English

Video Head Impulse Test

User Manual
And
Introduction to the Device

For Video Head Impulse Test

CE 2803

VIDEO HEAD IMPULSE TEST Unit

USER MANUAL

Document Reference No.....NE-P12-006
Issue.....00
Date.....07th Mar 2024

Software Version: V1.0.0.0
Dashboard Application VHIT: 9.2.11

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

Declaration of Language Translation:

VHIT 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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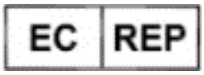
info@neuroequilibrium.in, www.neuroequilibrium.in/for-doctors/



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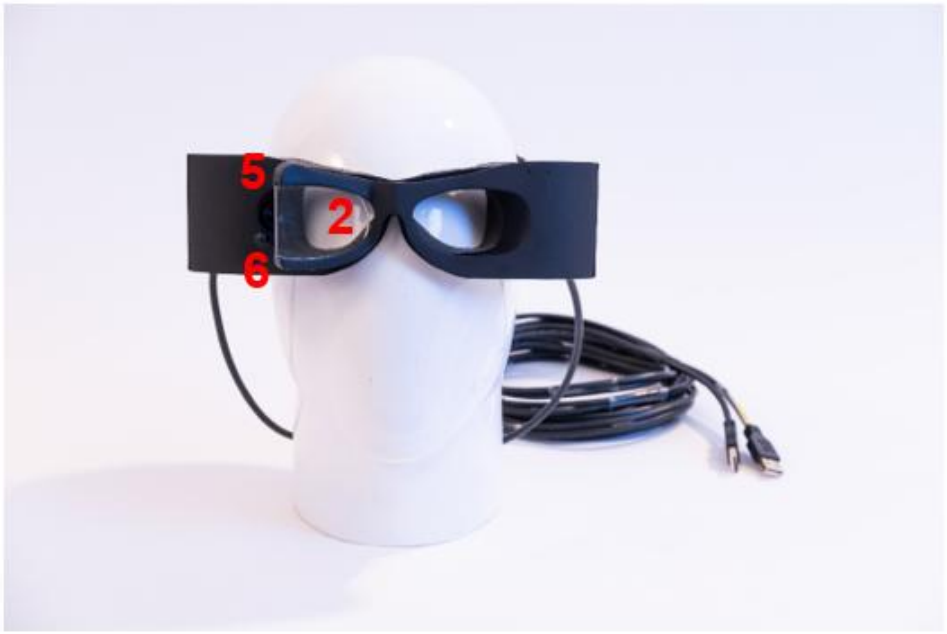
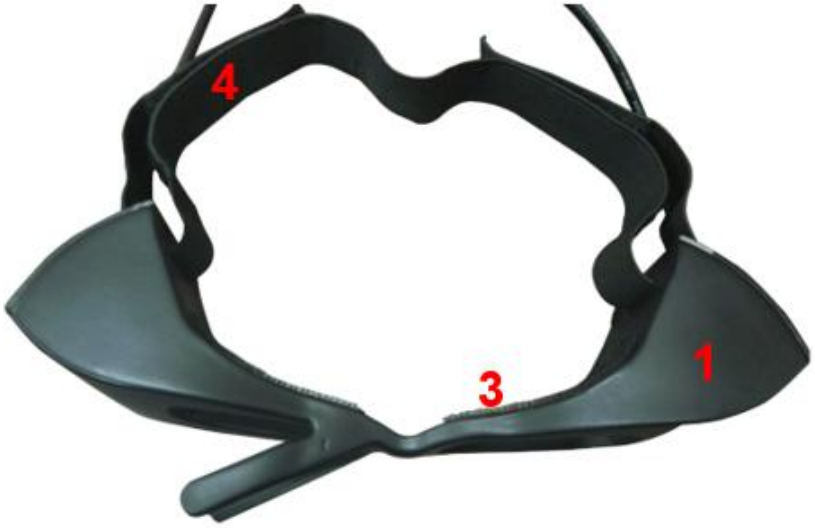
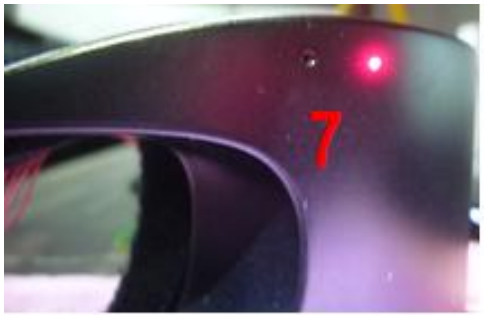
Over View of VHIT





1. Main Frame
2. Hot Mirror
3. Face foam
4. Velcro Strap
5. Camera
6. IR LED
7. Laser Diodes



1. Main Frame

Main Frame Consists of all electronics Assemblies.

