tréxō robotics

Trexo Plus User Manual

QMS-USR-753.006.EN-5 - Trexo Plus Manual
UNITED STATES

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Introduction

Welcome to the Trexo Plus family!

Intended Use

The Trexo™ is a powered exoskeleton intended to perform ambulatory functions in individuals aged 1-18 with motor disabilities due to musculoskeletal, neuromuscular and neurological impairments. The device must be used under the supervision of a trained companion or in a rehabilitation institute under the supervision of a trained rehabilitation professional. The companion and rehabilitation professional must complete Trexo's training program prior to use of the device. The Trexo™ is not intended for sports or stair climbing.

Trexo Robotics does not claim/guarantee clinical benefits. Results may vary.

For the most updated information and a digital version of the manual, please visit www.trexorobotics.com/user-manual.

Audience

This manual is intended to be read and used as a reference by care providers and/or individuals who have received training in the correct use of the Trexo Plus. The trained individual is responsible for the correct operation of the Trexo.

FDA Information

The Trexo Plus is a Class II medical device.

Maximum User Weight Restrictions

	Trexo Sizes		
	Small/Medium	Large	X-Large
Weight (lbs)	80	125	150
Weight (kg)	36.3	56.7	68

The maximum user weight restrictions exist for the safety of the Trexo User. Please ensure that the Trexo User is using the correct size Trexo for their weight.

Contraindications

Any individuals exhibiting the following may not be candidates for the Trexo:

- ❑ Knee flexion contracture > 20°
- ❑ Knee valgus > 40°
- ❑ Hip subluxation > 40% migration percentage with pain during walking
- ❑ Hip subluxation > 50% migration percentage unless with orthopedic clearance for weight bearing with the Trexo
- ❑ Hip flexion contractures > 10°
- ❑ Spasticity, resistance, or behavioural concerns that interfere with the use of the device may limit use
- ❑ Weight bearing restrictions (including from any recent Orthopaedic surgery, e.g. soft tissue releases and lower limb bony surgery)
- ❑ Moderate to severe Osteogenesis Imperfecta
- ❑ Osteoporosis/Osteopenia with history/suspicion of lower limb fragility fracture would require medical clearance
- ❑ The child is unable to communicate discomfort or pain (including non-verbal cues) to the Trexo Trained supervisor

Trexo Users should be monitored by their physical therapist and cleared for Trexo use, annually.

Multiple Devices

Clinics with more than one Trexo should configure their tablet to only remember one device's Wi-Fi network. Reference the device serial number label on the tablet and ensure it is connected with the corresponding device with the same serial number.

Essential Performance

The torque output of the motors and walking speed have been identified as the essential performance of the device. The device has been designed in a way to ensure that the torque does not exceed the specified limits (60N-m on the hips, 30N-m on the knees) regardless of any configuration. The device has also been designed in a way to ensure the walking speed does not exceed the safe maximum of 70 steps per minute regardless of configuration.

Important Safety Instructions

Please read this entire user manual carefully before you use the device and keep the manual for future reference. Additional copies are available on request.

ALL OPERATORS OF THE TREXO PLUS DEVICE MUST UNDERSTAND THAT POTENTIALLY SEVERE INJURY MAY OCCUR FROM MISUSE. TREXO ROBOTICS INC. IS NOT RESPONSIBLE FOR ANY INJURY, LOSS, OR DAMAGE CAUSED BY IMPROPER USE OR MAINTENANCE OF THE DEVICE.

BASIC TERMINOLOGY

The Trexo - Trexo Plus - Robotic legs attached to the Rifton Dynamic Pacer.

The Trexo User - The individual in the Trexo

The Trexo Trained Supervisor - The individuals who are trained and certified by the Trexo Robotics Customer Success team, to operate the Trexo for the Trexo users

WARNING – To reduce the risk of **fire, electric shock, or injury to persons**:

- Treat the Trexo with care. Do not drop it or expose it to any heavy shocks.
- In the case that the device has been dropped or damaged, start the device and run it without a Trexo User. Discontinue use of the Trexo if it does not operate normally and inform the Trexo Robotics Customer Success team using the Trexo Chat App.
- Do not use the device if any separate Trexo components or the device in its entirety have been exposed to rain or moisture and it does not operate normally.
- Do not use the Trexo in wet surroundings (e.g. in the rain, near a swimming pool, by a lake) as battery exposure to water can be dangerous.
- Do not immerse any Trexo components, including the robotic leg attachments, battery and cables in water or rinse under the tap. Please use alcohol based cleaning wipes that you would use on other pieces of electrical equipment.
- Do not use the Trexo if there is visible damage, broken components, or missing parts.
- The Trexo must never be used in conjunction with any treadmills or similar equipment other than the Trexo Certified Treadmill approved by Trexo Robotics Inc. Using a non-Trexo Certified Treadmill may result in serious injury or death.

Important Safety Instructions

Please read this entire user manual carefully before you use the device and keep the manual for future reference. Additional copies are available on request.

WARNING – To reduce the risk of **fire, electric shock, or injury to persons (continued)**:

- Do not operate the Trexo if the charger, battery, cables, or device itself have been damaged in any way. Additionally, do not use the device if there is liquid spilling out of it, or objects.
- Only use the original battery and chargers provided. If either component is damaged, contact Trexo Robotics at the Trexo Chat app for assistance.
- Check that the voltage indicated on the charger corresponds to your power outlet voltage before you charge the Trexo.
- Do not use or run the Trexo while the charger is plugged into the device.
- Make sure the cables remain unobstructed during the use of the device. Protect all cables from being pinched, particularly the plugs at the outlet and cables where they exit the joints.
- In the event the Trexo User is caught in the rain, the Trexo Trained Supervisor must turn off the device immediately, and seek shelter. Once in shelter, do not turn on the device or charge the device. Inform the Trexo Robotics team that the Trexo was exposed to rain and the team will assess the unit.
- Do not charge the Trexo outdoors. It should only be charged in an indoor setting.
- Do not leave small parts of the device laying around as there is a high risk for a choking hazard for young children.
- Do not allow the cables to be in contact with young children to play with as it poses a risk for strangulation hazard
- Do not connect the Trexo and parts with other equipment not described in the instructions for use.
- Do not modify the Trexo without authorization of the manufacturer.

Important Safety Instructions

CAUTION - To ensure the Trexo is used correctly and safely:

- The Trexo must be used under the supervision of a Trexo Trained Supervisor. The device cannot operate autonomously.
- The Trexo User must be within 3 meters of a Trexo Trained Supervisor at all times. The Trexo User must never be left unattended in the Trexo Device. Trexo Supervisors who leave the Trexo users unsupervised may be liable for injuries sustained.
- All Trexo Trained Supervisors must be trained by a member of the Trexo Robotics Customer Success team. The Trexo must never be operated by individuals who have not been certified by the Trexo Robotics Customer Success team to operate the device.
- The Trexo is not capable of turning by itself and requires assistance from the Trexo Trained Supervisor.
- Use the device on stable, even, and non-slippery surfaces without any obstacles in the way. Do not use the device on grassy surfaces, carpeted surfaces, muddy surfaces, rocky surfaces, hilly surfaces and/or other similar terrains.
- All four Rifton wheels must be firmly planted on solid ground at all times. The locks on the wheels must be unlocked with the wheels in a non-ratcheting position.
- Do not use the Trexo in areas which could lead to injury or harm, including near stairwells and inclined or elevated surfaces.
- Do not attach the Trexo Robotic legs to other pacers, gait-trainers, or walkers. The Trexo is only meant to be used with the provided Rifton Dynamic Pacer Gait Trainer.
- The Trexo User must be using the Rifton Chest prompt anytime they are using the device.
- The Trexo is not meant to be used for extensive periods of time. It is recommended that the Trexo be used with each Trexo user a maximum of 2 sessions daily for a maximum of 1 hour per session.
- If the Trexo User is using the the Trexo with a treadmill, it can only be used with the Trexo Certified Treadmill.

Important Safety Instructions

CAUTION - To ensure the Trexo is used correctly and safely:

- The Trexo Trained Supervisor must be familiar with the Trexo User's displays of pain, discomfort, fatigue and any signs of distress so when they display it, the Trexo Trained Supervisor must stop the device.
- In the event the Trexo User is in any significant pain, discomfort, or is displaying a high degree of spasticity, the Trexo Trained Supervisor must stop the device immediately and discontinue use.
- The Trexo Trained Supervisor must discontinue use if the Trexo User experiences any allergic reaction, skin irritation or abrasions at any points of contact with the Trexo.
- The Trexo Trained Supervisor is responsible for ensuring the Trexo User is using the Trexo in a safe environment at all times.
- Trexo Users with any open abrasions, or wounds should not use the Trexo to minimise the chance of further infection or injury and/or cross-infection with another Trexo User.
- To prevent infection, the Trexo must be cleaned using alcohol based wipes prior to each session.
- The Trexo Users must wear long trousers that cover the User's knees when using the Trexo to avoid friction burns.
- The Trexo User must wear shoes and/or AFOs to prevent injury or harm to the User's feet.
- The Trexo has an emergency stop for use in the event of a dangerous situation. The Trexo Trained supervisor must be within reach to stop it at all times.
- The Trexo User must be reassessed by their Primary Care Physician and Physical Therapist on an annual basis to ensure that the Trexo is appropriate for usage.
- Do not dispose the Trexo in normal waste. To ensure proper handling and disposal, please contact Trexo Support. This is crucial to promote sustainability and minimize the environmental impact.

