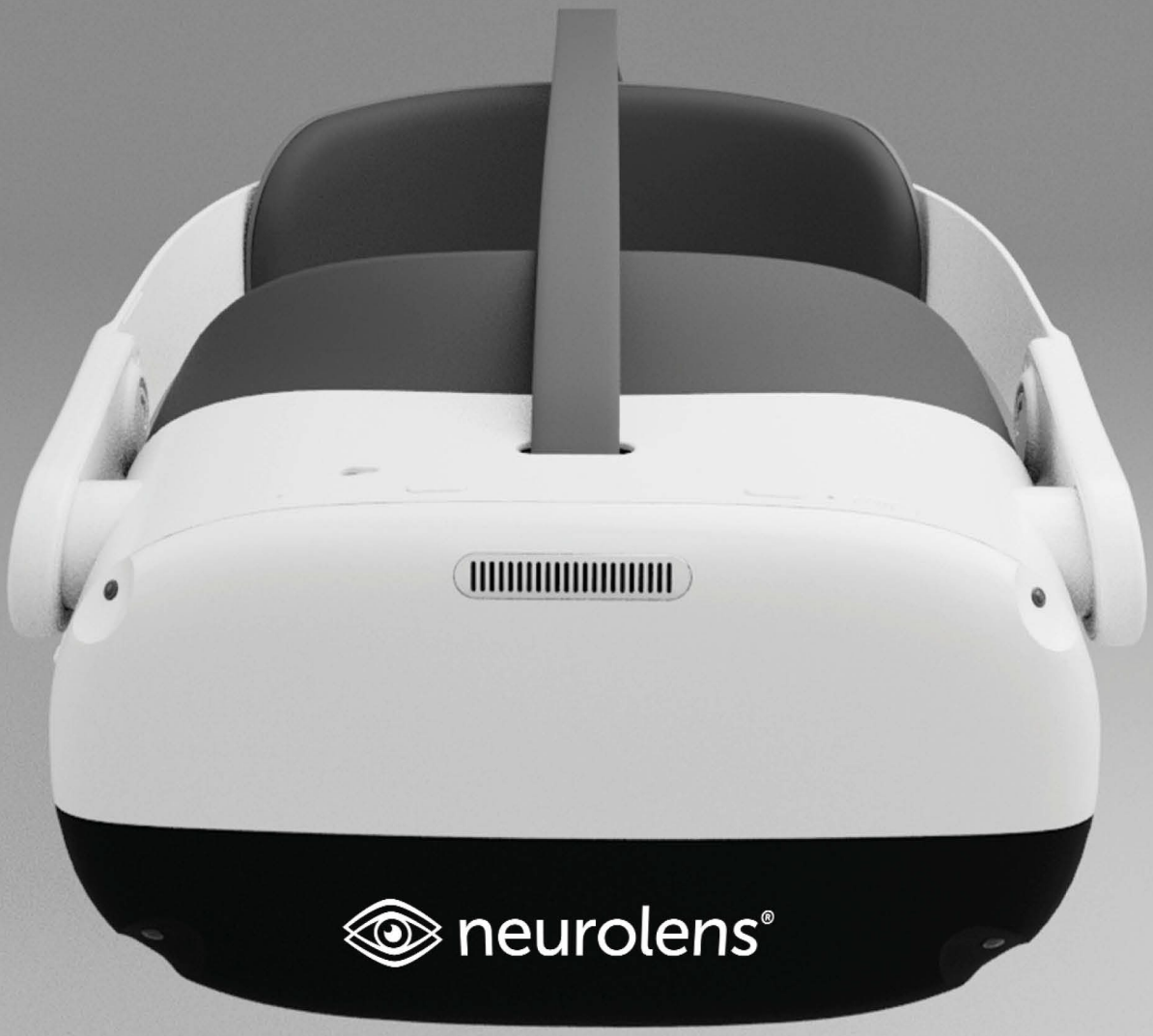
N3



USER MANUAL

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User's Manual

Model NMD3

neurolens® Measurement Device, N³

Neurolens®
1234 Lakeshore Dr, Suite 200
Coppell, TX 75019
888-236-2219
info@neurolenses.com
neurolens.com

nMD N^3 User's manual
P/N 90033 Revision 00

Neurolens®

neurolens® Measurement Device, N^3

Content subject to change without notice.

Please check Neurolens® portal portal.neurolens.com for updated versions of this document.

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)

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 lead to the danger of 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

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.**

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 may be 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**	▪ 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 N³, 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. op 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. o Epilepsy seizure, loss of consciousness, convulsions, involuntary movements, dizziness, disorientation, nausea, somnolence, or fatigue. o Eye pain or discomfort, eye fatigue, eye twitching, or visual abnormalities, (such as illusion, blurred vision, or diplopia) o Itchy skin, eczema, swelling, irritation or other discomforts. o Excessive sweating, loss of balance, impaired hand eye coordination, or similar motion sickness symptoms. ▪ 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 over tighten 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) 2400-2483.5MHz (WiFi), 5150-5350MHz (Indoor Only), 5470-5725MHz, 5725-5850MHz
RF Output Power	BT 9.84 dBm WiFi : 2400-2483.5MHz 20dBm, 5150-5350MHz (Indoor Only) 23 dBm 5470-5725MHz 23dBm 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.

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.

Neurolens® disclaims all liability for economic loss, loss of profits, overhead or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. Also, any implied warranty, including any warranty of merchantability or fitness for the particular purpose, is limited to one year. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

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
888-236-2219
accountmanagement@neurolens.com
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Table of Contents

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 N^3 is used to measure eye misalignment at distance and near. 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 should only be operated by properly trained clinical personnel, under the direction of a qualified eye doctor.

1.3 Overview

This document describes the features and functionality of the N^3.

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 N^3 is important in assessing patients who are being evaluated as part of a routine, comprehensive, and/or specialty vision examination.

