



COMFY AIRE SERIES® TRUE AIR MATTRESS  
SYSTEM  
ALX-T SERIES  
OPERATION MANUAL

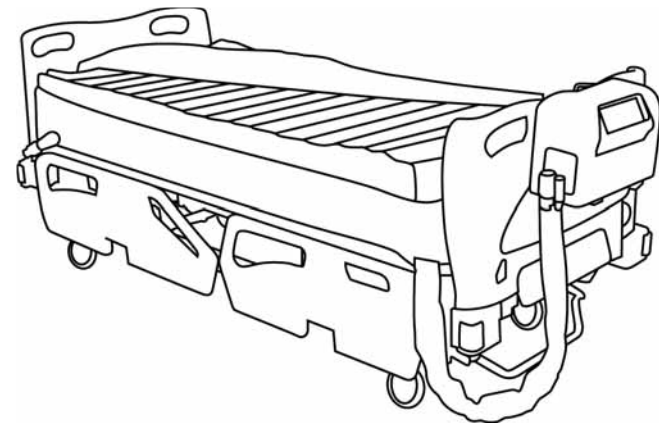


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**ATTENTION**

Before using this Medical Device read this manual. If you are unable to understand, contact your equipment provider for technical support before attempting to use this bed.

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## SECTION 1

# GENERAL GUIDELINES

### NOTE, CAUTION AND WARNING STATEMENTS:

**NOTES:** Indicates helpful tips

**CAUTION:** Indicates correct operating/maintenance procedures of the equipment or other property.

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

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

1. Patients are not allowed to operate the product. Always unplug this product immediately while it's not in use.
2. Do not disassemble the pump to avoid electrocution.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid. Do not use while bathing.
5. Do not reach for a product that has fallen into water. Unplug immediately.

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

1. The system must be operated with the mattress connected to the pump. Please do not Power-Off or unplug the pump while in use.
2. Always use the same voltage as stated on the label. Do not use other power cords on the pump. Avoid children and pets. Acquire the plastic packing to prevent suffocation hazards.
3. Equipment is not suitable to use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
4. Keep away from sharp objects.
5. Close supervision is necessary when this product is used by, on or near children or people with disabilities.
6. Use this product only for its intended use as described in this Instruction for Use. Do not use attachments not recommended by the manufacturer.
7. Never operate this product if the pump has a damaged power cord or plug, if the pump is not working properly, if the pump has been dropped or damaged, or if the pump has been dropped into water. Return the product to a service center or to the distributor for examination and repair.
8. Keep the power cord away from heated substances.
9. Never block the air openings of this product or place the product on a soft surface, such as a bed or couch, where the openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
10. Never drop or insert any object into any air opening or hose tube.

11. Avoid dropping or putting heavy objects on the pump.
12. Place the power cord and hose tube at the patient's foot area to avoid strangling of patient's neck.
13. The pump will have minor heat generated in operation, please do not directly contact the surface continuously for more than 1 minute.
14. When the mains supply is lost or has temporarily failed, the pump will stop and the power failure alarm will alarm up to 20 minutes. This is normal, and the product will return to normal operation once the mains supply is resumed.
15. Do not modify this equipment without authorization of the manufacturer.
16. The device incorporates electronic programmable systems. Do not attempt to access the systems without authorization.

**⚠ WARNING:** If the patient has a small body and the side rails are lifted, ensure the openings through the side rails or the openings between the side rails and the mattress do not pose a threat to the patient. Frequently check patient against entrapment.

