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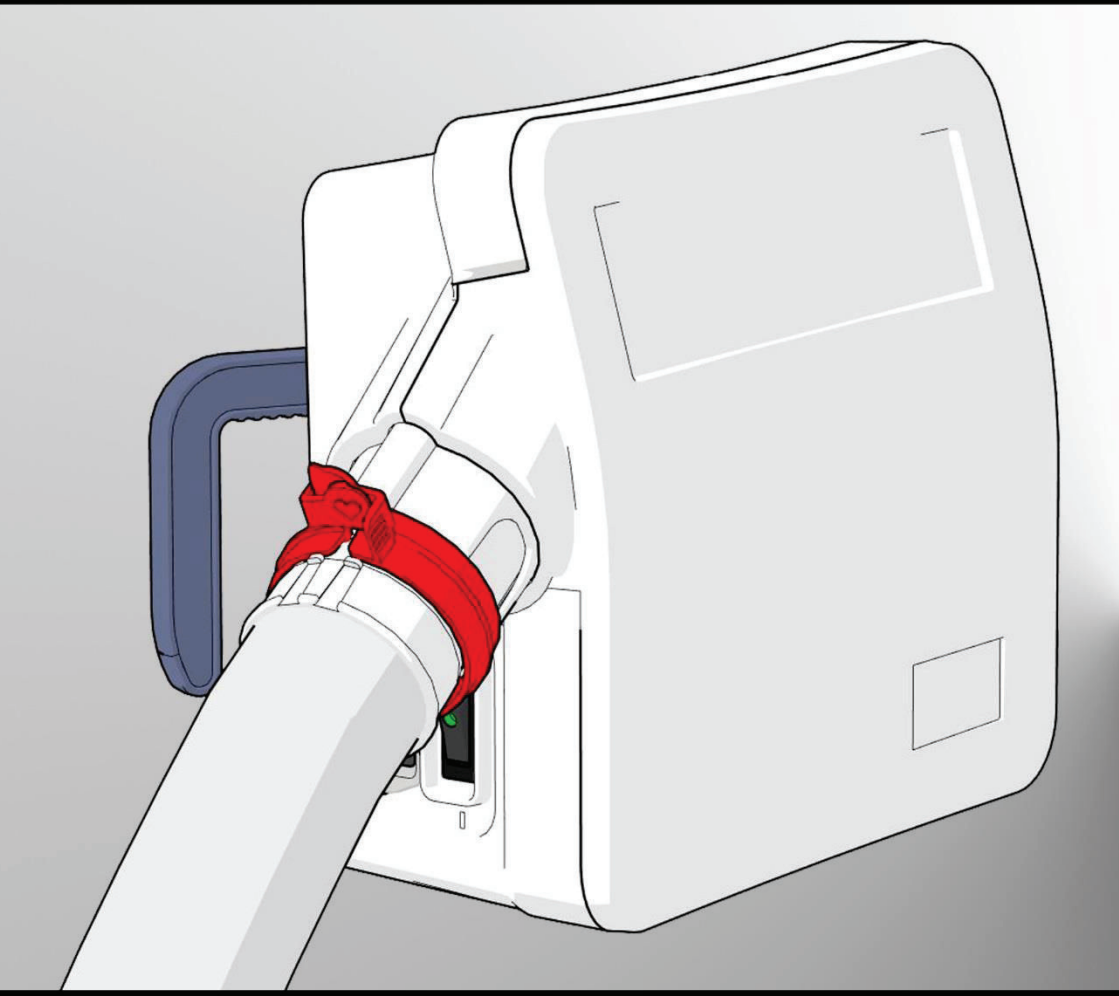


airflex®

Duo

USER INSTRUCTION MANUAL

USER INSTRUCTION MANUAL

INSTRUCTIONS FOR USE

Version 1.2

July 2015

Version History

Version	Implemented By	Revision Date	Approved By	Approval Date	Reason
1.0	Ben Smith	N/A	Tony Warr	April '15	Original copy
1.1	Ben Smith	June '15	Graham Ball	June '15	Reformatting, Amendment to Hooks, pg 10
1.2	Ben Smith	July '15			Corrective actions by Cranage EMC Testing Limited. *(IEC 60601-1)*

Table Contents

Introduction

Congratulations on purchasing the Airflex® DUO two-cell cycle alternating pressure air mattress. This high quality medical product, if installed and cared for in accordance with these instructions, will provide many years of trouble free service and outstanding clinical performance.

