

USER MANUAL





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TERMS AND CONDITIONS

GENERAL USAGE

- THE NEURO TOUCH DEVICE MUST BE USED IN ACCORDANCE WITH THIS MANUAL AND ALL ASSOCIATED LABELING AND THE INSTRUCTIONS FOR USE
- ANY DEVICE THAT DOES NOT FUNCTION AS EXPECTED MUST BE REPORTED & RETURNED TO YOSTRA LABS
- THE ELECTRICAL INSTALLATIONS ON WHICH THE NEURO TOUCH DEVICE WILL BE USED MUST COMPLY WITH THE APPROPRIATE NATIONAL FLECTRICAL STANDARDS
- THE NEURO TOUCH DEVICE SHOULD ONLY BE USED IN THE INDICATED ENVIRONMENT
- THE NEURO TOUCH DEVICE WILL NOT FUNCTION WHILE CHARGING, UNPLUG THE CHARGER FOR THE DEVICE TO FUNCTION
- · MAKE SURE THE NEURO TOUCH DEVICE IS SUFFICIENTLY CHARGED BEFORE STARTING THE SCREENING SESSION
- DO NOT USE THE NEURO TOUCH DEVICE WHEN LOW BATTERY WARNING IS DISPLAYED.
- DO NOT AUTOCLAVE OR UV STERILIZE THE NEURO TOUCH DEVICE
- DO NOT USE THE NEURO TOUCH DEVICE IF DAMAGED, IF THE DEVICE MALFUNCTIONS OR HAS FALLEN, BEEN DAMAGED OR IMMERSED IN WATER. CONTACT THE YOSTRA LABS SUPPORT IMMEDIATELY
- DO NOT DROP THE NEURO TOUCH DEVICE OR SUBJECT DEVICE TO STRONG SHOCKS OR VIBRATIONS
- ONLY USE THE CHARGER SUPPLIED BY YOSTRA LABS FOR THE NEURO TOUCH TO AVOID DAMAGING THE DEVICE
- DO NOT USE ANY ACCESSORIES THAT ARE NOT SUPPLIED/RECOMMENDED BY YOSTRA LABS
- . DO NOT USE THE DEVICE WITH OTHER MEDICAL ELECTRICAL (ME) EQUIPMENT SIMULTANEOUSLY
- . TURN THE DEVICE OFF WHEN NOT IN USE
- ALWAYS STORE THE NEURO TOUCH DEVICE IN COOL, DRY PLACE AND ONLY IN THE BOX PROVIDED.
- YOSTRA LABS DOES NOT HOLD ANY RESPONSIBILITY FOR ANY INJURY TO THE PATIENTS CAUSED DUE TO THE USE/MISUSE OF THE DEVICE
- THE ONUS OF OBTAINING THE CONSENT OF THE PATIENT FOR THE DIAGNOSIS WITH NEURO TOUCH DEVICE AND THE STORAGE OF DATA LIES WITH THE HEALTH CARE PROVIDER
- THE INTERPRETATION OF THE DATA AND FURTHER TREATMENT PROVIDED BY THE HEALTHCARE PROVIDER IS THE RESPONSIBILITY OF THE HEALTH CARE PROVIDER
- DO NOT USE THE NEURO TOUCH DEVICE FOR ANY PURPOSE OTHER THAN INTENDED
- DISPOSE OF THE NEURO TOUCH DEVICE, COMPONENTS AND ACCESSORIES ACCORDING TO APPLICABLE LOCAL REGULATIONS, UNLAWFUL DISPOSAL MAY CAUSE ENVIRONMENTAL POLLUTION

CLINICAL PRECAUTIONS

- DO NOT USE THE NEURO TOUCH DEVICE ON THE INJURED FOOT OR THE FOOT LINDER MEDICAL TREATMENT.
- ONLY USE THE NEURO TOUCH DEVICE ON THE FOOT WHEN THE SUBJECT IS IN SUPINE POSITION. DO NOT
 ATTEMPT TO SCREEN THE SUBJECT WHEN THE FOOT IS BEARING LOAD AND NOT IN FREE STATE
- DO NOT USE THE NEURO TOUCH DEVICE ON OR IN THE VICINITY OF THE OPEN WOUNDS
- STERILIZE THE PROBES ON THE NEURO TOUCH DEVICE WHICH COMES IN CONTACT WITH THE PATIENT SKIN AFTER EVERY USE WITH SURGICAL SPIRIT / ALCOHOL SWABS
- SINGLE USE CONSUMABLE SUCH AS MONOFILAMENTS SHOULD NOT BE REUSED AND SHOULD BE CHANGED BETWEEN EACH PATIENT

ABOUT YOSTRA LABS PVT. LTD.

