Artemis

Dynamic Mattress Systems

SIDHIL

Instructions for use

www.sidhil.com

Welcome to Sidhil
Still making it better...

At Sidhil, everything we do is designed around quality. From our modern and efficient manufacturing plant in Halifax, West Yorkshire, we manufacture a range of products for the healthcare market using leading edge production technology and finishing processes.

We are the only remaining volume manufacturer of hospital beds in the UK, bringing together innovation in product development, sales, customer service and logistics to provide clear benefits for our customers in terms of flexibility, short production timescales and support from our nationwide network of service and maintenance centres.

Excellence in customer service is our key objective. Alongside our focus on innovation, research and product development, we use our UK manufacturing facility to ensure optimum levels of product and spares availability, with unparalleled levels of reliability and performance.

Corporate social responsibility is also an issue for Sidhil. We have now received accreditation to ISO 14001, underlining our commitment to maintaining the highest levels of environmental awareness and sustainability across our manufacturing operation.

CONTENTS

1. INTRODUCTION

Thank you for purchasing this product. These instructions for use should be read carefully before operating the dynamic mattress and kept for future reference. Please ensure that you understand all instructions, if you have any questions concerning the operation or maintenance of the dynamic mattress please contact your provider.

2. CONTACT INFORMATION

For any service, warranty, sales or customer service information on this product please contact your provider or if in doubt contact Sidhil Ltd at the following address.

Please quote the control unit and/or mattress serial number on all correspondence.

Sidhil Ltd.
Sidhil Business Park
Holmfield
Halifax
West Yorkshire
HX2 9TN
UK

Service & Maintenance	**Spares**	**Customer Service**
Tel: +44 (0)1422 233136	Tel: +44 (0)1422 233138	Tel: +44 (0)1422 233000
Fax: +44 (0)1422 233010	Fax: +44 (0)1422 233010	Fax: +44 (0)1422 233010

sales@sidhil.com
www.sidhil.com

For Service & Support outside the UK & Northern Ireland please contact the local distribution company from where this equipment was purchased. Failure to do so may result in the manufacturer's warranty becoming void.

3. PRODUCT DESCRIPTION

3.1 Environment

Your dynamic mattress system is intended for use in the following environment:

- A hospital where intensive/acute care is provided and medical supervision is required and monitoring provided.

3.2 Intended Use

The Artemis dynamic mattress system is a high quality air support surface suitable for individuals at very high risk, those with up to and including grade 4 pressure ulcers, needing frequent monitoring and positioning. Via the automatic changing pressure in the air cells the mattress provides comfort and pressure relief to patients vulnerable to pressure damage by providing regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

The mattress system is designed for use on both standard and profiling bed frames. Ideally, patients allocated to this system will have some degree of independent mobility or can be repositioned according to individual needs.

For assistance in setting up, using or maintaining your dynamic mattress system or to report unexpected operation refer to the contact details found in section 2.

3.3 Features

Mattress

- 23 cells: 3 static head cells and 20 alternating cells (including 8 narrow heel cells).
- Cell on cell construction.
- 10 minute cycle period.
- Securing straps.
- 2 way stretch, vapour permeable and waterproof cover.
- Automatic patient egress detection (when function is activated on control unit).
- Cable management routing.

Control Unit

- Provides air supply to mattress.
- Automatically determines patient weight (±10kg).
- Automatically sets optimum pressure for patient.
- Operated via a touch panel with integrated visual display.
- Alternating, constant low pressure, pulsation and max inflate functions.
- Customisable functions.
- Fault indicator displays.

4. SAFETY

4.1 Warnings and Cautions

Warning

Warnings in these instructions for use highlight potential hazards that if disregarded could lead to injury or death.

Caution

Cautions in these instructions for use highlight potential hazards that if disregarded could lead to equipment damage or failure.

4.2 Risk Assessment

Bed frames used with the mattress system can vary greatly depending on the specific healthcare setting (i.e. hospitals, nursing homes, home care etc). It is the responsibility of the carer to carry out the necessary risk assessment to ensure the safety of the patient.

Before a patient uses the dynamic mattress system a risk assessment must be performed on a patient by patient basis. The risk assessment should include, but is not limited to:

- Product combinations (bed frame, mattress, side rails etc.).
- Extent of tissue damage (if any).
- Entrapment.
- Patient falls.
- Small adults (and children).
- Patients with learning difficulties.
- Unauthorised people with access to the controls.

4.3 Contraindicators

Patient conditions for which the application of pressure relief on an alternating mattress system is a contraindication are as follows:

- Cervical or skeletal traction
- Unstable spinal fractures

Other contraindications may be relevant which are specific to the patient or care environment.

4.4 Mattress Load

Maximum patient weight: 248kg (39 stone)

4.5 General Warnings

Warning

- The mattress system is to be installed and put into service in accordance with the information provided in these instructions for use.
- The mattress system is typically not suitable for child use, if it is to be used for child occupancy ensure a risk assessment has been undertaken taking into account the proportions of the child and dimensions of the mattress system.
- Misused electrical equipment can be hazardous.
- Exposure of the control unit to any liquid while it is plugged in could result in a severe electrical hazard.
- The control unit is a precision electronic product. Use care when handling or transporting it. Dropping or other sudden impacts may result in damage to the unit.
- Do not open the control unit – Risk of electrical shock.
- Repairs and service are to be conducted by suitably trained personnel. If the control unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately.
- Modification of the mattress or control box is not allowed without the permission of Sidhil Ltd – A hazard could be introduced.
- Occupants and users of this equipment must never smoke in close proximity to the control unit, mattress or bedding being used with it - Risk of fire.
- Accessories that have not been approved or designed for use with the mattress system are not be used.
- Control unit shall not be used in the presence of flammable gasses or used in oxygen rich environments – Risk of explosion / fire.
- Control unit functions must be locked out when a patient is left unattended.
- If children, adults with learning difficulties or even pets pose a potential risk of intentional or unintentional tampering with the control unit its suitability for use is to be considered during the initial patient / product risk assessment.
- The mattress is for single occupancy use. Additional weight could damage the mattress or affect the performance of the mattress system.
- Minimise articles (e.g. bedding) between the mattress surface and patient, and secure bed sheets loosely so as not to affect mattress functionality.
- Perform regular patient skin checks – Any tissue deterioration may require equipment reallocation and/or a re-assessment of the care being provided.

