NxSTEP™ UNWEIGHING SYSTEM

OPERATION MANUAL

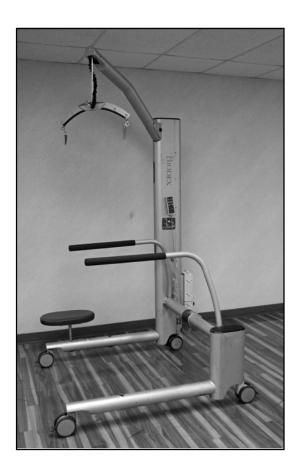
950-485 945-480





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NxStep™ Unweighing System



This manual covers operation procedures for the following products:

950-485 NxStepTM Unweighing System, 115 VAC945-480 Unweighing System, 115 VAC and 230 VAC



Contact Information

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Table of Contents

De	finition of Symbols	4
Bef	fore Proceeding	5
Bio	odex Warranty	6
1.	Introduction	8
	Intended Use	8
	Indications for Use	8
	Partial Weight Bearing Gait Therapy and Balance Training	8
	Benefits of Dynamic Unweighing Therapy	10
	Benefits Specific to the Biodex NxStep	11
2.	Assembly Instructions	13
	Assembling the NxStep Unweighing System	13
3.	NxStep Uweighing System Operation	16
	Steering Casters	16
	Installing and Removing the Handrails	16
	The Therapist Stool	17
	The Hand-held Controller	17
	The Battery Pack	17
	Positioning NxStep for Use with the Biodex Gait Trainer or RTM Treadmill	18
	Positioning NxStep for Use with the Biodex Balance System SD	18
	Free Wheeling	19
	Jogging	19
	Using the Unweighing Harness	20
	Safety Tether Operation	23
	Determination of Body Weight Support	23
	Unloading Patient Weight	23
	Patient Unloading Procedure	25
4.	Specifications	29
5.	References and Bibliography	30
6.	Parts and Assembly Illustrations	31

Definition of SymbolsThe following symbols and their associated definitions are used and implied throughout this manual.

Symbol

	Carefully read these instructions prior to use
\triangle	Caution
\triangle	General Warning
0	General Mandatory Action
4	Dangerous Voltage
	"On" Power
0	"Off" Power
<u>_</u>	Earth (ground)
\sim	Alternating Current
\bigoplus	Fuse
÷	USB Connector/Cable
	Waste in Electrical Equipment
M	Date of Manufacture
†	Type B Applied Part
(€	CE Mark
C € 0413	CE Mark for products with EC Certificate
c us Intertek	Certified for Safety by ETL Intertek

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 Biodex 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.



CAUTION: Modifications to this product are not allowed. 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.



ATTENTION: Des Modifications à ce produit ne sont pas autorisées. Modification non autorisée du produit peut entraîner des risques pour l'opérateur et le patient et annulera la garantie du fabricant. Ne modifiez pas cet équipement sans l'autorisation du fabricant.



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



AVERTISSEMENT: Si cet équipement est inspection modifiée, appropriée et essais doivent être effectués pour s'assurer a continué l'utilisation sécuritaire de l'équipement

For additional technical advice, service or education information, please contact: **Biodex Medical** Systems, Inc., 20 Ramsey Road, Shirley, New York 11967-4704; 1-800-224-6338 (Int'l 631-924-9000) or customerservice@biodex.com.

Biodex Warranty

1. Product Warranty

A. This equipment is warranted by BIODEX MEDICAL SYSTEMS, INC. against defects in materials for a period of two years (excluding cushions and vest) and workmanship for a period of one year from the date of shipment from BIODEX MEDICAL SYSTEMS, INC. During the warranty period, BIODEX MEDICAL SYSTEMS, INC. will in its sole discretion, repair, send replacement parts, or replace the equipment found to have such defects at no charge to the customer.

EXCEPT AS STATED ABOVE, THERE ARE NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OR MERCHANTABILITY OR FITNESS FOR USE. BIODEX DOES NOT ASSUME LIABILITY FOR INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES INCLUDING LOSS OF USE, SALES, PROFITS, OR BUSINESS INTERRUPTION.

- B. This warranty does not apply if the product, as determined by BIODEX MEDICAL SYSTEMS, INC., is defective due to abuse, misuse, modification, or service performed by other than a BIODEX MEDICAL SYSTEMS, INC. authorized repair representative. Misuse and abuse include, but are not limited to, subjecting limits, and allowing the equipment to become contaminated by fluid materials.
- C. In order to obtain warranty repair service and to expedite repair process, please contact BIODEX MEDICAL SYSTEMS, INC. Support Services Dept. at 800-224-6339, and select product support as prompted.

2. Warranty is non-transferable.

3. Non-Warranty Service

- A. Repairs and/or replacements not covered by this warranty may be performed by BIODEX MEDICAL SYSTEMS, INC. authorized service representatives.
- B. The cost of transportation to and from the service location will be the responsibility of the customer.

Service Procedure

If you think you have a service problem, take the following action:

- 1. Check to see that the problem occurs more than once.
- 2. Refer to the instruction manual's operations procedure.

If you still think you have a service problem, call BIODEX MEDICAL SYSTEMS, INC., Service Department at (800) 224-6339 and select product service as prompted.

Keep Yourself And The Phone Next To The Equipment

- 1. Service will ask you for a brief description of the problem. We will ask specific questions about the malfunction that occurred. This diagnostic process may take a few minutes, so call us when you can set aside an uninterrupted block of time.
- 2. After taking the information, we will advise on the action we will take. Sometimes service personnel must consult with engineering and it may take time to get back to you. Be sure to let the service representative know your schedule so that we can call at a convenient time.
- 3. The return call may be from a person other than whom you first reported the problem to.
- 4. After analyzing the problem, we will decide if the unit can be repaired on site, or replacement parts will be sent.
- 5. Non-warranty/non-service contract charges for repair are as follows
 - a. Materials

+

b. Time

+

c. Travel Zone

Contact information

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1. Introduction

Intended Use

The Biodex NxStep Unweighing System makes it safe, easy and comfortable for therapists and patients to apply and realize the benefits of Partial Body Weight Support Training. An open design with the offset unweighing support column provides total access for the therapist and clear viewing for the patient. A hand pendant-controlled battery powered lift and automatic unweighing load adjustment make it easy for one therapist to get a patient up and using the product.

