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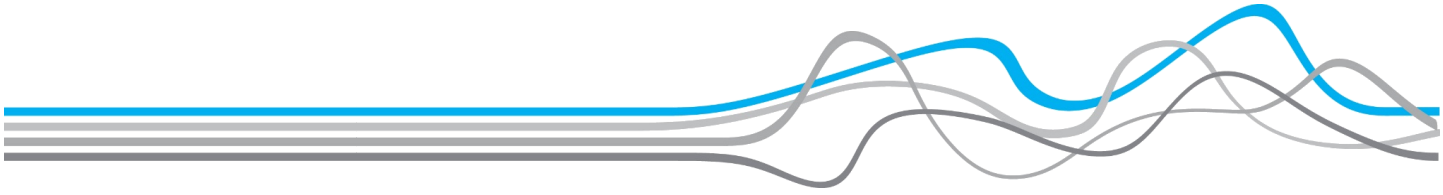
NoDec®

AIRSTREAM

OPERATIONS & MAINTENANCE MANUAL

Version 1.0

June 2015



VERSION HISTORY

Version	Implemented By	Revision Date	Approved By	Approval Date	Reason
1.0	Ben Smith	N/A	G. Ball	June '15	Original copy
1.1	Ben Smith	July '15			Corrective actions by Cranage EMC Testing Limited. *(IEC 60601-1)*

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1. INTRODUCTION

1.1. Purpose

The NoDec® AIRSTREAM is a two-cell cycle alternating pressure air mattress overlay system. It is designed to prevent and treat pressure sores for patients who are at medium to high risk of developing them. It also aids the healing of pressure sores in patients with existing Grade 1 and 2 pressure injuries.

The objective of the NoDec® AIRSTREAM is to reduce the contact pressure created by the patient lying on the mattress. This is achieved by sequentially inflating and deflating the air cells of the mattress overlay. This regularly reduces the contact pressure which restores blood flow and tissue oxygenation in the deep tissues about the vulnerable bony prominences.

The overlay can be used on top of any high specification foam mattress to replace conventional mattress in hospitals, nursing homes and in the community. This mattress replacement system is quiet, comfortable and simple enough for a single caregiver installation. All operator controls have been deliberately minimised to improve user interaction.

The system consists of an air filled mattress that is placed on top of a conventional bed frame and is connected via an air supply hose to a separate microprocessor controlled Power Unit.

The Power Unit is software driven using a solid-state pressure sensor so it has the capability to monitor the air pressure in the mattress continuously. The system is completely self regulating and automatically alters the air pressure depending on the weight of the patient and their position in bed.

An emergency deflation valve system is incorporated to allow cardiac resuscitation procedures. Named appropriately as a CPR unit, it also has self sealing valves which allow the mattress to remain inflated for 24 hours when disconnected from the system.

A number of audio and visual alarms exist to warn caregivers of any problems within the system.

N.B. As with all alternating mattress systems, the NoDec® AIRSTREAM is contraindicated for use where patients have unstable fractures or spinal injuries.

2. FULL MATTRESS SYSTEM DESCRIPTION

2.1. System Construction

The NoDec® AIRSTREAM system consists of two major elements: the mattress overlay and the power unit.

2.2. System Assembly

To assemble the NoDec® AIRSTREAM Power Unit with the corresponding mattress overlay, the CPR unit attached to the umbilical air hose is plugged into a specially designed dock within the Power Unit.

2.3. System Key Features

The main features of the system apart from the mattress, the power unit and the interconnecting umbilical air hose are those that allow it to be attached the bed. These include a number of 25 - 50mm webbing straps on the mattress, and mechanical hooks on the power unit.

3. MATTRESS

3.1. Mattress Construction

The mattress features a single layer of 17/18 lateral air-cells manufactured from a heavy duty polyurethane film. The cells are connected in sets of two, each set being sequentially inflated and deflated in turn to create pressure wave action which replicated the body's natural spontaneous movements.

Accompanying the air-cells are two longitudinal side formers that remain inflated. These formers provide a firm edge for the mattress overlay, creating a sense of security for the patient, help to prevent falls from beds and assisting when transferring from the bed to a chair.

The formers and one head-end cell are interconnected and remain inflated at all times. Together they provide an air reservoir, the pressure of which is continuously monitored.

All the formers and air cells are connected to pneumatic Ø10mm tubing that is in turn connected to the umbilical air hose that leads to the Power Unit.

The mattress is enveloped by a top and bottom cover. While the top cover is made from a two way stretch, water proof, vapour permeable material (protecting the mattress from soiling), the bottom cover is made from a durable PVC coated Nylon. Both materials have a smooth surface finish to facilitate cleaning.

3.2. Mattress Configurations

The NoDec® AIRSTREAM series has two main mattress configurations:

Integrated Cells

Single Cells

3.2.1. Integrated Cell Configuration

This configuration is when 18 lateral cells are manufactured so that they lie in a deck as one complete product. These are then in turn connected to the side formers, also manufactured as one.

3.2.2. Single Cell Configuration

This configuration is when 17 latera cells are manufactured separately and then using the side formers as support they are attached via toggles. In order to give further support, and so that the cells cannot move about freely, they are threaded through loops attached to the mattress' base cover.

3.3. Mattress Assemblies

Assembled in three groups, 'A' Cells, 'B' Cells and Static, the Air Cells are attaching via pneumatic tubing. These are in turn connected by barbed connections going into Ø10mm Bore Reinforced PVC Tubing. This makes up three different air lines going into the Power Unit via the CPR Unit.

4. POWER UNIT

4.1. Power Unit Construction

The power unit consists of the following:

Exterior Casing – Injection moulded in two halves, the casing is made from a V0 Fire Retardant Polycarbonate/ABS compound. The two halves are held together by twelve M3 Pozi Head Screws. On the front casing are membrane fascia panels, named appropriately for each model, which have a raised dome push button that pushes the underlying button switch from the Display PCB to navigate through operation modes. The on/off switch is mounted on the sidewall of the rear casing. This is a rocker type switch with an integral green LED – when illuminated, this indicates that the mains supply is present. A label bearing the unit serial number, type classification, ingress protection rating and electrical rating information, alongside appropriate symbols, is affixed to the rear casing.

CPR Unit Dock – Injection moulded in a Fire Retardant Acetal, this is crucial for the transfer of air through to the mattress.