5. TRANSPORT AND STORAGE

5.1 Storage

- Detach the control unit from the mattress.
- Rotate the CPR dial until it is open.
- Lay the mattress out flat and position upside down.
- Ensure there is no air trapped in the cells – Note, air will only escape from the CPR outlet and not the mattress connector.
- Position the control unit on the mattress.
- Roll from the head end towards the foot end (ensuring the control unit is fully covered).
- Place into storage bag to protect from dirt, debris, fluids etc.

Warning

The mattress system is to be decontaminated prior to any storage to avoid risk of cross contamination.

Caution

- Do not fold, crease or stack mattresses and/or control units - damage could be incurred.
- Do not store whilst inflated - damage could be incurred.

5.2 Transportation

Warning

- Do not remove mattress from bed frame if occupant is still on mattress – Risk of falling.
- If essential that patient is moved whilst staying on mattress the mattress must be re-plugged in immediately once desired location has been reached - Risk of tissue damage due to loss of cell alternation.

Caution

- Do not transport/move whilst inflated (unless safely secured to bed frame) – Damage could be incurred.
- Never drag the mattress - always carry it.

5.3 Environmental Conditions

The following conditions should be followed when transporting and storing the dynamic mattress system:

- Ambient temperature: -25°C to +70°C
- Humidity: < 93%, non-condensing

6. SYMBOL DEFINITION

The following symbols are found on this bed:

(See section 9.3 for interface symbols)

Warning

Beware of potential hazard

Refer to instructions for use - Mandatory

Failure to read the instructions for use could introduce a hazard

W.E.E.E Label

(Waste Electrical and Electronic Equipment)

Refer to section 12.1

No smoking near to mattress system or whilst occupying mattress - Risk of fire

Type BF Applied Part

Applied Part: The parts of the device that come into physical contact with the user/occupant in order for it to carry out its intended function (refer to secion 13 for a description of the applied parts).

Type BF: Applied parts which are electrically isolated from earth and other parts of the medical equipment - Complying with specific requirements for protection against electric shock to IEC 60601-1

Mattress

The following symbols are found on the mattress:

Machine wash at 71°C

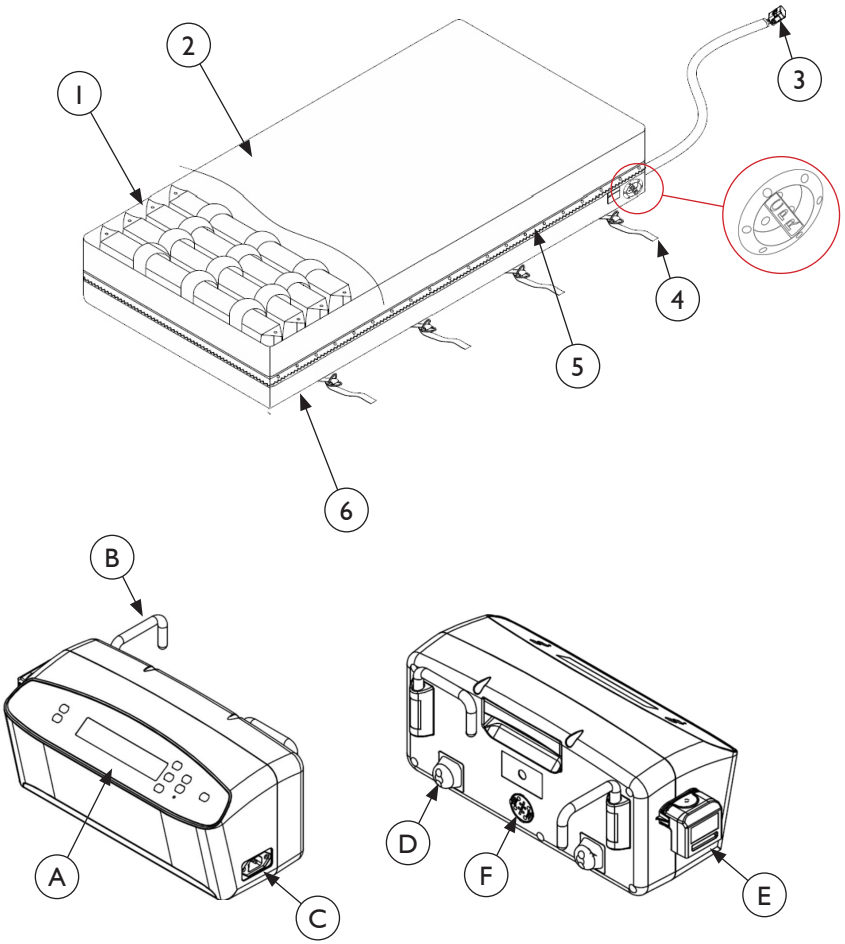
Do not iron

Do not bleach

Do not dry clean

Tumble dry on low heat

7. PARTS IDENTIFICATION



No.	Item Description	Qty.
1	Air Cell	23
2	Top Cover	1
3	Air Connector	1
4	Mattress Strap	8
5	Base Cover	1
6	CPR dial	1

No.	Item Description	Qty.
A	Control Interface	1
B	Hook	2
C	Mains Cable Port	1
D	Pad	2
E	Air Connector (attached to mattress)	1
F	Air Filter Cover	1

8. INSTALLATION

When specifying a mattress, bedframe and side rail combination a clinical assessment of the patient's needs must be carried out in line with local policy.

