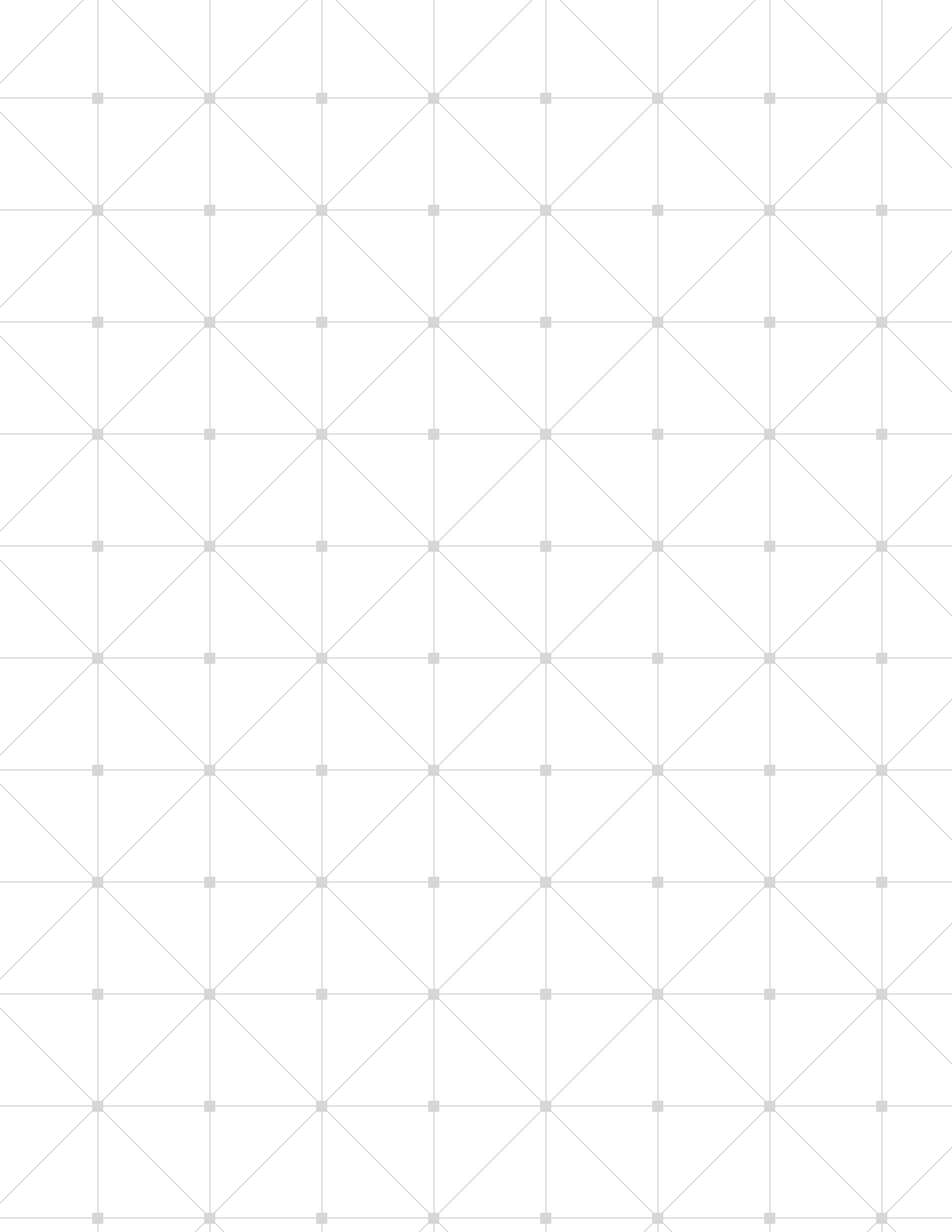


Operation manual



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This manual describes the iTero Element 2 Optical Impression Device.

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Class 1 laser compliance

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



Class 1 Laser Product

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 à la norme sur les appareils à laser de Classe 1

Cet appareil est conforme au code des règlements fédéraux « 21 CFR 1040.10 » et à la norme « EN 60825-1 ».



Appareil à laser de Classe 1

Conformité aux normes de l'Association canadienne de normalisation (CSA - Canadian Standards Association)

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

« Norme UL n° 60601-1 Appareils électromédicaux – Partie 1 : Exigences générales pour la sécurité »

**Conformité aux normes de la Commission fédérale des communications (FCC - Federal Communications Commission)**

Cet appareil est conforme à la partie 15 des règles de la FCC et son fonctionnement est soumis aux deux conditions suivantes :

1. Cet appareil ne doit pas causer d'interférences nuisibles.
2. Cet appareil doit accepter toute interférence reçue, notamment celles pouvant entraîner un dysfonctionnement.

**Avertissement de la FCC**

Toute modification non expressément approuvée par le fabricant est susceptible de conduire à l'annulation de vos droits à utiliser l'appareil dans le cadre des lois de la FCC.

Conformité aux normes de compatibilité électromagnétique (CEM)

Cet appareil est conforme à la norme CEM suivante :

« CEI 60601-1-2 Appareils électromédicaux - Partie 1-2 : Exigences générales pour la sécurité de base et les performances essentielles
Norme collatérale : Perturbations électromagnétiques - Exigences et essais ».

Conformité aux normes de sécurité

Cet appareil est conforme à la norme de sécurité suivante :

« CEI 60601-1 Appareils électromédicaux - Partie 1 : Exigences générales pour la sécurité de base et les performances essentielles. »

Conformité CE

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



Symbols

The following symbols may appear on iTerro Element 2 hardware components, and may also appear within this manual and other iTerro Element 2 literature.



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



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



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



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 manual.

"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.



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 this product in domestic or municipal waste. This device contains WEEE materials. Please contact EARN service. The link for the online request form <http://b2btool.earn-service.com/aligntech/select>.



Medical device manufacturer.



IEC 60417-5009: STAND-BY.



IEC 60417-5032: Alternating current.



IEC 60417-5031: Direct current.



Wand (scanning unit).



USB socket.



Order number.



Serial number.



Indicates the Authorized representative in the European Community.



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



Manufacturer's batch code



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



Electric battery.



