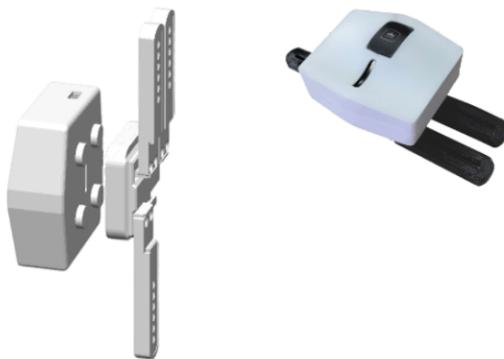




User's Guide for PULIH Wireless Low Back Pain Monitoring Device (Model No: NCPULIH-22BT01MY)



Nonivasi Care Sdn. Bhd.
M1-08-01, 8Trium Menara 1, Jalan Cempaka SD 12/5,
Bandar Sri Damansara, 52200, Kuala Lumpur



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Author: BME Engineer representing the Production Department.

Version No.	Author	Implementation Date	Description of Change
0	BME Engineer	28 July 2022	Initial Release
1	BME Engineer	30 January 2023	Inclusion on model number and SKU
2	BME Engineer	15 February 2023	Battery replacement instruction & PULIH App Interface inclusion
3	BME Engineer	6 April 2023	Update on the accessories list
4	BME Engineer	31 May 2023	Inclusion of ESD Strike in the Precaution list
5	BME Engineer	18 July 2023	Amend the Pulih Product name



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Important information

About this manual

This user guide is intended for PULIH Wireless Low Back Pain Monitoring Device (NCPULIH-22BT01MY). The manual overview describes the features of the device, setup, operation, and all other information. It has to be followed in order to obtain the optimal measurement and prevent any undesired event or measurements from occurring.

About PULIH

PULIH Wireless Low Back Pain Monitor Device is a Li-ion battery-powered device developed to provide a quantitative rehabilitation progress monitor of low-back pain patients. It consists of an electromyography (EMG) circuit integrated with Inertial Measurement Unit (IMU) to capture muscle activity at the lower back and motion data during intervention. The captured data is cleaned and sent to user's smartphone before sent to the cloud for enhanced processing. The processed data provides index of their low-back pain improvement throughout the rehabilitation program. The index will be of assistance to the rehabilitation doctors as a quantitative measure to assess progress the patients.

Intended use

PULIH is intended to be used for monitoring rehabilitation progress of patients with chronic low-back pain under supervision of healthcare providers, physicians, rehabilitation specialists, physiotherapist, chiropractors and normal user. PULIH will be used with PULIH mobile apps (iOS & Android) for control of the measurements and personal progress tracking. Clinicians will be able to monitor the patients progress remotely using the Dr Dashboard which can be accessed through internet browser. It is suitable to be used at home or healthcare facility.

Contraindications

- Do not use together with any active medical or surgical unit
- Do not use on irritated skin or open wound
- Do not use in critical care applications
- Do not use the device while the device is being charged



Technical Service and Support

Reach us through:

Website	www.nonivasi.com
e-mail	support@nonivasi.com
Address	Nonivasi Care, M1-08-01, 8Trium Menara 1, Jalan Cempaka SD12/5, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia



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Warnings

	<p>Consult all associated documentation for warnings and other pertinent information.</p>
	<p>Refer to the user manual for complete instructions.</p>
	<p>Keep the device free from liquids. The introduction of liquids into the device could impair its safety safeguards.</p>
	<p>Handle with care. Made of PU material and can break with excessive force.</p>
	<p>Do not store or operate the device in conditions of extreme cold or heat. Due to the availability of a replaceable and rechargeable Lithium-ion battery, the optimal storage and operating temperatures range from 15 to 45 degrees Celsius. Continuing to activate the device will result in a noticeable performance decline and compromise the safety feature.</p>
	<p>Battery changing or removal are only to be performed by qualified personnel appointed by NONIVASI CARE SDN BHD. Incorrect polarity can be hazardous and cause serious incident. Refer to the instruction during installation.</p>

