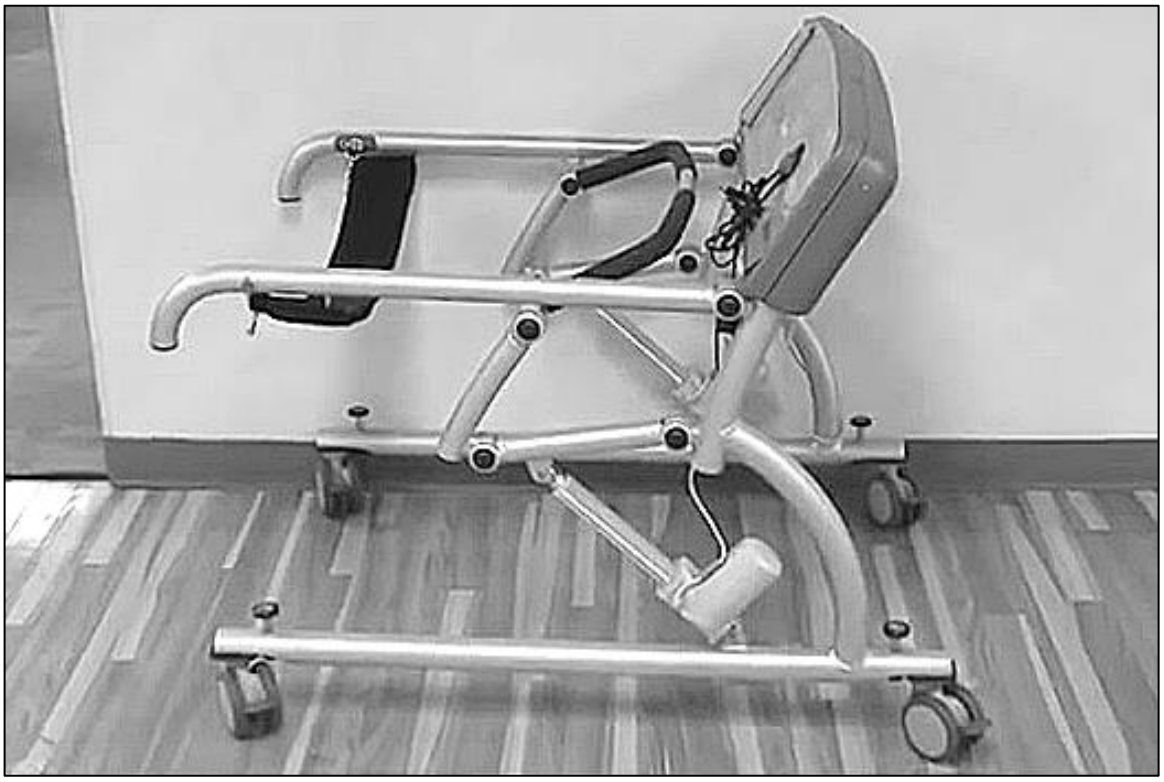
MOBILITY ASSIST

OPERATION MANUAL

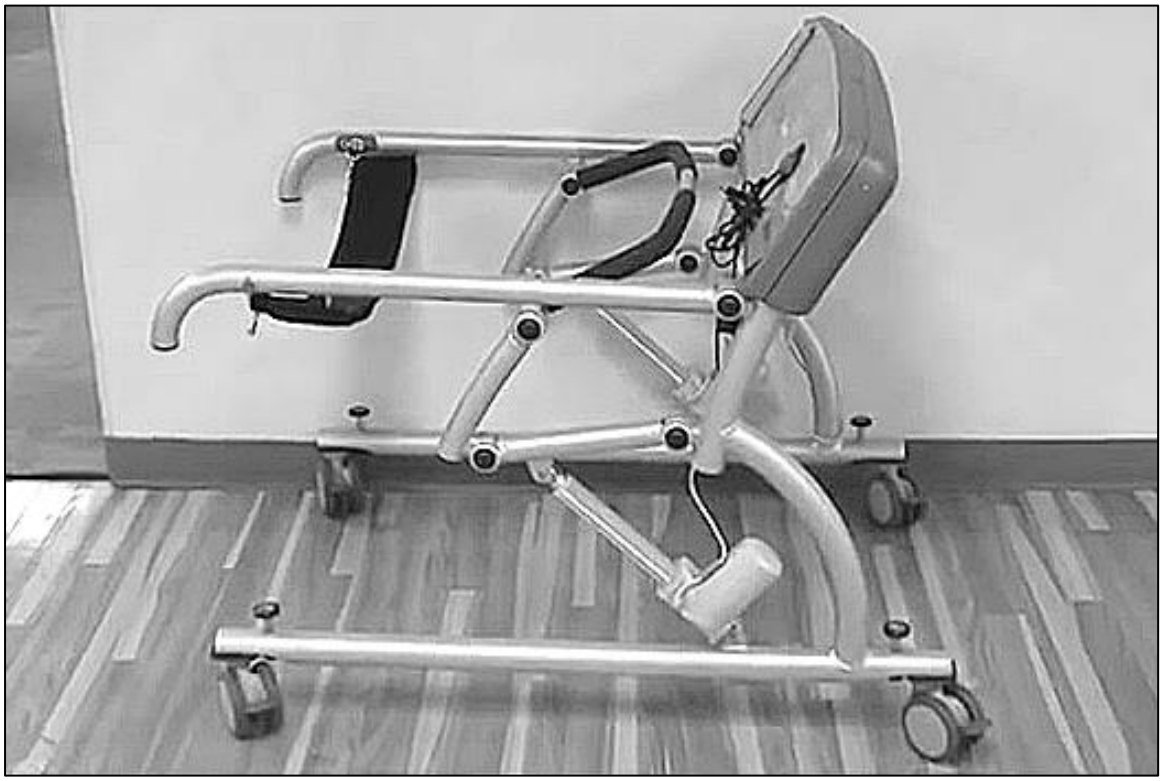
950-570



BIODEX
Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (*Int'l 631-924-9000),* Fax: 631-924-9338, Email: info@biodex.com, www.biodex.com

FN: 17-158 Rev A 7/17

Mobility Assist (Ambulation Therapy Aid)



This manual covers operation procedures for the following product:

950-570 Mobility Assist

An instructional video covering unpacking and operation is available at:
www.biodex.com/video/mobilityassist-setup

Table of Contents

Table of Illustrations

Definition of Symbols

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

Symbol	Definition
	Carefully read these instructions prior to use
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Waste in Electrical Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part
	CE Mark
	CE Mark for products with EC Certificate
	Certified for Safety by ETL Intertek

Product Certifications and Classifications

The Mobility Assist has received the following certifications, and falls within the following classifications:

- IEC 60601-1, 3rd Ed
- ISO 10535, clause 6
- IEC 60601-1-2: 2014
- FDA Class 1 Equipment
- CE Class 1

Type B Applied Part 

CE

Authorized European Community Representative:

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Before Proceeding

Before you get started with any of the setups described in this manual, there are a few preliminary points to consider that will help ensure safe and smooth operation of the Biodex Mobility Assist ambulation therapy aid:

- This system should be operated only by qualified personnel.
- 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 these operating instructions are fully understood 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: 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.

AVERTISSEMENT: 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 disposal information at the product's end of life, contact Biodex.

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.**

Biodex Warranty

1. Product Warranty

A. This equipment and its accessories are warranted by BIODEX MEDICAL SYSTEMS, INC. against defects in materials for a period of two years 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.

B. The harness and straps included with this Biodex product are warranted for 60 days from the date of shipment from Biodex Medical Systems, Inc.

   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.

C. 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.

D. 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

Manufactured by:

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704
Tel: 800-224-6339 (Int'l 631-924-9000)
Fax: 631-924-8355
email: supportservices@biodex.com
www.biodex.com

