

# EU

Artemis II Dynamic Mattress and Cushions Instructions for use



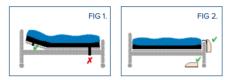
#### **ARTEMIS II** Mattress and Cushion

#### QUICK REFERENCE GUIDE P1 of 2

#### TO BE USED IN CONJUNCTION WITH THE FULL INSTRUCTIONS FOR USE FOR THIS PRODUCT. THIS <u>QUICK GUIDE</u> DOES NOT REPLACE THE FULL DOCUMENT.

#### Artemis II Mattress

The mattress is intended to support a single patient who is up to 267kg in weight and 185cm in height. For those patients of a very low weight, typically less than 40kg and a physical size less than 146cm, clinical judgment is to be used to determine suitability. A lower (or upper) age limit is not defined as it depends on the physical size of the patient in relation to the proportions of the mattress and bed frame.



- Mattress only for profiling beds, it is essential that straps are secured around the movable sections of the bed frame damage will be incurred when profiled if secured to fixed parts of the frame (FIG 1).
- Cushion only Ensure that the cushion is placed securely onto the chair with the pipes to the rear
- To avoid any risk of damage to the mattress/ cushion, ensure there are no sharp objects which may come into contact with it.
- Position the control unit by hanging the hooks over the foot board. If there is no foot board or the cushion is in use, 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 (FIG 2).
- Connect the mattress/cushion to the control unit (FIG 3).
- Plug in and switch on.
- The mattress/cushion will start to inflate. Inflation can take up to 45 mins. Once inflated, ensure the straps attaching the mattress/

cushion to the bed frame/ chair are secure and hold the device in place. Secure sheets loosely enough to ensure they do not interfere with cell alternation.



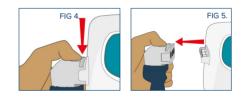
#### **Artemis II Cushion**

The cushion is intended to support a single patient who is up to 115kg in weight. A lower (or upper) age limit is not defined as it depend on the physical size of the patient in relation to the proportions of the cushion and the platform. Clinical judgement is to be used to determine patient suitability.

#### Transport Mode

You can achieve up to 8 hours transport time by carrying out the following procedure:

- Disconnect the umbilical cord from the power unit by pressing down the release button (FIG 4) and pulling away (FIG 5).
- Switch off the control unit.



#### **CPR** - mattress only

- 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 (FIG 7), once done the entire system will rapidly deflate.
- To re-inflate, turn the CPR dial to the closed position (FIG 8).
- Wait for the mattress system to reach optimal pressure prior to a return to normal use.

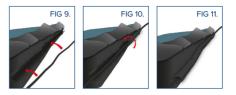


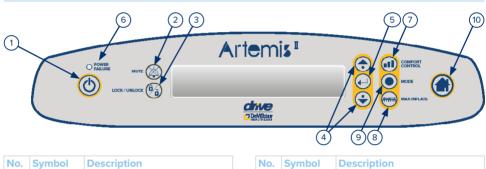


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#### **Mattress Cable Management**

- To reduce a risk of trip hazards, route the mains cable down the length of the mattress using the integral routing sheath. Detach the pop studs from the sheath (FIG 9), insert the cable and reattach all studs down the full length of the sheath (FIG 10 & 11).
- Always ensure cable is unplugged from mains power before moving the bed. It is advised not to wrap the cable tightly but to leave some slack.





No.	Symbol	Description	
1		Turns system on/off	
2		Mutes the audible signal for a 20 minute period	
3	6	Locks/unlocks interface functions	
4	$\odot$	Moves up/down through selected menu	
5	Ð	Selects chosen parameter / Enter button	
6		Illuminates if power is lost.	
7		Opens comfort control menu	
	1. Press	🐽 to open 'Comfort Control' Menu	
	2. Select 1. Comfort Level and press enter to		
	access comfort level screen		
	3. Press	Press 'down' 🕑 to select comfort setting	
	4. Press	'Enter' 🔁 to set	
8		Enters maximum inflation.	

No.	Symbol Description		Description
9	0		Mode select
	Com	fort Mo	de:
	1.		Lo open Option Menu
	2.	Press '	down' 😉 to highlight chosen
		comfor	t mode
	3.	Press '	Enter' 🕀 to set chosen comfort.
	Extended Functions:		
	1.	Press	to open comfort control
	2.	Press '	down' 😌 on page 1/2 or page 2/2
			tient weight is found on page 2/2)
	З.	Press '	Enter' 🔁 to access required
		functio	
	4.	Press '	down' 🕑 to highlight chosen
		setting	
10	6		Returns to 'Home' screen

QUICK REFERENCE GUIDE PART OF INSTRUC/ARTEMIS/2, 2022/03 - rev10

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## **1. INTRODUCTION**

Thank you for purchasing this product. These instructions for use should be read carefully before operating the dynamic system and kept for future reference. Please ensure that you understand all instructions, if you have any questions concerning the operation or maintenance of the support surface please contact your provider / supplier who will provide you with expert professional advice. These instructions for use are intended for medical professional users only and are not intended for lay users/patients.

Drive DeVilbiss Healthcare Ltd. recommend the system is assembled and maintained by Drive DeVilbiss Healthcare Ltd. service engineers or qualified personnel.

## **2. CONTACT INFORMATION**

For assistance in setting up, using, maintaining your dynamic system, to report unexpected operation or for any service, warranty, sales or customer service information regarding this product please contact your provider or if in doubt contact Drive DeVilbiss Healthcare Ltd. at the following address:

Drive DeVilbiss Healthcare Ltd.