Mechanical Hooks/Retainer – Two-shot Injection Moulded, the two hooks can move simultaneously thanks to a gearing mechanism. Held in place by the Hook Retainer and two consequent M3 Pozi Head Screws, the hooks lock into place with teeth that engage with the hook retainer. The hooks are manufactured with a rubber over-moulding on the bottom of them so that they have improved grip on the bed's footboard, and protect it from scratches.

Chassis Plate – Manufactured from machined and folded Aluminium sheet, this holds the majority of the electrical components needed for the Power Unit to function. To facilitate servicing and maintenance this can be removed from the casing by unscrewing four M3 Pozi Head Screws. There are a series of inserts to allow for different component configurations within the NoDec range.

Fuses – Situated adjacent to the power supply IEC connection port, the Power Unit uses two Bussman type S506-1.6-R Fuses. These fuses are rated at 250V~, 1.6 A, with a breaking capacity of 35 A.

4.2. Major Elements

The major elements in the Power Unit construction essential for the functioning of the power unit are:

Air Compressor
Solenoid Valves
Power PCB
Display PCB

4.2.1. Air Compressor

The compressor is a diaphragm blower whose outlet is located a top the plastic casing. This outlet it connected via 6mm bore silicone tubing to a high efficiency dual air filter and silencer. In addition to filtering the output air this also acts as a reservoir, helping to smooth pressure fluctuations in the system. The compressor operates from the AC mains voltage.

The compressor has rubber dog leg shaped mounting feet attached via four M4 Pozi Head Screws to inserts in the Chassis Plate. This arrangement minimises the transmission of vibration and noise to the case. Servicing is simple, thanks to the chassis plate. The compressor has flying lead connections fitted with a special plug for connection to the Power PCB.

4.2.2. Solenoid Valves

Pneumatic control of the system is achieved through the use of 3-way valves. The valves operate from a voltage of 12V DC, which is supplied by the Power PCB. The valves are fitted with plastic barbed connectors that allow them to be connected to the rest of the pneumatic circuit and the overall system via Ø6mm bore silicone tubing. The valves connect to the Power PCB via flying leads to a terminal block located on the PCB.

4.2.3. Power PCB

Fitted to the base of the Chassis Plate via four plastic snap fit Mounting Pillars, the Power PCB provides a 12V DV supply to operate the solenoid valves and the Display PCB. It also carries the interface components required to control the compressor.

The switch-mode power supply module U1 converts the incoming mains voltage to 12V DC. R1 is a voltage dependent resistor included to absorb any surges in the mains voltage that could otherwise damage the other components. RLA1 is a solid-state relay that turns the mains voltage supply to compressor on or off. This is controlled by the Microprocessor on the Display PCB.

The PCB is connected to the Solenoid Valves and the Compressor by flying leads, and to the Display PCB by a ribbon cable. It is connected to the mains lead via the v-lock input module fitted to the case - this also carries the protective fuses. It is important that only correctly rated fuses are fitted *[See Section 7.2.6]*. To ensure that the mains lead cannot be inadvertently pulled from the input module, please also use only the specified mains lead including the V-Lock feature.

4.2.4. Display PCB

The Display PCB is mounted to the front casing via six M3 Pozi Head Screws. It is connected to the Power PCB by the ribbon cable and is also connected to the Pneumatic System via a Ø2mm Bore Silicone Tube.

The Display PCB's major components are the controlling Microprocessor (U3), the 25 x 7 Dot Matrix Display (U9 – U13), the Pressure Sensor (U1), the Solenoid Valve driver (U2), the 5V Power Supply (U4), the back-up Battery, the Alarm Sounder (X2) and a DIP Switch Module (SW4). The user operates the Power Unit from a push button (SW1), fitted to the Display PCB alongside the Dot Matrix Display.

The 12V DC supply provided by Power PCB powers the Solenoid Valve drive chip U2 and trickle charges the NiMH Back-up Battery. U4 steps this 12V supply down to the 5V required by the Microprocessor and all other associated components. The on/off switch controls the 5V supply – the Power Unit is turned off by disabling the 5V supply. This allows the Back-up battery to continue to charge as long as the Power Unit is connected to the mains, even though the Power Unit itself is switched off. This Back-up Battery is only required to power the alarm during periods of mains supply failure and is not used for any other circumstances.

The Dot Matrix Display can show blue or red characters, to distinguish between normal and alarm conditions.

The Microprocessor carries a label showing the software version of the system, e.g. NoDec Airstream Version 5.02.

4.3. Pneumatic System Description

To remove the pressure from the patient, the air cells are sequentially deflated and inflated with pressures suitable for the patient. The Power unit controls this inflate / deflate cycle primarily through the combination of the Compressor and the Solenoid Valves. Essentially the Compressor delivers air to the Solenoid Valves which in turn control the flow of air into the air cells. The pressure of Air is then continuously monitored by the solid state pressure sensor.

When the Power Unit is switched on the Compressor starts running. Air is sucked through the Compressor's inlet, and then delivered to the Solenoid Valves, 'A' and 'B' and thus to the two sets of interlinked air cells. Meanwhile, air is delivered directly to the static cells. The Pressure Sensor monitors the pressure in this static line.

4.3.1. Alternating / Static Lines

In this mode of operation *[Section 6.2.4]* the 'A' Valve will be turned on, allowing the cells and tubes connected directly to the 'A' line to vent / deflate. All the other air cells will remain connected together through the 'B' valve, and the compressor will maintain the pressure in these cells. After the time allowed for venting / deflating, the 'A' valve will be turned off so that the 'A' cells are then connected to the rest of the mattress, and the 'A' cells will then re-inflate.

This can be described in the following table:

Phase	1	2	3	4
Description	'A' Cells vent ('A' Valve ON)	'A' Cell re-inflate (All valves OFF)	'B' Cells vent ('B' Valve ON)	'B' Cell re-inflate (All valves OFF)

In Static Mode *[Section 6.2.5]* all Valves will be turned off so that all cells are continuously inflated to the specified air pressure.

4.4. Integrated CPR Mechanism

Included within the system, as an interconnection between the Power Unit and the Mattress is the CPR Mechanism. This consists of three main parts:

CPR Dock
CPR Mid Body
CPR Hose End

The CPR Dock is held in place by the Power Unit casing and has barbed connectors attaching to the pneumatic tubing from the Solenoid Valves. The CPR Hose End also has barbed connectors and is attached to the pneumatic tubing from the Mattress.