RoHS (China).

Symboles

Les symboles suivants peuvent apparaître sur les composants matériels de l'iTero Element 2, et également dans ce manuel et d'autres supports de documentation liés à l'iTero Element 2.



Dès que ce symbole apparaît sur l'appareil, il est recommandé de se reporter à ce manuel pour obtenir des informations sur l'utilisation appropriée de l'appareil.



Pièce appliquée de type BF. Tout composant sur lequel ce symbole apparaît est une pièce appliquée de type BF à isolation électrique.



Les pièces ou accessoires sur lesquelles ce symbole apparaît ne doivent pas être réutilisé(e)s.



Attention : Ce symbole est utilisé pour souligner qu'il existe des avertissements ou des précautions associé(e)s à l'appareil. Dès que ce symbole apparaît sur l'appareil, il est obligatoire de se reporter aux informations liées à la sécurité se trouvant dans ce manuel.

"Rx only" : Sur prescription uniquement

ATTENTION : La loi fédérale des États-Unis restreint la vente de cet appareil par ou pour le compte d'un dentiste, d'un orthodontiste ou d'un professionnel dentaire agréé. Le système a valeur de prescription médicale et ne doit être manipulé que par des prestataires de soins de santé qualifiés.



Une collecte séparée des déchets d'équipements électriques et électroniques est requise. Conformément à la Directive relative aux déchets d'équipements électriques et électroniques (DEEE), ne pas jeter ce produit dans les déchets ménagers ou municipaux. Ce dispositif contient des matériaux, composants et substances pouvant se révéler dangereux ou préjudiciables pour la santé humaine et l'environnement si les déchets électriques et électroniques de ce dispositif ne sont pas éliminés correctement. Veuillez contacter le service EARN. Lien pour le formulaire de demande en ligne : <http://b2btool.earn-service.com/aligntech/select>.



Fabricant de l'appareil médical.



CEI 60417-5009 : « MARCHE » (sous tension).



Pièce à main (scanner).



CEI 60417-5032 : Courant alternatif.



CEI 60417-5031 : Courant continu.



Numéro de référence.



Numéro de série.



Prise USB.



Indique les limites de température auxquelles l'appareil médical peut être exposé en toute sécurité



Code de lot du fabricant



Indique le représentant agréé pour la Communauté européenne.



Batterie électrique.



Limitation de certaines substances dangereuses dans les équipements électriques et électroniques (Chine).



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

Safety instructions

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

The computer is provided with a Li-ion rechargeable battery pack. There is a danger of explosion if battery is incorrectly replaced. Replace only with same type recommended by the manufacturer. Discard used batteries according to the manufacturer's instructions.

WARNING – to avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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 iTero Element 2 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, iTero Element 2 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. 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.

- 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.
- 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 the rear side of the touch screen so there will be no direct eye contact with the laser beam or the flickering white LED emission 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.

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.
- 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.
- Do not block the air vents on the scanning unit and base unit.
- 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 EN60601-1-2. 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.

General

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

Instructions de sécurité

Avant de commencer à travailler avec le système, tous les utilisateurs sont tenus de lire ces instructions de sécurité.

L'ordinateur est fourni avec une batterie au lithium-ion (Li-Ion) rechargeable. Il y a un risque d'explosion si la batterie n'est pas correctement remplacée. Ne remplacez qu'avec le même type, recommandé par le fabricant. Mettez au rebut la batterie usagée conformément aux instructions du fabricant.

AVERTISSEMENT - Pour éviter tout risque de choc électrique, cet équipement doit uniquement être relié à l'alimentation secteur avec ligne de mise à la terre.

Alimentation électrique

- L'alimentation du système provient d'une alimentation électrique interne de qualité médicale.

Puissance des batteries

- Charge - La batterie sera entièrement chargée 2 heures après avoir été branchée à une source d'alimentation.
- Avec une batterie entièrement chargée, l'utilisateur peut effectuer des scans pendant 30 minutes maximum avec le scanner iTero Element 2 sans avoir besoin de brancher l'appareil sur l'alimentation.

Avertissement électrique

- **Risque de choc électrique !!** Seuls les techniciens Align Technology autorisés peuvent retirer les panneaux et les couvercles externes. Cet appareil ne contient aucun composant susceptible d'être réparé par l'utilisateur.
- Pour éviter tout risque de choc électrique, l'iTero Element 2 doit uniquement être relié à l'alimentation secteur avec ligne de mise à la terre.
- Seule une caméra Web ou DOK doit être branchée sur la prise USB à l'arrière du système.

Réseau local sans fil

- Le système est fourni avec une unité LAN 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 la pénétration d'eau avec effets nuisibles : Ordinaire.
- Équipement non adapté à une utilisation en présence de mélanges d'anesthésiques inflammables.
- Mode de fonctionnement : Continu.

Dispositif médical sur prescription

- Le système a la même valeur qu'une prescription médicale 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 (680 nm, Classe 1), ainsi que des émissions à LED blanches. L'utilisation normale du scanner ne présente aucun danger pour l'œil humain. Toutefois, les praticiens doivent éviter de diriger la lumière du scanner

directement dans les yeux du patient.

- Évitez de tordre, de nouer le câble, de tirer ou de marcher dessus.
- L'utilisation du scanner ne présente aucun danger pour l'œil humain. Toutefois, les praticiens doivent éviter de diriger la lumière du scanner directement dans les yeux du patient.
- Lorsque le système n'est pas en utilisation, le scanner doit être placé au sein du support, sonde face au montant du chariot et à la paroi arrière de l'écran tactile, afin qu'il n'y ait aucun risque de contact visuel direct avec le rayon laser ou les émissions à LED blanches clignotantes.
- Le praticien ne doit activer l'opération de numérisation que lorsque la sonde se trouve dans la bouche du patient.
- Les praticiens doivent éviter de positionner le scanner dans le support pendant que l'opération de numérisation est encore active.

Nettoyage et désinfection

- Pour éviter toute contamination croisée, il est obligatoire de remplacer le manchon jetable en plastique et de désinfecter le scanner après chaque session patient.
- Mettez au rebut les manchons de l'unité de numérisation conformément aux procédures d'exploitation normalisées ou à la réglementation locale pour la mise au rebut des déchets médicaux contaminés.

