

User Guide

8 Digital



 **Evocare**[®]

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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.

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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). 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: Minimize articles between the system 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 Control Unit 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 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
- Do not open the Control Unit – risk of electrical shock. 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 for repair and service information
- Do not place any objects or items, such as blankets, on or over the Control Unit
- 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

8 Digital Alternating Overlay System

The 8 Digital is an Alternating Mattress Overlay system providing pressure application and release to patients with, or vulnerable to, pressure ulcers. It is designed to be used on top of your existing single bed mattress and can be used on both standard and profiling bed frames.

The 8 Digital Alternating Mattress Overlay system consists of the following:

- Control Unit
- Mattress Overlay
- Power Cord
- User Manual
- Quick Setup Guide
- Carry Bag

The Control Unit provides the air supply to the Mattress Overlay. It is controlled by a digital touch membrane on the front panel which controls eight comfort settings, Alternating or Static Mode for treatment or transfers respectively, and Max Firm function to facilitate quick mattress inflation. The Alarm LED indicator and Alarm Mute completes the profile.

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

On the side of the Control Unit are two male air connectors for quick connection of dual air hoses. The connectors include a press button release system for ease of use.

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 comprises 18 high density cells including 3 static head cells to provide static 'pillow' support for optimum comfort. Air pressure in the other 15 cells is alternated over a 12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

The system includes a rapid release CPR tag for emergency deflation.

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 carry bag provided, in the event the product has to be shipped to an approved Novis Healthcare 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 Novis Healthcare Service Centre as soon as possible.

The box should contain the following items:

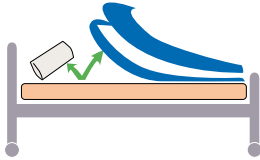
- **Completely assembled
8 Digital Mattress Overlay system**
- **Carry Bag**
- **Digital Control Unit**
- **Medical Grade Power Cord**
- **Quick Setup Guide**
- **User Manual.**

Installation

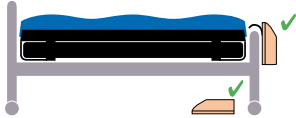
System Installation

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

- 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 foot of bed for Control Unit positioning.



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



- Check CPR hoses connections are pushed fully onto the connectors. You may need to unzip top cover to access CPR assembly.
- Confirm there are no sharp objects in the immediate area which may risk damage to the mattress replacement.

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

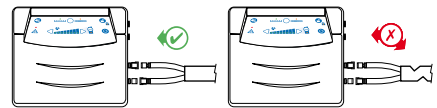
These systems are designed to operate in a controlled environment, which is free from extreme temperatures, high humidity and/or excessive amounts of airborne particles, such as dust and smoke.

Control Unit Installation

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



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



- Insert power cord into Control Unit, then into a **grounded 240 V AC 50 Hz electrical outlet**.

- Press the power button for more than two seconds to activate Control Unit. The pressure LEDs will flash indicating that the system has activated.

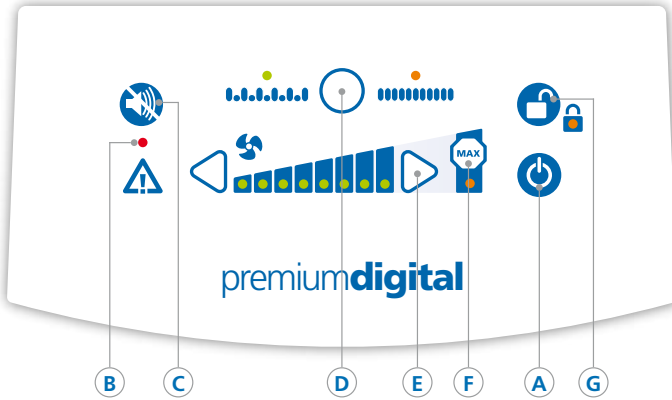
Allow up to 40 minutes for full inflation.



- Once ready, the second two pressure LED's 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).
- Once the overlay is fully inflated, bedding can be replaced. Secure sheets loosely enough to ensure they do not interfere with cell alternation.
- Transfer the patient to the overlay and perform a bottom out test to ensure that the patient is properly suspended. Slip your hand under top cover along a deflated cell underneath sacral area.

Operation

Control Unit Panel



A. Power Button

Turns system power on and off.

B. Alarm LED

This red light flashes, and an audible alarm sounds, to alert when Control Unit or Mattress Overlay pressure fails. The alarm has five different signals to indicate the cause of the failure.