The CPR Mid Body has an integrated valve system. When the three components are assembled these valves are opened to allow the air flow from the Power Unit, through the CPR Hose End and into the Mattress. When the components are disassembled the valves close, this enables CPR Deflation and Transport Mode.

CPR Deflation – Air escapes out of the mattress through the CPR Hose End

Transport Mode – The assembly of the CPR Mid Body and Hose End is removed from the CPR Dock and the CPR valves remain closed, so the Mattress remains inflated.

4.5. Symbol Explanations

In accordance with IEC 60601-1, markings and symbols have been included within the labelling of the Power Unit. It is important to follow these symbols to ensure that the Power Unit is used and maintained appropriately and responsibly.

Symbol	Explanation
	**Type B Applied Part –** *Although it does not hold an electrical charge, the Mattress, comes into contact with the patient so is a Type B Applied Part. The Power Unit is treated as a Type B Applied Part as, when in normal use, it is possible for the feet of the patient may come into contact with the unit.*
	**Class II Medical Device –** *The Power Unit is double insulated, meaning there are no provisions for protective earthing and all accessible metal parts are insulated.*
IP 42	**Ingress Protection Rating –** *The IP Rating given means that the Power Unit is protect from any foreign objects of 1 mm and from vertically falling water droplets (when the unit is tilted up to 15°) entering the internals.*
	**WEEE Mark –** *Rober Ltd complies with the WEEE Directive.*
CE	**CE Mark –** *Rober Ltd is CE Registered, and declares that the pump meets the requirements of the EC Directives.*
230V~ ±10%	**Mains Voltage Supply –** *The Power Unit requires a Mains Supply of 230V, AC with a tolerance of 10%*
0.1A	**Rated Power –** *The Power Unit's current consumption is rated at 0.1A*
50/60Hz	**Supply Frequency –** *The Power Unit requires a Supply Frequency of 50/60Hz*
	**Refer to Instructions –** *It is important for Operators and Service Personnel to read the appropriate manual instructions before use or maintenance of the Mattress System.*
I / O	**On / Off –** *The on / off switch is a rocker switch located at the side. The symbols are marked adjacent to the switch.*
 Mode	**'Mode' Button –** *The mode button is in the form of an embossed dome on the front display panel. Press this button to operate the Power Unit*

5. SOFTWARE

5.1. Software Description

Being a software controlled system, all servicing is simple and updates to the software are simply installed by replacing the Microprocessor Chip. The software controls the major elements discussed *[Section 4.2]*, to inflate/deflate the mattress depending on the mode selected.

Thanks to the use of the DIP Switch Module, a structure can be put into place to allow for variations across the NoDec range. Mattress control is broken down into four system variants, with five subsequent modes.

5.2. Software Structure

The software structure of NoDec Airstream Version 5.02 has been designed so that the 4 variations each have 5 pressure modes based upon the number of presses on the single push button located on the membrane panel at the front.

As an alternating pressure air mattress overlay system, while it is important for the air cells to alternate in inflating/deflating cycles it is also critical that there are comfort settings and static modes for different patients.

To cycle through these modes:

Mode	*0*	*1*	*2*	*3*	*4*
Description	Initial Inflate	Default State	State after 1 button press	State after 2 button presses	State after 3 button presses
Action	Inflation/ Calibration	Alternating Mode (Firm)	Static Mode (Firm)	Alternating Mode (Soft)	Static Mode (Soft)

Sequentially pressing the front panel button causes the system to switch between modes 1 – 2 – 3 – 4 – 1 – 2, etc. Note that Mode 0 only occurs after the system is first switched on (or restarting after a mains failure).

5.3. Software Configurations

5.3.1. Software Variations

The variations of the NoDec Airstream v5.02, including the air pressures with each mode (outlined above), are as follows:

		Mode			
	Variant	*1 (Default)*	*2 (1st Press)*	*3 (2nd Press)*	*4 (3rd Press)*
0	**NoDec Airstream v3.00**	55 mmHg *Alternating*	55 mmHg *Static*	45 mmHg *Alternating*	45 mmHg *Soft*
1	**NoDec Airstream v3.00-soft**	40 mmHg *Alternating*	40 mmHg *Static*	30 mmHg *Alternating*	30 mmHg *Soft*
2	**NoDec Airstream v3.30 AUS**	45 mmHg *Alternating*	45 mmHg *Static*	35 mmHg *Alternating*	35 mmHg *Soft*
3	**NoDec Airstream v3.22**	32 mmHg *Alternating*	62 mmHg *Static*	55 mmHg *Alternating*	32 mmHg *Soft*

[The variants listed in the table refer to the software versions supplied to different markets as used in the previous version of this product]

N.B. *The majority of static mode are either time limited (for 2 hours) or unlimited, as selected on the DIP switch [Section 5.3.2.]. Variant 2 (v3.30 AUS) has a time limit of 30 minutes.*

For Variant 3 (v3.22), on Mode 2 (Firm), static mode is limited to 15 minutes, irrespective of whether timed or untimed is selected on the DIP.

5.3.2. DIP Switch Settings

The software variations previously discussed are set using the DIP Switch Module (SW4). There are also other settings which can be changed to help to meet the customer's needs. This include a two cell or three cell cycle, software lock, static mode timer and filter change timer.

	SW4-1	SW4-2	SW4-3	SW4-4	SW4-5	SW4-6	
Software Variants							***Description***
0	ON	ON	X	X	X	X	*v3.00*
1	OFF	ON	X	X	X	X	*v3.00-soft*
2	ON	OFF	X	X	X	X	*v3.30 AUS*
3	OFF	OFF	X	X	X	X	*v3.22*
Software Options							***Description***
1	X	X	OFF	X	X	X	*2 Cell Cycle*
2	X	X	ON	X	X	X	*3 Cell Cycle*
3	X	X	X	OFF	X	X	*Software Lock OFF*
4	X	X	X	ON	X	X	*Software Lock ON*
5	X	X	X	X	OFF	X	*Static Time UNLIMITED*
6	X	X	X	X	ON	X	*Static Time LIMITED*
7	X	X	X	X	X	OFF	*Filter Timer OFF*
8	X	X	X	X	X	ON	*Filter Timer ON*

N.B. *Any or all of the software options on SW4-3 to 6 can be used alongside any of the different software variants selected on SW4-1 and SW4-2.*
'3 Cell Cycle' is assigned for future development.

