English

DYNAMIC VISUAL ACUITY

User Manual
And
Introduction to the Device
For Dynamic Visual Acuity (DVA)

CE 2803

Dynamic Visual Acuity Unit
USER MANUAL

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Software Version: V1.0.0.0
Dashboard Application DVA: 9.2.11

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

Declaration of Language Translation:

DVA 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 DVA

1. Velcro Strap
2. Top Cover with LED Indication
3. USB Cable

1. Velcro Strap

These elastic straps with velcro's provide a comfortable grip to hold the device to patient's head.

2. Top Cover with LED Indication

The LED Provides Power ON Indication once the USB Connected to the Computer/Laptop.

3. USB Cable

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

1. Introduction to the Device

1.1. Intended Use

Dynamic Visual Acuity is a device used for detection of vestibulotoxicity, Peripheral vestibulopathy, Rehabilitation tool and assessing outcome of rehabilitation.
DVA assesses the ability of the subject to maintain the image on the fovea of the retina. This function is carried out by VOR. Defective VOR results in slippage of image from the fovea resulting in blurring of vision. This is detected by DVA.

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

Dynamic Visual Acuity is used for

- Early detection of vestibulotoxicity
- Detection of bilateral peripheral vestibulopathy

How it works

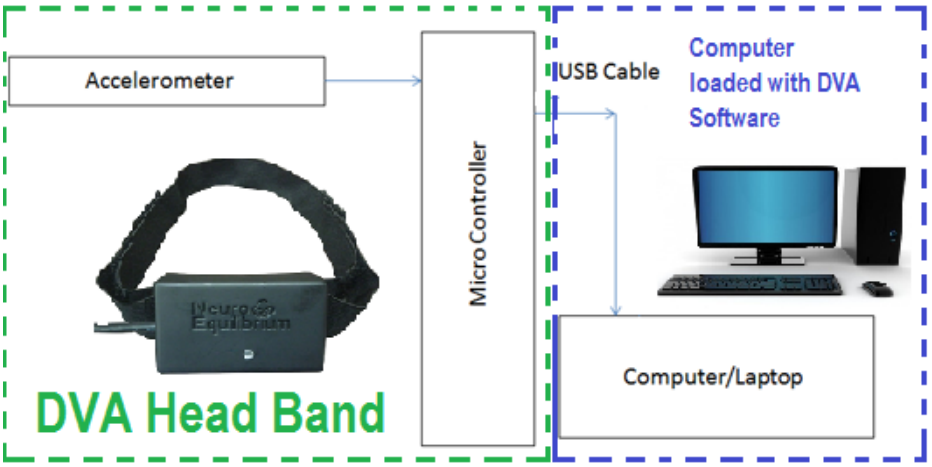
DVA assesses the ability of the subject to maintain the image on the fovea of the retina.
This function is carried out by VOR. Defective VOR results in slippage of image from the fovea resulting in blurring of vision and oscillopsia; this is detected by DVA.

NeuroEquilibrium DVA has the industry's leading Head Band Design.

- No user controls for leveling and Calibration.
- Light weight with direct USB connection to a Laptop or a Desktop Computer.

Principle of Operation

The patient is asked to read the projected optotypes while the head is fixed. Then the patient is asked to read the projected optotypes when the head is moved at a particular speed and at a particular tilt is done by a head mounted device equipped with IMU sensor.



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 head band. DVA head band is being powered by computers USB port.

The NeuroEquilibrium DVA software analyses the data of fovea of the retina reflex of the patients suffering from vertigo and/or balance disorders. The main parameters for evaluating the early detection of vestibulotoxicity, Detection of bilateral peripheral vestibulopathy.

1.7. Indications for Use

NeuroEquilibrium's DVA is indicated to be used on patients experiencing the symptoms of Vestibulotoxicity & Bilateral peripheral vestibulopathy while changing their general postures on day to day life.

1.8. Contraindications for Use

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

- Stiff Neck.
- Dislocation of discs.
- Severe shoulder pain

1.9. Clinical Benefits

- DVA assesses the ability of the subject to maintain the image on the fovea of the retina.
- Detection of bilateral peripheral vestibulopathy
- DVA is a diagnostic tool used to assess visual clarity during head movements
- DVA serves as a multifaceted clinical tool for balance assessment and rehabilitation.
- DVA can be a good initial screening tool for evaluation of semicircular canal function

1.10. Side Effects

No any side effects.

