Introduction

The NeurOptics® RAPiDo™ Binocular Pupillometer is a portable, all-in-one, device which offers clinicians quantitative infrared technology to objectively and accurately measure pupil size and reactivity in three different measurement modalities.

1. Relative Afferent Pupillary Defect (RAPD): Replaces the subjective and difficult to perform "swinging flashlight test" routinely conducted to screen for many different ophthalmic conditions.

2. Accurate Measurement Of Pupil Diameter: For refractive surgery screening and planning (LASIK and multifocal IOLs) under Scotopic, Low Mesopic and High Mesopic light settings.


The RAPiDo Pupillometer provides a comfortable, ergonomic design that can be used as a hand-held device (for supine Patients) or mounted onto a stand. It also provides an easy-to-read touchscreen LCD and graphics and simple Patient identification (ID). Pupil tracking and blink detection are automatic. Finally, Patient data may be uploaded via USB.

Indications for Use

The RAPiDo Pupillometer is an optical scanner which measures pupil size and pupil reactivity in Patients requiring ophthalmic or neurological pupil examinations. 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.

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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.

• Use of the Pupillometer - The Pupillometer is intended for use by trained clinical personnel, under the direction of a qualified physician.

• If a problem is recognized while operating the device, the device must be removed from use and referred to qualified personnel for servicing. Using an inoperative device may result in inaccurate readings.

• Electric shock hazard - Do not open any components of the device or the charging station. There are no user serviceable parts.

• The battery in the RAPiDo Pupillometer is only replaceable by a qualified service technician. Contact NeurOptics if you suspect an inoperative battery.

• Use only the NeurOptics RAPiDo 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 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 EN60601-1-4 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g., hospitals, research laboratories, etc.).

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

Classification

Type of Equipment: Medical Equipment, Class 1886.1700
Trade name: NeurOptics® RAPiDo™ Pupillometer
Manufactured by:

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Pat. No. 616736
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.
Getting Started

Safety Information

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

Unpacking the Pupillometer

The NeurOptics RAPiDo Pupillometer is packaged with the following components (Figure 1):

a RAPiDo™ Binocular Video Camera Module
b Control Module (connected to Video Camera Module)
c RAPiDo™ metallic Stand with Chin Rest and Video Camera Module tower support
d RAPiDo™ Charging Station
e RAPiDo™ Power Supply
f NeurOptics Lens Cloth (not shown)
g USB Data Cable (not shown)

Power Up

Initial Set-up

Position the Charging Station (d) over the magnets located on the metallic base plate. See the three possible placement options in Figure 2.

Connect the RAPiDo Pupillometer Power Supply (e) to the RAPiDo Charging Station (d) attached on the metallic stand and plug into a power outlet. The green light at the base of the Charging Station will indicate power has been established (Figure 3).
Mount the RAPiDo Video Camera Module (a) onto the metallic stand (Figure 4).

Place the Control Module of RAPiDo (b) into its Charging Station (d) (Figure 5). A magnet located at the bottom of the Control Module help proper insertion and contact with the Charging Station.

After powering on, the touchscreen will display the Main Screen of the RAPiDo (Figure 6), and the small battery icon on the top left will be blue indicating the device is charging. The battery icon will turn green when fully charged.

To modify the date and time, from the Main Screen, select the Settings icon and then select Set Date and Set Time (Figure 7). Follow the prompts to input the proper date and time using 24 hour time configuration and select Accept.

**Turning On the RAPiDo**

When not in use, the RAPiDo Control Module should be kept in the Charging Station. If the RAPiDo Control Module is not in the Charging Station, to conserve battery life the pupillometer will:

- Go into sleep mode after 5 minutes. Touch the touchscreen to turn on.
- Power down after 30 minutes. Press and hold the green button located on the top right edge of the Control Module to turn on.

**Entering Patient ID**

The default Patient ID is ID=0 (Figure 6). To change the ID, from the Main Screen press the bracelet icon (Figure 6) and then, press Enter ID to enter a new ID or select one of the old IDs listed in the same window. New IDs can be entered using the touchscreen keyboard (Figure 8). Select Shift to toggle from alpha to numeric as required. When the Patient ID number has been entered, check for accuracy and press ENTER.
Taking a Pupillary Measurement.

