

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 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 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.



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:

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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.

Table of Contents

Getting Started	2
Power Up	2
Enter a new Patient ID	3
Set Measurement Protocol	4
Measure Pupils	4
Browse Records	5
Download Records.....	6
Power Down	6
Troubleshooting	6
Cleaning and Maintenance.....	7
Ordering Information.....	7
Customer Service.....	7
Appendix A	
Pupillary Measurement Variables.....	8
Appendix B	
Technical Specifications.....	9

Getting Started

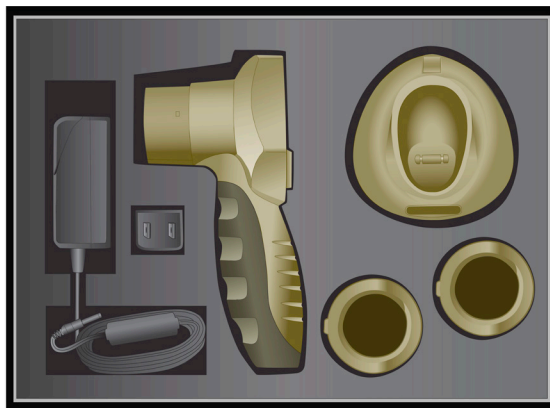
Safety Information

- 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

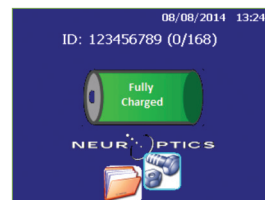
Initial Set-up

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).






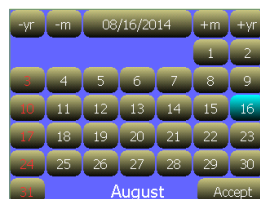
Ex. 2

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:

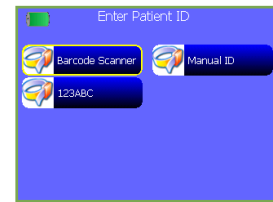
- Go into sleep mode after 5 minutes. Touch the screen to turn on.
- Power down after 30 minutes. Press and hold the Up arrow to turn on (Ex. 6).



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. 6) and they can be immediately re-entered.



Ex. 7

Pairing the PLR-3000 to the NeuroOptics Antimicrobial Barcode Scanner

Connect the NeuroOptics Antimicrobial 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.

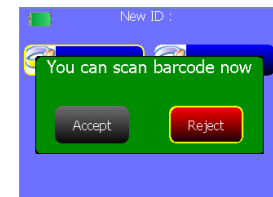


Ex. 8



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).

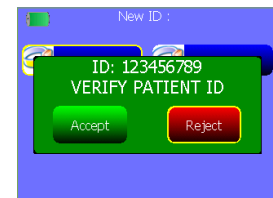


Ex. 9



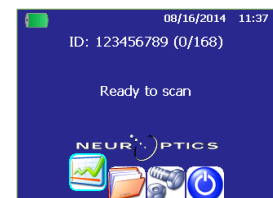
Ex. 10

The patient ID will now appear on the PLR-3000 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 11). Use **Customize ID** function  in the Settings menu (icon  from the main screen) to customize the barcode reading (for example if only a part of the barcode has to be reported).



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



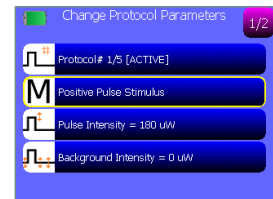
Ex. 14

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 active 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.


 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 41 seconds.

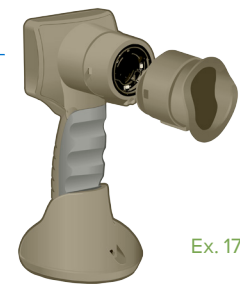
 **Pulse Duration.** This is the duration of the light pulse stimulation, a minimum of 0.03 sec for the Positive Pulse and 1 sec for the Negative Pulse.

 **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 showed 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.



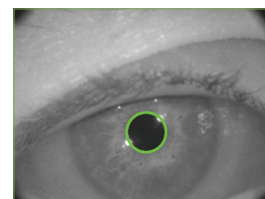
Ex. 17

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

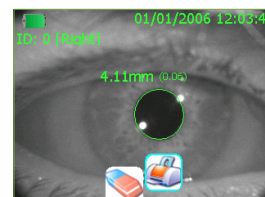
Press and hold either the **RIGHT** or **LEFT** until the eye is centered on the touch screen and the display shows a circle around the pupil (Ex.19). Once the circle appears (green for **RIGHT** and yellow for **LEFT**), release the button, holding the PLR-3000 in place for the entire duration of the 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

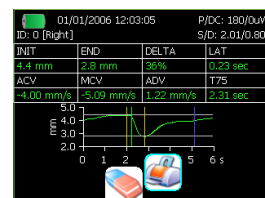
The results page for the Static Stimulus (Ex. 20) shows the diameter of the pupil in bold and the standard deviation of pupil diameter measured (in parenthesis and smaller font) during the scan. It also includes the ID number of the subject, the date and time of the measurement and, finally, which eye,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

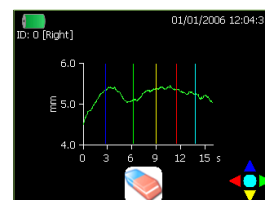


Ex. 21

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 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


Browse Records

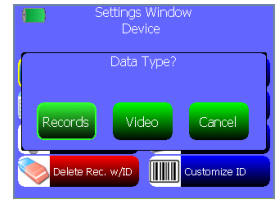
To browse, retrieve and print data from previous measurements select icon  from the main screen. In the browse records menu (Ex. 23) select **All Records** to browse all records in memory, or **Specify Patient ID** if only one specific patient needs to be retrieved. All the most recent patient IDs are 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. 23).



Ex. 23

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. 24

- In Windows 7 you could 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. 24).

- 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**.

Troubleshooting

Issue	Possible Reason	Solution
1. Device will not turn on	Using incorrect power supply	Use only power supply provided with Pupillometer. Check label on power supply
	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 charger
2. Pupil measurement will not initiate after release of the RIGHT or LEFT 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

Clean the PLR-3000, eye cup or charging station with 50% water/50% IPA solution as needed or per hospital protocol.

The PLR-3000 does not require any regularly scheduled maintenance. If the PLR-3000 is not working properly, or has been damaged, contact NeuroOptics Customer Service at Toll Free North America: 866.99.PUPIL or +1 949.250.9792.

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 NeurOptics Customer Service.

Toll Free North America: 866.99.PUPIL | **p:** 949.250.9792

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—Pupillary Measurement Variables

Broadcast Function	Range
Init = Maximum Diameter	Maximum pupil size before constriction
End = Minimum Diameter	Pupil diameter at peak constriction
Delta = % Change	% of change (Size-MIN)/Size 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 = Time to reach 75% recovery	The time to reach 75% of the original baseline pupil diameter after the peak of the 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	3.7V 3350 mAmp/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

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