Technical File for the Vein-Eye® Carry medical device

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General information concerning Near Infrared Imaging (Company) and the Vein-Eye Carry (VEC).

Near Infrared Imaging (Company) incorporated in the State of Delaware in 2013.

Company address: PO Box 264, Wrentham, MA, 02093, USA
Telephone: (Tel) 1 - 508- 384-3800.
Email: info@nearinfraredimaging.com
Website: https://nearinfraredimaging.com/

USA Employer Identification Number: 463678687

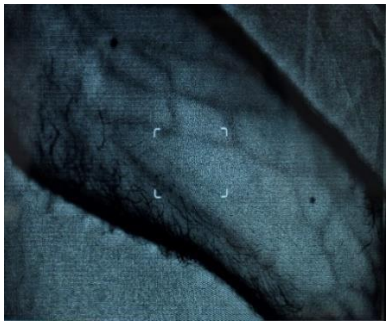
Near Infrared Imaging has filed its taxes every year and is a Corporation in Good Standing with both the Commonwealth of Massachusetts and the State of Delaware.

The Vein-Eye® Carry is registered with the FDA: **#3002736133**
Product code: **VEC 03**
Patent application filed in the USA: **# 17404755**
Approved by Health Canada as a Class 1 medical device

The Company (Near Infrared Imaging) is owned in part by

- The City University of New York (CUNY) - http://www2.cuny.edu/
- Lawrence Livermore National Laboratory (LLNL) - https://www.llnl.gov/
    - LLNL is a division of the Dept. of Energy.

The Vein-Eye® CARRY provides real-time video of sub-dermal veins**. The video is full high definition (1920 X 1080) and a "runway" image, necessary for IV placement.**



The Vein-Eye CARRY only weighs less than 10 lbs. and can be carried into the home, throughout the hospital or nursing home, used in an ambulance and carried into remote villages and towns.

There are 40M vein punctures everyday worldwide and 20% fail on the 1st attempt.

Care delays occur in approximately 25% of all patients regardless of care setting due to the inability to establish IV access.

Drawing blood or placing an IV is exceedingly difficult if the patient has diarrhea, is very young, is very old, or the veins have collapsed due to dehydration.

Drawing blood or placing an IV can be dangerous to both the patient and healthcare practitioner if the patient has the Coronavirus, Ebola, AIDS, SARS, Measles, Chicken Pox or Tuberculosis.

The failure rate of puncturing a vein is 10% to 40% when resuscitating a critically ill patient, where time is of the essence and vein punctures are challenging.

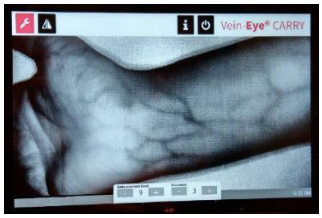
- Failure to puncture the vein causes increased stress and pain to the patient, the healthcare worker and to the patient's family.

- One in five attempts result in failure in adults, and one in three attempts result in failure in pediatrics.

- The average time requirement for peripheral IV cannulation is reported at 2.5 to 13 minutes, with difficult IV access requiring as much as 30 minutes.

- If intravenous therapy does not begin promptly, both patients and healthcare practitioners endure tremendous stress with repeated missed attempts.

- Below is an image of a three-year old child with a history of missed vein punctures due to illnesses.



Safety, testing and certification. EC declaration of conformity and classification to 93/42/EEC annex IX

According to the Council Directive 93/42/EEC, the Vein-Eye Carry is a Class 1 medical device and conforms to 93/42/EEC annex 1X. The Vein-Eye Carry is non-contact, non-invasive, low voltage, minimal risk, and does not need to operate in a sterile environment.

The Vein-Eye Carry has been tested and certified as safe. See Attachment B

TEST REPORT: 104473702BOX-001

Test Report Form Originator: Underwriters Laboratories Inc.

TESTING LABORATORY: Intertek Testing Laboratory, 70 Codman Hill Road, Boxborough, MA 01719 USA (www.intertek.com)

TESTING REPORTS: General requirements for basic safety and essential performance.

The VEC has been tested and certified to be safe to the general public for basic safety and essential performance according to the IEC 60601 2nd edition standards. All applicable tests according to the below specified standards have been carried out.

