drive

DeVilbiss HEALTHCARE

Hybrid-Power Pressure Care Mattress

Instructions for use

Drive DeVilbiss Healthcare manufacture beds, pressure area care equipment and hospital furniture at their UK manufacturing plant in Halifax, West Yorkshire.

This state of the art manufacturing plant uses the latest technology to cater for bespoke and high volume production, to meet the needs of the healthcare environment.

Research and development is undertaken following strict guidelines to ensure all products are fit for purpose and comply to the relevant product and industry standards.

Drive DeVilbiss Healthcare meet the requirements of EN ISO 9001, EN ISO 13485 and EN ISO 14001.

"Drive DeVilbiss exists to enhance the quality of life of the people we touch"

Contents

1. Contact Information

Thank you for purchasing this product. These instructions for use should be read carefully before using the mattress or cushion. Please ensure that you understand all instructions, if you have any questions concerning the operation or maintenance of the mattress or cushion, please contact your provider / supplier who will provide you with expert professional advice.

Contact Information

For assistance in setting up, using, maintaining your mattress or cushion, 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:

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Sidhil Business Park
Holmfield
Halifax
West Yorkshire
HX2 9TN
United Kingdom

Service & Maintenance
Tel: +44 (0)1422 233 136
Fax: +44 (0)1422 233 010

Spares
Tel: +44 (0)1422 233 138
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Sales
Tel: +44 (0) 845 0600 333
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info@drivedevilbiss.co.uk
www.drivedevilbiss.co.uk

Please quote the relevant serial number on all correspondence. There are individual serial numbers for the control unit and mattress / cushion. UDI and serial numbers can be found on the back of the control unit and inside the mattress / cushion.

For Service & Support outside the United Kingdom & 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 use of this device results in a serious incident occurring, reports should be forwarded to Drive DeVilbiss Healthcare Ltd and the MHRA or the local competent authority.

The mattress system is not to be used in any other environments – risk of product damage and/or unintended operation.

2. Product Description

2.1 Environment

Your mattress / cushion 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).

2.2 Intended User Group

When connected with the control unit pump, only the professional user is intended to operate the control panel interface.

2.2.1 Hybrid Power Mattress

When used in a powered state with a control unit pump, the Hybrid Power Mattress is intended to support a single patient who is up to 254kg in weight and 185cm in height. When used in an unpowered state, the mattress is intended support a single patient who is up to 226kg in weight. 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.

2.2.2 Hybrid Power Cushion

When used in a powered state with a control unit pump, the Hybrid Power Cushion is intended to support a single patient who is up to 190kg in weight. When used in an unpowered state, the cushion is intended support a single patient who is up to 170kg in weight. 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 cushion and seating platform.

2.3 Intended Use

Unpowered

The intended purpose of the mattress is to support the weight of the patient whilst sleeping and/or resting, to assist the user with pressure distribution as part of an overall plan of care.

Powered

The intended purpose of the mattress is to support the weight of the patient whilst sleeping and/or resting, and to assist the user with active pressure redistribution as part of an overall plan of care.

2.4 Indications

To assist as part of an overall programme of care where load distribution is required but active load redistribution through mechanical means may also be required.

2.5 Product Overview

The Hybrid-Power support surfaces combine the pressure redistributing properties of high specification foam, with dynamic alleviation. Castellated visco-elastic foam delivers a high degree of pressure redistribution as it conforms to the shape of the body, while alternating cells assist with pressure relief when the power unit is in use.

The Hybrid Power Mattress removes the need to move a patient out of bed to swap a support surface in the event a patient's treatment needs 'stepping up' or 'stepping down', providing a positive impact on quality nursing time. A turning pillow provides additional comfort for the patient.

The Hybrid Power Cushion allows for pressure alleviation whilst a patient is seated outside of a bed, alongside providing the pressure redistributing properties of high specification foam cushion.

