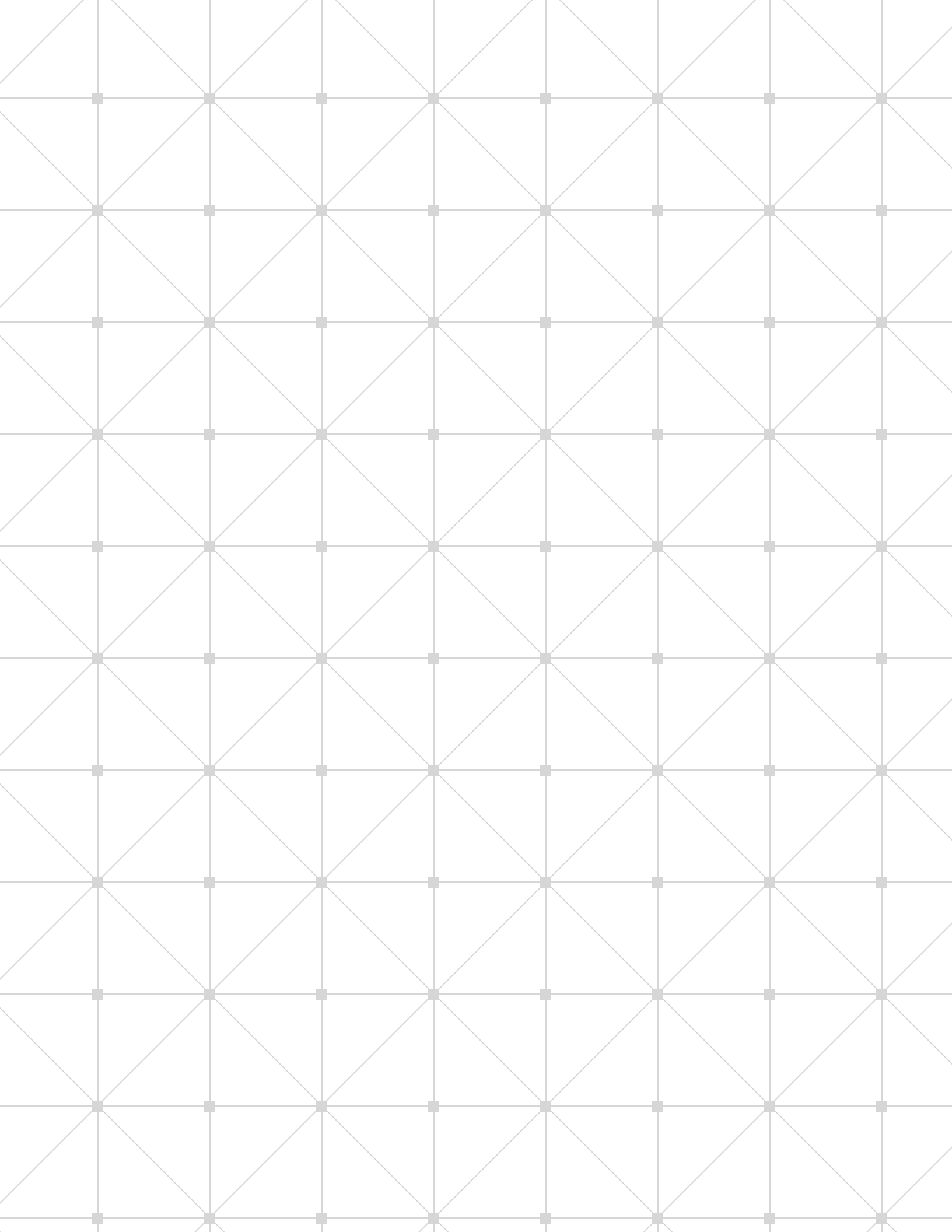


# Operation manual



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This manual describes the iTero Element Flex Optical Impression Device.

English language version. Updated January 2018.

## USA office

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

[www.aligntech.com](http://www.aligntech.com)

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



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

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

## Customer support

Tel: +1 (800) 577-8767

E-mail:  
[iterosupport@aligntech.com](mailto:iterosupport@aligntech.com)

E-mail:  
[orthocadsupport@aligntech.com](mailto:orthocadsupport@aligntech.com)

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## 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

## European authorized representative

Obelis s.a.  
Boulevard Général Wahis 53  
B - 1030 Brussels, Belgium

[www.obelis.net](http://www.obelis.net)

Tel: +32.2.732.59.54  
Fax: +322.732.60.03  
E-mail: [mail@obelis.net](mailto:mail@obelis.net)

### 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 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 iTero Element Flex hardware components, and may also appear within this manual and other iTero Element Flex 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.



CAUTION: DO NOT step on the Flex hub!



CAUTION: Flex hub must be kept dry!



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.

## Symboles

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



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 réutilisées.



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 la même valeur qu'une 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.



ATTENTION : NE marchez PAS sur le Flex hub !



Numéro de référence.



Numéro de série.



ATTENTION : Le Flex hub doit être maintenu au sec !



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.



