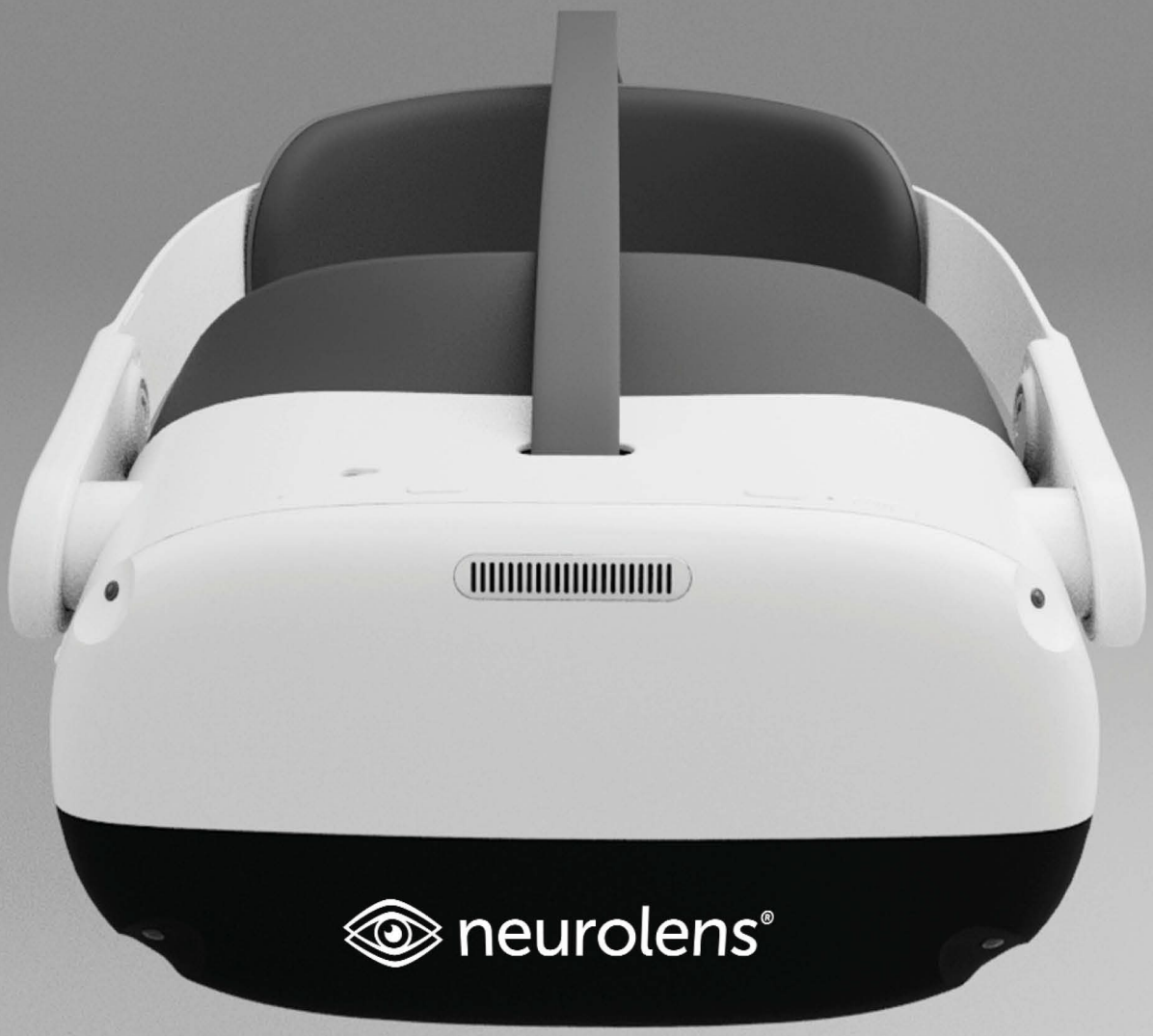
N3




# USER MANUAL

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**User's Manual**

# Model NMD3

**Neurolens® Measurement Device, N³**

Last Revision Date: 11/19/2025


**Manufacturer Information**
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EC REP

European Union Authorized Representative authorized to act on your behalf in accordance with the MDR

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**N³ User's manual**
P/N 90033 Revision 10
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## neurolens® Measurement Device, N³

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Please check Neurolens®'s website http://www.neurolens.com/n3-manual for updated versions of this document.

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Please direct all inquiries regarding this manual or for service assistance to Neurolens®, 1234 Lakeshore Dr, Suite 200 Coppell, TX 75019. Telephone +1 (888) 236-2219 (United States).

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## PRECAUTIONS

Since this product is a precision instrument, always use and keep it in a normal controlled living environment, within a temperature range of 10-30°C, humidity levels between 20-80% and an atmospheric pressure range of 700hPa-1,060hPa.

- The instrument should be placed away from direct sunlight.
- Do not set anything on the instrument.
- Connect all cables properly to charge before using and use proper cable routing to reduce the risk of tripping.
- Use power at rated voltage.
- When not in use, perform a software shutdown and switch off the power source.
- For accurate measurement results, take care to keep external optics clean and free of fingerprints, spots, and dust.

## SYMBOL INFORMATION

The following symbols appear on the instrument:

**This symbol is applicable for EU member countries only.**
To avoid potential damage to the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), or (ii) for all other countries, in accordance with local disposal and recycling laws.

Type B Product Classification
Class 2 Equipment, Battery Operated

### Electrical, Safety Standards

This System has been tested to comply with the following standards:
IEC 60601-1 (Safety)
IEC 60601-1-2 (EMC, Ed: 4)
IEC 62471 (Ed:1 Photobiological safety of lamps and lamp systems)

**Other Standards applied in Design and Manufacturing processes**

ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14791 Medical devices — Application of risk management to medical devices
ISO 15223 Medical devices — Symbols to be used with information to be supplied by the manufacturer
ISO 62304 Medical device software – Software life cycle processes
ISO 10993 Biological evaluation of medical devices — Evaluation and testing within a risk management process

### LED Emissions

The $N^3$ emits 850nm Infrared LED radiation. The emissions of the device are within the guidelines of IEC 60825 for continuous exposure up to 30,000 seconds and conforms to IEC 62471 and is exempt from additional labeling requirements.

## Electromagnetic 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).

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

## SAFETY DISPLAYS

To encourage the safe use of the instrument and to avoid danger to the operator and others as well as damage to properties, warnings are described in the Instruction Manual and marked on the instrument body.

We suggest you thoroughly understand the meaning of the following displays/icons and Safety Cautions, as well as read the Manual, and strictly observe the instructions.

### DISPLAYS

| DISPLAY | MEANING |
|---|---|
| **WARNING** | Improper handling or ignoring this display may result in death or serious injury. |
| **CAUTION** | Improper handling or ignoring this display may cause personal injury or physical damage. |

- Injury means hurt, burn, electric shock, etc.
- Physical damage means extensive damage that may involve building, peripheral equipment, and furniture.

### LABELS

| Label | Description/Meaning |
|---|---|
| | This user manual must be read prior to utilization of the device. |

**ICON**

| ICON | MEANING |
|---|---|
| | This icon indicates an action to be avoided. Specific contents are shown with words or illustration. |
| | This icon indicates Mandatory Action. Specific contents are shown with words or illustration. |
| | This icon indicates Hazard Alerting (Warning). Specific contents are shown with words or illustration close to the icon. |

**The N³ is the subject of U.S. patents and other pending U.S. and foreign patents. Refer to** https://www.neurolens.com/patents/ **for a list of awarded US Patents related to the N³.**

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**This instrument features the following:**
The **N³** utilizes a Class 2 AC powered charging power supply (Jiangsu Chenyang Electronics Co., Ltd. Model CK18W02U) (125/240 VAC; 0.5A; 50/60Hz) that converts to DC power through a power supply and charges a Li-ion battery. The device maybe run on battery only.

---

This Instruction Manual covers an overview of the basic operation, troubleshooting, checking, maintenance, and cleaning of the N³.

To get the best use of the instrument, read Safety Displays and Safety Cautions. Keep this Manual at hand for future reference.

**BASIC INSTRUCTIONS**

| | |
|---|---|
| **WARNING** | ▪ To avoid electrical shock, do not open the instrument or make modifications of any type. Refer all servicing to only qualified personnel. |
| **CAUTION** | ▪ Use of this equipment adjacent to or stacked 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. |
| **CAUTION** | ▪ Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. |

| | |
|---|---|
| **CAUTION** | ▪ 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 $N^3$, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
| **WARNING** | ▪ Confirm that the patient is in good health before using. Consult a doctor before use if you are pregnant, elderly, or have serious physical, mental, visual, or heart problems. |
| **CAUTION** | ▪ Ensure the headset is worn in a manner that the VR Lenses do not rub or impact prescription glasses. |
| **WARNING** | ▪ Do not use the device for more than 30 continuous minutes. If you experience discomfort or eye strain, discontinue use immediately. |
| **WARNING** | ▪ The VR environment will prevent the patient from being able to see objects around them. Ensure the patient is protected from falling or moving objects and is in a stationary seat, protected from falling downstairs, into windows, hot areas, or any hazardous area. |
| **WARNING** | ▪ Some people may experience severe dizziness, vomiting, palpitations, and even fainting when using VR Headsets. Consult a doctor if you have experienced any of the symptoms above. |
| **WARNING** | ▪ Some people may be allergic to plastic, PU, fabric, and other materials used in this product. Long-term contact with skin may result in symptoms such as redness, swelling, and inflammation. Stop using the product and consult a doctor if any of the above symptoms are experienced. |
| **WARNING** | ▪ Stop using the product immediately if the patient experiences any visual abnormalities (diplopia and sight distortion, eye discomfort or pain, etc.), excessive sweating, nausea, vertigo, palpitations, disorientation, loss of balance, etc. or other signs of distress. |
| **WARNING** | ▪ This product provides access to immersive virtual reality experience. Stop use immediately and seek medical attention if any of the following symptoms occur.<br>○ Epilepsy seizure, loss of consciousness, convulsions, involuntary movements, dizziness, disorientation, nausea, somnolence, or fatigue.<br>○ Eye pain or discomfort, eye fatigue, eye twitching, or visual abnormalities, (such as illusion, blurred vision, or diplopia)<br>○ Itchy skin, eczema, swelling, irritation or other discomforts. |

| | |
|---|---|
| | ○ Excessive sweating, loss of balance, impaired hand eye coordination, or similar motion sickness symptoms.<br>▪ Do not operate a motor vehicle, operate machinery, or engage in activities that may have potentially serious consequences until you have fully recovered from these symptoms. |
| **WARNING** | ▪ Comply with the expressly prohibition of the use of wireless equipment in medical and healthcare facilities, and shut down the equipment and any accessories. |
| **WARNING** | ▪ Radio waves generated by this product may affect the normal operation of implantable medical devices or personal medical devices, such as pacemakers, cochlear implants, hearing aids, etc. Please consult the medical device manufacturer about the restrictions on the use of this product if the patient uses these medical devices. |
| **WARNING** | ▪ Keep a distance of at least 15cm from the implanted medical devices (such as pacemakers, cochlear implants, hearing aids, etc.) when this product is connected. Stop using the headset if you observe a persistent interference with your medical device. |
| **WARNING** | ▪ Do not use this equipment during thunderstorms. Thunderstorms may cause product failure and increase the risk of electric shock. |
| **CAUTION** | ▪ Protect the imaging lenses from light. Keep the product out of ultraviolet rays, such as windowsills, automobile dashboards, or other strong light sources. |
| **WARNING** | ▪ Choking Hazard: This product may contain small parts. Please place these parts out of reach of children. |
| **WARNING** | ▪ Do not use high volume for extended periods of time to prevent possible hearing damage. |
| **WARNING** | ▪ Do not use the equipment near fuel stations or hazardous areas containing flammable articles and chemical agents. Follow all graphic or text instructions when in possession of the product around these areas. Operating this product in these hazardous sites poses risk of explosion and fire. |
| **WARNING** | ▪ Do not store or transport the product or its accessories in the same container as flammable liquids gasses or substances. |
| **WARNING** | ▪ Only charge the device using the provided charger. |

| | |
|---|---|
| **WARNING** | ▪ When charging is complete, disconnect the charger from device and power outlet. |
| **WARNING** | ▪ If the charging adapter or cable is damaged, discontinue using to prevent the risk of electric shock or fire. |
| **WARNING** | ▪ Do not operate equipment or charger with wet hands to avoid short circuit, failure, or electric shock. |
| **WARNING** | ▪ Do not use the charger or equipment if wet. |
| **WARNING** | ▪ VR Headsets are equipped with non-removable internal batteries. Do not attempt to replace the battery, as doing so may cause battery damage, fire, or human injury. |
| **WARNING** | ▪ Do not disassemble or modify the battery, insert foreign objects, or immerse in water or other liquid. Handling the battery as such can cause chemical leakage, overheating, fire, or explosion. If the battery appears to be leaking material, avoid contact with the skin or eyes. |
| **WARNING** | ▪ In case of material contact with skin or eyes, immediately rinse with clear water and contact your local poison authority. |
| **WARNING** | ▪ Do not drop, squeeze, or puncture the battery. Avoid subjecting the battery to high temperatures or external pressure, which may result in corruption and overheating of the battery. |
| **WARNING** | ▪ WARNING: Do not overtighten head strap. Overtightening may lead to bruising, cuts, or discomfort from impinging corrective eyewear onto the patient. |
| **WARNING** | ▪ WARNING: Ensure patient is wearing proper corrective eyewear or contacts. Improper corrective eyewear or contacts may lead to erroneous test results. |

## WORKING ENVIRONMENT

Temperature: 10°C-30°C
Humidity: 20-80% (without dew)
Atmospheric Pressure: 700hPa-1,060hPa
Keep away from rain or moisture.
Keep away from heat sources such as flames or electric heaters or places that may generate excessive temperatures.

## STORAGE, USAGE PERIOD AND OTHERS

ENVIRONMENTAL CONDITIONS FOR INSTALLATION (WITHOUT PACKAGE)
Temperature: 10 °C-40 °C
Humidity: 10%~95% (without dew)
Air Pressure: 700hPa-1,060hPa
THIS INSTRUMENT DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEMPERATURE MAY RISE ABOVE 40°C OR FALL BELOW 10°C.
Do not apply excessive pressure during storage to avoid damage to the equipment and lenses.

## WHEN STORING THE INSTRUMENTS, ENSURE THAT THE FOLLOWING CONDITIONS ARE MET:

(1) The instrument should not be splashed with water.
(2) Store the instrument where air pressure, temperature, humidity, ventilation, sunlight, dust, salty/sulfurous air, etc. are controlled.
(3) Do not store the instrument where chemicals are stored, or gas is generated.

## USAGE PERIOD

3 years from delivery providing regular maintenance is performed (according to the self-certification)

## ENVIRONMENTAL CONDITIONS FOR PACKING IN TRANSPORTATION

Temperature: -40°C~70°C
Humidity: 10%-95%

## POWER REQUIREMENTS

VOLTAGE/AMPERAGE: 125/240VAC/0.5A
FREQUENCY: 50/60Hz
Mains voltage is disconnected through power supply. It is recommended that the system be placed in a location with access to the power supply.

## INGRESS PROTECTION RATING: IP20

## WIRELESS PARAMETERS

| | |
|---|---|
| Frequency Band | 2400-2483.5MHz (BT)<br>2400-2483.5MHz (WiFi), 5150-5350MHz (Indoor Only), 5470-5725MHz, 5725-5850MHz |
| RF Output Power | Bluetooth 9.84 dBm<br>WiFi :<br>2400-2483.5MHz 20dBm,<br>5150-5350MHz (Indoor Only) 23 dBm<br>5470-5725MHz 23dBm<br>5725-5850MHz 13.98 dBm |

**CABLES**

Power charger to be used to charge battery. System should only use Jiangsu Chenyang Electronics Co., Ltd. CK18W02U power supply. Do not substitute power supply or power cable from the one provided.

