



User manual

iTero Lumina™

iTero Lumina™ PC-configuration

Intraoral scanners



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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 product 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

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** - When used as directed, the iTero scanner's level of electromagnetic radiation is similar to that of a personal computer.
- **Laser and LED radiation** - The iTero scanner is classified as a Class 1 Laser product and as Group 1 for LED radiation.

Symbols

The following symbols may appear on iTero Lumina hardware components and may appear within this document and other iTero Lumina 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 B applied part	To identify a type B 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

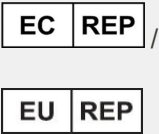
Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Waste electrical and electronic equipment (WEEE)	<p>Separate collection of electrical waste and electronic equipment is required. In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE), do not dispose of this product in domestic or municipal waste. This device contains WEEE materials.</p> <p>Contact your local Customer Support to arrange scanner collection.</p>	<p>EN 50419</p> <p>Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE).</p>	N/A
	Caution	<p>Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.</p>	EN/ISO 15223-1*	5.4.4
	Atmospheric pressure limitation	<p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p>	EN/ISO 15223-1*	5.3.9

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	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
	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

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	EN/ISO 15223-1*	5.3.2
	Prescription device	CAUTION: Rx Only. 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.
	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

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	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
	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
	Use-by date	Indicates the date after which the medical device is not to be used.	EN/ISO 15223-1*	5.1.4

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Warning; Laser beam	To warn of a laser beam. Class 1 laser product.	EN/ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs.	W004
	Importer	Indicates the entity importing the medical device into the locale.	EN/ISO 15223-1*	5.1.8
	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.	N/A	N/A
	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
 (iTero Lumina scanners only)	Regulatory Compliance Mark (RCM)	Australian RCM label	AS/NZS 4417.1:2012 Regulatory Compliance Mark For Electrical And Electronic Equipment	N/A
 (iTero Lumina scanners only)	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.

Laser and LED safety

- The iTero Lumina wand is classified as a class 1 laser product per IEC 60825-1, Safety of laser products, and Group 1 per IEC 62471, Photobiological safety of lamp and lamp systems (LED).
- **Warning:** Avoid eye contact with the laser beam or the flickering white LED emission. Eye contact could cause damage to the eyes.
- **Warning:** Avoid activating the wand while the tip of the wand is outside the patient's mouth, in order to reduce the risk of eye damage.
- **Warning:** In order to prevent eye contact:
 - Avoid shining the wand directly into anyone's eyes.
 - Avoid activating the wand while the tip of the wand is outside the patient's mouth.
 - Avoid placing the wand in the cradle while the scanning operation is still active.
 - Place the wand in the cradle with the optical window facing the cradle.
- For additional protection, it is recommended that children wear protective eyewear during scanning procedures.
- The wand emits blue laser light (450nm Class 1), green laser light (520nm Class 1), as well as white LED emissions. Avoid shining the wand directly into anyone's eyes.

Power supply

Power is supplied to the system via a medical-grade power supply. In iTero Lumina cart-configuration scanners, the power supply is enclosed in the base of the wheel stand. In iTero Lumina mobile-configuration scanners, the power supply is external. In the rest of the iTero Lumina family of products, the power supply is external.

Battery power^{*}

- Charging – the scanner battery will be fully charged after being plugged into a power source for 2.5 hours.
- A fully-charged battery supports a total of 30 minutes scanning using the cart-configuration scanner, or 10 minutes using the mobile-configuration scanner.

Cart-configuration scanners are provided with two Li-ion rechargeable battery packs. Mobile-configuration scanners are provided with one battery pack. The battery packs are placed in the back bottom half of the computing unit.

CAUTION: There is a danger of battery burning and/or explosion if the screen is damaged and/or the battery is not replaced according to Align's instructions. 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.

^{*}Not relevant for iTero Lumina PC configuration scanners. Refer to the computer manufacturer's safety instructions.

- **CAUTION:** 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 batteries supplied by Align for your specific device configuration.

Electric warnings

- **Warning:** Do not remove external panels and covers in order to avoid electrical shock. There are no user-serviceable parts inside. In iTero Lumina scanners, you may open the cover of the diagnostics panel in case of system failure, only when required by Customer Support.
- **Warning:** Do not connect any non-Align-approved external devices such as webcams, USB devices, LAN, or other mains-operated equipment, in order to avoid electrical shock.
- **Warning:** Do not remove and replace batteries without first disconnecting the power cable from the mains, and disconnecting the screen power cable.
- **Warning:** Do not connect the scanner to a mains supply without protective grounding, in order to avoid the risk of electrical shock.
- **Warning:** Use only the supplied power cable, which has a protective earth lead. Do not connect a power cable that is not supplied by Align Technology and/or do not use a power strip or extension cord to connect to the system in order to avoid electrical shock.

iTero Lumina PC configuration:

- **Warning:** The computer and all its accessories should be located at least 1.5m away from the patient. Do not scan a patient and touch the computer or any of its accessories at the same time. Not following these instructions may lead to electrical shock.
- **Warning:** When the laptop is being used, it must be connected to an external power source while scanning.
- **Warning:** Use only the medical-grade power adapter supplied by Align Technology.
- Do not connect anything besides the iTero wand and the off-the-shelf laptop or personal computer to the USB sockets on the interface box.
- During the medical procedure, do not touch the iTero Lumina interface box and the power adapter.

Wireless LAN*	<ul style="list-style-type: none">• The system comes equipped with a wireless LAN unit.• Warning: Never connect the LAN cable to the scanner, to avoid electrical shock.• 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	<ul style="list-style-type: none">• Type of protection against electrical shock: Class 1.• Type of applied part: Type B.• Degree of protection against harmful ingress of water: Ordinary.• Equipment not suitable for use in the presence of flammable anesthetic mixtures.• Mode of operation: Continuous.
Prescription health device	The system serves as a prescription medical device and should be operated by trained dental healthcare providers only.
Scanner warnings	<ul style="list-style-type: none">• Warning: When the system is not in use, the wand should be placed in the cradle with the optical window facing the cradle.• Warning: Avoid using the wand without a disposable sleeve in order to reduce the risk of cross-contamination, discomfort, and even burns.• CAUTION: Avoid twisting, knotting, pulling, and stepping on the wand cable and the power cable.• Warning: 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. As soon as any damage is observed, stop scanning immediately, disconnect the system from the electricity, and call Customer Support.• Warning: Do not clean, disinfect, or use the wand if any damage is found. Please contact iTero Customer Support for further instructions.• Warning: Do not use the wand if any damage is found on the optical surface. Please contact iTero Customer Support for further instructions.• Warning: Do not use the wand if any damage is detected. Please contact iTero Support for further instructions.• CAUTION: Do not use the cradle if any damage is detected. Please contact iTero Customer Support for further instructions.• CAUTION: Do not clean, disinfect, or use the cradle if any damage is detected. Please contact iTero Customer Support for further instructions.• CAUTION: Do not use the scanner screen if any damage is found. Please contact iTero Customer Support for further instructions.

*Not relevant for iTero Lumina PC configuration scanners

Cleaning & disinfection

In order to reduce the risk of cross-contamination, it is mandatory to adhere to the following:

- Thoroughly [clean and disinfect](#) the wand, cradle, and other system components before first use and immediately after each use. [Apply a new sleeve](#) before each patient.
- **Warning:** When disinfecting the wand, cradle, and other system components, use multiple fresh wipes, as necessary, to keep the system component surfaces wet for the full contact time, as recommended by the applicable disinfection wipes manufacturer.
- **Warning:** Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials to reduce the risk of biological hazards.
- Disinfect the touchscreen immediately after each patient.
- **Warning:** Remove and replace gloves after each patient session. Discard torn, contaminated, or removed gloves.
- **Warning:** Replace the iTero Lumina sleeve between each patient. Failing to replace the sleeve between patients may cause the inadvertent transfer of microorganisms and other contaminants from one patient to another.
- A new iTero Lumina sleeve or the protective sleeve may be applied to the wand after cleaning and disinfection have been performed.

Unpacking & installing

The system should be [unpacked and installed](#) following Align Technology's instructions.

CAUTION: Contact Customer Support if the scanner box is damaged. Do not unpack the scanner.

Notes:

- Only an Align-provided webcam may be connected via the USB port, for training purposes.
- The webcam must be disconnected after each training session.
- The webcam lens should be covered when the webcam is not actively in use.

Work environment

- **Warning:** The system should be moved between rooms with utmost care to avoid damage.
- **CAUTION:** Do not cover/block the air vents on the wand and the computing unit.
- iTero Lumina scanners: The system is intended for indoor use only. It should not be exposed to direct sunlight, excessive heat, or humidity.
- iTero Lumina mobile and laptop-configuration scanners: 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

The device with its scanner sleeve 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 electromagnetic interference and immunity in a typical clinic electromagnetic environment. Do not connect the device to any external devices or accessories during clinical use, including the webcam.

Avoid placing this device near frequency transmitting equipment including wireless products or other sources of electrical and electromagnetic interference (e.g. 5G cellular/cellular phones, mobile two-way radios, electrical appliances, RFID, MRI, diathermy, electrocautery, wireless power transfer (WPT)). 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.

Maintain minimal separation distance in accordance with the [recommended separation distances](#) between portable and mobile RF communications equipment and the iTero Lumina intraoral scanner.

Warning for Lumina scanners: Keep the wand's cradle 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, pacemakers, stents, and shunts.

Warning for iTero Lumina PC-configuration scanners: Keep the wand's cradle and interface box 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, pacemakers, stents, and shunts.

iTero Lumina PC configuration: In the event of a sharp drop in the input mains voltage, the system will not operate but will remain safe for the user. The system will return to its working state after the voltage returns to its nominal values.

General**Notes:**

- Do not make any modifications to this equipment.
- Use only on patients who are able to comply with directions.
- Cart configuration only: Do not remove the computing unit from the stand after assembly.
- Follow the instructions to [store the wand \(probe\) tip](#) under proper conditions.
- Follow the instructions to properly [clean and disinfect the device](#).
- Follow the instructions to properly [maintain and handle the instrument](#) in the specified manner and condition.
- Do not connect any non-Align-approved external devices such as webcams, USB devices, LAN, or other mains-operated equipment.

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.

iTero Lumina sleeves

- **Warning:** The iTero Lumina sleeves are intended for single use only. Do not reuse.
- **Warning:** The iTero Lumina sleeves are intended for single use and must be disposed of and replaced after each patient in order to reduce the risk of cross-contamination.
- **Warning:** To reduce the risk of cross-contamination, it is essential that the iTero Lumina scanner is fully cleaned and disinfected immediately after each patient, and that the [iTero Lumina sleeve is replaced](#) between patients.
- **CAUTION:** Do not use the iTero Lumina sleeves after the expiry date.
- **Warning:** If you notice any damage, do not use the iTero Lumina sleeves and contact Customer Support.
- iTero Lumina sleeves are supplied as non-sterile and should **not** be sterilized before usage.
- iTero Lumina sleeves comply with the applicable parts of ISO 10993 Biocompatibility international standard.
- **CAUTION:** Dispose of iTero Lumina sleeves according to standard operating procedures or local regulations for disposal of contaminated waste.

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 : Perturbations électromagnétiques -
Exigences et essais.

Conformité du produit laser de classe 1

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



Class 1 Laser Product

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.



R-NZ

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 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 au règlement (UE) 2017/745
sur les dispositifs médicaux.



Contre-indications – French

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

Nature du rayonnement émis par le scanner – French

- **Rayonnement électromagnétique** — Lorsqu'il est utilisé comme indiqué, le niveau de rayonnement électromagnétique du scanner iTero est similaire à celui d'un ordinateur personnel.
- **Laser et rayonnement DEL** — Le scanner iTero est classé comme un produit laser de classe 1 et comme Groupe 1 pour le rayonnement DEL.

Symboles – French

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

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 B	Pour identifier une pièce appliquée de type B 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
	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

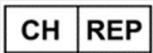
Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Déchets d'équipements électriques et électroniques (DEEE)	<p>Une collecte séparée des déchets électriques et des équipements électroniques est requise. Conformément à la directive européenne sur les déchets d'équipements électriques et électroniques (DEEE), ne jetez pas ce produit avec les déchets ménagers ou urbains. Cet appareil contient des matériaux DEEE.</p> <p>Veuillez contacter votre service client local pour organiser la collecte du scanner.</p>	<p>EN 50419</p> <p>Marquage des équipements électriques et électroniques (EEE) en ce qui concerne la collecte séparée des déchets d'EEE (DEEE).</p>	N/A
	Attention	Indique qu'il faut être prudent lors de l'utilisation de l'appareil ou de la commande à proximité de l'endroit où le symbole est placé, ou que la situation actuelle nécessite une sensibilisation de l'opérateur ou une action de l'opérateur afin d'éviter des conséquences indésirables.	EN/ISO 15223-1*	5.4.4

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	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
	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 numérisation..	N/A	N/A

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Identifiant unique de l'appareil	Signale un support qui contient les informations concernant un identifiant unique de l'appareil.	EN/ISO 15223-1*	5.7.10
	Pays de fabrication (y compris la date de fabrication).	<p>Identifier le pays de fabrication des produits.</p> <p>La date de fabrication est située à côté du symbole.</p>	EN/ISO 15223-1*	5.1.11
	Ne pas exposer directement aux rayons du soleil	Indique un dispositif médical qui doit être protégé des sources de lumière.	EN/ISO 15223-1*	5.3.2
	Dispositif sur ordonnance	ATTENTION : Sur ordonnance uniquement. 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 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

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	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
	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

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	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	N/A	N/A
	Veille	Identifier le bouton-poussoir de mise sous tension/veille.	CEI 60417 Symboles graphiques à utiliser sur l'équipement.	5009
	Utiliser avant le	Indique la date après laquelle l'appareil médical ne doit plus être utilisé.	EN/ISO 15223-1*	5.1.4
	Avertissement; Faisceau laser	Pour avertir d'un faisceau laser. Produit laser de classe 1	EN/ISO 7010 Symboles graphiques — Couleurs de sécurité et signaux de sécurité — Signaux de sécurité enregistrés.	W004
	État importateur	Indique l'entité qui importe le dispositif médical dans les paramètres régionaux.	EN/ISO 15223-1*	5.1.8

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Représentant agréé suisse	Indique le représentant autorisé en Suisse.	MU600_00_016 version 5.0 Obligations des opérateurs économiques en Suisse.	N/A
	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.	N/A
	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.	N/A	N/A
 / 	Représentant autorisé dans la Communauté européenne/l'Union européenne	Représentant autorisé dans la Communauté européenne/Union européenne	EN/ISO 15223-1*	5.1.11

Symbole	Nom du symbole	Description du symbole	Numéro et nom standard	Numéro de référence du symbole
	Il est interdit de monter sur l'appareil.	Indique qu'il ne faut pas monter sur la surface.	ISO 7010:2020	P019
 (Scanners iTero Lumina uniquement)	Marque de conformité réglementaire (RCM)	Étiquette RCM australienne	AS/NZS 4417.1:2012 Marque de conformité réglementaire pour les appareils électriques et électroniques	N/A
 (Scanners iTero Lumina uniquement)	Marque R-NZ	Étiquette radio néo-zélandais	Radiocommunications (Conformité) Avis 2020	N/A

***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 – French

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.

Sécurité relative aux lasers et aux DEL

- La tige iTero Lumina est classée en tant que produit laser de classe 1 selon la norme CEI 60825-1, Sécurité des produits laser, et groupe 1 selon la norme CEI 62471, Sécurité photobiologique des lampes et des systèmes de lampes (DEL).
- **Avertissement** : Évitez tout contact visuel avec le faisceau laser ou l'émission de DEL blanche scintillante. Le contact avec les yeux peut les endommager.
- **Avertissement** : Évitez d'activer la tige lorsque la pointe de celle-ci se trouve en dehors de la bouche du patient, afin d'éviter des lésions oculaires.
- **Avertissement** : Afin d'éviter tout contact visuel :
 - Évitez de diriger la lumière de la tige directement dans les yeux de quelqu'un.
 - Évitez d'activer la tige lorsque son extrémité se trouve à l'extérieur de la bouche du patient.
 - Évitez de placer la tige dans le socle tant que l'opération de scan est toujours active.
 - Placez la tige dans le socle avec la fenêtre optique tournée vers le socle.
- Pour une protection supplémentaire, il est recommandé que les enfants portent des lunettes de protection pendant les procédures de scan.
- La tige émet une lumière laser bleue (450 nm de classe 1), une lumière laser verte (520 nm de classe 1), ainsi que des émissions de DEL blanches. Évitez de diriger la lumière de la tige directement dans les yeux de quelqu'un.

Alimentation électrique

Le système fonctionne sur une alimentation interne de qualité médicale. Dans les scanners de configuration de chariot iTero Lumina, l'alimentation électrique est enfermée dans la base du support de roue. Dans les scanners de configuration mobile iTero Lumina, l'alimentation électrique est externe. Dans le reste de la famille de produits iTero Lumina, l'alimentation est externe.

Alimentation par batterie *

- Recharge – la batterie du scanner est complètement chargée après avoir été branchée à une source d'alimentation 2.5 heures
 - Une batterie entièrement chargée permet une durée total de 30 minutes de scan en utilisant le scanner de configuration de chariot, ou 10 minutes en utilisant le scanner de configuration mobile.
- Les scanners de configuration de chariot sont fournis avec deux batteries rechargeables Li-ion.

* Ceci ne concerne pas les scanners iTero Lumina PC configuration. Consulter les consignes de sécurité du fabricant de l'ordinateur.

Les scanners de configuration mobile sont fournis avec un bloc-batterie. Les blocs-batteries sont placés dans la moitié inférieure arrière de l'unité informatique.

ATTENTION : Il existe un risque de combustion et/ou d'explosion de la batterie si l'écran est endommagé et/ou si la batterie n'est pas remplacée conformément aux instructions d'Align. Ne pas utiliser le scanner s'il est tombé ou si des dommages sont constatés. Contacter le service client.

- Utiliser uniquement l'adaptateur CA/CC d'origine connecté au système pour charger les batteries.
- **ATTENTION** : une batterie Li-ion défaillante 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 des piles fournies par Align pour la configuration spécifique de votre appareil.
- **Avertissement** : 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 Lumina, vous pouvez ouvrir le couvercle du panneau de diagnostic en cas de défaillance du système, uniquement lorsque le SAV l'exige.
- **Avertissement** : Ne connecter aucun appareil externe non approuvé par Align tel que des webcams, des périphériques USB, un réseau local ou d'autres appareils fonctionnant sur secteur, afin d'éviter un choc électrique.
- **Avertissement** : Ne pas ôter ou remplacer les batteries sans avoir débranché au préalable le câble d'alimentation du secteur et déconnecté le câble d'alimentation de l'écran.
- **Avertissement** : Ne connectez pas le scanner à une alimentation principale sans prise terre, afin d'éviter tout choc électrique.
- **Avertissement** : Utiliser uniquement le câble d'alimentation fourni, qui a un fil de terre de protection. Ne connectez pas un câble d'alimentation qui n'est pas fourni par la Align Technology et/ou n'utilisez pas de câble électrique ou de rallonge pour la connexion au système afin d'éviter les chocs électriques.

Avertissements électriques

iTero Lumina PC configuration:

	<ul style="list-style-type: none"> • Avertissement : L'ordinateur 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. • Avertissement : Lorsque l'ordinateur portable est utilisé, il doit être connecté à une source d'alimentation externe pendant le scan. • Avertissement : Utilisez uniquement l'adaptateur électrique de qualité médicale fourni par Align Technology. • Ne connectez rien d'autre que la tige iTero et l'ordinateur portable ou personnel standard aux prises USB du concentrateur. • Pendant la procédure médicale, ne touchez pas l'iTero Lumina concentrateur et l'adaptateur d'alimentation.
Réseau local sans fil *	<ul style="list-style-type: none"> • Le système fourni est équipé d'une unité de réseau local sans fil. • Avertissement : Ne jamais connecter le câble de réseau local au scanner, afin d'éviter un choc électrique. • 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	<ul style="list-style-type: none"> • Type de protection contre les chocs électriques : Classe 1. • Type de pièce appliquée : Type B. • 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	Ce système est un dispositif médical soumis à prescription médicale et doit être utilisé par trained dentaire Réserve aux professionnels de santé.
Avertissements relatifs au scanner	<ul style="list-style-type: none"> • Avertissement : Lorsque le système n'est pas utilisé, la tige doit être placée dans le socle, la fenêtre optique faisant face au socle. • Avertissement : Éviter d'utiliser la tige sans manchon jetable afin de réduire le risque de contamination croisée, d'inconfort et même de brûlures. • ATTENTION : Évitez de tordre, de nouer, de tirer ou de marcher sur le câble de la tige et le câble d'alimentation. • Avertissement : 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. Dès que des dommages sont observés, arrêtez immédiatement le scan, débranchez le système de l'alimentation et appelez le service client. • Avertissement : Ne pas nettoyer, ne pas désinfecter et ne pas utiliser la tige en cas de dommage. Veuillez contacter le service client iTero pour plus d'instructions.

* Ceci ne concerne pas les scanners iTero Lumina PC configuration

- **Avertissement** : Ne pas utiliser la tige en cas de dommages à la surface optique. Veuillez contacter le service client iTero pour plus d'instructions.
- **Avertissement** : Ne pas utiliser la tige si des dommages sont détectés. Veuillez contacter le service clients iTero pour plus d'instructions.
- **ATTENTION** : Ne pas utiliser le socle si des dommages sont détectés. Veuillez contacter le service client iTero pour plus d'instructions.
- **ATTENTION** : Ne pas nettoyer, ne pas désinfecter et ne pas utiliser le socle en cas de dommage. Veuillez contacter le service client iTero pour plus d'instructions.
- **ATTENTION** : Ne pas utiliser l'écran du scanner si des dommages sont constatés. Veuillez contacter le service client iTero pour plus d'instructions.

Nettoyage & désinfection

Afin de réduire le risque de la contamination croisée, il est obligatoire de respecter ce qui suit :

- [Nettoyer et désinfecter](#) soigneusement la tige, le socle et les autres composants du système avant la première utilisation et immédiatement après chaque utilisation. [Appliquer une nouvelle manchon](#) avant chaque patient.
- **Avertissement** : Lors de la désinfection de la tige, du socle et d'autres composants du système, utilisez plusieurs lingettes fraîches, si nécessaire, pour garder les surfaces des composants du système humides pendant toute la durée du contact, comme recommandé par le fabricant de lingettes de désinfection concerné.
- **Avertissement** : Évitez de modifier le processus de nettoyage et de désinfection recommandé et de modifier ou remplacer les matériaux recommandés afin d'éviter les risques biologiques.
- Désinfecter l'écran tactile immédiatement après chaque patient.
- **Avertissement** : Enlever et remplacer les gants après chaque patient. Jetez les gants déchirés, contaminés ou déjà enlevés.
- **Avertissement** : Remplacez le Manchon iTero Lumina entre chaque patient. Ne pas changer la manchon entre les patients peut entraîner le transfert de micro-organismes et d'autres contaminants d'un patient à un autre par inadvertance.
- Un nouveau Manchon iTero Lumina ou le manchon de protection peut être appliqué sur la tige après le nettoyage et la désinfection.

Déballage et installation

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

ATTENTION : Contactez l'assistance client si le boîtier du scanner est endommagé. Ne pas déballer le scanner.

Remarques :

- Seule une webcam fournie par Align peut être connectée au port USB, à des fins de formation.
- La webcam doit être déconnectée après chaque séance de formation.
- L'objectif de la webcam doit être recouvert lorsque celle-ci n'est pas utilisée.

Environnement de travail

- **Avertissement:** Le système doit être déplacé d'une pièce à une autre avec le plus grand soin pour éviter de l'endommager.
- **ATTENTION :** Ne pas couvrir/bloquer les bouches d'aération sur la tige et l'unité informatique.
- iTero Lumina scanners: Ce système est destiné à un usage exclusivement intérieur. Il ne doit pas être exposé directement à la lumière du soleil, à une chaleur excessive ou à l'humidité.
- iTero Lumina 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

L'appareil avec son scanner manchon 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 et une immunité dans une installation médicale classique. Ne connectez pas l'appareil à des appareils ou accessoires externes, y compris la webcam, pendant une utilisation clinique.

Éviter de placer cet appareil à proximité d'équipements de transmission de fréquence y compris des produits sans fil ou d'autres sources d'interférences électriques et électromagnétiques (par exemple, téléphones portables/5G, radios mobiles bidirectionnelles, appareils électriques, RFID, IRM, diathermie, électrocautérisation, transfert d'énergie sans fil (WPT)). 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.

Maintenir une distance de séparation minimale conformément aux [distances de séparation recommandées](#) entre l'équipement de communication RF portable et mobile et le système d' iTero Lumina imagerie dentaire du.

Avertissement pour Lumina scanners: Maintenez le socle de la baguette à une distance de 6 pouces (15 cm) des dispositifs médicaux sensibles aux champs magnétiques, tels que les implants cochléaires, les neurostimulateurs, les stimulateurs cardiaques, les stents et les shunts.

Avertissement iTero Lumina PC-configuration scanners: Conservez le support de la baguette et concentrateur à une distance de 6 pouces (15 cm) des dispositifs médicaux sensibles au champ magnétique, tels que les implants cochléaires, les neurostimulateurs, les stimulateurs cardiaques, les stents et les shunts.

iTero Lumina PC configuration : En cas de chute brutale de la tension d'alimentation, le système ne fonctionnera pas, mais restera sans danger pour l'utilisateur. Le système reviendra à son état de fonctionnement lorsque la tension reviendra à ses valeurs nominales.

Informations générales

Remarques :

- N'apportez aucune modification à cet équipement.
- À utiliser uniquement sur les patients en mesure de se conformer aux instructions.

- Configuration du chariot uniquement : Ne pas retirer l'unité informatique du support après l'assemblage.
- Suivez les instructions pour [conserver l'embout de la tige \(sonde\)](#) dans des conditions adéquates.
- Suivez les instructions pour [nettoyer et désinfecter correctement le dispositif](#).
- Suivez les instructions pour [entretenir et manipuler l'instrument](#) de la manière et dans les conditions spécifiées.
- Ne connecter aucun appareil externe non approuvé par Align tel que des webcams, des périphériques USB, un réseau local ou d'autres appareils fonctionnant sur secteur.

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.

Manchons iTero Lumina

- **Avertissement** : Les Manchons iTero Lumina sont destinés à un usage unique. Ne pas les réutiliser.
- **Avertissement** : Les Manchons iTero Lumina sont destinés à un usage unique et doivent être jetés et remplacés après chaque patient afin d'éviter toute contamination croisée.
- **Avertissement** : Pour réduire le risque de contamination croisée, il est essentiel que le iTero Lumina scanner soit entièrement nettoyé et désinfecté immédiatement après chaque patient, et que le [Manchon iTero Lumina soit remplacé](#) Manchon iTero Lumina entre les patients.
- **ATTENTION** : N'utilisez pas les Manchons iTero Lumina après la date de péremption.
- **Avertissement** : Si vous remarquez des dommages, n'utilisez pas les Manchons iTero Lumina et contactez l'assistance client.
- Les Manchons iTero Lumina sont fournis non stériles et **ne doivent pas** être stérilisés avant utilisation.
- Les Manchons iTero Lumina sont conformes aux sections applicables de la norme internationale de biocompatibilité ISO 10993.
- **ATTENTION** : Jetez les Manchons iTero Lumina conformément aux procédures d'utilisation standard ou aux réglementations locales relatives à l'élimination des déchets contaminés.

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1 Introduction to iTero Lumina™ and iTero Lumina™ PC-configuration intraoral scanners

The iTero Lumina™ family of imaging systems is Align Technology's latest generation of intraoral scanners, which 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.

iTero Lumina PC-configuration intraoral scanners are wand-only configurations with any computer that meets our supported system requirements, as specified in <https://itero.com/our-solutions/itero-lumina/pc-configuration-scanner-specs>. They are available with different software packages and different capabilities depending on regulatory and commercial considerations.

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

iTero Lumina and iTero Lumina PC-configuration are intraoral scanners intended to record and display the topographical images of teeth, oral tissue and bite relationship and to obtain optical impressions for use in CAD/CAM of dental devices.

1.2 Indications for use

iTero Lumina scans can be used for computer aided design and manufacturing of restorative dental devices*, orthodontic devices and other dental devices such as night guards and bite splints.

Data generated from iTero Lumina may be used by dental healthcare professionals for assessing intraoral topographical images of hard and soft tissue and visual assessments. iTero Lumina does not treat or diagnose any disease.

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.

*Subject to regulatory or other required approvals and commercial availability in your country/region.

1.4 Intended patient population

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

1.5 Intended users

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

1.6 Use environment

The system may be used in a Professional Healthcare environment.

1.7 Clinical benefits

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

*Children are defined as age 6 onwards, in this context.

1.8 iTero Lumina and iTero Lumina PC-configuration hardware

The iTero Lumina scanner is available in two configurations:

- [iTero Lumina cart configuration](#)
- [iTero Lumina mobile configuration](#)

In addition, the iTero Lumina PC-configuration (iTero Lumina PC cfg model) scanner can be connected to a [laptop or desktop computer](#).

Refer to <https://itero.com/our-solutions/itero-lumina> for the minimum computer system requirements.

1.8.1 iTero Lumina cart configuration

Front view



Figure 1: Front view of the iTero Lumina cart-configuration intraoral scanner

Rear view



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

Figure 2: Rear view of the iTero Lumina cart-configuration intraoral scanner

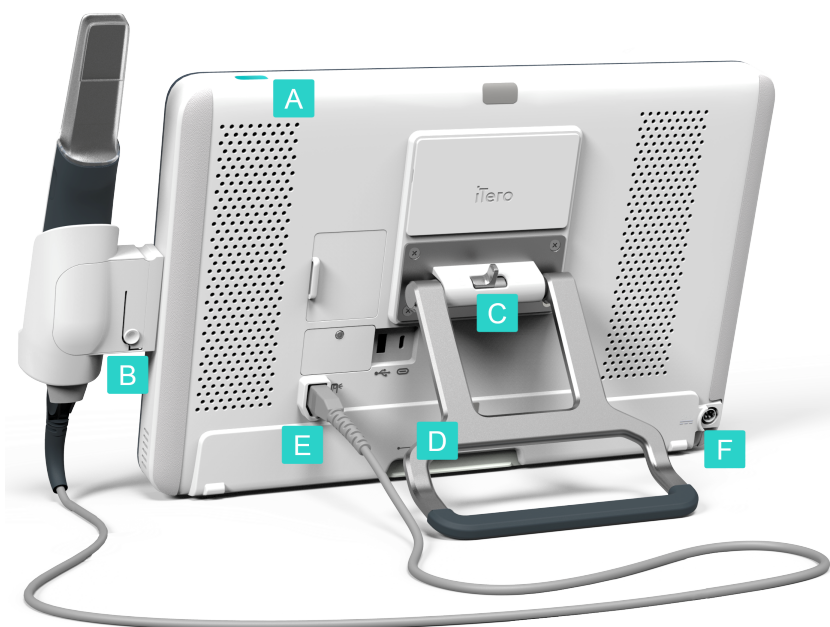
1.8.2 iTero Lumina mobile configuration

Front view



- A Full HD touchscreen
computing unit
- B Power button
- C Wand
- D Cradle

Figure 3: Front view of the iTero Lumina 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 socket

Figure 4: Rear view of the iTero Lumina mobile-configuration intraoral scanner

1.8.3 iTero Lumina PC-configuration scanners

The iTero Lumina PC-configuration scanners can be connected to an off-the-shelf laptop or desktop computer that meets the supported hardware and software system requirements, as specified in <https://itero.com/our-solutions/itero-lumina/pc-configuration-scanner-specs>.

1.8.3.1 iTero Lumina PC-configuration scanner with laptop



- A iTero Lumina wand
- B Cradle
- C Interface box

Figure 5: iTero Lumina PC-configuration scanner – with laptop

1.8.3.2 iTero Lumina PC-configuration scanner with desktop computer



- A iTero Lumina wand
- B Cradle
- C Interface box

Figure 6: iTero Lumina PC-configuration scanner – with desktop computer

1.8.4 iTero Lumina wand

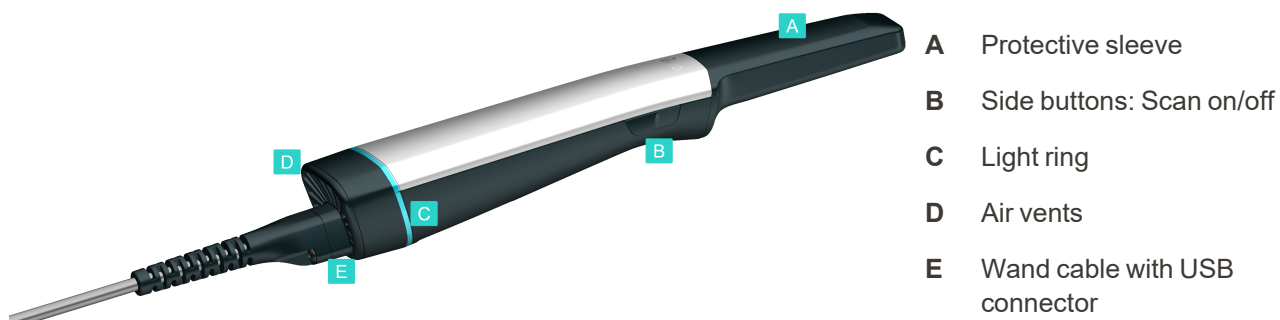


Figure 7: iTero Lumina wand

1.8.4.1 Wand sleeves

iTero Lumina sleeves are suitable for the iTero Lumina family of products. They are a single-use disposable component intended for use as a cover to the iTero Lumina scanner wand to reduce the risk of cross-contamination during the scanning procedure and to protect the optical window of the wand.

There are two types of wand sleeves:

- **Protective sleeve (dark):** 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 8: Protective sleeve

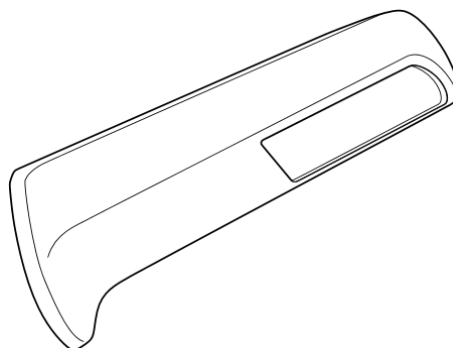


Figure 9: Disposable sleeve

1.8.4.2 Working with the iTero Lumina wand

After being switched on, the iTero Lumina system requires approximately 7 minutes to warm up before initial use. The LED light ring at the base of the wand indicates the state of the wand.

The wand can be in one of the following states:

- **Off** - The wand light ring is turned off.
- **Warming up/Initializing** - The LED light ring flickers slowly (pulsates) while the system is warming up. When you move to Scan mode, a  icon is displayed on the toolbar and the progress of the initialization is displayed. This takes approximately 7 minutes.
- **Standby/Ready/Scanning/Sending** - The LED light ring is turned on and is constant.
- **Maintenance** - The LED light ring flickers quickly indicating that maintenance is in progress. The *Login* page is displayed once the maintenance is complete.
- **Error** - The LED light ring flickers quickly and an error message is displayed on the screen.

To switch the wand on or off when in an active scan, firmly press one of the side buttons on the wand. A sound is emitted indicating that scanning has started or stopped. You can control the volume, as described in [Defining the default volume setting](#).

The wand should always be placed in the cradle with the cable positioned at the base and the optical window facing the cradle (away from you). If the wand is incorrectly placed in the cradle, a message is displayed, prompting you to check the wand placement.

1.9 About this manual

This manual provides general information and an overview of the iTero Lumina and iTero Lumina PC-configuration intraoral scanners and software.

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

Notes for iTero Lumina PC-configuration users:

- This manual describes the scanner operation using a touchscreen. If your computer does not support a touchscreen display, you can use standard Windows [mouse controls](#) to operate the scanner.
- This manual describes the software of the iTero Lumina system. Different features may be available in your region based on regulatory and commercial considerations.

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 computer (laptop or desktop for PC-configuration scanners), 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.

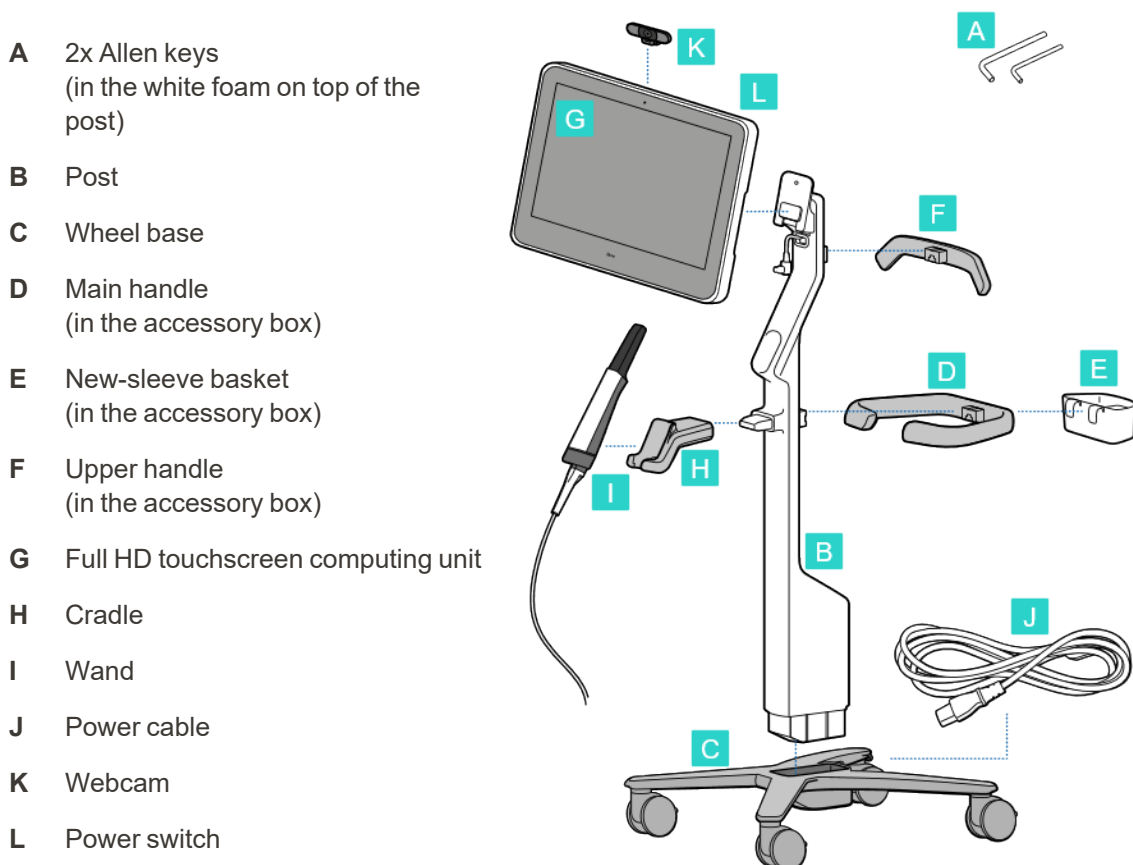
- [Assembling the iTero Lumina scanner – cart configuration](#)
- [Assembling the iTero Lumina scanner – mobile configuration](#)
- [Assembling the iTero Lumina PC-configuration scanner](#)

2.1 Assembling the iTero Lumina scanner – cart configuration

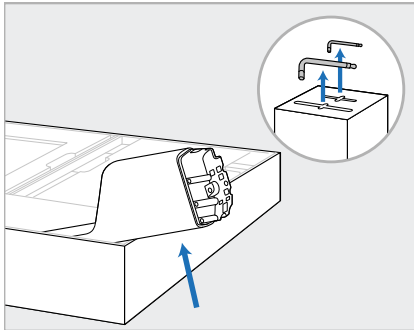
The scanner packaging is designed in a way that provides a simple and easy assembly process.

Before assembling the scanner, read and understand the [safety instructions](#). We recommend assembling the scanner at the point of use.

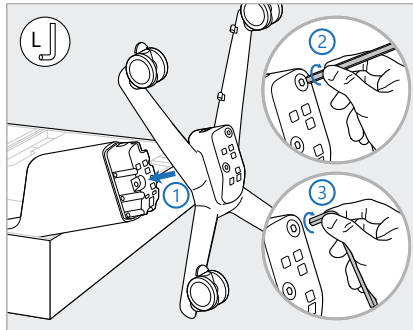
Follow the instructions below to assemble the scanner. Contact iTero Support for additional help.



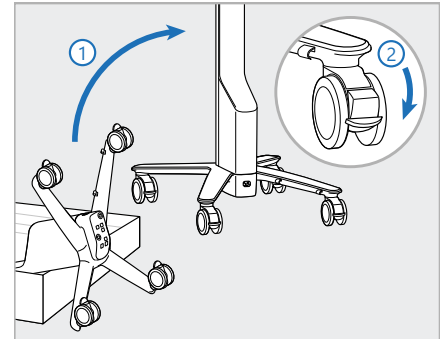
Note: If any damage to the system or accessories is found, do not assemble or use the scanner and contact iTero Support.



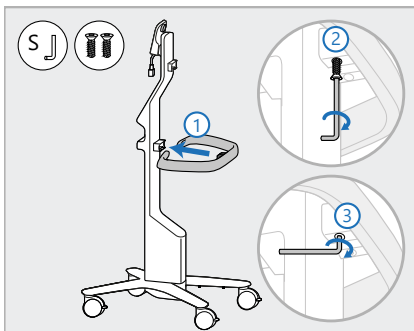
1. Remove all Styrofoam coverings from the box.
Note: The two Allen keys (A) are on top of the Styrofoam covering the post (B).
2. Lift the post (B), pull it out slightly, and rest it on the side of the box.



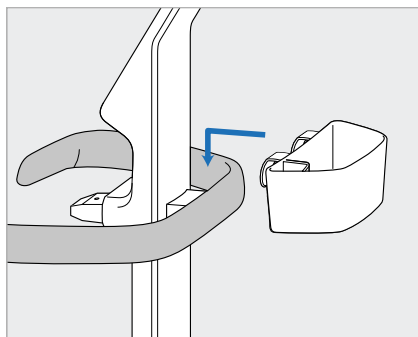
3. Attach the wheel base (C) to the end of the post (B) and tighten using first the longer side of the large Allen key and then the shorter side.



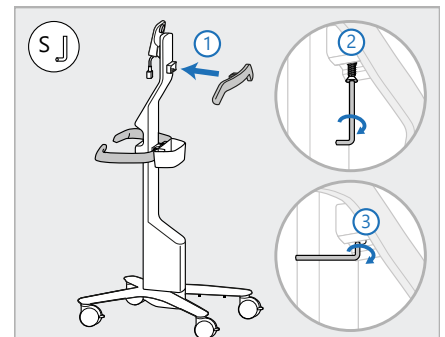
4. Move the wheel stand to an upright position and lock at least two wheels.



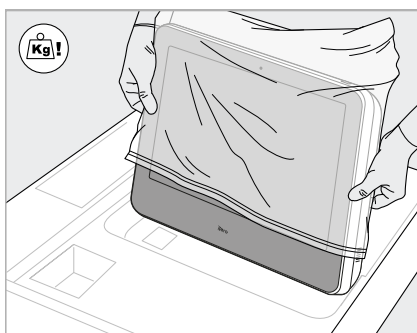
5. Remove the main handle (D) and the two screws from the accessory box. Attach the main handle and tighten using first the longer side of the small Allen key and then the shorter side.



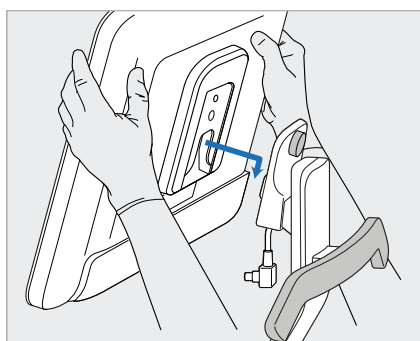
6. Remove the sleeve basket (E) from the accessory box and place it on the back of the main handle (D).



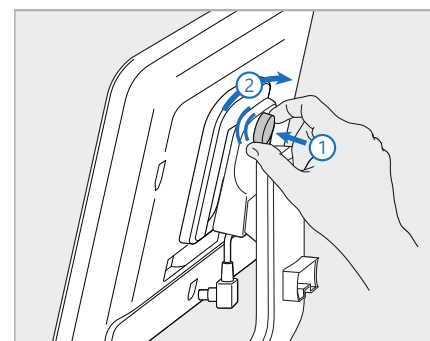
7. Remove the upper handle (F) from the accessory box and remove the pull tab to access the screw.
8. Attach the upper handle (F) to the post (B) and tighten using first the longer side of the small Allen key and then the shorter side.



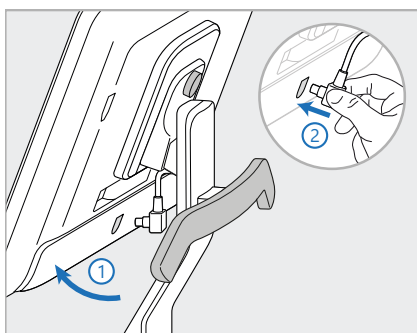
9. Carefully remove the computing unit (G) from its protective wrapping.
Note: The computing unit is heavy and must be lifted carefully.



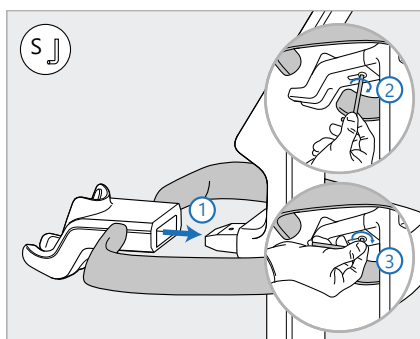
10. Standing behind the wheel stand, mount the computing unit (G) on the metal hinge and push down.
Note: Make sure the computing unit does not press on the screen cable. If it does, move the cable to the side.



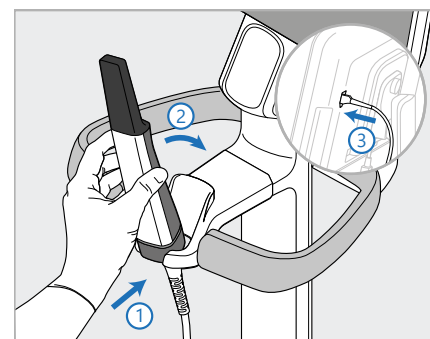
11. Attach the computing unit (G) by pushing in and tightening the screw.



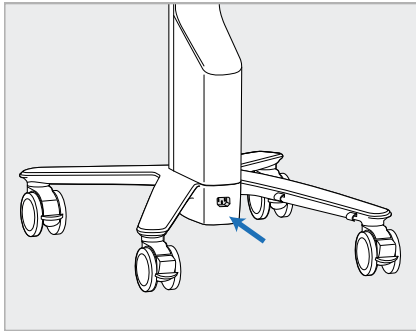
12. If the cable connector is covered, remove the cover.
 Tilt the screen upwards and connect the screen cable.



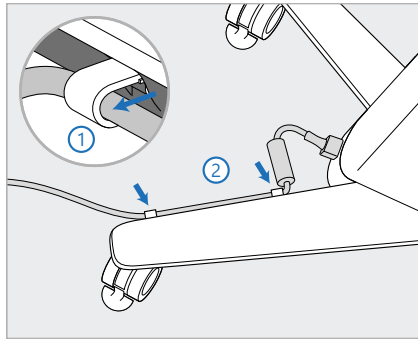
13. Attach the cradle (H) to the post (B) and tighten using first the longer side of the small Allen key and then the shorter side.



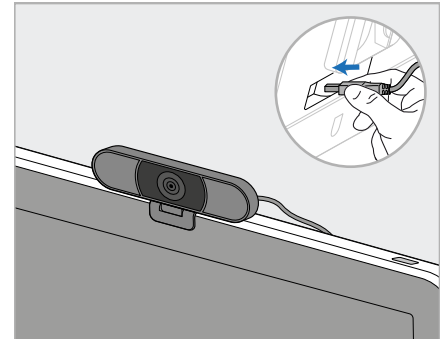
14. Insert the base of the wand (I) in the cradle (H) and then apply gentle pressure to make sure the wand is fully inserted and secure in the cradle.
 15. Connect the wand cable to the back of the screen (G).



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

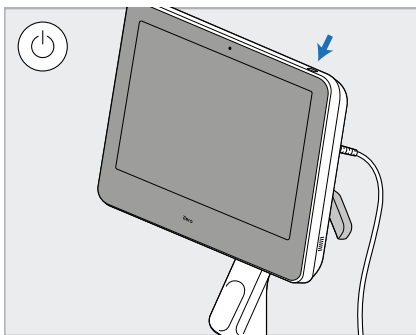


17. Secure the power cable (J) in the two cable clips, making sure it is fully inserted.



18. For remote training 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 session.



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

Notes:

- The webcam lens should be covered when the webcam is not actively in use.
- Always return the wand to the cradle after each use.
- When the system is not in use, the wand should be placed in the cradle with the optical window facing the cradle.
- 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.

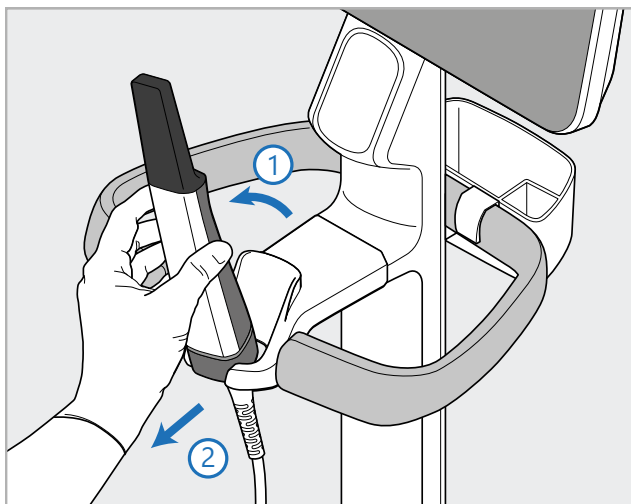


Figure 10: Removing the wand from the cradle

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

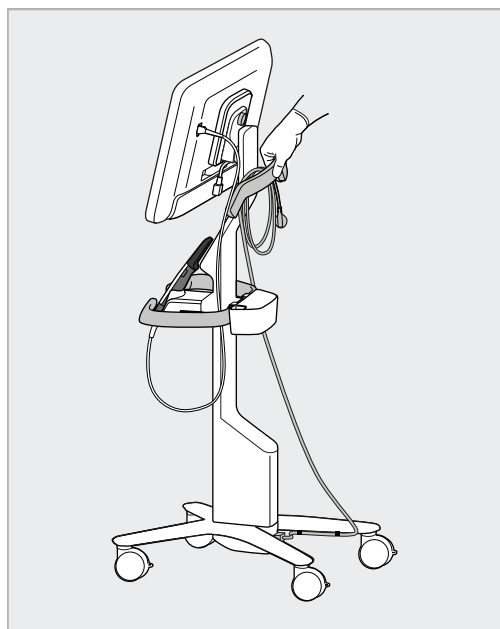


Figure 11: Moving the scanner

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

Do not use the main handle to lift the scanner.

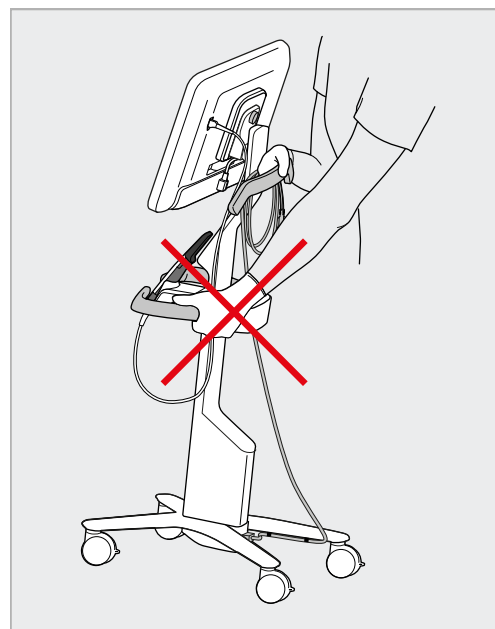


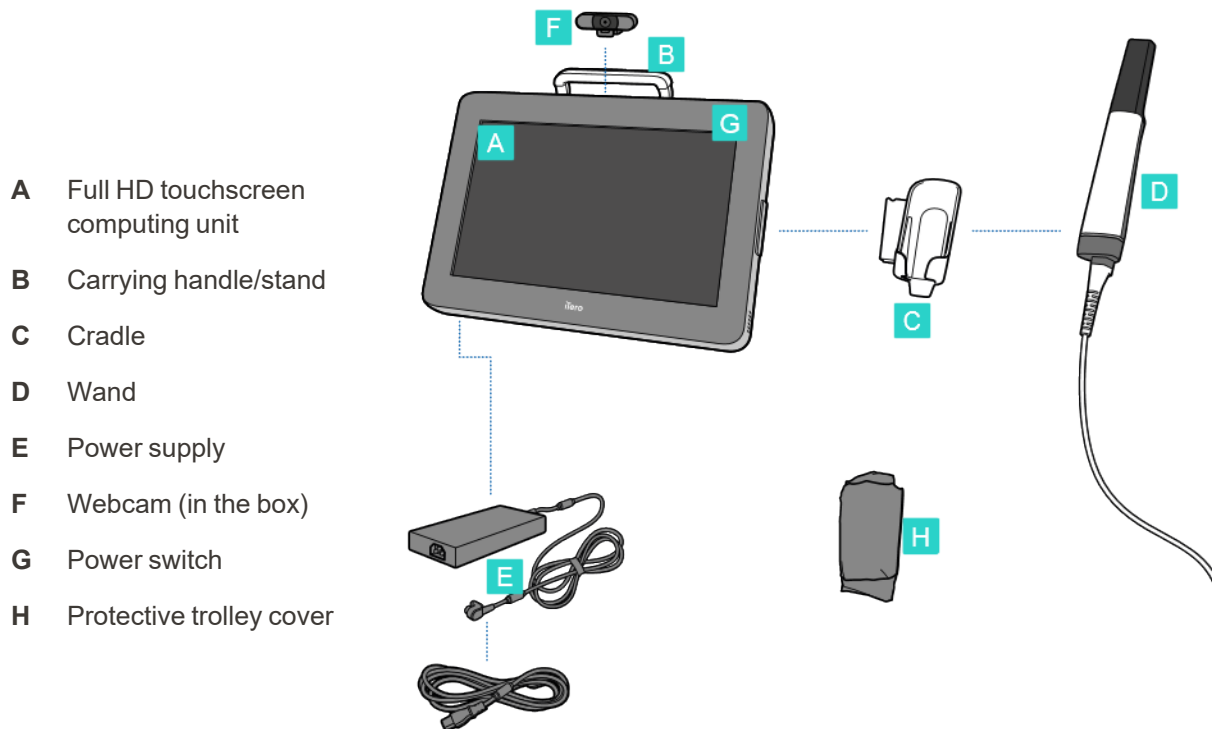
Figure 12: Do not lift the scanner using the main handle

2.2 Assembling the iTero Lumina scanner – mobile configuration

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

Before assembling the scanner, read and understand the [safety instructions](#). We recommend assembling the scanner at the point of use.

Follow the instructions below to assemble the scanner. Contact iTero Support for additional help.

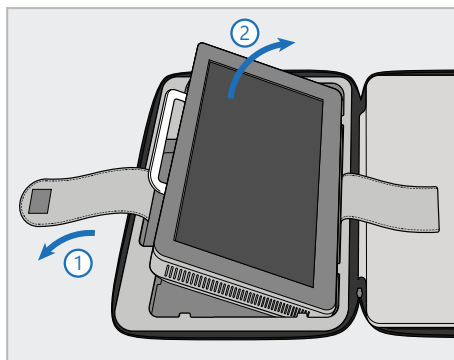


Note: If any damage to the system or accessories is found, do not assemble or use the scanner and contact iTero support.

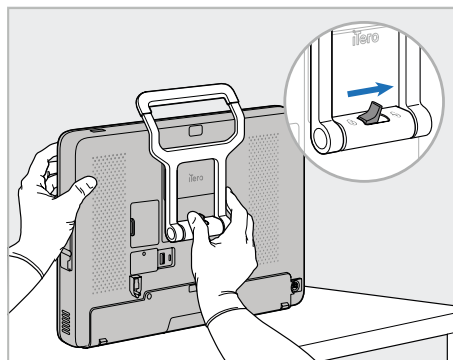
This section describes how to:

- [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](#)

2.2.1 Initial assembly

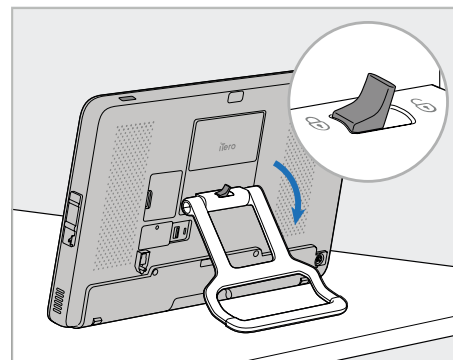


1. Undo the strap holding the computing unit (A), and then remove it using the handle (B).

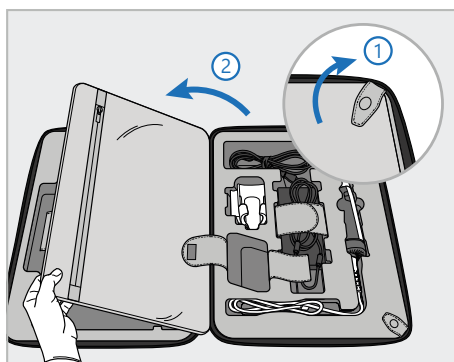


2. Rest the computing unit (A) on a smooth, flat surface and hold it with one hand.

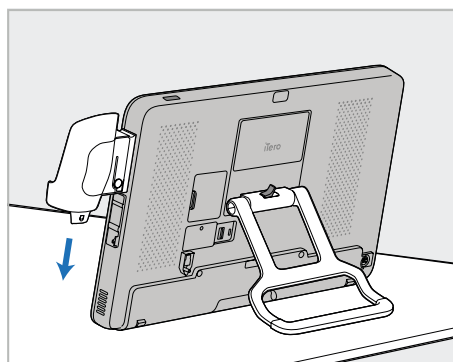
While holding the computing unit, slide the locking latch to the right until you feel a click, to unlock the handle (B).



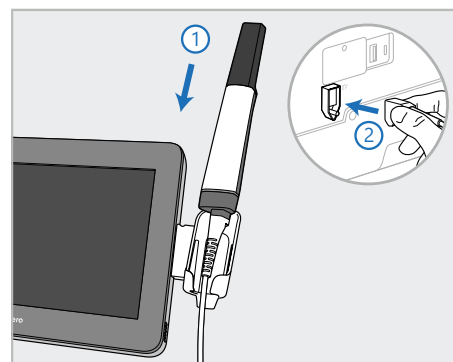
3. Move the handle (B) down to the standing position. Ensure that the handle is securely locked in place by trying to pull it back up.



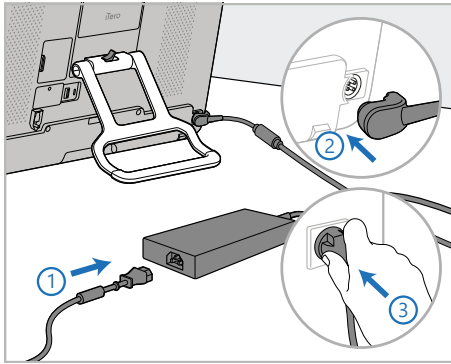
4. Undo the snaps and open the flap to remove the rest of the scanner components.



5. Slide the cradle (C) down along 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.

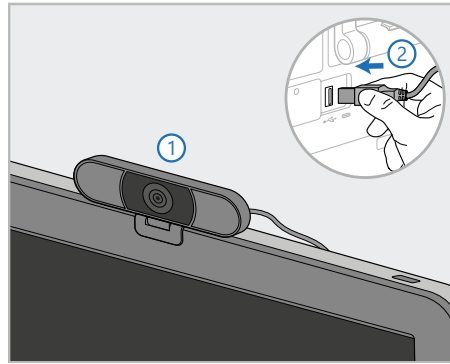


6. Place the wand (D) in the cradle (C) and connect the wand cable to the port marked  at the back of the computing unit (A).



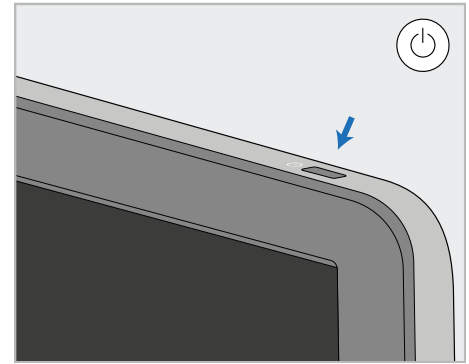
7. Connect the power cable to the power supply (E). Afterwards, connect one side of the cable to the back of the computing unit (A) and the other side to a power outlet.

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



8. For remote training 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.

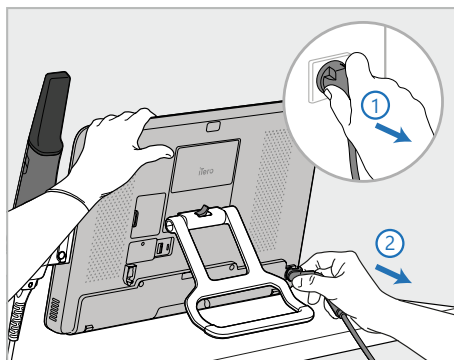
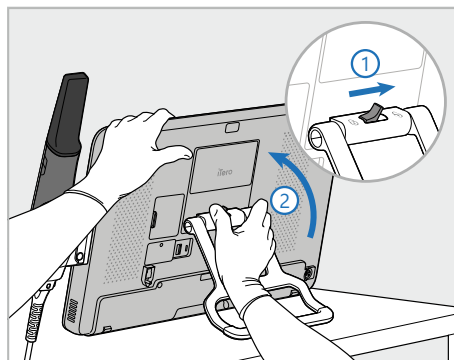
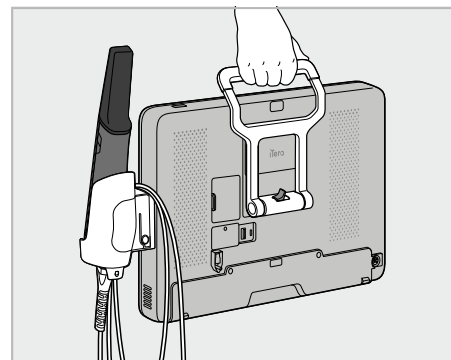


9. Press the power button (G) to turn on the scanner.

Notes:

- The webcam must be disconnected after each training session.
- The webcam lens should be covered when the webcam is not actively in use.
- Always return the wand to the cradle after each use.
- When the system is not in use, the wand should be placed in the cradle with the optical window facing the cradle.
- 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.

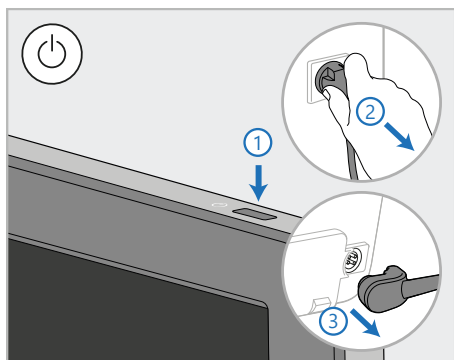
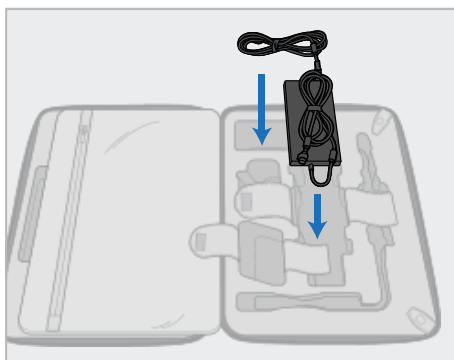
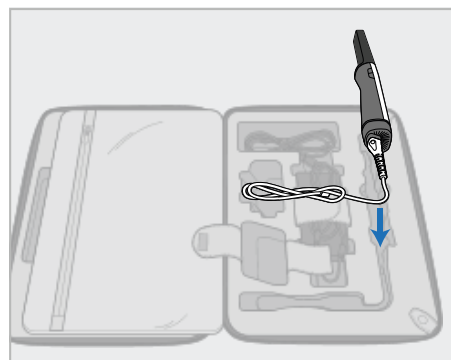
2.2.2 Moving the scanner within the clinic



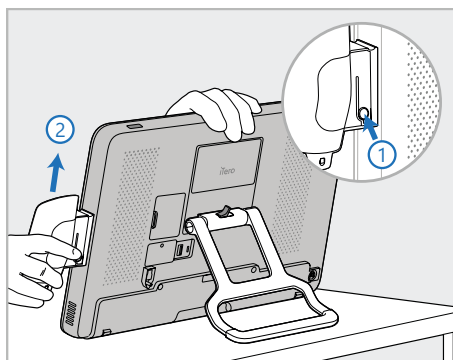
1. Ensure that the wand (D) is firmly positioned in the cradle (C).
2. Disconnect the power cable (E) from the mains and then from the back of the computing unit (A).
3. While holding the computing unit (A) with one hand, slide the locking latch to the right to unlock the handle (B) and then move the handle to the carrying position.
4. Loosely wrap the wand cable around the cradle (C) for easy and safe portability.

