

PLR[®]- 3000 Pupillometer

Instructions for Use



PLR[®]-3000 Pupillometer

Introduction

The NeurOptics[®] PLR[®]-3000 Pupillometer offers researchers quantitative infrared technology to objectively and accurately measure pupil size and dynamics 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 PLR-3000 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 NeurOptics PLR[®]-3000 is indicated for clinical ophthalmic practice and pupil research purposes. The PLR-3000 Pupillometer is a hand-held optical scanner which measures pupil size and dynamics under different light and experimental protocols. The results obtained from the Pupillometer scans are used for information only and are not to be used for 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.



Warnings and Cautions

Warnings

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

- The Pupillometer is intended for use by trained personnel.
- 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 PLR®-3000 Pupillometer is only replaceable by a qualified service technician. Contact NeurOptics if you suspect an inoperable battery.
- Use only the NeurOptics PLR®-3000 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.

Cautions

The following cautions apply when cleaning the device or when sterilizing device accessories.

- 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 an 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.

Bluetooth® Notice

Do not attempt to pair the PLR-3000 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® PLR®-3000

Pupillometer **Manufactured by:**

NeurOptics, Inc.

23041 Avenida de la Carlota, Suite 100
Laguna Hills, CA 92653 | USA



p: 949.250.9792

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NeurOptics.com

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Pupillometers:

Pat. No. 6116736

Pat. No. 6260968

Pat. No. 6820979

Pat. No. 7147327

Pat. No. 7670002

Pat. No. 8235526

Pat. No. 8393734

Pat. No. 7967442

Pat. No. 8534840

Pat. No. 9198570

Canadian Pat. No. 2368232 Other
Patents Pending

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.

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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, setup, operation, or maintenance of the device, please contact NeurOptics.

Unpacking the Pupillometer

The NeurOptics PLR®-3000 Pupillometer is packaged with the following components (Ex. 1):

- PLR-3000 Pupillometer
- PLR®-3000 Charging Station
- Eye Cups (2)
- PLR®-3000 Power Supply Adaptor
- PLR®-3000 Instructions for Use



Ex. 1

Power Up

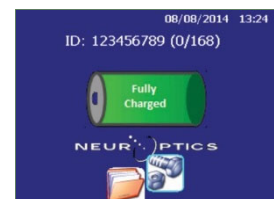
Initial Set-up

Connect the PLR-3000 Pupillometer Power Supply to the PLR-3000 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 PLR-3000 into its Charging Station. After powering on, the touchscreen will display a blue battery icon indicating the PLR-3000 is charging. The battery icon will turn green when fully charged (Ex. 3).



Ex. 3

To modify the date and time, from the main screen, select the **Settings** icon  and then select **Set Date**  and **Set Time**  (Ex. 4 and Ex. 5). Follow the prompts to input the proper date and time using 24 hour time configuration and select **Accept**.



Ex. 4



Ex. 5

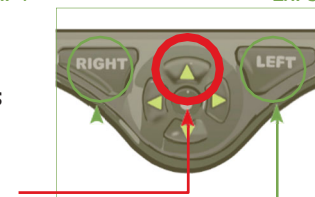
Turning On the PLR-3000

When not in use, the PLR-3000 should be kept in the Charging Station. If the PLR-3000 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. 6).


To get to home screen:

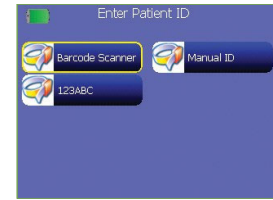
- Press **LEFT** or **RIGHT** Button (greencircles)



Ex. 6

Enter a new Patient ID

Patient ID is reported in the main screen (Ex. 3) and it enables recall of patient data. To assign a new Patient ID, from the main screen select icon  and then select either **Barcode Scanner** or **Manual ID** to indicate the patient ID entry method to be used (Ex. 7). In case other ID numbers are included in the PLR®-3000 database stored in memory, these will be listed in the same window (e.g. ID=123ABC, Ex. 7) and they can be immediately re-entered.



