



OPERATING MANUAL

EksoNR™ Robotic Exoskeleton

Copyright

© 2022 Ekso Bionics, Inc.

All Rights Reserved

No part of this publication may be reproduced transmitted, transcribed, stored in a retrieval system, or translated into any language or any computer language, in any form or by any third party, without the prior written permission of Ekso Bionic, Inc.



QAdvis EAR AB
Ideon Science Park
Scheelevägen 17
223 70 Lund, Sweden



Contact Information

HEADQUARTERS:

Ekso Bionics, Inc.
101 Glacier Point
Suite A
San Rafael, CA 94901
Office: 1.510.984.1761
Fax: 1.510.927.2647
www.eksobionics.com

EMEA OFFICE:

Ekso Bionics Europe GmbH
Friesenweg 20
22763 Hamburg
Germany
Office: +49 (0)40 800404920
enquiries@eksobionics.com

APAC OFFICE:

163, Tras Street #03-01
Lian Huat Building
Singapore 079024
Office: +6582338620
Fax: +6563248205

CUSTOMER EXPERIENCE

Monday – Friday 6 a.m. to 6 p.m. PST
Phone: 1.888.672.0538
techsupport@eksobionics.com

EMEA: +49 (0)40 800404920
service-europe@eksobionics.com

Table of Contents

| | | | |
|---|-----------|---|-----------|
| 1. Introduction..... | 5 | 8. Controller Navigation..... | 24 |
| Training and Levels of Certification for EksoNR Use | 6 | Controller Button and Icon Overview | 25 |
| Phase One: Initial Training/Level 1 Certification..... | 6 | Controller Touch Screen Overview | 27 |
| Phase Two: Advanced Training/Level 2 Certification: | 6 | Home Screen | 27 |
| 2. EksoNR Overview..... | 7 | Patient ID Menu | 27 |
| General Description | 7 | Patient Settings Menu | 28 |
| Therapeutic Benefits..... | 7 | Ekso Options Menu | 29 |
| Device Functions | 7 | Assistance Menu | 30 |
| 3. Caution & Safety Information..... | 8 | Walk Screen..... | 33 |
| Environment For Use | 8 | Expandable Menu | 34 |
| Indications for EksoNR Use | 8 | Statistics Screen | 35 |
| Patient Requirements..... | 8 | About Screen | 35 |
| Contraindications for Use..... | 9 | 9. Evaluation and Measuring for Fit | 36 |
| General Warnings..... | 10 | EksoNR Evaluation | 36 |
| Safety Reminders | 11 | Patient History | 36 |
| For Physical Therapists..... | 11 | Functional History | 36 |
| Device Specific Safety Considerations | 12 | Physical Evaluation..... | 37 |
| Adverse Events | 12 | Measuring for Fit in EksoNR..... | 38 |
| Clinical Delegation..... | 13 | Conversion to EksoNR Values..... | 39 |
| 4. EksoNR Components | 14 | Screening Form | 39 |
| Front | 14 | 10. Preparing to Walk..... | 40 |
| Back | 15 | Positioning of the EksoNR | 40 |
| 5. Adjusting the EksoNR | 16 | Chair Selection | 40 |
| Tools..... | 16 | EksoNR Positioning | 40 |
| Adjusting the Hips | 17 | Donning the EksoNR | 41 |
| Adjusting Hip Width | 18 | Prior to Patient Transfer..... | 41 |
| Adjusting Hip Abduction..... | 18 | Securing the Legs in EksoNR | 41 |
| Setting the Hip to Free Abduction..... | 18 | Completing EksoNR Donning | 42 |
| Adjusting the Legs | 19 | Before Each Patient Session: | 43 |
| Adjusting the Thigh Support | 19 | After Each Patient Session: | 43 |
| Adjusting the Upper Leg..... | 19 | Adjusting The Ekso With a Patient Seated Or Standing in the Device..... | 44 |
| Adjusting the Lower Leg..... | 19 | Leg Segment Adjustments in Standing | 44 |
| Adjusting the Ankle | 19 | Hip Width or Abduction Adjustments | 44 |
| Ankle Stiffness | 20 | Ankle Stiffness Adjustments | 44 |
| Ankle Resting Angle..... | 20 | Patient ID | 45 |
| 6. Batteries | 22 | To Enter>Select Patient ID: | 45 |
| Charging Batteries | 22 | Manually Save Patient Settings | 46 |
| Battery Alarms | 23 | Choosing Programming to Maximize Therapeutic Goals | 47 |
| Docking EksoNR Batteries..... | 23 | 11. Sit-to-Stand..... | 47 |
| Removing Batteries from the EksoNR.... | 23 | Auto Lean..... | 48 |
| 7. Turn EksoNR On and Off..... | 24 | Standing in EksoNR with a Walker – using Auto Lean Program | 50 |
| | | Standing in EksoNR with Crutches– using Auto Lean Program | 50 |

| | | | |
|---|-----------|--|------------|
| Standing in EksoNR with a Cane— using Auto Lean Program..... | 52 | Sequencing While Walking | 77 |
| Manual Lean..... | 52 | 21. Feedback Scores..... | 78 |
| Standing in EksoNR with a Walker – using Manual Lean Program | 54 | Feedback on the Walk Screen..... | 79 |
| Standing in EksoNR with a Cane – using Manual Lean Program | 54 | Swing Assist Feedback | 79 |
| Standing with Unilateral Upper Extremity Function..... | 55 | Min Assist Feedback | 80 |
| Sit-to-Stand Preparation with Sling.... | 55 | Stance Support Feedback | 80 |
| 12. Standing Visual Check | 56 | Swing Time Symmetry Feedback | 80 |
| 13. Pausing a Sit-to-Stand or Stand-to-Sit 56 | | Step Length Symmetry Feedback | 81 |
| Procedure For Pausing | 57 | Stats Feedback | 81 |
| Automatic Pause | 57 | 22. Statistics Menu | 81 |
| 14. Standing Time Out..... | 58 | 23. Progression While Walking - Swing Limb Focused..... | 82 |
| Likely Causes of a Standing Timeout..... | 58 | Five Step Progression | 83 |
| 15. Stand-to-Sit | 59 | Base of Support..... | 83 |
| Normal Lean Sit..... | 59 | Target Sounds | 83 |
| Minimal Lean Sit..... | 61 | Trajectory | 84 |
| Sitting in EksoNR with a Walker..... | 61 | Step Height..... | 84 |
| Sitting in EksoNR with Crutches..... | 61 | Step Length | 86 |
| Sitting in EksoNR with Cane | 63 | Swing Time..... | 86 |
| Sitting in EksoNR when One/Both Legs are Trajectory Free..... | 63 | Fixed Assist..... | 88 |
| 16. PreGait..... | 63 | Trajectory Free Options..... | 90 |
| Evaluation Mode..... | 63 | 2Free | 90 |
| When to Use Evaluation Mode: | 64 | Swing Assist Options for Trajectory Free Limb | 91 |
| How to Use Evaluation Mode: | 64 | Unilateral Assistance Modes | 91 |
| Hip Flexion Reference Table | 65 | 24. Stance Support in Walking | 92 |
| Weight Shift / Step in Place | 66 | Trajectory Controlled Stance | 92 |
| Squats | 67 | Trajectory Free Stance | 93 |
| 17. Preparing to Walk | 68 | 25. Guides for Patient Progression..... | 94 |
| Patient Handling | 68 | 26. Notification Messages..... | 100 |
| Practice Finding Initial Balance | 68 | 27. Turning..... | 101 |
| Choose Step Initiation Program | 69 | With Walker..... | 101 |
| Set Targets | 69 | Instructions for Therapists..... | 102 |
| Training Targets | 70 | Handling and Cueing | 102 |
| 18. Walking with a Walker | 71 | With Crutches..... | 103 |
| Initiating Walking In FirstStep | 71 | Handling and Cueing | 103 |
| Initiating Walking in ProStep | 73 | With a Cane | 103 |
| Initiating Walking in ProStep+ | 74 | Handling and Cueing | 103 |
| 19. Walking with Crutches | 74 | Turning Without Turn Mode | 103 |
| Finding Initial Balance..... | 75 | In 2Free..... | 103 |
| Sequencing While Walking | 75 | In Right- or Left-Affected | 103 |
| 20. Walking with a Cane | 77 | 28. Outcome Measures | 104 |
| | | 10-Meter Walk Test | 104 |
| | | 2-Minute Walk Test and 6-Minute Walk Test..... | 104 |
| | | 29. Stop Button Function..... | 105 |

| | | | |
|--|------------|--|------------|
| 30. Crutch Interface | 105 | Maintenance..... | 114 |
| Buttons | 106 | Every Day:..... | 114 |
| Mode Button..... | 106 | Every Month: | 114 |
| Step Button | 106 | Every Year:..... | 114 |
| Indicator Light | 106 | Preventative Service Intervals | 114 |
| Walking With Crutch Interface | 107 | Knee Brake Release Battery Replacement | 115 |
| Turning With Crutch Interface | 107 | | |
| 31. Free Hip Abduction..... | 108 | 35. Transport and Storage..... | 115 |
| 32. Errors..... | 109 | 36. Appendix A: Capacities | 116 |
| Critical Device Errors | 109 | 37. Appendix B: Regulatory Information | 117 |
| Safe Mode | 109 | EksoNR Unit Precautions and Warnings | 117 |
| Locked Knees | 112 | EksoNR Battery Precautions and Warnings..... | 118 |
| Step Abort | 112 | | |
| Swing Rescue..... | 113 | | |
| 33. Doffing..... | 113 | 38. Appendix C: Guidance and Manufacturer's Declaration | 119 |
| 34. Cleaning and Maintenance..... | 114 | 39. Appendix D: Error Codes..... | 126 |
| Cleaning | 114 | | |

1. Introduction

WARNING: Potentially severe injury may occur from misuse. DO NOT use the EksoNR unless you are capable of protecting the safety of the patient, yourself, and any other person in the vicinity. Ekso Bionics, Inc. is not responsible for any loss or damage that occurs in connection with your use of the EksoNR.

WARNING: The EksoNR may only be used under the direction of a physical therapist who has been certified by Ekso Bionics, Inc. to operate the EksoNR.

WARNING: In a medical facility, this product can only be used in areas permitting wireless or cellular communication.

WARNING: The long-term effects of walking with the EksoNR are unknown.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

EksoNR is a wearable, battery-operated exoskeleton that enables individuals with lower extremity weakness or paralysis to stand and walk. The EksoNR can also be used as a tool for physical therapy, providing walking assistance when and where help is needed by the patient.

The EksoNR must be properly fitted to each patient. Patients use balance and weight shift when wearing the EksoNR to achieve an efficient reciprocal gait pattern. The assistance software progressively adjusts the forces provided by the EksoNR to continuously challenge patients as they progress in strength and skill. The PreGait features provide further evaluation, balance training, and strengthening exercises. Physical therapists can take advantage of feedback provided by the EksoNR to see the step length and swing time symmetry, how hard the EksoNR is working to maintain stance, and how hard the EksoNR is working to complete swing. The optional functional electrical stimulation (FES) interface¹ enables advanced users to synchronize the EksoNR with a FES device, combining the benefits of the exoskeleton with those of stimulation.

The EksoNR also includes a data module called EksoPulse. EksoPulse automatically gathers and transmits statistics and reliability data from the EksoNR that can be accessed from a website. For more information on EksoPulse contact **Ekso Bionics Customer Experience**.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in Appendix B: Regulatory Information.

¹Not commercially available in the USA and Canada

Training and Levels of Certification for EksoNR Use

The Ekso Bionics training program occurs in two phases:

Phase One: Initial Training/Level 1 Certification

- Introduces the initial, basic feature set of the EksoNR.
- Prepares 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.

Introduces 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 can provide training to other physical therapists on EksoNR operation, in preparation for EksoNR certification by Ekso Bionics.

2. EksoNR Overview

General Description

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.

Therapeutic Benefits

EksoNR is a clinical tool that can:

- Address physical therapy gait retraining goals through patterning and reciprocal stepping.
- 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.

Device Functions

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. The EksoNR can be tuned and adjusted to fit a patient's precise needs.

When properly fit to a patient, the EksoNR enables the patient to stand and walk with the assistance of a front rolling walker, crutches, or cane. To use the device effectively, a patient must learn how to balance and weight shift when wearing the EksoNR, so that an efficient reciprocal gait pattern can be achieved.

| Device Functions | Patient Requirements | Assistive Device |
|---|--|---|
| <ul style="list-style-type: none"> • Sit-to-stand • Walking • Stand-to-sit • Pre-gait functions | <ul style="list-style-type: none"> • Active participation • Weight shifting • Maintaining balance (with assistance as needed) • Initiating steps (except in FirstStep) | <ul style="list-style-type: none"> • Required for EksoNR use • Helps to maintain balance • Used to help facilitate weight shifts |

3. Caution & Safety Information

Environment For Use

EksoNR must be used in appropriate and safe environments:

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

Indications for EksoNR Use

For customers outside of the US and Canada (CE mark):

The EksoNR is intended for use as gait training device to improve walking function and independence in patients with a neurological or muscular injury, illness, or weakness. It is intended to help facilitate the restoration or improvement of ambulation for its pilots under the supervision of a trained physical therapist (or equivalent medical professional) and operated by a Trained Spotter.

For customers in the United States and Canada (FDA clearance):

The EksoNR™ is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations:

- Individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least one arm)
- Individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least one arm).
- Individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms).
- Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms).

The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.

Patient Requirements

- 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 (\leq 0.5 in. or 1,3 cm) and lower leg discrepancy equal to or less than three-quarters of an inch (\leq 0.75 in. or 1,9 cm).

Contraindications for Use

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 follow directions
- 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:
 - Knee flexion contracture greater than 12°
 - Inability to achieve 0° neutral angle dorsiflexion with knee flexion up to 12°
- Leg length discrepancy greater than 0.5 inches (1,3 cm) for upper legs or 0.75 inches (1,9 cm) for lower legs
- Unresolved deep vein thrombosis
- Uncontrolled autonomic dysreflexia
- Lower limb prosthesis

General Warnings

Patients with the following conditions may have additional risks:

- Significant osteoporosis that may increase the risk of fractures caused by standing or walking. Patients should be evaluated by their physician to assess severity of osteoporosis and whether they can tolerate walking and standing prior to using the device.
- Recent history of uncontrolled orthostasis. Patients' blood pressure should be closely monitored to minimize risk associated with syncopal episodes.
- Hip dysplasia or hip axis abnormalities. Use of the device should be paused and checked for fit if the patient complains of hip discomfort or pain. If the fit is correct and the patient continues to experience discomfort, this device may not be appropriate for use with this patient.
- Patients with cranial defect or with cranial bone flap stored in abdomen should be wearing a helmet at all times and should be closely monitored when using the EksoNR.
- Impulsive behavior that may lead to unsafe turns, walking, or EksoNR use that may lead to injury to patient and physical therapist. If the patient exhibits cognitive or psychiatric concerns, which can lead to an inability to follow instructions, this device should not be used.
- If there are any unsafe changes in the patient's blood pressure or heart rate, the session should be immediately terminated.
- Only use the EksoNR on solid, dry, level ground with less than a 2% grade. Using the device on irregular surfaces could result in loss of balance and possible injury.
- The device must be fitted over clothing to prevent skin abrasions. Where necessary, use the extra padding provided with the device.
- Ensure that the device does not put excessive pressure on bony prominences.
- Skin integrity should be assessed before and after each use.
- Use only input power cables, battery chargers, and battery assemblies offered by Ekso Bionics.
- Ensure the EksoNR batteries are fully charged or adequate for the treatment session.
- Appropriate spotting must be done at all times, as the EksoNR is not designed to prevent falling. The spotter must remain within an arm's reach of the patient at all times while spotting. The role of the spotter is to provide guarding support to the patient while transferring, standing, walking, turning, and sitting. In an emergency, the spotter may help perform a long-legged sit maneuver.
- New patients and patients at higher risk of falling require more supervision and spotting.
- Always give clear, verbal instructions to patients, especially when beginning or changing an EksoNR action or when the patient is turning or is changing direction during EksoNR walking sessions.
- Further research is needed to determine the long-term effects of walking with the EksoNR.

- Be aware of leg length differences and/or bony abnormalities that would prevent safe operation. Use of the device should be paused and checked for fit if the patient complains of discomfort or pain. If the fit is correct and the patient continues to experience significant discomfort, this device may not be appropriate for use with this patient.
- The EksoNR should be removed before entering a magnetic resonance (MR) scan room or having an MR scan. The EksoNR has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of EksoNR in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Contact with or being in proximity to an MR scanner may cause the exoskeleton to move or lead to electric shocks and may result in patient injury.

Safety Reminders

For Physical Therapists

- 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.
- A dedicated spotter or tether is optional for additional safety with new or challenging patients. A safety suspension system may be attached to the Ekso nylon cord but must be kept slack for normal EksoNR walking (no pulling, dragging, or suspension). Additionally, the suspension tether must be removed during sit-to-stand and stand-to-sit transitions.

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 frayed 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. Examples of adverse reactions include:

- Skin integrity issues
- Bruising
- Pain
- Sudden nausea or changes in skin color, such as turning pale or red
- Unusual swelling

Any undesired EksoNR mechanical behavior should be noted and reported to **Ekso Bionics Customer Experience** before continuing operation. Examples of undesired behaviors include:

- Changes in normal walking or sit-to-stand/stand-to-sit transitions
- Uneven step lengths related to software rather than patient performance
- Unusual oscillations of any joint
- Unusual sounds not present during training or regular EksoNR operation

Clinical Delegation

Ekso Bionics Requires the Following for Safe Delegation:

- An Ekso Bionics-trained physical therapist must provide the initial evaluation and initial training sessions for each patient.
- An Ekso Bionics Level 2-trained physical therapist is responsible for each EksoNR device session and maintain awareness of the patient's status, condition, and EksoNR device settings while the device is in use.
- An Ekso Bionics-trained physical therapist must provide the training necessary for the support staff to safely handle any patient.

Ekso Bionics acknowledges that an Ekso Bionics Level 2-trained physical therapist may choose to delegate the patient to support staff when deemed appropriate, but the physical therapist does this at their sole risk and responsibility. Ekso Bionics acknowledges that all physical therapists must exercise their own best clinical judgment in compliance with the laws and regulations governing their practice in determining when delegation may occur.

Safe delegation of EksoNR sessions requires appropriate training and patient selection for the patient and spotter to be safely managed during a session. Delegation without proper training may result in injury to the patient or staff member; therefore, Ekso Bionics recommends the following:

- The patient that is delegated to support staff should:
 - Be a safely manageable EksoNR device user with minimal loss of balance during walking sessions.
 - Be safely manageable with the assistive device and EksoNR programming.
 - Be safely manageable with sit-to-stand and stand-to-sit transitions.
- The delegate that is working with the patient should be:
 - Trained sufficiently in EksoNR device operation to safely manage the patient in emergency operation procedures, such as Safe Mode, Pause, standing/sitting, etc.
 - Able to manage the patient and the EksoNR device weight in the event of a loss of balance to prevent a fall.

Ekso Bionics utilizes a training checklist and competency template for the purposes of training certified physical therapists and strongly recommends the adoption of similar documentation for clinical delegates.

4. EksoNR Components

Front



| Key # | Description |
|-------|-----------------------------|
| 1 | Backpack Straps |
| 2 | Chest Strap |
| 3 | Torso Pad and Straps |
| 4 | Knee Motor |
| 5 | Upper Leg Length Adjustment |
| 6 | Shin Support |
| 7 | Foot Binding and Strap |
| 8 | Battery and Torso |
| 9 | Hip Motor |
| 10 | Hip Joint |
| 11 | Thigh Brace and Strap |
| 12 | Knee Brake Release |
| 13 | Knee Joint |
| 14 | Lower Leg Length Adjustment |
| 15 | Adjustable Ankle Joint |
| 16 | Foot Plate |



The manual **Knee Brake Release** button is located on the side of each knee joint. This release button functions only when the EksoNR is powered OFF. Pressing the button enables knee flexion/extension. Releasing the button locks the knee in place.

Back



| Key # | Description |
|-------|--|
| 17 | Nylon Tethering Cord (for optional use) |
| 18 | Controller Seated on Magnetic Holder |
| 19 | Power Button (behind Controller – see photo below) |
| 20 | Torso Handles |
| 21 | Sacral Handle |

The **Power button** is located on the back of the torso. Press this toggle button to power ON or to power OFF the EksoNR. The button stays depressed when powered ON. Powering OFF and immediately powering ON is referred to as *rebooting* the EksoNR software and clears current patient settings and statistics. Rebooting the EksoNR is part of normal operations and may also be needed to clear certain error messages.

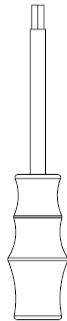


5. Adjusting the EksoNR

To ensure that the EksoNR adjustments are consistent among each member of your clinical team, it is best to adjust the device to show the entirety of the white indicator line without exposing any additional black background. All adjustments are made most easily with the EksoNR in a sitting position.

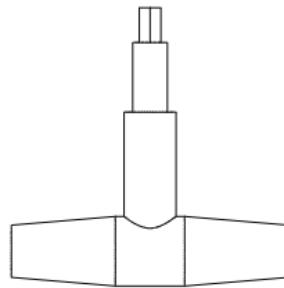
Tools

All adjustments must be made with the EksoNR tool(s) specified in the instructions.



Driver

Used to adjust the hip width and hip abduction screws.

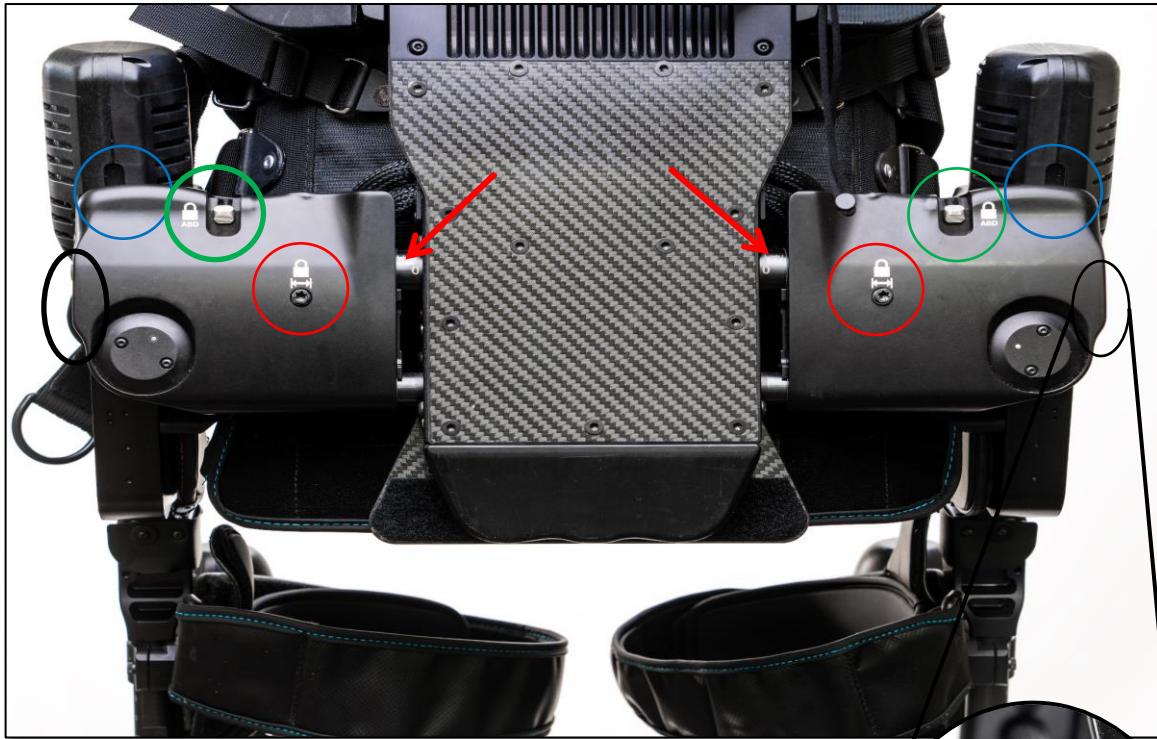


Calibrated T-handle Torque Wrench

Used for adjusting all other screws (besides hip width and hip abduction screws).

Tighten screws until the wrench emits one click

Adjusting the Hips



| Callout | Description |
|---------------|--|
| Blue Circle | Hip Abduction Adjustment Setting |
| Green Circle | Free Hip Abduction Lock |
| Red Circle | Hip Width Lock Screw |
| Red Arrows | Hip Width Adjustment Setting; read from the inside |
| Purple Circle | Hip Abduction Adjustment Screw; lateral view |
| Orange Circle | Hip Width Adjustment Screw; lateral view |



Adjusting Hip Width

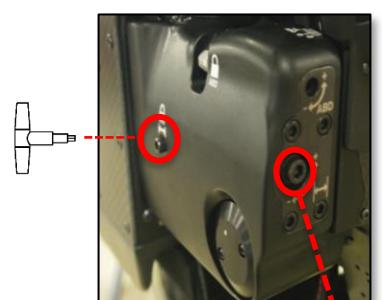
NOTE: Adjust each side separately and symmetrically.

To adjust the hip width:

1. Use T-handle torque wrench to loosen the Hip Width Lock Screw (left circle in photo).
2. Use driver to turn the Hip Width Adjustment Screw (right circle in photo) on end of hip to widen or narrow hips.
3. Use T-handle torque wrench to secure Hip Width Lock Screw; tighten until it clicks.



Align the hip value marked on the black tubing with the inside edge of the black hip mechanism box by looking straight at markings.



Adjusting Hip Abduction

NOTE: Adjust each side separately.

To adjust the hip abduction:

- Insert driver into Hip Abduction Screw (circled in first photo) on the lateral end of the EksoNR hip.
- Turn screw until desired hip abduction value is aligned with alignment markings on back of hip motor (circled in second photo).
- Confirm alignment by looking straight-on at markings.
- Each marking line represents 1 degree of movement.



Setting the Hip to Free Abduction

Free abduction controls the hip abduction/adduction behavior.



When in the unlocked position, hip abduction moves freely between the hip abduction adjustment setting and 22° of abduction.

To set to Free Abduction:

- Considered only after physical therapist determines patient can manage free control.
- Slide knob on back of the EksoNR upward to the unlocked icon.



May slightly shift patient's body weight side to side to find neutral resting point to allow for movement.



When the Free Hip Abduction is *unlocked*, the hip motor may create a pinch point that could injure the physical therapist's hand if the physical therapist is facilitating the patient's weight shifts by guiding the patient's lower trunk.

Adjusting the Legs

Adjusting the Thigh Support

To adjust the thigh support:

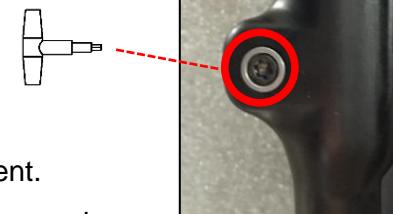
- Using the T-handle torque wrench, loosen the thigh brace screw
- Rotate the brace toward or away from the leg to achieve contact with the patient's thigh
- Tighten the screw using the T-handle torque wrench until the wrench clicks.



