

Argyll Dynamic Mattress System (ARG-142-2)

INSTRUCTIONS FOR USE

This manual **MUST** be read **BEFORE** using this product



Argyll Dynamic Mattress System (ARG-142-2)

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1. Introduction

This document outlines important information and instructions for use (IFU) pertaining to 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 directly; 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	<p>Warning: Safety warning. Failure to obey and understand could lead to injury to yourself or others, and in some circumstances death.</p>
 CAUTION	<p>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.</p>
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> NOTE </div>	<p>Note: Important information users should be aware of for correct use of the equipment.</p>



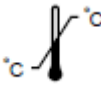










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3. Product Labelling








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

	<p>Instructions for Use Read the Instructions for use before use</p>
	<p>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.</p>
	<p>W.E.E.E Label Waste Electrical and Electronic Equipment.</p>
	<p>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 Winnicare PAC Ltd. immediately</p>
<p>IP21</p>	<p>Protected from touch by fingers and objects greater than 12mm. Protected from condensation.</p>
	<p>CE marking indicating conformity with European Community harmonized legislation. Figures indicate Notified Body supervision.</p>
	<p>UK marking indicating conformity with UK Medical Device Regulations 2002 (SI 2002 No 8, as amended)</p>
	<p>Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.</p>
	<p>Serial number</p>
	<p>Reference number</p>
	<p>Batch code</p>

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	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

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

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4. Warnings and Precautions for Use

 <p>WARNING</p> <p>Do not use device control unit in oxygen rich environment or near flammable gases. RISK OF FIRE AND BURN INJURY.</p>	 <p>WARNING</p> <p>CPR strap must be accessible at all times. RISK OF SERIOUS INJURY OR DEATH.</p>
 <p>WARNING</p> <p>Do not use device with a damaged power cable. RISK OF ELECTROCUTION AND FIRE.</p>	 <p>WARNING</p> <p>Ensure the device is assembled and operated as intended. RISK OF PRESSURE INJURY.</p>
 <p>WARNING</p> <p>Ensure appropriate cable management. Avoid operating the device with loose or severely taught cables. RISK OF TRIP AND FALL INJURY.</p>	 <p>WARNING</p> <p>Do not cover the control unit with blankets and other items. RISK OF FIRE.</p>
 <p>WARNING</p> <p>Do not open or repair the control unit whilst it is in use or connected to mains power supply. RISK OF ELECTRIC SHOCK.</p>	 <p>WARNING</p> <p>Do not spray liquid on the control unit whilst it is connected to mains power. RISK OF ELECTRICAL BURNS.</p>
 <p>WARNING</p> <p>Do not use the device as a repositioning tool. RISK OF PRESSURE INJURY.</p>	 <p>WARNING</p> <p>Do not expose any parts of the device to a naked flame. Do not smoke. RISK OF FIRE AND PROPERTY DAMAGE.</p>
 <p>WARNING</p> <p>Do not use the device as a repositioning tool. RISK OF PRESSURE INJURY.</p>	 <p>WARNING</p> <p>Ensure the patient is manually repositioned at frequent intervals. RISK OF PRESSURE INJURY.</p>

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 CAUTION <p>Complete a risk assessment if any accessory is used with the device.</p>	 CAUTION <p>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.</p>
 CAUTION <p>To ensure optimal function of the device, use suitably trained personnel for servicing and repair. Use original parts only.</p>	 CAUTION <p>Ensure the device is suitable for the patient. Complete a risk assessment if in doubt. Consult a medical professional if in doubt.</p>
 CAUTION <p>Ensure the device is plugged into mains power supply for optimal function.</p>	 CAUTION <p>Ensure the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.</p>
 CAUTION <p>Do not use device alongside hot water bottles or electric blankets. Device performance may be affected.</p>	 CAUTION <p>Complete a risk assessment when using device with incontinence products.</p>

<p>NOTE</p>	<p>Use a CE marked extension cable if device power cable cannot reach wall socket. If in use, do not overload.</p>
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5. Product Overview

This product is made of the following components:

Control Unit

1. Control Panel
2. On/Off Button
3. Female Air Connector Port
4. Air Filter
5. Fuse Holder
6. Pad
7. Hooks



Mattress

1. Top Cover
2. Air Cells
3. Air tube assembly leading to Male Air Connector (not shown)
4. CPR Pull Strap



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6. Product Features

ARG-142-2: Argyll Dynamic Mattress System	
Size (mm) L/W/H	1980 x 880 x 200
Maximum Patient Weight	< 230 kg (36 stone)
Safe working load	230 kg (36 stone)
Other Features	<ul style="list-style-type: none"> • One in two cell cycle design (AB cell pattern) • 20 cells: 3 static head cells and 17 fully alternating cells • 8" Cell on Cell design • Nylon PU air cell construction • Welded, multi-stretch, waterproof, vapour permeable cover with antibacterial and antifungal properties • Machine washable cover up to 95°C • CPR tag for rapid deflation • 11.5 mins cycle time • Pressure range: 10-52 mmHg • Audible low-pressure alert • Semi-auto pressure adjustment • Max air function with auto-return • Alert mute • Control panel lock

