FREESTEP SAS (Supported Ambulation System)

INSTRUCTIONS FOR USE AND ASSEMBLY

950-487

960-126

960-401

960-402

BIODEX

Biodex Medical Systems, Inc.

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FN: 19-052 Rev A 4/19

FreeStep SAS

This instructions for use document covers safe operation of the FreeStep SAS System – 950-487, 960-126, 960-401 and 960-402.

Additional information and resources are available upon request or directly from the Biodex website, www.biodex.com.

If the desired information is not found, please feel free to contact a local distributor or Biodex directly at supportservices@biodex.com.

Thank you,
Biodex Medical Systems, Inc.

Contact information

Manufactured by:

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Table of Contents

Definition of Symbols

The following symbols and their associated definitions are used and implied throughout this manual.

Symbol	Definition
	Carefully read these instructions prior to use
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Pinch Point
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Waste in Electrical Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part

FN: 12-286 Rev A 8/18

Before Proceeding

Before getting started with any of the setups described in this manual, there are a few preliminary points to consider that will help ensure safe and smooth operation of the FreeStep SAS System.

Be aware that use of Biodex products requires professional expertise for discerning appropriate treatment techniques. Each subject's unique situation should be taken into account before beginning any type of testing or rehabilitation program. Be sure you fully comprehend these operating instructions before attempting to treat a subject for testing or exercise. Practice setups and positioning with a healthy subject before attempting to treat an injured patient.

NOTE: *Service should be provided by qualified personnel only. Please do not attempt installation or repair on your own. Call Biodex Customer Service for assistance.*

WARNING: The FreeStep SAS System must be thoroughly inspected every time prior to usage with a patient to ensure safe operation. Refer to the Maintenance and Safety Inspection section for details.

CAUTION: The FreeStep SAS System should not be used if an issue requiring service by Biodex personnel is detected during inspection.

CAUTION: Ensure that the support rope safety stop does not come in contact with the support bar pulley when either a Biodex supplied harness or other manufacturer's harness is used to support the patient.

CAUTION: When service is required, the FreeStep SAS System should only be serviced by personnel authorized by Biodex Medical Systems, Inc. Failure to do so will void the warranty and no longer ensure safe operation.

CAUTION: Modifications to this product are only permitted by the manufacturer. Unauthorized modification of the product can result in hazards to the operator and patient, and will void the manufacturer's warranty. Do not modify this equipment without authorization from the manufacturer.

CAUTION: The harness is not designed to be a fall arrest device, but rather a fall prevention device. Never allow slack in the line supporting the patient.

CAUTION: This device should not be used anytime pressure around the abdomen, thighs, groin or shoulders is contraindicated.

For additional technical advice, service or education information, please contact:
Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, New York 11967-4704; 1-800-224-6339 (Int'l 631-924-9000) or customerservice@biodex.com.

Important Safety Information

CAUTION: Federal Law restricts this device to sale by, or on the order of a medical practitioner. When prescribed for therapeutic purpose, a physician should clearly define the parameters of use (i.e., total work, maximum heart rate, etc.) to reduce the risk of patient injury.

Follow the assembly and installation instructions document.

Before using this device, read the entire operation manual carefully. Failure to read the manual may result in user error or inaccurate data. Be sure to save all provided documents for future reference.

Make certain to understand all warning and caution labels as explained in the Before Proceeding section of this manual.

This product should be used only as specified in the operation manual.

WARNING: The FreeStep SAS System is designed for use in a patient environment.

For product specifications, refer to the Table of Contents.

Reference Cleaning and Maintenance instructions in the Table of Contents.

Biodex Warranty

Refer to the warranty card included with the product or contact Biodex Support Services.

1. Introduction

Intended Use

The FreeStep Supported Ambulation System (SAS) is used to support weakened or balance deficient patients without using additional floor space or requiring additional staff.

