



OPERATION MANUAL



COPYRIGHT

Copyright © by Align Technology Inc. 2019 All rights reserved.

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

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

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

This manual describes the iTero® Element™ 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 manual 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



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

E-mail:
orthocadsupport@aligntech.com

EUROPEAN AUTHORIZED REPRESENTATIVE

Align Technology, B.V.
Zekeringstraat 41
1014BV Amsterdam
The Netherlands

CLASS 1 LASER COMPLIANCE



Class 1 Laser Product

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 Second Edition – 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 DU LASER CLASSE 1



Produit Laser de Classe 1

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

CONFORMITÉ CSA



Ce dispositif est conforme à la norme CSA pour le Canada et les États-Unis « UL Std No. 60601-1 Second Edition – Medical Electrical Equipment Part 1: General Requirements for Safety »

CONFORMITÉ FCC



Ce dispositif est conforme à l'Article 15 des Réglementations FCC et son fonctionnement est soumis aux conditions suivantes :

- 1) Ce dispositif ne doit pas causer d'interférences nuisibles.
- 2) Ce dispositif doit accepter toute interférence reçue, y compris des interférences pouvant causer un dysfonctionnement.

Avertissement FCC

Toute modification apportée au dispositif n'ayant pas été expressément approuvée par le fabricant peut annuler votre droit à utiliser ce dispositif d'après les Réglementations FCC.

CONFORMITÉ CEM

Cet appareil est conforme aux normes de sécurité CEM suivantes :

"IEC 60601-1-2 Dispositifs électromédicaux - Partie 1-2 : Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale : Phénomènes électromagnétiques - Prescriptions et essais"

SÉCURITÉ DU DISPOSITIF

Cet appareil est conforme aux normes de sécurité suivantes :

"IEC 60601-1 Dispositifs électromédicaux – Article 1 : Exigences générales pour la sécurité de base et les performances essentielles".

CONFORMITÉ CE



Ce dispositif est conforme à la directive 93/42/CEE relative aux dispositifs médicaux.

SYMBOLS

The following symbols may appear on iTero Element hardware components, and may also appear within this manual and other iTero Element 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 B. Any component on which this symbol appears is electric isolation type B.



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 manual.



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.

SYMBOLES

Les symboles suivants peuvent apparaître sur des composants matériels de l'iTero Element tout comme dans ce manuel et d'autres publications relatives à l'iTero Element.



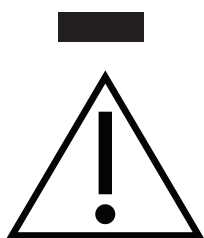
Lorsque ce symbole apparaît sur le dispositif, il est recommandé de vous reporter à ce manuel pour des informations sur l'utilisation appropriée de ce dispositif.



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



Il est nécessaire de collecter séparément les déchets d'équipements électriques et électroniques.



Attention : Ce symbole est utilisé pour souligner le fait qu'il existe des avertissements ou précautions spécifiques associés à ce dispositif. Lorsque ce symbole apparaît sur le dispositif, il est obligatoire de vous reporter aux informations concernant la sécurité dans ce manuel.



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

"Rx only"

ATTENTION : La Loi fédérale des États-Unis restreint la vente de ce dispositif par ou pour le compte d'un dentiste, d'un orthodontiste ou d'un professionnel dentaire agréé. Le système sert de dispositif de prescription médicale et devrait être utilisé uniquement par des prestataires de soins de santé qualifiés.



Fabricant du dispositif médical

SAFETY INSTRUCTIONS

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

- | | |
|--------------------------------------|--|
| Power Supply | <ul style="list-style-type: none"> Power is supplied to the system via an internal medical grade power supply. |
| Electric Warning | <ul style="list-style-type: none"> 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 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 | <ul style="list-style-type: none"> The system comes equipped with a Wireless LAN unit. |
| Safety Classifications | <ul style="list-style-type: none"> Type of protection against electrical shock: Class 1. Degree of protection against electrical shock: Type B. 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 | <ul style="list-style-type: none"> The system serves as a prescription medical device and should be operated by qualified health-care providers only. |
| Scanner Warnings | <ul style="list-style-type: none"> 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 holder with the probe facing to the rear side of the touchscreen so there will be no eye contact with the laser beam in any case. |
| Cleaning & Disinfection | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> The system should be unpacked and installed following Align Technology's instructions. |
| Work Environment | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 lire les consignes de sécurité.

