





Alternating Mattress Replacement / Overlay

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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.

We recommend you keep the manual 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 (October 2017).

Definition of Symbols Used

- **(i)** 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.
- Protection against foreign object and vertically falling water drops.

Overview

Product Overview

The BetterLiving alternating pressure surfaces are designed for the prevention and treatment of skin breakdown and pressure injuries.

The Alternating Pressure Mattress Replacement is designed to replace an existing bed mattress, on either a standard or profiling electric bed frame, as a solution for people at risk to high risk of pressure injuries.

The Alternating Pressure Mattress Overlay is designed for use on top of the existing standard bed mattress (or suitable underlay) as a solution for people at risk or low risk of pressure injuries. The systems are constructed from transverse air cells that cyclically inflate and deflate in an alternating pattern, providing gentle and dynamic support. Cyclic alternation of pressure prevents arterial and venous capillary occlusion in the patient's surface tissue — maintaining and stimulating the flow of blood and lymphatic fluids through these tissues to provide essential oxygen and remove metabolic waste.

The system consists of the following components:

Mattress Replacement/Overlay with umbilical air hoses and CPR release

- □ Control unit
- □ Power cord
- □ User guide
- □ Carry bag

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

Intended Use

☐ The prevention and treatment of skin breakdown and pressure injuries in patients at risk to high risk (replacement) or at risk to low risk (overlay).

Contraindications

Patient conditions for which the application of pressure therapy on the BetterLiving systems contraindications include:

- □ Instable spinal cord injury
- □ Cervical traction

Intended Care Setting

- □ Aged care
- □ Home care

Working Environment

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

Shipping/Storage Environment

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

Connecting to other devices

There no are other devices necessary for normal operation. The control unit can be fitted to the foot board of most hospital or aged care beds.

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

- A 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 manual.
- Do not place the overlay directly on the bed frame; designed for use on mattress.
- 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 either side of the mattress replacement 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.
- A 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 at the rear of the unit. Do not place items such as blankets over the control unit.
- 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 patient weight is 180 kilograms for the Mattress Replacement and 150 kilograms for the Mattress Overlay.
- ↑ The minimum recommended patient weight is 40 kilograms for both the Mattress Replacement and Mattress Overlay.
- Do not exceed this safe working load or you risk injury to the patient or carer and damage to the product.

Safety Precautions

Protections Against Hazards

Fluids

Avoid spilling fluids on any part of the control unit. If spills do occur:

- ☐ Turn off control unit power and disconnect the unit from the mains electricity supply.
- ☐ Immediately clean fluids from the casing by wiping with a soft cloth.
- Sensure there is no moisture in or near the power inlet, power switch and power cord before reconnecting the power supply.
- **3** 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

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).

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.

Mattress Replacement

Remove the existing mattress and place the mattress replacement on top of the bed frame.

Printed top cover facing upwards and umbilical cord towards the base of the bed.



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.





Mattress Overlay

Remove all bedding from the mattress and place the mattress overlay on the existing mattress (or suitable foam underlay).

Printed top cover facing upwards and umbilical hose towards the base of the bed.



Secure to the bed by sliding the elastic straps, located on the underside of the mattress overlay, around each end of the existing mattress. Ensure the straps fit firmly, and are not twisted or pulled towards the corners.



⚠ 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.

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



Hang the control unit over the foot end of the bed, using the in-built spring loaded hanging hooks. Pull the hooks by the rubber tabs to prevent accidentally trapping your fingers.

Ensure it is secure before use; failure to do so could result in equipment damage.



Connect the umbilical connectors to the corresponding sockets on the side of the control unit. Listen for a click as confirmation the connector is locked in place.

⚠ Straighten any twists in the umbilical air hoses.



⚠ Ensure the umbilical air hose is not trapped between the mattress and bed.



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

The Power indicator 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.

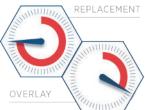


On the control unit, press and hold the Power button for a minimum of three seconds.
The Power indicator will illuminate to indicate the system is operational. While reaching initial operating

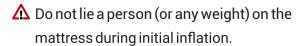


pressure, all five pressure setting indicators will flash green.

Allow up to 45 minutes for the Mattress Replacement and 20 minutes for the Mattress Overlay.



Once operating pressure is reached, both Alternate and Auto indicators will illuminate to indicate both alternating mode and automatic pressure setting are functioning.



When initial inflation is complete, the Pressure Setting and Max Inflate indicators will extinguish, to indicate the system is ready for use. The system automatically defaults to Alternating Mode at start up.