· CAN/CSA C22.2 No 601.1-M90 (1990), 2nd Edition 'Medical Electrical Equipment, Part 1: General Requirements for Safety'

· CENELEC EN 60601-1 (1990), 2nd Edition 'Medical Electrical Equipment, Part 1: General Requirements for Safety' + A1(93) + A2(95)

· IEC 60601-1 (1988), 2nd Edition, 'Medical Electrical Equipment, Part 1: General Requirements for Safety' + A1(91) + A2(95)

· UL 60601-1 (2003), 1st Edition 'Medical Electrical Equipment, Part 1: General Requirements for Safety'

- **ISSUED ON: 11-17-2020**
- **VALID TO: 11-17-2030** (**4**)

Input: 100-240VAC, 0.5A, 50/60Hz, Output: 5VDC, 3000mA; 9VDC, 2000mA; 12VDC, 1500mA (Specified Power Supply P/N: XY18W1204-PD)

Equipment Rated 12Vdc, 1.9A, 22.8W

STANDARDS: IEC 60601-1:1988 + A1:1991 + A2:1995

Country of Origin: USA

The Tariff Commodity Code (Harmonized International Code): 9006.30
The VEC uses a Class 1 laser.

A Class 1 laser is considered to be incapable of producing damaging radiation levels and is therefore considered safe under normal working conditions. These lasers are exempt from most control measures. Many lasers in this class are lasers which are imbedded in an enclosure that prohibits or limits access to the laser radiation, which are safe to the general public and require no measuring. **-** ***The above is a summary of laser classification taken from ANSI Z136.1.***

The VEC uses a gooseneck and super clamp so that the nurse or other healthcare practitioner is able to use the device in hands-free mode.

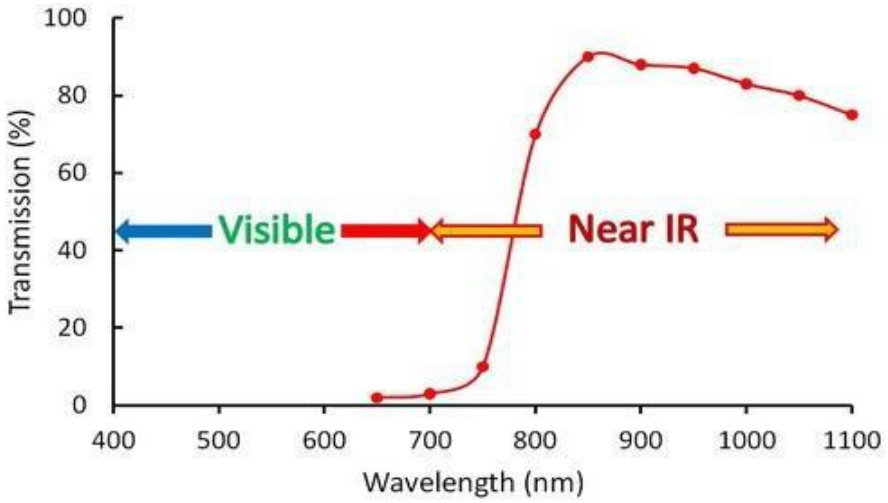
The novelty of our platform is that it is truly portable, lightweight, and can be carried to the patient. The Vein-Eye Carry can attach to home or hospital furniture, critically important for home healthcare, access to remote villages and towns, use in ambulances, use in medical evacuation vehicles.

Our technology uses two salient properties of light - polarization and near infrared wavelengths – and an innovative optics hardware platform. The result is an increased ability to visualize veins through skin, hair, fat, and tissue. Near infrared light is particularly good at identifying the oxygen (hemoglobin) in the veins.

The VEC is used to increase the ability of healthcare professionals to see the vein of the patient during the IV start/venipuncture procedure and enhance the success rate of the first attempt.

The design of Vein-Eye Carry-VEC03 is based on the principle that the blood will absorb near-infrared light and the tissue around the vein does not. This makes the images of the veins appear darker than its surrounding tissue, this makes easier to seethe vein map by the healthcare professionals.

The Near Infrared (NIR) camera emits wavelengths in the 850 nm range. The NIR light is projected onto a patient's skin and penetrates the body anatomy. The NIR light is absorbed differently by blood than by surrounding tissues. The reflected images are captured by the Vein-Eye Carry (VEC) camera.



