

NxSTEP™ UNWEIGHING SYSTEM

INSTRUCTIONS FOR USE AND ASSEMBLY

950-485

945-480



BIODEX

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NxStep™ Unweighing System

This instructions for use document covers safe operation of the NxStep Unweighing System – 950-485 and 945-480.

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 support@biodexrehab.com.

Thank you,
Biodex Medical Systems, Inc.

Contact information



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www.biodex.com

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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
	Operating Instructions
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Pinch Point
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Non-Ionizing Electromagnetic Radiation
	Waste in Electrical Equipment
	Disposal Classification and Identification of Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part

Before Proceeding



Before you get started with any of the setups described in this manual, there are a few preliminary points to consider which will help ensure safe and smooth operation of your NxStep Unweighing 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 NxStep Unweighing System must be thoroughly inspected every time prior to each usage with a patient to ensure safe operation. Refer to the Maintenance and Safety Inspection section for details.



CAUTION: The NxStep Unweighing 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 NxStep Unweighing 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.



WARNING: No modification of this equipment is allowed.




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.



WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Product Certifications and Classifications

The NxStep Unweighing System has received the following certifications, and falls within the following classifications:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint)
- ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010
- CAN/CSA-C22.2 No. 60601-1:2014
- FDA Class I Equipment
- EU MDR Class I Product
- Type B Applied Part 



- Electromagnetic Compatibility: This equipment complies with the Medical Equipment IEC 60601-1-2:2014 EMC Standard.

***NOTE:** Complete information on the Electromagnetic Compatibility for the NxStep system can be found in the Compliance Supplement located on the Biodex website (www.biodex.com) or can be obtained by contacting Biodex Customer Service (see Contact information).*

Authorized European Community Representative:



Emergo Europe
Westervoorsediik 60
6827 AT Arnhem
The Netherlands

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 Biodex NxStep Unweighing System is designed for use in a patient environment.



For product specifications, refer to the Table of Contents.



For Cleaning and Maintenance instructions, refer to the Table of Contents.



CAUTION: Battery Operation: 115 V or 230 V wall adapter for battery charging.



WARNING: Use approved wall pack adapters.

User Capacity

- Height: up to 78 inches (6 ft, 3 in) (191 cm)
- Weight: up to 400 lb

Operating Conditions

- Temperature: 10° C to 30° C (50° F to 86° F).
- Humidity Range: 30% to 70% (non-condensing).
- Atmospheric Pressure: 70kpa (10psi) to 106kpa (15psi).

Transport and Storage Conditions

- Temperature: -20° C to 70° C (-4° F to 158° F).
- Humidity Range: 10% to 100%.
- Atmospheric Pressure: Sea Level 101kpa (14.7psi) to 10,000 feet, 69 kpa (10.1 psi).

1. Introduction

Intended Use

- The NxStep Unweighing System is used for Partial Body-Weight Support with the capability to unload up to 30-40 percent weight bearing for patients with gait impairments.
- It is a versatile product, providing capabilities for patients with lower extremity weakness, core strength deficits, neurological and musculoskeletal disorders.
- It is intended to be used as a training tool to assist patients with gait performance with a goal for remediation of ambulation activity.

Indications for Use

The NxStep Unweighing System is used with patients who may be deconditioned due to weakness or diagnosed with disease processes such as Parkinson's disease, incomplete spinal cord injuries, multiple sclerosis, LE amputees, Cerebral Palsy, Traumatic Brain Injury, and all other patients with movement disorders effecting gait.

Contraindications for Use

The NxStep Unweighing System is not to be used for patients with any of the following:

- Severe osteoporosis
- Non-union fractures
- Bariatric patients greater than 400 lb
- Patients with poor safety awareness/cognition
- Acute conditions such as pulmonary embolus, thrombus
- Acute Myocardial Infraction
- Acute fractures
- BP over 180/110 Hg
- Severe debilitating dizziness

Precautions

Precautions should be taken with patients that have poor safety awareness/cognition, global weakness, a history of hazardous falls, and/or severe fatigue. Patients less than 30 lb may not register the appropriate loading weight.

