nMD2

neurolens® Measurement Device, Gen 2

neurolens®
Relief is in Sight

User's Manual

User's Manual

Model nMD

neurolens® Measurement Device, Gen 2

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nMD2 User's manual
P/N 90022 Revision A

neurolens®

neurolens® Measurement Device, Gen 2 (nMD2)

Content subject to change without notice.

Please check neurolens® portal portal.neurolenses.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.
- To ensure smooth operation, install the instrument on a level surface free of vibrations.
- Do not set anything on the instrument.
- Connect all cables properly before using and use proper cable routing to reduce the risk of tripping.
- Position the instrument so that the power switch at the rear panel is easily accessible to the operator.
- 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 1 Equipment, Continuous Operation

O OFF (Supply) - Indicates the Power Switch is set to OFF.

I ON (Supply) - Indicates the Power Switch is set to ON.

Alternating Current - Indicates that this instrument operates on alternating current.

Protective Earth - Indicates that a protective earth ground is connected where the symbol is located.

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 nMD2 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.
	Pinch Hazard. Keep hands clear of labeled location.

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 nMD2 is the subject of U.S. patents and other pending U.S. and foreign patents. Refer to https://www.neurolenses.com/patents/ **for a list of awarded US Patents related to the nMD2.**

This instrument features the following:

The nMD2 is an AC powered device (125/240 VAC; 10A; 50/60Hz) that converts to DC power through a medical grade power supply.

This Instruction Manual covers an overview of the basic operation, troubleshooting, checking, maintenance and cleaning of the nMD2.

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.
 **WARNING**	▪ To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth
 **WARNING**	▪ 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.
 **WARNING**	▪ 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.
 **WARNING**	▪ 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 nMD2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WORKING ENVIRONMENT

Temperature:	10°C-30°C
Humidity:	20-80% (without dew)
Atmospheric Pressure:	700hPa-1,060hPa

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.

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 or transport the instrument on a slope or uneven surface or in an area where it is subject to vibrations or instability.
(4) 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/10A
FREQUENCY: 50/60Hz
Mains voltage is disconnected through the appliance coupler in the rear of the system. It is recommended that the system be placed in a location with access to the appliance coupler (Labeled as power connector in section 1.6).

INGRESS PROTECTION RATING: IP20

WIRELESS PARAMETERS

Frequency Band	2.4 GHz ISM Bands 2.412-2.472 GHz, 2.484 GHz 4.9 GHz (optional band support for Japan only) 5.15-5.25 GHz (FCC UNII-low band) for US/Canada, Japan and Europe 5.25-5.35 GHz (FCC UNII-middle band) for US/Canada and Europe 5.475.725 GHz for Europe 5.725-5.825 GHz (FCC UNII-high band) for US/Canada
Data Transfer Rates	WLAN 2.4GHz: 11n: Up to 300Mbps(dynamic) 11g: Up to 54Mbps(dynamic) 11b: Up to 11Mbps(dynamic) WLAN 5GHz: 11n: Up to 300Mbps(dynamic) 11a: Up to 54Mbps(dynamic)
Media Access Control	CSMA/CA with ACK
Channel	2.4GHz: 1-13 (14 only for Japan) 5GHz: 36-48 149-165
Channel Spacing	5MHz

Spreading / Modulation	802.11a/g/n: OFDM: BPSK, QPSK, 16-QAM, 64-QAM - DSSS: DBPSK, DQPSK, CCK 802.11b: CCK(11, 5.5Mbps), DQPSK(2Mbps), BPSK(1Mbps)
RF Output Power	802.11a: Typical 15 dBm at 54M / 19dBm at 6M +- 2dBm 802.11b: Typical 19dBm +/- 2 dBm 802.11g: Typical 16 dBm at 54M / 19dBm at 6M +- 2dBm 802.11n 5G HT20: Typical 12 dBm at MCS23 / 18dBm at MCS0 +/- 2dBm 802.11n 5G HT40: Typical 11 dBm at MCS23 / 17dBm at MCS0 +/- 2dBm 802.11n 2.4G HT20: Typical 14 dBm at MCS23 / 18dBm at MCS0 +/- 2dBm 802.11n 2.4G HT40: Typical 11 dBm at MCS23 / 17dBm at MCS0 +/- 2dBm The two chain combined output power equals to single chain power plus 5dB (2Tx = 1Tx + 5dB).

CABLES

The power cable specified for use with the nMD2 is Qualtek P/N 233008-06. The Wi-Fi antenna specified for use with the nMD2 is Vox Micro P/N WAND5DBI-SMA. Regulatory Compliance has been satisfied using this cable and this Wi-Fi antenna. The use of a different a/c power cable and/or different Wi-Fi antenna may affect compliance.

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 nMD2 should only be performed by neurolens®, Inc. service personnel.
(2) The nMD2 should not be serviced while in use with a patient.

Limited Warranty
neurolens® warrants that the nMD2 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.

The warranty for repairs is 90 days for labor and one year on the part(s) that was replaced.

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

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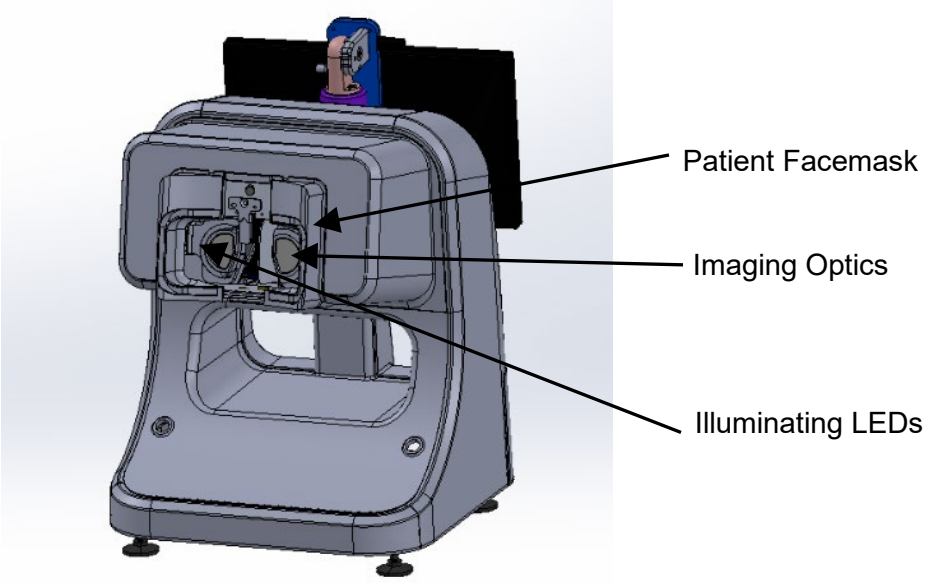
1234 Lakeshore Dr, Suite 200
Coppell, TX 75019
888-236-2219
info@neurolenses.com
neurolenses.com

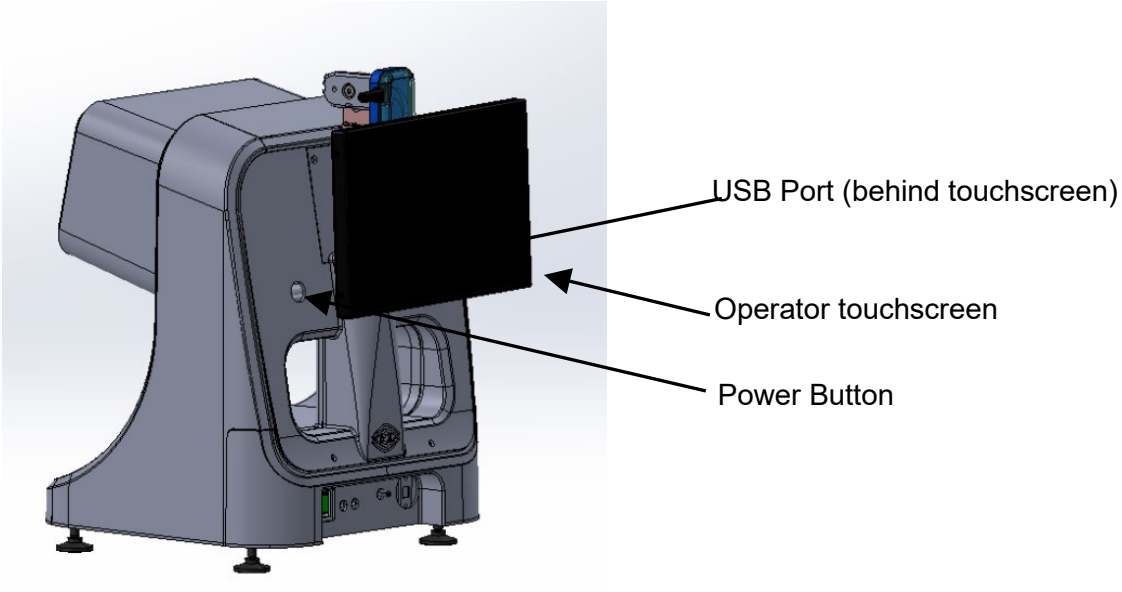
Table of Contents

1 Introduction and Intended Use

1.1 Introduction

The nMD2 is a microprocessor-controlled system 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.





Integrated safety and self-diagnostic features check system functions at start-up and during operation. Visual indicators report any errors.

The nMD2 uses an eye tracking system along with a stereoscopic display to measure eye alignment at distance and at near. From this information, a nMD2 number is calculated which is to be used 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 nMD2. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

1.2 Intended Use

The nMD2 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 nMD2 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 nMD2.
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 nMD2 characterizes how a person's eyes work together at distance and near by measuring eye alignment at a simulated distance of 6m 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 nMD2. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

1.4 Contraindications

Contraindications for using the nMD2 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.
- Use of contact lenses during testing.
- 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 +6D or Myopia greater than -9D of SE correction at distance.
- BCVA of 20/80 or worse in either eye
- Open lesions or sores around the chin 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 nMD2 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 nMD2. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

The nMD2 consists of a stereoscopic display, accommodating optics to simulate the refractive test distances 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 (6m) 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 each eye independently and the gross alignment value is a combination of the measurements.

