates – last day	57
Figure 59: Updates notification – Welcome window	58
Figure 60: Updates notification – home screen	59
Figure 61: iTero Element Flex intraoral scanner in the supplied carrying case	61
Figure 62: Moving the scanner	62
Figure 63: Carrying the scanner between rooms within the clinic	63
Figure 64: Transporting the scanner between clinics	63
Figure 65: iTero home screen	64
Figure 66: Percentage of remaining battery charge	65
Figure 67: Help overlay including the e-manual and Customer Support buttons	66

Figure 68: Scanner toolbar	67
Figure 69: Percentage of remaining battery charge	68
Figure 70: Help overlay including e-manual and Customer Support buttons	69
Figure 71: Settings window	71
Figure 72: Brightness settings	72
Figure 73: Volume settings	72
Figure 74: List of nearby Wi-Fi networks	73
Figure 75: Connecting to the clinic Wi-Fi network	74
Figure 76: Forgetting or Disconnecting from the network	74
Figure 77: Time zone settings	75
Figure 78: Scan Settings window	76
Figure 79: Only the scanning range is highlighted	78
Figure 80: Rx Settings window	79
Figure 81: Signature Settings window	81
Figure 82: Localization window	82
Figure 83: Set PIN window	83
Figure 84: Login Settings window	84
Figure 85: Diagnostics window	85
Figure 86: Licensing Information window	86
Figure 87: System Information window – iTero Element 2 Plus	87
Figure 88: Gently slide the new sleeve into place	88
Figure 89: New Scan window showing an empty Rx form and progress toolbar	89
Figure 90: New Scan window	91
Figure 91: Selecting the required procedure	92
Figure 92: Study Model/iRecord procedure – Scan Options area	94
Figure 93: Scan Options area – Invisalign Viverra procedure	95
Figure 94: Scan Options and Tooth Diagram areas – Fixed Restorative procedure	97
Figure 95: List of fixed restorative treatment options	98
Figure 96: Treatment settings window – Onlay restoration	98
Figure 97: Selected tooth and Treatment Information area – Onlay restoration	99
Figure 98: Treatment settings window – Crown restoration	100
Figure 99: Additional information area – Crown restoration	101
Figure 100: Selected tooth and Treatment Information area – Crown restoration	102
Figure 101: Copy restoration settings from a tooth requiring the same treatment type	102
Figure 102: Treatment settings window – Implant Based restoration	103

Figure 103: Expanded Restoration Type area	104
Figure 104: Expanded Crown area	104
Figure 105: Treatment settings window – Bridge restoration	105
Figure 106: Bridge range and teeth to be included	105
Figure 107: List of in-bridge treatment options	106
Figure 108: Bridge restoration – Pontic settings	106
Figure 109: Additional information area – Bridge restoration	107
Figure 110: Bridge treatment options – Implant Based	108
Figure 111: Expanded Restoration Type area	108
Figure 112: Expanded Crown area	109
Figure 113: Implant Planning procedure types	109
Figure 114: Implant Planning procedure – Tooth Diagram area for Surgical Guide Tooth Supported	110
Figure 115: Defining the teeth that need to be implanted	111
Figure 116: Implant Position window	111
Figure 117: Supporting teeth and teeth to be implanted displayed in the Tooth Diagram and Treatment Information areas	112
Figure 118: Denture/Removable procedure – Denture Details and Scan Options areas	113
Figure 119: Denture/Removable procedure types	114
Figure 120: Scanning option for scanning both the existing dentures and the patient	114
Figure 121: Defining the teeth to be included in the denture – Full Denture Implant Based procedure type	115
Figure 122: Implant Based settings window	116
Figure 123: Appliance details and Scan Options areas – Appliance procedure	117
Figure 124: Appliance procedure types	118
Figure 125: Adding a favorite material	119
Figure 126: Favorite materials pinned to the top of the Material list	119
Figure 127: Adding a new patient	120
Figure 128: Message notifying that a patient with the same details exists	121
Figure 129: Patient area of the New Scan window – searching for an existing patient	121
Figure 130: Search Patient window with a search field	122
Figure 131: Search criteria in the search field and list of matching patients	122
Figure 132: Selecting the required patient	123
Figure 133: Selected patient displayed in the Patient area of the New Scan window	123
Figure 134: Patient area of New Scan window – editing a patient	124
Figure 135: Edit Patient window and Update button	124
Figure 136: Message that a patient with the same details already exists	125

Figure 137: Clear patient details button	125
Figure 138: Clear confirmation message	126
Figure 139: Recommended scanning sequence – lower jaw	127
Figure 140: Wand guidance	127
Figure 141: Missing palatal area is highlighted in blue	128
Figure 142: Areas with missing anatomy shown with and without additional scan feedback – monochrome	129
Figure 143: Areas with missing anatomy shown with and without additional scan feedback – color mode	129
Figure 144: Model displayed in color and monochrome mode	130
Figure 145: Tap the opposite arch or tap the arrows to select it	131
Figure 146: Editing tools	132
Figure 147: Missing scan message and missing segments highlighted in red	133
Figure 148: Scan timer button on the toolbar and scan time	134
Figure 149: Notification about missing treatment information	135
Figure 150: Missing fields highlighted in red in the Treatment Information area	135
Figure 151: Complete Scan window	136
Figure 152: Invisalign Outcome Simulator Pro progress shown in the Viewer	137
Figure 153: Invisalign Outcome Simulator Pro progress shown in the patient's profile page	137
Figure 154: Viewer option in the Past Orders pane in the Orders page	138
Figure 155: Viewer option in the patient's profile page	138
Figure 156: Model in a 1-window view	139
Figure 157: Model in a 2-window view	140
Figure 158: Model in a 5-window view	140
Figure 159: Removing a wand sleeve	141
Figure 160: Optical surface of the wand	142
Figure 161: Gently slide the new sleeve into place	142
Figure 162: Patients page	143
Figure 163: Searching for a patient	144
Figure 164: Patients matching the search criteria are displayed	144
Figure 165: Patient's profile page	145
Figure 166: Patient's profile page – New Scan option	146
Figure 167: New Scan window with patient's details already filled in	147
Figure 168: Patient's profile page – View Rx option	148
Figure 169: Rx Details window	149
Figure 170: Patient's profile page – Viewer option	150
Figure 171: Scan displayed in the Viewer	150

Figure 172: Orders page	152
Figure 173: In Progress pane – options	152
Figure 174: Past Orders pane – options	153
Figure 175: Orders button notifying a returned order	154
Figure 176: Returned order in the In Progress pane	154
Figure 177: Messages page	155
Figure 178: iTero TimeLapse – selecting the scans to compare	158
Figure 179: iTero TimeLapse window showing the highlighted changes between the scans	158
Figure 180: Area of interest from the first scan displayed in the animation window	159
Figure 181: Area of interest from the second scan displayed in the animation window	159
Figure 182: iTero TimeLapse scale options	160
Figure 183: Progress Assessment window	162
Figure 184: Editing tools	163
Figure 185: Segment tool	164
Figure 186: Delete Selection tool	165
Figure 187: Expanded Delete Selection tool	166
Figure 188: Selected area of the anatomy is deleted	166
Figure 189: Fill tool	167
Figure 190: Areas that require scanning are highlighted in red – Fill tool	168
Figure 191: Auto-cleanup tool	169
Figure 192: Scan displayed with excess material showing	169
Figure 193: Eraser tool	170
Figure 194: Eraser tool options	170
Figure 195: Mark the area to be modified	171
Figure 196: Selected area removed, and scan tool enabled	171
Figure 197: Deleted area marked in red	172
Figure 198: Occlusal clearance between the opposing teeth	173
Figure 199: Occlusal Clearance range options	174
Figure 200: Occlusal Clearance tool and legend displayed in the Viewer	175
Figure 201: Edge Trimming tool	176
Figure 202: Edge Trimming tool options	176
Figure 203: Mark the area to be trimmed away	177
Figure 204: Selected area is highlighted, and the confirmation icon is enabled	177
Figure 205: Selected area has been removed	178
Figure 206: Green hint point centered on the prepped tooth	179

Figure 207: Die separation is displayed in high resolution	179
Figure 208: Die Separation tool options	180
Figure 209: Scan is displayed in high resolution	180
Figure 210: Before selecting the die separation	181
Figure 211: Prepped tooth is displayed in high resolution	181
Figure 212: Model display moves to the occlusal view, and zooms in on the prepped tooth	182
Figure 213: Margin Line tool options	183
Figure 214: Margin line is marked on the prepped tooth	183
Figure 215: Margin Line tool options	184
Figure 216: Viewer – Snapshot tool	185
Figure 217: Screen capture thumbnail is displayed after taking a screen capture	185
Figure 218: Option to download screenshots from the Orders page in MyiTero	186
Figure 219: Screenshot open in the Annotation Tool window and the annotations toolbar	187
Figure 220: Options to move or delete the annotation	188
Figure 221: Patient Gallery	189
Figure 222: Align Oral Health Report button	190
Figure 223: Align Oral Health Report – Summary page	190
Figure 224: Align Oral Health Report – Patient Gallery	191
Figure 225: Align Oral Health Report – Selected records in the right pane	192
Figure 226: Align Oral Health Report – selection stage	192
Figure 227: Wand without a wand sleeve	195
Figure 228: Remove gross contaminants using disinfecting wipes	196
Figure 229: Remove marks and stains using a soft bristle brush	197
Figure 230: Wipe the optical surface of the wand with IPA	198
Figure 231: Wiping the iTero Element 2 cradle	200
Figure 232: Wiping the iTero Element Flex cradle	200
Figure 233: Wiping the iTero Element 2 Plus cart-configuration cradle	200
Figure 234: Wiping the iTero Element 2 Plus mobile-configuration cradle	200
Figure 235: Brushing the iTero Element 2 cradle	201
Figure 236: Brushing the iTero Element Flex cradle	201
Figure 237: Brushing the iTero Element 2 Plus cart-configuration cradle	201
Figure 238: Brushing the iTero Element 2 Plus mobile-configuration cradle	201

1 Introduction to iTero Element™ 2, iTero Element™ Flex, and iTero Element™ 2 Plus intraoral scanners

iTero Element 2 intraoral scanners come in two configurations – wheel stand and laptop (iTero Element Flex).

The iTero Element 2 wheel-stand configuration scanner offers an all-in-one system available on a monitor with a fully interactive, touchscreen display and an easy-to-use wand. The topography of a patient's teeth can be viewed on the screen as they are being scanned, and determining the degree of occlusion of the bite can be analyzed when the scan is completed.

iTero Element Flex is a wand-only configuration with any laptop that meets our minimum system requirements, giving you the ultimate in mobility and the freedom to provide dedicated care wherever you choose to see patients.

The iTero Element 2 Plus family of imaging systems comes in two configurations – cart and mobile.

The bright full HD touchscreen display has wide visualization angles for an immersive and engaging experience and the powerful computing power enables a smoother and intuitive scanning experience. The ergonomics and elegance of the cart configuration will enhance your experience and elevate your practice brand image. The mobile configuration, with its dedicated trolley, enables professional and convenient inter-office portability.

This all-in-one system is designed to take patient experience and your productivity to the next level, ultimately helping you to grow your practice while making things easier.

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

1.1 Intended purpose/Intended use

The iTero Element 2, iTero Element Flex and iTero Element 2 Plus systems are intraoral scanners 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 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.

1.2 Indications for use

iTero Element scanners are indicated for use for orthodontic treatment planning and follow-up, restorative treatment planning and/or routine dental assessment.

1.3 Contraindications

For persons who have been diagnosed with Epilepsy, there is a risk of epileptic seizure from the flashing light of the iTero scanner.

1.4 Intended patient population

The system may be used on patients classified as Preadolescents, Adolescents, and Adults.

1.5 Intended users

The system serves as a prescription medical device and should be operated by trained healthcare providers only.

1.6 Use environment

Professional Healthcare and Home Healthcare Facility environment.

1.7 Clinical benefits

Digital impressions improve patient comfort and speed of process as compared to conventional impressions.

1.8 iTero Element 2 and iTero Element 2 Plus hardware

The iTero Element 2 scanner is available in two models:

- [iTero Element 2 wheel-stand configuration](#)
- [iTero Element Flex](#)

The iTero Element 2 Plus scanner is available in two configurations:

- [iTero Element 2 Plus cart configuration](#)
- [iTero Element 2 Plus mobile configuration](#)

1.8.1 iTero Element 2 wheel-stand configuration

Front view of the system



- A Full HD touchscreen
- B Power switch
- C Power LED
- D Wand
- E Cradle
- F Wheel base

Figure 1: Front view of the iTero Element 2 intraoral scanner

Rear view of the system



- A Wand connector
- B Wand cable
- C Screen power cable

Figure 2: Rear view of the iTero Element 2 intraoral scanner

1.8.2 iTero Element Flex



- A Laptop touchscreen
- B iTero Element Flex hub
- C Wand and cradle

Figure 3: iTero Element Flex intraoral scanner

1.8.3 iTero Element 2 Plus cart configuration

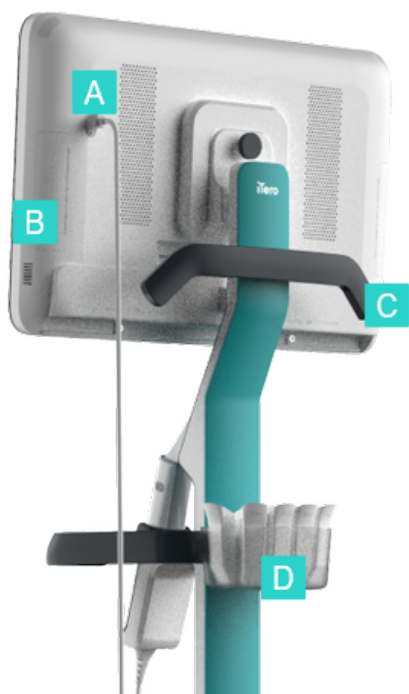
Front view



- A Full HD touchscreen
- B Power switch
- C Main handle
- D Wand
- E Cradle
- F Wheel stand

Figure 4: Front view of the iTero Element 2 Plus cart-configuration intraoral scanner

Rear view



- A** Wand connector
- B** Diagnostics panel
(for Support purposes only)
- C** Upper handle
- D** New-sleeve basket

Figure 5: Rear view of the iTero Element 2 Plus cart-configuration intraoral scanner

1.8.4 iTero Element 2 Plus mobile configuration

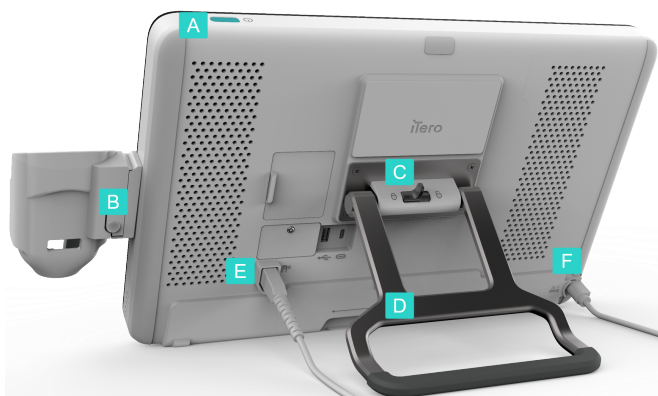
Front view



- A** Full HD touchscreen
computing unit
- B** Wand
- C** Cradle

Figure 6: Front view of the iTero Element 2 Plus mobile-configuration intraoral scanner

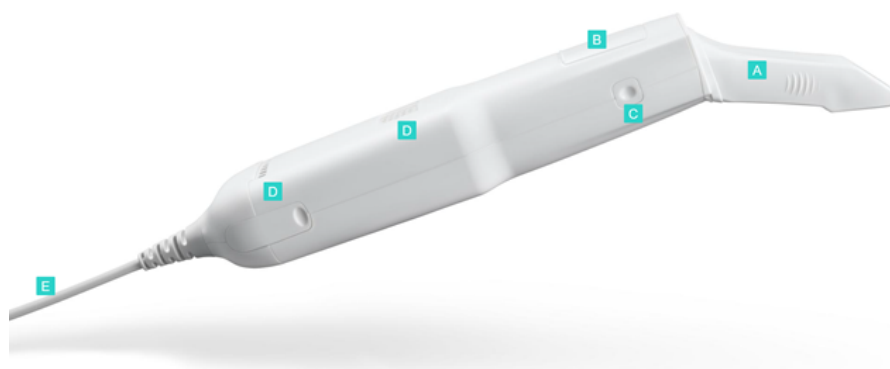
Rear view



- A** Power switch
- B** Cradle release button
- C** Locking latch
- D** Carrying handle/stand
- E** Wand cable
- F** Power cable

Figure 7: Rear view of the iTero Element 2 Plus mobile-configuration intraoral scanner

1.8.5 iTero Element wand



- A** Disposable sleeve
- B** Touchpad
- C** Side buttons: Scan, on/off, touchpad activation
- D** Air vents
- E** Detachable wand cable with USB connector

Figure 8: iTero Element wand

1.8.5.1 Wand sleeves

There are two types of wand sleeves:

- **Protective sleeve (blue):** Used when the scanner is not in use, to protect the optical surface of the wand.
- **Disposable sleeve:** Used while scanning. Before scanning the patient, [attach a new disposable sleeve](#).

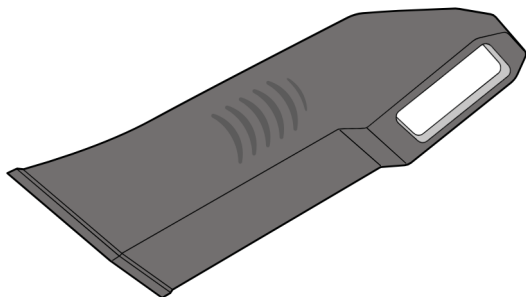


Figure 9: Protective sleeve

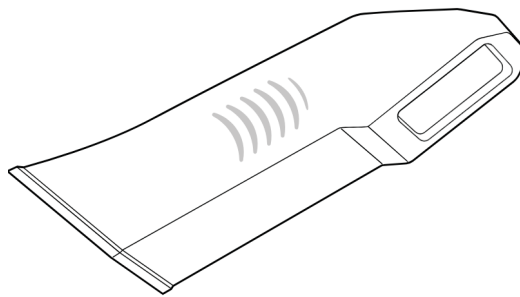


Figure 10: Disposable sleeve

Sleeve P/N 109236 or P/N 217596 should be ordered for use with the iTero Element 2 family.

1.9 About this manual

This manual provides general information and an overview of the iTero Element 2, iTero Element Flex, and iTero Element 2 Plus intraoral scanners and software.

In addition, this manual describes how to assemble the system, install the software on iTero Element Flex systems, start and shut down the system, clean and disinfect the system, and how to replace the wand sleeves between patients.

Disclaimer: The availability of the features and workflows described in this user manual depends on the installed software version, the clinic configuration (whether the clinic has more than one doctor), and your iTero subscription package. In addition, all screenshots displayed in this manual are for illustrative purposes only and may differ on your scanner depending on the software version, clinic configuration, subscription package, and personalized settings, such as Tooth ID.

2 Assembly instructions

This section describes how to assemble your new scanner.

- [Assembling the iTero Element 2 scanner](#)
- [Assembling the iTero Element Flex scanner](#)
- [Assembling the iTero Element 2 Plus scanner – cart configuration](#)
- [Assembling the iTero Element 2 Plus scanner – mobile configuration](#)

2.1 Assembling the iTero Element 2 scanner

Follow the instructions below to assemble the iTero Element 2 wheel-stand configuration scanner.



AC power



Battery



Click



DC power



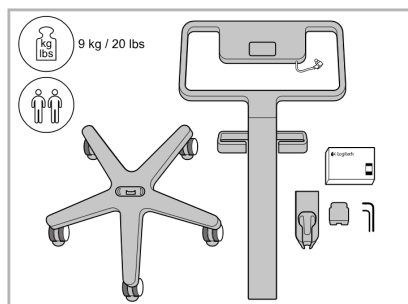
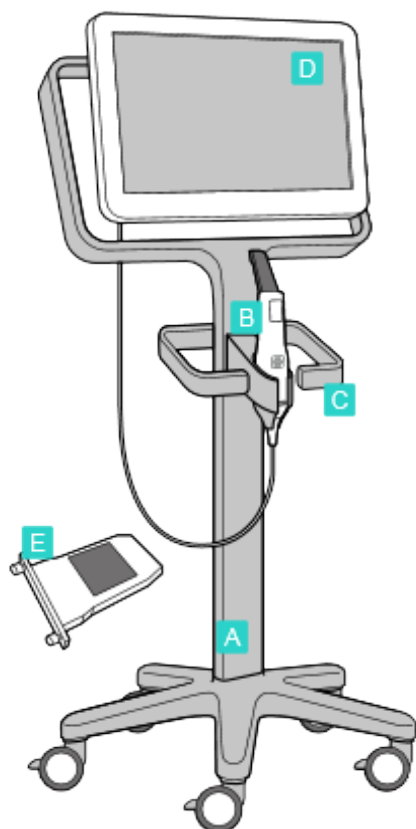
Power
button



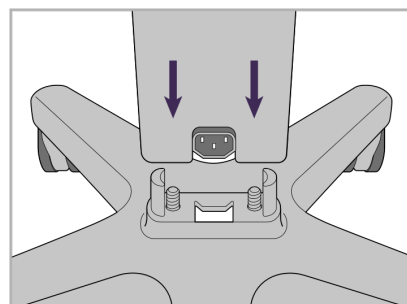
Wand



2 people are required
for installation

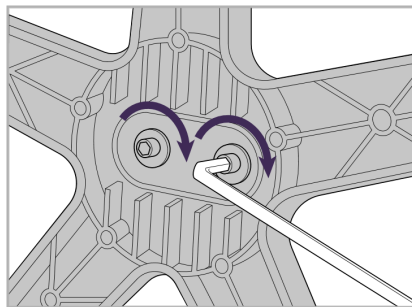


1. Check the contents of the boxes.

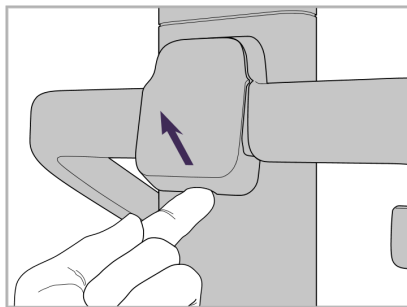


2. Connect the post to the wheel base.

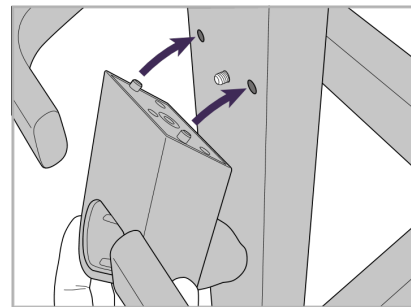
- A Wheel stand
- B Wand with cable
- C Wand cradle
- D HD touchscreen
- E External battery



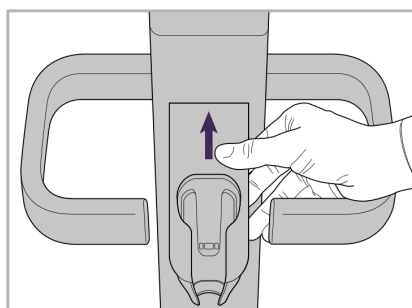
3. Tighten the two Allen screws using the larger Allen key.



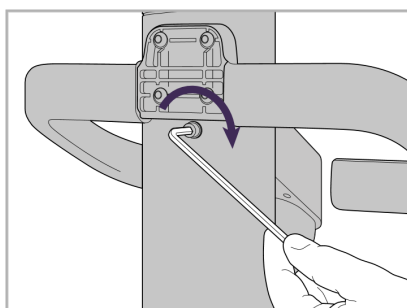
4. Remove the cover from the back of the handle.



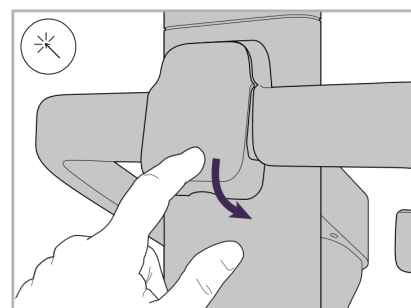
5. Attach the wand cradle to the front of the wheel stand.



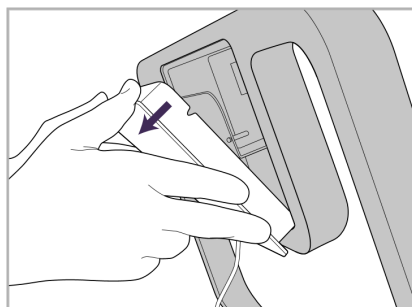
6. Hold the cradle.



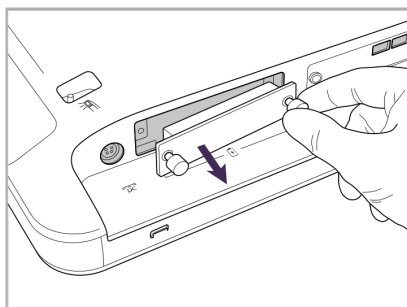
7. Tighten the back of the wand cradle with the Allen screw using the smaller Allen key.



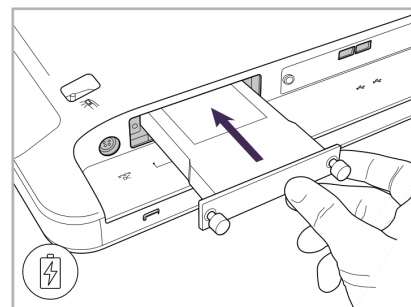
8. Reattach the cover behind the handle.



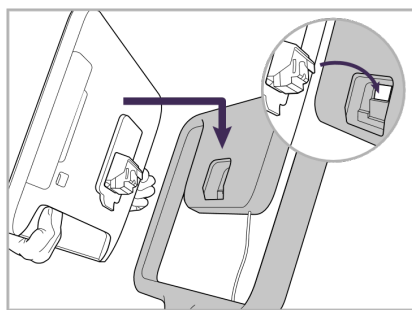
9. Remove the magnetic cover from the back of the wheel-stand frame.



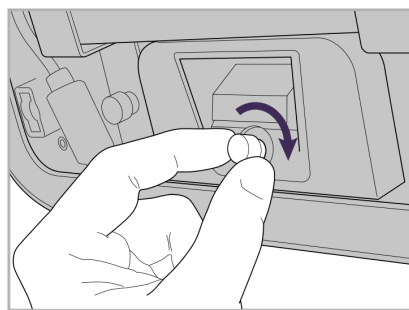
10. Loosen the thumbscrews and remove the battery cover.



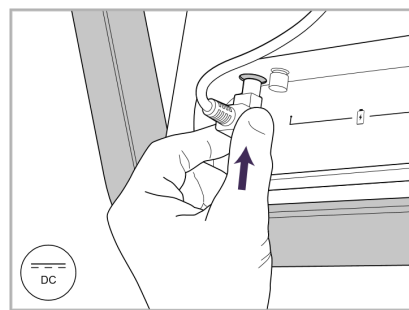
11. Slide the battery into the battery slot and tighten the thumbscrews.



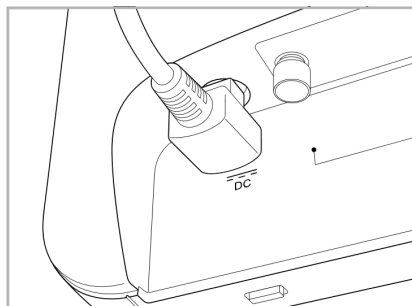
12. Lift the touchscreen to mount it.



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



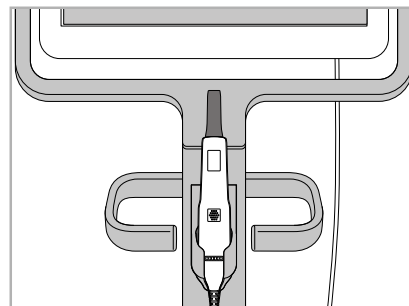
14. Connect the power cable to the port labeled DC, as shown in the next image.



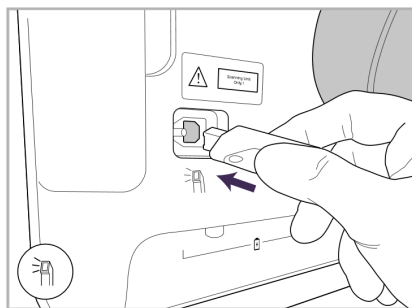
Power cable inserted.



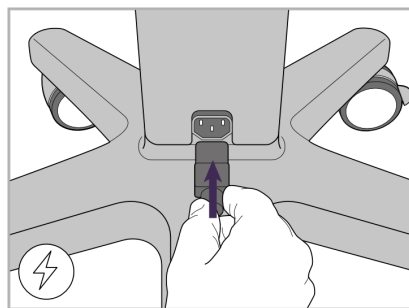
15. Attach the magnetic back cover.



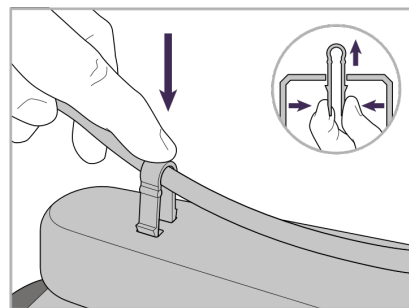
16. Place the wand in the cradle.



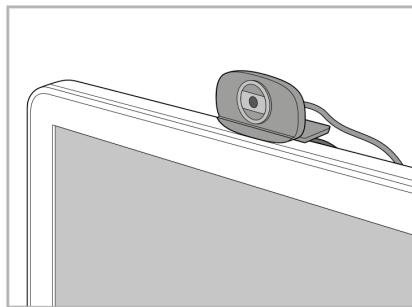
17. Connect the wand cable to the back of the touchscreen.



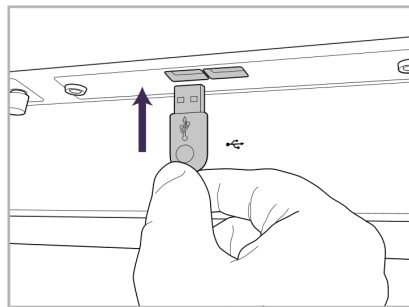
18. Connect the power cable on the bottom of the wheel stand.



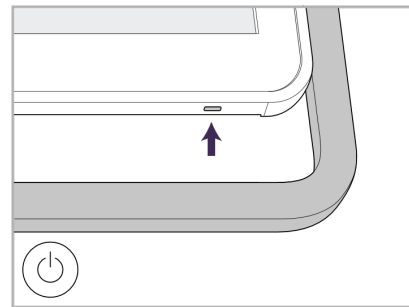
19. Secure the cable to the bottom of the wheel stand with the clip.



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



21. Connect the webcam to the USB port at the bottom of the touchscreen.

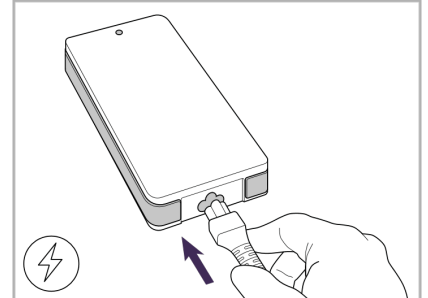
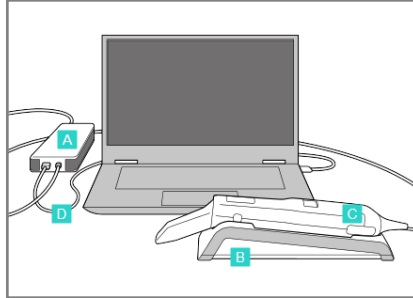


22. Plug the power cable into the AC power outlet and then press the Power button to switch on the scanner.

2.2 Assembling the iTero Element Flex scanner

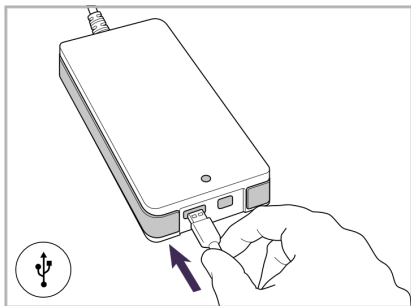
Follow the instructions below to assemble the iTero Element Flex scanner.

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

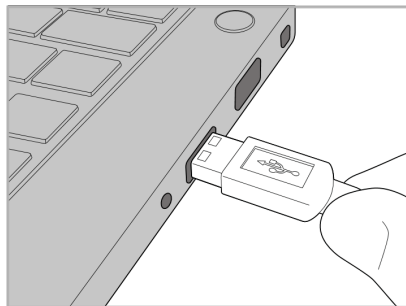


1. Place the wand in the cradle.

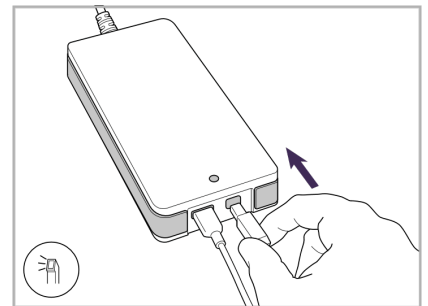
2. Connect the hub power cable to the hub.



3. Connect the USB cable to the hub.



4. Connect the USB cable to the laptop.



5. Connect the wand cable to the hub.

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

Notes:

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

2.2.1 Installing the iTero Element Flex software

New iTero Element 2 systems come with the software installed, but the user must download and install the software on iTero Element Flex systems.

For proper software installation and configuration of the iTero Element Flex system, please ensure the following:

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

- After installation, use only the desktop link to access the iTero software application. Do not use any pinned shortcuts, as that may affect the way the application is initiated.

Notes:

- Before installing the iTero software, please install all available Windows updates. New Windows computers should apply the updates automatically.
- Ensure that one of the following compatible antivirus programs has been installed: Norton, McAfee, or ESET. Ensure that you have an antivirus installed on your computer. If you are using an antivirus other than Microsoft Defender, exclude the following folders from the antivirus:
 - C:\Program Files\Cadent\
 - C:\ProgramData\Cadent\
 - C:\itero
 - C:\Program Files (x86)\Align\

To install the iTero software:

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

The *Welcome* screen is displayed.
6. [Register the scanner](#).

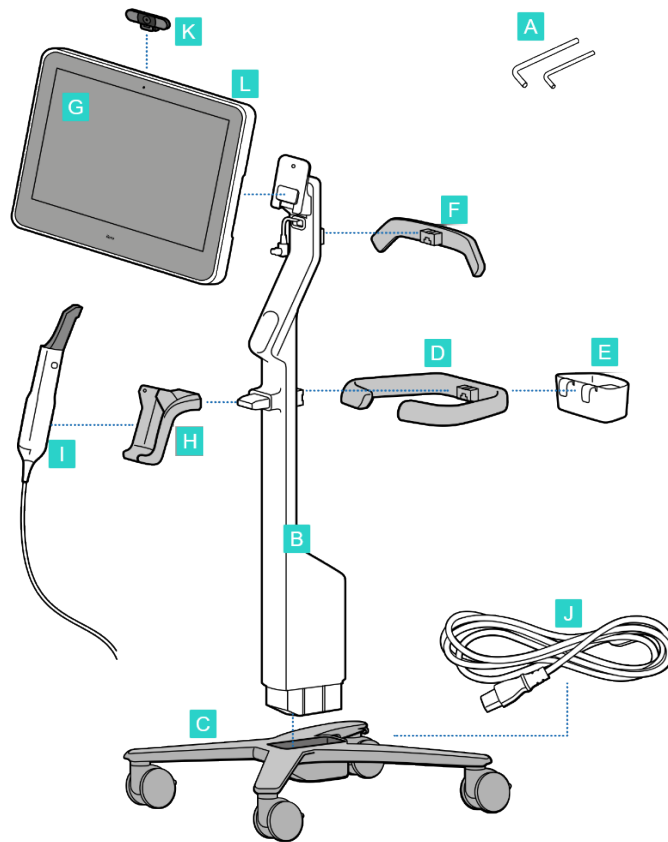
2.3 Assembling the iTero Element 2 Plus scanner – cart configuration

The scanner packaging is designed in a way that provides a simple and easy assembly process.

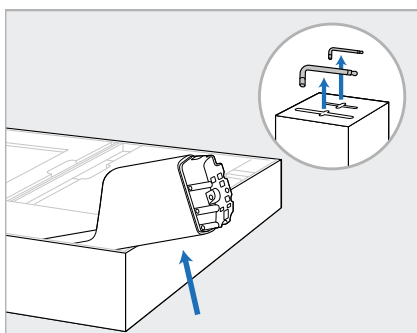
Follow the instructions below to assemble the scanner.

Contact iTero Support for additional help.

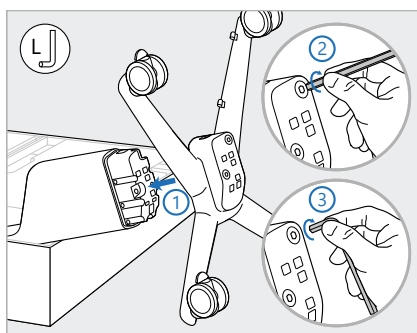
- A** 2x Allen keys
(in the white foam on top of the post)
- B** Post
- C** Wheel base
- D** Main handle
(in the accessory box)
- E** New-sleeve basket
(in the accessory box)
- F** Upper handle
(in the accessory box)
- G** Full HD touchscreen computing unit
- H** Cradle
- I** Wand
- J** Power cable
- K** Webcam
- L** Power switch



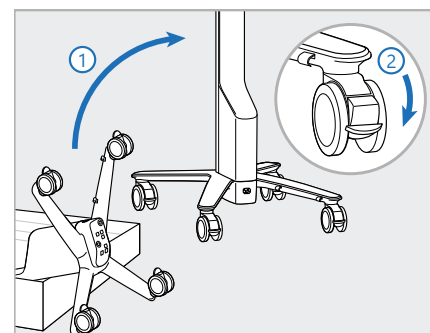
Note: If any damage to the system or accessories is found, do not assemble or use the scanner and contact iTero Support.



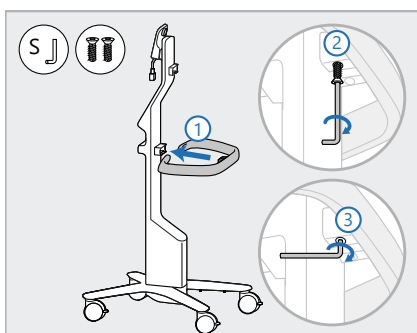
1. Remove all Styrofoam coverings from the box.
Note: The two Allen keys (A) are on top of the Styrofoam covering the post (B).
2. Lift the post (B), pull it out slightly, and rest it on the side of the box.



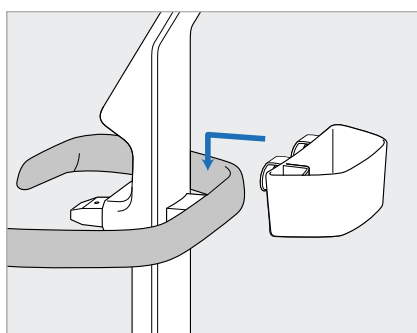
3. Attach the wheel base (C) to the end of the post (B) and tighten using first the longer side of the large Allen key and then the shorter side.



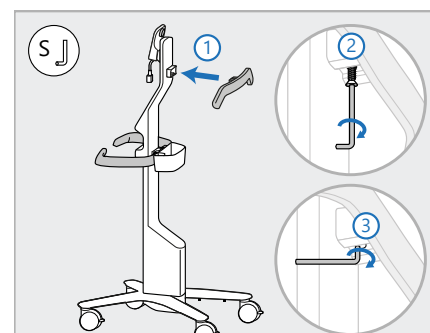
4. Move the wheel stand to an upright position and lock at least two wheels.



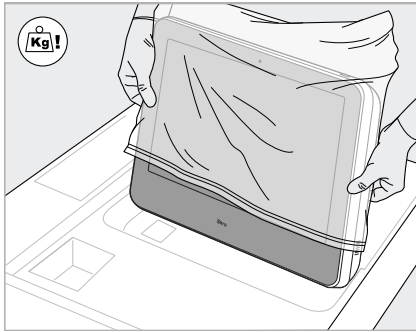
5. Remove the main handle (D) and the two screws from the accessory box.
Attach the main handle and tighten using first the longer side of the small Allen key and then the shorter side.



6. Remove the sleeve basket (E) from the accessory box and place it on the back of the main handle (D).

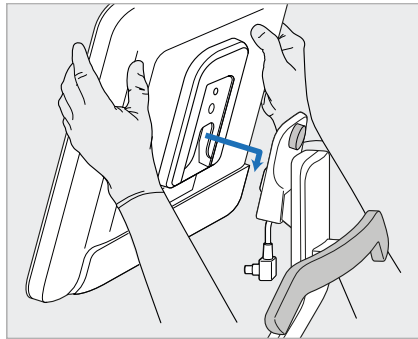


7. Remove the upper handle (F) from the accessory box and remove the pull tab to access the screw.
8. Attach the upper handle (F) to the post (B) and tighten using first the longer side of the small Allen key and then the shorter side.



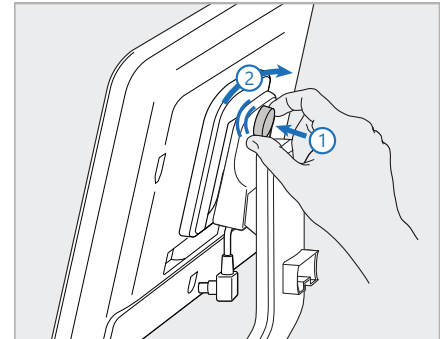
9. Carefully remove the computing unit (G) from its protective wrapping.

Note: The computing unit is heavy and must be lifted carefully.

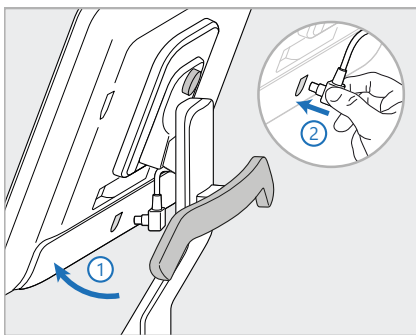


10. Standing behind the wheel stand, mount the computing unit (G) on the metal hinge and push down.

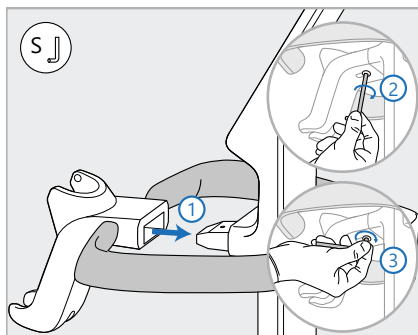
Note: Make sure the computing unit does not press on the screen cable. If it does, move the cable to the side.



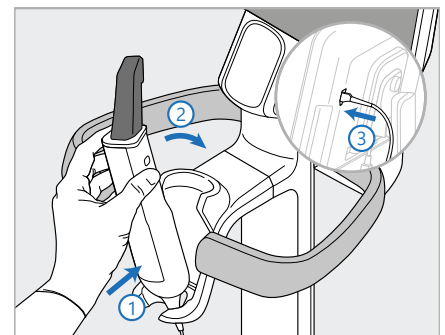
11. Attach the computing unit (G) by pushing in and tightening the screw.



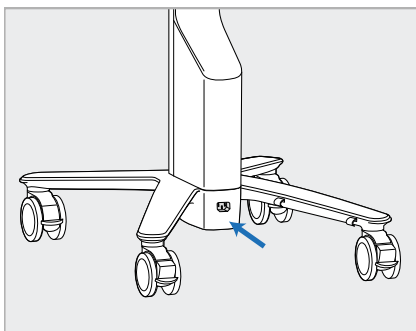
12. If the cable connector is covered, remove the cover.
Tilt the screen upwards and connect the screen cable.



13. Attach the cradle (H) to the post (B) and tighten using first the longer side of the small Allen key and then the shorter side.

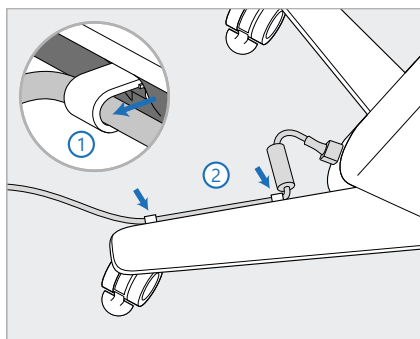


14. Insert the base of the wand (I) in the cradle (H) and then apply gentle pressure to make sure the wand is fully inserted and secure in the cradle.
15. Connect the wand cable to the back of the screen (G).

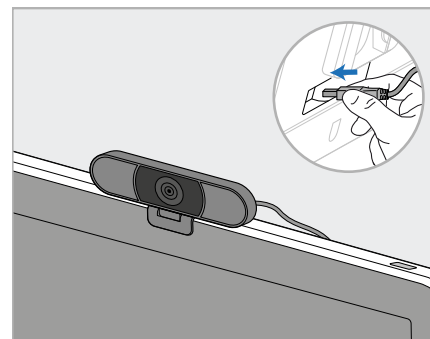


16. Connect the power cable (J) to the bottom of the wheel stand.

Warning: Use only the supplied power cable, which has a protective earth lead.

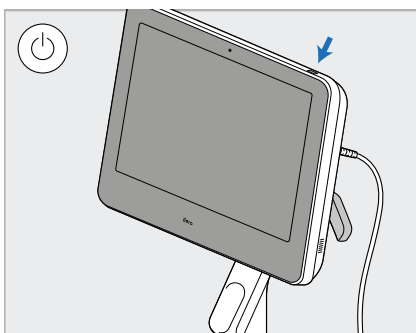


17. Secure the power cable (J) in the two cable clips, making sure it is fully inserted.



18. For remote training or support sessions, position the webcam (K) on the screen and then connect it to the USB port at the back of the screen.

Note: The webcam must be disconnected after each training or support session.



19. Plug the power cable (J) into a power outlet and then press the Power button (L) to switch on the scanner.

Notes:

- Always return the wand to the cradle after each use.
- The wand, cradle, and other system components should be [cleaned and disinfected](#) immediately after each patient.
- Ensure that the scanner is positioned in a location where it can easily be disconnected from the power outlet.

To remove the wand from the cradle, first pull the upper part of the wand towards you and then gently remove it from the cradle.

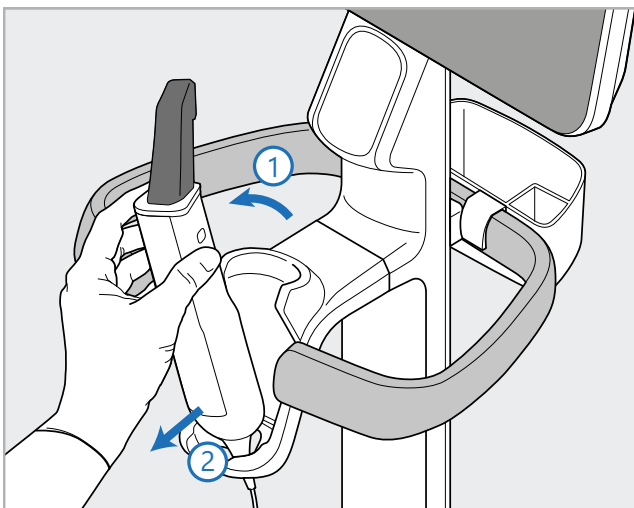


Figure 11: Removing the wand from the cradle

When moving the scanner, carefully wrap the power cable around the upper handle and then use the upper handle to push the scanner.

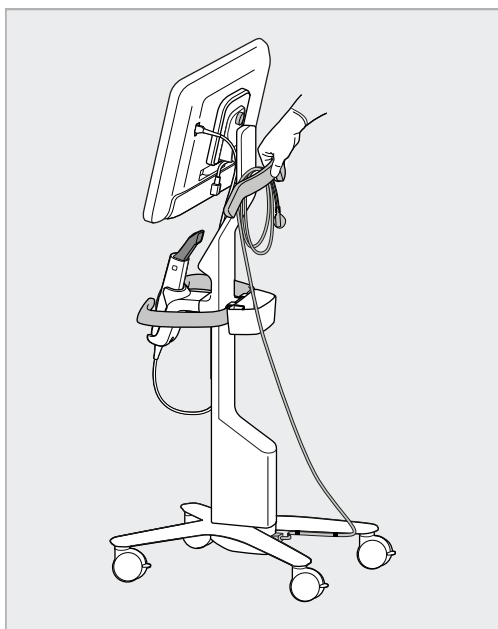


Figure 12: Moving the scanner

If the scanner needs to be lifted, use the upper handle and the post.

Do not use the main handle to lift the scanner.

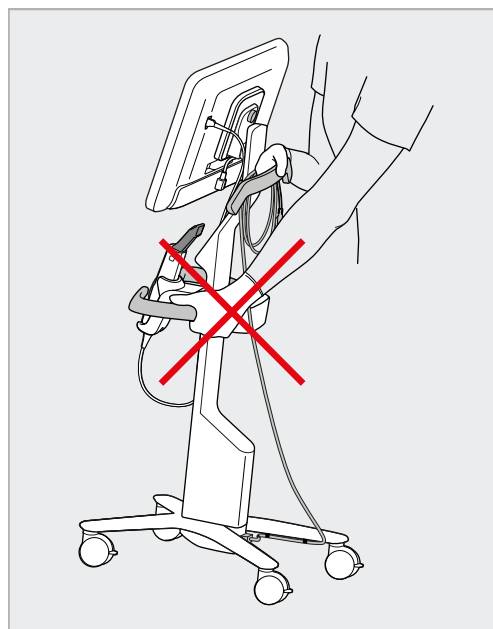


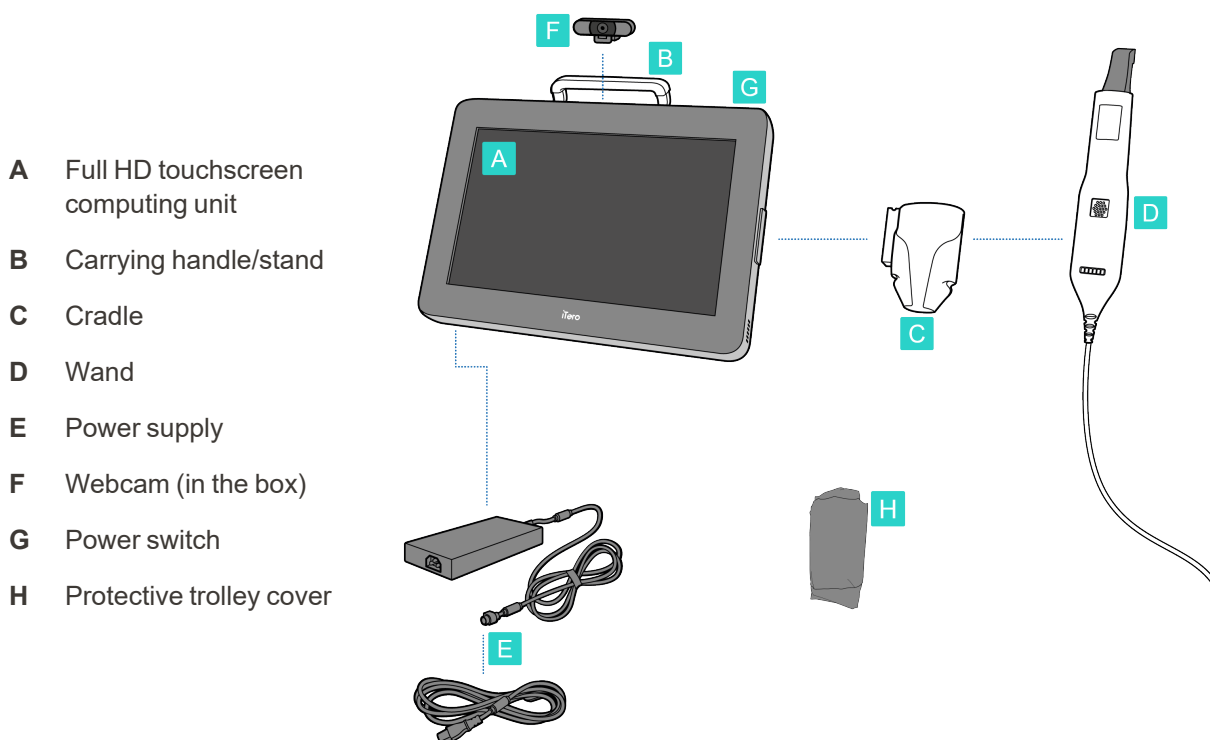
Figure 13: Do not lift the scanner using the main handle

2.4 Assembling the iTero Element 2 Plus scanner – mobile configuration

The scanner packaging is designed in a way that provides a simple and easy assembly process.

Follow the instructions below to assemble the scanner.

Contact iTero Support for additional help.

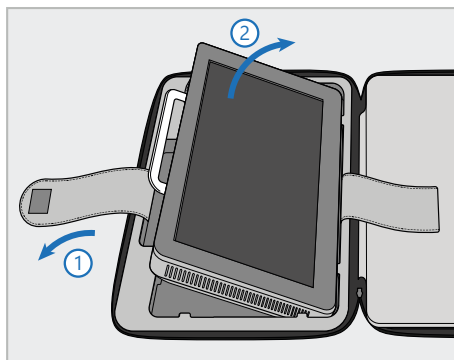


Note: If any damage to the system or accessories is found, do not assemble or use the scanner and contact iTero support.

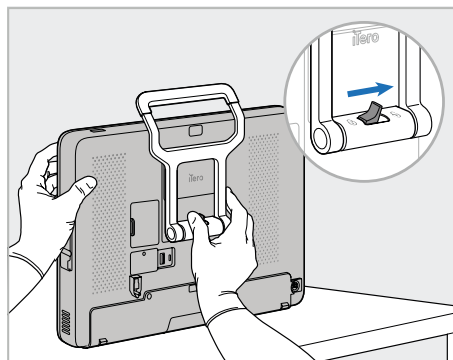
This section describes how to:

- [Assemble the scanner](#)
- [Move the scanner within the clinic](#)
- [Pack the scanner in the trolley before transporting it](#)
- [Protect the trolley with the optional protective cover](#)
- [Mount the scanner on a VESA mount](#)

2.4.1 Initial assembly

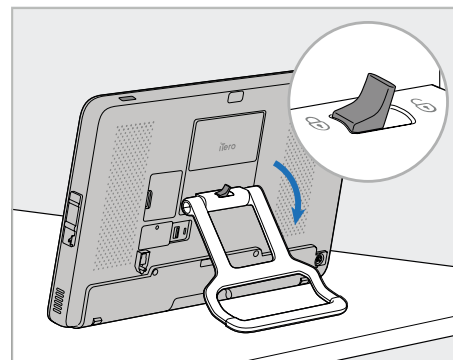


1. Undo the strap holding the computing unit (A), and then remove it using the handle (B).

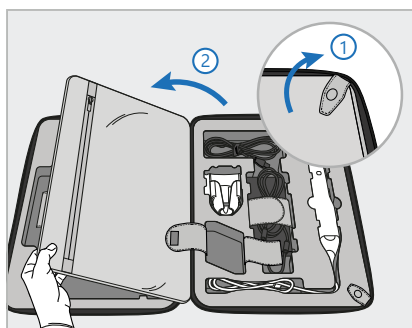


2. Rest the computing unit (A) on a smooth, flat surface and hold it with one hand.

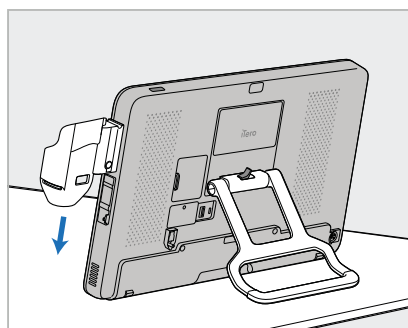
While holding the computing unit, slide the locking latch to the right until you feel a click, to unlock the handle (B).



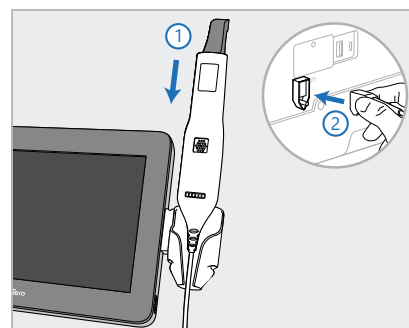
3. Move the handle (B) down to the standing position. Ensure that the handle is securely locked in place by trying to pull it back up.



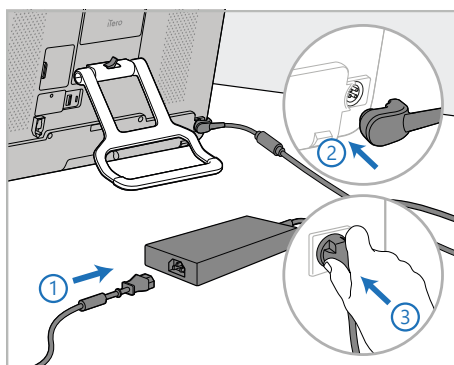
4. Undo the snaps and open the flap to remove the rest of the scanner components.



5. Slide down the cradle (C) on the slider on the side of the computing unit (A) until it clicks into place. Make sure the cradle is secure and cannot be removed.



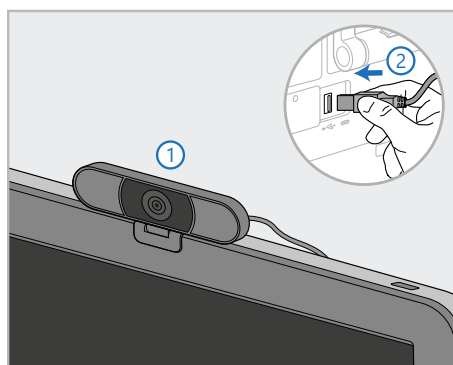
6. Place the wand (D) in the cradle (C) and connect the wand cable to the port marked  at the back of the computing unit (A).



7. Connect the power cable to the power supply (E). Afterwards, connect one side of the cable to the back of the computing unit (A) and the other side to a power outlet.

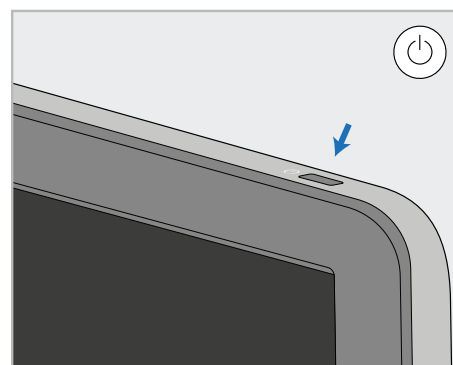
Warning: Use only the supplied power cable, which has a protective earth lead.

Note: Place the cable in a safe manner so that no one is likely to accidentally trip over it.



8. For remote training or support sessions, position the webcam (F) on the computing unit (A) and then connect it to the USB port at the back of the computing unit.

Note: The webcam is packed in the scanner box.

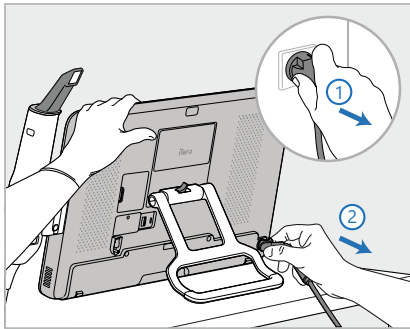


9. Press the power button (G) to turn on the scanner.

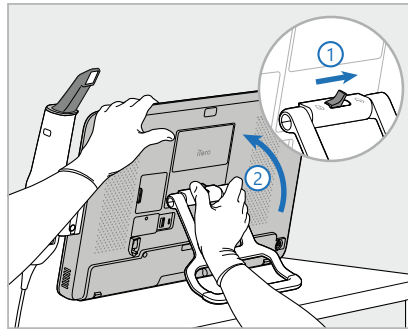
Notes:

- The webcam must be disconnected after each training or support session.
- Always return the wand to the cradle after each use.
- The wand, cradle, and other system components should be [cleaned and disinfected](#) immediately after each patient.
- Ensure that the scanner is positioned in a location where it can easily be disconnected from the power outlet.

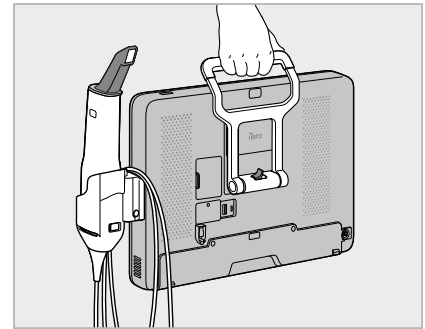
2.4.2 Moving the scanner within the clinic



1. Ensure that the wand (D) is firmly positioned in the cradle (C).
2. Disconnect the power cable (E) from the mains and then from the back of the computing unit (A).



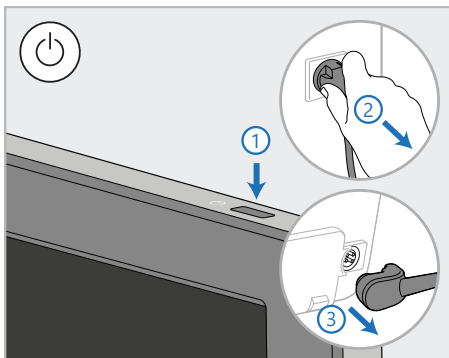
3. While holding the computing unit (A) with one hand, slide the locking latch to the right to unlock the handle (B) and then move the handle to the carrying position.



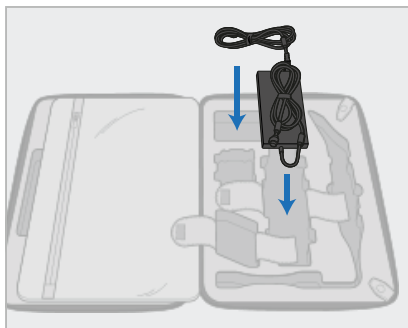
4. Loosely wrap the wand cable around the cradle (C) for easy and safe portability.

2.4.3 Using the trolley for transportation

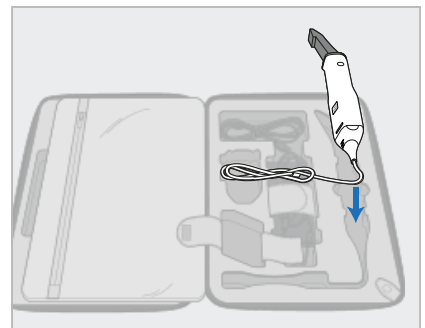
Before transporting the scanner, it must be packed into the supplied trolley.



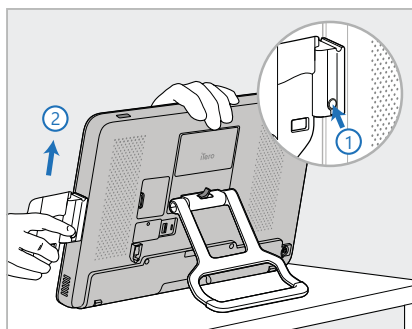
1. Turn off the scanner and disconnect the power cable (E) from the mains and then from the back of the computing unit (A).



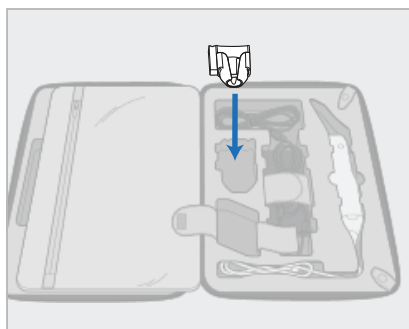
2. For easier packing, start by placing the power pack (E) in its designated compartment in the trolley. Wrap the thinner part of the cable and place it on top of the power supply, and then wrap the thicker part of the cable and place it in its compartment in the trolley.



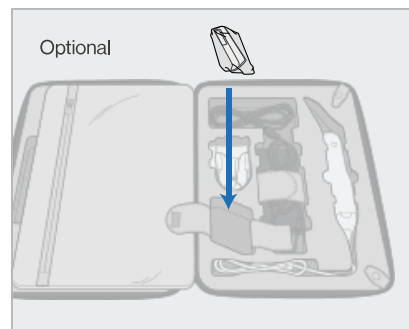
3. Disconnect the wand (D) and place it in its compartment in the trolley.



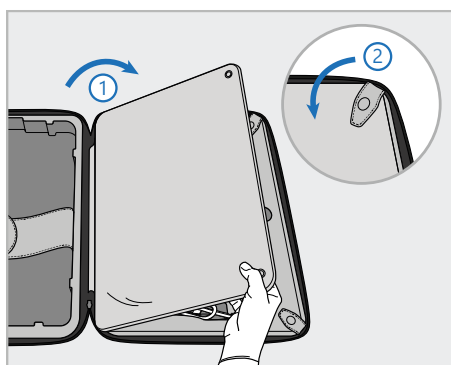
4. While holding the computing unit (A) with one hand, remove the cradle (C) by pressing the release button and pulling up the cradle.



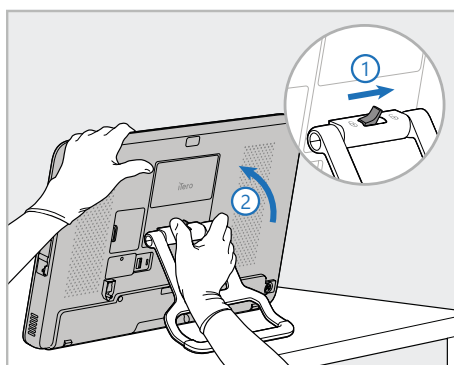
5. Place the cradle (C) in the trolley.



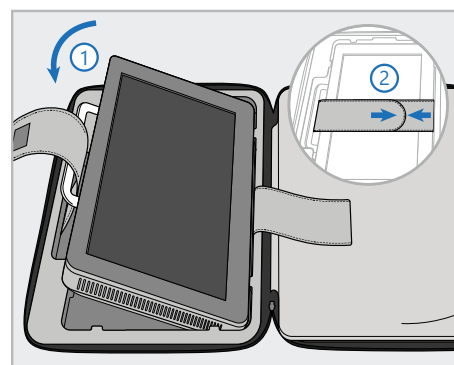
6. Optional: Place new sleeves in the compartment next to the cradle (C), instead of the protective trolley cover (H).