Warning

Refer to the warnings at the end of this section before proceeding with installation.

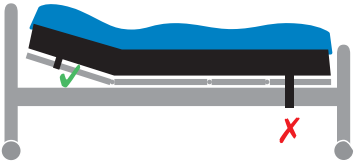
Caution

- Ensure the mains supply is compatible with the control unit (see section 13 for electrical specification)
- Avoid placing the mattress system in direct sunlight – Direct sunlight could damage the mattress cover.

- Open all packaging with care.
- Once removed from the packaging check product for any signs of damage. If damaged do not put into use and contact your provider or Sidhil Ltd. (see section 2).
- Remove all covers, sheets and the existing mattress from the bed.
- Position the mattress on top of the bed frame, top cover facing upwards and air hose at the foot of the bed for control unit positioning.
- Attach to the bed frame by securing the adjustable straps to the moving sections of the bed.

Caution

- For profiling beds, it is essential that straps are secured around the movable sections of the bedframe – Damage will be incurred when profiled if secured to fixed parts of frame.



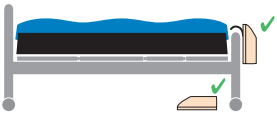
- To avoid any risk of damage to the mattress ensure there are no sharp objects which may come in contact with it.

- Ensure the CPR dial is rotated to a vertical or horizontal, and closed, position.

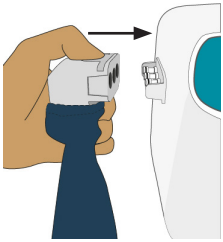
CPR Open:

CPR Closed:

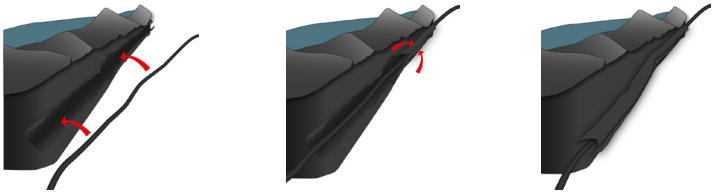
- Position the control unit by hanging the hooks over the foot board. If there is no foot board place the unit on the floor with the front facing upwards. Ensure the rear of the unit is not obstructed by carpet, rugs etc. It is advisable to place the unit on a firm surface.



- Attach the air connector to the control unit, ensuring the air hose does not kink or become trapped between parts of the bedframe.



- Route the mains cable down the length of the mattress using the integral routing sheath. Detach the pop studs from the sheath, insert the cable and reattach all the studs down the full length of the sheath.



- Plug the mains cable into a suitable mains supply and switch on the control unit (see section 9).

- The mattress system will start to inflate. Inflation will be complete within 20 minutes.

- Once inflated, ensure the straps that attach the mattress to the bed frame are secure and hold the mattress in place, adjust as necessary.
- Once the mattress is fully inflated, the bedding can be replaced. Secure sheets loosely enough to ensure they do not interfere with cell alternation.
- Proceed to section 9 for Operation.

Warning

- Ensure the mattress is used with a compatible side rail and bed frame combination – Incorrect combinations can lead to entrapment and/or falls hazards.
- Ensure the mattress is of the correct type for the patient – Incorrect mattress specification could lead to an injury.
- The mains plug is the disconnect device for the means of isolating the control unit from the mains supply, the plug must be accessible at all times.
- Ensure the mains cable is plugged into an appropriate power source at all times.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.
- Ensure the mains cable is not in tension, paying particular attention to when the bed travels up/down.
- Precautions are to be taken when routing the mains cable around the bed to ensure that it does not become squeezed, trapped or damaged by the bedframe or other ancillary equipment - Risk of electrocution.
- Any electrical cable that is part of the mattress system or associated ancillary equipment that is found to be damaged must be replaced immediately - Damaged electrical cables can create a risk of electrocution and / or fire.
- A CE marked extension cable must only be used when it is not possible to reach a wall socket with the equipment mains cable – Contact Sidhil Ltd for detail in regards to safe use of extension cables.
- If an extension cable is used never overload it by plugging in appliances that together will exceed the maximum current rating stated for the extension cable – Risk of fire.
- Block adaptors are not to be used.
- Ensure multiple socket outlets are not positioned under the bed frame - Liquids that leak onto such a socket could pose an electrical / fire risk.

Warning

- Consideration is to be taken in the positioning of the mains cable and air hose to minimise the risk of accidental strangulation resulting from patient, baby or child entanglement – Sidhil recommend the use of the mains cable routing sheath that is incorporated down the length of the mattress.
- Keep away from sources of heat and naked flames (e.g. cigarettes, fireplaces, electric fires, fan heaters, electric blankets etc.) – Close proximity could damage the electrical system and / or mattress cover, bedding could catch fire etc.
- Do not place any objects or items, such as blankets, on or over the control unit - Risk of fire.
- Avoid placing the mattress system in direct sunlight – Direct sunlight could damage the electrical system and / or mattress covers.
- Avoid placing the mattress system in a moisture rich environment - Prolonged exposure to moisture could damage the electrical system and pose an electrical/fire risk.