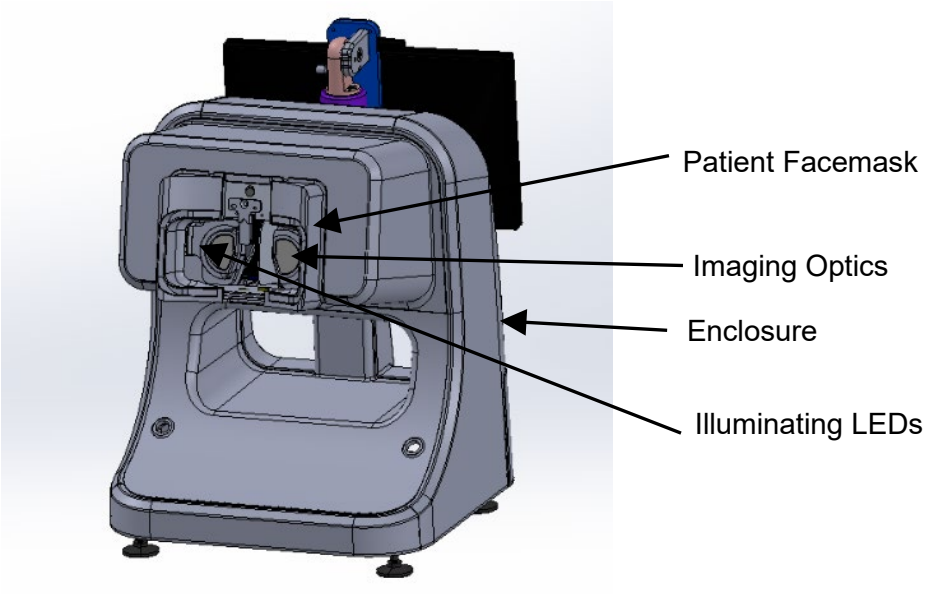
Once the patient's natural phoric posture is determined, the system presents a moving peripheral fusible image binocularly at the patient's phoric posture while instructing them to look at a fixation target which is presented to one eye at a time. This fixation target will iteratively move to neutralize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

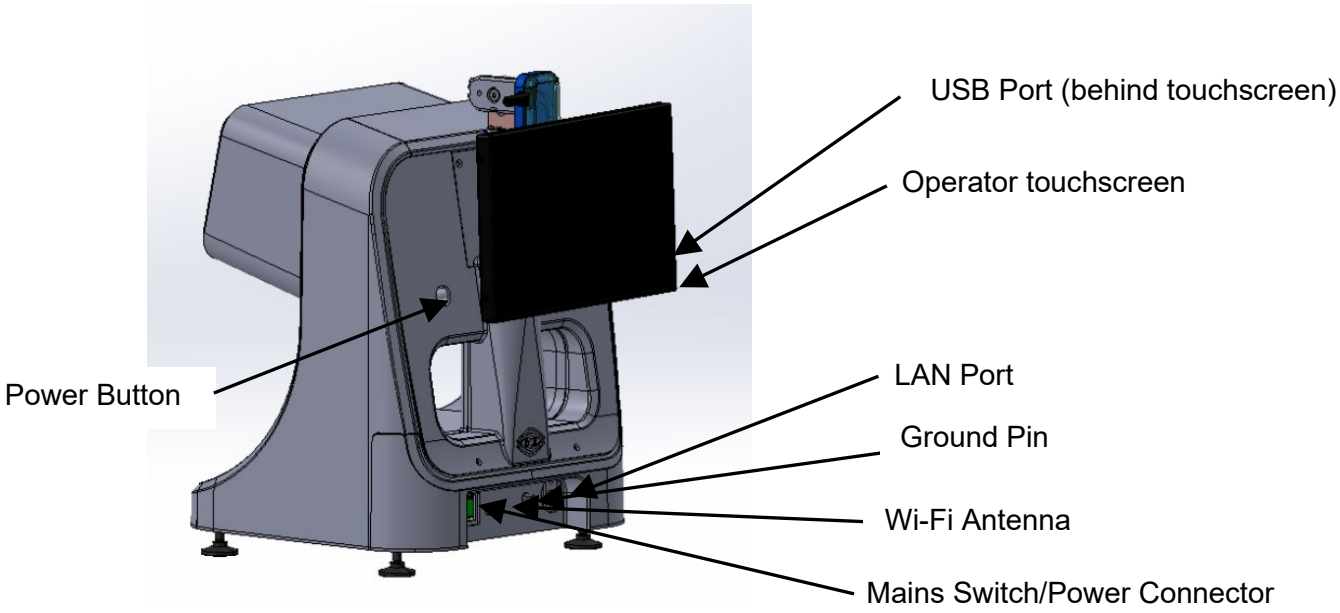
By incorporating a distance and a near measurement, a patient's accommodative convergence response is calculated, and an accommodative convergence to accommodation ratio (AC/A) is reported in the results of the device, along with a distance and near misalignment.

The nMD2 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 nMD2 does not have any Essential Performance.

1.6 Components





1.6.1 Calibration card (not shown, detachable)

The **Calibration card** is a special card simulating a pupillary distance of 63mm that is placed, in front of the face mask, during device startup for initial calibration verification. The device verifies that it can properly measure the card to validate its calibration before it allows use.

1.6.2 Patient Facemask

The **Patient Facemask** is a silicone piece 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.

1.6.3 Imaging Optics

The **Imaging Optics** are used to both simulate the desired focal distance to the patient as well as focus the camera on the pupil plane of the patient for eye tracking.

1.6.4 Enclosure

The **Enclosure** protects the user and patient from accessing internal components and shall only be removed by trained neurolens® personnel. The patient may contact the enclosure as it is an equivalent applied part.

1.6.5 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.

1.6.6 USB Port

The **USB Port** is restricted to connecting a keyboard, mouse or memory stick only. Only connect periphery components upon instruction from neurolens® service personnel.

1.6.7 Operator touchscreen

The **Operator touchscreen** provides the graphical user interface to control the device. All the device features are controlled through touch on this screen, which can be tilted and rotated to allow the operator a comfortable position that does not interfere with the patient measurement.

1.6.8 Power Button

The **Power Button** is used to start the device and can be used to turn it off if the user interface becomes unresponsive. A brief press initiates the SW shutdown process while pressing and holding the button for five seconds turns off power and works even if the software is in an unresponsive state.

1.6.9 LAN Port

The **LAN Port** supports an RJ 45 connector for connecting to a network via a hardwire cable (CAT-5, CAT-6, CAT- 7).

1.6.10 WiFi Antenna

The **WiFi Antenna** is to maintain WiFi signal strength to the system when utilizing WiFi for network connectivity.

1.6.11 Mains Switch/Power Connector

The **Mains Switch/Power Connector** is the primary power input to the nMD2. Disconnecting the power connector and/or turning off the mains switch will remove all power from the nMD2.

1.7 Preparations

1.7.1 Installation

- The nMD2 should be installed in an office environment, away from direct sunlight.
- To ensure smooth operation, the device should be set on a level surface that is free of vibrations.

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

- All cables should be properly connected before using. Make sure you are using power at rated voltage.
- 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.

WARNING To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth ground

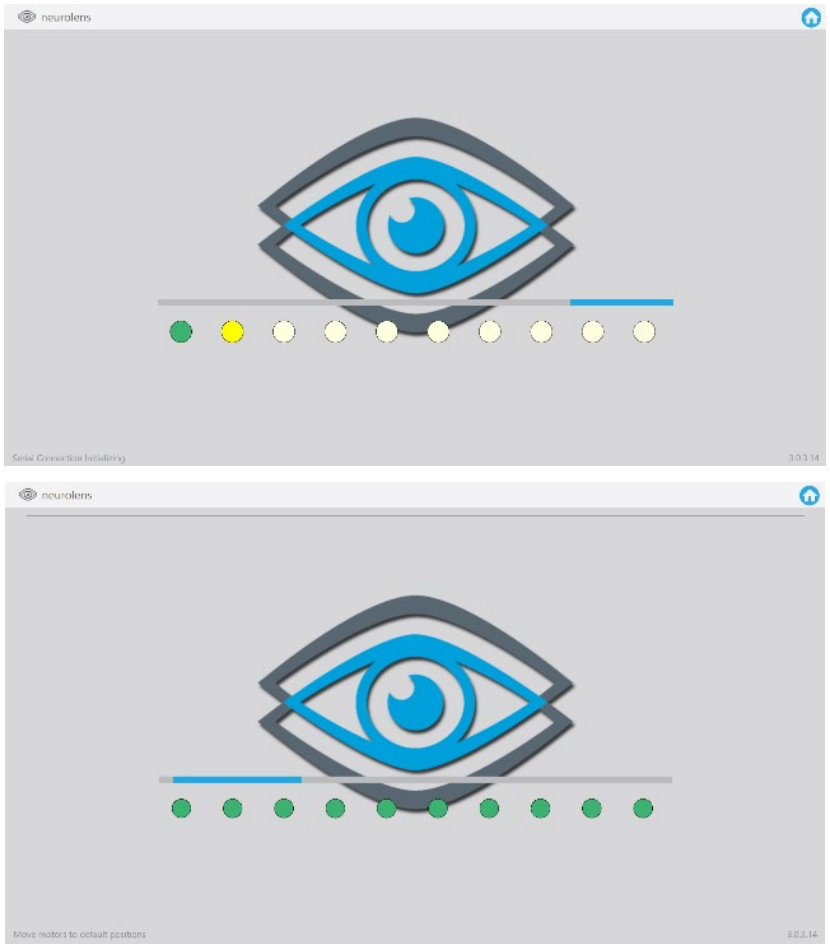
1.7.3 Maintenance and care

- 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. Wipe gently with a microfiber cloth and/or alcohol-based lens cleaner.
    - Wipe the eye mask with alcohol wipes between every patient.
    - The external surface of the enclosure may be cleaned with alcohol based cleaner, as necessary.
    - The touch screen may be cleaned with a lint-free cloth or microfiber. If necessary, you may dampen the cloth with water or alcohol-based lens cleaner. Do not apply liquid directly to the screen.

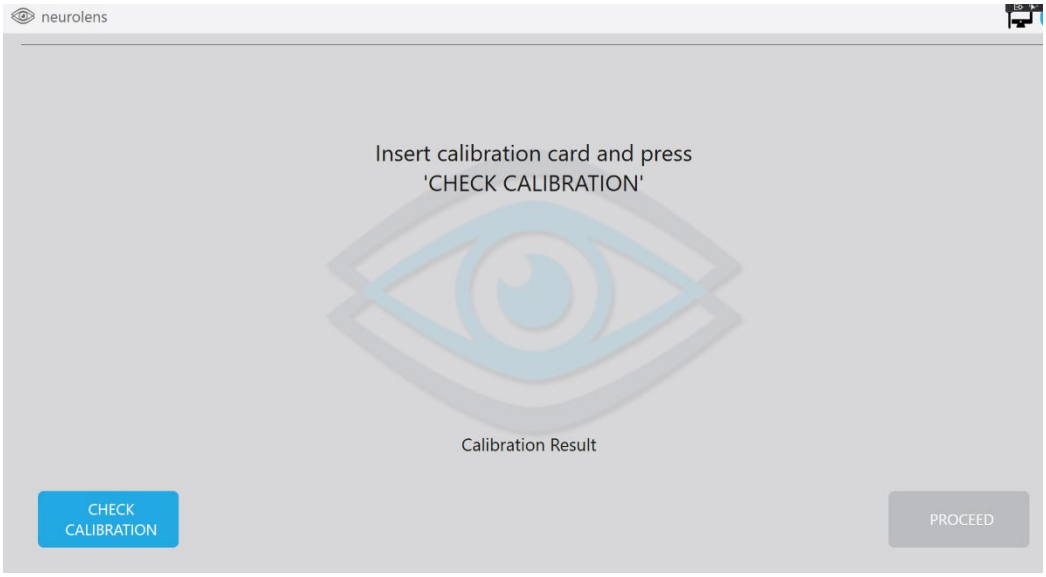
1.7.4 Calibration

Upon startup, nMD2 performs a calibration check procedure to ensure its measurements are accurate.

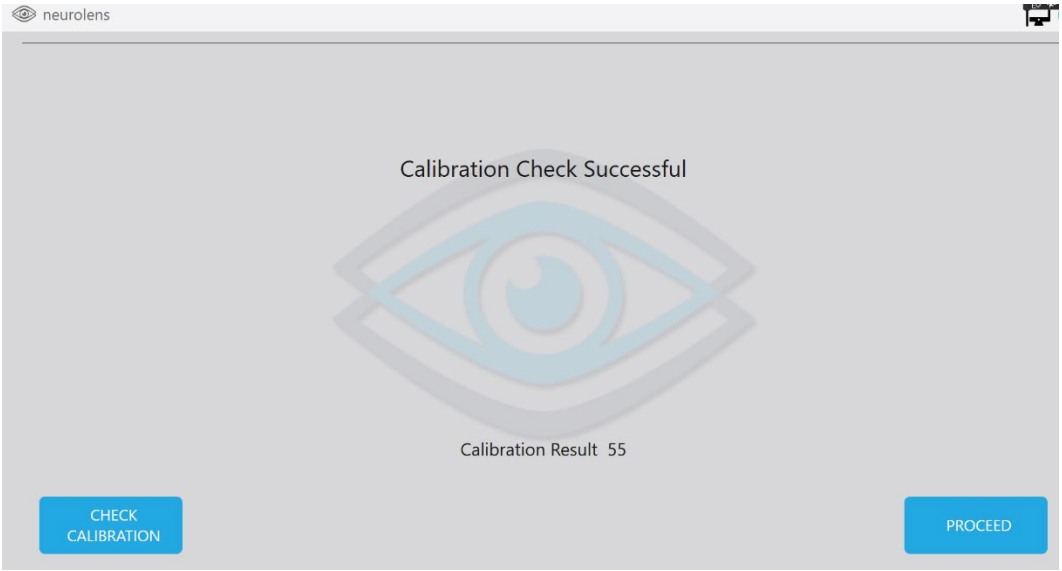
After the power button is pressed, the device shows the splash screen and initializes the system peripherals and performs a system check. As the system progresses through the startup systems check a series of green and yellow dots will display. If one of the dots turns red, it means the system check failed. Reboot the system and if the issue persists, contact neurolens® customer service.