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

Place the patient on to the mattress replacement overlay.

The system will automatically set an optimum pressure for the patient's weight and will continuously alternate over a 12 minute cycle.

Perform a 'bottoming out' test (a test to ensure the patient is adequately suspended away from the base), refer to page 10.





Patient Set Up

Pressure Setting

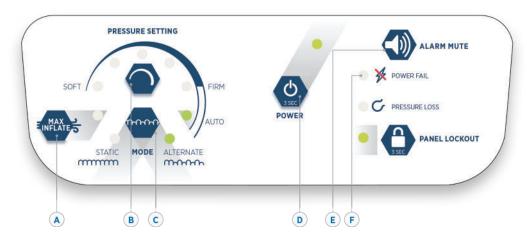
It is recomended that the Auto function remain active whenever possible. If Pressure Setting is manually adjusted always perform a Bottoming Out Test as details below.

Bottoming Out Test

- ☐ Check system is in alternation mode by ensuring the indicator above the Alternate button is illuminated, 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.
- ☐ With the patient lying supine, unzip one side of the top cover just past sacral region (lower spine).
- □ 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.
- ☐ 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 the test.
- ☐ 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 Alternate to return to an alternation cycle. Wait at least one more cycle (12 minutes) for pressure to increase before repeating the test.
- We recommend repeating the Bottoming Out test at least 12 minutes after any manual pressure readjustment.



Operation - Control Panel



A Max Inflate

Rapidly inflates mattress to maximum pressure in Static mode. System will automatically return to Alternating mode after 20 minutes.

B Pressure Setting

Allows manual adjustments to the automatic pressure setting (within reasonable limits for the patient's detected weight). Press the button to cycle from Soft to Firm pressure. Press the button again to cycle back to Auto – green indicator illuminates to indicate automatic pressure setting is functioning.

C Mode

Cycle between Indefinite Static and Alternating modes. Press the button to select required mode – indicator glows green above the selected mode to indicate the mode currently active.

See Mode on page 12 for more details

D Power

Press and hold for a minimum of three seconds to turn system power on and off.

Green light = power on.

E Alarm Mute

Turns audible alarm off temporarily. Press to mute the alarm. Alarm will resound in 20 minutes if the issue has not been resolved, or immediately if new fault detected.

F Power Failure

During a power failure, amber light flashes and an audible alarm sounds to alert carer.

G Pressure Loss

Indicates mattress has failed to reach required pressure. Indicator flashes amber and after five minutes, an audible alarm sounds to alert carers that the control unit has failed to reach the set pressure. Refer to Troubleshooting for support.

H Lock/Unlock

Lock and unlock the Control Unit panel to prevent unwanted interference.

Press and hold the button for a minimum of three seconds – a beep sounds and the light illuminates to indicate system is locked. When locked, only the Alarm Mute and Lock/Unlock button remain operational.

Press again for at least three seconds to unlock (beep sounds and light turns off).

Operation

Mode



In Alternating Mode, alternate mattress air cells inflate and deflate following a fixed cycle time of 12 minutes.



In Indefinite Static Mode, all mattress cells remain inflated, with adjustable pressure allowing for constant low pressure therapy benefits.

The system will operate in Indefinite Static Mode until manually changed to Alternating Mode.

The system will not automatically revert to Alternating mode from Indefinite Static mode.

Ouick Twist CPR

Rapid deflation of the mattress may be required for emergency treatment (or to decommission 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 treatment is required, turn the CPR valve to the 'OPEN' position. This will rapidly deflate the entire system, including static head cells.

To re-inflate the system after the Quick Twist CPR valve has been released, turn the tab to the 'CLOSED' position, ensure control unit is switched on and wait for the system to gain optimal pressure.

Transport

The mattress should be transported in Max Inflate mode, without control unit. Press the Max Inflate button and wait 12 minutes to ensure all air cells are inflated.

Before moving the mattress, ensure the control unit is switched off and disconnected from mains power. Disconnect the umbilical air hose from the control unit by unplugging the quick release connectors. Run the umbilical cord through the left-side cord retention loops and clip the male and female connectors around a cord retention loop to secure in place.







CPR IN THE CLOSED POSITION. TWIST IN EITHER DIRECTION TO OPEN



CPR IN THE OPEN POSITION. TWIST IN EITHER DIRECTION TO CLOSE

Operation

Deflation and Storage

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

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

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

Press the release buttons on the umbilical cord connectors to release the air hoses.



