novarix ltd

IV|eye®

USER MANUAL

English
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IV EYE
USER MANUAL

IV-eye is the registered trademark of Novarix Limited.

Novarix Limited
Core Business Centre
Milton Hill
Abingdon
Oxfordshire, OX13 6AB
United Kingdom

CE 0120

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

This product meets the requirements for a Class 1 Laser product under IEC/EN 60825-1 (2007) and IEC/EN 60825-1(2001).

The IV-eye is a BF applied part.

For External Use only.

ASSISTANCE

For further information or assistance regarding the IV-eye please contact your Supplier or Novarix at support@novarix.com or telephone +44 (0)1235 828292

Last Revised: 17 June 2014

CONTENTS

1. INTRODUCTION

This User Manual provides instructions for using the IV-eye to help identify and locate peripheral veins.

IMPORTANT

Read all the following instructions and their related warnings and cautions before using the IV-eye.

The IV-eye should only be used by medical personnel trained in vascular access techniques and should not be used as a substitute to standard medical procedures used in locating a vein, such as visualisation and palpation.

The IV-eye uses near infrared light at 850nm which is not visible to the naked eye. The light emitted does not pose a potential hazard under conditions for intended use and has been tested and approved as eye and skin safe to BS EN 60825-1:2007 – Performance Standards For Light Emitting Products. However users and patients should not stare at the LED's in the wings when the device is switched on for any extended period of time.

2. GENERAL WARNINGS & CAUTIONS

Warnings indicates potential safety hazards that could result in loss of life or serious injury to the user or patient and potential device damage through the proper use or misuse of the device.

Cautions alert the user to exercise special care necessary for the safe and effective use of the device.

⚠ Patient and User Safety — Warnings

The IV-eye assists trained medical personnel in locating peripheral veins but it is not a substitute for existing medical procedures such as visualisation and palpation.

The IV-eye does not indicate vein depth, it only provides an image of underlying veins.

The IV-eye's ability to image veins is affected by the depth of the vein, the type and amount of tissue covering the vein, irregularities on the skin's surface and other factors such as tattoos and hair.

Do not use the IV-eye on or near the head or neck.

Do not use on broken, bloody or damaged skin.

The IV Eye does not distinguish between veins and arteries – use normal clinical skills for verifying correct identification of the vein before cannulation.

Remove the IV-eye from the patient while performing any medical procedure such as venipuncture or cannulation.

When using the IV-eye, ensure it is placed firmly onto the patient's skin , failure to do so may produce a degraded image.

Do not use IV-eye if the camera window is scratched or damaged.

The IV-eye and its batteries must be kept out of the reach of children at all times.

When inserting or changing batteries do not touch patient at same time.

The IV-eye should only be used with a Novarix disposable cover attached (See S8. Operating Instructions). The use of non Novarix covers may degrade performance.

The IV-eye should be cleaned before and/or after each use (See S9. Cleaning & Maintenance for instructions).

If the IV-eye's plastic casing is broken or damaged the IV-eye may emit visible laser radiation. Please return to Supplier

⚠ Patient and User Safety — Cautions

The IV-EYE emits Visible and Invisible laser radiation.

This product meets the requirements for a Class 1 Laser product under IEC/EN 60825-1 (2007) and IEC/EN 60825-1(2001).

Use of controls or adjustments or performance of procedures other than specified herein may result in hazardous radiation exposure.

Stop using the IV-eye if the display does not illuminate when the Power button is pushed.

Stop using the IV-eye if the red index light does not illuminate when the Power button is pushed.

⚠ Equipment Care — Warnings

Do not immerse the IV-eye in liquid

Do not attempt to sterilize the IV-eye.

Do not clean the IV-eye when the battery door is open.

Electromagnetic Interference (EMI) can affect the proper performance of the device. Normal operation can be restored by removing the source of the interference.

Do not expose to temperature above 50°C (122°F) and below -20C (-4°F)

Store in a dry place

Inspect batteries regularly for damage (at least weekly). If damage is found, remove and replace before further use.

Remove batteries when the device is not likely to be used for a long time.

No modification of this equipment is allowed.

Other than changing the batteries, do not take the device apart. The IV-eye contains no customer serviceable components and should only be serviced by an authorized Novarix repair department.

