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# **PREFACE**

# Training and Levels of Certification for EksoNR Use

The Ekso Bionics training program for use of EksoNR occurs in two phases.

# Phase One: Initial Training / Level 1 Certification

- Introduce the initial, basic feature set of the EksoNR
- Prepare a Physical Therapist to begin use of the EksoNR in tandem with another EksoNR trained Level 1 physical therapist during the learning process
- Goal of Initial Training Safe and effective clinical use of the EksoNR and achieve Level 1 Certification
- At Level 1 Certification:
  - Physical therapist is approved to operate the EksoNR only with another physical therapist that has also completed Ekso Bionics Training and is certified at Level 1 (or higher)
  - EksoNR certified physical therapists work in pairs to continue use with the basic feature set, to prepare for independent use, and to progress through learning process
  - Modified Level 1 physical therapists may work with other support staff that were part of the initial training as documented on the Level 1 Clinical Competency form

# Phase Two: Advanced Training / Level 2 Certification

- Ideally scheduled 4 weeks after Initial Training or after recommended number of practice sessions
- Introduce the advanced features of the device
- Goal of Advanced Training Enhance clinical use of the EksoNR, including the advanced features, and achieve Level 2 Certification
- At Level 2 Certification:
  - Physical therapist can operate the EksoNR independently, or with any support personnel, when additional support is needed
  - Physical therapist is responsible for directing all aspects of EksoNR session
  - Physical therapist may delegate EksoNR treatment session to support personnel at their discretion

**NOTE:** When delegating tasks, the Level 2-trained physical therapist is still responsible for the patient, the EksoNR device, and for providing education to support personnel on device function and safety procedures

 Level 2-trained physical therapist is able to provide training to other physical therapists on EksoNR operation, in preparation for EksoNR certification by Ekso Bionics

# **INITIAL TRAINING**

# **EksoNR Device Description and Functions**

EksoNR is a wearable, battery-operated bionic exoskeleton that enables individuals with lower extremity weakness or paralysis to stand and walk on level surfaces. Motors power the hip and knee joints and all motion is initiated either through specific patient actions or the use of an external controller.

The EksoNR can provide either bilateral assistance or unilateral assistance to the lower extremities. The EksoNR can be programmed to provide *adaptive* assistance that constantly adapts motor output in response to patient performance. It can also provide a *fixed* ceiling amount of assistance that provides up to a predetermined maximum amount of motor power to one or both legs. Legs can also be set to *Free* with or without assistance which allows the patient to step in any way they desire. The EksoNR can be tuned and adjusted to fit a patient's precise needs.

Device functions: Sit-to-stand, walking, stand-to-sit, PreGait Patient requirements: Active participation, weight shifting, maintaining balance with assistance as needed

#### **Environment for use**

- Solid, dry, level ground with less than a 2% grade.
- Adequate supervision
- Use of an assistive device at all times

#### **Therapeutic Benefits**

- EksoNR is a clinical tool that can:
  - Address physical therapy gait retraining goals through patterning and reciprocal stepping.
  - Enforce correct gait mechanics eliminating ability for patient to compensate
  - o Control the amount of robotic assistance to:
    - Provide assistance, as needed, to complete the swing phase of gait
    - Provide support, as needed, during the stance phase of gait
    - Provide non-ambulatory individuals with the ability to walk

#### **Indications**

- Be screened and cleared by a physician prior to physical therapist evaluation for EksoNR use.
- Physical and cognitive ability to use crutches, walker, or cane to participate in initiation and maintaining of weight shift. Use does not need to be independent of clinical support.
- Ability to communicate pain and need to cease session, verbally or nonverbally.
- Ability to acknowledge communication from the therapist, verbally or nonverbally.
- Healthy bone density.
- Skeleton does not suffer from any unhealed fractures.
- Able to stand using a device such as a standing frame.
- Hip width or leg segment lengths are within the range of adjustability.
- Weight does not exceed 220 lb (100 kg).
- Standing hip width of 18 in. (45,6 cm) or less.
- Must have functional use of at least 2 extremities.
- Must have near normal range of motion in hips, knees, and ankles.
  - Neutral ankle dorsiflexion.

NOTE: The knee may flex up to 12° to obtain a neutral ankle.

- No more than 12° knee flexion contracture.
- No more than 17° hip flexion contracture.

NOTE: Evaluation mode should be used if more than 10°.

Upper leg length discrepancy must be equal to or less than half an inch (≤ 0.5 in. or 1,3 cm) and lower leg discrepancy equal to or less than three-quarters of an inch (≤ 0.75 in. or 1,9 cm).

#### **Contraindications**

People with the following conditions should not use the device:

- Severe concurrent medical conditions: infections, circulatory, heart or lung, pressure sores
- Severe spasticity (Modified Ashworth 4)
- Unstable spine or unhealed limbs or pelvic fractures
- Active heterotopic ossification interfering with lower extremity range of motion
- Significant contractures
- Psychiatric or cognitive situations that may interfere with proper operation of the device
- Cognitive impairments resulting in inability to express pain or need to stop session
- Pregnancy
- · Poor skin integrity in areas in contact with the device
- Decreased standing tolerance due to orthostatic hypotension
- Range of motion restrictions that would prevent a patient from achieving a normal, reciprocal gait pattern, or would restrict a patient from completing normal sit-to-stand or stand-to-sit transitions:
- Unresolved deep vein thrombosis
- Uncontrolled autonomic dysreflexia
- Lower limb prosthesis

### **Safety Reminders**

- Ekso should be donned/doffed on a solid chair without armrests or wheels
- An EksoNR -trained physical therapist must remain—or delegate another person who
  must remain—within arm's reach of a patient at all times in case of a patient loss of
  balance or a device power loss
  - EksoNR is NOT designed to prevent falling
- Always use the EksoNR with sufficient supervision and physical assistance
  - New patients, and those at higher risk of falling, may require more supervision and physical assistance
- Always use the EksoNR with an assistive device
- Give clear verbal instructions and physical cueing to patients and your colleagues
  - Provide clear instructions to patients whenever beginning or changing an EksoNR action and when stopping, turning, or changing direction. (For example, "beginning stepping now.")
  - Provide clear instructions to your colleagues as you work in pairs. Verbalize that each partner is ready prior to initiating standing, walking, turning, or sitting during a patient session. Efficiently push the **Stop** button if your partner indicates a stop or pause is necessary.
- Assess skin integrity before and after every training session
  - Special attention should be given to areas of EksoNR contact
- Patients should perform adequate lower extremity stretching before and after EksoNR sessions, as indicated by their physical therapist
- Discontinue use if the patient reports feeling discomfort or displays signs and symptoms of adverse reactions