1.11. Important Points in an Emergency

If the patient complains of any discomforts in-between the testing process, then pause the test and allow the patient to relax for some time and once they recover, precede 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 DVA 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

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 Dynamic Visual Acuity (DVA). 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 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.

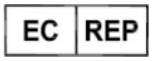
Manufacturer

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 DVA for Use

3.1 Unpacking the Device

Remove DVA from its packaging carefully. Check whether all parts are intact according to packing list. Check the device for any sign of damage. Contact your sales representative or NeuroEquilibrium directly if there are any missing or damaged parts.

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 shall be located 5 feet to 7 feet from the Monitor Screen.
- Better to mark the chair location as shown in the picture.
- The test room should be semi dark/minimal light to the operator to handle the computer and instruct the patient/Patient.

3.3 First Time Installation

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

3.4 Patient Preparation

Explain the steps clearly to the patient.
Adjust the Strap for proper fitting of the DVA 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:

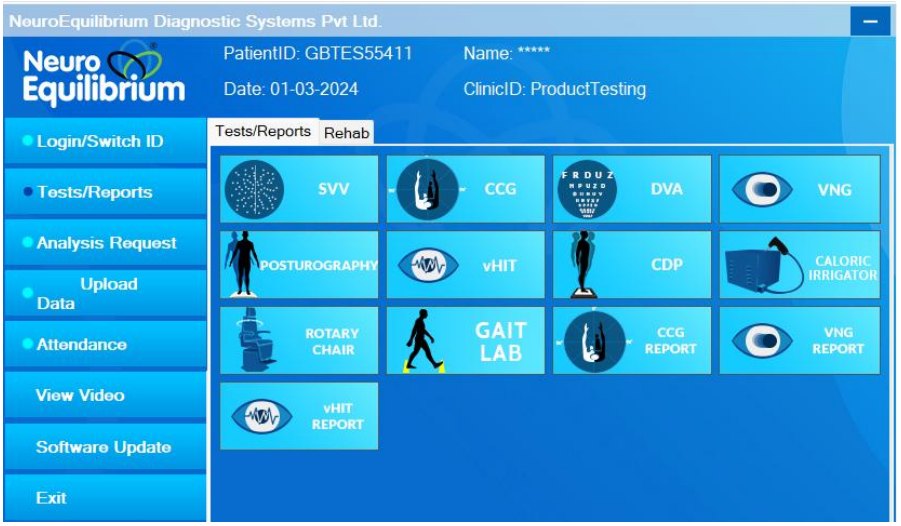
- Clean the Head Band before and after every use.
- Follow the cleaning Procedure defined in this manual.
- Arrange the wire/cables for free movement around the patient.
- Do not route the USB cable around the patient to avoid any strangulation or elongation or tripping over.
- Ensure the USB cable is free from knots and folding.
- Inspect the Head Band for any cracks or damages before use.
- Ensure the patient's chair is on the floor marks and projector not disturbed.
- Ensure the room light is easily controllable as per the test specifications.
- Arrange the wire/cables for free movement around the patient.
- Ensure the visibility of Key board and mouse for easy operation.
- While fixing the Head Band to the patient, care to be taken while locking the straps.
- Don't use excessive force while tilting patient head in different angels.
- Follow the trouble-shooting section for minor software issues.
- Do not attempt to open/dismantle the equipment in case of breakdown or not responding.
- DVA should not undergo mechanical stress/vibration.
- The Technician/Doctor should handle the patient from rear or from sides. They should not interfere the projected screen or the field of view of the patient. All cables to be routed only from rear side of the Patient.

4.2 Initiating DVA Tests

- DVA test should be performed in a well lightened room.
- Click on the DVA icon in "Dashboard".
- The patient should sit on a chair facing the Monitor screen-where the image is projected.

4.2.2. DVA TEST INSTRUCTIONS

- Login to **Dashbord.**
- Click on “DVA” Icon in the central software.



- Software loading window will open.
- After loading this test display will open.

