

Topaz 8

Alternating + Micro Low Air Loss Pressure Relief System

User Manual

Manufactured by: Air Kinetic Technologies Corp.

Distributed by: Quart Healthcare Inc.

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IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE OPERATING THIS DEVICE



NOTE, CAUTION AND WARNING STATEMENTS:

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 – Indicates a potential danger that requires correct procedures or practices in order to prevent personal injury.



WARNING – To reduce the risk of electrocution

1. Always unplug this product immediately when 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 burns, electrocution, fire or injury to persons

1. The operation of the system requires the mattress is connected to the PUMP, please do not power-off or unplug the PUMP while in operation.
2. This product should never be left unattended when in operation.
3. Close supervision is necessary when this product is used by, on, or near children or physically disabled individuals.
4. Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
5. Never operate this product if it has a damaged cord or power plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center or to the distributor for examination and repair.
6. Keep the cord away from heated surfaces.
7. Never block the air openings of this product or place it on a soft surface, such as a bed or a couch, where the openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
8. Never drop or insert an object into any opening or hose.
9. Connect this product to a properly grounded outlet only. See Grounding Instruction.
10. Place the PUMP and connect the hose tube at the bed's foot-end.
11. To avoid electromagnetic interference, the patient environment should not have

a strong electro-magnetic or RF generated equipment nearby.

12. The PUMP will have minor heat generated in operation, please do not use direct contact with the surface continuously for more than 1 minute.
13. The EMC specification is compliant with regulation requirements (please Refer to the EMC information at the last page). For power cords with ground pin (3 pin type), the connection with properly grounded power outlet would get a better EMC suppressing effect. The system will work correctly also for the power cord connection with the power outlet without grounding.
14. A temporary power loss or failure to the main supply (In 20 minutes) can cause the pump to stop and display power failure indication and alarm. The product can return to work after supply main power is stable.

SYMBOLS	DESCRIPTION
I	POWER ON
O	POWER OFF
	ATTENTION
	DOUBLE ISOLATION
	“BF” SYMBOL, INDICATE THIS PRODUCT IS ACCORDING TO THE DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK FOR TYPE BF EQUIPMENT
	CAUTION, READ THE INSTRUCTION BEFORE USE
	AWAY FROM THE FLAME
IP21	WATER AND DUST PROTECTION CLASSIFICATION
	FUSE SPECIFICATION
	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.
	UL CERTIFICATION LOGO (COMPLIANCE WITH IEC60601-1) With respect to electrical shock, fire and mechanical hazards only in accordance with STANDARD.
CB	CB CERTIFICATION LOGO
CE	CE CERTIFICATION LOGO

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1 INTRODUCTION

This manual should be used for initial set up of the Quart Healthcare Topaz 8 Low Air Loss **Mattress System** and for daily maintenance. **Please keep the manual available for reference.**

2 INTENDED USE

This product is intended to reduce the incidences of pressure wounds while optimizing patient comfort.

- Individuals in home care setting and/or long-term care who suffer from skin breakdown and pressure wounds.
- Pain management.

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

3 PRODUCT DESCRIPTION

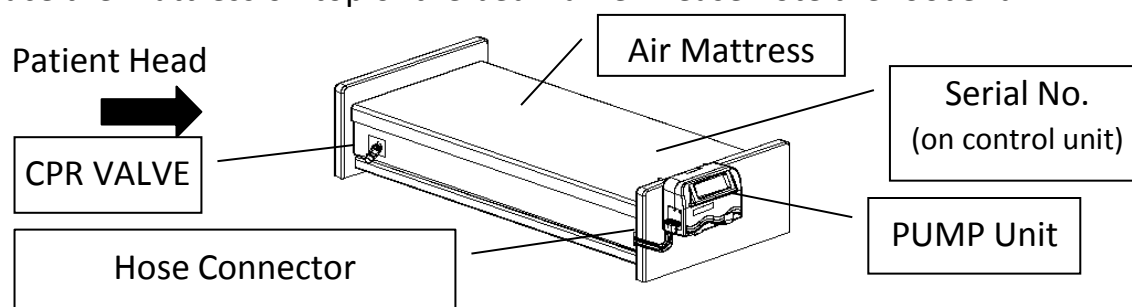
The Quart Healthcare Topaz 8 Low Air Loss **Mattress System** is a mattress replacement system used in the prevention and treatment of pressure ulcers. By using the established principles of alternating therapy, the Quart Healthcare Topaz 8 Low Air Loss **Mattress System** offer patients a comfortable and relaxing support surface which will aid in the prevention of skin breakdown and enhance healing.