1. Introduction

Intended Use

The Biodex Mobility Assist is a versatile, independently (not independent) operated mobility assistance device that incorporates rechargeable battery powered lifts to assist a patient from a seated to a standing position in a biomechanically correct motion. Standing balance is promoted as the patient is positioned so their center of gravity is always within the support of the device.

Easily maneuvered into position so the patient can get in independently or with minimal assistance, the Mobility Assist helps individuals stand-up, sit down and walk. Used as an ambulation therapy aid, it helps therapists, nurses and caregivers work with patients that have difficultly rising from a seated to a standing position.

Once positioned in the Mobility Assist the patient has controlled body-weight support and standing balance. Knowing this provides the confidence and reassurance needed to walk. While in the system, patients that can move their legs can ambulate, which should ultimately benefit their physical well-being. Their self-initiated active lower extremity usage addresses disuse atrophy, strengthens core and leg muscles, stimulates functional neural pathways and creates a sense of self-actualization.

Compact, lightweight and strong, the Mobility Assist comes fully assembled. It easily fits around standard wheelchairs and through standard 36" (91.4 cm) doors and can be used inside or even outside in a courtyard setting. The device moves with exceptional ease using the patient's power. All four casters feature locking brakes and can be set for steering forward/backward or free-wheeling in any direction.

The Mobility Assist battery provides hours of typical service, is easily recharged, and can be quickly swapped with an optional spare battery pack. A hand-held Controller provides right- or left-hand usage and therapist access while a comfortable, easy to secure Universal Patient Harness and Waist Support Strap provide unmatched patient security, comfort and positioning versatility.

Indications for Use

The Biodex Mobility Assist is ideal for patients with various physical and neurologic deficiencies that interfere with their ability to complete the sit-to-stand transition. Facility safety managers will especially appreciate the Mobility Assist as it addresses not only patient safety, but the well-being of staff members since caregivers do not need to lift patients in order to get them up and walking with this reliable and stable device. The Mobility Assist is designed to support patients weighing up to 350 lb (159 Kg). It accommodates patients ranging in height from 59.6" (159.4 cm) to 73.4" (186.4 cm).

Classification Rationale Statement

Class 1 as per Rule 12: Active Device intended for Transient Partial Patient Support.