- | | |
|---|--|
| Alimentation | <ul style="list-style-type: none"> • L'alimentation électrique est fournie au système via une alimentation interne pour le milieu médical. |
| Avertissement électrique | <ul style="list-style-type: none"> • Danger d'électrocution !! Seuls les techniciens Align autorisés peuvent retirer les panneaux et couvercles externes. Il ne contient aucune pièce réparable par l'utilisateur. • Afin d'éviter les risques d'électrocution, l' iTero® Element™ doit uniquement être connecté au secteur par une mise à la terre de protection. • Uniquement la webcam (approuvée par Align Technology) ou des clés USB peuvent être connectées au port USB à l'arrière du dispositif. |
| Réseau Local Sans Fil | <ul style="list-style-type: none"> • L'appareil est livré équipé d'une unité locale sans fil. |
| Classifications de Sécurité | <ul style="list-style-type: none"> • Type de protection contre l'électrocution : Classe 1. • Degré de protection contre l'électrocution : Type B. • Degré de protection contre la pénétration d'eau nuisible : Normal. • Dispositif ne convenant pas à une utilisation en présence de mélanges d'anesthésiques inflammables. • Mode de fonctionnement : Continu. |
| Dispositif de Prescription Médicale | <ul style="list-style-type: none"> • Le système sert de dispositif de prescription médicale et devrait être utilisé uniquement par des prestataires de soins de santé qualifiés. |
| Avertissements concernant le scanner | <ul style="list-style-type: none"> • Le scanner émet une lumière laser rouge (680 nm Classe 1) ainsi que de la lumière blanche via des DEL. Une utilisation normale du scanner ne présente aucun danger pour l'œil humain. Cependant, les praticiens devraient s'abstenir d'éclairer les yeux du patient directement avec le scanner. • Évitez de tordre le câble, de faire des nœuds, de tirer dessus ou bien de marcher dessus. • Lorsque le système n'est pas utilisé, l'unité de balayage devrait être placée dans le support prévu à cet effet avec la sonde tournée du côté de la face arrière du moniteur afin d'éviter tout contact entre le faisceau laser et les yeux. |
| Nettoyage et Désinfection | <ul style="list-style-type: none"> • Pour éviter toute contamination croisée, il est obligatoire de remplacer le manchon jetable en plastique après chaque session avec un patient et de désinfecter l'unité de balayage. • Jetez les manchons en plastique du scanner selon les procédures normalisées ou les réglementations locales concernant les déchets médicaux contaminés. |
| Déballage et Installation | <ul style="list-style-type: none"> • Le dispositif devrait être déballé et installé selon les instructions d'Align. |
| Environnement de Travail | <ul style="list-style-type: none"> • Le dispositif doit être déplacé d'une pièce à l'autre avec la plus grande précaution afin d'éviter de l'endommager en faisant preuve du plus grand soin. • Ne bloquez pas les ouvertures d'aération sur les unités de balayage et de base. • Le système est destiné à être utilisé en intérieur uniquement. Il ne doit pas être exposé directement à la lumière du soleil, ni à une chaleur excessive ou à l'humidité. |
| Interférence | <ul style="list-style-type: none"> • AVERTISSEMENT : Ce dispositif a été testé et est conforme aux exigences concernant les dispositifs médicaux d'après la norme EN60601-1-2. Cette norme est destinée à apporter une protection raisonnable contre des interférences nuisibles dans une installation médicale typique. Cependant, en raison de la prolifération d'équipements transmettant des radio-fréquences et d'autres sources de bruit électrique dans les environnements liés à la santé (téléphones portables, radios mobiles bidirectionnelles, appareils électriques), il est possible que des niveaux élevés d'interférences dues à la proximité ou à la puissance de la source entraînent une perturbation de la performance de ce dispositif. |
| General | <ul style="list-style-type: none"> • AVERTISSEMENT : Aucune modification de ce dispositif n'est autorisée. • AVERTISSEMENT : NE PAS UTILISER le moniteur en position horizontale ! |

