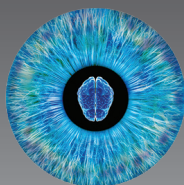


PLR[®]-4000 Pupillometer

Instructions For Use



NEUROPTICS[®]

Introduction

The NeurOptics® PLR®-4000 Pupillometer offers clinicians quantitative infrared technology to objectively and accurately measure pupil size and dynamics in an advanced design. The PLR-4000 provides a comfortable ergonomic design, incorporated barcode scanner, wireless charging, and easy-to-read touchscreen LCD and graphics.

Indications for Use

The PLR-4000 Pupillometer is a handheld optical scanner which measures pupil size and pupil reactivity. The results obtained from the PLR-4000 scans are used for information only and are not to be used for clinical diagnostic purposes. The PLR-4000 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.

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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.

- The PLR-4000 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. Do not use the device if damage to the housing or internal optical components is apparent. 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-4000 is only replaceable by a qualified NeurOptics' service technician. Contact NeurOptics if you suspect an inoperable battery.
- Use only the NeurOptics Charging Station for charging the PLR-4000.
- 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 PLR-4000 System in ambient environments with non-condensing humidity levels only. Using the PLR-4000 with condensation on optical surfaces may result in inaccurate readings.

Cautions

The following cautions apply when cleaning the device.

- The internal components of the PLR-4000 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 PLR-4000 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 IEC 60601-1-2 + A1 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.

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.

Classification

Type of Equipment: Medical Equipment, Class 1 886.1700

Trade Name: NeurOptics® PLR®-4000 Pupillometer

Manufactured by:



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For details, visit: www.NeurOptics.com/patents/

Safety Information

- Please review the following safety information prior to operating the device.
- Please read these Instructions fully before attempting to use the PLR-4000. 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.

Software Cybersecurity

The PLR-4000 is a standalone medical device. The device is not intended to connect to hospital networks, the internet, or general purpose IT infrastructure. The device is provided in a controlled software configuration and does not require user installation, configuration, or maintenance of cybersecurity software.

The PLR-4000 has no user software maintenance for updates or patches. The system has been designed to operate for its lifetime without software updates or modifications. In the event of a required software update, NeurOptics will contact the users and request the device be returned for exchange. The exchanged device will be updated to correct the issue.

Do not attempt to modify, install, remove, or alter software on the device. Do not attempt to access internal service functions or connect unauthorized equipment. Unauthorized software changes or tampering may affect device safety, performance, cybersecurity, and warranty status.

The device should not be tampered with, nor should any unauthorized modifications be made. Tampering or unauthorized modifications can introduce vulnerabilities and security risks, potentially leading to data breaches, malware infections, or system instability. The warranty of any devices that have been tampered with, or unauthorized modifications made to, will be voided.

- **CAUTION – SOFTWARE MAINTENANCE** The device does not require the user for software maintenance. The software is designed for the products lifetime.
- **CAUTION – SOFTWARE ALTERATION** The device software should not be modified or altered in any way. Do not attempt to alter software on the device; any alterations will void the warranty.
- **CAUTION – TAMPERING** The device should not be modified or tampered with; any tampering will void the warranty.
- **CAUTION – CYBERSECURITY INCIDENT** In the event of a suspected cybersecurity incident (e.g. unexpected behavior, recurring errors, freeze or crash of the software), shut down the device, take it out of service and contact the NeurOptics service for further investigation and application of immediate measures.

Getting Started

Unpacking the PLR-4000 Pupillometer System

The NeuroOptics PLR-4000 Pupillometer System is packaged with the following components (Ex. 1):

- PLR-4000 Pupillometer (A)
- Charging Station (B)
- Power Adapter and Plug (C)
- Eye Cups x 2 (D)
- Data Download Cable
- PLR-4000 Pupillometer Quick Start Guide



Initial Set-Up

- To set up the PLR-4000 for first-time use, please refer to the **Power Up** section below, ensuring the PLR-4000 is fully charged and Date/Time are set accurately prior to use.

Ex. 1

Power Up

Charging the PLR-4000 Pupillometer

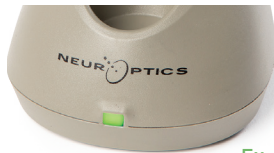
- Connect the PLR-4000 Power Adapter to the Charging Station and plug into a power outlet. The indicator light at the base of the Charging Station will display a white color to indicate power has been established to the Charging Station (Ex. 2).
- Place the PLR-4000 into the Charging Station. The Charging Station indicator light will turn **blue** (Ex. 3), and the LCD screen will display  within the battery icon, indicating the PLR-4000 is charging. The indicator light will turn **green** when fully charged (Ex. 4).
- An **amber/orange** indicator light on the Charging Station indicates a charging malfunction, and the PLR-4000 will not charge (Ex. 5). If this issue persists, please contact NeuroOptics Customer Service.