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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	2 years subject to regular maintenance and servicing.
Reusable	Devices are re-usable and 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 is not limited to: <ul style="list-style-type: none"> • 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 • Unauthorised people with access to the controls • Use with other medical accessories e.g. incontinence products

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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 air tube set at the foot end of the bed.
4. Attach the mattress to the bed frame by securing with the adjustable securing straps.

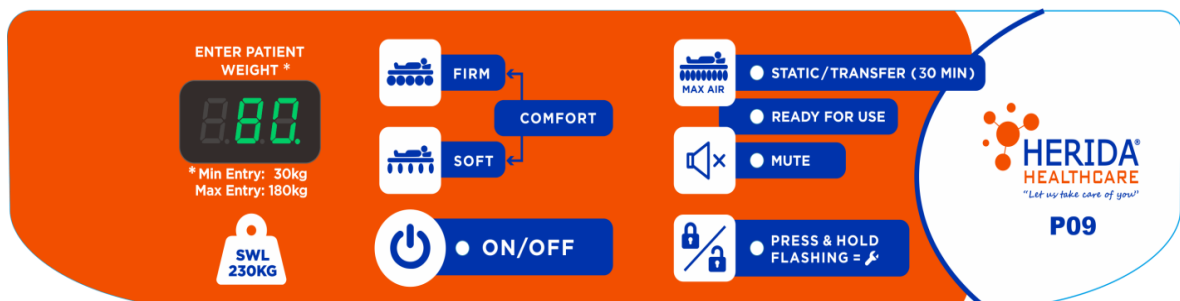
NOTE

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. Ensure the CPR pull strap is easily accessible at all times.
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 using the male air connector on the mattress to the female air connector port on the control unit, 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 be inflated when the control unit is switched on.
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.



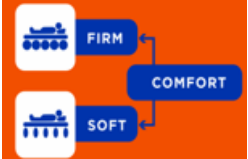




9. Product Operation

9.1 Control Panel



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9.2 Control Unit Operation

	<p>1. POWER Press to turn the pump on and off.</p>
	<p>2. ADJUSTING THE CELL PRESSURE TO SUIT THE PATIENT The system defaults to a patient weight of 80 kg. To adjust this to suit the individual, use the comfort control buttons to increase or decrease pressure within the cells.</p> <p>NOTE: The patient weight function is only to be used as guide to estimate the most comfortable pressure setting for the individual using the surface. If the weight entered is not providing a comfortable and supportive pressure, the weight can be increased or decreased accordingly to ensure a more comfortable and supportive pressure using the Comfort Control.</p>
	<p>3. COMFORT CONTROL Press FIRM to increase or SOFT to decrease the pressure. Each single push adjusts ± 5 kg. To advance the increase or decrease in pressure units faster, keep the button pressed.</p>
	<p>4. MAX AIR (also known as Max Inflate) All cells will fully inflate to 52 mmHg / 180 Kg and remain static (with no dynamic alternation – also known as max inflate). The digital display will show “- - -”. The control unit will revert to the previous alternating setting after 30 minutes.</p>
	<p>5. PRESSURE MONITOR The LED illuminates when pressure is normal. If there is an issue with pressure, the LED will not be illuminated. The LED will flash continuously when the cells are changing over from inflate to deflate (also known as change-over)</p>
	<p>6. MUTE When pushed, the audible alarm is silenced.</p>
	<p>7. LOCK/UNLOCK/MALFUNCTION</p> <ul style="list-style-type: none"> • Push the button for 2-3 seconds to lock / unlock the panel. • The LED will flash continuously: <ul style="list-style-type: none"> ○ when the mattress has not yet reached pressure during alternating cycles. ○ If the mattress has an air leak, or the pressure has dropped lower than 6 mmHg. • When the panel is unlocked, it will automatically lock after a few minutes. • The lock/unlock function will not operate if the system has a pressure failure.

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CAUTION

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

NOTE

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

NOTE

The mute setting will automatically cancel after **15** minutes. The audible signal will re-sound.