**MAINTENANCE AND CHECKS**

(1) Regularly maintain and check all equipment and parts.
(2) Before using equipment that has not been used in a while, be sure to confirm normal and safe operation before attempting any patient measurements.
(3) Keep the imaging optics free from fingerprints and dust.
(4) When the imaging optics become dirty or soiled, clean it according to the instructions listed in section 1.7.3 of the Instruction Manual.

**SERVICE**

(1) Service of the $N^3$ should only be performed by Neurolens®, Inc. service personnel.
(2) The $N^3$ should not be serviced while in use with a patient.

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**Limited Warranty**

Neurolens® warrants that the $N^3$ shall be free from defects in workmanship and materials and will perform in accordance with the product specifications for one year from the date of sale by Neurolens®. If the product fails to perform in accordance with the product specifications, Neurolens® will repair or replace at its option the defective material or part. Neurolens® will pay customary freight charges from Neurolens® to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to materials or workmanship.

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To exercise your right under this warranty, contact your local authorized Neurolens® dealer or contact Neurolens® Inc. at:

**Neurolens®**
1234 Lakeshore Dr, Suite 200
Coppell, TX 75019
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Table of Contents


**1 INTRODUCTION AND INTENDED USE ..... 4**

**1.1 Introduction ..... 4**
**1.2 Intended Use ..... 4**
**1.3 Overview ..... 4**
**1.4 Performance Characteristics ..... 5**
**1.5 Intended Patient Population ..... 5**
**1.6 Contraindications ..... 5**
**1.7 Basic Operating Principles ..... 6**
**1.8 Variant Configurations: ..... 7**
**1.9 Accessories ..... 7**
1.9.1 USB-C Cable ..... 7
1.9.2 Power Supply ..... 7
**1.10 Components ..... 8**
1.10.1 Applied Parts: ..... 8
1.10.1.1 Patient Facemask ..... 9
1.10.1.2 Side Straps ..... 9
1.10.1.3 Back Head Cushion ..... 9
1.10.1.4 Adjustment Strap ..... 9
1.10.2 Incidental contact parts: ..... 9
1.10.2.1 Imaging Optics ..... 9
1.10.2.2 Enclosure ..... 9
1.10.2.3 Illuminating LEDs ..... 9
1.10.2.4 USB-C Port ..... 9
1.10.2.5 Power Button ..... 9
**1.11 Preparations ..... 10**
1.11.1 Installation ..... 10
1.11.2 Connecting power (Charging) ..... 10
1.11.3 Maintenance and care ..... 10
1.11.4 Startup ..... 11
1.11.5 Setting up Wireless Fidelity (Wi-Fi) ..... 11
1.11.6 Device Initial Set-up ..... 14

**2 TAKING A MEASUREMENT ..... 15**

**2.1 Setting up a patient ..... 15**
**2.2 Starting a measurement ..... 16**
2.2.1 Entering a PIN ..... 16
2.2.2 Headset Alignment ..... 17
2.2.3 Eye Tracking Calibration ..... 18
2.2.4 Average Television Distance Base Alignment ..... 18
2.2.5 Average Television Distance Fine Alignment ..... 19
2.2.6 Average Reading Distance Base Alignment ..... 20
2.2.7 Average Reading Distance Fine Alignment ..... 20
2.2.8 Lifestyle Index within the device ..... 20
2.2.9 Patient Education ..... 23
2.2.10 Completing the measurement ..... 23

**3 PORTAL ..... 23**

**3.1 Patient Profile ..... 23**

**3.2 Patient Management** ..... **24**
3.2.1 Adding a patient ..... 24
3.2.2 Assigning a PIN ..... 26
3.2.3 Searching for patients ..... 27
3.2.4 Accessing Measurements and Lifestyle Index ..... 27
3.2.4.1 Measurement Results ..... 28
3.2.4.2 Measurement Results Details ..... 29
3.2.5 Monitoring Device and Exams in Progress through the Portal ..... 30
3.2.6 PIN Entry Assist ..... 31
3.2.7 Outputting Data ..... 32
3.2.8 Modifying patient data ..... 32
3.2.9 N3 Practice Customization (NPC) ..... 32
**3.3 User Management** ..... **36**

**4 SYSTEM WARNING MESSAGES** ..... **38**

**5 TROUBLESHOOTING** ..... **38**

**6 GLOSSARY** ..... **39**

**7 GUIDANCE AND MANUFACTURER'S DECLARATION** ..... **40**

**7.1 Emissions** ..... **40**
**7.2 Immunity** ..... **40**
**7.3 Immunity to RF wireless communications equipment** ..... **41**

# 1 Introduction and Intended Use

## 1.1 Introduction

The $N^3$ is a microprocessor-controlled system used to measure eye misalignment at TV viewing distance and reading distance. Eye misalignment is measured through a dissociative test where the eyes are shown independent non-fusible targets, and direction of gaze is measured. This measurement is combined with an associative test where peripheral fusion is attained, and central alignment is measured. Effectively this measurement of eye alignment is an objective measurement of the angle of strabismus, and/or an evaluation of binocular vision.

The $N^3$ uses an eye tracking system along with a stereoscopic display to measure eye alignment at TV viewing distance and reading distance. From this information, a Neurolens number is calculated which is to be used by Eye Doctors along with other clinical assessments in the diagnosis and management of visual disorders. Among the recommended therapies for these disorders are eye exercises and spectacles (another class 1 exempt medical device).

Do not prescribe treatment solely on the information provided by the $N^3$. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

## 1.2 Intended Use

The N3 measures binocular disparity and eye misalignment at simulated distance and near vision. It provides optometrists and ophthalmologists with a distance phoria and a near phoria measured in Diopters, and a recommendation for ophthalmic lens prism prescription. N3 provides an objective, accurate, and repeatable measurement of binocular alignment, which incorporates elements of heterophoria, fixation disparity, accommodative convergence response, and central and peripheral alignment. The measurement provides guidance for practitioners to prescribe corrective spectacles to correct binocular misalignment.

**Intended Users**: The $N^3$ should only be operated by properly trained clinical personnel, under the direction of a qualified eye doctor. No particular qualification or certification is required beyond the diligent reading of these instructions for use to operate this instrument. Any healthcare optical professional using instruments such as tonometer, autorefractor, or automated Wide Field Retinal imaging equipment may use the $N^3$ under the direction of a qualified eye doctor.

## 1.3 Overview

This document describes the features and functionality of the N3.

Eye misalignment, measured as fixation disparity and/or heterophoria, has shown to correlate with eye strain or Asthenopia. Asthenopia is a symptom set that includes fatigue, pain around the eyes, dry eye sensation, neck pain, blurred vision, headache, and double vision. These symptoms present themselves more often when a subject has worked for prolonged periods of time at near, such as reading, working on a computer, or using a mobile device for prolonged periods of time. More recently, the

populace has increasingly reported suffering from the symptoms of Asthenopia as the near work has increased. The measurement information provided by the N3 is important in assessing patients who are being evaluated as part of a routine, comprehensive, and/or specialty vision examination.

The N3 is utilized in Optometry offices and characterizes how a person's eyes work together at TV viewing distance and reading distance by measuring eye alignment at a simulated distance of 1.7m and 0.5m and providing an objective assessment of the patient's direction of gaze. The system consists of a sophisticated eye-tracking mechanism and stereo displays that present the test subject with independent images for each eye. This allows the system to measure elements of heterophoria, fixation disparity, and associated phoria. These measurements, along with the Optometrist's clinical assessment provide guidance on the prescribing of spectacles that can provide correction of eye misalignment at distance and near.

Do not prescribe treatment solely on the information provided by the $N^3$. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

## 1.4 Performance Characteristics

Interpupillary distance: Within the range 55 to 71 MM, +/- 0.6MM accuracy
Eye gaze angle accuracy of 0.2D (Measured on Fixture)
Heterophoria at simulated distance 1.7M: Within the range -10D (EXO) to +10D (ESO), repeatability of 1.0D Δ
Heterophoria at simulated distance 0.5M: Within the range -10D (EXO) to +10D (ESO), repeatability of 1.5D Δ

## 1.5 Intended Patient Population

Patients visiting an optometric practice seeking eye care services, aged between 12 and 75, without any of the contra-indications listed below.

## 1.6 Contraindications

Contraindications for using the $N^3$ include the following:

- Mental incapacity that prevents a subject from being able to follow simple instructions such as "look at the target."
- Anomalies such as corneal scarring, Pinguecula or Pterygium that could obfuscate or obscure reflections off the cornea.
- Significant dermatochalasis or ptosis of one or both eyelids that could obfuscate the pupil or reflections off the cornea.
- Elongation of the eye due to Keratoconus which causes the first Purkinje images to not be visible.
- Exophthalmos that prevents Purkinje reflections off the cornea.
- Physical tremors or muscle spasms that prevent a patient from sitting still.
- Lack of binocular vision, such as suppression in one eye.
- Inability to achieve binocular fusion.
- Severe strabismus or palsy resulting in greater than 10 prism diopters of misalignment in one eye.

- Greater than 20 Δ of eye misalignment.
- Greater than 4 D of astigmatism in either eye.
- Hyperopia greater than +3D or Myopia greater than -5D of Spherical Equivalent correction at distance.
- BCVA of 20/80 or worse in either eye
- Open lesions or sores around the head or eyes that will make contact with the device and may be subject to contraction or spread of infection.
- Interpupillary distance less than 55MM or greater than 71MM
- A history of seizures or seizure disorder.

## 1.7 Basic Operating Principles

The $N^3$ provides an objective, accurate, and repeatable measurement of binocular alignment, which incorporates elements of heterophoria, fixation disparity, accommodative convergence response, and central and peripheral alignment. The measurement provides guidance for practitioners to prescribe corrective spectacles that not only correct refractive error but also binocular misalignment.

Do not prescribe treatment solely on the information provided by the $N^3$. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

The $N^3$ consists of a stereoscopic display and a sophisticated eye-tracking mechanism for an objective measurement that does not rely on subjective assessments from either the practitioner or the patient. The patient simply needs to be able to maintain a gaze at a target throughout the duration of the test and the system does the rest.

The test consists of a distance measurement (1.7m) and a near measurement (50cm). Each measurement consists of a base alignment and fine alignment. The base alignment is a dissociative test where the system presents each eye with non-fusible images, and the patient is instructed to look at a fixation target that is geometrically placed at the measurement distance. While looking at the target, the system measures the complimentary eye for latent strabismus. This test is done while presenting the fixation target for one eye while the complementary eye is shown unrelated graphics.

Once the patient's natural phoric posture is determined, the system presents a moving peripheral fusible image binocularly at the patient's phoric posture while instructing them to look at a fixation target which is presented to one eye at a time. This fixation target will iteratively move to neutralize eye movement and determine the optimal binocular alignment of the patient at the testing distance. This test is most similar to a fixation disparity test.

By incorporating a distance and a near measurement, a patient's vergence response can be used to help identify whether a patient is Convergence Excess, Divergence Excess, or Convergence Insufficient.

The $N^3$ is designed for use in indoor office environments.

*Note: With regards to safety, Essential Performance is defined as performance where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable risk. The N³ does not provide any Essential Performance.*

## 1.8 Variant Configurations:

The N3 device has a single hardware and software configuration. As it pertains to the patient exam configuration, the Optometry practice may choose:
- The patient preferred language: English, Chinese (Simplified), Chinese (Traditional), Spanish, French (Canadian), Vietnamese, German, Arabic, Hindi, Punjabi, Korean, and Russian.
- Closed Captions (On / Off)

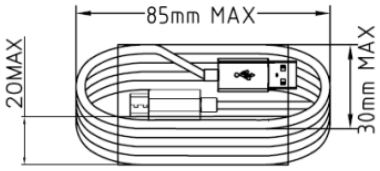
See section 3.2 Patient set-up for more details.

## 1.9 Accessories

The N3 comes with two accessories, intended to be used together to charge the device battery. It is required for N3 users to use the accessories provided below to charge the battery of the N3 device.

### 1.9.1 USB-C Cable

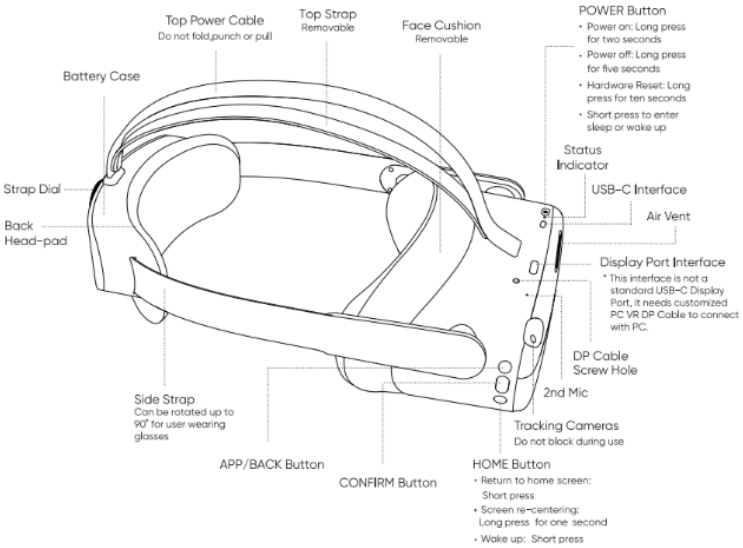
100% open circuit, short circuit, dislocation, intermittent open circuit test, high pressure: AC300 V/0. 01 sec, Insulation resistance: min. 10 mohm, ON resistance: max. L3 ohms.




### 1.9.2 Power Supply

Single USB Port, Adaptive 5V/3A, 9V/2A, 12V/1.5A Outputs, Fixed US style wall plug

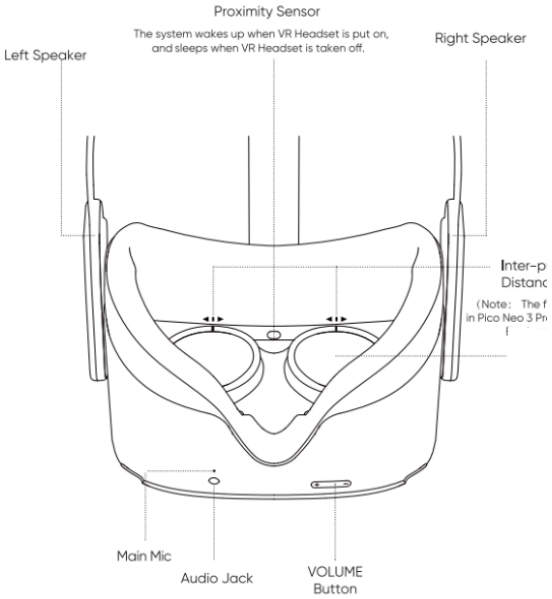
## 1.10 Components




**VR Headset Status Indicator Legend**

- Blue: Powered on with battery over 20%
- Blue flashing: Shutting down
- Yellow: Charging Battery is less than 98%
- Green: Charging complete
- Red: Charging Battery is less than 20%
- Off: Sleeping or Powered off
- Red flashing Battery is less than 20%

10




### 1.10.1 Applied Parts:

In contact with patient during the measurement (< 10 min)

#### 1.10.1.1 Patient Facemask

The **Patient Facemask** is a Polyurethane Foam that is placed in front of the eye openings to help position the patient accurately and comfortably for the measurement. The Facemask is an applied part and should be cleaned with isopropyl alcohol between uses.