Precautions

	<p>Stop using the device IMMEDIATELY when experiencing skin irritation or discomfort.</p>
	<p>Stop using the device IMMEDIATELY when sudden heating is observed. Contact Nonivasi care for technical support.</p>
	<p>Usage of the device are to be without simultaneously during charging.</p>
	<p>Contains a lithium-ion battery. Do not damage, crush, burn, freeze, or mishandle the device in any way. Only use authorised power supplies and chargers.</p>
	<p>For SERIOUS INCIDENTS, contact Nonivasi Care at support@nonivasi.com to report.</p>
	<p>The safety, reliability, and performance of the device are guaranteed by Nonivasi Care Sdn. Bhd., subject to the following conditions: the assembly, modifications, and repairs must be carried out by qualified technicians; the electrical installation must adhere to the relevant regulations; and the equipment must be used in accordance with the operating manual.</p>
	<p>Electrostatic Discharge (ESD) strike may cause device to restart to avoid incorrect/contaminated measurement. Start a new measurement if the device restarts.</p>

Device Information

	<p>Complies with requirements from Medical Device Authority. Internal Powered device. (IEC60601-1)</p>
	<p>Type BF Medical Device</p>
	<p>ON and OFF button. The device will toggle between ON and OFF state upon pressing this button.</p>
	<p>Manufacturer: Nonivasi Care, M1-08-01, 8Trium Menara 1, Jalan Cempaka SD12/5, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia</p>
	<p>Manufacturing Date (provided on the packaging and the device)</p>
	<p>Serial Number (provided on the packaging and the device)</p>
	<p>The device must be discarded in accordance with local regulations regarding ELECTRONIC WASTE.</p>
	<p>FCC ID: SH6MDBT50Q</p> <p>This device complies with part 15 of the FCC rules. Operation is subject to; (1) This device may not cause harmful interference; and (2) This device must accept any interference received, including interference that may cause undesired operation.</p>



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Browser Requirement

- Firefox (latest stable version)
- Google Chrome (latest stable version)
- Microsoft Edge (latest stable version; Chromium-based only)
- Safari (latest stable version)

iOS Device Requirement

- iOS 16 Operating systems and up to date.
- iPhone 8 current minimum requirements.
- RAM 2GB minimum.
- Storage 8GB minimum.

Android Device Requirement

- Android P (Pie) @ Android 9 (API 28) Operating system or later.
- BLE 4.2 Support
- RAM 1GB minimum
- Storage 8GB minimum
- Screen resolution 1280x720 (minimum), 1920x1080 (recommended)

Legend

Abb.	Meaning
NU	Normal User
DO	Device Owner
L4	Spine, Lumbar 4
L5	Spine, Lumbar 5



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Warranty Disclaimer

What is covered by this warranty?

Nonivasi Care Sdn. Bhd. warrants the PULIH device as the following; only PULIH main housing (internal components), and slider arm housing are covered for a period of ONE (1) YEAR and SIX (6) MONTHS respectively, from the date of original purchase by the end-user purchaser ("Warranty Period"). Guidelines are published include but not limited to information contained in technical specifications and instruction for use.

What is not covered by this warranty?

This warranty does not apply to (a) consumable parts, such as battery; to (b) cosmetic damage, including but not limited to scratches, dents and broken plastic on ports unless failure has occurred due to a defect in materials or workmanship; (c) to damage caused by accident, abuse, misuse, fire, earthquake or other external cause; (d) damage caused by operating the PULIH device outside Nonivasi Care's published guidelines (refer instruction for use and technical specification); (e) to damage caused by service or upgrade performed by anyone who is not a representative of Nonivasi Care or Nonivasi Care's authorised service provider; (f) to PULIH that has been modified to alter functionality or capability without the written permission of Nonivasi Care; (g) to defects caused by normal wear and tear or otherwise due to the normal aging of the PULIH device; (g) if any serial number has been removed or defaced from the PULIH device, or (h) from stolen and rental product.

If you submit a claim during the Warranty Period to Nonivasi Care or Nonivasi Care's authorised distributor in accordance with this warranty, Nonivasi Care may choose to:

(i) fix the PULIH device with new or pre-owned genuine parts that have been examined and found to meet Nonivasi Care functioning standards,

(ii) replace the PULIH device with a replacement product of the same model that is brand-new or made of brand-new and/or previously used PULIH device's parts and has been tested and passed Nonivasi Care's functional requirements (or, with your permission, a product that has the same or substantially similar features as the original product - for example, the same model in a different form or a different model with the same features).

