Neuro Equilibrium®

English

CRANIOCORPOGRAPHY

User Manual
And
Introduction to the Device
For CRANIOCORPOGRAPHY (CCG)

CE 2803

CRANIOCORPOGRAPHY Unit

USER MANUAL

Document Reference No..... NE-P12-004
Issue.....00
Date.....07th Mar 2024

Software Version: V1.0.0.0
Dashboard Application CCG: 9.2.11

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

Declaration of Language Translation:

CCG 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.

NeuroEquilibrium Diagnostic Systems Pvt Ltd.
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/

EC REP

Amstermed BV,
Saturnusstraat 46-62
Unit 032,
2132 HB Hoofddorp
The Netherlands
Telephone: +31 23 56 56 337.
Emailaddress:info@amstermed.nl.
https://www.amstermed.nl/.

Notified Body

HTCert,
Jacovides Tower,
81-83 Grivas Dighenis Av.,
1090 Nicosia, Cyprus
Website: www.htcert.com
info@htcert.com
Telephone: +35722060771-2

Contents

Over View of CCG

1. CCG Transmitter
2. IR Camera with Mounting Brackets
3. USB Cable
4. CCG Receiver
5. Head band with Strap
6. Battery Door
7. ON/OFF Switch

1. CCG Transmitters

CCG transmitter has two IR Transmitters which provides live tracking information to the camera. CCG transmitter sends patient's head position signals to computer via 2.4GHZ wireless communication.

2. IR Camera with Mounting Brackets

Ceiling Mounted Camera will capture the IR signals to track the patient's movement.

3. USB Cable

USB Cable provides power supply and communication to camera and CCG receiver.

4. CCG Receiver

CCG Receiver is synchronized with the CCG transmitter in the same 2.4GHZ band which receives the patient's live head position information

5. Head Band with Strap

Head strap facilitates comfort to the patient and avoids slippery of head band from patient's face.

6. Battery Door

CCG Transmitter has a Secondary battery which can be recharged externally.

7. ON/OFF Switch

This Push to ON and Push to OFF switch facilitates the user to enable the device when ever required. This is a hard boot switch which extends battery life.

1. Introduction to the Device

1.1 Intended Use

Cranio-Corpo-Graphy (CCG) is a device used for diagnosing vertigo and balancing disorder. CCG technique is to analyse the vestibulospinal reflex which evaluates balance during posture & Gait testing.
The tests evaluated include:
- Romberg test
- Tandem walking
- Unterburger's test

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

Neuroequilibrium Craniocorpography (CCG) is a neuro-otological investigation to evaluate the vestibulospinal reflex, which is responsible for maintenance of balance during gait testing.
The protocols evaluated by this screening include

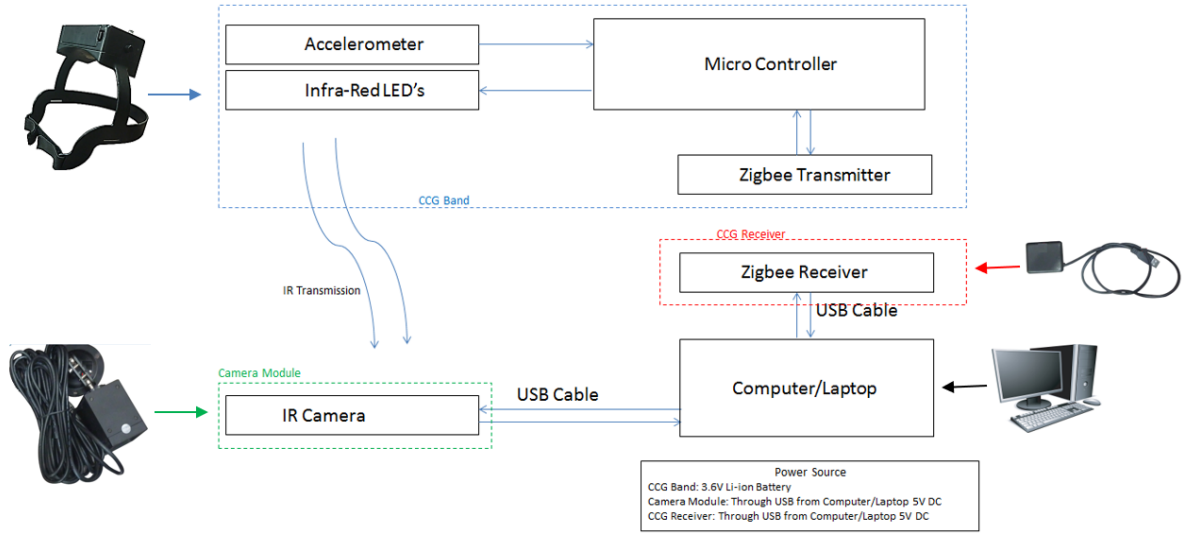
- Romberg test
- Tandem walking
- Unterberger's test, which evaluates the following parameters
    a. Displacement
    b. Sway

