

No. Unlike similar products, the permanently aligned and self-calibrating AV400 has no servicing or calibration requirements since it cannot go out of alignment. Simply inspect the AV400 to ensure that it is clean before each use.

Are Special Materials, Tools, or Precautions Necessary For Cleaning?

Since the AV400 has no fans or openings it can be cleaned without using special tools, eye protection or compressed air.

How Do I Clean The AV400?

To clean the body of the AV400 and its charging cradle, use a cloth moistened with soap and water, 70% alcohol, or any other approved material or disinfectant wipe. See <http://learn.accuvein.com/clean> for the latest information. Make sure that the cloth or wipe is slightly damp, not wet.

The optical area on the underside of the AV400 should be treated as any other optical surface, such as your eyeglasses. A cleaning solution that does not leave a residue should be used. Isopropyl alcohol wipes such as those used for cleaning the venipuncture site are appropriate for the optical area and can be used to clean the entire body of the AV400.

How Does The AV400 Detect Veins?

The AV400 uses two, safe, barcode-scanner class lasers. One is invisible infrared and the other is visible red. It scans them quickly across the body and watches the infrared reflection. Since hemoglobin absorbs infrared light, there is a reduction in the amount of infrared light reflected from the veins. A custom detection system uses this change in reflection to determine vein location. It then digitally re-projects the vein pattern, in real time, using the red laser to make the vein pattern visible to the clinician.

How Accurately Does It Project Veins?

“Sticking” the center line of the vein lumen is proper venipuncture technique. Therefore, the correlation between the actual center line of a vein and the projected center line of that

vein is the critical measure of operational accuracy.

Based on our testing, the center line accuracy of the AV400 projection was calculated to be accurate within 0.05 mm – about the width of a human hair.

One way to visualize this is to compare this magnitude of accuracy to the size of other common objects shown in the diagram at the right.

All non-contact optical vein detection systems can show veins slightly larger than the actual width of the vein. This effect may vary based on the distance from the patient’s body. However, this functionality has the positive benefit of making it easier for the clinician to see the vein location, much like **bold** text.

How Deep Can it Find Veins?

Tests were performed by AccuVein using ultrasound to confirm depth of penetration. The AV400 detected veins up to 10mm deep. As would be expected, the depth of veins detected can vary from patient to patient and should be used at the clinician’s discretion.

Can It See Arteries?

The AccuVein AV400 does not typically locate arteries underneath the skin. This is because most arteries are deeper than the maximum detection depth. If you happen to see an artery, it may be visibly pulsating or there is a palpable pulse.

What if the blood has low hemoglobin levels?

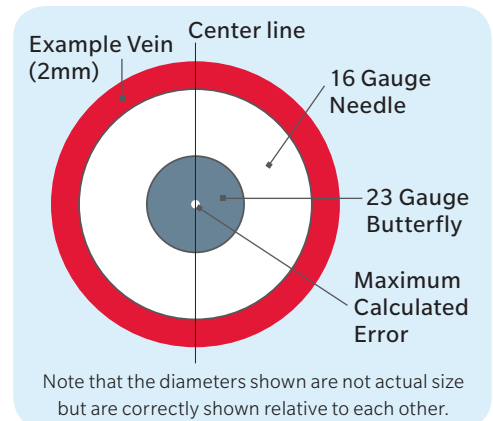
The AV400 will see veins regardless of hemoglobin levels.

Does Hair Interfere With Operation?

The AccuVein AV400 cannot see through large amounts of hair on the skin. Instead, select a site that does not have large amounts of body hair. If necessary, shave the area to remove the body hair before venipuncture procedure.

Do Tattoos Interfere With Operation?

The pigment present in tattoos may block the infrared laser from penetrating the skin. Choose an area free of tattoos.



Do Scars Interfere With Operation?

Depending on the pigmentation and roughness of a scar, it may reduce the ability of the AV400 to detect veins beneath the scar.

Is Skin Color A Concern?

The AV400 works on all skin colorations. Given that it is harder to see veins on dark skin unassisted, the AV400 may be an even greater help on dark skin.

What Are The Laser Safety Characteristics Of The AV400?

The AV400 display light comes from two low power lasers. For subjects with ordinary blink reflexes these Class 2 lasers are safe because the blink reflex limits exposure and prevents eye damage. Eye protection is only required when the patient has diminished bright light aversion response AND there is a chance that they might look directly into laser beam, but we recommend that eye protection be used whenever someone has diminished bright light aversion response (i.e., doesn’t blink in response to bright light). No eye protection is required for the clinician.

