English

# VIDEONYSTAGMOGRAPHY

# User Manual
# And
# Introduction to the Device
## For VNG

CE 2803

# VIDEONYSTAGMOGRAPHY

## USER MANUAL

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Software Version: v9.9.7
Dashboard Application VNG: 9.2.11

*Images shown in this manual for illustrative purpose only.*
*Specifications are subject to change without notice.*

*Declaration of Language Translation:*

VNG unit comes to you as a package, complete with Labels, User Manual and related Documents, all of which are in English. The product targets the customers who are proficient in the language and can read the instructions and understand the product better. This user manual will be supplied in the local language on request to EU customers.


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# Contents

# Overview of VNG


1. Main frame.
2. Hot Mirror.
3. 0.3MP IR Camera.
4. IR LED.
5. Spontaneous & Caloric Tests Reference.
6. Magnets for Front Cover Flap.
7. Strap to hold.
8. Face Foam.
9. USB Cable.
10. Front Cover Flap.

## 1. Main Frame

The main Frame comprises Electronics and Camera to fulfill the intended use.

## 2. Hot Mirror

This mirror has a reflective coating on one side which is being used to capture real time Video.

## 3. 0.3MP IR Camera

This is the vital part of this product. The camera can capture videos in dark mode.

### 4. IR LED

These invisible light emitting devices are the source to Cameras.

### 5. Green Indicator

This Green Indicator is used for a reference while performing Spontaneous & Caloric tests.

### 6. Magnets

Spontaneous, Caloric & Head shaking tests to be done in occluded and un-occluded conditions. These magnets will hold the Front Cover flap to block stray light entering the goggle.

### 7. Straps

These elastic straps with velcros provide comfortable grip to hold the goggle to patients face.

### 8. Face Foam

Face foam facilitates comfort to the patient and avoids slippery of goggle from patient's face.

### 9. USB Cable

This 4mts long USB Cable communicates between Computer and Goggle. This provides Power to goggle and two-way signal transfer.

### 10. Front Cover Flap

This Front cover flap is used in some tests (Refer Point No. 6).

# 1. Introduction to the Device

## 1.1 Intended Use

VNG is for the observation, measurement and analysis of eye movement to evaluate oculomotor system, positional and caloric tests in vertigo patients. Peripheral and central vestibular functions are evaluated based on the following tests.

Spontaneous nystagmus with & without optic fixation, Gaze evoked nystagmus, Saccades- random, Smooth tracking with varying frequencies, Optokinetic test, Head shaking test, Caloric test, Positional testing including Dix-Hallpike, McClure's, Supine, Deep Head Hanging, Skew deviation.

## 1.2 Intended Environment

Semi controlled Environment (Clinics / Vestibular Diagnostic and Rehabilitation lab)

Note: This Device not to be used under room light which consists of Infra-red, Ultra-violet and high frequency flicker sources.

## 1.3 User Qualification

If the device is used by professionals (Doctors), then they shall refer the user manual for operation. If the device is operated by other Healthcare Professionals, then they have to undergo training by NeuroEquilibrium.

## 1.4 Target User

Healthcare Professionals: Neurotologists, Neurologists, Psychiatrists, audiologists and Lab Technicians, etc.

## 1.5 Intended Patient Population

Age ≥6 for pediatrics and adults who can identify fonts and character orientations.

## 1.6 Description of the Functions

NeuroEquilibrium VNG is a non-invasive system for observation, measurement, analysis, and reporting of eye movement parameters within the approved operating environment and validated device/software configuration.

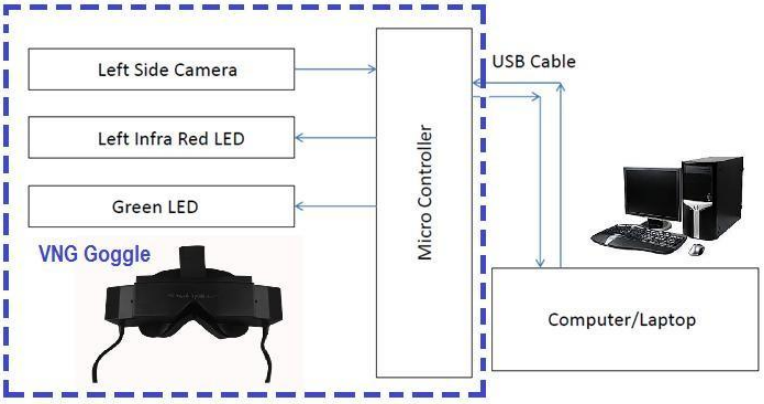
NeuroEquilibrium VNG Evaluates Peripheral and central vestibular functions are evaluated based on the following testing modes.

- Spontaneous nystagmus with & without optic fixation
- Gaze evoked nystagmus
- Saccades- random
- Smooth tracking with varying frequencies
- Optokinetic test
- Head shaking test
- Caloric test
- Positional testing including Dix-Hallpike, McClure's, Supine, Deep Head Hanging
- Skew deviation

**Principle of Operation**

An IR illumination is done through the IR LED's and an IR sensing camera is used to capture the movement of eyes when various types of visual stimulus are given. The eye tracking software captures the eye movement and graphs are plotted of eye movement with respect to the movement of visual stimulus.

Patient's real time eye movements are being sent to the computer by two USB cables. This is a two-way communication. These USB cables provide power to the goggle and communication between goggle and computer. VNG software controls the visible light source for fixation.




The NeuroEquilibrium VNG software analyses the oculomotor system, positional and caloric tests in vertigo patients and/or balance disorders. The main parameters for evaluating are the Tests of oculomotor function (with fixation): includes saccade, smooth tracking, and optokinetic tests, Tests of spontaneous nystagmus (with or without fixation, alertness level): includes gaze induced nystagmus, Caloric test, Tests for specific etiologies: includes Dix-Hallpike maneuver (dynamic positioning), pressure test (fistula), Others: head shake test, hyperventilation test.

## 1.7 Indications for Use

NeuroEquilibrium's VNG is indicated to be used on patients experiencing the below symptoms.

- Vertigo.
- Giddiness.
- Tendency to Fall.
- Un-steadiness.
- Difficulty in focusing on objects while moving.

## 1.8 Contraindications for Use

NeuroEquilibrium's VNG should not be used if the patient has the below complications.

- Blindness.
- Broken nose or other face/head trauma.
- Recent eye surgery.
- Lazy eye.
- Patients with severe back/neck problems.

## 1.9 Clinical Benefits

- VNG Evaluates Peripheral and central vestibular functions
- VNG is a non-invasive system for observation, measurement, analysis, and reporting of eye movement parameters within the approved operating environment and validated device/software configuration.
- VNG helps document unilateral/bilateral loss of vestibular function, confirm Benign Paroxysmal Positional Vertigo (BPPV), and detect central lesions that are missed during a routine physical exam.
- Algorithms are specifically designed to identify artifacts such as blinking.
- Recordings shall be performed under the intended semi-controlled environment and setup conditions described in this manual, including the stated room-light and display-setup limitations.
- Complete diagnostic system for recording, analysing, and reporting eye movements using video imaging technology.
- Variants of BPPV (Benign Paroxysmal Positional Vertigo), such as multiple canal BPPV, are also diagnosed using VNG.