The audible alarm also sounds when power is switched off – press Alarm Mute to silence.

C. Alarm Mute Button

Silences the audible alarm (on/off). Audible alarm will resume after 20 minutes if cause of failure not resolved.

D. Mode Button

Press to select either Alternation Mode (alternative cells cyclically inflating and deflating) or Static Mode (all cells fully inflated with no dynamic alternation).

E. Pressure Arrow Buttons

Press arrows to increase or decrease pressure setting. Eight pressure settings from soft to hard are available (18mmHg to 60mmHg; 6mmHg per step). The green LEDs illuminate to indicate which of the eight settings is operational.

F. Max Firm Button

Press to facilitate rapid inflation to maximum pressure setting (60mmHg). After 20 minutes, the system automatically reverts back to the previous pressure setting for patient safety.

G. Control Unit Lock/Unlock Button

Press for at least two seconds to lock the Control Unit settings – a beep sounds and the amber LED illuminates to indicate system is locked. When locked, only the Alarm Mute and Lock/Unlock buttons remain operational.

Press again for at least two seconds to unlock (beep sounds and amber LED turns off).

NOTE: the Control Unit will automatically unlock in the event of a power failure.



Mattress Overlay Function

Control Unit Panel

Establishing Pressure (supine patient)

With the patient lying supine (on their back, face upwards), use the Pressure arrows to cycle through the eight available pressure settings.

Based on patient weight and comfort requirements, establish the best setting for effective alternation, support and comfort.

Before changing or lowering the pressure, ensure the system is working effectively by performing a 'bottoming out' test:

- a. With the patient lying supine, unzip one side of the top cover just past sacral region (lower spine).
- b. Slide your hand underneath the patient and feel for a deflated cell under the patient's lower spine. The inner static cell will remain inflated, however your hand should easily slide between patient and base.
- c. If patient is adequately suspended, pressure setting can be lowered.

After approximately 20 minutes, reassess system function and patient comfort. In the event of a system malfunction, the alarm will activate and pressure LEDs will flash.

Establishing Pressure (inclined patient)

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

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

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

CPR Function

Rapid deflation of the Mattress Overlay may be required for emergency treatment or to decommission the unit. The CPR tag located at mattress head should be used in the event that patient CPR or emergency treatment is required.

Firmly pull the CPR tag to rapidly deflate the entire system, ensuring both sealing connectors are firmly disconnected from the internal Mattress Overlay air hoses.

To re-inflate the system after the CPR tag has been pulled, restore the CPR sealing connectors to the internal Mattress Overlay air hoses and wait for the system to gain optimal pressure.

Operation

Alarm Function

The red Alarm LED flashes, and an audible alert sounds, to indicate the Control Unit or mattress pressure has failed. The LED will remain illuminated until appropriate pressure is restored. The audible alarm can be silenced by pressing the Alarm Mute button.



The system has five different alarm signals, identified by five different Pressure Setting illumination sequences. The signals and corresponding Pressure Setting LED displays are illustrated below.

Display

Alarm Signal



Initial Failure

Mattress has failed to reach minimum operational pressure within 50 minutes



Low Pressure

Pressure has fallen 5mmHg or more below the setting minimum



High Pressure

Pressure has exceeded the setting maximum by 10mmHg or more



Alternating Mode failure

Mattress has failed to commence alternation



AC power failure

No pressure output due to mains power failure

If alarm activates and the system fails to inflate or loses pressure, refer to **Troubleshooting** on following pages.



Operation

Transport Function

1. Before patient transport, press the Static Mode button to switch modes and wait at least five minutes for cells to inflate to maximum pressure.
2. Once mattress pressure has reached maximum inflation, press the Power button **for at least two seconds** to switch off the Control Unit. Switch off the mains supply and unplug the power cable.
3. Press the release button on the dual hose connectors to disconnect both air hoses from the Control Unit. Connect the air hoses to each other by snapping the ends together. The length of time the air is retained in the Mattress Overlay will depend on the weight and height of the individual patient.

If the patient is responsive, check comfort level based on current pressure and adjust accordingly.

IMPORTANT: Always perform a 'bottoming out' test (see page 9) to ensure the patient is adequately supported and not touching bed base.

Dismantle System

1. Press the power button **for at least two seconds** to switch off the Control Unit. Switch off the mains supply and unplug the power cable.
2. Press the release button on the dual hose connectors to disconnect both air hoses from the Control Unit. This will deflate all cells except the three static head cells.
3. To deflate the head cells, firmly pull the CPR tag to disconnect the sealing connectors from the internal air hoses.
4. Place Control Unit and power lead on top of the Mattress Overlay and detach Mattress Overlay from bed.
5. Once air has been released from the cells, roll up the Mattress Overlay and return all items to Carry Bag for safe keeping.