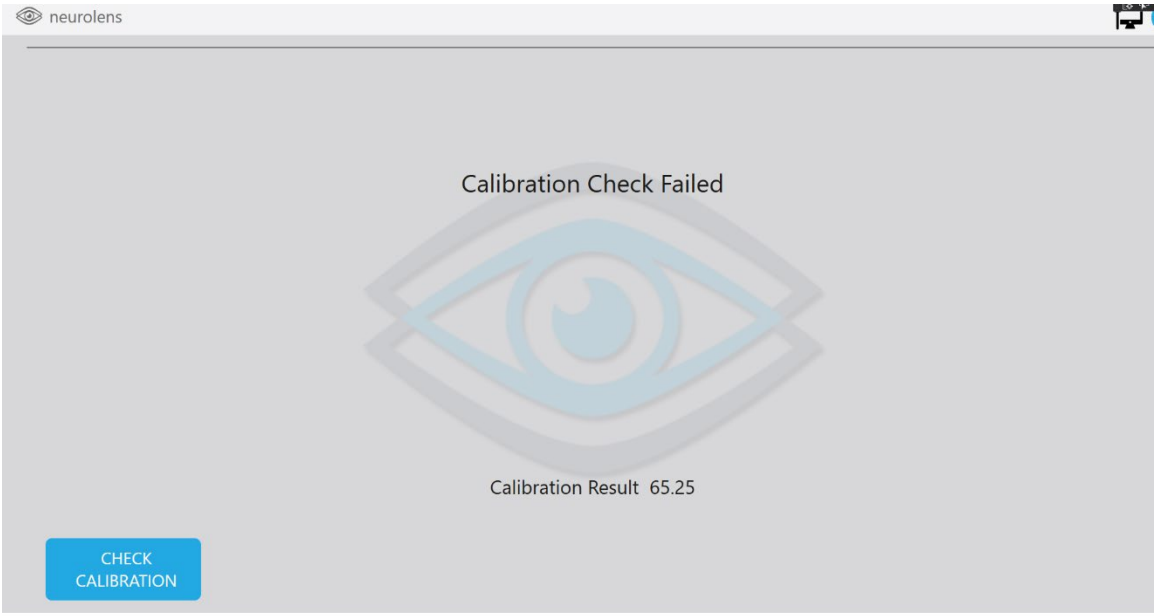
Once the initialization completes, the device pauses so you can make sure the calibration card is in place. After the calibration card is placed, touch **Check Calibration** to continue.

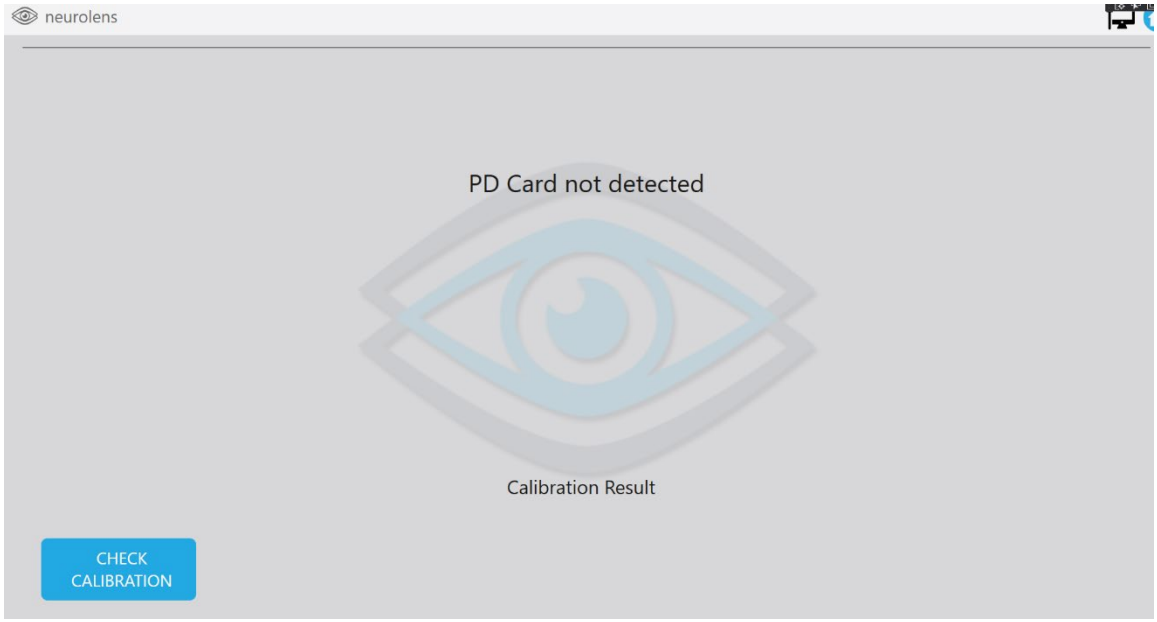


The device proceeds to measure the calibration verification tool. If the measurement succeeds, the device shows the results of the calibration check. Touch **Proceed** to start using the device.



If the calibration fails, you must redo the calibration check before proceeding. The system will indicate whether the calibration card is present and will remind the user to put the calibration tool on the device, or will indicate the failure and state the value of the failed measurement. Upon failure, the **proceed** button will be disabled until the system passes calibration check. If the calibration check continues to fail, clean the lenses and the calibration tool with optical cleaning fluid and try again. If it continues to fail, contact neurolens® customer support.

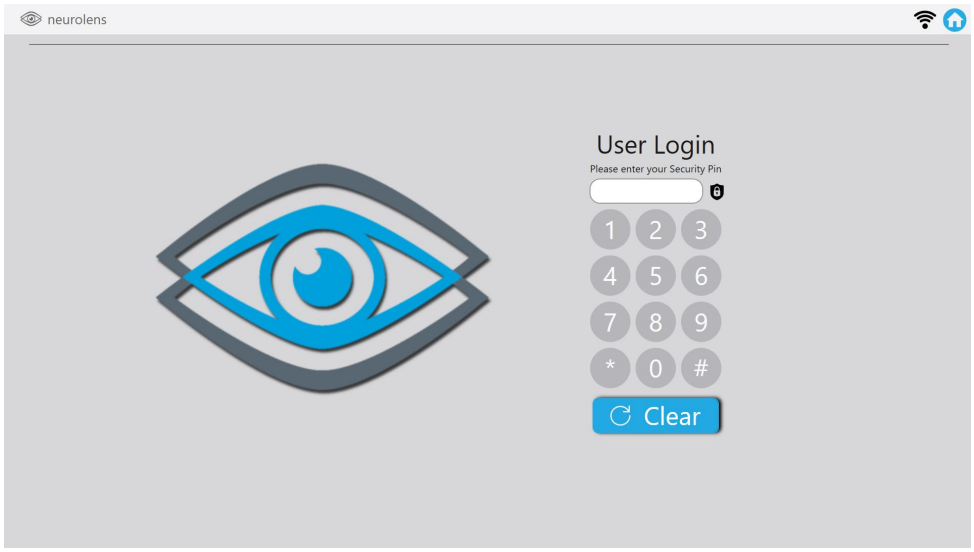




Once the calibration succeeds, you can click proceed to continue to the Login screen.

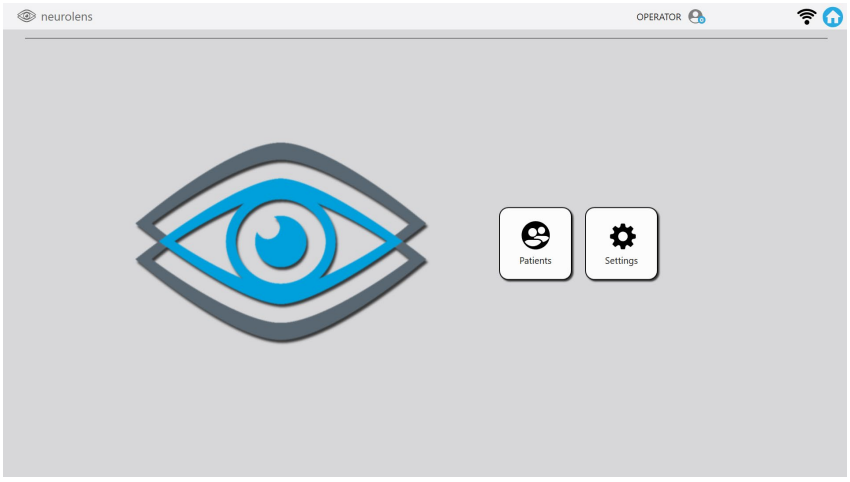
1.7.5 Login

Use of the device is protected by a 6-digit PIN code that is assigned upon delivery. To gain access to the User Interface, the operator must enter the PIN before use and whenever the device is inactive for more than 3 minutes.



Touch the numeric buttons to enter the 6-digit PIN. If the PIN is correct, the device will proceed to the Home screen. If it is incorrect the input field will clear and it will remain on the login screen.

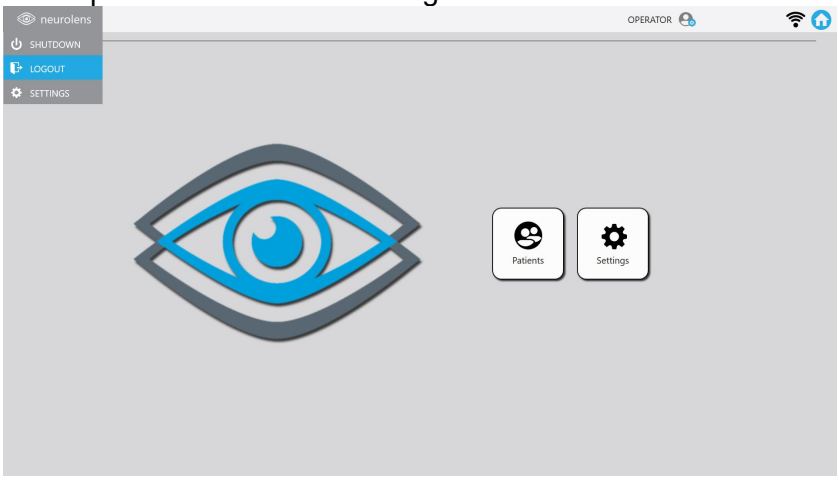
1.7.6 Home screen



The **Home** screen provides buttons for the basic functions provided by the device:

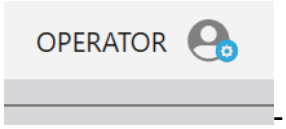
- **Patients** allows the operator to manage patients and take measurements.
- **Settings** provides access to configuration settings.

If you press the neurolens® logo in the top right corner it will give you the additional options of shutdown and logout.



- **Shutdown** powers off the device
- **Logout** logs the user out and takes them back to the login screen.