The Airflex® DUO is an alternating pressure mattress replacement system designed for the prevention of pressure ulcers.

This mattress system is manufactured to conform with international standards, EN 60601-1, EN 60601-1-2, and is registered to CE Mark.

Please read this Instruction Manual thoroughly before using the Airflex® DUO.

Further Information

The Airflex® DUO replaces the mattress on any hospital, style bed frame. This mattress replacement system is quiet, comfortable and simple enough for a single caregiver installation.

The frequent relief of contact (interface)pressure has been demonstrated to reduce the risk of pressure injury which is caused by reduced capillary blood flow in the tissue surrounding the bony prominences. The **Airflex® DUO** is also a valuable aid in the treatment of existing pressure injuries.

The objective of the Airflex® DUO is to reduce the contact pressure created by the patient lying on the mattress. This is achieved by sequentially inflating and deflating the air cells of the mattress. This regularly reduces the contact pressure which restores blood flow and tissue oxygenation in the deep tissues about the vulnerable bony prominences.

The system consists of an air filled mattress that is placed on top of a conventional bed frame and is connected via an air supply hose (umbilical) to a separate control unit. This mattress consists of 18 transverse air cells, protected by the cover.

The control unit is software driven which gives the capability to maintain the air pressure in the cells at the required level and to automatically alter the air pressure depending on the weight of the patient and their position in bed.

The additional presence of a CPR valve located at the side of the unit permits the rapid deflation of the mattress in an emergency.

Contraindications

As with all alternating mattress systems, the Airflex® DUO is contraindicated for use where patients have unstable fractures or spinal injuries.

Descriptions of Symbols

Throughout this user manual and on the pump unit itself, the Airflex® DUO has numerous symbols:

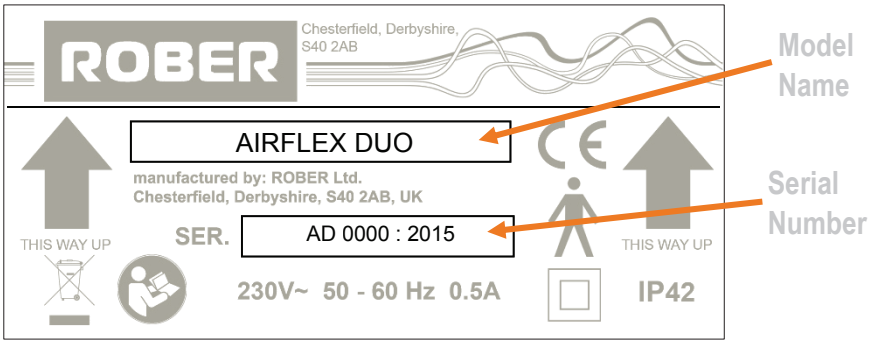
Symbol	Explanation
	*Type B – Applied Part*
	*Class II Medical Device*
O / I	*Off / On*
	*Refer to Instruction Manual*
	*General Warning*
	*Button (for operation of pump unit only)*

List of Components

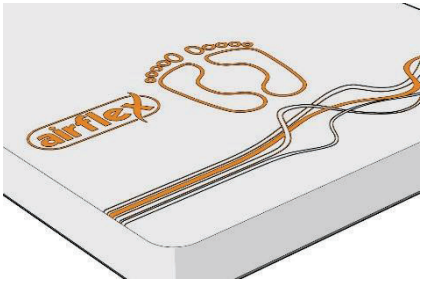
Unpack your Airflex® DUO mattress system and check that you have the following:

- Airflex® DUO Pump Unit:

  Please note the Name, Model and the Serial Number of your pump in case you need to reference these when contacting Rober.



- Airflex® DUO Mattress:



The top cover is made from Dartex™ which is an antimicrobial, mutli-stretch, vapour permeable, PU coated fabric. The bottom cover is made from durable PVC coated Nylon.

- Power Cord:

  The power plug should be appropriate to your country or region.

General Cautions / Warnings

Before setting up the mattress, it is important to read all of the safety instructions below. Any actions or operations performed outside the guidance of this manual are carried out at the user's risk. Rober and/or the supplier are not liable for any such actions.