The N^3 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 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 SE 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.
- A history of seizures or seizure disorder.

1.5 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.

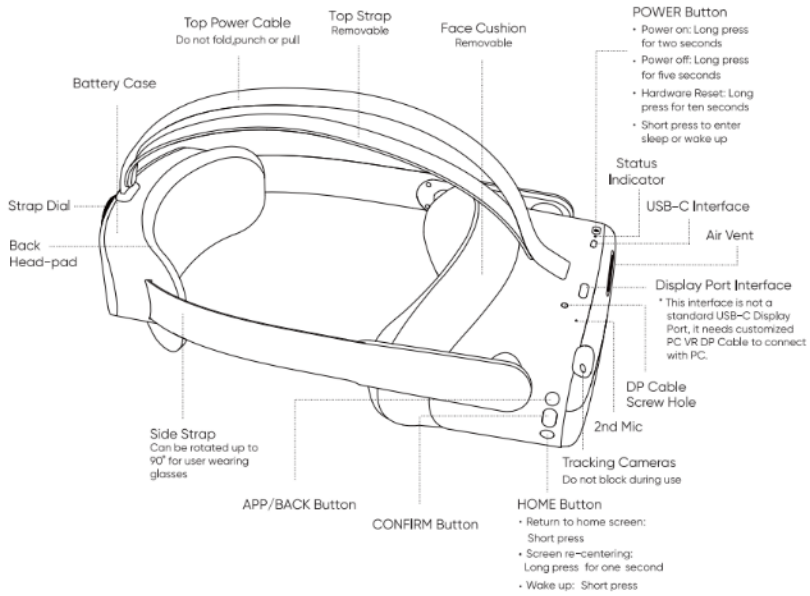
The N^3 is designed for use in indoor office environments.

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 N^3 does not provide any Essential Performance.

1.6 Components

In addition to the components shown in the diagram below there are the following detachable components:

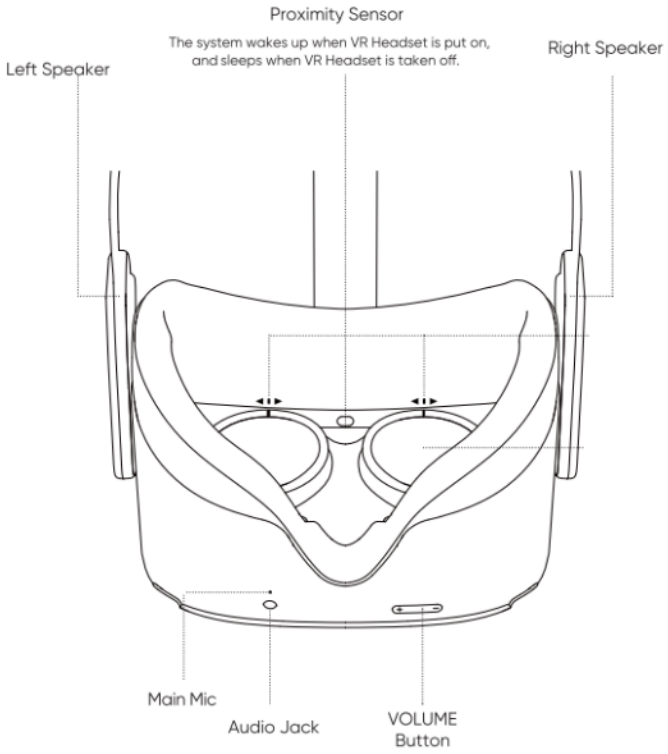
Power Supply
USB-USB-C cable
Facemask



VR Headset Status Indicator Legend

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

10



1.6.1 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.

1.6.2 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.

1.6.3 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.

1.6.4 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.

1.6.5 Imaging Optics

The **Imaging Optics** are used to both provide clear focus for the patient (1.7m) as well as focus the camera on the pupil plane of the patient for eye tracking.

1.6.6 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.

1.6.7 Illuminating LEDs

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

1.6.8 USB-C Port

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

1.6.9 Power Button

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

1.7 Preparations

1.7.1 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.

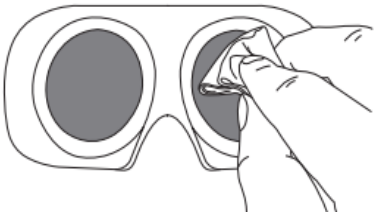
1.7.2 Connecting power (Charging)

- 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.

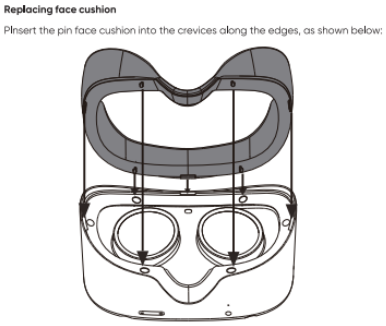
1.7.3 Maintenance and care

- 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.

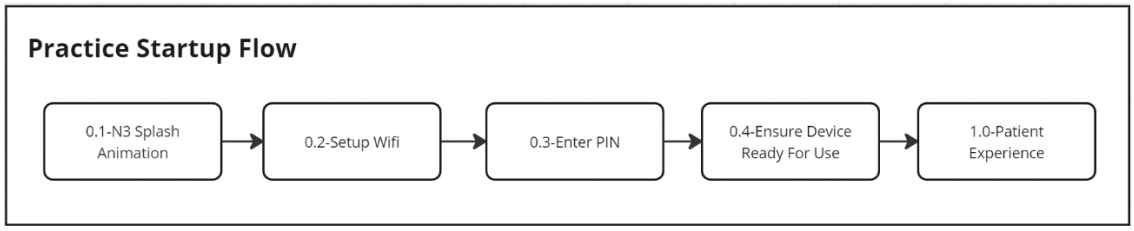


    - The external surface of the enclosure may be cleaned with an alcohol based cleaner, as necessary.