Sidhil Business Park,

Holmfield, Halifax,

West Yorkshire,

HX2 9TN,

United Kindom

Service & Maintenance	Spares	Sales
Tel: +44 (0)1422 233136	Tel: +44 (0)1422 233138	Tel: +44 (0) 845 0600 333
Fax: +44 (0)1422 233010	Fax: +44 (0)1422 233010	Fax: +44 (0) 845 0600 334

info@drivedevilbiss.co.uk www.drivedevilbiss.co.uk

Please quote the relevant serial number on all correspondence. There are three individual serial numbers for the following parts: control unit, top cover and base cover. UDI and serial numbers can be found on the back of the control unit and inside the mattress / cushion.

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. If a serious incident occurs in relation to the product, reports should be forwarded to Drive DeVilbiss Healthcare Ltd and the local competent authority.

## **3. PRODUCT DESCRIPTION**

#### **3.1 Environment**

Your dynamic system is intended for use in the following environments:

- A hospital where intensive/acute care is provided and medical supervision is required and monitoring provided.
- A long term care area where medical supervision is required and monitoring is provided if necessary (e.g. nursing homes, rehabilitation facilities, geriatric facilities).

#### 3.2 Intended User Groups

#### 3.2.1 Artemis II Cushion

The cushion is intended to support a single patient who is up to 115kg in weight. A lower (or upper) age limit is not defined as it depend on the physical size of the patient in relation to the proportions of the cushion and the platform. Clinical judgement is to be used to determine patient suitability.

#### 3.2.2 Artemis II Mattress

The mattress is intended to support a single patient who is up to 267kg in weight and 185cm in height. For those patients of a very low weight, typically less than 40kg and a physical size less than 146cm, clinical judgment is to be used to determine suitability. A lower (or upper) age limit is not defined as it depends on the physical size of the patient in relation to the proportions of the mattress and bed frame.

#### 3.3 Intended Use

The intended use of the mattress is to support the weight of the patient, as identified within section 3.2, whilst sleeping or resting and the intended use of the cushion is to support the weight of the patient whilst seated. Both assist the user with pressure redistribution as a part of an overall plan of care.

#### 3.4 Indications

To assist as part of an overall programme of care when active load distribution through mechanical means is required.

#### **3.5 Product Overview**

An air filled support surface is kept inflated by a compressor, housed within a control unit, where they are connected together via an umbilical tube.

The control unit is mains powered and it is expected to be permanently plugged into the mains when in use. Via the control unit the mattress can operate in three different modes:

- Alternating: air cells alternately inflate/deflate.
- Constant low pressure: all air cells inflated but kept at a low pressure.
- Max inflate: all air cells inflated to their maximum extent for 20 mins.

After inflation, the control unit automatically sets the cell pressure to a predetermined value, but the comfort level can be adjusted by manually adjusting the cell pressure up or down. Should a fault occur (such as a power failure or loss of pressure) an audio & visual alert is triggered.

The support surface and control unit are intended to be positioned on compatible support platforms only. Type of use/reuse for the devices is classed as multiple patient multiple uses: Devices can be used multiple times, by multiple patients.

#### 3.6 Features

Artemis II Mattress

- Cell on cell construction
- Bed platform securing straps
- 2 way stretch, vapour permeable and waterproof cover
- High frequency welded top cover
- 360° zip
- Covered feed pipes
- Cable management routing
- Automatic patient egress detection (when function is activated on the control unit)

#### Artemis II Cushion

- 2 way stretch, vapour permeable and waterproof cover
- High frequency welded top cover
- 360° zip
- Covered feed pipes

# 4. SAFETY

#### 4.1 Warnings and Cautions



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



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

Control Unit

- Provides an air supply to the mattress or cushion
- Rear bed hooks
- Accessible rear filter
- Automatically determines patient weight
- Automatically sets optimum pressure for patient
- Alternating, constant low pressure, pulsation and max inflate functions.
- Customisable functions
- Adjustable comfort control
- Lock out function
- Fault indicators with visual and audible alerts
- Touch panel with integrated visual display

#### 4.2 Risk Assessment

Support platforms used with the mattress or cushion 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 suitable product compatibility and the safety of the patient.

Before a patient uses the dynamic 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.
- Compatibility of the patient to the mattress size.
- Patient with burns.
- Unauthorised people with access to the controls.
- Patients who have reduced capacity and are agitated and/or restless.
- Small adults/children.

#### 4.3 Contraindications

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

- Cervical or skeletal traction, mattress only.
- Unstable skeletal fractures, mattress only.
- Unstable spinal injury, mattress only.
- Exceeds maximum patient weight of the support surface.
- Gross Oedema (when using alternating mode only)

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

#### 4.4 System Loads

Mattress maximum patient weights: ARTEMIS II - 267kg (42 stone)

Cushion maximum patient weight: ARTEMIS/2/CUSH/18 and /20 - 115kg (18 stone)

#### 4.5 Training

If these instructions for use are not deemed sufficient and the need for training is required please contact your distributer who will be able to define the intention and outcomes of any necessary training, who should attend, its duration and any potential costs involved.

#### 4.6 Patient Briefing

The professional user is to ensure the patient is sufficiently briefed in regards to the performance of the system, actions to take in the event of a change in its performance, safe use of the support surface and environmental considerations that may need to be taken.

#### 4.7 Fire Warning

In order to reduce the risk of fire:

- DO NOT SMOKE Smoking will contaminate the product and is NOT permitted around or on the support surface. This is a common cause of fatal fires. A cigarette could burn a hole in the support surface and cause damage. Patient clothing, bed sheets and other items, may be combustible and could catch fire. Failure to observe this warning could result in a severe fire, property damage, physical injury or death.
- DO NOT use candles on or around the system.
- DO keep hot equipment off and away from the system, e.g. hair dryer, curling tong, etc.
- DO keep heaters away from the support surface.
- Follow all manufacturers' instructions and warnings.
- It is advised that a full fire risk assessment is carried out prior to using this equipment.
- In case of fire, exit and call the emergency services.
- The use of other materials in combination with the mattress can degrade the fire performance.

#### 4.8 Biocides

Support surface covers contain a anti-fungal agent to control microbial deterioration. The active ingredient is 3-iodo 2-propynyl butylcarbamate. The active ingredient is fully encapsulated within the polymer coating. There are no special handling requirements.

