ProCair Prime

User Guide

Static Mode Programming Option

pressure care and patient handling specialists

novis.com.au / 1300 738 885

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.

We recommend you keep the User Guide near the product.

Therapeutic devices and/or medical equipment should only be used in accordance with manufacturer's instructions and under the consent, supervision and management of a suitably qualified health professional.

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

Novis Healthcare has a policy of continuous product improvement and reserves the right to amend specifications presented in this guide. Information correct at time of production (May2018) .

Definition of Symbols Used

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

- Important information
- Caution
- Electrical hazard
- Infection control
- Do not...
- Class II equipment
- Type B Applied part
- ~ Alternating Current
- Manufacturer
- Manufacturing Date
- SN Serial Number
- Refer to Manual
- Disposal: Do not dispose of this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
- IP21 Protection against foreign object and vertically falling water drops.

Contents

System Overview

The ProCair Prime is an alternating mattress replacement system for the prevention and treatment of skin breakdown and pressure injuries in patients of high to very high risk. It is designed to replace your existing bed mattress on either a standard or profiling electric bed frame.

The revolutionary Universal Therapy SystemTM (UTS) features an integrated control unit within the mattress, cyclically inflating and deflating the air cells in an alternating pattern, to help prevent arterial and venous capillary occlusion in the patient's surface tissue - maintaining the flow of blood and lymphatic fluids through these tissues to provide essential oxygen and remove metabolic waste.

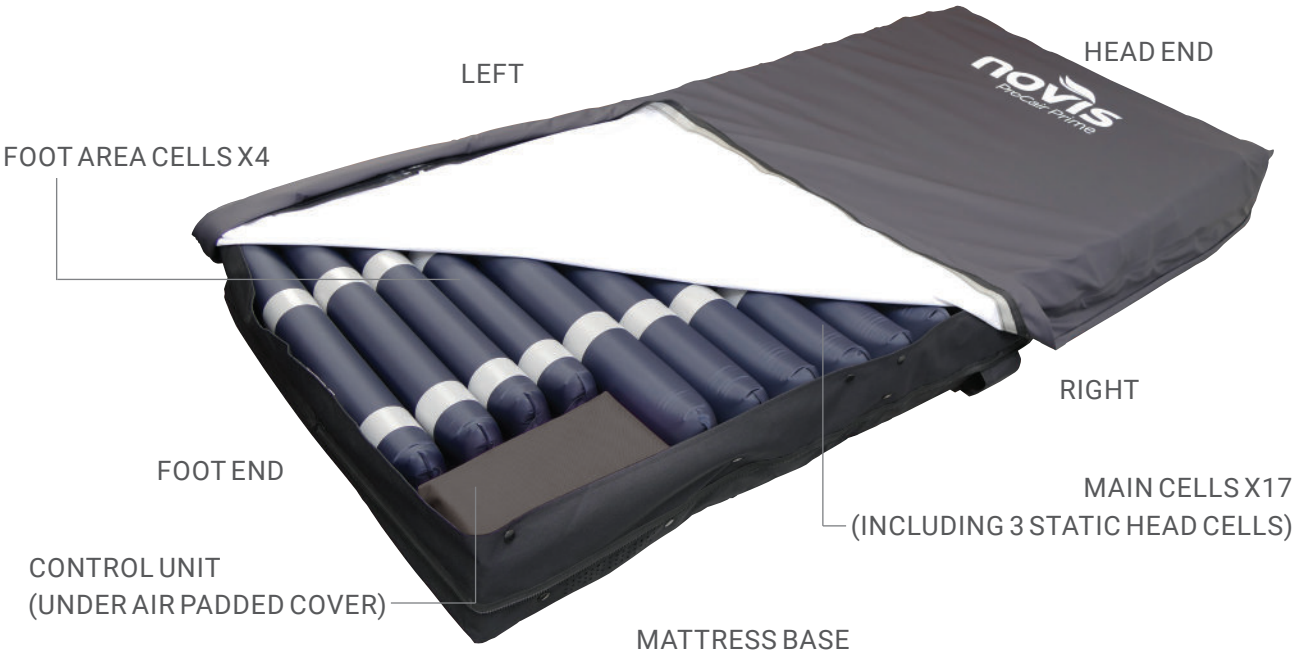
A full-size, movable foam sheet can be positioned at the bottom of the mattress, working in conjunction with the narrow foam inserts in the air cells to provide bottoming-out protection. Alternatively, the foam sheet can also be positioned on top of the air cells to convert the mattress to a hybrid support surface, providing additional comfort for the user as well as gentle alternating therapy.