1.7.4 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

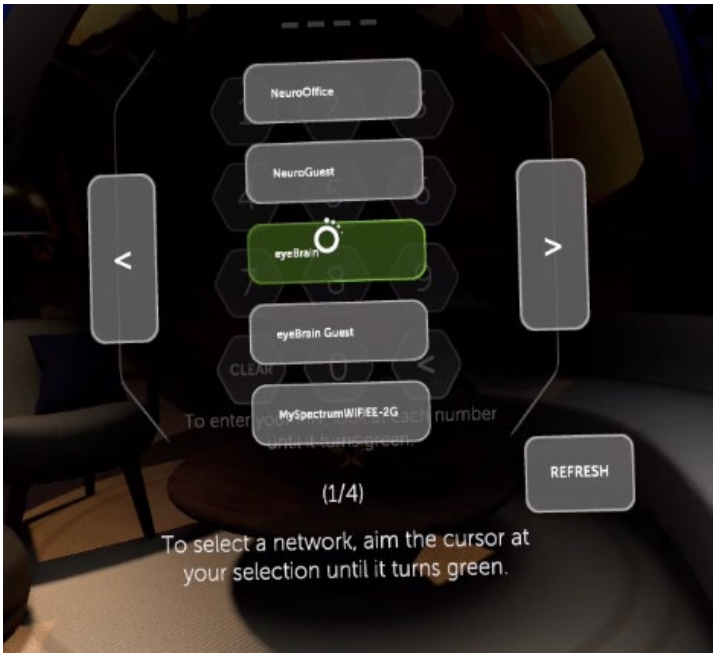
1.7.5 Setting up Wi-Fi

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.

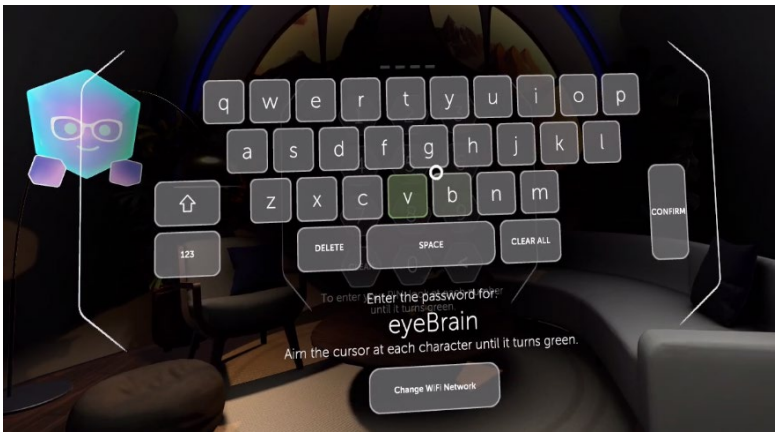
To make selections, the operator moves their head to direct the pointer and holds the pointer over the desired target until selected.

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

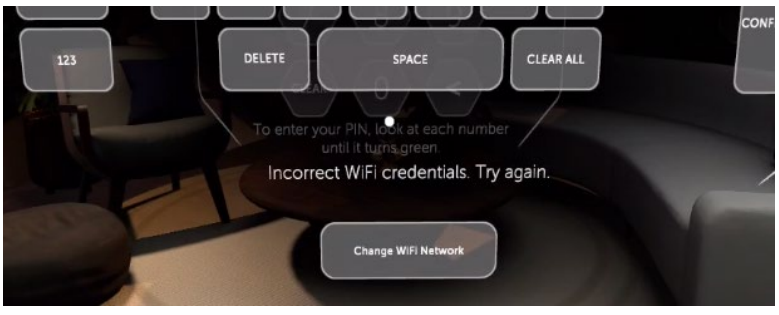
Select a network until it turns green.



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 “Wifi Connection Success”.

Once connected, the application will automatically resume.

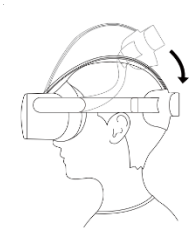
1.7.6 Device Setup and Training

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.

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.



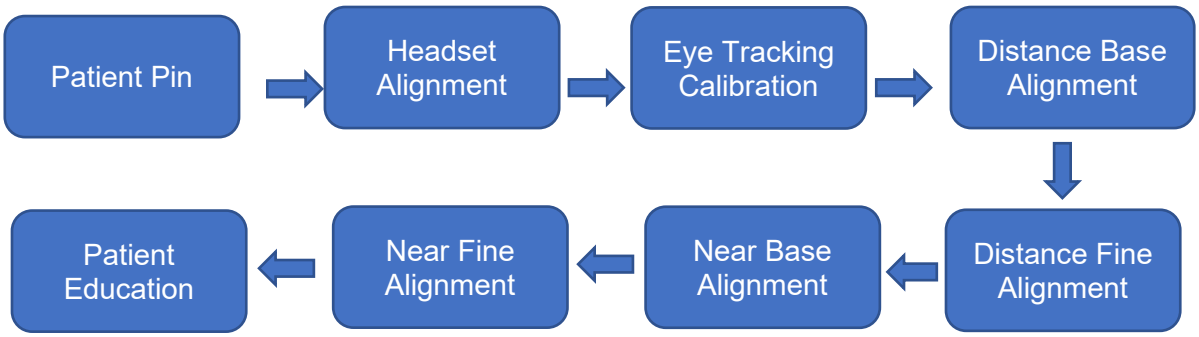
Warning	▪ WARNING: Do not over tighten head strap. Overtightening may lead to bruising, cuts, or discomfort from impinging corrective eyewear onto the patient.