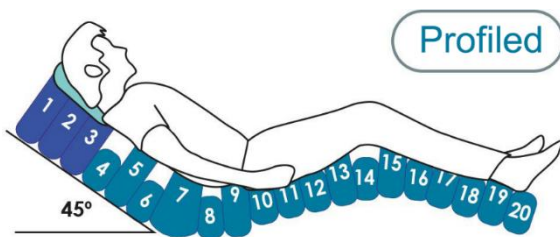
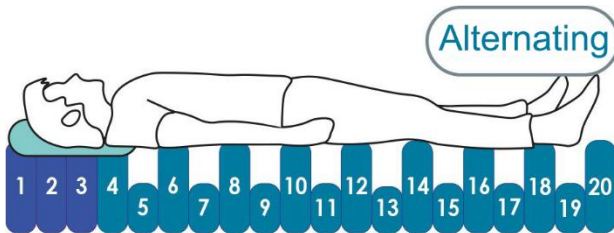
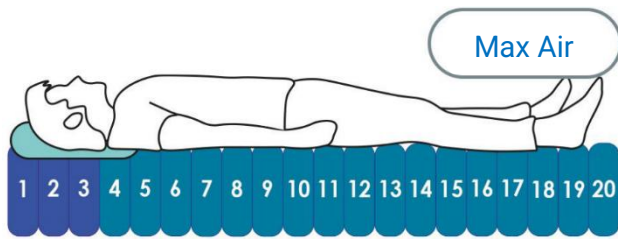
9.3 Mattress operation

1. Turn on the power to the control unit. The control unit will start to inflate the mattress.
2. The lock/unlock LED will continually flash whilst the system reaches pressure. Once the system reaches pressure (after approx.. 30-40 minutes) the Ready For Use LED will illuminate.
3. The system will default to a patient weight of 80 kg. This must be manually changed to suit the individual patient by using the comfort \pm buttons.

Weight (Kg)	Pressure (mmHg)	Weight (kg)	Pressure (mmHg)
30	10	110	26
40	12	120	28
50	14	130	30
60	16	140	32
70	18	150	34
80	20	160	40
90	22	170	46
100	24	180	52
This is subject to a tolerance of ± 3 mmHg			

4. If the weight entered is not providing a comfortable and supportive pressure, then the weight can be increased or decreased accordingly to ensure a more comfortable and supportive pressure using the Comfort Control. Switch off the function lock and adjust the pressure to provide a comfortable pressure level for the patient.
5. Using clinical judgement and with continuous monitoring of the patient for up to **72** hours, increase or decrease the pressure levels to suit the patients comfort levels.

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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.

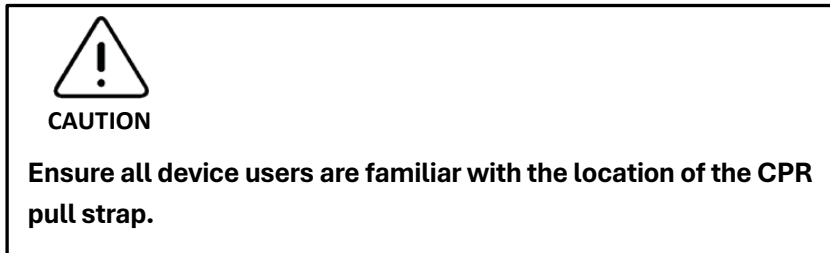
Semi-Auto Pressure Adjustment

Once the pressure level has been set, the control unit monitors the mattress pressure and maintains it at the set level. If the pressure falls below this level, the control unit will automatically speed up inflation of the mattress until the correct pressure is met. If the control unit is unable to maintain the set pressure, an audible alert will sound, and the low-pressure indicator light will flash. If this occurs, refer to the 'Troubleshooting' section.

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.

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To re-inflate push the CPR pull strap back into the closed position. The mattress will start to inflate. Wait for optimal pressure to be reached before using the mattress.

Max Air Mode

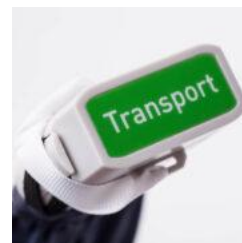
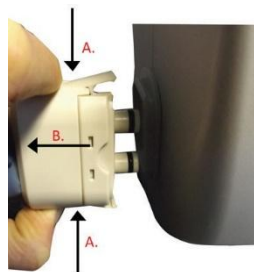
For patient safety, the mattress should always be used in alternating mode. Max Air mode may be selected for short periods to provide a firm base for clinical/nursing needs.

When max air mode is selected, all air cells inflate to the pressure set, creating a static surface.

If, after 30 minutes, the control unit is still set to max air 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 from the control unit by squeezing the two tabs (A) on the male connector and pull away from the control unit (B).
2. Seal using the cap marked "Transport" which is attached via a cord to the male connector.
3. Switch off the control unit.
4. Disconnect from the power supply.
5. The mattress can now be moved.

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NOTE

In the event of a power fail, 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.