Indications for Use

The FreeStep SAS is an overhead track and harness system that provides a safe ambulation environment for both therapist and patient. Without the fear of falling, patients can focus more fully on their tasks of gait and balance. Likewise, therapists can focus on assisting, rather than supporting.

Custom Configuration

The FreeStep SAS can be custom configured to any facility; complementing the existing equipment floor plan. Install as a simple loop for continuous ambulation over stairs or through parallel bars, or add side branches for equipment-specific stations to include treadmill exercise or balance training (sample configurations can be found at http://www.biodex.com/physical-medicine/products/supported-ambulation/freestep-sas).

NOTE: *A customized floor plan can be created using Biodex Floor Planner, which is available at www.biodex.com/planner/pm.*

Figure 1.1. Floor Plan Custom Configuration URL.

Training

To view the FreeStep SAS Clinical Applications eLearning course, visit:

www.biodex.com/freestep.

NOTE: *Scanning the code may require the Articulate app to be downloaded.*

Videos

There are also many FreeStep SAS videos located on the Biodex website; www.biodes.com/freestep.

These two videos focus on Parkinson's:

1. How to: FreeStep SAS for Parkinson's:

   www.biodex.com/video/freestep/pd

2. How to: FreeStep SAS for Parkinson's – Alignment and Static Balance:

   www.biodex.com/video/freestep/pd-align

Figure 1.2. FreeStep SAS Videos on Biodex Website.

2. Assembly Instructions

Attach Height Adjustment System to Track and Trolley

1. In preparation for attaching the Height Adjustment system to the track and trolley, remove the shackle pin (2) from the U-shaped clevis (1) using pliers or an adjustable wrench.

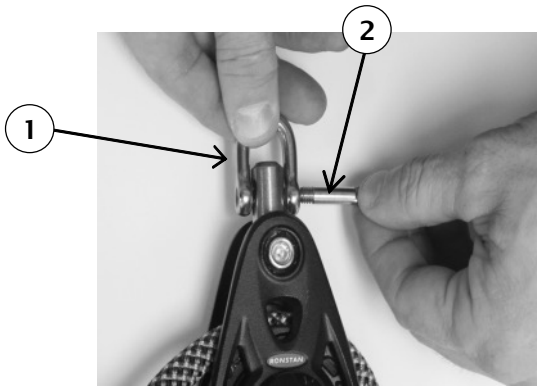

Figure.1.3. Removing Shackle Pin (2) from U-Shaped Clevis (1).

2. Insert the U-shaped clevis (1) through the eyehole of the trolley, line up the Height Adjustment System (2), and reinsert the shackle pin (3) initiating from the non-threaded end of the clevis.

