English

SUBJECTIVE VISUAL VERTICAL

User Manual
And
Introduction to the Device

For Subjective Visual Vertical (SVV)

CE 2803

Document Reference No.....NE-P12-002
Issue.....00
Date.....7th March 2024

Software Version: V1.0.0.0
Dashboard Application SVV: 9.2.11

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

Declaration of Language Translation:

SVV 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

Over View of SVV

1. Goggle enclosure
2. SVV Top Cover
3. USB Cable
4. Velcro Strap
5. Face foam

1. Goggle enclosure

The goggle enclosure consists of necessary electronics assemblies intended for this product.

2. SVV Top Cover

The pain PCBA and Cable termination chamber is covered by this top cover.

3. USB Cable

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

4. Velcro Strap

These elastic straps with Velcro's provide a comfortable grip to hold the goggle to patients face.

5. Face foam

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

1. Introduction to the Device

1.1 Intended Use

Subjective Visual Vertical is a device to evaluate the otolith system which is responsible for perception of verticality.

TESTS

-Static with head tilt vertical and inclined at 30 degrees.

-Dynamic Clockwise and anticlockwise moving background with head tilt vertical Positional testing including

-Dix-Hallpike, McClure's, Supine, and 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 technicians, then they have to undergo training by Neuroequilibrium.

1.4 Target User

Neurotologists, Neurologists, Psychiatrists and Lab Technician

1.5 Intended Patient Population

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

1.6 Description of the Functions

Subjective Visual Vertical (SVV) is an investigation to evaluate the otolith system which is responsible for perception of verticality. Static and dynamic SVV are important to:

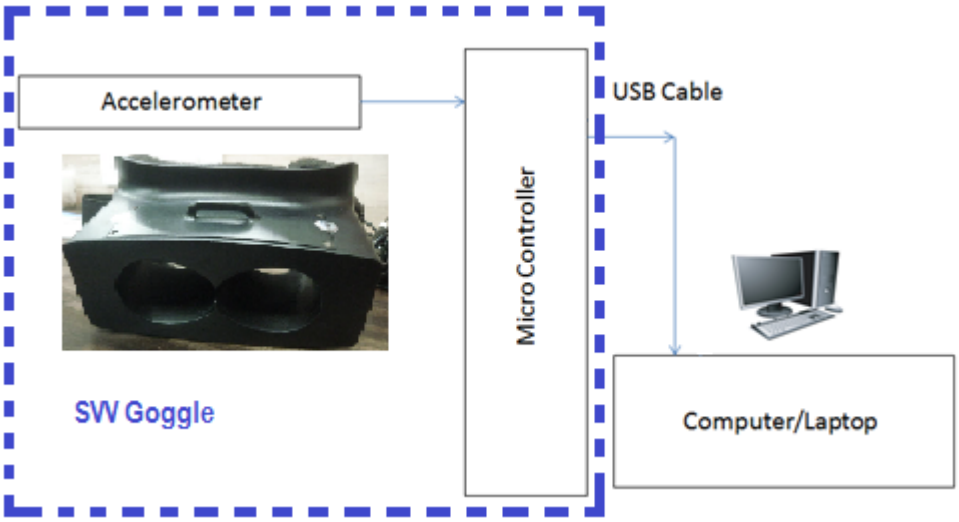
- Assess otolithic disorders
- Assess chronic dizziness
- Differentiate peripheral from central vestibular disorders
- Decide side of peripheral vestibular insult during the acute stage
- Diagnose compensated vestibular disorders

NeuroEquilibrium SVV has the industry's leading binocular goggle design.

- No adjustment required for focus.
- Light weight with direct USB connection to a laptop or a Desktop Computer.
- Easy fit magnetic cover allowing for both occluded and un-occluded measurements.
- Built-in fixation light to simplify testing.

Principle of Operation

The goggle provides a tubular vision and ensures that the head is at a fixed tilted position, which is done through a tubular goggle equipped with IMU sensor. The patient is asked to make the projected line vertical using a remote. The difference between the actual vertical & the perceived vertical is measured.



Patient's head position is communicated to the computer through USB protocol. This simple USB communication streams the software continuously to know patient's head position from Goggle.

SVV goggle is being powered by computer's USB port.

The NeuroEquilibrium Dashboard software analyses the data of the otolith system which is responsible for perception of verticality of the patients suffering from vertigo and/or balance disorders. The main parameters for evaluating the Assess otolithic disorders, chronic dizziness, differentiate peripheral from central vestibular disorders, decide side of peripheral vestibular insult during the acute stage, and diagnose compensated vestibular disorders.

1.7 Indications for Use

NeuroEquilibrium's SVV is indicated to be used on patients experiencing the below symptoms while changing their general postures on day to day life.

- Assess otolithic disorders
- Assess chronic dizziness
- Differentiate peripheral from central vestibular disorders

1.8 Contraindications for Use

NeuroEquilibirium's SVV should not be used if the patient has the below complications.

- Epilepsy.

1.9 Clinical Benefits

- To identify potential abnormalities in the utricle and superior vestibular nerve.
- Assess effect of rehabilitation in vertigo patients
- Compact device for the functional test of the otolith organs.
- Real time monitoring of patient head position.
- Measure Otolith dysfunction

1.10 Side Effects

No any side effect.