To maintain the lifetime of the device casing, do not store in strong sunlight.

If the Fault screen appears, stop using the IV-eye immediately and refer to this guide and your Supplier for technical support.

⚠ Equipment Care — Cautions

Use only Novarix approved AA 1.5v batteries (Duracell Ultra or similar). If the IV-eye is not to be used for an extended time, remove batteries and place in carry case.

Do not use Lithium or other rechargeable batteries, these carry a risk of fire.

Be careful not to scratch either the vein display screen or the camera window. A scratched display screen or camera window may affect the image displayed.

Clean only as directed (See S9 - Cleaning & Maintenance)

If the device is dropped, check the casing for cracks, and that the red index light at the front of the device is straight and pointing forward along the device centreline.

Dispose or recycle used batteries according to manufacturer's instructions or your local regulations.

3. INDICATIONS FOR USE

CAUTION:
US federal law restricts this device to sale by or on the order of a physician or other qualified medical professional.

For external use only.

The IV-eye is a hand-held, non-invasive imaging device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture.

The IV-eye should only be used in conjunction with standard techniques of visualisation and palpation in assessing and locating veins.

The IV-eye is intended only or skin contact via a disposable single use cover.

The IV-eye is internally powered using 2 x 1.5v AA alkaline batteries that are not suitable for recharging.

Contraindications

The IV-eye should not be used to locate veins on the head or neck.

The IV-eye is not intended to be used as a diagnostic device or as a form of treatment of any kind.

The IV-eye should not be used on limbs smaller than 30mm in width.

The IV-eye should not be used in locations with thick hair or on broken or damaged skin.

WARNING: Do not use the IV-eye on broken, bloody or damaged skin

4. PRODUCT DESCRIPTION AND LABELLING

The IV-eye transmits near infrared light into a patient's tissue at a wavelength of 850nm. As the light hits a vascular structure it is absorbed by the haemoglobin in the blood, whereas it passes through other tissue. The camera in the device captures the light that has passed through the patient and, in identifying the blocked light and applying a number of algorithms, the IV-eye is able to produce an image on its LCD display of the patient's vascular structure directly underneath the device. This appears as a darker colour to the contrasting tissue. The picture is updated in real-time and is close to actual size. Trained medical personnel can use the image of the patient's vascular structure to assist them in choosing a suitable vein for cannulation and venipuncture.

The IV-eye is designed to only be used in locating peripheral veins. The maximum depth that veins are displayed will vary from patient to patient.

WARNING: The IV-eye's ability to image veins is affected by the depth of the vein, the type and amount of tissue covering the vein, irregularities on the skin's surface and other factors such as tattoos and hair.

The IV-eye works on most patient types (young, old, different ethnic background and skin colour) but images may be degraded and affected by any or all of the following factors:

- depth and size of vein
- make-up of layers of tissue over vein (adipose cells, muscle etc.)
- skin surface condition (e.g., eczema, wrinkles)
- hair
- other markings such as tattoos, bruising.

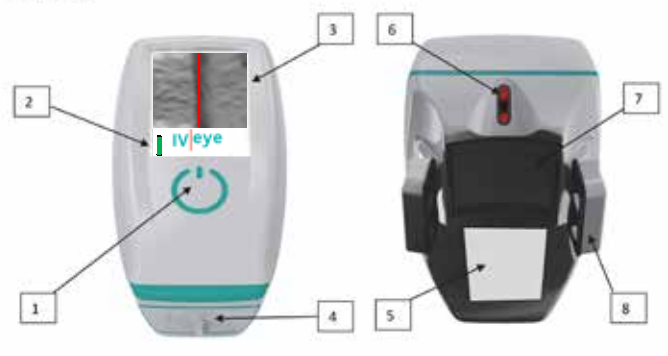
WARNING: The IV Eye does not distinguish between veins and arteries – use normal clinical skills for verifying correct identification of the vein before cannulation.

The IV-eye is intended to be used only by trained medical personnel to assist them in locating suitable veins for venipuncture and cannulation. It does not differentiate between arteries and veins and should therefore only be used in conjunction with standard techniques of locating veins.

WARNING: Users should clean the IV-eye before each use to avoid any chance of cross contamination. For more information see section on cleaning in this document.