This product doesn't contain Nano-materials and all components are latex free.

#### 4.9 General Warnings



The system is to be installed and put into service in accordance with the information provided in these instructions for use. The Artemis II mattress and cushions are 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 support surface.

- 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 support surface or control box is not allowed without the permission of Drive DeVilbiss Healthcare Ltd. – A hazard could be introduced.
- Occupants and users of this equipment must never smoke in close proximity to the control unit, mattress, cushion or bedding being used with it Risk of fire.
- 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 who lack capacity 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 mattresses and cushions are for single occupancy use. Additional weight could damage the support surface or affect the performance of the system.
- Minimise articles (e.g. bedding) between the support 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.
- External sources of heat and cold, (e.g. sunlight or air conditioning units) can impact the surface temperature of the support surface and/or control unit, ensure the system is appropriately positioned such that surface temperature is not adversely affected.
- Incompatible support platforms (e.g. a bed frame or chair) can create stability hazards.
- Misused electrical equipment can be hazardous.



## **5. TRANSPORT AND STORAGE**

#### 5.1 Storage

- Detach the control unit from the support surface.
- Release CPR or rotate the CPR dial until it is open.
- To deflate the cushion for storage, see sectiojn 9.6.
- Lay the mattress or cushion out flat and position upside down.
- Ensure there is no air trapped in the cells.
- Position the control unit on the mattress or cushion.
- All products can be rolled 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.



- To prevent the risk of cross infection, when removing the system from an end user's residence ensure that all activities in relation to the system are carried out using disposable gloves and that they are then discarded appropriately, unless it can be verified that the cushion, mattress and control unit have been suitably cleaned and disinfected prior to collection.
- On the return of the system from an end users residence, prior to putting into storage ensure it has been cleaned and disinfected in line with the local infection control policy and / or as defined in section 10 of these instructions for use.
- Do not remove the mattress/cushion from the support surface if the patient is still on it Risk of falling.
- If it is essential that the patient is moved whilst remaining on the mattress/cushion, ensure the system is immediately plugged back in to the mains power supply once relocated -Risk of tissue damage.



Do not store whilst inflated - damage could be incurred. Do not store objects such as side rails on top of the mattress or cushion - damage could be incurred.

## 5.2 Transportation

Where possible, it is recommended the transport of mattresses should be carried out on a flat based trolley or mattress trolley. Do not drag or pull the mattress by its cover. Please follow local moving and handling policies and guidelines when handling a mattress. It is recommended that two people manoeuvre the mattress.

## **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% max, non-condensing

# 6. SYMBOL DEFINITION

The following symbols are found on the control unit and support surface:

(See section 9.3 for interface symbols)



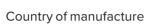
Warning Beware of potential hazard



Refer to instructions for use -Mandatorv

Failure to read the instructions for use could introduce a hazard.







Foot end



Do not iron



Tumble dry on low heat



Zip location



Conforms to the Medical E Devices Regulation 2017/745





Serial Number



Class II Electrical Device The user is protected by at least two layers of insulation between the current carrying parts and the metal accessible parts



No Smoking



Temperature limit

Mattress

Humidity Limit







Beware of potential product damage



Manufacturer

Caution

Machine wash at 71°C for no less than 3 minutes or 65°C for no less than 10 minutes. For full details see section 10.3.

Do not dry clean



Drip dry

Do not bleach



Keep out of direct sunlight



Medical device





Product Reference







European Union Authorized Representative



EU Importer

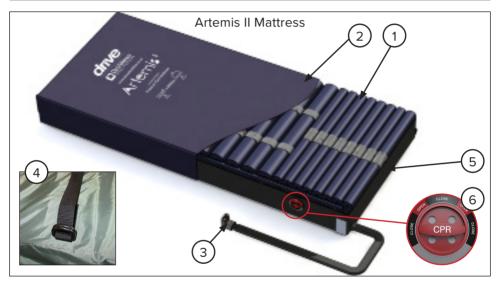


#### Type BF applied part

<u>Applied Part</u>: The parts of the device that come into contact with the patient in order to carry out its intended function (refer to section 16.2).

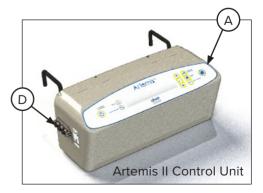
<u>Type BF</u>: Applied parts which are electrically isolated from earth and other parts of the medical equipment - Complying with specific requirements for protection against electric shock to IEC 60601-1.

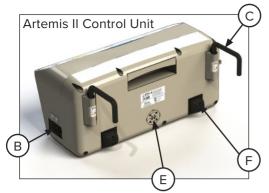
# 7. PARTS IDENTIFICATION



#### Artemis II Mattress:

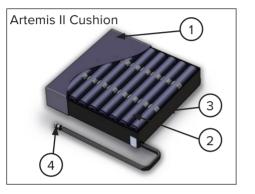
No.	Item Description	Qty.
1	Air Cell	23
2	Top Cover	1
3	Female Air Connector	1
4	Mattress Strap	8
5	Base Cover	1
6	CPR Dial	1





Artemis II Control Unit (continued):

No.	Item Description	Qty.
А	Control Interface	1
В	Mains Cable Port	1
С	Hook	2
D	Air Connector	1
E	Air Filter	1
F	Pad	1



Artemis	Ш	Cushion:

No.	Item Description	Qty.
1	Top Cover	1
2	Air Cell	9/10
3	Base Cover	1
4	Cushion Air Connector	1

## 8. INSTALLATION

When specifying a support surface, chair, bed frame and side rail combination, a clinical assessment of the patient's needs must be carried out in line with local policy.



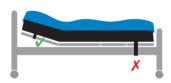
Refer to the warnings at the end of this section before proceeding with installation.

