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www.evocare.com.au
Phone:07 33558000 Fax:07 33555043



premium9digital user manual

bringing you the world in health



Important Notice

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

If you have any questions, please contact Novis Healthcare on 1300 738 885





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Safety Precautions

In General

CAUTION: Do not use this equipment in the presence of flammable anesthetics. Explosions could result.

IMPORTANT: Bed frames used with the systems can vary greatly depending on the specific health care setting, ie hospitals, nursing homes, home care, etc. Therefore, 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 systems surface and patient, and secure bed sheets loosely so as not to affect the alternating cell movement

Control Unit

- Only plug into a grounded power receptacle and use the power cord supplied with the system
- Exposure of the electronic controller to any liquid while it is plugged in could result in a severe electrical hazard
- Only use fuses that have the same specified rating (see Technical Specifications). Using fuses with higher ratings could result in damage and/or injury
- The electronic controller is a precision electronic product. Use care when handling or transporting. Dropping, or other sudden impacts, may result in damage to the unit
- Risk of electric shock. DO NOT OPEN. Do not attempt to repair or service the Control Unit. Repairs and service should be conducted by Novis Healthcare nominated Service Centres. If the Control Unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately. Contact Novis Healthcare on 1300 738 885 for repairs and service information.
- Do not place any objects/items, such as blankets, on or over the Control Unit. Excessive weight on the Control Unit could result in damage
- The power cord to the Control Unit should be positioned to avoid a tripping hazard and/or damage to the cord. Novis Healthcare recommends placing the cord under the bed frame and attaching it to an electrical outlet by the head of the bed.





Product Overview

premium9digital Alternating Mattress Replacement System

The premium9digital is an alternating Mattress Replacement system providing pressure application and release to patients with, or vulnerable to, pressure ulcers. It is designed to replace an existing mattress and can be used on both standard and profiling bed frames.

The premium9digital alternating Mattress Replacement system consists of the following:

- Control Unit
- Mattress Replacement
- Power Cord
- Instruction Manual
- Quick Setup Guide
- Carry Bag

The Control Unit provides the air supply to the mattress. It is controlled by a digital touch membrane on the front panel which controls up to four comfort settings, alternating or static mode for treatment or transfers respectively. An on/off button and alarm mute completes the array.

On the right side of the Control Unit are four male air connectors for connecting the rapid release handle.

The rapid release handle also has an attached cap which can be inserted into the four openings to seal air in the system for up to 30 hours as a transport feature.

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

The alarm function has a number of indications depending on the cause of the failure.

The mattress comprises 19 high density cells which all feature a permanently inflated internal cell. This prevents the patient "bottoming out" in the event of low pressure due to incorrect settings, electrical or cell failure. There are three head cells which provide static support whilst the air pressure in the other 16 cells is alternated over a 10~12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue. The alternating section also comprises a heel zone of thinner cells for individualized therapy to this sensitive area.

In addition, two permanently inflated side formers assist in lateral support for the user and carer.

A comforter cover can be used to provide additional comfort and warmth to the patient.



Installation

Unpacking & Inspection

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

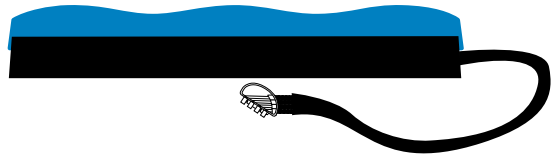
Carefully remove the Control Unit, Mattress Replacement and accessories from the shipping cartons. Inspect all items

for any damage that may have occurred during shipping. Any damages, or missing components, should be reported to a Novis Healthcare Service Centre as soon as possible.

The box should contain a completely assembled Mattress Replacement system consisting of:

- premium9digital Mattress Replacement
- Carry Bag
- Digital Control Unit
- Medical Grade Power Cord
- Quick Setup Guide
- User Manual

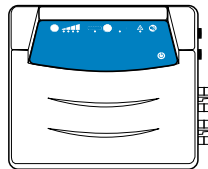
Mattress Replacement



Carry Bag



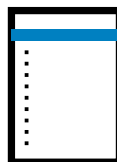
Digital Control Unit



Medical Grade Power Cord



Quick Setup Guide



User Manual

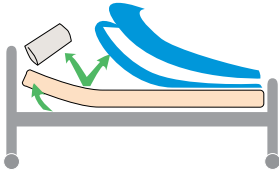


Installation

System Installation

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

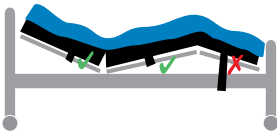
- Remove all covers, sheets and mattress from the bed.