Once air has been released from the system, detach the mattress from the bed. Roll the mattress from head end to foot end to remove additional air from the system.

Unroll the mattress slightly and place the control unit, power cord and umbilical cord on the mattress to keep them protected.

Roll the mattress with the control unit and power cord inside, and place all items in the custom carry bag for safe keeping.



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.
- 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 right).

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.

A Refer to the top cover wash tag for detailed cleaning instructions.

⚠ Do not use system without top cover.

Top Cover Removal

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

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

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



Base Cleaning

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

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

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

Control Unit 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.

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.

Troubleshooting

SYMPTOM	SOLUTION
	Ensure the main power is turned on and power cord is connecte to mains and control unit.
Low pressure indicator illuminated;	Check control unit/mattress air connections are fitted securely and reconnect umbilical cord if loose.
mattress is not inflating with control unit connected and switched on	Ensure control unit is turned on.
connected and switched on	Check air intake from filter is not blocked by linen/dust. Replace with new filter if needed.
	Ensure the air cells are free of damage or leaks
	Ensure the main power is turned on and power cord is connecte to mains and control unit.
Pressure Loss indicator constantly illuminated;	Check control unit/mattress air connections are fitted securely and reconnect umbilical cord if loose.
mattress is not inflating with control unit	Ensure control unit is turned on.
connected and switched on	Check air intake from filter is not blocked by linen/dust. Replace with new filter if needed.
press MAX INFLATE and wait unt	Ensure the air cells are free of damage or leaks. ion once the air leak has been closed, iil the low pressure indicator extinguishes. on to resume Alternation mode.
press MAX INFLATE and wait unt	ion once the air leak has been closed, til the low pressure indicator extinguishes.
press MAX INFLATE and wait unt Press the MODE butto	ion once the air leak has been closed, fil the low pressure indicator extinguishes. on to resume Alternation mode.
press MAX INFLATE and wait unt Press the MODE butto Control unit is making unusual noise	ion once the air leak has been closed, fil the low pressure indicator extinguishes. on to resume Alternation mode. Ensure control unit is resting against a solid surface Check control unit is connected to the mains power supply.
press MAX INFLATE and wait unt Press the MODE butto	ion once the air leak has been closed, til the low pressure indicator extinguishes. on to resume Alternation mode. Ensure control unit is resting against a solid surface Check control unit is connected to the mains power supply. Check for loose connection on plug and main power is switche
press MAX INFLATE and wait unt Press the MODE butto Control unit is making unusual noise	ion once the air leak has been closed, fil the low pressure indicator extinguishes. on to resume Alternation mode. Ensure control unit is resting against a solid surface Check control unit is connected to the mains power supply. Check for loose connection on plug and main power is switche on.
press MAX INFLATE and wait unt Press the MODE butto Control unit is making unusual noise	ion once the air leak has been closed, til the low pressure indicator extinguishes. In to resume Alternation mode. Ensure control unit is resting against a solid surface Check control unit is connected to the mains power supply. Check for loose connection on plug and main power is switche on. Check the fuses in control unit. Replace if necessary. Check condition of power cord and plug. Check if mains socket

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 orotherwise misuse the BetterLiving system.

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.

A RF mobile communications equipment can effect medical electrical equipment.

Recommended separation distance between portable and mobile RF communications equipment and the control unit

The control unit is intended for use in an electromagnetic environment (for home healthcare and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the control unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 VP 80 MHZ TO 800 MHZ D = 1.2 VP800 MHZ TO 2,5 GHZ D = 2.3 VP			
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.

Manufacturer's declaration-electromagnetic emissions

The 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

Emission test	Emission test	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The control unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	ClassB	
Harmonic emissions IEC 61000-3-2	Class A	The 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
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	for domestic purposes.

Manufacturer's declaration-electromagnetic immunity

The control unit is intended for use in the electromagnetic environment (for home healthcare) specified over. The customer or the user of the control unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance		
			(for home healthcare environment)		
Electrostatic discharge(ESD) IEC	Contact ±8 kV	Contact ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the		
61000-4-2	Air ±2, ±4, ±8, ±15 kV	Air ±2, ±4, ±8, ±15 kV	relative humidity should be at least 30%		
EL 16 .	± 2kV for power	± 2kV for power			
Electrical fast transient/burst	supply lines	supply lines	Mains power quality should be that of a typical home healthcare and professional healthcare		
IEC 61000-4-4	± 1kV for input/ output lines	± Not applicable	environment.		
	± 0.5, ±1 kV line(s) to	± 0.5, ±1 kV line(s) to			
Surge	line(s)	line(s)	Mains power quality should be that of a typical home healthcare and professional healthcare		
IEC 61000-4-5	± 0.5, ±1, ± 2kV line(s) to earth	± 0.5, ±1, ±2 kV line(s) to earth	environment.		
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0.5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles	Voltage dips: 0 % UT; 0.5 cycle 0 % UT; 1 cycle 70 % UT; 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		
	Voltage interruptions: 0 % UT; 250/300 cycle	Voltage interruptions: 0 % UT; 250/300 cycle	during power mains interruptions, it is recommended that the control unit be powered from an uninterruptible power supply or a battery.		
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.		