The camera then transmits the video image to a tablet that has a USB 3.0 port. USB 3.0 ports have 9 pins and a transfer rate of 5 Gbit/s.

The video of the subdermal veins is displayed onto the screen of the tablet so that the healthcare practitioners can see the veins and the depth and size of the veins. With the Vein-Eye Carry, medical professionals can place IV and draw blood more easily.

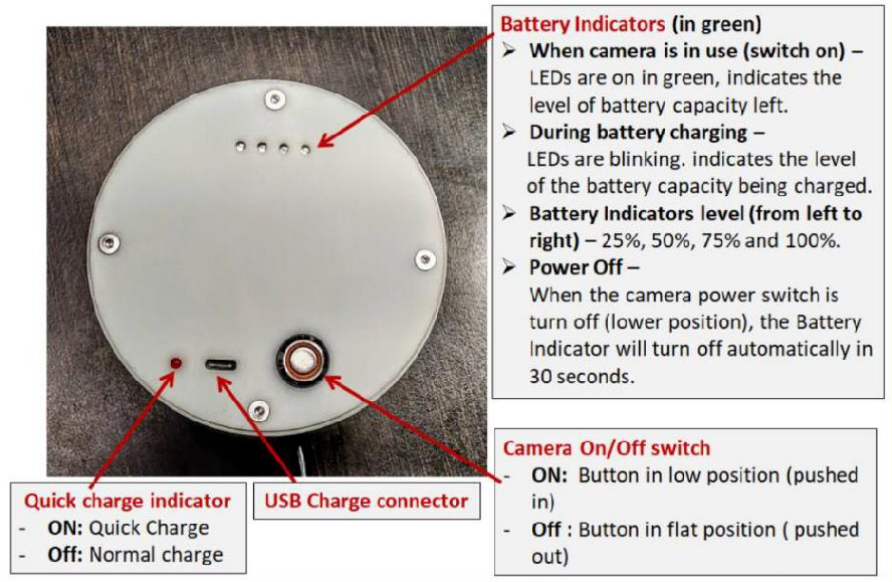
This ability to puncture a vein on the 1st attempt minimizes the discomfort of the patients, increases their satisfaction level, and allows the doctor and the patient to concentrate on the patient's medical problems

Vein-Eye Carry (VEC 03) system includes 6 key components.

1) **The near infrared camera**

1080p USB 3.0 Self Powered Camera

- IR 850nm 1920 * 1080 Full HD Video Resolution camera
- In case battery is drained, it can be concurrently charging while in use



2) **<u>Quick Wall Charger</u>**

Quick PD 3.0 18W Charger
Input: 100-240VAC 0.5a 50/60HZ
Quick Full Charge Time: 2.5 hours
UL approved

3) **Gooseneck:** Flexible and versatile mounting gooseneck for cameras.
   a. Holds up to 3 Lbs.

4) **Super Clamp:** Standard Stud: 1/4 & 3/8 Inch, Weight: 0.9lbs, holds up to 33lbs
Attachment: 16mm Hexagonal, 1/4 Inch Threads Attachment Type
Material: Die-Cast Meta

Gooseneck tube with super clamp and camera

5) **Tablet with laptop sleeve**

Windows 10 with proprietary video enhancement software
10.1 ” IPS full screen
1920 X 1200 (FHD) with USB 3.0 port
CPU: Intel Celeron N4500
Core: 2 cores, 2 threads, 1.1GHz-2.8GHz
GPU: Intel UHD Graphics, 350-750MHz

NIDOO 10 Inch Laptop Sleeve Case
Water Resistant Cover
Dark Grey Portable Bag for 10.2" Tablet

6) Carrying case

Customized hard-shell case for traveling
16” X 11.4 × 5”
Comes with an adjustable strap to carry the case with the handle or with the shoulder strap.