Indications for Use

This device is ideal for patients with various physical and neurological deficiencies. Harness slippage is automatically accommodated to maintain a constant and compliant amount of reduced weight with patients weighing up to 300 pounds (136 kg). The Biodex NxStep conveniently compresses to fit through a standard 36" door or onto an elevator. It moves easily from area to area within a facility, takes up minimal floor space and fits under 8-foot ceilings.

Partial Weight Bearing Gait Therapy and Balance Training

The loss of the ability to ambulate can be one of the most debilitating aspects of many neurological and musculoskeletal disorders. Any of the three main components of locomotion - posture, balance and coordination - can be affected by a variety of neurological or musculoskeletal pathologies resulting in the disruption of an individual's ability to walk normally.

Partial Weight Bearing (PWB) gait therapy has shown great promise in helping a wide variety of impaired patients as they relearn the walking function. It is an appropriate modality to use whenever gait therapy is prescribed for patients who lack the upper and/or lower body strength to support themselves during assisted ambulation. In addition to aiding gait pattern regeneration, partial weight bearing therapy allows patients to enhance their endurance, balance and posture.

PWB gait therapy makes use of a patient suspension system, such as the Biodex NxStep Unweighing System, to reduce the amount of total weight borne by a patient and provide proper upright posture. The suspension system is used to remove a pre-determined portion of the weight load from the patient's legs and redistribute it to the patient's trunk and upper thighs, thus freeing up the arms and legs.



Extreme caution should be taken to assure the stability of autonomic reflexes (in acute stages) as well as bone and muscle integrity (in chronic cases.)

With the patient supported by the suspension system, horizontal movement can be provided by setting the treadmill to a slow speed. The constant rate of movement provided by the treadmill provides rhythmic input to reinforce coordinated, reciprocal movement of the legs. The therapist can provide further assistance (especially with severely involved patients) by manually placing the patient's feet and/or assisting the patient in weight shifting.

Once the patient begins to gain a feel for a properly coordinated movement pattern, the treadmill speed and/or the amount of weight borne by the patient can be gradually increased to better simulate natural walking conditions. The increase in weight bearing and treadmill speed also helps the patient to relearn dynamic balance.

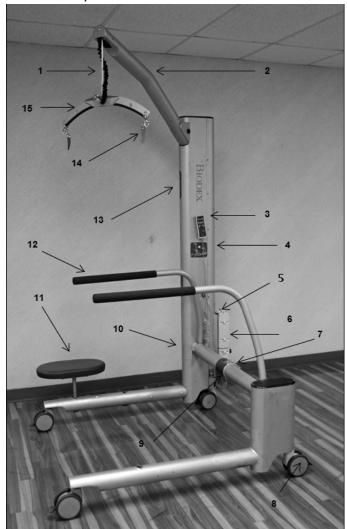


Figure 1.1. The NxStep Unweighing System parts and adjustments include:

Standard Parts and Adjustments:

- 1. Support Rope with Safety Tether
- 2. Support Bar
- 3. Hand-held Controller
- 4. Main Column
- 5. Allen Wrench (stored in slot near battery pack)
- 6. Battery Pack
- 7. Cross Tube
- 8. 5" Locking Casters (4)
- 9. Coupling Pull Pin
- 10. Handrail Release Buttons (one for each side)
- 11. Therapist Stool
- 12. Handrails
- 13. Unweighing Scale
- 14. Quick Release Vest Clips
- 15. Patient Harness Bar

Not shown:

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)

Once clinical goals on the treadmill have been achieved, the patient can be progressed to ambulating over ground while still in the NxStep. Ultimately, the goal should be for the patient to ambulate over ground independently or with an assistive device such as a cane or walker.

PWB therapy sessions typically last 30 minutes to an hour and are scheduled three to four times per week. Each hour of the session can be divided into three or four periods of activity followed by a rest period. Activity periods can be as short as three minutes (with five minutes of rest in between), but should not exceed 15 minutes, even if the patient is supported or partially supported by a suspension system. Each period should end at its predetermined time, especially if the patient's gait deteriorates or the patient or therapist feels fatigued. Because the repetition of coordinated walking patterns is the most essential element to the success of this therapy, be sure to provide consistent training without interruptions or unscheduled breaks.

Patients are evaluated over a two-week period and are expected to make some gains in their ability to coordinate movement during treadmill walking in this time frame. Continue the program for 8 to 12 weeks if sufficient progress is demonstrated. Continue for up to an additional four weeks for cases showing slower improvement. For acute patients who show little or no progress after the first two weeks of therapy, time may be better spent on different training activities.

The Biodex NxStep Unweighing System can be used in the recovery of balance and posture for patients with compromised posture or balance mechanisms. Toss the patient a ball to catch or provide perturbation manually to challenge their balance. The suspension system will prevent the patient from falling while providing proprioceptive cues. The amount of support can be reduced as the patient progresses.

Benefits of Dynamic Unweighing Therapy

Partial Weight-Bearing therapy, sometimes known as "unweighing," is a concept of rehabilitation that uses an external device to support a percentage of the patient's body weight, allowing them to perform a variety of therapeutic activities in an upright and safe environment. Typically used with neurological pathologies, 20 - 40% of the patient's body weight is supported to assist with developing proper gait patterns and improvements in cardiovascular and muscular endurance. The ability to initiate exercise early in the rehabilitation process can benefit the patient by allowing the development of neural pathways through muscular patterning.