Ex. 2



Ex. 3



Ex. 4



Ex. 5

Indicator Light Color	Meaning
White	Charging Station is plugged into a power outlet, and power has been established. PLR-4000 is out of Charging Station.
Blue	PLR-4000 is placed in Charging Station and successfully charging.
Green	PLR-4000 is fully charged.
Amber/Orange	Charging Malfunction – PLR-4000 is not charging. If issue persists, please contact NeuroOptics Customer Service.

The PLR-4000 Pupillometer goes to sleep in the Charging Station to efficiently charge:

- The PLR-4000 will initially turn ON (or remain on) upon being placed in the Charging Station.
- After 2 minutes in the Charging Station, the PLR-4000 will go to sleep to efficiently charge. The screen will go dark (Ex. 6). If any button is pressed or the screen is touched within this 2-minute window, the time period before the PLR-4000 goes to sleep is extended by an additional 2 minutes.
- To use the PLR-4000 after it has gone to sleep in the Charging Station, simply remove from the Charging Station, and it will wake up automatically.
- If the PLR-4000 does not turn on upon being placed in the Charging Station, the battery level may be too low for normal usage. The Charging Station indicator light should display a **blue** color, indicating the PLR-4000 is charging. Leave the PLR-4000 in the Charging Station until it powers on.



Ex. 6

If the PLR-4000 Pupillometer is not in the Charging Station, to conserve battery life it will:

- Go into sleep mode after 4 minutes. To turn ON, touch the screen or push any button.
- Power down after an additional 6 minutes.

Turning On the PLR-4000 Pupillometer

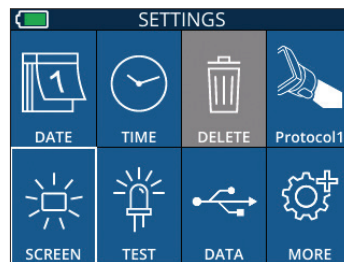
- If the PLR-4000 is out of the Charging Station and has powered down, press (do not hold) the **On/Off** button  on the side of the device (Ex. 7).
- If the PLR-4000 is in the Charging Station and has gone to sleep, simply remove from the Charging Station, and it will wake up automatically.



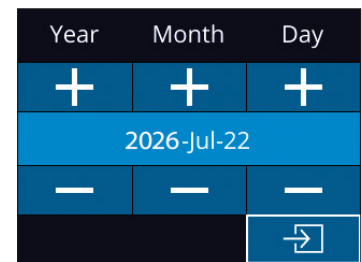
Ex. 7

Setting Date and Time

To modify the date and time, from the Home Screen, select the **Settings** icon  and then select **Date** or **Time** (Ex. 8). Follow the prompts to input the current date (Ex. 9) and time (Ex. 10) using 24-hour time configuration and select .



Ex. 8

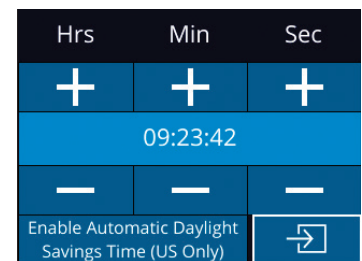


Ex. 9

Customers in the United States have the option to enable **Automatic Daylight Savings Time (DST)** in the **Time** settings. Automatic DST is disabled by default. Automatic adjustments occur based only on US DST regulations and are not updated according to geographic location, as the PLR-4000 is not connected to the internet or GPS.

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 PLR-4000. Changing the date and time will not alter the timestamps on previous measurements.
- Immediately adjust the time after any time change if Automatic DST is disabled.



Ex. 10

Returning to the Home Screen

Press the **LEFT** or **RIGHT** buttons (green circles) to return to the Home Screen (Ex. 11).



