NPi-Connect™

Instructions For Use

SmartGuard® Connectivity Hub

NEUR⬤PTICS®

Introduction

The NeurOptics® NPi-Connect™ SmartGuard Connectivity Hub is designed to enable secure data transfer from the NeurOptics SmartGuard® to the user's Electronic Medical Record (EMR) system. The NPi-Connect supports both wired and wireless data transfer options from the device to the EMR system and features an ergonomic design that is optimized for clinical environments.

The device is intended for placement on a flat, stable surface, such as a desktop, and is built for frequent, routine use. The NPi-Connect features a robust white housing with blue accents. It has a matte, lightly textured finish to support ease of handling in clinical settings.

Intended Use

The NeurOptics NPi-Connect is a SmartGuard Connectivity Hub that interfaces with an integration engine converting pupil data from the patient's SmartGuard into an HL7 format, per hospital specification. The resulting HL7 message is transmitted by the integration engine to the Electronic Medical Record for display in the patient's flowsheet. The NPi-Connect should only be operated by properly trained personnel.

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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 NPi-Connect – The NPi-Connect is intended for use by trained personnel.

- 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 is apparent. Using an inoperative device may result in inaccurate data transfer.

- Electric shock hazard – Do not open the device, there are no user serviceable parts.

- 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 it in fire.

- Store and use the NPi-Connect in ambient environments with non-condensing humidity levels only.

- 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.

Cautions

The following cautions apply when cleaning the device. The internal components of the NPi-Connect 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-Connect.

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: Non-Medical Equipment

Trade Name: NeurOptics® NPi-Connect™

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For details, visit: www.NeurOptics.com/patents/

Safety Information

- Please review the following safety information prior to operating the device.

- The NPi-Connect is EN60601-1-2 compliant and also adheres to FCC compliance related to EMC.

- Please read these Instructions fully before attempting to use the NPi-Connect. Attempting to operate the device without fully understanding its features and functions may result in unsafe operating conditions and/or inaccurate data transfer.

- If you have a question regarding the installation set-up, operation, or maintenance of the device, please contact NeurOptics.

Getting Started

Unpacking the NPi-Connect Hub

The NeurOptics NPi-Connect Connectivity Hub is packaged with the following components:

A. NPi-Connect (A)
B. NPi-Connect Power Adapter and Plug (B)
C. 6 ft Ethernet Cable (C)
D. NPi-Connect Packaging Insert (D)

Initial Set-Up

To set up the NPi-Connect for first-time use, please refer to the Power Up section below.
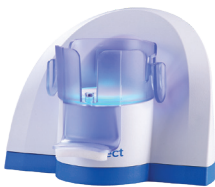
Power Up & Use

Powering the NPi-Connect

- The NPi-Connect automatically powers when the power adapter cable is connected to the device's USB-C port.
- The NPi-Connect powers off automatically when the power adapter is disconnected from the USB-C port.
- **Caution: Use only the power adapter supplied with the NPi-Connect. Use of unauthorized power adapters may result in malfunction or damage.**
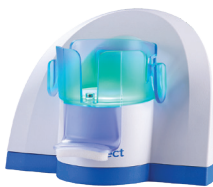
NPi-Connect Light Ring

The LED Light Ring of the NPi-Connect serves as the device's primary user interface, providing visual indicators of the device's status.
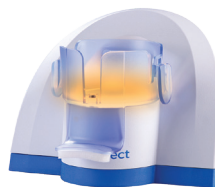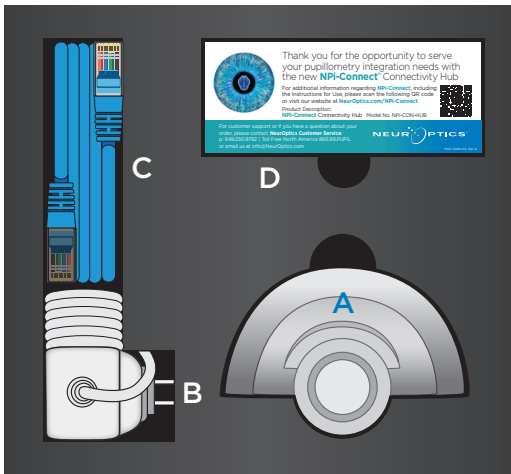

White Light Ring   **Blue** Light Ring   **Green** Light Ring   **Amber** Light Ring

Device Start-Up Light Ring Indicators	
Solid Blue	NPi-Connect is booting up. If this persists for an extended period of time, it may be indicative of a hardware failure.
Blinking White	NPi-Connect has initialized its internal hardware and is establishing network connections.
User Feedback Light Ring Indicators	
Solid White	NPi-Connect is ready and waiting for the SmartGuard to be positioned on the Light Ring.
Solid Blue	NPi-Connect recognizes the SmartGuard and is transferring data.
Blinking Green	NPi-Connect has successfully read all patient data from the SmartGuard and is pending confirmation of upload from the server; the user can now remove the SmartGuard from NPi-Connect if desired.
Solid Green	NPi-Connect has successfully transferred the patient's pupillometry data to the electronic medical record. The user will also hear an audible tone upon completion of data transfer.
Troubleshooting Light Ring Indicators	
Blinking Amber	NPi-Connect was unable to complete data transfer due to an error (e.g., incorrect patient ID, EMR connectivity issue, or server permission error). The indicator will continue to blink until the SmartGuard is removed or the issue is resolved.
Solid Amber	NPi-Connect has detected an interruption in data transfer (SmartGuard was removed prematurely). Wait until the Light Ring returns to Solid White before reattempting upload. Alternatively, NPi-Connect has detected a non-paired/empty SmartGuard. The indicator will remain on until the SmartGuard is lifted from the device.
Troubleshooting Light Ring Indicators (No SmartGuard Present)	
Blinking Amber	NPi-Connect is experiencing a communication failure due to connectivity issues.
Solid Amber	NPi-Connect has experienced a hardware failure.