Déballage et installation

- Le système doit être déballé et installé en suivant les instructions d'Align Technology.

Environnement de travail

- Le système doit être déplacé avec le plus grand soin d'une salle à l'autre, afin d'éviter tout dommage.
- Ne bloquez pas les ouvertures d'aération sur le scanner et l'unité de base.
- Le système est prévu Pour une utilisation interne uniquement. Il ne doit être exposé ni à la lumière directe du jour, ni à une chaleur ni une humidité excessives.

Interférences électromagnétiques

- **AVERTISSEMENT** : Cet appareil a été testé et déclaré conforme aux exigences requises pour les dispositifs médicaux conformément à la norme EN60601-1-2. Cette norme est destinée à fournir une protection raisonnable contre les interférences nuisibles dans une installation médicale typique. Toutefois, en raison de la multiplication des équipements de transmission à fréquence radio et d'autres sources de bruit électrique dans les environnements de soins de santé (p. ex. téléphones mobiles, émetteurs-récepteurs radios mobiles, appareils électriques), il est possible que des niveaux élevés de telles interférences, dues à la proximité ou à l'intensité de la source, entraînent une perturbation des performances de cet appareil.

Dispositions générales

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

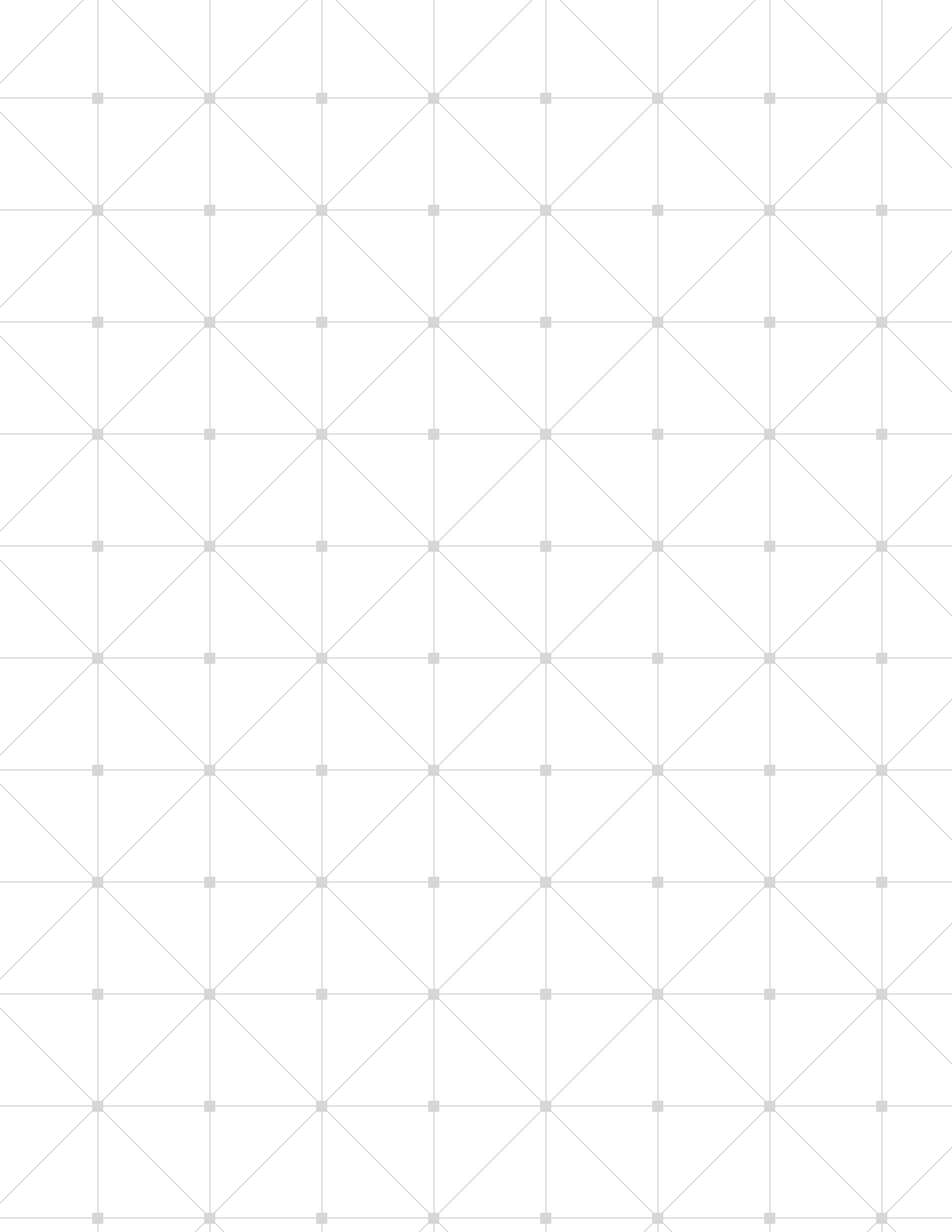


Table of contents

Chapter 1: Introduction	2
About this operation manual	2
Intended use	2
Benefits of the iTero Element 2 system	2
The iTero Element 2 user interface	3
Chapter 2: Basic hardware features	4
Front view of the system	4
Back view of the system	5
Scanning unit (wand)	6
Chapter 3: Assembly instructions	7
Step 1: Assembly of iTero Element 2 scanner	7
Step 1: Assembly of iTero Element 2 Counter Stand	10
Step 2: Make it Mine process	12
Chapter 4: Operating instructions	13
Initial power-up and boot	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
Recommended best practices for cleaning and disinfecting	14
Cleaning and disinfectant materials for scanning unit and base unit	15
Chapter 6: Changing sleeves between patients	16
Cleaning and disinfecting the scanning unit (wand)	16
Replacing disposable sleeves	16
Scanner sleeves	17
Chapter 7: Clinic LAN network guidelines	18
Introduction	18
Preparations	19
Router guidelines	19
Firewall	19
Wi-Fi tips	20
Align hostname recommendations	21
Appendix A: EMC declaration	22
Appendix B: Hardware specifications	23

Chapter 1:

Introduction

About this operation manual

The iTero Element 2 system is delivered as a proprietary, PC-based workstation for performing intra oral scans in the doctor's office. This operation manual describes how to boot 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

iTero Element 2 is an optical impression system (CAD/CAM) used to record the topographical images of teeth and oral tissue. Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories.

iTero Element 2 software is used with the iTero Element 2 scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. The software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, Orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.