Ex. 11

Measuring Pupils Using the PLR-4000 Pupillometer

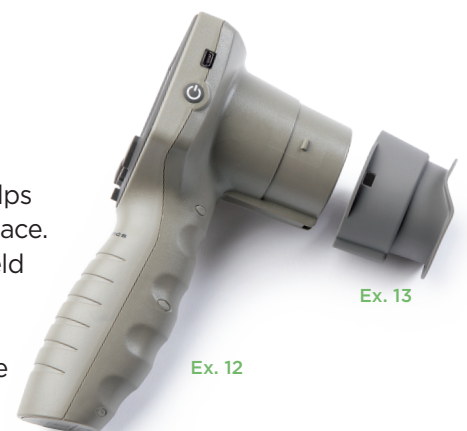
Attaching the Eye Cup to the Pupillometer

Two components are required to initiate a pupil measurement:

- PLR-4000 Pupillometer (Ex. 12)
- Eye Cup (Ex. 13)

The PLR-4000 should not be used without the eye cup positioned correctly (Ex. 13). 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 scan is 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 indentation in the lens shield of the Pupillometer 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.



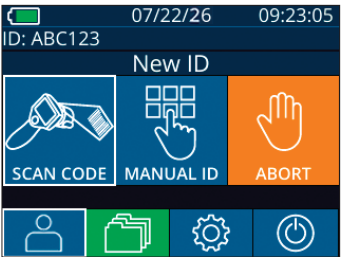
Ex. 12

Ex. 13

Enter a New Patient ID

There are two options for associating the Patient ID to the Pupillometer:

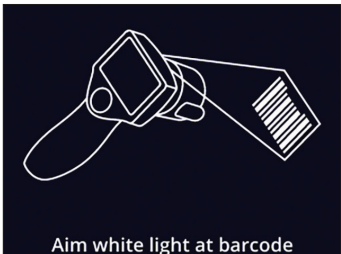
- 1) Scanning the patient’s barcode using the PLR-4000 Incorporated Barcode Scanner, or
- 2) Manually entering the Patient ID with either alpha or numeric characters (Ex. 14).



Ex. 14

Scan Barcode Using Incorporated Barcode Scanner

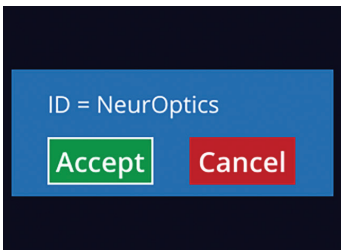
From the Home Screen, select then **Scan Code** . The PLR-4000 will emit a white light from the top of the device (Ex. 15). Center the light over the barcode until you hear an audible beep. The Patient ID will now appear on the PLR-4000 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 16). The PLR-4000 will display the Patient ID and read **Ready to Scan** (Ex. 17).



Ex. 15

Manual Entry of the Patient ID

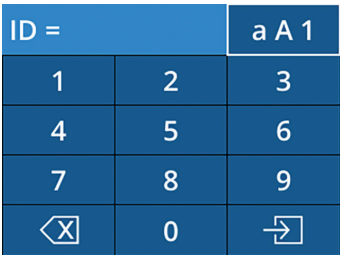
From the Home Screen select , then **Manual ID** . Using the touchscreen or keypad, enter the alpha or numeric Patient ID and select (Ex. 18). Confirm the patient information on the screen is correct and select **Accept** (Ex. 16). The PLR-4000 will display the Patient ID and read **Ready to Scan** (Ex. 17).



Ex. 16



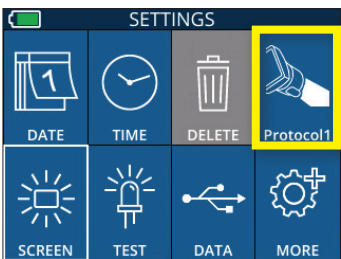
Ex. 17



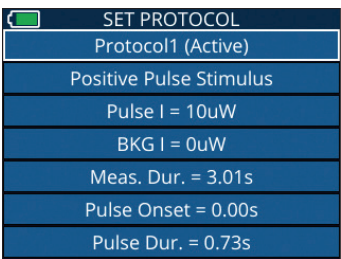
Ex. 18

Set Measurement Protocol

From the Home Screen, select the Settings icon and then the top right icon to navigate to the Set Protocol menu (Ex. 19). Each parameter listed on the page of this menu (Ex. 20) can be changed by moving down and up using the **DOWN** and **UP** keys on the directional keypad and then using the left and right keys keys to toggle between the values reported. Use the RIGHT or LEFT key to exit and save the protocol by pressing YES when asked “Save Changes?”



Ex. 19



Ex. 20

The characteristics of the light stimulus protocol are summarized in the table below:

Parameter	Description
Protocol#	Protocols are numbered from 1 to 5. To make a protocol “active”, select the number (e.g., “Protocol2”) and press the center button on the directional keypad. That protocol will now show as Active.