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

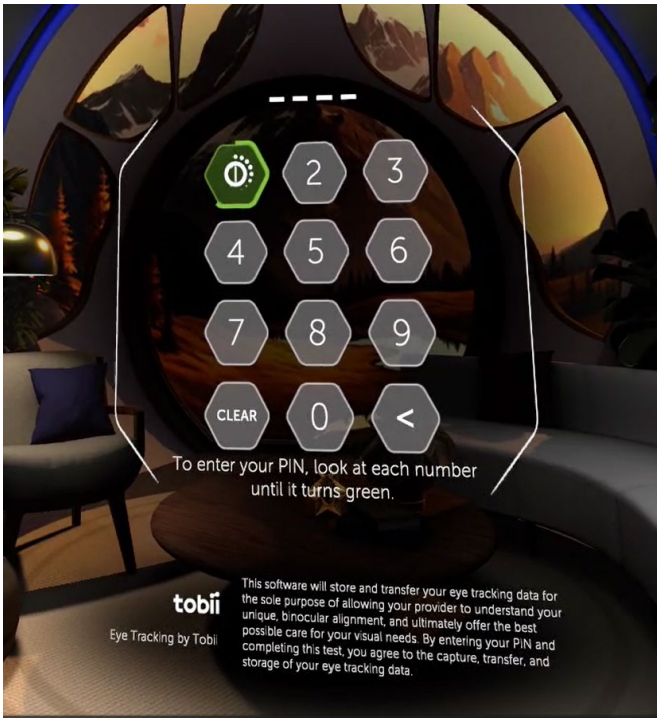
The Measurement Device is equipped with a sensor that detects when the headset is put on. Once a patient puts the device on it will automatically initiate a measurement. An avatar will show up and instruct the patient how to complete a measurement by going through the following steps.



2.2.1 Entering a PIN

After the eye tracking calibration is complete, the system will then 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 30 days.

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

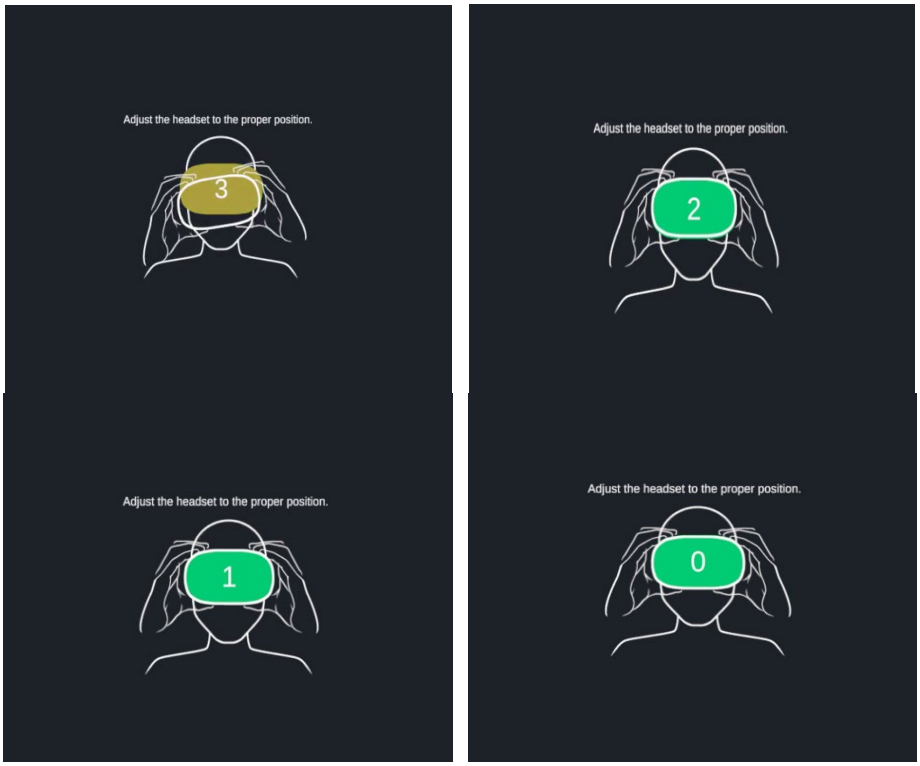
2.2.2 Headset Alignment

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 over tighten head strap. Overtightening may lead to bruising, cuts, or discomfort from impinging corrective eyewear onto the patient.

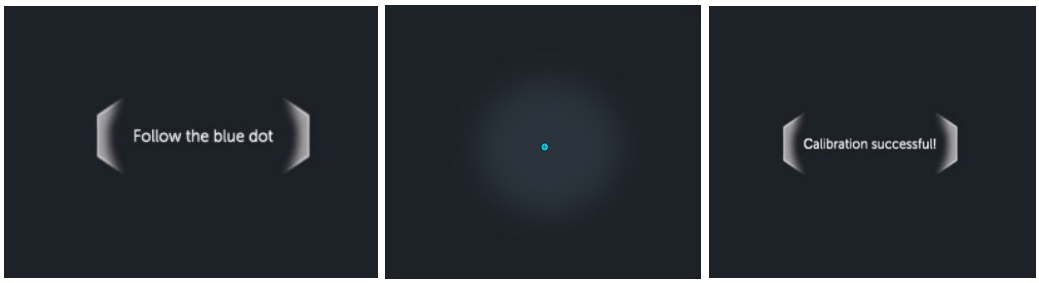


Headset Alignment Graphics

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.