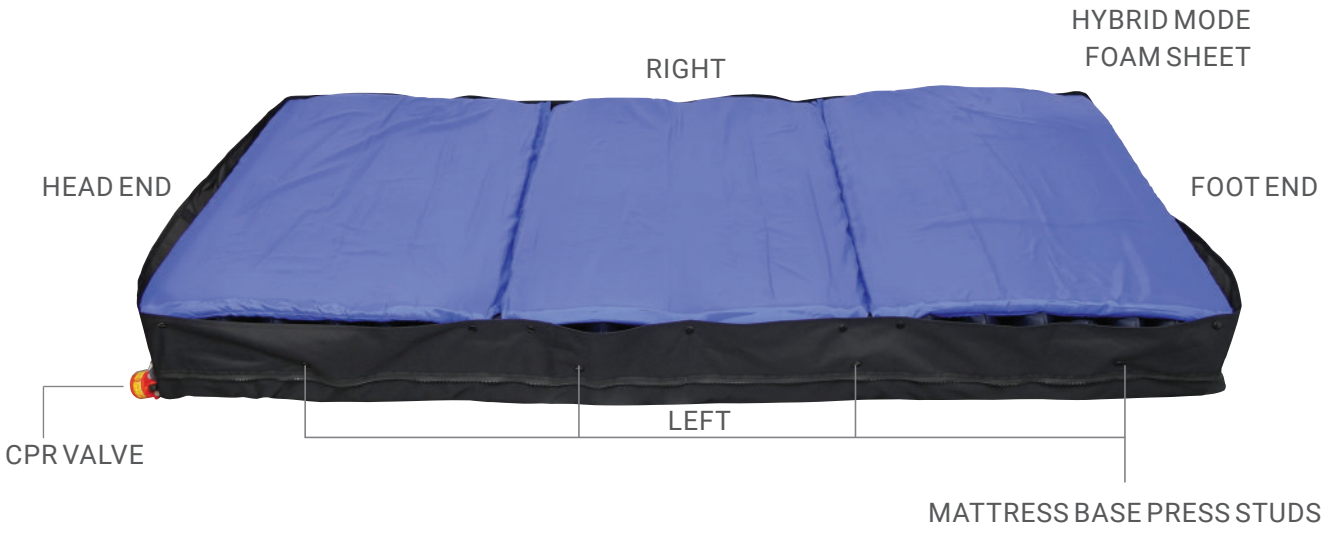
The ProCair Prime can be easily operated by the caregiver as well as the patient (subject to advice by a healthcare professional) via a simple-to-use handset with a long, flexible cord.

The system consists of the following components:

- Mattress replacement with integrated control unit, control handset, power cord and CPR release
- User Guide
- Carry bag

It is recommended that all packing materials and the User Guide be kept in the carry bag provided, for ease of storage and/or transport.





Intended Use

Indications

The ProCair Prime mattress replacement systems are indicated for:

- The prevention and treatment of skin breakdown and pressure injuries in patients of high to very high risk.

Contraindications

Patient conditions for which the application of pressure therapy on the ProCair Prime mattress replacement systems contraindications include:

- Instable spinal cord injury
- Cervical traction

Intended Care Setting

Intended care settings for the ProCair Prime mattress replacement systems are:

- Home healthcare
- Professional healthcare

Working Environment

- Temperature: 15°C to 35°C (59° F to 95° F)
- Humidity: 30% to 75% non-condensing

Shipping/ Storage Environment

- Temperature: 5°C to 60°C (41° F to 140° F)
- Humidity: 30% to 90% non-condensing

Connecting System to Other Devices

The ProCair Prime mattress replacement can be fitted to most standard hospital or single bed bases.

Therapeutic devices should only be used in accordance with manufacturer's instructions and under the consent, supervision and management of a suitably qualified health professional.

Novis Healthcare accepts no liability for any use, change or assembly of the product other than that stated in this User Guide. Refer to our Warranty Statement for more details.

Safety Precautions

The purpose of the following safety precautions are to direct attention to possible dangers. The safety symbols and their explanations require 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.

For your own safety and the safety of equipment, always take the following precautions.

General Safety Precautions

- **Read all instructions before using this medical device**
- This system must be used on top of an appropriate sized bed frame and the appropriate operating environment as stated in this User Guide.
- Before commencing set up or installation, ensure the power is switched off and disconnect the power cord from the control unit. Novis Healthcare recommends using the cord retention loops on the mattress base where possible and attaching it to an electrical outlet by the head of the bed.
- Minimise layers between patient and mattress and secure bed sheets loosely so as not to affect the alternating cell movement. As part of a sensible pressure injury prevention strategy, avoid wearing clothing that may cause areas of localised damage due to creases, seams, objects in pockets, etc.
- Never use sharp objects or electrically heated blankets on or under the system.
- Product top cover may present a suffocation risk. It is the responsibility of the caregiver to ensure that the patient can use this product safely.
- Avoid blocking the air intakes of the control unit, located on the right side of mattress base (when viewed from foot end).
- Bed frames used with the systems can vary greatly depending on the specific healthcare setting (ie hospitals, aged care, 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.
- Only the control unit and mattress combination as indicated by Novis Healthcare should be used, otherwise the correct function of the product cannot be guaranteed.

User Capacity

- The maximum recommended safe working load for this system is 200 kilograms.

  The minimum recommended safe working load for this system is 30 kilograms.
- Do not exceed this safe working load or you risk injury to the patient or carer and damage to the product.

Safety Precautions

Protection Against Hazards

Fluids

Avoid fluid contact on any part of the control handset or control unit, by keeping mattress top cover zipped closed and the waterfall skirt down. If spills do occur:

- Turn off control unit power and disconnect the unit from mains electricity supply.
- Immediately clean fluids from the casing by wiping with a soft cloth.

- Ensure there is no moisture in or near the power inlet, control handset and power cord before reconnecting the power supply.
- Check the operation of controls and other components around the spill area.
- Fluid or liquid remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards to patient and carers.

Explosion Hazard

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

Do not use in the presence of smoking materials or open flame – air flowing through the mattress will support combustion.

Do not open the control unit – risk of electrical shock. Refer servicing to qualified service personnel.

