VIP®-300
Pupillometer

Instructions for Use

VIP®-300 Pupillometer

Introduction

The NeurOptics® VIP®-300 Pupillometer offers clinicians quantitative infrared technology to objectively and accurately measure pupil size in an advanced design. The system acquires images using self contained infrared and visible illumination sources and a digital camera. It analyzes the captured image data and displays a summary of the measurement in the LCD window. The NeurOptics VIP-300 Pupillometer uses a menu driven graphical user interface (GUI), with a color touchscreen LCD screen for data display. A keypad completes the user interface and enables manual entry of individual patient identification (ID).

Indications for Use

The VIP-300 Pupillometer is a handheld optical scanner which measures pupil size at different background illuminations. The results obtained from the Pupillometer scans are used for information only and are not to be used for clinical diagnostic purposes. It should only be operated by properly trained clinical personnel, under the direction of a qualified physician.

Contraindications

Avoid use when the orbit structure is damaged, or surrounding soft tissue is edematous or has an open lesion.

Table of Contents

Warnings and Cautions

Warnings

Warnings and Cautions appear throughout this manual where they are relevant. The Warnings and Cautions listed here apply generally any time you operate the device.

- Use of the Pupillometer - The Pupillometer is intended for use by trained clinical personnel, under the direction of a qualified physician.
- If a problem is recognized while operating the device, the device must be removed from use and referred to qualified personnel for servicing. Using an inoperative device may result in inaccurate readings.
- Electric shock hazard - Do not open the device or the charging station. There are no user serviceable parts.
- The battery in the VIP®-300 Pupillometer is only replaceable by a qualified service technician. Contact NeurOptics if you suspect an inoperable battery.
- Use only the NeurOptics VIP®-300 Charging Station for charging the Pupillometer.
- Risk of fire or chemical burn – This device and its components may present a risk of fire or chemical burn if mistreated. Do not disassemble, expose to heat above 100°C, incinerate, or dispose of in fire.
- Store and use the VIP-300 System in ambient environments with non-condensing humidity levels only. Using the VIP-300 with condensation on optical surfaces may result in inaccurate readings.

Cautions

The following cautions apply when cleaning the device.

- The internal components of the Pupillometer are NOT compatible with sterilization techniques, such as ETO, Steam Sterilization, Heat Sterilization and Gamma.
- DO NOT submerge the device or pour cleaning liquids over or into the device.
- DO NOT use acetone to clean any surface of the Pupillometer or Charging Station.

Electromechanical Compatibility (EMC) Notice

This device generates, uses, and can radiate radio frequency energy. If not set up and used in accordance with the instructions in this manual, electromagnetic interference may result. **The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 for Medical Products**. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals, research laboratories).

Magnetic Resonance Imaging (MRI) Notice

This device contains components whose operation can be affected by intense electromagnetic fields. Do not operate the device in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

Wireless Notice

Do not attempt to pair the VIP-300 Pupillometer with the NeurOptics® Antimicrobial Barcode Scanner by Socket® while simultaneously using another barcode scanner in close proximity.

Classification

Type of Equipment: Medical Equipment, Class 1 886.1700

Trade name: NeurOptics®VIP®-300 Pupillometer

Manufactured by:

NeurOptics, Inc.
9223 Research Drive
Irvine, CA 92618 | USA
p: 949.250.9792
Toll Free North America: 866.99.PUPIL
info@NeurOptics.com
NeurOptics.com

Patents, Copyright and Trademark Notice

Federal Communications Commission Compliance

This device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference , and (2) this device must accept any interference received, including interference which may cause undesired operation.

