NPi®-300 **Pupillometer**

Instructions For Use

NEURO PTICS®

Introduction

The NeurOptics® NPi®-300 Pupillometer offers clinicians quantitative infrared technology to objectively and accurately measure and trend pupil size and reactivity in their critically ill patients. The NPi-300 provides a comfortable ergonomic design, incorporated barcode scanner, wireless charging, and easy-to-read touchscreen LCD and graphics.

Indications for Use

The NPi-300 Pupillometer is a handheld optical scanner which measures pupil size and pupil reactivity in patients requiring neurological pupil examinations. The results obtained from the NPi-300 scans are used for information only and are not to be used for clinical diagnostic purposes. The NPi-300 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.

Table of Contents

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 NPi-300 Pupillometer – The NPi-300 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 NPi-300 is only replaceable by a qualified NeurOptics' service technician. Contact NeurOptics if you suspect an inoperable battery.
- Use only the NeurOptics NPi-300 Charging Station for charging the NPi-300.
- 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 NPi-300 System in ambient environments with non-condensing humidity levels only. Using the NPi-300 with condensation on optical surfaces may result in inaccurate readings.
- The SmartGuard is NOT a sterile product. It is not intended to be cleaned between measurements. If the SmartGuard appears soiled or if the clinician becomes concerned about product cleanliness, the SmartGuard should be discarded and replaced before using the NPi-300 on a patient.

Cautions

The following cautions apply when cleaning the device. The internal components of the NPi-300 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 NPi-300 or Charging Station.

Electromechanical Compatibility (EMC) Notice

This device generates, uses, and can radiate radio frequency energy. If not set up and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals, research laboratories).

Magnetic Resonance Imaging (MRI) Notice

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

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® NPi®-300 Pupillometer

Manufactured by:

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Patents, Copyright and Trademark Notice

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 NPi-300. 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.

Getting Started

Unpacking the NPi-300 Pupillometer System

The NeurOptics NPi-300 Pupillometer System is packaged with the following components (Ex. 1):

- NPi-300 Pupillometer (A)
- NPi-300 Charging Station (B)
- NPi-300 Power Adapter and Plug (C)
- NPi-300 Pupillometer Quick Start Guide

Ex. 1

Initial Set-Up

- To set up the NPi-300 for first-time use, please refer to the **Power Up** section below, ensuring the NPi-300 is fully charged and Date/Time are set accurately prior to use.

Power Up

Charging the NPi-300 Pupillometer

- Connect the NPi-300 Power Adapter to the NPi-300 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).

Ex. 2

- Place the NPi-300 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 NPi-300 is charging. The indicator light will turn **green** when fully charged (Ex. 4).

Ex. 3

Ex. 4

- An **amber/orange** indicator light on the Charging Station indicates a charging malfunction, and the NPi-300 will not charge (Ex. 5). If this issue persists, please contact NeurOptics Customer Service.

Ex. 5

Indicator Light Color	Meaning
White	Charging Station is plugged into a power outlet, and power has been established. NPi-300 is out of Charging Station.
Blue	NPi-300 is placed in Charging Station and successfully charging.
Green	NPi-300 is fully charged.
Amber/Orange	Charging Malfunction – NPi-300 is not charging. If issue persists, please contact NeurOptics Customer Service.

The NPi-300 Pupillometer goes to sleep in the Charging Station to efficiently charge:

- The NPi-300 will initially turn ON (or remain on) upon being placed in the Charging Station.
- After 5 minutes in the Charging Station, the NPi-300 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 5-minute window, the time period before the NPi-300 goes to sleep is extended by an additional 5 minutes.
- To use the NPi-300 after it has gone to sleep in the Charging Station, simply remove from the Charging Station, and it will wake up automatically.
- If the NPi-300 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 NPi-300 is charging. Leave the NPi-300 in the Charging Station until it powers on.

Ex. 6

If the NPi-300 Pupillometer is not in the Charging Station, to conserve battery life it will:

- Go into sleep mode after 5 minutes. To turn ON, touch the screen or push any button.
- Power down after 20 minutes.