2.2.3 Using the trolley for transportation

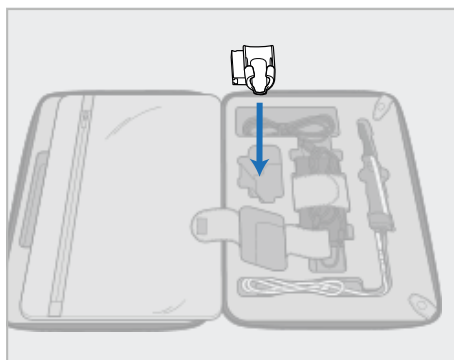
Before transporting the scanner, it must be packed into the supplied trolley.



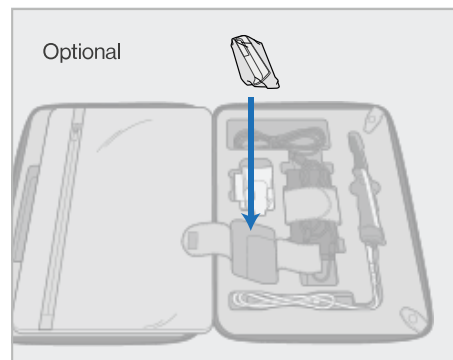
1. Turn off the scanner and disconnect the power cable (E) from the mains and then from the back of the computing unit (A).
2. For easier packing, start by placing the power pack (E) in its designated compartment in the trolley. Wrap the thinner part of the cable and place it on top of the power supply, 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.



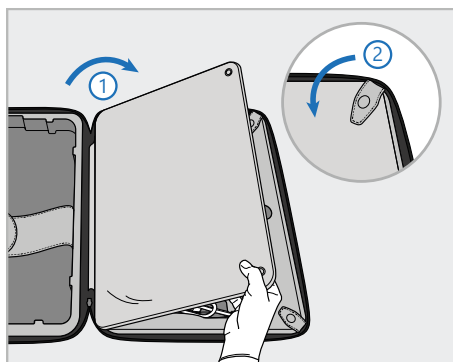
4. While holding the computing unit (A) with one hand, remove the cradle (C) by pressing the release button and pulling up the cradle.



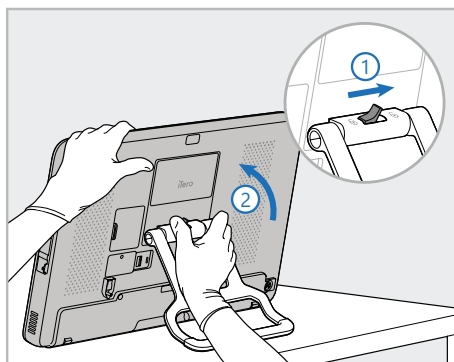
5. Place the cradle (C) in the trolley.



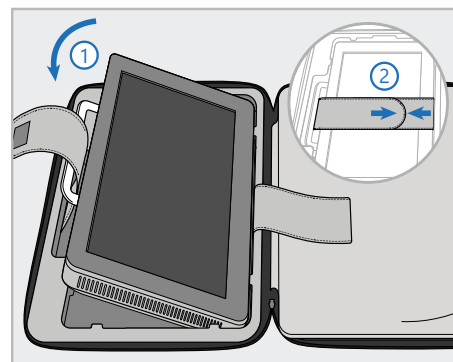
6. Optional: Place new sleeves in the compartment next to the cradle (C), instead of the protective trolley cover (H).



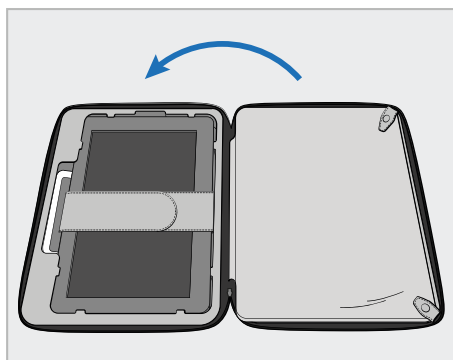
7. Move the flap to cover the scanner components and then secure the flap with the snaps.



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 (B) through the handle 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).

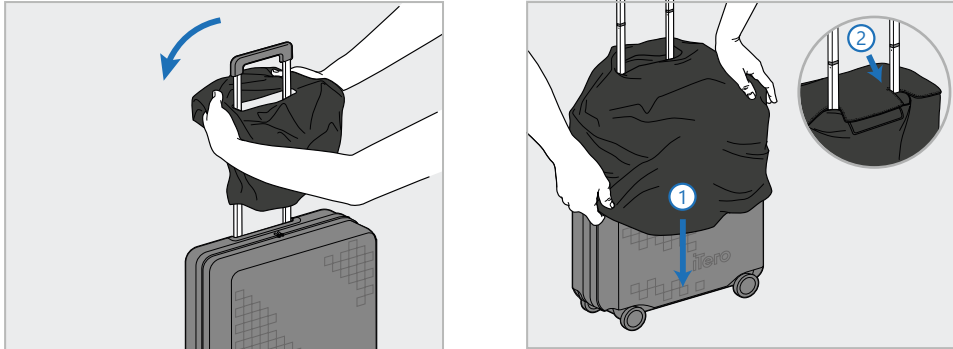
Notes:

- 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 reduce the risk of damage to the scanner that may be caused by uncontrolled transportation conditions.

2.2.4 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.



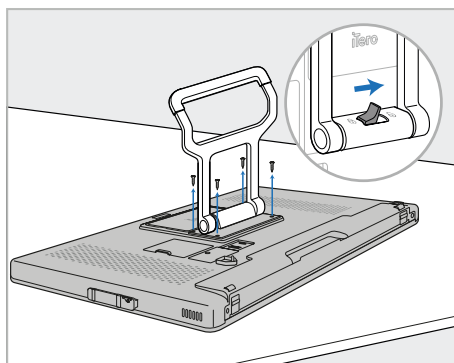
1. Open the VELCRO® flap and slip the protective cover (H) over the trolley handle.
2. Pull down to cover the trolley and then close the VELCRO® flap.

2.2.5 VESA mounting

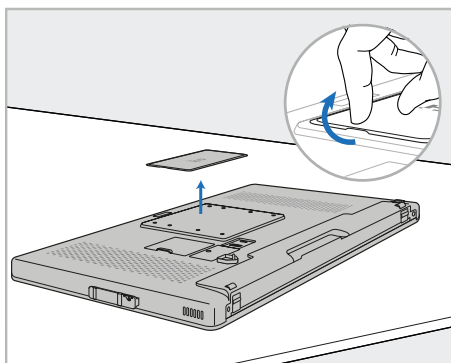
The scanner provides a standard 100mm VESA mounting interface that can be used for mounting it using 3rd party VESA-based mounting solutions.

Notes:

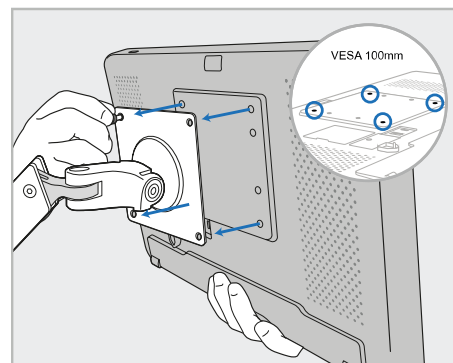
- **Ensure that the selected VESA mounting solution supports the following scanner specifications:**
 - VESA 100mm
 - Minimum weight: 6kg (including the computing unit, wand, and cradle).
Recommended weight: 9kg.
- If the scanner has already been assembled, you must remove the power cable and the cradle, 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.



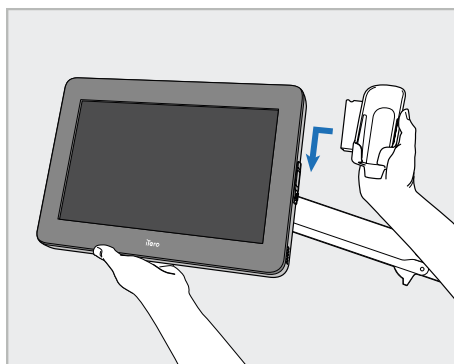
1. Lay the computing unit (A) face down on a smooth, flat surface.
Remove the 4 screws with a Phillips screwdriver, while holding and moving the handle (B), as required.



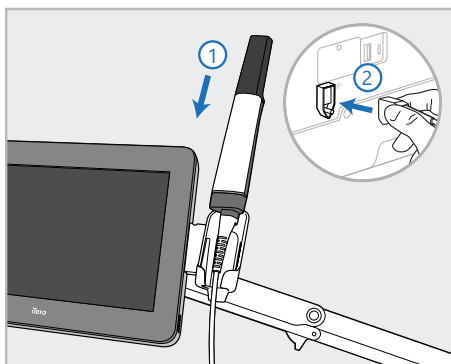
2. Remove the iTero back cover plate to expose the VESA screw holes. (It is recommended to store the cover plate and screws in the trolley.)



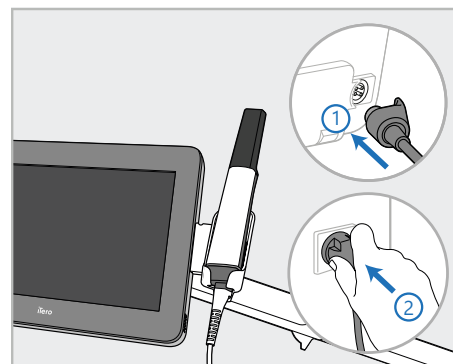
3. Connect the computing unit (A) to the external VESA mount (VESA 100) using the screws supplied with the mounting solution.
Optional: You can purchase a 3m power cable from Align, if required.



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 **A** 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.

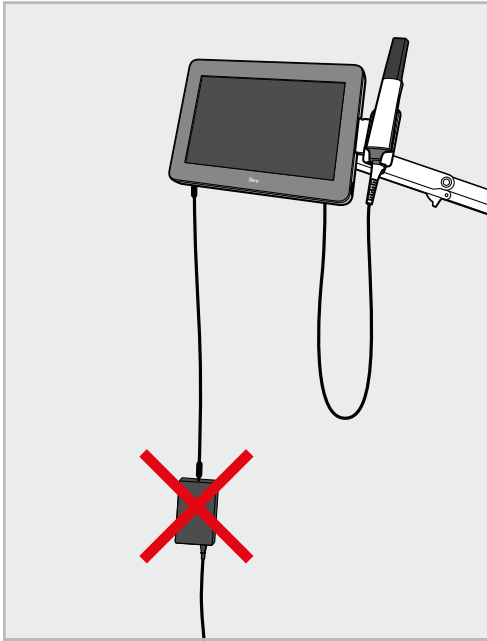


Figure 13: Do not allow the power pack to dangle in the air

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

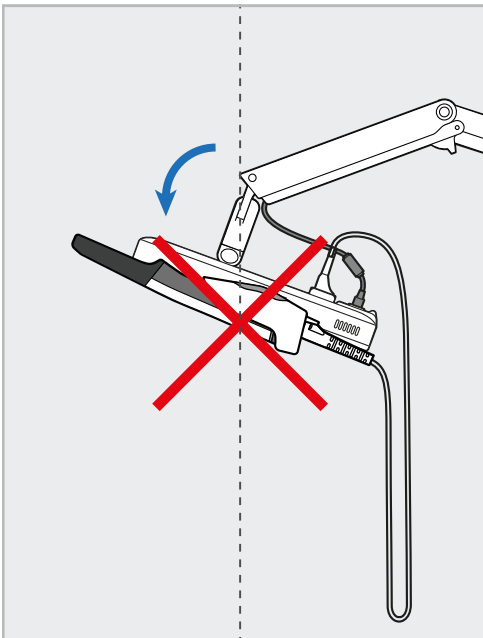
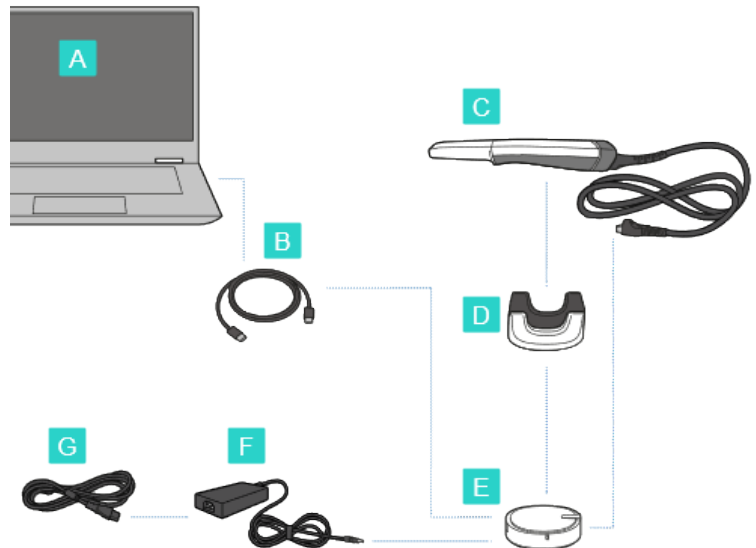


Figure 14: Never tilt the screen more than 45 degrees

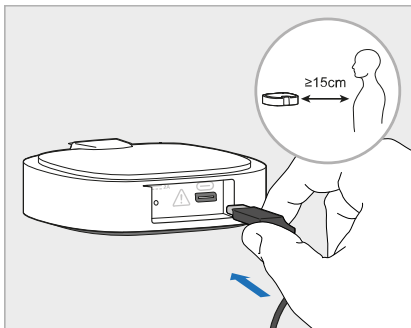
2.3 Assembling the iTero Lumina PC-configuration scanner

Before assembling the scanner, read and understand the [safety instructions](#). We recommend assembling the scanner at the point of use.

- A** Computer, with its own power supply, meeting supported HW and SW specifications
- B** USB-C cable to connect the computer to the interface box
- C** iTero Lumina wand and cable
- D** iTero Lumina cradle
- E** iTero Lumina interface box
- F** Power supply with cable
- G** Power cable

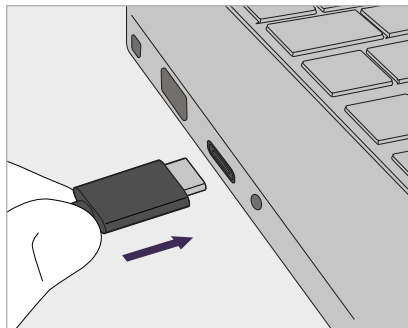


Note: If any damage to the system or accessories is found, do not assemble or use the scanner and contact iTero support.

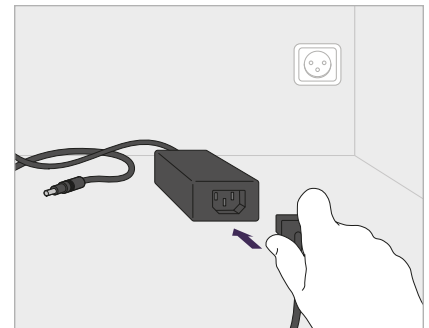


1. Connect the USB-C cable to the interface box.

Note for persons with implantable medical devices susceptible to magnetic energy: See the [Electromagnetic interference precautions](#) section in the Safety instructions for relevant warnings, and keep the interface box at least 15 cm away from the chest.

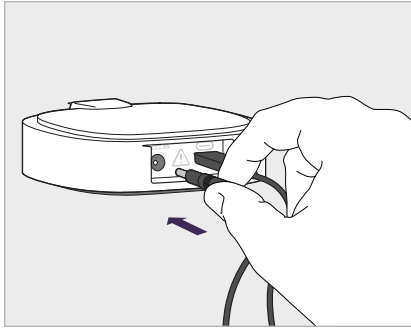


2. Connect the other side of the USB-C cable to the computer.

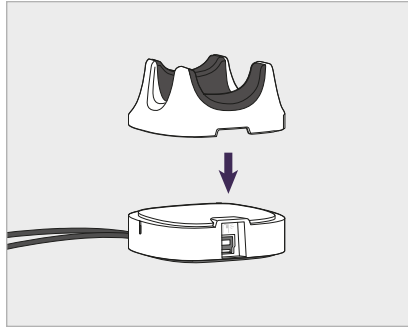


3. Connect the power cable to the power supply.

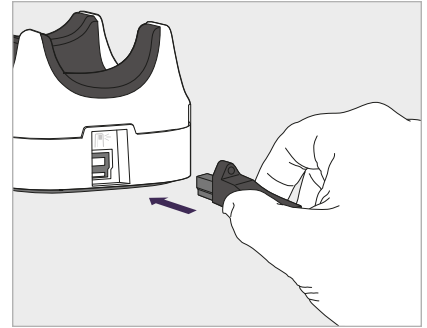
See the [Electric warnings](#) section in the Safety instructions for the relevant warnings.



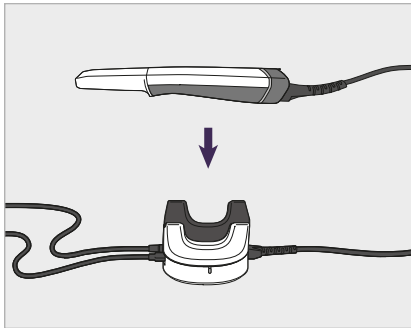
4. Connect the power cable to the interface box.



5. Place the cradle on the interface box, making sure it is securely positioned.

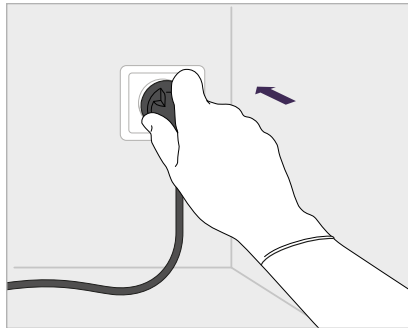


6. Connect the wand cable to the interface box.



7. Place the wand in the cradle.

Note: Make sure that the wand is placed securely in the cradle and cannot be bumped.



8. Connect the power cable to a power outlet.

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

Notes:

- The interface box must be connected to an AC wall outlet at all times, except during the cleaning process.
- The computer should be connected to an AC wall outlet during intraoral scanning.
- To get the best performance of the iTero scanner application during scanning, please ensure no other programs or applications are activated/running in the background.
- Always return the wand to the cradle after each use.
- When the system is not in use, the wand should be placed in the cradle with the optical window facing the cradle.
- The wand, cradle, and other system components should be [cleaned and disinfected](#) immediately after each patient. The interface box should be [cleaned](#) according to standard operating procedures.
- Ensure that the computer and the interface box are positioned in a location where they can easily be disconnected from the power outlet.

2.3.1 PC-configuration software

After you have assembled the iTero Lumina PC-configuration scanner, proceed as follows:

- If you purchased a computer without pre-installed iTero software, proceed to [Installing the iTero Lumina software](#).
- If you purchased a laptop with pre-installed iTero software through a third-party vendor, proceed to [Setting up the PC-configuration scanner](#).

2.3.1.1 Installing the iTero Lumina software

For proper software installation and configuration of the scanner system, please ensure the following:

- The wand is secure in the cradle and connected to the interface box
- The interface box is connected to the computer
- The computer is plugged into the AC wall socket during the entire software installation
- The Sleep settings for the screen and the device when the laptop is plugged in are set to **Never**:
 - Right-click the **Start** button -> **Settings** -> **System** -> **Power and battery**.
 - In the **Screen and sleep** area, set the screen and device settings when plugged in to **Never**.

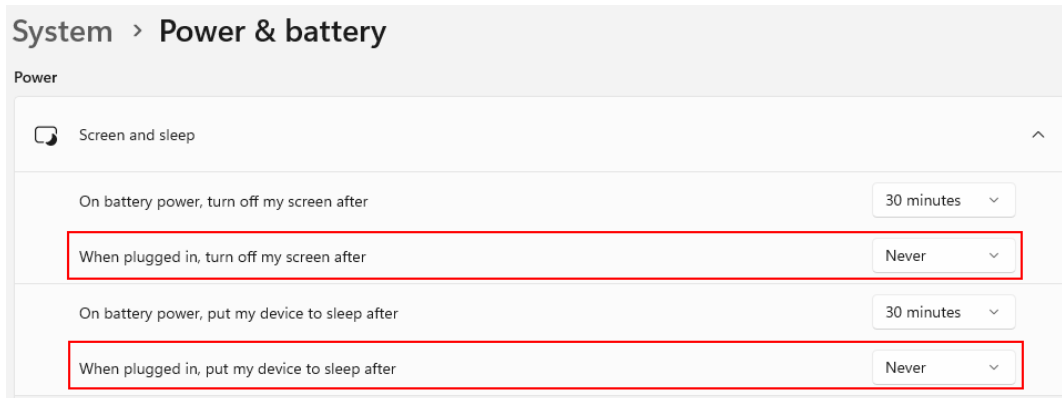


Figure 15: Sleep settings

- 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:

- Ensure that you have admin rights on the computer, as the installation requires changes to the system settings and the installation of drivers.
- The Hibernate function is disabled by default in Windows 11. Do not enable it.

- 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. In the registered email Inbox, look for the email “Your iTero was shipped”, which includes the download instructions.
2. Click the link to access the software download page or browse to <https://itero-ftidownloadpages-prod.iterocloud.com/luminapc-downloads>.
3. On the website, click the **Get Started** button. The **FirstTimeInstaller.exe** file will be downloaded.
4. Run the downloaded installation file and follow the instructions on the screen to complete the iTero software installation.

The *Welcome* screen is displayed.

5. When the software has been installed, tap the iTero Lumina shortcut  on the computer desktop.
The *Welcome* screen is displayed.
6. [Register the scanner](#).

2.3.1.2 Setting up the iTero Lumina PC-configuration laptop scanner with pre-installed iTero software

To set up a laptop scanner with pre-installed software:

1. Complete the full Windows Out-of-Box Experience (OOBE) set up on the new laptop.

2. Tap the Lumina shortcut  on the laptop desktop to open the iTero software.

The *Welcome* screen is displayed.

3. [Register the scanner](#).

3 Getting started

3.1 Logging in to the scanner for the first time

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

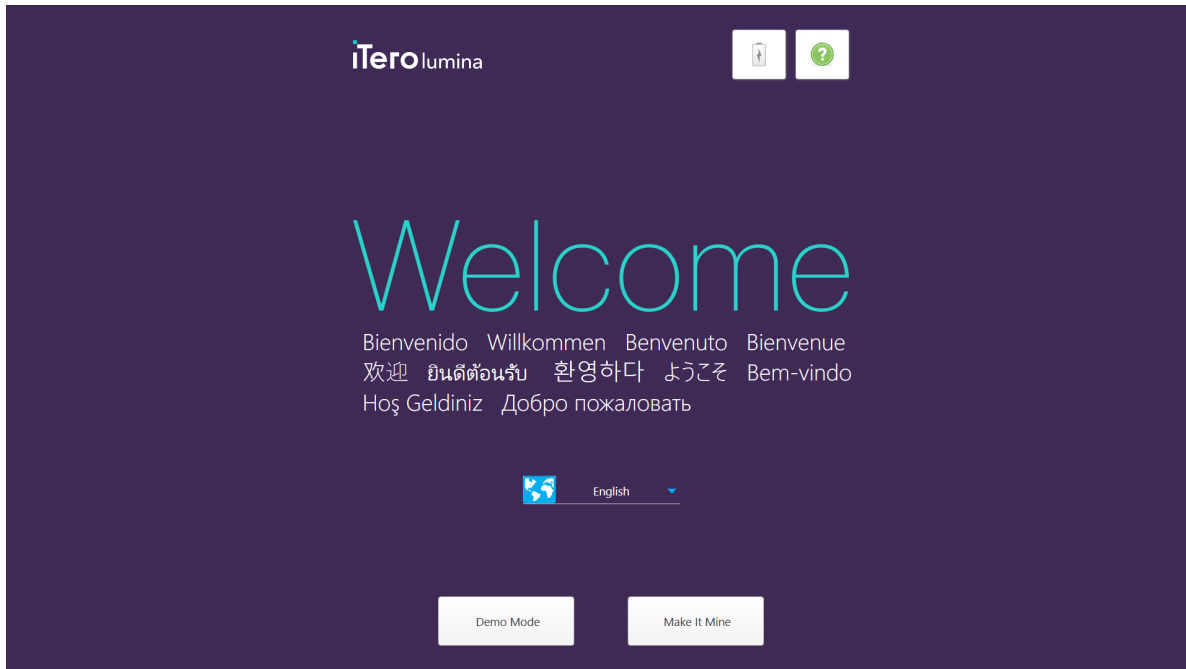


Figure 16: Welcome screen

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**. If you have a PC-configuration scanner, proceed to step 5.

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

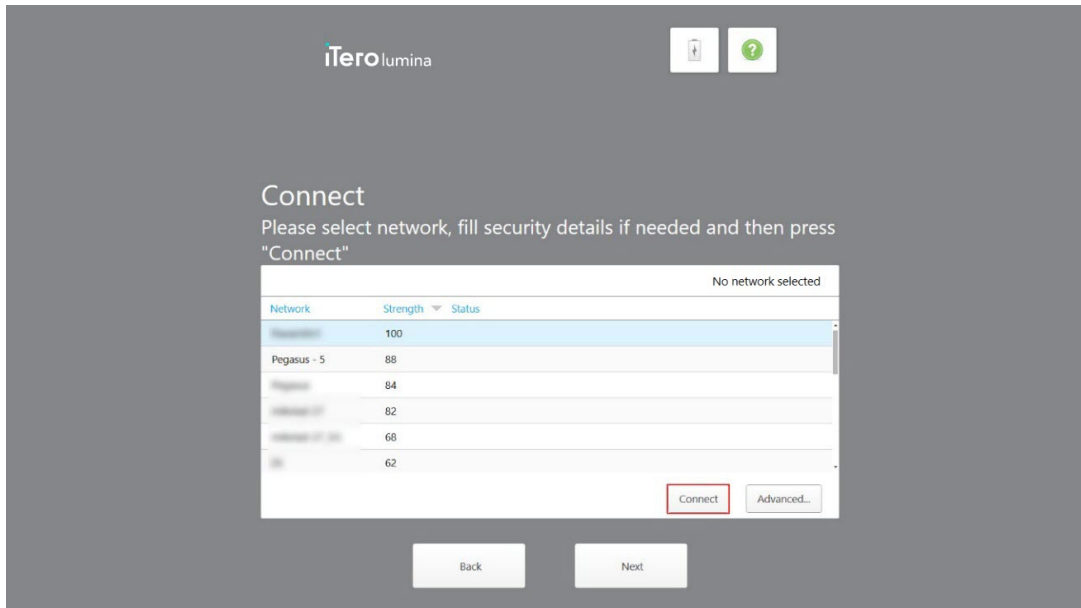


Figure 17: Connect page listing the available networks

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

You are prompted to enter the network security key.

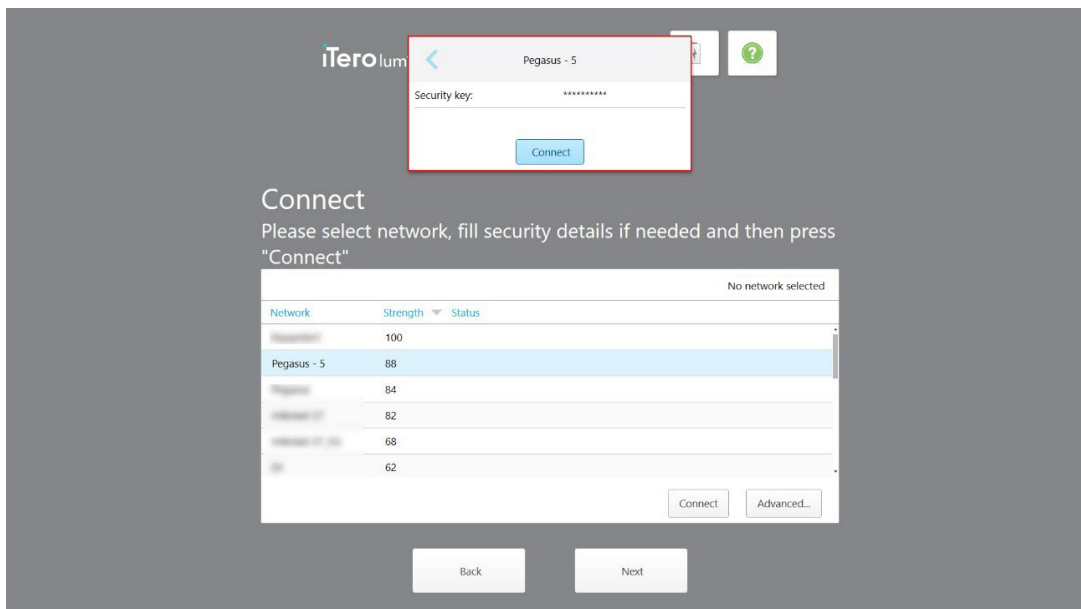


Figure 18: Entering the security key

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

The scanner is now connected to the Internet and online.

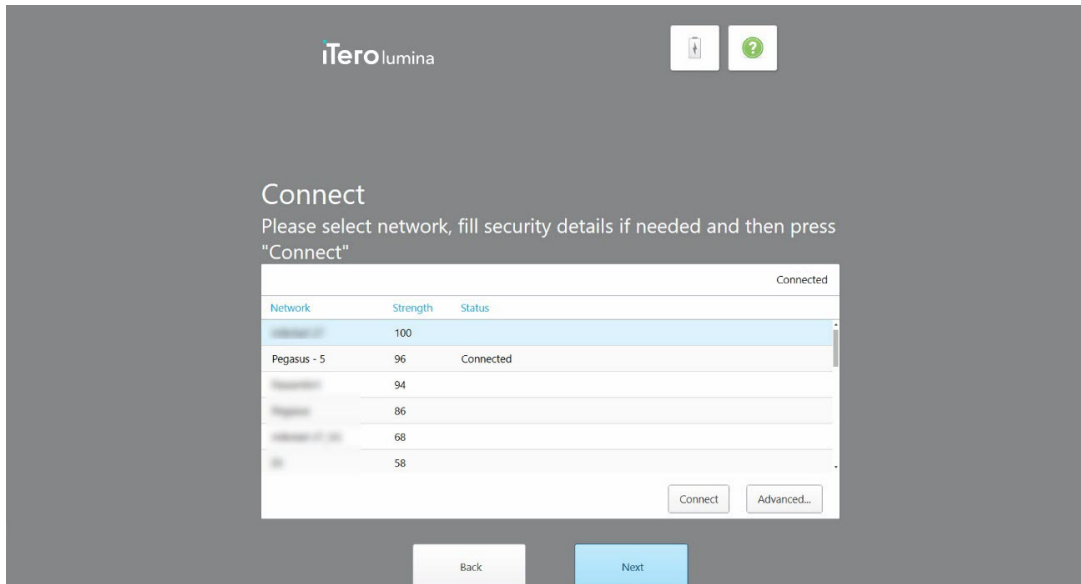


Figure 19: Scanner is connected to the Internet and online

5. Tap **Next**.

The communication with Align is verified.

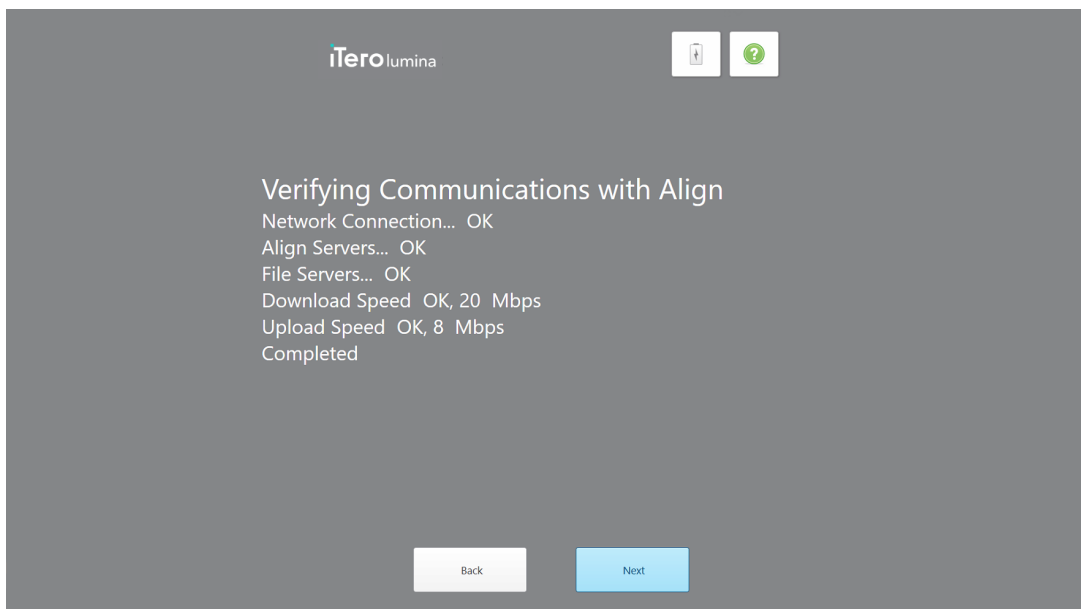


Figure 20: Verifying the communication with Align

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

The *Time Zone* page is displayed.

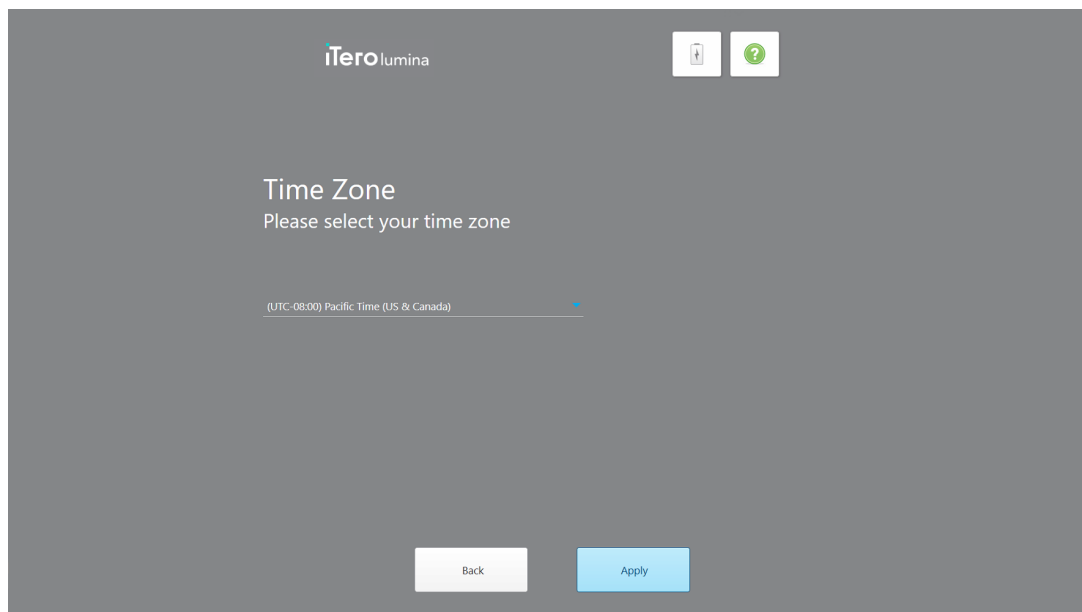


Figure 21: Selecting the time zone

- 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.

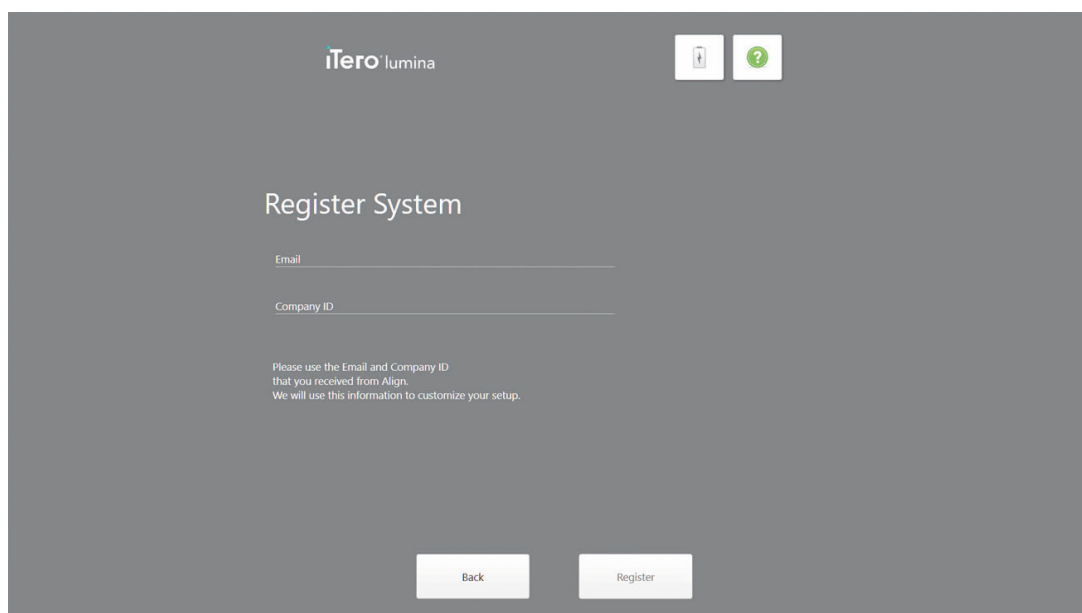


Figure 22: Registering the system to customize the setup

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.

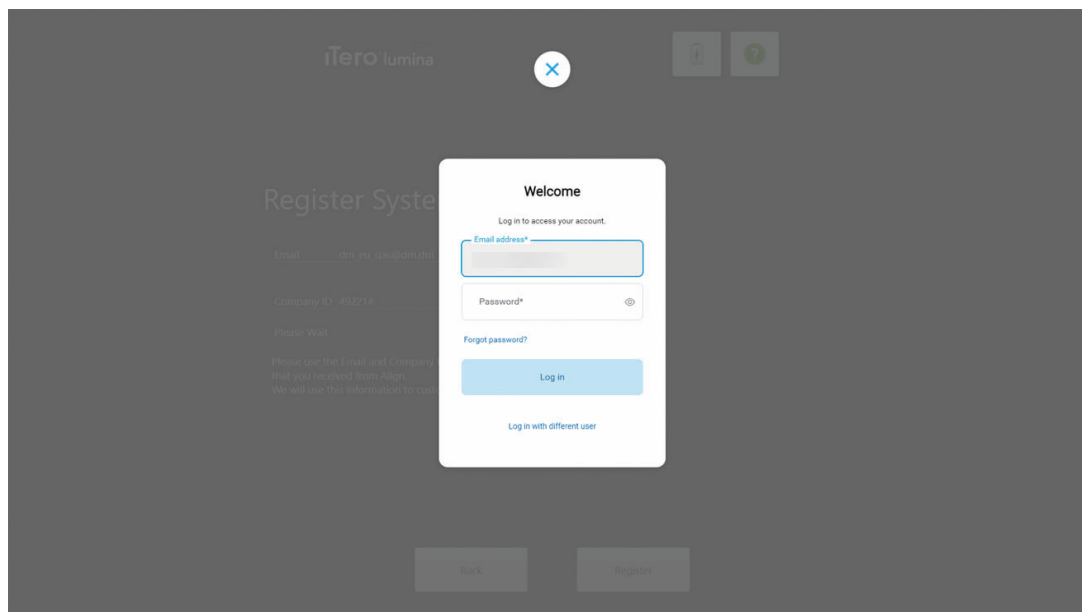


Figure 23: Welcome popup screen

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.

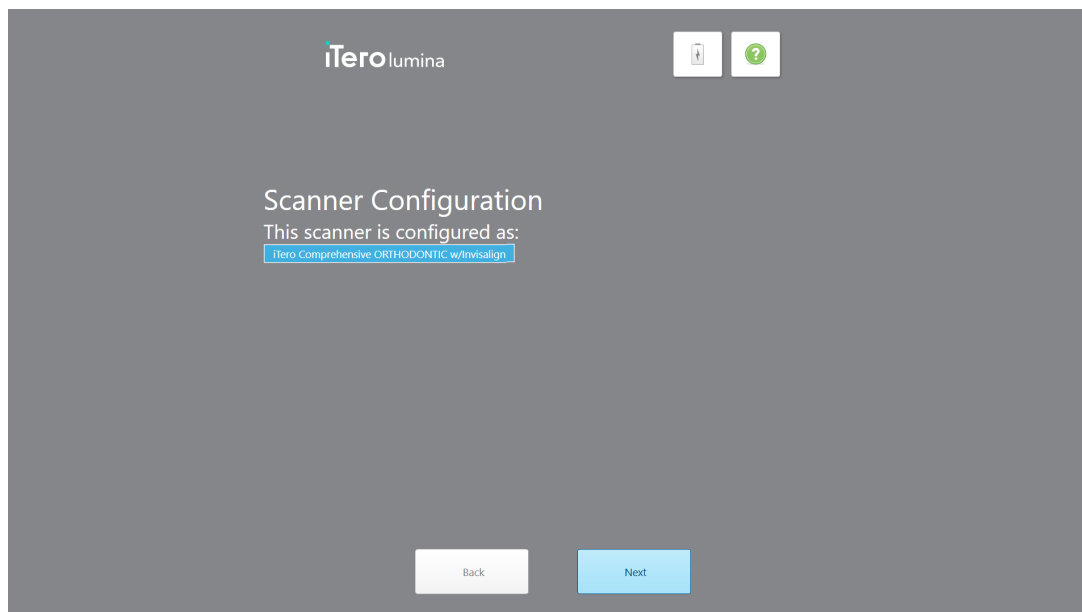


Figure 24: Example of an iTero subscription package

11. Tap **Next**.

The *License Agreement* page is displayed.

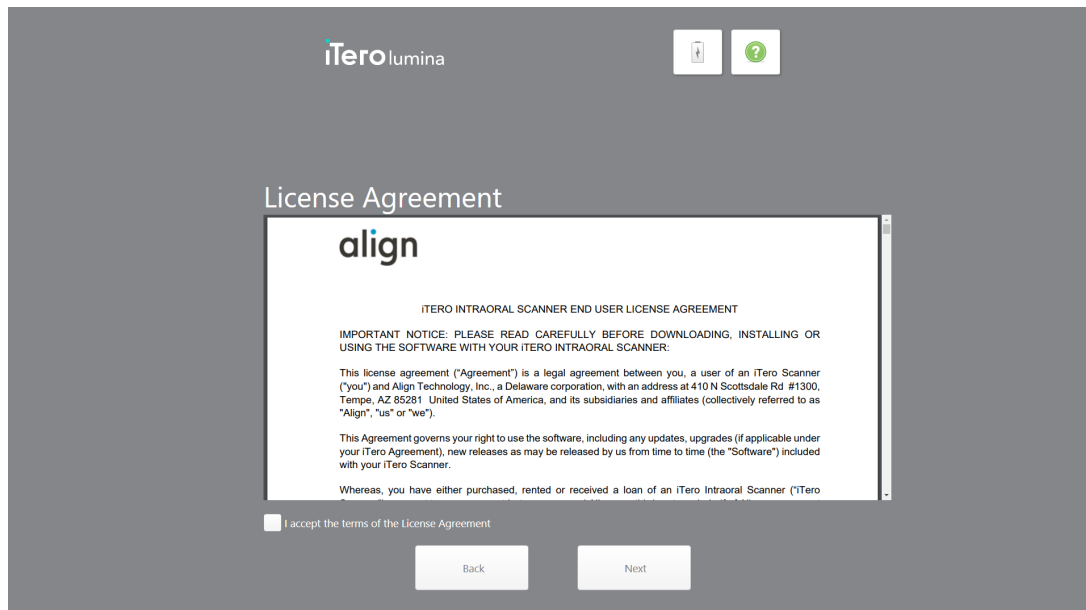


Figure 25: License agreement

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.

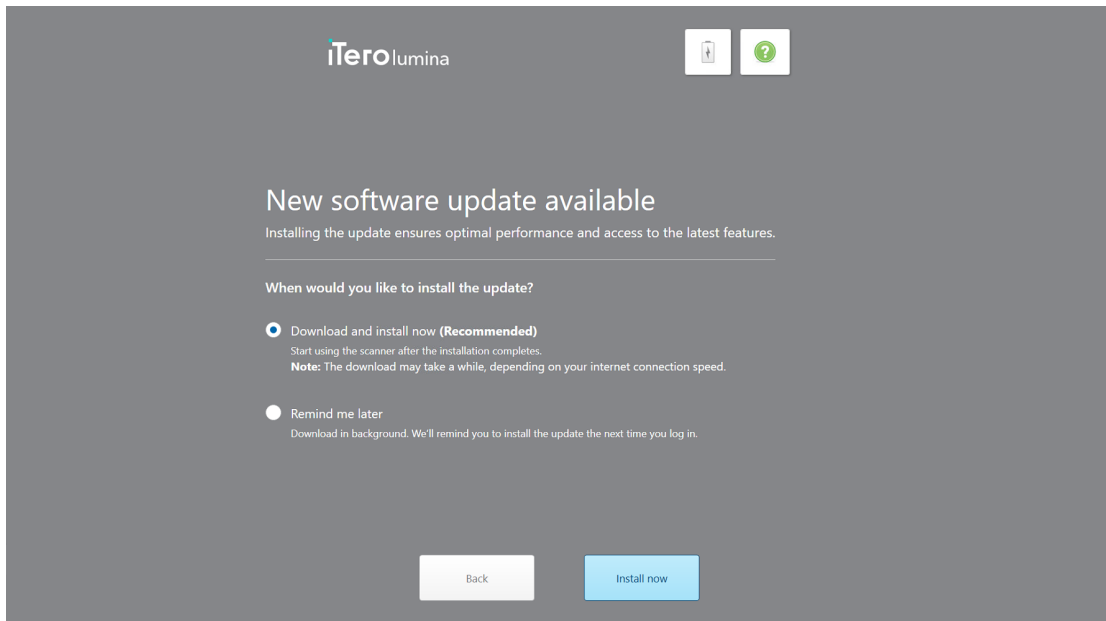


Figure 26: New software update available – installation options

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.

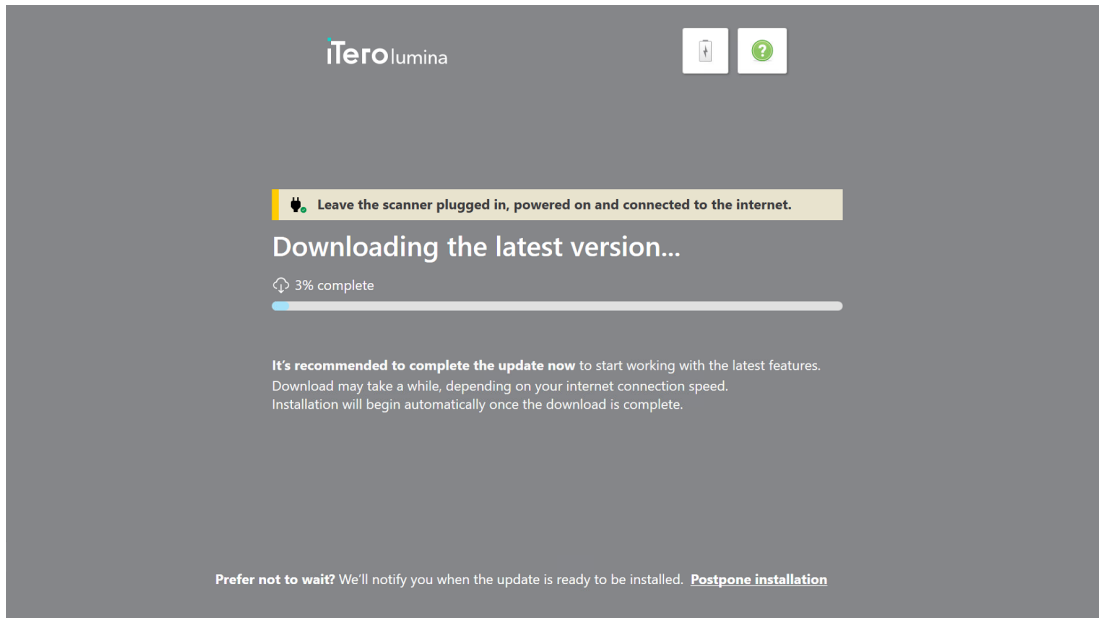


Figure 27: Downloading the latest version

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 iTeror** – 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.

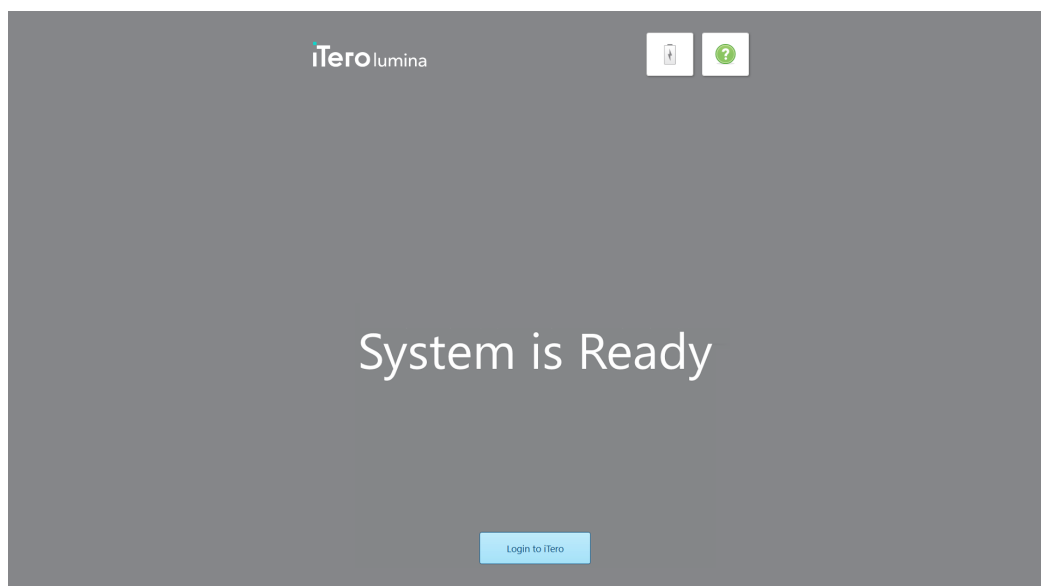


Figure 28: System is registered and ready for use

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**.

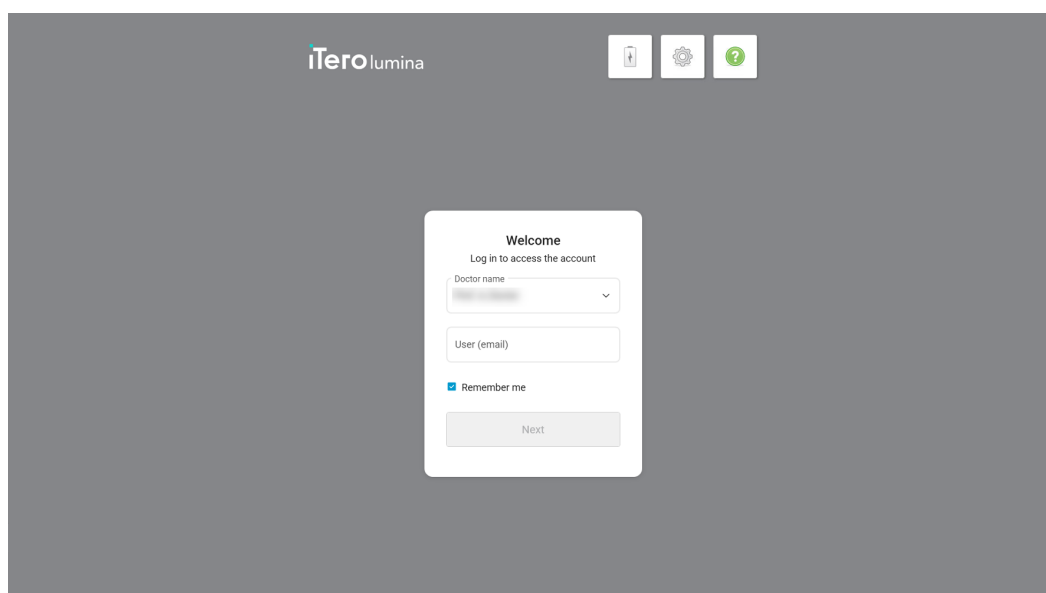


Figure 29: Welcome screen – enter email address

The *Welcome* window is updated.

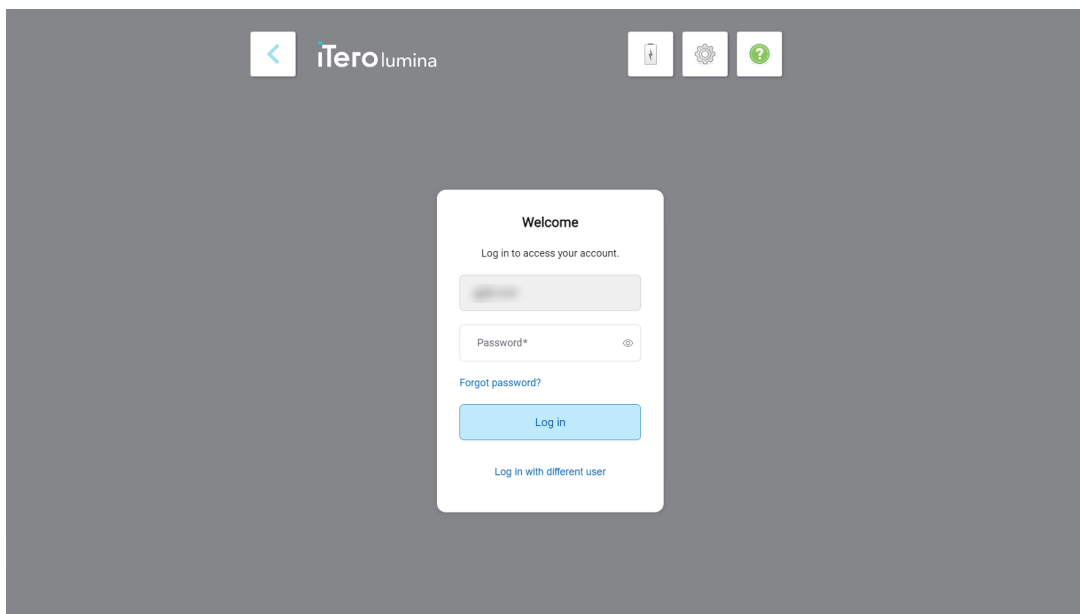


Figure 30: Welcome screen – enter password

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.

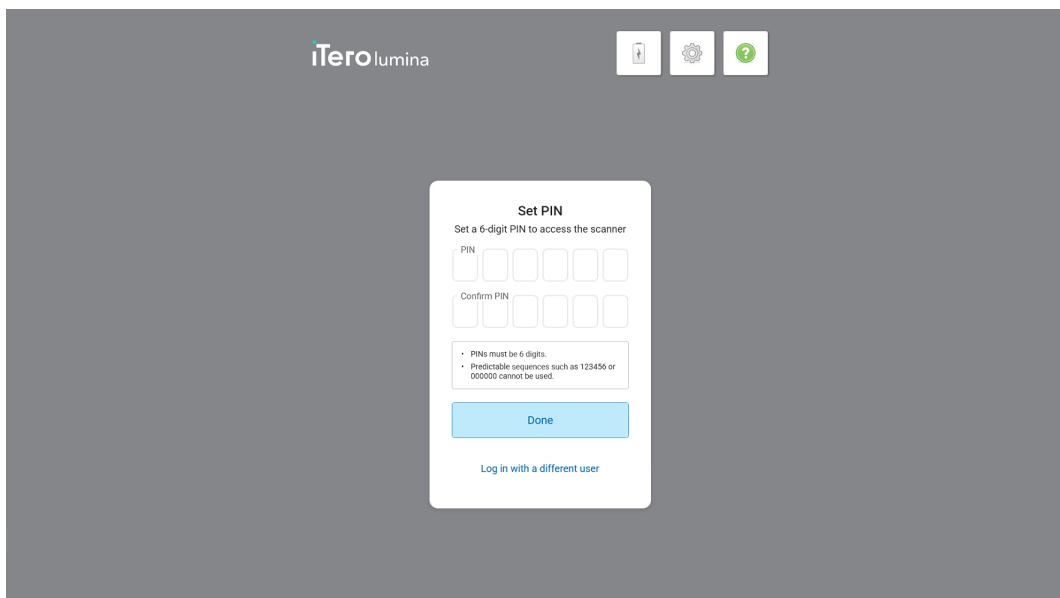


Figure 31: Set PIN screen

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

The PIN confirmation page is displayed.

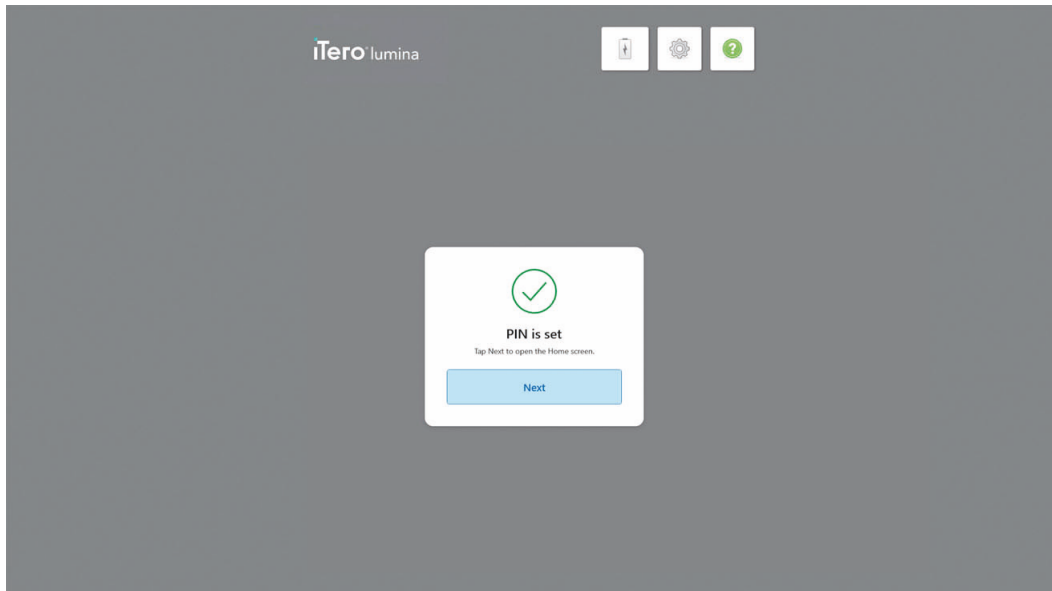


Figure 32: PIN confirmation screen

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 Lumina logo at the top of the scanner screen.

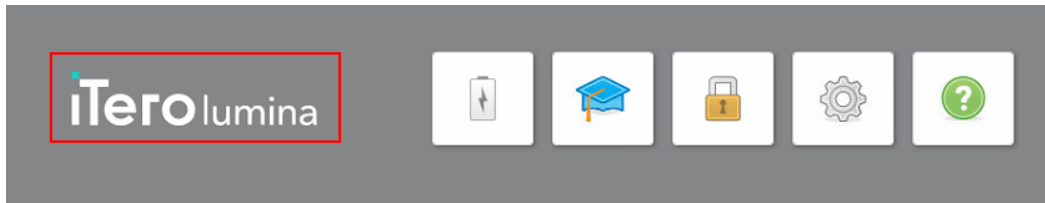


Figure 33: iTero Lumina logo

2. Tap **Demo Mode**.

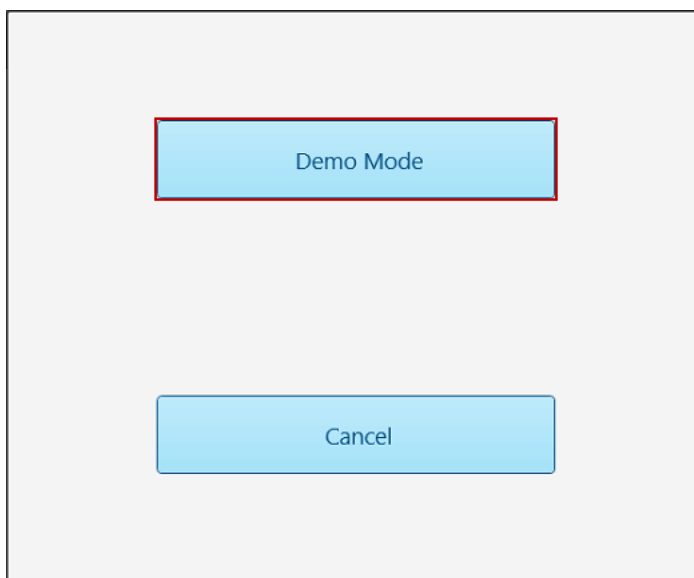
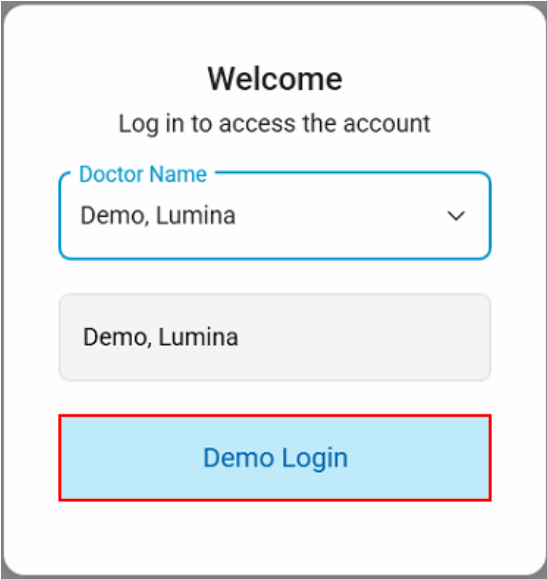


Figure 34: Demo Mode option

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

3. Select **Demo, Lumina** from the drop-down list.



The image shows a 'Welcome' login screen. At the top, it says 'Welcome' and 'Log in to access the account'. Below this is a 'Doctor Name' dropdown menu with 'Demo, Lumina' selected. Underneath the dropdown is a text input field containing 'Demo, Lumina'. At the bottom of the form is a blue button labeled 'Demo Login' which is highlighted with a red rectangular border.

Figure 35: 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.

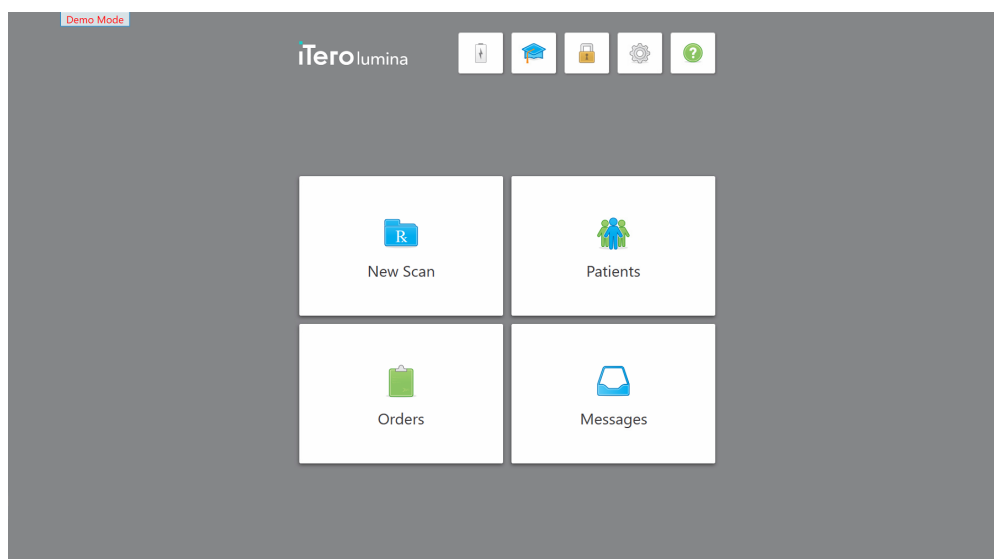


Figure 36: Demo Mode home screen

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.