Benefits

Research has shown the benefits of PWB therapy to occur in a variety of physiological ways.

Physiological Benefits

Symmetrical Loading of the Lower Extremities - This assists with equal weight distribution over the base of support. Equal weight distribution in turn provides the proper biomechanics to correct step length deficits and time distribution between limbs.

Reduction Of Muscular Splinting - Parasympathetic tones typically associated with neurological pathologies can be reduced through PWB therapy. Minimizing parasympathetic stimuli helps to reduce muscular tension, in turn allowing for increased range of motion and focus on motor control exercises.

Reduction Of Cardiovascular And Metabolic Demands - Relieving graded portions of body weight allow the patient to exercise with less stress to the cardiopulmonary system. This is beneficial for extremely deconditioned patients, as it allows them to initiate exercise without increasing cardiopulmonary demand. VO2 levels are maintained better at 40% unweighing than at 0%, so the patient can then exercise for a longer period of time. This application can be beneficial for cardiac and pulmonary rehabilitation—particularly in cases of obese patients— as exercise can be prolonged to enhance conditioning.

Additional Benefits

Acute Injury And Post-Surgical - Unweighing can also provide a safe environment to start acute therapy following injury or surgical procedures. This is especially true with patients suffering from low back pain, whether it is acute or chronic. Unweighing provides an environment around the injured joint with reduced gravitational effects. This can be coupled with exercise to enhance joint stability. Vertical traction is accomplished to provide patient relief. This same approach can be taken with other orthopedic injuries. By using the Biodex NxStep you can be assured that your patient is working in a dynamic environment, with patient weight unloaded to physician specifications. Should the patient become incapacitated, the patient will be fully supported, thus preventing a fall or encumbering the therapist with catching and holding the patient.

Balance Training - Securing your patient in the NxStep will eliminate the risk of falling during balance training. This will allow your patient to work with more confidence during rehabilitation.

Benefits Specific to the Biodex NxStep

Oscillation of Center of Gravity (COG) - Normal oscillation for the center of gravity during gait is approximately 2" (5cm). This is easily achieved with the dynamic suspension of the Biodex NxStep Unweighing System. By allowing oscillation, the patient is able to maintain a smooth gait pattern (Hoppenfeld). When a static support system is used and the center of gravity is raised, the system is not able to maintain a constant unweighing. During the "toe off" stage in the gait cycle, the patient may actually be full weight bearing, which may cause undesired firing patterns of the musculature, resulting in poor training effects.

Knee Flexion Throughout Gait Cycle - In order to provide for shock absorption and mechanical efficiency, the knee must flex at various points during the gait cycle. During toe off, the COG will rise, and the knee flexes to approximately 40° to counterbalance this effect. A static unweighing system will not allow this to occur and will therefore promote poor mechanics during gait training. Poor mechanics can lead to increased stress placed on compensatory joints and muscles and also inappropriate motor control patterns. Knee flexion also allows ground reaction forces (GRF) to occur. GRFs are important for motor firing patterns associated with motor pattern and central pattern generators. The dynamic environment of the Biodex NxStep allows for development and utilization of these GRF in the re-training of gait.

Single Point Design - A single point of suspension allows proper shifts of the COG and proper pelvic rotation during gait. By providing natural shifts of the COG strengthening and coordination can be rehabilitated to their original state. Unweighing systems that provide a two point support design do not allow for the necessary shift of the COG over vital points necessary for gait. A two point design suspends the patient in a static "hanging" position, not allowing lateral pelvic tilts and pelvic rotation necessary for efficient gait mechanics.

Lateral pelvic tilt of approximately 1" allows the body weight to be centered over the hip; this allows the non-weight bearing leg to swing through. The pelvis then rotates forward with the weight bearing hip acting as a fulcrum, allowing forward movement of the non-weight bearing limb. The single point design of the Biodex NxStep allows for proper biomechanics of the pelvis and utilization of trunk musculature for stabilization and forward propulsion.

Display of Unweighing Load – The display incorporated on the Biodex NxStep Unweighing System provides feedback in regards to the amount of weight being relieved from the patient. This is beneficial as it allows for consistency between treatments, thus providing a therapeutic environment for improved gait mechanics and neurological patterning.

2. Assembly Instructions

Assembling the NxStep Unweighing System

The Biodex NxStep Unweighing 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 you need to transport the system through a doorway, hallway, etc., the cross tube can again 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 move easily around the NxStep frame during installation.



MISE EN GARDE: Au moins deux personnes sont tenues d'accomplir la procédure suivante. Garantissez que le système non pesant sera rassemblé sur une surface de niveau. Garantissez qu'il y a assez de pièce pour bouger facilement autour de la charpente de système non pesante pendant l'installation.



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

Assembly Procedure

(See Figures 3 – 8.)

Tools Required:

Allen wrench (provided; adjacent to the battery pack on the main column of the NxStep.)

- Position the NxStep in the room or area where it will be used. Remove all packing materials and ensure there is room to walk around the system during the assembly procedure.
- 2. Lock the two 5-inch locking casters on the tall (column) side of the NxStep by pressing fully down on each caster lever with your foot.

 Ensure the two locking casters are released on the short (non-column) side of the system by pulling the caster levers fully up.
- 3. Remove the Allen wrench from its storage position adjacent to the battery pack.
- 4. Use the Allen wrench to loosen the two bolts on the top side of the cross tube coupling. Alternate the turns of the bolts (a half turn each time) so that neither bolt is bearing too much weight pressure.
- 5. Locate the pull pin at the center underside of the cross tube coupling and pull it back. With the aid of a second person, slowly slide the cross tube out of the coupling until fully extended. Release the pull pin as the tube is extending. Ensure the pull pin "pops in" and is fully reengaged.
- 6. Using the Allen wrench, tighten the two coupling bolts. Again, alternate the turns of the bolt heads. Tighten the bolts until the bolt heads will not turn any further and there is a slight bend in the Allen wrench as a result of the pressure being applied to it (Figure 5).
- 7. Lock the two 5" locking casters on the short side of the NxStep by pressing down on each caster lever with your foot. All four casters should now be in the locked position.