• Ensure the mains supply is compatible with the control unit (see section 13 for electrical specification).



If the system has come from a storage / transport temperature environment near to the minimum or maximum values stated allow the cushion/mattress and control unit to adjust to room temperature for a minimum of 2 hours prior to plugging into the mains supply - Risk of electrical system damage if operated outside of the recommended temperatures.

- Open all packaging with care.
- Ensure the mattress and control unit are free from dirt, dust and moisture upon arrival.
- Once removed from the packaging check the product for any signs of damage. If damaged do not put into use and contact your provider or Drive DeVilbiss Healthcare Ltd. (See Section 2).
- Remove all covers, sheets and the existing mattress/cushion from the bed/chair.
- 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.
- If using a cushion, position the cushion onto a fixed chair which has a padded seat, with the top cover facing upwards and air hose at a rear corner of the seat for control unit positioning.
- If using the mattress attach to the bed frame by securing the adjustable straps to the moving sections of the bed.
- If using the cushion, loosely secure the cushion to the chair frame by using the attached securing straps.
- For profiling beds, it is essential that the straps are secured around the movable sections of the bed frame – Damage will be incurred when profiled if secured to fixed parts of the 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, closed position.

CPR Closed:

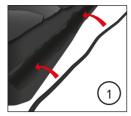


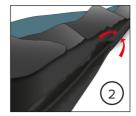
 Position the control unit by hanging the hooks over the foot board. If there is no foot board place the unit on the floor with the front facing upwards. Ensure the rear of the unit is not obstructed by carpet, rugs etc. It is advisable to place the unit on a firm surface.



- Attach the male air connector to the control unit, ensuring the air hose does not kink or become trapped between parts of the bed frame.
- 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. See steps 1 to 3 below.





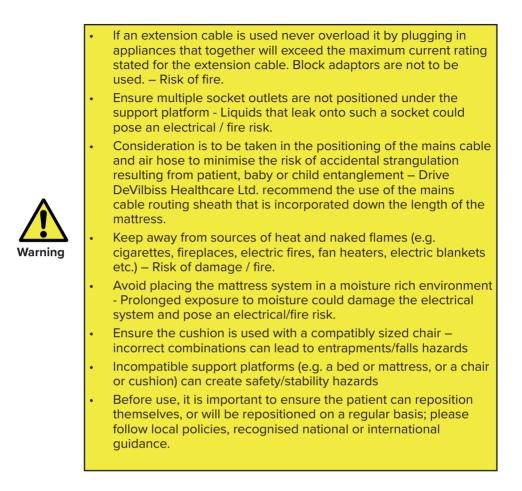




- Plug the mains cable into a suitable mains supply and switch on the control unit (see section 9).
- The support surface will start to inflate. Inflation will can take upto 45 mins product dependent. Once inflated, ensure the straps that attach the mattress to the bed frame are secure and hold the mattress 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.
  - After assembly of the device there should be no loose parts remaining, however consideration is to be taken in the event of spare components and small packaging parts (cable ties, plug pin protector) being evident to minimise the risk of them being swallowed by the occupant or any other person; this could pose a choking hazard.
  - 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 support surface 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.
  - Do not route the mains cable through/around mechanical bed assemblies, or in a position that may cause a trip hazard and/or damage to the cable.
  - Ensure the mains cable is not in tension, paying particular attention to when the bed/chair travels up/down.
  - Precautions are to be taken when routing the mains cable around the bed or chair to ensure that it does not become squeezed, trapped or damaged by the bed frame or other ancillary equipment Risk of electrocution.
  - Do not place any objects or items, such as blankets, on or over the control unit Risk of fire.
  - 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 Drive DeVilbiss Healthcare Ltd. for detail in regards to safe use of extension cables.





## 9. OPERATION

#### 9.1 Environmental Limits when in Operation

The following conditions should be followed when operating the system:

- Ambient temperature: +5°C to +40°C.
- Humidity:

15-93%, non-condensing.

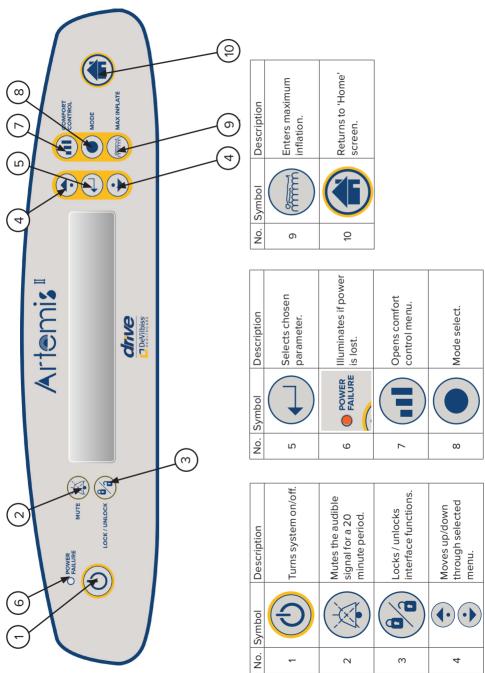
Atmospheric pressure: 700 hPa to 1060 hPa

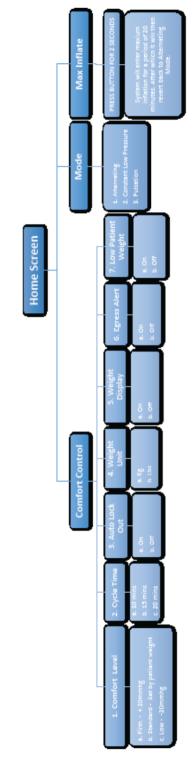
## 9.2 Preparing for Use

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

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

17





Starting from the home screen and using the control interface the flow chart below shows how to navigate around the Artemis II menu functions.

Notes:

- Shaded menus will automatically take the user back to the previous menu/home screen once a selection has been made.
- After 10 secs of inactivity whilst in a menu, the system should automatically revert back to the home screen.

