



Armedica®
BY PIVOTAL HEALTH SOLUTIONS

Parallel Bars

Electric Platform Mount

User Manual

MD

REF

Applies to the following Configurations:

EPB10080

EPB10080B

EPB10010

EPB10010B

EPB10012

EPB10012B



Important! This User Manual contains important information for the user of the product. All who use this product should review and completely understand its contents. Remember to keep this manual in a place where it is always available to those using the product.

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Introduction:

Congratulations on receiving your Electric Platform Mount Parallel Bars, proudly designed and manufactured in the USA.

This manual contains general information on how to unbox, operate and care for your equipment. Reading and following instructions thoroughly will maximize the life and efficiency of your equipment and aid in its safe operation.

Intended Use: Electric Parallel Bars are intended for use in a therapy setting for medical purposes such as to redevelop muscles or restore motion to joints or as an adjunct treatment for obesity.

Safety Precautions & Definitions:



WARNING: Never leave patient unattended.



CRUSH HAZARD: Powered components used to elevate and lower handrails present a potential crush hazard. KEEP CHILDREN AWAY FROM TREATMENT AREA. Allow only the patient and authorized staff in treatment area.



ELECTRICAL CONNECTION: For your personal safety, the battery charging unit must be grounded. This product is equipped with a power supply cord having a three (3) prong grounding plug. To minimize possible shock hazard, it must be plugged into a mating three (3) prong grounding type wall receptacles, grounded in accordance with the National Electrical Code and local code ordinances. If a mating wall receptacle is not available, it is the responsibility and obligation of the customer to have a properly grounded three (3) prong wall receptacle installed by a qualified electrician. Power requirements of the electric parallel bar unit are found in the Technical Data Section.



Applied parts. An applied part is one specifically intended to come into direct contact with patient during normal use. This includes the handrails and base, which encompass part numbers below:

	Handrail / Parallel Bars, Part Number	Cap on Handrails, Part Number	Base parts, Part Numbers
8' model	EPB1109 (qty=2)	EPB1120 (qty=4)	EPB1042, EPB1041, EPB1051
10' model	EPB1077 (qty=2)	EPB1120 (qty=4)	EPB1042, EPB1041, EPB1051, EPB1068
12' model	EPB1098 (qty=2)	EPB1120 (qty=4)	EPB1042, EPB1041, EPB1051
8' bariatric model	EPB1109 (qty=2)	EPB1120 (qty=4)	EPB1042B, EPB1041B, EPB1051B
10' bariatric model	EPB1077 (qty=2)	EPB1120 (qty=4)	EPB1042B, EPB1041B, EPB1051B, EPB1068B
12' bariatric model	EPB1098 (qty=2)	EPB1120 (qty=4)	EPB1042B, EPB1041B, EPB1051B






Before using this equipment follow the following safety precautions:






- Before using this equipment make sure you have read and understand this entire manual.
- A doctor or clinician authorized by the state must ensure that the patient's health and physical condition are appropriate for any treatment being applied when the patient is on the table and treatment must be performed under the direction of a licensed clinician.
- Never exceed the unit's maximum supported weight.

- Connect the battery charging unit only to an outlet that is grounded and connected to a circuit with a fused circuit breaker in accordance with the National Electrical Code and local codes and ordinances.
- Use only on dry, level surfaces to ensure no slipping or sliding.
- NOT intended for use with accessories other than those indicated in this manual.
- Do not operate this device in an environment where other devices that intentionally radiate electromagnetic energy in an unshielded manner are present.
- Always explain to the patient how to properly get on and off the equipment.
- Do not allow children unintended near the device and do not allow children to play on the parallel bars.
- Keep patient's hands positioned on the top side of the parallel bars at all times.
- Keep hands and feet away from moving parts and pinch points.
- Never leave patient unattended on this equipment, be sure to assist patient to prevent falls.
- Follow preventative maintenance instructions provided in this manual.
- Ensure all components have been inspected for damage and are fully functional, including handrail fasteners and weldments that if damaged or broken may lead to injury.
- Inspect cables and connectors before each use.
- Inspected for damage prior to each use; if damage is found that could impact patient safety do not use the device.
- If you need service assistance contact Armedica by Pivotal Health Solutions at 1-800-743-7738.
- Device is not to be used as a patient lift

Symbols:

Warning and Precautions through this manual are indicated by specific symbols. Applicable symbols are shown below along with a description of the symbol. Review these symbols and all safety precautions before operating the table.