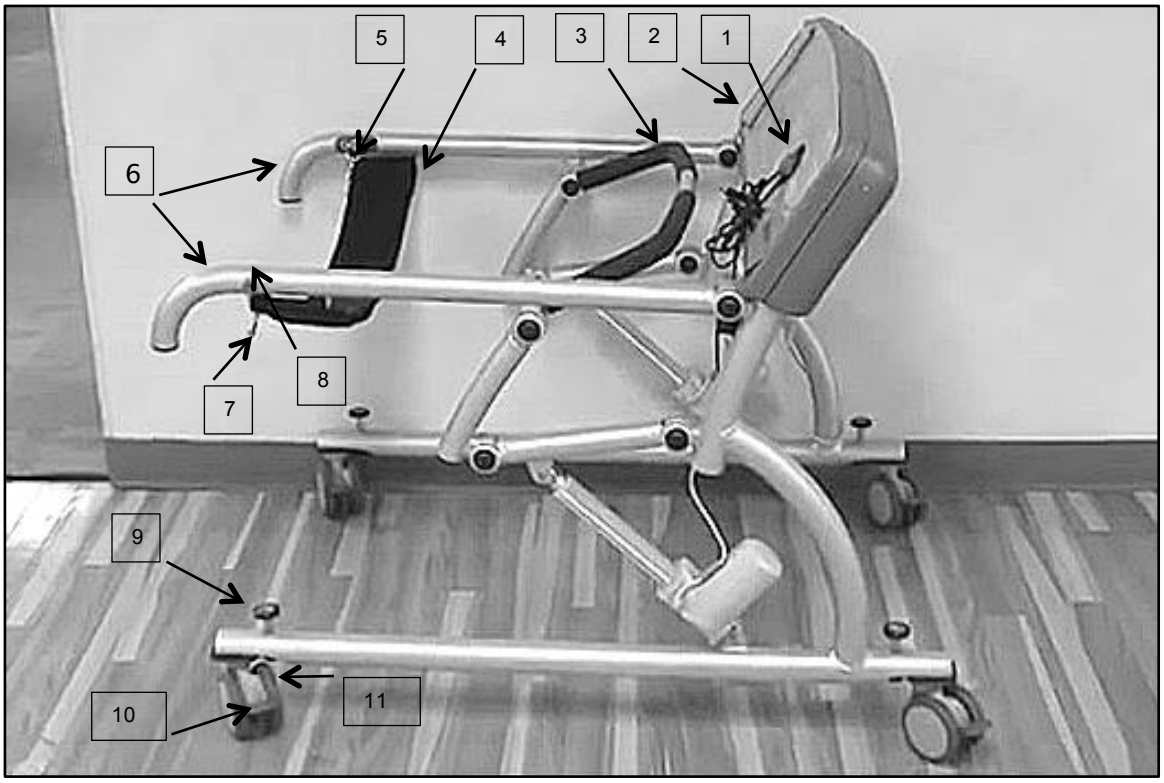


Figure 1.1. Mobility Assist device parts and adjustments.

Parts and Adjustments:

1. *Emergency Stop*
2. *Hand-Held Controller*
3. *Patient Cross Handle*
4. *Stabilization Strap*
5. *Blue Side Label*
6. *Patient Support Handles (2)*
7. *Universal Harness Attachment Clips (2)*
8. *Red Side Label*
9. *Steering Lock (4)*
10. *Brake Lever (4)*
11. *4" Steering/Locking Casters (4)*
12. *Universal Patient Harness (Inset, Figure 1-2.)*
13. *Battery Pack (Inset, Figure 1-3.*
14. *Control Box (Inset, Figure 1-3.)*
15. *Battery Charging Jack (Inset, Figure 1-3.)*
16. *Hand Controller Jack (Inset, Figure 1-3.)*

Optional:

950-571 Charger, Battery – Mobility Assist Device
950-572 Batterey - Mobility Assist Device

NOTE: *To make attaching the Patient Harness easier, the Mobility Assist is color-coded. With the patient facing the dashboard, patient left is designated as the blue side while patient right is designated as the red side. Colored labels corresponding to each side are located on the Patient Support Handles.*

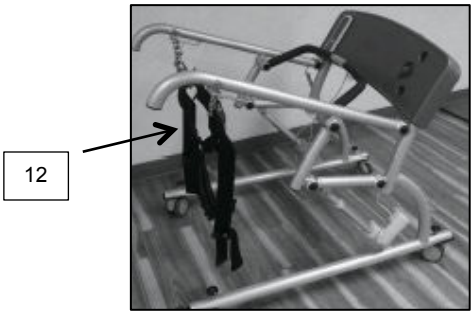


Figure 1-2. Universal Patient Harness.

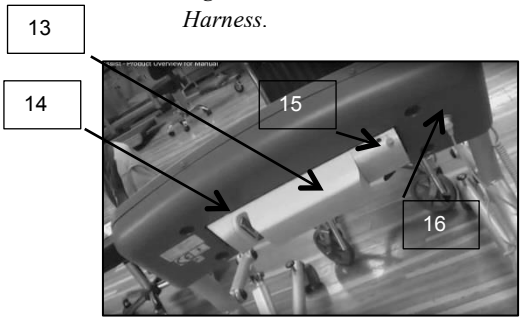


Figure 1-3. Control Box and Battery.

2. Clinical Considerations

The Mobility Assist is a versatile device designed to assist therapists, nurses and caregivers with patients that have difficulty rising from a seated to a standing position and walking on their own. It is ideal for use with patients having various physiological and neurological deficiencies including traumatic brain injury (TBI), stroke recovery, prosthetic use, multiple sclerosis (MS), cerebral palsy (CP) and other conditions that make it difficult to stand and walk. Patients can range from 59.6" (159.4 cm) to 73.4" (186.4 cm) tall and can weigh up to 350 lb (159 Kg).

