IntraOp Alignment System™
INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The subject IntraOp Alignment (IOA) System consists of an optical tracking sensor, touchscreen computer, a mobile cart (stand) including an extension arm, and an electronics box with frame grabber, ports for video cables, power cables and external storage devices.

The subject IntraOp Alignment System is a software-based system that from one end interfaces with a mobile C-arm fluoroscope through a video cable and a frame capture device to receive fluoroscopic images as they are acquired, and from the other end connects to an optical position tracking sensor to track the position and orientation of a C-arm in real-time. By using subject IntraOp Alignment System along the side of mobile C-arm fluoroscopy equipment, the user of the system can combine multiple fluoroscopic images, as they are being acquired, into stitched long bi-planar radiographic images for intraoperative visualization and assessment. The user is required to identify the location of the spine in both bi-planar views to scale the image content and provide information regarding the depth of the operative anatomy. The user can then use the measurement tools available on the subject IntraOp Alignment System to visualize and assess the spinal alignment for intraoperative planning of the surgical procedure.

The IntraOp Alignment System is intended for use by trained healthcare professionals, and appropriately trained clinical and non-clinical personnel. The IntraOp Alignment System device is intended for use in operating room environments of hospitals and surgical centers. System setup may be performed by trained non-clinical personnel. The intended patient population for the IntraOp Alignment System is adults.

INDICATIONS FOR USE:

The IntraOp Alignment System is intended for use in applications where a mobile C-arm fluoroscope is incorporated to aid in diagnosis and treatment during spinal surgery.

The IntraOp Alignment System is intended to assist healthcare professionals in viewing, storing and measuring spinal alignment assessment images at various time points during surgery as well as planning spinal surgical procedures.

The IntraOp Alignment System is intended for use with patients aged 18 years or older.

GENERAL CAUTIONS

⚠ Do not block the line of sight between the tracking sensor and tracking markers during use.

⚠ Return the C-arm to default rotation settings prior to starting the imaging process.

⚠ Do not move the IOA System during imaging. If the IOA System has been moved, images should be retaken.

⚠ Do not move the patient during imaging. If the patient or bed has been moved, images should be retaken.

⚠ The IOA System is an accessory to a C-arm. The C-arm monitor should always remain in the direct line of site of the physician so that the original x-ray images can be referred to at any time.

⚠ If a captured image is of extremely poor quality, DO NOT attempt to try to use it with IOA.

⚠ The IOA System cannot substitute for sound medical judgment. If the image displayed is not of sufficient quality, DO NOT attempt to perform the procedure using this image.

⚠ Do not apply excessive force to any of the IOA hardware.

⚠ Do not use unsupported connection ports.

⚠ Do not use the system if the NDI position tracking sensor has registered a “bump detected” error. If a bump has been detected, NDI recommends performing an accuracy assessment procedure with the NDI Accuracy Assessment Kit (AAK), to confirm that the Position Sensor is still calibrated. If the system fails the NDI Accuracy Assessment Kit (AAK) check, then the position sensor should returned to Alphatec for recalibration since the recalibration.

⚠ To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ Do not use unsupported connection ports.

⚠ Unauthorized access to the ports, including Wi-Fi network, of the physical system creates the potential for malware to be uploaded which could result in the system malfunctioning or becoming inoperable.

⚠ Ensure that the hospital network is secure and has the necessary firewalls to prevent unauthorized access that could lead to system vulnerabilities.

⚠ It is critical that the C-arm image setting, including the image magnification, rotation, and mirroring be reset during C-arm positioning. These settings should stay unchanged during imaging, or the images produced by the system will be rendered incorrect.

If using a GE OEC Elite Image Intensifier C-arm, adjust the system settings to reset to home when starting a new case. Then rotate the image using the clockwise rotation button as far as the system will allow before creating a new case on the C-arm to confirm that that the mechanical rotation is returned to exactly 0 degrees.