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10. Cleaning and Disinfection

Cleaning and disinfection of the device is mandatory. As a minimum, cleaning and disinfection should be performed before 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.

 <p>WARNING</p> <p>Wear appropriate personal protective equipment (PPE) when cleaning the mattress or control unit. RISK OF SKIN IRRITATION</p>	 <p>CAUTION</p> <p>Do not immerse or soak the control unit. Do not spray any cleaning solution onto the control unit.</p>
 <p>CAUTION</p> <p>Do not attempt to clean the device whilst its connected to mains power.</p>	 <p>CAUTION</p> <p>Do not use Phenol-based solutions or abrasive compounds.</p>
 <p>CAUTION</p> <p>Do not use top cover if strike-through or damage is suspected.</p>	 <p>CAUTION</p> <p>Do not autoclave.</p>

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 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 around 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 putting back into use.

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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 cloth moistened with a mild detergent and diluted in warm water (40°C).
3. Rinse with cold clean water using 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. Re-assemble 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.

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11. Storage

Follow the instructions below to prepare the product for storage.


 CAUTION Ensure device is cleaned and disinfected prior to storage.	 CAUTION Do not fold, crease or stack mattress.
 CAUTION Do not stack control units with other medical equipment.	 CAUTION Do not stack the control units when in storage.
 CAUTION Do not store whilst inflated.	

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 from dirt, debris, fluids etc. with a suitable identification tag.
7. If taking a device out of storage, unfold the mattress and allow to lie unfolded for several minutes. Allow product to acclimatise to the operating conditions.

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12. Troubleshooting

Table below provides a guide to the product's 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.
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Problem	Actions
Power Failure	<ol style="list-style-type: none"> 1. Turn off the control unit to silence the alarm and unplug from the mains supply <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">NOTE</p> <p>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.</p> </div> <ol style="list-style-type: none"> 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 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 'Technical Specifications' section. 8. Turn on the control unit. 9. If control unit still fails to operate, turn off at the mains and contact your approved service provider.
Incomplete inflation/low pressure	<ol style="list-style-type: none"> 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 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.

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Problem	Actions
	6. If a low-pressure indicator is still evident turn off at the mains and contact your approved service provider
Alternating mode failure	<ol style="list-style-type: none"> 1. Turn off the control unit. 2. Disconnect the male air connector to reduce cell pressure. 3. Reconnect 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	<ol style="list-style-type: none"> 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 ‘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 in accordance with these instructions. Winnicare 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 Winnicare PAC Ltd to arrange your annual service. Failure to do so may invalidate 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.

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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 pertaining to your product.

Any warranty claims during the warranty period must be investigated by Winncare PAC Ltd, where return of the original product maybe 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 unauthorized modifications.

15. Disposal

Should the product reach the end of its use and no longer be repaired, ensure that it is disposed of in accordance with 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.



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16. Technical Specifications

16.1 Control Unit

Control Unit: PUMP1009	
Dimensions (mm) H x W x D	140 x 260 x 95
Weight (kg)	1.35
Cycle time (min)	11.5
Air Output (L/min)	>5
Power cord length (m)	4.5
Noise Level	≤45dB
Supply Rating	220 ~ 240V, 50Hz, 8W
Fuse Rating	Mains Plug – 3A Control Unit – F1A, 250V
Mains Plug	Type G/BS1363/A
Electrical classification	Electrical shock protection: Type BF Applied Part: Liquid ingress protection: IP21 Not AP or APG equipment*
<i>*Not suitable for use in the presence of flammable aesthetic mixtures with air, oxygen or nitrous oxide.</i>	

16.1.1 Internal Cell Pressure

According to the weight data manually selected to suit the individual patient, the table below highlights the corresponding internal cell pressure.

Weight (kg)	Pressure (mmHg)
30	10
40	12
50	14
60	16
70	18
80	20
90	22
100	24

Weight (kg)	Pressure (mmHg)
110	26
120	28
130	30
140	32
150	34
160	40
170	46
180	52

This is subject to a tolerance of ±3 mmHg

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16.2 Mattress and Top Cover

Mattress Base Unit: D1002 and Top Cover: E1002	
Number of cells	20
Cell Material	Nylon PU
Cell depth (inches)	8" Cell on Cell
Base Material	Nylon PVC
Weight (kg)	10
Emergency	CPR pull strap
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 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

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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 interferences 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 manufacturers 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	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	Complies	

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IEC 61000-3-3			
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.
<i>†UT is the a.c. mains voltage prior to application of the test level.</i>			
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.

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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
			<p>Recommended separation distance. $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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:</p> 
<p>* 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 Dynamic mattress system is used exceeds the applicable RF compliance level above, Dynamic mattress system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.</p> <p>** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

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.
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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

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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.

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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.