Select Medical
purely pressure care

Dynamic Pressure Redistribution Mattress

User Manual

(IFU-217-01)

Select Medical Ltd: 01 June 2024

Pure Air 8 Auto Reactive IFU-217-01

Review V1.1

USER MANUAL - Pure Air 8 Auto Reactive

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STATEMENTS AND SYMBOLS


Refer to manual


Warning to highlight potential hazards that, if disregarded, could lead to injury or death.


Caution to highlight potential hazards that, if disregarded, could lead to equipment damage or failure.

NB: Tips or information users should be aware of

IMPORTANT NOTICE


Before operating this medical equipment, it is important to read this manual and understand the operating instructions and safety precautions. If you have any questions regarding the use of this equipment please contact your supplier.

INTRODUCTION


Thank you for choosing the Pure Air 8 Auto Reactive dynamic, pressure redistribution system. This manual should be read carefully before using the mattress as it contains important safety and maintenance information to ensure long lasting and reliable service.

CONTACT INFORMATION

For any service, warranty, sales or customer service information on this product please contact your supplier or, if in doubt, contact Select Medical Ltd. at the following address:

Select Medical Ltd, Unit 10 Philips Rd, Whitebirk Ind Estate, Blackburn, BB1 5NA.

Customer Service: +44 (0)1254 685538 **Sales:** +44 (0)1254 668899
Email: info@selectmedical.co.uk
www.selectmedical.co.uk

PRODUCT OVERVIEW

Environment

Your dynamic mattress system is intended for use in the following environments:

- A hospital where medical supervision and monitoring are provided.
- A care environment where medical supervision and monitoring are provided (e.g. nursing homes, care home, rehabilitation facilities etc.)
- A domestic environment where the mattress is used to alleviate or compensate for an injury or disability.

Intended Use

Pure Air 8 Auto Reactive is a top of the range, dynamic pressure redistribution system suitable for individuals up to **very high risk** of developing a pressure ulcer or for those with existing tissue damage.

Pure Air 8 Auto Reactive provides regular periods of pressure reduction to vulnerable tissue areas, aiding blood and lymphatic flow which is vital to maintaining healthy tissue. The mattress system is designed to be used on standard or profiling beds.

For assistance in setting up, using or maintaining your dynamic mattress system, or to report unexpected operation refer to the contact details found on page 2.

FEATURES

Please refer to the CE label on the back of the control unit for your product code.

SM036V2-AR **Mattress**	**Control Unit**
• One in two cell-cycle design giving optimum therapy • 20 fully alternating air cells • 8” depth, split cell design including static base • Durable PU air cell construction • Welded, PU multi-stretch waterproof and vapour permeable cover • Machine washable cover up to 95°C • Easy turn CPR for rapid deflation • 3 year warranty (subject to annual service)	• Optional 10/15 mins cycle time • Silent running pump at optimum support pressures • Audible low pressure alert • Automatic pressure adjustment • Optional manual pressure adjustment • Static with auto-return • CLP function • Cycle fault audible alert • Alert mute • Control panel lock

SAFETY

General Safety

- The mattress system & control unit must be installed and used in accordance with the information provided in this manual.
- The mattress system is typically not suitable for children. If it is to be used by a child ensure a risk assessment has been undertaken.
- Before using the system ensure that the mains lead is free from damage and is positioned so as not to cause an obstruction or trip hazard.
- Exposure of the control unit to any liquid while it is plugged in could cause a severe electrical hazard.
- Use care when handling or transporting the control unit. Dropping or other sudden impacts may result in damage to the unit.
- Do not open the control unit or attempt to repair or service the unit. Repairs and servicing should always be undertaken by suitably trained personnel.
- If the control unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately.
- Do not use the system near a heat source or naked flame.
- Do not use with hot water bottles or electric blankets.
- Do not use liquids near the control unit if plugged in.
- Do not place any objects, such as blankets, on or over the control unit.
- Do not use the control unit near flammable gas or in oxygen rich environments as this poses a fire risk or risk of explosion.
- The control unit should be locked when a patient is left unattended.
- Always assess the risk of intentional or unintentional tampering of the control unit.