QUESTIONNAIRE

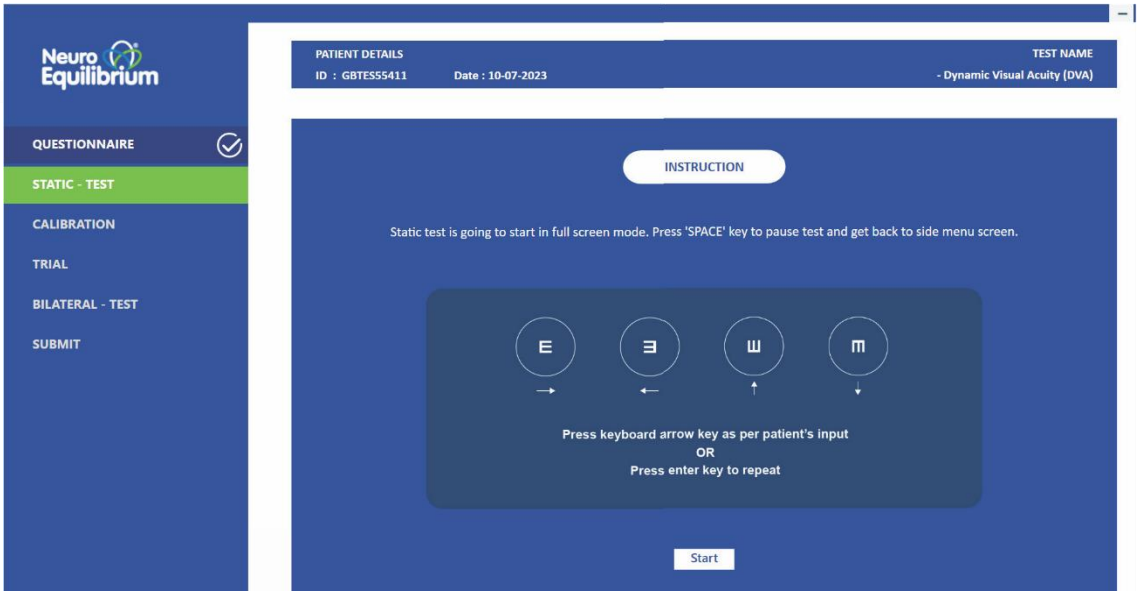
- If the patient is performing the test with their specs on then click on the check box followed by clicking on the **DONE** button.
- If not then click on **DONE** button with unchecked box.

INSTRUCTIONS

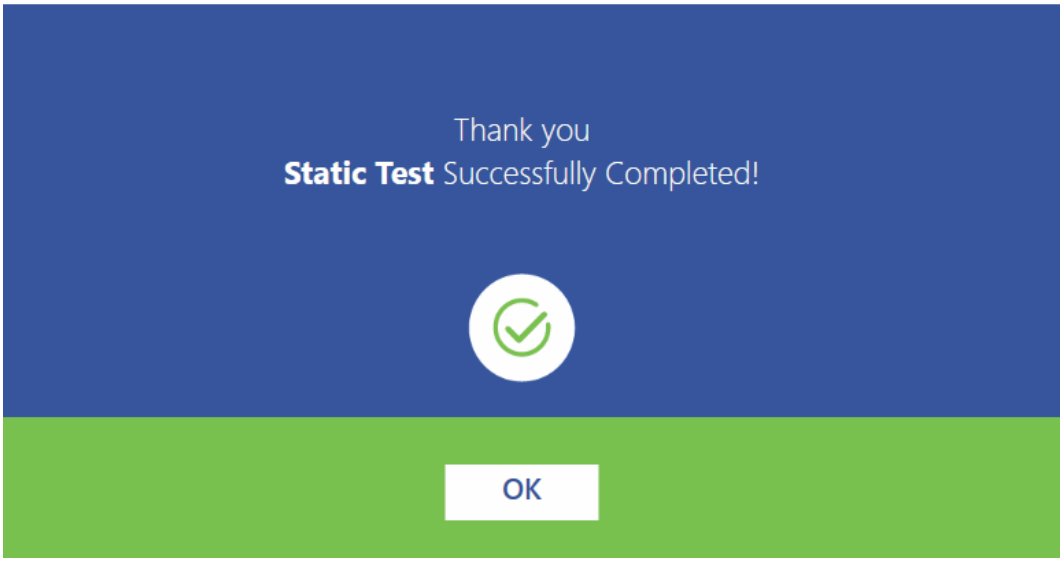
- Position - The patient should sit facing the screen 7 feet away and from monitor. Patient's eyes and the height of the monitor screen must be at the same level.
- Select the **Static Test**, Letter E will appear on screen.
- Ask the patient to indicate the direction of the letter " E" legs (Up/Down/Right/Left).
- Press the arrow key (← ↑ → ↓) from the num pad as directed by the patient.
- If the patient is not able to see or indicate the direction of letter E, then click on "ENTER" to skip that attempt.