Disposal

Dispose of all components (control unit including batteries, air filter, air cells, mattress cover and base) according to local procedures and regulations or contact Novis Healthcare for advice.

Power Cord

Periodically inspect the power cord for damage. The system should never be operated with a worn or damaged power cord. Keep the cord away from heated surfaces. Should the power cord be found to be worn or damaged, contact Novis Healthcare for a replacement.

Interference

Although this equipment conforms to the intent of directive IEC 60601-1-21 in relation to Electromagnetic Compatibility, all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact Novis Healthcare.

1 IEC 60601-1-2. Medical Electrical Equipment - Part 1: General Equipments for Safety, Amendment No. 2. Collateral Standard. Electromagnetic Compatibility Requirements and Test).

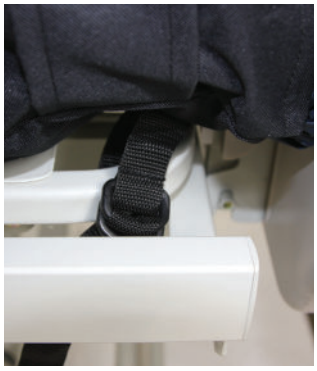
System Preparation

Carefully unpack the system and inspect each item for any damage that may have occurred during transit and handling. Any damage or missing components should be reported to Novis Healthcare as soon as possible.

⚠ Confirm there are no sharp objects in the immediate area which may risk damage to the mattress replacement.

1 Remove existing mattress from bed, release the main strap to unroll ProCair Prime mattress. Place the mattress on top of the bed base – printed top cover facing upwards.

2 Attach to the bed by securing the adjustable straps, located on the underside of the mattress base under each bed end. On a profiling bed, secure the straps around the moveable sections of the base. Ensure the buckles are securely fastened and straps are pulled tight.



⚠ Do not secure mattress straps to bed side rails – straps will tear.

⚠ Ensure that straps do not interfere with the operation of the bed, and that the mattress is properly secured. Failure to do so could result in patient injury or equipment damage.

3 Check CPR sealing valve is closed – the turning tab and the arrows must be aligned to 'CLOSED' position.

System Preparation

4 Check the internal quick release control unit air connectors are securely connected. Open the top cover by unzipping the right side of the mattress (zipper located at foot end), check the two connectors are secure by pushing the male and female ends together, there should be no movement. If a connection is open, a click will be heard once connector is firmly closed.

5 Snap the hanging hook over the back of the control handset as shown. Hang the control handset over the foot end of the bed.

Ensure the handset is secure and not at risk of falling off before use to prevent equipment damage.

6 Feed power cord through the cord retention loops along either side of the mattress base. Insert power cord plug into the side of the control unit, then connect to an appropriate electrical outlet and switch on mains power.

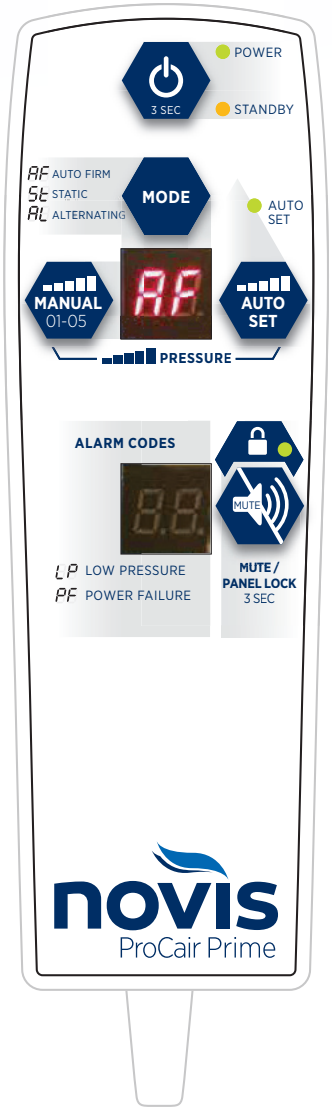
The Standby indicator on the handset will glow amber, confirming the control unit is connected to a power source.

⚠ Ensure the power cord is not under strain; is free from obstruction; and is secured safely so as not to be a trip hazard.

System Preparation

7 On the control handset, press and hold the Power button for a minimum of three seconds. The Power indicator will glow green to indicate the system is operational and automatically inflating.

While inflating, the mode/pressure indicator will display “AF” for **A**uto **F**irm, indicating mattress is being inflated to maximum pressure in preparation for use. Allow up to 45 minutes for complete inflation.



⚠ Do not lie a person (or any weight) on the mattress during initial inflation.

8 When initial inflation is complete, a beep will be emitted and the mode/pressure indicator will display “AL” for **AL**ternating, to indicate the system is ready for use in Alternating Mode.

⚠ The system defaults to pressure setting 02 upon full initial inflation. Press “AUTO SET” to activate automatic weight detection. This feature monitors patient weight every alternation cycle and automatically selects the appropriate pressure setting accordingly.
This feature can be deactivated for manual pressure setting (see page 14 for details).

Hybrid Mode

9 The ProCair Prime is initially configured as a full dynamic mattress, with the patient in direct contact with the air cells for maximum therapeutic benefits.

To convert to hybrid mode, refer to instructions on page 12.