## 1.10 Side Effects

None.

## 1.11 Important Points in an Emergency

If the patient complains of any dis-comforts in-between the testing process, then pause the test and allow the patient to relax for some time and once they recover, proceed the test.

# 2. Labels & Symbols

## 2.1 Description of the User manual

Please read this user manual carefully to ensure safe and effective use of NeuroEquilibrium's VNG and to be prepared for testing. If you have additional questions about information in the user manual, you may contact the local distributor or NeuroEquilibrium directly. Keep this manual where it can be reached easily.

**Caution!**
The icon defines the possibility of causing dis-comfort to the patient/Patient.

**Warning!**
The icon defines a possible danger which can result in simple - mild injury.
This symbol is Also used to indicate user errors which can result in damage to the device


**Attention!**
This icon provides necessary additional information.

## 2.2 User Responsibility

This user manual is intended to provide important information for the proper operation, maintenance and cleaning of the Videonystagmography (VNG). Failure to follow these instructions may result in:

- Decreased efficiency of operation.
- Faulty instructions to patients which can result in erratic results.
- Detrimental effects on the health of the patient, the user or other persons.
- Data's collected may not help the doctor.

***Please note:***

- Pay attention while using the device
- The user is responsible for checking the device for broken Cables and other worn, broken, or missing straps on a regular basis and arranging for maintenance and repair.
- Before and After use of every patient, the goggle Pads, Mirrors and Straps should be cleaned as per the cleaning procedure specified in this manual.
- The product must be checked periodically up to the expected service life of 10 years.
- Inform the manufacturer for re-evaluation for fitment and functionality of the device, once the device exceeds the service lifetime.
- A defective product should not be used.
- Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately.
- Neither this product nor any of its parts should be repaired in any manner
- Other than in accordance with written instructions provided by NeuroEquilibrium.
- The product must not be altered without the prior written approval of the NeuroEquilibrium Quality Assurance Department.
- Do not use the device apart from the Intended use mentioned in this Manual.
- Before performing the caloric test, the clinician must verify that the patient does not have a ear perforation. The patient should be asked to provide a recent ear examination report. The test must not be conducted if any perforation is present

## 2.3 Labels and Symbols

***CAUTION:*** *Should product repair or part replacement become necessary, please call or make a written request for service to the nearest NeuroEquilibrium Regional Service Centre. Only NeuroEquilibrium trained personnel should carry out the service, maintenance or repair of this product.*

This Device is not intended to use in Oxygen rich, flammable anesthesia gases and other flammable substance or gas mixtures environment.

The owner of this product shall have the sole responsibility for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than NeuroEquilibrium.

- A defective product should not be used.
- Inspect the electrode and cables thoroughly for any cracks/damages prior to usage on a patient.
- Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately.
- Neither this product nor any of its parts should be repaired in any manner other than in accordance with written instructions provided by NeuroEquilibrium.
- The product must not be altered without the prior written approval of NeuroEquilibrium. Quality Assurance Department.
- Ensure the electrical wall socket at the device usage site is properly grounded.
- Use only Power source indicated on the Technical Specifications of this manual.
- Confirm AC mains socket meets the relevant local safety standard.
- Un-plug the equipment from wall socket before cleaning/maintenance/service.
- The device shall not be moved while operating.
- To avoid explosion, do not use this product in the presence of flammable gases or flames. Operation of any electrical instruments in such environment constitutes a safety hazard.
- To avoid any personal injury, do not dismantle the device.
- To avoid injury to the operator and prevent damage to the device, inspect the mains for any earth leakage voltage, before turning on the system.
- The Device not to be used near high frequency surgical equipment's.
- Use only accessories/cable specified with the device. Using other non-specified accessories/cables may increase electrical emission or decrease electrical immunity of this device.
- Internal components of this device are electrostatic sensitive. So please do not touch the connector pins while inserting the Electrode to the connectors.
- Avoid using portable RF communication equipment's near this device. This may affect the device performance.
- Verify that the device usage site supply voltage corresponds to the power supply voltage range. See "Technical Specifications".
- Avoid mechanical shocks and vibration to the device.
- No user serviceable parts inside. Do not attempt to service the device except the simple Trouble shooting method mentioned in this user manual. For any other servicing please contact the authorized service center/service personnel.
- Please do not allow any liquid enter inside the device.
- Verify that the device usage site supply voltage corresponds to the power supply voltage range. See "Technical Specifications".
- Pay attention while using the device.

Pay attention to accompanying documents!

A warning calls attention to hazardous or dangerous situations inherent to the cleaning, operation and maintenance of the equipment which may result in personal injury or death of the operator or Patient.


Medical Device

Read User manual/Instructions before use.

To indicate the acceptable Upper and Lower Limits of Relative humidity for Transport and Storage.

To indicate the maximum and minimum temperature limits at which the item can be stored, transported or used.

Manufacturer

Date of Manufacture


Serial Number of the Device


Model Number


Unique Device Identification


Authorized Representative in the European Community

Keep Away From Sunlight

Device complies with 2017/745 (MDR)

Keep Dry

This product must not be disposed of with household waste; it must be taken to a collection point for electrical and electronic equipment


Non-Sterile

Fragile

Do not Step

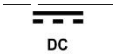

ROHS Compliant

Recycling Symbol

Consult Instructions for Use

Caution, ignition


Do not Stack




DC Only

USB

Way Up

Applied Part: Type B

# 3. Preparing VNG for Use

## 3.1 Unpacking the Device

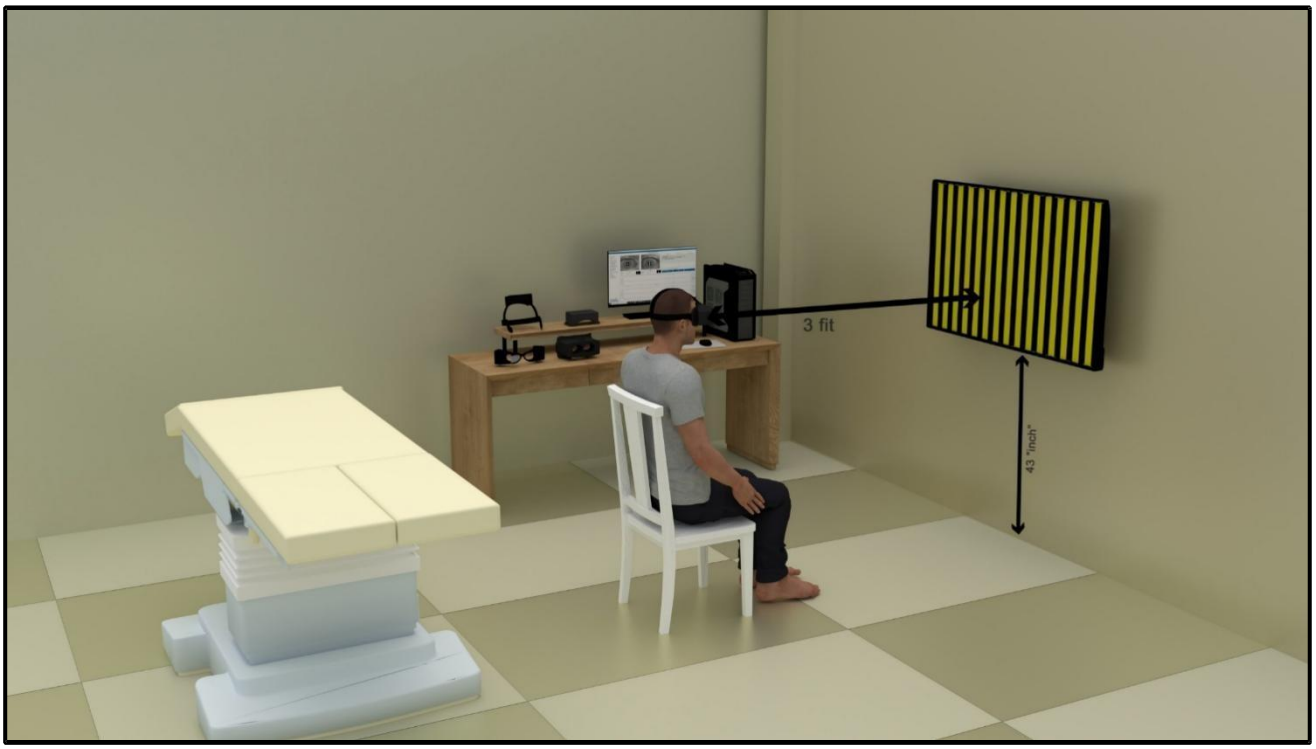
Remove the VNG from its packaging carefully. Check whether all parts are intact according to the packing list. Inspect the goggles for any signs of damage. If there are any missing or damaged parts, please contact your sales representative or NeuroEquilibrium directly for assistance.