	CAUTION: Text with a "CAUTION" indicator will explain possible safety infractions that could have the potential to cause injury.
	WARNING: Text with "WARNING" indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.
	Pinch Point: Indicates space between manually adjustable moving and stationary parts where body parts may become caught, leading to minor injury.
	Warning: High Voltage
	Crush Hazard: Indicates space between powered moving and stationary parts that represent a potential crush hazard.

	Instructions for Use: Indicates the need for the user to consult the instructions for use.
	EXPLOSION HAZARD Text with “EXPLOSION HAZARD” indicator will explain possible safety infractions if this equipment is used in the presence of flammable anesthetics.
	Contains electronic materials. Recycle and dispose of device properly in accordance with local, state and federal laws.
	Indicates the device manufacturer.
	Type B Applied part. An applied part complying with specified requirements for protection against electric shock. Applied part is generally not conductive and can be immediately released from the patient.



WARNING: Under no circumstances should this product be modified from its original design. Contact Pivotal Health Solutions if you need help with service.



DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.

Installation & Unpacking:

THIS DEVICE IS VERY HEAVY. A MINIMUM OF FOUR PEOPLE ARE REQUIRED TO LIFT AND MOVE THE ELECTRIC PARALLEL BAR UNIT. LIFT THE UNIT BY THE LONG SIDES OF THE BASE ONLY. DO NOT LIFT OR SUPPORT BY THE END RAMPS OR COLUMNS. DAMAGE OR SERIOUS PERSONAL INJURY MAY OCCUR!



WARNING: Do not install/use this equipment adjacent to, or stacked with, other equipment as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify they are operating normally.

After removing the top and side panels of the shipping crate, you may notice bands and/or plastic cable ties connecting the product to a pallet. These are used to secure various sections and must be removed. Once removed, the product must be lifted directly upward in order to clear all shipping restraints.

Once the product is out of the shipping crate, place it on a firm, level section of the floor where the product will be stable.



CAUTION: Ensure device is positioned so that the battery is easily removable and the controls are easily accessible.

If the product requires assembly, follow the assembly instructions that are with the product.

Inspect for damage prior to use to include, verifying that parallel bars are attached securely and there isn't damage apparent to parallel bars, that there is no damage to the walking surface and no damage to the two batteries, the battery charging cradle, including any cords. Contact Armedica by Pivotal Health Solutions or your dealer with any questions or concerns.

Instructions for Damaged Merchandise: The contents of this shipment have been checked and packed by experienced personnel. If your company arranged the shipping, damage should be noted on the Bill of Lading before signing to accept the shipment, then articles damaged in transit should be reported at once to delivering carrier and a claim must be filed by you. If freight was arranged by Pivotal Health Solutions, note any damage on the Bill of Lading before signing acceptance of product and notify Pivotal Health Solutions right away. Failure to inspect for shipping damage prior to signing for the product may affect your warranty. We can neither be responsible for, nor can we accept the return of merchandise damaged in transit during shipment arranged by outside parties.



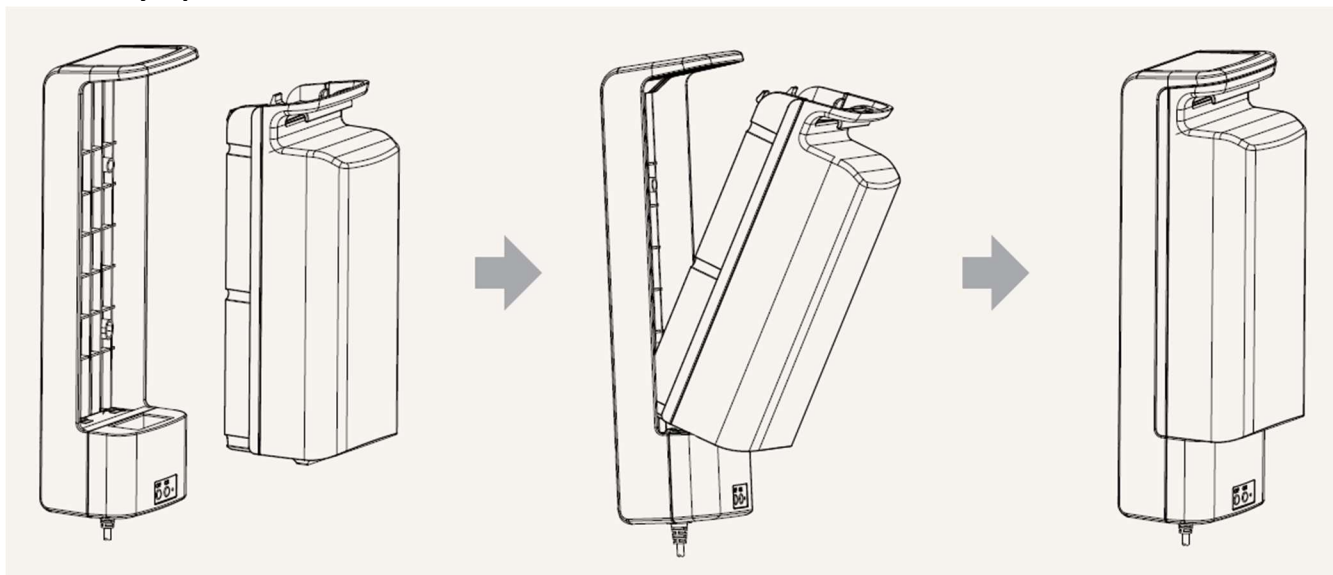
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the unit including cables associated with this unit. Otherwise, degradation of the performance of this equipment could result.