NeuroEquilibrium CCG has the industry's leading binocular wireless head band design.

- No adjustment required for focus of mirror setting.
- 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

Craniocorpography - The patient wears a headband with IR LED's. A roof mounted IR sensing camera is then used to capture the movement of the patient as the patient is asked to carry out various kinds of tasks.



Patient's head position is communicated to the computer through a wireless protocol. This is a two-way communication. The software can enable and disable the Infra-red source whenever required and at the same time receives patient's head position from head band.

The wireless communication is a high-level communication protocol used to create personal area networks with a small low-power digital radio. CCG receiver and camera is connected to USB port of a computer/Laptop. CCG Receiver is powered up through the USB port. The head band is powered by a secondary source (Li-ion Battery).

The NeuroEquilibrium Dashboard software analyses the numerical data of vestibulospinal reflex of the patients suffering from vertigo and/or balance disorders. The main parameters for evaluating the standing test are the longitudinal and lateral sway in cm, the torticollis angle in degrees, and the forehead covering area in cm^2. The parameters for the stepping test evaluation are the longitudinal and lateral sway in cm, the angular deviation in degrees, and the self-spin in degrees.

1.7 Indications for Use

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

- Lower back pain.
- Paralysis
- Difficulty on standing due to leg issues/implants
- Dislocation of discs

1.9 Clinical Benefits

- Detects lateral sway & Gait instability.
- CCG can be used to assess the chronic dizziness.
- CCG is useful method in examination of balance disorder.
- Valuable tool for initial diagnosis patients with acute unilateral disorders.
- Simple test to evaluate the functional status of the vestibulospinal system.
- Useful techniques for investigating vestibular function in cases of Dizziness.
- Measures angular deviation, body rotation, and linear displacement in Unterberger/ Fukuda test.

1.10 Side Effects

No 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, 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 CCG 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 Craniocorpography (CCG). 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 CCG for Use

3.1 Unpacking the Device

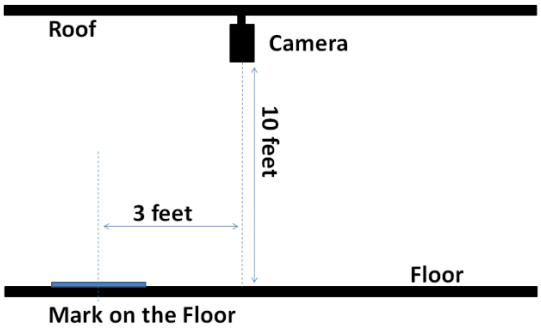
Remove CCG from its packaging carefully. Check whether all parts are intact according to packing list. Check the device for any sign of damage. Contact your sales representative or NeuroEquilibrium directly if there are any missing or damaged parts.

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

- Camera to be mounted straight at10' above the floor level.
- Make a "T" mark 3' behind the center of the camera.
- Follow the below pictures for installation.
- 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 CCG Software) will be performed by Authorized company representatives.

Future software updates shall be done by online (Team viewer) for Dashboard & CCG Software.

3.4 Patient Preparation

Explain the steps clearly to the patient.