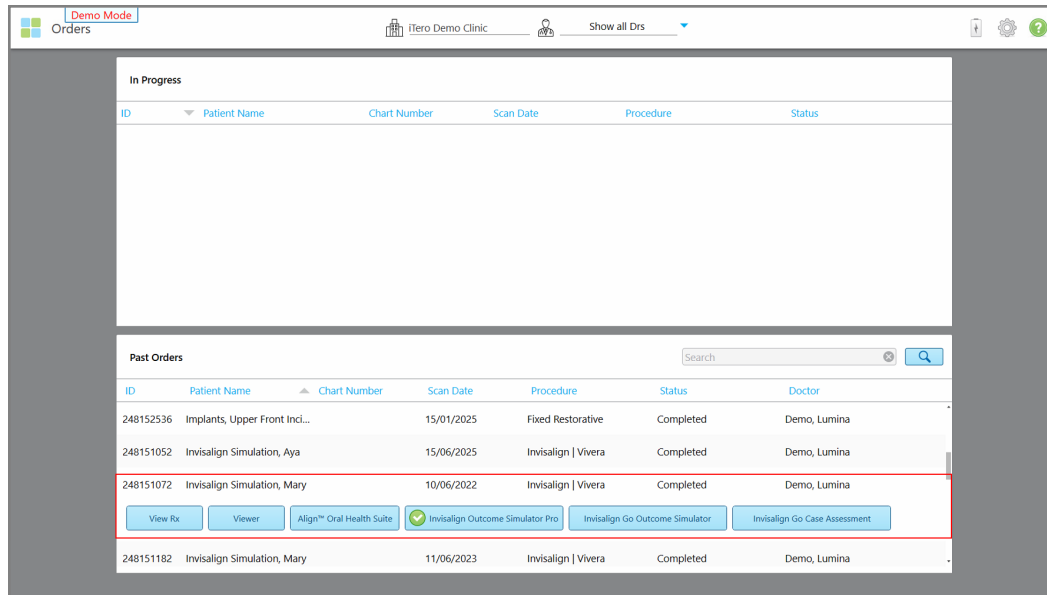


Figure 37: Past Orders pane – options

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

3.3.1 Exiting Demo Mode

To exit Demo mode:

1. Tap  to move to the home screen and then tap the iTerio Lumina logo at the top of the screen.

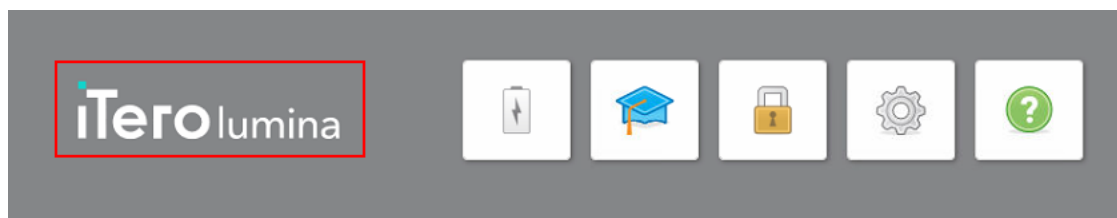


Figure 38: iTerio Lumina logo

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



Figure 39: Exiting Demo mode

4 Working with the scanner

4.1 Logging in to the scanner

iTero Lumina scanners: When the scanner is powered on, the *Welcome* window is displayed.

iTero Lumina PC-configuration scanners: On the computer desktop, tap the iTero Lumina shortcut  to access the *Welcome* window.

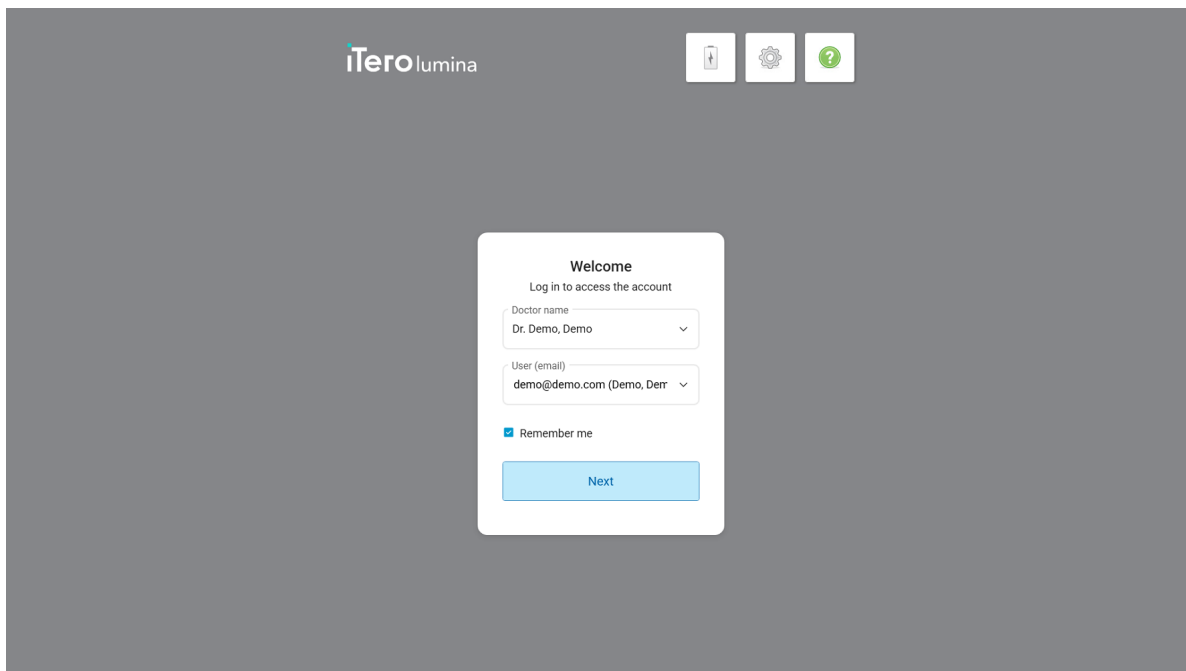


Figure 40: Welcome window

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](#).

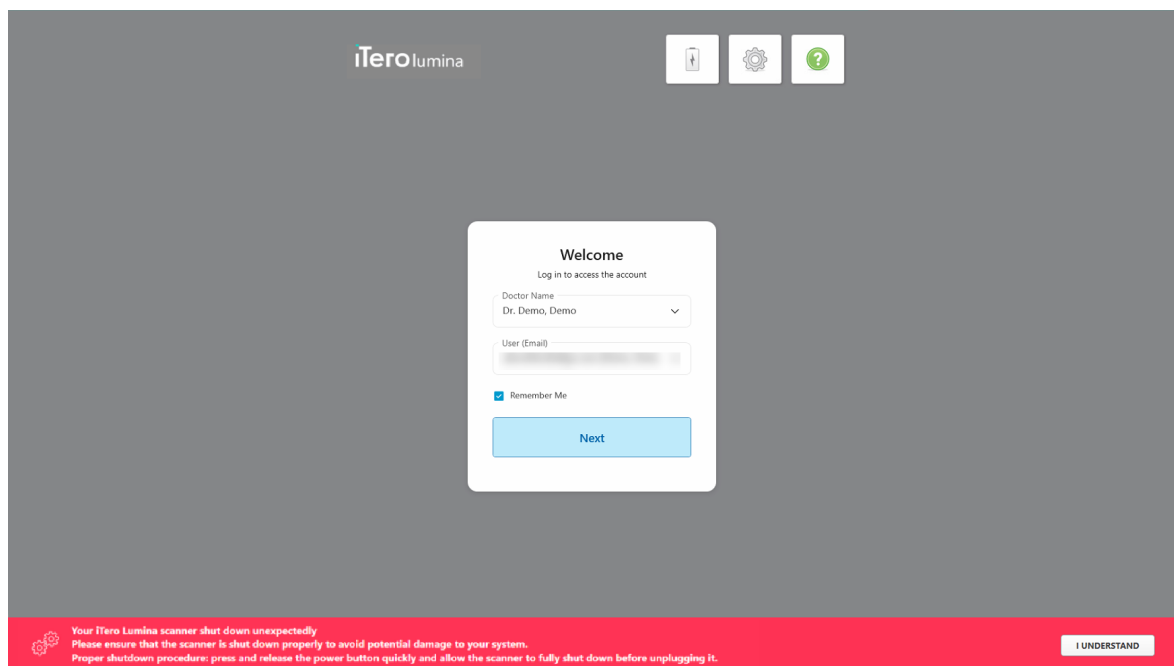
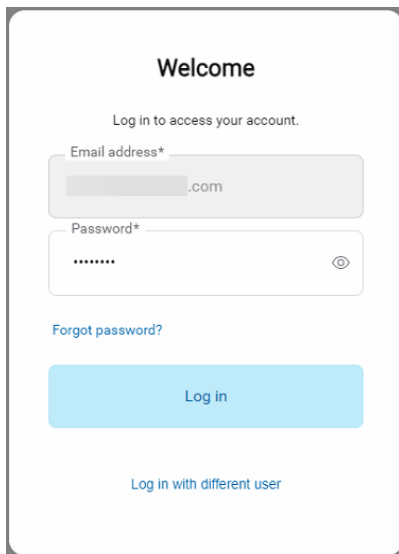


Figure 41: Unexpected shutdown notification

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.



Welcome

Log in to access your account.

Email address*

.....@......com

Password*

.....

[Forgot password?](#)

Log in

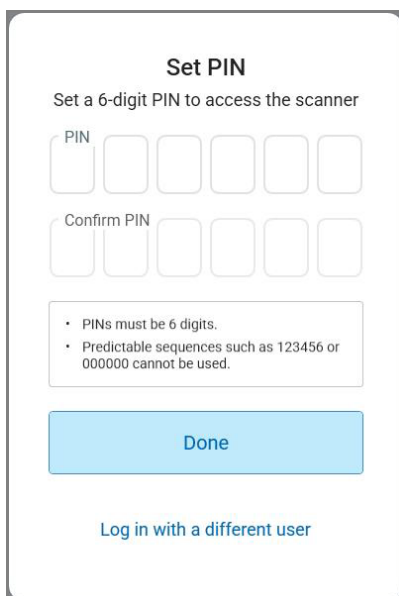
[Log in with different user](#)

Figure 42: 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.



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 43: 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.

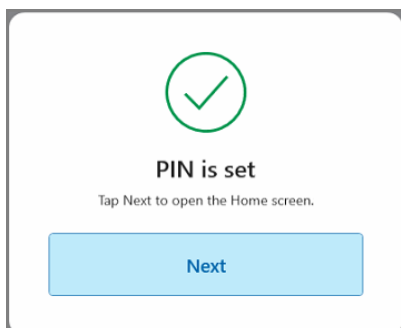


Figure 44: PIN set confirmation window

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.

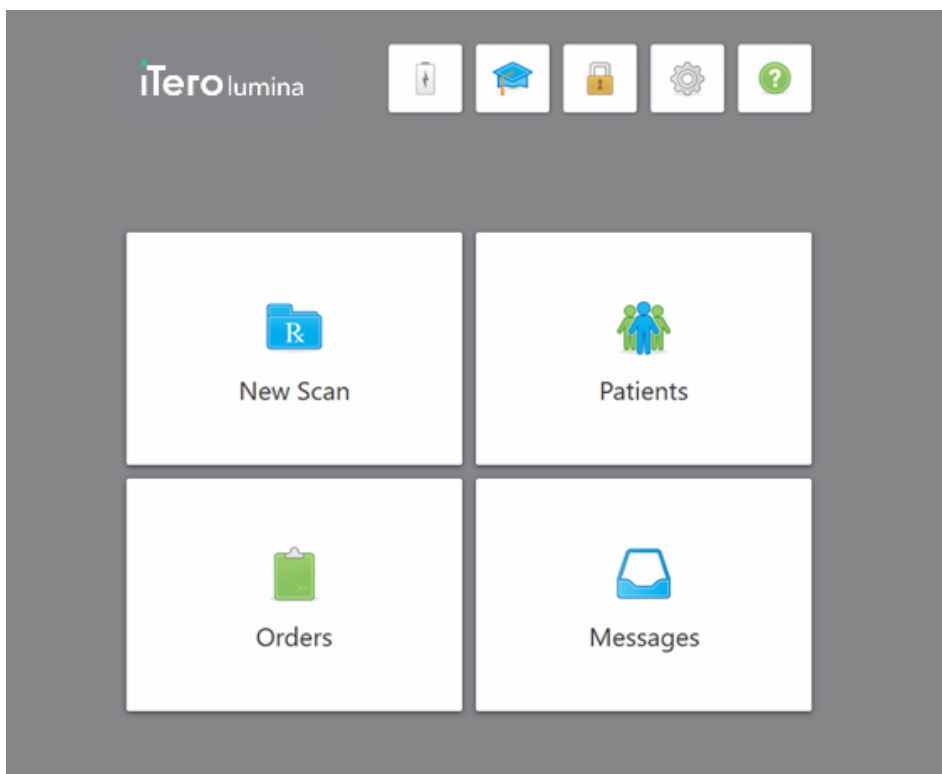


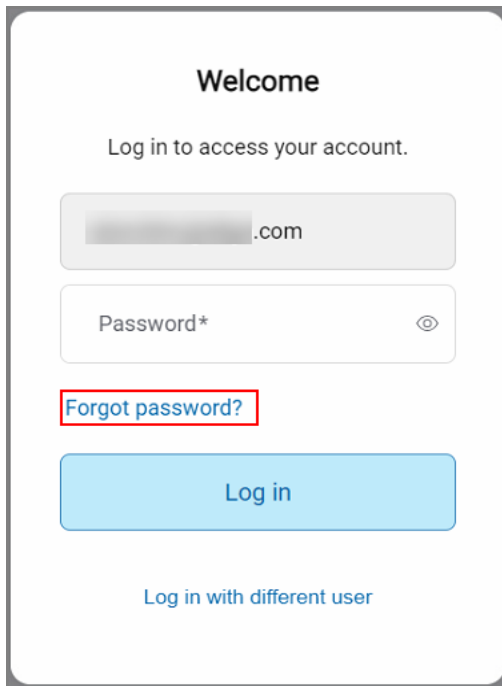
Figure 45: iTero home screen

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:

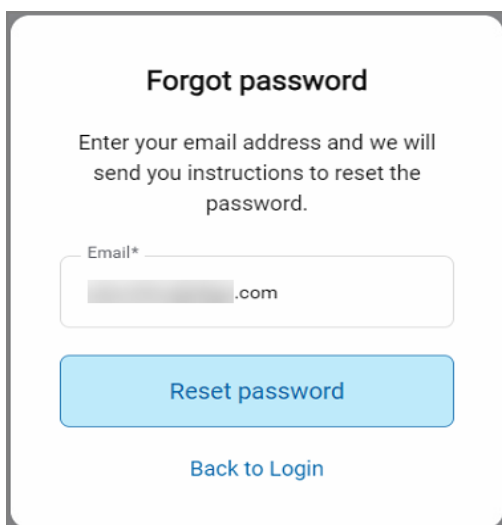
1. In the *Welcome* window, tap **Forgot Password**.



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 46: 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 bottom, there is a link that says 'Back to Login'.

Figure 47: 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.

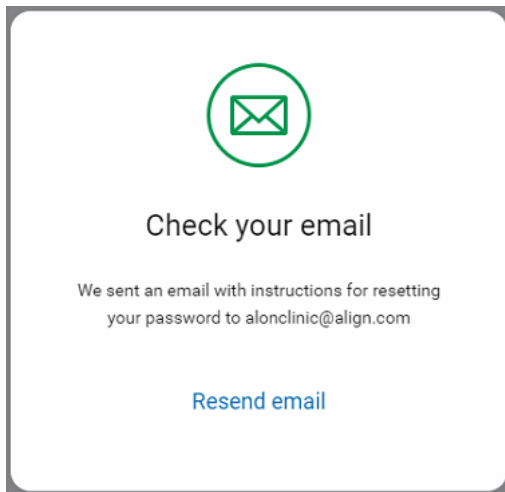


Figure 48: Check your email notification

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.

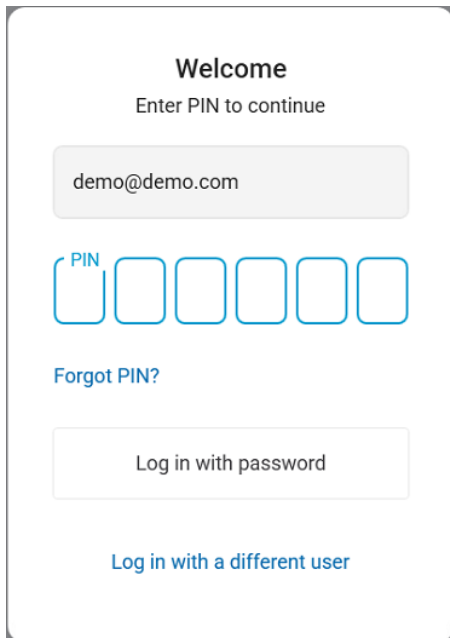


Figure 49: Welcome window - Enter PIN

2. Enter your 6-digit PIN.
The home screen is displayed.

4.1.2.1 Resetting the PIN

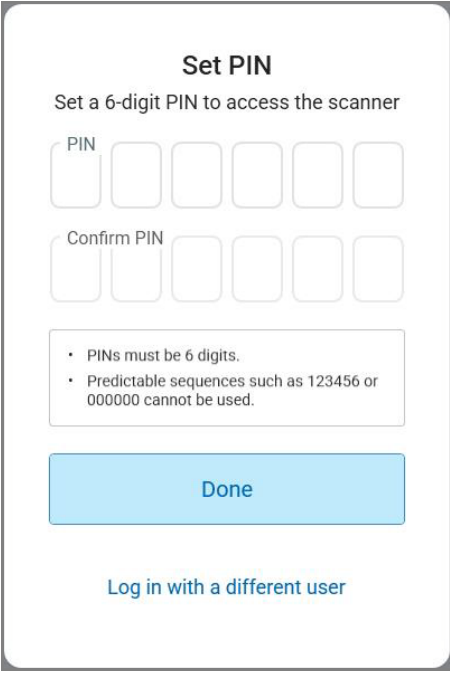
If you have forgotten your PIN or would like to change it, you can reset it from the *Welcome* window, or from the [Scanner settings](#).

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 50: 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.

Note: The **Install at 11:00 PM tonight** option is not available for PC-configuration scanners.

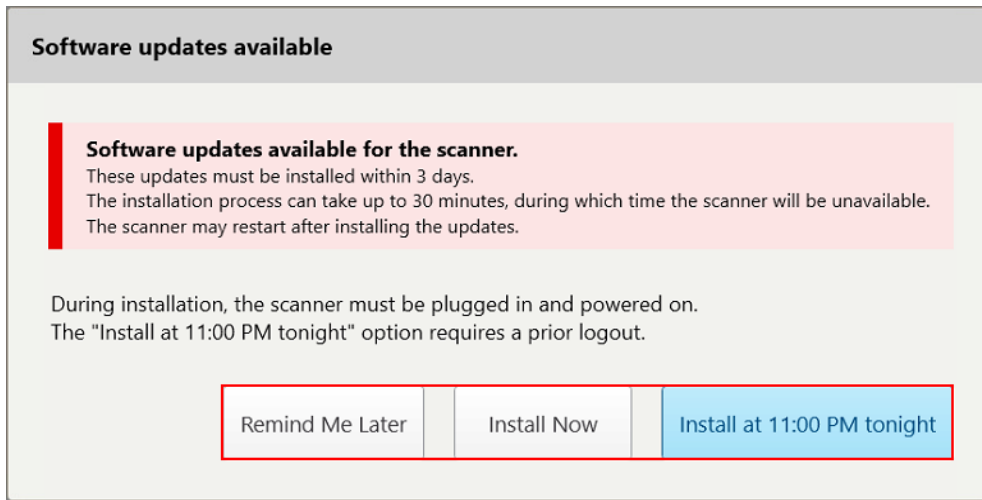


Figure 51: Software updates available window – scheduling options

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.

Note: The **Install at 11:00 PM tonight** option is not available for PC-configuration scanners.

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 52: 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.

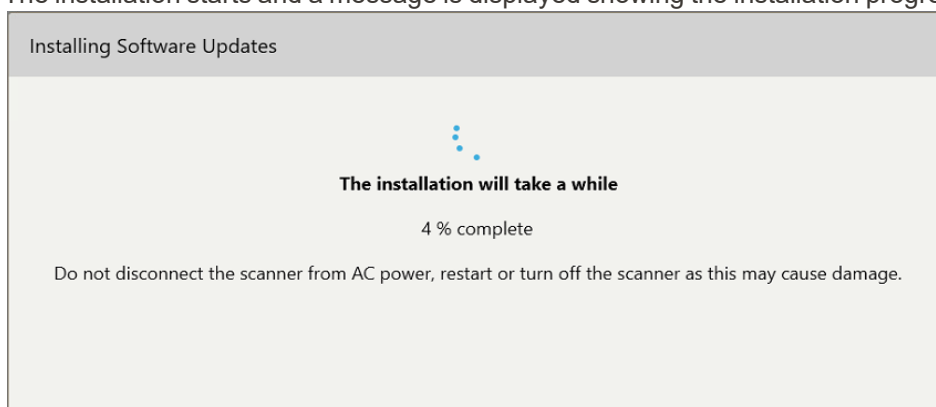


Figure 53: Installation in progress

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.

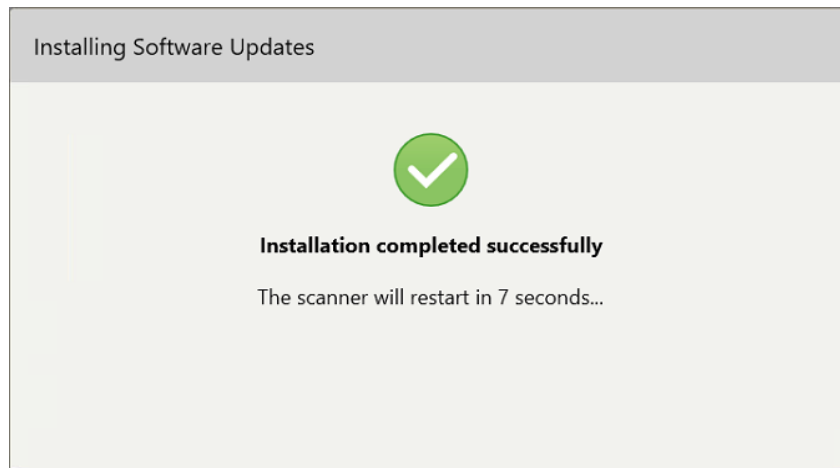


Figure 54: Installation completed successfully

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.

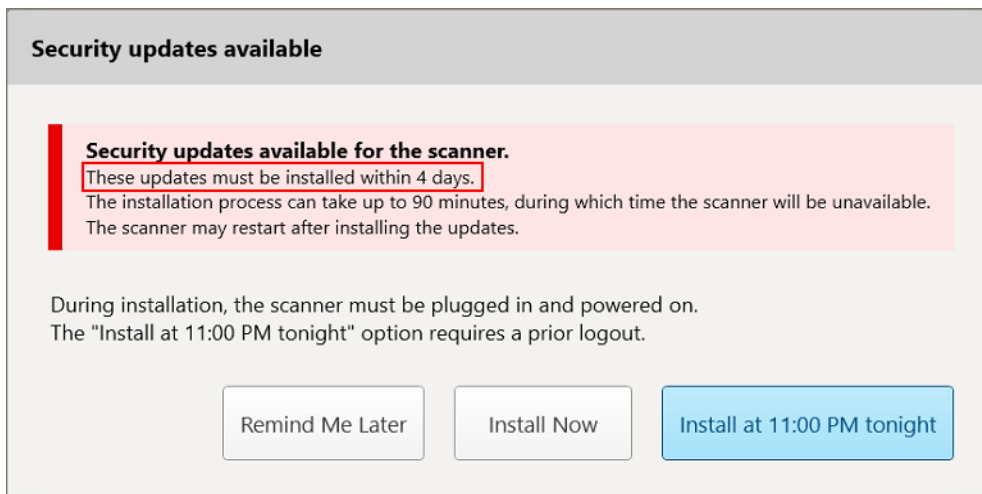


Figure 55: Security updates – number of days until the updates must be installed

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.

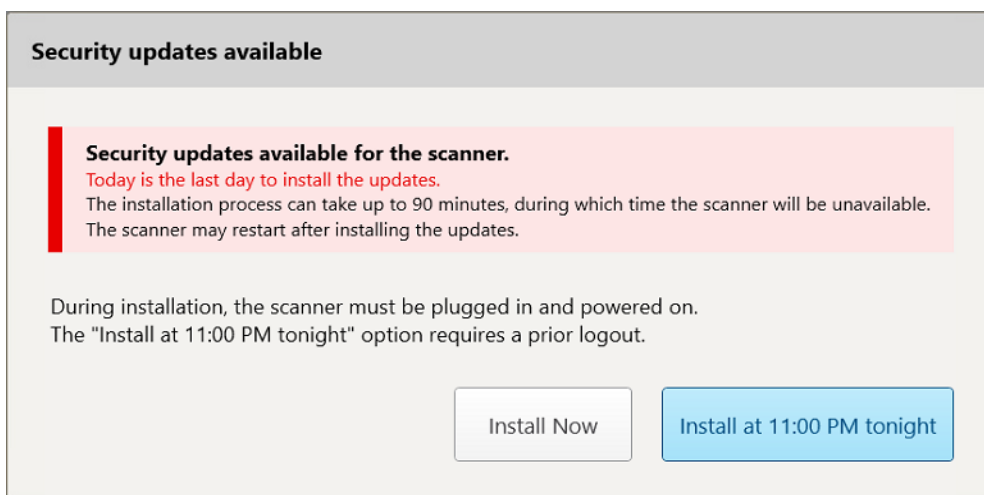


Figure 56: Security updates – last day

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.

Note: The **Install at 11:00 PM tonight** option is not available for PC-configuration scanners.

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.

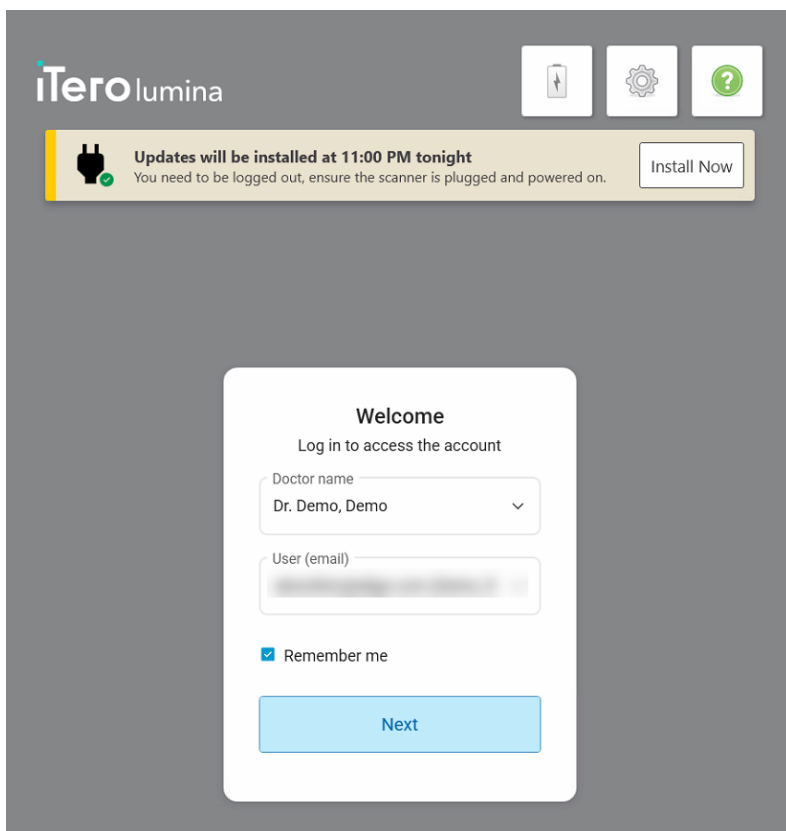


Figure 57: Updates notification – Welcome window

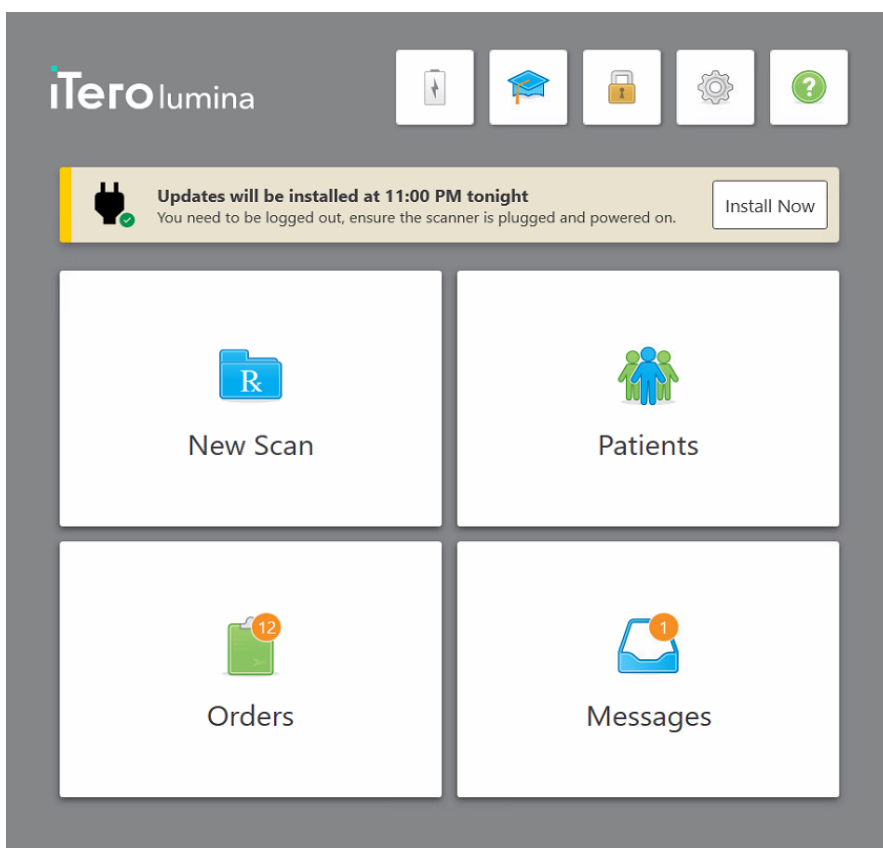


Figure 58: Updates notification – home screen

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 iTero Lumina cart and mobile configuration scanners:

- Press and release the Power button to shut down the system. The Power button is located on the top right of the screen.

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.

To shut down the iTero Lumina PC-configuration scanner:

- On the iTero Lumina home screen, tap the close button  on the top right-hand corner to exit the iTero software.

4.4 Moving the scanner

4.4.1 Moving the iTero Lumina 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.

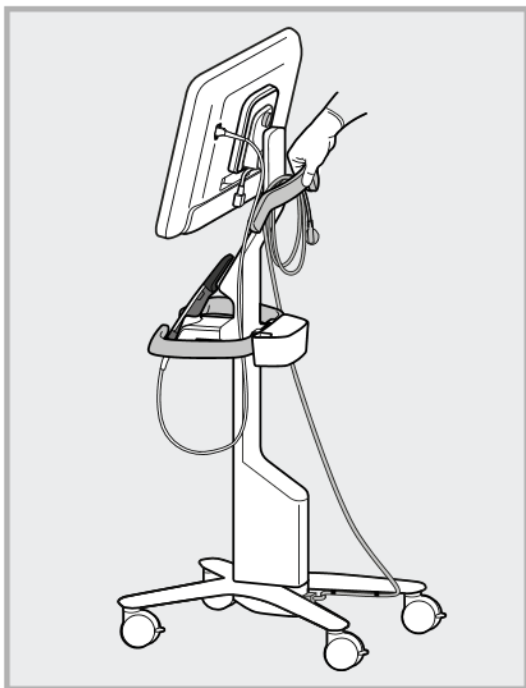


Figure 59: Moving the scanner

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 reduce the risk of the scanner toppling over or damage to the cable.

4.4.2 Carrying the iTero Lumina 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.

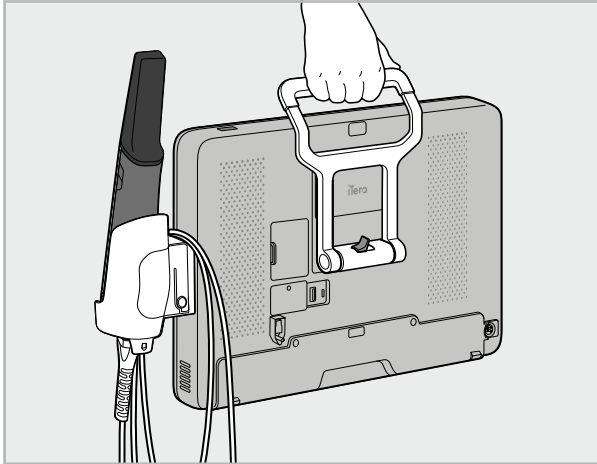


Figure 60: Carrying the scanner between rooms within the clinic

4.4.3 Transporting the iTeror Lumina 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 61: 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](#).

If you are using a PC-configuration scanner and your computer does not support [touchscreen gestures](#), you can use standard Windows [mouse controls](#).

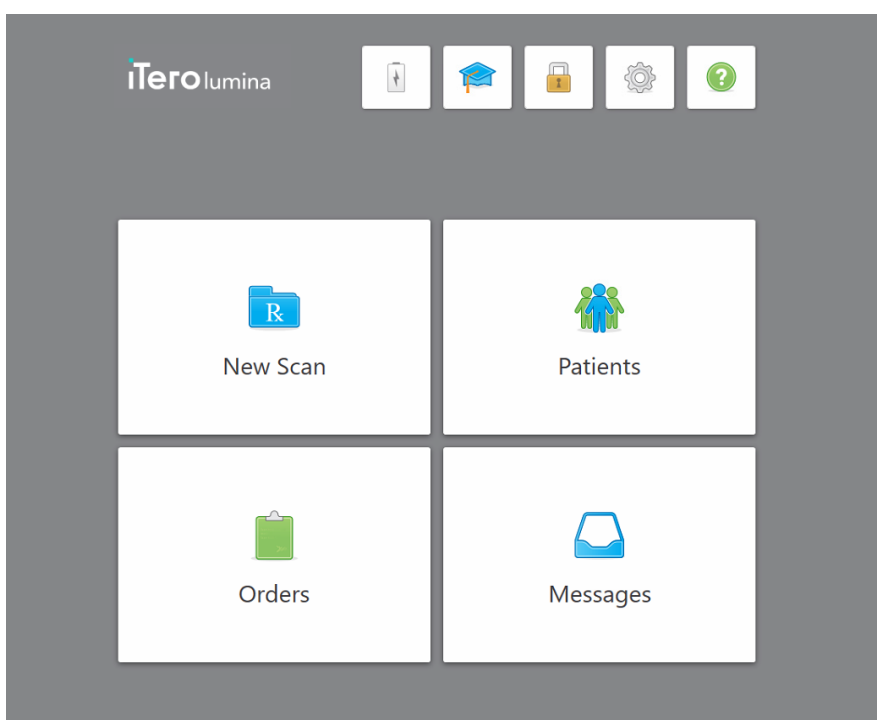


Figure 62: iTero home screen

The following buttons are displayed on the home screen:



Displays the status of the 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:

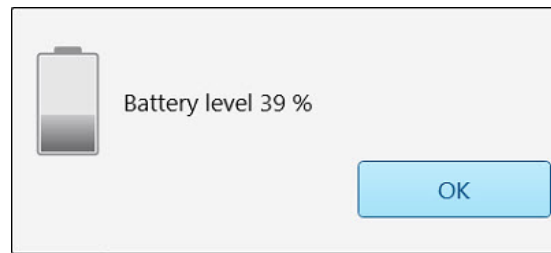


Figure 63: Percentage of remaining battery charge



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:

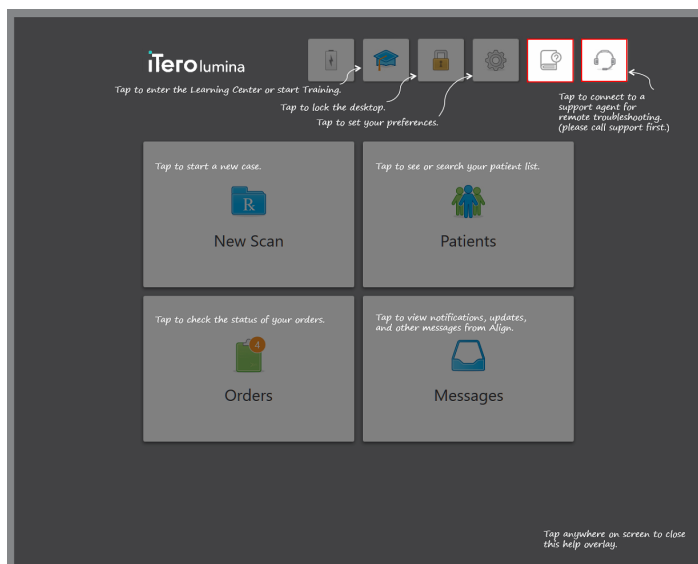


Figure 64: Help overlay including the e-manual and Customer Support buttons

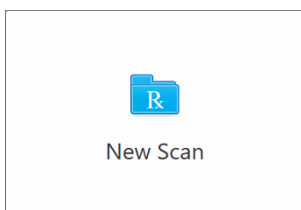


Tap to access the relevant iTerro Lumina e-manual.

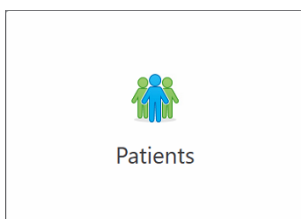


Tap for remote assistance from Customer Support. Customer Support is available from every Help overlay.

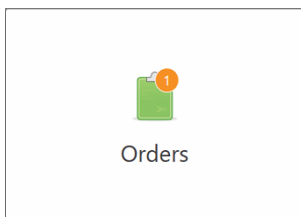
Note: Please call Customer Support before trying to connect remotely.



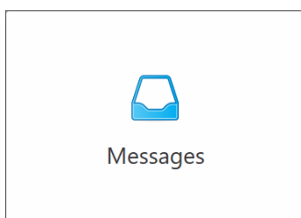
New Scan: Tap to open the *New Scan* window to fill in the Rx before starting a new scan.



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.

In addition, the close button , which enables you to exit the iTero Lumina software, is displayed on the top right-hand corner of the home screen.

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 65: 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.



Indicates that the wand is still in the initialization and warm-up phase and not ready for use.



Displays the status of the 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:

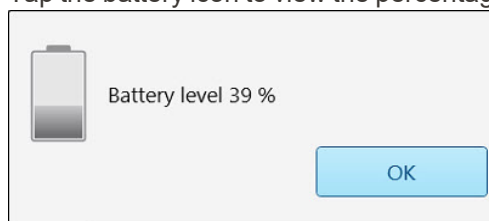


Figure 66: Percentage of remaining battery charge



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:

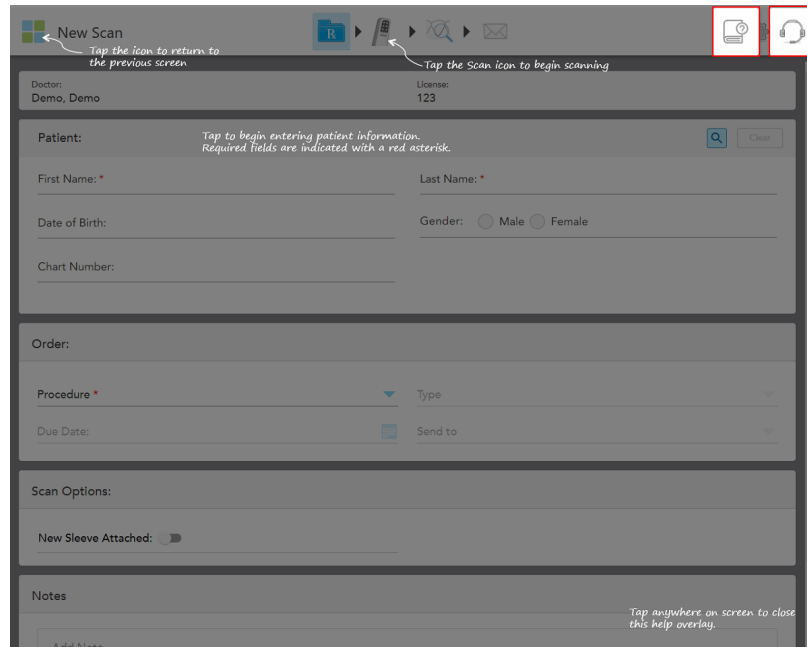


Figure 67: Help overlay including e-manual and Customer Support buttons



Tap to access the relevant iTero Lumina 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

4.5.3 Mouse controls

If your computer does not support a touchscreen, you can perform the following common actions using standard Windows mouse controls:

- Rotate the model – Press and hold the left mouse button and drag the scanned model to the required angle.
- Move the model – Press and hold the right mouse button and drag the scanned model to the required location.
- Zoom in/out – Scroll up or down using the wheel button.
- Open a sub-menu, for example, Segment, Fill, Selection – Right-click anywhere on the screen.
- Pan (center the model) – Double-click the model.
- Long press – Right-click anywhere on the screen.
- Left click + CTRL – Zoom (up to zoom out, down to zoom in).
- Scroll down – Zoom out (for Invisalign Outcome Simulator, this is zoom in).
- Scroll up – Zoom in (for Invisalign Outcome Simulator, this is zoom out).

- Scan mode:
 - Rotate the model – Press and hold the left mouse button and drag the scanned model to the required angle.
 - Move the model – Press Shift, hold the left mouse button and drag the scanned model to the required location.
 - Zoom in/out – Scroll up or down using the wheel button.
 - Open a sub-menu, for example, Segment, Fill, Selection – Right-click anywhere on the screen
- View mode:
 - Rotate the model – Hold the left mouse button and drag the scanned model to the required angle.

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.

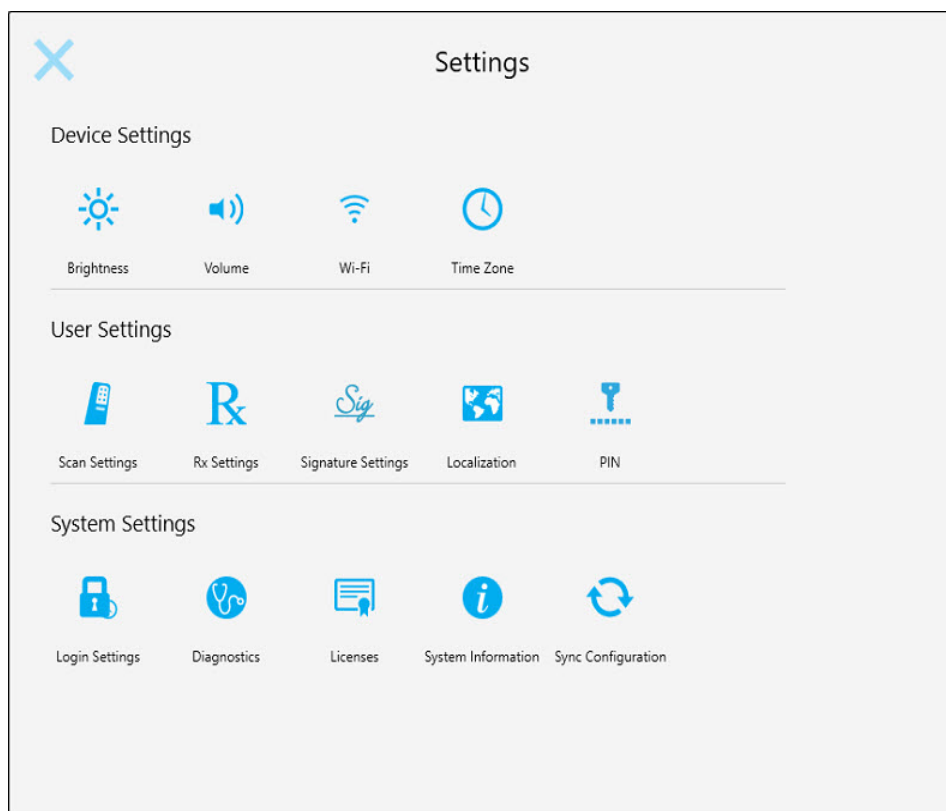


Figure 68: Settings window

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 69: 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.

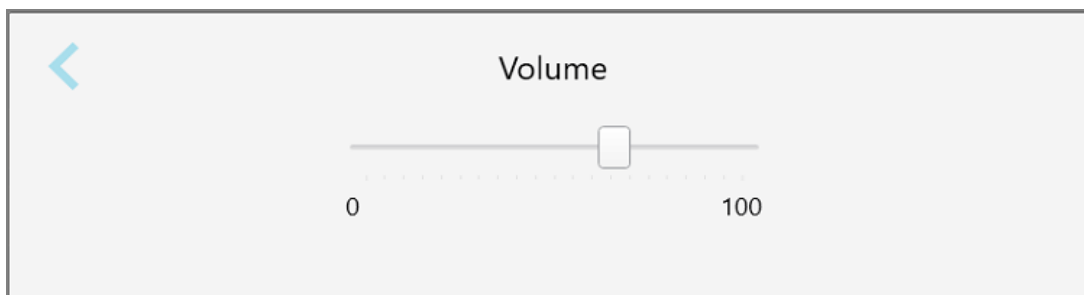


Figure 70: Volume settings

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.

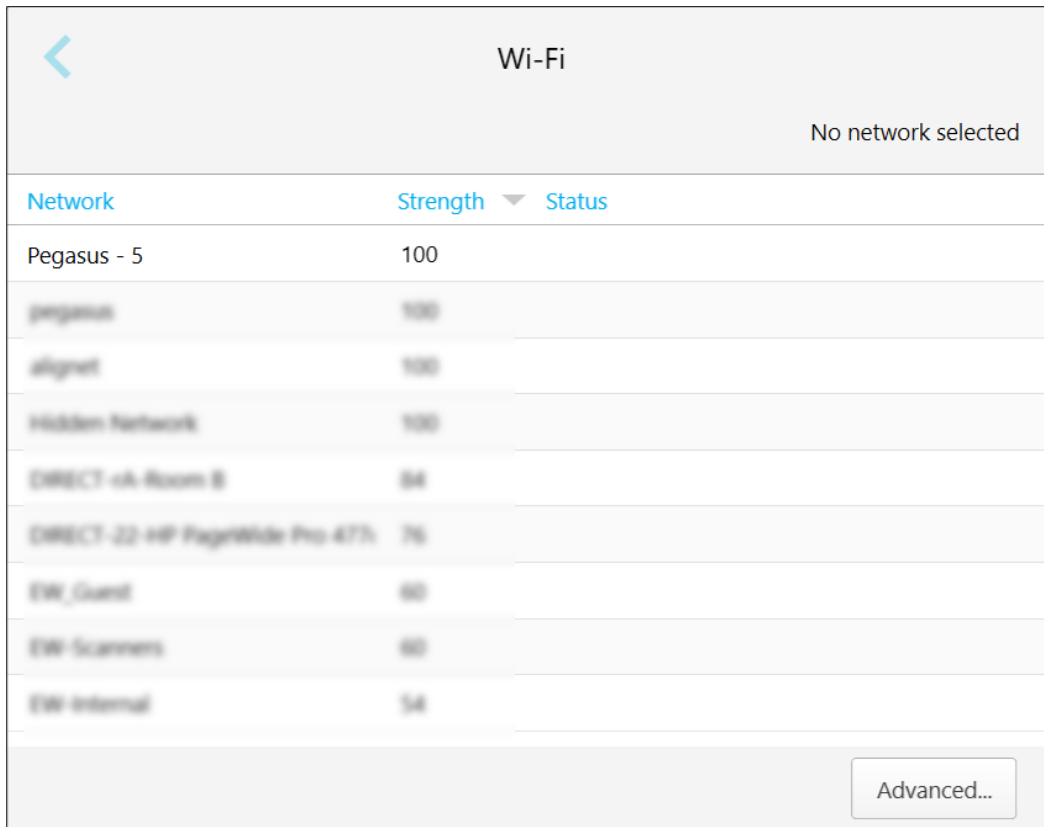


Figure 71: List of nearby Wi-Fi networks

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**.

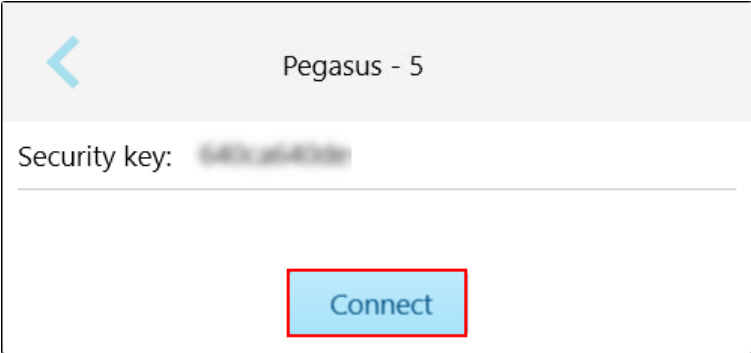


Figure 72: Connecting to the clinic Wi-Fi network

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.

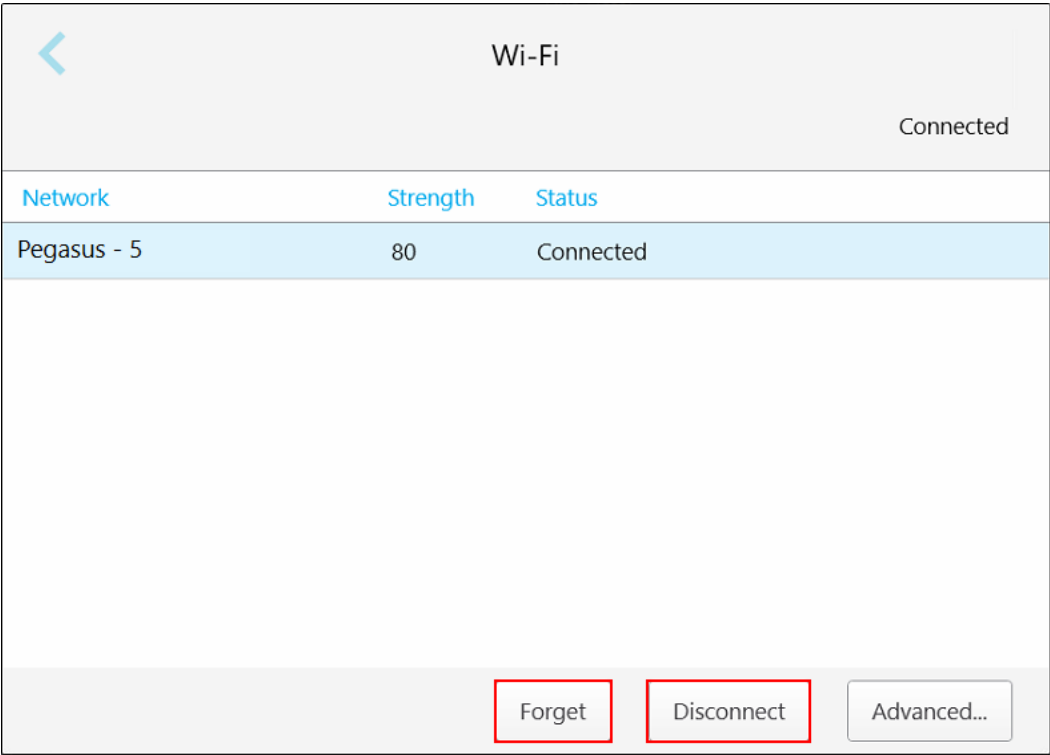


Figure 73: Forgetting or Disconnecting from the network

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.

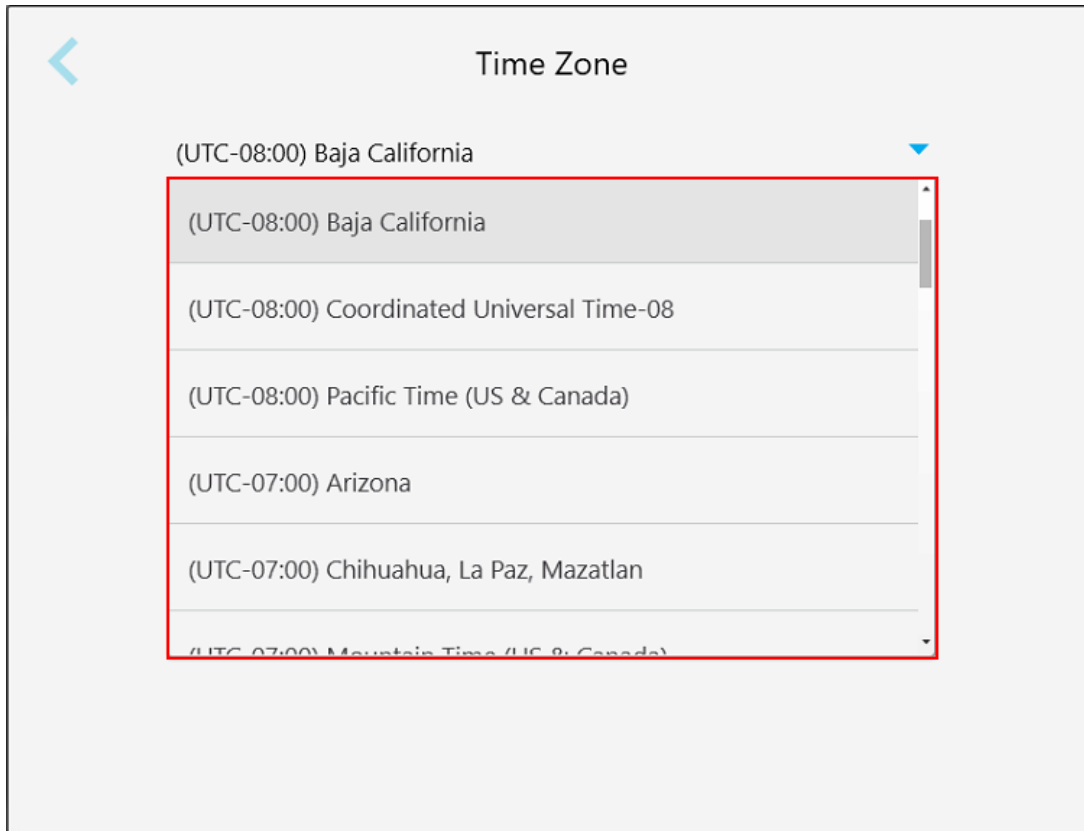


Figure 74: Time zone settings

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.

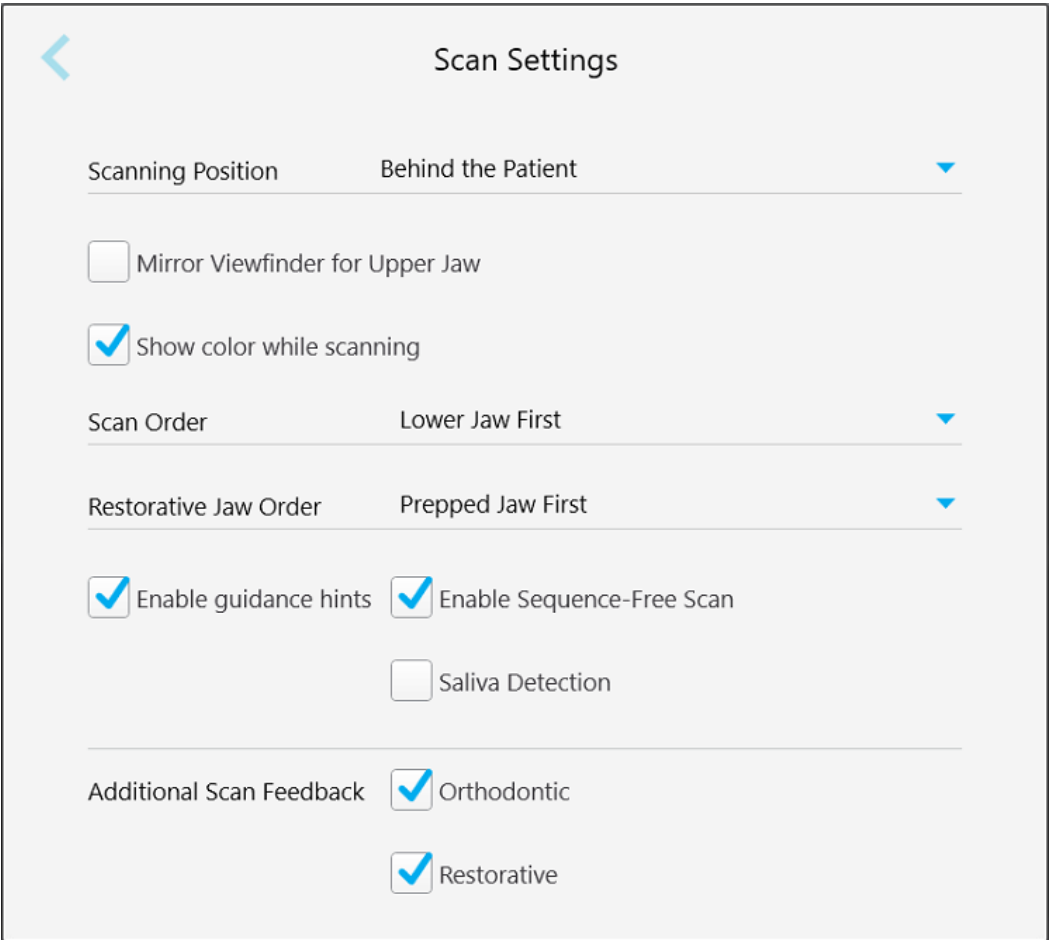


Figure 75: Scan Settings window

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

Scan setting	Scan options
Scanning Position	<p>Select your position while scanning the patient:</p> <ul style="list-style-type: none"> • Behind the patient • In front of the patient
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	<p>Select the order in which to scan the jaws:</p> <ul style="list-style-type: none"> • Upper Jaw First • Lower Jaw First
Restorative Jaw Order	<p>Select the order in which to scan the jaws for fixed restorative procedures:</p> <ul style="list-style-type: none"> • Opposite Jaw First • Prepped Jaw First
Enable guidance hints check box	Select this check box to display guidance when scanning .
Enable Sequence-Free Scan	<p>Select this check box to enable scanning without a set protocol.</p> <p>If this check box is not selected, you will need to follow the Align scanning protocol.</p>
Saliva Detection	<p>Select this check box to enable saliva detection when scanning.</p> <p>If you clear the check box, a confirmation message is displayed notifying that saliva moisture control is still required and that areas in which saliva is detected may need to be removed and rescanned.</p>

Scan setting	Scan options
Additional Scan Feedback	Select the relevant check boxes to display areas of missing anatomy while scanning . <ul style="list-style-type: none">• 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.

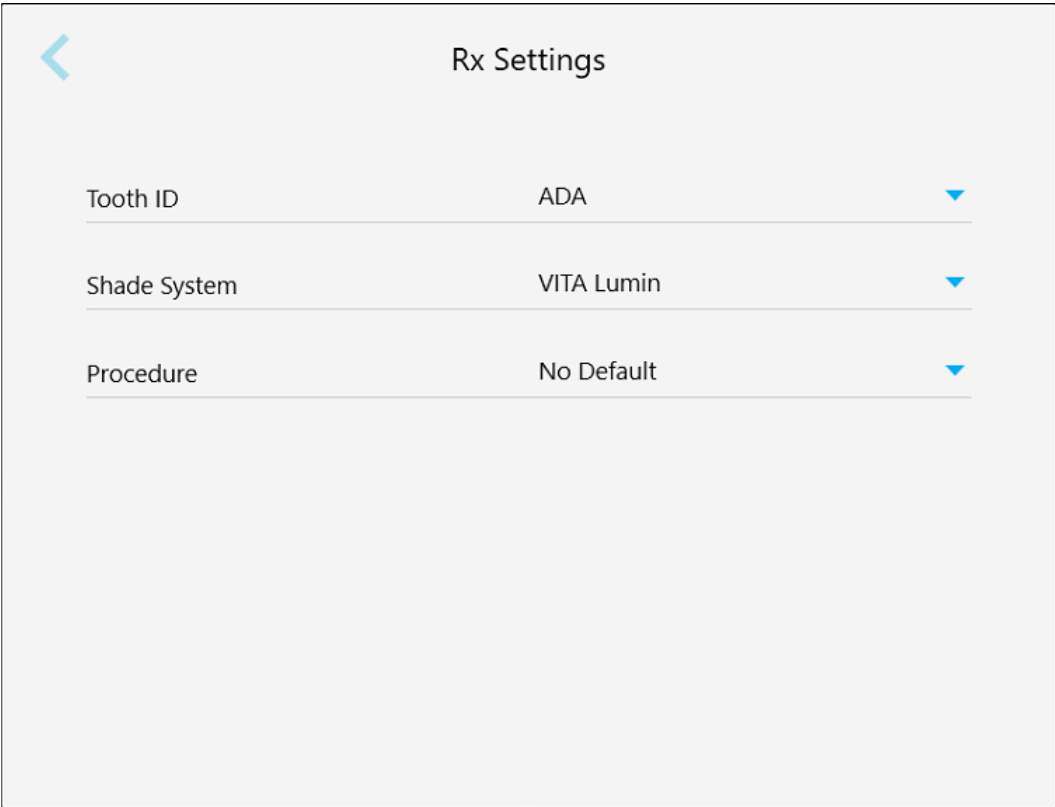


Figure 76: Rx Settings window

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

Rx setting	Rx options
Tooth ID	Select the default tooth ID system: <ul style="list-style-type: none">• FDI• ADA• Quadrant
Shade System	Select the default shade system: <ul style="list-style-type: none">• VITA Lumin• VITApan 3D Master• Other
Procedure	Select the default procedure: <ul style="list-style-type: none">• Appliance• Denture/Removable• Fixed Restorative• Implant Planning• Invisalign Viverra• Study Model/iRecord• No Default <p>Note: The list of available procedures changes according to your iTero subscription package.</p>

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.

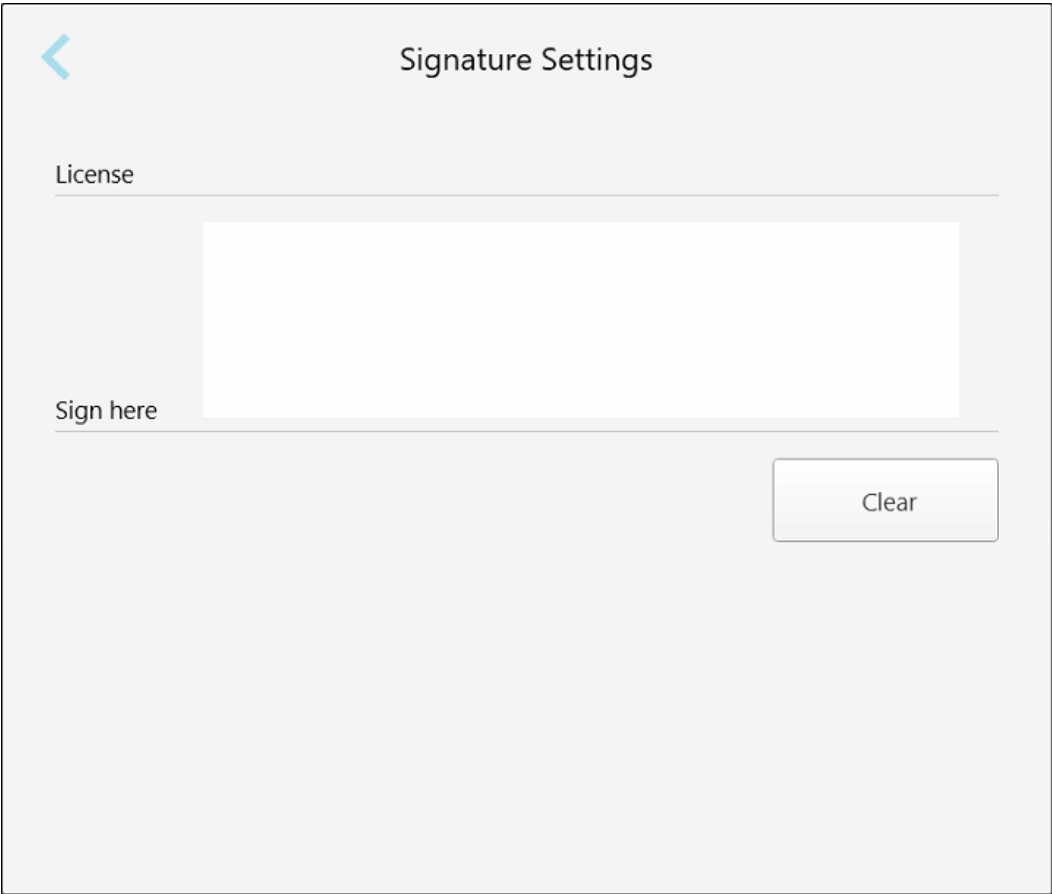


Figure 77: Signature Settings window

- 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.

