Pure Air 105 /110 / 120 / 135 / 150 Dynamic Mattress System (PUR-105 / PUR-110 / PUR-120 / PUR-135 / PUR-150)

INSTRUCTIONS FOR USE

This manual MUST be read BEFORE using this product

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Contents

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1. Introduction

This document outlines important information and instructions for use (IFU) on the safe and effective use of the product. Read all instructions carefully before using the product. Store the IFU in a designated area, where it is always easily accessible. If unsure, consult a medical professional regarding the correct use of the product. For further product-related information, contact Winncare PAC Ltd; see the "Contact Information" section 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 not followed, 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 the correct use of the equipment.

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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 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 indicates 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

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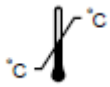
	Batch code
	Name and address of the manufacturer
	Date of manufacture
	Temperature limitation indicates the temperature limitation for the product during usage
	Unique device identifier
	Authorized Representative in the European Community
	Disinfect by wiping the surface using a hypochlorite solution 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 the system is dry before storing, use and reuse.
	Do not place heavy objects on the surface of the cover other than the patient

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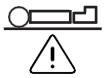
	Do not use when damp, ensure surface is dry before use
	Do not fold. Roll pack the system
	Do not use sharp objects
	Max Patient weight defines the maximum total load of the patient kg (lb)
	Safe Working load (SWL) is the maximum combined weight of the patient and any equipment that the mattress can 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 pull 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.

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CAUTION

Complete a risk assessment if any accessory is used with the device.

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

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

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 device is plugged into mains power supply for optimal function.

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.

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5. Product Overview

This product is made of the following components:

Pure Air 105 /110 / 120 / 135 / 150 Dynamic Mattress Systems		
Control Unit	CU-PUR-7	
Mattress Base Unit	PUR-105: PUR-105-M PUR-110: PUR-110-M PUR-120: PUR-120-M	PUR135: PUR-135-M PUR150: PUR-150-M
Top Cover	PUR105: SMP821 PUR110: SMP878 PUR120: SMP814	PUR135: SMP552 PUR150: SMP553

Control Unit

1. Control Panel
2. Air Filter
3. On/Off switch
4. Mains Power Cable
5. Female Air Connector Port
6. Pad
7. Hooks

Mattress

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

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6. Product Features

Pure Air 105 /110 / 120 / 135 / 150 Dynamic Mattress Systems	
Size (mm) L/W/H	2000 x 1050 x 203 (PUR-105) 2000 x 1100 x 203 (PUR-110) 2000 x 1200 x 203 (PUR-120) 2000 x 1350 x 203 (PUR-135) 2000 x 1500 x 203 (PUR-150)
Maximum Patient Weight	298 kg / 47 stone (PUR-105 / PUR-110/ PUR-120) 381 kg / 60 stone (PUR-135 / PUR-150)
Safe working load	298 kg / 47 stone (PUR-105 / PUR-110/ PUR-120) 381 kg / 60 stone (PUR-135 / PUR-150)
Other Features	• One in two cell-cycle design giving optimum therapy • 8” depth • Nylon/PU air cell construction • Multi-stretch, waterproof and vapour permeable cover • CPR pull strap for rapid deflation • Machine washable cover up to 95°C • Mattress weight: 10 kg (PUR-105 / PUR-110), 11 kg (PUR-120), 12.5 kg (PUR-135), 14 kg (PUR-150) • Optional 10/15 mins cycle time • Pressure range: 30-60 mmHg • Silent running pump at optimum support pressures • Audible low-pressure alert • Semi-auto pressure adjustment • Static function with auto-return • Cycle time control • Pressure adjustment • Alert mute

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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 servicing.
Reusable	Devices are reusable but must be cleaned between each patient use.
Maintenance or calibration	Perform regular mattress audits to check for fluid ingress and strike-through on the 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 is not 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:

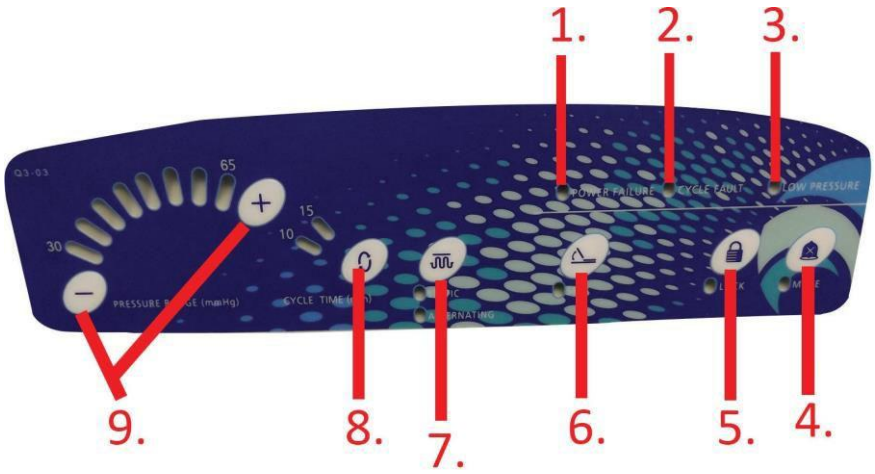
1. Carefully open the packaging.
2. Check the product for any signs of damage. Do not use if damaged and contact your provider or Winncare PAC Ltd.
3. Place the mattress on top of the bed frame with the top cover facing upwards and the male air connector at the foot end of the bed.
4. Attach the mattress 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. Check the CPR connector is firmly in position.
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 with the male air 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. Plug the mains cable into a suitable mains supply and switch on the control unit.
9. The mattress will start to inflate and will be completely inflated within 30-45 minutes.
10. Once fully inflated, adjust the straps that attach the mattress to the bed frame, ensuring the mattress is held securely in place.
11. 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 Failure A red indicator flashes and an audible alert sounds if a power failure occurs.
2.	Cycle Fault A red indicator flashes and an audible alert sounds if alternation failure occurs.
3.	Low Pressure A red indicator illuminates when setting the pressure during installation. A red indicator flashes and an audible alert sounds if the pressure becomes unacceptably low during operation.
4.	Alert Mute/Reset To mute an audible alert, press the button. The amber indicator will illuminate. Press the button to reset the alert.
5.	Function Lock The control unit will automatically lock out all functionality approximately 2 minutes after a function change. To unlock the control unit, the 'lock' button is pressed for 2 seconds. To re-engage the lock, the button can either be pressed for 2 seconds or the user can wait for the automatic lock to re-engage.

CAUTION

Ensure there is no accidental deactivation of the system. Function lock does not lock the on/off switch.

6. Seat Function
Can be used to increase the pressure when backrest is raised on profiling beds. Press the seat button and the amber light illuminates. The green light for alternating goes off.

NOTE	There is no auto-return on seat function. To return to static/alternating mode press lock symbol for 2 seconds. Select alternating/static mode. Lock will automatically re-engage or press lock symbol for 2 seconds to re-engage

7. Static/Alternating Mode
Press to select 'alternating' mode. This inflates and deflates the cells in sequence over the cycle time selected – green light illuminated.
Press to select 'static' mode. This fully inflates all cells with no dynamic alternation (also known as max inflate) – amber light illuminated. For safety, static mode will auto-return to alternating mode after 30 minutes.

8. Cycle Time
Press the button to change between cycle times. The green indicator next to the '10' will be illuminated to show it is selected. When '15' is selected, both lights will be illuminated.

NOTE	Static mode will automatically reset to alternating mode after 30 minutes.

9. Pressure Adjustment
Press + to increase the pressure and press - to decrease the pressure.
There are 8 available pressure settings from soft to firm (30 mmHg to 65 mmHg). The green lights illuminate to indicate which of the 8 settings is operational.

9.3 Mattress operation

1. Turn on the power on the control unit. The pump will start to inflate the mattress.
2. The red low-pressure indicator will illuminate as inflation commences.
3. Green indicators will illuminate to show the cycle time, pressure range and mode selected. The system defaults to alternating mode, 10-minute cycle time and the 3rd pressure setting.
4. After 2 minutes, the amber function lock indicator will be illuminated.
5. Once optimum pressure is reached (after 30-40 minutes), the amber low-pressure indicator will switch off.
6. Switch off the function lock and adjust the pressure to provide a comfortable pressure level for the patient.
7. Using clinical judgement and continuous monitoring of the patient for up to 72 hours, increase or decrease the pressure levels to suit the patient's comfort levels.

NOTE	The mattress can be used on a profiling bed where the backrest is profiled to an angle of 65°. Pressure settings may need to be increased. Use clinical judgement to optimise pressure relief.