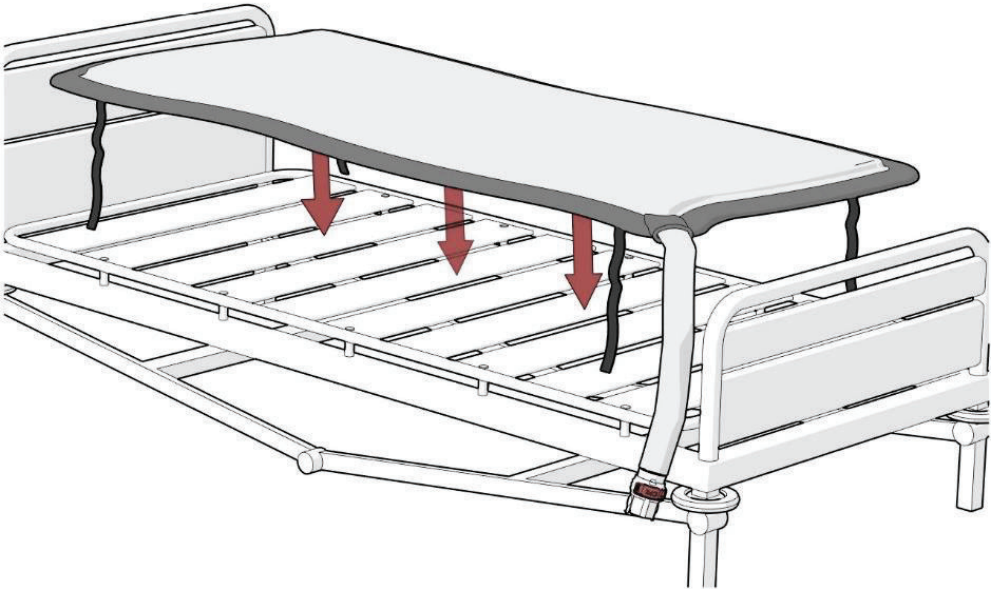
- Inspect before use. If any faults are discovered, the mattress system should not be used and the supplier immediately notified.,
- Check the power cord is positioned so there is no risk of obstruction or potential injury.
- **Risk of explosion:**
  Do not use in the presence of flammable chemicals or gases.
- **Risk of fire:**
  Do not place near heat sources or naked flames.
- **Risk of electrocution:**
  Ensure that the mains power is fully earthed.
  Never partially or fully submerge electrical equipment in fluids.
  Check the power cord is free from any damage.
  Never handle the plug with wet hands.
  Do not open the case.Any repairs should be made by qualified service engineers.
  Do not spill food or liquids on the pump unit. *If spillage occurs, disconnect from the mains and allow to dry before re-use.*
- Do not use phenol based cleaning solutions on the mattress or cover.

- Do not place any components of the mattress system in either heat or steam autoclaves.
- **Risk of Suffocation:**
  The cover is not air permeable. Assure the patient can use the product safely.
- Do not drop the pump unit and do not drop objects onto it.
- Never use sharp objects on or near the mattress.
- Never insert objects into the pump.

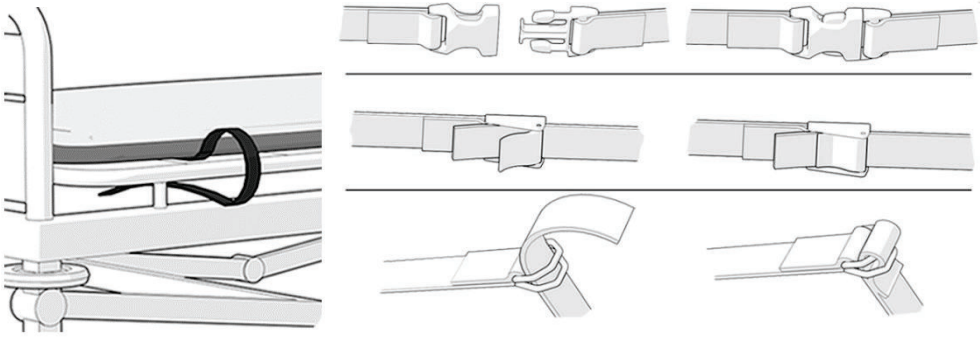
Installation

Please follow these instructions to install your Airflex® TRIO mattress replacement safely and appropriately.