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 system is provided with a Flex hub containing a power supply for the scanning unit. The Flex hub must be kept dry and be guarded against breakage.

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

## Power supply

- Power to the scanning unit is supplied via an internal medical grade power supply inside the Flex hub.

## Electric warning

- **Electric shock hazard!!** There are no user-serviceable parts inside the Flex hub.
- To avoid risk of electric shock, iTerO Element Flex must only be connected to a supply mains with protective grounding.
- Connect the Flex hub device only to a laptop that is approved according to IEC60950, and to UL60950-1. Laptop and all its accessories shall be located at least 1.5m away from the patient. Do not scan a patient and touch the laptop or any of its accessories at the same time.
- Only the Align Technology scanning unit and the approved laptop should be connected to the USB sockets on the Flex hub.
- Only the Align Technology approved power cable should be used to connect the Flex hub with the AC outlet.

## 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.
- When the system is not in use, the scanning unit should be placed inside the cradle with the probe facing down so there will be no eye contact with the laser beam in any case.

- Doctors should activate the scanning operation only while 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 offices inside its designated case to avoid damage.
- Do not block the air vents on the scanning unit.
- System is intended for indoor use only. It should not be exposed to direct sunlight, excessive heat or humidity.
- The system should only be used following operating temperatures as defined in Appendix B.
- If iTerO Element Flex has just been brought into the office from a hot or cold or humid environment, it should be set aside until it has adjusted to the room temperature to avoid internal condensation.

## 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.
- 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

- **WARNING:** No modification of this equipment is allowed.

## Instructions de sécurité

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

Le système est fourni avec un Flex hub contenant une alimentation électrique pour le scanner. Le Flex hub doit être maintenu au sec et protégé de toute détérioration.

**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 scanner provient d'une alimentation électrique interne de qualité médicale au sein du Flex hub.

## Avertissement électrique

- **Risque de choc électrique !!** Le Flex hub ne contient aucun composant susceptible d'être réparé par l'utilisateur.
- Pour éviter tout risque de choc électrique, l'iTero Element Flex doit uniquement être relié à l'alimentation secteur avec ligne de mise à la terre.
- Ne connectez le Flex hub qu'à un ordinateur portable approuvé, conformément aux normes CEI60950 et UL60950-1. L'ordinateur portable et tous ses accessoires doivent être situés à une distance minimale de 1,5 m du patient. Ne scannez pas un patient tout en touchant l'ordinateur portable, ni aucun de ses accessoires en même temps.
- Seul le scanner Align Technology et l'ordinateur portable approuvé doivent être branchés sur les prises USB du Flex hub.
- Seul le câble d'alimentation approuvé Align Technology doit être utilisé pour brancher le Flex hub sur la prise de courant CA.

## 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 valeur de prescription médicale et ne doit être manipulé que par des prestataires de soins de santé qualifiés.

## Avvertissements 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.

- Lorsque le système n'est pas utilisé, le scanner doit être placé au sein du support, sonde face vers le bas, afin qu'il n'y ait aucun risque de contact visuel avec le rayon laser.
- Les praticiens ne doivent 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