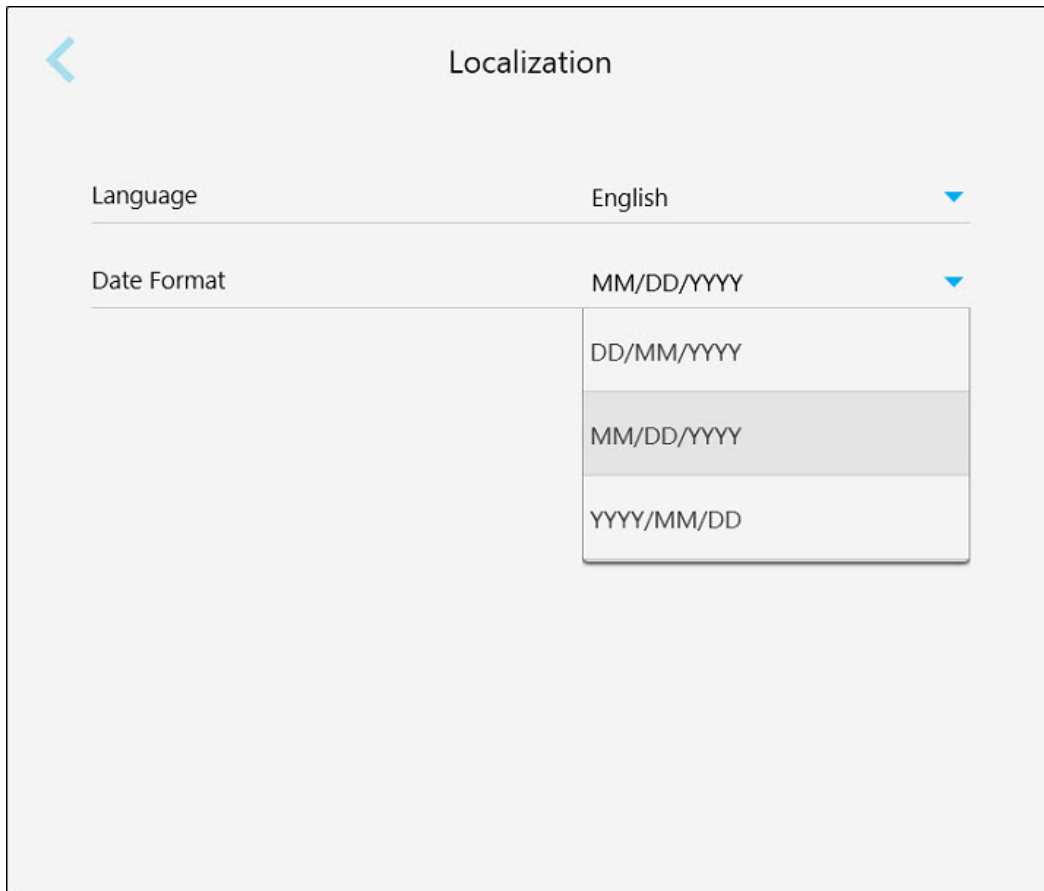


Figure 78: Localization window

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.

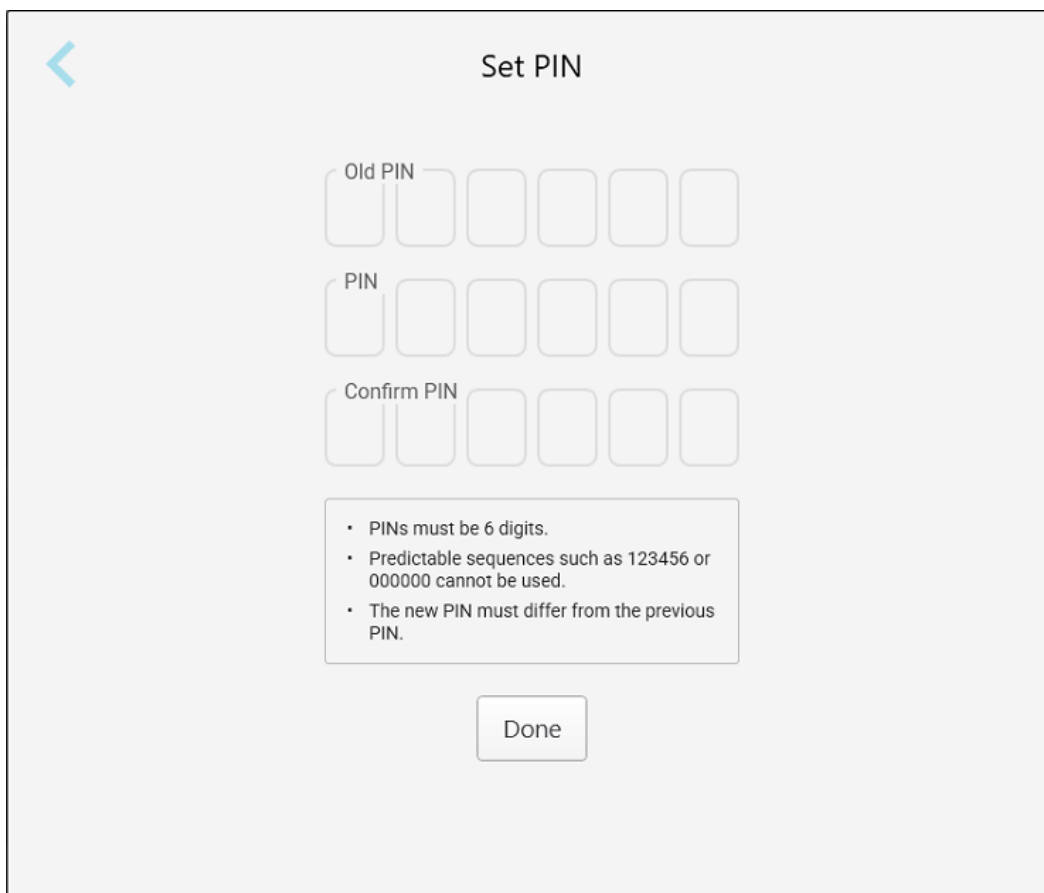
The screenshot shows a mobile application window titled "Set PIN". In the top-left corner, there is a blue back arrow icon. The window contains three input fields, each consisting of a label and six adjacent boxes for digits. The first field is labeled "Old PIN", the second "PIN", and the third "Confirm PIN". Below these fields is a white box with a thin 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 of the window is a rounded rectangular button labeled "Done".

Figure 79: 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.

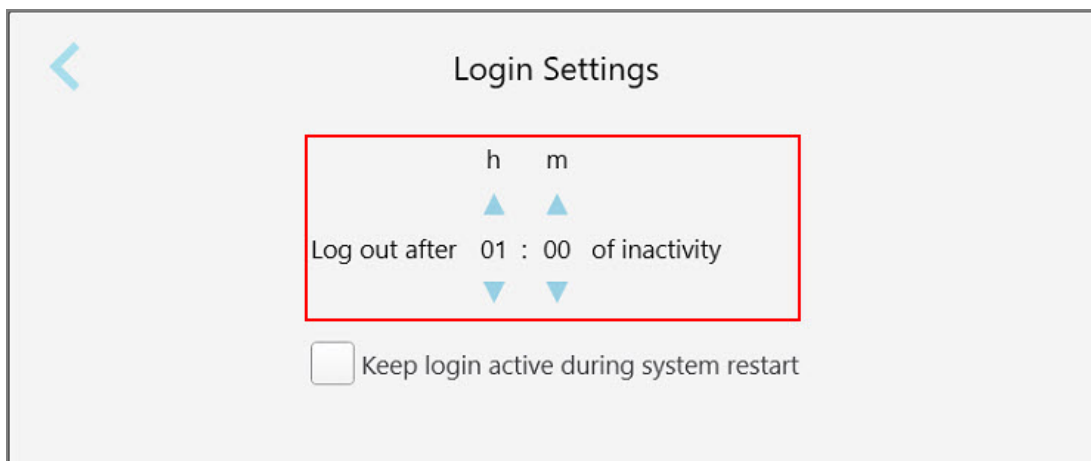


Figure 80: Login Settings window

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.

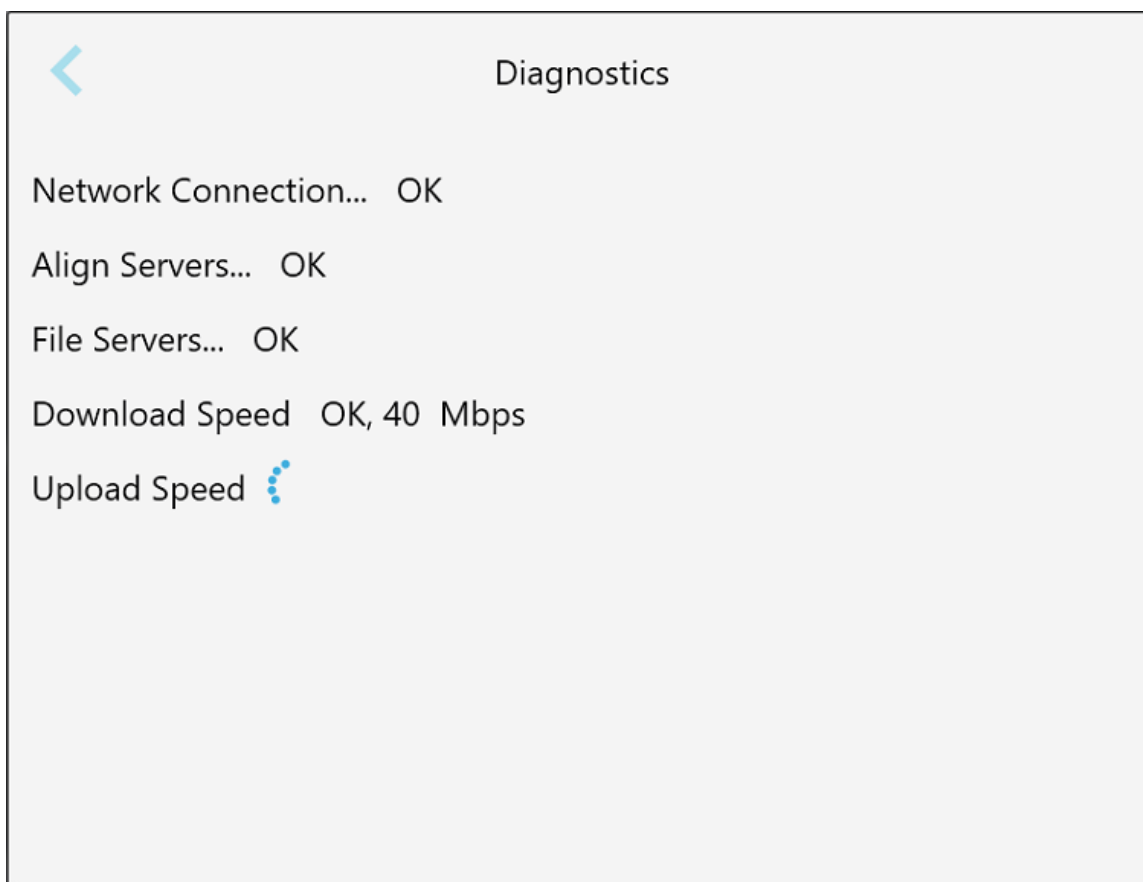


Figure 81: Diagnostics window

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.

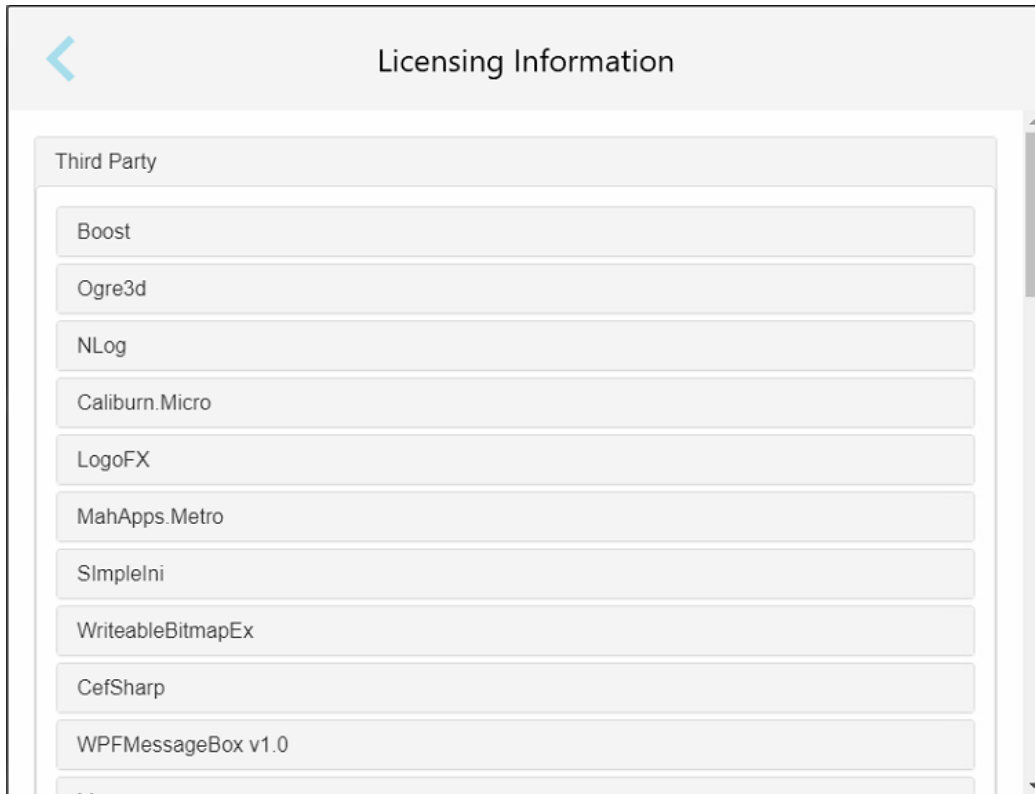


Figure 82: Licensing Information window

4.6.3.4 System information

Tap the **System Information** button to view details about the software versions installed, the hardware serial numbers, the office ID, and the regulatory symbols of the scanner.

Tap  to return to the *Settings* window.

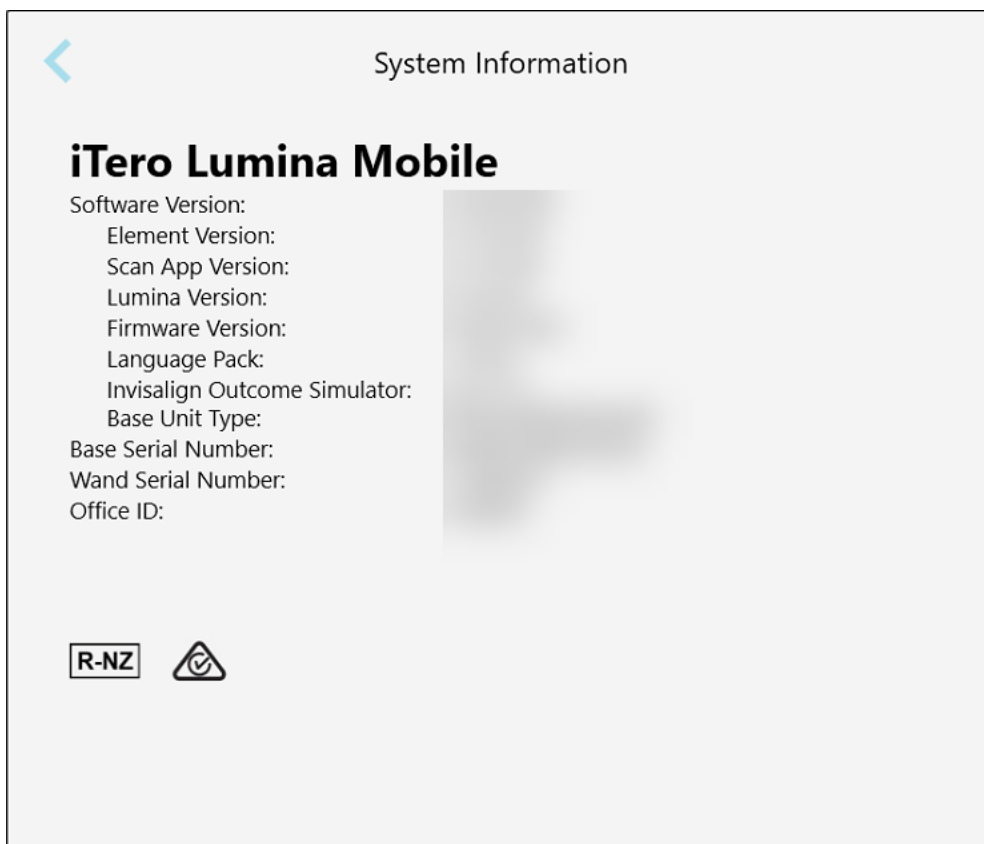


Figure 83: System Information window – iTero Lumina mobile configuration

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 sleeve](#) to reduce the risk of cross-contamination.
- 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 sleeve

To apply a wand sleeve:

1. Gently remove the dark protective sleeve from the wand.

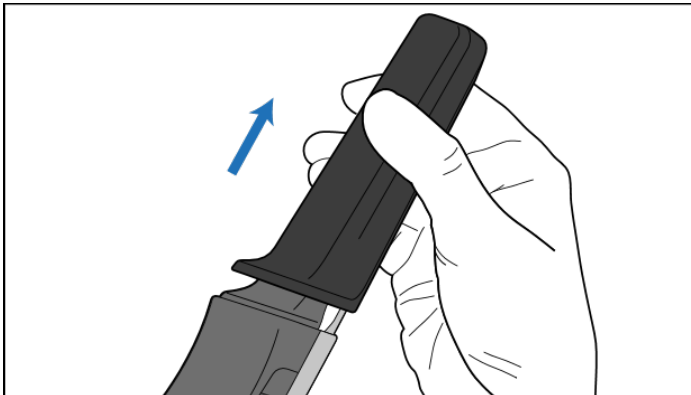


Figure 84: Remove the protective sleeve

2. Wearing gloves, gently slide a new sleeve onto the tip of the wand until it clicks into place.

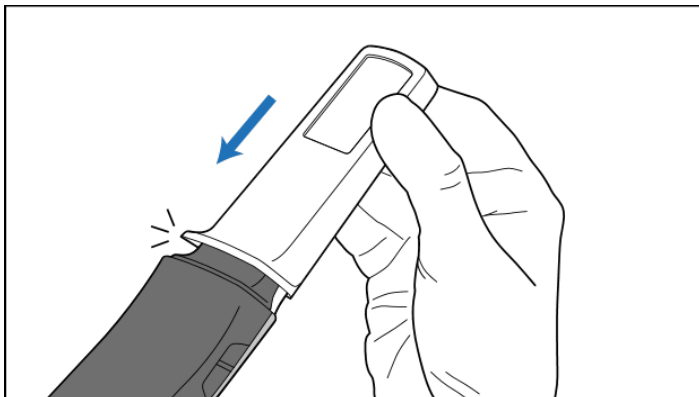


Figure 85: Gently slide the new sleeve into place

Note: Do not touch the sleeve window.

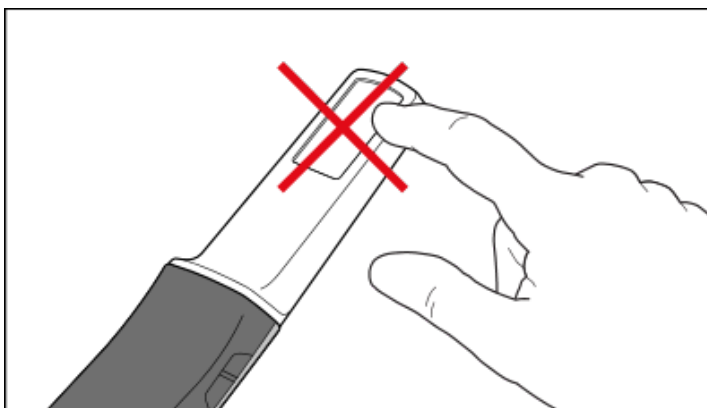
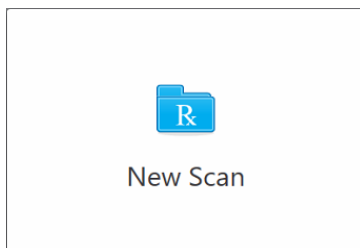


Figure 86: Do not touch the sleeve window

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.

The screenshot shows the 'New Scan' window. At the top, there is a toolbar with icons for a blue square, a mobile phone, a magnifying glass, and an envelope, all enclosed in a red box. Below the toolbar, the window is divided into several sections: 'Doctor' (Dr. Demo, Demo) and 'License' (12345); 'Patient' (with fields for First Name, Last Name, Date of Birth, Gender, and Chart Number); 'Order' (with fields for Procedure, Type, Due Date, and Send to); 'Scan Options' (with a toggle for 'New Sleeve Attached'); and 'Notes' (with an 'Add Note' button).

Figure 87: 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 iTerio 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.

Figure 88: 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 89: 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 | Viverra**: 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.

*Subject to regulatory or other required approvals and commercial availability in your country/region.

7. In the **Scan Options** area, turn on/off the following toggles, depending on the procedure selected, as required.
 - **New Sleeve Attached**: Turn on the **New Sleeve Attached** toggle to confirm that a new sleeve has been attached.
 - **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.

Notes:

 - 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.
 - When scanning a Fixed Restorative procedure, you can select up to 5 additional bites.
 - **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.
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 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:**
 - All Study Model/iRecord scans are available for Invisalign.
 - Procedure: * Study Model/iRecord (dropdown menu)
 - Ortho Model/iCast: ☐
 - Due Date: *
 - Send to: *
- Scan Options:**
 - New Sleeve Attached: ☐
 - 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 90: Study Model/iRecord procedure – with Attachments 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 | Vivera procedures

The Invisalign | Vivera 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 | Vivera procedure:

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

The *New Scan* window is displayed as follows:

Figure 91: Order area – Invisalign | Vivera procedure

3. From the **Type** drop-down list, select the type of Invisalign procedure required, depending on your iTerio 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 is removed automatically from around the edges of the model during scanning. If required, you can disable this by pressing on the screen and then tapping the [Enable appliance scan tool](#).

 - Vivera Retainer – maintains the position of the teeth after treatment. If brackets are still present, they will be removed by the iTerio software. The Vivera retainers will be provided at the debonding appointment.
 - Invisalign Retainer
4. 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 7, **Scan Options**, 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 **Tooth Diagram** area showing the tooth numbers and illustrations and an **Attachments** area.

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

- Header:** 'New Scan' title and navigation icons.
- Doctor:** Dr. Demo, Demo; License: 12345.
- Patient:**
 - First Name: Patient; Last Name: Demo.
 - Date of Birth: ; Gender: Male (selected), Female.
 - Chart Number:
- Order:**
 - Procedure: Fixed Restorative; Type:
 - Due Date: ; Send to:
- Scan Options:**
 - New Sleeve Attached: ☐; Pre-Treatment Scan: ☐; Multi-Bite: ☐.
- 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 92: Tooth Diagram area – 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.
 - New Sleeve Attached:** Turn on the **New Sleeve Attached** toggle to confirm that a new sleeve has been attached.

- **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.
- **Multi-Bite:** Turn on the **Multi-Bite** toggle if you would like to scan additional bites and then select the bite types to scan. You can select up to five additional bite types.

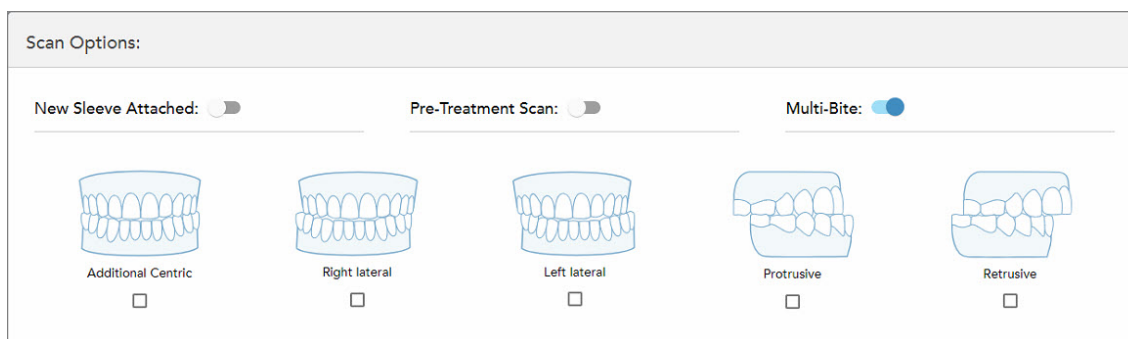


Figure 93: Multi-Bite options

6. In the **Tooth Diagram** area, tap the tooth to be restored.
A list of available options for the selected tooth is displayed.

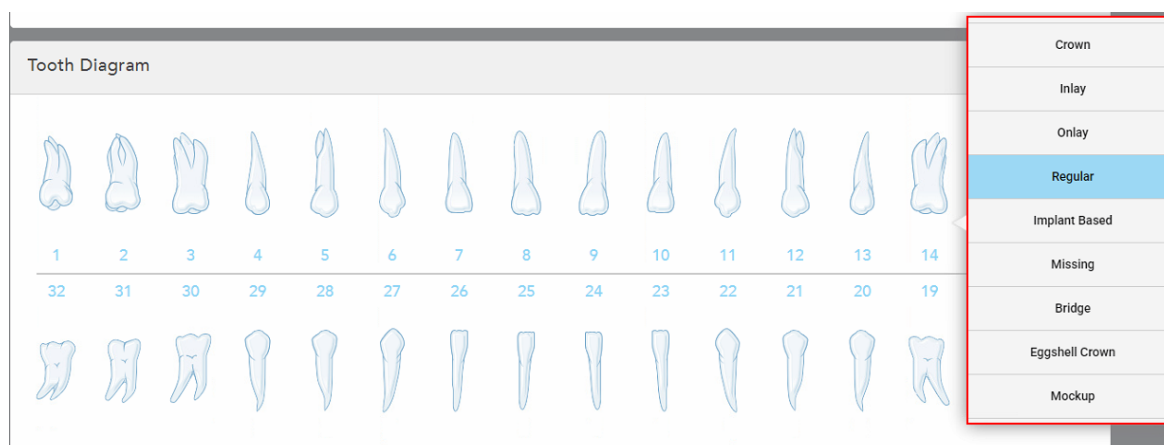


Figure 94: List of fixed restorative treatment options

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.

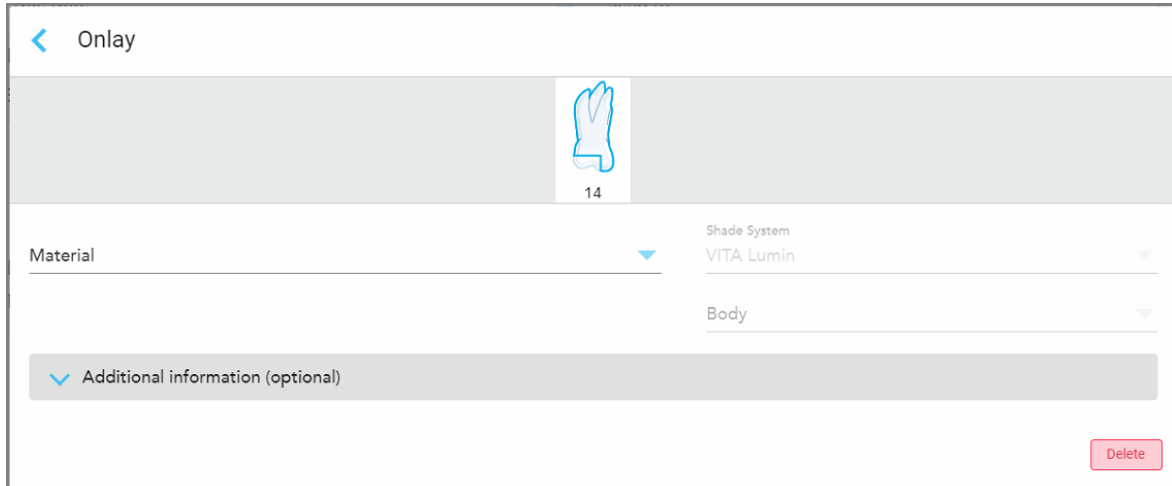


Figure 95: Treatment settings window – Onlay restoration

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 96: 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.

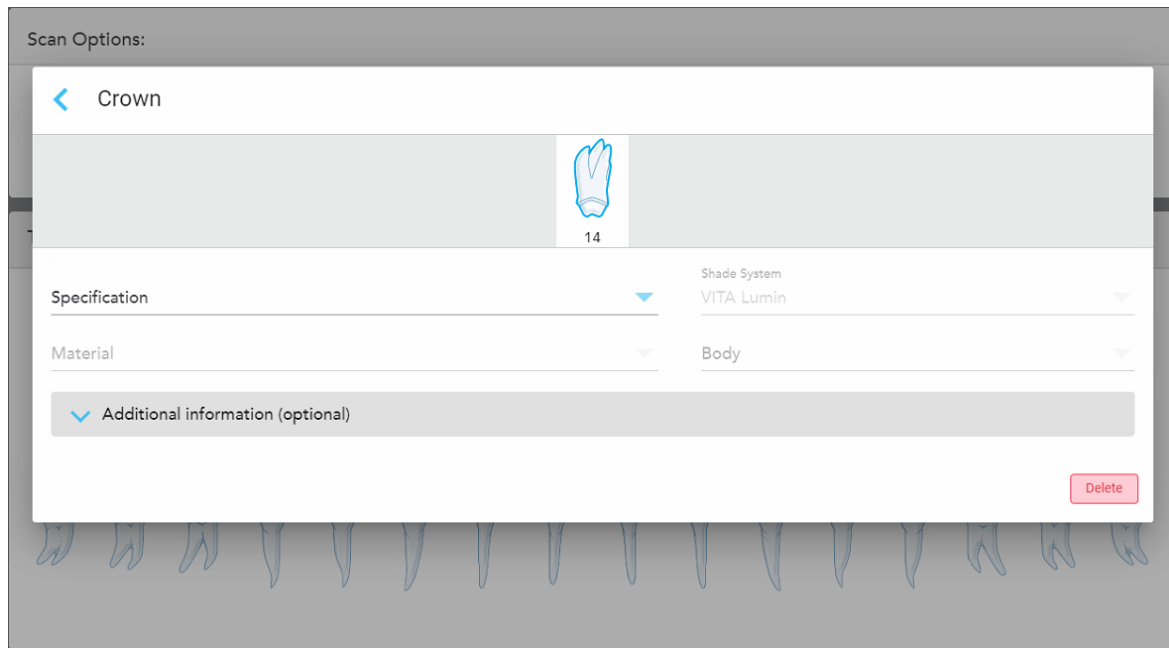
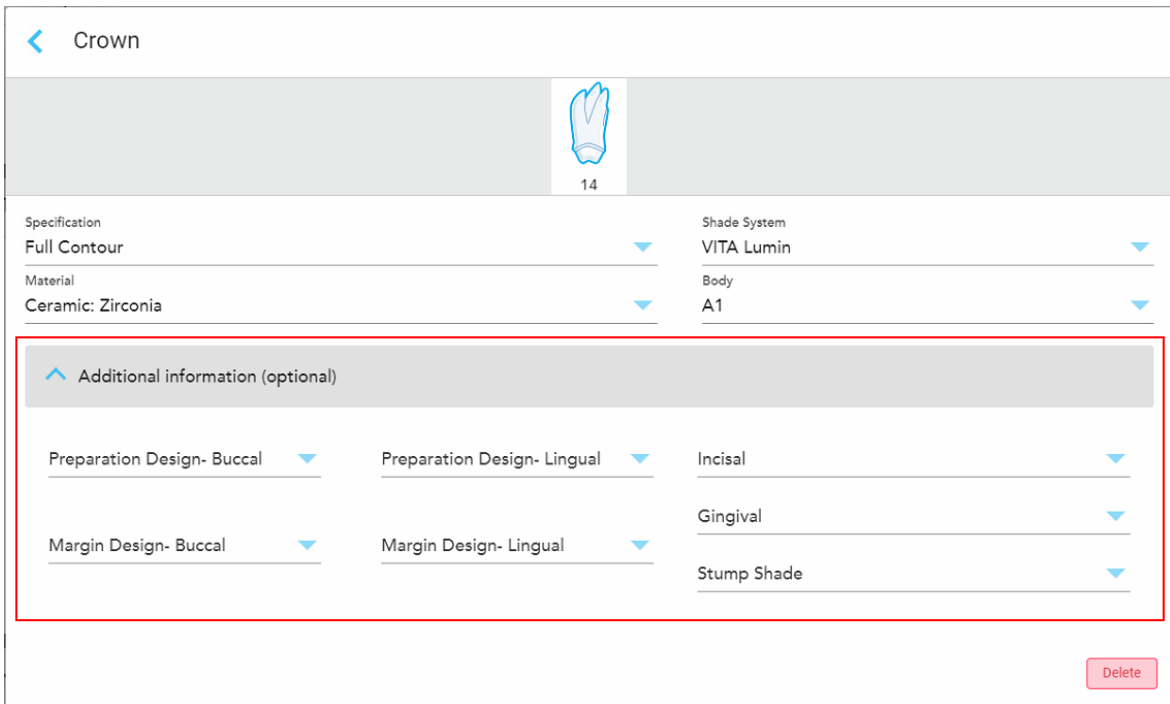


Figure 97: Treatment settings window – Crown restoration

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. After 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:



← Crown

14

Specification
Full Contour ▼

Material
Ceramic: Zirconia ▼

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 98: 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.

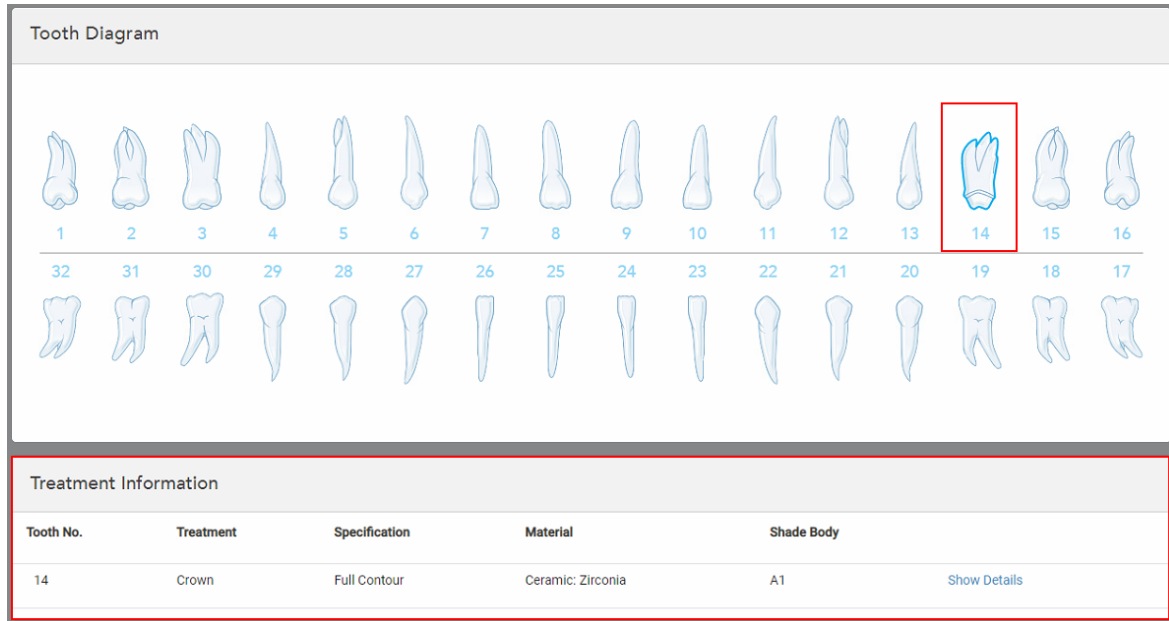


Figure 99: Selected tooth and Treatment Information area – Crown restoration

- 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.

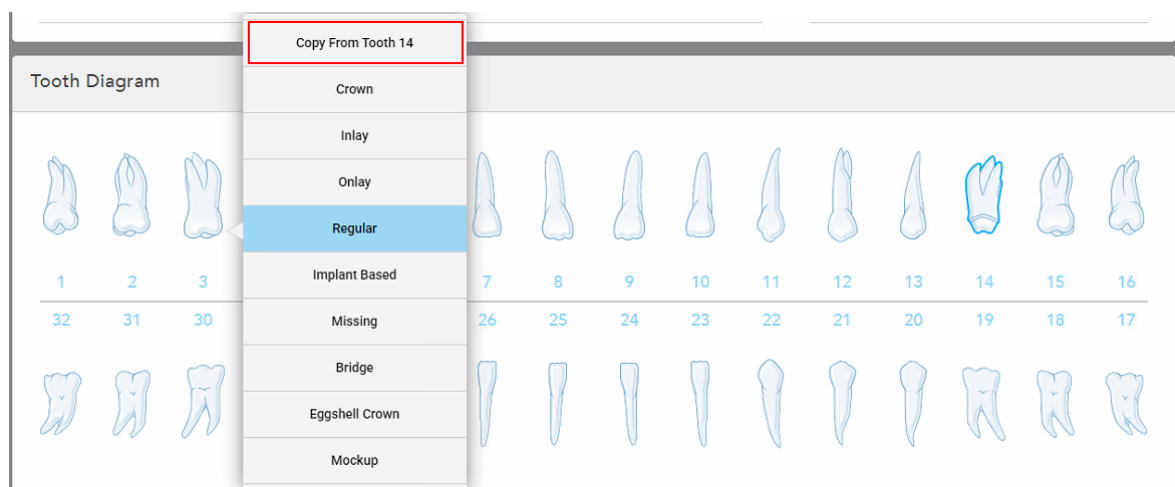


Figure 100: Copy restoration settings from a tooth requiring the same treatment type

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.

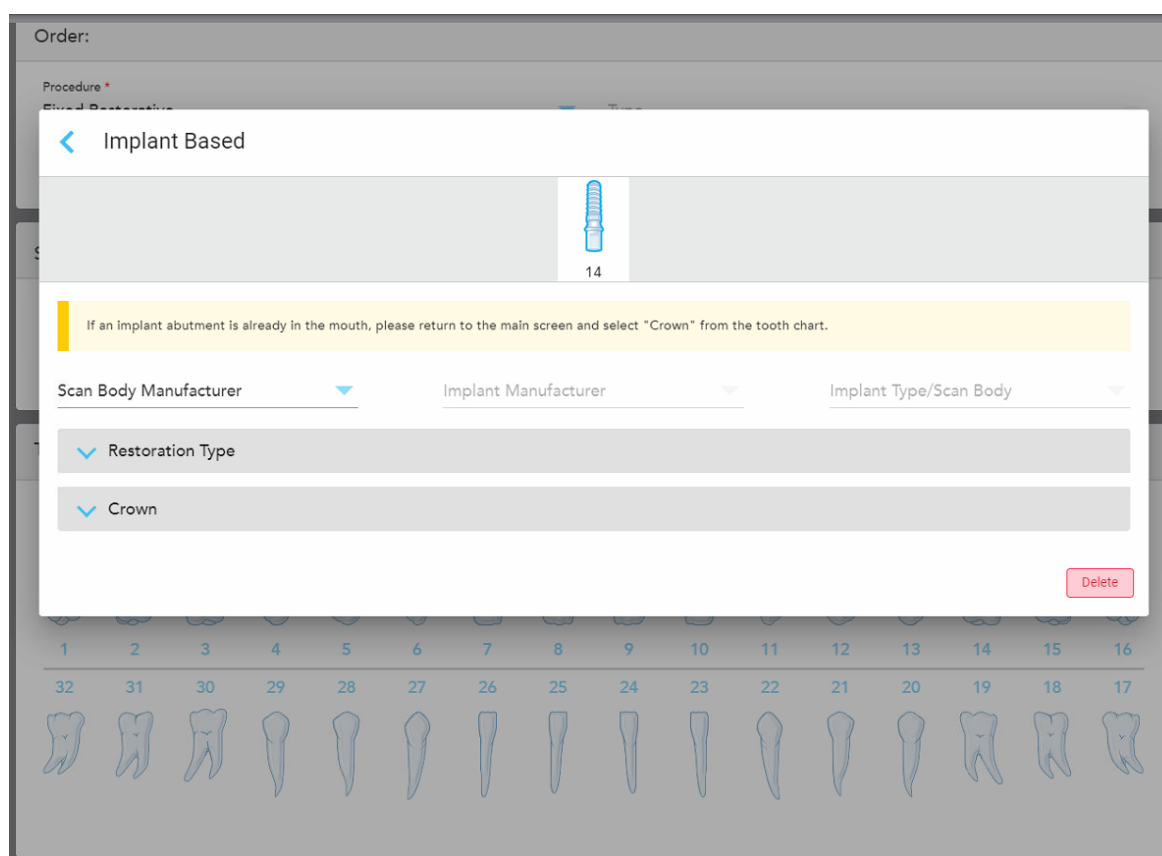


Figure 101: Treatment settings window – Implant Based restoration

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](#).

3. 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.

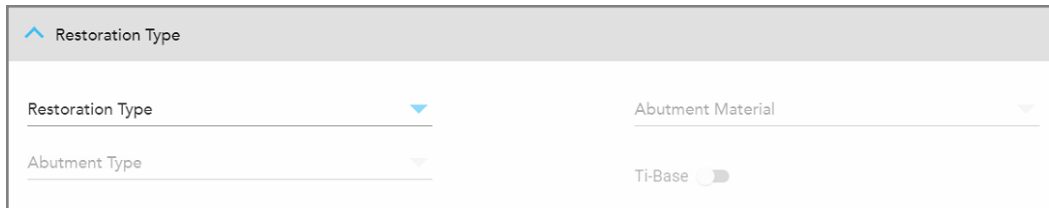


Figure 102: Expanded Restoration Type area

4. 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.

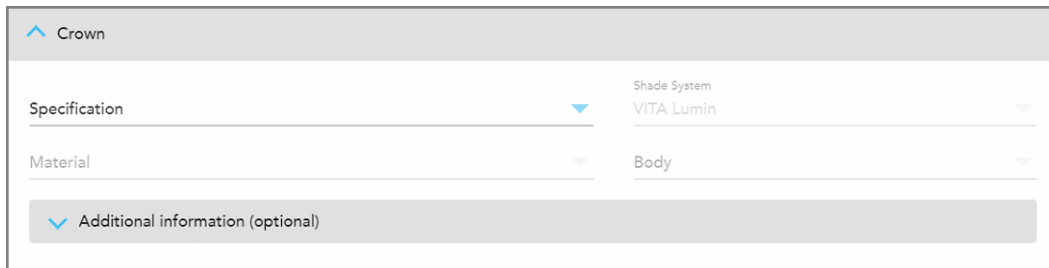


Figure 103: Expanded Crown area

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

1. 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.

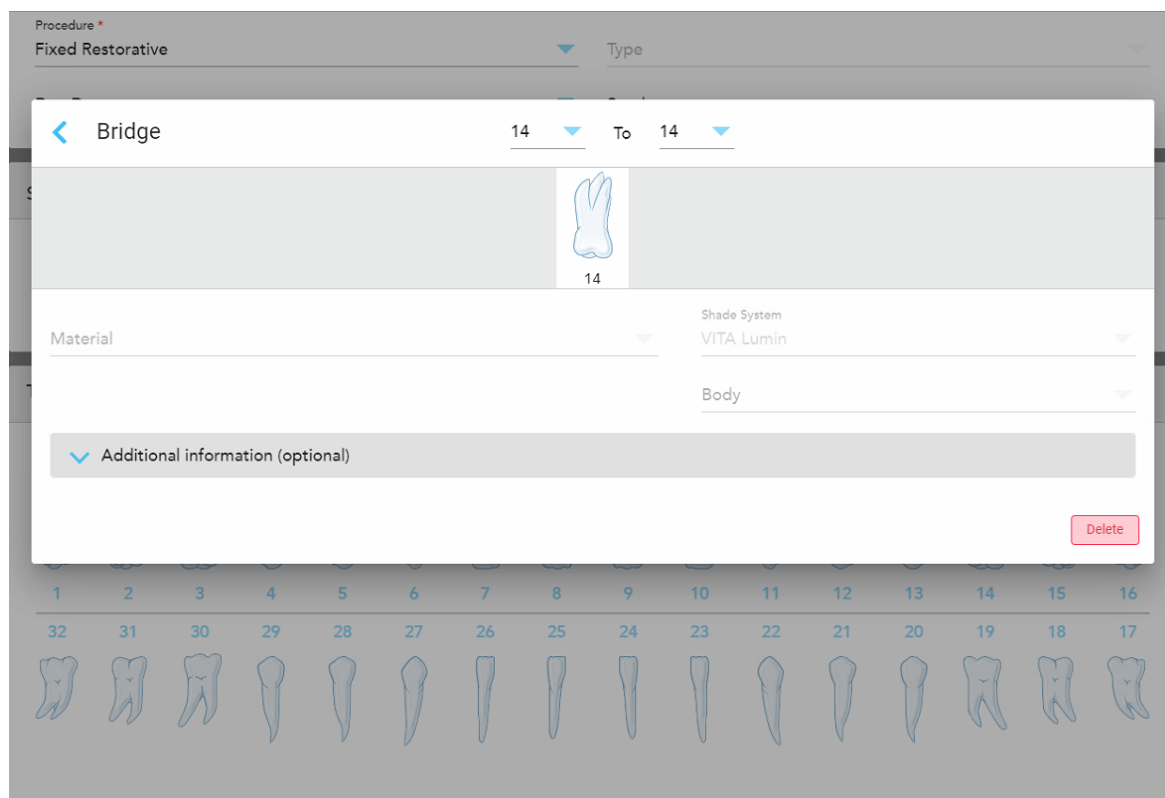


Figure 104: Treatment settings window – Bridge restoration

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.

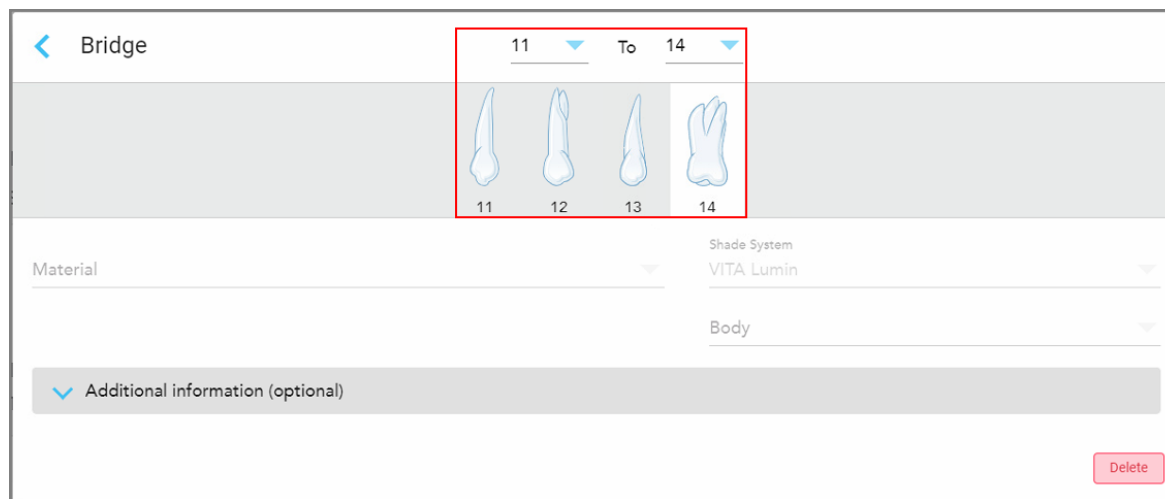


Figure 105: Bridge range and teeth to be included

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

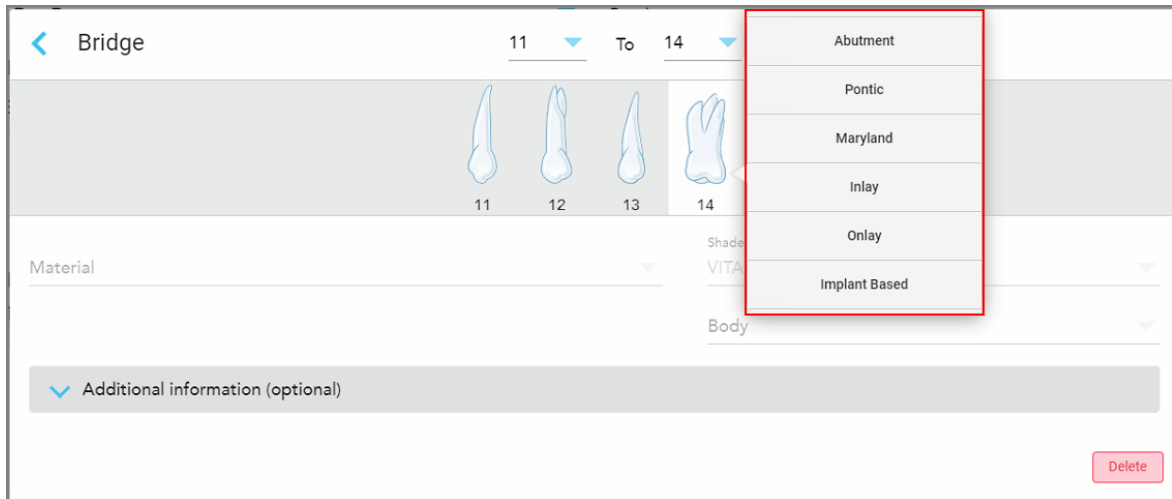


Figure 106: List of in-bridge treatment options

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

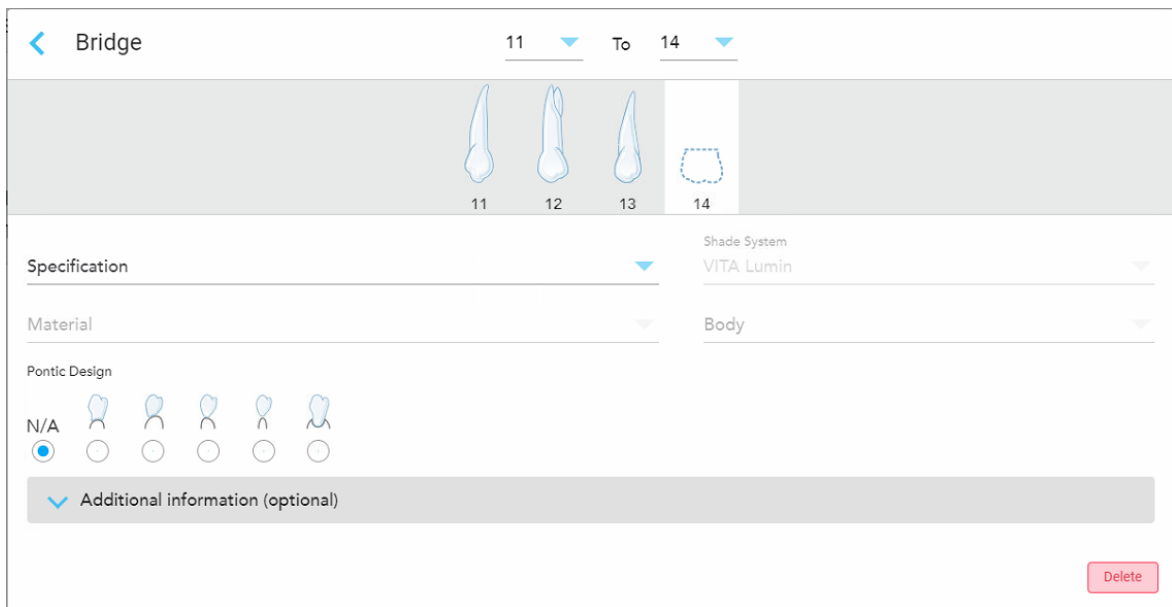
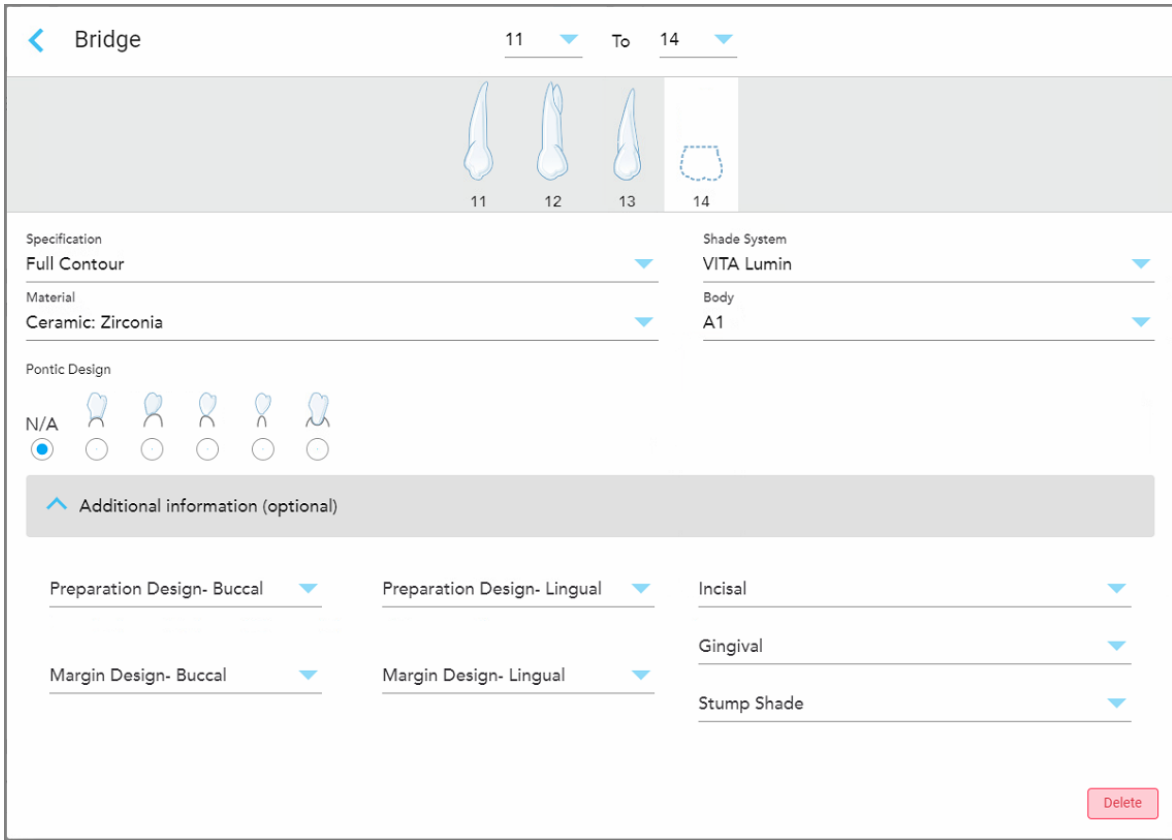


Figure 107: Bridge restoration – Pontic settings

- Specification:** The type of restoration to be fabricated.
- 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](#).
- Shade System:** The system used for choosing the shade of the restoration.
- Body:** The shade for the body area of the restoration.
- 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 ▼

Shade System
VITA Lumin ▼

Body
A1 ▼

Pontic Design
N/A 

Additional information (optional)

Preparation Design- Buccal ▼ Preparation Design- Lingual ▼ Incisal ▼

Margin Design- Buccal ▼ Margin Design- Lingual ▼ Gingival ▼

Stump Shade ▼

Delete

Figure 108: 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 109: 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 110: 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 111: 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 112: 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, and user settings.
- 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: *
- Scan Options:**
 - New Sleeve Attached: ☐
- 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 113: Implant Planning procedure – Tooth Diagram area for Surgical Guide Tooth Supported

4. If required, tap the calendar in the **Due Date** field and then select the date the plan is due.
5. 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.
6. In the **Scan Options** area, turn on/off the following toggles, as required.
 - **New Sleeve Attached**: Turn on the **New Sleeve Attached** toggle to confirm that a new sleeve has been attached.

7. 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.

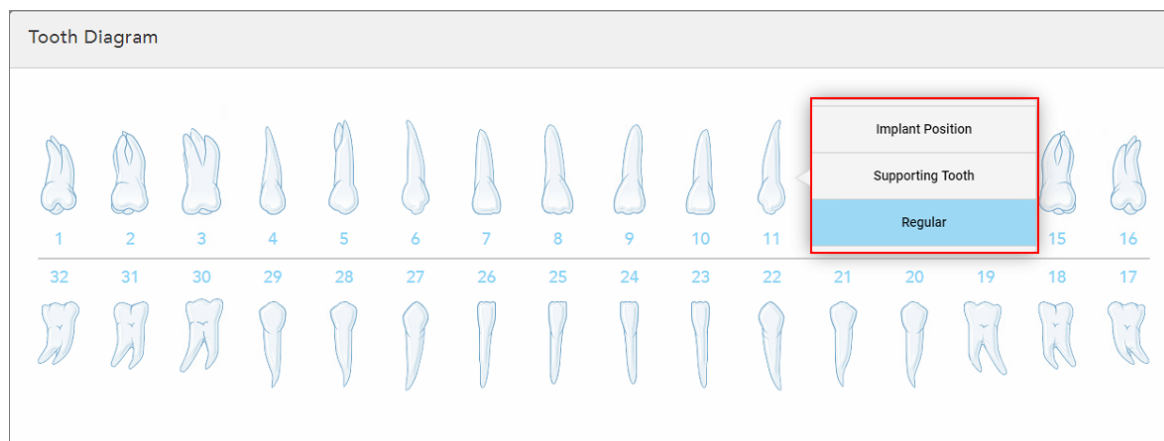


Figure 114: Defining the teeth that need to be implanted

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

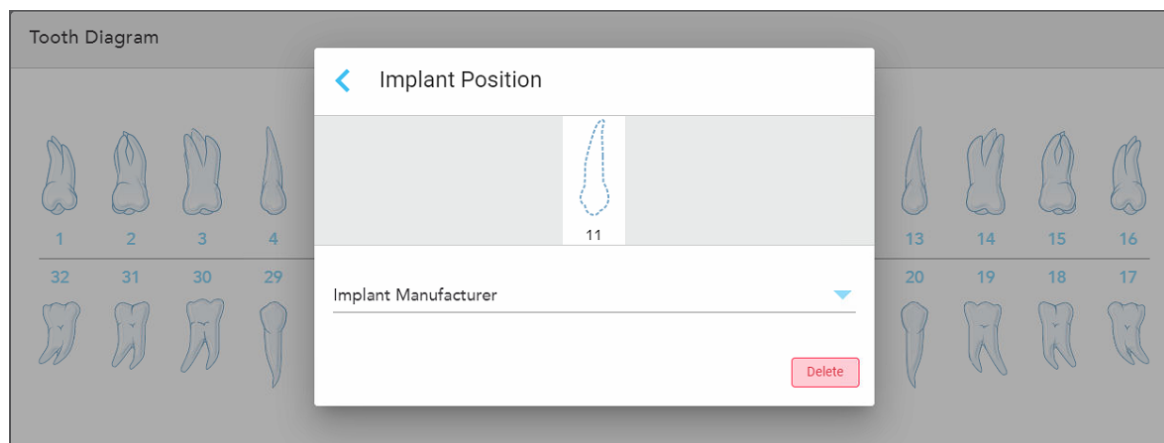


Figure 115: Implant Position window

8. Select the implant manufacturer from the drop-down list. If required, you can save the implant manufacturers you use most often as [favorites](#).
9. 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.

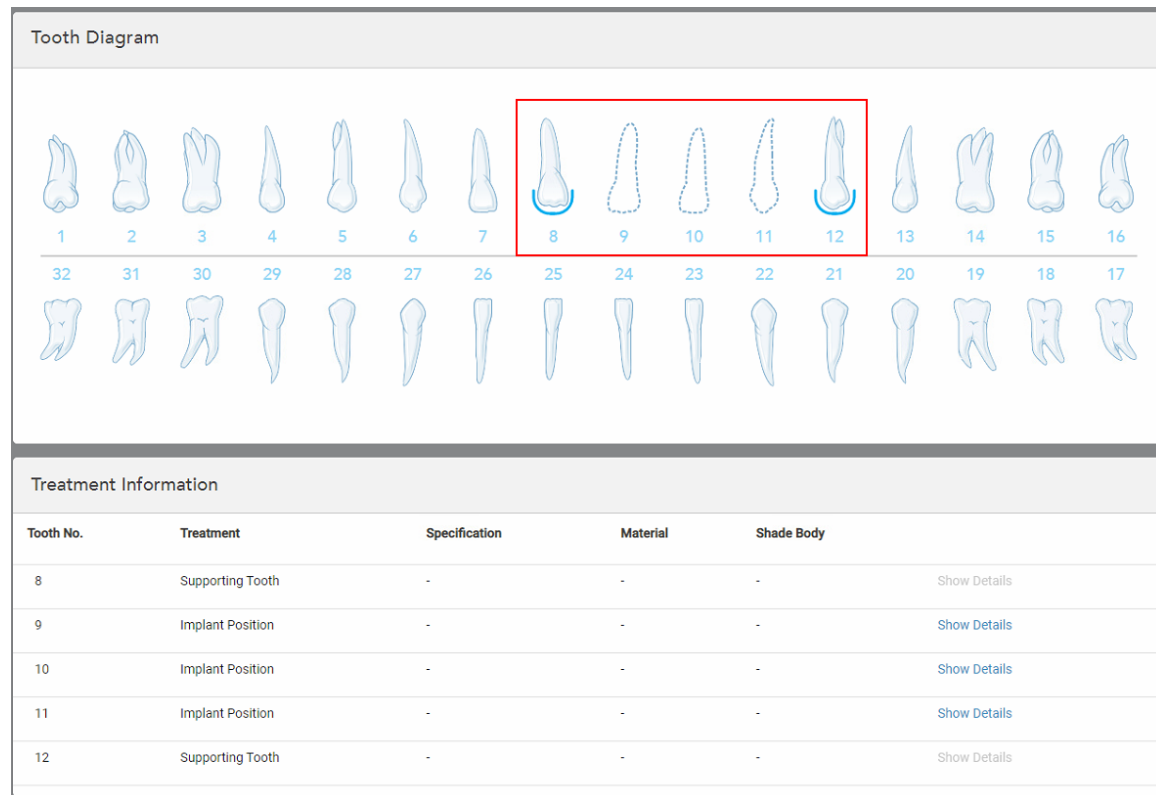


Figure 116: Supporting teeth and teeth to be implanted displayed in the Tooth Diagram and Treatment Information areas

- 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** and **Attachments** areas.

The screenshot shows the 'New Scan' window in the iTero software. The window has a title bar with 'New Scan' and several icons. The main content area is divided into several sections:

- Doctor:** Dr. Demo, Demo
- License:** 12345
- Patient:** Search and Clear buttons. Fields for First Name (Patient), Last Name (Demo), Date of Birth, Gender (Male/Female), and Chart Number.
- Order:** Procedure (Denture/Removable), Type, Due Date, and Send to.
- Denture Details:** This section is highlighted with a red border. It includes fields for Stage, Mould, Upper Denture, Lower Denture, Shade System (VITA Lumin), Teeth Shade, and Gingival.
- Scan Options:** New Sleeve Attached and Denture Copy Scan toggle switches.
- Attachments:** This section is also highlighted with a red border. It contains 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:** A text area with an 'Add Note' button.