- On a standard bed, position Mattress Replacement, with top cover, on top of the bed. Position hose ends at foot of bed for Control Unit positioning.



- On a profiling bed, secure the side straps around the moveable sections of the bed base. **DO NOT SECURE TO THE SIDE RAILS - STRAPS WILL TEAR OFF**



- Confirm there are no sharp objects in the immediate area which may risk damage to the Mattress Replacement.

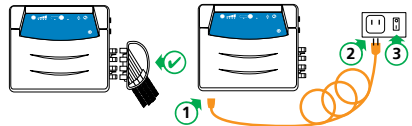
Important: Check that the attachment of the Mattress Replacement does not interfere with the movement or operation of the bed.

Control Unit Activation

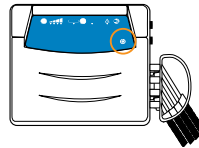
- Position Control Unit by hanging hooks over foot board of the bed or place unit on the floor under the bed.



- Press on the Rapid Release Handle to the Control Unit. Ensure air hoses do not kink between bed frame and Control Unit.



- Insert power cord into the Control Unit, then into a **grounded 240 Vac 50 Hz electrical outlet**.
- Press the power button **for at least three seconds** to activate the Control Unit. The pressure LEDs will flash indicating that the system has activated.



Allow up to 40 minutes for full inflation.



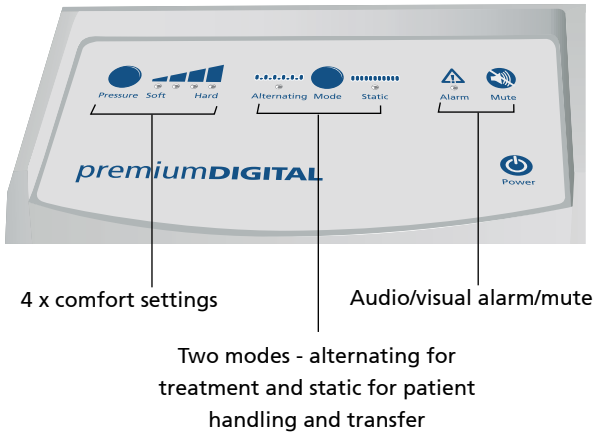
- Once ready, the first two pressure LED's plus alternating LED will illuminate to indicate that the system is ready for use (system automatically defaults to alternation mode after start-up).
- Once the Mattress Replacement is fully inflated, bedding can be replaced. Secure sheets loosely enough to ensure they do not interfere with cell alternation.

Operation

Basic Features

Control Unit Panel

The premium9digital Control Unit front panel is shown below.



IMPORTANT: When lowering the pressure setting, ensure the patient is not 'bottoming out' (insufficiently

supported by the air cells and therefore coming in contact with bed base) 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

(by approximately 20%) to provide added support and to avoid 'bottoming out'.

Mattress Replacement Function

Establishing pressure (supine patient)

Once the patient is in place, use the Pressure select button to reach the desired setting for effective alternation and patient comfort.

Based on patient weight, find the best setting that combines the required pressure, support and comfort.

Establish a minimum air pressure measure for the patient and select one of the four comfort levels to suit.

After approximately 20 minutes, reassess whether the patient is comfortable and the unit is functioning correctly. The alarm light will activate and the comfort setting lights will flash to indicate if system malfunctions.

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

IMPORTANT: Wait a minimum of 10-12 minutes between pressure adjustment and patient assessment, as it may take a full cycle for the system to adjust to any new setting.