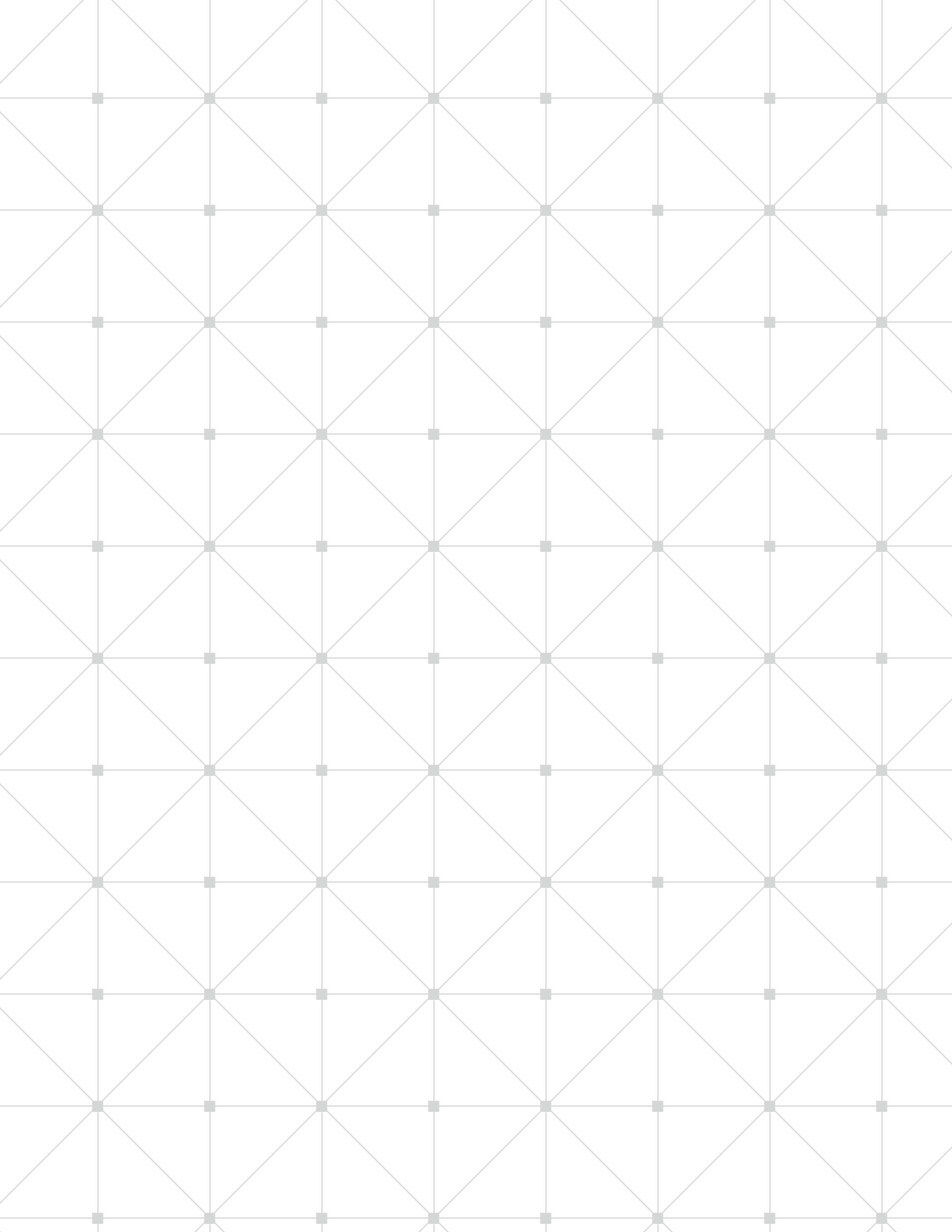
- Le système doit être déplacé d'une salle à l'autre dans sa propre mallette, afin d'éviter tout dommage.
- Ne bloquez pas les ouvertures d'aération sur le scanner.
- Le système est prévu pour un usage en intérieur uniquement. Il ne doit être exposé ni à la lumière directe du jour, ni à une chaleur ni une humidité excessives.
- Le système ne doit être utilisé que dans le cadre des températures de fonctionnement définies à l'annexe B.
- Si l'iTero Element Flex a été amené dans le cabinet après avoir été soumis à un environnement chaud, froid ou humide, il doit être mis de côté jusqu'à ce qu'il se soit adapté à la température ambiante, afin d'éviter une condensation interne.

## Interférences électromagnétiques

- **AVERTISSEMENT** : Cet appareil a été testé et déclaré conforme aux exigences requises pour les dispositifs médicaux conformément à la norme CEI60601-1-2. 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.
- Dans l'éventualité d'une chute brutale dans la tension d'entrée, le système ne fonctionnera pas mais ne constituera pas de danger pour l'utilisateur. Le système reprendra son état de fonctionnement habituel dès que la tension aura retrouvé ses valeurs nominales.

## Dispositions générales

- **AVERTISSEMENT** : Aucune modification à cet équipement n'est autorisée.



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<b>Table of contents</b>	
<b>Chapter 1: Introduction</b>	<b>2</b>
About this operation manual	2
Intended use	2
Benefits of the iTero Element Flex system	2
The iTero Element Flex user interface	3
<b>Chapter 2: Basic hardware features</b>	<b>4</b>
Front view of the system	4
Scanning unit (wand)	5
Mobile system packaging (for transport)	6
Moving the system	6
<b>Chapter 3: Assembly and software installation</b>	<b>7</b>
Step 1: Assembly	7
Step 2: Download iTero Element Flex software	8
Step 3: Make it Mine process	9
<b>Chapter 4: Operating instructions</b>	<b>10</b>
Initial power-up and boot	10
Web cam	10
<b>Chapter 5: Scanner handling, cleaning, and disinfection instructions</b>	<b>11</b>
Handling of the scanning unit (wand)	11
Handling of the scanning unit cable	11
Recommended best practices for cleaning and disinfecting	11
Cleaning and disinfectant materials for scanning unit and base unit	12
<b>Chapter 6: Changing sleeves between patients</b>	<b>13</b>
Cleaning and disinfecting the scanning unit (wand)	13
Replacing disposable sleeves	13
Scanner sleeves	14
<b>Chapter 7: Clinic LAN network guidelines</b>	<b>15</b>
Introduction	15
Preparations	16
Router guidelines	16
Firewall	16
Wi-Fi tips	17
Align hostname recommendations	18
<b>Appendix A: EMC declaration</b>	<b>19</b>
<b>Appendix B: Hardware specifications</b>	<b>20</b>

**Chapter 1:**

# Introduction

**About this operation manual**

The iTero Element Flex system is delivered as a proprietary, laptop-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**

iTerero Element Flex is a mobile optical impression system (CAD/CAM) used to record the topographical images of teeth and oral tissue. The system can be connected to laptops approved by Align Technology to reduce office space requirements and increase system mobility.

Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories.

iTerero Element Flex software is used with the iTero Element 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 scanning 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 Flex system**

The iTero Element Flex 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.