The mattress is suitable for use for all categories of pressure ulcer including Deep Tissue Injury (DTI) and Unstageable, alongside a completed risk assessment taking into consideration but not limited to mobility status, skin condition, nutritional and continence status plus a patient specific turning schedule.

2.6 Compatibility

Hybrid POWER "1" is compatible with Hybrid Power pump (covered by this IFU). Hybrid Power "2" is compatible with THEIA pump, see INSTRUC/THEIA IFU for details on use of the control unit.
Adapters are available to allow cross-compatibility between either system. Please contact your provider or Drive DeVilbiss Healthcare for more information on the use of the adapters.

3. Safety

3.1 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.

3.2 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 mattress / cushion, 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, chair, mattress, side rails etc.).
- Extent of tissue damage (if any).
- Entrapment.
- Patient falls.
- Compatibility of the patient to the mattress size.
- Patients who have reduced capacity and are agitated and/or restless.
- Patients with burns.
- Unauthorised people with access to the controls.
- Small adults/children.

3.3 Contraindications

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

Mattress and Cushion:

- Exceeds maximum patient weight of the support surface.
- Gross Oedema (when using alternating mode only).
- Unstable skeletal fractures.
- Unstable spinal fractures and injuries.

Mattress only:

- Cervical or skeletal traction. Other contraindications may be relevant. Which are specific to the patient or care environment.

3.4 System Loads

Hybrid Power Mattress maximum patient weights:

Powered with control unit:
254kg (40 stone)
Unpowered without control unit:
226kg (35.5 stone)

Hybrid Power Cushion maximum patient weights:

Powered with control unit:
190kg (30 stone)
Unpowered without control unit:
170kg (26.7 stone)

3.5 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/fire. 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 NOT – Use electric blankets with the mattress 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 system can degrade the fire performance.

3.6 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.

3.7 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.

3.8 Biocides

The Hybrid Power Mattress and Cushion cover contains a biocide agent to control microbial deterioration called Fresche.

The active ingredient is fully encapsulated within the polymer coating. There are no special handling requirements.

The mattress, cushion and cover are free from natural rubber latex.

4. Symbol Definition

The following symbols can be found in the manual and also on the mattress, cushion and/or control unit. Product identification labels are located on the inside of the mattress / cushion cover. See section 10 for control unit interface symbol definitions.


Attention, instructions to be read


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


CE Mark


Type BF Applied Part


Caution
Be aware of potential product damage


Warning
Be aware of potential hazards


Disposal of Electrical & Electronic Equipment (WEEE). See section 15.


Manufacturer

Date of manufacture


Drip dry


Tumble dry on low heat
Do not exceed 40°C


Do not iron

Washing temperature


Do not dry clean


No Smoking

REF Product code

MD Medical device

SN Serial number

LOT Lot number

UDI Unique Device Identifier


Maximum Patient Weight


Safe Working Load


Foot End


Mattress


Fuse


Zip location

EC REP Authorised representative in the EU Community

IP21 IP Rating

5. Product Features

5.1 Mattress Features

- Max inflate, Alternating mode & Static mode (remove pump).
- Auto-lock function.
- Audible & visual alerts.
- 1-in-2 alternating mode.
- A full width heel zone with smaller castellations to support the vulnerable heel area.
- High density side formers to support and assist with patient transfers in and out of the bed.
- Turning pillow & 14 alternating cells (10 body section & 4 heel zone cells) on a foam base.
- Optional cable management routing.

5.2 Cushion Features

- Includes 4 foam filled alternating cells on a foam base.
- Cushion cover is PU coated with welded seams and a 270° zip with protective flap.
- Max inflate, Alternating mode & Static mode (remove pump).
- Auto-lock function.

5.3 Hybrid Power Control Unit Features

- Provides an air supply to the mattress/ cushion.
- Rear bed hooks.
- Accessible rear filter.
- 3 comfort levels available for a variety of patient weights.
- 1 in 2 alternating cycle.
- 10 minute cycle time.
- 20 minute timed static mode.
- Lock out function.
- Low Pressure Indicator (alarm and LED).
- Power Failure Indicator (alarm and LED).