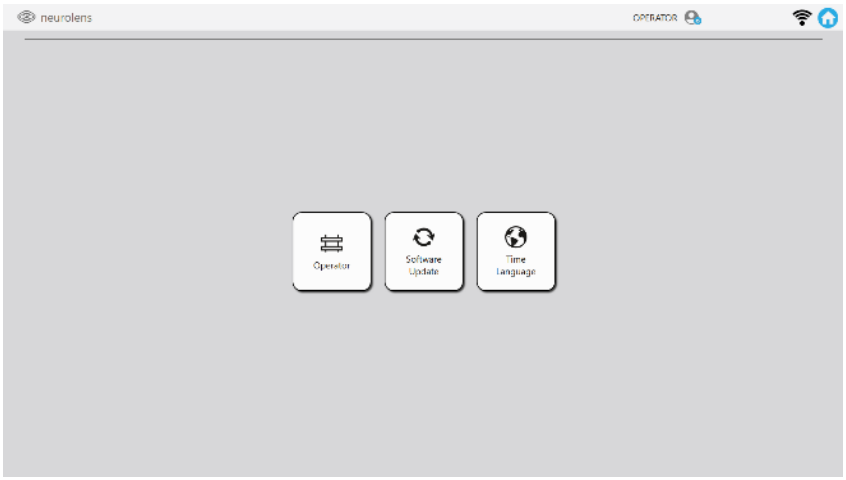
Additional icons available in the top menu bar are:

-  - Home button to go back to the home screen
- 

- Identifies the login username.

-  - Internet status and setup.

1.7.6.1 Settings Screen



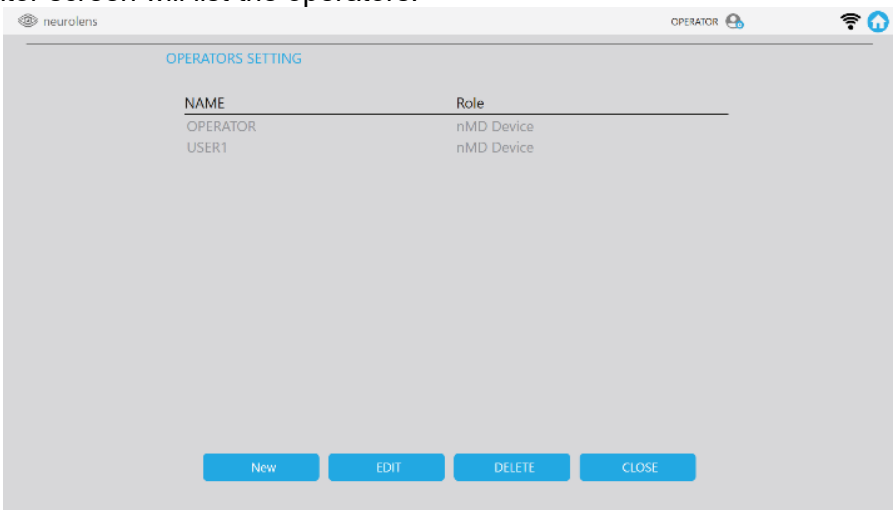
The settings screen allows the user to perform the following functions:

- Add a new nMD2 operator, edit an existing operator, or delete an existing operator.
- Set up WiFi- use icon on the top right of the menu bar.
- Check for software updates and update the software.
- Change the language or time zone.

1.7.6.1.1 Adding, removing or editing Operators

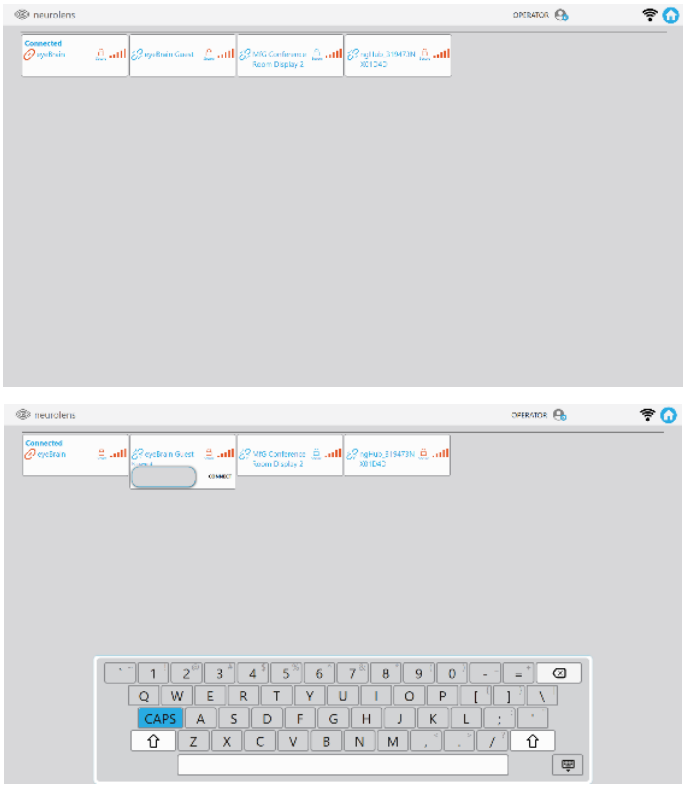
To add, remove or edit a nMD2 operator select the **Operator** button to go to the operator's screen.

The operator screen will list the operators.

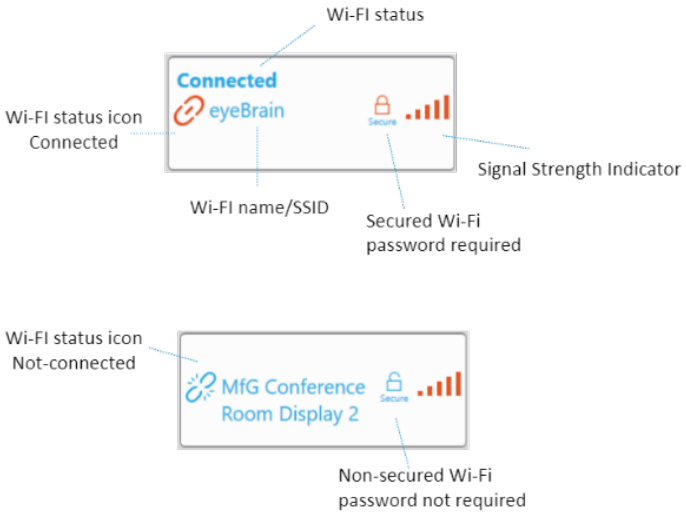


To edit the login or name an existing operator select the operator that you would like to edit and then press the edit button. Once in the edit mode you can change the name or the login pin and save. If you change the login pin you must confirm the pin before saving.
To remove an existing operator, select the operator you would like to remove and then press the delete button.
To set up a new operator, tap on the **new** button and enter the new operators name and pin, confirm the pin, and hit save.

1.7.6.1.2 Setting up Wi-Fi

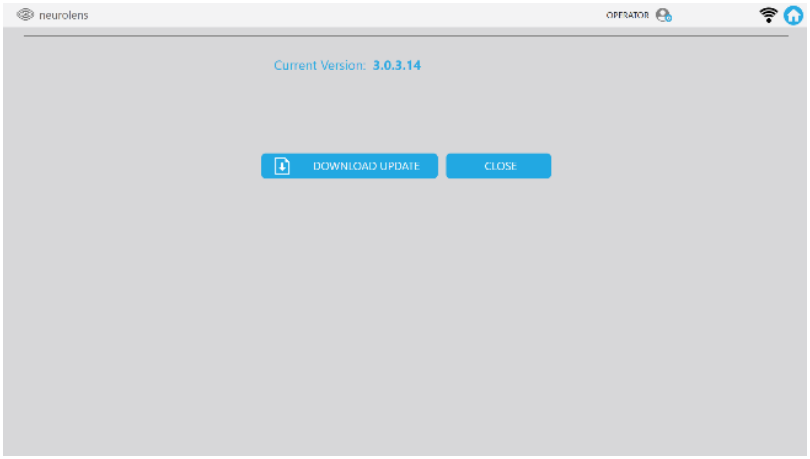


The icons will provide information on Wi-Fi status and security as shown below.



To set up a Wi-Fi connection, tap on the **Wi-Fi** button on the Home screen to get to the Wi-Fi screen. The Wi-Fi screen shows available networks and provides buttons to Connect, Disconnect and Forget a network

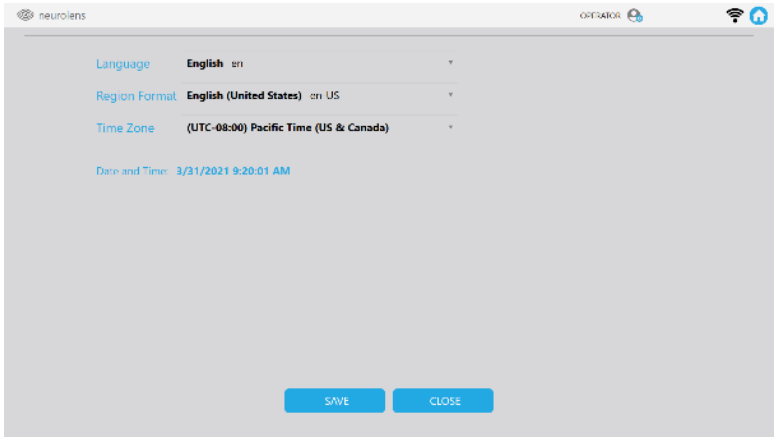
1.7.6.1.3 Checking for software updates



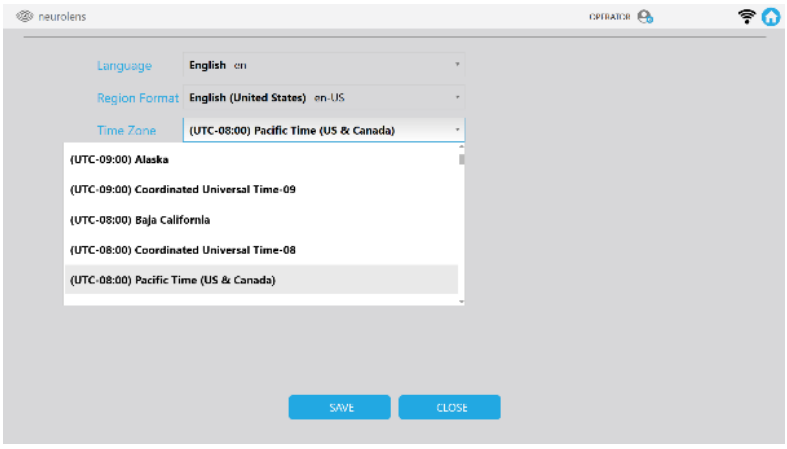
To check for software updates, click on the software update button. If a newer version of software is available, click **Download Update**. The update will be downloaded. Subsequent to the download the update will be applied after the next system restart.

1.7.6.1.4 Changing Time Zone or Language

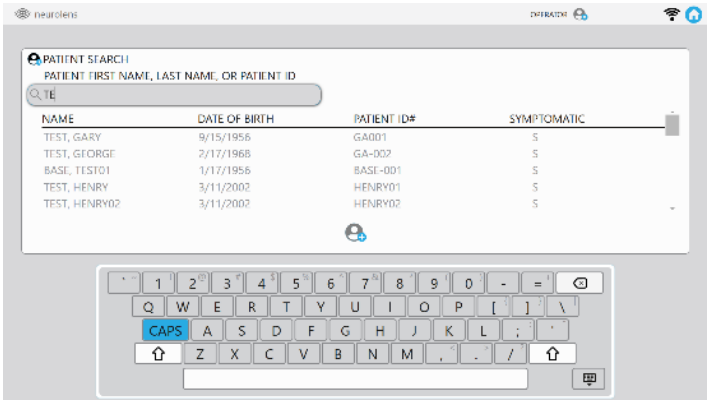
The nMD2 allows users to change the time zone of the system as well as change to another supported language. Only languages supported by available manual translations and approved regulatory bodies are available.