Type of protocol	The second setting toggles between 1) “Positive Pulse Stimulus” (light stimulus); 2) “Static Stimulus”, (no light stimulation and no pupil reflex; “Pulse Intensity” needs to be equal to the “Background Intensity”); and 3) “Extended”, (no light stimulation, pupil is recorded continuously for a maximum duration of 10 minutes).
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Parameter	Description
Pulse Intensity (PI)	Use this setting to change the intensity of the light stimulus. Unit of light is radiometric and provided in micro Watts, uW. Six different intensities are provided: 0uW, 1uW (approx. 9 lux), 10uW (approx. 90 lux), 50uW (approx. 454 lux), 121uW (approx. 1,110 lux), and 180uW (approx. 1,634 lux).
Background Intensity (BKG)	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 in case of a Static Stimulus protocol, Background Intensity must be equal to Pulse Intensity.
Measurement Duration	Use this setting to change the duration of the measurement (a minimum of 3 seconds up to a maximum of 24 seconds.)
Pulse Onset (PO)	Use this setting to change the delay of the start of the light stimulus (Pulse).
Pulse Duration (PD)	Use this setting to change the duration of the light stimulus (Pulse) (a minimum of 0.03 sec up to the entire duration of the measurement).

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 21).
- 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.



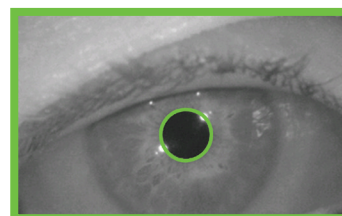
Ex. 21



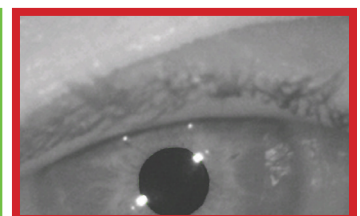
Ex. 22

Measurements must be taken when the Pupillometer is on the Home Screen (Ex. 22). The Home Screen shows the date and time, patient ID number, and which Protocol is active: For example, "Protocol1 (Pos. PLR)" = Positive Pulse Stimulus, "Protocol2 (Static)" = No Limit Stimulus, "Protocol3 (Inf)" = Extended. The screen should read "READY TO SCAN."

Press and hold either the **RIGHT** or **LEFT** button until the pupil is centered on the touchscreen and the display shows a green circle around the pupil. A green frame around the screen indicates the pupil is properly targeted (Ex. 23), while a red frame indicates the pupil needs to be re-centered on the screen before the measurement is initiated (Ex. 24). Once the green frame appears, release the button, holding the PLR-4000 in place for approximately three seconds until the results screen is displayed.



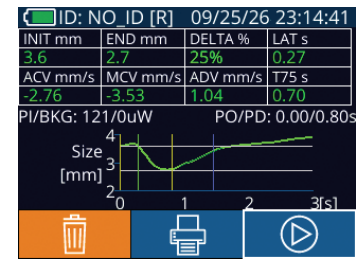
Ex. 23



Ex. 24

Results Page for Positive Stimulus

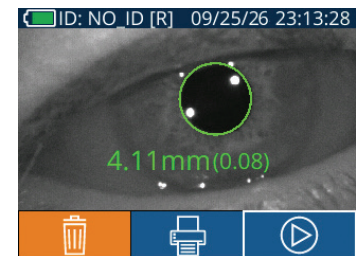
The results page for the Positive Stimulus (Ex. 25) shows the pupil diameter waveform plotted as a function of time. The two vertical yellow lines show where the stimulus started and ended. The green vertical line shows the latency and the blue line the T75. Latency and T75 are two of the variables calculated by the analysis and they are explained in Appendix A. If a variable could not be calculated (for example, because of excessive blinking) it is reported with dashes or in red font in the table.



Ex. 25

Results Page for Static Stimulus

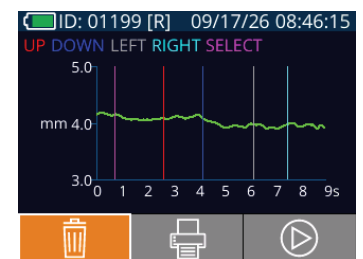
The results page for the Static Stimulus (Ex. 26) shows the diameter of the pupil in bold and the standard deviation of pupil diameter measured (in parenthesis) during the scan. It also includes the ID number of the subject, the data and time of the measurement, and finally, which eye (Right or Left) was measured.