How Was Laser Safety Validated?

The AccuVein AV400 was tested and classified as a Class 2 laser device in accordance with international laser safety standard IEC/EN 60825-1. This is the same stringent safety standard that is used by laser based bar code scanners commonly seen in retail stores that are safely used by store clerks and consumers every day.

For comparison, those laser systems commonly used in healthcare which require

interlocks and clinician eye protection are Class 3 laser systems. The Class 2 AV400 doesn't require these precautions.

AccuVein meets this standard through a design that carefully monitors the intensity of the laser output and the movement of the mirrors. If any issues arise, the lasers are immediately shut off. All critical safety systems have two or three levels of redundant protections.

What Are The Attributes of the Lasers?

AV400 includes two lasers, a 642nm wavelength red laser operating at 45mW and either a 785nm or an 830nm wavelength IR laser at 25mW. These lasers are scanned and there are 114 scans per second with 10.7µs per scan line.

AccuVein believes that it is appropriate to take a very conservative position when it comes to patient and practitioner safety. As part of our safety analysis, we considered not only the "pass/fail" aspects of the laser safety standard as was required of us, but we went above and beyond simply meeting the standard. We considered potential uses and misuses of the AV400 and how they could impact patient safety.

Are These Issues Unique to Lasers?

Simply put, No. Lasers are at the heart of many of today's most innovative and popular consumer products. As an example, "Blu-Ray" refers to the blue laser found in the DVD player. Most importantly, the laser camera / projector system in the AV400 allows it to be much smaller, lighter and easier to use than alternative products.

We have a pair of moving mirrors that keeps the laser spot moving rapidly over the projection area so no one spot gets too much energy. Rapidly, in this case, means 30,000 times per second in one direction and 120 times per second in the other direction. That's why you see a rectangle rather than a dot. What if the mirrors should slow down or stop? We have multiple safety systems built in to turn off the lasers if this should happen. Our users get the benefit of lasers – long focus range, long battery life, no fans, fast

turn on, no calibration, tolerance of hand and patient movement –all in a safe, simple to use handheld device.

All bright light sources require special considerations. For example, neonates under bili lights always have eye protection. You wouldn't think of shining a very bright flashlight directly into a baby's eyes and all projection systems, even LED-based ones, are basically very bright flashlights.

These vein detection systems use bright LEDs rather than lasers. The instructions for use of these systems all require the same eye protection that is required of the AV400.

Do I Need To Dim The Room Lights?

No. If you are working directly under a close exam lamp, you may want to redirect it or shut it off, but still use the regular room lights.

What About Sunlight?

Avoid direct sunlight, or near-direct sunlight, by pulling the shades or blinds or by blocking the light with your body.

What Kind Of Batteries Are Used?

The AV400 is powered by a lithium ion rechargeable battery. Some other products use inconvenient, removable batteries. The AV400 battery always remains in the unit - even during charging. This prevents losing the battery and eliminates work for the clinicians from managing both the device and separately charged batteries.

How Long Does The Battery Last?

Three hours of projection is typical on a fully charged battery. Remember, lithium ion batteries last longer when they are kept charged. Storing the AccuVein AV400 in its charging cradle is the best way to ensure long battery life.

How Long Does It Take To Charge?

Typical charge time for the AccuVein AV400 is 2 to 5 hours depending on the discharge level.

Is The AV400 MRI Safe?

The AV400 is MRI safe in zones 1, 2 and 3.

What Other Resources Are Available?

AccuVein provides an online Learning Center which has training videos and downloadable

documentation. Visit the Learning Center at <http://learn.accuvein.com> for these resources.

What Is The Product Lifecycle?

AccuVein supports products for a minimum of 5 years after purchase.

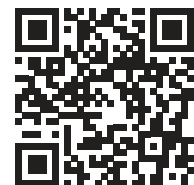
Can We Self Service?

All of AccuVein's products and accessories require specialized assembly and calibration equipment and must be factory serviced.

How Do I Get Technical Support?

Please call +1 (816) 997-9400 and press 3. AccuVein's customer support hours are from 8:00 am to 6:00 pm CST (14:00GMT to 24:00GMT). To ensure quality service, email and web-based support are not available.

You can get more information about AccuVein's Products, Support and Warranty Programs at



<http://www.accuvein.com/support/>