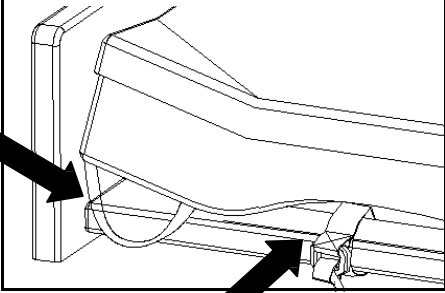
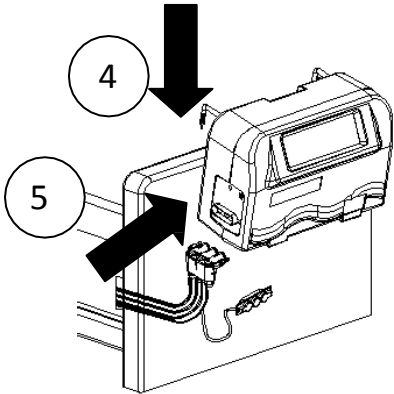
The CONTROL UNIT of the Quart Healthcare Topaz 8 Low Air Loss **Mattress System** is a compact pump featuring an audible and visual low pressure, power failure and machine malfunction alarms, and a digital pressure adjustment function. The 19 cell mattress unit provides a unique design which keeps the lower layer of air cells constantly inflated while alternating and deflating the upper layer. The head section of cells remains static. The mattress has a heavy-duty nylon base sheet with a vapor permeable PU coated stretch cover.

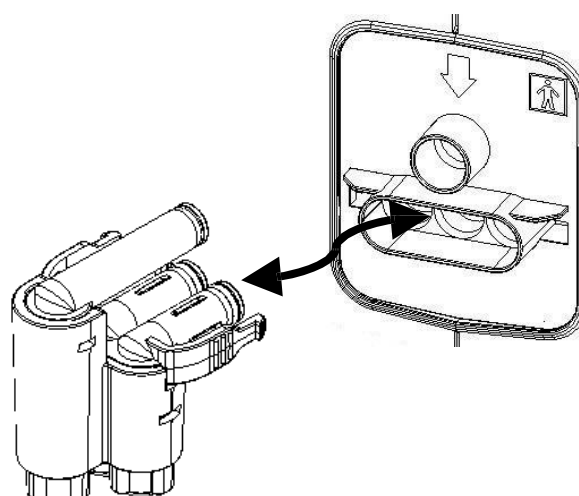
In the event of cardiac arrest, rapid deflation is achieved by opening the highly visible CPR valve and disconnecting the air hose assembly from the CONTROL UNIT.

4 PRODUCT INSTALLATION GUIDE

1. Unpack the box to inspect for any damage, which may have occurred during shipping. If there are any damages, please contact your dealer immediately.
2. Place the mattress on top of the bed frame. Please note the foot end.



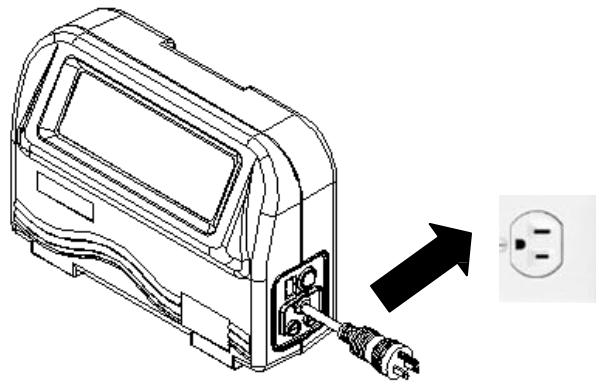
<p>3. Fix the mattress onto the bed frame</p>	 <p>Elastic belt, or</p> <p>Ribbon</p>
<p>4. Hang the Control Unit/Pump on the Foot-End of the bed.</p> <p>5. Unplug the cover of the hose connector and connect the hose connector to the pump unit.</p>	