Benefits of the iTero Element 2 system

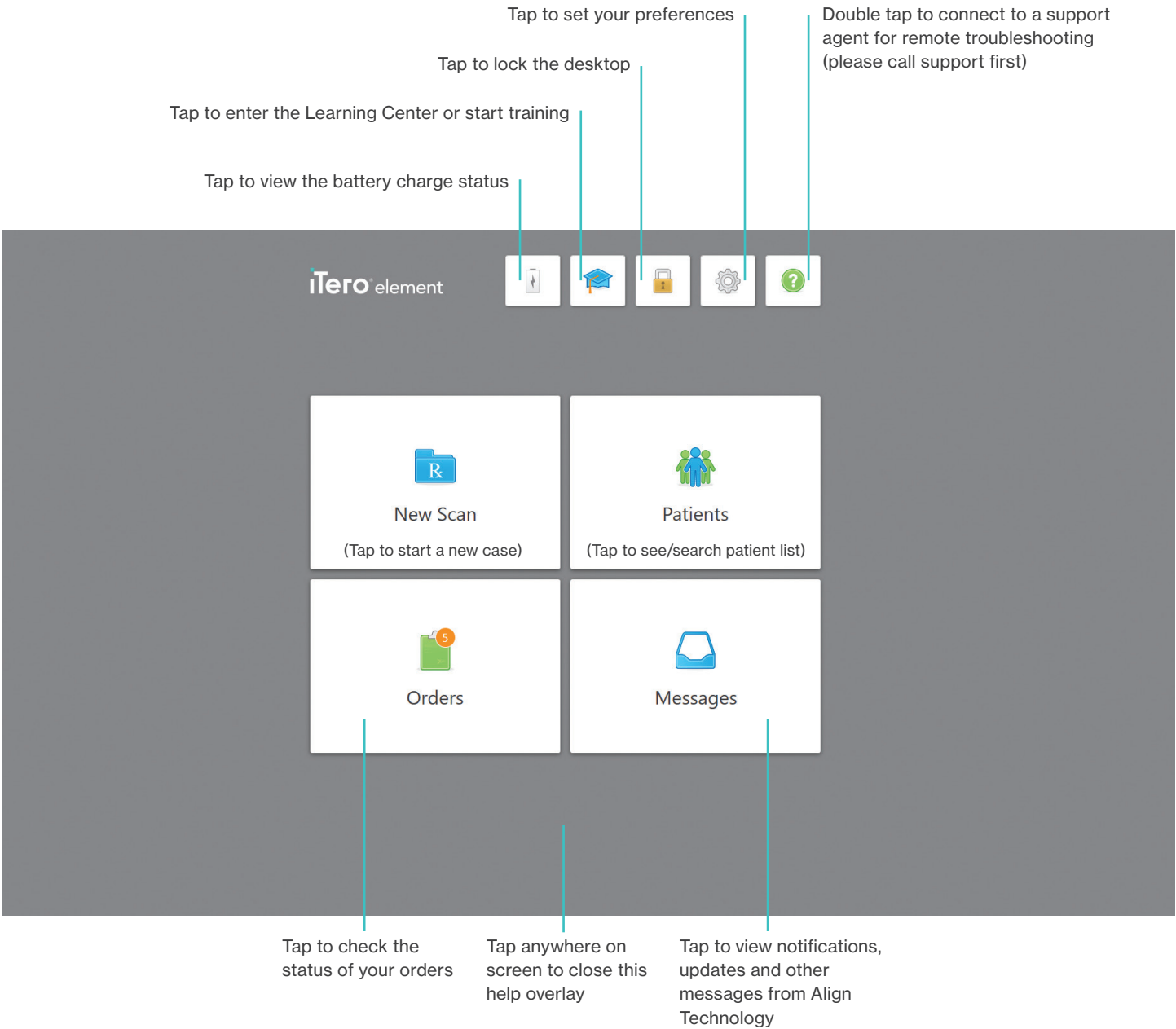
The iTero Element 2 system provides important advantages over existing crown-production methods, including powder-free scanning, greater crown-production accuracy, and immediate feedback during the scanning process.

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 2 user interface

The iTero Element 2 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 touch screen 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.



