Introduction

The NeurOptics® NPi®-200 Pupillometer offers clinicians quantitative infrared technology to objectively and accurately measure and trend pupil size and reactivity in their critically ill patients with neuronal injuries in an advanced design. The NeurOptics NPi-200 Pupillometer is designed to upload into any hospital electronic medical record (EMR) system using the SmartGuard™ Reader by Omnikey®. The NPi-200 provides a comfortable ergonomic design, easy-to-read touchscreen LCD and graphics, simple patient identification (ID) number entry and trending capabilities customized to the clinician preference.

Indications for Use

NPi-200 Pupillometer is a handheld optical scanner which measures pupil size and pupil reactivity in patients requiring 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.

Contraindications

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

Table of Contents

Warnings and Cautions ................................................. 2
Classification .............................................................. 2
Patents, Copyright and Trademark Notice ..................... 2
Getting Started ........................................................... 3
Power Up ..................................................................... 3
Scan the Patient ID ....................................................... 4
Measure Pupils ............................................................... 5
  Pupil Measurement Considerations ............................... 6
Trend for Changes ......................................................... 6
The Neurological Pupil index (NPi®)
  Pupil Reactivity Assessment Scale ............................... 6
Upload into EMR ........................................................... 6

Power Down ................................................................. 7
Troubleshooting .......................................................... 7
Cleaning and Maintenance ............................................ 7
Ordering Information .................................................... 7
Customer Service ......................................................... 7
Appendix A
  Pupillary Measurement Parameters ............................ 8
Appendix B
  Technical Specifications ............................................ 8
Appendix C
  Bluetooth® and Radio Frequency Identification Device (RFID) Broadcast Range and Frequency .................. 9
Warnings and Cautions

Warnings

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

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

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

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

• The battery in the NPi-200 Pupillometer is only replaceable by a qualified service technician. Contact NeurOptics if you suspect an inoperative battery.

• Use only the NeurOptics NPi-200 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 EN60601-1-3 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals, research laboratories).

Magnetic Resonance Imaging (MRI) Notice

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

Bluetooth® Notice

Do not attempt to pair the NPi-200 Pupillometer and the SmartGuard™ using 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®NPI®-200 Pupillometer

Manufactured by:

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Irvine, CA 92612, USA
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Patents, Copyright and Trademark Notice

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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
Canadian Pat. No. 2368232
Other Patents Pending

SmartGuard:
Pat. No. 7216985
Pat. No. 7488074
Pat. No. 7901079
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 NPi-200 Pupillometer is packaged with the following components (Ex. 1):

• NPi-200 Pupillometer
• NPi-200 Charging Station
• NPi-200 Power Supply Adaptor
• NeurOptics Lens Cloth
• NPi-200 Pupillometer Quick Start Guide

Power Up

Initial Set-up

Connect the NPi-200 Pupillometer Power Supply to the NPi-200 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).

Place the NPi-200 into its Charging Station. After powering on, the touchscreen will display a blue battery icon indicating the NPi-200 is charging. The battery icon will turn green when fully charged (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). Follow the prompts to input the proper date and time using 24 hour time configuration and select Accept.

Turning On the NPi-200

When not in use, the NPi-200 should be kept in the Charging Station. If the NPi-200 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. 5).
Scan the Patient ID

Open a new SmartGuard (Ex. 6).
Gently squeeze the SmartGuard side tabs to position onto the NPi-200. There will be an audible click when the SmartGuard is properly positioned (Ex. 7).

For the first patient use, in order to automatically write the patient ID into the SmartGuard memory, scan the patient’s ID bracelet with the Barcode Scanner.

Select either Barcode Scanner or Manual ID to indicate the patient ID entry method to be used (Ex. 8).

Pairing the NPi-200 to the NeurOptics Antimicrobial Barcode Scanner

Connect the NeurOptics Antimicrobial Barcode Scanner and Charging Cradle to the power supply and plug into a power outlet (Ex. 9). 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 NPi-200.

On the NPi-200, select Barcode Scanner. The NPi-200 will display “Connecting...” on the touchscreen (Ex. 10). Once successfully paired, the touchscreen will prompt when the device is ready to scan the patient ID barcode (Ex. 11).

The patient ID will now appear on the NPi-200 touchscreen. Confirm the patient information is correct and select Accept (Ex. 12).

The NPi-200 will display the patient ID number and read “Ready to scan” (Ex. 13).