6. Plug the power cord into the electrical outlet

⚠ NOTE: Make sure 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 it for any other purpose (applied part: air mattress)

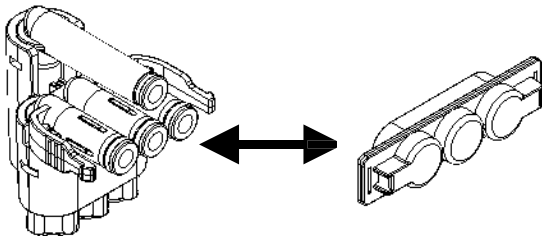


7. Make sure the CPR valve is CLOSED before turning on the power. Switch the CPR to OPEN position to release the air for emergencies or storage

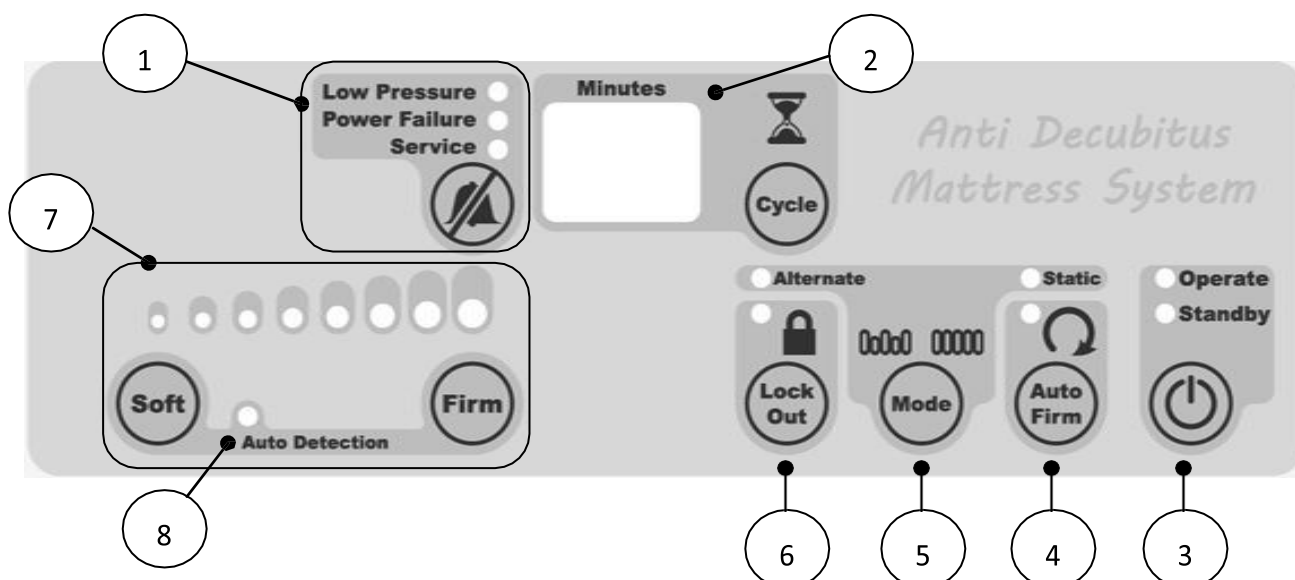
CPR Position Indicator



8. By putting on the hose connector cover for transportation the mattress will retain pressure for up to 24hrs



5 PANEL DISPLAY AND THE OPERATION GUIDE



5.1 PANEL DISPLAY

- ① Alarm Mute and Alarm Indicator
 - Low Pressure Alarm Indicator
 - Power Failure Alarm Indicator
 - Service (Malfunction) Alarm Indicator
- ② Alternate Cycle Time or Warning code Display
- ③ Operating or Standby
- ④ Auto-Firm
- ⑤ Function Mode Selection (Alternate & Static)
- ⑥ Panel Lock-out
- ⑦ Comfort Control
- ⑧ Auto Detection



5.1.1 ALARM MUTE

Press alarm mute button to temporarily suspend the Low-Pressure/Power Failure/Static Overtime /Service alarms. Should the situation not resolve and the fault conditions continue, the alarm shall resume notifying the patient/caregiver.