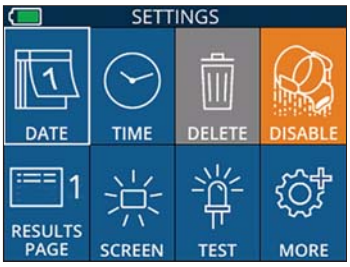
Turning On the NPi-300 Pupillometer

- If the NPi-300 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 NPi-300 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 NPi-300 is not connected to the internet or GPS.

Ex. 10

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 NPi-300 and SmartGuard. 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. 11

Returning to the Home Screen

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

Measuring Pupils Using the NPi-300 Pupillometer

The NPi-300 provides objective pupil size and reactivity data independent of examiner – removing variability and subjectivity. The NPi-300 expresses pupil reactivity numerically as the Neurological Pupil index, NPi (see the Neurological Pupil index Scale below).

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, Immeasurable, or Atypical Response

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

Taking a Bilateral Pupil Measurement

Two components are required to initiate a bilateral pupil measurement:

- NPi-300 Pupillometer (Ex. 12)
- Single Patient Use SmartGuard (Ex. 13)

Open a new SmartGuard. Slide the SmartGuard onto the NPi-300 with the foam pad at the bottom (Ex. 12). There will be an audible click when the SmartGuard is properly positioned.

Ex. 12

Ex. 13

1. Associate SmartGuard with Patient ID

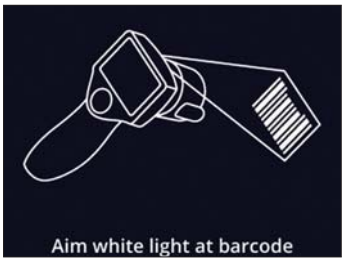
For the first patient use, the SmartGuard requires a one-time association of the Patient ID. For subsequent measurements, the Patient ID will be permanently saved on the SmartGuard, which can store up to 168 bilateral pupil measurements of the associated patient.

Ex. 14

There are two options for associating the Patient ID to the SmartGuard. Select **Scan Code** to scan the patient's wristband barcode using the NPi-300 Incorporated Barcode Scanner, or select **Manual ID** to manually enter the Patient ID with either alpha or numeric characters (Ex. 14).

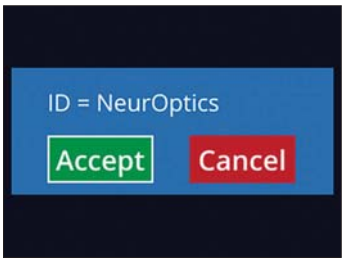
Scan Barcode Using Incorporated Barcode Scanner

Select **Scan Code**. The NPi-300 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 (Ex. 16). The Patient ID will now appear on the NPi-300 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 17). The NPi-300 will display the Patient ID and read **Ready to Scan** (Ex. 18).



Ex. 15

Ex. 16



Ex. 17

Ex. 18

Manual Entry of the Patient ID

Select **Manual ID**. Using the touchscreen or keypad, enter the alpha or numeric Patient ID and select  (Ex. 19). Confirm the patient information on the screen is correct and select **Accept** (Ex. 17). The NPi-300 will display the Patient ID and read **Ready to Scan** (Ex. 18).

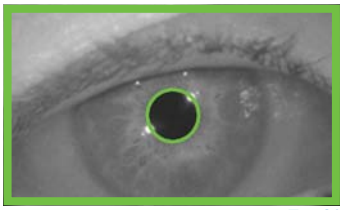
Ex. 19

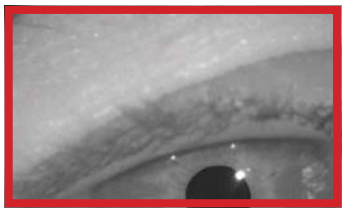
2. Measure Pupils

Position the NPi-300 with SmartGuard at a right angle to the patient's axis of vision, minimizing any tilting of the device (Ex. 20).

Ex. 20

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. 21), while a red frame indicates the pupil needs to be re-centered on the screen before the measurement is initiated (Ex. 22). Once the green frame appears, release the button, holding the NPi-300 in place for approximately three seconds until the results screen is displayed.


Ex. 21


Ex. 22

Repeat the scan procedure for the patient's other eye to complete the bilateral pupil exam. When the bilateral pupil exam is complete, the NPi-300 measurement results will be displayed in green for the Right eye and in yellow for the Left eye.