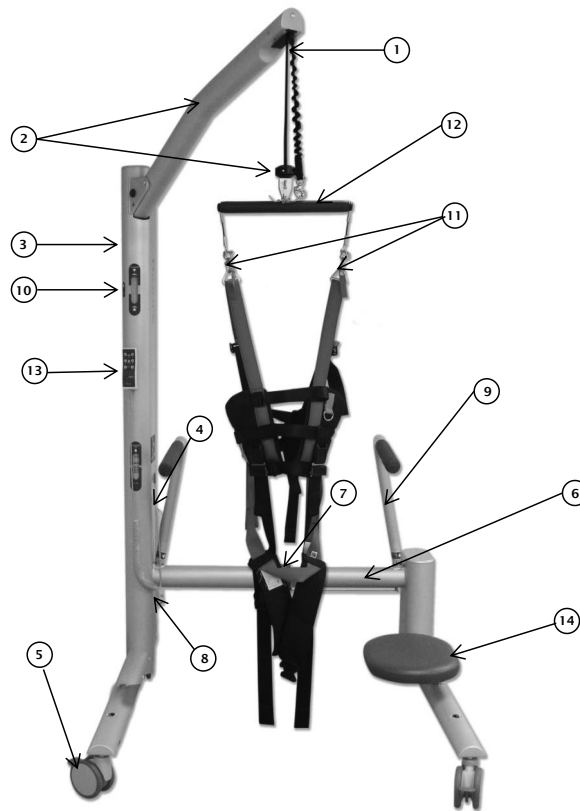


Figure 1.1. The NxStep Unweighing System parts and adjustments include:

Standard Parts and Adjustments:

1. Safety Tether
2. Support Bar with Donut
3. Main Column
4. Allen Wrench (stored in slot near battery pack)
5. 5" Locking Casters (4)
6. Cross Tube
7. Coupling Pull Pin
8. Handrail Release Buttons (one for each side)
9. Handrails
10. Unweighing Scale
11. Quick Release Vest Clips
12. Patient Harness Bar with Bumper

13. Hand-Held Controller
14. Therapist Stool

Not shown:

- Battery Pack
- AC power adapter(s) (115 VAC adapter for US customers, 115 and 230 VAC adapters for customers outside of the US)
- Pelvic Stabilization Straps (945-462, two included)

Optional:

- Additional Therapist Stool (950-486)

Training

Biodex supplements on-site training with many training resources.

For further customer support, use the following link to access a collection of instructional videos on the NxStep System:



<https://www.youtube.com/playlist?list=PLbahIcb7EfwgL28wLh16pAbMloCs-OVCP>

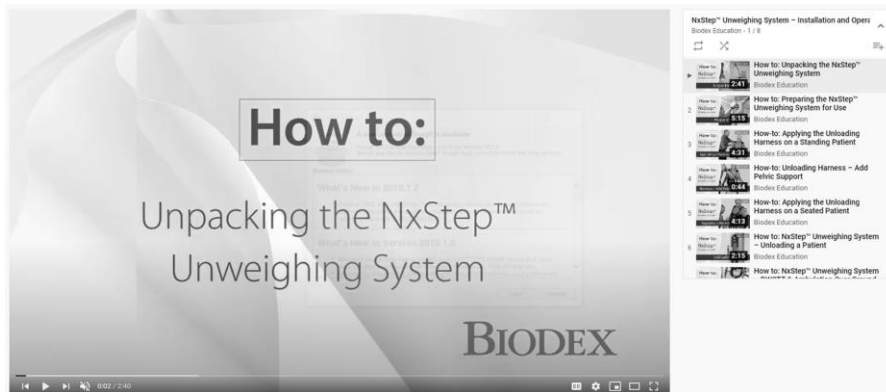


Figure 1.2. NxStep Unweighing System Instructional Videos

2. Assembly Instructions

Assembling the NxStep Unweighing System

The system should arrive at your facility fully assembled. It is shipped in a compressed position with the support bar tilted down and the cross tube compressed. Initial use will require fully expanding the cross tube and setting the support bar to the fully raised position.

