INSTRUCTIONS FOR USE

Polaris II, Nexus, Tertius mattress systems

Contents

1. Packaging Contents

- Control Unit x 1
- Power Cable x 1
- Mattress/Cushion (depending on system) x 1

2. Alternating Pressure Operation Principle

Patients who spend a lot of time in bed will often experience vascular compression on any part of their body where there is a bony protrusion, such as the shoulders and sacrum. This can easily cause decubitus pressure ulcers to form, leading to further complications such as infection.

The interleaved pressure relief areas on our alternating pressure support surfaces provide periodic relief from vascular compression to the whole body by dynamically redistributing your patient's weight, preventing and alleviating decubitus pressure ulcers. For your patient's comfort, the three-cell pillow zone at the head of the mattress is designed to provide static support for your patient's head.

3. Guidelines

Always use pressure care systems under the advice of a suitably qualified medical professional. The patient's pressure ulcer risk assessment scores, weight and the handling considerations for caregivers should be considered to ensure that the appropriate system is selected.

4. Specifications

Technical Specifications	
Therapy modes	Dynamic & Static
Compressor air flow	Approx. 10lpm
Cycle time	10 minutes
Anti-particle filter	Yes
Visual and audible alarms	Yes
Electrical power supply	220 – 240V / 50Hz
Power consumption	9W
Fuse rating	F2A 250VAC
Electrical isolation	Class I 2a
Ingress protection	IP21
IEC conformity	60601-1, 60601-1-2, 60601-11
Warranty	1 year against all manufacturing faults

Atmospheric Specifications	
Storage temperature	-25 - 70°C
Transport temperature	-25 - 70°C
Operating temperature	5 - 40°C
Humidity	10 - 90%
Atmospheric pressure	700 - 1060hPa

5. General Precautions

- ✓ Ensure this equipment is not setup or used near sources of high heat or excessive electromagnetic, electrostatic or radiation fields including UV radiation, such as direct sunlight.
- ✓ Do not use system in the presence of any flammable anaesthetic mixture with air, nitrous oxide or oxygen or in the presence of smoking materials or open flame - risk of explosion.
- ✓ Do not use this equipment for anything other than what it is specifically designed for. The use of accessories or parts not recommended or specifically designed for this equipment is prohibited and be voided the warranty.
- ✓ Do not modify or connect this equipment to other parts or equipment not specifically designed for use with this system.
- ✓ Do not allow young children to operate, play with or remove any part of this medical system.
- ✓ Do not use this equipment near sources of excessive moisture such as nebulizers or steam kettles.
- ✓ Do not use corrosive cleaning products such as industrial degreasers or acetone solvents.
- ✓ The product can only be operated by personnel who are qualified to perform general nursing procedures and has received adequate training in knowledge of prevention and treatment of pressure ulcer.
- ✓ Close supervision is necessary when this product is used on or near children. The device is mains powered and contains small parts so presents electrical and choking hazards.
- ✓ The mattress cover has passed skin sensitization and skin irritation test. If you suspect that you may have had or are having an allergic reaction to the mattress cover, consult a physician immediately.

5.1 Mattress Precautions

- ✓ Do not place any layers of material between the patient and top cover of the mattress; this will compromise the support system therapy. The following are included:
    - Hospital sheets - regular or fitted
    - Sheepskins or equivalent
    - Incontinence sheets
    - Slide sheets
    - Electric heating blankets
- ✓ Ensure the patient's clothing does not cause skin damage due to ties, buttons, creases, seams, objects in pockets and jewellery.
- ✓ Do not place any sharp items on or near the mattress such as syringes or scalpels or any instrument that could hole the top cover.
- ✓ Do not place any solid items on top of the system besides the patient.
- ✓ No natural rubber latex is used in the construction of this system.

5.2 Control Unit Precautions

- ✓ Do not open the control unit, as there is risk of electric shock and it will void your warranty.
- ✓ Do not block the air inlet at the rear of the control unit.
- ✓ Do not spill any liquids onto the control unit. If a spillage occurs:
    - Turn off power to the control unit at the wall and disconnect the power cable from the control unit.
    - Wipe dry any excess moisture on the external casing.
    - Check that the interior of the IEC socket, rocker switch and power plug are dry.
- ✓ Ensure that the power lead is undamaged, safely run and properly connected so that it does not pose an electrocution or trip hazard.
- ✓ Ensure that the power cable is positioned away from any moving bed part, which may kink or damage the power cord.
- ✓ Ensure that the power cable does not interfere with cleaning around the bed or the use of cleaning liquids especially on the floor.

