Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

INSTRUCTIONS FOR USE

This manual MUST be read BEFORE using this product

WIN CARE

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

Contents

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

1. Introduction

This document outlines important information pertaining to the safe and effective use of the product. Store this IFU in a designated area, where it is always easily accessible. If unsure, consult a medical professional regarding the correct use of the product. There may be sections in this document which do not apply to your specific model, please read all instructions carefully. For further product related information contact Winncare PAC Ltdee contact information at the end of this document.

2. Symbols

Symbols and advisory notices are used in this document to help safe and optimal operation of the product. See information below for definitions of the symbols.

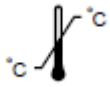
 **WARNING**	**Warning:** Safety warning. Failure to obey and understand could lead to injury to yourself or others, and in some circumstances death.
 **CAUTION**	**Caution** to highlight potential hazards that, if failed to follow, could lead to damage or failure in parts or all of the system and equipment.
NOTE	**Note:** Important information users should be aware of for correct use of the equipment.

3. Product Labelling

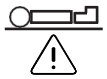
The labels shown are for illustrative purposes only – some symbols on your product may differ from the examples shown.

	**Instructions for Use** Read the Instructions for use before use
	**Type BF Applied Part** Applied Part: The parts of the device that come into physical contact with the user/occupant in order for it to carry out its intended function. Type BF: Applied parts which are electrically isolated from earth and other parts of the medical equipment - Complying with specific requirements for protection against electric shock to IEC 60601-1
	**W.E.E.E Label** Waste Electrical and Electronic Equipment.
	**Class II electrical device** The user/occupant is protected by at least two layers of insulation between the current carrying parts (e.g. mains cable) – If damage is noticed to the control unit or mains cable assembly turn off at the mains supply and contact your provider or Winncare UK Ltd. immediately
IP21	Protected from touch by fingers and objects greater than 12mm. Protected from condensation.
	CE marking indicating conformity with European Community harmonized legislation. Figures indicate Notified Body supervision.
	UK marking indicating conformity with UK Medical Device Regulations 2002 (SI 2002 No 8, as amended)
	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
	Serial number
	Reference number
	Batch code

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

	Name and address of the manufacturer
	Date of manufacture
	Temperature limitation to indicate the temperature limitation for the product during usage
	Unique device identifier
	Authorized Representative in the European Community
	Disinfect by wiping the surface using a hypochlorite solution diluted 1000 ppm.
	Machine wash up to 95°C.
	Tumble dry on a low setting
	Do not use harsh abrasives or Phenol cleaners
	Do not iron
	Ensure system is dry before storing, use and reuse.
	Do not place heavy objects on surface of cover other than the patient
	Do not use when damp, ensure surface is dry before use

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

	Do not fold. Roll pack the system
	Do not use sharp objects
	Max Patient weight defines the maximum total load of the patient kg (lb)
	Safe Working load (SWL) is the maximum combined weight of the patient and any equipment that the mattress can safely support.
	Foot end
	Resistant to ignition
	Recycling

4. Warnings and Precautions for Use

WARNING

Do not use device control unit in oxygen rich environment or near flammable gases. RISK OF FIRE AND BURN INJURY.

WARNING

Do not use device with a damaged power cable. RISK OF ELECTROCUTION AND FIRE.

WARNING

Ensure appropriate cable management. Avoid operating the device with loose or severely taught cables. RISK OF TRIP AND FALL INJURY.

WARNING

Do not open or repair the control unit whilst it is in use or connected to mains power supply. RISK OF ELECTRIC SHOCK.

WARNING

Do not use the device as a repositioning tool. RISK OF PRESSURE INJURY.

WARNING

CPR dial / strap must be accessible at all times. RISK OF SERIOUS INJURY.

WARNING

Ensure the device is assembled and operated as intended. RISK OF PRESSURE INJURY.

WARNING

Do not cover the control unit with blankets and other items. RISK OF FIRE.

WARNING

Do not spray liquid on the control unit whilst it is connected to mains power. RISK OF ELECTRICAL BURNS.

WARNING

Do not expose any parts of the device to a naked flame. Do not smoke. RISK OF FIRE AND PROPERTY DAMAGE.

WARNING

Ensure the patient is manually repositioned at frequent intervals. RISK OF PRESSURE INJURY.

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

CAUTION

Ensure the device is used with compatible equipment and accessories. Complete a risk assessment if in doubt.