Photographs of product usage

List of applicable standards

- ISO 13485
- ISO 9001
- IEC6061-2nd Edition

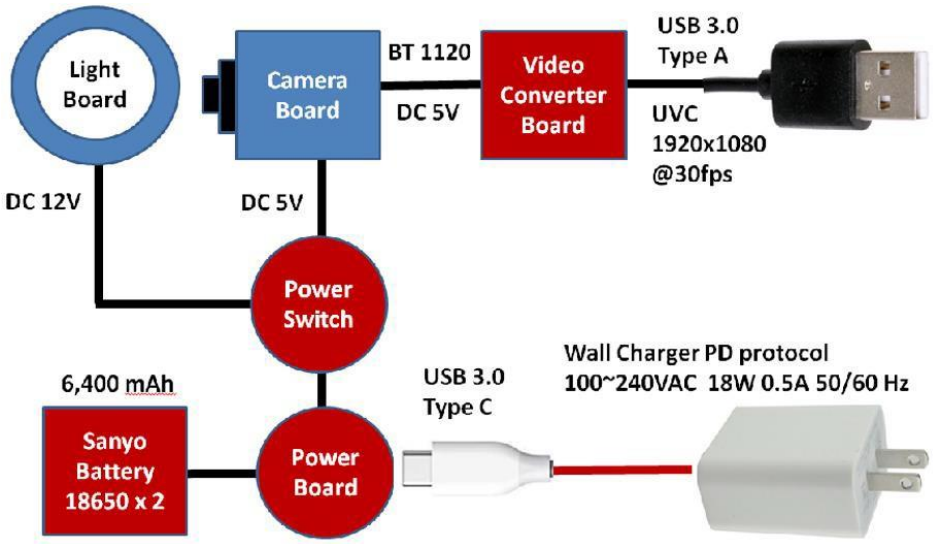
List of components

Part Description	QTY
IR Camera (850nm) with USB cable	1
Gooseneck tube 19”	1
Super Clamp	1
Wall Charger 18W USB Type-C	2
Carrying Case: 16” length X 12” width X 6” Height	1
Product Label	2
10-inch Tablet (1920x1200) with laptop sleeve	1
12” X 10” X .50 (1/2”) packing foam	2

Packaging specification

- Place the flat foam on the bottom of the carrying case.
- Place the tablet in the protective sleeve
- Place the fully assembled Vein-Eye Carry in the lower chamber of the carrying case
- Put the tablet on top of the gooseneck tube.
- Put the chargers in the zippered pocket
- Put the carrying case within a carton before shipping.

Sub-assembly drawings, drawings of components (circuitry)



QA specification (e.g., QC specs, in-process and end-controls, end-release etc.)

- All cameras are 100% tested before shipment.
- Near Infrared Imaging's managers and engineer check the performance of the product every month to guarantee that there no loss of performance.

- Camera check items:
  - USB cable connection
  - IR lighting check – all 8 lights must be all on
  - Camera focus distance at 23 cm
  - Battery charging
  - Burn-in 3 hours

- System-check items:
  - Fully assemble the camera, gooseneck tube and super clamp
  - Check the camera function normally (image is in focus, battery is fully charged)
  - Connect USB cable of the camera to tablet, make sure the image enhancement program function properly.

Labelling, accompanying documents, package insert

Labelling is on the camera, on the Tablet, and on the carrying case.

Description about the creation of a Lot or Charge No.

It is based on the customer order.

Instructions for use (e.g., EN 1041)

Please refer to the separate End User Assembly and User Guide

Intended / clinical use

The Vein-Eye Carry is a hands-free and portable medical device that helps medical professionals locate superficial veins. It is intended to be used as a supplement to the medical training and experience of the healthcare professionals.

Customer Service - Contact your Distributor

The end user and/or healthcare professional should not attempt to fix the Vein-Eye CARRY or provide any maintenance without the express consent of the Distributor. Contact your local Distributor first.

A Return Merchandise Authorization (RMA) number will be issued for repairs.

If you cannot contact your Distributor, please feel free to contact Near Infrared Imaging at: Email: info@nearinfraredimaging.com, available 24 hours per day, 7 days a week, 365 days a year.

Product verification

Our product verification process ensures that the product conforms within the design specifications.

Testing data and reports, functionality studies, wet lab or bench top testing

The Testing data and report by Intertek is in Attachment B. In addition, Sparqtron tests each component of the system and the entire system prior to shipping.

EMC testing and certificates

The Vein-Eye Carry has been tested by certified by Intertek based on IEC6061-2 safety standards. See Attachment B.

Compatibility studies (connection to other devices)

The Vein-Eye Carry system is a standalone device and should not be connected to other devices.