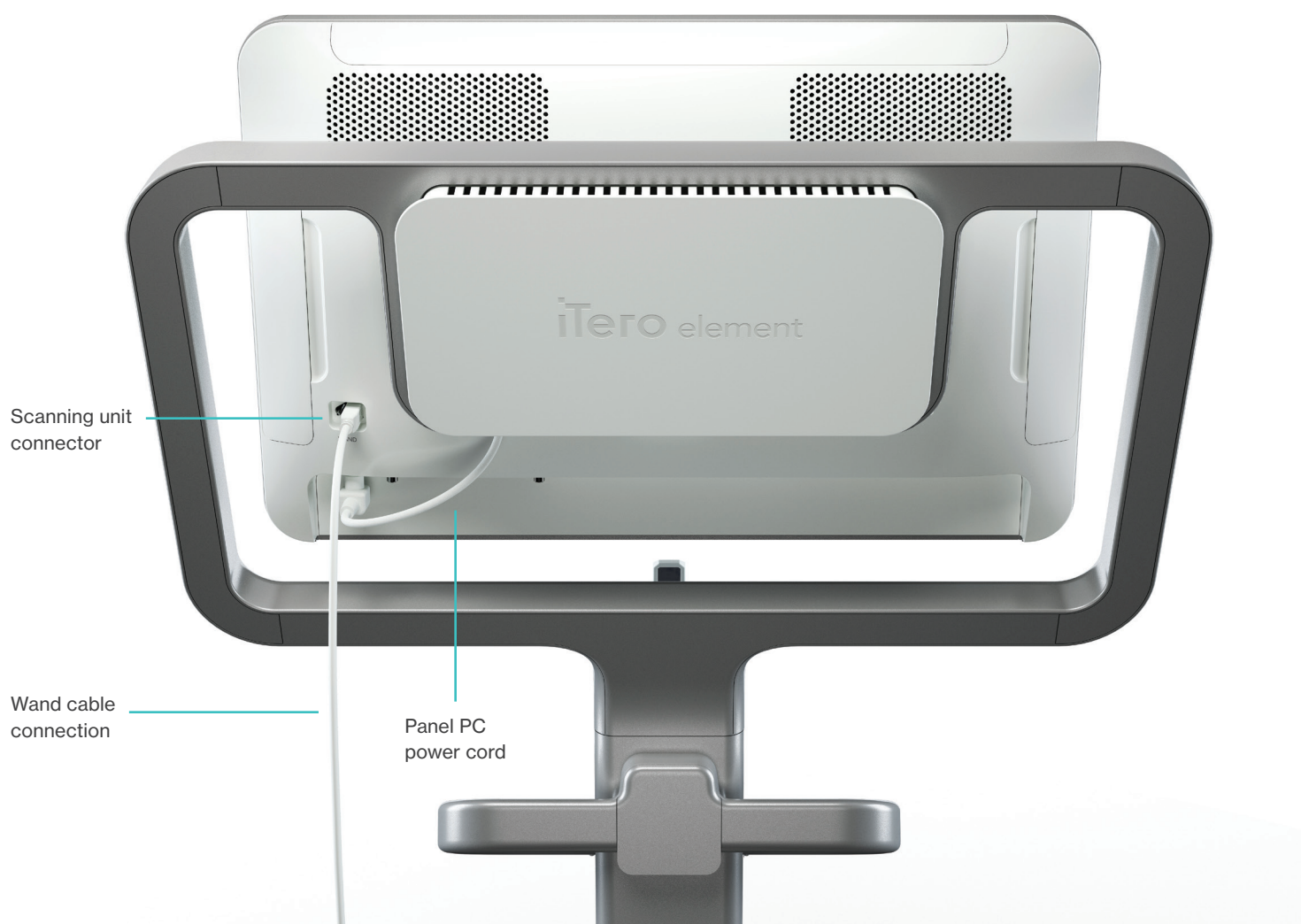
Chapter 2:

Basic hardware features

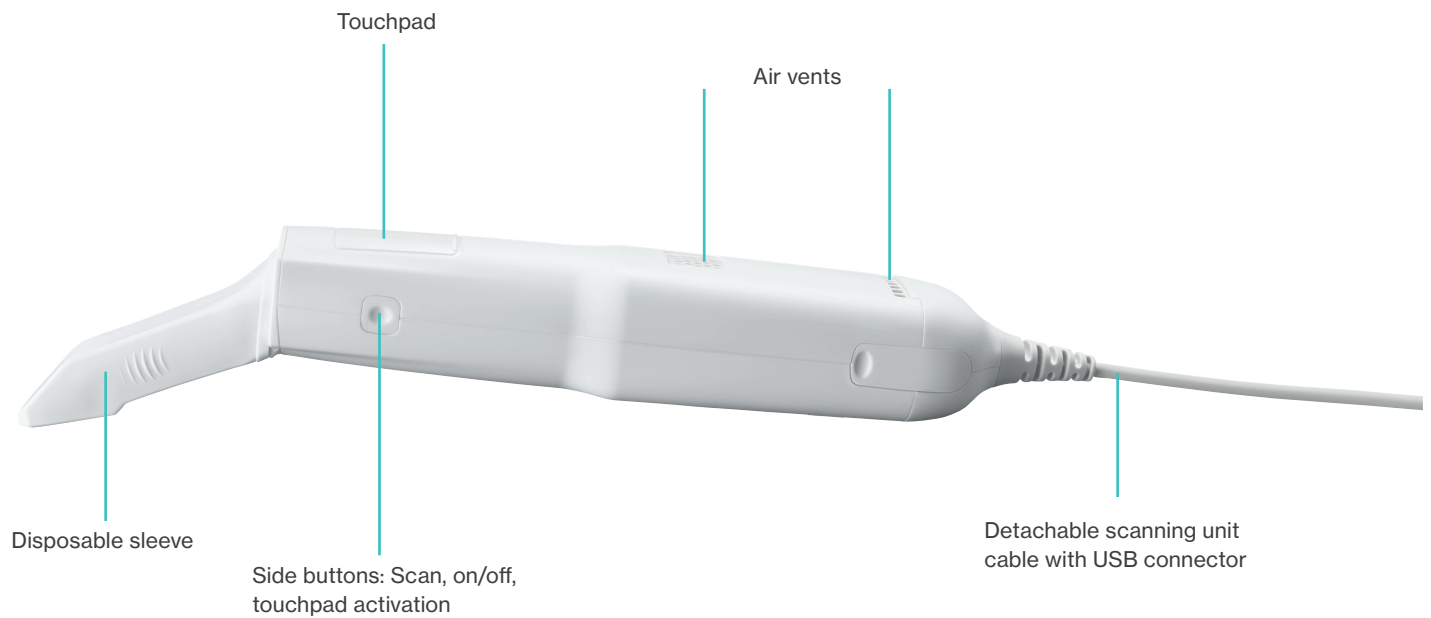
Custom wheel stand hardware features: Front view of the system



Custom wheel stand hardware features: Back view of the system



Scanning unit (wand)



Chapter 3:

Assembly instructions

Assembly of iTero Element 2 scanner

Please follow the instructions below to assemble your iTero Element 2 scanner:



AC power



Battery



Click



DC power



Power button

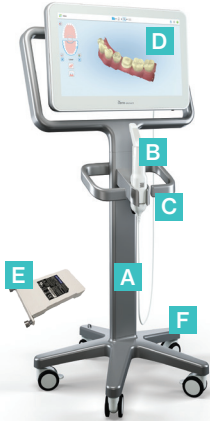


Wand
(scanning unit)