Other than regular cleaning and replacement of batteries, the IV-eye requires no routine or preventative maintenance.

THE IV EYE:



1. Power button
2. Battery Life Indicator
3. Display Screen with red centre line
4. Battery Door
5. Label
6. Index light aperture
7. Camera window
8. Wings with infrared LED's

External Labelling:

Internal Labelling:

For use only during manufacture or troubleshooting by Novarix

i) PCB serial number label.
ii) For manufacturing and Novarix technical staff, mandatory laser warning label on PCB internal to casing. ("CAUTION CLASS 2 LASER RADIATION WHEN OPEN, DO NOT STARE INTO THE BEAM")

5. ENVIRONMENTAL CONDITIONS THAT AFFECT USE

Atmospheric conditions:

The device is intended to function normally

- between 5°C and 35°C ambient temperature.
- between 20% and 90% RH (non-condensing) humidity.
- at an atmospheric pressure in the range 110kPa- 80 kPa (-750 to 2,000m altitude).

Electromagnetic Environment:

The device has been tested for Electromagnetic Compatibility to EU standard BS EN 60601-2-2007 and is safe for EMC immunity as well as emissions, but its performance may be affected by extreme electromagnetic fields. If this happens remove from the source of interference. See detailed EMC guidance in section 19.

6. SET-UP INSTRUCTIONS

The IV-eye and its carrying case come in a protective cardboard box.

Remove the cardboard outer packaging and dispose of properly.

Open case.

The contents of the case include:

1 x IV-eye device
2 x AA 1.5v non-rechargeable batteries.
1 x Box of 24 single use disposable covers
1 x IV-eye User Guide.
1 x Instruction card.

WARNING: Take the User Guide from the box and read it thoroughly.

To prepare the IV-eye for first use:

- Remove the IV-eye from its plastic bag
- Remove the protective shield from the Display Screen
- Remove the protective shield from the Camera Window
- Remove the 2 batteries from the case
- Open battery door and Insert the 2 batteries as indicated below:

Batteries and Battery Door Mechanism

1. To open the battery door, press in the battery door button on the rear of the device and turn left (anti-clockwise) through ninety degrees.

2. Pull open the door.

IMPORTANT

Please ensure batteries are inserted as shown in diagram to the right.

3. Insert the batteries as shown above.

4 Close the door and push and turn button ninety degrees right (clockwise).

The IV-eye is then ready for use as it requires no calibration.

WARNING: When inserting or changing batteries do not touch patient at same time.

The user guide, videos, and additional educational material are also available at **www.novarix.com**

7. CONTROLS & FREQUENTLY USED FUNCTIONS

The IV-eye has a single Power switch to power the device off and on.

To power up the device, press the Power switch and hold down for 1.5 seconds. The Novarix Logo will appear briefly on the screen.

When this logo disappears the device is ready to locate veins.

To power off the device, press on the Power button and hold for 0.5 (half) a second.

WARNING: If the IV-eye display does not illuminate check the batteries for correct installation and life. If device still does not illuminate return to supplier.

Display Time-Out

Device time-out: To preserve battery life, the IV-eye automatically turns itself off after 5 minutes of continuous use. To restart simply press the Power button again.

Frequently Used Functions

1. Powering on & off the device (see above)
2. Changing the batteries (see Set-up instructions)

8. OPERATING INSTRUCTIONS

CAUTION

Federal law restricts this device to sale by or on the order of a physician or other qualified medical professional.

For external use only.

WARNINGS:

Read all warnings and cautions at the beginning of this guide.

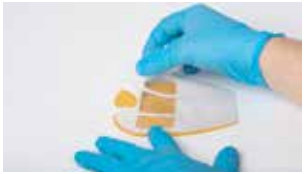
The IV-eye enables trained medical personnel to visualise and locate peripheral veins. It is not a substitute for standard medical procedures for the location and assessment of veins.

Only use the IV-eye when its batteries have sufficient charge (indicated when the battery life indicator at the lower right of the LCD display screen shows a green or orange bar).

Do not use on the head or neck.

Below is a step by step guide explaining how to use the IV-eye:

1. Take a new cover from the box of disposable covers and peel off waxed paper.



2. Place the cover on a clean surface or on the peeled off waxed paper with the adhesive side facing upwards

3. Place IV-eye onto cover, aligning the camera window with the middle transparent window and press the rear of the IV-eye onto the adhesive strip at foot of cover.