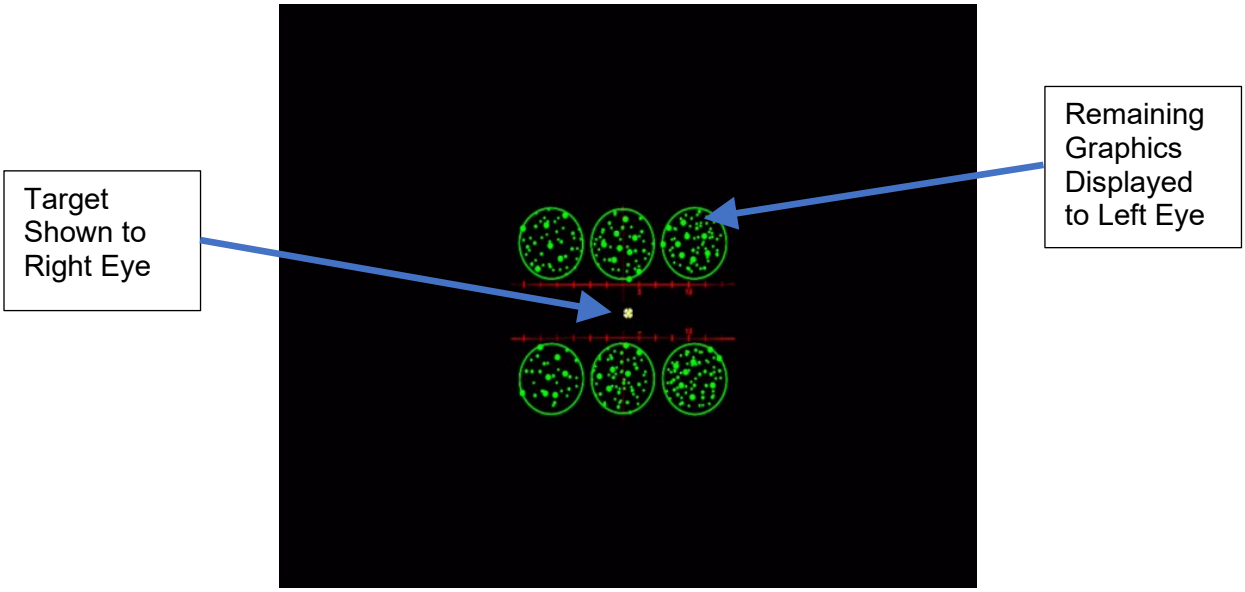
If the patient does not cooperate or the system is unable to track the patient's eyes, the system will notify the patient that the test is unsuccessful and instruct them to return the headset.



Eye Tracking Calibration Graphics

2.2.4 Distance Base Alignment

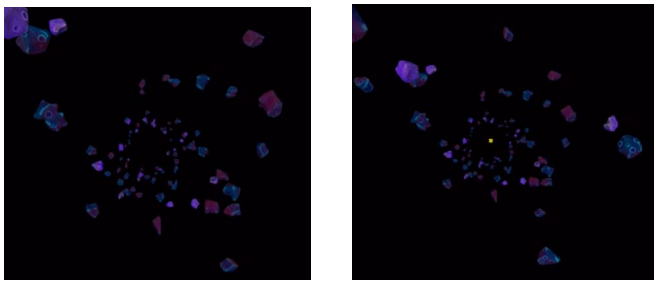
The system will automatically proceed from PIN input to Distance Base Alignment. Base alignment is most similar to a disassociated phoria measurement. The patient will be instructed to look at a target within the device. The target will be displayed only to the right eye, with the left eye being shown unrelated graphics. The disassociated left eye will be tracked, and the amount of deviation will be measured as the base alignment.



Distance Base Alignment Graphic

2.2.5 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.



Distance Fine Alignment Graphic

2.2.6 Near Base Alignment

The system will automatically proceed from Distance Fine Alignment to Near Base Alignment. This test is similar to the 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.

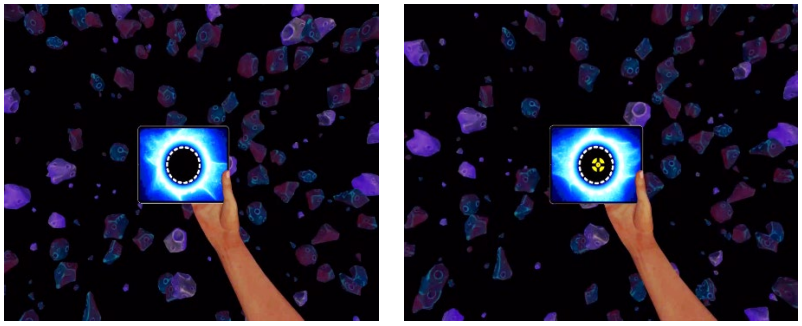
2.2.7 Near Fine Alignment

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.



Near Fine Alignment Graphic

2.2.8 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.

2.2.9 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 scheduled and assigned a pin for the patient to input during the measurement (See section 2.2.3).

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

3.1 Patient management

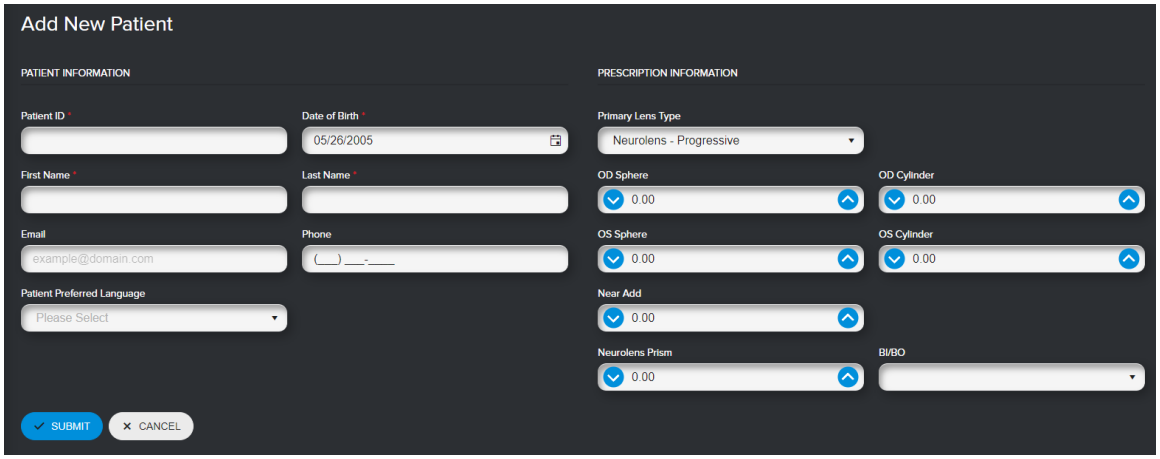
The device maintains a local database of patients containing the following information:

- **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.
- **Name**: the patient's first name.
  This field can be left blank.
- **Last**: 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.
- **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.