1. Place the mattress onto the bed frame, ensuring the light grey top cover is facing upwards and the air supply hose (umbilical) is positioned at the foot end of the bed.

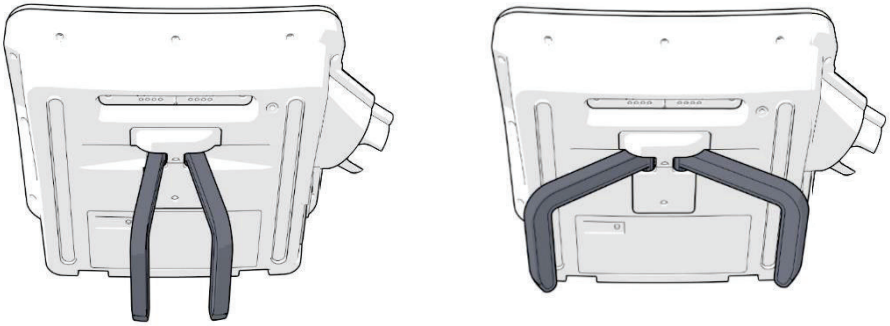


2. Secure the mattress to the bed using the straps and fasteners provided.

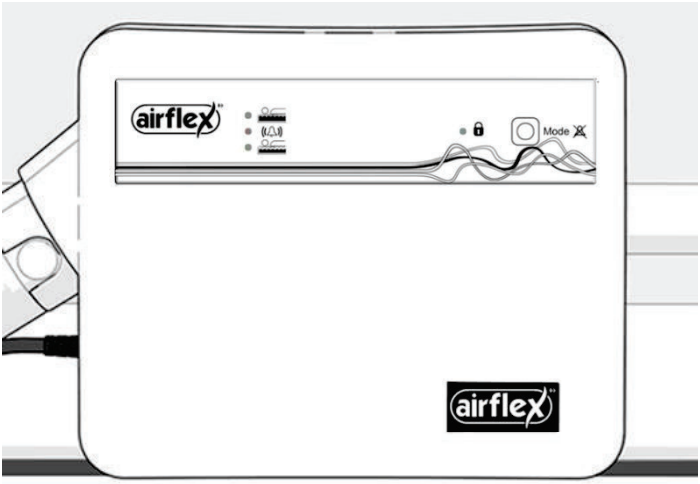


Ensure that fastened straps do not restrict the operation of any moving parts of the the hospital bed. Straps attached around both moving parts and fixed parts of a bed frame will cause severe damage to the mattress. After installation carefully test the functions of the bed to ensure the mattress moves freely with the bed platorm.

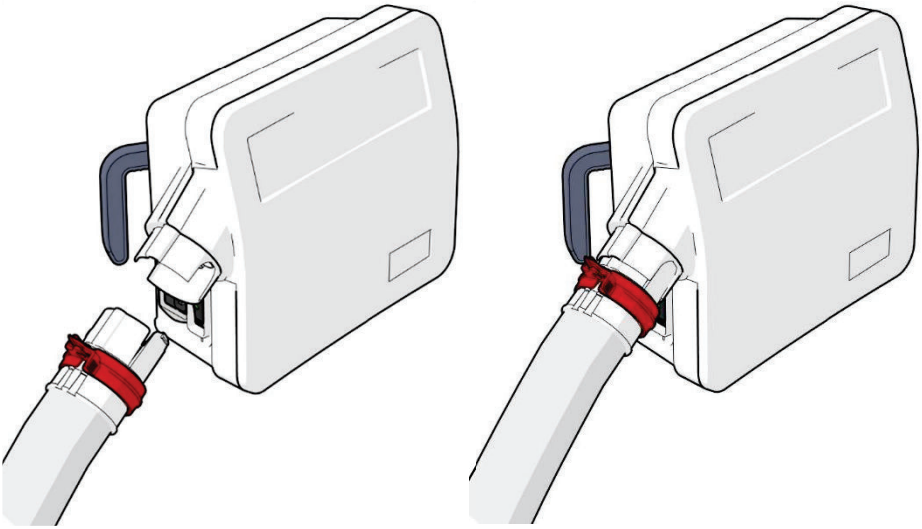
3. The hooks on the back of the Airflex® DUO have been designed to accommodate a variety of bed frames and can be pulled apart simulatenously by pushing down and rotating either arm.