5.4. Service Mode

By holding down the push button on the front of the case while turning on the On/Off Switch the Power Unit will display the Service Screen. This screen shows the following:

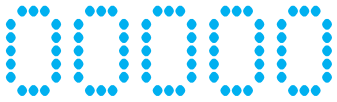
Total Running Time (hours / h)

Software Version / Variation

Filter Timer

5.4.1. *Total Running Time*

The first service screen shows the complete number of hours that the system has been running. This is shown in blue and the maximum time that can be displayed is 99999 h – corresponding to more than 11 years continuous running. Once this has surpassed 99999 h the timer will restart from 00000. This time can also be set to zero by pressing SW2 on the PCB on the PCB while the number of running hours is displayed.



The time is stored within the microprocessor, so that if the installed software is updated at any time by replacing the chip, the original value will be lost. A new chip will show the time 99999 h – this will roll over to 00000 h after 1 h of continuous running, or the time can be manually zeroed by following the procedure above.

5.4.2. *Software Version / Variation*

Pressing the button a second time when in Service Mode will display the current version number of the installed software alongside the variant currently selected on the DIP Switch Settings *[Section 5.3.2]*.

For example:

Software version installed is NoDec Airstream v5.02 and Variant 3 is selected (NoDec Airstream v3.22).

Software version installed is NoDec Airstream v5.02 and Variant 0 is selected (NoDec Airstream v3.00).

5.4.3. *Filter Timer*

If the filter timer is turned on via the DIP Switch Module (SW4-6), a third press of the button will show the current number of hours since the filter timer was last zeroed. Once the filter has been changed then it is recommended to zero the filter time. This can be done by pushing the push button for a fourth time.

Like the total running hours screen, the filter timer will display 00000 however in red rather than blue.

N.B. *If using a newly installed chip, the run timer must have been zeroed before this procedure will be effective. The zeroed filter time will not be stored correctly while the run timer is still showing 99999 h.*

5.4.3.1. Filter Replacement Timer

*Turned on/off via the DIP Switch Settings [Section 5.3.2], this feature is intended to warn the user that the air filter should be replaced after a number of hours of operation. The message '***Filter***' is flashed on screen for approximately 0.5 seconds at 30 second intervals. This display does not interfere with normal operation of the Power Unit but is merely a reminder to change the filter.*

In NoDec Airstream v5.02 and subsequent software versions, the timer is set at 8000 h (approximately 11 months) of continuous use.

6. FULL MATTRESS SYSTEM USAGE

6.1. Installation

Installing the full pressure mattress overlay system into a medical environment is simple and can be done in a safe manner when the following steps are taken:

1. *Place the mattress overlay on top of the mattress, ensuring the light grey top cover is facing upwards and the air supply hose (umbilical) is positioned at the foot end of the bed.*
2. *Secure the mattress to the bed using the straps and fasteners provided. Ensure that the straps do not restrict any movement of the hospital bed. Straps attached around both moving parts and fixed parts will cause severe damage to the mattress. The mattress should move freely with the bed platform.*
3. *Adjust the hooks on the back of the Power Unit to accommodate the bed frame.*
4. *Hang the unit onto the bed frame at the foot end of the bed with the control panel facing outwards.*
5. *Check that the CPR is "Closed" and plug the umbilical hose into the dock.*
6. *Plug the power cable into the pump and then plug the other end into the mains socket,ensure that both connections are easily accessible. Turn the unit on using the on/off switch. Ensure that the cable is safely guided through the cable tidies located under the skirt, reducing any hazards in relation to the cable.*
7. *Wait for approximately 20 minutes and the system is ready to use.*

N.B. System Removal – To remove the system from the bed safely, the majority of the steps above can be done in reverse order. However, please note that the Power Cable has a specially designed connection so that it cannot be pulled out accidently. Before removing the Power Cable, turn off the Mains Power at the socket and remove plug. To remove the Power Cable from the Power Unit, simply depress the yellow button and remove.

6.2. Operation

Operation is intentionally simple and the majority of user interface is done through the push button on the front control panel.

6.2.1. *Start Up*

Start Up is initiated as soon as the Power Unit is turned on via the On / Off Switch. The compressor fully inflates the mattress to the pre-set air pressure of the software variant. While this procedure is being carried out there will be four cells shown simultaneously inflating on the Dot Matrix Screen. Only when the mattress has finished inflating can care begin.

6.2.2. Automatic Alternating Mode

Once the Power Unit has fully inflated the mattress it will automatically default to the Firm Alternating Mode defined by the Software Variant. This will automatically calibrate to the patients weight and body position.

6.2.3. Lockout Function

If the 'Software Lock' feature has been enabled on the DIP Switch Module *[Section 5.3.2.],* 60 seconds after either full inflation, mode change or system reset, the system will automatically lock out the display panel to stop any unwanted mode changes. This is indicated by the blue dotted line beneath the padlock symbol. To unlock the front panel hold down the "Mode" button for 10 seconds. Once unlocked, the user can cycle through the four modes.

6.2.4. Alternating Mode

The 18 air cells of both mattress overlay configurations are pneumatically connected into three groups:

- A Cells
- B Cells
- Static

The static cells consist of the Side Formers in the Integrated Cell configuration and both Side Formers and one head cell in the Single Cell configuration.

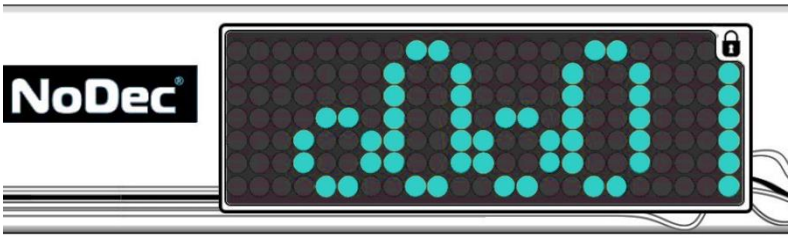
While the static cells remain permanently inflated at all time for stability and patient, the remaining air cells inflate and deflate with a cycle time of 10 minutes.

