NPi-Connect™

Instructions For Use

SmartGuard® Connectivity Hub

NEURO 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 IEC 60601-1-2 + A1 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

FCC ID: 2BWE8-NPICONNECT

Contains FCC ID: MCQ-CCIMX6UL

FCC Part 15 Statement

This device complies with Part 15 of the 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 that may cause undesired operation.

FCC Modification Warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC RF Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm from all persons.

Classification

Type of Equipment: Non-Medical Equipment

Trade Name: NeurOptics® NPi-Connect™

Manufactured by:

NeurOptics, Inc.
9223 Research Drive
Irvine, CA 92618, USA
p: 949.250.9792
Toll Free North America: 866.99.PUPIL
info@NeurOptics.com
NeurOptics.com

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.
- The NPi-Connect is IEC 60601-1-2 + A1 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.

Software Cybersecurity

The NPi-Connect may require software maintenance for updates or patches. In the event of a required software update, NeurOptics will facilitate remotely.

Do not attempt to modify, install, remove, or alter software on the device. Do not attempt to access internal service functions or connect unauthorized equipment. Unauthorized software changes or tampering may affect device safety, performance, cybersecurity, and warranty status.

The device should not be tampered with, nor should any unauthorized modifications be made. Tampering or unauthorized modifications can introduce vulnerabilities and security risks, potentially leading to data breaches, malware infections, or system instability. The warranty of any devices that have been tampered with, or unauthorized modifications made to, will be voided.

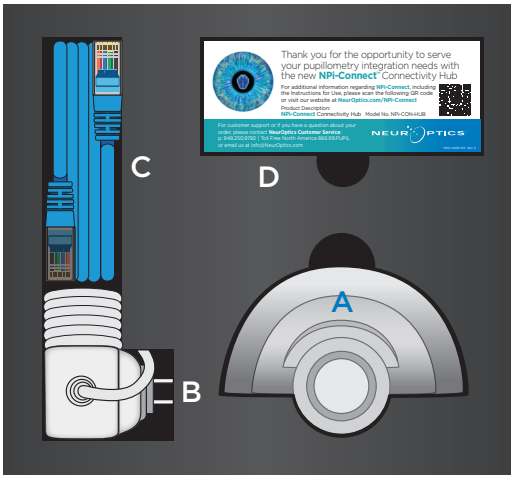
- **CAUTION – SOFTWARE MAINTENANCE** The device does not require the user for software maintenance.
- **CAUTION – SOFTWARE ALTERATION** The device software should not be modified or altered in any way. Do not attempt to alter software on the device; any alterations will void the warranty.
- **CAUTION – TAMPERING** The device should not be modified or tampered with; any tampering will void the warranty.
- **CAUTION – CYBERSECURITY INCIDENT** In the event of a suspected cybersecurity incident (e.g. unexpected behavior, recurring errors, freeze or crash of the software), shut down the device, take it out of service and contact the NeurOptics service for further investigation and application of immediate measures.”

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

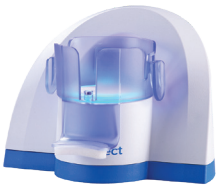
Powering the NPi-Connect

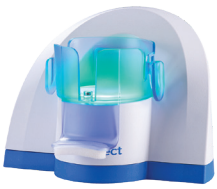
- The NPi-Connect automatically powers when the power adapter cable is connected to the device's USB-C port.
- The NPi-Connect powers off automatically when the power adapter is disconnected from the USB-C port.
- **Caution: Use only the power adapter supplied with the NPi-Connect. Use of unauthorized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

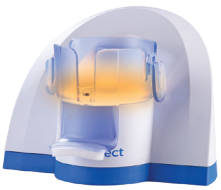
NPi-Connect Light Ring

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**.

This IFU is provided electronically and can be accessed through our website. If a paper copy is required, please notify customer service.

eIFU Access

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 – Guidance of EMC and other Interference

1. **WARNING:** Use of this equipment adjacent to or stacking with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.
3. **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions The NPi-Connect is intended to use in the electromagnetic environment specified below. Customers and users of the device must ensure that it is used to this type of environment.		
Emissions Test	**Compliance**	**Guidance**
RF emissions CISPR 11	Group 1	The NPi-Connect uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NPi-Connect is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	The device is battery powered and not connected to a public mains network during normal operation.
Voltage fluctuations / flicker IEC 61000-3-3	Not applicable	The device is battery powered and not connected to a public mains network during normal operation.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity The NPi-Connect is intended to use in the electromagnetic environment specified below.		
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Complies
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz	Complies
Conducted RF IEC 61000-4-6	3 Vrms 0.15 – 80 MHz	Complies
Electrical fast transient/burst IEC 61000-4-4	±2 kV	Complies
Surge IEC 61000-4-5	±1 kV differential ±2 kV common mode	Complies
Power frequency magnetic field IEC 61000-4-8	30 A/m	Complies
Voltage dips and interruptions IEC 61000-4-11	Per standard	Complies

Proximity Fields from RF Wireless Communications Equipment

The NPi-Connect was tested for immunity to proximity fields from RF wireless communications equipment in accordance with IEC 60601-1-2 + A1, and met all applicable requirements.

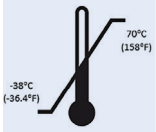
Appendix C – Radio Frequency Identification Device (RFID) Broadcast Range

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

Appendix D – 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
	Standard: ISO 15223-1 Symbol Reference No: 5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific device can be identified
	Standard: ISO 15223-1 Symbol Reference No: 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the device can be identified
	Standard: ISO 15223-1 Symbol Reference No: 5.1.2	Manufacturer	Indicates the device manufacturer
	European Union Conformity Mark, the product complies with the Medical Device Regulation (2017/745 EU MDR) or other applicable EU directives	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.
	Standard: ISO 15223-1 Symbol Reference No: 5.4.3	EU Representative	Indicates the authorized representative in the European Union
	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 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 device that needs to be protected from moisture

Appendix D – International Symbol Definition Continued

	Standard: ISO 15223-1 Symbol Reference No: 5.3.7	Temperature Limit	Indicates the temperature limits to which the device can be safely exposed
	Standard: ISO 15223-1 Symbol Reference No. 5.3.1	Fragile, handle with care	Indicates a device that can be broken or damaged if not handled carefully

CE EU REP

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

NEUROPTICS®

Advancing the Science of NPi® Pupillometry

9223 Research Drive
Irvine, CA 92618 | USA
p: +1 949.250.9792
Toll Free North America: 866.99.PUPIL
info@NeurOptics.com
NeurOptics.com