User Guide ProCair 3000





Important Notice

Before operating this medical equipment, it is important to read this User Guide and understand the operating instructions and safety precautions. Failure to do so could result in patient injury and/or damage to the product.

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Safety Precautions

The purpose of safety precautions are to attract your attention to possible dangers. The safety symbols and the explanations with them, require your careful attention and understanding.

The safety warnings by themselves do not eliminate any danger. The instructions or warnings they give are not substitutes for proper accident prevention measures.

The following symbols may appear in this User Guide, on the Control Unit, or on its accessories. Some of the symbols represent standards and compliances associated with its use.



SAFETY ALERT SYMBOL: Indicates caution or warning.

> WARNING: Failure to obey a safety warning can result in serious injury to yourself or to others. Always follow the safety precautions to reduce the risk of fire, electric shock and personal injury.



Double insulation is a safety concept of electrical equipment which eliminates the need for earth grounding. Whenever there is electric current in the Control Unit there are two complete sets of insulation to protect the user. All exposed metal parts are isolated from the internal metal motor components with protecting insulation.

WARNING: The double insulated system is intended to protect the user from shock resulting from a break in the Control Unit's internal wiring. Observe all normal safety precautions related to avoiding electrical shock

WARNING: Servicing a Control Unit with double insulation requires extreme care and knowledge of the system and should only be performed by a qualified service technician. For service we suggest you return the Control Unit to your nearest Medistore Authorised Service Centre for repair. When servicing, use only identical replacement parts.



OPERATING INSTRUCTIONS

WARNING: Do not attempt to operate this product until you have thoroughly read and completely understand the safety rules, etc contained in this User Guide. Failure to comply can result in accidents involving fire, electric shock or serious personal injury. Save this User Guide and review frequently for continual safe operation and for instructing others who may use this product.

△! Maximum recommended patient weight for this system is 120kg.

Only the Control Unit and Mattress combination as recommended by Medistore should be used, otherwise the correct function of this product cannot be guaranteed.

Safety Precautions

In General

WARNING: This device is not suitable for use in the presence of a flammable anaesthetic mixture with air, or in the presence of a flammable anaesthetic mixture with oxygen or nitrous oxide.

WARNING: Bed frames used with the systems can vary greatly depending on the specific health care setting (ie hospitals, nursing homes, home care, etc). It is the responsibility of the caregiver to take the necessary precautions to ensure the safety of the patient. This includes, but is not limited to, the appropriate use of side rails to prevent falls and/or patient entrapment.

IMPORTANT: Minimise articles between the system surface and patient, and secure bed sheets loosely so as not to affect the alternating cell movement.

WARNING: Significant risks of reciprocal interference may be posed by the presence of the system during specific investigations or treatments. Potential electromagnetic or other interference between the system and other devices may occur. If interference is suspected, move equipment from sensitive devices or contact Medistore.

Control Unit

Only plug into a grounded power receptacle and use the power cord supplied with the system.



Exposure of the electronic Control Unit to any liquid while it is plugged in could result in a severe electrical hazard.



Medistore recommends placing the cord under the bed frame and attaching it to an electrical outlet by the head of the bed.



The power cord to the Control Unit should be positioned to avoid a tripping hazard and/or damage to the cord.



Do not place any objects or items, such as blankets, on or over the Control Unit.



The electronic Control Unit is a precision electronic product. Use care when handling or transporting. Dropping or other sudden impacts may result in damage to the unit. Before attaching the Control Unit to the floor or the foot board of the bed, ensure they are sufficiently robust and free of damage.



WARNING: Do not open the Control Unit - risk of electrical shock. Do not attempt to repair or service the Control Unit. If parts need to be repaired, circuit diagrams and parts lists can be provided by Medistore to suitably qualified service personnel.



WARNING: Only use fuses that have the same specified rating (see Technical Specifications). Using fuses with higher ratings could result in damage and/or injury.

NOTE: No special skills, training or knowledge are required to operate the Control Unit.

Product Overview ProCair 3000 Alternating Mattress Overlay System

The ProCair 3000 is an Alternating Mattress Overlay System providing pressure application and relief for patients with, or vulnerable to, pressure ulcers. It is designed to be used on top of an existing single bed mattress and can be used on both standard and profiling bed frames.

The ProCair 3000 Alternating Mattress Overlay System consists of the following:

- Control Unit
- Mattress Overlay
- Power Cord
- User Guide
- Carry Bag.