Dynamic Mode

Hybrid Mode

System Preparation

Universal Therapy™ System Mattress Configuration

Dynamic Mode

The ProCair Prime is initially configured as a full dynamic mattress, the patient is placed in direct contact with the air cells for optimum pressure offloading during alternation, and the foam sheet is positioned in its storage compartment at the bottom of the mattress to provide bottoming out protection.

Hybrid Mode

Hybrid mode allows greater comfort for the patient by adding a softly padded foam sheet over the air cells to allow immersion of the patient's body over the mattress surface, while providing a limited degree of alternation and pressure offloading (in comparison to dynamic mode).

To convert to hybrid mode:

1. Unzip zippers from the foot end of the mattress and remove the top cover.

2. Undo 4 press studs on one side of the mattress base cover and remove the foam sheet from its compartment at the bottom of the mattress.

3. Align the 7 press studs on each side of the foam sheet with those along the top edges of the mattress base, fasten the foam sheet over the air cells.

To return to Dynamic Mode, simply remove foam sheet from the top of the mattress by undoing the press studs and returning the sheet to its storage compartment at the bottom of the mattress. If necessary, the foam sheet may be cleaned and dried before returning to its compartment, the foam is NOT washable.

⚠ The patient must be removed from the mattress during the conversion between Hybrid and Dynamic modes.

⚠ Consult your health professional for the suitability of Hybrid Mode according to the patient's condition and pressure injury risk.

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Patient Set Up

Once initial inflation is complete, a patient may be placed on the system.

1 Once the mattress is fully inflated, bedding can be replaced.
Secure sheets loosely enough to ensure they do not interfere with cell alternation.

2 Place the patient on to the ProCair Prime mattress.
The system defaults to a pressure setting 02 upon full inflation. Press “AUTO SET” to activate automatic pressure settin. This feature monitors patient weight (30-200kg) every alternation cycle and automatically selects the appropriate pressure setting accordingly

3 Perform a ‘bottoming out’ test (a test to ensure the patient is adequately suspended away from the base).

‘Bottoming Out’ Test

1 Check system is in alternation mode by ensuring the mode/pressure indicator is displaying “AL” and that one set of air cells is inflated while the other set is deflated.
You may need to unzip the cover to feel the cells for inflation.

2 With the patient lying supine, unzip one side of the top cover just past sacral region (lower spine).

3 Slide your hand underneath the patient and feel for a deflated cell under the patient’s lower spine (in Hybrid Mode, place hand underneath the foam sheet under the patient’s lower spine) your hand should easily slide between patient and base.

4 If your hand can pass under the patient, then patient is adequately suspended. If not, manually adjust pressure to ‘firmer’ and wait at least one cycle (12 minutes) for pressure to increase before repeating step 3.
If manual pressure adjustment fails, press Max Inflate to force mattress to full inflation. Wait at least one cycle (12 minutes) for pressure to reach maximum pressure, then press Alt to return to an alternation cycle. Wait at least one more cycle (12 minutes) for pressure to increase before repeating step 3.

5 We recommend repeating the Bottoming Out test at least 12 minutes after any manual pressure readjustment.

Operation

Control Handset

A Power

Press and hold the Power button for at least 3 seconds to turn the system power on and off.

Power LED - in operation
Standby LED - power connected

B Mode Selection

Press button to cycle between the following modes, as indicated by the mode/pressure indicator:

AF Auto Firm (Max Inflate)
St Static
AL Alternating

Refer to the next page on details of the above modes of operation.

C Mode/Pressure Indicator

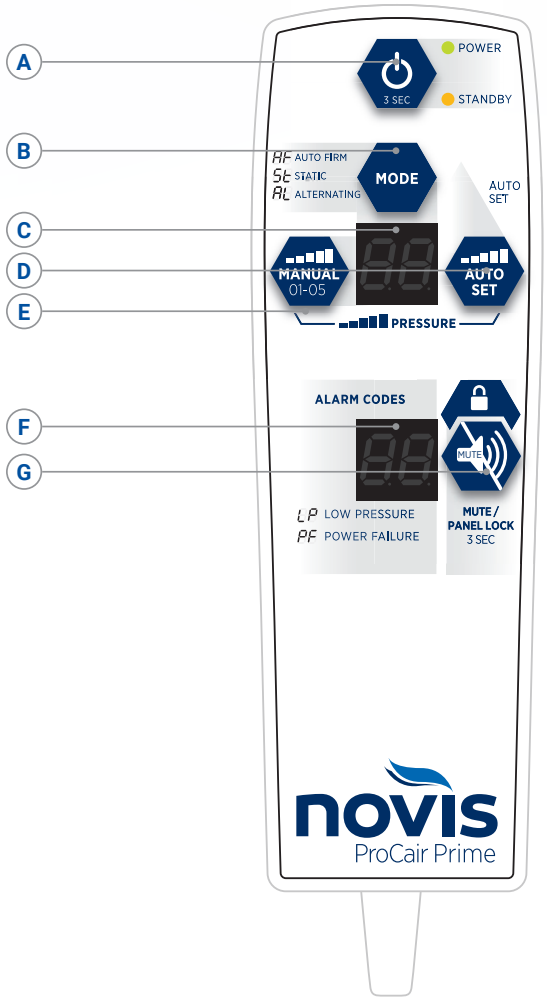
Normally displays the current mode of operation (AF, St, AL). Also displays pressure levels from **01** to **05** for 10 seconds when mattress pressure is manually adjusted, before returning to Mode display.