6. Storage

It is recommended that the control unit is stored in a sealed plastic bag in a cool, dry area. Ensure that no heavy items are placed on top of the system during storage as this may damage it.

7. Warranty

The control unit is guaranteed for 1 year from the date of purchase against all manufacturing faults, on the condition that it is stored and operated in the conditions recommended in this instruction document. Proof of purchase is required in order to claim the guarantee. The warranty will be void if the control unit is dismantled by the user as shown on the warning sticker on the side of the unit.

This guarantee is not a substitute for any legal guarantees. Contact your local sales agent for technical support.

Fig: 1

8. Symbols

Attention: See Instructions for use

CE Marking indicating conformance to EC Directive No. 2007/47/EC concerning medical devices

Type BF Applied Part (patient isolation from electrical shock)

Class II Product

Operation Instructions

Indicates separate collection for electrical and electronic equipment (WEEE)

IP21 Protection against finger and dripping water

Manufacturer

Date of manufacture

Note: Follow the requirements of your local authority regarding disposal of the unit.

9. Polaris ll, Nexus, Tertius Front Panel

1	Unlock
2.	Static CLP therapy
3.	Dynamic pressure therapy
4.	Auto & override pressure setting
5.	Cushion mode
6.	Care/firm mode
7	Seating boost
8	Leaking/power outage alarm mute

Fig: 2

10. CPR Valve Operation (Mattresses only)

The CPR valve allows the mattress to deflate quickly when CPR is to be performed on the patient. The CPR valve is located at the head end of the mattress. The system will operate normally when the CPR pull tag (Fig. 3) is securely located in the CPR air outlet and will deflate when the CPR pull tag is pulled from the CPR air outlet.

Fig: 3

11. Installation

11.1 Mattresses

12. Unroll the mattress on the bed with the connector hoses at the foot end.
13. Secure the mattress to the bed base with the attachment straps.
14. Hang the control unit at the foot of the bed using the hooks
15. Connect the mattress hoses (Fig: 4) and power cable (Fig: 5) to the control unit then guide it along the bed to the nearest plug socket and plug it in, taking care not to create a trip hazard.
16. Check that CPR tag is securely pressed down into CPR air outlet.
17. Switch on the rocker switch on the control unit. (Fig: 5)
18. Pump will flash all LEDS before defaulting to AS (Autoset) and dynamic mode
19. The pump setting is set to default to automatic – you do not need to enter the patient weight.
20. The mattress will take up to 45 minutes minutes to inflate. Cushions will take 10 minutes to inflate

Fig: 4

Fig: 5

⚠ WARNING:

The power cable must be installed to avoid interference with the articulated parts of the bed or the wheels and to prevent personnel from tripping up. Failure to install the power cable correctly may result in risk of bodily injury and/or material damage.

11.2 Cushions

1. Place the cushion on the seat with hoses protruding from the back corner.
2. Hang the control unit on the back of the seat.
3. Connect the cushion hoses and power cable to the control unit then guide it to the nearest plug socket and plug it in, taking care not to create a trip hazard.
4. Switch on the rocker switch on the control unit.
1. The cushion will take up to 5 minutes to inflate. Select the button with a cushion symbol if you want to pair the pump up with an air cushion. This will ONLY work with the Andway Saiph cushion so please ensure you use the correct cushion. WARNING> Do NOT use this cushion mode with the pump connected to a mattress – the pressures will be incorrect and it will cause the pump to alarm

12. Bottoming Out Test

It is important to check that your patient has not bottomed out on the support system. This is where the patient's sacrum sinks too far into the mattress and contact pressure from the bed frame is exerted on the patient. To check for this, slide two fingers between the air cells underneath the patient's sacrum. The patient should be clear of your fingers. If the patient has bottomed out, increase the pressure setting on the control unit then wait for 10 minutes before repeating the bottoming out test. This test does not refer to cushion systems.

13. Settings & operation

13.1 Factory default settings

The default setting for the Polaris ll, Nexus, Tertius control unit is dynamic mode. The control panel on your Polaris ll, Nexus, Tertius control unit will lock after 30 seconds of inactivity. You can unlock with a single press of the unlock button and re-lock with a single press of the button (or it will lock automatically after 30 seconds)

The pump setting for patient weight and pressure is automatic. When you switch on, it will default to AS (AutoSet) so you do not need to enter the patient weight. It will also automatically select Dynamic mode .