Yostra Labs Private Limited is a healthcare technology firm pioneering smart innovations to make healthcare more effective, affordable, and sustainable for the cost-sensitive developing market. We are committed to solving pertinent healthcare issues through innovative, practical, and cutting-edge technology solutions.

INTENDED USE

NEURO TOUCH™ is a point of care screening device for Peripheral Neuropathy. Perform the following tests using NEURO TOUCH™:

- Protective Sensation Test (Monofilament Test)
- Vibration Perception Test
- · Hot and Cold Perception Test
- Infrared Skin Temperature Measurement

INDICATIONS FOR USE

NEURO TOUCH™ enables screening of diabetic patients for symptoms of Peripheral Neuropathy. Diabetic Peripheral Neuropathy (DPN) refers to symptoms and signs of neuropathy in a patient with diabetes in whom other causes of neuropathy have been excluded.



TECHNICAL SPECIFICATIONS

Digital Monofilament Vibration Perception Test

Hot Perception Test

Cold Perception Test Infrared Skin Thermometer

Batterv

Local Memory

Unit Dimensions

Weight

Power Source Test Report 1 °C to 50 °C Approximately 8 hours 50 patients' data

0 V to 50 V at 170 Hz

Ambient temperature to 49 °C *

Ambient temperature to 10 °C *

Length 220 mm, Width 59 mm, Height 97 mm

375 g

0 a to 50 a

Charging adapter with output of 5V 2A Bluetooth connectivity with smartphone.

Web server based report

^{*} Under standard clinical conditions. Temperature increases or decreases by 15 °C from current ambient

Device	Do not open the device Do not use the device in case of any malfunction Do not use the device if it the device handle feels hot	
Liquid Ingress	Ingress Protection Rating: IP22 Do not use the device in the vicinity of wet area Do not pour water, surgical spirit on any liquid on the device	
Wound area	Do not use the device in the vicinity of wounds or vulnerable skin. Non-Invasive device	
Hot thermal test	The hot thermal test probe will be at elevated temperatures ($<$ 49 °C). Do not place the probe in contact with skin for a long duration of time.	
Cold thermal test	The cold thermal test probe will be at lowered temperatures ($>$ 0 °C). Do not place the probe in contact with skin for a long duration of time.	
Battery	Use only the charger provided with the device Do not use the device if you find the battery is inflated Warranty of the battery is 12 months	
Protective sensation test	The monofilaments used in protective sensation test must not be used beyond the intended use	
User Instructions	nstructions Read this Manual before using the NEURO TOUCH™ Devic Clean Temperature & Vibration probes before and after use Store the device in cool and dry place. Use the device under room temperature conditions.	

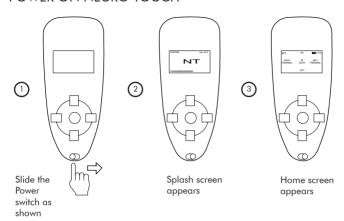
WARNING: No modification of this equipment is allowed. NEURO TOUCH™ is a Continuous operating mode device.

CAUTION: This device is intended to be used as a long term screening device. It is recommended to run additional tests to verify any signs of Neuropathy before beginning any treatment. This device is to only be used for protective sensation, temperature differential and vibration sensation screening.