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 SVV 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 a 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 Subjective Visual Vertical (SVV). 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 device 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 life time.
- 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.

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.

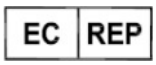
Manufacturer

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

Batch Code

Applied Part: Type B

Protect from heat and radioactive sources

3. Preparing SVV for Use

3.1 Unpacking the Device

Remove the SVV 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 First Time Installation

First Time installation (Hardware, Dash board and SVV Software) will be performed by Authorized company representatives.
Future software updates shall be done by online (Team viewer) for Dashboard & SVV Software.

3.4 Patient Preparation

Explain the steps clearly to the patient.
Adjust the Strap for proper fitting of the SVV head band to the patient.

4. Operation

4.1 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 google 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 wire/cables for free movement around the patient.
- Do not route the USB cable around the patient to avoid any strangulation or elongation or tripping over.
- Ensure the keyboard and mouse are visible for easy operation.
- When fixing the goggles on 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 SVV to mechanical stress or vibration.
- Technicians/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.

4.2 Initiating SVV Tests

- SVV test should be performed in a semi dark room.
- Connect the LED/LCD.
- Click on the SVV icon in "Dashboard".
- The patient should sit on a chair facing the LED/LCD screen where the image is projected.

4.2.1 Prerequisites:

- Connect and start the LED/LCD Screen.
- Place display in extended mode.

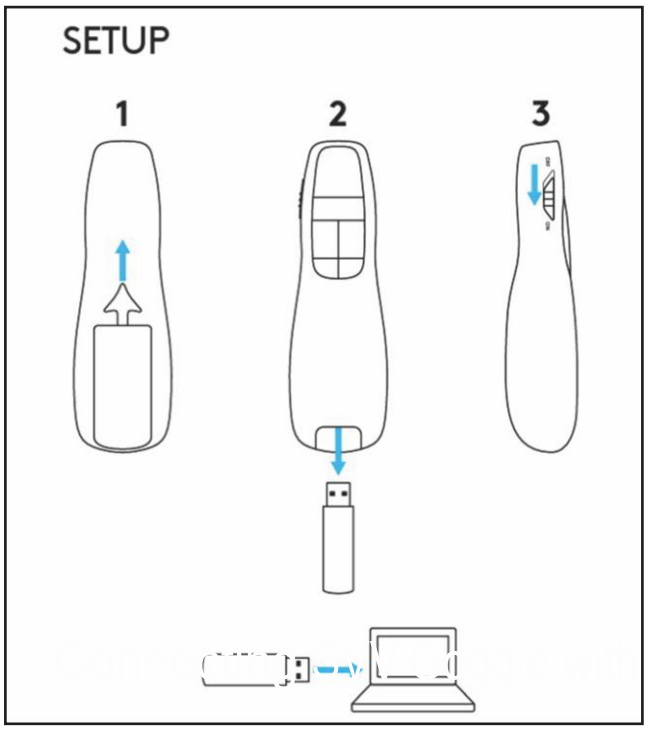
4.2.2 Instructions to use:

Setup

Step 1: SVV Goggle has to be connected to the system.
Step 2: Place the SVV Goggle on the table or floor properly.

NOTE: LED/LCD screen is required to perform SVV test.

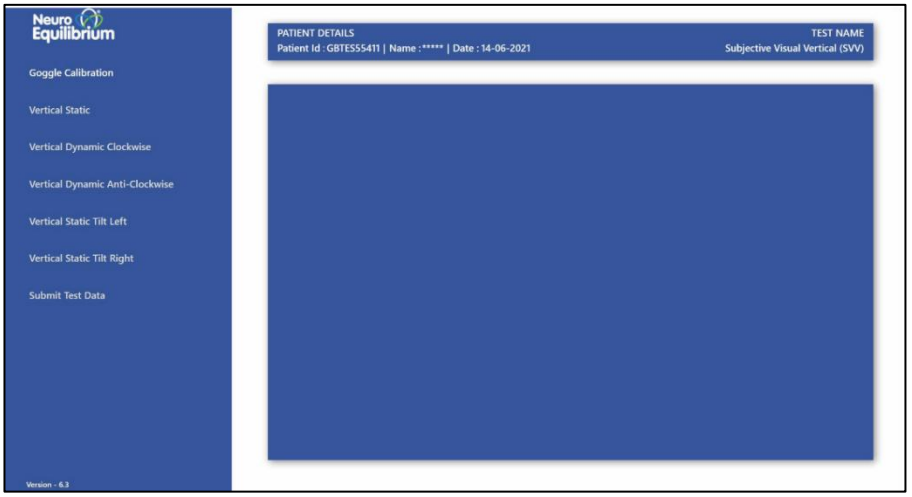
Step 3: SVV test requires a **Wireless Remote**.
Insure that Wireless Receiver is connected to the system and the remote is switched ON.