**⚠ CAUTION:** Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## SYMBOLS



## DESCRIPTION

- POWER ON
- POWER OFF
- ATTENTION
- DOUBLE ISOLATION
- BF" SYMBOL: indicates this according to the degree of protection against electric shock for type bf equipment
- CAUTION: read instruction before use
- CAUTION: keep away from flammables
- IP21 WATER AND DUST PROTECTION CLASSIFICATION
- FUSE SPECIFICATION
- SERIAL NUMBER
- HUMIDITY LIMITATION
- TEMPERATURE LIMIT
- USE NO HAND HOOKS
- IMPORTER
- DISPOSAL OF ELECTRICAL & ELECTRONIC EQUIPMENT (WEEE):  
This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment.
- MEDICAL DEVICE
- CATALOGUE NUMBER
- BATCH CODE
- MANUFACTURER
- SGS CERTIFICATION LOGO  
With respect to electrical shock, fire and mechanical hazards only in accordance with IEC 60601-1

## SECTION 2

# INTRODUCTION

This manual provides information required for the initial set up and for the normal operation of the ALX-T Series Alternating Mattress System. Before operating the ALX-T Series Alternating Mattress Series, be sure the operator has read and understood in detail the content of this manual.

## INTENDED USE

The ALX-T Series is intended for prevention of pressure ulcers. The ALX-T Series may be used in a variety of settings including, but not limited to, individual home care setting and long-term care of whom suffering from pressure ulcer or pain management as prescribed by physician.

The mattress is not suitable for use on patients with unstable fractures.

**NOTE:** Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

## PRODUCT DESCRIPTION

The ALX-T Series Alternating Mattress System is an alternating pressure air mattress replacement system used for the prevention of pressure ulcers by using the established principles of alternating therapy.

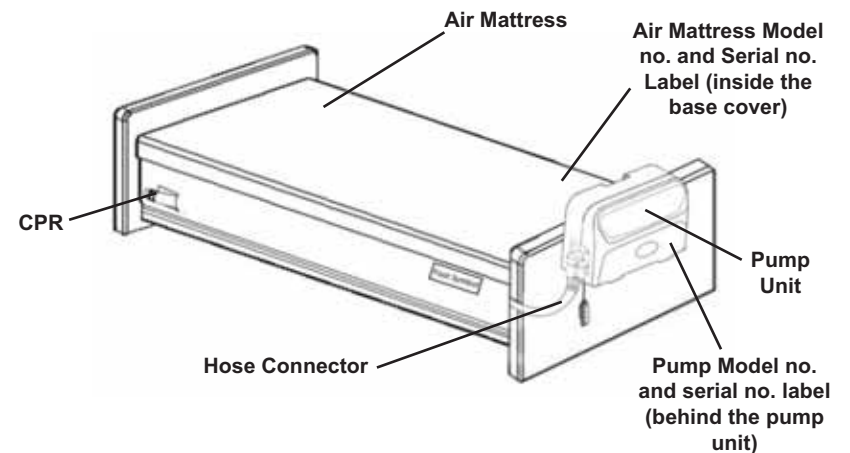
The control unit of the ALX-T Series Alternating Mattress system is a pump featuring a digital pressure adjustment function, mode selections, and audiovisual alarms. The 20 air cells mattress unit alternates with 3 static head cells which remain static and provide a “pillow” support for optimum comfort. The mattress has a heavy-duty nylon PVC base sheet with a vapor permeable PU coated nylon cover.

The system includes a rapid release twist CPR valve by the head section of the mattress for the event of cardiac arrest.

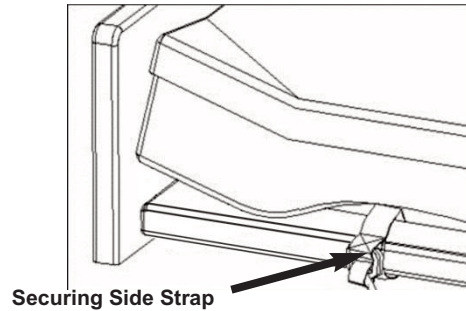
## SECTION 3

# INSTALLATION GUIDE

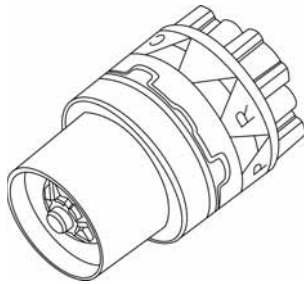
1. Unpack the box to inspect all items for any damage that may have occurred during shipping. If there is any damage, please contact your dealer immediately for assistance.
2. Place the mattress on top of the bed frame. The foot symbol on both sides of the mattress indicates location of the foot end.



