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Operation Manual

Portable Limb Load Monitor (PLLM)

September 2019

Portable Limb Load Monitor Assist Device
Featuring Touch Screen Audio/Visual Feedback on Weight Bearing

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Specifications Control Unit

General

Rated power source	9v DC
Format	Battery PP3
Max current consumption	116mA
Dimensions (L x W x H)	141 x 81 x 40 mm
Weight	266g

Specifications Wireless

Transmission (Tx) Load Unit

General

Rated power source	9v DC
Format	Battery PP3
Max current consumption	45mA
Dimensions (L x W x H)	115 x 69 x 28 mm
Weight	115g

Cleaning

All surfaces of this system should be cleaned with WET WIPE between each use.

Indications and Intended Use

PLLM is an Assist Device and along with the practitioner they will guide the patient through rehabilitation by monitoring gait, movement and balance. The PLLM Assist Device is with the gait rehabilitation patient all the time and augments gait rehabilitation and enhances gait retraining.

The PLLM is an Assist Device that is designed to aid recovery from the following pathologies/injuries: Lower Limb Amputation, Acquired Brain Injury, Cerebral Vascular Accident (stroke), Parkinson's Disease as well as most conditions which affect the Central Nervous System.

PLLM will also assist orthopaedic surgical patients to comply with a Weight Bearing Program from non-weight bearing up to full weight bearing after orthopaedic surgery.

Theory of Operation

To obtain accurate results and maintain comfort we recommend that the patient wears shoes with an insole that can be easily removed such as runners / sneakers.

The PLLM Assist Device default setting is to “**Alert After Target**” mode which means the patient gets feedback when their weight to their affected limb falls at or above the target. This mode maybe used to **discourage** weight-bearing.

The alternative setting is “**Alert Before Target**” mode which means the patient gets feedback when their weight to their affected limb is at or below the target. This mode maybe used to **encourage** weight-bearing.

Next consideration is the choice of two **Load Challenges** to be undertaken by the patient:

1. Absolute Body Weight (Abs BW) Level Challenge - here the PLLM Assist Device provides a numeric level of patient's effort according to forefoot and heel sensors (you can use scales to associate the numeric level with the scale reading);

2. Percentage of Body Weight Challenge is for restricted weight-bearing as prescribed by the specialist. This is achieved by the patient applying 100% body weight, putting all weight through the non-affected leg. Press Start on the Control Unit to capture 100% Body Weight. The insole with sensor pads then needs to be swapped to the shoe on the affected leg. For further instructions see page 8.

PLLM Standard Unit

If you have ordered the PLLM Standard Unit you should have the following:

See Drawing 1 – Quick start guide - page 13

Operation Manual; version: nCounters September 2019
Control Unit with stylus; nCounters Model: PLLM C3.1, D1
Control Unit Pouch; nCounters Model: Classified 30
Wireless Transmission Load Unit (Tx Load Unit);
nCounters Model: NCPLLMW
Ankle Strap; nCounters Model: ASTX
Sensor Pads; nCounters: Forefoot NCFPP and Heel NCHP Pads
Insoles; nCounters – 3 sizes – small, medium and large
Headphone; Electrovision Model: A069 for individual use, or supply your own 3.5 mm Headphones
2x 9v Lithium UltraLife batteries (included)

PLLM Deluxe Unit

This unit includes everything that is in the standard unit plus a Data Logger that will log weight-bearing data from the two sensor pads. Data, including all key gait parameters, is displayed in Excel using nCounters software.

User Instruction

Install battery

First out of package task is to install the battery

You will require two 9V Lithium Batteries (recommend ULTRALIFE) for Control Unit and Tx Load Unit. Slide back panel at rear of each enclosure and attach the 9V battery clip to the battery.

Caution: ENSURE CORRECT POLARITY

Sensor pad placement

To obtain accurate results and maintain comfort we recommend that the patient wears shoes with an insole that can be easily removed such as runners / sneakers.

1. Leave socks on patient. Choose an nCounters insole that fits easily into the patient's shoe. Small, medium and large insoles are provided (see *Figure 1*). If there is already an insole in the patient's shoe it is a good idea to remove it before inserting nCounters insole.