Ex. 26

Results Page for Extended Mode

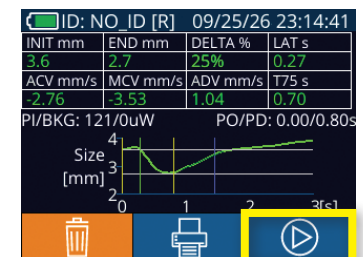
The results page for the Extended Mode shows the whole pupil measurement as a function of time (Ex. 27). Colored vertical lines correspond to the up, down, left, right arrow keys and center select key. The user can press any of those keys during the recording and the time(s) of the press (or presses) are reported in the plot and saved with the record. Note that an extended pupil recording is ended once the original starting **RIGHT** or **LEFT** key is pressed – the duration of the measurement is not defined. Maximum duration is 10 minutes.



Ex. 27

Video Replay

From the Results screen, select the **Video** icon  to view the video playback of the reading. Only the last measurement's video can be played back. Once the PLR-4000 has powered off, or if the RIGHT or LEFT button is pressed during the scan, the last video is not accessible (Ex. 28).



Ex. 28

Browse Records

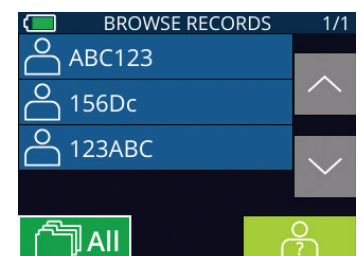
To review records stored on the PLR-4000:

- From the Home Screen: Select the **Records** icon  (Ex. 29).
- To browse records by Patient ID, select the ID from the list or use the **UP**  and **DOWN**  arrows on the screen to browse additional IDs available in the list. The IDs of the most recent measurements taken on the PLR-4000 will appear at the top of the list.
- To search for a specific Patient ID, select  (Ex. 30), then type in the Patient ID and select .
- To browse all pupil measurements stored on the PLR-4000 in chronological order (including all Patient ID's), select the **All Records** icon  (Ex. 30) and press the **DOWN Arrow** button  on the keypad to scroll through all previous measurements stored on the PLR-4000.
- When the **No more records** message appears, the earliest pupil measurement stored has been reached.

The pupillometer stores up to 1,200 measurement records on the device. After the 1,200 measurement limit has been reached, each new record will replace the oldest record stored on the device.



Ex. 29

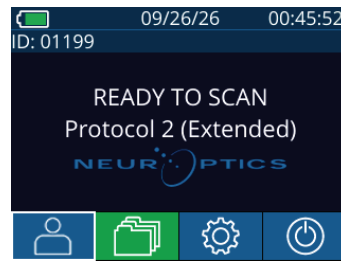


Ex. 30

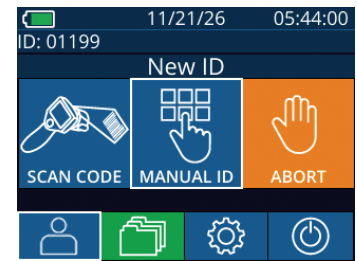
Switching Patient ID's

To switch Patient ID's, select  from the home screen (Ex.31).

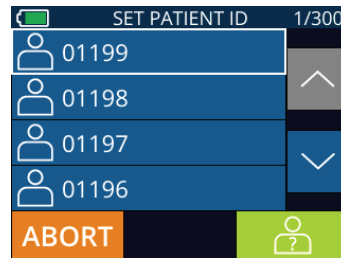
Select  (Ex. 32) and choose the Patient ID from the SET PATIENT ID look up menu (Ex. 33) and **Accept** the change (Ex. 34). If you prefer to type in the Patient ID, then select  and enter the alpha or numeric characters and press  then **Accept**.



