

VEA Align

cSVA 14 mm

C2-C7 -21°

T1 Slope 43°

L1-L4-S1 0% 100%

L1-S1 -9°

L4-S1 -9°

PI-LL 52°

SVA 91 mm

PT 41°

SS 20°

PI 61°

TPA 41°

Instructions for Use

LL Dist

Knee Flexion R 14°

Knee Flexion L 12°

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NOTE

ANY PERSONAL DATA APPEARING IN THE SCREEN CAPTURES OF THIS DOCUMENT IS FICTIONAL.

**WARNING**

THE INSTRUCTIONS FOR USE MAY BE UPDATED AT ANY TIME BY THE MANUFACTURER. TO BENEFIT FROM THE LATEST CONTENT, ALWAYS CONSULT THE VERSION AVAILABLE ONLINE.

NOTE

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Introduction

VEA Align software is an online medical device accessible from the EOS Insight platform at the following address: <https://eos-insight.com/> from the United States.

Using the VEA Align application requires training by a qualified employee from Alphatec Spine or EOS imaging.

The VEA Align Instructions for Use is available in an electronic version as a PDF from the page <https://atecspine.com/ifu-documentation/> of the ATEC website. The functions of VEA Align are described in two dedicated user manuals that are available upon request.

A PDF version of the User Manual can be sent by contacting EOS imaging (see “Contact Us” section). Additionally, a paper version of the Instruction for Use or the User Manual can also be sent by contacting EOS imaging (see “Contact Us” section).

In the event of a minor software update that does not require additional training, the user will receive a report by email listing the changes included in the new version available.

Indications for Use

This cloud-based software is intended for orthopedic applications in both pediatric and adult populations.

2D X-ray images acquired in EOS imaging’s imaging systems is the foundation and resource to display the interactive landmarks overlaid on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment.

For additional assessment, alignment parameters compared to published normative values may be available.

This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older.

Clinical judgment and experience are required to properly use the software.

NOTE

THE PRODUCT OPERATES IN TWO MODES: (1) ALIGNMENT ASSESSMENT AND (2) 3D.

ALIGNMENT ASSESSMENT MODE USERS MAY ADJUST INTERACTIVE LANDMARKS DISPLAYED ON THE 2D BIPLANAR X-RAY IMAGES IN THIS MODE. THE INITIAL SIZING AND PLACEMENT OF THE INTERACTIVE LANDMARKS ARE BASED ON A 3D RECONSTRUCTION MODEL BUILT FROM THE 2D BIPLANAR X-RAY IMAGES. THE 3D RECONSTRUCTION MODEL IS NOT VISIBLE TO THE USER; HOWEVER, THE ADJUSTMENTS TO THE INTERACTIVE LANDMARKS WILL UPDATE THE CLINICAL PARAMETERS FOR ALIGNMENT ASSESSMENT.

3D MODE USERS WILL ADJUST HANDLES ASSOCIATED WITH THE VISIBLE 3D RECONSTRUCTION MODEL, BUILT FROM 2D BIPLANAR X-RAYS IMAGES. ADJUSTMENT OF THE 3D RECONSTRUCTION MODEL WILL UPDATE 3D LANDMARKS USED FOR CLINICAL ALIGNMENT MEASUREMENTS.

Target Population

The device is indicated only for patients 7 years and older.

Type of Users

VEA Align Alignment Assessment mode is designed for surgeons and clinical staff, such as physician assistants, who possess the requisite training and credentials for treating orthopedic patients. Individual hands-on training will be provided for each end user utilizing the application.

VEA Align 3D mode is designed for 3D Services team members. Individual hands-on training will be provided for each end user utilizing the application.

Precautions for Use

**IMPORTANT**

READ THE USER MANUAL CAREFULLY BEFORE USING.

Contraindications

VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.) and supernumerary/missing vertebrae.

Warnings

Prerequisites and Context of Use

VEA Align should not be used as the sole basis for making clinical decisions relating to patient diagnosis, treatment, or care.

**LIMITATIONS**

THE 3D RECONSTRUCTION MODELS PROVIDED BY VEA ALIGN IN 3D MODE ARE DESIGNED TO DISPLAY THE SPATIAL RELATIONSHIP BETWEEN ANATOMICAL STRUCTURES AND ARE UNABLE TO HIGHLIGHT LOCAL BONE ALTERATIONS SUCH AS: BONES WITH SIGNIFICANT CHANGES IN GEOMETRY FOLLOWING SURGICAL INTERVENTION; FRACTURES; OSTEOPHYTES; FIBROCARILAGE CALLUSES. THESE 3D RECONSTRUCTION MODELS CAN BECOME INACCURATE AND EVEN IMPOSSIBLE WHEN ANATOMICAL STRUCTURES CANNOT BE IDENTIFIED AS SUCH IN THE FOLLOWING CASES: PROSTHESES OR INSTRUMENTS MASKING OR REPLACING ANATOMICAL MARKERS, CERTAIN PATHOLOGICAL CONDITIONS THAT ALTER THE BONE COMPOSITION, SUCH AS OSTEOPOROSIS.