Important Safety Instructions

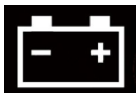
CAUTION - To ensure the Trexo is used correctly and safely:

- The Trexo should be operated where the environmental conditions are the following: ambient temperature is between 5° C - 35° C degrees (41° F - 95° F), relative humidity range of 30%RH - 75%RH (Non-condensing), atmospheric pressure range of 70.0 kPa - 106.6kPa.
- The Trexo should be stored where the environmental conditions has an ambient temperature between -20° C to 50° C (-4° F - 122° F), relative humidity range of 0% RH - 70% RH (non-condensing), atmospheric pressure range of 50.0 kPa to 106.6kPa.
- Allow the Trexo to acclimate to the environment for at least 2 hours before operating the device, if the device has been in extreme warm or cool conditions.
- In the event there is Wi-Fi interference from other common home devices, which may cause connectivity issues, please keep the source a safe distance away from the Trexo (in another room).
- Only the Trexo Robotic Legs and the Trexo provided headrest clamp should be mounted on the rear-side of the Rifton Dynamic Pacer. Do not mount anything else there.
- Upon pressing the start button on the Trexo App, the Trexo's legs will commence automated gait patterns. The movement will persist until halted by the Trexo Trained Supervisor who can stop the action either through the tablet interface or using the Emergency-Stop button on the unit.
- The Trexo user and the Trexo supervisor cannot be the same person. The Trexo user being assisted by the device and the Trexo trained supervisor controlling the device must be separate individuals while the device is in operation.
- The Trexo unit's legs are not designed to support the Trexo User's weight. For weight support, the Rifton Dynamic Gait Trainer and the appropriate Rifton support accessories serve as the designated support system, ensuring the safety and stability of the patient during use.
- Do not turn on and use the device until training. Log-in credentials will be provided during training.

Symbol Directory

Symbol	Description	Standard Reference
REF	Catalog number	ISO 7000-2493
SN	Serial number	ISO 7000-2498
LOT	Model number	IEC 60417-6050
	Date of manufacture	ISO 7000-2497
	Manufacturer	ISO 7000-3082
UDI	Unique device identifier	ISO 15223
	Temperature limit	ISO 7000-0632
	Humidity limitation	ISO 7000:2620
	Atmospheric pressure limitations	ISO 7000:2621
IP 22	Ingress protection rating	IEC 60529
	Do not dispose of the device in normal waste, contact the manufacturer.	EU Directive 2012/19 EU
	Refer to instruction manual.	ISO 7010-M002
	This part is a type Body Floating (BF) applied part.	IEC 60417-5333
	Signifies an emergency stop button.	IEC 60417-5638
	Indicates that situations exist that need operator awareness or operator action in order to avoid undesirable consequences	ISO 7000-0434A

Symbol Directory

Symbol	Description	Standard Reference
	Non-ionizing radiation; radiofrequency interference may occur near this device.	IEC 60417-5140
	Indicates the item is a medical device.	ISO 15223
	Battery Connected	ISO 7000-0247
	Battery Disconnected	ISO 7000-2063

Device specifications

User Sizes (cm)	Small		Medium		Large		X-Large	
	Min	Max	Min	Max	Min	Max	Min	Max
Hip to floor	40	47	43	53	29	76	62	94
Hip to knee	18	18	21	24	26	34	30	39
Knee to floor	22	29	22	29	29	42	33	50
Hip width	20	33	20	33	20	35	22	41
Thigh girth	20	38	20	50	20	70	20	70
Shin girth	12	30	12	38	12	50	12	50
User Weight								
Weight (kg)	-	36	-	36	-	56	-	68
Weight (lbs)	-	80	-	80	-	125	-	150

Technical specs

	Small/Medium	Large	X-Large
Dimensions of device (cm)	76 x 66	91 x 71	101 x 80
Height of device (cm)	55 - 69	72 - 98	79 - 104
Weight of device (kg)	43	45	47

	Minimum	Maximum
Speed	10 steps/min	70 steps/min

*The gait speed is measured in steps per minute.

	Extension	Flexion
Hip joints	30°	50°
Knee joints	0°	90°

What comes with the Trexo

The Trexo Plus comes fully equipped with everything required for operation. Trexo Plus is designed to work with a Rifton Dynamic Pacer Gait Trainer K630 or K640 or K650 for which additional accessories may be purchased separately.

A fully assembled and ready for use Trexo Plus is displayed in the image above.

The device consists of the following parts:

1. Two robotic legs
2. Set of shin cuffs
3. Foot plates of different sizes
4. Battery Box
5. Battery, Wi-Fi Transceiver & Charger
6. Tablet with preinstalled Trexo app
7. Rifton Pacer Gait Trainer with saddle and accessories
8. Maintenance kit
9. Piston Stopper

The following parts of the Trexo are Type BF parts: Trexo robotic legs, foot plates, headrest, chest prompt, multi-position saddle, and arm prompts. Any accessories which attach to the upper frame of the Rifton are considered as type BF applied parts.

Trexo Features

In addition to our two modes, endurance and strength mode, the Trexo has the following features. We are continuously investing in research and development and we will release updates through the Trexo software on your Trexo tablet.

- **Backwards Walking:** Studies have shown that backwards walking contributes to coordination and strength and overall this transfers to walking forwards.
- **Stander Mode:** Children can use trexo as a standing frame or to take breaks from walking
- **Extensor Tone Mode:** This gait pattern helps reduce knee extensor tone spasticity in the walking pattern by limiting full knee extension.
- **Initiation for both legs:** Now you can track initiation on both left and right leg independently.

Trexo Robotics Accessories

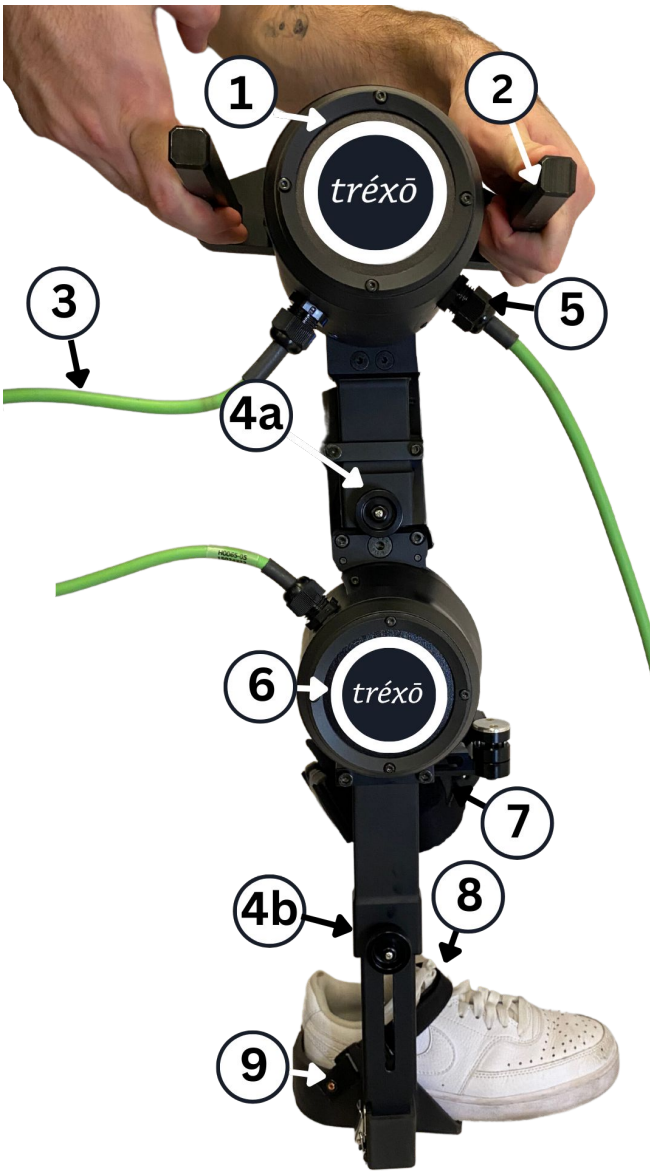
Trexo Treadmill

Headrest

Rifton-Treadmill Size Compatibility Matrix

Rifton Standard Base	MED	LRG	X-LRG
Treadmill	REG	REG	X-LRG

Familiarize Yourself with the Trexo Robotic Legs



Robotic leg components

Your Trexo comes equipped with two robotic legs which can be attached to the Rifton pacer.

Each leg consists of several parts displayed in the figure to the left.

The components are as follows:

1. Powered hip joint
2. Leg attachment slider
3. Hip to knee motor cable
4. Height adjustment knobs
   a) Thigh knob
   b) Shin knob
5. Battery box to hip cable
6. Powered knee joint
7. Shin cuffs
8. Foot plate ankle strap
9. Foot plate
10. Trexo leg clamp (x2)

Inspect the Trexo legs each time you use the device for any visible damage. If you find any components that are missing or are damaged, do not proceed with the use of the device.

*Shoes are not included. Pictured for display purposes.

Familiarize Yourself with the Rifton Dynamic Pacer

This guide is for quick reference on Rifton features. For full user guide and instructions on using your Rifton, please refer to the manual enclosed with the Rifton Dynamic Pacer.