5.1.2 Alternate Cycle Time Display

Alternating Cycle Time can be selected from 10~30mins at 5min intervals by pressing the CYCLE button



5.1.3 Operate or Standby

Press this button to start operating or go into standby.

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



5.1.4 Inflate/Auto-Firm

The PUMP will go into the Inflate 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.



5.1.5 Function Mode Switch

- ALTERNATE - for the mattress to operate at alternating mode the air cell of the mattress will be proportionally deflated to reduce the surface pressure. The alternating cycle will continue at the selected cycle time until another mode is selected.
- STATIC - This mode allows the mattress to maintain at the selected pressure. After 20 minutes, the STATIC OVER TIME alarm will be triggered for 10mins at every 15 seconds interval. Without further action, the PUMP will go into ALTERNATE mode automatically.



5.1.6 Panel Lock-Out

Should the panel remain untouched for 30 seconds or press the Lock-out button, the lock-out feature will lock the screen to prevent changing the setting without notice. To unlock, press the Lock-out button for 3seconds.



5.1.7 Comfort Level

Comfort level controls the air pressure output. When pressing the FIRM button,

the output pressure will increase and higher pressure output will support heavier weight, for decreasing air pressure, vice versa. Check to see if the suitable pressure is selected by sliding one hand between the air cells and the patient to feel patient's buttocks. Users should be able to feel the minimum contact. Always leave at least 1 inch space between user's buttock areas and air cells under to prevent bottoming out.



5.1.8 Auto Detection


When pressing the SOFT and FIRM button together, the pump will automatically detect the weight of the patient and set the appropriate pressure output for patient comfort.


5.2 OPERATION GUIDE

5.2.1 GENERAL OPERATION :




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









- Press  to turn on the unit, all indicators on the control panel will light up accompanied with a beep for 2 seconds (You can also check the indicator for failure if any), and the indicator of STANDBY on the control panel will light up (In case the pump was turned off at OPERATE, it will go to OPERATE directly).

Ps: To test if the battery is working properly, press  to turn off the power. Power failure alarm should be triggered. If not, please call customer service.



- Push on the OPERATE button , the system will start inflation and the "AUTO-FIRM" indicator will flash.
- The mattress should be fully inflated within 20 minutes, and automatically return to the last operating mode, otherwise the low pressure alarm will be triggered.
- 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.

Weight and Comfort Level Reference Table


Topaz 8 Control Unit									
Comfort Control (Auto-Detection)	Pump output Pressure(mmHg)	Patient Weight (KG)							
		20	40	60	80	100	120	140	160 180
	20	< 40							
	25	20~60							
	30	40~80							
	35	60~100							
	40	80~120							
	45	100~140							
	50	120~160							
	55	140~180							

5.2.2 CPR

When CPR is required, quickly rotate the CPR valve to “OPEN” position, at the same time, disconnect the hose connector from the PUMP to speed up the air release.

5.2.3 AUDIBLE AND VISIBLE ALARM

- (1) Power Failure – When electrical shortage occurred or power cord is unplugged without turning off the pump, the “POWER FAILURE” indicator will light up along with buzzer. Check to ensure power cord is connected properly

 **NOTE:** When the PUMP has not been used for more than 3 months, it might need 6-hours operating time or more for the Alarm to function properly.















- (2) Low Pressure –When an abnormal low pressure occurred in body section for 4 minutes, the "Low Pressure" indicator will flash and beep every 4 seconds.



The Low Pressure alarm will continue until alarm mute button is pressed. Should the situation not be resolved and fault condition continues, the alarm will resume.

- (3) Static Overtime – When Static mode lasts for more than 20 minutes, "Static" indicator will flash and beep every 15 seconds. Press the MODE key to change to alternating mode will disable the alarm, or press the MUTE button to pause the alarm for 20 minutes. If not dealt with, the system will automatically enter into alternating mode after 10 minutes.