**Software installation instructions**

Please consult the list of approved laptops and approved Antivirus applications at [www.itero.com](http://www.itero.com).

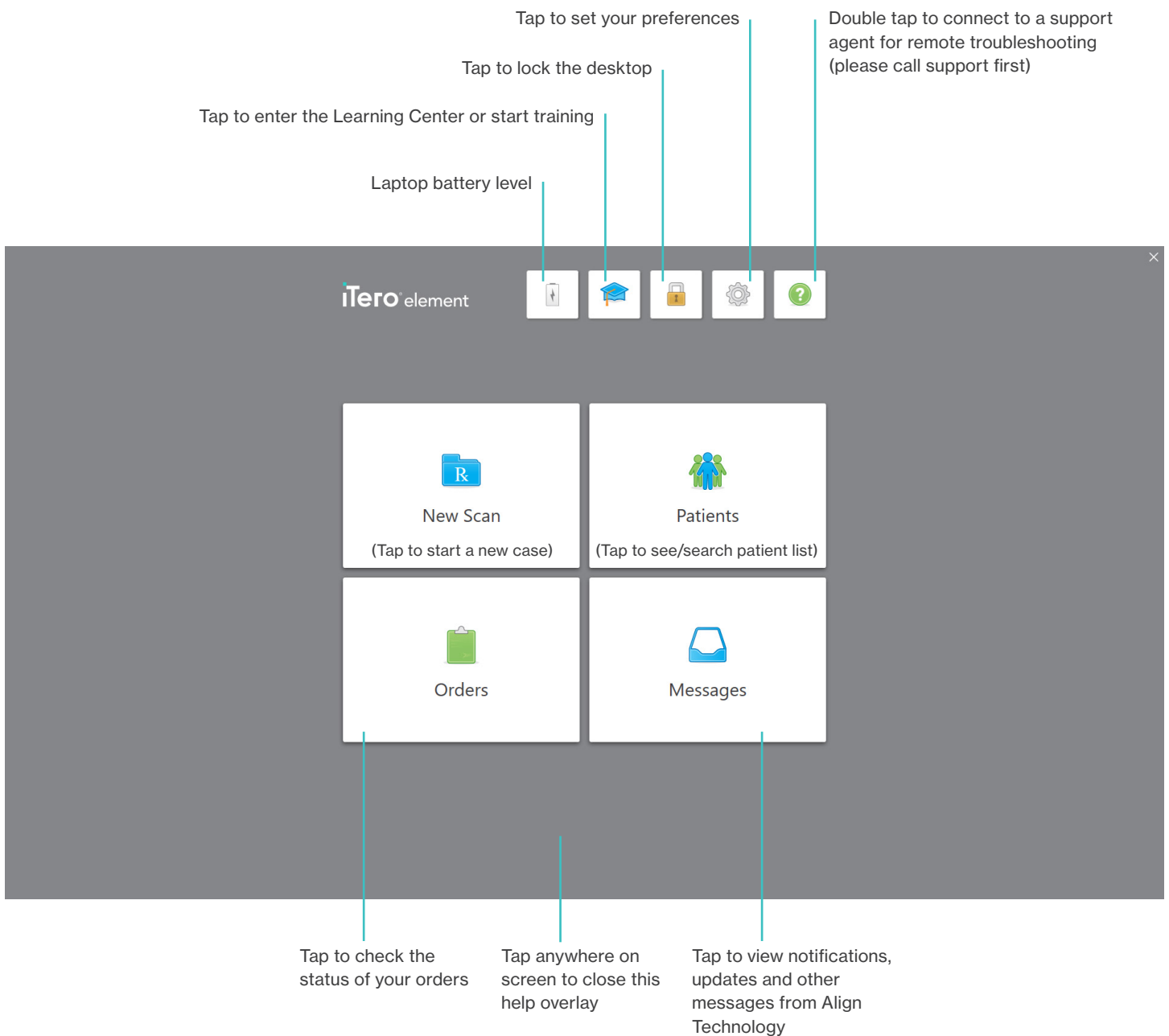
To ensure optimal performance use of the iTero application, only approved laptops must be used with the iTero Element Flex system.

### The iTero Element Flex user interface

The iTero Element Flex 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 laptop's touch screen and the wand buttons are used to respond to screen instructions during the scanning process.