#### 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 10mmHg and 70mmHg, dependent on the function chosen.

The heel section has narrower and lower cells.

#### 9.5 Control Unit Operation

#### 9.5.1 Turning On / Off

Hold the power button down until an audible signal sounds, the button will illuminate green and the screen will turn on.



The system will be ready for use after an initial inflation period of upto 45 minutes. 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 45 minutes (see section 11).

To turn the system off hold the button down for 2 seconds 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 5 minutes. Once weight detection is complete the mattress automatically defaults to alternating mode.

#### 9.5.2.1 Alternating

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 = 34 mmHg and B = 33 mmHg



#### 9.5.2.2 Patient Weight and Pressure

When the system detects a patient it calculates the optimum pressure level for the patient. The process is repeated 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 quidance indicator is accurate to  $\pm 2$  display segments.



Please note, a number of factors can affect the weight detection, these may include, but are not limited to:

- Patient placement upon the support surface
- Patient weight distribution across the support surface
- · Patients who are particularly higher in weight
- Movement of patient during the detection period



The weight indicator is not to be used for medical purposes or as a measurement function, it is to act as information only. If the inclusion of the weight indicator could introduce a hazard it can be hidden, see 9.5.4.8. Clinical judgement is to be used to determine the suitability of the mattress to the patient, the pressure provided and patient support, via the use of a risk assessment. See also section 4.2.

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 providing suitable support. Clinical judgement should be used to ensure the mattress system is suitable for the patient.

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 3 seconds. To reengage the lock the button can be pressed for 1 second or the user can wait for the automatic lock to re-engage. To lock out all functions except mute, press the power button and the lock/unlock during the weight detection.

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 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 20 minutes and the audible signal will re-sound.

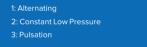


When silencing the 'power failure' indicator the audible signal will not reactivate after 20 minutes and all lights will extinguish – There will be no indication that the system is powered down. Ensure power is returned to the system as soon as possible to resume pressure relief.

#### 9.5.4 System Functions

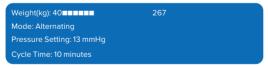
#### 9.5.4.1 Mode Selection

When pressed a menu appears offering 3 different settings:



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

1) <u>Alternating</u>: Operates an 'AB' cycle where alternate cells deflate and inflate over a defined time period (see section 9.5.4.5).



2) <u>Constant low pressure</u>: Patients should always be nursed on the mattress in alternating mode but the CLP mode maybe selected for short intervals if a patient is finding it difficult to tolerate the alternating mode. (This could occur if, for example, the patient feels discomfort, nauseated or perhaps having difficulty getting to sleep).

When CLP is selected all cells inflate at the pressure to which the control unit is set, thereby offering a non-moving surface.

The control unit will not return to alternating mode unless manually selected by the user.



CLP mode will not automatically default back to alternating mode. Alternating mode must be reselected manually by the user.

3) <u>Pulsation:</u> Increases and decreases the cell pressure of the constant low pressure mode by 30% in each direction.

When using the pulsation setting, to return to alternating it is necessary to manually re-select alternating from the comfort menu, it will not automatically default back.



#### 9.5.4.2 Max inflate

Inflates the cells to maximum pressure to provide a stable, static support surface. The system will automatically revert back to alternation mode after 20 minutes for patient safety.

#### 9.5.4.3 Comfort Control

Before changing the pressure or cycle time, clinical judgement is required from frequent monitoring and repositioning of the patient.

#### 9.5.4.4 Comfort Level

When pressed a comfort level control menu appears:



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 =	+ 20% mmHg
Medium =	Automated Pressure Setting
Soft =	– 20% mmHg

#### 9.5.4.5 Cycle Time

When pressed a menu appears offering 3 different settings:



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.

#### 9.5.4.6 Auto Lock

When pressed a menu appears offering 2 different settings:



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.



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

## 9.5.4.7 Weight Unit

When pressed a menu appears offering 2 different settings:



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

#### 9.5.4.8 Weight Display

When pressed a menu appears offering 2 different settings:



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

#### 9.5.4.9 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.

#### 9.5.4.10 Low Patient Weight

If clinical judgement and a risk assessment deems that a patient of low weight (typically <40kg) is suitable to use the mattress, 'Low Patient Weight' can be activated.

'Low Patient Weight' reduces internal cell pressures further for patients of low weight.

7: Low Patient Weight	a: on b: off
	0.01

Weight(kg): 40	250
Mode: Alternating	(06,11)
Pressure Setting: 13 mmHg *Low	/ Wt
Cycle Time: 10 minutes	

To deactivate, the control unit needs to be switched off and back on again. While low patient weight is selected frequent monitoring and repositioning is advised.

#### 9.5.4.11 Service Timer

The audio visual signal activates after 365 days (8,760 hours), please contact your service engineer.

\*\*\*\*Service Due\*\*\*\* Service due, contact maintenance provider as soon as possible.

#### 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 25° the screen on the control interface advises that the backrest has been raised. The pressure then increases by 10% until it is lowered when it will then automatically revert to normal pressure.

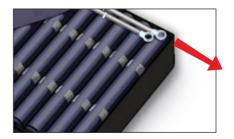
Weight(kg): 40 Mode: Auto-Seat Pressure Setting: 16 mmHg Cycle Time: 10 minutes

## 9.6.2 Cushion Mode

The seat cushion can be operated with the Artemis II pump, the system will be automatically recognised once connected.