D Auto Pressure Setting

Press to activate and deactivate automatic pressure setting. Once activated, as indicated by the green LED above the button, the system will automatically detect patient weight every alternating cycle and adjust pressure accordingly if necessary.

E Manual Pressure Select

After initial inflation, the system defaults to setting **02** (30mmHg), manual adjustments may be made according to patient weight, levels of support and comfort required.



Press button to cycle pressure settings from 01 to 05, pressure levels are as follows:

01 20mmHg

02 30mmHg

03 40mmHg

04 50mmHg

05 60mmHg

F Alarm Indicator

LP - low pressure due to possible air leak
PF - power failure, mains power disconnected

For further details refer to Troubleshooting on Page 20

G Alarm Mute/Panel Lock Button

If alarm sounds, press once to mute alarm buzzer for 20 minutes to minimise disturbance.

Panel Lock - Long press for 3 seconds to lock control panel to prevent tampering or unintended operation, an amber LED indicator above will illuminate.

To unlock panel, long press for 3 seconds again. After 5 minutes of inactivity, the panel will re-lock automatically.(30mmHg), manual adjustments may be made

Modes of Operation

In Alternating Mode, alternate mattress cells inflate and deflate following a fixed cycle time of 12 minutes, with the exception of static head cells. Alternating mode is used for normal therapeutic function.

In Indefinite Static Mode, all mattress cells are inflated thereby suspending the alternation cycle and providing constant low pressure therapeutic patient benefits. System will continue in auto detection mode unless pressure level is manually selected.

In Auto Firm Mode, all mattress cells are inflated to maximum pressure to create the firmest possible base for stable patient handling, transfer or other special circumstances.

⚠ The system will operate in Auto Firm Mode for a maximum of 30 minutes, after which it will automatically revert to Alternating Mode for patient safety. The system will operate in Static Mode until manually changed to another mode.

⚠ During power failure/outage, the ProCair Prime Universal Therapy System will stop functioning and PF arlam code will be displayed on the Alarm Indicator, accompanied by an audible alarm. The system will return to its normal operation when mains power supply is resumed.

Quick Twist CPR

Rapid deflation of the mattress may be required for emergency treatment (or to pack up the unit). The Quick Twist CPR valve is located at the top of the mattress, to the right of the patient's head. If emergency resuscitation is required, turn the CPR valve so the arrows are aligned with the 'OPEN' position markers. This will rapidly deflate the entire system, including static head cells.

CPR in the Closed position.
Twist in either direction to OPEN

To reinflate the system after the Quick Twist CPR valve has been released, turn the tab and align the arrows with the the 'CLOSED' position markers, ensure control unit is switched on and wait for the system to regain optimal pressure.

CPR in the OPEN position.
Twist in either direction to Close

Operation

Transport Function

To prepare for patient transport, press the Mode button and select Auto Firm mode, wait 12 minutes to ensure all cells are fully inflated.

Ensure Quick Twist CPR valve is set to the CLOSED position. Switch off control unit by long pressing the **Power** button for 3 secs.

Open top cover, disconnect the air connectors from the control unit and connect the male connector to the female connector to ensure air does not escape from the mattress. Tuck hoses under an air cell.

Air will remain in the system for up to 24 hours, depending on patient and environmental circumstances.To convert to hybrid mode:

Tuck hoses under an air cell

Deflation and Storage

1 Press the power button for a minimum of three seconds to switch off the control unit.

2 Switch off mains power and unplug the power cord from the mains outlet.

3 Turn the Quick Twist CPR to OPEN to release air and deflate all cells.

4 Once air has been released from the system, detach the mattress from the bed by unfastening all mattress straps, place handset and power cord on the centre of the mattress, then fold and roll the mattress from head end to foot end.

5 Fasten main strap to keep mattress in rolled position. Return all items to the custom carry bag for safe keeping.

6 The bag is designed to fit snugly around the mattress. It may be easier to turn the open carry bag upside down, and then wrap the bag around the rolled up mattress, turn over bag, then tuck in the mattress as you zip up the bag.

Care and Cleaning

- To prevent cross contamination, the mattress should be examined and disinfected between patient use.
- Clean the mattress in accordance with local infection control policy and government regulations. Failure to do so could cause patient or personal injury.
- The mattress is not protected against excessive amounts of fluid.
- Switch off and disconnect the control unit from mains power supply before cleaning. Do not immerse the control unit in fluid.
- Do not use high temperature autoclave steam cleaning devices or phenolic based products for cleaning. This could result in damage to the equipment and may result in damage to the polyurethane coating, or negate the biocompatibility properties of the fabric.

Cleaning and Infection Control

- It is recommended that the system is cleaned every two weeks if in constant use.

Top Cover Cleaning

Unzip and remove the top cover from the base before washing (refer page 19 for instructions).

For basic care and cleaning, wipe down with warm water containing PH neutral detergent. The top cover can also be machine washed at a maximum of 95° C (203° F) using neutral detergents.

- Refer to the top cover wash tag for detailed cleaning instructions.
- Do not use system without top cover.

Base and Foam Sheet Cleaning

Swab the mattress base, air cells and the foam sheet with a solution of sodium hypochlorite or similar (up to 10,000 ppm available chlorine). Dry thoroughly before reassembly.

Do not machine wash or tumble dry the air cells, mattress base or the foam sheet.

- If cleaning or disinfection is required, do not allow fluid to enter air cells and air hoses.

