Near Infrared Imaging

Vein-Eye[™] Attached Unit (AU)



Drawing blood or starting an IV can be a very challenging task, even for the skilled medical professional. The Vein-Eye makes this task easier. The technology of the Vein-Eye is paramount in patients who are very young, aged, obese, have dark skin, or their veins have collapsed.

The patented technology of the Vein-Eye provides real-time video of sub-dermal veins located on various parts of the body, particularly the patient's arm or hand. The video displays a "runway" image of the patient's vein, necessary for IV placements.

The Vein-Eye HC uses harmless near-infrared light to locate veins and display high-quality images on a monitor. There is no radiation and the light source is an array of LEDs.

Everyone who starts IVs or draws blood knows how difficult and frustrating it is to obtain venous access in many patients. Factors such as small vessel size, fragility, skin pigmentation, edema, adipose tissue, and other issues can make venous access challenging to even the most experienced clinician.

Benefits

- *Increase in the number of "first-stick" successes,
- *Saves time and improves staff efficiency,
- *Improves patient satisfaction ratings for pain management, one of the HCAHPS survey measures,
- *Decreases medically-unnecessary PICC lines, reducing cost and infection risk associated with placement and maintenance of central catheters,

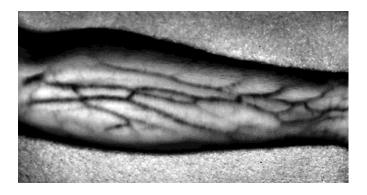
*Reduces escalation calls,

*Decreases the potential for accidental needle sticks.

Advantages

- *Affordable
- *Rapid assessment of all veins due to a large viewing area,
- *Rapid assessment of all veins due to the ability to zoom in and focus on the best vein segment,
- *Clear, unobstructed view of the patient by showing veins on a monitor,
- *Lightweight, easy to clamp onto a chair or bed, and takes up a small amount of space for easy attachment to a fixture/furniture and easy access to the patient.

Below is an untouched picture of an arm displayed on the Vein-Eye monitor. The arm belongs to the inventor of the Vein-Eye. The Vein-Eye images can also be displayed on a PC or other PDA device.



Properly Using the Vein-Eye

*Do not attempt to use the Vein-Eye when the camera or the patient is in direct sunlight.

*The camera should be held approximately 10 inches to 18 inches from the patient.

*The end user should not adjust the fixed internal camera and monitor settings.

*The camera and monitor are configured at the factory.

*Please consult the User Manual and Assembly Manual for all warnings and specific directions on the use and assembly.

Vein-Eye AU Specifications in inches, feet, pounds and Fahrenheit

Maximum height when extended vertically is 34" maximum Weight: 7.5 pounds Width: 6.5" Shipping in-the-box dimensions: 23" x 23" x 12" (thickness)

Shipping-in-the-box weight: 10 pounds

Operating temperature in storage or in transport: 39.02°F to 104.9°F

Operating humidity in storage or in transport: 5.1% to 86% relative humidity, non-condensing

Power: Electrical power is obtained by connecting to a publicly provided power source by means of the 12V (volt), 2.0A (amps) power adapter and power splitter.

Input: 100-240 V AC, 50/60 Hz, 0.8-4 A

Near infrared wavelength: 850nm

Output to camera and monitor: 12V DC, 2.5 A

Vein-Eye HC Certifications and Registrations

FDA, Class 1, 510K Exempt (The Vein-Eye was initially called the AVV-1.)

Conforms to ANSI/AAMI Std ES60601-1

Certified to CSA Std C22.2 No. 60601-1

IEC 60601-1-2:2007 / IEC 60601-1-2 (3rd edition) Class A for Emissions, Immunity for Non Life-Supporting Equipment

ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1

CSA C22.2#60601-1 Issued: 2008/02/01 Ed:2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01

IEC 60601 3rd edition Risk Management File.

CE Marking with the Declaration of Conformity.

NII's manufacturer is ISO 13485 and ISO 9001 certified.

Tariff Commodity Code: 9006.30 - Schedule B

For more information about the Vein-Eye AU, please contact us at <u>infor@nearinfraredimaging.com</u> or visit us at <u>www.nearinfraredimaging.com</u>