3. Secure the mattress onto the bed frame by using the securing side straps.

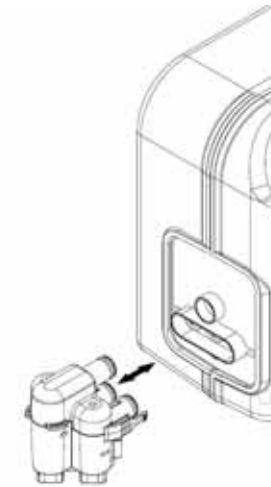
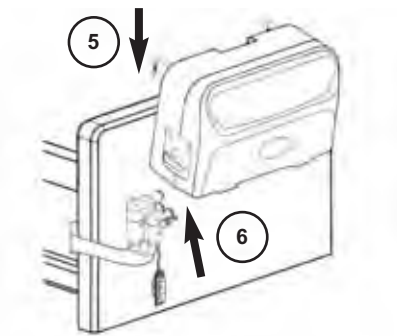


4. Ensure the CPR valve is at CLOSE position before turning on the power.



5. Position the pump by its elastic hanger brackets over the footboard of the bed. The elastic hanger brackets will self-adjust onto the footboard tightly.

6. Remove the Transport Cap of the hose connector and connect the hose connector to the pump unit. Firmly push the hose connector into position and a "click" sound will secure the connection.

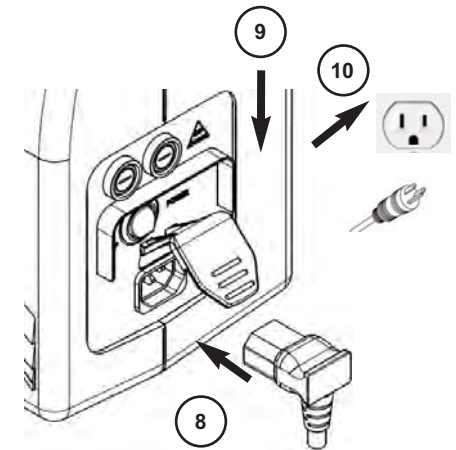


Follow the direction for Connection

7. Connect the power cord to the pump. The power switch should remain off.

8. Press the red power cord protector downward to secure the power cord.

9. Plug the power cord into the electrical outlet.

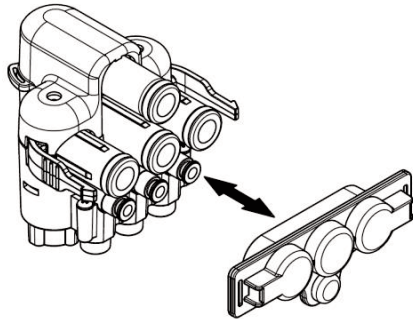


**NOTE:** Check and ensure the pump unit is suitable for the local power voltage.

**⚠CAUTION:** The pump can only be applied to the mattress recommended by the manufacturer. Do not use the pump for any other purpose.

**⚠WARNING:** Do not place the pump unit in an area where the power cord can come off easily or in an inaccessible area.

10. For the patient's transportation, press the "Auto-Firm" button and wait for 5 minutes for the mattress to be inflated. Disconnect the hose from the pump unit and put on the hose connector Transport Cap to keep the mattress inflated.



## SECTION 4 PANEL DISPLAY



- Alarm Mute
  - Low pressure Alarm Indicator
  - Power Failure Alarm Indicator
  - Service (Malfunction) Alarm Indicator
- Alternate/Pulsate Cycle Time Selection or Warning Code Display
- Operating or Standby
- Auto-Firm
- Mode Selection (Alternate, Pulsate, Static)
- Panel Lock-Out
- Comfort Control
- Bariatric

### **ALARM MUTE**

Press the Alarm Mute button to temporarily suspend alarms. Should the situation not be resolved and fault conditions continue, the alarm will resume notifying the patient and caregiver.

### **ALTERNATE/PULSATE CYCLE TIME SELECTION**

Alternate cycle time can be selected between 5, 10, 15, 20, 25, or 30 minutes by pressing the Cycle button. Pulsate cycle time can be selected between 1 and 20 minutes by pressing the cycle button.