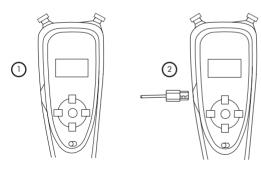
Rx ONLY CAUTION: Federal law restricts this device to use by or on the order of a physician



POWER ON NEURO TOUCHTM



CHARGE NEURO TOUCH™



Ensure Power switch is OFF

Connect the charger provided

- * When using the first time, ensure NEURO TOUCHTM is fully charged (~ 8 hours)
- ** In case of low battery indication, charge NEURO TOUCHTM fully before use



- Only use the charger provided to charge NEURO TOUCHTM
- ** DO NOT use NEURO TOUCHTM if you find battery is inflated *** Warranty for the batteries is 12 months

INSTALL AND LAUNCH NEURO TOUCHTM



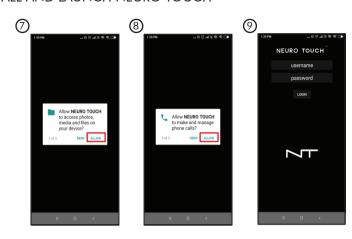


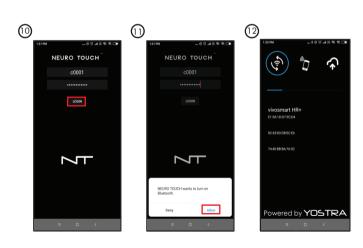




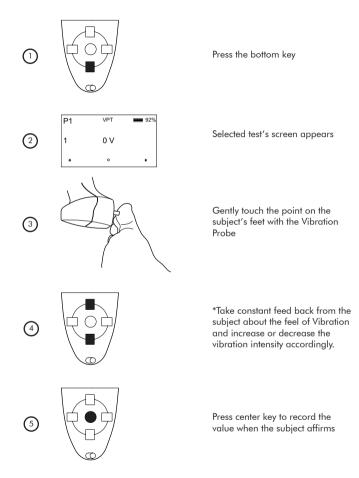








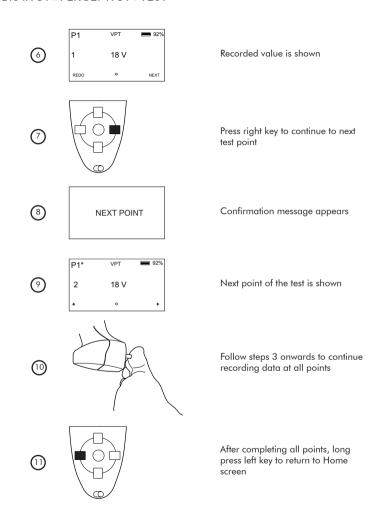
VIBRATION PERCEPTION TEST



* Press top key to increase vibration intensity or bottom key to decrease vibration intensity

Long press moves values faster

VIBRATION PERCEPTION TEST



INDICATION OF SAVED DATA



^{*} indicates data is saved

ERASE DATA





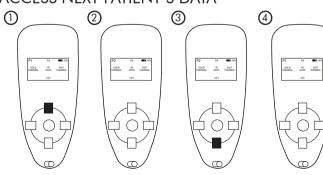


Long press on the Home screen

Press to erase data

Press to confirm

ACCESS NEXT PATIENT'S DATA

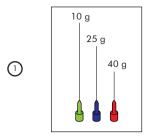


Long press on the Home screen

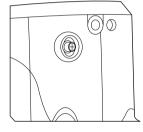
Perform test on next patient

Long press on the Home screen

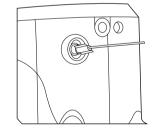
Perform test on previous patient



Select the required monofilament



Locate Monofilament base on the top

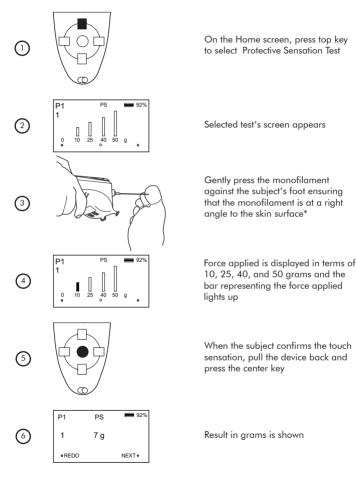


(3)

