

TrueView Accuracy as Determined by 3,000 Data Points

The Facts:

VeinViewer® uses near-infrared light to detect subcutaneous blood and create a high-definition digital image of the patient's superficial vein pattern projected directly onto the surface of the skin.

The accuracy of the projected image has been tested against ultrasound in four clinical studies since 2010. During these studies over 3,000 data points were collected from 547 patients to assess vein width imaging accuracy.

Data analysis showed that VeinViewer has an overall vein width imaging accuracy of +/- 0.5mm when compared to ultrasound. For veins that measure 3.0 - 7.0mm wide, VeinViewer imaging accuracy increases to +/- 0.06mm.

TrueView 3000 Data Point Summary

Vein Width	Vein Width Accuracy
0.0mm – 10.0mm	+/- 0.5mm
3.0mm – 7.0mm	+/- 0.06mm

Conclusion

VeinViewer vein width projection is highly accurate and can be trusted to deliver quality images to the clinician performing vascular access.

IN SUMMARY:

Knowing that image projection accuracy is important for vascular access assistive devices; Christie Medical Holdings began a series of clinical research studies aimed at understanding VeinViewer image projection accuracy. In August of 2010, the first clinical study for VeinViewer Vision began collecting and comparing vein width projection data to ultrasound, the gold-standard of vascular access assistive devices. After its release in 2012, the clinical studies then incorporated VeinViewer Flex.

The study methodology consisted of imaging veins with ultrasound and VeinViewer in areas that are accessed most often: the antecubital fossa, ventral forearm, hand and/or the wrist. The vein widths measured with VeinViewer were then compared with measurements taken with ultrasound (figure 1) and a percent error was calculated. During the course of the research over 3,000 data points from 547 participants were collected on VeinViewer Vision and VeinViewer Flex.

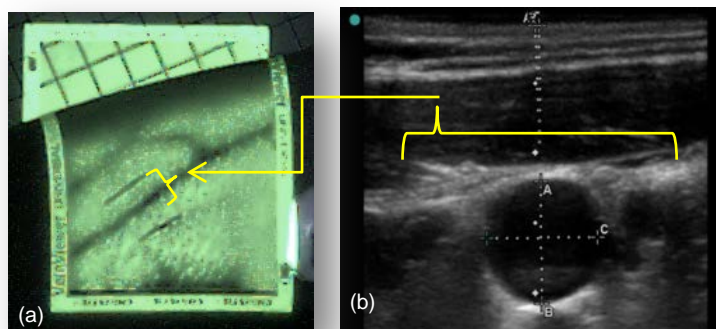


Figure 1 VeinViewer Image (a) with Representative Ultrasound Image (b).

The results of the data analysis showed that, overall, VeinViewer vein width projection accuracy was +/- 0.5mm from ultrasound. The VeinViewer accuracy improved upon analysis of veins that are most often accessed. For veins that were measured to be 3.0-7.0mm wide using ultrasound, VeinViewer vein width projection accuracy increased to +/- 0.06mm. Further, when VeinViewer vein width accuracy was analyzed as a function of depth (Real Depth Accuracy Value) the results demonstrated near-perfect image projection in veins up to 10mm deep.

Ref: Data on File