If using a GE OEC One CFD Flat Panel C-arm, confirm that the rotation setting is set to 0 degrees on the screen before capturing images.

⚠ The bed height cannot be adjusted during imaging.

⚠ Do not use the system if the NDI position tracking sensor has registered a “bump detected” error. If a bump has been detected, NDI recommends performing an accuracy assessment procedure with the NDI Accuracy Assessment Kit (AAK), to confirm that the Position Sensor is still calibrated. If the system fails the NDI Accuracy Assessment Kit (AAK) check, then the position sensor should be returned to Alphatec for recalibration since the recalibration.

- The camera extension must either be fully extended or fully collapsed to avoid the extension arm dropping during use.
- Do not block the line of sight between the tracking sensor and tracking markers during use.
- Return the C-arm to default rotation settings prior to starting the imaging process.
- Do not move the IOA System during imaging. If the IOA System has been moved, images should be retaken.
- If a captured image is of extremely poor quality, DO NOT attempt to try to use it with IOA.
- The IOA System cannot substitute for sound medical judgment. If the image displayed is not of sufficient quality, DO NOT attempt to perform the procedure using this image.
- Do not move the patient during imaging. If the patient or bed has been moved, images should be retaken.
- Software does not allow the user to progress to evaluation until depth correction is performed using the “Spine & Pelvis” or “Spine Only” tool. Depth correction can be performed using the “Calibrate” button.
- Maintain minimum separation distances of 30 cm between the IOA system and portable RF communication equipment. Performance of the IOA system might degrade if proper distance is not maintained during use of Wi-Fi features.

CYBERSECURITY RELATED CAUTIONS

- Unauthorized access to the ports, including Wi-Fi network, of the physical system creates the potential for malware to be uploaded which could result in the system malfunctioning or becoming inoperable.
- Ensure that the hospital network is secure and has the necessary firewalls to prevent unauthorized access that could lead to system vulnerabilities.

USER CONSENT STATEMENT

By using the IntraOp Alignment System for a surgical procedure, the user consents to the cybersecurity related cautions outlined above.

MRI SAFETY INFORMATION

The IntraOp Alignment System is considered “MR Unsafe.” “MR Unsafe” items pose unacceptable risks to patient, medical staff, or other persons within the MR environment. Keep the system away from magnetic resonance imaging (MRI) equipment.

OPTICAL RADIATION SAFETY

The tracking sensor illuminators emit invisible infrared radiation with a pulsed duration of up to 2.2 ms and 4.4% duty cycle resulting in a maximum average measured power of 127 µW. The tracking sensor has been assessed and found not to pose a potential hazard to the eye under any foreseeable viewing condition. The tracking sensor emits IR light that may interfere with IR-

controlled devices. It is recommended that system be tested if you intend to use it in an environment where other IR-controlled devices are in use.

The tracking sensor positioning laser is a Class 2 laser, with a wavelength of nominally 650 nm (645 nm to 665 nm) and a maximum output of 1 mW. The Polaris Vega System containing a positioning laser conforms to the following standards:

- ANSI Z136.1 (2014)
- IEC 60825-1 (2014) and IEC 60825-1 (2007)
- FDA/CDRH 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CLEANING, DISINFECTION, AND MAINTENANCE:

Maintenance:

Responsibility for maintenance of the security of any sensitive data entered the IOA PC either in the application or otherwise lies solely with the user.

Contact ATEC Customer Service in the instance that any cyber incident occurs.

The expected service life of the device is 5 years. In a solid-state system, there is no need for routine mechanical maintenance. However, Alphatec recommends that each unit should sent to be serviced by the manufacturer on a yearly basis for routine review, or at any time if there is physical damage, system dysfunction or when recommended by ATEC service technician.

Alphatec requires that the system undergo a yearly routine replacement of tracking markers and camera calibration check performed on-site by an ATEC service tech.

Note: Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of system components.