Before requesting warranty service, please access and review the online help materials listed below. Please utilise the information below to get in touch with a Nonivasi Care's representative if the PULIH device is still not working properly after using these resources. If your PULIH device needs servicing, Nonivasi Care's representative will help decide whether it does and, if so, will let you know how Nonivasi Care will handle it. Depending on where you are, additional fees can apply when calling Nonivasi Care.

Online information with details on obtaining warranty service is provided.



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PULIH Technical Specification

PULIH (NCPULIH-22BT01MY)	
GENERAL SPECIFICATION	
DIMENSION (MAIN PULIH DEVICE)	(H)90MM X (W)100MM X (L)40MM
WEIGHT	120g
ENCLOSURE MATERIAL	POLYURETHENE
ELECTRICAL PROPERTIES	
CHARGING VOLTAGE	5.0v
CHARGING CURRENT	1.0A
WORKING VOLTAGE	3.3v
BATTERY TECHNOLOGY	LITHIUM - ION (18650)
WIRELESS TECHNOLOGY	BLUETOOTH 5 LOW ENERGY
ENVIRONMENTAL CONDITION	
OPERATING CONDICTION	15 °C TO 40 °C
	10% - 90% RELATIVE HUMIDITY (NONCONDENSING)
STORAGE CONDITION	15 °C TO 40 °C
	10% - 90% RELATIVE HUMIDITY (NONCONDENSING)
EMG SPECIFICATION	
CHANNEL	SINGLE DIFFERENTIAL CHANNEL
SAMPLING RATE	5,000 Hz
BANDPASS FREQUENCY	5 - 1000 Hz
FEATURES	
SINGLE BUTTON CONTROL	ON AND OFF MEMBRAN SWITCH
LED INDICATION	INDICATES BETWEEN CONNECTION AND MEASUREMENT STATE
TYPE-C USB	CHARGING PORT
MOBILE APPLICATION	USER OPERATION AND MEASUREMENT
DOCTOR DASHBOARD	ADMINSTRATION AND REMOTE PATIENT PROGRESS MONITOR
ADJUSTABLE ELECTRODE SLIDER	ERROR PROOF MAGNETIC CONNECTOR FOR ELECTRODE. ELECTRODE WIDTH AND DISTANCE ADJUSTABLE MECHANISM
SNAP ADAPTOR	SINGLE USE BIOPOTENTIAL ELECTRODE SNAP METHOD
SAFETY STANDARDS	IEC 60601-1 (IN PROGRESS)
	IEC 60601-1 -2 EMC (IN PROGRESS)
EXPECTED SERVICE LIFETIME	
BATTERY CHARGING COUNTS	~500 CYCLES (NCR18650B)
SLIDER - ELECTRODE LEADS	~2000 COUNTS OF SNAP IN & OUT
PULIH MAIN HARDWARE	4 YEARS



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PULIH Lower Back Pain Monitoring System – Overview

The PULIH Mobile EMG Lower Back Pain Monitor is a battery-powered device (NCPULIH-22BT01MY) intended to automate the diagnosis of Lower Back Pain by utilising specialised algorithms. This makes detection reliable, quantifiable, and straightforward. The device features remote monitoring, allowing data collecting to occur with and without close clinical supervision. Normal personal user can receive free training to identify their electrode placement locations.

PULIH is equipped with Bluetooth connection that is always available when PULIH is switched on and can be made through PULIH mobile application during setup. The device integrated with sensors that is essential to calculate the Lower Back Pain algorithm. The device contains replaceable and rechargeable lithium-ion battery. The battery status can be monitored via the LED indicator. Battery replacement can only be conducted by certified personnel, as per guarantees regulation. Our Eco-friendly product design policy make it so that the device will automatically shut down after 15 minutes idling.

The device main housing function together with the slider housing that connect to the electrode. The slider can be removed and be replaced with another, according to the user's body type and size. The placement is adjustable assuming the position of the electrode. To replace any part, the slider leg and battery require to be done by authorise personnel or else the warranty of the device will be void.