Adjust the Strap for proper fitting of the CCG 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 device before and after every use. Follow the cleaning Procedure defined in this manual.
- Ensure the USB cable is free from knots and folding.
- Inspect the device for any cracks or damages before use.
- Ensure the room light is easily controllable 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 visibility of Key board and mouse for easy operation.
- While fixing the device 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.
- CCG should not undergo mechanical stress/vibration.
- The Technician/Doctor should not interfere the field of view of the patient.

4.2. Initiating CCG Tests

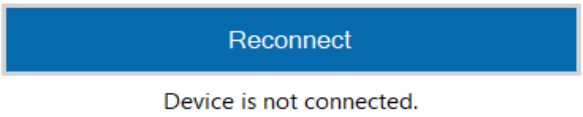
- CCG test should be performed in a semi dark room.
- Click on the CCG icon in "Dashboard".
- The patient should stand on a marked position.
- Assist the patient to wear the head band.

4.3. Connecting CCG to Computer and Initiating the Test

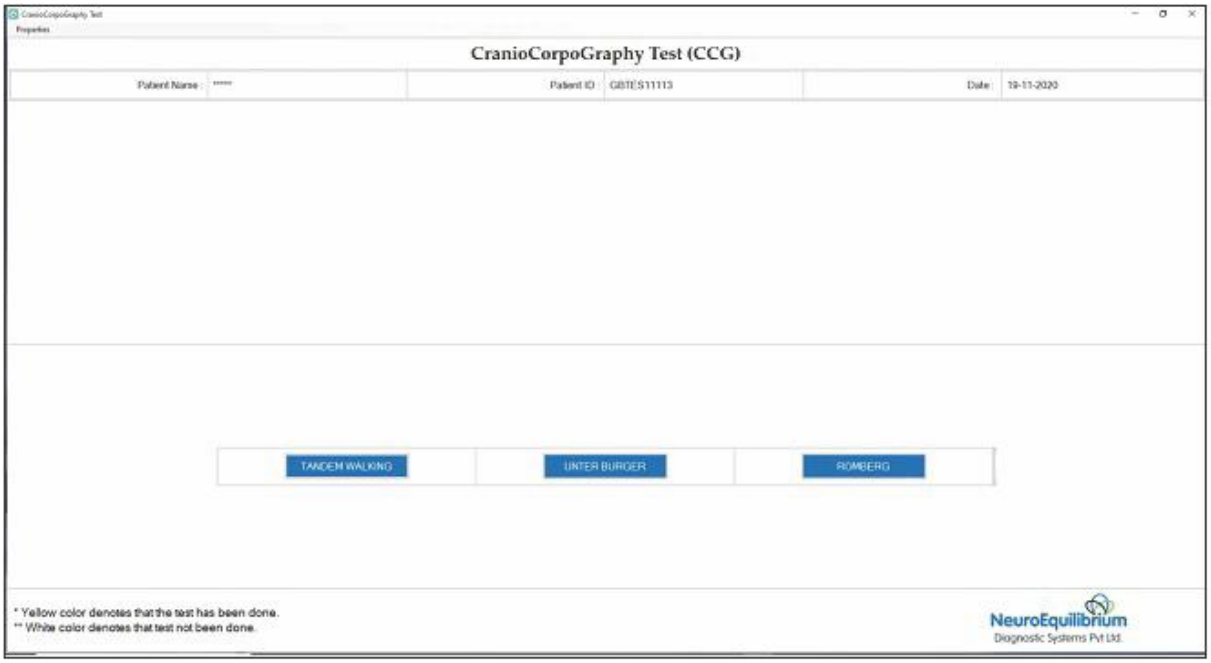
- Insert the rechargeable battery with correct polarity.
- Push the switch on the band and look for the Green LED.
- If LED Turns Red, then recharge/replace battery before use.
- Do not remove the battery when the device is ON or in paired condition.
- Follow section 4.5 for battery replacement.
- Connect CCG Receiver to a Free USB Port of a computer/Laptop.
- Place the band on patient's head in such a way that the IR transmitters towards the camera and lock the velcro's.

4.3.1. Click “CCG” Icon in Central software.4.3.2. If an error is displayed for Controller or Band, please check for the connectivity and restart band again.