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

3.1.1 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.



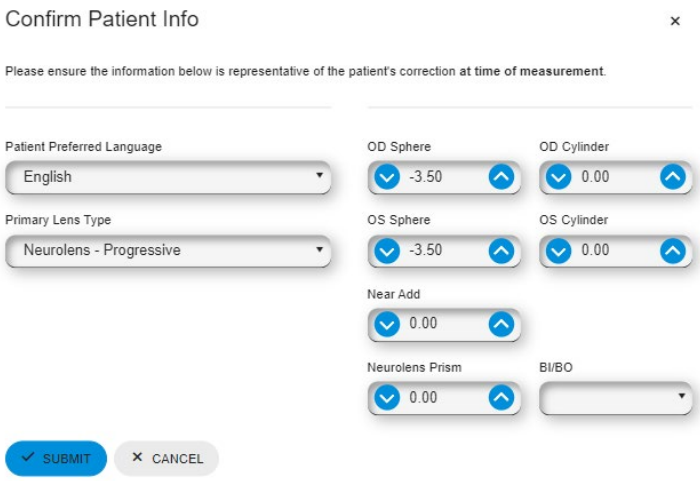
●	Make sure the patient's prescription data is correctly entered. Incorrect prescriptive information may lead to incorrect measurements.

The Following Information is Required:

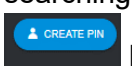
- Patient ID (A unique identifier for that patient)
- OD Sphere (the right eye distance sphere prescription for glasses)
- OD Cylinder (the right eye cylinder, axis is not needed)
- OS Sphere (the left eye distance sphere prescription for glasses)
- OS Cylinder (the left eye cylinder, axis is not needed)
- Date of Birth

3.1.2 Assigning a PIN

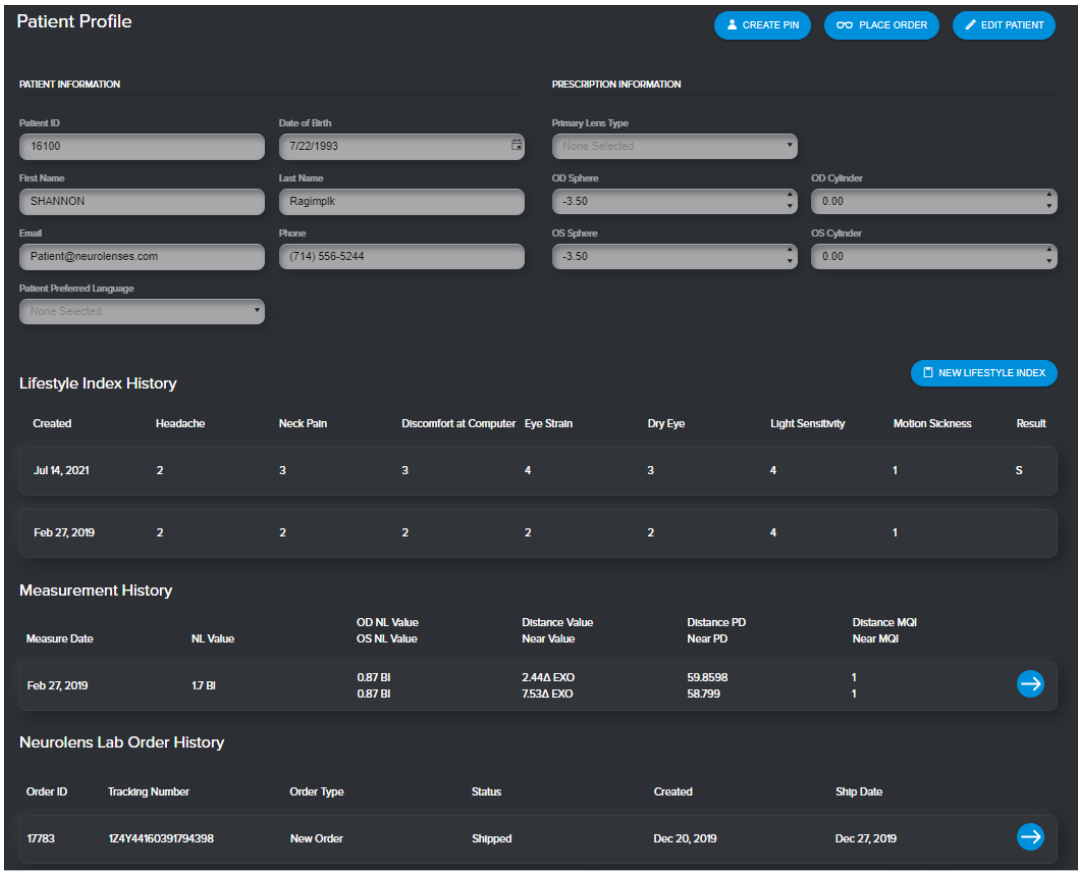
Once a patient's information is input into the portal the user can click SUBMIT. The user will be prompted as to whether they want to assign a PIN.



If a patient is in the database is saved without a PIN, a PIN can be assigned by searching for the patient (Section 3.1.3) and clicking on the **CREATE PIN**



button.



3.1.3 Searching for patients

The Patient Search screen will show all the patients that have been entered and scheduled for today's date. The patients can only be scheduled for future dates if entered via the online portal (see section 3).