9. OPERATION

9.1. Environmental Limits When in Operation

The following conditions should be followed when operating the dynamic mattress system:

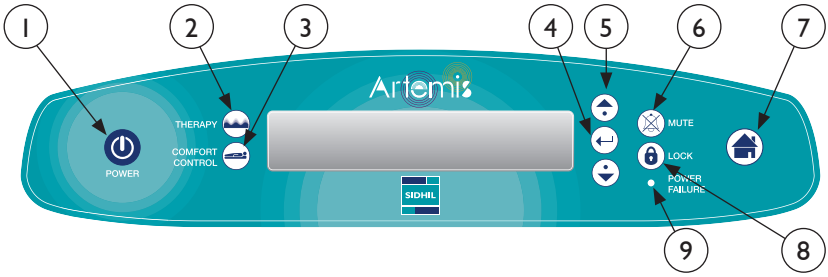
- Ambient temperature: +5°C to +40°C.
- Humidity: 15-93%, non-condensing.
- Atmospheric pressure: 700 hPa to 1060 hPa

9.2. Preparing For Use

Prior to patient usage of the dynamic mattress system the following must be performed:

- Ensure the bed and mattress system are at room temperature.
- Ensure the bed and mattress system have been cleaned and disinfected (see section 10).
- 'Ensure the mattress cover has been checked for tears, punctures, abrasion marks etc. and that their are no signs of fluid ingress.'

9.3. Control Interface



No.	Symbol	Description
1		Turns system on and off (see 9.5.1).
2		Opens therapy menu – Provides 4 different therapy settings (see 9.5.4.1).
3		Opens comfort control menu – Provides 3 different comfort settings (see 9.5.4.2).
4		Selects and initiates the chosen parameter.

No.	Symbol	Description
5		Moves the cursor up / down the selected menu.
6		Mutes the audible signal for a 30 minute period (see 9.5.3.2).
7		Returns to main screen.
8		Locks / unlocks interface functions (see 9.5.3.1).
9	-	Illuminates if power is lost

9.4. Mattress Overview

The zoned mattress offers 3 static head cells, 12 torso cells and 8 heel cells.

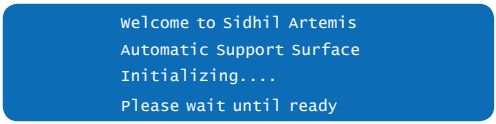
The cells can be inflated between a range of 13mmHg and 70mmHg, dependent on the function chosen.

The heel section has narrower and lower cells. The lower cells offload pressure to protrusions such as the heels and the narrower cells offer a more supportive surface and ensure localised pressure relief for vulnerable areas.

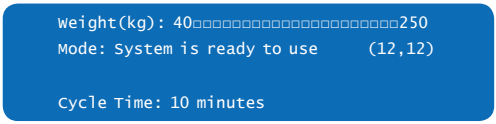
9.5. Control Unit Operation

9.5.1. Turning On / Off

Hold the button down until an audible signal sounds for a brief period. The screen illuminates.



The system will be ready for use after an initial inflation period of 20minutes. Once the mattress is fully inflated the panel will instruct the user that the system is ready for use and a short audible signal will sound.



If the system does not reach the required pressure it will sound a 'low pressure' indication after 20 minutes (see section 11).

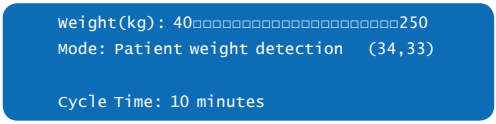
To turn the system off hold the button down until the screen extinguishes.

9.5.2. System Setup

Once a patient is positioned on the mattress the system will determine the patient's approximate weight and optimum pressure level within a period of 4 minutes. Once weight detection is complete the mattress automatically defaults to alternation mode.

9.5.2.1. Alternation

The mattress utilises an 'AB' alternation cycle where alternate cells deflate and inflate. As the system is detecting the patient weight the screen shows the changing pressure differential between the A and B cells at that moment in time. In the illustration below A = 34mmHg and B = 33mmHg



9.5.2.2. Patient Weight and Pressure

When the system is determining the patient weight the control unit is also calculating the optimum pressure level for that weight of patient. The process occurs every 60 minutes or when the control unit detects a significant change in weight. The detection works by increasing the pressure in all cells to maximum and then decreasing them to the lowest possible supportive pressure where the patient weight is at its heaviest (i.e. sacral, legs etc.).

The weight guidance indicator is accurate to ± 10kg. In the illustration below the weight is approximated to be 100kg with an alternating pressure of 13mmHg.

Warning

The weight indicator is not to be used for medical purposes, it is to act as information only. If the inclusion of the weight indicator could introduce a hazard it can be hidden, see 9.5.4.3.

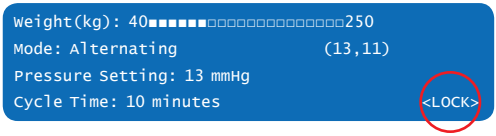
Once the system has set itself for the patient, re-check it after approximately 20-30 minutes to ensure the patient is comfortable and that the system is functioning correctly.

9.5.3. Safety Functions

9.5.3.1. Function Lock

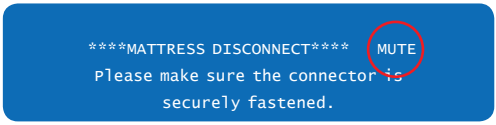
The control unit will automatically lockout all functionality 2 minutes after a function change. To unlock the control unit the 'lock' button is pressed for 2 seconds. To re-engage the lock the button can either be again pressed for 2 seconds or the user can wait for the automatic lock to re-engage.