PULIH Hardware

Accessories List

Bill	Components	Quantity
1	Main housing (SKU No: 202301-PU-0001)	1
2	Slider housing (SKU No: 202301-SL-0002)	1
3	Type-C charging cable	1

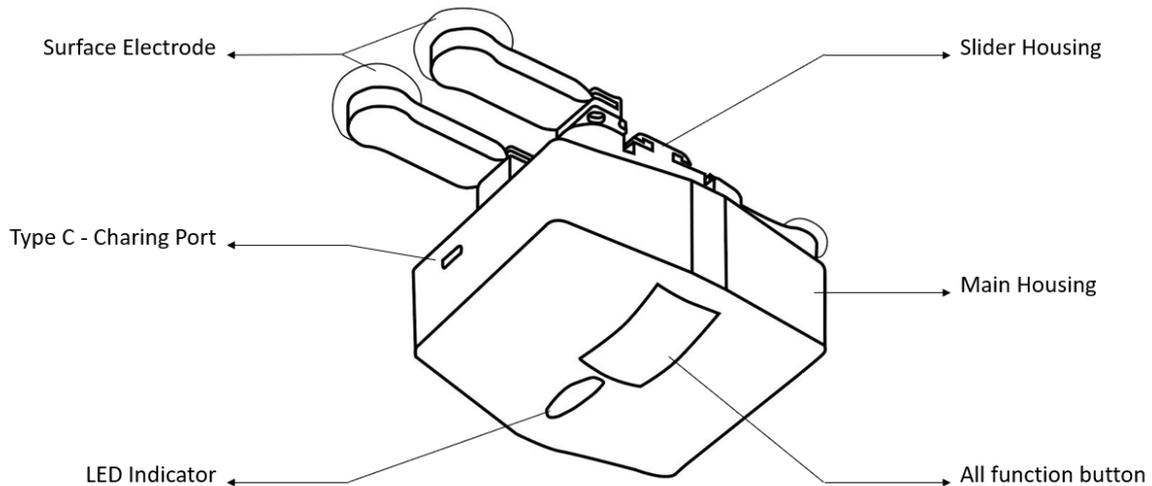
LED indicators

PULIH present their status through the different LED colours and blink patterns that is indicated inside the following table. Each state is described, and example figures are shown.

	State	Colour	Pattern
General States			
1	Power Off	Off	None
2	Power On	Red-Green-Blue	Alternate
Connection States			
6	Finding Bluetooth Connection	Blue	Blink
7	Bluetooth Connection Established	Blue	Solid
Measurement States			
8	Ready for Measurement	Green	Fade
9	Measurement In Progress	Green	Blink
10	Measurement Complete	Green-Blue	Solid