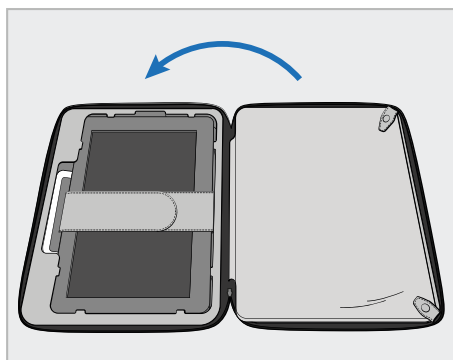
7. Move the flap to cover the scanner components and then secure the flap with the snaps.



8. Slide the locking latch to the right to unlock the stand (B) and then move it to the carrying position.



9. Place the computing unit (A) in its compartment in the trolley. Thread the outer strap through the handle (B) and close the straps to ensure that it is held securely in place.



10. Close the trolley by lifting the side with the fastened flap and then zipping it closed.

You are now ready to travel with the scanner.
If required, you can use the optional protective [trolley cover](#) (H).

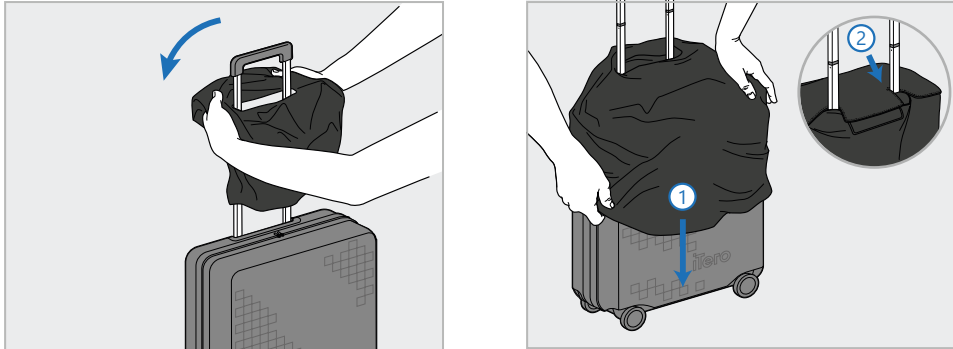
Notes:

- The trolley must be handled with care.
- Avoid leaving the trolley in the sun in order to prevent the scanner from reaching extreme temperatures.
- Make sure the trolley is kept dry to protect the system components from humidity.
- If the scanner has just been brought into the office from a hot, cold, or humid environment, it should be set aside until it has adjusted to room temperature, to avoid internal condensation.
- Do not check the trolley as baggage when traveling by air, to prevent damage to the scanner that may be caused by uncontrolled transportation conditions.

2.4.4 Optional protective trolley cover

The trolley is supplied with an optional protective cover that helps protect it against wear and tear and adverse weather conditions.

Note: The protective cover provides a certain level of protection against rain, but is not waterproof.



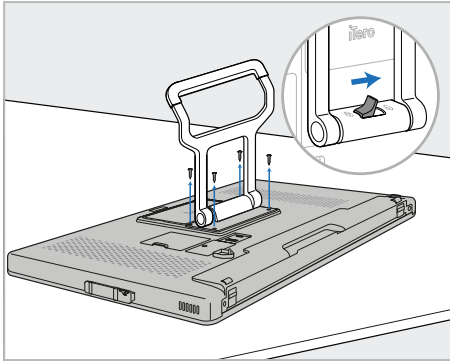
1. Open the VELCRO® flap and slip the protective cover (H) over the trolley handle.
2. Pull down to cover the trolley and then close the VELCRO® flap.

2.4.5 VESA mounting

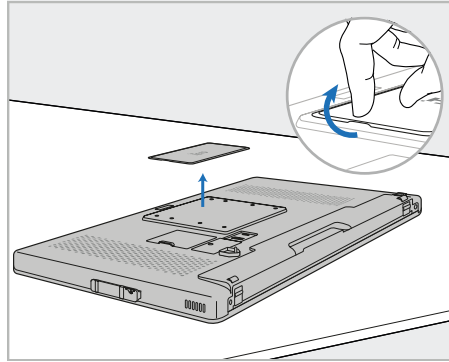
The scanner provides a standard 100mm VESA mounting interface that can be used for mounting it using 3rd party VESA-based mounting solutions.

Notes:

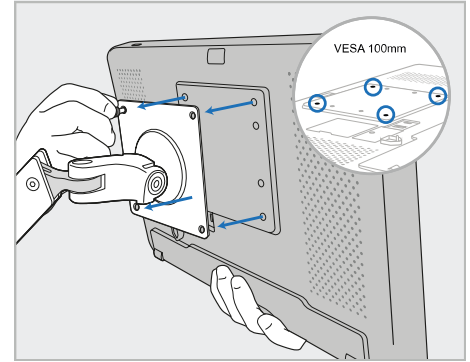
- **Ensure that the selected VESA mounting solution supports the following scanner specifications:**
 - VESA 100mm
 - Minimum weight: 6kg (including the computing unit, wand, and cradle).
Recommended weight: 9kg.
- If the scanner has already been assembled, you must remove the power cable and the cradle, as described in [Using the trolley for transportation](#).
- We recommend that connecting the computing unit to the VESA mount, step 3 below, be performed by two people.



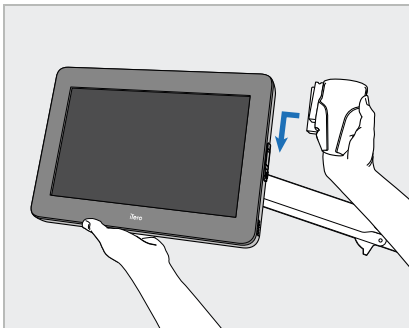
1. Lay the computing unit (A) face down on a smooth, flat surface.
Remove the 4 screws with a Phillips screwdriver, while holding and moving the handle (B), as required.



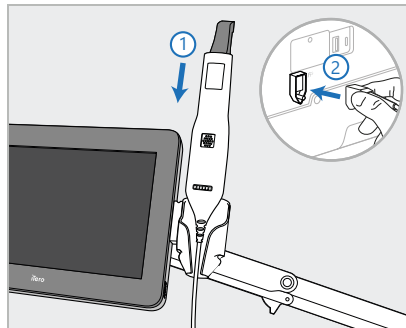
2. Remove the iTero back cover plate to expose the VESA screw holes. (It is recommended to store the cover plate and screws in the trolley.)



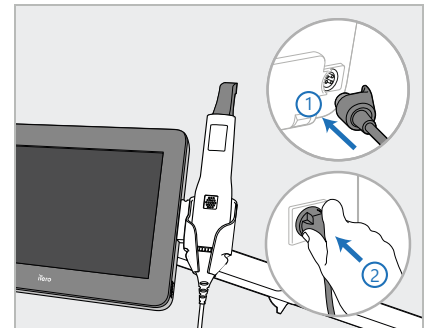
3. Connect the computing unit (A) to the external VESA mount (VESA 100) using the screws supplied with the mounting solution.
Optional: You can purchase a 3m power cable from Align, if required.



4. While supporting the computing unit (A) with one hand, slide the cradle (C) on the slider on the side of the computing unit until it clicks into place.
Make sure the cradle is secure and cannot be pulled off.



5. Place the wand (D) in the cradle (C) and connect the wand cable to the port marked at the back of the computing unit (A).



6. Connect the power cable (E) to the back of the computing unit (A) and then to the mains.

Notes:

- Ensure that the power pack rests on the floor or on a table and does not dangle in the air.

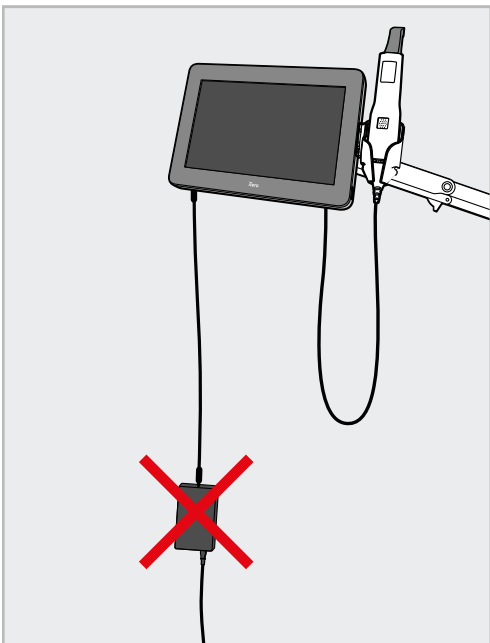


Figure 14: Do not allow the power pack to dangle in the air

- Never tilt the screen more than 45 degrees to make sure that the wand does not slip out of the cradle.

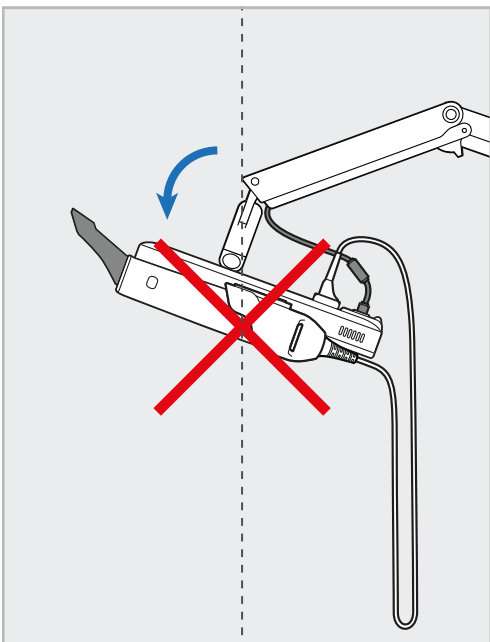


Figure 15: Never tilt the screen more than 45 degrees

3 Getting started

3.1 Logging in to the scanner for the first time

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

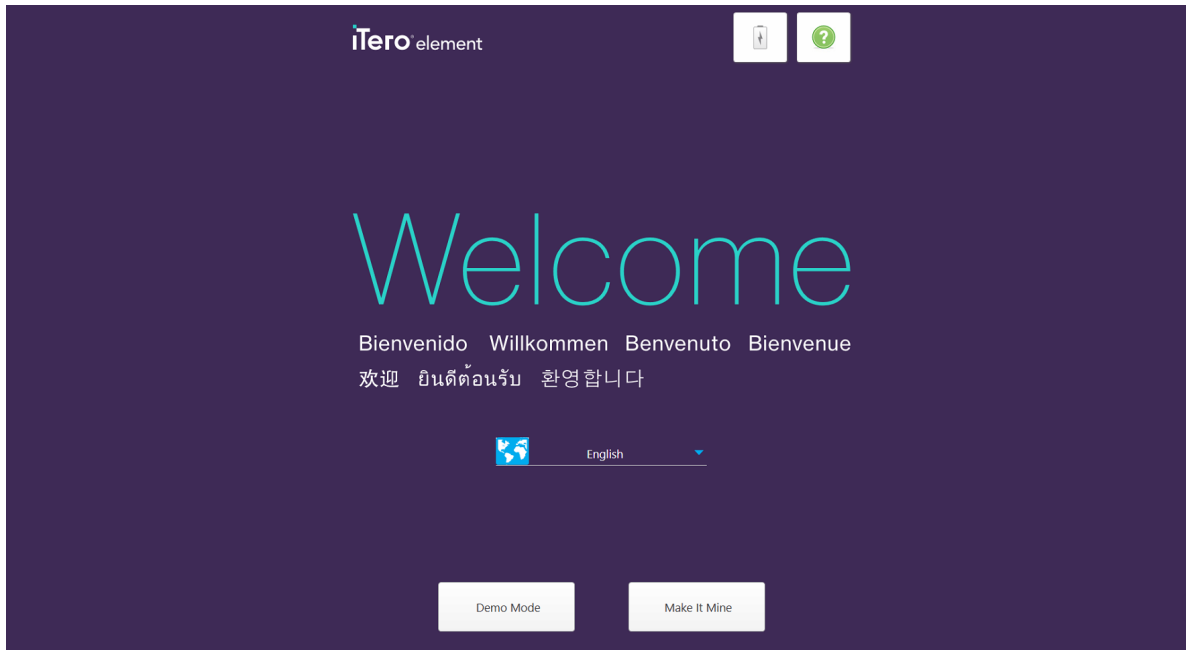


Figure 16: Welcome screen

Select the required language and one of the following options:

- [Make it Mine](#): Enables you to register the scanner.
- [Demo Mode](#): Enables you to familiarize yourself with the scanner's features and perform practice scans without submitting the scans.

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

3.2 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.

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.

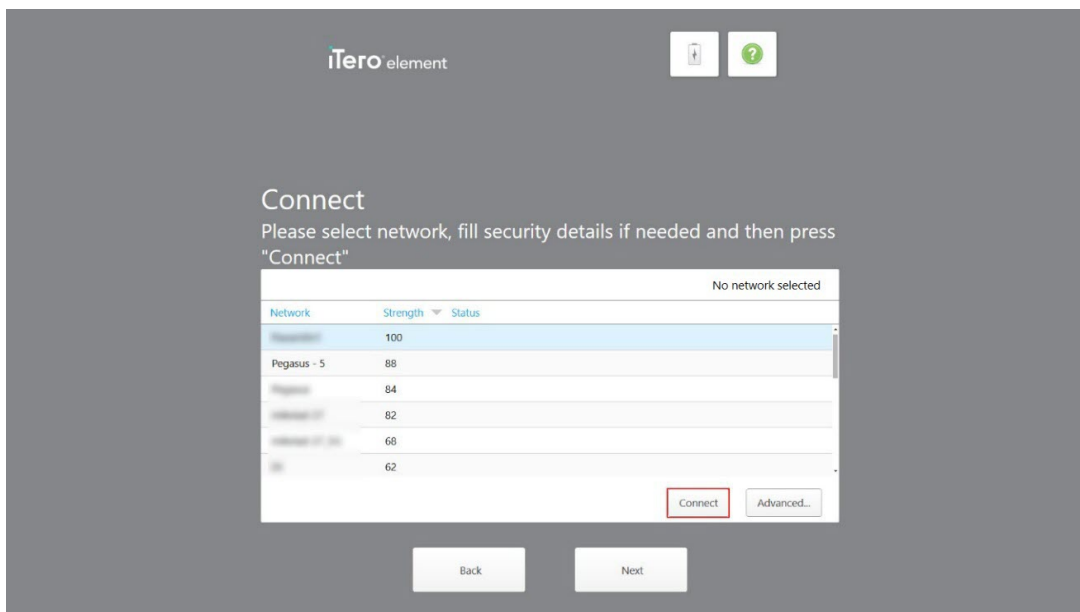


Figure 17: Connect page listing the available networks

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

You are prompted to enter the network security key.

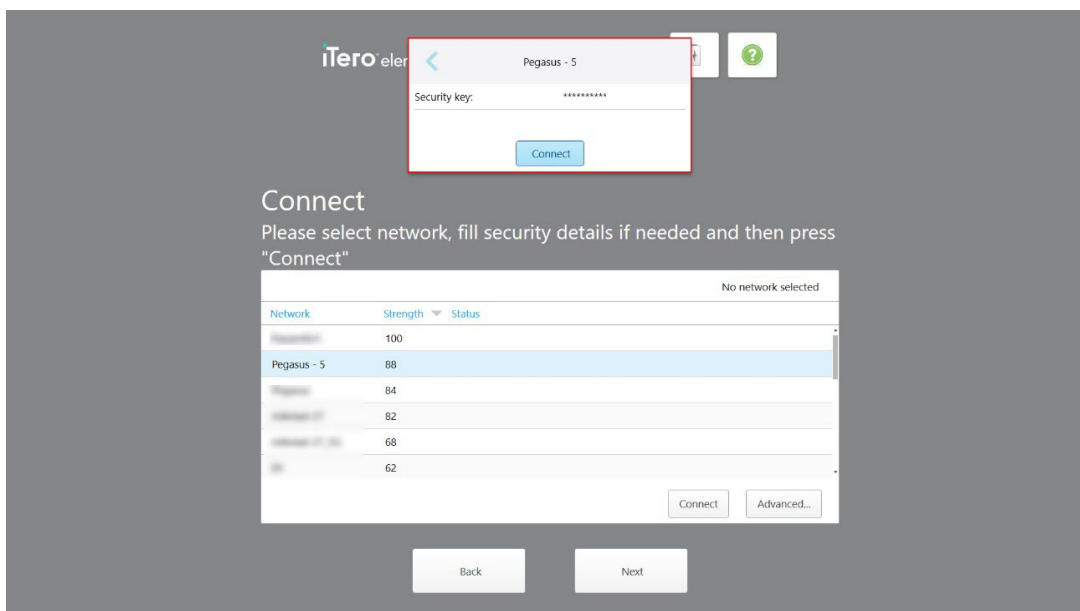


Figure 18: Entering the security key

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

The scanner is now connected to the Internet and online.

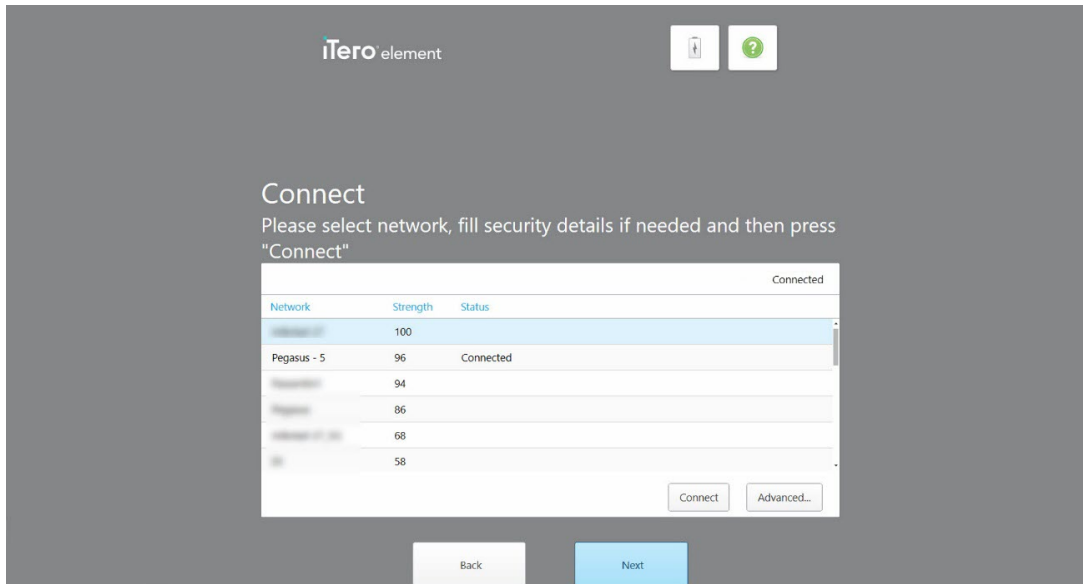


Figure 19: Scanner is connected to the Internet and online

5. Tap **Next**.

The communication with Align is verified.

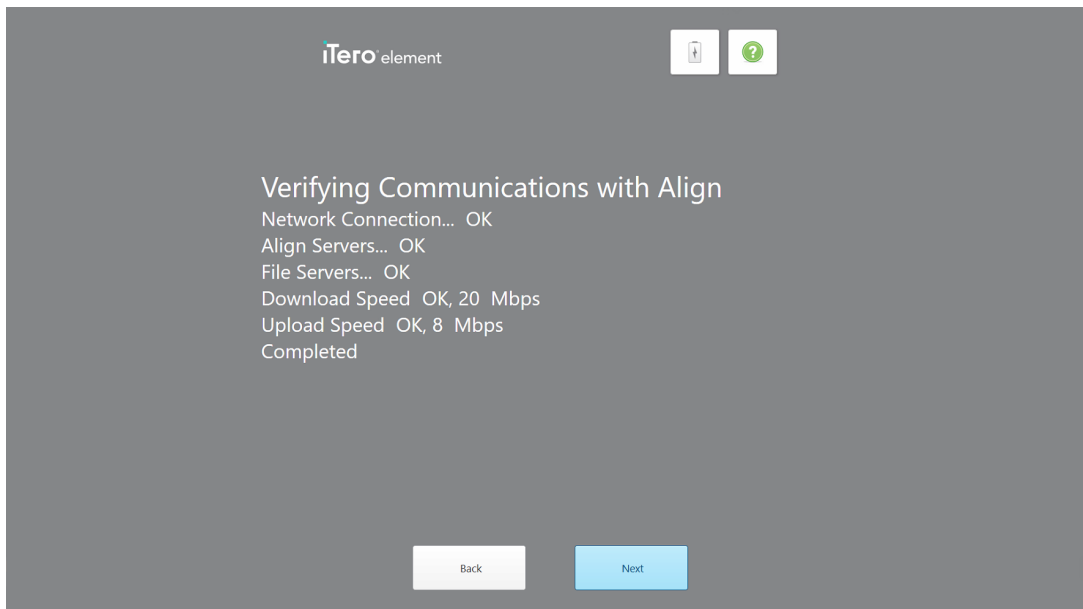


Figure 20: Verifying the communication with Align

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

The *Time Zone* page is displayed.

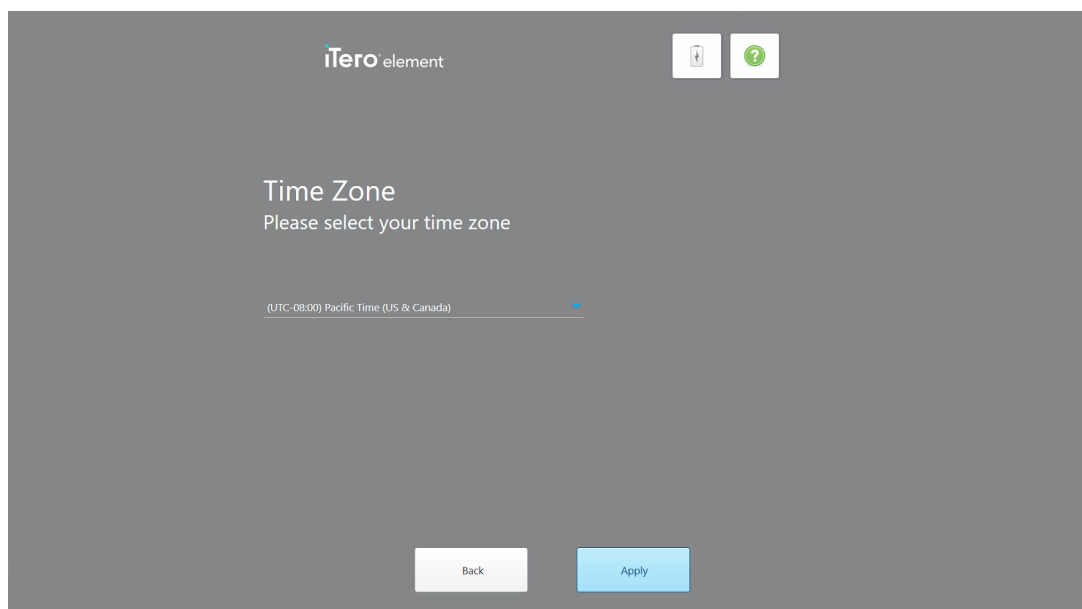


Figure 21: Selecting the time zone

- 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.

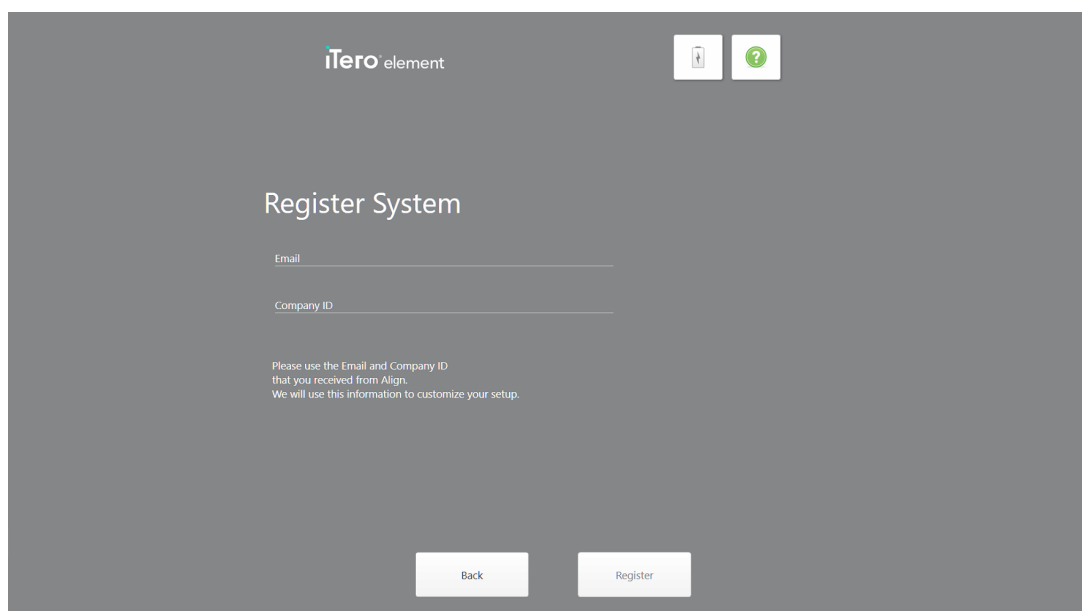


Figure 22: Registering the system to customize the setup

8. Enter the email and company ID listed in the email from iTero in the provided fields and then tap **Register**.
The *Welcome* popup screen is displayed.

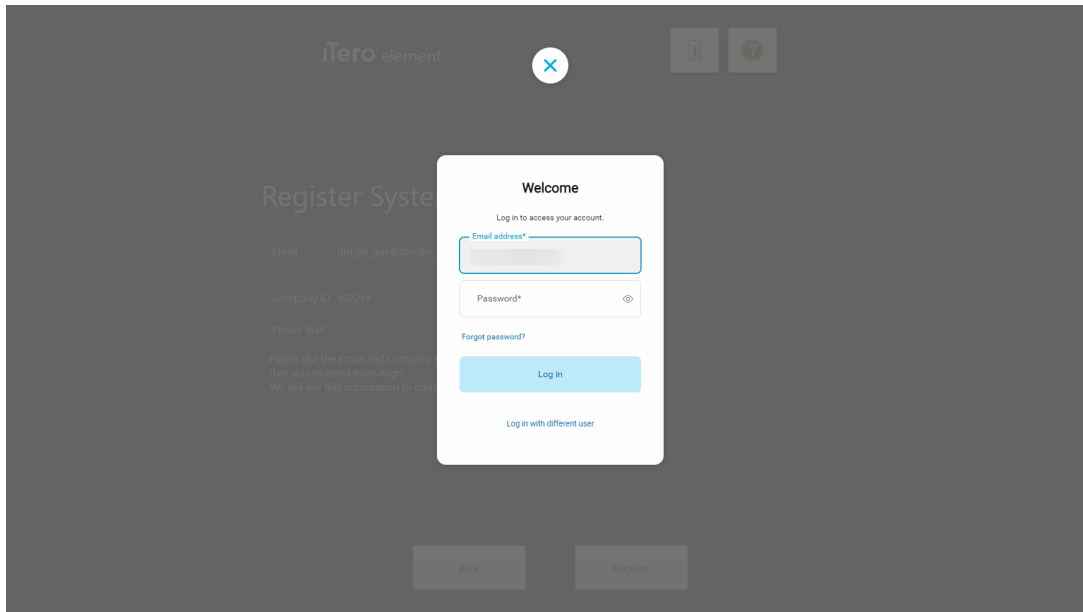


Figure 23: Welcome popup screen

9. Enter your password and then tap **Log in**.
10. After the system has been registered, tap **Next**.

The *Scanner Configuration* page is displayed, showing your iTero subscription package.

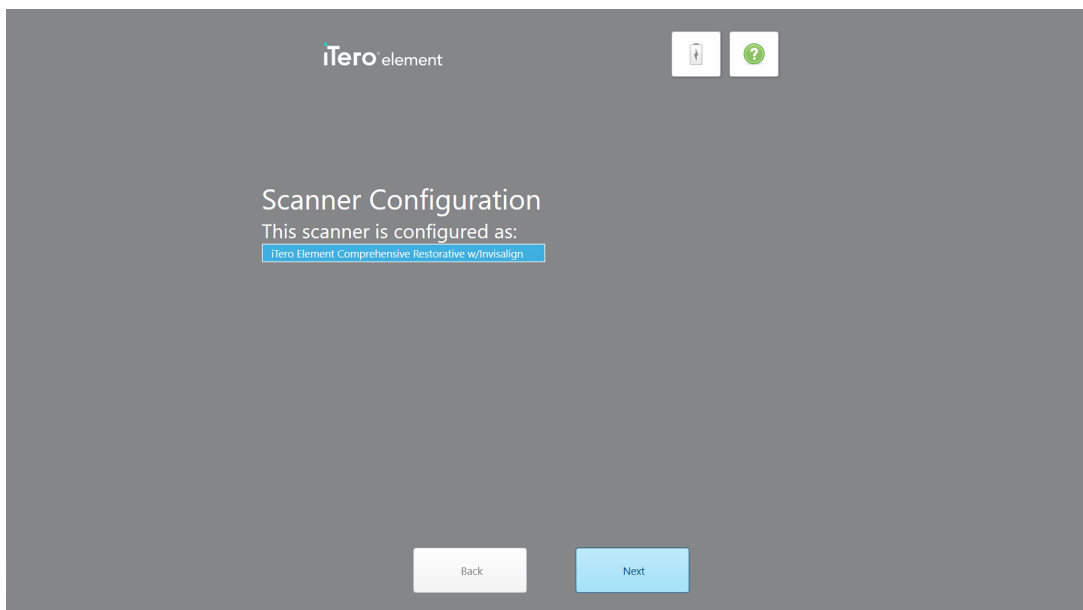


Figure 24: Example of an iTero subscription package

11. Tap **Next**.

The *License Agreement* page is displayed.

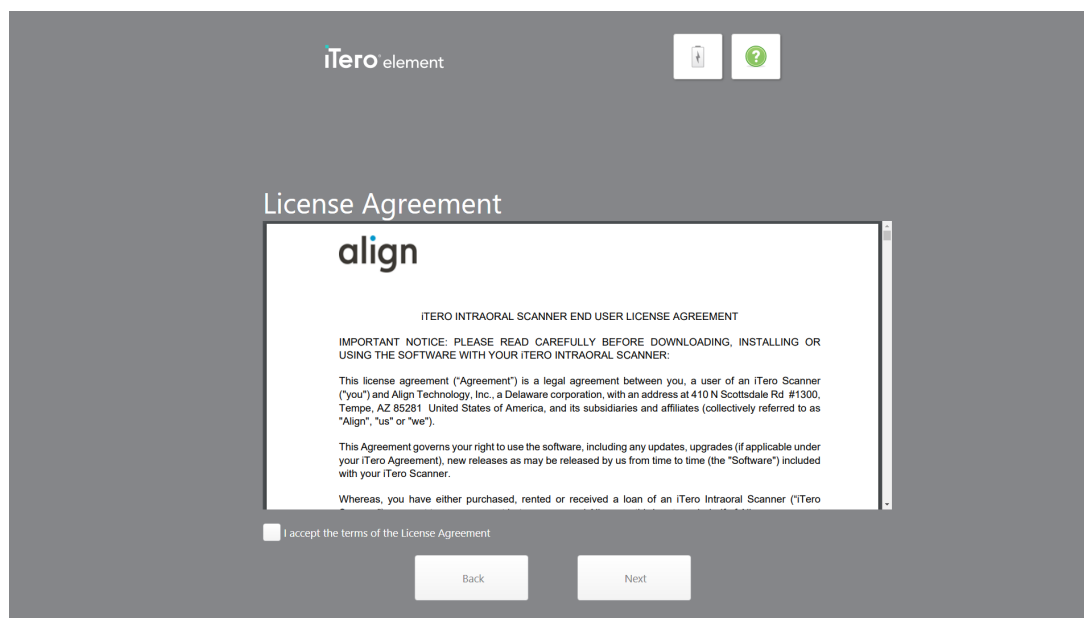


Figure 25: License agreement

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

13. The system checks whether there are any available software updates.
 - If there are no available software updates, proceed to [step 15](#).
 - If the system detects that there is a software update available, the *New software update available* page is displayed, enabling you to select when to install the update.

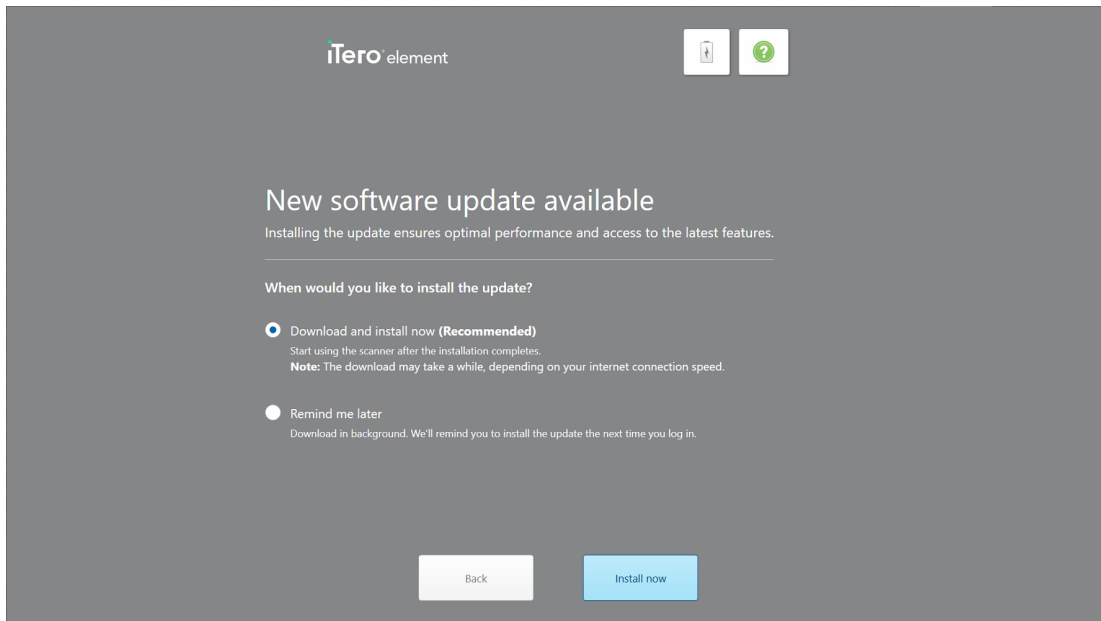


Figure 26: New software update available – installation options

14. Select one of the following options for installing the updated software and then proceed to [step 17](#):

- **Download and install now (Recommended)** and then tap **Install now** – you will be able to use the scanner only after the installation completes.

You are prompted to leave the scanner plugged in, powered on, and connected to the internet while the latest version is being downloaded and installed.

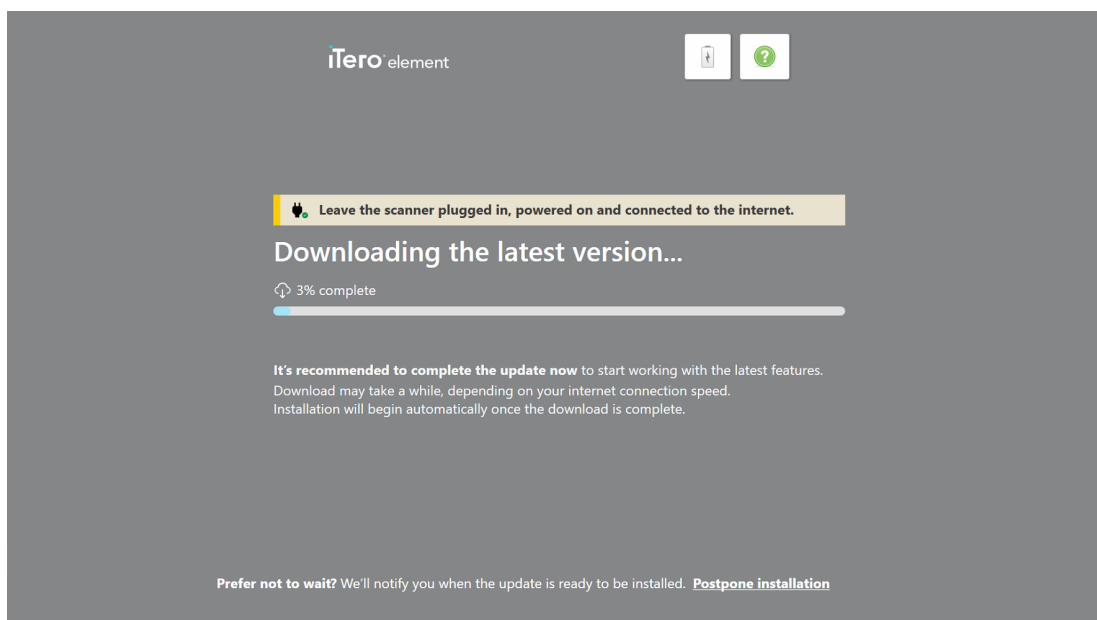


Figure 27: Downloading the latest version

If you decide not to wait for the update to finish before you can start working on the scanner, tap the **Postpone installation** link at the bottom of the screen to continue downloading the updates in the background, and then continue with the registration process.

- **Remind me later** and then tap **Login to iTero** – you can use the scanner immediately after registration. The software is downloaded in the background and you will be reminded to install it the next time you log in to the scanner.

The *Welcome* window is displayed, enabling you to log in to the scanner.

Note: If you are prompted to install security updates, select one of the [scheduling options](#).

15. If the system did not find any updates, tap **Next**.

The system is ready for use.

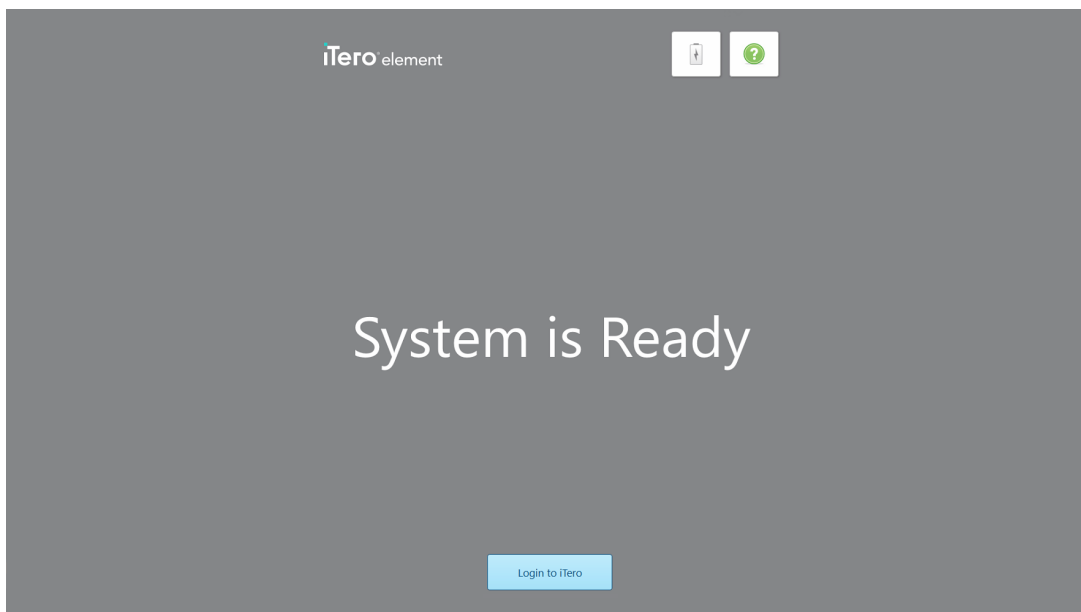


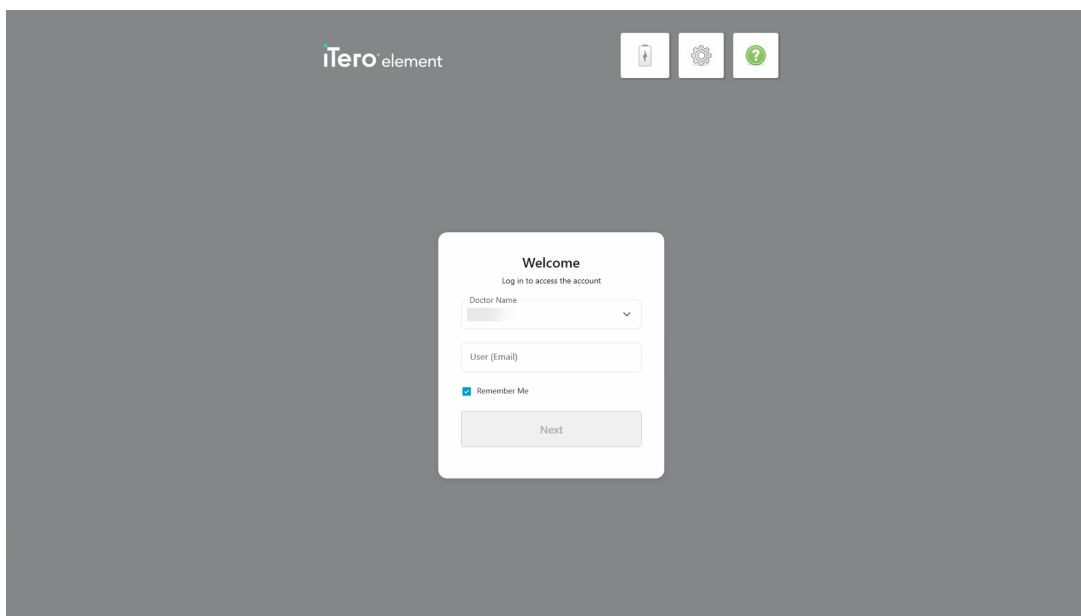
Figure 28: System is registered and ready for use

16. Tap **Login to iTero**.

The *Welcome* window is displayed, enabling you to log in to the scanner.

Note: If you are prompted to install security updates, select one of the [scheduling options](#).

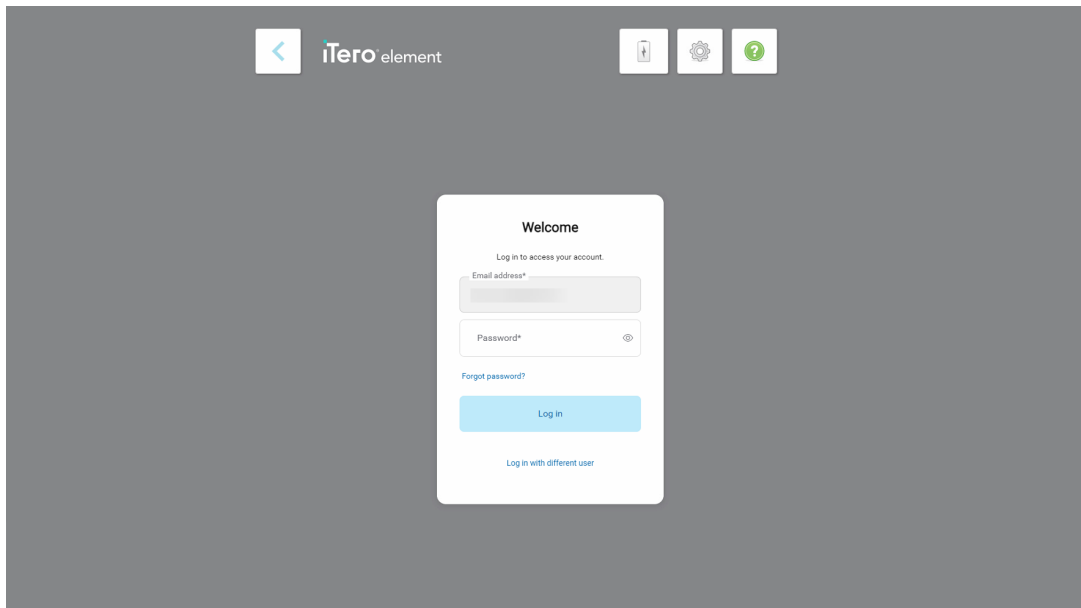
17. Select the username from the **Doctor Name** drop-down list, enter the email address you used when registering with myaligntech.com, and then tap **Next**.



The screenshot shows the iTero Element mobile application's welcome screen. At the top, the 'iTero element' logo is on the left, and three icons (a smartphone, a gear, and a question mark) are on the right. In the center, a white card titled 'Welcome' contains the text 'Log in to access the account'. Below this, there is a 'Doctor Name' drop-down menu, a 'User (Email)' text input field, a checked 'Remember Me' checkbox, and a 'Next' button.

Figure 29: Welcome screen – enter email address

The *Welcome* window is updated.



The screenshot shows the updated iTero Element mobile application's welcome screen. At the top, a back arrow icon is added to the left of the 'iTero element' logo. The central white card now has the text 'Log in to access your account.' followed by an 'Email address*' text input field, a 'Password*' text input field with an eye icon, a 'Forgot password?' link, a blue 'Log In' button, and a 'Log in with different user' link at the bottom.

Figure 30: Welcome screen – enter password

18. Enter your password and then tap **Log in**.

The *Set PIN* page is displayed, allowing you to set up a PIN for logging in to the scanner in both online and offline modes.

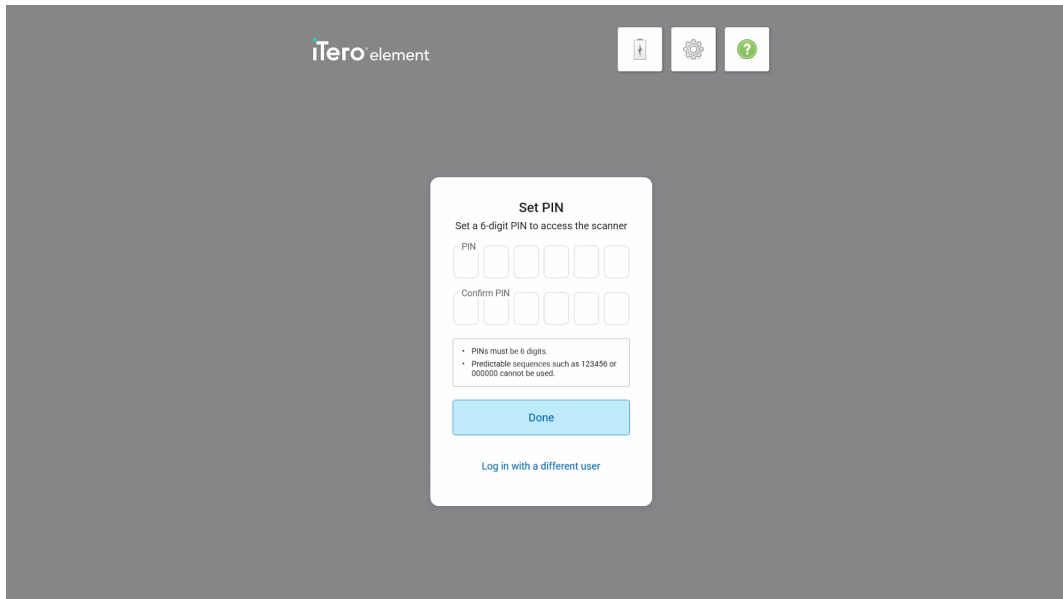


Figure 31: Set PIN screen

19. Enter and confirm a 6-digit PIN and then tap **Done**.

The PIN confirmation page is displayed.

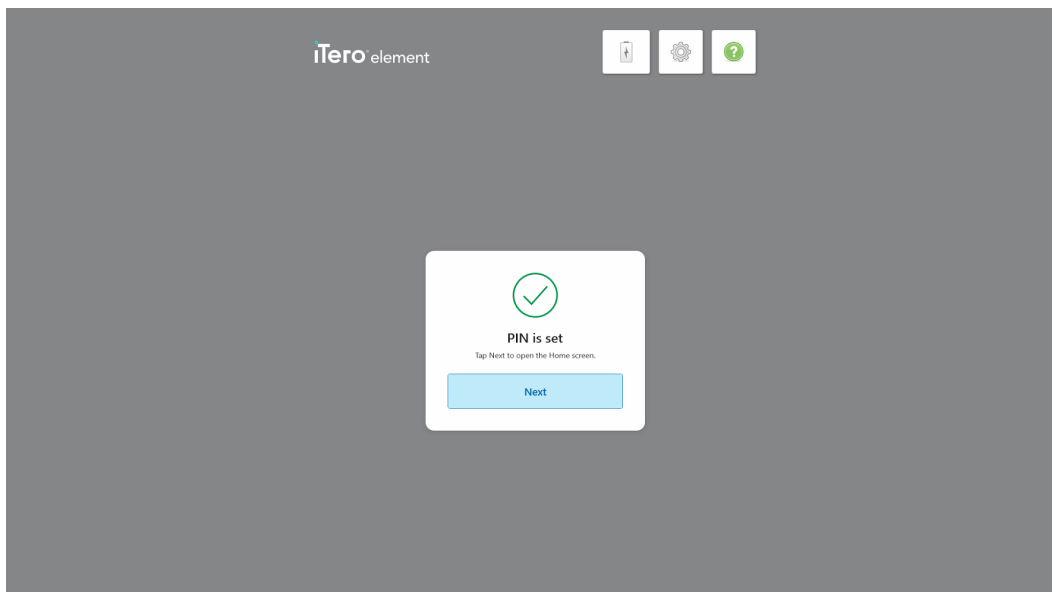


Figure 32: PIN confirmation screen

20. Tap **Next**.

The home screen is displayed.

3.3 Working in Demo Mode

Demo Mode is designed for training new staff members and for practicing scanning. It is available anytime for training on an iTero scanner, for scanning techniques, how-to guidelines for prescription forms, procedures and procedure types, and to familiarize yourself with the iTero interface. Demo Mode features all the aspects of the scanning process and includes a wide variety of sample cases, including clinical cases, Invisalign | Viverra cases, and restorative cases.

The words **Demo Mode** are displayed in red on the top left of the screen to indicate that you are in Demo Mode, and when scanning, a lightly striped background is displayed.

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

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.

To enter Demo Mode after logging in:

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

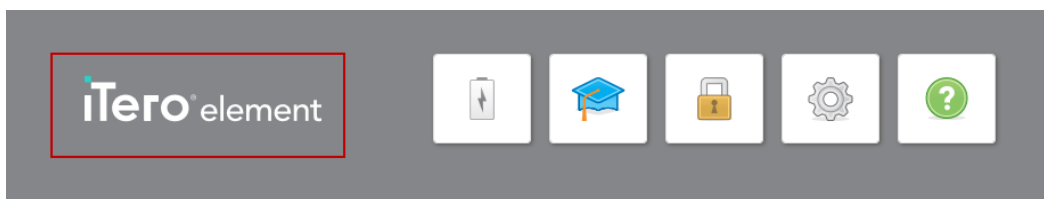


Figure 33: iTero Element logo

2. Tap **Demo Mode**.

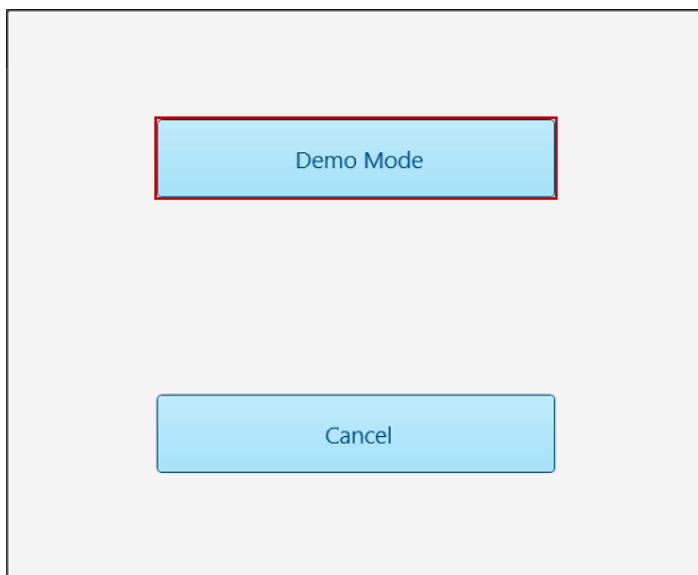
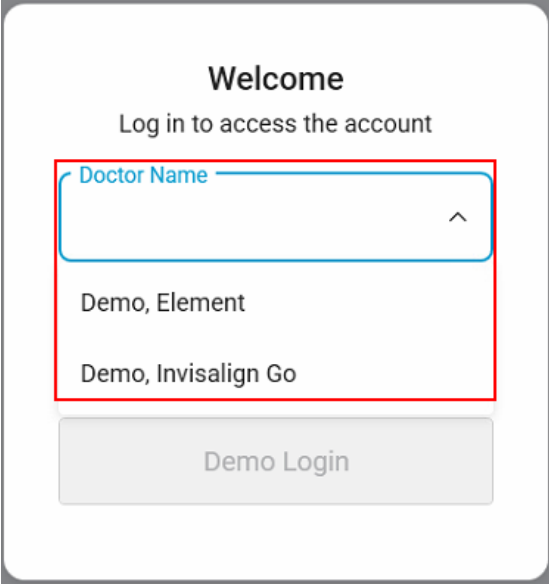


Figure 34: Demo Mode option

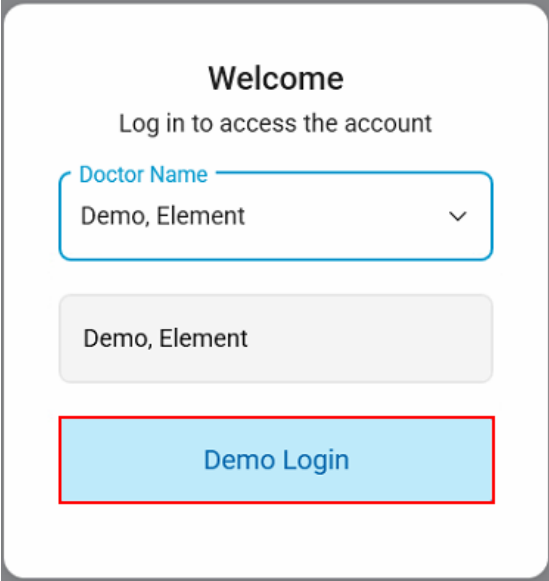
The *Login* window is displayed, enabling you to select the demo user.



The login window displays a 'Welcome' message and a prompt to 'Log in to access the account'. A dropdown menu labeled 'Doctor Name' is highlighted with a red border. The dropdown list shows two options: 'Demo, Element' and 'Demo, Invisalign Go'. Below the dropdown is a 'Demo Login' button.

Figure 35: Login window with a list of demo users

- From the **Doctor Name** drop-down list, select **Demo, Element** to work with restorative cases or **Demo, InvisalignGo** to work with orthodontic cases.



The login window shows the 'Doctor Name' dropdown menu with 'Demo, Element' selected. The 'Demo Login' button is highlighted with a red border.

Figure 36: 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.

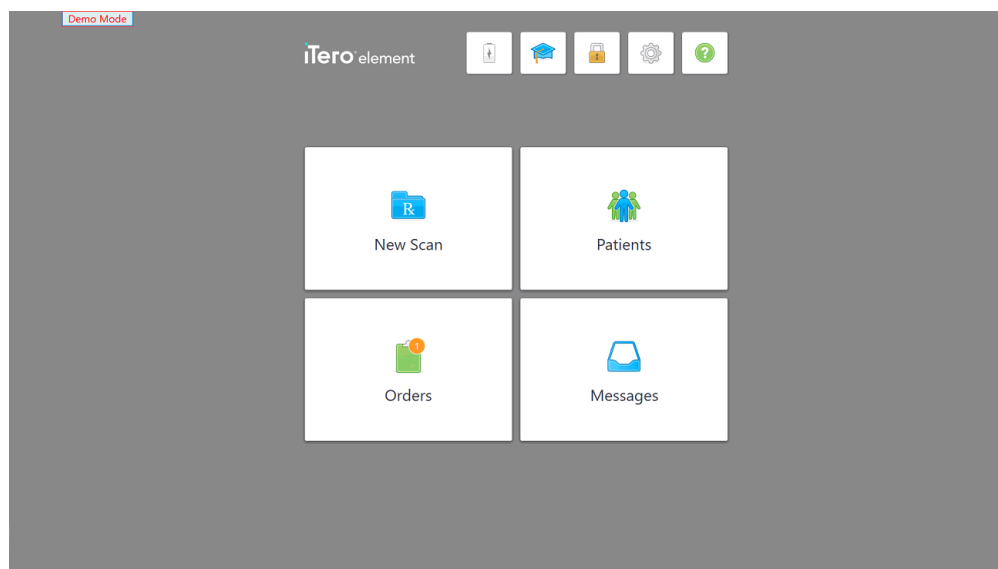


Figure 37: Demo Mode home screen

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

A list of demo cases is displayed in the **Past Orders** pane, according to your iTero subscription package.

6. Tap the required demo case.

The selected case is expanded to show the available options.

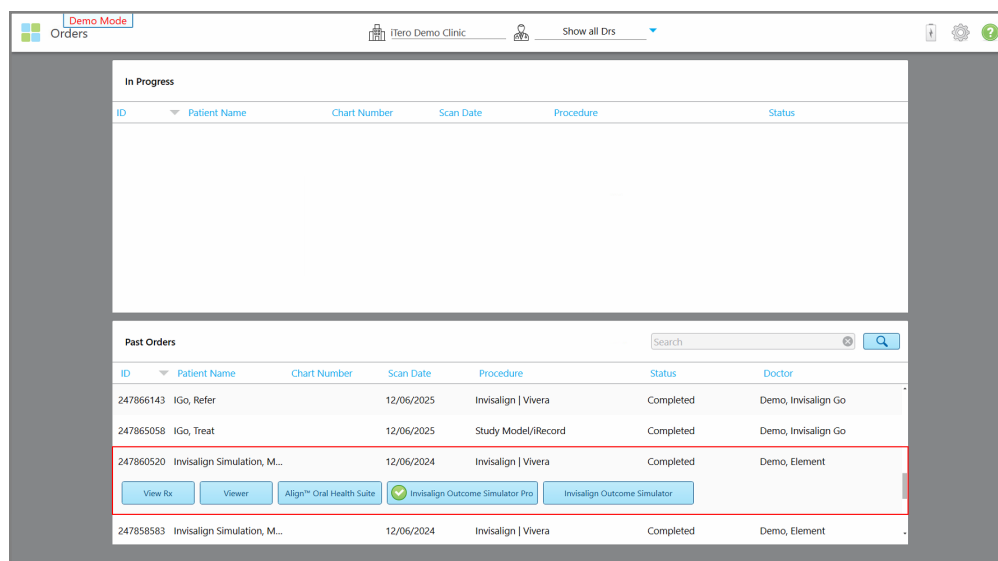


Figure 38: Past Orders pane – options

For more information, see [Working with orders](#).

3.3.1 Align Oral Health Suite

Align Oral Health Suite is a comprehensive digital suite integrating multiple proprietary iTero visualization and diagnostic-aid tools into one easily accessible, patient-centric interface.

Note: Align Oral Health Suite is available on iTero Element 2 Plus intraoral scanners only.

You can access Align Oral Health Suite when sending the scan by tapping **Send & View**, or after sending the scan from the patient's profile page or the **Orders** page. In addition, you can access Align Oral Health Suite from MyiTero.

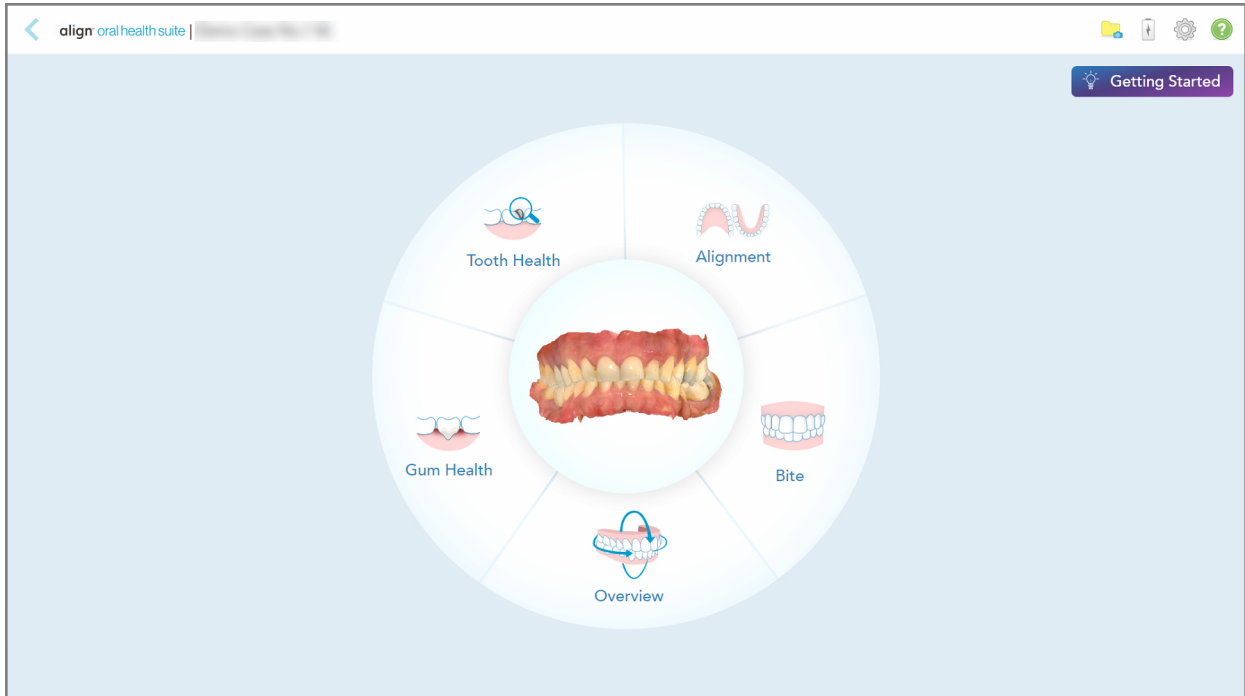


Figure 39: Align Oral Health Suite home screen

Align Oral Health Suite enables you to view the scan in the context of select dental conditions and comprehensively explore potential areas of interest.

When you select a condition, the default view and tools for that condition are automatically selected so that you may start viewing the scan.

Tap the **Getting Started** button for more information regarding using Align Oral Health Suite.

3.3.2 Exiting Demo Mode

To exit Demo mode:

1. Tap  to move to the home screen and then tap the **iTero Element** logo at the top of the screen.

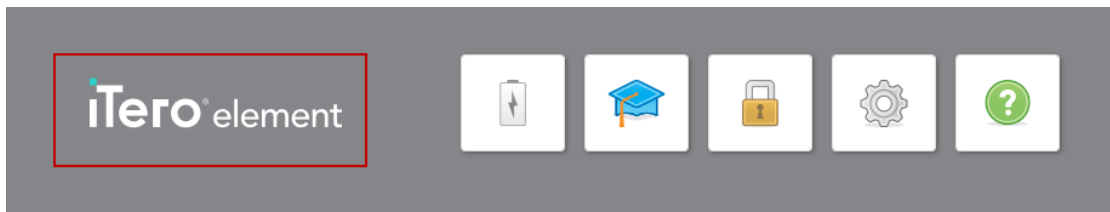


Figure 40: iTero Element logo

2. Tap **Exit Demo** to exit Demo mode.



Figure 41: Exiting Demo mode

4 Working with the scanner

4.1 Logging in to the scanner

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

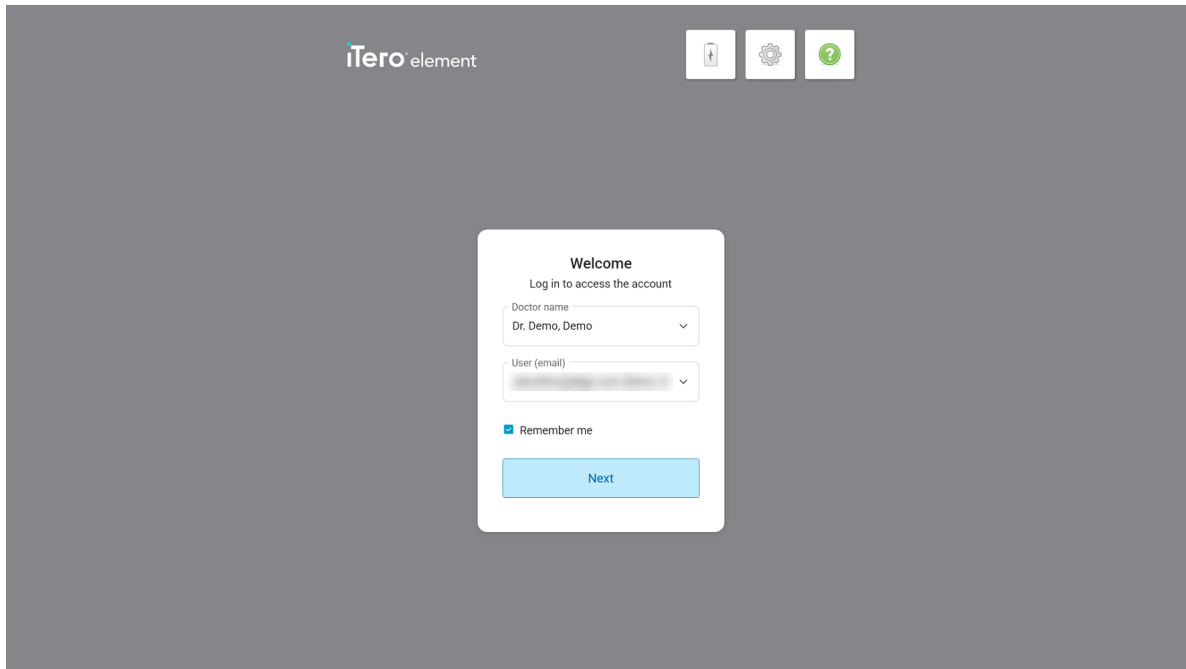


Figure 42: Welcome window

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:

- This user manual is written for dental clinics with more than one doctor. If your clinic has only one doctor, you do not need to select your name from the **Doctor Name** drop-down list or set a PIN the first time you log in.
- In order to ensure that you are using the latest version of the iTero software and that all security patches are up to date, a notification is displayed as soon as software or security updates are available for installation. For more information on scheduling the installation of these updates, see [Updating the scanner software and security](#).

- 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, see [Shutting down the scanner](#).