When the 'A' cells deflate, interface pressure is reduced in that portion of the body in contact with those cells, similarly for the 'B' Cells

Initially, the 'A' cells deflate while being vented (to atmosphere) for a period of 3 minutes. After this time, the A' cells begin to re-inflate, and complete re-inflation will be achieved in 2 minutes. At the 5 minute mark, the cycle repeats for the 'B' cells, and so on, so that a complete cycle of 'A' cell deflation & re-inflation and 'B' cell deflation & re-inflation is completed in 10 minutes. When left on Alternating Mode the display will show the cells being inflated and deflated in pseudo real time.

6.2.4.1. Firm Alternating Mode

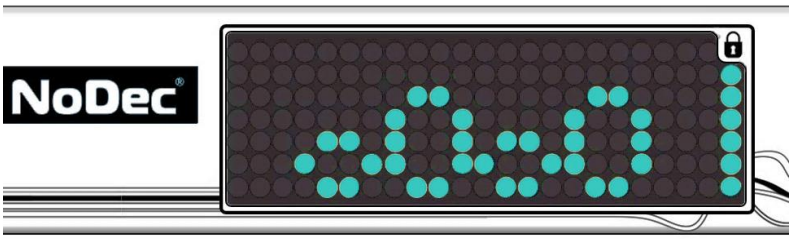
When Firm Alternating Mode is selected the following screen is shown:



This displays the two groups of cells, 'A' and 'B'. As seen here 'A' Cells are currently deflating while 'B' Cells remain inflated. For the pressures used in this mode see ***Section 5.3.1. Mode 1****.*

6.2.4.2. Soft Alternating Mode

When Soft Alternating Mode is selected, the mattress changes to a lower range of pressure settings more suited to the comfort of small and under weight patients. The following screen is shown for this mode:



Again this displays both groups of cells 'A' and 'B', but with smaller cells. For the pressures used in this mode see ***Section 5.3.1. Mode 3.***

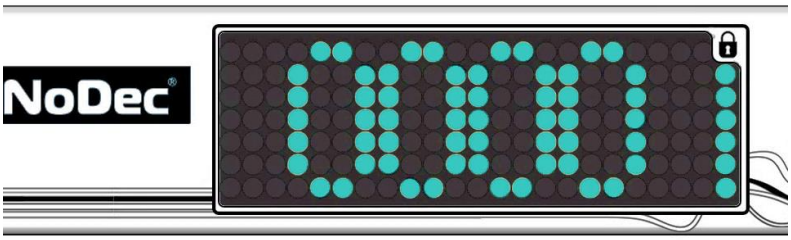
6.2.5. Static Mode

Static Mode is used within the hospitals to assist nursing procedures, physiotherapy and to help get out of bed. It is also needed within Transport Mode *[Section 6.2.6].*

In Static Mode the mattress calibrates to the patient's weight and all cells are inflated and alternating therapy ceases. Static Mode can be timed or untimed depending on the DIP Switch Settings selected.

6.2.5.1. Firm Static Mode

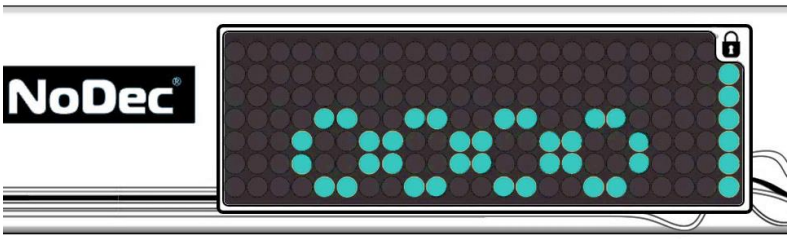
When Firm Static Mode is selected the following screen is shown:



This displays the two groups of cells, 'A' and 'B'. As seen here all cells are inflated. For the pressures used in this mode see ***Section 5.3.1. Mode 2****.*

6.2.5.2. Soft Static Mode

When Soft Static Mode is selected, the mattress remains at the lower range of pressure settings suitable for smaller patients. The following screen is shown for this mode:



Again this displays both groups of cells 'A' and 'B', but with smaller cells. If the Static Timer is set up then the Soft Static Mode will revert to Soft Alternating Mode once the timer is up. For the pressures used in this mode see ***Section 5.3.1. Mode 4.***

6.2.6. Transport Mode

Essential for moving patients around the hospital, to enable Transportation Mode simply select appropriate Static Mode and once inflated, turn off the Power Unit and unseat the air supply hose (umbilical), buy pushing in the clips located at either side.

6.2.7. CPR Deflation

If a medical emergency arises where cardio resuscitation may be necessary, the CPR unit can be deployed by simply gripping the unit and pushing the Red Button. The two parts of the unit will separate and the mattress will rapidly deflate.

6.3. Alarm Conditions

Four types of Alarms are incorporated into the software. Each alarm has its own display, featuring various red symbols and a fixed tone, pulsed audible alarm.

Regardless of the alarm type, the audible alarm can be silenced by pressing the front control panel button and just the alarm display will continue to flash without the audible alarm. If the alarm situation continues, the sounder will be restarted after 15 minutes. Again, it can be silenced again for a further 15 minutes and so forth.

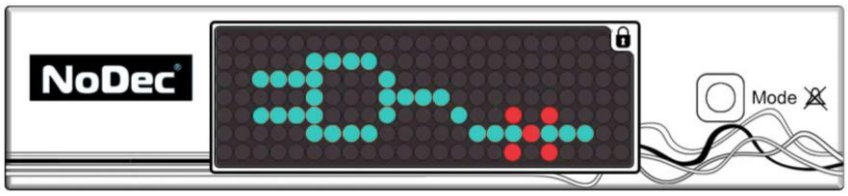
To reset / turn off the alarm, turn the Power Unit off then on again.