TABLE OF CONTENTS

CHAPTER 1: Introduction	2
About this Operation Manual	2
Intended Use	2
Benefits of the iTero Element System	2
The iTero Element User Interface	3
CHAPTER 2: Basic Hardware Features	4
Front View of the System	4
Back View of the System	5
Custom Counter Stand	6
Scanning Unit (Wand)	7
CHAPTER 3: Operating Instructions	8
Initial Power-Up and Boot	8
End-of-Day Shut Down	8
Moving System within the Office	8
CHAPTER 4: AC Power Problems—Troubleshooting	9
Checking & Replacing Main Fuses	9
CHAPTER 5: Scanner Handling, Cleaning, and Disinfection Instructions	10
Handling of the Scanning Unit (Wand)	10
Handling of the Scanning Unit Cable	10
Recommended Best Practices for Cleaning and Disinfecting	10
Cleaning and Disinfectant Materials for Scanning Unit and Base Unit	11
CHAPTER 6: Changing Sleeves between Patients	12
Cleaning and Disinfecting the Scanning Unit (Wand)	12
Replacing Disposable Sleeves	12
Scanner Sleeves	13
APPENDIX A: EMC Declaration	14
APPENDIX B: Hardware Specifications	17

CHAPTER 1:

Introduction

About this Operation Manual

The iTero Element 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 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 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 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 System

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

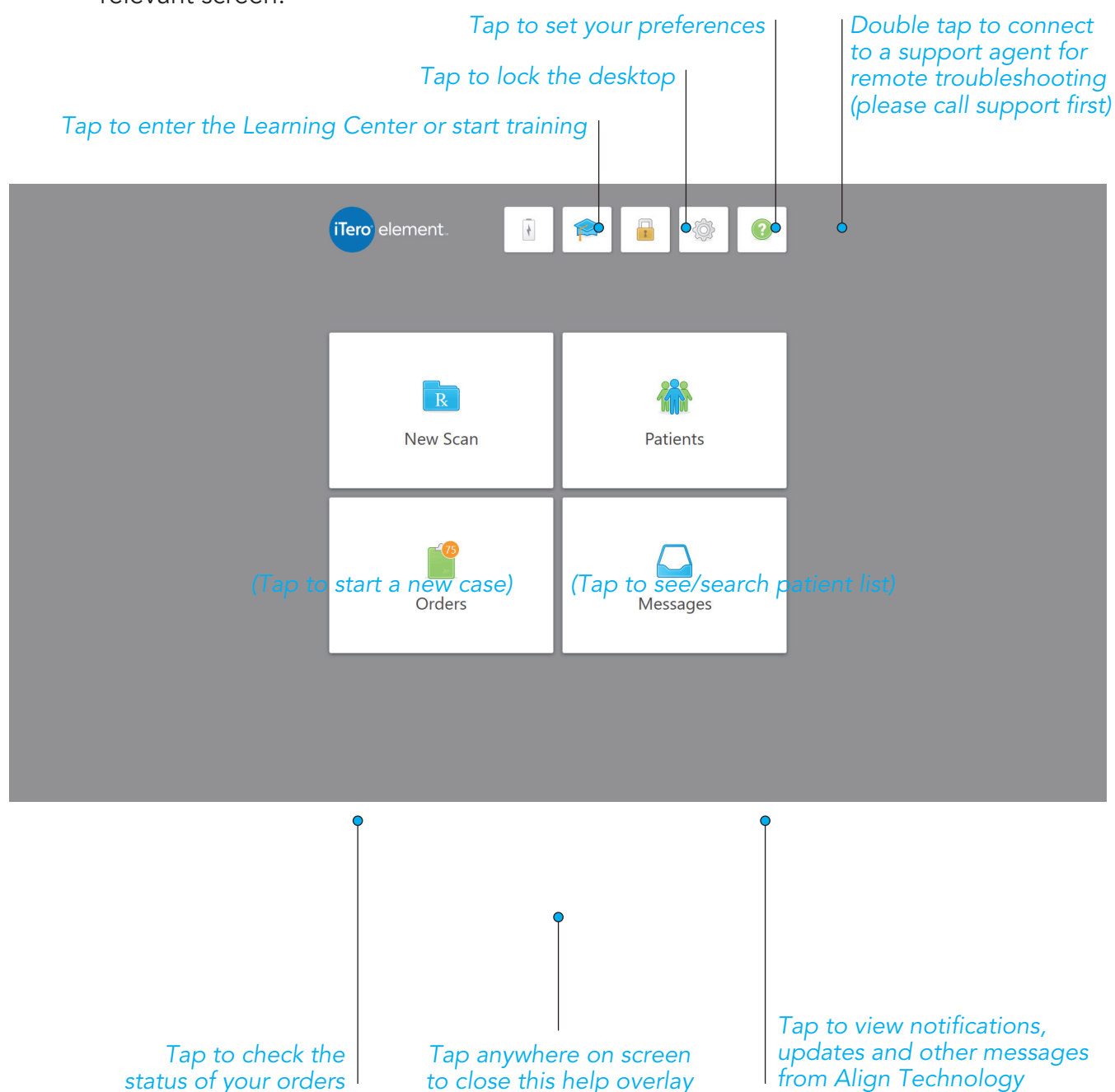
Refer to our website <http://www.itero.com> to learn how the iTero Service can enhance your business by increasing patient satisfaction, improving clinical outcomes, and enhancing office efficiency.