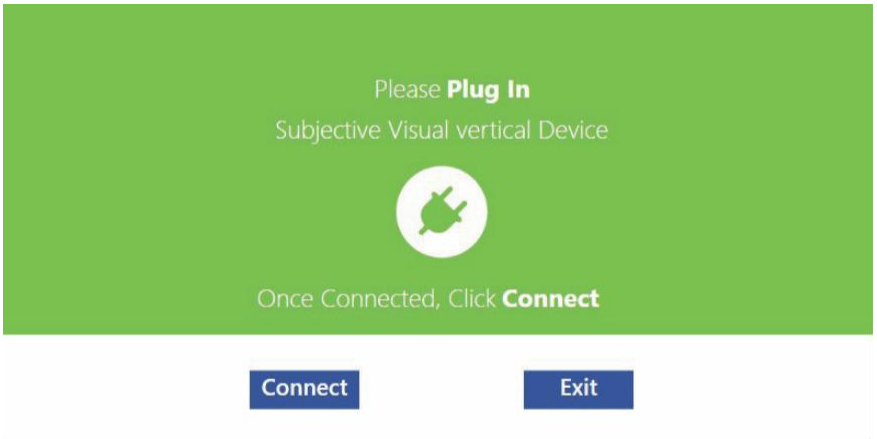
Connecting SVV Goggle with

Step 1: Login the **Dashboard.**

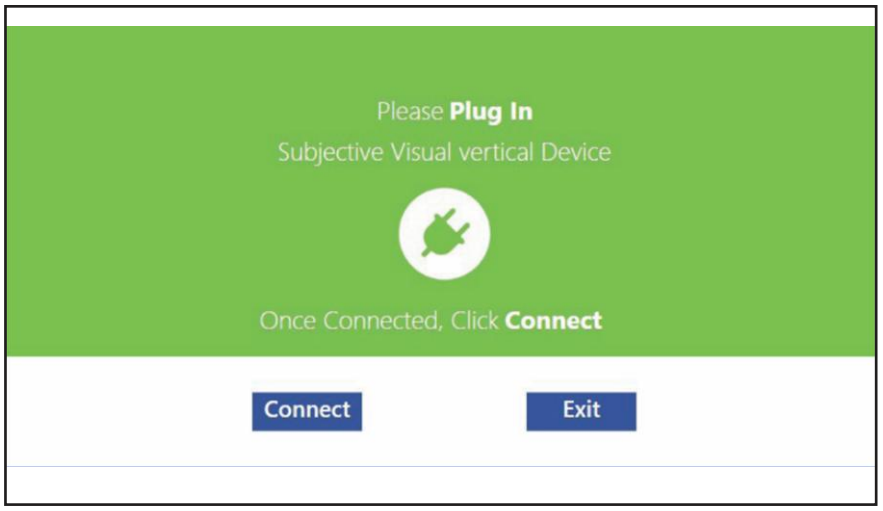
Step 2: Click on the **SVV** icon and a test window will appear as shown below.



NOTE: If the SVV device is not connected then the error below will appear.



Step 3: Plug in the SVV device properly and proceed further, click on Connect.



NOTE: Vertical Line can be rotate from -20 to +20 degree

Line Angle Calibration

Step 1: Once logged in, to open the calibration setting, press "**Ctrl + Shift + S**" button. (A window will appear as shown below.)

Main screen **Extended screen**

Step 2: A line will appear in the SVV window and the same will be projected on the screen.

Step 3: Use the Plumb provided to align the line such that it attains perfect vertical.

Step 4: The examiner can slightly orient the line by using **Page Up** and **Page Down** buttons or wireless remote.

Step 5: Once perfect vertical is attained, press the button "**Save Setting**".

Note: - This has to be performed only once, at the time of installation. Further, if the settings (LED/LCD) have been changed, one can re-calibrate.

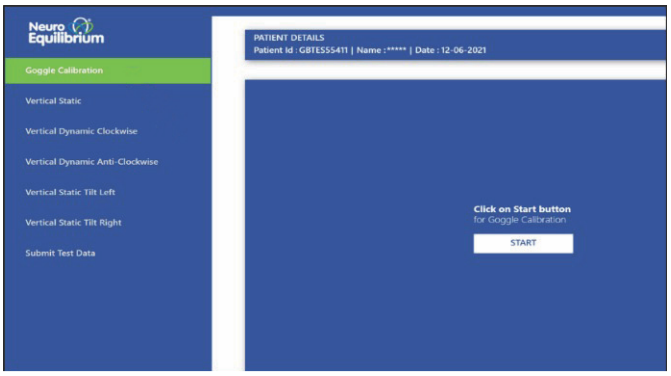
Goggle Calibration

Step 1: While performing device calibration the device should be properly placed on the flat surface (table or floor).