CAUTION

To unsure optimal function of the device, use suitably trained personnel for servicing and repair. Use original parts only.

CAUTION

Ensure the device is plugged into mains power supply for optimal function.

CAUTION

Ensure there are no additional layers between the surface of the mattress and the patient. Device performance may be affected. Complete a risk assessment if in doubt.

CAUTION

Ensure the device is suitable for the patient. Complete a risk assessment if in doubt. Consult a medical professional if in doubt.

CAUTION

Ensure the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.

CAUTION

Ensure the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.

CAUTION

Do not use device alongside hot water bottles or electric blankets. Device performance may be affected.

CAUTION

Complete a risk assessment when using device with incontinence products.

NOTE	Use a CE marked extension cable if device power cable cannot reach wall socket. If in use, do not overload.

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

5. Product Overview

This product is made of the following components:

PUR-8-AC: Pure Air 8 Acute Dynamic Mattress System	
Control Unit	CU-PUR-6
Mattress Base Unit	PUR-8-AC-M
Top Cover	SMP934

Control Unit

1. Control Panel
2. Mains Cable Port
3. Hook
4. Female Air Connector Port
5. Pad
6. Air Filter Cover

Mattress

1. Air Cells
2. Top Cover
3. Easy-turn CPR
4. Air Tube Set with Male Air Connector
5. Securing Straps
6. Base Cover

Pure Air 8 Acute Dynamic Mattress System (PUR-8-AC)

6. Product Features

PUR-8-AC: Pure Air 8 Acute Dynamic Mattress System	
Size (mm) L/W/H	2000 x 900 x 203
Maximum Patient Weight	250 kg (40 stone)
Safe working load	250 kg (40 stone)
Other Features	• 23 Cells: 3 static head cells and 20 alternating cells (including 12 torso cells and 8 narrow heel cells) • Cell-on-cell construction • PU air cell construction • Mattress weight: 10kg • Easy turn CPR for rapid deflation • Welded, multi-stretch waterproof and vapour permeable, machine washable cover up to 95°C • Optional 10/15/20 mins cycle time • Pressure range: 17-70 mmHg • Low-pressure alert • Cycle fault alert • High-pressure alert • Egress alert • Mattress connector alert • Max inflate/static function • CLP function • Pulsation mode • Auto seat function • Low weight function • Cycle timing control • Pressure adjustment • Alert mute • Power fail alert • Panel Lock • LCD screen • Auto patient/pressure detection • Manual pressure control • Service indicator

7. Product Description

Intended Use	To provide pressure relief and aid in the prevention and management of pressure-related injuries as part of a standard package of care.
Target Population	Typical adults with limited mobility, undergoing some medical supervision and monitoring. Individuals assessed as “at risk” and up to “very high risk” of pressure damage and/or with existing tissue damage as determined by a combination of clinical judgment and validated assessment tools.
Contraindications	Patients below the minimum or maximum user weight listed for the associated device. Cervical or skeletal traction. Unstable skeletal fractures. Unstable spinal injury.
Users	Caregivers, laypersons and/or medical professionals.
Warranty	3 years subject to regular maintenance and serving.
Reusable	Devices are re-usable but must be cleaned in between each patient use.
Maintenance or calibration	Perform regular mattress audits to check for fluid ingress and strike-through on mattress top cover. The system should be serviced once a year, as a minimum.
Accessories	Devices are not sold with accessories.
Risk Assessment	It is the responsibility of the end user/care provider to carry out the necessary risk assessment to ensure the patient’s safety. This should be carried out before using the mattress system. A risk assessment should include, but not be limited to: • Product combinations (bed frame, mattress, side rails, etc.) • Extent of tissue damage (if any) • Entrapment • Patient falls • Small adults (and children) • Patients with learning difficulties • Patients with atypical anatomy • Unauthorized people with access to the controls • Use with other medical accessories e.g. incontinence products

8. Installation

To install the device, follow the instructions below:

1. Carefully open the packaging.
2. Check the device for any signs of damage. Do not use if damaged and contact your provider or Winncare PAC Ltd.
3. Place the mattress on top of the bed frame with the top cover facing upwards and the air tube set at the foot end of the bed.
4. Attach the mattress to the bed frame by securing it with the adjustable securing straps.