Rapid deflation of the cushion can be achieved by removing the cushion top cover, and disconnecting 1 or more of the cell quick release valves. To re-inflate the cushion, reconnect the quick release valves to the cells, and wait for the cushion to reach optimal pressure prior to a return to normal use. Cushion Mode: Alternating Pressure Setting: 60 mmHg Cycle Time: 10 minutes

(59,60)



## 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:



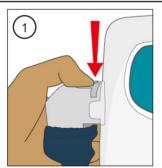


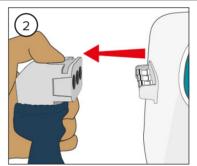
To allow the system to inflate correctly and effectively, it may be necessary to restart the control unit by switching off and then on, and allowing the mattress to re-calibrate without the patient on the mattress

## 9.8 Support Surface Disconnection and Power Cuts

If the support surface is to be disconnected from the power supply for an extended period of time and the support surface 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).





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

Note, on the mattress 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.



- 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.

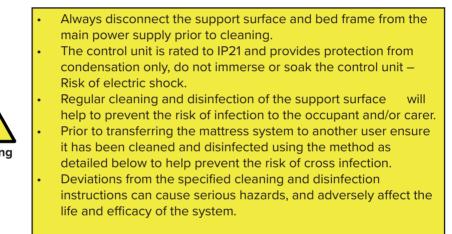
## 9.9 Use of Incontinence Products

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.





- 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.

## 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 and Cushion

Before attempting to clean 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.



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



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 down with cold clean water using a clean cloth.
- Dry off with paper towels Always ensure the cleaned surfaces are allowed to fully dry before putting back into use.

#### **10.3** Alternative Cover Cleaning Instructions

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

- Remove 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 HTM 01-04 for further details).

## 11. TROUBLESHOOTING



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

Symptoms	Indications	Actions
Power Failure	<ul> <li>Amber 'power failure' light flashes.</li> <li>Audible signal sounds.</li> <li>Screen extinguishes.</li> </ul>	<ol> <li>If mains plug, cable or outer casing is visibly damaged turn off at the mains and contact your approved service engineer.</li> <li>Turn off the control unit to silence the alert and turn off the mains supply (Note, the mute button does not silence the power failure indication).</li> <li>Check the mains cable is fully connected to the control unit and plugged into a wall socket.</li> <li>Switch on at the wall (to ensure the socket is working, plug in a fused device that is known to work).</li> <li>Turn on the control unit.</li> <li>If control unit still fails to operate turn off at the mains and contact your approved service provider.</li> </ol>
Service Due	<ul> <li>Audible signal sounds.</li> <li>Screen shows:</li> <li>Service Due ***</li> <li>Service due, contact maintenance provider as soon as possible.</li> </ul>	Service due alert will present itself after 8760hours of service when the control unit is turned on. The alert will disperse and the system can be used as normal. To reset the service due alert, contact your service provider to arrange the necessary service & maintenance to be performed.

Incomplete inflation / Low pressure	Audible signal sounds.     Screen shows:     ""LOW PRESSURE ""     Please check system including CPR. To restart Artemis II press Power off/on.	<ol> <li>Ensure the mattress air connector is correctly connected to the control unit.</li> <li>Ensure the CPR dial is closed and there is no air leakage.</li> <li>Turn the unit off and then on again to clear the indicator.</li> <li>If a 'low pressure' indicator continues to illuminate:</li> <li>Open the mattress and ensure there is no air leakage within the mattress – cells, tubing and connectors.</li> <li>Turn the unit off and then on again to clear the indicator.</li> <li>If a low pressure indicator is still evident turn off at the mains and contact your approved service provider.</li> </ol>
High Pressure	<ul> <li>Audible signal sounds.</li> <li>Screen shows:</li> <li></li></ul>	<ol> <li>Ensure the mattress umbilical is not trapped or being squeezed.</li> <li>Open the mattress and ensure none of the air pipes are kinked.</li> <li>Turn the unit off and then on again to clear the indicator.</li> <li>If a high pressure indicator is still evident turn off at the mains and contact your approved service provider.</li> </ol>
Mattress Disconnection	Audible signal sounds.     Screen shows:     "" SYSTEM FAILURE ""     Please check system     including CPR. To restart Artemis II press     Power off/on.	<ol> <li>Ensure the mattress air connector is correctly connected to the control unit.</li> <li>Turn the unit off and then on again to clear the indicator.</li> <li>If the indicator is still evident turn off at the mains and contact your approved service provider.</li> </ol>
Patient is bottoming out		<ol> <li>Ensure the patient is suited to the maximum rating of the mattress.</li> <li>Ensure the patient is centrally positioned on the mattress.</li> <li>Increase the pressure setting – Refer to section 9.5.4.2</li> </ol>
Egress Alert	<ul> <li>Audible signal sounds.</li> </ul>	<ol> <li>Ensure the patient is centrally positioned on the mattress.</li> <li>Turn the unit off and then on again to clear the indicator.</li> </ol>

## 12. MAINTENANCE

- 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 dynamic 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 Drive DeVilbiss Healthcare Ltd. approved components specified for the Artemis dynamic system are to be used - if in doubt contact Drive DeVilbiss Healthcare Ltd. or your local distributor.

Only authorised service personnel or Drive DeVilbiss Healthcare Ltd. 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.** Drive DeVilbiss Healthcare Ltd. 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.

Drive DeVilbiss Healthcare 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 fluid ingress/staining 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. The power supply cord is non-detachable, if either is damaged it must be replaced with a complete assembly by authorised service personnel, the plug must never be re-wired.
- Check that all markings are legible and in sufficiently good condition if not replace parts and / or adhesive labels as required.
- Check the system automatically selects pressure after inflation.
- Check the zip for any signs of damage, and ensure it is fully closed.
- Check between air cells for signs of fluid ingress.
- Ensure the screen print is in a good condition and readable.



When servicing or repairing a system, ensure that all activities are carried out using disposable gloves and any other personal protective equipment deemed necessary.

For more detailed service information, spare parts, circuit diagrams etc. please refer to the service manual. Copies are available from Drive DeVilbiss Healthcare 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 Drive DeVilbiss Healthcare Ltd. to arrange for collection, alternatively follow local recycling and disposal policies.

