drive

DeVilbiss HEALTHCARE

Theia

Dynamic System

Instructions for use

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

Overlay Mattress	Air on Foam Mattress	Dynamic Cushion
The mattress is intended to support a single patient who is up to 180kg 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.	The mattress is intended to support a single patient who is up to 180kg 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.	The cushion is intended to support a single patient who is up to 120kg 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.

Weight Range Settings (1 to 8)

Product	1	2	3	4	5	6	7	8
OVERLAY (OVERLAY/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	140 kg	160 kg	180 kg
AIR ON FOAM (FULL/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	140 kg	160 kg	180 kg
18" CUSHION (DYN/CUSH/18)	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	100 kg	120 kg
AIR ON AIR (AIR/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	150 kg	170 kg	200 kg

The settings shown above are to act as a guide only, before changing the control a clinical judgement is required from frequent monitoring and repositioning of the patient.

- 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: It is the responsibility of the carer to ensure the chair is suitable for product compatibility and the safety of the patient. Position the cushion with the pipes at the rear of the chair
- 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).
- The mattress /cushion will start to inflate. Inflation can take up to 40mins. Please select the max weight range setting upon initial set up to ensure full inflation. Once inflated, ensure the straps attaching the mattress to the bed frame are secure and hold the mattress in place. Secure sheets loosely enough to ensure they do not interfere with cell alternation.
- Connect the mattress/cushion to the control unit (FIG 5) ensuring the feed pipes do not kink or become trapped between bed/chair parts.
- Switch pump on by the ON/OFF switch (FIG 3).
- Mattresses - ensure that the CPR tag is fully engaged within the mattress and all connectors are lined up correctly (FIG 4).

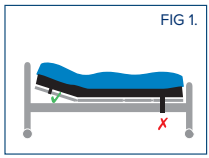


FIG 1.

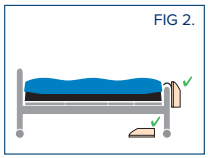


FIG 2.

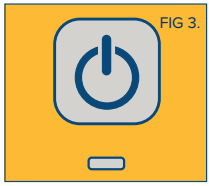


FIG 3.

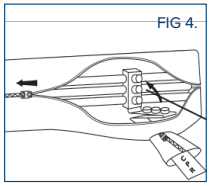


FIG 4.

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

Transport Mode

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

- Disconnect the umbilical cord from the power unit by squeezing the two tabs and pulling away (FIG 5).
- Seal using the cap marked 'Transport' (FIG 6).
- Switch off the control unit.

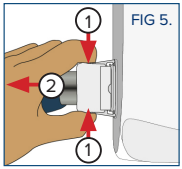


FIG 5.

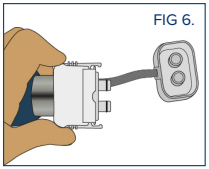
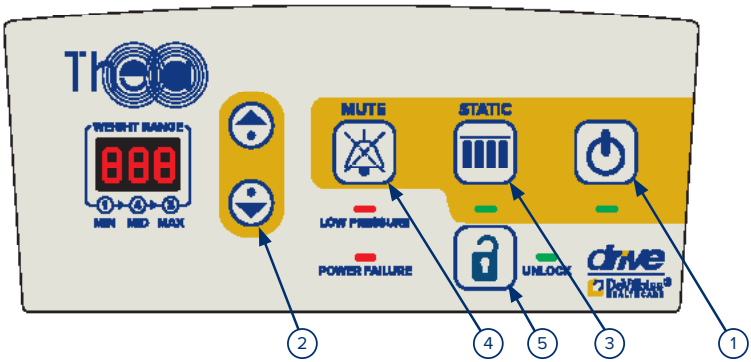
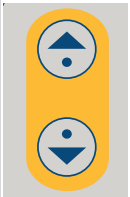


FIG 6.

CPR - mattress only

- Rapid deflation of the mattress may be required for emergency treatment or system deflation. The CPR pull tag is located at the foot end of the mattress.
- Pull the CPR tag to disengage from the mattress, once done the entire system will rapidly deflate.
- To re-inflate, re attach the CPR tag (FIG 4).
- Wait for the mattress system to reach optimal pressure prior to a return to normal use.



No.	Symbol	Description
1		**Power Button:** Press to turn system ON/OFF, green light will indicate pump is ON.
2		**Comfort Control:** Press the UP arrow to increase pressure and the DOWN arrow to decrease pressure, comfort setting shown in the digital display. It's recommended to adjust comfort control to the max when inflating, before adjusting the pressure to the patient's needs. Before changing the comfort control a clinical judgement is required.