The iTero Element User Interface

The iTero Element 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.



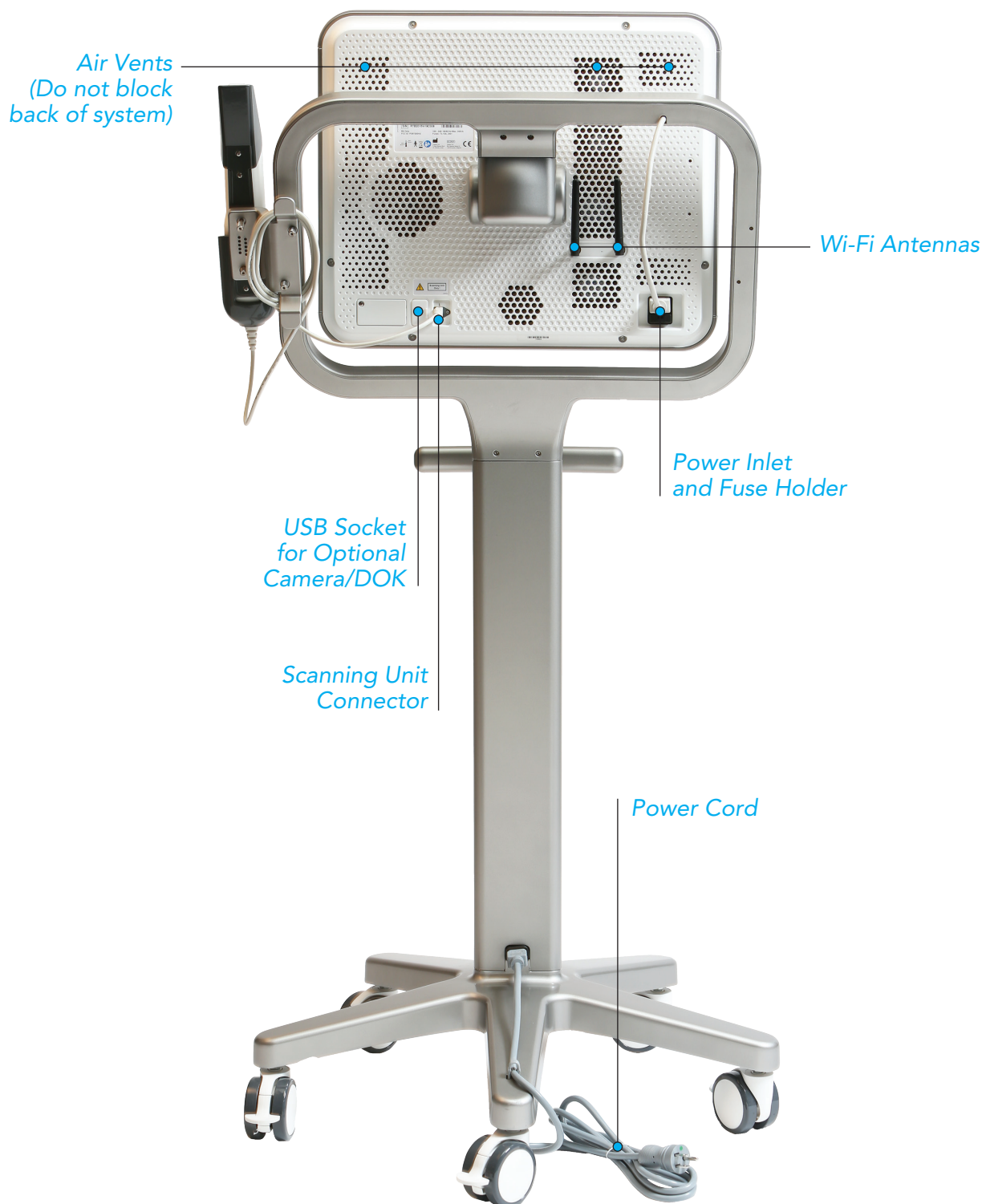
CHAPTER 2:

Basic Hardware Features

CUSTOM WHEEL STAND HARDWARE FEATURES: **Front View of the System**



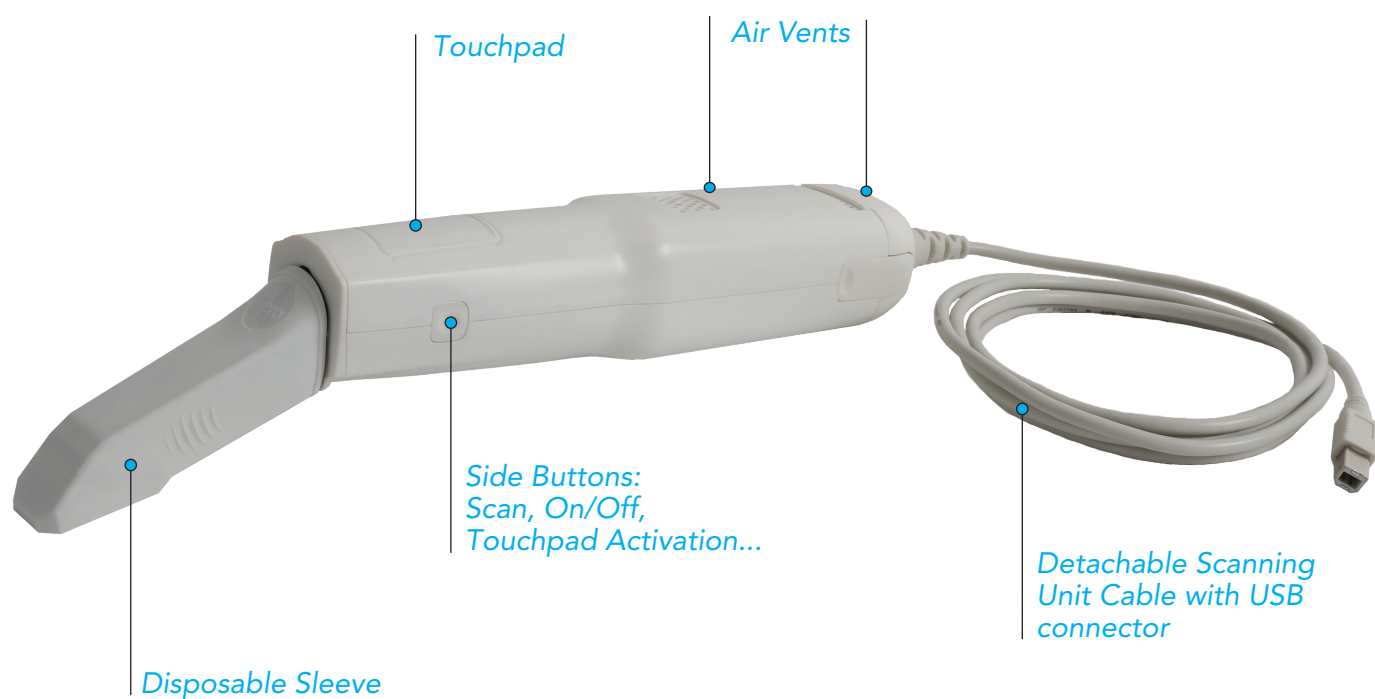
CUSTOM WHEEL STAND HARDWARE FEATURES: Back View of the System



CUSTOM COUNTER STAND: Front and Back View of the System



SCANNING UNIT (WAND)



CHAPTER 3:

Operating Instructions

INITIAL POWER-UP AND BOOT



- 1 Plug main cable into the Base Unit socket and other end into wall outlet;



- 2 Plug free end of Wheel Stand main cable into wall socket.