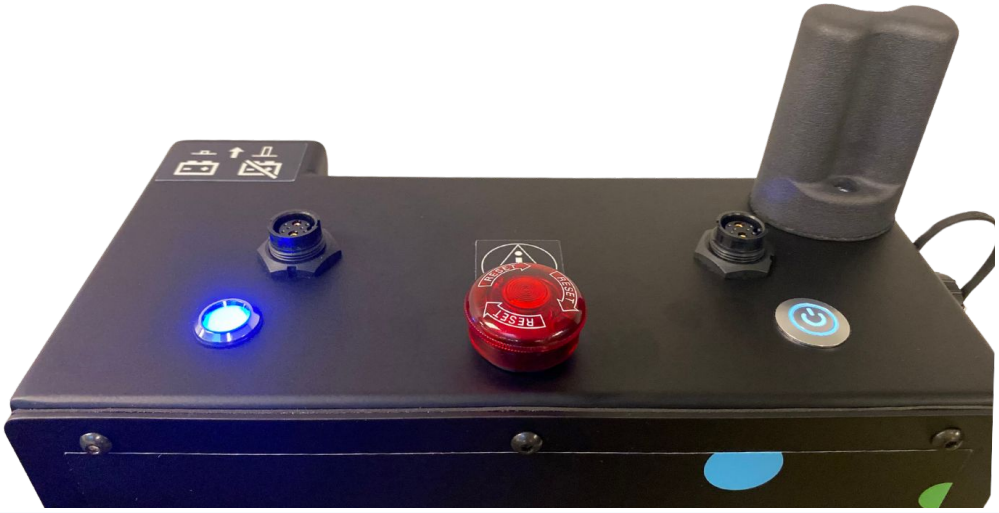
The components are as follows:

1. Dynamic upper frame
2. Standard base (Alternate Option: Utility Base)
3. Swivel wheel
4. Swivel release
5. Swivel lock
6. Brake
7. Direction lock
8. Multi-position saddle
9. Seat location adjustment
10. Saddle tilt adjustment
11. Saddle height adjustment
12. Side-to-side movement lock
13. Dynamic movement lock
14. Frame height adjustment
15. Arm Prompts
16. Chest Prompt

Familiarize Yourself with the Rifton Dynamic Pacer

Label	Rifton Parts	Part Number
1	Dynamic upper frame	Medium (K631) Large (K641) XL (K651)
2	Standard base (Alternate Option: Utility Base)	Medium Standard Base (K634) Large Standard Base (K644) X-Large Standard Base (K654) Medium Utility Base (K636) Large Utility Base (K646)
8	Multi-position saddle	Medium (K673) Large (K674)
15	Arm Prompts	Small (K512) Large (K532)
16	Chest Prompt	Small (K514) Medium (K524) Large (K534)

Quick Trexo Battery Box LED Guide



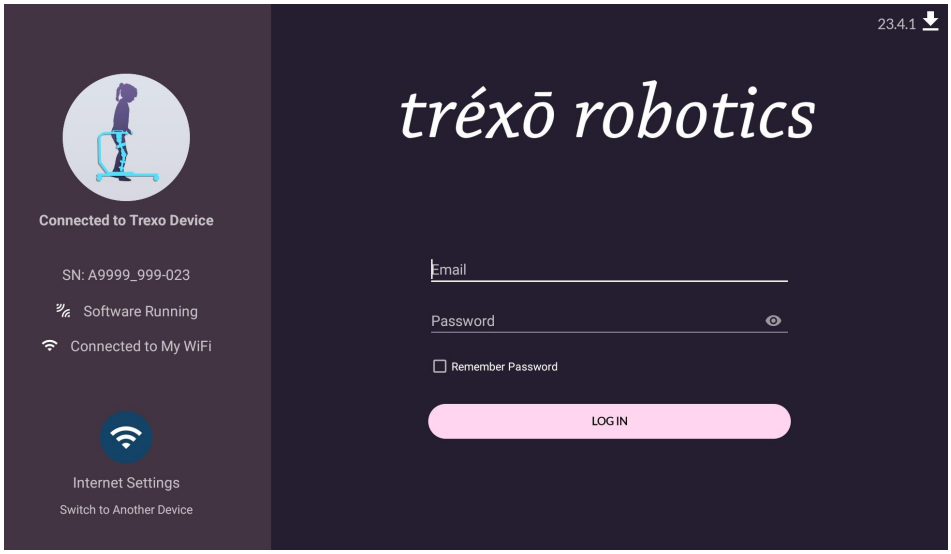
Battery Box Indicator

- **(Pulsing blue: 0.5 sec ON; 0.5 sec OFF)**
  Starting up
- Unable to operate
  Due to some condition
- Ready to operate or operating
- **(blinking blue: 2 quick blinks; 2 sec OFF)**
  Software malfunction

Connect your Trexo Plus to Wi-Fi

1. **Select “Internet Settings” in your login screen of the Trexo App.**

2. **Provide your Wi-Fi network credentials and select “connect to Wi-Fi”**



The tablet should auto-connect to the Wi-Fi network called “Trexo_device_<serialnumber>”. If unable to connect automatically, click “Connect Device” in the app and connect.

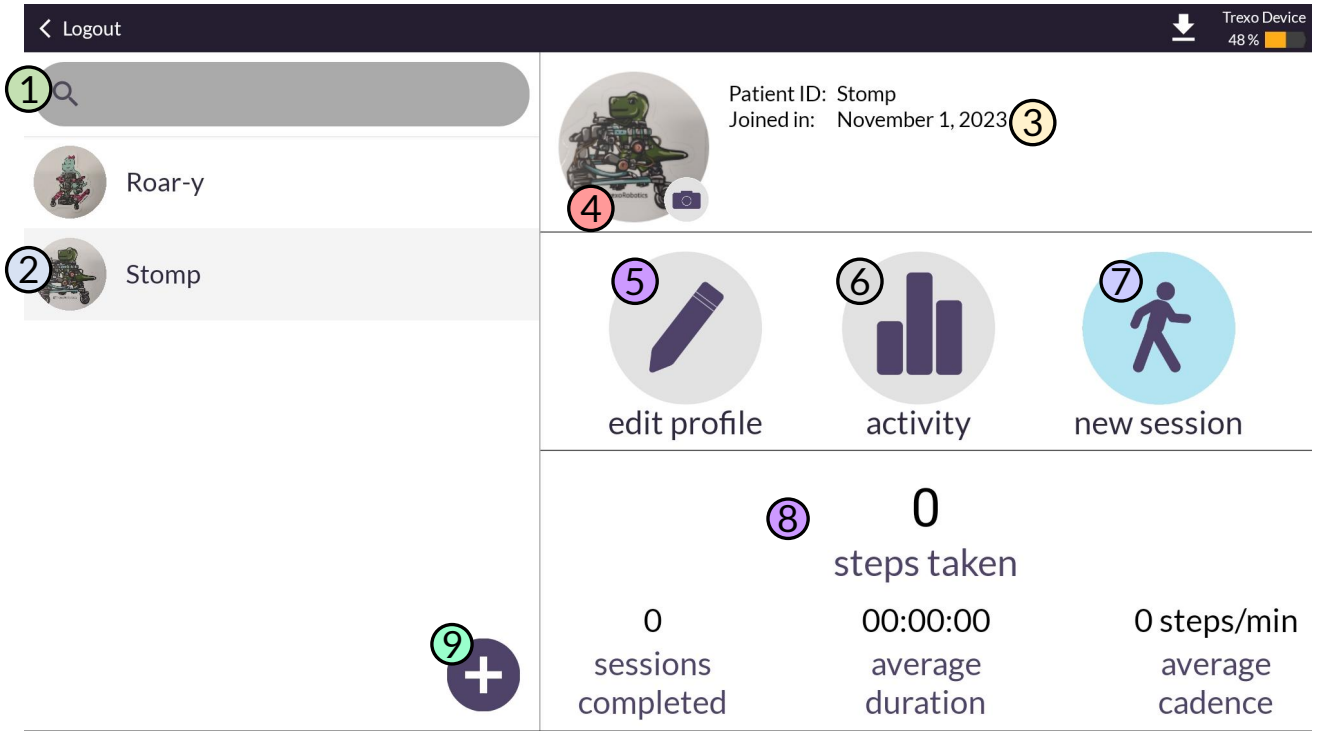
Alternate option is to go to check **Settings > Wi-Fi** in the tablet and try to connect to “Trexo” manually. Confirm that the serial number in the app matches the device’s serial number.

Please do not connect your tablet directly to your local wi-fi. The tablet should only connect to the Trexo. Internet access should only be connected through the Trexo app.

The tablet comes pre-loaded with the network information needed to connect with the device. If you are having trouble connecting, please contact Trexo on the Chat App for assistance. Do not install any other apps on the tablet provided by Trexo. Only use the Tablet provided by the Trexo Robotics team.

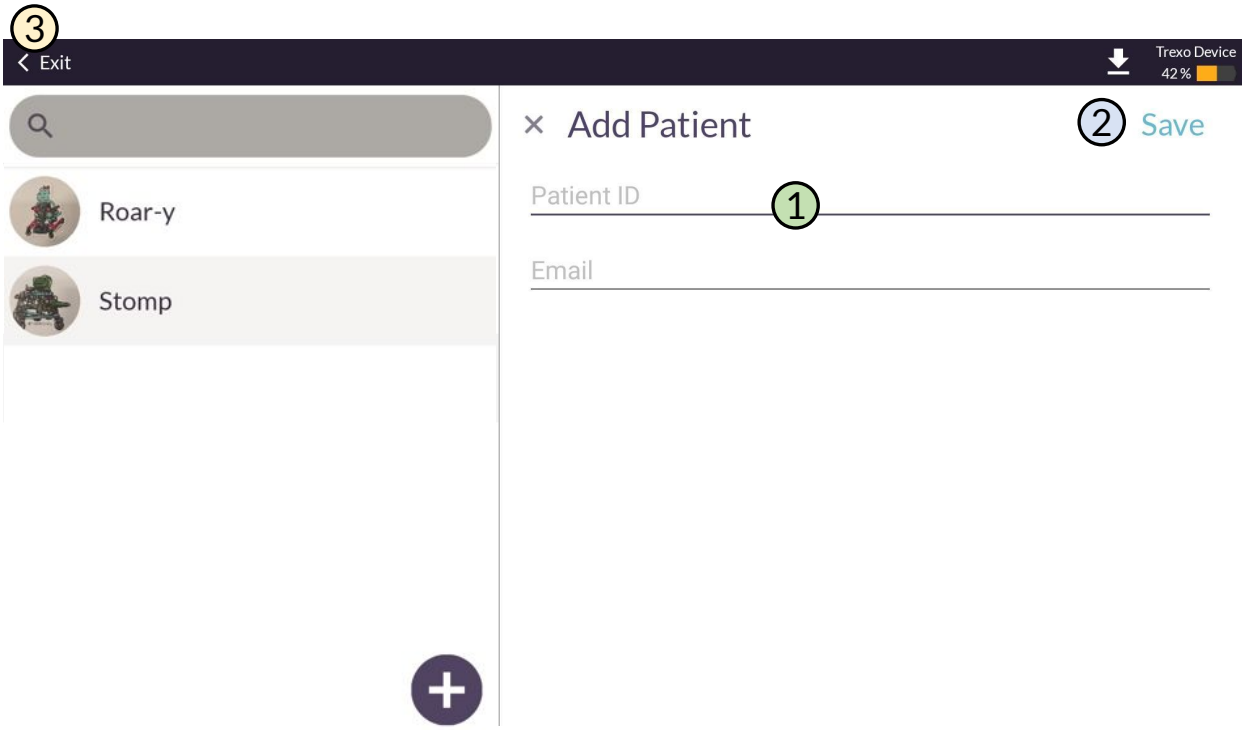
Device will not charge or power on until you push-in the battery disconnect cut-off switch. When you receive your device, the battery disconnect cut-off switch will be pulled out (refer to page 50 for a visual).

