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. 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. The NPi-200 Pupillometer 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 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 EN60601-1-2 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.

Bluetooth® Notice

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

NeurOptics, Inc.
23041 Avenida de la Carlota, Suite 100
Laguna Hills, CA 92653, USA
p: 949.250.9792
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Patents, Copyright and Trademark Notice

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
Pat. No. 9198570
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
- NPi-200 Pupillometer Cleaning and Maintenance Instructions

Ex. 1

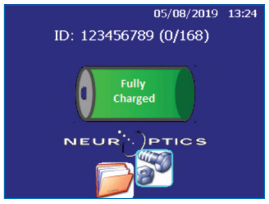
Power Up

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).

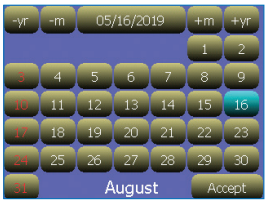
Ex. 2

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. 4A & 4B). Follow the prompts to input the proper date and time using 24 hour time configuration and select **Accept**.



Ex. 4A

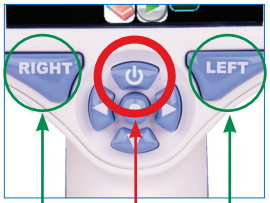
Ex. 4B

Turning On the NPi-200

When not in use, the NPi-200 will remain powered **ON** when seated in the NPi-200 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. To turn **ON**, touch the screen, push any button, or place in the Charging Station.
- Power down after 30 minutes.



Ex. 5

To Turn On the NPi-200

- Press and hold the button (red circle).

To Get to the Home Screen

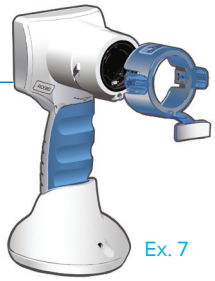
- Press **LEFT** or **RIGHT** button (green circles).

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

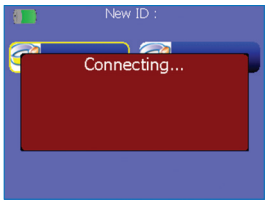
For the first patient use, in order to properly input the patient ID into the SmartGuard, select either Barcode Scanner or Manual ID to indicate the patient ID entry method used (Ex. 8).

Ex. 8

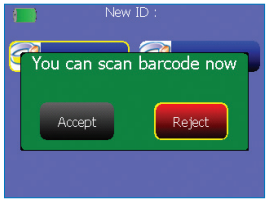
Pairing the NPi-200 to the Barcode Scanner

Connect the Barcode Scanner and Charging Cradle to the power supply and plug into a power outlet. 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. 9). Once successfully paired, the touchscreen will prompt when the device is ready to scan the patient ID barcode (Ex. 10).

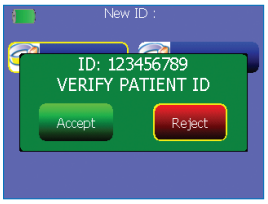


Ex. 9



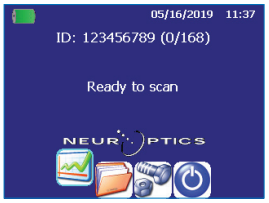
Ex. 10

The patient ID will now appear on the NPi-200 touchscreen. Confirm the patient information is correct and select **Accept** (Ex. 11).



Ex. 11

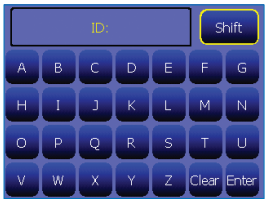
The NPi-200 will display the patient ID number and read ***"Ready to scan"*** (Ex. 12).



Ex. 12

Manual Entry of the Patient ID

Press Manual Entry. Using the touchscreen, press the **Patient ID**. Select **Shift** to toggle from alpha to numeric (Ex. 13 & 14) as required. When the patient ID number has been manually entered, check for accuracy and press **Enter**.



