REX Clinical Assessment Guide

REX-7133

REX BIONICS

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REX
BIONICS

Contents

1 Introduction

Purpose

The purpose of this document is to provide technical information about REX and the physiological and psychological indications and contraindications to use, so as to assist a clinician in determining whether REX is suitable for use by a potential user.

REX – Product Description

REX is a hands-free, self-supporting device that allows for mobilization without the use of crutches or a walking frame to maintain stability. It can be used by those with minimal upper extremity function.

The User is supported securely within the device using a pelvic harness, and thigh and calf cuffs.

REX is designed for use in a clinical environment, under the supervision of a REX-trained Clinician. It is sophisticated, yet simple to use and operate. REX can be easily adjusted to suit a variety of Users.

The User typically transfers into REX, with appropriate assistance, in a seated position. Once aligned properly and strapped in, the User is passively moved by REX into standing and walking positions.

The User or Clinician controls REX with a 3 button keypad and joystick or T-bar. REX is powered by an on-board rechargeable, interchangeable battery pack.

The functionality of REX enables a User to perform the following mobility functions within a controlled environment, on a flat, horizontal surface:

- Stand
- Sit
- Walk
- Turn
- Shuffle (Side-Step)
- Backward-Step
- REXercises

REX is adjusted by a REX-trained Clinician, working closely with the User, to ensure an accurate alignment of the User's limb dimensions to REX's at the ankle, knee, and

hip joints. Adjustments are independent of each other, enabling individualized postural support.

REX TECHNOLOGY

01 Motion is generated by 10 custom designed linear actuators which generate the power to move REX with a 100kg user

02 The carbon fibre pelvis withstands the high torque applied by the hip actuators

03 Custom-design sensors with high frequency sampling can accurately detect the location of limbs and joints. Half a million lines of proprietary code control 27 onboard microprocessors that manage the actuator systems and ensure REX is safe and balanced

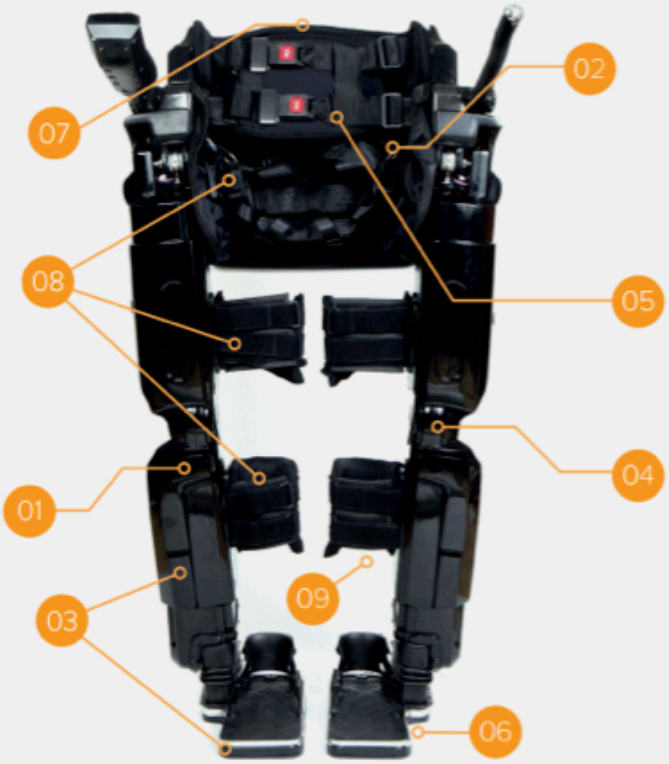
04 Height adjustable REX allows precise and accurate alignment of the user's joints and can be quickly adjusted in minutes between different patients

05 Harness supports 40% of the user's body weight to allow controlled weight-bearing

06 Wide acetal foot plates provide stability and ease of movement across flat surfaces

07 Lithium-polymer battery (33.6V, 18Ah) carries a charge sufficient for at least 60 minutes of continuous use and is fully re-charged in 90 minutes. Two batteries are provided

08 Four double tethered leg straps, upper harness and abdominal support



09 Custom designed cuffs hold the legs firmly, but without creating pressure points. The washable foam padding allows easy maintenance and compliance with infection control regimens

2 Clinical Assessment

In order to mitigate, as far as possible, any risk associated with using REX, it is recommended that a potential User meet the following criteria, as assessed by a suitably qualified healthcare professional. However, as every potential User is unique, any one question, or a combination of questions answered in the negative may not necessarily preclude the potential User from using REX, and conversely, answering all questions in the affirmative does not guarantee the suitability of REX for the potential User, but merely indicates that, in your medical opinion, there are no apparent contraindications to use.

Screening Questions

User fitment

- Is the intended User between approximately 4'8" and 6'4" in height (1.42 m to 1.93 m)? ☐ Yes ☐ No
- Does the intended User weigh between 40-100 kg (88 – 220 pounds)? ☐ Yes ☐ No
- Does the intended User have sufficient passive range of motion at:
  - **Hip**
    - > 90 degrees flexion ☐ Yes ☐ No
    - 0 degrees hip extension ☐ Yes ☐ No
    - Neutral hip rotation ☐ Yes ☐ No
    - 5 degrees abduction ☐ Yes ☐ No
    - 5 degrees adduction ☐ Yes ☐ No
  - **Knee**
    - 0 degrees extension ☐ Yes ☐ No
    - > 90 degrees flexion ☐ Yes ☐ No
  - **Ankle**
    - 0 degrees dorsiflexion (plantigrade) ☐ Yes ☐ No
    - Neutral inversion ☐ Yes ☐ No
    - Neutral eversion ☐ Yes ☐ No