Risk management documentation (EN ISO 14971)

The Company uses ISO 14971 (ISO 14971) for risk analysis, risk evaluation, risk mitigations, and a residual risk analysis and management. There are no documents at this time.

Hazard Analysis

As part of our human factors engineering process, the Company conducts a hazard analysis to identify potential hazards or hazardous issues from the environment and usability of the device. We also analyze residual risk of the device.

Power and battery information

Tablet power: Battery: 22.42W, 7.6v, 2950mA

- 6 hours of continuous use
- 260 hours of standby

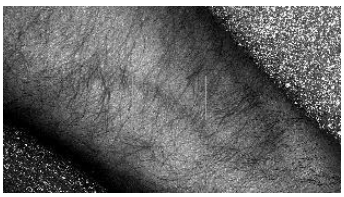
Camera power: Long lasting 6,700 mAh battery

- 4 hours continuous usage

Product validation

The Company, along with our ISO 9001 and ISO 13485 partners, have designed and manufactured vein finder medical devices for more than 7 years The complaints from the medical industry regarding vein finder products are:

- The devices are too expensive,
- They cannot be carried into the home,
- The veins look to be the same depth,
- They cannot penetrate hair to find a vein.
- **The Vein-Eye Carry solves those problems.**



- The MSRP of the VEC is approximately 50% less than the leading selling device.

- Home healthcare is one of our targets. The VEC can easily be carried into the home, from room to room in a hospital or nursing home, and to remote towns and villages.

- The images of the subdermal veins with the VEC clearly show the depth of the veins and their exact locations. **(15)**

- The VEC technology penetrates layers of fat, hair, moisture and skin color to provide accurate real-time images of veins in every patient.

The company uses customer feedback as a means of product validation. This has been very helpful to improve our technology and to streamline development.

Validation of the packaging/ageing studies

The product packing is based on the dimension and weight of our product, which allows ease of use and carry for our customer. Both the carry case and the corrugated box carton are used to protect the device when shipping to customer.

Process validation (e.g., sterilization, manufacturing, production)