NOTE	On profiling beds, it is essential that adjustable straps are secured around the movable sections of the bed frame, otherwise the mattress may be damaged.

5. Rotate the CPR dial (located at the foot end of the mattress) to a vertical or horizontal, closed position (see image).

6. Using the hooks on the back of the control unit, hang the unit over the frame/board at the foot end of the bed. If there is no foot frame/board, lay the unit on the floor, under the bed, with the front control panel facing upwards.

7. Attach the air tube set via the male air connector (air hose connector) on the mattress to the female air connector port on the control unit/pump, ensuring the air tubing is not kinked or trapped between parts of the bed frame/other equipment.

8. Route the mains cable down the side of the bed using the cable management system.

9. Plug the mains cable into a suitable mains supply and switch on the control unit.
10. The mattress will start to inflate and will be completely inflated within 20 minutes.

11. Once fully inflated, adjust the straps that attach the mattress to the bed frame, ensuring the mattress is securely held in place.
12. Cover the mattress loosely with a sheet, ensuring it does not interfere with cell alternation.

9. Product Operation

9.1 Control Panel

9.2 Control Unit Operation

	1. Power Press to turn the control unit on and off.
	2. Therapy Mode Opens therapy menu with 4 different therapy settings.
	3. Up/down Moves the cursor up and down.
	4. Select Selects and initiates the chosen parameter
	5. Alert Mute Mutes audible signal for a 30-minute period.
	6. Home Returns to main screen.
	7. Power Fail Illuminates if power is lost.

	8. Lock Locks/Unlocks the control panel.
	9. Comfort control Opens comfort control menu – Provides 3 different comfort settings

9.3 Turning on/off

Hold the button down until an audible signal sounds for a brief period. The screen illuminates.

The system will start to inflate and be fully inflated in approximately. 20 minutes. Once the mattress is fully inflated, the panel will instruct the user that the system is ready for use, and a short audible signal will sound. If the system does not reach the required pressure, a 'low pressure' alert will sound after 40 minutes.

To turn the system off, hold the button down until the screen clears.

9.4 System Setup

Once a patient is positioned on the mattress, the system will calibrate to the patient's approximate weight, position and posture and will set the optimum pressure level within 4 minutes. Once this is complete, the mattress automatically defaults to alternation mode.

Alternation:

The mattress utilises an 'AB' alternation cycle where alternate cells deflate and inflate. Whilst the system is calibrating to the patient's weight, position and posture, the screen will show the changing pressure differential between the A and B cells at that moment in time.
In the example below A = 34 mmHg and B = 33 mmHg.

Patient Weight & Pressure:

When a patient is placed on the mattress, the control unit detects the back pressure within the cells, which is determined by the patient's weight, position and posture.

The control unit then calculates the optimum pressure level for the patient, based on back pressure, therefore providing individualised care. This process occurs every 60 minutes or when the control unit detects a significant change in back pressure. The patient may sense this happening as the cells will inflate and deflate during this process until the lowest possible supportive pressure is established where the patient's weight distribution is greatest (i.e. the sacrum).

The weight guidance indicator is accurate to ±10 kg and should therefore not be relied upon as an accurate weight for the patient. In the example below, the weight is approximated to be 80 kg with an alternating pressure of 13 mmHg.

To ensure the patient is comfortable and the system is functioning correctly, a check should be performed after approximately 20-30 minutes following system calibration.

Safety Functions

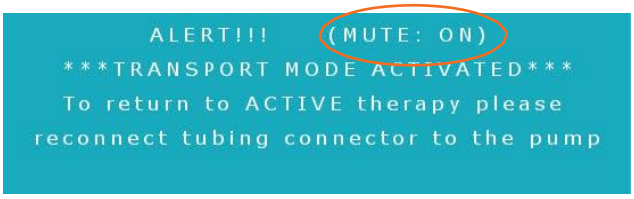
Function Lock:

The control unit will automatically lock out all functionality 2 minutes after a function change. To unlock the control unit, press the 'lock' button for 2 seconds. To re-engage the lock, the button can either be pressed again for 2 seconds or the user can wait for the automatic lock to re-engage.

When pressed, the lock indicator illuminates:

Mute:

The audio-visual alert activates if a fault is detected. To silence the audible alert, press the 'mute' button. When the system is muted, the screen shows:



Pressing the mute button reactivates the audible signal.
The mute setting will self-cancel after 30 minutes, and the audible alert will resound.