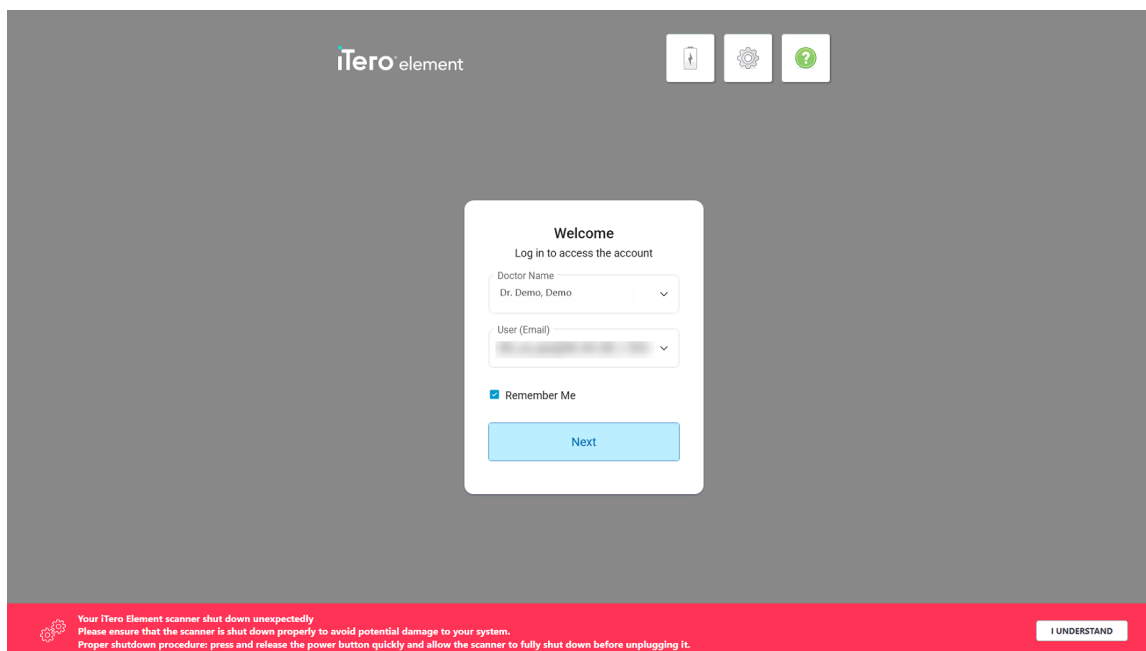


Figure 43: Unexpected shutdown notification

To log in to the scanner:

1. Select your 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. 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 (or PIN) to access the scanner.
4. Tap **Next**.
5. Enter your password in the field provided.

The text is masked as asterisks.

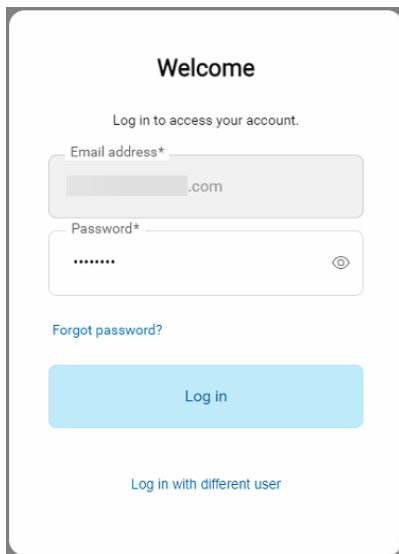
A screenshot of a mobile application's login screen. At the top, the word "Welcome" is centered. Below it, the text "Log in to access your account." is displayed. There are two input fields: "Email address*" and "Password*". The email field contains a masked address ending in ".com". The password field contains seven asterisks and has an eye icon to its right. Below the password field is a link "Forgot password?". At the bottom is a large blue button labeled "Log in" and a smaller link "Log in with different user" below it.

Figure 44: Password is masked

If you have forgotten your password, you can [reset](#) it.

6. Tap **Log in**.

The *Set PIN* window is displayed, enabling you to set a PIN to unlock the scanner in both online and offline modes.

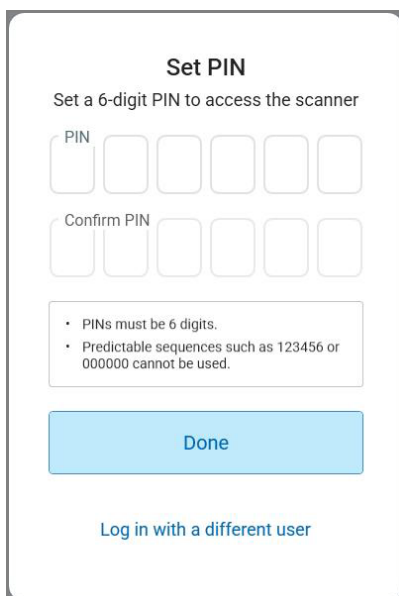
A screenshot of a mobile application's "Set PIN" screen. The title "Set PIN" is at the top, followed by the instruction "Set a 6-digit PIN to access the scanner". There are two rows of six input boxes each, labeled "PIN" and "Confirm PIN". Below these is a box containing two bullet points: "• PINs must be 6 digits." and "• Predictable sequences such as 123456 or 000000 cannot be used." At the bottom is a large blue button labeled "Done" and a smaller link "Log in with a different user" below it.

Figure 45: Set PIN window

7. Enter a 6-digit PIN and then confirm it.

8. Tap **Done** to set the PIN.

A confirmation window is displayed.

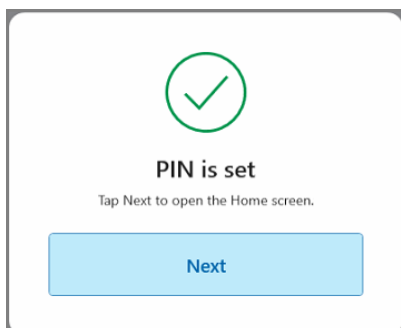


Figure 46: PIN set confirmation window

The first time you log in to the scanner every day, you must enter your password. You can then [use the PIN](#) for all subsequent logins.

9. Tap **Next** to log in to the scanner.

The iTero home screen is displayed.

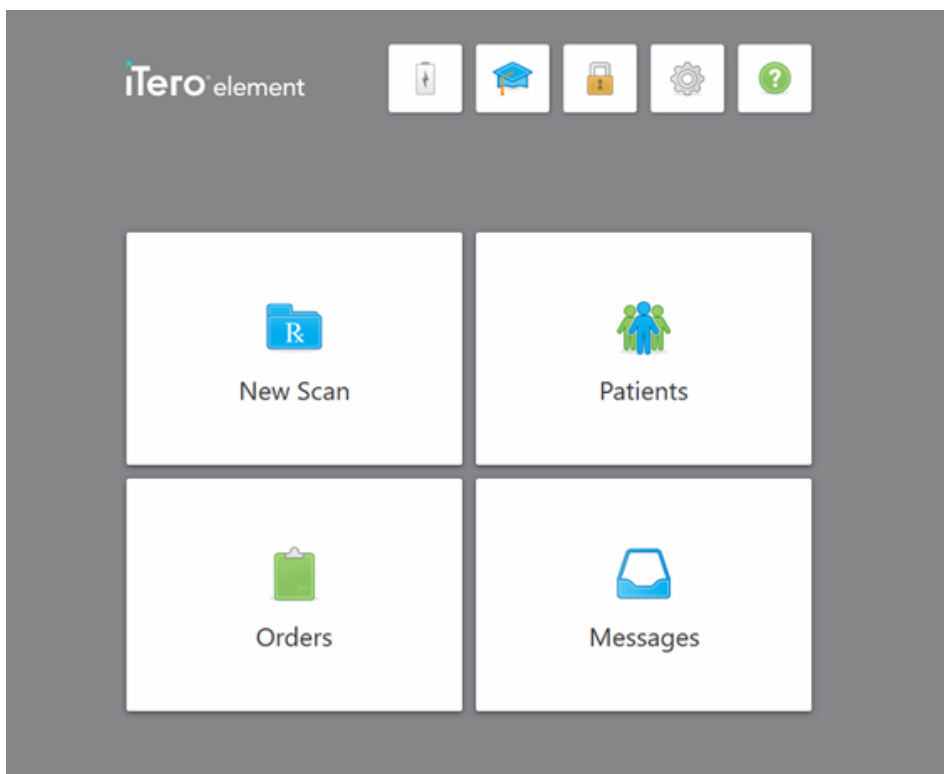


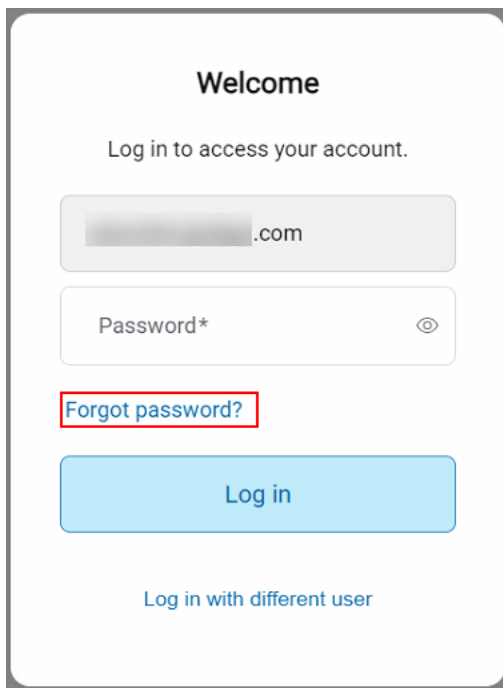
Figure 47: iTero home screen

4.1.1 Resetting your password

You can reset your password, if required. The instructions for resetting your password will be sent to your email address.

To reset your password:

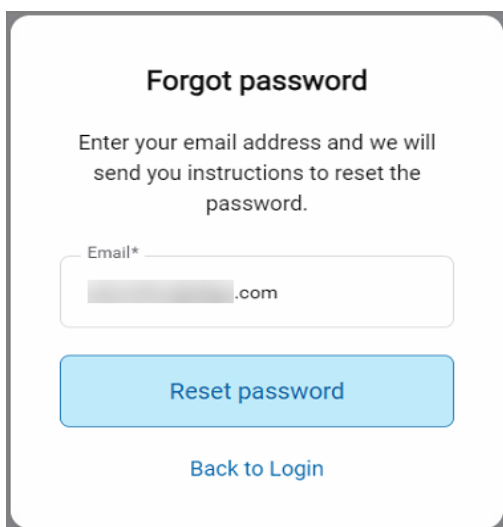
1. In the *Welcome* window, tap **Forgot Password**.



The screenshot shows the 'Welcome' login screen. At the top, it says 'Welcome' and 'Log in to access your account.' Below this are two input fields: one for email (showing a masked address ending in '.com') and one for 'Password*' with a toggle icon. A red rectangle highlights the 'Forgot password?' link located below the password field. At the bottom, there is a blue 'Log in' button and a link that says 'Log in with different user'.

Figure 48: Forgot Password link

The *Forgot password* window is displayed.



The screenshot shows the 'Forgot password' window. It has the title 'Forgot password' and the instruction 'Enter your email address and we will send you instructions to reset the password.' Below this is an 'Email*' input field with a masked address ending in '.com'. A blue 'Reset password' button is positioned below the input field. At the very bottom, there is a link that says 'Back to Login'.

Figure 49: Forgot password window

2. Enter your email address if you did not select the **Remember Me** checkbox.

3. Tap **Reset password**.

A message is displayed notifying you to check your email for instructions on how to reset your password.

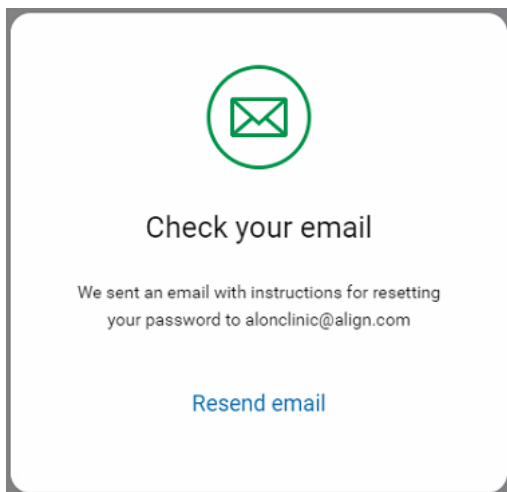


Figure 50: Check your email notification

4.1.2 Logging in with a PIN

The first time you log in to the scanner every day, you need to enter your password. For each subsequent login, you can enter your 6-digit PIN.

To log in to the scanner with a PIN:

1. In the *Welcome* window, select your name and user (email) and then tap **Next**.

You are prompted to enter your PIN to continue.

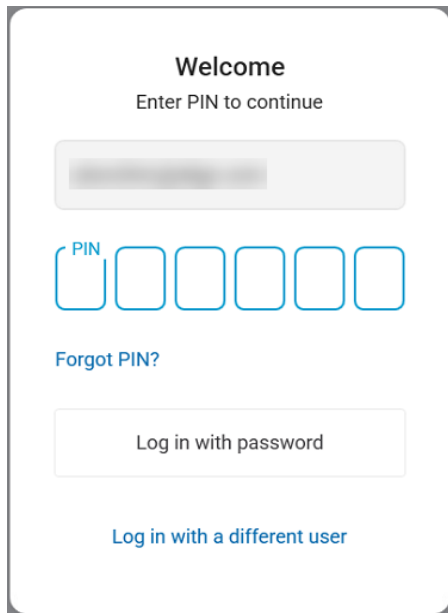


Figure 51: Welcome window - Enter PIN

2. Enter your 6-digit PIN.

The home screen is displayed.

4.1.2.1 Resetting the PIN

If you have forgotten your PIN or would like to change it, you can reset it from the *Welcome* window, or from the [Scanner settings](#).

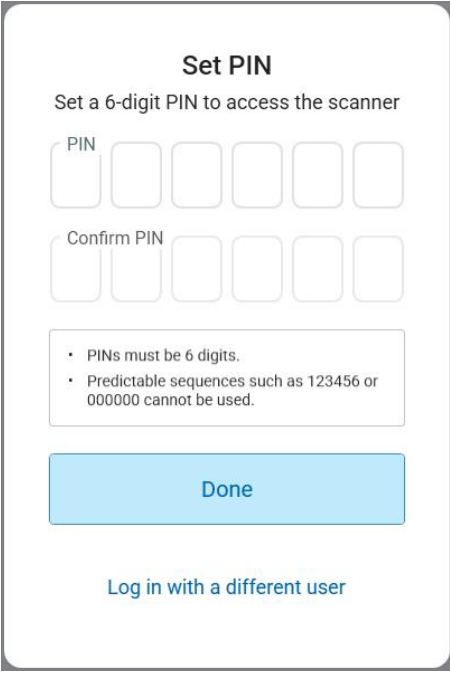
To reset the PIN from the Welcome window:

1. In the *Welcome* window, tap **Forgot PIN?**.

You are prompted to enter your password.

2. Enter your password and then tap **Log in**.

The *Set PIN* window is displayed.

The image shows a mobile application window titled "Set PIN". Below the title is the instruction "Set a 6-digit PIN to access the scanner". There are two rows of input fields: the first row is labeled "PIN" and the second row is labeled "Confirm PIN". Each row contains six empty square boxes for digits. Below these fields is a list of rules: "PINs must be 6 digits." and "Predictable sequences such as 123456 or 000000 cannot be used." At the bottom of the window is a large blue button labeled "Done" and a link labeled "Log in with a different user".

Set PIN

Set a 6-digit PIN to access the scanner

PIN

Confirm PIN

- PINs must be 6 digits.
- Predictable sequences such as 123456 or 000000 cannot be used.

Done

[Log in with a different user](#)

Figure 52: Set PIN window

3. Enter and then confirm the 6-digit PIN.

Note: The PIN cannot be the same as the previous PIN.

4. Tap **Done** to log in.

4.1.3 Updating the scanner software and security

In order to ensure that the scanner software is up to date, and to support the continuous cyber security of the scanner, any available software or security updates are automatically downloaded to the scanner. These updates must be installed within a predefined period – 3 days for software updates or 7 days for security updates.

You are notified of the available updates when you log in to the scanner and must then schedule a time they should be installed – postponed daily for up to the defined time for the specific update, immediately, or at 11:00 PM that same night.

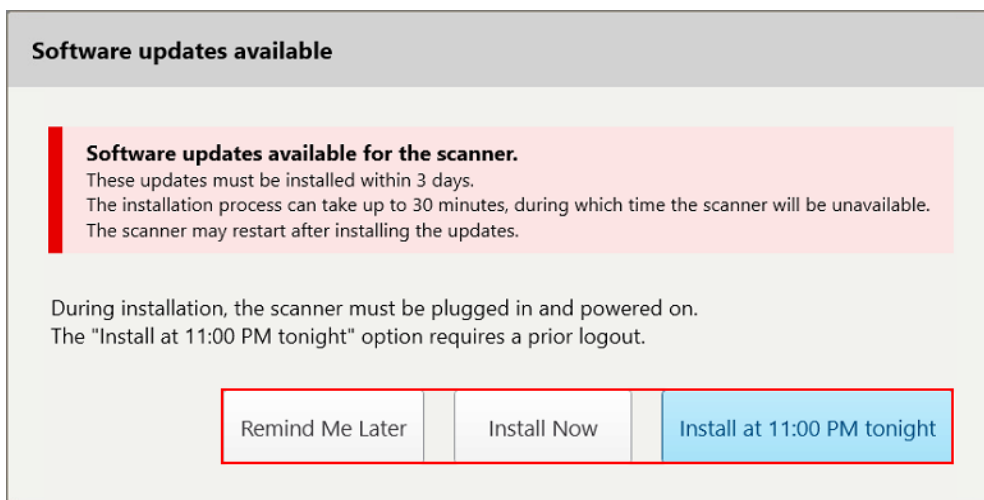


Figure 53: Software updates available window – scheduling options

To install the software updates, the scanner needs to be connected to the AC power and switched on. If you are installing the software later that night, you need to log out.

Notes:

- Installing the updates should take up to 30 minutes for software updates, and up to 90 minutes for security updates, during which time the scanner cannot be used.
- Once the installation starts, it cannot be paused or canceled.
- If you ignore the message and do not install the software updates within the defined time, they will be installed automatically the next time the scanner is restarted.

To schedule the update installation:

1. In the relevant updates window, tap one of the following scheduling options:
 - **Remind Me Later:** The installation is postponed for up to 3 or 7 days.
 - **Install Now:** The software is installed immediately.
 - **Install at 11:00 PM tonight:** The updates will be installed at 11:00 PM that night.

2. Before the installation is due to take place, make sure that the scanner is connected to the AC power and switched on. If you will be installing the software later that night, make sure that you have logged out.

If the scanner is not connected to the AC power, you are prompted to connect it.



Figure 54: Connect the scanner to the AC power

- Plug in the scanner and then tap **Continue**.

The installation starts and a message is displayed showing the installation progress.

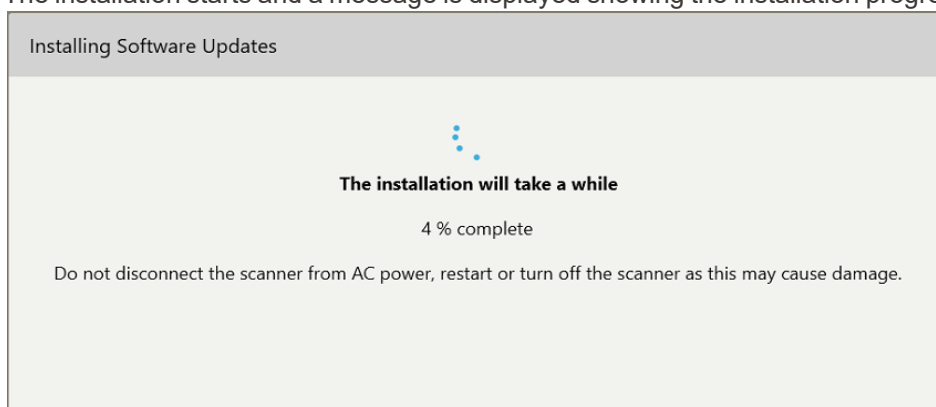


Figure 55: Installation in progress

Note: Do not unplug, restart, or turn off the scanner while the software updates are being installed.

Once the software has been installed, a success notification is displayed and the scanner restarts.

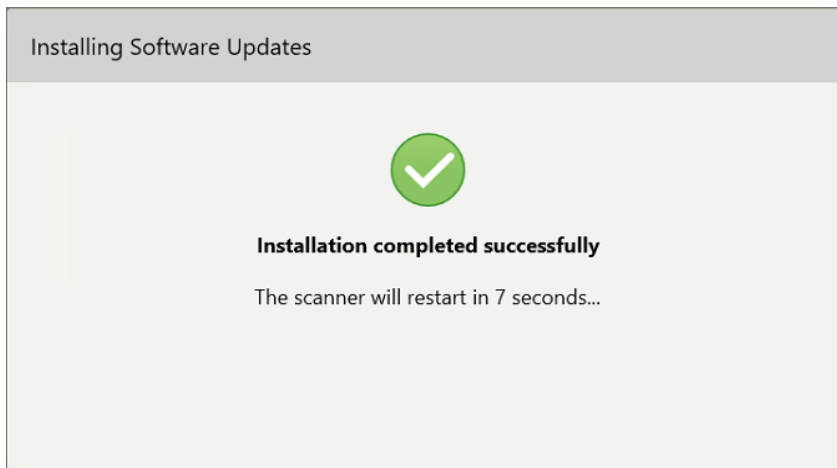


Figure 56: Installation completed successfully

4.1.3.1 Remind Me Later – Postponing the update installation

You can postpone the update installation for up to 3 or 7 days, depending on the type of update. Every day, the notification will display the number of days remaining until the updates have to be installed. You can select to postpone the updates, install them immediately, or schedule them for 11:00 PM that night.

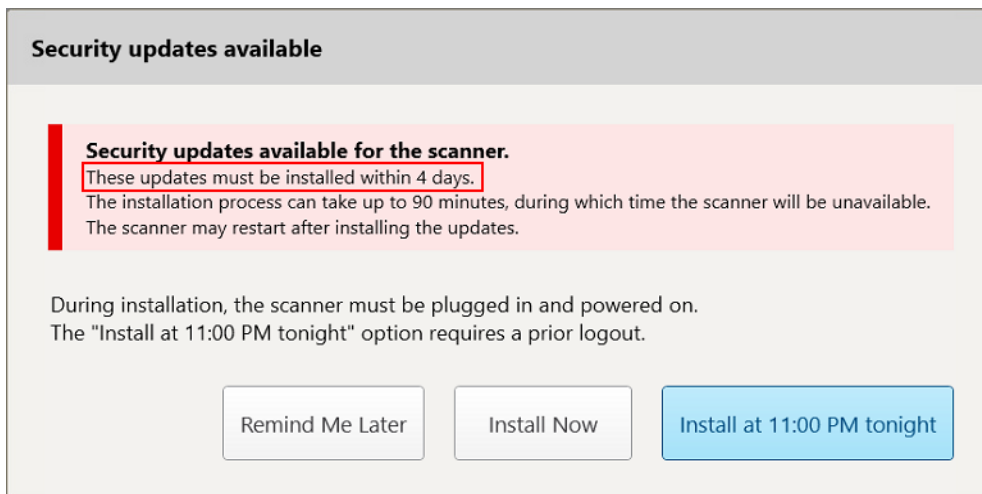


Figure 57: Security updates – number of days until the updates must be installed

On the last day, the updates must be installed. You can select whether to install them immediately, or schedule the installation for 11:00 PM that night, as described below.

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

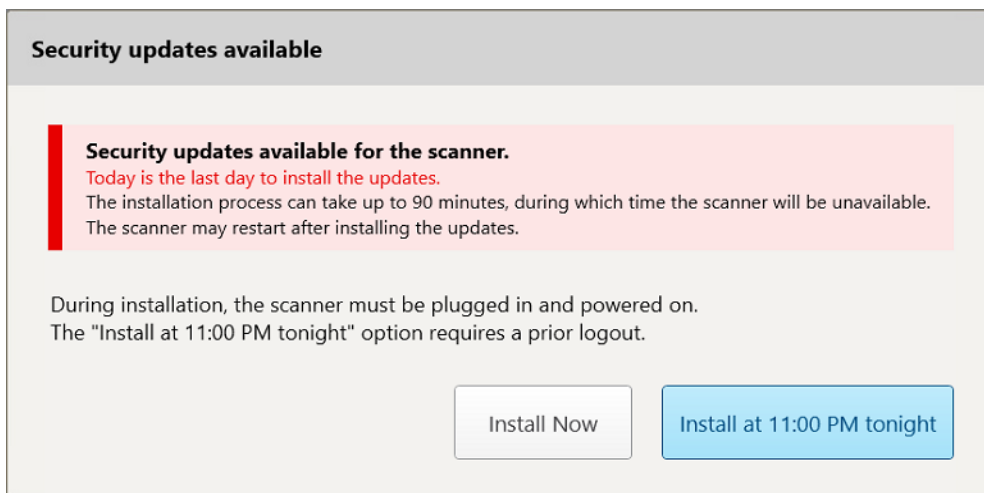


Figure 58: Security updates – last day

4.1.3.2 Install at 11:00 PM tonight – Installing the updates later that night

If you select to install the updates at 11:00 PM that night, a banner is displayed above the scanner *Login* window and the home screen reminding you that you need to log out and the scanner needs to be connected to the AC power and switched on.

In addition, you can tap the **Install Now** button on the banner if at any stage you decide to install the updates immediately rather than wait until 11:00 PM that night.

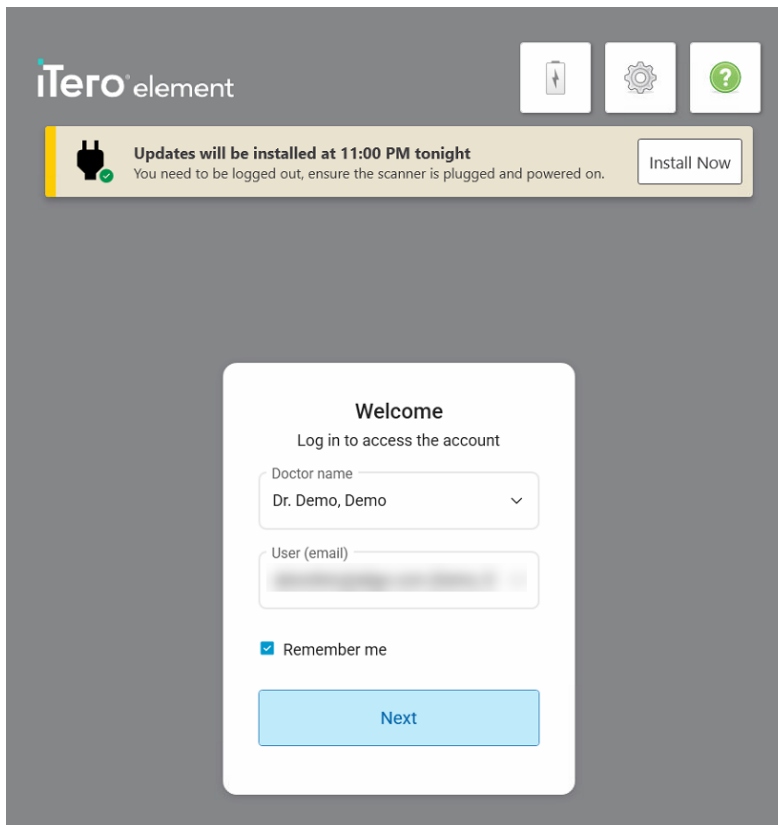


Figure 59: Updates notification – Welcome window

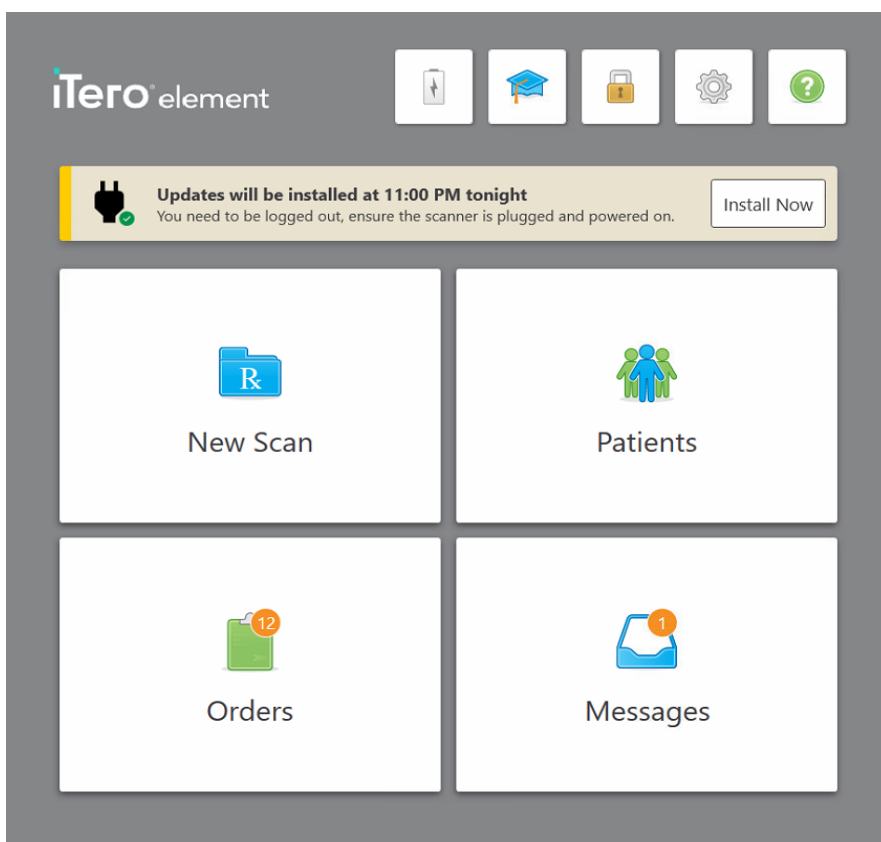


Figure 60: Updates notification – home screen

4.2 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. Your password will *not* be remembered by the system.

By default, you will be logged out after a predefined period of inactivity, which can be defined in the [Login](#) settings.

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.

4.3 Shutting down the scanner

It is recommended to shut down the scanner at the end of each day, to ensure optimal performance.

Note: Do not shut down the scanner if you have scheduled a software installation for [that night](#).

To shut down the scanner:

- Press and release the Power button to shut down the system. The Power button is located on the bottom right of the screen in iTero Element 2 systems and on the top right of the screen in iTero Element 2 Plus systems.

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 letting the battery run down and by pressing the Power button for longer than 4 seconds, which activates a hard reset and can cause problems such as gray and blue screens.

4.4 Moving the scanner

4.4.1 Moving the iTero Element 2 wheel-stand configuration 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, with the optical window facing the cradle.
2. Unplug the system from the wall outlet.
3. Move the system to its new location and plug it into a wall outlet.

4.4.2 Transporting the iTero Element Flex intraoral scanner

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

1. Attach the blue protective sleeve onto the wand.

2. Place all items in the supplied carrying case to move the system between offices.



Figure 61: iTero Element Flex intraoral scanner in the supplied carrying case

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

4.4.3 Moving the iTero Element 2 Plus cart-configuration scanner

The scanner can be moved between rooms within the office and while you are seated, with a patient.

To move the scanner between rooms:

1. Ensure that the wand is firmly positioned in the cradle, with the optical window facing the cradle.
2. Unplug the system from the wall outlet and carefully wrap the power cable around the upper handle, to prevent the cable from being caught between the wheels.
3. Using the upper handle, move the system to its new location and plug it into a wall outlet.

Note: If the scanner needs to be lifted, lift it using the upper handle and the post.

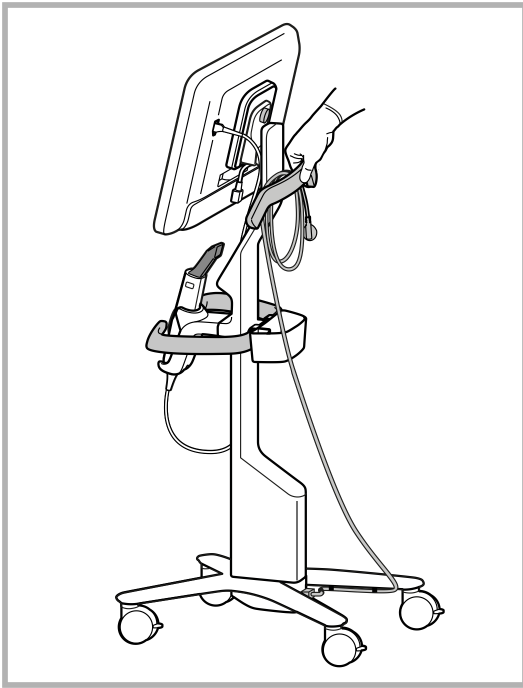


Figure 62: Moving the scanner

To move the cart-configuration scanner while in a seated position:

- Use the main handle to move the scanner.
- The screen height is optimized for a more ergonomic experience while seated. If required, you can adjust the tilt of the screen.

Note: Do not use the wand or the wand cable to move the scanner, in order to prevent the scanner from toppling over or damage to the cable.

4.4.4 Carrying the iTero Element 2 Plus mobile-configuration scanner within the clinic

The mobile-configuration scanner can be carried between rooms within the clinic as well as transported between clinics.

When carrying the scanner, you should always move the handle to the carrying position and wind the wand cable around the cradle.

To carry the mobile-configuration scanner within the clinic:

1. Ensure that the wand is firmly positioned in the cradle, with the optical window facing the cradle.
2. Disconnect the power cable from the mains and then from the back of the computing unit.
3. While holding the computing unit with one hand, slide the locking latch to unlock the handle and then move the handle to the carrying position. For more information, see [Moving the scanner within the clinic](#).

4. Loosely wrap the cable around the cradle for easy and safe portability.

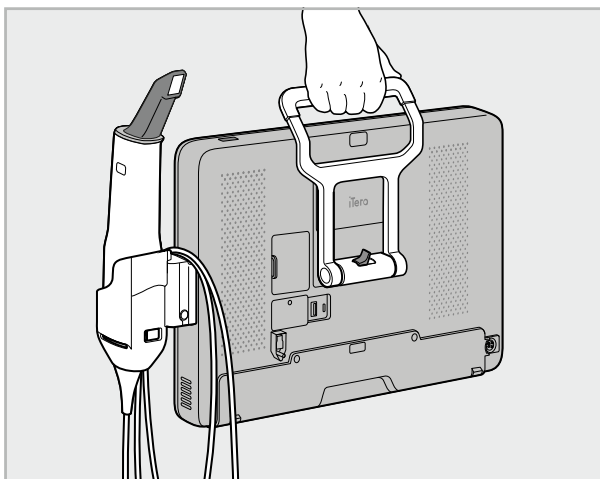


Figure 63: Carrying the scanner between rooms within the clinic

4.4.5 Transporting the iTero Element 2 Plus mobile-configuration scanner between clinics

When transporting the mobile-configuration scanner between clinics, always [pack the scanner in its supplied trolley](#).

To transport the scanner between clinics:

1. [Turn off the scanner](#).
2. Disconnect the power cable from the mains and then from the back of the computing unit.
3. Disconnect the scanner components and [pack them in their designated compartments in the trolley](#).
4. Close and secure the trolley flap and then close the trolley by lifting the side with the fastened flap and zipping it closed.



Figure 64: Transporting the scanner between clinics

5. If required, use the [optional protective cover](#) to protect the trolley against wear and tear and adverse weather conditions.

4.5 User interface

The iTero system provides an intuitive user interface for performing digital scans for Restorative or Orthodontic use. The touchscreen is used to interact with and control the software, while the wand buttons are used to start and stop the scan.

For a list of the touchscreen gestures that can be used, see [Touchscreen gestures](#).

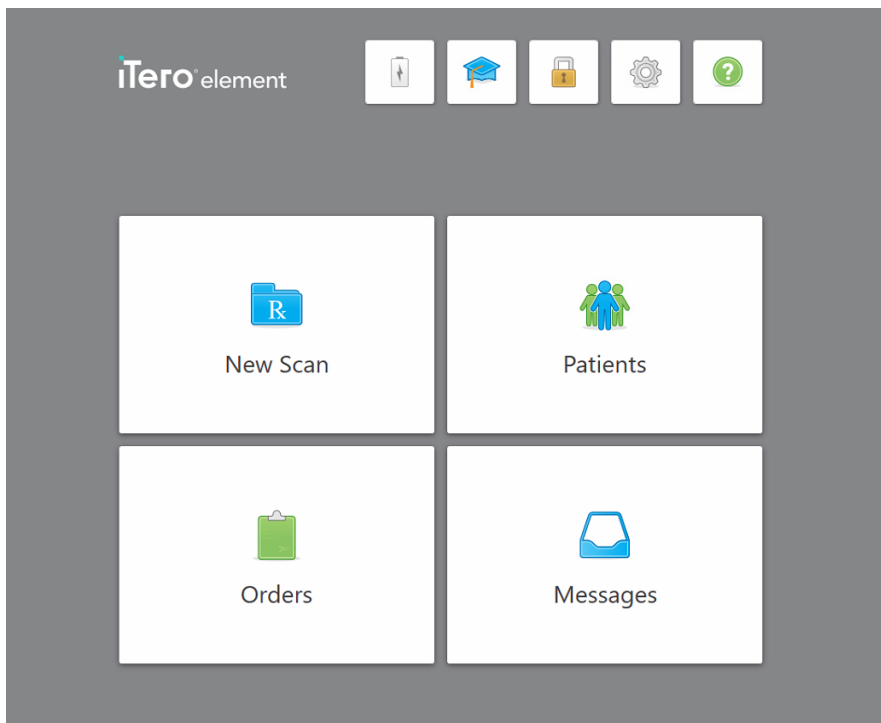


Figure 65: iTero home screen

The following buttons are displayed on the home screen:



Displays the status of the external battery:

- A lightning bolt indicates that the scanner is connected to the power, and the battery is charging.
- When using battery power, the remaining charge level is displayed on the battery icon. When the remaining charge level falls below 25%, the battery

icon is displayed in red.



- Tap the battery icon to view the percentage of remaining charge:

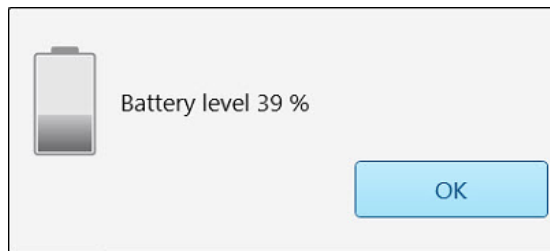
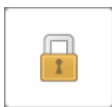


Figure 66: Percentage of remaining battery charge



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



Lock: Tap to log out of your account whenever the scanner is not in use. 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.



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

In this view, the **Help** button changes to two new buttons – e-manual and Customer Support:

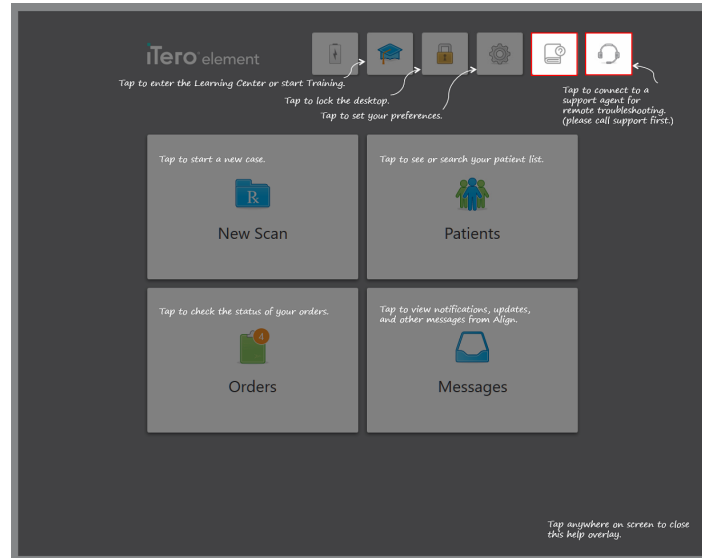


Figure 67: Help overlay including the e-manual and Customer Support buttons

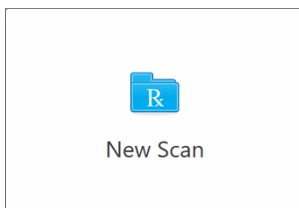


Tap to access the relevant e-manual.

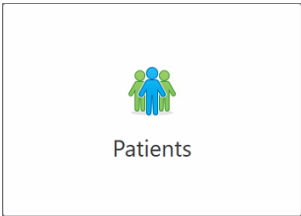


Tap for remote assistance from Customer Support. Customer Support is available from every Help overlay.

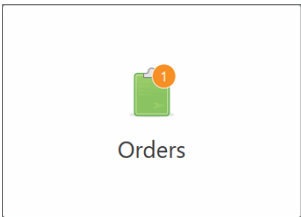
Note: Please call Customer Support before trying to connect remotely.



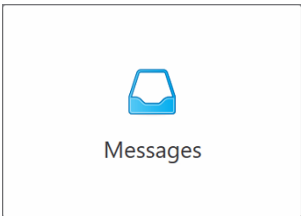
New Scan: Tap to open the *New Scan* window to fill in the Rx before starting a new scan.



Patients: Tap to view the *Patients* page with a list of all patients registered in your iTero system, and if relevant, their chart number, date of birth, and the date of their last scan.



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



Messages: Tap to view the messages from Align Technology.

The **Battery** and **Settings** buttons are displayed on each of the scanner windows as well, as described in [Scanner toolbar](#).

4.5.1 Scanner toolbar

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



Figure 68: Scanner toolbar

The 4 center buttons indicate the 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](#).



Tap to move to Scan mode to [scan the patient](#).



Tap to move to View mode to [view the scanned model](#).



Tap to [send the scanned model](#) to the lab, your chairside milling software, or your MyiTero account.



Tap to [capture a screenshot of the scanned model](#).

Note: This button is displayed in View mode only.



Tap to open the Patient Gallery to [view and edit the screenshots](#) taken on the scanner.

Note: This button is displayed in View mode only.



Tap to [time how long it takes to scan the model](#).

Note: This button is displayed in View mode only.



Displays the status of the external battery:

- A lightning bolt indicates that the scanner is connected to the power, and the battery is charging.
- When using battery power, the remaining charge level is displayed on the battery icon. When the remaining charge level falls below 25%, the battery icon is displayed

in red .

- Tap the battery icon to view the percentage of the remaining charge:

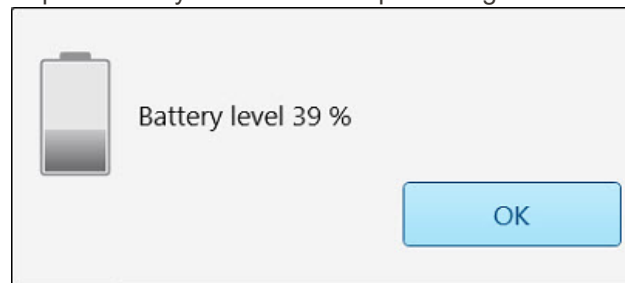


Figure 69: Percentage of remaining battery charge



Tap to [adjust the scanner preferences](#), for example, for wand configuration, localization, user settings, and more.



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

In this view, the **Help** button changes to two new buttons – e-manual and Customer Support:

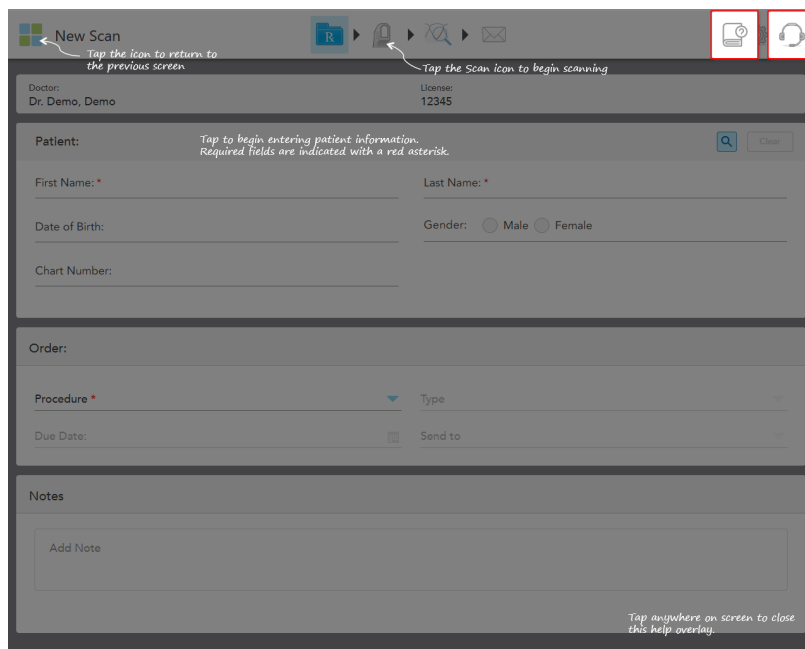


Figure 70: Help overlay including e-manual and Customer Support buttons



Tap to access the relevant e-manual.



Tap for remote assistance from Customer Support. Customer Support is available from every Help overlay.

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

4.5.2 Touchscreen gestures

The iTero software supports touchscreen (also known as multi-touch) gestures. These gestures are predefined motions used to interact with multi-touch devices.

Examples of common touchscreen gestures:



Tap



Double tap



Long press



Scroll



Rotate



Swipe



Pan



Zoom out



Zoom in

4.6 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.

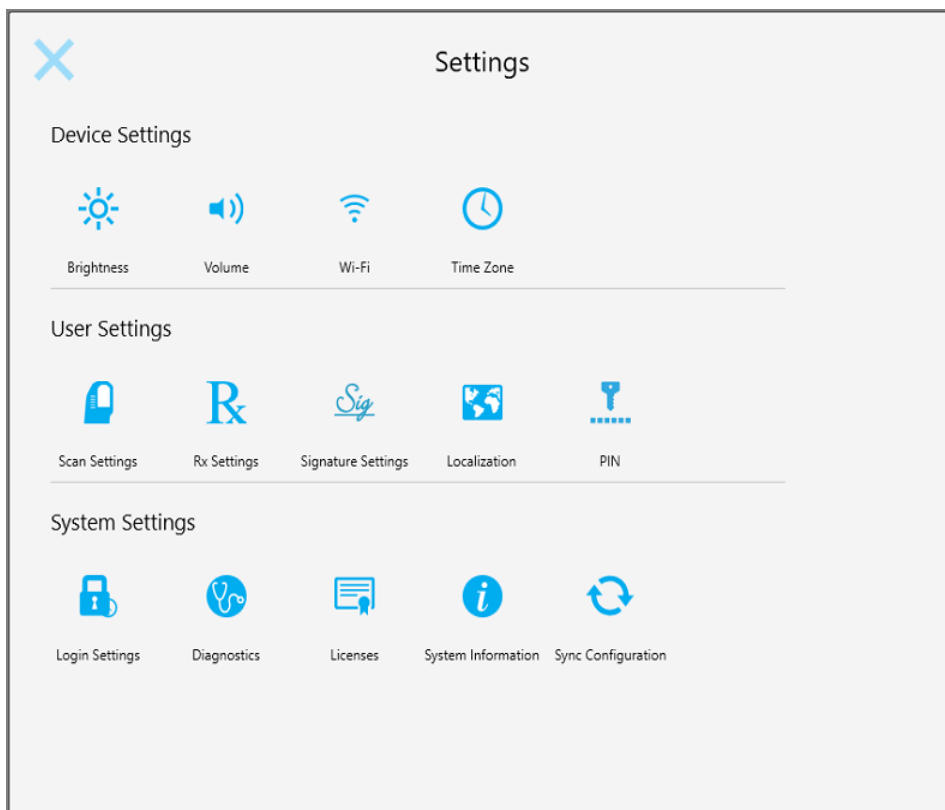


Figure 71: Settings window

2. Tap the settings you would like to define.
 - [Device settings](#)
 - [User settings](#)
 - [System settings](#)

The relevant window opens.

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

4.6.1 Defining the Device settings

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

4.6.1.1 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 72: Brightness settings

4.6.1.2 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.

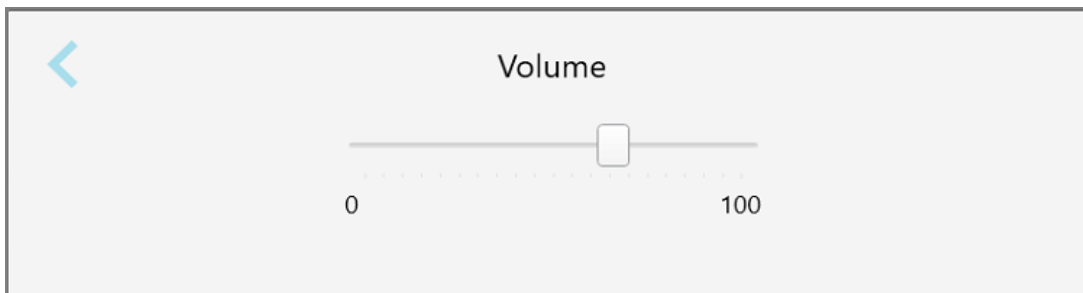


Figure 73: Volume settings

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

Center .

4.6.1.3 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. If you want to connect to a different Wi-Fi network, select the new network and enter the relevant password.

To reconnect to a Wi-Fi network:

1. Tap the **Wi-Fi** button.
- A list of nearby Wi-Fi networks is displayed.

Wi-Fi		
No network selected		
Network	Strength ▾	Status
Pegasus - 5	100	
pegasus	100	
alignit	100	
Hidden Network	100	
DIRECT -A-Room B	84	
DIRECT-22 HP PageWide Pro 475	76	
EW_Guest	60	
EW-Scanners	60	
EW-Internal	54	
Advanced...		

Figure 74: 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**.

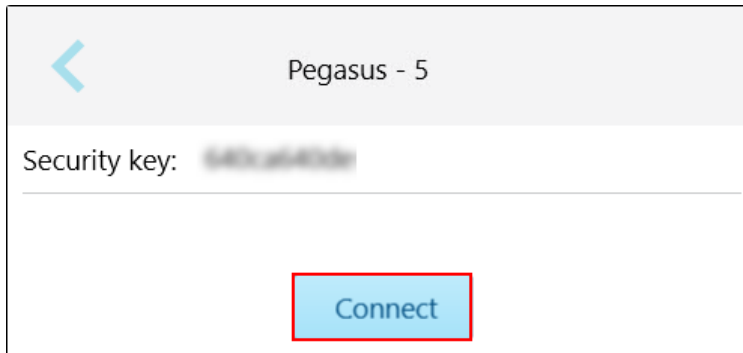


Figure 75: Connecting to the clinic Wi-Fi network

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.

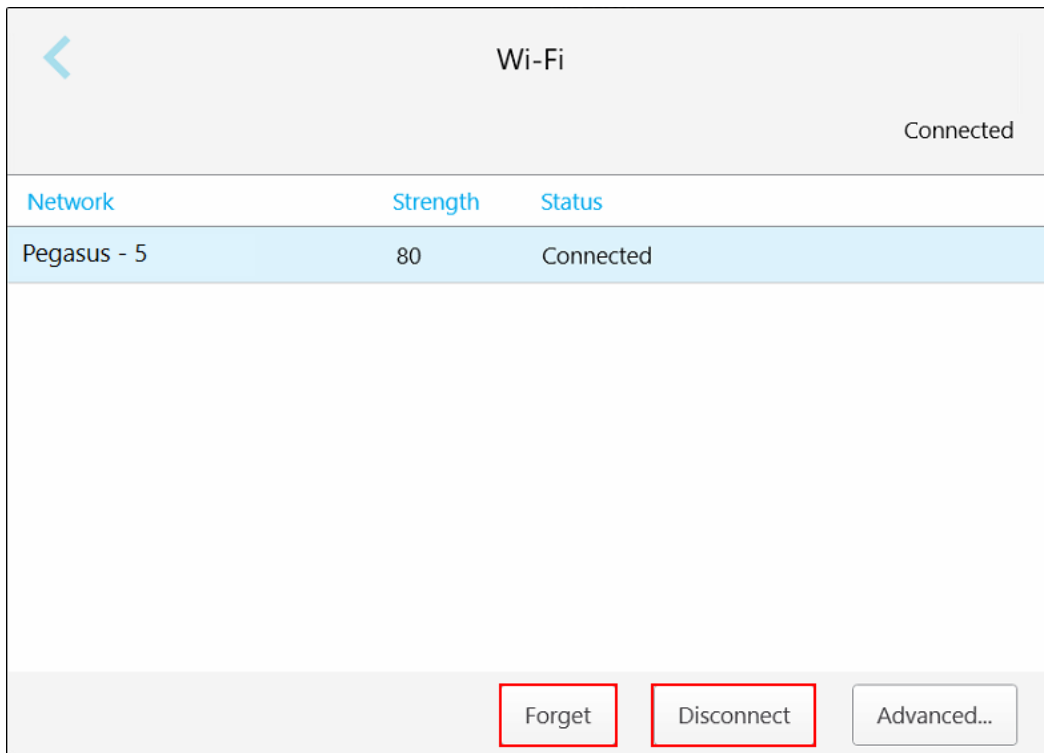


Figure 76: Forgetting or Disconnecting from the network

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

4.6.1.4 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.

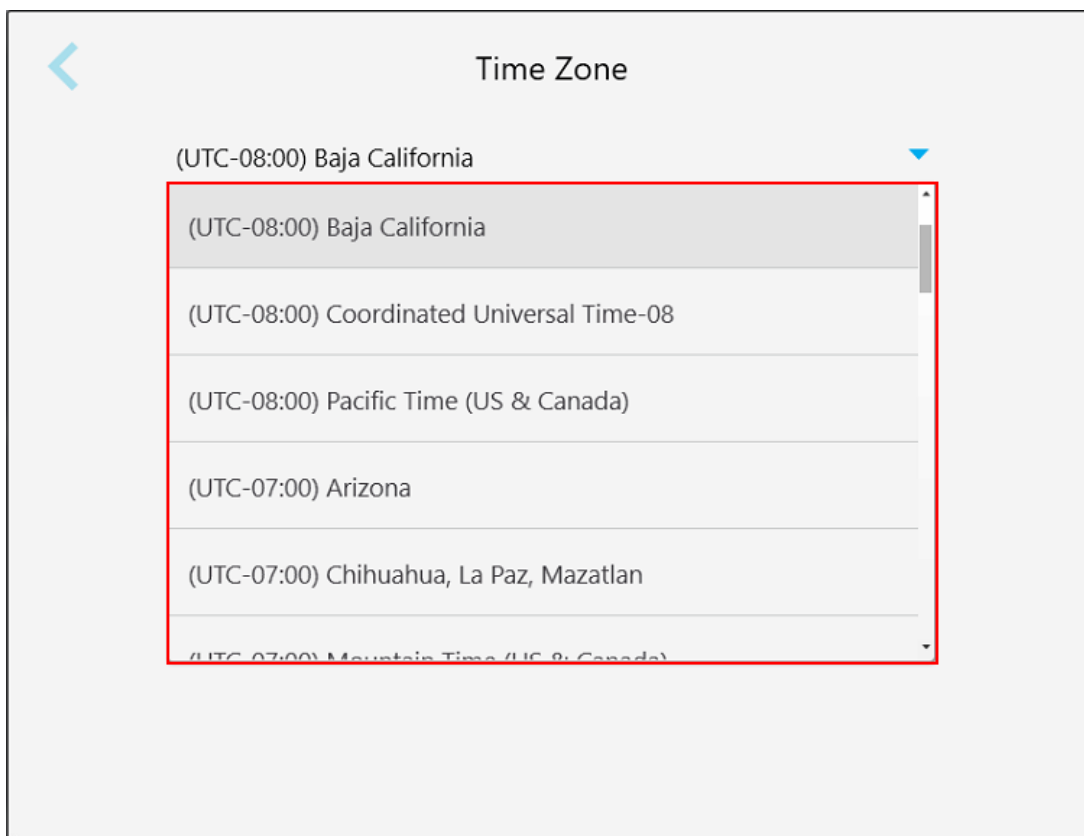


Figure 77: Time zone settings

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

4.6.2 Defining the User settings

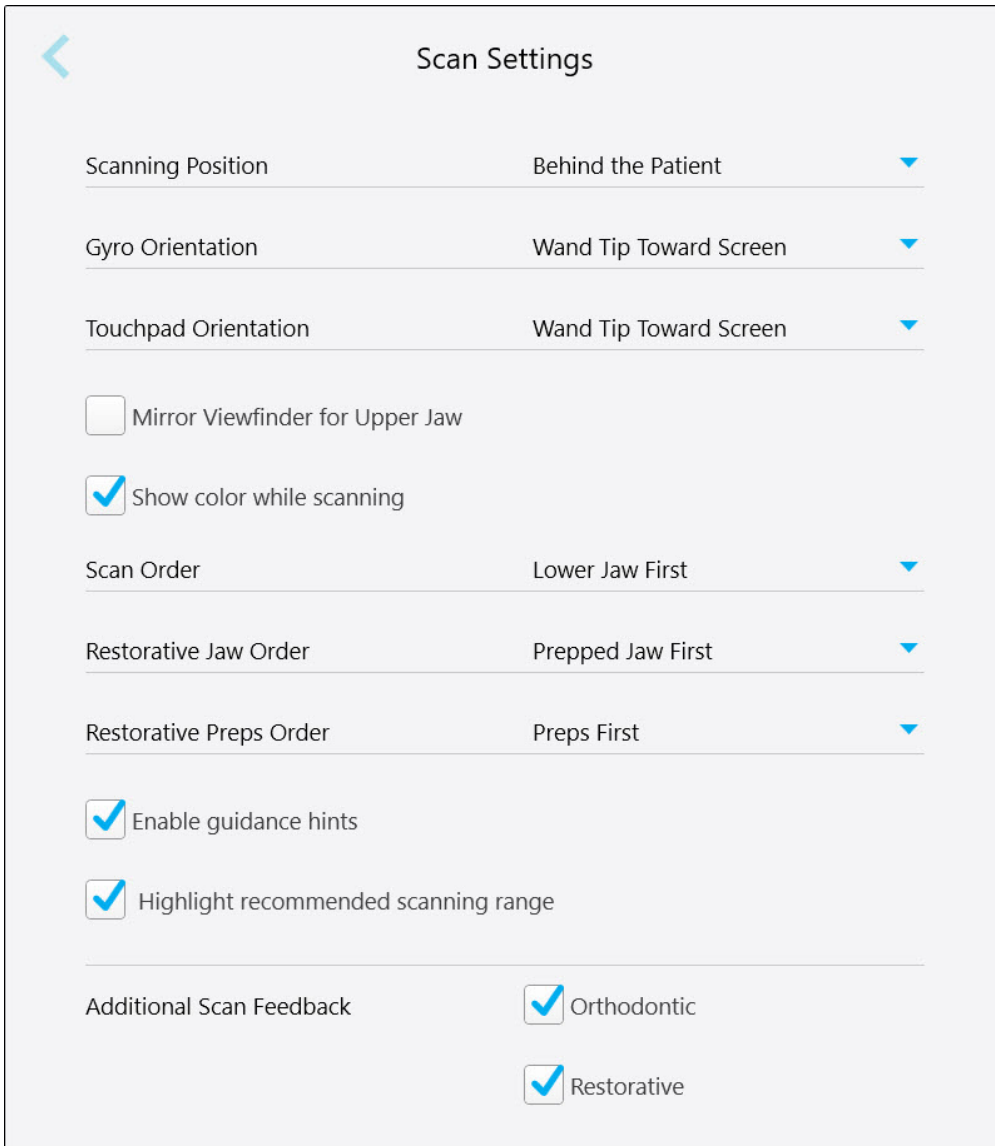
The User settings enable each user to define the settings that are displayed by default when the specific user logs in to the scanner.

4.6.2.1 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.



Scan Settings	
Scanning Position	Behind the Patient
Gyro Orientation	Wand Tip Toward Screen
Touchpad Orientation	Wand Tip Toward Screen
☐ Mirror Viewfinder for Upper Jaw	
☒ Show color while scanning	
Scan Order	Lower Jaw First
Restorative Jaw Order	Prepped Jaw First
Restorative Preps Order	Preps First
☒ Enable guidance hints	
☒ Highlight recommended scanning range	
Additional Scan Feedback	☒ Orthodontic
	☒ Restorative

Figure 78: 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: • Behind the patient • In front of the patient
Gyro Orientation	Select the default gyro orientation: • Wand Tip Toward Screen • Wand Base Toward Screen
Touchpad Orientation	Select the default touchpad orientation: • Wand Tip Toward Screen • Wand Base Toward Screen
Mirror Viewfinder for Upper Jaw check box	Select this check box to define the orientation of the viewfinder when scanning the upper jaw.
Show color while scanning check box	Select this check box to show the 3D model in color while scanning, by default.
Scan Order	Select the order in which to scan the jaws: • Upper Jaw First • Lower Jaw First
Restorative Jaw Order	Select the order in which to scan the jaws for fixed restorative procedures: • Opposite Jaw First • Prepped Jaw First
Restorative Preps Order	Select the order in which to scan the prepped teeth and the arches in fixed restorative procedures: • Preps First • Arch First • No Guidance
Enable guidance hints check box	Select this check box to display guidance when scanning .

Scan setting

Highlight recommended scanning range check box

Scan options

Select this check box to highlight only the scanning range on the navigation controls. Relevant for restorative procedure types only.

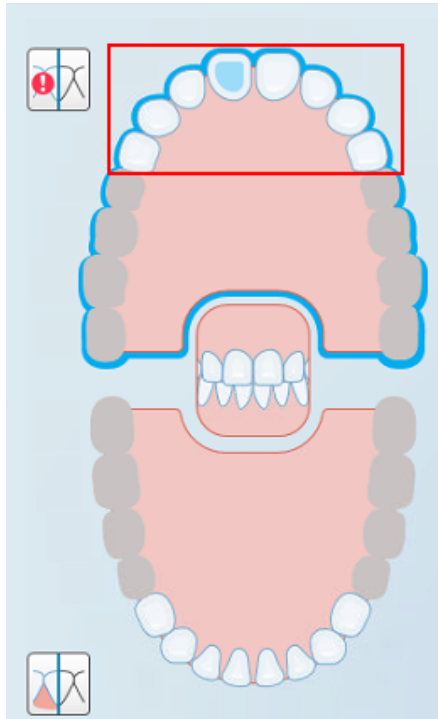


Figure 79: Only the scanning range is highlighted

Additional Scan Feedback

Select the relevant check boxes to [display areas of missing anatomy while scanning](#).

- Orthodontic
- Restorative

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

4.6.2.2 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 80: 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: • FDI • ADA • Quadrant
Shade System	Select the default shade system: • VITA Lumin • VITApan 3D Master • Other
Procedure	Select the default procedure: • Appliance • Denture/Removable • Fixed Restorative • Implant Planning • Invisalign Viverra • Study Model/iRecord • No Default Note: The list of available procedures changes according to your iTero subscription package.
Palatal & gingival feedback	Select whether palatal and gingival scanning feedback should be disabled by default when scanning Invisalign and Study Model/iRecord procedures.

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

4.6.2.3 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.

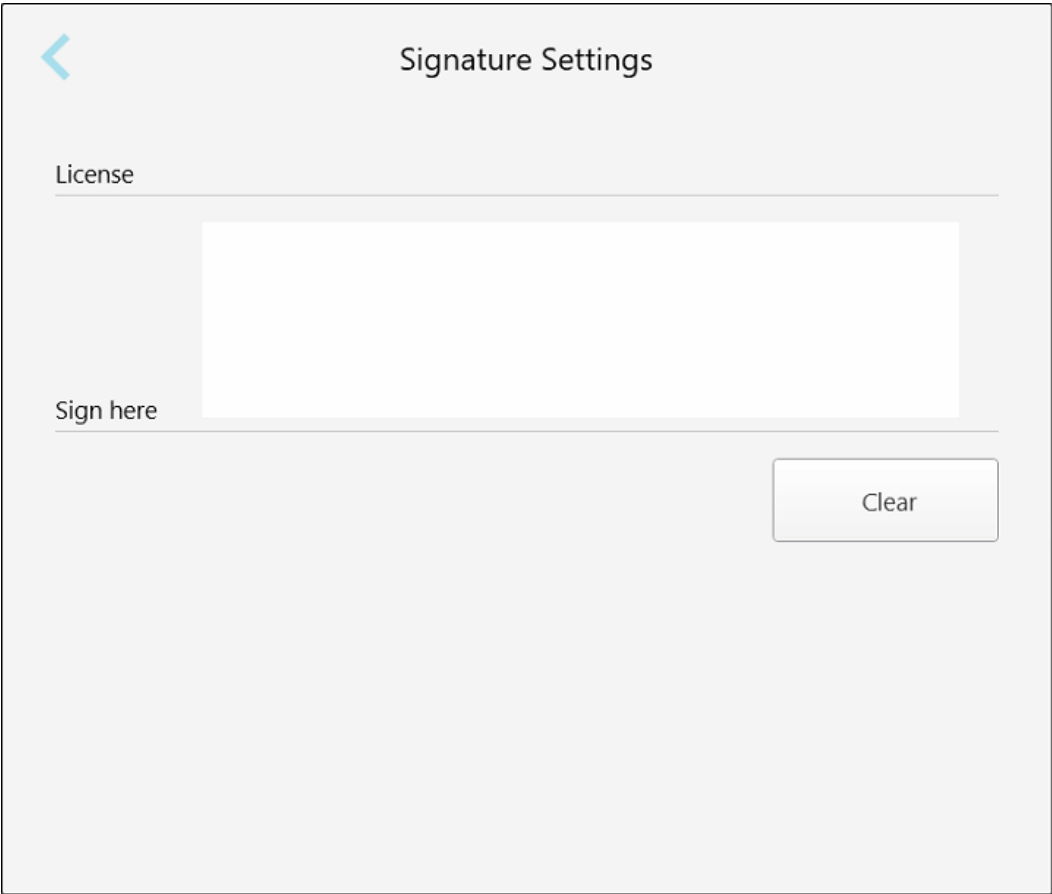


Figure 81: Signature Settings window

- 2. Define the default signature settings.