Ex. 7

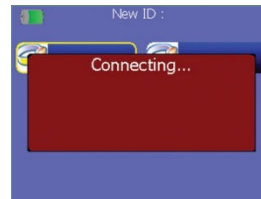
Pairing the PLR-3000 to the NeuroOptics Barcode Scanner

Connect the NeuroOptics Barcode Scanner and Charging Cradle to the power supply and plug into a power outlet (Ex. 8). 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 PLR-3000.

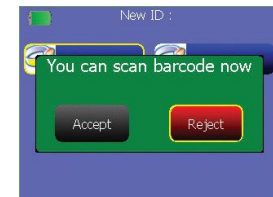


Ex. 8

On the PLR-3000, select Barcode Scanner. The PLR-3000 will display **“Connecting...”** on the touchscreen (Ex. 9). Once successfully paired, the touchscreen will prompt when the device is ready to scan the patient ID barcode (Ex. 10).



Ex. 9



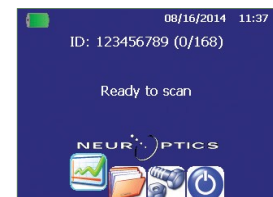
Ex. 10

The patient ID will now appear on the PLR-3000 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 11).



Ex. 11

The PLR-3000 will display the patient ID number and read **“Ready to scan”** (Ex. 12).



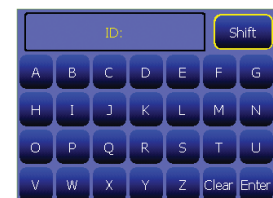
Ex. 12

Manual Entry of the Patient ID

Press **Manual ID 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. 13 & 14).





Ex. 13



Ex. 14

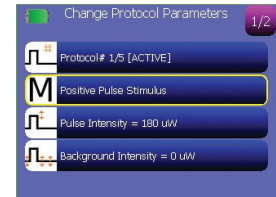
Set Measurement Protocol

From the main screen (Ex. 12), select the **Settings** icon  and then the top right icon  (**Define Protocol**, Ex. 15) to

navigate to the **Change Protocol Parameters** menu (Ex. 16). Each parameter listed in the two pages of this menu (Ex. 16) can be changed by toggling the values reported using the left “<” and right “>” keys in the directional keyboard.



Ex. 15



Ex. 16

 Five different experimental protocols can be saved in

memory and retrieved later when a specific protocol is needed. Press **Select** to activate a protocol. Use the left “<” and right “>” keys in the directional keyboard to change the protocol number. Use the list of parameters below to change the settings of the selected protocol.


M Use this setting to change the type of the experiment:


Positive Pulse Stimulus: standard pupil light reflex, a bright pulse over a dimmer background triggers a pupil constriction.

Negative Pulse Stimulus: dim pulse over a brighter background triggers a dark reflex and pupil dilation.

Static Stimulus: no light stimulation and no pupil reflex, just a continuous and static light background.

Extended Mode: pupil is recorded at a lower frequency for an extended period of time (maximum duration 10 minutes).

 **Pulse Intensity.** Use this setting to change the intensity of the light stimulus. Unit of light is radiometric and provided in micro Watts, uW. Five different intensities are provided: 0uW, 1uW, 10uW, 50uW, 121uW, and 180uW.

 **Background Intensity.** Use this setting to change the background light intensity. Note that in case of a Positive Pulse Stimulus protocol, Background Intensity must be less than Pulse Intensity whereas, for a Negative Pulse Stimulus, protocol it is the opposite -- Background must be higher than the Pulse Intensity.

Measurement Duration. This setting is for setting the duration of the measurement, a minimum of 3 seconds up to a maximum of 41seconds.

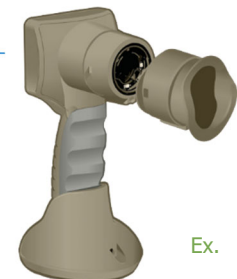
 **Pulse Duration.** This is the duration of the light pulse stimulation, a minimum of 0.03 sec for the Positive Pulse and 1 sec for the Negative Pulse.

 **Pulse Onset.** This is the start of the Pulse stimulation.

In case there is a conflict in the settings, for example the Background Intensity is set brighter than the Pulse Intensity in a Positive Pulse Stimulus protocol, then the corresponding icons are shown in red and the Define Protocol menu cannot be exited until the conflict is resolved.