CAUTION: *The Mobility Assist is an ambulation therapy aid. It is not designed to be a bodyweight support system. It is intended for use in an institutional facility setting with an attending therapist, nurse or caregiver present and overseeing its use at all times.*

ATTENTION: *Le Mobility Assist est une aide à la thérapie de la vibration. Il n'est pas conçu pour être un système de soutien de poids corporel. Il est destiné à être utilisé dans un établissement institutionnel avec un thérapeute, une infirmière ou un dispensateur de soins présents et supervisant son utilisation à tout moment.*

CAUTION: *The Mobility Assist is not intended to be used unsupervised. A therapist, nurse or caregiver will most likely be needed to assist the patient for at least some of the required tasks for using the device such as unlocking the casters.*

ATTENTION: *Le Mobility Assist n'est pas destiné à être utilisé sans supervision. Un thérapeute, infirmier ou le soignant sera probablement nécessaire pour aider le patient pendant au moins une partie des tâches nécessaires pour l'utilisation de l'appareil tels que le déverrouillage des roulettes..*

CAUTION: *Never leave a patient unattended on this device.*

ATTENTION: *Ne laissez jamais un patient sans surveillance sur cet appareil.*

CAUTION: *Check the patient harness and fittings before each use. Use of the Waist Support Strap, or additional stabilization straps, may be required.*

ATTENTION*: Vérifier le faisceau et les raccords du patient avant chaque utilisation. L'utilisation de la sangle de soutien de la ceinture, ou des sangles de stabilisation supplémentaires, peut être nécessaire.*

CAUTION: *The Mobility Assist should never be used near a stairway.*

ATTENTION: *Le dispositif Mobility Assist ne doit jamais être utilisé près d'un escalier.*

CAUTION: *Use caution when operating the Mobility Assist on uneven surfaces.*

ATTENTION: *Soyez prudent lorsque vous utilisez le Mobility Assist sur des surfaces irrégulières*

CAUTION: *The maximum weight of the patient is 350 lb (159 Kg).*

ATTENTION: *Le poids maximal du patient est de 350 lb (159 Kg).*

3. Mobility Assist Operation

The Mobility Assist comes completely assembled and is both safe and easy to operate. With appropriate supervision, it can be used indoors or even outside in a courtyard setting.

Be sure to fully familiarize yourself with the Mobility Assist operation before progressing to use with patients. Make sure to fully review Chapter 2, Clinical Considerations before proceeding.

Steering/Locking Casters

The Mobility Assist has four steering/locking casters, each with two Brake Lever and two Steering Lock positions. All four casters can be individually adjusted as follows:

- Brake Lever down: the wheel is locked.
- Brake Lever up: the wheel is unlocked and can roll or swivel in any direction.
- Steering Lock down: the caster can only be rolled forward or backward and will not swivel or turn.
- Steering Lock up: the caster is free to swivel or turn in any direction.

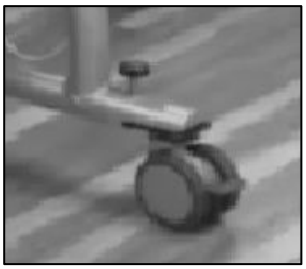


Figure 3-1. Steering/Locking Caster Brake Lever in the locked position.

NOTE: *The Steering Locks may be used to free or lock the steering for all four casters individually. It is best if the front casters are directionally locked when the patient is steering the unit or the therapist is steering from behind the patient. For higher level patients (both physically and cognitively) with a greater ability to ambulate, freeing all four casters is a consideration to be explored.*

The Emergency STOP Button

Located on the front right side of the dashboard, the red Emergency Stop button can be pressed at any time to instantly stop the device from operation. When the therapist presses this button, the battery-powered lifts immediately lock in place. To free the unit for operation after pressing the Emergency Stop button, turn the Emergency Stop Button clockwise until it pops back up. The therapist can use the Hand-Held Controller to resume operation.

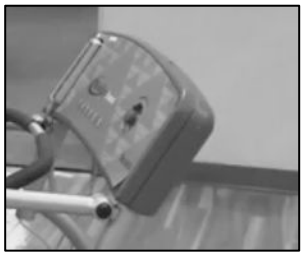


Figure 3-2. Press the red Emergency STOP button at any time to instantly stop operation of the Mobility Assist battery powered lifts.

The Hand-Held Controller

The Hand-Held Controller is used to easily raise or lower the patient, assisting patients as they rise or lower themselves to a standing or seated position. The controller plugs into the Hand-Held Controller Jack on the back of the display. It also displays the current strength of the battery charge.

To raise or lower the patient press on the <UP> or <DOWN> buttons until the desired bar height is achieved.

When not in use, store the Hand-Held Controller in the controller port on the front left side of the dashboard. The controller is magnetic, so it instantly adheres to the port when positioned.

Figure 3-3. The Hand-Held Controller is used to easily raise or lower the Patient Cross Handle while assisting the patient to sit or stand.

The Battery

The Battery connects to the Control Box on the back of the display panel. Slide the Battery Pack onto the receiving port until it snaps into place.