No.	Symbol	Description
3		**Static Mode:** Press to set the air within the support surface to stay static, green light will indicate static mode is selected. The system will revert back to alternating mode after 20 mins.
4		**Mute :** The audible alert will sound when the pressure within the system is low or a power failure is detected. To mute, press the mute button and to reactivate the alert re-press the mute button.
5		**Unlock:** The THEIA/2 control unit will automatically lockout all functionality 5 mins after a function change. To unlock the control unit the 'un-lock' button is pressed for 3 seconds.

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1. INTRODUCTION

Thank you for purchasing this product. These instructions for use should be read carefully before operating the system. Please ensure that you understand all instructions, if you have any questions concerning the operation or maintenance of the system please contact your provider/supplier who will provide you with expert professional advice. Drive DeVilbiss Healthcare Ltd. recommend the system is maintained by Drive DeVilbiss Healthcare Ltd. service engineers or qualified personnel.

2. CONTACT INFORMATION

For assistance in setting up, using, maintaining your 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. (within GB) or Drive DeVilbiss Sidhil Ltd. (ouside of GB) at the following addresses:

Drive DeVilbiss Healthcare Ltd.
Sidhil Business Park,
Holmfield,
Halifax,
HX2 9TN
Great Britain

Drive DeVilbiss Sidhil Ltd.
4 Trench Road,
Mallusk,
Newtownabbey,
BT36 4TY,
Northern Ireland

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

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).
- A domestic area.

3.2 Intended User Groups

3.2.1 Cushion

The cushion is intended to support a single patient who is up to 120kg 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 Mattresses

The Air on Foam and Overlay mattresses are intended to support a single patient who is up to 180kg in weight and 185cm in height. The Air on Air mattress is intended to support a patient who is up to 200kg 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 support surface is for sleeping/resting/sitting and it is intended to assist in alleviation or prevention of a pressure related injury.

The support surface is intended to support a single adult. A risk assessment must always be performed on the suitability of the patient to the support surface to ensure they are both mentally and physically suited to using the support surface with minimal risk of personal injury. The patient is only defined as such when situated on the mattress/cushion.

The 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.

3.4 Product Overview

The Theia control unit controls air cell pressure within the support surface, which is attached by an umbilical tube. The support surface is made up of a single layer of air cells or two layers, a top layer of air cells, and a bottom layer of foam to provide additional support where needed. The control unit is intended for continuous use.

The control unit is intended to be positioned on compatible bed frames only.

3.5 Indications

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

3.6 Features

Control Unit

- Provides an air supply to the mattress or cushion
- Rear bed hooks
- Accessible rear filter
- 1 in 2 alternating cycle
- 10 minute cycle time
- Static inflate mode
- Adjustable comfort control
- Fault indicators with visual and audible alerts

Mattress

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

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

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 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 who have reduced capacity and are agitated and/or restless.
- Patients with burns.
- Unauthorised people with access to the controls.

4.3 Contraindications

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 skeletal fractures.
- Unstable spinal injury.
- Exceeds maximum patient weight of the mattress.
- Gross Oedema (when using alternating mode only).

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

4.4 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.

4.5 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 does not contain any Nano-materials and all components are latex free.

4.6 General Warnings

Warning

- The system is to be installed and put into service in accordance with the information provided in these instructions for use.
- The 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 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 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.
- Accessories that have not been approved or designed for use with the 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 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 support surface 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 support surface and patient, and secure bed sheets loosely so as not to affect product functionality.
- Perform regular patient skin checks – Any tissue deterioration may require equipment reallocation and/or a re-assessment of the care being provided.
- Incompatible support platforms (eg. bed frame or mattress) can create safety/stability hazards.

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.
- 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.
- The product should be rolled from the head end towards the foot end (ensuring the control unit is fully covered).
- Place into storage bag/holdall to protect from dirt, debris, fluids etc.

Warning

- 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.

Caution

- Do not crease or stack mattresses, cushion and/or control units - damage could be incurred.
- 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

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

• Disconnect the umbilical cord from the control unit by squeezing the two tabs and pulling away (FIG 5).

• Seal using the cap marked 'Transport' (FIG 6).

• Switch off the control unit.

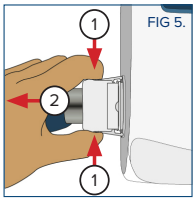


FIG 5.

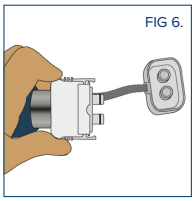


FIG 6.