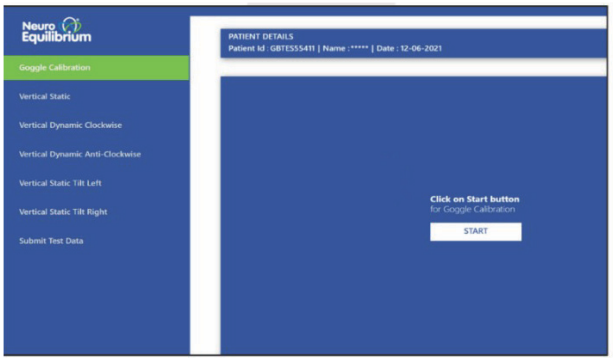
Correct

Incorrect

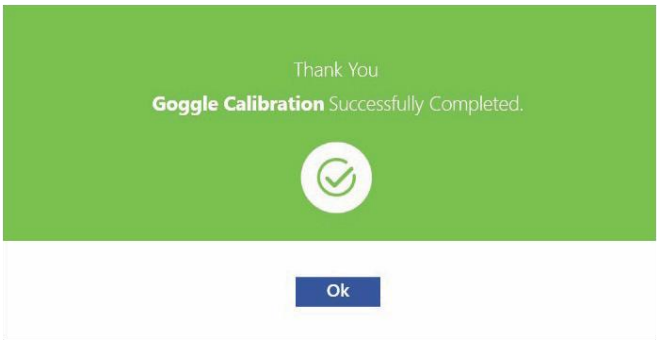
Step 2: Select **Goggle Calibration.**



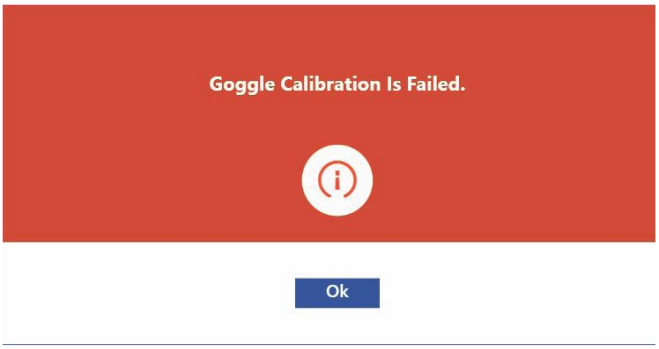
Step 3: Click on **START** button for goggle calibration.



Step 4: There is a screen showing whether calibration is correct or incorrect.



If the calibration is correct



If the calibration is incorrect

Step 5: If the calibration is done then click **Ok** Button and next test has to be performed.

NOTE: If the calibration is incorrect, the SVV Goggle must be put back in table or floor and Click on Goggle calibration.

Vertical Static

Test instructions for the doctor

Step 1: Select Vertical Static from the main screen.
Step 2: In the vertical static Test, the patient has to sit on a chair in front extended screen.

Patient chair

Extended screen

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

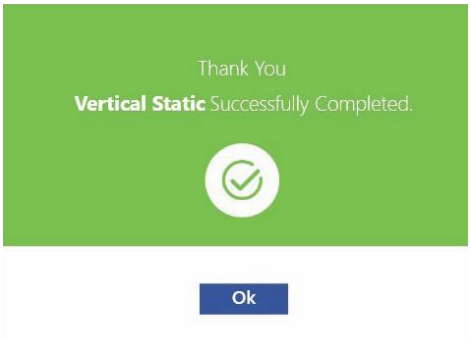
Step 3: There will be a tilted line appear on the second screen.

Step 4: Every time the patient confirms that he/she has made the line straight, press the **Submit** button on the monitor screen so the line goes back to a tilted position in the opposite side.

Main screen **Second screen**

Step 5: Test will be repeated for 6 trails. After completion of the test next Test has to be selected.
Step 6: A pop-up will appear to submit the data, Click on Ok button and select next test.

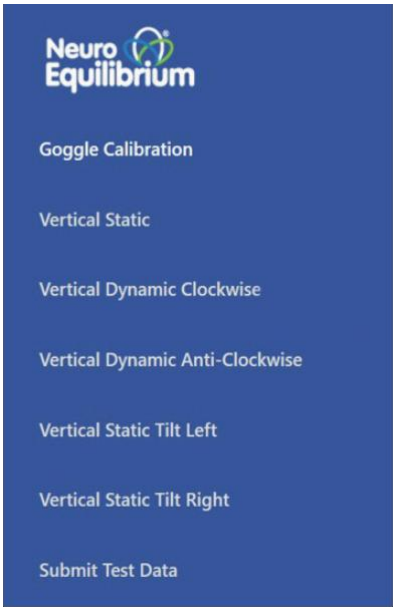
NOTE:



- If the patient does not understand or cannot use the remote control, the examiner can hold the remote and the patient will tell to move the line until he/she sees it straight and tells the same to the examiner.
- If the patient over rotates the line to more of a vertical position, the examiner can help the patient to slightly orient by using the Page Up and Page Down buttons.
- **Vertical Line can be rotate from -20 to +20 degree**