The four alarm types are as follows:

Mains Fail Alarm
Low Pressure Alarm
High Pressure Alarm
Electrical Valve Failure Alarm

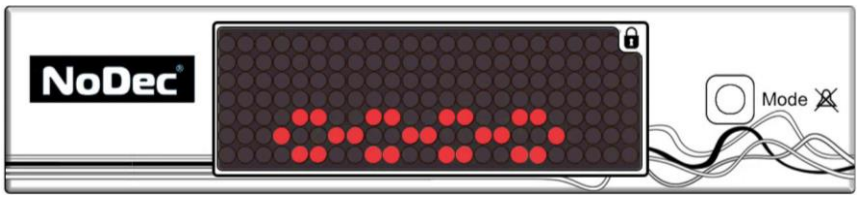
6.3.1. Mains Fail Alarm

This is displayed when there is a failure of the mains power supply or the unit is accidently unplugged from the mains. If the mains supply is reinstated while the Mains Fail Alarm is displayed, operation will restart automatricly. However as a fail-safe the mattress will first fully inflate to the pressure corresponding to the Firm or Soft comfort settings previously selected before automatically returning to normal operation in alternating mode. The Mains Fail Alarm displays the following:



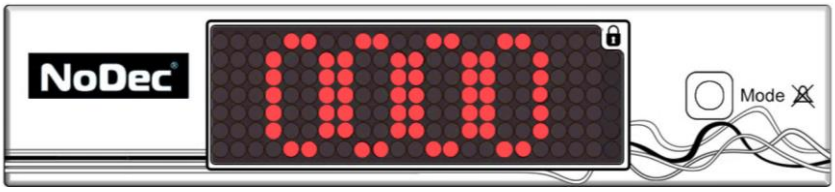
6.3.2. Low Pressure Alarm

This alarm condition is normally caused by releasing the CPR valve or by a leak in the mattress. The alarm delay time for this alarm is set at 45 seconds. This enables a reliable alarm system and prevents spurious low pressure alarms when using the softer [air] pressure modes. The Low Pressure Alarm displays the following:



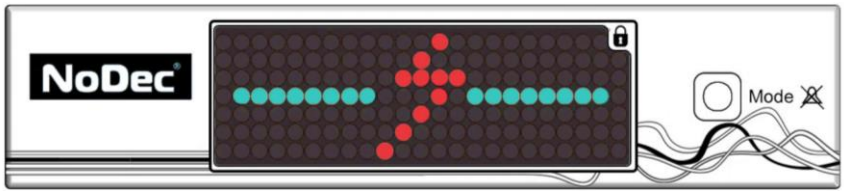
6.3.3. High Pressure Alarm

This alarm condition could be caused by an over pressure in the mattress e.g. by another person sitting on the mattress. This alarm's delay time is also set at 45 seconds and the display shows the following:



6.3.4. Electrical Failure Alarm

If any of the 3-way valves, or their associated wiring, within the pump should fail, this will be indicated by the normal audible alarm, alongside the following display:



6.4. Operating / Environmental Conditions

The environmental conditions of the pump unit should stay fairly consistent throughout use, this includes installation and transportation around the hospital *[Transport Mode, Section 6.2.6]*. These environmental conditions should apply as follows:

Ambient Temperature	+10°C to 40°C
Relative Humidity	30% – 75% non condensing
Atmospheric Pressure	700hPA – 1060hPA

6.4.1. Storage (and Shipping)

The Power Unit should be stored standing upright in a vertical manner and not laid flat. Before putting either the Power Unit or Mattress into storage the following conditions should apply:

Ambient Temperature	+10°C to 40°C
Relative Humidity	10% – 100% non condensing
Atmospheric Pressure	700hPA – 1060hPA

7. MAINTENANCE

7.1. Cleaning Procedures

Cleaning the mattress system every week is recommended, or sooner if heavily soiled. Hands should be cleaned and appropriate protective clothing worn before commencing cleaning process.

Phenol based products should not be used on either the mattress or mattress cover. Heat or steam autoclaves should be used to clean any of the components within the Full Mattress Overlay System.

7.1.1. Cleaning the Mattress

The following steps should be taken to correctly clean the mattress:

1. Leave the cover on the mattress and disconnect the mattress from the unit.
2. Clean the surface of the wash-down table with hypochlorite solution or an equilavent disinfectant.
3. Wash mattress top cover using hot water (60 °C) and detergent. Dry with a paper towel.
4. Fold mattress in half length ways and clean both the table and the exposed mattress.
5. Turn over mattress so the other bottom half is exposed and clean both mattress and table.
6. Repeat Steps 3 – 5 using hypochlorite solution or equivalent disinfectant.
7. Wipe the umbilical hose with hot water and detergent. Dry with a paper towel and repeat wiping down using hypochlorite or equivalent solution.

If necessary, the cover can be removed and machine-washed at a maximum temperature of 80°C for a minimum of 10 minutes.

7.1.2. Cleaning the Power Unit

The Power Unit can be cleaned by wiping a cloth dampened by a disinfectant solution or sterilised using ETO or Draeger processes.

7.2. Routine Maintenance Procedures

It is recommended that the Full Mattress System is part of a planned preventative maintenance programme. To prevent damage, normal electrostatic control procedures must be observed when working on the Power Unit. Electrical safety checks should be carried out on completion of any repair or routine maintenance. For any maintenance or repairs needed on the components it is easier to remove the Chassis Plate Assembly to access these components. Before opening the case, unplug the mains supply cable from the wall socket, and remove the mains cable connector from the pump unit. Keep the yellow button on the underside of the connector body depressed, and the connector will pull straight out. Hold the body of the connector only, do not pull on the cable to remove it.

Rober Ltd *will supply any service personnel with the appropriate circuit diagrams, pneumatic diagrams, calibration instructions and servicing diagrams upon request.*

WARNING: No repairs are to be carried out while the Mattress System is in use.

WARNING: Do not modify any components of the Mattress System without the authorization of *Rober Ltd*. If any modifications are made, appropriate inspection and testing must take place to ensure continued use of the Mattress System is safe.

7.2.1. Power Unit – General

The following steps should be taken to routinely maintain the Power Unit:

1. Remove any accumulation of dust from outside and inside the casing, using a small portable vacuum cleaning or similar.
2. Check the Air Inlet Filter that is located within the casing's handle. If it is dirty then remove the two M3 Pozi Head Screws to replace the Filter.
3. Check the security of wiring, the tightness of screws and the condition of any component mounting – rectify if necessary
4. Switch on the Power Unit.
5. Check that the display is working properly and that the inflation / loading sequence is in place.
6. Check that the Compressor is working.
7. Check all pneumatic connections for air leaks and rectify if necessary.
8. Check pneumatic tubing for any damage and rectify as necessary.