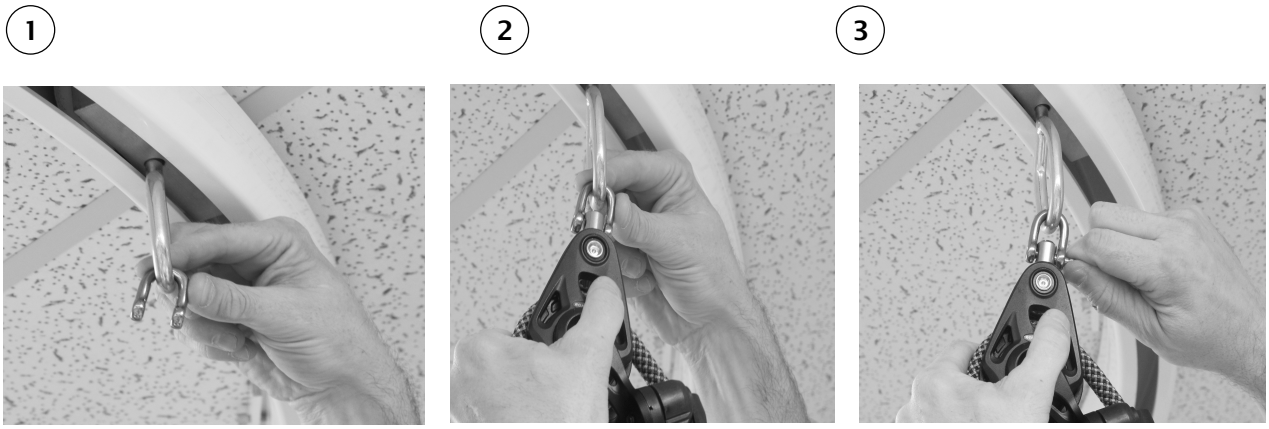

Figure 1.4. Inserting Height Adjustment System into Track with U-Shaped Clevis and Shackle Pin.

3. Securely tighten the shackle pin with pliers or wrench by turning in the clockwise direction and apply a zip tie.

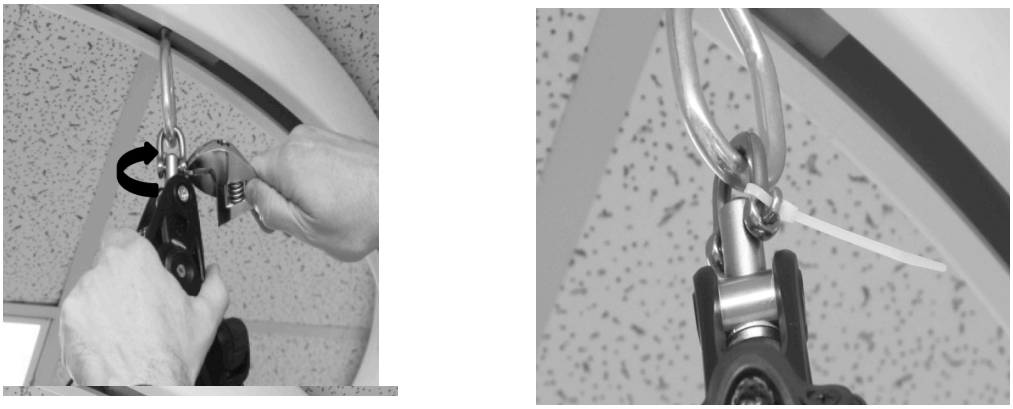

Figure 1.5. Tighten Shackle Pin and Apply Zip Tie.

***NOTE:** It is recommended that a zip tie is added to the shackle pin to ensure it does not back out of the clevis.*

FreeStep SAS Operation

Using the Pulley and Rope:

1. Adjust the tension to a level that best supports the patient while participating in ambulatory level and/or therapeutic activities by pulling down to raise the pulley. This pull locks the rope in the cam cleat.