Trexo Interface – User Profile



1. Search by first or last name.
2. List of current profiles.
3. User information.
4. User picture.
5. Edit user information.
6. See previous activity and session information history.
7. Start a new session for selected user.
8. Activity summary since start of usage.
9. Add new user.

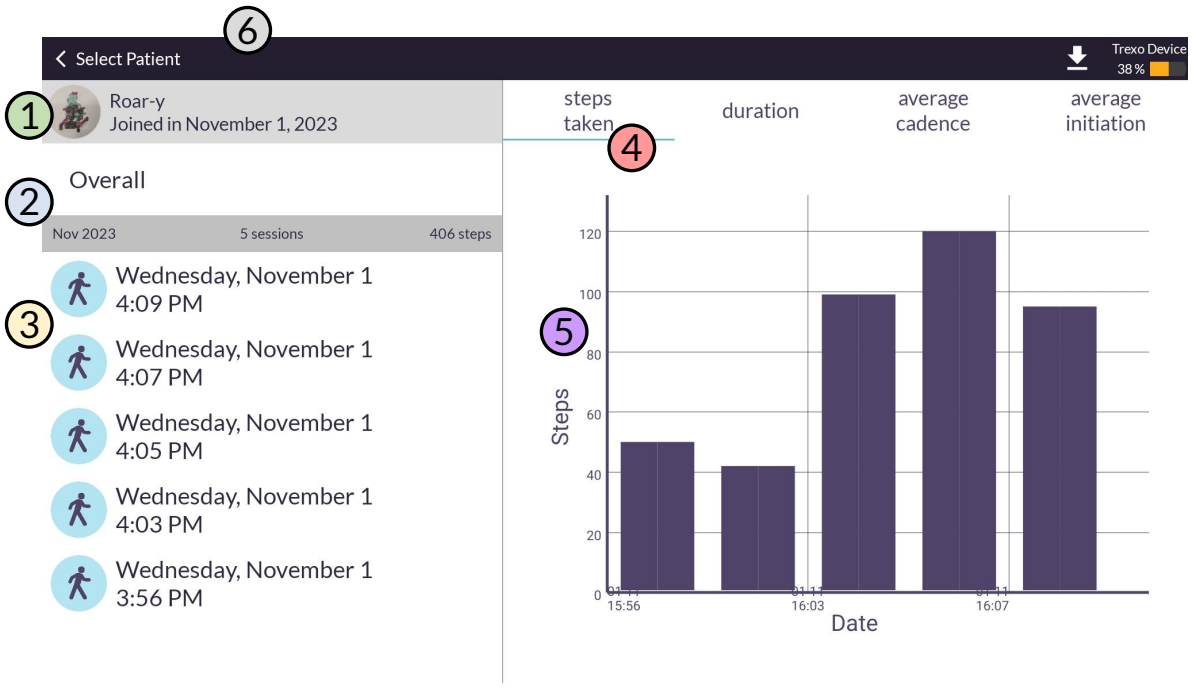
Trexo Interface – User Profile



1. Provide user information.
2. Save once ready.
3. Exit without saving.

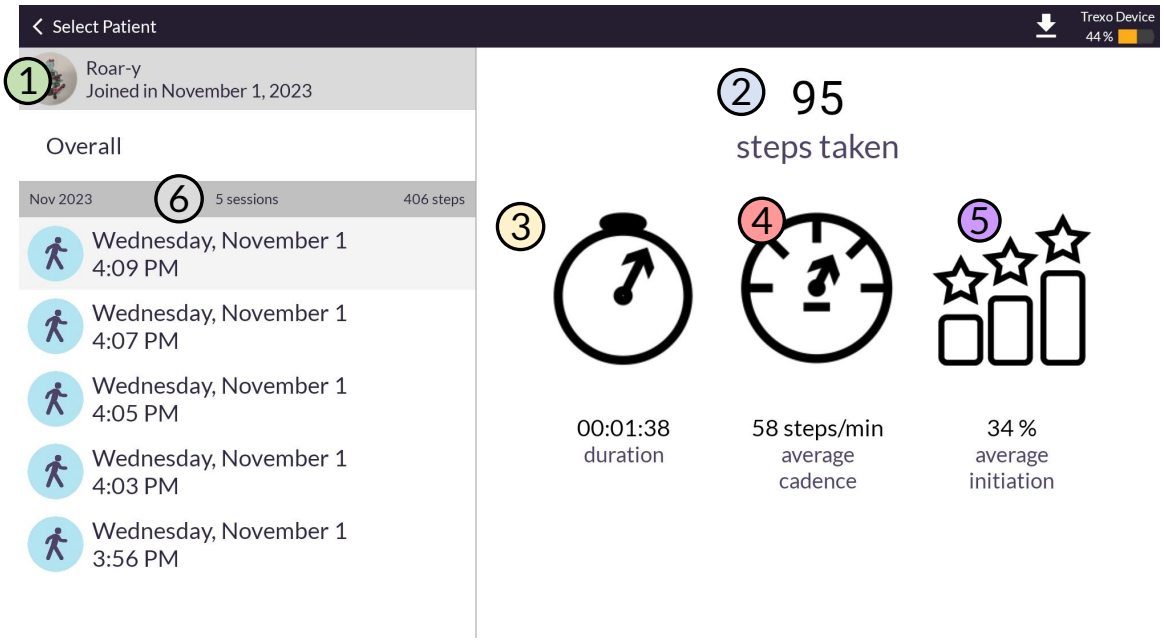
Note: you may add user picture to the profile after it has been created.

Trexo Interface – Activity Information



1. Selected user.
2. Summary graphs of the previous completed sessions.
3. Session specific history.
4. Menu for summary graphs.
5. Graph summarizing selected usage data.
6. Back to patient profile and selector screen.

Trexo Interface – Activity Information



1. Selected user.
2. Total number of steps taken during the session.
3. Active walking time.
4. Average cadence during session.
5. Average initiation during session.
6. Total number of sessions and steps taken in a month.

Trexo Interface – User Session

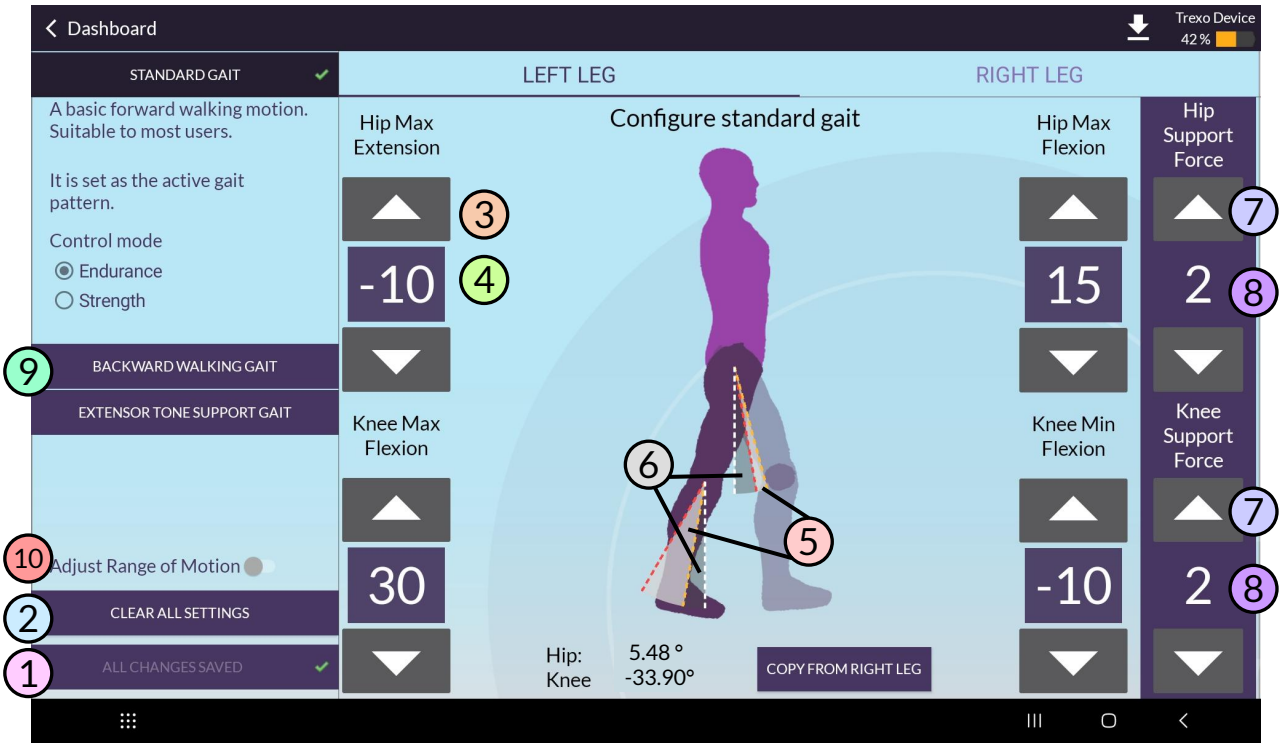
1. Set Trexo legs to standing position.
2. Use to set and adjust gait and support force of device.
3. Take user profile picture.
4. Open Patient Info containing measurements.
5. Current status of device.
6. Walking time
7. Current speed of the device
8. Initiation: how often the user is actively helping the Trexo take steps.
9. Speed adjustment controls.
10. Battery Level of the Trexo (NOT THE TABLET BATTERY)
11. Install updates for the Trexo software

Since there are multiple Trexo users for your device, please confirm that you select the right user profile before starting your session.

