

Aluma Elite Basic Changing Table User Manual

Applies to the following Models:

MD

A4327-3052 A4327-3052ADA

REF

A4327-3052EL A4327-3052ELADA



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:

Ease of use, multiple options and a sleek but durable design make the Aluma Elite Basic Changing Table line of tables the choice of caretakers everywhere. The Aluma Elite Basic Changing Table is constructed of precision-cut flat and tube aluminum for durability and style.

Intended Use:

The Aluma Elite Basic Changing Table line of tables are intended for use in a clinical environment to support patients during treatment



Safety Precautions & Definitions:



WARNING: Never leave patient on table unattended.

If you need assistance, contact Pivotal Health Solutions service at 1-800-743-7738.

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

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 coded and 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 table are found in the Technical Data Section.

Before using this equipment follow the following safety precautions:

- Before using this equipment make sure you have read and understand this entire manual.
- Explain proper use to all employees. This table should be used only by qualified, trained personnel.
- Never exceed the table's maximum supported weight.
- DO NOT SIT, LEAN, OR OTHERWISE OVERWEIGHT TILTING HEADPIECE. This tilting section is not meant
 to hold more than the weight of the body part that the piece is intended to hold.
- Connect table 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 surfaces. Ensure the tables feet do not slide.
- Make sure casters are locked.
- This table is NOT for patient transport.
- NOT intended for use with accessories other than those indicated in this manual.
- Do not operate the table 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 table. Be sure to assist patient to prevent falls.
- Keep patient's hands positioned on the top side of cushions at all times.
- Keep hands and feet away from moving parts and pinch points.
- Ensure controls have locked properly prior to positioning or releasing patient.
- Never leave patient unattended on table.
- Follow preventative maintenance instructions provided in this manual.
- Ensure all components have been inspected for damage and are fully functional.
- Inspect cables and connectors before each use.



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.
<u>^</u>	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.
4	Warning: High Voltage
72	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.
MD	Indicates the product is a medical device.

WARNING: Under no circumstances should the table 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:

A MINIMUM OF TWO PEOPLE ARE REQUIRED TO LIFT AND MOVE THE TABLE. LIFT THE TABLE BY THE BASE FRAME!

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 metal bands and plastic cable ties. These are used to secure various sections of the table and must be removed. Once all bands and cable ties are removed, the table must be lifted directly upward in order to clear all shipping restraints.

Once the table is out of the shipping crate, place table in a level location and inspect the table cushions, frame, cables, etc. for damage. If no damage is noted, plug in the table and test the elevation, drops, and any other options that are on your table. Contact 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 table including cables associated with this table. Otherwise, degradation of the performance of this equipment could result.



Technical Specifications:

Base Model Number	A4327-3052	A4327-3052EL	A4327-3052ADA	A4327-3052ELADA
Model Name	Aluma Elite Changing Table	Aluma Elite Elevating Changing Table	Aluma Elite ADA Changing Table	Aluma Elite Elevating ADA Changing Table
Cushion	Head Cushion: PT30331-XXX			
Configurations Available	Main Body Cushion: A4936-XXX Side Rail Cushion: S3149-XXX (Qty 2) *XXX = Color Code			
Foot Control Option		A4975 (optional)		A4975 (optional)
Other Options	Shelf; shelf with sliding door; paper roll holder/cutter			
Dimensions	~39" W (includes rails) x ~67" L			
Height	~27"H	~28-37" H	~22"H	~22-32"H
Head Angle	+45° to -90°			
Foam	2" High Density Foam Cushions with rounded corners			
Rated Voltage	120V			
Rated Frequency	60 Hz			
Rated Current	10A			
Fuse Type	No User Serviceable Fuse			
Safe Working Load	500 lbs. (266 kg)			
Duty Cycle	2 Minutes On, 18 Minutes Off			
Electrical Classification	Class 1			
Electrical Type	Type B			
Power Cord (120V)	96 in (243 cm) cable length, 10A, unshielded			



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

Operating Conditions: This table 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 table 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 10 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: Not for patient transport.