NOTE: *If the system needs to be transported through a doorway, hallway, etc., the cross tube can be compressed and the support bar lowered to make moving the system easier. Fully compressed, the system will fit through a 36" wide opening.*



WARNING: *At least two people are required to complete the following procedure. Ensure that the NxStep will be assembled on a level surface. Ensure that there is enough room to easily move around the NxStep frame during installation.*



Figure 2.1. The Biodex NxStep in the fully compressed position.

Assembly Procedure

The unpacking and assembly procedures are covered in the following videos, see [link on Page 10](#).

- NxStep Unweighing System Installation and Operational Instructions
- Preparing the NxStep Unweighing System for Use

3. NxStep Unweighing System Operation



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



CAUTION: *The system 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.*

Straight Hanger Bar with Quick Disconnect

The straight hanger bar is illustrated in Figure 3.1 below.



Figure 3.1. 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 3.2) 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.*

NOTE: *Further operation instructions for the NxStep System are detailed in the NxStep instructional videos, see link on Page 10.*

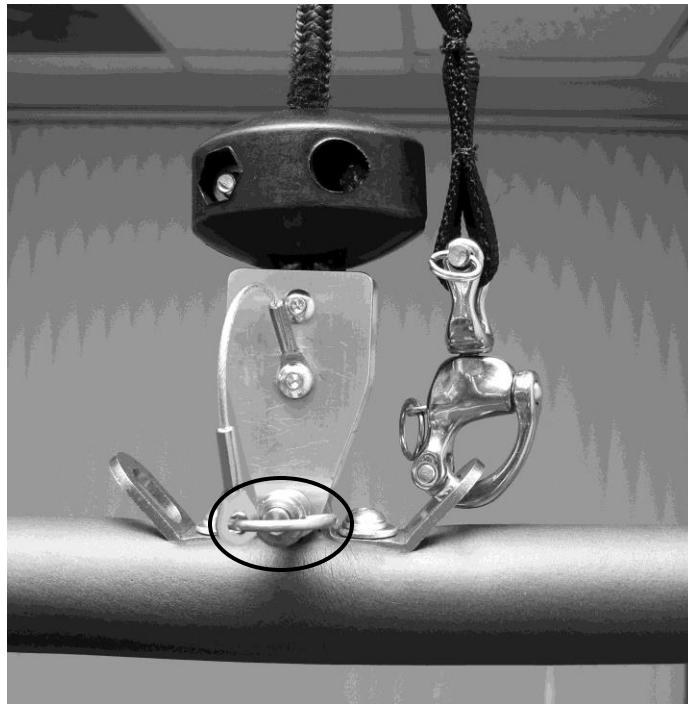


Figure 3.2. Quick Disconnect Apparatus Illustrating Quick Release Pin.

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



Figure 3.3. Direct Connection to a Single Point Harness.

Steering Casters

The NxStep has four locking casters. The rear casters have two lever positions:

- Lever down: the wheel is locked.
- Lever up: wheel is unlocked and rolls and swivels in any direction.

The front casters have three lever positions:

- Lever down: the wheel is locked.
- Lever up halfway: wheel is unlocked, and therefore rolls and swivels in any direction.
- Lever all the way up: Wheel rolls, but only in the direction it is set (it will not swivel.)

Steering tends to be easiest when the two rear casters are unlocked and the front casters are directionally locked in the 'forward' orientation.



Figure 3.4. The front casters have three setting: completely locked, completely unlocked, and directionally locked.

Installing and Removing the Handrails



Figure 3.5. The handrail release button.

The handrails can be used to assist the patient, or removed to provide more of a challenge. To install or remove the handrails, push in on the appropriate handrail release button.

The Therapist Stool

NOTE: Setting up the Therapist Stool, Hand-Held Controller, and Battery Pack, is explained in the *Preparing the NxStep Unweighing System for Use* video, which can be found [here](#):

One Therapist Stool comes standard with each NxStep. An additional stool can be purchased separately (catalog product code: 950-486). While seated on the stool, a clinician can easily observe or assist patients with foot placement and weight shifting.