7.2.2. Power Unit – Compressor

The following steps should be taken to clean and service the Compressor:

1. Remove the four M4 Pozi Head Screws attaching the Compressor to the Chassis Plate and carefully remove the Compressor.
2. Checks can be performed on the Inline Air Filter by pushing the clip on the bottom of the Compressor. If the Filter is dirty then simply replace it and close the cover.
3. Check the security of the lead connectors.
4. Check the rubber mounting feet of the compressor to check that they are not damaged.
5. Relocate the Compressor and reconnect the tubing.

7.2.3. Power Unit – Solenoid Valves

The following steps should be taken to clean and service the 3-way Solenoid Valves:

1. Disconnect the 'A' Valve from the Power PCB and connect it to a 12V DC supply rated at a current of 300mA or more, Check the action of the Valve as the voltage is applied.
2. Repeat for any other Solenoid Valves inside the unit.
3. If necessary to replace the Valve, remove the two M3 Pozi Head Screws from the Valve attaching it to the Chassis Plate and replace.

7.2.4. Power Unit – Power PCB / Display PCB

To prevent damage, normal electrostatic control procedures must be observed when working the on the PCBs. The following steps should be taken to service the PCBs in the Power Unit:

1. Check that all electrical connections are tight and have not become loose.
2. In the event of suspect faults the PCBs must be replaced. No repairs can be carried out on site and the PCBs must be returned for repair.

7.2.5. Power Unit – Back-up Battery Replacement

The Back-Up Battery is to supply the alarm with power during a mains failure alarm and should be replaced routinely every 2–3 years. The following steps should be taken to service the Back-Up Battery in the Power Unit:

1. The battery is situated on the Display PCB, at the bottom left of the PCB as viewed from inside the case, adjacent to the text JP4.
2. The battery is held in place by a retaining strap. Remove the left hand retaining screw (nearest the edge of the PCB) using an M3 N.1o Pozi screwdriver. The washer is permanently retained on the screw. A magnetised head on the screwdriver will make the job easier. The free end of the strap can then lifted clear, and the battery will simply pull out of the gold plated sockets on the PCB.
3. Replace the appropriate battery *[100PUM2021]* from the spares list by plugging it into the sockets on the PCB and then refitting the strap using the original screw.

7.2.6. Power Unit – Fuse Replacement

If a fuse should blow please follow the steps below. Even if only one fuse has failed, it is recommended that both fuses are replaced. Bussmann type S506-1.6-R is recommended *[See Appendix A]*. (IEC Code 5 x 20mm T1.6AL 250V~).

WARNING: *Do not*, under any circumstances, fit fuses rated higher than 1.6 amps.

1. Ensure the mains cable connector is removed from the pump. *[Section 6.1.]*
2. Using a flat-bladed screwdriver, with a blade width of 6.5mm, unscrew the two fuse holders from the black mains connecotr unit and remover them. Pull the old fuses from the holders and dispose of them carefully.
3. Push the new fuses into the holders and refit them. Do not over tighten the holders.
4. Reconnect the mains supply and re-test the power unit.
5. If fuses blow repeatedly this indicate and internal fault. In this instant please contact your local distributor for assistance.

7.2.7. Mattress – General

The following steps should be taken to routinely maintain the Mattress:

1. Remove the Mattress cover
2. Check the Mattress visually for obvious signs of damage, i.e. rips, holes.
3. Check the pneumatic tubing and connectors, joining the cells together for any obvious signs of damage.
4. Connect the Mattress to the Power Unit and run the Full Mattress System.
5. Check the Mattress for any leaks, specifically at tubing connections, and rectify if necessary.
6. Check the CPR unit connection between the Power Unit and Mattress for any leaks.

For the Single Cell Mattress Configuration, if leaks are found in the Air Cells they can be replaced indiviually.

7.2.8. Full System Check – Operation

The following steps should be taken to check the Full Mattress System once Routine work has been carried out:

1. Connect the Mattress and Power Unit. Switch on and check that all air cells and formers inflate.
2. Check that the Power Unit automatically switches to Alternating Mode once fully inflated.
3. Check that the cells inflate/deflate in sequence and that the static cells remain inflated.
4. Check that the system cycles properly through the inflate/deflate sequence.
5. Select the Firm settings (both Alternating and Static) and check that the displays are correct. *Check that the air pressures correspond with those described in Section 5.3.1.*
6. Select the Soft settings (both Alternating and Static) and check that the displays are correct. *Check that the air pressures correspond with those described in Section 5.3.1.*
7. Activate the CPR deflation and allow the Mattress to deflate. Check that the audio/visual alarms are activated and the 'Low Pressure' display is visible. Cancel the audible alarm by pressing the front panel button. Switch the Power Unit off, reconnect the CPR unit and switch the Power Unit on again.
8. Disconnect the mains power cable from the Power Unit and check that the 'Mains Failure Alarm' is activated. Cancel the alarms and reset the Power Unit.

8. TECHNICAL DATA

8.1. Power Unit

Model	NoDec® Airstream
Dimensions (L x W x H)	400 x 160 x 250 mm
Weight	2.8 Kg
Power Supply	230V~ ±10%, 50 / 60 Hz
Power Consumption	20w max
Fuses	2 x T1.6A, 250V~ 5 x 20mm
Ingress Protection Rating	IP42
Classification	Class B Medical Device Class II.
Operating Cycle	10 minute (Continuous)
Flammability Rating	UL94 V0

Internal Components Operating Conditions

Ambient Temperature	*+10°C to 40°C*
Relative Humidity	*30% – 75% non condensing*
Atmospheric Pressure	*700hPA – 1060hPA*

8.2. Mattress

8.2.1. Single Cell Configuration

Model	NoDec® AIRSTREAM
Model Configuration	Single Cell
Number of Air Cells	17
Dimensions (L x W x H)	2000 x 850 x 120 mm *2000 x 850 x 160 mm (with foam inlay)*
Weight	5.5 Kg
Mattress Material	Polyurethane
Flammability Rating	Complies with BS7175 Ignition Source 0, 1 and 5
Maximum Weight of Patient	**160kg**