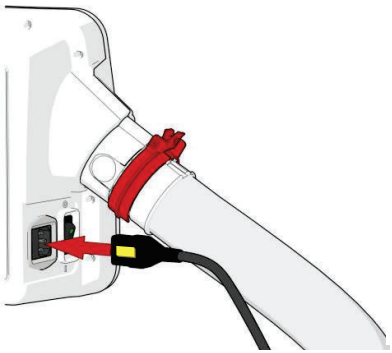
4. Hang the unit onto the bed frame at the foot end of the bed with the control panel facing outwards.

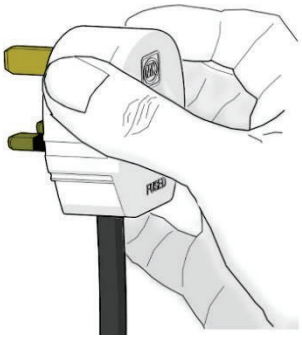


5. Check that the CPR clip is in the closed position and plug the umbilical hose into the dock.



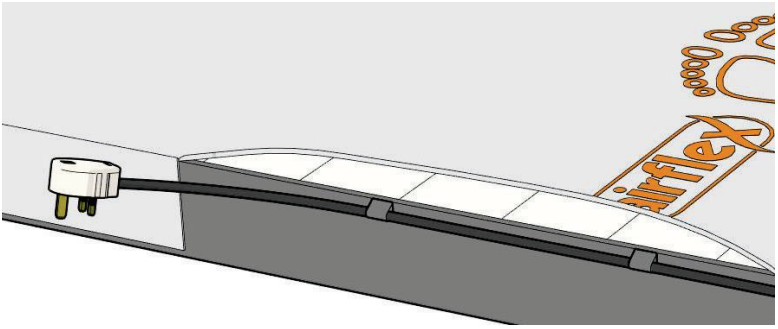
6. Plug the power cable into the pump using the international connector and then plug the other end (*the main disconnection devise*) into an **easily accessible** mains supply socket. Turn the unit on using the switch to the right of the unit's international plug socket.





Due to the special design on the power cable's connection, it cannot be pulled out easily without pushing the yellow button. Ensure that the pump unit is positioned so this button is accessible.

Ensure that the power cable is safely guided through the loops located under the skirt (waterfall). This will help reduce any hazards in relation to the power cable.



7. Wait for approximately 20-30 minutes and your **Airflex® DUO Mattress Replacement System is ready for use.**

Display Screens / Operation Modes

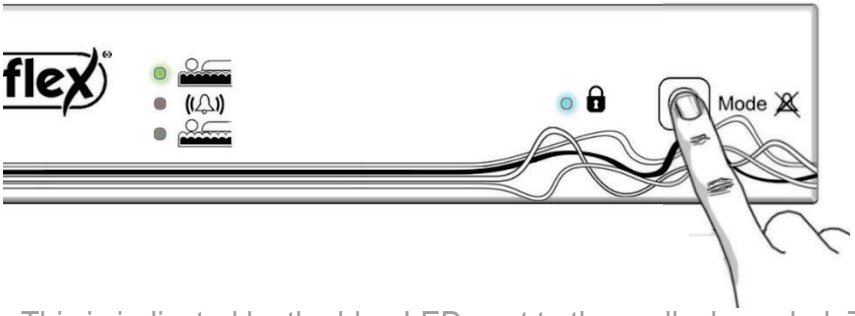
Before using your Airflex® DUO it is important to understand the display on the front panel of the pump unit and the various operation modes of the system

Loading

Whilst the Airflex® DUO is inflating the mattress two GREEN LEDs, flash alternately.

Lockout Function

60 seconds after either full inflation, mode change or system reset, the system will automatically lock out the display panel.



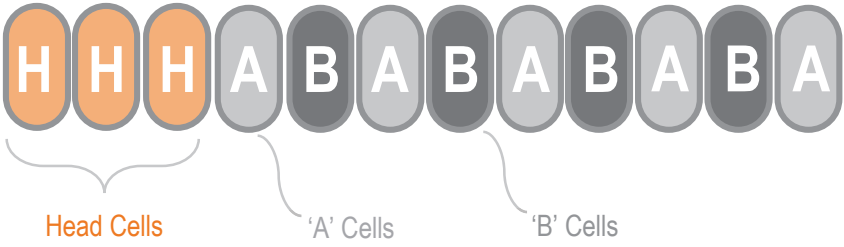
This is indicated by the blue LED next to the padlock symbol. To unlock the front p anel hold down the “Mode” button until the Blue LED goes out.