The Trexo battery level indicator is located at the top right hand corner of the Trexo App.

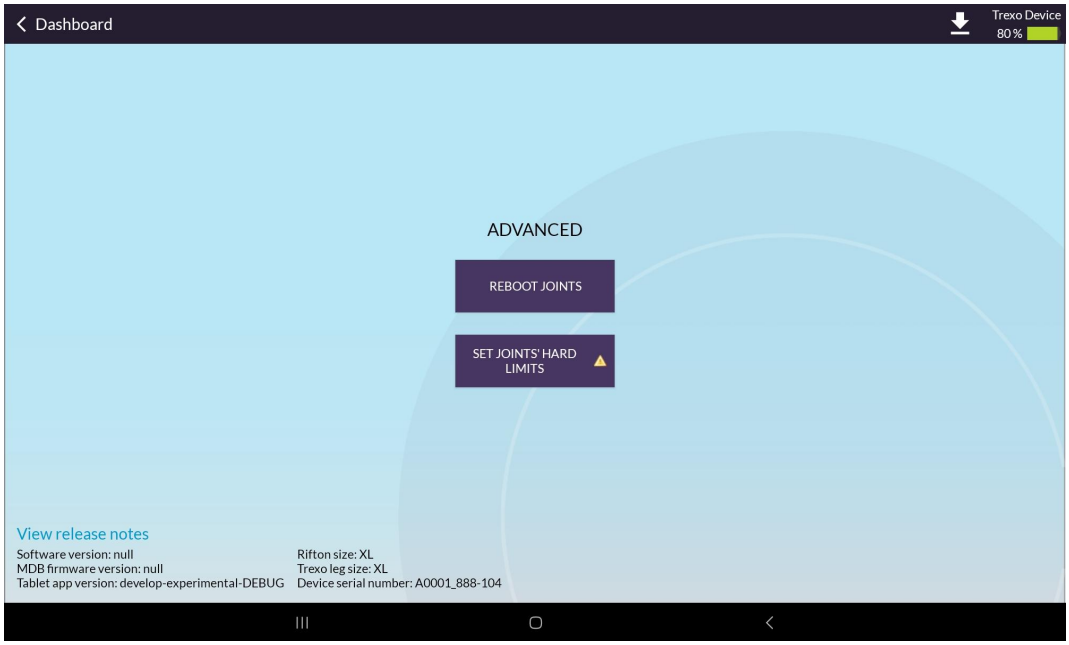
Trexo Interface – Setting and Modifying Gait

Gait angles can be changed while walking. Adjust Gait can only be used while the Trexo is paused.



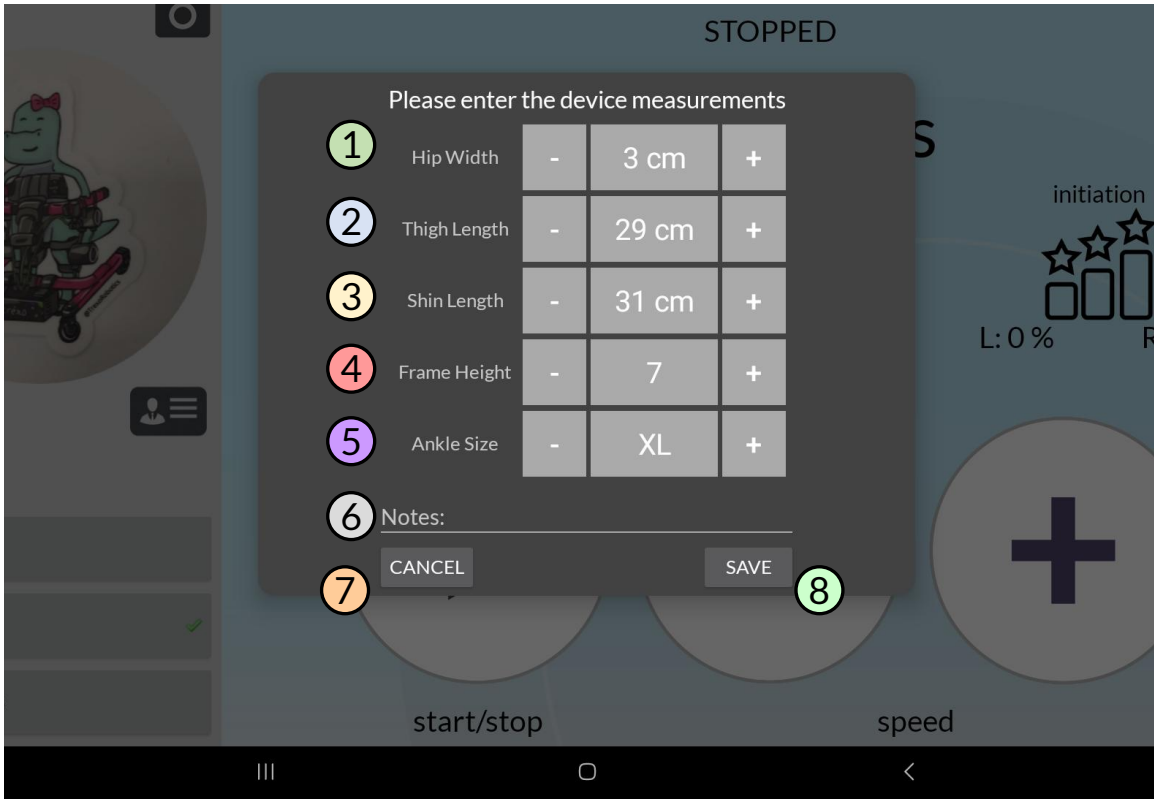
1. Save all changes.
2. Delete all settings, including previously set joint range motion limits.
3. Modify joint angles with up and down arrows.
4. Current angles of joints (show by the red and yellow dashed lines).
5. Range covered by current gait setting.
6. User's available range of motion (Go to page 35 to update)
7. Increase or decrease support force at each joint separately.
8. Current support force.
9. Select the gait training mode
10. Toggle on in order to adjust joint angle hard limits. Then run each leg through the desired motion (only available while device is not walking)

Trexo Interface - Settings



Reboot joints	Resets the joints for troubleshooting.
Set joints hard limits	Calibrate the joints, only use if trained.

Trexo Interface – User Information

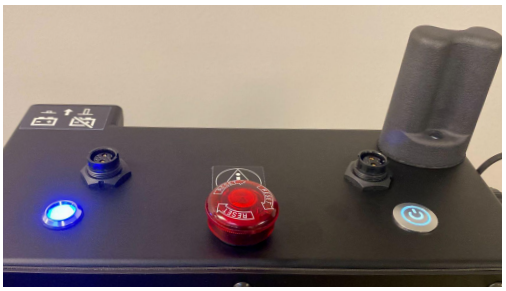


1. Hip width position using the markers on the Trexo leg posts.
2. Thigh length as indicated on the Trexo leg between knee and hip.
3. Shin length as indicated on the Trexo leg between the knee and footplate.
4. Frame height as indicated on the Rifton pacer frame (in front).
5. Ankle size provided on the inside of the footplate.
6. Included any additional notes on the set-up of the Trexo.
7. Cancel, all changes will be lost.
8. Save the information.

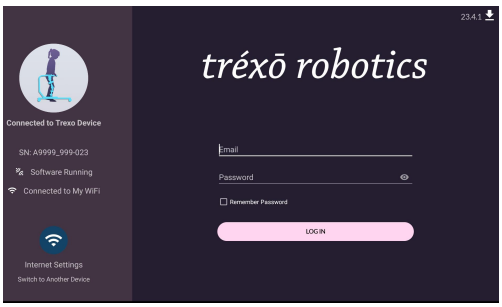
Starting your Trexo Plus

1 **Power on the system by pressing the power button on the battery box.**

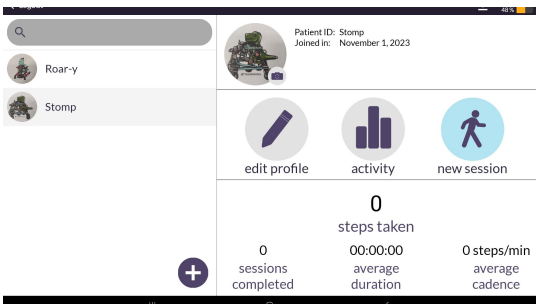
Wait 1-2 minutes for device to boot up.



2 **Open Trexo app and connect the Trexo to the internet.**



3 **Select user and then click “new session”.**



4 **Start when ready.**

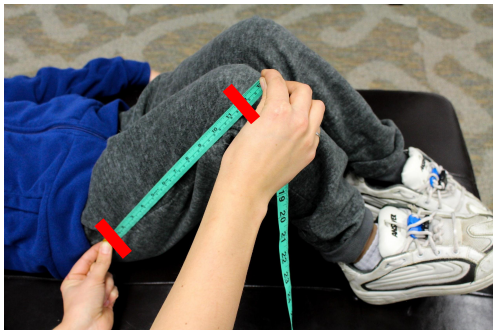
Setting the Trexo Leg Lengths

Use the app

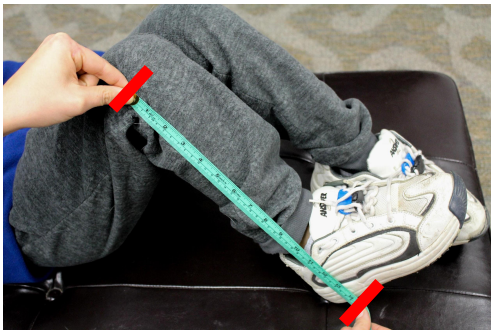
Store the measurements for future use in “User profile > Patient info”

The Trexo User should be measured on their back as shown below.