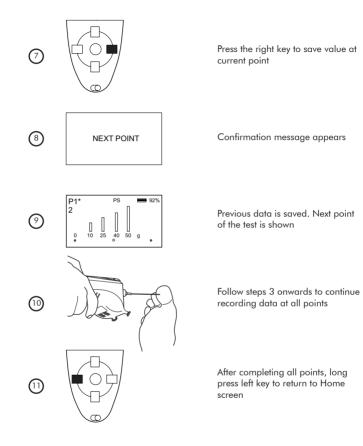
Place the monofilament into the 'Monofilament Base' and gently push till it tightly fits

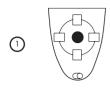




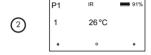


^{*} If the subject doesn't feel sensation at 10 g (green colour) monofilament, use the 25 g (blue colour) filament. If the 25 g filament too cannot be sensed, use the 40 g (red colour) monofilament.

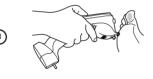




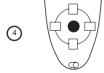
On the Home screen, press center key to select IR Thermometer Test



Selected test's screen appears



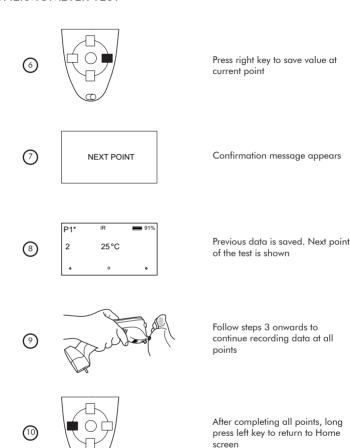
Hold the device less than 1.5 centimeter away from the subject's skin. LED light will focus with minimum radius of illumination

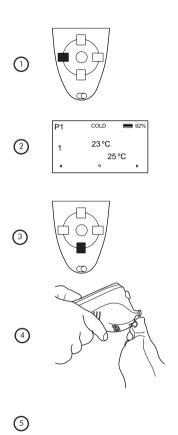


Press center key to freeze the value



Result is shown





On the Home screen, press to left key to select Cold Perception Test

Selected test's screen appears

Set temperature (25 C in image)
Probe temperature - Actual (23 C in img)

Set the temperature using the bottom key to decrease the temperature in steps of 1 or 2 degrees.

* Press top button to increase temperature & bottom button to decrease temperature

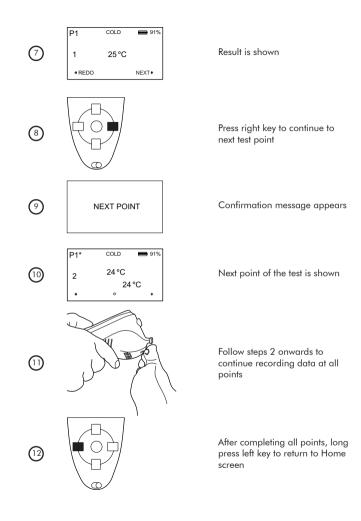
Long press moves values faster

Gently touch the point on the subject's foot with the Cold probe so that the flat surface of the probe touches the skin

Take constant feedback from the subject about the feel of temperature and increase/decrease temperature accordingly.

Always wait for the probe temperature to reach the desired set temperature.

Press center key to freeze the value when subject confirms



HOT PERCEPTION TEST



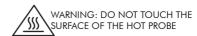












On the Home screen, press right key to select Hot Perception Test

Selected test's screen appears

Probe temperature - Actual (23 C in img)
Set temperature (25 C in image)

Set the temperature using the top key to increase the temperature in steps of 1 or 2 degrees.

* Press top button to increase temperature & bottom button to decrease temperature

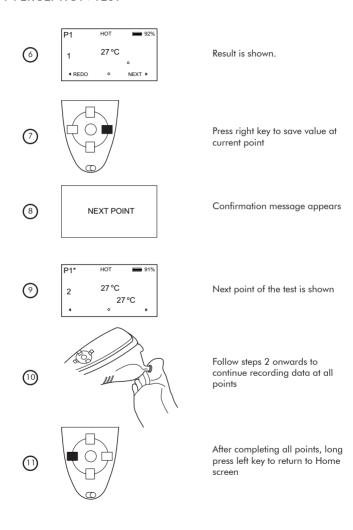
Long press moves values faster

Gently touch the point on the subject's foot with the Hot probe so that the flat surface of the probe touches the skin

Take constant feedback from the subject about the feel of temperature and increase/decrease hotness accordingly.

