

NxSTEP™ UNWEIGHING SYSTEM

INSTRUCTIONS FOR USE AND ASSEMBLY

950-485
945-480



BIODEX

Biodex Medical Systems, Inc.

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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 supportservices@biodex.com

Thank you,
Biodex Medical Systems, Inc.

Contact information



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







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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.



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.

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.

Product Certifications and Classifications

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

- ANSI ES 60601-1
- IEC 60601-1
- IEC 60601-1-2
- CAN/CSA C22.2 No. 60601-1:2014
- FDA Class I Equipment
- EU Class I Product
- CE Marked.

- Type B Applied Part 



- Electromagnetic Compatibility: This equipment complies with the Medical Equipment ICC 60601-2 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
Prinsessegracht 20
2514 AP, The Hague
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

Biodex Warranty

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

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.

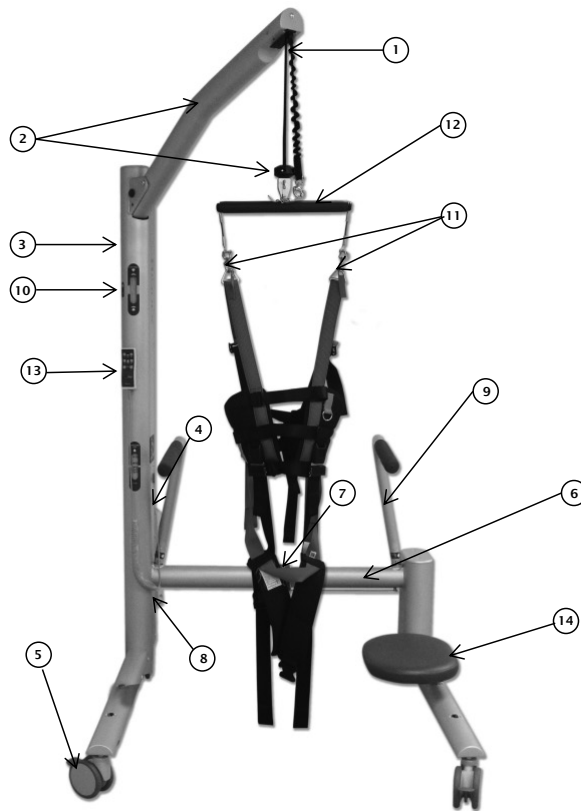


Figure 1.1. The NxStep Unweighing System parts and adjustments include:

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 detailed information on the NxStep System:

- Visit www.biodex.com and register for the NxStep eLearning course by navigating to: Physical Medicine/Education & Training/Training: Interactive eLearning.

<https://www.biodex.com/physical-medicine/biodex-university/training-interactive-elearning>



NOTE: There are also courses for clinical applications of Biodex products for Stroke, Parkinson's, and Peripheral Neuropathy.

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

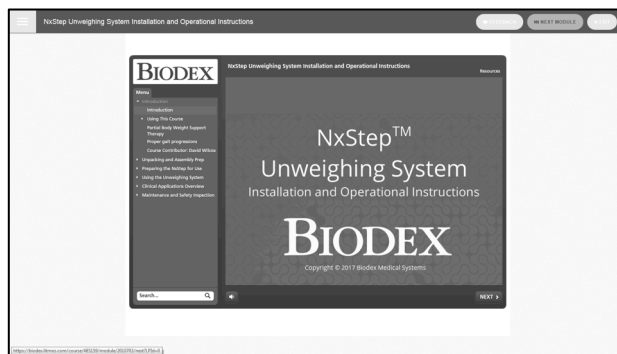


Figure 1.2. NxStep eLearning Course

- Browse the NxStep Unweighing System videos available on the Biodex website:

<https://www.biodex.com/physicalmedicine/products/pbws/nxstep/videos-0>



2. Assembly Instructions

NOTE: The Assembly Instructions are detailed in the Unpacking and Assembly Prep segment of the NxStep eLearning course.

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.