Figure 1: Small, medium and large insoles provided

ENSURE SENSOR PADS ARE CORRECTLY POSITIONED ON THE INSOLE, UNDER THE PATIENT'S FOOT PRIOR TO INSERTING INTO THE PATIENT'S SHOE

2. Place the insole under patient's foot with attached Velcro™ exposed. The sensor pads can be moved along the insoles to ensure the correct position. Securely attach the sensor pads as described below:

- For forefoot sensor pad place 'X' in line with base of 5th toe – at base of ball of forefoot and then attach the pad via the Velcro™ to the insole.
- For heel sensor pad place 'X' directly under the patient's heel and then attach the pad via the Velcro™ to the insole.

See Figures 2 – 6



Figure 2: Forefoot and heel sensor pad placement on insole



Figure 3: Correct forefoot and heel sensor pad placement



Figure 4: Correct forefoot and heel sensor pad placement



Figure 5: Insert insole with sensor pads into shoe



Figure 6: Insole with sensor pads in shoe

3. Insert the nCounters insole into the patient's shoe, right side up (sensor pad's X showing). Then place the patient's foot inside the shoe on top of the sensor pads. **Ask the patient to transfer weight from heel to ball of foot in a rocking motion for approximately 10 seconds. This will condition the sensors.**
4. Secure the ankle strap above the ankle with Velcro™ loop exposed. The Transmission (Tx) Load Unit attaches to the ankle strap.



Figure 7: Correct position for ankle strap



Figure 8: Transmission Tx Load Unit attached to ankle strap

The Transmission (Tx) Load Unit

This unit collects data from patient's heel and/or forefoot and transmits this data to Control Unit.



Figure 9: Front wireless Tx Load Unit

- After securing the ankle strap with Tx Load Unit above the ankle, put sensor pad leads into sockets as shown below and turn Unit ON.

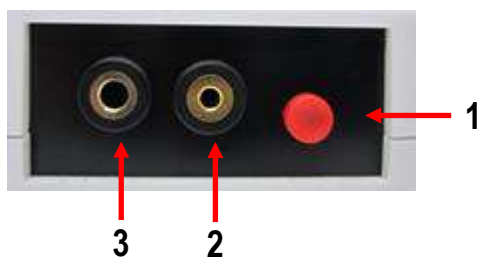


Figure 10: On/Off button and sensor pad sockets Tx Load Unit

- On / Off Button- single press**
Single press turns the Tx Load Unit On / Off

Plugs from sensor pads are inserted here

- Heel sensor plug is inserted here**
Heel plug only fits heel socket
- Forefoot sensor plug is inserted here**
Forefoot plug only fits forefoot socket

You can use both sensors or one at a time

The Control Unit

This is the component that provides audio visual feedback to patient and practitioner / therapist while guiding the patient through rehabilitation by monitoring gait, movement and balance.



Figure 11: Control Unit

4 Four LEDs

Two yellow and two red LEDs indicate how far the patient is above / below target.

No lights indicate that target has been achieved.

R2	LED Red 2:	very high under / over target
R1	LED Red 1:	high under / over target
Y2	LED Yellow 2:	medium under / over target
Y1	LED Yellow 1:	low under / over target

5 Graphic Display Screen

The screen provides Mode of Operations with:

- Quick start mode
- Options
- User settings
- Help instructions
- Live Data analysis

Power Switch
Headphone socket
Speaker

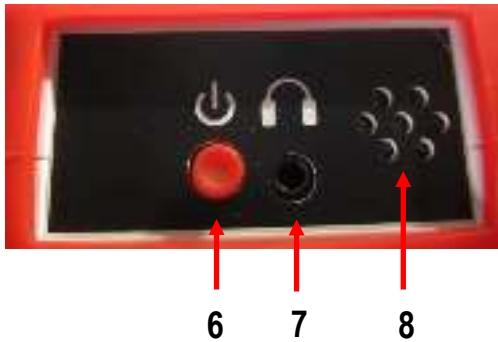


Figure 12: Side panel CONTROL UNIT

- 6** On / Off Button- Single press - on / off
- 7** Headphone socket – headphone plug is inserted here
- 8** Speaker output

Individual Headphones



- 6.** For individual use, or supply your own 3.5 mm Headphones

Position the Control Unit in pouch



Control Unit pouch

Two ways of wearing the pouch

Secure the pouch onto the patient using the strap as shown below:



Pouch attached using belt



Pouch attached using strap



Figure 13: Control Unit positions

The Control Unit is only inserted into the pouch after the settings have been finalized by the therapist.