Set up:

Electric Parallel Bars are exclusively battery operated, with easy exchange between the two batteries provided. A battery charging block and cradle is packaged with the product and must be used for charging the battery when not connected to the Electric Parallel Bars.

Note: *Charging the battery while connected to the Electric Parallel Bars will void the battery warranty.*

Battery Operation:



Interpreting Battery LED for status determination when on unit:

Status	Capacity	LED	
Hi charging	>80%	Green	Continuous on
Charging	<80%	Green	Short dimming (1 sec / 1 sec)
Hi battery	>25%	Green	Long dimming (0.5 sec / 4 sec)
Low battery	<25%	Orange	Long dimming (0.5 sec / 4 sec)
Protection	<20%	-	Off
Failure	-	Orange	Continuous on

Interpreting Battery LED for status determination when charging the battery:

Note: From low battery to a fully charged battery takes approximately 10 hours.


Status	Capacity	LED	
Hi charging	>80%	Green	continuous on
Charging	<80%	Orange	continuous on

Initial Motor Synchronization Instructions: (Leveling handrails)

(With the unit powered On, allowing 5 seconds for initialization of the control tower)

1. Press and hold the Green safety switch on the side of the control tower along with both the UP and DOWN arrows on the Height Button until the handrails stop moving and the Height Button display reads 020
2. If the bars stop moving and the button display does not show 020 release and repeat Step 1 until the display reads 020
3. REPEAT Steps 1-3 for Width Button.

Technical Specifications:

Model Name	Parallel Bars Electric Platform Mount			
Platform Width Dimensions	50" Wide		(Bariatric) 56" Wide	
Configurations Available <i>(length is handrails)</i>	EPB10080	8'L x 50"W	EPB10080B	8'L x 56"W
	EPB10010	10'L x 50"W	EPB10010B	10'L x 56"W
	EPB10012	12'L x 50"W	EPB10012B	12'L x 56"W
Table Mass	EPB10080	510 lbs (231 kg)	EPB10080B	550 lbs (250 kg)
	EPB10010	640 lbs (290 kg)	EPB10010B	690 lbs (312 kg)
	EPB10012	720 lbs (327 kg)	EPB10012B	780 lbs (354 kg)
Safe Working Load	800 lbs. (362 kgs) (400 lbs/181kg per bar)		1000 lbs. (453 kgs) (500 lbs/226 kgs per bar)	
Maximum Temperature	41.4 °C (106.5 °F) – see Conditions for Safe Use disclosure below			
Handrail Movement Range	Minimum Height: ~25" <i>(narrowest)</i> Maximum Height: ~42" <i>(widest)</i>		Minimum Height: ~23" <i>(narrowest)</i> Maximum Height: ~41" <i>(widest)</i>	
	Minimum Width: ~5" <i>(Highest)</i> Maximum Width: ~32" <i>(Lowered)</i>		Minimum Width: ~11" <i>(Highest)</i> Maximum Width: ~37" <i>(Lowered)</i>	
Rated Voltage – Battery Charger Cradle	120V/240V			
Rated Frequency	50/60 Hz			
Rated Current	10A			
Duty Cycle	2 Minute On, 18 Minutes Off			
Electrical Classification	Class 1			
Battery Charger Electrical Type	 Type B			
Battery Charger Cable Length	98" (2500mm)			



CAUTION. Conditions for Safe Use Disclosure:

To prevent/eliminate the potential for patient OR clinician injury by heat exposure during Parallel Bar Positioning, Parallel Bars are NOT to be operated outside MAX Duty Cycle. IF parallel bars are operated outside the MAX duty cycle as noted in the User Manual, the Clinician conducting treatment may become at potential risk of injury by heat exposure to PN TR102 – Green Momentary Push Button Switch, due to a potential rise in Temperature to 41.4 degrees Celsius (106.5 degrees Fahrenheit).