NOTE	If the 'power failure' indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.

9.5 System Functions

Therapy Selection:

When pressed, a menu appears offering 4 different settings:

Use the up/down cursor keys followed by the selection key to initiate the chosen setting.

1. Alternating: Operates an 'AB' cycle where alternate cells deflate and inflate over a defined time causing the pressure under any one part of the body to change regularly, actively encouraging tissue perfusion.

2. Constant Low Pressure: Reduces contact pressure by increasing the surface area over which the patient is supported and by contouring to the shape of the body, pressure is redistributed away from vulnerable areas, through immersion and envelopment. In this setting, the system runs in a static mode where the cells are not alternating and are within a pressure range of 10 to 40 mmHg (depending on patient morphology).

NOTE	When using the constant low-pressure setting, to return to alternating it is necessary to manually reselect alternating from the therapy menu, it will not automatically default back.

3. **Pulsation:** Creates tissue stimulus by alternately increasing and decreasing the cell pressure within Constant Low-Pressure mode by 20% in each direction.

NOTE	When using the pulsation setting, to return to alternating, it is necessary to manually select alternating therapy from the menu; it will not automatically default.

4. **Max Inflate:** Inflates the cells to maximum pressure (40 mmHg) to provide a stable, static support surface.

NOTE	The system will automatically revert back to alternation mode after 20 minutes for patient safety.

9.6 Comfort Control

When pressed, a menu appears offering 3 different settings:

Use the up/down cursor key followed by the selection key to initiate the chosen setting.
By selecting this function, the softness/firmness of the mattress can be manually altered, depending on the patient's requirements. The control unit defaults to medium.

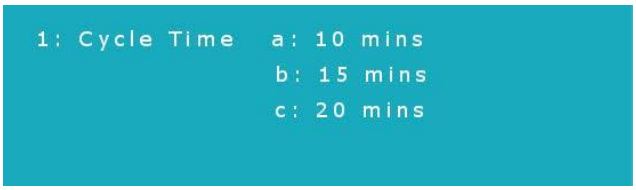
Firm = + 5 mmHg
Medium = Automated pressure setting
Soft = – 5 mmHg

Use clinical judgement from frequent monitoring and patient repositioning to determine any changes in pressure settings.

9.7 Additional Settings:

First, access the comfort control menu and press the lock button and down cursor key together. A hidden menu will appear.

1. **Cycle Time:** When pressed, a menu appears offering 3 different settings:



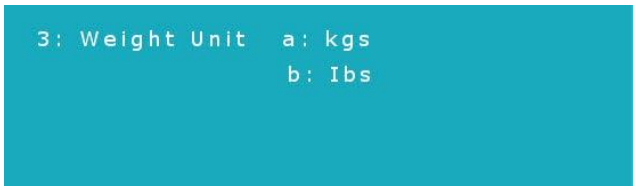
By selecting this function, the alternation sequence cycle time can be manually altered, based on the patient's requirements.

NOTE	The default cycle time for the system when first turned on is 10 minutes. Use the up/down cursor key followed by the selection key to initiate the chosen setting.

2. **Auto Lock:** When pressed, a menu appears offering 2 different settings:

By selecting 'disable', the interface will not automatically lock itself. Use the up/down cursor key followed by the selection key to initiate the chosen setting.

3. **Weight Unit:** When pressed, a menu appears offering 2 different settings:



Use the up/down cursor key followed by the selection key to initiate the chosen unit of measure.

4. **Weight Display:** When pressed, a menu appears offering 2 different settings:

Use the up/down cursor key followed by the selection key to show/hide the weight indicator on the main screen.

5. Egress Alert: If activated, the control unit provides an audio-visual alert if it senses the occupant has got out of bed, due to a sudden change in back pressure within the cells.

When selected, a menu appears offering 2 different settings:

Use the up/down cursor key followed by the selection key to activate/deactivate the egress alert. If active and the occupant gets out of bed, an audible alert sounds and a 'warning' screen illuminates for approximately 1 minute, followed by a 'no patient' indication:

To cancel the audio-visual alert, press any button on the control unit interface.

9.8 Mattress Operation

Auto Seat Mode:

The mattress allows for profiling in an upright position. Pressure will be automatically increased when the patient is sitting in an upright position, and depending on patient comfort and clinical judgement, the comfort setting can be adjusted to suit the patient. When the backrest travels beyond an angle of 20°, the screen on the control unit interface advises that the backrest has been raised.