The Patient should be comfortably seated facing the binocular camera module (Figure 9). On the Main Screen, press one of the three buttons corresponding to the different measurement modalities to enable the live binocular video.

Adjust the height of the chinrest if needed by turning the blue knob on the right hand side of the chin rest (Figure 10). After adjustment, pull knob OUT to lock. Instruct the Patient to slightly bend over the binocular camera and look inside into the two cameras.

Measurements should be conducted in a dark environment. Avoid any source of illumination laterally or in front of the subject. Even a closed window or door could leak some extra light and alter the measurement. This could be particularly problematic when that source of light is on one side of the subject. Carefully avoid all possible sources of light in the room.

Carefully take the following steps:

1. The rubber eyecups serve to maintain the proper distance of the Patient’s eyes to the lens of the device. Although the eyecups can support the weight, the area around the Patient’s face should be touching the eyecups but not pressing down hard into them.

2. Pupils should be in focus. If needed, adjust the Pupillary Distance (PD) to center the pupils horizontally inside the blue boxes by turning the blue knobs on either side of the Camera Modules (Figure 10). Pupils should be centered as much as possible within the blue boxes (Figure 11) although it is acceptable to have a minimal section of the pupil outside (especially for large pupils when centering could be more problematic.)

3. There is a dim red fixation point in the right or the left camera. Instruct the Patient to fixate on this red light and to keep fixating on this point for the entire duration of the measurement.

4. Blinks are allowed and tolerated if they don’t occur too many times. Always ask the Patient to avoid blinking as much as possible and to keep the eyes open wide.

When both videos show two circles around the pupils, (green for the right pupil and yellow for the left pupil) (Figure 11), the measurement can start and the horizontal button at the bottom of the touchscreen will turn blue and read “Ready. Press this button to start.” Press this button on the touchscreen.

Measuring the Relative Afferent Pupillary Defect (RAPD)

To measure the RAPD, press the RAPD button on the Main Screen of the touch screen. The measurement takes about 24 seconds. It could be longer depending on the type and frequency of the blinks. An array of squares displayed at the bottom of the screen below the two videos shows the progression of the measurement. Each square represents a light stimulus delivered to one eye, ten stimuli per eye for a total of 20 squares. They are yellow when the stimulus is being delivered and then become green once successfully delivered (Figure 12). A red square means a blink, in which case a new pair of squares is added to the protocol and the duration of the measurement could increase correspondingly by a few seconds. It is always a good idea to accompany the measurement with a few words of encouragement to the Patient, such as “You are doing well”, “Almost there”, “Keep fixating” in order to keep the subject alert and make them aware that you are still present.

The Results Page (Figure 13) shows a snapshot of the two eyes and the size of the pupil at rest (2.9 mm and 3.0 mm in the example). RAPD is shown with an arrow pointing to a horizontal directional scale (left eye RAPDs are on the right and right eye RAPDs are on the left side of the scale), and reported with a number in log units (0.1 in the example). An asterisk next to the RAPD value indicates an elevated number of blinks during the measurement. In this case, repeat the measurement if possible, trying to prevent blinks or other measurement artifacts.
The interval highlighted in blue around the 0.0 indicates the normal range for RAPD. If the results are outside of this normal range (between 0.0 and 0.3) then it is always a good idea to repeat the measurement after a minute or two to confirm the abnormality which may have clinical relevance.

Finally, if the two pupils in the image are outlined with a solid red circle, this alerts the clinician to the presence of anisocoria (the size of the two pupils differ by more than 1mm). Anisocoria may have clinical relevance and could bias the RAPD results.