Risk Assessment

It is the responsibility of the carer/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.
- Unauthorised people with access to the controls.

Contraindicators

Patient conditions for which the application of pressure relief on an alternating mattress system is a contraindication are as follows:

- Cervical or skeletal traction.
- Unstable spinal fractures.

Other contraindications may be relevant which are specific to the patient or care environment.

Mattress Load

Minimum Weight Limit:	No minimum
Maximum Weight Limit:	222kg (35 stone)

SYMBOL DEFINITIONS: CONTROL UNIT & MATTRESS

Control Unit

The following symbols are found on the control unit:

Warning: beware of potential hazard

Refer to manual: failure to do so could introduce a hazard

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 Select Medical Ltd. immediately.

IP21 Protected from touch by fingers and objects greater than 12 millimetres. Protected from condensation.

Mattress

The following symbols are found on the mattress:

Disinfect by wiping the surface using a hypochlorite solution diluted 1000ppm. In extreme circumstances 10,000ppm can be used, wipe with cold water to finish.

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

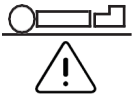
Do not place heavy objects on surface of cover other than the patient

Do not use when damp, ensure surface is dry before use

Do not fold. Roll pack the system

Do not use sharp objects

Only use in conjunction with appropriate medical advice



Max Patient Weight

= 222kg

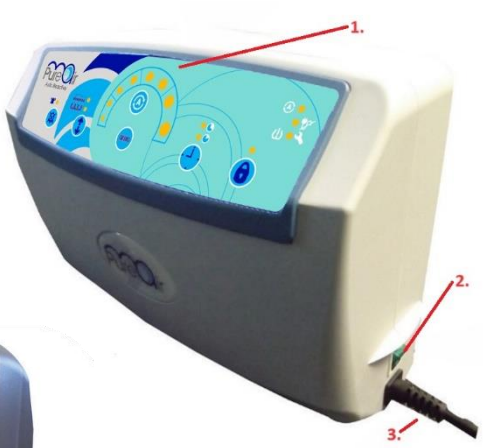
Safe Working Load

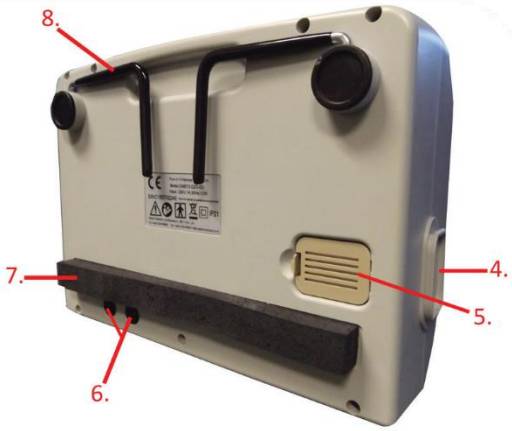
= 222kg

CONTROL UNIT/MATTRESS PARTS

Control Unit

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





Mattress

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

INSTALLATION

Before installing the mattress system please read the warning and caution notes carefully. These highlight risk areas to ensure patient safety.

- Ensure the mattress is only used with compatible equipment/ accessories.
- Ensure the mattress is of the correct type for the patient.
- Ensure the CPR dial is easily accessible at all times.
- Ensure the plug is accessible at all times so the mattress can be disconnected from the mains supply quickly, if required.
- Ensure the mains cable is plugged into an appropriate power source at all times.
- Ensure the mains cable is not taut, particularly if being used on a profiling bed that moves up and down (check all positions).
- Ensure that the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.
- Replace any damaged cable immediately as these cables can create a risk of electrocution and/or fire.
- A CE marked extension cable must only be used when it is not possible to reach a wall socket with the equipment mains cable.
- If an extension cable is used never overload it by plugging in appliances that together will exceed the maximum current rating stated for the extension cable.
- Do not use block adaptors.
- Ensure extension cables or sockets are not placed under the bed frame as liquids could leak onto them posing an electrical/ fire risk.