Low Patient Weight:

The mattress accommodates patients whose weight would be considered particularly low (<40 kg). It significantly reduces internal cell pressures to suit lower-weight patients. To activate, press the selection button ↵ for 5 seconds - 'low weight patient' illuminates on the screen:

To deactivate the low patient weight mode, the control unit needs to be switched off and then back on again. When the low patient weight mode is selected, frequent monitoring and repositioning are advised.

CPR Function

In an emergency, rapid deflation of the mattress may be required. The CPR dial is located at the foot end of the mattress. Rotate the CPR dial to the open position, and the entire system will rapidly deflate.

To re-inflate, turn the CPR dial to the closed position. The mattress will start to inflate. Wait for optimal pressure to be reached before using the mattress.

Transporting the mattress

To transport a patient whilst the device is in use or in the event of mains power failure, follow the steps below to maintain mattress inflation.

1. Disconnect the air tubing from the control unit by pressing the tab on the top of the connector and pulling away from the control unit.
2. Switch off the control unit (if still operational).
3. Disconnect from the power supply.
4. The mattress can now be moved.

NOTE	There is no need for the air connector to be sealed with a cap, as the connector has a non-return valve.
NOTE	In the event of a power failure, the mattress will remain inflated for up to 24 hours. The mattress should be returned to the mains supply as soon as possible. If not plugged into the mains, device performance will be affected.
NOTE	Do not drag the mattress, always carry it.

WARNING

Do not remove the mattress from the bed frame if the occupant is still on the mattress. RISK OF FALL.

WARNING

When not connected to a mains power supply, alternating mode will not be available. RISK OF LIMITED PRESSURE RELIEF.

10.Cleaning and Disinfection

Cleaning and disinfection of the device is mandatory. As a minimum, cleaning and disinfection should be performed as soon as the device is taken out of storage, between each patient, at regular intervals whilst in use and before being returned to storage. Consult local practice guidelines for more details on cleaning and disinfection of reusable medical devices. Follow the instructions below to achieve a minimum level of cleaning and disinfection for safe use of the device.

WARNING

Please wear appropriate personal protective equipment (PPE) when cleaning the mattress or control unit. RISK OF SKIN IRRITATION

CAUTION

Do not immerse or soak the control unit. Do not spray any cleaning solution onto the control unit.

CAUTION

Do not use phenol-based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.

CAUTION

Do not use top cover if strike-through or damage is suspected.

CAUTION

Do not use Phenol-based solutions or abrasive compounds.

CAUTION

Do not attempt to clean the device whilst its connected to mains power.

CAUTION

Do not autoclave.

10.1 Cleaning and Disinfection Protocol: Control Unit

1. Visually check the control unit for external damage – do not use if damage is found.
2. Place the control unit on a work surface and, using a clean, soft, non-abrasive cloth, wipe the outside of the case with a prepared sodium hypochlorite solution (recommended 1,000 ppm).
3. The control unit should be cleaned by starting with the cleanest areas and systematically moving to the dirtiest areas. Extra care should be taken in areas where excess dirt or dust may gather.
4. Change the cloth if it becomes dirty.
5. Once clean, wipe down with a fresh, clean, soft, non-abrasive cloth moistened with clean water to remove detergent residue.
6. Dry off with a paper towel. Always allow the surfaces to dry thoroughly before re-use.

10.2 Cleaning and Disinfection Protocol: Mattress

1. The mattress should be regularly checked for damage or tears. Replace if damaged.

NOTE	Before attempting to clean the mattress, the top cover should be checked for physical signs of damage that may lead to strike-through (ingress of fluid through cover). Staining to the underside of the top cover is a sign of strike-through.

2. Wipe down with a clean, soft, non-abrasive cloth moistened with a mild detergent and diluted in warm water (40˚C).
3. Rinse with cold, clean water and a clean, soft, non-abrasive cloth. Allow to fully dry before re-use.