To change the language, region format, or time zone simply click on the downward arrow next to the field which you would like to change and select from the available dropdown options. Click ‘Save’ to save any changes you may have made.



1.7.7 Patient Search screen



The **Patient Search** screen allows you to perform the following functions (refer to section 2.0 for detailed information on this functionality):

- **Find** existing patients to view and edit their prescriptive information, view previous measurement history, or take a new measurement.
  - If a patient has been input into the portal but is not displayed on the device, reduce the keyboard and press the **sync** button to pull data from the cloud.

- **Add** a new patient (see 2.1.1)

●	The nMD2 must be reliably connected to the internet to enable customer support, software updates and data retrieval.

2 Operation

Normal operation of the device involves the following steps:

1. Choosing a patient to measure
    a. Selecting an existing patient from a list and updating his/her eye prescription if needed
    b. Entering a new patient
2. Placing the patient in the device
3. Adjusting the patient's eyes, so they are well centered and aligned.
4. Running the distance measurement
5. Re-adjusting the patient if necessary.
6. Running the near measurement
7. Viewing and printing the results

2.1 Patient management

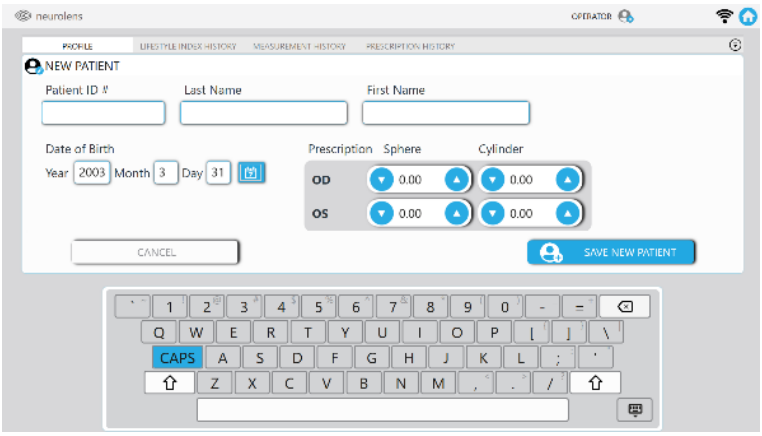
The device maintains a local database of patients containing the following information:

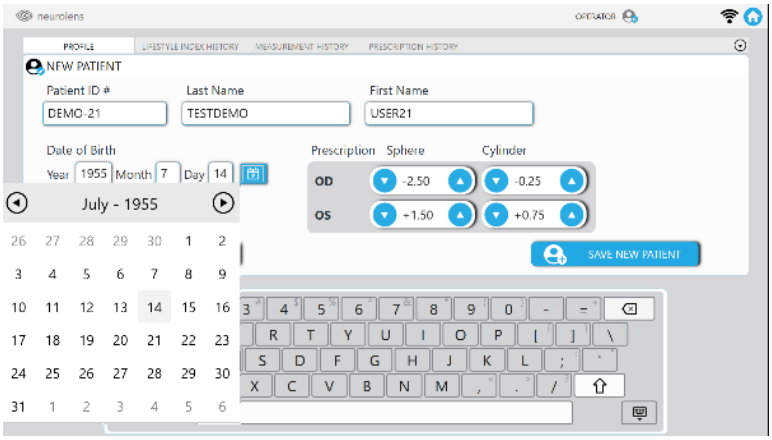
- **Patient ID**: an identifier that can be used by the practice to associate the patient with an entry in their patient management system.
  This field cannot be left blank. The Patient ID must be unique to that patient in that practice.
- **Name**: the patient's first name.
  This field can be left 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.
- **Scheduled Appointment Date**: The day the operator scheduled the patient to be measured on the nMD2. If the patient is entered on the nMD2, the Scheduled Appointment Date is the day the patient was entered.

2.1.1 Adding a patient

To add a patient, touch on **New Patient** from the Patient Search screen to open the New Profile screen, then touch on any field to bring up the keyboard and start filling the fields, by default, the Patient ID is selected.

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





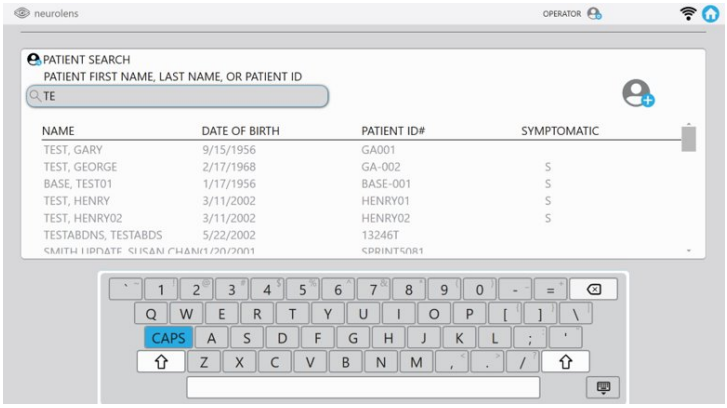
●	Make sure the patient's prescription data is correctly entered, as the device will use the information to choose the correct focus for the lenses for the measurement. Incorrect prescriptive information will lead to incorrect measurements.

nMD2 requires the following information to be provided:

- 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

Once all fields are completed, touch on the top left arrow on the keyboard to dismiss it and click **Save** to save the patient's profile and go to the Profile view screen.

2.1.2 Searching for patients



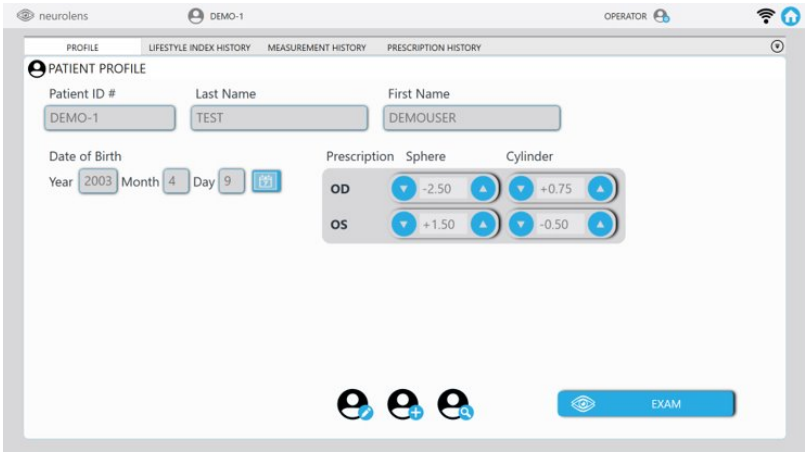
The Patient Search screen will show all the patients that have been entered and scheduled for today's date. The patients can only be scheduled for future dates if entered via the online portal (see section 3). All patients entered through the nMD2 are scheduled for the date they are entered. To proceed with any patients on today's schedule simply select them by touching the patient's name.
In the **Patient Search** screen, you can search for patients that have previously been entered into the nMD2 by typing at least 2 characters of the:

- First Name
- Last Name
- Patient ID

To start searching, touch on the search field to reveal the keyboard and type at least 2 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."

Once the patient has been found, you can touch the top left arrow to dismiss the keyboard or select by touching the patient's name from the list, which will navigate you to that patient's profile.

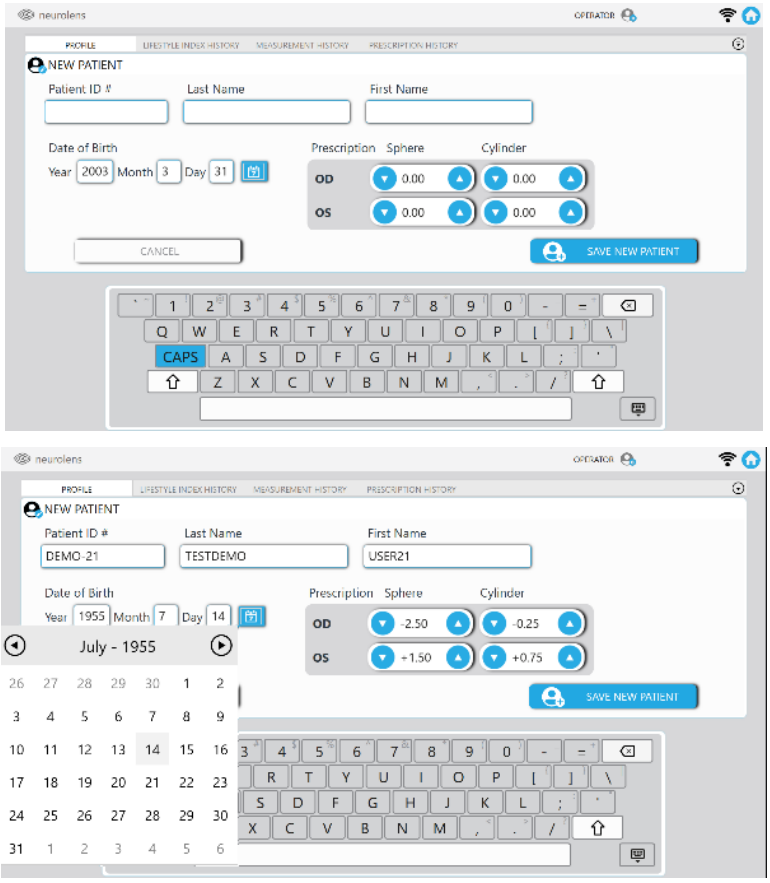
2.1.3 Viewing a patient



From the Patient Profile view screen, you can:

- Touch on **Logout** to go back to the **Login** screen (through neurolens® dropdown menu)
- Touch on **Shutdown** to shut the machine down immediately (through neurolens® dropdown menu)
- Touch on **search icon** to go back to the **Search** screen.
- Touch the **new patient icon** to go to the new patient entry screen.
- Touch the **edit patient icon** to edit the patient fields.
- Touch on **Exam** to start the measurement process.
- Touch on **Prescription History** to get a list of the patient's previous prescriptions.
- Touch on **Measurement History** to view the measurement history.
- Touch on **Lifestyle Index History** to view the patient's lifestyle index history.