#### **Device Specific Safety Considerations**

- Do not use the EksoNR if the device is not operating properly
- Discontinue use if the controller directs
- Never use the EksoNR if the device has fraved or broken wires
- Never use the battery charger if the charger cord is frayed or compromised in any way
- Ensure the EksoNR batteries are fully charged or adequate for treatment session

#### **Adverse Events**

Any adverse reactions noticed by a physical therapist or patient during or following the use of the EksoNR should be documented thoroughly and reported to **Ekso Bionics Customer Experience** immediately. This includes any undesired EksoNR mechanical behavior.

#### **Patient Evaluation**

ROM measurements are all passive. Critical values include:

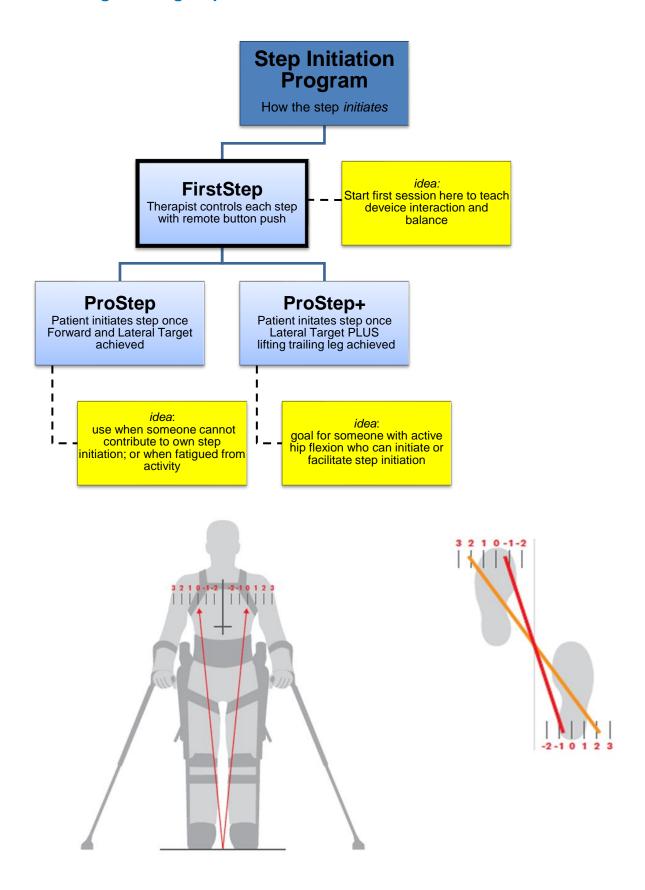
- Ankle dorsiflexion: Patient must achieve a neutral ankle
  - If patient has ankle dorsiflexion limitations with knee in full extension, assess if patient can achieve 0° dorsiflexion by flexing knee
    - Note what degree of knee flexion is required to achieve 0° dorsiflexion.
- Knee extension: Patient must have less than or equal to a 12° knee flexion contracture.
  - If knee flexion measurement is 12° or less, physical therapist can program this knee flexion angle into EksoNR
- Hip extension: Patient must have less than or equal to 17° contracture
- Hip flexion: Ability or inability to get to 110° will determine stand and sit programming

Ekso measurements are completed using calipers then converted to Ekso values using the conversion chart.

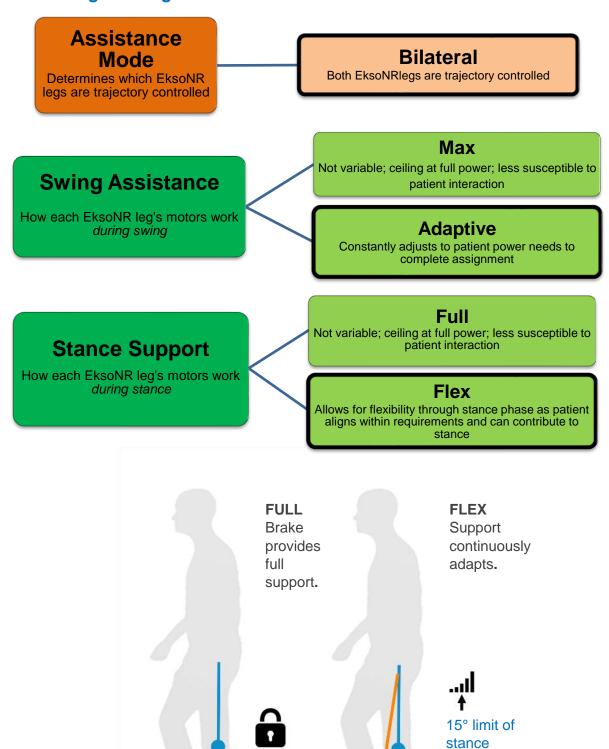
MEASUREMENT	POSITION	DESCRIPTION
Hip Width	Standing (if able) or Supine	<ul> <li>Align pelvis for neutral rotation/obliquity.</li> <li>Align hips in neutral rotation/abduction.</li> <li>Place measuring tool at greater trochanters.</li> <li>Maintain alignment of measuring tool over greater trochanters.</li> <li>Apply pressure to compress adipose, if necessary.</li> <li>Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment.</li> <li>Read measurement tool on screen.</li> </ul>
Upper Limb Length	Supine	<ul> <li>Flex hip to approximately 90° and have patient rotate away from side to be measured.</li> <li>Place lower arm of measuring tool under patient leg in line with femur.</li> <li>Patient returns to neutral pelvis posture.</li> <li>Position hip in 90° of flexion with knee resting in maximum flexion.</li> <li>Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment</li> <li>Read measurement tool on screen.</li> </ul>
Lower Limb Length	Sitting	<ul> <li>Place foot on step stool; patient must wear the shoes to be used during EksoNR walking sessions.</li> <li>Position leg with hip in &gt;90° flexion so that knee joint is higher than hip joint.</li> <li>Align tibia to vertical and place measuring tool under heel.</li> <li>Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment.</li> <li>Read measurement tool on screen.</li> </ul>

Complete screening form, developing a plan for any "no" answers to determine if it is safe to proceed with EksoNR walking.