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 or foam core. Please follow local moving and handling policies and guidelines when handling a mattress. It is recommended that two people manoeuvre the mattress.

6. SYMBOL DEFINITION

The following symbols are found on this bed:

Warning
Beware of potential hazard

Caution
Beware of potential product damage

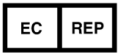
Refer to instructions for use - Recommended
Failure to read the instructions for use could introduce a hazard

Refer to instructions for use - Mandatory
Failure to read the instructions for use could introduce a hazard

Lot number

Date of manufacture

Manufacturer



Authorized representative in the European Community

Serial number

Catalogue number

Medical device

No Smoking

Class II electrical device

The user/occupant is protected by at least two layers of insulation between the current carrying parts (e.g. control box and mains cable) and the metal accessible parts – If damage is noticed to any electrical component, turn off at the mains and contact your provider or Drive DeVilbiss Healthcare Ltd. immediately.

CE certification

Type BF applied part

Applied Part: The parts of the bed that come into physical contact with the user/occupant in order for the bed to carry out its intended function (refer to section 16.2 for a list of 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 EN 60601-1.

Do not iron

Tumble dry on low heat

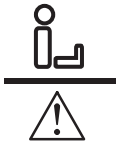
Machine wash at 95°C

Do not dry clean

Drip Dry

Keep out of direct sunlight

Maximum patient weight
(mattress)



Maximum patient weight
(cushion)

Safe working load

Mattress

CPR

CPR Release

7. INSTALLATION

Warning

- Ensure the support surface 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 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 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.
- 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.
- 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.
- 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 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 system in a moisture rich environment - Prolonged exposure to moisture could damage the electrical system and pose an electrical/fire risk.

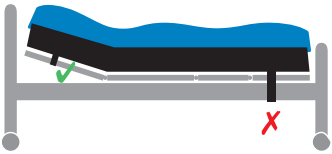
Caution

- 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.
- 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 a cushion, loosely secure the cushion to the chair frame by using the attached securing straps.

Caution

- 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.

- 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.
- Plug the mains cable into a suitable mains supply and switch on the control unit.
- The system will start to inflate. Inflation will be complete within 40 minutes. Please select the max weight range setting upon initial set up to ensure full inflation.
- Once inflated and the low pressure light is out, ensure the straps that attach the mattress/cushion to the bed frame/chair are secure and hold the mattress/cushion 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. Now select desired weight range setting.

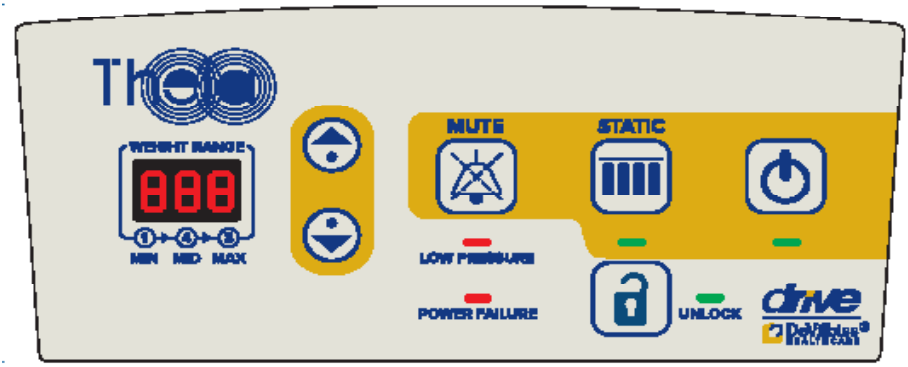
8. OPERATION

8.1 Preparing for Use

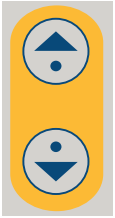
Prior to patient usage of the system the following must be performed:

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

8.2 Control Interface



Power Button - Press to turn system ON/OFF, green light will indicate pump is ON.



Comfort Control - Press to UP arrow to increase pressure and the DOWN arrow to decrease pressure, comfort setting shown in the digital display. It's recommended to adjust comfort control to the max when inflating, before adjusting the pressure to the patient's needs. ***The settings shown below are to act as a guide only, before changing the control a clinical judgement is required from frequent monitoring and repositioning of the patient.***

Product	1	2	3	4	5	6	7	8
OVERLAY (OVERLAY/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	140 kg	160 kg	180 kg
AIR ON FOAM (FULL/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	140 kg	160 kg	180 kg
18" CUSHION (DYN/CUSH/18)	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	100 kg	120 kg
AIR ON AIR (AIR/MAT)	40 kg	60 kg	80 kg	100 kg	120 kg	150 kg	170 kg	200 kg

Static Mode - Press to set the air within the support surface to stay static, green light will indicate static mode is selected.