13.2 Clinician auto override. Item 1, Figure 2, Section 9

The default setting for the patients pressure setting is automatic. However if a trained clinician decides that his or hers patients weight or body shape does not suit the automatic selection then they can override the AutoSet setting. Press and hold the unlock button (Item 1 Figure 2 section 9) for 3 seconds until the lock button LED light goes out then use the arrow button (Item 4 Figure 2 Section 9) to scroll through the choices available. The first choice is +l which is 10% firmer than AS, if you press the up arrow again then +ll appears in the LED screen (item 8, Figure 2,Section 9) this is 20% firmer than AS. If you press the up arrow again then is goes to -ll which is 20% softer than AS, and if you press the up arrow again then -l will appear in the LED screen which is 10% softer than AS. If you press the up arrow again you return to AS the Automatic pressure setting for your patients weight. Please REMEMBER this setting is based on weight ONLY and it cannot determine body shape. Short wide patients can require a different setting to say tall thin patients to double amputees – even though they may weigh the same. A clinician should perform a hand test (section 12) to determine if the patient is correctly supported.

13.3 Dynamic & Static (CLP) modes. Items 2 & 3, Figure 2, Section 9

The factory default setting for this pump is dynamic (alternating) which means that cells A will inflate for 5 minutes followed by cells B inflating for 5 minutes whilst cells A are deflated. This is a 10 minute cycle. However a trained clinician MAY choose static CLP therapy mode. This mode means that ALL the cells remain inflated with any dynamic or alternating at much lower internal pressure. Press and hold unlock for 3 seconds until the LED light goes out and then press the CLP therapy mode.

13.4 Care Mode (also known as FIRM or Nursing mode)Item 6, figure 2 section 9

The factory default setting for care mode is OFF. However this mode maybe selected for use when changing dressings, toileting a patient and other general assistance. This mode will inflate the mattress to maximum and is very firm. The mattress will NOT alternate Because of this, this mode will automatically switch OFF after 30 minutes use to protect the patient and should NOT be reused straightaway unless by a trained clinician. To select this mode press and hold UNLOCK for 3 seconds until the LED light goes out and then select Care. The Dymanic mode LED light will then goes out. After 30 minutes the Care mode will automatically switch OFF and the Dymanic mode will come back resume by default.

13.5 Upright boost. Item 7, Figure 9,Section 9

The factory default setting for upright boost is OFF. However this mode maybe selected for heavier patients, patients who due to their body shape tend to sit lower in the mattress and double/single amputees to give them a boost when the bed is profiled in sitting/eating/watching TV position. This mode gives about an extra 20% more internal pressure to support the patient when they are in an upright position. To select this mode press the UNLOCK button for 3 seconds until the LED light goes out. Then select UPRIGHT BOOST. The UPRIGHT BOOST LED light will light up. This mode has NO time limit and will remain on until the clinician turns it off. To turn it off, press the uNLOCK button and press the UPRIGHT BOOST once – and the LED light will go out.

13.6 Cushion mode Item 5, Figure 2, Section 9

The factory setting for this mode is OFF. However if you want select this mode Please read section 11.2 FIRST. You must NOT use this mode unless the pump is connected to a Andway Saiph cushion . You can cause injury to the patient if you use CUSHION mode whilst the pump is operating the mattress. To select this mode connect the pump to the cushion as in 11.2 and then press the UNLOCK button for 3 seconds until the LED light goes out and then select CUSHION mode. The CUSHION mode LED light will come on. There is NO time limit to this mode and it will remain in CUSHION mode until the clinician changes it.

13.7 Unlock and factory re-set – Item 1, Figure 2, Section 9

The pump will automatically lock after 30 seconds of inactivity. The LED light will come on and none of the pump functions will work when locked apart from the alarm mode. To unlock the pump press and hold the UNLOCK button for 3 seconds. Then you make your function selection before the pump automatically locks after 30 seconds. The UNLOCK buttons also acts as a factory re-set should you become confused about what is in the pumps memory mode especially when you swap the pump to a new patient. To reset the pump back to factory settings switch the pump off at the rocker switch on the side. Now press and HOLD the UNLOCK button and keeping holding it whilst you switch the rocker switch back on. You will hear three rapid beeps – you may now release the UNLOCK button and the pump is now reset to factory settings.

14. Alarms

14.1 Low Pressure Alarm Item 8, Figure 2, Section 9

When there is low pressure in the system the control unit will beep continuously and the corresponding red LED will flash.

Press and hold the unlock button for two seconds to unlock the control panel. (Fig: 2)

Press the low pressure alarm mute button (Fig: 2) to mute the alarm, and then check the following connections for leakage:

- The connection between the mattress and the control unit
- The connection of the CPR valve to the mattress
- The connection between the cells and the connecting hose

If the fault is not solved the check the following for leakage:

- The CPR valve
- The connecting hose
- The air cells

If the fault persists, contact your Andway Spica distributor for service repair.