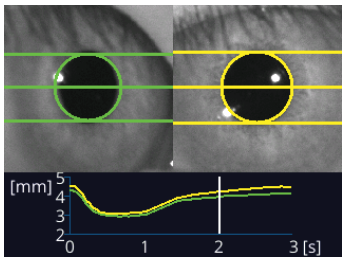
The NPi-300 is defaulted to open "Results Page 1," displaying NPi and Size measurements, following the completion of the Bilateral Pupil Measurement (Ex. 23). To adjust Default Results Page Settings, see **NPi-300 Pupillometer Navigation Guide.**

Ex. 23

Ex. 24

Using the touchscreen or keypad, select 1 to view "Results Page 2" with additional Pupillary Measurement Parameters (Ex. 23). Select 2 to view the Pupillary Light Reflex Waveform (Ex. 24). To return to "Results Page 1" with NPi and Size, simply select (Ex. 25).

Ex. 25



Ex. 26

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 NPi-300 has powered off, the last video is not accessible (Ex. 26).

3. Trend for Changes

To review the patient's previous bilateral pupil measurements stored on the attached SmartGuard and Trend for Changes:

- If still on the Results Page following completion of the last measurement: Press the **DOWN Arrow** button on the keypad.
- From the Home Screen: Select the **Records** icon (Ex. 27), then select the **SmartGuard** icon (Ex. 28). The most recent measurement will appear first. Press the **DOWN Arrow** button on the keypad to scroll through all previous patient measurements stored on the attached SmartGuard.

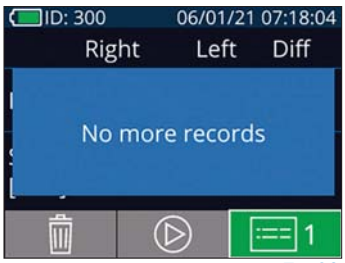
Ex. 27

Browse Records

To review records stored on the NPi-300 if the patient's SmartGuard is unavailable:

- From the Home Screen: Select the **Records** icon (Ex. 27).
- 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 ID's available in the list. The ID's of the most recent measurements taken on the NPi-300 will appear at the top of the list.
- To search for a specific Patient ID, select (Ex. 28), then type in the Patient ID and select .
- To browse all pupil measurements stored on the NPi-300 in chronological order (including all Patient ID's), select the **All Records** icon All (Ex. 28) and press the **DOWN Arrow** button on the keypad to scroll through all previous measurements stored on the NPi-300.
- When the **No more records** message appears, the earliest pupil measurement stored has been reached (Ex. 29).

Ex. 28



Ex. 29

The NPi-300 also offers both quantitative (**NPi Summary Table**) and graphical (**NPi/Size Trending Graph**) summaries of all pupil measurements taken on any patient's SmartGuard that is attached to the NPi-300:

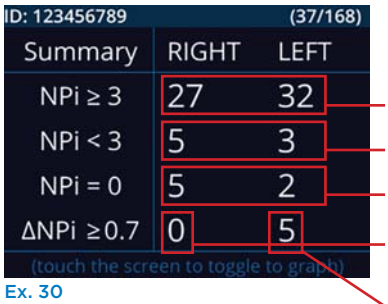
NPi Summary Table

The NPi Summary Table (Ex. 30) provides a quantitative summary from the attached SmartGuard of the number of Right and Left Eye NPi Measurements in the following categories:

- NPi ≥ 3
- NPi < 3
- NPi = 0
- ΔNPi ≥ 0.7

To view the NPi Summary Table

- Return to the Home Screen by pressing either the **RIGHT** or **LEFT** buttons on the keypad.
- Select the **Trend** icon from the bottom left of the Home Screen.