Automatic Alternating Mode

Once the unit has inflated the mattress it will automatically default to Firm Alternating Mode (see below) and calibrate to the patients weight.

Different Modes / Displays

The 18 air cells of the Airflex® DUO mattress are pneumatically connected into two groups.

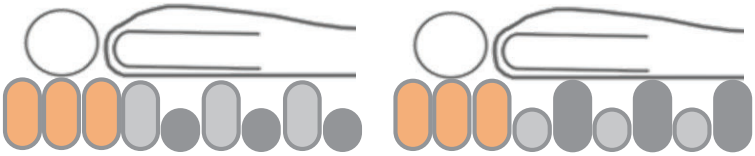


The 3 air cells at the head of the mattress ("head" cells) remain permanently inflated.

The remaining 15 air cells inflate and deflate in a 1 in 2 pattern with a cycle time of 10 minutes.

When the "A" cells deflate, pressure is relieved in that portion of the body in contact with those cells.

After 5 minutes, the "A" cells re-inflate and the "B" cells deflate for the next 5 minutes.



At the end of 10 minutes, contact pressure is reduced under all parts of the body in contact with the active components of the mattress.

Airflex® DUO has four modes:

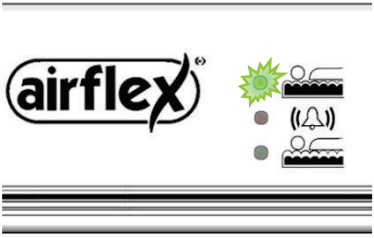
- **Firm Alternating**
- **Firm Static**
- **Soft Alternating**
- **Soft Static**

Push the mode button to cycle through these different modes, until the desired mode is found.

Firm Alternating

TOP GREEN LED – ***FLASHING***

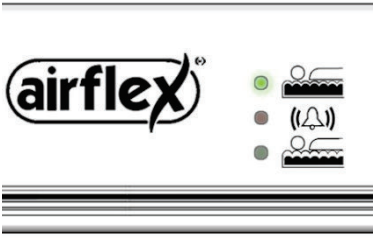
On start-up the system defaults to Firm alternating mode and automatically calibrates to patient weight and body position.



Firm Static

TOP GREEN LED – ***STEADY***

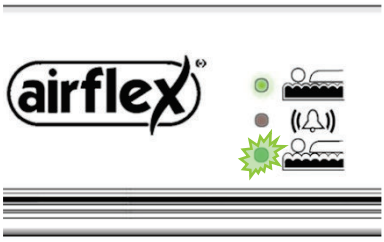
The mattress calibrates to patient weight and remains in static mode for 30 minutes. In static mode all cells are inflated.



Soft Alternating

BOTTOM GREEN LED – ***FLASHING***

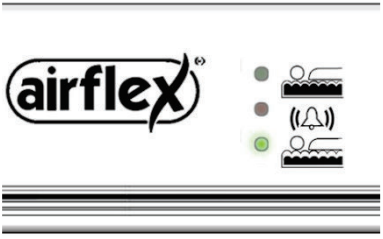
The mattress changes to a lower range of pressure settings more suited to the comfort of small and under weight patients.



Soft Static

BOTTOM GREEN LED – ***STEADY***

The mattress remains at the lower range of pressure settings and alternation ceases. The Airflex DUO reverts back to 'Soft Aternating' after 30 minutes.



The 'SOFT' setting of the Airflex® DUO is suitable for frail underweight patients and children.

N.B. *Both Static Modes revert to Alternating Mode after a preset period of 30 or 120 minutes, depending on your local distributor.*

Alarms

Each of the following alarm displays will be accompanied by a fixed tone audible alarm.. The audible alarm can be cancelled by pressing the “Mode” Button, however if the cause of the alarm is not resolved after 15 minutes the audible alarm will reactivate.

To turn off the alarm permanently, or reset the pump after fixing the cause of the alarm, simply swicth the pump unit off and then on again.

