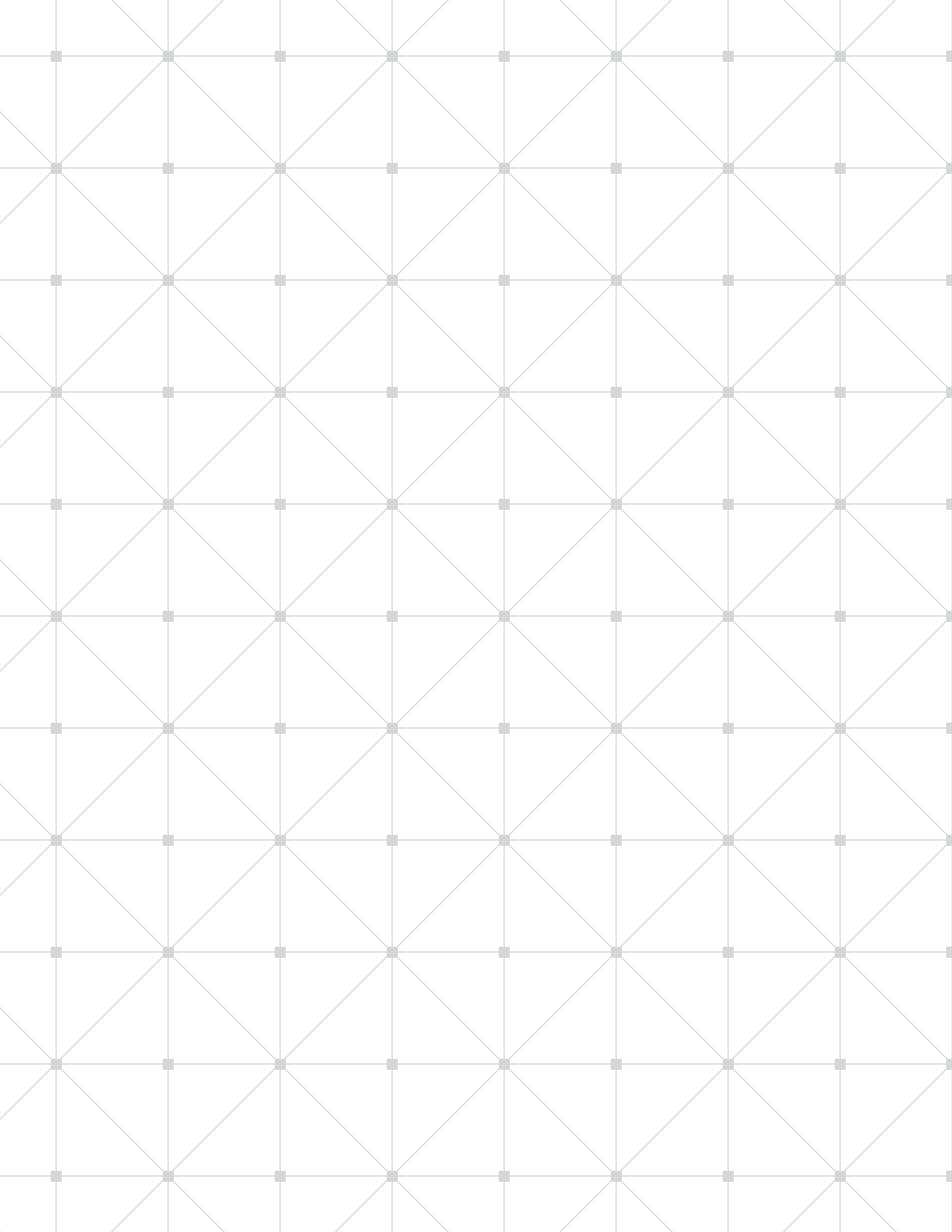


Wheel stand configuration **operation** **manual**



Copyright

© 2019 Align Technology, Inc. All Rights Reserved.

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

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

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

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

Trademarks

The following are trademarks and/or service marks of Align Technology, Inc. or one of its subsidiaries or affiliated companies and may be registered in the U.S. and/or other countries: Align Technology Inc., iTero®

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

USA office

Corporate Headquarters
Align Technology, Inc.
2820 Orchard Parkway
San Jose, California 95134

www.aligntech.com

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

Customer support

Tel: +1 (800) 577-8767

E-mail:
iterosupport@aligntech.com

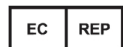
E-mail:
orthocadsupport@aligntech.com



Israel office

Align Technology Ltd.
3 Ariel Sharon Boulevard
Or-Yehuda 6037606
Israel

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



Align Technology B.V.
Arlandaweg 161
1043HS Amsterdam
The Netherlands

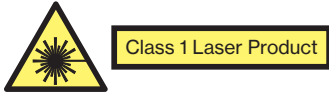
Netherlands office

International Headquarters
Align Technology B.V.
Arlandaweg 161
1043 HS Amsterdam

Tel: +31 (0) 20-586-3600
Fax: +31 (0) 20-586-3751

Class 1 laser compliance

This device complies with: “21 CFR 1040.10” and “EN 60825-1”.

**CSA compliance**

This device complies with the following CSA standard for Canada and the USA:

“UL Std No. 60601-1 – Medical Electrical Equipment Part 1: General Requirements for Safety”

**FCC compliance**

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

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

**FCC warning**

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

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”.

Safety compliance

This device complies with the following safety standard:

“IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance.

CE compliance

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



Conformité laser de classe 1

Cet appareil est conforme aux normes : « 21 CFR 1040.10 » et « EN 60825-1 ».



Produit laser de classe 1

Conformité CSA

Cet appareil est conforme à la norme CSA suivante pour le Canada et les États-Unis :

« UL Std No. 60601-1 - Appareils électromédicaux, partie 1 : exigences générales de sécurité »



Conformité FCC

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

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



Avertissement de la FCC

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

Conformité CEM

Cet appareil est conforme à la norme CEM suivante :

« IEC 60601-1-2 :2007 Equipement médical électrique - Section 1-2 : Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale : Electromagnétisme - Exigences et essais ».

Conformité aux normes de sécurité

Cet appareil est conforme à la norme de sécurité suivante :

« IEC 60601-1 : Appareils électriques médicaux – Section 1 : Exigences générales pour la sécurité de base et les performances essentielles. »

Conformité CE

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



Symbols

The following symbols may appear on iTero Element 5D hardware components, and may also appear within this document and other iTero Element 5D literature.



Wherever this symbol appears on the device, it is recommended to refer to this document for information on proper usage of the device.



Applied part type BF. Any component on which this symbol appears is electric isolation type BF.



Separate collection of electrical waste and electronic equipment is required.



Attention: This symbol is used to highlight the fact that there are specific warnings or precautions associated with the device. Wherever this symbol appears on the device, it is mandatory to refer to safety-related information within this document.



Parts or accessories on which this symbol occurs should not be reused.

"Rx only"

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



Medical device manufacturer.



Order number.



Serial number.



Indicates the Authorized representative in the European Community.



IEC 60417-5032: Alternating current.



Indicates a medical device that needs to be protected from moisture.



Indicates the temperature limits to which the medical device can be safely exposed.



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



Manufacturer's batch code.



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



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



Fragile, handle with care.



This side should be up.



IEC 60417-5031: Direct current.



Wand (scanning unit).



USB socket.



Electric battery.



RoHS (China).



IEC 60417-5009: STAND-BY.

Symboles

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



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



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



Une collecte séparée des déchets électriques et des équipements électroniques est requise.



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



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

"Rx
uniquement"

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



Fabricant de dispositif médical.



Numéro de commande.



Numéro de série.



Indique le Représentant agréé dans la communauté européenne.



IEC 60417-5032 : Courant alternatif.



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



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



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



Numéro de lot de fabrication.



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



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



Fragile, à manipuler avec soin.



Ce côté doit être placé vers le haut.



IEC 60417-5031 : Courant continu.