**Unpacking Instructions**.

- Open the lid.
- Remove the top foam.
- Gently pull out the device with cables.
- Remove the polythene cover on the device.
- Place the polythene cover & top foam inside the box.
- Preserve the box for re-packing/referring labels.

## 3.2 Installation

- The patient's chair should be positioned between 3 feet to 5 feet away from the LCD/LED.
- It is advisable to mark the chair location as demonstrated in the picture.
- The test room should have semi-dark lighting to allow the operator to handle the computer and provide instructions to the patient.



### 3.3 Pre-Test Preparation

**Instructions**

- Brief the patient about the goggles used in the test and assist the patient in wearing them.
- Confirm the chair position (3 to 5 feet) and head position.
- Ensure the patient is seated in a position facing either the screen or the wall where the image is projected.
- Verify proper detection of the pupils.
- Check for any ear perforations; if present, avoid the caloric test.
- If the patient feels uneasy at any moment during the test, immediately stop the test and reassure the patient.
- Proceed with the tests only when the patient is ready. Contact the doctor in case of any need or emergency.
- Confirm the head and chair position according to the markings.

**Patient Instructions**

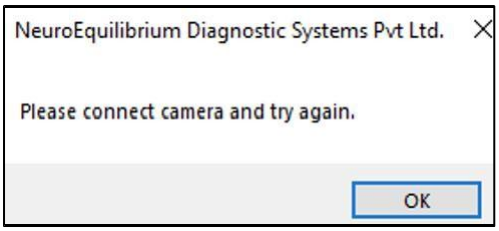
- Remove all eye makeup before the test.
- Try to avoid blinking during the test.
- Only move the eyes and not the head or neck while observing the images projected on the screen.
- Adjust the Strap for proper fitting of the VNG head band to the patient.

## 4. Operation

### 4.1 Connection Details

- Connect the VNG device to the available USB ports on the computer/laptop before opening the Dashboard Software.
- If the device is not connected, the Dashboard Software will display an error message stating "Please connect camera and try again."

Do not start or continue a VNG test if the camera / VNG goggle is not detected, if the live video is unavailable, or if the software displays a camera/device connection warning. Reconnect the USB cable, confirm that the VNG goggle is connected to the approved computer/laptop USB port, restart the software if required, and proceed only after live acquisition and device communication are restored. If the warning persists, contact authorized service personnel.




- Connect the LCD/LED TV to the available HDMI port on the laptop/computer.

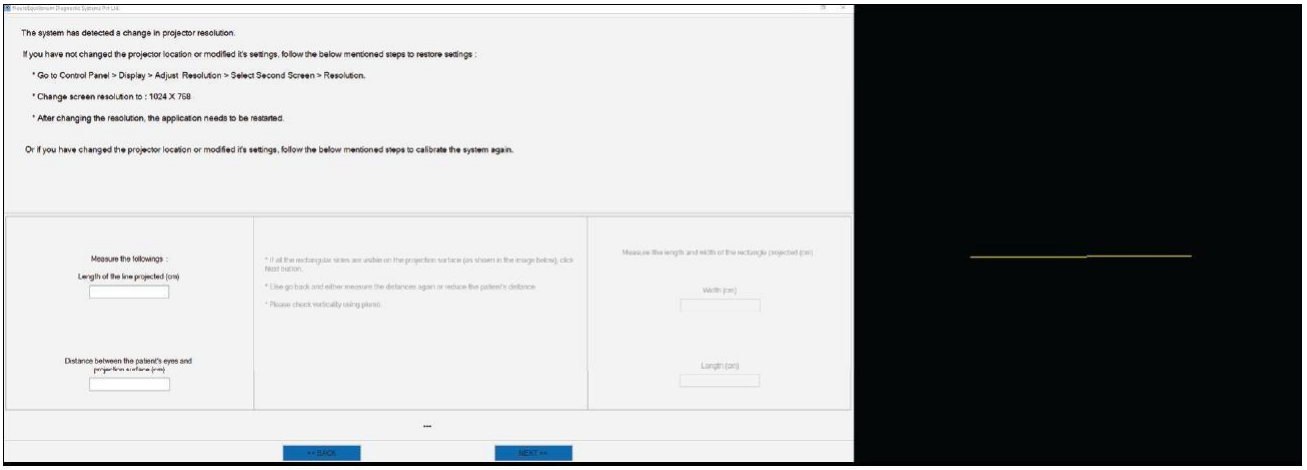
For workflows requiring visual stimulus or simulation / animation display, confirm that the external display is connected, configured as the extended screen, visible to the patient, and successfully calibrated before starting the test. Do not perform display-dependent tests if the external display is unavailable, incorrectly configured, or if the software indicates a display/output condition is not available.

**Note: The second monitor shall be minimum 43” of display size (Diagonal)**

## 4.2 Screen Calibration

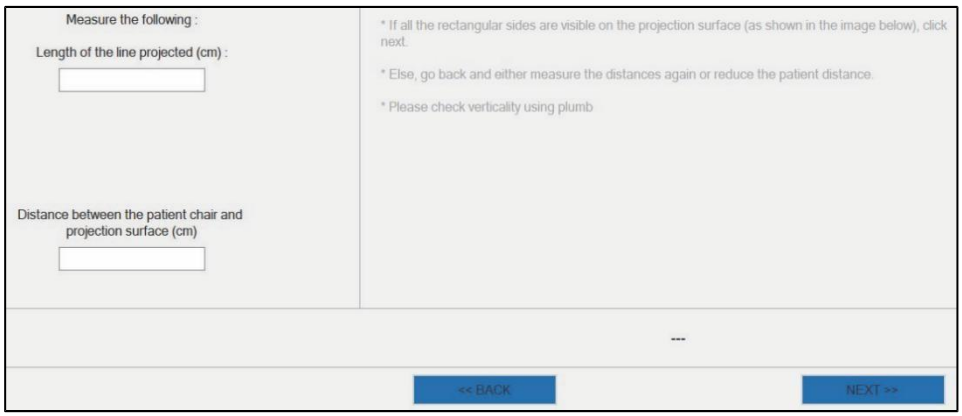
To begin calibration, open VNG from Dashboard, click on "Properties," then select "Extended Screen Calibration."