Getting Started

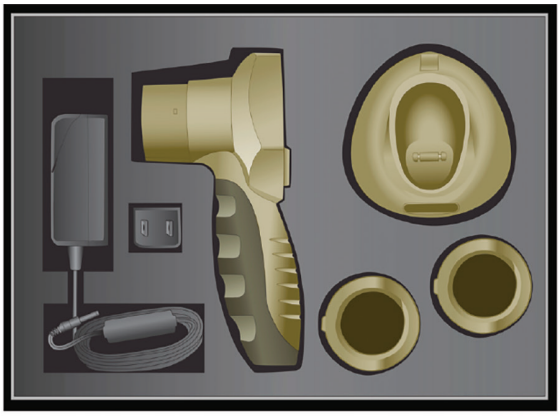
Safety Information

- Please review the following safety information prior to operating the device.
- Please read the Operating Instructions fully before attempting to use the Pupillometer. Attempting to operate the device without fully understanding its features and functions may result in unsafe operating conditions and/or inaccurate results.
- If you have a question regarding the installation, set up, operation, or maintenance of the device, please contact NeurOptics.

Unpacking the Pupillometer

The NeurOptics VIP®-300 Pupillometer is packaged with the following components (Ex. 1):

- VIP-300 Pupillometer
- VIP®-300 Charging Station
- Eye Cups (2)
- VIP®-300 Power Adapter and Plug
- VIP®-300 Instructions for Use



Ex. 1

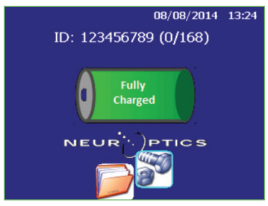
Power Up

Initial Set-up

Connect the VIP-300 Pupillometer Power Adapter and Plug to the VIP-300 Charging Station and plug into a power outlet. The green light at the base of the Charging Station will indicate power has been established (Ex. 2).

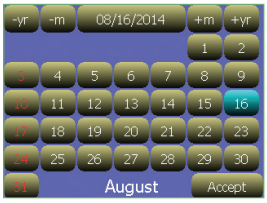
Ex. 2

Place the VIP-300 into its Charging Station. After powering on, the touchscreen will display a blue battery icon indicating the VIP-300 is charging. The battery icon will turn green when fully charged (Ex. 3).



Ex. 3

To modify the date and time, from the Home Screen, select the **Settings** icon and then select **Set Date** and **Set Time** (Ex. 4). Follow the prompts to input the proper date and time using 24 hour time configuration and select **Accept**.



Ex. 4

Date and Time Maintenance

Regular quarterly maintenance is necessary to ensure date and time are correct. The set date and time will affect the timestamp listed for subsequent patient pupil measurements on the VIP-300. Changing the date and time will not alter the timestamps on previous measurements.

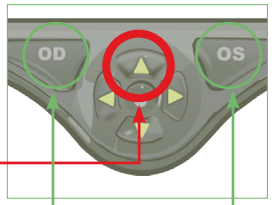
Turning On the VIP-300

When not in use, the VIP-300 should be kept in the Charging Station. If the VIP-300 is not in the Charging Station, to conserve battery life the Pupillometer will:

- Go into sleep mode after 5 minutes. Touch the screen to turn on.
- Power down after 30 minutes. Press and hold the Up arrow to turn on (red circle Ex. 5).

To get to the Home Screen:

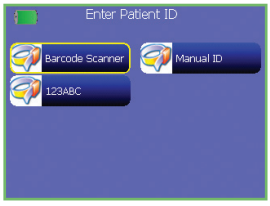
- Press **LEFT** or **RIGHT** Button (green circles)



Ex. 5

Enter a new Patient ID

Patient ID is reported in the Home Screen (Ex. 3) and it enables recall of patient data. To assign a new Patient ID, from the Home Screen select icon and then select either **Barcode Scanner** or **Manual ID** to indicate the patient ID entry method to be used (Ex. 6). In case other ID numbers are included in the VIP®-300 database stored in memory, these will be listed in the same window (e.g. ID=123ABC , Ex. 6) and they can be immediately re-entered.