The control unit used with your system is not to be disposed of in general municipal waste as it is to be considered as Waste Electrical and Electronic Equipment (WEEE). Some of the electrical components could be harmful to the environment and where viable the components and materials can be recovered and recycled. The control unit is to be disposed of following local WEEE policy or using an approved WEEE recycling service.

The mattress or cushion is unable to be recycled and as such this is to be disposed of in general municipal waste.

The cardboard packaging that the mattress system was originally supplied in is widely recyclable and is to be disposed of following local card recycling policy.

The polythene bag that the mattress was supplied in is recommended to be retained as this can be used to store the mattress in when it is not in use.



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

#### **ARTEMIS II MATTRESS SPECIFICATION** 13.1

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Mattress
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50Hz, 25W
Fuse Rating:	Mains Plug – 10A
Mains plug:	Type G/BS1363
Battery Type:	NiMH (Nickel Metal Hydride)
Mattress Dimensions:	(L) 2000mm x (W) 880mm x (D) 200mm
Mattress Weight:	11kg
Maximum Patient Weight:	267kg (42 stone)
No. of Cells:	23 cells which include:
	3 static head cells
	20 alternating cells (inc. 8 narrow heel cells)
Alternating Mode:	AB pattern
Cycle Time:	10, 15 or 20 minutes
Pressure Range:	Alternating Mode: 13 – 70 ±2mmHg
	Constant Low Pressure Mode: 10 $-$ 40 $\pm$ 2mmHg
	Pulsation Mode: +30% & -30% of CLP setting
	Max Inflate: 70 ±2mmHg
Control Unit Dimensions:	(L) 180mm x (W) 390mm x (D) 165mm
Control Unit Weight:	4.1 kg
Cover Material:	Dartex®
Cell Material:	TPU
Base Material:	Nylon/PU
Transport and Storage Conditions:	Ambient Temp: -25°C to +70°C
	Llumiditur < 0.20/ non condensing
	Humidity: < 93%. non-condensing
Operational Conditions:	Humidity: < 93%, non-condensing Ambient Temp: +5°C to +40°C
Operational Conditions:	Ambient Temp: +5°C to +40°C
Operational Conditions: Atmospheric Pressure:	
Atmospheric Pressure:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing
	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m
Atmospheric Pressure: Operating Altitude:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m Degree 2
Atmospheric Pressure: Operating Altitude: Pollution:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m
Atmospheric Pressure: Operating Altitude: Pollution: UV:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m Degree 2 Intended for indoor use only
Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level:	Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m Degree 2 Intended for indoor use only 60.3dB(A)
Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level:	Ambient Temp: $+5^{\circ}$ C to $+40^{\circ}$ C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa $\leq$ 2000m Degree 2 Intended for indoor use only 60.3dB(A) IEC/EN 60601-1
Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level: Safety Standards:	Ambient Temp: $+5^{\circ}$ C to $+40^{\circ}$ C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa $\leq$ 2000m Degree 2 Intended for indoor use only 60.3dB(A) IEC/EN 60601-1 IEC/EN 60601-1-11
Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level: Safety Standards:	Ambient Temp: $+5^{\circ}$ C to $+40^{\circ}$ C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa $\leq$ 2000m Degree 2 Intended for indoor use only 60.3dB(A) IEC/EN 60601-1 IEC/EN 60601-1-11 IEC/EN 60601-1-2

# 13.2 ARTEMIS II CUSHION SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Cushion
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50Hz, 25W
Fuse Rating:	Mains Plug – 10A
Mains plug:	Type G/BS1363
Battery Type:	NiMH (Nickel Metal Hydride)
Cushion Dimensions:	CUSH/18 = (L) 458mm x (W) 458mm x (D) 60mm CUSH/20 = (L) 508mm x (W) 508mm x (D) 60mm
Cushion Weight:	1kg
Maximum Patient Weight:	115kg (18 stone)
No. of Cells:	CUSH/18 = 9 cells
	CUSH/20 = 10 cells
	alternating cells.
Alternating Mode:	AB pattern
Cycle Time:	10, 15 or 20 minutes
Pressure Range:	Alternating Mode: 40 – 90 ±2mmHg
	Constant Low Pressure Mode: 10 – 40 ±2mmHg Pulsation Mode: +30% & -30% of CLP setting
	Max Inflate: 90 ±2mmHg
Control Unit Dimensions:	(L) 180mm x (W) 390mm x (D) 165mm
Control Unit Weight:	4.1 kg
Cover Material:	Dartex®
Cell Material:	TPU
Base Material:	Nylon/PU
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:	60.3dB(A)
Safety Standards:	IEC/EN 60601-1
	IEC/EN 60601-1-11
	IEC/EN 60601-1-2
	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	3 Years**
	35

\*Not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide (Not AP or APG equipment)

\*\*If the system and its components are serviced and maintained in accordance with the information detailed in section 12 of these instructions for use then the system can be expected to provide in excess of the 3 years of service.

\*\*\* IP21 = water ingress protection from condensation only.

## 14. ELECTROMAGNETIC COMPATIBILITY (EMC)

The control unit has been designed to meet the EMC requirements of EN 60601-12 however it may still be affected by or emit harmful radio frequency (RF) energy. The RF emissions from the 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.

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.

The dynamic system is to be installed and put into service according to the information provided within this section to ensure of reliable operation, however if the control unit continues to operate abnormally turn off at the mains supply and contact Drive DeVilbiss Healthcare Ltd. or your local distributor (see section 2).

 Portable RF communications equipment (e.g. mobile/cordless phones) should be used no closer than 30 cm (12") to the control unit or its mains cable, otherwise degradation of the performance of this equipment could result.



- Use of accessories other than those specified or provided by Drive DeVilbiss Healthcare could result in increased electromagnetic emissions or decreased electromagnetic immunity of the control unit and result in improper operation.
- The control unit should not be used adjacent to or stacked with other equipment where possible, if adjacent or stacked use is necessary the control unit should be observed to verify normal operation in the configuration in which it is to be used.

