

# Panacea® AIR EASE MATTRESS

# Owner's Manual

Please keep and refer to this Owner's Manual.

Thank you for purchasing a Direct Supply<sup>®</sup> Panacea<sup>®</sup> Air Ease Mattress. Please read this entire guide carefully and keep it for future reference. This guide will provide you with instructions, warnings, warranty information, and other important information about your air mattress. Share this information with those individuals who will be assembling, using, servicing, and/or cleaning the product to help ensure it is cared for properly.

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### Introduction

#### Introduction

The Panacea® Air Ease alternating pressure and limited low air loss mattress is designed to assist in the prevention and treatment of pressure injuries for Long Term Care residents. The resident support surface fits most standard healthcare beds and consists of 20 air cells that run laterally underneath the entire body. The air flotation system aids in pressure redistribution.

The Panacea® Air Ease mattress uses a control unit, which provides alternating pressure and limited low air loss therapy. The inflation levels are designed to maintain low interface pressures throughout the mattress, to redistribute peak interface pressures during the cycle, and to further relieve peak pressure points as the cycle alternates. The limited low air loss feature helps reduce maceration and further skin breakdown by keeping the skin surface cool and dry.

### **Definitions & Symbols**

NOTE: Indicates a tip.

**CAUTION:** Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

**WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

**PRODUCT or DEVICE:** Panacea® Air Ease Mattress

YOU and YOUR: The facility, community or other entity that has purchased the device.

WE, US and OUR: Direct Supply Manufacturing, Inc.

 $\Delta$ : Attention! Read the instructions.

# **Product Description & Specifications**

### **Product Description**

#### INDICATIONS FOR USE:

The Panacea Air Ease is a flotation therapy mattress which provides pressure management to assist in the prevention and treatment of pressure injuries. The alternating pressure and limited low air loss mode on the Panacea Air Ease mattress is indicated for use as a preventive tool against further complications associated with many critically ill residents or immobility.

#### CONTRAINDICATIONS FOR USE:

Use the Panacea Air Ease mattress with extreme caution for patients with spinal fractures.

#### **AIR CELLS**

Air cells provide A-B-A-B alternating pressure therapy. These air cells inflate to a height of 8". Cells in the torso region include micro- holes which allow the Panacea Air Ease mattress to provide limited low air loss.

#### A WARNING: FOR U.S. ONLY

Medical Equipment – Air Pump, with respect to electrical shock, fire, and mechanical hazards only in accordance with IEC 60601-1

**NOTE**: This equipment is not suitable for use in the presence of flammable anesthetic mixture with air, or with pure oxygen or nitrous oxide.

### **Product Specifications**

#### **PUMP/CONTROL UNIT**

Power Supply: 100 - 120 VAC, 60 Hz Fuse Rating: F1.0AL 250V Maximum Air Output:  $\geq$  8 L/min Pressure Range: 30 – 80 mmHg Alternating Cycle Time: 10 minutes Noise: ≤ 30 dB

#### **CONTROL UNIT FUNCTIONS**

Power On/Off Switch: Powers the mattress system on and off. Power on indicated with LED. Firmness Dial: Adjusts the pressure within the mattress. Alternating/Static Mode Switch: Allows the user to select Static or Alternating pressure functions. Normal Pressure: Green LED when active. Low Pressure: Indicates loss of air pressure. Orange LED when active, audio alarm annunciates. Alarm Mute: Silences the low pressure alarm audio.

#### MATTRESS

Dimensions: 35"W (900mm) x 79"L (2010mm) x 8"H (200mm) Top Cover: Nylon + Polyurethane Bottom Cover: Nylon + PVC Air Cells: Nylon/PVC 20 Air Cells, Cells #6-12 with Limited Low Air Loss Pillow Function: Cells #1-4 at head end are static and do not alternate CPR Valve for emergency procedures Weight Capacity: 450 lbs.

 $\Delta$  1. Resident's body cannot exceed the width of the mattress.