Mute - The audible alert will sound when the pressure within the system is low or a power failure is detected. To mute, press the mute button and to reactivate the alert re-press the mute button.

Locking Function - The THEIA/2 control unit will automatically lockout all functionality 5 minutes after a function change. To unlock the control unit the 'unlock' button is pressed for 3 seconds. When locked the LED indicator illuminates green.

8.3 CPR Function

When there is an emergency requirement to perform CPR on the patient, pull the CPR strap at the foot end of the mattress to this will release the air quickly from the mattress. The CPR strap is located at the left-hand side of the mattress.

8.4 Low Pressure Warning

When abnormal low pressure occurs, the low pressure indicator will illuminate and the audible alert will be activated to alert of a low pressure condition.

Check if the connections are secure and correctly installed according to the relevant instructions. If the pressure is consistently low, open the zipper and confirm that all of the hoses are properly connected. Check for any noticeable leakage from any of the tubes.

If necessary, contact your local dealer to replace any damaged tubes or hoses.

8.5 Power Failure Warning

If there should be power failure, for example caused by power cord unplugged or power off when pump is working, the audible alert will be activated and power failure indicator will flash. When power is back, the pump will automatically start working, the power button does not require pressing again.

9. 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 support surface and bed frame 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 support surface will help to prevent the risk of infection to the occupant and/or carer.
- Prior to transferring the 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.
- Deviations from the specified cleaning and disinfection instructions can cause serious hazards, and adversely affect the life and efficacy of the system.

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.

9.1 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 clean water.
- Dry off with a paper towel - Always ensure the cleaned surfaces are allowed to fully dry before putting back into use.

9.2 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 system.

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.
- Ensure the internal foam and air cells are orientated correctly to the mattress covers when reassembling.

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.

9.3 Alternative Cover Cleaning Instructions

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

- Remove mattress cover.
- Machine wash at 71°C for no less than 3 minutes or 65°C for no 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).

10. 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 Drive DeVilbiss Healthcare Ltd. approved components specified for the Theia 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 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 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.
- Check that all markings are legible and in sufficiently good condition – if not replace parts and/or adhesive labels as required

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.

11. DISPOSAL

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.

Mattress foams can be recycled at recycling centres that offer suitable PU recycling programs.

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/cushion 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/cushion was supplied in is recommended to be retained as this can be used to store the mattress/cushion in when it is not in use.

Warning

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

12.1 STORAGE AND OPERATIONAL CONDITIONS

Please note, the operational conditions differ to the storage and shipping conditions. Storage and shipping conditions can be found on the original packaging, however if this has not been retained they are as follows:

	Operational Conditions	Shipping & Storage Conditions
Ambient Temperature:	+5°C to +40°C	-25°C to +70°C
Relative Humidity:	15% to 90%, non-condensing	0% to 90%, non-condensing
Atmospheric Pressure:	700hPa to 1060hPa	700hPa to 1060hPa

12.2 18" CUSHION (DYN/CUSH/18) SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Cushion
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50 Hz, 12W
Fuse Rating:	Mains Plug - 5A
	Control Unit - T1A, 230VAC
Mains plug:	Type G/BS1363
Cushion Dimensions:	(L) 500mm x (W) 450mm x (D) 100mm
Cushion Weight:	2kg
Maximum Patient Weight:	120kg (18 stone)
No. of Cells:	6 cells
Alternating Cycle:	AB pattern
Cycle Time:	10 mins
Pressure Range:	20-55mmHg
Control Unit Dimensions:	(L) 270mm x (W) 155mm x (H) 100mm
Control Unit Weight:	1.6kg
Cover Material:	PU
Cell Material:	TPU
Base Material:	Nylon fabric with Foam Insert
Pollution:	Degree 2
UV:	Intended for indoor use only
Noise level:	<40dB(A)

Safety Standards:	IEC 60601-1
	IEC 60601-1-11
	IEC 60601-1-2
	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	2 Years**