Always wait for the probe temperature to reach the desired set temperature.

Press center key to freeze the value when subject confirms

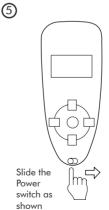








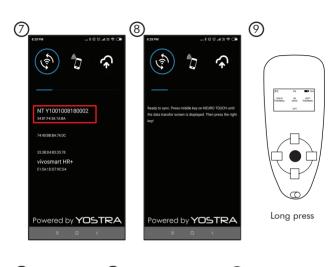


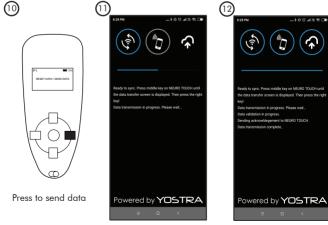




appears

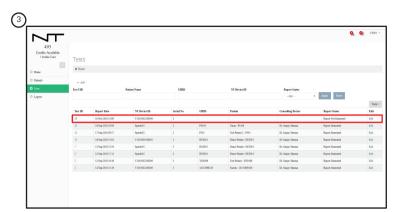
6















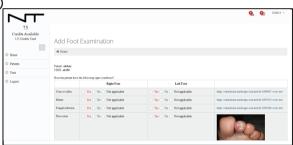
Provide information in case of new patient

Provide information in case of existing patient

(5)

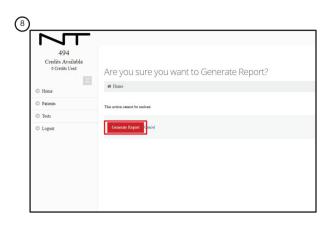


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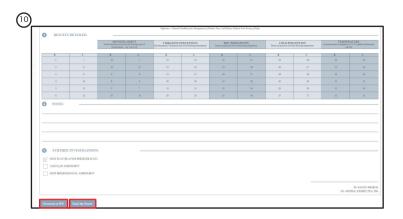


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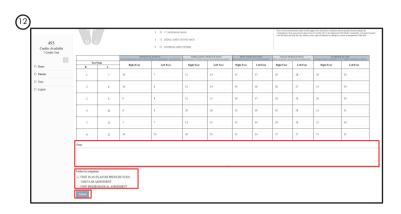




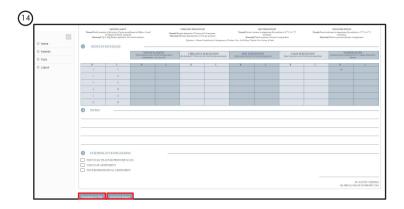




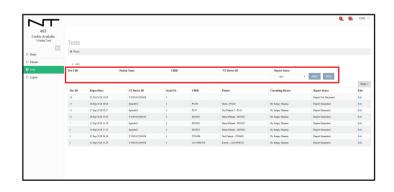








SEARCH REPORT



STORAGE AND TRANSPORT

- Store in a cool & dry place. Recommended conditions are ambient temperature of 20 °C to 30 °C at a humidity of 50% to 85% RH
- Handle with care. Do not subject the device to shock and extreme vibrations and temperature
- Use packing box provided by Yostra Labs for transportation. Ideal recommended transport conditions are temperature of 10 $^{\circ}\text{C}$ to 50 $^{\circ}\text{C}$ at a humidity of 50% to 85% RH

RECOMMENDED ACCESSORIES

- 1. Graduated Monofilament of 10 g, 25 g, and 40 g provided by Yostra labs
- 2. Charging Adapter: OUTPUT: 5 V, 2 A, 10 W; INPUT: 110-240 V, 0.3 A, 50-60 Hz

