

Electric Epidural Positioning Device (E-EPD)

User Manual

Applies to the following Models:

MD

REF

EEPD100



Product Description

Intended Use: The EEPD is intended to assist in the support and positioning of a patient during epidural procedure and other spinal anesthetic procedures. This device is intended for use by trained professionals in a hospital or clinical setting. Patient weight not to exceed 600 lbs. (272 kg)



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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Safety Instructions

Before using, be sure that:

- You have read the instructions and understand all warnings, precautions, and safety labels.
- 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 using this device and treatment must be performed under the direction of a licensed clinician.
- All components have been inspected for damage, are fully functional, and properly lock.
- Battery is fully charged.

Warnings:

- Patient weight not to exceed 600 lbs. (272 kg)
- This device is NOT a standalone support, patient transport, or patient lifting device.
- This device is NOT intended for use with accessories other those specified in this manual.
- Never leave patient unattended. Have a hand on patient at all times while using this device.
- Patient must be seated on stationary bed, exam table or gurney while using this device.
- NEVER ALLOW PATIENT TO STAND ON FOOT REST. Foot rest is only intended to support the patient's legs while patient is seated on bed or gurney.
- Use only on dry surfaces. Ensure casters do not slide before proceeding with use.
- Allow only patients and authorized staff in treatment area. Powered components present a potential crush hazard for children. KEEP ALL CHILDREN AWAY FROM TREATMENT AREA.
- Contact Pivotal Health Solutions if service to device is needed (1-800-743-7738).



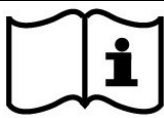
Never leave patient unattended during use.



Under no circumstances should the EEPD be modified. Contact Pivotal Health Solutions for more information.

Warnings and Precautions throughout this manual and on the device are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment.

Definitions of symbols are as follows:

	Caution: Text with a “CAUTION” indicator will explain possible safety infractions that have the potential to cause injury.
	Pinch Point: Indicates space between manually adjustable moving and stationary parts where body parts may become caught leading to injury.
	Crush Hazard: Indicates space between powered moving and stationary parts that represent a potential crush hazard.
 	WARNING: FOOTREST ONLY. DO NOT STAND: Indicates footrest is only intended to support the patient’s legs while they are seated on a bed or gurney. NEVER ALLOW PATIENT TO STAND ON FOOT REST.
 	Crush Hazard Warning: A specific crush warning sticker located between the adjustable top section of EEPD and LDS footrest. Proper clearance must be maintained between the patient’s knees and armrest to prevent this crush hazard.
	Indicates to refer to the user manual instructions.
	Indicates the product is a medical device.
	Indicates device manufacturer.



Crush Hazard Warning: Take Care with proximity of patient's knees to arm rest while making adjustments. MAINTAIN PROPER CLEARANCE. It is recommended, before beginning treatment, to educate the patient on the risk of knees touching the back of arm rest inadvertently and in turn putting pressure on legs.

Definitions and parts

#	Part Number	Part Description
1	EPD335	Arm Rest
2	EPD336	Head Cushion
3	EPD205	Locking Spring Plunger
4	EPD323	Chest Cushion
5	LDS1010	Caster Lock Pedal (Left)
6	LDS1009	Caster
7	LDS1011	Caster Lock Pedal (Right)
8	LDS1114	Control Box
9	LDS1134	Crush Hazard Decal
10	LDS1133	Crush Hazard Decal (for Hand Control)
11	LDS1127	Hand Control
12	LDS1115	Battery
13	LDS 1129	Battery Charger
14	LDS1016	Do not Stand Warning Decal (for Footrest)
15	89671	Crush Hazard Decal
16	89670	Pinch Point Decal
17	LDS1135	Lock/Unlock Stickers



Operating the Hand Control

The Hand Control is used for adjusting the height of the EPD Section and Foot Rest. Arrows on the hand control correspond to direction of travel when the hand control is held in an upright position, as shown in the picture below.

Motion stops whenever button is released.



When not in use always store hand control on designated hanger located next to arm rest toggle.