Figure 117: Denture/Removable procedure – Denture Details area

- 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 a software interface for configuring a dental procedure. The 'Order:' section includes a 'Procedure *' dropdown set to 'Denture/Removable' and a 'Due Date:' field with a calendar icon. Below this is the 'Denture Details:' section, which contains 'Stage', 'Mould', 'Upper Denture' and 'Lower Denture' toggles, 'Teeth Shade', and 'Gingival' dropdowns. A red box highlights the 'Type *' dropdown menu, which is open and shows five options: 'Partial Denture/Framework', 'Partial Immediate Denture', 'Full Immediate Denture', 'Full Denture Tissue Based', and 'Full Denture Implant Based'.

Figure 118: 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.
 - New Sleeve Attached:** Turn on the **New Sleeve Attached** toggle to confirm that a new sleeve has been attached.

- **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.

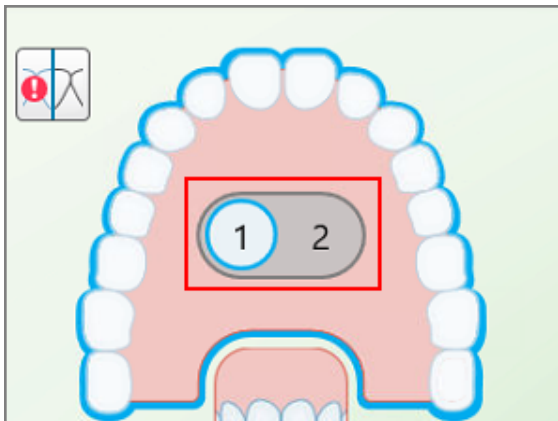


Figure 119: Scanning option for scanning both the existing dentures and the patient

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.

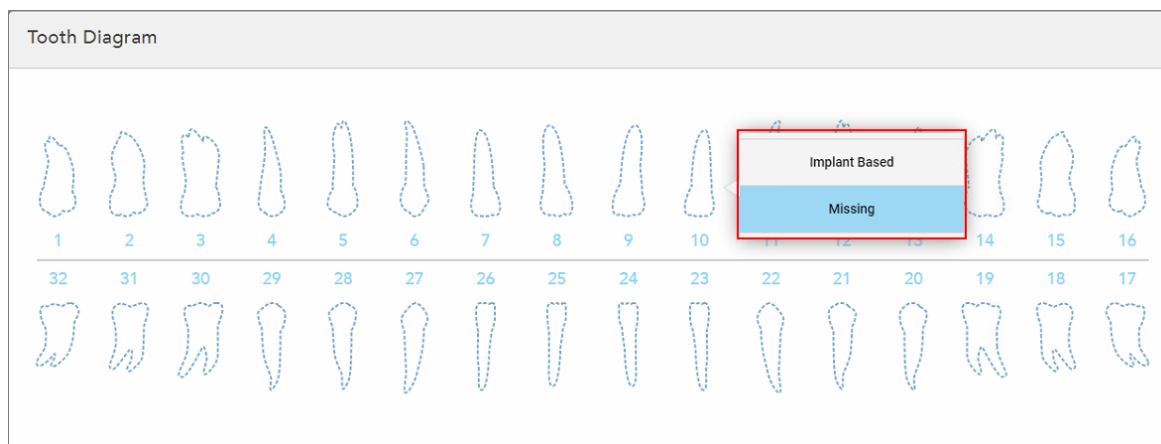


Figure 120: Defining the teeth to be included in the denture – Full Denture Implant Based procedure type

- 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.

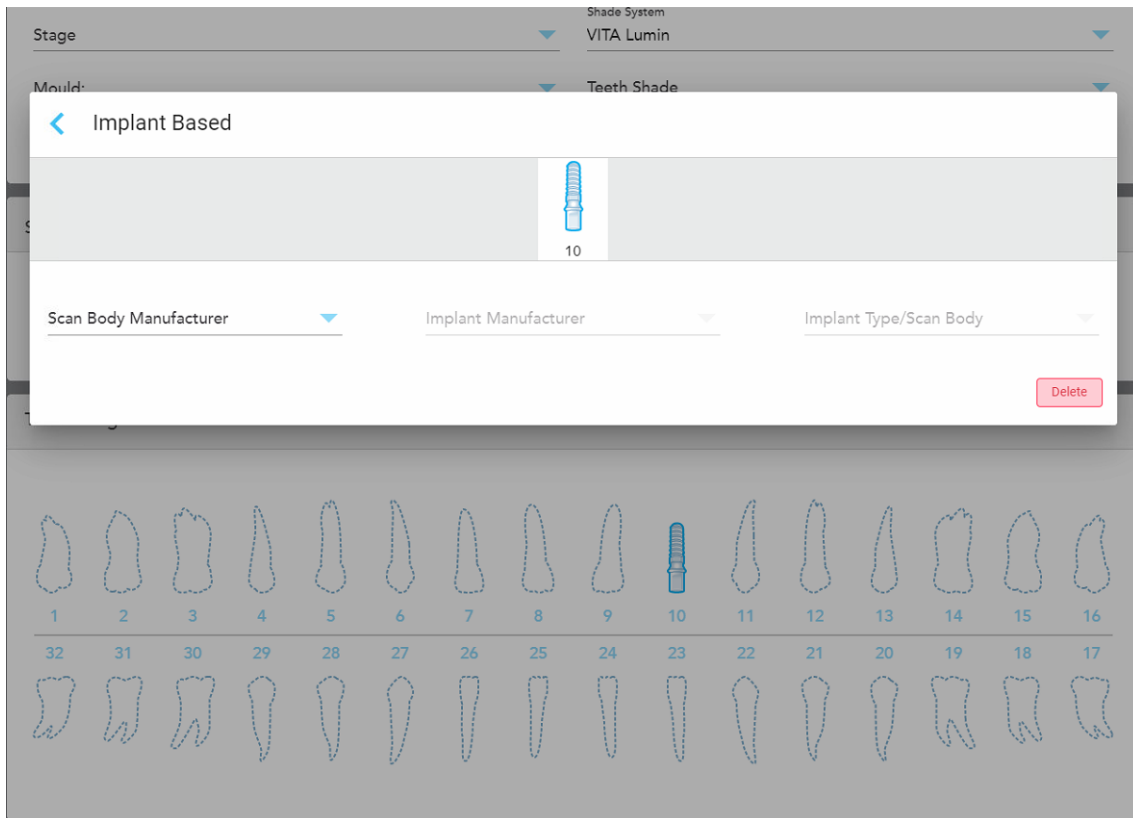


Figure 121: Implant Based settings window

- 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 is automatically removed from around the edges of the model during scanning. If required, you can disable this by pressing on the screen and then tapping the [Enable appliance scan 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** 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 (Patient), Last Name (Demo), Date of Birth, Gender (Male/Female), and Chart Number.
- Order:** Procedure (Appliance), Type, Due Date, and Send to.
- Appliance details:** Arch (Upper/Lower) with toggle switches. This section is highlighted with a red border.
- Scan Options:** New Sleeve Attached and Multi-Bite with toggle switches.
- Attachments:** Text indicating that external case-related files (images, videos, X-rays) can be shared with the lab, and a note to use myiTero.com for uploads.
- Notes:** A text area with a placeholder 'Add Note'.

Figure 122: Appliance details area – 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 configuring an appliance. On the left, there is a form with the following fields: 'Order:' (empty), 'Procedure *' (set to 'Appliance'), 'Due Date:' (empty), and 'Appliance details:' (set to 'Upper'). To the right of the 'Procedure *' field, a dropdown menu is open, showing a list of appliance types: 'Night Guard', 'Bite Splint', 'Sports/Mouth Guard', 'Apnea/Sleep Appliance', and 'Ortho Appliance'. The 'Type *' dropdown is highlighted with a red border. The 'Appliance details:' section has two toggle switches for 'Upper' and 'Lower' arches, both of which are currently turned off.

Figure 123: 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.

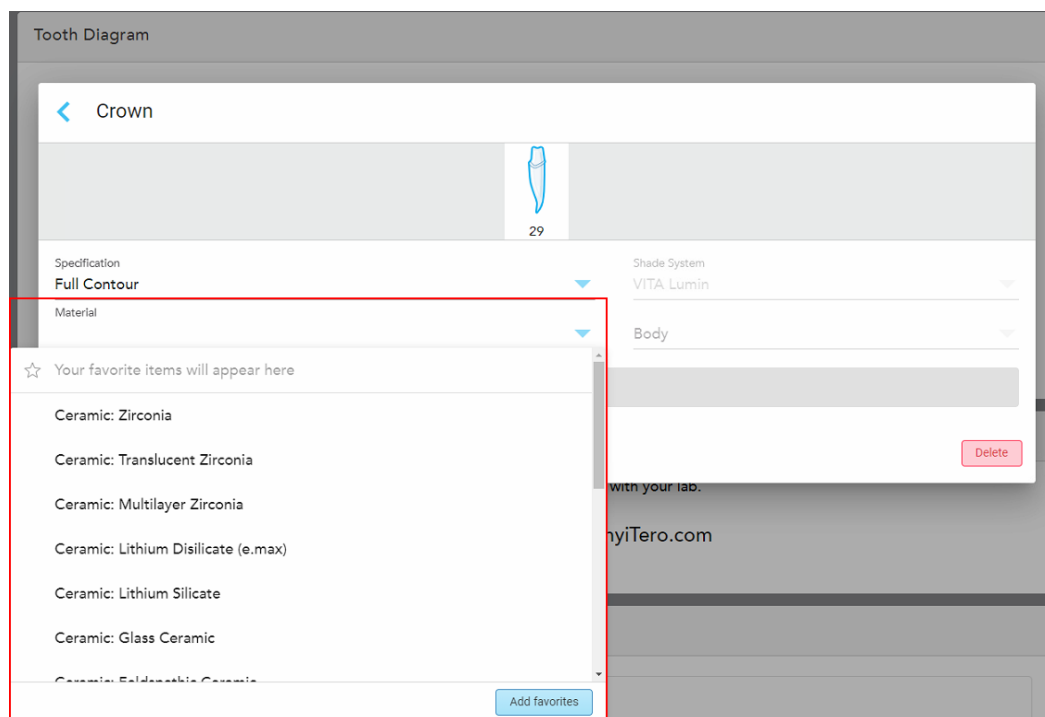


Figure 124: Adding a favorite material

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.

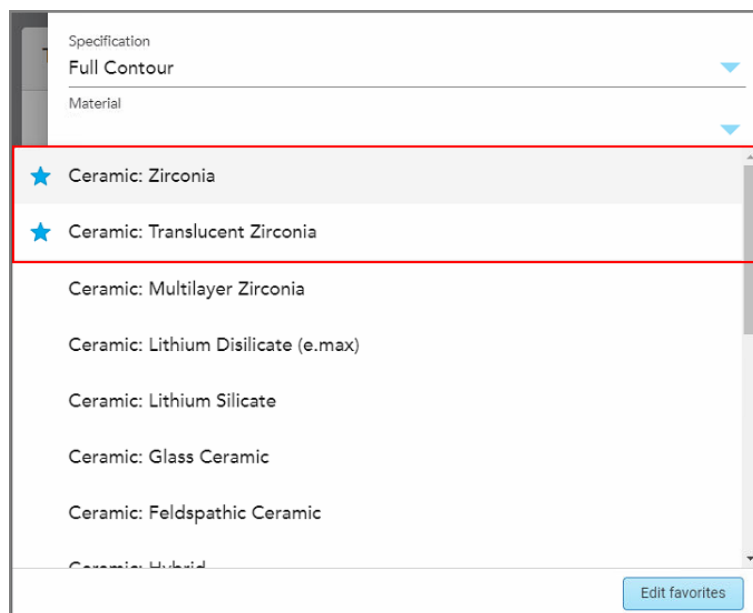


Figure 125: Favorite materials pinned to the top of the Material list

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

5.3.8 Confirming a new sleeve between patients

In order to reduce the risk of cross-contamination, you must replace the sleeve for each patient.

You are required to confirm the new sleeve using one of the following options:

- Activating the **New Sleeve Attached** option [when filling in a new Rx](#). This method is minimally intrusive and will not alarm the patient.
- Pressing either of the wand buttons or tapping **OK** when prompted, [when trying to access Scan mode](#).

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

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

5.3.8.1 Confirming the new sleeve when filling in the Rx

In the *New Scan* window, turn on the **New Sleeve Attached** toggle to confirm that a new sleeve is attached to the wand.

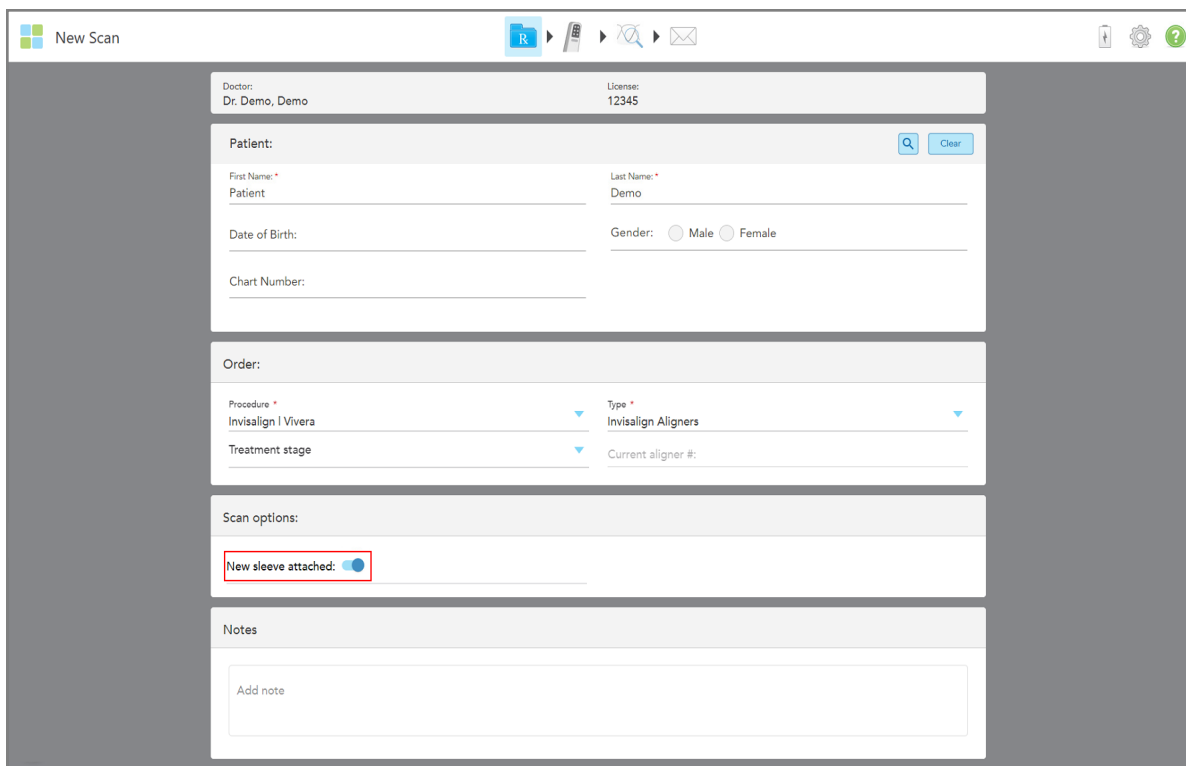
The screenshot shows the 'New Scan' window with a top toolbar containing icons for a prescription (Rx), a mobile device, a magnifying glass, and an envelope. The main form is divided into several sections: 'Doctor' (Dr. Demo, Demo) and 'License' (12345) at the top; 'Patient' information including First Name, Last Name (Demo), Date of Birth, Gender (Male/Female), and Chart Number; 'Order' information including Procedure (Invisalign | Viverra), Type (Invisalign Aligners), Treatment stage, and Current aligner #; 'Scan options' with a 'New sleeve attached' toggle switch that is turned on and highlighted by a red rectangle; and a 'Notes' section at the bottom with an 'Add note' text area.

Figure 126: Confirming that a new sleeve is attached

- If the **New Sleeve Attached** toggle is turned on, you will not see any further messages and are able to scan upon entry to Scan mode.
- If the **New Sleeve Attached** toggle is not turned on, you will be blocked from accessing Scan mode and will have to confirm the new sleeve, as described in the following section.

5.3.8.2 Confirming the new sleeve when accessing Scan mode

If you did not turn on the **New Sleeve Attached** toggle when filling in the new Rx, the following message is

displayed when tapping the Scan tool :

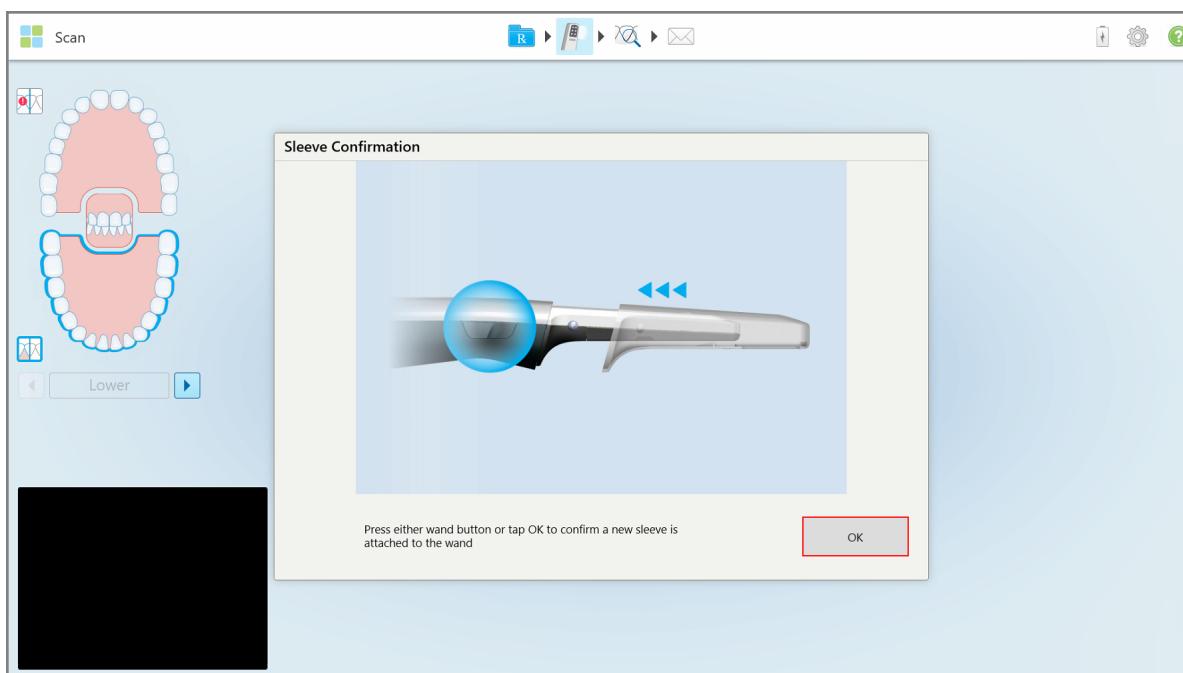


Figure 127: Popup confirmation message before scanning

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

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.

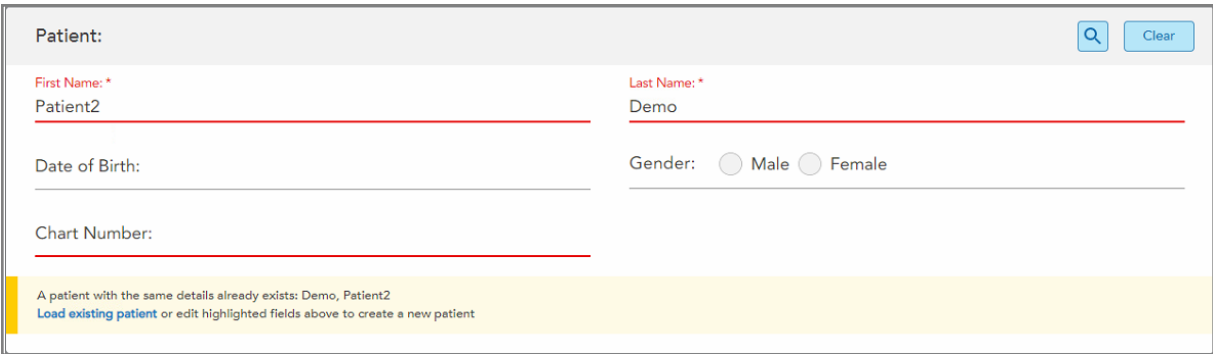
Note: By default, the date is written in DD/MM/YYYY format. If required, you can [change the date format](#).

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, Scan, and other functions. The main content area is divided into several sections. The 'Patient' section is highlighted with a red border and contains the following fields: 'First Name' with the value 'Patient1', 'Last Name' with the value 'Demo', 'Date of Birth' with the value '20/03/1983', 'Chart Number' with the value '123', and 'Gender' with radio buttons for 'Male' and 'Female' (the 'Female' option is selected). To the right of these fields are 'Search' and 'Clear' buttons. Below the 'Patient' section is the 'Order' section, which includes 'Procedure', 'Type', 'Due Date', and 'Send to' fields. Below that is the 'Scan Options' section with a 'New Sleeve Attached' toggle switch. At the bottom is the 'Notes' section with an 'Add Note' button.

Figure 128: 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 a search icon and a 'Clear' button. The form contains the following fields: 'First Name: *' with the value 'Patient2', 'Last Name: *' with the value 'Demo', 'Date of Birth:', 'Gender:' with radio buttons for 'Male' and 'Female', and 'Chart Number:'. A yellow message box at the bottom states: 'A patient with the same details already exists: Demo, Patient2. Load existing patient or edit highlighted fields above to create a new patient'. The 'First Name', 'Last Name', and 'Chart Number' fields are highlighted with red borders.

Figure 129: Message notifying that a patient with the same details exists

- a. If the new patient and the existing patient are the same person, tap **Load existing patient**.
- b. 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.

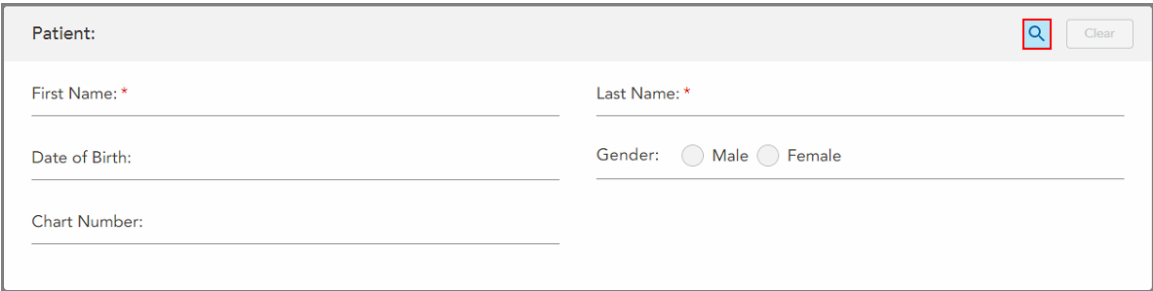
5.4.2 Searching for existing patients

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:

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



The screenshot shows the 'Patient:' form with a search icon and a 'Clear' button. The form contains the following fields: 'First Name: *', 'Last Name: *', 'Date of Birth:', 'Gender:' with radio buttons for 'Male' and 'Female', and 'Chart Number:'. The search icon is highlighted with a red square.

Figure 130: Patient area of the New Scan window – searching for an existing patient

The *Search Patient* window is displayed.

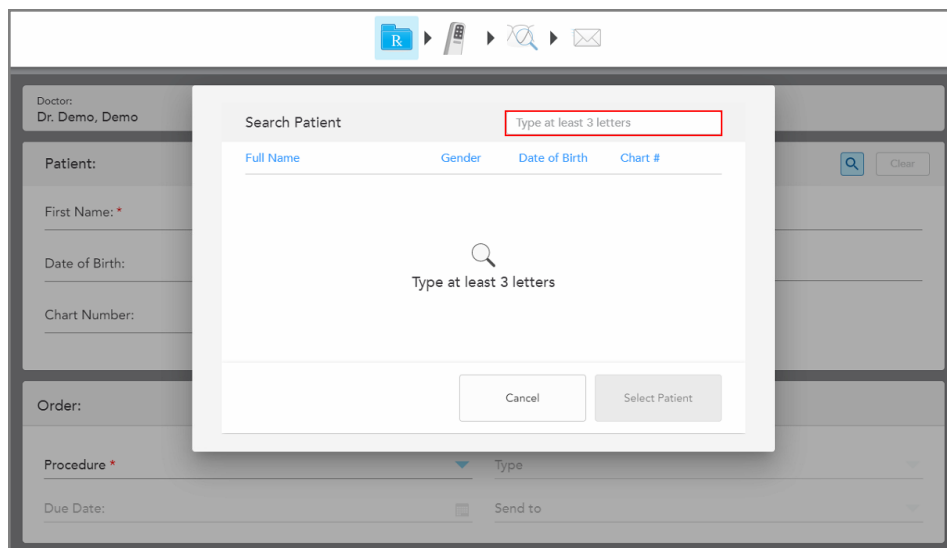
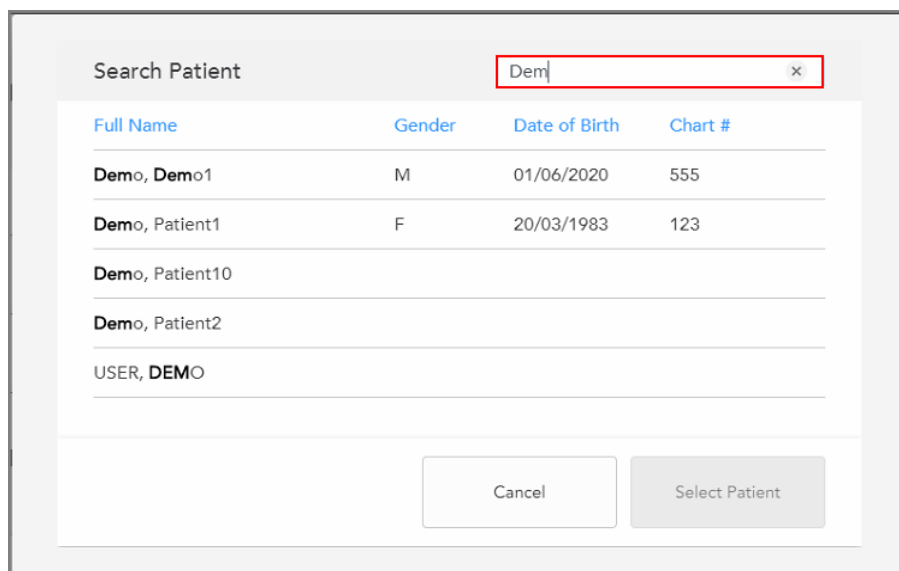


Figure 131: Search Patient window with a search field

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.



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: 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 133: 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

Chart Number: 123

Gender: ☐ Male ☒ Female

Figure 134: 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.

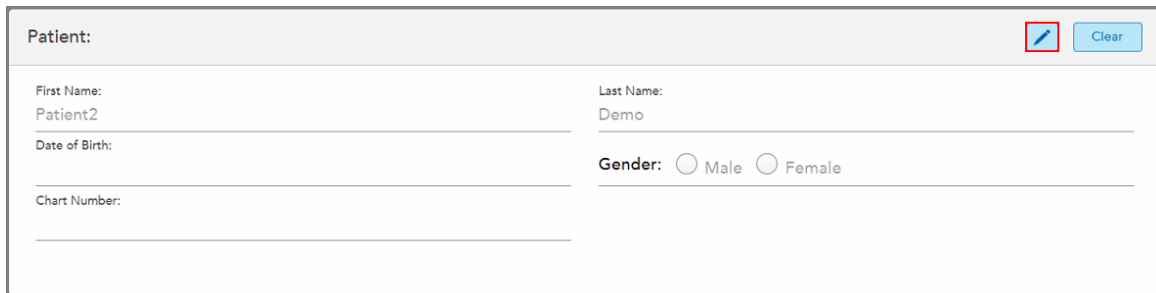
In addition, you can edit the patient's details when opening the Rx from the [patient's profile page](#).

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 .

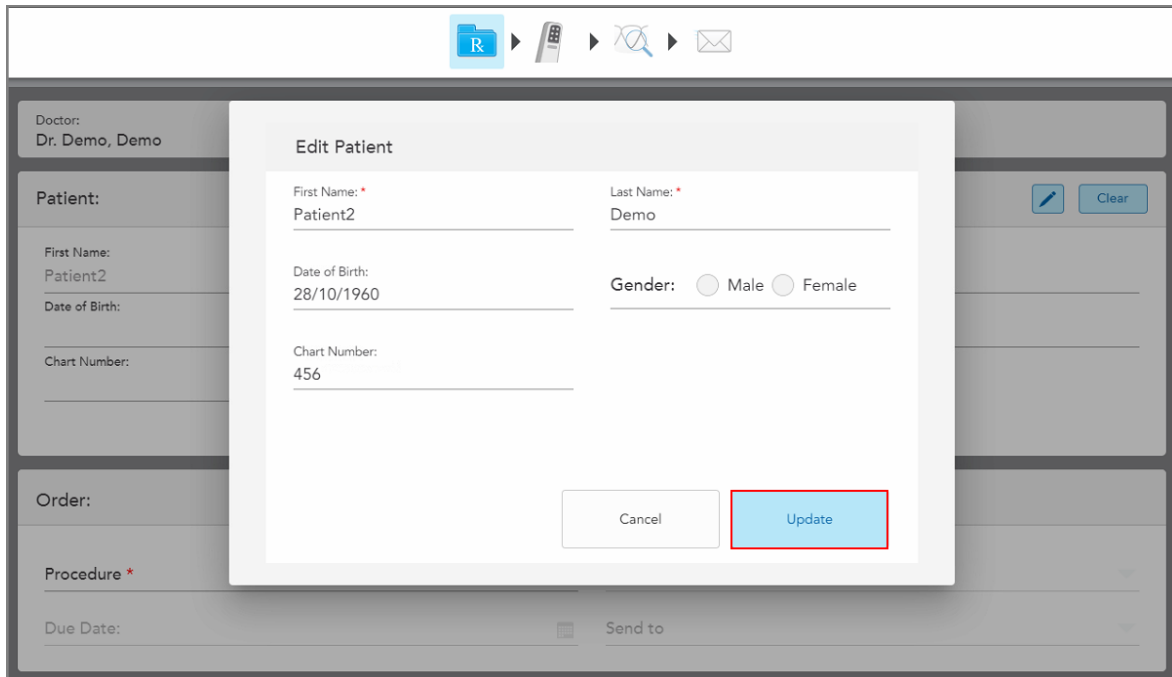


The image shows a 'Patient' form with the following fields: First Name (Patient2), Last Name (Demo), Date of Birth, Gender (radio buttons for Male and Female), and Chart Number. An edit icon (pencil) and a 'Clear' button are in the top right corner.

Figure 135: Patient area of New Scan window – editing a patient

The *Edit Patient* window is displayed.

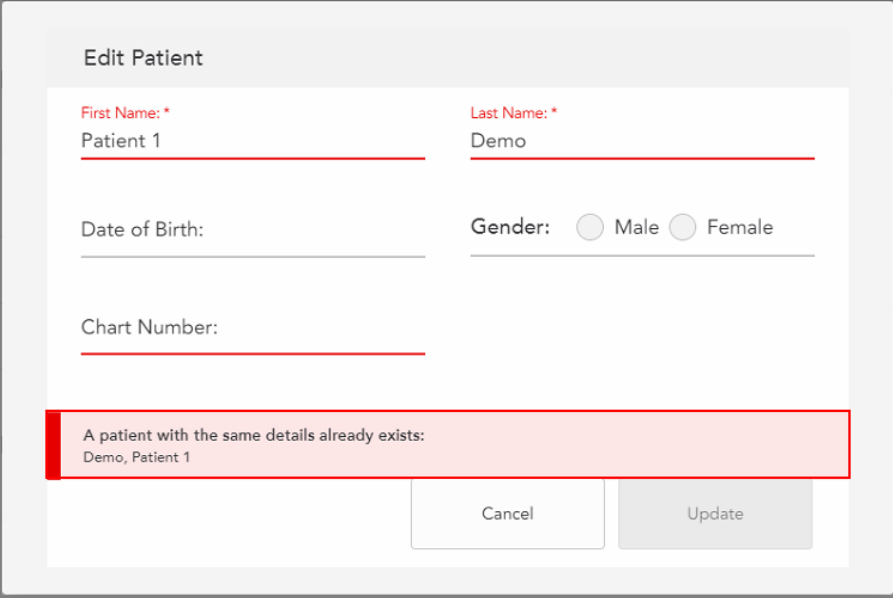
3. Edit the patient's details as required and then tap **Update**.



The image shows the 'Edit Patient' window overlaid on the 'New Scan' window. The 'Edit Patient' window contains the same fields as Figure 135, but with additional values: Date of Birth (28/10/1960) and Chart Number (456). The 'Update' button is highlighted with a red box.

Figure 136: 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: First Name (Patient 1), Last Name (Demo), Date of Birth, Gender (Male/Female), and Chart Number. A red message box at the bottom states: 'A patient with the same details already exists: Demo, Patient 1'. The 'Update' button is disabled.

Figure 137: Message that a patient with the same details already exists

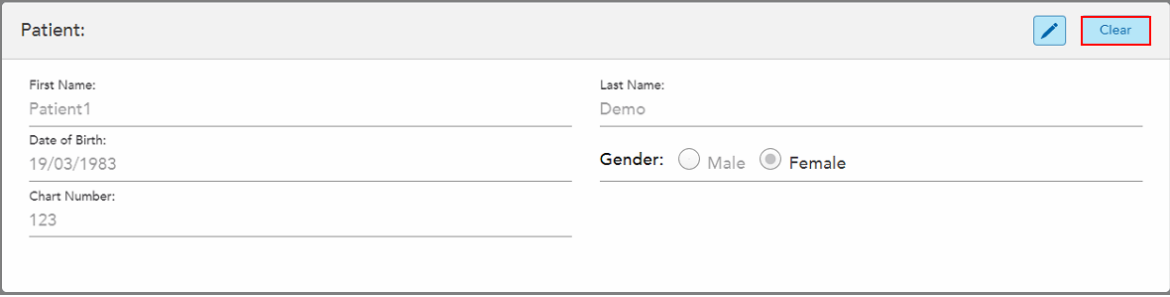
To differentiate between patients with the same details, enter a unique identifier in the **Chart Number** field.

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: First Name (Patient1), Last Name (Demo), Date of Birth (19/03/1983), Gender (Male/Female), and Chart Number (123). The 'Clear' button is highlighted with a red box.

Figure 138: Clear patient details button

A confirmation message is displayed.

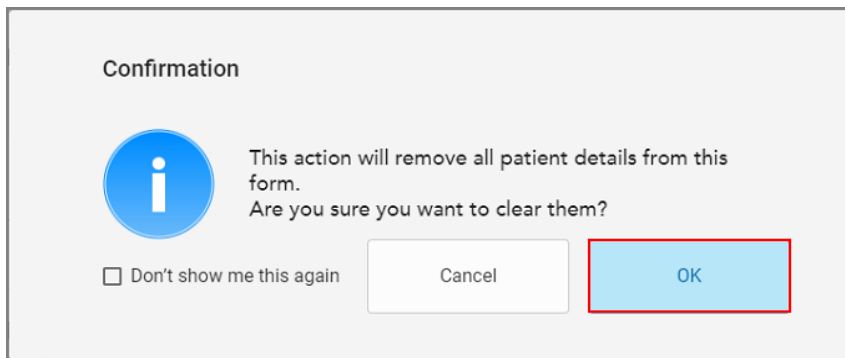


Figure 139: Clear confirmation message

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.

Note: After switching on the scanner, the system requires approximately 7 minutes to initialize and warm up. If the wand is not ready for use,  is displayed on the scanner toolbar and a progress bar displays the status of the initialization.

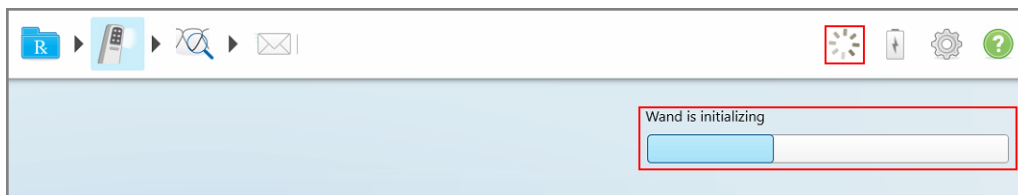


Figure 140: Wand initialization icon and progress bar

Ensure that the patient's mouth is dry both before and during the scan.

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

- [Hide or view additional scan feedback](#)
- [Toggle between color and monochrome mode](#)

You can also edit the scan, as follows:

- [Delete a segment](#)
- [Trim away excess soft tissue](#)

- [Erase selected areas of the scanned model](#)
- [Display the excess tissue when extra-orally scanning appliances or materials](#) such as partial dentures or putty



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](#).

iTerо Lumina supports sequence-free scanning, which means that you do not have to scan according to a set protocol. For more information on working with unstitched scanned segments, see [Working with unstitched scanned segments](#).

iTerо recommends you follow the displayed scanning sequence for best results.

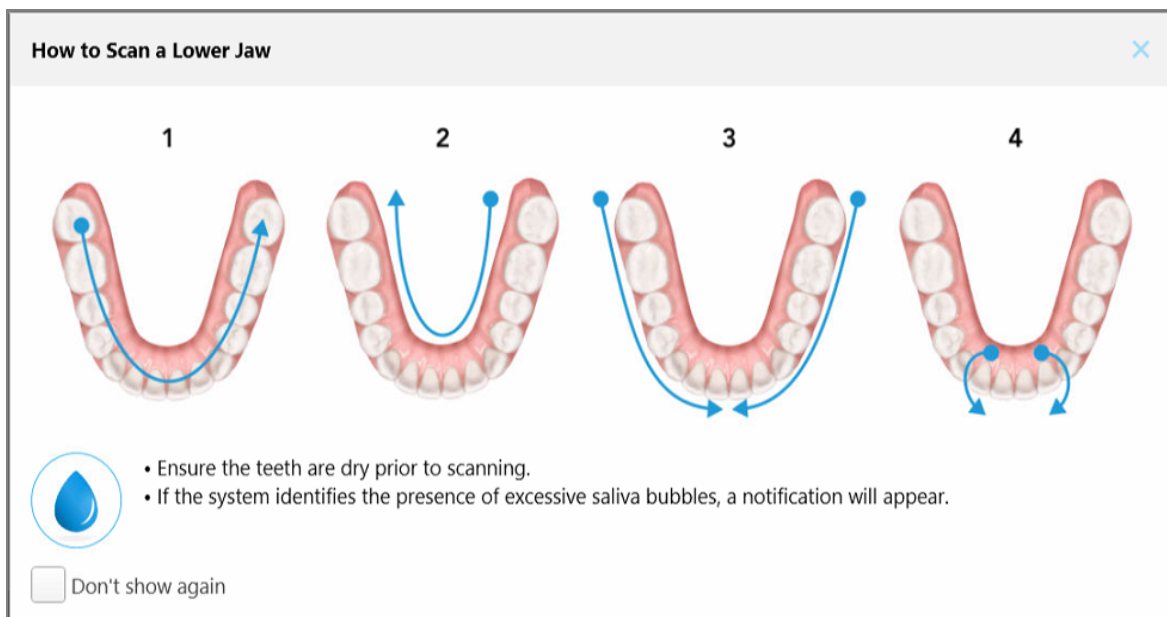


Figure 141: Recommended scanning sequence – lower jaw

Note: If you select the **Do not show again** check box, this guidance will not be displayed in future scans. You can return the guidance by enabling it in the [Scan settings](#).

Firmly press either of the wand buttons to begin scanning. The wand emits a sound, indicating that scanning has started.

To allow optimal capturing of 3D images, the wand should be held 4mm above the patient's teeth.

5.5.1.1 Saliva detection

By default, saliva detection during scanning is disabled. If required, you can [enable saliva detection](#) for the current scan by pressing on the screen and then tapping **Enable Saliva Detection**. You can also [enable saliva detection, by default](#) for all scans.

If saliva detection is enabled, when saliva bubbles are detected by the system during the scan, a saliva drop icon appears at the bottom of the screen indicating saliva detection. The area on the 3D model where the saliva was detected is removed, such that a hole is formed on the model's surface.

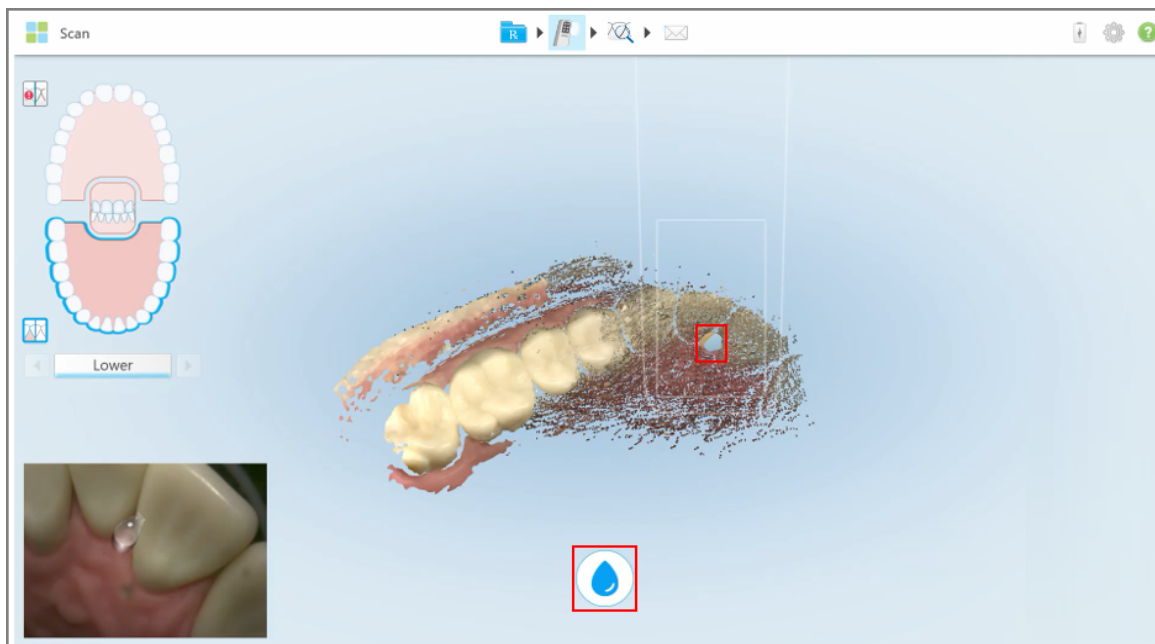


Figure 142: Saliva detection – area with saliva bubbles is shown as a hole and a drop icon is displayed

All areas with saliva bubbles need to be dried and rescanned before sending the scan. The drop icon reappears when hovering over the area, if the saliva still exists.

When pausing the scan, the area with saliva bubbles is displayed in light blue.



Figure 143: Saliva detection – area with saliva bubbles is displayed in light blue when scanning is paused

5.5.2 Scanning best practices

Before scanning the patient, read and understand the [Safety instructions](#).

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

- Ensure that the sleeves remain in the labeled box or in the sleeve basket on the cart-configuration scanner, until the time of use.
- Before applying the sleeve, inspect it for any visible discoloration, damage, or distortion that may prevent proper application. Ensure that the clear window is not scratched. After scanning, inspect the clear window to make sure it is not cracked. If damage is observed, see the **iTero Lumina sleeves** section in the [Safety instructions](#).
- If the patient bites down on the sleeve, stop the procedure and inspect the sleeve for visible damage.
 - If damage is observed, remove the sleeve and visually inspect the optical tip of the wand.
 - If cracks are observed on either the optical surface or the tip of the wand, do not use the wand, contact iTero Support, and see the **Scanner warnings** section in the [Safety instructions](#).
 - If no damage to the wand is observed, replace the sleeve and continue the scan.

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

- The preps should be scanned as part of the complete jaw, as described in [Scanning Fixed Restorative procedures](#). There is no need to scan each prep separately.
- 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.

5.5.2.1 Scanning Fixed Restorative procedures

When scanning a Fixed Restorative procedure, the preps are scanned as part of the arch. If required, you can erase and rescan the prep areas.

To scan a Fixed Restorative procedure:

1. After filling in the Rx, tap  on the toolbar to enter Scan mode.
The scanning guidance hints for Fixed Restorative procedures are displayed.
2. Scan the entire arch, including any preps.

3. If you would like to erase and rescan any of the preps, tap the **Prep editing**  button.

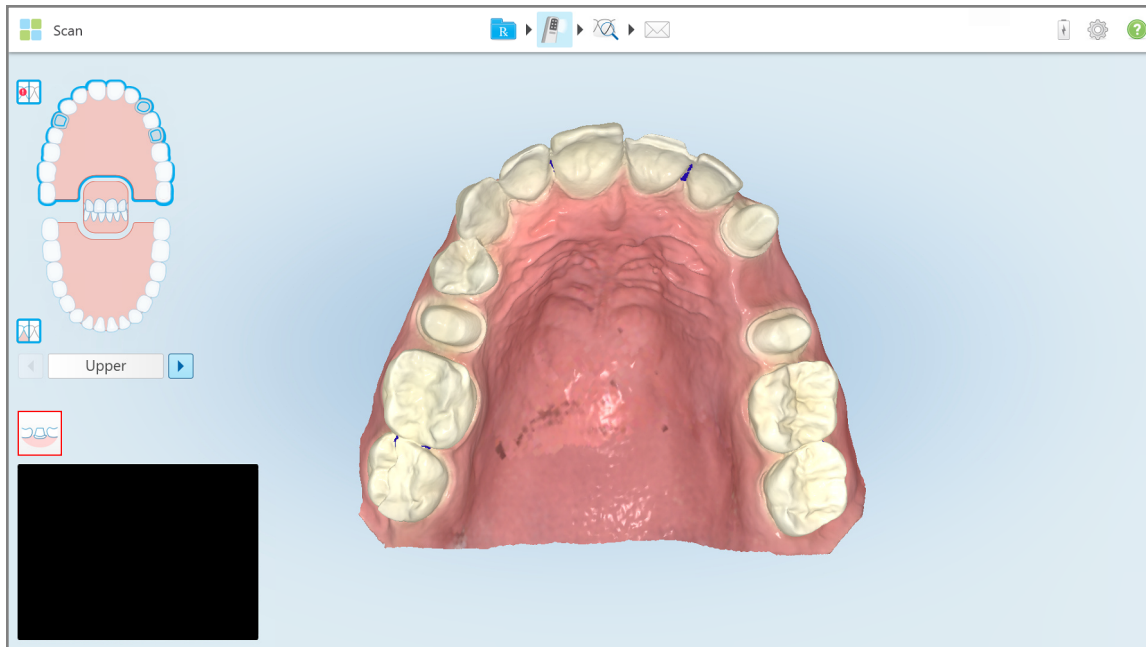


Figure 144: Prep editing button

The *Prep editing* window is displayed.

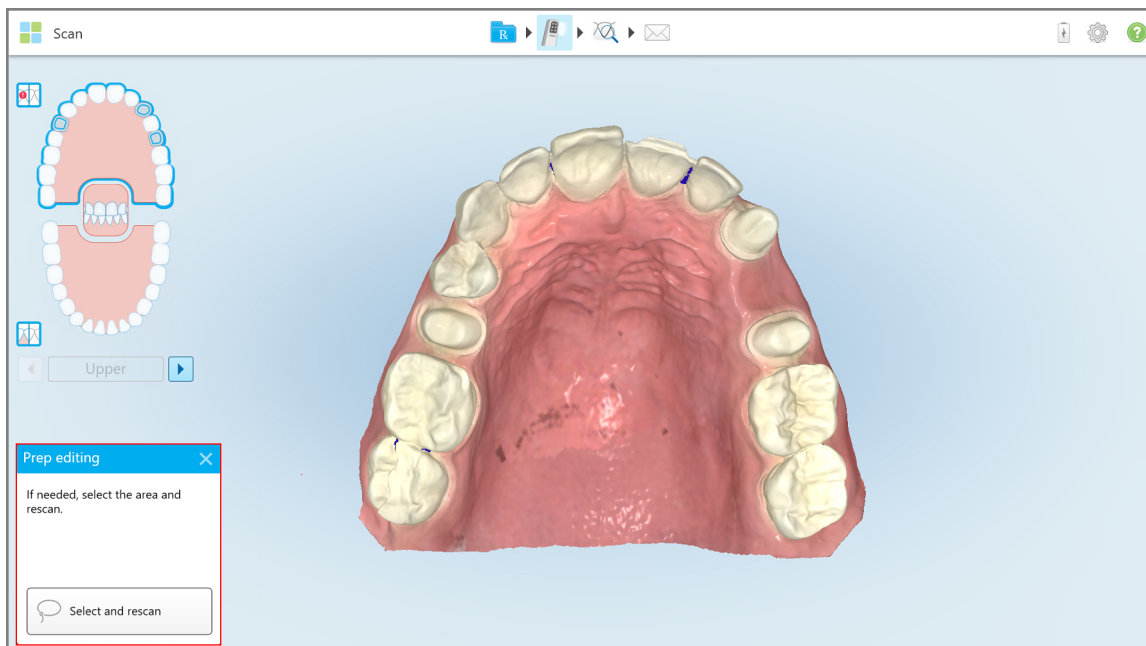


Figure 145: Prep editing window

4. Tap **Select and rescan** and then select the area you would like to erase and rescan.

Note: Ensure that you create a closed loop around the selected area.

After selecting the area, the *Prep editing* window enables you to erase and rescan the selected area or undo the selection and choose a new area to scan.

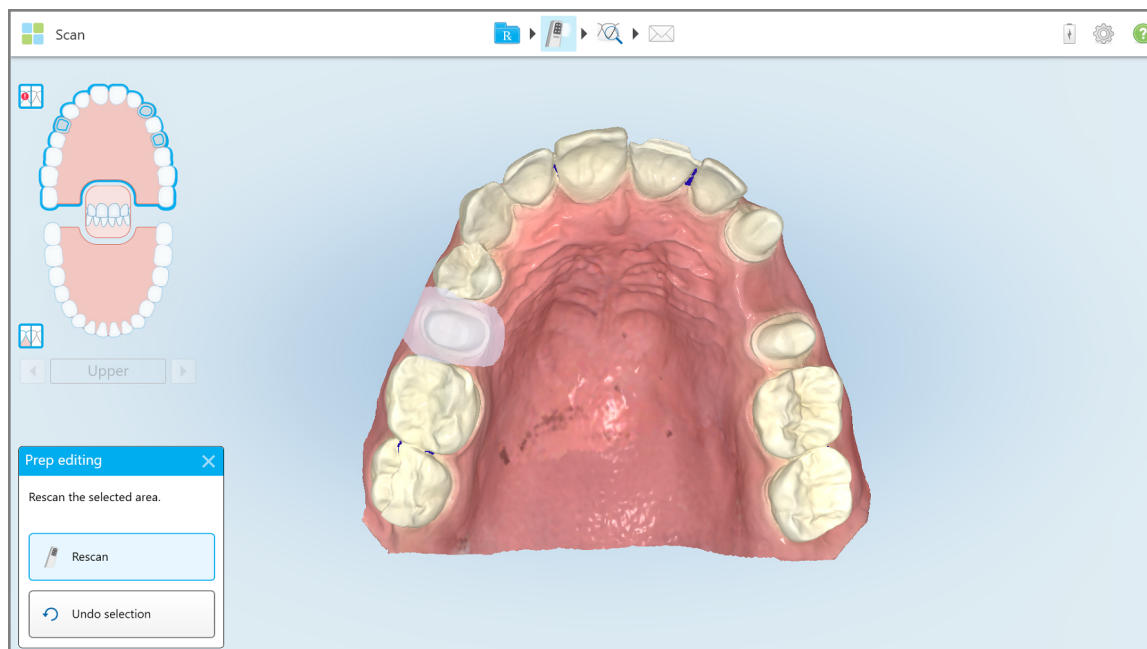


Figure 146: Prep editing options

5. Tap **Rescan** and start scanning the prep.

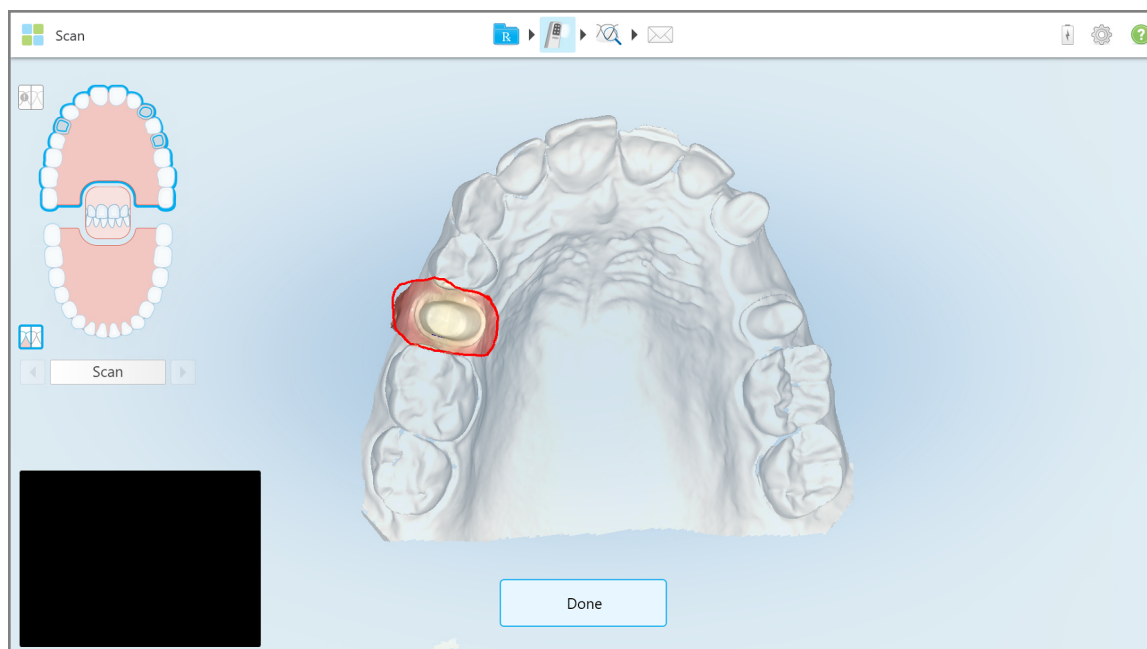


Figure 147: Rescanned prep and Done button after rescanning a prep

6. Tap **Done** after you have rescanned the prep.

Note: If you tap **Done** without scanning the prep, the selected area is deleted from the model.

7. If you would like to rescan another prep, repeat steps 4 to 6, or tap  to close the *Prep editing* window.

8. After you have scanned both arches and the bite, tap  on the toolbar to move to View mode, where you can review the scan.

5.5.3 Scan options

In Scan mode, you can select the following options:

- [Additional scan feedback](#)
- [Toggle between color and monochrome](#)
- [Switch to the next scan segment](#)
- [Switch to an unstitched scanned segment](#)
- [Delete unstitched segments](#)
- Edit the scan:
 - [Delete a segment](#)
 - [Trim away excess tissue](#)
 - [Erase a selected area of the scanned model](#)
 - [Enable scanning an appliance](#)
 - [Enable saliva detection](#)

5.5.3.1 Real-time scan assistant

The Real-time scan assistant feature helps to mitigate color and surface artifacts because of improper data capture and to avoid over-scanning of certain areas.

It visually indicates, while scanning, areas that need to be scanned because they weren't captured or weren't captured properly. To ensure the successful capture of the desired surface, make sure that all areas highlighted in dark blue have been scanned, prior to sending the model for post-processing.

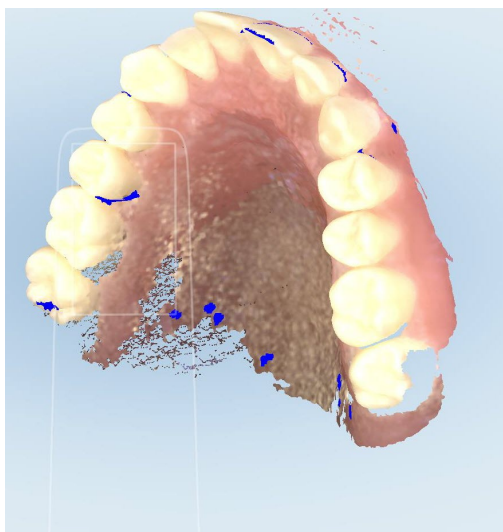


Figure 148: Real-time scan assistant indicating areas that need to be scanned

The Real-time scan assistant feature is enabled by default. You can disable it for all scans via the [Scan settings](#) or disable it per scan by simply tapping the dedicated icon  on the top left-hand side of the screen.

5.5.3.2 Toggling the scan color

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

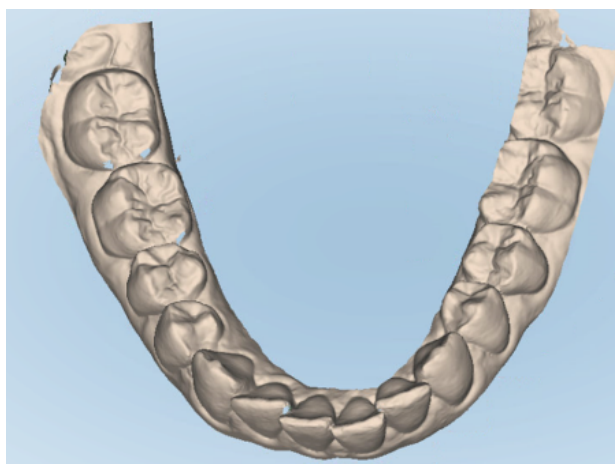


Figure 149: Model displayed in color and monochrome mode

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

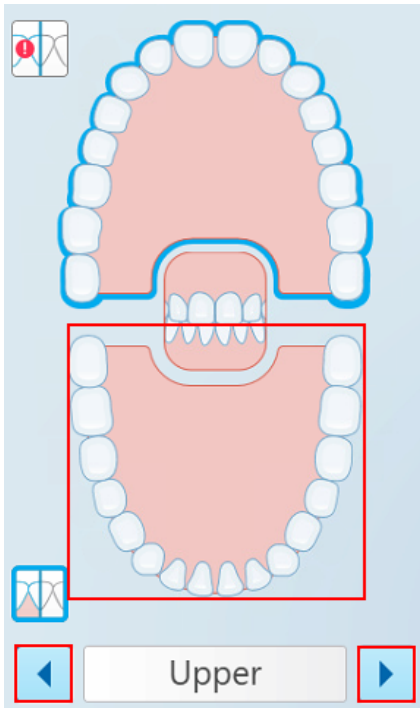


Figure 150: Tap the opposite arch or tap the arrows to select it

5.5.3.4 Working with unstitched scanned segments

iTero Lumina supports sequence-free scanning, which means that you do not have to scan your patient according to a set protocol.

While scanning, any unstitched segments of the 3D model are saved on the side of the *Scan* window. The latest segment is displayed in full color, but the older segments appear faded. You can see up to 4 segments without pausing the scan to view any additional detected segments.

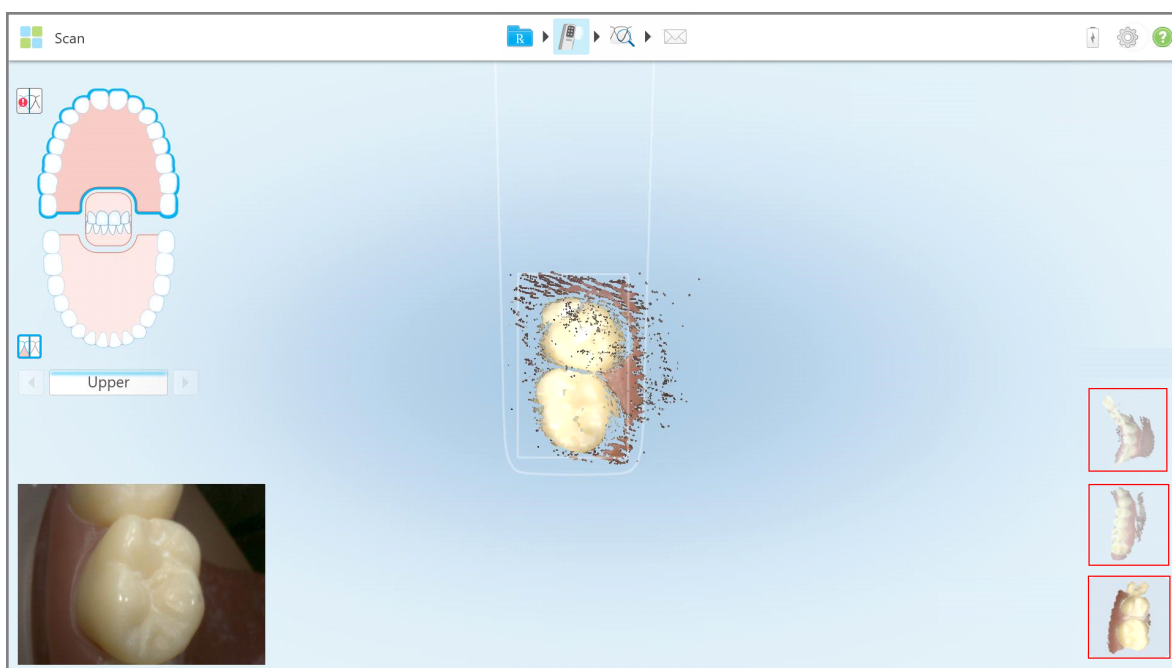


Figure 151: Unstitched scanned segments displayed on the right of the Scan window.

When you scan the overlapping area between the 3D model and an unstitched segment, the system stitches them together in the *Scan* window and removes the segment from the side of the window.

If required, you can double-tap an unstitched segment to display it in the center of the window instead of the 3D model of the scan. You can also press the segment and then tap **Switch to main segment**.

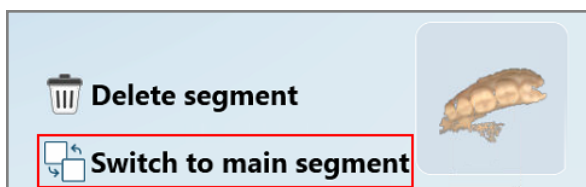


Figure 152: Switching to the main segment

You can delete an unstitched segment by pressing it and then tapping **Delete segment**.

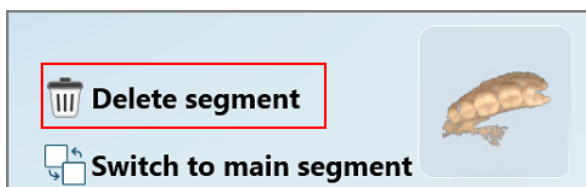


Figure 153: Deleting an unstitched segment

By default, sequence-free scanning is enabled, but you can disable it from the [Scan settings](#).

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](#)
- [Trim tool](#)
- [Eraser tool](#)
- [Enable appliance scan tool](#)
- [Enable Saliva Detection tool](#)

The editing tools are accessed by pressing on the screen.

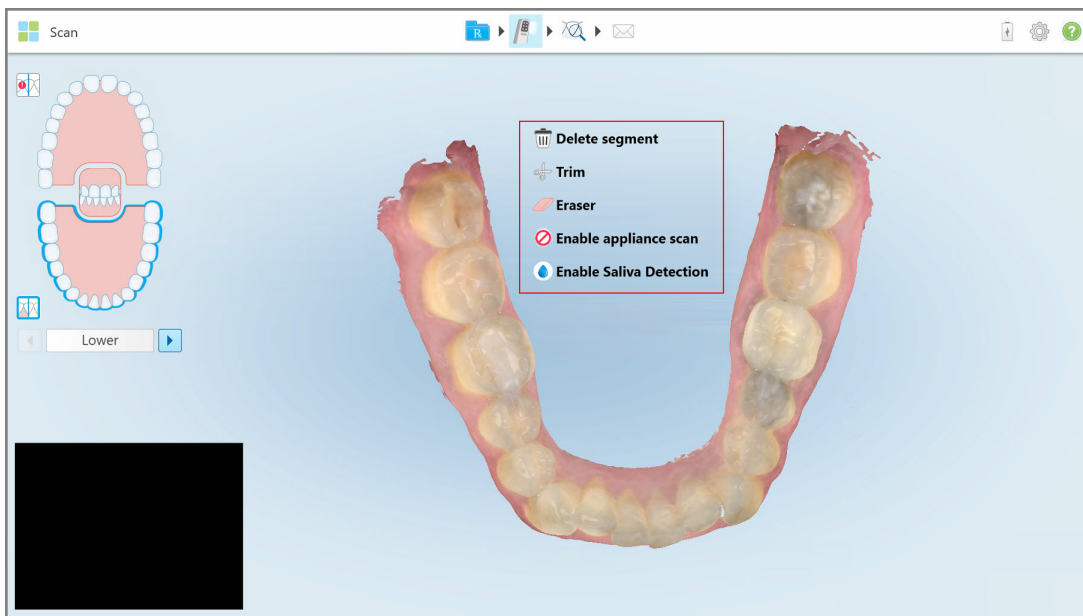


Figure 154: Editing tools

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:

- [Trim excess tissue from the scan.](#)
- [Define the margin line.](#)

- [View an area of interest using the Review tool.](#)

Note for PC-configuration scanners: The Review tool may not be available, depending on the software package, and regulatory and commercial considerations.