#### 1.10.1.2 Side Straps

The **Side Straps** are polypropylene straps that are on the side of the patient's head that holds the headset in place laterally. The side straps are applied parts and should be cleaned with isopropyl alcohol between uses.

#### 1.10.1.3 Back Head Cushion

The **Back Head Cushion** holds the headset in place in combination with the facemask and is made of Polyurethane Foam. The Back Head Cushion is an applied part and should be cleaned with isopropyl alcohol between uses.

#### 1.10.1.4 Adjustment Strap

The Adjustment Strap is a rubber strap that goes over the top of the patient's head and provides vertical support of the device. The Adjustment Strap is an applied part and should be cleaned with isopropyl alcohol between uses.

### 1.10.2 Incidental contact parts:

Some parts of the device may be touched or come into contact with the technician or eye care provider while setting up the device for initial examination. This has been described in detail in the following sub sections.

#### 1.10.2.1 Imaging Optics

The **Imaging Optics** are used to both provide clear focus for the patient at both distance and near virtual distances and as well as focus the camera on the pupil plane of the patient for eye tracking.

#### 1.10.2.2 Enclosure

The **Enclosure** protects the user and patient from accessing internal components. The patient may contact the enclosure as it is an equivalent applied part.

#### 1.10.2.3 Illuminating LEDs

The **Illuminating LEDs** are located around the imaging optics and utilize eye safe infrared illumination (l = 850nm) to illuminate the eye for tracking purposes.

#### 1.10.2.4 USB-C Port

The **USB-C Port** is restricted to connecting the provided power supply.

#### 1.10.2.5 Power Button

The **Power Button** is used to start the device and can be used to turn it off if the device becomes unresponsive.

## 1.11 Preparations

### 1.11.1 Installation

- The $N^3$ should be installed in an office environment, away from direct sunlight.

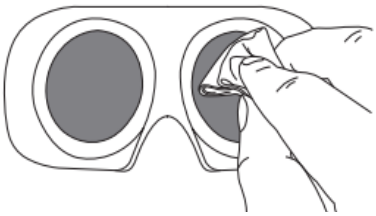
Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

### 1.11.2 Connecting power (Charging)

- The system requires charging with the supplied charger prior to utilization.
- To avoid the risk of tripping, make sure power cables are properly routed and not in the way.
- When the device is not in use, perform a software shutdown.
- To avoid the potential of damage to the device, it is recommended to connect the power to an uninterruptible power supply.

### 1.11.3 Maintenance and care

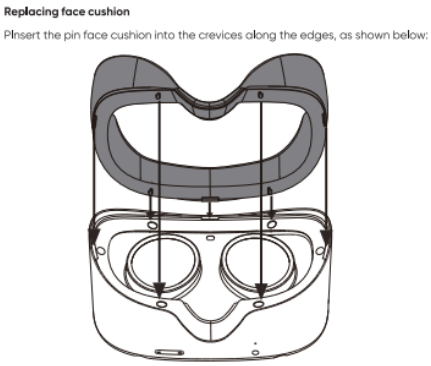
- Before taking measurements, always make sure that the imaging optics are clean, free from fingerprints and dust.
- To avoid contamination, it is recommended to clean areas of patient contact with an antibacterial such as isopropyl alcohol or similar.
- Avoid sudden movements of the device, as they can cause internal parts to move and affect calibration.
- Make sure the device is kept in a dry environment, and it is not exposed to humidity or extreme temperatures.
- Cleaning:
    - Regularly check the imaging optics in the eye mask for fingerprints and dust. Use an optical lens microfiber cloth dipped in a little water or non-alcoholic disinfectant wipe to clean the lenses. Do not wipe the lenses with alcohol or other harsh or abrasive cleaning solutions, as this may lead to damage.



    - Wipe the eye mask with alcohol wipes or a microfiber dry cloth dipped in a small amount of 75% alcohol solution and gently wipe

the surface and surrounding areas that contact with the skin between every patient.

- Note: The face cushion may exhibit the following effects after repeated cleaning and disinfection. Replace the face cushion if the cushion exhibits color change, sticky surface, or decreased comfort. See below diagram for replacing the face cushion.

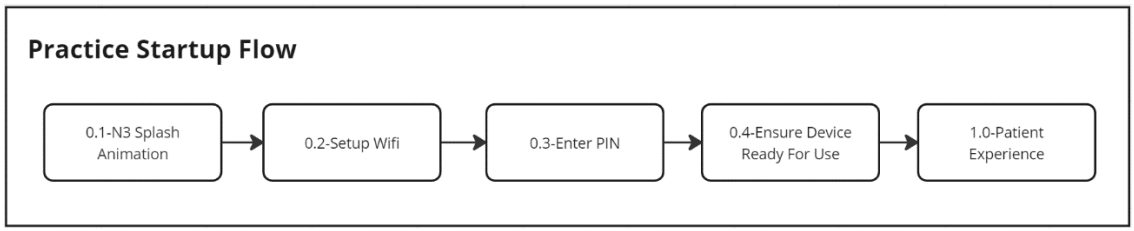



- The external surface of the enclosure may be cleaned with an alcohol based cleaner, as necessary.

### 1.11.4 Startup

To power on the device, put the headset on and press and hold the power button until you see the Pico logo. The system will initialize, and the Neurolens Measurement application will automatically start.

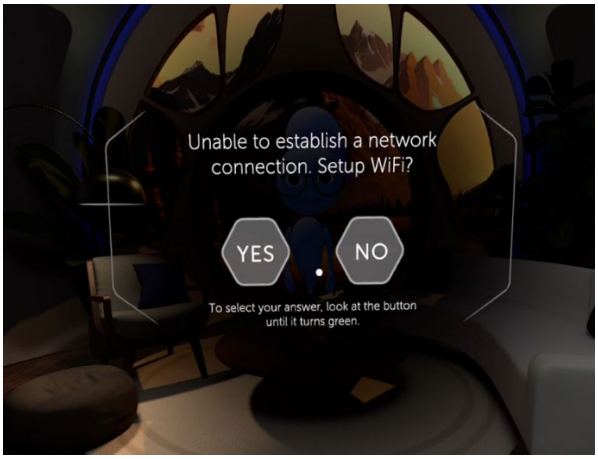
Upon the first startup the device will initialize through a sequence of steps to ensure the device is connected to the cloud database, the system is in proper operating condition, and sufficient training has been completed.



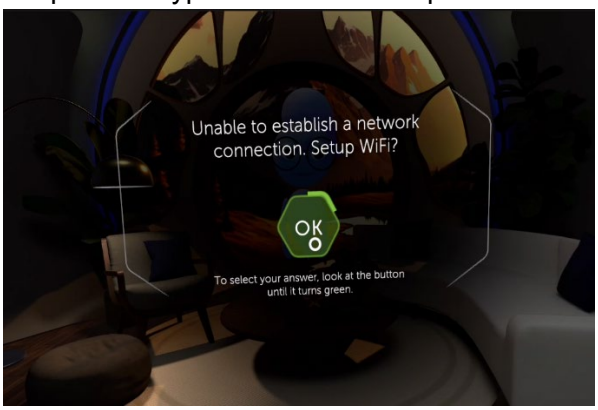

Initialization Sequence

### 1.11.5 Setting up Wireless Fidelity (Wi-Fi)

Upon initial setup, if the system detects it is unable to connect to the cloud during startup the application will automatically direct the user to the WiFi setup screen. The user will be prompted to set up WiFi. If the user selects “No” they will be asked if they would like to enter Demo Mode. Demo Mode will not save any measurement data and is for providing experience only.

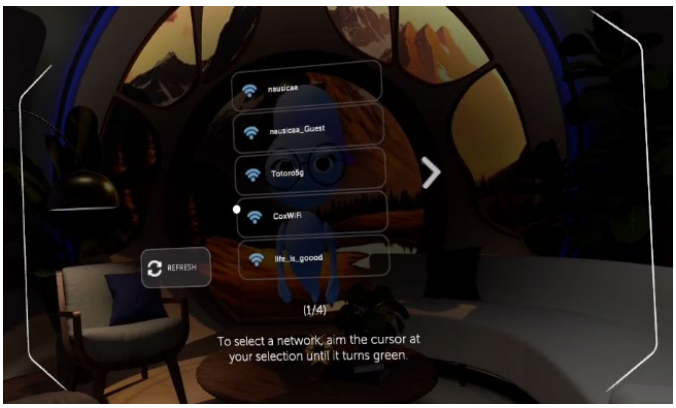



After a WiFi network has been previously established, if the WiFi network is subsequently unavailable, the user will be prompted to set up WiFi but will not be given the option to bypass the WiFi setup and continue in Demo Mode.

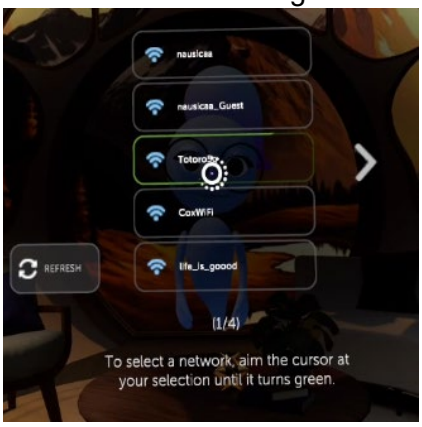



To make selections, the operator moves their head to direct the pointer and holds the pointer over the desired target until selected.

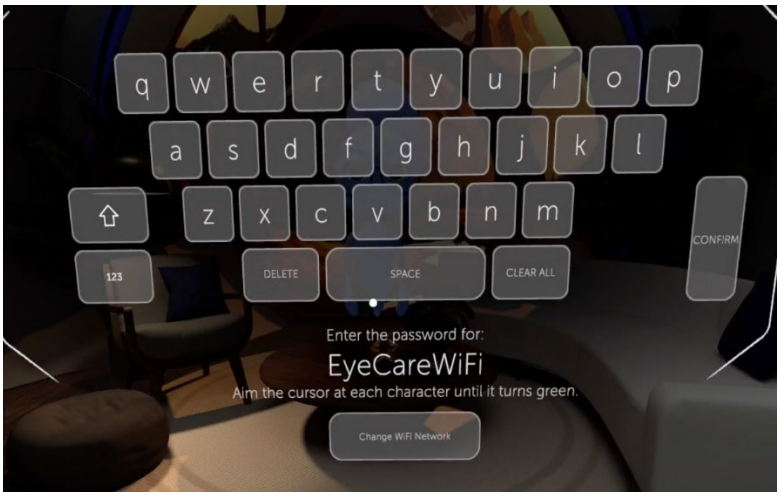
Once the user has selected “Yes” or “OK, the application will display available Wi-Fi network:



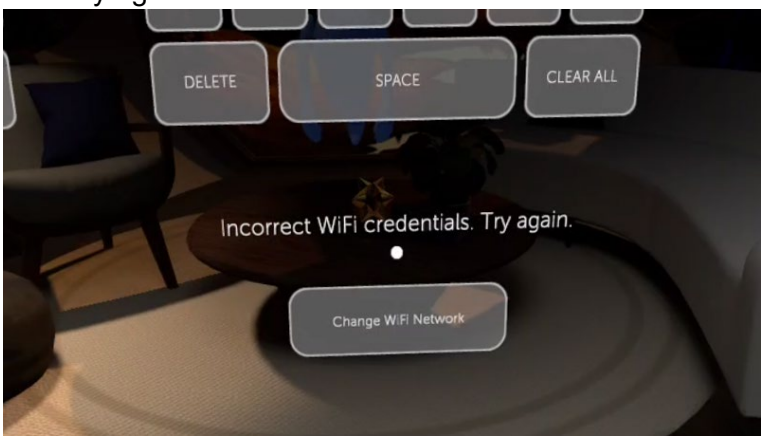
Select a network until it turns green.




Enter Wi-Fi password. When it's done, select CONFIRM until it turns green.




If an incorrect password is entered, the application will display "Incorrect WiFi credentials. Try again."



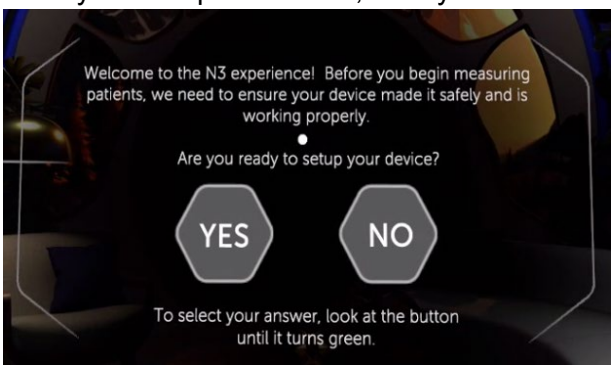
If the device is successfully connected to the selected Wi-Fi network, the application will display “Wi-Fi Connection Success”.

Once connected, the application will automatically resume.

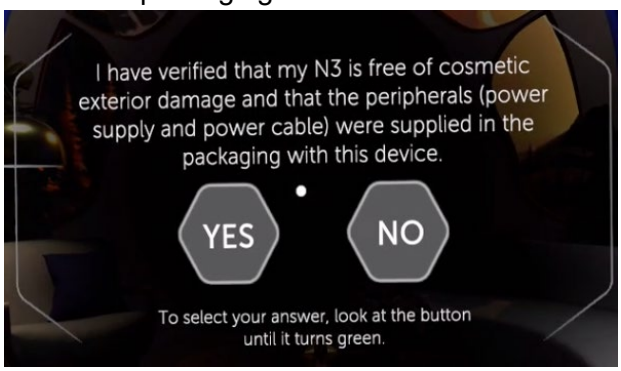
### 1.11.6 Device Initial Set-up

After the device is connected the application will proceed through an orientation and device setup instructions. Prior to receiving your $N^3$, you will have received an email containing a practice / staff PIN for the initial set-up. If you don’t have a practice / staff PIN, please contact your Neurolens authorized representative. Put the $N^3$ on and enter the practice / staff PIN when prompted.

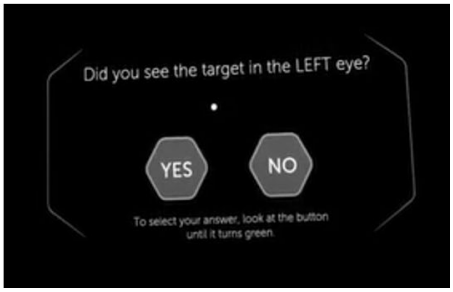
When you are ready to set-up the device, click yes on the following prompt




Answer the following statement that “I have verified that my N3 is free of cosmetic exterior damage and that the peripherals (power supply and power cable) were supplied in the packaging with this device

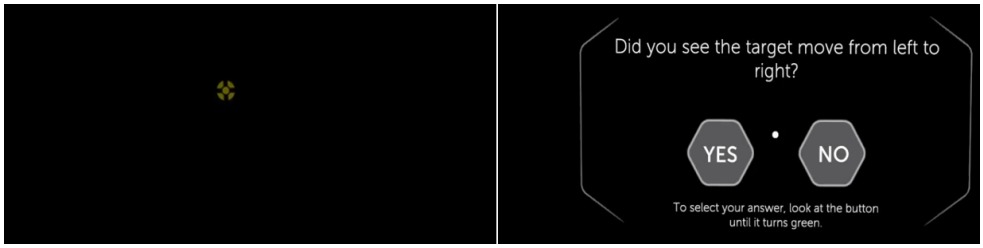


Answer the prompted question: Did you see the target in the LEFT eye?




Answer the prompted question: Did you see the target in the RIGHT eye?

Answer the prompted question: Did you see the target move from left to right?