## OPERATING OR STANDBY

Press this button to start operating or go into standby.

**NOTE:** The power switch on the side of the pump must be turned on. Powering on the unit will resume in the state before the last power-off.

## AUTO-FIRM

The pump will go into the inflation mode (LED lights flashing) every time the operate mode is triggered. This insures the mattress to be able to reach its maximum operating pressure. Once the max pressure level is reached, the pump will automatically switch into the previous selected mode and comfort level. User can also use this function as full mattress inflation during patient sit-up or ingress/egress for better support.

## MODE SELECTION

- **Alternate**—the air cells of the mattress are proportionally deflated to reduce the interface pressure. The alternating cycle will continue at the selected cycle time until another mode is selected.
- **Static**—the mattress maintains a constant lower pressure
- **Pulsate**—the mattress maintains in static mode and oscillates at the selected pressure at the selected cycle time. The pulsate cycle will continue until another mode is selected.

## PANEL LOCK-OUT

Press the Lock-Out button to lock the panel. Should the panel remain untouched for 30 seconds, the Lock-Out feature will lock the panel to prevent accident from changing setting without notice. To unlock, press the Lock-Out button for 3 seconds.

## COMFORT CONTROL


Comfort Control controls the air pressure output level. Press Firm button and the output pressure will increase and higher pressure output will support heavier weight patient, for decreasing air pressure, vice versa. Check to see if the suitable pressure is selected by sliding one hand between a deflated air cell and the patient's buttocks areas and there should be minimum contact. Always leave at least 1 inch space between a deflated air cell and patient's buttocks areas to prevent "bottoming-out". Refer to **Table 1 Weight and Comfort Level Reference** for weight and comfort level suggestion.





## BARIATRIC MODE

Bariatric Mode enhances the output of the pump for heavier patient support. Refer to **Table 1 Weight and Comfort Level Reference** for weight and comfort level recommendation.


## SECTION 5 OPERATION GUIDE


**NOTE:** The power switch  is located on the side of the pump.

Press  to turn on the unit. All LED indicators on the control panel will light up, accompanied with a beep for 2 seconds (check for indicator failure if any). The indicator of Standby on the control panel will light up. If the pump was previously shut off in operate mode, then the pump will enter operate mode directly.



To test the battery, press  to turn off the power, and the power failure alarm should be triggered. Refer to **Audiovisual Alarm** if the alarm was not triggered.



Press the Operate button  and the system will begin to inflate and the “Auto-Firm” indicator will be flashing.




The mattress should be full inflated within 5 minutes and automatically enter the previous operating mode, otherwise the low pressure alarm with warning code will  be triggered.



**NOTE:** Do not proceed to other settings before inflation is completed.

After initial inflation is completed, press the Auto-Firm button  for moving the patient onto the mattress. The mattress will turn into a steady condition after about 5 minutes. Move the patient onto the mattress and press Auto-Firm  again to cancel Auto-Firm mode and select the appropriate mode.

According to the weight of the patient, adjust the pressure setting to the most suitable level without “bottoming-out”. User can determine an appropriate pressure by adjusting the Comfort Level. Please consult with your physician for a proper setting.

**⚠WARNING:** The pump unit should always be operating to prevent pressure injury from occurring.


In operate mode, press operate/standby button  for the system to enter standby mode. The system should be in standby mode before shut down. Switch the power switch  to off, and the warning code  will appear on the display to shut off the system.

**NOTE:** For reminding purposes, power failure alarm will be triggered if the power is switched off in operating mode (**Audiovisual Alarm**). Press the power switch  to restart the system, or press Alarm Mute  to turn off the system.

## CPR

When CPR needs to be performed, quickly rotate the CPR valve to the “OPEN” position, and at the same time, disconnect the hose connector from the pump to speed up the air release.

## AUDIBLE AND VISIBLE ALARMS

**Power Failure** - When electrical shortage occurred or power cord is unplugged without turning off the pump or  is pressed (intentionally or unintentionally), the “Power Failure” indicator will light up along with the buzzer and will last 20 minutes.