2. Hot Mirror

It is in such a way that the reflective surface facing inside the Goggle.

3. Face Foam

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

4. Velcro Strap

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

5. Camera

VGA Camera Captures the Eye movements in Night mode.

6. IR LED

This is the illumination source for the camera.

7. Laser Diodes

These laser Diodes are being used for Calibration.

1. Introduction to the Device

1.1 Intended Use

The VHIT is an instrumented bedside technique used to diagnose reduction in vestibular function in one ear vs. the other.

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

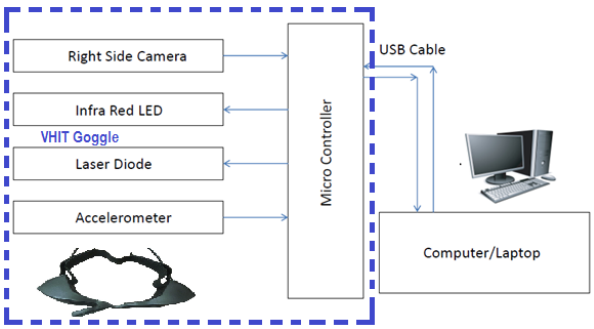
The VHIT enables to test all 6 semi-circular canals at high frequency as well as the saccades strategies (overt and covert). It provides quick, ear-specific assessment of the vestibulo-ocular reflex response to stimuli at high frequency corresponding to natural range of head movement.

NeuroEquilibrium VHIT 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 patient's head is moved in a particular direction and with a particular speed and then the eye and head movement are recorded. This is done by a goggle equipped with IR sensing camera and mirror reflection setup to record the eye movement and an IMU sensor to record the head movement.



Patient's head position is communicated to the computer through USB protocol. This is a two-way communication. The software can enable and disable the Laser diode which is used for calibration, receives eye movements and gets patients head position information.

The NeuroEquilibrium Dashboard software analyses the reduction in vestibular function from one ear to another ear of the patients suffering from vertigo and/or balance disorders.

1.7 Indications for Use

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

- Migraine dizziness

1.8 Contraindications for Use

NeuroEquilibirium’s VHIT should not be used if the patient has the below complications.

- Stiff Neck.
- Dislocation of discs.
- Blindness.
- Recent Eye Surgery.
- Lazy Eye.

1.9 Clinical Benefits

- VHIT offers a quicker and more objective evaluation that can assess all the six semi-circular Canals.
- VHIT provides measures of the absolute level of canal function
- VHIT is used as an initial screening tool to detect vestibular dysfunction
- VHIT is a useful tool in patients with acute vertigo.
- VHIT helps to distinguish peripheral vestibular loss (positive test) from a central vestibular lesion (negative test).
- VHIT effectively reduces eyelid artifacts

1.10 Side Effects

No any side effects.

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 VHIT 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 VHIT. 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 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

Laser Light

Protect from heat and radioactive sources

3. Preparing VHIT for Use

3.1 Unpacking the Device

Remove the VHIT 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 1.2 meter to 1.5 meter away from the marked wall.
- It is advisable to mark the chair location.
- The test room should be well lightened 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 VHIT Software) will be performed by Authorized company representatives.
- Future software updates shall be done by online (Team viewer) for Dashboard & VHIT Software.

3.4 Patient Preparation

- Explain the steps clearly to the patient.
- Adjust the Strap for proper fitting of the VHIT 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 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.
- Ensure the wall 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.
- 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 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 VHIT 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 VHIT Tests

- VHIT test should be performed in a well lightened room.
- Click on the VHIT icon in "Dashboard".
- The patient should sit on a chair facing the wall.
- Assist the patient to wear the goggle.

4.3. General Information

- VHIT test should be performed in a well lightened room.
- Patient's chair shall be placed 1.2 meter to 1.5 meter from the wall.
- The Spot should be located straight to the patient's eyes

Calibration Instructions

(a) Ask the patient to fix the eyes on the center point.

(b) Drag the green rectangle in the 'ROI' box such that it encloses the pupil.

