10" Lateral Rotation Mattress Replacement System with On Demand Low Air Loss

USER MANUAL

Item # LS9500N

PreserveTech™
Stays Cleaner • Lasts Longer

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This manual should be used for the initial set up of the system and for future reference.

DOCUMENT SYMBOLS

OPERATING INSTRUCTIONS

Indicates correct operating or maintenance procedure in order to prevent damage to or destruction of the equipment.

Note

Indicates tips or information users should be aware of.

Caution

Indicates a potentially hazardous situation which, if not avoided, could result in property damage or minor injury or both.

Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Danger

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

IMPORTANT PRECAUTIONS

The Lateral Rotation System with on Demand Low Air Loss, is a Class 2 medical device that must be installed and operated in the manner for which it was intended. The user is responsible for reading and understanding the product user manual. Drive DeVilbiss Healthcare is not responsible for any injuries resulting from failure to comply with the instructions and precautions in this manual.

Danger

Do not use in the presence of flammable anesthetics. Do not use in the presence of smoking materials or open flames. Air flowing through the mattress will support combustion.

Danger

To reduce the risk of electrocution, adhere to the following instructions. Failure to do so could result in personal injury or equipment damage.

- Immediately after using the Lateral Rotation System, unplug this product from its power source.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquids.
- Do not open the control unit without referring to Drive DeVilbiss technical service department first.

IMPORTANT PRECAUTIONS

Warning

Do not strap the mattress to the bed frame at the head and foot ends. Secure mattress straps to the bed deck at the head and foot ends and to the bed frame at the center of the bed.

Warning

To reduce the risk of burns, electrocution, fire, or injury, adhere to the following instructions. Failure to do so could result in personal injury or equipment damage.

- This product should only be used for its intended purpose as described in this manual.
- Only use attachments and /or accessories that are recommended by the manufacturer.
- Do not use this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped, damaged, or immersed in water. Return to your provider for a warranty claim.
- Keep the cord away from heated surfaces, i.e. space heaters.
- Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of debris such as lint and hair.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors or operate where aerosol (spray) products are used.
- Connect this product to a properly grounded outlet only.
- Do not spill food or liquids onto the control unit. If a spillage does occur, turn off the unit, disconnect it from its power supply and allow at least 24 hours for drying.

Warning

Drive DeVilbiss Healthcare support surfaces are designed as mattress replacement systems. The risk of entrapment may occur when mattresses are placed on bed frames that do not properly fit and leave gaps between the mattress and head panel, foot panel and bed or side rails. This system is NOT to be used when such gaps are present.

User/Facility staff are responsible for ensuring that all mattresses properly fit the bed frames. Drive DeVilbiss is not responsible for the improper placement of its systems on ill-fitting bed frames. Health care professionals assigned to each patient should make the final determination whether side or assist rails are warranted after assessing patient risks based on the individual's needs and condition.

An optimal bed system assessment should be conducted on each patient by a qualified clinician or medical provider to ensure maximum safety. The assessment should be conducted in compliance with the state and federal guidelines related to the uses of restraints and bed system entrapment guidance including but not limited to the below:

1) US FDA Entrapment Guidelines. "A Guide to Bed Safety," https://www.fda.gov/medical-devices/hospital-beds/guide-bed-safety-bed-rails-hospitals-nursing-homes-and-home-health-care-facts

2) US FDA Hospital Bed System Dimensional and Assessment Guidance to Reduce Bed Entrapment, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment

INTRODUCTION

Pressure injuries are defined as *localized injuries of the skin and/or underlying tissue over a bony prominence as a result of pressure or pressure in combination with shear.*[1] Support surfaces or specialized mattress systems are used as part of an overall, multi-disciplinary, multi-dimensional care plan intended to prevent and treat pressure injuries.

The Lateral Rotation mattress replacement is a high quality, combination therapy active system that is specifically designed for the prevention and treatment of pressure injuries, while optimizing patient comfort.

Indications for Use

Note

Effective pressure redistribution therapy, wound management and device selection should be based on the patient's specific clinical condition and complete assessment of needs, recognizing that pressure prevention devices are only one component of a comprehensive pressure injury management program. Support surfaces are not substitutes for turning, repositioning or functional weight shifts by caregivers.