**NOTE:** When the pump has not been used for more than 3 months or after the Power Failure Alarm has been buzzing for a long time, the pump may need 6 hours or more of charging time (in operate or standby mode) for the alarms to function properly.

**Low Pressure** - When an abnormal low pressure occurred in body section, the “Low Pressure” indicator will flash and beep. Should the situation not be resolved and fault conditions continue, the alarm will resume.

**Service (Malfunction)** - When fault conditions occur, the “Service” indicator will light up along with the buzzer.

**NOTE:** Refer to **Table 2 for Warning Code Reference** or **Troubleshooting** if error code appears on the display.

## ALARM MUTE

When alarms are triggered, both LED light and buzzer will turn on to warn the patient and caregiver. By pressing the button, it will temporarily mute the buzzer so the caregiver may check for possible causes. Should the situation not be resolved and fault conditions continue, the alarm will resume. Refer to **Troubleshooting**. During “Power Failure”, pressing “Alarm Mute” will cease all buzzers and indicators and will turn off the system. During “Low Pressure Alarm”, if the pressure resumes back to normal then the low pressure alarm will stop. When more than one alarm is triggered, the alarm will be performed according to priority level. Refer to **Table 2 Warning Code Reference** for priority level.

**Table 1 Weight and Comfort Level Reference**

ALX863T (48") / ALX874 (54") / ALX885T (60")

Body Shape: Standard											
Bariatric Indicator	Comfort Control Indicator	Patient Weight									
		66	88	110	132	165	220	275	352	(lb)	
		30	40	50	60	75	100	125	160	(kg)	
●	●●●●●●●●●●	■	■								
●	●●●●●●●●●●	■	■	■							
●	●●●●●●●●●●		■	■	■						
●	●●●●●●●●●●			■	■	■					
●	●●●●●●●●●●				■	■	■				
●	●●●●●●●●●●					■	■	■			
●	●●●●●●●●●●						■	■	■		
●	●●●●●●●●●●							■	■	■	

Body Shape: Bariatric											
Bariatric Indicator	Comfort Control Indicator	Patient Weight									
		120	162	220	298	403	546	739	1000	(lb)	
		54	73	100	135	183	248	335	454	(kg)	
●	●●●●●●●●●●	■	■								
●	●●●●●●●●●●	■	■	■							
●	●●●●●●●●●●		■	■	■						
●	●●●●●●●●●●			■	■	■					
●	●●●●●●●●●●				■	■	■				
●	●●●●●●●●●●					■	■	■			
●	●●●●●●●●●●						■	■	■		
●	●●●●●●●●●●							■	■	■	

**Table 2 Warning Code Reference**

PRIORITY HIGHER ↓ LOW	WARNING CODE	INDICATOR LED	AUDIBLE OUTPUT MODE	WARNING DESCRIPTION	REMARKS
0	N/A	N/A	ONCE	Key Tone from Functional Buttons	Key Tone
1	S d	Power Failure	ONCE	Shutdown	Shutdown
2	B B	ALL LED	ONCE	All Indicators On	Power-On
3	N/A	N/A	ONCE	No Display	State/Mode Switching
4	I E	Auto-Firm	ONCE	Inflation Ended	Mattress Inflation Completion
5	R E	Auto-Firm	ONCE	Auto-Firm Ended	Auto-Firm Completion
6	S E	Static	ONCE	Static Ended	Static Completion
7	N/A	Power Failure	REPEAT (Cycle 4 sec.)	No Display	Power Failure Alarm
8	I F	Low Pressure	REPEAT (Cycle 4 sec.)	Inflation Failure	Power-On Inflation Failure Alarm
9	R F	Low Pressure	REPEAT (Cycle 4 sec.)	Auto-Firm Failure	Auto-Firm Failure Alarm
10	L P	Low Pressure	REPEAT (Cycle 4 sec.)	Low Pressure	Low Pressure Overtime Alarm
11	H P	Service	REPEAT (Cycle 4.5 sec.)	High Pressure	High Pressure Overtime Alarm
12	H T	Service	REPEAT (Cycle 4.5 sec.)	High Temperature	High Ambient Temperature Alarm
13	U I	Service	REPEAT (Cycle 4.5 sec.)	Air Valve 1 Failure	Air Valve 1 Positioning Failure Alarm
14	L b	Service	REPEAT (Cycle 15 sec.)	Low Battery	Low Battery Alarm
15	S i	Service	REPEAT	Service Indicator	
16	C U	NONE	NONE	Calibration Uncompleted	Calibration Uncompleted
17	C C	NONE	NONE	Calibration Completed	Calibration Completed