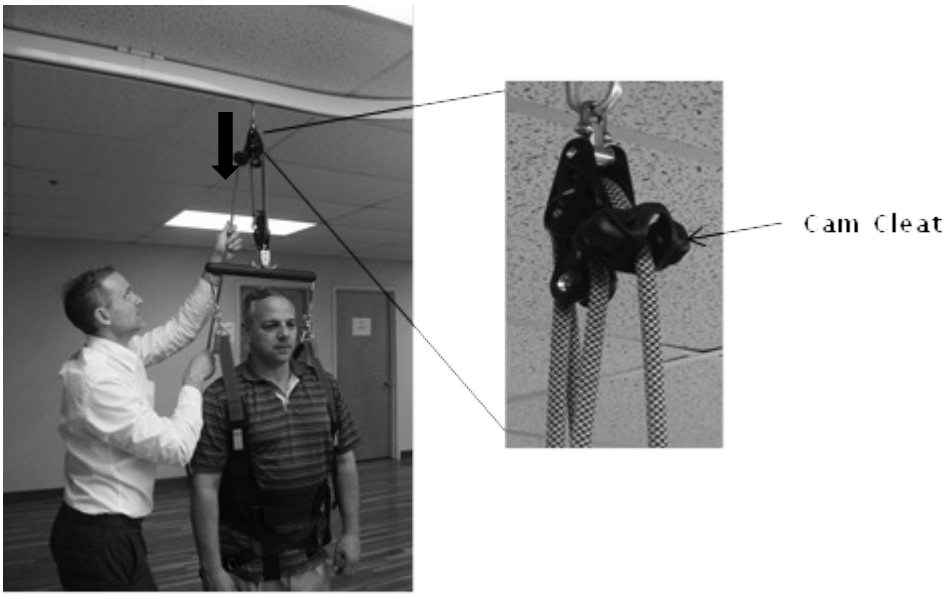

Figure 1.6. Raise the Pulley to Lock the Rope in the Cam Cleat.

2. Use a quick rope tug or 'flip' to disengage the rope from the cam cleat.

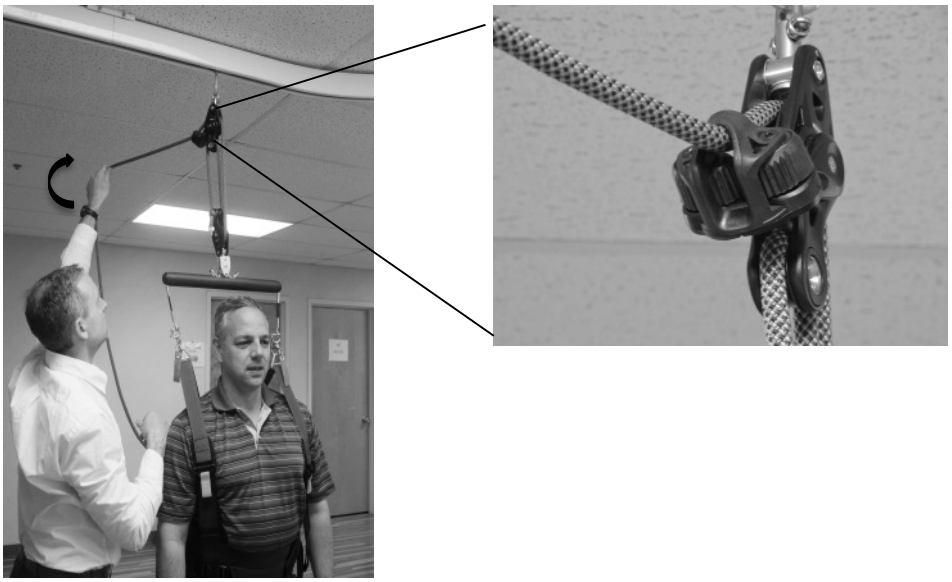

Figure 1.7. Tug the Rope to Disengage the Rope from the Cam Cleat.

NOTE: *In theory, the FreeStep pulley system creates a 3:1 advantage of leverage meaning that the patient's weight will only feel one third as heavy as it actually is. However, in practice, the friction between the rope and the pulleys will add about 10% of the weight back to the required force necessary for hoisting.*

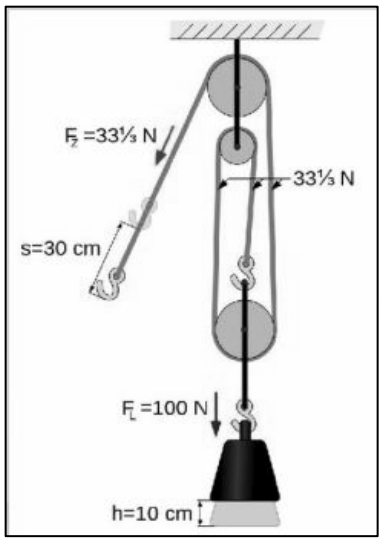

Figure 1.8. Pulley Physics.

Emergency Procedures

In an emergency or urgent situation where the cam cleat cannot be easily disengaged:

1. Turn the patient perpendicular to the track and place the wheelchair under the patient.

Figure 1.9. Patient is positioned perpendicular to the track with wheelchair positioned underneath.