User Instructions for PLLM

1. After completing the sensor pad placement, condition the sensors (see page 3, step 3) then turn on the Tx Load Unit and YELLOW LED lights. Replace battery when RED LED is on
2. NEXT turn on the Control Unit with a single press of the on / off button and the following welcome screen appears:



Figure 14: Welcome screen

3. The Transmit Error Closing Screen means the Tx Load Unit is not transmitting or Tx Load Unit not turned ON



Figure 15: Transmit Error screen

4. Once the Tx Load Unit is recognized by the Control Unit the following "CHOICE SCREEN" appears (Figure 16). **Weight is the default setting so press OK**

The Angle option is only available if you have the Portable Angle Monitor (PAM)



Figure 16: Choice screen

5. You are now in the Choice screen Figure 16

See PLLM Mode of Operations screens for mode and load options and detailed examples of operation pages 10-12

The Start / Options Screen

Apply weight and press start to receive feedback after target, on body weight through sensor pads (default settings)



Figure 17: Start / Options screen

Press Options to choose settings:

- **Alert / feedback** before or after target
- **Load Challenge** either Absolute Body Weight (Abs BW) Level or Percentage of Body Weight (BW 100%)

Make selection then press OK



Figure 18: Setting screen

You will return to Start / Options screen Figure 17 – then press Start

USING THE PLLM FOR ABSOLUTE BODY WEIGHT (Abs BW)

Use the Setting Screen to select mode of feedback



Figure 19: Setting screen Mode After / Load AbsBW selected

Load the affected limb with **the target weight** at which you want the patient to receive feedback

A set of scales maybe useful when using this mode to correlate the number on the Control Unit screen with the weight shown on the scales.

If the therapist has chosen Alert After Target and Absolute Weight as above, they will see this Live Data screen.



Figure 20: Example of Live Data screen Mode After / Load AbsBW

The **Rep Counter** records the number of times the patient has reached or gone above the target

Current Level is the numeric weight that the patient is placing though the forefoot and heel sensors at any one time.

Target Lvl (Level) @ XX (Live Data screen 1) represents the numeric weight at which the patient receives feedback after the session has been started.

Target can be altered using the “-“ or “+” button



Figure 21: Live Data screen Mode After / Load AbsBW

Feedback on numeric weight bearing

Alert after target selected.

Patient has received feedback 12 times by reaching or going above target 12 times.

Numeric value of weight through pads is 35 (currently under target).

Patient currently receiving NO feedback.

Target = 40 this value was determined when the user pressed the START button. See Figure 17 which captures target weight going through both pads.

The Target Lvl @ value can be changed using “-“ and “+” buttons.

Alert before Target setting

Feedback stops when patient reaches target.

Use this mode to encourage weight bearing.

NB No audio feedback while foot is off the ground (during swing phase of gait)



Figure 22: Setting screen Mode Before / Load AbsBW selected

USING THE PLLM FOR PERCENTAGE OF BODY WEIGHT (% BW)

Obtain 100% body weight by:

inserting the insole with correctly positioned sensor pads (see earlier instructions pages 2-3) in the shoe of the non affected leg

Turn on Tx Load Unit and Turn on Control Unit

1. After choosing Weight (see Figure 16),
2. Choose Options (Figure 17)
3. Select BW100% and press OK (Figure 23)
4. You return to Figure 17
5. Encourage the patient to put all their weight through non affected leg.
6. **THEN PRESS Start**



Figure 23: Setting screen Mode After / %BW selected

The Control Unit captures that numeric value as representing 100% BW

Then insole with sensor pads in place must be swapped to the shoe on the affected leg.

Explaining Figure 24: Live Data screen

The **XX** below **BW:** is the numeric value of 100% Body Weight – this number does not change

The “**Current BW@ XX**” represents the current value of weight going through the sensor pads at any one time.

The Target Level (Target Lvl @ 100 represents 100% Body Weight for e.g. if user wants the target to be 50% use the “-“ button the reduce the % BW at which the user receives feedback.



Figure 24: Example Live Data screen Mode After / %BW selected

An example of a Live Data screen after the user presses start is below:



Figure 25: Live Data screen Mode After / %BW selected

Explaining Figure 25: Live Data screen:

60 represents the numeric value at 100% BW – this value does NOT change

Target level of 50% of total BW

Current BW@ 35 represents the weight currently through the sensor pads and that value keeps changing.