## SECTION 6

# CLEANING

Wipe the pump unit with a damp cloth pre-soaked with a mild detergent, and keep the pump unit away from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastics case of the pump unit.

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

Clean the mattress cover by using single use wipes with a solution of neutral detergent and hand hot water. Rinse thoroughly with clean water and damp dry the mattress using single use wipes. When cleaning, always visually check the mattress for cuts, tears, cracks, pin holes or snags. Do NOT use a mattress with a damaged cover – If the inner core of the mattress is heavily soiled, you are advised to replace it.

## DISINFECTING THE COVER

If the cover is heavily soiled or has been exposed to bodily fluids such as blood, it will require a more thorough cleaning procedure.

Use single use wipes with a 0.1 % chlorine solution (1,000 ppm) and cold water to wipe the cover. Rinse thoroughly with clean water and damp dry the mattress using single use wipes. Ensure the cover is completely dried before refitting to the mattress.

Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of mattresses. Cover surfaces should be protected during use and rinsed and dried thoroughly after disinfectant.

## LAUNDERING

Mattress covers should be completely removed before laundering.

Mattress covers can be laundered as followed:

- Pre-wash 140°F for 15 minutes
- Main wash 140°F for 15 minutes
- This should be followed by a cold rinse and extraction.

## DRYING

Mattress should be hung from a line or bar and drip dried in a clean indoor environment. Covers must be completely dried before refitting to the mattress.

Mattress covers can be tumble dried on a low heat setting for 90 minutes. Drying temperature must not exceed 104 °F. Exceeding the temperature can cause significant damage to the mattress cover.

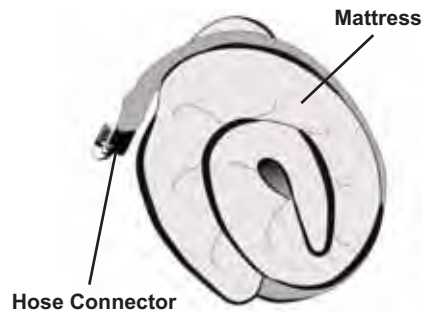
**CAUTION:** Do not use phenolic-based product for cleaning.

**CAUTION:** After cleaning, dry the mattress without direct exposure of sunlight.

## SECTION 6

# STORAGE

- Rotate the CPR valve to OPEN position and disconnect the hose connector to release the air.
- Lay the mattress flat and roll the mattress from the head end towards the foot end.
- Tight the packing strap around the rolled mattress to prevent unrolling.
- Ensure the hose connector is wrapped around the mattress to prevent kink on the hose connector.



The pump power cord can be coiled around the pump or disconnected for storage.

## SECTION 8

# MAINTENANCE

**⚠WARNING:** Maintenance shall only be performed when the device is not in use.

## GENERAL

- Check main power cord and plug if there are abrasions or excessive wears.
- Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are stubbed together correctly.
- Check the air hoses for any kink or break. For replacement, please contact your local dealers.

## FUSE REPLACEMENT

- Disconnect the plug from mains power when a blown fuse is suspected.
- Remove the cover of the fuse holder by means of a small screwdriver.
- Insert a new fuse of the correct rating in, and replace the cover of the fuse holder back. The fuse rating should comply with the requested specification.

## AIR FILTER REPLACEMENT

After checking *Troubleshooting*, if the air filter needs to be replaced:

- Replace the air filter located at the back of the pump.
- The filter is reusable and can be washed gently with a mild detergent and water. Dry the filter before use.
- Check and replace air filter regularly if environment is dirty.