# **Ekso Programming - Options**



# **Ekso Programming - Assistance**



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flexion

#### **Batteries**

When a battery is plugged into the charger, the light on the charger should turn *red-orange*, indicating that the battery is seated correctly and charging.

When charging is complete, it will turn back to *green*.

It is important to take note of the *red-orange* light when initially plugged in because the charger's light will also be green when nothing is plugged into the charger or if the battery is plugged in incompletely.

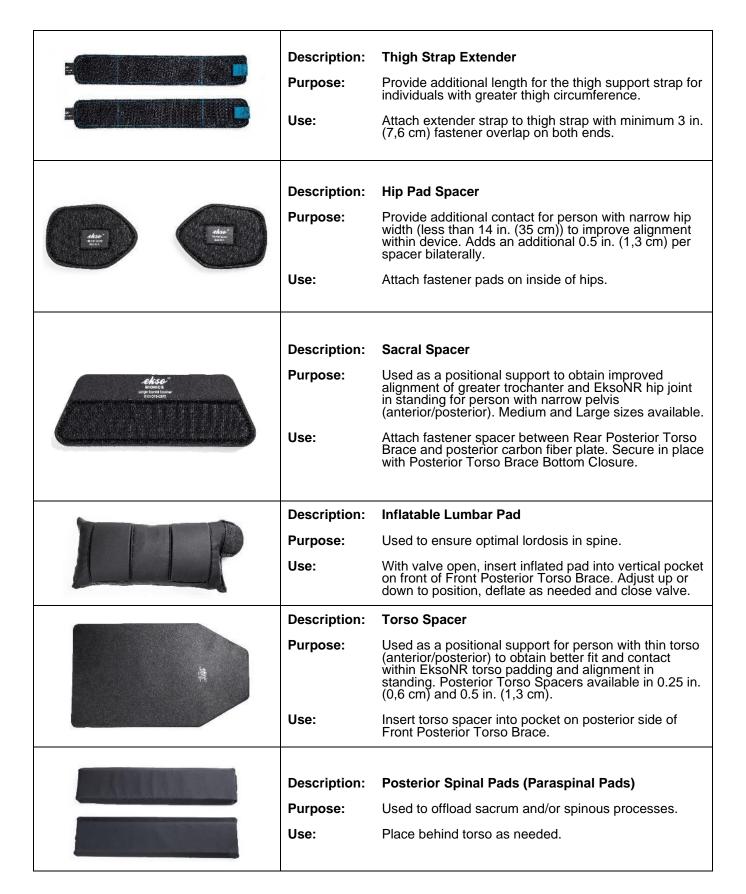
#### **Battery Alarms**

- At 25% remaining battery level, the EksoNR alerts the therapist. The patient should walk to a chair and perform a powered sit
- At 15% remaining battery level, the EksoNR allows only a powered sit
- At 10% remaining battery level, the EksoNR will go into **Safe Mode** and a long-legged sit is required
- A battery mismatch error will occur upon turning on the Ekso if there is >20% charge discrepancy between right and left batteries

# **Donning and Fit Kit**

Utilize black laminated Donning quick guide and safety checklist

	Description: Purpose: Use:	Foot Binding Pad Provide additional padding for increased foot comfort. Attach fastener pads on inside of binding.
	Description:	Foot Lift
nous nous nous nous nous nous nous nous	Purpose:	Provide additional height. Foot Lifts are available in sizes 0.125 in., 0.25 in., and 0.5 in. Metric units convert to 0,3 cm, 0,6 cm, and 1,3 cm.
	Use:	Insert foot lift under shoe before securing binding.
	Description:	Tibial Spacer
A Company of the Comp	Purpose:	Used as a positional support for persons with thin lower extremities (anterior to posterior) to obtain better contact and postural support with EksoNR knee joint in standing. Can also be placed medially to the tibial space to help reduce knee valgus. Small (0.125 in./0,3 cm) and Medium (0.25 in./0,6 cm) sizes available.
	Use:	Attach fastener spacer on inside of tibial pad.



Small Anterior Torso Pad



Medium, Large, and Extra-Large Anterior Torso Pads (have similar look)



**Description: Anterior Torso Pad** 

Purpose: Provide the abdominal support within device. Available

in Small, Medium, Large, and Extra-Large. Lower Anterior Torso Pad attaches to the Anterior Torso Pads to increase length or improve abdominal girth

capture.

Use: Select the small, medium, large or extra-large torso

pad, as appropriate for the patient.

The small pad is generally used for a patient with a small frame and/or good trunk strength

The medium pad is generally used for a patient with a higher level of injury and/or large torso length and width.

The large and extra-large pads are generally used for a patient with a larger abdominal girth.



**Description: Arm Sling** 

Purpose:

Provide upper extremity support when needed. Can be used for either right or left side. Plastic fasteners on sling straps integrate into EksoNR Shoulder Straps (torso backpack straps) for ease of use. Adjustable in length to support forearm appropriately.

Use: Attach Arm Sling fasteners into clips located on

EksoNR Shoulder Straps (torso backpack straps). Adjust strap length to support forearm appropriately. Use extra fastener strap to hold excess folded sling

around elbow. Adjust positioning as needed.



**Description: Posterior Sling** 

**Purpose:** Provide posterior support during sit-to-stand. Adjusts

in length to support posterior appropriately.

Use: Fits over hip motors.

IMPORTANT: The Posterior Sling must be used with every patient during a sit-to-stand transition. Once standing, the sling should be removed.

#### **Patient ID**

It is important to assign patient IDs for the following reasons:

- EksoPulse tracks data for each session and requires a patient ID to identify which session belongs to which patient
- EksoNR controller saves settings and options menu for each patient to save time when programming subsequent sessions

# **Sit-to-Stand and Stand-to-Sit Programs**

You will choose between two stand and sit programs in the options menu:

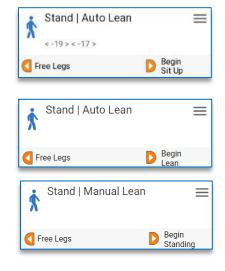
**Stand:** Programs for *sit-to-stand transitions*; the choice of stand program is based on individual patient need and goals.