Measure Pupils

The PLR-3000 should not be used without the eye cup positioned correctly (Ex. 17). 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.

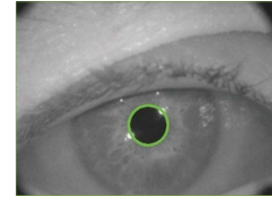
Position the PLR-3000 with the eye cup at a right angle to the patient's axis of vision, minimizing any tilting of the device (Ex. 18).



Ex. 18

Measure Pupils (cont.)

Press and hold either the **RIGHT** or **LEFT** until the eye is centered on the touch screen and the display shows a circle around the pupil (Ex.19). Once the circle appears (green for **RIGHT** and yellow for **LEFT**), release the button, holding the PLR-3000 in place for the entire duration of the measurement. When the pupil measurement is complete, pupil data are analyzed and then results will be displayed (Ex.20).



Ex. 19

Results page for Static Stimulus

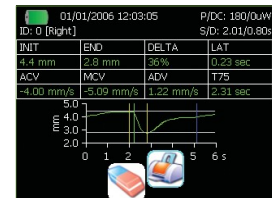
The results page for the Static Stimulus (Ex. 20) shows the diameter of the pupil in bold and the standard deviation of pupil diameter measured (in parenthesis and smaller font) during the scan. It also includes the ID number of the subject, the date and time of the measurement and, finally, which eye, (Right or Left) was measured.



Ex. 20

Results page for Positive or Negative Stimulus

The results page for the Positive Stimulus (Ex. 21) shows different information. The pupil diameter waveform is plotted as a function of time. The two vertical yellow lines show where the stimulus started and ended. The green vertical line shows the latency and the blue line the T75. Latency and T75 are two of the variables calculated by the analysis and they are explained in Appendix A. If a variable could not be calculated (for example, because of a blink) it is reported with dashes or in red in the table.

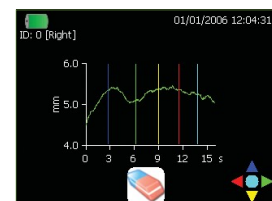


Ex. 21




The characteristics of the light stimulus are summarized in the top right corner: P/DC reports the intensity of the stimulus and the background in uW (here, 50uW for the pulse intensity over a 0uW background). S/D reports the Pulse Onset (2.01 sec in the example) and Pulse Duration (0.80 seconds in the example).

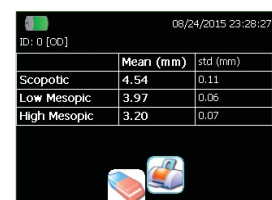
Results page for Extended Mode

The results page for the Extended Mode shows the whole pupil function as a function of time (Ex. 22). The colored vertical lines correspond to the five different keys of the directional keypad. The user can press any of those keys during the recording and the time(s) of the press (or presses) are reported in the plot and saved with the record. Note that an extended pupil recording is ended by a press of the RIGHT or LEFT key - the duration of the measurement is not defined.




Ex. 22

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 Bluetooth printer using the **Print** icon . Contact NeurOptics® for information about the printer.



Ex. 23


Browse Records

To browse, retrieve and print data from previous measurements select icon  from the main screen. In the browse records menu (Ex. 23) 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.24).



Ex. 24

Download Records

Data can be downloaded to an external computer via Bluetooth.  Verify the computer is in “Discoverable” mode (i.e., in the Bluetooth Settings, the box for “**Allow Bluetooth devices to find this computer**” should be checked.) Select the Bluetooth icon in the Settings menu of the Pupillometer and then follow the instructions. The device might need to be paired the first time. If so, a PIN is provided in the instructions. Initiate the Receive Files protocol in the receiving external computer. You can either right click on the Bluetooth icon in the notification area near the task bar and then click on “Receive a File” or:



Ex. 25

- In Windows 7, click on the Start button and type fsquirt in the box that says Search programs and files.
- In Windows 8 and 8.1, open the Start screen and type fsquirt.
- In Windows 10, right-click Start and select Run, type fsquirt into the box and press Enter.

This will open the Bluetooth File Transfer window. Select the Receive Files option then press “Dismiss” on the Pupillometer and go to the next page.

Select what type of data should be downloaded (Ex. 25).