A Yellow line will be displayed on the extended screen.




Monitor Window

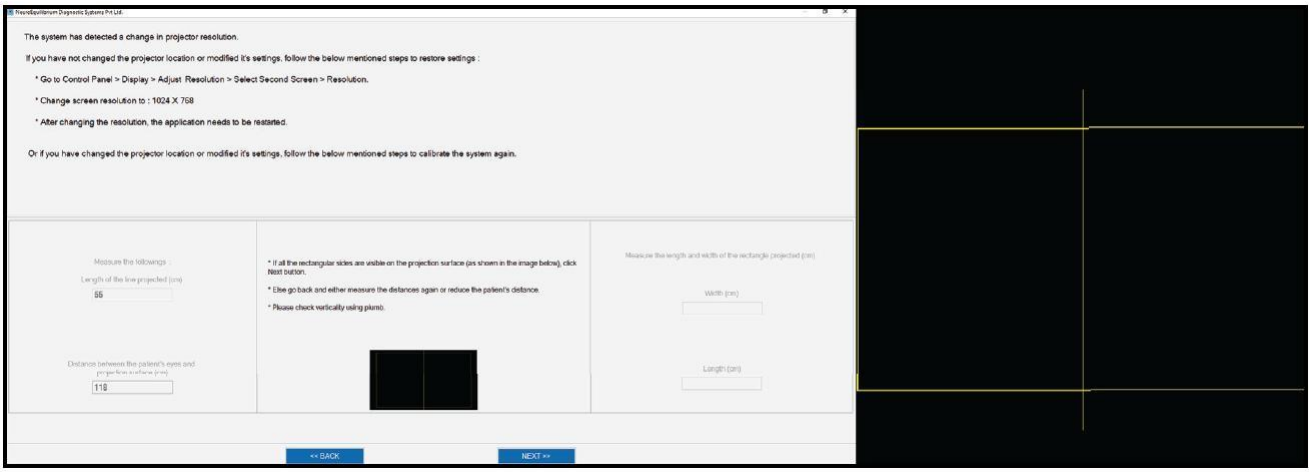
Extended Screen Window




Monitor Window

Measure the length of the line projected on screen (in cm) with a measuring tape and enter the value in the upper box.

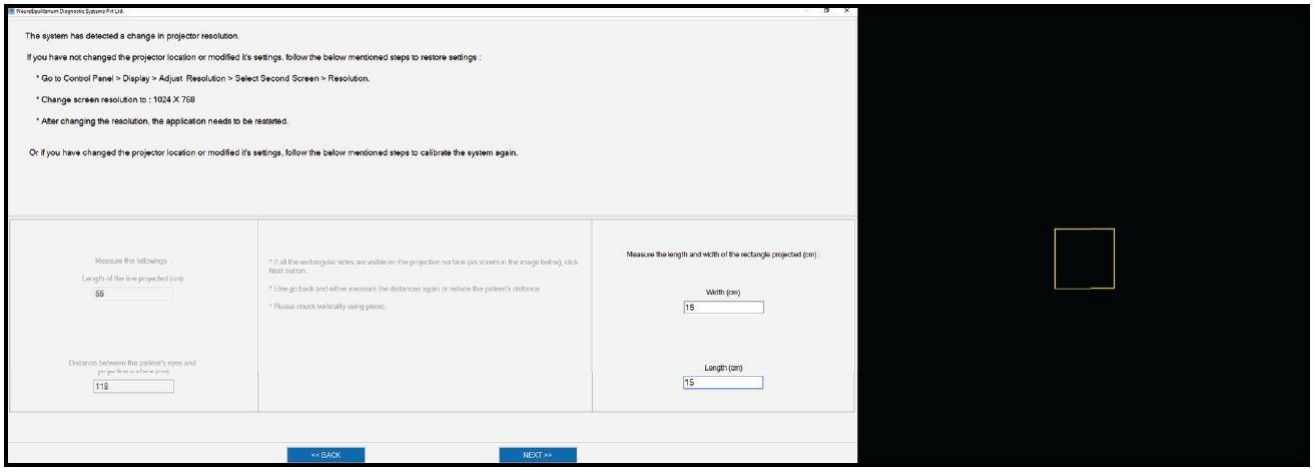
Measure the distance between the patient's eyes and the screen (in cm) and enter the value in the lower box.




Monitor Window

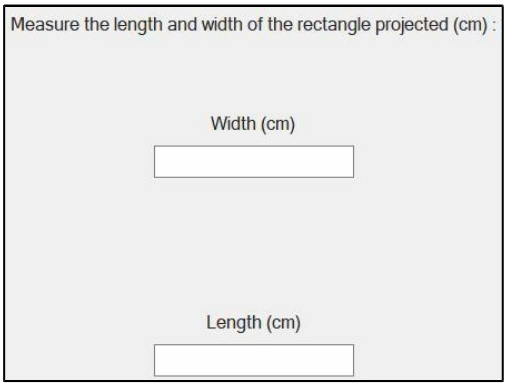
Extended Screen Window

Click on the "Next" button, then a rectangle will appear on the screen. Measure the length and width of the rectangle projected on the screen using a measuring tape (in cm) and enter the values.



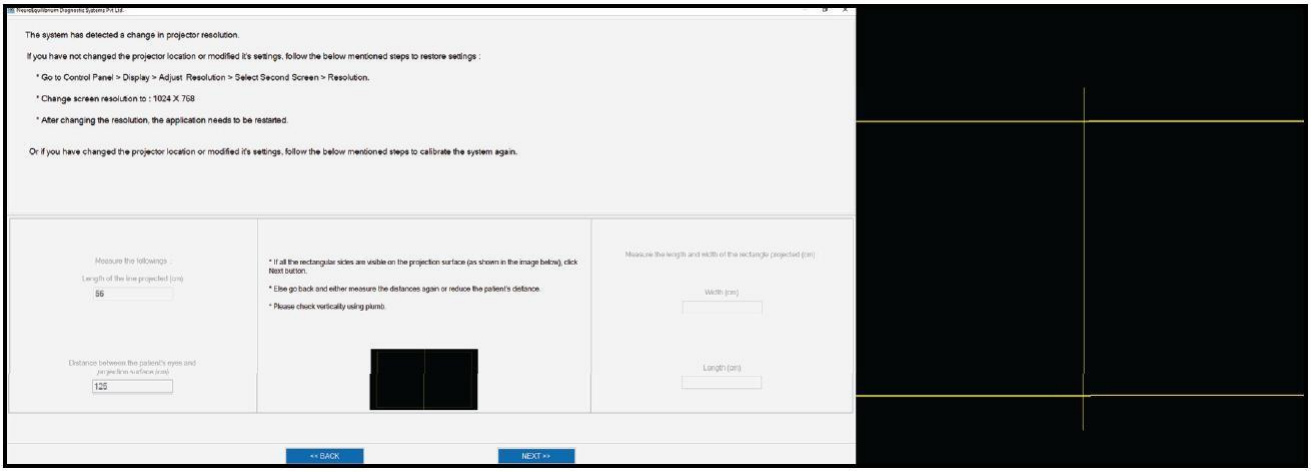

Monitor Window

Extended Screen Window




Monitor Window

This rectangle should be completely visible on the screen. If not, then keep decreasing the distance gradually by half feet until it becomes completely visible.