2. Take the rope and step away from the track. A hard flip will disengage the rope from the cam cleat.

Figure 2.0. Putting Pressure on the Rope.

NOTE: *These steps are explained in the FreeStep SAS eLearning course.*

3. Lower the patient into the chair.

Figure 2.1. Lowering the Patient into the Chair.

If two people are available:

4. One person takes the patient under the arms and lifts the patient until there is slack in the rope.

5. The second person disengages the rope from the cam cleat and lowers the patient.

3. FreeStep SAS System Operation

CAUTION: Never leave a patient unattended on this device. Check all cables, harness and fittings before each use.

CAUTION: The FreeStep SAS uses a special harness to support the patient. It is vital that the harness fits properly on the patient. Refer to the video available on the Biodex website.

Using the Standard Unweighing Harness

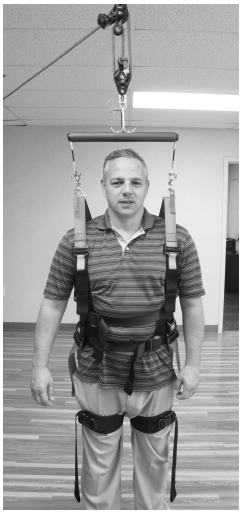

Figure 2.2. Standard Unweighing Harness.

The FreeStep SAS can be used with most two-point harnesses. The harness that is supplied with the system provides maximum support for patients needing consistent body weight unloading. It also provides increased trunk stability. A two-panel design allows for a wide range of adjustability and easy application in sitting and supine positions, while a unique pelvic support piece prevents excessive pressure in the groin area.

Standing Harness Application

Note: *Applying the Biodex Standard Unweighing Harness while the patient is in a standing position is covered in a video that is offered within the Products section of the Biodex Home website: www.biodex.com/harnesses.*

Sitting Harness Application

Note: *Applying the Standard Unweighing Harness while the patient is in a seated position is covered in a video that is offered within the Products section of the Biodex Home website: www.biodex.com/harnesses.*