The Lateral Rotation system is intended for:

1) Pressure redistribution for individuals with but not limited to the following conditions:

- At risk for or present pressure injuries
- Pulmonary complications
- Neurological conditions
- Amputations
- Grafts
- Burns
- Dermatological conditions
- Flaps
- Rehabilitation needs
- Pain management as prescribed by a physician.

2) Shear & Friction Reduction:

Friction is defined as the resistance to motion in a parallel direction relative to the common boundary of two surfaces. For patients this can occur when their skin rubs against another surface.

Shear (or shear stress) is the force per unit area exerted parallel to the perpendicular plane of interest. Shear strain occurs when skin is distorted or deformed as a result of shear stress.

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[1] European Pressure Ulcer Advisory Panel and United States National Pressure Ulcer Advisory Panel. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guidelines. National Pressure Ulcer Advisory Panel; 2009.

INTRODUCTION

3) Spinal Cord Injury:

The Lateral Rotation system can be used for patient's with spinal cord injury once the acute injury has been stabilized and these patients have been assessed and cleared by the appropriate clinician.

These instructions and recommendations are in accordance with the 2019 Clinical Practice Guidelines of the National Pressure Injury Advisory Panel (NPIAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA).

Contraindications

Patient conditions for which the application of pressure redistribution therapy on a lateral rotation system is contraindicated are as follows:

1) Unstable spinal cord injuries

UNPACKING YOUR LATERAL ROTATION SYSTEM

1) Carefully remove all components from packaging.
2) Confirm that you have received the control unit intended.
3) Check all components for damages. Contact your medical provider if any components are damaged. DO NOT use damaged components.

PRODUCT FEATURES

The Lateral Rotation System is comprised of two components:

1) Therapy air cell Mattress, with 10” high side air bolsters

2) Therapy Control Unit

Control Unit: LS9500NP

Mattress

Warning

When using a therapy mattress system, always ensure that the patient is positioned properly within the confines of the bed. The patient’s head should be positioned in the center of the top section of the therapy mattress. Do not let any extremities protrude over the side or between the bed rails when the therapy mattress is being used.

- 20 individual split air cells provide customizable turn and rotation angles for patient comfort, pressure redistribution and micro-climate control.
- Preserve Tech™, mattress cover is manufactured with an anti-microbial* agent that helps to minimize the growth of stain and odor-causing bacteria, mold, mildew, fungus and algae on treated surfaces. Treated surfaces on this product include the mattress cover.
- 10” high side air bolsters provide fall prevention protection and facilitates safe patient transfers.
- Tubing quickly and easily disconnects with EZ lock/quick release design.
- Able to accommodate patients up to 500 lbs.

* EPA registration 92760-9 is Ultra-Fresh DW-30, which is registered to control the growth of fungi, bacteria and algae in “polyurethane foams, rubber, non-aqueous coatings, adhesives, PVC and grout mortar and mastics.” Antimicrobial properties are built in to protect the products. These products do not protect users or others against bacteria, viruses, germs or other disease organisms.

PRODUCT FEATURES

Note

Please be sure to read this manual in its entirety before attempting to set up and operate this system.

Control Unit

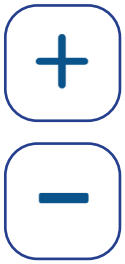
Power switch is located on the side of the control unit. Use the power switch to turn the system off and on.

Power Button (1)

- Press the Power button on the panel, the pump will start/stop operation.

Cycle Time (2)

- The cycle time can be selected from the panel to choose the appropriate cycle time of the inflation modes.
- The cycle time value options are: 10, 20, 30 or 60 minutes



Weight Settings (3)

- Weight settings can be used to adjust the pressure of the inflated cells based on the patient's weight and comfort level.
- For extra firm support during patient ingress and egress, patient wound care or cleaning, it is recommended to set the comfort level to max firm.

Mute Button(4)

- The audible/visible information signal turns on when low pressure or power failure occur.
- To mute the audible information signal, press the Mute button. The visible information signal indicator will continue flashing until the issue is resolved.
- Re-press the Mute button to reactivate the information signal.

Rotation Mode (5)

- Turning mode can be selected from the panel to choose the appropriate turn positon.
- Turning modes include combinations of ¼, ½, ¾, and adjustable turning positions up to 40 degrees with left, right, both or none (static) directions.