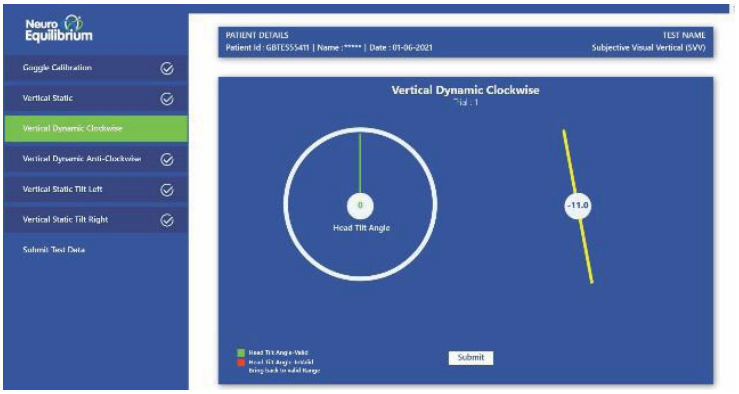
Vertical Dynamic Clockwise

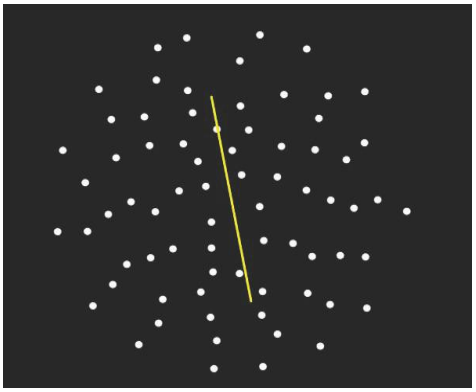
Vertical Dynamic Clockwise



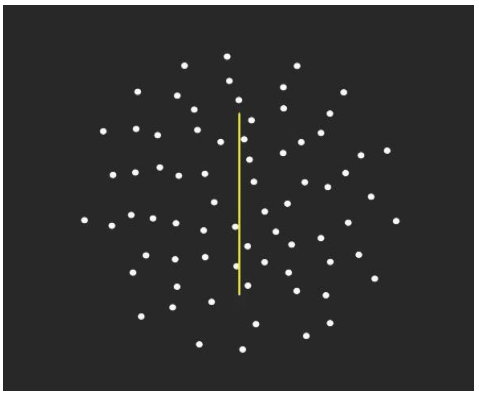
Test instructions for the doctor

Step 1: Select Vertical Dynamic Clockwise from the main screen.
Step 2: There will be tilted line with clockwise rotating dots in the background on the second screen.
Validation: Line should be in +-3 degree left and right.





Step 3: Every time the patient confirms that he/she has made the line straight, press the **Submit** button on the monitor screen so that the line goes back to a tilted position in the opposite side.



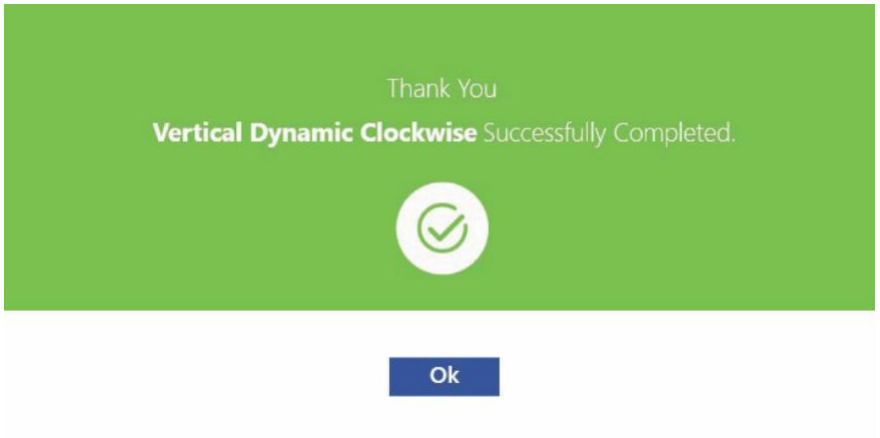
Step 4: The test will be repeated for 6 trails. After completion of the test next test has to be selected.

• If the patient does not understand or cannot use the remote control, the examiner can hold the remote and the patient will tell to move the line until he/she sees it straight and tells the same to the examiner.

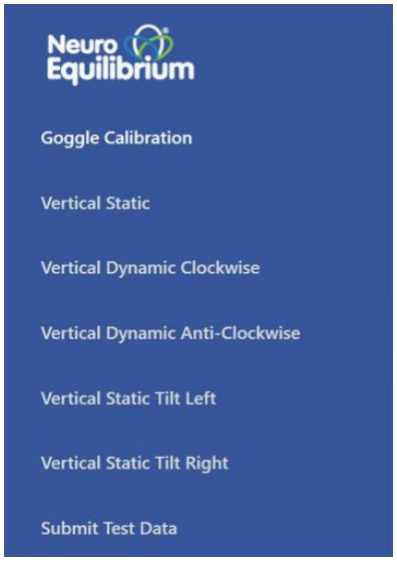
• If the patient over rotates the line to more of a vertical position, the examiner can help the patient to slightly orient the by using the Page Up and Page Down buttons.

• Vertical Line can be rotate from -20 to +20 degree

Step 5: A pop-up will appear to submit the data, Click on **Ok** button.