Static Test

- Select the **STATIC TEST,** instructions will appear on the screen.
- Ask the patient to identify the direction of 'E' letter.
- Read the instructions, then click on the **Start** button**.**

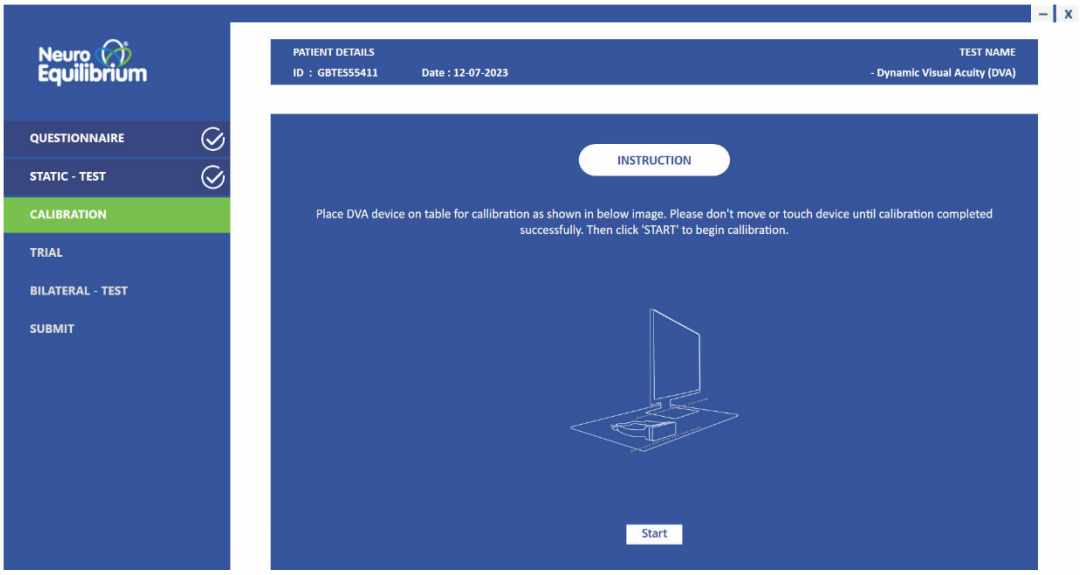


- Letter **E** will appear on screen.
- Ask the patient to indicate the direction of letter " E" legs or opened side of **'E'** (Up/Down/Right/Left).
- Press the arrow key from the provided wireless Num Pad or Keyboard's Num Pad (← ↑ → ↓) as directed by the patient.
- If the patient identifies the correct direction then the size of the **E** letter will be decreased else it will increase.
- If the patient is not able to see properly, then press '**Enter'** button from Keyboard or Num Pad.
- After few steps test will be saved automatically.