- [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.

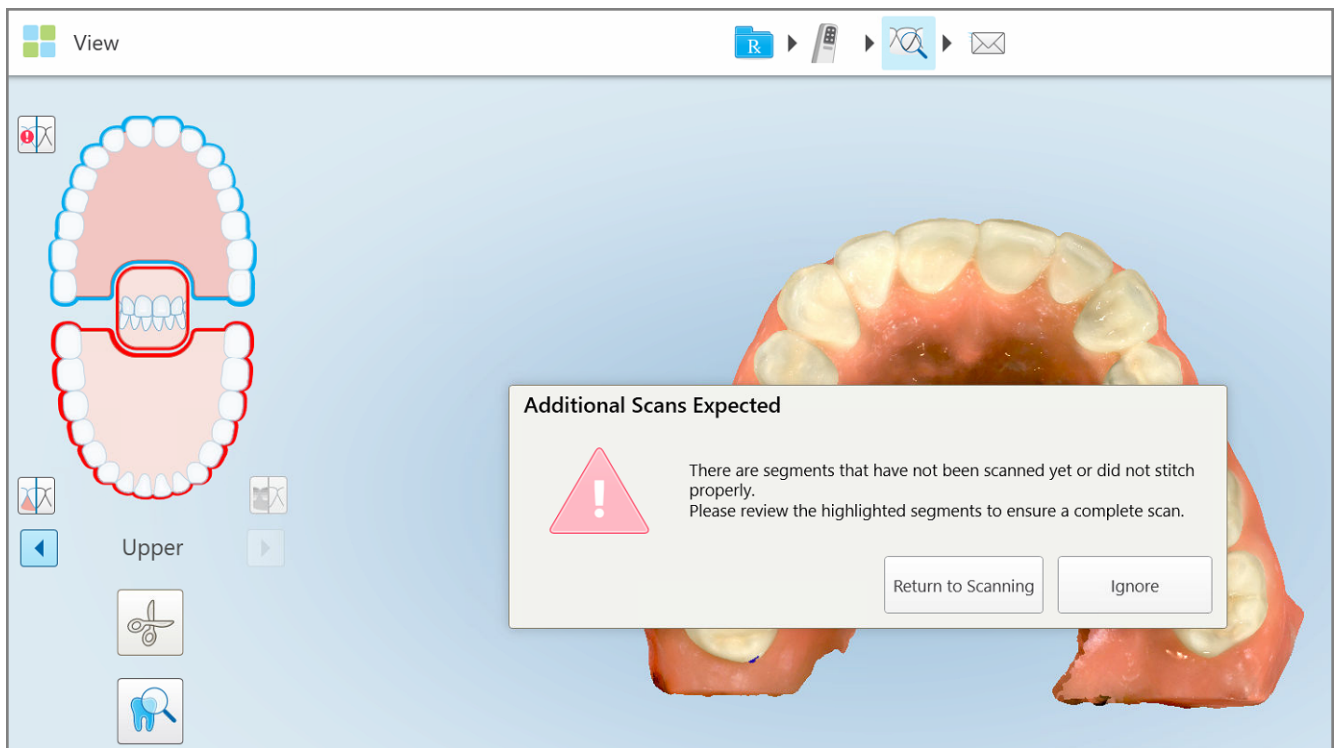


Figure 155: Missing scan message and missing segments highlighted in red

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.

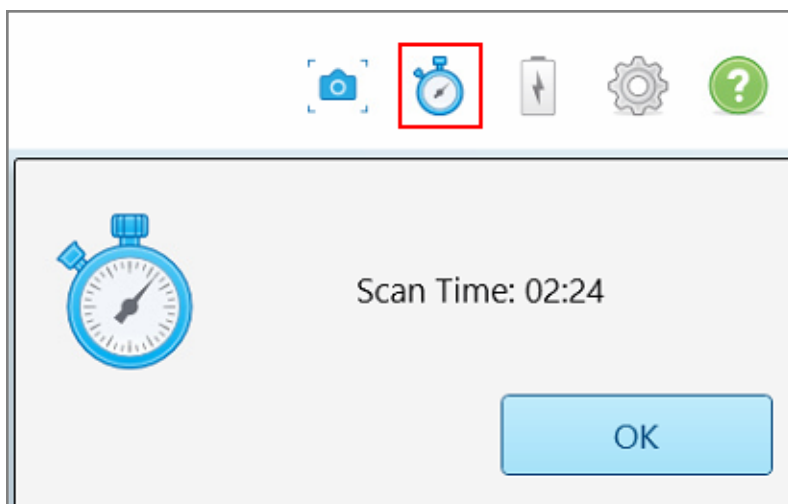


Figure 156: Scan timer button on the toolbar and scan time

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.

Notes:

- Ensure that the wand is placed back in the cradle, with the optical window facing the cradle, before sending the scan.
- 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 for the purposes of dental care and for further processing in accordance with your End User License Agreement.
- The wand lights may flicker during the sending process.
- Evaluate the fitting of the dental devices manufactured using the data generated from the scanner according to the standard of care procedure.

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.

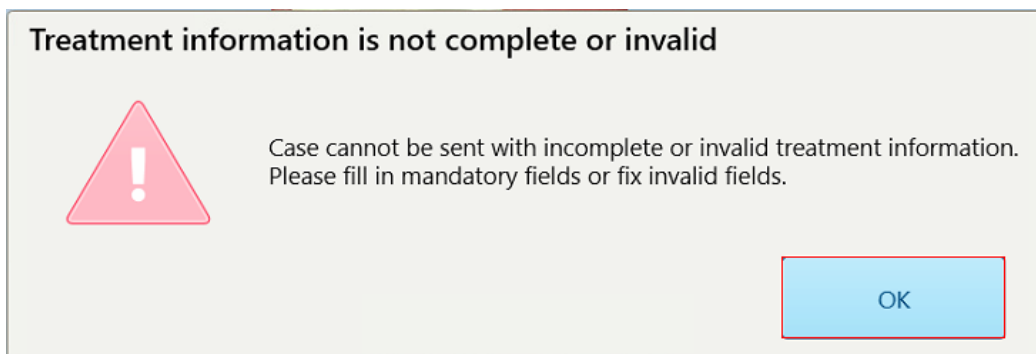


Figure 157: Notification about missing treatment information

- 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					

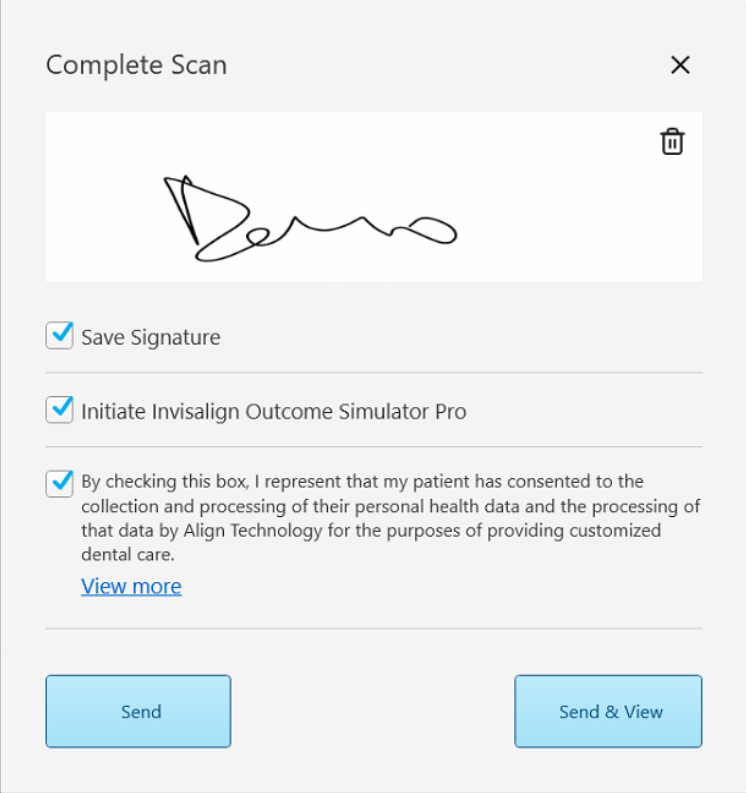
Figure 158: Missing fields highlighted in red in the Treatment Information area

- 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](#)

Figure 159: 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](#).

Note: In order to enable the simulation, ensure that your iTero account is paired with your Invisalign Doctor Site account.

5. Ensure that the patient consent check box is selected, confirming that you have received the patient's consent to have their health data collected and processed by Align for the purposes of dental care and for further processing in accordance with your End User License Agreement.
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 for Study Model/iRecord and Invisalign | Viverra procedures only.

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 160: Invisalign Outcome Simulator Pro progress shown in the Viewer

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

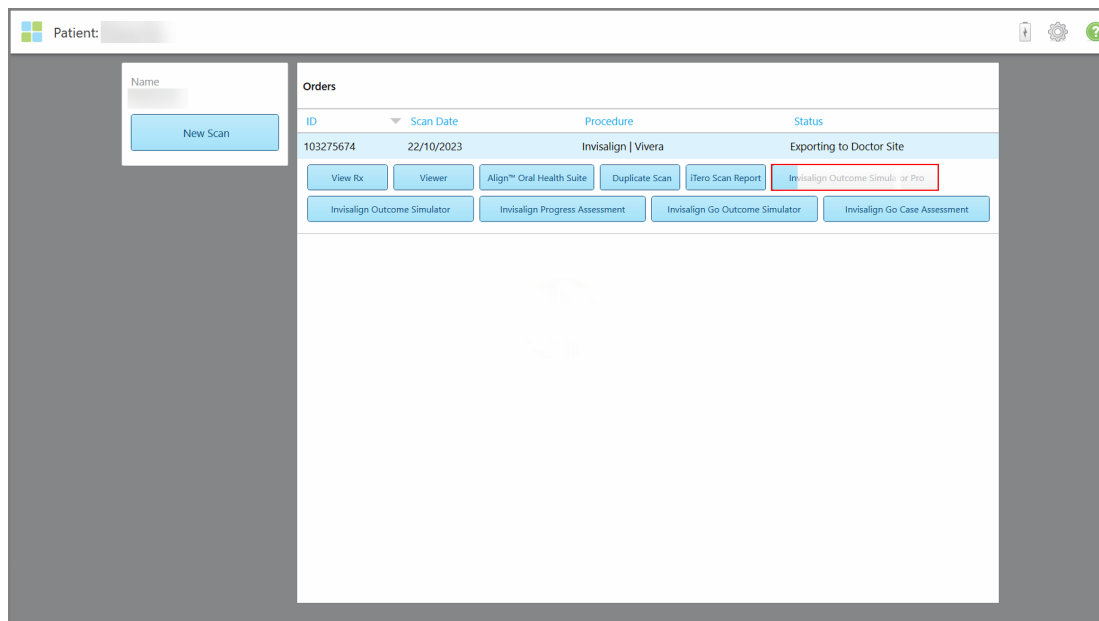


Figure 161: Invisalign Outcome Simulator Pro progress shown in the patient's profile page

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.

5.8 Working with the Viewer

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

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

Past Orders Search						
ID	Patient Name	Chart Number	Scan Date	Procedure	Status	Doctor
281065785			12/01/2026	Invisalign Vivera	Completed	Dr. Demo, Demo
281058816	Demo, Patient	123	30/12/2025	Study Model/iRecord	Completed	Dr. Demo, Demo
<div> <div>View Rx</div> <div>Viewer</div> <div>Align™ Oral Health Suite</div> <div>Duplicate Scan</div> <div>Invisalign Outcome Simulator Pro</div> <div>Invisalign Outcome Simulator</div> <div>Invisalign Progress Assessment</div> <div>Align™ Oral Health Report</div> </div>						
281058794			30/12/2025	Fixed Restorative	Completed	Dr. Demo, Demo

Figure 162: Viewer option in the Past Orders pane in the Orders page

<

Patient: Demo, Patient

Show all Drs

Name

Demo, Patient

Chart Number

123

Date of Birth

20/03/1983

Gender

Female

New Scan

Orders

ID	Scan Date	Procedure	Status	Doctor
☐ 281058816	30/12/2025	Study Model/iRecord	Completed	Dr. Demo, Demo
<div><div>View Rx</div><div>Viewer</div><div>Align™ Oral Health Suite</div><div>Duplicate Scan</div><div>Invisalign Outcome Simulator Pro</div><div>Invisalign Outcome Simulator</div><div>Invisalign Progress Assessment</div><div>Align™ Oral Health Report</div></div>				
☐ 281058794	30/12/2025	Fixed Restorative	Completed	Dr. Demo, Demo
☐ 222319228	21/10/2025	Study Model/iRecord	Completed	Dr. Demo, Demo

Timeline

21/10/2025

30/12/2025

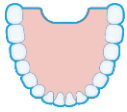
Compare Selected

Figure 163: Viewer option in the patient's profile page

In the Viewer, you can tap the following to:



Show/hide the upper jaw.



Show/hide the lower jaw.



Show both jaws.



Open the [Review tool](#) to view an area of interest.



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 164: 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.

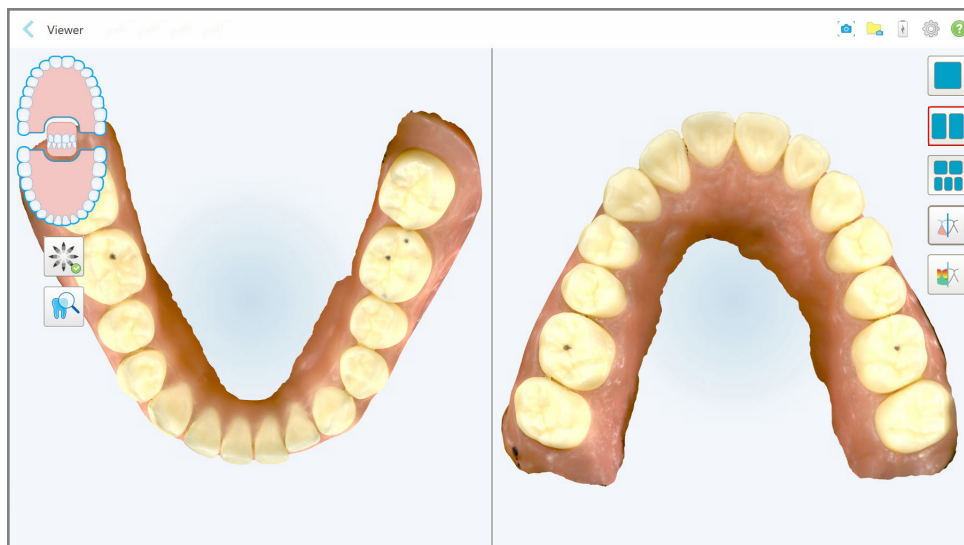


Figure 165: Model in a 2-window view

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.

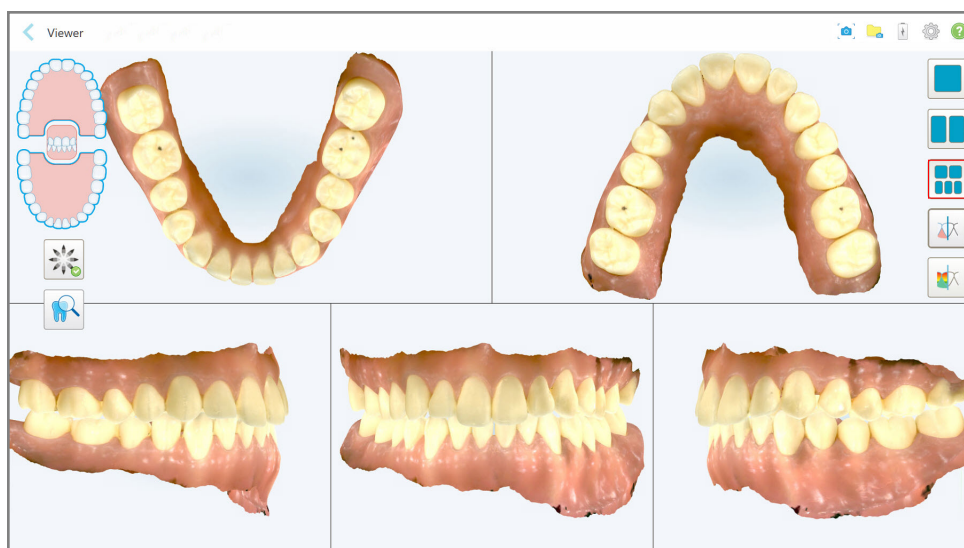


Figure 166: Model in a 5-window view

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 sleeve

Before removing and disposing of the sleeve, see the **iTero Lumina sleeves** section in the [Safety instructions](#).

To remove the wand sleeve:

1. Once the scan is complete, or if the scan has been interrupted, slowly pull the sleeve off the wand, and discard it.

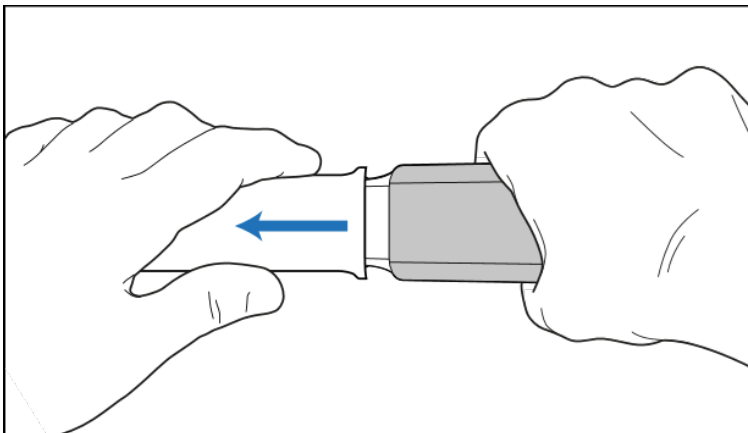


Figure 167: Removing a wand sleeve

Note: 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.

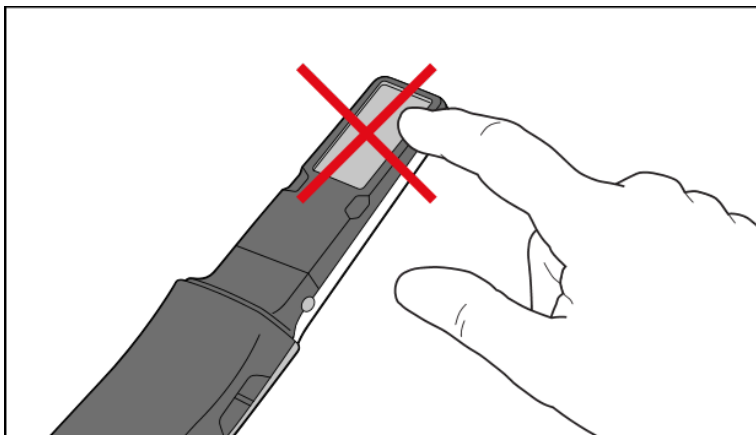


Figure 168: Optical surface of the wand

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 dark protective sleeve.

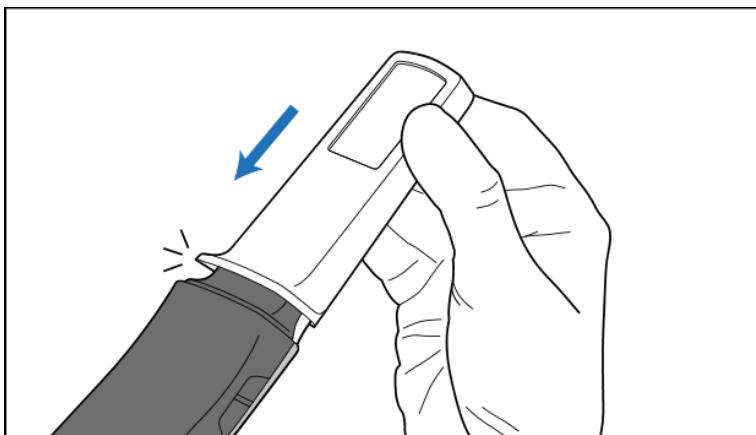
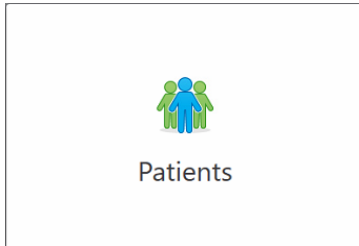


Figure 169: Gently slide the new sleeve into place

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.

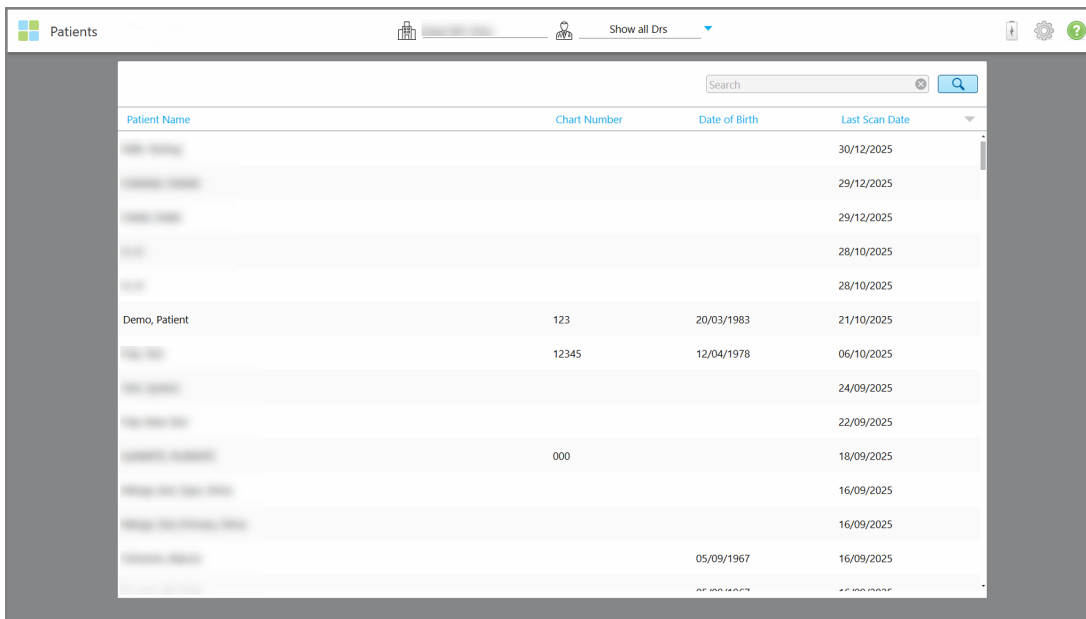


Figure 170: Patients page

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 .

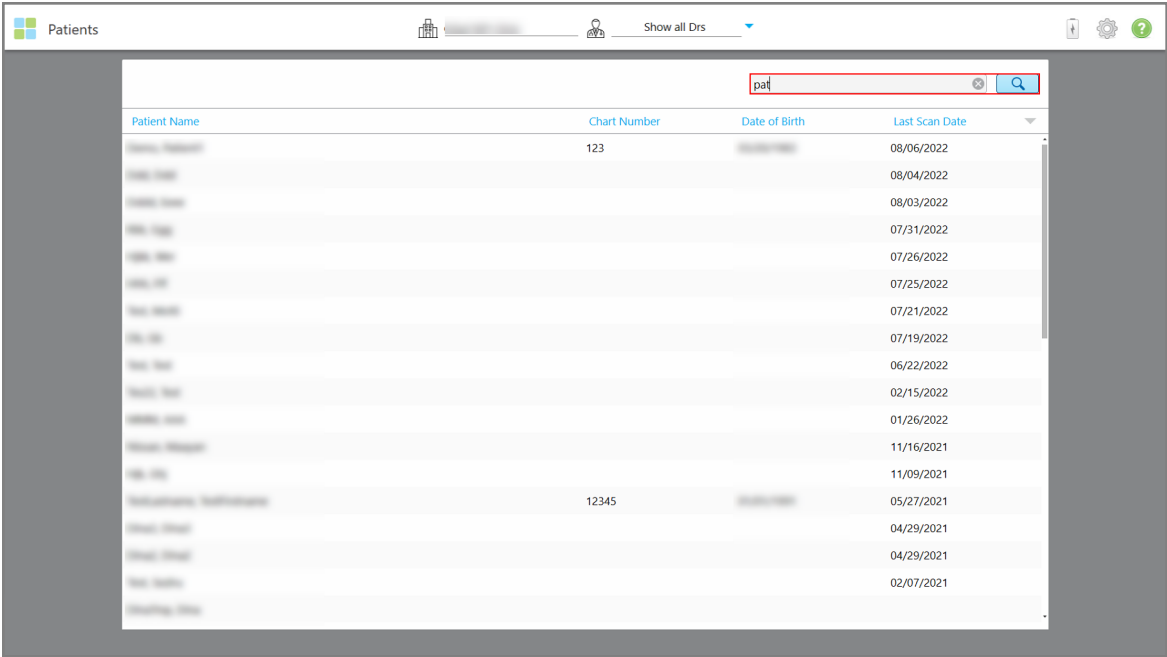


Figure 171: Searching for a patient

The patients that match the search criteria are displayed.

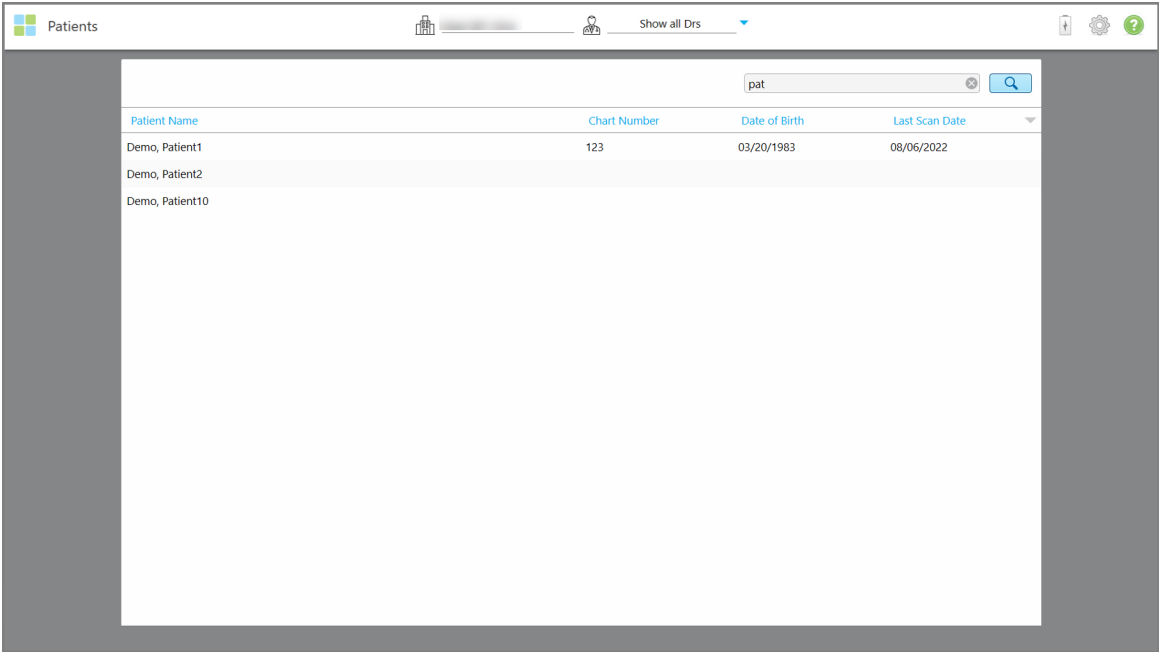


Figure 172: Patients matching the search criteria are displayed

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:

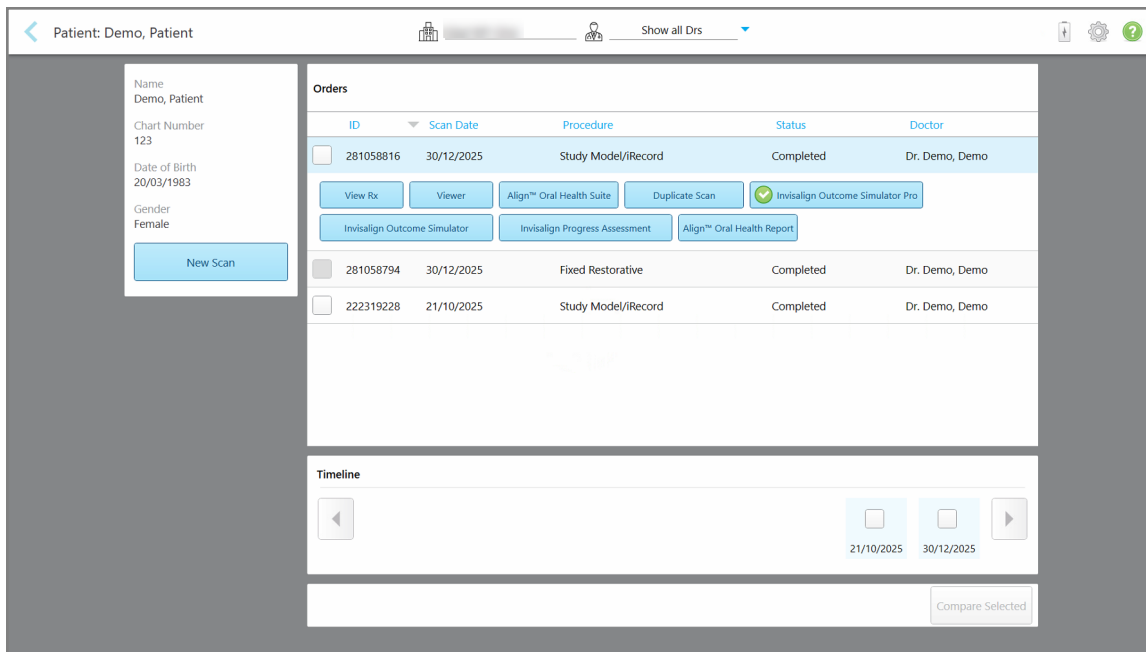


Figure 173: Patient's profile page

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](#)
- Duplicate and adapt this order as follows:
 - Study Model/iRecord, Invisalign | Viverra, Appliance orders – duplicate the scan and then send it as a Fixed Restorative case, for example, after adding only the prepped area.
 - Fixed Restorative orders – duplicate the scan and then add additional indications, for example, additional crowns, etc.

This option is available for orthodontic and Fixed Restorative orders only, and only for a short period after the scan, depending on scanner resources.

- [Create an Align Oral Health Report](#)
- [Compare two previous scans using iTerio 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**.

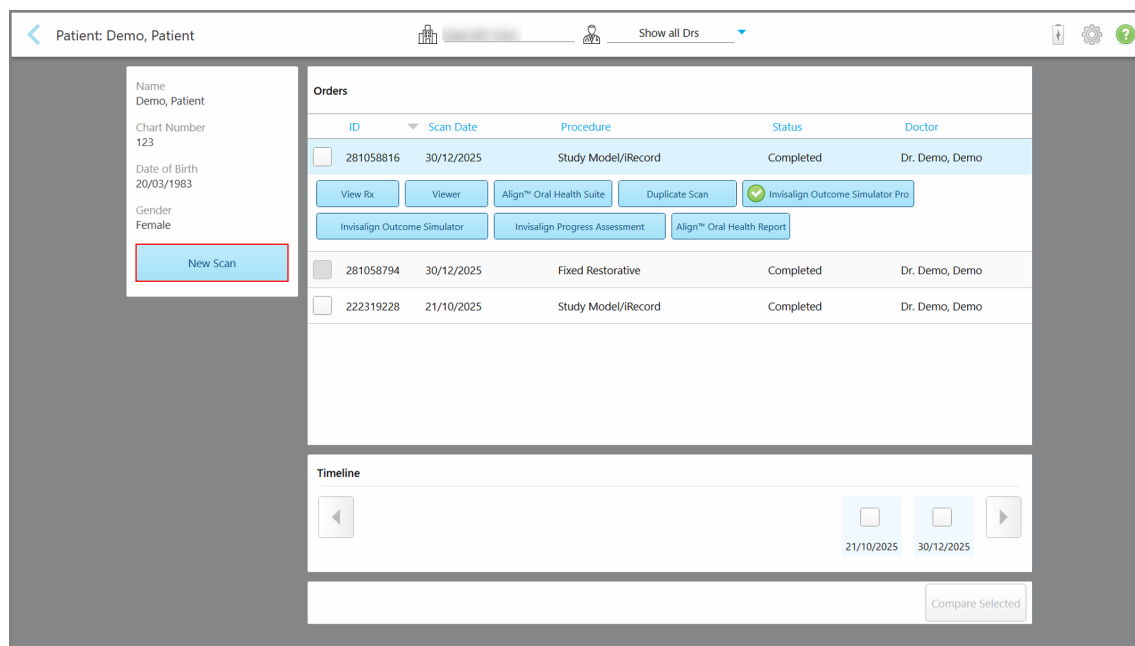


Figure 174: Patient's profile page – New Scan option

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

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

- Doctor:** Dr. Demo, Demo
- License:** 12345
- Patient:**
 - First Name: Patient
 - Last Name: Demo
 - Date of Birth: 20/03/1983
 - Chart Number: 123
 - Gender: ☐ Male ☒ Female
- Order:**
 - Procedure:
 - Type:
 - Due Date:
 - Send to:
- Scan Options:**
 - New Sleeve Attached: ☐
- Notes:**
 - Add Note:

Figure 175: 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**.

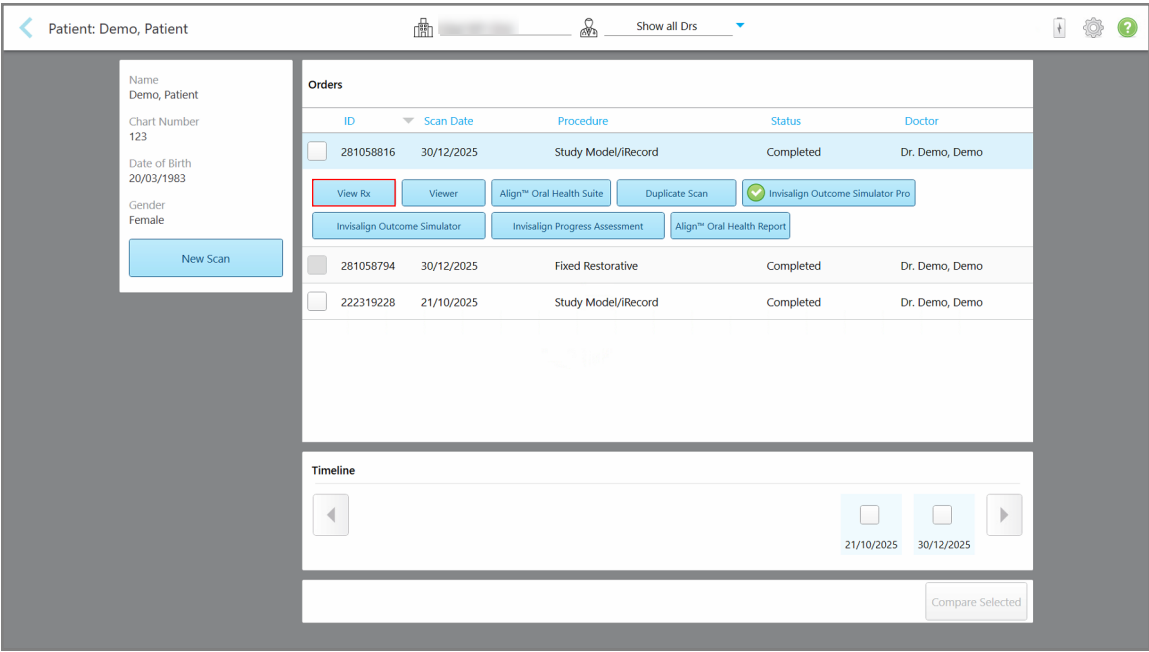


Figure 176: Patient's profile page – View Rx option

The *Rx Details* window is displayed.

Rx Details

This Form is Read-only.

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

Order:

All Study Model/Record scans are available for Invisalign.

Procedure * Study Model/iRecord Ortho Model/Cast ☐
Due Date: Send to

Scan Options:

New Sleeve Attached: ☐ Multi-Bite: ☐

Notes

Figure 177: 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**.

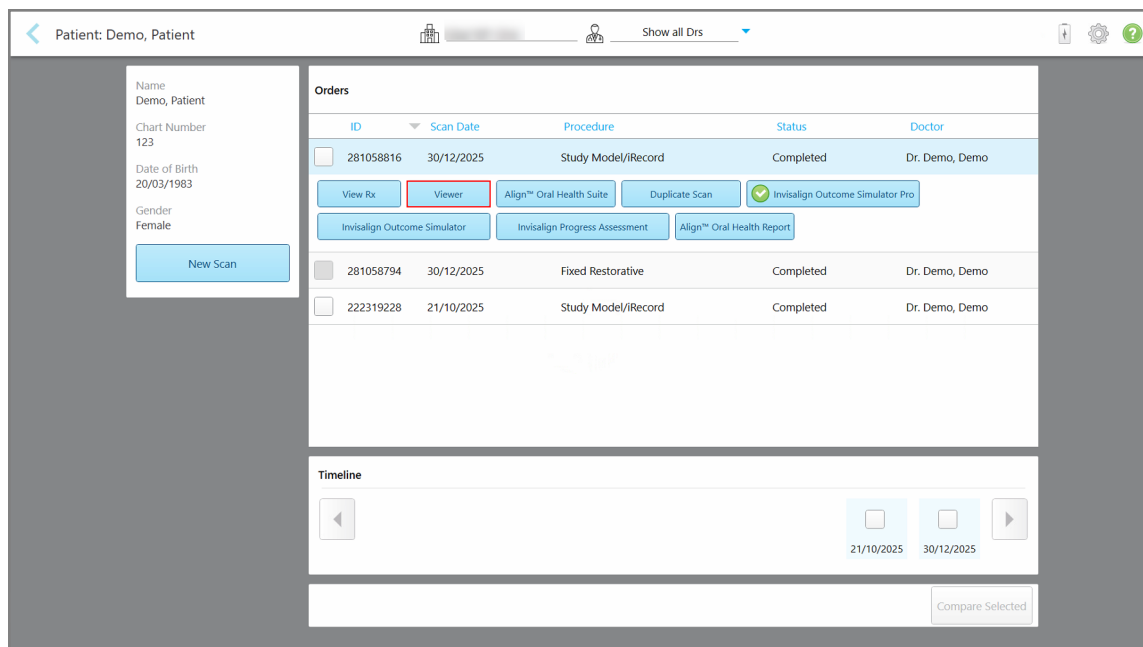


Figure 178: Patient's profile page – Viewer option

The scan is displayed in the Viewer.

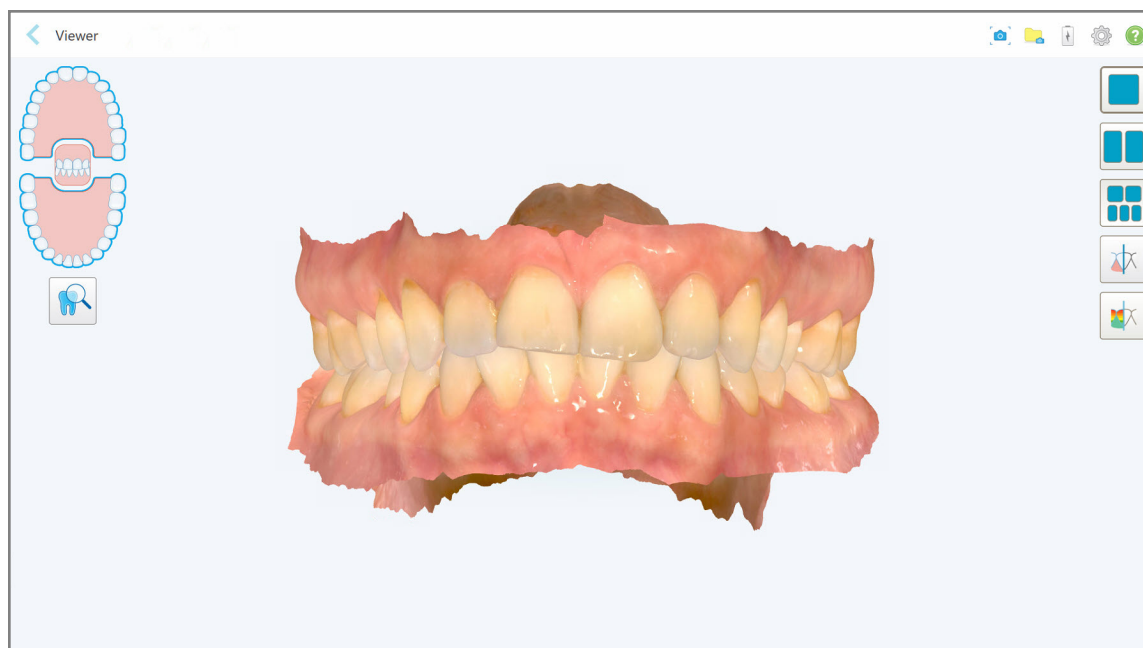


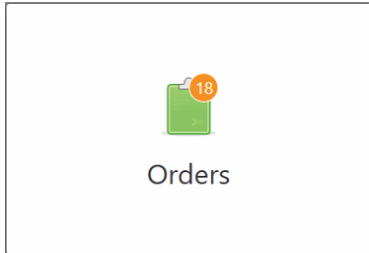
Figure 179: Scan displayed in the Viewer

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.

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 180: 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:

In Progress					
ID	Patient Name	Chart Number	Scan Date	Procedure	Status
	Demo, Patient1		11/02/2026 10:51	Study Model/iRecord	Scanning
<div> <div>View Rx</div> <div>Scan</div> <div>View Scans</div> <div>Delete</div> </div>					
				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 181: 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 iTerio subscription package:

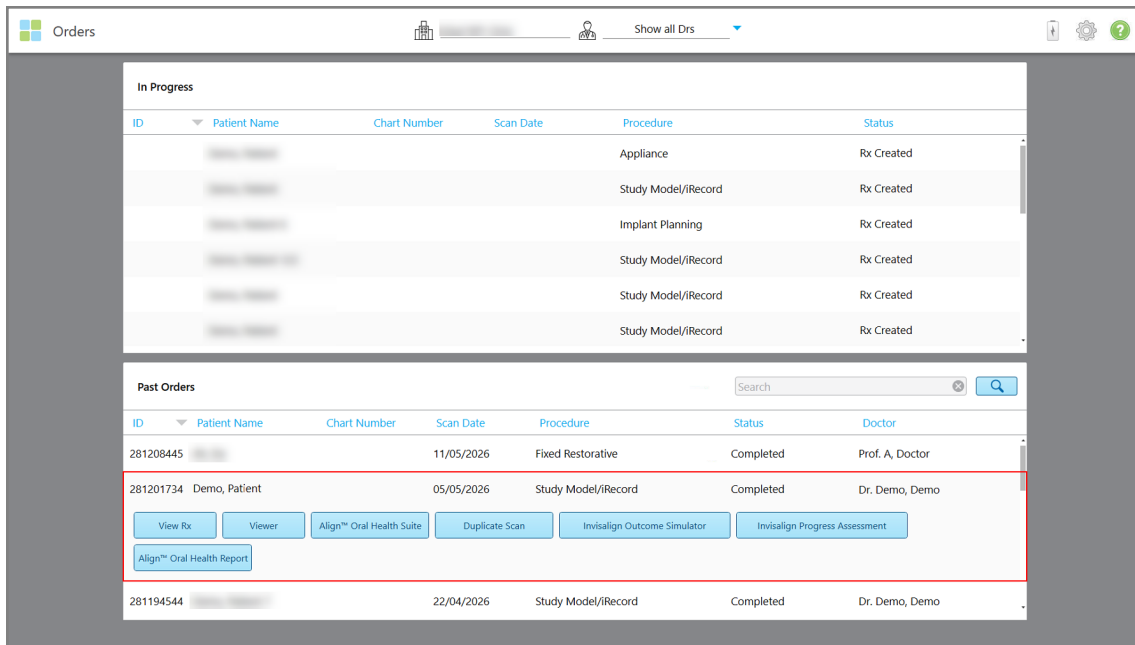


Figure 182: Past Orders pane – options

- **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.
- **Duplicate Scan:** Opens the *New Scan* window of a previously scanned orthodontic or Fixed Restorative order and enables you to adapt it as follows:
 - Study Model/iRecord, Invisalign | Vivera, Appliance orders – you can duplicate the scan and then send it as a Fixed Restorative case, for example, after adding only the prepped area.
 - Fixed Restorative order – you can duplicate the scan and then add additional indications, for example, additional crowns, etc.

This option is 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.

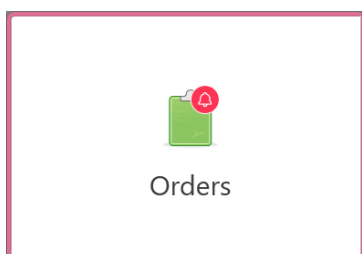


Figure 183: Orders button notifying a returned order

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 184: Returned order in the In Progress pane

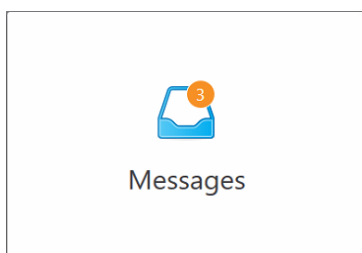
To fix a returned order:

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.

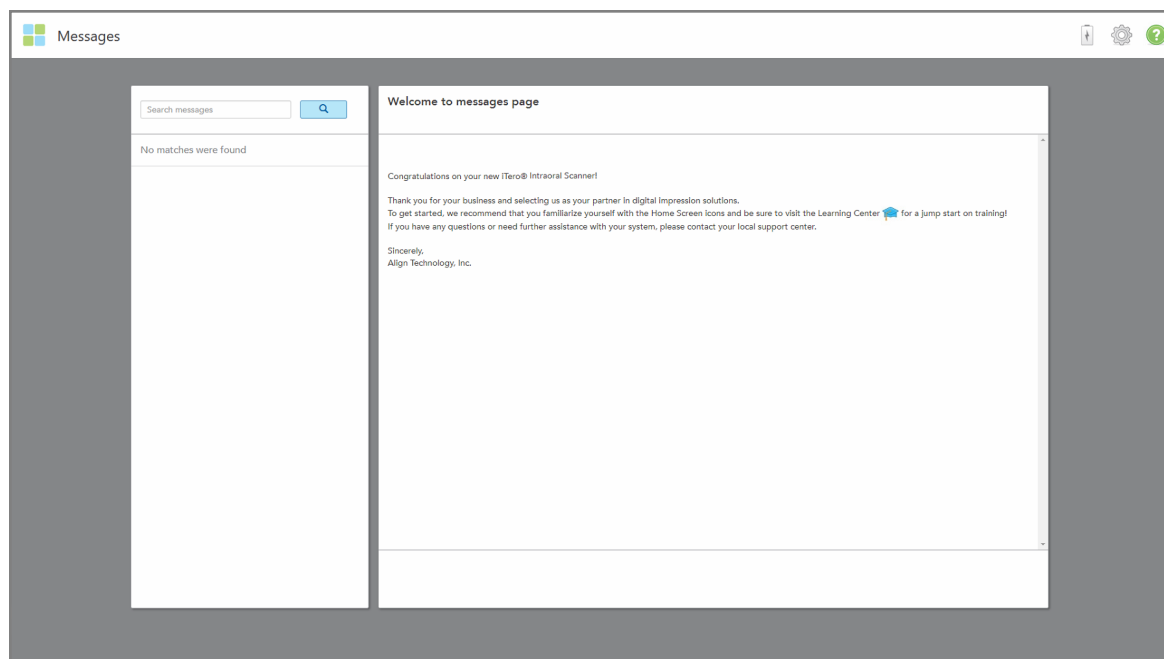


Figure 185: Messages page

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:

- [Comparing previous scans using Tero TimeLapse technology](#)
- [Invisalign Outcome Simulator Pro](#)
- [Invisalign Outcome Simulator](#)
- [Invisalign Progress Assessment](#)
- [Invisalign Go system](#)
- [Align Oral Health Report](#)
- [Align Oral Health Suite](#)
- [Editing tools](#)
 - [Delete segment tool](#)
 - [Trim tool](#)
 - [Eraser tool](#)
 - [Enable appliance scan tool](#)
 - [Enable Saliva Detection tool](#)
- Scan tools:
 - [Occlusal clearance tool](#)
 - [Margin line tool](#)
 - [Review 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 is intended to provide a visual comparison between 3D scans captured at different points in time, for the purpose of supporting patient communication. The feature displays visual differences using animation and adjustable viewing tools to help patients understand scan-to-scan changes.

The iTero TimeLapse feature does not perform measurements but displays a heatmap for scale reference, and multiple comparison methods are available. It is intended solely for communication purposes and must not be used for diagnosing, treating, mitigating, or preventing diseases, injuries, or disorders, nor for assessing or modifying anatomical structure or function.

Disclaimers: Users should be aware that the results generated by the application may not be precise and should be used for communication purposes only. Align does not assume responsibility or liability for any misunderstandings or miscommunications that may occur during the review of the images.

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.
2. In the patient's profile page, select two scans to compare. You can select the scans by selecting the check boxes next to the relevant orders, or by selecting the check boxes in the **Timeline** area at the bottom of the page.

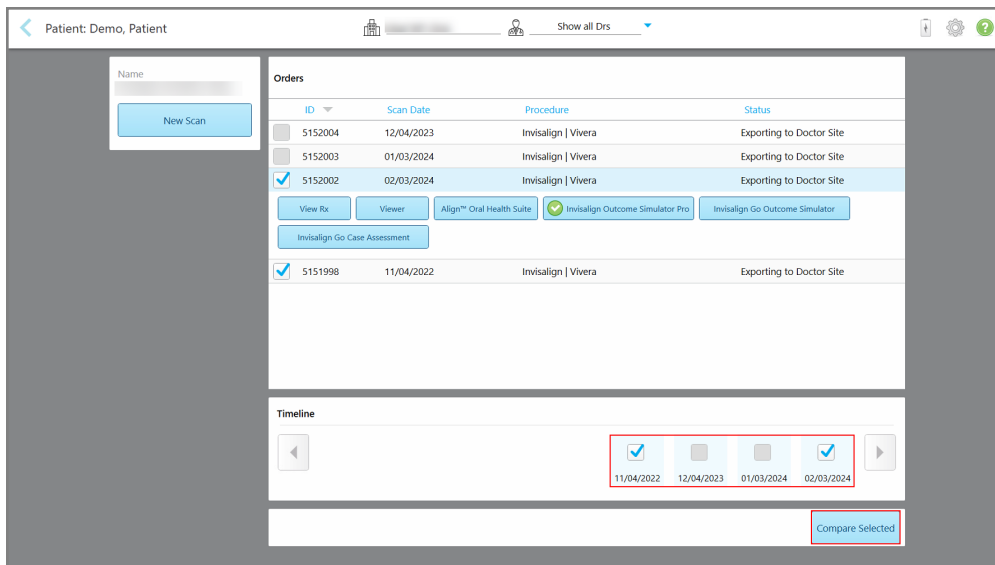


Figure 186: iTero TimeLapse – selecting the scans to compare

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

The *iTero TimeLapse* window is displayed, highlighting the areas with changes between the scans. The darker the color, the bigger the change between the scans, as displayed in the legend.

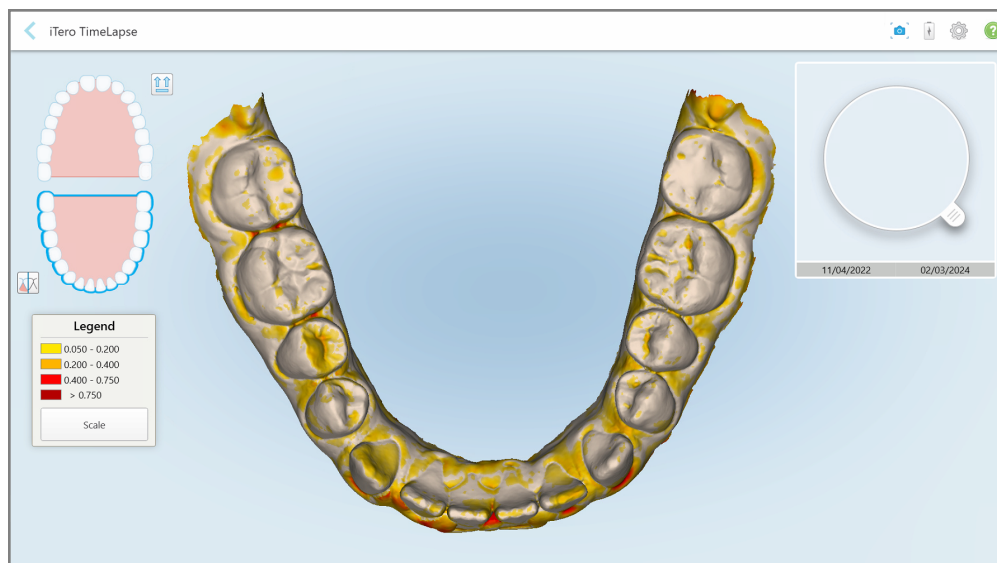


Figure 187: iTero TimeLapse window showing the highlighted changes between the scans

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

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

4. Drag the loupe onto the model to view areas of interest and potential treatment areas in the animation window. An animation is displayed, comparing the state of the teeth in the current area of interest on the selected scan dates.

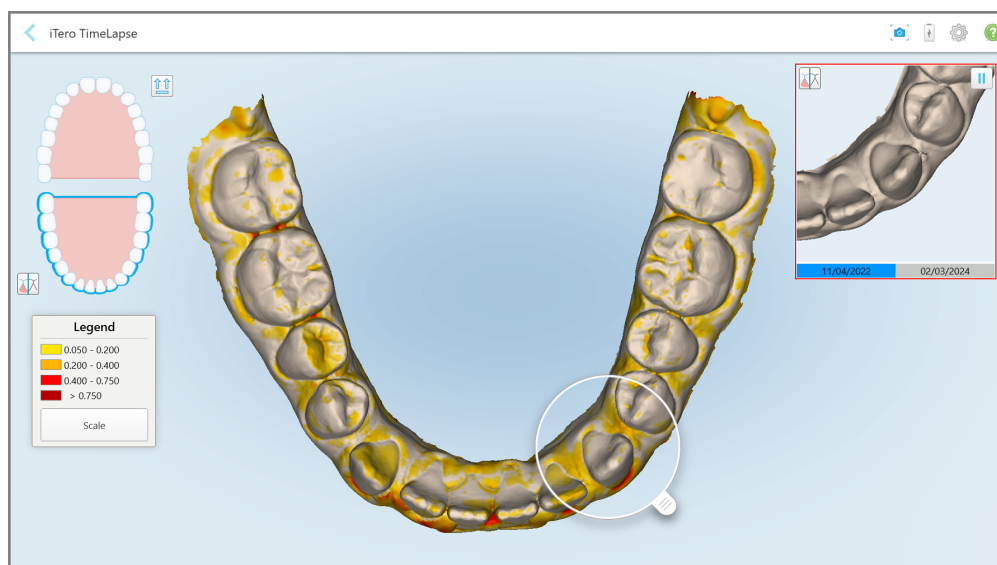


Figure 188: Area of interest from the first scan displayed in the animation window

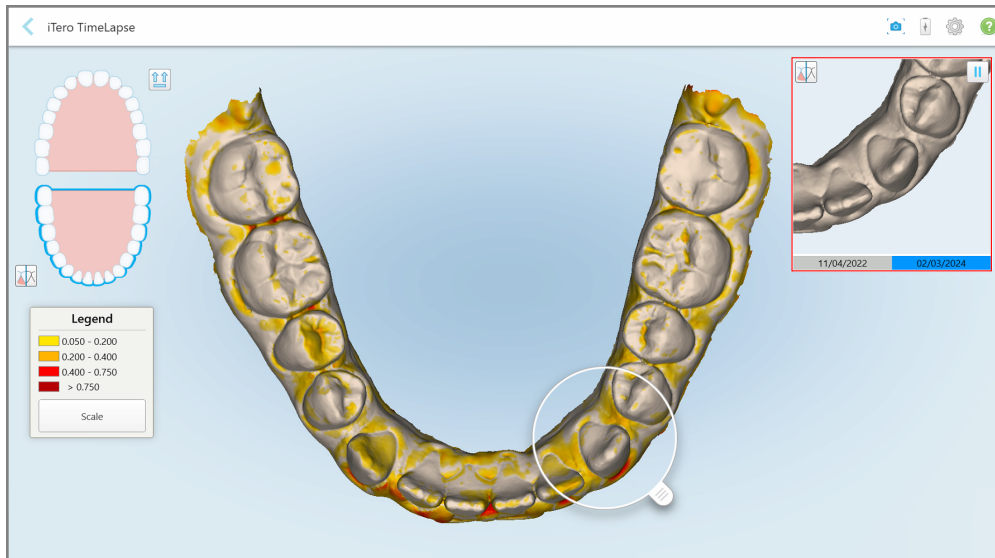


Figure 189: Area of interest from the second scan displayed in the animation window

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:

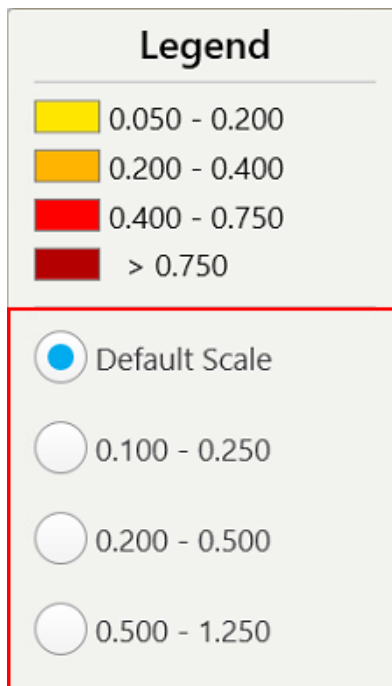


Figure 190: iTerio TimeLapse scale options

- 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 *iTerio 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:

- **iTerio PC-configuration:** Invisalign Outcome Simulator Pro may not be available, depending on the software package, and regulatory and commercial considerations.
- 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](#).

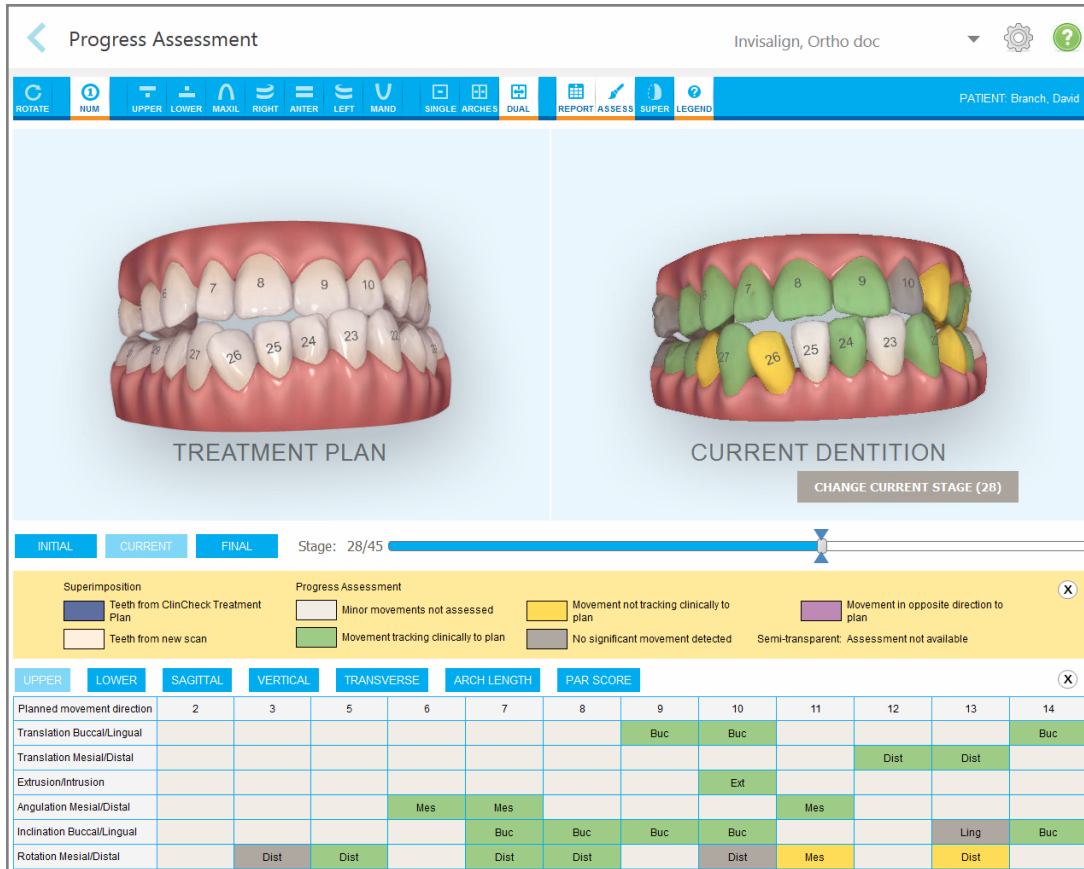


Figure 191: Progress Assessment window

For more information, refer to the **Progress Assessment** section in the *Invisalign Outcome Simulator User Guide* <https://guides.iterio.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](#)
- [Trim tool](#)
- [Eraser tool](#)
- [Enable appliance scan tool](#)
- [Enable Saliva Detection tool](#)

Note: When disabling auto-cleanup or enabling saliva detection, you should select the tool immediately after starting the scan. The tool is activated from that point on.

The editing tools are accessed by pressing on the screen.

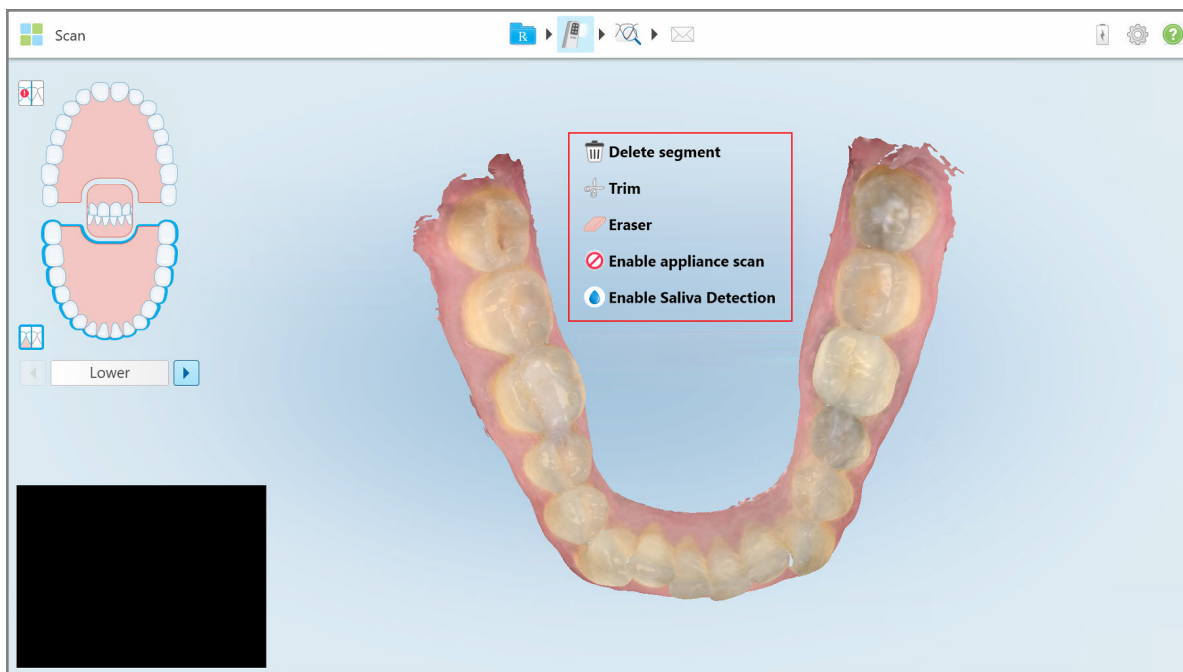


Figure 192: Editing tools

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 .