CPR Function

Deflation of the Mattress Replacement may be required for emergency procedures or to decommission the unit. To deflate quickly, completely remove the rapid release handle from the side of the Control Unit



Alarm Functions

ALARMS

The following flashing and audio alarms are provided on the premium digital Control Unit:

Display

Alarm Signal

- | | |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------|
| ○ ○ ● ● | <p>Pressure too high
Pressure has exceeded the maximum setting for therapeutic benefit</p> |
| ● ● ○ ○ | <p>Pressure too low
Pressure has fallen 5mmHg or more below minimum for the selected setting</p> |
| ○ ○ ○ ○ | <p>AC power failure
No pressure output due to mains power failure</p> |
| ○ ● ● ○ | <p>Dynamic Mode failure
The Mattress Replacement has failed to commence alternation</p> |
| ● ○ ○ ● | <p>Initial failure
Mattress has failed to reach minimum operational pressure within 40 minutes of switching on the power</p> |

Generally, if the alarm activates and the system fails to inflate or loses pressure, refer to the trouble shooting section on the following pages.

Bottoming Out Test

1. Ensure system is on alternation mode but is not undergoing an alternation.
2. Unzip top cover just past sacral (bottom) region.
3. Slip hand under top cover, over side bolster and along a deflated cell under the patients sacrum.
4. If hand can pass under patient then patient is adequately suspended.

System Removal & Transport

Mattress Replacement Removal

1. Switch off the Control Unit switch off the mains supply.
2. Remove the rapid release CPR handle from the Control Unit.
3. Remove the Control Unit and power lead and place on top of the Mattress Replacement.
4. Once air has been released from the cells, roll up the Mattress Replacement and remove from the bed.

NOTE:



Prior to re-starting the system, ensure the rapid release CPR handle is replaced and fully connected to the male air connectors on the Control Unit.

Mattress Transport Function

1. Switch modes from alternating to static prior to transport and wait five minutes for cells to inflate to maximum pressure.
2. Turn off Control Unit and then remove the rapid release CPR handle from the Control Unit.
3. Allow air to escape for a couple of seconds before sealing with the attached handle cap. This will soften the mattress surface for pressure relief and comfort. If patient is responsive, question comfort based on current pressure and adjust accordingly.
4. **IMPORTANT:** Ensure that patient is not bottoming out onto bed base as air pressure is released from **all** internal static cells as well as alternating sections. **Perform bottom out test.**




Troubleshooting

This section provides a basic trouble shooting support for digital control unit alarms and malfunctions.

Alarm/Fault	Cause	Solution
Control unit does not operate or none of the display lights are illuminated.	The Control Unit may not be attached to a power source or a fuse may need replacing.	<ol style="list-style-type: none"> 1. Check the Control Unit is connected to an electrical power outlet with the correct voltage. 2. Check the Control Unit is switched on. Power off and unplug the unit before restarting. 3. Check the mains plug fuse first (3 AMP) then check both Control Unit fuses (1 AMP) - fuses can be released using a screwdriver to push and turn. Warning! Do not try to open the control unit. Opening the unit could cause personal injury or equipment damage.
Alarm LED  + audible alarm	Pressure too high	<ol style="list-style-type: none"> 1. Reset the alarm - turn off power and press the Alarm Mute button. 2. Disconnect the air hoses to reduce pressure - reconnect when pressure has decreased. 3. Check for twists in the air hoses between mattress and Control Unit. 4. Switch on power (system automatically starts in Static Mode and will revert to Alternating Mode when operational pressure is reached).
Alarm LED  + audible alarm	Pressure too low	<ol style="list-style-type: none"> 1. Reset the alarm - turn off power and press the Alarm Mute button. 2. Check the CPR tag is intact, ensuring both sealing connectors are fully fitted to the Mattress Replacement air hoses. 3. Check all air hoses along the inside of the Mattress - each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 4. Check all cells, pipes and hoses for any air leakage. 5. Check that the air filter cover is correctly secured and the air filter is clean.