EPD Section* - Up/Down Control

*EPD Section includes the head, arm rest, and chest sections. (See Point of Reference Below)

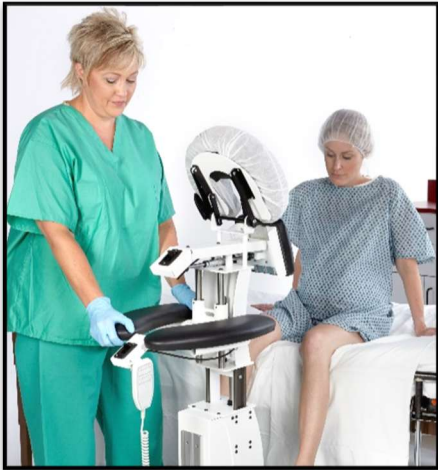
Foot Rest - Up/Down Control

Point of Reference:



Operation

- 1) Have patient sit squarely on bed or gurney and roll E-EPD in front of patient.



- 2) Lock casters by pushing downward on brake lever.



- 3) Using top set of UP/DOWN buttons on hand control adjust the EPD section to desired height.



PRECAUTIONS



DO NOT EXCEED LOAD RATING. Patient weight must not exceed 600 lbs. (272 kg).



CAUTION
FOOTREST ONLY.
DO NOT STAND.

NEVER ALLOW PATIENT TO STAND ON FOOT REST.

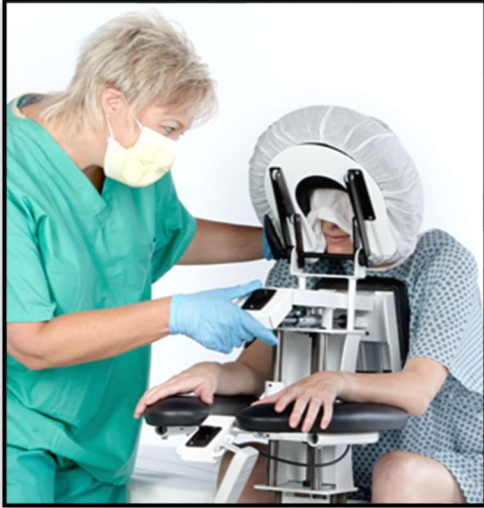


ENSURE CASTERS LOCK.



Crush Hazard Warning:
MAINTAIN PROPER CLEARANCE between **PATIENT'S KNEES AND ARM RESTS.**

- 4) Have patient lean slightly into EEPD with face resting on face rest and arms placed on arm rest.



- 5) Adjust face rest to desired position.



- 6) Adjust arm rest by pressing toggle switch and sliding into position. Release to lock.



PRECAUTIONS



USE FACE REST COVERS:

Always use Sani-Cover
Disposable Face Rest
Covers.

- 7) Using BOTTOM set of UP/DOWN buttons on hand control adjust the foot rest to desired height.



PRECAUTIONS

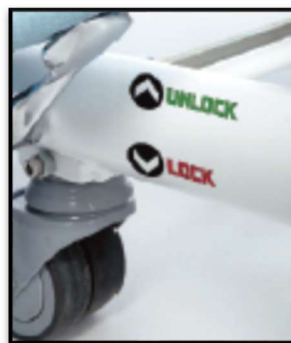
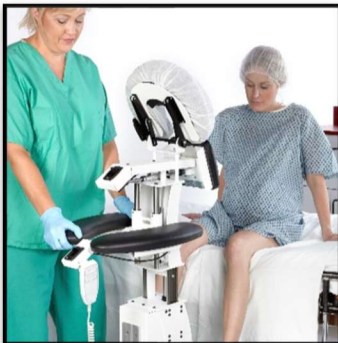


CRUSH WARNING:
MAINTAIN PROPER
CLEARANCE between
PATIENT'S KNEES AND ARM
RESTS.

- 8) Adjust chest support by pressing down toggle switch and sliding with gentle pressure.



- 9) After procedure have patient lean back into a normal sitting position.



- 10) Unlock casters by lifting up on brake lever and roll E-EPD out of the way.

Charging the Battery



Never charge batteries in a wet area.

Indications for Charging Battery: Battery alarm will sound when there is approximately 50% of battery charge left. In the event of low battery voltage, a signal from the control box will sound. The sound will occur only when a button on the hand control is depressed. When this happens, the battery must be charged as soon as possible even though there is still power remaining. An additional battery may be purchased from PHS Medical.

Charging and Maintenance: To get maximum battery life, it is important to charge the battery regularly. We recommend charging after use of the device. Batteries are fully charged after approximately 4 hours.

To Charge Battery: To charge the battery remove it from the EEPD device and mount it on the charger. The charger must be plugged into a grounded 100-240V/ 50-60 Hz electrical outlet. The green light indicates power is being supplied to the charger. The yellow light indicates the battery is charging. When the yellow light on the Charger is no longer illuminated, the battery is fully charged. Note: If the light has not turned off after 8 hours of charging, the battery may need to be replaced. Stop charging and replace the battery.