Tige (unité de numérisation).



Prise USB.



Batterie électrique.



RoHS (Chine).



IEC 60417-5009 : EN ATTENTE.

Safety instructions

Before beginning to work with the system, all users are required to read these safety instructions.

Power supply

- Power is supplied to the system via an internal medical grade power supply.

Battery power

- Charging – Battery will be fully charged after being plugged into a power source for 2 hours.
- With a fully charged battery, the user can scan up to 30 minutes with the iTerero Element 5D scanner, without having to plug in for power.

Electric warning

- **Electric shock hazard!** Only authorized Align Technology technicians can remove external panels and covers. There are no user-serviceable parts inside.
- To avoid risk of electric shock, iTerero Element 5D must only be connected to a supply mains with protective grounding.
- Only Align Technology approved Web Camera or DOK should be connected to the USB socket on the back side of the System.

Wireless LAN

- The system comes equipped with a Wireless LAN unit.

Safety classifications

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

Prescription health device

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

Scanner warnings

- The scanner emits red laser light (680nm Class 1) as well as white LED emissions, and 850nm LED emissions. Normal usage of the scanner does not present any danger to the human eye. However, doctors should refrain from shining the scanner directly into the patient's eyes.
- Avoid twisting cable, knotting cable, pulling on cable, stepping on cable.
- When the system is not in use, the scanning unit should be placed inside the cradle with the probe facing towards the cart's post and rear side of the touch screen so there will be no eye contact with the laser beam or the flickering white LED emission, and 850nm LED emissions in any case.
- The doctor should activate scanning operation only while the scanner's probe is inside the patient's mouth.
- Doctors should avoid placing the scanner in the cradle while scanning operation is still active.
- If scanner malfunction occurs, stop scanning and call service support.

Cleaning & disinfection

- To avoid cross contamination, it is mandatory that after each patient session the disposable plastic sleeve be replaced and the scanning unit be disinfected.
- To avoid cross contamination, it is mandatory that after each patient session the gloves shall be removed and replaced.
- To avoid cross contamination, discard gloves when torn, contaminated, or removed for any reason.
- Dispose of scanner sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Unpacking & installing

- The system should be unpacked and installed following Align Technology's instructions.

Work environment

- The system should be moved between rooms with utmost care to avoid damage.
- **WARNING:** Do not block the air vents on the Scanning Unit and Base Unit.
- **WARNING:** System is intended for indoor use only. It should not be exposed to direct sunlight, excessive heat or humidity.

Electro magnetic interference

- **WARNING:** This device has been tested and found to comply with the requirements for medical devices according to standard IEC60601-1-2. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the healthcare environments (e.g., cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of source, may result in disruption of performance of this device. ESD may cause an interference during scanning. In case of ESD interference the system will stop scanning / displaying proper viewfinder image. If the failure occurs within scan, the user may be required to press the wand scan button to restart the scan. The viewfinder will always recover automatically.

General

- **WARNING:** No modification of this equipment is allowed.
- **WARNING:** The touchscreen always needs to be in a stand while in operation!

Consignes de sécurité

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

Alimentation électrique

- Le système est alimenté via une alimentation interne de qualité médicale.

Puissance de la batterie

- Chargement en cours - La batterie sera complètement chargée après avoir été branchée à une source d'alimentation au bout de 2 heures.
- Avec une batterie complètement chargée, l'utilisateur peut numériser jusqu'à 30 minutes avec le scanner iTero Element 5D sans avoir à le recharger.

Avertissement électrique

- Risque de choc électrique !** Seuls les techniciens agréés par Align Technology peuvent retirer les panneaux et les capots externes. L'appareil ne contient aucune pièce réparable par l'utilisateur.
- Pour éviter tout risque d'électrocution, le iTero Element 5D doit uniquement être connectée à une prise de courant avec une prise terre de protection.
- Seule une caméra Web ou DOK approuvée par Align Technology doit être connectée à la prise USB située à l'arrière du système.

Réseau local sans fil

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

Classifications de sécurité

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

Dispositif médical sur ordonnance

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

Avertissements liés au scanner

- Le scanner émet une lumière laser rouge (680nm de classe 1), ainsi que des émissions à LED blanches et des émissions à LED de 850 nm. L'utilisation normale du scanner ne présente aucun danger pour l'œil humain. Cependant, les médecins doivent éviter de placer le scanner directement dans les yeux du patient.
- Évitez de tordre le câble, de nouer le câble, de tirer sur le câble, de marcher sur le câble.
- Lorsque le système n'est pas utilisé, l'unité de numérisation doit être placée à l'intérieur du socle avec la sonde orientée vers la colonne verticale du chariot et du côté arrière de l'écran tactile afin d'éviter tout contact visuel avec le faisceau laser ou l'émission de LED blanche environnante et des émissions de LED de 850 nm dans tous les cas.

- Le médecin ne doit activer l'opération de numérisation que lorsque la sonde du scanner est dans la bouche du patient.
- Les médecins doivent éviter de placer le scanner dans le socle tant que l'opération de numérisation est encore active.
- En cas de dysfonctionnement du scanner, arrêtez la numérisation et appelez le support technique.

Nettoyage et désinfection

- Pour éviter toute contamination croisée, il est obligatoire de remplacer le manchon en plastique à usage unique après chaque séance avec un patient et de désinfecter l'unité de numérisation.
- Pour éviter toute contamination croisée, il est obligatoire de retirer et de remplacer les gants après chaque séance avec un patient.
- Pour éviter toute contamination croisée, jetez les gants déchirés, contaminés ou retirés pour une raison quelconque.
- Jetez les manchons du scanner conformément aux procédures d'utilisation standard ou aux réglementations locales relatives à l'élimination des déchets médicaux contaminés.

Déballage et installation

- Le système doit être déballé et installé conformément aux instructions fournies par Align Technology.

Environnement de travail

- Le système doit être déplacé d'une pièce à l'autre avec le plus grand soin pour ne pas l'endommager.
- AVERTISSEMENT :** Ne bloquez pas les fentes d'aération de l'unité de numérisation et de l'unité de base.
- AVERTISSEMENT :** Le système est conçu pour une utilisation en intérieur uniquement. Il ne doit pas être exposé aux rayons directs du soleil, à une chaleur excessive ou à l'humidité.

Interférence électro-magnétique

- AVERTISSEMENT :** Cet appareil a été testé et approuvé conforme aux exigences des dispositifs médicaux selon la norme IEC60601-1-2. Cette norme est conçue pour fournir une protection raisonnable contre les interférences nuisibles dans une installation médicale classique. Toutefois, en raison de la prolifération des équipements de transmission sur fréquence radio et d'autres sources de bruit électrique dans les environnements de soins de santé (par exemple, téléphones portables, radios mobiles bidirectionnelles, appareils électriques), il est possible que des niveaux élevés d'interférences dus à la proximité ou à la force d'une source puissent entraîner des perturbations de fonctionnement de cet appareil. Les DES (décharges électrostatiques) peuvent provoquer des interférences lors de la numérisation. En cas d'interférence DES, le système s'arrêtera de numériser ou d'afficher la bonne image dans le viseur. Si la défaillance se produit pendant l'analyse, il peut être demandé à l'utilisateur d'appuyer sur un bouton spécifique pour relancer l'analyse. Le viseur se réinitialisera toujours automatiquement.

Informations générales

- AVERTISSEMENT :** Aucune modification de cet équipement n'est autorisée.
- AVERTISSEMENT :** L'écran tactile doit toujours être installé sur un support pendant son fonctionnement !