Click on the "Next" button, and the calibration is successfully completed.

**NOTE**: Re-calibration is required whenever the screen resolution of the LCD/LED TV is modified.

### 4.3 Operating Precautions

All the users are strongly advised to read this manual and understand its contents before operating the equipment.

The following precautions must be taken at all times:

- Clean the mirrors before and after every use following the cleaning procedure defined in this manual.
- Ensure the USB cable is free from knots and folding.
- Inspect the goggles for any cracks or damages before use.
- Ensure the patient's chair is positioned on the floor marks and the LCD/LED is not disturbed.
- Ensure the LCD/LED surface is free from dust and insects.
- Ensure the room light can be easily controlled as per the test specifications.
- Arrange the wires/cables for free movement around the patient.
- Ensure the keyboard and mouse are visible for easy operation.
- Do not route the USB cable around the patient to avoid any strangulation or elongation or tripping over.
- When fixing the goggles to the patient, take care while locking the straps.
- Avoid using excessive force while tilting the patient's head at different angles.
- Refer to the troubleshooting section for minor software issues.
- Do not attempt to open or dismantle the equipment in case of breakdown or unresponsiveness.
- Avoid subjecting the VNG to mechanical stress or vibration.
- Healthcare Professionals/ Doctors should handle the patient from the rear or sides, avoiding interference with the extended screen or the patient's field of view. All cables should be routed only from the rear side of the patient.

### 4.4 Sequence of Tests

- Calibration:
  - Horizontal
  - Vertical
- Spontaneous
- Gaze:
  - Left 25
  - Right 25
  - Up 15
  - Down 15
- Smooth Pursuit
- Random Saccade:
  - Horizontal
- Optokinetic:
  - 30°/sec Left
  - 30°/sec Right
- Skew Deviation
- Hyperventilation
- Valsalva
- Head Shaking

- Positional:
  - Supine Head Roll Right
  - Supine Head Roll Left
  - Dix-Hallpike Right
  - Dix-Hallpike Left
  - Deep Head Hanging
- Caloric:
  - Right Warm
  - Left Warm
  - Right Cold
  - Left Cold

## 4.5 Initiating VNG Tests

- The VNG test should be performed in a semi-dark room.
- Connect the VNG device.
- Click on the VNG icon in the "Dashboard."
- The patient should sit on a chair facing the extended screen where the image is projected.
- Assist the patient in wearing the goggle.

## 4.6 Eye Positioning & Pupil Detection

- Instruct the patient to focus on the yellow box displayed on the extended screen (center of the projection area).
- If the eyes are not being captured, adjust the goggle manually.
- Use the up/down and left/right sliding bars to move the patient's eyes on the window to the center of the box.
- After adjustments, a clear circle should be visible in the box using the "Threshold" sliding bar.
- Ensure that there are no white patches near the white circle seen in the box.

If pupil detection is unstable, unclear, low-confidence, or if the software displays a tracking / validation warning, do not rely on the affected measurement segment for final interpretation. Reposition the goggle, adjust the pupil-detection / threshold settings as instructed, ask the patient to relax, and repeat the test where required. Proceed only when pupil tracking is stable and the software permits valid acquisition.

When clicking on the VNG icon in the dashboard, the following window will open. The header includes options for "Video" and "Exit" to view eye recording videos and exit from the software, respectively.

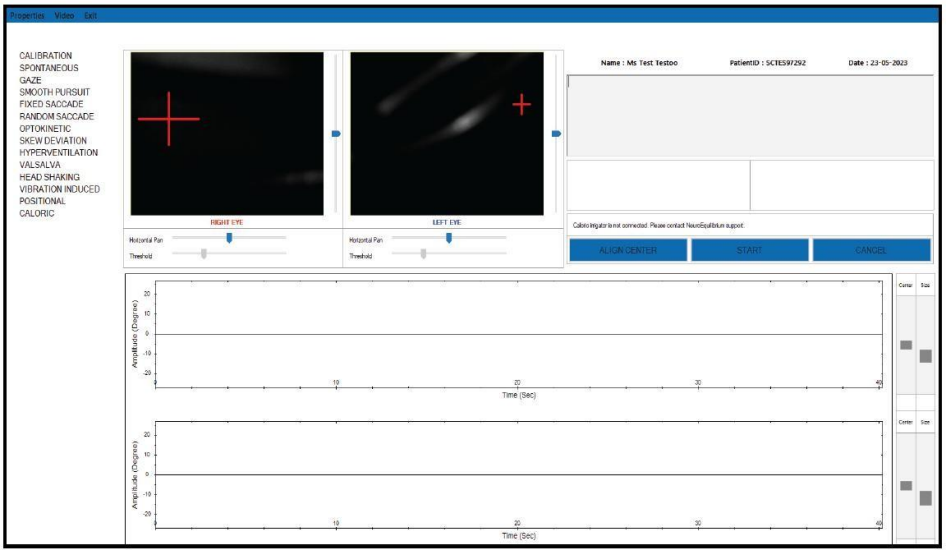



Figure 01

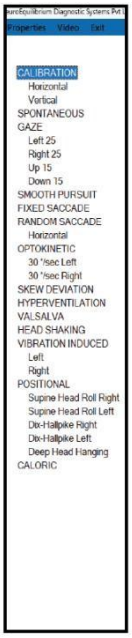



Figure 02

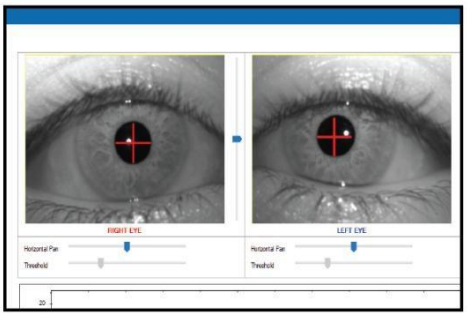



Figure 03

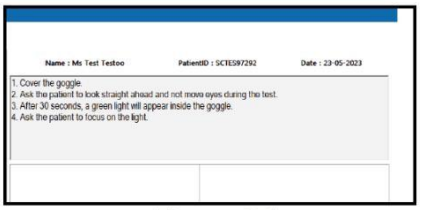



Figure 04


Figure 05

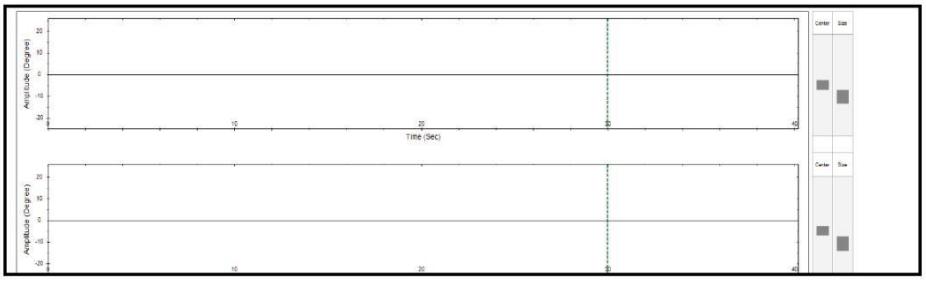



Figure 06

Figure 02: You can select the test by clicking on the name from this test index.
Figure 03: You can adjust and see the live pupil tracking from here.
Figure 04: Operational instructions specific to the selected test will be displayed here.
Figure 05: You can start or cancel the test with the help of buttons provided.
Figure 06: Horizontal and vertical graphs will be plotted here.