THE PUMP MUST BE RESET AFTER ANY ALARM EVENT.
ALL ALARM CONDITIONS ARE SHOWN WITH A ***RED LED***

High Pressure Alarm

This condition could be caused by an over pressure in the mattress e.g. by another person sitting on the mattress. This alarm is shown by a ***FAST*** FLASHING RED LED.

To resolve this issue, unclip the CPR clip and let out a small amount of air and then reseal the CPR clip. Reset the pump afterwards. Persistent high pressure alarms may indicate an internal fault. If if this occurs Care should cease. The pump should immediately be sent for servicing.

Low Pressure Alarm

This condition could be caused by releasing the CPR clip or a leak in the mattress. This alarm is shown by a ***SLOW*** FLASHING RED LED.

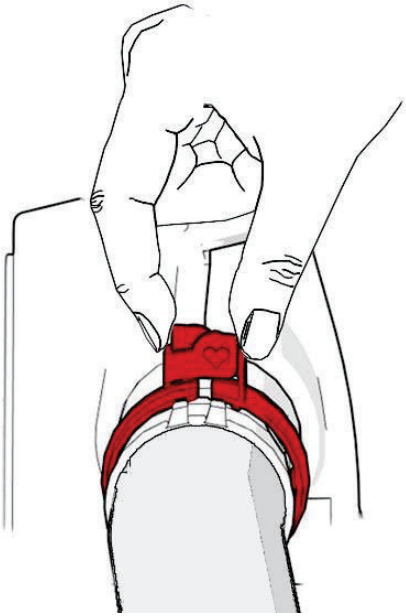
Power Failure Alarm

If there is a failure of the mains power supply or the unit is accidently unplugged from the mains then a ***CONTINUOUS*** RED LED will show.

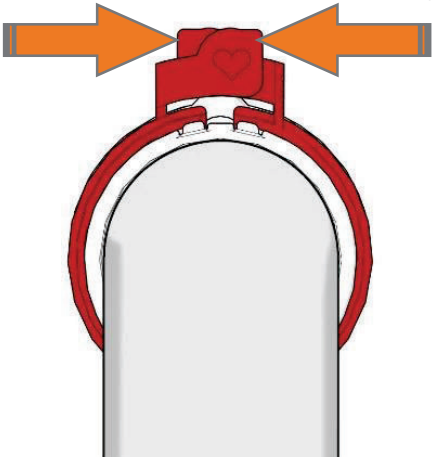
N.B. *The Power Failure Alarm is powered through a small battery.*
The sole function of this battery is to operate the alarm in case of a mains power failure.

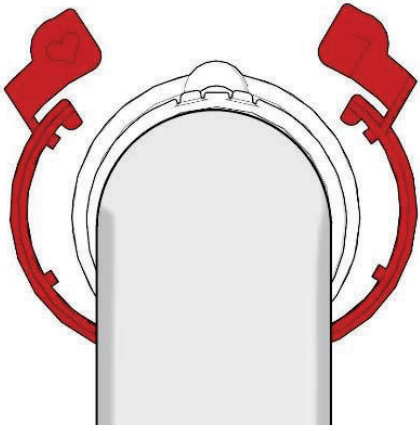
CPR Emergency

In the case of a patient emergency where CPR may be necessary, the Airflex® TRIO has been equipped with a CPR release which rapidly deflates the mattress so that cardiac resuscitation can be performed on a firm surface.



To deploy this emergency system, simply grip the RED CLIPS between thumb and forefinger and PINCH. The clips will fall down and the mattress will rapidly deflate.





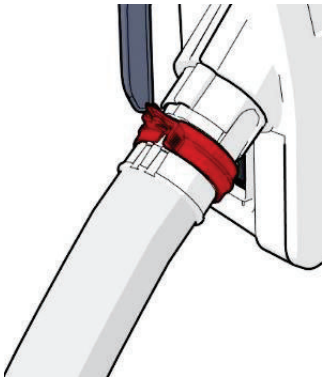
Ensure that after the CPR release has been disconnected, the CPR cilp is reconnected and the pump is reset.

Transportation Mode

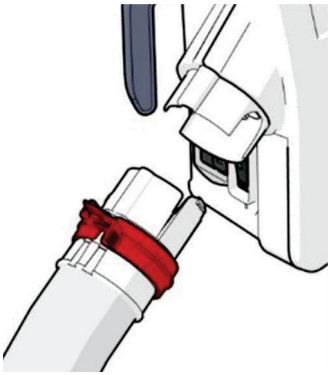
In this configuration the mattress can be transported easily around the hospital.

