

FREQUENTLY ASKED QUESTIONS

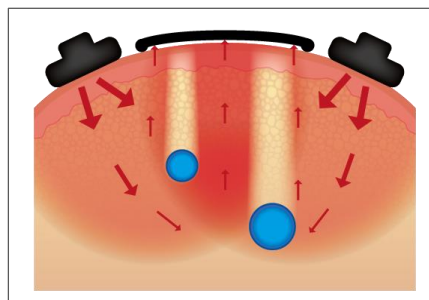
Summary of the IV-eye®

The IV-eye® is a simple, portable, hand-held imaging device which can assist healthcare professionals trained in vascular access to locate, identify and assess peripheral veins for the purposes of venepuncture and cannulation in line with the Vessel Health and Preservation framework.

It is suitable for both adult and pediatric use in all areas where cannulation and venepuncture take place (e.g. anaesthesiology, hematology, oncology, blood transfusion, accident and emergency, home nursing, plus many more).

How does the device work?

The IV-eye® uses near infrared (NIR) LEDs to trans-illuminate the patient's limb from both sides of the target area from the device wings. This enables the NIR light to penetrate deep into the patient's skin and subcutaneous tissue before being captured by the IV-eye® camera and processed to display a real time image of the patient's vascular structure. The display also shows a red line down the center which is used to line up the vein. This line is continued as a red index light projected onto the patient's skin to help to identify the needle insertion point.



Does it need calibrating for different patients?

No, this is not required. Simply switch the device on and it's ready for use on all patient skin types. Novarix recommends the use of the dedicated disposable covers for limiting possible cross contamination and enabling the device to glide easily over the patient's skin if clammy or sweaty. The specific make-up of a patients' tissue will mean that results may vary.

Is it harmful to patients?

No. The IV-eye falls into Class I for eye safety, meaning that it is intrinsically safe and that no protective eyewear is required by users or patients, even if the patient's pupils are dilated or they have an impaired blink reflex. Using auto exposure algorithms, the device only uses the minimum amount of near infrared light required to achieve a high quality image. This class of eye safety also applies to the red index light. In addition, the IV-eye has been designed to be safe on a patient's skin, with an automatic power off after 5 minutes of continuous use, preventing any heat build-up from the LEDs.

Can it be used for both peripheral and central access IV lines?

The device has been designed for only peripheral venepuncture and cannulation use. It may show deeper lying veins elsewhere, but its performance in other areas remains untested and hence not recommended by Novarix.

How deep can the device visualize veins?

This varies from patient to patient, but it's approximately 10mm depth under the skin. Visualization will vary on obese or bariatric patients as the vessels may be very small and too deep. It can also be challenging with patients with lots of muscle, tendon, or hair. Thin or small vessels can also be challenging. Medical professionals should not expect to see a perfect map of every vein on every patient.

How do I use the device?

The User Manual should be read in full before using the IV-eye on a patient. The following is a quick reference guide for those who are already fully trained on the device, to be used in accordance with local policy.

1. Attach a disposable cover (see User Manual or quick reference card for instructions)
2. Switch on the IV-eye (press and hold the power button firmly for 1-2 seconds)
3. Place the IV-eye on the patient's lower arm or on the back of the patient's hand with the display and red index light pointing towards the distal end of the limb (hand/fingers).
4. Move the IV-eye slowly over the patient's limb applying a little downward pressure until a suitable vein is identified (it is recommended to start at the wrist and work back up the arm). The IV-eye display works in real-time, so you can move the device across a patient's skin to search for a vein. See picture below.





5. Once a suitably straight length of vein has been identified, align the vein with the red center line on the display and hold the device steady in this position.
6. Once aligned, identify the spot where the red index light is shining on the skin and draw the IV-eye back approximately 6-8mm and mark this point through memory, by using your finger, capillary pressure or with a derma pen.
7. Remove the device from the patient before completing your prescribed procedure for venepuncture or cannulation. Continue with final palpation and visualization and/or cleaning the insertion area according to your medical procedure or local policy.
8. Once you have finished with the device, press and hold the power button firmly for 1 second. The screen will go blank.
9. Discard the disposable cover if used and clean and store the device according to your local policy.

Where can I use the device on a patient?

The IV-eye is designed to be used only on the back of the hand and forearm where most peripheral venepuncture and cannulation procedures take place.

Where should the device not be used?

The IV-eye should not be used to locate veins on the head, neck, legs or core of the body

The IV-eye should not be used on broken skin or open wounds

The IV-eye should not be used on Neonates or New Born Infants (0-28 days)

The IV-eye should not be used as a diagnostic device for treatment of any kind

The IV-eye should not be used on peripheral limbs smaller than the camera window (30mm) example; young paediatrics 0-5 years (weight dependant)

The IV-eye should not be used to locate arteries.