Do not modify this equipment without the authorisation of the manufacturer.

6. Transport and Post-delivery

6.1 Transporting

Where possible, it is recommended the transport of mattresses should be carried out within a holdall 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 the mattress.

The Hybrid Power Cushion may be transported by hand. Ensure the cushion is held from underneath rather than carrying by the top cover.

- Do not remove the mattress from the bed frame if the patient is still on the mattress - Risk of falling.
- If it is essential that the patient is moved whilst remaining on the mattress, ensure the system is immediately plugged back in to the mains power supply once relocated - Risk of tissue damage.

6.2 Storage

For ease of storage, mattresses should be stored in a storage rack. To prevent damage during storage:

- Ensure mattress is cleaned before storing.
- Store in a polythene cover/bag.
- Do not store objects such as side rails or bed ends on top of the mattress.

Steps to prepare the system for storage:

- Detach the control unit from the mattress.
- Place the control unit on the mattress.
- Place the system in a protective bag for storage.

To prevent the risk of cross infection, when removing a mattress system after use ensure that all activities in relation to the mattress are carried out using disposable gloves unless it can be verified that the mattress and control unit has been suitably cleaned and disinfected prior to collection.

On the return of a mattress system after use, 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 these instructions for use.

6.3 Pre-use Checks

- Assess the mattress for any damage which may have been caused during transit.
- Ensure the mattress is suitable for the product combination (bed platform, side rails etc.).
- A comprehensive risk assessment should be carried out to ensure the mattress is suitable for the patient, the surrounding environment and compatibility with the bed.
- The Hybrid-Power is a full replacement mattress, remove all existing mattresses and place the new mattress directly on to the bed frame.
- Ensure the mattress is suitable for the intended patient and maximum patient weight.
- It is important the patient can either reposition themselves or are repositioned on a regular basis; please follow local policies, recognised national or international guidance.
- If stored in a cold area, remove all packaging materials and allow the system to lie flat in a room with an approx. temperature of 22°C for a minimum of 2 hours before use.

6.4 Damage Prevention

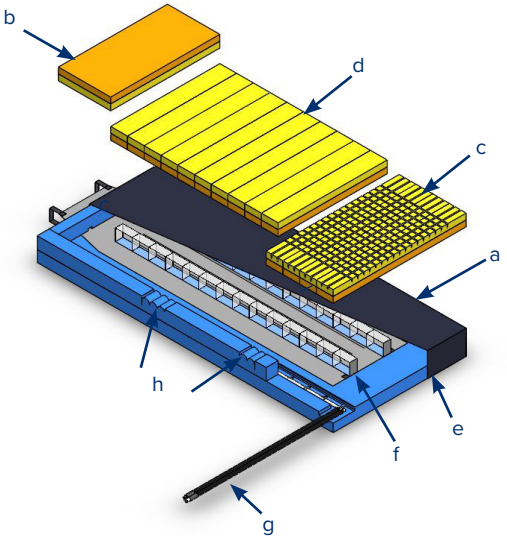
Avoid puncturing the cover as this will allow fluid ingress and ultimately contaminate the mattress. To prevent damage to the cover:

- Remove all packaging with care.
- Do not place sharp objects such as hypodermic needles or scalpels on to the mattress.
- Avoid wearing protruding jewellery such as rings with large stones or watches.
- Take extra care when using medical devices such as drip stands, side rails or transfer boards.

7. Parts Identification

7.1 Control Unit

Item	Part
1	Control Panel
2	Bed Hooks
3	Male Connector
4	Female Connector
5	Filter & Case
6	Fuse
7	Mains Inlet
8	Rear Case
9	Front Case
10	Main On/Off Switch



7.2 Mattress

Item	Part
a	Top Cover
b	Static Head Section
c	Alternating High Pressure Cells
d	Alternating Support Cells
e	Base Sheet
f	Cell Holder
g	Air Feed Pipe
h	Castellated Side Formers

The Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Service Personnel to repair parts that are designated as repairable by Service Personnel.