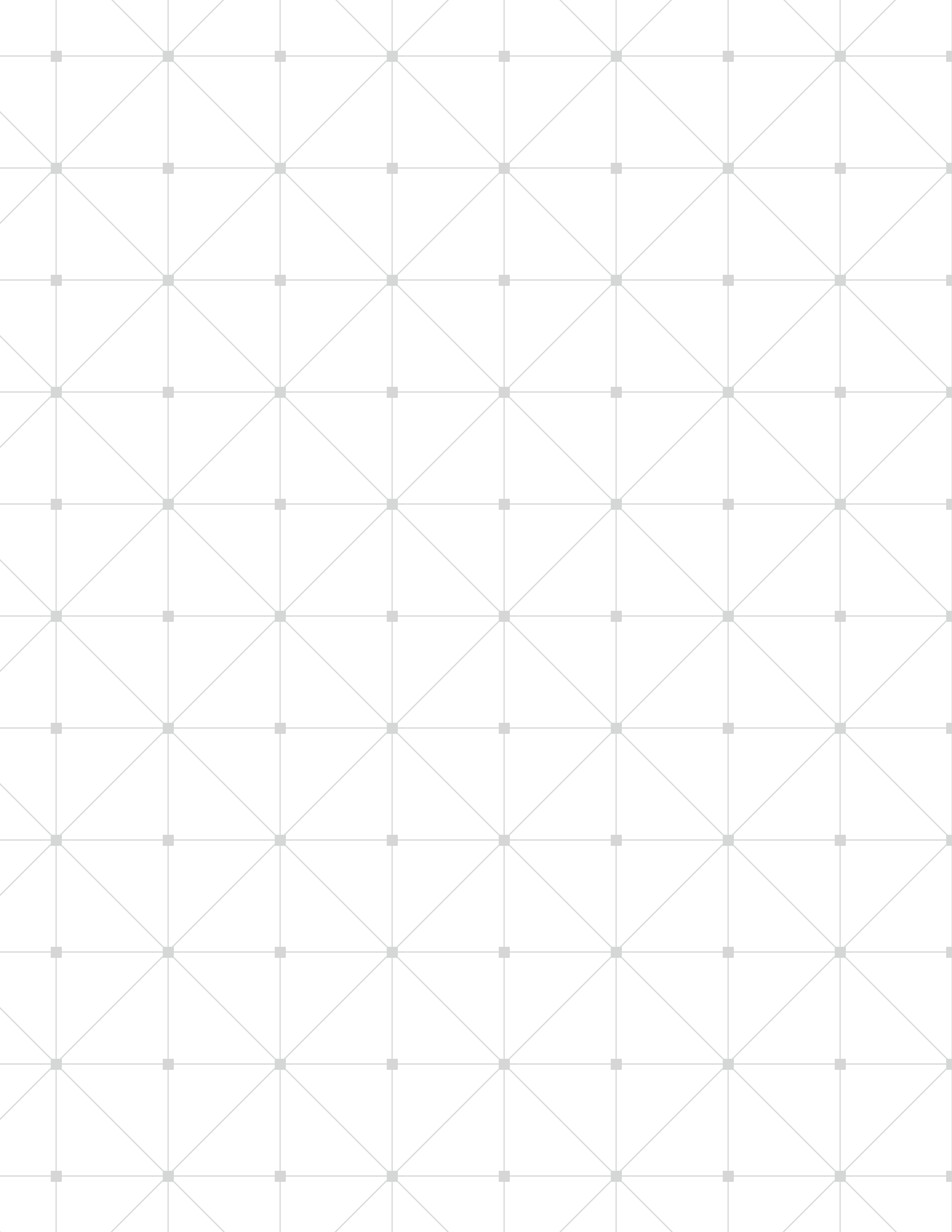


Table of contents	
Chapter 1: Introduction	2
About this document	2
Intended use / indication for use	2
Benefits of the iTero Element 5D system	2
The iTero Element 5D user interface	3
Chapter 2: Basic hardware features	4
Front view of system	4
Back view of system	5
Scanning unit (wand)	6
Chapter 3: Assembly instructions	7
Step 1: Assembly	7
Assembly of iTero Element 5D counter stand	10
Step 2: Make it mine process	12
Chapter 4: Operating instructions	13
End-of-day shut down	13
Moving system within the office	13
Chapter 5: Scanner handling, cleaning, and disinfection instructions	14
Handling of the scanning unit (wand)	14
Handling of the scanning unit cable	14
Cleaning the scanning unit	14
Disinfecting the scanning unit	14
Chapter 6: Changing sleeves between patients	15
Replacing disposable sleeves	15
Scanner sleeves	16
Chapter 7: Accessories (options)	17
Counter stand and cradle	17
Articulator	17
Chapter 8: Clinic LAN network guidelines	18
Introduction	18
Preparations	19
Router guidelines	19
Internet connection guidelines	19
Firewall	19
Wi-Fi tips	20
Align hostname recommendations	21
Appendix A: EMC declaration	22
Appendix B: System specifications	23

Chapter 1:

Introduction

About this document

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

Intended use / indication for use

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

1. The optical impression (CAD/CAM) feature of iTero Element 5D is intended/indicated for use to record the topographical images of teeth and oral tissue. Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories.
2. iTero Element 5D software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. iTero software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.
3. The Element 5D NIRI functionality, is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.

Benefits of the iTero Element 5D system

The iTero Element 5D system provides important advantages over existing crown-production methods, including powder-free scanning, greater crown-production accuracy, and immediate feedback during the scanning process.

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

The iTero Element 5D user interface

The iTero Element 5D system provides an intuitive user interface for performing digital scans for Restorative or Orthodontic use. The doctor is guided through the scanning sequence by means of visual and text assistance. The touchscreen and wand buttons are used to respond to screen instructions during the scanning process.



One tap on the question mark will enable a transparent Help overlay that will provide a brief overview. Please note that the Headset image appears instead of the question mark while in this view. Tap anywhere to close the help screen and return to the relevant screen.

The screenshot shows the iTero Element 5D user interface with the following callouts:

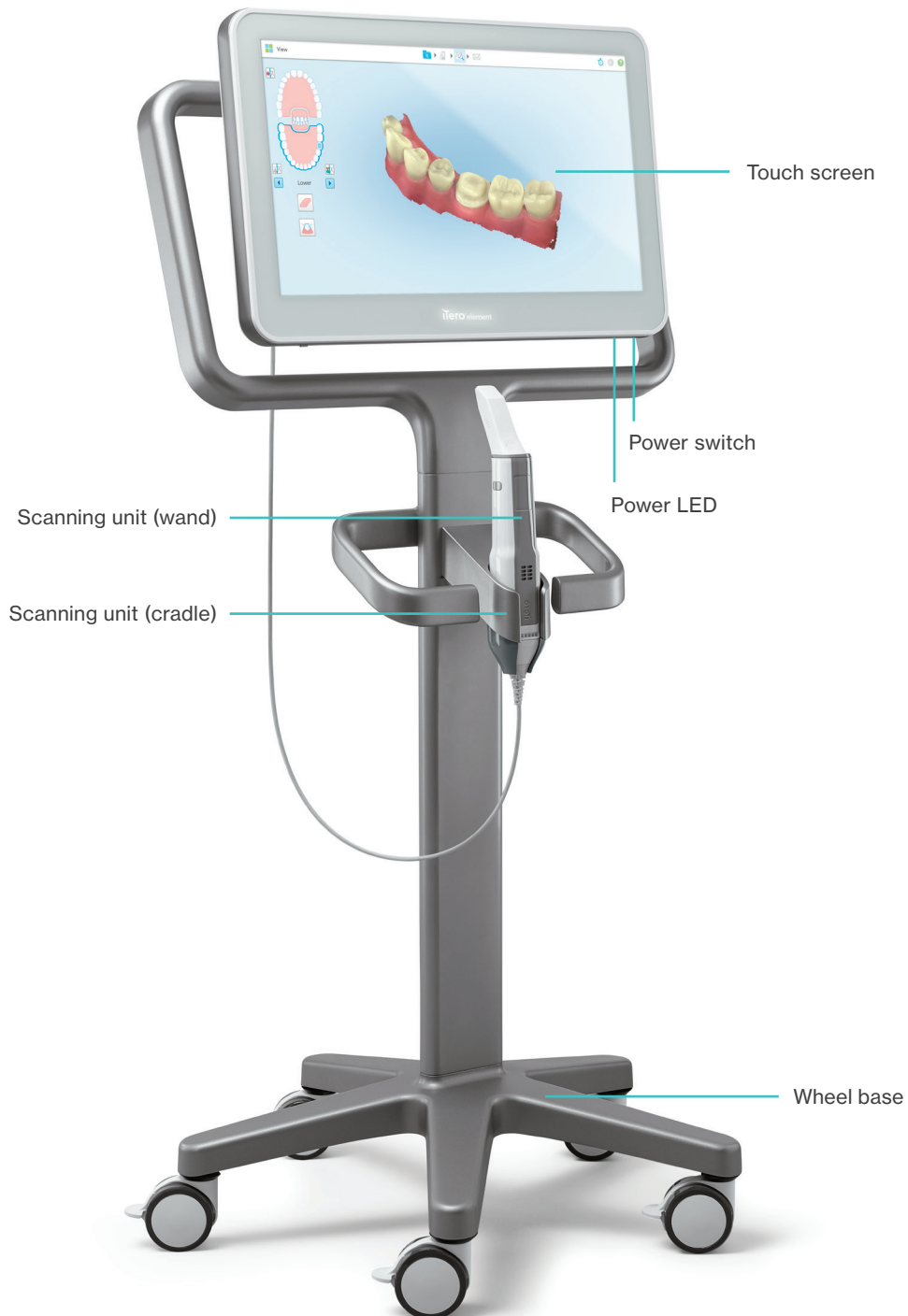
- Tap to set your preferences**: Points to the gear icon in the top navigation bar.
- Tap to lock the desktop**: Points to the padlock icon in the top navigation bar.
- Tap to enter the Learning Center or start training**: Points to the graduation cap icon in the top navigation bar.
- Tap to view the battery charge status**: Points to the battery icon in the top navigation bar.
- Double tap to connect to a support agent for remote troubleshooting (please call support first)**: Points to the question mark icon in the top navigation bar.
- Tap to check the status of your orders**: Points to the Orders button (green folder icon with a red notification badge).
- Tap anywhere on screen to close this help overlay**: Points to the bottom of the screen.
- Tap to view notifications, updates and other messages from Align Technology**: Points to the Messages button (blue envelope icon).

The main interface features the iTero element logo and four primary action buttons: New Scan (blue folder with 'R'), Patients (blue group of people), Orders (green folder with '5'), and Messages (blue envelope).

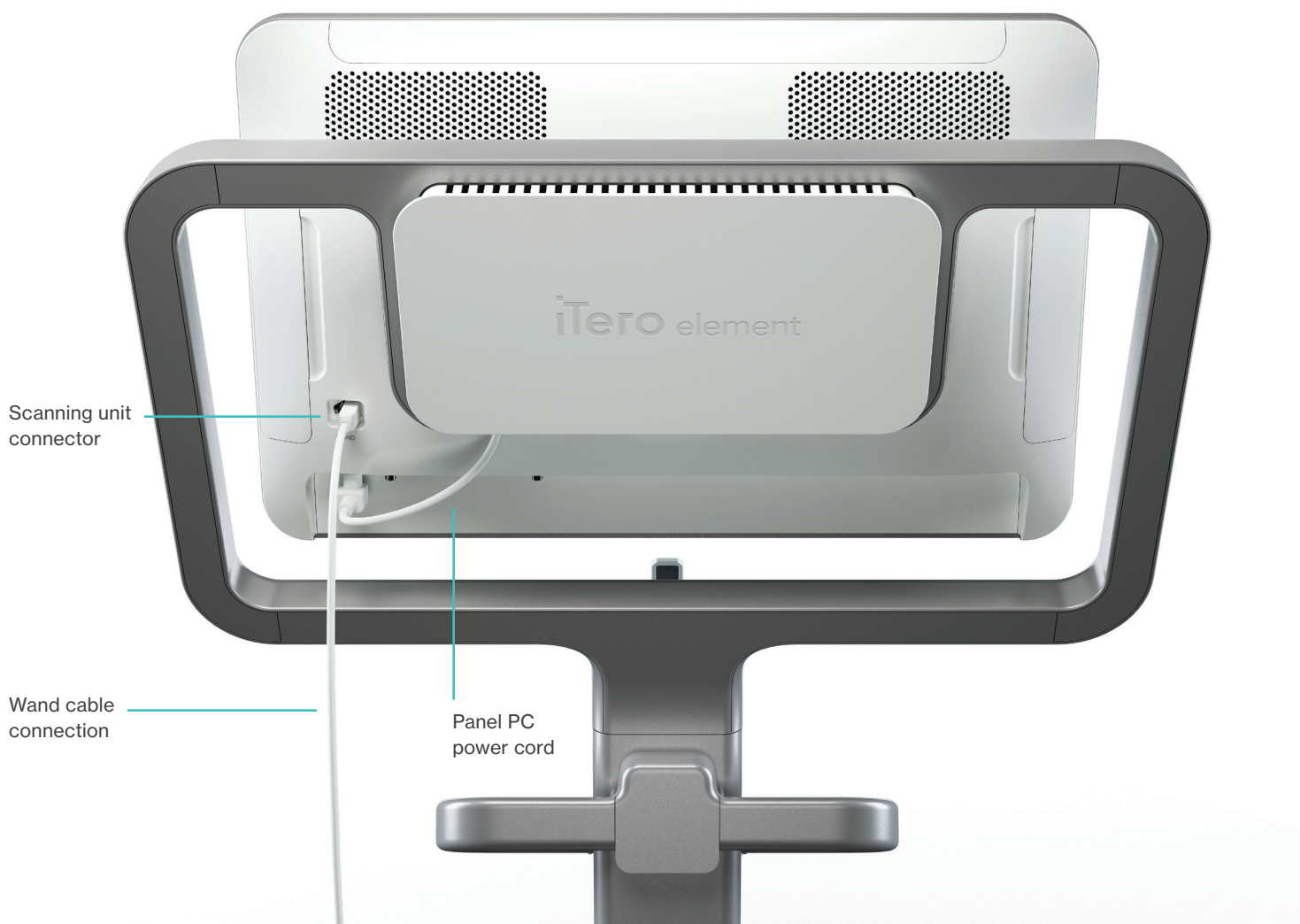
Chapter 2:

Basic hardware features

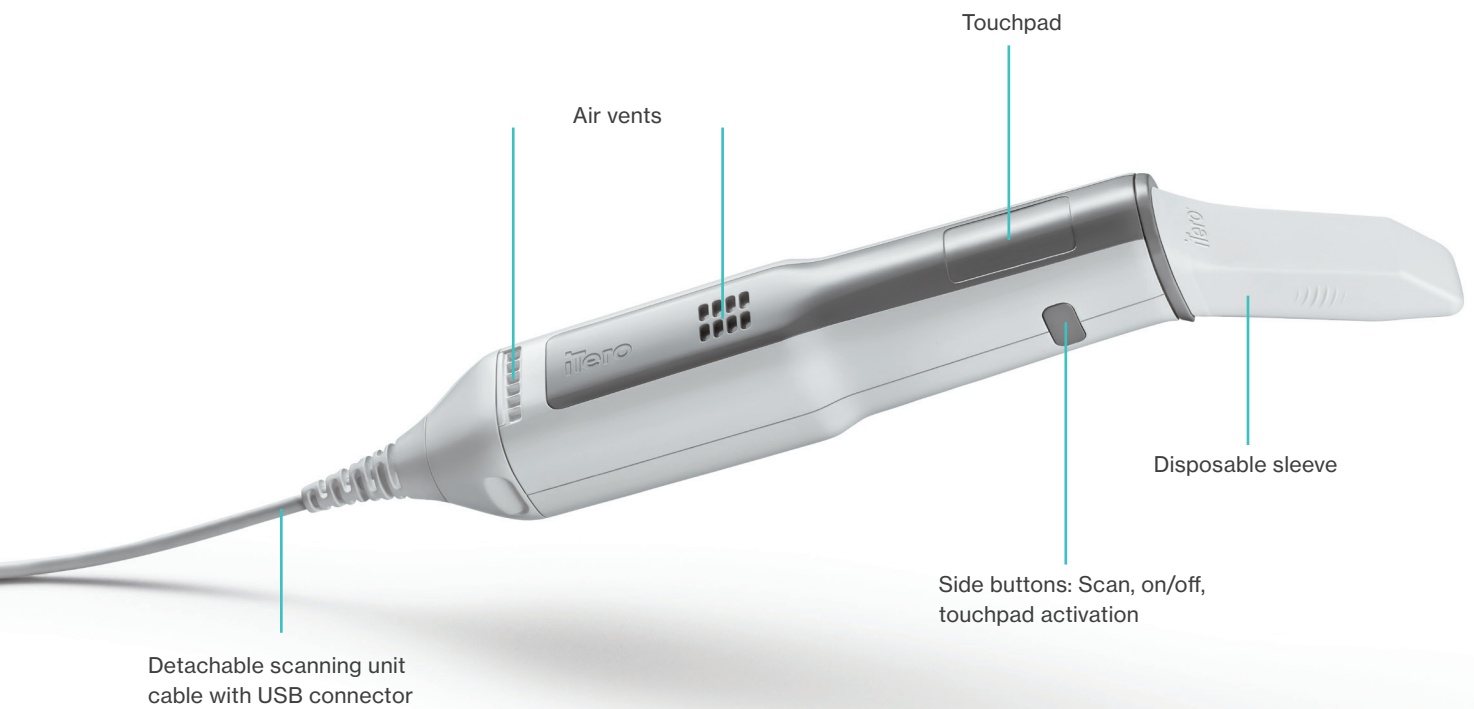
Custom wheel stand hardware features: Front view of the system



Custom wheel stand hardware features: Back view of the system



Scanning unit (wand)



Chapter 3:

Assembly instructions

Step 1: Assembly

Please follow the instructions below to assemble your iTero Element 5D scanner:



AC power



Battery



Click



DC power



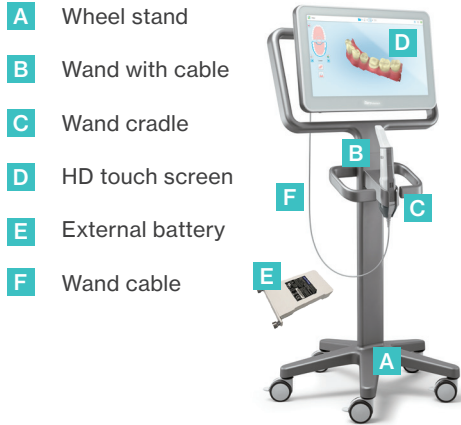
Power button



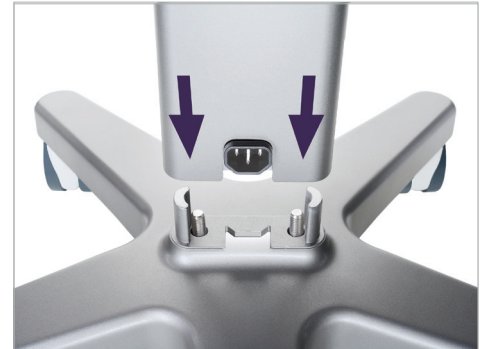
Wand
(scanning unit)



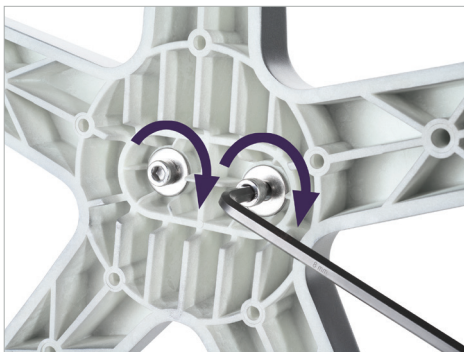
2 people are required
for installation



1. Check the content of the box



2. Connect post to the wheel base



3. Tighten the two allen screws using the larger wrench



4. Remove cover from the back of the handle



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



6. Hold the cradle



7. Tighten the wand cradle allen screw on the back using the smaller wrench



8. Reattach the cover behind the handle



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



10. Remove the battery cover



11. Slide the battery into the battery slot and tighten the thumb screws



12. Lift the HD screen to mount it



13. Turn the scanner around and tighten the thumb screw to secure the HD screen



14. Attach the power cable to the port labeled DC



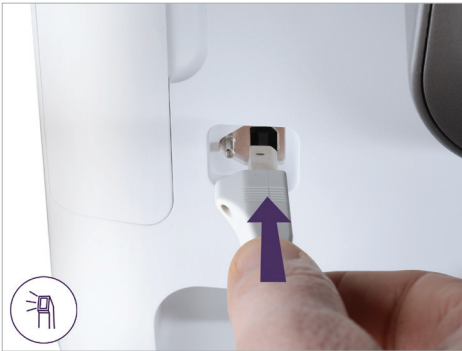
15. Power cable inserted



16. Attach the magnetic back cover



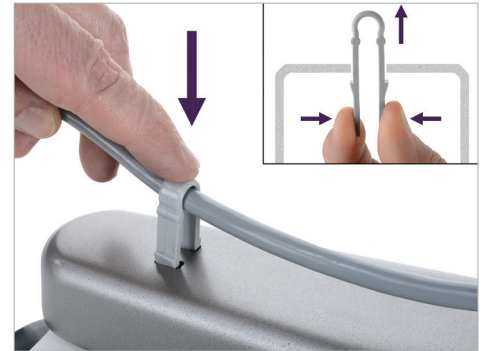
17. Place the wand into the cradle



18. Attach the wand cable on the back of the HD screen



19. Attach the power cable on the bottom of the wheel stand



20. On the bottom of the wheel stand, post and secure the cable with the clip



21. Plug in the power cable



22. Position the web camera on the HD screen for remote training or support sessions



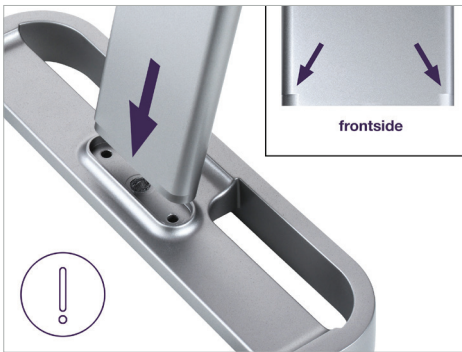
23. Plug in the webcam to the USB port at the bottom of the HD screen



24. Press button to switch on the scanner

Assembly of iTero Element 5D counter stand

Please follow the instructions below to assemble your iTero Element 5D counter stand:



1. Insert post into frame.



2. Tighten the post using the allen wrench



3. Remove cover



4. Install new cover



5. Lift the HD screen to mount it.



6. Turn the scanner around and tighten thumb screw to secure HD screen



7. Place the cover



8. Attach the power cable to the port labelled DC



9. Attach the wand cable on the back of the HD screen



10.
Plug in the power cable

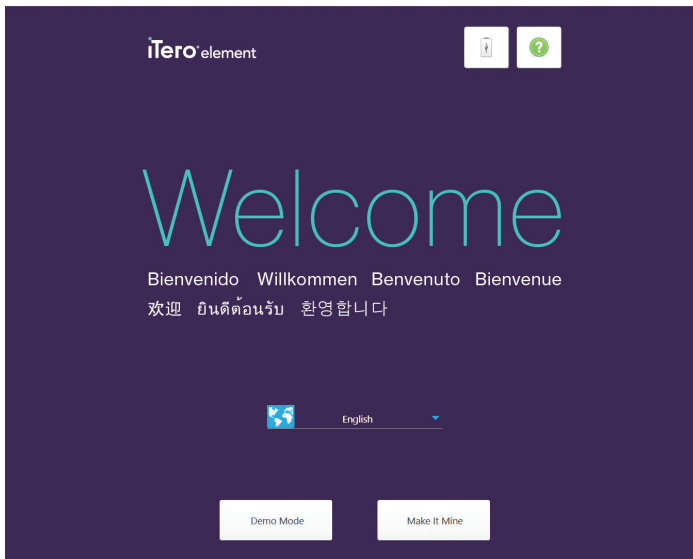


11.
Position the web camera on the HD screen
for remote training or support sessions

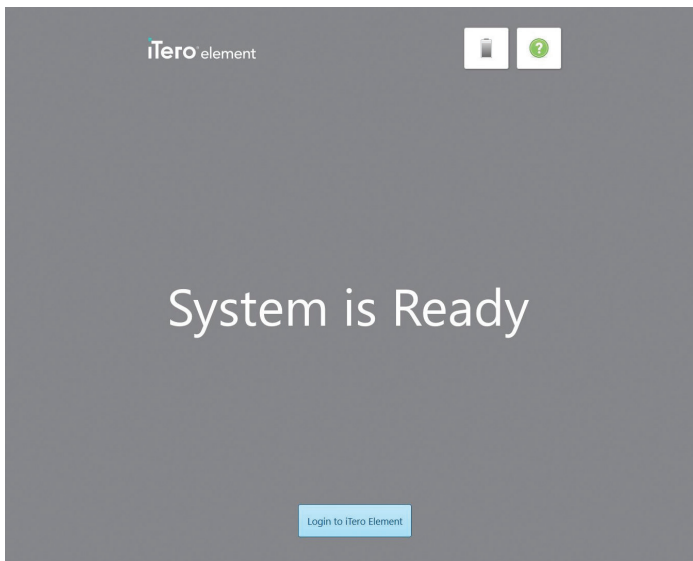


12.
Plug in the webcam to the USB port at the
bottom of the HD screen

Step 2: Make it Mine process



1. Select language of preference and tap on the Make it Mine button to start the Wizard.



2. Follow the Wizard instructions on the screen to complete the customization of the iTero Element 5D.

Chapter 4:

Operating instructions

It is recommended to keep the system in operation during office hours to allow background file transfers between the doctor's office, the doctor's partnered labs, and the Align Technology Center. It is recommended to shut down the system at the end of the day, and to reboot in the morning.

End-of-day shut down

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

Moving system within the office

To ensure maximum system protection, it is recommended to have two people move the system. Follow these instructions for relocating the system:

1. Verify the scanning unit (wand) sits well inside the scanning unit cradle (holder).
2. Unplug system from the wall outlet.
3. Move the system carefully using two people.
4. Place the system at its new location and it plug into a wall outlet.

Chapter 5:

Scanner handling, cleaning, and disinfection instructions

Handling of the scanning unit (wand)

The scanning unit contains delicate components and should be handled with care.

Handling of the scanning unit cable

- The scanner cable should be treated with care to avoid possible damage.
- Between patient sessions, it is recommended to undo any twists and knots in order to relieve all tension from the scanner cable.

The scanning unit requires proper cleaning & disinfection before first use and before each additional use, and no later than 30 minutes after the last scan.

Cleaning and disinfecting the scanning unit

The scanning unit (wand) should be cleaned and disinfected as follows:

- Soak a lint free cloth in ready to use CaviCide 1, and squeeze until the cloth is moist.
- Wipe the wand thoroughly to remove gross debris.
- The entire device needs to be visually inspected to ensure that no residual or debris remains prior to continuing to the next step.
- Soak two additional lint free cloths in CaviCide 1, and squeeze until the cloth is moist. Then wipe the device thoroughly, ensuring with special care that all the surfaces, to all edges and slots, are covered. Contact time will be at least 2 minutes.
- Then wet lint free cloths with distilled water and wipe all surfaces for at least 15-30 seconds.
- Then use dry lint free cloths to dry the surfaces.

Maintenance


The industrial camera is maintenance-free.

Chapter 6:

Changing sleeves between patients

iTero Element 5D sleeve is intended for single patient use and shall be replaced after each patient with the purpose to avoid cross contamination.

For sleeve replacement proceed with the steps below.

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

Replacing disposable sleeves

**Step 1**

When pulling a sleeve OFF or ON, hold the center of the sleeve.

**Step 2**

Press slightly on both sides of the disposable sleeve, pull the sleeve slowly off the scanning unit and discard.

**Step 3**

Gently slide on new sleeve onto scanning unit until it clicks into place.

**WARNING: Optical surface!**

DO NOT touch the optical surface. Contact may cause damage. If cleaning is necessary, use the wipes and anti-static cloth found inside the sleeves box. For proper use, refer to the directions found in the scanner sleeves box.

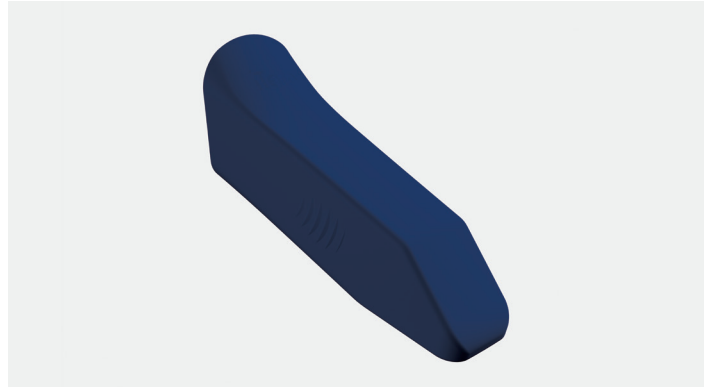
Scanner sleeves

There are two types of sleeves intended for use with the scanner unit (wand):



Disposable sleeve

The white sleeve is a single use sleeve for patient scanning. Always replace the white sleeve on the scanning unit between patients to avoid cross contamination. Please dispose of the white sleeve after every patient.



Protective sleeve

The blue protective sleeve is used to protect the optical surface lens when the scanning unit is not in use. Please keep the blue sleeve in a safe place so that it does not get lost or damaged.



Scanner sleeves packaging box

Scanner sleeves may be ordered online in boxes of 25 from the iTerO store.

www.store.itero.com

Chapter 7:

Accessories (optional)

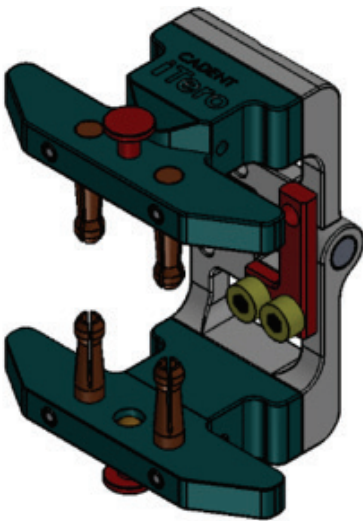
Counter stand and cradle



Back view



Front view



Articulator

The articulator is intended to use as a mechanical device that simulates movements of a patient's upper and lower jaws. Plaster casts of the patient's teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient's jaws. The articulator is intended to fit dentures or provide orthodontic treatment.

Chapter 7:

Clinic LAN network guidelines

Introduction

The iTero Element 5D scanner uses the Wi-Fi internet connectivity in order to send and retrieve scans to and from the iTero cloud.

As a recommendation, it is always best to have the state-of-art available technology. Here 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 Element 5D scanner, ensure that the Wi-Fi signal strength is “Excellent” or at least “Good”.
- **CAUTION:** While scanning a patient, do not connect a LAN cable to iTero Element 5D – it is forbidden due to safety hazard reasons.