1 **Hip to knee**



2 **Knee to floor**



Set up the device leg height to correspond with the The Trexo User’s leg height.

3 **Hip to knee**

4 **Knee to floor**

Running a Session

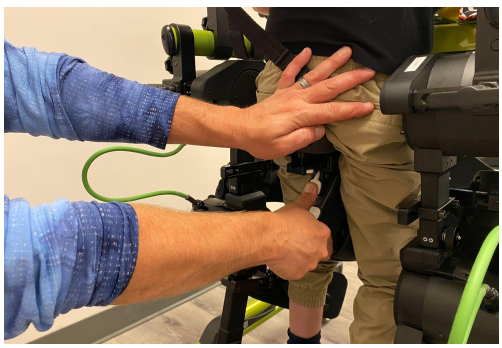
1. Ensure breaks are secured on the Rifton Pacer.

2. Put footplates on the Trexo User's foot and secure with strap (do this step first, only for anterior set-up).

3. If applicable, rotate the headrest away from the Trexo User prior to seating.

4. Seat the Trexo User comfortably on saddle and secure the chest prompt on the child.

5. Adjust to align hips.



6. Bring the Trexo legs closer to the Trexo User by sliding the hips inwards.

Running a Session - Continued

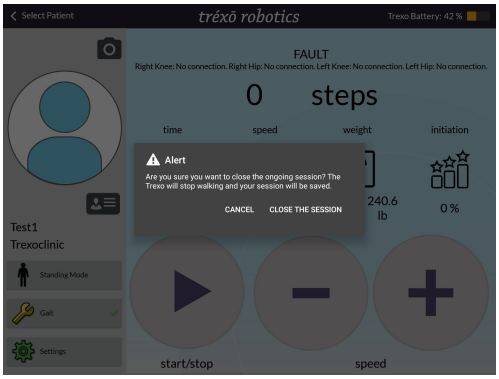
7 **Clip the footplate attachments into the Trexo leg.**

8 **Secure and tighten the shin cuffs using the buckles.**

9 **Release the breaks on the Rifton.**

10 **Start new session using Trexo app.**

11 **At end of session, close the session to save data.**



Readjusting Device Height

1 **Raise the Rifton to its maximum height.**

2 **Put ankles on the Trexo User's foot and secure with strap.**

3 **Set up the device with the Trexo User. Feet won't touch the ground yet.**

4 **Adjust the robotic leg lengths as necessary using the knobs.**

5 **Clip in all straps and conduct a visual check to confirm correct leg coupling.**

6 **Switch to standing mode. Then adjust frame height as necessary (instruction on next page).**

Readjusting Device Height - continued

You will need to adjust the frame height in the very first session and then before every session where you adjust the leg length.

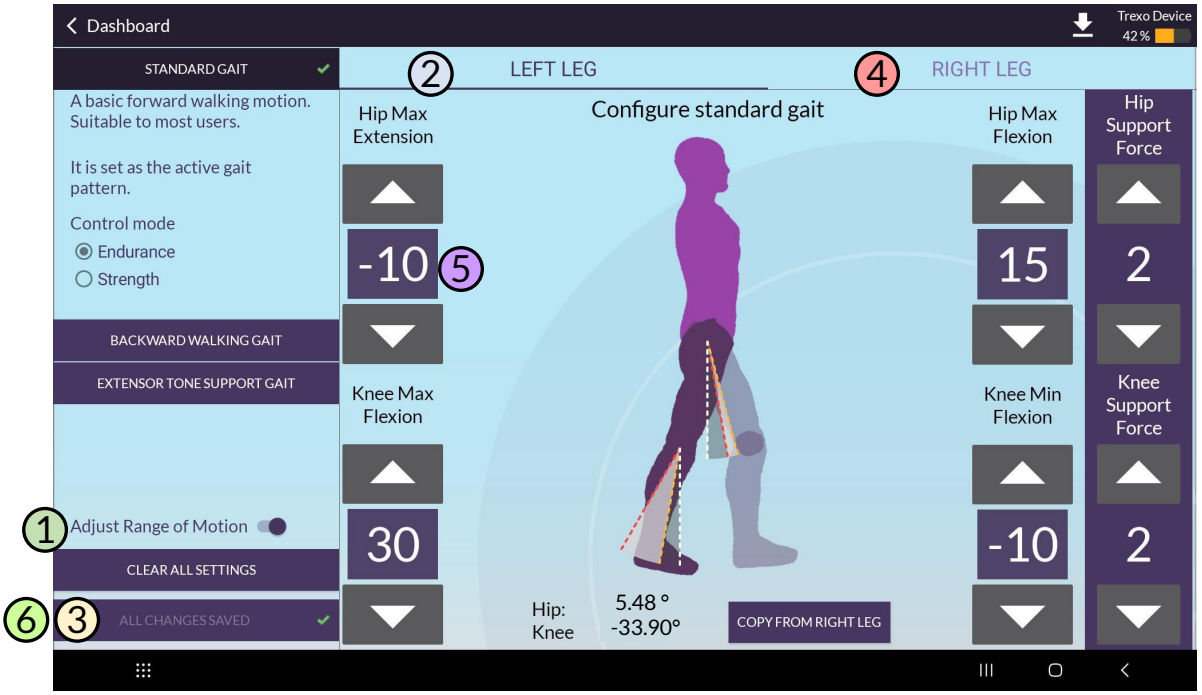
To proceed with raising or lowering the frame:

1. Adjust the Rifton frame by gently pressing and holding the white button located at the front of the pacer frame.
2. Lower the device until both heels are comfortably on the ground.
3. Observe for foot clearance and heel to ground contact. Readjust the height of the frame if necessary.
4. Note height of the frame for subsequent use in the Trexo app.

Setting Gait Pattern

In the event you need to readjust the safe range of motion and gait pattern, you may do so using the Trexo app.

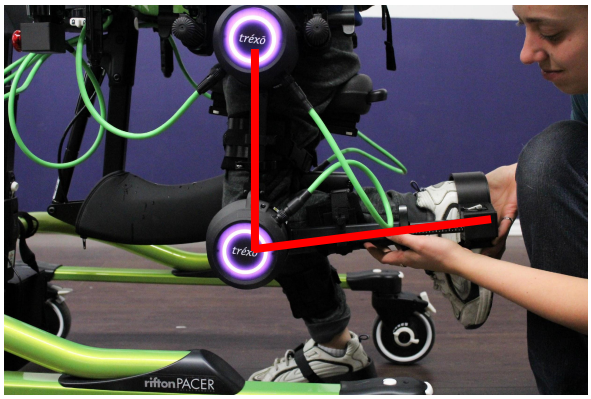
Before starting, set up the Trexo User in the device and make sure it is not walking. Proceed by selecting “Gait” in the User profile.



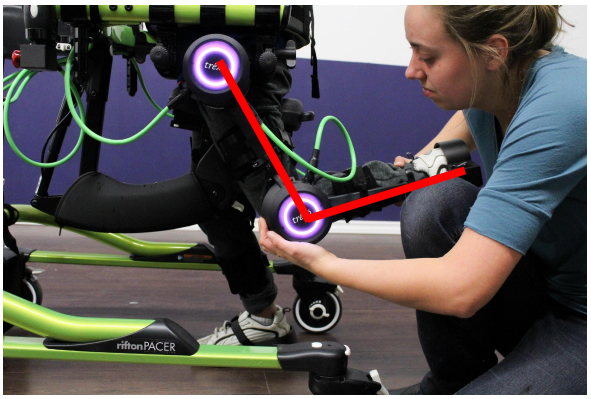
1. Unlock “Adjust Range of Motion” toggle to start
2. Select left leg and move it through the range of motion as shown on the next page.
3. Click save.
4. Select the right leg and repeat steps two and four.
5. Using arrows, adjust to a comfortable gait pattern.
6. Make sure all settings are saved and return to main dashboard.

Setting Gait Pattern - continued

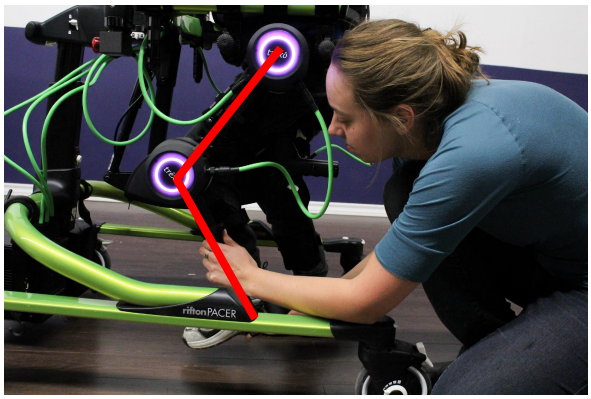
Move each leg through the entire comfortable range of motion. You may have to move each leg back and forth a few times to get the full range.



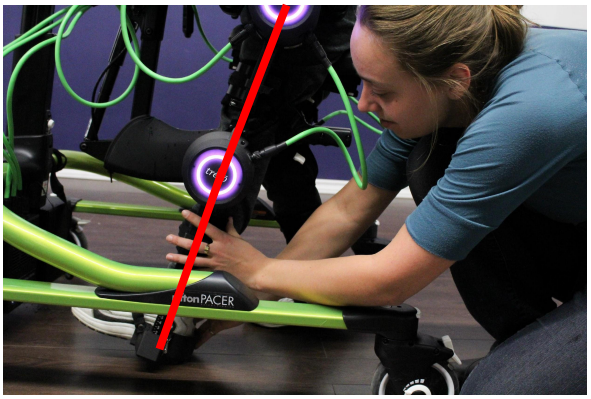
Start by flexing the knee.
Maximum knee flexion: 90°



Pull the leg back into hip extension.
Maximum hip extension: 30°



Push the leg forward into hip flexion.
Maximum hip flexion: 50°



Extend the knee.
Minimum knee flexion: 0°

Conducting an Inspection Check

Use the app

Store the measurements for future use in “User profile > Patient info”

Final inspection

Once set-up, do a visual check for the following:

- ❑ The Trexo User is seated comfortably
- ❑ There are no asymmetries
- ❑ The cuffs are in a comfortable place with no pinching or pulling
- ❑ Knees are in line with the knee joints
- ❑ Hips are in line with the hip joints

Be cautious around the moving parts of the Trexo and do not obstruct it.