Adjusting the Upper Leg

To adjust the upper leg:

- Use T-handle torque wrench to loosen upper leg screw. (circled in photo.)
- Slide the upper leg to adjust to desired EksoNR setting.
NOTE: Bias exists in mechanism to keep neutral alignment.
- Use T-handle torque wrench to tighten the screw until the wrench emits one click.



Adjusting the Lower Leg

To adjust the lower leg:

- Use T-handle torque wrench to loosen lower leg screw.
- Slide the lower leg to adjust to desired EksoNR setting.
- Use T-handle torque wrench to tighten the screw until the wrench emits one click.



Adjusting the Ankle

- Does not require tools
- Two different adjustments, Ankle Stiffness and Resting Angle, allow for customizing patient positioning and performance.

Ankle Stiffness

- Four (4) levels of stiffness adjustment: 4 = most stiff; 1 = least stiff
- Aids in single limb stance stability and balance assist.
- Adjustments still allow for heel strike and reciprocal stepping



To adjust ankle stiffness:

- Advance or retract the sliding lever on the front of the ankle joint.
- Align number of the desired stiffness setting with entry of the ankle box. The lowest visible number is the setting. The picture shows the ankle stiffness set to 1.



Slight plantarflexion pressure at the ankle aids in sliding the lever.

Table 1 - Ankle Stiffness Recommendations (Only use as a Guide)

| Stiffness | 1 | 2 | 3 | 4 |
|-----------|--|--|--|---|
| | Strong/Normal plantarflexion strength | Fair/Good plantarflexion strength and weight under 130 lb (60 kg) | Fair plantarflexion strength and weight 130-180 lb (60-80 kg) | Poor/Fair plantarflexion strength and weight 180-220 lb (80-100 kg) |
| | | | Absent plantarflexion strength and weight under 140 lb (64 kg) | Absent plantarflexion strength and weight over 140 lb (64 kg) |

Ankle Resting Angle

- Refers to optimal standing balance point that allows for minimal upper extremity use in static stance.
- Controlled by a six-sided knob at the back of the ankle.
- Available range is from -3 to +2.
- Each value represents a 1-degree change in the direction indicated.
- Value visible on top side of knob represents the set angle.
- Baseline, or 0, provides slight closed chain dorsiflexion to balance the EksoNR.
- Positive direction is toward relative dorsiflexion.
- Negative direction is toward relative plantarflexion.



To set the ankle resting angle:

- Position the foot in slight dorsiflexion (increasing angle) or slight plantar flexion (decreasing angle)
- Disengage six-sided knob and start at 0.
- Adjust back or forward to find a balanced position and foot flat on ground.
- Changes to programmed Knee Flexion impact the Ankle Resting Angle. If the physical therapist determines an appropriate Ankle Resting Angle for a patient, and then *later changes the knee flexion value*, the Ankle Resting Angle *needs to be reassessed* to find the new optimal balance point for the EksoNR.
- When the EksoNR knees are programmed between 0° to 3° flexion, the Ankle Resting Angle is likely optimized at -3.
- When the EksoNR knees are flexed 10° to 12°, the Ankle Resting Angle is likely optimized at 2.
- For patients with complete paraplegia:
 - A more balanced, upright setting decreases the upper extremity effort required.
 - A stiffer ankle setting provides increased stability during single limb stance and tibial progression, aiding in decreased upper extremity overuse.
- For patients with ankle range of motion restrictions:
 - If the patient requires higher programmed knee flexion angle, they may also need a Resting Angle in the positive range to aid in balance.
- For patients with hemiparetic presentation when walking in EksoNR Right- or Left-Affected:
 - Higher value of Ankle Stiffness on weaker limb helps stabilize in stance.
 - Slight increase in EksoNR Ankle Stiffness may contribute to stance stability on free limb if needed.



If attempting to adjust with a patient standing in the device, and the knob does not easily disengage, the patient may need to shift weight forward or backward to relieve preloading and find the easy position for disengaging.

To facilitate knob change, slight weight shift in the direction of the desired change aids in movement.

6. Batteries

The EksoNR uses two 48-volt rechargeable batteries. The batteries attach to each side of the EksoNR torso when pins and other positioning pieces are in proper alignment. EksoNR batteries work together as a set of two. Each pair should be replaced and/or recharged simultaneously to maximize battery life and ensure proper functionality of the EksoNR.

When batteries are attached to the EksoNR torso and the device is turned ON, EksoView displays the power level in the upper right corner.

- Check EksoView to determine if the batteries are sufficiently charged prior to each patient session.
- Check that both batteries are properly attached to the torso prior to each patient session.
- Always use two batteries during EksoNR operations
- Respond promptly to Low Battery warnings displayed by EksoView.
- Remove or replace batteries only when the EksoNR is turned OFF and in a sitting position.
- Recharge each battery at least once every two months.
- Use only the two Ekso Bionics-provided Battery Chargers to charge batteries.
- Always check that a Battery Charger is plugged in before plugging in a battery for recharging.
- Never use the Battery Chargers if the charger cord is frayed or compromised in any way.

Further regulatory information regarding the battery and Battery Chargers is located in Appendix B.

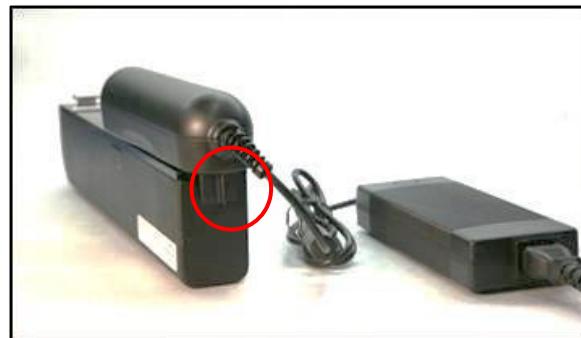
Charging Batteries

Ekso Bionics supplies two Battery Chargers with each EksoNR. Each charger has an AC/DC power supply with a removable connector and cable. The connector plugs into the charger and the other end of the cable plugs into an electrical outlet.

While charging, place the battery on a non-flammable, heat resistant, and non-conductive surface. Keep flammable and volatile materials away from the charging area. Do not leave the charging batteries unattended or unsupervised.

Follow the charge conditions specified below.

- Ensure that the removable connector is fully plugged into the AC/DC power supply. The LED is lit when everything is properly connected.
- Using the charger seating guide (circled in photo), connect the battery to the charger.
- The charger light changes from green to red-orange if discharged battery is connected properly.
- Ensure there is full contact between the battery and the charger while charging. Loose contact will elicit an insufficient charge.
- A green LED indicates the battery is fully charged and ready for use. Batteries reach a full charge in approximately 60 minutes.



Battery Alarms

- Low batteries: At 25% remaining battery level, the EksoNR alerts the therapist. The patient should walk to a chair and perform a powered sit.
- Very low batteries: At 15% remaining battery level, the EksoNR allows only a powered sit.
- Critical batteries: At 10% remaining battery level, the EksoNR will go into Safe Mode and a long-legged sit is required.

Docking EksoNR Batteries

To dock the batteries to the EksoNR torso:

- Grip handle on side of torso to steady the EksoNR.
- Carefully line up the bottom of the battery (top of the battery is flat) and the torso pins.

NOTE: Docking a battery upside-down may cause serious damage to the battery or the EksoNR.

- Dock lower battery cleat into EksoNR first.
- Ensure cleat is seated down in receiving slot. (Note the “V” shape formation.)
- Push battery toward EksoNR torso until battery clicks into place.

NOTE: To avoid damage, take the time to properly align the battery and the pins with the torso. Attach the battery *only* when bottom cleat is correctly seated, and all pins are aligned.



Removing Batteries from the EksoNR

To remove the batteries from the EksoNR torso:

- With the EksoNR in a sitting and secure position, power OFF the device.
- Grip the battery firmly with one hand to support.
- With the other hand, depress the battery latch at the top of the torso connection (circled in photo).
- Gently pull the battery outward and upward to remove it from the lower cleat.



The battery latch is spring-loaded. When a physical therapist removes a battery, they must hold the battery to prevent the battery from falling off the torso when the latch is pressed.

7. Turn EksoNR On and Off

Turn ON the EksoNR by pressing the Power Button on the back of the torso. The Button stays depressed when turned ON.

When the EksoNR is ready, EksoView displays the Home screen.

The EksoNR may be turned OFF at any time by pressing the Power Button again; however, the patient should be removed from the EksoNR before turning OFF. When turned OFF, the hips go free and the knees lock in place.

NOTE: Ekso Bionics recommends that the EksoNR be turned off after each patient session to return the device to default settings and clear statistics.

8. Controller Navigation



The EksoNR handheld EksoView allows the physical therapist to program and operate the device. When not in use, EksoView should be stored on the upper back of the torso, where a magnet holds and secures it in place.

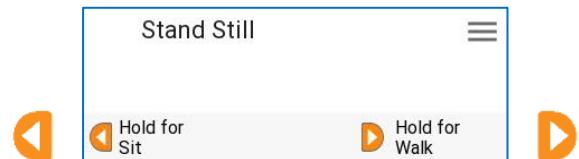
The physical therapist should use the adjustable wrist strap on EksoView to help prevent dropping or accidental button pushing. The strap should be tight but comfortable around the wrist.

EksoView utilizes both a touch screen and buttons for navigation.

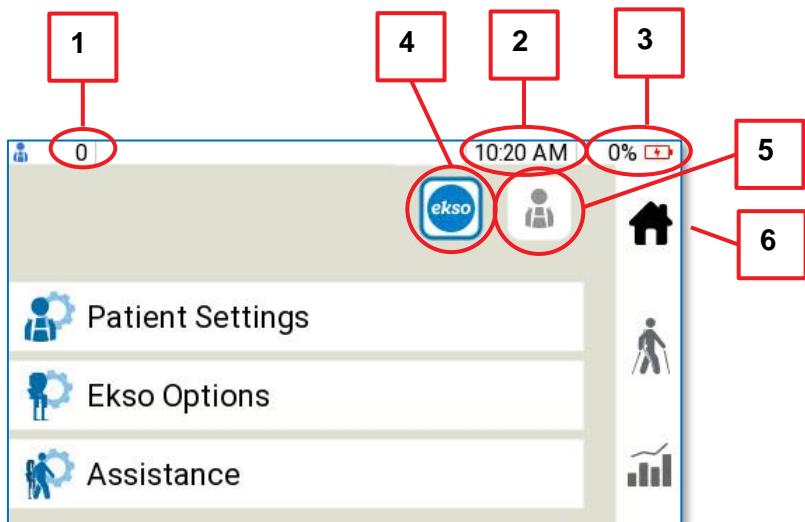
NOTE: All actions must be initiated using the physical buttons on EksoView.

Controller Button and Icon Overview

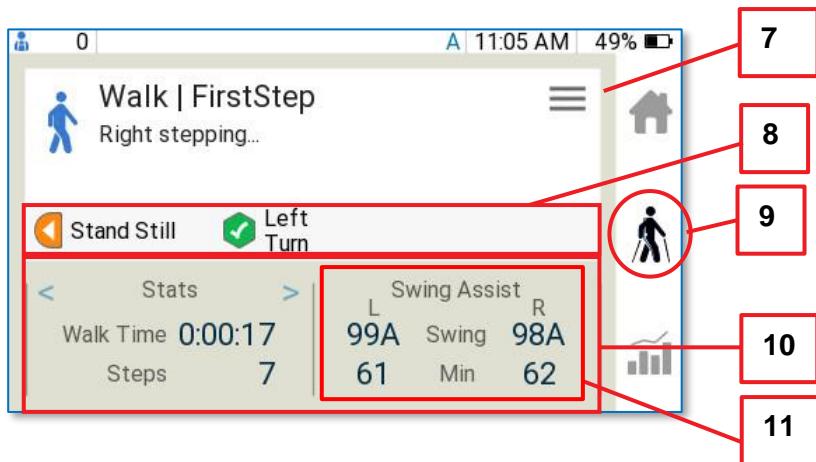
- Up ⬆ and Down ⬇ arrows
 - Navigate/scroll through menus
 - Adjust values of selected setting
- Check ✅ button
 - Move to a submenu or setting screen
 - Select a value for editing
 - Accept an edited value
 - Clear an error message
 - Enter and exit Turn Mode
- Left ⬅ and Right ⬅ arrow
 - Action buttons
 - Held depressed to prepare for EksoNR action
 - Pressed to direct EksoNR operation
 - Controller touch screen indicates action command
- Previous ⬅ arrow
 - Return to a higher menu
 - Cancel edited value
 - Acknowledge error message
- EksoNR Stop ⚡ button
 - Stops any EksoNR action
 - During walking: Places the EksoNR in Full Stand Still which stops walking action and provides full support
 - During stand/sit: Pauses EksoNR motion in place
- Page up ⬆ and page down ⬇ icon
 - Scroll up/down through the menu options
- Page left ⬅ and page right ⬅ icon
 - View the previous/next feedback screen



The ⚡ Stop Button is a secondary method to return the EksoNR to **Full Stand Still** while walking or to pause EksoNR motion during a stand or sit. If the physical therapist is navigating in the **Home Screen** during walking, using the EksoNR **Stop** button is the fastest and the safest way to stop EksoNR operation.



| Callout | Description |
|---------|-------------------------|
| 1 | Patient ID Number |
| 2 | Current Time |
| 3 | Battery Remaining |
| 4 | About Icon |
| 5 | Patient ID Icon |
| 6 | Home Screen Icon |
| 7 | Expandable Menu Icon |
| 8 | Action Bar |
| 9 | Walk Screen Icon |
| 10 | Real-Time Feedback Area |
| 11 | Quick Assist Adjust |
| 12 | Page Arrows |
| 13 | Statistics Screen Icon |

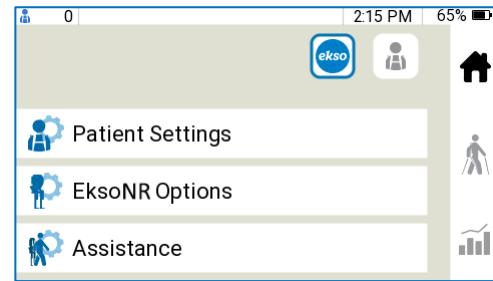


Controller Touch Screen Overview

- Power the EksoNR device ON.
- Observe the battery levels at upper right of screen display.

Home Screen

- Use Up ▲ and Down ▼ arrows or touchscreen to scroll through submenus: **Patient Settings**, **Ekso Options**, and **Assistance**.
- Use Check ✓ button to select submenu.
- Access to Patient ID icon  and About Icon 



Patient ID Menu

NOTE: The Patient ID enables physical therapist to store the patient's last settings for future sessions and can help with troubleshooting technical issues.

- Tap the  (Patient ID icon) on the **Home** screen to enter or select a Patient ID:
 - If the patient is a returning patient with an established ID number, scroll to the number and touch it to select the patient ID number from the list.
 - If the patient is new, touch the **Enter ID** button and use the virtual keypad to enter a unique ID number.



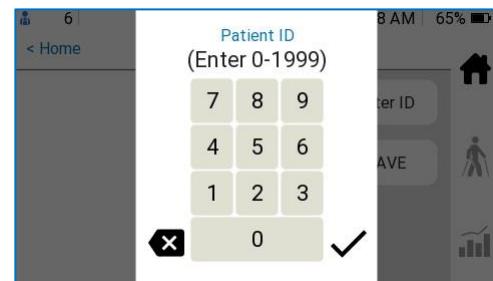
NOTE: “Review Settings” message remains on the screen to remind the physical therapist to ensure that all settings are accurate for each patient session. Reviewing all settings, options, and selecting the Assistance menu settings clears the message.

- Use Previous arrow ⏪ to access the **Home** screen.

By default, the EksoNR automatically saves selections at the end of a patient session.

If desired, the settings can be saved earlier, by doing the following:

- Go to patient ID screen
- Click “save as...” button and select appropriate ID



Patient Settings Menu

- **Patient Settings** menu is accessed from the **Home** screen.
- Programs settings specific to patient, device, and gait session data.
- When using a stored patient ID, EksoNR automatically loads the last personal programming entered for a patient in the **Patient Settings** and **Ekso Options** menus; however, physical therapist must manually set desired values and/or accept default values for **Assistance** menu.
- Scroll through and set/accept all **Patient Settings** parameters.

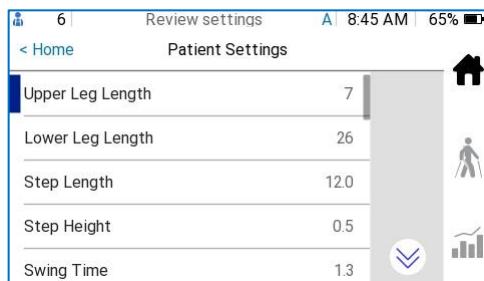


Table 2 - Patient Settings Menu Options

| Parameter | Description | Default Value | Range |
|-------------------------|--|---------------------|--|
| Upper Leg Length | Enter the EksoNR value as recorded on Form 2 | 10 | 0 to 40 |
| Lower Leg Length | Enter the EksoNR value as recorded on Form 2 | 20 | 0 to 50 |
| Step Length | Gait parameter: The number of inches each foot advances during the swing phase. | 12 in. (30,5 cm) | 8 to 18 in. (20 to 46 cm) |
| Step Height | Gait parameter: The foot clearance during the swing phase. | 0.5 in. (1,3 cm) | 0.0 (low) to 1.5 in. (high) (0 to 3,8 cm) |
| Swing Time | Gait parameter: The time the EksoNR takes to complete the swing phase for each leg. | 1.3 seconds | 0.8 to 2.0 seconds |
| Stand Time | Length of time to complete a sit-to-stand transition. | 3.5 seconds | 1.5 to 5.0 seconds |
| Hip Flex | The patient's hip flexion angle when standing. Hip Flex automatically sets to half of the entered Knee Flex. Hip Flex angle can be adjusted independent of Knee Flex angle. Both hip and knee angles are maintained in <i>both</i> Stand Mode and Walk Mode. | 0.0° | -9° to 12.0° |
| Knee Flex | The maximum extension for the EksoNR knee. Both hip and knee angles are maintained in <i>both</i> Stand Mode and Walk Mode. | 0.0° | 0° to 12.0° |
| Forward Shift | The forward target that the patient must achieve when taking a step. | 2 | -1 to 3 |
| Lateral Shift | The level of lateral shift that the patient must achieve when taking a step. | 0 | -2 to 3 |

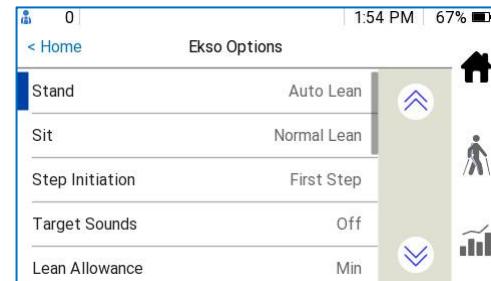
NOTE: A “Review Settings” message displays at the top of the screen to remind the physical therapist to address all settings for each patient. Physical therapist must scroll through all **Patient Settings** and **Ekso Options** menu settings and change or accept the default **Assistance** menu setting for the “Review Settings” message to clear.

The **Knee Flex** and **Hip Flex** angles are linked. When the **Knee Flex** angle is set, the **Hip Flex** angle is set automatically to half of the **Knee Flex** angle to maintain an upright torso posture. To achieve a specific **Hip Flex** angle, the desired **Hip Flex** angle should be entered after entering the **Knee Flex** angle.

Ekso Options Menu

Ekso Options menu is accessed from the **Home** screen. Use the and arrows to scroll through the Ekso Options. Bold option indicates the default.

- **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.
 - Manual Lean: A single-phase stand transition in which the patient must be leaning forward prior to initiating.
- **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.”
 - 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.
- **Step initiation:** Programs the *Step Initiation Mode* - how the EksoNR step is initiated; the choice of step program is based on individual patient need.
 - **FirstStep:** Physical therapist controls stepping action when patient achieves balanced, weight-shift.
 - Begin sessions here to teach patient device interaction and balance.
 - ProStep: Patient initiates stepping by achieving a forward and lateral weight shift target.
 - Often used for patients who do not have physical strength to initiate swing phase, or once fatigued from participating in swing initiation.
 - ProStep+: Patient initiates stepping by achieving lateral weight shift target on stance leg and unweighting trailing leg.
 - Best used for patients with lower extremity strength who can actively contribute to swing initiation; may best be preferred by patient for natural walking pattern and timing.

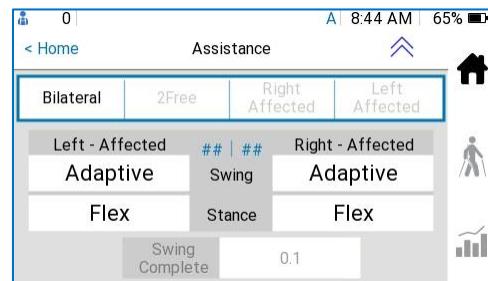


- **Target Sounds:** Programs audio feedback (beeps and chirps) for training.
 - **Off**
 - Both
 - Lateral (chirp)
 - Forward (beep)
- **Lean Allowance:** Audio feedback of when patient is leaning too far forward at heel strike.
 - **Minimum**
 - Maximum
 - Off
- **FES:** Enable or disable the Functional Electrical Stimulation (FES) interface. (If this device is not configured for FES, this choice is not available.)

Assistance Menu

Assistance Mode: Determines which EksoNR legs are trajectory controlled versus trajectory free. Bold fault indicates the default.

- **Bilateral**
 - Maintains a programmed gait trajectory while providing swing assistance and stance stability to both lower extremities.
- **2Free**
 - Provides no programmed gait trajectory in swing and offers graded physical therapist-selected Stance Support and Swing Assistance.
 - Patient moves the EksoNR legs within their own movement pattern.
 - EksoView displays a reminder message to press the check button to go to free legs
 - When in Stand Still, both legs can move freely within the determined safety boundaries of knee flexion (0 to 35°).
- **Left-Affected or Right-Affected**
 - Provides swing assistance and stance stability in the programmed trajectory *for indicated (affected) limb only*.
 - Contralateral limb is free of trajectory control but still has trajectory-free Swing Assistance and Stance Support options.
 - EksoView displays a reminder message to please shift to affected side to free contralateral limb.



The **Assistance** menu changes to show only relevant swing and stance parameters depending on the mode selection.

Swing Assistance Options:

- Trajectory Controlled:
 - Max
 - Provides maximum power to tightly control movement of the limb through predetermined trajectory.
 - May be best program option for high spasticity.
 - **Adaptive**
 - Continually adapts motor output dependent upon the patient's ability to lead the swing leg through the predetermined limb trajectory.
 - Fixed (0-100)
 - Useful when the goal is to focus on maximal effort from the patient with the least amount of motor assistance.
 - When the swing assistance is set to a fixed value, that number is the ceiling amount of swing assistance provided throughout the swing phase while remaining adaptive below the fixed swing assistance. The patient may use up to, or less than, the programmed value to complete the swing.
 - At times, this program may result in a degradation of swing quality if programmed to a level close to the patient's ability, as the patient is required to provide more effort to complete the gait cycle.
 - Swing Complete will maintain safety by finishing a step if the patient cannot in a given amount of time.
 - Swing assist is set independently for each leg.
- Trajectory Free:
 - High assist
 - Low assist
 - **Neutral**
 - Low resist
 - High resist

Stance Support Options:

- Trajectory Controlled:
 - Full
 - Provides full knee support using locked brakes during the stance phase of gait.
 - **Flex**
 - Continuously adjusts the amount of Stance Support based on the support the patient needs as they move through each step.

- Trajectory Free:
 - Very high
 - **High**
 - Medium
 - Low

Table 3- Assistance and Swing/Stance Interactions

| Swing/Stance Options | ASSISTANCE MODE OPTIONS | | | |
|-------------------------------|--|--|--|--|
| | Bilateral* | 2Free | Right Affected | Left Affected |
| Left-Affected Swing Assist | Max, Adaptive*, 100-0 | — | — | Max, Adaptive*, 100-0 |
| Right-Affected Swing Assist | Max, Adaptive*, 100-0 | — | Max, Adaptive*, 100-0 | — |
| Left-Affected Stance Support | Full, Flex* | — | — | Full, Flex* |
| Right-Affected Stance Support | Full, Flex* | — | Full, Flex* | — |
| Left-Free Swing Assist | — | High Assist, Low Assist, Neutral*, Low Resist, High Resist | High Assist, Low Assist, Neutral*, Low Resist, High Resist | — |
| Right-Free Swing Assist | — | High Assist, Low Assist, Neutral*, Low Resist, High Resist | — | High Assist, Low Assist, Neutral*, Low Resist, High Resist |
| Left-Free Stance Support | — | Very High, High*, Medium, Low | Very High, High*, Medium, Low | — |
| Right-Free Stance Support | — | Very High, High*, Medium, Low | — | Very High, High*, Medium, Low |
| Swing Complete | 0.1*, 0.3, 0.5, 1.0, 1.5, 2.0, 2.5 seconds | — | 0.1*, 0.3, 0.5, 1.0, 1.5, 2.0, 2.5 seconds | 0.1*, 0.3, 0.5, 1.0, 1.5, 2.0, 2.5 seconds |

* Indicates the default setting.

NOTE: Only certain menu options are available during the Initial Training. Additional items are made accessible during the Advanced Training.

Initial Training features:

- Bilateral
- Swing Assist of Max and Adaptive
- Stance Support of Full and Flex
- FirstStep, ProStep, ProStep+
- Portions of PreGait

Advanced Training features:

- 2Free, Left-Affected, or Right-Affected
- Trajectory-controlled Swing Assist: Fixed
- Free Swing Assist options: High Assist, Low Assist, Neutral, High Resist, Low Resist
- Free Stance Support options: Very High, High, Medium, Low
- Remaining portions of PreGait and supplemental features

Walk Screen

Accessed through  icon on the right menu bar.

Initiate motion to operate the EksoNR and see real-time feedback.

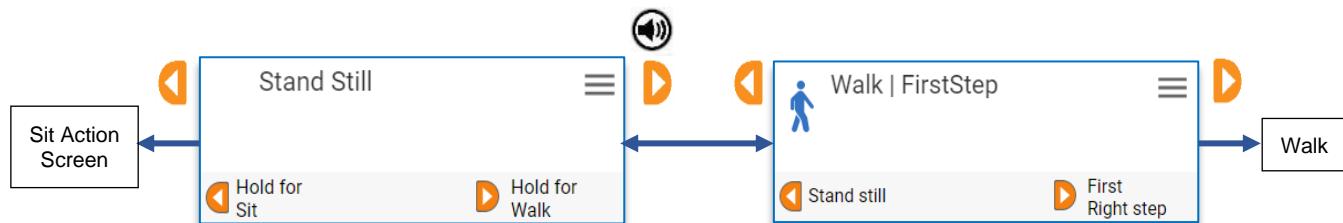
EksoView indicates the available EksoNR action or state-changing options. The top line of EksoView displays the EksoNR mode with or without the walking icon ().