Ex. 13

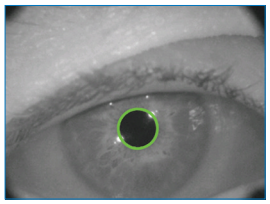
Ex. 14

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. 15).

Ex. 15

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. 16). Once the green circle appears, release the button, holding the NPi-200 in place for approximately three seconds until the result screen is displayed.



Ex. 16

Repeat the scan procedure for the patient's other eye to complete the bilateral pupil exam (Ex. 17).

When the bilateral pupil exam is complete, the NPi-200 measurement results will be displayed in green for the Right eye and in yellow for the Left eye (Ex. 18).

Ex. 17

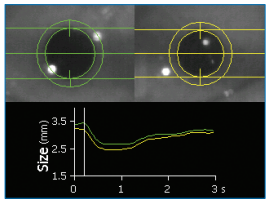
Ex. 18

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. 19).

Ex. 19

Video Replay

From the Results screen, select the **Video** icon to view the video playback of the reading (Ex. 20). Only the last measurement's video can be played back. Once the device has been turned off, the last video is not accessible.



Ex. 20

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 SG** and follow the prompts (Ex. 21A & 21B).

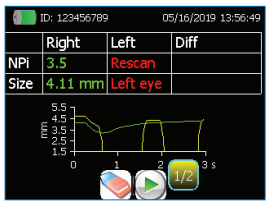
Ex. 21A

Ex. 21B

Pupil Measurements - Special Considerations

Blinking During Measurement

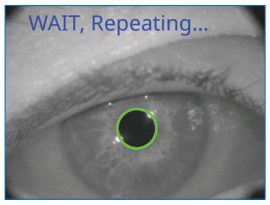
If the measurement was affected by a tracking problem (e.g., blinks), then measurement results are all displayed in red font on the results screen and NPi is reported as “Rescan”. In this case, the measurement results are not valid and should not be relied upon and the measurement should be repeated (Ex. 22).



Ex. 22

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. 23). If the operator believes a second confirmatory measurement is not necessary, then press the **RIGHT** or **LEFT** button to skip.



Ex. 23

Small “Pinpoint” Pupil Measurement

Pupillometer Resolution Threshold: Pupil Size

The NPi-200 Pupillometer measurement threshold for measuring pupil size is 1.0 mm, which means the pupillometer can measure pupils as small as 1.0 mm in diameter. If the pupil size is < 1.0 mm, the pupillometer will not detect the pupil, and it will not initiate a measurement.

Pupillometer Resolution Threshold: Change in Pupil Size

The NPi-200 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.

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**

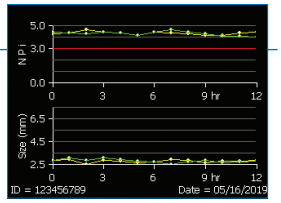
** NPi < 3 is considered an abnormal/ “sluggish” pupil assessment, per the Neurological Pupil index (NPi) algorithm.*
** A difference in NPi between Right and Left pupils of ≥ 0.7 may also be considered an abnormal pupil reading*

NPi Measurement of “0”

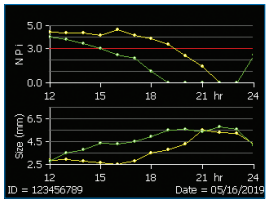
The NPi-200 Pupillometer will measure an NPi of 0 in the following clinical assessment scenarios:

- 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

Trend for Changes



Ex. 24



Ex. 25

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. 24 & 25).

Choose desired parameters to trend

To trend additional parameters, select **Trending Variables** from the **Settings** menu, and choose the desired parameters to trend (Ex. 26).

Ex. 26

Power Off

To turn the NPi-200 off, select the from the main screen and confirm **Yes**.

Rebooting the NPi-200 Pupillometer

As with any electronic device, the NPi-200 Pupillometer may occasionally require a System Reboot. To reboot the NPi-200 Pupillometer, simply press and hold the button on the device until the Pupillometer powers ON.