Signature setting	Signature options
License	Add your license number.
Sign here	Add your signature.

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

4.6.2.4 Defining the localization settings

You can define the default scanner language and the date format to be used in the Rx and displayed in all related windows.

To define the localization settings:

1. Tap the **Localization** button.

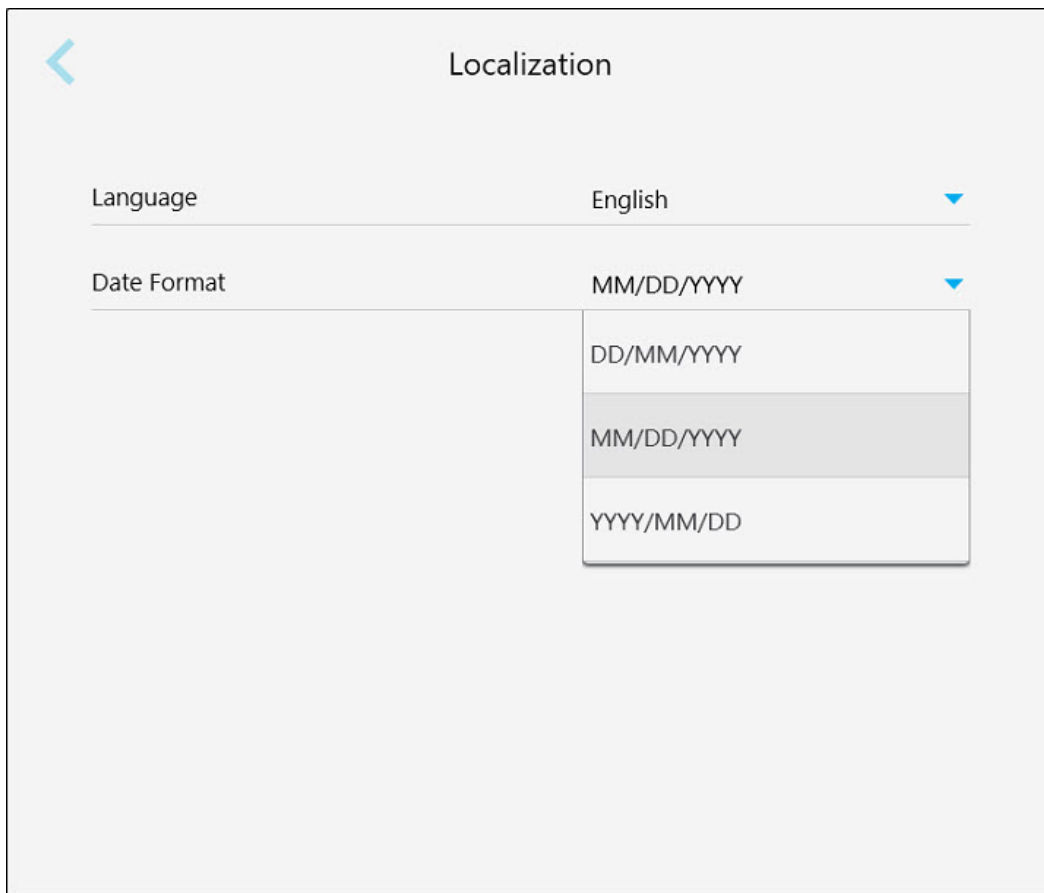


Figure 82: Localization window

2. Select the required scanner language from the **Language** drop-down list.
3. Select the required date format to be used in the Rx and all related windows from the **Date Format** drop-down list.
4. Tap  to save the changes and return to the *Settings* window.

4.6.2.5 Defining a new PIN

You can reset the PIN and define a new one, based on the listed PIN requirements.

Note: You can reset the PIN only when you are logged in to the scanner.

To reset the PIN:

1. Tap the **PIN** button.

The *Set PIN* window is displayed.

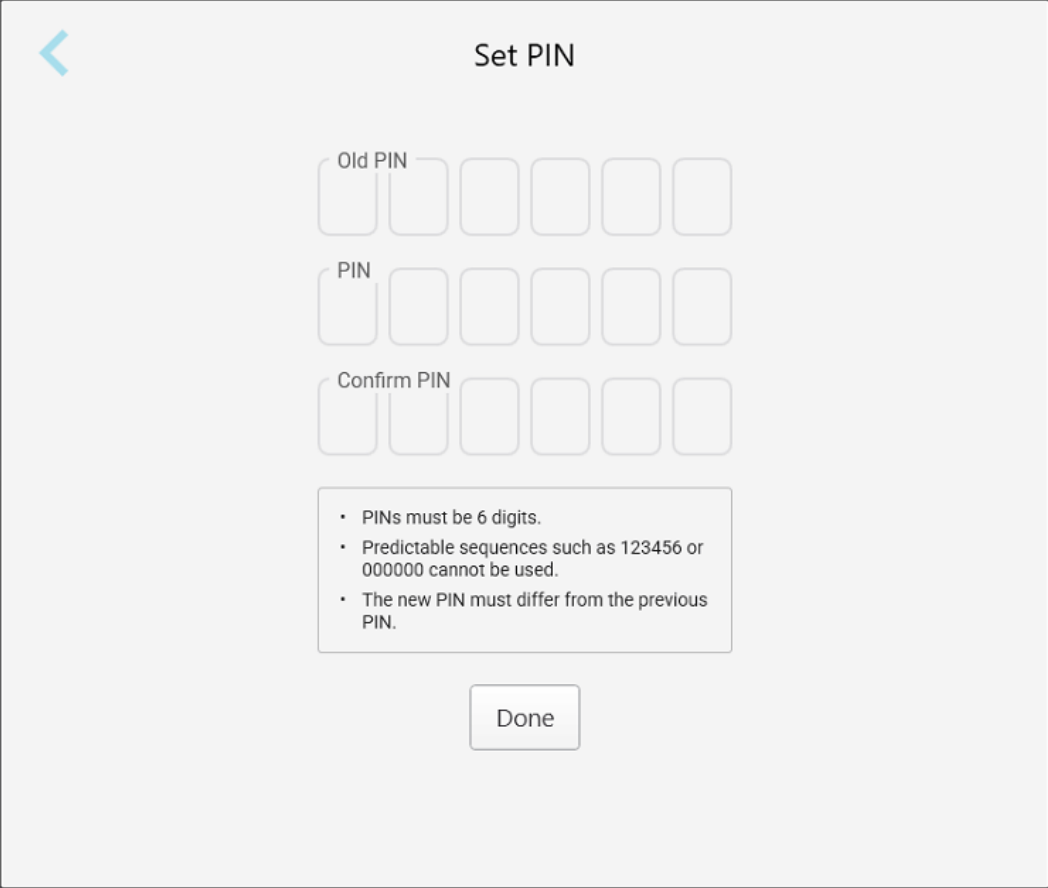
The screenshot shows a 'Set PIN' window with a light gray background. At the top left is a blue back arrow icon. The title 'Set PIN' is centered at the top. Below the title are three rows of input fields, each with a label to its left: 'Old PIN', 'PIN', and 'Confirm PIN'. Each row contains six rounded square boxes for digits. Below these fields is a white box with a gray border containing three bullet points: '• PINs must be 6 digits.', '• Predictable sequences such as 123456 or 000000 cannot be used.', and '• The new PIN must differ from the previous PIN.' At the bottom center is a white button with a gray border labeled 'Done'.

Figure 83: Set PIN window

2. Enter the current PIN in the **Old PIN** field.
3. Enter and then confirm the new PIN in the relevant fields, based on the listed requirements.
4. Tap **Done**.

4.6.3 Defining the System settings

The System settings enable you to set the login settings, run diagnostics, view the licenses, view the system information, and synchronize new updates from the server.

4.6.3.1 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.

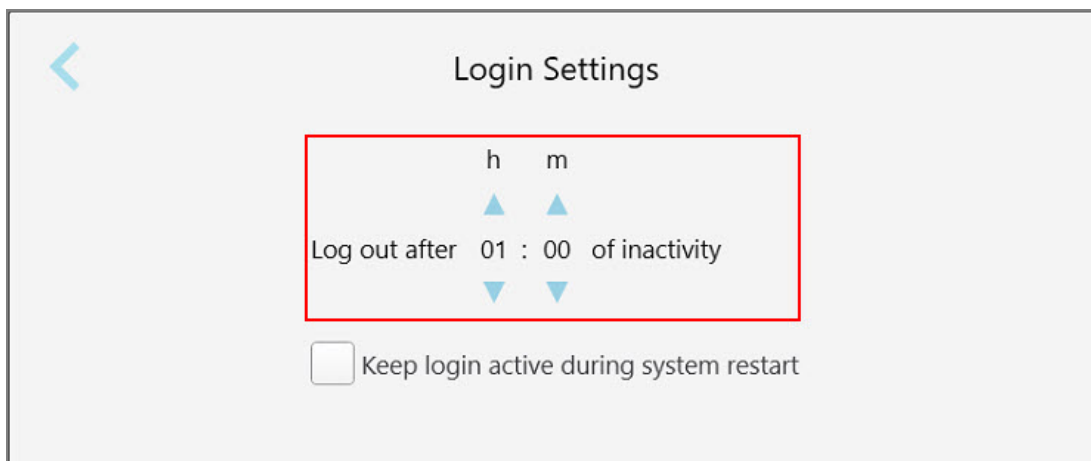


Figure 84: Login Settings window

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.

4.6.3.2 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.

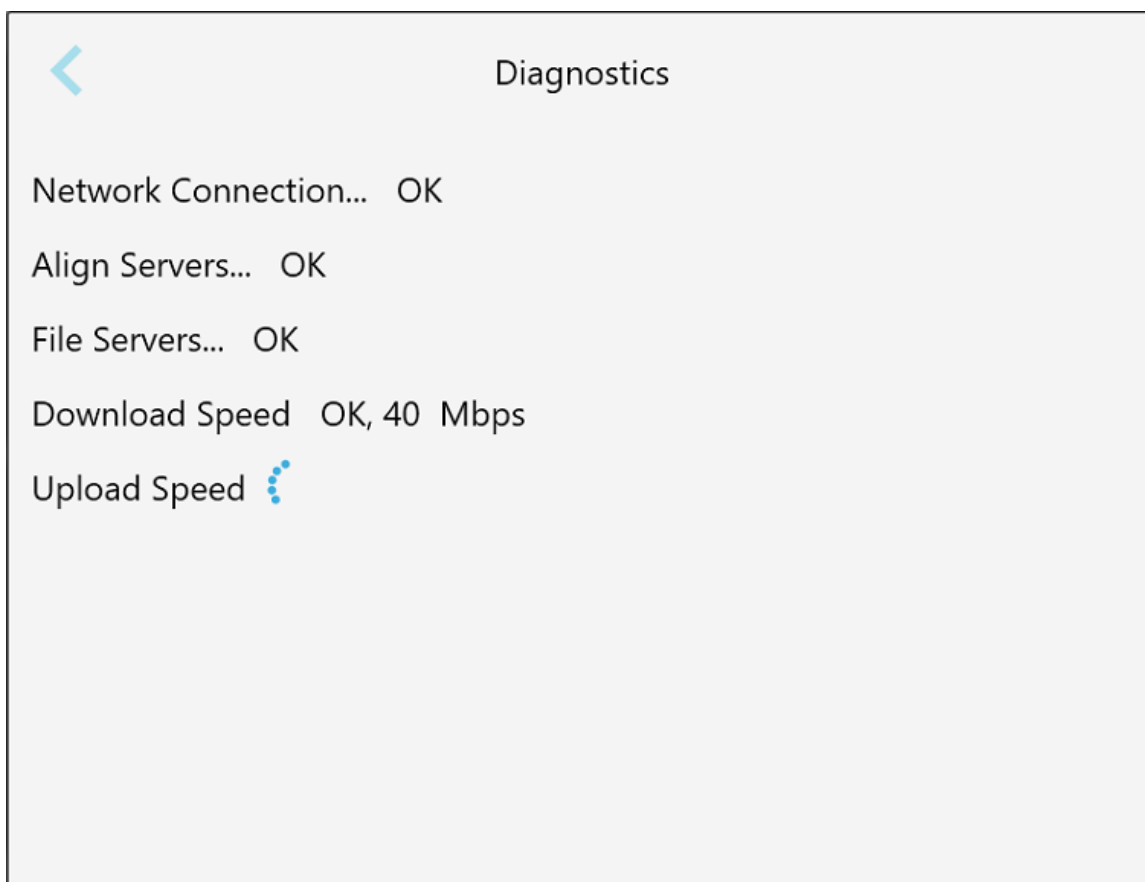


Figure 85: Diagnostics window

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

4.6.3.3 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.

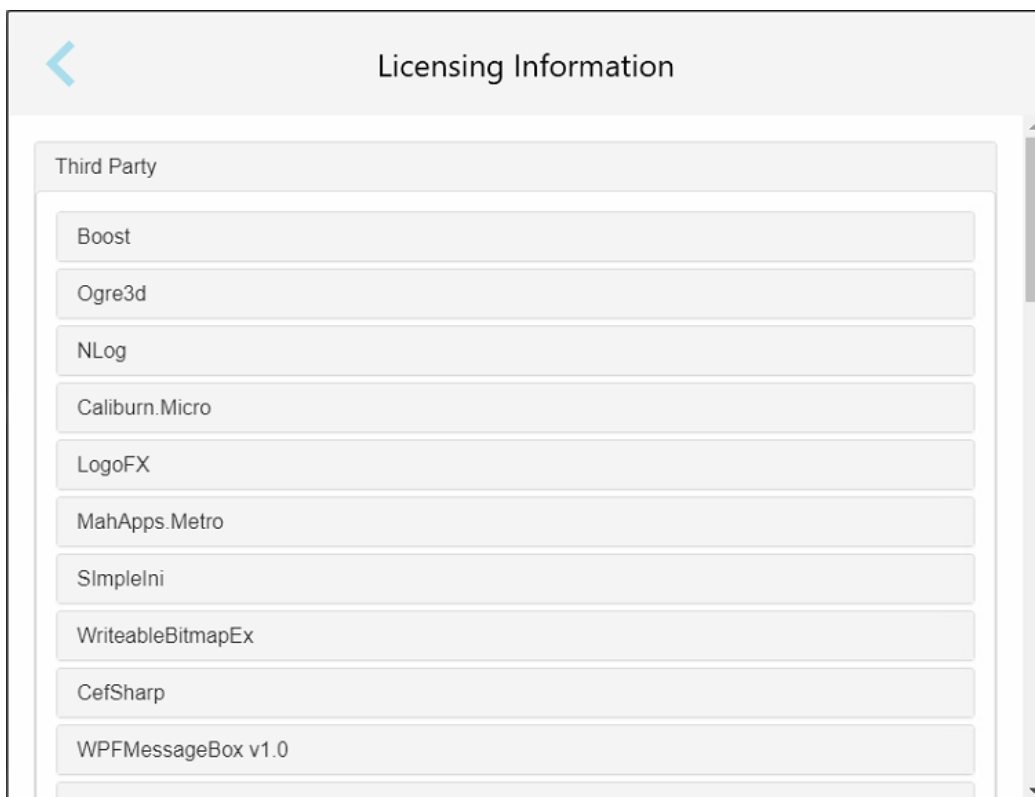


Figure 86: Licensing Information window

4.6.3.4 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.

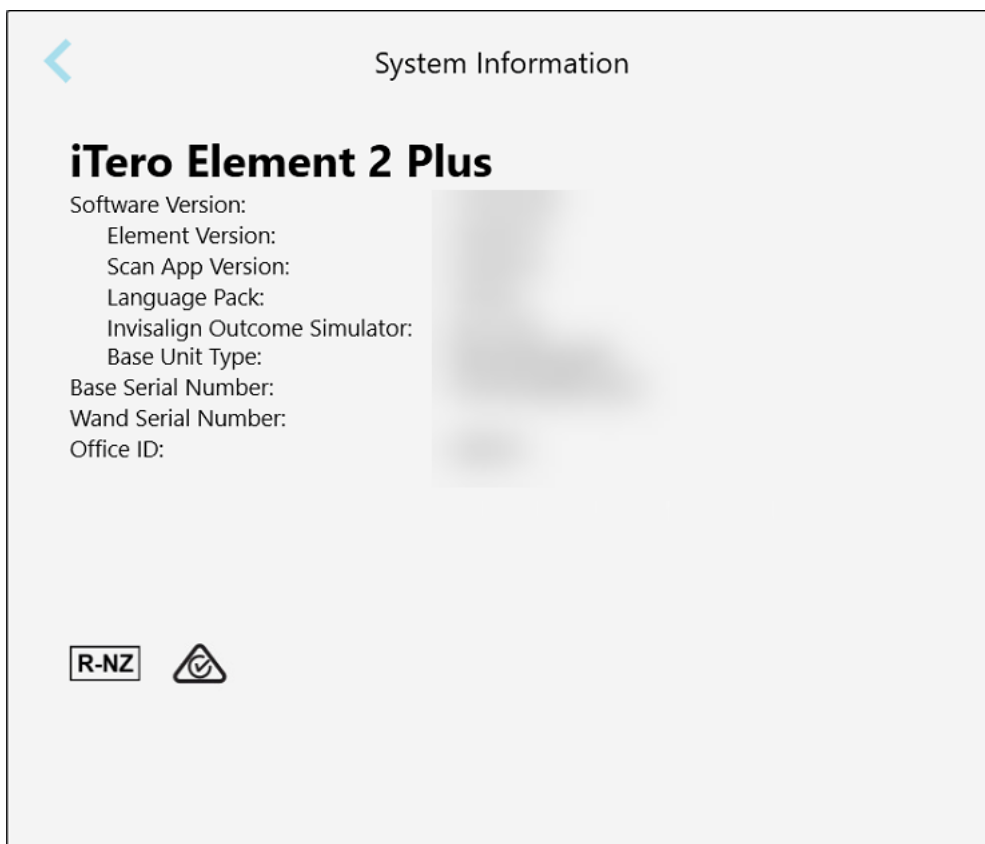


Figure 87: System Information window – iTero Element 2 Plus

4.6.3.5 Sync configuration

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

5 Starting a new scan

Before starting a new scan, you must:

- Check whether there are any particles on the wand. If so, [repeat the cleaning and disinfection process](#).
- [Apply a new wand sleeve](#) to prevent cross-contamination.
Note: If you notice any damage, do not use the wand sleeves and contact Customer Support.
- Fill in the Rx form in the *New Scan* window.
 - [Enter the details of a new patient](#) into your iTero system, or [search for an existing patient](#).
 - [Enter the details for the required procedure](#).

5.1 Applying a wand sleeve

To apply a wand sleeve:

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

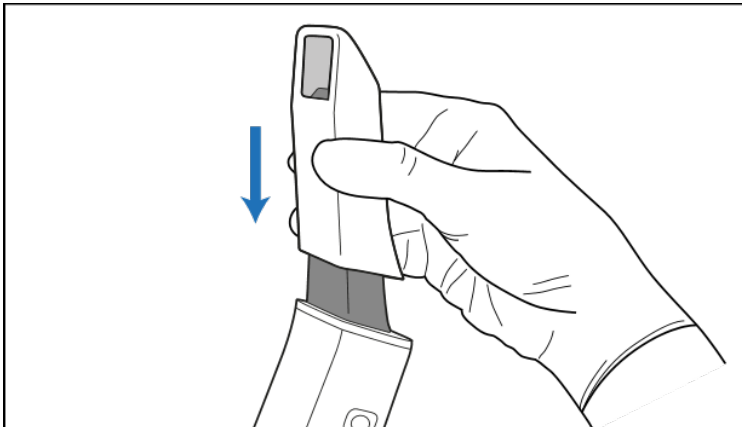
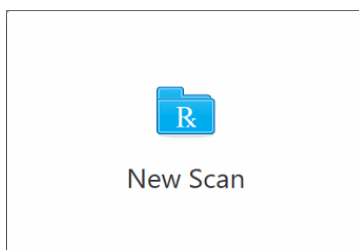


Figure 88: Gently slide the new sleeve into place

5.2 Starting the scanning process

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 89: New Scan window showing an empty Rx form and progress toolbar

The *New Scan* window shows the Rx form, which is made up of the following areas:

- **Doctor:** Displays the doctor's name and license number.
- **Patient:** Enables you to add a new patient to your iTero system or search for an existing patient for whom to prescribe the treatment. Once the patient's details are displayed, you can edit them, or clear the details from the *New Scan* window. For more information, see [Patient management](#).
- **Order:** Enables you to define the details of the required procedure, for example, Invisalign | Viverra.
- **Scan Options:** Enables you to turn on toggles regarding, for example, whether the order should include a multi-bite scan.
- **Notes:** Enables you to enter any specific notes to the lab regarding the patient's treatment. For example, you can write special instructions for delivery or manufacturing. After entering your note, tap anywhere outside the **Notes** area to add the note. Each note shows the author of the note, with a timestamp, and can be edited and deleted.

Additional areas and options may be displayed, depending on the procedure and procedure type selected in the **Order** area.

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



[Filling in the Rx](#)



[Scanning the patient](#)



[Viewing the scan](#)



[Sending the scan](#)

Your current progress is highlighted on the toolbar.

5.3 Filling in the Rx

The first step in the scanning process is filling in the Rx (prescription) form. The *New Scan* window has a simple, intuitive workflow that fulfills all restorative and orthodontic application needs. It enables efficient collaboration with the labs and reduced back and forth by ensuring that all information required by the lab for production is included.

After entering the patient details, you can enter the details about the required procedure and procedure type, if relevant, as well as enter notes for the lab regarding the scan. Fields marked with a red asterisk are mandatory before scanning.

Note for Fixed Restorative and Denture/Removable procedures: Some fields become mandatory only after scanning, before sending the scan.

New Scan

Doctor: Dr. Demo, Demo License: 12345

Patient:

First Name: * Last Name: *

Date of Birth: Gender: ☐ Male ☐ Female

Chart Number:

Order:

Procedure * Type

Due Date: Send to

Notes

Add Note

Figure 90: New Scan window

To fill in the Rx:

1. In the **Patient** area, enter the first name and last name of the new patient.
If required, enter the patient's date of birth, gender, and a unique chart number.

Or

Tap  to [search for an existing patient](#).

- In the **Order** area, from the **Procedure** drop-down list, select the required procedure.

Note: The list of procedures displayed depends on your iTero subscription package.

Figure 91: Selecting the required procedure

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

- **[Study Model/iRecord](#)**: A simple scan with no additional modification, mainly used for studying purposes and referencing instead of storing the plaster model, as required by law. It can also be scanned as iCast, and is available on your Invisalign Doctor Site.
- **[Invisalign | Vivera](#)**: The basic scan for all Invisalign treatments, including retainers.
- **[Fixed Restorative](#)**: A scan for all restorative treatments, for example, crowns and bridges.
- **[Implant Planning](#)**: Enables ordering a surgical guide from the lab.
- **[Denture/Removable](#)**: Enables comprehensive planning and fabrication of partial and full dentures.
- **[Appliance](#)**: A scan for various dental appliances, for example, night guards and Apnea/Sleep appliances.

The **Order** and **Scan Options** areas of the *New Scan* window are displayed according to the selected procedure.

- If relevant, from the **Type** drop-down list, select the procedure type required.
Note: Procedure types are not relevant for Study Model/iRecord and Fixed Restorative procedures.
- If required, tap the calendar in the **Due Date** field and then select the date the case is due back from the lab.
- From the **Send To** drop-down list, select the lab to which the scan should be sent, your chairside milling software, or your MyiTero account.
- Depending on the procedure selected, fill in the relevant additional details.

7. In the **Scan Options** area, turn on/off the following toggles, depending on the procedure selected, as required.
 - **Multi-Bite:** Turn on the **Multi-Bite** toggle if a multi-bite scan is required. This enables you to preserve the 2-bite relation based on your needs, and delivers comprehensive bite information to the lab for appliance fabrication.

For Invisalign from Study Model/iRecord procedures, it is recommended that the first bite is scanned bilaterally. Only the first bite will be used in the ClinCheck software.
 - **Pre-Treatment Scan:** Turn on the **Pre-Treatment Scan** toggle 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.
 - **Denture Copy Scan:** Turn on the **Denture Copy Scan** toggle if you would like to include a scan of the existing dentures or temporary dentures.
 - **Palatal & gingival feedback:** Turn off the **Palatal & gingival feedback** toggle if you would like to disable the in-model indication of the missing palatal areas that are required for Invisalign Palatal Expansion submission. If required, you can [disable this feedback](#) for all scans, by default.
8. Depending on the procedure and procedure type selected, enter the relevant details in the additional areas that are displayed, for example, the **Tooth Diagram** area or the **Denture Details** area. In addition, the **Attachments** area notifies you that you can upload attachments such as videos, images, and X-rays via MyiTero.
9. In the **Notes** area, if required, enter any specific notes to the lab regarding the patient's treatment. For example, special instructions for delivery or manufacturing. After entering your note, tap anywhere outside the **Notes** area to add the note. Each note shows the author of the note, with a timestamp, and can be edited and deleted.
10. Tap  on the toolbar to move to Scan mode to [scan the patient](#).

5.3.1 Filling in the Rx for Study Model/iRecord procedures

The **Study Model/iRecord** procedure requires a simple scan without any additional modification.

If you are an Invisalign doctor, all scans will be uploaded to the Invisalign Doctor Site and will be available in the ClinCheck software.

To fill in the Rx for a Study Model/iRecord procedure:

1. In the **Patient** area, enter a patient's details or [search for an existing patient](#).
2. In the **Order** area, select **Study Model/iRecord** from the **Procedure** drop-down list.

The *New Scan* window expands to display **Scan Options** and **Attachments** areas.

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

- Doctor:** Dr. Demo, Demo; **Location:** 12345
- Patient:**
 - First Name: * Patient
 - Last Name: * Demo
 - Date of Birth: *
 - Gender: ☐ Male ☐ Female
 - Chart Number: *
- Order:**
 - All Study Model/iRecords scans are automatically available in your account on the Invisalign Doctor Site
 - Procedure: * Study Model/iRecord
 - Due Date: *
 - Ortho Model/iCast: ☐
 - Send to: *
- Scan Options:**
 - Palatal & gingival feedback: ☒
 - Multi-Bite: ☐
- Attachments:**
 - Now you can share external case-related files, including images, videos, and X-rays, with your lab.
 - To upload files please use myiTero.com
- Notes:**
 - Add Note

Figure 92: Study Model/iRecord procedure – Scan Options area

3. If required, turn on the **Ortho Model/iCast** toggle to order a digital dental case.
4. Continue filling in the prescription from step 4, **Due Date**, as described in [Filling in the Rx](#).

5.3.2 Filling in the Rx for Invisalign | Viverra procedures

The Invisalign | Viverra procedure is used to create prescriptions for all Invisalign orders, including retainers. The model must be scanned without any holes to ensure that the aligners are a perfect fit with the patient's teeth.

To fill in the Rx for an Invisalign | Viverra procedure:

1. In the **Patient** area, enter a patient's details or [search for an existing patient](#).
2. In the **Order** area, select **Invisalign | Viverra** from the **Procedure** drop-down list.

The *New Scan* window expands to display a **Scan Options** area.

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

- Header:** Doctor: Dr. Demo, Demo; License: 12345
- Patient:**
 - First Name: * (empty)
 - Last Name: * Demo
 - Date of Birth: (empty)
 - Gender: ☐ Male ☐ Female
 - Chart Number: (empty)
- Order:**
 - Procedure: * Invisalign | Vivera
 - Type: * Invisalign Aligners
 - Treatment Stage: (empty)
 - Current Aligner #: (empty)
- Scan Options:** (highlighted with a red border)
 - Palatal & gingival feedback: ☒
- Notes:**
 - Add Note (text input field)

Figure 93: Scan Options area – Invisalign | Vivera procedure

- From the **Type** drop-down list, select the type of Invisalign procedure required, depending on your iTero subscription package:
 - Invisalign Aligners – [Invisalign Outcome Simulator Pro](#) is available only for **Invisalign Aligners** procedure types.
 - Invisalign First Aligners
 - Invisalign Palatal Expander

Note: Excess soft tissue will not be removed automatically from around the edges of the model during scanning. If required, you can [enable automatic cleanup](#) by pressing on the screen and then tapping the Auto Cleanup tool.
 - Viverra Retainer – maintains the position of the teeth after treatment. If brackets are still present, they will be removed by the iTero software. The Viverra retainers will be provided at the debonding appointment.
 - Invisalign Retainer
- For Invisalign Aligners, First Aligners, and Palatal Expanders, you can select the **Treatment Stage**:
 - Initial Record – for the first Invisalign treatment scan. By default, the Current Aligner # is set to 0.
 - Progress Record – for multiple scans during the ongoing treatment. In addition, enter the patient's current Aligner number in the **Current Aligner #** field.
 - Final Record – for the scan done when treatment is completed. In addition, enter the patient's current Aligner number in the **Current Aligner #** field.

5. Continue filling in the prescription from step 8 , as described in [Filling in the Rx](#).

For more information, refer to the Invisalign documentation.

5.3.3 Filling in the Rx for Fixed Restorative procedures

The Fixed Restorative procedure covers a range of restorations, including crowns, bridges, veneers, inlays, onlays, and implant-based restoration. When selecting fixed restorative procedures, 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.

Note: Some fields are not mandatory before scanning the patient but must be filled in before you can send the scan.

To fill in the Rx for a Fixed Restorative procedure:

1. In the **Patient** area, enter a patient's details or [search for an existing patient](#).
2. In the **Order** area, select **Fixed Restorative** from the **Procedure** drop-down list.

The *New Scan* window expands to display a **Scan Options** area, a **Tooth Diagram** area showing the tooth numbers and illustrations, and an **Attachments** area.

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

- Doctor:** Dr. Demo, Demo License: 12345
- Patient:**
 - First Name: * Patient
 - Last Name: * Demo
 - Date of Birth: *
 - Gender: ☐ Male ☐ Female
 - Chart Number: *
- Order:**
 - Procedure: * Fixed Restorative
 - Type: *
 - Due Date: *
 - Send to: *
- Scan Options:**
 - Pre-Treatment Scan: ☐
- Tooth Diagram:**
 - Top row of teeth (1-16): 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16
 - Bottom row of teeth (17-32): 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17
- Attachments:**
 - Now you can share external case-related files, including images, videos, and X-rays, with your lab.
 - To upload files please use myiTero.com
- Notes:**
 - Add Note

Figure 94: Scan Options and Tooth Diagram areas – Fixed Restorative procedure

- If required, tap the calendar in the **Due Date** field and then select the date the restoration is due from the lab.
- From the **Send To** drop-down list, select the lab to which the scan should be sent, your chairside milling software, or your MyiTero account.
- In the **Scan Options** area, turn on/off the following toggles, as required.
 - Pre-Treatment Scan:** Turn on the **Pre-Treatment Scan** toggle 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.

6. In the **Tooth Diagram** area, tap the tooth to be restored.

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

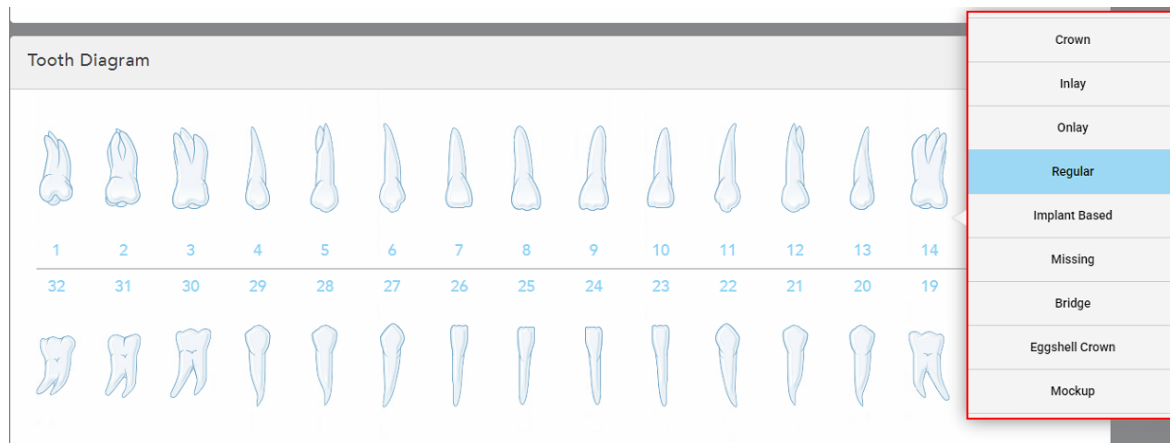


Figure 95: List of fixed restorative treatment options

7. Select the required treatment option.

Depending on the fixed restorative treatment option selected, a treatment window is displayed.

Note: Treatment options are mandatory before sending the scan, but can be filled in after scanning.

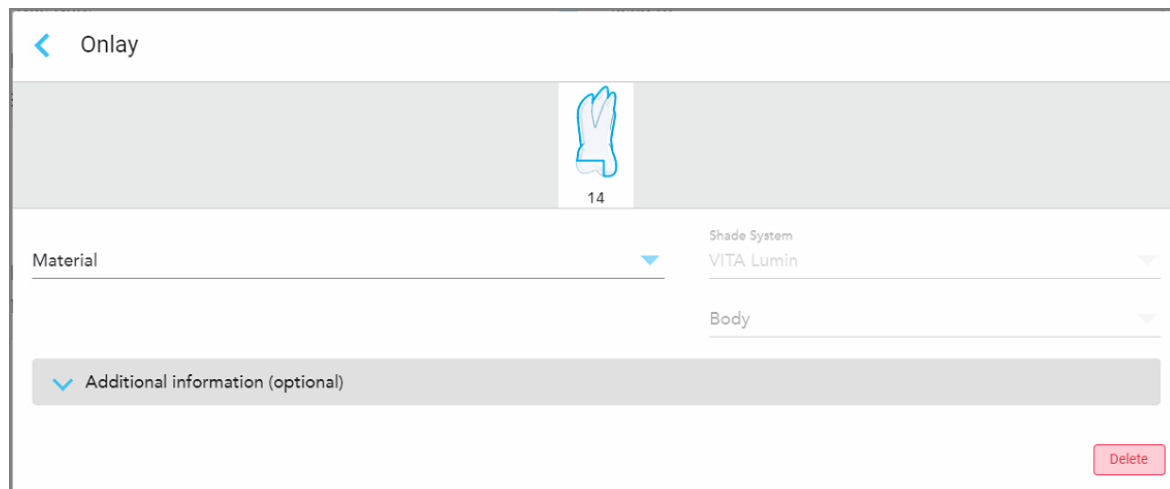


Figure 96: Treatment settings window – Onlay restoration

8. Select the relevant treatment settings for each tooth, according to the treatment option selected:

- [Crown](#)
- [Inlay/Onlay](#) (relevant for molars and premolars only)
- [Implant Based](#)

Note: If an implant abutment is already in the mouth, select **Crown** from the drop-down list.

- [Veneers/Laminates](#) (relevant for the incisors and premolars only)

- [Bridge](#)
- [Eggshell Crown](#)
- [Mockup](#)

In addition:

- If a tooth is missing, tap **Missing**
- To delete a restoration plan, tap **Regular**

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

The selected teeth are highlighted and the selected treatment options are displayed in the **Treatment Information** area below the **Tooth Diagram** area.

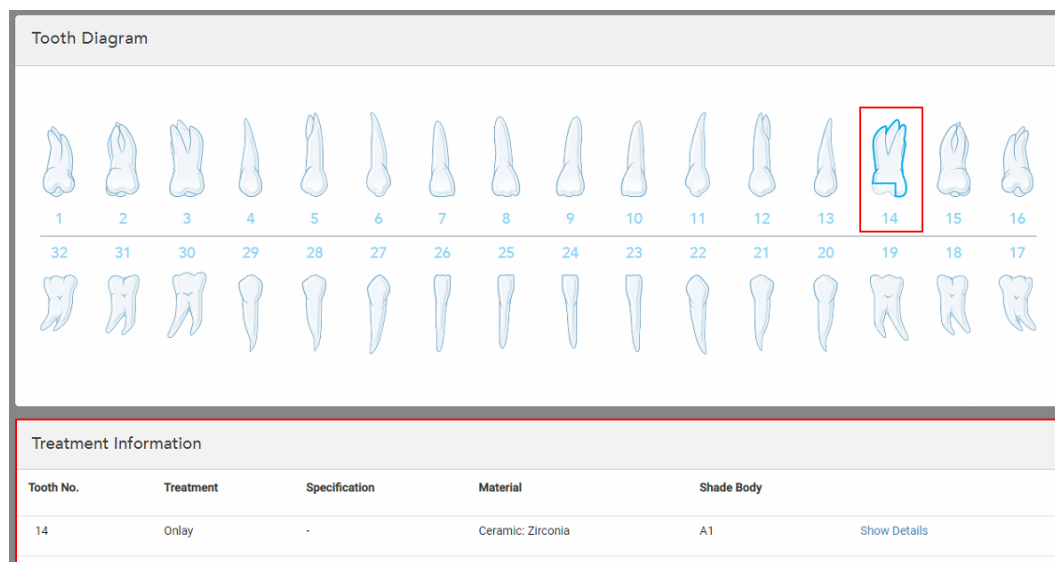


Figure 97: Selected tooth and Treatment Information area – Onlay restoration

You can change the selected treatment options at any time before sending the scan by tapping **Show Details** and editing the settings of a specific tooth.

10. In the **Notes** area, if required, enter any specific notes to the lab regarding the patient's treatment. For example, special instructions for delivery or manufacturing. After entering your note, tap anywhere outside the **Notes** area to add the note. Each note shows the author of the note, with a timestamp, and can be edited and deleted.

5.3.3.1 Mockups, and Crown, Veneer/Laminate, Inlay, and Onlay restorations

Follow the procedure below to complete filling in the Rx for Mockups, and Crown, Veneer/Laminate, Inlay, and Onlay restorations.

Note: If more than one tooth requires restoration, you can copy the treatment settings to each tooth requiring the same restoration type.

To fill in the Rx for a Mockup, or Crown, Veneer/Laminate, Inlay, or Onlay restoration:

1. In the **Tooth Diagram**, tap the tooth that needs a mockup or restoration and then select the required treatment option from the drop-down list, for example, **Crown**.

The relevant treatment settings window is displayed.

Scan Options:

< Crown

14

Specification

Material

Shade System
VITA Lumin

Body

Additional information (optional)

Delete

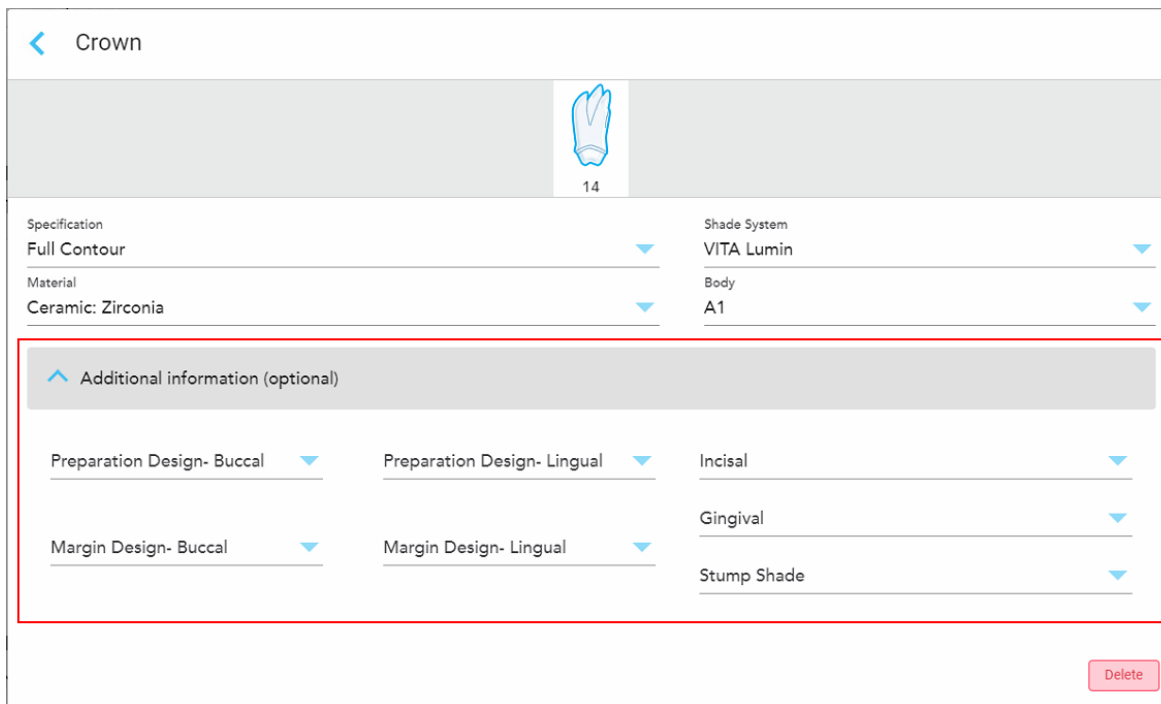
Figure 98: Treatment settings window – Crown restoration

2. Select the following mandatory settings from the relevant drop-down lists:
 - a. **Specification:** The type of mockup or crown to be fabricated.

Note: Relevant for Mockup and Crown treatments only. Once you have selected the specification, you can select the rest of the options.
 - b. **Material:** The material from which the mockup or restoration should be fabricated, depending on the specification selected. This can be copied to all teeth included in the restoration.

If required, you can save the materials you use most often as [favorites](#).
 - c. **Shade System:** The system used for choosing the shade of the mockup or restoration.
 - d. **Body:** The shade for the body area of the mockup or restoration.

3. If required, tap  to expand the **Additional information** area to display additional optional settings:



The screenshot shows the 'Crown' restoration settings screen. At the top, there is a back arrow and the title 'Crown'. Below this is a header area with a crown icon and the number '14'. The main settings area includes two columns of dropdown menus. The left column has 'Specification' set to 'Full Contour' and 'Material' set to 'Ceramic: Zirconia'. The right column has 'Shade System' set to 'VITA Lumin' and 'Body' set to 'A1'. Below these is an expanded 'Additional information (optional)' section, which is highlighted with a red box. This section contains five dropdown menus: 'Preparation Design- Buccal', 'Preparation Design- Lingual', 'Incisal', 'Margin Design- Buccal', 'Margin Design- Lingual', 'Gingival', and 'Stump Shade'. A 'Delete' button is located at the bottom right of the screen.

Figure 99: Additional information area – Crown restoration

- **Preparation Design (Buccal and Lingual):** 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 (Buccal and Lingual):** 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.
- **Incisal:** The shade for the incisal area of the restoration.
- **Gingival:** The shade for the gingival area of the restoration.
- **Stump Shade:** The shade of the prepped tooth.

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

The selected treatment options are displayed in the **Treatment Information** area below the **Tooth Diagram** area. You can change the selected treatment options at any time before sending the scan by tapping **Show Details** and editing the settings of a specific tooth.

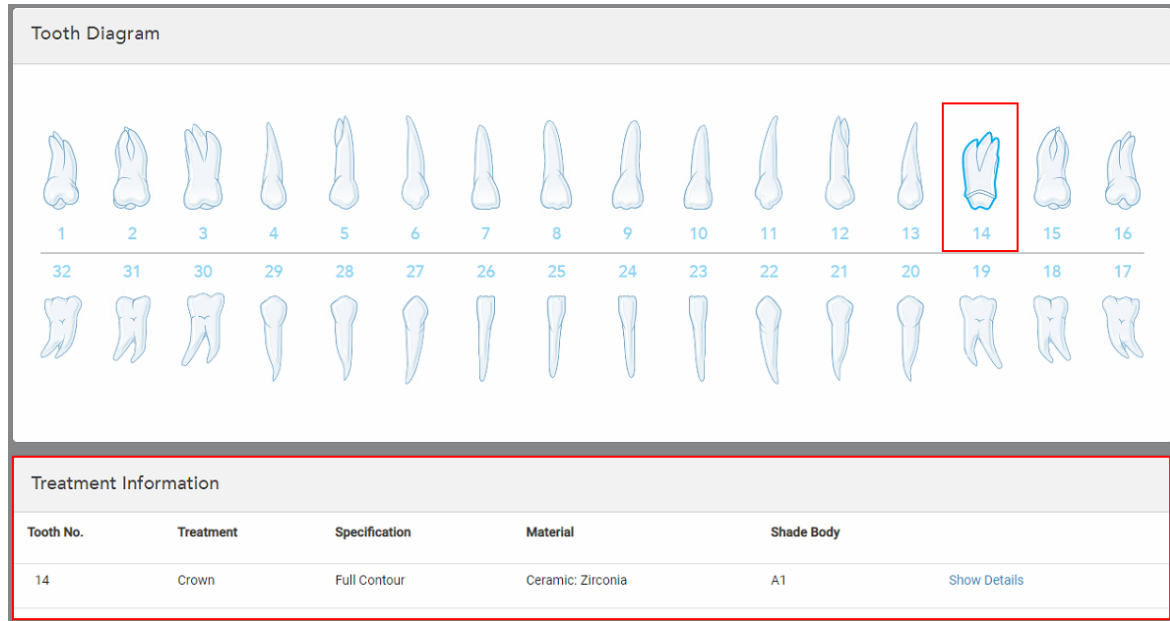


Figure 100: Selected tooth and Treatment Information area – Crown restoration

- Repeat this procedure for each tooth requiring treatment.

If a tooth requires the same treatment as a tooth for which you have already defined the treatment settings, you can copy the settings by tapping the tooth and then selecting **Copy From Tooth #** from the drop-down list.

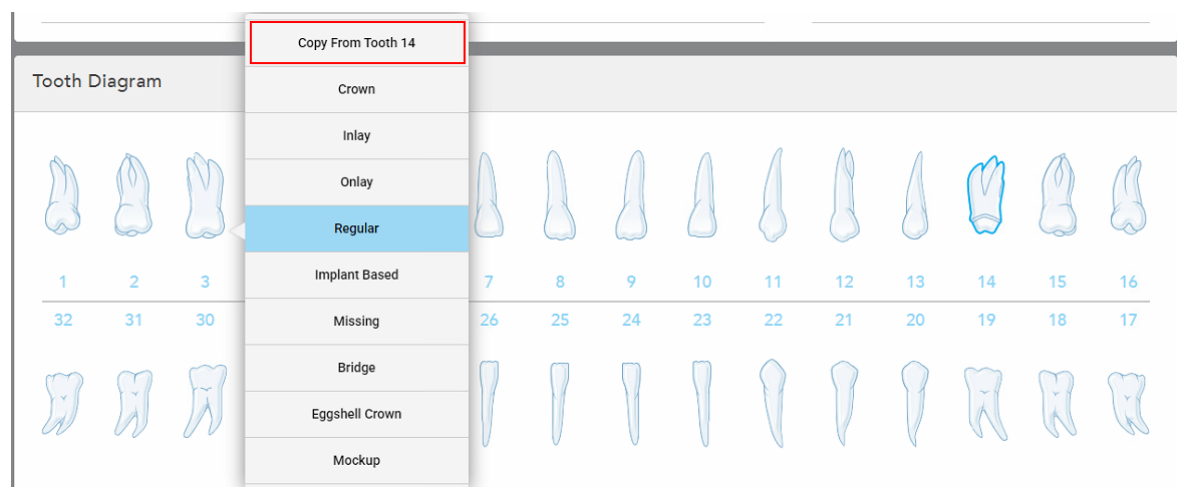


Figure 101: Copy restoration settings from a tooth requiring the same treatment type

The treatment settings are copied to the tooth and are displayed in the **Treatment Information** area below the **Tooth Diagram** area.

- Complete [filling in the details](#) in the *New Scan* window.

5.3.3.2 Implant Based restorations

Implant Based restorations are created as part of [Fixed Restorative procedures](#).

After starting to fill in the Rx for Fixed Restorative procedures, continue with the procedure below for Implant Based restorations.

Note: If an implant abutment already exists, you should select the [Crown restoration](#).

To fill in the Rx for an Implant Based restoration:

1. In the **Tooth Diagram**, tap the tooth that needs an implant abutment and then select **Implant Based** from the drop-down list.

The **Implant Based** treatment settings window is displayed.

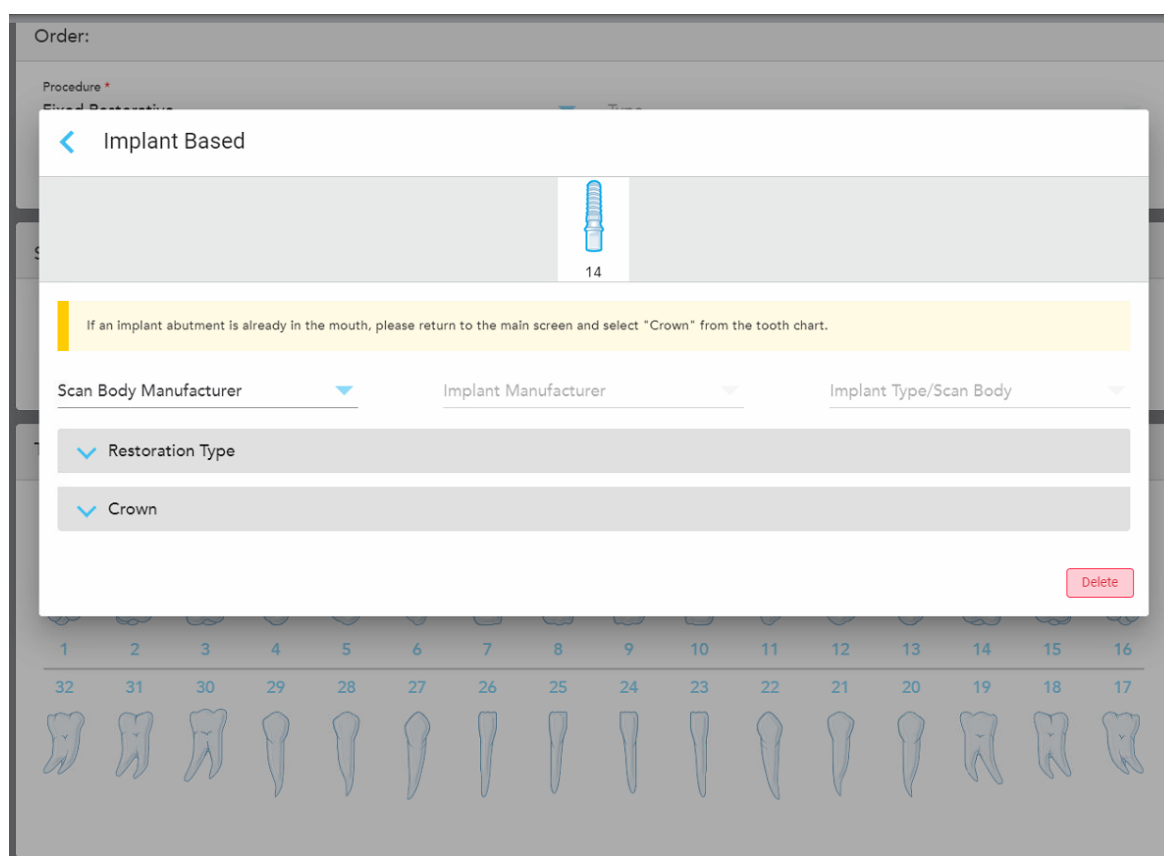


Figure 102: Treatment settings window – Implant Based restoration

2. Select the scan body manufacturer, implant manufacturer, and then the implant type/scan body from the relevant drop-down lists. If required, you can save the scan body and implant manufacturers you use most often as [favorites](#).

- Tap  to expand the **Restoration Type** area and then select the restoration type, abutment type, and abutment material from the relevant drop-down lists. If a titanium base is in place, turn on the **Ti-Base** toggle. You can select these options after scanning, but they must be selected before sending the scan.

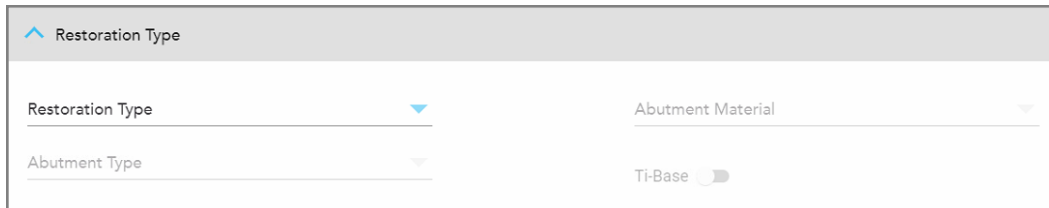


Figure 103: Expanded Restoration Type area

- Tap  to expand the **Crown** area and then [select the required settings](#) from the relevant drop-down lists. You can select these options after scanning, but they must be selected before sending the scan.

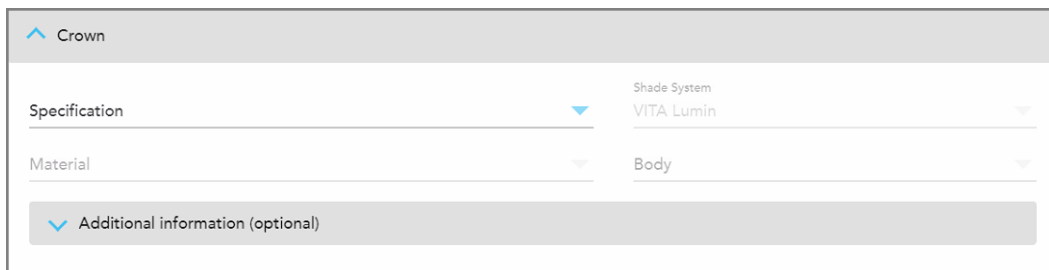


Figure 104: Expanded Crown area

- Tap  to save the selection and return to the *New Scan* window.
- Complete [filling in the details](#) in the *New Scan* window.

5.3.3.3 Bridge restorations

Follow the procedure below to complete filling in the Rx for Bridge restorations.

To fill in the Rx for a Bridge restoration:

- In the **Tooth Diagram** area, tap the first or last tooth in the span of teeth to be included in the bridge and then select **Bridge** from the drop-down list.

The **Bridge** treatment settings window is displayed.

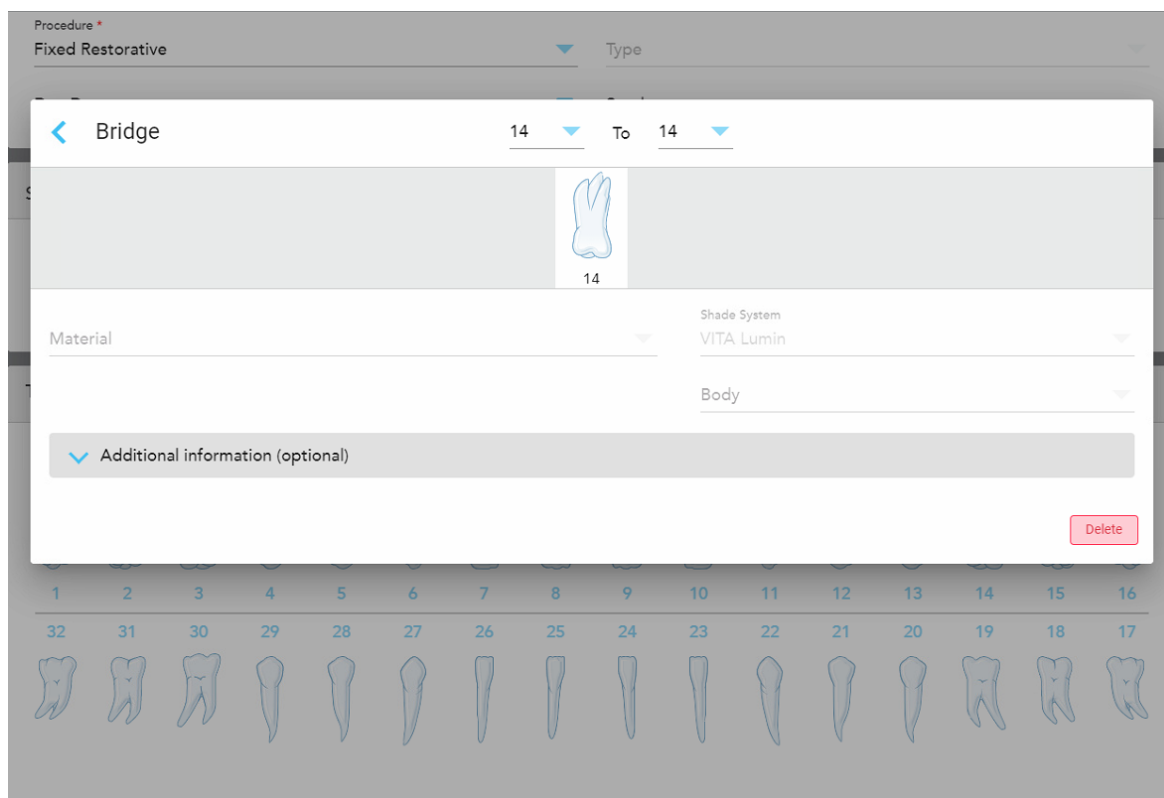


Figure 105: Treatment settings window – Bridge restoration

2. Select the span of the teeth to be included in the bridge from the arrows at the top of the window.
The teeth to be included in the bridge are displayed.

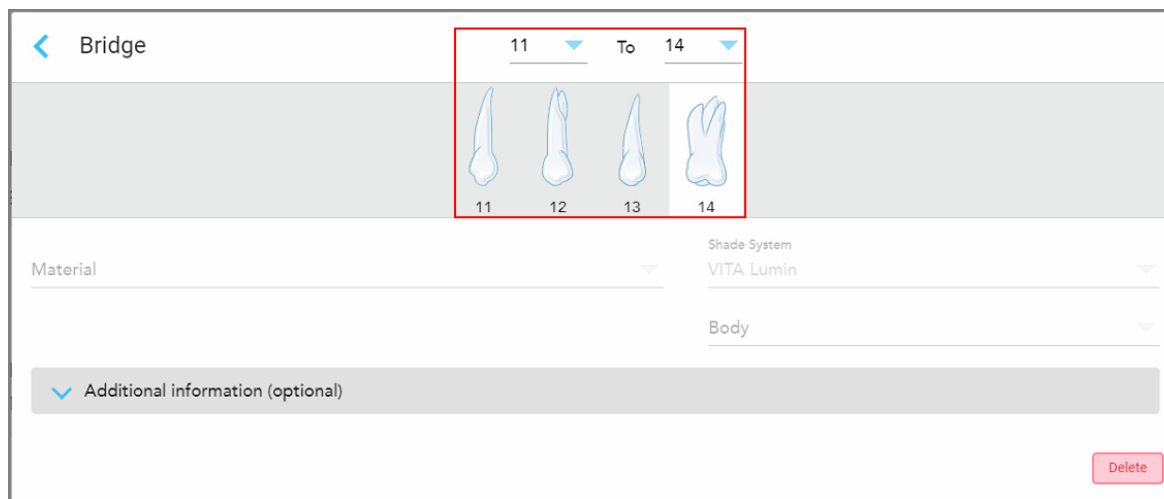


Figure 106: Bridge range and teeth to be included

3. Tap each tooth in the tooth range and then select the in-bridge treatment option from the list:

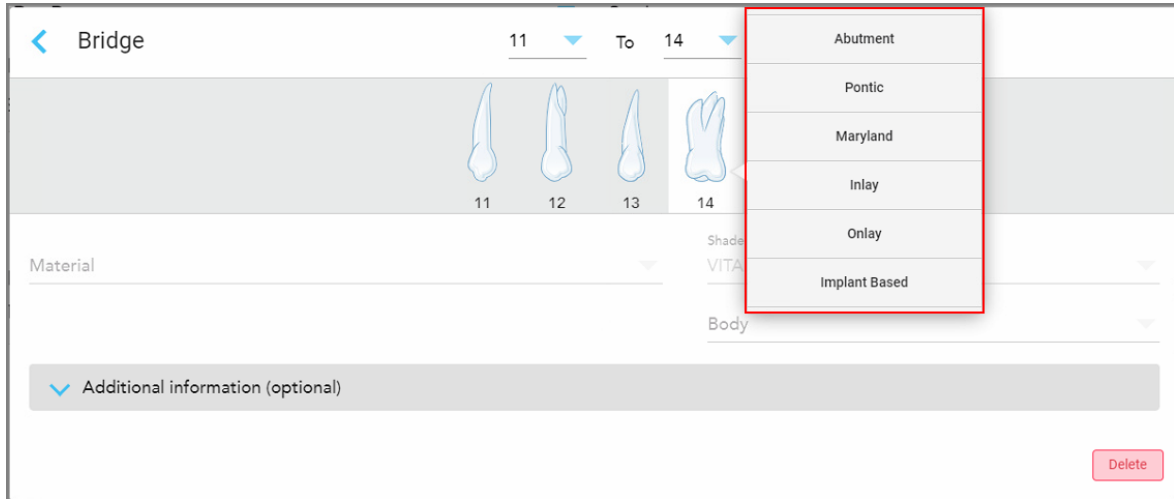


Figure 107: List of in-bridge treatment options

4. For all options besides **Implant Based**:

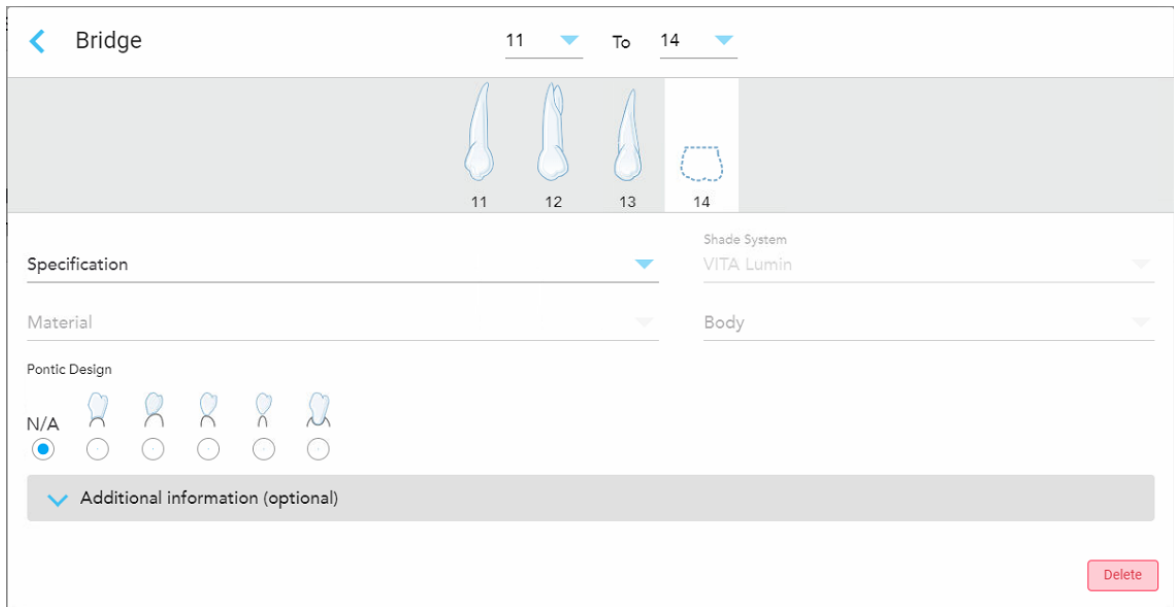
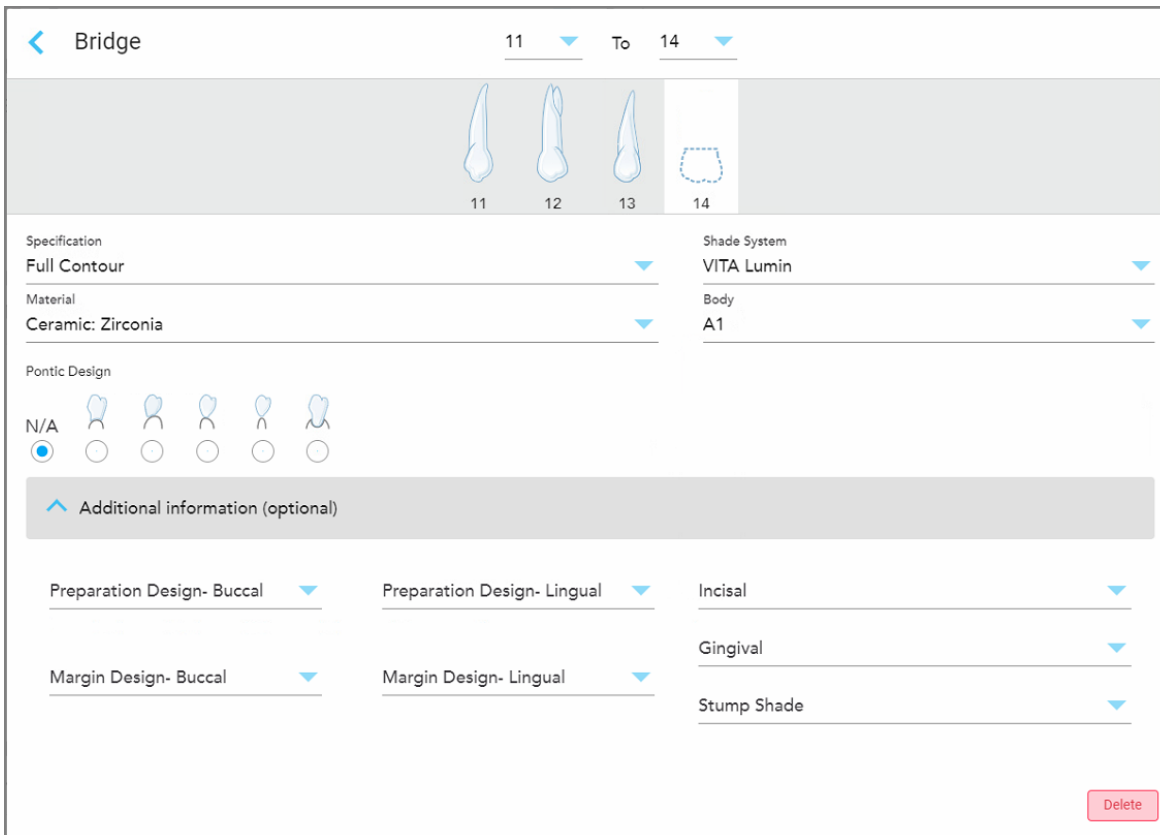


Figure 108: Bridge restoration – Pontic settings

- a. **Specification:** The type of restoration to be fabricated.
- b. **Material:** The material from which the restoration should be fabricated. This is automatically copied to each tooth in the restoration. If required, you can save the materials you use most often as [favorites](#).
- c. **Shade System:** The system used for choosing the shade of the restoration.
- d. **Body:** The shade for the body area of the restoration.
- e. **Pontic Design:** Relevant only if **Pontic** was selected as the in-bridge treatment option.