- The Walking icon () indicates that the next press of the  or  button results in an EksoNR movement.
- No Walking icon indicates that the next press of the  or  button results in the EksoNR switching states but does *not* cause the EksoNR to move.

Below, the left screenshot example indicates that this is a state-changing screen and no EksoNR movement will occur when a button is pressed. The state-changing options are to transition to the Sit mode (with the  button 3-second hold) or to the Walk mode (with the  button 3-second hold). The  icon in the right screenshot example identifies that a  button triggers a movement, in this case a right step.

- When changing from a non-movement state (such as Stand Still) to a movement state (such as Walk or Sit Down), EksoView emits a rapid sequence of 4 beeps.

- When EksoView is displaying any action screen (Stand Up, Walk, Sit Down), EksoNR times out after 90 seconds of no button activity and returns to the Home screen. As a safeguard after such a screen timeout, EksoNR requires that a physical therapist first hold and then press a button before the device enables an action.



Expandable Menu

- Submenus accessed through the Expandable Menu icon (≡) in the upper right corner of the **Walk** screens.
- Quick Settings Menu** provides access to frequently adjusted settings while in **Walk** mode.
- PreGait Menu**
 - Evaluation Mode
 - Eval–Right/Eval–Left: Evaluation Mode for Right leg and Left leg.
 - Weight Shift/Step in Place
 - Weight Shift is available in Initial Training.
 - Step in Place is not available until Advanced Training.
 - Squats
 - Squats not available until Advanced Training.
- EksoOutcomes**
 - Allows the clinician to collect a walking test in EksoNR. All EksoOutcomes results are editable and viewable in the statistics menu.
 - Walking test options include:
 - 10-meter walk test
 - 2-minute walk test
 - 6-minute walk test

Statistics Screen

- Accessed through the  icon on the right menu bar.
- Provides summary statistics of individual training session.
- Data include: **Walk Time**, **Up Time**, and **Steps**.
- Detailed feedback scores for each leg; scores provide averages for patient's last 120 steps.
- Symmetry graphs for step length and swing time.

NOTE: The EksoNR clears data when the device is powered OFF; therefore, retrieve session data prior to powering OFF.

NOTE: Data is available on EksoPulse if failed to record data or data lost during a device error.

About Screen

- Accessed through the  icon on the **Home** screen.
- Contains device-specific information, such as:
 - Screen setup and clock setup through the **Control Panel**
 - Device Serial Number and Software version
 - Left and right battery charge level
 - Total device step count

9. Evaluation and Measuring for Fit

WARNING: Each patient needs to be thoroughly evaluated, measured, and screened to determine appropriateness for EksoNR use. Physical therapists need to evaluate patient strength, range of motion, spasticity, skin integrity, and mobility. Failure to adequately evaluate a patient for appropriateness for EksoNR use could lead to patient injury, poor gait quality, and/or damage to the EksoNR. Accurate range of motion assessments are essential when determining appropriateness for EksoNR use.

EksoNR Evaluation

- Goal is a thorough, yet concise, evaluation to determine if it is safe and appropriate to proceed with an EksoNR training session.
- Not intended to replace a comprehensive physical therapy evaluation.
- Complete the entire evaluation even if screen failure is identified, as this can help to determine if future use may be appropriate.
- Typically completed in 20 to 30 minutes.

Patient History

- Review onset and details of injury.
 - Identify other concurrent injuries.
 - Identify any previous surgical interventions.
- Review immediate post-onset health (for example, skin integrity, infections).
- Review general health prior to and since injury.

Functional History

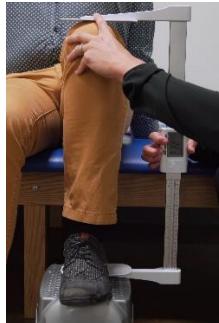
- Transfer function
- Standing program
 - Orthoses and assistive device used.
 - Frequency, distance, deviations, and physical assistance required
- Cognitive screen
 - Assess gross ability to comprehend verbal cues and new learning.
 - Should have the ability to clearly express pain.

Physical Evaluation

- Gross assessment of strength, range of motion, and spasticity/tone.
- Detailed assessment of critical range of motion measurements.
 - **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 equal to or less than 12° knee flexion contracture.
 - If knee flexion measurement is 12° or less, physical therapist can program this knee flexion angle into EksoNR to achieve patient's neutral standing ankle range of motion in device.
 - **Hip extension:** Patient must have equal to or less than 17° hip flexion contracture.
 - If contracture is 10° or more, evaluation mode should be used.
- Qualitative assessment of pelvic posture and lumbar mobility.
- Check skin integrity of sacrum, tibias, and any other areas of concern.

Measuring for Fit in EksoNR

Hip width, upper leg length, and lower leg length are taken for each patient. Ekso Bionics provides a measuring caliper. The physical therapist converts the initial measurements into EksoNR Values using the conversion chart. These converted values are the adjustment values for the EksoNR. 2. Record the measurements on *Form 2: EksoNR Sizing Log* in the Patient Measurement fields.

| MEASUREMENT | POSITION | DESCRIPTION |
|---|------------------------------|---|
| Hip Width  | Standing (if able) or Supine | <ul style="list-style-type: none"> Align pelvis for neutral rotation/obliquity. Align hips in neutral rotation/abduction. Place measuring tool at greater trochanters. Maintain alignment of measuring tool over greater trochanters. Apply pressure to compress adipose, if necessary. Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment. Read measurement tool on screen. |
| Upper Limb Length  | Supine | <ul style="list-style-type: none"> Flex hip to approximately 90° and have patient rotate away from side to be measured. Place lower arm of measuring tool under patient leg in line with femur. Patient returns to neutral pelvis posture. Position hip in 90° of flexion with knee resting in maximum flexion. Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment Read measurement tool on screen. |
| Lower Limb Length  | Sitting | <ul style="list-style-type: none"> Place foot on step stool; patient must wear the shoes to be used during EksoNR walking sessions. Position leg with hip in >90° flexion so that knee joint is higher than hip joint. Align tibia to vertical and place measuring tool under heel. Maintain vertical alignment of measurement arms by avoiding overpressure at upper attachment. Read measurement tool on screen. |

Conversion to EksoNR Values

- Use *Form 3: EksoNR Sizing Conversion Chart* to convert measurements to EksoNR values.
- Values in the conversion chart are starting points for segment lengths and hip abduction settings.
- Change and adjust values, as necessary, only after a thorough visual assessment of joint alignment when the patient is fitted to the device.
- Upper leg length discrepancy must be ≤ 0.5 in. (1,3 cm).
 - Select the EksoNR value in the middle of the Left/Right conversion value for discrepancies ≤ 0.5 in. ($\leq 1,3$ cm).
- Lower leg length discrepancy must be ≤ 0.75 in. (1,9 cm).
 - Use a shoe lift on shorter leg and set the EksoNR value to the longer conversion value for discrepancies ≤ 0.75 in. ($\leq 1,9$ cm).

IMPORTANT: Final assessment of EksoNR fit and safety for each patient must be determined by the Ekso Bionics-certified physical therapist.

Screening Form

- Use *Form 4: Patient Screening* to answer the screening questions.
- Answer all questions YES or NO first.
- Comment on reasons for NO.
- Develop a plan for each NO to determine if it is safe to proceed with EksoNR walking.

10. Preparing to Walk

Positioning of the EksoNR

EksoNR can be set up on a chair or mat. A chair is optimal as it provides a backrest for stability of device during donning. A chair is required when standing with crutches, to allow for correct crutch placement during sit-to-stand transitions. When preparing to stand with crutches, the patient must place the crutches out and behind their body; this is not possible when sitting on a mat table.

Chair Selection

- Solid chair (i.e. not folding) without armrests or wheels.
- Tall, solid backrest.
- Seat Height: recommended between 18 to 20 in. (46 to 51 cm). Various height chairs may be used for taller or shorter patients to optimize positioning and sit/stand transitions
- Be cognizant of chairs that may tip forward if person performs an excessive forward lean.

EksoNR Positioning

- Place the EksoNR seat cushion (optional) and **posterior sling** on the chair with U-shaped loop positioned toward the front edge of chair and EksoNR legs abducted.
- Place the EksoNR device on the chair with both hip motors positioned on the seat.
 - Press the silver **Hip Release Lever** and abduct the legs to approximately 45° to provide clearance for sitting.
 - Internally rotate one EksoNR leg to move hardware below the seat surface and out of transfer path in preparation for patient transfer.



Donning the EksoNR

Refer to laminated Ekso Reference Card for the Quick Donning Guide.

Donning of the EksoNR should be performed with the patient and the EksoNR sitting in an upright, neutral posture.

Donning the EksoNR should be done from either a mat table, a sturdy padded chair, or a sturdy chair with the seat cushion provided that can support both the EksoNR and the patient.

A spotter must be present during all transfers.

Prior to Patient Transfer

- Place the Posterior Sling on the chair, glossy side up with loop facing forward.
- Sit the EksoNR in the chair with device legs abducted.
- Adjust the EksoNR to appropriate patient settings.
- Press the Power button on the back of the EksoNR.
- Select appropriate Patient ID
- Program patient settings and set legs in Legs Free Mode
- Have the patient transfer to the chair.

NOTE: Patient should not use EksoNR legs to stabilize for transfer. Spot patient closely to prevent hitting the EksoNR motors or other parts during transfer.

Securing the Legs in EksoNR

- Reposition EksoNR leg so that both legs are abducted slightly wider than patient's legs.
- Secure one leg at a time.
- Internally rotate hip and align foot into foot binding with foot back against heel stop.
- Position leg inside shin and thigh supports
 - Extend knee or have patient posteriorly rotate the ipsilateral pelvis to assist with positioning patient's leg within the EksoNR leg.
 - If the thigh support causes *too much pressure on the thigh*, check to ensure the EksoNR hip joints align with the patient's greater trochanters.
 - Raise the EksoNR to align the EksoNR hip with greater trochanter by hand using the backpack lift technique.
 - After aligning EksoNR hip joints with patient, adjust the thigh supports via internal or external rotation as needed to maintain close contact with thigh.



Note: Thigh support should remain at most proximal end of EksoNR upper leg. White indicators for upper leg measurements should remain fully visible.

- Smooth any pant leg wrinkles that are under the shin support.
- Secure all leg and foot straps.
- Repeat for the other leg.

Completing EksoNR Donning

- Adduct legs until locked in neutral.
- Ensure patient is sitting upright in neutral pelvis posture and EksoNR is upright.
- Verify alignment of hip joints with the patient's greater trochanters.
- Raise the device manually, if needed, using the backpack lift technique.
- Adjust the lumbar support position and inflation to ensure optimal lordosis in spine.
- Secure torso pad – lower straps first, then upper.
- Put on backpack straps.
 - Adjust upper length of backpack straps if needed to align blue piping of strap vertically along patient's torso.
- Fasten chest strap and tighten backpack straps.
- Secure and position **posterior sling** by looping the circular straps around the hip motors.
- Passively move each leg through the patient's available range of motion to ensure proper alignment and fit.
 - Visual check of joint alignment is the best method for confirmation.
 - Passive range of motion here may help detect mechanical binding if EksoNR lower leg is too short.
- Enter patient settings into controller for each session and perform safety checklist.



The patient's seated posture impacts their alignment in EksoNR during setup as well as their standing posture. The picture below shows good seated posture for donning. *Prior to securing the torso pad and backpack straps, make sure both the patient and the EksoNR are seated upright.*

If a patient is resting in a posterior pelvic tilt and a curved trunk, they may be tightened into this posture when the physical therapist secures the straps. This may lead to unnecessary extra pressure through the trunk in both sitting and standing, and suboptimal alignment in standing.



Before Each Patient Session:

- Verify the patient's blood pressure is stable prior to donning EksoNR (if area of concern).
- Verify the battery level is sufficient prior to operation.
- Check that both hip abduction angle and hip width settings are symmetrical.
- Check to ensure the free hip abduction feature is locked or set appropriately for the patient.
- Check that the leg length settings are symmetrical for the upper and lower leg.
- Check all joint alignments between the EksoNR and the patient.
- Check to ensure all straps are fastened securely on the patient.
- Check to ensure that the hip abduction joints are locked in place.
- Check to ensure the bilateral ankle settings are appropriate for the patient.
- Verify correct positioning and placement of the posterior sling.
- Verify the EksoNR programming and level of assistance (Bilateral/2Free/Right-Affected/Left-Affected) are correct for the patient.
- Verify the assistive device has been properly adjusted.
- If the arm sling is used, ensure the affected arm is sufficiently protected during sit-to-stand transition.
- Make sure that there is a clear way to communicate the patient's needs.
- Remember to perform a visual check after standing.

After Each Patient Session:

- Take the patient's blood pressure (if area of concern).
- Document all session data in the patient's file.
- Turn OFF the EksoNR.

Adjusting The Ekso With a Patient Seated Or Standing in the Device

When assessing joint alignment, if Ekso and patient's joints are misaligned, these can be adjusted in a sitting position with patient in the device. In sitting, loosen screws as usual to adjust leg segments. To adjust upper leg, slight rotation in and out may aid in adjusting. To adjust lower leg, knee extension may aid in lengthening limb segment while knee flexion with patient leaned forward and weightbearing may aid in shortening limb segment.

Leg Segment Adjustments in Standing

At times, the physical therapist may have to make an adjustment while the patient is standing in the EksoNR. Such adjustments always require two people—one to support the patient safely, and one to make the needed adjustments.

Only one EksoNR part should be adjusted at a time.

For leg segment adjustments, loosen screws as little as possible to maintain sufficient friction between the EksoNR adjustable parts to continue to support the patient. Always use the proper tool for an adjustment.

- The person acting as the spotter should stand behind the patient to support and steady them by holding the torso handles.
- The physical therapist uses EksoView to direct the EksoNR to Stand Still mode
- Instruct the patient to shift their weight in the direction relevant to the adjustment (for example, weight shift to the right side, if the EksoNR lower left leg needs to be lengthened).
- Loosen screws just enough to minimally move—but not freely slide—the appropriate EksoNR piece(s).
- Adjust and align.
- Tighten screws.
- Confirm alignment.

Hip Width or Abduction Adjustments

For hip width or abduction setting changes, the patient can be standing with equal weight through both legs. Using the driver, adjust one side at a time.

Ankle Stiffness Adjustments

For ankle stiffness setting changes, have the patient place the desired foot forward and shift weight slightly backward to make sliding the handle easier. Alternately, the patient can stand with feet in neutral alignment and lean slightly back onto the person guarding the patient from behind, creating closed-chain plantar flexion.

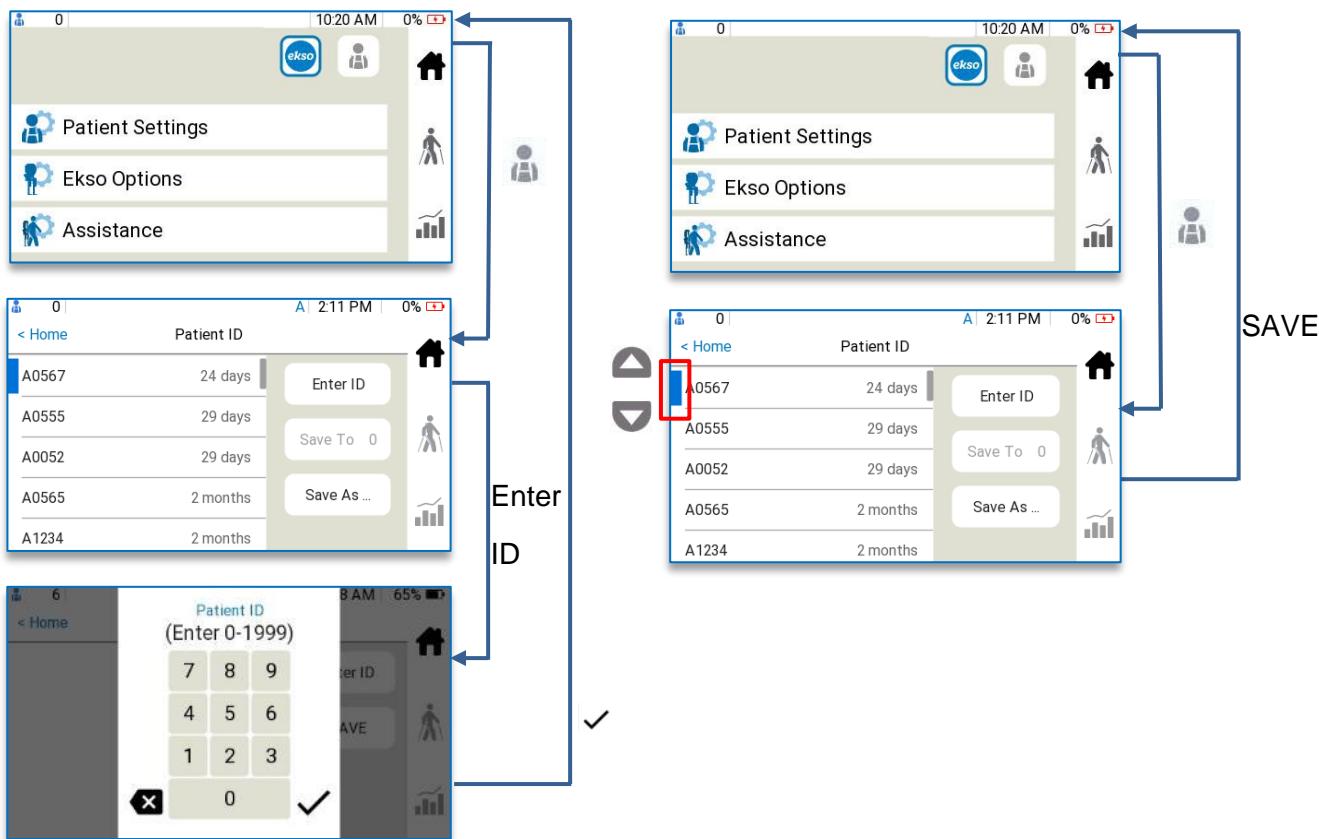
Patient ID

Patient identification (ID) numbers enable the EksoNR to save the last values set for a patient in both the **Patient Settings** and **Ekso Options** menus. **Assistance** values will not be saved. When an ID number is used, the EksoNR saves all patient settings automatically at the end of a session.

NOTE: EksoPulse transmits EksoNR data to aid in technical support and patient progress tracking. A *Patient ID number should be set up for each patient and entered at the start of each session to optimize this feature.*

To Enter>Select Patient ID:

- Touch  icon to select patient.
- Touch Enter ID button and type a new patient ID or select a patient ID from the displayed list
 - NOTE:** The Patient ID should be entered/selected before proceeding with the patient setting programming. (Settings may be saved prior to powering OFF if patient ID is not created initially.)
- Enter a new Patient ID or select an existing Patient ID:
 - Enter a new patient ID by doing the following:
 - Tap the Enter ID button.
 - Using the virtual keypad, enter the desired ID number.
 - NOTE:** An ID number may be between 0 and 1999.
 - Tap the ✓ on the virtual keypad to confirm the ID number entered.
- Select an existing patient ID from the list of 20 most recent ID numbers
 - Use the scroll bar if necessary.
 - Tap the **Save** button.
- The **Home** screen displays the Patient ID in the upper left corner.



The system requires review of the values/choices in the **Patient Settings**, **Ekso Options**, and **Assistance** menus prior to walking.

- When a *new* ID number is entered, the EksoNR supplies default values for the **Patient Settings** and **Ekso Options** menu choices.
- When an *existing* ID number is entered, the EksoNR loads all the **Patient Settings** and **Ekso Options** from the most recent walking session.
- Regardless of new or existing ID, the physical therapist must enter new or accept the default values for the **Assistance** menu settings.

NOTE: Once set, the “Review Settings” message clears.

Manually Save Patient Settings

By default, the EksoNR automatically saves settings at the end of a patient session. If desired, the settings can be saved earlier, by doing the following:

- Go to the **Patient ID** screen.
- Tap the **Save to #####** button, where ##### is the current Patient ID.

NOTE: Alternately, the **Save As** button can be tapped to save the settings to a different Patient ID.

- A “*Settings Saved*” message displays.

Choosing Programming to Maximize Therapeutic Goals

To begin each session, a physical therapist must choose and program each patient-specific setting. To determine the desired mobility and patient interaction to best facilitate the goals of a session, one must choose:

- **Assistance Mode:** Which legs are trajectory-controlled.
- **Step Initiation Program:** How the EksoNR steps are initiated, and how patient may contribute.
- **Swing Assistance:** How the motors facilitate the swing phase.
- **Stance Support:** How the motors facilitate the stance phase.

The decision of which combination to use for each patient is determined based on the patient evaluation and the desired goals of each session. Options may be changed throughout each session, depending on the physical therapist's intentions with each session.

11. Sit-to-Stand

NOTE: Initial descriptions for guarding during mobility skills include language as indicated during an Initial Training, with physical therapists learning in pairs. These two-person techniques may also be used when guarding a patient who is:

- Performing mobility skills for first time
- More involved
- Heavier
- Larger
- Easily distracted

Or in any other appropriate situation when primary physical therapist determines need for second-person assistance

Standing in the EksoNR requires some amount of physical contribution from the patient. If able, the patient should push through their arms and/or legs to assist. Patients who have one upper extremity that is less functional than the other, or nonfunctional, may still effectively participate in the sit-to-stand transition. The patient should be encouraged to participate in the transition. Physical therapist should take care to determine optimal positioning of the impaired upper extremity. After assessment, the physical therapist decides if it is appropriate for the patient to use the arm to contribute to the transition.

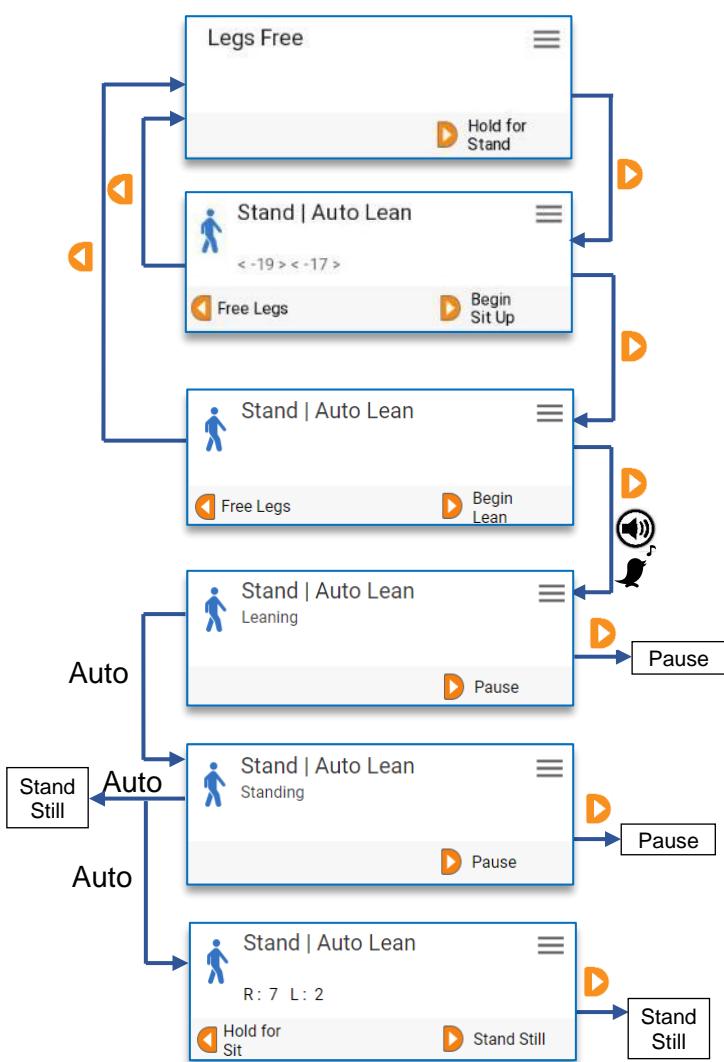
There are two program options for sit-to-stand transition:

- Auto Lean (default)
- Manual Lean

NOTE: Prior to standing, ensure patients feet are positioned between -15 to -20° as indicated on EksoView

Auto Lean

- Provides trunk stability to the patient by controlling the entire motion of the transition from sitting upright, leaning forward, and standing.
- Three-phase motion that requires two button pushes on the Controller to complete the action.
 - Sit upright phase: Seats patient upright at 90° of hip flexion.
 - First button push.
 - Lean and stand phases: Transition from leaning to standing.
 - Second button push begins leaning phase.
 - Automatically transitions from leaning phase into standing phase. The leaning phase is indicated by three beeps, and then a chirp indicates the transition to stand.
 - Patient pushes to stand *at the same time* device transitions to standing phase.



The **Auto Lean** sit-to-stand transition has *two distinct phases*, each activated by the **D** button

Begin Sit Up (Phase One).

- First press of the **D** button.
- This provides trunk support to patients by locking the EksoNR hips at 90° and knees at their position.
- To progress to the next phase, press the **D** button again.

Leaning/Standing (Phase Two).

- Both the **Leaning** and **Standing** phases last the amount of time set as Stand Time (3.5 seconds at default).
- During the **Leaning** phase, a total of four (4) tones—three (3) beeps and a chirp—signal the timing for the patient. The patient must keep their body weight forward and be ready to push themselves forward and up to maintain balance as soon as the chirp sounds and the **Standing** phase begins.

- Patient position:
 - Ensure feet are slightly behind knees.
 - Controller states degrees of current knee flexion angle from vertical; recommend -15° to -20°.
- Instructions to patient:
 - During lean phase, patient should lean forward with the device and not resist the forward lean.
 - When the physical therapist indicates it is time to beginning standing, the patient should push through the assistive device to aid in transition.
 - Keep body weight forward over feet while pushing up.
 - Physical therapist may need to assist this; patient can actively work on this as well.
 - Once standing, reposition assistive device to find a relaxed balance position.
- Physical therapist's cueing and handling:
 - Physical therapist stands alongside of patient.
 - If two people are required, each person stands on one side of patient.
 - Lead physical therapist has one hand on torso handle and one hand holding the Controller.
 - If two-person assist is needed to aid with stand, second physical therapist has one hand on **torso handle**.
 - Lead physical therapist holds  button to put EksoNR in action screen ().
 - Ensure the patients feet are positioned between -15° to -20°.
 - Lead physical therapist presses the **Begin Sit Up**  button to initiate upright sit at 90°.
 - Lead physical therapist provides verbal cueing to indicate when leaning phase begins, and when transition to standing occurs.
 - Lead physical therapist presses the **Begin Lean**  button to initiate leaning and standing transition.
 - Physical therapist provides verbal cueing, "Leaning now – 3, 2, 1 – Stand now."
 - Ensure patient pushes to stand at the same time the device transitions to stand.
 - A patient trying to stand early—or late—leads to ineffective stands and loss of balance.
 - Encourage the patient to stand at the same pace of the EksoNR (default is 3.5 seconds).
 - Physical therapist(s) work to maintain patient's body weight over base of support.
 - Emphasize a balanced stand technique as you would in normal sit-to-stand transitions.
 - Control errors outside of base of support early.
 - Typically needed to assist with keeping patient forward over feet when patient is newly learning.
 - Lifting of patient is rarely required.