1. Camera Status	Working properly.
2. Link Status	Link not found.
3. Band Status	Band not found.

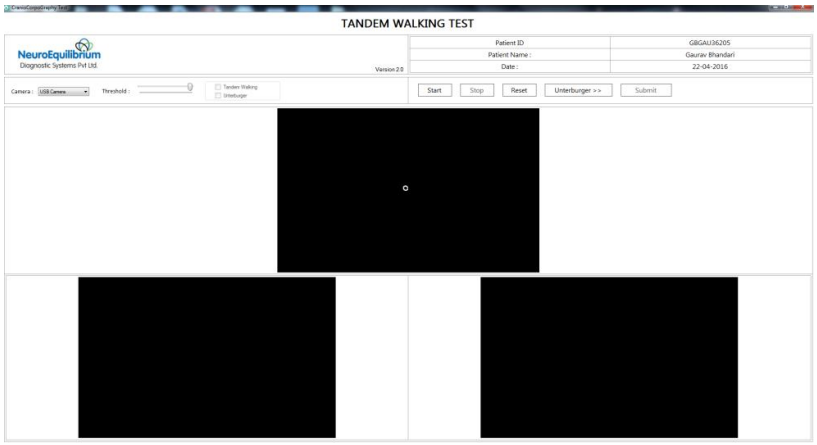


4.3.2 If the login is successful, a window will open like -



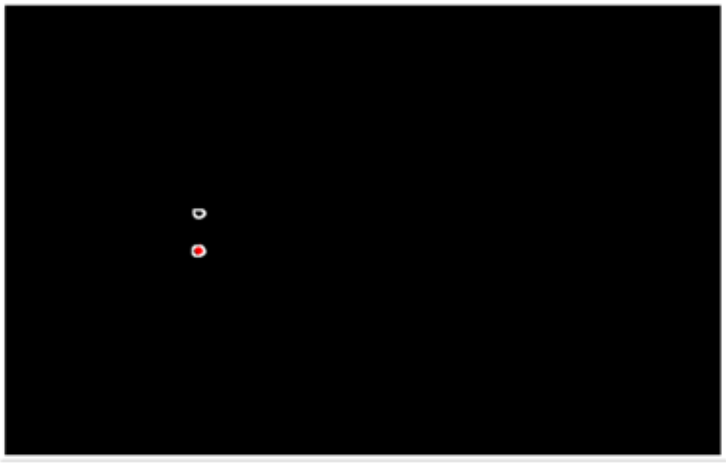
TANDEM WALKING TEST

4.3.3. First, we will perform the "**TANDEM WALKING"** test.



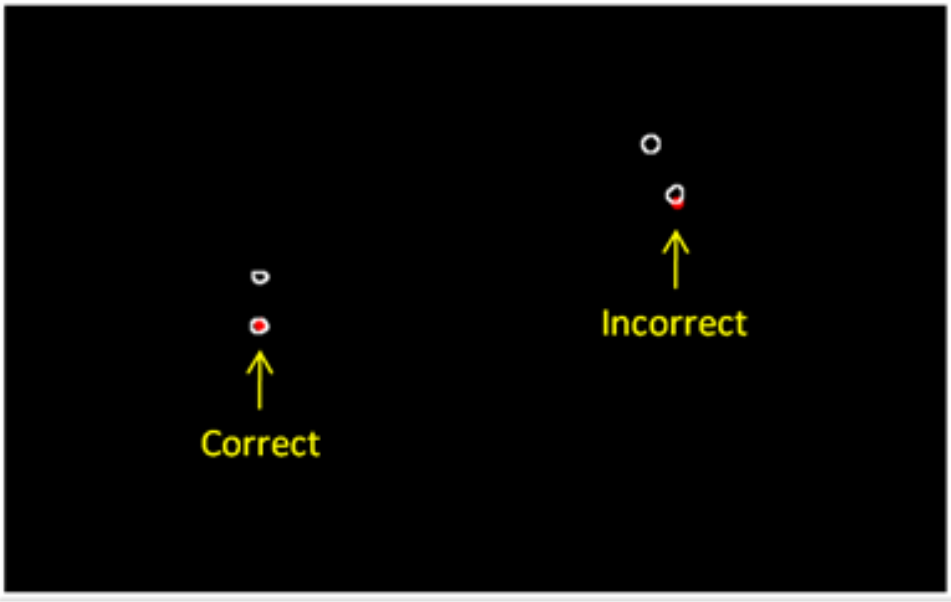
4.3.4. Ask the patient to stand at the starting Marked position.