Press the yellow button “1/2” on the touch screen to move to the second page (Figure 14). Here a table summarizes the results and includes information about the REPD (Relative Efferent Pupillary Defect). Remember, the RAPD (afferent) value compares the two stimuli (left and right) by averaging the reactivity of the two pupils. The REPD (efferent) compares the reactivity of the two pupils by averaging the two stimuli. In the example (Figure 12), the left pupil was 2% less reactive than the right pupil (averaging left and right stimuli all together). Normal values are expected to be zero or close to zero (pupils equally reactive).

Measuring Pupil Size

Press the Pupil Size button on the Main Screen of the touch screen to measure pupil diameter only. Two options are possible: Light Off, is about 4 seconds long and measures the mean and standard deviation (in parentheses) of the two pupil diameters in complete darkness. Variable does the same thing but the protocol is repeated three times in sequence for three different conditions of background illumination: Scotopic, Low Mesopic and High Mesopic. Sample data are shown in a table (Figure 15).

Horner’s syndrome Protocol

To measure Horner’s syndrome, press the Horner’s Syndrome button on the Main Screen of the touch screen. For Horner’s syndrome, a bright and long light stimulus is delivered simultaneously to both eyes. The Result Page simply shows the two pupil waveforms in the same graph (Figure 16) – no analysis or interpretation are provided in this case. The clinician is invited to look at the area between the two pupil waveforms in the graph. Horner’s syndrome is typically associated to a significant disparity between the two pupil waveforms, especially in the dilation phase when one pupil recovers faster than the other pupil. The area between the two waveforms is highlighted to facilitate comparison.

Video Replay

From the Results Page, select the Video icon to view the video playback of the measurement (Figure 17 shows an example of an RAPD measurement). Only the last measurement’s video can be played back. Once the device has been turned off or another measurement has been attempted, the last video is not accessible.

Browse Records

To browse all records saved in memory, use icons Prev. and Next in the Results Page. Use the Eraser icon to delete a record from memory. Browsing may also be accessed by selecting the folder icon from the Main Screen. In the Browse Records menu (Figure 18), select Browse 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=0 in Figure 18).
Downloading Measurements

Data can be downloaded to an external computer via USB. To download, FIRST from Results or Settings Page select the download icon . After pressing the icon, the screen will read “File: XYZ.xls Download Completed!” THEN press “Close Link” and connect the USB Data Cable (g) to the mini-B connector located at the bottom of the Control Module next to the charging blades (Figure 19). The downloaded file is an Excel compatible summary of the measurement results. The file name shows the date and time of the download. Files are accessible from the external computer in the “External (Removable) (Disk)” folder.

When you download from Results (or while browsing browsing records), a bitmap copy of the screen of the Results page is also saved on the SD card. Delete the bitmaps from the SD card after copying them. Only a maximum of 50 images may be saved and maintained in storage. Once this limit is reached, the oldest bitmaps are automatically overwritten.

Miscellaneous Settings

The Settings window (accessible from the Main Screen by selecting the Settings icon ) allows the user to set the date and time as specified above and to: 1) select the fixation point (right, left, and off), 2) select the type of Pupil Size protocol (Variable or Light Off), or 3) delete all records from memory or only those associated with a specific ID.

Power Down

To turn the RAPiDo off, select the power icon from the Main Screen and confirm Yes. The power icon is only active when the Control Module is out of the Charging Station. (Note: the RAPiDo will always turn on when placed onto the Charging Station or when the green power button is pressed.) The device may also be turned off by pressing and holding the green power button.
## Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Possible Reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Device will not turn on.</td>
<td>Using incorrect power supply</td>
<td>Use only power supply provided with RAPiDo. Check label on power supply.</td>
</tr>
<tr>
<td></td>
<td>Power cord is not fully plugged into the wall or the charging station</td>
<td>Check connections</td>
</tr>
<tr>
<td></td>
<td>Battery completely discharged</td>
<td>Charge the battery by positioning the RAPiDo on the Charging Station. Confirm that the charging icon is displayed when on the Charging Station.</td>
</tr>
<tr>
<td>2. Pupillometer never ready to start a measurement.</td>
<td>Too much blinking</td>
<td>Gently hold the Patient’s eyes open with your finger.</td>
</tr>
<tr>
<td></td>
<td>Patient’s pupils not in blue tracking area</td>
<td>Reposition the Patient’s face and/or adjust the Pupillary Distance to center the pupils within the blue squares.</td>
</tr>
<tr>
<td>3. Battery will not charge.</td>
<td>Battery low</td>
<td>Charge the battery by positioning the RAPiDo on the Charging Station.</td>
</tr>
<tr>
<td></td>
<td>Device is not placed on the charging station correctly</td>
<td>Make sure the RAPiDo is sitting flat in the charging station and the charging icon is displayed.</td>
</tr>
</tbody>
</table>
Cleaning and Maintenance