Preparation

When separating the pump unit from the mattress the unit should first be SET TO STATIC MODE. When all cells are inflated the pump should be SWITCHED OFF and the umbilical hose separated.



Simply push the buttons on the sides of the umbilical dock and the umbilical will disconnect. The mattress itself will remain inflated for several hours.



Storage (and Shipping)

The Power Unit should be stored standing upright in a vertical manner NOT laid flat.The following conditions should apply, where possible, for the longevity of internal components:

Ambient Temperature	+10°C to 35°C
Relative Humidity	10% – 100% non condensing
Atmospheric Pressure	700hPA – 1060hPA

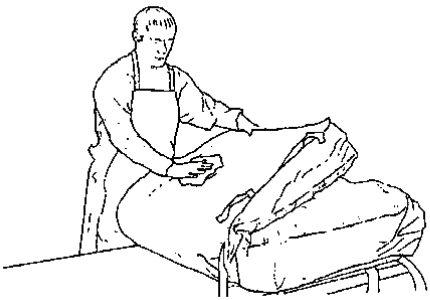
Cleaning and Maintenance

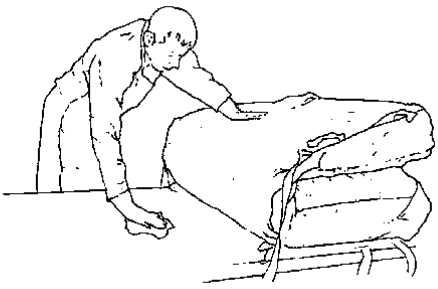
Cleaning Procedures

Cleaning the mattress system every week is recommended, or sooner if heavily soiled. Please make sure that hands are cleaned and appropriate protective clothing is worn before commencing cleaning process.

Cleaning the mattress

1. Leave the cover on the mattress and disconnect the mattress from the unit.
2. Clean the surface of the wash-down table with hypochlorite solution or an equilavent disinfectant.
3. Wash mattress top cover using hot water (60 °C) and detergent. Dry with a paper towel.
4. Fold mattress in half length ways and clean both the table and the exposed mattress.





5. Turn over mattress so the other bottom half is exposed and clean both mattress and table.
6. Repeat Steps 3 – 5 using hypochlorite solution or equivalent disinfectant.

7. Wipe the umbilical hose with hot water and detergent. Dry with a paper towel and repeat wiping down using hypochlorite or equivalent solution.

*If required, the cover can be removed and machine-washed at a temperature of **80°C for a minimum of 10 minutes.***

The cover may also be sterilised using ETO or Draeger processes.

Cleaning the Pump Unit

The Pump Unit can be cleaned by wiping a cloth dampened by a disinfectant solution or sterilised using ETO or Draeger processes.

Ensure the unit is disconnected from the mains electricity supply before cleaning.

DO NOT autoclave the mattress or pump unit.

Maintenance

Only qualified technicians, trained or formally approved by Rober Limited, may carry out maintenance, modifications or repairs on the mattress system.

NO maintenace or servicing should take place while the Mattress System is in use. Ensure that the patient is clear of the system when carrying out maintenance.

Technical Parameters

Power Unit

Model	Airflex® DUO
Dimensions (L x W x H)	400 x 160 x 250 mm
Weight	2.8 Kg
Power Supply	230V~ ±10%, 50 / 60 Hz
Fuses	2 x T1.6A, 250V~ 5 x 20mm
Power Consumption	20w max
Ingress Protection Rating	IP42
Classification	Class B Medical Device Class II
Operating Cycle	10 minute (Continuous)
Flammability Rating	UL94 V0

Mattress

Model	Airflex® DUO
Dimensions (L x W x H)	1900 x 880 x 200 mm *(Standard)* 1900 x 800 x 200 mm *(Narrow)*
Number of Air Cells	18
Weight	9.2 Kg
Mattress Material	Polyurethane
Flammability Rating	Complies with BS7175 Ignition Source 0, 1 and 5
Maximum Weight of Patient	**220kg**

Internal Components Operating Conditions

Ambient Temperature	+10°C to 35°C
Relative Humidity	30% – 75% non condensing
Atmospheric Pressure	700hPA – 1060hPA

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