Control Unit/Handset Cleaning

Disconnect control unit from mains power before cleaning. Gently wipe down the external case with a soft cloth.

Soak the cloth in warm water containing mild PH neutral detergent, and wring any excess water before gently wiping all external controls. Repeat the process with a dry cloth to remove excess moisture. A soft bristled nylon brush can be used to gently clean crevices.

- Ensure the control unit is disconnected from mains power before cleaning.
- Do not spray disinfectant directly on to the control unit, or immerse the unit in water or other fluid.

Care and Cleaning

Disinfection

The mattress, top cover and control unit may be decontaminated by a solution of sodium hypochlorite or similar (up to 10,000 ppm available chlorine). Dry thoroughly before use.

For infection control, swab with a solution of sodium hypochlorite or similar (up to 10,000 ppm available chlorine). Dry thoroughly before reattaching and use.

Top Cover Removal

1 Raise the waterfall skirt and locate the zippers at the foot end of the mattress.

2 Starting with either zipper, run the zipper along the side of the mattress towards the centre of the head end.

3 Repeat with other zipper. The top cover can now be detached from the mattress base.

To reattach the top cover to the mattress base, reattach the zippers, then run them along the sides of the mattress back towards the centre of the foot end.

Troubleshooting

Alarm Codes

An audible alarm, accompanied by an Alarm Code display, indicate the control unit or mattress is experiencing a fault. The Alarm Code display will continue to flash until the fault is cleared. The audible alarm can be silenced for **20 minutes** by pressing the Alarm Mute button. It will reactivate if the fault is not rectified or if a new fault is detected.

ALARM CODE	TRIGGER	SOLUTION
 Low Pressure	Air cells have failed to reach the pre-set pressure after two cycles	Ensure mains power is turned on and power cord is connected to mains and control unit. Check control unit/mattress air connections are fitted securely. Ensure CPR valve is set to CLOSE position. Replace CPR valve if air leak is found. Check air intake foam filter is not blocked by linen/dust. Replace with new filter if needed..

For faster mattress reinflation once the air leak has been closed, select **Auto Firm Mode (AF)** *and wait until the LP alarm code stops displaying. Select* **Alternation Mode (AL)** *to resume alternation.*

FAULT	TRIGGER	SOLUTION
 Power Failure	Power Failure	Check control unit is connected to the mains power supply. Check for loose connection on plug and main power is switched on. Check condition of power cord and plug. Check if mains socket is faulty.
Control unit does not operate; no display or lights		Check control unit is connected to the mains power supply. Check for loose power cord connection and ensure main power is switched on. Check condition of power cord and plug. Check if mains socket is faulty.
Patient is sinking or 'bottoming out' whilst lying flat on the mattress		The pressure may be set too low for the patient's weight – increase the pressure setting by manually setting a higher pressure level by pressing the "MANUAL" button. Check for air leaks in the mattress and air hoses.
Control unit controls lock up, or freezes		Turn off and unplug the control unit from mains power. Rest the control unit for one minute before reconnecting the control unit to mains power and switching on.
Air flow output varies unstably or stops erratically		This may be caused by electromagnetic disturbance or unstable mains power supply. Ensure system is used in an area with a stable power supply, if this is not possible, consider connecting an Uninterrupted Power Supply (UPS) unit between the system and the mains power supply to stabilise power. Restart system by power OFF and then powering ON again.

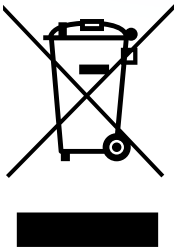
If the problem persists, move patient to another mattress and contact Novis Healthcare.

Technical Specifications

SYSTEM	MODEL		ProCair Prime
	SYSTEM CODE		APMPC-R03
	CAPACITY		30 - 200 kg
	NO OF CELLS		21, including 3 static head cells and 4 narrow foot cells
	COMPLIANCE		IEC60601-1, IEC60601-1-2 and IEC60601-1-11
	ARTG		289458
CONTROL UNIT	PART NO.		APMPC-CU03
	CONTROL SYSTEM		Digital micro controller
	CASING MATERIAL		ABS
	CYCLE TIME		12 minutes (fixed)
	VOLTAGE / CURRENT		AC100 - 240V / 50Hz-60Hz / 0.2-0.1A
	MIN / MAX PRESSURE		20 ~ 60 mmHg +/- 6 mmHg
	PROTECTION TYPE		Class II Type BF
	INGRESS PROTECTION RATING		IP22
	HANDSET MODEL		HS-NBE
	HANDSET PART NO.		FO-NVS0001
	HANDSET CASING MATERIAL		ABS
MATTRESS DIMENSIONS	LENGTH		2000 mm
	WIDTH		900 mm
	HEIGHT		180 mm
	WEIGHT		12 kg
	MATERIAL	TOP COVER	PU laminated nylon
		BASE COVER	PVC laminated polyester
		AIR CELL	TPU-laminated nylon
OPERATING ENVIRONMENT	AIR HUMIDITY	OPERATION	30% to 75% non-condensing
		STORAGE	30% to 90% non-condensing
	AMBIENT TEMPERATURE	OPERATION	15° C to 35° C
		STORAGE	5° C to 60° C
	ATMOSPHERIC PRESSURE RANGE		700 hPa to 1060 hPa
	ALTITUDE		-310 metres to 3000 metres

Technical Specifications

Waste Disposal



This product has been supplied from an environmentally aware manufacturer that complies with the European Community's Waste Electrical and Electronic Equipment Directive (WEEE).