8. General Warnings

- The system is to be installed and put into service in accordance with the information provided in these instructions for use.
- The Hybrid Power mattress / cushion 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 support surface.
- 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 Hybrid Power system are not to be used.
- If children, adults with reduced 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 mattress / cushion is 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.
- Ensure the patient can reposition themselves, or are repositioned on a regular basis; please follow local policy
- The mattress / cushion is not to be removed from the support surface (bed / chair) when in use with a patient and should not be used as a transfer aid.
- Consideration should be taken when profiling sections of a bed frame as this may cause shear / frictional forces on the patient's skin.
- 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.
- Do not use the mattress in temperatures exceeding 40°C.
- Incompatible support platforms (e.g. a bed frame or chair) can create stability hazards.
- 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.
- Misused electrical equipment can be hazardous.
- 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
- 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.

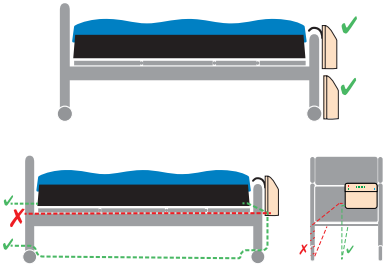
- Control unit shall not be used in the presence of flammable gasses or used in oxygen rich environments – Risk of explosion / fire.
- Control unit functions must be locked out when a patient is left unattended.
- Block adaptors are not to be used. If an extension cable is used, never overload it by plugging in appliances that together will exceed the maximum current rating stated for the extension cable – Risk of fire.
- Ensure multiple socket outlets are not positioned under the bed frame – Liquids that leak onto such a socket could pose an electrical / fire risk.
- Avoid placing the mattress system in a moisture rich environment – Prolonged exposure to moisture could damage the electrical system and pose an electrical/ fire risk.
- 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.
- Do not place any objects or items, such as blankets, on or over the control unit - Risk of fire.
- In case of emergency, the pump can be isolated at the Main On/Off Switch or by unplugging the mains cable from the source.

9. Installation

If the mattress / cushion system has come from a storage / transport temperature environment near to the minimum or maximum values stated allow the 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.

Prior to installing and setting up the system ensure the general warnings in section 8 have been understood and actioned.

- When specifying a mattress, bed frame and side rail combination, a clinical assessment of the patient's needs must be carried out in line with local policy.
- Once removed from the packaging, check the product for any signs of damage. If damaged do not put into use and contact your distributer.
- Remove all covers, sheets and the existing mattress from the bed.
- Position the mattress on top of the bed frame, top cover facing upwards and feed pipes at the foot of the bed for control unit positioning.
- Position the control unit by hanging the hooks over the foot board. If there is no foot board place the unit on the floor and stand upright. Ensure the rear of the unit is not obstructed by carpet, rugs etc. It is advisable to place the unit on a firm surface.



Avoid placing the mattress system in direct sunlight – Direct sunlight could damage the mattress cover.

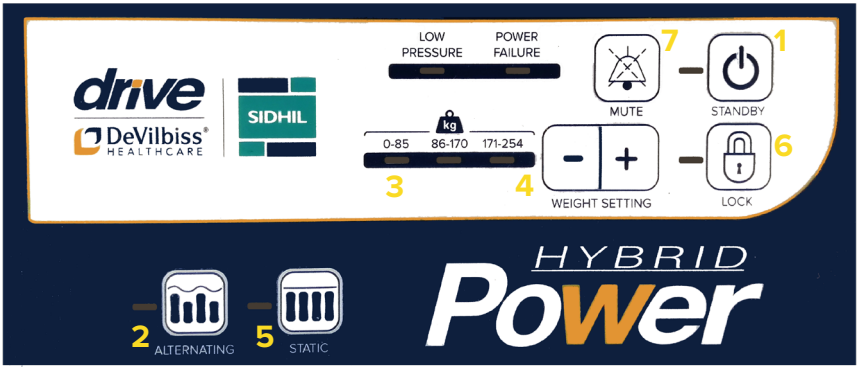
- Attach the male and female feed pipes to the control unit, ensuring the feed pipes do not kink or become trapped between parts of the bed frame.
- Connect the mains plug to the nearest source.