2. Check the weight capacity of the bed to make sure both the mattress and bed are capable of supporting additional weight.



### Warnings

Read and follow all directions and warnings before using this device.

#### **▲ WARNING**:

- 1. Failure to comply with all directions and warnings may result in injury or death; use only as directed.
- 2. This device is not suitable for all individuals. Other devices may be required.
- 3. Inspect the device for damage before each use, and do not use it if it appears to be damaged or not functioning properly.
- 4. Never alter the device in any way.
- 5. This device is designed for indoor use only within close proximity to skilled caregivers.
- 6. This device is not designed to operate with patients or residents weighing more than 350 lbs.

**NOTE:** Resident's body cannot exceed the width of the mattress at any weight capacity.

 $\triangle$  **NOTE**: This device is designed to help provide pressure redistribution\* and may require other equipment. This may include, but is not limited to:

- 1. Bedrails for repositioning and fall prevention.
- 2. Resident monitoring devices for elopement prevention.
- 3. Other devices as specified by the caregiver.

**WARNING**: To reduce the risk of electrocution:

- 1. Always unplug this unit immediately after using.
- 2. Do not operate near water.
- 3. Do not place or store device where it can fall or be pulled into a tub or sink.
- 4. Do not place in or drop into water or other liquid.
- 5. Do not reach for a device that has fallen into water. Unplug immediately.
- 6. Do not remove control unit cover. Risk of electrical shock.

**WARNING**: To reduce the risk of burns, fire or injury to persons:

- 1. Use this unit only for its intended use as described in the operating instructions.
- 2. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the unit for examination and repair.
- 3. Keep the cord away from heated surfaces.
- 4. Never drop or insert any object into any opening or hose.
- 5. Do not use outdoors.

**WARNING**: This device is only a tool to assist with pressure reduction as part of an overall care plan. Failure to comply with all instructions, warnings and precautions, or using the device for a purpose other than the recommended use, could result in bodily injury or death.

This device is not designed to replace good caregiving practices, including, but not limited to:

- Direct patient and resident supervision.
- Adequate care plans and training for staff personnel for entrapment and fall prevention.
- Inspection and testing before use.

\* This pressure redistribution support surface may be appropriate for use as part of an overall care plan to prevent and treat decubitus ulcers. Resident-specific assessment could alter your particular usage of this mattress.

### Directions for Use

▲: Attention! Read and follow all directions and warnings before using this device.

#### Installation

- 1. Open the outer packaging and check the product for any damage incurred during shipping. If the product has been damaged, **DO NOT USE** and immediately contact your distributor for further instruction. Keep carton and packing material for return shipment if it should become necessary.
- 2. Place the Panacea Air Ease mattress on the bed frame with the hoses exiting at the foot of the bed.
- 3. Secure the mattress to the bed deck using the black straps attached to the bottom of the mattress. Be sure to only attach the straps to the parts of the bed that articulate and not any stationary parts of the frame.
- 4. Hang the control unit on the end of the bed using the hangers, or place on a stable horizontal surface.



5. Ensure the air hoses are not kinked or tucked under the mattress. Connect the mattress to the control unit by pushing the connector into the ports on the side of the pump until you hear it "click" securely into place. The mattress operation will not be affected by the hose/ connector orientation.



6. Ensure the power switch on the control unit is in the OFF position, then plug in the power cord and switch to ON. The POWER ON light is now illuminated.

**NOTE:** After installation, ensure any excess cord or tubing is removed from possible foot traffic to avoid accidental tripping. All equipment should be positioned to allow unhindered resident access by physicians and caregivers.



#### **Control Unit Operations**



1. **FIRMNESS DIAL:** Turn the dial to adjust the pressure within the mattress, clockwise to increase pressure; counterclockwise to decrease pressure. The recommended pressure settings correspond to the user weight values around the dial. Pressure should be adjusted according to individual comfort preferences.