Standing in EksoNR with a Walker – using Auto Lean Program



***Position at end of
“Begin Sit Up”, with
hips locked at 90°. One
hand up, one hand on
lower handle.***



***Leaning phase
positioning that starts
with “Begin Stand.”***



***Automatic transition
into standing, while
maintaining balance
over tibias.***

Follow instructions for Auto Lean Stand above with the following modifications:

- Patient position:
 - Hands on walker with elbows up.
 - If using walker with two-level handles, place stronger hand on lower handle, and other hand on higher handle to increase leverage with push to stand.
- Instructions to patient:
 - Once standing, roll walker forward slightly to find a relaxed balance position.

Standing in EksoNR with Crutches– using Auto Lean Program

The **Auto Lean** Stand program should be used when a person is using crutches to complete a sit-to-stand transition. The leaning phase gives the patient time to correctly position their crutches to prepare for the stand transition

Follow instructions for Auto Lean Stand above with the following modifications:

- Patient position:
 - Position crutches out to side, in preparation to pull in during leaning.
- Instructions to patient:
 - Draw crutches in as close as possible during the leaning phase.
 - Crutch tips must end in line with hip joints.
 - Elbows point backward and up.
 - Typically ask patient to focus on physical therapist cues rather than device sounds.
 - Patient pushes self forward and up through crutches when cued to stand.
 - If crutch tips end up in front of hip joint, this results in patient pushing themselves backward when trying to press through crutches.
 - Pushing before or after transition occurs may lead to loss of balance and less successful stand.
- Physical therapist's cueing and handling:
 - Lead physical therapist stands to one side of patient.
 - Out of way of crutch movement.
 - Close enough to aid with body weight transition forward, if needed.
 - Second physical therapist stands (or sits) in front of patient.
 - Most helpful when patient is new, to aid with decreasing fear of coming too far forward.
 - May have best view of crutch tip placement during new patient learning phase.
 - Remind patient to drift crutches forward to establish balance in standing.
 - Crutches in line with feet lead to instability in stance.



Seated upright at 90°, crutches behind, waiting to be pulled in line with hips.



Crutch tips in line (or just behind) hip joints, ready to push forward and up at end of lean phase.



Pushing forward with optimal alignment, keeps center of mass balanced over tibias.



Balanced with crutches repositioned in front of feet for stability.

Standing in EksoNR with a Cane– using Auto Lean Program

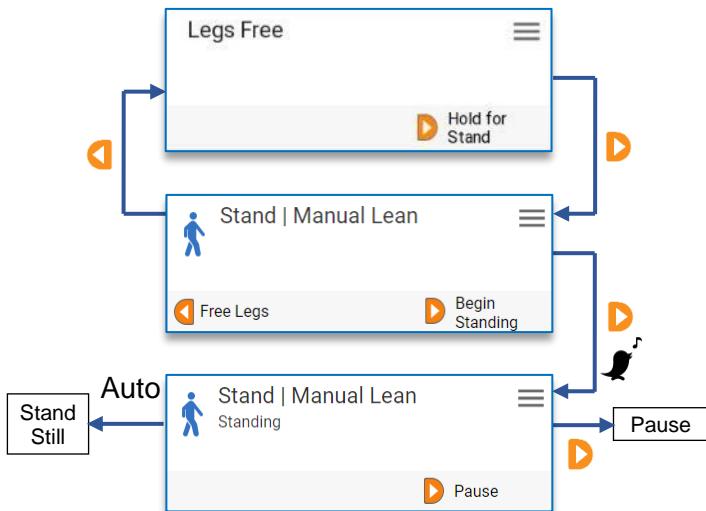
Follow instructions for Auto Lean Stand above with the following modifications:

- Patient position:
 - Position cane on the patient's strong side and slightly diagonal.
 - Instruction to patient:
 - Push down on cane when rising to stand
 - Physical therapist's cueing and handling:
 - Second physical therapist has one hand on the far **Torso Handle** and the other hand holding the weak upper extremity if necessary.
 - The weak or hemiparetic upper extremity is held with the elbow flexed and out to the side during sit to stand to prevent the arm from being pinched during hip flexion.

Manual Lean

- Requires patient to already be leaned forward before physical therapist begins action with Controller.
 - Stand begins from forward leaned position.
 - Patient must maintain weight forward and push to stand when directed.
 - One button push on the Controller; the device emits only a chirp as it begins transition to stand.

NOTE: With any type of stand program and assistive device, the patient is always expected to contribute some assistance to push up to stand.



The **Manual Lean** sit-to-stand transition emits a chirp and begins standing immediately upon pressing the  button

To safely stand in this program option, the patient must be positioned with their body weight leaning forward in preparation to stand before the action is initiated on EksoView. The patient then maintains their center of mass over their feet during transition.

- Patient position:
 - Forward trunk lean—patient's trunk should be over their lap, able to see down toward toes.
 - Ensure feet are slightly behind knees.
 - Controller states degrees of current knee flexion angle from vertical; recommend -15° to -20°.
- Instructions to patient:
 - Lean forward first.
 - Maintain body weight over feet throughout standing transition.
 - Push down on assistive device to assist with standing.
 - Once standing, may need to adjust assistive device to find a relaxed balance position.
- Physical therapist's cueing and handling:
 - Physical therapist stands alongside of patient.
 - If two people are required, each person stands on one side of patient.
 - Lead physical therapist has one hand on torso handle and one hand holding the Controller.
 - If two-person assist is needed to aid with stand, second physical therapist has one hand on **torso handle**.
 - Lead physical therapist holds  button to put EksoNR in action screen ().
 - Ensure the patients feet are positioned between -15° to -20°.
 - Lead physical therapist provides verbal cueing to indicate when standing will begin.
 - Lead physical therapist presses  button to initiate Stand.
 - Physical therapist(s) and patient work to maintain patient's body weight over base of support.
 - Emphasize a balanced stand technique as you would in normal sit-to-stand transitions.
 - Control errors outside of base of support early.
 - Typically needed to assist with keeping patient forward over feet when patient is newly learning

Standing in EksoNR with a Walker – using Manual Lean Program

Follow instructions for Manual Lean Stand above with the following modifications:

- Patient position:
 - Hands on walker with elbows up.
 - If using walker with two-level handles, place stronger hand on lower handle, and other hand on higher handle to increase leverage with push to stand.
- Instructions to patient:
 - Once standing, may need to roll walker forward slightly to find a relaxed balance position.



Forward leaning position for standing in EksoNR with hands on walker.

Maintaining center of mass over base of support while pushing down on walker.

Standing in EksoNR with a Cane – using Manual Lean Program

Follow instructions for Manual Lean Stand above with the following modifications:

- Patient position:
 - Position cane on the patient's strong side and slightly diagonal.
- Instructions to patient:
 - Cane positioning on right or left is the same as instructions for Auto Lean Programming.

Standing with Unilateral Upper Extremity Function

If the arm cannot or should not be positioned on the walker handle to push to stand, the arm should be *held out of the way of the forward lean to eliminate the chance of the arm being pressured* between the torso and the knee motor. Once standing, the appropriate positioning of the impaired limb can be performed in preparation for walking.

Either Stand Program may be utilized, based on patient goals and ability to coordinate.



The **Auto-Lean** program is a nice option to assist with the transition forward. Often, a patient may better participate in this forward lean if they can practice a forward lean before engaging the Stand Program and understands the required motions.

Sit-to-Stand Preparation with Sling

- May best be performed with arm in neutral rotation or held out to side.
- Done to decrease chance paretic arm may be pressed into knee motor with forward lean.
- Positioning for walking managed once standing.
- May need additional person to manage arm during sit to stand.



12. Standing Visual Check

After Stand transition is complete, a visual inspection of the patient from the front view is essential prior to ambulation to ensure optimal set up.

- Confirm alignment of hip and knee joints.
- Confirm proper hip width setting.
- Confirm security of all straps.
- Ensure straps are not binding or pinching patient.
- Ensure **Abdominal Pad** is low, capturing abdomen, and secure.
- Adjust **Torso Pad** and backpack straps, if necessary.
- If it is the patient's first time standing, determine resting angle of ankle joint.
- Once standing, if **Assistance** is set to **Right-Affected** or **Left-Affected**, prompt the patient to shift weight right for **Right-Affected** or left for **Left-Affected**. If **Assistance** is set to **2Free**, after standing, prompt the patient that both legs will go free.
- Press the  button to initiate the **Assistance** option specified.

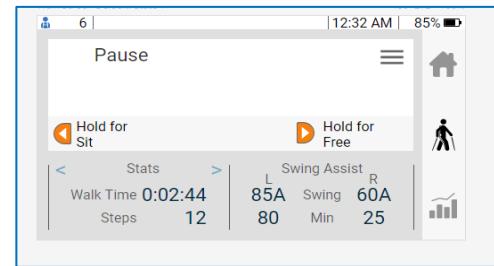
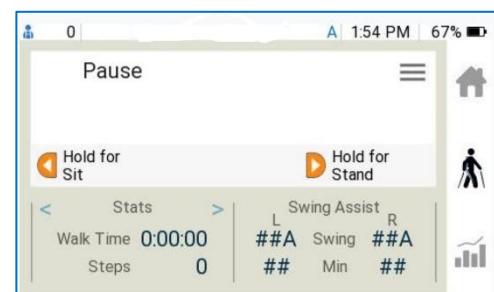
13. Pausing a Sit-to-Stand or Stand-to-Sit

During a sit or stand maneuver, the physical therapist has the option to **Pause** the EksoNR in the device's current position, locking the hip and knee joints. The **Pause** feature is normally used if the physical therapist sees an unsafe situation develop or if the patient complains of fear or pain during standing or sitting. The same button that starts the motion also pauses the motion.

- During **Stand Up**, press the  button or the  EksoNR **Stop** button to **Pause**.
- During **Sit Down**, press the  button or the  EksoNR **Stop** button to **Pause**.

Procedure For Pausing

- Lead physical therapist maintains thumb position above the ▶ throughout the sit-to-stand transition.
- Observe patient for cues of pain or need to stop—words or expressions.
- Press the ▶, or the ⚡ (EksoNR Stop button), to **Pause** sit-to-stand transition.
- Pause holds current patient position.
- Maintain patient balanced over feet.
- This often requires pushing body weight forward.
- Read Controller screen for option and determine best choice based on reason for pausing.
- If paused when the EksoNR is closer to a full stand, the options are:
 - ◀ Hold for Sit
 - ▶ Hold for Stand
- If paused when the EksoNR is closer to a sit, the options are:
 - ◀ Hold for Sit
 - ▶ Hold for Free
 - Never select **Free Legs** if patient is not in contact with chair.
 - Selecting **Free Legs** causes an immediate release of the EksoNR knee and hip joints, resulting in unsupported EksoNR legs. The patient must be guarded appropriately so that this action does not result in an uncontrolled fall.



Automatic Pause

To complete a safe and smooth sit-to-stand transition, the patient must have sufficient trunk lean forward. If the EksoNR torso angle is excessively posterior, the EksoNR automatically switches to the **Pause** state, and EksoView beeps and displays a “*Stand Failed error*” (Error #110). With the EksoNR in automatic **Pause**, EksoView offers two options:

- ◀ Hold for Sit
- ▶ Hold for Free

Only when a patient is seated should **Free Legs** be selected.

14. 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.

The Controller screen may display a **Standing Timeout (Error #111)** after a patient is in the standing position. A warning message and associated warning sound notify the physical therapist that attention needs to be taken. When this message appears, the physical therapist should take the following actions:

- Press  to acknowledge.
- Hold  to continue.
- Note the right knee (**RK**) and left knee (**LK**) values
- Gently press on the EksoNR knee joints to see if the brakes engage.
- If an audible click is heard on both knees, the brakes have engaged.
- Press  for **Stand Still** and proceed with session as normal.
 - 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.
- After an assessment has determined the cause of the **Standing Timeout** and the resolution has been established, repeat the stand. If the stand transition occurs as expected and the EksoNR reaches **Stand Still**, proceed with the session, otherwise repeat steps above to determine the cause of the timeout.

Once the **Standing Timeout** issue is resolved, the patient's walking session may proceed. Failure to correct the cause of the **Standing Timeout** may result in patient injury, decreased gait quality, and/or excessive heat in the knee motors because the patient's knee is not allowing the EksoNR knee to extend to the programmed knee flexion setting.

Likely Causes of a Standing Timeout

- Knee joint malalignment between the patient and the EksoNR knees. Adjusting the EksoNR leg lengths may be necessary to improve alignment. The alignment is best assessed while standing, but if the EksoNR brakes have not locked, the adjustment should be made with the patient seated.
- Knee range of motion restriction beyond the angle currently set for the Knee Flex angle. The physical therapist can increase the angle of the Knee Flex setting to accommodate a range of motion restriction.
- Ankle Clonus/Spasticity. The physical therapist can increase the Stand Time setting to slow the rate of standing.

After making an adjustment or setting change, repeat the sit-to-stand transition to determine if the Standing Timeout has been corrected.

15. Stand-to-Sit

When preparing to sit, ensure that the patient is in front of the chair with approximately 4 in. (10 cm) of clearance between the back of the patient's legs and the chair.

EksoNR offers two **Sit** programs—**Normal Lean** and **Minimal Lean**—for use during stand-to-sit transitions. The physical therapist should use the **Sit** program that is appropriate for the individual patient.

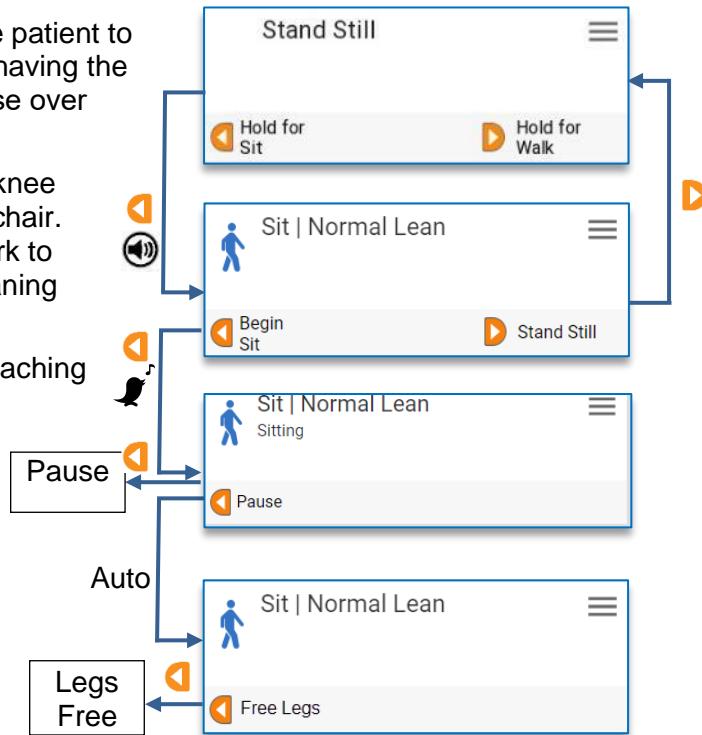
- Switch the EksoNR from **Stand Still** mode to **Sit Down** mode by pressing and holding the  button.
 - If not already in **Bilateral**, EksoView displays a message to push the  button to initiate **Bilateral** and emits two (2) beeps.
- EksoView prompts the physical therapist to initiate sitting and emits four (4) beeps.
- When the patient is ready to sit, press the  button to select **Begin Sit**. The EksoNR emits a chirp and then flexes the knee and hip joints, lowering the patient into the chair.
- EksoView prompts the physical therapist to press the  button to transition the EksoNR to the **Legs Free** mode.

Normal Lean Sit

Normal Lean Sit 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.”

With **Normal Lean**, the EksoNR flexes both the knee and hip joints while lowering the patient into the chair. The physical therapist and the patient should work to keep the patient balanced over their toes and leaning forward while descending in a balanced posture.

The EksoNR will continue to lean forward until reaching the maximum lean angle, and only then will the device sit upright.



- Patient position:
 - Confirm **Sit > Normal Lean** has been selected in **Ekso Options** menu.
 - Position chair approximately 4 in. (10 cm) behind patient's legs.
- Instructions to patient:
 - Balance over feet, with relaxed effort.
 - Center of mass positioned over feet.
 - Maintain weight over feet as device lowers.
 - Patient should descend balanced over their feet.
 - Center of mass maintained over base of support.
 - Patient should bend waist to keep "nose over toes" and bend with the EksoNR.
 - Remind patient to utilize upper extremities to assist with lowering.
 - Inform patient of amount of trunk flexion at point of contact with chair.
- Physical therapist's cueing and handling:
 - Each physical therapist stands on either side of patient.
 - Lead physical therapist has one hand on **Torso Handle** and one hand on the Controller.
 - If two-person assist is needed, second physical therapist has one hand on **Torso Handle**.
 - Lead physical therapist holds the  button to put the EksoNR in **Action** screen ( - Lead physical therapist provides verbal cueing to indicate when Sit will begin.
 - Lead physical therapist presses the  button to **Begin Sit**.
 - Physical therapist(s) help maintain patient's body weight over base of support.
 - Goal: Keep tibias vertical during descent.
 - Patient should work to maintain their bodyweight over base of support with the physical therapist.
 - Emphasize a balanced sit technique as you would in normal sit-to-stand transitions.
 - Control errors outside of base of support early.
 - Spot patient in chair and set the EksoNR in **Legs Free** mode.

Minimal Lean Sit

Minimal Lean Sit keeps the trunk more upright during the descent but puts more balance requirement to the physical therapist to keep the patient stable during transition.

With **Minimal Lean**, the EksoNR does not flex the hips as much as during **Normal Lean**, so the patient does not lean as far forward.

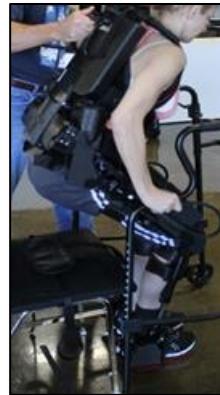
Follow instructions for Normal Lean Sit while keeping in mind that the physical therapist needs to provide more balance assistance during the second half of the transition because the patient's center of mass may be posterior to their feet. The descent may appear to be somewhat fast if the patient is not aided by the physical therapist.

Sitting in EksoNR with a Walker

Follow instructions for Normal Lean Sit.



Attain balance point in standing, with weight balanced. Patient should be able to maintain upright.



During descent, maintain center of balance over feet, keeping tibias vertical. Bend forward while lowering in column.



Once seated, follow path of EksoNR as trunk flexes to 110° before sitting upright.

Sitting in EksoNR with Crutches

To sit safely with crutches, a patient *must* have at least 50° of bilateral shoulder extension. Take care to assess this range of motion initially and recall if the patient has the available range of motion to complete this motion. If the patient does not, simply provide the walker for stand-to-sit transitions.

EKSONR OPERATING MANUAL

Follow instructions for Normal Lean Sit above with the following modifications:

- Instructions to patient:
 - Balance on back edge of standing balance with crutches placed behind body.
 - Center of mass *balanced over heels* versus forefoot.
 - Minimal weight bearing on crutches.
 - While patient maintains upright and balance on back edge of heels, crutches are placed as far back and to the sides as arms allow.
 - Upright balance should not be compromised by arm/crutch position.
 - Patient should be able to hold themselves in this position. (Photo illustrates correct balance point found.)
- Physical therapist's cueing and handling:
 - Second physical therapist stands or sits in front of patient, if needed.



Balance is key.

Patient on back edge of heels, but able to hold self. Crutches wide and back, as far as arms allow, without losing stability.



Patient begins to lower down. Crutch placement of wide and back now holds their balance as buttocks lowers to chair. Stays balanced over tibias.



Lowers easily into chair.

NOTE: Patient has available shoulder extension. EksoNR flexes to 110° to complete sit, before sitting upright.

Sitting in EksoNR with Cane

Follow instructions for Normal Lean Sit above with the following modifications:

- Patient position:
 - Cane at side and slightly in front of patient
- Instructions to patient:
 - Utilize their upper extremity on the cane to assist with lowering.

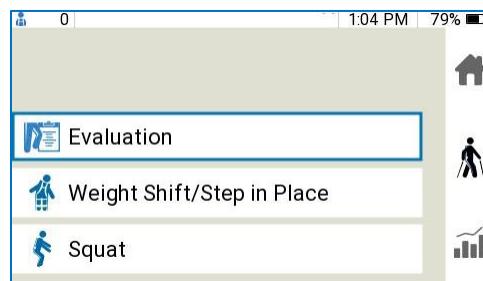
Sitting in EksoNR when One/Both Legs are Trajectory Free

Initiate **Sit Down** mode by pressing and holding the  button. The Controller screen prompts with a message to push  for **Go Full Bilateral** and emits a beep-beep sound. Pushing the  puts the EksoNR in **bilateral stance support** for sitting and straightens the free leg and emits three (3) beeps. When the patient is ready to sit, press  again to **Begin Sit**. At the push of this button, the EksoNR emits a chirp and begins the transition to sit.

16. PreGait

The **PreGait** submenu, accessed through the Expandable Menu icon () , offers two distinct types of pre-walking activities:

- A way to perform a specific hip extension range of motion assessment.
- PreGait exercises using EksoNR in a non-walking mode.



The physical therapist scrolls through the submenu to find desired exercise, then selects using the  button. The touch screen can also be utilized to select the desired activity.

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. This important assessment is made *prior* to ambulation to ensure patient comfort and safety.

NOTE: If a physical therapist chooses to use these evaluation features to assess standing range of motion, the patient *must* have sufficient range of motion to complete a sit to stand/stand to sit action.

The EksoNR trailing limb moves into 10 degrees of hip extension in relation to the patient's trunk angle during walking. Any change to the **Hip Flex** settings increases or decreases this maximum hip extension.

In this standing assessment, the Controller displays and constantly updates the degree of hip and knee motion as the physical therapist moves the patient's free leg during evaluation.

Ekso Bionics recommends that two (2) physical therapists (or one physical therapist and one spotter) conduct any **PreGait** evaluations while using Evaluation Mode to ensure proper spotting and to guard patient safety throughout an evaluation.

When to Use Evaluation Mode:

- At any time when a physical therapist wishes to have a more functional assessment of patient's presentation or tolerance for split leg stance before taking any steps in EksoNR.
- For individuals with *hip flexion contractures* $\geq 10^\circ$, or if concerned about proper hip/spinal mobility during walking.
- For individuals with limited lumbar spine mobility.
- If the patient's upper leg segment is set at zero and their greater trochanter is inferior to the EksoNR hip joint.

How to Use Evaluation Mode:

The PreGait evaluation modes are:

- **Eval-Left:** Full support on right leg; free motion/no support on left leg; allows for physical therapist to perform left hip extension range of motion evaluation. Patient must maintain weight on *right* leg.
- **Eval-Right:** Full support on left leg; free motion/no support on right leg; allows for physical therapist to perform right hip extension range of motion evaluation. Patient must maintain weight on *left* leg.

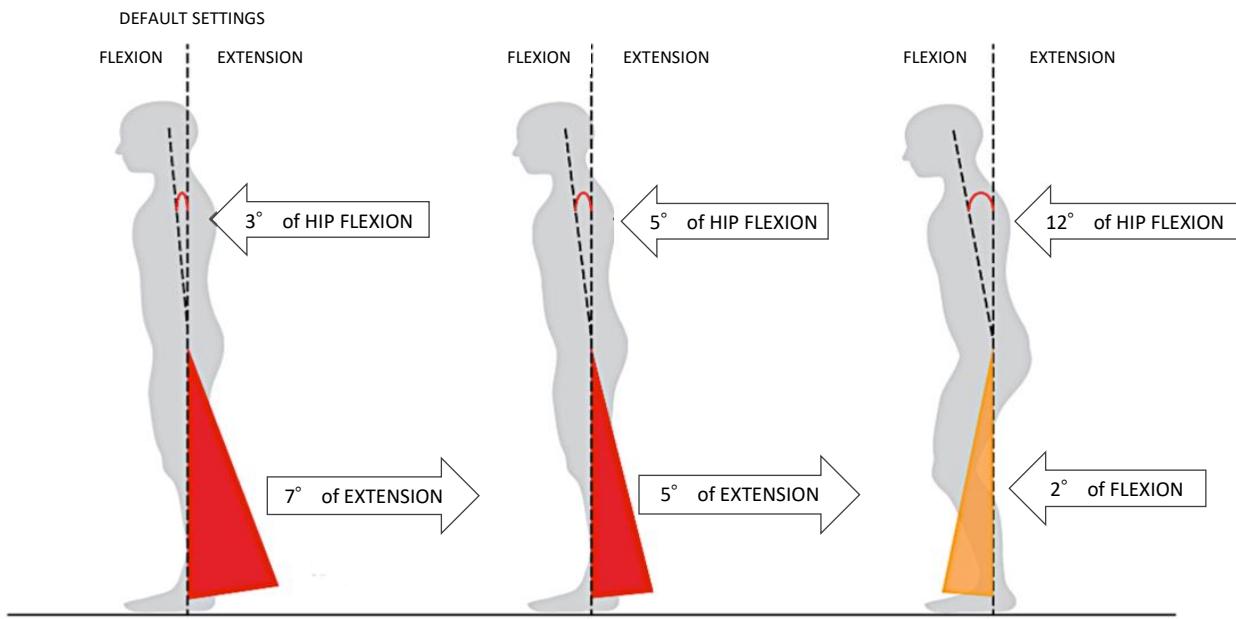
NOTE: Patient must be spotted closely throughout as Eval-Left and Eval-Right sets the selected leg to Free.

- The Hip Flex Reference table on the following page provides a guide for determining an initial **Hip Flex** setting.
- Start by having patient shift weight over opposite leg prior to entering commands on Controller.
- Select either Eval-Left or Eval-Right.
- Once selected leg is unweighted, press the  button to *immediately* free the selected leg.
 - Ensure patient stays weight shifted appropriately off selected leg.
- Move free leg into trailing limb position while viewing Controller screen.
 - Controller screen displays hip and knee angle continuously.
 - Monitor for patient comfort, available end range, trunk posture changes, or other clinical indications of patient's tolerance.
- Use angle measurements on screen to determine best choice for hip flexion based on clinical assessment.
- When assessment is complete, return the tested leg in line with the other leg and Press the  button to **Stand Still**.
 - Motor power is returned to the selected leg that was free.

Hip Flexion Reference Table

All patients should be individually evaluated by a physical therapist to determine most appropriate software settings given individual presentations. Shaded sections indicate it is necessary to use **Evaluation Mode** to determine appropriate patient settings.

10° Arc of Motion at the Hip During Walking



| 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 0° (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 |

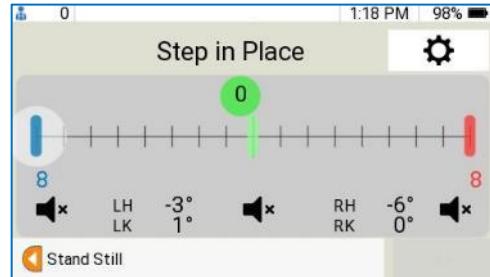
Weight Shift / Step in Place

Weight Shift is feature that allows the physical therapist to set cues—both visual and audio—for learning weight shifting to the left and right and maintaining center.