Are there any product training videos?

Yes. Please visit our website: www.novarix.com/videos/

Does the red index light correlate with the top of the screen?

The red index light is effectively a continuation of the red center line on the display screen. The start of the red index light on the skin is a few millimetres in front of the top edge of the LCD screen. It is therefore important that a suitable straight length of vein is identified, then draw back the device approximately 6-8mm to align the exact point to insert the needle.

How do I access the batteries?

Replacing the batteries is easy, just open the battery door at the back of the unit, no screwdriver required. Novarix recommend the use of 2x AA Duracell Ultra batteries (or similar) to get the best performance. There is a battery life indicator on the display which will indicate full power (green),

less than 15 mins remaining (yellow) and low power (red). See the quick reference card for diagrammatic instructions.

Note: when the device is powered on and monitoring a patient's vascular structure, it will use more power than when it is powered on and not in use. This is due to the energy required by the device to power the LEDs.

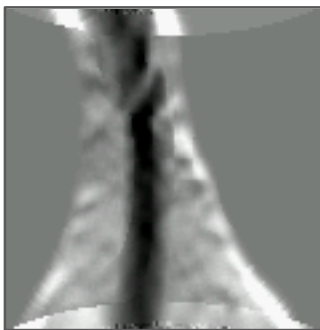
How should I clean the device?

The device should be wiped clean with standard off the shelf common alcohol and non-alcohol based wipes and allowed to air dry for a few minutes before storage. In addition, a disposable cover is available and should be used with the device to reduce possible cross contamination. The device has also been tested with a number of leading brand chlorohexidine clinical wipes of which all have proved to be satisfactory and will not cause any unit damage or display crazing.

Note: the unit should not be sterilised or submerged in water or other types of cleaning liquids.

Why is the device showing two grey patches on the sides of the screen?

When using the device, it can be confused by ambient light leaking in from the sides – this can resemble black/grey lines or patches. It is important to have the device seated as firmly and comfortably on the skin surface as possible and the correct way around (red index light pointing towards the hand/fingers). Focus should be on the center of the screen. Applying a slight up and downward pressure when using the device on a patient will help the camera to focus on specific veins.



Is the device suitable for pediatric use?

The device will work on pediatrics but should not be used on neonates and new-borns (up to 28 days old) or infants (28 days to 1 year) and young paediatrics (1 year to 5 years) as the camera aperture size is often too wide (30mm). Novarix recommend the use of the device on patients from 5 years onwards.

Does it work on the neck?

This is not recommended. Curvature of the IV-eye makes it difficult to seat the device well and it is not designed for this area. It is only designed to be used on a patient's arms and hands.

**How robust is it?**

The device has passed the steel ball drop test required for CE Mark approval from 1 metre high (this is also required for other international approvals and standards). The device has also been drop tested internally onto a concrete floor from 1.5m and remains intact, with no damage and still works!

Can I use re-chargeable AA batteries in the device?

Yes, but Novarix have found AA rechargeable batteries do not hold their charge for long periods. Using AA Duracell Ultra batteries provides sufficient power for standard usage without any charging requirements.

How long does the device last?

The estimated service life is up to 5 years, depending on good care, attention to cleaning and on the environment in which the device is used and stored.

What should I do if the device breaks?

Novarix offer a 2 year warranty on the device against manufacturing defects, fault or workmanship. Evidence of physical abuse or being used outside the recommended manufacturing guidelines would invalidate the warranty. An extended warranty on the device for an additional year can also be purchased, extending your total warranty period to 3 years.

Note: the device is not serviceable or repairable and does not require any form of calibration.

What temperature does the device work at and what temperatures can it be stored at?

0°C to 35°C operating usage and -20°C to 50°C device storage.

Will it work if the patient is very cold/shut down?

This will vary patient to patient and pending medical condition. It is a common medical practice to warm the patient up slowly using heat packs, if very cold, to aid visualization.

How often should I use it?

The device is designed to assist healthcare professionals in finding, identifying and assessing suitable veins for venepuncture and cannulation in patients with difficult to locate veins. It does not replace traditional visualization and palpation techniques, unlike other devices or ultrasound, but acts as a tool to assist and enhance cannulation and venepuncture procedures. The more the device is used, the more confident in its performance the user will become.

Is there a docking station or wall mount bracket?

An IV-eye “desk-top” stand is currently being designed as an accessory for the IV-eye. This is for the nurse’s trolley or station and can house one pack of disposable covers, spare batteries and a skin marking (derma) pen.



What is the best way to mark off a needle insertion site?