Manual Entry of the Patient ID

Press Manual Entry. Using the touchscreen, press the Patient ID. Select Shift to toggle from alpha to numeric as required. When the patient ID number has been manually entered, check for accuracy and press Enter (Ex. 14 & 15).
Measure Pupils

Position the NPi-200 with SmartGuard at a right angle to the patient’s axis of vision, minimizing any tilting of the device (Ex. 16).

Press and hold either the RIGHT or LEFT button until the eye is centered on the touchscreen and the display shows a green circle around the pupil (Ex. 17). Once the green circle appears, release the button, holding the NPi-200 in place for approximately three seconds, making sure the patient maintains an open eye position.

Repeat the scan procedure for the patient’s other eye to complete the bilateral pupil exam (Ex. 18).

When the bilateral pupil exam is complete, the NPi-200 measurement results will be displayed in yellow for the Left Eye and in green for the Right Eye (Ex. 19).

Using the touchscreen or keypad, select page 1 (1/2) or 2 (2/2) to display the results of the pupil measurement parameters and pupillary light reflex waveform (Ex. 20).

Video Replay
From the Results screen, select the Video icon to view the video playback of the reading (Ex. 21). Only the last measurement’s video can be played back. Once the device has been turned off, the last video is not accessible.

Disabling Smart Guard
The SmartGuard is designed for single patient use. To assist facility compliance with HIPAA guidelines, the patient data stored on each SmartGuard can be disabled once pupil exams are no longer required. To permanently disable the patient data on the SmartGuard, in the Settings menu press Disable SG and follow the prompts (Ex. 22).
Measure Pupils (cont.)

Pupil Measurements- Special Considerations

**Blinking During Measurement**
If the measurement was affected by a tracking problem (e.g., blinks) then measurement results are all displayed in red font on the results screen and NPi is reported as “Rescan”. In this case, the measurement results are not valid and should not be relied upon and the measurement should be repeated (Ex. 23).

**Non-Responsive Pupil**
In case of a non-responsive pupil, before reporting the results on the LCD screen, the measurement is automatically repeated for confirmation. The operator is simply asked to wait a few more seconds before removing the device. If the operator believes a second confirmatory measurement is not necessary, then press the RIGHT or LEFT button to skip (Ex. 24).

**Trend for Changes**
To visualize the parameter trend display, use either the keypad or the touchscreen to select the Chart icon from the main screen of the NPi-200. Select the Down arrow on the keypad to view a trend display of the patient’s NPi and Size measurements (Ex. 25 & 26).

**Choose desired parameters to trend**
To trend additional parameters, select Trending Variables from the Settings menu, and choose the desired parameters to trend (Ex. 27).

**The Neurological Pupil index™ (NPi®) Pupil Reactivity Assessment Scale**

<table>
<thead>
<tr>
<th>Measured Value*</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0 – 4.9</td>
<td>Normal/“Brisk”</td>
</tr>
<tr>
<td>&lt;3.0</td>
<td>Abnormal/“Sluggish”</td>
</tr>
<tr>
<td>0</td>
<td>Non-Reactive or Atypical Response</td>
</tr>
</tbody>
</table>

*A difference in NPi between right and left pupils of ≥0.7 can also be considered an abnormal pupil reading
*Per the Neurological Pupil index (NPi) algorithm

**Upload into EMR**

The NPi-200 is designed to integrate into all hospital Electronic Medical Record (EMR) systems by interfacing through the hospital information technology (IT) infrastructure using the NeurOptics SmartGuard Reader. Please contact your IT department to identify the next steps required to integrate the NPi-200 into your hospital EMR system.
Power Down

To turn the NPi-200 off, select the \( \text{Select} \) from the main screen and confirm Yes.

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 Pupillometer. 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 Pupillometer into the charger</td>
</tr>
<tr>
<td>2. Pupil measurement will not initiate after release of the RIGHT or LEFT key</td>
<td>Too much blinking</td>
<td>Gently hold patient’s eye open with your finger during measurement</td>
</tr>
<tr>
<td></td>
<td>Device not held correctly</td>
<td>Hold device at a 90-degree angle to patient’s face. Make sure patient’s eye is centered on the screen</td>
</tr>
</tbody>
</table>

Cleaning and Maintenance

Clean the NPi-200 and Charging Station with 50% water/50% IPA solution as needed or per hospital protocol.