- 3 Press and release the power switch on the bottom of the screen frame, on the right side. The power LED will turn on.

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 Press and release the Power Switch on the bottom of the screen to shut down the system.
- 3 Unplug system from the wall outlet.
- 4 Move the system carefully using two people.
- 5 Place the system at its new location and it plug into a wall outlet.
- 6 Press and release the power switch to power ON the system.

CHAPTER 4:

AC Power Problems–Troubleshooting

CHECKING & REPLACING MAIN FUSES



- 1 Unplug Cord from Wall**
Unplug the power cord from the wall socket.



- 2 System Access**
Move system away from any wall to allow easy access to the power cord and fuse tray.



- 3 Disconnect Cord from Base Unit**
Unplug the power cord from the back of the system.



- 4 View Fuse Tray**
The fuse tray is located below the power socket.



- 5 Open Fuse Tray**
Push down on the small plastic part on the fuse tray to release it, then pull the fuse tray out.



- 6 Remove & Check Fuses**
Carefully remove each fuse from the tray. Check fuses visually (and with tester if available).



- 7 Replace Fuse**
If either fuse is blown or suspect, replace both fuses. (See "Fuse Type" specs at the end of the manual.)



- 8 Close Fuse Tray**
Close the fuse tray and insert cord firmly.

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 cable, etc.
- Between patient sessions, it is recommended to undo any twists and knots in order to relieve all tension from the scanner cable

RECOMENDED 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 (holder). 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



1 Step1

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



2 Step 2

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



3 Step3

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 may be ordered online in boxes of 25 from the iTero store.

www.store.itero.com

APPENDIX A:

EMC Declaration

Guidance and Align Technology's Declaration – Electromagnetic Emissions – for iTero Element

iTero Element is intended for use in the electromagnetic environment specified below.

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	iTero Element uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Complies, class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	iTero Element is suitable for use in all establishments, Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Align Technology's Declaration – Electromagnetic Immunity – for iTero Element

iTero Element is intended for use in the electromagnetic environment specified below.

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines NA	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iTero Element system requires continued operation during power mains interruptions, it is recommended that the iTero Element system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the A.C. mains voltage prior to application of the test level.

Guidance and Align Technology's Declaration – Electromagnetic Immunity – for iTero Element that is not Life-Supporting

The iTero Element is intended for use in the electromagnetic environment specified below.

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

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

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

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

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iTero Element system is used exceeds the applicable RF compliance level above, the iTero Element system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iTero Element system. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the iTero Element System that is not Life-Supporting

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{\sqrt{P}}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,01	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

APPENDIX B:

Hardware Specifications

ITEM	DESCRIPTION
Monitor	19" 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.
Mains Fuses	T3.15AL (3.15A, slow-blow) 250V glass tube fuses (5 x 20 mm).
Operating Power	100-240VAC- 50/60 Hz – 350VA (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 (69.3 kPa to 101.3 kPa) Altitude: 0 feet to 10,000 feet
Storage/Transportation Pressure & Altitude	Pressure: 430 mmHg to 760 mmHg (57.3 kPa to 101.3 kPa) Altitude: 0 feet to 15,000 feet
Relative Humidity	Operating: 40% to 70%; Storage: 30% to 90%
Dimensions	Base Unit: Height: 389 mm (~15 Inches) Width: 459 mm (~18 Inches) Depth: 123 mm (~5 Inches) Scanning Unit: Length: 338.5 mm (~13 Inches) Width: 53.5 mm (~2 Inches) Depth: 69.8 mm (~3 Inches)
Net Weight	Base Unit: 11 kg (~24 lbs) Scanning Unit: 0.47 kg (~1 lbs)
Shipping Weight	~37.5 KG (~83 LBS)



CORPORATE HEADQUARTERS

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

©2019 Align Technology, Inc.