- Do not route the mains cable through/around mechanical bed assemblies; it is recommended to use cable management systems (where available), or to position the cables so they run along the floor under the bed, in a position that will not cause a trip hazard and/or damage to the cable. The mattress system mains cable should not be in tension when the bed is operated through the range of travel available to the user.
- Ensure the control units mains lead is positioned in such a way that there is no risk of entrapment/trips or fall hazards.

The Hybrid Power Cushion may be placed on any seating surface as long as the underside of the cushion is fully supported. The cushion must be placed with the top cover facing up but can be placed in any orientation based on the patient's clinical needs.

10. Control Unit Functions

For use of the Hybrid Power Mattress and Cushion with the THEIA pump, please refer to the THEIA IFU.



10.1 Power On/Off

Switch the pump on using the main On/Off switch located at the side of the pump next to the mains power inlet.

Press Standby to power the pump on (item 1 on the above image).

Ensure the pump is fully switched off both at the membrane and power switch if used as a non-powered system.

10.2 Initial setup

Following an audible 'beep' the pump will begin operating.

The pump will take 10 minutes to make the system ready for receiving the user.

Upon initial setup, the pump will default to alternating mode and a green LED will light to indicate this (item 2 on the above image). The pump will also default to the 0-85kg comfort/ patient weight setting and a green LED will light to indicate this (item 3 on the above image).

10.3 Pressure/Comfort Levels

The system's pressure can be increased/ decreased where required by pressing the + & - buttons labelled WEIGHT SETTING (item 4 in the above image). Before changing or lowering the pressure, clinical judgment is required in regards to how it may affect the patient.

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

10.4 Alternating

To select this function press the button labelled ALTERNATING (item 2 on the above image). A green LED will light to indicate that the system is in alternating mode.

The cells will alternate to a 1 in 2 cycle.
Cycle time: 10 minutes.

10.5 Static

To select this function press the button labelled STATIC (item 5 on the above image). An amber LED will light to indicate that the system is in static mode.

The system will resume alternating after 20 minutes.

Patients should always be nursed on the mattress in alternating mode unless static mode is required.

- Ensure comfort levels are set appropriately for higher weight patients to reduce the risk of the mattress bottoming out.
- When the backrest section of the bed is raised, ensure pressures are increased accordingly to reduce the risk of the mattress bottoming out.
- Ensure the pump is fully switched off both at the membrane and power switch if used as a non-powered system.

10.6 Lock Out

After 5 minutes of inactivity, the pump will lock out it's functions. To unlock, press and hold the Lock Out button (item 6 on the on the image on page 15) for 3 seconds.

⚠ In the event of a power failure, the control unit's functions will unlock when restarted.

10.7 Alarm Mute

If a fault is detected, press the Alarm Mute button to silence the audible alarm (item 7 on the image on page 15). The alarm will silence and the red LED will continue to flash until the issue is resolved.

10.8 Control Unit Icons

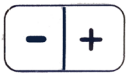
On/Off Standby

Static

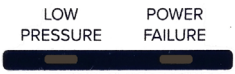
Alternating

Lock / Unlock

Alarm mute



Patient Comfort/Weight Settings



Alarm indicators

11.1 CPR Facility

Rapid deflation of the system may be required for emergency treatment.