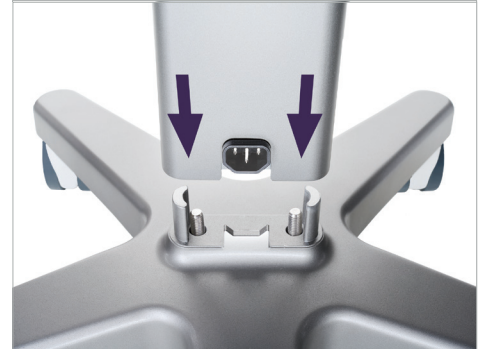


2 people are required
for installation

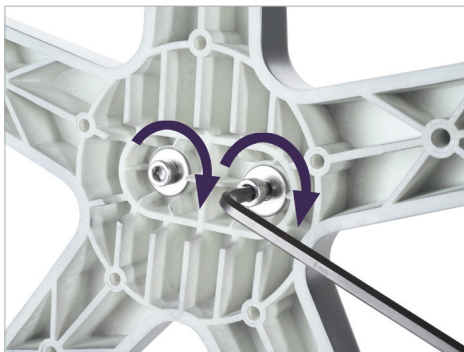
- A** Wheel stand
- B** Wand with cable
- C** Wand cradle
- D** HD touch screen
- E** External battery
- F** Power cable



1. Check the content of the box



2. Connect post to the wheel base



3. Tighten the 2 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



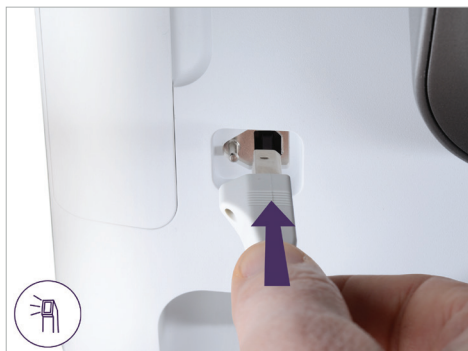
15.
Power cable inserted



16.
Attach the magnetic back cover



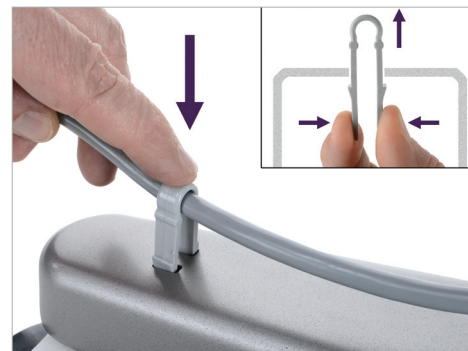
17.
Place the wand into the cradle



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



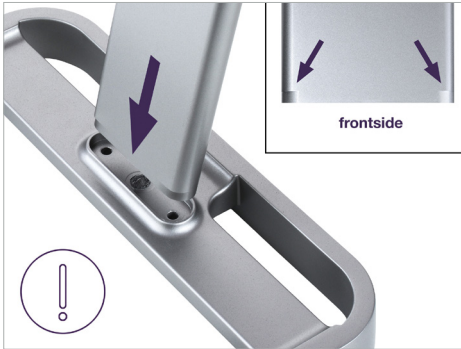
23.
Plug in the webcam to the USB port at the bottom of the HD screen



24.
Press button to switch on the scanner

Assembly of iTerro Element 2 Counter Stand

Please follow the instructions below to assemble your iTerro Element 2 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

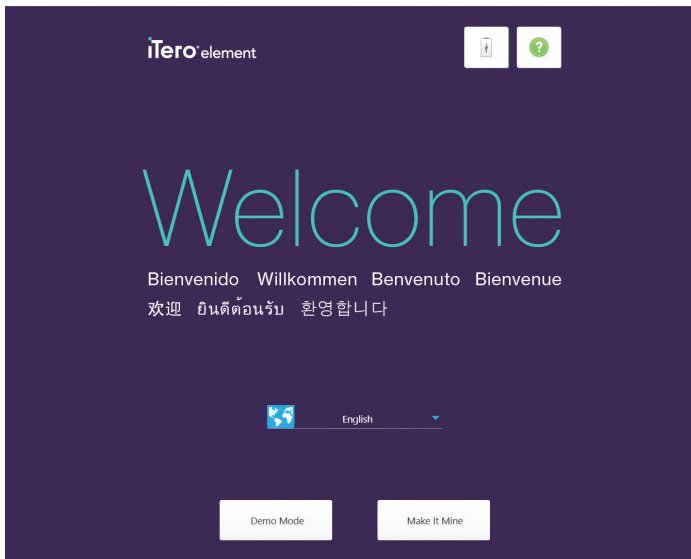


11.
Position the web camera on the HD screen
for remote training or support sessions

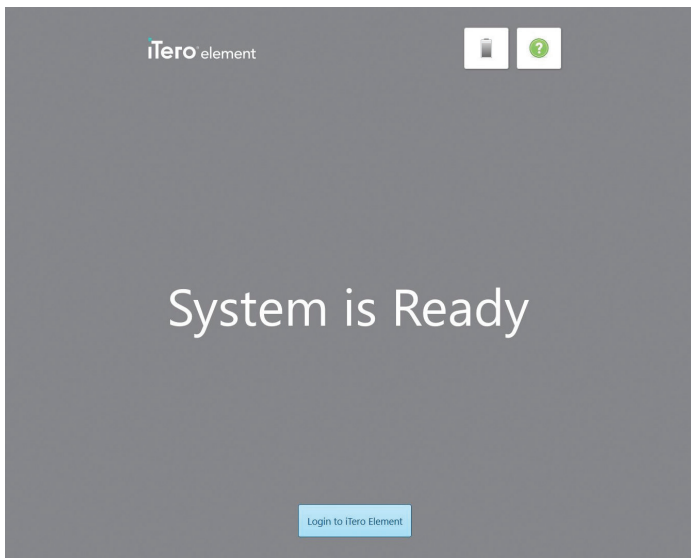


12.
Plug in the webcam to the USB port at the
bottom of the HD screen

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 2.

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.
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

Recommended best practices for cleaning and disinfecting the scanning unit, base unit, wheel stand and/or counter stand in between patients.