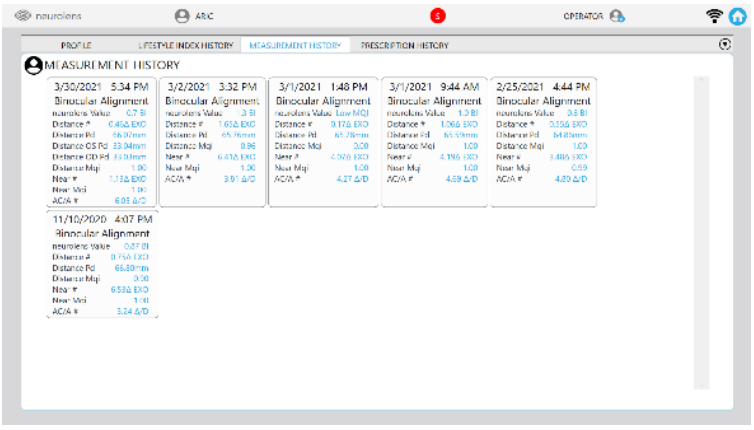
2.1.4 Modifying patient data



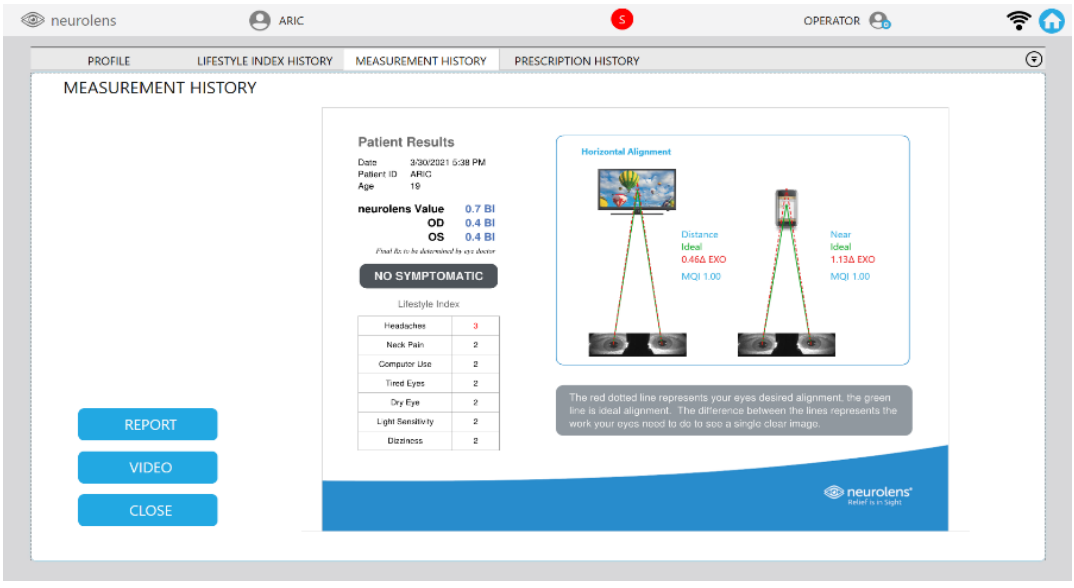
The New/Edit Profile screens allow you to enter/update the patient's data. Touch any field to bring the keyboard up to edit fields. To save, touch the arrow on the top left of the keyboard to minimize the keyboard and then click **Continue** to save the profile and begin a measurement. If you do not 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**.

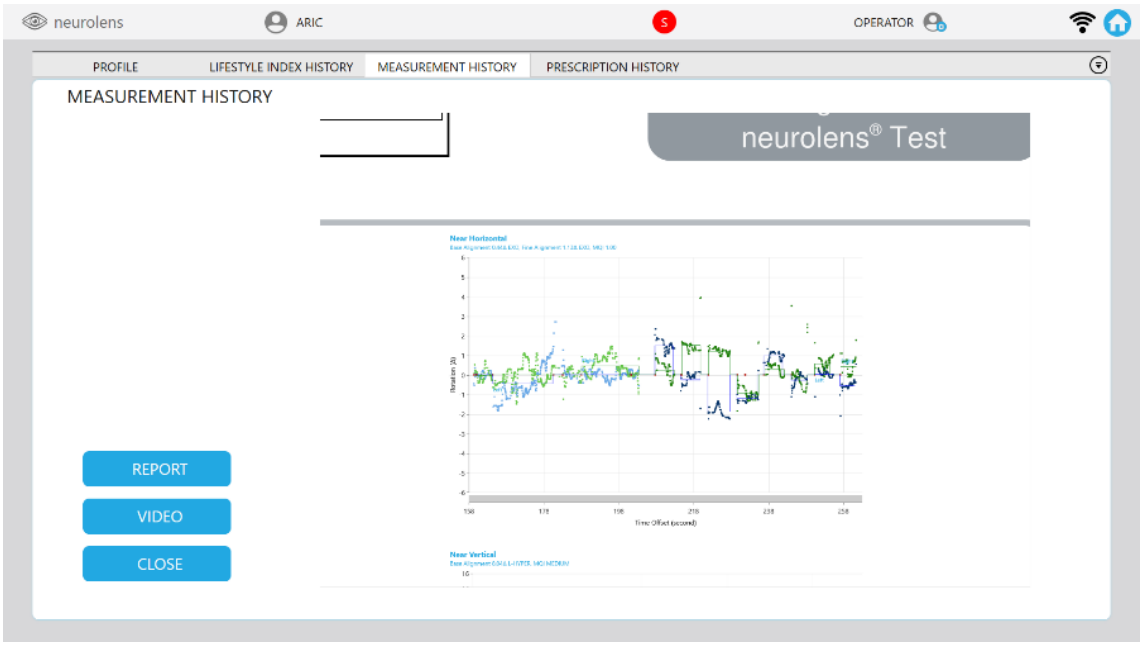
2.1.5 Viewing measurement, prescription and lifestyle index history

From the Patient search results, you can select a result and touch on **Measurement History** to see the measurement history for that patient.

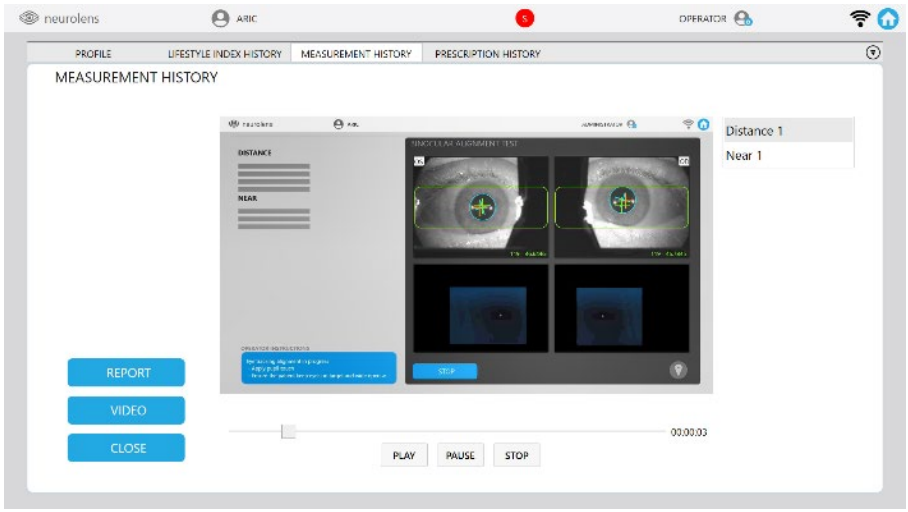


The history view shows all measurement data that is stored on the device from previous measurement sessions. You can select and view a specific measurement by tapping on it. It will default to the measurement report. See section 2.3 on the results description.

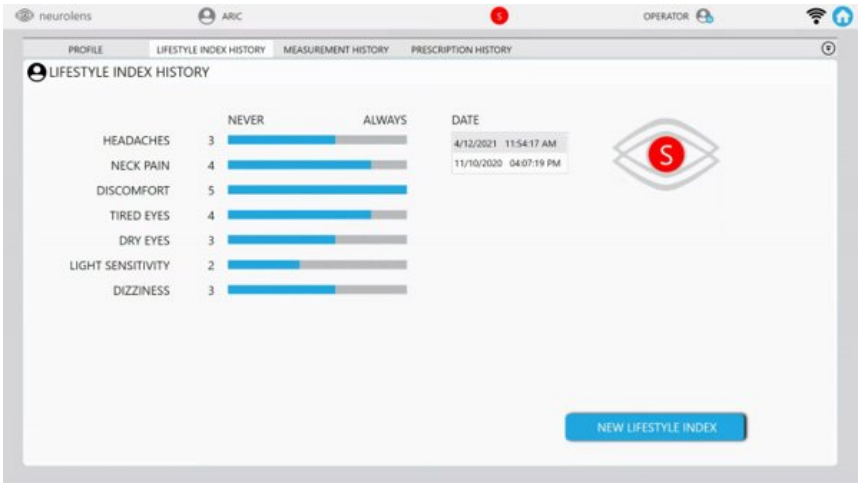




From the report screen the user can view video of the measurement to reassess patient cooperation and tracking by clicking on the **Video** button.



From the Patient search results, you can select a result and touch on **Lifestyle Index History** to see the lifestyle index history for that patient.



After you are done viewing previous measurements or lifestyle indexes, touch **Home Icon** to take you back to the home screen.

2.2 Taking a measurement

Touch **Exam** on the Patient Profile screen to start the measurement process. A measurement consists of the following steps:

1. Entering the lifestyle index responses
2. Distance accommodative stimulus
3. Patient alignment for distance
4. Distance measurement
    a. PD measurement
    b. Base alignment
    c. Fine alignment
5. Near accommodative stimulus
6. Patient alignment for near
7. Near measurement
    a. PD measurement
    b. Base alignment
    c. Fine alignment

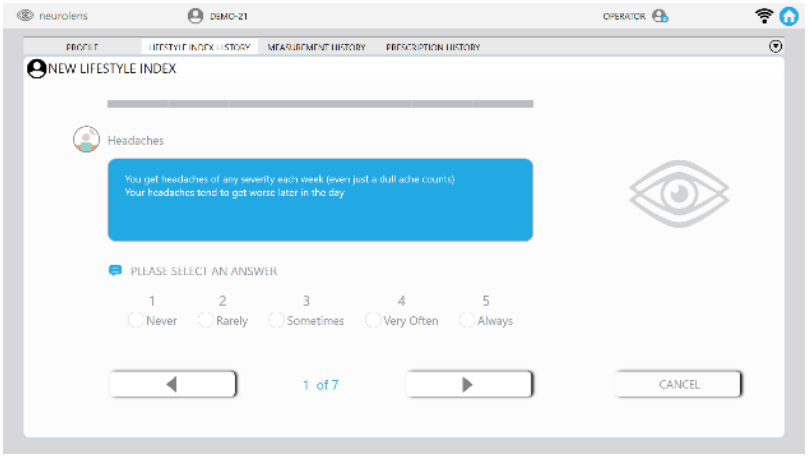
Throughout the test, the patient needs to look directly at a centrally located target. It is best to instruct the patient before the test starts to ensure proper patient cooperation.

Note: To detect issues, the device keeps track of measurement quality. Each step (distance and near) has an associated MQI (Measurement Quality Index). If the MQI for a step falls below 0.7, the software will alert the operator and recommend that the measurement is repeated.

2.2.1 Entering Lifestyle Index Responses

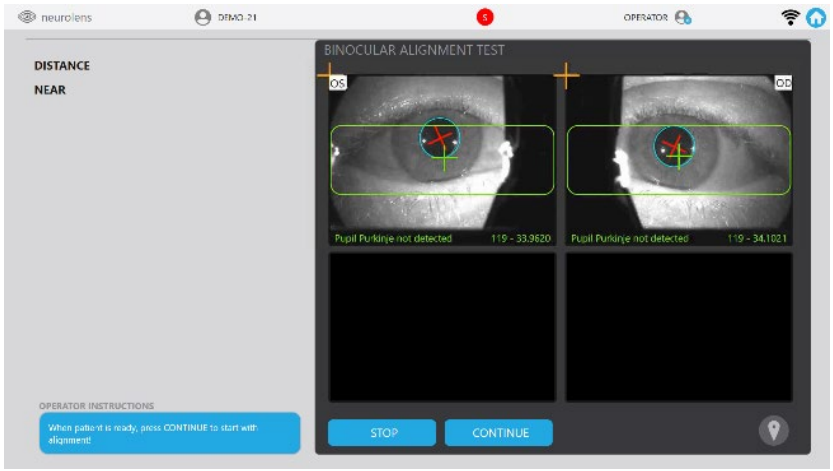
If the patient is being entered through the nMD2, or if the lifestyle index was not input into the portal within the previous 30 days, the device will prompt the operator to fill out the questionnaire on the device. The device will sequence through the questions and automatically advance with each response. The continue button will be disabled until all questions are answered. If you are

unsure if you correctly answered a question, you can hit the back button to review the answers.



2.2.2 Distance Patient Alignment screen

When the measurement session starts, the patient alignment screen is immediately shown, and the device adjusts the accommodative power according to the patient's spherical equivalent and desired distance.