- After the NPi-Connect is powered on, allow approximately one minute for the Light Ring to illuminate solid white. This indicates that the device is ready to read the SmartGuard.

- The SmartGuard is used to transfer patient pupillometry data via NPi-Connect. It may be placed directly onto the NPi-Connect Light Ring when it is solid white. Alternatively, the SmartGuard can remain attached to pupillometer and can be positioned over the NPi-Connect Light Ring. The method of placement is based on user preference. Please see below.

Tap and hold the NPi-300 Pupillometer with the SmartGuard attached to NPi-Connect.		**OR**	**Remove** the SmartGuard from the NPi-300 Pupillometer **and place** the SmartGuard on the NPi-Connect Light Ring.

Note: Integration must be completed by the facility's Information Technology (IT) department.

Integration Set Up

Wired or Wireless

- During the intial project planning phase with NeurOptics and the customer, the preferred method of data integration—wired (Ethernet) or wireless (Wi-Fi)—will be determined.

- The initial network connection must be established using a wired Ethernet connection. Once the device is successfully connected, the selected connectivity method (wired or wireless) will be configured to correspond with the customer's designated access point.

As integration requirements may vary by site, technical assistance is available. For support or additional documentation on NPi-Connect, please contact NeurOptics at **Integration@NeurOptics.com**.

Handling, Cleaning and Maintenance

Cleaning the NPi-Connect

Isopropyl alcohol (IPA)-based cleaning solutions, in formula concentrations up to 70% IPA, are recommended for use in cleaning the NPi-Connect. Do not use chemicals that can damage the NPi-Connect surface. Some chemicals can weaken or damage plastic parts and may cause instruments to not operate as intended. Use all cleaning products per manufacturers' instructions, being careful to squeeze out excess liquid prior to wiping the NPi-Connect 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-Connect.

- **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-Connect.

- **DO NOT** immerse the NPi-Connect in liquid, or attempt to sterilize the product, as damage to the electronic componentry could occur.

Drying and Inspection Following Cleaning

Confirm the NPi-Connect is thoroughly dry before using the NPi-Connect.

Customer Service

For customer 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: **customerservice@NeurOptics.com**.

Ordering Information

NPi-CON-HUB	NPi-Connect Hub
PWR-0400-00	NPi-Connect Power Adapter

Returned Goods Policy

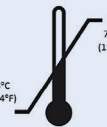NeurOptics does not accept product returns.

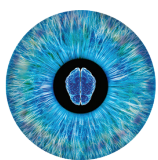# Appendix A — Technical Specifications

Parameter	Description
Degree of protection against electric shock	NPi-Connect – Type B Applied Part provided protection + Power Adapter-Type B 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
Power Adapter	Input: 100-240 VAC +/- 8%, 50-60Hz, 0.6A Output: 5V, 1.2 Amps, 6.0W
Operating Environment	Temperature Range: 0° C (32° F) to 40° C (104° 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
Product Box Dimensions	9.25" W x 9" L x 5"
Product Box Weight	1200 grams or 2.645 lbs
Device Dimensions	7.5" H, 3.5" W, 3.5" D
Device Weight	395 grams +/- 10 grams, with base, 163 grams +/- 5 grams without base
Operating System (OS)	Linux V6.6
NAND Memory Capacity	256MB
Wired Communication	Gbit Ethernet port
Wireless Communication	802.11a/b/g/n/ac Wi-Fi
Console/Debug Port	Internal
Power/Communication Connectivity	1 USB-C external port

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

Broadcast Function	Range	Frequency
RFID memory tag in SmartGuard from NPi-300 Pupillometer	Up to 2 centimeters	13.56 MHz
RFID memory tag in SmartGuard to NPi-Connect	Up to 2 centimeters	13.56 MHz

Appendix C – International Symbol Definition

Symbol	Source/Compliance	Title of	Description of Symbol
⚠	Standard: ISO 15223-1 Symbol Reference No: 5.4.4	Caution	Indicates caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
SN	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
REF	Standard: ISO 15223-1 Symbol Reference No: 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
🏭	Standard: ISO 15223-1 Symbol Reference No: 5.1.1	Manufacturer	Indicates the medical device manufacturer
📖ℹ	Standard: ISO 15223-1 Symbol Reference No: 5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use at **NeurOptics.com**
(((•)))	Standard: IEC TR 60878 Symbol Reference No: 5140	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
☂	Standard: ISO 15223-1 Symbol Reference No: 5.3.4	Keep Dry	Indicates a medical device that needs to be protected from moisture
🌡 70°C (158°F) -38°C (-36.4°F)	Standard: ISO 15223-1 Symbol Reference No: 5.3.7	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed
🍷	Standard: ISO 15223-1 Symbol Reference No. 5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully

NEUROPTICS®

Advancing the Science of NPi® Pupillometry