**Note 1:** In case of Accidental movement of the device while testing, ensure the correct fitting of the device with the patient and proceed further.

**Note 2:** Repeat the process in case of any difficulty on getting the results or un successful testing activity once the patient is relaxed.

## 5. Color Notation

**Black Colour:** The black color of the test name indicates that the particular test has not been performed.


**Red Colour**: The red color of the test name indicates that the particular test has been performed.


**Blue Colour**: The blue color of the test name indicates that the particular test has been performed but the data has not been uploaded.


**If data wasn't submitted and saved for upload, go to the main dashboard and click on the blue strip where it is written "Upload Data."**

Treat the test data as not fully submitted / uploaded until the software displays the applicable successful submission confirmation or the test status no longer indicates pending upload. If "Data Submitted Successfully" is not displayed, if the test remains marked as pending upload, or if upload/storage fails, retry the upload from the Dashboard. Do not close the patient record as complete until submission/storage is confirmed. If the condition persists, contact authorized service/support personnel.

# 6. VNG Report Generation

Click on the VNG Report icon from the Dashboard.


New window will be seen on the screen.

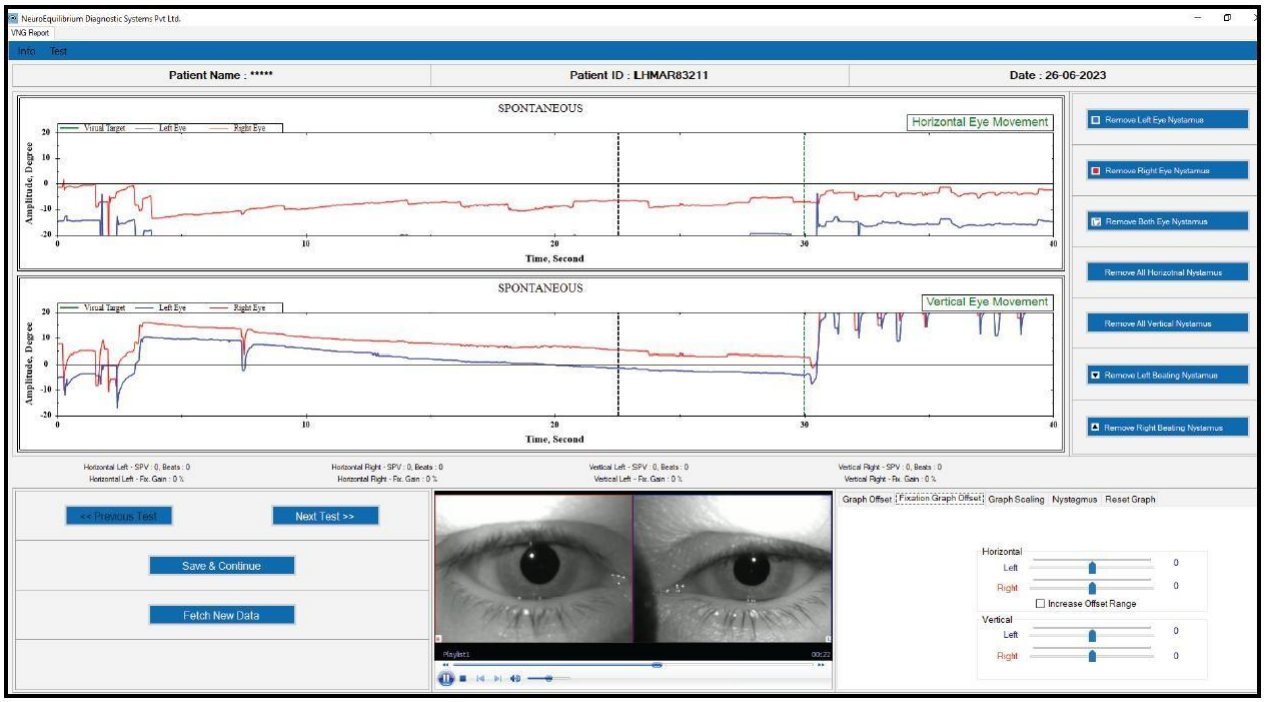



Figure 01

When you click on the VNG icon in the dashboard, the following window will open. On the header, there is a "Test" option given to select any particular test from the software.

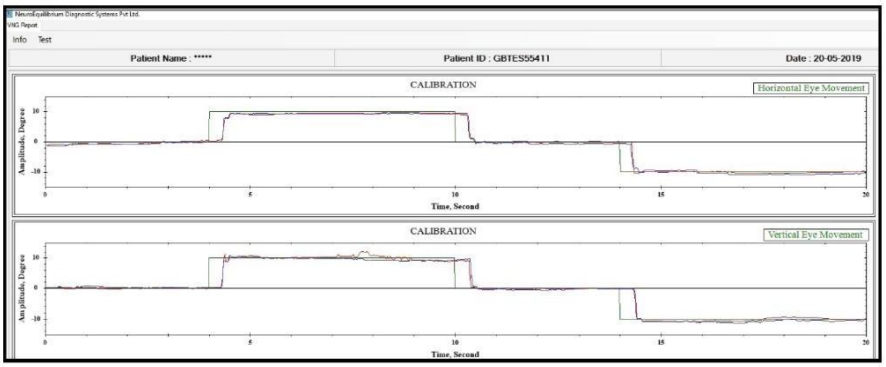



Figure 02


Figure 03


Figure 04

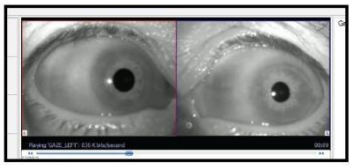


Figure 05

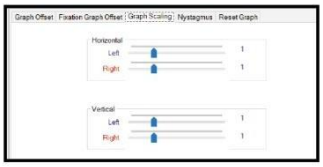



Figure 06

Figure 02: Horizontal and vertical graphs with beats will appear here.
Figure 03: You can remove artifacts from here.
Figure 04: You can submit, fetch new data, skip, and move to the previous or next test from here.
Figure 05: You can see the eye recording video synchronized with the graph from here.
Figure 06: You can make alterations in the report from here.

Press “Exit” button to quit the software

## 7. Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member state in which the user and patient is established.

## 8. Shutdown Procedure

No special Procedure required for this device.
Whenever the device usage is over, stop the operation, remove the USB cable.

## 9. Hygiene & Care

NeuroEquilibrium VNG cleaning instructions.

- Please use dry cloth or cotton to clean the goggles and the head strap.
- Use dry cotton cloth and wipe the surface of the strap and goggles if needed to remove the moisture or sweat etc.