CPR Function

In an emergency, rapid deflation of the mattress may be required. The CPR pull strap is located at the head end of the mattress.

To reinflate, push the CPR connector back into the closed position. The mattress will start to inflate. Wait for optimal pressure to be reached before using the mattress.

Static Mode

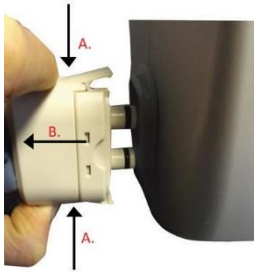
The mattress should always be used in alternating mode. Static mode (also known as max inflate) can be selected for short periods if a patient to provide a firm base for clinical/nursing needs.

When static mode is selected, all air cells inflate to the pressure that is set, creating a static surface. If, after 30 minutes, the control unit is still set to static mode, it will automatically return to alternating mode. This is for patient safety, to ensure they are not left on a constantly inflated surface.

Transporting the Mattress

If the mattress is disconnected from the power supply so it can be moved, or in the event of a mains power failure, carry out the following procedure to maintain mattress inflation:

1. Disconnect the air tube set with the male connector from the power unit by squeezing the two tabs (A) and pulling away from the control unit (B).



2. Seal using the cap marked “Transport”, which is attached to the male connector.
3. Switch off the control unit.
4. Disconnect from the power supply.
5. The mattress can now be moved.

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.
NOTE	Complete instructions above quickly to minimize air loss

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 mains power supply, alternating mode will not available. RISK OF LIMITED PRESSURE RELIEF.

10. Cleaning and Disinfection

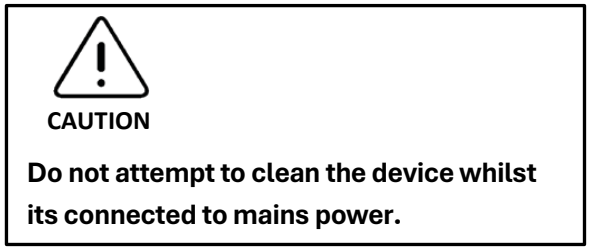
Cleaning and disinfection of the product is mandatory. As a minimum, cleaning and disinfection should be performed as soon as the device is taken out of storage, between each patient, at regular intervals whilst in use and before being placed into storage. Consult local practice guidelines for more details 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

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

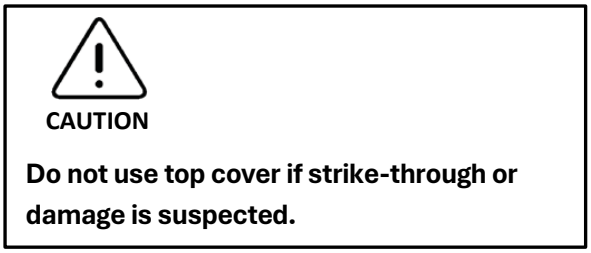
CAUTION

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



CAUTION

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

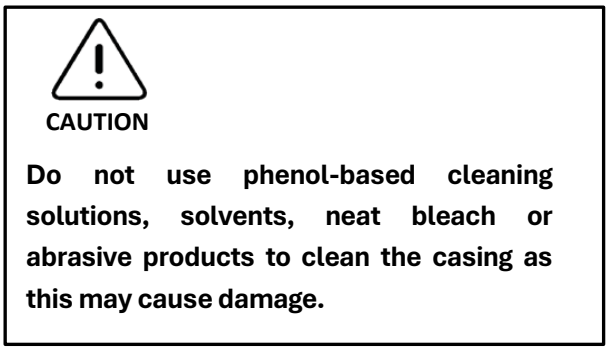


CAUTION

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

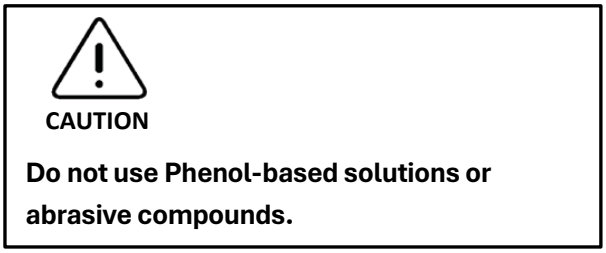
CAUTION

Do not autoclave.



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 Phenol-based solutions or abrasive compounds.