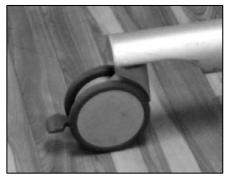


Figure 2.2. Caster locking lever in the locked position.



Figure 2.3. The Allen wrench is located alongside the battery pack.



Figure 2.4. The cross tube coupling. Be sure to tighten bolts until Allen wrench bends slightly from torque pressure.

- 8. Use the Allen wrench to remove the two screws, one on each side, at the base of the support bar (item #2 in Figure 1.0). Retain screws.
- With the help of a second person, raise the support bar fully and use the Allen wrench to install both screws in the higher screw hole, securing the bar in the fully raised position. Return the Allen wrench to its holder.

NOTE: When compressing the system, the two support bar screws are positioned in the original, lower screw holes.

10. Attach the battery pack to the main column by sliding it over the battery support post. The charging receptor is located beneath the battery support post. To charge the battery, plug the AC power adapter into a wall outlet, and then plug the other end of the cord into the charging receptor.

NOTE: Unweighing systems shipped to facilities outside of the US will arrive with two AC adapters—one for 115 VAC outlets and one for 230 VAC outlets. Be sure to identify the voltage of the outlet you will be using and then select the correct adapter.

A green light indicates it is fully charged, and amber means it is still charging. (LED light will not activate unless charger is plugged in.) The red button on the battery is a safety button; pushing it in cuts off all power to the device.

- 11. Plug the hand-held controller cord into the remaining port on the column. The controller itself can then be attached magnetically anywhere along the column.
- 12. To install or remove the handrails, push in on the appropriate handrail release button.
- 13. To remove the therapist stool, simply lift it up. To install the therapist stool, fit the stool support into either of the two position holes along each support bar. The seat can face either in or out from the subject.
- 14. Ensure there is a familiarity with all *Warnings* and *Cautions* affixed to the system main column before proceeding any further.



Figure 2.5. Positioning the Support Bar.



Figure 2.6. The battery pack component fits on top of the base.



Figure 2.7. The hand-held controllerplugs into the main support column.

3. NxStep Uweighing System Operation



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



ATTENTION: Ne jamais laisser un patient sans surveillance sur cet appareil. Vérifiez tous les câbles, les harnais et les raccords avant chaque utilisation. Voir le chapitre 4, « Maintenance et Inspection de sécurité, » pour obtenir des instructions supplémentaires.



CAUTION: The Biodex NxStep Unweighing System uses a special harness to support the patient. It is vital that the harness fits properly on the patient. Refer to the Biodex Standard Harness Operation Manual, supplied with your harness, for specific information about harness use.



ATTENTION: Le système Unweighing de NxStep de Biodex utilise un harnais spécial pour soutenir le patient. Il est vital que le harnais s'ajuste correctement sur le patient. Voir ot Biodex Standard harnais Mode d'emploi fourni avec votre harnais, pour plus d'informations sur l'utilisation du harnais.

Steering Casters

The Biodex NxStep has four locking casters.

The rear casters have two lever positions.

- Lever down: the wheel is locked.
- Lever up: wheel is unlocked, and therefore 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.

Installing and Removing the Handrails

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 the appropriate handrail release button.



Figure 3.1. The front casters have three setting: completely locked, completely unlocked, and directionally locked.



Figure 3.2. The handrail release button.



CAUTION: There is no handrail height position adjustment. If a treadmill has side rails, the NxStep handrails are not to be used. Handrails are most often used during free-wheeling activities.

The Therapist Stool

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.

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.





Figure 3.3. The therapist stool



Figure 3.4. The hand-held controller.

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.

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, you will see one of two LED lights: 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 RTM Treadmill

The NxStep can be positioned for use with the Biodex RTM Treadmill or Gait Trainer.

- 1. Remove handrails (if treadmill has its own handrails) and unlock all casters.
- 2. Roll the NxStep into position so 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 locking casters and proceed with treadmill use.



Figure 3.5. The NxStep ready for use with the Biodex
Gait Trainer.



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.



ATTENTION: Lorsque vous utilisez le système Unweighing de NxStep avec un tapis roulant, les roulettes de direction doivent être positionnées à l'arrière du tapis roulant. Cela rendra plus facile à manœuvrer sur le pont du tapis roulant.

Positioning NxStep for Use with the Biodex Balance System SD

- 1. The Biodex NxStep Unweighing System is ideal for use with the Biodex Balance System SD.
- 2. Position the NxStep so that the cross tube is almost touching the the Balance System SD display support column. (Be careful not to knock into it.)
- 3. Lock all four locking casters.



Figure 3.6. The NxStep ready for use with the Biodex Balance System SD.

Free Wheeling

The Biodex 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.



Figure 3.7. The NxStep ready for free-wheeling across the floor.



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.



ATTENTION: Il est préférable de garder les roues avant directionnellement verrouillées dans le cadre de l'avant si le thérapeute sera gouvernait l'unité derrière le patient..

Jogging

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

Pelvic Stabilization Straps

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 then place the hooks in the rings on the patient harness.



Figure 3.8. Stabilization strap hooked into harness ring.

Using the Unweighing Harness

The Biodex 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).

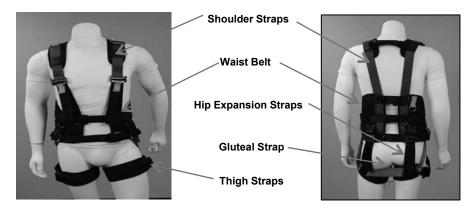
For a list of all unweighing harnesses offered through Biodex, visit www.biodex.com. For video instructions on using the standard harness provided.