For any 'NO' answer above, list current ROM:

Hip: _____

_____

_____

Knee: _____

_____

_____

Ankle: _____

_____

_____

Medical Contraindications and Warnings

Determining suitability of a patient to use REX is at the discretion of the Qualified Healthcare Professional. Contraindications and warnings for using REX include but are not limited to the following:

Medical Contraindications

Use of the REX is contraindicated in people who have:

Impaired skin integrity, including but not limited to wounds or skin lesions where the REX cuffs, pads and straps come in contact with the User.	☐ Yes	☐ No
Musculoskeletal impairment which influences the fit of the REX or places the User at risk of injury during **full** weight bearing or movement, i.e. severe contractures, recent fractures or severe osteopenia.	☐ Yes	☐ No
High risk of autonomic dysreflexia in response to standing or walking.	☐ Yes	☐ No
Other contraindications to standing or walking.	☐ Yes	☐ No
Any condition that would pose an unacceptable infection control risk.	☐ Yes	☐ No
A spasticity score > 3 on the Modified Ashworth scale in the lower extremeties.	☐ Yes	☐ No

Does the intended User have any of the contraindications listed above to exclude use of REX at this time? ☐ Yes ☐ No

If yes, please specify: _____

_____

_____

Medical Warnings

Extra Care should be taken with individuals who have:

- Lower limb musculoskeletal impairment; including but not limited to hypomobility, hypermobility, joint deformities, contracture or heterotopic ossification.
- Compromised cardiovascular function; including but not limited to significant cardiac disease, orthostatic hypotension, peripheral vascular disease or those that take blood thinning medications.
- Impaired cognitive function which may impact the Users ability to operate the REX safely under clinical guidance.
- Impaired cognitive function which may result in the user becoming agitated and restless while in the device.
- Impaired cognitive function that means the User is unable to fully grasp what is required of them during the use of REX resulting in the inability to give informed consent.
- A stoma bag or PEG feed in situ which could be negatively affected by REX's support structures and straps.

3 Assessment Form

Please complete Form:

Date	Name	Date of Birth	Primary Language
			English ☐ Yes ☐ No Other _____ Is a translator required ☐ Yes ☐ No Other _____

Home Address	GP / Primary Care Physician Details

Social History

☐ Patient requires assistance with ADL's and/or transfers
- ☐ Provided by family
- ☐ Provided by Caregiver
- ☐ Other: _____

☐ Patient is currently participating in a physical therapy program
- ☐ At a hospital
- ☐ At an outpatient clinic
- ☐ At home

☐ Patient is currently participating in a standing program
- ☐ At a hospital
- ☐ At an outpatient clinic
- ☐ At home

PMH – Previous Medical History

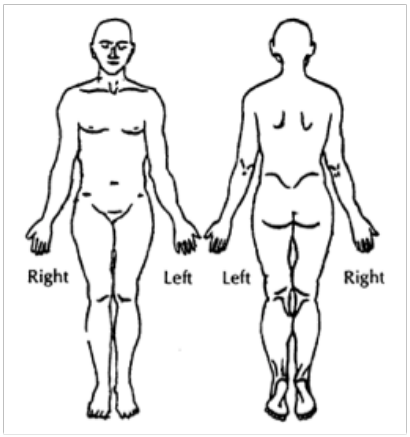
Presenting Condition:
- ☐ Spinal Cord injury-please state level ____ ☐ Complete ☐ Incomplete
- ☐ CVA ☐ TBI ☐ MS ☐ CP
- ☐ Other Neurological Condition _____
- ☐ Skin Issues/Open wounds _____
- ☐ Cardiovascular Conditions _____
- ☐ Diabetes _____
- ☐ Bone Density Issues or Fractures _____
- ☐ High/Low Blood Pressure _____
- ☐ Catheter Usage _____
- ☐ Incontinence _____
- ☐ Arthritis _____
- ☐ Epilepsy _____
- ☐ Recent operations _____
- ☐ Other _____

Functional Status: please check appropriate box

Bed Mobility: Supine to Sitting (edge of bed)	Maintaining Sitting (edge of the bed)	Transfers: Bed to Wheelchair	Wheelchair to Vehicle	Gait: ☐ Yes ☐ No

Pain

Location



Severity (0-10 scale) _____

Cognition / Communication

Please check box for those that apply and explain limitations and adaptations:

Follows Commands _____
- ☐ Verbal _____
- ☐ Visual _____
- ☐ Tactile _____
- ☐ Other _____

Able to Communicate _____
- ☐ Verbal _____
- ☐ Written _____
- ☐ Communication Device _____
- ☐ Other _____

Visual Limitations
- ☐ Neglect _____
- ☐ Hemianopsia _____
- ☐ Visual Field Loss _____
- ☐ Other _____

Medication List

_____
_____
_____
_____
_____
_____

Activity Levels: (how often do you exercise? What kind of exercise?)

_____
_____
_____
_____
_____
_____
_____
_____

DECLARATION

In my informed opinion, based on the information provided in this document, as well as my own professional training and experience in practice, I consider the potential User named below as having no apparent contraindications (except where explicitly stated) to using REX in the manner described within this document.

User's Name _____

Are there any precautions to use of REX for this patient:

_____

_____

_____

Doctor / Clinician Details

Doctor / Clinician Name _____

Title & Designation _____

License Number _____ State _____ Country _____

Address _____

_____

Email or Contact Number _____

Signature _____ Date _____

VOLUNTEER DECLARATION

I hereby consent to a voluntary trial session of the REX as a User of the device with supervision of a REX Clinician and assistance from my caregiver. I have read and understand the indications / contraindications, risks and benefits of this trial session.

Signature _____ **Date** _____