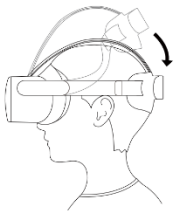



Click OK on the following statement: Your device is ready for use!
By clicking ‘OK’, you confirm and certify that you have adhered and will comply with all given instructions of the operating manual that can be downloaded at **www.neurolens.com/N3-Manual**
**If you had to answer “No” to any of the initial set-up questions, please contact your Neurolens authorized representative for further assistance.**

# 2 Taking a Measurement

## 2.1 Setting up a patient

Prior to starting a measurement, ensure the patient is wearing refractive correction that is within 0.5 diopters of their spherical equivalent distance manifest refraction. Patient may wear contacts or corrective spectacles (single vision or progressive). If wearing spectacles, ensure they fit comfortably within the headset and do not impart uncomfortable force on the patient’s face when tightening the head strap.

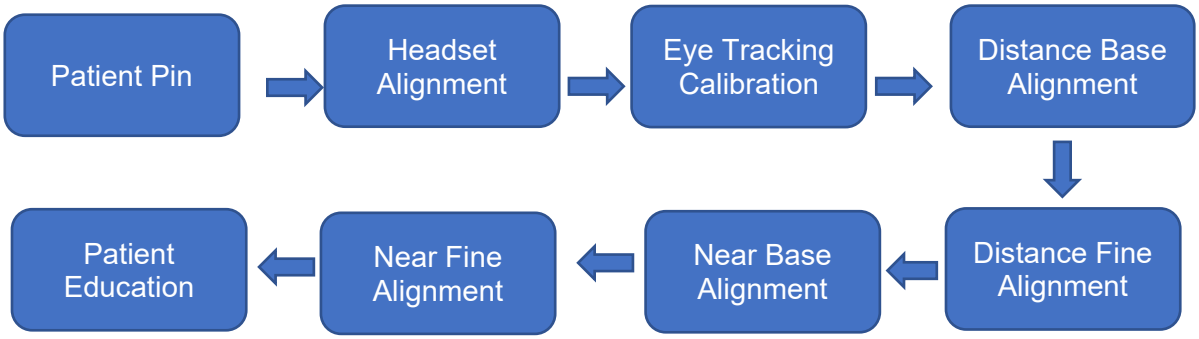


| | |
|---|---|
| **Warning** | ▪ WARNING: Do not overtighten head strap. Overtightening may lead to bruising, cuts, or discomfort from impinging corrective eyewear onto the patient. |

After the device is connected the application will proceed through an orientation and device setup instructions. Follow the prompts to ensure the device is functioning properly.
Once the device is set up, the user will be presented with brief training on what the device does and how to take measurements.

## 2.2 Starting a measurement

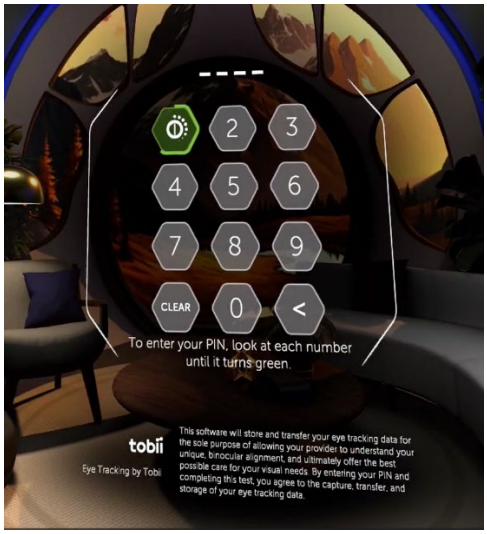
The Measurement Device is equipped with a sensor that detects when the headset is put on. Once a patient puts the device on it will automatically initiate a measurement. An avatar will show up and instruct the patient how to complete a measurement by going through the following steps.




### 2.2.1 Entering a PIN

Before the patient can begin the headset alignment, the system will prompt the patient to input a unique PIN. The PIN is generated from the Neurolens portal (Reference section 3) and is unique to that patient ID and practice. The PIN will expire after 7 days if not used, or after 1 hour of last use.

To enter the PIN the patient needs to move their head until the pointer highlights each number in sequence. The patient must maintain their gaze at the number until it is fully highlighted, and the number appears above the keypad.




Patient PIN Input Screen

From the Neurolens portal, the user can assist patient with the PIN entry (Reference section 3).

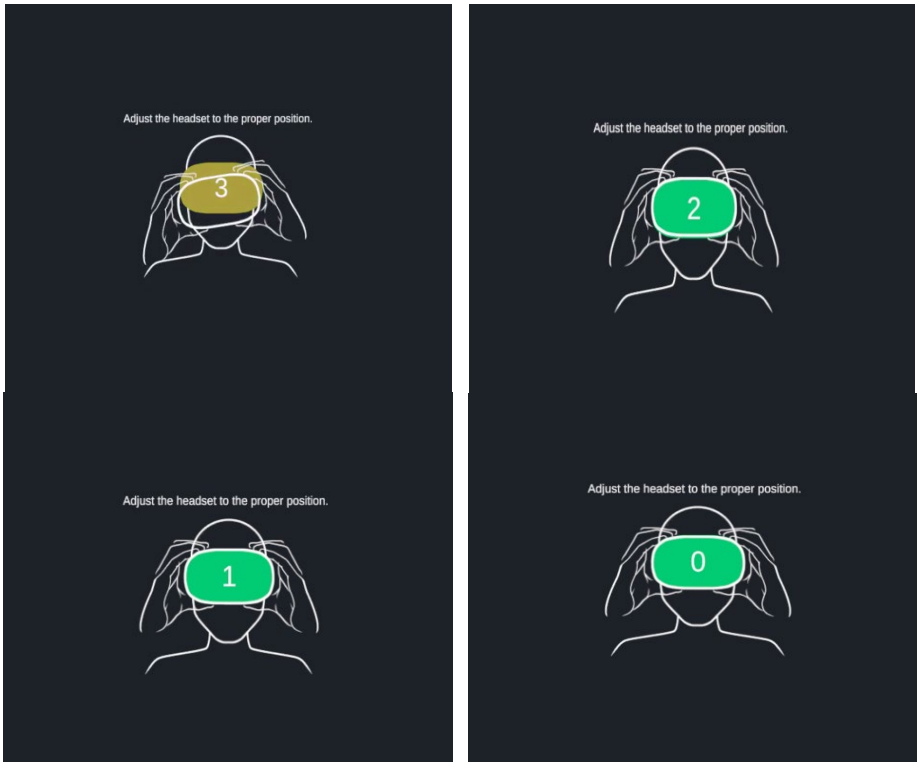
### 2.2.2 Headset Alignment

When the headset is put on, the device will provide visual and audible queues to walk the patient through the test. Initially the system will audibly instruct the patient to align the headset to their eyes and provide intuitive graphical instructions.

The instructions will show how the headset is aligned on the patient's head along with a counter, showing how long the headset has been aligned. The headset must be aligned for three seconds in order to proceed to the next portion of the calibration. The graphics will display yellow with an indication of direction of misalignment if the headset is not properly aligned. Once aligned, the graphic will display as green and count down from 3-0 to ensure the headset is aligned and stable.

The patient should adjust and release the headset rather than hold it in place. If the headset will not remain in place when released, tighten the head strap adjustment.

| | |
|---|---|
| **Warning** | ▪ WARNING: Do not overtighten head strap. Overtightening may lead to bruising, cuts, or discomfort from impinging corrective eyewear onto the patient. |

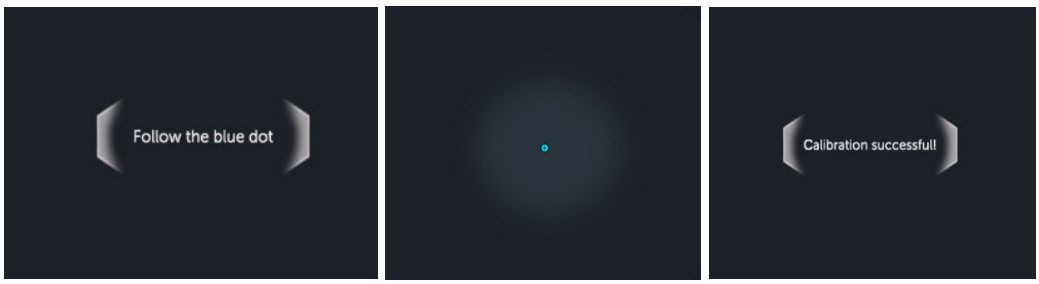



Headset Alignment Graphics

### 2.2.3 Eye Tracking Calibration

Once the headset is properly adjusted on the patient's head the system will prompt eye tracking calibration. The patient will be asked to follow a blue dot to across several quadrants of the display.

If the patient does not cooperate or the system is unable to track the patient's eyes, the system will notify the patient that the test is unsuccessful and instruct them to return the headset.

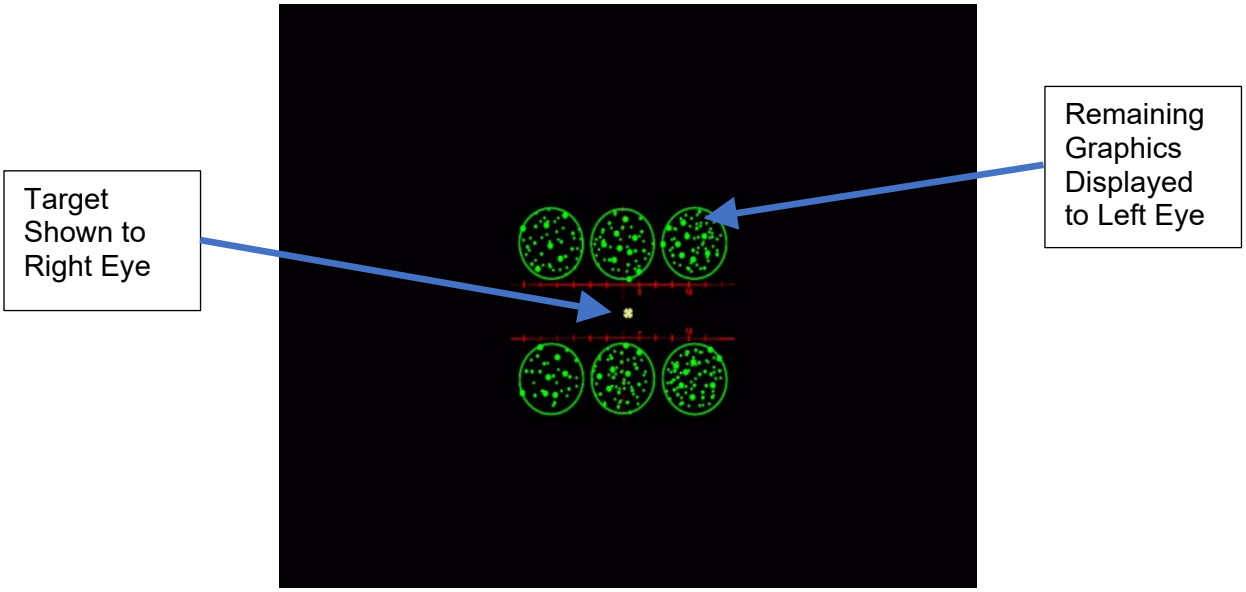



Eye Tracking Calibration Graphics

### 2.2.4 Average Television Distance Base Alignment

The system will automatically proceed from PIN input to Average Television Distance (1.75 m) Base Alignment. Base alignment is most similar to a

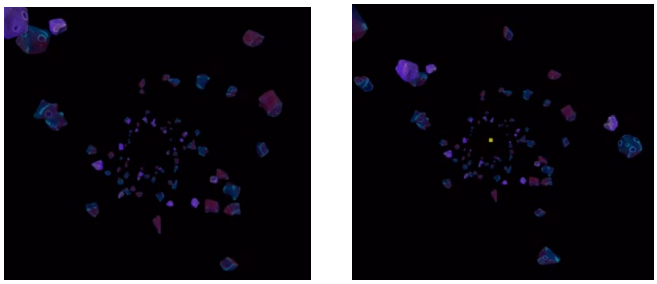
disassociated phoria measurement. The patient will be instructed to look at a target within the device. The target will be displayed only to the right eye, with the left eye being shown unrelated graphics. The disassociated left eye will be tracked, and the amount of deviation will be measured as the base alignment.




Average Television Distance Base Alignment Graphic

### 2.2.5 Average Television Distance Fine Alignment

After the base alignment is complete the system will present a moving peripheral stimulus at a location determined by the base alignment step. In the central region of the measurement a target is displayed in one eye at a time.
First, a target is shown to the right eye centered relative to the peripheral stimulus.
The target will then disappear from the right eye and appear centered in the left eye. The system will track eye movement and if eye movement is detected, the target positions will be adjusted and the system will iterate the target positions, displaying the right eye and then the left eye again.
The system will continue to iterate the target position until eye movement is neutralized. This final target position is the misalignment measurement that is reported.



Average Television Distance Fine Alignment Graphic

### 2.2.6 Average Reading Distance Base Alignment

The system will automatically proceed from Average Television Distance Fine Alignment to Average Reading Distance Base Alignment. This test is similar to the Average Television Distance Base Alignment, except the target position is designed to simulate 0.5m. The patient will be instructed to look at a target within the device. The target will be displayed only to the right eye, with the left eye being shown unrelated graphics. The disassociated left eye will be tracked, and the amount of deviation will be measured as the base alignment.

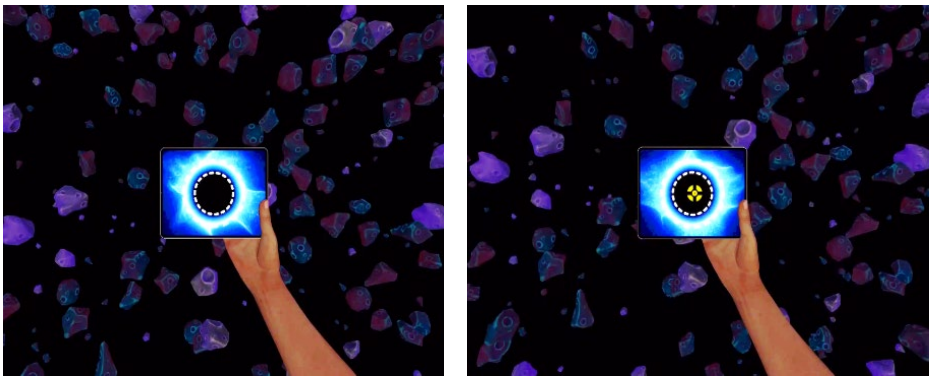
### 2.2.7 Average Reading Distance Fine Alignment

After the base alignment is complete the system will present a moving peripheral stimulus at a location determined by the base alignment step. In the central region of the measurement a target is displayed in one eye at a time.

First, a target is shown to the right eye centered relative to the peripheral stimulus.

The target will then disappear from the right eye and appear centered in the left eye. The system will track eye movement and if eye movement is detected, the target positions will be adjusted and the system will iterate the target positions, displaying the right eye and then the left eye again.

The system will continue to iterate the target position until eye movement is neutralized. This final target position is the misalignment measurement that is reported.