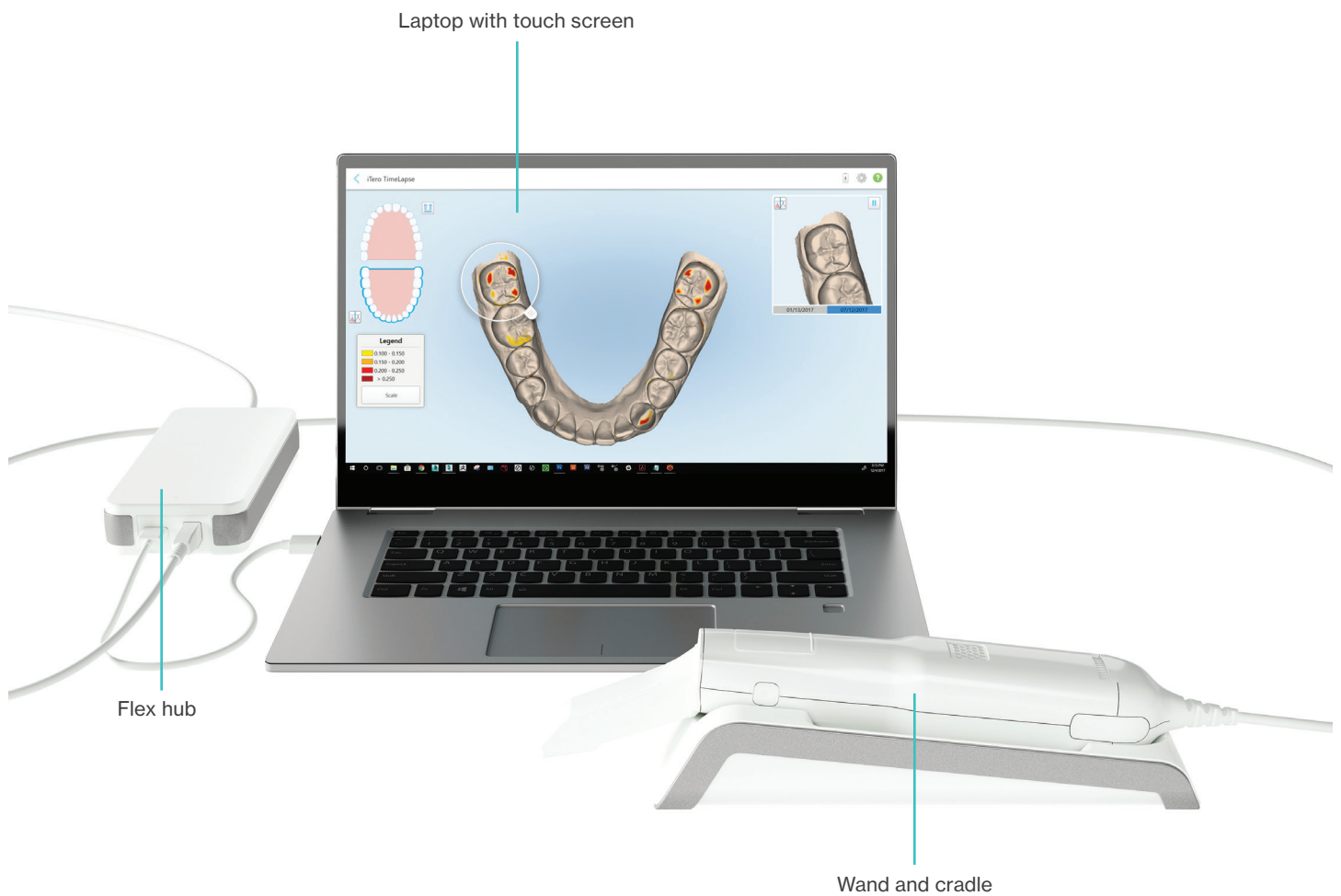
One tap on the question mark will enable a transparent Help overlay that will provide a brief overview. Please note that the Headset image appears instead of the question mark while in this view. Tap anywhere to close the help screen and return to the relevant screen.



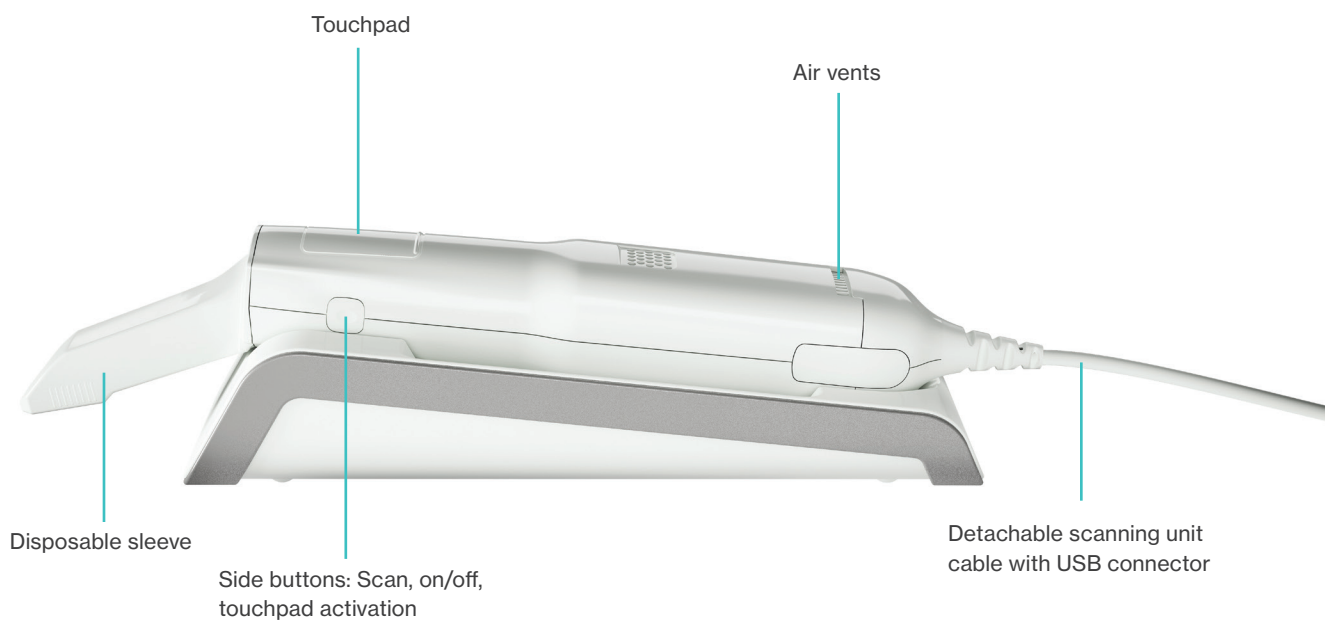
Chapter 2:

# Basic hardware features

## Front view of the system



Scanning unit (wand)



## Mobile system packaging (for transport)

### Transportation

Use the supplied case to move the system between offices.



### Moving the system

To ensure maximum system protection, it is recommended to move the system with care. Follow these instructions for relocating the system:

1. Attach the blue protective sleeve onto the wand.
2. Verify the scanning unit (wand) sits well inside the case.
3. Unplug the Flex hub and laptop AC power cables from the wall outlet.
4. Place all items in the case (see picture above).
5. Make sure the case is kept dry to protect the system components from humidity.

**Chapter 3:**

# Assembly and software installation

**Step 1: Assembly**

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



AC power

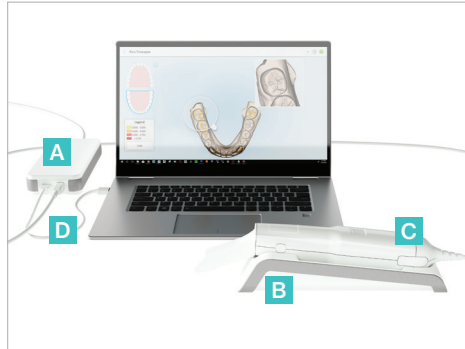


Wand  
(scanning unit)



USB port

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



1. Place the wand in the cradle



2. Connect hub power cord to the hub



3. Connect USB cable to the hub



4. Connect USB cable to the laptop



5. Connect wand cable to the hub



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



7. Final installation/iTero Element Flex system setup

**Two important notes:**

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

## Step 2: Download iTerero Element Flex software

For proper software installation and configuration of your iTerero Element Flex scanner, please ensure your iTerero wand is secure in the cradle and connected to the hub, and the hub is connected to the laptop. Please make sure your laptop is plugged into the AC wall socket during the entire software installation.

1. Laptop setup
  - A. Turn on the laptop.
  - B. Update the Windows to the latest version.
2. iTerero software download
  - A. Open the registered email inbox in the browser. Look for the email "Your iTerero was shipped" which includes instructions.
  - B. Click on the link to get to the page with software downloads.  
*or*
  - C. Alternatively, open the browser and go to (type the address into your browser) [download.itero.com](https://download.itero.com).
3. iTerero software installation
  - A. Click on the "Get started" button.
  - B. Run the downloaded installation file.
  - C. Follow the instructions on the screen to complete the download of the iTerero software.

It is highly recommended to regularly check for Windows updates and install them. Please enable updates.

It is also recommended to exit to Windows and shut down the computer at the end of each day to allow updates to install.

Before installing the iTerero Element Flex software for first time, please install all available Windows updates. New Windows computers should apply updates automatically.

To check for Windows Updates, open "Settings" (Windows key + I), choose "Update & Security", and then "Windows Update". Click "Check for updates" to see if there are new updates available.

**It is recommended to close other software programs while using the iTerero Element Flex system for scanning.**

Language English ▼

# Welcome

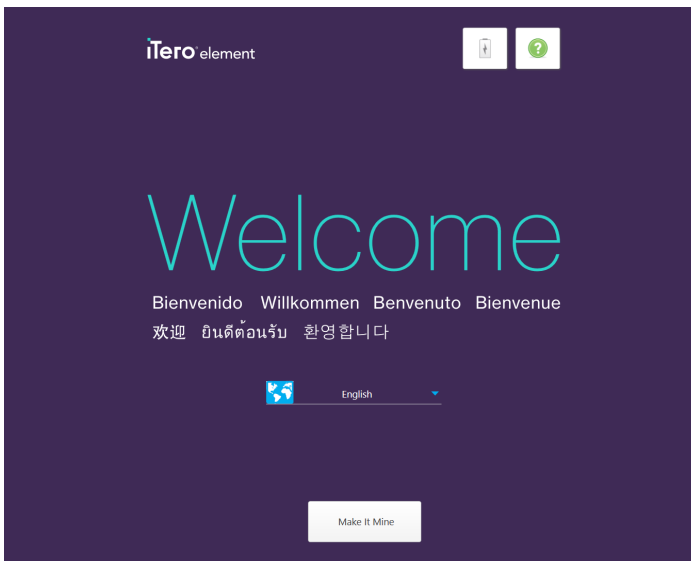
Bienvenido Willkommen Benvenuto Bienvenue