- Select Records to download a file (Excel compatible) with all the records saved in memory.
- Select Video to download the video of the latest collected measurement.

The video is not in standard format. NeurOptics can provide a Matlab® script for reading and interpreting the video file (contact NeurOptics® Customer Service at Toll Free North America: 866.99.PUPIL or +1 949.250.9792.)

The Pupillometer will display a list of available Bluetooth devices. Select the computer name set to Receive Files. Be aware that the search for all available Bluetooth devices around the Pupillometer could take several minutes. The list is updated continuously on the screen of Pupillometer. Follow the instructions shown on the Computer and Pupillometer then wait until the download is complete. Press the Close link button on the Pupillometer to complete the download.

Power Down

To turn the PLR-3000 off, select the  from the main screen and confirm **Yes**.

Rebooting the PLR-3000 Pupillometer

As with any electronic device, the PLR-3000 Pupillometer may occasionally require a System Reboot. To reboot the PLR-3000 Pupillometer, simply press and hold the  button on the device until the Pupillometer powers ON.

Cleaning and Maintenance

ALWAYS handle the PLR-3000 Pupillometer and PLR-3000 Charging Station with care because sensitive metal, glass, plastic and electronic components are contained inside. The PLR-3000 Pupillometer and PLR-3000 Charging Station can be damaged if dropped, or if they come in contact with liquid.

The PLR-3000 Pupillometer and PLR-3000 Charging Station do not require any regularly scheduled maintenance. If the PLR-3000 Pupillometer and PLR-3000 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: Support@NeurOptics.com.

Cleaning the PLR-3000 Pupillometer and PLR-3000 Charging Station

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA (70% IPA), are recommended for use in cleaning the PLR-3000 Pupillometer and PLR-3000 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 PLR-3000 Pupillometer handle, and the gold connector pins located in the base of the PLR-3000 Charging Station.
- **DO NOT** use an oversaturated cloth. Be sure to squeeze out excess liquid prior to wiping the PLR-3000 Pupillometer or the PLR-3000 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 PLR-3000 Pupillometer or PLR-3000 Charging Station.
- **DO NOT** immerse the PLR-3000 Pupillometer or the PLR-3000 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 PLR-3000 Pupillometer is thoroughly dry before placing in the PLR-3000 Charging Station to charge. Once thoroughly dry, place the PLR-3000 Pupillometer into the PLR-3000 Charging Station and plug in the PLR-3000 Power Supply to the back of the charging station to power ON.

- **DO NOT** place the PLR-3000 Pupillometer into the PLR-3000 Charging Station until all components are completely dry.
- **DO NOT** reconnect the PLR-3000 Power Supply to the PLR-3000 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 PLR-3000 Pupillometer handle (Figure 26), and the gold connector pins located in the base of the PLR-3000 Charging Station (Figure 27.)

PLR-3000 Pupillometer

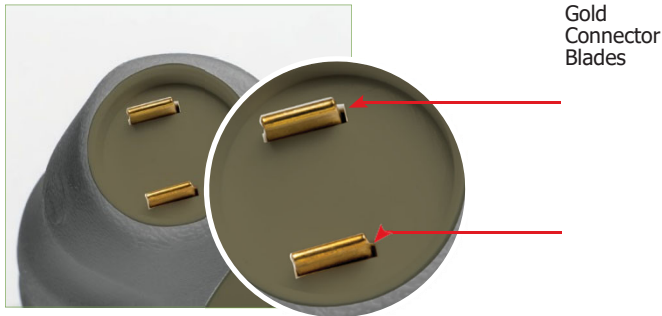


Figure 26- Gold Connector Blades

PLR-3000 Pupillometer

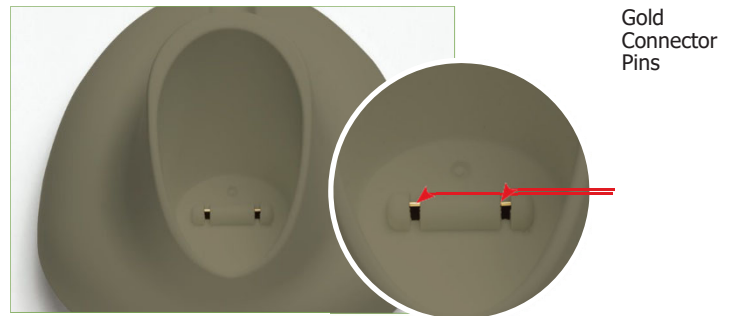


Figure 27- Gold Connector Pins

- **DO NOT** use products containing sodium hypochlorite (bleach) to clean the gold connector blades located on the bottom of the PLR-3000 Pupillometer handle, and the gold connector pins located in the base of the PLR-3000 Charging Station