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
3. "Rescan" displayed following measurement	Pupillometer is moved from position prior to completion of the measurement	Repeat the scan and maintain proper position of the Pupillometer until the measurement is completed and pupillary measurements are displayed.
	Patient blinked during measurement	Hold the patient's eyelid open and repeat the scan.

Cleaning and Maintenance

ALWAYS handle the NPi-200 Pupillometer and NPi-200 Charging Station with care because sensitive metal, glass, plastic and electronic components are contained inside. The NPi-200 Pupillometer and NPi-200 Charging Station can be damaged if dropped, or if they come in contact with liquid.

The NPi-200 Pupillometer and NPi-200 Charging Station do not require any regularly scheduled maintenance. If the NPi-200 Pupillometer and NPi-200 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-200 Pupillometer and NPi-200 Charging Station

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA, are recommended for use in cleaning the NPi-200 Pupillometer and NPi-200 Charging Station. Do not use chemicals that can damage the pupillometer 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 pupillometer 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** allow any cleaner more than 70% IPA to contact the gold connector blades located on the bottom of the NPi-200 Pupillometer handle or the gold connector pins located in the base of the NPi-200 Charging Station.
- **DO NOT** use an oversaturated cloth. Be sure to squeeze out excess liquid prior to wiping the NPi-200 Pupillometer or the NPi-200 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-200 Pupillometer or NPi-200 Charging Station.
- **DO NOT** immerse the NPi-200 Pupillometer or the NPi-200 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-200 Pupillometer is thoroughly dry before placing in the NPi-200 Charging Station to charge. Once thoroughly dry, place the NPi-200 Pupillometer into the NPi-200 Charging Station and plug in the NPi-200 Power Supply to the back of the charging station to power ON.

- **DO NOT** place the NPi-200 Pupillometer into the NPi-200 Charging Station until all components are completely dry.
- **DO NOT** reconnect the NPi-200 Power Supply to the NPi-200 Charging Station until all components are completely dry.

Cleaning Considerations: Gold Connector Pins and Blades

In instances where there is concern of exposure to highly resistant bacteria, viruses, fungi or spores (ie: Clostridium difficile, or “C. diff”), hospital protocols may require use of cleaning solutions containing sodium hypochlorite (bleach) when cleaning equipment. Please be aware solutions containing sodium hypochlorite (bleach) will corrode the gold connector blades located on the bottom of the NPi-200 Pupillometer handle (Figure 1), and the gold connector pins located in the base of the NPi-200 Charging Station (Figure 2).

NPi®-200 Pupillometer

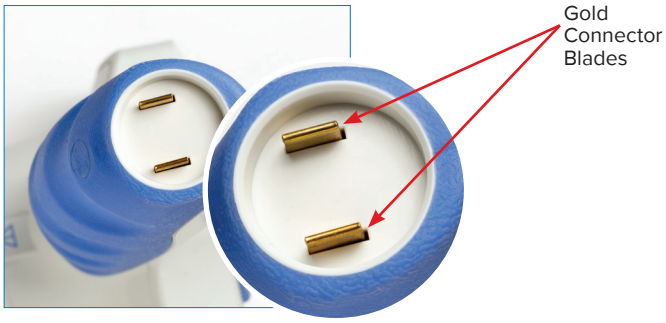


Figure 1- Gold Connector Blades

NPi®-200 Charging Station

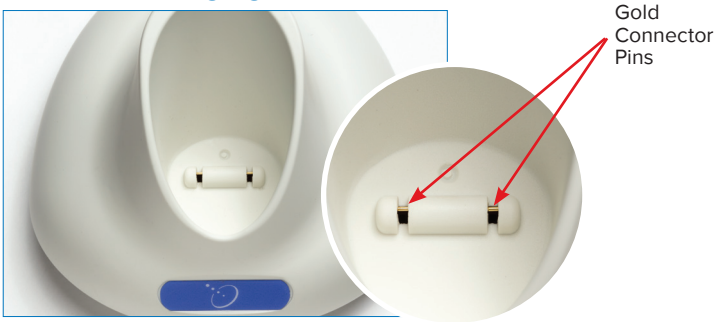


Figure 2- Gold Connector Pins

- **DO NOT** use products containing sodium hypochlorite (bleach) to clean the gold connector blades located on the bottom of the NPi-200 Pupillometer handle, and the gold connector pins located in the base of the NPi-200 Charging Station.