**NOTE:** Every time the mattress is initialized (inflated), it is recommended to set the dial to the maximum setting to hasten inflation. You can then adjust the air mattress to the desired firmness before use.

- 2. **STATIC MODE:** Press the right side of the Mode Switch to select static pressure mode.
- 3. **ALTERNATING PRESSURE MODE:** Press the left side of the Mode Switch to select alternating pressure mode.
- 4. **NORMAL PRESSURE:** The LED illuminates when the mattress is pressurized to the desired level of firmness.
- 5. **LOW PRESSURE:** An alarm that indicates loss of air pressure. The LED illuminates and audible tone annunciates when the alarm is active.
- 6. **ALARM MUTE:** Press the Mute key to silence the low-pressure audible alarm. Press the Mute key again to reactivate the audible alarm function. If no action is taken to correct the low pressure indicated, the audio will re-annunciate after 3 minutes.

### Directions for Use (cont.)

### Use Instructions

- 1. With power connected, turn the power switch to the ON position. Wait approximately 30 minutes for the mattress to fully inflate. It is recommended to set the mattress to Static Mode and firmness to the maximum setting to promote faster initial inflation.
  - a. The low-pressure indicator (orange LED) will illuminate while the mattress is pressurizing.
  - b. Is the set pressure value is not reached after 60 minutes, check for leaks in the external hose, internal tubing, and mattress air cells.
- 2. When the appropriate pressure is reached, the low-pressure indicator (orange LED) will turn off and the normal-pressure indicator (green LED) will illuminate. The mattress is now ready for use.
- 3. After preparing the mattress surface with appropriate linens (not included), place the resident on the mattress.

**LINEN NOTE:** Deep-pocketed sheets are recommended (not included). Multiple lavering of linens or under pads beneath the resident can negatively affect the mattress's pressure management capabilities and should be avoided unless recommended by a caregiver.

- 4. Adjust firmness as necessary for resident comfort, support, and immersion into the mattress for optimal pressure redistribution.
  - a. A common method for sizing an air mattress is to check to see if suitable pressure is selected by sliding one hand between the bottom mattress cover and the air base under the resident's buttocks. Users should be able to feel the space between their hand and the resident's buttocks with the acceptable range being 25 to 40mm (1" to 1½"). This hand check procedure is issued by AHCPR (Agency for Health Care Policy and Research).
  - b. Adjust the firmness by turning the dial: Counterclockwise for more immersion (if too much space during hand check, too firm) or clockwise for less immersion (not enough space during hand check. too soft)
- 5. An audio-visual alarm is sounded in the event of low pressure.
  - a. Audio alarm can be muted using alarm silence key. WARNING: Only mute the alarm if a caregiving or medical professional will be present with the resident while the alarm is silenced.

**CAUTION**: Be careful not to puncture the mattress with needles or sharp instruments. This may result in loss of integrity of the cover or internal air system.

**NOTE**: This product is only one element of care in the prevention and treatment of pressure injuries by medical professionals and skilled caregivers to assist in the treatment and prevention of decubitus ulcers for residents under their care. This product is not designed to and cannot replace good caregiving practices and treatment including, but not limited to:

- Appropriate nutrition and hydration, frequent positioning, routine skin assessment, wound treatment, infection control, and other generally accepted standards of care and prevention.
- Adequate training for and precautions by staff personnel for bed entrapment.
- Selection of an appropriate bed system to use with the product and proper maintenance and use of the product.
- Testing of the product before each use.



# Transportation & CPR

### Transportation

- 1. Disconnect the hose from the pump and quickly place the cap over the end of the hose to prevent air loss.
- 2. Check the fit of the cap for leaks.
- 3. Verify the red CPR valve at head-end of the mattress is closed and no air is escaping.
- 4. Remove pump from bed/footboard.

You may now transport the resident while in bed. A properly sealed mattress will continue to support a resident for approximately one hour without power. It is not possible to provide an exact time because it is dependent upon on the resident's weight. Reattach the pump as soon as possible to restore mattress performance.

