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.

EMC compliance
This device complies with the following EMC standard:
"IEC 60601-1 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 standards:
"IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance."

CE compliance

Class 1 Laser Product
C US

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

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 is: http://b2btool.earn-service.com/aligntech/select.

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.

IEC 60417-5031: Direct current.

Wand (scanning unit).

RoHS (China).

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.

IEC 60417-5032: Alternating current.

USB socket.

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

Medical device manufacturer.

IEC 60417-5009: STAND-BY.

Order number.

Manufacturer’s batch code

Indicates the Authorized representative in the European Community.
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 I.
• 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.
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- The iTero Element 2 user interface 3

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Chapter 1: Introduction

About this operation manual

The iTero Element 2 system is delivered as a proprietary, PC-based workstation for performing intraoral 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.

Tap to set your preferences

Tap to view the battery charge status

Tap to check the status of your orders

Tap anywhere on screen to close this help overlay

Tap to view notifications, updates and other messages from Align Technology

Double tap to connect to a support agent for remote troubleshooting (please call support first)
Chapter 2: Basic hardware features

Custom wheel stand hardware features: Front view of the system

- Touch screen
- Power switch
- Power LED
- Scanning unit (wand)
- Scanning unit (cradle)
- Wheel base

Custom wheel stand hardware features: Back view of the system

- Scanning unit connector
- Wand cable connection
- Panel PC power cord
Chapter 3: Assembly instructions

Step 1: Assembly
Please follow the instructions below to assemble your iTero Element 2 scanner:

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 stand
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
1. Slide the battery into the battery slot and tighten the thumb screws.
2. Lift the HD screen to mount it.
3. Turn the scanner around and tighten the thumb screw to secure the HD screen.
4. Attach the power cable to the port labeled DC.
5. Slide the battery into the battery slot and tighten the thumb screws.
6. Lift the HD screen to mount it.
7. Turn the scanner around and tighten the thumb screw to secure the HD screen.
8. Attach the power cable to the port labeled DC.
10. Attach the power cable on the bottom of the wheel stand.
11. Attach the wand cable on the back of the HD screen.
13. Attach the magnetic back cover.
14. Place the wand into the cradle.
15. Attach the magnetic back cover.
16. Place the wand into the cradle.
17. Press button to switch on the scanner.
18. Attach the power cable on the bottom of the wheel stand.
19. On the bottom of the wheel stand, post and secure the cable with the clip.
20. Attach the web camera on the HD screen for remote training or support sessions.
21. Attach the power cable on the bottom of the wheel stand.
22. Plug in the webcam to the USB port at the bottom of the HD screen.
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.

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 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.

<table>
<thead>
<tr>
<th>Description</th>
<th>pH</th>
<th>Manufacturer P/N</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birex® Quat disinfectant wipes</td>
<td>7.6</td>
<td>BI-240</td>
<td>Biotrol Intl.</td>
</tr>
<tr>
<td>CaviCode AF</td>
<td>12.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CaviCode CaviWipe</td>
<td>12.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CaviCode CaviWipe 1</td>
<td>12.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clorox Healthcare® hydrogen peroxide</td>
<td>2-3</td>
<td>30828, 30829</td>
<td>Clorox Healthcare**</td>
</tr>
<tr>
<td>Clorox Healthcare® hydrogen peroxide</td>
<td>2-3</td>
<td>30824, 30825</td>
<td>Clorox Healthcare**</td>
</tr>
<tr>
<td>Opti-Cide 3% liquid</td>
<td>7.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opti-Cide 3% wipes</td>
<td>7.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPTIM 33TB liquid</td>
<td>2.5-3.5</td>
<td></td>
<td>SciCan Inc.</td>
</tr>
<tr>
<td>OPTIM 33TB wipes</td>
<td>2.5-3.5</td>
<td></td>
<td>SciCan Inc.</td>
</tr>
<tr>
<td>ProSpray ProSpray wipes</td>
<td>10</td>
<td></td>
<td>Certol</td>
</tr>
<tr>
<td>Webcon® alcohol prep pads</td>
<td>7</td>
<td></td>
<td>Medtronic</td>
</tr>
</tbody>
</table>
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](http://www.store.itero.com), where available.
**Appendix A:**