Ex. 30

Number of NPi measurements on attached SmartGuard greater or equal to 3.0

Number of NPi measurements on attached SmartGuard less than 3.0 and greater than 0

Number of NPi measurements on attached SmartGuard equal to 0

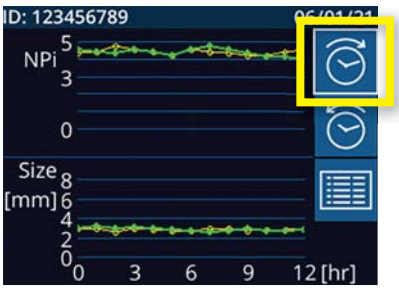
RIGHT: Number of Bilateral NPi Measurements on attached SmartGuard where Right NPi was less than Left NPi by more than or equal to 0.7

LEFT: Number of Bilateral NPi Measurements on attached SmartGuard where Left NPi was less than Right NPi by more than or equal to 0.7

NPi/Size Trending Graph

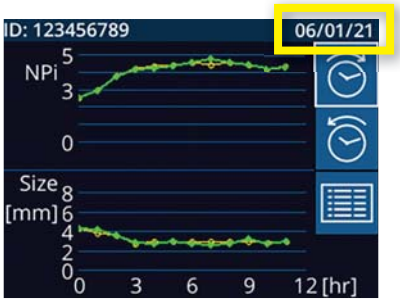
To visualize the trend of all NPi and Size measurements taken on the attached SmartGuard over 12-hour time windows:

- Navigate to the NPi Summary Table from the Home Screen by selecting the **Trend** icon .
- Tap anywhere on the screen to access the NPi/Size Trending Graph.
- Move forward and backward in time on the graph by pressing the **Forward** (Ex. 31) or **Backward** (Ex. 32) **Clock** icons. The date of measurements currently displayed on the graph will show in the top right hand corner of the Trending Screen (Ex. 33).



Ex. 31

Ex. 32



Ex. 33

Pupil Measurements – Special Considerations

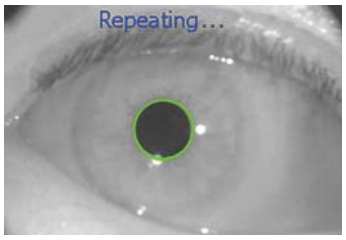
Blinking During Measurement

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" (Ex. 34). In this case, the measurement results are not valid and should not be relied upon and the measurement should be repeated.

Ex. 34

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 (Ex. 35).



Ex. 35

Small "Pinpoint" Pupil Measurement

Pupillometer Resolution Threshold: Pupil Size

The NPi-300 Pupillometer measurement threshold for measuring pupil size is 0.80 mm, which means the pupillometer can measure pupils as small as 0.8 mm in diameter. If the pupil size is < 0.8 mm, the pupillometer will not detect the pupil, and it will not initiate a measurement.

Pupillometer Resolution Threshold: Change in Pupil Size

The NPi-300 Pupillometer's minimum measurement threshold for detecting a change in pupil size is 0.03 mm (30 microns). In the event a change in pupil size is < 0.03 mm, the pupillometer will not be able to measure a change in pupil size, and it will display an NPi of 0.

NPi Measurement of "0"

The NPi-300 Pupillometer will measure an NPi of 0 in the following clinical assessment scenarios:

- Non-Reactive response = Non-reactive pupillary response; no pupillary light reflex (PLR) waveform.
- Immeasurable response = Change in pupil size < 0.03 mm (30 microns).
- Atypical response = An abnormal pupillary light reflex (PLR) waveform.

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, Immeasurable, or Atypical Response

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

NPi-300 Pupillometer Navigation Guide

Returning to the Home Screen

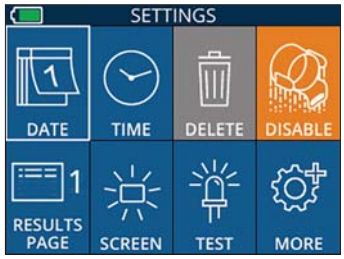
Press the **RIGHT** or **LEFT** buttons (green circles) to return to the Home Screen (Ex. 36).

Ex. 36

Settings

Using the touchscreen or keypad, select **Settings** icon  icon (Ex. 37) from the Home Screen to navigate to the Settings Menu (Ex. 38).

Ex. 37



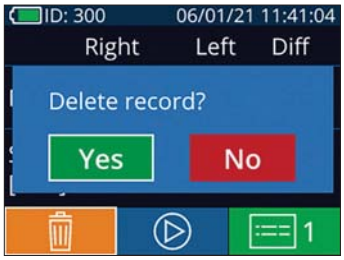
Ex. 38

Date and Time

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

Delete Records

To delete records off of the device memory of the NPi-300 (does not disable or delete records off of the attached SmartGuard), navigate to the Settings Menu and press **Delete**  then select **Yes** to proceed to delete record (Ex. 39). Records on the device can be deleted for a specific Patient ID or All Records.