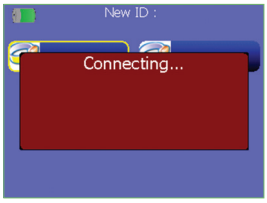
Ex. 6

Pairing the VIP-300 to the NeurOptics Antimicrobial Barcode Scanner

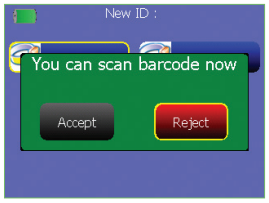
Connect the NeurOptics Antimicrobial Barcode Scanner and Charging Cradle to the power adapter and plug into a power outlet (Ex. 7). Turn on the Barcode Scanner until an audible beep is heard and a blue light on the device flashes. Position the **Barcode Scanner** next to the VIP-300.


Ex. 7

On the VIP-300, select Barcode Scanner. The VIP-300 will display ***"Connecting..."*** on the touchscreen (Ex. 8). Once successfully paired, the touchscreen will prompt when the device is ready to scan the patient ID barcode (Ex. 9).

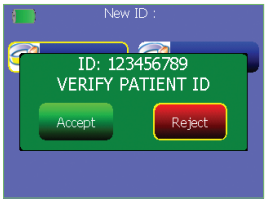


Ex. 8



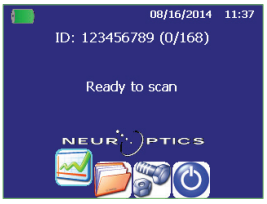
Ex. 9

The patient ID will now appear on the VIP-300 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 10).



Ex. 10

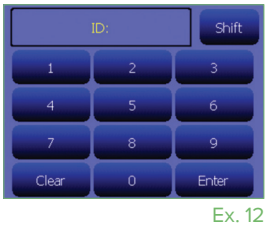
The VIP-300 will display the patient ID number and read ***"Ready to scan"*** (Ex. 11).



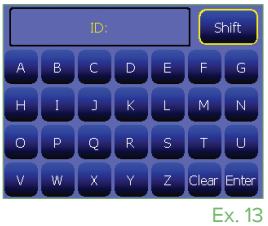
Ex. 11

Manual Entry of the Patient ID

Press Manual Entry. Using the touchscreen, press the **Patient ID**. Select **Shift** to toggle from alpha to numeric as required. When the patient ID number has been manually entered, check for accuracy and press **Enter** (Ex. 12 & 13).



Ex. 12



Ex. 13

Set Measurement Protocol

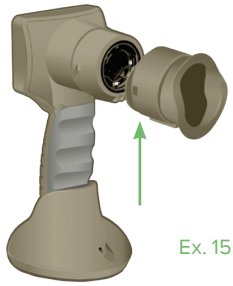
From the Home Screen, select the **Settings** icon and then the top left icon to toggle between **Light Off** and **Variable** modes (Ex. 14).

Ex. 14

In the **Variable** mode, the eye is exposed to a sequence of three consecutive light backgrounds simulating **Scotopic, Low Mesopic** and **High Mesopic** viewing conditions and the duration of the measurement is approximately 12 seconds. During Scotopic, the background is off. Low Mesopic (approx. 0.3 lux), simulates lighting conditions such as moon illumination, driving at night outside of urban areas, or a dimly lit room. High Mesopic (approx. 3 lux) simulates conditions such as moderate night streetlights or early twilight. Patient should be dark adapted prior to taking a measurement in variable mode.

The **Light Off** mode is approximately 2 seconds and there is no light background.

The VIP-300 should not be used without the eye cup positioned correctly (Ex. 15). It is very important that the eye cup be correctly fitted. A snug fit helps reduce the possibility of stray light entering the eye while the scans are taking place. The eye cup has a tab in the rim, which fits into the indentation in the lens shield of the Pupillometer. Position the tab in the eye cup rim into the indent in the lens shield and press into place. The tabs on either side of the lens shield should also snap into the holes on either side of the eye cup.