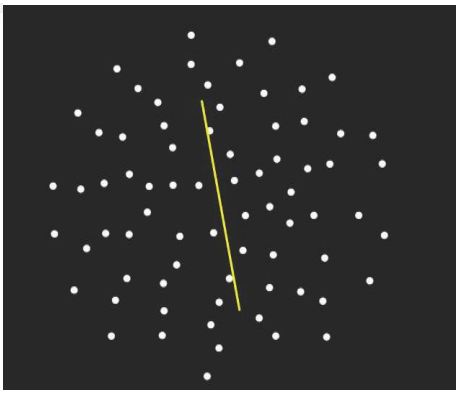
Vertical Dynamic Anti-Clockwise



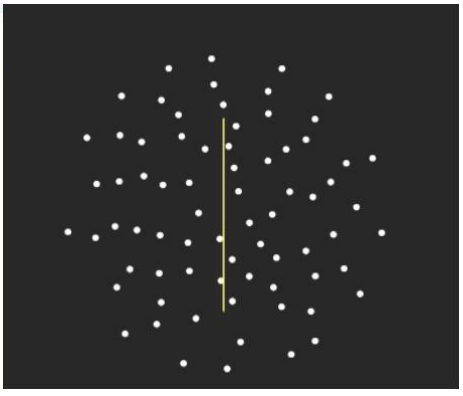
Test instructions for the doctor

Step 1: Select Vertical Dynamic Anti-Clockwise from the main screen.

Step 2: There will be tilted line with circles rotating Anti-clockwise on the second screen.



Step 3: Every time the patient confirms that he/she has made the line straight press the **Submit** button on the monitor screen so the line goes back to a tilted position in the opposite side.



Step 4: The Test will be repeated for 6 trails. After completion of the test next test has to be selected.

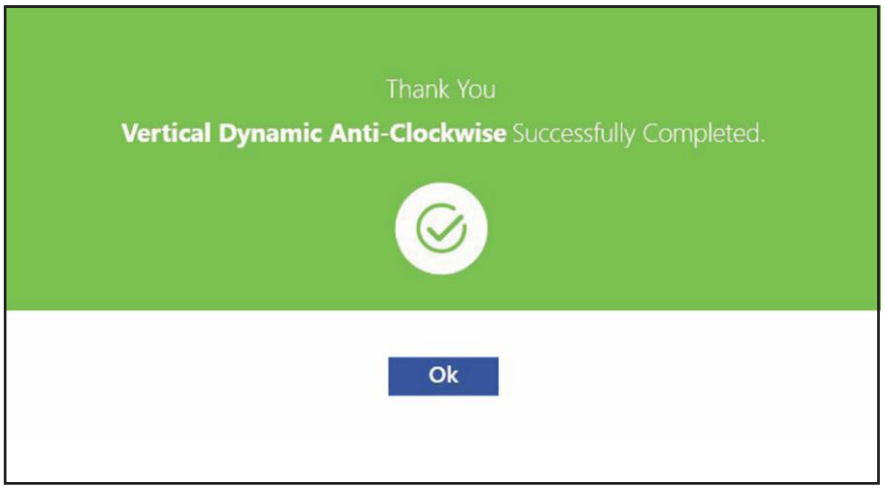
NOTE:

• If the patient does not understand or cannot use the remote control, the examiner can hold the remote and the patient will tell to move the line until he/she sees it straight and tells the same to the examiner.

• If the patient over rotates the line to more of a vertical position, the examiner can help the patient to slightly orient the by using the Page Up and Page Down buttons.

• Vertical Line can be rotate from -20 to +20 degree.

Step 5: A pop-up will appear to submit the data, Click on **Ok** button.



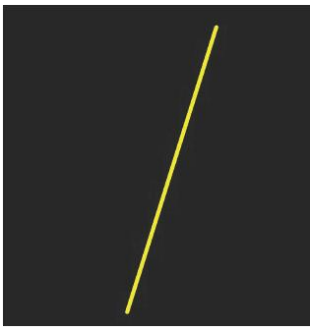
Vertical Static Tilt Left

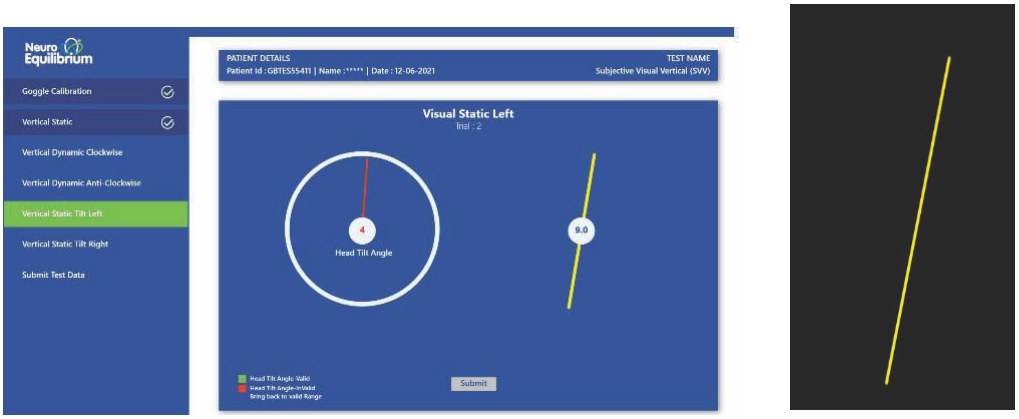
Test instructions for the doctor

Step 1: Select Vertical Static Tilt Left from the main screen.