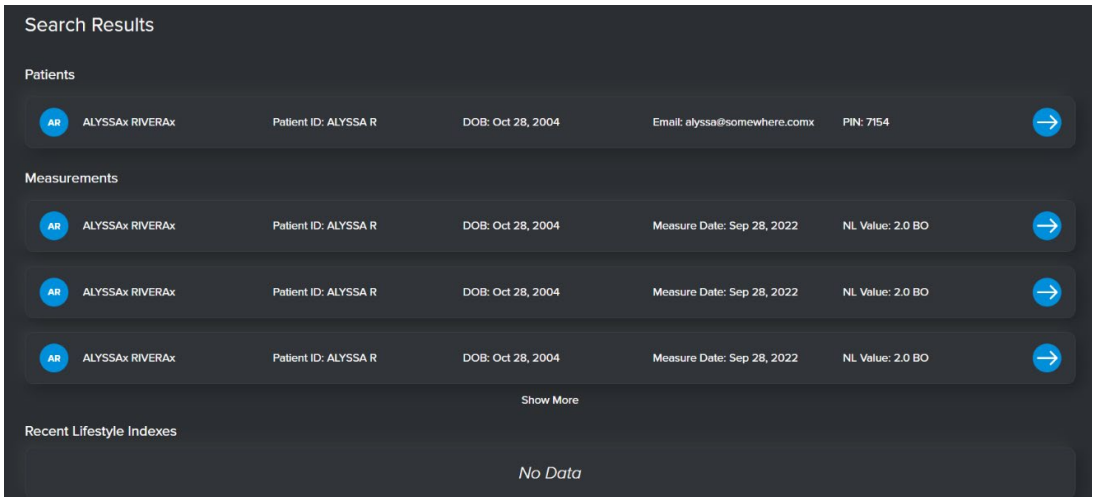
In the **Patient Search** screen, you can search for patients that have previously been entered into the portal by typing at least 2 characters of the:

- First Name
- Last Name
- Patient ID

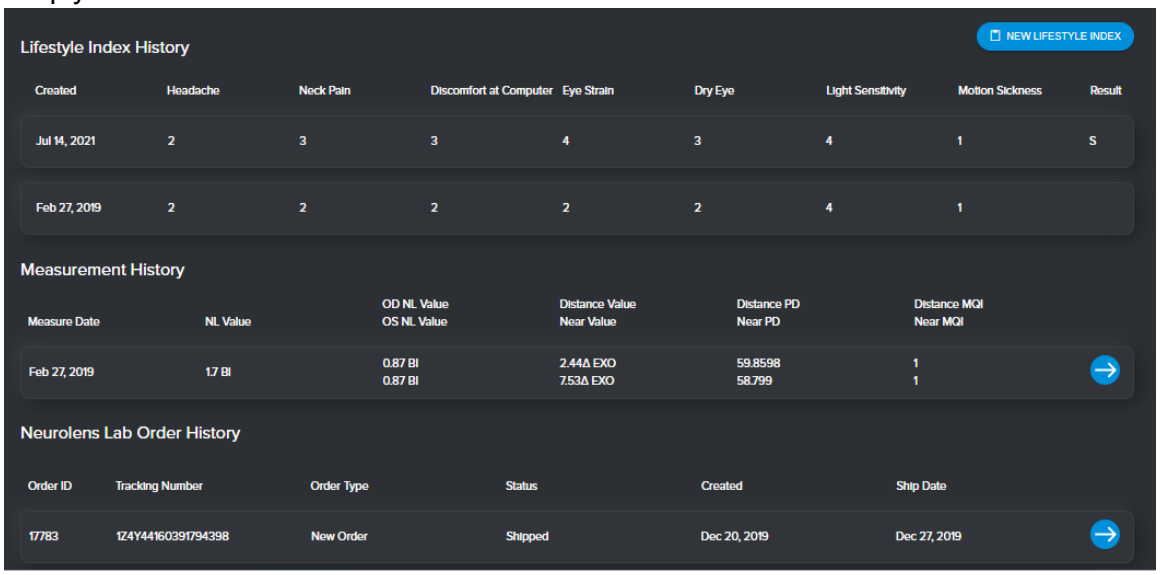
To start searching, click within the search field and type at least two characters. Note that the search is done on all fields and a word base, so, for example, you can type "Joh A," and the search will return "**Joh**n **A**shleigh," "**Joh**anna **A**mes" and "**A**ndrew **Joh**nson."

3.1.4 Accessing Measurements and Lifestyle Index

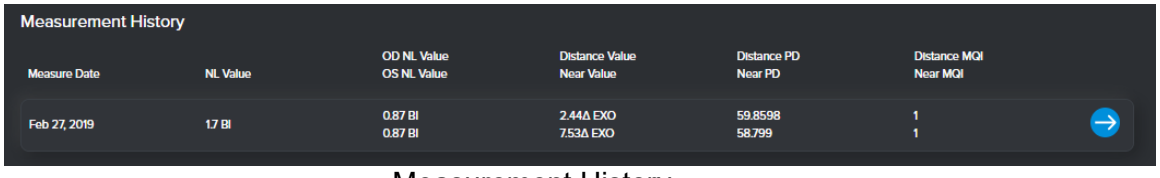
To access measurements, search for a patient according to 3.1.3 and select the patient that you wish to view the measurement.