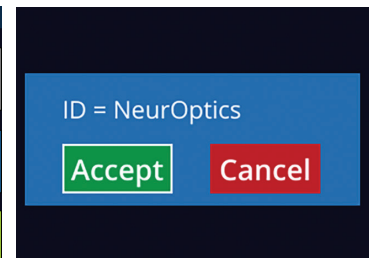
Ex. 31



Ex. 32



Ex. 33

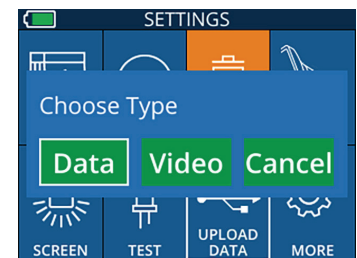


Ex. 34

Download Data

From the Home Screen, select the **Settings** icon , then select then select Upload Data . Two choices will appear "Data" or "Video" (Ex 35). If you choose "Data" a text message will appear on the screen instructing the user to "connect USB cable & copy R_#####_#####.xls." If you choose "Video" an AVI file will be saved, and a text message will appear on the screen instructing the user to "connect USB cable & copy V_#####_#####.avi." Connect the USB cable from the pupillometer to the computer (Ex 36). The computer will show as "Neuroptics" drive on the computer. Click on the drive, copy the XLS file or the AVI file and paste it on your computer. Press "DONE" in the small window on the pupillometer screen only after the copy has been completed, as the file will then be erased.

Note: Only the last measurement can be downloaded as a video, and it must be done immediately after a measurement is captured.



Ex. 35



Ex. 36

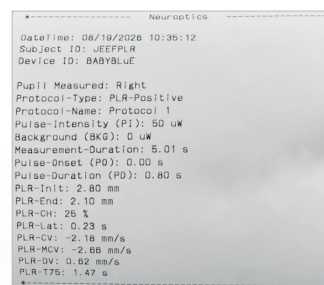
Print Data

Attach the power supply to the printer as shown in Ex 37. Turn the printer on and the green light will illuminate. The patient measurement result currently displayed in the results window (Ex 38) can be printed by selecting the  at the bottom of the screen.

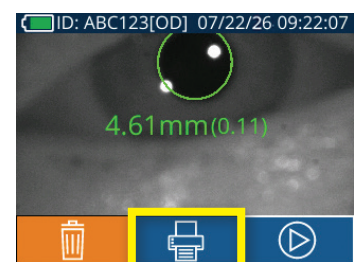
The system will only print a record when a measurement result is displayed on the screen. If you want to print a measurement other than the last measurement taken, refer to the "Browse Records" section above. Consult the printer's instruction manual for specific printer operation instructions.



Ex. 37



Sample Printout



Ex. 38

Pupil Measurements – Special Considerations

Blinking During Measurement

If the measurement was affected by a tracking problem (e.g., excessive blinking), then measurement results are all displayed in red font on the results screen and as “NA” (Ex. 39). In this case, the measurement results are not valid and should not be relied upon and the measurement should be repeated.



Ex. 39

PLR-4000 Pupillometer Navigation Guide

Returning to the Home Screen

Press the **LEFT** or **RIGHT** buttons (green circles) to return to the Home Screen (Ex. 40).



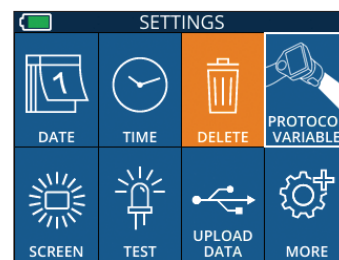
Ex. 40

Settings

Using the touchscreen or keypad, select the **Settings** icon  (Ex. 41) from the Home Screen to navigate to the Settings Menu (Ex. 42).



Ex. 41



Ex. 42

Date and Time

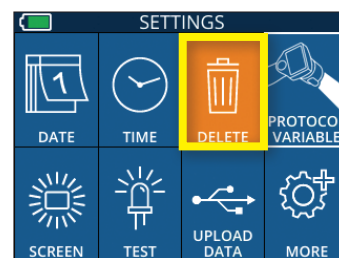
See **Setting Date and Time** section on Page 5.

Delete Records

To delete records off of the device memory of the PLR-4000, navigate to the Settings Menu and press **Delete** , then select **Yes** to proceed to delete record (Ex. 43). Records on the device can be deleted for a specific Patient ID or All Records.

LCD Screen Brightness

The PLR-4000 is defaulted to maximum brightness of the LCD Screen. Adjust to medium brightness by pressing . Adjust to low brightness by pressing . To return to maximum brightness, simply press the  one more time.



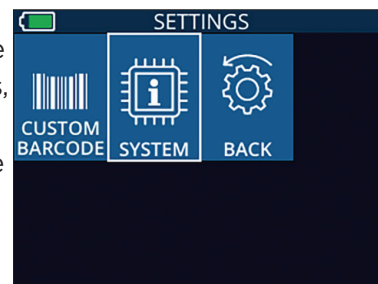
Ex. 43

Test LED

Pressing the Test icon  demonstrates a sample of the LED light that is emitted from the PLR-4000 when taking a pupil measurement. The test should show LEDs lit up at 3, 6, 9 and 12 o'clock on the lens side. This test is for demonstration purposes only and does not affect usage of the device.