- The EksoNR puts both legs in **Stand Still**.
- The physical therapist can direct the patient to the desired position for weight shift.
 - Lean in the direction of the desired target
- Once the device has leaned past the centerline, the target on that side may be set by one of the following methods:
 - Press the button to move the target away from the center line. (Increase the number up to 8.)
 - Press the button to move the target towards the center line. (Decrease the number down to 0.)
 - Use the up/down arrows to increase/decrease the target or touch the line to set the target at that location.
- Once a weight shift cue is set, the audio cue chirps to indicate patient has found correct set position.
- The audio indication can be individually enabled or disabled for each lateral target and the centerline position by tapping the respective speaker icon below the horizontal line. The audio cue chirps each time a lateral target is reached and a beep to indicate the center midline.
- The EksoNR Controller screen displays a moving line that tracks the patient's movement during weight shifting. This line can serve as a visual cue for the patient.

Step in Place utilizes the same target setting method as Weight Shift and can be initiated by holding the button for Free Legs.

- Both left and right legs are free of trajectory control. The EksoNR provides trajectory-free stance support while the patient attempts to lift one leg at a time off the ground.
- Allows variety of **PreGait** stepping tasks while providing adjustable, bilateral, and symmetrical stance support in trajectory-free movement.
- Physical therapist must select the Right and Left leg **Swing Assistance** and **Stance Support** values. These may be changed by tapping the Settings icon () in the upper right corner of the Step-In-Place screen.
- Displays hip and knee range of motion during activity.
- Safety of soft stop added to limit amount of knee flexion.



Squats

The EksoNR provides stance support (**Squat Support**) and limits maximum knee flexion (**Squat Angle**) while the patient performs a squat.

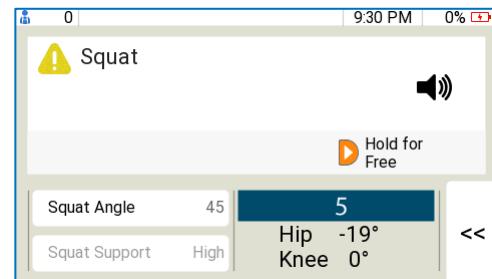
When utilizing the **PreGait** submenu's **Squat** option, the Controller prompts the therapist to make changes to the ankle settings as well as the base of support. To improve balance, leading to greater success while performing squats, make the following adjustments:

- Decrease the ankle spring resistance to 1
- Set the ankle degree towards the positive direction +2
- Widen the foot placement using either the free hip abduction lock or by increasing hip abduction towards the most positive value.

It is important to return these settings back to the patient's original settings before resuming walking activities.

In the **Squats** setting:

- Both left and right legs are free of trajectory control.
- The EksoNR provides trajectory-free **Stance Support** while the patient attempts to perform the squat.
- The EksoNR provides stance support using the **Squat Support** setting and limits maximum knee flexion using the **Squat Depth** setting.
 - The **Squat Support** level may not be adjusted until the legs are free but can be adjusted afterwards at any time.
 - For example, for a weaker patient, **Squat Support** can be set to low during patient's descent and changed to very high to aid with ascent.
- There is an audible beep when the patient achieves the specified squat depth and a second beep when they return to standing.
- During the **Squats** exercise, the EksoNR Controller displays the degree of knee and hip flexion or extension as leg pairs and the number of squats completed.



NOTE: If additional support is required to return to **Stand Still**, the EksoNR **Stop** button will return the EksoNR to **Full Stand Still**.

17. Preparing to Walk

Walking in the EksoNR requires the patient to learn how to shift their weight and balance within the EksoNR. Because EksoNR provides the external stability where it is needed, a patient does not need to hold themselves up or provide excessive upper body motion to unweight and advance their legs.

Patient Handling

- To provide better tactile feedback to the patient, cue and spot from an area that is sensate
 - Shoulders, if mechanically stable
 - Torso
- Device handles should be used only during sit-to-stand/stand-to-sit transitions or when physical power is required for safety.

Practice Finding Initial Balance

- A patient should achieve a balanced resting posture that allows for relaxed upper extremities.
- When patient is weight shifted into correct balance point and the **Ankle Resting Angle** knobs are adjusted properly, they should be able to maintain that position without strenuous physical effort.
- Demonstrate that physical therapist handling can be removed yet patient remains balanced.
- Practice lateral weight shifting:
 - Shift left and hold.
 - Return to center position and hold.
 - Shift to right and hold.
 - Use of the **Weight Shift** option in the **PreGait** submenu may aid with this learning.

During the initial learning process, a patient requires physical assistance and guidance from the physical therapist on how to position themselves and sequence these tasks.

While initially learning to balance and control their own weight shift, a patient may need time to transition through the tasks. Walking in EksoNR is best achieved when a patient knows how to balance and weight shift, and can do so efficiently and quickly, without stopping between each step.

When a patient's step is taken or initiated with their body in the optimal alignment, a natural heel-strike pattern can be achieved.

This is true regardless of the Step Initiation program or the assistive device that is being used.

Choose Step Initiation Program

To set the Step Initiation program, select the desired action in Ekso Options > Step Initiation: FirstStep / ProStep / ProStep+.

- **FirstStep** – Physical therapist initiates stepping action when patient achieves balanced, weight-shift.
 - Begin sessions here to teach patient device interaction and balance.
- **ProStep** – Patient initiates stepping by achieving a forward and lateral weight shift target.
 - Often used for patients who do not have physical strength to initiate swing phase, or once fatigued from participating in swing initiation.
- **ProStep+** – Patient initiates stepping by achieving lateral weight shift target on stance leg *and* unweighting trailing leg.
 - Best used for patients with lower extremity strength who can actively contribute to swing initiation; may be preferred by patient for natural walking pattern and timing.

Set Targets

- To set the **Forward Shift** for **ProStep**, select the desired value in **Patient Settings > Forward Shift**.
- To set the **Lateral Shift** for **ProStep** and **ProStep+**, select the desired value in **Patient Settings > Lateral Shift**.

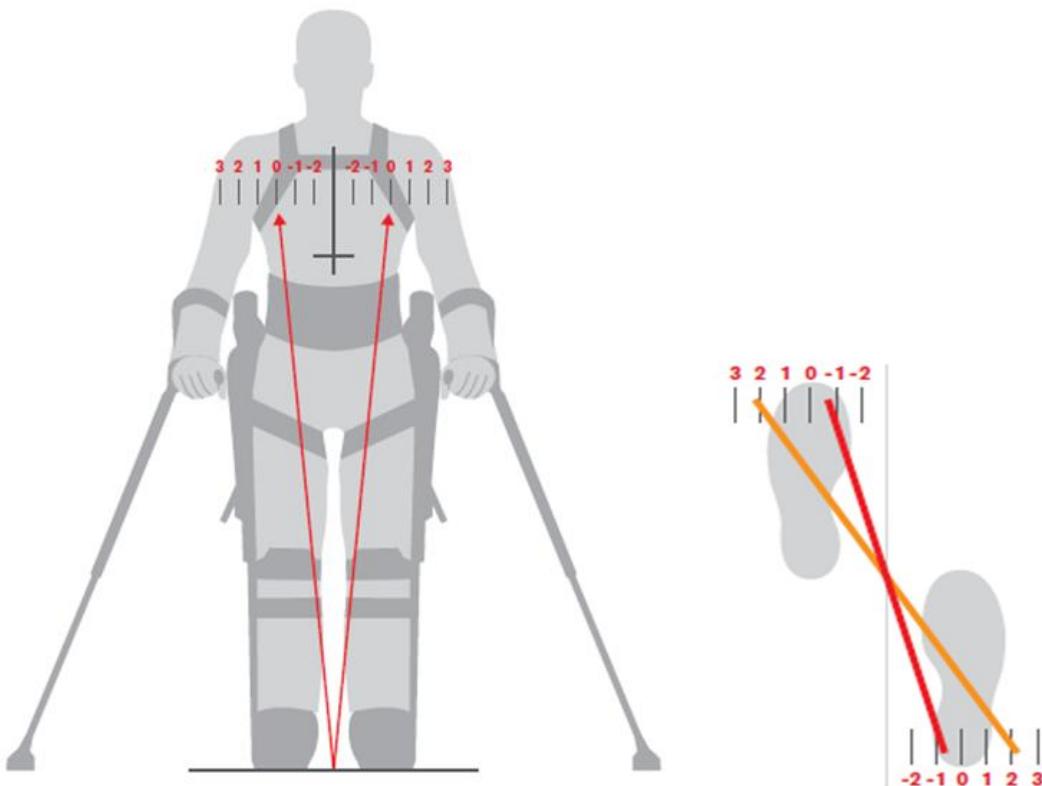
To assist patients in achieving the desired **Lateral Shift** and **Forward Shift**, the EksoNR provides training audio feedback. Select the desired audio action in **Ekso Options > Target Sounds**. The audio options are:

- **Off** – No training sounds are audible
 - Not recommended for new patients or when progressing **Step Initiation** programs.
- **Forward** - The EksoNR emits one beep when the patient achieves the desired Forward Shift.
 - Can be used as a reference for forward weight shifting, once tuned appropriately.
- **Lateral** - The EksoNR emits two quick chirps when the patient achieves the desired Lateral Shift
 - Use this if planning to progress to **ProStep+**.
- **Both** - Turns on the sounds for both forward and lateral target.
 - Use this if planning to progress to **ProStep**.

Training Targets

Training targets have a range of -1 to 3 for Forward and -2 to 3 for Lateral targets.

- Default: 2 Forward, 0 Lateral.
- 0 or negative indicates less forward; 3 indicates more forward.
- 0 or negative indicates more midline; 3 indicates more lateral.
- Achieving the Forward target causes a beep sound.
- Achieving the Lateral target causes a chirp sound.
- Instruct patient to continue to focus on achieving consistent weight shift and balance.

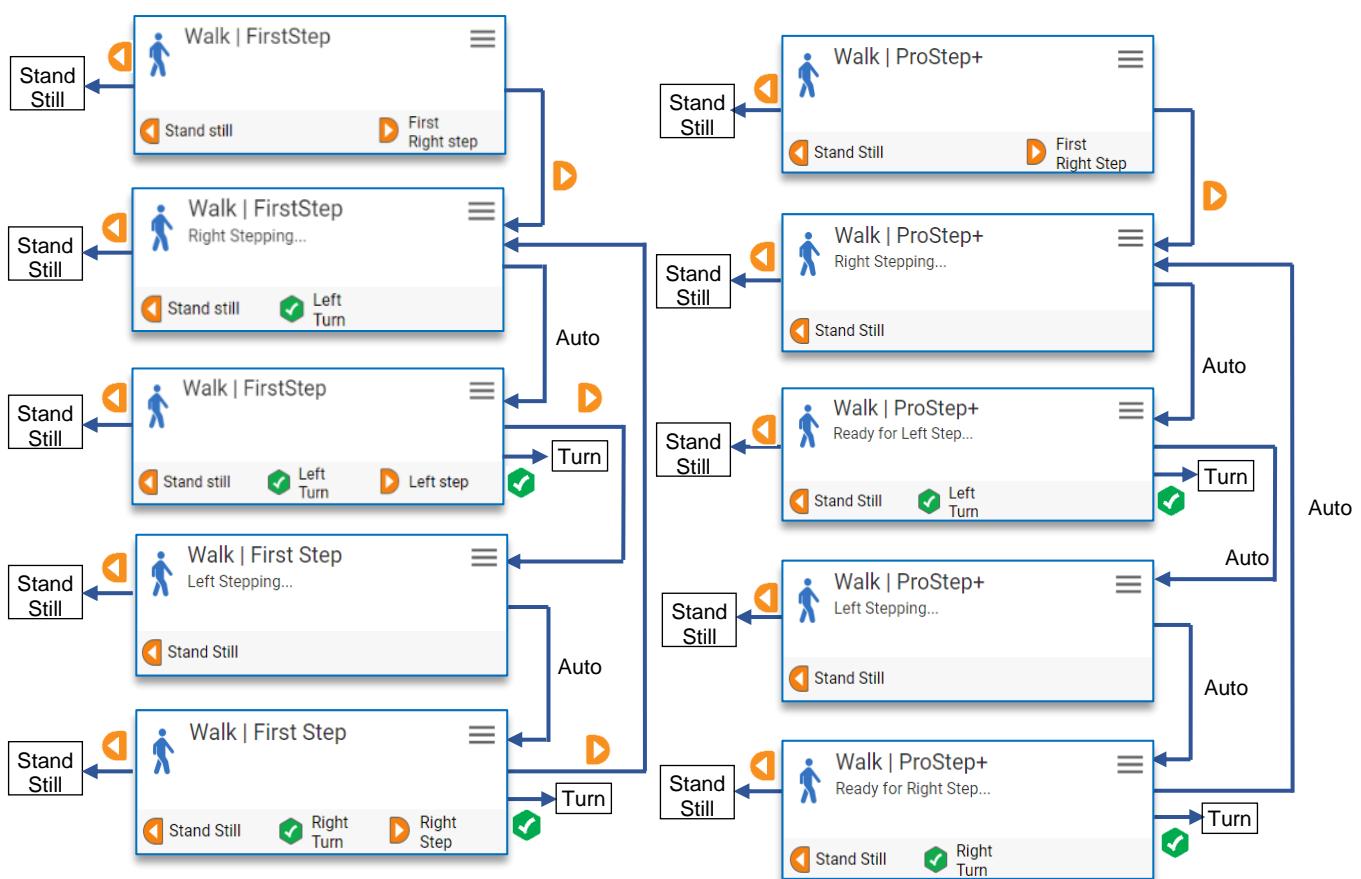


The pictures above demonstrate the lateral target options and how changing this target changes the amount of weight shift required to initiate a step.

18. Walking with a Walker

Initiating Walking In FirstStep

- Press and hold  (right arrow) button with thumb to transition from Stand Still to Walk Mode ().
 - Listen to the device for beeps to indicate the transition.
- Remind the patient of the sequence for walking as needed.
- Move the walker forward.
 - Moving the walker is not necessary for the initial step.
 - Forward walker progression is critical for achieving appropriate forward weight shift.
- Shift weight lateral and forward over stance limb.
 - Initial step is only lateral over the left foot because starting from a neutral stance.
- Step
 - Initial step is always with the right foot.
 - The physical therapist provides the verbal cue for step *not* the patient.
 - Press the  button to initiate each step.
- Target Sounds
 - Set targets for patient as quickly as possible to give feedback to patient.
 - Verify targets with “look good, sound good” methodology to assure appropriate balanced position on stance leg.
- Progress to **ProStep** or **ProStep+**
 - Once training targets are verified, progress to **ProStep** or **ProStep+** as soon as safe to do so.
 - Patients generally learn the device more quickly in these modes.



Initiating Walking in ProStep

ProStep is an automatic stepping program that improves the patient's learning curve and enhances the walking in the EksoNR. **ProStep** allows the patient to initiate swing by achieving the lateral and forward targets that the physical therapist has assessed and determined is appropriate for the patient. As soon as the patient reaches both targets on the stance leg, the swing leg advances. Setting the **Target Sounds** to **BOTH** optimizes this decision-making process. In **ProStep**, the first step is manually triggered—either by the physical therapist through the Controller or by the patient on the **Crutch Interface**. All remaining steps occur by patient reaching both lateral and forward targets on stance leg.

- In Ekso Options menu, change the Step Initiation program to ProStep.
- Press and hold ▶ (right arrow) button with thumb to transition from Stand Still to Walk Mode ().
- Instruct patient for initial step:
 - Right step is always first, when walking in Bilateral.
 - Shift weight to left.
 - Physical therapist triggers first step with ▶ (right arrow) button on Controller.
- For the following steps:
 - Patient shifts weight lateral and forward onto leading stance leg.
 - Achieving both targets on stance causes the next swing to initiate.
- Instruct the patient how to stop prior to beginning walking:
 - Prepare the patient to stop 1 to 2 steps prior to stopping.
 - Following foot contact and while in double limb support, maintain body weight over back foot to avoid weight shift to reach the targets.
 - Physical therapist uses ◀ (left arrow) button to return to Stand Still.
- Patient should move walker fluidly as they progress forward.

Initiating Walking in ProStep+

ProStep+ incorporates the coordination of foot sensors and the lateral target to initiate a step. Once a patient achieves their lateral target, swing limb advancement is initiated by the patient lifting the foot off the ground, releasing pressure from the forefoot sensors.

- In the **Ekso Options** menu, change the **Target Sounds** setting to **LATERAL**.
- Instruct the patient to continue to focus on achieving consistent weight-shift and balance.
- A patient with delayed motor coordination may benefit from cues to lift their leg once they have achieved correct lateral weight shift onto stance leg.
- Press and hold  (right arrow) button with thumb to transition from Stand Still to Walk Mode (.
- In the **Bilateral Mode**, the initial step is always with the right foot.
 - Have patient shift left for initial right step.
- Trigger first right step using the  (right arrow) button on Controller.
- For continued stepping, patient shifts weight to reach lateral target on stance leg and initiates swing.
 - Patient should be guided or taught to reach correct balanced posture on stance leg when initiating swing to maintain optimal upright body posture.
- Patient should move walker fluidly as they progress forward.

19. Walking with Crutches

Unlike using a walker, using crutches with EksoNR affords the patient some ability to provide balance reactions for safety.

To balance easily and safely when standing with crutches, a patient should always place their crutches either in front of or behind their feet. This increases the overall base and allows for easy balance.

If a patient keeps their crutches in line with their ankles, they do not find easy stability. This position requires excessive upper body movement to maintain and the patient does not achieve a quiet, easy balance spot.

Use of crutches:

- May be presented as a preview initially to indicate balance control needed to progress onto crutches, then find success on walker.
- Produces a more natural, fluid gait pattern due to improved patient ability to weight shift.
- May help the patient achieve lateral weight shift more easily.
- Requires patient to balance and understand balance point over forward leg.
- Creates increased challenge to patient balance and coordination.

Instruct and demonstrate crutch walking prior to having the patient walk with crutches. When switching assistive devices, progression back to FirstStep is recommended to allow time to instruct on sequencing the new device. Some patients require repetitions to learn the coordination and the sequencing of crutch use that allows for optimal progression and setup to take the next step.

Finding Initial Balance

- Position crutches in front of feet.
- Help patient position body in neutral position of balanced posture.
- Ensure that upper extremities are relaxed.
 - Upper extremities are not relaxed if base of support through crutches is too narrow.
- Demonstrate handling can be removed, yet patient remains balanced when in correct position.
- Practice lateral weight shifting:
 - Regain balanced standing in center position.
 - Shift left and hold.
 - Return to center position and hold.
 - Shift to right and hold.
- Emphasize use of upper extremities for producing weight shift.
- The upper extremity on the side the patient is shifting to should remain relaxed while shifted.

Sequencing While Walking

- Instruct the patient that the sequence for walking with crutches is similar to what they have already been performing while using a walker.
- Instruct patient that they are required to have three points of contact at all times.
 - 2 crutches and 1 leg, or 1 crutch and 2 legs.
 - Do not move crutch and leg at the same time.
 - Do not lift both crutches at the same time.
- Sequence for walking with crutches:
 - Left crutch – shift left – step (right leg)
 - Right crutch – shift right – step (left leg)
- Crutch Placement:
 - Shorter and wider crutch placement than used for brace walking.
 - Forward crutch should be placed at estimated point where the contralateral toes should land with next step.
- Weight shift laterally:
 - Push down on right crutch and extend right elbow to shift weight left.
 - Left elbow flexes to absorb/control weight shift.
 - Push down on left crutch and extend left elbow to shift weight right.
 - Right elbow flexes to absorb/control weight shift.



The patient is balanced on the two crutches and stance leg, preparing for pre-swing.



Both crutches stay static during swing. Leading crutch placed out to estimated end of swing step.



Swing leg lands with toes in line with leading crutch, setting up for optimal alignment and weight shift for next step.



Patient is stable on legs and right crutch as they move left crutch. Left crutch lands in line with predicted right.



Stable point changes to both crutches and left leg by weight shifting. Patient pushes laterally from right to left. With crutch placed, right swing begins.



Right toes land in line with left crutch. Patient stable on legs and left crutch as they move right crutch.



Right crutch is placed. Patient weight shifts to make stable point on both crutches and right leg. Weight shift achieved by pushing laterally left to right.

20. Walking with a Cane

May be better introduced once patient has learned initial balance and midline orientation as patient may be more able to weight shift onto weaker/paretic limb.

Patient may require higher level of unilateral assistance first.

Sequencing While Walking

- Instruct the patient that the sequence for walking with a cane is similar to what he has already been performing while using a walker.
- Instruct patient that he is required to have two (2) points of contact at all times.
 - 2 legs, cane and right leg, or cane and left leg.
 - Do not move cane and leg at the same time.
 - Do not hold the cane in the air while walking.
- Sequence for walking with a cane:
 - For cane in right upper extremity: Shift Left – Step (Right Leg) – Cane – Step (Left Leg).
 - For cane in left upper extremity: Shift Left – Step (Right Leg) – Step (Left Leg) – Cane.
- Cane Placement:
 - The cane should progress at a forward diagonal and line up with the toes of the leg completing the step.
- Weight shift laterally:
 - Push down on cane in right upper extremity and extend right elbow to shift weight left. Relax and flex right upper extremity to shift weight right.
 - Push down on cane in left upper extremity and extend left elbow to shift weight right. Relax and flex left upper extremity to shift weight left.



Choosing an Assistive Device for Patients with Hemiparetic Upper Extremity

Patients with impaired upper extremity function may still benefit from initial EksoNR training using a walker, if the physical therapist feels it is safe and appropriate for impaired upper extremity to be managed on a walker. Some patients with stroke have shown improved ability to learn stepping pattern and weight shift toward paretic limb when given a walker initially. This scenario may require another person to assist with walker and upper extremity management from the front of the patient to walk in a straight line. Each patient situation should be assessed individually to determine optimal clinical choice.

21. Feedback Scores

EksoNR provides feedback in two locations:

- Feedback on the bottom of the Walk screen, which is continuously updating the summary of the last 10 steps.
- Detailed Swing Assist and Stance Support information in the Feedback screens, which records the last 120-step average.

When the **Swing Assist** is programmed to **Adaptive** or **Fixed** and/or when the affected **Stance Support** is programmed to **Flex**, the EksoNR provides quantifiable feedback relating to EksoNR motor output for each leg for both swing and stance. Feedback information is available only with these programming choices.

The feedback data provided is related to each specific set of gait parameters. When a gait parameter is changed, the feedback numbers will also change based on that new trajectory created.

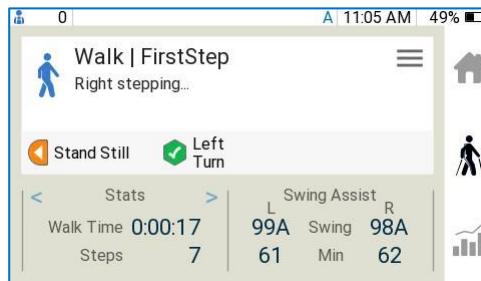
- For swing phase, the scores indicate how much effort is needed to move the leg forward in the swing.
- For the stance phase, the feedback information reports how much support the knees and hips are providing to keep a patient upright.

NOTE: Feedback scores range from 0 to 100; the greater the number indicates more **Swing Assist** or **Stance Support** provided. The feedback scores that the EksoNR provides during gait sessions should be compared to an individual patient's sessions for progression; the scores should not be compared between multiple patients.

Feedback on the Walk Screen

The EksoNR Controller displays two feedback boxes directly on the walk screen. The right feedback box defaults the most important feedback for the assist mode selected. The left feedback box allows the therapist to scroll through additional feedback. These options will change based on the assist mode to show only feedback values that are pertinent. All values are updated in real time.

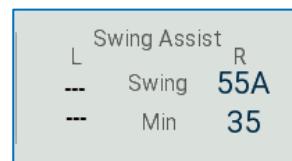
- Feedback screens may include walk time, up time (time in standing), total number of steps, swing time symmetry, step length symmetry, swing assist scores, and stance support scores.
- Each value displayed is an average value over the last ten steps (five steps for each leg).
- Access the other feedback screens by touching < or > on feedback screen.



Swing Assist Feedback

The **Swing Assist Feedback** scores display the amount of assistance that the machine provides to the patient in the forward direction. These **Swing Assist** scores are dependent upon the **Swing Assistance** programming in either **Adaptive** or **Fixed**.

- In **Fixed**, this number simply matches the **Left-Affected Swing Assist** and/or **Right-Affected Swing Assist** value(s) set by the PT.
- In **Adaptive**, this number varies based on the swing assistance that the patient requires to produce smooth and regular motion at the given **Swing Time**. If the EksoNR is programmed in **Adaptive**, the **Swing Assist** score ends with an uppercase 'A' to indicate that the device leg is programmed in **Adaptive** swing assistance. The upper screenshot indicates that **Adaptive Assistance** was programmed for both legs.
- When a leg is set to **Free**, feedback for that leg is displayed as dashes (---) as the lower screenshot's **Left** leg display shows.



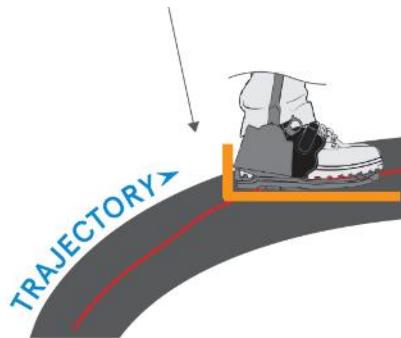
Min Assist Feedback

This value indicates the *estimated or detected* swing assistance that the patient will require to complete each trajectory assigned step pattern. The **Min Assist** score is always less than or equal to **Swing Assist**.

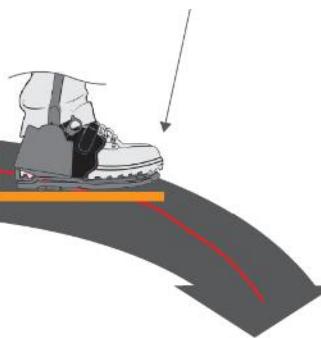
In **Fixed**, if EksoNR detects that the programmed fixed value of **Swing Assist** is not enough for the patient to complete the step and **Swing Complete** is activated, the **Min Assist** score displays a plus sign (+) after the number. (For example, the **Swing Assist** score in the adjacent screenshot shows that **Left-Affected Swing Assist** is programmed to a fixed value of 45. The **Min Assist** score of 45+ indicates that over the last five steps, the **Left-Affected Swing Assist** average value was greater than the set **Swing Assist** value and **Swing Complete** activation may push the **Min Assist** over the set **Swing Assist**.)

| L | Swing Assist | R |
|-----|--------------|-----|
| 45 | Swing | 98A |
| 45+ | Min | 51 |

EKSONR LEADING/PUSHING THE PATIENT
EQUALS HIGH SWING ASSIST



PATIENT LEADING/PULLING THE EKSONR
EQUALS LOWER SWING ASSIST



Stance Support Feedback

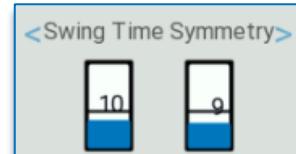
The **Stance Support Feedback** screen provides Left/Right information on how much Stance Support the EksoNR knees and hips are providing to keep a patient upright during stance phase.

| L | Stance Support | R |
|----|----------------|----|
| 32 | Hip | 29 |
| 1 | Knee | 30 |

Swing Time Symmetry Feedback

Swing Time Symmetry feedback shows the timing of the swing cycle for both the left and right leg. The black line shows the programmed swing time in settings. The blue bars show the 5-step average swing time for each leg.