Validation: - Head tilt angle must be in between -26 to -30 degree left then only patient can move the line and technician can submit the particular trail else every action will be suspended

Step 2: There will be a tilted line appear on the second screen.





Step 3: The patient has to tilt the head 30 degree left then only the software will allow to click on the **Submit** Button. The **Submit** button will remain disabled until the line turns from red to green.

Step 4: Every time the patient confirms that he/she has made the line straight, press the **Submit** button on the monitor screen so the line goes back to a tilted position in the opposite side.

Step 5: The Test will be repeated for 6 trails. After completion of the test next test has to be selected.

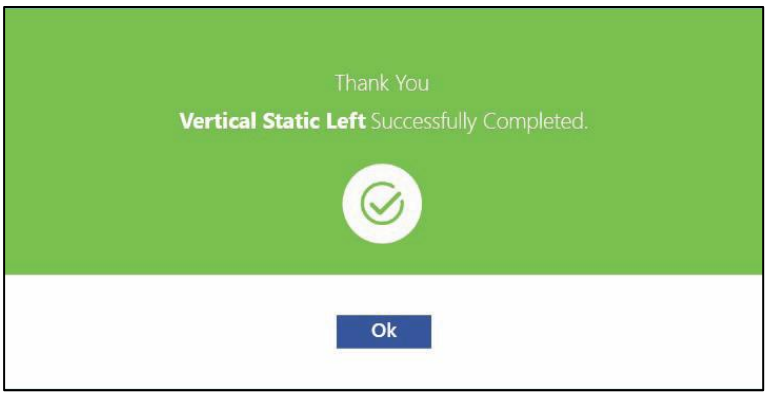
NOTE:

• If the patient does not understand or cannot use the remote control, the examiner can hold the remote and the patient will tell to move the line until he/she sees it straight and tells the same to the examiner.

• If the patient over rotates the line to more of a vertical position, the examiner can help the patient to slightly orient the by using the Page Up and Page Down buttons.

• **Vertical Line can be rotate from -20 to +20 degree.**

Step 6: A pop-up will appear to submit the data, Click on **Ok** button.

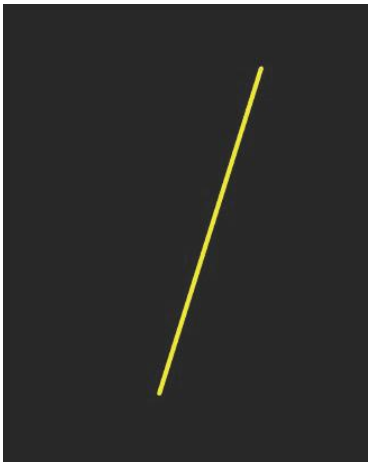


Vertical Static Tilt Right

Test instructions for the doctor

Step 1: Select Vertical Static Right Left from the main screen.

Validation: Head tilt angle must be in between +26 to +30 degree Right, then only patient can move the line and technician can submit the particular trail else every action will be suspended.



Step 2: There will be tilted line appear on the second screen.

Step 3: The patient has to tilt the head 30 degree right then only the software will allow to click on the **Submit** button. The **Submit** button will remain disabled until the line turns from red to green.

Step 4: Every time the patient confirms that he/she has made the line straight, press the **Submit** button on the monitor screen so the line goes back to a tilted position in the opposite side.

Step 5: The Test will be repeated for 6 trails.

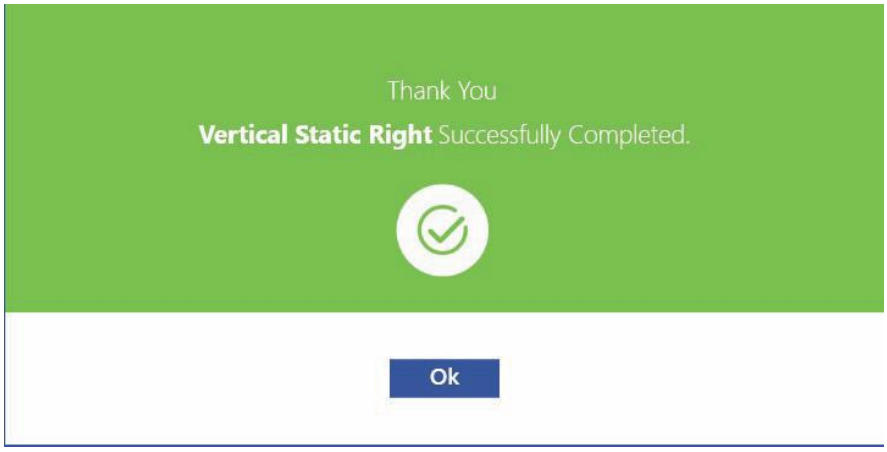
Note:

• If the patient does not understand or cannot use the remote control, the examiner can hold the remote and the patient will be told to move the line until he/she sees it straight and tells the same to the examiner.

• If the patient over rotates the line to more of a vertical position, the examiner can help the patient to slightly orient the by using the Page Up and Page Down buttons.

• Vertical Line can be rotate from -20 to +20 degree

Step 6: A pop-up will appear to submit the data, Click on **Ok** button.



• Once all the tests have completed, click on the **Submit Test Data**.