Troubleshooting

Alarm/Fault	Cause	Solution
Alarm LED  + audible alarm	AC power failure	<ol style="list-style-type: none"> 1. Press the Alarm Mute button to silence the audible alert. 2. Check the power cable is firmly plugged into the mains outlet and the control unit; and check the mains power is switched on. 3. Check the mains plug fuse first (3 AMP) then check both Control Unit fuses (1 AMP) - fuses can be released using a screwdriver to push and turn.
Alarm LED  + audible alarm	Alternating Mode Failure (no alternation)	<ol style="list-style-type: none"> 1. Reset the alarm - turn off power and press the Alarm Mute button. 2. Disconnect the air hoses to reduce pressure - reconnect when pressure has decreased.
Alarm LED  + audible alarm	Initialization failure	<ol style="list-style-type: none"> 1. Reset the alarm - turn off power and press the Alarm Mute button. 2. Check all air hoses along the inside of the mattress - each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 3. Check all cells, pipes and hoses for any air leakage. 4. Switch on power (system automatically starts in Static Mode and will revert to Alternating Mode when operational pressure is reached).
Patient is sinking or "bottoming out" whilst lying flat on the mattress replacement	The pressure may be set too low for the patient's weight.	<ol style="list-style-type: none"> 1. Increase the pressure setting. 2. To check effective system performance, conduct a "Bottom out" test as described on page

NOTE:

If the problem is not resolved, please contact an authorised Novis Healthcare Service Centre.



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.

NOTE: The top cover seams are sealed to prevent moisture ingress and bacterial growth in the seam stitching.

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.

Mattress Replacement Top Cover Washing and Disinfecting

If there are visible signs of body fluids and or substances present, the top cover should be washed. Top covers can be machine washed (up to 70°C) using disinfectant according to manufacturers' 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 sanitized.

1. Apply an intermediate level disinfectant (or a solution of Sodium Hypo chlorite or similar up to 10,000 ppm available chlorine) to the top cover upper surface either by spraying or by hand application.
2. 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 Hypo chlorite 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.

CPR Handle

The exterior of the CPR handle can be periodically wiped using a cloth a dampened with disinfectant.

Air Cell Assembly

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

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





Maintenance & Cleaning

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 the Control Unit 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 Hypo chlorite or similar) and dry thoroughly before use.

Air Filter Replacement

1. Switch off the power supply to the Control Unit.
2. Disconnect the electrical lead and air hoses.
3. 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).
4. Carefully pry off the air filter cover, remove and discard the filter material and fit new filter (there may be a small locking screw - use a small Phillips Head screwdriver to remove this first).
5. 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. Replacement air filters are available from a Novis Healthcare Service Centre.

Fuse Replacement

1. Ensure the Control Unit is deactivated.
2. Remove the power cord from the electrical socket on the side of the Control Unit.
3. Using a small Flat Head screwdriver insert into the groove and turn anti-clockwise (1/4 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 (1/4 turn).



Technical Specifications

Premium9

Cycle Control:	Purpose designed distributor valve supplying operating air to the inflatable cells
Cycle Time	12 minutes
Supply Voltage	230V, 50Hz 120V, 60Hz 0.2A for Control Unit
Fuse Rating	Mains Plug - 3A, Control Unit - 1A (x2)
Power Rating	12VA
Mattress Replacement Order Code	MC-9D
Cells	19 cell in cells (including 3 non alternating head cells) plus 2 side bolsters

Mattress Replacement Dimensions

Length	1970mm
Width	900mm
Height	250mm
Weight	8.4kgs

Control Unit Dimensions

Height	272mm
Width	290mm
Depth	128mm
Weight	2.9kgs

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	Nylon with PVC membrane, PU leather, base is polyester
Micro Air Loss Cells	N/A
Hose Connection	Push on connector handle
Emergency	CPR rapid release handle
Standards	CE, UL
Mode of Operation	Non-continuous
Environment	
Air humidity	30% to 75%
Ambient temperature	0°C to 70°C

All product specifications are subject to change without notice.



Warranty Information

Novis Healthcare 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 Novis Healthcare P/L.

Control Units	2 years
Soft Goods	2 years

During the warranty period, Novis Healthcare P/L 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 (1) customer damage, negligence and or misuse or (2) unauthorized 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 Novis Healthcare Service Centre by prepaid transportation. Novis Healthcare will return the repaired/replaced product at no charge. Warranty repairs do not extend the length of the warranty period.

Neither Novis Healthcare, its distributors, officers, directors, employees or agents shall be liable for consequential or other damages, including but no 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 or replacement or the Novis Healthcare products.

Novis Healthcare 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 60601-1 standard for Medical Electrical Equipment.