Ex. 15

Patient and Environment Preparation

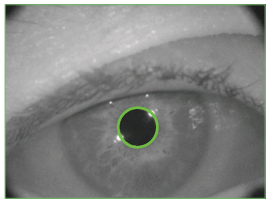
- Before initiating the measurement scan, turn off or reduce overhead lighting to ensure that the room is darkened (if maximum pupil size is desired).
- Instruct the patient to focus on a small target object (for example, a wall chart or a dim flashing light that is at least 10 or more feet [3 meters] away) with the eye that is not being tested. The operator should not stand in the line of sight between the patient and the distant target.
- Ask the patient to keep their head straight and both eyes wide open during both targeting and measurement. In some cases if targeting becomes a problem, it may be necessary to gently hold the patient's eye open with your finger.
- The operator should position the instrument at a right angle to the patient's axis of vision and any tilting of the instrument should be minimized (Ex. 16).
- It may be helpful for the operator to be at the same level as the patient when performing the scan to minimize tilting. If necessary, both patient and operator can sit down facing each other during targeting and measurement.


Ex. 16

Measure Pupils

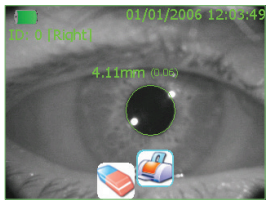
Position the VIP-300 with the eye cup at a right angle to the patient's axis of vision, minimizing any tilting of the device (Ex. 16).

Press and hold either the **OD** or **OS** button until the eye is centered on the touchscreen and the display shows a circle around the pupil (Ex. 17). Once the circle appears (green for OD and yellow for OS), release the button, holding the VIP-300 in place for approximately 2 seconds for Light Off mode or 12 seconds for Variable mode, making sure the patient maintains an open eye position.


Ex. 17

When the pupil measurement is complete, pupil data are analyzed and then results finally displayed. If the measurement was affected by a tracking problem (e.g. excessive blinks) then results are reported as **NA**.

The results page in Light Off mode (Ex. 18) shows the diameter of the pupil in bold and (in parenthesis and smaller font) the standard deviation of pupil diameter measured during the scan. It also includes the ID number of the subject, the date and time of the measurement and, finally, which eye, (OD or OS) was measured.

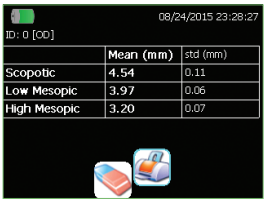


Ex. 18

Measure Pupils (cont.)

From the results page, you may select the **Video** icon to view the video playback of the scan. Records can also be deleted using **Delete** icon or printed using a Wireless printer using the **Print** icon. Contact NeurOptics® for information about the printer.

The results page in Variable mode (Ex. 19) shows the diameter and the standard deviation of pupil diameter measured during the scan at the three different light levels.



Ex. 19

Browse Records

To browse, retrieve and print data from previous measurements select icon from the Home Screen. In the browse records menu (Ex. 20) select **All Records** to browse all records in memory, or **Specify Patient ID** if only one specific patient needs to be retrieved. All the most recent patient IDs are reported in the browse records catalog so that it is possible to select directly from the catalog without having to re-enter the Patient ID using option Specify Patient ID (e.g. ID=123ABC , Ex. 20).

Ex. 20

Rebooting the VIP-300 Pupillometer

As with any electronic device, the VIP-300 Pupillometer may occasionally require a System Reboot. To reboot the VIP-300 Pupillometer, simply press and hold the button on the device until it powers OFF and then power it back on.

Power Down

To turn the VIP-300 off, select the from the Home Screen and confirm **Yes**.