## THE DISPOSAL OF THE AIR MATTRESS

When the air mattress is broken or no longer useable, the mattress and the pump may be discarded for recycle.

## SECTION 9

# TROUBLESHOOTING


PROBLEM	SOLUTION
The mattress is not able to connect with the pump	<ul style="list-style-type: none"> <li>• Check if the mattress model (model no. located inside the cover by the foot end) xxAAAxxx matches with the pump model xxBBB-xxx. The AAA should be the same as BBB. If not, please contact the agent or distributor.</li> <li>• Check if the Transport Cap is removed and make sure the connector is not broken.</li> </ul>
The pump is showing no indications of working.	<ul style="list-style-type: none"> <li>• Check if the plug is connected to the mains supply.</li> <li>• Check if the power switch is switched to ON position.</li> <li>• Check if there is any blown fuse.</li> </ul>
Power failure alarm failed	<ul style="list-style-type: none"> <li>• If the pump is in operation but failed to trigger the power failure alarm during power off, charge the pump for 6 hours or more of operating time. If there power failure still does not work, then please contact the dealer or agent for further investigation.</li> </ul>
The low pressure light is constantly flashing and the alarm is sounded	<ul style="list-style-type: none"> <li>• Check if the CPR is at CLOSE position</li> <li>• Check if the connection between air tubes to pump unit is tightly secured.</li> <li>• Check if all coupling connections along mattress are secured.</li> <li>• If the mains supply is normal but there is no sound of the pump, please remove the connector from the pump to check if air comes out. If not, please turn off the machine and contact the dealer or agent for further investigation.</li> <li>• If all of the above steps have been checked, press "Alarm Mute" for system to be verified again.</li> </ul>
The pump is on but the mattress is not alternated	<ul style="list-style-type: none"> <li>• Ensure the mattress inflation is completed.</li> <li>• Check the pump control panel the indicator of "Alternate" should be lighted on, if not, switch it to "Alternate."</li> <li>• Check if "Service" alarm indicator is on with buzzer, if yes, contact the dealer or agent for further investigation.</li> </ul>
Service (Malfunction) Alarm is on	<ul style="list-style-type: none"> <li>• Press "alarm mute" for system to be verified again. If the alarm is still on, please contact dealer or agent.</li> </ul>
The pump is operating noisily	<ul style="list-style-type: none"> <li>• Make sure the pump is resting against a solid surface.</li> <li>• If the noise is getting louder, contact the dealer or agent for further investigation.</li> </ul>
Patient is bottoming out (without alarm triggered)	<ul style="list-style-type: none"> <li>• Pressure setting might be inadequate for the patient, adjust comfort level to FIRM (refer to Table 1 Weight and Comfort Level Reference Table) and wait for a few minutes for better comfort.</li> <li>• Follow the procedures "The low pressure light is constantly flashing and the alarm is sounded" for inspection.</li> </ul>

If the above information does not solve the problem, please contact your local dealer or agent for further support.

## SECTION 10

# TECHNICAL DATA

## PRODUCT SPECIFICATION

PUMP UNIT	
MODEL	VD221
DIMENSION (in)	16(W) x 7(D) x 11(H)
WEIGHT (lbs)	14.3
ALTERNATE CYCLE TIME (minutes)	5/10/15/20/25/30
PULSATE CYCLE TIME (minutes)	1 to 20
AUTO-FIRM TIME (minutes)	20
PUMP OUTPUT FLOWRATE (LPM)	> 1000 (120V) Note: The flow rate may be varied due to the fluctuation of input voltage.
PUMP OUTPUT PRESSURE RANGE (mmHg)	20 to 46 (± 5)
INPUT VOLTAGE	AC 120 V/60 Hz
INPUT CURRENT	4.8 A <sub>MAX</sub> (@132V~)
FUSE RATING	T5AL 250 VAC
FREQUENCY	60 Hz (120V)
DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK	Class II  Type BF 
WARRANTY	1 year