- To remove the therapist stool, simply lift it up. To install the therapist stool, fit the stool support into either of the two positioning holes along each support bar. The seat can face either in or out from the subject, and the height of the seat can be adjusted by moving the bolt into any of the six holes in the stool post.

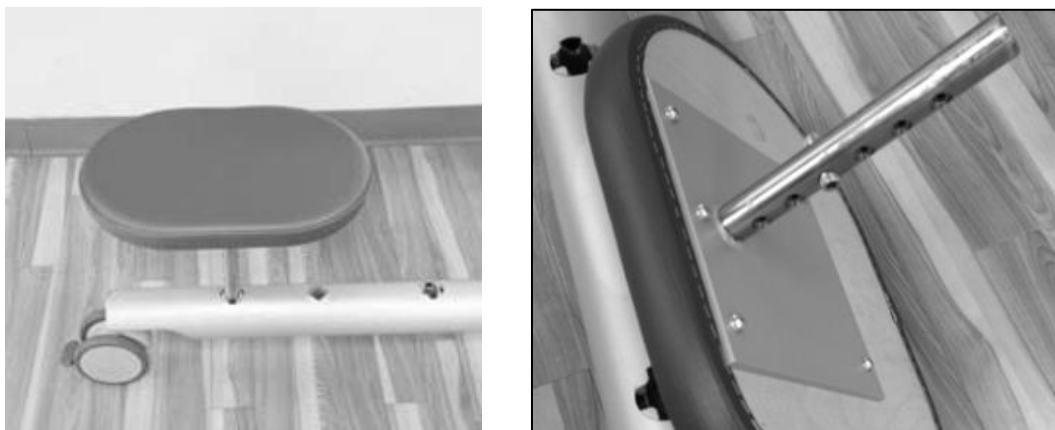


Figure 3.6. The Therapist Stool.

The Hand-Held Controller

The hand-held controller is used to easily raise or lower the patient harness bar, adjust the amount of weight to unload from the patient, or to turn the auto unload feature ON or OFF for unweighing activities. The controller is magnetic, allowing for easy-to-reach positioning anywhere along the main column when not being held by the therapist.

- To raise or lower the patient harness bar, press on the Bar Adjustment <UP> or <DOWN> buttons until the desired bar height is achieved.
- To raise or lower the amount of weight to be unloaded from the patient, press on the Unweigh Load <UP> or <DOWN> buttons until the desired amount to be unloaded from the patient is centered in the appropriate zone of the UNWEIGHING LOAD scale.
- The Auto Unload Feature allows the system to automatically adjust the unweighing load as the patient progresses through unweighing activities to compensate for any slight loosening of the harness as the patient moves. To turn Auto Load on or off, press on the Auto Load <ON> or <OFF> button. A green indicator light will illuminate next to the LOAD RANGE scale when Auto Unload is activated.



Figure 3.7. The Hand-Held Controller.

The Battery Pack

The battery pack attaches to the main column. Slide the battery pack onto the support posts. The plug and cord are located beneath the lower battery. To charge the batteries, plug the charging cord into a wall socket.

- While the battery is being charged, one of two LED lights is illuminated: A green light means the battery is fully charged and an amber light means it is currently charging.
- The red button on the battery is a safety button. Pushing it in removes all power to the device. If it is pulled out, the device will be powered for normal use.

NOTE: The battery can also be charged with a remote charger (part #: C10396). If battery power is drained, the device can still be used with the battery plugged in and charging.

Positioning NxStep for Use with the Biodex Gait Trainer or Treadmill



Figure 3.8. The NxStep ready for use with the Biodex Gait Trainer.

The NxStep can be positioned for use with treadmills to 38" w and 13.5" h (97 x 34 cm).

1. Remove handrails (if treadmill has its own handrails) and unlock all casters.
2. Roll the NxStep into position ensuring the patient harness bar is closest to the control panel end of the treadmill. The treadmill control panel should be easily accessible.
3. Position the patient in the center of the treadmill belt and closer to the front than the back of the treadmill deck.
4. Lock all four casters and proceed with treadmill use.