Troubleshooting

Issue	Possible Reason	Solution
1. Device will not turn on	Using incorrect power adapter	Use only power adapter provided with Pupillometer. Check label on power adapter
	Power cord is not fully plugged into the wall or the charging station	Check connections
	Battery completely discharged	Charge the battery by positioning the Pupillometer into the Charging Station
2. Pupil measurement will not initiate after release of the OD or OS key	Too much blinking	Gently hold patient's eye open with your finger during measurement
	Device not held correctly	Hold device at a 90-degree angle to patient's face. Make sure patient's eye is centered on the screen

Cleaning and Maintenance

ALWAYS handle the VIP-300 Pupillometer and VIP-300 Charging Station with care because sensitive metal, glass, plastic and electronic components are contained inside. The VIP-300 and Charging Station can be damaged if dropped or by prolonged exposure to liquid or high humidity environments.

The VIP-300 Pupillometer and VIP-300 Charging Station do not require any regularly scheduled maintenance. If the VIP-300 Pupillometer and VIP-300 Charging Station are not working properly, or are believed to have been damaged, immediately contact NeurOptics Customer Service at **Toll Free North America**: 866.99.PUPIL (866-997-8745), international: +1-949-250-9792, or email: **info@NeurOptics.com.**

Cleaning the VIP-300 Pupillometer and VIP-300 Charging Station

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA (70% IPA), are recommended for use in cleaning the VIP-300 Pupillometer and VIP-300 Charging Station. Do not use chemicals that can damage the pupillometer and charging station surface. Some chemicals can weaken or damage plastic parts and may cause instruments to not operate as intended. Use all cleaning products per manufacturer's instructions, being careful to squeeze out excess liquid prior to wiping the pupillometer and charging station and do not use an oversaturated cloth.

Wipe all exposed surfaces. Follow the cleaner's manufacturer instructions as to the time required to leave the solution on the device surface.

- **DO NOT** allow any other cleaner other than 70% IPA to contact the gold connector blades located on the bottom of the VIP-300 Pupillometer handle, and the gold connector pins located in the base of the VIP-300 Charging Station.
- **DO NOT** use an oversaturated cloth. Be sure to squeeze out excess liquid prior to wiping the VIP-300 Pupillometer or the VIP-300 Charging Station.
- **DO NOT** allow the cleaner to collect on the instrument.
- **DO NOT** use any hard, abrasive or pointed objects to clean any part of the VIP-300 Pupillometer or VIP-300 Charging Station.
- **DO NOT** immerse the VIP-300 Pupillometer or the VIP-300 Charging Station in liquid, or attempt to sterilize the product, as damage to the electronic and optical componentry could occur.

Drying and Inspection Following Cleaning

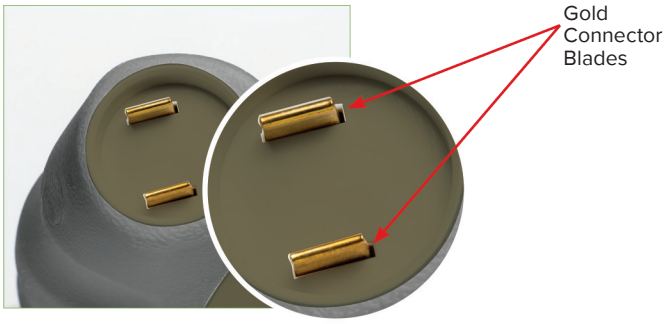
Confirm the VIP-300 Pupillometer is thoroughly dry before placing in the VIP-300 Charging Station to charge. Once thoroughly dry, place the VIP-300 Pupillometer into the VIP-300 Charging Station and plug in the VIP-300 Power Adapter to the back of the Charging Station to power ON.

- **DO NOT** place the VIP-300 Pupillometer into the VIP-300 Charging Station until all components are completely dry.
- **DO NOT** reconnect the VIP-300 Power Adapter to the VIP-300 Charging Station until all components are completely dry.

Cleaning Considerations: Gold Connector Pins and Blades

In instances where there is concern of exposure to highly resistant bacteria or viruses (ie: Clostridium difficile, or “C. diff”), we understand that hospital protocols may require use of cleaning solutions containing sodium hypochlorite (bleach) when cleaning equipment. Please be aware solutions containing sodium hypochlorite (bleach) will corrode the gold connector blades located on the bottom of the VIP-300 Pupillometer handle (Figure 21), and the gold connector pins located in the base of the VIP-300 Charging Station (Figure 22.)