Important Notes

- · Always read the manual before using the harness.
- The harness should only be used under the direct supervision and assistance of a qualified healthcare provider.
- 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.
- This device should not be used anytime pressure around the abdomen, thighs, groin or shoulders is contraindicated.
- Never use the harness without checking the comfort levels (both physical and psychological) of client frequently.
- The harness is not designed as passive lifting device. Use only with people who can participate actively in the therapeutic process and can bear a majority of their own weight through their lower extremities once standing.
- The harness has a maximum load capacity of 300 lbs (136 kg).
- Inspect all components of the harness on a regular basis to ensure safety. Replace harness at first sign of wear.
- Hand wash all components of the harness in a mild sanitizing detergent and air dry.

Helpful Hints and Tips

- Loosen all straps sufficiently prior to applying harness--especially the back straps on the waist belt.
- Some readjustment and tightening of the harness may be needed as you work with the patient.
- Practice manipulating and adjusting the buckles and straps prior to using it on a patient.



Standing Harness Application

- Place upper vest portion of harness on patient as if putting on a jacket. Adjust straps so that seat belt buckles on the bottom of the front portion of the waist belt are positioned at or in front of the anterior superior iliac spines (ASIS.) Attach front buckles and snug firmly.
- 2. Adjust length of shoulder straps and needed by pulling down on barrel adjustment straps to tighten or pulling up on orange tabs to loosen.
- 3. Attach the lower portion of the harness by first attaching the hip extension (black) straps to the buckles on the back of the waist belt.
- 4. Adjust length of straps so that the gluteal strap (red webbing) is positioned just beneath the patient's gluteal fold.
- 5. Attach the thigh straps around each thigh and position them as high as possible. There is a label indicating right "R" and left "L" sewn into the back portion of each thigh strap.
- 6. Attach the front seat belt buckles (red webbing) to the buckles located on the lower front of waist belt and snug firmly.











Sitting Harness Application

- 1. Place upper vest portion of harness on patient. Adjust back and front straps so that seat belt buckles on the bottom of the front portion of the waist belt are positioned at or in front of the anterior superior iliac spines (ASIS.) Snug firmly.
- 2. Adjust length of shoulder straps by pulling down on barrel adjustment straps to tighten or by pulling up on orange tabs to loosen.
- 3. Attach the thigh straps loosely around each thigh and position them as high as possible by shifting patient side to side and pulling up on thigh straps. There is a label indicating right "R" and left "L" sewn into the back portion of each thigh strap. Once in position snug each thigh strap.
- 4. As the patient is brought to a standing position, attach the hip extension (black) straps to the seat belt buckles on the back of the waist belt and tighten as the patient stands. These buckles may need to be released and reattached each time the patient sits or stands.
- 5. Attach the front seat buckles (red webbing) to the buckles located on the lower front of waist belt. Remove most slack in the webbing but leave a small amount to allow for hip extension as the patient stands.



Figure 3.14. Steps 1 and 2.



Figure 3.15. Step 3.



Figure 3.16. Step 4.



Figure 3.17. Step 5.

Safety Tether Operation



CAUTION: To ensure patient safety, it is vital that the safety tether be attached at all times during unweighing activity.



ATTENTION: Afin d'assurer la sécurité des patients, il est vital que la sangle de sécurité attaché à tout moment lors activité

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.



Figure 3.18. The safety tether (the rippled elastic cord) attaches to the center of the patient harness bar.

Taking into consideration the patient's shoulder width, attach the harness clips using either the wide position holes (shown above) or the more narrow set of holes.

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 set either manually or using the Auto Unload feature. Once the patient is in the harness and upright in the Biodex NxStep, proceed as follows using either the procedure for Manual Mode or Auto Unload.

Manual Mode

- 1. The patient can be manually unloaded by using the UNWEIGH LOAD controls on the hand pendant. Press the <UP> or <DOWN> buttons until the compliant unweighing load is indicated (30 lb, 40 lb, etc.) on the UNWEIGHING LOAD scale (Figure 29). At this point the LOAD RANGE indicator should be in the center of the compliant green zone (Figure 28).
- 2. As the patient walks, the harness may slip upward on the patient's torso. This may cause the compliant load indicator to move down and out of the LOAD RANGE green zone. To address this issue, use the <UP> button on the BAR HEIGHT section of the hand pendant to adjust the load back to the center.

Auto Unload

- 1. The patient can be automatically unloaded and stay in the center of the compliant range by pressing the Auto Unload <ON> button on the hand pendant. The patient support bar will move up until a sensor indicates the patient is in the center of the range.
- 2. An indicator light beside the load range scale indicates Auto Unload is activated.
- 3. As the patient walks, the harness may slip upward on the patient's torso. This will cause the compliant load indicator to move down in the compliant range until the Auto Unload sensor is activated. When this happens, the patient harness bar will be automatically moved up at a steady rate, smoothly bringing the patient back to the center of the compliant range.
- 4. To turn OFF the Auto Unload feature at any time, simply press the Auto Unload <OFF> button on the hand pendant to return the system to manual mode. If the BAR HEIGHT <UP> or <DOWN> button is pressed, Auto Unload will be turned off.

NOTE: The patient unweighing load can be adjusted by raising or lowering the patient harness bar at any time—you do not have to turn the Auto Unload function off first. Auto Unload automatically turns off any time the patient harness bar is adjusted.

Patient Unloading Procedure

Ambulatory Patients

- 1. For use with a Biodex RTM Treadmill, Balance System or other therapeutic device, press down fully on the locking lever for all four casters and ensure the casters are fully locked in place.
- 2. Taking into consideration the broadness or narrowness of the patient's shoulders, choose which set of harness connection holes on the patient harness bar should be used to secure the patient to the NxStep (Figure 27). The outside holes are 21" apart. The inside holes are 14" apart. Release the quick release clips on the harness, slide them into the proper holes, and snap the clips closed.
- 3. Use the hand controller pendant to adjust the height of the patient harness bar to just above the patient's head.
- 4. Position the patient and, with the patient standing, adjust the harness as needed before unloading any weight.