- To charge the battery, plug the charging cord into a wall socket and insert the jack end into the Battery Charging Jack on the Control Box.
- While the battery is being charged, the therapist will see one of two LED lights: A green light means the battery is fully charged. An amber light means the battery is still charging.
- Recharge the battery at the end of each day or as needed based on system use.

Figure 3-4. The Battery Pack attaches to the Control Box at the back of the dashboard. The charging port is also located on the Control Box

Figure 3-5. An optional stand-alone charging base allows a spare battery to be fully charged and ready for use at all times.

NOTE: *The Mobility Assist will not operate while the charger is plugged into the Battery Charging Jack. Biodex recommends purchase of a separate remote Mobility Assist Device Charging Base (950-571) and a spare Battery (950-572).*

Securing the Universal Patient Harness

CAUTION: *The Universal Patient Harness provides security and support as a patient attempts to stand, ambulate or walk. It is not designed to be a body weight support system.*

ATTENTION: *Le harnais patient universel assure la sécurité et le soutien pendant que le patient tente de se tenir debout, de marcher ou de marcher. Il n'est pas conçu pour être un ystème de soutien de poids corporel.*

Figure 3-6. Universal Patient Harness ready to receive the patient.

The one-size-fits-all Universal Patient Harness is used to provide security ensuring patents do not fall while on the Mobility Assist device. It also provides support as the patient attempts to stand, ambulate, or sit back down.

The harness features patient “Left” and “Right” labels to make it easy to secure the harness to the patient. The harness is also color-coded blue for left and red for right. The color coding matches the blue and red color coding on the Mobility Assist.

Figure 3-7. Secure the blue and red coded leg straps around the patient’s legs and attached to the appropriate color-coded buckles.

To Secure The Harness To A Patient Who Can Stand Or Rise Slightly From The Seat:

1. Assist the patient to stand or rise slightly from the seat.
2. Place the Universal Patient Harness, fully open to receive the patient, on the seat with the red side on the patient’s right and the blue side on the patient’s left. The leg straps should hang over the side of the chair.
3. Have the patient sit down with the harness on the chair. Secure the blue label harness leg strap around the patient’s left leg. Secure the red label harness leg strap around the patient’s right leg.
4. Use the Stabilization Strap either in front or behind the patient as needed for intended support.

Figure 3-8. The Universal Patient Harness clips easily to the Mobility Assist.

To Secure The Harness To A Patient That Is Unable To Stand Or Rise Slightly:

1. Gather the harness under one of the patient’s buttocks with the red side on the patient’s right and the blue side on the patient’s left.
2. Have the patient shift weight to the opposite buttock while the gently sliding the harness underneath the non-weight bearring side.
3. Adjust the harness to ensure it is underneath both the right and left buttocks. Be aware that the patient may have to weight-shift side-to-side allowing the harness to be adjusted and the Waist Support Strap to be secured.
4. Secure the blue label harness leg strap around the patient’s left leg. Secure the red label harness leg strap around the patient’s right leg.

To Secure The Harness To A Patient Positioned On A Mat Table:

NOTE: *The Biodex Mobility Assist is designed to fit under a mat table.*

1. Have the patient transfer to the mat (or bed) as per the transfer status and ability. Position the patient comfortably in a supine position.
2. Have the patient roll to the opposite buttock while gently sliding the harness underneath the non-weight bearing side.
3. Instruct the patient to return to the supine position and roll onto the opposite buttock while gently sliding the harness underneath the non-weight bearing side.
5. Have the patient return to supine and adjust the harness ensuring it is underneath both the right and left buttocks. Be aware that the patient may have to weight-shift side-to-side so the harness can be adjusted and the Waist Support Strap can be snugly secured.
6. Secure the blue label harness leg strap around the patient's left leg. Secure the red label harness leg strap around the patient's right leg.

Attaching the Patient to the Mobility Assist

1. Position the Mobility Assist so that the open end is centered directly in front of the seated patient.

CAUTION: *The height of the Mobility Assist, Mat Table or bed may need to be adjusted prior to the following steps to allow the patient to easily and safely move into position and to attach the patient in the Mobility Assist. It may also be necessary to provide patients with additional assistance during the following steps.)*

ATTENTION: *La hauteur de l'aide à la mobilité, de la table de mat ou du lit doit être ajustée avant les étapes suivantes pour permettre au patient de se déplacer facilement et en toute sécurité en position et d'attacher le patient à l'aide à la mobilité. (il peut également être nécessaire de fournir une assistance supplémentaire aux patients pendant les étapes suivantes.)*

2. With all four wheels unlocked, instruct the patient to grasp both Patient Support Handles and pull the Mobility Assist into position so support handles roughly align with the chair back**.**

3. Clip the blue side harness leg strap to the blue Universal Patient Harness Attachment Clip on patient's left side support handle. Do the same for the right (red) side harness leg strap.
   NOTE: *There are three Universal Patient Harness Attachment Clips on each side of the Mobility Assist to allow for varying patient size and height. Use the clips that best position the harness straps with just a slight bit of play and not stretched tight.*

Figure 3-9. The Mobility Assist in position for the patient to stand with assistance.