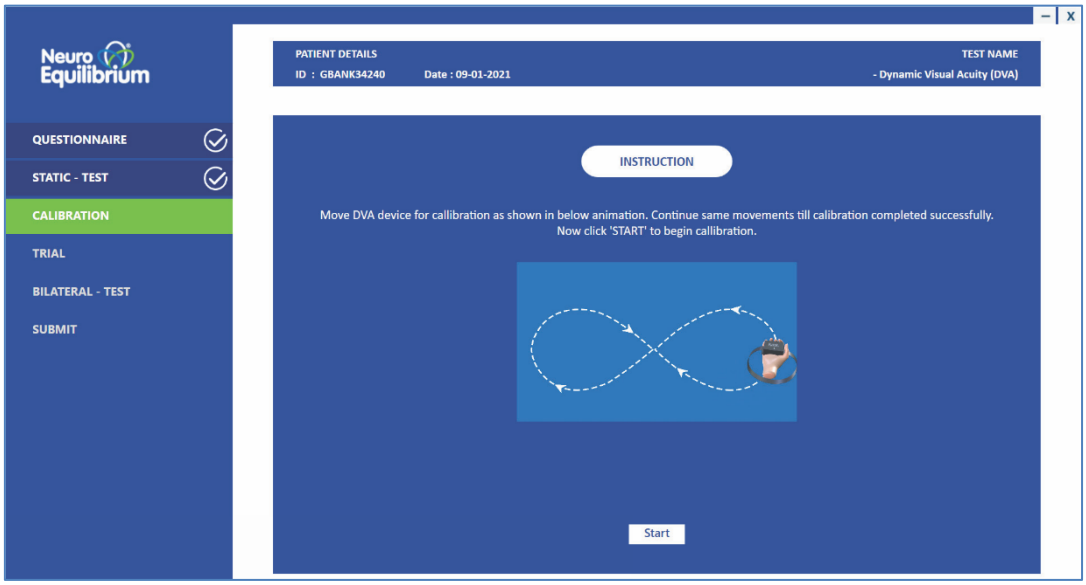
CALIBRATION

- Select CALIBRATION, the Instructions will appear on screen to calibrate the DVA band.

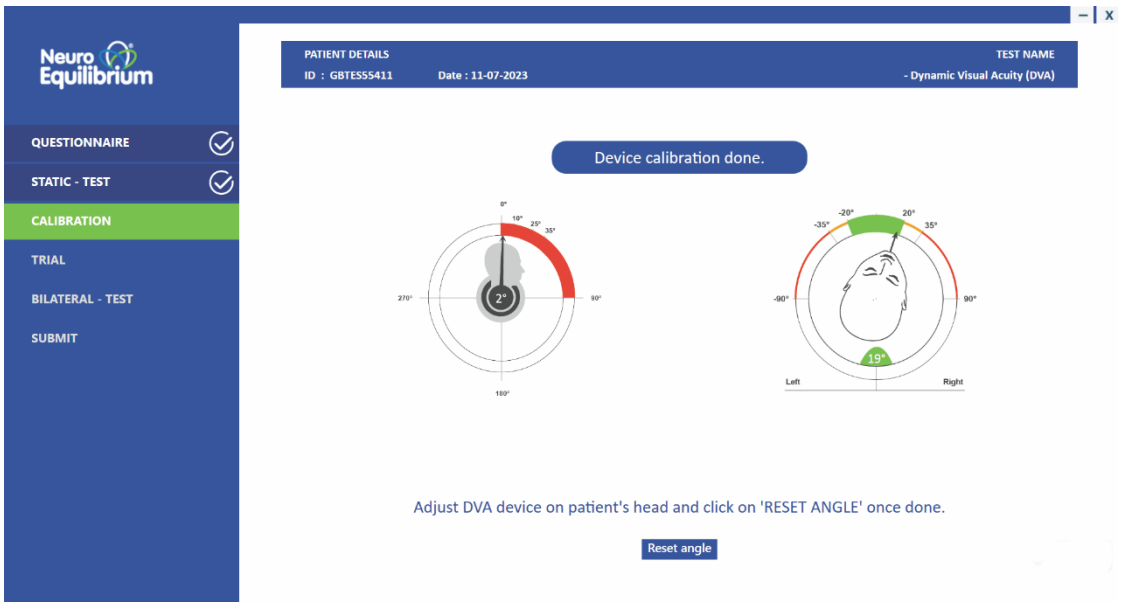


Note: In case of Accidental movement of the device while testing, ensure the correct fitting of the device with the patient and proceed further.

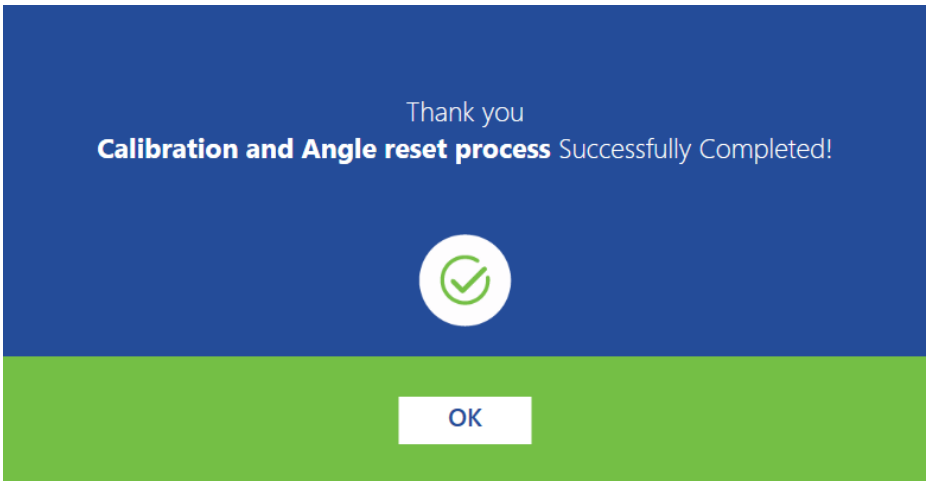
- Read the instructions then click on the Start button, then the Device Calibration will start.
- Move DVA device for the calibration as per the instructions after clicking on the Start button.