Static mode (6)

- Press the select turn button on the panel to none to set the system to static therapy mode. The system will remain in no rotation (or center position) at the constant desired patient comfort level.

PRODUCT FUNCTION

Auto Firm (7)

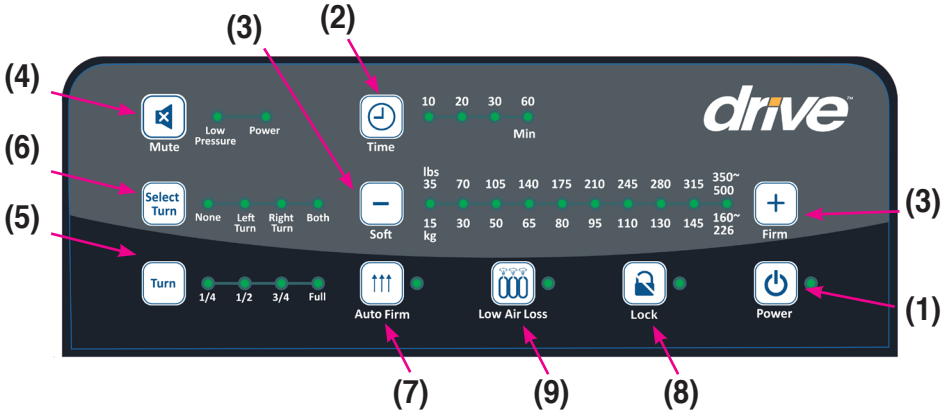
- Press to set the air mattress to quick inflation mode, which facilitates nursing and caring. The system will revert to the previously set therapy mode after 30 minutes.

Lock button (8)

- Auto: control unit panel automatically locks in 5 minutes without operation.
- Manual: press lock button for 3 seconds to lock the panel, press again for 3 seconds to unlock the panel.

Low Air Loss (9)

- Press to activate the on demand low air loss feature, which will turn on a separate compressor within the control unit and blows air through the periphery tubing of the mattress. Once engaged the on demand low air loss feature will remain on indefinitely. Press the button again to disengage low air loss. This is a standalone feature which helps control the micro-climate, keeping an individual cool and dry.



Mattress

- The Lateral Rotation mattress replacement comes with a hose connection at the foot end of the mattress with 20 individual split air cells, 10” high side air bolsters over a 2” foam base providing fall prevention and power outage protection.
- Combination therapy active system incorporates the functions of lateral rotation and low air loss to assist with pulmonary blood flow and mucosal drainage, as well as providing micro-climate control to keep the patient cool and dry.
- Removable quilted four way stretch polyurethane coated cover is manufactured with an anti-microbial* agent and is fluid resistant, low shear and vapor permeable helping protect the skin from friction and moisture.
- The cell material, Nylon/TPU blend, provides a specialty surface that conforms to the specific shape of the patient, minimizing soft tissue distortion, reducing bone penetration into muscle fascia, and promoting improved blow flow compared to traditional surfaces.

PRODUCT FUNCTION

CPR deflation valve

- Remove the quick connector on the right side of control unit to release the air immediately from the mattress for rapid deflation. Deflation time varies depending on patient weight and profile.

Quick Connector

- Used to connect the therapy mattress to the control unit.

*EPA registration 92760-9 is Ultra-Fresh DW-30, which is registered to control the growth of fungi, bacteria and algae in “polyurethane foams, rubber, non-aqueous coatings, adhesives, PVC and grout mortar and mastics.”

Warning

For important precautions, see pages three and four

Caution

Do not place the control unit on the floor. Position the power cord to prevent tripping hazards.

1) Remove all existing covers and sheets from mattress on bed.

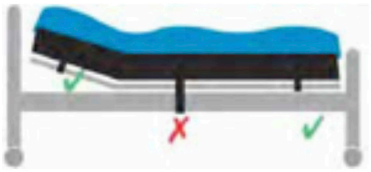
2) Unpack the Lateral Rotation mattress replacement system and inspect all components for damage. Do NOT use the system if any component is damaged.

3) Confirm there are no sharp objects in the immediate area which may risk damage to the Mattress.

4) Position the Lateral Rotation Mattress Replacement on top of bed, printed top cover facing upwards and air hoses towards the foot end of the bed.