When pressed the lock indicator illuminates:



9.5.3.2. Mute

The audio visual signal activates if a fault is detected. To silence the audible signal the 'mute' button is pressed. When the system is muted the screen shows:



(note, fault shown is an example only)

Re-pressing the mute button reactivates the audible signal.

The mute setting will self-cancel after 30 minutes and the audible signal will re-sound.

Note: If the 'power failure' indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.

Warning

When silencing the 'power failure' indicator the audible signal will not reactivate after 30 minutes and all lights will extinguish – There will be no indication that the system is powered down. Ensure power is returned to the system as soon as possible to resume pressure relief.

9.5.4. System Functions

9.5.4.1. Therapy Selection

When pressed a menu appears offering 4 different settings:

Use the up/down cursor key followed by the selection key to initiate the chosen setting.

1) Alternating: Operates an 'AB' cycle where alternate cells deflate and inflate over a defined time period (see section 9.5.4.3) causing the pressure over any one part of the body to change regularly, actively encouraging tissue perfusion.

2) Constant low pressure: Reduces the contact pressure by increasing the surface area over which the patient is supported and by contouring to the shape of the body, therefore redistributing pressure away from vulnerable areas. In this setting the system runs in a static mode where the cells are not alternating and are within a pressure range of 10 to 40mmHg (patient weight dependent).

When using the constant low pressure setting, to return to alternating it is necessary to manually reselect alternating from the therapy menu, it will not automatically default back.

3) Pulsation: Creates tissue stimulus by alternately increasing and decreasing the cell pressure of the constant low pressure mode by 20% in each direction.

When using the pulsation setting, to return to alternating it is necessary to manually reselect alternating from the therapy menu, it will not automatically default back.

4) Max inflate: Inflates the cells to maximum pressure (40mmHg) to provide a stable, static support surface.

The system will automatically revert back to alternation mode after 20 minutes for patient safety.

9.5.4.2. Comfort Control

When pressed a menu appears offering 3 different settings:

```
1: Soft/Firm Control  a: Firm
                      b: Medium
                      c: Soft
```

Use the up/down cursor key followed by the selection key to initiate the chosen setting.

By selecting this function the softness / firmness of the mattress can be manually altered, dependent on the patient's requirements. The pump defaults to medium.

Firm = + 5mmHg

Medium = Automated pressure setting

Soft = – 5mmHg

Before changing the pressure a clinical judgement is required from frequent monitoring and repositioning of the patient.

9.5.4.3. Additional Settings

On accessing the comfort control menu ( ) and then pressing the lock ( ) and down arrow ( ) buttons together a hidden menu is accessed:

```
1: Cycle Time
2: Auto Lock
3: Weight Unit (kg or lbs)
              Page 1/2
```

```
4: Weight Display On/Off
5: Egress Alert On/Off
6: Back to the Main Screen
              Page 2/3
```

1) Cycle time: When pressed a menu appears offering 3 different settings:

```
1: Cycle Time     a: 10 mins
                  b: 15 mins
                  c: 20 mins
```

By selecting this function the cycle time of the alternation sequence can be manually altered, dependent on the patient's requirements. Note, the default cycle time for the system when first turned on is 10 minutes.

Use the up/down cursor key followed by the selection key to initiate the chosen setting.

2) Auto lock: When pressed a menu appears offering 2 different settings:

```
2: Auto Lock      a: Enable
                  b: Disable
```

By selecting 'disable' the interface will not automatically lock itself (see section 9.5.3.1).

Use the up/down cursor key followed by the selection key to initiate the chosen setting.

Warning

The lock is only to be disabled in an environment where intentional/ unintentional tampering cannot occur – Sidhil recommend that the lock is always set to 'enable' regardless of the environment.

3) Weight unit: When pressed a menu appears offering 2 different settings:

```
3: Weight Unit    a: kg
                  b: lbs
```

Use the up/down cursor key followed by the selection key to initiate the chosen unit of measure.

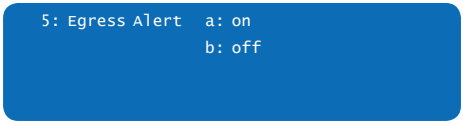
4) Weight display: When pressed a menu appears offering 2 different settings:

```
4: Weight display a: on
                   b: off
```

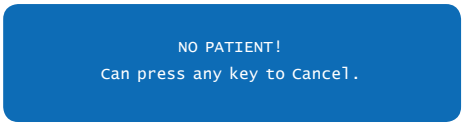
Use the up/down cursor key followed by the selection key to show/hide the weight indicator on the main screen.

5) Egress alert: If activated the pump provides an audio-visual signal if it senses that the occupant has got out of the bed, due to a sudden change in force being exerted on the cells.

When selected a menu appears offering 2 different settings:



Use the up/down cursor key followed by the selection key to activate/deactivate the egress alert. If active and the occupant gets out of bed an audible signal sounds and a 'warning' screen illuminates for approximately 1 minute followed by a 'no patient' indication:



To cancel the audio-visual signal any button on the control interface can be pressed.

9.6. Mattress Operation

9.6.1. Auto Seat Mode

The mattress design allows for it to be profiled in an upright position. Pressure will be increased when the patient is sitting in an upright position but depending on patient comfort and clinical judgement the comfort setting may need to be changed.

When the backrest travels beyond an angle of 20° the screen on the control interface advises that the backrest has been raised.

```
Weight(kg): 40■■■■■■□□□□□□□□□□□□□□250
Mode: Auto-Seat
Pressure Setting: 14 mmHg
Cycle Time: 10 minutes
```

9.6.2. Low Patient Weight

The mattress accommodates patients whose weight would be considered as particularly low (<40kg). It significantly reduces internal cell pressures to make it suitable for lower weight patients. To activate press the selection button (↵) for 5 seconds - 'low weight patient' illuminates on the screen:

```
Weight(kg): 40□□□□□□□□□□□□□□□□□□□□250
Mode: Alternating                (10,11)
Setting: Low Weight Patient
Cycle Time: 10 minutes
```

To deactivate the low patient weight mode the control unit needs to be switched off and then back on again.