The IOA System may gradually fill its own memory with study information. If the IOA system is displaying a “Hard Disk Filling Up” notification, study files should be removed by an ATEC service rep at that time.

Camera calibration and marker registration is to be performed by a system administrator on a recurring yearly basis.

Cleaning & Disinfection

Cart

Use only 70% isopropanol solution and a soft lint-free cloth to remove handling smudges from the cart. Other fluids may cause damage. Do not use any paper products for cleaning. Paper products may cause scratches.

Inspect each cart to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

Cleaning and inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal prior to each use.

Computer
During normal use of the POC (Point-of-Care Terminal), also referred to as the computer, the device may become dirty and should be regularly cleaned.
Steps:
1. Disconnect this equipment from any AC outlet before cleaning. Use a damp cloth. Do not use liquid or spray detergents for cleaning and keep this equipment away from humidity.
2. Prepare cleaning water.
3. Wipe the POC with a clean cloth that has been moistened in the cleaning solution.
4. Wipe thoroughly with a dry clean cloth.

- Do not immerse or rinse the POC or its peripherals. If liquid is accidentally spilled on the device, disconnect the unit from the power source. Contact IT support regarding the continued safety of the unit before placing it back in operation.
- Do not spray cleaning agent on the chassis.
- Do not use disinfectants that contain phenol.
- Do not autoclave or clean the POC or its peripherals with strong aromatic, chlorinated, ketone, either, or ether solvents, sharp tools, or abrasives. Never immerse electrical connectors in water or other liquids.

Inspect each computer to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

Cleaning and inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal prior to each use.

If one of the following situations arises, have the equipment checked by ATEC field representative.

- The power cord or plug is damaged.
- Liquid has penetrated into the equipment.
- The equipment has been exposed to moisture.
- The equipment does not work well, or not working according to the user manual.
- The equipment has been dropped and damaged.
- The equipment has obvious signs of breakage.

Tracking Markers
Use only 70% Isopropyl Alcohol, bleach and water (1:25 mixture), Virex II 256, MadaCide FD, or CaviCide and a soft lint-free cloth to remove handling smudges from the tracking markers. Other fluids may cause damage to the illuminator filters. Do not use any paper products for cleaning. Paper products may cause scratches on the illuminator filters.

Inspect each marker to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Inspect markers for any other damage, wear, and/or corrosion.

Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal prior to each use.

NDI Camera (Position Tracking Sensor)
Use only 70% isopropanol solution and a soft lint-free cloth to remove handling smudges from the NDI Camera. Accel TBWipes and Meliseptol can also be used. Other fluids may cause damage to the illuminator filters. Do not use any paper products for cleaning. Paper products may cause scratches on the illuminator filters.

Inspect each camera to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.

Cleaning and inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal prior to each use.

STORAGE AND POWER SUPPLY

Classification: Class 1
Power Supply: 120 VAC, 60 Hz (input); 12 VDC, 2.5A (output)
Mode of Operation: Continuous
Power Consumption: < 150 W
Operating Environmental Limits:
Temperature: 50°F (10°C) to 104°F (40°C)
Relative Humidity: 30%–75%
Altitude: Up to 2000 meters above sea level
Atmospheric pressure: 700 hPa to 1,060 hPa
Transport and Storage:
Temperature: -40°F (-40°C) to 158°F (70°C)
Humidity Range: 10–100%, including condensation
Atmospheric Pressure: 942 hPa to 1,060 hPa

DECOMMISSIONING

User will be notified when the IOA System has reached end of life and decommissioning is required. During decommissioning, all sensitive and confidential data will be removed from the device.

REPROCESSING OF REUSABLE INSTRUMENTS:

Reprocessing is not applicable to IntraOp Alignment System.

STERILIZATION AND RESTERILIZATION:

Sterilization and resterilization is not applicable to IntraOp Alignment System.

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING / REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com
For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc., Customer Service directly customerservice@atecspine.com.

℞only CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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