NOTE: Prior to p the system, ensure the CPR tag is replaced and sealing connectors are fully inserted into the internal air hoses.

Troubleshooting

Alarm/Fault

Control Unit does not operate; no display lights illuminate

Display

The Control Unit may not be attached to a power source or a fuse may need replacing

Solution

1. Check the Control Unit is connected to mains power outlet with the correct voltage.
2. Check the Control Unit is switched on. Switch off and unplug the unit before restarting.
3. Check the mains plug fuse (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

Initial failure

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.

Alarm LED



+ audible alarm

Pressure too low

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 firmly fitted to the internal Mattress Overlay 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.
6. Switch on Power.

Troubleshooting

Alarm/Fault

Alarm LED



+ audible alarm

Display

Pressure too high

Solution

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 Overlay and Control Unit.
4. Switch on Power.

Alarm LED



+ audible alarm

Alternating Mode Failure (no alternation)

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

AC power failure

1. Press the Alarm Mute button to silence the audible alarm.
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 (3 AMP) then check both Control Unit fuses (1 AMP) – fuses can be released using a screwdriver to push and turn.

Patient is sinking or “bottoming out” whilst lying flat on the Mattress Overlay

The pressure maybe set too low for the patient’s weight

1. Increase the pressure setting by pressing up the Pressure arrow.
2. To check effective system performance, conduct a “bottoming out” test as described on page 9.

NOTE: If the problem is not resolved, please contact an authorized Novis Healthcare Service Centre.



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 Base

Once deflated, disconnect air cells from the base by unfastening the press studs at each end. Remove double tubing from main base air tubes and slide the cell out from the cell straps. Swab the cell with a solution of Sodium Hypochlorite or similar (up to 10,000ppm available chlorine). Dry thoroughly before refastening.

CAUTION: Do not machine wash or dry the air cells or Mattress Overlay base. The air cell assembly does not need to be cleaned or disinfected.

IMPORTANT: Do not disassemble the Mattress Overlay unless cleaning is required. If cleaning or disinfecting is required, do not disconnect the hoses from the air cells.



Cleaning

Top Cover

NOTE: Refer to the top cover wash tag for cleaning instructions.

If there are visible signs of body fluids or other substances, the top cover should be washed. The top cover 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 manufacturer's 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.

If there are no visible signs of body fluids or other substances, the top cover should be sanitized.

Apply an intermediate level disinfectant (or a solution of Sodium Hypochlorite or similar up to 10,000ppm available chlorine) to the top cover surface. Rinse well with a clean damp cloth and air dry before use.

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.

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



Maintenance

Air Filter Overlay

1. Switch off the power supply to the Control Unit.
2. Disconnect the power lead and air hoses.
3. Place the Control Unit on a flat surface with back panel uppermost (place soft cloth under unit to prevent scratches).
4. Carefully remove air filter cover, remove and discard the filter material and fit new filter (there may be a small locking screw – use a small flat head screwdriver to remove).
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. Overlay air filters are available from Novis Healthcare Service Centre.

Fuse Overlay

1. Switch off the power supply to the Control Unit.
2. Remove the power cord from the electrical socket on the side of the base of the Control Unit.
3. Insert a small flat head screwdriver into the groove and turn anti-clockwise (quarter 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 (quarter turn).

Technical Specifications

Control System	Digital micro controller
Cycle Time	12 minutes (fixed)
Supply Voltage	230V, 50Hz 120V, 60Hz 0.2A for Control Unit
Fuse Rating	Mains Plug – 3AMP, Control Unit – 1AMP (x2)
Power Rating	12VA
Standards	CE, UL
No of Cells	18 cell in cells (including 3 static head cells)
Cell Height	115mm
Maximum patient weight	120kgs

Mattress Overlay Dimensions

Length	2000mm
Width	880mm
Height	115mm
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
Hose Connection	Press on dual connector hoses
Emergency	CPR tag
Mode of Operation	Non-continuous

Operating environment

Air humidity	30% to 75%
Ambient temperature	0°C to 40°C

NOTE: 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.

Control Units	2 year
Soft Goods	2 year

During the warranty period, Novis Healthcare 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 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 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 Overlay or the Novis Healthcare products.



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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 (93/142/EEC).

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