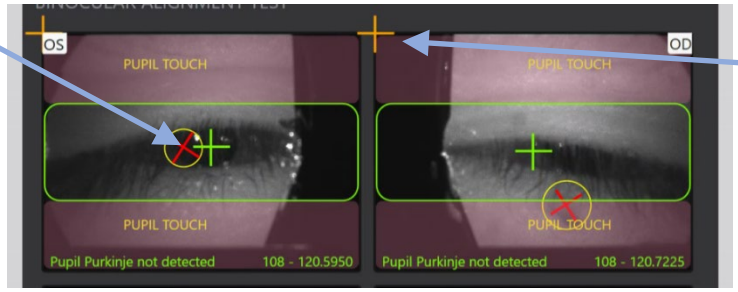


After the focus is set, touch the approximate location of the pupil center to align the patient eyes such that the pupils are centered on the screen. The patient's pupils should be aligned such that they are within the rectangles.
Looking at the patient's eyes, you will notice 2 dots around the pupils. These dots are the first Purkinje images (P1) from two LED lights that the device shines on each patient's cornea to aid in tracking. This guide will refer to these dots as P1 reflections. When the system can detect the P1 reflections, you will see an orange cross to indicate the position of the center of the P1 reflections. The device also shows a blue circle and cross to indicate the center of the pupil.

***Tip**: Before lens focus starts, the lenses are placed at a distance of 63 mm. During the Pupillary Distance measurement, the device aligns the lenses to the patient's pupils. In certain cases where the patient has a very small or very large PD, this initial position can cause tracking to fail. If you see that the lenses are significantly misaligned with the patient's pupils, use the left/right arrows to align the lenses such that the pupils are centered.*

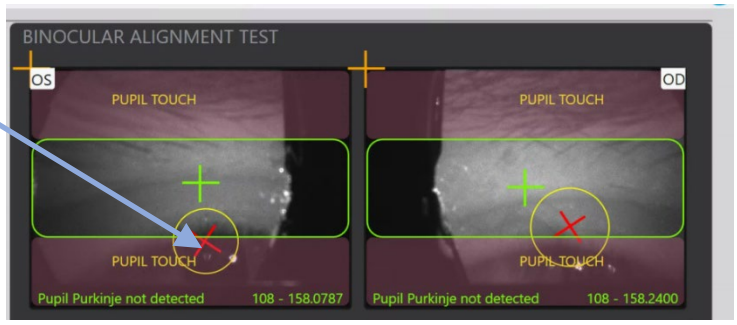
Due to the varying physiology of patients, it is sometimes more difficult to track some pupils than others. It is important to look for the graphics that indicate the location of the P1 reflections and pupil center during the alignment screen. It is recommended that the operator utilize the pupil touch tracking to ensure the device is properly tracking and centered on the pupil, this is particularly important if one or both eyes are not properly identifying the pupil center as indicated by a missing pupil graphic, a graphic that is jumping around the screen, or a graphic that is misplaced. Also, ensure the patient's eyes are wide open and there is no hair crossing the pupil boundary (eyelashes, eyebrows, or long hair can interfere with the measurement), further ensure that the patient's forehead is touching the face mask and nose is indexed on the nose piece as proper distance and placement of the patient's eyes are required for a successful measurement. If the system is unable to properly track the continue button will be disabled until properly aligned.

Not tracking (red circle and cross)



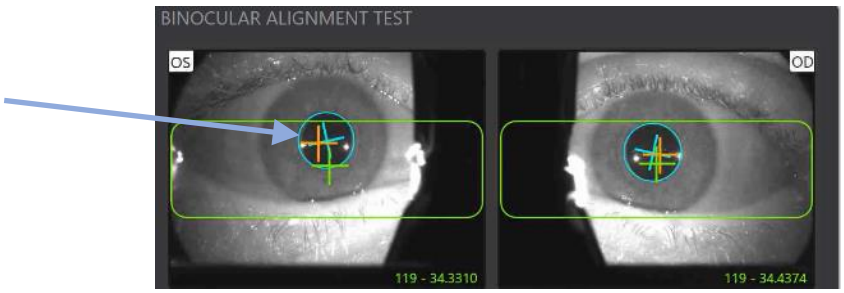
Orange Cross Top Left Indicates lost P1 reflections.

Tracking out of range.



If the patient is not tracking properly check to make sure you can see the pupil and at least two adjacent P1 reflections. Some challenges result from droopy eyelids, downward facing eyelashes, dark mascara, or any combination of the aforementioned. To track difficult patients, instruct the patient to open their eyes wide and look at the target. If they are still unable to track, while their eyes are wide open touch the touch screen on their non-tracking eye at the center of the pupil. The system should display graphics indicating successful tracking as well as a blue border around the pupil. If the border around the pupil does not display correctly, try touching again.

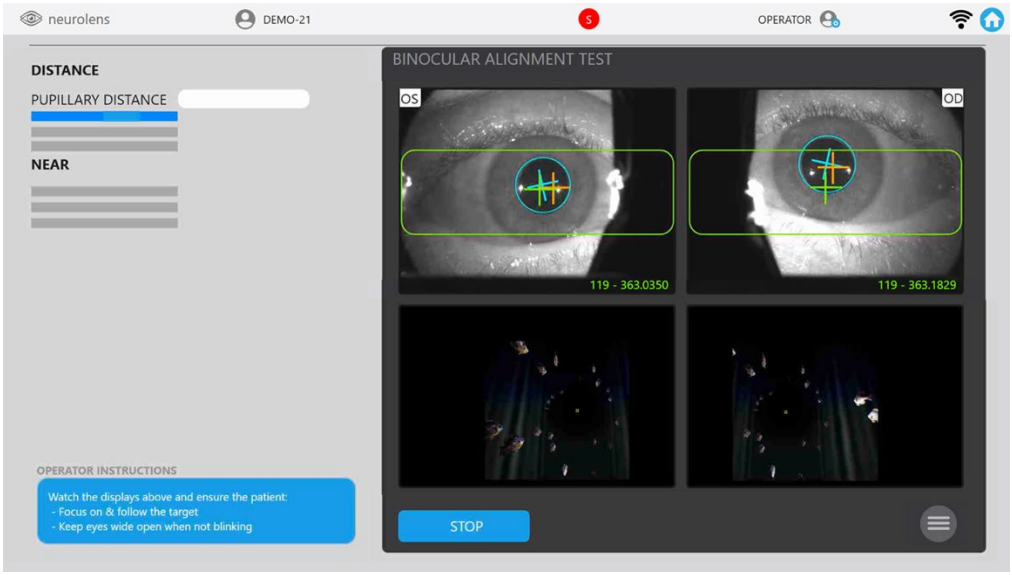
Blue circle centered on pupil



Once the alignment is completed, and the pupils are within the rectangle, touch **Continue** to start the distance measurement.

2.2.3 Distance PD

The first step of the distance measurement is to determine the patient's pupillary distance. The device uses this measurement to align the lenses to the patient's pupils accurately as well as properly display graphics to simulate distances.



While the system is performing the measurement, the operator is presented with the **Distance Measurement** screen, which displays the following information:

- The **camera views are** showing the patient's eyes, with rectangles.
- An orange cross is also displayed to show tracking of the P1 reflections, and a blue cross will show the indicated pupil center and a blue circle will indicate the pupil boundary after pupil touch.
- The **patient views** showing what the patient sees for each eye.
- The **measurement steps**, indicating progress and partial results.
- The **operator instructions**, which indicate how to instruct the patient through the measurement process.

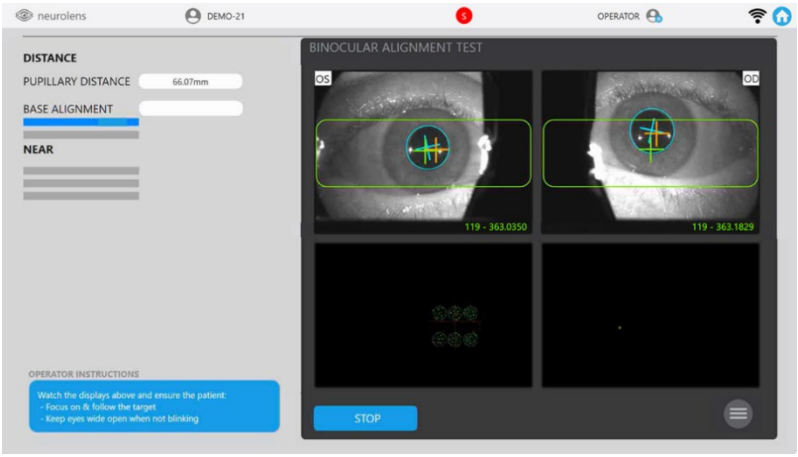
Also, the screen provides the following button:

- **Stop**, which stops the measurement and goes back to the **Patient Profile** screen.

2.2.4 Distance Base alignment

The Base alignment step presents the patient with the target on one screen and a disassociated image on the other screen. The patient is instructed to look at the target while the complimentary eye moves to its natural phoric posture. The patient may observe the target “moving” relative to the other graphics. However this is just a result of the complimentary eye moving to its phoric posture.

The device tracks both eyes and determines the natural phoric posture.



2.2.5 Distance Fine alignment

The Fine alignment step is the last step of the distance measurement. In this step, the device measures a patient’s eye misalignment. For this step to be effective, the patient should be instructed to concentrate on looking at the yellow target on the screen. The target may move around the screen, and the patient should look at the target wherever it goes.

The process works as follows:

1. A background is displayed for fusion at a position determined by the measurement distance and results from the base alignment.
2. A target is presented to only one eye at the center of the moving peripheral stimulus.
3. The target is then turned off, and another dot is presented to the other eye at the center of the moving peripheral stimulus.
4. The device tracks the patient’s eyes and measures the movement when the targets are swapped.
5. If eye movement is detected, the presentation of the targets is repeated, adjusting based on the amount of eye movement detected.
6. The process continues until a target position can be identified for each eye that results in no eye movement.
7. Once the correct positions for each target are achieved, the process completes, and the device displays the result, which is the sum of the individual rotation values for each eye in diopters.

***Troubleshooting tip**:*
If measurement results in a low MQI, repeat the measurement and remind the patient to look at the target. Look at the video display to ensure the patient is cooperating, and the system is properly tracking the eyes. Remind the patient to keep their eyes wide open while not blinking.

2.2.6 Near Measurement

After the Distance Fine Alignment measurement completes, the system automatically proceeds to the near measurement. The system refocuses to simulate a distance of 0.5 meters.

2.2.7 Near PD

The Near Pupillary Distance measurement is like the one at distance. Instruct the patient to look at the yellow target on the screen and make sure the system correctly aligns the lenses to the pupil centers.
Also, the screen provides the same buttons as during the distance measurement. During the near measurement, the **Repeat** button takes the user back to the screen alignment for the near measurement.

2.2.8 Near Base Alignment

The Near Base Alignment is like the one at distance. Instruct the patient to look at the target. Keep an eye for tracking errors and make sure the patient keeps their eyes wide open when not blinking for best results.

2.2.9 Near Fine Alignment

The step is similar to the one at Distance, so simply instruct the patient to keep their eyes wide open and look at the target.

***Troubleshooting tip**:*
If measurement results in a low MQI, repeat the measurement and remind the patient to look at the dot or cross. Look at the video display to ensure the patient is cooperating, and the system is properly tracking the eyes. Remind the patient to keep their eyes wide open while not blinking.