**Caution!**
Do not immerse VNG in any liquid.
Liquid ingression may cause serious damage and the device can be unusable.
Do not apply force/Lean/step on the product.

**Note:**
Warning: Clean the device before and after the use to avoid the Infection and Contamination.

## 10. Trouble Shooting

| Trouble Symptom | Cause | Action |
|---|---|---|
| Hardware Not Detected | USB Handshaking Time out | Re-connect USB Connectors |
| Unable to view real time Video | USB Port Might be slow | Try another USB Port |
| Smoky video | Finger marks/Dust on Mirror | Clean the mirror and try again |
| Software Freezes /Slow /Not Responding | Computer/Laptop related | Remove USB, Restart the computer/laptop and connect again |
| Distorted/Mis-alligned video | Hardware disturbed | Contact Service team or return the Goggle for Service /Replacement |
| Unable to calibrate | Hardware disturbed | Contact Service team or return the Goggle for Service/Replacement |
| Camera Status: Not Found / Please connect camera and try again | VNG goggle/camera not connected, USB communication unavailable, or camera driver/acquisition path unavailable | Reconnect USB, try another approved USB port, restart software if required, and proceed only after live video/device communication is restored. Contact service if unresolved. |
| Display / stimulus not shown on external screen | HDMI/display not connected, extended screen not configured, or display path unavailable | Connect HDMI display, configure extended screen, repeat screen calibration, and do not perform display-dependent tests until corrected. |
| Tracking / validation warning or unreliable pupil detection | Poor goggle fit, patient movement/blinking, poor pupil visibility, or invalid acquisition condition | Refit goggle, adjust pupil detection/threshold, allow patient to relax, and repeat affected test if required. |
| Data not submitted / upload pending / no success confirmation | Database/storage/upload confirmation not completed | Retry upload/submission from Dashboard and confirm successful submission before treating the record as complete. Contact service if unresolved. |

## 11. Storage

Store the device as mentioned in the Technical Specifications of this manual.
Do not store/keep VNG under direct Sunlight. Store VNG in dry environment.
This Device is intended to be used in clinical environment by Doctor or by trained Healthcare Professionals.

## 12. Service

No User Serviceable Parts inside. In case of any malfunction/defect contact the dealer/manufacturer for service/replacement.
The product should be sent back to the dealer/manufacturer for service/replacement.
VNG is subject to clean after or before every use. Follow section 4.3 “Operating Precautions” and section 9 “Hygiene and Care”.

## 13. Preventive Maintenance

Though no special preventive maintenance required, check the fitness and quality of face foam and for any physical damage on USB cable.

**Note:** The device shall be handled only by authorized person from the organization who is trained by NeuroEquilibrium Diagnostic Systems Pvt Ltd.

## 14. Member States the Device are sold

Globally.

## 15. Technical Specifications

**Device**
Dimensions l X W X h (in mm).....265 X 105 X 100
Weight with Face Foam.....450gms

**Operation***
Temperature Limits .....+15° C to +35° C (+59° F to +95° F)
Relative Humidity .....30 – 90% non-condensing

**Transportation/Storage***
Temperature Limits .....0° C (-°32 F) to +50° C (+122° F)
Relative Humidity .....10 – 95%, non-condensing

**Energy Source**
Type..... USB 2.0 Type-A
Supply Voltage..... .....5V DC
Rated Maximum Current .....180mA

**VNG Specifications**

Image Sensor .....CMOS 1/3 inch
Sampling Rate.....30 fps - 100 fps
Horizontal Resolution of Video Camera..... 640 Pixels(max)
Vertical Resolution of Video Camera..... 480 Pixels(max)
Horizontal Eye Tracking.....0 to 25 degrees
Infrared Light Wavelength.....950nm
Green LED Wavelenth.....560-520nm

**Duration**

Mode of Operation ..... Continuous

**Ingress Protection**

Protection against Dust/Ingress Liquids.....Not Protected (IPX0)

**RoHS II** ..... Yes

**Compatible Accessories**

Computer Minimal Configuration .....Intel Core i5 processor or better
16 GB RAM Minimum HDMI Port for external monitor
Monitor resolution 1920 x 1080 or better
USB 2.0/3.0 Type A ports Windows® 10 (64-bit) / Windows® 11 validated
environment, as supplied or approved for the released VNG software configuration.
Suggested to use CE Certified Medical Grade Power Adapters

Multimedia Requirements .....Min. 43" LED/LCD TV with HDMI Cable
Native Resolution 1920 x 1080 pixels.

**Regulatory Standards****

Equipment Designed to comply with necessary safety measures guided by ..... EC 60601-1
IEC 60601-1-2
EN 62304

**Classification of Applied Part**..... Type B

**Temperature and Humidity limits are derived from the equivalency device.*
***All the standards are referencing to current edition of the standard.*

# 16. Electromagnetic Compatibility

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). They must be installed and used in accordance with the EMC information contained in the accompanying documents.

The device is intended for use in the areas of domestic healthcare and in medical facilities. It has been tested for operation in residential areas and buildings that are used for residential purposes and are connected to a public supply network.

**Warnings:**
The use of this device next to other devices or with other devices in a stacked form should be avoided, as this could result in incorrect operation. If use in the manner described above is necessary, this device and the other devices should be observed to ensure that they are working properly.

Portable RF communications equipment (including peripheral devices such as antenna cables and external antennas) should be used no closer than 30 cm to any part of VNG, including cables specified by the manufacturer. Otherwise, the performance of this device may be negatively impacted.

The use of accessories, converters and cables that are not specified or provided by the manufacturer of this device can lead to increased electromagnetic emissions or decreased electromagnetic immunity of this device and to improper operation.

The electromagnetic compatibility was tested in accordance with the information in IEC 60601-1-2. No special precautions are necessary for compliance with the technical specifications and safety over the expected service life. The stimulation frequency and the max. current levels are not influenced by electromagnetic fields.