While low patient weight mode is selected frequent monitoring and repositioning is advised.

9.7. CPR

Rapid deflation of the mattress may be required for emergency treatment or system deflation. The CPR dial is located at the foot end of the mattress.

Rotate the CPR dial to the open position, once done the entire system will rapidly deflate.

To re-inflate turn the CPR dial to the closed position. Wait for the mattress system to reach optimal pressure prior to a return to normal use.

CPR Open:

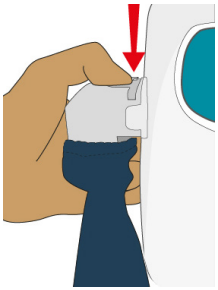
CPR Closed:

9.8. Mattress Disconnection and Power Cuts

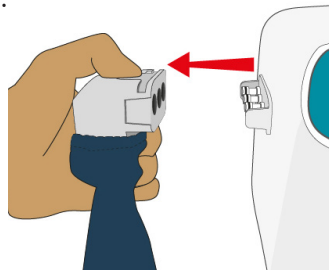
If the mattress is to be disconnected from the power supply for an extended period of time and the mattress is to remain inflated or in the event of a mains power failure, carry out the following procedure:

- Disconnect from the power unit by pressing the tab on the top of the connector (1) and pulling away from the control unit (2).

1.



2.



- Switch off the control unit (if still operational).
- Disconnect from the power supply.

Note, there is no need for the air connector to be sealed with a cap due to the use of the mattress using non-return valve technology.

Warning

- The mattress will remain inflated for a maximum of 10 hours only – Return the system to the mains supply as soon as is practical.
- Whilst unplugged alternating mode will not be operational – Pressure relief will not be provided.

9.9. Use of Incontinence Products

Incontinence products such as sheets or pads can be used with the system, however product performance is likely to reduce due to the reduced effectiveness of the alternating pressure distribution.

If incontinence products are to be used it is recommended that regular patient skin checks are performed to ensure skin integrity is maintained.

10. DECONTAMINATION / CLEANING

Infection control and routine cleaning must be carried out in accordance with your local Infection control policy or regulatory body.

Warning

- Always disconnect the mattress system and bedframe from the main power supply prior to cleaning.
- The control unit is rated to IP21 and provides protection from condensation only, do not immerse or soak the control unit – Risk of electric shock.
- Regular cleaning and disinfection of the mattress system will help to prevent the risk of infection to the occupant and/or carer.
- Prior to transferring the mattress system to another user ensure it has been cleaned and disinfected using the method as detailed below to help prevent the risk of cross infection.

Caution

- If any of the below washing instructions are not followed the product warranty will be invalidated.
- Do not use solvents, neat bleach, phenolic based cleaning solutions or abrasive products to clean the casing or mattress.

Sidhil recommend the use of Tristel 'Fuse' sachets and Tristel 'Jet' gel. Sidhil also recommend the use of Chlor-clean tablets.

Follow the product documentation for concentration guidelines and instructions for use.

10.1. Control Unit

- Check for external damage – If damaged take the control unit out of use.
- All surfaces to be wiped down with a disposable soft cloth moistened with a mild detergent and diluted in warm water (40°C).
- The control unit is be cleaned by starting with the cleanest parts of it and systematically moving to the dirtiest parts. Extra care should be taken around areas where excess dirt or dust may gather.
- The cloth should be changed during the cleaning process if it becomes soiled.
- Wipe down with a clean cloth moistened with clean water to remove detergent residue.
- If there are blood spillages or bodily fluids present wipe surfaces down with 0.1% Chlorine solution (1,000 ppm).
- Wipe down with a clean cloth moistened with water.
- Dry off with a paper towel - Always ensure the cleaned surfaces are allowed to fully dry before putting back into use.

10.2. Mattress

Before attempting to clean the mattress the top cover is to be checked for physical signs of damage that may lead to strike-through (ingress of fluid through cover). This is achieved by unzipping the top cover and looking for signs of staining to the white underside. Any evidence of strike-through (and / or cover damage) will require a new cover to be fitted to the mattress.

Warning

The cover must not be used if strike-through is evident – Risk of cross infection.

Caution

Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.

General Cleaning:

- Wipe down with a clean cloth moistened with a mild detergent and diluted in warm water (40°C).
- Rinse with cold clean water and a clean cloth and allow to fully dry before use.

Decontamination:

- Mop up any fluid with paper towels.
- Wipe cover down using cold clean water.
- Wipe down with a 0.1% Chlorine solution (1,000ppm) in cold water, where necessary a 1% Chlorine solution (10,000ppm) is to be used instead.
- Rinse with cold clean water and a clean cloth and allow to fully dry before use.
- Infection control and routine cleaning must be carried out in accordance with local policy.

10.3. Alternative Mattress Cover Cleaning Instructions

Alternatively disinfection of the mattress cover may be achieved by laundering as follows:

- Remove mattress cover.
- Machine wash at 71°C for not less than 3 minutes or 65°C for not less than 10 minutes. Heavily soiled items should also have a pre-wash/sluice cycle.
- Allow covers to fully dry before use.

(Refer to the Department of Health document CFPP 01-04 for further detail).

11. TROUBLESHOOTING

Warning

The control unit is not to be opened – risk of electrocution.