Prior to transporting the pump unit, turn the Power switch to OFF and unplug the power supply.

**WARNING:** DO NOT attempt to use the mattress as a carrying device, as it is not designed to carry a resident's weight unsupported.

### CPR

The standards for life support by the American Heart Association recommend a hard, level surface for performing CPR, moving the person to the floor if possible. If unable to move the resident to another surface to perform CPR, place a crash board underneath the resident and follow appropriate CPR procedures.

To deflate the mattress for CPR function, disconnect the hoses from the control unit and remove the CPR plug from the hose located at the head end of the mattress. To remove the CPR plug, squeeze the red plug cover labeled "CPR" and pull gently. The control unit should be turned off and/or removed to prevent the mattress from re-inflating during CPR.

In case of emergency, use a scissors or knife to cut the hose and/or the air cushions in the mattress.

# Cleaning

#### Mattress

Only the outer cover requires cleaning and maintenance. Disassembly of the mattress for cleaning of internal components is not recommended.

The cleaning of the air mattress should be carried out in an aerated state (to prevent the detergent from penetrating into the inner cavity of the air mattress).

Wipe down the cover with a damp cloth presoaked with warm water (do not exceed 65°C) containing a mild detergent.

Use products in dilutions as specified on the manufacturer's label. DO NOT USE BLEACH. DO NOT USE HARSH SOLVENTS OR CLEANERS.

Avoid dust and proximity to dusty areas. All components should be air-dried thoroughly before use

**CAUTION:** Do not dry the mattress in direct sunlight. The mattress and cover should be aerated to fully dry.

The carrying bag (if available) should be turned inside out and completely wiped down using disinfectant solutions. Allow it to air-dry thoroughly, and then turn it back and wipe down the outside of the bag with disinfectant solutions.

### **Control Unit**

**WARNING** – Before attempting to clean the control unit, turn off the unit and disconnect the power cord from the power source.

**CAUTION:** Do not use phenolic-based products for cleaning.

**CAUTION:** Do not heat or steam in autoclave.

**CAUTION:** Do not immerse or soak the pump unit in liquids.

Wipe down the pump unit with a damp cloth presoaked with a mild detergent. Avoid contact with dust and proximity to dusty areas. Make sure any cleaning agents you use will not harm or corrode the plastic casing on the pump unit. Use products in dilutions as specified on the manufacturer's label.

Once the control unit is clean, wipe the unit, the power cord, and the cord plug down with a clean, dry cloth. Place the control unit to dry in a cool and dry area for an hour before operating the unit again. If the control unit is not used immediately, place the control unit in a plastic bag and store it in a storage area.

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# Periodic Inspection, Preventative Maintenance, Storage & Disposal

#### **Periodic Inspection & Preventative Maintenance**

Prior to each use, ensure the mattress is functioning correctly and is not damaged. If damage or malfunction is identified or suspected, do not use until the damage or malfunction is corrected.

It is important to periodically test the Panacea Air Ease mattress control unit to verify the proper functionality. Lack of regular maintenance can result in poor or reduced resident support.

- 1. The air filter for the control unit should be checked routinely for signs of dirt or contamination. The frequency for replacing depends on the environment's air quality.
- 2. The air filter is accessible on the back side of the control unit; covered by a plastic cover. Remove the plastic cover.
- 3. The cotton filter will darken in color due to the collection of dirt. To clean the filter, wash or soak in warm water and thoroughly dry. If soaking does not remove the dirt build-up, replace with a new filter.
- 4. Replace the plastic cover.
- 5. Dispose of any waste.

#### Storage

- 1. Always store the mattress flat on a clean, level surface.
- 2. Do not expose the mattress to sunlight for a long time to slow down the aging rate of the air mattress.
- 3. Avoid storage of other equipment on top of the support surface.
- 4. Store the pump in a dry and clean place with hooks at the bottom of the pump.