## PRODUCT SPECIFICATION

AIR MATTRESS	
MODEL	ALX863T ALX874T ALX885T
DIMENSION (in)	79(L) x 48(W) x 10(H) 79(L) x 54(W) x 10(H) 79(L) x 60(W) x 10(H)
WEIGHT (lbs)	25 27 29
AIR CELL MATERIAL	Nylon-TPU
NO. OF AIR CELLS	20 CELLS
COVER MATERIAL	Nylon-PU with Quilt
BOTTOM MATERIAL	Nylon-PVC
STANDARD MAX. WEIGHT (lbs)	350
BARIATRIC MAX. WEIGHT (lbs)	1000

ENVIRONMENTAL CONDITIONS	
Operating Conditions	41 °F to 95 °F at a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure $\geq$ 50 hPa; and an atmospheric pressure range of 700 hPa to 1060 hPa.
Transport & Storage Conditions	-13 °F to 158 °F; 10 % to 90 % RH
Altitudes	$\leq$ 3000 m
Degree of Protection Against Ingress	IP21

## EMC INFORMATION

**⚠WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**⚠WARNING:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Description	Cable Length
Power Cable (non-shielding)	5 M

**⚠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 this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


Manufacturer's Declaration-Electromagnetic Emissions		
The <u>device(s)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the <u>device(s)</u> should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The <u>device(s)</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>device(s)</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

## MANUFACTURER'S DECLARATION-ELECTROMAGNETIC IMMUNITY

The <u>device(s)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the <u>device(s)</u> should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ±1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, +1kV line(s) to line(s) ± 0.5kV, +1kV,+ 2kV line(s) to earth	± 0.5kV, +1kV line(s) to line(s) ± 0.5kV, +1kV,+ 2kV line(s) to earth	Mains power quality should be that of a typical home and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles  Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 30 cycles  Voltage interruptions: 0 % UT; 300 cycle	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the <u>device(s)</u> requires continued operation during power mains interruptions, it is recommended that the <u>device(s)</u> be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m  50 Hz or 60 Hz	30 A/m  60 Hz	The <u>device(s)</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.

**NOTE:** UT is the a.c. mains voltage prior to application of the test level.

## MANUFACTURER'S DECLARATION-ELECTROMAGNETIC IMMUNITY

The <u>device(s)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the <u>device(s)</u> should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz  6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms: 0,15 MHz – 80 MHz  6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	<p><b>Portable and mobile RF communications equipment should be used no closer to any part of the <u>device(s)</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</b></p> <p><b>Recommended separation distance:</b>  <math>d = 1,2 \sqrt{P}</math>  <math>d = 1,2 \sqrt{P}</math> 80MHz to 800 MHz  <math>d = 2,3 \sqrt{P}</math> 800MHz to 2,7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1	

**NOTE:** At 80 MHz and 800 Mhz, the higher frequency range applies.  
**NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICES.

<p>The <u>device(s)</u> is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the <u>device(s)</u> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <u>device(s)</u>, as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz  d =1,2√P	80 MHz to 800 MHz  d =1,2√P	800 MHz to 2,7 GHz  d =2,3√P
0, 01	0, 12	0, 12	0, 23
0, 1	0, 38	0, 38	0, 73
1	1, 2	1, 2	2, 3
10	3, 8	3, 8	7, 3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><b>NOTE:</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p><b>NOTE:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

## MANUFACTURER'S DECLARATION-ELECTROMAGNETIC IMMUNITY

<p><b>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.</b> The <u>device(s)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the <u>device(s)</u> should assure that it is used in such an environment.</p>							
Test Frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home and professional healthcare)
385	380 - 390	TETRA 400	Pulse Modulation b) 18 Hz	1, 8	0, 3	27	27
450	430 - 470	GMRS 460 FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0, 3	28	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation b) 217 Hz	0, 2	0, 3	9	9
745							
780							
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5,	Pulse Modulation b) 18 Hz	2	0, 3	28	28
870							
930							
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation b) 217 Hz	2	0, 3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse Modulation b) 217 Hz	2	0, 3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation b) 217 Hz	0, 2	0, 3	9	9
5500							
5785							
<p><b>NOTE:</b> If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</p>							
<p>a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>							