4.3.5. Click on the start button, two points should appear on the left black space.



4.3.6. If 2 points are not visible, ask the patient to stand properly and click **Reset** and again, press **Start** button. Repeat till 2 points are obtained.

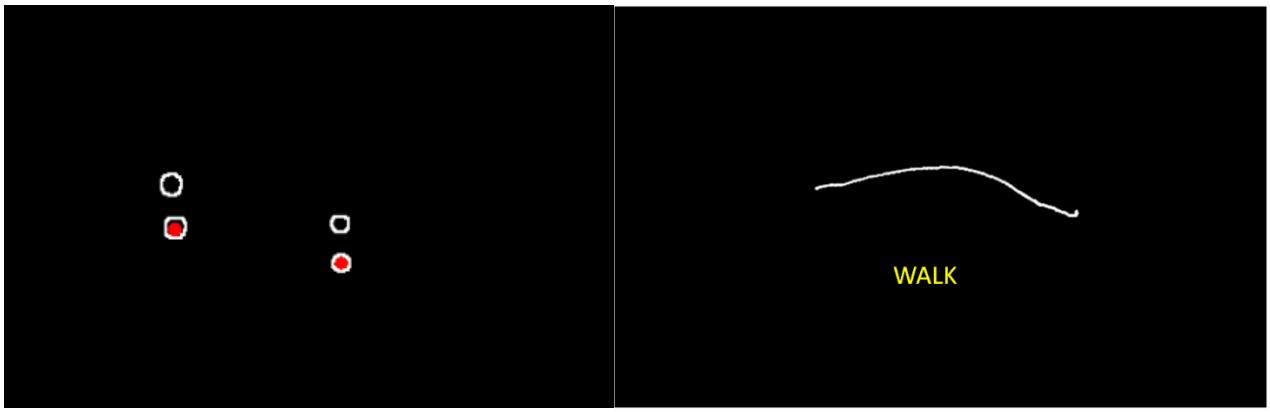
4.3.7. Also, one of the points should be filled with red colour. If it is not so, repeat till it is obtained.



4.3.8. Next, put on eye shades on the patient's eyes and ask the patient to do the tandem walk for 5 steps forward, matching the toe with the heel, looking straight ahead.

4.3.9. Once, the patient has walked 5 steps, click on the stop button.

4.3.10. Again, 2 points should appear. If 2 points are not visible, ask the patient to stand straight and click on **Stop** again. Repeat till 2 points are seen.



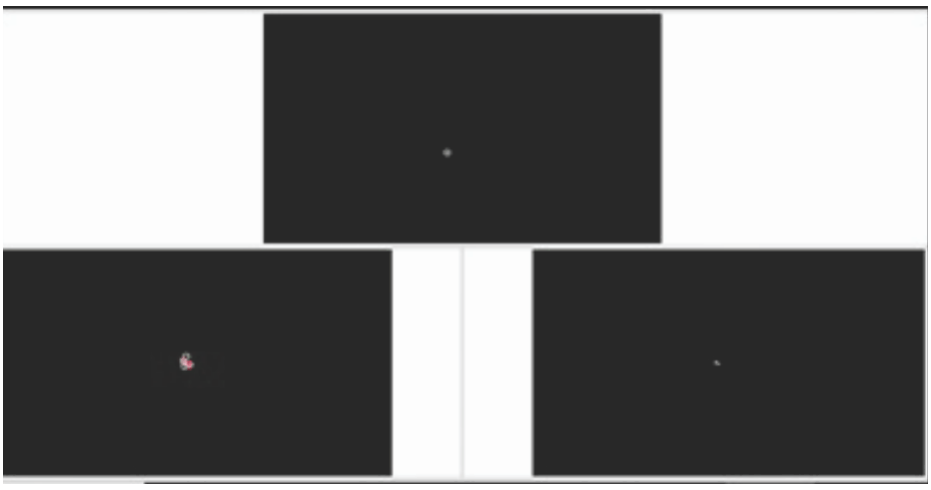
Note: In case of Accidental movement of the device while testing, ensure the correct fitting of the device with the patient and proceed further.