CRUSH HAZARD: Powered components used to elevate and lower this table 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 top side of cushions when lowering, raising and tilting table to keep from potential pinch points, including but not limited to side rails.

Note to user: If a serious incident occurs, report the incident to Pivotal Health solutions. (See section with Manufacturer Contact Information for contact details).

Ensure the area is clear and table is free of obstruction

Side Rail Operation:

- 1) Hold onto the metal of the side rail to support its weight.
- 2) Pull down on the spring loaded knob to release.
- 3) Lift or lower the side rail to the desired position. (up/down)
- 4) Release the spring loaded knob to lock the rail into position.

Verify that the side rail is locked into the desired position by firmly pushing/pulling, the side rail.

The side rail should not move from the desired position. If the side rail moves, repeat the steps 1-4 of Side Rail Operation.

Mechanical Headpiece Tilt:

This section uses a mechanical friction locking mechanism, which allows free travel in a single direction and a continuous lock the opposite direction.

- 1) To elevate, manually lift section into desired position, automatically locking into place.
- 2) To lower, support the section and rotate the lever handle, lower to the desired height and release the handle.

Assisting Patient onto Table:

- 3) Ensure that the table is in lowest position and flat configuration prior to start.
- 4) The practitioner or trained staff should always assist the patient on the table. Do not allow the patient to get on the table by him/herself.
 - a. Patient should sit on center of the main body cushion then swing feet up onto the table.
 - b. Patient should not sit on the corners of the table nor the head end.
- 5) The patient should check clothing for keys, wallet, belt, or any other items that may cause discomfort during treatment or damage upholstery.
- 6) Never leave patient unattended while on the table.

DO NOT SIT, LEAN, OR OTHERWISE **OVERWEIGHT TILTING HEADPIECE** AND RAIL SECTIONS.



Table Operation:

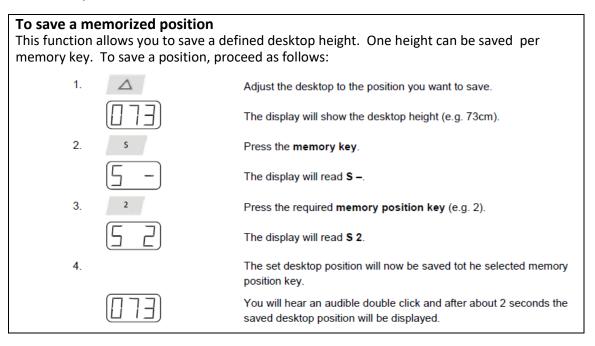
- 1) To begin treatment, ensure table is in lowest position and flat.
- 2) Position the patient on the table as above.
- 3) Elevate to the desired height once the patient is in place. (EL models)
- 4) Perform the treatment desired. Refer to the 'Operation' section and/or the individual component functions below for operation of specific table features
- 5) After treatment, return the table to a level and straight configuration.
- 6) Lower the table to the lowest position.

Assisting Patient off of Table:

- 1) Caution the patient not to get up from the table alone so as to prevent any strain that could void the treatment, and to ensure the patient is not lightheaded from lying down which can cause imbalance.
- 2) Allow patient to get full balance before coming to a standing position. Best practice is to keep a hand on the patient at all times.

Elevation (A4327-3052EL and A4327-3052EL-ADA models only):

- 1) Use the mounted switch on the front edge of the table to raise and lower the height of the table using the up and down arrows individually, until the desired height is reached.
 - Note: Memorized positions can be set on buttons 1-4



Foot Switch: (Optional for elevating models only)

Step on foot switch button to raise table. Release at desired position. Step on the opposite foot switch button to lower the table. Release at desired position.



Preventative Maintenance:



WARNING: Disconnect table from power source before wiping down mechanical parts to avoid personal injury.