In the event of a cardiopulmonary resuscitation (CPR) whilst the pump is in alternating or static mode, release both male and female feed pipes from the pump by pressing and holding the connector locking clips and pulling them away from the pump unit. Air within the cells will exit through the feed pipes.

Do not block or join the feed pipes together curing CPR.

The control unit will sound and the Low Pressure LED will illuminate as a result.

To re-inflate the system, reconnect the male and female feed pipes and restart the control unit by switching off and then on. The control unit will carry out its initial set-up procedure.

To allow the system to inflate correctly and effectively, it may be necessary to reinitialise without the patient on the mattress.

11.2 Transport Mode

If required, the mattress male and female connectors can be disconnected from the control unit and joined together. This will equalise the cells.

- The mattress will remain inflated for a maximum of 24 hours only – Return the system to the mains supply as soon as is practical.
- Whilst unplugged the alternating mode will not be operational, pressure relief will not be provided.

11.3 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.

12.1 Low Pressure - Medium Priority

The Low Pressure LED will flash red and the alarm will sound intermittently when the pressure drops below a predetermined tolerance of 5mmHg. Alarm will sound after 3 minutes of loss in pressure.

12.2 Power Fail - Medium Priority

The Power Failure LED will flash red and the alarm will sound when the mains power is cut. The alarm will sound as soon as the power is cut.

When muted, the alarm will not restart, however the LED will continue to flash.

When switching off the control unit ensure the Power button is pressed as disconnecting straight from the mains will sound the Power Fail alarm and as a result will deplete the internal battery.

The power failure alarm is maintained via an internal battery that is automatically kept in a continually charged state by the mains supply.

13. Decontamination and Cleaning

The following guidelines are suggested by Drive DeVilbiss Healthcare Ltd. as being suitable infection control procedures. Further information is available upon request.

- Always disconnect the mattress/cushion system 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.

13.1 Control Unit

- Use a cloth dampened with a mild detergent and warm water (40˚C) solution.
- This may be followed either by wiping with a sodium hypochlorite solution to a dilution of 1,000ppm/0.1% or by using an alcoholic wipe.
- Wipe thoroughly with a cloth dampened with clean cold water or a damp single use wipe. Remove any excess sodium hypochlorite solution.
- Dry off with a paper towel - Always ensure the cleaned surfaces are allowed to fully dry before putting back into use.

- Do not use phenolic, biological or phenol based cleaning solutions.
- Do not use any abrasive compounds or cleaning pads.
- Do not submerge the control unit into water or any other liquids.

13.2 Mattress/Cushion

- Cleaning should be completed when not in use with a patient. If it is not possible to move the patient, a risk assessment should be conducted on the suitablility of the cleaning method and materials.
- Personal Protective Equipment should be worn during the entire cleaning process.
- Regular cleaning and disinfection of the mattress/cushion system will help to prevent the risk of infection to the occupant and/or carer.
- Prior to transferring the mattress system to another user, ensure it has been cleaned and disinfected using the method as detailed to help prevent the risk of cross infection.

Inspection:
Before attempting to clean the mattress, the top cover is to be checked for physical signs of damage that may lead to strikethrough (ingress of fluid through the cover). This is achieved by unzipping the top cover and looking for signs of staining to the white underside.

- Replace the cover if strike-through is evident – Risk of cross infection.
- Replace the cover if there are any signs of damage (tearing, punctures, abrasion, damaged seams etc.)

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.
- Dry off with paper towels - Always ensure the cleaned surfaces are allowed to fully dry before putting back into use.

13. Decontamination and Cleaning

Decontamination:
The foam used in this product cannot be decontaminated, therefore, it is recommended that any contamination must result in the foam being replaced.

If the mattress cover is heavily soiled or has been exposed to bodily fluids follow your organisations decontamination procedure, alternatively:

- 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.
- 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.

- Frequent or prolonged exposure to higher concentration disinfectant solutions may affect the longevity of the mattress and affect its functionality.
- Do not use alcohol, biological or phenol based cleaning solutions.
- Do not use any abrasive compounds or cleaning pads.
- Drying temperature must not exceed 40°C. Exceeding this temperature can cause significant damage to the mattress cover.

