



VEA ALIGNMENT APP

INSTRUCTIONS FOR USE

GENERAL INFORMATION:

VEA is intended for use by trained healthcare professionals as a standalone software for viewing, measuring, and storing of x-ray images. The app is a medical device software used to measure spinal parameters from patient x-ray images taken with the device's camera. These measured parameters provide a quantifiable way to assess a patient's spinal deformity and correction correlated to health-related quality of life (HRQOL) scores based on published literature. VEA is intended for use on mobile phones only. Do not use VEA on any type of tablet, iPod, or non-mobile phone device. For VEA to work appropriately, users must be running minimum operating systems as defined in the Minimum Device Requirement table. Minimum device requirements are listed below.

Minimum Device Requirements		
	Android	iOS
Minimum Screen Resolution (Pixels)	1080 x 2400	828x1792
Minimum Screen Size (Inches)	6.4	6.1
Rear Camera Resolution	50 MP	12 MP
Operating System	Android 13	iOS 15

Compatible Operating Systems		
	Android	iOS
Operating System	Android 13	iOS 15 and iOS 16

INDICATIONS FOR USE:

VEA assists healthcare professionals in viewing, measuring, and storing images as well as planning orthopedic surgeries. The app allows the healthcare professional to perform generic and specialty measurements of the images, and to plan surgical procedures. The app includes tools for measuring anatomical components for implant selection and offers the possibility to share data among VEA users. The app is for planning use only and is not intended for primary diagnostic use.

CONTRAINDICATIONS:

None.

WARNING/CAUTIONS/PRECAUTIONS:

1. Confirm that at least two of the image corners align with the green corner markers on the image capture display. This will assist in confirming that the device is parallel to and aligned vertically with the image taken. Do not tilt or rotate the device when taking an image. Images taken with the device not properly aligned may result in inaccurate measurements. Measurements are accurate within 2 degrees, provided the device is not tilted more than 5 degrees. Take care to ensure the device is not rotated more than 5 degrees when capturing an image.
2. Proper anatomical landmark placement using the features described is critical to the accuracy of the calculated parameters.

3. For accurate parameter calculation it is important for the user to visually confirm the correct landmark placement on the x-ray image in the results screen and use the described back arrow icon to correct any identified errors in landmark placement.
4. This application was designed to measure spinopelvic features on a vertically oriented x-ray (i.e., cranial towards top, caudal towards bottom). Measurements made outside of these conditions may be inaccurate.
5. Clinical judgment and experience are required to properly use the software.
6. Operating System (i.e., iOS, Android) updates are not recommended to be executed until the compatibility has been tested by Alphatec. However, security updates to the device operating system are still encouraged.
7. To maintain the accuracy of the alignment results,
 - a. Refrain from disabling the default device auto-brightness feature. If this feature is disabled, the minimum brightness should be set to 25% or higher.
 - b. If the screen is not visible due to the mirroring of light or glare/reflections, adjust the angle with which you are viewing your screen.

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 at customerservice@atecspine.com.

For additional information, please reference the ATEC Alignment App User Manual (LIT-84919).



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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