#### Auto Lean

- A multi-phase stand transition that provides trunk stability to the patient while controlling the forward lean at the torso
- First button push: Sit upright phase Sits patient upright at 90° of hip flexion
- Second button push: Lean and stand phases -Transition from leaning to standing
- Requires 110° of hip flexion

#### Manual Lean

- A single-phase stand transition in which the patient must be leaning forward prior to initiating
- Requires patient to already be leaned forward before physical therapist begins action with Controller



**Sit:** Programs for *stand-to-sit transitions*; the choice of sit program is based on individual patient needs.

#### Normal Lean

- Provides the opportunity for the patient to stay balanced over their feet during descent by having the EksoNR bend at the hips and knees to keep "nose over toes."
- o Requires 110° of hip flexion

# Sit | Normal Lean Begin Sit Stand Still

#### Minimal Lean

 Keeps the trunk more upright during the descent but places more balance requirement on the physical therapist to keep the patient stable during transition

# **Standing Visual Check**

After stand transition, check for the following to ensure optimal set up:

- Confirm alignment of the hip and knee joints, including confirming the proper hip width setting
- Confirm security of all straps, including pulling down torso pad, if necessary
- Remove posterior sling
- If it is patient's first time standing, confirm resting angle of ankle joint provides balance

# **Ankle adjustments**

There are two adjustments at the ankle: the stiffness and the angle.

#### **Ankle Stiffness**

- Four levels of adjustment with 1 being the least stiff, 4 being the most stiff
- Aids in single limb stance stability and tibial progression
- Sliding lever on front of ankle, can be aided by slight plantarflexion pressure on the footplate
- Can be set asymmetrically
- The two factors we utilize to choose this setting are patient weight and plantar flexion strength
  - Spasticity in the gastrocnemius may be viewed as perceived strength when making this selection

Stiffness	1		2		3	4	
	Strong/Normal plantarflexion strengt	plantar h and	Fair/Goo flexion s weight u O lb (60 k	trength nder	Fair plantarflexion strength and weight 130-180 lb (60-80 kg) Absent plantarflexion strength and weight under 140 lb (64 kg)	(80-100)	strength 0-220 lb (g) arflexion weight
LEFT ANKLE STIFFNESS SETTING RI				RIG	HT ANKLE STIFFNES	S SETTING	

# **Ankle Resting Angle**

- Adjustment achieves optimal standing balance
- Must be set symmetrically
- Controlled by 6-sided knob on the back of the ankle
- Begin first session at 0 this is Ekso's baseline and will be slight closed chain dorsiflexion
- Negative numbers result in more relative plantarflexion. Positive numbers result in more relative dorsiflexion.

#### To adjust:

- Once patient is in standing, help them find their balanced position. This should be where they are in good plumbline alignment when viewing from the side
- Disengage 6 sided dial to adjust

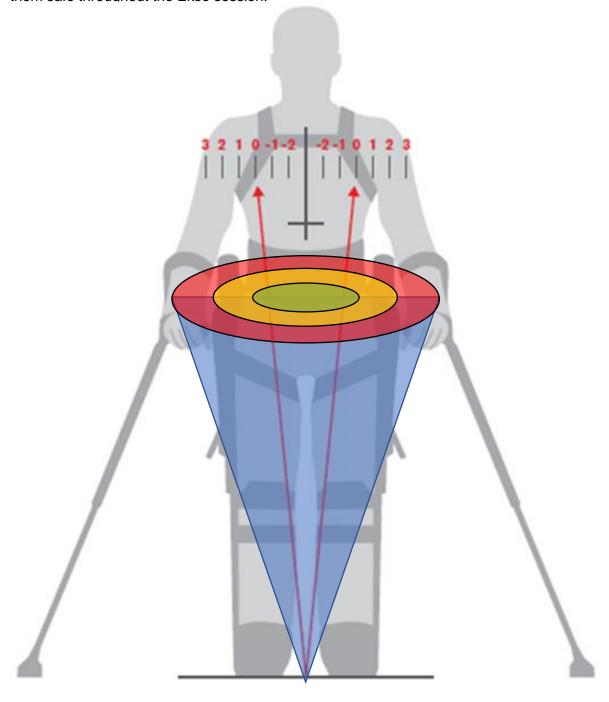
NOTE: The dial cannot be turned from -3 directly to 2.

• Use the chart to identify the correct value for the ankle angle setting based on the knee flexion setting that the patient requires.

Knee flexion angle	Ankle angle setting
0, 1, or 2 degrees	-3
3 or 4 degrees	-2
5 or 6 degrees	-1
7 or 8 degrees	0
9 or 10 degrees	1
11 or 12 degrees	2

# **Handling Technique**

The goal is to keep your patient's center of mass over their base of support. The therapist's hands are going to help keep them there. Using the figure below, the goal is to keep patients in their green area – allowing them space to shift their weight between feet but not get outside of a safe base of support. As they enter the yellow and then the red areas, not only are their weight shifts inefficient, but they enter a position of imbalance. By preventing them from moving beyond the green zone, the therapist reinforces the correct balance point to the patient as well as keeps them safe throughout the Ekso session.