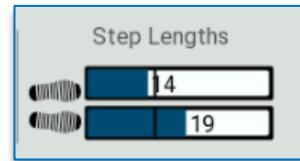
NOTE: A Free Leg will not be controlled by the swing time, however the programmed swing time still displays.



Step Length Symmetry Feedback

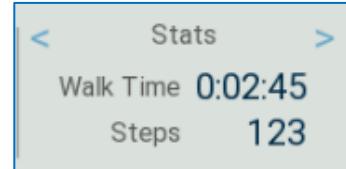
Step Lengths feedback shows the step length so that the therapist can compare right and left step lengths and the setting. The step length programmed in Settings is indicated by a black line, and the blue bar represents the 5-step average.

NOTE: A Free Leg will not be controlled by step length; however, the programmed setting still displays.



Stats Feedback

Stats feedback shows the walk time and number of steps completed.



22. Statistics Menu

To access **Statistics**, touch the icon on the right menu bar.

- Use the page arrows to scroll through the various statistic screens.

The bottom of the statistics screen displays the session **Walk Time**, **Up Time**, and the number of **Total Steps** taken.

Use < and > arrows on the bottom of the screen to scroll among these statistics screens:

- Swing and Stance assistance scores for the last 120 steps (60 steps on each leg)
- Graph of step lengths of right and left legs
- Graph of swing times of right and left legs
- Outcome measures taken that session
 - Data is editable from this screen by touching on a specific test completed.



23. Progression While Walking - Swing Limb Focused

As patients begin to demonstrate proficiency achieving an appropriate weight-shift and maintaining their balance for stepping in **FirstStep**, consider alternate **Step Initiation** programs. This requires appropriate guarding and facilitation to help the patient learn progression. **Step Initiation** program progression decisions are based on patient presentation and goals.

Prior to beginning an EksoNR session, various patient-specific settings must be programmed into the EksoNR. When progressing or optimizing a patient's walking in the EksoNR, some of these settings may be adjusted. A physical therapist can change certain settings while the patient is actively walking in **Walk** mode. This feature is used only when the patient is walking in **ProStep** or **ProStep+**.

To change settings while walking, the physical therapist presses the previous button  while in **Walk** mode or touches the Controller screen to return to the **Home**, **Quick Settings**, or **Assistance** menus. The following settings are adjustable while walking:

- Patient settings: Step Length, Step Height, Swing Time, Hip Flexion, Knee Flexion, Forward Shift, Lateral Shift
- Ekso Options: Target Sounds, Lean Allowance, FES (If the device is not configured for FES, this choice is not available)
- Assistance: Swing Assist, Stance Support, Swing Complete

CAUTION: When navigating away from the **Walk** screen to change the above listed features during Walking, the only way to stop an action is to use the  EksoNR **Stop** button.

CAUTION: Ekso Bionics recommends only changing settings during walking if the patient is skilled and well-balanced while walking in the EksoNR. Changing these settings *immediately* alters the gait trajectory or requirements of the patient for walking. Therefore, care should be taken to use this feature only when appropriate.

Frequently adjusted settings are also available in **Quick Settings** accessed by touching the **Expandable Menu** icon (). These include: Lateral shift, step height, step length, swing complete, and swing time.

Starting in **Adaptive Swing Assist** provides the patient and physical therapist with optimal EksoNR walking and allows the patient to learn the assigned trajectory that the physical therapist has programmed. This ensures that there is enough EksoNR motor power in use to complete steps, while fully allowing for interactive patient actions. The Controller screen displays the dynamic values of EksoNR motor performance (Swing Assist and Min Assist). Adaptive programming allows for a rapidly adapting motor output that responds to the amount of effort the patient contributes to the pre-determined EksoNR assigned trajectory. This program automatically adapts to the amount of patient influence on the motor power of the EksoNR and increases or decreases as needed throughout the swing phase of gait. The patient must sync with, and then lead, the EksoNR programmed gait trajectory and use their power in that pattern before the EksoNR motors decrease assistance.

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 in. (2.5 cm) between the patient's feet during mid-swing.
- A narrow base of support is helpful to reduce the workload on the patient by reducing the lateral weight shift workload.

Target Sounds



Assigning Target Sounds

- Target Sounds may be used as a tool to teach the patient how far to weight shift in a certain direction.
- First, the physical therapist must assess the correct target positioning and selection for the patient.
- During this assessment phase, the physical therapist should be using the sounds to complete the decision-making process, and the patient should be discouraged from walking toward the sounds.
- Once the physical therapist determines the targets are set correctly for patient and goal, then the patient should be cued to listening for the audible tones.
- If the targets are not assessed and tuned for a patient, the patient will not have good quality walking.

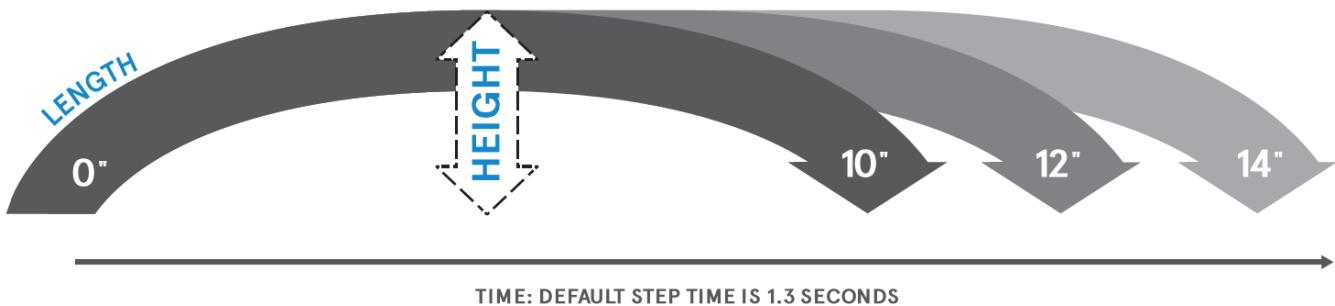
- Begin with quality walking in **FirstStep** ("Like What You See").
- Determine consistency of achieving Forward target (beep) and Lateral target (chirp) at default target settings.
- If targets are not consistently being achieved, decrease targets by 1.
 - Must continue to perform quality walking.
- Continue to decrease Forward and Lateral target until patient consistently achieves targets.
 - Lower until target sounds too early, *then return to the one value prior.*
 - Frequently, the lateral targets are negative numbers for advanced patients.
- Forward and lateral targets should be achieved in close proximity to each other ("Like What You Hear").

Trajectory

When a patient has active lower extremity power to contribute to the walking pattern of EksoNR, it is essential that the physical therapist makes assessments of optimal gait parameter programming.

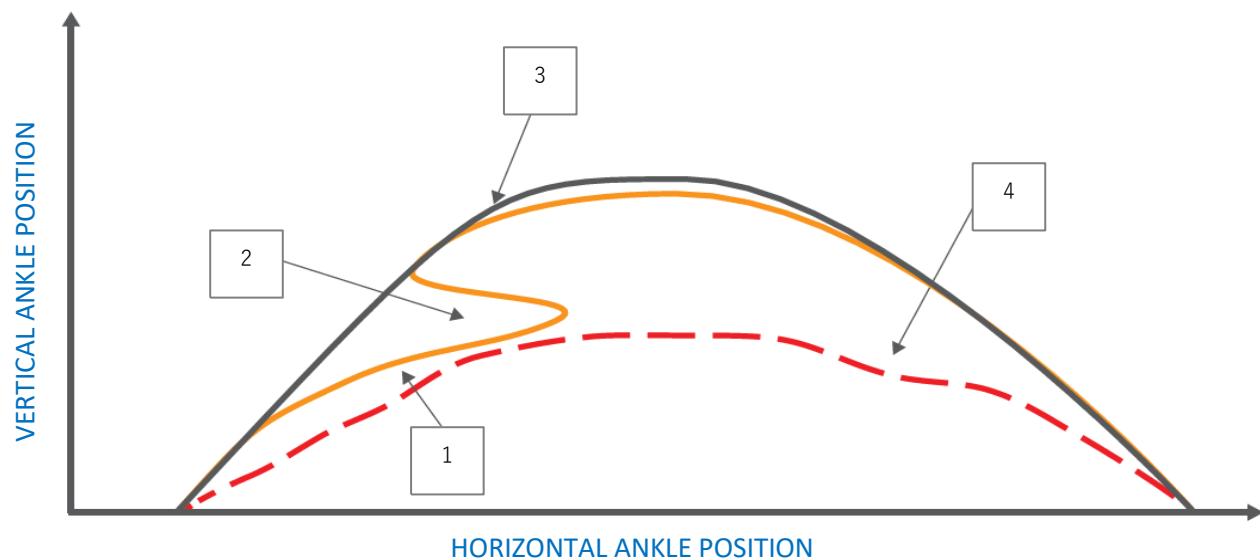
The gait parameters in the **Patient Settings** menu define the projected path that the EksoNR leg moves through during swing. Optimizing these parameters given each patient's individual presentation and the goals of the treatment session aligns the pathway that a patient contributes to and that EksoNR assists throughout.

Trajectory is the designated assignment each joint must achieve to complete the assigned **Step Length** and **Height**, in the **swing time** set by the physical therapist.



Step Height

- Default: 0.5 in. (1,3 cm)
- Range: 0.0 - 1.5 in. (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.
- Goal is minimum height while achieving ground clearance by the Ekso footplate.
- Physical therapist may want to cue the patient to bend knee more if needing to address knee flexion goal in swing.
- Increase **Step Height** for uneven floors (for example, tile and thresholds).
- Increase **Step Height** if spasticity results in foot drag

**PATHS**

- DESIRED ANKLE TRAJECTORY
- PATIENT'S ANKLE TRAJECTORY
- - THERAPIST ADJUSTED STEP HEIGHT

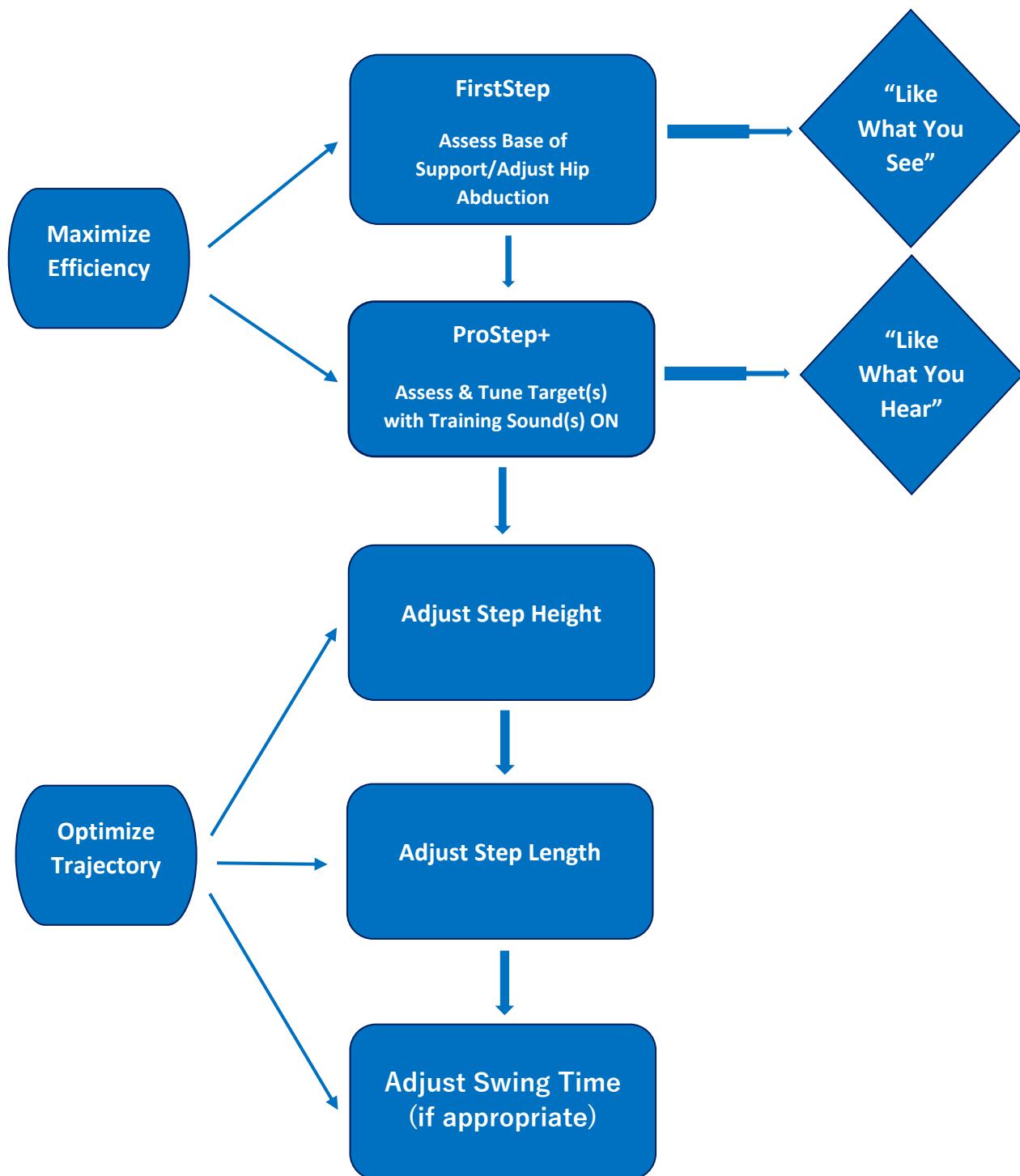
| | |
|---|---|
| 1 | Patient's selected trajectory pattern, too low. |
| 2 | Large trajectory error creates corrective force by EksoNR that overpowers patient's forward push ("leg bounce") and elevates the patient to correct trajectory. |
| 3 | Demonstrates programmed step height and trajectory path.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

Step Length

- Default: 12.0 in. (30,5 cm)
- Range: 8.0 - 18.0 in. (20 – 46 cm)
- Consider increasing **Step Length** early for taller patients.
- Longer **Step Length** may feel more natural, especially if the patient has leg strength.
- Longer **Step Length** may make forward progression more difficult, especially for patients with complete paraplegia.
- Even if this is ultimately the best choice for the patient's walking, the patient may need assistance to manage this change initially.
- Shorter **Step Length** may result in weight shifting beyond forward target.
- A longer **Step Length** may trigger more spasticity.

Swing Time

- Default: 1.3 seconds
- Range: 0.8 - 2.0 seconds
- Increase **Swing Time** to slow down the swing.
- 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.
- Decreasing **Swing Time**:
 - May be more challenging for the patient with lower extremity motor power to lead the EksoNR and decrease motor assistance.
 - May feel more natural.
 - Can generate more forward momentum and challenge balance, especially for patients with complete paraplegia.



Fixed Assist

Fixed programming allows for setting a specific ceiling amount of EksoNR motor assist throughout the swing phase in a less constrained environment, offering more time for the patient to complete the assigned trajectory. If programmed to a level that challenges the limit of the patient's function, this may lead to a slower swing and more isolated functional movements or effort through the swing phase.

The **Fixed** value is programmed based on the **Min Assist** feedback score while the patient successfully leads the **Swing Assist** in **Adaptive**. The physical therapist uses the **Min Swing Assist** value to fix the appropriate **Swing Assist** at the patient's determined level of function. The **Fixed** value will be the ceiling amount of assistance provided by the EksoNR while remaining **Adaptive** below the set amount of swing assistance.

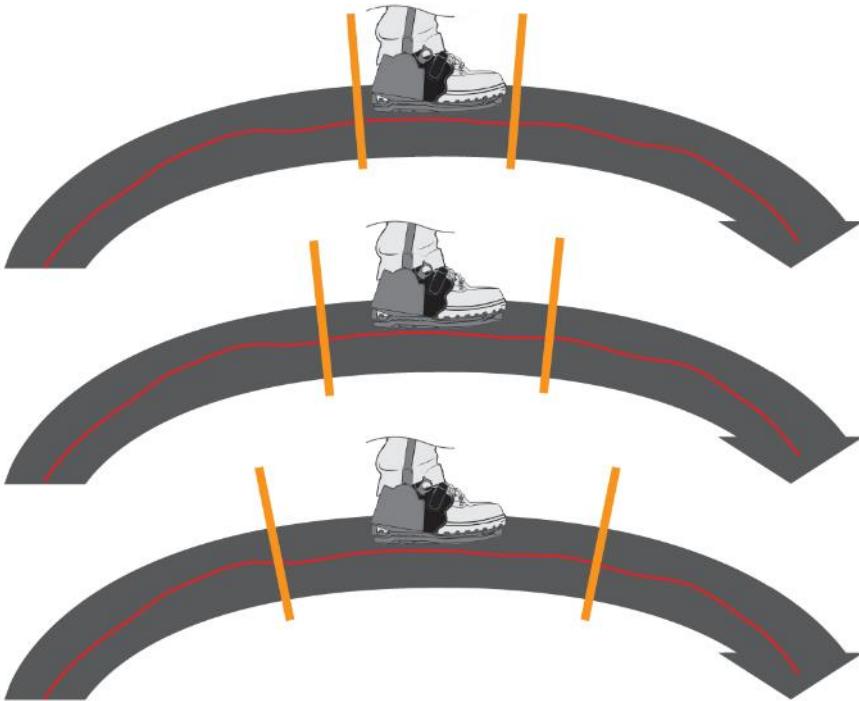
If the patient provides the work to meet the time requirement while moving in the trajectory (that is, leading), the EksoNR **Min Assist** decreases.

As the **Swing Assist** value lowers (in either **Adapt** or **Fixed**), the EksoNR provides less assistance to complete the step. At the same time, the patient will have a less constrained trajectory pattern, and the patient has more time to succeed from an anterior/posterior perspective.

As the **Swing Assist** value (Fixed or adaptive) decreases, patient is less constrained along the trajectory and has more "room" to succeed from an anterior/posterior perspective.

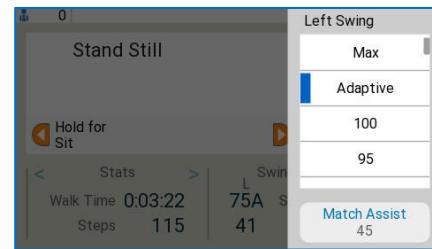
100
fixed or
adaptive

70



As the patient learns the pattern of the trajectory-controlled leg(s), they may be able to reduce the programmed motor assistance and "Chase the Success." The physical therapist may choose to challenge the patient's strength, endurance, control, or progress to a trajectory-free gait motion with the use of supplemental **Swing** and **Stance Support** options. The physical therapist should always be aware of the patient's presentation and have completed a thorough evaluation and ongoing reevaluations as needed to determine optimal progression.

The fixed value can be changed in the assistance menu under swing assist but can be quickly adjusted by touching right or left side of the swing assist score box. This opens a menu for adjusting the respective leg's assistance. A "Match Assist" button is also available to allow the therapist to quickly match the patient's ability based on their current score.



Swing Complete is a feature, active in **Fixed** swing assistance, that detects when a patient is unable to or taking too long to provide their own strength to complete the assigned trajectory pattern. When triggered, the EksoNR provides full power until the step is completed. The EksoNR emits a sequence of tones as an audio signal to the physical therapist and patient.

The physical therapist decides the timing of this feature engagement. Slowing down the time engagement can increase the patient's motor planning contribution to swing.

- The Swing Complete setting represents the additional time in seconds that the EksoNR will give the user to complete the step before initiating the swing complete to finish the step.
- Swing Complete can be set to one of the following timings: 0.1, 0.3, 0.5, 1.0, 1.5, 2.0, or 2.5 seconds; the setting defaults to 0.1 seconds.
- When Swing Complete is set to a lower setting (for example, 0.1, 0.3, or 0.5) the EksoNR more quickly detects that the patient's leg is not moving fast enough in relation to the programmed Swing Time. This is useful to continue the flow of walking despite the patient not having enough strength to finish the step.
- When the Swing Complete setting is increased to a higher setting (for example, 1.0, 1.5, 2.0, 2.5) the patient is given more time to employ their own muscle contribution and complete the step before Swing Complete activates.
- When Swing Complete is activated during swing, the Controller sounds to notify the physical therapist and patient that the patient needed increased time or assistance to complete the step.

WARNING: Swing Complete is an indicator that the patient requires more swing assistance. If the patient or physical therapist are not prepared, **Swing Complete** can be disruptive to walking and cause loss of balance. Generally, **Swing Complete** should only engage occasionally if the **Swing Assist** is properly set.

Trajectory Free Options

Max, Adapt, and Fixed assistance provide a trajectory for the leg to move through during swing phase. In these modes, the EksoNR also provides the selected **Stance Support (Full or Flex)**. Trajectory free motion is also available for each leg.

If an **Assistance** mode is chosen that results in trajectory-free motion, **Swing Assist (Neutral, High/Low Assist, High/Low Resist)** may provide graded amounts of assistance or resistance for trajectory-free gait training. Additionally, the **Stance Support** in the trajectory-free leg can also be adjusted (**Very High, High, Medium, and Low**) to customize training.

| Assistance Selection | | | | |
|----------------------|-----------------------|-----------------|-----------------------|-----------------------|
| | Bilateral | 2Free | Right Affected | Left Affected |
| Left Leg | Trajectory-Controlled | Trajectory-Free | Trajectory-Free | Trajectory-Controlled |
| Right Leg | Trajectory-Controlled | Trajectory-Free | Trajectory-Controlled | Trajectory-Free |

2Free

Progression with each programming option always relies on the physical therapist having performed a thorough patient assessment, and having specific goals looking to be addressed. When a patient has higher-level ambulation goals, and has goals to ambulate over-ground, **2Free** programming may be an option.

2Free is best for patients who:

- Are working to decrease compensatory strategies.
- Are focusing on specific phases of gait without EksoNR facilitation.
- Need some assistance in stance phase, but are strong enough to hold some of their bodyweight.
- Need some assistance in swing phase, but are strong enough to initiate a step independently.
- Require assistance for postural alignment.

Each leg can be programmed independently.

When placing the patient in Stand Still using the  button, both legs are able to move freely within the determined safety boundaries of knee flexion from 0° to 35°.

When placing the patient in Stand Still using the  button, this results in a Full Stand Still, which is a Bilateral, trajectory-controlled Stand Still.

Initially when going into 2Free, “enable walking” must be selected to release the safety boundaries. A hard block at 45° will continue throughout gait.

Swing Assist Options for Trajectory Free Limb

- **Neutral:** Compensates for the EksoNR leg weight but provides no assistance or resistance to patient's leg; all leg movement is under patient's control.
- **High Assist/Low Assist:** Gives the patient freedom to control a step but provides a programmed amount of extra assistance to amplify patient's volitional movement to assist the patient against gravity.
- **Low Resist/High Resist:** Offers the patient resistance and somatosensory input as they lift and swing their leg through a self-selected step.

Swing assist can be changed in the assistance menu, or by clicking on the right or left sides of step length symmetry feedback box.

If the patient is taking inconsistent steps or does not replicate desired gait pattern with the trajectory-free leg(s), setting the device to **Bilateral** constrains that leg to the programmed trajectory as determined by the **Patient Settings** menu. Such programming may improve the functional gait pattern produced while walking in the EksoNR.

Unilateral Assistance Modes

If a patient lacks sufficient strength or control for one leg while in 2Free, a unilateral assistance mode will provide trajectory control swing and stance for one leg.

In **Right-Affected**, the right leg is trajectory controlled and the left leg is trajectory free.

In **Left-Affected**, the left leg is trajectory controlled and the right leg is trajectory free.

The EksoNR is in **Bilateral** after standing and requires the patient to weight shift to the affected side (with a prompt from the physical therapist to weight shift Left or Right) to let the necessary leg go free. When the patient has weight shifted appropriately, the Controller screen prompts with a message to push the  button. When the button is pushed, the non-weighted leg goes free.

When the device is programmed in **Right-Affected** or **Left-Affected**, the opposite leg is trajectory free. EksoNR provides the same options for swing and stance on that limb as were available in 2Free.

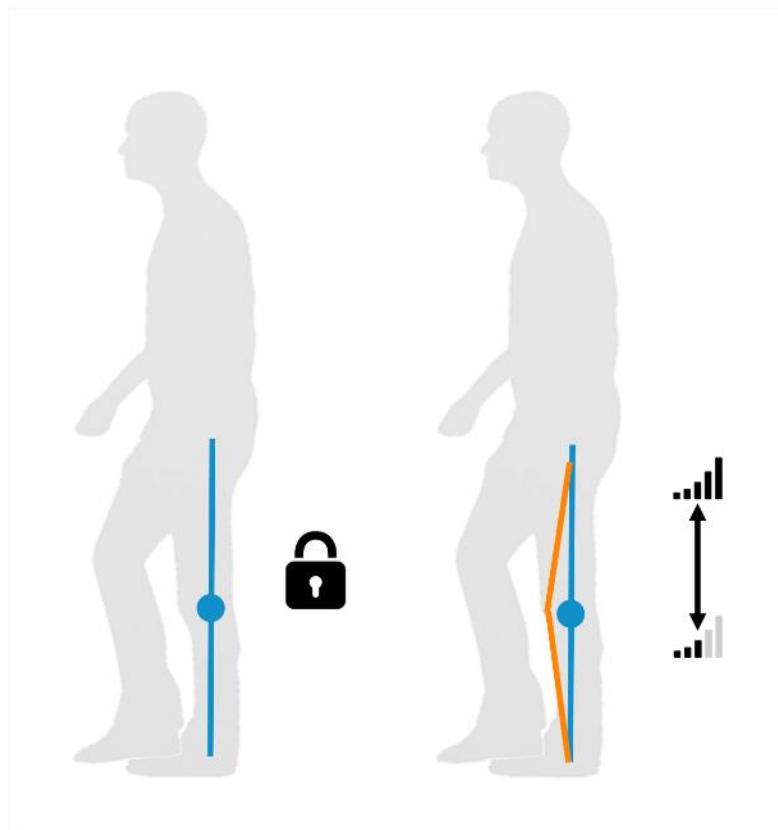
The first step will always be with the trajectory-controlled limb, meaning that in **Left-Affected**, the left foot will initiate walking. The contralateral limb, the free limb, can step when and however the patient desires. To initiate subsequent steps on the affected limb, patient must meet requirements of step initiation program chosen.