Disinfection

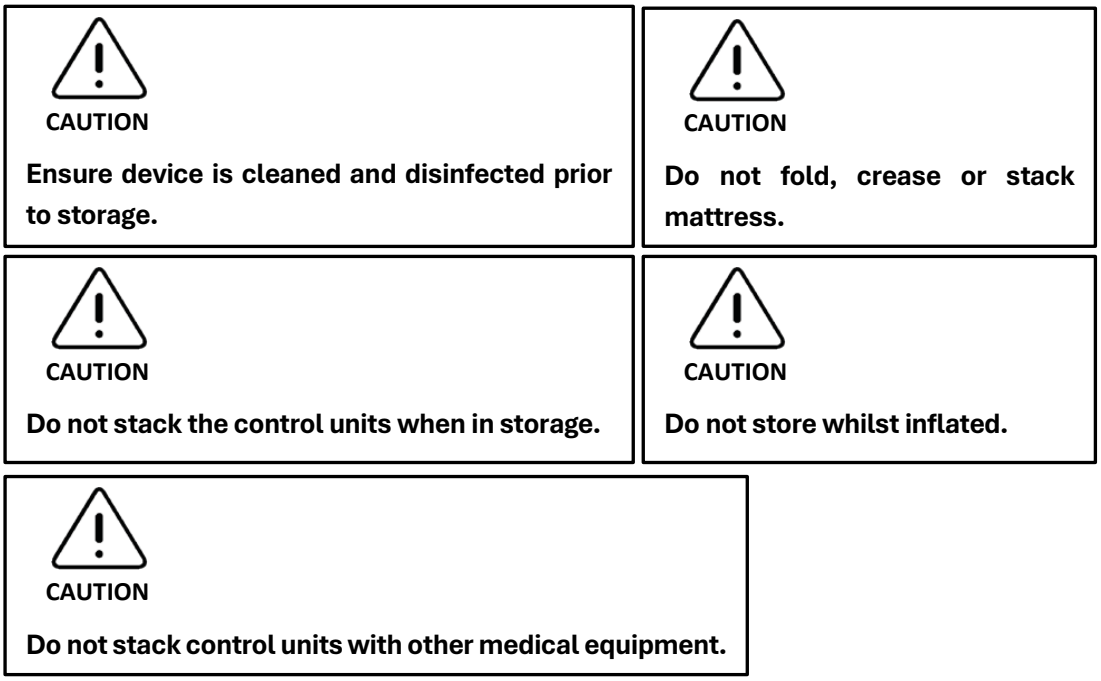
1. Unzip the top cover from the mattress.
2. The top cover can be machine washed up to 95°C and tumble dried on a cool setting.
3. Unsnap the air cells from the mattress base on both sides.

4. Carefully clean with (1,000 ppm) prepared solution of sodium hypochlorite and allow to dry completely. In extreme circumstances, 10,000 ppm can be used, wipe with cold water to finish. Frequent cleaning with a high-concentration disinfectant solution (i.e. 10,000 ppm available chlorine) may reduce the lifespan of the system.
5. Make sure to disconnect all the air cells and spray the cleaning solution on all sides, including the connecting tubes and hoses.
6. Reassemble the mattress.
7. Ensure the mattress is completely dry before storage or re-use.

NOTE	Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.

11.Storage

Please follow the instructions below to prepare the product for storage.



1. Detach the control unit from the mattress.
2. Rotate the CPR dial until it is open.
3. Ensure there is no air trapped in the cells.
4. Lay the mattress out flat and roll the mattress from the foot end towards the head end.
5. Store in a sealed polythene bag to protect from dirt, debris, fluids, etc., with a suitable identification tag.
6. Store the control unit in a sealed polythene bag to protect it from dirt, debris, fluids, etc., with a suitable identification tag.

7. If taking a device out of storage, unfold the mattress and allow it to lie unfolded for several minutes. Allow the product to acclimatise to the operating conditions.

12.Troubleshooting

The table below provides a guide to the device alerts.

WARNING

Do not open or repair the control unit whilst it is in use or connected to mains power supply. RISK OF ELECTRIC SHOCK.

NOTE

If mains cable or plug is visibly damaged turn off power supply at the mains and contact your approved services engineer.