- Do not spray disinfectant directly on scanner system surfaces.
- Spray the disinfectant on a towel, or use disinfectant wipes for the scanning unit, and base unit.
- **Warning: over saturation of disinfectant product on the scanner system surfaces may cause damage, including internal components.**
- Follow the disinfectant manufacturers' instructions for appropriate contact time. Remove residual liquid disinfectant with a lint-free, clean cloth.
- **Note: follow standard precautions for personal protection, as appropriate.**
- **Warning: DO NOT touch the optical surface of the scanning unit (wand).**

Cleaning and disinfectant materials for scanning unit and base unit

The following cleaning and disinfectant materials are recommended for use for the scanning unit and the base unit.

Description	pH	Manufacturer P/N	Manufacturer
Birex® Quat disinfectant wipes	7.6	BI 240	Biotrol Intl.
CaviCide AF	12.7	13-800	Metrex
CaviCide CaviWipe	12.5	13-1000 13-1100	Metrex
CaviCide 1 CaviWipe 1	12.5	13-5000 13-5100	Metrex
Clorox Healthcare® hydrogen peroxide cleaner disinfecting liquid	2-3	30828, 30829	Clorox® Healthcare™
Clorox Healthcare® hydrogen peroxide cleaner disinfectant wipes	2-3	30824, 30825	Clorox® Healthcare™
Opti-Cide 3® liquid	7.6	DOCS12-024, DOCP04-128	Biotrol Intl.
Opti-Cide 3® wipes	7.6	DOCW06-100	Biotrol Intl.
OPTIM 33TB liquid	2.5-3.5	OPT33-1GAL, OPT-33-1QT	SciCan Inc.
OPTIM 33TB wipes	2.5-3.5	OPT33-W10X10, OPT-33-W12	SciCan Inc.
ProSpray ProSpray wipes	10	PSC240 PSW-1	Certol
Webcol® alcohol prep pads	7	5110	Medtronic

Chapter 6:

Changing sleeves between patients

Cleaning and disinfecting the scanning unit (wand)

To avoid cross contamination, it is essential that after each patient you fully clean and disinfect the scanning unit and the disposable sleeve. First spray disinfectant material on towel or use disinfectant wipes to clean the scanning unit and scanning unit cradle. Then proceed with the steps below to remove the used sleeve and attach a new disposable sleeve.



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.

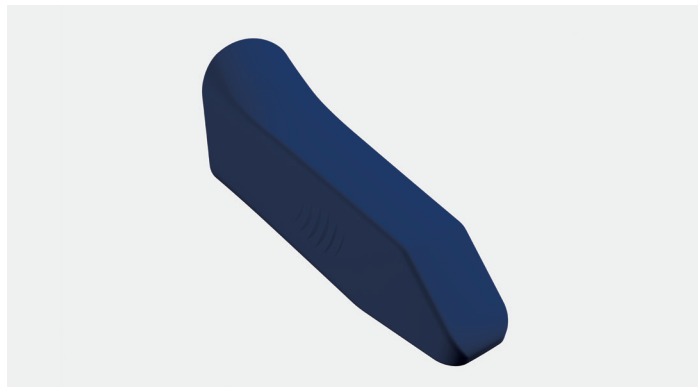
Scanner sleeves

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, where available.

Chapter 7:

Clinic LAN network guidelines

Introduction

The iTero Element 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 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 - 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 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 (900) 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 iTero 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
Cbserver.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

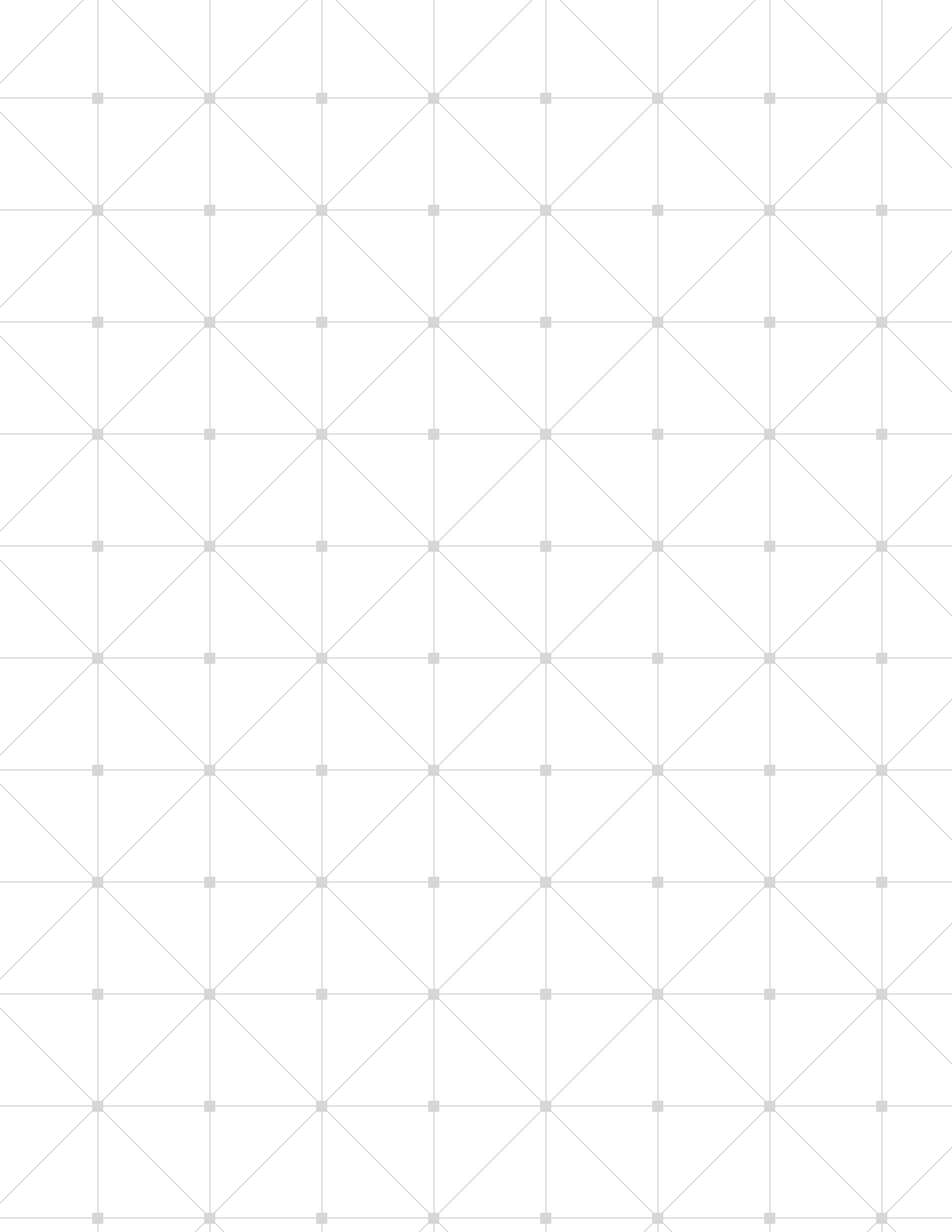
Summary of EMC test results for iTerro Element 2