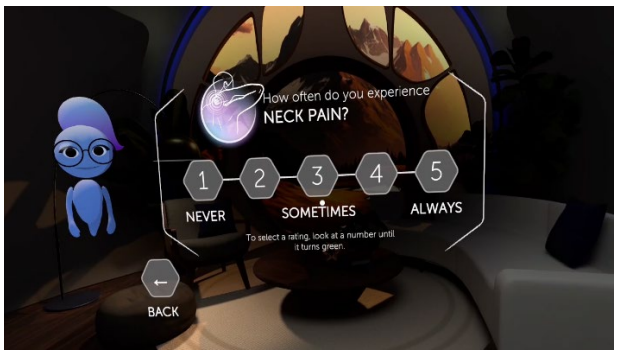
Average Reading Distance Fine Alignment Graphic

### 2.2.8 Lifestyle Index within the device

The user will be prompted to complete a Lifestyle Index in the device if there is no Lifestyle Index on file that has been completed in the last 30 days. The user be asked to select a number from one to five indicating the frequency they experience the following 7 symptoms:

1. Headaches

2. Neck Pain

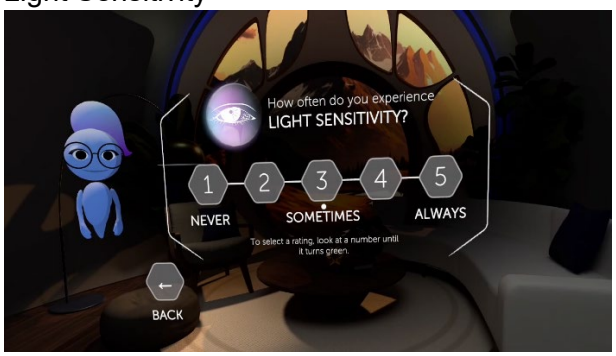



3. Discomfort at a computer

4. Eye Strain

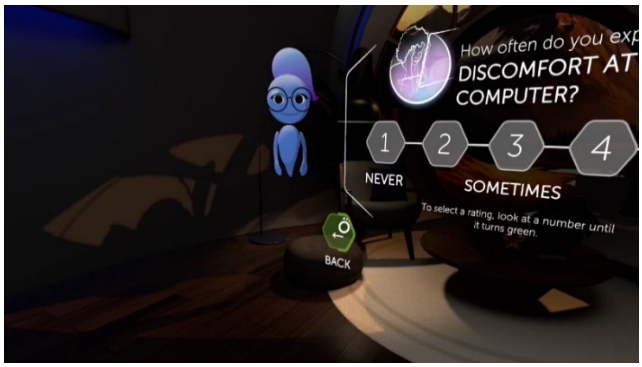
5. Dry Eye

6. Light Sensitivity




7. Motion Sickness

If the user wishes to return to a previous question they may select the back button.



### 2.2.9 Patient Education

After the alignment measurements are complete the device will provide the patient with education about how eye misalignment can affect the brain and cause symptoms such as eye strain, headache, neck ache, and other asthenopic symptoms.

### 2.2.10 Completing the measurement

Once the patient education is complete, the patient will be instructed to take the headset off. Although a charge may last a full day, it is recommended that the headset be plugged back in after every use to ensure the device is charged for the next patient.

The test may be terminated at any point during the test by asking the patient to take the headset off.

# 3 Portal

In order to run a patient and see results, the patient must be entered into the cloud database through the Neurolens Portal. Additionally, the patient needs to be assigned with an active pin for the patient to input during the measurement (See section 2.2.1).

Finally, the practice needs to access the patient results through the portal.

The Neurolens Customer portal requires a modern, up-to-date browser such as Chrome or Safari and Windows 10 (or later) or iOS 15 or later. Minimum hardware requirements include an Intel i5 (or equivalent) processor, 8 GB RAM, and a 256 GB SSD. Network characteristics for both the N3 and the Neurolens Customer Portal shall support minimum upload and download speeds of 10 Mbps and support secure protocols such as HTTPS and TLS 1.2 or higher. Security measures will enforce authentication and role-based user access and permissions. Regular updates, modernized security and controls along with encrypted backups will be maintained by Neurolens, Inc.

## 3.1 Patient Profile

Patient profile contains the following information:

- **Patient ID**: an identifier that can be used by the practice to associate the patient with an entry in their patient management system.
  This field cannot be left blank. The Patient ID must be unique to that patient in that practice.
- **First Name**: the patient's first name.
  This field can be left blank.
- **Last Name**: the patient's last name.
  This field can be left blank.

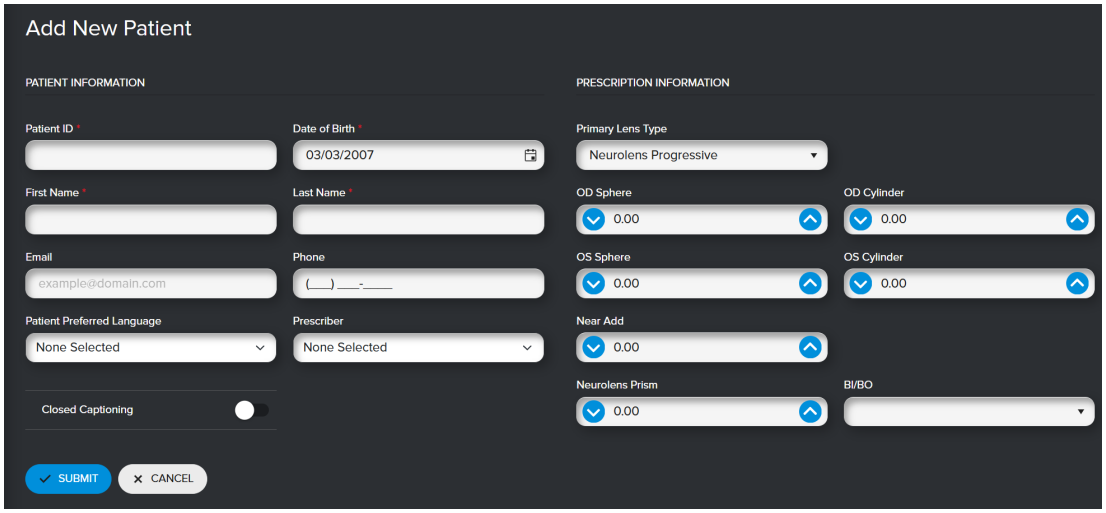
- **Date of birth**: the patient's date of birth, entered as mm/dd/yyyy or mm-dd-yyyy.
  This field must contain a valid date.
- **Email**: the patient's email. This field can be left blank.
- **Phone**: the patient's phone number. This field can be left blank.
- **OD Sphere**: the distance sphere value for the right eye[1].
  If left blank, the value defaults to 0.
- **OD Cylinder**: the cylinder value for the right eye[1].
  If left blank, the value defaults to 0.
- **OS Sphere**: the distance sphere value for the left eye[1].
  If left blank, the value defaults to 0.
- **OS Cylinder**: the cylinder value for the left eye[1].
  If left blank, the value defaults to 0.
- **Primary Lens Type**: the patient's primary lens type. This field can be left unassigned as "None Selected". However, it must be assigned during PIN confirmation dialog. If the patient does not wear any correction, assign this field to "No Correction".
- **Near Add**: the add power value for both eyes. If left blank, the value defaults to 0.
- **OD Standard Prism**: the distance standard prism for the right eye[1]. If left blank, the value defaults to 0.
- **OS Standard Prism**: the distance standard prism for the left eye[2]. If left blank, the value defaults to 0.
- **Neurolens Prism**: the combined distance Neurolens prism (aka Neurolens Value) for both eyes. If left blank, the value defaults to 0.
- **BI/BO**: the direction of prism (Base In or Base Out).
- **Preferred Language**: the patient's language for audio and visual cues on the device. This field can be left unassigned as "None Selected". However, it must be assigned during PIN confirmation dialog.
- **Prescriber**: the practice prescriber for this patient. This field can be left unassigned as "None Selected".
- **Closed Captioning**: the patient's option to enable closed captioning on the device. This field's default value is disabled.

## 3.2 Patient Management

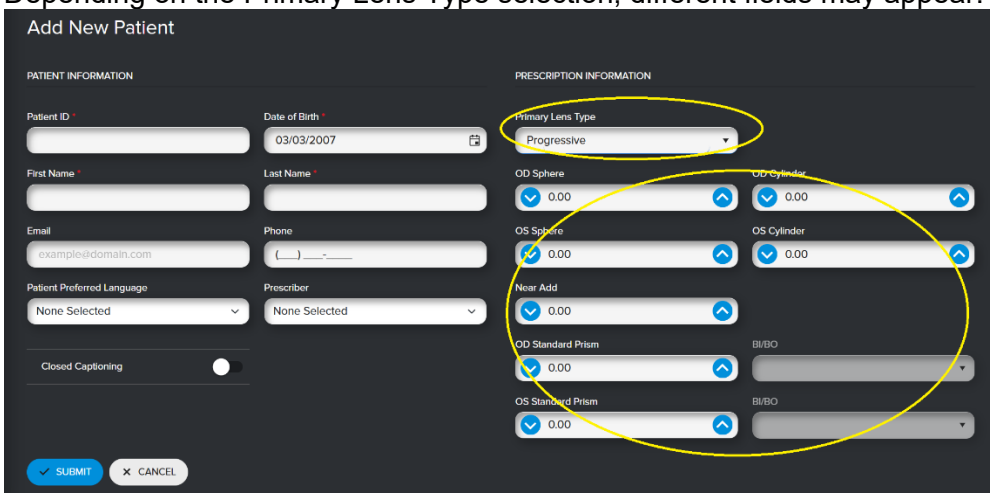
### 3.2.1 Adding a patient

To add a patient, touch on **New Patient Icon** from the Patient Search screen to open the New Profile screen, then complete the form online.

[1] Use patient's most accurate distance refractive correction from either comprehensive exam, previous prescription, and/or auto-refractor measurement.




Depending on the Primary Lens Type selection, different fields may appear.

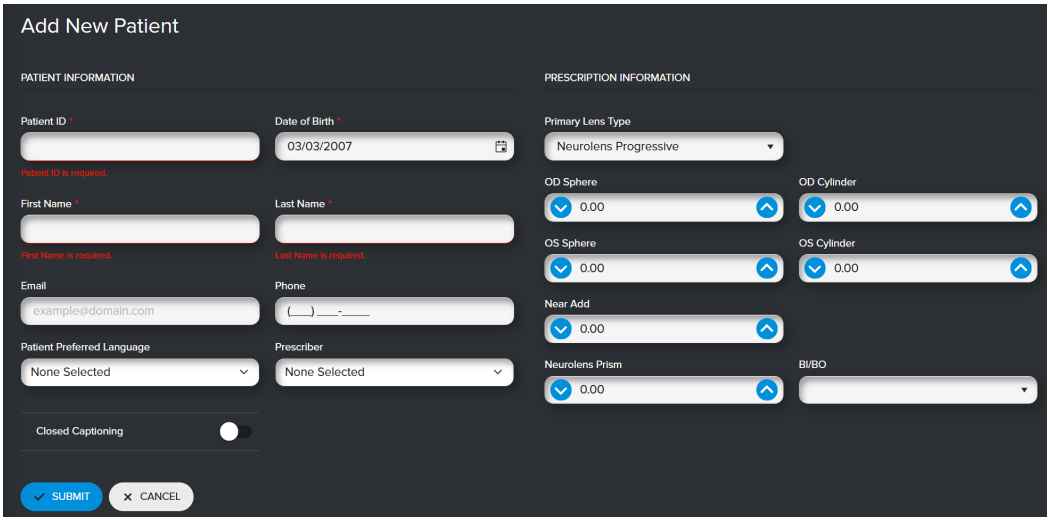



| | |
|---|---|
| ● | Make sure the patient's prescription data is correctly entered. Incorrect prescriptive information may lead to incorrect measurements. |

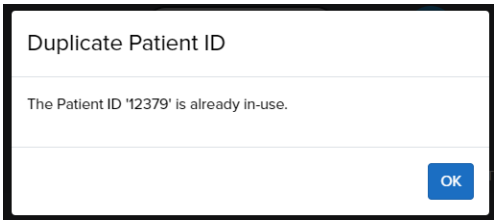
The Following Information is Required:

- Patient ID (A unique identifier for that patient)
- Date of Birth
- First Name
- Last Name

Validation error messages will display to indicate invalid or incomplete data entry.

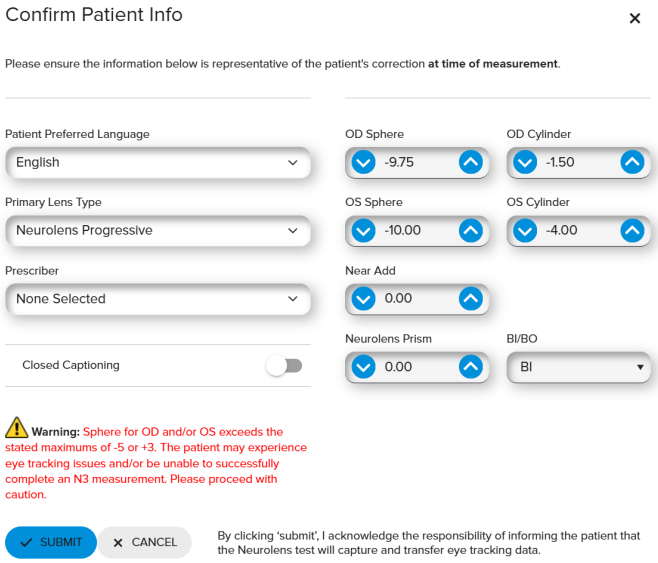


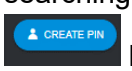

A pop-up message will display to indicate if a duplicate patient ID is detected.



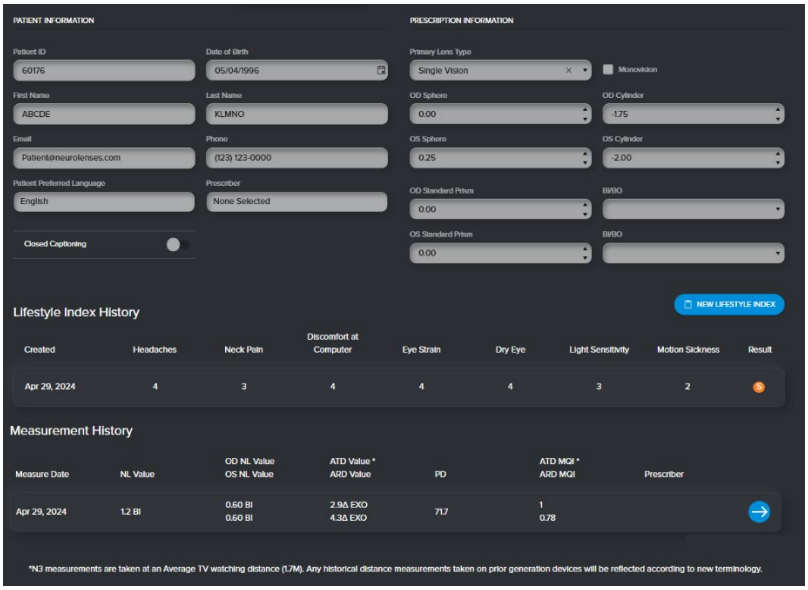

### 3.2.2 Assigning a PIN

Once a patient's information is input into the portal the user can click SUBMIT. The user will be prompted as to whether they want to assign a PIN.

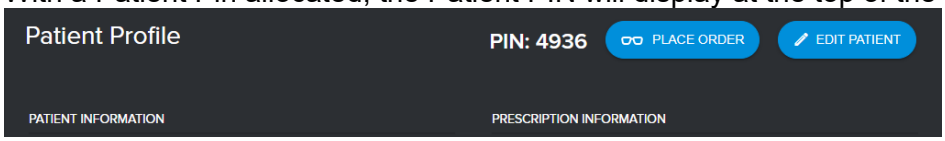



If a patient in the database is saved without a PIN, a PIN can be assigned by searching for the patient (Section 3.2.3) and clicking on the **CREATE PIN** 

button.




With a Patient Pin allocated, the Patient PIN will display at the top of the screen.




### 3.2.3 Searching for patients

.