WARNING: Keep this unit out of high moisture areas. For indoor use only.

Operating Conditions: This unit should be operated, between 40° F (4.4° C) and 100° F (37.8° C), with relative humidity ranging from 30% - 80%.

Transport & Storage Conditions: This unit should be transported and stored in temperatures between -40° C (-40° F) and 70° C (158° F) with relative humidity 10%-100%

Expected Life: This product has an approximate expected life time of 5 years when correctly handled, serviced, and inspected in accordance with these instructions.

Design and Quality: Pivotal Health Solutions is certified in accordance with ISO 13485, the standard for the medical device industry.

Product Changes: Pivotal Health Solutions, Inc. reserves the right to make products changes without prior notice. Contact your Pivotal Health Solutions representative for advice and information about product upgrades.

Operation:



WARNING: Use of accessories and cables other than those specified or provided by Pivotal Health Solutions could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.



WARNING: Ensure platform is clear and there are no obstructions under the handrails before actuating the columns to adjust height. Serious personal injury and/or damage to equipment may occur.



WARNING: Patient is not intended to operate this device in any way. This unit shall be operated by trained, qualified and authorized personnel ONLY.



CRUSH HAZARD: Powered components used to elevate and lower the parallel bars present a potential crush hazard. KEEP CHILDREN AWAY FROM TREATMENT AREA. Allow only the patient and authorized staff in treatment area.



PINCH POINT: Always keep patient's hands positioned on the top side of the parallel bars.




Before Each Use:

- 1) Device should be inspected for damage prior to each use; includes verifying that the parallel bars are attached securely and there isn't damage apparent to parallel bars, that there is no damage to cords, battery or battery components, that there is no damage to the walking surface, that all components operate smoothly as expected. If damage is found that could impact patient safety do not use the device. Contact Armedica by Pivotal Health Solutions for assistance.

Note to user: If a serious incident occurs, report the incident to Pivotal Health solutions. (See section with Manufacturer Contact Information for contact details). If the incident occurs in the EU, also report any serious incident to the Competent Authority of the Member State in which the user and/or patient is established.

Operation: With the unit powered On (allowing 5 seconds for initialization)

- 1) Ensure the unit is in the correct position prior to patient entering the platform of the unit.

<p>Safety Switch Operation</p> 		<p>A safety switch is located on the side of the control tower, used to prevent unintended handrail movement.</p> <p>With the battery connected, press and hold the green activation button (safety switch).</p> <p>(No movement will occur until the Height or Width button is pressed)</p>
<p>Width Operation</p> 	<p>Height Operation</p> 	<p>Press and hold the green button (safety switch) during operation of the digital control screens.</p> <p>When the Height or Width touch pads are active with digital display numerals, continue pressing the safety switch and touch the up or down arrows to adjust.</p> <p>(After 30 seconds of inactivity the display numerals will disappear)</p>

- 2) Confirm that the patient's hands are empty, dry and free of any lotion/creams/oils, to ensure proper grip of parallel bars during use. Ensure patient's clothing will not get caught in the device.
- 3) Assist the patient onto the platform. Patients with mobility issues should be assisted at all times when using, entering or exiting this device.

Assisting Patient Off of unit:

- 1) Caution the patient not to exit the unit alone so as to prevent any strain that could void the treatment, and to ensure the patient is not lightheaded or weak, which can cause imbalance.
- 2) Allow patient to get full balance before exiting. Best practice is to keep a hand on the patient at all times.

Preventative Maintenance:



WARNING: Disconnect the battery from unit before wiping down mechanical parts to avoid personal injury.



WARNING: Failure to follow recommended maintenance instructions may cause damage to equipment, personal injury and void warranty.

INSPECTION:

Before Each Use:

Device should be inspected for damage prior to each use to include verifying:

- Weldments and handrail fasteners are in good condition and not broken
- Walking surfaces are in good condition
- Parallel bars are attached securely and there isn't damage apparent to parallel bars
- Verifying there is no damage to cords or battery components
- Verify that all components operate smoothly as expected

If damage is found that could impact patient safety do not use the device.

