

## AT PRODUCT REVIEW: Lite Run Gait Trainer by Lite Run, Inc.

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### Overview

The Lite Run™ Gait Trainer is an innovative assistive and rehabilitation device for the treatment of persons with gait and balance difficulties from injuries such as spinal cord injury, traumatic brain injury, polytrauma and/or stroke. It uses a specialized soft exosuit ("spacesuit" pants) that unweights veterans by up to one-half of their body weight. The pants attach to an over-ground, unconditionally stable, walker that maintains the pants pressure to the desired level of unweighting. This provides safety and stability for veterans and reduces the therapist's need to physically support them, freeing his/her hands for therapy and allowing a more dynamic therapy session. The system supports sit-to-stand transitions from wheelchairs and other surfaces so that a single therapist can safely transition a patient to standing for gait training. The Gait Trainer has a compact frame that provides easy maneuverability, and open design that allows the therapist access to the veteran's legs. The Gait Trainer has an easy to use touch screen interface that accepts variable unweighting, and displays distance walked, walking speed and other metrics. Compared to standard harness lifts, the suit more evenly distributes the patient's body weight, improving comfort and greater unweighting which ultimately increases the amount of time spent upright during a therapy session. These features reduce physical burden for the therapist and allow for a more diverse population of veterans that can utilize it. Many veterans have lower extremity contractures and/or weigh too much to safely attempt ambulation with even three therapists. Often this patient population is very distractible. There are many built in features that can be utilized to improve focus on desired therapeutic intervention (i.e. screen black out, fixing casters in one direction, adjusting unweighting, etc.)

### Indications

The device is intended for use in a clinical environment on any patient who may benefit from over-ground, body weight supported gait therapy. Patients for whom a harness is uncomfortable may find the exosuit much more comfortable.

### Contraindication

Patients that are > 350 pounds, have active lower extremity blood clots, and/or have open wounds. Pregnancy is a precaution.

### Criteria for Evaluation of Assistive Technology Device

#### Affordability:

The System costs \$xx,xxx which is well less than robotic exoskeletons and over-head track ceiling unweighting systems. There are no additional training and certification costs, as a one-hour onsite training is sufficient. This differs from the significant training required to certify for exoskeletons. Furthermore, unlike over-ground harness systems, no facility modifications are required by the system.

#### Compatibility:

The Lite Run Gait Trainer has been used with knee-ankle-foot orthotics, functional electrical stimulation devices and prosthetic lower limbs, without difficulty. The patients' orthotics and prosthetics in these cases fit underneath the soft exosuit. It has been shown to be very helpful for patients that are adjusting to a new prosthesis.

#### Consumer Repairability:

The Company maintains or repairs the device if needed. User repairs are not recommended.

#### Dependability:

The device and exosuits have been reliable for us.

#### Durability:

The device appears to be very well made. The base of the device is very sturdy and can withstand bumping into walls and other surfaces without compromising its safety with use. The Company offers a 7-year extended warranty.

### Ease of Assembly:

The device rolls out of the shipping crate and is ready to use. The amount of time it takes to set a patient up in device depends on many variables (cognition, medical comorbidities, etc). We found an average of 5 minutes in our clinics.

### Ease of Maintenance:

No specific daily maintenance is required beyond routine cleaning of patient contact points such as the arm rests, a wipe down of the exosuits, and recharging the batteries. The Company offers annual routine maintenance which consists of a battery change-out. This may also be done by an in-house biomed technician.

### Effectiveness:

In a clinical study (1) at our VA facility with a crossover comparator, patients were able to walk twice as far and stay upright twice as long in the Lite Run gait device as in a harness system. This may allow increased rehabilitation volume and yield better outcomes.

- Koehler-McNicholas SR, Cataldo A, Koch E, Rud B, Gude L, Brenteson C, Johnson D, Wigness B, Hauck J, Oddsson L, Hansen AH, Evaluation of A Novel Gait Training Device Using A Pressure Suit to Support Body Weight. Proceedings of the 2018 Design of Medical Devices Conference DMD2018, April 9-12, 2018, Minneapolis, MN, USA.

### Flexibility:

The device includes 9 different adult exosuit sizes. In addition, pediatric sizes are available. Included in the system are durable arm rest platforms with 5 degrees-of-freedom adjustability, to accommodate different patient heights, sizes and preferences

### Learnability:

Once the one-hour training is complete, therapists may use immediately with patients as desired. Any clinician that underwent the initial training can train other clinicians. Patients' (cont. page 9)

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caregivers were able to learn device as well and actively participate in the veteran's rehabilitation.

### Operability:

The device is easy to learn and operate. The Company provides a 1 hour in-service training, at which point therapists are able to begin using the device with patients. A touch-screen display is used to begin unweighting, or to change the amount of unweighting in pounds anytime as desired. This is straightforward to use and remember. The device also has electric castors allowing for a full swivel, a swivel lock for 'straight line' walking or a brake, selectable with a button tap on the touchscreen. The device provides distance walked, walking speed, average unweighting and other metrics on the display.

### Personal Acceptability:

The device itself as well as the exosuits are attractively designed. Patients have voiced comfort while wearing it in more public common areas at the Minneapolis VA. One veteran was willing to be filmed and presented on national television.

### Physical Comfort:

Pain to the user has not been reported. In a crossover clinical study, patients in the Lite Run device walked twice as far and were vertical more than twice as long compared to a harness system. This may reflect greater patient comfort, or more effective unweighting.

### Portability:

The Lite Run Gait Trainer is portable within the clinic, easily rolling into elevators to support multi-floor use. The battery charge lasts for 4 hours of continuous usage. Plugging into the charger is recommended between patients and over breaks, which generally supports full day usage.

### Securability:

The device is compact (it is about 3' long by about 2' wide, just over 3' high), for storage in a secure area.

### Supplier Repairability:

The Company will have local service for diagnosis and simpler repairs if necessary. If a more extensive repair is required, the Company may supply a loaner or replacement device.

#### Clinicians' Quotes:

*"It is a great all-around ambulation option to safely mobilize non or minimally ambulatory patients."*

*"It is very easy to operate."*

*"It is a great option to push step count and intensity during treatment."*

*"Patients feel very safe and secure when in the device."*

*"It is very easy to use."*

*"It is very comfortable for veteran's and the flexibility of it allows for a larger variety of veterans that can use it!"*

*"As a PT, my goal is to do whatever I can to get my patients up and moving to return to walking. Lite Run has allowed me to do that."*

*"Sometimes it only took 2 or 3 sessions in Lite Run to remind the body how to walk and gave my patients the confidence they needed to return to over ground walking."*

*"This should be at every rehabilitation facility."*

*"Long term care facilities should have the Lite Run. Often veterans do not get the opportunity to walk because they are not safe to do so leading to further physical decline which spirals into further morbidity. You do not have to be a skilled PT to use this device. Nurses and nursing assistants would be able*

1	2	3	4	5
Not satisfied at all	Not very satisfied	More or less satisfied	Quite Satisfied	Very Satisfied
	Category		Score	
	Affordability		4.5	
	Compatibility		5	
	Consumer Repairability		4.5	
	Dependability		5	
	Durability		5	
	Ease of Assembly		5	
	Ease of Maintenance		4.8	
	Effectiveness		5	
	Flexibility		4.8	
	Learnability		5	
	Operability		5	
	Personal acceptability		5	
	Physical Comfort		5	
	Physical Security		5	
	Portability		5	
	Securability		5	
	Supplier Repairability		5	
	Average		4.9	