Problem	Actions
Power Failure Indicators: - Amber 'power failure' light flashes. -Audible signal Sounds. -Screen extinguishes. 	1. Turn off the control unit to silence the alarm and unplug from the mains supply. NOTE: If the 'power failure' indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button. 2. Check the mains socket is working - plug in a device that is known to work. 3. Plug the control unit back into the wall socket. 4. Turn on the control unit. If the control unit still fails to operate: 5. Turn off the control unit at the wall & replace the plug fuse. 6. Turn on the control unit. If the control unit still fails to operate: 7. Replace control unit fuses. For fuse types, see the specification table in later sections of this document. 8. Turn on the control unit. If the control unit still fails to operate, turn off at the mains and contact your approved service provider.
Incomplete inflation/low pressure Indicators: -Audible signal	

sounds. -Screen shows	1. Ensure the mattress air connector is properly connected to the control unit, is not constricted in any way and has no kinks. 2. Ensure the CPR dial is closed, and no air is leaking. 3. Turn the unit off and then on again to clear the indicator. If the 'low pressure' indicator continues to illuminate: 4. Remove the top cover and ensure there is no air leakage within the mattress cells, tubing and connectors. 5. Turn the unit off and then on again to clear the indicator. If a low-pressure indicator is still evident, turn off at the mains and contact your approved service provider
High Pressure Indicators: -Audible signal sounds. -Screen shows	 1. Ensure the mattress air hose is not trapped or being squeezed. 2. Open the mattress and ensure none of the air hoses are kinked. 3. Turn the unit off and then on again to clear the indicator. If a high-pressure indicator is still evident, turn off at the mains and contact your approved service provider.
Mattress Disconnection Indicators: -Audible signal sounds. -Screen shows	 1. Ensure the mattress air hose connector is correctly connected to the control unit. 2. Turn the unit off and then on again to clear the indicator. If the indicator is still evident, turn off at the mains and contact your approved service provider.
Cycle Fault Indicators: -Audible signal sounds. -Screen shows	 1. Contact the engineer for immediate repair/replacement of the timing motor
Patient is bottoming out	1. Ensure the patient is suited to the rating of the mattress. 2. Ensure the patient is centrally positioned on the mattress. 3. Increase the pressure setting – Refer to the 'comfort control" section of this document.

	4. If the patient is still bottoming out refer to 'incomplete inflation' above

13.Care and Preventative Maintenance

The expected service life of this product is 6 years, subject to appropriate servicing and use following these instructions. Winncare PAC Ltd. recommends annual servicing of this product as a minimum. For optimal performance of the device, more frequent visual and operational inspections are encouraged wherever possible. Contact Winncare PAC Ltd to arrange your annual service. Failure to do so may invalidate the product warranty.

NOTE	Always disconnect the control unit from the mains power supply prior to performing any maintenance procedures (when viable).
NOTE	No modification of this equipment is allowed. Use original parts only.
NOTE	The mattress system should be vacated by the patient before any maintenance or inspection takes place. If this is not possible due to the patient's mobility, care should be taken for the service engineer not to make contact with the patient when working on electrical items.

14.Warranty

This product is covered by manufacturer's warranty as part of the General Terms and Conditions of Business. Some warranty periods may differ – refer to the product features section of this document for the exact warranty period of your product.

Any warranty claims during the warranty period must be investigated by Winncare PAC Ltd, where return of the original product may be required. A warranty claim is successful if the product is faulty due to a manufacturing defect. This warranty does not cover any other damage, including but not limited to: misuse, natural wear and tear, lack of maintenance, accidental damage and unauthorised modifications.

15. Disposal

Should the product reach the end of its use and may no longer be repaired, ensure that it is disposed of following local W.E.E.E. (Waste Electrical and Electronic Equipment) policies. Alternatively, contact Winncare PAC Ltd to arrange for collection. The metal and plastic components used in both the mattress and control unit should be separated and recycled – consult local recycling practices for further information.

WARNING

Do not dispose in general waste. RISK OF ENVIRONMENTAL CONTAMINATION.

CAUTION

Ensure device is cleaned and disinfected prior to disposal.

16.Technical Specifications

16.1 Control Unit

Control Unit: CU-PUR-6	
Dimensions (mm) H x W x D	180 x 390 x 193.4
Weight (kg)	4.1
Cycle time (min)	10,15 &20 / AB
Air Output (L/min)	13
Power cord length (m)	4.5
Noise Level	<40dB(A)
Supply Rating	230V, 50Hz, 12W
Fuse Rating	Mains Plug – 5A Control Unit - T1A, 250VAC
Mains Plug	Type G/BS1363/A
Electrical classification	Electrical shock protection: Class II, Type BF Applied Part: Mattress Liquid ingress protection: IP21 not AP or APG equipment*
**Not suitable for use in the presence of flammable aesthetic mixtures with air, oxygen or nitrous oxide.*	