14.2 Power Failure Alarm Item 8, Figure 2, Section 9

When the power to the control unit fails, it will beep continuously and the corresponding red LED will flash.

Press and hold the unlock button for two seconds to unlock the control panel. (Fig: 2)

Press the power failure alarm mute button (Fig: 2) and check the following;

- That the power cable is connected to the power outlet and that the outlet is switched on
- That the power cable is connected to the control unit
- That the fuse in the power cable has not blown
- That the fuse in the IEC socket on the control unit has not blown

If one, or both, of the fuses has blown check the power cable for damage and replace it immediately if necessary.

If the fault persists, contact your Andway Spica distributor for service repair.

15. Replacing the Air Filter

The air filter must be replaced annually. To replace the air filter, remove the air filter cover (Fig: 8) from the back of the control unit and replace the cotton filter inside after cleaning any residual dust from the air filter cavity and cover.

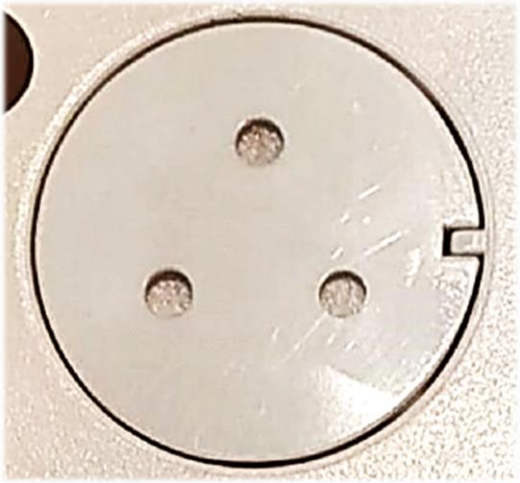

Fig: 8

16. Cleaning

16.1 On-site cleaning

When necessary the top cover and base can be cleaned and disinfected on site once the patient has been removed from the mattress. The following on-site cleaning procedure is recommended for top cover and control unit. Note that a summary of the below is printed at the foot end flap of the top cover. Do not immerse the control unit in water.

1. Ensure gloves are worn and all disinfection and occupational health and safety protocols of the facility are adhered to.
2. Wipe down with a clean cloth using a disinfectant solution comprising of warm water and a neutral detergent or with a sodium hypochlorite solution (Chlorine 1000 ppm)
3. Proprietary disinfectants may be used provided manufacturer's instructions are followed.
4. All cleaning agents and disinfectants must be thoroughly rinsed off and the surface dried before storage or re-use. Failure to do this may result in the accumulation of reagent that could damage the polyurethane coating, react with the bed frame or negate the bio-compatibility results of the fabric.

16.2 Machine washing / drying

The mattress cover and base can be machine washed. To machine wash the base - all cells and hoses must be removed. Wash at a temperature ***up to 71°C (160°F)***, using normal detergents.

Dry the cover by air drying, spinning or tumbling at temperatures ***up to 130°C*** (266°F); do not mangle.

In washing machines, it may be difficult to fully soak the mattress cover. Also, spinning and tumbling may not remove water trapped between layers. It may be helpful to interrupt the washing or drying cycles to alleviate this.

16.3 Troubleshooting

The instructions below are for end-user maintenance of the pressure care system. If these instructions do not resolve the fault, contact your Andway Spica distributor for service repair.

Fault	Solution
Control unit does not operate	1. Check that the power cable is connected to the wall socket and the IEC socket on the control unit correctly. 2. Check the fuses in the power plug and in the IEC socket. Be sure to use the correct fuse specification.
Low pressure in mattress	1. Check that the mattress is connected to the control unit and that the CPR tag is securely pressed into the CPR air outlet. 2. Check the air cells and connecting hose for punctures, tears or leaking connections.
Air cells at uneven heights	1. Remove the top cover and check for air cell press studs that are disconnected.

APPENDIX A: EMC INFORMATION

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group1	The device 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	
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % U_T (>95 % dip in U_T)for 0,5 cycle 40 % U_T (60 % dip in U_T)for 5 cycles 70 % U_T (30 % dip in U_T)for 25 cycles <5 % U_T (>95 % dip in U_T)for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms150 kHz to 80 MHz outside ISM bands[a] 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5G MHz 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 meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, 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) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could

cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

Recommended separation distances between portable and mobile RF communications equipment and this device:

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

Rated maximum output power	**Separation distance according to frequency of transmitter** m		
of transmitter W	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
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

or transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

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.