4. Pull up and attach adhesive flaps to the front of the IV-eye, taking care to ensure middle transparent window is not creased.

5. Place the device with cover attached onto the patient with the display and index light aperture pointing towards the distal end of the limb.

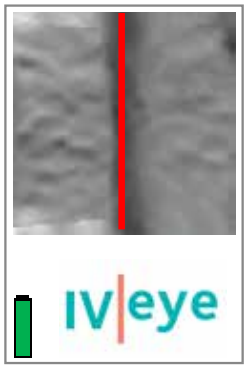
6. Switch on the IV-eye by pressing down on the Power button on top of the case for 1.5 seconds.

   Note The distance between the device and the operator's eyes should be less than 50cm.

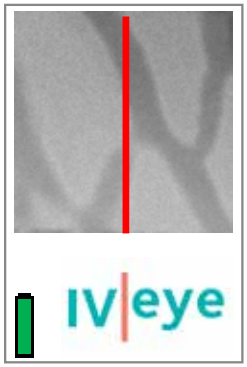
7. Slide the IV-eye slowly with light pressure on the patient's limb until a suitable vein is identified.

WARNING: The IV-eye may not be suitable for patients with limbs narrower than the camera light window (approx 30mm).

WARNING: To view vein location accurately, you must position the IV-eye with light downward pressure on the patient so that no light can enter the camera window underneath.



Vein centred with red line



Vein not centred with red line

WARNING: Depending on the depth of the vein, it may appear slightly wider or narrower than the actual vein.

8. Once a suitably straight length of vein has been identified then align the vein with the red centre line on the display and hold the device steady in this position. This will accurately locate the centre of the vein and the red index light at the front of the device will show the location on the skin directly beneath the top of the red centreline seen on the display.

9. Once a suitable vein is located, identify the place on the skin where the red index light is indicating and mark this point through memory, use a finger or marking the skin with a derma pen.

WARNING: Do not hold the IV-eye during cannulation or venipuncture. The IV-eye should be removed from the patient once the desired vein location is identified.

10. Remove the device from the patient before attempting cannulation or venipuncture.

11. After use, remove the used cover from the IV-eye and dispose of the cover with general surgical waste or in-line with local regulations.

12. To switch off the IV-eye, press down on the Power button for 0.5 (one-half) second. The screen should go black.

13. The device will turn itself off automatically after 5 minutes of use – press the Power button to restart.

14. When not being used, the IV-eye should be stored in its carrying case.

If you have any questions about the use of the IV-eye, please contact your supplier.

Using the Instruction Card and Familiarisation

The IV-eye comes with a simple [6] step instruction card that demonstrates how to apply the disposable cover, position and use the device properly on a patient. Novarix also recommends clinicians practice with the IV-eye to compare veins that can be seen with the naked eye or identified through palpation.

9. CLEANING AND MAINTENANCE

WARNINGS:
The device should be used with a protective, single use cover.

Users should inspect the IV-eye and clean and disinfect the IV-eye before or after every use to ensure that it is sufficiently clean before each use.

If the device becomes cracked or brittle the device should be returned to the Supplier for servicing or disposal.

The device is designed to be used on multiple patients. A disposable cover should be used for each patient and the device thoroughly cleaned with a chlorine, iso-propyl alcohol (IPA) or CHG-based medicated cleaning wipe before or after each use.

WARNING:
If the camera window is scratched, damaged or unable to be cleaned, the IV-eye should not be used and should be returned to Supplier for servicing or disposal.

When cleaning the IV-eye please pay attention to the warnings below:

WARNINGS:
Do not rinse or immerse the IV-eye in liquid.

Do not attempt to sterilize the IV-eye.

Do not clean the IV-eye when the battery door is open.

To clean the IV-eye use a cloth or wipe moistened with either:

- 70% Isopropanol
- Chloraprep (or 10% chlorine in distilled water)
- Chlorhexadinegluconate (CHG) 2%,

and make sure the entire device is wiped thoroughly. A general detergent may also be used.

The IV-eye is an optical instrument and therefore to maximise quality of imaging the display screen, the camera window and the LED lenses in the wings should be cleaned gently using only 70% isopropyl alcohol wipes.