VIP®-300 Pupillometer



VIP®-300 Pupillometer

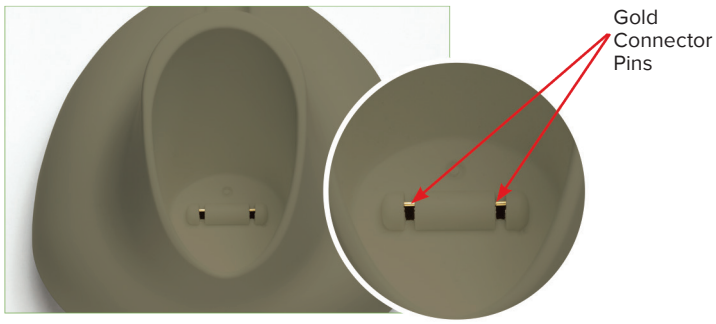


Figure 22- Gold Connector Pins

- **DO NOT** use products containing sodium hypochlorite (bleach) to clean the gold connector blades located on the bottom of the VIP-300 Pupillometer handle, and the gold connector pins located in the base of the VIP-300 Charging Station

If products containing sodium hypochlorite (bleach) are used to clean the gold connector blades located on the bottom of the VIP-300 Pupillometer and the gold connector pins located in the base of the VIP-300 Charging Station, the cleaning process should be followed by a second cleaning using 70% IPA solution to ensure that all residue is completely removed from the device in order to minimize damage to the gold connector pins and blades.

Cleaning Considerations: Pupillometer Liquid Crystal Display (LCD)

For best protection of the liquid crystal display (LCD), use a clean, soft, lint-free cloth and 70% IPA cleaning solution to clean the VIP-300 LCD.

In instances where there is concern of exposure to highly resistant bacteria or viruses (ie: Clostridium difficile, or “C. diff”), we understand that hospital protocols may require use of cleaning solutions containing sodium hypochlorite (bleach) when cleaning equipment. If products containing sodium hypochlorite (bleach) are used to clean the LCD of the VIP-300 Pupillometer, the cleaning process should be followed by a second cleaning solution with a 70% IPA solution to ensure that all bleach residue is completely removed from the LCD using a clean, soft, lint-free cloth.

Ordering Information

VIP-300	VIP-300 Pupillometer
NEUR-2059-01	Eye Cup
BCS-CC-01	NeurOptics® Antimicrobial Barcode Scanner by Socket®
NEUR-PRTS445-BT	Seiko printer

Customer Service

For technical support, or if you have a question about your order, please contact NeurOptics Customer Service.
Toll Free North America: 866.99.PUPIL (866-997-8745) | **p:** 949.250.9792 | International +1-949-250-9792, or
email: info@neuroptics.com

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact, to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling. Determination of a product defect or mislabeling will be made by NeurOptics, which determination will be final. Products will not be accepted for replacement or credit if they have been in the possession of the customer for more than 30 days.

Appendix A—Technical Specifications

Parameter	Description
Measurement Characteristics	Input= Human pupil sizing varying from 1 mm–9 mm Mean and standard deviation of pupil diameter at different background illuminations Accuracy: +/- 0.03 mm
Degree of protection against electric shock	Pupillometer & Eyecup-Type BF Applied Part provided protection Charging Station & Power Adapter-Type B Applied Part provided protection
Classification of the equipment against ingress of liquids	Ordinary equipment
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not an AP or APG category equipment
Mode of Operation	On Demand battery operation
Power Adapter	Input: 100-240 VAC +/- 8% Output: 6V, 2.8 Amps
Battery	3.6V 11.70 Wh 3350 mAh/hour Li: Ion Cell
Operating Environment	Temperature Range: 0° C (32° F) to 40° C (104° F) Relative Humidity: Non-condensing at all times
Transportation and storage environment	Temperature Range: -38° C (-36.4° F) to 70° C (158° F) Relative Humidity: Non-condensing at all times
Dimensions	With eye cup = 7.5" H, 3.5" W, 4.5" D Without eye cup = 7.5" H, 3.5" W, 3.5" D
Weight	320 grams +/- 10 grams
Classification	Class 1 LED product per IEC 62471