5. If required, tap  to expand the **Additional information** area to display other optional settings:



Bridge 11 To 14

11 12 13 14

Specification
Full Contour

Material
Ceramic: Zirconia

Pontic Design
N/A

Shade System
VITA Lumin

Body
A1

Additional information (optional)

Preparation Design- Buccal Preparation Design- Lingual Incisal

Margin Design- Buccal Margin Design- Lingual Gingival

Stump Shade

Delete

Figure 109: Additional information area – Bridge restoration

- **Preparation Design (Buccal and Lingual):** 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 (Buccal and Lingual):** 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.
- **Incisal:** The shade for the incisal area of the restoration.
- **Gingival:** The shade for the gingival area of the restoration.
- **Stump Shade:** The shade of the prepped tooth.

6. If you selected **Implant Based**, the Bridge treatment options are displayed as follows:

Figure 110: Bridge treatment options – Implant Based

- Select the scan body manufacturer, implant manufacturer, and implant type/scan body from the drop-down lists.
- Tap  to expand the **Restoration Type** area and then select the restoration type, abutment type, and abutment material from the relevant drop-down lists. If a titanium base is in place, turn on the **Ti-Base** toggle.

You can select these options after scanning, but they must be selected before sending the scan.

Figure 111: Expanded Restoration Type area

- Tap  to expand the **Crown** area and then [select the required settings](#) from the relevant drop-down lists.

You can select these options after scanning, but they must be selected before sending the scan.

Figure 112: Expanded Crown area

7. Tap  to save the selection and return to the *New Scan* window.
8. Complete [filling in the details](#) in the *New Scan* window.

5.3.4 Filling in the Rx for Implant Planning procedures

The **Implant Planning** procedure enables efficient communication with the labs regarding surgical-guide prescription requirements. If required, orders can also be sent to your chairside milling software and seamlessly imported directly into exoplan™ or other chairside planning software.

To fill in the Rx for an Implant Planning procedure:

1. In the **Patient** area, enter a patient's details or [search for an existing patient](#).
2. In the **Order** area, select **Implant Planning** from the **Procedure** drop-down list.
3. From the **Type** drop-down list, select the type of surgical guide required:

Figure 113: Implant Planning procedure types

The **New Scan** window expands to show **Tooth Diagram** and **Attachments** areas:

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

- Header:** 'New Scan' title, navigation icons (R, Save, Zoom, Mail), and system icons (Up, Settings, Help).
- Doctor:** Dr. Demo, Demo | License: 12345
- Patient:**
 - First Name: * Patient | Last Name: * Demo
 - Date of Birth: | Gender: ☐ Male ☐ Female
 - Chart Number: |
- Order:**
 - Procedure: * Implant Planning | Type: * Surgical Guide Tooth Supported
 - Due Date: | Send to:
- Tooth Diagram:** A grid of 32 tooth icons arranged in two rows of 16. The top row is numbered 1-16 and the bottom row is numbered 32-17. The entire section is highlighted with a red border.
- Attachments:**

Now you can share external case-related files, including images, videos, and X-rays, with your lab.

To upload files please use myiTero.com
- Notes:**

Add Note

Figure 114: Implant Planning procedure – Tooth Diagram area for Surgical Guide Tooth Supported

- If required, tap the calendar in the **Due Date** field and then select the date the plan is due.
- From the **Send To** drop-down list, select the lab to which the scan should be sent, your chairside milling software, or your MyiTero account.

- In the **Tooth Diagram** area, select each tooth to be implanted and select **Implant Position** from the drop-down list.

If you selected **Surgical Guide Tooth Supported** as the procedure type, you can also select each supporting tooth and then select **Supporting Tooth** from the drop-down list. Supporting teeth are displayed in the **Tooth Diagram** area with a line under them.

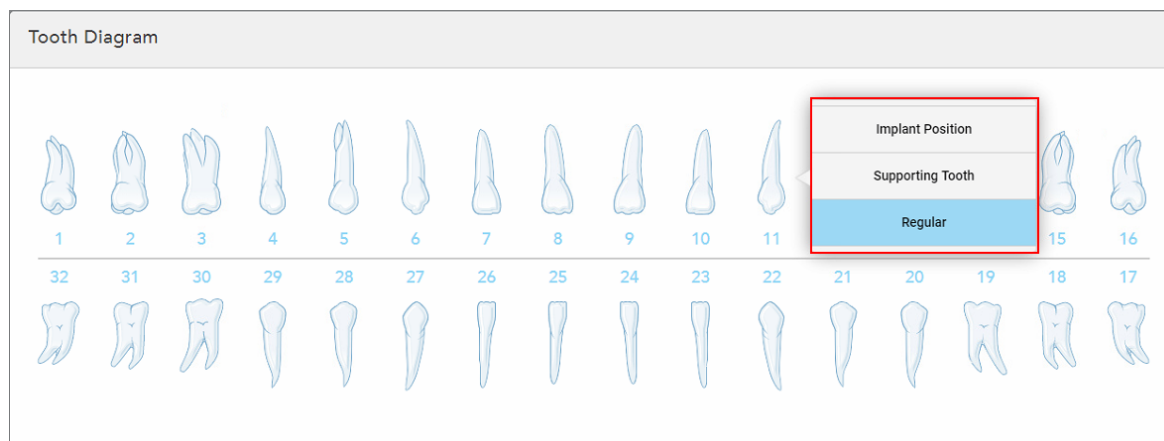


Figure 115: Defining the teeth that need to be implanted

For each tooth selected to be implanted, the *Implant Position* window is displayed.

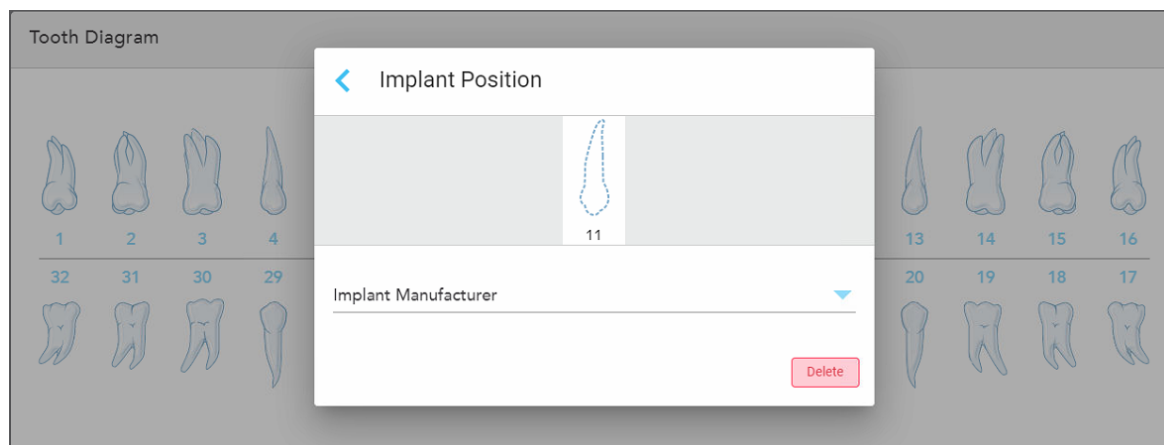


Figure 116: Implant Position window

- Select the implant manufacturer from the drop-down list. If required, you can save the implant manufacturers you use most often as [favorites](#).
- Tap  to save your changes and return to the *New Scan* window.

The teeth to be implanted and the supporting teeth, if relevant, are displayed in the **Tooth Diagram** area. Supporting teeth have a line under them and the teeth to be implanted are shown with a dotted line.

The details of each relevant tooth are displayed in the *Treatment Information* area below the **Tooth Diagram** area.

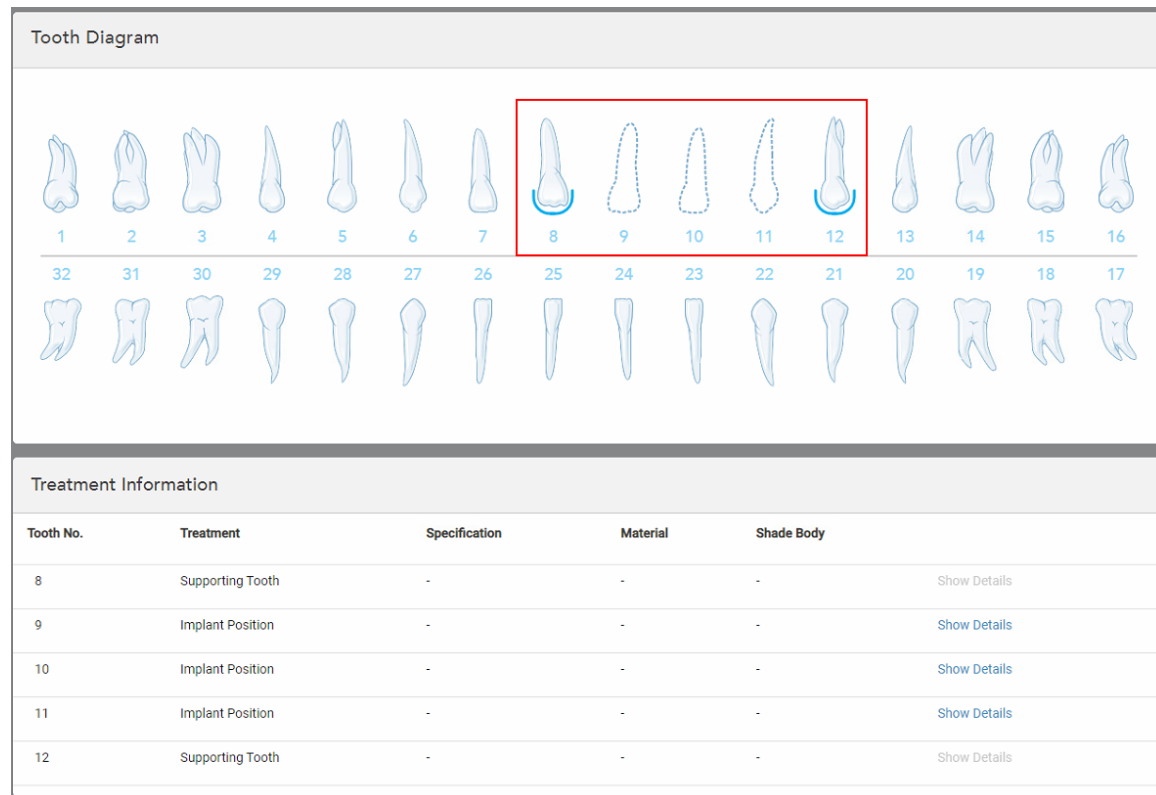


Figure 117: Supporting teeth and teeth to be implanted displayed in the Tooth Diagram and Treatment Information areas

- In the **Notes** area, if required, enter any specific notes to the lab regarding the patient's treatment. For example, special instructions for delivery or manufacturing. After entering your note, tap anywhere outside the **Notes** area to add the note. Each note shows the author of the note, with a timestamp, and can be edited and deleted.

5.3.5 Filling in the Rx for Denture/Removable procedures

The Denture/Removable procedure enables comprehensive planning and fabrication of partial and full dentures.

Note: Some fields are not mandatory before scanning the patient but must be filled in before you can send the scan.

To fill in the Rx for a Denture/Removable procedure:

- In the **Patient** area, enter a patient's details or [search for an existing patient](#).
- In the **Order** area, select **Denture/Removable** from the **Procedure** drop-down list.

The *New Scan* window expands to display **Denture Details**, **Scan Options**, and **Attachments** areas.

The screenshot shows the 'New Scan' window in the iTero software. The window title is 'New Scan'. The top bar contains icons for a blue square with 'R', a scanner, a magnifying glass, and an envelope. The main content area is divided into several sections:

- Patient:** Includes fields for Doctor (Dr. Demo, Demo), License (12345), First Name (Patient), Last Name (Demo), Date of Birth, Gender (Male/Female), and Chart Number.
- Order:** Includes Procedure (Denture/Removable), Type, Due Date, and Send to.
- Denture Details:** This section is highlighted with a red border. It includes Stage, Mould, Upper Denture, Lower Denture, Shade System (VITA Lumin), Teeth Shade, and Gingival.
- Scan Options:** This section is also highlighted with a red border. It includes a Denture Copy Scan toggle.
- Attachments:** Includes a message: 'Now you can share external case-related files, including images, videos, and X-rays, with your lab. To upload files please use myiTero.com'.
- Notes:** Includes a text area for adding notes.

Figure 118: Denture/Removable procedure – Denture Details and Scan Options areas

- From the **Type** drop-down list, select the type of denture required. Depending on the type selected, the **Tooth Diagram** area is displayed.

The screenshot shows the 'Order' section of the iTerio software. The 'Procedure' is set to 'Denture/Removable'. The 'Due Date' field has a calendar icon. The 'Denture Details' section includes 'Stage', 'Mould', and 'Upper Denture'/'Lower Denture' toggles. The 'Type' dropdown menu is open, showing five options: 'Partial Denture/Framework', 'Partial Immediate Denture', 'Full Immediate Denture', 'Full Denture Tissue Based', and 'Full Denture Implant Based'. The 'Teeth Shade' and 'Gingival' dropdowns are also visible.

Figure 119: Denture/Removable procedure types

- If required, tap the calendar in the **Due Date** field and then select the date the denture is due from the lab.
- From the **Send To** drop-down list, select the lab to which the scan should be sent, your chairside milling software, or your MyiTero account.
- If required, in the **Denture Details** area, select the denture stage, mould, and shade system, including the teeth shade and the gingiva shade from the relevant drop-down lists.

Upper/Lower Denture: The relevant arch toggle turns on automatically according to the tooth indications in the **Tooth Diagram** area.

- In the **Scan Options** area, turn on/off the following toggles, as required.
 - Denture Copy Scan:** Turn on the **Denture Copy Scan** toggle to include a scan of the existing dentures or temporary dentures. When you move to Scan mode, tap **1** to scan the existing dentures, and then tap **2** to scan the patient.

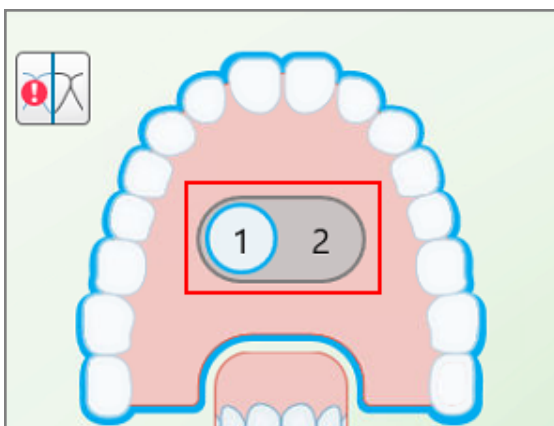


Figure 120: Scanning option for scanning both the existing dentures and the patient

8. In the **Tooth Diagram** area, define the teeth to be included in the denture according to the procedure type selected. This area is not relevant for Full Immediate Denture and Full Denture Tissue Based procedure types.

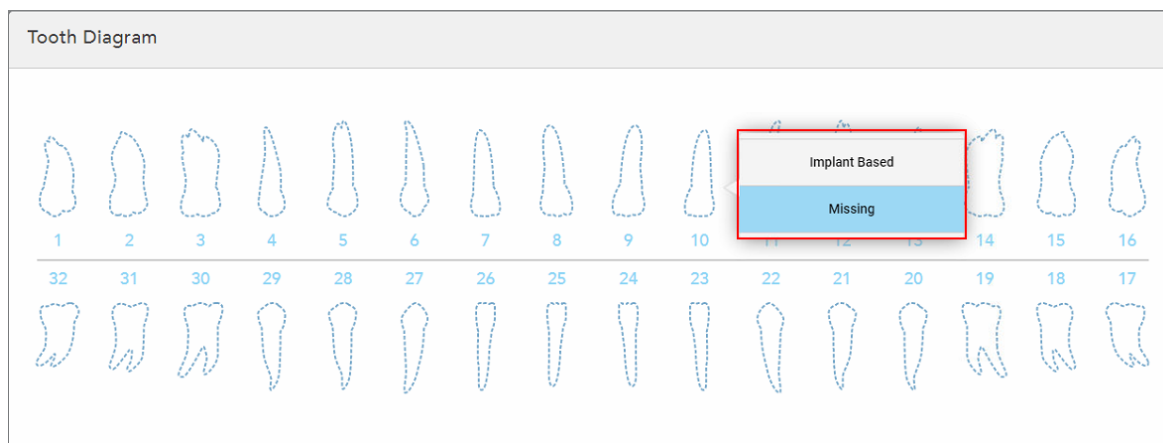


Figure 121: Defining the teeth to be included in the denture – Full Denture Implant Based procedure type

- Partial Denture/Framework – Tap each relevant tooth and select either **Clasp** or **Missing**.
- Partial Immediate Denture – Tap each relevant tooth and select either **Clasp** or **To Be Removed**.

- Full Denture Implant Based – Tap each relevant tooth and select either **Implant Based** or **Missing**. If you select **Implant Based**, the *Implant Based* settings window is displayed, with all fields mandatory.

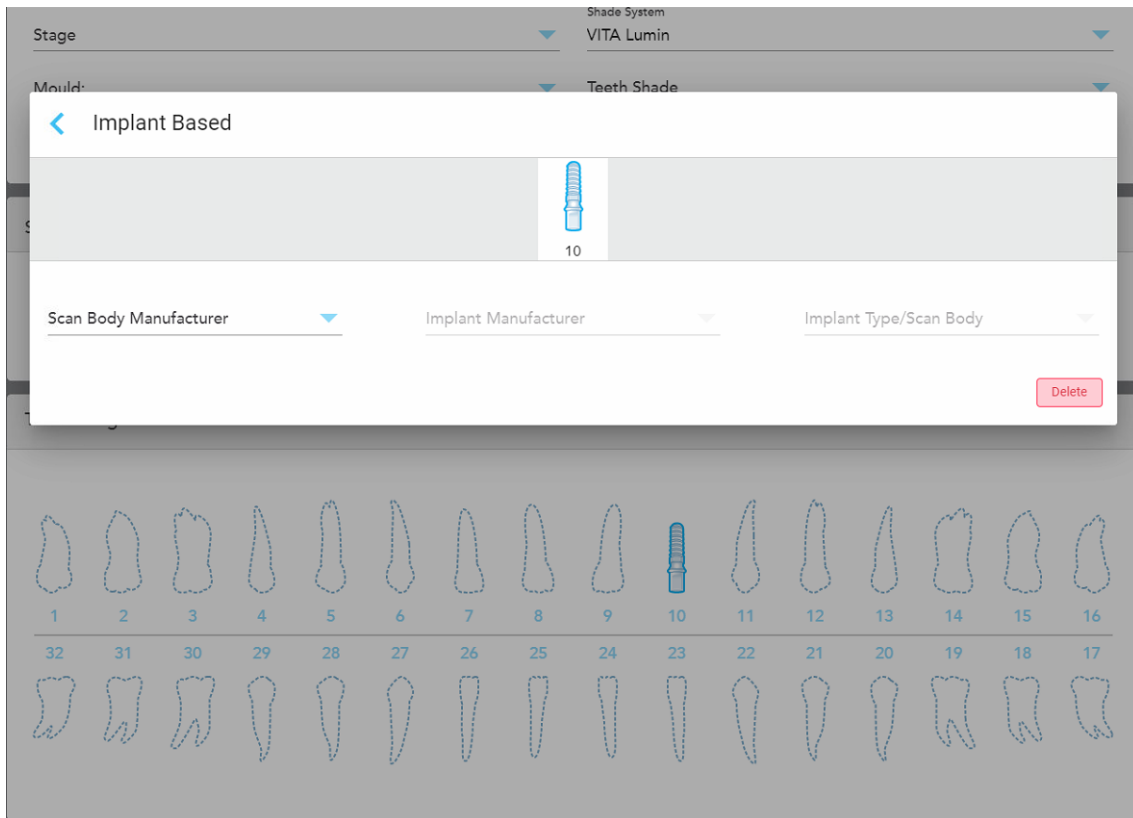


Figure 122: Implant Based settings window

- For each Implant-based tooth, select the scan body manufacturer, the implant manufacturer, and the implant type/scan body from the relevant drop-down lists. If required, you can save the scan body and implant manufacturers you use most often as [favorites](#).
 - Tap  to save your changes and return to the *New Scan* window.
- The **Treatment Information** area displays all indications for each tooth. If required, edit the details for each tooth by tapping **Show Details**.
 - In the **Notes** area, if required, enter any specific notes to the lab regarding the patient's treatment. For example, special instructions for delivery or manufacturing. After entering your note, tap anywhere outside the **Notes** area to add the note. Each note shows the author of the note, with a timestamp, and can be edited and deleted.
 - Tap  on the toolbar to move to [Scan mode](#).

Note: Excess soft tissue will not be removed automatically from around the edges of the model during scanning. If required, you can [enable automatic cleanup](#) by pressing on the screen and then tapping the Auto Cleanup tool.

5.3.6 Filling in the Rx for Appliance procedures

The Appliance procedure enables you to create a prescription for various dental appliances, such as night guards and sleep appliances.

To fill in the Rx for an Appliance procedure:

1. In the **Patient** area, enter a patient's details or [search for an existing patient](#).
2. In the **Order** area, select **Appliance** from the **Procedure** drop-down list.

The New Scan window expands to display **Appliance details**, **Scan Options**, and **Attachments** areas.

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

- Header:** Doctor: Dr. Demo, Demo; License: 12345
- Patient:** Search bar with 'Clear' button. Fields for First Name (*), Last Name (*), Date of Birth, Gender (Male/Female), and Chart Number.
- Order:** Procedure (*): Appliance; Type (*); Due Date; Send to.
- Appliance details:** Arch: Upper (selected), Lower; Toggles for Upper and Lower.
- Scan Options:** Multi-Bite: (toggle).
- Attachments:** Text: 'Now you can share external case-related files, including images, videos, and X-rays, with your lab. To upload files please use myiTero.com'.
- Notes:** Add Note button.

Figure 123: Appliance details and Scan Options areas – Appliance procedure

- From the **Type** drop-down list, select the type of appliance required. If the required appliance is not listed, select **Ortho Appliance** and then enter your requirements in the **Notes** area at the bottom of the window.

The screenshot shows a software interface for ordering an appliance. It includes a 'Procedure' dropdown set to 'Appliance', a 'Due Date' field, and an 'Appliance details' section with 'Arch' selection for 'Upper' and 'Lower'. A 'Type' dropdown menu is open, showing a list of appliance types: Night Guard, Bite Splint, Sports/Mouth Guard, Apnea/Sleep Appliance, and Ortho Appliance. The 'Ortho Appliance' option is highlighted.

Figure 124: Appliance procedure types

- In the **Appliance details** area, select whether the appliance is for the upper arch, lower arch, or both.
- If you selected Night Guard or Apnea/Sleep Appliance as the appliance type, you can select the type of material used – Soft, Dual laminate, or Hard.
- Continue filling in the prescription from step 4, **Due Date**, as described in [Filling in the Rx](#).

5.3.7 Saving list items as favorites

If required, you can select the materials, scan body manufacturers, and implant manufacturers you use most often and save them as favorites, which are pinned to the top of each relevant list.

To save a list item as a favorite:

- In the relevant Material, Scan Body Manufacturer, or Implant Manufacturer list, tap **Add favorites** and then select one or more items in the list.

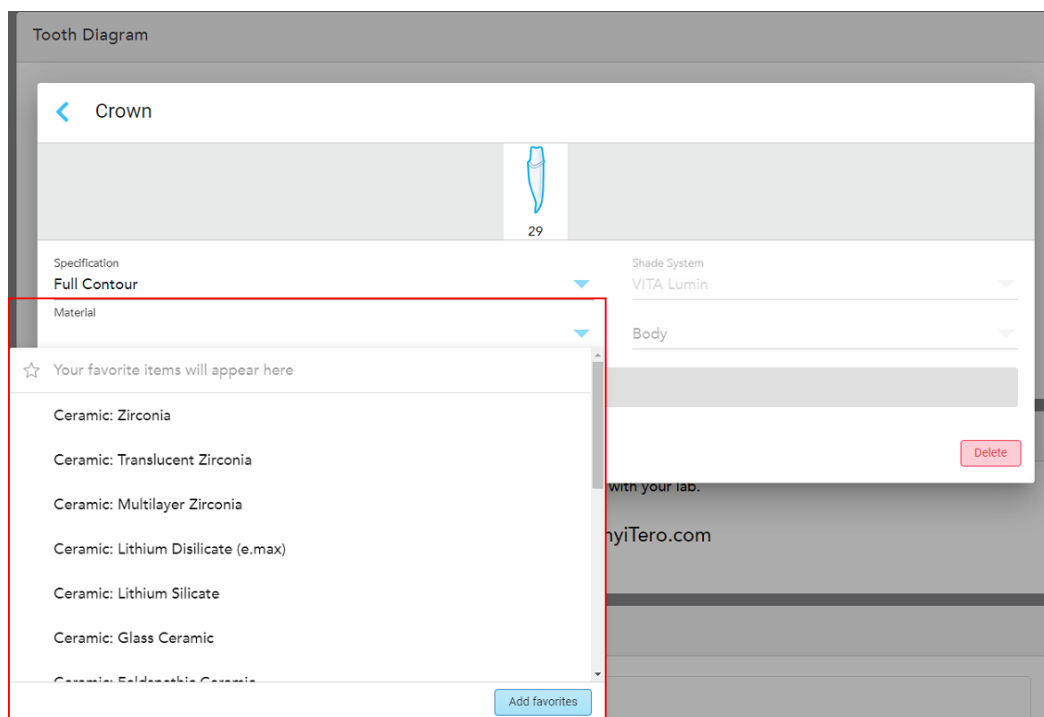


Figure 125: Adding a favorite material

2. Tap **Done**.

The selected items are displayed with a star at the top of the list and are easily visible when filling out the Rx.

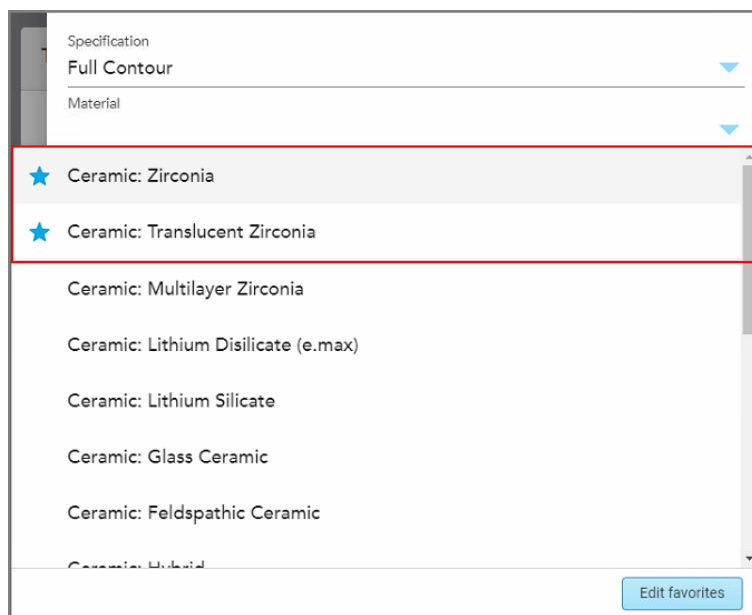


Figure 126: Favorite materials pinned to the top of the Material list

3. To remove a favorite or add additional favorites, tap **Edit favorites**.

5.4 Patient management

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

You can:

- [Add a new patient](#)
- [Search for an existing patient](#)
- [Edit a patient's details](#)
- [Clear the patient details from the *New Scan* window](#)

5.4.1 Adding new patients

You can add a new patient while filling in the Rx. The patient's details will be saved once you move to the *Scan* window and can later be [edited](#).

In addition, you can add new patients using MyiTero or your Dental Program Management Services (DPMS) software.

To add a new patient:

1. In the *New Scan* window, in the **Patient** area, enter the patient's first name and last name.
2. If required, enter the patient's date of birth, select the patient's gender, and enter a unique identifier as the patient's chart number.

Note: By default, the date is written in DD/MM/YYYY format. If required, you can [change the date format](#).

The new patient's details are displayed in the **Patient** area of the *New Scan* window.

The screenshot shows the 'New Scan' window with a top toolbar containing icons for Rx, a patient icon, a magnifying glass, and an envelope. The main content area is divided into three sections: 'Patient', 'Order', and 'Notes'. The 'Patient' section is highlighted with a red border and contains the following fields: 'First Name' (Patient1), 'Last Name' (Demo), 'Date of Birth' (20/03/1983), 'Chart Number' (123), and 'Gender' (radio buttons for Male and Female, with Female selected). The 'Order' section contains 'Procedure' (with a dropdown arrow), 'Type' (with a dropdown arrow), 'Due Date' (with a calendar icon), and 'Send to' (with a dropdown arrow). The 'Notes' section contains an 'Add Note' button.

Figure 127: Adding a new patient

Note: If you try adding a patient who already exists, the **First Name**, **Last Name**, and **Chart Number** fields are highlighted, and a message is displayed notifying you that a patient with the same details already exists.

The screenshot shows a 'Patient:' form with the following fields: First Name (labeled 'First Name: *'), Last Name (labeled 'Last Name: *'), Date of Birth, Gender (with radio buttons for Male and Female), and Chart Number. The 'First Name' field contains 'Patient2', the 'Last Name' field contains 'Demo', and the 'Chart Number' field is empty. All three fields are highlighted with a red border. At the bottom, a yellow message box states: 'A patient with the same details already exists: Demo, Patient2. Load existing patient or edit highlighted fields above to create a new patient.' There are 'Search' and 'Clear' buttons in the top right corner.

Figure 128: Message notifying that a patient with the same details exists

- If the new patient and the existing patient are the same person, tap **Load existing patient**.
- If the new patient and the existing patient are different people, edit the highlighted fields – First Name, Last Name, or Chart Number – to create a new patient.

The patient's details are displayed in the *New Scan* window.

5.4.2 Searching for existing patients

When searching for an existing patient, you must 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.

To search for an existing patient:

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

This screenshot is identical to the one in Figure 128, showing the 'Patient:' form with 'Patient2' and 'Demo' in the First Name and Last Name fields respectively. The search icon (a magnifying glass) in the top right corner is highlighted with a red square.

Figure 129: Patient area of the New Scan window – searching for an existing patient

The *Search Patient* window is displayed.

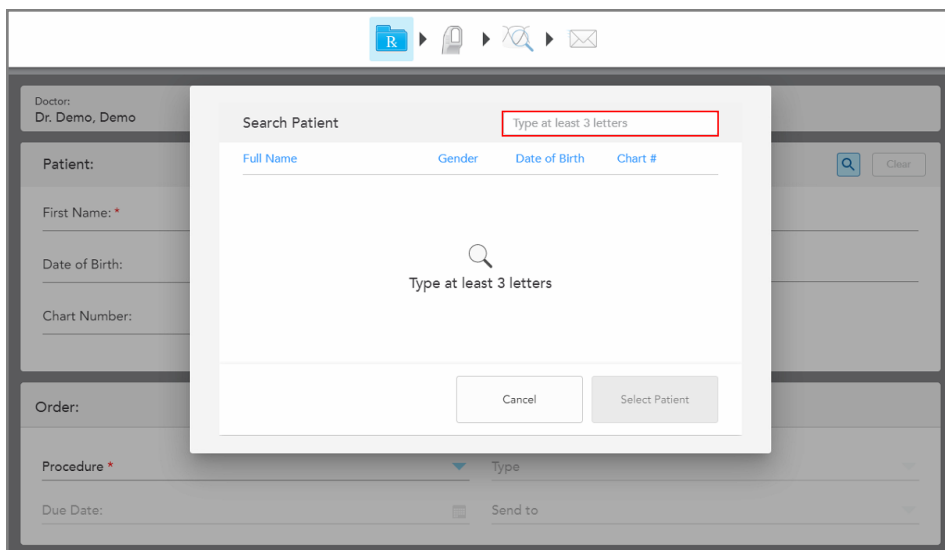


Figure 130: Search Patient window with a search field

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.

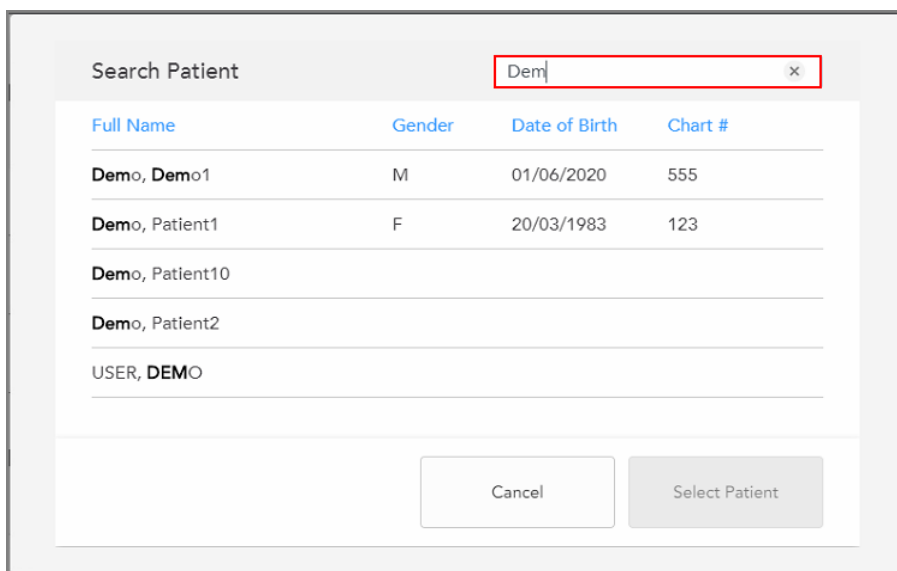


Figure 131: Search criteria in the search field and list of matching patients

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

Full Name	Gender	Date of Birth	Chart #
Demo, Demo1	M	01/06/2020	555
Demo, Patient1	F	20/03/1983	123
Demo, Patient10			
Demo, Patient2			
USER, DEMO			

Figure 132: Selecting the required patient

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

Doctor: Dr. Demo, Demo License: 12345

Patient:

First Name: Patient1 Last Name: Demo

Date of Birth: 20/03/1983 Gender: ☐ Male ☒ Female

Chart Number: 123

Figure 133: Selected patient displayed in the Patient area of the New Scan window

5.4.3 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](#).

To edit a patient's details:

1. [Search for an existing patient](#).

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

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

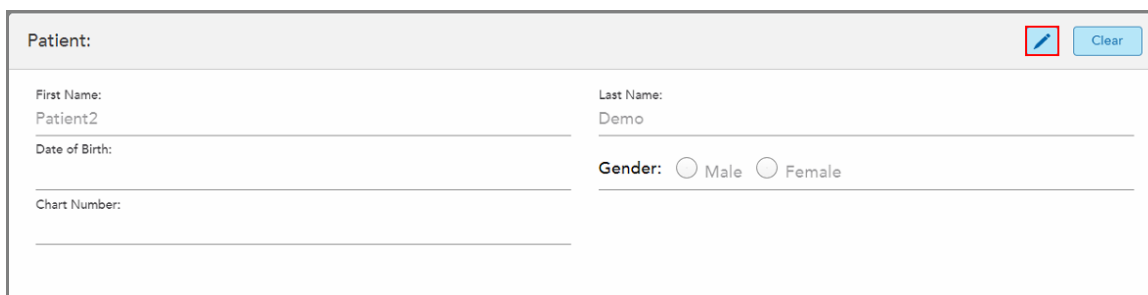


Figure 134: Patient area of New Scan window – editing a patient

The *Edit Patient* window is displayed.

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

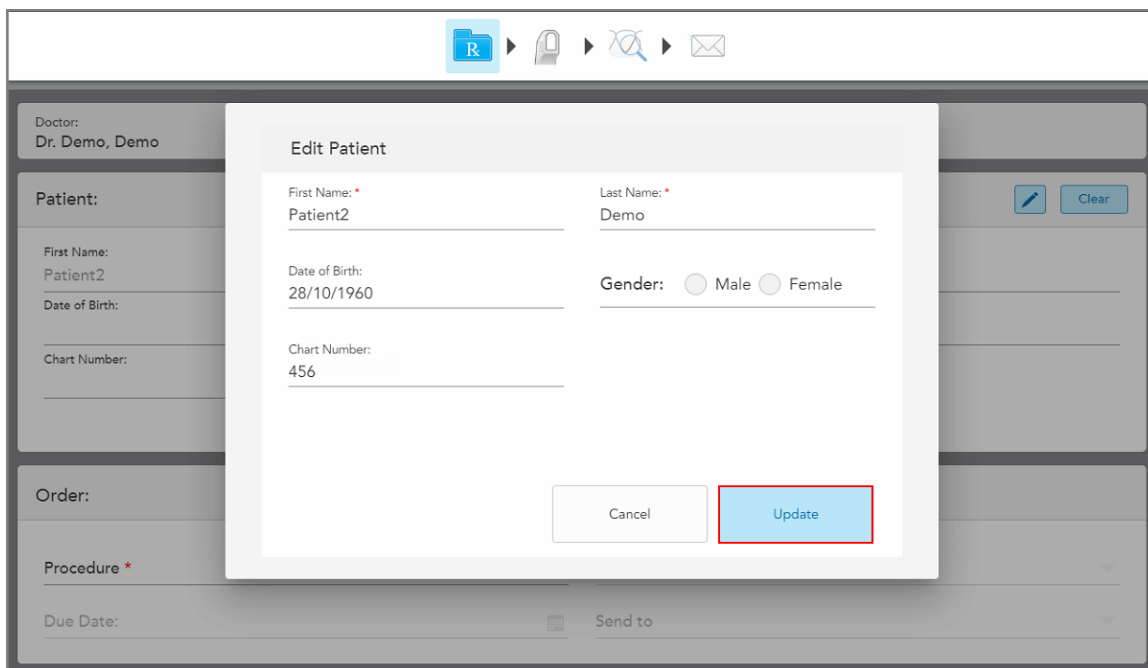


Figure 135: Edit Patient window and Update button

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

The screenshot shows the 'Edit Patient' form with the following fields and values:

- First Name: *** Patient 1
- Last Name: *** Demo
- Date of Birth:** (empty)
- Gender:** ☐ Male ☐ Female
- Chart Number:** (empty)

A red-bordered message box at the bottom states: "A patient with the same details already exists: Demo, Patient 1". Below the message box are 'Cancel' and 'Update' buttons.

Figure 136: Message that a patient with the same details already exists

To differentiate between patients with the same details, enter a unique identifier in the **Chart Number** field.

5.4.4 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:

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

The screenshot shows the 'Patient' form with the following fields and values:

- First Name:** Patient1
- Last Name:** Demo
- Date of Birth:** 19/03/1983
- Gender:** ☐ Male ☒ Female
- Chart Number:** 123

In the top right corner, there is a 'Clear' button highlighted with a red border.

Figure 137: Clear patient details button

A confirmation message is displayed.

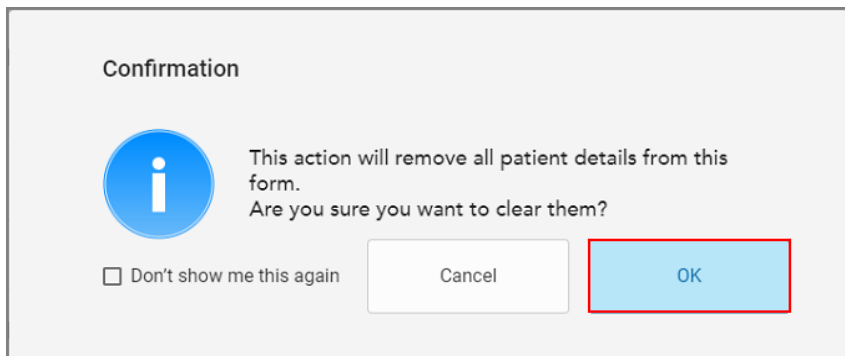


Figure 138: Clear confirmation message

2. Tap **OK** to clear the patient's details.

If required, you can select the **Don't show me this again** check box. In the future, the patient details will be cleared from the *New Scan* window as soon as you tap the **Clear** button.

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

5.5 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 in Scan mode, you can perform the following actions:

- [View additional scan feedback](#)
- [Toggle between color and monochrome mode](#)

You can also edit the scan, as follows:

- [Delete a segment](#)
- [Delete a selected area](#)
- [Capture areas with missing anatomy](#)
- [Display the excess tissue around the edges of the 3D model](#)



When you have finished scanning the patient, tap  on the toolbar to move to **View** mode, where you can review the scan.

5.5.1 Scanning guidance

As soon as you move to Scan mode, the recommended scanning sequence for the selected scan segment is displayed, by default, 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.

If required, you can [disable the scanning guidance for all scans](#).

iTero recommends you follow the scanning sequence for best results.

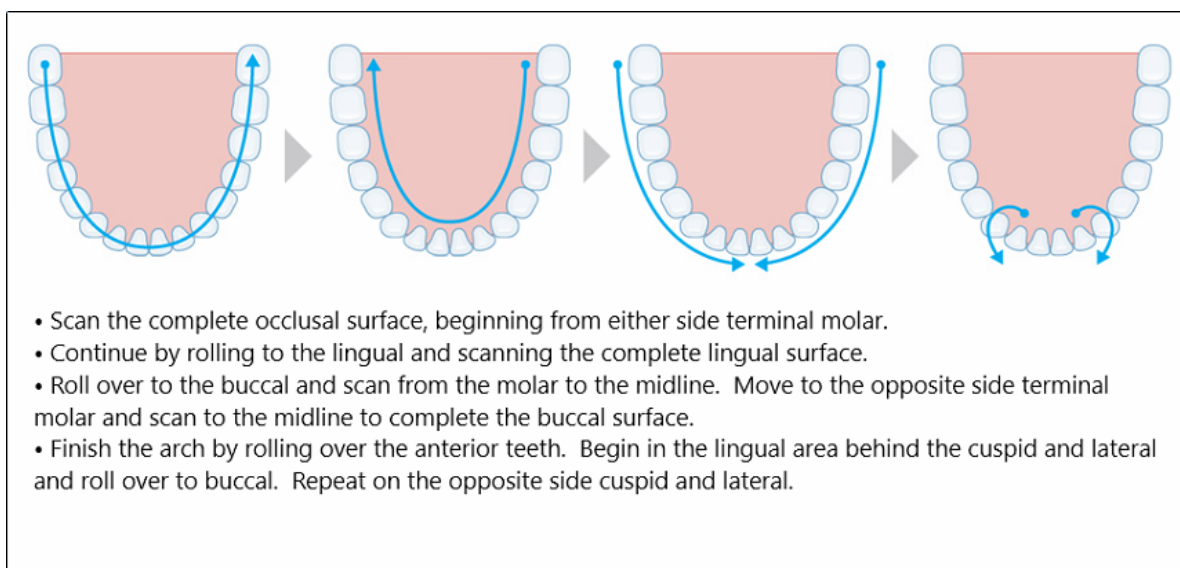


Figure 139: Recommended scanning sequence – lower jaw

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

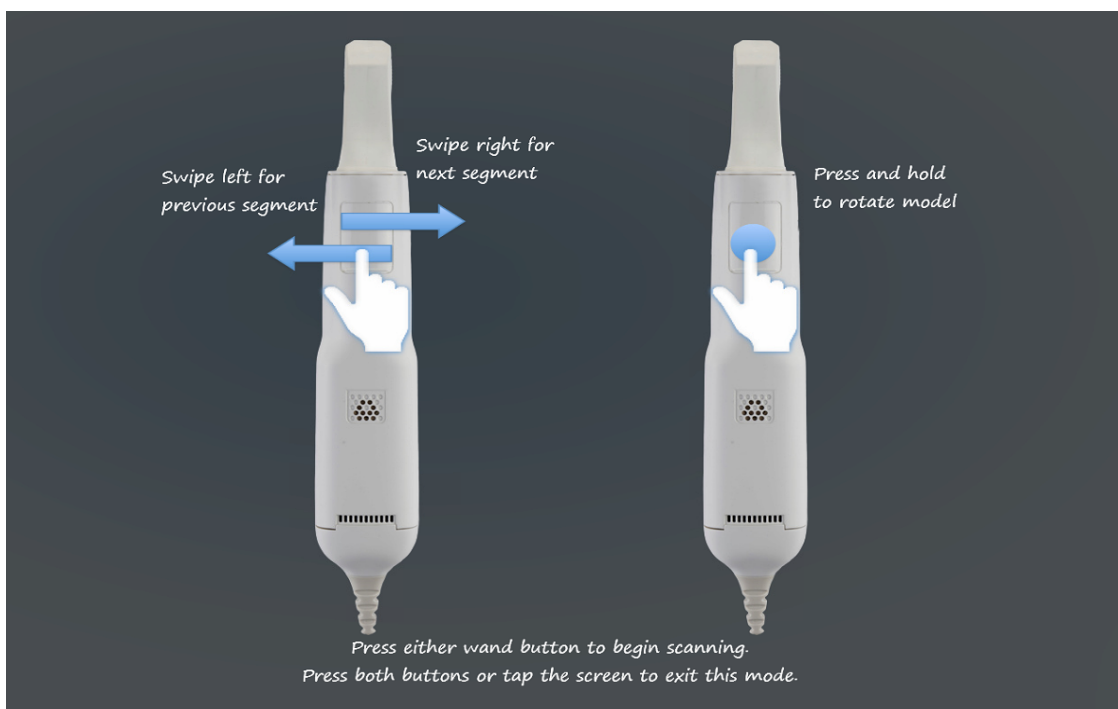


Figure 140: Wand guidance

Press either of the wand buttons to begin scanning.

5.5.1.1 Palatal and gingival feedback

Invisalign Palatal Expander submissions require the palate to be fully captured. iTero automatically provides feedback of palatal areas that have not been fully captured for Invisalign procedures with Invisalign First Aligners and Invisalign Palatal Expander procedure types. By default, Palatal and gingival feedback is enabled for the rest of the Invisalign procedure types and for Study Model/iRecord procedures. If required, you can disable it for a [specific scan](#) or for [all scans](#).

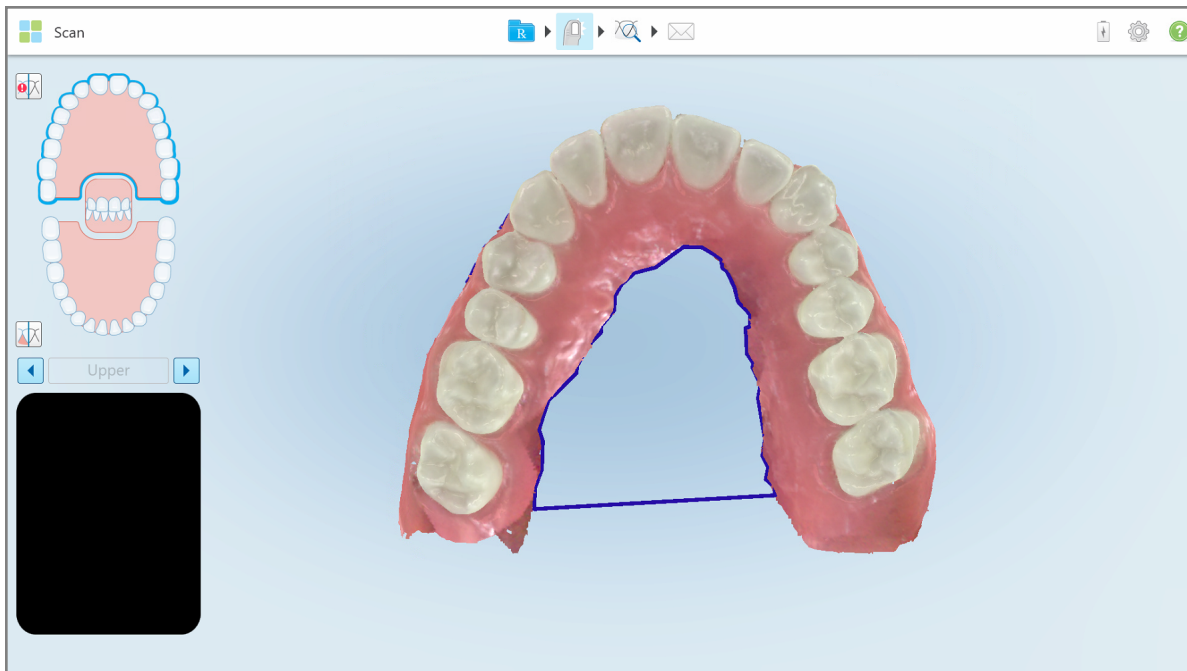


Figure 141: Missing palatal area is highlighted in blue

5.5.2 Scanning best practices

iTero recommends the following best practices for scanning fixed restorative procedures:

- Ensure that the prepped tooth and the surrounding area are 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.

5.5.3 Scan options

In Scan mode, you can select the following options:

- [Additional scan feedback](#)
- [Toggle between color and monochrome](#)

- Edit the scan:
 - [Delete a segment](#)
 - [Delete a selection](#)
 - [Fill in missing anatomy](#)
 - [Disable auto-cleanup](#)

5.5.3.1 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.

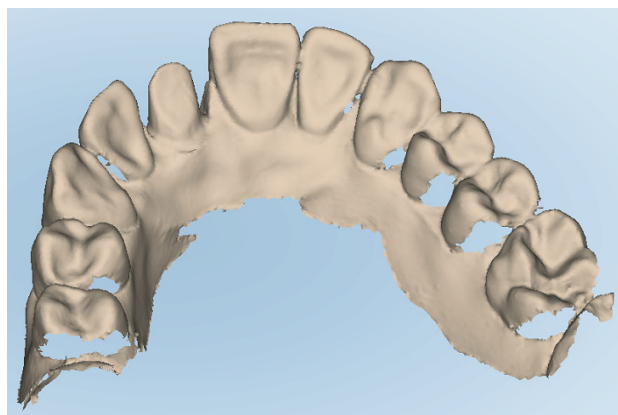
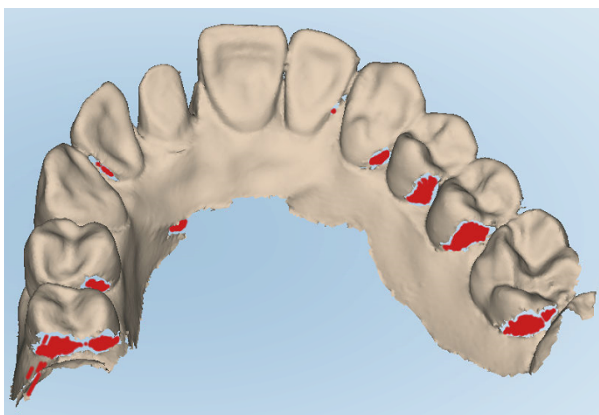


Figure 142: Areas with missing anatomy shown with and without additional scan feedback – monochrome

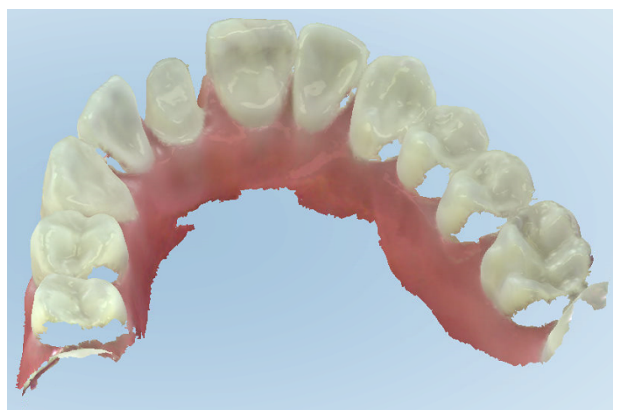
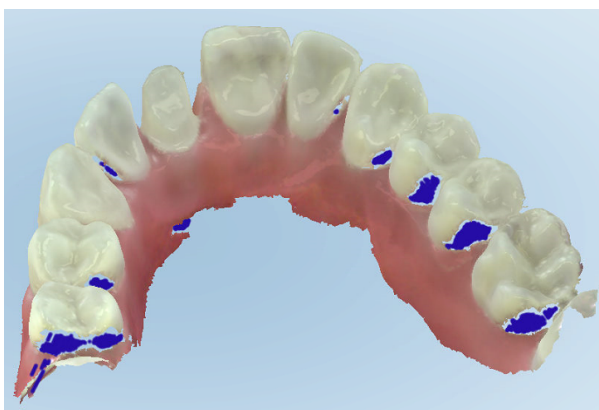


Figure 143: Areas with missing anatomy shown with and without additional scan feedback – color mode



By default, this mode is enabled, but it can be disabled per case by tapping  or by default in the [Scan Settings](#).

5.5.3.2 Scan color toggle



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

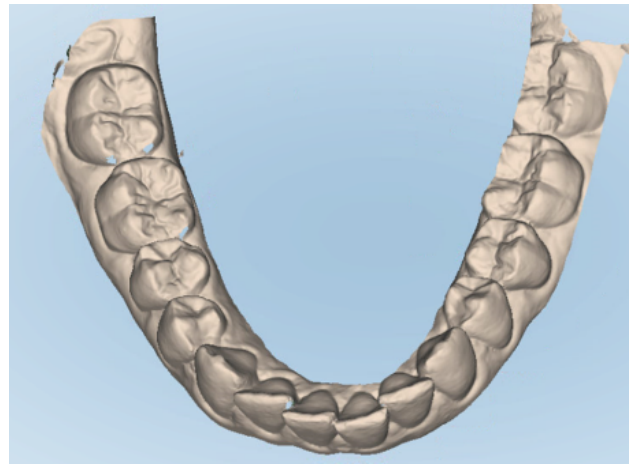


Figure 144: Model displayed in color and monochrome mode



By default, models are scanned in color, but you can toggle the display per case by tapping  or by default in the [Scan settings](#).

5.5.3.3 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 side buttons to stop the wand from scanning. The system emits a sound when stopping the scan and again when restarting the scan.

You can move to the next segment by:

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

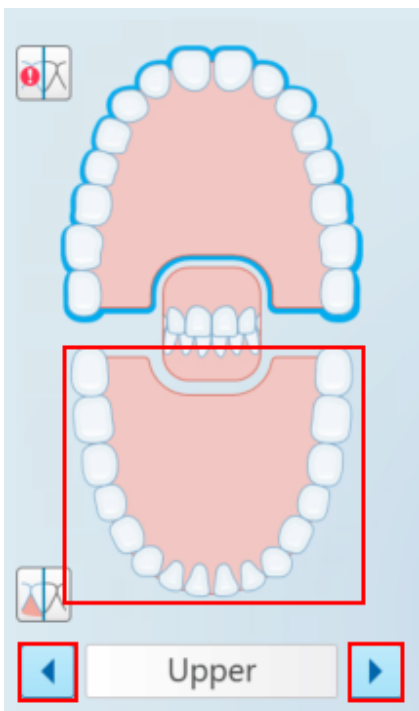


Figure 145: Tap the opposite arch or tap the arrows to select it

- Swiping to the left or the right on the wand touchpad.
To enable the wand touchpad, press and release both wand buttons simultaneously.

5.5.4 Editing a scan

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

- [Delete Segment tool](#)
- [Delete Selection tool](#)
- [Fill tool](#)
- [Disable auto-cleanup tool](#)

The editing tools are accessed by pressing on the screen.

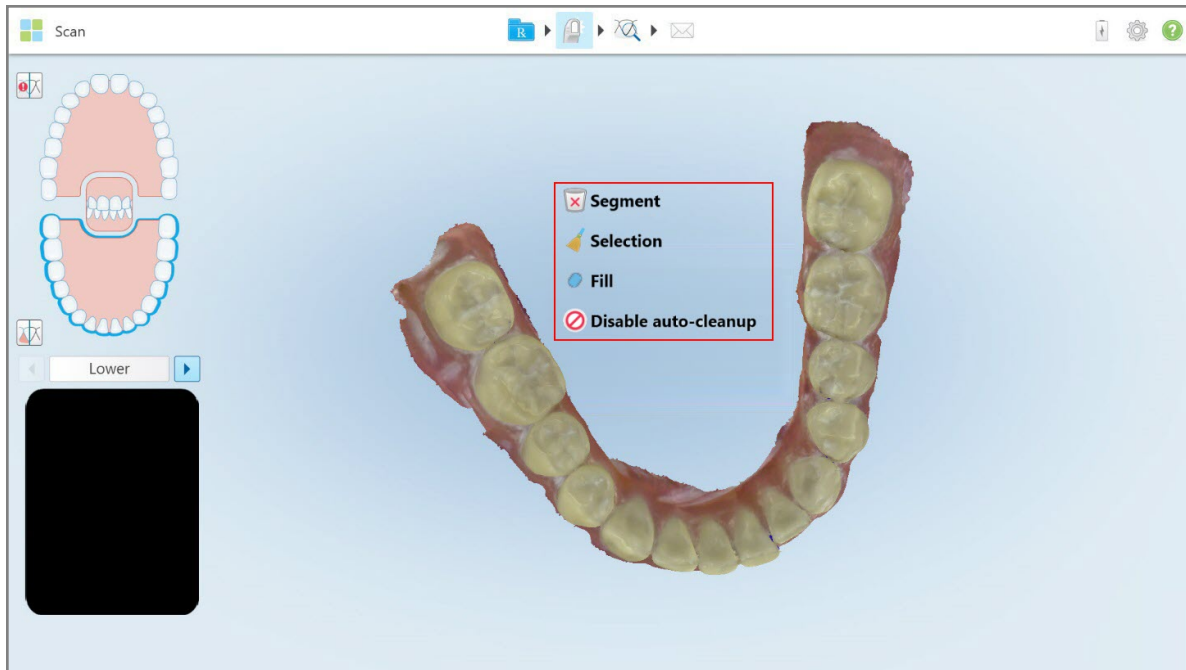


Figure 146: Editing tools

5.6 Viewing the scan

After scanning the patient, tap  to move to View mode. After the post-processing stage is complete, you can inspect the model in high resolution to ensure that sufficient anatomy has been captured, and that the model is accurate and complete.

If there are [missing scan segments or missing bites](#), a message will be displayed at the beginning of the post-processing stage notifying you of this and enabling you to go back and add the missing areas of the scan.

While viewing the scan, you can:

- [Delete selected areas of a scan.](#)
- [Manually create the die separation](#) if the green hint point was not on the center of the prepped tooth during scanning.
- [Define the margin line.](#)
- [Capture a screenshot of the model.](#)
- [View and annotate screenshots of the model.](#)

After you have reviewed the scan to ensure that it is complete, tap  on the toolbar to [send the scan](#) to the lab, your chairside milling software, or your MyiTero account.

Note for Fixed Restorative and Denture/Removable procedures: After viewing the scan, return to the *New Scan* window to fill in any mandatory fields that were not filled in. These fields were not mandatory when scanning the patient but must be filled in before sending the scan. If there are missing fields when sending the scan, a message is displayed, prompting you to fill in all mandatory fields highlighted in red in the **Treatment Information** area.

5.6.1 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 add the missing areas of 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 scan may be returned from the lab if you do not fix the issues.

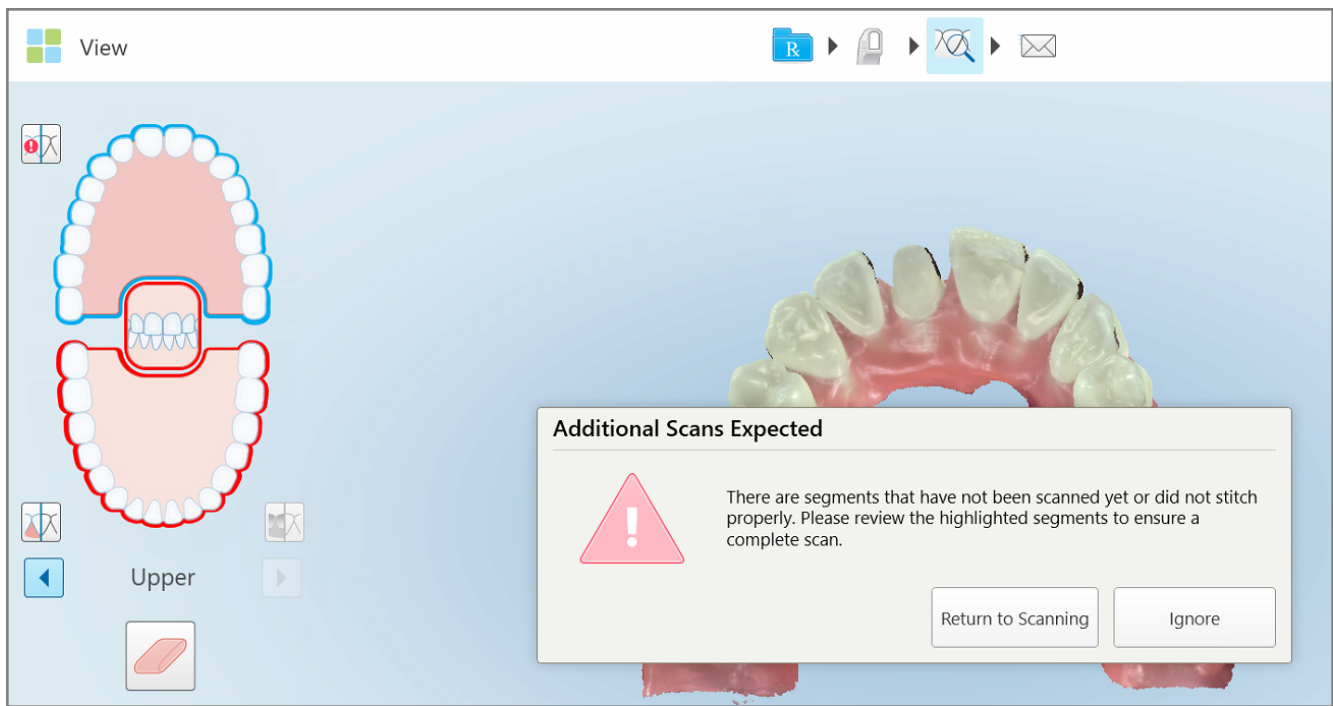


Figure 147: Missing scan message and missing segments highlighted in red

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.

5.6.2 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.

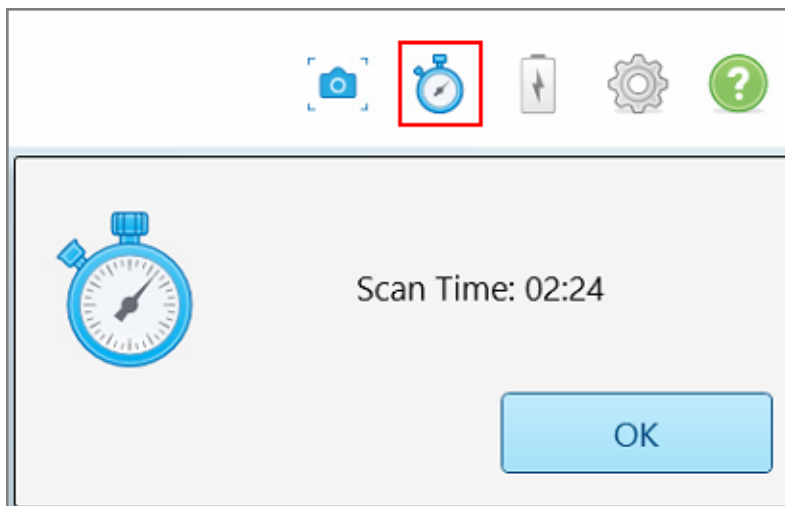


Figure 148: Scan timer button on the toolbar and scan time

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

5.7 Sending the scan

After you have scanned the patient and reviewed the Rx to ensure that no data is missing, you can send the scan to the lab, your chairside milling software, or to your MyiTero account, depending on the procedure.

Note: Before you can send the scan, you have to confirm that you have received the patient's consent to have their health data collected and processed by Align.

To send the scan:

1. Tap  on the toolbar to send the scan, including screenshots of the scanned model, if relevant.

Note for Fixed Restorative and Denture/Removable procedures: Some fields in the Rx become mandatory only after the patient has been scanned. If you have not completed all the mandatory information required, a message is displayed prompting you to fill in the missing fields.

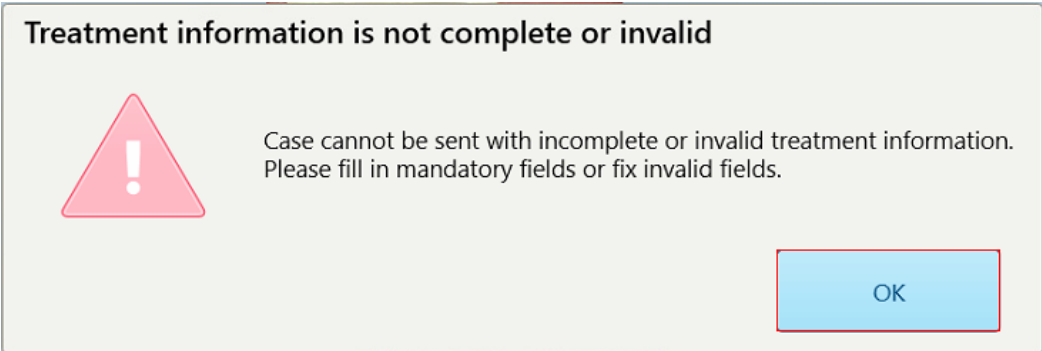


Figure 149: Notification about missing treatment information

- a. Tap **OK** to display the *Rx Details* page, showing a notification in the **Treatment Information** area for each treatment missing required fields.

Treatment Information					
Bridge : 14 - 16					
Tooth No.	Treatment	Specification	Material	Shade Body	
14	Implant Based	-	-	-	Show Details
Required Fields are Missing for Treatment					
15	Pontic	-	-	-	Show Details
Required Fields are Missing for Treatment					
16	Implant Based	-	-	-	Show Details
Required Fields are Missing for Treatment					

Figure 150: Missing fields highlighted in red in the Treatment Information area

- b. Tap **Show Details** to open the treatment options and fill in the missing details.

