NPi®-200
Pupillometer

Instructions for Use

NPi®-200 Pupillometer

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.

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NEUROPTICS

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 inoperable 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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Pupillometers:	SmartGuard:
Pat. No. 6116736	Pat. No. 7216985
Pat. No. 6260968	Pat. No. 7488074
Pat. No. 6820979	Pat. No. 7901079
Pat. No. 7147327	Other Patents Pending
Pat. No. 7670002	
Pat. No. 8235526	
Pat. No. 8393734	
Pat. No. 7967442	
Pat. No. 8534840	
Canadian Pat. No. 2368232	
Other Patents Pending	

Federal Communications Commission Compliance

This device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference , and (2) this device must accept any interference received, including interference which may cause undesired operation.

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Getting Started

Safety Information

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

Ex. 1

Power Up

Ex. 2

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).
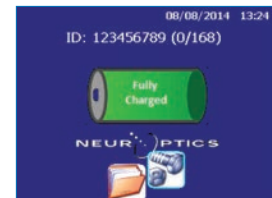
Ex. 3

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**.
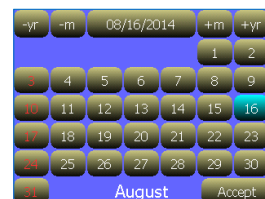
Ex. 4

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.
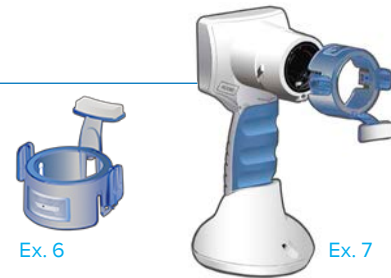- Power down after 30 minutes. Press and hold the Up arrow to turn on (Ex. 5).

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).

Ex. 6   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).

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.
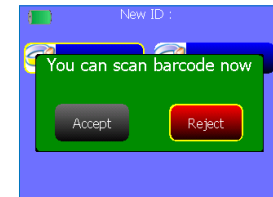
Ex. 9

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).
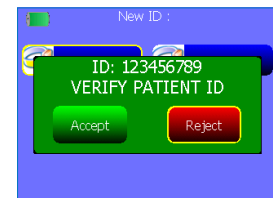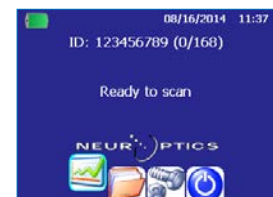
Ex. 10   Ex. 11

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

Ex. 12

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

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).

Ex. 14   Ex. 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).

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.
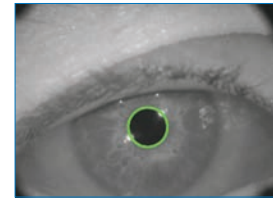
Ex. 17

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).


Ex. 18

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).


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.
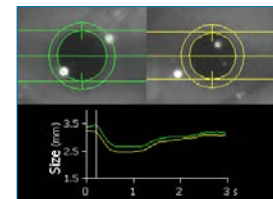
Ex. 21

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).
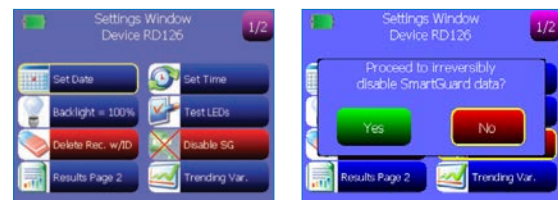
Ex. 22

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).


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).
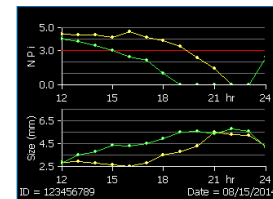

Ex. 24

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).
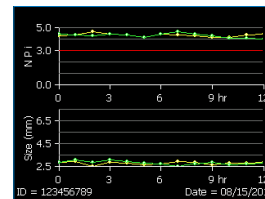
Ex. 25

Ex. 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).

Ex. 27

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

Measured Value*	Assessment
3.0 – 4.9	Normal/"Brisk"
<3.0	Abnormal/"Sluggish"
0	Non-Reactive or Atypical Response

*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 ⏻ 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 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

NPi-200	NPi®-200 Pupillometer
SG-200	SmartGuard™
BCS-CC-01	NeurOptics® Antimicrobial Barcode Scanner by Socket®
SGR-01	SmartGuard™ Reader by Omnikey®

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

Parameter	Description
Size = Maximum Diameter	Maximum pupil size before constriction
MIN = Minimum Diameter	Pupil diameter at peak constriction
% CH = % Change	% of change (Size-MIN) / Size as a %
LAT = Latency of constriction	Time of onset of constriction following initiation of the light stimulus
CV = 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
DV = 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

Appendix B—Technical Specifications

Parameter	Description
Measurement Characteristics	Input= Human pupil sizing varying from 1 mm–9 mm
	Output= NPi® (Neurological Pupil index), Size, and Min diameter, percentage change, latency, average and maximum constriction velocity, average dilation velocity
	Accuracy: +/- 0.03 mm
Degree of protection against electric shock	Pupillometer SmartGuard-Type BF 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 Supply	3.7V 3350 Amp/hour Li: Ion Cell (battery)
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 SmartGuard = 7.5" H, 3.5" W, 4.5" D
	Without SmartGuard = 7.5" H, 3.5" W, 3.5" D
Weight	320 grams +/- 10 grams
Classification	Class 1 LED product per IEC 60825

Appendix C—Bluetooth® and Radio Frequency Identification Device (RFID) Broadcast Range and Frequency

Broadcast Function	Range	Frequency
Bluetooth Barcode Scanner to/from NPi-200 Pupillometer	Up to 100 yards depending on environment	2.45 GHz
RFID memory card in SmartGuard to/from NPi-200 Pupillometer	Up to 2 centimeters	13.56 MHz
RFID memory card in SmartGuard to/from SmartGuard Reader	Up to 2 centimeters	13.56 MHz