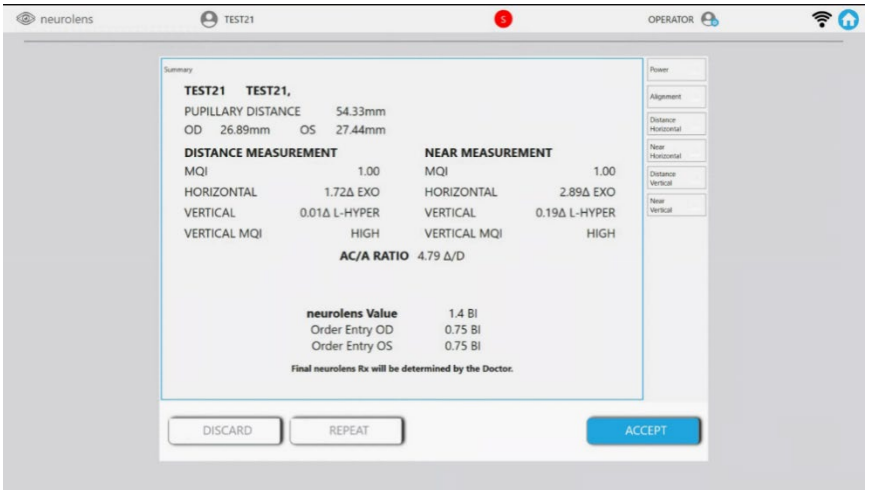
2.3 Viewing results

The results view collects all data from the distance and near measurement steps and displays it to the operator, with the following options:

- **Repeat**, which discards the results and starts again from the **distance** measurement **Patient alignment** screen.

- ***Note:***
- *- The printer has two buttons on the top. Repeatedly pressing these buttons can cause the printer's configuration to change. If the printout is illegible, it may need to be reconfigured. Refer to troubleshooting for instructions on how to reconfigure.*
- *- The printer uses 2 ¼ in/po x165 ft/pi or 57 mm x 50 m thermal paper.*

- **Accept results**, which records the data and goes back to the **Home** screen.
- **Summary** Button



- **Pupillary Distance** is the 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.
- **MQI** this 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.
- **Horizontal** is the total measured misalignment at distance and near. It most closely correlates to a prism corrected subjective cover test, however, is a unique measurement that combines elements of heterophoria, fixation disparity, peripheral and central visual misalignment, and response to divergence eye conditioning.
- **Vertical Base**- Is an objective measure 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.

- **Vertical MQI**- this is the measurement quality of the vertical measurement. The system determines whether the tracking was consistent and the patient cooperative during the measurement. 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.
- **AC/A Ratio**- The calculated gradient AC/A based on the near and distance horizontal measurement.
- **neurolens® Value**- This is the value of horizontal prism at distance that neurolens® algorithms determined closest meet the patient's requirement.
    - The neurolens® Value is also presented.

Do not prescribe treatment solely on the information provided by the nMD2. Measurements are to be used in combination with other information attained in a comprehensive eye exam.

- **Distance Horizontal** Button shows the scatter plot of how the eyes tracked horizontally during the distance test.

  The scatter plot represents the eye movement of the patient during the test. The zero line represents ideal alignment. For each phase of the test, we identify different misalignments. In the base alignment phase, we show the misalignment that occurs in each eye when disassociated from the complementary eye. Finally, the offset from zero is the total final misalignment of the patient's eyes.

- **Distance Vertical** Button shows the scatter plot of how the eyes tracked vertically during the distance base alignment test.

The scatter plot represents the eye movement of the patient during the test. The zero line represents ideal alignment. For each phase of the test, we identify different misalignments. In the base alignment phase, we show the misalignment that occurs in each eye when disassociated from the complementary eye.

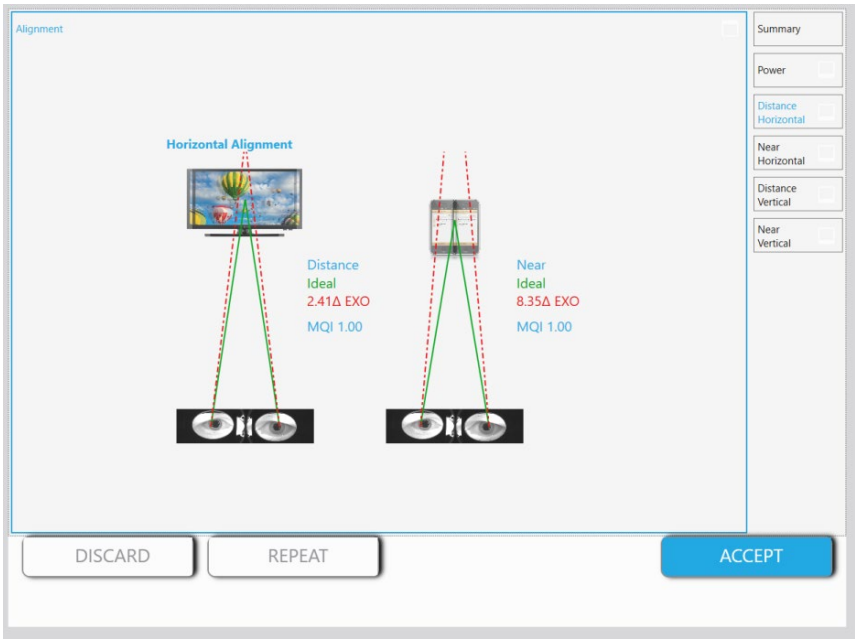
- **Near Horizontal** Button shows the scatter eyes traced horizontally during the near test.

Similar to the distance plot, the near plot shows the misalignment of the eyes during each phase of the test.

- **Near Vertical** Button shows the scatter eyes traced vertically during the near test.

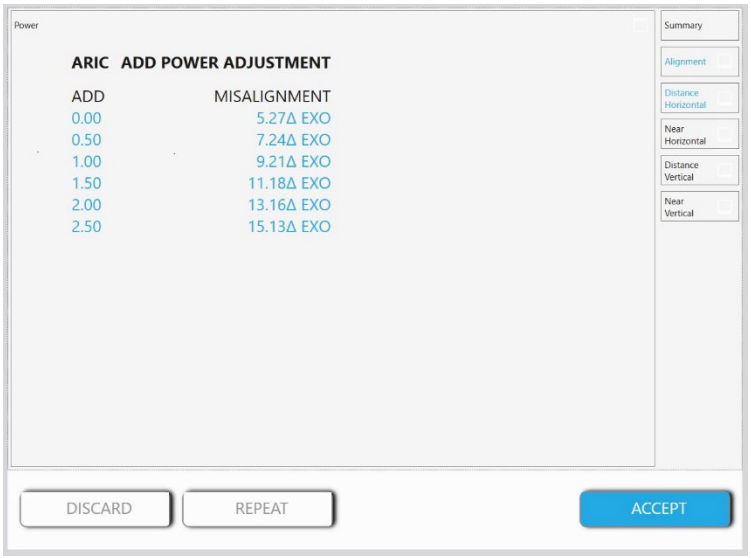
Similar to the distance plot, the near plot shows the vertical misalignment of the eyes during the base alignment.

- **Alignment** Button



The alignment chart shows how the patient's eyes are aligned horizontally (Red dotted lines) vs. ideal alignment (Green solid line). It also shows a numerical value of the patient's measurement.

- **Adjustment** Button



Since accommodation and convergence are inextricably linked via the accommodative convergence to accommodation ratio, which is calculated by the nMD2, the effect on alignment from providing add power can be predicted. This chart shows how the patient's alignment becomes more exophoric as add power is introduced to their visual system.

Tips:

- *Doctors should not rely solely on nMD2 to prescribe.*
- *Measurements with an MQI lower than 0.7 should be repeated.*
- *Measurement data is stored locally on the device and remotely on the neurolens® cloud.*
- *Pupillary distance at near is on average about 1.5mm smaller than at distance.*
- *nMD2 number for near is typically more EXO than for distance.*

2.4 System Warning Messages

Warning Message	Possible Cause	Possible Action
Failed to open Serial Port COM6, COM7, COM8, or COM9.	Serial Port COM6, COM7, COM8, or COM9 is not available for the system to communicate with micro controller.	Call neurolens Inc. for service
System initialization failed! Please SHUTDOWN and restart the system.	• Micro controller initialization is taking longer than 3 minutes. • Stepper motor gets stuck. • Camera is unresponsive.	• Restart the system to retry startup routine. • Call neurolens Inc. for service

Invalid Device Key. Patient measurement will not be allowed. Please check system setting! 00000000-0000-0000-0000-000000000000	System Device Key has not been assigned.	Call neurolens Inc. for service
Supported Sphere Value is between -10 and 6.	Entered Sphere value out of supported range	If sphere is outside the range, measurement cannot be taken.
Supported Cylinder Value is between -5 and 5.	Entered Cylinder value out of supported range	If cylinder is outside the range, measurement cannot be taken.
Please check the OD and OS Values and confirm it was entered correctly.	The difference between OD and OS Spherical Equivalent is greater than 2.0D.	• Continue with measurement. • Do no proceed with measurement.
Unable to start cameras. Please try to reboot the system!	System cannot start camera(s)	• reboot the system to re-initialize camera. • Call neurolens Inc. for service.

3 Troubleshooting

Symptom	Possible cause	Solution
Measurement fails	Lens misalignment	• During patient alignment, make sure the lenses are aligned with the patient's pupils such that pupils are well within the visible area. If not, manually align them before starting the measurement. • During PD measurement, verify that the device correctly centers the lens on the patient's pupils. If not, restart the measurement and manually correct the position of the lenses before starting the measurement. • Note: This may occur more often if a patient's pupillary distance is greater than 70mm or less than 55mm.
Measurement fails	Tracking issues: • Horizontal bars are red most of the time • Vertical bars are not present most of the time	• Make sure the patient has his/her eyes wide open. • Make sure the patient's face is pressed against the facemask. • Make sure the patient is not wearing contact lenses. • If the patient is wearing mascara, make sure their eyes are wide open, and the mascara is not "touching" the pupil. • If the patient has very long eyelashes, make sure their eyes are wide open, and at least two adjacent P1 are visible and highlighted by the SW. • Use pupil touch tracking to find the pupil.

Symptom	Possible cause	Solution
Failed calibration	Incorrectly placed calibration card	• Make sure the calibration card is installed and correctly placed. (flip upside down if uncertain) • Make sure the eye holes are clean. • Repeat the process. • If calibration still fails, restart the device. • If calibration continues to fail, contact neurolens® for service.
Failed to set focusing motors	Initialization Problem	• Power cycle the system and try again. Use the power button located on the rear of the device. • If the problem persists, contact neurolens® for service.
Camera not detected	Camera initialization issues	• Power cycle the system and try again. Use the power button located on the rear of the device. • If the problem persists, contact neurolens® for service.
Incorrect measurement results	Poor tracking	• Repeat the measurement and be aware of tracking issues. 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 observe the patient's eyes during the exam to ensure they are looking at the dot or cross. • 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.
Cannot login	Forgot PIN	• Contact neurolens® to have the PIN reset.
Unable to find patient on portal	nMD2 not connected to internet	• Check to make sure nMD2 is connected to network. • See section 1.7.6.1.2
Unable to find patient on portal	Operator has not accepted results.	• On the nMD2 click **Accept Results**
Patient not listed on nMD2 that was entered in the portal	nMD2 not connected to internet	• Check to make sure nMD2 is connected to network. • See section 1.7.6.1.2
Device Touchscreen goes blank and becomes unresponsive	Electrostatic discharge from an operator, or electrical fast transients on the power mains wall outlet.	• Power cycle the system and try again. Use the power button located on the rear of the device. • If the problem persists, contact neurolens® for service.

4 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).
nMD2 Number	The measured value of fixation disparity between central vision targets of each eye at either infinity or 0.5m. The combined nMD2 Numbers for each eye result in visual alignment of binocular vision.
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.

5 Guidance and Manufacturer’s Declaration

5.1 Emissions

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.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The nMD2 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 nMD2 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	

5.2 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. If the user of the nMD2 requires continued operation during power mains interruptions, it is recommended that the nMD2 be powered from an uninterruptible power supply or a battery.
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

5.3 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.

Service Notice
Read this manual thoroughly before performing service or maintenance on the nMD2. 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 nMD2.

1. Tools and Equipment

No user maintenance is required on the nMD2.

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