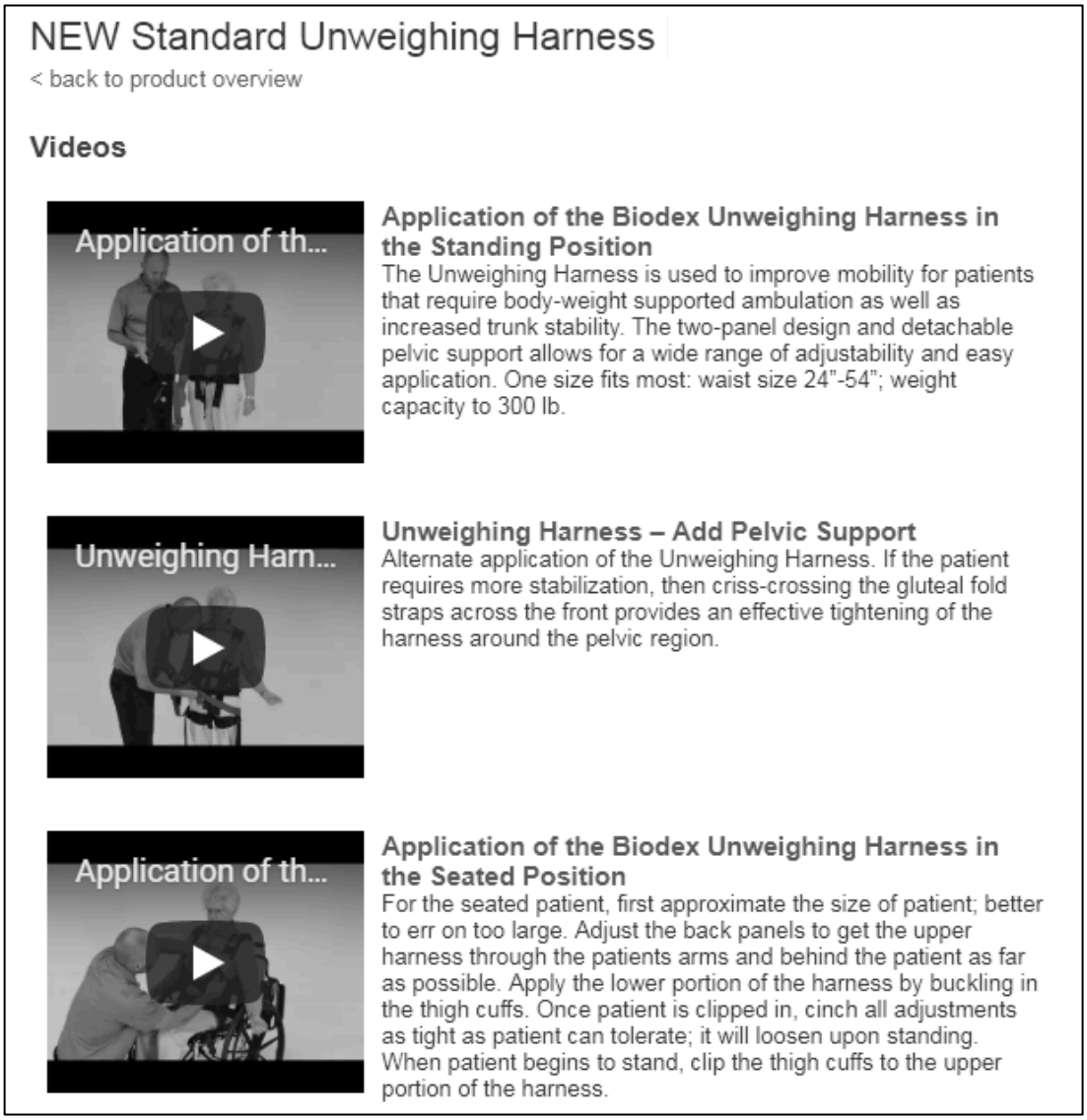

Figure 2.3. Unweighing System Harness Application Videos.

Support Harness DLX

Figure 2.4. Support Harness DLX Double Shoulder Point Connection.

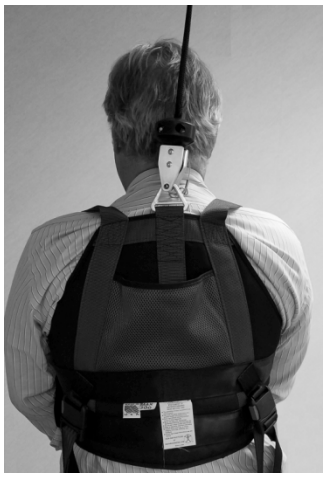

Figure 2.5. Single Connection Point.

Worn as a vest around the upper torso, the Support Harness DLX provides patients with security and safety from falling when used with the FreeStep SAS or Unweighing System. Versatility includes double shoulder point connections to spreader bar or, a single connection point for low ceiling applications with tall patients (6'3" on a treadmill or 6'11" on the floor). A pelvic support strap is included to keep the harness in place when limited body weight support is intended. For information on how to apply the Pelvic Support Strap, go to www.biodex.com/harnesses and click on the Manuals tab.

NOTE: *For a video on Applying the Support Harness DLX, visit: www.biodex.com/harnesses.*

Figure 2.6. Support Harness DLX Video.

Straight Hanger Bar with Quick Disconnect

Some systems will ship with a straight hanger bar as illustrated in Figure 2.7 below.