24. Stance Support in Walking

Stance Support options available are based on if leg is under trajectory control or is free of trajectory.

Trajectory Controlled Stance

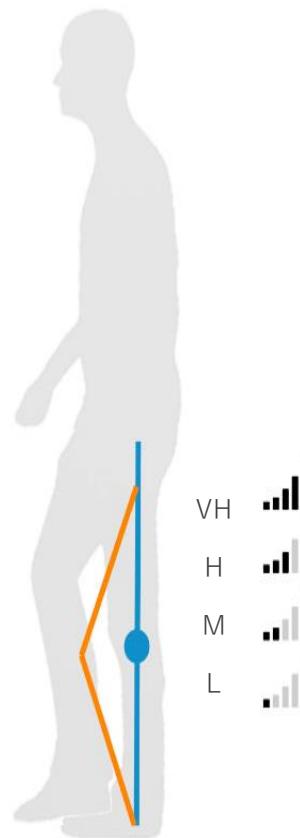
- **Full:** When **Left/Right Stance Support** is set to **Full**, the EksoNR provides maximum stabilizing control and support through the hip and knee during stance. The brakes are activated at the knees when the programmed knee flexion angle is achieved. This is demonstrated by the picture on the left, below.
- **Flex:** Continuously adjusts the amount of **Stance Support** based on the support the patient needs as they move through each step. Enables the patient to contribute their available strength to maintaining an upright posture and softens slightly as the patient demonstrates success. The knee brakes are not utilized in this mode. This is demonstrated by the picture on the right, below.



Trajectory Free Stance

- **Very High, High, Medium, Low:** Provides differing amounts of supplemental stance support at the knee.
- The physical therapist should account for the patient's lower extremity strength and their weight when determining Stance Support setting.
- If a patient needs more than Very High Stance Support to maintain standing on a trajectory-free leg, the EksoNR leg should be programmed to provide trajectory-controlled power on that side. This is achieved by returning to Bilateral or Right/Left-Affected Assistance Modes in the Assistance menu.
- In a trajectory-free leg, the software provides a resistance to complete buckling between 35° to 45° knee flexion.

Free Stance Support



The EksoNR always provides a certain amount of stance support on the Free stance leg. However, when programming a patient to have a Free leg, the physical therapist should be confident that the patient can stand on that leg using their own strength plus the additional EksoNR stance support. If a patient fatigues in **Free Leg Stance Support**, the maximum allowable amount of standing knee flexion is 45 degrees. If a patient needs significant stance support to maintain standing on a leg, the EksoNR leg should be set to **Trajectory Stance Support** on that side.

25. Guides for Patient Progression

| Patient who is: | Progression available | Purpose | Examples for clinical use |
|--------------------|--|--|--|
| Motor Complete SCI | FirstStep to ProStep | Autonomy to patient Increased speed Improved learning curve | Ideal during first session to improve learning. More consistency for patient. |
| | Optimize targets | Increase efficiency More natural walking pattern Improve walking speed | Targets are ideally set to easiest, effective setting. As patients improve, the targets may be able to be reduced to allow velocity/momentun to initiate earlier steps. |
| | Parameter changes | Match trajectory to patient (early) Increase speed (later) | Trajectory changes usually related to tone interference. Increasing Step Length and decreasing Swing Time is functional challenge and natural skill progression. |
| | Walker to crutches | More functional gait Higher balance requirement Improved speed (when mastered) Less upper extremity weightbearing Patient better able to facilitate weight shift | Ideal to progress in first few sessions if able. Crutch training can be challenging as patient must balance better. Ideal to use ProStep with targets set safely at first. |
| | Turning program or box turns to advanced turns | More functional gait Higher balance requirement Improved speed (when mastered) Less upper extremity weightbearing | Advanced turning skills in ProStep and ProStep+ require improved balance and EksoNR control. Patients can facilitate turns by using the swing leg to turn in the desired direction during walking. Careful when in ProStep or ProStep+. |
| | Terrain challenges | Balance challenges Prepare for advanced EksoNR use | Carpets, doorways, sidewalks. |

| | | | |
|---|---|--|---|
| Motor Incomplete SCI, CVA, ABI/Other | FirstStep to ProStep+ | Allows patient motor initiation Allows patient-robot interaction, aiming to facilitate motor recovery/retraining Autonomy to patient Increased speed Improved learning curve | Usually done early as long as the patient is appropriately balanced (lateral and anterior/posterior) when attempting to initiate swing. If patient is stepping before FirstStep button is pressed, move to ProStep+ . |
| | Parameter changes (Adaptive) | Match trajectory to patient (early) Optimize robotic pattern to facilitate gait for patient Increase speed (later) | Important to use visual info (swing conflict, leg bounce, late swing adjustments); Controller screen info (lift/extend and other feedback) and patient report to adjust Step Height/Length and Swing Time for optimal/smooth step. Less conflict will lead to better walking and less EksoNR assistance. |
| | Adaptive: Encourage lower Swing Assist | Encourage patient to lead the learned trajectory by pulling the EksoNR versus being pushed. The Swing Assist will decrease as patients learn to initiate/lead step. | Recognize increased patient engagement by decreased Swing and Min Assist scores. |
| | Walker to crutches/cane | More functional gait Higher balance requirement Improved speed (when mastered) Less upper extremity weightbearing | |
| | Turning program to advanced turns | Have patient turn with swing leg rather than turning program | May cause the Swing Assist numbers to go up as the patient changes focus to the turn. |

| | | | |
|--|---|--|--|
| ADVANCED Motor Incomplete SCI, CVA, ABI/Other | Adaptive to Fixed at Min level (or close) | Work at strength threshold | Lowers ceiling to Min value (or just above/below) and make the patient work harder at strength threshold. Similar to weightlifting with maximum weights. Swing Complete may be disruptive if occurs often. |
| | Decrease Fixed Swing Assist value | Lowers ceiling of EksoNR swing assist as Min Assist value decreases making patient do more Loosens constraint of robot and is easier (softer) for patient | "Chase the success" by lowering the Fixed value as patient learns/improves and Min Assist value decreases. Watch for higher fatigue levels and other compensatory body movements (such as, trunk leans, heavier upper extremity use to try to lift weight of leg). Should monitor for results based on clinical goal. |
| | Increase Swing Complete value (Fixed only) | Gives patient more time for motor planning Increased balance requirement to maintain posture with swing delay | Ideal for working at strength threshold. Patient has time to learn and improve step quality. May lead to more parameter changes. When successful, may lead to lowering Fixed value. May be more successful with Swing Complete at 1.0, 1.5, 2.0, or 2.5 seconds and at a lower Fixed value. This is because of allowed time to motor plan, as compared to the same Fixed value with a faster Swing Complete . |
| | Bilateral to 2Free | 2Free , non-trajectory assisted swing with programmable Stance Support , challenges patient to use own power in swing and stance without being constrained to a trajectory | Allows patients to have more control over speed and step symmetry without trajectory constraint. Generally done with a patient with quad/glute strength (>3+). Challenges here include: lowering stance support, adding low/high resistance, unlocking hip abduction. Gait challenges include: gradual ramps, stepping over objects, single-leg-stance balance activities, some uneven terrain. After walking in 2Free , try going back to Adaptive and work to lower feedback scores to see if the patient is able to be more precise with timing and muscle activation. |

| | | | |
|--|---|---|--|
| | Bilateral to Right- or Left-Affected | Challenges patient to use own power in swing and stance without being constrained to a trajectory in the free leg. Trajectory-controlled swing and stance in Affected leg only. | Ideal if symmetry is maintained. Allows for patient to learn/make mistakes with pattern while trying to return to reciprocal pattern. May benefit from return to Bilateral if step-to gait pattern, or other gait abnormalities, develop. Bilateral mode can help facilitate patient carryover with a reciprocal, step-through gait pattern. This can lead to higher success or quicker learned time when switching into Right-/Left-Affected . |
| | Add Low or High Resistance to the trajectory free leg | Requires the free leg to work harder in swing | This progression allows the free leg to be challenged incrementally without constraint to a trajectory. The caution here is with fatigue or diminished strength. The leg may be delayed in progressing forward; therefore, the patient's body must remain balanced until the leg steps through. |
| | Select Stance Support in the trajectory-free leg: Medium, Low | Challenges the patient to greater control with knee position in stance phase | As the amount of support is lowered, this requires greater control at the knee from the patient during stance phase. Caution: The patient is carrying the weight of the EksoNR and may allow up to 45° of knee flexion and stance. |
| | Decrease swing time (Adaptive or Fixed) | Challenges patient to complete step in less time | Generally, the EksoNR assistance will increase if Swing Time is decreased. This allows patient to accommodate to the challenge of having less time to complete the swing and lead the step progression. Occasionally, the EksoNR assistance decreases, indicating that the EksoNR was working to slow the leg during swing. |
| | Increase Step Height | Challenges patient to use more hip/knee flexors; use as exercise | Raising the Step Height is like making a patient step up onto a step, or over an object on the ground. This is advanced and requires good balance from patient. It may lead to more gait disruption and higher feedback scores. |

| | | | |
|--|--|--|---|
| | Raise Fixed value to increase challenge | Tightens constraint and makes patient work more precisely to maintain same score **should already have optimized gait parameters determined before trying this activity ** | Example: A strong patient (limited community ambulator) has learned how to drive the Min Assist (actual Swing Assist) to 0 with the Fixed Swing Assist at 20. A treatment goal would be to raise the Fixed value and challenge the patient to keep the Min Assist value at 0. This strategy can be used with any numbers as long as there is a delta between the Fixed and Min values. Changing back into Adaptive after being in Fixed can also check learning of trajectory and appropriate muscle activation, by observing lower feedback scores. |
| | PreGait skills in Right-/Left-Affected (Stand mode) | Allows PreGait stepping forward/back with free leg | Allows practice with weight shifting and stepping with free leg. |
| | PreGait practice with weak leg free (Stand mode) | Allows PreGait stepping forward/back with free leg | Allows practice with weight shifting and stepping with free leg. May also add Low or High Resistance to challenge the patient when stepping forward and back or to touch a target, such as a cone. Further challenge: unlocking hip abduction on the free leg to challenge controlling leg in a sagittal plane or allowing lateral movement to reach targets outside of the sagittal plane. |
| | PreGait: Stepping in Place | Allows marching or independent leg movement with both legs free and a programmable Bilateral and symmetrical Stance Support | Allows stepping in place with or without weight shift sounds on, lifting legs to touch a target. Here, the hip abduction can also be unlocked to allow motion outside of the sagittal plane or just challenge maintenance of sagittal plane during activities. Offers hip and knee flexion angles in stepping leg. Variations: lowering the stance support, changing from neutral to low or high resistance as an added challenge. |

| | | | |
|-------|------------------------------------|--|---|
| | 2Free: Stepping in Place | Allows marching or independent leg movement with both legs free and a programmable Bilateral , though asymmetrical, Stance Support | Allows stepping in place with or without weight shift sounds on, lifting legs to touch a target. Here, the hip abduction can also be unlocked to allow motion outside of the sagittal plane or just challenge maintenance of sagittal plane during activities. DOES NOT offer hip and knee flexion angles in stepping leg. Variations: lowering the stance support, changing from neutral to low or high resistance as an added challenge. |
| | PreGait: Squats | Allows squatting practice, strengthening, activating of sit->stand muscles | Programming allows 3 levels of squatting which sets the hard stop for the depth of the motion. With this program you can challenge the patient to the deepest squat (90) and also facilitate decreased upper extremity use during the motion. Challenge would be to decrease the Squat Support . |
| Ankle | Decreasing ankle stiffness support | Challenge ankle workload by reducing stiffness | Caution here as patient is carrying the EksoNR (50 lb/23 kg) and may have stance problems. Generally, this would be done with a patient with significant quad/glute and sufficient gastrocnemius strength (>3+) in free leg. Stance Support may need to be Very High or High . |

26. Notification Messages

The EksoNR may provide additional swing notifications to inform the physical therapist and patient what area of swing is not being matched to the programmed trajectory. These notifications appear in real time as icons on the top row of the **Walk** screen. The swing notification can be lift, extend, or both. These swing notifications provide the following feedback:

- **Lift icon** (↑) indicates the patient needs to flex their knee and/or hip more during the swing.
- **Extend icon** (↓→) indicates the patient needs to extend their knee and/or hip more during the swing.



NOTE: Extending the hip during the swing phase relates to lowering the leg toward the ground. This walking behavior often occurs when a patient has strong hip flexors and holds the leg in the air longer than desired.

- **Lift & Extend icon** (↑↓→) indicates the patient needs to complete *both* actions during the swing and is often late on both knee flexion and knee extension during the swing trajectory.

A swing notification is displayed when the patient needs to provide more effort to swing, or when the patient significantly deviates from the programmed path.

Example: If a patient is stepping too low, you will likely see a **Lift icon** on the **Walk** screen. The **Min Value** will have a higher value. You may also see the leg bounce as it is re-directed into the trajectory and additionally pushed into the middle of the trajectory. Physical therapist choices are to cue the patient into more knee (and possibly hip) flexion or lower the step height (a lower step height reduces the amount of hip/knee flexion required).

27. Turning

With Walker

The **Turn Mode** can be used through the Controller to aid with turns when the assistance mode is programmed to **Bilateral**. The balance and weight shifting that is required for turning while walking may initially be considered an advanced skill. A skilled patient may perform gradual turns while in **Walk Mode** instead of **Turn Mode**.

WARNING:

Users should not lift the EksoNR off the ground during a turn. Repeated jumping or lifting could potentially damage the EksoNR and/or harm the patient.

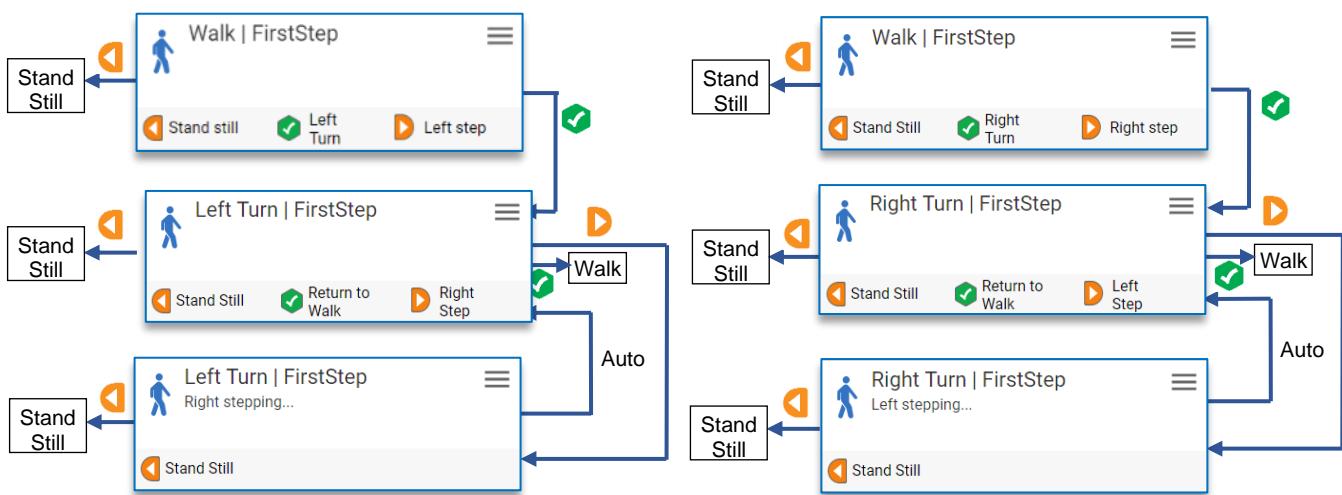
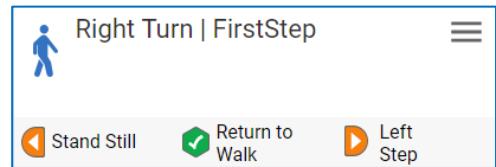
If the EksoNR is in **Stand Still** or **Turn** mode and the legs remain in split stance for longer than 15 seconds, EksoView beeps and displays Error Code #159. The error message instructs the physical therapist to move the patient's feet together to return their legs to a neutral stance.

Turning mode is only available when in **Bilateral** Assistance mode.

- The **Turn Mode** allows the patient to take repeated steps with the same leg to complete a turn with a small radius.
- Turning occurs through a Turn Mode, accessed on the EksoNR Controller or crutch interface.
 - Turns are initiated in split stance.
 - **Turn Mode** facilitates turns toward the back leg, from walking.
- Cue patient to turn toward back leg.
 - Begin by turning walker and upper body in direction of turn.
 - Cue patient to push down on walker while turning toward back leg, while still keeping weight through feet.
- Patient should pivot on front of feet, slightly unweighting heels, to facilitate 90° turn.
- Emphasize communication among team to ensure safety and consistent timing.

Instructions for Therapists

- During **Walk Mode**, when ready to begin **Turn Mode**, press (checkmark) button when patient is in split stance, with one leg behind other.
 - If turning right, press when the right leg is behind the left.
 - If turning left, press when the left leg is behind the right.
- Pivot body weight slightly forward onto toes in direction of back leg, until feet are in neutral position (90°).
- Weight shift to leg in turning direction to unload the stepping leg.
- Press to repeat a new step with the same leg.
- Shift body weight and repeat steps until patient is reoriented to the desired direction.
- Press to return to **Walk Mode**.
- All first steps after returning to **Walk Mode** are with the right leg.



Handling and Cueing

- Cue patient first to contribute to motion for turning.
- If patient does not require much assistance, physical therapist may facilitate turn slightly through shoulders or torso.
- If patient needs moderate assistance to pivot and turn, the physical therapist may facilitate through the device, by the hip motors or torso handles.
- If increased assistance is needed, a second person can assist by stabilizing the device from the front or by aiding with the turn by guarding the patient through their hips.
- Leaning patient onto toes helps with pivot.

With Crutches

Turning with crutches requires coordination and patient understanding of the process. Clear communication should be maintained between the patient and the physical therapist.

The technique for turning with crutches is consistent with the technique for turning with the walker.

Turning with crutches may create considerable instability if crutches are misplaced or patient makes uncoordinated movements. Use extra caution guiding new patients turning with crutches.

Handling and Cueing

- Patient positions crutches in front of body.
- Patient leans forward while pushing downward on crutches, while still keeping weight through the feet.

With a Cane

The technique for turning with a cane is consistent with the technique for turning with the walker.

Handling and Cueing

- Position cane in front of body.
- Patient leans slightly forward while pushing downward on the cane.

Turning Without Turn Mode

There may be instances when the physical therapist chooses *not* to enter the **Turn Mode**. Balance and coordination for turning during motion is a higher-level skill and may be attempted by skilled patients. Skilled patients performing gradual turns:

- Pivot on stance foot with balanced weight shift during swing.
- Turns should be managed on the front of the EksoNR foot pad.
 - Patient needs to shift weight slightly onto forefoot to decrease friction on the foot.

In 2Free

The Controller-operated **Turn Mode** is not available when the EksoNR is programmed in **2Free**. The patient may step forward or backward with either leg to facilitate a turn in the desired direction.

In Right- or Left-Affected

The Controller-operated Turning program is not available when EksoNR is programmed in **Right-Affected** or **Left-Affected**. Use of  for a 'soft' **Stand Still** is required to stop the Step Initiation mode in the Affected EksoNR leg. The patient can step backward or forward with the trajectory free leg, and then pivot their weight on their toe to initiate the turn. Using this technique until the patient is facing the desired direction facilitates ease with turning.

28. Outcome Measures

Pressing the Expandable Menu on the **Walk** screen allows the clinician to collect a walking test in EksoNR. To access, tap the  icon, select **Ekso Outcomes**. A test menu will appear in place of the feedback boxes. Select the appropriate test.

All EksoOutcomes results are editable and viewable in the statistics menu. The test may also be marked as “self-selected” speed or “fastest” speed.

10-Meter Walk Test

- Need to have distance measured before starting test.
 - Ekso does not measure distance.
- Cannot be started from rest.
- No setting changes permitted during test.
- If stop button is used during test, the test is aborted, and no results are saved.

2-Minute Walk Test and 6-Minute Walk Test

- Can be started from rest (timer begins when the first step is initiated).
- No setting changes permitted during test.
- Can stop or turn during test, but timer continues.
- Distance needs to be measured by therapist at completion of test.



29. Stop Button Function

| Assistance Mode Programmed to: | Pressing EksoNR 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. |

30. Crutch Interface

Depending on the patient and their goals, the physical therapist may want the patient to control navigation into and out of **Stand Still** and **Walk Modes**. This can be achieved through use of a **Crutch Interface**.

The **Crutch Interface** attaches to the assistive device grip with a fastener strap and a rubber strap. Attach it to the side where the patient has the most strength and/or functionality. Once attached to the walker or a crutch, plug it into the EksoNR torso.

The **Crutch Interface** setup procedure is the same on the Walker or Crutches:

- Fit the two halves of the **Crutch Interface** around the top and bottom of the Walker or Cutch grip.
- Wrap the two straps around the grip tightly and attach.
- Plug the **Crutch Interface** cable into EksoNR torso.
- Secure the cable with Velcro tabs on the appropriate side of the torso and hip.

An EksoNR certified physical therapist must determine that a patient is sufficiently proficient with EksoNR walking before progressing to using the **Crutch Interface**. Patients must have sufficient hand strength to operate the **Crutch Interface**. As with all features of the EksoNR, patients require a period of operational, balance, and gait training to progress to and safely use the **Crutch Interface** and associated software.



Step Button:

- 4 buttons; each button has same action.
- Press with one finger to trigger a step.

Mode Button:

- Pressed with thumb
- Used to enter Stand Still, Walk, and Turn modes.

Buttons

Mode Button

A button to change the mode is located on each side of the **Crutch Interface**. These two **Mode Buttons** function identically when pressed by either thumb; the **Crutch Interface** may be used with either hand.

- To enter **Walk Mode** from **Stand Still**, press and hold **Mode Button** for 3 seconds.
- To enter **Stand Still** from **Walk Mode**, press **Mode Button**.
- To enter **Turn Mode** from **Walk Mode**, press **Mode Button** twice, quickly.
- To enter **Walk Mode** from **Turn Mode**, press **Mode Button** twice, quickly.
- To enter **Stand Still** from **Turn Mode**, press **Mode Button**.

Step Button

The **Crutch Interface** has four buttons that are located on the underside. Depressing any of the four buttons triggers a step in turn mode or can be used to initiate the first step in ProStep or ProStep+.

Indicator Light

The **Crutch Interface** includes a green LED located on top of the end piece, in between either **Mode Button**. The **Crutch Interface** must be plugged into the torso for the Indicator Light to function.

- In **Stand Mode**, the green LED is OFF.
- In **Walk Mode**, the green LED turns ON.
- In **Turn Mode**, the green LED blinks rapidly.

Walking With Crutch Interface

While the EksoNR is in **ProStep** or **ProStep+**, the **Crutch Interface** is automatically enabled whenever the **interface** is plugged in and disabled when the **interface** is unplugged. The physical therapist has the option to operate the EksoNR in **ProStep** or **ProStep+** with or without a plugged-in **Crutch Interface**. The physical therapist also has the option to start a patient walking session with the **Crutch Interface** unplugged and then switch to using the **Crutch Interface** as the session progresses.

While in **ProStep** or **ProStep+**, if the physical therapist unplugs the **Crutch Interface** while the patient is walking or in **Stand Still** mode:

- The Controller screen displays “Crutch Interface Unplugged” (error #164).
- The physical therapist should acknowledge the error and do one of the following:
 - Proceed with the patient walking session with the Crutch Interface unplugged and disabled, or
 - Plug in the Crutch Interface; the Crutch Interface automatically re-enables itself.

Turning With Crutch Interface

When a patient is walking in **ProStep** or **ProStep+**, they may use the **Crutch Interface** to operate the **Turning** program.

- Double press on **Crutch Interface Mode** (thumb) button lets patient enter **Turn Mode** (indicated by a distinctive medley of beeps).
- **Crutch Interface** displays a rapid blinking green light indicating **Turn Mode** has been entered.
- **Step Trigger** buttons on bottom of **Crutch Interface** allows for repeated stepping of forward leg.
- Patient must weight shift to the back leg and use **Step Trigger** button on bottom of **Crutch Interface** to activate the single step to turn.
- Patient turns in the direction of the back leg; feet return to neutral stance.
- Patient repeats the activation of one step with the **Step Trigger** button and turning until they have completed the turn.
- To exit **Turn Mode**:
 - A single press of the Mode (thumb) button returns to Stand Still.
 - A double press of the Mode (thumb) button returns to Walk Mode.
 - After leaving Turn Mode, the first step in Walk Mode is always a right step.

31. Free Hip Abduction

For patients with sufficient lower extremity strength, unlocking **Free Hip Abduction** can add an increased challenge by affording the patient more freedom for individual gait control. **Free Hip Abduction** allows for 22° of abduction from the starting point (-3° to +3°). The patient should be challenged to maintain sagittal plane motion during the swing phase and avoid falling into any compensatory swing patterns in the frontal or transverse planes. Inconsistent base of support and weight shifts may be noted.

Before unlocking these motions, the physical therapist should assess the patient to ensure they have enough strength to control these motions.

NOTE: Free Hip Abduction should remain locked for all sit-to-stand transfers.

- Unlock joints once in a standing position. Be sure to relock the joints prior to sitting.
 - Having patient slowly shift weight side to side will help in finding position where lock lines up and can be easily engaged or disengaged.
- Both hip joints may be free at the same time. To do this, both locks must be unlocked.
- Can be incorporated into PreGait activities including side stepping, squats, and targeted stepping in a unilateral program.
- Cue the patient to avoid compensatory patterning in both swing and stance phases of gait.
- If the patient cannot maintain the leg in the sagittal plane after cues from the physical therapist, relock the free abduction until the patient can maintain independent control.
- When the free hip abduction is unlocked, the hip motor may create a pinch point that could injure the PT's hand if the PT is facilitating the patient's weight shifts by guiding the patient's lower trunk.

32. Errors

Patient training is essential for successful weight shifting and walking in EksoNR. Barriers to successful patient learning may be related to one or more of these areas.

- Device adjustments:
 - Lateral weight shift errors may be related to incorrectly set Leg Length or Hip Abduction.
- Patient-specific issues:
 - Spasticity or range of motion limitations in ankle may challenge forward weight shifting.
 - Structural malalignment (for example, scoliosis) may make lateral weight shift more difficult.
 - Vertical orientation errors or misinterpretation.
 - Tense upper body movements may limit lateral and/or forward weight shifting.
 - Patient using excessive compensatory methods to attempt to advance or clear lower extremities.
- Patient-device considerations:
 - Loose backpack straps may result in suboptimal or challenging lateral or forward weight shifting.
 - Excessive hip width of the device may cause inappropriate lateral weight shifting.
 - Need for fit kit items for improved sagittal plane alignment within the EksoNR.

Critical Device Errors

The EksoNR does the following when it detects an error:

- Emits a beeping alert (from the top back portion of the EksoNR torso).
- Displays an error code and message (often including instructions) on EksoView.