5) Secure the therapy mattress to the movable parts of the bed frame or bed deck. Ensure buckles are securely fastened and straps are pulled tightly.

5)



DO NOT SECURE TO THE SIDE RAILS - STRAPS WILL TEAR OFF.

PRODUCT FUNCTION

a) Position the control unit by hanging hooks over foot board of the bed. *visual reference provided*

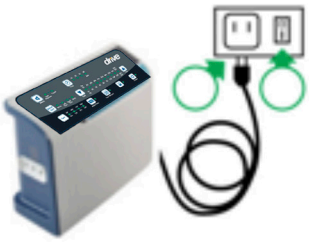
b) Attach the air hoses to the therapy mattress securely using the quick connector. When properly installed, the quick connector will audibly click into place. Ensure air hoses do not kink between mattress, bed frame and control unit. *visual reference provided*

c) Plug the power cord into an electrical outlet with grounded AC power. *visual reference provided*

a)

b)

c)



Note

Before inserting the plug into the outlet, make sure the voltage is compatible and the product is well grounded.

d) Switch the power switch on the side of the control unit on. The mattress replacement system may take up to 20 minutes for full inflation regardless of the control unit being used.

OPERATION

Note

Always read the operating instructions in this manual before use.

General

This product is designed to provide pressure redistribution while maximizing comfort to patients. Please be sure to operate this equipment as instructed to optimize its value. Please be sure to follow the instructions corresponding to the control unit being used.

Note

Please follow instructions below for detailed operating procedure of each type.

Operation using the (LS9500NP) Digital Control Unit

Step 1 Step 1 Turn on the power switch located on the side of the control unit. Next press the power button on the front of the control panel. A beep will sound to alert that the system is on.

Step 2 The control unit will automatically default to none (static) mode of therapy and begin inflating. It may take up to 20 minutes to reach full inflation. If full inflation is not reached within 20 minutes, the low pressure information signal will illuminate. Press the Mute button to mute the information signal. The information signal LED will continue flashing. Press the Mute button again to re-enable the audible information signal.

Step 3 Press the Auto Firm button to automatically inflate the mattress to the maximum level for about 30 minutes. The pressure will return to a previously set level after 30 minutes.

Step 4 Once fully inflated, the control unit will switch into none (static) therapy mode at the default setting of 10 minutes. Select desired settings from the touch panel to adjust the cycle time and pressure level to the patients' specific requirements.

Note

Press the Auto Firm mode button from the touch panel to provide a firm surface that makes it easier for the patient to transfer or reposition. The system will revert back to the previously selected therapy mode after 30 minutes.

PATIENT POSITIONING AND COMFORT

Note

During normal operation, the unit will monitor pressure. If the mattress pressure is lower than the set pressure, the pump will automatically inflate the mattress to readjust to the set level. The alarm will beep and its LED will come on to alert a low pressure condition. Press the Mute button to mute the information signal. The information signal LED will continue flashing. Press the Mute button again to re-enable the audible information signal.

Note

For suitable pressure, please refer to page 14 for the hand check procedure.

CPR function

When there is an emergency requirement to perform CPR on the patient, remove the quick connector at the right-hand side of the control unit to release the air quickly from the mattress.

Pressure range selection (+/-)

Users can adjust the pressure level of the air mattress, using the (+) and (-) buttons, to a desired firmness based on personal comfort or weight setting.

Note

It is recommended to press Auto Firm on the panel when the mattress is first inflated. Users can then easily adjust the air mattress to a desired firmness according to the patient's weight and comfort.

Low pressure indicator

When the air pressure in the system falls below the selected pressure range, a low pressure condition will signal the low pressure indicator. Check if the connections are secure and correctly installed according to the relevant instructions.

Note

If the pressure is consistently low, open the zipper and confirm that all the hoses are properly connected. Then check for any noticeable leakage in any of the tubes. If necessary, contact your local dealer to replace any damaged tubes or hoses.

General Repositioning

Patients should be turned or repositioned based on their individually planned treatment schedule or per facility policy. Support surfaces are not substitutes for turning/repositioning or functional weight shifts.