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

- 5. Using the hand pendant control, 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 (Figure 29).
- 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 28). At this point the set unloading amount is accurately applied to the patient.



Figure 3.19. The unweighing load range scale is located on the main column.



Figure 3.20. Unweighing load scale.



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.



ATTENTION: Vérifiez que la lanière de sécurité est connectée avant que le patient commence à exercer. Afin d'assurer la sécurité des patients, la longe de sécurité doit être connectée chaque fois que se déroulent des activités unweighing

- 7. If desired, activate the system automatic unloading feature by pressing the AUTO UNLOAD <0N> 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.



ATTENTION: Les thérapeutes doivent s'assurer de suivre de près certains patients sélectionnés. Une forte augmentation de la pression artérielle ou de la baisse des niveaux d'oxygène peut nécessiter le patient étant descendu rapidement du système Unweighing NxStep. Dans de tels cas, tirez les languettes rouges sur les boucles de dégagement rapide pour enlever rapidement le patient tout en portant toujours le harnais.

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.

Non-Ambulatory Patients

Non-ambulatory patients need to have the unweighing harness strapped on when sitting or, preferably, laying on a mat table. In this instance, the therapist must work the harness under the patient or roll the patient sideways onto the harness while on the mat table. Once the patient has the harness on, the NxStep is positioned to lift the patient. The system can be positioned around a chair or wheelchair, and the legs will fit under a mat table.

1. With the patient harness secured and the patient in an appropriate position, use the BAR HEIGHT <DOWN> button on the hand pendant to lower the patient harness bar until it is just above the patient's head.



CAUTION: It may be necessary to disconnect the safety tether for the patient harness bar to be lowered to chair height. Ensure the safety tether is reconnected before the patient starts to exercise. To ensure patient safety, the safety tether must be connected whenever unweighing activities are conducted.



ATTENTION: Il peut être nécessaire de déconnecter le cordon de sécurité pour la barre de harnais patient à être abaissé à hauteur de la chaise. S'assurer de que la longe de sécurité est rebranchée avant que le patient commence à exercer. Afin d'assurer la sécurité des patients, la longe de sécurité doit être connectée chaque fois que se déroulent des activités unweighing.

- 2. Taking into consideration the broadness or narrowness of the patient's shoulders, choose which set of harness connection holes on the patient harness bar should be used to secure the patient to the NxStep. The outside holes are 21" apart. The inside holes are 14" apart. Release the quick release clips on the harness, slide them into the proper holes, and snap the clips closed.
- 3. Using the hand pendant BAR HEIGHT <UP> button, raise the patient bar as desired. This will assist the patient to his feet. Patients may need guidance from the therapist to position themselves.

NOTE: The therapist may leave the casters unlocked at this point so that the system can adjust to where the patient is standing, or the casters can be locked and patient instructed to take a step forward to become fully upright.

- 4. Once the patient is standing upright, final adjustments can be made to the harness and patient weight can be unloaded as explained previously.
- 5. If the patient still needs to be positioned on a treadmill or balance system, guide the patient over while supported by the NxStep. The patient harness bar can be raised a little more to assist the patient up onto the treadmill or balance system deck. Or you can activate the Auto Unload function, and this will cause the bar to raise automatically.



CAUTION: You will have to lower the patient harness bar for patients that need to step down from a deck at the end of their exercise session.



ATTENTION: Vous devez abaisser la barre de harnais patient pour les patients quiont besoin de démissionner depuis un pont à la fin de leur session d'exercice.

When the exercise session is finished, the unload setting will continue to be applied. Position the patient is over the wheel chair or mat table and lower the patient harness bar down to allow the patient to move to a seated or prone position. When the patient bar is just above the head and there is no longer any unloading support being applied, the harness can be disconnected. Move the NxStep out of the way and remove the patient harness to end the session.

NOTE: Therapists are often called upon to assist the patient's leg movements during unweighing ambulation activities whether on the floor or treadmill. The NxStep has an option for use of one or two therapist seats to provide support for this task. To view video of therapist assist using the ambulation stool, visit http://biodex.com/physical-medicine/biodex-university/interactive-elearning and register for the NxStep eLearning course.

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:

1. 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: Try this method on an inconspicuous spot before using it 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.
- 3. Rub gently.
- 4. Rinse with a water-dampened cloth to remove bleach concentration.
- 5. 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: Try this method on an inconspicuous spot before using it 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

Manufacture states that any cleaner or disinfectant can be used.

4. Specifications

Dimensions: Operational:

I.D. 38.8" w x 48 d x 94" h (99 x 122 x 239 cm) **O.D.** 47.5" w x 48" d x 94" h (121 x 122 x 239 cm)

Retracted (not for operation):

O.D. 32" w x 48" d 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' 7" (201 cm) on a standard treadmill in an

8' (244 cm) ceiling height room.