If products containing sodium hypochlorite (bleach) are used to clean the gold connector blades located on the bottom of the NPi-200 Pupillometer and the gold connector pins located in the base of the NPi-200 Charging Station, the cleaning process should be followed by a second cleaning using up to 70% IPA solution to ensure that all residue is completely removed from the device in order to minimize damage to the gold connector pins and blades.

Cleaning Considerations: Pupillometer 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 cleaning solution to clean the pupillometer optics.

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-200 Pupillometer, the cleaning process should be followed by a second cleaning solution with up to 70% IPA solution to ensure that all bleach residue is completely removed from the LCD using a clean, soft, lint-free cloth.

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-200	NPi®-200 Pupillometer
SG-200	SmartGuard®
BCS-CC-04-(1D or 2D)	Barcode Scanner by Socket®
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 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	
Pupillometer Measurement Detection Threshold	Pupil diameter (minimum)	1.00 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 Supply	Input: 100-240 VAC +/- 8% Output: 6V, 2.8 Amps	
Battery	3.6 V 11.70 Wh 3350 mAh/hour Li: Ion Cell	
Operating Environment	Temperature Range: 18° C (65° F) to 30° C (86° F) Relative Humidity: 20% to 70% RH. Non condensing at all times	

Appendix B—Technical Specifications (cont.)

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 62471

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

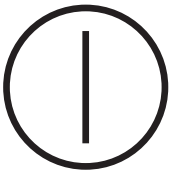
Broadcast Function	Range	Frequency
Bluetooth Barcode Scanner to/from NPi-200 Pupillometer	Up to 100 yards depending on environment	2.45 GHz
RFID memory card in SmartGuard to/from NPi-200 Pupillometer	Up to 2 centimeters	13.56 MHz
RFID memory card in SmartGuard to/from SmartGuard Reader	Up to 2 centimeters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

Appendix D—Pupillometer Display Limits for Electronic Medical Record (EMR) Flowsheet Integration

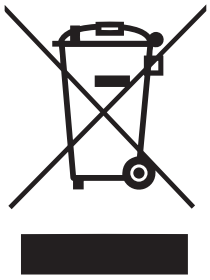
The following low and high display limits are included to inform hospital staff of the specific parameter display limits for consideration in the development of neurological parameter flow sheets.

Parameter	LOW	HIGH
NPi	0.0	4.9
Size	1.00 mm	10.00 mm
MIN	1.00 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

NPi 200 IFU Appendix E- International Symbol Definition

Symbol	Source/Compliance	Title of Symbol	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 connection or disconnection to internal battery supply.
	Section 1.1 of Chapter I of Annex IX to Directive 93/42/EEC. U.S. 21 CRF 801.5(c.)	Intermittent Use	To indicate use to be Transient or intermittent with contact to intact skin with duration less than 60 minutes.
	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.
	Standard: ISO 15223-1 Symbol Reference No: 5.1.5	Batch Code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.

NPi 200 IFU Appendix E- International Symbol Definition

Symbol	Source/Compliance	Title of Symbol	Description of Symbol
	BS EN 50419 Article 11(2) of the European Community Directive 2002/96/EC (WEEE) 2006/66/EC	Crossed Out Trash Can	Identifies product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2012/19/EU Directive for recycling of electronic equipment. The black bar underneath the bin indicates goods that were placed on the market after 13 August 2005.
	U.S. 40 CRF 273.2 European Community Directive Article 21 of 2006/66/EC	Recycle. Battery contains Lithium.	Dispose of according to local procedures for products containing lithium Ion batteries and products containing lithium perchlorate.
	Standard: ISO 15223-1 Symbol Reference No: 5.1.1	Manufacturer	Indicates the medical device manufacturer, 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 Européene 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 Européene 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.

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