Clean the RAPiDo, Eye Cups, and Charging Station with 50% water / 50% IPA solution as needed or per hospital protocol.

The RAPiDo does not require any regularly scheduled maintenance. If the RAPiDo is not working properly, or has been damaged, contact NeurOptics Customer Service at  **Toll Free North America: 866.99.PUPIL** or +1 949.250.9792 outside of North America

Returned Goods Policy

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement Characteristics</td>
<td>Input= Human pupil sizing varying from 1 mm–9 mm</td>
</tr>
<tr>
<td>RAPD Mode:</td>
<td>• Relative Afferent Pupillary Defect</td>
</tr>
<tr>
<td></td>
<td>• Pupil diameter</td>
</tr>
<tr>
<td></td>
<td>• Relative Efferent Pupillary Defect</td>
</tr>
<tr>
<td>Pupil Size Mode:</td>
<td>• Mean and standard deviation of pupil diameter with no background illumination</td>
</tr>
<tr>
<td></td>
<td>• Mean and standard deviation of pupil diameter for scotopic, low mesopic and high mesopic background illumination</td>
</tr>
<tr>
<td>Horner’s syndrome Mode:</td>
<td>• Waveforms of the two pupil light reflexes.</td>
</tr>
<tr>
<td>Accuracy</td>
<td>+/- 0.03 mm</td>
</tr>
<tr>
<td>Classification of the equipment against ingress of liquids</td>
<td>Ordinary equipment</td>
</tr>
<tr>
<td>Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide</td>
<td>The equipment is not an AP or APG category equipment</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>On Demand battery operation</td>
</tr>
<tr>
<td>Power Supply</td>
<td>Input: 100-240 VAC, 40-60Hz 1.6A</td>
</tr>
<tr>
<td></td>
<td>Output: 6V, 5A</td>
</tr>
<tr>
<td>Battery</td>
<td>3.7V, 3350 mAmp/hour Li:Ion Cell</td>
</tr>
</tbody>
</table>
Appendix A—Technical Specifications (continued)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Environment</td>
<td>Temperature Range: 18° C (65° F) to 30° C (86° F)</td>
</tr>
<tr>
<td></td>
<td>Relative Humidity: 20% to 70% RH. Non condensing at all times</td>
</tr>
<tr>
<td>Transportation and</td>
<td>Temperature Range: 0° C (32° F) to 75° C (167° F)</td>
</tr>
<tr>
<td>storage environment</td>
<td>Relative Humidity: 10% to 95% RH. Non-condensing at all times</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Stand: 18” H, 11.5”W, 13.5”D</td>
</tr>
<tr>
<td></td>
<td>Control Module: 4”H, 6”W, 1”D</td>
</tr>
<tr>
<td></td>
<td>Video Camera Module: 5”H, 6”W, 5.5”D</td>
</tr>
<tr>
<td></td>
<td>Charging Station: 2.75”H, 4.75”W, 4”D</td>
</tr>
<tr>
<td></td>
<td>Chin Rest: Min – 8.25”H, 4.5”W, 3”D</td>
</tr>
<tr>
<td></td>
<td>Max – 11.5”H, 4.5”W, 3”D</td>
</tr>
<tr>
<td>Weight</td>
<td>4.1 kg (9lb)</td>
</tr>
<tr>
<td>Classification</td>
<td>Class 1 LED product per IEC 60825</td>
</tr>
</tbody>
</table>

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