Preparations

- The required Modem/Router should be configured with WPA2 Security standard, including a password.
- Ensure that your IT professional staff would be available when the scanner installation is planned to take place.
- Make sure that your Wi-Fi SSID credentials are available: Login & password.
- The minimal Wi-Fi strength signal for the system should display at least two “stripes”, as shown in chapter 2, above).
- Diagnostic tool under “Settings”, or the Connectivity Tool are suggested below.
- Test the local Wi-Fi connection with any PC computer, using the iTero connectivity tool (run the test as near as possible to the scanner location).
- Connectivity Tool Download at fc1.orthocad.com/download/AlignSupport/ConnectivityCheck2.0.exe
- Following are some suggestions for the office IT person, regarding what should be considered in order to prevent issues such as access or connectivity to/with the iTero scanner:
 1. Hostname recommendations related to Align services listening to ports 80 and 443.
 2. Do not prevent FTP communication since the scanner sends specific file types (.3ds and .3dc/.3dm).
 3. Disable any proxy client for data communication through TCP/IP.
 4. Do not add the scanner to any domain group.
 5. Do not run any group policy on the scanner as it may disrupt its proper functioning.

Router guidelines

Minimum Standards: 802.11N / 802.11AC

Internet connection guidelines

In order to achieve the best performance of your iTero Element 5D scanner, ensure that your internet connection upload speed is at least 1Mbps per scanner. Also, note that any additional devices connected to the internet in parallel to the scanner may affect the scanner's performance.

Firewall

Open Ports (in case Firewall is working):

- a. 80 - HTTP - TCP
- b. 443 - HTTPS - TCP

Wi-Fi tips

Wi-Fi routers allow you to access your internet system using a Wi-Fi connection from essentially any place within the functional range of the wireless network. Nevertheless, the number, depth and position of walls, ceilings, or additional partitions that the wireless signals must travel through may limit the range and strength of the signal. Normal signals vary depending on the material types and background RF (radio frequency) noise in your home or business.

1. Be sure to have a minimal number of walls and ceilings between the router and other network devices. Each barrier can reduce your adapter's range by 1-3 meters (3-9 feet).
2. 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 (90°) a wall or partition (instead of at an angle).
3. Construction materials make a difference. A solid metal door, or aluminum nails, can be very dense and may have an adverse effect on a Wi-Fi signal. Try to position access points, wireless routers, and computers so that the signal travels through drywalls or open doorways. Materials and objects such as glass, steel, metal, walls with insulation, water tanks (aquariums), mirrors, file cabinets, brick, and concrete may reduce your wireless signal.
4. Keep your iTerero product away (at least 3-6 feet or 1-2 meters) from electrical devices or appliances that generate RF noise.
5. If you are using 2.4GHz cordless phones or X-10 (wireless products such as ceiling fans, remote lights, and home security systems), your wireless connection may severely degrade or entirely drop. The base of many wireless devices transmits an RF signal, even if the device is not in use. Position your other wireless devices as far as possible from your scanner and router.
6. 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.

Align hostname recommendations

Align constantly improves its products and services. Hence, can rather commit to a Hostname, though not to a certain IP.

The following hostnames list was created to provide Align's scanners the proper operation functions, in order to be able to utilize all the advanced capabilities of the scanner performance.

Align hostnames recommendation:

Host name	Port
Mycadent.com	80, 443
Myaligntech.com	80, 443
Export.mycadent.com	80, 443
Cbobserver.mycadent.com	80, 443
Matstore.invisalign.com	80, 443
Matstore2.invisalign.com	80, 443
Matstore3.invisalign.com	80, 443
Matstore4.invisalign.com	80, 443
Matstoresg.invisalign.com	80, 443
Matstorechn.invisalign.com.cn	80, 443
AWS IP range - Amazon global CDN service - IP address range varies depending on the location of the scanner.	80, 443
cloud.myitero.com	443
speedtest.tele2.net	80
alignapi.aligntech.com	80, 443
http://www.google.com	80, 443
http://www.microsoft.com	80, 443
http://www.yahoo.com	80, 443
iterosec.aligntech.com	80, 443
storage.cloud.aligntech.com	443

Appendix A:

EMC declaration

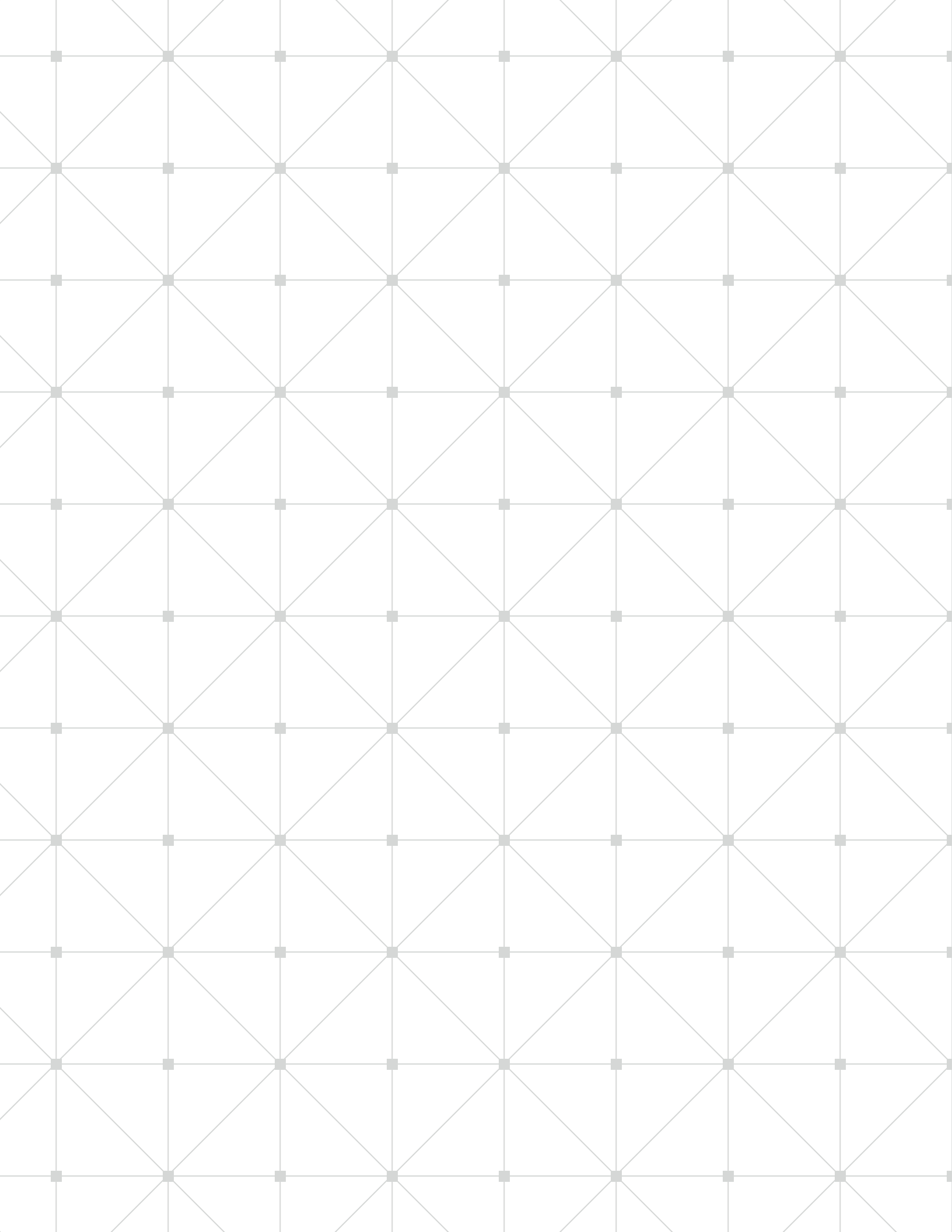
Summary of EMC test results for iTero Element 5D