- c. Tap  to send the scan.
The *Complete Scan* window is displayed.

2. Sign in the signature area to authorize the order.

Complete Scan

☒ Save Signature

☒ Initiate Invisalign Outcome Simulator Pro

☒ By checking this box, I represent that my patient has consented to the collection and processing of their personal health data and the processing of that data by Align Technology for the purposes of providing customized dental care.
[View more](#)

Send Send & View

Figure 151: Complete Scan window

3. If required, select the **Save Signature** check box to save your signature for authorizing sending future scans.
4. If you have scanned a Study Model/iRecord procedure or an Invisalign Aligners procedure type, the **Initiate Invisalign Outcome Simulator Pro** check box is displayed and selected. Keeping this option selected will trigger the simulation. For more information regarding Invisalign Outcome Simulator Pro, see [Invisalign Outcome Simulator Pro](#).

Notes:

- In order to enable the simulation, ensure that your iTero account is paired with your Invisalign Doctor Site account.
 - Invisalign Outcome Simulator Pro is supported on iTero Element Plus series scanners only.
5. After receiving the consent of the patient to have their data processed and sent to Align, ensure that the patient consent check box is selected.
 6. Tap **Send** to send the scan or **Send & View** to send the scan and open it in [Align Oral Health Suite](#).

Note: Align Oral Health Suite is supported on iTero Element Plus series scanners only, and only for Study Model/iRecord and Invisalign | Viverra procedures.

A notification is displayed that the model is being sent, and depending on the send option you tapped, either the patient's profile page is displayed showing the status of the order or the scan is displayed in Align Oral Health Suite.

If you selected to run an Invisalign Outcome Simulator Pro simulation and tapped **Send**, the Viewer is displayed showing the progress of the simulation.

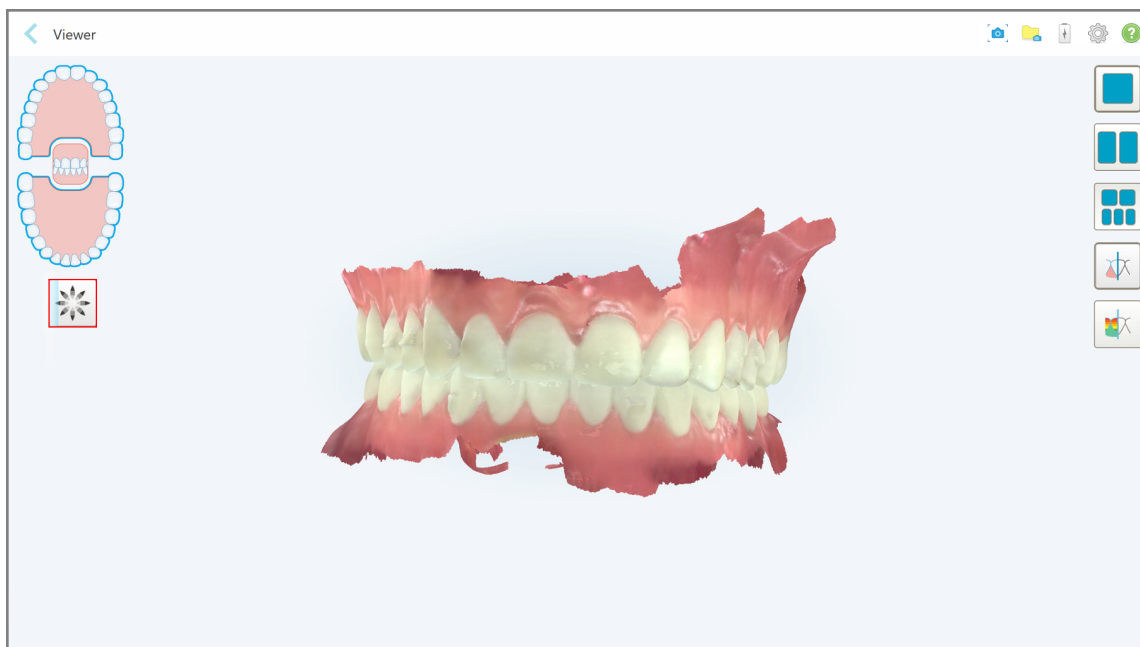


Figure 152: Invisalign Outcome Simulator Pro progress shown in the Viewer

You can also view the progress of the simulation in the patient's profile page.

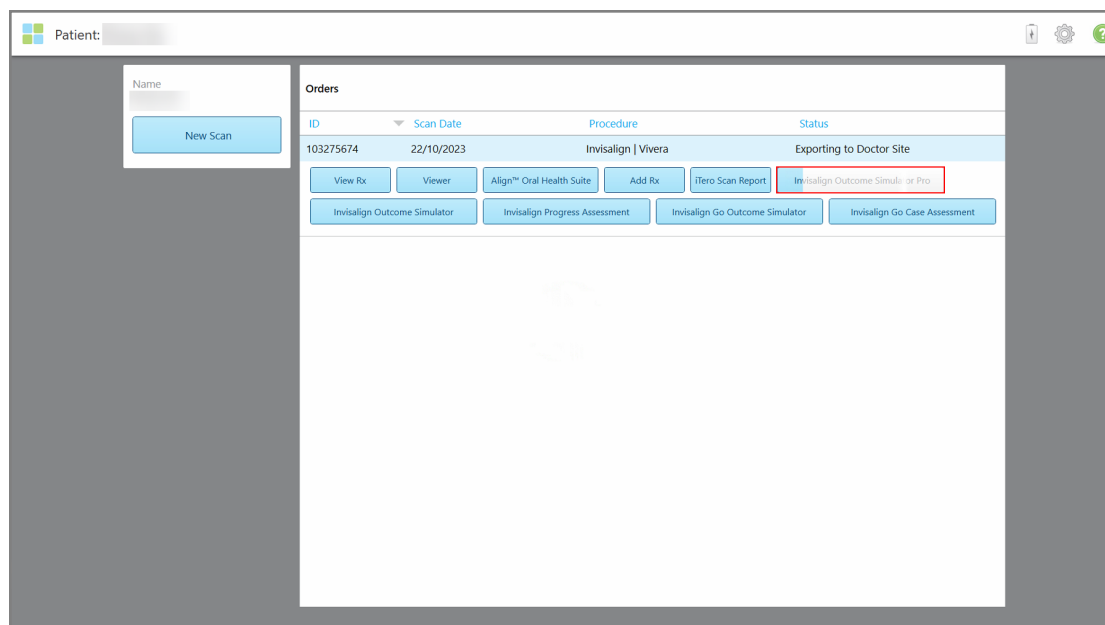


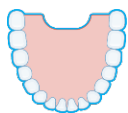
Figure 153: Invisalign Outcome Simulator Pro progress shown in the patient's profile page

If you did not select to run Invisalign Outcome Simulator Pro, a notification is displayed that the model is being sent and then the patient's profile page is displayed showing the status of the order.

In the Viewer, you can tap the following to:



Show/hide the upper jaw.



Show/hide the lower jaw.



Show both jaws.



Display the [Invisalign Outcome Simulator Pro tool](#). Available only for Study Model/iRecord procedures and Invisalign Aligners procedure types.



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

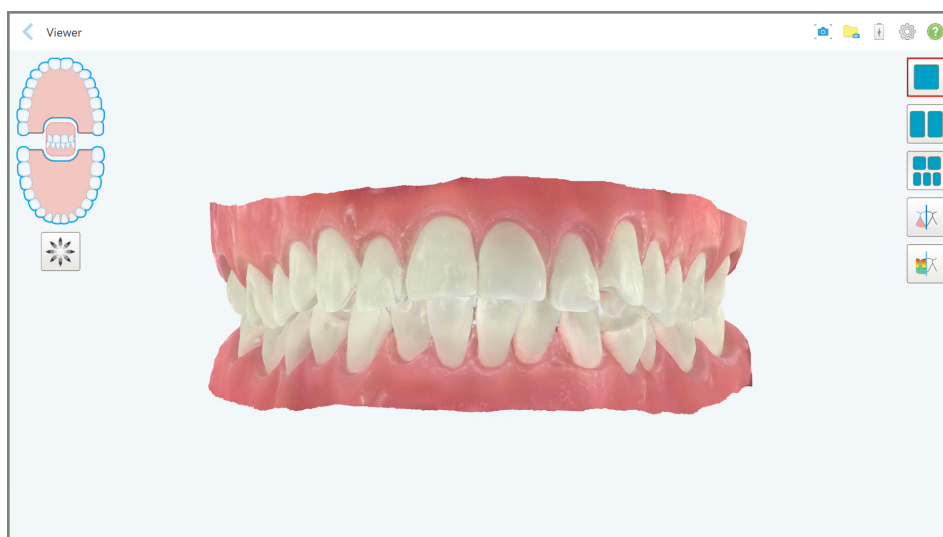


Figure 156: Model in a 1-window view

Relevant for Orthodontic procedures 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.

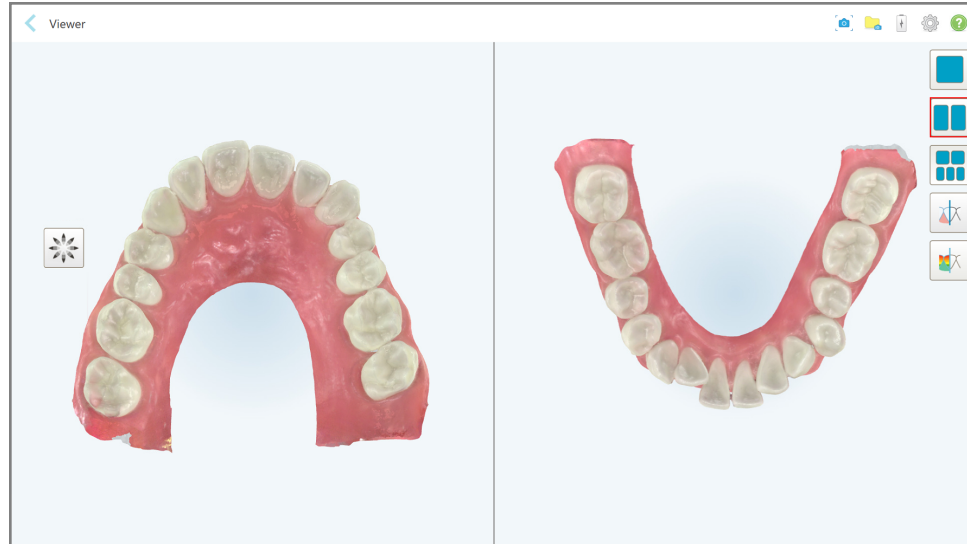


Figure 157: Model in a 2-window view

Relevant for Orthodontic procedures 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 158: Model in a 5-window view

Relevant for Orthodontic procedures only.



Display/hide the margin line of the prepped tooth.

Relevant for Restorative procedures 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 procedures only.



Toggle between viewing the model in color or monochrome.



Show/hide the [occlusal clearance](#) between the opposing teeth. This option is enabled only if the bite was scanned.

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.

5.9 Removing the wand sleeve

The wand sleeves are intended for single 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, slowly pull the sleeve off the wand, and discard it.

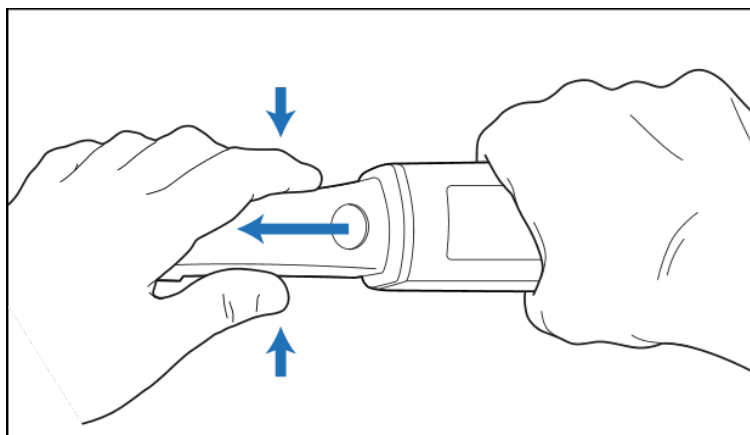


Figure 159: Removing a wand sleeve



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 described in [Wand cleaning and disinfection](#) is necessary, use the anti-static cloth found inside the sleeve box. For more information, refer to the instructions in the box.

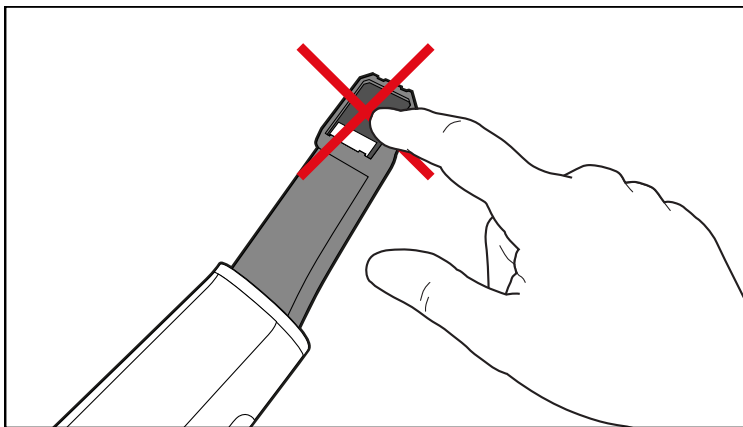


Figure 160: Optical surface of the wand

2. [Clean and disinfect the wand.](#)
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.

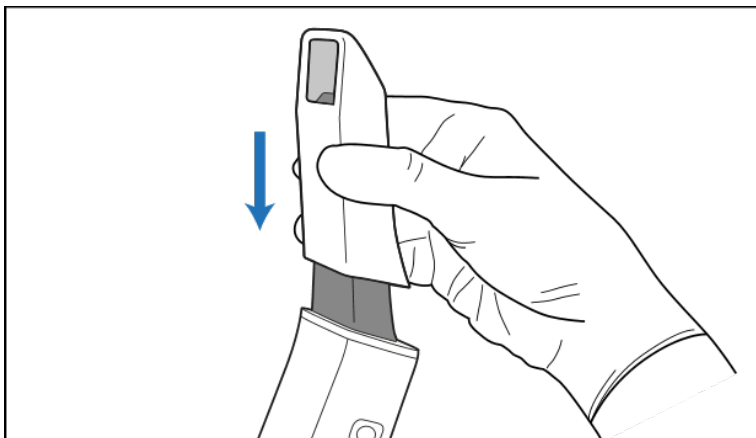
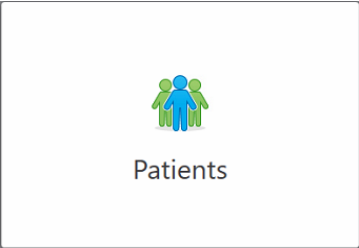


Figure 161: Gently slide the new sleeve into place

6 Working with patients

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



The *Patients* page displays a list of all patients registered in your iTero system, and if relevant, their chart number, date of birth, and the date of their last scan.

If your clinic has more than one doctor, and you have permissions to view the patients and orders of the other doctors, you can also see the patients of all or a selected doctor in the clinic. For more information on Full Order Visibility, contact your system administrator.

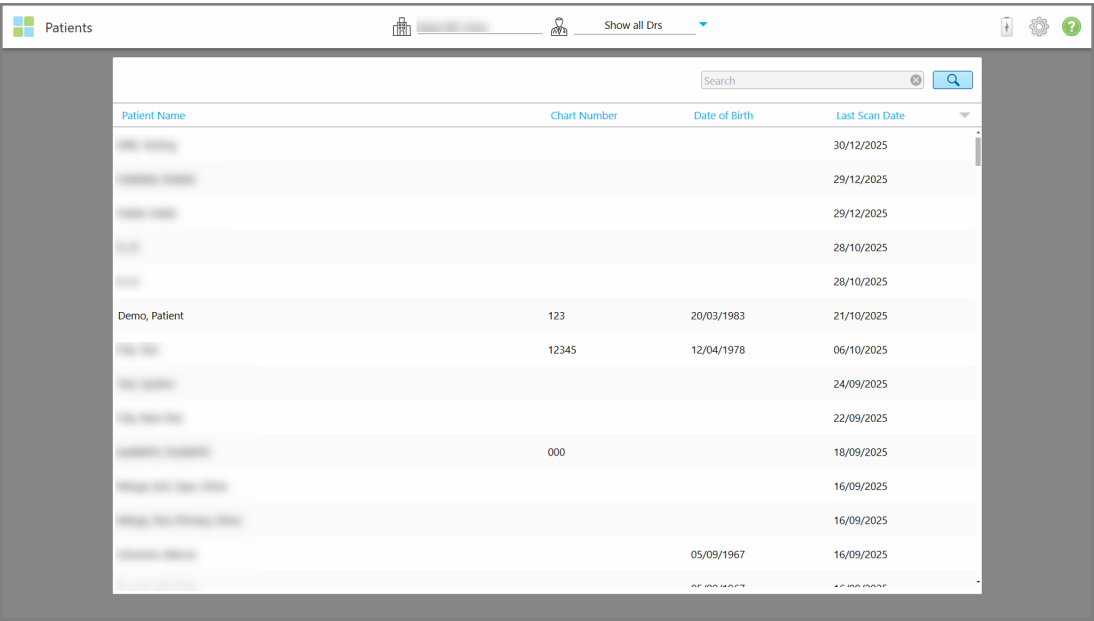


Figure 162: Patients page

By default, all the patients belonging to the clinic are displayed. If required, you can select a doctor from the drop-down list to show only that doctor's patients.

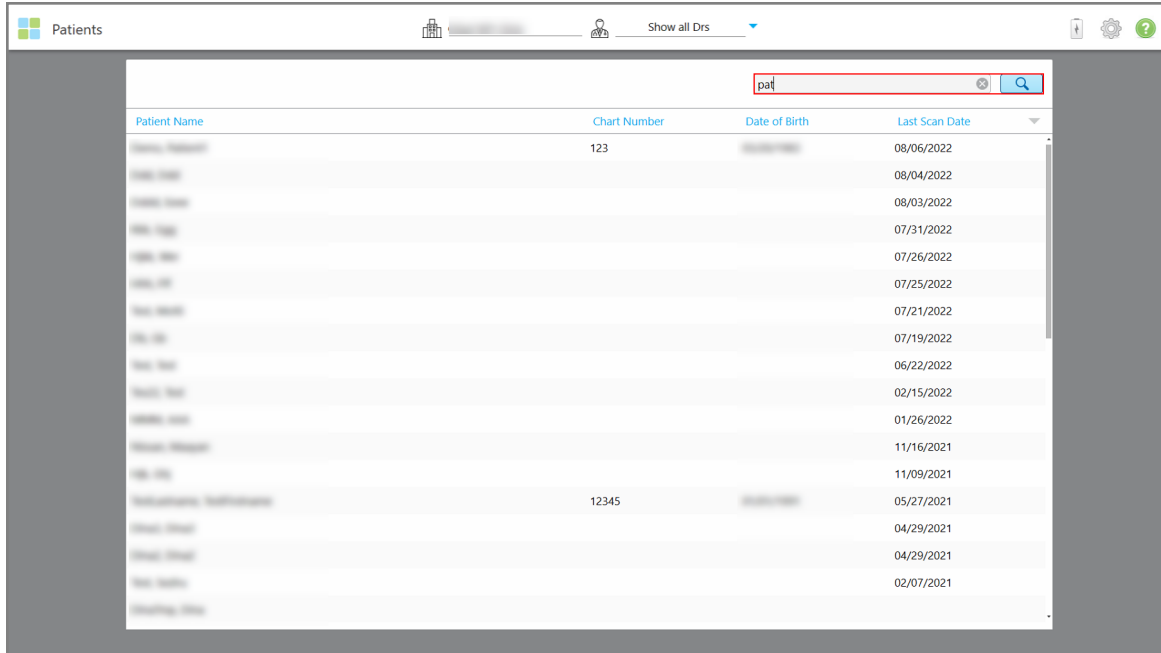
Tap a patient to view the patient's profile page with the patient's details.

6.1 Searching for patients

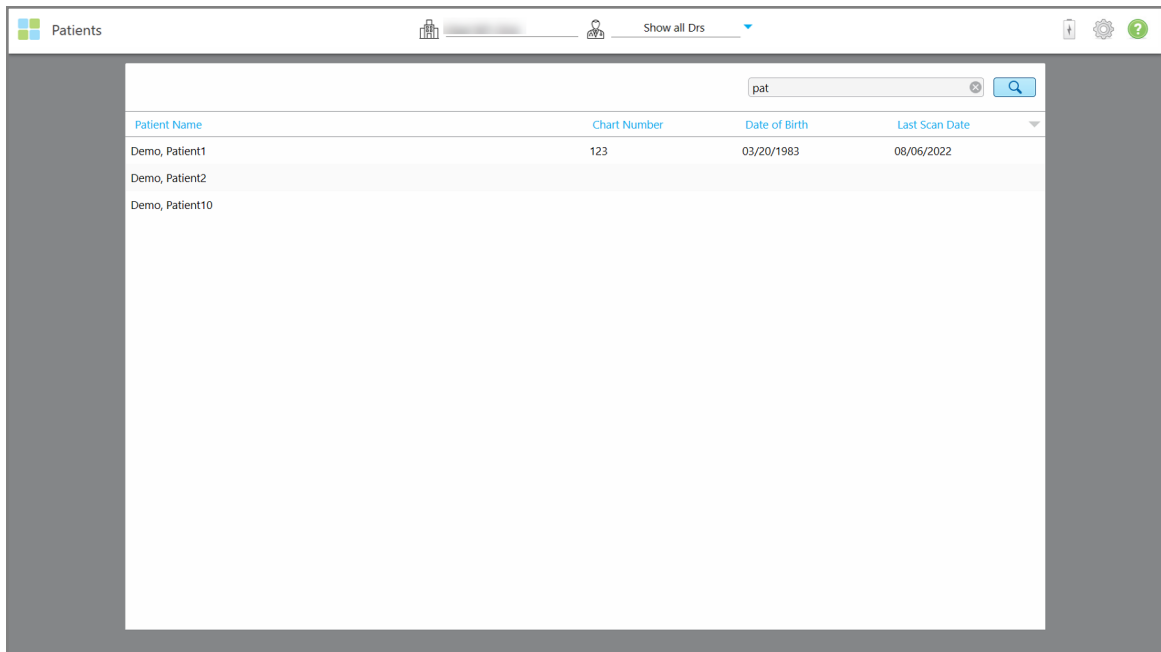
If required, you can search for patients in the iTero database using their names or chart numbers.

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 163: Searching for a patient**

The patients that match the search criteria are displayed.

**Figure 164: Patients matching the search criteria are displayed**

6.2 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:

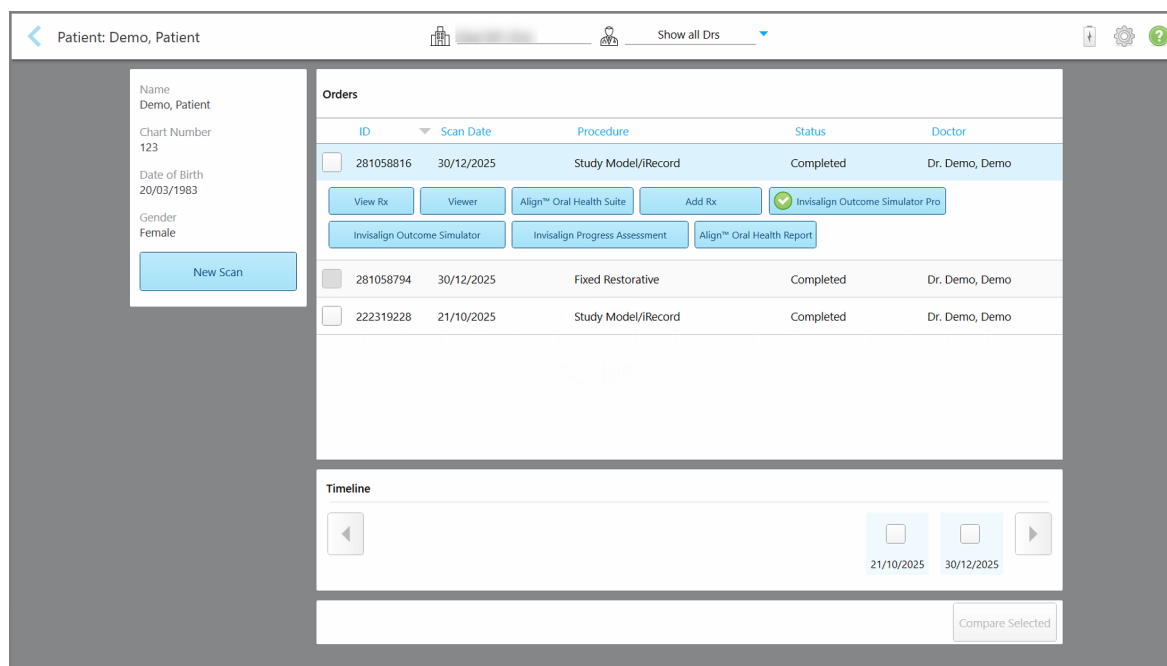


Figure 165: Patient's profile page

From the patient's profile page, you can:

- [Create a new scan for the specific patient](#)
- [View the Rx details and edit the patient's details](#)
- [View the patient's previous scans in the Viewer](#)
- [View the scan in Align Oral Health Suite](#)
- Add a prescription for this order by tapping **Add Rx**.
Note: This is applicable for orthodontic orders only, and available only for a short period after the scan, depending on scanner resources.
- [Create an Align Oral Health Report](#)
- [Compare two previous scans using iTero TimeLapse technology](#)
- View any Invisalign-related processes

6.3 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**.

The screenshot displays the 'Patient: Demo, Patient' profile page. On the left, a sidebar contains patient details: Name (Demo, Patient), Chart Number (123), Date of Birth (20/03/1983), and Gender (Female). A 'New Scan' button is highlighted with a red rectangle. The main area features an 'Orders' table with columns for ID, Scan Date, Procedure, Status, and Doctor. The table lists three orders, with the first one selected. Below the table is a 'Timeline' section with navigation arrows and date markers for 21/10/2025 and 30/12/2025. A 'Compare Selected' button is located at the bottom right.

ID	Scan Date	Procedure	Status	Doctor
☒ 281058816	30/12/2025	Study Model/Record	Completed	Dr. Demo, Demo
☐ 281058794	30/12/2025	Fixed Restorative	Completed	Dr. Demo, Demo
☐ 222319228	21/10/2025	Study Model/Record	Completed	Dr. Demo, Demo

Figure 166: Patient's profile page – New Scan option

The *New Scan* window is displayed, with the patient's details already filled in.

New Scan

Doctor: Dr. Demo, Demo License: 12345

Patient:

First Name: Patient Last Name: Demo

Date of Birth: 20/03/1983 Gender: ☐ Male ☒ Female

Chart Number: 123

Order:

Procedure * Type

Due Date: Send to

Notes

Add Note

Figure 167: New Scan window with patient's details already filled in

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

6.4 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**.

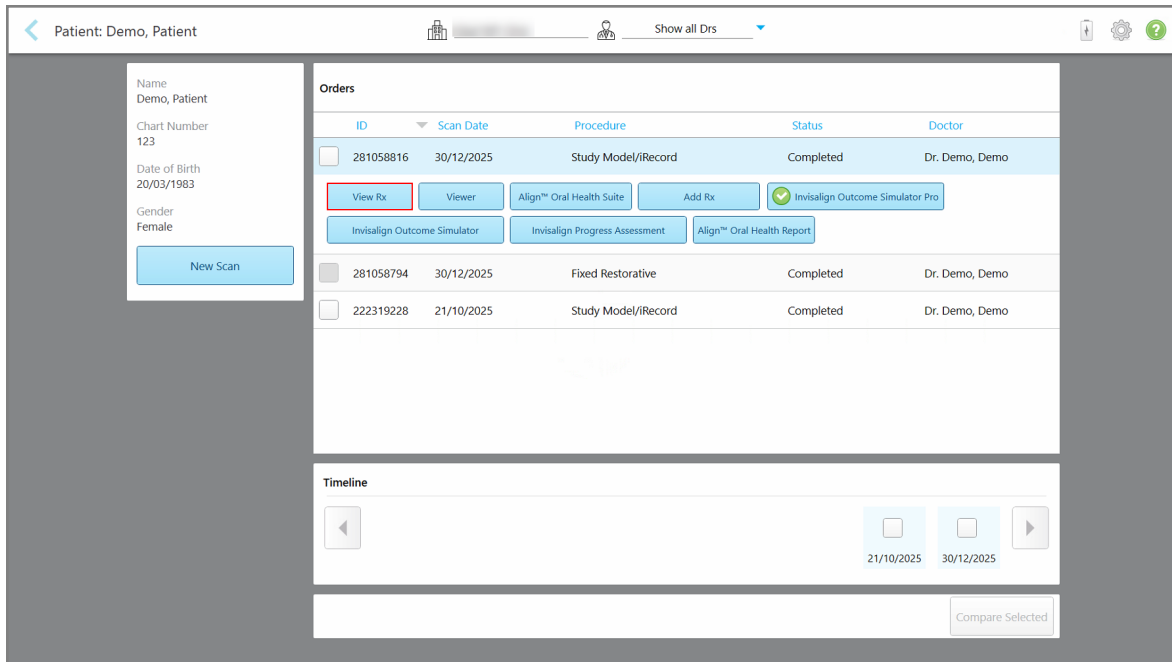


Figure 168: Patient's profile page – View Rx option

The *Rx Details* window is displayed.

The screenshot shows the 'Rx Details' window with a back arrow and title 'Rx Details' at the top left, and icons for print, settings, and help at the top right. The form is divided into several sections:

- Header:** A light blue bar with the text 'This Form is Read-only.'
- Doctor:** A section with 'Doctor: Dr. Demo, Demo' and 'License: 12345'.
- Patient:** A section containing:
 - First Name: Patient1
 - Last Name: Demo
 - Date of Birth: 20/03/1983
 - Gender: ☐ Male ☒ Female
 - Chart Number: 123
- Order:** A section with a light blue bar stating 'All Study Model/Record scans are available for Invisalign.' Below it:
 - Procedure *: Study Model/i/Record (dropdown menu)
 - Ortho Model/i/Cast (toggle switch)
 - Due Date: (text field)
 - Send to: (dropdown menu)
- Scan Options:** A section with 'Multi-Site: ☐
- Notes:** A large empty text area at the bottom.

Figure 169: Rx Details window

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

6.5 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**.

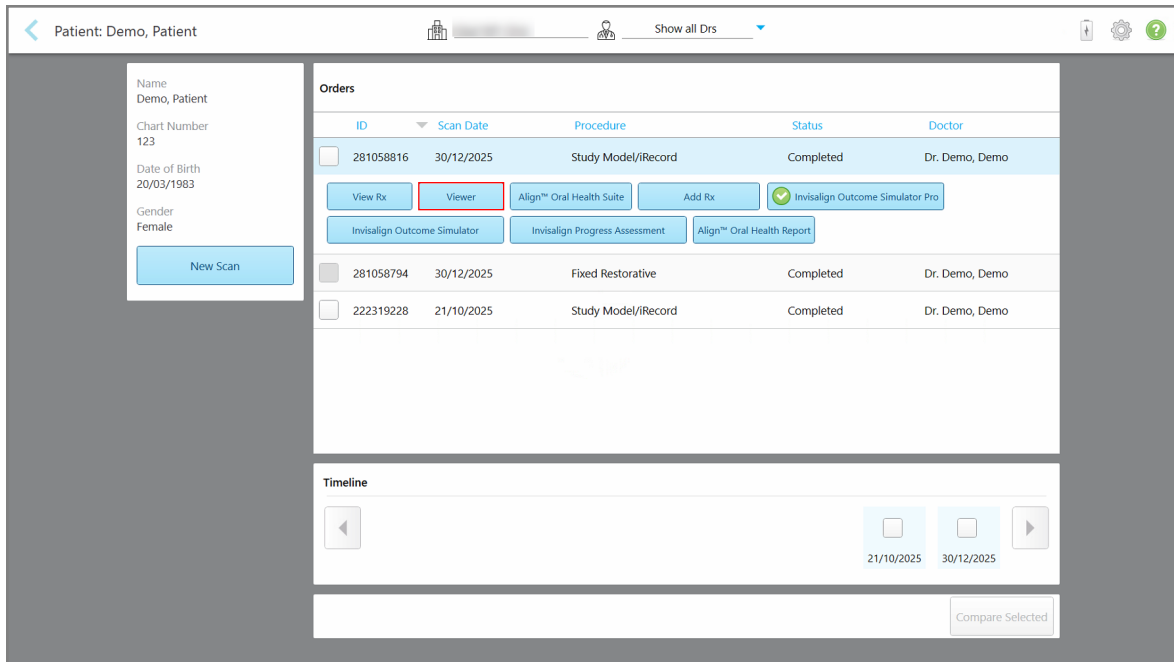


Figure 170: Patient's profile page – Viewer option

The scan is displayed in the Viewer.



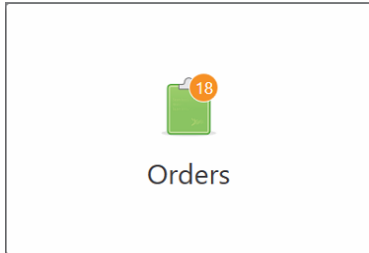
Figure 171: Scan displayed in the Viewer

For more information, see [Working with the Viewer](#).

7 Working with orders

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

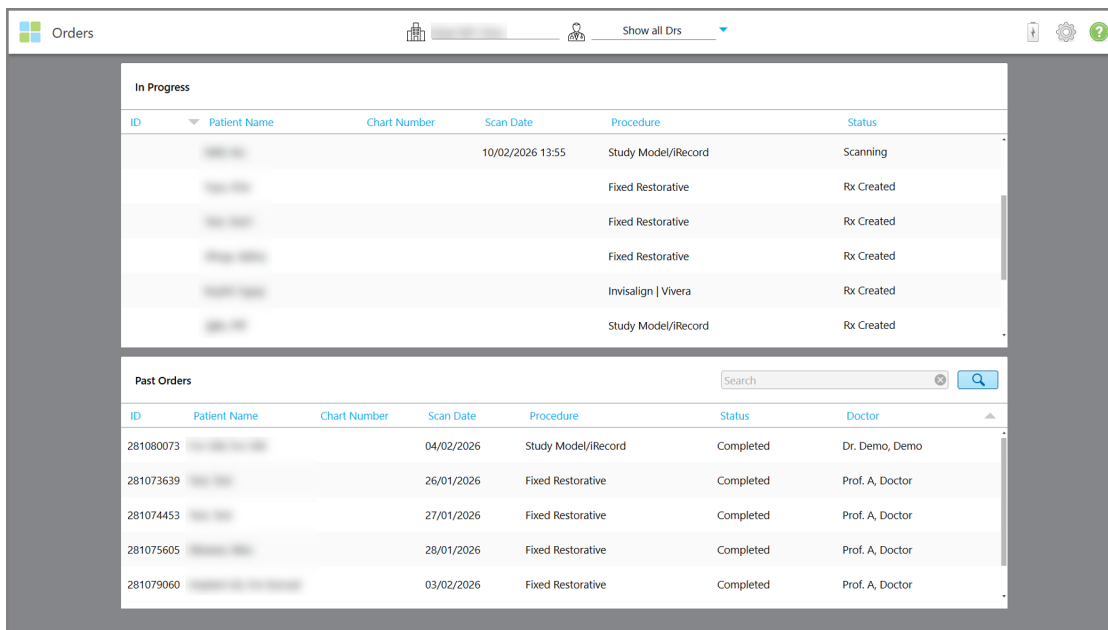
If your clinic has more than one doctor, and you have permissions to view the patients and orders of the other doctors, you can also see the past orders of all or a selected doctor in the clinic. For more information on Full Order Visibility, contact your system administrator.

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 order ID, patient's name, chart number, the scan date, procedure, and the status of the order. In addition, if you have the relevant permissions, you can see all the scanned patients in the clinic, as well as the name of the doctor who scanned the patient.

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

- **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 scan has been sent.
- **Failed to Send:** The scan was not sent.
- **iTero Modeling:** The scan has been sent to iTero Modeling.
- **Ortho Modeling:** The scan has been sent for modeling.
- **[Returned](#):** The scan was rejected by the lab and has been sent back for rescanning or other adjustments.
- **Align Production:** The scan is undergoing an internal process.
- **Exporting to Doctor Site:** The scan is on the way to the IDS portal.
- **Completed:** The flow has been completed.



The screenshot shows the 'Orders' page with two main panes: 'In Progress' and 'Past Orders'.

In Progress

ID	Patient Name	Chart Number	Scan Date	Procedure	Status
			10/02/2026 13:55	Study Model/iRecord	Scanning
				Fixed Restorative	Rx Created
				Fixed Restorative	Rx Created
				Fixed Restorative	Rx Created
				Invisalign Vivera	Rx Created
				Study Model/iRecord	Rx Created

Past Orders

ID	Patient Name	Chart Number	Scan Date	Procedure	Status	Doctor
281080073			04/02/2026	Study Model/iRecord	Completed	Dr. Demo, Demo
281073639			26/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281074453			27/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281075605			28/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281079060			03/02/2026	Fixed Restorative	Completed	Prof. A, Doctor

Figure 172: Orders page

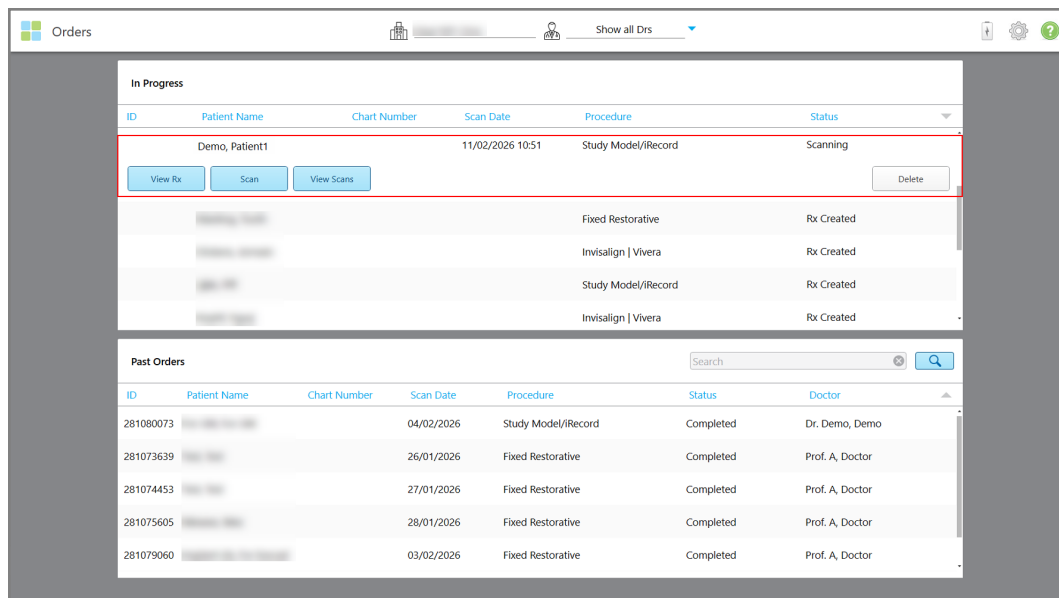
To view or review orders:

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

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



The screenshot shows the 'Orders' page with the 'In Progress' pane expanded to show options for a specific order. The 'Past Orders' pane remains visible below.

In Progress

ID	Patient Name	Chart Number	Scan Date	Procedure	Status
	Demo, Patient1		11/02/2026 10:51	Study Model/iRecord	Scanning
View Rx Scan View Scans Delete					
				Fixed Restorative	Rx Created
				Invisalign Vivera	Rx Created
				Study Model/iRecord	Rx Created
				Invisalign Vivera	Rx Created

Past Orders

ID	Patient Name	Chart Number	Scan Date	Procedure	Status	Doctor
281080073			04/02/2026	Study Model/iRecord	Completed	Dr. Demo, Demo
281073639			26/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281074453			27/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281075605			28/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281079060			03/02/2026	Fixed Restorative	Completed	Prof. A, Doctor

Figure 173: 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 procedure and your iTero subscription package:

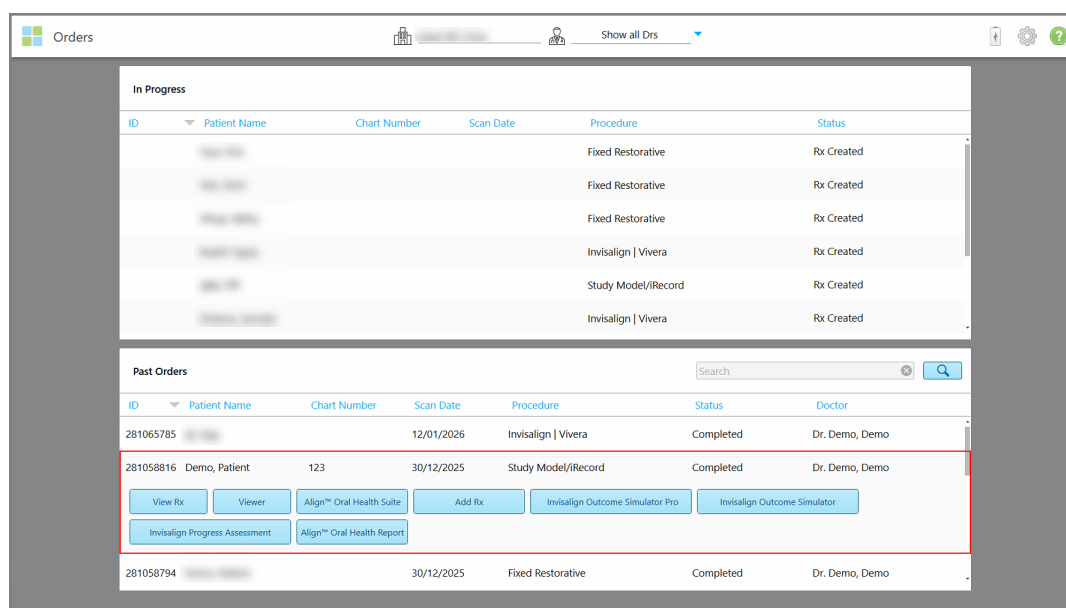


Figure 174: Past Orders pane – options

- **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.
- **[Align Oral Health Suite](#):** Opens Align Oral Health Suite and enables you to view the scan in the context of select dental conditions.
- **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 only for a short period after the scan, depending on scanner resources.
- **Align Oral Health Report:** Opens the Align Oral Health Report and enables you to customize and share it with the patient.
- Invisalign users can also select the following Invisalign features:
 - [Invisalign Outcome Simulator Pro](#)
 - [Invisalign Outcome Simulator](#)
 - [Invisalign Progress Assessment](#)
 - [Invisalign Go system](#)

7.1 Working with returned orders

Labs can return orders within 30 days if the scan is incomplete and needs to be rescanned, for example, if there are missing scans, bite issues, or if the margin line is not clear. If the lab returns an order, the **Orders** button is highlighted in red with an alarm icon badge.

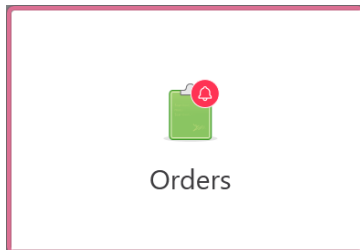


Figure 175: Orders button notifying a returned order

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	Procedure	Status	
103181639	Demo, Patient1	123	11/02/2026 10:51	Appliance	Returned	
		12345		Invisalign Vivera	Rx Created	
				Invisalign Vivera	Rx Created	
				Invisalign Vivera	Rx Created	
				Invisalign Vivera	Rx Created	
				Study Model/iRecord	Rx Created	
				Invisalign Vivera	Rx Created	
				Study Model/iRecord	Rx Created	
Past Orders						
ID	Patient Name	Chart Number	Scan Date	Procedure	Status	Doctor
281080073			04/02/2026	Study Model/iRecord	Completed	Dr. Demo, Demo
281073639			26/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281074453			27/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281075605			28/01/2026	Fixed Restorative	Completed	Prof. A, Doctor
281079060			03/02/2026	Fixed Restorative	Completed	Prof. A, Doctor

Figure 176: Returned order in the In Progress pane

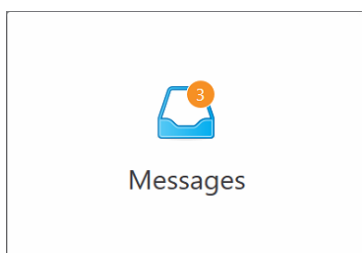
To fix a returned order:

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

8 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.



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.

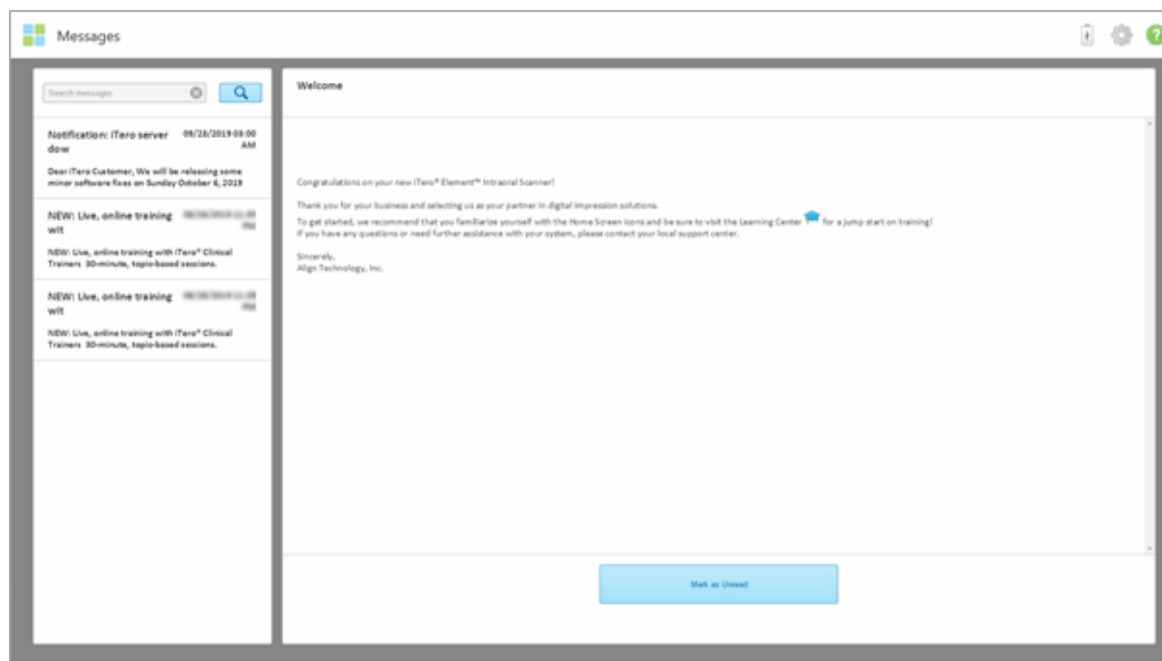


Figure 177: Messages page

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**.

9 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.

10 iTero scanner features and tools

This section describes the following iTero scanner features and tools:

- [iTero TimeLapse technology](#)
- [Invisalign Outcome Simulator Pro](#)
- [Invisalign Outcome Simulator](#)
- [Invisalign Progress Assessment](#)
- [Invisalign Go system](#)
- [Align Oral Health Report](#)
- [Editing tools](#)
 - [Delete segment tool](#)
 - [Delete selection tool](#)
 - [Fill tool](#)
 - [Disable auto-cleanup tool](#)
- Scan tools:
 - [Eraser tool](#)
 - [Occlusal clearance tool](#)
 - [Edge Trimming tool](#)
 - [Die Separation tool](#)
 - [Margin line tool](#)
 - [Snapshot tool](#)
 - [Patient Gallery](#)

10.1 Comparing previous scans using iTero TimeLapse technology

Patients who are scanned regularly 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 in 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 Orthodontic procedures only.

To use iTero TimeLapse technology:

1. In the *Patients* page, select the patient for whom to create an iTero TimeLapse visualization.

- 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.

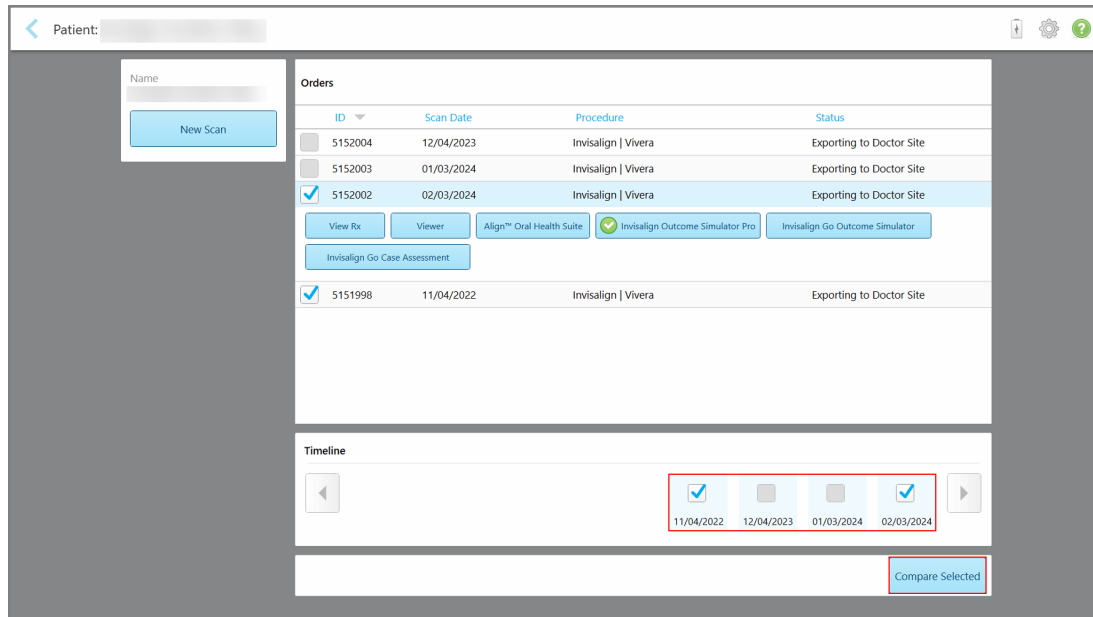


Figure 178: iTerio TimeLapse – selecting the scans to compare

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

The *iTerio 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.

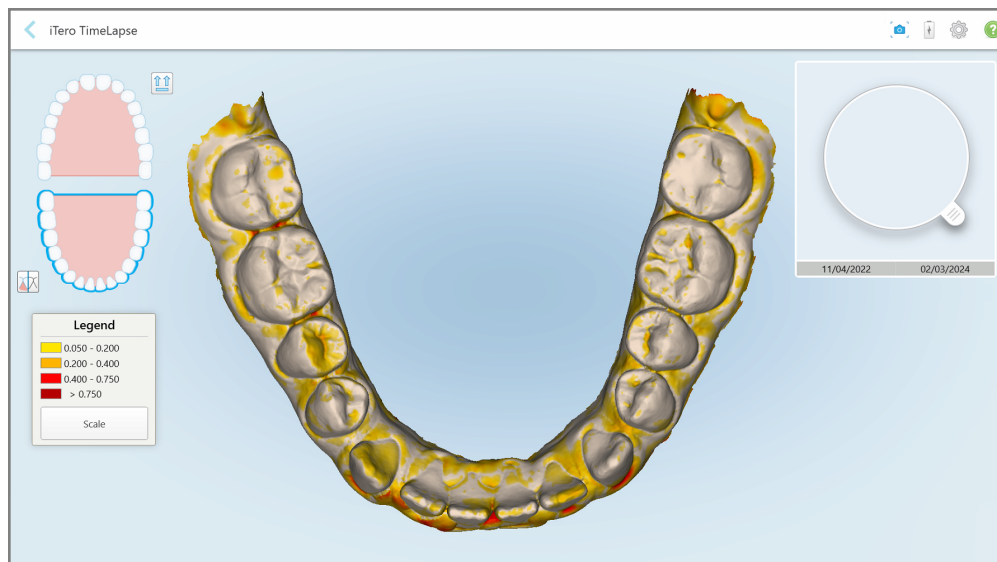


Figure 179: iTerio TimeLapse window showing the highlighted changes between the scans

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.

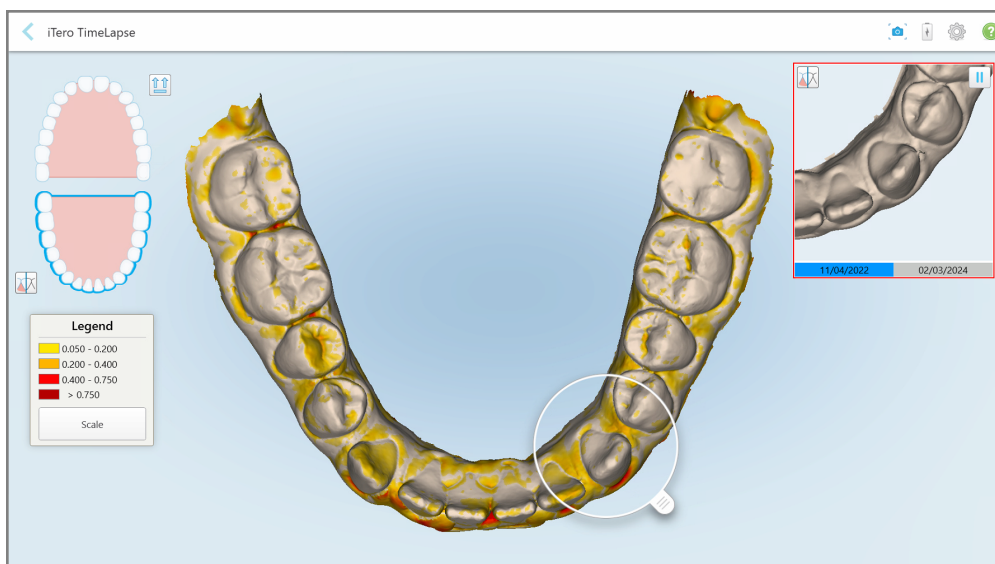


Figure 180: Area of interest from the first scan displayed in the animation window

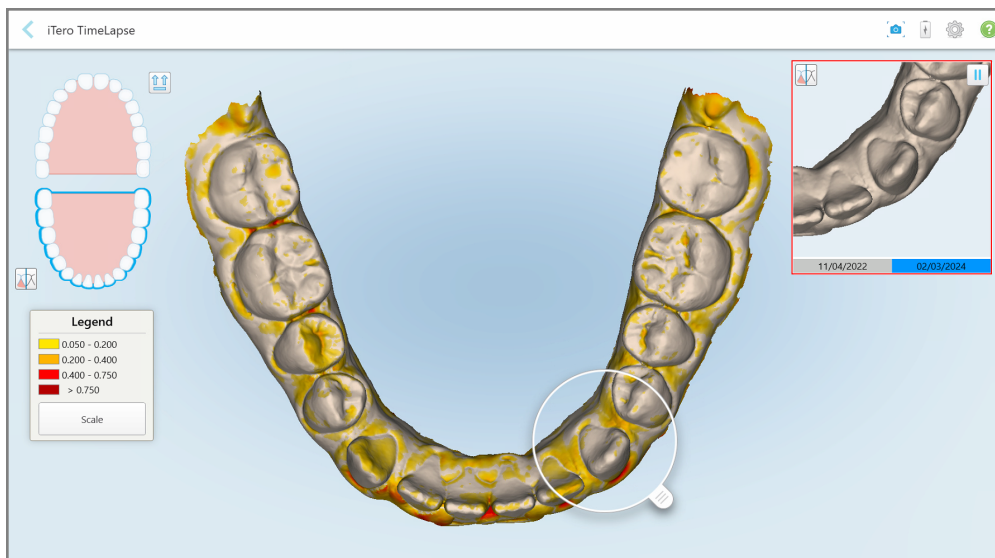


Figure 181: Area of interest from the second scan displayed in the animation window

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:

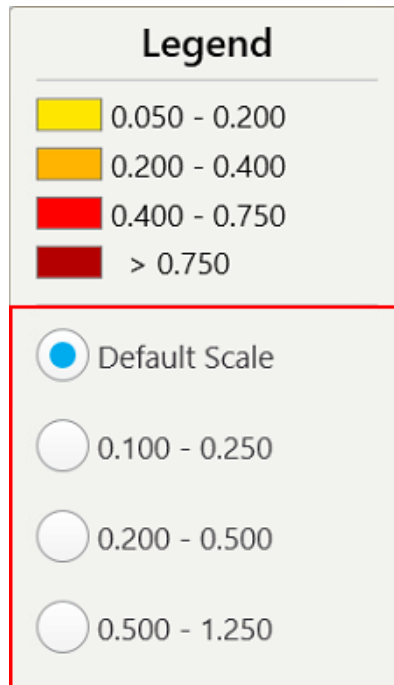


Figure 182: iTero TimeLapse scale options

- 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, see [Working with the Snapshot tool](#).
6. Tap  to exit the *iTero TimeLapse* window and then tap **Yes** to confirm exiting.
- The patient's profile page is displayed.

10.2 Invisalign Outcome Simulator Pro

Invisalign Outcome Simulator Pro is an advanced patient communication software tool that enables you to show patients the simulated outcome of their Invisalign treatment on an image of their own face. This tool provides additional information for the patient in their decision to begin Invisalign treatment.

Notes:

- Invisalign Outcome Simulator Pro is supported on iTero Element Plus series intraoral scanners only.
- The Invisalign Outcome Simulator Pro simulation is available only for **Study Model/iRecord** procedures and **Invisalign Aligners** procedure types, and is automatically triggered when sending the scan.

- Invisalign Outcome Simulator Pro requires pairing your Invisalign Doctor Site account with your iTero account. For more information, contact iTero Customer Support.



Once the simulation is complete, you can tap  in the Viewer or the **Invisalign Outcome Simulator Pro** button in the [Orders page](#).

For more information, refer to the Invisalign Outcome Simulator Pro documentation.

10.3 Invisalign Outcome Simulator

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.

To open the Invisalign Outcome Simulator tool, after sending the scan, tap **Invisalign Outcome Simulator** in the [Orders page](#) or in the [patient's profile page](#).

For more information, refer to the *Invisalign Outcome Simulator User Guide* <https://guides.itero.com>.

10.4 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.

To open the Invisalign Progress Assessment tool, after sending the scan, tap **Invisalign Progress Assessment** button in the [Orders page](#).

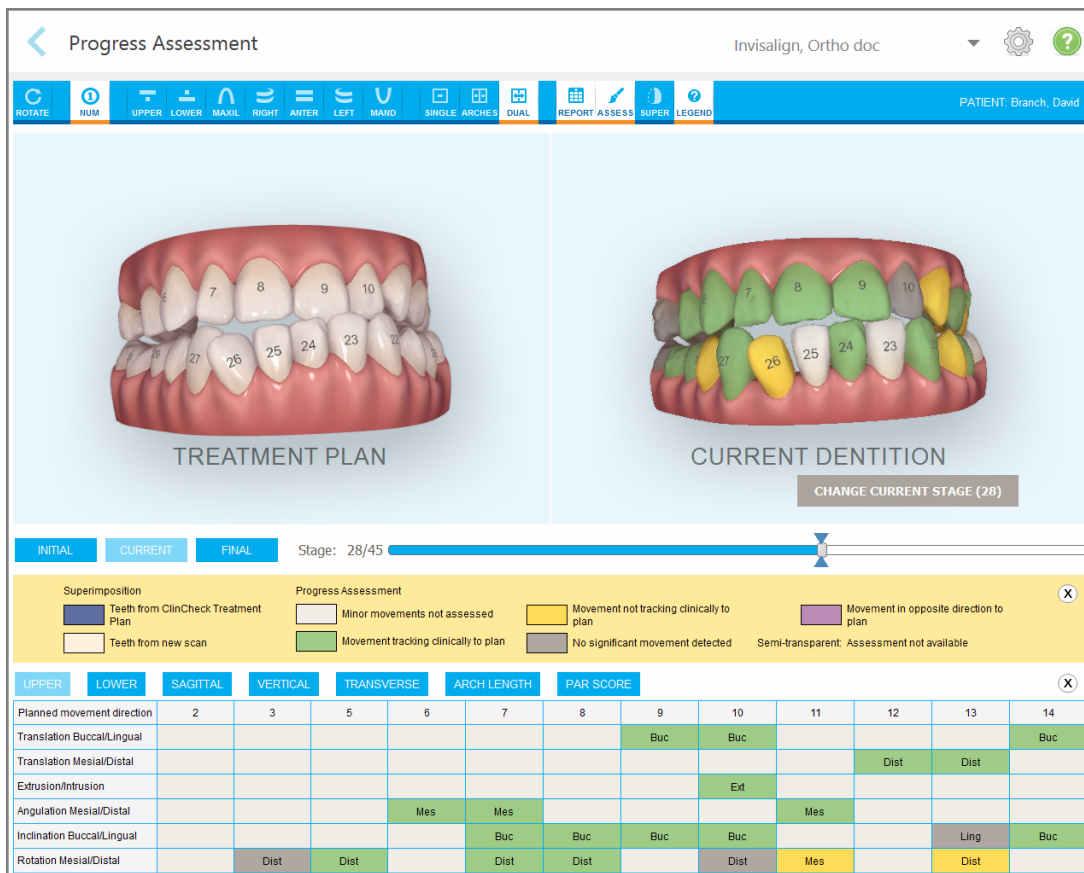


Figure 183: Progress Assessment window

For more information, refer to the **Progress Assessment** section in the *Invisalign Outcome Simulator User Guide* <https://guides.itero.com>.

10.5 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.

10.6 Editing tools

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

- [Delete segment tool](#)
- [Delete Selection tool](#)
- [Fill tool](#)
- [Disable auto-cleanup tool](#)

The editing tools are accessed by pressing on the screen.



Figure 184: Editing tools

10.6.1 Deleting a segment

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

To delete the segment:

1. Press the screen to display the editing tools.

2. Tap the **Delete segment** tool .

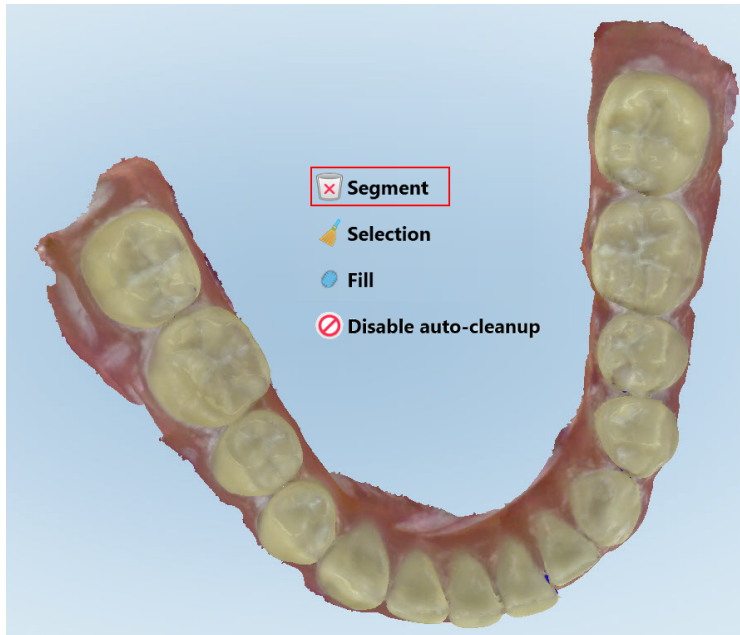


Figure 185: Segment tool

A confirmation message is displayed.

3. Tap **OK** to confirm the deletion.
The entire scanned segment is deleted.

10.6.2 Deleting a selection

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

To delete a selection:

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

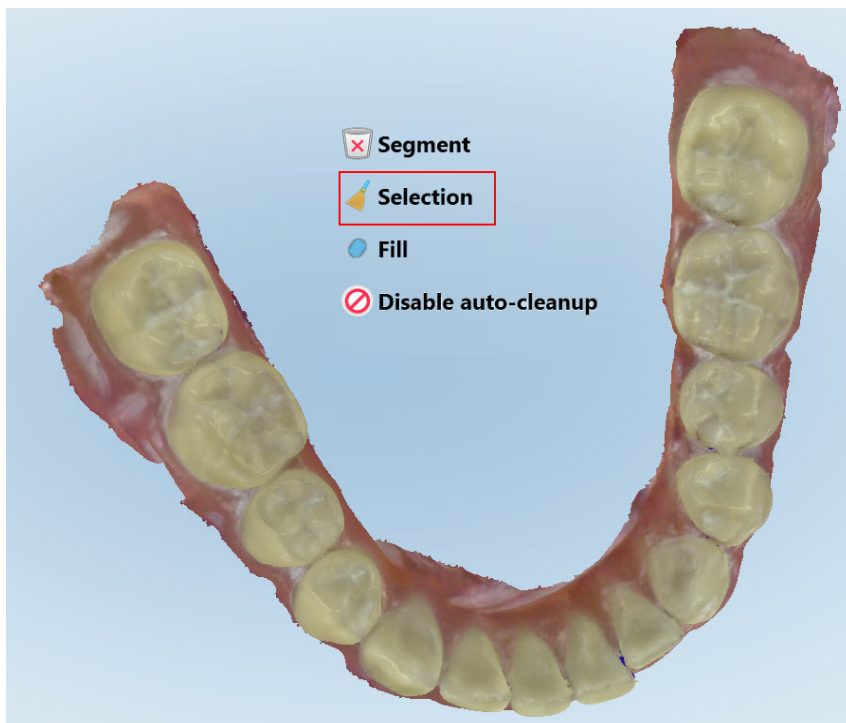


Figure 186: Delete Selection tool

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

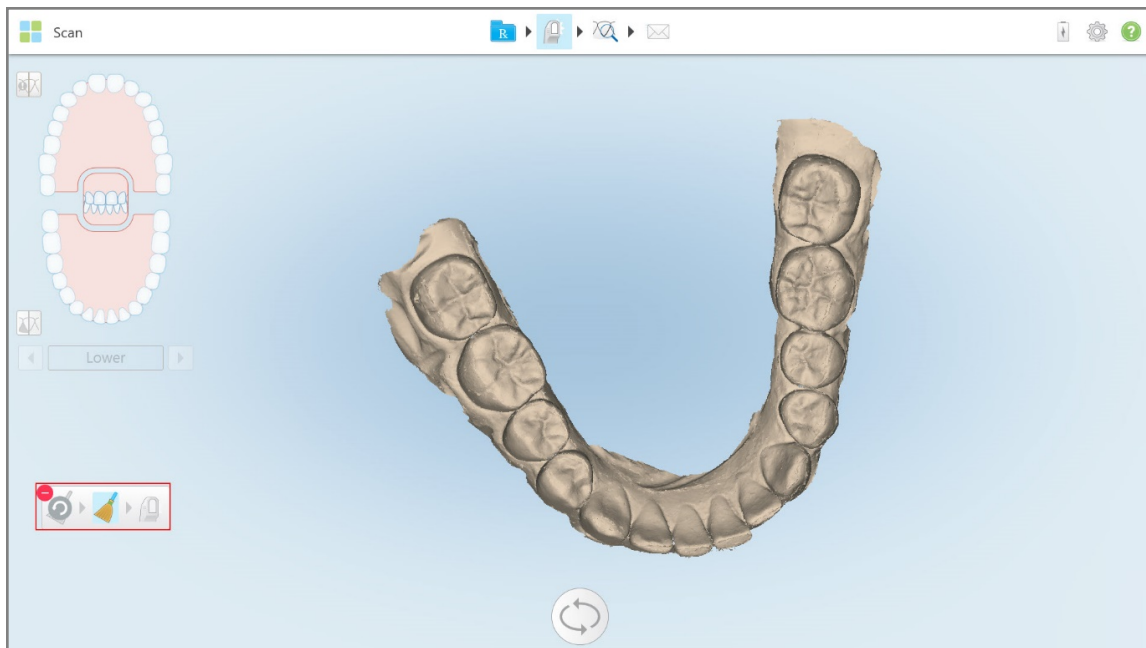


Figure 187: Expanded Delete Selection tool

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

The selection is removed.