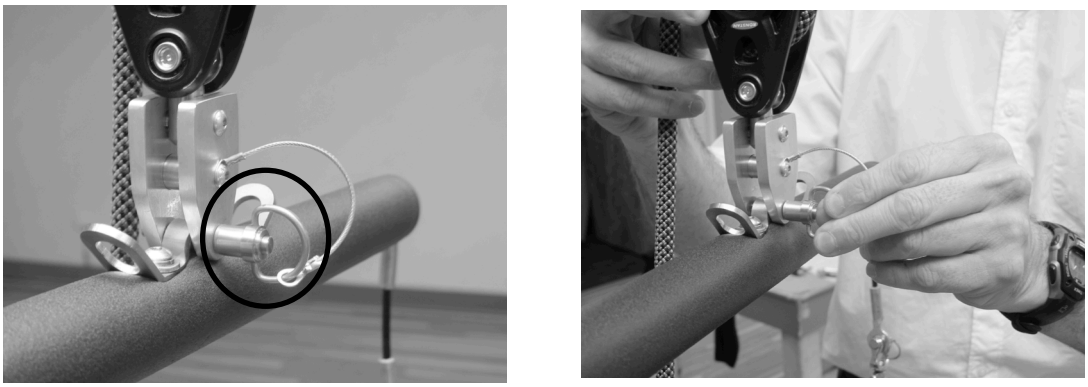

Figure 2.7. Straight Hanger Bar with Quick Release

The straight hanger bar features a quick disconnect that allows the use of a single point harness when the intention is slight support or safety from falling during activity.

The Quick Release pin (see Figure 2.7) is used to disconnect the hanger bar from the clevis. It can be reconnected to a Single Point Support harness either directly or a carabiner can be used.

NOTE: *The Straight Hanger Bar with quick disconnect can also be used with the FreeStep Rail System.*

Figure 2.8. Direct Connection to a Single Point Harness.

Reconnect to the Single Point harness either directly or using a carabiner.

Braking Trolley (Optional)

The Braking Trolley is an accessory to the FreeStep SAS. It contains two sets of rollers and a braking mechanism that provides compression for increased friction against a FreeStep overhead rail track. The larger eyelet (between the rollers) is where the patient height adjuster or single line drop hardware is attached. Refer to the Braking Trolley Installation/Operation Manual for detailed information on installation and usage.

Figure 2.9. Braking Trolley Accessory.

Figure 3.0. Tightening Pole.

***NOTE:** The eyelet with the yellow tag is not to bear weight in any circumstance. The yellow-tagged eyelet is for adjusting rail friction only.*

Ropeman

A spring loaded cam cleat provides a closed loop system that can be used for higher level balance activities.

If using the single point attachment with the carabiner, position the ropeman so it is parallel to the V loop on the posterior aspect of the Support Harness DLX. Attach the carabiner to the V loop and pull to tighten. This will create the closed loop.

Figure 3.1. Creating a Closed Loop with the Ropeman.

If using a dual point attachment, position the ropeman so it is parallel with the spreader bar. Attach the carabiner to the bracket as illustrated in Figure 3.2.

Figure 3.2. Ropeman Using a Dual Point Attachment.

The mechanism needs to be positioned to the teeth are facing down. It is in the correct position if it can be moved freely in the upward direction only.

To move the safety ropeman in the downward direction, pull on the release tab.

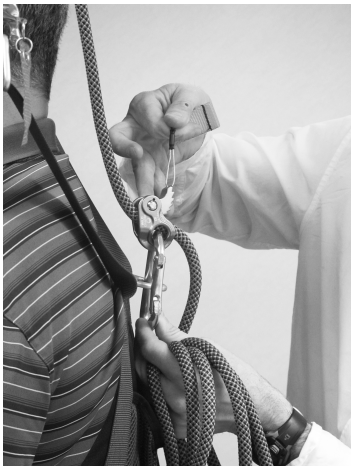

Figure 3.3. Pulling the Release Tab.