Ex. 39

Disabling SmartGuard

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**  and select **Yes** to proceed to irreversibly disable SmartGuard data (Ex. 40).

Ex. 40

Adjusting Default Results Page

The NPi-300 Pupillometer is defaulted to open "Results Page 1," displaying NPi and Size measurements, following the completion of the Bilateral Pupil Measurement. To set the default to Results Page 2, displaying additional Pupillary Measurement Parameters, select the **Results Page 1** icon  (Ex. 41) to toggle to the **Results Page 2** icon  (Ex. 42).

Ex. 41

LCD Screen Brightness

The NPi-300 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. 42

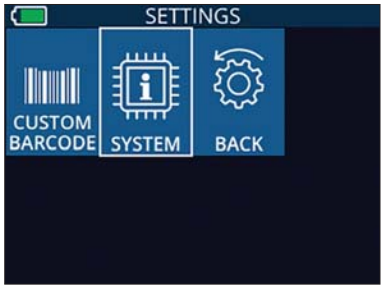
Test LED

Pressing the Test icon  demonstrates a sample of the LED light that is emitted from the NPi-300 when taking a pupil measurement. This test is for demonstration purposes only and does not affect usage of the device.

More Settings

Customize Barcode Scanner

The NPi-300 Incorporated Barcode Scanner can be customized to truncate or expand the alpha or numeric characters read from a hospital barcode, if required. The **Default** settings automatically adjust to read most types of 1D and 2D hospital barcodes, and "Default" should remain selected unless a specific customization needs to be applied to all barcodes scanned by the NPi-300. Select **Custom Barcode** (Ex. 43), 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. 43

System Information

Select **System** (Ex. 43) to view the NPi-300's system information, displaying the Serial Number, Software Application, and Firmware versions of the device.

Troubleshooting

Issue	Possible Reason	Solution
1. NPi-300 Pupillometer will not turn on	Using incorrect Power Adapter	Use only Power Adapter provided with NPi-300. 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 NPi-300 into the Charging Station.
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 pupil is centered on the screen.
3. NPi-300 returned to Home Screen while taking a measurement	RIGHT or LEFT 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. "Rescan" displayed following measurement	NPi-300 is moved from position prior to completion of the measurement	Repeat the scan and maintain proper position of the NPi-300 until the measurement is completed and pupillary measurements are displayed.
	Patient blinked during measurement	Hold the patient's eyelid open and repeat the scan.

Power Off

To turn the NPi-300 Pupillometer OFF, either:

- Navigate to the Home Screen, and select the **Power** icon , then confirm **Yes** to power OFF (Ex. 44).
- Press and hold the **On/Off** button on the side of the NPi-300.

The NPi-300 may occasionally require a System Reboot. To reboot, simply press and hold the **On/Off** button on the side of the NPi-300 until it powers OFF.

Ex. 44

Handling, Cleaning and Maintenance

Always handle the NPi-300 Pupillometer and NPi-300 Charging Station with care because sensitive metal, glass, plastic and electronic components are contained inside. The NPi-300 and Charging Station can be damaged if dropped or by prolonged exposure to liquid or high humidity environments.

The NPi-300 and Charging Station do not require any regularly scheduled maintenance. If the NPi-300 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 NPi-300 Pupillometer and NPi-300 Charging Station

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA, are recommended for use in cleaning the NPi-300 and Charging Station. Do not use chemicals that can damage the NPi-300 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 NPi-300 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 NPi-300 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 NPi-300 or Charging Station.
- **DO NOT** immerse the NPi-300 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 NPi-300 and Charging Station are thoroughly dry before placing the NPi-300 back into the Charging Station.

Cleaning Considerations: NPi-300 Liquid Crystal Display (LCD)

For best protection of the liquid crystal display (LCD), use a clean, soft, lint-free cloth and up to 70% IPA to clean the NPi-300 optics. Occasional cleaning of the Incorporated Barcode Scanning Window (located just above the NPi-300 Lens) is also recommended using a clean, soft, lint-free cloth and up to 70% IPA.