If everything looks correct during the inspection, proceed to the next step.

Quick Trexo Joint LED guide

White
Joint is powered, ready to operate the device.

Purple
Joint is running.

Pink
Joint is detecting resistance. Use this to determine required support forces on the joint.

Blue (hips only)
Joint is detecting initiation.

Spinning Purple
Joint is powered, not ready to run due to E-Stop/ not calibrated/ error.

Turning

The device is not capable of turning independently and requires assistance.

You must assist the user in turning. Prior to turning, ensure the swivel lock is released from the wheels and you choose an environment with sufficient room to turn.

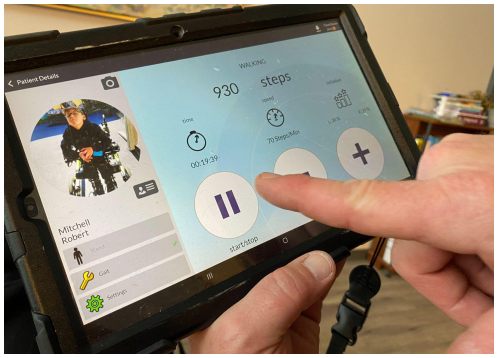
Steer the device in the desired direction.

Turn the device with each step.

Set device straight when turn is complete.

Ending a Session

1 **Pause the device.**

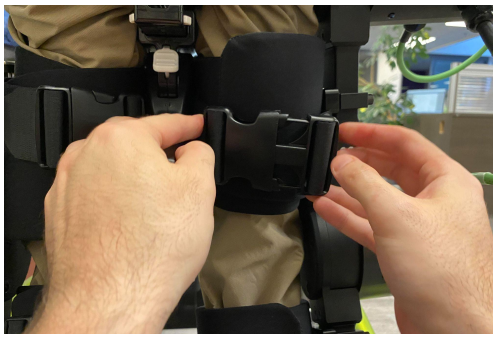


2 **Lock the wheels on the Rifton**

3 **If applicable, rotate the headrest away from child prior to removal.**

4 **Undo clasps and velcro straps on footplates.**

5 **If applicable, undo the thigh cuffs.**



6 **Undo the clasps on shin cuffs.**

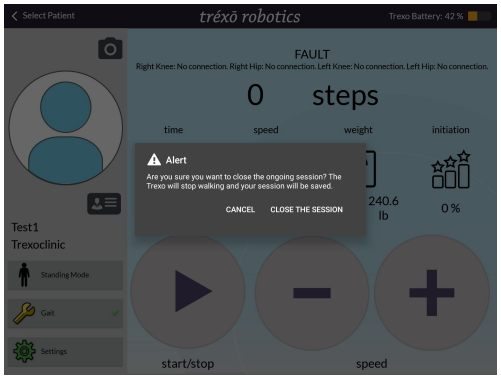
Ending a Session

7 **Slide the seat back to make removal of the Trexo User easier.**

8 **Undo straps on the chest prompt last.** This is the safety piece that is keeping the Patient in place.

9 **Lift the Trexo User off the saddle and remove from the Trexo.**

10 **End the session and log out on the tablet to save all session data.**

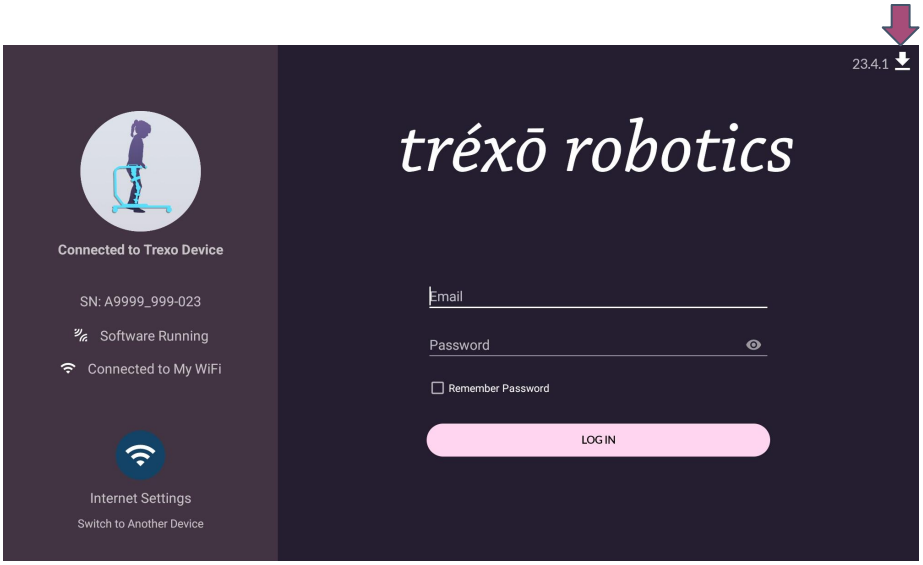


Remember

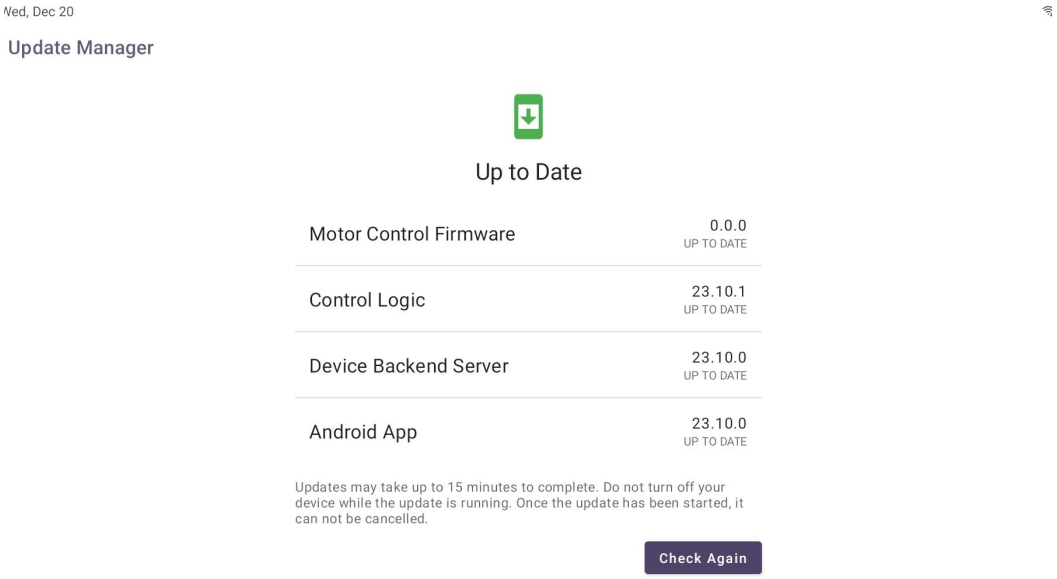
- After you have completed the session, make sure you close the session on the tablet by going back to the main screen.
- Shutting down the Trexo without closing the session may lead to loss of session data.
- The Trexo Trained Supervisor must ensure that the cuffs on the Trexo User's legs is unstrapped before unstrapping the chest prompt.

Install Trexo Software Updates

1 **Make sure both the legs are plugged into the battery box before starting. Go on the main page and click on this download icon to start the process.**

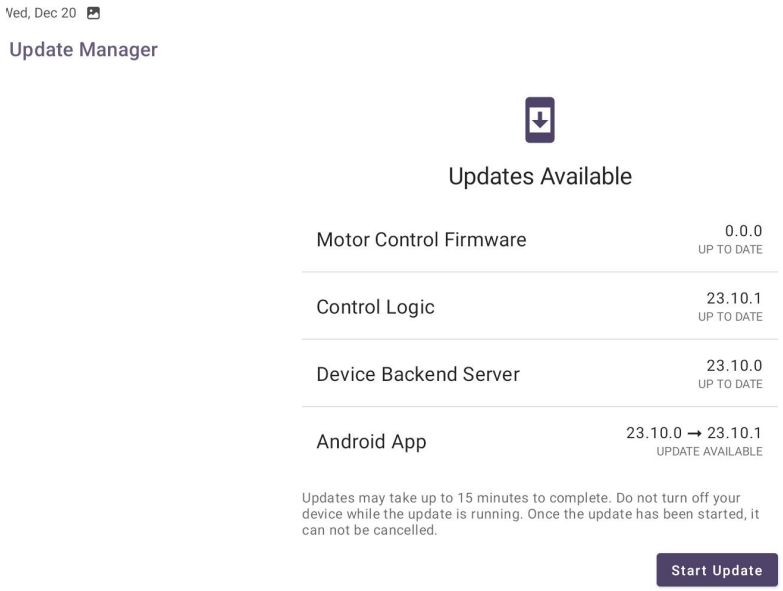


2a **No updates available. The device has the most up-to date software. No action required.**

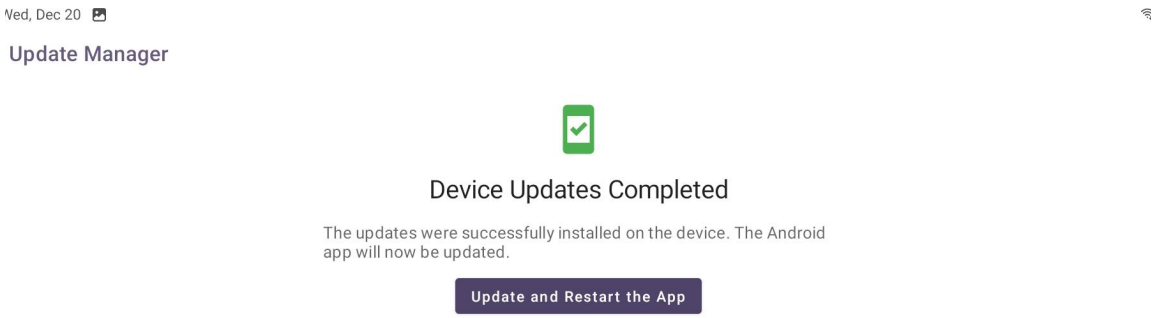


Install Trexo Software Updates

2b Update Available. Click “Start Update” to begin.