Symptoms	Indications	Actions
Power Failure	• Amber 'power failure' light flashes. • Audible signal sounds. • Screen extinguishes. 	If mains plug, cable or outer casing is visibly damaged turn off at the mains and contact your approved service engineer. 1. Turn off the control unit to silence the alarm and turn off the mains supply (Note, the mute button does not silence the power failure indication). 2. Check the mains cable is fully connected to the control unit and plugged into a wall socket. 3. Switch on at the wall (to ensure the socket is working plug in a fused device that is known to work). 4. Turn on the control unit. If control unit still fails to operate: 5. Turn off the control unit at the wall. 6. Replace the mains plug fuse – See section 13 for fuse types. 7. Turn on the control unit. If control unit still fails to operate turn off at the mains and contact your approved service provider.
Incomplete inflation / Low pressure	• Audible signal sounds. • Screen shows: 	1. Ensure the mattress air connector is correctly connected to the control unit. 2. Ensure the CPR dial is closed and there is no air leakage. 3. Turn the unit off and then on again to clear the indicator. If a 'low pressure' indicator continues to illuminate: 4. Open the mattress and ensure there is no air leakage within the mattress – cells, tubing and connectors. 5. Turn the unit off and then on again to clear the indicator. If a low pressure indicator is still evident turn off at the mains and contact your approved service provider.

Symptoms	Indications	Actions
High Pressure	• Audible signal sounds. • Screen shows: 	1. Ensure the mattress umbilical is not trapped or being squeezed. 2. Open the mattress and ensure none of the air pipes are kinked. 3. Turn the unit off and then on again to clear the indicator. If a high pressure indicator is still evident turn off at the mains and contact your approved service provider.
Mattress Disconnection	• Audible signal sounds. • Screen shows: 	1. Ensure the mattress air connector is correctly connected to the control unit. 2. Turn the unit off and then on again to clear the indicator. If the indicator is still evident turn off at the mains and contact your approved service provider.
Patient is bottoming out		1. Ensure the patient is suited to the maximum rating of the mattress. 2. Ensure the patient is centrally positioned on the mattress. 3. Increase the pressure setting – Refer to section 9.5.4.2

12. MAINTENANCE

Warning

- Always disconnect the control unit from the main power supply prior to performing any maintenance procedures (when viable).
- No modification of this equipment is allowed.
- The mattress system should be vacated by the patient before any maintenance or inspection takes place. If this is not possible due to the patient's mobility care should be taken for the service engineer not to make contact with the patient when working on electrical items.
- Only Sidhil approved components specified for the Artemis dynamic system are to be used - if in doubt contact Sidhil Ltd or your local distributor.

Only authorised service personnel or Sidhil service engineers should carry out repairs or service activities. For Service & Support outside of the UK & Northern Ireland please contact the local distribution company from where this equipment was purchased. Failure to do so may result in the product warranty becoming void. ***The mattress system must be serviced once yearly, as a minimum.*** Sidhil also recommends that the carer performs frequent visual and operational inspections. If there are any signs of damage or the system is not performing as it should withdraw it from service until the system has been repaired and is fit for use again.

Sidhil Ltd recommends that the following maintenance procedure is performed every 12 months:

- Check that the air filter is in good condition and replace or clean as required.
- Check that all electrical functions operate correctly on the control unit.
- Check that all audible and visual indicators work appropriately (when plugged in and unplugged from mains supply).
- Check that the battery is still functional and operates in the event of a power loss.
- Check that the mattress reaches the required pressures.
- Check the CPR connection on the mattress.
- Check the cover for tears, punctures, abrasion marks and split seams.
- Check for signs of signs of fluid ingress to the underside of the cover.
- Check that all piping and cells within the mattress are in good condition and that there is no kinking evident.
- Check the control unit housing is not cracked or damaged, if damaged the control unit must be removed from operation immediately.
- Check that the mains cable and plug are in good condition, if either is damaged it must be replaced with a complete assembly, the plug must never be re-wired.

For more detailed service information, spare parts, circuit diagrams etc. please refer to the service manual. Copies are available from Sidhil Ltd. Contact details can be found in section 2.

12.1. Disposal of Parts

When the electrical system has come to the end of its useful life contact your provider or Sidhil Ltd (see section 2) to arrange for collection, alternatively follow local recycling and W.E.E.E. (Waste Electrical and Electronic Equipment) policies.

The control unit used with the mattress system is not to be disposed of in general municipal waste. Some of the electrical components could be harmful to the environment and where viable the components can be recovered and reused/ recycled.

The metal and plastic components used in both the mattress and control unit are also to be separated and disposed of following local recycling policy as these can also be recovered and reused/recycled.

Warning

The mattress system is to be decontaminated before disposal to avoid risk of cross contamination

13. SPECIFICATION

Classification:	Electrical shock protection: Class I, Type BF Applied Part: Mattress Liquid ingress protection: IP21 Not AP or APG equipment*
Supply Rating:	230V, 50Hz, 25W
Fuse Rating:	Mains Plug – 13A
Mains Plug:	Type G/BS1363
Mattress Dimensions:	(L) 2000mm x (W) 880mm x (D) 200mm
Mattress Weight:	11kg
Maximum Patient Weight:	248kg (39 stone)
No. of Cells:	23 cells which include: 3 static head cells 20 alternating cells (including 8 narrow heel cells) with cell-on-cell function
Alternating Therapy:	AB pattern
Cycle Time:	10, 15 or 20 minutes
Pressure Range:	Alternating Mode: 13 – 70 ±2mmHg Constant Low Pressure Mode: 10 – 40 ±2mmHg Pulsation Mode: 80% & 120% of CLP setting Max Inflate: 40 ±2mmHg
Control Unit Dimensions:	(L) 180mm x (W) 390mm x (D) 14.5mm
Control Unit Weight:	4.1kg
Cover Material:	Dartex®
Cell Material:	TPU
Base Material:	Nylon fabric with PU coating
Transport and Storage Conditions:	Ambient Temp: -25°C to +70°C Humidity: < 93%, non-condensing
Operational Conditions:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing
Atmospheric Pressure:	700hPa to 1060hPa
Operating Altitude:	≤ 2000m
Pollution:	Degree 2
UV:	Intended for indoor use only
Noise level:	<40dB(A)
Expected Service Life:	3 years
Safety Standards:	IEC 60601-1: 2005 IEC 60601-1-2:2007 IEC 60601-1-11:2010 - Partial

* Not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.