PATIENT POSITIONING AND COMFORT

Hand Check Procedure:

A suitable way to verify that the patient is not bottoming out is to perform a hand check as described below:

1) Ensure that the patient is lying supine (on his/her back) in the middle of the mattress.
2) Place a hand with four (4) fingers stacked vertically beneath the air cell directly underneath the sacral region.
3) Ensure that the 4 fingers can slide with minimal resistance between the patients' sacral region and the lower portion of the mattress.
4) Adjust the comfort setting as needs.
5) Wait for the mattress to adjust to the selected range.
6) Revaluate with the hand check and adjust to patients' comfort level.

Recommended Linen:

Drive DeVilbiss Healthcare bed support surfaces are designed to be used with appropriate linens. Deep pocketed fitted or flat sheets are recommended. Multiple layering of linens or underpads beneath the patient should be avoided, when possible, for the prevention and treatment of pressure injuries.

Incontinence

Moisture against the skin surface is an extrinsic risk factor for acquiring a pressure injury as it weakens the skin tissue leading to maceration. To protect skin integrity, incontinence barrier pads may be used to absorb excess moisture.

Warning

Specialty active and reactive support surfaces are designed to redistribute pressure and reduce shearing/ friction forces against the patients'skin. Patient migration is possible due to the nature of these products. Always ensure the patient is positioned properly within the confines of the bed and specialty system.

CLEANING & MAINTENANCE

Note

It is important to follow these procedures before using the system or between patient use.

Control Unit

Caution

DO NOT immerse or soak the control unit in any water or fluids.

DO NOT spray any cleaning solution directly on the surface of the control unit.

DO NOT use a Phenolic based cleaning solution as this may cause damage to the case.

1) UNPLUG the control unit from its power source prior to cleaning.
2) Check for external damage and move the control unit to the cleaning area.
3) Place the control unit on a work surface and wipe the outside of the case with a clean cloth to remove any dust or particles. Make sure all areas are clean (top and bottom, both sides).
4) Spray cloth with cleaning solution and clean faceplate and control unit casing. DO NOT allow excess cleaning solution on faceplate or control panel. (If solution gets inside, damage will occur.)
    a. quaternary ammonium solution may be used.
5) After the control unit is thoroughly cleaned and dried, proceed to plug in the control unit and test for normal functioning.
6) Unplug the control unit and store with proper identification tag until needed for use.
7) Avoid long exposure to sunlight.

Mattress

8) Remove any soiled or used bedding.
9) Examine the mattress for visible soilage of bodily fluids.
10) If no disinfection is required, brush off or wipe down all surfaces of the cover sheet with soap and water before wetting with any liquid disinfectant.
11) If disinfection is required, follow the procedure below:
    a. Use rubber gloves and eye protection.
    b. Unzip the top cover from the mattress.
    c. Prepare detergent/disinfectant solution (registered by the EPA recommended) according to the preparation recommended for correct use-dilution.
    d. 1:9 Bleach and water dilution may be used.
    e. With the mattress fully deflated, wipe down all surfaces around and in between the air cells, including the cells.

f. Covers may be immersed and soaked in disinfectant for the required incubation period. After pre-soaking, the cover may be rinsed through a regular cycle in a washer with no soap then laundered with mild detergent (wash temperature 93°F/34°C, rinse temperature 78°F/26°C or on the coldest setting).

g. Allow all covers and parts to aerate until they are fully dry.

12) Repeat the process with the tubing set: spray/wipe, incubate, and air dry.

13) Dry the mattress on a flat surface area after cleaning, away from exposure to the sun.

14) Avoid long exposure to sunlight.

HANDLING AND STORAGE

- Lay the mattress out flat and upside down.
- Roll from the foot end towards the head end; the foot-end strap can then be stretched around the rolled mattress to prevent unrolling.
- Do not fold, crease or stack the mattress.

MAINTENANCE

General

- Check the power cord and plug to see if there are abrasions or excessive wear.
- Check the mattress cover for signs of wear or damage. Ensure the mattress cover and tubes are connected correctly.
- Plug in the control unit and check the airflow from the hose connection port. The airflow should alternate between ports every half-cycle time.
- Check the air hoses to see if there are any kinks or breaks. For replacement, please contact your local agent or dealer.
- Make sure the mattress tube is well connected.
- Check the control unit and make sure both power indicators are off when the switch is turned off.

Low pressure

Examine if there is any air leakage between the control unit and the mattress connections or from the air mattress tubes:

1) Check connectors between the air mattress and control unit. If there is any disconnection, please reconnect it.