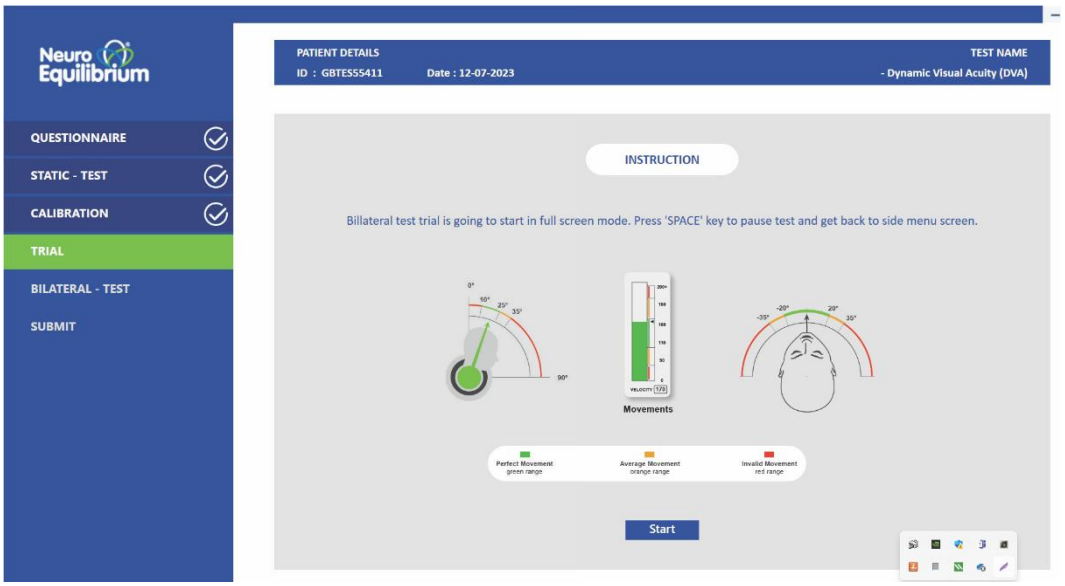
- After the Calibration, the test window will open.



- Adjust DVA device on patient's head and click on Reset Angle button.
- After click on **RESET ANGLE** button, the calibration process has completed by following Pop-up window.



- Click on OK and a new screen will open.