12.3 AIR ON FOAM (FULL/MAT) SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Mattress
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50 Hz, 12W
Fuse Rating:	Mains Plug - 5A
	Control Unit - T1A, 230VAC
Mains plug:	Type G/BS1363
Mattress Dimensions:	(L) 2030mm x (W) 900mm x (D) 177mm
Mattress Weight:	9.7kg
Maximum Patient Weight:	180kg (28 stone)
No. of Cells:	17 cells
Alternating Cycle:	AB pattern
Cycle Time:	10 mins
Pressure Range:	20-55mmHg
Control Unit Dimensions:	(L) 270mm x (W) 155mm x (H) 100mm
Control Unit Weight:	1.6kg
Cover Material:	PU
Cell Material:	Nylon/TPU
Base Material:	Nylon fabric with PVC coating
Pollution:	Degree 2
UV:	Intended for indoor use only
Noise level:	<40dB(A)
Safety Standards:	IEC 60601-1
	IEC 60601-1-11
	IEC 60601-1-2
	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	2 Years**

12.4 OVERLAY (OVERLAY/MAT) SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Mattress
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50 Hz, 12W
Fuse Rating:	Mains Plug - 5A
	Control Unit - T1A, 230VAC
Mains plug:	Type G/BS1363
Mattress Dimensions:	(L) 2030mm x (W) 900mm x (D) 127mm
Mattress Weight:	4.2kg
Maximum Patient Weight:	180kg (28 stone)
No. of Cells:	17 cells
Alternating Cycle:	AB pattern
Cycle Time:	10 mins
Pressure Range:	20-55mmHg
Control Unit Dimensions:	(L) 270mm x (W) 155mm x (H) 100mm
Control Unit Weight:	1.6kg
Cover Material:	PU
Cell Material:	Nylon/TPU
Base Material:	Nylon fabric with PVC coating
Pollution:	Degree 2
UV:	Intended for indoor use only
Noise level:	<40dB(A)
Safety Standards:	IEC 60601-1
	IEC 60601-1-11
	IEC 60601-1-2
	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	2 Years**

12.5 AIR ON AIR (AIR/MAT) SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF
	Applied Part: Mattress
Ingress protection:	IP21***
	Not AP or APG equipment*
Supply Rating:	230V, 50 Hz, 12W
Fuse Rating:	Mains Plug - 5A
	Control Unit - T1A, 230VAC
Mains plug:	Type G/BS1363
Mattress Dimensions:	(L) 2030mm x (W) 900mm x (D) 200mm
Mattress Weight:	7.3kg
Maximum Patient Weight:	200kg (31.5 stone)
No. of Cells:	20 cells
Alternating Cycle:	AB pattern
Cycle Time:	10 mins
Pressure Range:	30-60mmHg
Control Unit Dimensions:	(L) 270mm x (W) 155mm x (H) 100mm
Control Unit Weight:	1.6kg
Cover Material:	PU
Cell Material:	Nylon/TPU
Base Material:	Nylon fabric with PVC coating
Pollution:	Degree 2
UV:	Intended for indoor use only
Noise level:	<40dB(A)
Safety Standards:	IEC 60601-1
	IEC 60601-1-11
	IEC 60601-1-2
	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	2 Years**

*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.

13. ELECTROMAGNETIC COMPATIBILITY (EMC)

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

Warning

The Theia control unit should not be used adjacent to or stacked with other medical electrical equipment, where viable. If adjacent or stacked use is necessary, the sytem and associated medical electrical equipment should be observed to verify normal operation - If not taken in to account abnormal operation could occur.

Guidance and manufacture's declaration – electromagnetic emissions		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Theia uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Theia 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 and compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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	±2kV for power supply lines ±1 kV for Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the Theia be powered from an uninterrupted power supply.

Guidance and manufacture's declaration – electromagnetic immunity		
Immunity test	IEC 60601 test and compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U*T is the a.c. mains voltage prior to application of the test level.

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

Recommended separation distances between portable and mobile RF communications equipment and the Theia 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. 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.			

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 Theia 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 6 Vrms in ISM bands	3 Vrms 6 Vrms in ISM bands	d = 1.2√P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 V/m 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	d = 1.2√P 80 MHz to 800 MHz d = 2.3√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 metres (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 Theia is used exceeds the applicable RF compliance level above, the Theia should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientating or relocating the Theia.

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

14. 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 1 year (which specifically is - 1 year 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 1 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 1 year warranty gives you specific legal rights and you may also have other rights.

Drive DeVilbiss Healthcare Ltd. cannot be held responsible for any injury or incident which relates to the use of this bed in conjunction with accessories manufactured by companies other than Drive DeVilbiss Healthcare Ltd.

Drive DeVilbiss Healthcare Ltd. has a policy of continual product improvement and reserves the right to amend specifications covered in this document. No part of this document may be reproduced without the written approval of Drive DeVilbiss Healthcare Ltd.

NOTES

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EC REP

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ORIGINAL INSTRUCTIONS
INSTRUC/THEIA, 2022/08 - Rev8