Includes: one therapist seat

Accommodates Treadmill Decks: to 38" wide 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)

Power: 115 VAC (for model 950-485), 115 VAC and 230 VAC (for model 945-480)

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

Weight: 275 lb (125 kg)

Compliance: IEC 60601-1 and ISO 10535 for safety, EMC to 60601-1-2

CE Conformity: to IEC 60601-1

Warranty: Two years parts; one-year labor

5. References and Bibliography

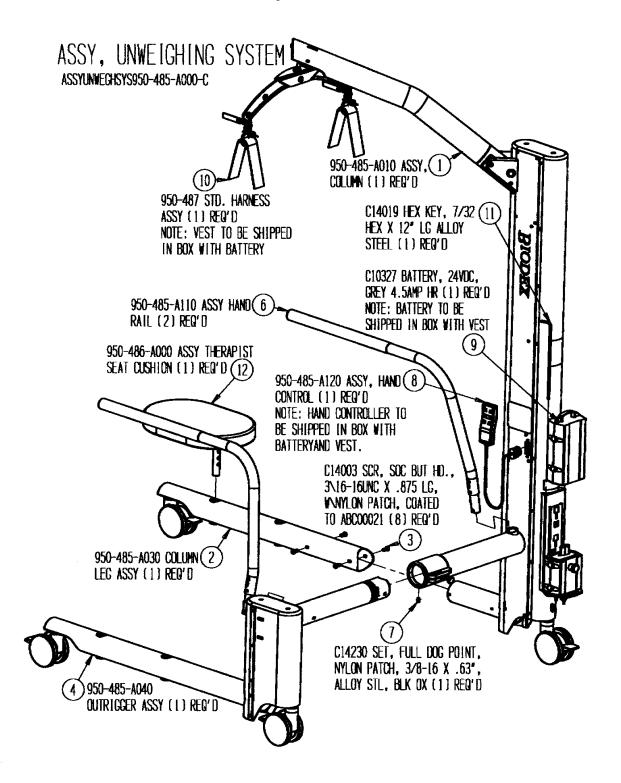
For a sampling of specific applications and biographical references, please visit www.biodex.com.

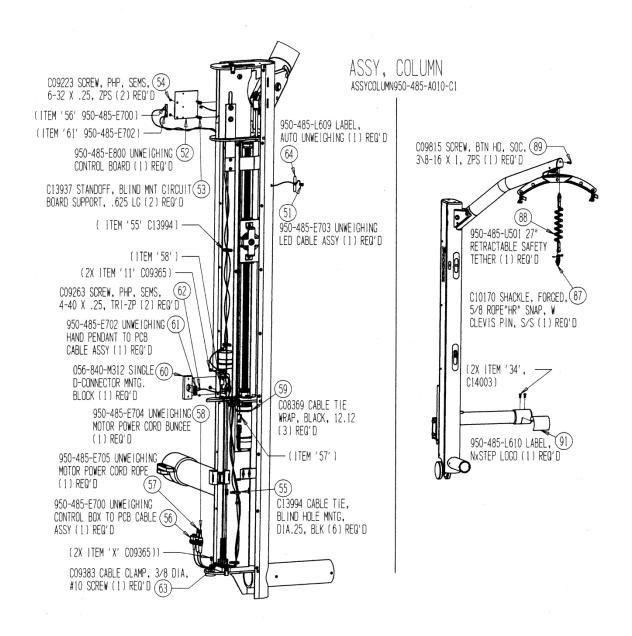
From the Home Page, select <Physical Medicine>, <Products>, <Partial Body Weight Support>, <NxStep> and then <Applications>.

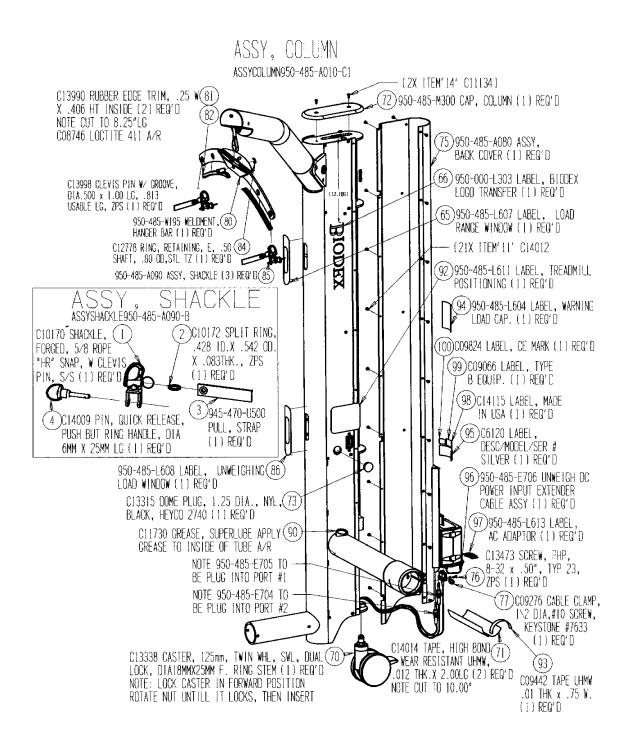
Use the chart below as a quick reference for determining unweighing percentages:

BODY WEIGHT LB KG	PERCENT OF 20%	BODY WEIGH	TUNLOADED 40%	
100/45	20/9	30/14	40/18	1
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	U
160/73	32/15	48/22	64/29	N
170/77	34/15	51/24	68/31	WE
180/82	36/16	54/25	72/33	ī
190/86	38/17	57/26	76/35	GH
200/91	40/18	60/27	80/36	1
210/95	42/19	63/29	84/38	N G
220/100	44/20	66/30	88/40	
230/104	46/21	69/31	92/42	0
240/109	48/22	72/33	96/44	A
250/113	50/23	75/34	100/45	Ĭ
260/118	52/24	78/35	104/47	H
270/122	54/24	81/37	108/49	
280/127	56/25	84/38	112/51	H
290/132	58/26	87/40	116/53	H
300/136	60/27	90/41	120/54	