16.2 Mattress and Top Cover

Mattress Base Unit: PUR-8-AC-M and Top Cover: SMP934	
Number of cells	23
Cell Material	TPU
Cell depth (inches)	8 (4x4 static base)
Base Material	Nylon PVC
Weight (kg)	11
Emergency	CPR Dial
Top Cover Material	PU and Polyester mix

16.3 Transport and Operating Conditions

Transport and storage conditions	Temperature: -25°C to +70°C Humidity: < 93% max, non-condensing
Operational conditions	Temperature: +5°C to +40°C Humidity: 15% - 93%, non-condensing Atmospheric Pressure: 700hPa to 1060hPa Operating Altitude: ≤ 2000m Pollution: Degree 2 UV: Intended for indoor use only

16.4 Safety Standards

BS EB 60601-1:2006+A13:2024
IEC 60601-1-11
IEC 60601-1-2
BS EN 61000
IEC 61000-3-3
IEC 61000-3-2
IEC 61000-4-2
IEC 61000-4-4
IEC 61000-4-5
IEC 61000-4-11
IEC 61000-4-8
IEC 61000-4-6
IEC 61000-4-3

16.1 Electromagnetic Compatibility

The control unit has been designed to meet the EMC requirements of BS EN 61000. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. They are in place to provide reasonable protection against dangerous interference in a medical or residential environment.

Immunity to electromagnetic interference - this refers to the levels of electromagnetic interference that the control unit can withstand from nearby sources radiating radio frequency (RF) energy (e.g. from mobile phones, network devices etc).

Electromagnetic emissions - this refers to the levels of RF energy the control unit emits.

The immunity levels are set out in the following manufacturer's guidance. If these levels are exceeded, then the system may not operate correctly or stop operating. It is important, therefore, to try to ascertain the source of the interference by turning nearby equipment off. There are simple measures that can be taken to correct the problem:

- Remove or relocate the interfering equipment,
- Increase the separation distance between the control unit and the interfering equipment.

The RF emissions are set out in the following manufacturers' guidance. The control unit generates very low RF energy, however, interference to sensitive equipment is still possible. If interference to radio/TV reception and/or other equipment is suspected, turning the control unit off and on can determine if this is the case. There are simple measures that can be taken to correct the problem:

- Relocate the receiving antenna,
- Increase the separation distance between the control unit and affected equipment.

Due to the increasing number of wireless devices, such as laptops and mobile phones, it is important that the system is installed following the manufacturer's guidance to ensure continued and reliable operation.

Requirements according to BS EN 61000 and BS EN 60601-1:2006+A13:2024: Guidance and manufacturer's declaration – electromagnetic emissions		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emission CISPR 11	Group 1	The control unit 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 emission CISPR 11	Class B	The Dynamic Mattress System 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Requirements according to BS EN 61000 and BS EN 60601-1:2006+A13:2024: Guidance and manufacturer's declaration – electromagnetic immunity			
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 differential mode ±2 kV common mode	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)	±1 kV differential mode	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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
†UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000- 4-6 **Radiated RF IEC 61000- 4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*,

			should be less than the compliance level in each frequency range**. Interference may occur in the vicinity of equipment marked with the following symbol: 

* Field strengths from fixed transmitters 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 dynamic mattress system is used exceeds the applicable RF compliance level above, the dynamic mattress system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the control unit			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m) Electromagnetic environment – guidance		
	150 KHZ TO 80 MHZ D = 1.2√P	80 MHZ TO 800 MHZ D = 1.2√P	800 MHZ TO 2.5 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
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.

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

17.Contact Information

WINNCARE PAC Ltd.
Unit 2 Interchange Way,
Oakenshaw
Bradford,
BD12 7AZ
United Kingdom

Customer Service
Tel +44 0800 193 6030
Email: askus@winncare.uk
Servicing Email: askservice@winncare.uk
www.winncare.uk

WINNCARE France
4, Le Pas du Chateau,
85670 Saint-Paul-Mont-Penit
France
Tel. +33 (0)4 66 02 15 15

www.winncare.fr

NOTE	Inform the competent authority if you believe or have reason to believe that the device presents a serious risk or that it has been tampered with. All serious incidents which are related to the device must be notified to the manufacturer and the competent authority of the member state in which the user and/or patient resides.