Customize Barcode Scanner

The PLR-4000 Incorporated Barcode Scanner can be customized to truncate or expand the alpha or numeric characters read from a barcode, if required. The **Default** settings automatically adjust to read most types of 1D and 2D barcodes, and “Default” should remain selected unless a specific customization needs to be applied to all barcodes scanned by the PLR-4000. Select **Settings** , more , **Custom Barcode**  (Ex. 44), then select **Scan Sample** to scan a sample barcode and program the required customizations (truncation or expansion) to be used for all future scans. Contact NeurOptics for additional information.



Ex. 44

System Information

Select **System**  (Ex. 44) to view the PLR-4000's system information, displaying the Serial Number, Software Application, and Firmware versions of the device.

Troubleshooting

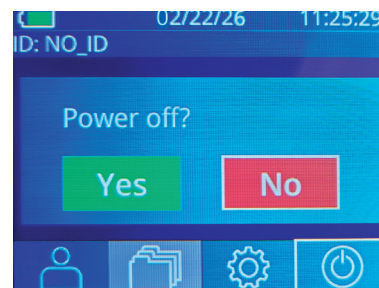
Issue	Possible Reason	Solution
1. PLR-4000 Pupillometer will not turn on	Using incorrect Power Adapter	Use only Power Adapter provided with PLR-4000. Check label on Power Adapter.
	Power cord is not fully plugged into the wall or the Charging Station	Check connections.
	Battery completely discharged	Charge the battery by placing the PLR-4000 into the Charging Station.
2. Pupil measurement will not initiate after release of the LEFT or RIGHT key	Too much blinking	Gently hold patient's eye open with your finger during measurement.
	Device not held correctly	Hold eye cup at a 90-degree angle to patient's face. Make sure patient's pupil is centered on the screen.
3. PLR-4000 returned to Home Screen while taking a measurement	LEFT or RIGHT button was pressed while measurement was being completed, causing measurement to be aborted	Repeat the scan, ensuring no buttons are pressed until the scan is completed and results appear on the screen.
4. Error message appears on the screen	Various	Reboot the PLR-4000 by pressing and holding the ON/OFF button on the side of the device until it powers OFF and then power it back on. If the issue persists, call NeuroOptics Customer Service.
5. "NA" displayed following measurement	PLR-4000 was moved from position before measurement has been completed	Repeat the scan and keep the PLR-4000 in place until the measurement is completed and pupillary measurement results are displayed.
	Patient blinking excessively during measurement	Hold the patient's eyelid open and repeat the scan.
6. Download not initiated or not completed	Cable not well seated inside the housing of the device	Verify that cable is fully connected to the PLR-4000 .
	Downloaded file does not appear on the destination computer	Copy the downloaded file to the computer before pressing "Done" on the PLR-4000.
7. Measurement results do not print	The PLR-4000 is not close enough to the printer.	Make sure PLR-4000 is $\leq 1\text{m}$ from the printer
	PLR-4000 cannot "find" the printer.	Remove or turn off other devices which may be interfering with the connection.

Power Off

To turn the PLR-4000 Pupillometer OFF, either:

- Navigate to the Home Screen, and select the **Power** icon  , then confirm **Yes** to power OFF (Ex. 45).
- Press and hold the **On/Off** button  on the side of the PLR-4000 for about 3 seconds.

The PLR-4000 may occasionally require a System Reboot. To reboot, simply press and hold the **On/Off** button  on the side of the PLR-4000 until it powers OFF and then power it back on by pressing (do not hold) the **On/Off** button .



Ex. 45

Handling, Cleaning and Maintenance

Always handle the PLR-4000 Pupillometer and PLR-4000 Charging Station with care because sensitive metal, glass, plastic and electronic components are contained inside. The PLR-4000 and Charging Station can be damaged if dropped or by prolonged exposure to liquid or high humidity environments.

The PLR-4000 and Charging Station do not require any regularly scheduled maintenance or calibration. If the PLR-4000 and 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 PLR-4000 Pupillometer, Charging Station and Eye Cup

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA, are recommended for use in cleaning the PLR-4000, Charging Station, and eye cup. Do not use chemicals that can damage the PLR-4000 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 PLR-4000 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** use an oversaturated cloth. Be sure to squeeze out excess liquid prior to wiping the PLR-4000 or the 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-4000 or Charging Station.
- **DO NOT** immerse the PLR-4000 or the 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-4000 and Charging Station are thoroughly dry before placing the PLR-4000 back into the Charging Station.