Software Operation

The browser may crash and lose WebGL functionality, making alignment evaluation impossible. WebGL enables 3D elements to be managed in the browser. Software detects WebGL accidents and proposes, through an information message, to relaunch the alignment application to continue.

Precision on Values

All values displayed in the software are rounded to the nearest degree or millimeter.

Saving**WARNING**

WHEN SAVING, IT IS IMPORTANT TO KEEP THE BROWSER OPEN AND AVOID REFRESHING THE PAGE OR SHUTTING DOWN THE COMPUTER UNTIL THE PROCESS CONCLUDES.

Possible Secondary Effects

There are no known side effects associated with the use of VEA Align.

Patient Positioning

VEA Align outputs with the patient in a seated position may be inaccurate.

Minimal Configurations

VEA Align should be used with the minimal configuration specified in this document. EOS imaging cannot guarantee the proper functioning of VEA Align if minimal configuration is not met.

VEA Align is not designed for use on mobile devices.

System Input Requirements

The software algorithm exclusively uses biplanar 2D X-ray images. Software compatibility is limited to the following imaging systems:

- EOS imaging systems with a software version 1.7.3 and higher.
- EOSedge imaging systems with a software version 2.0.4 and higher.

Imaging requirements:

- Full spine or full body protocols

- Single biplanar image acquisition
- The following DICOM fields must be completed:
 - Referring Physician
 - Date of Birth
 - Patient Name
 - Patient ID

Advised Configurations

The minimal configuration of the user's computer is the following:

- A stable internet connection is required (see "Internet Configuration" section).
- With Windows 10 or 11: Google Chrome in version 121 or higher, and Edge in version 121 or higher.
- With Mac OS Monterey or Ventura: Google Chrome in version 121 or higher.

It is the user's responsibility to keep his/her web browser up to date for better functioning of the software.



WARNING

FOR OPTIMAL USE OF VEA ALIGN, THE WEB BROWSER AND COMPUTER ZOOM MUST BE SET TO 100%.

Screen Resolution

EOS imaging cannot guarantee the full display of the interface on screens that do not meet the minimum required resolution.

The minimum screen resolution ensuring full display of the interface is 1366 x 768.

NOTE

HD SCREENS ARE COMPATIBLE WITH THE APPLICATION.

Mouse and Trackpad

An optical mouse is recommended for better software use. A trackpad may be sufficient (in Mac and PC environments) but not recommended. The use of a "Magic Mouse" is not recommended (in the Mac environment).

NOTE

THE "TRACKPAD" DRIVERS MUST BE UP TO DATE TO ZOOM INTO THE SOFTWARE. OTHERWISE, IT WOULD ZOOM IN THE BROWSER WINDOW (UNWANTED EFFECT).

Internet Configuration

A stable high-speed internet connection is required: DSL 100Mb/s connection or higher, Wi-Fi or Ethernet.

NOTE

OTHER CONNECTIONS SUCH AS A 5G/4G/3G CONNECTION CAN BE USED, BUT THEY MUST BE STABLE. THE USER MAY THEN EXPERIENCE A RELATIVELY LONG LOAD TIME FOR THE SOFTWARE.

Web Browser Cache

Complete instructions regarding cache management to ensure the proper functioning of VEA Align.

EOS imaging cannot guarantee the proper functioning of VEA Align if instructions are not followed correctly.

When a new version of the software is deployed, it is strongly recommended that the web browser cache be emptied. The “Appendix 1: Clearing your browser cache” explains how to perform this operation.

Enabling Hardware Acceleration

It is possible to improve the fluidity of some browsers by activating the hardware acceleration of the computer.

The following are the methods to be used for each browser:

Google Chrome:

- Type `chrome://settings/` in the address bar, then press Enter.
- A web page opens. At the bottom click on “System”
- Enable “Use hardware acceleration when available.”

Microsoft Edge:

- Type `edge://settings/profiles` in the address bar, then press Enter.
- A web page opens. At the bottom click on “System and performance”
- Enable “Use graphics acceleration when available”

Security Recommendations

The use of VEA Align does not require any additional software on the user's computer except an up-to-date web browser.

VEA Align provides access to sensitive patient health information (PHI), and the user should be mindful while using VEA Align. The user is responsible for the security aspects of their computer.

The following section provides common recommendations about security on the web that applies to the use of VEA Align.

User Credentials

VEA Align requires users to login before accessing any data or resources. An automatic logout is configured (30 minutes of inactivity).

Each user has a unique account created when purchasing VEA Align. Accounts and credentials shall not be shared among multiple users.

VEA Align uses the following security measures to protect accounts:

- User must define strong password:
 - The size of the password must be between 8 and 72 characters and include 3 out of the 4 criteria below:
 - Has at least one uppercase
 - Has at least one lowercase
 - Has at least one number
 - Has at least one symbol (!@#\$%^&*()_+~`{|}~:~";~'~",~.<~/?)
- Accounts use multi-factor authentication:
 - The user identity is verified by sending a message, or notification, to the user's phone when attempting to login.
 - The user's phone number is specified when creating an account.
 - The multi-factor authentication uniquely identify your device when you first enroll. If you've lost your phone, reach out to your representative, or account administrator to enroll a new device.