Safe Mode

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

WARNING: In an emergency, press the **Power** button to free the hips and lock the knees, similar to **Safe Mode**. Then lower the patient and device to the ground using a long-legged sit.

The following occurs during Safe Mode:

- Hip motors go free with a damping component that slows the hip motion to assist the patient in staying upright (as long as EksoNR is still powered on), resisting the motion for hip flexion.
- EksoNR knees lock in their current position.
- Alarm sounds immediately and continuously until acknowledged on Controller.

Spotting patient involves:

- Provide full extension moment through hips to provide mechanical stability
 - Physical therapist stabilizes the patient's hip by positioning physical therapist's hip against the lower torso of the device.
 - Hold Torso Handle to extend torso OR
 - Place one hand on Torso Handle and one hand on Sacral Handle.
 - Pull back on Torso Handle and push forward on Sacral Handle to position patient's hips anterior to shoulders.
 - Second physical therapist spots as necessary.
 - When safe to do so, read the message on EksoView and note the error code.
- Press the  button to stop the audible alarm (beeping alert) and to acknowledge the critical device error.
- Hold the  button to clear the message and error code number from the screen.
- Correct the error as instructed.
- If unable to clear message, begin long-legged sitting:
 - Emphasize communication among team (physical therapists and patient).
 - Lead physical therapist provides primary support, standing behind patient.
 - Second person assists patient as necessary.
 - Lead physical therapist instructs second person to retrieve chair when patient is in a safe position.
 - Chair positioned behind patient back to estimated length of lower extremities.
 - Lead physical therapist stands to side while second person assists with sitting.



- Lead physical therapist controls lowering of patient into the chair while legs stay locked in their current position.
 - Position patient upright in the chair; make sure patient is seated squarely in the chair.
 - Second person moves to support lower extremities (see photo).
 - Lead physical therapist uses Controller screen to navigate into Legs Free mode when safe.
 - Position patient's feet squarely on floor to stabilize in sitting.
- If the error message reoccurs after making the appropriate adjustments, discontinue EksoNR use and contact **Ekso Bionics Customer Experience**.



Ekso is in **Safe Mode** when:

- Immediately powering on the device, before selecting **Legs Free** from walk menu.
- When device is powered OFF.
- When an alarm is signaled, that results in immediate **Safe Mode**.

NOTE: If the physical therapist wishes to purposely enter Safe Mode to lower a patient directly to the ground—in the event of severe medical event requiring immediate attention in supine—this is done through turning OFF the EksoNR through the Power button. In this situation, no damping is applied to the hip motors and they are fully free.

General considerations:

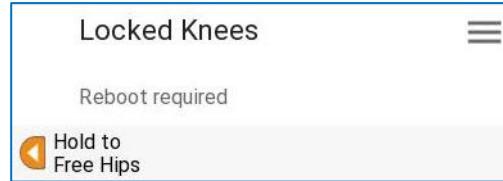
- Hips go free in the event that the physical therapist needs to lower the patient all the way down to the floor.
 - In the event of a device issue, the physical therapist needs to overcome the dampening motor resistance while lowering the patient using a long-legged sit.

Depending on the patient's presentation, the patient's ability to manage **Safe Mode** varies:

- Patient with trunk and lower extremity weakness or paralysis *require full assistance* to stabilize in **Safe Mode**.
 - Physical therapist needs to provide stability through the EksoNR hips, placing the EksoNR in an extension moment through hips, maintaining mechanical stability.
- Patient with lower extremity strength with ability to ambulate over ground may be able to contribute some amount of stability upright when the EksoNR is in **Safe Mode**.
 - Physical therapist should still provide assistance to maintain the EksoNR torso in an upright position.

Locked Knees

Locked Knees is a *safety feature* that occurs if a critical device error occurs in relation to the knee joint of the EksoNR. When the device enters **Locked Knees**, the EksoNR emits a distinct alarm cueing the physical therapists that immediate spotting is required for patient safety.



The following occurs during a Locked Knees:

- 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.
- Alarm sounds immediately and continuously until acknowledged on Controller.

Spotting patient involves:

- Provide full extension moment through hips to provide mechanical stability as this sound is the same as **Safe Mode**.
 - Physical therapist holds **Torso Handle** to maintain support to extended torso.
- OR
- Place one hand on **Torso Handle** and one hand on **Sacral Handle**. Second physical therapist spots as necessary.
- Physical therapist(s) will follow commands on Controller and process recovery similar to **Safe Mode**.



Step Abort

The EksoNR automatically aborts the step and returns to **Stand Still** if the device ever detects an unsafe situation.

Step Abort only occurs when a step has been triggered but the stepping leg is in contact with the ground. When a **Step Abort** occurs, a message (code #168) is activated that says, “*Step Aborted - Ekso in Stand Still*”.

Example situations for **Step Abort** include:

- A patient with some motor power swings their right leg forward before the physical therapist initiates the step. The physical therapist triggers the right step on the Controller as the patient thinks the step is finished and is shifting their weight onto right foot and off their left foot. This would result in a Step Abort and the EksoNR returning to Stand Still.
- A patient programmed in Bilateral is shifted to their right with all their weight on the right leg and no weight on the left leg. If a right step is triggered, the Step Abort occurs and returns to Stand Still.

Swing Rescue

- The EksoNR is programmed to complete the swing of the stepping leg and emits an audible tone if the device detects an unsafe situation.
- Swing Rescue** occurs when the EksoNR recognizes the patient's weight has shifted too far forward; a sound emits from EksoNR and the swing leg immediately completes the stepping pattern.

Example situations for Swing Rescue include:

- A patient is walking in **Adaptive** swing assistance and continues to translate their body weight too far forward prior to completing the step, an audible sound will emit from EksoNR to notify the PT of the **Swing Rescue**.
- A patient is walking in **Fixed** swing assistance and **Swing Complete** is set to 2.0. The patient is unable to follow the step trajectory and requires increased cueing to complete the step. When attempting to match the swing, the patient continues to transition their forward weight shift without completing their swing to create a heel strike, **Swing Rescue** will complete the step for safety and emit an audible sound. The Swing Rescue sound is different than the swing complete sound and only one of these tones will be heard per swing.

33. Doffing

The physical therapist needs to help the patient doff the EksoNR after each session is concluded. The patient must be sitting in a chair or on a mat table that can support both the EksoNR and the patient during the entire doffing procedure. The EksoNR does not need to be turned OFF for doffing.

EksoNR straps can be loosened and unfastened in any order; however, maintaining patient balance and stability is crucial.

Make sure that the patient does not hit their buttocks on the hip abduction joint or the thigh support brace during the transfer.

- Physical therapist positioned in front of the patient.
- Start at the top and work down to the **Foot Binding** straps:
 - Release the **Chest** strap
 - Loosen the **Backpack** straps and the **Torso Pad**
 - Unfasten the **Thigh** and **Lower Leg** straps.
 - Release the **Foot Binding** straps.
- Release the EksoNR legs into abduction by pressing the silver hip abduction tab
 - May require slight adduction pressure to release.
- Remove the patient's legs from the device.
- Internally rotate EksoNR leg to allow for a clean path to transfer.
- Document statistics of the session
- Power OFF device at the end of each patient session
 - Powering OFF clears all statistics and returns settings to default.

34. Cleaning and Maintenance

Cleaning

Contact areas of the EksoNR and the Crutch Interface should be wiped down with a disposable, non-bleach, disinfecting towelette between patients.

In the case of body fluid contact:

- Wipe down all contaminated surfaces with a disposable disinfecting towelette to clean and to remove bioburden.
- Disinfect the cleaned surface with a fresh towelette.
- Let all cleaned surfaces dry before using the EksoNR with another patient.
- DO NOT spray the device with germicidal solutions; such actions will damage batteries and EksoNR components.

Maintenance

Every Day:

- Before each use and when adjusting the EksoNR for patients, inspect the device for any changes in appearance or stability.
- Ensure proper battery charging technique is being used.
- Make sure the thigh brace is never lowered below zero on the upper leg adjustment.

Every Month:

- Wipe down all adjustment tubes with isopropyl alcohol and move them through the full adjustment range 3-4 times.
- Check for wear on all adjustment screw heads. If a screw is so worn that the torque wrench slips out of the head before a click is heard, replace using the **Spare Screws and Washer Kit** provided.

Every Year:

- Replace Torque Wrench adjustment tools. The **Ekso Bionics Customer Experience** team will notify you once the tools are approaching one year of use and will ship a new set prior to their expiration date. Dispose of old tools upon receiving the new ones as they have expired, and their proper function is not guaranteed.

Preventative Service Intervals

- The first Ekso Service is due at 303,000 Steps.
- Subsequent Ekso Service is dictated by the Customer Service Report.

Knee Brake Release Battery Replacement

Each EksoNR leg has a manual knee brake release that is activated by a button that functions only when the EksoNR is turned OFF. A 9-volt alkaline battery powers the brake release. This battery is housed in a compartment located inside the upper leg, just above the knee joint. The compartment is covered by a plate with four screws. In the event that this battery needs to be replaced, perform the following procedure:

- Turn OFF the EksoNR.
- Remove the battery cover plate from the leg.
- Remove the battery by disengaging the terminals from the snap connector.
- Replace the spent battery with an Energizer® 9-volt alkaline battery. Ekso Bionics recommends this battery because of the brand's higher-rated performance and reliability.
- Position and insert the battery and wired snap connector in the internal compartment. A label in the compartment shows the proper placement and alignment.
- Replace the cover plate and the four screws.
- Test the brake release by pressing the button. The knee should be free to bend when the button is pressed.

35. Transport and Storage

Moving the EksoNR short distances within a building can be accomplished using methods such as:

- A wheelchair (with EksoNR in a seated position).
- A manual patient lift (with EksoNR secured by a tether).
- Two people (with EksoNR flexed in a seated position and a person on each side) lifting and carrying from the torso handles and under the upper legs.
- Piggy-back carrying the EksoNR

The EksoNR should always be shipped in the Ekso Bionics-designed shipping container.

The EksoNR should be kept where unauthorized or unsupervised personnel cannot use the device.

When not in use, the EksoNR should be stored on a sturdy, stable chair, or a flat surface.

36. Appendix A: Capacities

| Capacities | |
|--|---|
| User Weight | Maximum 220 lb (100 kg) |
| User Height | Approximately 5 ft, 0 in. to 6 ft, 4 in. (1.53 m to 1.95 m) |
| User Hip Width | Maximum 18 in. (45.6 cm) |
| Performance | |
| Expected Service Life | 4 years or 1.25 million steps |
| Walking | |
| Step Length | 8 to 18 in. (20 – 46 cm) |
| Step Height | Approximately 0.0 to 1.5 in. (0 to 3.8 cm) |
| Swing Time | 0.8 to 2.0 seconds |
| Joint Movements | |
| Hip | Range of motion: 10° extension to 135° flexion Abduction: -2° to 4° |
| Knee | Range of motion: 0° extension to 130° flexion |
| Ankle | Range of motion: 10° dorsiflexion to 10° plantarflexion Resting Angle: 3° to 8° Dorsiflexion stiffness: Settings 1 to 4 |
| Batteries | |
| Materials | Li-Ion |
| Voltage | 48.1 VDC |
| Capacity | 2000 mAh |
| Charging Time | Approximately 60 minutes |
| Power Source | 110 – 220 VAC, 50 – 60 Hz |
| Safety | IEC 62133 |
| Charger Specifications | |
| Input power | 110 – 220 VAC, 50 – 60 Hz |
| Safety | IEC 60601-1:2005 |
| EMC standards | IEC 60601-1-1:2007 |
| Environmental | |
| Operating temperature range | 41°F to 104°F (5°C to 40°C) |
| Storage, Shipping, and Transport temperature range | -12°F to 158°F (-25°C to 70°C) NOTE: If storage or transport temperature is outside the operating temperature range, allow a minimum of 4 hours for device temperature to stabilize in the operating environment. |
| Relative Humidity range | 15 to 90% RH |
| Atmospheric Pressure range | 700 to 1060 hPa |
| Operating temperature range | 41°F to 104°F (5°C to 40°C) |

37. Appendix B: Regulatory Information

EksNR Unit Precautions and Warnings

CAUTION

- Federal law restricts this device to sale by or on the order of a physician.
- No operator-serviceable parts inside unit.
- Refer servicing to qualified personnel.
- Use only data cables offered by Ekso Bionics, Inc. for this system.

WARNING

- This equipment can radiate radio frequency energy. If this equipment does cause harmful interference to other devices, the user is encouraged to increase the separation distance between this device and the affected device.
- The use of accessories, transducers, and/or cables other than those specified—with the exception of those sold by the manufacturer as replacement parts for internal components—may result in increased emissions or decreased immunity of the equipment or system.
- The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.
- This product contains a radio with FCC ID: IHDT56PJ1 that transmits data in the frequency range 850 to 1900 MHz. The highest measured power is 0.914 Watts ERP for Part 22 of FCC Rules and 1.127 Watts EIRP for Part 24 of FCC Rules.
- This unit contains a radio that may interfere with pacemaker operation. Based on current research and guidance from the FDA, the type of radio frequency interference generated by this device would not seem to pose a significant health problem for the vast majority of pacemaker wearers.

| | | |
|---------------|--------------------------------|-----------|
| Head SAR | UMTS / GSM, Wi-Fi, Bluetooth | 1.50 W/kg |
| Body-worn SAR | UMTS 850 MHz, Wi-Fi, Bluetooth | 0.97 W/kg |

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

CE NOTICE - INFORMATION FOR THE USER

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. This device is also found to comply with the limits for a Class B digital device, pursuant to presently harmonized European standards. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at the expense of the user.

The user may find the following publication prepared by the Federal Communications Commission helpful:

How to Identify and Resolve Radio-TV Interference Problems (Stock Number 004-000-00345-4), available exclusively from the Superintendent of Documents, Government Printing Office, Washington, DC 20402 (telephone 202-512-1800).

WARNING

Changes or modifications not expressly approved by the party responsible for compliance to Part 15 of the FCC Rules could void the user's authority to operate the equipment.

EksNR Battery Precautions and Warnings

CAUTION

- Do not use or leave the battery in a place exposed to direct sunlight or in a car unattended.
- Follow the instructions given in this manual regarding battery installation.
- Fully charge the battery before using the first time. Do this by carefully reading and following the instructions specified for the charger and learn how to charge the battery correctly.
- To save battery life, turn off your equipment power switch after each use.
- Replace the battery if alerted by a low battery warning.

WARNING

- Use the battery in only the following conditions:
 - In Use: -4 to +140°F (-20 to +60°C)
 - While Charging: 32 to 113° F (0 to 45°C)
 - Storage: The battery may be stored up to 2 months at room temperature—68°F ± 5° (20°C +/- 5°)—without charging.
- Do not put the battery into a fire or heat it.
- Do not connect any battery terminals with metal objects, such as wire.
- Keep out of reach of children.
- Do not allow the battery to get wet.
- Do not throw, drop, hammer, stamp, or impact the battery.
- Do not disassemble or alter the battery.
- Do not use the battery if it appears damaged.

38. Appendix C: Guidance and Manufacturer's Declaration

Emissions

All Medical Electrical Equipment and Medical Electrical Systems

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | |
|--|--|
| The EksoNR is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment | |

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|-----------------------------|---|
| RF Emissions CISPR 11 | Group 1 | The EksoNR uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | The EksoNR is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes |
| Harmonics Emissions EN 61000-3-2 | Not Applicable ¹ | |
| Voltage Fluctuations/ Flicker Emissions EN 61000-3-3 | Not Applicable ¹ | |

¹The EksoNR is battery powered and does not contain any AC or DC power ports. The EksoNR does not contain any input/output lines longer than 3 m.

Immunity

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The EksoNR is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|--|---|-------------------------------|--|
| ESD IEC 61000-4-2 | ± 8 kV Contact ± 15 kV Air | ± 8 kV Contact ± 15 kV Air | Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%. |
| EFT IEC 61000-4-4 | ± 2 kV Mains ± 1 kV I/O lines | Not Applicable ¹ | The EksoNR is battery powered. |
| Surge IEC 61000-4-5 | ± 1 kV Differential ± 2 kV Common | Not Applicable ¹ | The EksoNR is battery powered. |
| Voltage Dips/Dropout IEC 61000-4-11 | >95% Dip for 0.5 Cycle, >95% Dip for 1 Cycle, 30% Dip for 25/30 Cycles, >95% Interruption for 250/300 Cycles | Not Applicable ¹ | The EksoNR is battery powered. |
| Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

¹The EksoNR is battery powered and does not contain any AC or DC power ports. The EksoNR does not contain any input/output lines longer than 3 m.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Immunity

Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The EksoNR is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|--|-----------------------------|-----------------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | Not Applicable ¹ | Portable and mobile communications equipment should be separated from the EksoNR by no less than the distances calculated/listed below: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz | 3 V/m | $d = 1.2 \sqrt{P}$ 80 to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz |
| | | | where P is the maximum output power rating of the transmitter in watts (W), and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment containing a transmitter. |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |
| 1The EksoNR is battery powered and does not contain any AC or DC power ports. The EksoNR does not contain any input/output lines longer than 3 m. a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EksoNR is used exceeds the applicable RF compliance level above, the EksoNR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EksoNR. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EksoNR

Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting

Recommended Separations Distances for the EksoNR

The EksoNR is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the EksoNR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the EksoNR as recommended below, according to the maximum output power of the communications equipment.

| Max Output Power (Watts) | Separation (m) 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ | Separation (m) 80 to 800 MHz $d = 1.2 \sqrt{P}$ | Separation (m) 800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$ |
|--------------------------|---|---|--|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Emissions

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The EksoNR Battery Charger is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---------------------------|------------|---|
| RF Emissions CISPR 11 | Group 1 | The EksoNR Battery Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class B | The EksoNR Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics EN 61000-3-2 | Class A | |
| Flicker EN 61000-3-3 | Complies | |

Immunity

All Medical Electrical Equipment and Medical Electrical Systems

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|--|--|--|
| The EksoNR Battery Charger is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment. | | | |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|--|--|--|--|
| ESD IEC 61000-4-2 | ± 8 kV Contact ± 15 kV Air | ± 8 kV Contact ± 15 kV Air | Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%. |
| EFT IEC 61000-4-4 | ± 2 kV Mains ± 1 kV I/O lines | ± 2 kV Mains ± 1 kV I/O lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV Differential ± 2 kV Common | ± 1 kV Differential ± 2 kV Common | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips/Dropout IEC 61000-4-11 | >95% Dip for 0.5 Cycle, 60% Dip for 5 Cycles, 30% Dip for 25 Cycles, >95% Dip for 5 Seconds | >95% Dip for 0.5 Cycle, 60% Dip for 5 Cycles, 30% Dip for 25 Cycles, >95% Dip for 5 Seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the EksoNR Battery Charger requires continued operation during power mains interruptions, it is recommended that the EksoNR Battery Charger be powered from an uninterruptible power supply or battery. |
| Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

Immunity

Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The EksoNR Battery Charger is intended for use in the electromagnetic environment specified below. The customer or user of the EksoNR should ensure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|--------------------------------|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile communications equipment should be separated from the EksoNR Battery Charger by no less than the distances calculated/listed below: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = 1.2 \sqrt{P}$ 80 to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz |
| | | | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment containing a transmitter. |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. | | | |
| NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EksoNR Battery Charger is used exceeds the applicable RF compliance level above, the EksoNR Battery Charger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EksoNR Battery Charger. | | | |
| b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

**Recommended Separation Distances Between
Portable and Mobile RF Communications Equipment and the EksoNR Battery Charger
Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting**

Recommended Separations Distances for the EksoNR Battery Charger

The EksoNR Battey Charger is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the EksoNR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the EksoNR as recommended below, according to the maximum output power of the communications equipment.

| Max Output Power (Watts) | Separation (m) 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ | Separation (m) 80 to 800 MHz $d = 1.2 \sqrt{P}$ | Separation (m) 800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$ |
|-------------------------------------|---|---|--|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

39. Appendix D: Error Codes

| Error Code(s) | Resolution |
|-----------------------------|--|
| 0 | <p>Low batteries, walk ends at 15%</p> <ul style="list-style-type: none"> • Sit patient normally at earliest convenience • Power off the Ekso • Replace with charged batteries • Power on the Ekso and resume normal use |
| 1 | <p>Very low batteries, walking discontinued</p> <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso • Replace with charged batteries • Power on the Ekso and resume normal use |
| 2 | <p>Critical batteries, replace and reboot</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso • Replace with charged batteries • Power on the Ekso and resume normal use |
| 3, 4 | <p>Missing X battery, replace and reboot</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso • Remove and reinstall (charged) battery, making sure that both batteries are fully seated to torso • Power on the Ekso and resume normal use |
| 5 | <p>Batteries over heated, walking discontinued</p> <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso • Wait 5 minutes • Power on the Ekso and resume normal use |
| 6 | <p>Batteries overheated, reboot once cooled</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso • Wait 10 minutes • Power on the Ekso and resume normal use |
| 7, 8 | <p>Charge X battery, replace and reboot</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso • Replace with charged batteries • Power on the Ekso and resume normal use |
| 9 | <p>Mismatched batteries, replace and reboot</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso • Replace with charged batteries • Power on the Ekso and resume normal use |
| 10 | <p>Batteries are not compatible</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Replace with charged batteries • Contact Customer Experience |
| 20, 21, 23, 27 | <p>Sensor Error, reboot Ekso</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Get patient out of the Ekso • Contact Customer Experience |
| 22, 24, 25, 26, 51 | <p>Sensor Error, leg diagnostic required</p> <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Get patient out of the Ekso • Contact Customer Experience |
| 40, 41, 42, 43 | <p>Foot Sensor Error, walking discontinued</p> <ul style="list-style-type: none"> • Sit patient normally at earliest convenience • Reboot the Ekso • If error reoccurs, contact Customer Experience |

| | | |
|-------------|--|--|
| 80, 81 | Sensor Error, torso diagnostic required | <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Get patient out of the Ekso • Contact Customer Experience |
| 100 | Motor Error, Ekso in SAFE MODE | <ul style="list-style-type: none"> • Follow directions on Walk screen to perform desired next action • If error reoccurs, contact Customer Experience |
| 110 | Stand failed, lean forward and retry | <ul style="list-style-type: none"> • Put patient in proper position to retry the stand; the controller screen provides two options: • Sit patient using an Ekso-controlled sit • Put the Ekso into Legs Free and manually reposition patient • Direct patient to lean more forward and retry sit-to-stand transition |
| 111 | Standing time out | <ul style="list-style-type: none"> • Follow directions on Walk screen to continue • Gently press on knee joints to see if the brakes engage. If an audible click is heard, press for standstill and proceed with session • If brakes do not engage, return to sit and assess cause of error |
| 120, 121 | Motor Error, Ekso in SAFE MODE | <ul style="list-style-type: none"> • Follow directions on Walk screen to perform desired next action • If error reoccurs, contact Customer Experience |
| 122 | ROM/align question, sit and check Operating Manual | <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso • Check patient ROM and joint alignment • Return to normal use once questions have been addressed |
| 123 | Ekso Torso Hot, reboot Ekso | <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso for at least 10 minutes • Check patient ROM and joint alignment • Return to normal use once questions have been addressed |
| 132, 133 | Motor Error, Ekso in SAFE MODE | <ul style="list-style-type: none"> • Follow directions on Walk screen to perform desired next action • If error reoccurs, contact Customer Experience |
| 135 | ROM/align question, sit and check Operating Manual | <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso • Check patient ROM and joint alignment • Return to normal use once questions have been addressed |
| 136 | Ekso Motor hot, reboot Ekso | <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Power off the Ekso for at least 10 minutes • Check patient ROM and joint alignment • Return to normal use once questions have been addressed |
| 137, 138 | Motor Error, call Ekso Bionics | <ul style="list-style-type: none"> • Sit patient normally at current location • Power off the Ekso • Contact Customer Experience |
| 141, 142 | Sensor Error, leg diagnostic required | <ul style="list-style-type: none"> • Sit patient at current location using long-legged sit • Get patient out of the Ekso |

| | | |
|------------------------|--|--|
| | | <ul style="list-style-type: none"> Contact Customer Experience |
| 151 | LCD unplugged, Ekso in SAFE MODE | <ul style="list-style-type: none"> Plug EksoView into the Torso Follow directions on Walk screen to resume patient session and perform next desired action |
| 152 | WARNING: Debug mode, call Ekso Bionics | <ul style="list-style-type: none"> Do not use the Ekso Contact Customer Experience |
| 154 | Velocity exceeded, Ekso in SAFE MODE | <ul style="list-style-type: none"> Follow directions on Walk screen to resume patient session and perform next desired action |
| 155 | Current exceeded, Ekso in SAFE MODE | <ul style="list-style-type: none"> Follow directions on Walk screen to resume patient session and perform next desired action |
| 159 | Move feet together while in StandStill | <ul style="list-style-type: none"> Move the patient's feet together in a normal standing position Resume patient session and perform next desired action |
| 160 | StandStill or FREE to change setting | <ul style="list-style-type: none"> If patient is sitting change the Ekso to Legs Free or if patient is standing change the Ekso to StandStill Make desired changes to patient setting(s) Resume patient session and perform next desired action |
| 164 | Crutch Interface unplugged | <ul style="list-style-type: none"> OK to continue using ProStep or ProStep+ without Crutch Interface Ensure Crutch Interface is plugged in and reselect walk option to enable Crutch Interface |
| 165 | Move feet back and retry standing | <ul style="list-style-type: none"> Position the patient's feet so that the heels are slightly behind the knees Retry the stand again |
| 168 | Step aborted, Ekso in StandStill | <ul style="list-style-type: none"> Instruct patient in weight shift and gait timing Retry walking If error reoccurs, increase assistance or switch to Max |
| 190 | StandStill to enable PreGait | <ul style="list-style-type: none"> Press yellow button Retry PreGait activity |
| 1056 | Motor error, reboot Ekso | <ul style="list-style-type: none"> Sit patient at current location using long-legged sit Reboot the Ekso If error reoccurs, contact Customer Experience |
| 1090, 1091 | Unexpected reboot, review settings | <ul style="list-style-type: none"> Follow directions on Walk screen to resume patient session and perform next desired action If error reoccurs, contact Customer Experience |
| 1180 | LCD error, reboot Ekso | <ul style="list-style-type: none"> Sit patient at current location using long-legged sit Ensure the EksoView is plugged in. Reboot Ekso If error reoccurs, contact Customer Experience |
| 1186 | LCD error, Ekso in SAFE MODE | <ul style="list-style-type: none"> Follow directions on Walk screen to resume patient session and perform next desired action |
| 1220, 1221, 1222, 1224 | Language not loaded, defaulting to English | <ul style="list-style-type: none"> Get patient out of the Ekso Contact Customer Experience |
| 1225 | Settings corrupted, call Ekso Bionics | <ul style="list-style-type: none"> Sit patient at current location using long-legged sit Reboot the Ekso If error reoccurs, Contact Customer Experience |
| | *Many errors codes contain the text "Software Error" | <ul style="list-style-type: none"> Do not use the Ekso Contact Customer Experience |