INSPECTION:

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

- Inspect the table to make sure that there is no external damage or loose hardware. Tighten loose hardware. Hardware that does not tighten needs replacement.
- Inspect table for obvious signs of damage or wear such as cracked welds, loose bolts, frayed or damaged cords. Do not use a table with damaged cords.
- Check moveable components (electrical and non-electrical) to ensure functionality.
- Check components to ensure they lock and function properly.
- Contact Pivotal Health Solutions with questions or concerns.

Upholstery Cleaning & Care:



CAUTION: Read carefully, improper cleaning will void the warranty. Never use alcohol-based cleaning agents.

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 and dry.

FOR STAINS: Dampen a soft white cloth in a one to one (1:1) solution of Fantastik® and water OR Formula 409® and water. Rub gently and rinse with a water dampened cloth.

FOR MORE DIFFICULT STAINS: Dampen a soft white cloth with a solution of household bleach (10% bleach / 90% water). Rub gently and rinse with a water dampened cloth to remove bleach concentration.

WHAT NOT TO USE: Using the wrong cleaning agents you will VOID YOUR WARRANTY and crack, dry out and destroy your vinyl. Do not use any cleaning agents that contain alcohol, harsh chemicals or abrasives.

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	1.	Verify power supply connections.		
	2.	Check that outlet is working and breaker is not tripped.		
	3.	If the problem persists, contact Pivotal Health Solutions.		
Elevation: Table will not	1.			
raise or lower.		in the horizontal direction.		
	2.	Check to see if cord running from foot control to control box is		
		connected properly.		
	3.	Look for damage to controls.		
	4.	4. Make sure outlet is working properly.		
	5.	If the problem persists, contact Pivotal Health Solutions.		
Motor runs Intermittently	a)	Verify system load does not exceed rating and remove weight		
and requires repeat switch		as needed.		
activation.	b)	Perform "System Reset Procedure"		
		System Reset Procedure		
		Remove motor cables from "M" slots on the controller		
		(M1, M2, etc.), keeping the switch (the "HS" slot) and		
		power cord plugged into the control box; for dual drive		
		systems, ensure that motor cables are removed for both		
		control boxes. After removing the M1 and M2 cables, a		
		reset will be triggered automatically.		
		The motor controller ports are labeled on the top side of the control box.		
		2. Re-install the M1 and M2 plugs in to their respect ports on		
		the control box		
		3. Press and hold the down button on the switch; at this		
		point, the system will slowly begin moving downwards.		
		Once the cylinders hit the bottom, they will automatically		
ı		creep forward a slight distance (to the systems "home"		
		position).		
		4. After the legs have stopped, remove finger from the down button.		

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:

A therapy table is considered a medical device by the Food and Drug Administration. Therefore, it is necessary that Pivotal Health Solutions, Inc. be notified if the table is sold, destroyed, or otherwise disposed of. Please notify in writing providing your name and the serial number of your table 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>	Part Number
Head Cushion	PT30331-xxx
Changing Table Cushion (Main Body - 30"x 52")	A4936-xxx
Side Rail Cushion	S3149-xxx
Foot Switch (Optional for EL models)	A4975
½-13 Fixed Lever Handle	S1123
Suspa Hydraulic System	A7191
Locking Side Rail Mount (Spring Loaded Knob)	S3190

^{*}xxx is a place holder for the color code. Contact Pivotal Health for the appropriate color code for your table.



Warranty:

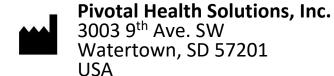
Warranty details can be found at: https://www.phsmedicalsolutions.com/customer-service/service-and-warranty

Note: Warranty periods listed apply only to products purchased in new condition. Any tables sold as a factory blemish or in used condition are sold 'as-is' and are limited to a (1) year warranty on the frame only, commencing on the date of delivery.

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.

Manufacturer Contact Information:

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