- (4) Power Failure Overtime – When the power is lost for more than 20 mins, the “Power Failure” indicator will flash along with a beep at every 15 seconds, Press the MUTE button to cease the alarm, and then proceed with safety checks.
- (5) Service (Malfunction)–When fault conditions occur, the "SERVICE" indicator will light up along with buzzer. Refer to Table 2 for Warning code and call your service provider.

Table 2 Warning Code Reference Table

PRIORITY HIGH ↓ LOW	WARNINGCODE	INDICATOR LED	AUDIBLE OUTPUT MODE	CONDITION OF OUTPUT	WARNING DESCRIPTION	REMARKS
0	N/A	N/A	ONCE	Not in System Shutdown	Key Tone	Key Tone from Functional Button
1		Power Failure	ONCE	POWER-OFF	System Shutdown	
2		ALL LED	ONCE	OPERATE OR STANDBY	Power-On	All Indicators Light On
3	N/A	N/A	ONCE	OPERATE OR STANDBY	State/Mode Switching	
4		AutoFirm	ONCE	OPERATE	Mattress Inflation Completion	Inflation Ended
5		AutoFirm	ONCE	OPERATE	Auto-Firm Completion	Auto-Firm Ended
6		Static	ONCE	OPERATE	Static Completion	Static Ended
7	N/A	Power Failure	REPEAT (cycle4sec.)	POWER-OFF	Power Failure Alarm	No Display
8		Low Pressure	REPEAT (cycle4sec.)	OPERATE OR STANDBY	Power-On Inflation Failure Alarm	
9		Low Pressure	REPEAT (cycle4sec.)	OPERATE OR STANDBY	Auto-Firm Failure Alarm	
10		Low Pressure	REPEAT (cycle4sec.)	OPERATE OR STANDBY	Low Pressure Overtime Alarm	
11		Service	REPEAT (cycle4.5sec.)	OPERATE OR STANDBY	Constant Pressure Control Failure Alarm	
12		Service	REPEAT (cycle4.5sec.)	OPERATE OR STANDBY	High Pressure Overtime Alarm	
14		Service	REPEAT (cycle4.5sec.)	OPERATE OR STANDBY	High Ambient Temperature Alarm	Environment Temperature Over Specification Limit
15		Service	REPEAT (cycle4.5sec.)	OPERATE OR STANDBY	Air Valve 1 Positioning Failure Alarm	Air Valve 1 failure
16		Service	REPEAT (cycle4.5sec.)	OPERATE OR STANDBY	Air Valve 2 Positioning Failure Alarm	Air Valve 2 failure
18		Service	REPEAT (cycle15sec.)	OPERATE OR STANDBY	Battery Low Alarm	Battery would need to be replaced

20		NONE	NONE	FACTORY CALIBRATION MODE	Calibration Not Completed	
21		NONE	NONE	FACTORY CALIBRATION MODE	Calibration Completed	

5.2.4 ALARM MUTE

When alarms are triggered, both the LED light and buzzer will sound to warn the patient/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 the fault conditions continue the alarm will resume. When in Power Failure situation, pressing alarm mute will cease the buzzer and turn off the “Power Failure” indicator.

6 CLEANING

Wipe the PUMP UNIT with a damp cloth pre-soaked with a mild detergent and hot water, and keep it away from dust. If other detergents are 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 pump unit.

By using a single use wipe, clean the MATTRESS COVER with a solution of neutral detergent and hot water. Rinse thoroughly with clean water and a damp single use wipe.

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.

Wipe the cover using a single use wipe and a 0.1% Chlorine Solution (1,000ppm) and cold water. If required a 1% Chlorine Solution (10,000ppm) and cold water can be used. Rinse thoroughly with clean water and a damp single use wipe. Make sure 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. Surfaces must be protected during use and rinsed and thoroughly dried after application of a disinfectant.

Laundering

Before laundering mattress covers should be completely removed. Where required mattress covers can be laundered as follows:

Pre wash 60°C + 15 minutes

Main wash 60°C + 15 minutes

This should be followed by a cold rinse and extraction.