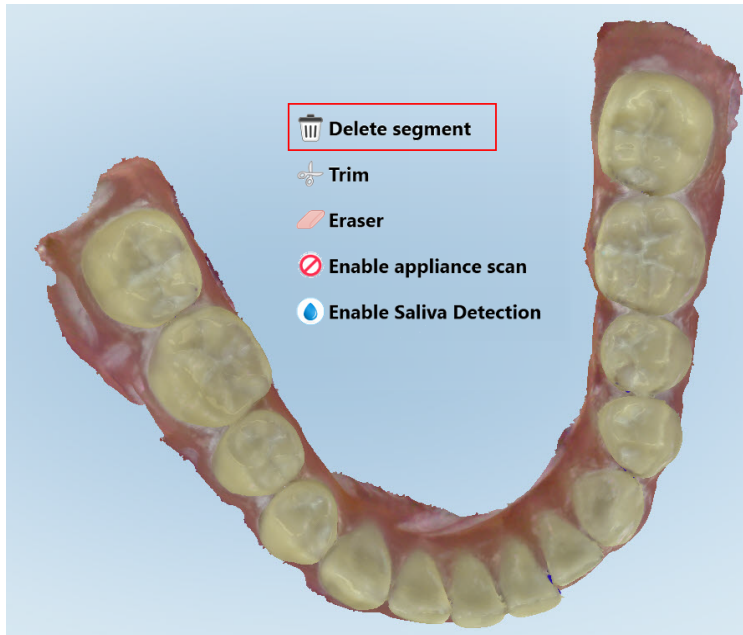


Figure 193: Delete segment tool

A confirmation message is displayed.

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

10.6.2 Working with the Trim tool

The **Trim** 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.

The Trim tool can be accessed from the *Scan* window or the *View* window.

To trim the excess material:

1. In the *Scan* window, press the screen to display the editing tools and then tap the **Trim** tool .

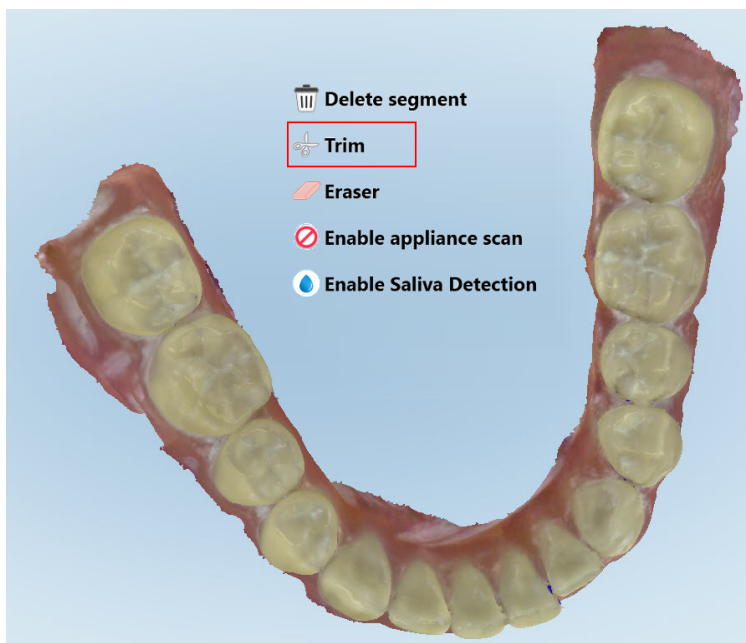


Figure 194: Trim tool from the Scan window

Or

In the *View* window, tap the Trim tool .

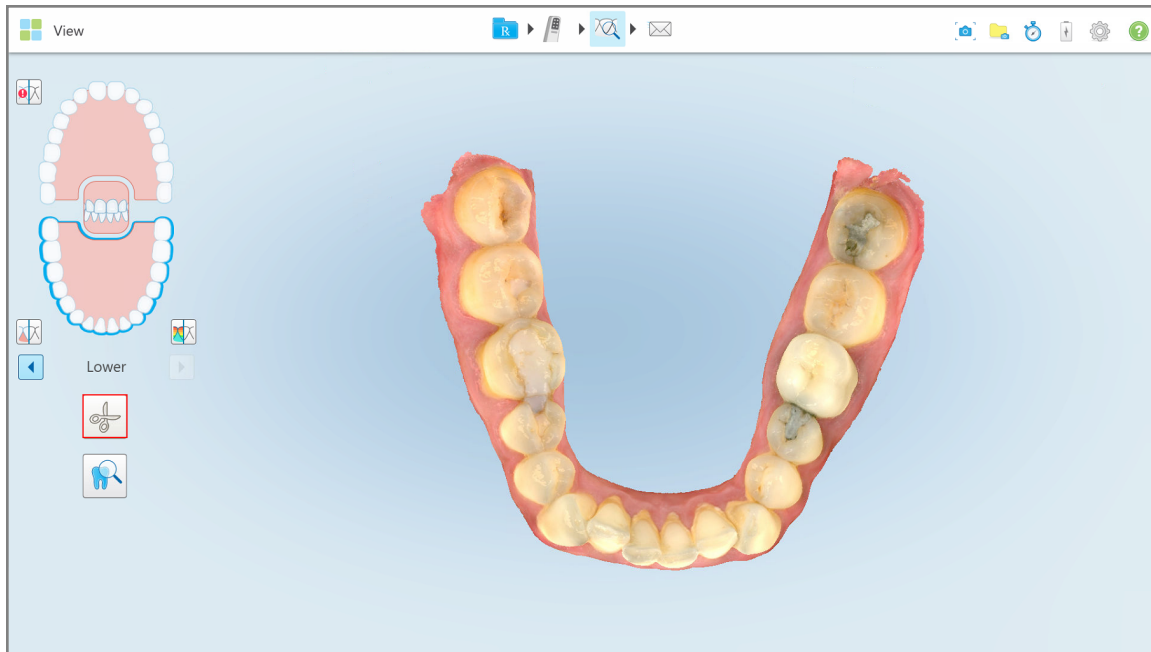


Figure 195: Trim tool from the View window

The Trim tool expands to show the following options:



Figure 196: Trim tool options

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

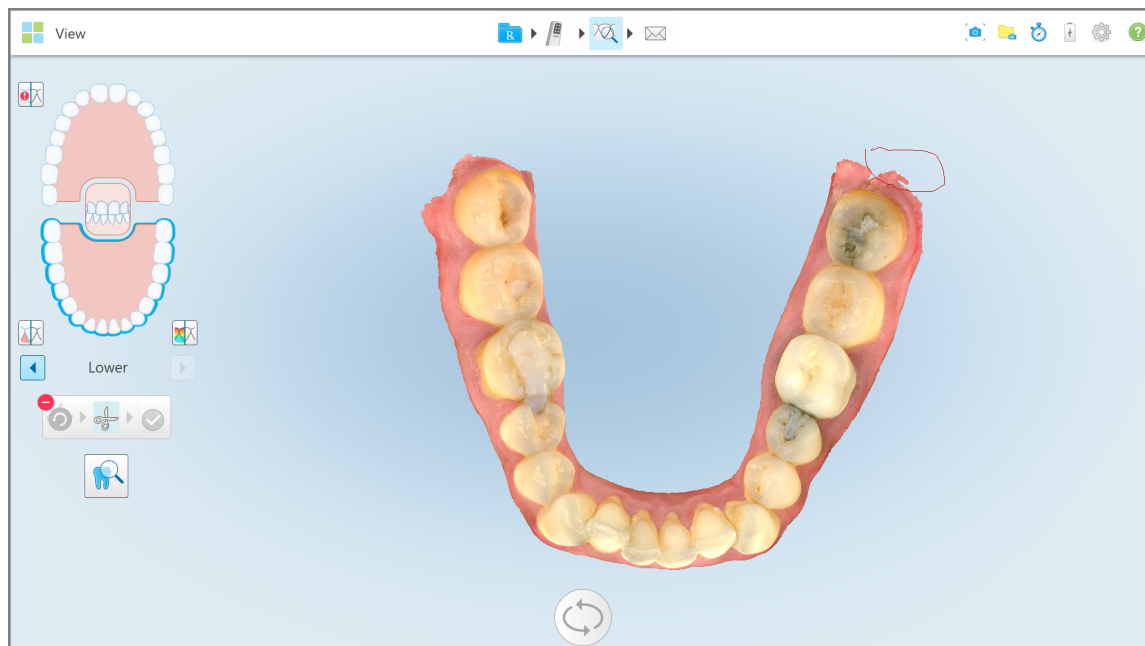


Figure 197: Mark the area to be trimmed away

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

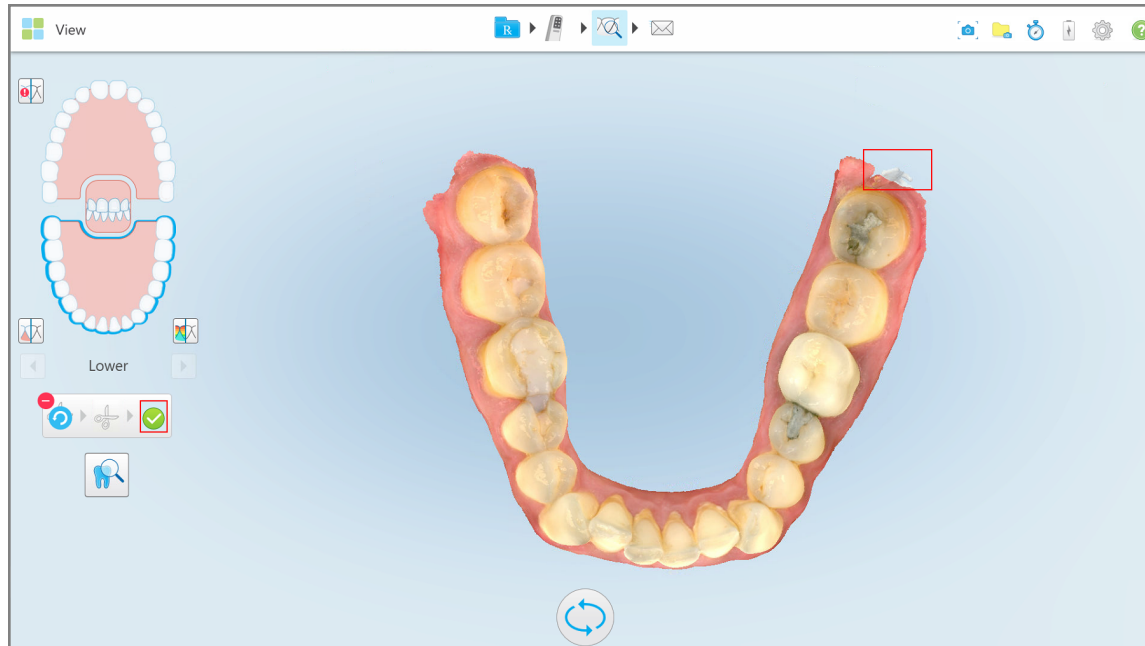


Figure 198: Selected area is highlighted, and the confirmation icon is enabled

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

4. Tap  to confirm the trimming.

The selected area is removed.

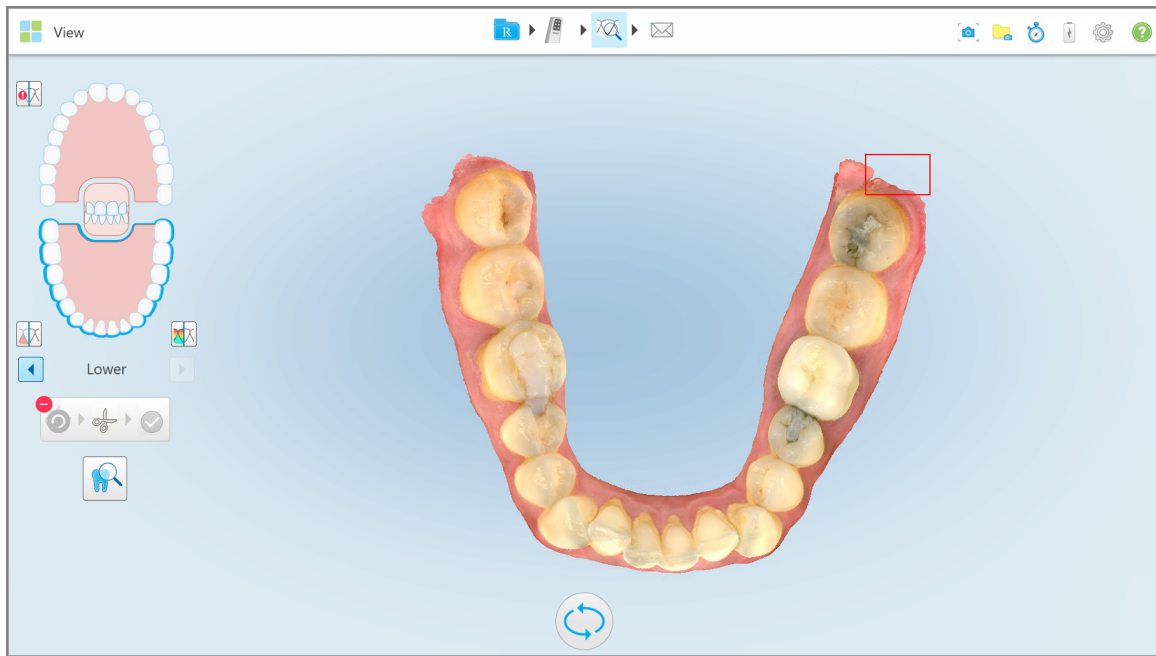


Figure 199: Selected area has been removed

10.6.3 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.

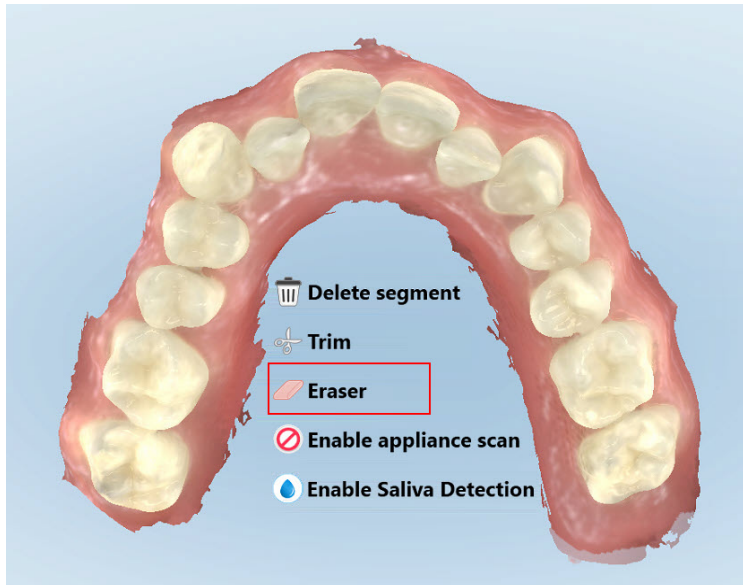
For example:

- You can remove moisture and artifacts, such as blood or saliva, that are covering the margin.
- If there are areas of red on the Occlusal Clearance legend after post-processing (*View* mode), you can reduce the relevant tooth, return to *Scan* mode to erase the area on the model, and then rescan it.

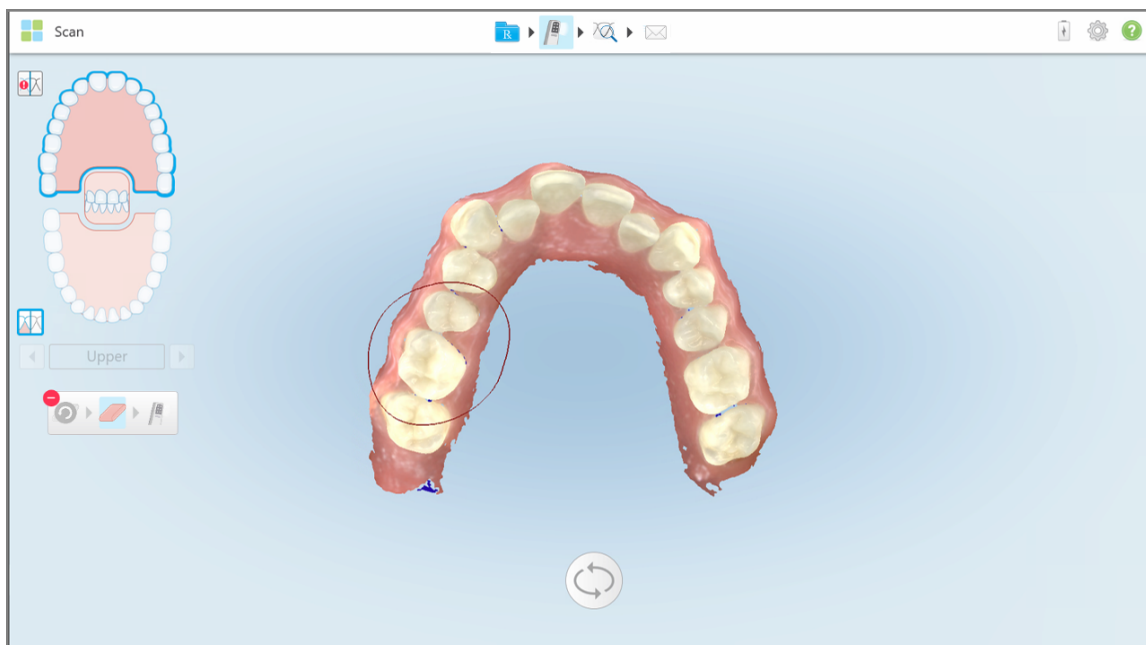
Note: The Eraser tool is available only for Study Model/iRecord, Invisalign | Viverra, and Appliance procedures.

To erase part of the scan:

1. In the *Scan* window, press the screen to display the editing tools.
2. Tap the Eraser tool .

**Figure 200: Eraser tool**

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

**Figure 201: Mark the area to be modified**

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

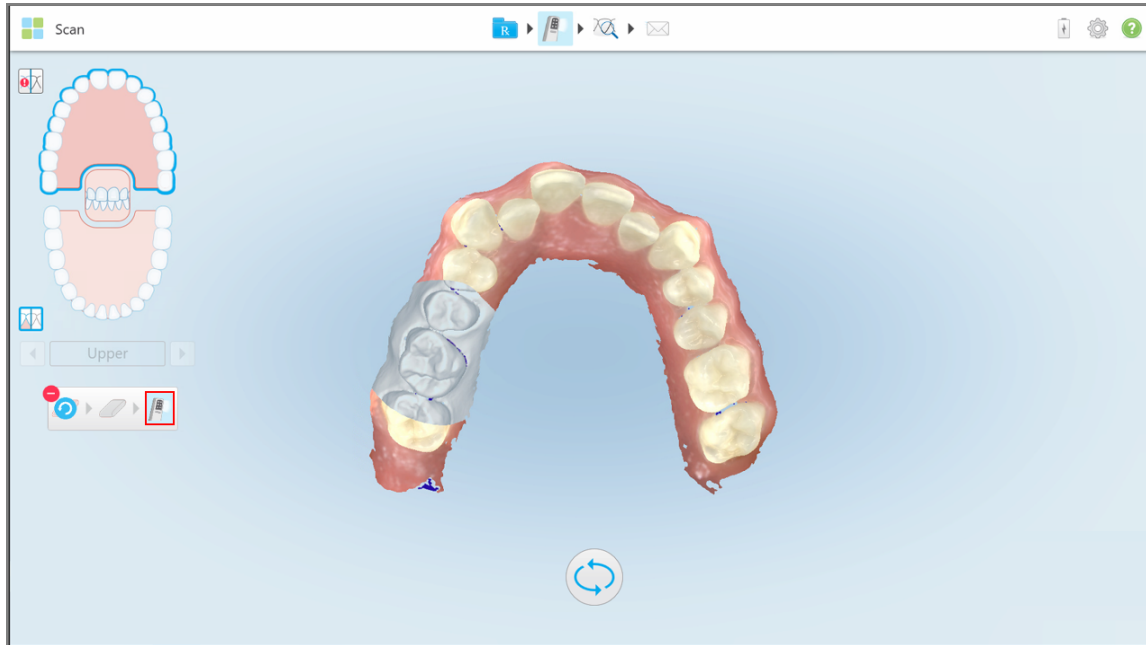


Figure 202: Selected area removed, and scan tool enabled

4. If required, tap  to undo the deletion.
5. Tap  to return to Scan mode and rescan the deleted area.

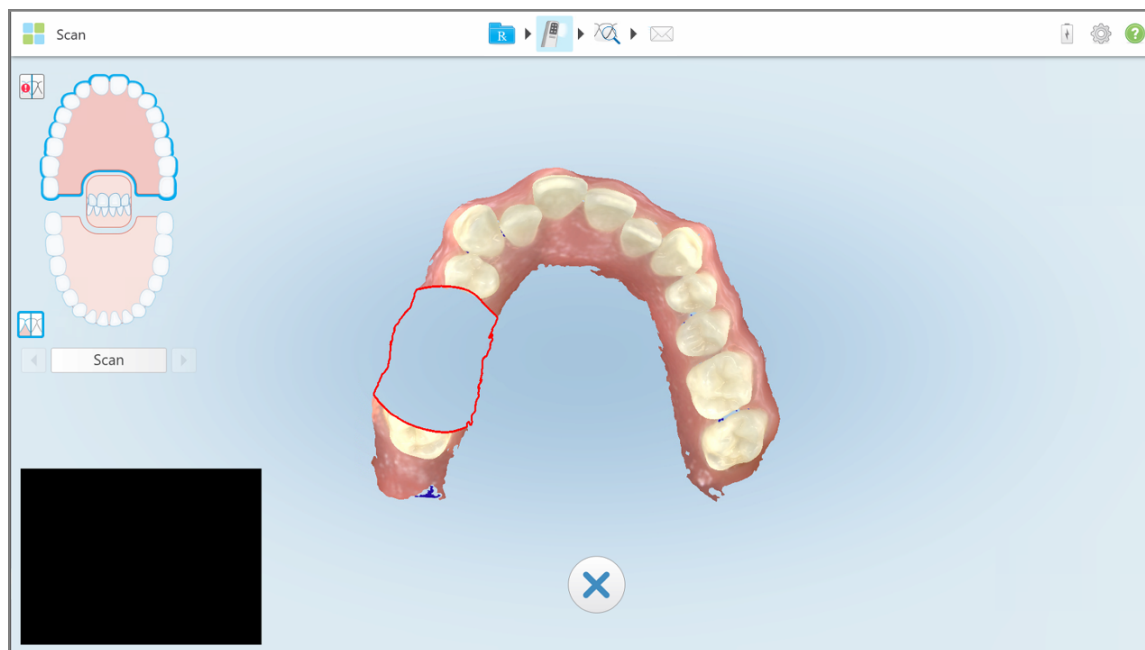


Figure 203: Deleted area to be rescanned

10.6.4 Enabling scanning an appliance

By default, excess tissue is removed from around the edges of the 3D model during scanning. When extra-orally scanning appliances or materials such as partial dentures or putty, turn off this functionality for the current scan.

Notes:

- Enabling this tool may result in you scanning your fingers, gloves, etc. To minimize this, make sure to hold the appliance in areas that are not being scanned.
- Enabling scanning an appliance is relevant only from the point at which this feature is enabled and only for the current scan session. Excess material will be removed by default in the next scan.

To enable scanning an appliance:

1. Start scanning the appliance, pause the scan, and then press the screen to display the editing options.

2. Tap the **Enable appliance scan** tool .

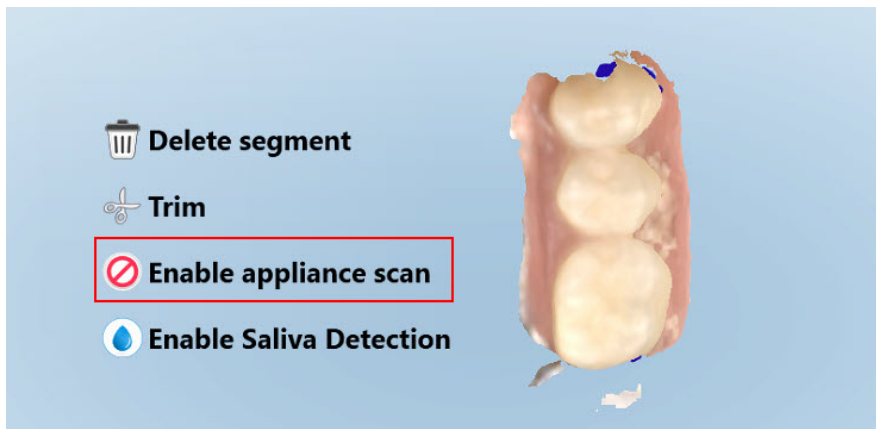


Figure 204: Enable appliance scan tool

3. Continue scanning the appliance.
The scan is displayed showing the entire appliance, including any metal, etc.

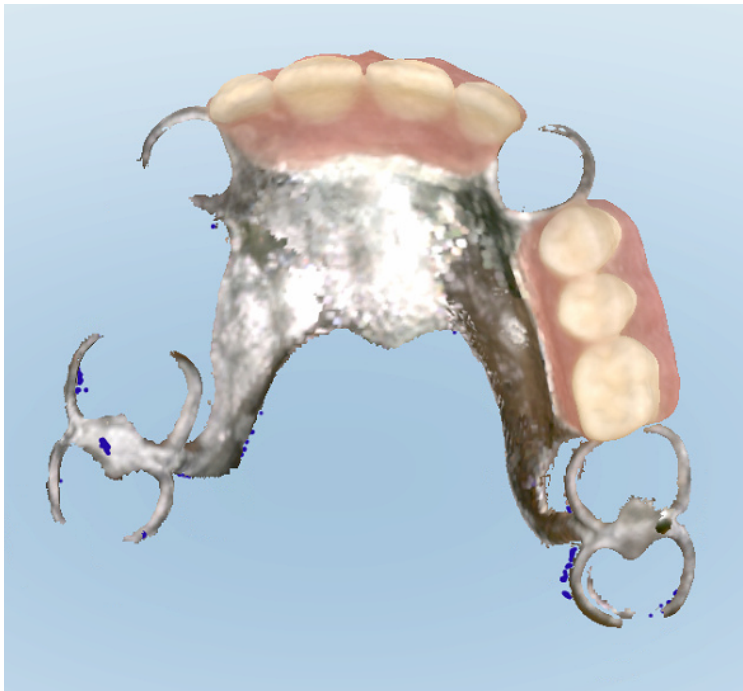


Figure 205: Scan of the appliance including the metal

4. To return to scanning without excess tissue, press the screen to display the editing options and then tap **Disable appliance scan**. From this point on, scanned excess tissue is removed from the model.

10.6.5 Enabling saliva detection

You can enable saliva detection while scanning, applicable only from the point at which this feature is enabled and only for the current scan session. You will not be notified regarding saliva detection in the next scan.

If required, you can [enable saliva detection for all scans by default](#).

To enable saliva detection while scanning:

1. In the *Scan* window, pause the scan, and then press the screen to display the editing tools.

2. Tap the **Enable Saliva Detection** tool .

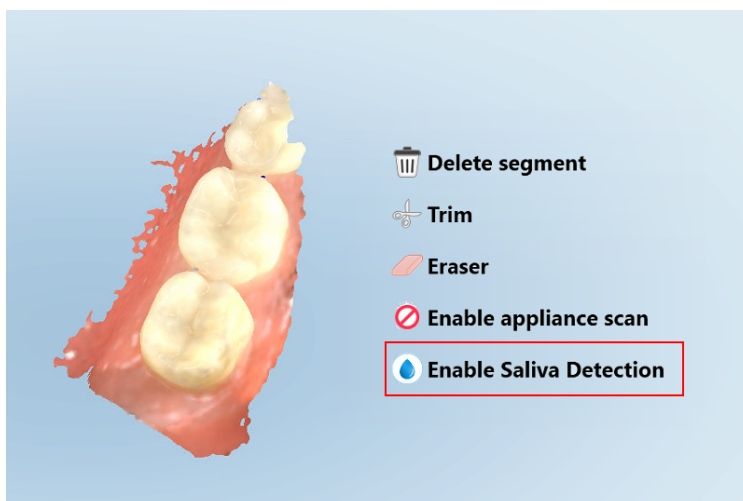


Figure 206: Enable Saliva Detection tool

From this point on during the scan, whenever saliva is detected, a drop icon is displayed on the screen and holes are displayed on the 3D model in the areas where the saliva was detected.

10.7 Working with the Occlusal Clearance tool

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

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

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

To display the occlusal clearance while in View mode:

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

The occlusal clearance between the opposing teeth is displayed.

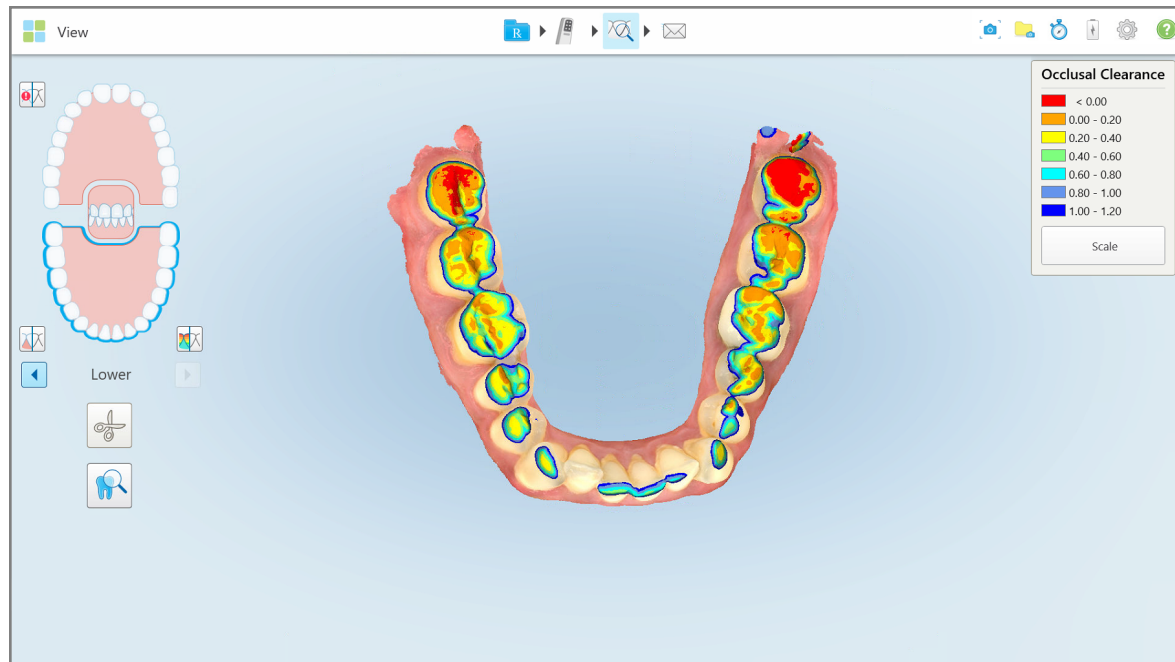


Figure 207: Occlusal clearance between the opposing teeth

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.

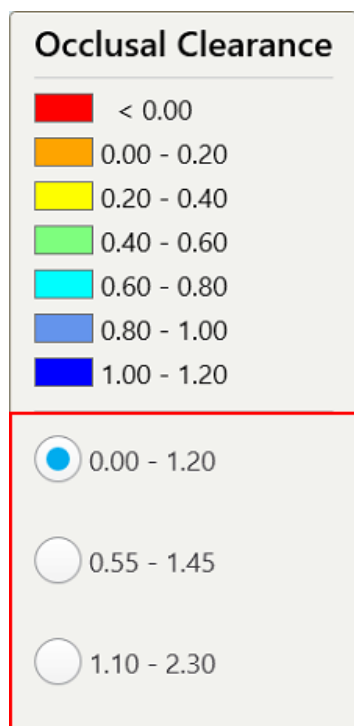


Figure 208: Occlusal Clearance range options

- 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.

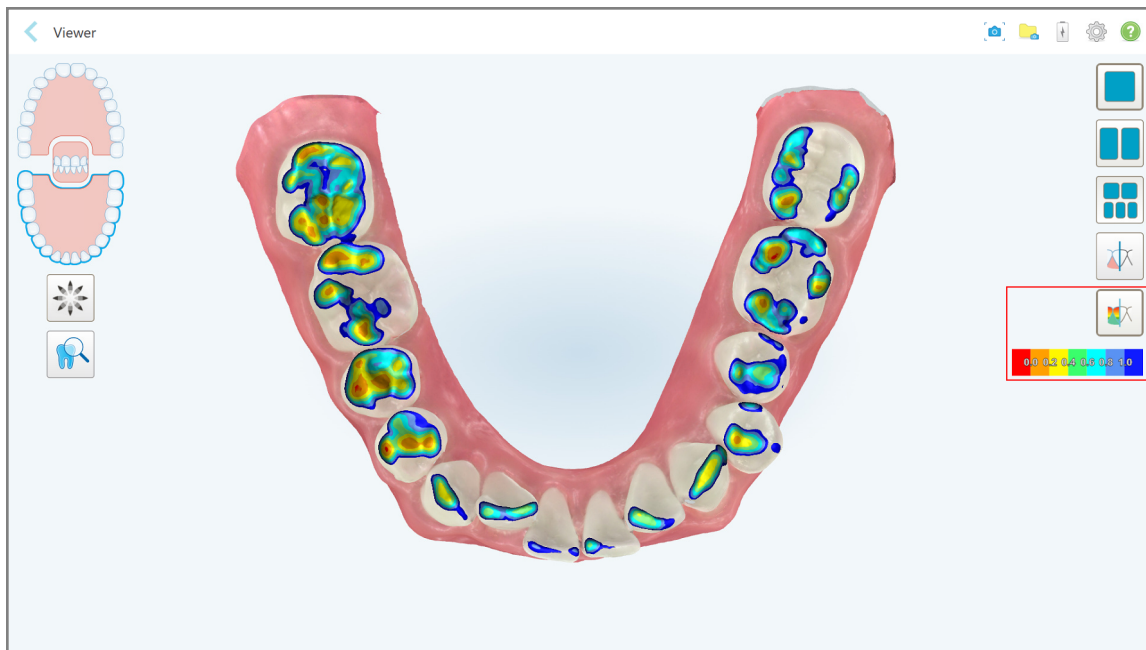


Figure 209: Occlusal Clearance tool and legend displayed in the Viewer

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](#).

10.8 Working with the Margin Line tool

The Margin Line tool automatically detects and marks a suggested margin line on Fixed Restorative procedures requiring crowns. Once the margin line has been created, you can tweak it or recreate it if it has been deleted. In addition, you can manually mark the margin line if you are not satisfied with the suggested margin line, or for other indications besides crowns.

To detect the margin line:

1. Scan the arch, including the preps, and then move to View mode.
After post-processing, the occlusal clearance of the scan is displayed.

2. Tap the Margin Line tool .

You are prompted to tap the prepped tooth on the model to detect the margin line.

3. Tap the relevant prep.
iTero zooms in to show the suggested margin line on the prep.

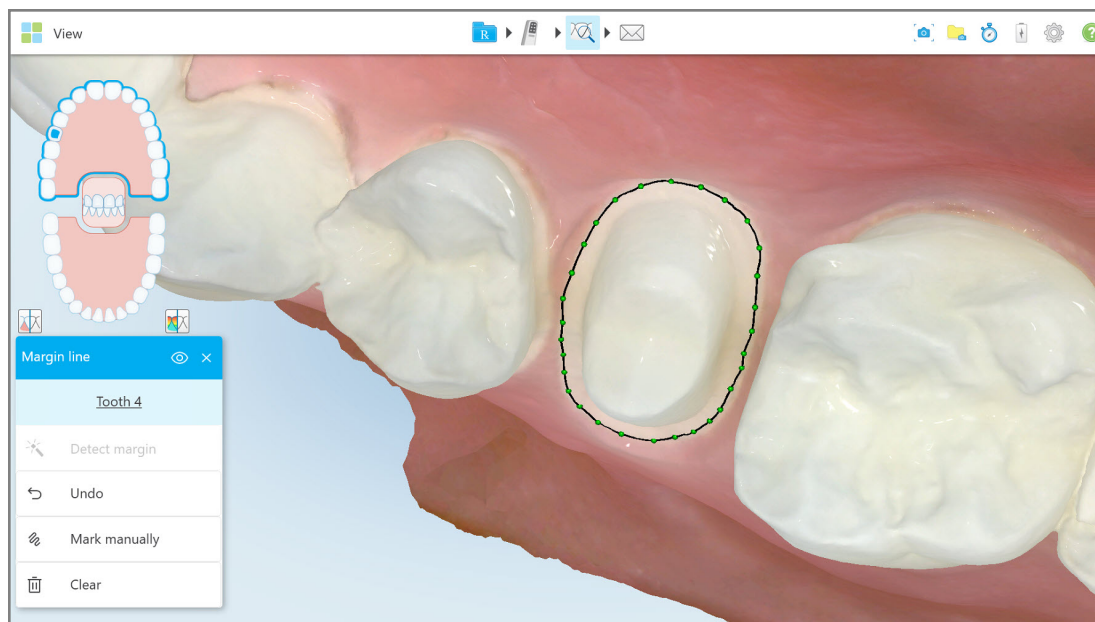


Figure 210: Margin line is displayed

4. Review the suggested margin line, and if required, adjust the margin line by dragging any of the green points.
5. If required, tap **Mark manually** to clear the automatic margin line and then mark it manually:
 - Tap around the prepped tooth to draw a point-by-point line. Once the margin line is closed, the red points turn green.

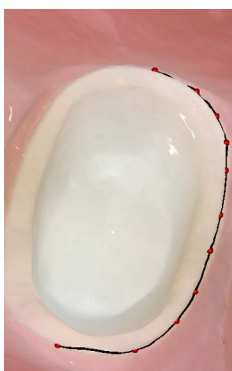


Figure 211: Manual margin line points

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.

- Tap **Undo** to undo the last action, such as the last point that was added manually.
 - Tap **Clear** to delete the entire margin line.
6. If required, you can tap  or  to hide or show the margin line.

10.9 Working with the Review tool

The View mode includes a **Review tool** that enables you to view the colored intraoral images captured during the scan, for every area of interest. These images are displayed in the image pane, on the right of the View window.

In addition, you can:

- [Zoom in and out of the image](#) in the image pane
- [Adjust the brightness and contrast of the image](#) in the image pane
- [Capture screenshots of the image](#)

Note for PC-configuration scanners: The Review tool may not be available, depending on the software package, and regulatory and commercial considerations.

To activate the Review tool:

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

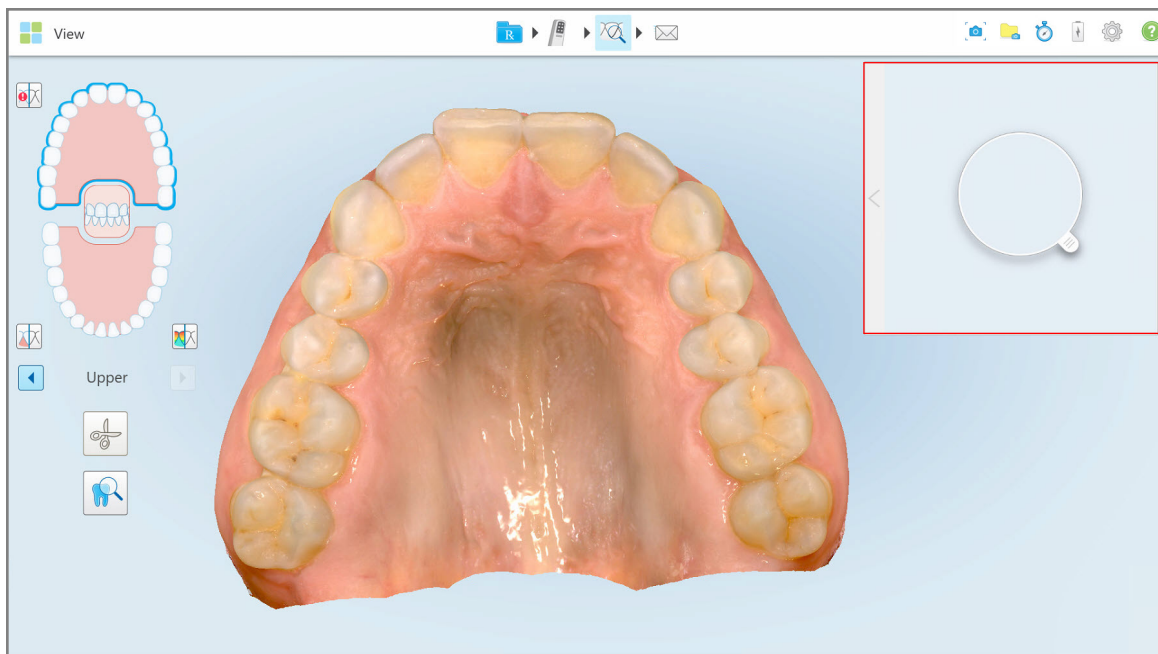


Figure 212: Review tool with the loupe in the right pane

The area within the loupe is displayed in the image pane on the right. The display in the image pane changes according to the position of the loupe.

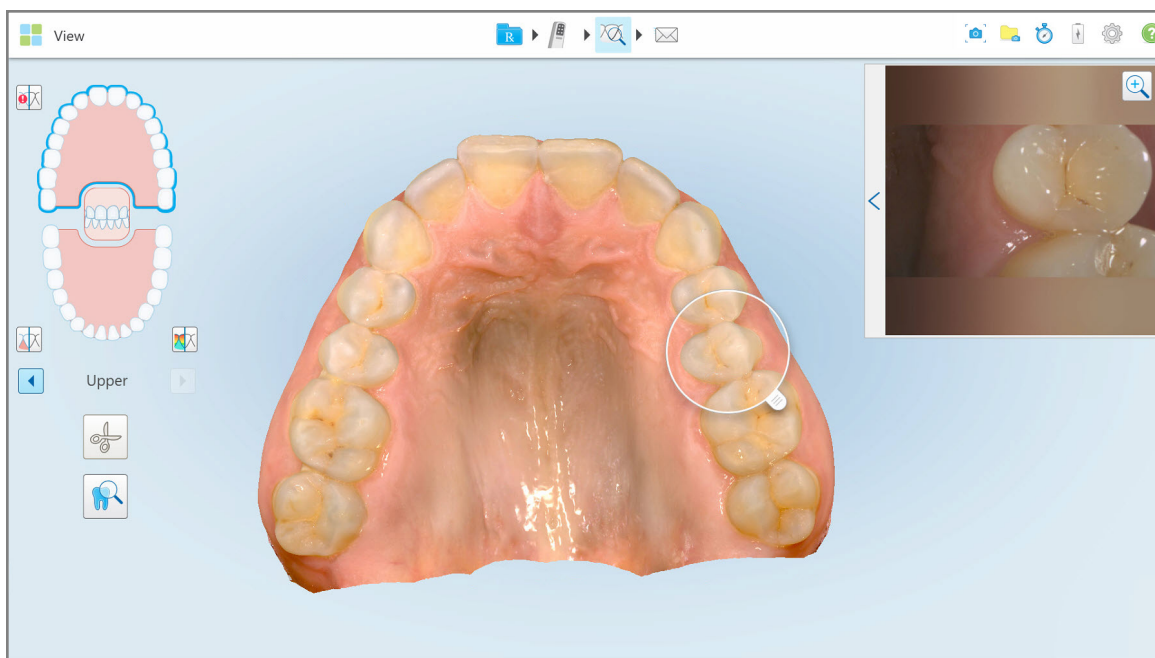


Figure 213: Image pane on the right showing the area of interest

10.9.1 Zooming in to and out of the images in the image pane

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

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

- Using a spreading or pinching gesture on the image displayed in the image pane
- Double-tapping the image in the image pane to toggle zoom in/zoom out
- Tapping the zoom button displayed on the image

To zoom in or out using the zoom button:

1. Tap  on the colored intraoral image to zoom in to the area of interest.

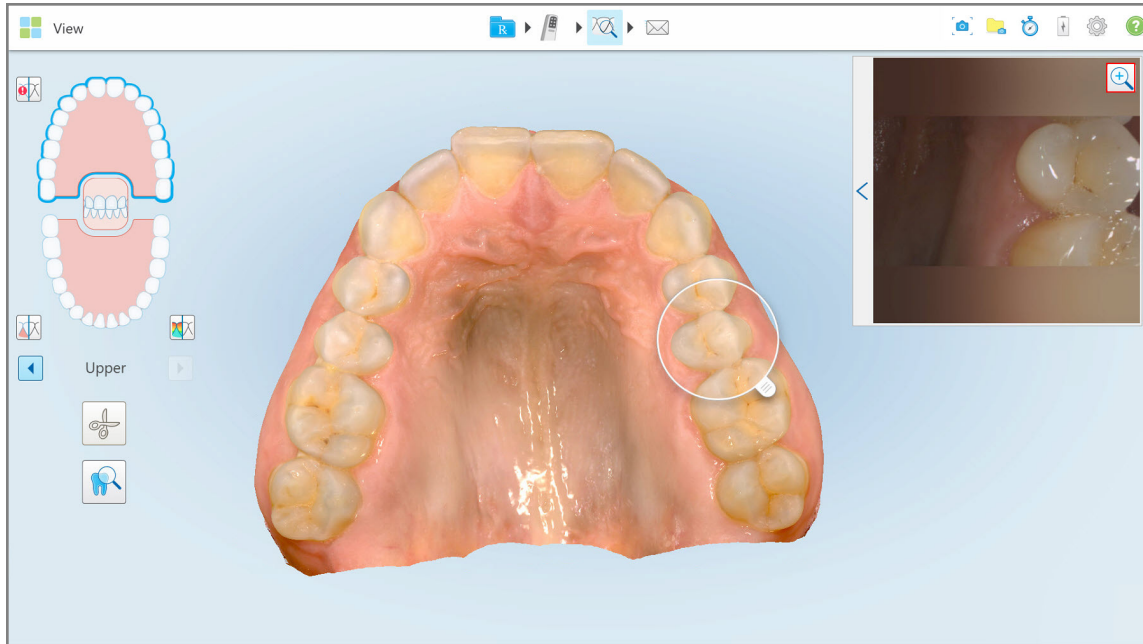


Figure 214: Zoom-in button on the image in the image pane

The image pane is enlarged to display the zoomed-in image.

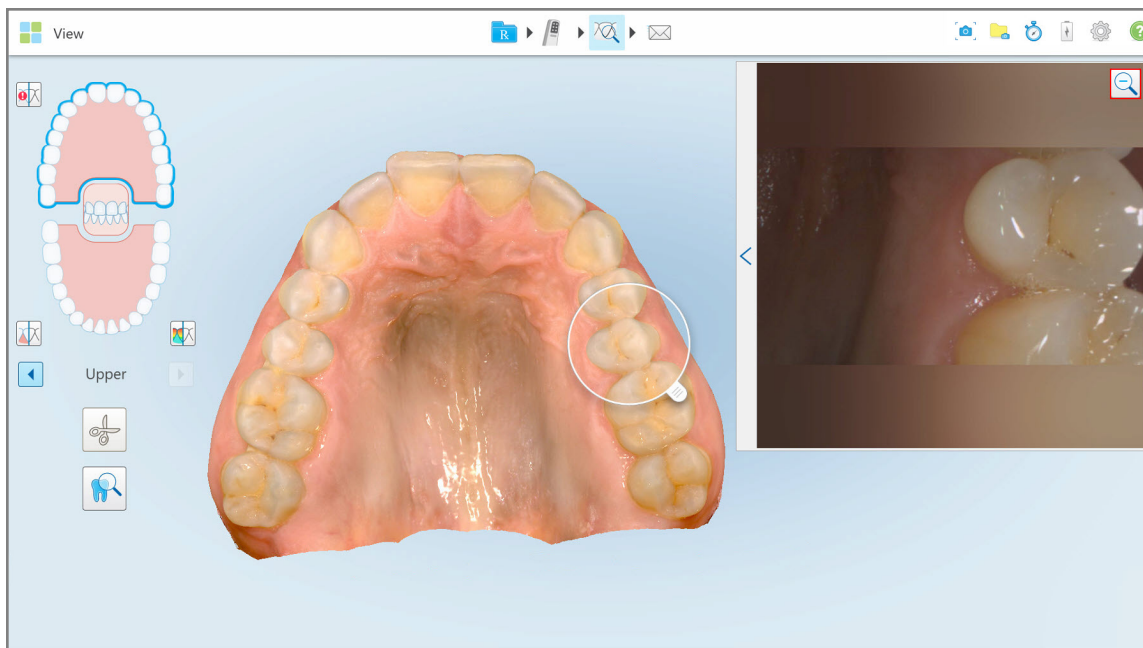


Figure 215: Zoomed-in image displayed in the enlarged image pane

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

10.9.2 Adjusting the brightness and contrast of images in the image pane

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

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

By default, the brightness and contrast toolbar is collapsed.

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

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

To adjust the brightness and contrast of the images in the image pane:

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

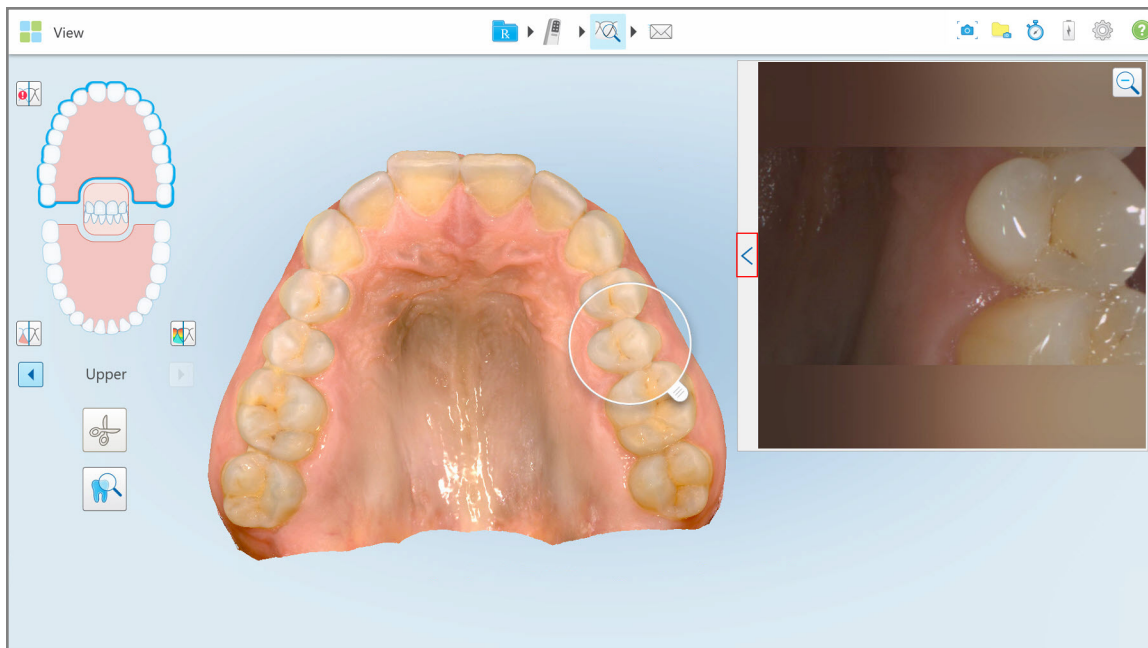


Figure 216: Brightness and contrast toolbar is collapsed

A brightness and contrast adjustment toolbar is displayed on the window in the image pane. By default, the brightness level is set to the lowest position and the contrast is set to the middle position.

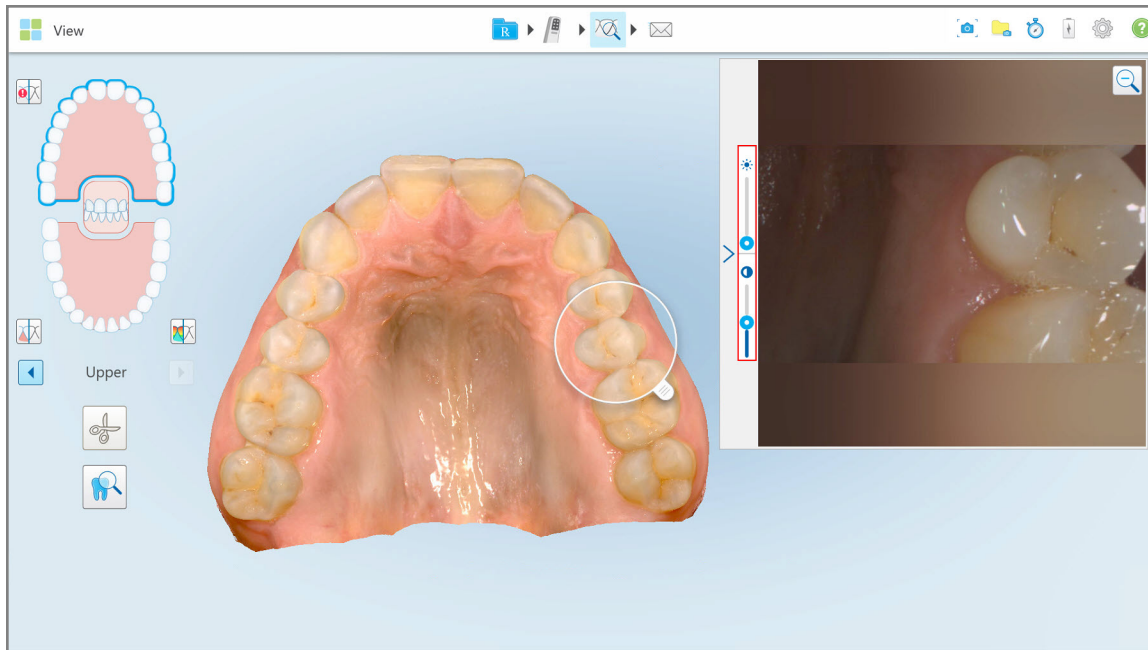


Figure 217: Brightness and contrast toolbar

2. Move the slider up or down to adjust the brightness  or contrast.

Tip: You can tap anywhere in the slider area and drag up or down to adjust the settings.

3. Tap  to collapse the toolbar.

10.9.3 Capturing the Review tool images

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

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

10.10 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 218: 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 219: 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.

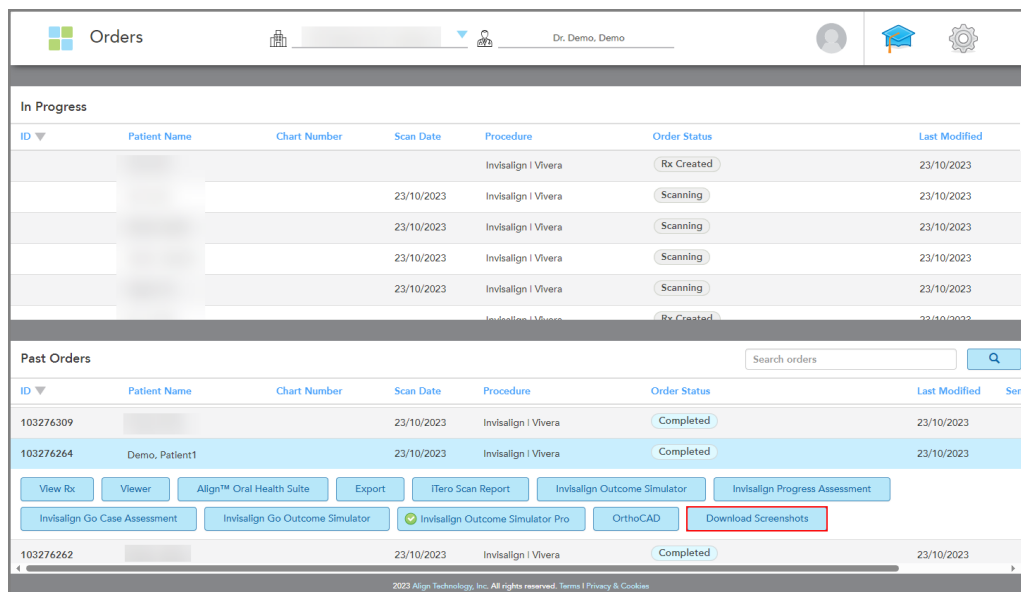


Figure 220: Option to download screenshots from the Orders page in MyiTero

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

If you are taking screenshots while using the Review tool, the following screenshots are included:

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

10.10.1 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.

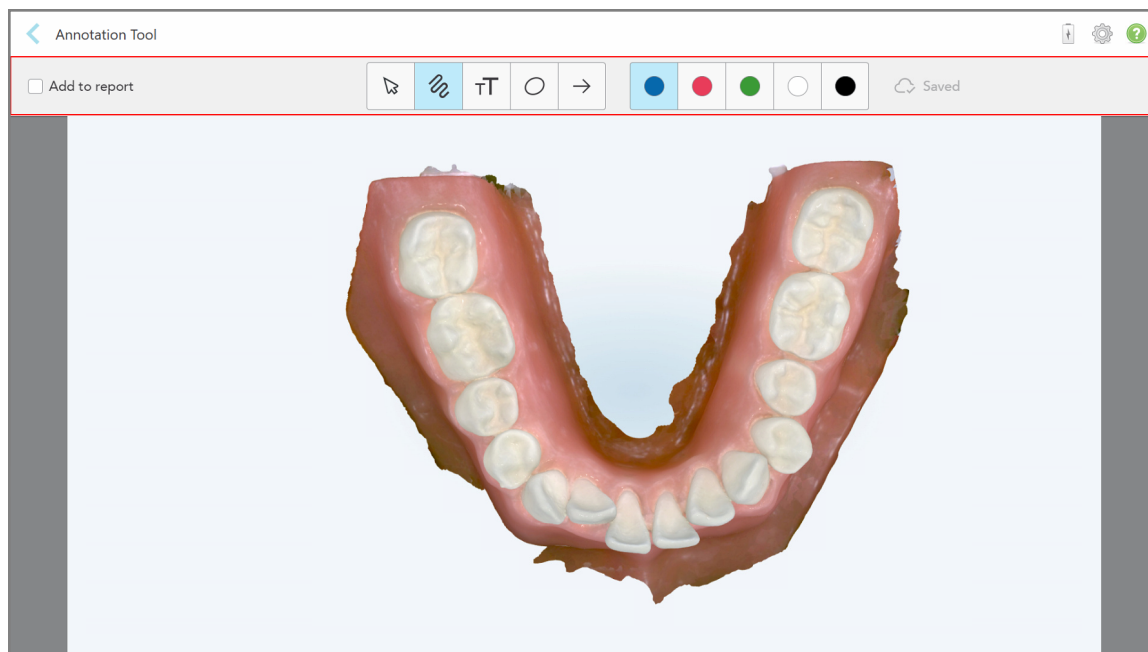


Figure 221: Screenshot open in the Annotation Tool window and the annotations toolbar

The Annotation Tool toolbar contains the following buttons:

☐ Add to report	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.

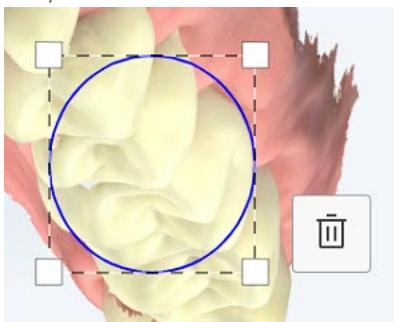


Figure 222: Options to move or delete the annotation

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.

10.11 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.

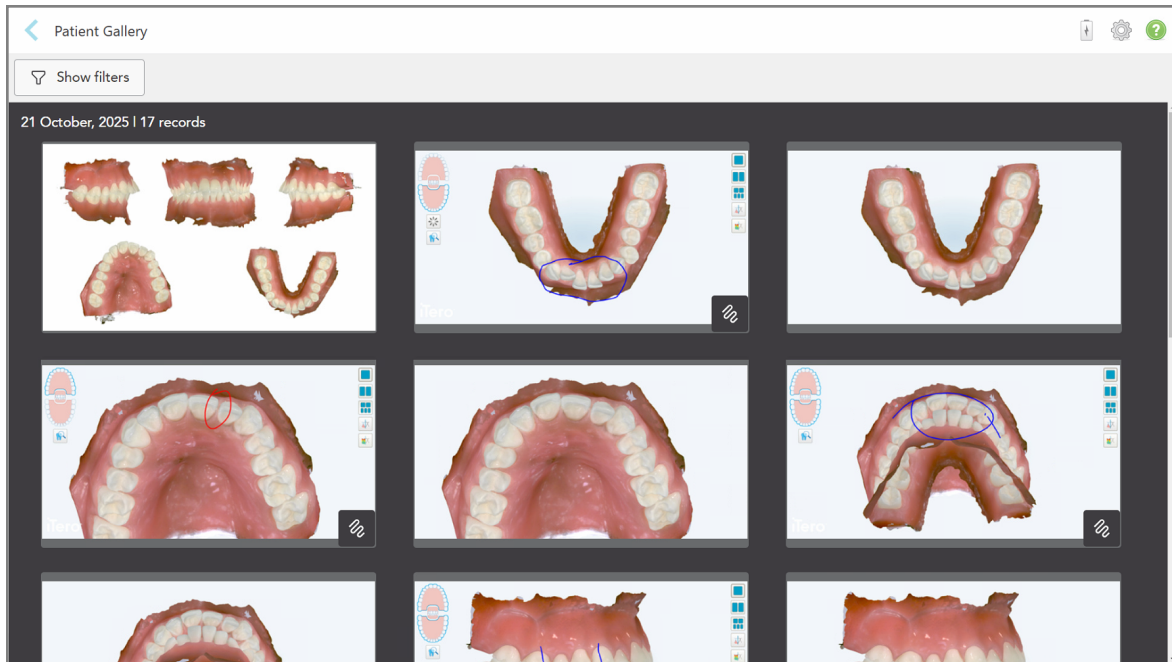


Figure 223: Patient Gallery

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.

10.12 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.

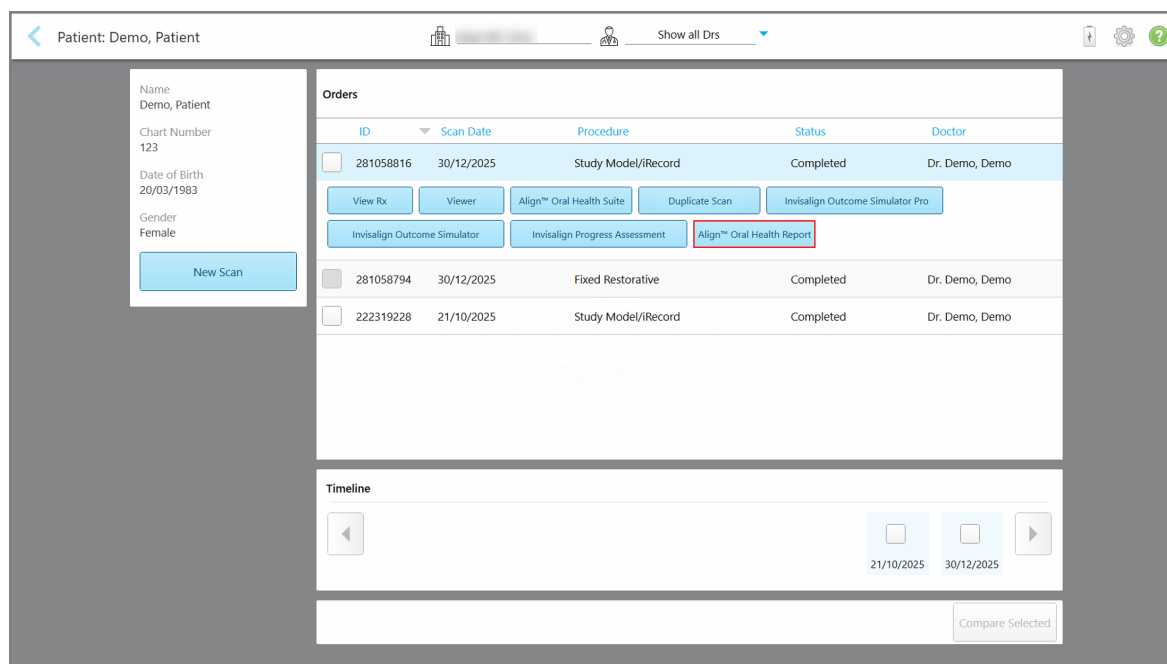


Figure 224: Align Oral Health Report button

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.