Other than regular cleaning and replacement of batteries, the IV-eye requires no routine or preventative maintenance.

WARNING: Inspect batteries regularly for damage (at least weekly). If damage is found, remove and replace before further use.

10. BATTERIES

The device requires 2 x AA 1.5v batteries for use. Novarix recommend Duracell Ultra or similar batteries.

WARNING: Keep the IV-eye and its batteries out of the reach of children at all times.

Battery Life Indicator: Using the recommended batteries should provide the user with up to 2 hours of continuous use. The display has a battery life indicator in the lower right corner which indicates how much available operating life is available from the batteries.

Up to 2 Hours Continuous Use

Less than 15 minutes

Batteries need replacing

To insert or replace the batteries, open the battery door at the rear of the device and the AA batteries can easily be inserted or removed from the battery compartment (see Section 6 Set-up Instructions for detailed instructions)

CAUTIONS:
Dispose of used batteries according to local regulations.
Novarix recommend Duracell AA 1.5v Ultra Batteries.

WARNINGS:
Inspect batteries regularly for damage (at least weekly).
If damage is found, remove and replace before further use.
Remove batteries when the device is not likely to be used for a long time.
Do not use Lithium or other rechargeable batteries, these carry a risk of fire.

11. STORAGE

While not in use, the IV-eye should be stored in its carry case.

If the IV-eye is not going to be used for an extended period, Novarix recommends removing its batteries and placing them in the case in the spaces provided.

WARNING: Store in a dry location. Dampness or humidity may affect performance and cause malfunction.

Storage Environmental Specifications

Temperature: -20°C to +50°C [-4°F to 122 °F]

Humidity: 20% to 90% RH non-condensing

12. FAULTS AND WARNINGS

If the IV-eye detects that it cannot operate properly, it turns off the vein display light and displays the following Fault screen:

WARNING: If the Fault screen appears, you should stop using the device immediately and turn it off by pressing the Power button below the LCD screen. If after turning the IV-eye back on again it resumes working properly, it's safe to continue using the device. Otherwise, the IV-eye safety check circuitry prevents the vein display from turning on.

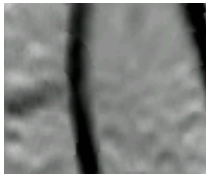
Should such a fault occur, please contact the Supplier even if the device begins working properly again.

WARNING: Other than replacing the batteries, do not attempt to take the device apart. The IV-eye contains no customer serviceable components and should be returned to Supplier if in need of servicing or repair.

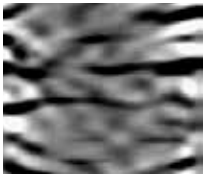
13. TROUBLESHOOTING

Imaging

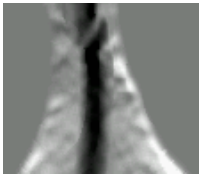
If the image is of poor quality it may be due to the placement of the device on the patient's limb. To get a good image the device should be placed firmly on the patient such that no light can enter from underneath. The imaging of veins may also be affected by markings or hair on the skin.



Good Image
Light pressure on limb



Poor Image - Hair



Poor Image - Camera window not pressed onto limb or limb too small

WARNING: Use only Novarix covers and accessories with the IV-eye. The use of non Novarix covers and accessories may degrade performance.

Failure to use Novarix covers may also affect the quality of the image.

Display does not come on

If the display on the IV-eye does not start when the on button is pressed check that the batteries have been inserted correctly

If the display still does not come on, then check that the batteries are not dead.

If the display does not come on with correctly inserted good batteries then contact your supplier.

Other

Other than the two AA batteries, there are no serviceable parts on the IV Eye device. If the device is not functioning as expected, if the casing is cracked or the laser line appears off-centre or distorted, contact the Supplier.

WARNING: Other than replacing the batteries, do not take the device apart. The IV-eye contains no customer serviceable components. If servicing is required please return the device to the Supplier.