13.3 Laundering

Decontamination of the mattress cover may be achieved by laundering, launder as per

- Frequent or prolonged exposure to laundering at high temperatures may prematurely age the cover
- The cells in the system cannot be laundered - cell material unable to tolerate the process.
- This system must not be steam cleaned or used in an autoclave.

your organisation's decontamination policy, alternatively:

- Remove both mattress top and bottom covers.
- Drive DeVilbiss Healthcare recommends following the NHS Health Technical Memorandum HTM 01–04*: Wash at 65°C for not less than 10 minutes or 71°C for not less than 3 minutes.
- Maximum washing temperature is 95°C.
- Heavily soiled items should also have a pre-wash/sluice cycle.
- Allow covers to fully dry before use - Mattress covers can be tumble dried on a low heat setting for 90 minutes. Drying temperature: 40°C.

(* Refer to the Department of Health document HTM 01-04 for full details).

13.4 Drying

Mattress inners and tube sets should be hung from a line or bar and drip dried in a clean indoor environment.

Covers must be completely dried before refitting to the mattress.

14. Maintenance

14.1 Maintenance

Only authorised service personnel or Drive DeVilbiss Healthcare Ltd. service engineers should carry out repairs or service activities. For Service & Support outside of the United Kingdom, please contact the local distribution company from where this equipment was purchased. Failure to do so may result in the product warranty becoming void. This 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 use.

14.2 General Pump Maintenance

- Ensure the casing is free from damage. If damaged, remove from use immediately.
- Ensure the main power cord and plug are free from abrasions and/or excessive wear. Replace if damaged.
- Ensure air connectors are in good order, replace if damaged.
- Check that the battery is still functional and operates in the event of a power loss.
- Check that all markings are legible and in sufficiently good condition – if not replace parts and / or adhesive labels as required.
- Check the air filter is in good condition and replace or clean as required.
- Ensure all alarm signals and visual indicators operate as intended.
- Ensure all functions work as intended.
- Replacements and spares are supplied by Drive DeVilbiss Healthcare Ltd.
- Check that the pump does not output air if the main On/Off switch is powered up/on, and the front membrane is switched off. If this does occur, remove from service and replace the main PCB.

14.3 Mattress Inspection

Mattresses should be checked regularly to ensure they remain 'fit for purpose', clinically effective and pose no risk of infection to either the patient or the carer. Drive DeVilbiss Healthcare Ltd. recommend that a thorough inspection of both the interior (cells) and exterior (cover) of the mattress is carried out on a weekly basis or each time a new patient is placed on the mattress. Visual checks should be carried out daily to identify any significant signs of damage or infection risk.

Weekly checks:

- Check for any signs of staining on the inner substrate of the cover.
- Check for any signs of tearing and/or puncture marks.
- Check all the seams for any signs of splitting.
- Check the zip for any signs of damage, also ensure this is fully closed at all times.
- Check between the cells for any signs of fluid ingress/staining.
- Check connectors for damage and security.
- Check tubing condition, security and damage, ensure there are no kinks or twists.

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- 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 the service engineer is to perform maintenance whilst a patient is on the mattress, the maintenance procedure must not impede the performance of the product.
- Only Drive DeVilbiss Healthcare Ltd. approved components specified for the Hybrid-Power system are to be used - if in doubt contact Drive DeVilbiss Healthcare Ltd. or your local distributor.
- When servicing or repairing a mattress system ensure that all activities are carried out using disposable gloves and any other personal protective equipment deemed necessary, unless it can be verified that the mattress and control unit have been suitably cleaned and disinfected.

14. Maintenance

14.4 Service Life

It is advised that the system is serviced in conjunction with the systems environment. 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 1.