# **Lean Allowance and Swing Rescue**

Lean allowance and swing rescue are two audible sounds to alert the therapist of potentially unsafe situations

#### Lean allowance

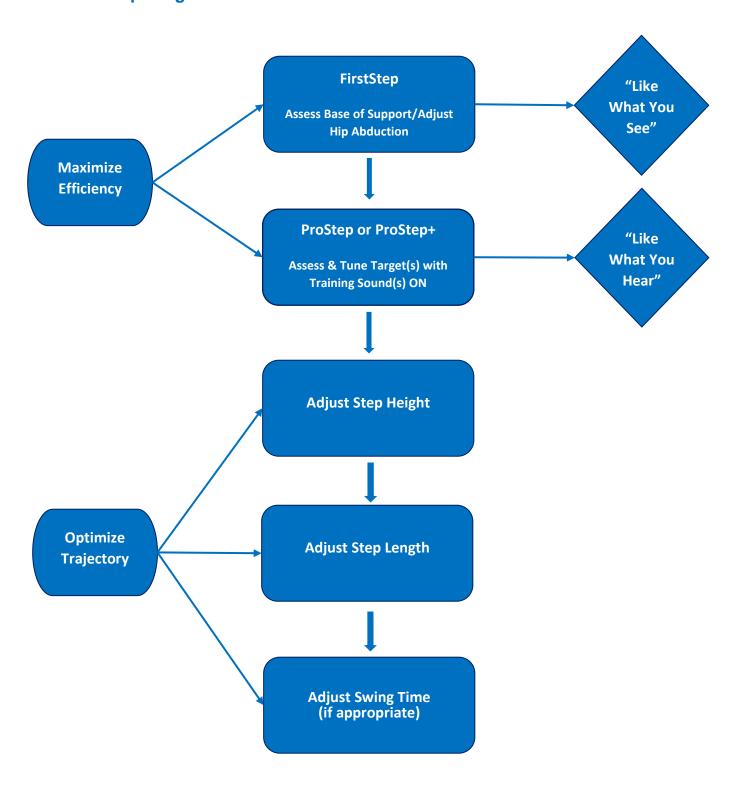
Alerts therapist if patient is leaning too far forward at heal strike

- Minimum sound will alert if patient is beyond 8 degrees of hip flexion upon heal strike
- Maximum sound will alert if patient is beyond 11 degrees of hip flexion upon heal strike
- Off sound will alert if patient is beyond 14 degrees of hip flexion upon heal strike

#### **Swing rescue**

Will complete the swing of the stepping leg and emit an audible tone if the device detects an unsafe situation

# **Five Step Progression**



#### **Base of Support**

- Assure that the appropriate hip abduction setting is appropriate for the walking session
- Ideal base of support is 1 inch (2,5 cm) between the patient's feet during mid-swing

#### **Target Sounds**

Sounds can be turned on/off in the options menu: Both, forward, lateral, or off

Chirp sounds indicates that the patient has achieved their lateral target, while beep sounds indicate they have met their forward target

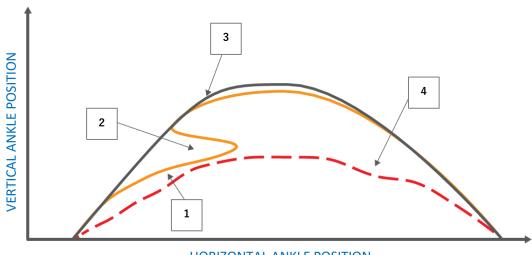
- Training targets have a range of -1 to 3 for forward and -2 to 3 for lateral targets
  - o 0 or negative indicates less forward; 3 indicates more forward
  - 0 or negative indicates more midline; 3 indicates more lateral

To tune these targets, begin with walking in FirstStep, calling for steps when patient is in midstance ("like what you see"). Move targets so that they are consistently being heard and where both targets are achieved in close proximity to each other ("like what you hear").

#### **Step Height**

Range: 0.0-1.5 inches (0 - 3.8 cm)

Decreasing step height decreases how much the hip and knee are required to bend during initial swing, which often allows for more fluid motion during swing and feels more comfortable to the patient.



HORIZONTAL ANKLE POSITION

1	Patient's selected trajectory pattern, too low.
2	Large trajectory error creates corrective force by EksoNR that overpowers patient's forward push ("leg bounce") and elevates the patient to correct trajectory.
3	Demonstrates programmed step height and trajectory path.
4	Step Height is lowered for easier, more appropriate assignment of trajectory, requiring decreased knee and hip flexion.

#### **Step Length**

Range: 8.0-18.0 inches (20 – 46 cm)

Consider increasing Step Length early for taller patients (12 in. to 13 in. or 14 in.).

#### **Swing time**

Range: 0.8-2.0 seconds

Can increase Swing Time to minimize quick stretch response and help improve gait pattern if the patient has spasticity.

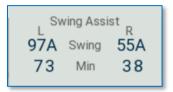
Changing Swing Time is often the last change made when trying to cue the patient to reduce the motor assistance of the EksoNR.

#### Feedback scores

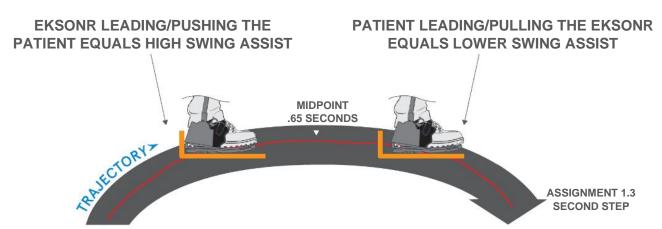
#### **Swing**

**Swing Assist** - the real time amount of assistance the EksoNR is doing to complete the forward swing along the trajectory

**Min Assist** - the minimal amount of assistance the EksoNR estimates it will need to achieve a complete step



The patient must sync with, and then lead, the EksoNR programmed gait trajectory and use their power in that pattern before EksoNR motors decrease assistance.



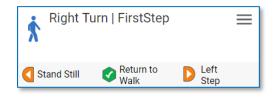
#### **Stance**

**Hip** – the amount of assistance the EksoNR is providing to keep the hip joint extended **Knee** – the amount of assistance the EksoNR is providing to keep the knee joint extended

# **Turning**

The **Turn Mode** can be used through the Controller to aid with turns when the assistance mode is programmed to **Bilateral**.