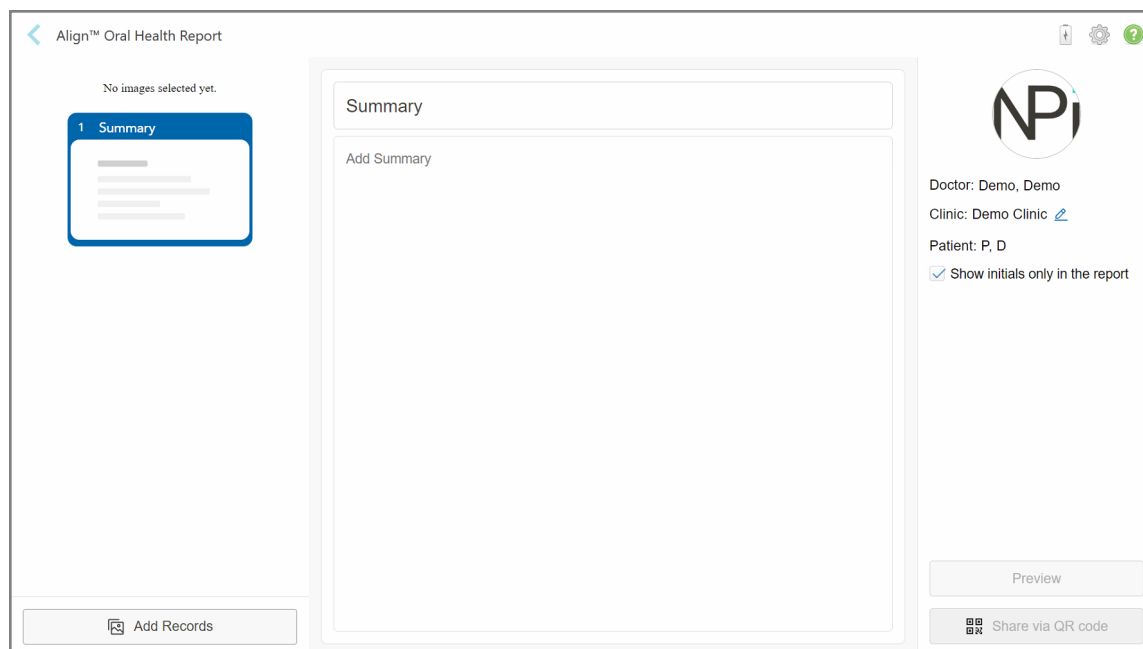


Figure 225: Align Oral Health Report – Summary page

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.

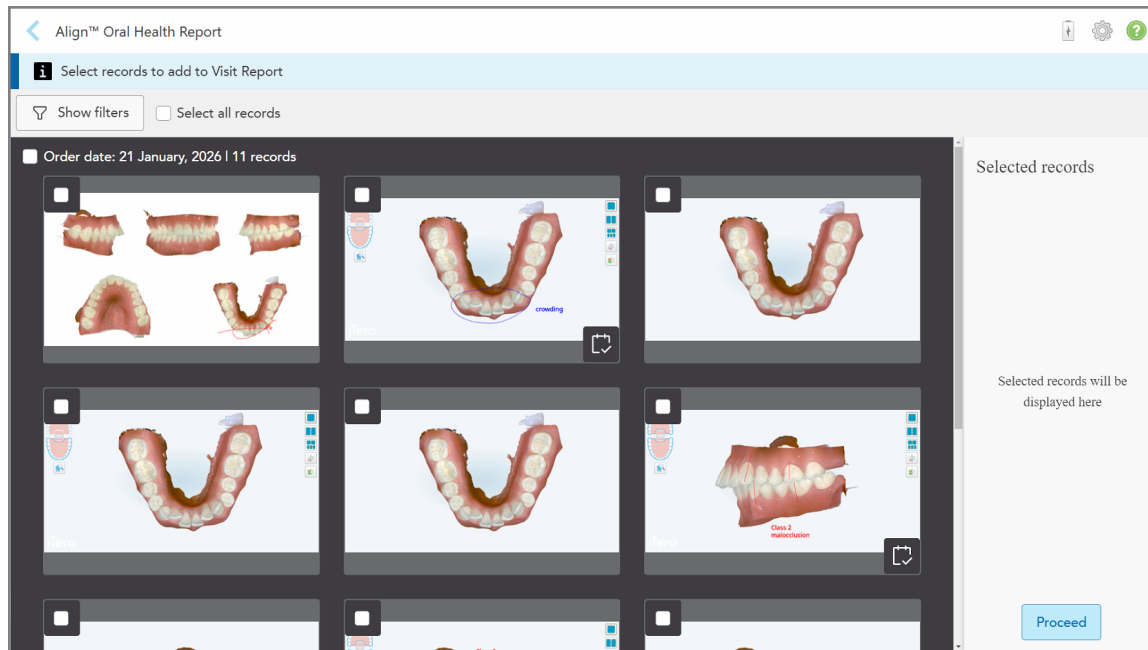


Figure 226: Align Oral Health Report – Patient Gallery

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.

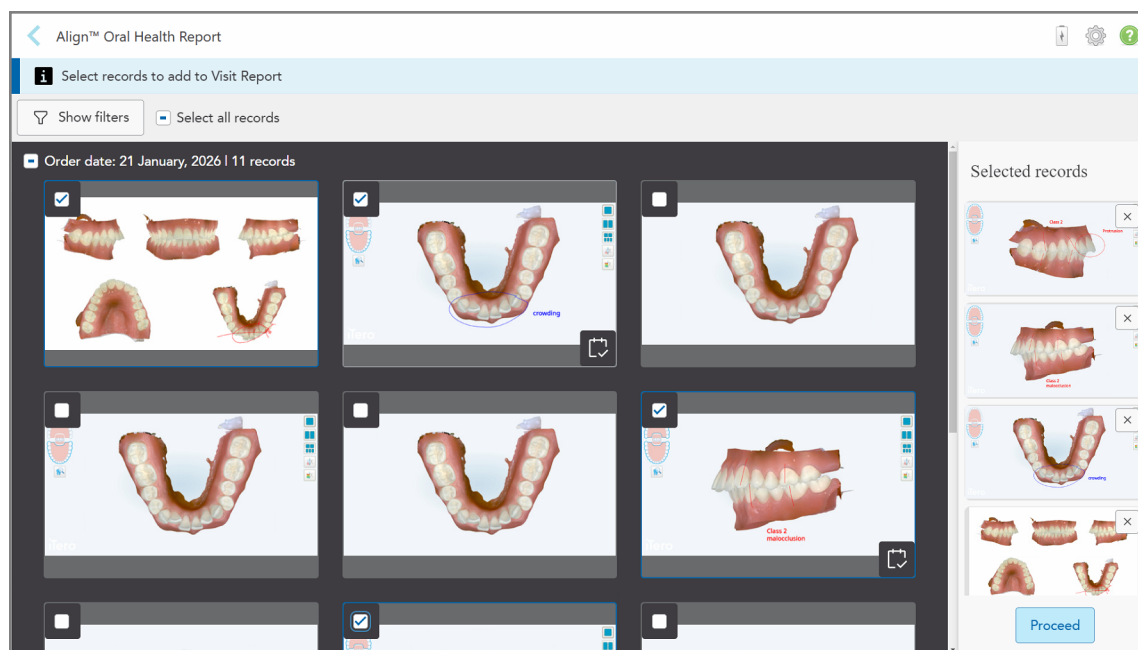


Figure 227: Align Oral Health Report – Selected records in the right pane

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.

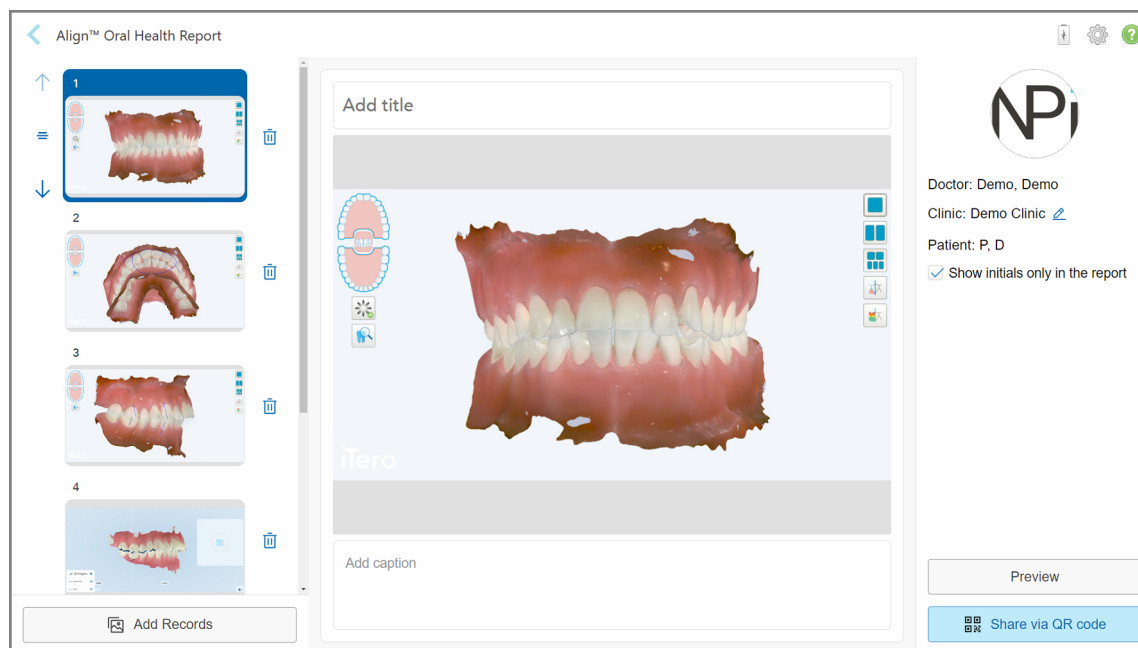


Figure 228: Align Oral Health Report – selection stage

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.

10.13 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 for PC-configuration scanners: Align Oral Health Suite may not be available, depending on the software package, and regulatory and commercial considerations.

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.

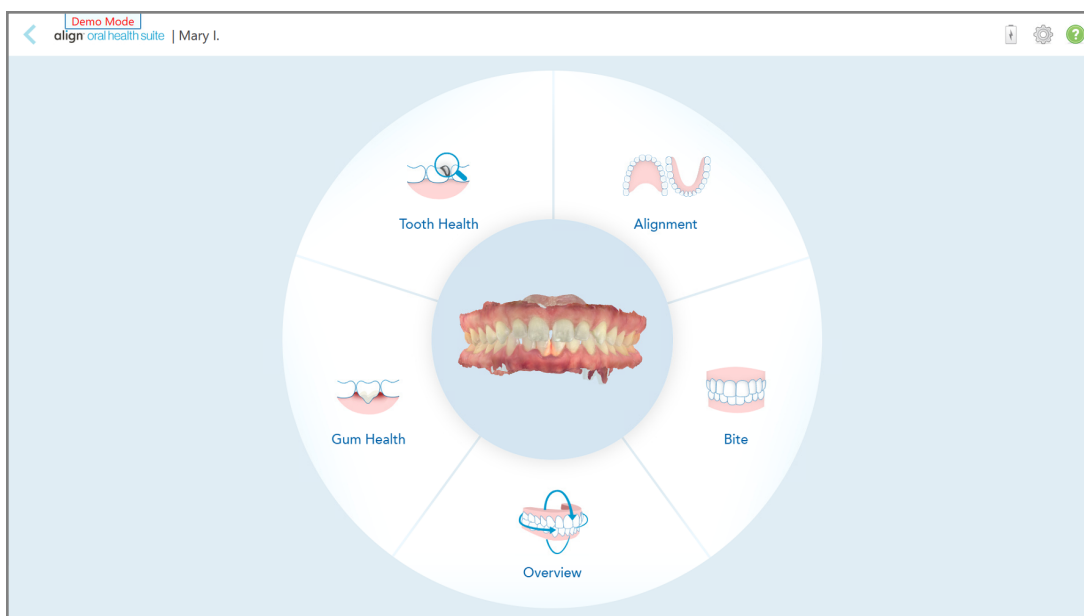


Figure 229: Align Oral Health Suite home screen

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

- **Tooth Health** - visualizes tooth health and supports interproximal caries detection.
- **Gum Health** - visualizes gum health, including the [gingiva line location versus the CEJ](#).

Note: The Gumlines tool is subject to regulatory or other required approvals and commercial availability in your country/region.

- **Bite** - assists in assessing inter-arch tooth contact by analyzing the bite distribution.
- **Alignment** - visualizes malocclusion and previews potential treatment outcomes.
- **Overview** - provides patient-centric views for a holistic understanding of the dental condition.

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

10.13.1 Working with the Gumlines tool

The Gumlines tool* in Align Oral Health Suite is intended to visualize the position of the gum line and the cemento-enamel-junction (CEJ) on a patient-specific 3D model of the oral cavity. The software application is indicated to enhance communication between the patient and the dental healthcare providers, for education purposes.

The tool displays two lines on the model – a solid black line that depicts the patient's current gum line, and a dotted purple line that shows the patient's CEJ.

The Gumlines tool does not treat or diagnose any disease.

*Subject to regulatory or other required approvals and commercial availability in your country/region.

Disclaimers and limitations:

- The Gumlines visual should be used at the clinician's own discretion.
- The CEJ may be inaccurately visualized if it resides under the gum line, along with other factors:
 - Partial scan capture, holes in scan
 - Ongoing orthodontic braces treatment or Invisalign buttons
 - Severe gingivitis and hyperplasia
 - Missing teeth (no CEJ) and unerupted dentition (CEJ is subgingival)
 - Distal molars
- This software is not intended for use:
 - As a virtual anatomical model for (1) the diagnosis or monitoring of a disease, injury or disability, or (2) the investigation of the anatomy or of a physiological process
 - To provide therapy to a person through the provision of information
 - To recommend a treatment or intervention to a Healthcare Professional or patient
 - To monitor the state or progression of a disease or condition
 - In relation to diagnosing or screening for a disease or condition
- The tool does not alter, modify, or corrupt the original data generated by the iTero scanner.

To display the gum and CEJ lines on the model:

1. In Align Oral Health Suite, tap **Gum Health** and then tap the Gumlines button .

The **AI Insights** pane is displayed on the screen, and the gum line (solid black line) and the CEJ line (dotted purple line) are displayed on the 3D model.



Figure 230: Gum line and CEJ line displayed on the model

2. In the AI Insights pane, tap the relevant visibility toggles  or  to hide or show the AI Insights, the gum line, and/or the CEJ.

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.

Note: Refer to the disinfecting agent manufacturer's user manuals and data sheets for additional information and instructions for use.

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 sleeve](#) before each patient session.
- Dispose of the 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 dark protective sleeve attached.

Between patients, undo any twists and knots in the wand cable in order to relieve all tension.

11.2 Cleaning and disinfecting the wand

The iTerio 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

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 sleeve](#), making sure not to touch the optical surface of the wand.

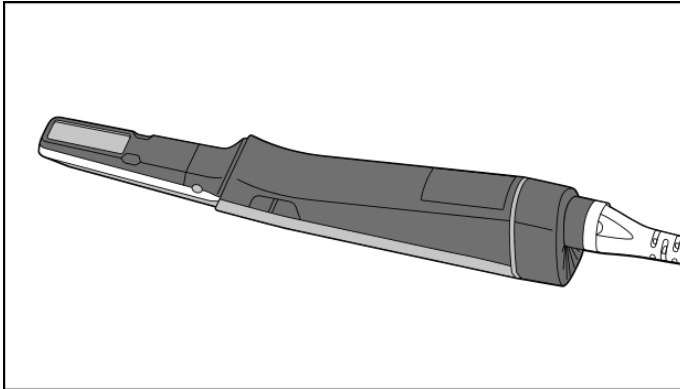


Figure 231: Wand without a sleeve

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

If damage is found, see the **Scanner warnings** section in the [Safety 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 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](#)

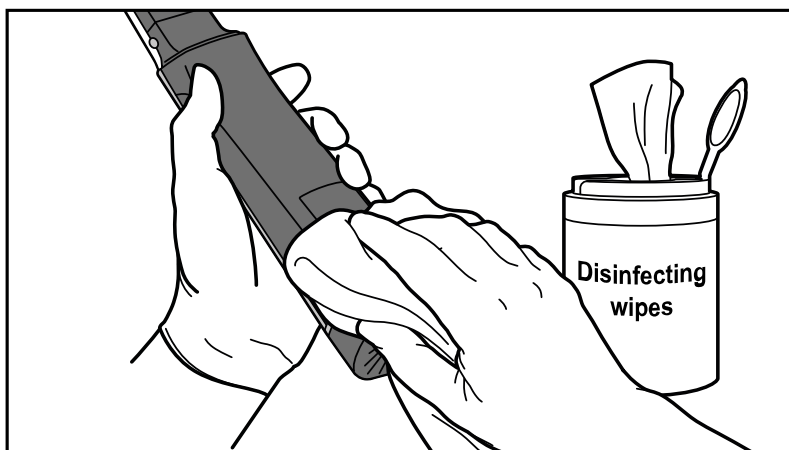


Figure 232: Remove gross contaminants using CaviWipes¹

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

Note: Do not use the brush on the optical surface to avoid damage to the wand.

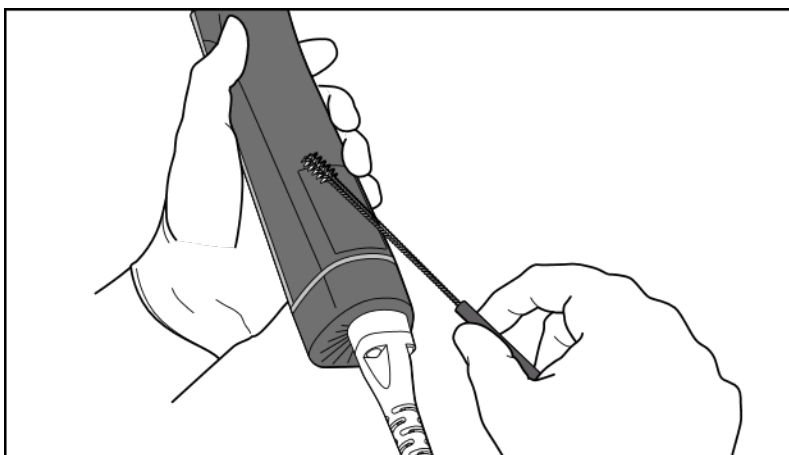


Figure 233: Remove marks and stains using a soft bristle brush

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 lint-free wipe(s) wetted (but not dripping) with 70% Isopropyl Alcohol (IPA), thoroughly wipe the wand body and tip, *excluding* the optical surface of the wand, one (1) time.
3. 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.

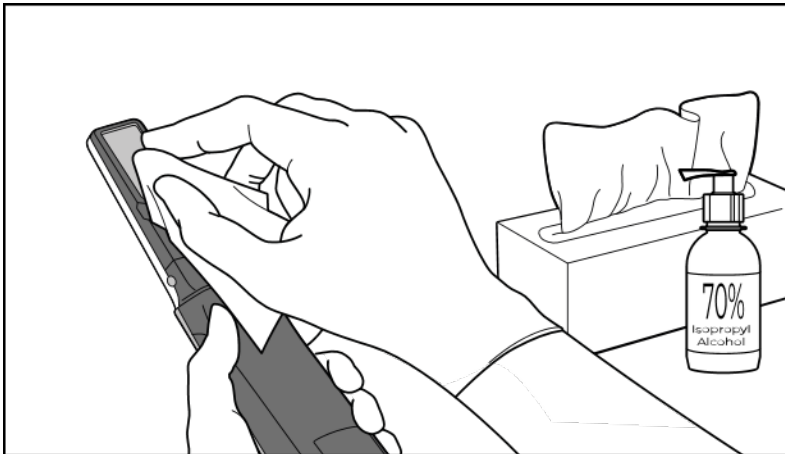


Figure 234: Wipe the optical surface of the wand with IPA

4. Wait until the optical surface dries (approximately 5–10 seconds).
5. Remove any residue from the optical surface using a dry lint-free wipe.
6. Visually inspect the optical surface for any noticeable damage, for example, scratches, stains, murkiness, or opaqueness.

If damage is found, see the **Scanner warnings** section in the [Safety 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.

If damage is found, see the **Scanner warnings** section in the [Safety instructions](#).

2. Place the dark protective sleeve on the wand tip.
3. Place the wand in the [cleaned and disinfected cradle](#).

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

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.

If damage is found, see the **Scanner warnings** section in the [Safety 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

11.3.2.1 Cleaning and disinfecting the cradle – cart and mobile configuration

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.

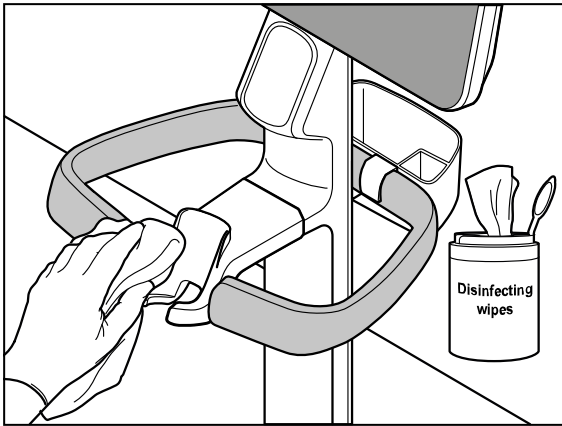


Figure 235: Wiping the iTeror Lumina cart-configuration cradle

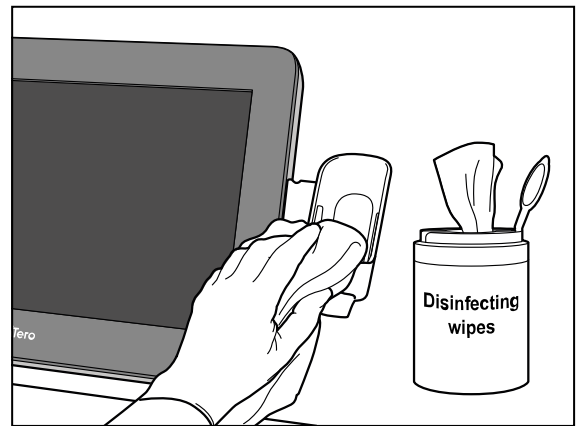


Figure 236: Wiping the iTeror Lumina mobile-configuration cradle

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

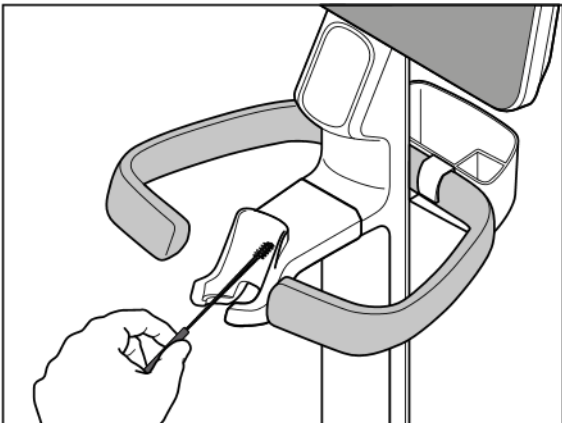


Figure 237: Brushing the iTeror Lumina cart-configuration cradle

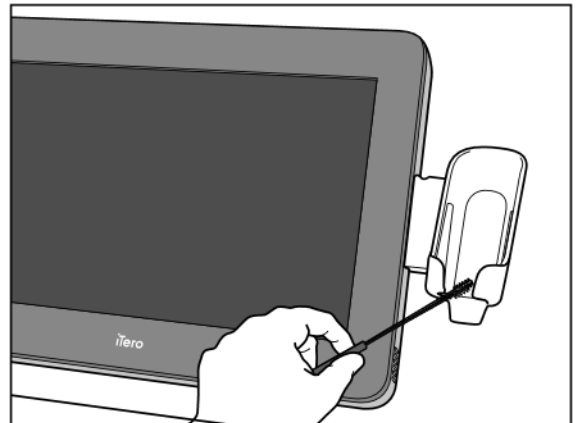


Figure 238: Brushing the iTeror Lumina mobile-configuration cradle

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

5. 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.

11.3.2.2 Cleaning and disinfecting the cradle – iTero Lumina PC configuration

Cleaning

1. Remove the cradle from the interface box.

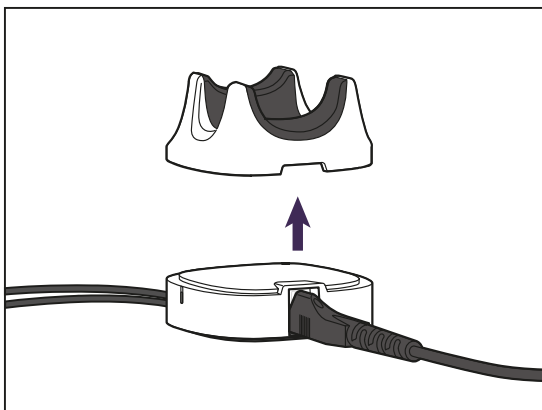


Figure 239: Removing the cradle from the interface box

2. 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.

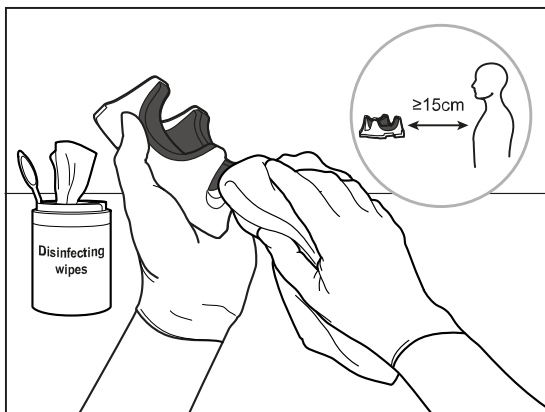


Figure 240: Wiping the iTero Lumina PC-configuration cradle

Note for persons with implantable medical devices susceptible to magnetic energy: See the [Electromagnetic interference precautions](#) section in the Safety instructions for relevant warnings, and keep the cradle at least 15 cm away from the chest.

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

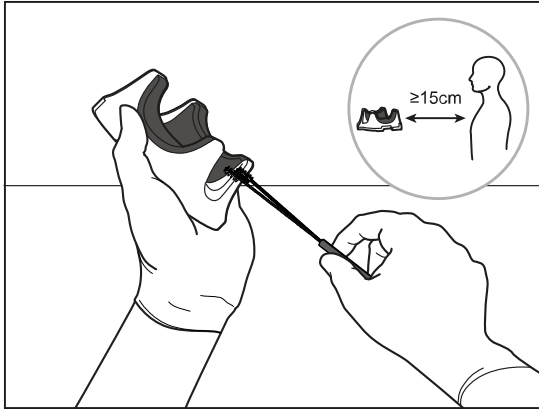


Figure 241: Brushing the iTerio Lumina PC-configuration cradle

- 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 4 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.

If damage is found, see the **Scanner warnings** section in the [Safety instructions](#).

11.4 Cleaning and disinfecting the scanner touchscreen and the main handle

The scanner screen and 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.

If damage is found, see the **Scanner warnings** section in the [Safety instructions](#).

11.5 General cleaning and disinfection comments

All scanner parts, reusable accessories, and associated equipment not outlined above should be thoroughly cleaned (and disinfected if applicable) according to standard operating procedures or local regulations. For instructions on cleaning the iTero Lumina PC-configuration interface box, see below.

Note: Refer to the disinfecting agent manufacturer's user manuals and data sheets for additional information and instructions for use.

iTero scanners are typically cleaned and disinfected in the use environment. In addition to the processes described above, national standards and regulatory requirements may apply.

11.5.1 Cleaning the iTero Lumina PC-configuration interface box

The interface box should be thoroughly cleaned when required (until visibly clean), per standard operating procedures, and at the end of each working day at a minimum.

1. Turn off the system, disconnect the interface box from the mains, and remove the wand and cradle.

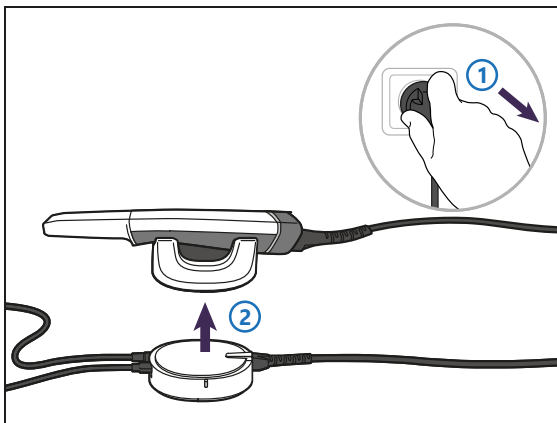


Figure 242: Disconnecting the interface box from the mains and removing the wand and cradle

2. Using lint-free wipes, wetted (but not dripping) with 70% isopropyl alcohol (IPA) or ethanol, remove any gross contaminants on the interface box until visibly clean.

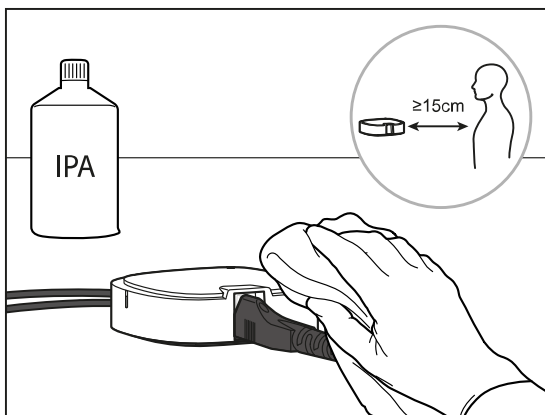


Figure 243: Wiping the interface box

Note for persons with implantable medical devices susceptible to magnetic energy: See the [Electromagnetic interference precautions](#) section in the Safety instructions for relevant warnings, and keep the interface box at least 15 cm away from the chest.

3. Using lint-free wipes, wetted (but not dripping) with 70% isopropyl alcohol (IPA) or ethanol, remove any remaining marks, stains, and contaminants on the interface box, paying special attention to the interface box surface grooves and joints.
4. Visually inspect the interface box in a well-lit area to ensure all surfaces are visibly clean.
5. If required, repeat step 3 until no visual contamination is observed.

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.

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.

Material	Active Ingredient	Contact time (minutes)
CaviWipes1/CaviCide1	Quats-alcohol (Quaternary Ammonium Chloride)	1
CaviWipes/CaviCide	Quats-alcohol (Quaternary Ammonium Chloride)	3
Clinell Universal Range Wipes	0.5% Didecyltrimethylammonium Chloride (DDAC)	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% Didecyltrimethylammonium Chloride (DDAC), 7.5% Ethanol, and 15% Isopropanol

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.

11.7 Disposal instructions

Do not dispose of this product in domestic or municipal waste. This device contains WEEE materials.

Contact your local Customer Support to securely decommission the system by sanitizing the product of sensitive, confidential, and proprietary data and software, and to arrange scanner collection.

Dispose of batteries in accordance with local environmental laws and guidelines.

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

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.

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 declaration

B.1 EMC declaration

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.
(Relevant for iTero Lumina cart and mobile configurations only.)

Environment for intended use

- Professional Healthcare
- Home Healthcare Facility Environment (Relevant for iTero Lumina cart and mobile configurations only.)

The device does not have Essential Performance according to IEC 60601-1 definition.

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

- This device may not cause harmful Electromagnetic (EM) interference.
- This device must accept any EM interference received, including any that may cause undesired operation.

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

Notes:

- “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.
- Interference may occur in the vicinity of the device.
- 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.
- Before scanning the patient, see the **Electromagnetic interference precautions** section in the [Safety instructions](#).
- iTero Lumina-PC configuration scanners only:
 - In the event of a sharp drop in the input mains voltage, the system will not operate but will remain safe for the user. The system will return to its working state after the voltage returns to its nominal values.

The following is a summary of the EMC test results for iTero Lumina 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 @50Hz; 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 (230/240 V @ 50 Hz & 220 V @ 60 Hz)	Cart and mobile configuration: Complies PC configuration: N/A (Power consumption < 75W)
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	Cart and mobile configuration: 8 kV contact discharges & 15 kV air discharges (AC mode (230 V @ 50 Hz & 220 V @ 60 Hz)) PC configuration: 8 kV contact discharges & 15 kV air discharges (AC mains (230 V @ 50 Hz & 220 V @ 60 Hz))	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3 / EN 61000-4-3	Cart and mobile configuration: 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) PC configuration: 3 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz (AC mains (230 V @ 50 Hz & 220 V @ 60 Hz))	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	Cart and mobile configuration: ± 2.0 kV on AC mains (230 V @ 50 Hz & 220 V @ 60 Hz); Tr/Th – 5/50 ns, 100 kHz PC configuration: ± 2.0 kV on AC mains Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5 / EN 61000-4-5	Cart and mobile configuration: ±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

Test	Standard	Class / Severity level	Test results
		PC configuration: ±2.0 CM / ±1.0 kV DM on AC mains Tr/Th – 1.2/50 (8/20) µs	
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6 / EN 61000-4-6	Cart and mobile configuration: 6 VRMS on AC mains; (230 V @ 50 Hz & 220 V @ 60 Hz) & Patient cable; 0.15÷ 80 MHz, 80% AM, 1 kHz PC configuration: 3; 6 (ISM band) VRMS on AC mains; Patient cable; & USB cable 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8 / EN 61000-4-8	Cart and mobile configuration: 30 A/m @ 50 Hz & 60 Hz (AC mode and Battery mode) PC configuration: 30 A/m @ 50 Hz & 60 Hz (AC mains)	Complies
Immunity to proximity magnetic fields in the frequency range 9kHz to 13.56MHz	IEC 61000-4-39	Cart and mobile configuration: 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) PC configuration: 8 A/m 30kHz CW 65 A/m @134.2kHz PM 2.1kHz 50% 7.5 A/m @13.56MHz PM 50kHz 50% (AC mains)	Complies

Test	Standard	Class / Severity level	Test results
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11 / EN 61000-4-11	<p>Cart and mobile configuration:</p> <p>On AC mode (240 V @ 50 Hz, 100 V @ 50 Hz): 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles;</p> <p>On AC mode (220 V @ 60 Hz): 0 % - 0.5 cycle & 1 cycle; 70% - 30 cycles; 0% - 300 cycles</p> <p>PC configuration:</p> <p>On AC mains (240 V @ 50 Hz, 100 V @ 50 Hz): 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles;</p> <p>On AC mains (220 V @ 60 Hz): 0 % - 0.5 cycle & 1 cycle; 70% - 30 cycles; 0% - 300 cycles</p>	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

B.2 Guidance and Align Technology's Declaration – Electromagnetic Immunity – for iTero Lumina that is not Life-Supporting

The iTero Lumina intraoral scanner is intended for use in the electromagnetic environment specified below.

The customer or the user of the iTero Lumina should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the iTero Lumina system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	<p>Recommended separation distance:</p> $d = \left[\frac{3.5}{V1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey

should be considered. If the measured field strength in the location in which the iTero Lumina system is used exceeds the applicable RF compliance level above, the iTero Lumina system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iTero Lumina system. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

B.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the iTero Lumina Intraoral scanner that is not Life-Supporting

iTero Lumina is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iTero Lumina can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iTero Lumina system as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distances Between Portable and Mobile RF Communications and the Activator			
Rated maximum output power of transmitter Watts (W)	Separation distance according to frequency of transmitter Meters (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 kHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix C: FCC compliance information statement (SDoC)

We Align Technology Ltd. declare:

Type of equipment: The iTero Lumina scanner is capable of intraoral optical impressions for CAD/CAM of dental devices which also captures 2D color images.

Note: This section is not relevant for iTero Lumina PC-configuration scanners.

Brand name or trademark: iTero Lumina

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

TCB		GRANT OF EQUIPMENT AUTHORIZATION Certification Issued Under the Authority of the Federal Communications Commission By:		
Qualcomm Atheros, Inc. 1700 Technology Dr San Jose, CA 95110 Attention: Paul Guckian, Vice President, Regulatory Engineering		UL Verification Services Inc. (formerly UL CCS) 47173 Benicia Street Fremont, CA 94538		
NOT TRANSFERABLE				
EQUIPMENT AUTHORIZATION is hereby issued to the named GRANTEE, and is VALID ONLY for the equipment identified hereon for use under the Commission's Rules and Regulations listed below.				
FCC IDENTIFIER: Name of Grantee: Equipment Class: Notes: Modular Type:		PPD-QCNFA364AH Qualcomm Atheros, Inc. Digital Transmission System 802.11a/b/g/n/ac + BT 4.1 M.2 2230 Type Card Single Modular		
Grant Notes	FCC Rule Parts	Frequency Range (MHz)	Output Watts	Frequency Tolerance
CC MO	15C	2402.0 - 2480.0	0.002	
CC MO	15C	2412.0 - 2472.0	0.51	
CC MO	15C	2422.0 - 2462.0	0.423	
CC MO	15C	5745.0 - 5825.0	0.371	
CC MO	15C	5755.0 - 5795.0	0.401	
CC MO	15C	5775.0 - 5775.0	0.569	

Output power listed is maximum combined conducted. This device supports 20 and 40MHz bandwidths for 2.4 GHz. This module may be installed only by the OEM or an OEM integrator. This transmitter has been approved for use in mobile RF exposure category configurations with the antenna(s) installed to provide a separation distance of at least 20 cm from all persons. Installation in portable devices is limited to the display section of a laptop or notebook PC where the antennas used during SAR testing (or equivalent antennas) are installed to provide at least 1cm distance from the base of the device and with an antenna-to-antenna separation distance of at least 3cm. The antennas used for this transmitter must not be collocated or operating in conjunction with any other antenna or transmitter within a host device, except in accordance with FCC multi-transmitter product procedures. Grantee must provide installation and operating instructions for complying with FCC multi-transmitter product procedures. Grantee must coordinate with OEM integrators to determine applicable host configurations to ensure RF exposure compliance, including simultaneous transmission. The highest reported SAR for body and simultaneous transmission conditions are 0.75 W/kg and 0.75 W/kg respectively.

CC: This device is certified pursuant to two different Part 15 rules sections.
 MO: This Multiple Input Multiple Output (MIMO) device was evaluated for multiple transmitted signals as indicated in the filing.

Country of origin: Israel

Manufacturer: Align Technology Ltd.

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

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

Telephone: +1 (408) 470-1000

Internet E-Mail: iterosupport@aligntech.com

Standards applied:

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

Test reports / certificates issued by:

- For Cart configuration, FCC Part 15 Subpart B - Test report number 7212312205 by SII.
- For Mobile configuration, FCC Part15 Subpart B - Test report number 7212312202 by SII.
- For QUALCOMM module PPD-QCNFA364AH, FCC Part 15 Subpart C & E - Test report number RF150107E07B-1 by Bureau Veritas Consumer Product Service (H.K) Ltd. & Advantech DoC.

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

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

Thus, is placed on the product .

Appendix D: iTero Lumina Family product security whitepaper

This whitepaper applies to the iTero Lumina 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 Lumina™ 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.

- iTero has developed a Software Bill of Materials (SBOM) for iTero Lumina intraoral scanners to support our customers in effectively managing their assets, understanding the potential impact of identified vulnerabilities to the medical device system, and deploying countermeasures to maintain the device's safety and effectiveness. The SBOM will be provided to customers upon request.

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 Lumina™ 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 is 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
- **Detect malicious and mobile code:** It is the customer's responsibility to select and implement anti-virus/anti-malware protection for the iTerio Lumina PC 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 for accounts used to access scanners and Align systems. The more characters used in a password, including 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 a 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.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 iTerio Lumina™ 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.
 - The customer should disconnect the webcam when not in use for a training session.¹
 - The webcam lens should be covered when the webcam is not actively in use.¹

Control and monitor physical access to the iTerio Lumina Family of products through the use of mechanisms such as security cameras and security badges.³

For the iTerio Lumina PC configuration scanners, shut down physical ports of network equipment not in use to prevent unauthorized access to the application.²

- **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

¹ Only applicable for iTerio Lumina and iTerio Lumina Pro scanners

² Only applicable for iTerio Lumina PC configuration scanners

³ Applicable for iTerio Lumina, iTerio Lumina PC configuration, and iTerio Lumina Pro scanners

If you have any questions or concerns, please do not hesitate to contact Customer Support.

Appendix E: System specifications

This section includes the specifications for the following systems:

- [iTero Lumina cart and mobile configurations](#)
- [iTero Lumina PC-configurations](#)

E.1 System specifications – iTero Lumina cart and mobile configurations

	Cart configuration	Mobile configuration
Monitor	21.5" Full HD (1920x1080) touchscreen	15.6" Full HD (1920x1080) touchscreen
Wand	<p>The wand emits the following radiation:</p> <ul style="list-style-type: none"> • Blue laser, operating at 450 nm, pulsed illumination. • Green laser, operating at 520 nm, pulsed illumination. <p>The laser illumination complies with EN 60825-1 Ed. 3.0 -2014 (Safety of laser products – Part 1: Equipment classification, requirements, and user's guide).</p> <ul style="list-style-type: none"> • White LEDs, pulsed illumination complies with EN 62471:2006 (Photobiological safety of lamps and lamp systems). <p>Wand operating voltage: 15VDC.</p> <p>Wand capturable distance: 0 to 25mm.</p> <p>Wand maximum external surface temperature:</p> <ul style="list-style-type: none"> • Body: 48°C (118.4°F) • Tip (applied part): 43°C (109.4°F) <p>Note: The temperature of the wand tip without a sleeve can reach 51°C (123.8°F).</p>	
Wireless LAN	<p>A LAN card provides local network communications with wireless connectivity</p> <ul style="list-style-type: none"> • 2.4GHz, 5GHz • 802.11ac 	
Security	See the iTero Lumina 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)
- **Pressure** 430mmHg to 771mmHg (57kPa to 103kPa)
- **Altitude** -400 feet to 12,000 feet

Transportation environmental conditions

- **Temperature** -29°C to 60°C (-20.2°F to 140°F)
- **Relative Humidity** 30% to 90% (non condensing)
- **Pressure** 430mmHg to 760mmHg (57kPa to 101kPa)
- **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)
- **Pressure** 430mmHg to 771mmHg (57kPa to 103kPa)
- **Altitude** -400 feet to 12,000 feet

Physical properties

- **Wand (maximum dimensions)**
 - Length: 248.2 mm (~9.8 in)
 - Width: 43.9 mm (~1.7 in)
 - Depth: 39.2 mm (~1.5 in)

Cart configuration

- Height: 356 mm (~14 in)
- Width: 544 mm (~21.5 in)
- Depth: 60.5 mm (~2.3 in)

Cart configuration

- Height: 1279 mm (~50.3 in)
- Width: 544 mm (~21.4 in)
- Depth: 562 mm (~22.1 in)

Cart configuration

Wand cable: 1.8 m typical
Power cable: 3000 mm

Cart configuration

Computing unit: 10.5 kg (~23.1 lbs.)
Wand: ~0.26 kg (~0.57 lbs.) without the cable
Wheel stand: ~12.5 kg (~27.5 lbs.)

Mobile configuration

- Height: 275 mm (~10.8 in)
- Width: 419 mm (~16.5 in)
- Depth: 41.5 mm (~1.6 in)

Mobile configuration

N/A

Mobile configuration

Wand cable: 1.8 m typical
Power cable: 1600 mm or 3000 mm

Mobile configuration

Computing unit with cradle and wand: ~5.5 kg (~12.0 lbs.)
System packed in trolley: ~11 kg (~24.0 lbs.)
Wand: ~0.26 kg (~0.57 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 scanning (cart configuration) and 10 minutes (mobile configuration)
- <2.5 hours for a full recharge

Scanner and wand cross-contamination protection

- Single-use, disposable sleeves

Sleeve handling instructions

- Keep away from sunlight.
- Do not reuse.
- Keep dry.

Accessible ports	<ul style="list-style-type: none">• USB type A port intended to be connected only to an Align-provided webcam for training purposes.• USB type C port is not in use and should not be connected to any external devices.
Scanning technology	iTero Multi-Direct Capture [™] technology
Scanning properties	<ul style="list-style-type: none">• Enables hovering, while also allowing a scan to be performed at 0 mm.• No field calibration needed.• Flexible scanning protocol (start anywhere, automated segment stitching).• Automated heating of the tip to avoid fogging of the lens.• Illumination: White LEDs illumination meets Risk Group 1 (Low-Risk) according to EN 62471, Photobiological safety of lamps and lamp systems. Laser illumination is classified as a class 1 laser product per IEC 60825-1, Safety of laser products - Equipment classification and requirements.• Global accuracy – Per ADA Standard No. 132 Scanning Accuracy of Dental Chairside and Laboratory CAD/CAM Systems, as measured on test specimen three – Long Distance specimen:<ul style="list-style-type: none">◦ Absolute mean measurement error: $\leq 0.25\%$◦ Absolute STD of measurement error: $\leq 0.25\%$• Local accuracy – Per ADA Standard No. 132 Scanning Accuracy of Dental Chairside and Laboratory CAD/CAM Systems, as measured on Test specimens one and two – Crown and Inlay specimens:<ul style="list-style-type: none">◦ Absolute mean measurement error $\leq 1\%$◦ Absolute STD of measurement error $\leq 1\%$
Scan time	<ul style="list-style-type: none">• Orthodontic scans: Full mouth can be completed in as little as 60 seconds.• Restorative scans: Full mouth can be completed in 120 seconds plus 30 seconds for each prep.
Cloud storage	Data can be stored and accessed on the web using cloud storage and the MyiTero web portal.
Service lifetime	5 years

E.2 System specifications – iTero Lumina PC-configuration

Monitor	Laptop/Desktop screen, based on the iTero Lumina PC-configuration supported computer requirements.
Wand	<p>The wand emits the following radiation:</p> <ul style="list-style-type: none"> • Blue laser, operating at 450 nm, pulsed illumination. • Green laser, operating at 520 nm, pulsed illumination. <p>The laser illumination complies with EN 60825-1 Ed. 3.0 -2014 (Safety of laser products – Part 1: Equipment classification, requirements, and user's guide).</p> <ul style="list-style-type: none"> • White LEDs, pulsed illumination complies with EN 62471:2006 (Photobiological safety of lamps and lamp systems). <p>Wand operating voltage: 15VDC.</p> <p>Wand capturable distance: 0 to 25mm.</p> <p>Wand maximum external surface temperature:</p> <ul style="list-style-type: none"> • Body: 48°C (118.4°F) • Tip (applied part): 43°C (109.4°F)
Security	See the iTero Lumina Family product security whitepaper .
Operating Power	100-240 VAC- 50/60 Hz- 110 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)
• Pressure	490mmHg to 771mmHg (65kPa to 103kPa)
• Altitude	-400 feet to 12,000 feet
Transportation environmental conditions	
• Temperature	-18°C to 60°C / 0°F to 140°F
• Relative Humidity	30% to 90% (non condensing)
• Pressure	430 mmHg to 771mmHg (57kPa to 103kPa)
• 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)
- **Pressure** 430mmHg to 771mmHg (57kPa to 103kPa)
- **Altitude** -400 feet to 15,000 feet

Physical properties

- **Wand (maximum dimensions)**
 - Length: 248.2 mm (~9.8 in)
 - Width: 43.9 mm (~1.7 in)
 - Depth: 39.2 mm (~1.5 in)
- **iTero Lumina interface box**
 - Length: 105 mm (~4.1 in)
 - Width: 95 mm (~3.7 in)
 - Depth: 29 mm (~1.1 in)
- **Cradle**
 - Length: 105 mm (~4.1 in)
 - Width: 95 mm (~3.7 in)
 - Depth: 45 mm (~1.8 in)
- **Cable length**
 - Wand cable: 1800 mm
 - USB C cable: 1800 mm
 - Power cable: 3000 mm
- **Net Weight**
 - Wand: ~0.26 kg (~0.57 lbs.) without the cable
 - iTero Lumina interface box: ~0.2kg (~0.44 lbs)

Scanner and wand cross-contamination protection

- Single-use, disposable sleeves

Sleeve handling instructions

- Keep away from sunlight.
- Do not reuse.
- Keep dry.

Scanning technology

iTero Multi-Direct CaptureTM technology

Scanning properties

- Enables hovering, while also allowing a scan to be performed at 0 mm.
- No field calibration needed.
- Flexible scanning protocol (start anywhere, automated segment stitching).
- Automated heating of the tip to avoid fogging of the lens.
- Illumination: White LEDs illumination meets Risk Group 1 (Low-Risk) according to EN 62471, Photobiological safety of lamps and lamp systems. Laser illumination is classified as a class 1 laser product per IEC 60825-1, Safety of laser products - Equipment classification and requirements.

- Global accuracy – Per ADA Standard No. 132 (May 2015) Scanning Accuracy of Dental Chairside and Laboratory CAD/CAM Systems, as measured on test specimen three – Long Distance specimen:
 - Absolute mean measurement error: $\leq 0.25\%$
 - Absolute STD of measurement error: $\leq 0.25\%$
- Local accuracy – Per ADA Standard No. 132 (May 2015) Scanning Accuracy of Dental Chairside and Laboratory CAD/CAM Systems, as measured on Test specimens one and two – Crown and Inlay specimens:
 - Absolute mean measurement error $\leq 1\%$
 - Absolute STD of measurement error $\leq 1\%$

Cloud storage

Data can be stored and accessed on the web using cloud storage and the MyiTero web portal.

Service lifetime

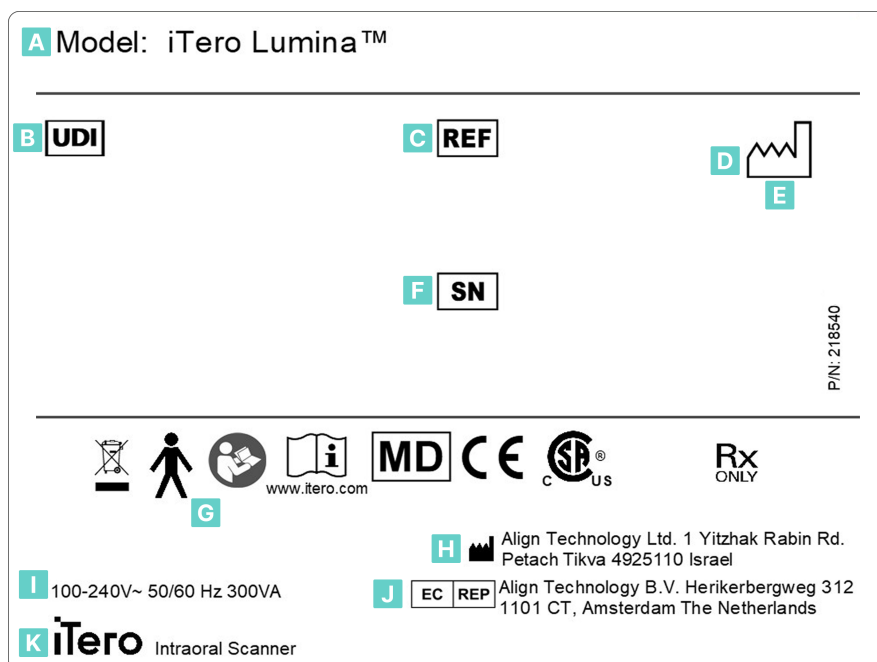
5 years

Appendix F: Scanner labels

This appendix provides an overview of the structure of the scanner labels and the information typically included on them.

F.1 Package labels

F.1.1 Package label – iTero Lumina cart



- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Country of origin
- E** Manufacturing date
- F** Serial number
- G** [Applicable symbols](#)
- H** Manufacturer
- I** Electrical rating
- J** Authorized representative in the European Community
- K** Brand name

F.1.2 Package label – iTero Lumina mobile

A Model: iTero Lumina™ Mobile

B UDI **C** REF **D**  **E**

F SN

P/N: 218541

    **MD** **CE**  **Rx ONLY**

G www.itero.com

I 100-240V~ 50/60 Hz 250VA **J** **EC** **REP** **H**  Align Technology Ltd. 1 Yitzhak Rabin Rd. Petach Tikva 4925110 Israel

K **iTero** Intraoral Scanner

- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Country of origin
- E** Manufacturing date
- F** Serial number
- G** [Applicable symbols](#)
- H** Manufacturer
- I** Electrical rating
- J** Authorized representative in the European Community
- K** Brand name

F.1.3 Package label – iTero Lumina PC configuration

A Model: iTero Lumina™ - PC cfg

B UDI **REF**

C

P/N: 223162

	REF	QTY
iTero Lumina - PC cfg Intraoral Scanning Unit	223112 CE	1 EA SN D
iTero Lumina Interface Box	223060 CE	1 EA
iTero Lumina Scanner Sleeves	215470 CE	1 EA 

    **MD**  **Rx ONLY** **F**  **G**

Packed by: **E** www.itero.com

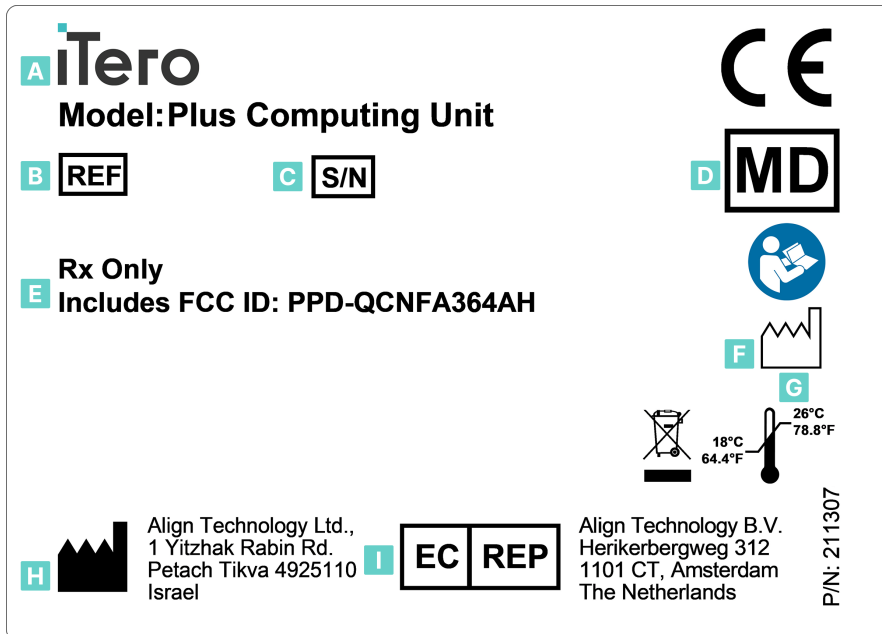
H **EC** **REP** Align Technology B.V. Herikerbergweg 312 1101 CT, Amsterdam The Netherlands

I **iTero** Intraoral scanner **J** 100-240V~ 50/60 Hz 110VA Country of Origin: **K**

- A** Model name
- B** Unique Device Identifier
- C** Catalog number
- D** Serial number
- E** [Applicable symbols](#)
- F** Country of origin
- G** Manufacturing date
- H** Authorized representative in the European Community
- I** Brand name
- J** Electrical rating
- K** Country of origin

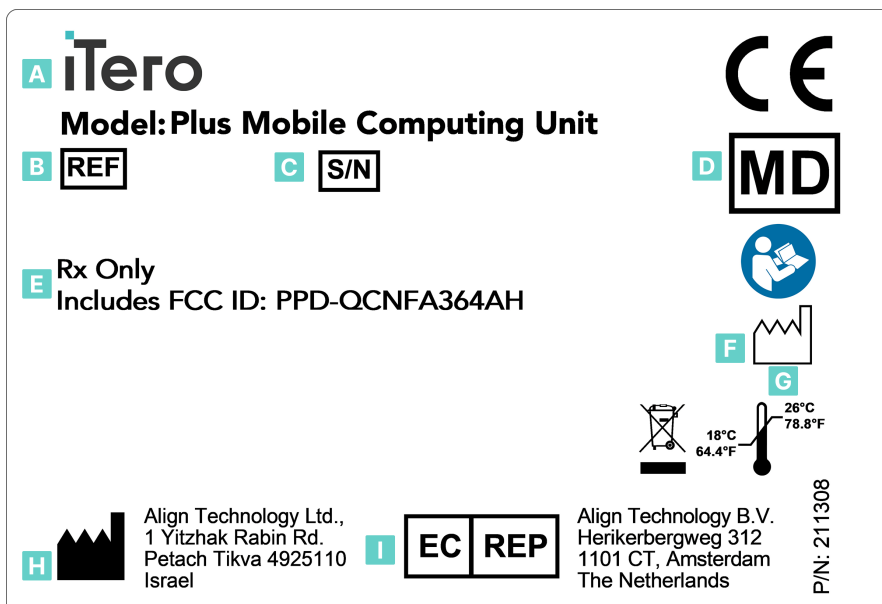
F.2 Computing unit labels

F.2.1 Computing unit – iTerо Lumina cart



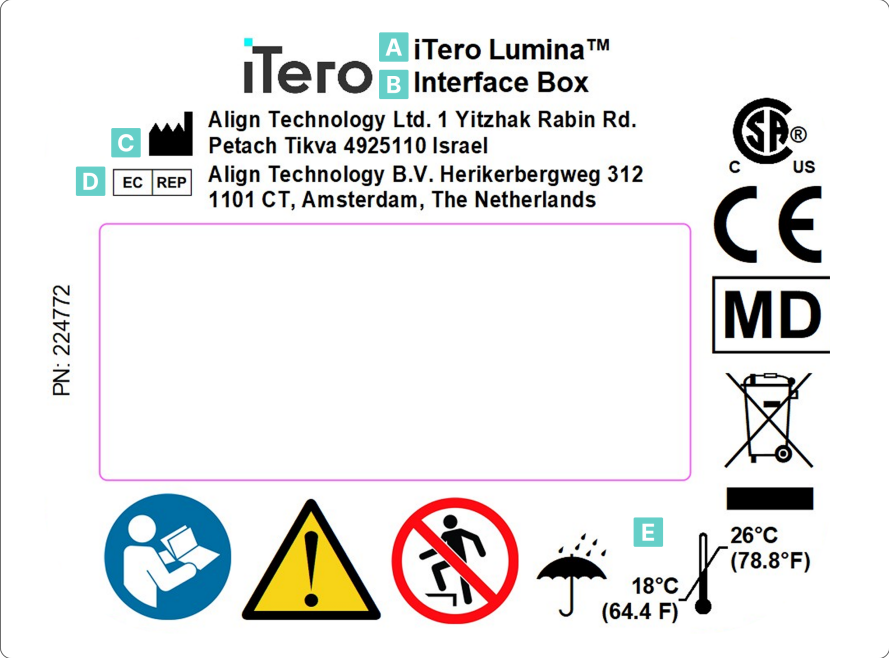
- A** Model name
- B** Catalog number
- C** Serial number
- D** [Applicable symbols](#)
- E** FCC ID
- F** Country of origin
- G** Manufacturing date
- H** Manufacturer
- I** Authorized representative in the European Community

F.2.2 Computing unit – iTerо Lumina mobile



- A** Model name
- B** Catalog number
- C** Serial number
- D** [Applicable symbols](#)
- E** FCC ID
- F** Country of origin
- G** Manufacturing date
- H** Manufacturer
- I** Authorized representative in the European Community

F.2.3 Computing unit – iTero Lumina PC configuration interface box

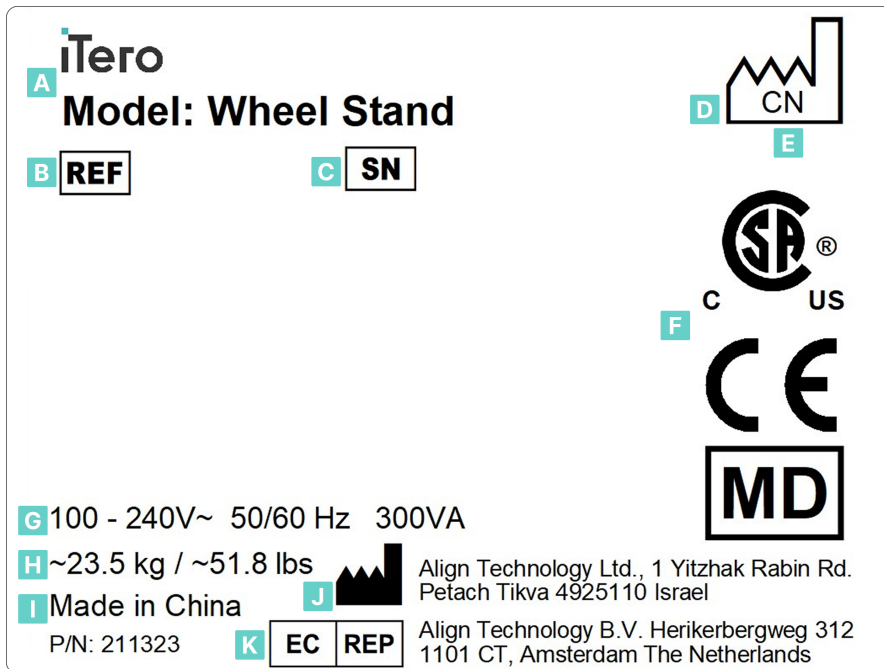


- A Model name
- B Brand name
- C Manufacturer
- D Authorized representative in the European Community
- E [Applicable symbols](#)



- A Catalog number
- B Country of origin
- C Serial number
- D Country of origin
- E Manufacturing date
- F Unique Device Identifier

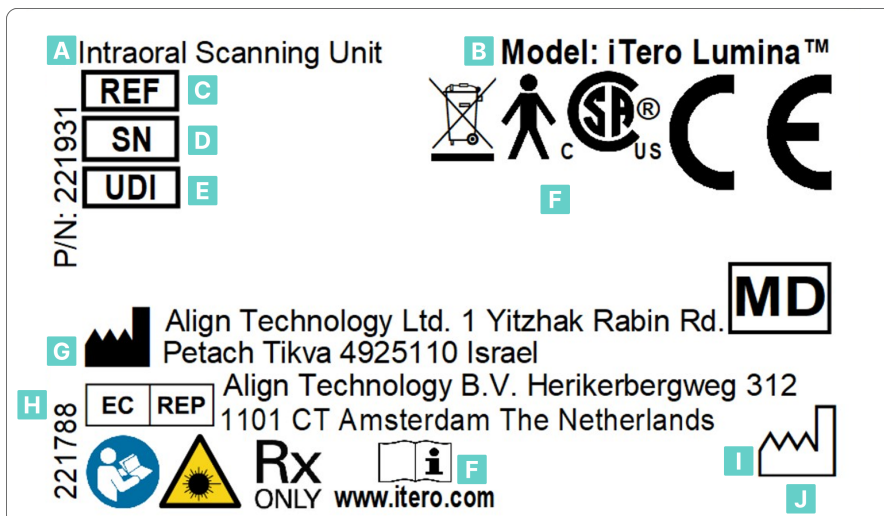
F.3 Wheelstand label



- A** Model name
- B** Catalog number
- C** Serial number
- D** Country of origin
- E** Manufacturing date
- F** [Applicable symbols](#)
- G** Electrical rating
- H** Wheelstand weight
- I** Country of origin
- J** Manufacturer
- K** Authorized representative in the European Community

F.4 Wand labels

F.4.1 Wand label – iTero Lumina



- A** Brand name
- B** Model name
- C** Catalog number
- D** Serial number
- E** Unique Device Identifier
- F** [Applicable symbols](#)
- G** Manufacturer
- H** Authorized representative in the European Community
- I** Country of origin
- J** Manufacturing date

F.4.2 Wand label – iTero Lumina PC configuration



- A Model name
- B Catalog number
- C Serial number
- D Unique Device Identifier
- E [Applicable symbols](#)
- F Manufacturer
- G Authorized representative in the European Community
- H Brand name
- I Country of origin
- J Manufacturing date



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