Drying

Mattress covers 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 using perma press setting only. **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 to sunlight.*

7 STORAGE

- To quickly deflate the mattress for storage, rotate the CPR valve to OPEN position and disconnect the hose connector to release the air.
- Roll from the head end towards the foot-end
- Foot-end strap can then be stretched around the rolled mattress to prevent unrolling
- The power cord could be wrapped with attached velcro strap.

8 MAINTENANCE

8.1 8.1 General

- Check main power cord and plug for any excessive wear.
- Check mattress cover for signs of wear or damage.
- Check the air hoses for any kink or break. For replacement, please contact your service provider.

8.2 8.2 FUSE REPLACEMENT

- Disconnect the plug from main 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, and replace the cover of the fuse holder.
The fuse rating should comply with the requested specification.

8.3 8.3 AIR FILTER REPLACEMENT

- 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 the air filter monthly and replace as needed.

9 DISPOSAL OF AIR MATTRESS

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

10 TROUBLESHOOTING

PROBLEM	SOLUTION
The mattress is not able to connect with the PUMP	<ul style="list-style-type: none"> ● Check if the mattress is compatible with the pump. If not, please contact with the service provider ● Check if the connector cover is removed and make sure the connector is not broken
The pump is showing no indication it is working	<ul style="list-style-type: none"> ● Check if the plug is connected to power outlet ● Check if the main power switch is at ON position ● Check if there is a blown fuse
Power Failure Alarm Failure	<ul style="list-style-type: none"> ● The pump is in operation but the power failure alarm is not working at power down, please call service provider
The low pressure light is constantly flashing and the alarm is sounded	<ul style="list-style-type: none"> ● Check if the CPR is at CLOSE position ● Check if the power was suddenly shut down ● Check if the connection between air tube to pump unit is tightly secured ● Check if all coupling connections along mattress are secured
Power Failure Alarm Failed	<ul style="list-style-type: none"> ● If the PUMP is in operation but failed to trigger the Power Failure Alarm at Power Off, please contact service provider for further investigation
The pump is on but the mattress is not alternating	<ul style="list-style-type: none"> ● Make sure the mattress inflation is completed ● Check the pump control panel to determine if "ALTERNATE" is lit, if not, switch it to "ALTERNATE" ● Check if "Service" alarm indicator is on with buzzer, if yes, contact your service provider for further investigation
The pump is operating noisily	<ul style="list-style-type: none"> ● Make sure the pump is resting against a solid surface ● If the noise is getting louder, contact your service provider for further investigation
Patient is bottoming out (without alarm triggered)	Pressure setting might be inadequate for the patient, adjust comfort level to FIRM and wait for a few minutes for better comfort

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

11 TECHNICAL DATA

WARNING

- Connect the Master Control unit to a proper power source
- Do not use the system in the presence of any flammable gases (such as Anesthetic Agents)
- Keep the pump and mattress away from sources of liquid and open flames
- Keep mattress away from sharp objects
- The device is not AP/APG protected
- Keep mattress system away from heating devices
- No modification of this equipment is allowed



CAUTION

- Consult a clinical professional before using the mattress
- Support surfaces should always be used in conjunction with a care plan that includes the turning/repositioning of the patient over a 24 hour period
- The control unit should only be repaired by an authorized vendor/distributor
- Do not drop the control unit and avoid direct sunlight or extreme cold conditions
- Operation Temp: 5°C ~ 35°C, Relative Humidity: 30% ~75 %
- During operations, cellular devices with output power over 2W shall be kept at least 3.3 meters away

Contraindications

- The system should not be applied to patients suffering from polytrauma with fractures of spine, pelvis, extremities and skull. Patients with neurological impairments and missing body perception should require a physician's prescription. Alternating pressure should not be applied to patients that are experiencing pain or pain sensitive patients. In these cases we recommend the application of static mode or other suitable foam overlays or other materials which can be found in the Quart Healthcare product range
- People who may be allergic to any materials/substances used for the mattress and cells should not be positioned on the mattress.


Maintenance / inspection

- Maintenance at regular intervals (mandatory each year) is necessary to preserve the function of the control unit. Maintenance at regular intervals may only be performed by qualified and authorized personnel. Filters must be exchanged within this period.
- Maintenance and/or inspection should be performed by an authorized dealer or a distributor at client's expense.