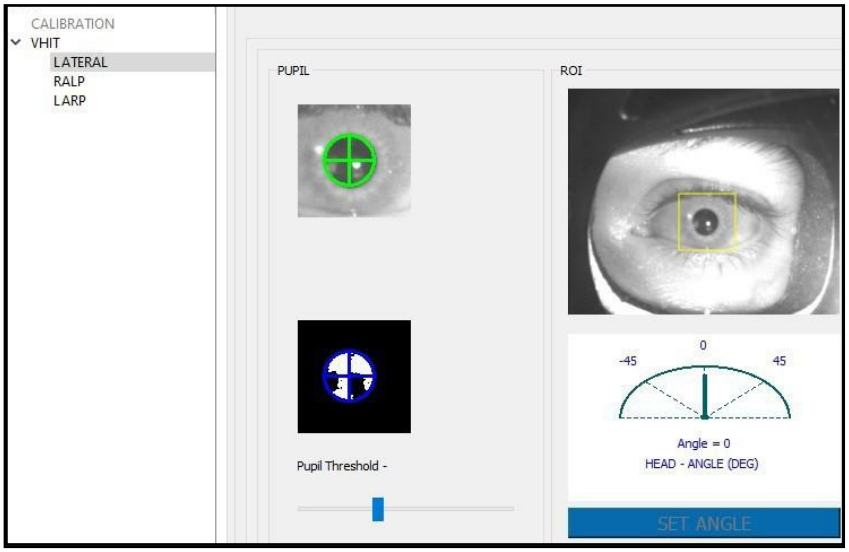
(c) Adjust the 'Pupil Threshold' by dragging the horizontal slider such that the pupil is correctly detected. Correct detection of the pupil is verified by an outer green circle on the periphery of the pupil and a small blue circle at the center.

(d) Click on the 'START' button to start the Calibration process.

(e) Ask the patient to follow the laser spot on the front wall with the eyes without moving head.

Note: Click on the 'Default Calibration' checkbox if explicit calibration is not possible.

LATERAL Test



(a) Ask the patient to fix the eyes on the center point.

(b) Drag the green rectangle in the 'ROI' box such that it encloses the pupil.

(c) Click on the 'START' button to start the Lateral Test.

(d) Adjust the 'Pupil Threshold' by dragging the horizontal slider such that the pupil is correctly detected. Correct detection of the pupil is verified by an outer green circle on the periphery of the pupil and a small blue circle at the center.

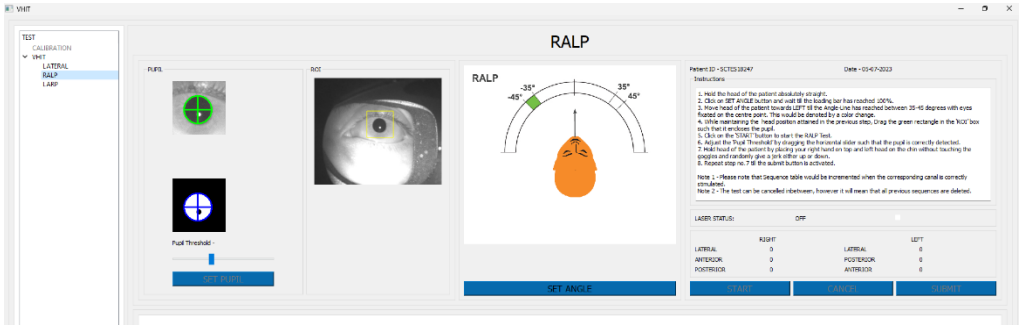
(e) Hold the head of the patient by placing both hands on top without touching the goggles and give a jerk randomly to either the left or right side.

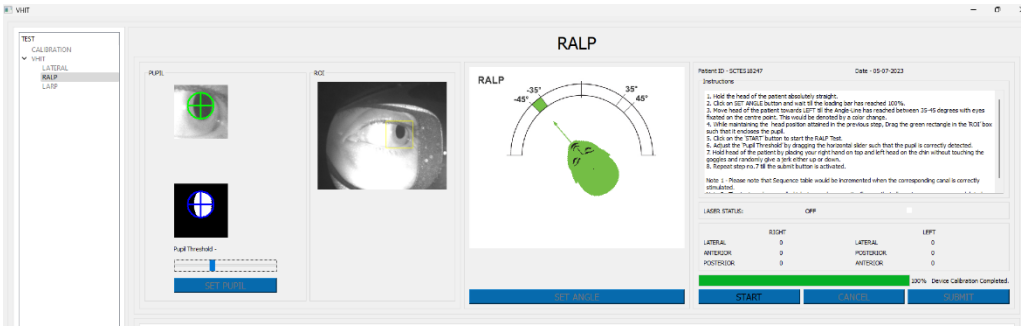
(f) Repeat step No.5 till the submit button is activated.

Note 1 - Please note that Sequence table would be incremented when the corresponding canal is correctly stimulated.

Note 2 - The test can be cancelled in-between, however it will mean that all previous sequences are deleted.