NB In this instance the BW of 35 is above the target and the patient will receive feedback

Rep Counter records that the patient has exceeded the target 12 times.

Volume (Vol) button

Speaker and headphone have different volume controls and maybe used at the same time. Speaker is on by default. To deselect speaker, press Vol and uncheck button then press OK. Check HPhone radio button to use headphone. Check either speaker or HPhone radio button to change volume. Adjust volume using “-“ and “+“ buttons. Press **OK** and return to Live Data screen

Visual Feedback Screen

When you wish to finish the session press the **END** button and the following Visual Feedback screen will appear (Figure 26)

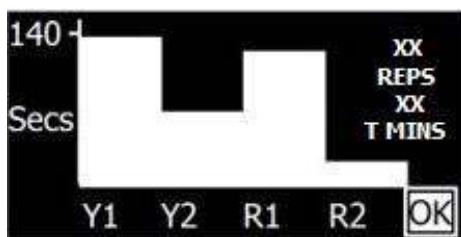


Figure 26: Visual Feedback screen

Understanding the Visual Feedback screen with graphs, repetitions and time.

The number shown at top left of screen in Figure 26 (in this instance 140 secs) changes, as this number is the total maximum number in seconds any one LED was on for.

XX REPS number of times user received feedback.

T MINS Total Session Time.

Turning off the Control Unit

Press **OK** and Goodbye screen (Figure 27) appears and the Control Unit turns off by itself. The Tx Load Unit must be manually turned off.

To turn off at any time, press On / Off for > 2seconds.

You will be notified If the battery requires replacing.

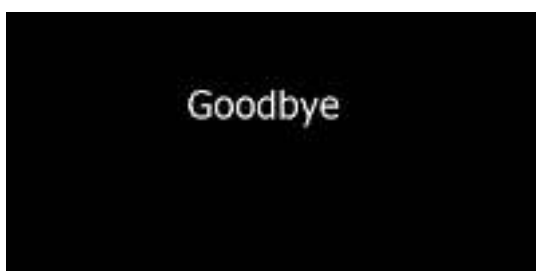


Figure 27: "Goodbye" screen

Troubleshooting

The forefoot pad appears to have different sensitivity to the heel pad.

The two pads should be equally sensitive. This can be tested by rocking the foot backwards and forwards. It is almost always that the forefoot pad not the heel pad is the

one that needs repositioning. If the pad feels too sensitive, then move the pad back further behind the ball of the foot. If the pad seems not sensitive enough then move it towards or slightly under the ball of the foot.

Words "NO DATA" appear on the Control Unit.

Try switching the Tx Load Unit, off then on again and wait for the node to reconnect with the Control Unit. The session will proceed as normal and the words "No Data", will disappear from the screen. At the end of the session check the Tx Load Unit's battery.

For further information on the Portable Limb Load Monitor please refer to our website for videos and other resources.

Warranty

- This device comes with 12 month warranty on parts from date of purchase.
- Wherever possible a replacement unit will be provided while yours is being repaired.
- **Free** firmware and software upgrades are available for the first 12 months of purchase

Returns / Repairs Policy

All items for return or repair must have a returns number given by nCounters attached to it.

Items should be sent to:

nCounters

PO BOX 2336

KEW VICTORIA 3101

AUSTRALIA

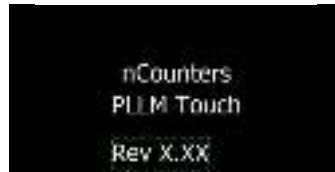
Visit our website:

ncountersonline.com

For tips on different ways of using the PLLM and for any updates on products or services to complement your device from nCounters.

PLLM MODE OF OPERATIONS SCREENS

Welcome screen



TRANSMIT ERROR SCREEN



No Tx Load Unit has been detected. Control Unit will shut down.