Warranty

- Quart Healthcare guarantees that this equipment is free from defects in materials and workmanship. Our obligation under this warranty is limited to the repair of the Topaz 8 Control unit when returned to the place of purchase within 24 months of delivery date. This warranty also applies to the Topaz 8 Mattress when returned to the place of purchase within 12 months of delivery date.
- We agree to service/adjust any equipment returned, and to replace or repair any part that is proven to be a warranty defect, at no charge
- This warranty excludes equipment damage through shipping, tampering, improper maintenance, carelessness, accident, negligence or misuse, or products that have been altered, repaired or dismantled other than with the manufacture's written authorization and by its approved procedures and by properly qualified technicians
- In no event shall Quart Healthcare be liable for any direct, indirect or consequential damages or losses resulting from the use of equipment

11.1 PRODUCT SPECIFICATION

PUMP UNIT		AIR MATTRESS	
MODEL	Topaz 8	MODEL	8" Mattress Series
DIMENSION(cm)	33 (W) x 22 (D) x12 (H)	DIMENSION(cm)	89 (W) x 200 (L) x 21 (H)
WEIGHT(kg)	3.5kg	WEIGHT(kg)	10Kg
CYCLE TIME	10/15/20/25/30minutes	CELL MATERIAL	Nylon TPU or TPU film
STATIC TIME	30 minutes		
AUTO FIRM TIME	20 minutes		
PUMP OUTPUT FLOW RANGE (Liter)	> 8L (@120V or 230V) Note: The flow rate may be varied because of the fluctuation of input voltage		
PUMP OUTPUT PRESSURE RANGE (mmHg)	25 to 60 (± 2)	NO. OF AIR CELL	19 CELLS
POWER	AC120V 60Hz or AC230 V 50Hz	COVER MATERIAL	2-Way Stretched Polyester with PU coated
CURRENT	0.25 A _{MAX} (@132V~) or 0.12A _{MAX} (@253V~)	BOTTOM MATERIAL	Nylon-TPU
FUSE RATING	T1AL 250VAC	MAX WEIGHT	160kg = 350lb
FREQUENCY	60Hz (120V) or 50 Hz (230V)	MAX PRESSURE	103.5 mmHg
CLASSIFICATION	Class II		
	Type BF 		
WARRANTY	2 years	WARRANTY	1 year
SHELFLIFE	2 years	SHELFLIFE	1 year
ENVIRONMENTAL CONDITIONS			

OPERATION ENVIRONMENT	5°C ~40°C 15%RH ~ 93%RH(no condensation)
STORAGE ENVIRONMENT	-25°C~70°C ≤93%RH(no condensation)
ENVIRONMENT PRESSURE	70 kPa-101.3kPa
ENVIRONMENTHORIZONTAL LEVEL	≤3000m
WATER AND DUST PROTECTION CLASSIFICAION	IP21

11.2 EMC INFORMATION

Guidance and manufacturer's declaration-electromagnetic emissions		
<p>The <u>GD311-301</u> is intended for use in the electromagnetic environment specified below.</p> <p>The customer or the user of the <u>GD311-301</u> should assure that it is used in such an environment.</p>		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	<p>The <u>GD311-301</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.</p> <p>The <u>GD311-301</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.</p>
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	


Guidance and manufacturer's declaration-electromagnetic immunity

The [GD311-301](#) is intended for use in the electromagnetic environment specified below.

The customer or the user of the [GD311-301](#) should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GD311-301 requires continued operation during power mains interruptions, it is recommended that the GD311-301 be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The GD311-301 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration-electromagnetic immunity			
The GD311-301 is intended for use in the electromagnetic environment specified below.			
The customer or the user of the GD311-301 should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the GD311-301 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800\text{MHz to } 2,5 \text{ GHz}$ <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>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GD311-301 is used exceeds the applicable RF compliance level above, the GD311-301 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GD311-301.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distance between
portable and mobile RF communications equipment and the GD311-301**

The GD311-301 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GD311-301 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GD311-301 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.