3 Update completed. Click “Update and Restart the App” to finalize the process.



If you have any issues or need help updating the software, please reach out to your customer success manager on the Trexo Chat App.

Warranty

The Trexo has a service life of 5 years. Subject to separate coverage for certain parts and the exclusions and limitations described in this Warranty, the Warranty covers the repair or replacement necessary to correct defects in the materials or workmanship of any parts manufactured or supplied by Trexo Robotics Inc. (Company) that occur under normal use for a period of 2 years.

Battery: The Battery, like all Nickel-Cadmium batteries, will experience gradual energy or power loss with time and use. Loss of Battery energy or power over time or due to normal battery usage is NOT covered under this Warranty. With proper maintenance of the battery, as outlined in the Charging Best Practices section, the service life will be approximately 500 charge cycles

This Warranty does not cover any damage or malfunction directly or indirectly caused by, due to or resulting from normal wear or deterioration, abuse, misuse, negligence, accident, improper maintenance, operation, storage or transport, including, but not limited to, any of the following:

1. Failure to take the Trexo Plus to, or make repairs or service recommended by the Company upon discovery of a defect covered by this Warranty;
2. Accidents, collisions, or objects striking the Trexo Plus;
3. Any repair, alteration or modification of the device that was made inappropriately, or the installation or use of parts or accessories, made by a person or facility not authorized by the Company;
4. Any damage to the Trexo Plus hardware or software, or any loss or harm to any personal information/data uploaded to the Trexo Plus resulting from unauthorized access to the data or software from any source, including non-Trexo parts or accessories, third party applications, viruses, bugs, malware, or any form of interference or cyber-attack;
5. Theft or vandalism;
6. Fire, explosion, lightning, hail, flood, or water exposure;
7. Using the device over rough, uneven or hazardous surfaces;
8. Overloading the Trexo Plus beyond the maximum weight rating;
9. The environment or an act of God.

In addition to the above exclusions and limitations, expendable items such as footplates, paddings, straps, and cuffs are limited in coverage for a period of 6 months, subject to the exclusions and limitations already described in this Warranty.

The Rifton Dynamic Pacer gait trainer, if provided with the Trexo Plus, is NOT part of this Warranty, and has its own warranty provided by Rifton Equipment. Please contact Rifton for any issues relating to the gait trainer.

Response Procedures for Faults

List of Errors	Response
Undervolt	Charge device for at least 3 hours while turned off If issue persists, contact Trexo Support.
No voltage	Reboot device, if persists, contact Trexo Support.
No connection	Check the cable connection by unplugging and replugging the cables connected to the fault joint. If the fault persists, reset joints. If the issue is not resolved then reboot the device. If the issue is not resolved, contact Trexo Support.
Unknown fault	Contact Trexo through the Chat App
Overcurrent	
No supply voltage	
No bus voltage	
Hall sensor error	
Conflicting data (hall & incremental)	
Conflicting data (absolute & incremental)	
Absolute encoder error	
Incremental encoder error	
No absolute encoder calibration data	
EEPROM failure	
Extreme limits	
Communication bad packet	
Communication bad command	
Failed to start a task	
Bad current readings	
Motor driver chip fault	
Supply voltage outside expected range	
Current sensor calibration error	

Response Procedures for Faults

List of Errors	Response
Hall invalid transition	Contact Trexo through the Chat App
Undetected comms timeout	
Firmware watchdog timeout	

Maintenance Instructions

Regular maintenance of the hardware should be conducted every **6 months**. The system will require routine maintenance for at least five years of operation.

Maintenance checklist:

- ❑ Inspect each joint for cracks
- ❑ Inspect each strap and paddings for tears or damage
- ❑ Inspect each cable and connector points for exposed or pinched wiring
- ❑ Confirm the fan in the battery box is running by turning the device on

Troubleshooting instructions

If the device is experiencing issues, please contact Trexo Robotics by emailing support@trexorobotics.com or messaging on the Trexo Chat App.

Cleaning instructions

- Clean the device with alcohol wipes.
- Do not clean with excessive amounts of water or place under running water.
- The strap cushioning uses a hospital grade fabric that can be wiped with standard disinfectant tools. The cushions are fluid-proof and breathable with anti-bacterial and anti-fungal properties.
- The outer straps can be wiped with disinfectant wipes, machine washed and/or replaced as necessary.
- The Trexo should be cleaned before each use with disinfectant wipes.

Storage instructions

Keep your Trexo inside in a dry place with access to an outlet. Charge your Trexo and accompanying tablet between uses. The Trexo should be stored where the environmental conditions has an ambient temperature between -20° C to 50° C (-4° F - 122° F), relative humidity range of 0% RH - 70% RH (non-condensing), atmospheric pressure range of 50.0 kPa to 106.6kPa

Battery Charger Colors

LED Indications

Cell-CON 10-20 cell NiMH/NiCd battery charger

Charge Indications	
Yellow	Fast Charge (or soft start)
Flashing yellow	Top-off
Green	Trickle
Green flashing	Battery not connected
Red flashing	Error
Wait Mode Indications	
Yellow with 1 red blink	Battery temperature is too low (<0°C)
Yellow with 2 red blinks	Battery temperature is too high (>40°C)
Error Indications (Contact Trexo if the following error states occur)	
2 red blinks	Battery is connected to charger with wrong polarity
3 red blinks	Charger output is shorted. Check output cable connection.
4 red blinks	Battery voltage is low. Check battery status or voltage (ss timer).
5 red blinks	Warm error. Temperature >60°C
6 red blinks	NTC missing or short (if mandatory)
LED off	Battery voltage is too high. Check battery voltage.

Battery Cut-off Switch

The Trexo Battery Box contains a battery cut-off switch which completely disconnects the battery from the device. This switch is to be used when the Trexo will not be used for longer than one week.

DISCONNECTED

CONNECTED

To CONNECT the battery, push the plunger in. To DISCONNECT the battery, pull the plunger out. The device WILL NOT turn on or charge if the plunger is pulled out

Charging Best Practices

Following these practices will ensure that the Trexo's battery life is maximized and remains in good condition.

- ❑ Turn off the Trexo before charging it. The battery will not properly charge if it's on.
- ❑ When you see a green light on the charger, the battery is fully charged and you should unplug it. Do not use the Trexo while it is plugged in.
- ❑ Occasionally deplete the battery entirely. Using the battery's full capacity once every few weeks will extend its useful life.
- ❑ A fully drained battery can take 12-14 hours to fully recharge.
- ❑ Disconnect the battery if you aren't going to be using the Trexo for more than a week.

Trexo Support Forces: Torque Settings

The Trexo has adjustable support forces. The support forces go from levels 1-10. Please see the table below for the conversion of support force levels to torque measured in newton-metres.

Device Leg Size	Hip Minimum (Nm)	Hip Maximum (Nm)	Knee Minimum (Nm)	Knee Maximum (Nm)
Small	12.75	39	9.5	22
Medium	14.75	46	9.5	25
Large	17	55	9.5	28
Extra Large	19	60	9.5	28

Disclaimer: The values presented in this table are subject to change in the future. While Trexo Robotics strives to provide accurate and up-to-date information, various factors may impact the data displayed. We recommend users to verify the latest information through the Trexo Robotics site or contact the Trexo Support team for the most current and reliable updates. This disclaimer serves as a precautionary note, acknowledging the dynamic nature of certain data points and the potential for adjustments over time.

Electromagnetic Compatibility (EMC) Table

Electromagnetic compatibility, means a medical device is compatible with (no interference is caused by) its electromagnetic environment and it does not emit levels of electromagnetic energy that cause electromagnetic interference in other devices in the vicinity. The Trexo has passed the following EMC tests.

Phenomenon	Basic EMC Standard	Test Level
RF Conducted and Radiated Emissions	CISPR 11	Class B – Group 1
Harmonic Current Emissions	IEC 61000-3-2	Class A
Electrostatic Discharge	IEC 61000-4-2	±8kV Contact ±15kV Air Planned Locations specified under #26 below
Radiated RF EM Field	IEC 61000-4-3	10V/m – 80 MHz to 2.7 GHz, Extra test frequencies as per IEC 60601-1-2:2014 Table 9 (copied below)
Electrical Fast Transients/Bursts	IEC 61000-4-4	Mains Supply: ±2kV, 100kHz repetition frequency SIP/SOPS: ±1kV, 100kHz repetition frequency
Surges Line-to-Line	IEC 61000-4-5	±0.5kV, ±1kV
Surges Line-to-Ground	IEC 61000-4-5	±0.5kV, ±1kV, ±2kV
Conducted Disturbances induced by RF fields	IEC 61000-4-6	3Vrms – 0.15 MHz to 80 MHz, 6Vrms in ISM and amateur radio bands between 0.15 MHz to 80 MHz. (A list of these frequencies is copied below)
Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m
Voltage Dips (single phase a.c mains)	IEC 61000-4-11	0% U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°
		0% U_T: 1 cycle 70% U_T: 30 cycles At 0°
Voltage Interruptions	IEC 61000-4-11	0% U_T: 300 cycles

Additional test frequencies for the Conducted Immunity and the Radiated Immunity tests for the Trexo.

The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Assistance

For assistance
Website: www.trexorobotics.com/contact
Call: Toll Free - (844) 844-0607
Email: support@trexorobotics.com

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Mississauga, ON L5N 5M4
Canada

QMS-USR-753.006.EN-5 - Trexo Plus Manual