Choice screen



Choose WEIGHT or ANGLE for feedback

Start screen



Press Start or select Options

Select **Options** to choose

- **Alert / feedback** before or after target
- **Load Challenge** either Absolute Body Weight (Abs BW) Level or Percentage of body Weight (BW 100%)

Make selection then press OK
Return to Start Screen and select Start



Settings screen

Example of Live Data screen



Displays Mode of Feedback, Load Challenge, Number of repetitions achieved, Current Level and Target Level

Visual Feedback screen



Analysis screen with graphs, repetitions and time. Screen displays number of seconds each feedback LED has been on. **XX REPS** number of times user received feedback. **T MINS** Total Session Time. Press **OK** and Goodbye screen appears and the Control Unit turns off by itself. The Tx Load Unit must be manually turned off.

Goodbye screen



Control Unit turns itself OFF

Hard turn off – press ON / OFF button for at least 2 seconds and machine turns off – can occur anytime during operation

SETTINGS SCREEN

Choose mode of feedback:

- Before mode (Alert ON at or below Target)
- After mode (Alert ON at or above Target) **DEFAULT MODE**

Select Load Challenge:

Abs BW - Absolute Body Weight - DEFAULT MODE - threshold is a number corresponding to the weight through forefoot and heel sensors

- **BW100%** the threshold is a **Percentage of Body Weight** corresponding to the weight through forefoot and heel sensors

Settings screen



Live Data screen



Live Data screen 1

Examples - Live Data screens



Live Data screen 2



Live Data screen 3



Live Data screen 4

LIVE DATA SCREEN

Rep Counter If Alert AFTER target has been selected the Rep Counter records the number of times the patient has reached at or above the target. If Alert BEFORE target has been selected the Rep Counter records the number of times the patient has been below or at the target.

Current Lvl (Level) @ XX (Live Data screens 1 and 3) represents the numeric weight that the patient is placing through the forefoot and heel sensors at any one time (represented as **UNITS**).

Target Lvl (Level) @ XX (Live Data screens 1 and 3) represents the numeric weight at which the patient receives feedback after the session has been started.

Current BW (Body Weight) @ XX (Live Data screens 2 and 4) represents the current numeric value of weight that the patient is placing through the forefoot and heel sensors at any one time

Target Lvl (Level) @100 (Live Data screens 2 and 4) represents 100% Body Weight. This percentage value can be changed after the session has been started.

BW: XX **BW:XX (Live Data screens 2 and 4)** represents the numeric value for 100% of Body Weight and does NOT change. For example if Target Lvl @ is changed from 100% to 50% and BW is 80, then Target Lvl @ corresponds to 40.

TWO EXAMPLES OF LIVE DATA SCREENS EXPLAINED



Feedback on numeric weight bearing

Alert after target selected. Patient has received feedback 12 times by reaching or going above target 12 times. Numeric value of weight through pads is 35 (currently under target). Patient currently receiving NO feedback. Target = 40 this value was set when the user pressed the START button. The Target Lvl @ value can be changed using “-” and “+” buttons.

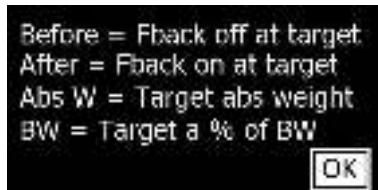


Feedback on percentage of body weight bearing

Alert after target selected. Patient has received feedback 12 times by reaching or going above target 12 times. Current BW @ 35 is the numeric value of weight through the pads (currently over target). Patient is receiving feedback. **(NB Target value is 50% of 60 = 30)**. Target Level @ % of Body Weight = 50%. The Target Lvl @ value can be changed using “-” and “+” buttons. **BW: 60** is value of 100% Body Weight that was set when the user pressed the START button. This value does NOT change.

UTILITY SCREENS

HELP SCREEN



NO DATA SCREEN



Probable causes for “No Data” and alarm sounding:

- **Low Battery** in Tx Load Unit
- Two units are **out of range** – when back in range the alarm will stop, the words “No Data” will disappear and device will return to normal operation. Tx Load Unit accidentally turned off.
- **Electromagnetic interference** is disrupting transmission.

CHECK SCREEN



User to **CHECK** if sensor plugs are fully inserted into sockets in Tx Load Unit

If the unit is not put back in range after 30 seconds the device will turn off.

AUDIO FEEDBACK via headphone and / or speaker



Speaker and headphone have different volume controls and maybe used at the same time. Speaker is on by default. To deselect speaker, press Vol and uncheck button then press OK. Check HPhone radio button to use headphones. Adjust volume using “-” and “+” buttons. Press **OK** and return to Live Data screen.