**EMC declaration**

**Summary of EMC test results for iTero Element 2**

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard</th>
<th>Class / Severity level</th>
<th>Test result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation (IEC 60601-1-2 sections 4 and 5)</td>
<td>section 4.1</td>
<td>--</td>
<td>Complex</td>
</tr>
<tr>
<td>General/requirements for EMC</td>
<td>section 5.1</td>
<td>--</td>
<td>Complex</td>
</tr>
<tr>
<td>External labels</td>
<td>section 5.2.1</td>
<td>--</td>
<td>Complex</td>
</tr>
<tr>
<td>Conformity of users’ manual</td>
<td>section 5.2.2</td>
<td>--</td>
<td>Complex</td>
</tr>
<tr>
<td>Accuracy of technical description</td>
<td>section 5.2.2</td>
<td>--</td>
<td>Complex</td>
</tr>
</tbody>
</table>

**Emission (IEC 60601-1-2 / EN 60601-1-2 section 7)**

| Conducted emission | CISPR 11 | Group 1 Class B 230, 120 & 100 VAC mains (50 Hz), 230 VAC mains (50 & 60 Hz) | Complex |
| Radiated emission | CISPR 11 | Group 1 Class B | Complex |
| Harmonic current emission test | IEC 61000-3-2 | 230 VAC mains (50 Hz & 220 V (60 Hz) | Complex |
| Voltage changes, voltage fluctuations and flicker test | IEC 61000-3-3 | 230 VAC mains & 220 VAC mains | Complex |

**Tolerance (IEC 60601-1-2 section 8)**

| Immunity from electrostatic discharge (ESD) | IEC 61000-4-2 | 8 kV contact discharges & 15 kV air discharges | Complex |
| Immunity from radiated electromagnetic fields | IEC 61000-4-3 | 10.0 V/m; 80 MHz - 2.7 GHz, 80% AM, 1 kHz | Complex |
| Immunity from proximity field from wireless communications equipment | IEC 61000-4-3 | List of frequencies, from 9 V/m up to 28 V/m, FM (85 Hz or 217 Hz), FM (1.1 kHz) | Complex |
| Immunity from electrical fast transient (EFT) | IEC 61000-4-4 | ±2.0 kV - on AC mains; 50/60 Hz, 100 kHz | Complex |
| Immunity from surge | IEC 61000-4-5 | ±2.0 kV / ±0.6 kV DM on AC mains; 50/60 Hz, 100 kHz | Complex |
| Immunity from conducted disturbances induced by radio-frequency fields | IEC 61000-4-6 | 3.0, 5.0 V/m, 230 VAC mains & wand cable, 0.35 - 60 MHz, 80% AM 1 kHz | Complex |
| 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 | Complex |

**Appendix B:**

**Hardware specifications**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor</td>
<td>21.5” monitor</td>
</tr>
<tr>
<td>Scanner</td>
<td>Scanner emits red laser light (650nm Class 3) as well as white LED emissions.</td>
</tr>
<tr>
<td>Wireless LAN</td>
<td>LAN card provides local network communications with wireless connectivity.</td>
</tr>
<tr>
<td>Operating power</td>
<td>100–240VAC / 50/60 Hz – 200VA (max)</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>18°C to 26°C / 64.4°F to 78.8°F</td>
</tr>
<tr>
<td>Storage/transportation temperature</td>
<td>-5°C to 50°C / 23° to 122°F</td>
</tr>
<tr>
<td>Operating pressure &amp; altitude</td>
<td>Pressure: 520 mmHg to 760 mmHg (~69 kPa to ~101 kPa)</td>
</tr>
<tr>
<td>Storage/transportation pressure &amp; altitude</td>
<td>Pressure: 430 mmHg to 760 mmHg (~57 kPa to ~101 kPa)</td>
</tr>
<tr>
<td>Net weight</td>
<td>iTero HD touch monitor: 8.3 kg (~18.3 lbs)</td>
</tr>
<tr>
<td>Shipping weight</td>
<td>-37.5 kg (~83 lbs)</td>
</tr>
</tbody>
</table>