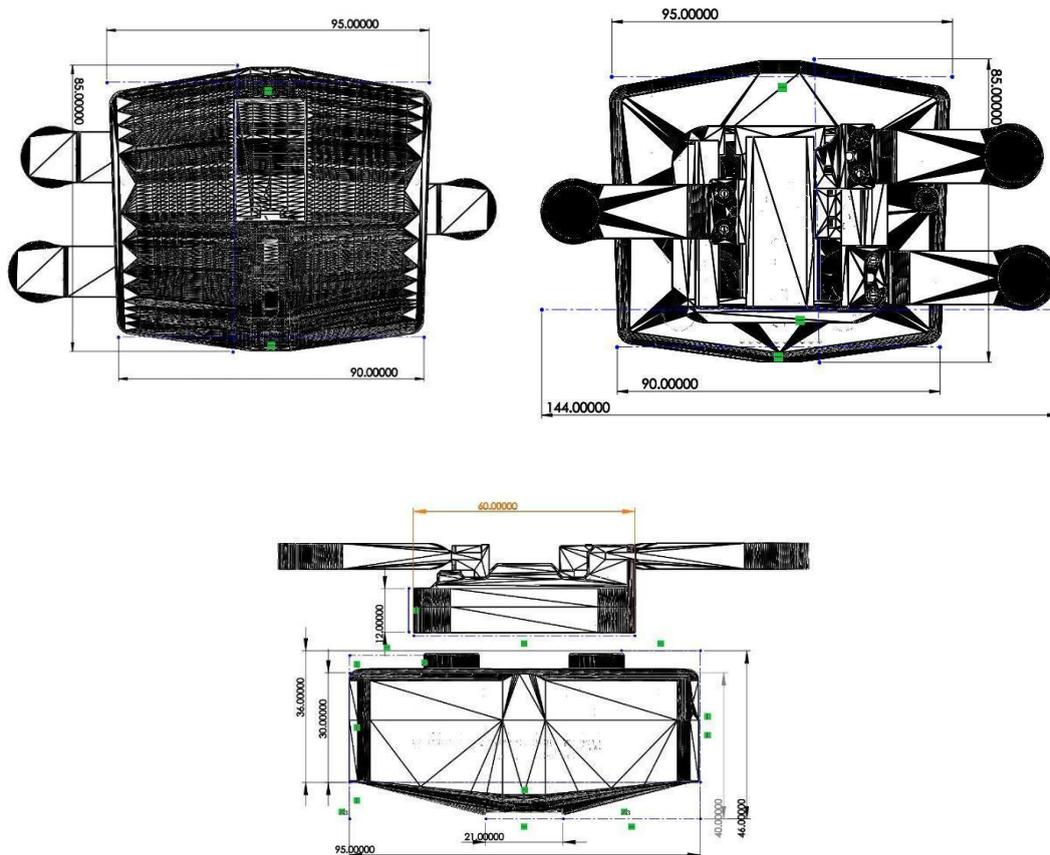


Device Parts and Description PULIH Wireless Lower Back Pain



Bill	Part	Description
1	Main housing	To house all the components
2	Slider housing	To house the slider arm
3	All function button	To turn on the device & turn off the device
4	Type C charging port	To charge the battery
5	LED indicator	To serve as indicator for status of the device
6	Surface electrode	Biopotential electrode that will collect data from the user

Diagram below is the sketch of the original device with dimension of the device shown on the screen.





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PULIH Mobile Application

User Types

There are 2 user type when registering for the PULIH Mobile Application account. The user types are; the "Device Owner" (DO) and "Normal User" (NU)

Device registration

Registration for DO is made through the PULIH Doctor Dashboard. Given that DO already register in the PULIH Doctor Dashboard, DO can log in into the app using the designated USERNAME (EMAIL) and PASSWORD. Successful login will direct DO to the HOME screen. Unsuccessful login with prompt ERROR. FORGOT PASSWORD option is available if password is forgotten. SIGN UP link provided for NORMAL USER only.

Registration for NU is made in the mobile application. Successful registration will create an account and will be guided to the GET STARTED screen. LOGIN is for NU with existing account. Successful login will direct NU to the HOME screen. Unsuccessful login with prompt ERROR. FORGOT PASSWORD option is available if password is forgotten.

Device Pairing

To pair PULIH device to the mobile application, after first time registration, NU will be guided to the GET STARTED screen and then LINK PULIH screen to scan QR CODE on the PULIH device. For DO the DEVICES options allows DO to see lists of registered devices and to register new devices. To register a new device, click on REGISTER PULIH Device and then in the following screen click on LINK PULIH.

Measurement

MEASURE screen is accessible from the NAVIGATION BAR in the HOME screen. It starts with a general GUIDE for the intervention process that is required during the measurement. CONTINUE button is to proceed with the measurement. (It will only be enabled if there is a minimum (1) device registered.) START button is only enabled when Bluetooth connection is established between the device and the mobile apps. If Bluetooth is disconnected. BLUETOOTH button is ENABLED to enable user to connect to PULIH DEVICE. On START button pressed, STOP button will be ENABLED, RESTART button (DISABLED) will appear, and USER ANIMATION will move. On STOP button pressed, RESTART button will be ENABLED, STOP button will be DISABLED and USER ANIMATION will be in standing position (RESET). After 30 seconds from START/RESTART measurement, ALERT DIALOG for sufficient data collected will be shown and redirected to RESULT screen. On CONTINUE button pressed, page is directed to HOME screen.