As a result of talking to many professional clinical IV nursing staff from many international locations, it seems to vary from using standard visualization and memory techniques, to using the Capillary Refill Time/Compression (CRT) technique to the use of a derma pen. Novarix recommend the use of a derma pen (these can be purchased from many OEM outlets. Novarix do not supply these), however this choice is at the discretion of the user.

How can I site the device so it does not fall off?

The device is designed to be handheld and portable and therefore removed once assessment of veins is complete, to allow a two handed venepuncture/cannulation technique. However, some users want to have the device held in situ during the procedure and are using a disposable tourniquet to wrap around the patient and the device in order to hold the device on the forearm or hand and still allow the device to be comfortably moved around (Novarix do not supply tourniquets). This technique of securing the device is at the professional discretion of the user.

Why does the device keep turning off?

The device has an auto timer built into it that will turn the device off after 5 minutes of continuous use from the moment it is switched on. Simply pressing the power button again will reset the auto timer back to another 5 minutes from the time it was pressed.

Note: the auto timer is a safety feature to prevent any heat build-up from the LED's and ensure that it is safe on a patient's skin. This feature also helps to preserve battery life.

Can I see the needle go into the vein?

A needle will reflect light, so it may not be possible to see it go into a vessel. Moreover, the device is not designed for this process and Novarix do not recommend this type of usage.

Do you supply a tourniquet or derma pens with the device?

Novarix do not supply these products, but can recommend certain common brands that will complement the IV-eye. These recommendations may vary from country to country and can usually be purchased locally quite easily.

Do you supply a carry case?

Yes. The IV-eye has a dedicated carry case which is designed to keep the device safe and secure during storage and transportation. This is available as an optional extra. Please contact us if you would like more information.

What is the storage life for the disposable covers and are they sterile?

The storage/shelf life from manufacture is 3 years (36 months). By the time the disposable covers are packaged, shipped and then stored (possibly 3-6 months) there is typically 30 months left before expiration. The disposable covers are 'socially clean' and are to be used to limit cross contamination from patient to patient and recommended for general use.

How do I apply the disposable cover?

Please refer to the back of the disposable covers box, the quick reference card or the device User Manual for guidance. There is also a video showing the best technique for this on our website:

www.novarix.com/videos/

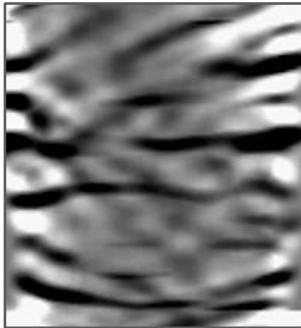
Will the device work on patients with excessive hair?

Like most near infrared (NIR) vein imaging devices, excessive arm hair will cause the image on the display to be challenging to read and will often distort the image or create a grainy look. This will vary from patient to patient. Normally, excessive hair will be trimmed prior to procedure.

Will the device work on patients with tattoos?

For all near infrared (NIR) vein imaging devices, extensive tattooing will cause the image on the display to be challenging to read and will often be distorted or grainy. This will vary from patient to patient.

Will the device work on patients with dark skin?



Yes, the IV-eye performs equally on all shades of skin. In fact, it can be particularly useful on patients with dark skin due to the possible decreased visibility of the veins to the naked eye.

Are tanning creams or skin dyes a problem?

Some creams and skin dyes contain inorganic chemicals such as zinc oxide or titanium dioxide which can act as a physical sun block and reflect light. This is known to affect results in authentication technology. Novarix has not carried out any tests with the IV-eye in this area or condition.

Can the device be used in bright light, at night time or in poor light conditions?

The device will work in all of these conditions. Direct natural sun light on the screen can sometimes be a little challenging, but with a small screen, it is easy to tilt the device slightly to obtain a clear image.

What are the size dimensions of the screen?

The viewable display area is 47mm x 34mm and the area within this which displays the vein image is 32mm x 32mm.

Why is the display not bigger?

Upon research, our customers wanted a small pocket sized, handy device that was portable, easy to use and to move away from the larger more cumbersome devices – hence small and lightweight. The screen size is also to aid focus in finding the more difficult veins and not as a general visualization tool.



What are the cost benefits of using the device?

There are many third party publications and articles available regarding the incremental costs of cannulation and venepuncture escalation relating to staff time, delays in therapy, material costs of using advanced techniques (CVC, PICCS) and overall health care costs over time due to poor vascular access procedures. Improving procedure will reduce these costs.

Is the device available for trial?

Yes. Please talk to your nearest authorized representative / distributor or contact us directly at Novarix and we can put you in touch with them.

Who do I contact regarding any issues or for more information about the product?

Please contact Novarix, using the details below or your local supplier.

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