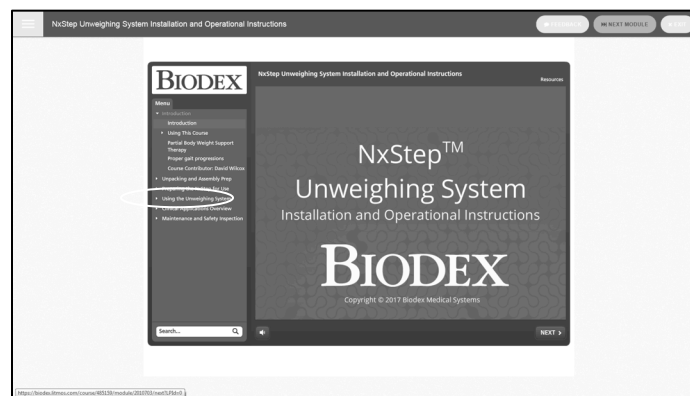
WARNING: At least two people are required to complete the following procedure. Ensure that the NxStep will be assembled on a level surface. Ensure that there is enough room to easily move around the NxStep frame during installation.



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

Assembly Procedure

The entire assembly procedure is covered in the NxStep eLearning Course. To watch the video detailing the assembly process, please register for the course.



3. NxStep Unweighing System Operation

NOTE: System Operation instructions are detailed in the Using the Unweighing System segment of the NxStep eLearning course. This includes an Operational Overview and a separate segment on using the hand-held controller.



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.



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 settings: 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, are all fully explained in the *Preparing the NxStep for First Use* segment of the NxStep eLearning Course.

One Therapist Stool comes standard on 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

NOTE: Instructions for Positioning the NxStep for use with a treadmill and the use of the Therapist Stool are detailed in the Clinical Applications Overview: Treadmill Training segment of the NxStep eLearning course.



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 bar 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 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 that is offered 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.

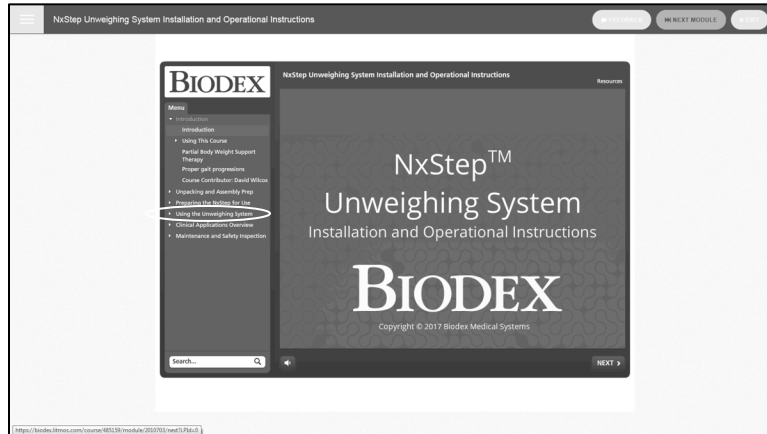
The NxStep can be used with most two-point harnesses. The harness that is supplied with your NxStep provides maximum support for patients needing consistent body weight unloading. It also provides increased trunk stability. A two-panel design allows for a wide range of adjustability and easy application 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 the NxStep eLearning course and a video that is offered at www.biodex.com/harness.

Sitting Harness Application

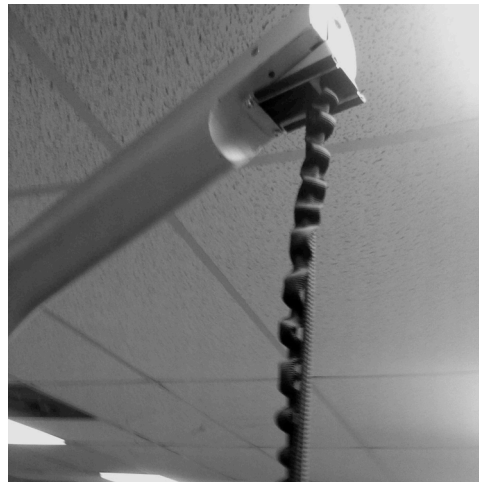
NOTE: Applying the harness while the patient is in a seated position is covered in the NxStep eLearning course and a video that is offered at www.biodex.com/harness.