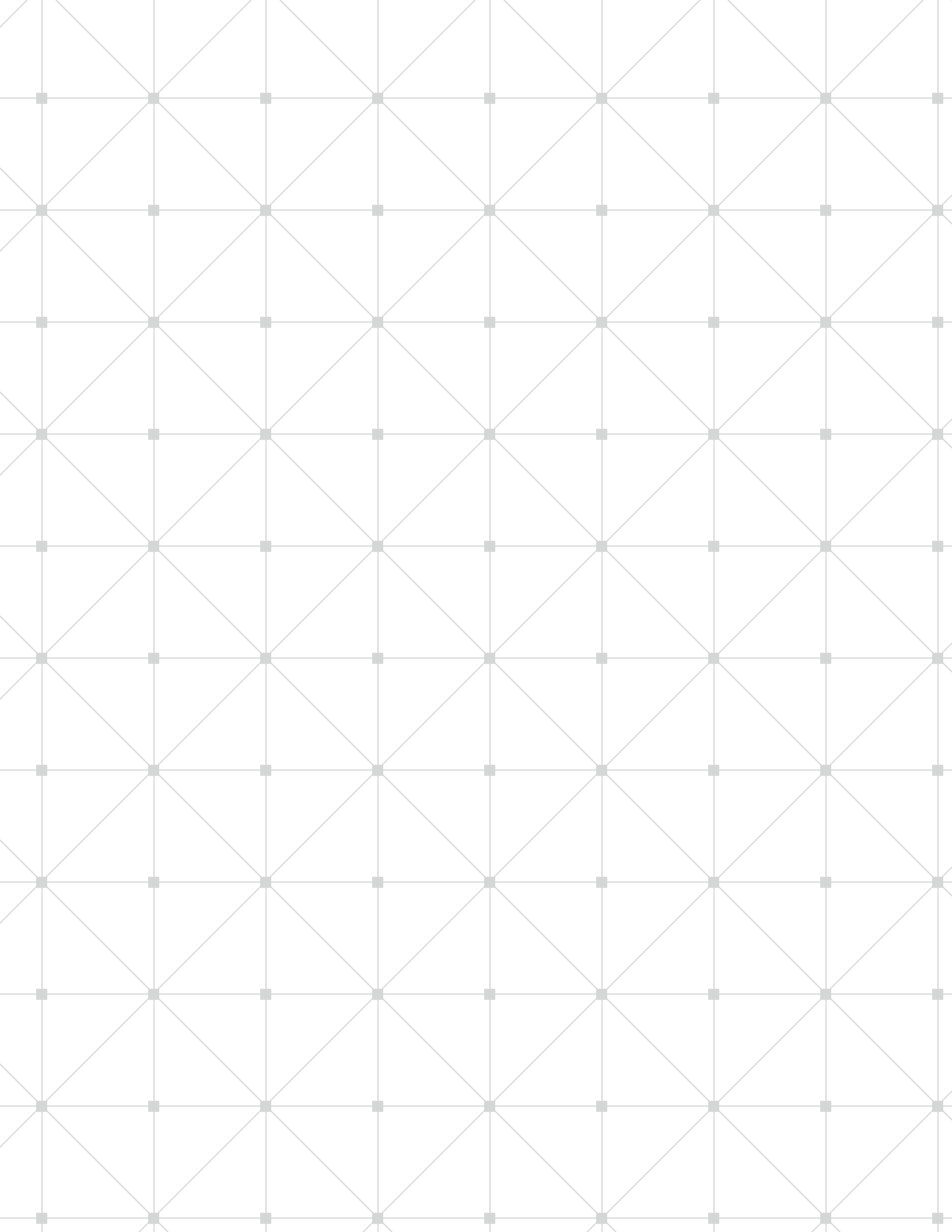
Test	Standard	Class / Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1	--	Complies
External labels	section 5.1	--	Complies
Conformity of users' manual	section 5.2.1	--	Complies
Accuracy of technical description	section 5.2.2	--	Complies
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:

Hardware specifications

Item	Description
Monitor	21.5" monitor
Scanner	Scanner emits red laser light (680nm Class 1) as well as white LED emissions.
Wireless LAN	LAN card provides local network communications with wireless connectivity.
Operating power	100-240VAC- 50/60 Hz – 200VA (max)
Operating temperature	18°to 26°C / 64.4° to 78.8°F
Storage/transportation temperature	-5°to 50°C / 23° to 122°F
Operating pressure & altitude	Pressure: 520 mmHg to 760 mmHg (-69 kPa to -101 kPa) Altitude: 0 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	iTero HD touch monitor: Height: 356 mm (-14 in) Width: 552 mm (-21.7 in) Depth: 65 mm (-2.5 in) iTero Element wand: Length: 338.5 mm (-13 in) Width: 53.5 mm (-2 in) Depth: 69.8 mm (-3 in) Wheel stand: Height: 1280 mm (-50 in) Width: 645 mm (-25 in) Depth: 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) iTero Element wand: 0.47 kg (-1 lbs) Wheel stand: 13.6 kg (-30 lbs) iTero Element 2 Counter Stand: 2.5 kg (-5.5 lbs)
Shipping weight	~37.5 kg (-83 lbs)







iTero element 2

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