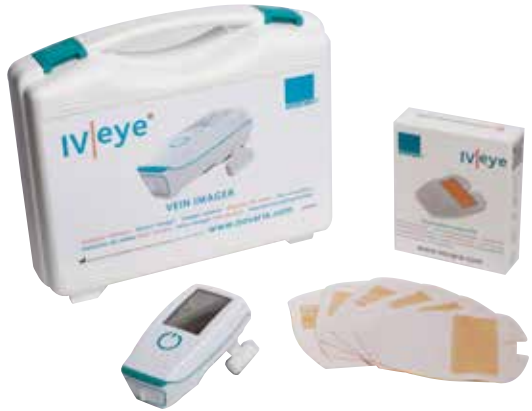
14. COVERS & ACCESSORIES

Protective Covers (Product Ref: IVEYE00120)

A single-use, disposable cover is available in boxes of 24.

Carrying Case (Product Ref: IVEYE00140)

The IV-eye comes in a case has been designed to keep the device safe and secure between uses and when being transported. The case includes moulded compartments for spare batteries and a box of disposable covers. Whilst travelling, ensure that the case is closed and safely secured.



Visit the Novarix Web site for further accessories as they become available: **www.Novarix.com**

15. SERVICE AND SUPPORT

If the IV-eye is in need of servicing then please contact your supplier.

There are no serviceable parts on the IV Eye device. If the device is not functioning as expected, if the casing is cracked or the laser line appears off-centre or distorted, contact the Supplier.

WARNING: Do not attempt to take the device apart. Other than the two AA batteries, the IV-eye contains no customer serviceable components. If servicing is required please return the device to the Supplier.

16. WARRANTY & LIMITATION OF LIABILITY

We agree subject to the terms of this limited warranty, to correct any defects in design, materials or workmanship in any product covered by this limited warranty which occurs during normal use and is reported to us in writing during the period of one (1) year from the date you purchased the product from us. Our obligation hereunder shall be to provide, on an exchange basis, the part or parts necessary to correct any defect covered by this warranty. We will pay normal transportation costs for delivery of replacement product to you but shall not be liable for any other expense, including the cost of returning any product to be replaced by us. You shall not return any product to us for replacement or analysis under this warranty without first obtaining a "Return Material Authorisation (RMA) number" from us and clearly marking this on the returned product. We shall evaluate returned products and in the event that it qualifies for the terms of this warranty shall replace the returned product.

The warranty period for any product repaired or replaced shall be the unexpired portion of the initial warranty period provided in the preceding paragraph or a period of three months from the date that the product is repaired or replaced, whichever is longer.

We shall not be liable for a product's failure to comply with the warranty set out above in any of the following events:

- you make use of such Products after you have given notice to us of a potential breach of warranty;
- the defect arises because you have failed to follow our oral or written instructions as to the storage, commissioning, installation, use and maintenance of the products or (if there are none) good trade practice regarding the same;
- you alter or repair the Products without our written consent;
- the defect arises as a result of fire, accident, misuse, fair wear and tear, willful damage, negligence, or abnormal storage or working conditions;
- the defect has arisen from any design, specification, component or material supplied by or on behalf of the Distributor; or
- the products have not been used solely for their proper purpose.

If upon inspection, we determine that the returned product's claimed defect was not due to its design, workmanship or materials, you will be charged in full for a new product in exchange.

The warranty provided above does not apply to any product covers or to any part of the product which is a consumable (including but not limited to batteries) and we shall not be liable for any breach of warranty which arises out of or in connection with any defect in or damage caused by a product cover or consumable (including but not limited to batteries).

All other representations and warranties relating to the products are excluded to the maximum extent permitted by law.

17. TECHNICAL SPECIFICATIONS

Operating Conditions	
Temperature	5°C to 35°C (41°F to 95°F)
Humidity	20% to 90% RH non-condensing
Transport & Storage	
Temperature	-20°C to 50°C (-4°F to 122°F)
Humidity	20% to 90% RH non-condensing
IV-EYE Product Specifications	
Size	11 x 5 x 5.5 cm (4.3" x 2" x 2.2")
Weight	130 grams (4.6 oz) Excluding batteries
	185 grams (6.5 oz) Including batteries
Batteries	2 x AA 1.5v Batteries – Duracell Ultra or similar recommended
Battery Life	Up to 2 hours typical (Continuous run time on full charge on patient)
Water Ingress	IPX0 No Water Ingress Protection
Illumination Wavelengths	850nm (LED's) 650nm (Red Index Light)
IV-EYE Characteristics and performance specification	
IR wavelength	850nm
Index laser wavelength	650nm
Display type	Transflective (for viewing in daylight or indoors)
Display Refresh rate	10Hz
Displayed Image Resolution	0.3mm per pixel
Display Brightness	210-300 cd/m2
Display Contrast Ratio	240:1 - 400:1
Display Viewing angle	80 degrees in all directions

18. SYMBOLS

Table of symbols used

Warning

RxOnly US federal law restricts this device to sale by or on the order of a physician or other qualified medical professional. For external use only.