This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according the legislation. Please be environmentally responsible and contact your local authority on available options to recycle this product at its end of life.

Service Life

The expected service life of a control unit and a mattress is highly dependent on frequency of use, servicing, care and maintenance.

To maintain the condition of the alternating mattress system, service the system regularly according to the schedule recommended by Novis.

- Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the ProCair Prime system or any of its components.
- All product specifications are subject to change without notice.

Technical Specifications

⚠ Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

⚠ RF mobile communications equipment can effect medical electrical equipment.

Recommended separation distances between portable and mobile RF communications equipment and the ProCair Prime Universal Therapy System M31 control unit

The ProCair Prime Universal Therapy System M31 control unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ProCair Prime Universal Therapy System M31 control unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ProCair Prime Universal Therapy System M31 control unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **(W)**	Separation distance according to frequency of transmitter **(m)**		
	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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical Specifications

Guidance and Manufacturer's declaration-electromagnetic emissions

The ProCair Prime Universal Therapy System M31 control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the ProCair Prime Universal Therapy System M31 control unit should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The ProCair Prime Universal Therapy System M31 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 emissions CISPR 11	Class B	The ProCair Prime Universal Therapy System M31 control unit 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	Compliance	
** During the test, the LED display panel on the wired control box would flash, however it would return to the normal, continuously lit status after the test. This does not affect the device's essential performance or basic safety. Please refer to the Risk Management Report for details		

Guidance and Manufacturer's declaration-electromagnetic immunity

The ProCair Prime Universal Therapy System M31 control unit is intended for use in the electromagnetic environment specified below.

The customer or the user of the ProCairPrime Universal Therapy System M31 control unit should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	Contact ±8 kV	Contact ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
	Air ±2, ±4, ±8, ±15 kV	Air ±2, ±4, ±8, ±15 kV	
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
	± 1kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	± 0.5, ±1 kV line(s) to line(s)	± 0.5, ±1 kV line(s) to line(s)	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
	± 0.5, ±1, ± 2kV line(s) to earth	Not applicable	

Technical Specifications

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0.5 cycle 0 % U_T; 0.1 cycle 70 % U_T; 250/300 cycles	Voltage dips 0 % U_T ; 0.5 cycle 0 % U_T 0.1 cycle 70 % U_T; 25/30 cycles	Mains power quality should be that of a typical home healthcare and professional healthcare environment. If the user of the control unit requires continued operation during power mains interruptions, it is recommended that the control unit be powered from an uninterruptible power supply or a battery.
	Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage interruptions: 0 % U_T; 250/300 cycle	
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The control unit power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare and professional healthcare environment.
NOTE UT is the AC mains voltage prior to application of the test level			
Conducted RF IEC 61000-4-6	3 Vrms: 0.15 MHz – 80 MHz	3 Vrms: 0.15 MHz – 80 MHz	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 d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz 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, [A] should be less than the compliance level in each frequency range.[B] Interference may occur in the vicinity of equipment marked with the following symbol:
	6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz	6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz	
	80% AM at 1 kHz	80% AM at 1 kHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 the ProCair Prime Universal Therapy System M31 control unit is used exceeds the applicable RF compliance level above, the ProCair Prime Universal Therapy System M31control unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ProCair Prime Universal Therapy System M31 control unit.

B Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Technical Specifications

Manufacturer's declaration-electromagnetic immunity Test specifications for Enclosure Port Immunity to RF wireless communications equipment

The ProCair Prime Universal Therapy System M31 control unit is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below. The customer or the user of the control unit should assure that it is used in such an environment.

Test frequency (MHz)	Band [A] (MHz)	Service [A]	Modulation [B]	Maximum power (**W**)	Distance (**m**)	Immunity test level (V/m)	Compliance level (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation [B] 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation [B] 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [B] 18 Hz	2	0.3	28	28
870							
930							
1,720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [B] 217 Hz	2	0.3	28	28
1,845							
1,970							
2,450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [B] 217 Hz	2	0.3	28	28
5,240	5 100-5 800	WLAN 802.11a/n	Pulse modulation [B] 217 Hz	0.2	0.3	9	9
5,500							
5,785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

A For some services, only the uplink frequencies are included.

B The carrier shall be modulated using a 50 % duty cycle square wave signal.

C As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Warranty Statement

This warranty is provided by

Novis Healthcare (ABN 45 102 735 491)
of Unit 11/12 Mars Road Lane Cove West
New South Wales 2066.

Novis Healthcare (Novis) products are manufactured to the highest quality standards and are thoroughly tested and inspected before leaving our factory. In addition to any statutory rights and remedies you may have, Novis warrants all of its products sold directly or via an Authorised Novis Australia Dealer against defective workmanship and faulty materials from the date of purchase by the end user for a period of twelve months unless otherwise specified for that product and its components.

Warranty Claims

To claim under this warranty, please contact Novis Healthcare and have your receipt or proof of purchase available. Novis Healthcare may need to assess the defect before determining any claim, and additional information may be requested to process your claim. Claims without proof of purchase may not be able to be processed.

Novis Healthcare may at its option inspect the goods on site or require them to be returned to its premises or one of its Authorised Service Agents in person or freight prepaid by you.