2) Check the air-connecting tubes. Ensure each single cell is properly functioning.

3) Set the pressure at Auto Firm. Keep the tubes fully inflated and inspect for air leakage.

4) Check if there is any air leakage from cells. Ensure no leakage occurs. If any leakage occurs, please contact your local agent or dealer.

TROUBLESHOOTING

Problems		Reasons	Maintenance
Mattress fails to inflate or does not inflate completely.	Pump issue	1. Pump does not work.	1. After powered on, check if visible LED light turns on. If not, please check the below issues: 1.1 Check if power cord is plugged into appropriate voltage AC outlet. 1.2 Contact your provider for possible warranty claim.
		2. Air pressure from pump is too low.	1. Contact your provider for possible warranty claim.
	Mattress issue	1. Quick connector on mattress does not connect well with pump. 2. Air tube connected to T/L connector and air valve is loose. 3. One way valve is broken. 4. Air cell is leaking.	1. Make sure quick connector on mattress is connected well with pump. 2. Make sure T/L connector and air valve is connected well. 3. Change air cell. 4. Contact your provider for possible warranty claim.
Pump is working but synchronous motor does not work; thus mattress does not, and failure alarm is activated.		1. Synchronous motor is out of order. 2. Wires inside synchronous motor not connect well. 3. Lower PCB is out of order.	1. Contact your provider for possible warranty claim.
Pump and motor keep working, but cycle time is incorrect. The alarm is activated.		1. Micro switch on the exchanger is out of order. 2. Lower PCB is out of order.	1. Contact your provider for possible warranty claim.
When powered on, compressor stop after working some time; but the exchanger keep rotary.		1. Pressure detector is out of order.	1. Contact your provider for possible warranty claim.
Mattress pressure is low but alarm is not activated.		1. Pressure detector is out of order.	1. Contact your provider for possible warranty claim.
Push button on panel is not operated well, and LED indicator does not light up.		1. Push button is not operated well. 2. LED is out of order.	1. Contact your provider for possible warranty claim.
Mattress pressure is too high or too low.		1. Pressure sensor is out of order.	1. Contact your provider for possible warranty claim.
Power failure alarm can't be activated after power failure.		1. Battery is out of order.	1. Contact your provider for possible warranty claim.

SPECIFICATION

Control Unit	Mattress
Item #: LS9500NP	Item: LS9525N
Power Supply: 120/60Hz	Size: 35.4” (W) x 80” (L) x 10” (H)
Air Output: 42~50 liter/min	Top cover: 43% Polyurethane + 57% Polyester
Pressure Range: 8-35mmHg (side rails remain 55mmHg)	Air cells: 69% Polyurethane + 31% Nylon
Cycle Time: 10/20/30/60 minutes	Base: 50% PVC + 50% Nylon
Case Material: Flame retardant ABS	Quantity & Height of Air Cells: 20 each, 8” air cells x 2” foam base with 10” side air bolsters
Information Signal: Low Pressure, Power Failure	CPR valve for emergency procedures
Size: 14.9" (L) x 6.7" (W) 10.5" (H)	Product Weight: 29 lbs.
Product Weight: 14 lbs.	Quick connectors
Fuse: 250V/1A*1	Maximum Weight Capacity: 500 lbs.
Weight: 14 lbs / 6.35 kg	
FUSE: 250V/2A*2	

The above specifications are also applicable to those areas operating with the same power supply range.

Note

The above specifications are also applicable to those areas operating with the same power supply range.

The Lateral Rotation System with on Demand Low Air Loss, has been tested and certified for the following standards:

- UL
- c-UL
- UL 60601-1 & 60601-1-11
- CAN/CSA C22.2 No. 601.2

CE

Y.Sung Handelvertretung
Duesselthaler St. 24, 40211
Duesseldorf, Deutschland,
Germany

WARRANTY

LS9500N: 24 months for control unit and mattress

Your Drive brand product is warranted to be free of defects in materials and workmanship for 24 months of the original consumer purchaser.

This device was built to exacting standards and carefully inspected prior to shipment. This 24 month Limited Warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear. The warranty does not extend to non-durable components, such as rubber accessories, casters, and grips, which are subject to normal wear and need periodic replacement.

If you have a question about your Drive device or this warranty, please contact an authorized Drive dealer.

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