P-600 Lift (Optional)

The P-600 simplifies height adjustments when using the Biodex FreeStep SAS for supported ambulation in a therapy setting. Lightweight and portable, this motorized lift attaches to the support harness to provide complete control for the therapist. With a patient load capacity of 600 pounds, this heavy-duty lift is suitable for higher weight transfers.

Powered by non-proprietary batteries, the P-600 offers a cost-effective option to institutions. Additionally, the P-600 comes standard with a full range of features such as on-board controls and emergency lowering. Its on-board controls are complemented by a pneumatic hand control, enhancing maneuvering options for the lift.

Equipped with a digital display, the P-600 offers real-time feedback, a battery indicator, lift counter and preventative maintenance notification. These features and more make the P-600 a popular addition to our range of products for Safe Patient Handling & Mobility.

4. Operating Instructions

The following details the steps to be taken to operate the FreeStep SAS system:

1. Determine what harness is to be used:
    - Standard Unweighing Harness
    - Support Harness DLX
    - Bariatric Harness
    - Pediatric Harness
2. Attach the patient to the FreeStep SAS as follows:

    Single Point Attachment:

    a. Only the Support Harness DLX can be used.

    b. Position the FreeStep on the lower pulley ensuring it is lined up with the metal ‘v’ loop of the support harness (see Figure 3.7).

    Dual Point Connection with Spreader Bar:

    a. Use either the Standard Unweighing Harness or the Support Harness DLX.

    b. Open the Quick Connect Shackle by pulling on the orange tab and connect it to the metal ‘v’ loops located on the shoulder straps (see Figure 3.3).

3. After the patient is securely harnessed in the FreeStep, make any necessary adjustments until there is some tension in the rope.
4. When a desired tension is achieved, place the extra rope in the bag on the back of the harness meant for that purpose.
5. If using the Support Harness DLX, there is a bag on the posterior aspect of the vest meant for that purpose.

5. Maintenance and Cleaning

The FreeStep is virtually maintenance free. By following the instructions below at suggested time intervals, or as often as necessary, the system will remain in “like new” condition.

1. As required, hand-wash all components of the harness on a regular basis with a mild detergent solution, such as Parker Laboratories Protex Disinfectant or any one-step disinfectant that does not contain bleach.

2. Inspect all components of the harness on a regular basis to ensure safety. Replace the harness at the first sign of wear.

Disposal

An appropriate waste disposal company is to be contacted (i.e., the local collection point for waste separation). Properly dispose of the device at the end of its service life:

- The device packaging is disposed of through resource recycling.
- The metal parts of the machine go to scrap metal disposal.
- Plastic parts are disposed of as hazardous waste.

The disposal of equipment must be in accordance with the respective national regulations.

Wear parts are considered hazardous waste! After being replaced, wear parts must be disposed of according to country-specific waste laws.

6. Specifications

Support Harness DLX:

Torso Circumference: 28" to 50" (71 to 127 cm)
User Capacity: rated for 300 lb (136 kg)
Warranty: 60 days, parts

Standard Unweighing Harness:

Torso Circumference: 24" to 54" (61 to 137 cm)
User Capacity: rated for 300 lb (136 kg)
Warranty: 60 days, parts

Bariatric Harness:

Torso Circumference: 52" to 72" (132 to 183 cm)
User Capacity: rated for 600 lb (272 kg)
Warranty: 60 days, parts

Pediatric Harness:

Torso Circumference: 14" to 36" (36 to 91 cm)
User Capacity: rated for 30 to 100 lb (13 to 45 kg)
Warranty: 60 days, parts

Optional Parts:

960-117	Portable Motorized Lift
960-143	Trolley Assembly, Standard
960-144	Trolley Assembly, Braking
960-145	Pole, Tightening
960-146	Single-Line Drop, Adjustment, Ropeman
950-487	Harness, Standard Unweighing
960-126	Harness, Support, DLX
960-401	Harness, Bariatric
960-402	Harness, Pediatric

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