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidan (for home healthcare environment)
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 a
	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 e)	80% AM at 1 kHz e)	Recommended separation distance:
	10 V/m	10 V/m	d = 1,2 √P
	80 MHz – 2.7 GHz b)	80 MHz – 2.7 GHz	d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,7 GHz
Radiated RF IEC 61000-4-3			Where P is the maximum output power ra of the transmitter in watts (W) according the transmitter manufacturer and d is the recommended separation distance in me (m).
	80 % AM at 1 kHz c)	80 % AM at 1 kHz	Field strengths from fixed RF transmitters determined by an electromagnetic site sushould be less than the compliance level frequency range. ^B
			Interference may occur in the vicinity of equipment marked with the following syr



UT is the A.C. mains voltage prior to application of the test level.

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 control unit is used exceeds the applicable RF compliance level above, the control unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the control unit.

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

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

The 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			Pulse				
745	704-787	LTE Band 13, 17	$modulation^{\scriptscriptstyle B}$	0.2	0.3	9	9
780			217 Hz	Z			
810	GSM 800/900,	Pulse					
870	800-960	IDEN 820 CDMA	modulation ^B	2	0.3	28	28
930	_	850, LTE Band 5	18 Hz				
1,720		GSM 1800; CDMA 1900; -1990 GSM 1900; r DECT; LTE Band 1, 3, 4, 25; UMTS	D 1	2	0.3	28	
1,845	1700-1990		Pulse modulation ^B 217 Hz				28
1,970							
2,450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^B 217 Hz	2	0.3	28	28
5,240		NA// A N I	Pulse				
5,500	5100-5800	WLAN 802.11a/n	$modulation^\mathtt{B}$	0.2	0.3	9	9
5,785		3 - 2 ,	217 Hz				

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.

	MODEL		Matterna Davida and a	Makkusas Ossail		
	MODEL		Mattress Replacement	Mattress Overlay		
	SYSTEM CODE		APMBL-R01	APMBL-L01		
SYSTEM	CAPACITY		40 to 180 kg	40 to 150 kg		
STOTEW	NO OF CELLS		15, including 3 static head	Icells		
	ARTG		289458	289458		
	COMPLIANCE		IEC60601-1, IEC60601-1-2 and IEC60601-1-11			
	CONTROL UNIT CODE		APMBL-CU02	APMBL-CU01		
	CONTROL SYSTEM		Full digital control			
	CYCLE TIME		12 minutes (fixed)			
	SUPPLY VOLTAGE		AC100 - 240V / 50Hz-60H	z		
	MAXIMUM CURRENT		0.2 to 0.1 A			
CONTROL UNIT	FUSE RATING		T2AL 250V			
	MIN/ MAX PRESSURE		$20 \sim 60 \text{mmHg}$ +/- 6mmHg			
	PROTECTION TYPE		Class II Type BF			
	INGRESS PROTECTION RATING		IP21			
	HEIGHT x WIDTH x DEPTH		195 x 265 x 120 mm			
	WEIGHT		2 kg			
	LENGTH x WIDTH x HEIGHT		2000 x 880 x 200 mm 2000	0 x 880 x 130 mm		
	WEIGHT		8 kg	4.5 kg		
MATTRESS		TOP COVER	Polyurethane-laminated nylon			
	MATERIAL	BASE COVER	PVC laminated polyester			
	AIR CELL		TPU laminated nylon			
	TEMPERATURE		15°C to 40°C			
OPERATING	HUMIDITY		30% to 75% non-condensing			
ENVIRONMENT	ATMOSPHERIC PRESS	ATMOSPHERIC PRESSURE RANGE		700 hPa to 1060 hPa		
	OPERATION ALTITUDE		-310 metres to 3000 metre	es		

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.

Soft Goods 2 year

Control unit 2 year

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.

Warranty Statement

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. in person or freight prepaid by you.

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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