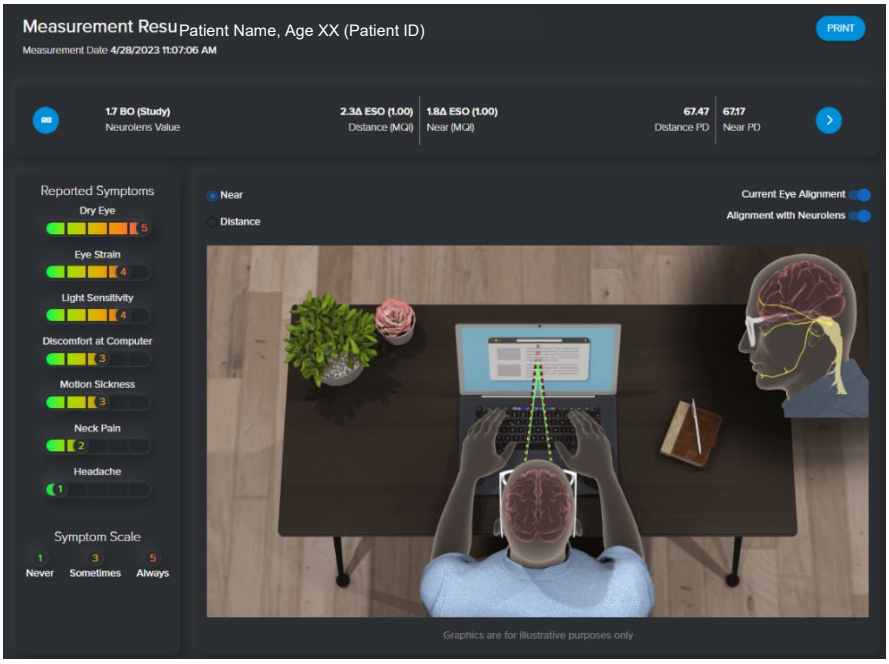
Once the patient is selected there will be their history of lifestyle indexes and measurements. To access the results of any of the measurements or indexes simply select the measurement of interest.



Lifestyle Index History

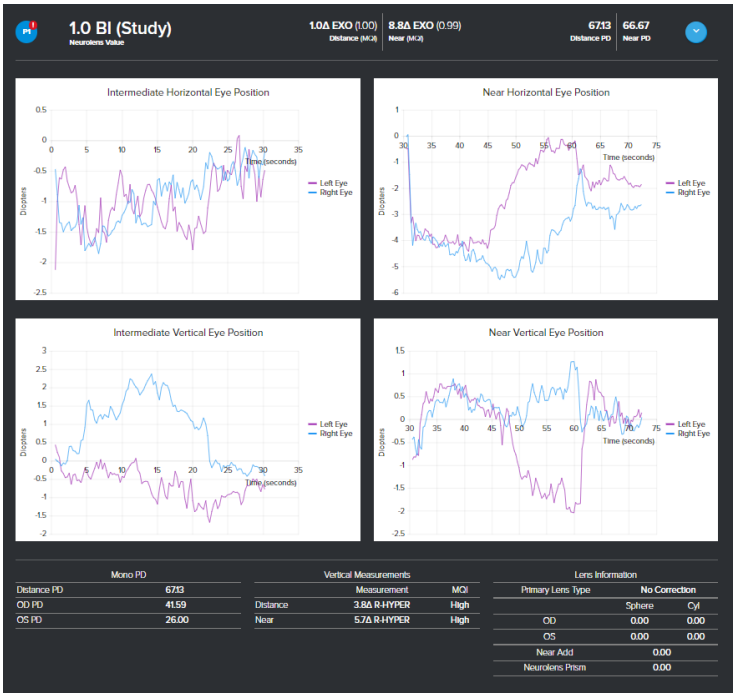


Measurement History



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.

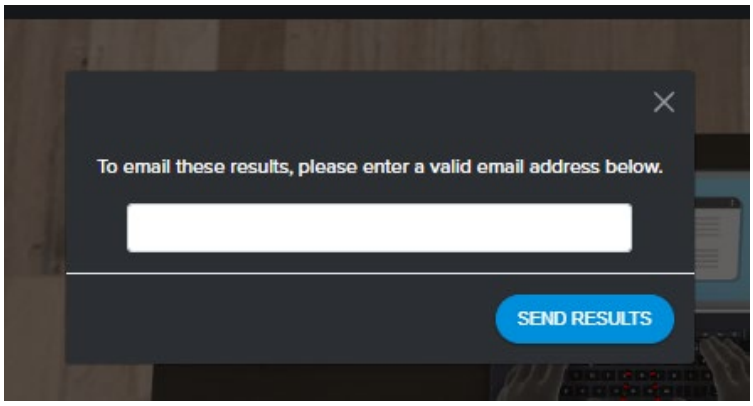


Measurement Details

3.1.5 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 

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3.1.6 Modifying patient data

The New/Edit Profile screens allow you to enter/update the patient's data. Click within any field to edit fields. To save, touch the arrow on the top left of the keyboard to minimize the keyboard and then click **Continue** to save the profile and begin a measurement. If you do not want to measure the patient, press **Cancel**, and it will take you back to the patient search screen. To go back without writing changes, touch the arrow on the top left of the keyboard to minimize the keyboard and then touch on **Cancel**.

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 Poor tracking Patient correction is out of range	• Ensure the patient's pupillary distance is within the range of the measurement device 55-71mm • If the patient is wearing spectacles, ensure the Rx is within the supported prescriptive range (+3 to -5 Spherical Equivalent) • Ensure the patient does not have a condition, disease, or physiology that would prevent a measurement (see contraindications)
Failed calibration	Patient cooperation Poor tracking Patient correction is out of range	• Remind the patient to keep their eyes wide open when not blinking and to track with the target. • If the patient is wearing spectacles, ensure the Rx is within the supported prescriptive range (+3 to -5 Spherical Equivalent) • 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 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. • 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. • 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. • 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 Patient PIN has expired.	• Verify the patient has an associated PIN by searching for the patient in the portal. • 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.

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.
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 N^3 is intended for use in the electromagnetic environment specified below. The customer or user of the N^3 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 nMD2 is intended for use in the electromagnetic environment specified below. The customer or user of the nMD2 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >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 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 IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V[1)] in ISM between 0.15 MHz and 80 MHz[2)] 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V[1)] in ISM between 0.15 MHz and 80 MHz[2] 80 % AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

7.3 Immunity to RF wireless communications equipment

The nMD2 is intended for use in the electromagnetic environment specified below. The customer or user of the nMD2 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
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [2] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [2] 18 Hz	2	0.3	28
1720 1845 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 5500 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.

2. 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 refer to the manual on the Neurolens Portal Library.

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