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

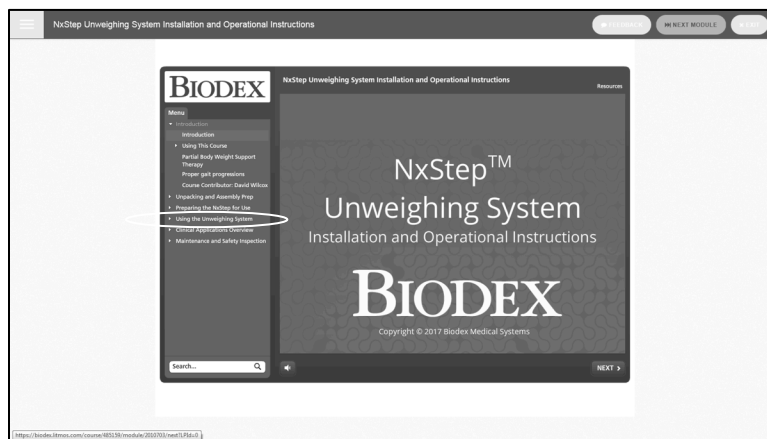
Heel/ground contact during ambulation is lost in patients when weight relief is in excess of 40% body weight (Visintin and Barbeau, [1989], Gardner, et al., [1988]) chose a level of weight relief in which the patient achieved heel/ground contact bilaterally for ten consecutive steps.

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

NOTE: Instructions for unloading patient weight are detailed in the Using the Unweighing System segment of the NxStep eLearning course. To watch the video detailing the process, please go to www.biodex.com/elearning.



The patient unweighing load can 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.



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

NOTE: To view a video detailing harness fitting and adjustment, visit: www.biodex.com/harness.

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.
6. 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.

7. If desired, activate the system automatic unloading feature by pressing the AUTO UNLOAD <ON> button on the hand pendant.
8. 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.
9. 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.
10. 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.

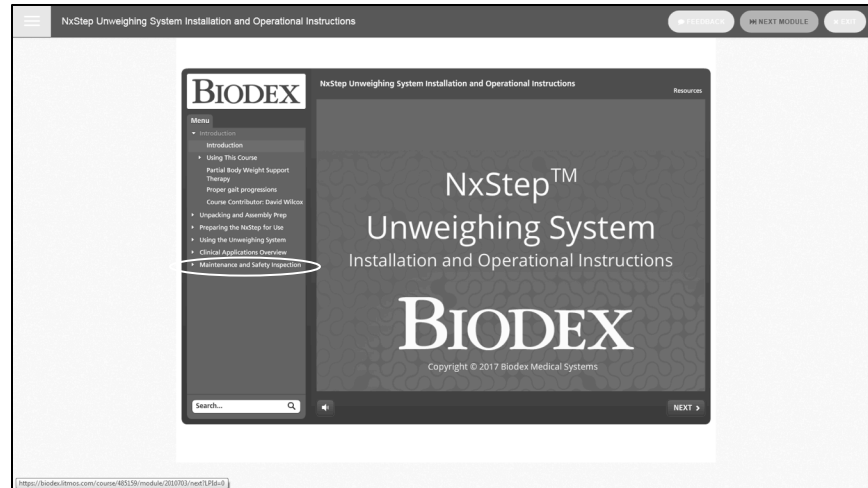


CAUTION: Therapists must be sure to monitor patients closely. A sharp rise in blood pressure or drop in oxygen levels may necessitate the patient being taken down quickly from the NxStep Unweighing System. In such cases, pull the red tabs on the quick release clips to quickly remove the patient while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

11. 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. Maintenance and Safety Inspection

NOTE: The Maintenance and Safety Inspection Information is detailed in the Maintenance and Safety Inspection segment of the NxStep eLearning course.



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.

5. 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 unweighthing 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

UNWEIGHTING LOAD

6. 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)

Compliance:

- ANSI ES 60601-1
- IEC 60601-1
- IEC 60601-1-2
- CAN/CSA C22.2 No. 60601-1:2014
- FDA Class I Equipment
- EU Class I Product
- CE Marked.

Warranty: Two years parts; one year labor.



BIODEX

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