Getting Started

Setup PULIH Hardware

- Components of the PULIH Hardware
 - Main body (SKU No: 202301-PU-0001)
 - Slider (SKU No: 202301-SL-0002)
 - Biopotential electrodes
- Parts included in the PULIH packaging
 - Main body (SKU No: 202301-PU-0001)
 - Slider and housing (SKU No: 202301-SL-0002)
 - USB Type-C cable
 - Rechargeable battery

Switching ON

Turn on PULIH for the first time. Red, green, and blue LED will illuminate alternatively, indicating Power On. Set aside for preparation to pairing. Note the labelling, identify the QR code that will be used later. Establish connections via **Item 2 b) iii)** for pairing the device with the mobile apps. Observe LED states based on **Item 2 a) vi)**. Different LED colour provide sufficient information of the states of the device.

Charging

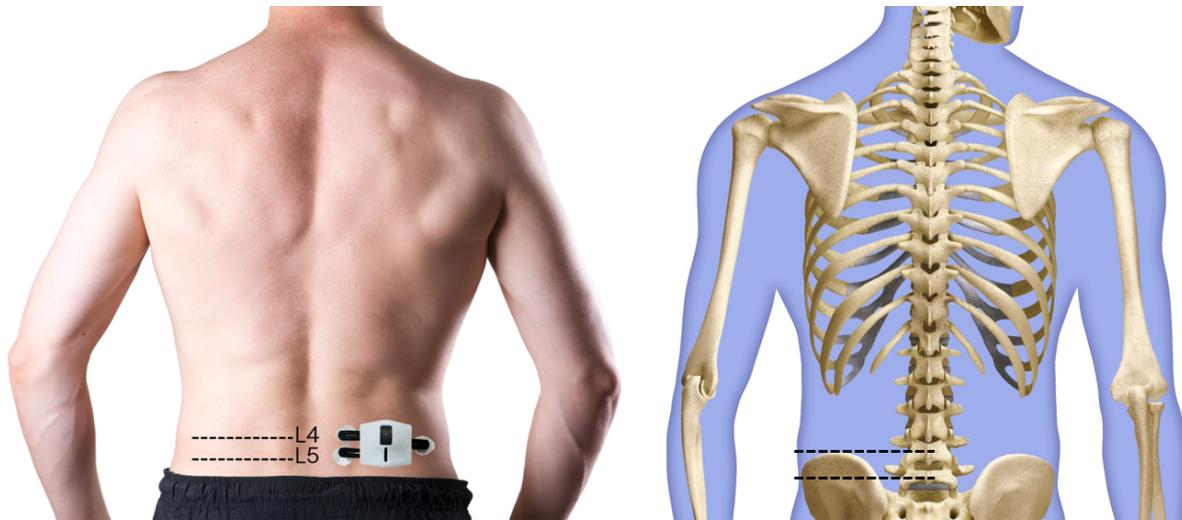
Connect the USB cable included in the packing to the female USB port on the device. Connect the opposite end of the USB cable to a certified charging block that is plugged into an electrical outlet. Upon activating the outlet, a red LED will illuminate for the duration of the charging procedure. Once the lithium-ion battery is fully charged, an orange LED will illuminate.

Slider Assembly

Assemble slider to the housing. Connect slider to the main body via magnetic connector with aid of the magnetic slot. The magnetic connector provides power supply from the battery to the slider for data acquisition.

Placement of User

Get your physician assistance for first time fitting for electrode placement. The placement of the electrode requires for palpation technique to properly identify the location of the Lumbar 4 and Lumbar 5. First and second electrode for potential differences are placed respectively at each level, 2 cm from the midline of the body. Placement of the electrode should be as the following diagram:



L4 = Lumbar 4, refer to the level of the lumbar spine.

Measurement

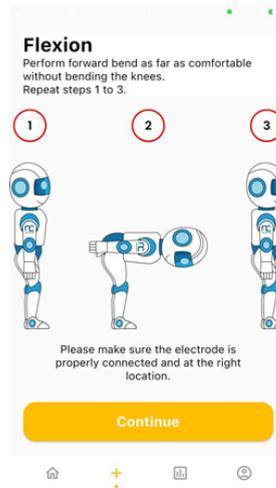
After PULIH are safely placed on the user's lower back muscles, measurements can be taken. Using mobile applications, adhere to **Item 2 b) iv)**. The green LED will fade to indicate that measurements are prepared to be taken. Throughout the duration of the measurement, green LED blinks when the measurement is initiated. LEDs re-illuminate in green and blue alternatively after the measurement is complete and the data collection is recorded. Measurement protocol can be observed through the mobile apps or can be accessed from our website; www.nonivasi.com.