10.1 Cleaning and Disinfection Protocol: Control Unit

1. Visually check the product for external damage – do not use if damage is found.
2. Place the pump 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 reuse.

10.2 Cleaning and Disinfection Protocol: Mattress

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.

1. The mattress should be regularly checked for damage or tears. Replace if damaged.
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 and allow to fully dry before use.

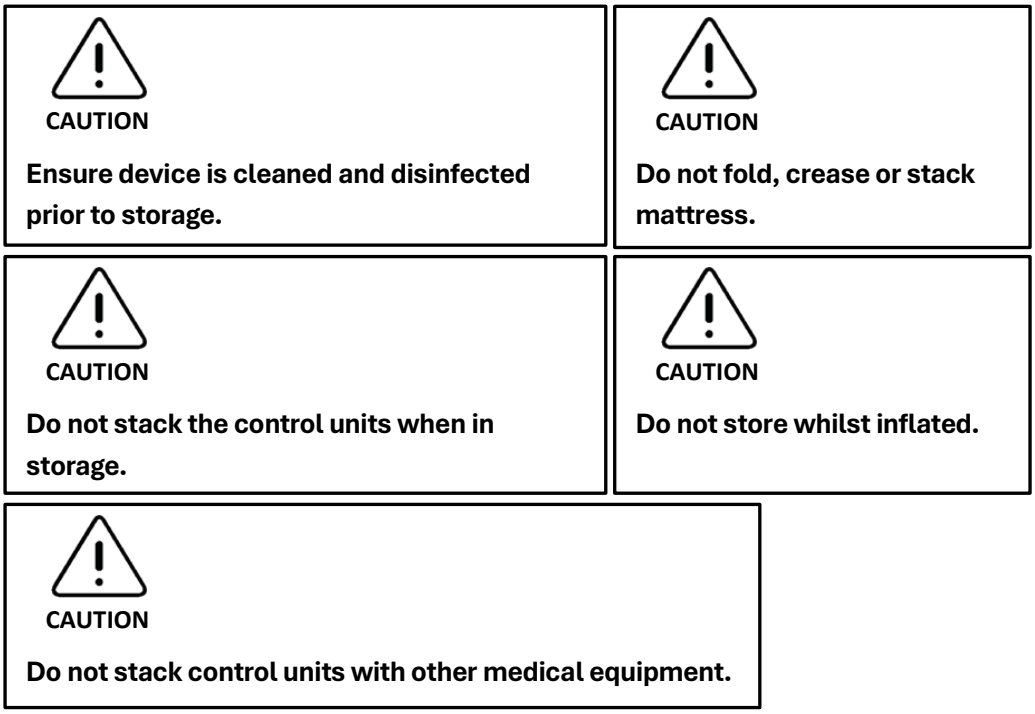
Disinfection

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 life span 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 either storing or reusing.

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

11. Storage

Follow the instructions below to prepare the product for storage.



1. Detach the control unit from the mattress.
2. Pull the CPR pull strap 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

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	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 'Technical Specifications' section. 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	1. Ensure the mattress air tube set is properly connected to the control unit, is not constricted in any way and has no kinks. 2. Ensure the CPR pull strap is firmly in place 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
Alternating mode failure	1. Turn off the control unit. 2. Disconnect the air tube set with the male air connector to reduce cell pressure. 3. Reconnect the air connector. 4. Turn on the control unit. 5. If alternating mode is still inoperable, turn off at the mains and contact your approved service provider
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 'Mattress Operation' section. 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 a 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

CU-PUR-7	
Dimensions (mm) H x W x D	250 x 369 x 135
Weight (kg)	3.6
Cycle time (min)	10 & 15 (AB)
Air Output (L/min)	12
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-105-M	PUR-110-M	PUR-120-M	PUR-135-M	PUR-135-M
Top Cover	SMP821	SMP878	SMP814	SMP552	SMP553
Number of cells	20				
Cell Material	TPU				
Cell depth (inches)	8				
Base Material	Nylon PVC				
Weight (kg)	10	10	11	12.5	14
Emergency	CPR pull strap				
Top Cover Material	PU + 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 EN 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

16.5 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 manufacturer's 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 IEC 61000-4-8	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.

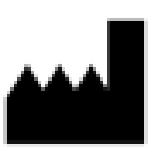
The dynamic mattress system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) 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



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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.