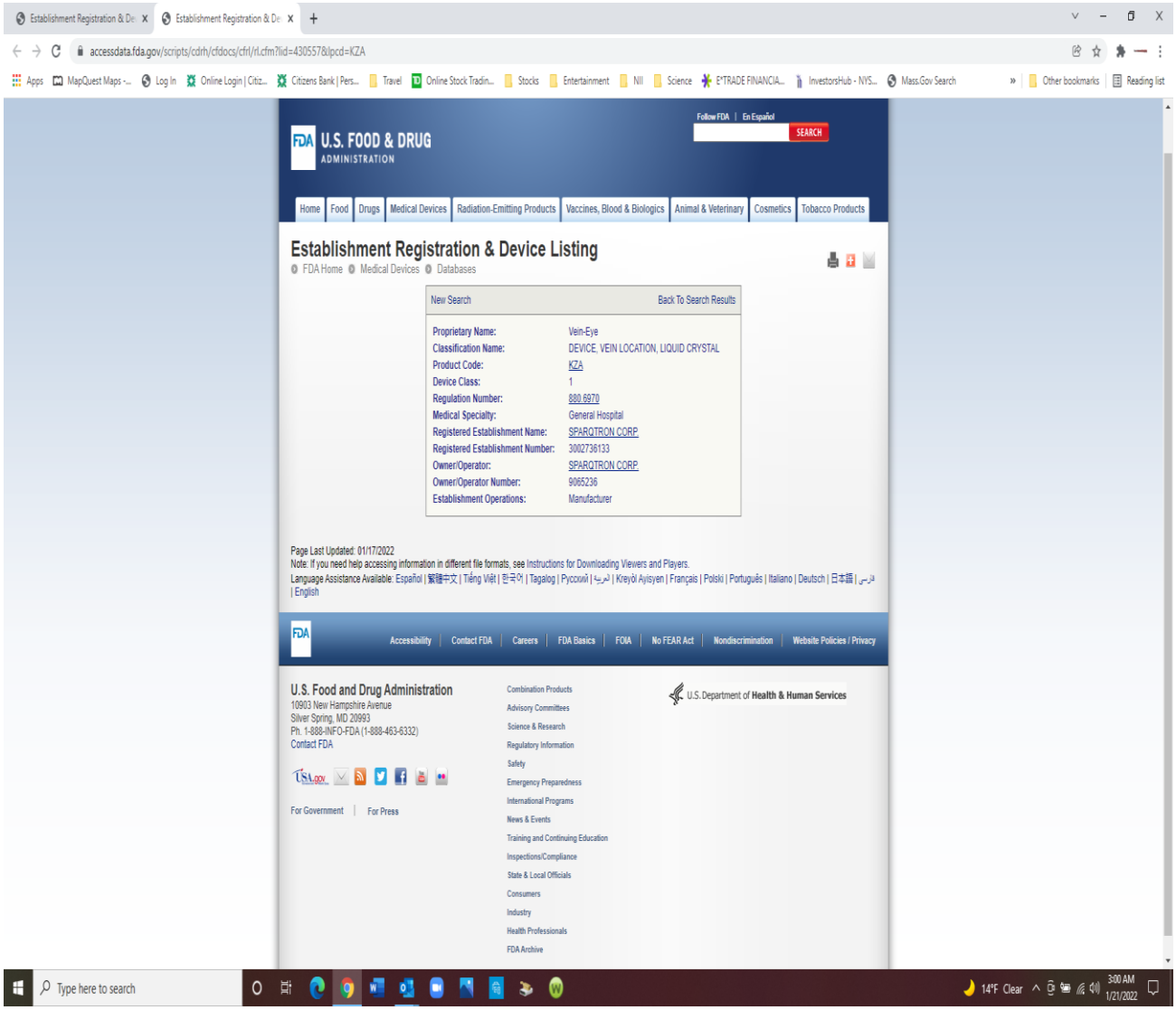
Cleaning and Disinfecting

1. Always disconnect the Vein-Eye CARRY from any power source before performing any maintenance or cleaning.
2. Clean surfaces with a damp cloth using water only. Dry thoroughly.
3. AOID CLEANING AROUND CONNECTORS. Excess moisture in, on or around the case, cables or air fittings could affect operation.
4. Clean the Vein-Eye CARRY as needed and per Hospital/clinic guidelines.
5. To clean the Vein-Eye CARRY, wipe the surfaces of the case with a clean cloth moistened in water only.
6. To disinfect the Vein-Eye CARRY, wipe everything with a hospital grade disinfectant.
7. Do NOT spray cleaners or pour liquids directly onto the surfaces of VEC03. Doing so may cause fluids enter into the device and may damage the device.

System parameters

Height:	6”	Without accessories
	2	With accessories
Weight:	4 lbs.	Without accessories
	6 lbs.	With accessories
Width:	NA	
Operating	Temperature	3.9°C to 40.5°C (39.02°F to 104.9°F)
	Humidity	5.1% to 86% RH non-condensing
Transport	Temperature	-19.5°C to 51°C (-3.1°F to 123.8°F)
	Humidity	4.9% to 86% RH non-condensing
Storage	Temperature	-21°C to 51°C (-5.8°F to 123.8°F)
	Humidity	4.9% to 86% RH non-condensing

Attachment A



Test Report issued under the responsibility

intertek

Total Quality. Assured.

of:

IEC 60601-1 **Medical electrical equipment** **Part 1: General requirements for basic safety and essential performance**	
Report Reference No.....:	104473702BOX-001
Date of issue.....:	17-November-2020
Total number of pages.....:	97
CB Testing Laboratory.....:	Intertek Testing Services N.A. Inc.
Address.....	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name .....:	Near Infrared Imaging Inc.
Address.....:	115 King James Way Wrentham, MA 02093-1375 USA
Test specification:	
Standard .....:	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure .....:	CB Scheme
Non-standard test method……..:	CER Report
Test Report Form No.....:	IEC60601_1C_II
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2011-11

General disclaimer:

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Test item description .....:	Vain Illumination System
Trade Mark .....:	Vein-Eye®
Manufacturer.....:	Near Infrared Imaging Inc.
Model/Type reference.....:	Vein-Eye CARRY
Ratings.....:	Input: 100-240VAC, 0.5A, 50/60Hz, Output: 5VDC, 3000mA; 9VDC, 2000mA; 12VDC, 1500mA (Specified Power Supply P/N: XY18W-1204-PD) Equipment Rated 12Vdc, 1.9A, 22.8W