Step by Step Guide for Conducting Measurement

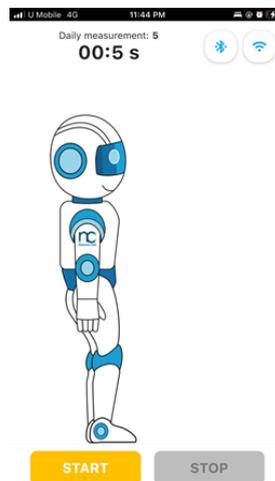
1. Turn the device ON by pressing the ON/OFF button on the device. LED indication on the device should illuminate Red, green, and blue alternatively.



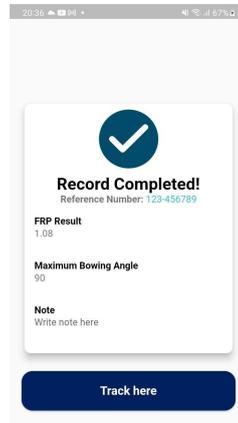
2. Establish connections to the mobile apps (if not yet; can refer to Page 14).
3. Clean the skin using alcohol swab for electrode placement.
4. Remove the sticker on the patch, place the patch onto the lower back muscle location, 2cm to the right of the midline from L4 and L5.
5. Attach the slider attachment to the electrode patch via the clip connector.
6. Attach the main housing to the slider attachment via magnetic slot.
7. Standby the mobile apps at the measurement screen. Once the user standing in the comfortable position and read the instruction on the Standby screen, click on "Continue" as shown in the image below.



- The app screen will show a robot assistant standing upright. this robot assistant will represent the user and follow the the user's flexion movement as the user perform flexion. Once the user is ready to perform flexion, press "start" button in the mobile apps as shown in the image below.



- Conduct the movement shown in the mobile apps for the duration of 30 seconds.
- If the measurement taken are correct, the apps will automatically prompt a "Record Completed" message box and show the measurement summary. "track here" option will lead to Progress page.



11. If there are measurement error, the process stops automatically after 30 seconds and the apps will ask to retry the measurement or to cancel.
12. The progress of the user can be tracked to observe improvement in the Progress page.

Battery Installation/Replacement Instruction (By Qualified Personnels Only)



WARNING: Disassembly of PULIH device is hazardous and dangerous. This procedure has to be conducted by qualified personnels or legally appointed contractors by NONIVASI CARE SDN BHD. Disassembly of PULIH without written permission or by qualified personnels will render the warranty void.

- 1) Detach slider from the main PULIH device. Ensure the device in OFF state (no LED).
- 2) Remove the label on the side of the PULIH device (next to the charging port).
- 3) Locate two screw point at the back of the PULIH device.
- 4) Unscrew both screws and slowly detach the back cover.
- 5) Locate the battery and remove the battery from the holder.
- 6) Check the new battery. Read the label on the battery carefully and identify the marking of "NCR18650B" and the polarity of the battery.
- 7) Observe the battery holder on the PULIH device. Identify the polarity marking.



WARNING: Incorrect polarity installation may cause hazardous incident. Check the polarity of the battery and the battery holder before installing the battery.



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- 8) Carefully place the battery, the NEGATIVE first in the battery holder and the cautiously, push the POSITIVE side into the holder.
- 9) Attach the back cover carefully. Make sure the sealant rubber installed around the inner wall of the cover are placed carefully inside the enclosure wall.
- 10) Press on the back cover and start to tighten the screws back into the points. Ensure the gap in between of the back and front cover to PULIH enclosure is well placed.
- 11) Attach the new label and ensure the label has the same numbering as the previously removed labels.
- 12) Switch ON the device to use or charge to ensure full charge before measurement.

-END-