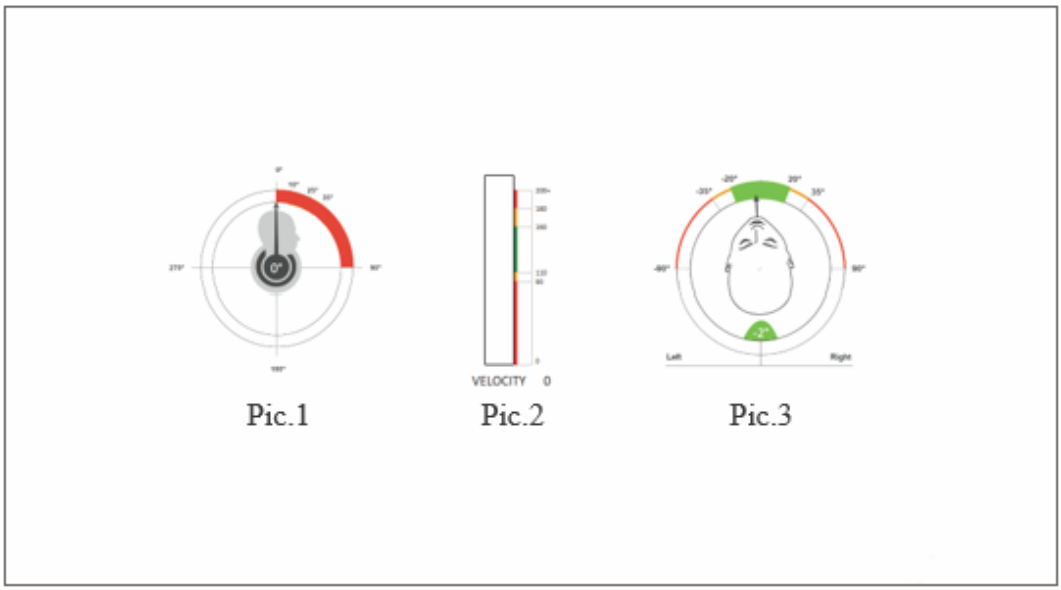


INSTRUCTIONS

Note- Bilateral test trail is going to start in full screen mode. Press 'SPACE' key to pause test and get back to side menu screen.

BILATERAL-TEST

- After clicking on the **Start** button the **TRAIL** will start.

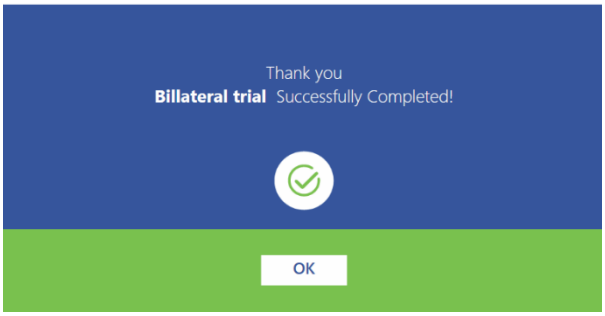


Pic.1 Pic.2 Pic.3

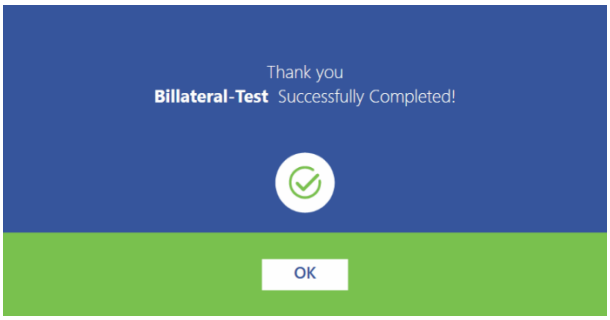
- Instruct the patient to sit straight and look at the top of the screen.
- Arrow should be red at that time (check Pic.1)
- Ask the patient to bend down his head till the arrow turns from RED to GREEN (down and check Pic.1)
- Instruct the patient to read the optotype while moving his head (Pendulum movement @ velocity of 90-200 °/sec. Check Pic.2).
- Kindly note Pic. 3 will show you the amplitude of the head movement in both the directions and positions of device.
- Make sure that all the movements should meet the recommended criteria. Also, very important thing is that the patient should not change his position after shaking the head once it has fixed, otherwise you will see the blank window during the Bilateral test.
- Letter **E** will appear on the screen followed by the observation screen as shown below, then press the arrow key from **Num-Pad** or **Key-Board** (← ↑ → ↓) as directed by the Patient.

OBSERVATION	
Optotype Duration	104 ms

- If the patient identifies the correct direction, then the size of the **E** letter will be decreased else it will increase.
- If the patient is not able to see properly, then press the '**Enter'** key from the Keyboard or Num Pad.
- Click on **OK**. Then the next test Starts.
- Now repeat the same process for the **BILATERAL TEST** until completed**.**