CAUTION: When using the NxStep Unweighing System with a treadmill, the steering casters should be positioned at the rear of the treadmill. This will make it easier to maneuver around the treadmill deck.

Free Wheeling



Figure 3.9. The NxStep ready for free-wheeling across the floor.

The NxStep can be used over the floor or with other exercise devices. Be aware of the adjustments required when moving from one device to another. For example, when stepping down from a treadmill, the step-up height of the treadmill must be taken into account; the harness will need to be lowered. The opposite is true when going from the floor to the treadmill.

When traveling across the floor there is no need to spin the entire unweighing system around when the patient runs out of floor space. Simply turn the patient around and move in the opposite direction.



CAUTION: When using the NxStep Unweighing System with a treadmill, the steering casters should be positioned at the rear of the treadmill. This will make it easier to maneuver around the treadmill deck.

Jogging

The dynamic suspension provides ample dynamics to allow patients to walk briskly or even jog while attached to the NxStep.

Pelvic Stabilization Straps (Retention Cords)

NOTE: Using the Biodex Standard Unweighing Harness for additional pelvic support is covered in a video at www.biodex.com/harness.

If desired, use the two included pelvic stabilization straps for additional support during partial body weight support activities. Place the strap loops around the handrails and place the hooks in the rings on the patient harness.



Figure 3.10. Retention Cords hooked into harness ring.

Using the Unweighing Harness



CAUTION: The NxStep uses a special harness to support the patient. It is vital that the harness fits properly on the patient. Refer to the video available at www.biodex.com/harness.

The NxStep can be used with most two-point harnesses. The harness that is supplied with your NxStep 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. The harness fits most patients (waist size 24-54"). Maximum weight capacity is 300 lbs (136 kg).

Standing Harness Application

NOTE: Applying the harness while the patient is in a standing position is covered in a video at www.biodex.com/harness.

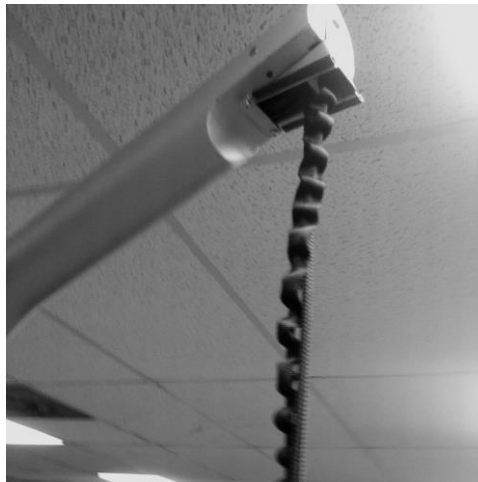
Sitting Harness Application

NOTE: Applying the harness while the patient is in a seated position is covered in a video at www.biodex.com/harness.

Safety Tether Operation



CAUTION: To ensure patient safety, it is vital that the safety tether is attached.



The Figure 3.11. The safety tether (the rippled elastic cord) attaches to the center of the patient harness bar.

The safety tether is factory installed, but a few simple adjustments may be required to ensure proper operation during device usage. The tether strap is elastic, but its maximum stretched length is about 25 inches.

Determination of Body Weight Support

Heel/ground contact during ambulation is lost in patients when weight relief is in excess of 40% body weight (Visintin and Barbeau, [1989], Gardner, et al., [1988]) chose a level of weight relief in which the patient achieved heel/ground contact bilaterally for ten consecutive steps.

When determining body weight support, keep in mind the patient's comfort, as well as their pathology level of involvement. A patient who is considerably challenged may require a greater percentage of weight relief.

Use the scale in the Bibliography section to determine how much body weight is being lifted. The scale will show the relief amount in pounds and kilograms. For example, 30 pounds means that the patient will “feel” 30 pounds “lighter”. For a 150-pound patient, this would equal 20% of his or her body weight.