#### **Storage Conditions:**

Temperature: 40°F to 105°F (-40°C to 40°C) Humidity: within 85% RH Atmospheric Pressure: 7.3 to 15.4 psi (500 to 1060 hPa) No corrosive gas, well-ventilated room

### Disposal

When this device reaches the end of its useful life, it must be properly disposed of. It must not be disposed of as unsorted municipal waste. The device should be disposed of in accordance with the local laws regarding the disposal of waste electrical and electronic equipment.

It is everyone's responsibility to help maintain the environment and to reduce the effects of hazardous substances contained in electrical and electronic equipment on human health. Please do your part by making certain that this device is properly disposed of. The symbol shown indicates that this device must not be disposed of in unsorted municipal waste programs.



# Troubleshooting

#### Mattress will not inflate or every other cell is not inflating:

- Disconnect the control unit and make sure air is flowing from the open ports. This is done by disconnecting the control unit from the mattress and physically feeling the air blowing out from one port and then the other. It may take several minutes to switch from one port to the other depending on the control unit's cycle time. If the control unit is not blowing air out of the ports, call for service.
- Check to make sure the control unit is on.
- Check to make sure the control unit is properly connected to the mattress.
- Check to make sure the red CPR plug is closed.
- Open mattress and inspect the internal connections to make sure each individual air cell is properly connected and not leaking. If a defect is discovered, call for repair or replacement of defective component.
- Visually inspect each air cell to make sure there are no cuts, punctures, or tears in the material with the exception of the low air loss holes designated by the white circles on the air cells. If a defect is discovered, call for repair or replacement of defective component.
- Check to make sure there are no kinks or leaks in the internal and external hoses. If a defect is discovered, call for repair or replacement of defective component.

# Mattress is soft and will not increase pressure or Low Pressure Alarm is sounding:

- Check control unit to make sure it is on and functioning properly. If the control unit is not functioning, call for service.
- Inspect the air filter to make sure it is clean. The filter is located on the back of the control unit. The filter should be white in color and free of dust or other debris. If the filter is not clean, replace with a new filter.
- Visually inspect each air cell to make sure there are no cuts, punctures or tears in the material with the exception of the low air loss holes designated by the white circles on the air cells. If a defect is discovered call for repair or replacement of defective component.

**NOTE:** The pressure in the mattresses lowers when the weight of the resident is removed from the mattress. The alarm will sound until the pump re-establishes the pressure level. In this situation wait approximately 5 minutes and check it again.

### Control unit is not working:

- Check to make sure the control unit is plugged into a live electrical socket.
- Make sure the control unit is turned on.
- Check the external fuses to make sure the fuses are in good condition. **Make sure the control unit is unplugged from the power source when checking fuses.** Locate the fuses on the back side of the control unit under the air filter cover. Unscrew the fuse cap and inspect the fuse to see if the filament, small wire inside of the glass tube, is broken. If the filament is broken, install new fuse and reinsert the fuse cap. Be sure the replacement fuse is of the same voltage and amperage as the previous fuse.



# EMI (Electromagnetic Interference)

This product conforms to the electromagnetic compatibility requirement of IEC 60601-1-2:2014 standard. This product shall be used and operated in accordance with the instructions and Manufacturer's Statement below.

### Manufacturer's EMC Declaration

**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 device. Otherwise, degradation of the performance of this equipment could result.