CLEANING PROCEDURE

- Wipe the probes that comes in contact with subjects's skin with surgical spirit/alcohol before and after use
- Use a soft damp cloth or sponge to clean the exterior of the unit
- Do not use abrasive cleaners or strong solvents to clean the device
- If the NEURO TOUCHTM device becomes contaminated by body fluids, it should be cleaned using a hospital grade disinfectant and a disposable soft cloth or paper towel as per the standard hospital or office protocol

MAINTENANCE PROCEDURE

- NEURO TOUCHTM is not intended to be serviced by the user. Only a trained service
 personnel authorized by Yostra Labs can perform the maintenance of the device
- Yostra Labs will make available on request, the circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair if the equipment is serviceable
- · Contact Yostra support immediately for any malfunction or requirement of servicing
- Contact Yostra Labs support team for the yearly maintenance

PROCEDURE FOR DISPOSAL

- Dispose the NEURO TOUCH™ device, components and accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution
- Alternatively, Return the device to below mentioned address at the end of life to discard

Yostra Labs Private Limited, #31, Ground floor, 3rd Cross, Venkat Reddy Layout, 80 Feet Road, Koramangala 6th Block, Bangalore 560095 Karnataka, India.

TROUBLESHOOTING

Display	Description	Possible cause	Solution
Error 1	Hardware Error in IR Thermometer function	No communication on I2C lines	Contact Support
Error 2	Hardware Error in Battery Gas Gauge IC	No communication on I2C lines	Contact Support
Error 3	Hardware Error in Hot and Cold Perception Test	Over temperature or incorrect temperature values	If hot probe over heats or cold probe over cools, wait for the probes to return to ambient temperature; then use the device. If error still persists, Contact Support.
Low Battery	Battery output not sufficient to function	Battery below 25% charge	Recharge the device to 100% (until charging indicator LED switches off)
Off Mode	Battery output not sufficient to function	Battery drained out	Recharge the device to 100% (until charging indicator LED switches off)
Charging LED Indicator	Charging LED Indicator is off	Battery drained out or charging LED Indicator is defective	Connect device to charger. If the charging LED indicator is still off, switch ON the device. If the display indicates battery status or Low Battery, Contact Support.
Display	Display is defective	Battery drained out or display is not working	Recharge the device to 100% (until charging indicator LED switches off). If the device does not switch ON, Contact Support.
IR LED Pointer	IR LED Pointer is Off in IR Skin temperature test	IR LED Pointer is defective	Contact Support
Protective Sensation Test	PS test is not recording any value	Blockage around monofilament base or error in monofilament hardware	Check and clear any blockage around the monofilament holder. If the problem still persists, Contact Support.
VPT	Vibration not sensed at the tip of the vibration probe or unusual sound generated by the device during the VPT	Defective VPT module	Contact Support.
Charging	Device not charging	Defective charger, or batteries	Contact Support.
Device getting warm	Device getting warm during charging or during use	Defective charger, or batteries	Contact Support.
-	Unexpected Data Quality	Obstructions between Probes and Patient Skin	Clear the obstructions.

GLOSSARY

DPN - Diabetic Peripheral Neuropathy

V – Volt

- Gram

PS - Protective Sensation

VPT - Vibration Perception Test

°C – Degree Centigrade USB – Universal Serial Bus

IR - Infra Red

IP - Ingress Protection

EU Declaration of Conformity (DoC)

We

Company name: Yostra Labs Private Limited

Postal address: No. 200 2nd Cross 1st Block Koramangala

Postcode: 560034

City: Bangalore

City: Bangalore

Telephone number: +91 91083 58538

E-Mail address: neurotouch@yostra.com

declare that the DoC is issued under our sole responsibility and belongs to the following product.