8.2.2. Integrated Cell Configuration

Model	NoDec® AIRSTREAM
Model Configuration	Integrated Cell
Number of Air Cells	18
Dimensions (L x W x H)	1850 x 880 x 100 mm
Weight	5 Kg
Mattress Material	Polyurethane
Flammability Rating	Complies with BS7175 Ignition Source 0, 1 and 5
Maximum Weight of Patient	**160kg**

9. CONTACTS

Manufacturer

Rober Limited
Wheatbridge Road
Chesterfield
Derbyshire
S40 2AB
UK
t +44 (0)1246 245404
f +44 (0)1246 245400
e info@roberlimited.com

Distributors

Rober (India) Private Limited
Subsidiary of Rober Limited UK
No 1, Ground Floor, RNG Palazzo
K.P.E. Extension
Bangalore 560001
Karnataka India
t +91 (0) 8065555683
e info@roberlimited.in
w www.roberlimited.in

Al Mashriq Medical Supplies LLC
#306, Al Nabooda Building,
Abela & Co Building,
Near Al Tayer Motors,
Al Garhoud, Dubai
UAE
t +971 4 2827870
f +971 4 2827873

Gerromed Pflege-und Medizintechnik Gmbh
Papenreye 55
22453
Hamburg
Germany
t +49 (0)40 54 73 03 0
f +49 (0)40 54 73 03 33

Pegasus Healthcare
Victoria
437 Nepean Highway
Brighton
VIC 3187
Australia
t +61 (03) 9596 6277
f +61 (03) 9596 6343

Pegasus Healthcare
New South Wales
1/30 Heathcote Road
Moorebank
NSW 2170
Australia
t +61 (02) 9601 6909
f +61 (02) 9601 7870

dtf medical
19 rue de la Presse
CS60132
St Etienne dedex 1
France
t +49 (0)4 77 74 51 11
f +49 (0)4 77 79 67 72

Zibo Athene A/S
Blokken 23
3460 Birkerød
Denmark
t +49 49 168 480
f +49 49 168 481

Bergen Medikal as
Gyldenprisven 16A
5056
Bergen
Norway
t +47 55947700
f +47 55947701

Senectovia Medizinalttecnhnik AG
In der Luberzen 1
CH-8902
Urdorf
Switzerland
t +41 (0) 44 735 35 45
f +41 (0) 44 735 35 40

Lorca Marin SA
Ctra. Alicante 28
CP 30007
Murcia
Spain
t +34 968 24 04 62

Birtely Pharma
Office No. 13 & 14
ASAS Real Estate Building.
Industrial Area #18.
Maliha Road
Sharjah
UAE
t +971 6 545 9805
f +971 6 545 9807

APPENDIX A: SPARES LIST

Power Unit		
Part Number	Component	Quantity (Per System)
100PUM2143	Case Front	1
100PUM2142	Case Rear	1
100PUM2144	Air Filter Cover	1
100PUM2145	V-Lock Frame	1
100PUM2147	Hook (Complete Assy)	2
100PUM2148	Hook Retainer (with Toothed Comb)	1
100CPR3002	CPR Dock	1
100PUM3010	Chassis Plate	1
100PUM2004	Solenoid Valve 1679	2
100PUM2064	Elbow Barbed Thread	3
100PUM2065	Straight Barbed Thread	1
100PUM2100	T Barbed Thread	2
100PUM2060	Barbed Reducing T Connector	1
100PUM2001	VC0100 Compressor	1
100PUM3001	Silencer-Filter	1
100MAT2045	Ø6mm Bore Silicone Tubing	-
100PUM3002	Ø2mm Bore Silicone Tubing	-
100PCB2001	Power PCB	1
100FIX3001	Mounting Pillars	4
100PCB2002	Display PCB	1
100PUM2021	V.2 Battery	1
100ELE2001	On / Off Rocker Switch	1
100ELE3006	Switch Connector	1
100ELE2049	Mains Power Entry Module V-Lock	1
100ELE3001	T1.6A Fuse	2
100ELE3002	Mains Connector	1
100ELE3003	Compressor Connector	1
100ELE3004	PCB Connector	1
100ELE2051	Power Cord Set with V-Lock	1
100FIX2061	M3 x 25mm, Pozi Head Screws	11
100FIX3001	M3 x 16mm, Pozi Head Screws	5
100FIX2007	M3 x 6mm, Pozi Head Screws	12
100FIX3002	M3 x 20mm, Pozi Head Screws	4
100FIX2011	M4 x 8mm, Pozi Head Screws	4
100PUM3003	Rear Rubber Bumpers	2
100FIX2024	Self-Adhesive Rubber Feet	4
050PUM5004	Primary Air Filter	1

Mattress – *Single Cell Configuration*		
Part Number	Component	Quantity (Per System)
100MAT2001	*Individual Air Cell (with toggles)*	*17*
100MAT2002	*Former (LHS)*	*1*
100MAT2003	*Former (RHS)*	*1*
100MAT2020	*Ø10mm Bore Silicone Tubing*	*3.7 m*
100MAT2047	*Ø10mm Bore PVC Reinforced Tubing*	*4.64 m*
100MAT2023	*Barbed Tee Push Connector*	*15*
100MAT2021	*Barbed Elbow Push Connector*	*4*
100MAT2015	*Stretch Top Cover*	*1*
100MAT2016	*Base Cover*	*1*
100MAT3015	*Umbilical Sleeve*	*1*
100CPR3001	*Premium CPR Unit (Sub Assembly)*	*1*
100MAT2033	*Base Sheet Envelope (with Loops)*	*1*
100MAT2014	*Foam Inlays (if required)*	*1*

Mattress – *Integrated Cell Configuration*		
Part Number	Component	Quantity (Per System)
100MAT2037	*Air Cell Deck (Incl. Barbed Connectors)*	*1*
100MAT2038	*Side Formers (Assy)*	*1*
100MAT2020	*Ø10mm Bore Silicone Tubing*	*3.6 m*
100MAT2047	*Ø10mm Bore PVC Reinforced Tubing*	*4.55 m*
100MAT2023	*Barbed Tee Push Connector*	*1*
100MAT2021	*Barbed Elbow Push Connector*	*3*
100MAT2041	*Stretch Top Cover*	*1*
100MAT2042	*Base Cover*	*1*
100MAT3015	*Umbilical Sleeve*	*1*
100CPR3001	*Premium CPR Unit (Sub Assembly)*	*1*