**Turn Mode** allows the patient to take repeated steps with the same leg to complete a turn with a small radius.



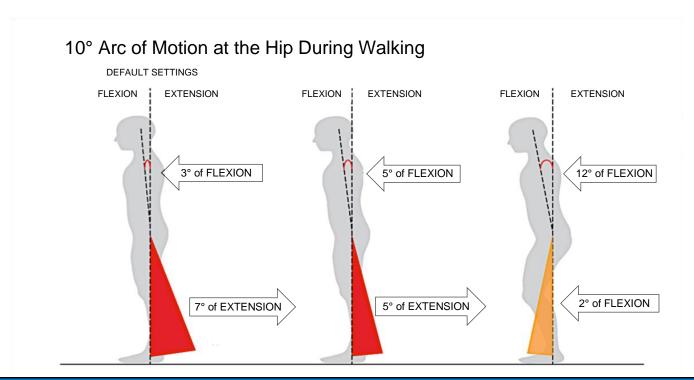
- Turns are initiated in split stance, facilitating a turn towards the back leg
  - o Begin by turning the walker in the direction of the turn.
  - Cue patient to push down on walker while turning towards back leg, while still keeping weight through feet
  - Patient should pivot on front of feet, slightly unweighting heels
- Turn 90 degrees at a time.
  - If more than a 90-degree turn is required, initiate another step from turn mode screen to reenter split stance and repeat this process.

#### **Evaluation Mode**

**Evaluation Mode** is a standing assessment and safety feature that is used to determine a patient's maximum hip extension range of motion available in trailing limb for safe ambulation in EksoNR.

When to use:

- For individuals with hip flexion contractures ≥ 10°, or if concerned about proper hip/spinal mobility during walking.
- If the patient's upper leg segment is set at zero and their greater trochanter is inferior to the EksoNR hip joint.



Hip Flexion Reference Table				
Patient's Hip Extension range of motion measured in prone	Suggested Hip Flex setting programmed into EksoNR	How far EksoNR hip will extend during walking		
Between neutral and 5°FLEX	0	7° EXT		
6° FLEX	1	7° EXT		
7° FLEX	2	7° EXT		
8° FLEX	3	7° EXT		
9° FLEX	4	6° EXT		
10° FLEX	5	5° EXT		
11° FLEX	6	4° EXT		
12° FLEX	7	3° EXT		
13° FLEX	8	2° EXT		
14° FLEX	9	1° EXT		
15° FLEX	10	0°		
16° FLEX	11	1° FLEX		
17° FLEX	12	2° FLEX		

# **Error Messages**

#### Standing time out

A **Standing Timeout** error occurs when the EksoNR knee joints take longer than expected to—or never fully—reach the programmed **Knee Flex** angle during a sit-to-stand transition.

- 2. Hold oto continue.
- 3. Gently press on the EksoNR knee joints to see if the brakes engage.
- 4. If an audible click is heard on both knees, the brakes have engaged. Press of for **Stand Still** and proceed with session as normal.
- 5. If brakes do not engage, press to **Hold for Sit**. Sit down and begin an assessment of what prevented the knee joints from reaching the programmed **Knee Flex** angle during the sit-to-stand transition.

Likely causes of STO:

- Knee joint malalignment
- Knee ROM restriction
- Ankle Clonus/Spasticity

#### Safe Mode

**Safe Mode** is a *safety feature* that occurs if a critical device error occurs. When the device enters **Safe Mode**, the EksoNR emits a distinct alarm cueing the physical therapists that immediate spotting is required for patient safety.

- Hip motors go free with a damping component that slows the hip motion to assist the patient in staying upright, resisting the motion for hip flexion.
- Provide full extension moment through hips to provide mechanical stability (see photo).
- Lower patient to chair via long-sit with partner

#### **Locked Knees Error**

Locked Knees is a *safety feature* that occurs if a critical device error occurs in relation to the knee joint of the EksoNR.

- Hip motors engage/lock resisting the motion for hip flexion.
- Knee motors turn OFF and knee brakes engage, keeping EksoNR knees locked in current position.
- React as if it is a Safe Mode, follow controller to free hips and long-sit patient

# Pausing Sit-to-Stand or Stand-to-Sit

- Yellow button or same arrow that initiated the movement will pause the patient during transition
- Follow commands on screen to continue patient towards sit or stand
- ONLY select to free leas if patient is in contact with the chair



# **Device Progression**

- Begin patients on walker
- Using cane utilize 3-point gait pattern
- Using crutches use 4-point gait pattern (crutch follows the step on the same side)
  - o See Operating Manual for detailed instructions

# **Cleaning and Maintenance**

• Monthly – wipe down inner tubing of upper and lower legs to remove dust

#### **ADVANCED TRAINING**

#### Introduction

Advanced Features introduce programs to increase or decrease the amount of motor assistance from Ekso during swing and stance phases of gait. These programs provide the ability to:

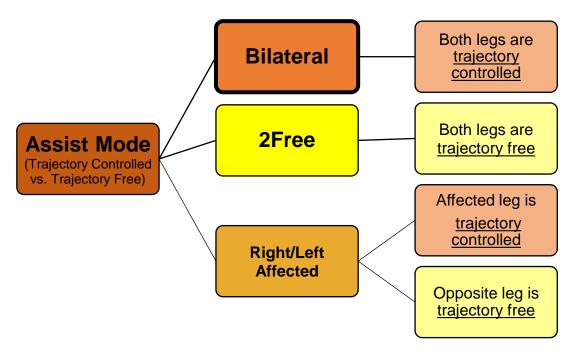
- Alter the swing assistance for the Ekso leg moving forward during the swing phase
- Alter the stance support and stability control for the Ekso leg during stance phase
- Cap the assistance needed to keep the Ekso leg on the given trajectory determined by step height, step length and swing time
- Remove the trajectory and allow the patient to create self-selected stepping pattern in trajectory free environment

These programs allow Ekso to be a stronger rehab training tool used for gait, pregait, and standing balance/midline/weight shifting activities. Ekso provides quantifiable feedback measures used for gait performance once a patient has been taught basic concepts for walking.