ETL Classified means that most system elements conform to IEC 60601 3rd Edition

Temperature Limitations

SN Serial Number

REF Reference to Model Number

Date of Manufacture YYYY/MM

Read the User Manual

Manufacturer

Single Use only

European Union Waste Electrical and Electronic Equipment Directive Logo. Return is allowed for proper disposal.

Caution

CE 0120 Conformité Européenne (European Conformity). Conforms to the European medical Directive 93/42/EEC

Type BF applied part

Humidity Limitations

Recyclable packaging

Keep away from Sunlight

Fragile, handle with care

Direct Current. Example: 3.0 V indication of battery voltage

Keep dry

IPX0 No water ingress protection

LOT Lot or Batch Number

Atmospheric Limitations

Rev 1.0 Software Version incorporated in IVEYE

19. REGULATORY COMPLIANCE

1) EYE and Skin Safety: BS EN 60825-1

The IV-EYE emits Visible and Invisible laser radiation.

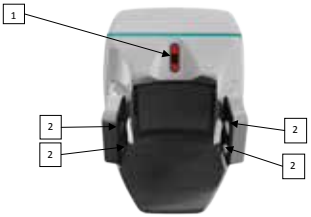
This product meets the requirements for a Class 1 Laser product under IEC/EN 60825-1 (2007) and IEC/EN 60825-1(2001).

Fur users in USA, Complies with 21 CFR 1040.10 and 21 CFR 1040.11 – Performance Standards for Light Emitting Products, except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CAUTION – use of controls or adjustments or performance of procedures other than specified herein may result in hazardous radiation exposure

Wavelength 850nm (Near Infra-red LEDS)

1.19mW peak power.
Four LED apertures on flexible wings as shown below (parts #2).



Wavelength 650nm (Red Index light)

0.11mW peak power.
One Red Index Light aperture as shown above (part #1).

Internally 0.66mW peak is accessible only when the product is disassembled by Novarix personnel. The following label is placed internally and only applicable during manufacture or trouble shooting by Novarix or their Contract Electronics Manufacturer.

2) Electromagnetic Compatibility (EMC)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The IV Eye is intended for use in the electromagnetic environment specified below. The customer or the user of the IV Eye should assure that it is used in such an environment			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distances between portable and mobile RF communications equipment and the IV Eye			
The IV Eye is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IV Eye can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IV Eye as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The IV Eye is intended for use in the electromagnetic environment specified below. The customer or the user of the IV Eye should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Class B	The IV Eye is suitable for use in all establishments including domestic premises.
RF Emissions CISPR 11	Group1	The IV Eye uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronics.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The IV Eye is intended for use in the electromagnetic environment specified below. The customer or the user of the IV Eye should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the IV Eye than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in Watts (W) according the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IV Eye is used exceeds the applicable RF compliance level above the IV Eye should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IV Eye. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

20. ADDITIONAL STANDARDS INFORMATION

BS EN 60601-1:2006 - Medical electrical equipment General requirements for basic safety and essential performance

BS EN 60601-1-2:2007 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests

BS EN 60825-1:2007 - Safety of laser products – Part 1: Equipment classification and requirements" for the index laser pointer and
BS EN 60825-1:2001 - Safety of laser products – Part 1: Equipment classification and requirements" for the Infrared LEDs which is equivalent to the "exempt" risk group to EN 62471 (2008) "Photobiological Safety of Lamps and Lamp Systems"

CAN/CSA-C22.2 NO. 60601-1:08 - Medical Electrical Equipment Safety

BS EN ISO 15223-1:2012 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements

Novarix Ltd is an ISO 13485 certified company and devices are manufactured for Novarix by an ISO 13485 certified contract electronic manufacturer.

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