<table>
<tr><th>Requirement – Test</th><th>Limits</th><th>Result/Comment</th></tr>
<tr><td colspan="3">Clause 7 - Emissions</td></tr>
<tr><td>Radiated Emission CISPR 11</td><td>30MHz to 230 MHz 40<br>230 MHz to 1000 MHz 47, 10mts, Group 1 Class A<br>Polarization: Horizontal & Vertical</td><td>Within Limit</td></tr>
<tr><td>Conducted RF Emissions per CISPR 11</td><td>0.15MHz to 0.50 MHz 79<br>0.50 MHz to 30 MHz 73</td><td>Within Limit</td></tr>
<tr><td>Harmonic Distortion per IEC61000-3-2 Class A</td><td></td><td>Within Limit</td></tr>
<tr><td>Voltage Fluctuations and Flicker per IEC61000-3-3</td><td></td><td>Within Limit</td></tr>
<tr><td colspan="3">Clause 8 - Immunity</td></tr>
<tr><td>Electrostatic Discharges Per IEC 61000-4-2:2008</td><td>Air – Direct: 2, 4, 8, 15 KV<br>Contact – Direct: 2, 4, 6, 8 KV<br>Contact – Indirect: 2, 4, 6, 8 KV<br>Discharge Level: + ve & - ve<br>No. of Discharge per Location: 10<br>Ext Locations Accessible by Hand: HCP & VCP</td><td>No Malfunctions Observed</td></tr>
<tr><td>Radiated RF EM Fields per IEC 61000-4-3</td><td>Frequency Bandwidth: 80 MHz to 2700 MHz<br>Modulation: 80% AM at 1kHz<br>Level: 3V/m<br>Frequency Step: 1%</td><td>No Malfunctions Observed</td></tr>
<tr><td>Electrical Fast Transients and bursts per IEC 61000-4-4</td><td>Input AC Power Port: ±2 KV<br>Coupling Method: Direct Injection<br>Repetition Frequency:100 kHz</td><td>No Malfunctions Observed</td></tr>
<tr><td>Surges perIEC61000-4-5</td><td>Input AC Power Port: 0.5KV and 1.0KV: L-L<br>0.5KV, 1.0KV & 2.0KV: L-E<br>Combination Wave: 2µs x 50µs V, 8µs x 20µs A</td><td>No Malfunctions Observed</td></tr>
<tr><td>Conducted Disturbances, induced by RF fields per IEC 61000- 4- 6</td><td>Input AC Power Ports: 150kHz to 80MHz<br>Level: 3 V RMS outside the ISM band, 6 V RMS in the ISM bands<br>Modulation: 80% AM at 1kHz<br>Frequency Step: 1%</td><td>No Malfunctions Observed</td></tr>
<tr><td>Voltage Dips and Interruptions per IEC61000-4-11</td><td>
<table>
<tr><th>Voltage Dips % UT</th><th>Cycles</th><th>Sync Angle (degrees)</th></tr>
<tr><td>>95</td><td>0.5</td><td>0,45,90,135,180,225,270,315</td></tr>
<tr><td>>95</td><td>1</td><td>0</td></tr>
<tr><td>30</td><td>25</td><td>0</td></tr>
<tr><td>Voltage Interruption % UT</td><td>Cycles</td><td>Sync Angle [degrees]</td></tr>
<tr><td>>95</td><td>250</td><td>0</td></tr>
</table>
</td><td>No Malfunctions Observed</td></tr>
<tr><td>Rated Power-frequency Magnetic Field IEC61000-4-8</td><td>Frequency: 50Hz<br>Level: 30 A/m</td><td>No Malfunctions Observed</td></tr>
</table>

## 17. Warranty

NeuroEquilibrium Diagnostic Systems Pvt Ltd warrants that this product will be free from defects in materials and workmanship for a period of 1 year for the device from the date of shipment. If any such product proves defective during this warranty period, NeuroEquilibrium Diagnostic Systems Pvt Ltd, at its option, either will repair the defective product without charge for parts and labor or will provide a replacement in exchange for the defective product. Parts, modules and replacement products used by NeuroEquilibrium Diagnostic Systems Pvt Ltd for warranty work may be new or reconditioned to like new performance. All replaced parts, modules and products become the property of NeuroEquilibrium Diagnostic Systems Pvt Ltd.

In order to obtain service under this warranty, customer must notify NeuroEquilibrium Diagnostic Systems Pvt Ltd of the defect before the expiration of the warranty period and make suitable arrangements for the performance of service. Customer shall be responsible for packaging and shipping the defective product to the service center designated by NeuroEquilibrium Diagnostic Systems Pvt Ltd, with shipping charge prepaid.

This warranty shall not apply to any defect, failure or damage caused by improper use or improper or inadequate maintenance and care or any Intentional Acts of Mis-use by using the device apart from the Intended use mentioned on this manual or improper storage. NeuroEquilibrium Diagnostic Systems Pvt Ltd shall not be obligated to furnish service under this warranty.

a. To repair damage, resulting from attempts by personal other than NeuroEquilibrium Diagnostic Systems Pvt Ltd representatives to install, repair or service the product;
b. To repair damage resulting from improper use or connection to incompatible equipment;
c. To repair any damage or malfunction caused by the use of non- NeuroEquilibrium Diagnostic Systems Pvt Ltd supplies;
d. To service a product that has been modified or integrated with other products when the effect of such modification or integration increases the time or difficulty of servicing the product.
e. To repair damage, resulting from electrical faults.

This Warranty is given by NeuroEquilibrium Diagnostic Systems Pvt Ltd with respect to the product in lieu of any other warranties, express or implied. NeuroEquilibrium Diagnostic Systems Pvt Ltd and its vendors disclaim any implied warranties of Merchantability to repair or fitness for a particular purpose. NeuroEquilibrium Diagnostic Systems Pvt Ltd sole and exclusive remedy provided to the Customer for breach of this warranty. NeuroEquilibrium Diagnostic Systems Pvt Ltd and its vendors will not be liable for any Indirect, special, incidental, or consequential damages irrespective of whether NeuroEquilibrium Diagnostic Systems Pvt Ltd or the vendor has advance notice of the possibility of such damages.

## 18. Declaration of Medicinal Substances

By design, this Videonystagmography does not incorporate any medicinal substances.

## 19. Disposal

Dispose of the instrument according to local disposal and recycling laws.

This product must not be disposed of with household waste; it must be taken to a collection point for electrical and electronic equipment.
Some Parts of the equipment contains material which must be disposed off in special areas designated by the local health authorities or other local regulations at the end of the equipment's life cycle.
In particular the equipment contains the following material and / or components:

1. Enclosure: Contains non-biodegradable plastic material.
2. Product Assembly: Contains PCB Assemblies, Copper wires with PVC sleeves, Steel springs & Steel Screws and nuts.
3. PCB Assembly: Contains Semiconductors, Glass Epoxy material and metals Tin, Silver, Gold & Copper.
4. Straps: Contains nylon and fabric material.

***The Manufacturer and the Distributor do not accept any responsibility for the disposal of equipment or parts discarded by the user and the related costs.***
***Do not open the equipment. The equipment can be refurbished only by NeuroEquilibrium qualified technician.***

## 20. Additional Information

- Inspect the elastic strap before every use. If the strap needs replacement then inform the dealer/manufacturer for spare. Insert the Velcro side on the slots and lock the strap to required head size.
- Inform the dealer/manufacturer if the labels on the device peeled off.
- Data Storage: Data's are stored in internal memory of the computer/laptop and also on cloud storage.
- The laptop/Computer used for testing should have Internal Firewall/Anti-virus protection.

The VNG software shall be used only on the approved computer/laptop configuration by authorized and trained users. Do not disable required endpoint security, firewall, login, or USB-key/access controls. Do not modify, copy, replace, or install VNG software files, database files, drivers, configuration files, or stored patient/test records except as instructed by NeuroEquilibrium or authorized service personnel.

- Frequently Used function for this product is the Software provided with the device.
- Only Face Foam and Strap are the parts which come in direct contact with the patient & No Electrical contact with the patient. So these are classified as Type B applied part.
- For more hygiene, operator/healthcare professional/doctor may use disposable facial/eye patch between patient's face and goggle.

## 21. Customer Support

### Registered office

140, Shrigopal Nagar, Gopalpura Bypass Road, Jaipur-302015, Rajasthan, India.

### Manufacturing Site

1st Floor, Pooja Tower, Gopalpura Bypass Road, Jaipur-302018, Rajasthan, India.
info@neuroequilibrium.in, www.neuroequilibrium.in/for-doctors/

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