4. The Universal Patient Harness is adjustable to fit patients of various sizes so it is important to ensure that the harness is snuggly secured to the patient along the buttocks and at the waist area. This can be achieved by synching the Waist Support Strap. As a general rule, it is best to have the harness snugged as tightly as possible. Once the patient is standing, check to ensure the Waist Support Strap is snug and has been adjusted appropriately.

Operating the Mobility Assist

CAUTION: *The Mobility Assist is an ambulation therapy aid. It is not designed to be a bodyweight support system. It is intended for use in a facility with an attending caregiver or therapist present and overseeing its use at all times. It is not intended to be used unsupervised.*

ATTENTION: *Le Mobility Assist est une thérapie à la marche de l'aide. Il n'est pas conçu pour être un système de soutien de poids corporel. Il est conçu pour être utilisé dans une installation avec un soignant ou un thérapeute présent et surveiller son utilisation à tout moment. Il n'est pas destiné à être utilisé sans supervision.*

With the patient fully secured in the Universal Patient Harness and the harness attached to the Mobility Assist, assisting the patient to a standing position is easy.

Figure 3-10. Ready position.

1. Instruct the patient to grasp the Patient Cross Handle with both hands. Inform the patient that the system will assist them with the standing motion. Instruct the patient to extend and lock their legs as they attain a standing position.
2. Press the <Up> button on the Hand-Held Controller to smoothly assist the patient to a standing position. Either the patient or caregiver can operate the controller. When the patient achieves the standing position, stow the Hand-Held Controller on the dashboard.
3. Once the patient is in the standing position, check to ensure the waist support strap is snug and has been adjusted appropriately. The patient can now walk as long as the caster brakes are disengaged.

   NOTE: *If the patient should not be able to ambulate, ensure all four casters are locked.*

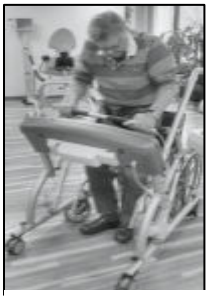


Figure 3-11.Assisted rise to standing position.

4. If the patient requires additional support, position the Stabilization Strap behind or in front of the patient as appropriate. The Stabilization Strap is indicated for patients that require additional assist to maintain postural control and alignment.
5. To return the patient to a seated position, instruct the patient to simply sit down while either the patient or caregiver presses the <Down> button on the Hand-Held Controller.
6. Detach the patient from the system and remove the Universal Patient Harness from the patient.

Figure 3-12. Assisted ambulation.

CAUTION: *It is best to keep the front casters directionally locked in the forward setting if the therapist will be steering the unit from behind the patient.*

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.*

4. Maintenance and Service

The Biodex Mobility Assist has been designed to provide many years of dependable use. To help ensure that this product performs according to maximum specifications and to increase the life of the product, please note the following general cleaning instructions and maintenance procedures.

Daily Maintenance

NOTE: *Do not use cleaning solutions containing ammonia.*

1. As required, clean all metal and plastic exterior surfaces with a solution of warm water and mild detergent.
2. As required, clean the foam grim on the Patient Cross Handle with Hypalon cleaning solution.
3. As required, clean all straps as described below.
4. Inspect harness and all straps for wear.
5. Change or charge the battery as needed. The Hand-Held Controller displays the current strength of the battery charge with two LED lights. A green light means the battery is fully charged. An amber light means the battery needs to be recharged. Recharge the battery at the end of each day or as needed based on system use.

Annual Maintenance

1. Check to be sure that all functions are operating smoothly.
2. Check entire system for signs of wear.
3. Check for noisy components.

Cleaning The Harness And Straps

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, use 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.
2. 

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

ATTENTION: *Soyez extrêmement prudent avec cette méthode. Se terminer seulement dans un endroit bien ventilé et loin de toute flamme nue.*

CAUTION: *Try this method on an inconspicuous spot before using it on the original stain/soiling.*

ATTENTION: *Essayez cette méthode sur une tache discrète avant de l'utiliser sur la tache / souillure d'origine.*

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.
   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.

CAUTION: *Try this method on an inconspicuous spot before using it on the original stain/soiling.*

ATTENTION: *Essayez cette méthode sur une tache discrète avant de l'utiliser sur la tache / souillure d'origine.*

5. Specifications

950-570 Mobility Assist

Dimensions: Outside: 32½ (82.5 cm), Inside: 26½ (67.3 cm), Length 44 (111.8 cm), Height 37½ (95.25 cm)
Weight: 90 lb (41 kg)
Patient weight capacity: 350 lb (159 Kg)
Patient height range: 59.6" (159.4 cm) to 73.4" (186.4 cm)
Power: Rechargeable Lead Acid Battery
Compliance: IEC 60601-1, 3rd Ed.; ISO 10535, clause 6; IEC 60601-1-2, 2014; FDA Class 1 Equipment; CE Class 1
Warranty: Two years parts, one year labor. Includes one Universal Patient Harness. Harness is warranted for 60 days.

Optional:

950-571	Base, Charging
950-572	Battery

Replacement:

950-576	Harness, Universal Patient
950-579	Stabilization Strap

NOTE: *The optional charging base and battery are needed only if a second battery is desired. A battery charger is provided with the Mobility Assist which plugs directly into the battery while the battery is in the device. The optional Charging Base can be wall-mounted or table top. The battery charger provided with the Mobility Assist is used with the charger base.*

Figure 5-1. An optional stand-alone charging base allows a spare battery to be fully charged and ready for use at all times.