The Control Unit provides the air supply to the Mattress Overlay. It is controlled by a simple analogue interface with a dial to control comfort settings and a visible alarm to warn of system low pressure or power failure.

On the left side of the Control Unit are two quick release air connectors for connecting the overlay hoses.

The mains supply to the Control Unit can be easily disconnected and is designed to detach if pulled too firmly – protecting the internal wiring of the unit.

The Mattress Overlay comprises 21 high density cells whuch alternate over a 10-12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.



Installation Unpacking & Inspection

NOTE: It is recommended that all packing materials and instructions be kept in the carry bag provided, in the event the product has to be shipped to an approved Medistore Service Centre.

Carefully remove the Control Unit, Mattress Overlay and accessories from the shipping cartons. Inspect all items for any damage that may have occurred during shipping. Any damage or missing components should be reported to a Medistore Service Centre as soon as possible.

The box should contain the following items:

- Completely assembled ProCair 3000 Alternating Mattress Overlay System
- Carry Bag
- Analogue Control Unit
- Medical Grade Power Cord
- User Guide.

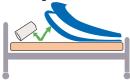
The Mattress Overlay is treated as an applied part.

Installation

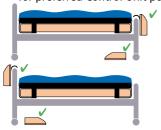
System Installation

The following describes the procedures to follow upon setting up the system for the first time.

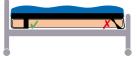
a) Remove all covers and sheets from the existing mattress.



 Position overlay, with its top cover, on top of existing mattress and position hose ends at the foot or head end of bed for preferred Control Unit positioning.



c) Secure end straps completely under the mattress. Ensure end straps are not twisted or pulled towards the corners of the mattress.



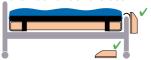
 d) Confirm there are no sharp objects in the immediate area which may risk damage to the overlay/mattress.

IMPORTANT: Make sure that the attachment of the overlay does not interfere with the movement or operation of the bed.

These systems are designed to operate in a controlled environment, which is free from extreme temperatures, high humidity and/or excessive amounts of airborne particles, such as dust and smoke.

Control Unit Installation

 a) Position Control Unit by its hanging hooks over foot board of the bed or on the floor under the bed.



b) Attach two inflation air hoses to Control Unit with the press-on quick release connectors. Ensure air hoses do not kink between bed frame and Control Unit.



- c) Position the power cord through the cord retention loops along the side of the mattress base and insert power cord into Control Unit, then into a grounded 240 V AC 50 Hz electrical outlet.
- d) Switch on the power and turn the pressure dial up to maximum to commence inflation.

Allow up to 40 minutes for full inflation.



- e) Once ready, the second LED as well as the alternating LED will illuminate to indicate that the system is ready for use (system automatically defaults to alternation mode after startup).
- f) Once the Mattress Overlay is fully inflated, bedding can be replaced. Secure sheets loosely enough to ensure they do not interfere with cell alternation.
- g) Transfer the patient to the Mattress Overlay and perform a 'bottoming out' test to ensure that the patient is properly suspended. Refer to page 10 for more details.

Operation Basic Features

Control Panel

The ProCair 3000 Analogue Control Unit front panel is shown in the diagram below.



Analogue Comfort Control Dial

Overlay Function

Establishing pressure (supine patient)

Once the patient is in place, adjust the dial for the best comfort setting that combines the required pressure, support and comfort (refer to patient weight guide labelling on the side of the Control Unit).

After approximately 20 minutes, re-assess whether the patient is comfortable and the unit is functioning correctly.

IMPORTANT: When lowering the pressure setting, ensure the patient is not 'bottoming out' (not sufficiently supported by the air cells and therefore coming in contact with mattress). You should be able to slide your hand between the cells underneath the patient's sacral area (bottom) along a cell that is deflated. Ensure patient is in a supine position for this assessment.

Establishing Pressure

(inclined patient)

When moving the patient to a more upright position, pressure may need to be increased (approximately 20%) to provide added support and to avoid 'bottoming out'.

NOTE: It is important to return the original pressure setting when the patient returns to the supine position.

IMPORTANT: Wait a minimum of 10 minutes between any adjustment and patient assessment as it may take a full cycle for the system to adjust to any new setting.