In the **Patient Search**, you can search for patients that have previously been entered into the portal by typing at least 2 characters of the:

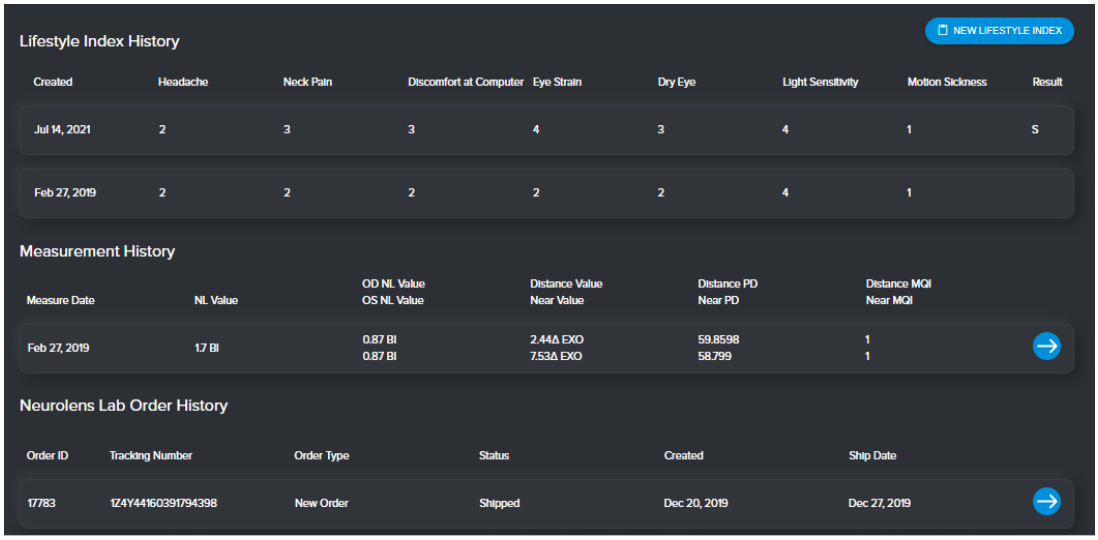
- First Name
- Last Name
- Patient ID
- Email Address
- Phone Number

To start searching, click within the search field and type at least two characters. Note that the search is done on all fields and a word base, so, for example, you can type “Joh A,” and the search will return “**Joh**n **A**shleigh,” “**Joh**anna **A**mes” and “**A**ndrew **Joh**nson.”

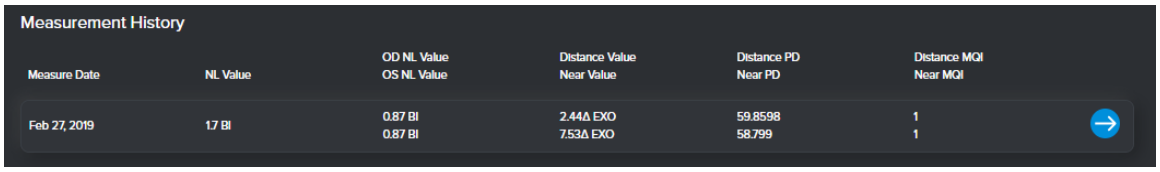
### 3.2.4 Accessing Measurements and Lifestyle Index

To access measurements, search for a patient according to 3.2.3 and select the patient that you wish to view the measurement.

Once the patient is selected there will be their history of lifestyle indexes and measurements. To access the results of any of the measurements or indexes simply select the measurement of interest.

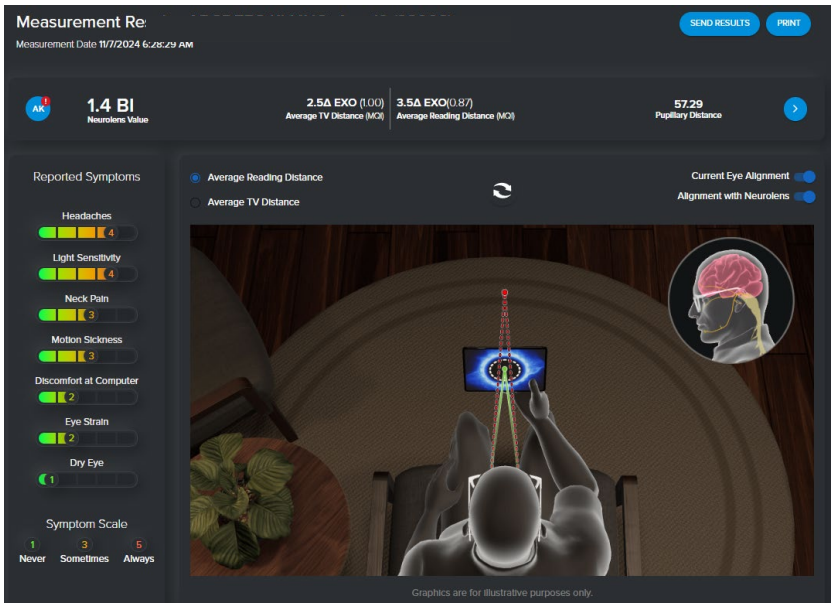



Lifestyle Index History

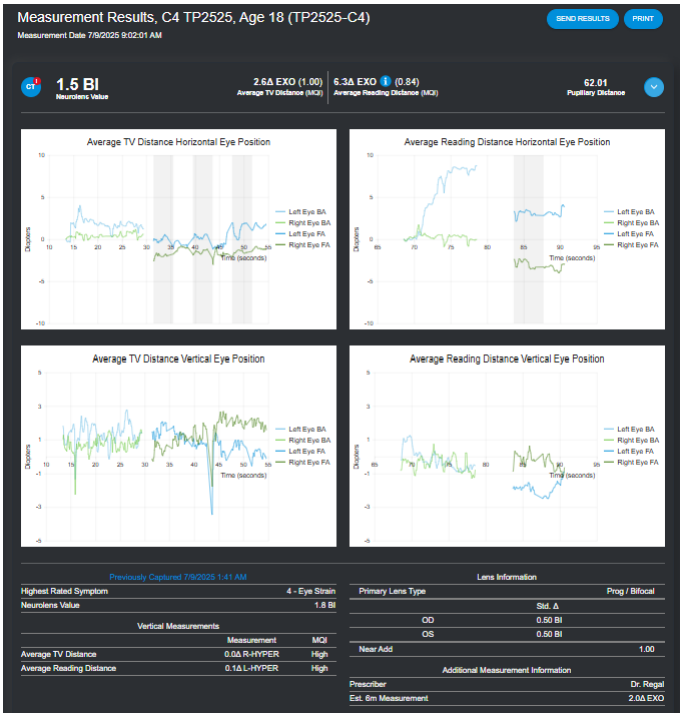



Measurement History

### 3.2.4.1 Measurement Results




For more detailed results about how the eyes tracked throughout the test as well as how they might be affected by add power, click on the **side arrow** button.



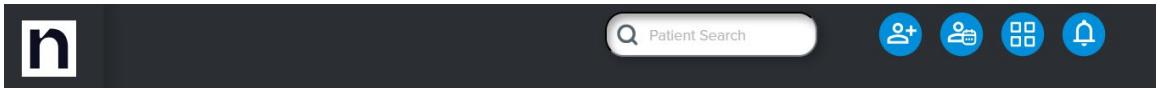

If the compensatory convergence response is detected during the measurement, the following tooltip message is available:
“Compensatory convergence response observed. The patient may have actively adjusted eye position during testing, which can mask their true phoric posture. Verification with in-chair phoria assessment is recommended.”

### 3.2.4.2 Measurement Results Details

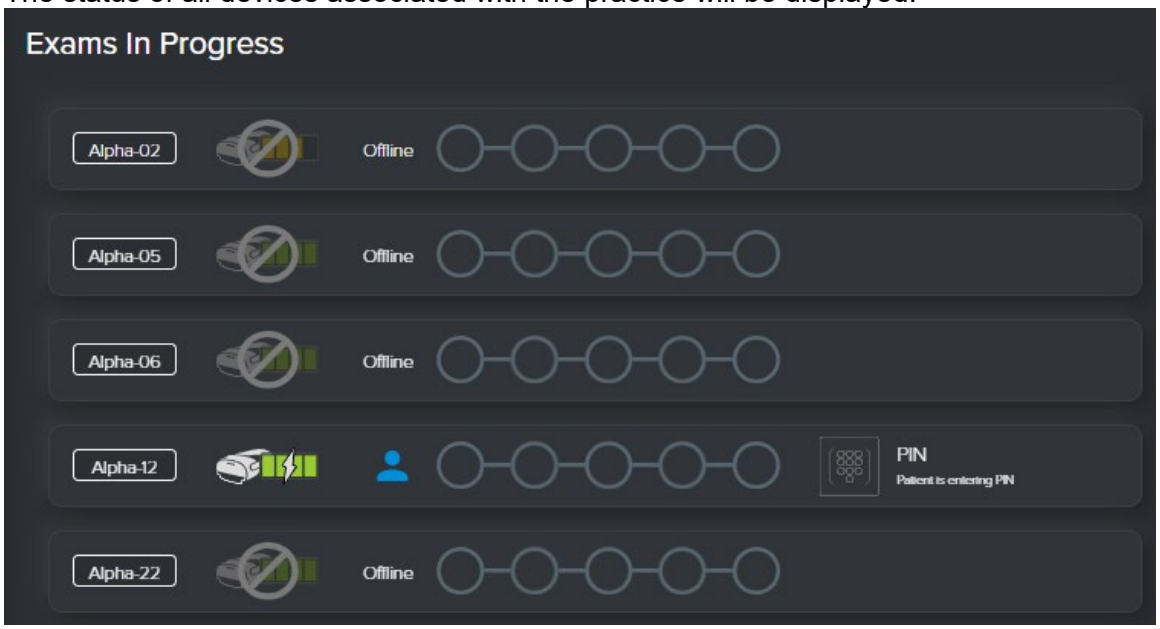
**Neurolens Value**: This is the value of horizontal prism at distance that Neurolens® algorithms determined closest meet the patient’s requirement.
**Horizontal (EXO / ESO)** presented at the top of the eye charts in the center are the total measured misalignments at TV distance and Reading distance. They are unique measurements that combine elements of heterophoria, fixation disparity, peripheral and central visual misalignment, and response to divergence eye conditioning.
**MQI is the measurement quality index**: It is based on the ability of the system to identify eye misalignment. If there is poor cooperation, poor tracking, or the patient has indeterminate eye misalignment this will read below 0.7 and the system will report low MQI. For vertical, it will yield a qualitative assessment of low, med, or high. High means the measurement was good 90% confidence, medium means the measurement showed some anomalies but is likely still good 65% confidence, and low means the measurement was poor and will not be displayed.
**Pupillary Distance**: distance in mm between the pupils at the pupil plane. This measurement is repeatable to less than 0.25mm. The near measurement is typically 1-1.5mm smaller than the distance measurement.
**Vertical Measurements**: objective measures of the vertical misalignment when a patient is disassociated. It is most similar to a vertical disassociated phoria. Results are reported as L-Hyper or R-Hyper.

### 3.2.5 Monitoring Device and Exams in Progress through the Portal

The state of devices assigned to a Practice may be monitored through the portal. From the portal home screen, select the icon.

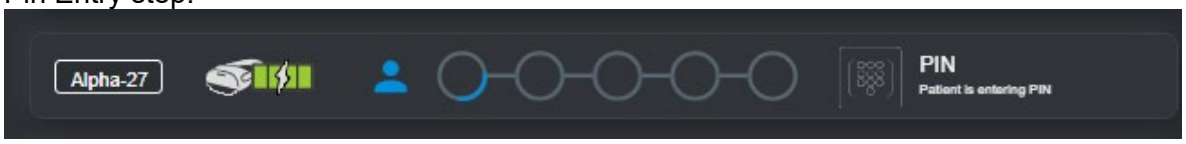



The status of all devices associated with the practice will be displayed.

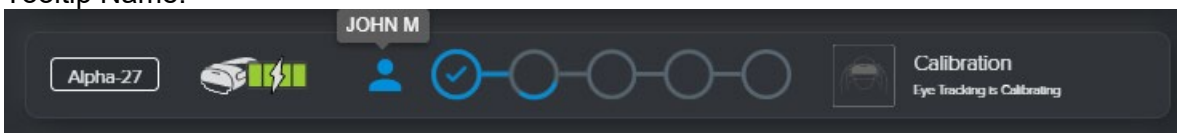



The last known battery charge state for the device, and the current state of the device and the current step of any exams in progress will be displayed as described in the following images.

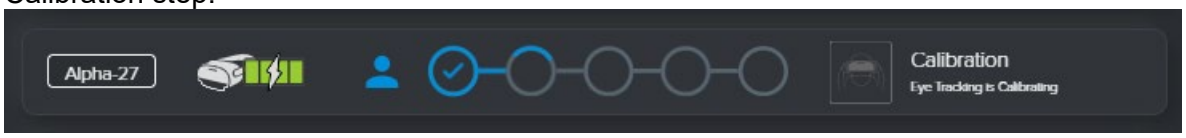
Pin Entry step:



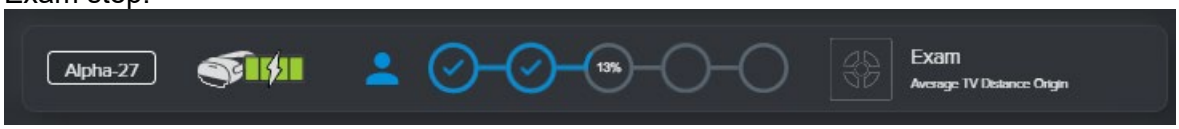

Tooltip Name:

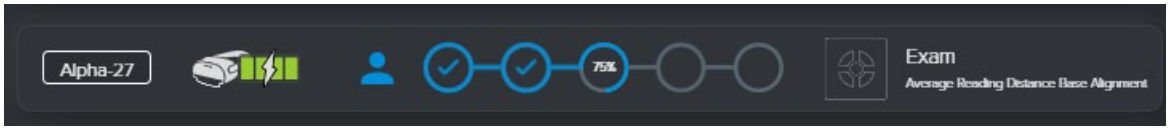



Calibration step:

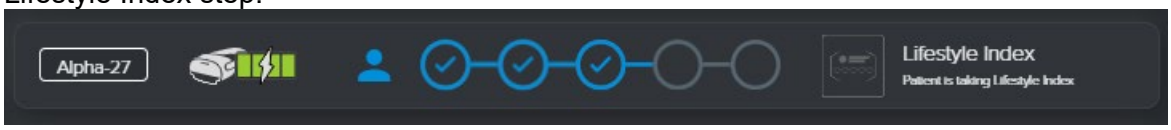



Exam step:

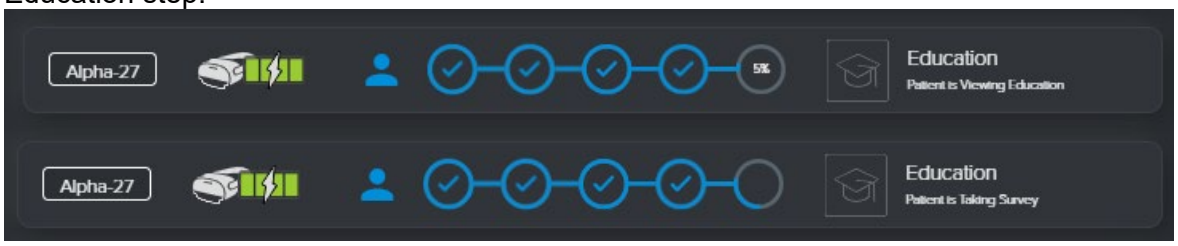




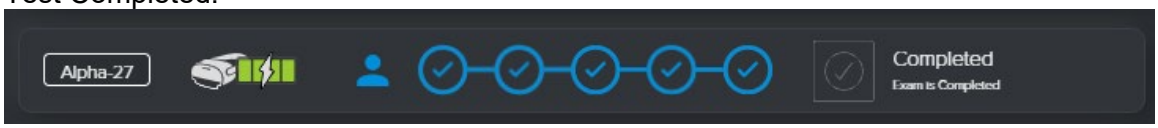

Lifestyle Index step:



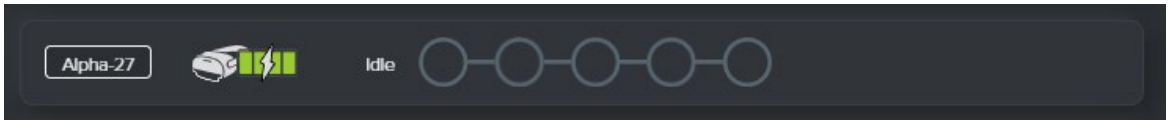

Education step:



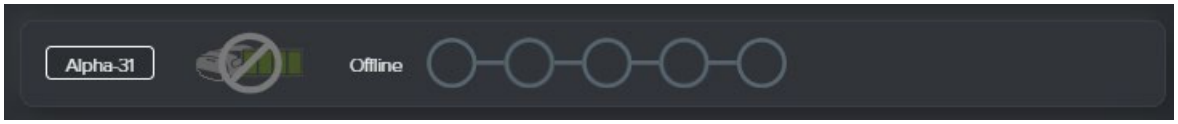

Test Completed:




Idle State:



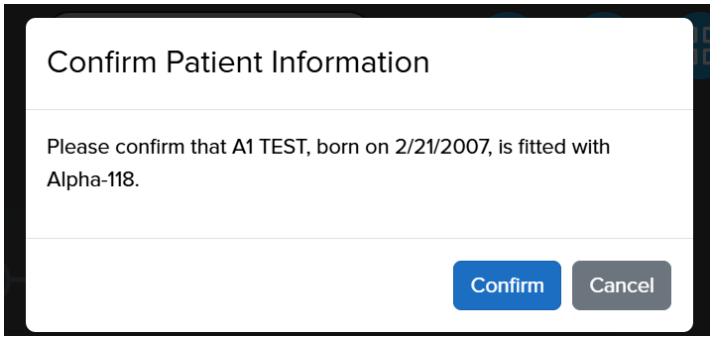

Offline State:




### 3.2.6 PIN Entry Assist

From the Exams in Progress screen, the user can assist patient with PIN entry while the patient is waiting in the PIN screen on the device by clicking on the button.

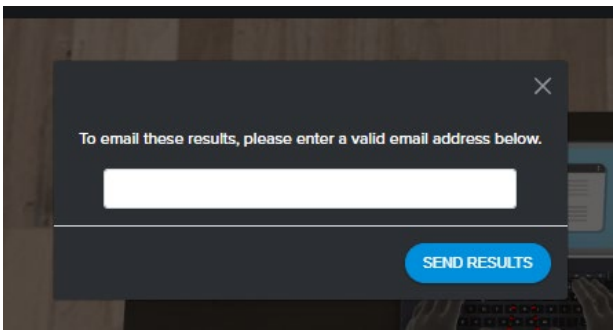
After entering the valid PIN, verify the following confirmation dialog and click the **CONFIRM** button to continue.




### 3.2.7 Outputting Data

The system allows the results to be sent to the patient via their email address by clicking on the **SEND RESULTS**

button. This will prompt the user to input the patient's email address.

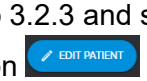



Send Results

Additionally, results can be printed, or a PDF can be saved by clicking on the **PRINT** button

.

### 3.2.8 Modifying patient data

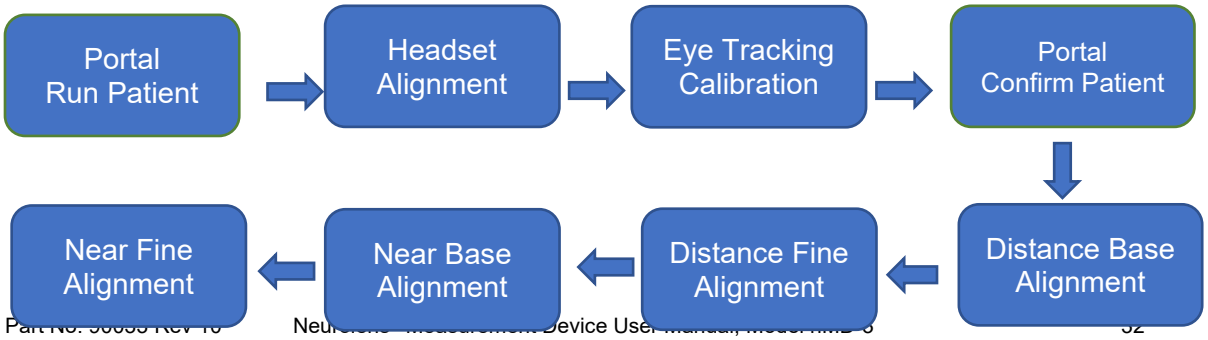
Search for the patient according to 3.2.3 and select the patient that you wish to modify. Click **EDIT PATIENT** button 

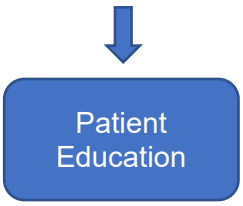
to update patient's data, except for Patient ID. To save, click the **SUBMIT** button

.

### 3.2.9 N3 Practice Customization (NPC)

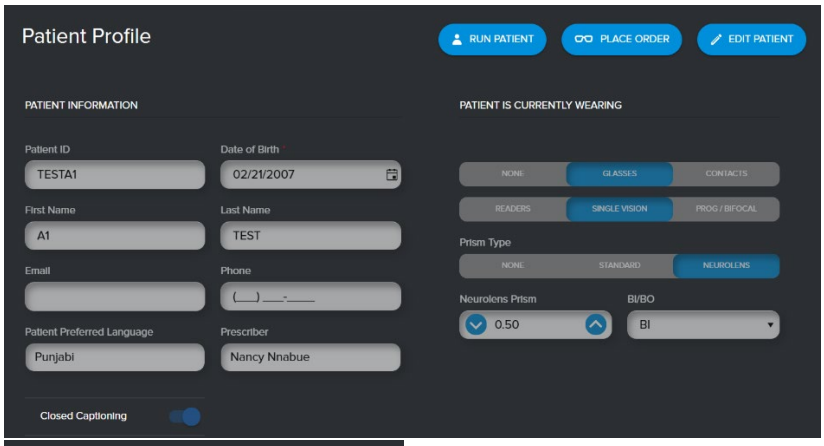
When N3 Practice Customization setting is enabled for the practice, once the patient puts the device on, from the Neurolens portal, the user can assist the patient to complete a measurement by going through the following steps.

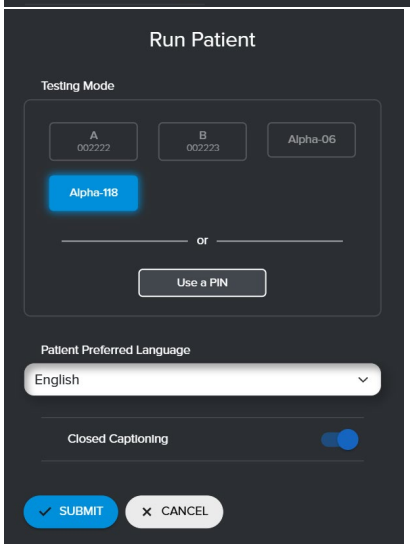




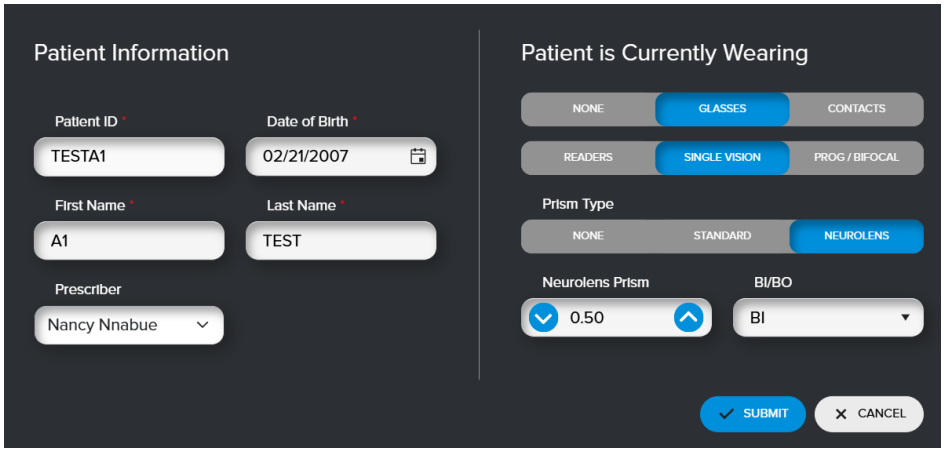

From the Neurolens portal, click the **RUN PATIENT** button from one of the following screens:

1. **Patient Profile**

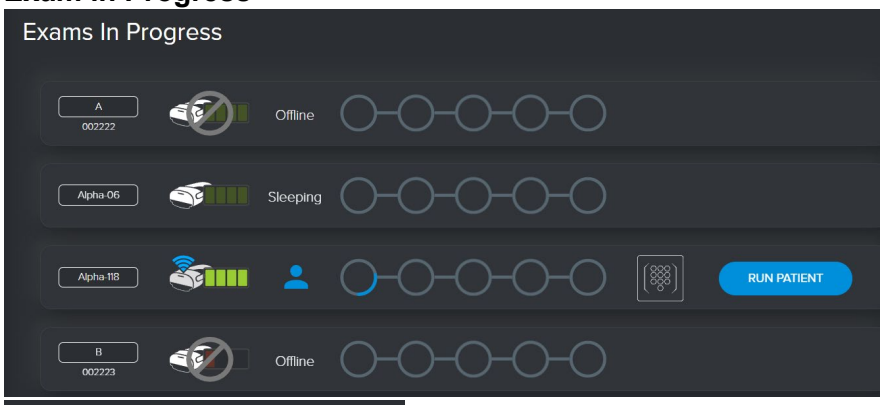


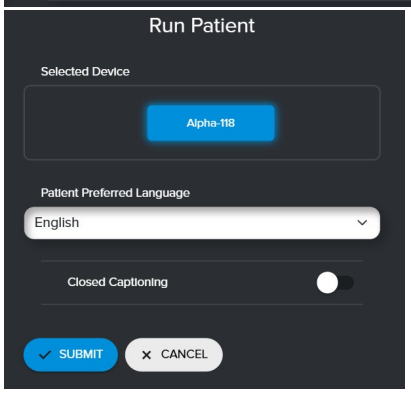




On the Run Patient dialog, select the device and specify the Patient Preferred Language and Closed Captioning option, then click **SUBMIT** button which will start the Headset Alignment and Eye Tracking Calibration steps on the device. Meanwhile, confirm the following Patient Information, including the refractive correction that the patient is wearing, and click **SUBMIT** button. Once the Eye Tracking Calibration step is completed, the patient continues with the alignment measurement.



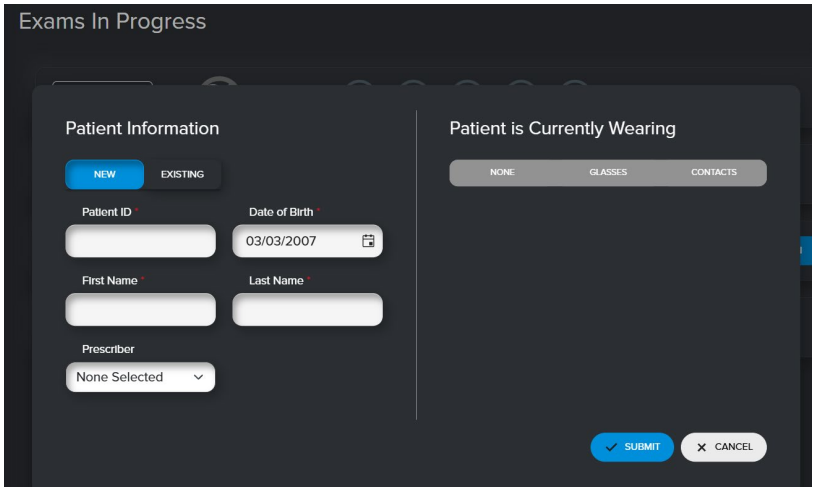

## 2. Exam in Progress

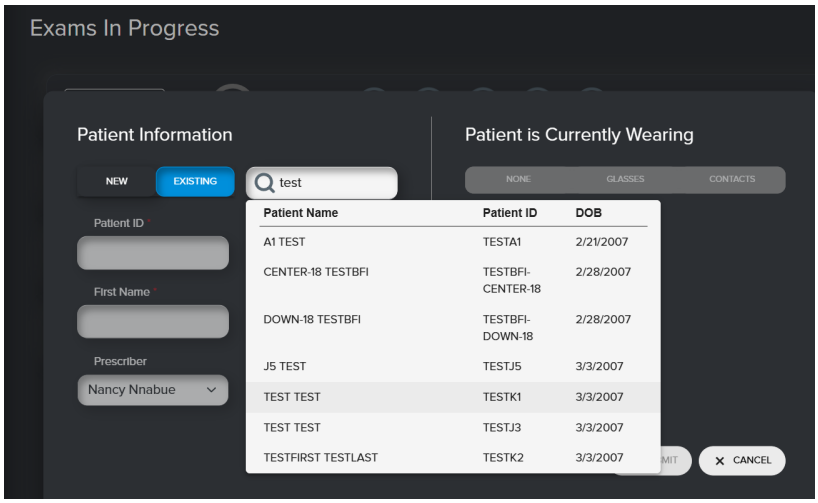


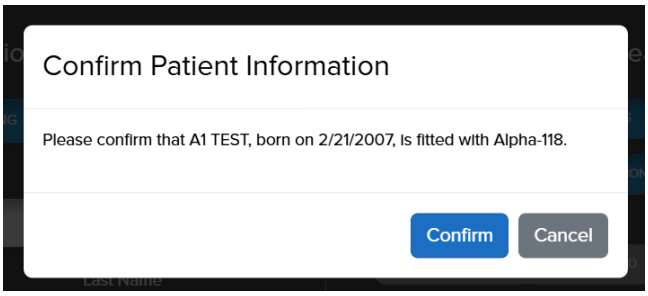

On the Run Patient dialog, specify the Patient Preferred Language and Closed Captioning option, then click **SUBMIT** button which will start the Headset Alignment and Eye Tracking Calibration steps on the device.

Meanwhile, create a new Patient Information or search for an existing patient.

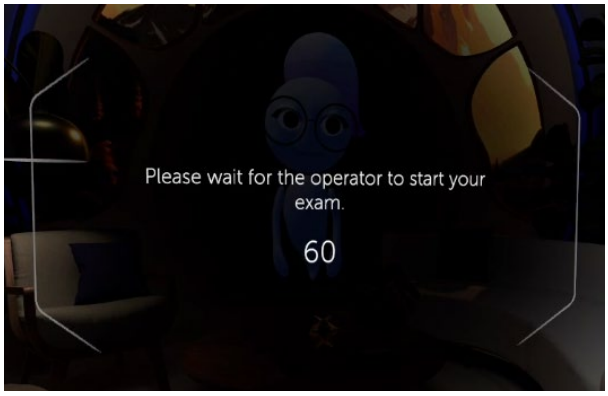


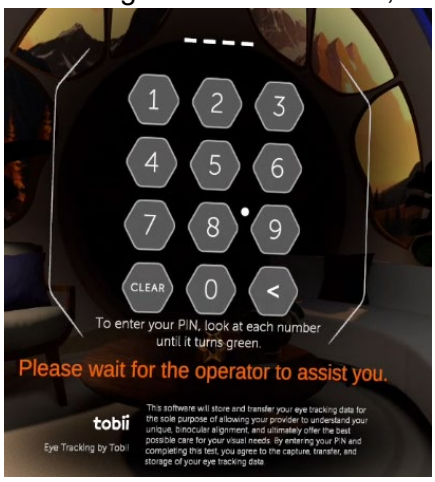

Once Patient Information is assigned, including the refractive correction that the patient is wearing, click the **SUBMIT** button and verify the following confirmation dialog. Click the **CONFIRM** button to continue. Once the Eye Tracking Calibration step is completed, the patient continues with the alignment measurement.