The installation process will take a few minutes to complete

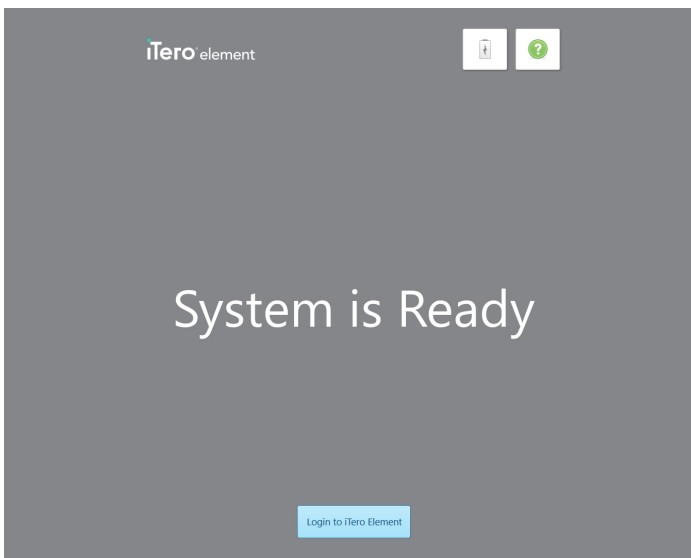
Step 1: Connect laptop with iTerero Flex hub and wand  
Step 2: Download and install iTerero software  
Step 3: Customize your account - Make it mine

[Get Started](#)

### Step 3: 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 and installation of the iTero Element Flex.

**Chapter 4:**

# Operating instructions

Multiple security controls are implemented into the scanner in order to provide a smooth and safe workspace for the user; anti-virus software is one of those controls. Hence, Align strongly recommends for anti-virus software to be downloaded onto the laptop.

Another security control is the users' Windows password. In order to meet the minimum security requirement, it is recommended to use a password that meets the following requirements:

1. At least 10 characters long
2. At least 1 uppercase character (A-Z)
3. At least 1 lowercase character (a-z)
4. At least 1 digit (0-9)
5. At least 1 special character (punctuation) – please note that a space is designated as a special characters as well
6. At most 128 characters - not more than 2 identical characters in a row (e.g., 111 or CCC not allowed)

Make sure the laptop is connected to an AC wall outlet, to ensure the battery level does not reach its low battery status, at which time scanning will no longer be possible.

To start iTero program:

1. Power up the laptop
2. Login to Windows application with your Windows local password (if required)
3. Double click the iTero Icon



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.

**Web cam**

Connect the web cam to the laptop following the product instructions.

**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.
- Avoid twisting, knotting, pulling or stepping on the cable, etc.
- 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 in between patients.**

To avoid cross-contamination, please take the required actions and means of protection for the laptop.

- Do not spray disinfectant directly on scanner system surfaces.
- Spray the disinfectant on a towel, or use disinfectant wipes for the scanning 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 cradle

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

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.

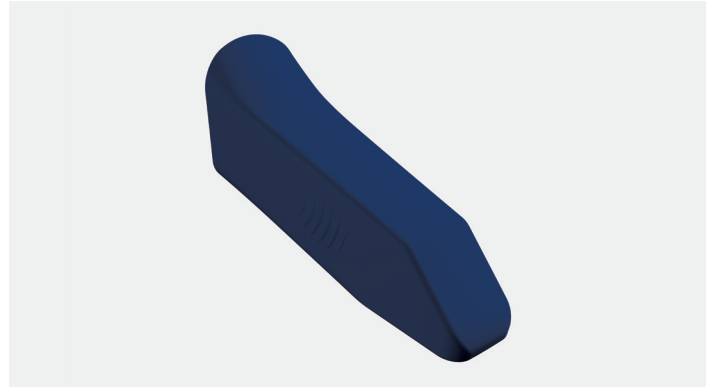
## Scanner sleeves

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 iTerero store [www.store.itero.com](http://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 iTerero 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](http://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 iTerero 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 iTerero 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 (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 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