Operation

Operation System Removal

Overlay Removal

- Switch off the Control Unit. (If applicable reset the alarm indication on the power-down alarm. Switch off the mains supply and disconnect the power-down alarm from the electrical outlet).
- Disconnect the air hoses from the Control Unit to release air from the system.
- Remove the Control Unit, (power-down alarm if applicable) and power cord from the bed and place on the overlay.
- 5. Roll up the Mattress Overlay and remove from the bed.

Transport Function

Overlay Transport Function

- When preparing for transport mode, it is best if the patient is not inclined but supine. Turn the comfort control dial up to maximum pressure and wait 10 minutes for the setting to take effect.
- Ensure that the overlay is not currently undergoing an alternation. If not, then turn off Control Unit and disconnect both hoses. Immediately connect the air hoses together.
- Once the air hoses are connected together, the air pressure will average out between the fully inflated cells and the deflated cells, providing an immersive surface for pressure relief during patient transportation.

Bottoming Out Test

- 1. Unzip one side of the top cover.
- Slide your hand underneath the patient, feeling for a deflated cell under the patient's lower spine – your hand should easily slide between patient and base.
- For optimal pressure: patient should be immersed 30-50% into fully inflated cells.
- If patient is not appropriately immersed, decrease pressure setting and repeat test every 10-12 minutes, until optimal pressure is reached.

Troubleshooting

Cause

Problem

Control unit does not operate.	The control unit may not be attached to a power source or a fuse may need replacing.	Check the control unit is connected to an electrical power outlet.
		Check the control unit is switched on.
		Check the mains plug fuse (3 AMP) and both control unit fuses (1 AMP).
Control unit operational but red Alarm LED illuminates.	The alarm illuminates when Mattress Overlay pressure fails to reach or drops below	Check both air hoses are properly attached to the control unit.
to inflate this	the accepted minimum level, this can be an indication of an air leak in the system.	Check all hoses along the inside of the overlay – each should be firmly connected.
		Check each air cell is securely attached to the connecting air pipe.
		Check all cells, pipes and hoses for any air leakage.
		Check that the air filter cover is correctly secured and the air filter is clean.
		Do not try to open the control unit. Opening the unit could cause personal injury or equipment damage.
Patient is sinking or 'bottoming out' while lying flat on the mattress overlay.	The pressure may be set too low for the patient's weight.	Increase pressure setting – usually an incremental increase is sufficient, however wait 10-12 minutes (one full cycle) before checking the increase was sufficient.
		Check effective system performance by conducting

Solution

If the problem cannot be resolved, please contact a Medistore Service Centre for further support.

a 'bottoming out' test as described on page 10.

Maintenance & Cleaning

Infection Control and routine cleaning must be carried out in accordance with your local Infection Control Policy. It is suggested that all disinfection be done with a high grade disinfectant in accordance with manufacturer's instructions.

WARNING: Do not use high temperature autoclave, or use Phenolic based products for cleaning.

IMPORTANT: It is recommended the system is cleaned between patients and approximately every two weeks if in constant use.

Overlay Top Cover Washing and Disinfecting

If there are visible signs of body fluids and/or substances present, top covers should be washed. Top covers can be machine washed (up to 70°C) using disinfectant according to manufacturer's instructions. To determine the amount of disinfectant to use, determine the amount of water in the washer and then follow the manufacturers' instructions for dilution. Soak the Top Cover in the disinfectant during the wash cycle. Rinse well in clean water and dry thoroughly before use.

CAUTION: Do NOT dry the Top Cover using the HEAT cycle or a dryer. Air dry or select a low or NON heat dry cycle.

Washing Alternative

If there are no visible signs of body fluids and/or substances on the top cover, it can be sanitised

- Apply an intermediate level disinfectant (or a solution of Sodium Hypochlorite or similar up to 10,000 ppm available chlorine) to the Top Cover upper surface either by spraying or by hand application.
- Ensure the surface is completely covered with the disinfectant and remains in contact with the surface according to manufacturer's instructions.
- 3. Remove disinfectant and rinse thoroughly.
- 4. Allow to air dry before use.

Outside Shell

Wipe down with disinfectant (or a solution of Sodium Hypochlorite or similar up to 10,000 ppm available chlorine), ensuring that all surfaces come in contact with the disinfectant. Rinse off well with a clean damp cloth and air dry.

Air Cell Assembly

CAUTION: DO NOT machine wash or dry the air cells. The air cell assembly does not routinely need to be cleaned or disinfected.