ATEC and EOS imaging employees do not have access to user passwords, and in any event, would never ask users to provide their password. If this happens, immediately contact your ATEC/EOS representative, or use the contact information available in the "Contact Us" section.

User Environment

The use of an auto-updated browser is recommended.

The user must respect the common recommendations about security on the web:

- Apply security updates to the user's computer as soon as they are available
- Use antivirus software on the user's computer

- Download applications only from official websites
- Don't diffuse any information, especially about application's access and patient data on social networks
- Separate personal and professional uses
- Avoid public or unknown Wi-Fi networks

The surgical planning application temporarily stores information on the user's computer to display information in the web-application.

Follow your organization policy to decommission the computer when no longer in use. At minimum, you must clear your browser cache and delete your user account.

User Access

VEA Align implements HTTPS protocol for communication between the user's web browser and the application's server. The protocol encrypts end-to-end communication to ensure confidentiality and integrity of information.

The user must respect the common recommendations about security on the web:

- Use only the following address to access the application: **<https://eos-insight.com/>**
- Make sure that the connection uses HTTPS protocol to access the application
- Log out from the application after each use

A TEC and EOS products use a trusted certificate authority to enable https. If your browser notifies an untrusted certificate when using VEA Align, close your browser, and contact immediately your ATEC/EOS representative, or use the contact information available in section "Contact Us" below.

The surgical planning application monitors user's connection on the web application. The security measures include:

- Bot protection: identifies if an autonomous program tries to login on the application. When triggered, an additional captcha is required on login;
- Brute-force protection: identifies if an attacker tries to multiple attempts to guess credentials. When triggered, user's account is blocked. Please reach out to your representative, or account administrator to unblock your account.

Application's Servers

VEA Align and the EOS Insight platform are web applications hosted and deployed on a datacenter certified for hosting Patient Health Information (PHI) and is HIPAA compliant. VEA Align relies on the EOS Insight platform for support capabilities such as user access control and data acquisition access.

The main feature of the server is to protect personal health information. The server is installed in an environment that complies with the standards in force for this type of use. Moreover, the https protocol is used to connect to it, thus ensuring data transfer security.

Server(s) security and data retention is under the responsibility of the manufacturer.

The user can request the deletion of patient data from the application's server. If you want to delete data, please contact us. Contact details are available in the "Contact us" section.

Information to the User

The deployment of a new version of the device is followed by an information to the user on which updates have been performed on the device. The user has direct access to the last version of the device through the web application.

If a cybersecurity vulnerability or event is detected on the device, depending on its severity and impact on the user, a communication is performed with details on vulnerabilities and recommendations.

Report a Cybersecurity Incident

If you believe a potential security vulnerability occurred in one of our products or services, please contact us immediately. Contact details are available in the "Contact us" section.

In order to proceed with a proper investigation to initiate corrections as soon as possible, please provide at least the following:

- Contact details (name and address of the site, contact person name, function, phone number and email address)
- Device impacted (model and serial number)
- Date and time of incident
- Any error message that has appeared
- Any action made by the user before and after the security vulnerability was suspected
- Any other event or source from which the security vulnerability is suspected to come from
- Any additional information you judge necessary to understand and investigate the event

NOTE

A PDF VERSION OF THE SOFTWARE BILL OF MATERIALS (SBOM) CAN BE SENT BY CONTACTING EOS IMAGING (SEE "CONTACT US" SECTION).

Product Information

Information for product identification is available from the about page of the software.

The following symbols are used on this page:

Symbol	Meaning
	Medical device
	Unique Device Identifier
	Manufacturer
	Consult the provided documentation
Rx only	Valid for the United States: Caution: Federal law restricts these devices to sale by or on the order of a physician.

Contact Us

For any questions or assistance, you can contact:

- Telephone: +1 800 9221356
- Email: eos-insight@atecspine.com
- Website: <https://eos-insight.com>

Appendix 1: Clearing your Browser Cache

Google Chrome:

- In Chrome, at the top right, click .
- Click on “More tools” then “Delete browsing data”.
- At the top of the page, choose “All time” in the “Time range” drop down list.
- Check the boxes “Cookies and website data” and “Cached images and files”.
- Click on “Delete Data”.
- Close the page.

Edge:

- In Edge, at the top right, click .
- Click on “Settings” then “Privacy, search and services” in the left panel
- In the part “Clear browsing data” click on the button “Choose what to clear”.
- At the top of the page, choose “All time” in the “Time range” drop down list.
- Check the boxes “Cookies and other site data” and “Cached images and files”.
- Click on “Clear now”.
- Close the page.



Please read carefully the labeling provided with the medical device.
Caution: US Federal law restricts these devices to sale by or on the order of a physician.
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