- Ensure the mains supply is compatible with the control unit (see page 23 for electrical specification)
- Avoid placing the mattress system in direct sunlight as this could damage the mattress cover.

1. Carefully open the packaging.
2. Although unlikely, please check the product for any signs of damage. Do not use if damaged and contact your provider or Select Medical Ltd (see page 2).
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 with the adjustable, securing straps.

- 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 (as below).

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.

- If you are placing the control unit on the floor it is advisable to place the unit on a firm surface.

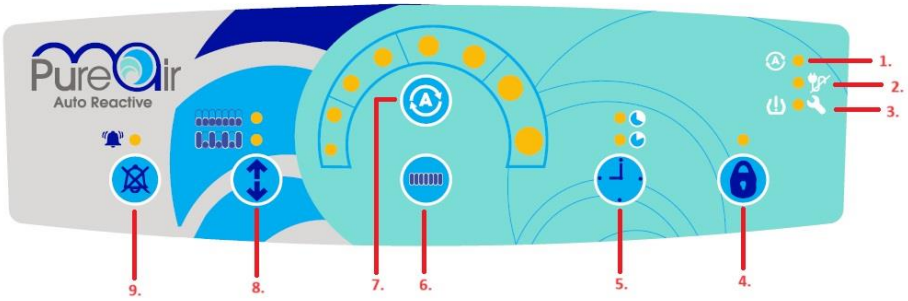
7. Attach the male air connector on the mattress to the female air connector port on the control unit/pump, ensuring the air hose is not kinked or trapped between parts of the bed frame/other equipment.
8. Plug the mains cable into a suitable mains supply and switch on the control unit.

- Ensure the mains cable is positioned so as not to cause a trip hazard.

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 in place securely.
11. Cover the mattress loosely with a sheet, ensuring it does not interfere with cell alternation.

OPERATION

Control Panel



Control Unit Operation

1. Automatic Pressure Adjustment
An amber indicator illuminates when in the default automatic pressure adjustment mode. The amber indicator will switch off when in manual pressure adjustment mode.

2. Power Failure
An amber indicator flashes and an audible signal sounds if a power failure occurs.

3. Low Pressure/Cycle Fault
An amber indicator illuminates when setting the pressure initially.
An amber indicator flashes and an audible signal sounds if the pressure becomes unacceptably low during operation.
An amber indicator illuminates and an audible signal sounds if alternation failure occurs.

4. Function Lock

The control unit will automatically lock out all functionality 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 again pressed for 2 seconds or the user can wait for the automatic lock to re-engage.

When the system is locked an amber indicator illuminates

- When the lock is engaged it does not stop the on/off switch from being pressed. Ensure during use there can be no risk of accidental deactivation of the system.

5. Cycle Time

Press the button to change between cycle times. Please refer to the CE label on the back of the control unit for product code.

SM036V2-AR

15 minutes

10 minutes

The green indicator next to the icons will be illuminated to show which one is selected.

6. Static Mode

Selecting 'Static' mode fully inflates all cells with no dynamic alternation – amber light illuminated.

NB: To ensure patient safety, static mode will automatically revert back to alternation mode after 30 minutes.

7. Mode Select/Comfort Adjustment

Press and hold to switch between automatic & manual pressure adjustment modes. When in manual pressure adjustment mode, press to cycle through the pressure settings.

In alternating mode there are 4 available pressure settings (20mmHg, 25mmHg, 35mmHg, 45mmHg ±2mmHg).

In CLP mode there is 1 available pressure setting (15mmHg). The green light illuminates to indicate which of the settings is operational.

8. Operation Modes – Alternating & CLP Modes

Please refer to the CE label on the back of the control unit for product code.

Selecting 'Alternating' mode  inflates and deflates the cells in sequence over the cycle time selected – green light illuminated.

CLP (Constant Low Pessure):

Selecting 'CLP' mode  inflates all cells to deliver continuous low pressure increasing the area of support – amber light illuminated.

