

Does The AV400 Require Scheduled or Other Preventative Maintenance?

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 Any Special Materials, Tools, or Precautions Necessary When Cleaning The AV400?

Since the AV400 has no fans or openings it can be cleaned with out using special tools 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% isopropyl alcohol, or a 10% dilution of chlorine bleach in distilled water. You can also use normal disinfectant wipes. In selecting a wipe, if it is safe to use on skin, it is safe to use on the AV400. 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 Accurately Does The AV400 Project Veins?

“Sticking” the centerline of the vein lumen is proper venipuncture technique. Therefore, the correlation between the actual centerline of a vein and the projected centerline of that vein is the critical measure of operational accuracy.

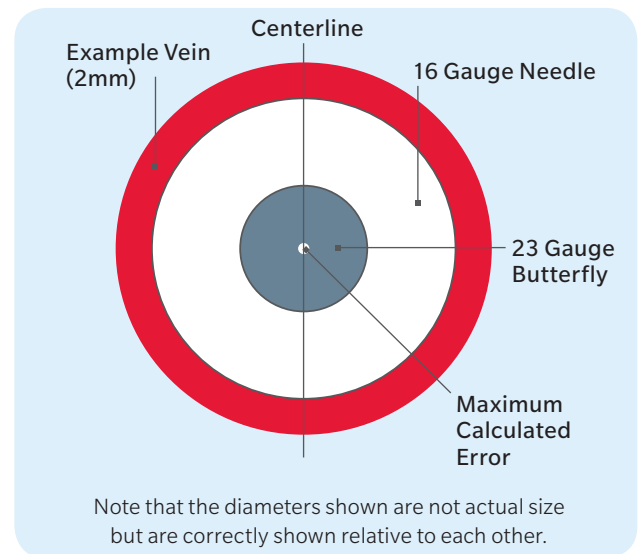
Based on our testing, the centerline accuracy of the AV400 projection was calculated to be accurate within 0.05 mm – about the the width of a human hair.

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.



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.

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.

Does Hair Interfere With The Operation Of The AV400?

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 The Operation Of The AV400?

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

Do Scars Interfere With The Operation Of The AV400?

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 visually 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. Therefore, when scanning patients with reduced blink reflexes the use of eye protection is recommended. 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 The AV400 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 Technical Attributes of the Lasers?

AV400 includes two lasers, a 642nm wavelength red laser operating at 45mW and a 785 nm or an 830 nm wavelength IR laser at 25mW. These lasers are scanned and there are 114 scans per second with 10.7 μ s 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 Safety 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 and lighter 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. And 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, 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 bright flashlights so you should consider eye protection even for these systems.

Other 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.

What Kind Of Batteries Are Used In The AV400?

The AV400 is powered by a lithium ion rechargeable battery.

Some other products use 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.

Are There Any Special Considerations Use Near MRIs?

The AV400 uses two moving mirrors to create its projection. Since the AV400 uses small magnets to move the mirrors, care needs to be taken when using the AV400 around MRI machines.

The AV400 should be kept away from the MRI machine even when it is not active as they can contain permanent magnets. We suggest that any venipuncture using vein visualization be performed before the patient is brought into the MRI room or to remove the AV400 prior to activating the MRI system.

What Other Resources Are Available?

In addition to the printed documentation that comes with the AV400, there are manuals in many languages that can be downloaded from our website. We also provide training videos that can be viewed from our website or uploaded to your internal training system.