Y10 series

Apparatus model/Product: NEURO TOUCHTM

Type: Screening Device

Object of the declaration:

Serial number:



 $The {\it object} {\it of the declaration described above is in conformity with the relevant Union Harmonization legislation:}$

Medical Device Directive (MDD) 93/42/EEC

The following harmonized standards and technical specifications have been applied:

Title, Date of standard/specification:

Safety
Quality
Risk
EMC

IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ISO 13485:2016 Medical devices - Quality management systems Requirements for regulatory purposes

ISO 14971:2015 Medical devices - Application of risk management to medical devices

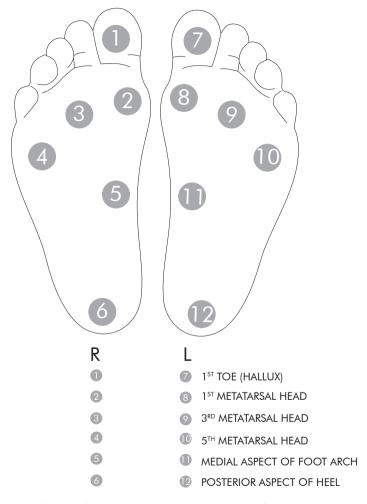
IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

Signed for and on behalf of:

Bangalore Vinayaka P Nandalike, CEO

Place of issue Name, function, signature

1 CR



Use NEURO TOUCH™ to perform the Peripheral Neuropathy tests at 12 test points on the feet, and to generate an online test report. Ensure that you perform each test in the same sequence as given here.

Thank You for placing your trust in NEURO TOUCHTM
Kindly fill the below details to secure your limited warranty of 12 months for the device.

Date of Purchase:

Name of purchaser:	
Contact No.:	
Serial No.(DSN):	Authorized partner stamp

Terms & Conditions of Warranty

- The terms apply to Limited Warranty from Yostra Labs Pvt. Ltd. for NEURO TOUCH purchased directly or from authorised partner(s) of Yostra Labs and it is (a) endorsed with company stamp; and (b) not defaced or altered.
- The limited warranty is for 12 months from the date of purchase or 1500 tests by the device, whichever is earlier and is valid only in India.
- This Warranty does not cover the accessories such as charges, monofilaments, eyepatch, carry case etc. supplied as such by Yostra Labs along with NEURO TOUCH device
- 4. The original warranty card and purchase receipt must be presented while requesting the limited warranty services.
- 5. The warranty covers defects in material and workmanship encountered under normal use only. The defective devices will be replaced (with comparable or refurbished devices or parts) as determined by Yostra Labs Private Limited's at its sole discretion.
- 6. Loss or damage to the device are not covered arising from or in connection with (i) abuse, tampering modification or disassembling other than Yostra Labs authorized personnel (ii) negligent use and/or misuse (including improper storage and failure to follow the recommended precautions and operating instructions) (iii) defective and non standards consumable items (iv) using charger other than the prescribed specifications (v) accidental damage
- Only Yostra Labs or service personnel authorized by Yostra Labs are allowed to open the device which otherwise will void this warranty
- 8. This warranty applies to the original purchaser only and is not transferable.
- Customers are required to register the device serial number of the device with Yostra Labs after purchase for the warranty to be valid by contacting the customer support via email or telephone.
- 10. Yostra Labs provides a limited warranty of 6 months on the internal battery or 500 charge cycles, whichever is earlier. At Yostra Lab's sole discretion, on need basis, after thorough examination, battery will be replaced for the device in the warranty period if found to be underperforming.
- 11. Warranty does not cover misuse of the device such as using the device for the purposes other than intended and affixing the equipment to any nonstandard accessory attachment
- 12. This warranty does not cover any equipment on which the serial number sticker has been removed, modified, or made illegible.
- 13. Yostra reserves the right to withhold approval of a warranty claim pending visual inspection of the alleged defect.
- 14. Warranty on NEURO TOUCH device can be extended by additional 12 months by availing AMC/CMC plans. For more information contact Yostra Labs



An ISO 13485 Certified Company

Handle with care

Read user manual before use

Temperature limit

Fragile



Store in dry place

IP22 Ingress Protection

Caution! Hot surface

Lithium-ion batteries

Do not discard device



Do not dispose device in fire



CE marking



Bluetooth

Yostra Labs Private Limited #31, Ground floor, 3rd Cross,

Venkat Reddy Layout, 80 Feet Road, Koramangala 6th Block, Bangalore 560095, Karnataka, India

www.yostra.com

Call: +91 9108358538 Email: neurotouch@yostra.com