14. ELECTROMAGNETIC COMPATIBILITY (EMC)

The Artemis control unit has been designed to meet the EMC requirements of IEC 60601-1-2: 2007 however it may still be affected by or emit harmful radio frequency (RF) energy. The RF emissions from the mattress control unit are very low and are not likely to cause any interference to nearby electronic equipment, however interference to sensitive equipment is still possible. Likewise if the immunity limits of the control unit are exceeded the system may be seen to operate abnormally.

Interference can be received from fixed transmitters (e.g. commercial radio and television towers) and portable / mobile RF communications equipment (e.g. mobile phones). Due to the increasing number of mobile phones and other wireless devices the possibilities of interference to the control unit and other surrounding equipment results in the need for special precautions to be taken regarding EMC. The Artemis is to be installed and put into service according to the information provided within this section to ensure continued and reliable operation.

Wireless communications equipment such as wireless network devices, mobile phones, cordless telephones including their base stations and walkie-talkies could all affect the electrical operation of the control unit - separation distances must be considered.

If the control unit or any alternative equipment is found to be operating abnormally turn off the piece of equipment that is believed to be causing the interference (if possible) to identify the source of the RF energy. Once identified mitigation measures are to be taken, such as the separation distances being increased and/or the device(s) being re-orientated. As an example a mobile phone typically has a recommended separation distance of at least 3.3m from the control unit.

14.1. Requirements According to IEC 60601-2:2007

The Artemis is intended for use in the electromagnetic environment specified below. The customer or the user of the Artemis should ensure that it is used in such an environment.

Warning

The Artemis control unit should not be used adjacent to or stacked with other equipment where possible, if adjacent or stacked use is necessary the Artemis should be observed to verify normal operation in the configuration in which it is to be used.

Guidance and manufacture's declaration – electromagnetic emissions		
Emission test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The Artemis 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 emission CISPR 11	Class B	The Artemis is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	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 IEC 61000-4-11	<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 the Artemis requires continued operation during power mains interruptions, it is recommended that the Artemis be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Artemis control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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] 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 Artemis is used exceeds the applicable RF compliance level above, the Artemis should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienteering or relocating the Artemis.

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

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

Recommended separation distances between portable and mobile RF communications eqiupment and the Artemis control unit			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz d= 1.2√P	80 MHz to 800 MHz d= 1.2√P	800 MHz to 2.5 GHz d= 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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.			

15. WARRANTY

Sidhil Ltd guarantees this product is free from defects in material and workmanship under normal use for 2 years (full parts and labour) from the date of purchase from Sidhil Ltd and its subsidiary companies or its authorised dealers. All implied warranties, including but not limited to those implied warranties of fitness and merchantability, are limited in the total duration of 2 year from date of purchase. Proof of purchase must be presented with any claim. Except as provided herein, Sidhil Ltd, product warranty does not cover damage caused by misuse or abuse, accident, the attachment of any unauthorised accessory, alteration to the product, or any other conditions whatsoever that are beyond the control of Sidhil Ltd. Sidhil Ltd and its subsidiary companies shall have no liability or responsibility to customer or any other person or entity with respect to any liability, loss or damage caused direct or indirectly by use or performance of the product or arising out of any breach of this warranty, including but not limited to any damages resulting from inconvenience, loss of time, property, revenue, or profit or any indirect, special, incidental or consequential damages, even if Sidhil Ltd or their subsidiary companies or authorised dealers has been advised of the possibility of such damages.

In the event of a product defect during the warranty period you should contact Sidhil Ltd or their authorised dealer who will at its option unless otherwise provided by law; a) correct the defect by product repair without charge for parts and labour b) replace the product with one of the same or similar design or c) refund the purchase price. All replaced parts and products on which refund is made become the property of Sidhil Ltd. New or reconditioned parts and products may be used in the performance of warranty service. Repaired or replaced parts and products are warranted for the remainder of the original warranty period. You will be charged for repair or replacement of the product made after the expiration of the warranty period.

This warranty does not cover; a) damage or failure by or attributes to acts of God, abuse, accident, misuse, improper or abnormal usage, failure to follow instructions, improper installation or maintenance, alterations, lightning or other incidence of excess voltage or current, b) any repairs other than those provided by a Sidhil Ltd authorised technician, c) consumables such as fuses, d) cosmetic damage, e) transportation, shipping or insurance costs or f) costs of product removal, installation setup service adjustment or re-installation.

This limited 2 year warranty gives you specific legal rights and you may also have other rights.

Sidhil Ltd cannot be held responsible for any injury or incident which relates to the use of this mattress system in conjunction with accessories manufactured by companies other than Sidhil Ltd.

All products carry the CE mark in accordance with EC Directive on Medical Devices (93/42/EEC).

Sidhil has a policy of continual product improvement and reserves the right to amend specifications covered in these instructions for use.

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