If the patient completes the Eye Tracking Calibration step before the Patient Information is submitted and confirmed, the device displays the following wait dialog with 60 seconds countdown.




If it takes longer than 60 seconds, the device displays the PIN screen.




If the user clicks the **CANCEL** button during the Patient Information dialog, as long as the patient remains with the headset on, the user has the option to resume the session by clicking the **RESUME SESSION**

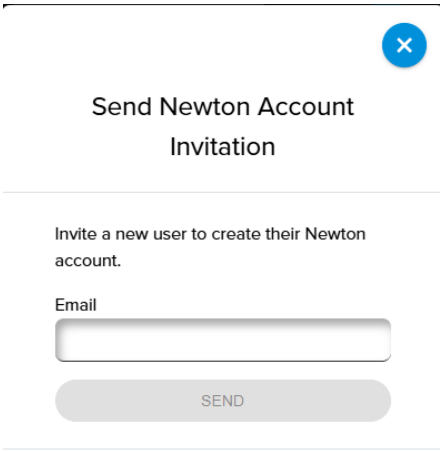
button on the Exam in Progress screen. On resume session, the patient does not have to repeat the calibration.

## 3.3 User Management

To invite a new Portal user, click on the **USERS**

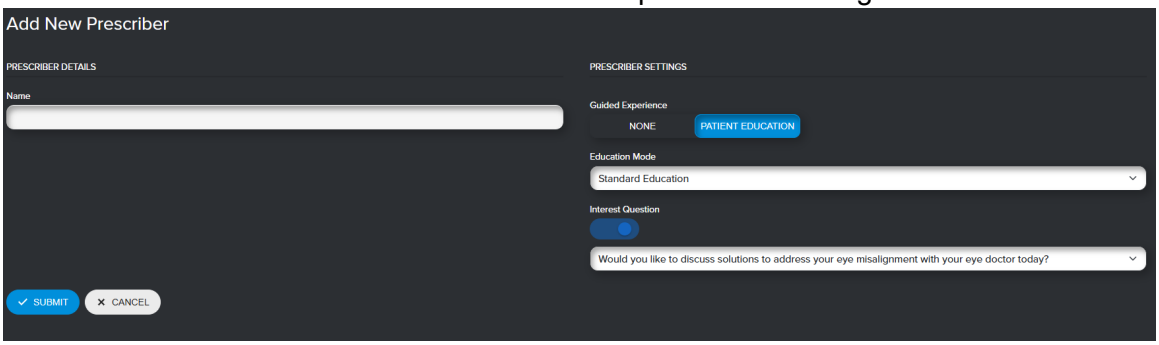
button on the Practice Profile screen, then the **INVITE NEW USER**

button to complete the following form:



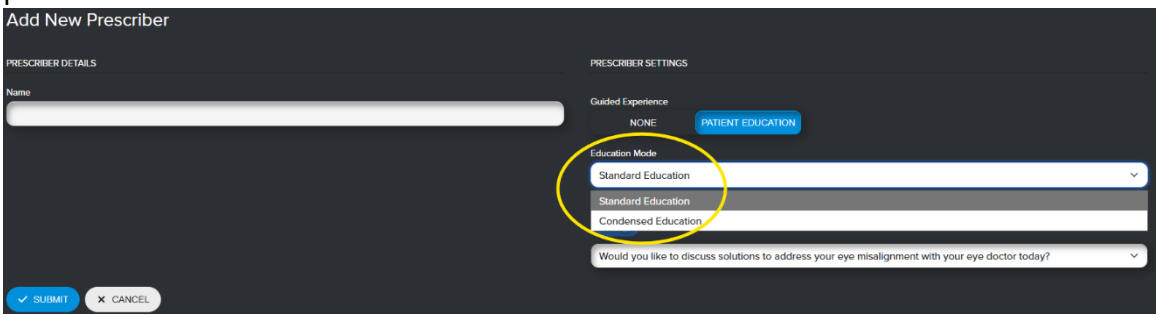

This INVITE NEW USER button is limited to Newton Admin users and practice with only legacy users with no previous access to Isaac portal (Newton, Inc learning platform product portal).

To add a new Portal Prescriber, click on the **PRESCRIBER SETTINGS** PRESCRIBER SETTINGS button on the Practice Profile screen, then the **ADD NEW PRESCRIBER** ADD NEW PRESCRIBER button to complete the following form:

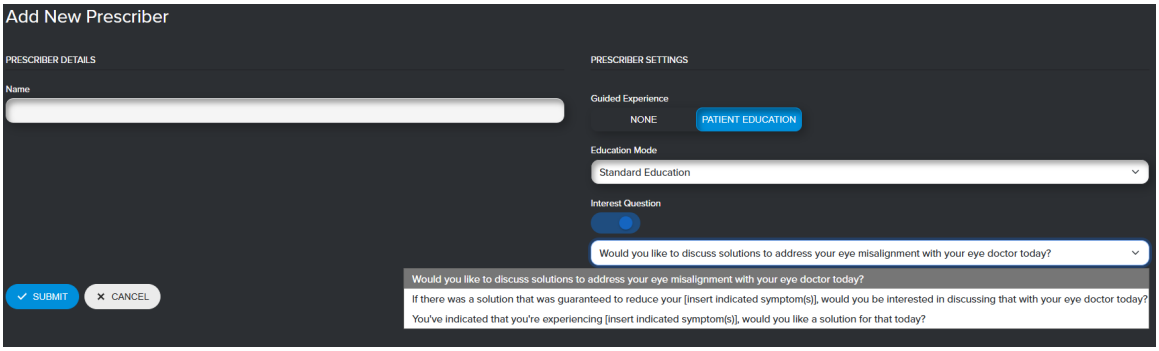



If the user is also a prescriber, it includes the following settings:

- **Patient Education**: the option to enable/disable the patient education after the alignment measurement on the device. There are two types of patient education, namely: Standard Education and Condensed Education. The Condensed Education option is only available if the NPC is enabled for the practice.



- **Interest Question**: the option to enable/disable interest question dialog after the patient education. This field is disabled if the Patient Education option is disabled. If the NPC is enabled, there will be more than one interest questions to choose from; otherwise, there will be only 1 option available.




# 4 System Warning Messages

| Warning Message | Possible Cause | Possible Action |
|---|---|---|
| Invalid PIN | Patient is inputting the wrong PIN. | Reiterate to the patient that they need to move their head to point to the right number and ensure the numbers above the keypad are the same as the PIN. |
| Duplicate Patient ID | A patient ID is input into the portal that has already been used. Each patient ID must be unique to that practice. | Search for the patient ID and ensure it is the desired patient, or enter a new patient ID. |

# 5 Troubleshooting

| Symptom | Possible cause | Solution |
|---|---|---|
| Measurement fails | Lens misalignment<br>Poor tracking<br>Patient correction is out of range | • Ensure the patient's pupillary distance is within the range of the measurement device 55-71mm<br>• If the patient is wearing spectacles, ensure the Rx is within the supported prescriptive range (+3 to -5 Spherical Equivalent)<br>• Ensure the patient does not have a condition, disease, or physiology that would prevent a measurement (see contraindications) |

| Symptom | Possible cause | Solution |
|---|---|---|
| Failed calibration | Patient cooperation<br>Poor tracking<br>Patient correction is out of range | • Remind the patient to keep their eyes wide open when not blinking and to track with the target.<br>• If the patient is wearing spectacles, ensure the Rx is within the supported prescriptive range (+3 to -5 Spherical Equivalent)<br>• Ensure the patient does not have a condition, disease, or physiology that would prevent a measurement (see contraindications) |
| Unable to align headset | Headset too loose<br>Unable to follow instructions | • Use the headset adjustment knob to tighten the headset around the patient's head until it stays in place when adjusting.<br>• Instruct the patient to hold the edges of the headset and move it up and down and/or tilt it so that they understand how the graphic interacts with the device movement. |
| Incorrect measurement results | Poor tracking | • Repeat the measurement and instruct the patient to keep his/her eyes wide open and try to not move during the measurement.<br>• Use pupil touch tracking during patient alignment. |
| Incorrect measurement results | Poor patient cooperation | • Repeat the measurement and remind the patient to look at the target.<br>• Continually instruct the patient to look at the dot or cross throughout the test. |
| Incorrect measurement results | Lens misalignment | • See Measurement fails/Lens misalignment above. |
| PIN doesn't work | $N^3$ not connected to internet<br>Patient PIN has expired. | • Verify the patient has an associated PIN by searching for the patient in the portal.<br>• Restart the headset and, if prompted, follow the WiFi setup instructions. |
| Unable to find patient on portal | $N^3$ not connected to internet | • Restart the headset and, if prompted, follow the WiFi setup instructions. |

Any serious incident or injury that has occurred in relation to the device should be reported to Neurolens (the manufacturer) and the competent authority of the Member State (EU) or FDA (US) in which the user and/or patient is established.

# 6 Glossary

| Name | Description |
|---|---|
| AC/A | Accommodative Convergence/ Accommodation (measured in prism diopters/diopters). The convergence response of an individual (the amount the eyes turn inward) about the amount of stimulus of accommodation (eye focusing). The normal ratio is 4:1. |
| Asthenopia | Symptoms of "eye-strain" including headaches, tearing, itching, burning, and blurred vision. |

| Name | Description |
|---|---|
| Binocular Fusion | The neural process by which the images in each retina are synthesized or integrated into a single percept. In normal binocular vision, this process occurs when corresponding (or nearly corresponding) regions of the retina are stimulated. This process can occur when the images are either in the central part of the retinae (central fusion) or the peripheral part of the retinae (peripheral fusion). |
| ESO | Inward deviation of the eye |
| EXO | Outward deviation of the eye |
| Fixation | The ability to aim the eye and hold that aim on an object, such as a word in a line of print. |
| Fixation Disparity | Over-convergence or under-convergence, or vertical misalignment of the eyes under binocular viewing conditions small enough in magnitude so that fusion is present. |
| Heterophoria | An eye condition in which the directions that the eyes are pointing at rest position, when not performing binocular fusion, are not the same as each other, or "not straight." |
| Phoria | The relative directions assumed by the eyes during binocular fixation of a given object in the absence of an adequate fusion stimulus. |
| Prism Diopters (Δ) | The amount of induced angle provided by a prism lens. P = 100*tan(d) where P is Prism Diopters and d is the deflection angle. One prism Diopter is equal to the amount of angular deflection that induces 1cm of deflection at 1m. |
| Pupillary Distance (PD) | The distance from the center of one pupil to the center of the other pupil. Used for proper positioning of eyeglass lenses in front of the eye. This measurement can be taken for distance viewing (far PD) or near viewing (near PD). |
| Strabismus | Strabismus, more commonly known as cross-eyed or wall-eyed, is a vision condition in which a person cannot align both eyes simultaneously under normal conditions. One or both eyes may turn in, out, up, or down. |

# 7 Guidance and Manufacturer's Declaration

## 7.1 Emissions

The nMD3 is intended for use in the electromagnetic environment specified below. The customer or user of the nMD3 should ensure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The $N^3$ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | The $N^3$ is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics IEC 61000-3-2 | Complies | |
| Flicker IEC 61000-3-3 | Complies | |

## 7.2 Immunity

The nMD3 is intended for use in the electromagnetic environment specified below. The customer or user of the nMD3 should ensure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| ESD<br>IEC 61000-4-2 | ±8kV Contact<br>±15kV Air | ±8kV Contact<br>±15kV Air | Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%. |
| EFT<br>IEC 61000-4-4 | ±2kV Mains<br>±1kV I/O's | ±2kV Mains<br>N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1kV Differential<br>±2kV Common | ±1kV Differential<br>±2kV Common | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips<br>IEC 61000-4-11 | >95% Dip for 0.5 Cycle<br><br>>95% Dip for 1 Cycle<br><br>30% Dip for 25/30 Cycles<br><br>>95% Dip for 250/300 Cycles | >95% Dip for 0.5 Cycle<br><br>>95% Dip for 1 Cycle<br><br>30% Dip for 25/30 Cycles<br><br>>95% Dip for 250/300 Cycles | Mains power quality should be that of a typical commercial or hospital environment. |
| Power Frequency 50/60Hz Magnetic Field<br>IEC 61000-4-8 | 30 A/m | 30A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |
| NOTE: UT is the a.c. mains voltage prior to application of the test level. | | | |
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>0.15 MHz-80 MHz<br>6 V[1)] in ISM between 0.15 MHz and 80 MHz[2)]<br>80 % AM at 1 kHz | 3 V<br>0.15 MHz-80 MHz<br>6 V[1)] in ISM between 0.15 MHz and 80 MHz[2]<br>80 % AM at 1 kHz | PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz | 3 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz | PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT |

## 7.3 Immunity to RF wireless communications equipment

The nMD3 is intended for use in the electromagnetic environment specified below. The customer or user of the nMD3 should ensure that it is used in such an environment.

| Test Frequency | Band [1] | Service [1] | Modulation [2] | Maximum Power | Distance | Immunity Test Level |
|---|---|---|---|---|---|---|
| MHz | MHz | | | W | Meters | (V/m) |
| 385 | 380 - 390 | TETRA 400 | Pulse modulation [2] 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 - 470 | GMRS 460, FRS 460 | FM [3] ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710<br>745<br>780 | 704 - 787 | LTE Band 13, 17 | Pulse modulation [2] 217 Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800 - 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation [2] 18 Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700 - 1900 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation [2] 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400 - 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation [2] 217 Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100 - 5800 | WLAN 802.11a/n | Pulse modulation [2] 217 Hz | 0.2 | 0.3 | 9 |

NOTE: If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[3] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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**Service Notice**

Read this manual thoroughly before performing service or maintenance on the $N^3$. This manual contains advanced troubleshooting, calibration, and maintenance instructions. All maintenance and repair work should be performed by qualified biomedical technicians who have received appropriate training and authorization to provide maintenance, repair, and service for the $N^3$.

## 1. Tools and Equipment

No user maintenance is required on the $N^3$ outside of precautions mentioned in section 1.11.3 Maintenance and care, and the patient facemask change mentioned in the section hereafter.

## 2. Patient Facemask Change Instructions

The patient facemask is the only component subject to replacement in the N3 based on regular wear and tear and repeated cleaning. In order to get a replacement patient facemask, contact your Neurolens or local Authorized Representative. To replace the patient facemask, follow the following steps:

Ensure the device is un-plugged and powered off.

Press on the side of the existing facemask first and firmly pull it apart from the headset, starting on the side, then the bottom, until it comes off the headset. Ensure the black insert is taken off as well, it will be reused with the new facemask.

Gently separate the black insert from the old facemask and attach it to the new facemask and ensure the mating point clips in properly.

Attach the New Facemask by pressing down on the two sides first until it clips in.

## 3. Software Update

The $N^3$ is subject to ongoing software updates. As such, to ensure this manual is up to date with the current software, please check Neurolens®'s website http://www.neurolens.com/n3-manual for updated versions of this document.

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