Appendix B—Wireless Broadcast Range and Frequency

Broadcast Function	Range	Frequency
Wireless Barcode Scanner to/from VIP-300 Pupillometer	Up to 100 yards depending on environment	2.45 GHz

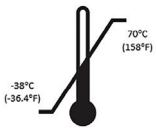
Appendix C— International Symbol Definition

Symbol	Source/Compliance	Title of Symbol	Description of Symbol
	Standard: ISO 15223-1 Symbol Reference No: 5.4.4	Caution	Indicates caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Standard: IEC 60417 Symbol Reference No: 5333	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1
	Standard: IEC 60417 Symbol Reference No: 5840	Type B Applied Part	To identify a type B applied part complying with IEC 60601-1
	Section 1.1 of Chapter I of Annex IX to Directive 93/42/EEC. U.S. 21 CRF 801.5(c.)	Intermittent Use	To indicate use to be Transient or intermittent with contact to intact skin with duration less than 60 minutes
	Standard: ISO 15223-1 Symbol Reference No: 5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	Standard: ISO 15223-1 Symbol Reference No: 5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Standard: ISO 15223-1 Symbol Reference No: 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified

Appendix C— International Symbol Definition (cont.)

LOT	Standard: ISO 15223-1 Symbol Reference No: 5.1.5	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	BS EN 50419 Article 11(2) of the European Community Directive 2002/96/EC (WEEE)	Recycle: Electronic Equipment	Identifies product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2012/19/ EU Directive for recycling of electronic equipment. Do not dispose of this product in unsorted municipal waste stream
	Standard: IEC TR 60417 Symbol Reference No: 6367	Coin Cell; Coin Battery	To provide information on packaging that it contains a small round cell or battery where the overall height is less than the diameter, and which contains non-aqueous electrolyte, for example a lithium cell or battery. To identify a device related to the power supply by such cell or battery, for instance a cover for the battery compartment
	U.S. 40 CRF 273.2 European Community Directive Article 21 of 2006/66/EC	Recycle. Battery contains Lithium.	Dispose of according to local procedures for products containing lithium Ion batteries and products containing lithium perchlorate
	Standard: ISO 15223-1 Symbol Reference No: 5.1.1	Manufacturer	Indicates the medical device manufacturer
CE	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	Conformité Européene or European Conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation
CE 0123	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	Conformité Européene or European Conformity with Identification of Notified Body	Indicates that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation and that the product is listed through TUV SUD as the Notified Body
EC REP	Standard: ISO 15223-1 Symbol Reference No: 5.1.2	Authorized representative in the European Community / European Union	Indicates the authorized representative in the European Community / European Union

Appendix C—International Symbol Definition (cont.)

Symbol	Source/Compliance	Title of	Description of Symbol
	Standard: ISO 15223-1 Symbol Reference No: 5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use at **NeurOptics.com**
	Standard: IEC TR 60878 Symbol Reference No: 5140	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
	Standard: ISO 15223-1 Symbol Reference No: 5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture
	Standard: ISO 15223-1 Symbol Reference No: 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Standard: ISO 15223-1 Symbol Reference No. 5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Standard: ISO 15223-1 Symbol Reference No: 5.7.7	Medical Device	Indicates the item is a medical device
	Standard: ISO 15223-1 Symbol Reference No: 5.7.10	Unique device identifier	Indicates a carrier that contains unique device identifier information

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