- Charger indicator:
 - Green LED: Charger is connected to mains
 - Yellow LED: Charging
 - Yellow LED is no longer illuminate: Battery Fully Charged

Technical Specifications

E-EPD Specifications

- | | |
|---------------------|--|
| • Weight | 110 lbs. |
| • Load Rating | Patient weight not to exceed 600 lbs. (272 kg) |
| • Arm Rest Range | 6" Range |
| • Arm Rest Size | 16.75" X 4.5" |
| • Chest Piece Range | 6" Range |
| • Chest Piece Size | 6.5" x 6.5" |
| • Shipping Weight | 170 lbs. |
| • Shipping Box | 36.5"x38.5"x50" |

Battery Charger (Part Number: LDS1129)

- Medically approved
- Charger affixed to bracket to allow wall-mounting
- Mains voltage: 100-240 V / 50 – 60 Hz, 400mA
- Out: 29.5 VDC max. 19W, Class II, IPX5, Type B
- Fuse T 1.25A 250V
- Tested to IEC 60601-1:2005
- The battery charger has been evaluated for *Means of Operator Protection* (MOOP) when connected to mains. Control units cannot be operated while the charger is connected to mains supply. The battery charger is evaluated for MOPP when not connected to mains, the battery voltage is then present in battery charger.

Battery Pack Information (Part Number: LDS1115)

- Type: Lead-Acid
- Approximate Charging Time: 4 hours
- Duty cycle: 10% or 2 min. continuous use then 18 min. not in use.
- Typical battery life: 50-100 cycles
- Ambient temperatures: + 5° to + 40°C
- Additional Battery Packs may be purchased

Control Box (PART NUMBER: LDS1114)

- Output voltage: 24 V DC
- Protection Class: IPX5
- Electronic overload protection (EOP)
- Acoustic battery alarm at approximately 50% battery
- Emergency Lowering: Push a narrow object into the hole marked on the control box (marked Emergency). Note: If the battery loses charge, this operation is not functional

LINAK Actuator System:

- complies with the EMC Directive: 2014/30/EU according to following standards: EN 61000-6-1:2007, EN 61000-6-2:2005, EN 61000-6-3:2007, EN 61000-6-4:2007
- complies with Low Voltage Directive 2014/35/EU according to the standard: EN 60601-1:2006+CORR.1+CORR.2
- complies with RoHS2 Directive 2011/65/EU according to the standard: EN 50581:2012

Additional information:

The Linak system does also comply with the standard: EN 60601-1-2: 2007, 3rd edition, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests EN 10535:2006, Hoists for the transfer of disabled persons - Requirements and test methods, clause 4.3.1.23. (However, the EEPD is not intended for and should never be used as a standalone support, patient transport, or patient lifting device – See Warnings on page 2).



E-EPD complies with Directive 2002/96/EEC on waste electrical and electronic equipment (WEEE). Old batteries are to be deposited at the nearest recycling facility in accordance with local regulations.

Inspection and Maintenance

For trouble-free use, certain details should be checked each day the EEPD is used:

- Inspect the EEPD to make sure that there is no external damage.
- Check moveable components (electrical and non-electrical) to ensure functionality.
- Check all casters to ensure they lock properly and wheel grip is in good condition.
- Charge the battery each day the EEPD is used and make sure the charger works.
-  **DO NOT** lubricate mechanical locks on chest and arm support. These components function using a friction locking spring. Lubrication will cause them to fail.

Upholstery Cleaning and Care

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

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.

Accessories

Part Number FRC 03-3110: Sani-Cover® Medical Grade, Latex-Free Disposable Face Rest Covers.

Sani-Covers® are designed to fit on arm rests in addition to face rest.

Box of 25: FRC 03-3110

Case of 8 Boxes: FRC 03-3110-CASE



Troubleshooting

Unit will not raise or lower	1. Verify battery is connected to unit 2. Verify hand control is plugged in 3. Look for damage to controls 4. <i>If problem persists, contact Pivotal Health Solutions.</i>
If you hear unusual noise	1. Contact Pivotal Health Solutions.

Service & Warranty

<http://www.phsmedicalsolutions.com/customer-service/warranty.aspx>

Additional information:

Expected Life: The 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 product changes without prior notice. Contact your Pivotal Health Solutions representative for advice and information about product upgrades.

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