The NPi-200 does not require any regularly scheduled maintenance. If the NPi-200 is not working properly, or has been damaged, contact NeurOptics Customer Service at Toll Free North America: 866.99.PUPIL.

Ordering Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPi-200</td>
<td>NPI®-200 Pupillometer</td>
</tr>
<tr>
<td>SG-200</td>
<td>SmartGuard™</td>
</tr>
<tr>
<td>BCS-CC-01</td>
<td>NeurOptics® Antimicrobial Barcode Scanner by Socket®</td>
</tr>
<tr>
<td>SGR-01</td>
<td>SmartGuard™ Reader by Omnikey®</td>
</tr>
</tbody>
</table>

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 Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size = Maximum Diameter</strong></td>
<td>Maximum pupil size before constriction</td>
</tr>
<tr>
<td><strong>MIN = Minimum Diameter</strong></td>
<td>Pupil diameter at peak constriction</td>
</tr>
<tr>
<td><strong>% CH = % Change</strong></td>
<td>% of change (Size-MIN) / Size as a %</td>
</tr>
<tr>
<td><strong>LAT = Latency of constriction</strong></td>
<td>Time of onset of constriction following initiation of the light stimulus</td>
</tr>
<tr>
<td><strong>CV = Constriction Velocity</strong></td>
<td>Average of how fast the pupil diameter is constricting measured in millimeters per second</td>
</tr>
<tr>
<td><strong>MCV = Maximum Constriction Velocity</strong></td>
<td>Maximum velocity of pupil constriction of the pupil diameter responding to the flash of light measured in millimeters per second</td>
</tr>
<tr>
<td><strong>DV = Dilation Velocity</strong></td>
<td>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</td>
</tr>
</tbody>
</table>

## Appendix B—Technical Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement Characteristics</strong></td>
<td>Input= Human pupil sizing varying from 1 mm–9 mm</td>
</tr>
<tr>
<td></td>
<td>Output= NP® (Neurological Pupil index), Size, and Min diameter, percentage change, latency, average and maximum constriction velocity, average dilation velocity</td>
</tr>
<tr>
<td></td>
<td>Accuracy: +/- 0.03 mm</td>
</tr>
<tr>
<td><strong>Degree of protection against electric shock</strong></td>
<td>Pupillometer SmartGuard-Type BF Applied Part provided protection</td>
</tr>
<tr>
<td><strong>Classification of the equipment against ingress of liquids</strong></td>
<td>Ordinary equipment</td>
</tr>
<tr>
<td><strong>Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide</strong></td>
<td>The equipment is not an AP or APG category equipment</td>
</tr>
<tr>
<td><strong>Mode of Operation</strong></td>
<td>On Demand battery operation</td>
</tr>
<tr>
<td><strong>Power Supply</strong></td>
<td>3.7V 3350 Amp/hour Li: Ion Cell (battery)</td>
</tr>
<tr>
<td><strong>Operating Environment</strong></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><strong>Transportation and storage environment</strong></td>
<td>Temperature Range: 0° C (32° F) to 75° C (167° F)</td>
</tr>
<tr>
<td></td>
<td>Relative Humidity: 10% to 95% RH. Non-condensing at all times</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>With SmartGuard = 7.5&quot; H, 3.5&quot; W, 4.5&quot; D</td>
</tr>
<tr>
<td></td>
<td>Without SmartGuard = 7.5&quot; H, 3.5&quot; W, 3.5&quot; D</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>320 grams +/- 10 grams</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Class 1 LED product per IEC 60825</td>
</tr>
</tbody>
</table>
## Appendix C—Bluetooth® and Radio Frequency Identification Device (RFID) Broadcast Range and Frequency

<table>
<thead>
<tr>
<th>Broadcast Function</th>
<th>Range</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluetooth Barcode Scanner to/from NPI-200 Pupillometer</td>
<td>Up to 100 yards depending on environment</td>
<td>2.45 GHz</td>
</tr>
<tr>
<td>RFID memory card in SmartGuard to/from NPI-200 Pupillometer</td>
<td>Up to 2 centimeters</td>
<td>13.56 MHz</td>
</tr>
<tr>
<td>RFID memory card in SmartGuard to/from SmartGuard Reader</td>
<td>Up to 2 centimeters</td>
<td>13.56 MHz</td>
</tr>
</tbody>
</table>

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