IMPORTANT: DO NOT disassemble the overlay, unless cleaning is required. If cleaning or disinfecting is required, DO NOT disconnect the hoses from the air cells.



Control unit

WARNING: Ensure the Control Unit is disconnected from the mains electricity supply before cleaning.

WARNING: DO NOT spray disinfectant directly on to the Control Unit, or immerse in any type of liquid. This could result in a severe electrical hazard as this equipment has no protection against ingress of water.

WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

External cleaning

Wipe down Control Unit with warm water containing detergent (or with a solution of Sodium Hypochlorite or similar), dry thoroughly before use.

Air Filter Replacement

- Switch off the power supply to the Control Unit.
- 2. Disconnect the power cord and air hoses.
- Place the Control Unit on a flat surface with its back panel uppermost (NOTE: be sure to place soft cloth under unit to prevent scratches).

- Carefully pry off the cover of the air filter, remove and discard the filter material and fit new (there may be a small locking screw – use a small Philips head to remove this first).
- Refit the air filter cover to the Control Unit. The Control Unit is now ready for re-connection.

NOTE: Good filter maintenance is critical to maintain your system in optimal operating condition. Failure to keep the filters clean will result in system downtime and increase repair costs. It is recommended that the air filter be replaced annually. Air filters are available from a Medistore Service Centre. Preventative inspection and calibration is not required.

Fuse Replacement

- 1. Ensure the Control Unit is deactivated.
- Remove the power cord from the electrical socket on the side of the Control Unit.
- Using a small flat head screwdriver insert into the grove and turn anti-clockwise (¼ turn).
- 4. Remove the "blown" fuse from the fuse holder clip and discard.
- 5. Insert a new fuse into the plug. Push against the force of the spring and turn clockwise with the screwdriver a ¼ turn.



Technical Specifications

Cycle Control: Purpose designed distributor valve supplying operating air to the

inflatable cells

Cycle Time 10-12 minutes

Supply Voltage 230V, 50Hz 120V, 60Hz

0.2A for Control Unit

0.01 - 6A for power down alarm

(availability of supply monitored by in-line power-down alarm

which provides failure indication)

Fuse Rating Mains Plug - 3A, Control Unit - 1A

Overlay Dimensions & Weight

Control Unit Dimensions & Weight

2000mm Length Height 115mm Width 880mm Width 135mm 270mm Height 90mm Depth Weight 8.4kgs Weight 2.1kgs

Power Rating 12VA

Cells 21 cells

Cell material 0.15mm TPU film laminated on 210 Denier Nylon fabric

Base material Nylon fabric 420 Denier with a 0.1mm TPU coating

Cover Material PU coated polyester

Connection Quick release connectors

Standards CE, UL

Mode of Operation Continuous

Environment

Air humidity 30% to 75% Ambient temperature 0°C to 70°C Altitude \leq 2000m

All product specifications are subject to change without notice.



Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Medistore warrants each of its products to perform in accordance with established specifications for the following time periods, starting from the date the product is shipped from Medistore.

Control Units 2 years
Soft Goods 2 years

During the warranty period, Medistore, through its distributors, will repair or replace at no charge, any products that are not performing in accordance with established specifications, unless the problem/failure is due to:

- customer damage, negligence and/or misuse
- unauthorised repairs.

Items not covered under warranty include, but are not limited to: stains, punctures, cuts, damages to electrical cords, rips or tears, dents and/or lost/missing parts.

All products returned for warranty repairs must be assigned a Return Authorisation Number prior to return. Returns should include information describing the problem and/or requested repair and be sent to a Medistore Service Centre by prepaid transportation. Medistore will return the repaired/replaced product at no charge Warranty repairs do not extend beyond the length of the warranty period.

Neither Medistore, nor its distributors, officers, directors, employees and agents shall be liable for consequential or other damages, including but not limited to personal injury, loss, or any other expense, directly or indirectly arising from the use of its products. The sole remedy for breach of the limited warranty granted herein shall be repair of the Mattress or Control Unit or related parts.

Medistore has a policy of continuous product improvement and reserves the right to amend specifications presented in this brochure.

This product carries the CE mark in accordance with EC Directive on Medical Devices (93142IE EC) .

Control Number 95CG. Classified by Underwriter's Laboratory Inc. for UL 2601-1 standard for Medical Electrical Equipment.



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