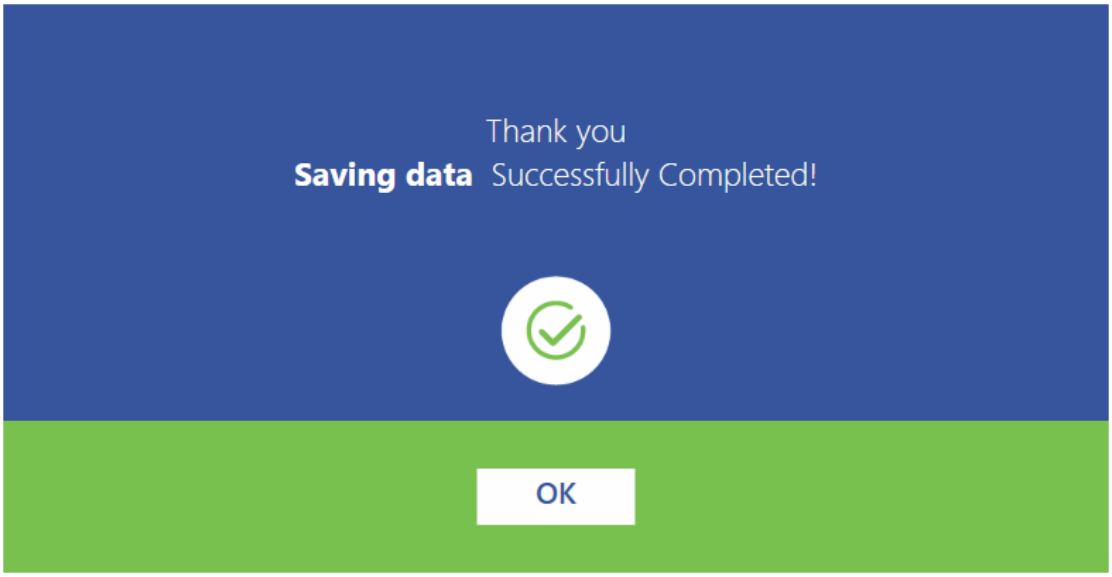


Trail Completion Window



Test Completion

- After clicking on SUBMIT button, a popup of saving data will appear which indicates that the data has been submitted for the test.



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, close the software and remove the USB cable from computer/laptop.

7. Hygiene & Care

NeuroEquilibrium DVA cleaning instructions.

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

Caution!
Do not immerse DVA 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
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 device for Service/Replacement

9. Storage

Store the device as mentioned in the Technical Specifications of this manual.
Do not store/keep DVA under direct Sunlight. Store DVA 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.
DVA is subject to clean after or before every use. Follow section 4.1 “Operating Precautions” and section 7 “Hygiene and Care”.

11. Preventive Maintenance

Though no special preventive maintenance required, check the fitness and quality of strap 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.

12. Member States the Device are sold

Domestic Market. India.

13. Technical Specifications

Device
Dimensions l X W X h (in mm)…….. …88 X 45 X 33
Weight with USB Cable…….. ……70gms
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
Voltage…… ……..……..……..5V DC
Rated Maximum Current……..……..180mA
DVA Specifications
Digital Output Triple-axis ……+/-2g, +/-4g, +/-8g & +/-16g
Shock Tolerant……10000 g
Sensitivity Scale Factor tolerance……25°C
Cross Axis Sensitivity……..……...+/-2%
Gyroscope Mechanical Frequencies……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)
RoHSII……..……..……Yes

Compatible Accessories

Computer Minimal Configuration……..……Intel Core i5 processor or better
16 GB RAM Minimum
USB 2.0/3.0 ports
Monitor resolution 1920 x 1080 or better
Windows® 10 (64-bit)
Use CE Certified Power Adapters

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 DVA, 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
230 MHz to 1000 MHz 47, 10mts, Group 1
Class A
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
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
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</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
Modulation: 80% AM at 1kHz
Level: 3V/m
Frequency Step: 1%</td><td>No Malfunctions Observed</td></tr>
<tr><td>Electrical Fast Transients and bursts per IEC61000-4-4</td><td>Input AC Power Port: ±2 KV
Coupling Method: Direct Injection
Repetition Frequency:100 kHz</td><td>No Malfunctions Observed</td></tr>
<tr><td>Surges per IEC61000-4-5</td><td>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</td><td>No Malfunctions Observed</td></tr>
<tr><td>Conducted Disturbances, induced by RF fields per IEC61000-4-6</td><td>Input AC Power Ports: 150kHz to 80MHz
Level: 3 V RMS outside the ISM band, 6 V RMS in the ISM bands
Modulation: 80% AM at 1kHz
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
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 Dynamic Visual Acuity 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 are stored in the internal memory of the computer/laptop.
- The laptop/Computer used for testing should have Internal Firewall/Anti-virus protection.
- Frequently Used function for this product is the Software provided with the device.
- Only Enclosure 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.

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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