6. Conformance to Standards

This equipment conforms to the following safety standards:

Table 1.1 Safety standards.

Standard	***Edition and/or date***
IEC60601-1-2	2014

Accompanying EMC Documents

This medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers and cables other than those specified, with the exception of accessories, transducers and cables sold by the manufacturer of this equipment, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment.
- The Mobility Assist should not be used adjacent to or stacked with other equipment. If the Mobility Assist is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

List of Cable Accessories

The list in Table 1.2 includes all accessory cables supplied with the Mobility Assist for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Mobility Assist.

Table 1.2 Mobility Assist cables.

Cable description	***Part no.***	***Cable length***
Power Input Cable 120 – 220VAC	-	6ft

Declaration of Conformity

Emissions

Manufacturer's declaration electromagnetic emissions		
The Mobility Assist is intended for use in the electromagnetic environment specified below. The customer or the user of the Mobility Assist should assure that it is used in such an environment		
Emission test	***Compliance***	***Electromagnetic environment***
RF emissions CISPR 11	Group 1	The Mobility Assist generates RF energy only for its internal functions. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Mobility Assist is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
Harmonic distortion EN 61000-3-2	Class B	
Voltage fluctuations and flicker EN 61000-3-3	Complies	

Immunity

Manufacturer's declaration electromagnetic immunity			
The Mobility Assist is intended for use in the electromagnetic environment specified below. The customer or the user of the Mobility Assist should assure that it is used in such an environment.			
Immunity test	***IEC 60601-1-2 Test level***	***IEC 60601-1-2 Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	Direct Contact ± 8 kV Air ± 2 , ± 4, ± 8, ±15 kV Indirect Vert Cpl plane ± 8 kV	Direct Contact ± 8 kV Air ± 2, ± 4, ± 8, ± 15 kV Indirect Horiz Cpl plane ± 8 kV	Floor should be wood, concrete or ceramic tiles. If floor is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	Power ± 2 kV Signal ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5 kV, ± 1 kV diff mode 0.5 kV, ± 1 kV ± 2 kV common mode	0.5 kV, ± 1 kV diff mode 0.5 kV, ± 1 kV ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment

Immunity test	*IEC 60601-1-2 Test level*	*IEC 60601-1-2 Compliance level*	*Electromagnetic environment – guidance*
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% of dip in UT) for 1/2 cycle 40% UT (60% of dip in UT) for 5 cycle 70% UT (30% of dip in UT) for 25 cycle < 5% UT (> 95% of dip in UT) for 5 sec	< 5% UT (> 95% of dip in UT) for 1/2 cycle 40% UT (60% of dip in UT) for 5 cycle 70% UT (30% of dip in UT) for 25 cycle < 5% UT (> 95% of dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If a better mains power quality is required, it is recommended that the Mobility Assist is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the Mobility Assist display further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Conducted RF IEC 61000-4-6	3 Vrms, 6 Vrms in ISM 150 KHz to 80 MHz ISM bands: 6.765-6.795,13.553-13.567, 26.957-27.283,40.66-40.70 Amateur radio bands: 1.8-2.0, 3.5-4.0,5.3-5.4,7-7.3,10.1-10.15,14-14.2,18.07-18.17,21.0-21.4,24.89-24.99,28.0-29.7,50.0-54.0	3 Vrms, 6 Vrms in ISM 150KHz to 80 MHz ISM bands: 6.765-6.795,13.553-13.567, 26.957-27.283,40.66-40.70 Amateur radio bands: 1.8-2.0, 3.5-4.0,5.3-5.4,7-7.3,10.1-10.15,14-14.2,18.07-18.17,21.0-21.4,24.89-24.99,28.0-29.7,50.0-54.0	Portable and mobile RF communications equipment should be used no closer to any part of the Mobility Assist, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7GHz	10 V/m, 80 MHz to 2.7GHz	

Note 1. UT is the AC mains voltage prior to application of the test level.

Note 2. At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

[a] Field strength from mixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM or FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mobility Assist is used exceeds the applicable RF compliance levels above, the Mobility Assist should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mobility Assist.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Mobility Assist. Table 6			
The Mobility Assist is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Mobility Assist can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Mobility Assist as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter [W]	***Separation distance according to frequency of transmitter [m]***		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2**. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Operating Temperature

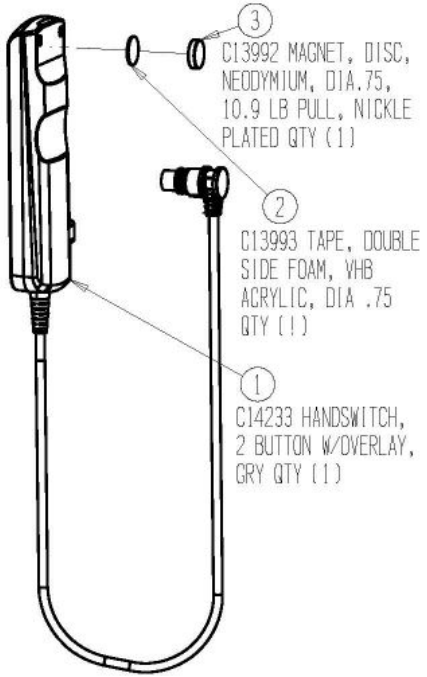
Do not expose the equipment to a temperature change of more than 5˚ F (3˚ C) per hour.