6. Parts and Assembly Illustrations

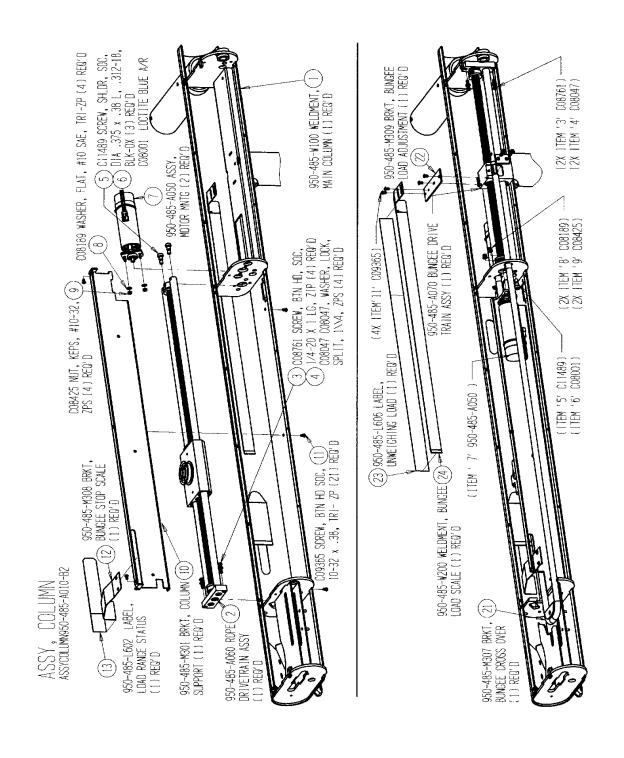




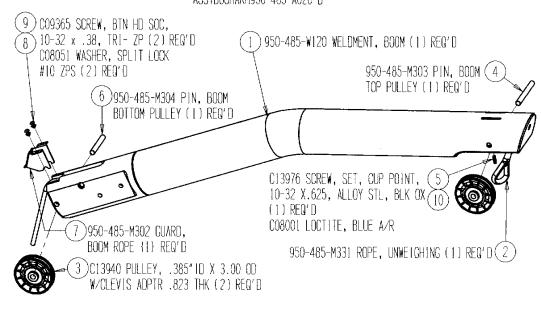


ASSYCOLUMN950-485-A010-B2 950-485-WI20 WELDMENT.(30) BOOM (1) REQ'D C11061 SCR. BTN HD. SOC. 3\8- 16X1.25LG, BLK OX STL ((2) REQ'D CO8001 LOCTITE BLUE A/R C13940 PULLEY, .385" ID X 3.00 0D (35) 34)C14003 SCR, SDC BUT HD., W/CLEVIS ADPTR .823 THK (3) REQ'D 3\16-16UNC X .875 LG, APPLY ITEM '90' GREASE WNYLON PATCH, COATED TO TO ITEM'38' AND SIDE OF ABC00021 4 REQ'D FRAME, TYP. BOTH SIDES 32)C13999 SHOULDER BOLT, (45 950-485-M305 DIA.50 X .63 LG. 3\8-16 LINKAGE, BUNGEE THR'D. (2) REQ'D SMALL STOP (1) REQ'D 33) CO9667 CAP, FINISHING. C10365 RETAINING RING, O POLYETHLENE, BLK EXT, E- STYLE, .375 (2) REQ' D SHAFT, SST, (4) REQ'D (43) (31)C08617 WASHER, 1\2" SCREW FINISHING CAP (2) REQ'D C13980 BRG. THRUST .3751D.X.87500D.X.058TH 41)C13989 MAGNETIC. DISC. ALNICO. K. PLASTIC G300, IGUS (38) 42) DIA 125X .25 THK, .26 LB PLLL, (4) REQ'D GRADE 5 (1) REQ'D CO8472 ADHESIVE C13610 BEARING, THRUST (39) HOUSEHOLD A/R WASHER, .80" OD x .50" ID x .059 THK (4) REQ'D (40)950-485-M320 PIN. BUNGEE STOP (2) REQ'D 950-485-M306 LINKAGE. BUNGEE LARGE STOP 46)950-485-M317 GUARD, (1) REQ'D ROPE (1) REQ'D (2X ITEM'11' C09365) (ITEM '6' C08001) (2X ITEM'11' C09365) (ITEM '6' C08001)

ASSY, COLUMN

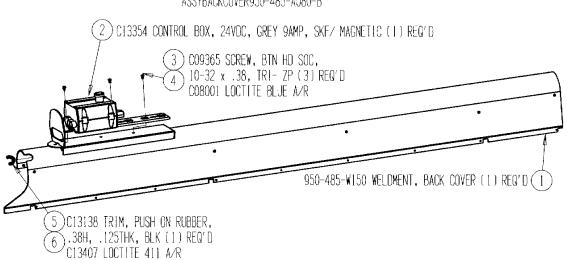


ASSY, BOOM ARM ASSYBOOMARM950-485-A020-B

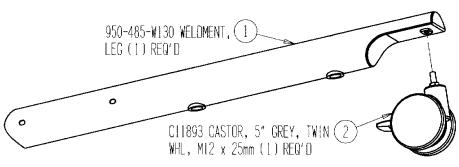


ASSY, BACK COVER

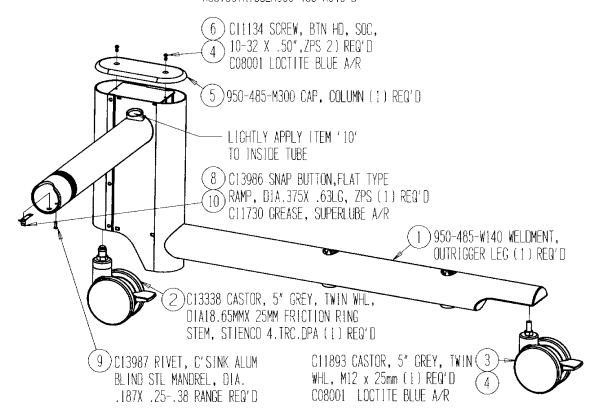
ASSYBACKCOVER950-485-A080-B



ASSY, COLUMN LEG ASSYCOLUMNLEG 950-485-A030-B



ASSY, OUTRIGGER ASSYOUTRIGGER950-485-A040-B



ASSY, MOTOR MOUNTING ASSYMOTORMOUNTING950-485-A050-A