# **Training Concepts and Details**

**Assistance** changes what programs are available for **SWING ASSISTANCE** and **STANCE SUPPORT.** 

Stance and swing decisions must be made for each leg



#### Trajectory Controlled

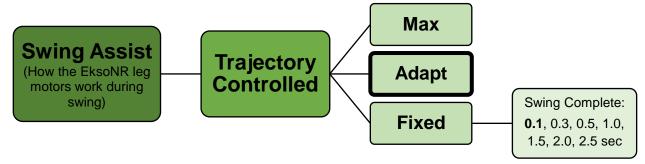
- Motion of Ekso leg determined by programmed trajectory parameters
- Used to facilitate/encourage gait patterning
- Patient should be instructed to feel/learn/lead swing phases of gait

#### Trajectory Free

- Motion of Ekso leg determined by patient's active, volitional control
- Patient must have enough strength to initiate steps and provide some stance control
- Both swing and stance phase can be supplemented in varying amounts
- Can change between programs easily to change goals, assess progress, support when fatigued

# **Trajectory Controlled**

#### **Swing**



NOTE: \*asterisk denotes Default program option

#### **SWING ASSISTANCE**

- Max: Ekso does not run variable assistance. Best used for patients with high spasticity
- **Adaptive\***: Adjusts constantly in swing, given patient output at hip and knee, along the trajectory
  - o Goal: repetition, high number of steps (endurance training)
  - Patient must lead the Ekso, ahead of the selected swing time setting, in the trajectory to decrease the adaptive motor assistance
- Fixed: Offers a ceiling amount of assistance <u>up to the programmed level</u> of Ekso motor output, based on patient effort and maintains variable assistance below fixed value
  - Goal: patient recruiting own muscles (strength training)
  - Depending on programming and patient ability, can be less fluid as patient works to recruit muscle activation

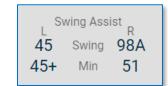
#### Start new patient assessment in Adaptive Swing Assistance

- To assess efficient progression, follow these steps and monitor feedback numbers for desired outcomes and patient goals:
- Patient Efficiency:
  - First Step: Assess base of support, approximately one inch (2,5 cm) between Ekso feet in split stand.
  - Transition to ProStep+: Narrow lateral targets to lowest, successful setting

- Maximize Patient's Appropriate Trajectory:
  - Lower step height to lowest, successful setting
  - Adjust step length
  - Consider swing time, as appropriate. Faster swing time (decreasing swing time value) will make it more difficult for patient to lead the swing and will result in increased swing and min assist values
- Goal: Min value to 70 or lower
- Feedback scores will provide estimated value on where patient will be challenged at a fixed swing assistance value (Min value when in Adaptive)

#### Swing Assistance feedback is displayed on the bottom line of the Controller

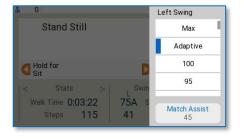
 Swing Assist scores are graded 100-0 and followed by the letter A when in Adaptive. Ekso is providing the full amount of assistance when the value is at 100 and as the assistance is reduced due to patient participation, the scores will reflect a lower Swing and Min assist value.



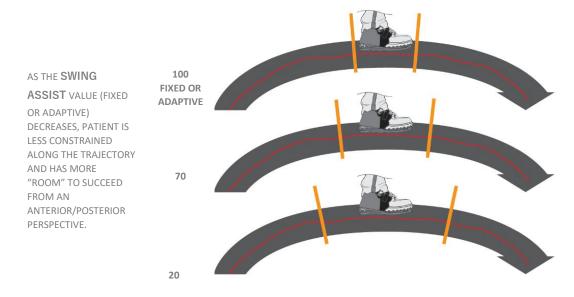
- Swing Assist: Real time amount of assistance Ekso is providing to lead the swing leg forward along the trajectory on time
- Min Assist: Estimated or projected amount of assistance provided to lead the swing leg forward along the trajectory on time

# Move to Fixed Swing Assistance

- Reduce the amount of swing assistance to require the patient to contribute a greater amount effort to lead the swing leg along the correct path.
- Can be used for constant stepping (set above min value), or can challenge patient (set at/near/below min value)

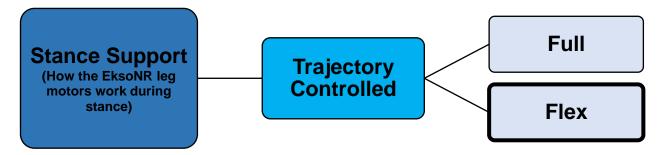


 Lower fixed values are less constrained and feel softer to the patient than higher fixed values or Adaptive with a high swing assistance



- Swing Complete (Only utilized with Fixed Swing Assist)
  - Safety feature to provide swing assistance to complete the step when in Fixed Swing Assistance
  - Will complete the swing if a patient needs more than the programmed fixed motor assist and exceeds the allowable time to complete the swing
  - Swing Complete reaction time is programmable, based on goal of session and patient needs
  - Various reaction times available:
    - **0.1\*,** 0.3, 0.5, 1.0, 1.5, 2.0, 2.5 seconds
  - Patients' forward progression (at trunk) must be controlled when Swing Complete is set at a longer time variance
  - Higher programmed time options provide more time to allow patient to learn/coordinate/recruit
- Swing Rescue (utilized in all trajectory-controlled Swing Assistance)
  - A safety feature to complete the swing of the stepping leg and emits an audible tone if the device detects an unsafe situation
  - Occurs when the Ekso recognizes the patient's weight has shifted too far forward, a sound emits from Ekso and the swing leg immediately completes the stepping pattern
- Swing Assistance feedback is displayed on the bottom line of the controller
  - Swing Assist: Becomes the fixed, programmed swing assistance
  - Min Assist: Becomes the real time amount of assistance provided during the swing phase
    - Min value carries over to bottom of walking screen

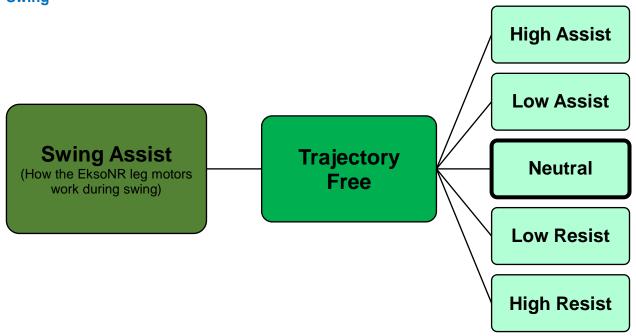
#### Stance



- Full: provides the highest amount of stance support to the patient, with knee brakes engaged
- Flexible\*: Provides softer control in stance phase at hip and knee, decreasing control as patient provides support and maintain stance control. Ekso may allow up to 15° of knee flexion if patient has demonstrated functional ability

- Stance support feedback available by scrolling through to the feedback screen options on the bottom line of the controller
  - Available when programmed Flexible stance support only, in trajectory-controlled program.
  - Hip and Knee scores range from 100-0. Ekso is providing the full amount of stance support when the value is at 100 and as the assistance is reduced due to patient participation, the scores will reflect a lower Hip and Knee stance support value.