NB: When in CLP mode pressure remains at a constant 15mmHg.

Alternating Sequence:

SM036V2-AR

9.Alert Mute

To mute an audible alert press the button. The amber indicator will illuminate. Re-press the button to reset the alert.

NB: The mute setting will automatically cancel after 15 minutes and the audible signal will re-sound.

NB: If the 'power failure' indicator activates the mute button will not silence the audible signal. To silence, the on/off switch on the control unit must be switched to the 'off' position.

Mattress Operation

1. Turn on the power on the control unit. The pump starts to inflate the mattress.

2. The mattress will inflate in default 'Alternating' automatic pressure adjustment mode. Four indicators on the pressure dial will illuminate. The amber low pressure/cycle fault indicator will illuminate as inflation commences.

3. Green indicator will illuminate to show which cycle time, by default the control unit will be on 10 minutes cycle time, pressure range and mode are selected.

By default the following are selected:

SM036V2-AR
Operation Mode: Alternating Alternating Cycle Time: 10 minutes Pressure Setting: 25mmHg

Complete settings:

SM036V2-AR
Operation Mode: Alternating Alternating Cycle Times: • 10 minutes • 15 minutes Pressure Settings: • 20mmHg (Stage 1) • 25mmHg (Stage 2) • 35mmHg (Stage 3) • 45mmHg (Stage 4)

4. After 2 minutes the amber function lock indicator will be illuminated.

5. Once optimum pressure is reached (about 30-45 minutes) the control unit will beep twice and the amber low pressure/cycle fault indicator will switch off. Once a patient is positioned on the mattress the control unit will enter automatic pressure adjustment mode and the pressure setting will be automatically determined by the downward force of the patients weight.

6. If automatic pressure adjustment mode is not desired, switch off the function lock, switch to manual pressure adjustment mode and adjust the pressure to provide a comfortable pressure level for the patient.

7. 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. If possible, having regular dialogue with the patient is key.

NB: The mattress can be used in an upright position, however the pressure setting may need to be increased. Use clinical judgement to ensure patient comfort and effective pressure relief is maintained.

Automatic/Manual 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 the inflation of the mattress until the correct pressure is achieved. If the control unit is unable to maintain the set pressure an audible signal will sound and the low pressure indicator light will flash. If this occurs refer to the section on 'Troubleshooting' on page 20.

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.

- Carers/care providers should always familiarise themselves with the position of the CPR valve.

CLP Mode
When CLP mode is selected all air cells inflate to deliver continuous low pressure increasing the area of support, with the aim of reducing peak pressure at the interface.

- For optimum performance in CLP mode it is recommended that the surface be utilised in a recumbent position.

Static Mode
For patient safety the mattress should always be used in alternating mode but static mode may be selected for short periods if a patient is finding it difficult to tolerate the alternating mode or 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.

Using Incontinence Products with the Mattress

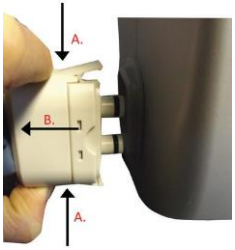
Incontinence products, such as sheets or pads, can be used with the system, however this may compromise the effectiveness of the alternating pressure distribution.

- If incontinence products are being used it is important to carry out a risk assessment and regular patient skin checks.

Transporting the Mattress & Power Cuts

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 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 for safety 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.

NB: Complete the action quickly to limit air loss.

- The mattress will remain inflated for up to 24 hours - return the system to the mains supply as soon as possible.
- Whilst unplugged alternating mode will not be operational and pressure relief will not be provided.
- Do not remove the mattress from the bed frame if the occupant is still on the mattress.
- If it is essential that the patient is moved whilst remaining on the mattress, the mattress must be re-plugged in immediately once the desired location has been reached to reduce the risk of tissue damage.

- Never drag the mattress, always carry it.

CLEANING & DECONTAMINATION

Cleaning

Cleaning is required regularly between patients to prevent cross infection. It is therefore important to clean and decontaminate the control unit and mattress following these procedures.