UNTERBURG

4.3.11. Next, we would perform the "**UNTERBURGER"** test.
4.3.12. Ask the patient to stand at the starting marked position, with hands stretched out.
4.3.13. Put the eye shade provided on the eyes of the patient.
4.3.14. Click on the **Start** button.
4.3.15. Once the 2 points appear ask the patient to do stepping for 90 times.
4.3.16. Once, the patient is done stepping, click on the **Stop** button.
4.3.17. Next, click on the submit button to save data.

ROMBERG TEST

4.3.18. Ask the patient to stand just under the CCG camera with the legs together.
4.3.19. Click on the Start button.
4.3.20. Once the two points appear, instruct the patient to remain standing in the same position with the hands stretched in front.
4.3.21. Click the **Stop** button if the patient gets unbalanced before 60 seconds, otherwise, the test will automatically stop after 60 sec.



4.3.22. Next, click on **Submit** button to save the data.

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

4.4. Replacing Rechargeable CCG Head Band Battery.

4.4.1. Ensure the Switch is OFF Position and Green LED not glowing.
4.4.2. Remove the side panel of the band using allen key.
4.4.3. Pull out the drained battery from + ve side.
4.4.4. Ensure the battery polarity.
4.4.5. Insert a charged battery with – ve side first and snap it to the holder.

4.4.6. Replace the cap and screw again.

Note: If the Battery shape found changed then remove the battery Immediately. Do not force to place a bulged/swelled battery to the battery holder which results pressure over the battery.
Dispose the battery as per the local governance. Do not dispose the battery with regular waste.

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 CCG cleaning instructions

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

Caution!
Do not immerse CCG 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 capture real time tracking	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 head band for Service/Replacement

9. Storage

Store the device as mentioned in the Technical Specificaitons of this manual.
Do not store/keep CCG under direct Sunlight. Store CCG 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.
CCG 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 Head band 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)……..……..162.5 X 172.5 X 169.5

Weight ……..……..…300gms

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

Camera and CCG Receiver

Type……...……..USB Type 2 Supply

Voltage……..……..……..……5V DC

Rated Maximum Current……...…..180mA

CCG Head Band

Type……...……PANASONIC NCR 18650B 3400 mAh Li-Ion Battery

CCG Specifications

Wireless Communication

Indoor/urban range……..…….... Up to 90 m (300 ft)

Outdoor RF line-of-sight range…….....……. Up to 3200m (2 mi)

Transmit power output (maximum)……..…. 63 mW (+18dBm)

RF data rate…….. ……..…..250,000 b/s

Receiver sensitivity……..……-101 dBm

Operating frequency band……..…….. ISM 2.4 - 2.5 GHz

Tracking sources

Infrared Light Wavelength……..……..…950nm

IR Camera

Image sensor……..……..…. 1/4" CCIQ III digital qsxga cmos camera module

Pixel size……..…… 1.4um x 1.4um

Scan mode……..……..…… Progressive

Built-in lens…….. 4.5mm/F2.8 (5MP Auto focus)

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

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 CCG, 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 Craniocorpography 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.

3. PCB Assembly: Contains Semiconductors, Glass Epoxy material and metals Tin, Silver, Gold & Copper.

4. Straps: Contains nylon and fabric material.

5. Battery: Device battery shall be disposed as per the local governance. Do not dispose the battery with house hold or common waste.

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 require head size.
- Inform the dealer/manufacturer if the labels on the device peeled off.
- Data Storage: Data are stored in internal memory of the computer/laptop.
- The laptop/Computer used for testing should have Internal Firewall/Anti-virus protection.
- If the battery size changes due to aging then replace a new rechargeable battery with PANASONIC NCR 18650B 3400 mAh Li-Ion Battery.
- If the backup time reduces then replace a new rechargeable battery with PANASONIC NCR 18650B 3400 mAh Li-Ion Battery.
- 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/

*****