Cleaning Considerations: PLR-4000 Liquid Crystal Display (LCD) & Lens Cover Glass

For best protection of the liquid crystal display (LCD), use a clean, soft, lint-free cloth and up to 70% IPA to clean the PLR-4000 LCD. Occasional cleaning of the PLR-4000 Lens and the Incorporated Barcode Scanning Window (located just above the Lens) is also recommended using a clean, soft, lint-free cloth and up to 70% IPA.

Customer Service

For technical support, or if you have a question regarding your product or order, please 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.

This IFU is provided electronically and can be accessed through our website. If a paper copy is required, please notify customer service.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



eIFU Access

Ordering Information

PLR-4000-SYS	PLR®-4000 Pupillometer System
NEUR-2059-01	Eye Cup
CBL-0006-00	Data Download Cable
NEUR-PRTS445	Wireless Printer Kit

Returned Goods Policy

NeurOptics does not accept product returns.

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Appendix A – Pupillary Measurement Parameters

Parameter	Description
INIT = Maximum Diameter	Maximum pupil size before constriction (mm)
END = Minimum Diameter	Pupil diameter at peak constriction (mm)
DELTA = % Change	(INIT-END)/END as a %
LAT = Latency of constriction	Time of onset of constriction following initiation of the light stimulus (sec)
ACV = Constriction Velocity	Average of how fast the pupil diameter is constricting measured in millimeters per second
MCV = Maximum Constriction Velocity	Maximum velocity of pupil constriction of the pupil diameter responding to the flash of light 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	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
Pupillometer Measurement Detection Threshold	Pupil diameter (minimum) 0.80 mm
	Pupil diameter (maximum) 10.00 mm
	Change in Size approximately 0.03 mm (30 microns)
Size Accuracy	Approximately +/- 0.03 mm (30 microns)
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
	RF Wireless Charging Output: 5 W, Qi Compliant
Battery	3.6 V 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.

Appendix B – Technical Specifications Continued

Parameter	Description
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	344 grams +/- 10 grams
Classification	Class 1 LED product per IEC 62471

Appendix C – Guidance of EMC and other Interference

- 1. WARNING:** Use of this equipment adjacent to or stacking with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 2. WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.
- 3. WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Pupillometer is intended to use in the electromagnetic environment specified below. Customers and users of the Pupillometer must ensure that it is used to this type of environment.

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The Pupillometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Pupillometer is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	The device is battery powered and not connected to a public mains network during normal operation.
Voltage fluctuations / flicker IEC 61000-3-3	Not applicable	The device is battery powered and not connected to a public mains network during normal operation.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

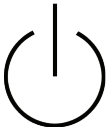
The PLR-4000 is intended to use in the electromagnetic environment specified below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Complies
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz	Complies
Conducted RF IEC 61000-4-6	3 Vrms 0.15 – 80 MHz	Complies
Electrical fast transient/burst IEC 61000-4-4	±2 kV	Complies
Surge IEC 61000-4-5	±1 kV differential ±2 kV common mode	Complies
Power frequency magnetic field IEC 61000-4-8	30 A/m	Complies
Voltage dips and interruptions IEC 61000-4-11	Per standard	Complies

Proximity Fields from RF Wireless Communications Equipment

The PLR-4000 was tested for immunity to proximity fields from RF wireless communications equipment in accordance with IEC 60601-1-2 + A1, and met all applicable requirements.

Appendix D – International Symbol Definition

Symbol	Source/Compliance	Title of	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
	Standard: IEC 60417 Symbol Reference No: 5009	Stand-by	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption
	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
	Standard: 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
	European Union Conformity Mark, the product complies with the Medical Device Regulation (2017/745 EU MDR) or other applicable EU directives	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 Union Conformity Mark with Identification of Notified Body, the product complies with the Medical Device Regulation (2017/745 EU MDR) or other applicable EU directives	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

Appendix D – International Symbol Definition Continued

Symbol	Source/Compliance	Title of	Description of Symbol
	Standard: ISO 15223-1 Symbol Reference No: 5.1.2	EC Representative	Indicates the authorized representative in the European Community/ European Union
	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
	Standard: ISO 15223-1 Symbol Reference No: 5.7.8	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information

Appendix E – Wireless Printing Range and Frequency

Parameter	Description
Wireless Printing Range	Up to 100 cm
Wireless Printing low energy operation frequency	2.4 GHz



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