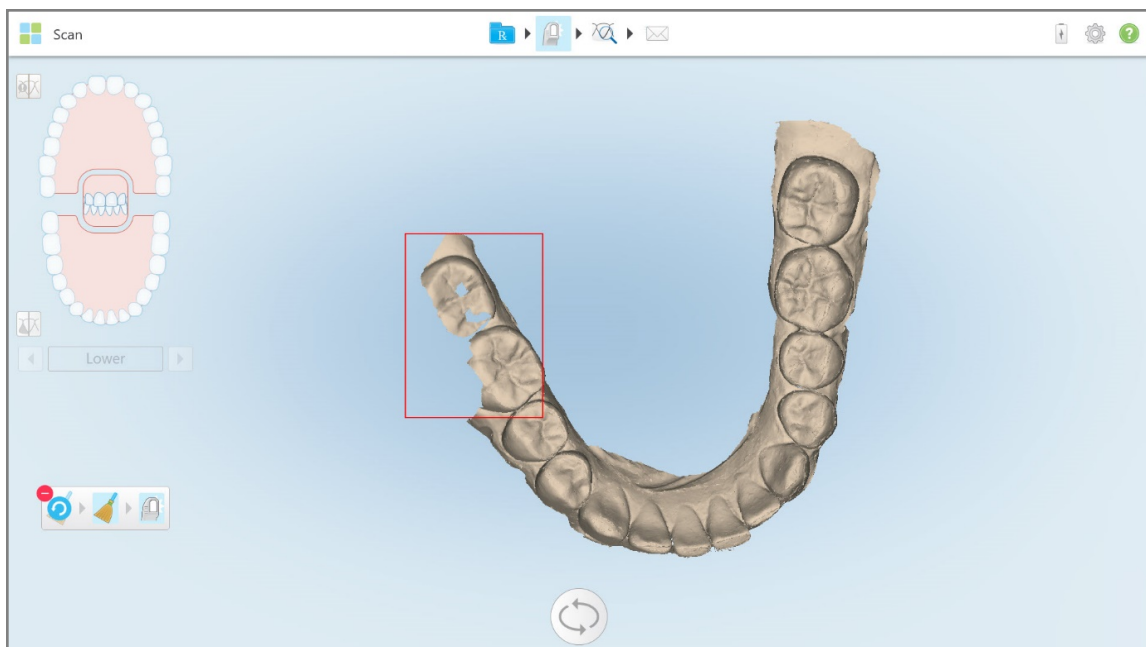


Figure 188: Selected area of the anatomy is deleted

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

10.6.3 Filling in missing anatomy

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

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

To use the Fill tool:

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

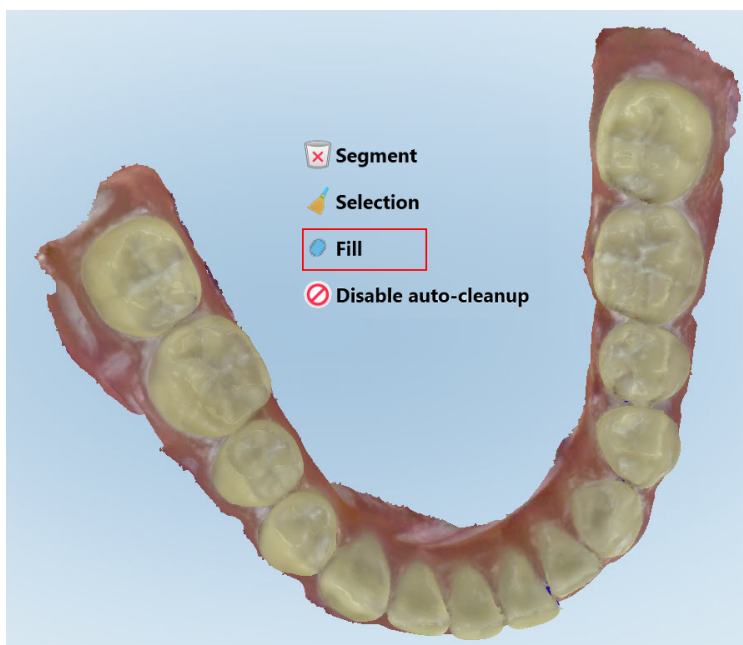


Figure 189: Fill tool

Areas that require scanning are highlighted in red.

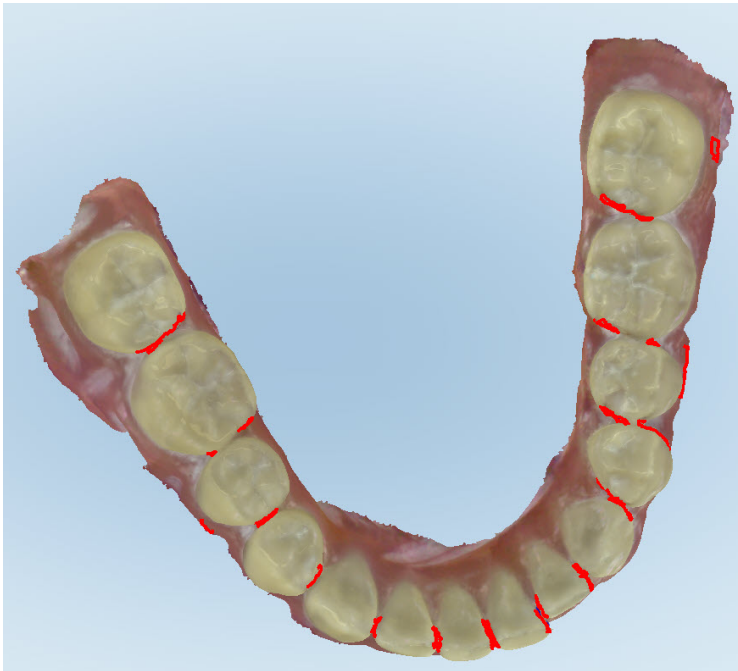


Figure 190: Areas that require scanning are highlighted in red – Fill tool

3. Rescan the patient.

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

10.6.4 Disabling auto-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 scan.

Notes:

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

To disable auto-cleanup:

1. Press the screen to display the editing tools.

2. Tap the **Disable auto-cleanup** tool .

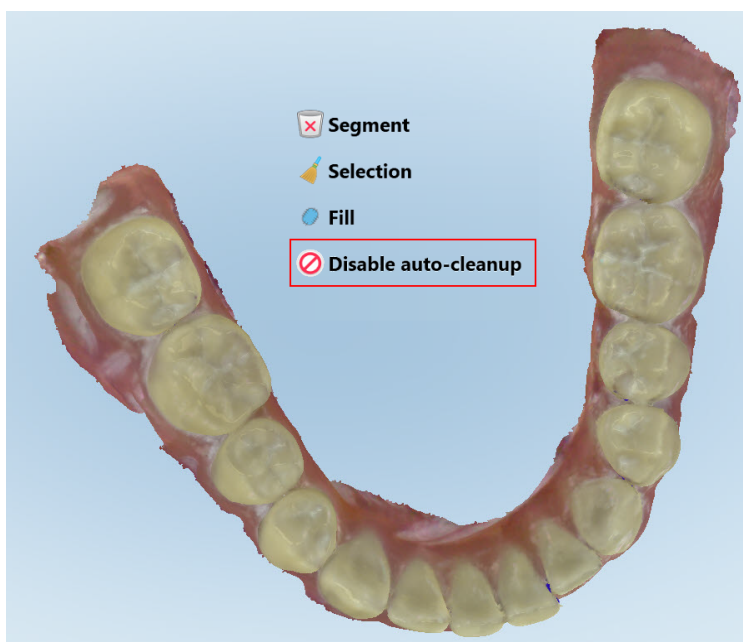


Figure 191: Auto-cleanup tool

The scan is displayed with the excess material showing.



Figure 192: Scan displayed with excess material showing

3. To return the excess tissue, press the screen to display the editing options and then tap **Enable auto-cleanup**.

10.7 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

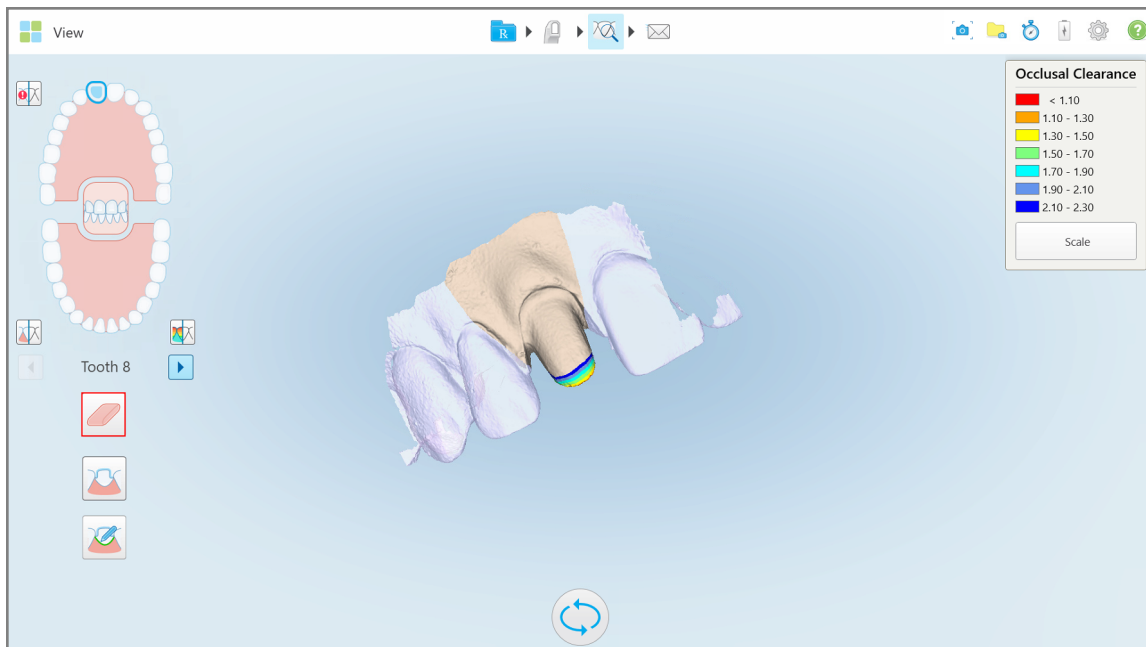


Figure 193: Eraser tool

The Eraser tool expands to show the following options:



Figure 194: Eraser tool options

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

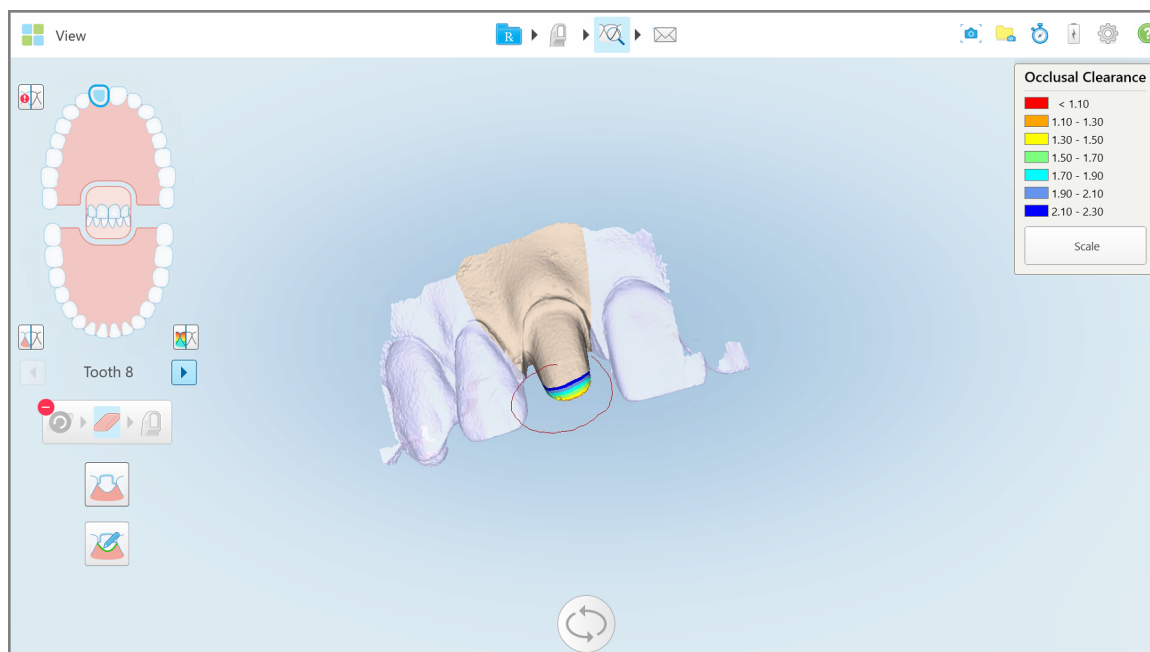


Figure 195: Mark the area to be modified

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

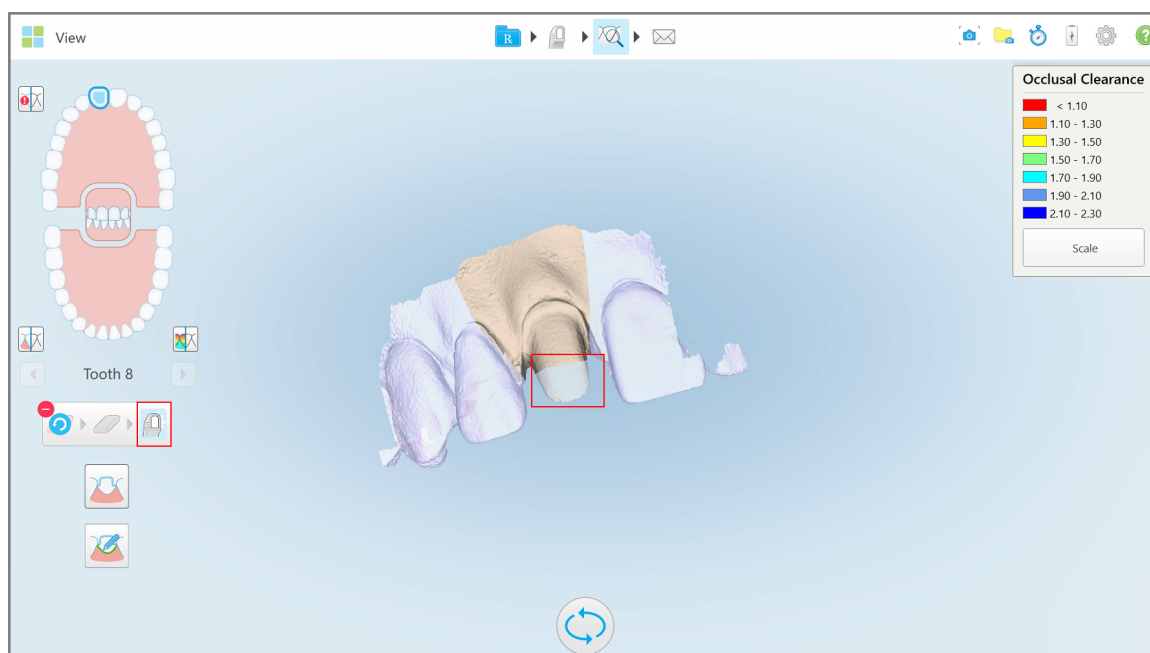


Figure 196: Selected area removed, and scan tool enabled

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

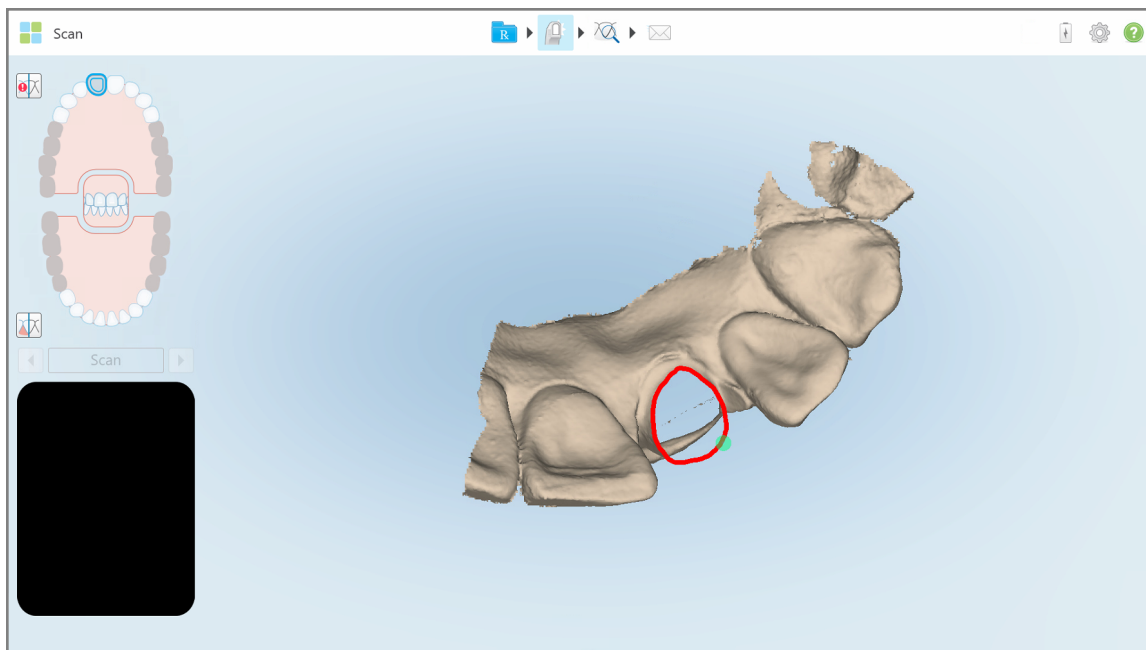


Figure 197: Deleted area marked in red

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

10.8 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.

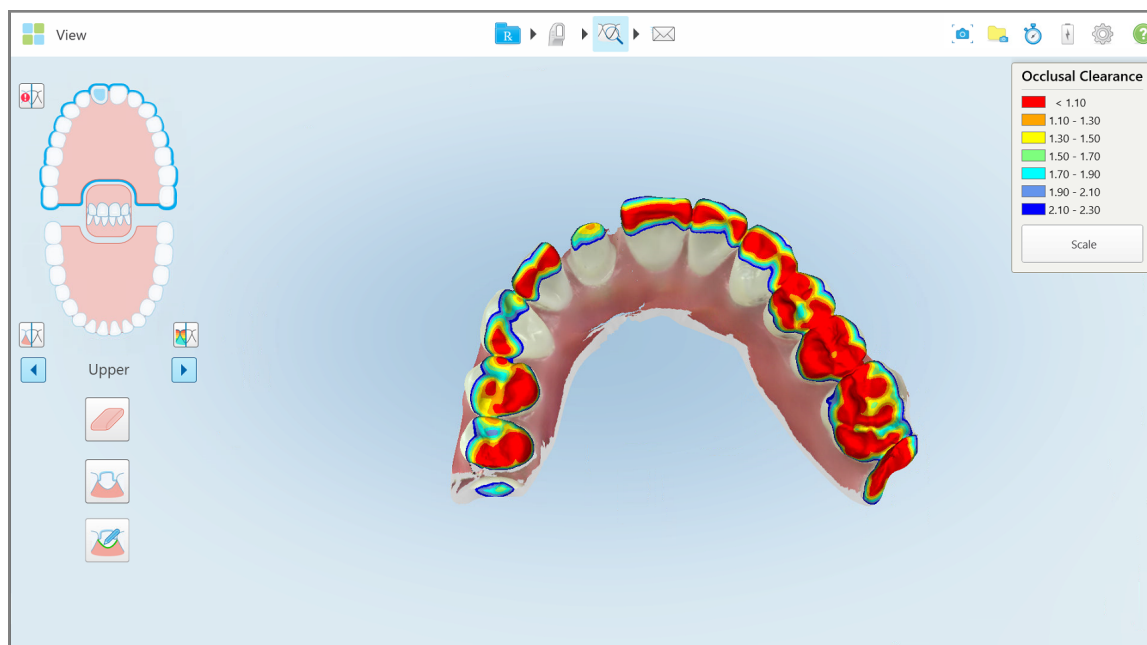


Figure 198: Occlusal clearance between the opposing teeth

2. If necessary, reduce the prepped tooth, [erase the relevant section from the model](#), and rescan the area.
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.

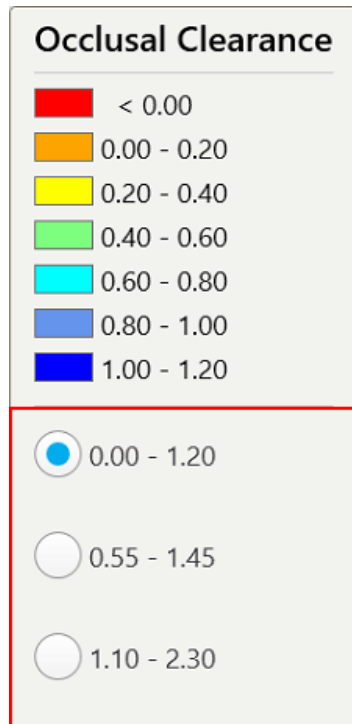


Figure 199: Occlusal Clearance range options

- b. Select the required scale.
- c. The occlusal clearance is displayed according to the new scale.

4. If required, tap  to [capture a screenshot](#) of the occlusal clearance.

To display the occlusal clearance from the Viewer:

1. Open the past order of a specific patient in the *Orders* page, or from a specific patient's profile page, tap **Viewer** to display the Viewer.



2. In the Viewer, tap .
3. 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.

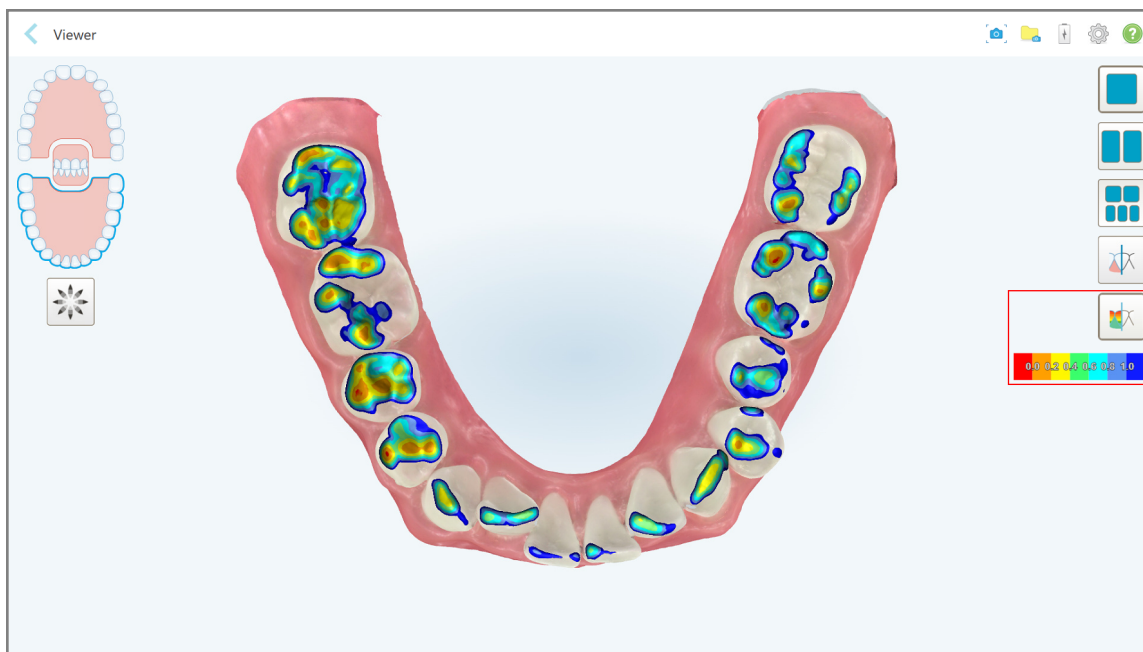


Figure 200: Occlusal Clearance tool and legend displayed in the Viewer

4. If required, tap  to capture a screenshot of the occlusal clearance. For more information on capturing screenshots and adding annotations, see [Working with the Snapshot tool](#).

10.9 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 Orthodontic procedures only.

To trim the excess material:

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

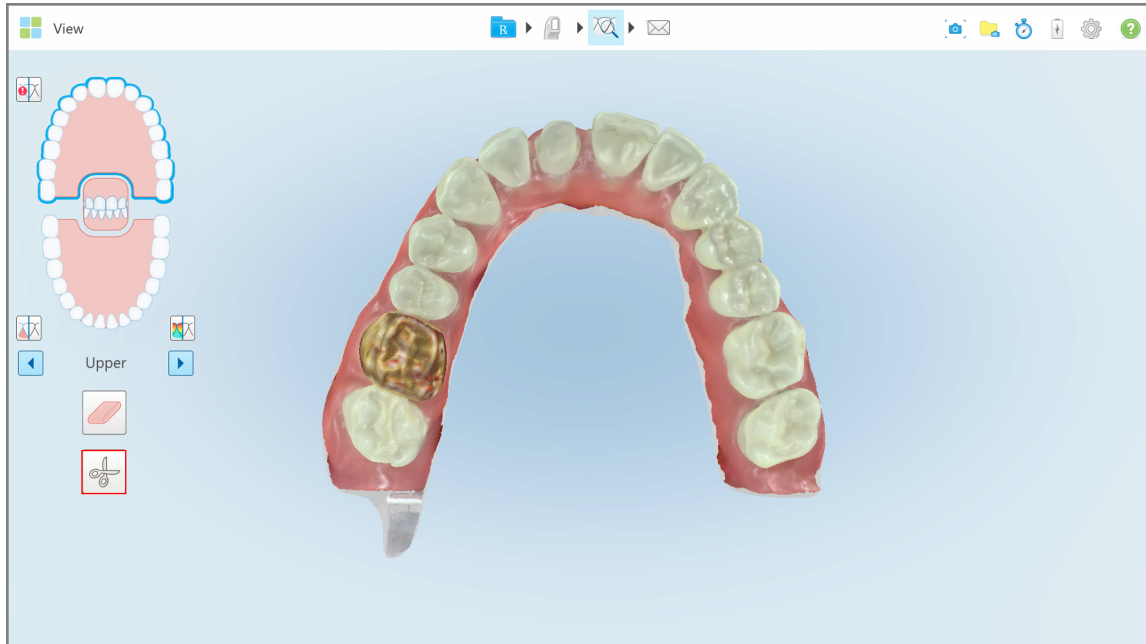


Figure 201: Edge Trimming tool

The Edge Trimming tool expands to show the following options:



Figure 202: Edge Trimming tool options

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

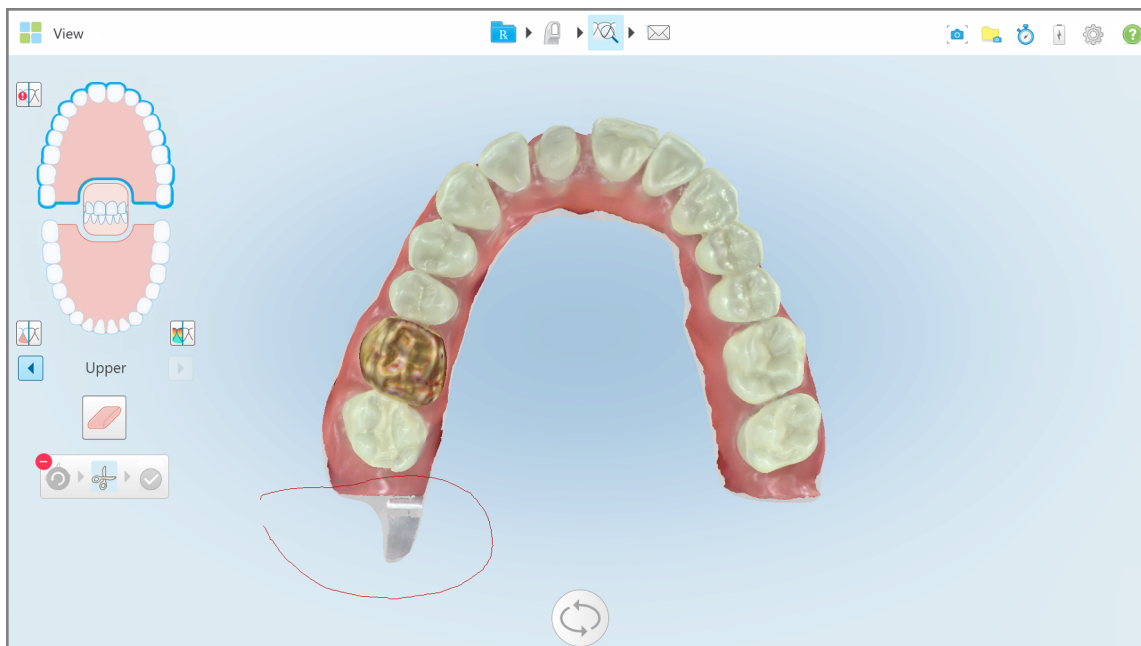


Figure 203: Mark the area to be trimmed away

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

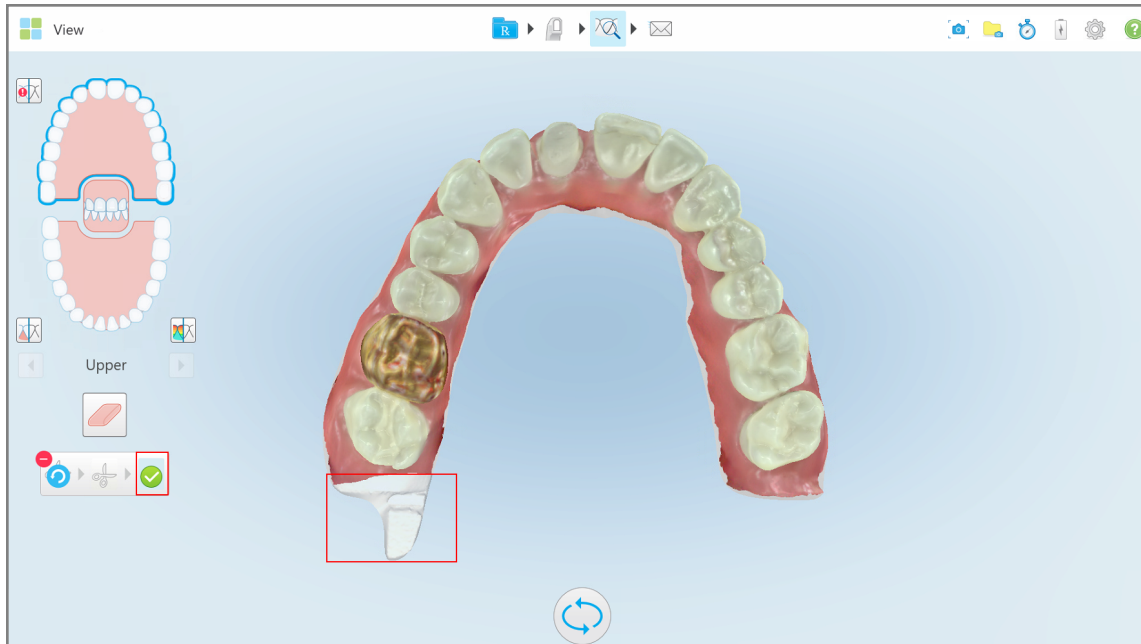


Figure 204: Selected area is highlighted, and the confirmation icon is enabled

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

4. Tap  to confirm the trimming.

The selected area is removed.

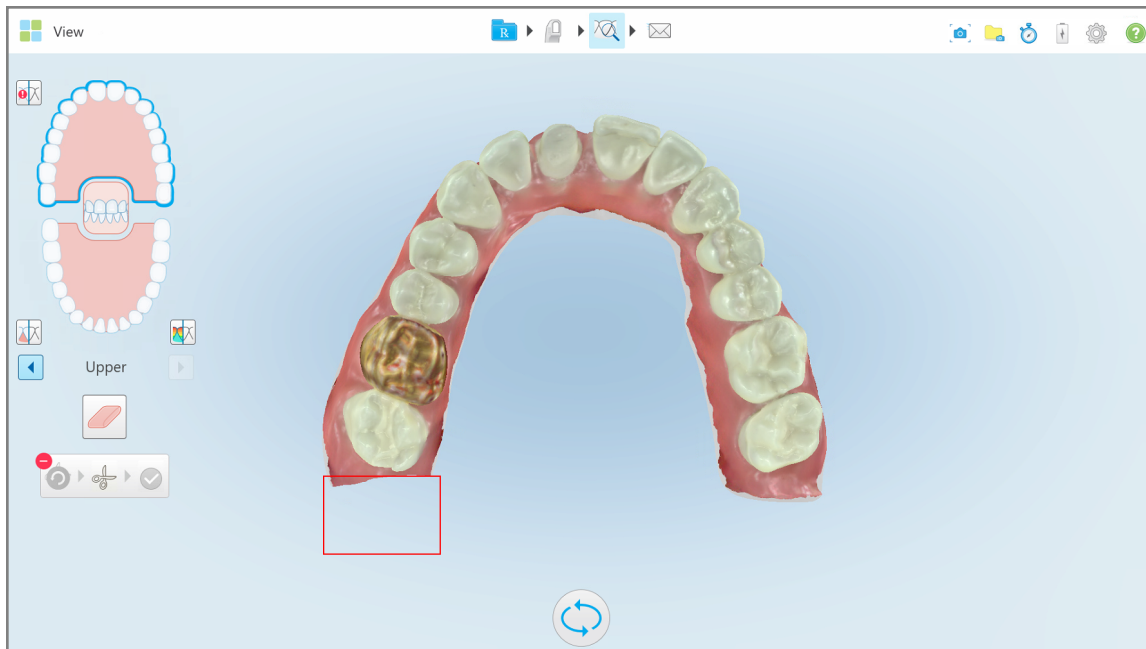


Figure 205: Selected area has been removed

10.10 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.

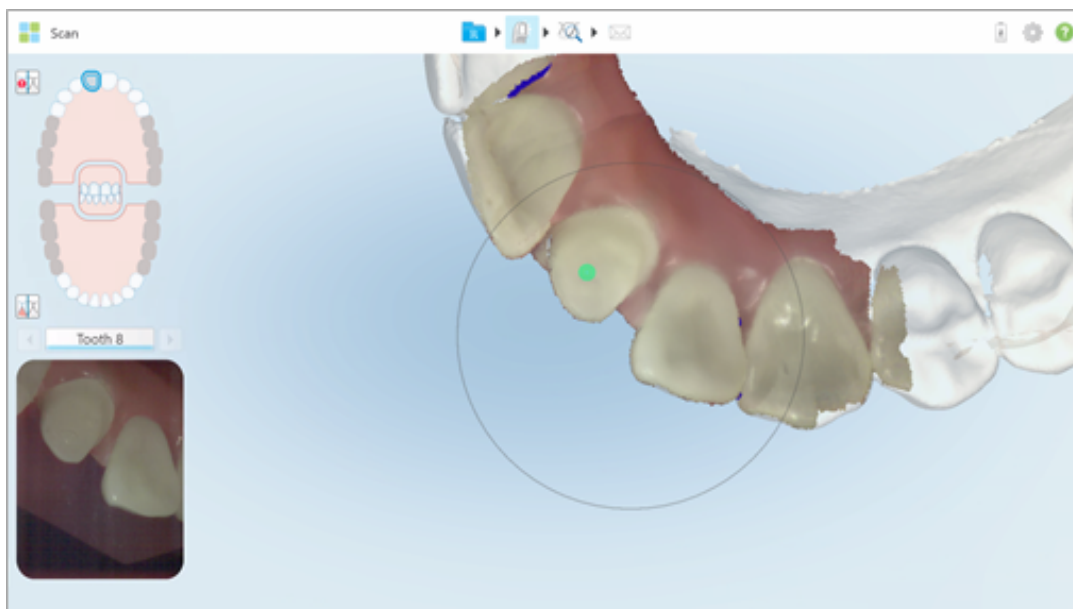


Figure 206: Green hint point centered on the prepped tooth

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 color in high resolution, and the complete 3D model in monochrome. You can switch between color and monochrome modes using the color toggle button .

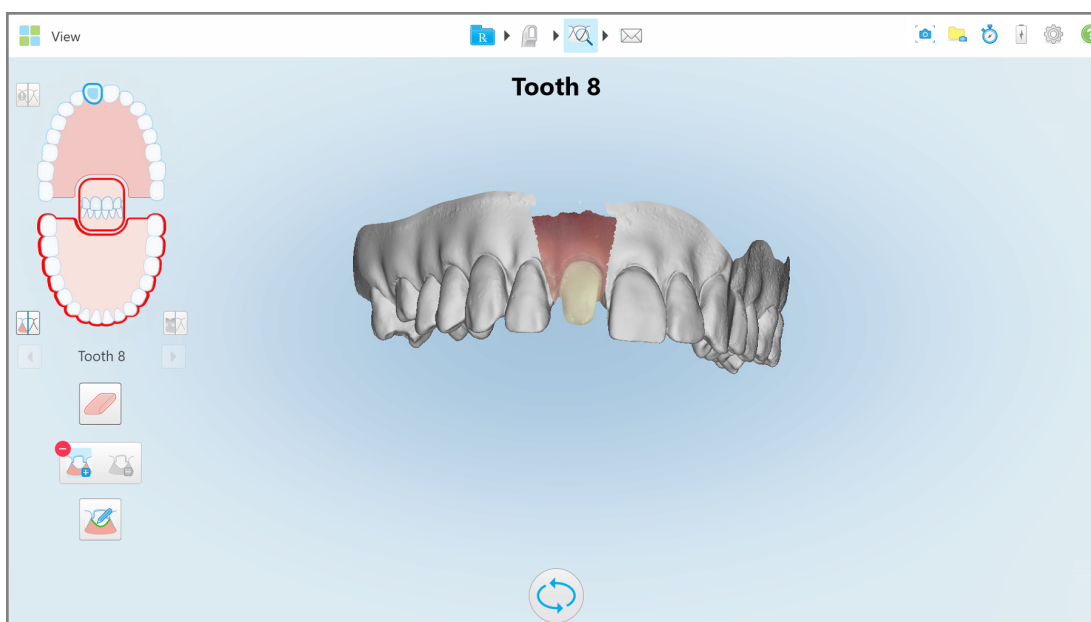


Figure 207: Die separation is displayed in high resolution

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 208: Die Separation tool options

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

The scan is displayed in high resolution.

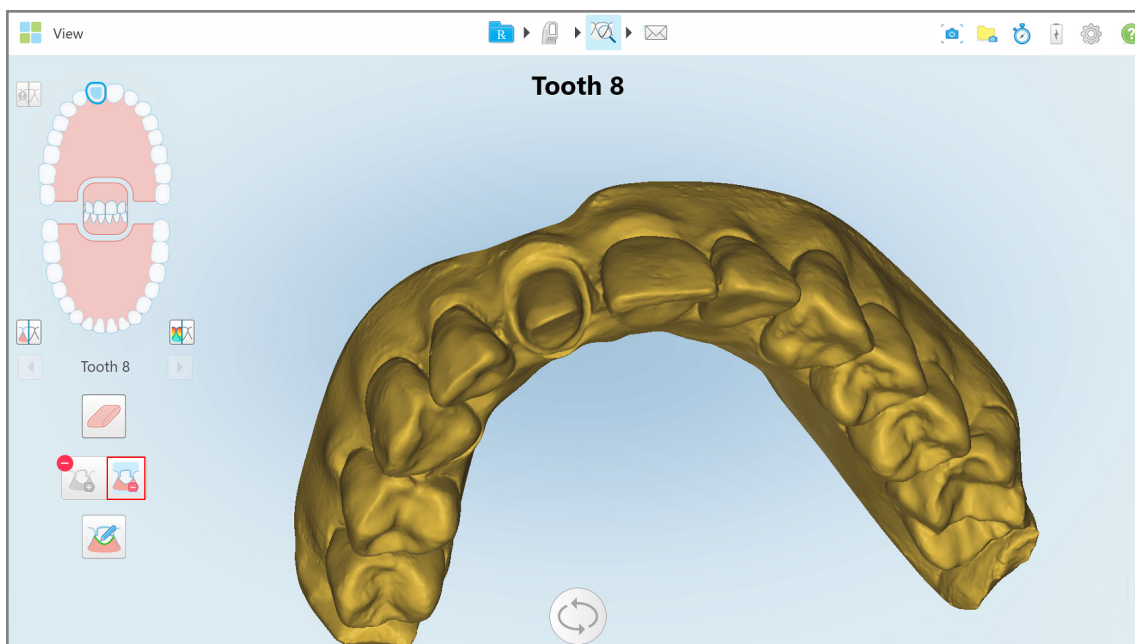


Figure 209: Scan is displayed in high resolution

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

The model is displayed in monochrome, as follows:

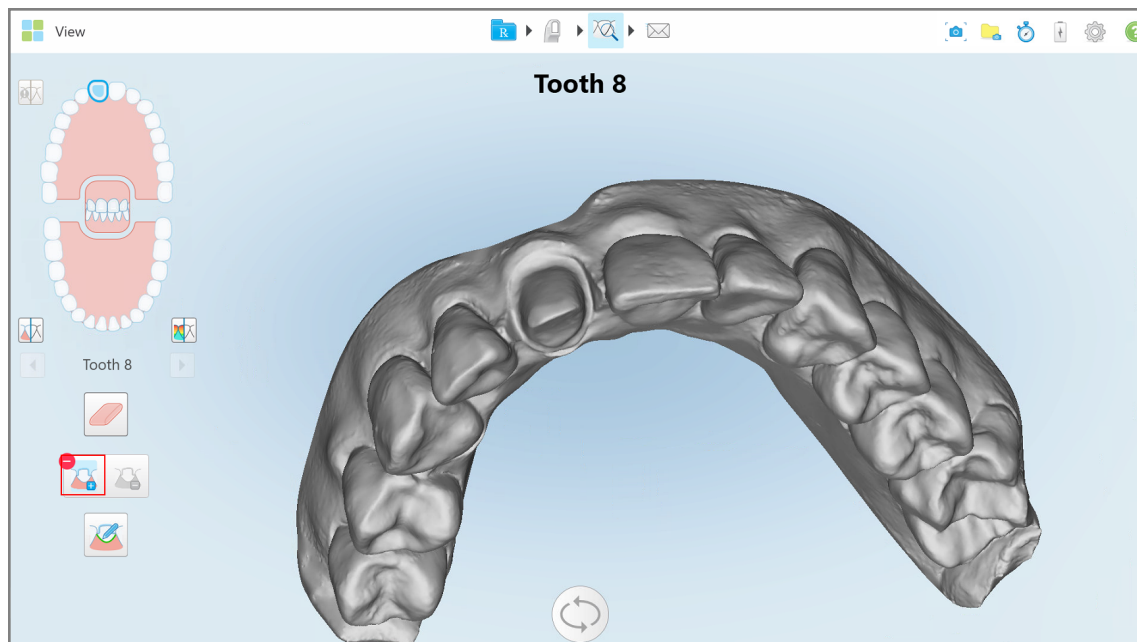


Figure 210: Before selecting the die separation

4. Draw the area for the die separation.

The selected area is displayed in high resolution.

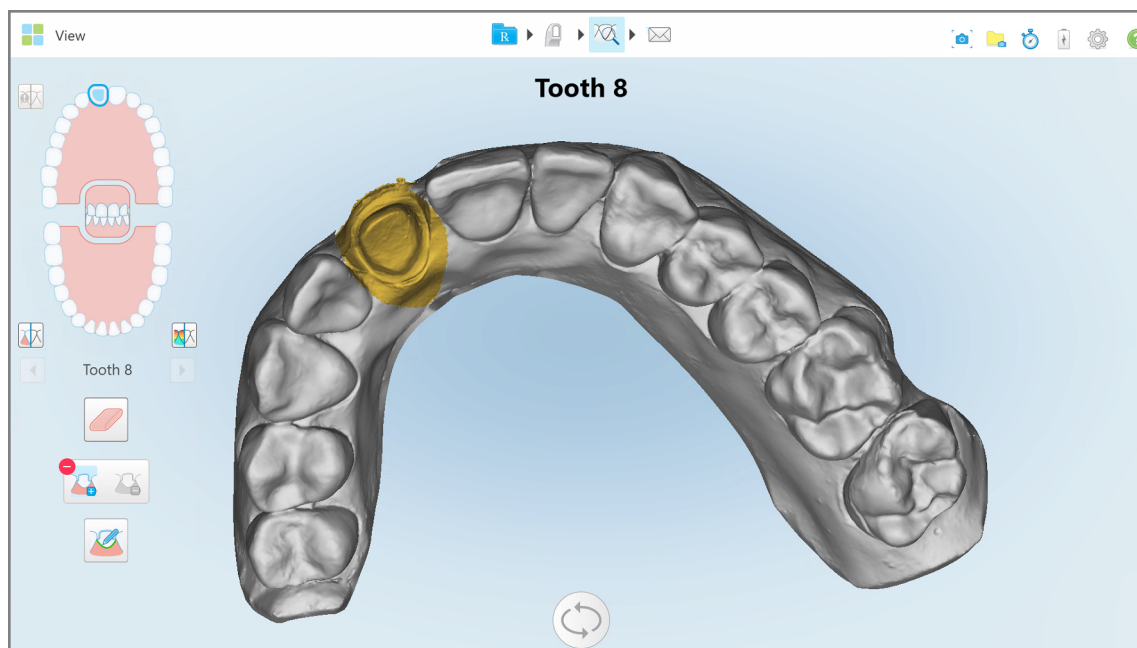


Figure 211: Prepped tooth is displayed in high resolution

10.11 Working with the Margin Line tool



The Margin Line tool automatically detects and marks the margin line on Fixed Restorative procedures 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.

10.11.1 Automatically defining the margin line

The Margin Line tool automatically detects and marks the margin line on Fixed Restorative procedures that require crowns.

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](#).

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.

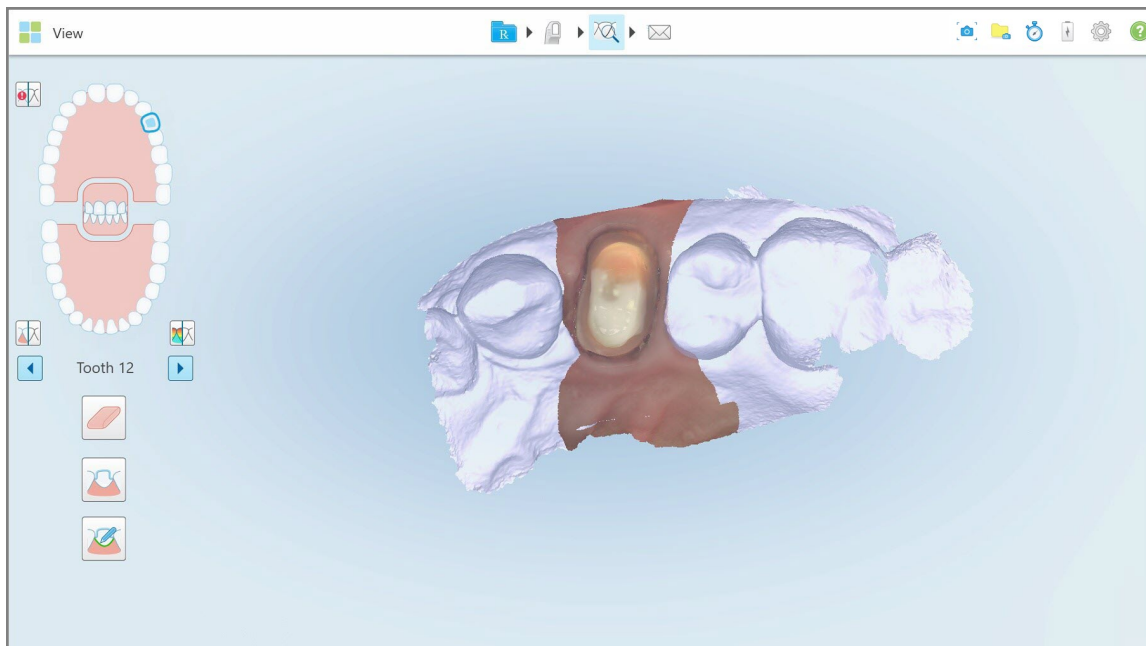


Figure 212: Model display moves to the occlusal view, and zooms in on the prepped tooth

2. Tap the Margin Line tool .

The Margin Line tool expands to show the following options:



Figure 213: 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.

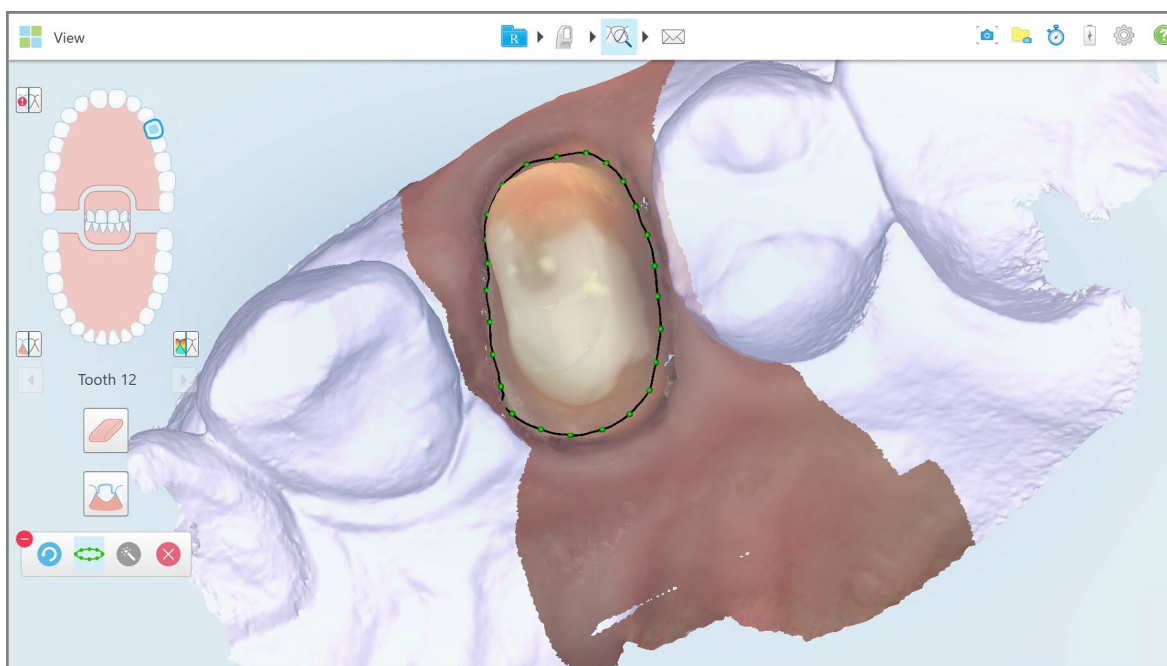


Figure 214: Margin line is marked on the prepped tooth

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.

10.11.2 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 215: 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 scan, you will receive a notification that the partial margin line will be deleted. You can go back and complete the margin line.

10.12 Working with the Snapshot tool



The Snapshot tool  enables you to capture screenshots of the scanned model from any window that includes the tool on the scanner toolbar. These screenshots can be annotated immediately or later viewed and annotated from the Patient Gallery, and downloaded from MyiTero. In addition, these screenshots can be shared with the patient via the [Align Oral Health Report](#).

To capture a screenshot of a scanned image:

1. From Align Oral Health Suite, the Viewer, or from any relevant window, tap the Snapshot tool  on the toolbar.



Figure 216: Viewer – 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. Afterwards, a pop-up message is displayed at the bottom of the screen for a few seconds, notifying you that the screenshot will be uploaded to MyiTero.



Figure 217: 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 *Annotation Tool* window is displayed, showing a screenshot of the model.

Note: You can also add annotations at any time in the future from the [Patient Gallery](#).

3. If required, you can download the screenshots from the Orders page in MyiTero.

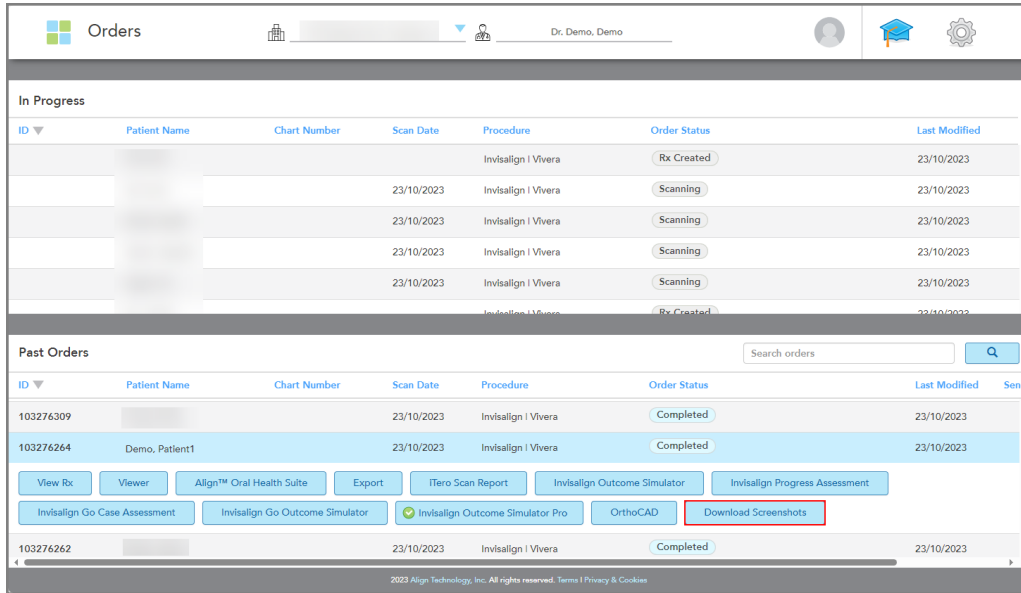


Figure 218: Option to download screenshots from the Orders page in MyiTero

By default, the following images are captured and saved in a separate folder, whose name includes the Order ID, and date and time of the screenshots, and which can be downloaded from MyiTero:

- Entire View window
- 3D image
- 2D color viewfinder image (if the loupe has been dragged onto the 3D image)

10.12.1 Working with the Annotation Tool

The Annotation Tool enables you to add annotations to screenshots captured in View mode after scanning the model, or anytime after the scan has been sent, from the Patient Gallery. In addition, it enables you to add annotated screenshots to the [Align Oral Health Report](#).

To access the Annotation Tool:

1. After [capturing a screenshot](#), tap the model thumbnail on the bottom left of the screen.

Or

From the Viewer or any other relevant screen, tap the Patient Gallery icon  on the toolbar and then the required screenshot.

The *Annotation Tool* window is displayed, showing a screenshot of the model, and an annotations toolbar on the top.

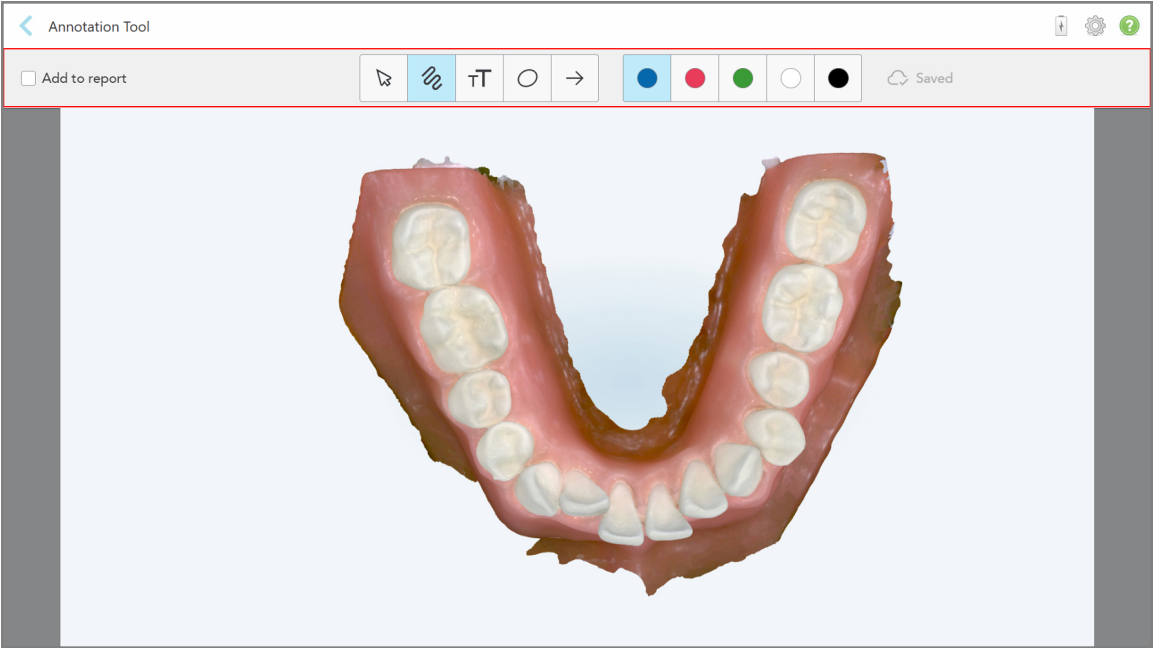
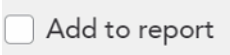


Figure 219: Screenshot open in the Annotation Tool window and the annotations toolbar

The Annotation Tool toolbar contains the following buttons:

- | | |
|---|---|
|  | Select to add the screenshot to the Align Oral Health Report. |
|  | Tap to select and move or delete an annotation. |
|  | Tap to draw on the screenshot. |
|  | Tap to add text on the screenshot. |
|  | Tap to draw a spherical area on the screenshot. |
|  | Tap to draw an arrow on the screenshot. |
|  | Tap the color for the drawing and text. By default, these will be the same color. |
|  | Shows the status of the annotation. |

2. Tap the required tool and color and then add your annotations.
3. To move, edit, or delete the annotation, select the  tool and then tap the relevant annotation to move, edit, or delete it.

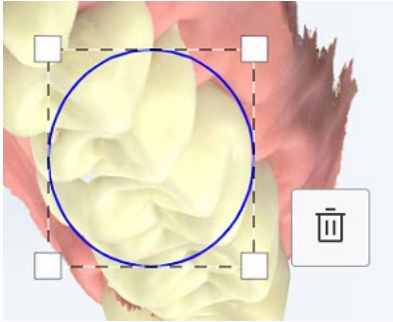


Figure 220: Options to move or delete the annotation

4. To add the screenshot to the Align Oral Health Report, select the **Add report** check box.
5. To keep the annotation and exit the Annotation Tool, tap  on the top left of the screen.
The screenshots and annotations can now be viewed in the Patient Gallery or downloaded from MyiTero.

10.13 Working with the Patient Gallery

The Patient Gallery contains all the screenshots of a selected patient, according to date captured.

It can be opened from the View tool while viewing a scan or anytime after the scan has been sent, from any screen that shows the  button, for example, Align Oral Health Suite and the Viewer.

To open the Patient Gallery:

1. In the Viewer, or any relevant screen, tap the  button on the toolbar.
The Patient Gallery is displayed, showing all the screenshots captured of the relevant patient, according to date.

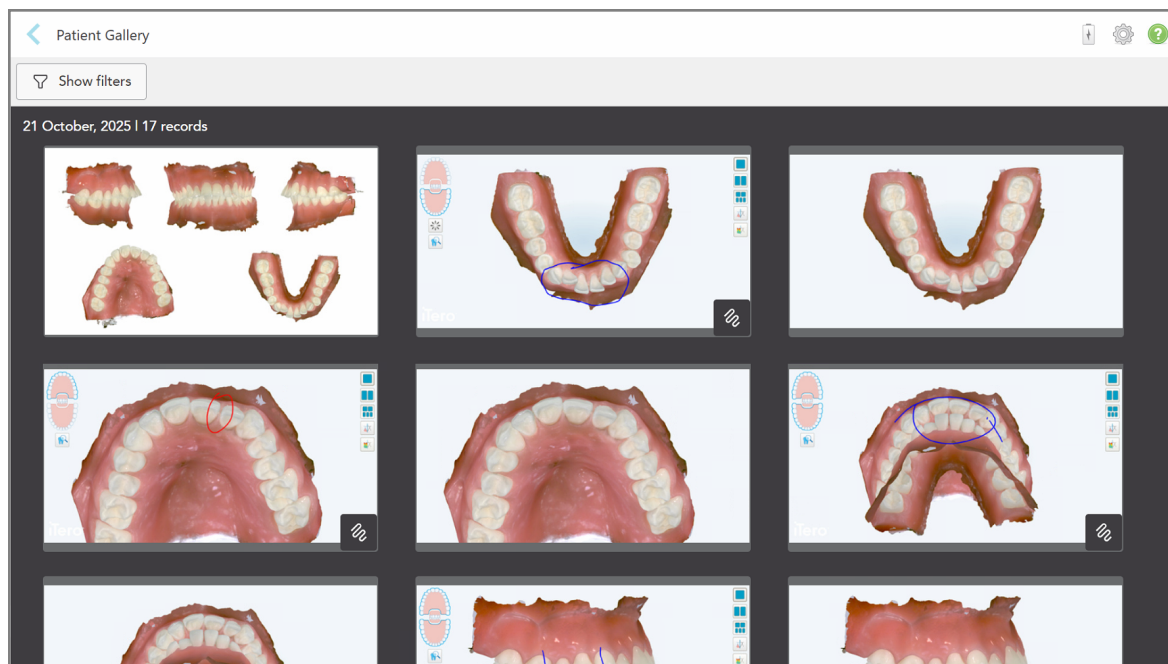


Figure 221: Patient Gallery

2. If required, you can:
 - Tap **Show filters** to filter the screenshots according to the date captured.
 - Tap a screenshot and [add annotations](#).
 - Tap a screenshot with  to view or edit the existing annotations.
3. Tap  to return to the previous screen.

10.14 Working with the Align Oral Health Report

The Align Oral Health Report is a personalized oral health report containing full-screen images captured during the current session or any other session in the past. It can instantly be shared with patients or with other dentists or specialists, using a QR code.

To create and share the Align Oral Health Report:

1. After scanning the patient and sending the order, tap **Align Oral Health Report** in the Past Orders pane or from the patient's profile page.

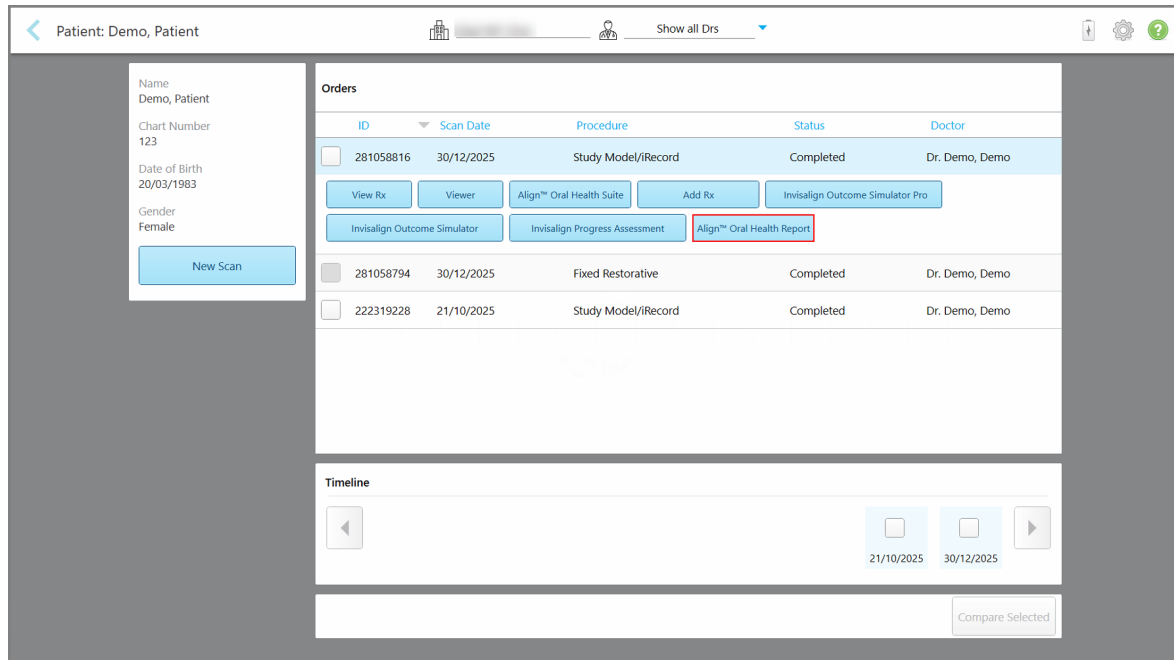


Figure 222: Align Oral Health Report button

The Summary page of the Align Oral Health Report is displayed. If any screenshots were added to the report while [adding annotations](#), they are displayed in the left pane.