Note: After the completion of all the tests there should be a tick mark in front of the name of all the tests.

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

5. 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.

6. Shutdown Procedure

No special Procedure required for this device.
Whenever the device usage is over, stop the operation, remove the Cable, switch off the device by pressing the ON/OFF button.

7. Hygiene & Care

NeuroEquilibrium SVV cleaning procedure

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

Caution!
Do not immerse SVV 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.

8. Trouble Shooting

Trouble Symptom	Cause	Action
Hardware Not Detected	USB Handshaking Time out	Re-connect USB Connectors
Unable to view real time Position	USB Port Might be slow	Try another USB Port
Software Freezes/Slow/Not Responding	Computer/Laptop related	Remove USB, Restart the computer/laptop and connect again
Unable to calibrate	Hardware disturbed	Contact Service team or return the Goggle for Service/Replacement

9. Storage

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

10. 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.
SVV is subject to clean after or before every use. Follow section “Operating Precautions” and “Hygiene and Care”.

11. Preventive Maintenance

Though no special preventive maintenance required, check the fitness and quality of face foam and USB cable.
Note: The device shall be handled only by authorized person from the organization who is trained by NeuroEquilibrium Diagnostic Systems Pvt Ltd.

12. Member States the Device are sold

Domestic Market. India.

13. Technical Specifications

Device
Dimensions l X W X h (in mm)……170.7 X 92 X 100
Weight with Face Foam……200gms
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……Type 2 USB Supply

Supply Voltage……5V DC

Rated Maximum Current……..180mA

SVV Specifications

Digital Output Triple-axis ……+/-2g, +/-4g, +/-8g & +/-16g

Shock Tolerant……....10000 g

Sensitivity Scale Factor toelerance……..…25°C

Cross Axis Sensitivity……....+/-2%

Gyroscope Mechanical Frequemcies X- Axis, Y-Axis & Z-Axis:..30 – 36KHZ, 27 – 33KHZ & 24 – 30KHZ

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, USB 2.0/3.0 ports
HDMI Port for external monitor
Monitor resolution 1920 x 1080 or better
Windows® 10 (64-bit)
Use CE Certified Power Adapters

Multimedia Requirements……Min. 43” LED/LCD TV
(With HDMI Port)

Regulatory Standards

Equipment Designed to comply with necessary safety measures guided by……IEC 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.*

14. 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 SVV, 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.

Requirement – Test	Limits	Result/Comment
Clause 7 - Emissions		
Radiated Emission CISPR 11	30MHz to 230 MHz 40 230 MHz to 1000 MHz 47, 10mts, Group 1 Class A Polarization: Horizontal & Vertical	Within Limit
Conducted RF Emissions per CISPR 11	0.15MHz to 0.50 MHz 79 0.50 MHz to 30 MHz 73	Within Limit
Harmonic Distortion per IEC61000-3-2 Class A		Within Limit
Voltage Fluctuations and Flicker per IEC61000-3-3		Within Limit
Clause 8 - Immunity		
Electrostatic Discharges Per IEC 61000-4-2:2008	Air – Direct: 2, 4, 8, 15 KV Contact – Direct: 2, 4, 6, 8 KV Contact – Indirect: 2, 4, 6, 8 KV Discharge Level: + ve & - ve No of Discharge per Location: 10 Ext Locations Accessible by Hand: HCP & VCP	No Malfunctions Observed
Radiated RF EM Fields per IEC 61000-4-3	Frequency Bandwidth: 80 MHz to 2700 MHz Modulation: 80% AM at 1kHz Level: 3V/m Frequency Step: 1%	No Malfunctions Observed
Electrical Fast Transients and bursts per IEC61000-4-4	Input AC Power Port: ±2 KV Coupling Method: Direct Injection Repetition Frequency:100 kHz	No Malfunctions Observed
Surges per IEC61000-4-5	Input AC Power Port: 0.5KV and 1.0KV: L-L 0.5KV, 1.0KV & 2.0KV: L-E Combination Wave: 2µs x 50µs V, 8µs x 20µs A	No Malfunctions Observed
Conducted Disturbances, induced by RF fields per IEC61000-4-6	Input AC Power Ports: 150kHz to 80MHz Level: 3 V RMS outside the ISM band, 6 V RMS in	No Malfunctions Observed

<table>
<tr><td></td><td>the ISM bands
Modulation: 80% AM at 1kHz
Frequency Step: 1%</td><td></td></tr>
<tr><td>Voltage Dips and Interruptions per IEC61000-4-11</td><td>
<table>
<tr><th>Voltage Dips % U_T</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 % U_T</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
Level: 30 A/m</td><td>No Malfunctions Observed</td></tr>
</table>

15. 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.

16. Declaration of Medicinal Substances

By design, this Subjective Visual Vertical does not incorporate any medicinal substances.

17. 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, Lithium Ion Battery, Steel springs & Steel Screws and nuts.

1.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.

18. 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.
- The laptop/Computer used for testing should have Internal Firewall/Anti-virus protection.
- Patient can use Computer/Laptop key board Up/Down keys to straighten the line. Targus remote is an option.
- 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/technician/doctor may use disposable facial/eye patch between patient's face and goggle.

19. 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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