If products containing sodium hypochlorite (bleach) are used to clean the gold connector blades located on the bottom of the PLR-3000 Pupillometer and the gold connector pins located in the base of the PLR-3000 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 pupillometer optics.

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 PLR-3000 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

PLR-3000	PLR®-3000 Pupillometer
NEUR-2059-01	Eye Cup
BCS-CC-01	NeuroOptics® 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 NeuroOptics Customer Service.
Toll Free North America: 866.99.PUPIL (866-997-8745) | **p:** 949.250.9792 | **International** +1-949-250-9792,
or email: Support@neurooptics.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 NeuroOptics, 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—Pupillary Measurement Variables

Broadcast Function	Range
Init = Maximum Diameter	Maximum pupil size before constriction
End = Minimum Diameter	Pupil diameter at peak constriction
Delta = % Change	$(\text{Init} - \text{End}) / \text{Init}$ as a %
LAT = Latency of constriction	Time of onset of constriction following initiation of the light stimulus
ACV = Constriction Velocity	Average velocity of how the pupil diameter is constricting measured in millimeters per second
MCV = Maximum Constriction Velocity	Maximum velocity of how the pupil diameter is constricting measured in millimeters per second
ADV = Dilation Velocity	The average pupillary velocity when, after having reached the peak of constriction, the pupil tends to recover and to dilate back to the initial resting size, measured in millimeters per second
T75 = 75% Recovery Time	The time taken by the pupil to recover 75% of the initial resting pupil size after it has reached the peak of constriction

Appendix B—Technical Specifications




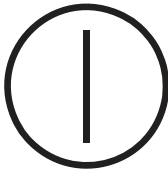





Parameter	Description
Measurement Characteristics	Input= Human pupil sizing varying from 1 mm–9 mm Mean and standard deviation of pupil diameter at different background illuminations Accuracy: +/- 0.03 mm
Degree of protection against electric shock	Pupillometer is double insulated (Class II protection)
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 Supply	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: 18° C (65 F) to 30° C (86° F)
	Relative Humidity: 20% to 70% RH. Non-condensing at all times
Transportation and storage environment	Temperature Range: 0° C (32° F) to 75° C (167° F)
	Relative Humidity: 10% to 95% RH. 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 60825

Appendix C—Bluetooth® Broadcast Range and Frequency







Broadcast Function	Range	Frequency
Bluetooth Barcode Scanner to/from PRL-3000 Pupillometer	Up to 100 yards depending on environment	2.45 GHz

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Appendix D— International Symbol Definition

Symbol	Source/Compliance	Title of Symbol	Description of Symbol
	Standard: ISO 15223-1 Symbol Reference No: 5.4.4	Caution	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	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.
	Standard: IEC 60417, Symbol Reference No: 5010	“ON”/ “OFF” (Power)	To indicate electronic power connection or disconnection to internal battery supply.
	Section 1.1 of Chapter I of Annex IX to Directive 93/42/EEC. U.S. 21 CFR 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: 5.4.4	Non-sterile. Single patient use only	Indicates a medical device that has not been subjected to a sterilization process. Intended for single patient use.
	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	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	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.

Appendix D—International Symbol Definition (cont.)

Symbol	Source/Compliance	Title of	Description of
	BS EN 50419 Article 11(2) of the European Community Directive 2002/96/EC (WEEE) 2006/66/EC	Crossed Out Trash Can	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. The black bar underneath the bin indicates goods that were placed on the market after 13 August 2005.
	U.S. 40 CFR 273.2 European Community Directive Article 21 of 2006/66/EC	Recycle. Battery contains	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, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	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 Européenne or European Conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.
	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 Européenne 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
	Standard: ISO 15223-1 Symbol Reference No: 5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.



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