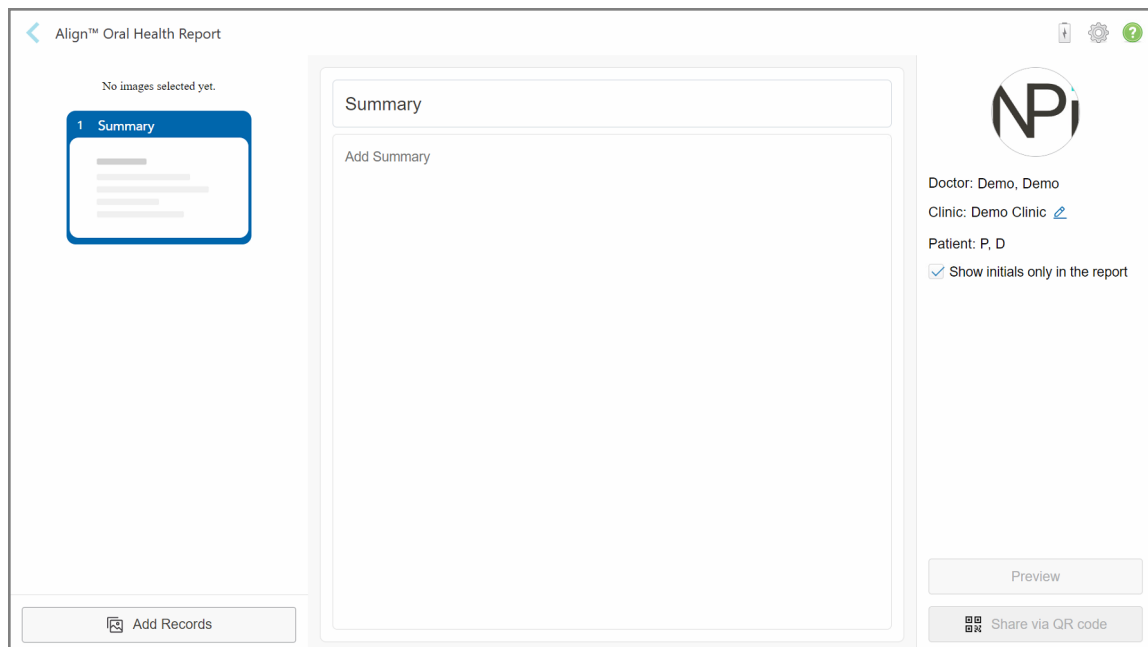


Figure 223: Align Oral Health Report – Summary page

2. Enter a description of the report in the **Summary** area.
3. If required, you can edit the name of the clinic.

4. By default, only the patient's initials are displayed in the report. If required, clear the **Show initials only in the report** check box to display the patient's full name.
5. Tap **Add Records** to select the screenshots to include in the report.

All screenshots in the patient's Patient Gallery are displayed.

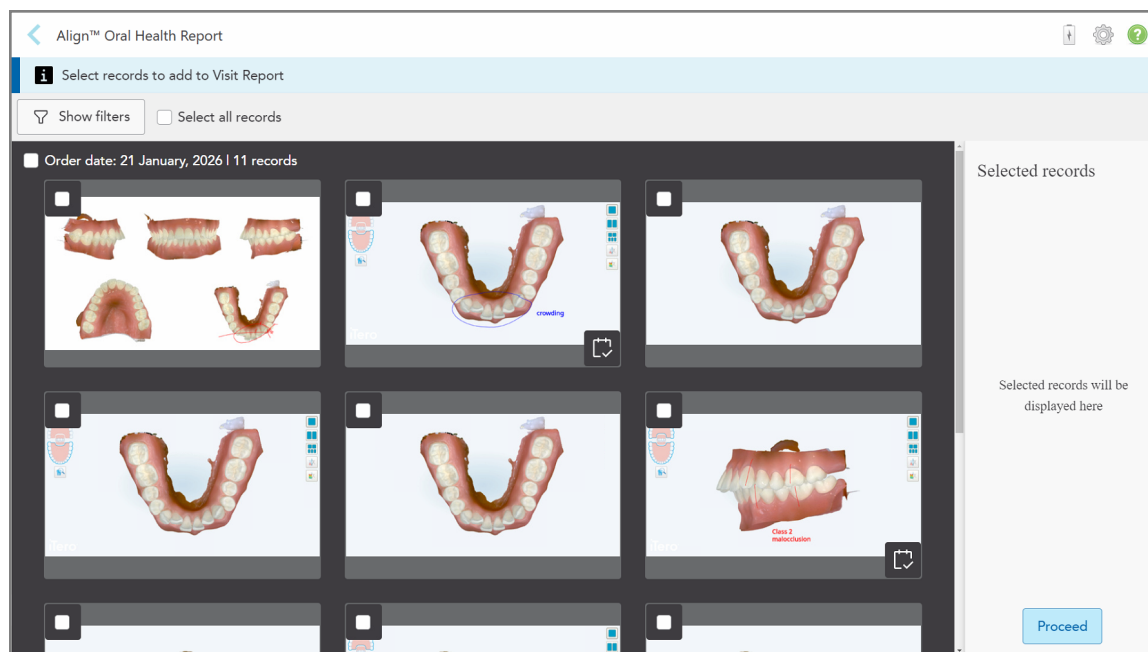


Figure 224: Align Oral Health Report – Patient Gallery

6. Select the screenshots to be included in the report. You can select screenshots from the current session or from any session in the past. If required, you can tap **Show filters** to show a list of dates for which there are screenshots, or you can select the **Select all records** check box to quickly display all the existing screenshots in the report.

The selected screenshots are displayed in the panel on the right.

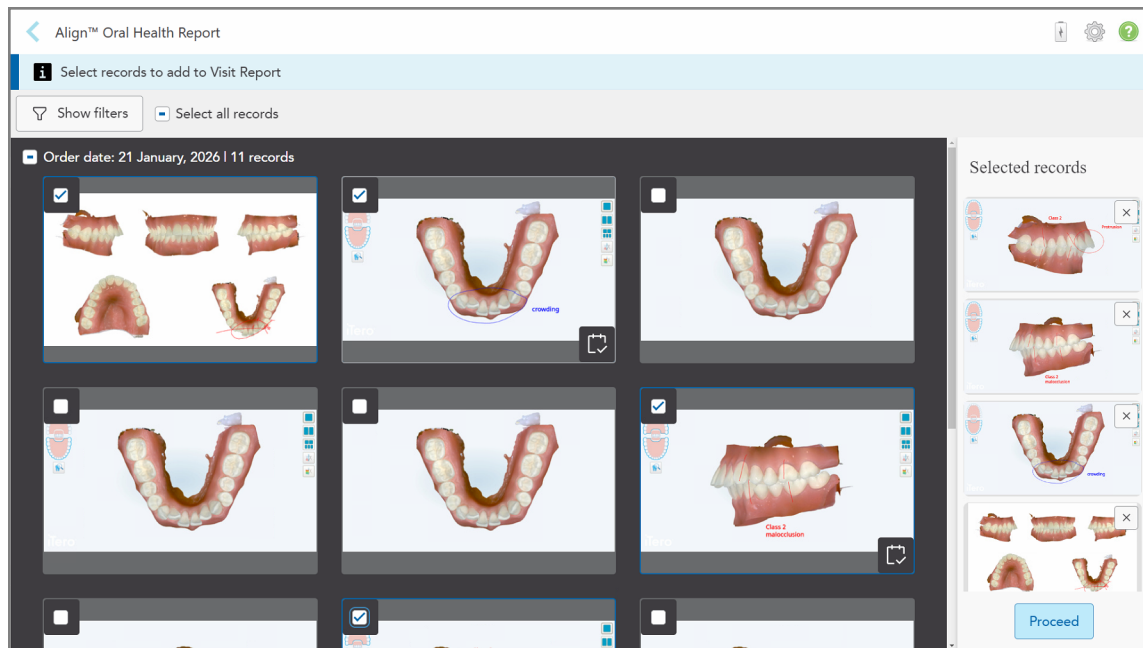


Figure 225: Align Oral Health Report – Selected records in the right pane

7. Tap **Proceed** after you have selected all the required screenshots.

The Align Oral Health Report is displayed, with the selected screenshots in the left pane and the highlighted screenshot in the center pane.

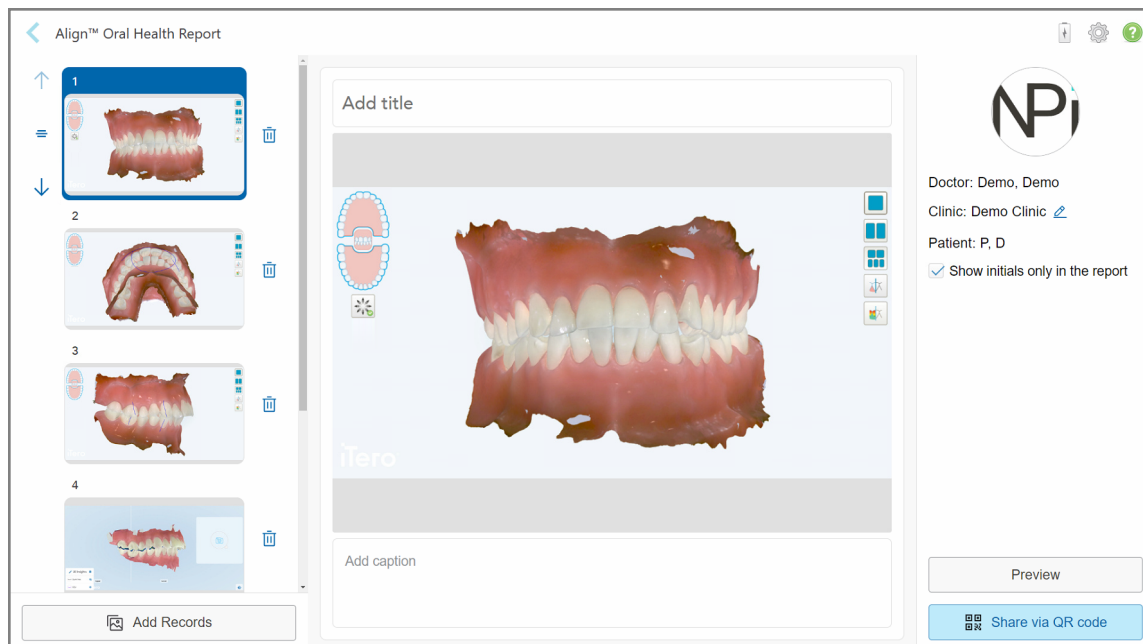


Figure 226: Align Oral Health Report – selection stage

8. If required, you can select a predefined title for each screenshot from the drop down list, or enter a title and caption for each screenshot.
9. If required, you can remove a selected screenshot from the report or arrange the screenshots in the report in the left pane, as follows:
 - Tap  to remove a screenshot from the report.
 - Tap the up or down arrows to reorder the screenshots.
 - Press  to drag and drop the screenshot in the required position.
10. If required, you can tap **Preview** to see a preview of the report.
11. When the report is ready, tap **Share via QR code** to share the report with the patient. Before the QR code is displayed, you are prompted to acknowledge that you understand regarding the privacy and security of the patient data when sharing/downloading the report.
12. Tap **Yes, continue** to display the QR code for sharing the report.

11 Care and maintenance

Align scanners do not require specific maintenance. During the service lifetime, support including replacement of malfunctioning main system components, or software maintenance including software upgrades to improve the user's experience might be performed, in accordance with the service contract.

Before cleaning and disinfecting the scanner, read and understand the **Cleaning and Disinfection** section in the [Safety instructions](#).

Note for users in Australia: This document refers to Caviwipes¹ and their designated contact time of one (1) minute as the default instruction for the cleaning and disinfection procedure. For a list of alternative active ingredients approved in Australia, see [Approved cleaning and disinfection materials \(Australia only\)](#). When following the cleaning and disinfection procedure detailed in this manual, please refer to the manufacturers' instructions and specified contact time for the selected disinfecting wipes.

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 reduce the risk of cross-contamination, it is mandatory to:

- Thoroughly clean and disinfect the wand, cradle, and other system components, as described in the following sections.
- [Attach a new wand sleeve](#) before each patient session.
- Dispose of the wand sleeve after each patient and in accordance with standard operating procedures or local regulations for the disposal of contaminated medical waste.
- Wear gloves when using the touchscreen.
- Remove and replace gloves after each patient procedure.
- Discard torn, contaminated, or used gloves.

11.1 Handling the wand and cable

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

When not in use, the wand should be kept in its cradle, with the optical surface facing the cradle, and with the blue protective sleeve attached. If you have a laptop- or mobile-configuration scanner, the wand should be stored in the supplied carrying case or trolley, with the protective sleeve attached.

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.

11.2 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
- Immediately after each patient

Warning: Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials to prevent biological hazards.

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

11.2.1 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 scan or by going back to the home screen.
2. [Remove the wand sleeve](#), making sure not to touch the optical surface of the wand.

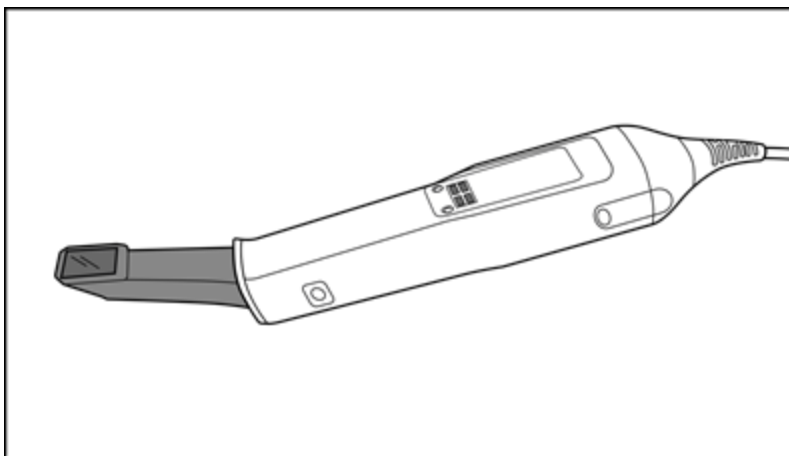


Figure 227: Wand without a wand sleeve

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 iTero 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 [Approved cleaning and disinfecting materials](#))
 - 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.

11.2.2 Wand cleaning and disinfection

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

Cleaning

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

Note: If you are using an alternative disinfectant, see the following sections for the required contact time.

- [Outside Australia](#)
- [Australia](#)

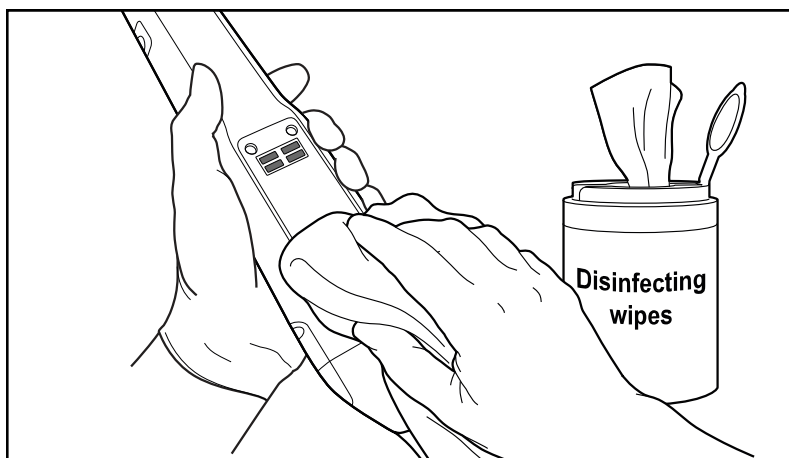


Figure 228: Remove gross contaminants using disinfecting wipes

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 avoid damage to the wand.

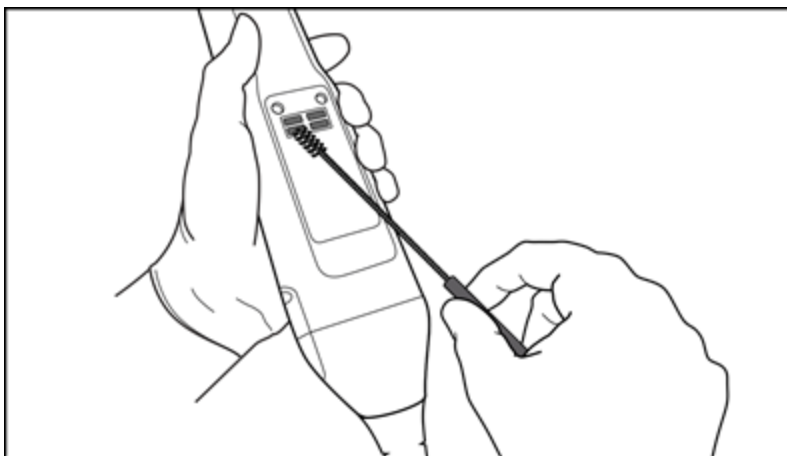


Figure 229: Remove marks and stains using a soft bristle brush

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.
5. If required, repeat step 3 until no visual contamination is observed.

Disinfection (intermediate-level disinfection)

Note: Use multiple fresh wipes to keep the wand's surfaces wet, paying special attention to the hard to disinfect areas (i.e., notches, seams, sleeve snappers, and buttons).

Ensure the wand surfaces remain wet for the full one (1) minute contact time.

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.

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

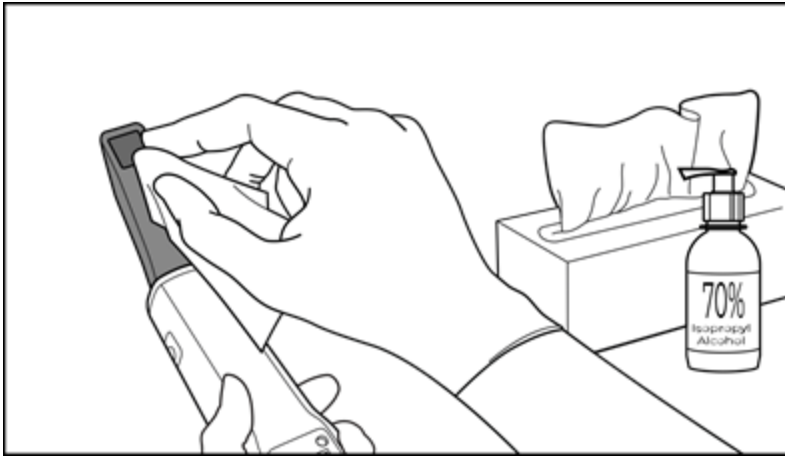


Figure 230: Wipe the optical surface of the wand with IPA

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.
5. Visually inspect the optical surface for any noticeable damage, for example, scratches, stains, murkiness, or opaqueness.

Warning: Do not use the wand if any damage is found on the optical surface. Please contact iTero Customer Support for further instructions.

11.2.3 Drying – wand body

Air-dry the disinfected wand at room temperature.

11.2.4 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](#).
4. If you have a laptop- or mobile-configuration scanner, store the wand in the carrying case or trolley when not in use.

11.3 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
- Immediately after each patient

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

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

11.3.1 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 [Approved cleaning and disinfecting materials](#))
 - 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.

11.3.2 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, see [Approved cleaning and disinfecting materials](#) for the required contact time.

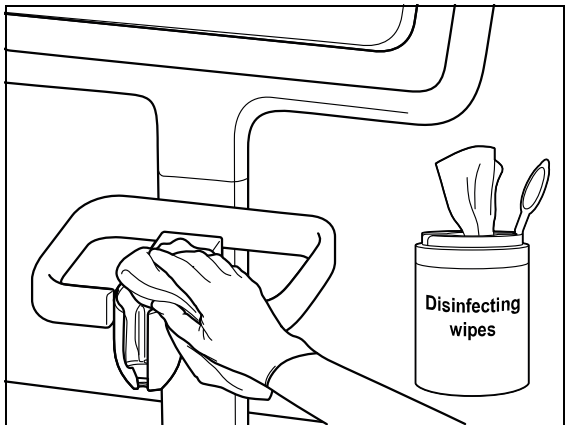


Figure 231: Wiping the iTero Element 2 cradle

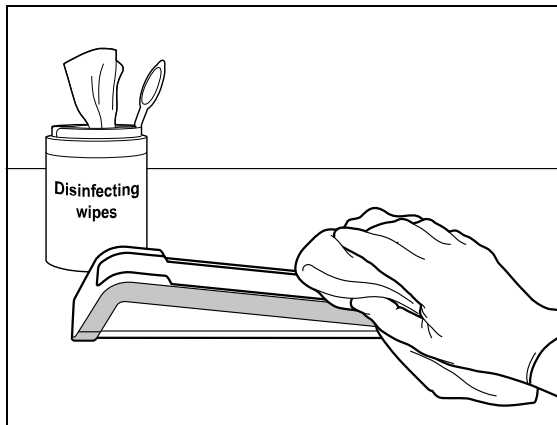


Figure 232: Wiping the iTero Element Flex cradle

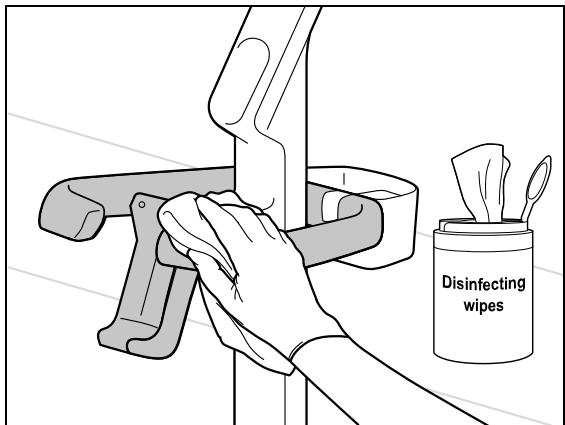


Figure 233: Wiping the iTero Element 2 Plus cart-configuration cradle

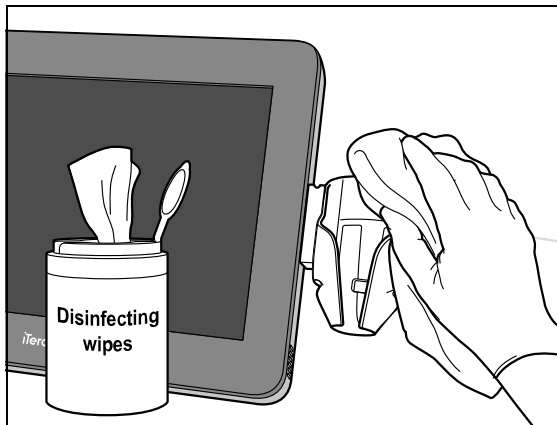


Figure 234: Wiping the iTero Element 2 Plus mobile-configuration cradle

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

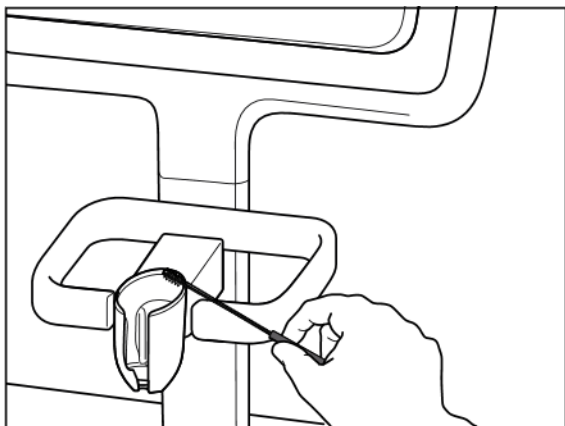


Figure 235: Brushing the iTero Element 2 cradle

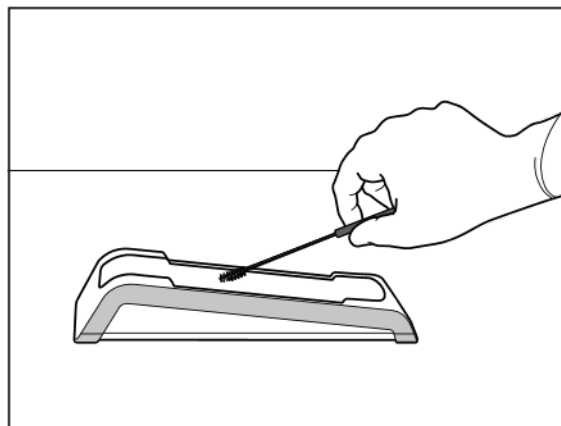


Figure 236: Brushing the iTero Element Flex cradle

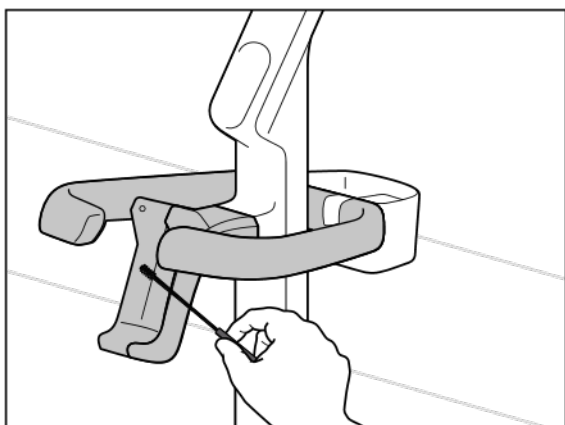


Figure 237: Brushing the iTero Element 2 Plus cart-configuration cradle

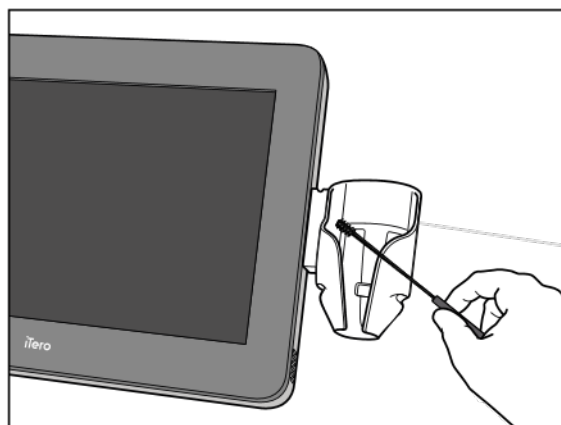


Figure 238: Brushing the iTero Element 2 Plus mobile-configuration cradle

- Using CaviWipes¹, remove any remaining contaminants on the cradle.
- Visually inspect the cradle in a well-lit area to ensure all surfaces are visibly clean.
- If required, repeat step 3 until no visual contamination is observed.

Disinfection (intermediate-level 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.

11.3.3 Drying – cradle

Air-dry the disinfected cradle at room temperature.

11.3.4 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.

The iTero Element Flex cradle should be stored in the carrying case when not in use.

11.4 Cleaning and disinfecting the scanner touchscreen and the wheel-stand handle or main handle

The scanner screen and wheel-stand handle or main handle must be cleaned and disinfected (low-level disinfection) immediately after each patient, as follows:

1. Clean and disinfect all outer surfaces using [approved disinfectant wipes, or approved disinfectant liquid](#) with a clean lint-free wipe, and follow the manufacturer's instructions.
2. Remove any residual liquid disinfectant with a clean lint-free wipe.
3. Visually inspect the scanner screen and the main handle in a well-lit area to ensure all surfaces are visibly clean. Repeat the cleaning procedure according to the manufacturer's instructions until no visual contamination is observed.
4. Visually inspect the scanner screen for any noticeable damage, for example, scratches or stains, and confirm the responsiveness of the touchscreen.

Warning: Do not use the scanner screen if any damage is found. Please contact iTero Customer Support for further instructions.

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

11.5 General cleaning and disinfection comments

All scanner parts and reusable accessories not outlined above should be thoroughly cleaned (and disinfected if applicable) according to standard operating procedures or local regulations.

Note: Refer to the disinfecting agent manufacturer's user manuals and data sheets for additional information and instructions for use.

In addition to the processes described above, national standards and regulatory requirements may apply.

iTero scanners are typically cleaned and disinfected in the use environment.

11.6 Approved cleaning and disinfecting materials

11.6.1 Approved cleaning and disinfection materials (not relevant for Australia)

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

If you are using a 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 (Quaternary Ammonium Chloride)	1
CaviWipes/CaviCide	Quats-alcohol (Quaternary Ammonium Chloride)	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 capable of intermediate-level disinfection, including being able to disinfect against at least Hepatitis and Tuberculosis.

11.6.2 Approved cleaning and disinfection materials (Australia only)

The following table lists the Align-recommended active ingredients and concentration levels for cleaning and disinfecting materials.

	Active ingredients and concentration levels
1	0.76% Didecyldimethylammonium Chloride (DDAC), 7.5% Ethanol, and 15% Isopropanol
2	1.4% Hydrogen Peroxide
3	≤50% Peracetic Acid

Consult your local supplier of disinfecting materials for approved cleaning and disinfecting materials in your region. Cleaning and disinfecting products must meet local regulatory requirements and be listed as Class IIb on ARTG, have the above-mentioned active ingredients and concentration levels, and in addition, must be capable of intermediate-level disinfection, including being able to disinfect against at least Hepatitis and Tuberculosis.

If you are using a 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.

When following the cleaning and disinfection procedure detailed in this manual, please also refer to the disinfecting agent manufacturer's user manuals and data sheets for additional information and instructions for use, including recommended contact times.

Appendix A: Clinic LAN network guidelines

A.1 Introduction

The scanner is capable of connecting to the wireless LAN in order to support the file transfer to and from the iTero cloud. Connection to other wireless devices is not supported.

Ensure that your local network is configured to provide IPv4 connectivity.

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 three 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 port 443.
 - 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

To ensure proper operation, the iTero scanner must communicate with cloud-based SaaS services. Please verify that all required hostnames and network ports are allowed through the clinic firewall. Blocking or restricting these endpoints may result in degraded functionality or service unavailability.

Hostname	Port	Domain
*.myitero.com	TCP/443	HTTPS
*.myaligntech.com	TCP/443	HTTPS
*.mycadent.com	TCP/443	HTTPS
*.iterocloud.com	TCP/443	HTTPS
*.itero.com	TCP/443	HTTPS
*.aligntech.com	TCP/443	HTTPS
*.invisalign.com	TCP/443	HTTPS
*.cloudfront.net	TCP/443	HTTPS
*.rackcdn.com	TCP/443	HTTPS
identityitero.com	TCP/443	HTTPS
*.amazonaws.com	TCP/443	HTTPS
.aws.	TCP/443 TCP/9243	HTTPS HTTPS
*.teamviewer.com	TCP/5938 TCP/5939 TCP/443 (alternative) TCP/80	HTTPS HTTPS HTTPS HTTP
api.data.com	TCP/443	HTTPS
*.sentinelone.net	TCP/443	HTTPS
google.com	TCP/443	HTTPS
microsoft.com	TCP/443	HTTPS
yahoo.com	TCP/443	HTTPS
*.windowsupdate.com	TCP/443	HTTPS
*.akamaitechnologies.com	TCP/443	HTTPS

Hostname	Port	Domain
*.amazonses.com – Required for running EFRA on the scanners.	TCP/465 TCP/587	SMTP SMTP
*.1e100.net – Required for the 3D Viewer on the scanner as it accesses Google URLs	TCP/443	HTTPS
*.auth0.com	TCP/443	HTTPS
*.jsdelivr.net	TCP/443	HTTPS
www.google-analytics.com	TCP/443	HTTPS
www.googletagmanager.com	TCP/443	HTTPS

A.7.1 Align hostname recommendations – China

Hostname	Port	Service
*.myitero.cn	TCP/443	HTTPS
*.invisalign.com.cn	TCP/443	HTTPS
*.amazonaws.com.cn	TCP/443	HTTPS
Baidu.com	TCP/443	HTTPS
cn.bing.com	TCP/443	HTTPS
qq.com	TCP/443	HTTPS

Appendix B: EMC declarations

B.1 EMC declaration – iTero Element 2 and iTero Element Flex

IEC 60601-1-2 Edition 4.1 (2014 + A1: 2020)/EN 60601-1-2 (2015/A1: 2021)

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
(relevant for iTero Element 2 only)

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 2 and iTero Element Flex intraoral scanner essential performances are:

- Display viewfinder and 3D imaging without interference on the touchscreen.
- 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 touchscreen. 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 2 and iTero Element Flex scanners:

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

Test	Standard	Class / Severity level	Test results
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on 230 VAC @ 50 Hz; & 220 VAC mains @ 60 Hz; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±2.0 CM / ±1.0 kV DM on 230 VAC mains @ 50 Hz; & 220 VAC mains @ 60 Hz; Tr/Th – 1.2/50 (8/20) 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 to proximity magnetic fields in the frequency range 9kHz to 13.56MHz	IEC 61000-4-39	8 A/m 30kHz CW 65 A/m @134.2kHz PM 2.1kHz 50% 7.5 A/m @13.56MHz PM 50kHz 50%	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 VAC & 100 VAC mains @ 50 Hz: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles; on 220 VAC mains @ 60 Hz: 0 % - 0.5 cycle & 1 cycle; 70% - 30 cycles; 0% - 300 cycles	Complies

Test	Standard	Class / Severity level	Test results
Emission (per ETSI EN 301 489-1, ETSI EN 301 489-17)			
(relevant for iTero Element 2 only)			
Conducted emissions on mains terminals in freq. range 150 kHz - 30 MHz	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 55032	Group 1 Class B 230 VAC mains	Complies
Radiated emissions in freq. range 30 - 6000 MHz	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 55032	Class B	Complies
Harmonic current test	ETSI EN 301 489-1; ETSI EN 301 489-17 / EN 61000-3-2	230 VAC mains	Complies
Flicker tests	ETSI EN 301 489-1; EN 61000-3-3	230 VAC mains	Complies
Immunity (per ETSI EN 301 489-1, ETSI EN 301 489-17)			
(relevant for iTero Element 2 only)			
Immunity from Electrostatic discharge (ESD)	EN 61000-4-2	4 kV contact discharge 8 kV air discharge	Complies
Immunity from radiated electromagnetic fields	EN 61000-4-3	3.0 V/m, 80 MHz , 6.0 GHz, 80% AM, 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	EN 61000-4-4	AC mains: ± 1.0 kV; Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	EN 61000-4-5	AC mains: ± 1.0 kV DM / ± 2.0 kV CM, Tr/Th – 1.2/50 (8/20) 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

B.2 EMC declaration – iTero Element 2 Plus

IEC 60601-1-2 Edition 4.1 (2014 + A1: 2020)/EN 60601-1-2 (2015/A1: 2021)

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 (2020).

ETSI EN 301 489-1, ETSI EN 301 489-17

Electromagnetic Compatibility (EMC) standard for radio equipment and services.

Environment for intended use

Professional Healthcare and Home Healthcare Facility Environment.

The iTero Element 2 Plus intraoral scanner essential performances are:

- Display viewfinder and 3D imaging without interference on the touchscreen.
- 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 touchscreen. 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 2 Plus scanners:

Test	Standard	Class / Severity level	Test results
Emission (IEC 60601-1-2 / EN 60601-1-2 section 7.1 & 7.2)			
Conducted emission Freq. range: 150 kHz - 30 MHz	CISPR 11 / EN 55011	Group 1 Class B: – AC mains (240 V, 230 V, 120 V, 100 V; 220 V @ 60 Hz)	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11 / EN 55011	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2 / EN 61000-3-2	AC mains (230 V @ 50 Hz & 220 V @ 60 Hz)	Complies
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3 / EN 61000-3-3	AC mains (230 V @ 50 Hz & 220 V @ 50 Hz)	Complies

Test	Standard	Class / Severity level	Test results
Immunity (IEC 60601-1-2 / EN 60601-1-2 sections 8.9 and 8.10)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2 / EN 61000-4-2	8 kV contact discharges & 15 kV air discharges (AC mode (230 V @ 50 Hz & 220 V @ 60 Hz) & Battery mode)	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3 / EN 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz (AC mode (230 V @ 50 Hz & 220 V @ 60 Hz) & Battery mode)	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3 / EN 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 / EN 61000-4-4	± 2.0 kV on AC mains (230 V @ 50 Hz & 220 V @ 60 Hz); Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5 / EN 61000-4-5	±2.0 CM / ±1.0 kV DM on AC mains (230 V @ 50 Hz & 220 V @ 60 Hz); Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6 / EN 61000-4-6	6 VRMS on AC mains; (230 V @ 50 Hz & 220 V @ 60 Hz)& Patient cable; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8 / EN 61000-4-8	30 A/m @ 50 Hz & 60 Hz (AC mode and Battery mode)	Complies

Test	Standard	Class / Severity level	Test results
Immunity to proximity magnetic fields in the frequency range 9kHz to 13.56MHz	IEC 61000-4-39	8 A/m 30kHz CW 65 A/m @134.2kHz PM 2.1kHz 50% 7.5 A/m @13.56MHz PM 50kHz 50% (AC mode and Battery mode)	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11 / EN 61000-4-11	On AC mode (240 V @ 50 Hz, 100 V @ 50 Hz): 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles; On AC mode (220 V @ 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) Not relevant for laptop-configuration scanners			
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

Test	Standard	Class / Severity level	Test results
Immunity (per ETSI EN 301 489-1, ETSI EN 301 489-17) (Not relevant for laptop-configuration scanners)			
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

Appendix C: iTero Element™ Family 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 with the goal of implementing 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, and IEC/TR 80001-2-2.

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.³
- **Data-in-transit is encrypted:** PII and intraoral scan images that are backed up to Align supporting systems is transmitted over supported transport layer security (TLS) encryption using trusted certificates. This helps to prevent an attacker from capturing patient information while in transit.³
- **Anti-malware protections are in place:** The scanners come with pre- installed anti-virus and security tools that check for malicious files on the system. The anti-virus software definitions are updated frequently and scans are scheduled to run daily on the devices.¹
- **Remote maintenance is not possible without permission:** The devices use a commercially available off-the-shelf software to establish remote sessions. The 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.³
- **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.¹
- **User access management controls are enforced:** A user account and password are required to utilize the scanners. This helps protect access to the scanner and protects against unauthorized use.³

- **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 and Staff. This helps ensure the ability to track activities performed by individual users better protecting the device.³

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 Family of products, 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 laptop configuration scanners, 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.³
- **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.³
- **Detect malicious and mobile code:** It is the customer's responsibility to select and implement anti-virus/anti-malware protection for the iTero laptop configuration 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.²
- **Create strong passwords and protect login credentials:** It is the customer's responsibility to set strong passwords 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.³
- **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 or Staff. 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.³

- **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 supporting systems and are being restarted as requested to ensure latest scanner updates are being applied.³
- **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.²

¹ Only applicable for iTero Element 2, iTero Element 5D, iTero Element 2 Plus, iTero Element 5D Plus, and iTero Element 5D Plus Lite

² Only applicable for iTero laptop configurations: iTero Element Flex, iTero Element 5D Laptop Configuration, iTero Element 5D Imaging System with Plus Package

³ Applicable for iTero Element 2, iTero Element 5D, iTero Element 2 Plus, iTero Element 5D Plus, iTero Element 5D Plus Lite, iTero Element Flex, iTero Element 5D Laptop Configuration, and iTero Element 5D Imaging System with Plus Package

If you have any questions or concerns, please do not hesitate to contact Customer Support.

Appendix D: System specifications

This section includes the specifications for the following systems:

- [iTero Element 2 system specifications](#)
- [iTero Element Flex system specifications](#)
- [iTero Element 2 Plus system specifications](#)

D.1 iTero Element 2 system specifications

Monitor	21.5" Full HD (1920x1080) touchscreen	
Wand	- 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	
Security	See iTero Element™ Family product security whitepaper .	
Operating Power	100-240 VAC- 50/60 Hz- 200 VA (max)	
Operating environmental conditions		
- Temperature - Relative Humidity - Pressure - Altitude	18°C to 26°C / 64.4°F to 78.8°F 40% to 70% 520 mmHg to 771 mmHg (~69 kPa to~103 kPa) -400 feet to 10,000 feet	
Storage/Transportation environmental conditions		
- Temperature - Relative Humidity - Pressure - Altitude	-5°C to 50°C / 23°F to 122°F 30% to 90% 430 mmHg to 760 mmHg (~57 kPa to ~101 kPa) -400 feet to 15,000 feet	
Dimensions	iTero Full HD touchscreen computing unit: - Height: 356 mm (~14 in) - Width: 552 mm (~21.7 in) - Depth: 65 mm (~2.5 in) Wand: - Length: 338.5 mm (~13 in) - Width: 53.5 mm (~2 in) - Depth: 69.8 mm (~3 in)	Wheel stand: - Height: 1280 mm (~50 in) - Width: 645 mm (~25 in) - Depth: 595 mm (~23 in)
Net Weight	- Monitor: 8.3 kg (~18.3 lbs.) - Wand: 0.47 kg (~1.0 lbs.) without the cable - Wheel stand: ~13.6 kg (~30 lbs.)	

D.2 iTero Element Flex system specifications

Monitor	Laptop screen
Wand	- The wand emits red laser light (680nm Class 1) as well as white LED emissions. - Wand operating power: 15VDC
Security	Align Technology takes the responsibility of securing the data of our customers and their patients very seriously. All patient data is transmitted via an encrypted TLS channel, and communications and information are securely stored, enabling our customers to take reasonable measures to protect their patient data.
Operating power	100-240VAC- 50/60 Hz-40VA (max)

Operating environmental conditions

• Temperature	18°C to 26°C / 64.4°F to 78.8°F
• Relative humidity	40% to 70%
• Pressure	520 mmHg to 771 mmHg (~69 kPa to ~103 kPa)
• Altitude	-400 feet to 10,000 feet

Storage/Transportation environmental conditions

• Temperature	-5°to 50°C / 23° to 122°F
• Relative humidity	30% to 90%
• Pressure	430 mmHg to 760 mmHg (~57 kPa to ~101 kPa)
• Altitude	-400 feet to 15,000 feet

Dimensions	iTero Element Flex hub:	iTero Element Flex cradle:
	- Length: 206 mm (~8 in) - Width: 94 mm (~3.7 in) - Depth: 36.5 mm (~1.4 in)	- Length: 262 mm (~10 in) - Width: 89 mm (~3.5 in) - Depth: 52 mm (~2 in)
	iTero Element wand:	Carrying case:
	- Length: 338.5 (~13in) - Width: 53.5 mm (~2 in) - Depth: 69.8 mm (~3 in)	- Height: 326.5 mm (~13 in) - Width: 455 mm (~18 in) - Depth: 184 mm (~7 in)

Net weight	iTero Element Flex hub: ~0.5 kg (~1 lbs.)
	iTero Element Flex wand: 0.47 kg (~1 lbs.)
	Empty carrying case: ~3.9 kg (~8.6 lbs.)
Shipping weight	~8 kg (~17.6 lbs.)

D.3 iTero Element 2 Plus system specifications

	Cart configuration	Mobile configuration
Monitor	21.5" Full HD (1920x1080) touchscreen	15.6" Full HD (1920x1080) touchscreen
Wand	- The wand emits red laser light (680nm Class 1) as well as white LED emissions. - Wand operating voltage: 15VDC	
Wireless LAN	A LAN card provides local network communications with wireless connectivity 2.4GHz, 5GHz 802.11ac	
Security	See iTero Element™ Family product security whitepaper .	
	Cart configuration	Mobile configuration
Operating Power	100-240 VAC- 50/60 Hz- 300 VA (max)	100-240 VAC- 50/60 Hz- 250 VA (max)
Operating environmental conditions		
Temperature	18°C to 26°C / 64.4°F to 78.8°F	
Relative Humidity	40% to 70% (non condensing)	
Altitude	-400 feet to 10,000 feet	
Transportation environmental conditions		
Temperature	-5°C to 50°C / 23°F to 122°F	
Relative Humidity	30% to 90% (non condensing)	
Altitude	-400 feet to 15,000 feet	
Storage environmental conditions		
Temperature	-5°C to 50°C / 23°F to 122°F	
Relative Humidity	30% to 90% (non condensing)	
Altitude	-400 feet to 15,000 feet	

Physical properties

• Wand • iTero Full HD touchscreen computing unit • Wheel stand • Cable length • Net Weight	• Length: 338.5 mm (~13 in) • Width: 53.5 mm (~2 in) • Depth: 69.8 mm (~3 in)	Cart configuration • Height: 356 mm (~14 in) • Width: 544 mm (~21.5 in) • Depth: 60.5 mm (~2.3 in)	Mobile configuration • Height: 275 mm (~10.8 in) • Width: 419 mm (~16.5 in) • Depth: 41.5 mm (~1.6 in)
		Cart configuration • Height: 1279 mm (~50.3 in) • Width: 544 mm (~21.4 in) • Depth: 562 mm (~22.1 in)	Mobile configuration N/A
		Cart configuration Wand cable: 1.8 m typical Power cable: 3000 mm	Mobile configuration Wand cable: 1.8 m typical Power cable: 1600 mm or 3000 mm
		Cart configuration Computing unit: 10.5 kg (~23.1 lbs.) Wand: 0.47 kg (~1.0 lbs.) without the cable Wheel stand: ~12.5 kg (~27.5 lbs.)	Mobile configuration Computing unit with cradle and wand: ~5.5 kg (~12.0 lbs.) System packed in trolley: ~11 kg (~24.0 lbs.) Wand: 0.47 kg (~1.0 lbs.) without the cable
CPU Specifications	Intel® Core™ i7		
GPU Specifications	Nvidia		
Battery	Integrated battery for uninterrupted scanning and ease in office portability without plugging in or rebooting, providing: • At least 30 minutes of active continuous scanning (cart configuration) and 10 minutes (mobile configuration) • <2.5 hours for a full recharge		
Scanner and wand cross-contamination protection	• Single-use, disposable wand sleeves		
Accessible ports	USB types A and C		
Scanning technology	Parallel Confocal technology		

Scanning properties

- No hovering required – scanning can be done at a distance of 0mm.
- No field calibration needed.
- Flexible scanning protocol (start anywhere, auto stitching).
- Automated heating of the tip to avoid fogging of the lens.

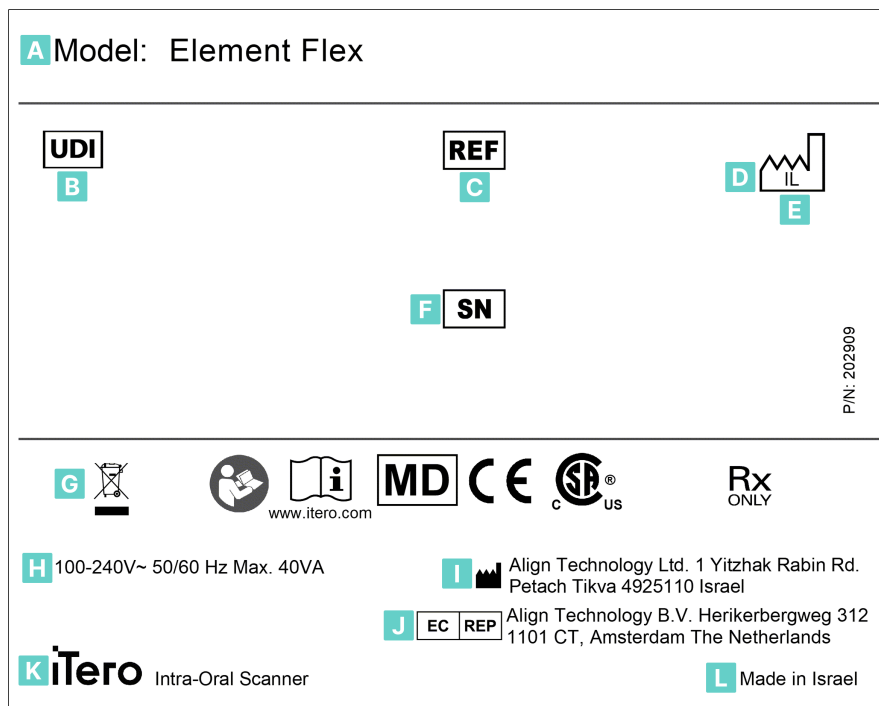
Scan time

Full mouth can be completed in as little as 60 seconds.

Cloud storage

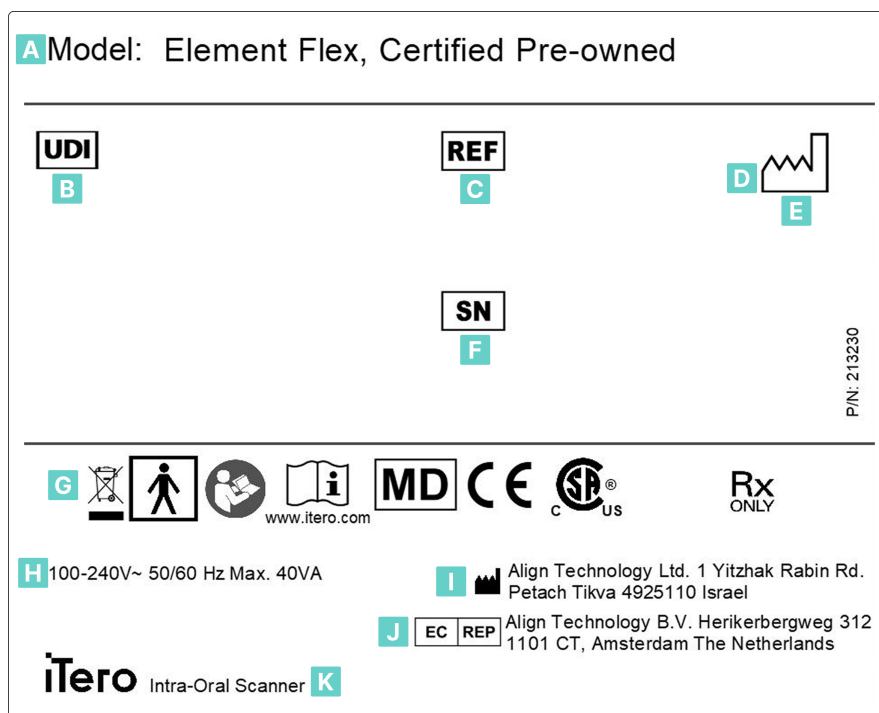
Data can be stored and accessed on the web using cloud storage and the MyiTero web portal.

E.1.2 Package label - iTero Element Flex



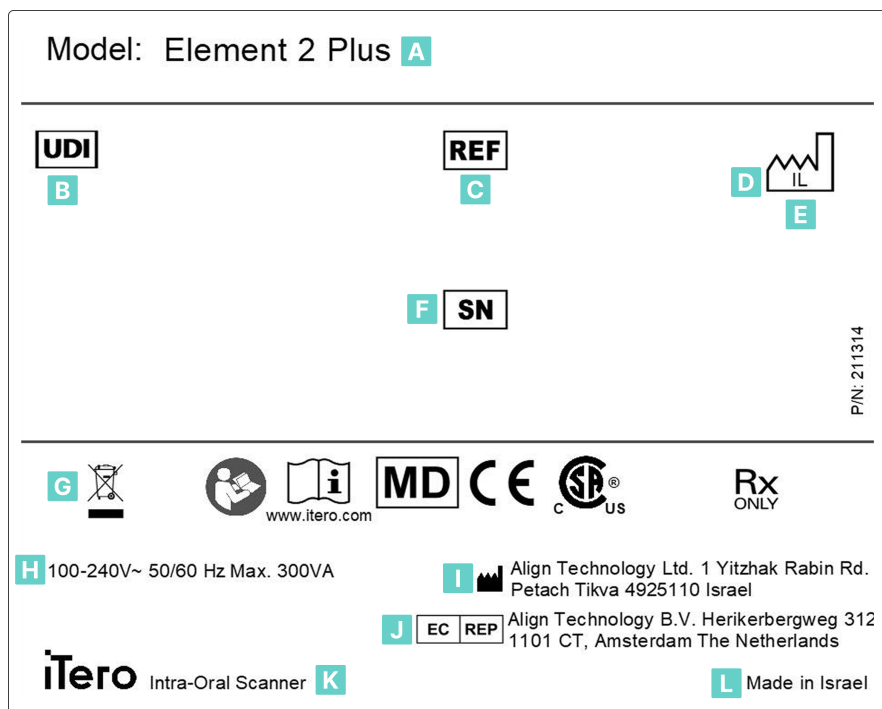
- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Country of origin
- E** Manufacturing date
- F** Serial number
- G** [Applicable symbols](#)
- H** Electrical rating
- I** Manufacturer
- J** Authorized representative in the European Community
- K** Brand name
- L** Country of origin

E.1.3 Package label - iTero Element Flex (Certified pre-owned)

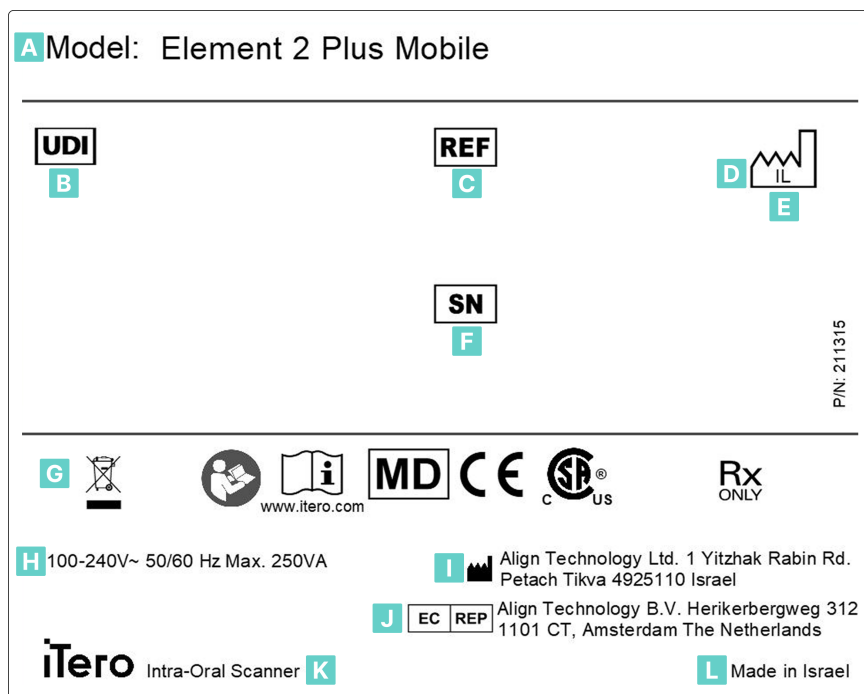


- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Country of origin
- E** Manufacturing date
- F** Serial number
- G** [Applicable symbols](#)
- H** Electrical rating
- I** Manufacturer
- J** Authorized representative in the European Community
- K** Brand name

E.1.4 Package labels - iTero Element 2 Plus cart and iTero Element 2 Plus mobile

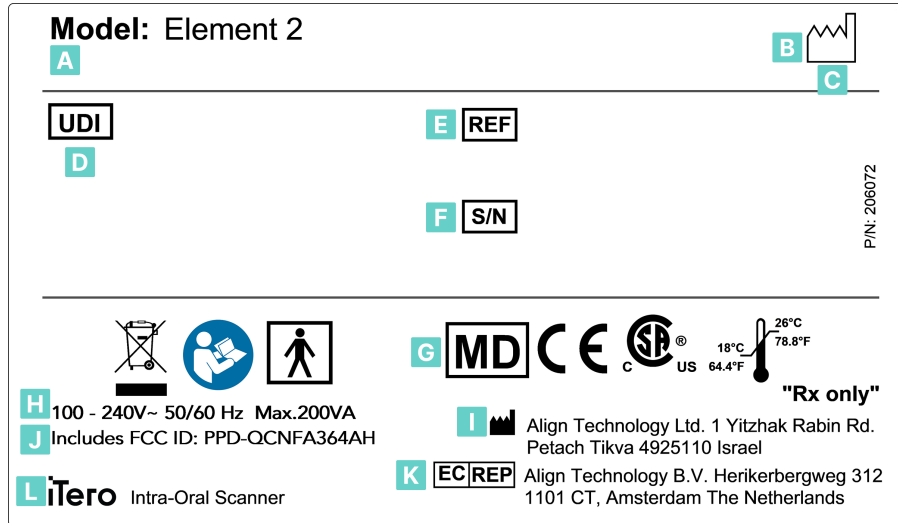


- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Country of origin
- E** Manufacturing date
- F** Serial number
- G** [Applicable symbols](#)
- H** Electrical rating
- I** Manufacturer
- J** Authorized representative in the European Community
- K** Brand name
- L** Country of origin



E.2 Computing unit labels

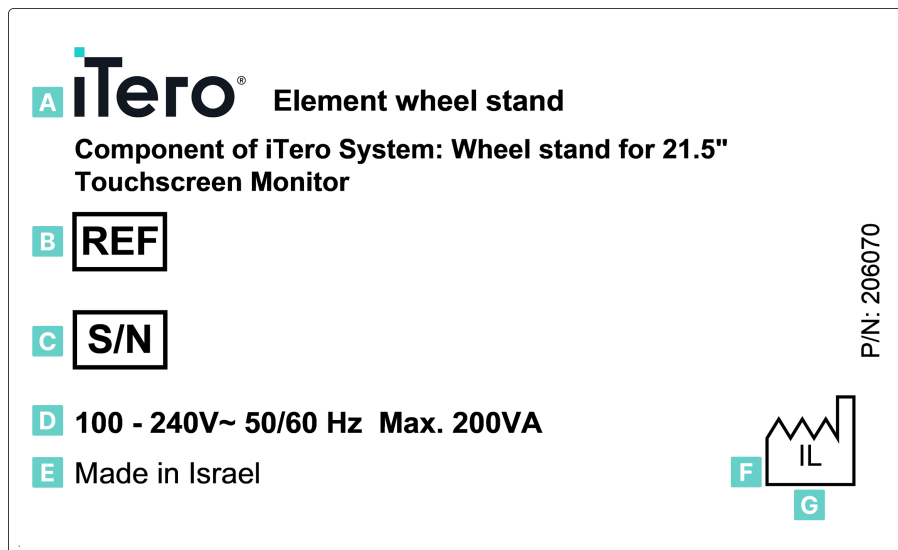
E.2.1 Computing unit - iTero Element E2



- A** Model name
- B** Country of origin
- C** Manufacturing date
- D** Unique Device Identifier
- E** Catalog number
- F** Serial number
- G** [Applicable symbols](#)
- H** Electrical rating
- I** Manufacturer
- J** FCC ID
- K** Authorized representative in the European Community
- L** Brand name

E.3 Wheelstand labels

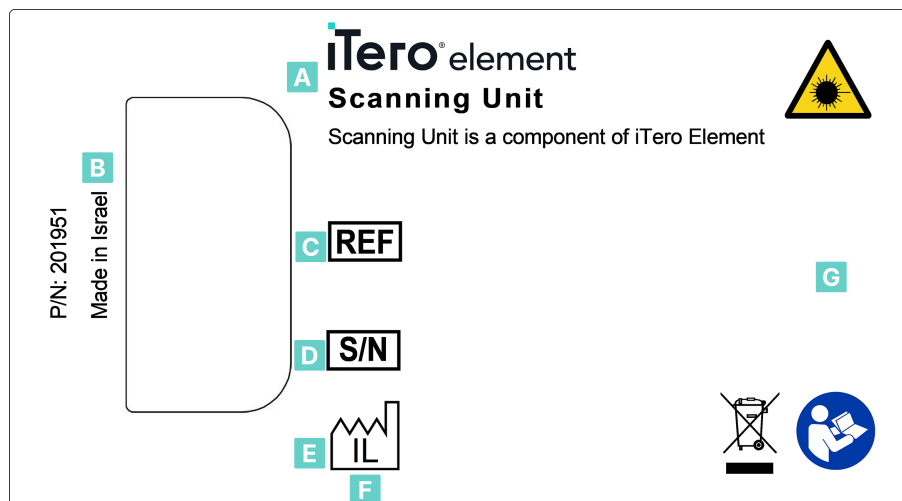
E.3.1 Wheelstand labels - iTero Element 2



- A** Model name
- B** Catalog number
- C** Serial number
- D** Electrical rating
- E** Country of origin
- F** Country of origin
- G** Manufacturing date

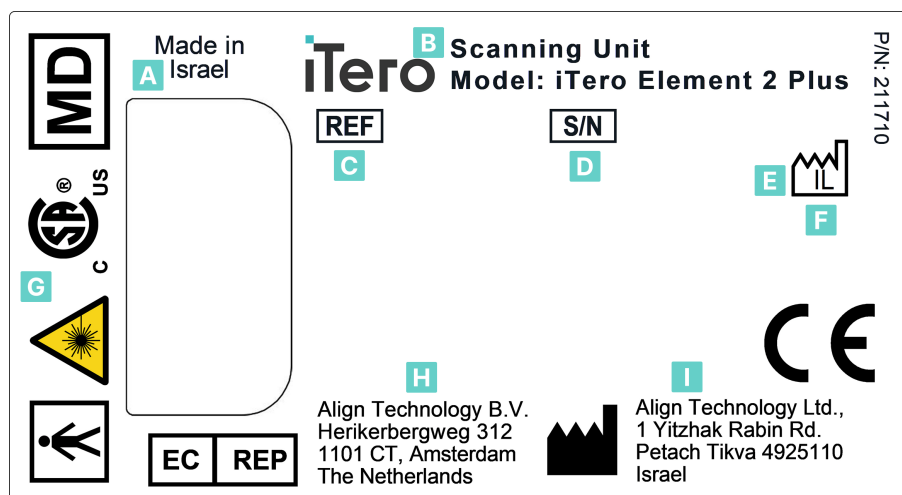
E.4 Wand labels

E.4.1 Wand label - iTero Element 2



- A Brand name
- B Country of origin
- C Catalog number
- D Serial number
- E Country of origin
- F Manufacturing date
- G [Applicable symbols](#)

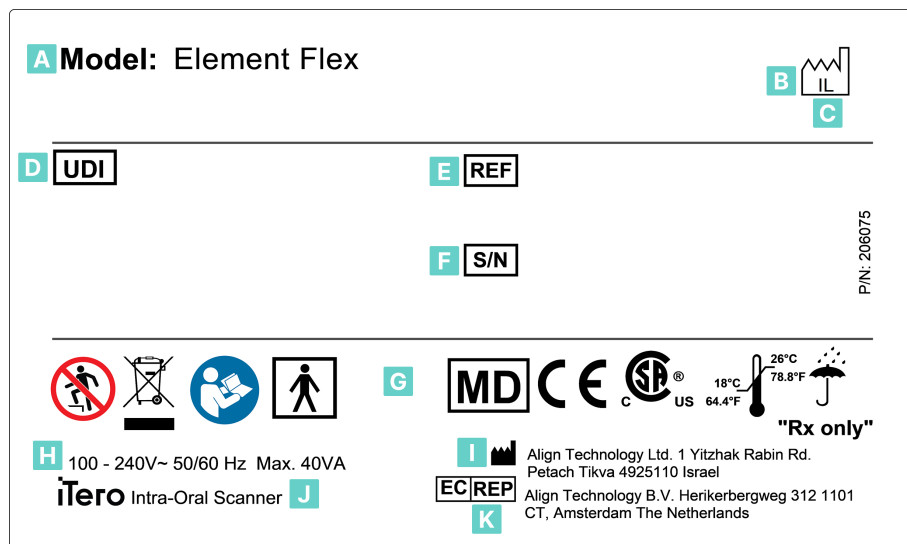
E.4.2 Wand label - iTero Element 2 Plus



- A Country of origin
- B Model name
- C Catalog number
- D Serial number
- E Country of origin
- F Manufacturing date
- G [Applicable symbols](#)
- H Authorized representative in the European Community
- I Manufacturer

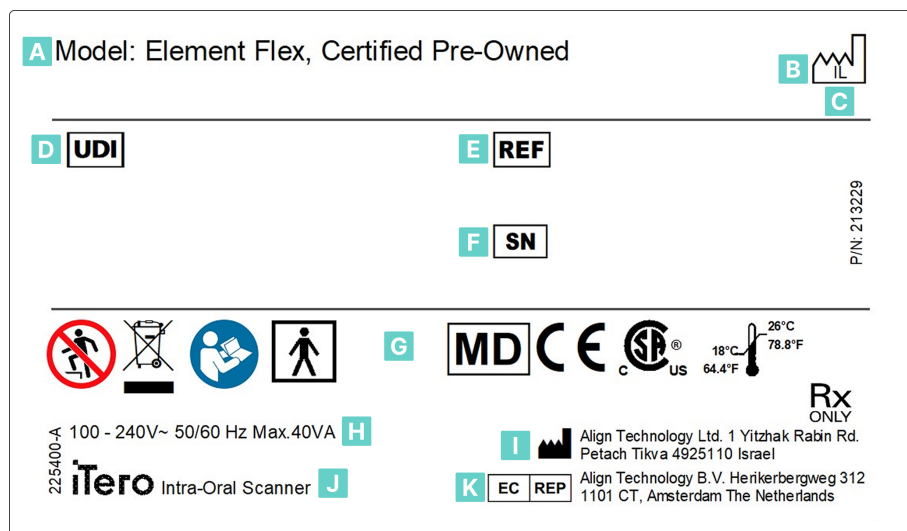
E.5 Hub labels

E.5.1 Hub label - iTeror Element Flex



- A Model name
- B Country of origin
- C Manufacturing date
- D Unique Device Identifier
- E Catalog number
- F Serial number
- G [Applicable symbols](#)
- H Electrical rating
- I Manufacturer
- J Brand name
- K Authorized representative in the European Community

E.5.2 Hub label - iTeror Element Flex (Certified pre-owned)



- A Model name
- B Country of origin
- C Manufacturing date
- D Unique Device Identifier
- E Catalog number
- F Serial number
- G [Applicable symbols](#)
- H Electrical rating
- I Manufacturer
- J Brand name
- K Authorized representative in the European Community



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

© 2026 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. 218501 Rev. E