#### 14.1 Emissions & Immunity Compliance

The system is to be installed and put into service according to the information provided within this section to ensure of reliable operation, however if the control unit continues to operate abnormally turn off at the mains supply and contact Drive DeVilbiss Healthcare Ltd. or your local distributor.

Emission test	Compliance
RF emission CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact
IEC 61000-4-2	±15 kV air	±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines
Surge	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)
IEC 61000-4-5	$\pm$ 2 kV line(s) to earth	$\pm$ 2 kV line(s) to earth
Voltage dips, short interruptions	Voltage dips:	Voltage dips:
and voltage variations on power	0 % UT; 0,5 cycle	0 % UT; 0,5 cycle
supply input lines	0 % UT; 1 cycle	0 % UT; 1 cycle
IEC 61000-4-11	70 % UT; 25/30 cycles	70 % UT; 25/30 cycles
	Voltage interruptions:	Voltage interruptions:
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m
Conducted RF	3 Vrms:	3 Vrms:
IEC 61000- 4-6	0,15 MHz – 80 MHz	0,15 MHz – 80 MHz
IEC 01000- 4-0		
	6 Vrms <sup>.</sup>	6 Vrms <sup>.</sup>
	in ISM and amateur radio bands	in ISM and amateur radio
	between 0,15 MHz and 80 MHz	bands between 0,15 MHz and 80 MHz
	80 % AM at 1 kHz	
		80 % AM at 1 kHz
Radiated RF	10 V/m	10 V/m
IEC 61000- 4-3	80 MHz – 2,7 GHz	80 MHz – 2,7 GHz
	80 % AM at 1 kHz	80 % AM at 1 kHz

NOTE  $U_{\tau}$  is the a.c. mains voltage prior to application of the test level.

# 15. COMPATIBILITY & ACCESSORIES

Refer to Drive DeVilbiss Healthcare Ltd. bed instructions for use to ascertain suitable mattress compatibility.

The Artemis II control unit is suitable for use with:

- Artemis II Dynamic Mattress (sold as system only) DYN/DIG/ARTEMIS/2
- Artemis II Dynamic Cushions ARTEMIS/2/CUSH/18 and ARTEMIS/2/CUSH/20



Incompatible support platforms (eg. a bed frame) can create safety hazards.

#### 15.1 Artemis II Cushions

The Artemis II 18" and 20" cushions are intended for chairs which have a platform of approximately 18" x 18", or 20" x 20" respectively.

#### 15.2 Artemis II Mattress

The Artemis II mattress is intended for use with medical bed frames which have a platform of approximately 2000mm x 900mm and with suitable mattress retention.

The following Drive DeVilbiss Healthcare Ltd. bed frames are known to have mattress support platforms compatible with the Artemis II dynamic mattress. Refer to individual bed instructions for use for side rail compatibility.

Bed Frame	Mattress Support platform	
	Width	Length
INNOV8/LOW Range	900mm	2000mm
INNOV8/IQ Range	880mm	2000mm
BRADSHAW Range*	905mm	1990mm
CASA ELITE Range	907mm	2002mm
Alphalite Range	905mm	2010mm
Solite Pro Range	905mm	2010mm

\*BRAD/STD/COLOUR & BRAD/LOW/COLOUR Only. This excludes bariatric or junior bed variants.

Drive DeVilbiss Healthcare bedframes reference suitable mattress compatibility in their instructions for use along with side rail compatibility. These instructions are to be consulted prior to using a mattress with a specific bed and side rail combination. Alternatively contact Drive DeVilbiss Healthcare or the local distributor for compatibility advise. If in doubt always seek advice.

## 16. WARRANTY

Drive DeVilbiss Healthcare Ltd. warrants that this product will perform in accordance with its specification and will remain free from defects in material and workmanship when used under normal conditions for a period of 2 years (full parts and labour) from the date of purchase from Drive DeVilbiss Healthcare Ltd. and its subsidiary companies. If purchased from an authorised dealer or international distributor, the product is warranted for 2 year parts only. Drive DeVilbiss Healthcare LTD. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, AND ALL IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED. IN NO EVENT WILL Drive DeVilbiss Healthcare LTD. BE LIABLE FOR PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, OR FOR AN AMOUNT IN EXCESS OF THE PURCHASE PRICE OF THE DEFECTIVE Drive DeVilbiss Healthcare LTD. PRODUCT OR PRODUCTS.

Proof of purchase must be presented with any claim. Except as provided herein, this warranty will not apply to any Drive DeVilbiss Healthcare Ltd. products that have been (a) damaged by lightning, water, or power surges, (b) neglected, altered, abused, or used for a purpose other than the purpose for which they were designed, (c) repaired by you or any other party without Drive DeVilbiss Healthcare Ltd. prior written authorisation, (d) used in conjunction with a third party product or products not approved in advance by Drive DeVilbiss Healthcare Ltd., (e) damaged or failed by or attributes to acts of God, (f) damaged, caused by failure to follow instructions, or (g) otherwise used in a manner inconsistent with any instructions provided by Drive DeVilbiss Healthcare Ltd. The warranty explicitly exempts consumable items.

This warranty contains the entire agreement between you and Drive DeVilbiss Healthcare Ltd. with respect to any warranty matters, and supersedes any and all other written or oral statements, representations or agreements relating to the subject matter of this warranty.

In the event of a product defect during the warranty period you should contact your supplier, whether it be Drive DeVilbiss Healthcare Ltd., its subsidiary companies, authorised dealers or international distributors who will at their option unless otherwise provided by law; a) correct the defect by product repair within the terms of the warranty 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 a refund is made become the property of Drive DeVilbiss Healthcare Ltd. 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 limited 2 year warranty gives you specific legal rights and you may also have other rights.

Drive DeVilbiss Healthcare Ltd. has a policy of continual product improvement and reserves the right to amend specifications covered in this document.

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