**A WARNING:** Do not use this product next to or stacked with other devices.

The monitor is suitable for use in the specified electromagnetic environment. The customer and or user of the monitor should assure that it is used in an electromagnetic environment as described below:

1.1 Compliance Information for Emissions Test

EMISSIONS Test	Compliance
Radiated Emissions CLSPR 11	Group 1
Radiated Emissions CLSPR 11	Class B
Harmonic Distortion IEC 61000-3-2	Class A
Voltage Fluctuations and Flicker IEC 6100-3-3	Complies

### **Electromagnetic Immunity (IEC60601-1-2)**

IMMUNITY Test	Compliance Level		
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 KV contact ±15 KV air		
Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50 Hz		
Electrical Fast Transients IEC 61000-4-4	±2 KV for power supply lines		
Surges IEC 61000-4-5	Line to Line ±1KV		
Voltage Dips and Interruptions IEC 61000-4-11	Dips: 100% During 0.5 Periods, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% During 1 Periods, at 0° 30% During 25/30 Periods, at 0°		
	Interruptions: 100% During 250/300 Cycles		
Line to Line ±1KV Surges IEC 61000-4-5	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz		
Conducted Disturbances Induced by RF Fields IEC 61000-4-6	3V 0.15 MHz - 80 MHz 6 V in ISM Bands Between 0.15 MHz and 80 MHz 80% AM at 1 KHz		

1.2 Compliance Information for Immunity Test

# Enclosure Port Immunity From RF Wireless Communications Equipment (IEC 60601-1-2)

1.3 Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

Test Frequency (MHz)	Banda (MHz)	Service a)	Modulation b)	Maximum Power (W)	Distance (m)	IMMUNITY Test LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5 kHz Deviation 1 kHz Sine	2	0.3	28
710	704 - 787		Pulse			
745		LTE Band 13, 17	Modulation	0.2	0.3	9
780		,	217 Hz			
810	800 - 960	GSM 800/900				
870		TETRA 800, iDEN 820,	Pulse Modulation	2	0.3	28
930		CDMA 850, LTE Band 5	18 Hz			
1720	1700 - 1990	GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28



# Limited Warranty

We, Direct Supply Manufacturing, Inc. offer to you, as the original purchaser, a warranty for the Direct Supply<sup>®</sup> Panacea<sup>®</sup> Air Ease Mattress. Our warranty applies for the limited warranty period stated below. If any product or product part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a product or product part will be at our discretion.

Our warranty applies only if the product is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the product or damage caused by abuse, improper use, failure to maintain, use which exceeds the published product limitations or the combination of any product with another product. In addition, our warranty does not cover fading, colorfastness, stains, spills or exposure to chemicals, odors, heat or light. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts and ask you to perform a repair or adjustment or replace a defective part.

Our warranty gives you specific legal rights, and you may also have other rights, which vary from state to state. Please note that our limited warranty period begins when we ship the product to you. The limited warranty period and our obligations under the warranty end once you transfer the product to someone else or at the end of the applicable limited warranty period identified below, whichever is earlier.

Device	Warranty Period
Mattress & Cover	1 year
Pump / Electrical Components	2 years

Anticipated Usable Product Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the product as described in this guide, as the product may need to be replaced sooner than anticipated in particular situations.

DIRECT SUPPLY MANUFACTURING, INC. MAKES NO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; THESE AND ALL OTHER IMPLIED WARRANTIES ARE SPECIFICALLY DISCLAIMED. TO THE FULLEST EXTENT ALLOWED BY LAW, DIRECT SUPPLY MANUFACTURING, INC. WILL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR LOST PROFITS THAT MAY RESULT FROM THE PRODUCT OR YOUR USE OF OR INABILITY TO USE THE PRODUCT EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. OUR TOTAL LIABILITY TO YOU, IF ANY, IS LIMITED TO THE PRICE OF THE PRODUCT OR SERVICE GIVING RISE TO YOUR CLAIM. Some states do not allow an exclusion or limitation of incidental or consequential damages, or how long an implied warranty lasts, so the above limitations or exclusions may not apply to you. If implied warranties are not excluded, and to the extent allowed by law, we limit any and all implied warranties to the applicable warranty period identified above. Except for rights under any applicable state law, the remedies provided under this warranty are your sole and exclusive remedy for any breach of our warranty and state the entire limit of our responsibilities.

### **Customer Service**

If you have any questions about the Panacea<sup>®</sup> Air Ease Mattress you have purchased or would like to request warranty service, please contact your distributor.



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