# Trajectory Free (2 Free and R/L affected) Swing



- Ekso does not follow trajectory swing pattern. Free motion of Ekso leg, as controlled solely by patient in self-selected, volitional movement and stepping pattern.
- Goal is for patient to replicate learning and carryover of trajectory-controlled stepping pattern

#### O Neutral\*:

- Provides assistance to support the weight of Ekso only
- Begin each patient in Neutral to assess ability

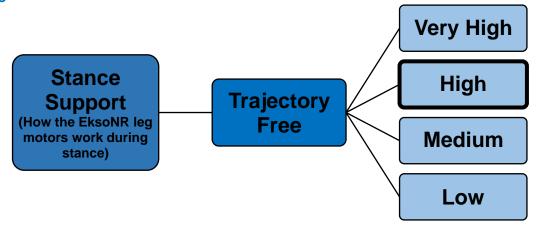
#### Hi/Lo Assistance:

- Provides graded boost to amplify patient movement to aid in swing phase
- Appropriate for patients with low or emerging strength

#### Hi/Lo Resistance:

- Provides graded resistance for patients to push against with to complete swing
- Appropriate for patient with movement disorder, ataxia, or motor apraxia

#### **Stance**



- Ekso provides graded amounts of knee support to supplement patient's ability in stance
- Ekso provides knee flexion safety, block at 45 degrees
- To select stance support option, consider patients strength (glutes/quads) and weight. (Lower strength and higher weight; consider higher support. Higher strength and lower weight; consider lower support)
  - Very High
    - If a patient cannot maintain stance stability safely at this level, or goals for training session are not being met, PT should return to trajectorycontrolled program
  - High\*
  - Medium
  - Low

#### 2Free

Offers non-trajectory-controlled gait programming on both legs for higher level patients. Goal is for patient to replicate learning and carryover of trajectory-controlled stepping pattern

- Ekso does not control which leg steps first
- PT or patient must still engage the first step on controller, or through CI, to engage software and remove soft limits at joints to allow for free walking and for steps to count in statistics
- Can easily transition in/out of 2Free to trajectory-controlled programs to focus on varying goals throughout session
- Left Arrow Stand Still engages soft limits at 35 deg at hip and knee joints in swing and stance
- NOTE on STAND STILL:
  - When entering Stand Still via Left Arrow from walk screen, the device maintains a trajectory-free support, and engages the soft limits to 35 deg at hip/knee only
  - The Ekso Stop button (Yellow) will engage Full Stand Still if patient fatigues or needs full rest/support from Ekso.

# **Right or Left Affected**

- Allows for gait training with one trajectory-controlled leg (AFFECTED), and one trajectory-free leg (FREE)
- Will need to program Swing Assistance and Stance Support on both AFFECTED and FREE limbs
- Ekso Stop Button- returns device to a Full Stand Still position with motor support to the free leg
- Turning is achieved with Left-Arrow Stand Still to terminate step initiation programming of affected Ekso leg.
  - The patient utilizes the free leg to step forward or backwards to create split stance and desired direction to pivot to complete the turn.

#### Sits and Stands when not in Bilateral

All Sit-to-Stand and Stand-to-Sit transitions are operated with bilateral leg power, regardless of walking in 2Free, Right or Left Affected

- After Stand completed:
  - Controller prompts PT to select 2Free or shift right or left towards the selected Right or Left affected configuration.
- Before beginning Sit action:
  - Controller prompts PT to "Go to full bilateral" with a left arrow button push to acknowledge and transition to sit with one additional left arrow push to "Begin Sit"
  - Two action screens now required to navigate, before beginning Sit

# **PreGait Submenu**

Additional exercises added to PreGait suite for lower level or earlier mobilization tasks

- Easily transition from one program to another, before walking or interspersed throughout session
- Weight Shift / Step in Place
  - Combined weight shift and step in place modes allow for adjustment of weight shifting targets and level of trajectory free swing assist and stance support during any pre-gait stepping activities
  - PT begins in weight shift mode to set lateral targets but can transition to step in place by pressing and holding the right arrow to free the legs
    - Alternating heel strikes, forward step weight shifts, marching in place, side-stepping
    - Ekso offers range of motion values for the hip and knee angles
  - Targets from Weight Shift screen will remain on in Step in Place mode for training carryover
  - Both legs change to Trajectory Free
    - PT selects appropriate Swing Assistance for each leg
    - PT selects appropriate Stance Support for each leg

#### Squats

- Allows squatting exercises from standing to three pre-determined limits for knee flexion motion
  - 45 degrees, 65 degrees, 90 degrees
  - Follow instructions on controller to consider base of support, resting ankle settings, and ankle stiffness settings prior to squats
    - Open base of support with driver or unlocking free hip abduction
    - Set ankle stiffness to 1
    - Set ankle angle to 2
  - Real time hip and knee flexion ROM values will appear on the controller and blue numbers will record the knee and hip angles for the max squat achieved
  - The controller also tallies the number of successfully completed squats
- o Both legs change to a "Trajectory-Free" free leg stance mode
  - PT selects appropriate setting for Stance Support
- Ekso Stop Button (Yellow) available to recover patient to standing if patient fatigues

# **Ekso Stop Button Reference Table**

Assistance Mode Programmed to:	Pressing Ekso Stop Button at any time results in:	Pressing Left Arrow during Walking results in:	Actions same or different	Turning Options
Bilateral	Full Stand Still:  Both legs locked	Stand Still: Both legs locked	SAME	Green Checkmark. enables turning program
2 FREE	Full Stand Still	Stand Still: Both legs stay free, with the 35°- 45° soft stops in place	DIFFERENT	No turning program Instruct patient to turn with either free leg.
R/L Affected	Full Stand Still	Stand Still: Affected leg locked, free leg stays free with selected Stance Support and Swing Assistance	DIFFERENT	No turning program. Utilize Left Arrow for Stand Still and step with free leg.

# **EksoNR Programming Decisions**