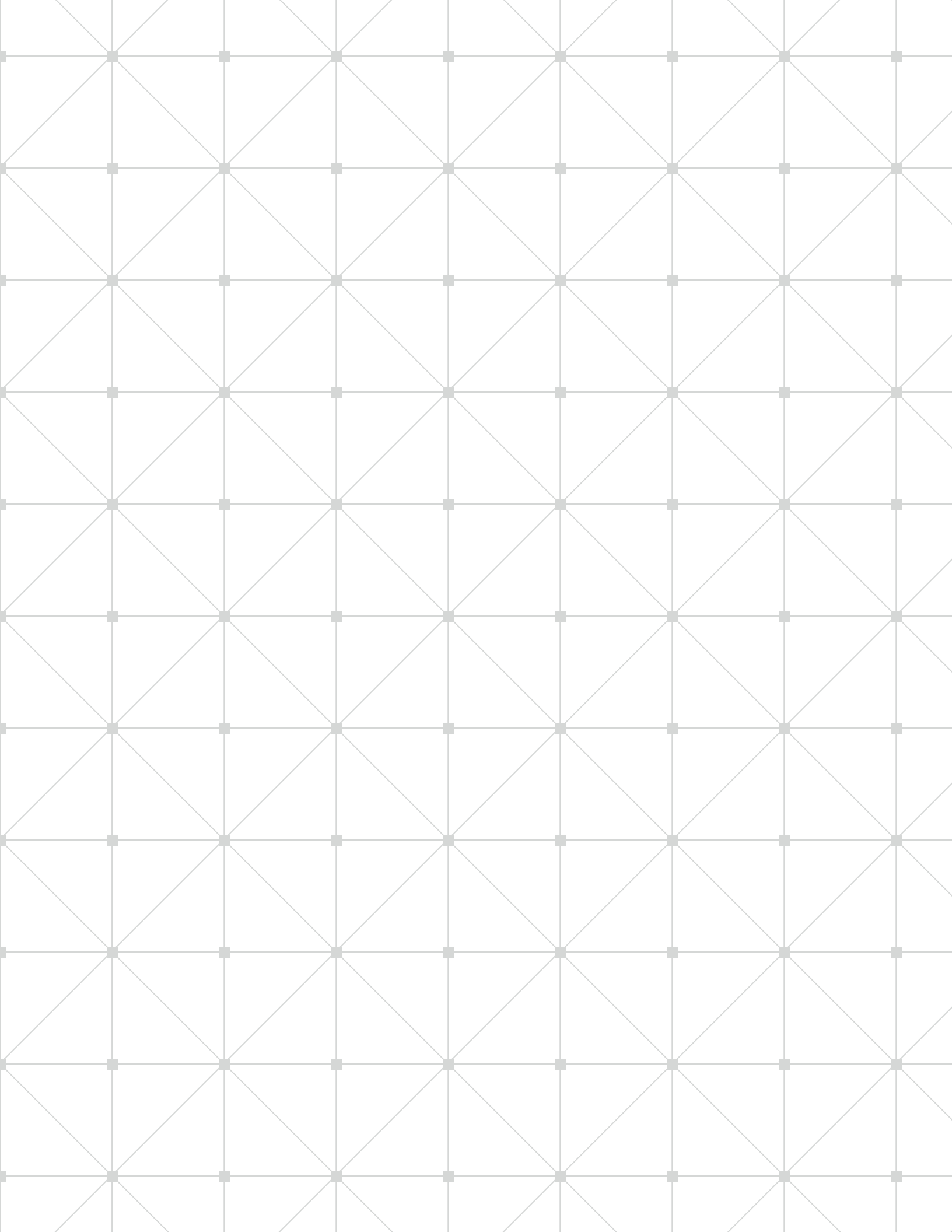
Test	Standard	Class / Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1	--	Complies
External labels	section 5.1	--	Complies
Conformity of users' manual	section 5.2.1	--	Complies
Accuracy of technical description	section 5.2.2	--	Complies
Emission (IEC 60601-1-2 / EN 60601-1-2 section 7)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B 230, 120 & 100 VAC mains (50 Hz); 220 VAC mains (50 & 60 Hz)	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	230 VAC mains (50 Hz & 220 V (60 Hz)	Complies
Voltage changes, voltage fluctuations and flicker test	IEC 61000-3-3	230 VAC mains & 220 VAC mains	Complies
Immunity (IEC 60601-1-2 section 8)			
Immunity from electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from electrical fast transient (EFT)	IEC 61000-4-4	± 2.0 kV - on AC mains; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from surge	IEC 61000-4-5	±2.0 CM / ±1.0 kV DM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0, 6.0 VRMS on 230 VAC mains & wand cable; 0.15÷ 80 MHz, 80% AM 1 kHz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles on AC mains	Complies

Appendix B:

System specifications

Item	Description				
Monitor	21.5" monitor				
Scanner	Scanner emits red laser light (680nm Class 1) as well as white LED emissions, and 850nm LED emissions.				
Wireless LAN	LAN card provides local network communications with wireless connectivity.				
Security	The iTero password is unique for each user and should not be shared with others. The iTero password policy requires high level of password strength.				
Operating power	100-240VAC- 50/60 Hz – 200VA (max)				
Operating temperature	18°C to 26°C / 64.4°F to 78.8°F				
Storage/transportation temperature	-5° to 50°C / 23° to 122°F				
Operating pressure & altitude	Pressure: 520 mmHg to 771 mmHg (-69 kPa to -103 kPa) Altitude: -400 feet to 10,000 feet				
Storage/transportation pressure & altitude	Pressure: 430 mmHg to 760 mmHg (-57 kPa to -101 kPa) Altitude: 0 feet to 15,000 feet				
Relative humidity	Operating: 40% to 70%; Storage: 30% to 90%				
Dimensions	<table border="0"> <tr> <td>iTero HD touch monitor: Height: 356 mm (-14 in) Width: 552 mm (-21.7 in) Depth: 65 mm (-2.5 in)</td> <td>iTero Element 5D wand: Length: 346 mm (13.3 in) Width: 50 mm (2.0 in) Depth: 68 mm (2.7 in)</td> <td>Wheel stand: Height: 1280 mm (-50 in) Width: 645 mm (-25 in) Depth: 625 mm (-24.5 in)</td> <td>Counter stand: Height: 480 mm (-19 in) Width: 552 mm (-21.7 in) Depth: 220 mm (-8.7 in)</td> </tr> </table>	iTero HD touch monitor: Height: 356 mm (-14 in) Width: 552 mm (-21.7 in) Depth: 65 mm (-2.5 in)	iTero Element 5D wand: Length: 346 mm (13.3 in) Width: 50 mm (2.0 in) Depth: 68 mm (2.7 in)	Wheel stand: Height: 1280 mm (-50 in) Width: 645 mm (-25 in) Depth: 625 mm (-24.5 in)	Counter stand: Height: 480 mm (-19 in) Width: 552 mm (-21.7 in) Depth: 220 mm (-8.7 in)
iTero HD touch monitor: Height: 356 mm (-14 in) Width: 552 mm (-21.7 in) Depth: 65 mm (-2.5 in)	iTero Element 5D wand: Length: 346 mm (13.3 in) Width: 50 mm (2.0 in) Depth: 68 mm (2.7 in)	Wheel stand: Height: 1280 mm (-50 in) Width: 645 mm (-25 in) Depth: 625 mm (-24.5 in)	Counter stand: Height: 480 mm (-19 in) Width: 552 mm (-21.7 in) Depth: 220 mm (-8.7 in)		
Net weight	iTero HD touch monitor: 8.3 kg (-18.3 lbs) Tero Element 5D wand: 0.47 kg (-1 lbs) Wheel stand: 13.6 kg (-30 lbs)				
Shipping weight	-37.5 kg (-83 lbs)				





iTero element 5D

Align Technology, Inc.
2820 Orchard Parkway
San Jose, CA 95134
USA

Align Technology B.V.
Arlandaweg 161
1043HS Amsterdam
The Netherlands

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