Control Unit

- Disconnect the mains cable from the power socket before attempting to clean the control unit.
- Do not immerse or soak the pump.
- Do not spray any cleaning solution directly on the surface of the control unit.

- If any of the cleaning/washing instructions are not followed the product warranty will be invalidated.
- Do not use phenol based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.

1. Check for external damage – do not use if damage is found.

2. Place the pump on a work surface and using a clean cloth wipe the outside of the case with a prepared sodium hypochlorite solution (1000ppm).

3. The control unit should be cleaned by starting with the cleanest parts and systematically moving to the dirtiest parts. 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 new clean 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.

Mattress

N.B: 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.

- Do not use the cover if strike-through or damage is found – risk of cross infection. Replace with a new top cover.
- Do not use solvents or alcohol-based cleansers e.g. Phenicol, Hibiscrub, Clearsol, Stericol or Hycoline as these will destroy the mattress materials.
- Do not autoclave.

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

General Cleaning:

1. Wipe down with a clean cloth moistened with a mild detergent and diluted in warm water (40˚C).

2. Rinse with cold clean water and a clean cloth and allow to fully dry before use.

Decontamination

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 (1000ppm) prepared solution of sodium hypochlorite and allow to dry completely. In extreme circumstances 10,000ppm can be used, wipe with cold water to finish.

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 (see pg 19) or reusing.

STORAGE

- The mattress system must be decontaminated prior to any storage to avoid risk of cross contamination.

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 separate, sealed polythene bag to protect from dirt, debris, fluids etc. with a suitable identification tag.

- Do not fold, crease or stack mattresses.
- Do not stack control units.
- Do not store whilst inflated.

Environmental Conditions

The following conditions should be followed when storing the mattress system:

- Ambient temperature: -25°C to +70°C
- Humidity: < 93% max, non-condensing

TROUBLESHOOTING

- DO NOT open the control unit - risk of electrocution
- If mains plug, cable or outer casing is visibly damaged turn off at the mains and contact your approved service engineer.

Problem	Actions
Power Failure	1. Turn off the control unit to silence the alarm and unplug from the mains supply (NB: the mute button does not silence the power failure indication). 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 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 control unit still fails to operate: 7. Replace control unit fuses – See page 23 for fuse types. 8. Turn on the control unit. If 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 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
Alternating mode failure	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.	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' pg 13-14 4. If the patient is still bottoming out refer to 'incomplete inflation' above.

MAINTENANCE

- Always disconnect the control unit from the mains power supply prior to performing any maintenance procedures (when viable).
- No modification of this equipment is allowed.
- 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.
- Only Select Medical approved components specified for Pure Air 8 are to be used - if in doubt contact Select Medical Ltd or your local distributor.

- Only authorised service personnel or Select Medical service engineers should carry out repairs or service activities. Failure to do so may result in the product warranty becoming void.
- The mattress system should be serviced once a year, as a minimum.

General Maintenance

Select Medical recommend that frequent visual and operational inspections are undertaken. Clean the air filter, found at the back of the control unit, once a month with mild detegent. If there are any signs of damage, or the system is not performing as it should, withdraw it from service until the system has been repaired and is fit for use again.

Yearly Maintenance

- Check the air filter is in good condition and replace or clean as required.
- Check that all electrical functions operate correctly on the control unit.
- Check that all audible and visual indicators work appropriately (when plugged in and unplugged from mains supply).
- Check that the mattress reaches the required pressures.
- Check the CPR connection on the mattress.
- Check the cover for tears, punctures, abrasion marks and split seams.
- Check for signs of strike-through (fluid ingress) to the underside of the cover.

- Check that all piping and cells within the mattress are in good condition and that there is no kinking evident.
- Check the control unit housing is not cracked or damaged, if damaged the control unit must be removed from operation immediately.
- Check that the mains cable and plug are in good condition, if either is damaged it must be replaced with a complete assembly, the plug must never be re-wired.