Limits of low and high operating temperature ranges are 59˚ to 86˚ F (15˚ C to 30˚ C).

7. Parts and Assembly Illustrations

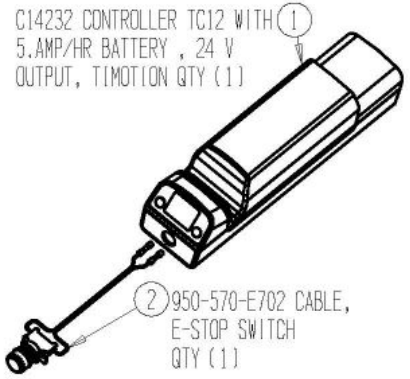
ASSY, HAND PENDANT

HANDPENDANTASSY950-570-A010-B



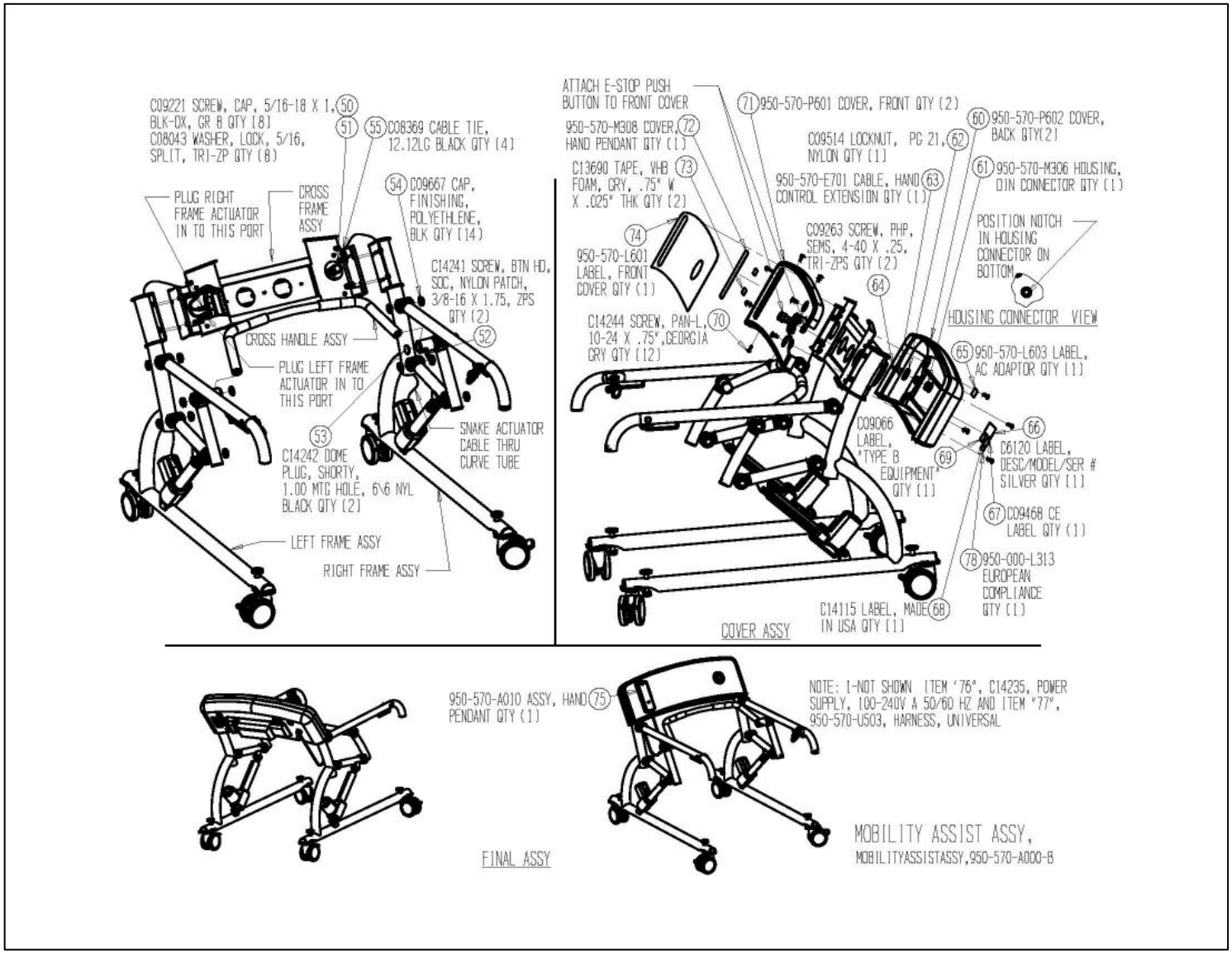
MODIFIED CONTROL BOX ASSY

MODIFIED CONTROL BOX ASSY950-570-A020-A



SHACKLE ASSY,

SHACKLEASSY,950-570-A030-A



BIODEX
Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (*Int'l 631-924-9000),* Fax: 631-924-9338, Email: info@biodex.com, www.biodex.com