Unloading Patient Weight

The patient unweighing load can be set either manually or using the Auto Unload feature.

NOTE: *The patient unweighing load can be adjusted by raising or lowering the patient harness bar at any time; the Auto Unload function does not need to be turned off first. Auto Unload automatically turns off any time the patient harness bar is adjusted.*

Patient Unloading Procedure

Ambulatory Patients:

1. Use the hand-held controller to adjust the height of the patient harness bar to just above the patient's head.
2. Position the patient and, with the patient standing, adjust the harness as needed before unloading any weight.
3. For use with a treadmill, or other therapeutic device, press down fully on the locking lever for all four casters to ensure the casters are fully locked into place.
4. Select which set of harness connection holes on the patient harness bar should be used to secure the patient to the NxStep. Release the quick release clips on the harness, slide them into the proper holes, and snap the clips closed.

NOTE: Further instructions on harness fitting and adjustment can be found in a video here: www.biodex.com/harness.



Figure 3.12. The Unweighing Load Range Scale is Located on the Main Column.

5. Using the hand-held controller, set the unweigh load for the patient with the UNWEIGH LOAD <UP> or <DOWN> buttons. The unweigh load will be displayed in the UNWEIGHING LOAD scale on the main column of the system.

- Using the BAR HEIGHT <UP> button on the hand pendant, raise the patient harness bar to begin applying unloading the selected weight. Continue pressing the BAR HEIGHT <UP> button until the indicator is in the center (green zone) of the load range scale located on the main column (Figure 3.13). At this point the set unloading amount is accurately applied to the patient.



Figure 3.13. Unweighing Load Scale.



CAUTION: Do not let the patient harness bar touch the pulley or support bar.



CAUTION: Ensure the safety tether is connected before the patient starts to exercise. To ensure patient safety, the safety tether must be connected whenever unweighing activities are conducted.

- If desired, activate the system automatic unloading feature by pressing the AUTO UNLOAD <ON> button on the hand pendant.
- If desired, the pelvic stabilization elastic straps can be attached to the rings on the harness by the patients hips then attached to the uprights of the handrails.
- If the patient will be walking over ground, the casters must be unlocked. All four casters can be set to fully rotate, or the front casters can be locked directionally to straight ahead.
- For over-ground walking, the patient or therapist can guide the NxStep with the handrails.

NOTE: The unloading amount can be adjusted at any time.



CAUTION: Therapists must be sure to monitor patients closely. A sharp rise in blood pressure or drop in oxygen levels may necessitate the patient being taken down quickly from the NxStep Unweighing System. In such cases, pull the red tabs on the quick release clips to quickly remove the patient while still wearing the harness.

- When the patient has finished exercising and is ready to be removed from the NxStep, the therapist can either press the AUTO UNLOAD <OFF> button or simply lower the patient harness bar until the unload weight amount is gone. At that point, the patient can be removed from the harness.

4. Cleaning Instructions

Harness vest, upholstery, straps, and pads

For light soiling:

1. A solution of 10% household liquid dish soap with warm water applied with a soft damp cloth will remove most soiling.
2. If necessary, a solution of liquid cleanser and water applied with a soft bristle brush. Wipe away the residue with a water-dampened cloth.

For heavier soiling not solved by above method:

Dampen a soft white cloth with lighter fluid (naphtha) and rub gently. Rinse with a water-dampened cloth.

***NOTE:** Use extreme caution with this method. Conduct only in a well-ventilated area and away from any open flame.*

***NOTE:** You should try this method on an inconspicuous spot before using on the original stain/soiling.*

For the most difficult stains not removed by the above methods:

1. Dampen a soft white cloth with a solution of household bleach (sodium hypochlorite); 10% bleach, 90% water.
2. Rub gently.
3. Rinse with a water-dampened cloth to remove bleach concentration.
4. If necessary, allow a 1:10 diluted bleach solution to puddle on the affected area or apply with a soaked cloth for approximately 30 minutes. Rinse with a water-dampened cloth to remove any remaining bleach concentration.