RALP Test





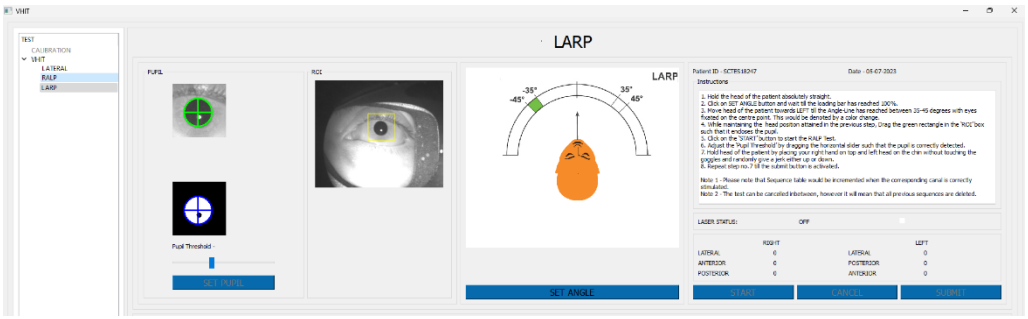
1. Hold the head of the patient absolutely straight.
2. Click on SET ANGLE button and wait till the loading bar has reached 100%.
3. Move head of the patient towards LEFT till the Angle-Line has reached between 35-45 degrees with eyes fixated on the center point. This would be denoted by a color change.
4. While maintaining the head position attained in the previous step, drag the green rectangle in the 'ROI' box such that it encloses the pupil.
5. Click on the 'START' button to start the RALP Test.
6. Adjust the 'Pupil Threshold' by dragging the horizontal slider such that the pupil is correctly detected.
7. Hold head of the patient by placing your right hand on top and left head on the chin without touching the goggles and randomly give a jerk either up or down.
8. Repeat step no.7 till the submit button is activated.

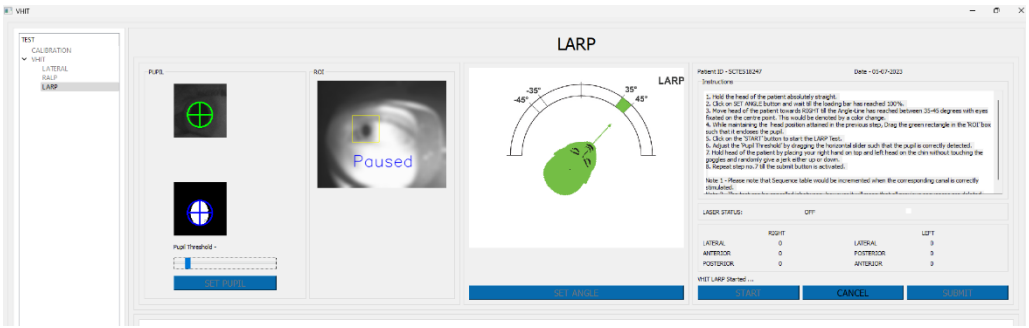
Note 1: Please note that Sequence table would be incremented when the corresponding canal is correctly stimulated.

Note 2: The test can be cancelled in between, however it will mean that all previous sequences are deleted.

Note 3: Repeat the process in case of any difficulty on getting the results or un successful testing activity once the patient is relaxed.

LARP Test





1. Hold the head of the patient absolutely straight.
2. Click on SET ANGLE button and wait till the loading bar has reached 100%.
3. Move the head of the patient towards RIGHT till the Angle-Line has reached between 35-45 degrees with eyes fixated on the center point. This would be denoted by Head color change.
4. While maintaining the head position attained in the previous step, drag the green rectangle in the 'ROI' box such that it encloses the pupil.
5. Click on the 'START' button to start the LARP Test.
6. Adjust the 'Pupil Threshold' by dragging the horizontal slider such that the pupil is correctly detected.
7. Hold the head of the patient by placing your right hand on top and left head on the chin without touching the goggles and randomly give a jerk either up or down.
8. Repeat step no.7 till the submit button is activated.

Note 1: Please note that Sequence table would be incremented when the corresponding canal is correctly stimulated.
Note 2: The test can be cancelled in between, however it will mean that all previous sequences are deleted.
Note 3: In case of Accidental movement of the device while testing, ensure the correct fitting of the device with the patient and proceed further.

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 VHIT cleaning procedure

- Please use dry cloth or cotton to clean goggle and 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 VHIT 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 Video	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 Specifications of this manual.
Do not store/keep VHIT under direct Sunlight. Store VHIT 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.
VHIT 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 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)…… …230 X 62 X 56
Weight with Face Foam……260gms

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

VHIT Specifications

Accelerometer

Motion Tracking Device Sensor……MPU-6000/MPU-6050
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

Camera

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 degree

Source

Infrared Light Wavelength……950nm

Laser

Driver……Integrated APC driver circuit
Lens……Aspherical plastic lens provides Dot Laser
Dimensions……Φ7 x 21 mm (Φ0.276" x 0.827")
Wavelength……635 / 650 nm
Output power……Class II – less than 1mW / Class IIIa – less than 5mW
Beam Divergence (Half Angle)……0.6 mRad
Power……2.6~5 VDC operation
Connection type……Lead wire / Connector

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
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 VHIT, 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 % 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 Video Head Impulse Test 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, 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.

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 and also on cloud storage.
- 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 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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