In instances where there is concern of exposure to highly resistant bacteria, viruses, fungi or spores (ie: Clostridium difficile, or "C. diff"), we understand that hospital protocols may require use of cleaning solutions containing sodium hypochlorite (bleach) when cleaning equipment. If products containing sodium hypochlorite (bleach) are used to clean the LCD of the NPi-300, the cleaning process should be followed by a second cleaning using a clean, soft, lint-free cloth and up to 70% IPA to ensure that all bleach residue is completely removed from the LCD.

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**.

Ordering Information

NPi-300-SYS	NPi®-300 Pupillometer System
SG-200	SmartGuard®
SGR-01	SmartGuard® Reader (Please contact Customer Service to determine the specific reader compatible with the hospital requirements)

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact, to be accepted for 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 credit if they have been in the possession of the customer for more than 30 days.

Appendix A – Pupillary Measurement Parameters

Parameter	Description
NPi® = Neurological Pupil index™	Numerical expression of pupil reactivity. Please refer to the Neurological Pupil index™ (NPi®) Pupil Assessment Scale (Page 5) for additional information.
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	
Pupillometer Measurement Detection Threshold	Pupil diameter (minimum)	0.80 mm
	Pupil diameter (maximum)	10.00 mm
	Change in Size	0.03 mm (30 microns)
Size Accuracy	+/- 0.03 mm (30 microns)	
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 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 45° C (113° F)	
	Relative Humidity: Non-condensing at all times.	
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 SmartGuard = 7.5” H, 3.5” W, 4.5” D	
	Without SmartGuard = 7.5” H, 3.5” W, 3.5” D	
Weight	344 grams +/- 10 grams	
Classification	Class 1 LED product per IEC 62471	

Appendix C – Radio Frequency Identification Device (RFID) Broadcast Range

Broadcast Function	Range	Frequency
RFID memory card in SmartGuard to/from NPi-300 Pupillometer	Up to 2 centimeters	13.56 MHz
RFID memory card in SmartGuard to/from SmartGuard Reader	Up to 2 centimeters	13.56 MHz

Appendix D – NPi-300 Pupillometer Display Limits for Electronic Medical Record (EMR) Flowsheet Integration

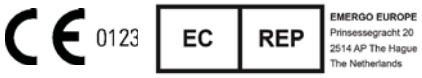
The following low and high display limits are included to inform hospital staff of the specific parameter display limits for consideration in the development of neurological parameter flow sheets.

Parameter	LOW	HIGH
NPi	0.0	4.9
Size	0.80 mm	10.00 mm
MIN	0.80 mm	10.00 mm
CH	0%	50%
CV	0.00 mm/s	6.00 mm/s
MCV	0.00 mm/s	6.00 mm/s
LAT	0.00 sec	0.50 sec
DV	0.00 mm/s	6.00 mm/s

Appendix E – International Symbol Definition

Symbol	Source/Compliance	Title of	Description of Symbol
	Standard: ISO 15223-1 Symbol Reference No: 5.4.4	Caution	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	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: 5010	“ON”/“OFF” (Power)	To indicate electronic power “ON”/ “OFF” (Power) connection or disconnection to internal battery supply.
	Standard: ISO 15223-1 Symbol Symbol Reference No: 5.1.5	Batch Code	Indicates the imanufacturer’s batch code so that the batch on lot can be identified.
	Standard: ISO 15223-1 Symbol Reference No: 5.4.4	Non-sterile. Single patient use only	Indicates a medical device that has not been subjected to a sterilization process. Intended for single patient use.
	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	Catalog Number	Indicates the manufacturer’s catalog number so that the medical device can be identified.
	BS EN 50419 Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE) Fig. 1	Recycle: Electronic Equipment	Do not throw in trash.

Symbol	Source/Compliance	Title of	Description of Symbol
	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 containing Ion batteries and products containing lithium perchlorate.
	Standard: ISO 15223-1 Symbol Reference No: 5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/ EEC and 98/79/EC.
	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	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 Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive	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.
	Standard: ISO 15223-1 Symbol Reference No: 5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.
	Standard: ISO 15223-1 Symbol Reference No: 5.4.3	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use at **NeurOptics.com**.
	Standard: ISO 60878 Symbol Reference No: 5140	Non-ionizing electromagnetis radiation	Includes RF Transmitters.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied 5.3.4	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied 5.3.7	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Reference No. 5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.



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