Contact Armedica by Pivotal Health Solutions at 800-743-7738 for assistance in repairing damage.

Only approved Pivotal Health Solutions replacement parts may be used.

At least monthly the unit should be thoroughly inspected for wear and tear, loose hardware and parts, and other damage.

- Inspect to make sure that there is no external damage or loose hardware. Tighten loose hardware. Hardware that does not tighten needs replacement.
- Inspect for obvious signs of damage or wear such as cracked welds, loose bolts, frayed or damaged cords. If damage is found that could impact patient safety do not use the device
- Check moveable components (electrical and non-electrical) to ensure functionality.
- Check components to ensure they function properly.
- Contact Armedica by Pivotal Health Solutions at 800-743-7738 with questions or concerns.

LUBRICATION:

The bearings are self-lubricating and should not require lubrication.

Cleaning & Care:



CAUTION: Read carefully, improper cleaning will void the warranty.



WARNING: This unit is not rated for wash down or sterilization, it should not be exposed to standing or quantities of liquid. Do not clean any electronic device with water. Electrical shock and/or damage to electronics may occur.

Inspect product's surface after each use and dry any wet surfaces.

Sharp or rough objects can scratch the surface. Avoid dragging objects along the surface.

Clean with a damp cloth as needed. Wipe dry.

PAINTED: Should be cleaned with a commercial disinfectant and wiped with a dry cloth to remove any biological contamination when necessary.

STAINLESS STEEL: Mix 70% Isopropyl alcohol with water to remove dirt and oil, then wipe dry with a clean cloth.

DISINFECTING: There is a disinfecting wipe on the market called *Protex Ultra Disinfectant Wipes*. Many of our customers use these.

FOR DAY TO DAY CLEANING: A solution of 10% mild household liquid dish soap with warm water, applied with soft damp cloth. Rinse with clean water on a damp cloth and towel dry.

Service:

Refer to Warranty section in this manual for specific warranty information.

When replacing worn parts, use genuine Pivotal Health Solutions, Inc. parts by contacting our service department. When ordering replacement parts:

- Ask for the service department, 800-743-7738
- Have the model number and serial number available
- Specify parts by the numbers/description below

Troubleshooting:

No Power	<ol style="list-style-type: none">1. Verify that the battery is charged2. Verify that the battery is connected properly into the cradle3. Confirm that the power button on the battery unit is ON and shows charged4. <i>If the problem persists, contact Pivotal Health Solutions.</i>
Handrails are not level with each other, motors out of synchronization (“re-calibration”)	<ol style="list-style-type: none">1. Press and hold the Green safety switch on the side of the control tower along with both the UP and DOWN arrows on the Height Button until the handrails stop moving and the Height Button display reads “020”.2. If the bars stop moving and the button display does not show “020” release and repeat Step 1 until the display reads “020”.3. REPEAT Steps 1-3 for Width Button4. <i>If the problem persists, contact Pivotal Health Solutions.</i>
If you hear unusual noise.	<i>Contact Pivotal Health Solutions</i>

Technical Information:

Pivotal Health Solutions will make available, upon request, circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel.

Resale or Disposal:

Electric parallel bars are considered a medical device by the Food and Drug Administration. Therefore, it is necessary that Pivotal Health Solutions, Inc. be notified if the product is sold, destroyed, or otherwise disposed of. Please notify in writing providing your name and the serial number of your product to:

Pivotal Health Solutions
Attn: Quality
3003 9th Ave. SW
Watertown, SD 57201



Recycle and dispose of device properly in accordance with local, state and federal laws. Over the years, tons of electronics equipment with hazardous materials have been thrown away with standard garbage. Over time, these materials leech out of the electronic causing damage to the environment. It is important to try and properly dispose of retired devices in order to prevent damage to our environment.

Replacement Parts:

<u>Part Name</u>	<u>Part Number</u>
TDH4 Digital Hand Control Switch	EPB1065
TiMotion TA29 Actuator, 50mm Stroke (Width)	EPB1091
TiMotion TA29 Actuator, 200mm Stroke (Height)	EPB1092
TiMotion TC14 Control Box	EPB1093
TiMotion Y Cable, 2000mm L	EPB1094
On-Off Switch for TR1000 Momentary push button	TR102
TiMotion TBB7-222A111-3 battery	EPB1020
TiMotion TBC3 Charger and Charging Cradle	EPB1119

Warranty:

<https://www.phsmedicalsolutions.com/customer-service/service-and-warranty>

Manufacturer Information:

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