***NOTE:** You should try this method on an inconspicuous spot before using on the original stain/soiling.*

***NOTE:** To restore luster, a light coat of spray furniture wax can be used. Apply for 30 seconds and follow with a light buffing using a clean white cloth.*

Handlebar Foam Grips

Manufacturer states that any cleaner or disinfectant can be used.

5. Maintenance and Safety Inspection

Daily Inspection Tasks

1. Inspect Harness Rope and Safety Tether – Lower the harness rope using Handle #1 until the rope is at its maximum length of approximately 50 inches (150 cm). The Harness rope should lower smoothly to its full length. Inspect both rope and safety tether for any signs of wear, which may include: fraying, cuts, or kinks. Firmly tug on the rope to assure it is secure.

NOTE: *If Harness Rope or Safety Tether show any signs of wear, immediately contact Biodex Customer Service at 1-800-224-6339 or 631-924-9000 (in New York State).*

2. Inspect Harness Spreader Bar – Inspect Harness Spreader Bar and clips for signs of wear. Make sure to release clips and lock them into place to ensure they are functioning properly.
3. Check All Casters – Inspect the four casters for uneven wear. Ensure they are attached firmly to the Unweighing System. Check that the wheels lock and unlock properly.
4. Harness – Inspect the harness for wear-and-tear; check both the heavily-stitched fabric and the elastic neoprene.
5. Handrails – Handrails should be fully inserted and secure.

Semi-annual Inspection Tasks

1. Check Cross Tube lock bolt.

NOTE: *If device was recently moved, or collapsed to move through doorway, verify Cross Tube Bolt is tight before use.*

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. References and Bibliography

For a sampling of specific applications and biographical references, please visit the applications tab at www.biodex.com.

Use the chart below as a quick reference for determining unweighing percentages:

BODY WEIGHT		PERCENT OF BODY WEIGHT UNLOADED					
		20%		30%		40%	
LB	KG	LB	KG	LB	KG	LB	KG
100/45		20/9		30/14		40/18	
110/50		22/10		33/15		44/20	
120/54		24/11		36/16		48/22	
130/59		26/12		39/18		52/24	
140/64		28/13		42/19		56/25	
150/68		30/14		45/20		60/27	
160/73		32/15		48/22		64/29	
170/77		34/15		51/24		68/31	
180/82		36/16		54/25		72/33	
190/86		38/17		57/26		76/35	
200/91		40/18		60/27		80/36	
210/95		42/19		63/29		84/38	
220/100		44/20		66/30		88/40	
230/104		46/21		69/31		92/42	
240/109		48/22		72/33		96/44	
250/113		50/23		75/34		100/45	
260/118		52/24		78/35		104/47	
270/122		54/24		81/37		108/49	
280/127		56/25		84/38		112/51	
290/132		58/26		87/40		116/53	
300/136		60/27		90/41		120/54	

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7. Specifications

Dimensions:

Operational:

I.D. 38.8" w x 48" depth x 94" h (99 x 122 x 239 cm)

O.D. 47.5" w x 48" depth x 94" h (121 x 122 x 239 cm)

Suitable for use with 8' ceilings (244 cm) or higher.

Retracted (not for operation):

O.D. 32" w x 48" depth x 79" h (81 x 122 x 201 cm) will fit through a standard 36" x 80" door.
Battery adds 4" (10.2 cm) to depth.

Accommodates Patients: from pediatric up to 6' 3" (191 cm) when standing over a treadmill with 7" (18 cm) step-up, such as the Gait Trainer 3.

Includes: one therapist seat

Accommodates Treadmill Decks: to 38" w and 13.5" h (97 cm x 34 cm)

Vertical Adjustment: 50" (127 cm)

Unloading Weight Capacity: 160 lb (73 kg)

User Capacity: 400 lb (181 kg)

Charger Power: 115 VAC adapter (for model 950-485), or 230 VAC adapter (for model 945-480).

Battery: Rechargeable 24V. Battery automatically charges when system is plugged in.

Weight: 275 lb (125 kg)

Warranty: Two years parts; one year labor.



BIODEX

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