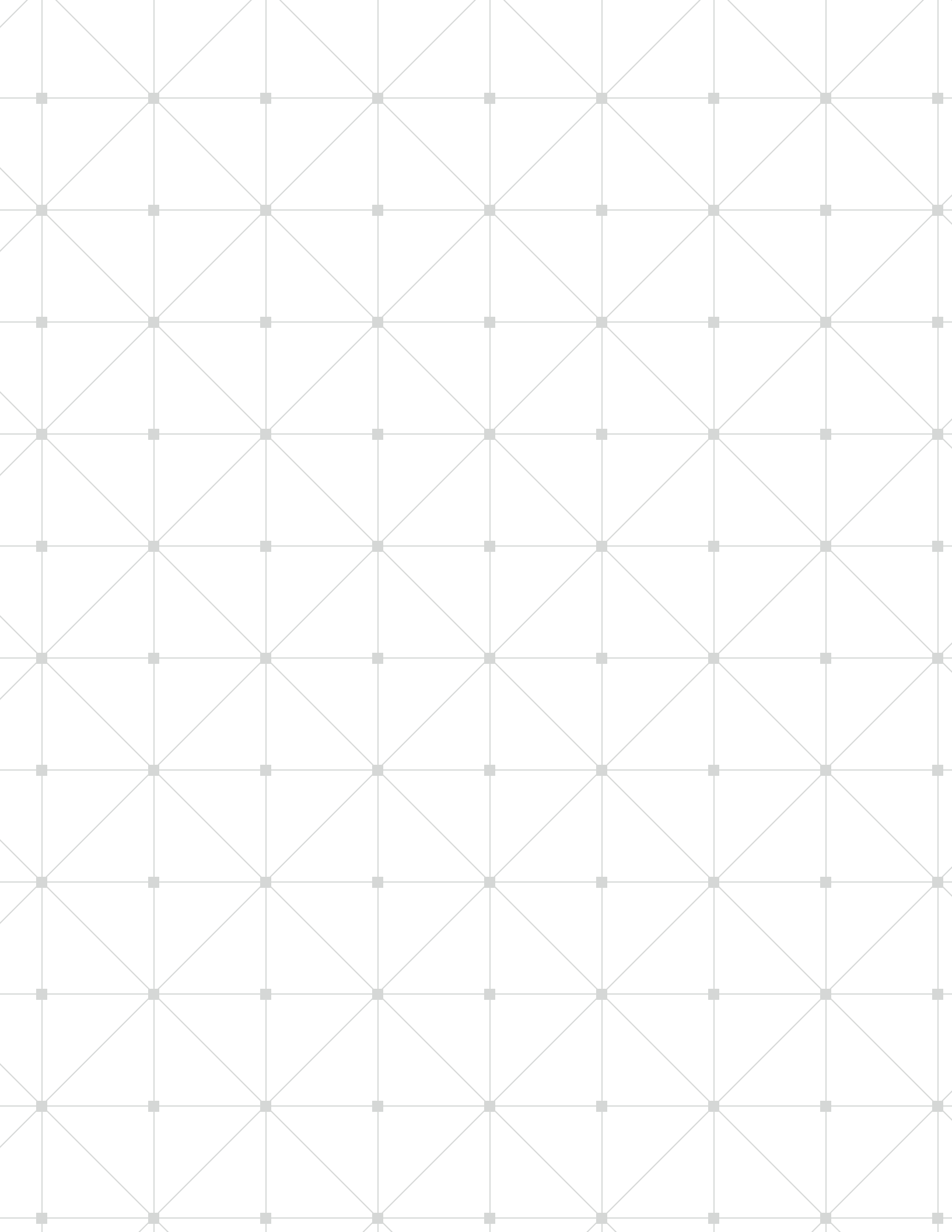
## Summary of EMC test results for iTero Element Flex

Test	Standard	Class / Severity level	Test result
<b>Documentation (IEC 60601-1-2 sections 4 and 5)</b>			
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
<b>Emission (IEC 60601-1-2 section 7)</b>			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B 230, 120 & 100 VAC mains @ 50 Hz; 220 VAC mains @ 60 Hz	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	230 VAC mains @ 50 Hz & 220 V @ 60 Hz	Complies
Voltage changes, voltage fluctuations and flicker test	IEC 61000-3-3	230 VAC mains @ 50 Hz & 220 V @ 60 Hz	Complies
<b>Immunity (IEC 60601-1-2 section 8)</b>			
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 230 VAC mains @ 50 Hz & 220 VAC mains @ 60 Hz; Tr/Th – 1.2/50 (8/20) ms	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0, 6.0 VRMS on 230 VAC mains & wand cable; 0.15÷ 80 MHz, 80% AM @ 1 kHz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 VAC & 100 VAC mains @ 50 Hz: 0% - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles on 220 VAC mains @ 60 Hz: 0% - 0.5 cycle & 1 cycle; 70% - 30 cycles; 0% - 300 cycles	Complies

**Appendix B:**

# Hardware specifications

Item	Description
Monitor	Laptop monitor
Scanner	Scanner emits red laser light (680nm Class 1) as well as white LED emissions.
Operating power	100-240VAC- 50/60 Hz – 40VA (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 Element Flex hub: Length: 206 mm (-8 in) Width: 94 mm (-3.7 in) Depth: 36.5 mm (-1.4 in)  iTero Element wand: Length: 338.5 mm (-13 in) Width: 53.5 mm (-2 in) Depth: 69.8 mm (-3 in)  Cradle: Length: 262 mm (-10 in) Width: 89 mm (-3.5 in) Depth: 52 mm (-2 in)  Case: Height: 326.5 mm (-13 in) Width: 455 mm (-18 in) Depth: 184 mm (-7 in)
Net weight	iTero Element Flex hub: -0.5 kg (-1 lbs) iTero Element wand: 0.47 kg (-1 lbs) Empty Case: -2 kg (-4.5 lbs)
Shipping weight	-8 kg (-17.6 lbs)





# iTero element flex

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

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

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