Novis will undertake at its option, to repair or replace, free of charge, each product or part thereof on the condition that:

- The product found on examination, to be suffering from a manufacturing defect;
- The product or relevant part has been serviced regularly by Novis or one of its Authorised Service Agents and has not been subjected to misuse, neglect or been involved in an accident;
- The repairs are not required as part of normal wear and tear.

At our option

- Goods repaired may be replaced by refurbished good of the same type rather than being repaired.
- Refurbished parts may be used to repair goods.
- Novis Healthcare will not be held responsible for any repair other than those carried out by it or one of its Authorised Service Agents.

Warranty repairs do not extend the length of the warranty period.

Limited Liabilities

Our liability under this manufacturer's warranty is subject to us being satisfied that a defect was caused by faulty parts, manufacture or workmanship, and was not caused or substantially contributed to by other factors or circumstances beyond our control, including (but not limited to) defective installation, maintenance or repair, product modification or alteration, any neglect, misuse, or excessive use, normal wear and tear or failure to follow manufacturer's instructions.

Warranty Statement

IMPORTANT NOTICE FOR AUSTRALIAN CONSUMERS:

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. To obtain compensation, you will need to provided documentary evidence of the loss or damage suffered and documentary evidence that such loss or damage was a reasonable foreseeable consequence of a failure Novis Healthcare to comply with a consumer guarantee under the Australian Consumer Law. Subject to the provisions of the Australian Consumer Law, Novis Healthcare excludes, to the fullest extent permitted by law, all liability in respect of loss of profit or other economic loss, direct to indirect or consequential, special, general or other damages or other expenses or costs which may include negligence.

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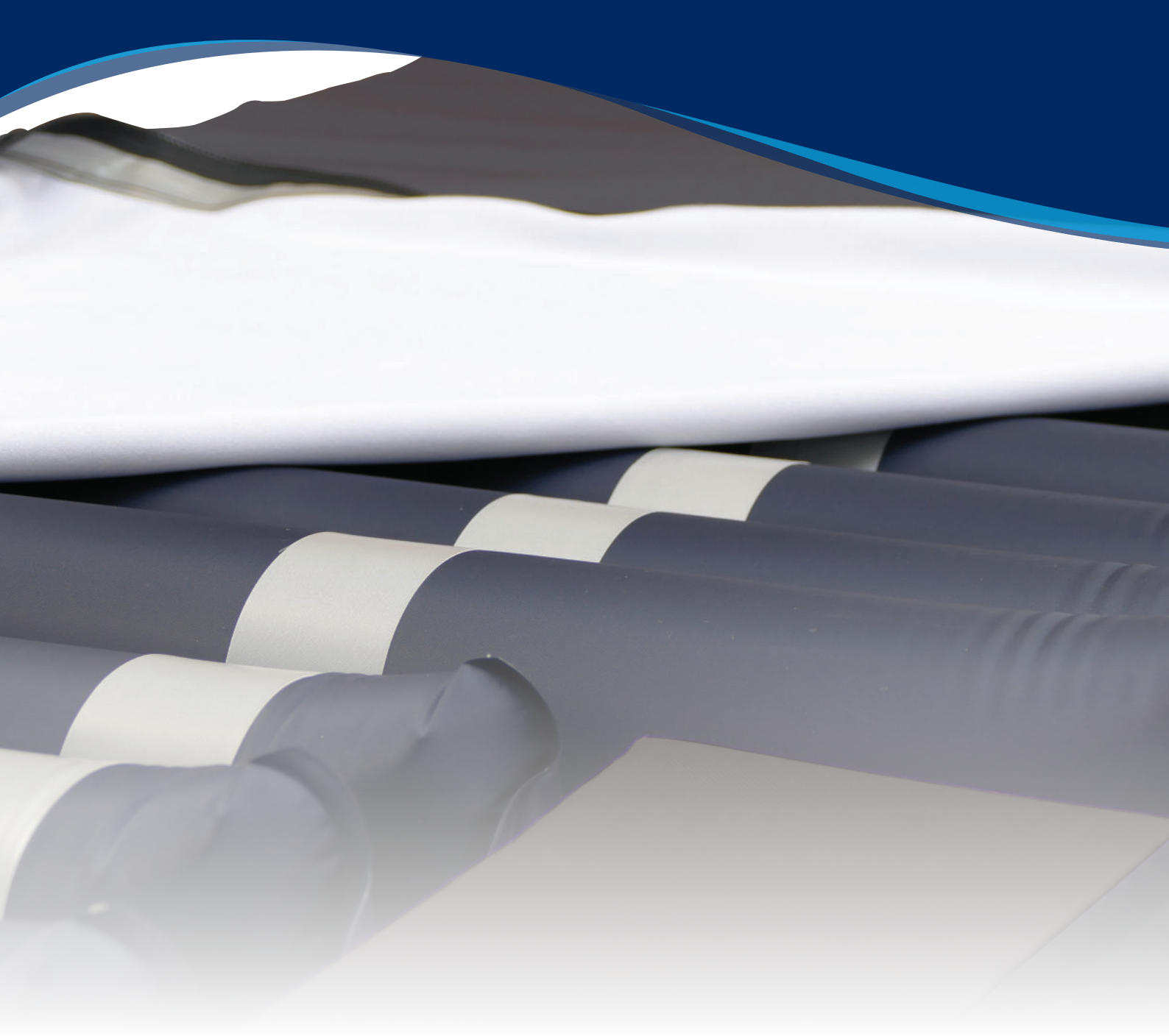

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