Disposing of Parts

When the electrical system has come to the end of its useful life, contact your provider or Select Medical Ltd. (see pg 2) to arrange for collection, alternatively follow local recycling and W.E.E.E. (Waste Electrical and Electronic Equipment) policies.

- The control unit should not be disposed of in general municipal waste. Some of the electrical components could be harmful to the environment and where viable the components can be recovered and reused/recycled.

The metal and plastic components used in both the mattress and control unit are also to be separated and disposed of following local recycling policy as these can also be recovered and reused/recycled.

- The mattress system is to be decontaminated before disposal to avoid risk of cross contamination.

SPECIFICATION: CONTROL UNIT & MATTRESS

Classification:	Electrical shock protection: Class II, Type BF Applied Part: Mattress Liquid ingress protection: IP21 Not AP or APG equipment*
Supply Rating: Fuse Rating: Mains Plug:	230V, 50Hz, 12W Mains Plug – 5A Control Unit - T1A, 250VAC Type G/BS1363/A

SPECIFICATION

Mattress Dimensions (inflated): Mattress Weight: Maximum Patient Weight: No. of cells: Alternating Therapy: Cycle Time: Pressure Range:	2000mm x 900mm x 203mm 10kg 222kg (35 stone) 20 cells SM036V2-AR: AB pattern, static base SM036V2-AR: Selectable 10 or 15 minute cycle 20mmHg to 45mmHg, ±2mmHg
Control Unit Dimensions: Control Unit Weight:	(H) 206mm x (W) 280mm x (D) 104mm 2.6kg
Cover Material: Cell Material: Base Material:	PU PU Nylon/PVC
Transport and Storage Conditions: Operational Conditions: Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level:	Ambient Temp: -25°C to +70°C Humidity: < 93%, non-condensing Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m Degree 2 Intended for indoor use only <40dB(A)
Warranty:	3 years (subject to annual service)
Safety Standards:	IEC 60601-1: 2005+ A1: 2012 IEC 60601-1-11: 2015 IEC 60601-1-2: 2014 EN 60601-1-2:2015 EN 60601-1: 2006 + A11: 2011 + A1: 2013 + A12: 2014 EN 60601-1-1-11: 2015 CE The control unit is tested and CE marked in line with Medical Device Directive 93/42/EEC
* Not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.	

ELECTROMAGNETIC COMPATIBILITY

The control unit has been designed to meet the EMC requirements of IEC 60601-1-2:2007. 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 IEC 60601-1-2:2007

Pure Air 8 is intended for use in the electromagnetic environment specified below.

- The control unit should not be used next to or stacked with other equipment where possible. If this is unavoidable the control unit should be observed to verify normal operation.

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	Pure Air 8 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	

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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
N.B: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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 $d = 1.2\sqrt{P}$ 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 metres (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: 
N.B: At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagationis affected by absorption and reflection from structures, objects and people.			
* 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 Pure Air 8 is used exceeds the applicable RF compliance level above, Pure Air 8 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienteering or relocating the system. ** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Pure Air 8 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 Pure Air 8 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

N.B: 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.

WARRANTY & SERVICE

- Select Medical Ltd guarantees this equipment under normal use for a period of 3 years (subject to annual service) after delivery to the original purchaser, proof of purchase must be presented with any claim.
- For any equipment returned within the warranty period and proven to be defective we agree to either:
  a) correct the defect by product repair
  b) replace the product with one of the same or similar design or
  c) refund the purchase price, without charge.
  Repaired or replaced parts and products are under warranty for the remainder of the original warranty period. You will be charged for repair or replacement of the product made after the expiration of the warranty period.
- This warranty excludes equipment damage or failure through acts of god, an incidence of excess voltage or current, shipping, tampering, improper maintenance, carelessness, accidental damage, negligence or misuse, or products which have been altered, repaired or dismantled other than with the manufacturer's written authorisation and by its approved procedures and by properly qualified technicians.
- In no event shall Select Medical be liable for any direct or indirect damages or losses resulting from the use of the equipment.

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