14.5 Control Unit - Filter

Dust from the surrounding environment can affect the performance of the control unit. Check that the air filter is in good condition and replace or clean as required.

- Should the Control Unit fail to operate, a suitable fuse of the same rating and a replacement Mains Cable supplied by Drive DeVilbiss Healthcare Ltd should be fitted by Service Personnel only. Failure to fit the correct fuse or mains cable could result in damage to the control unit and a fire hazard.

15. 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 WEEE (Waste Electrical and Electronic Equipment) policies.

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

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

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

16. Specification

For THEIA pump, please refer to the THEIA IFU.

Hybrid Power Pump Specification

Power Supply:	220-240V, 50/60Hz, 0.25A 16W
Fuse Rating:	T1A 250V
Cycle Time:	10 minutes
Dimensions:	310 x 210 x 125mm
Weight:	2.5kg
Modes:	Alternating & Static
Air Output:	8 litres per minute
Pressure Range:	15mmHg - 40mmHg ±10%
Noise Level:	<30dB
Electric Protection:	Class II
Applied Parts:	Type BF
Medical Device:	Class IIa (Control Unit)
Usage:	Continuous operation
Ingress Protection:	IP21
Environment Operating:	Ambient Temp: +10°C to +35°C Humidity: 20% to 80% non-condensing
Environment Transport & Storage:	Temperature: -25°C to +70°C Humidity: <93% max, non-condensing

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

Mattress Specification

User Weight:	Maximum: 254kg (40st)
Dimensions:	1980x 880 x 160mm (fully inflated)
Weight:	16kg
Cells:	14 foam filled cells 1 static foam head cell
Alternating Mode:	1 in 2
Medical Device:	Class I (Mattress)
UV:	Indoor use only
Cover Material:	PU coated fabric substrate
Base Material:	PU coated fabric substrate
Fire resistance:	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	5 years*

Cushion Specification

User Weight:	Maximum: 190kg (30st)
Dimensions:	465 x 455 x 145mm (fully inflated)
Weight:	2kg
Cells:	4 foam filled cells
Alternating Mode:	1 in 2
Medical Device:	Class I (Cushion)
UV:	Indoor use only
Cover Material:	PU coated fabric substrate
Base Material:	PU coated fabric substrate
Fire resistance:	Cover complies with BS7175:1989 - Medium Hazard
Expected Service Life:	5 years*

*If the system and its components are serviced and maintained in accordance with the information detailed in section 14 of these instructions for use then the mattress/cushion system can be expected to provide in excess of 10 years of service.

17. Troubleshooting

- The control unit is not to be opened - Risk of electric shock.
- If mains plug, cable or outer casing is visibly damaged turn off at the mains, remove from use and contact your approved service provider.

17.1 Power Failure

1. Press the mute button on the control unit to silence the alarm and turn off the mains supply (Note, the mute button does not deactivate the power failure indicator).
2. Ensure that the main On/Off switch next to the mains inlet is switched on.
3. Check the mains cable is plugged into a wall socket and also into the control unit.
4. Switch on at the wall (to ensure the socket is working, plug in a fused device that is known to work).
5. Turn on the control unit.

If control unit still fails to operate:

1. Turn off the control unit at the wall.
2. Replace the mains plug and control unit fuses.
3. Turn on the control unit.
4. If control unit still fails to operate, turn off at the mains and contact your approved service provider.

17.2 Incomplete / Low Pressure

1. Ensure the mattress feed pipes are correctly connected to the control unit.
2. Turn the unit off and then on again to clear the indicator.

If a ‘low pressure’ indicator continues to illuminate:

1. Open the mattress and ensure there is no air leakage within the mattress – cells, tubing and connectors. Turn the unit off and then on again to clear the indicator.
2. If the low pressure indicator is still evident turn off at the mains and contact your approved service provider.

17.3 Bottoming Out

1. Pressure setting may be inadequate for the patient, adjust Patient Comfort/Weight Setting.
2. Ensure the patient is centrally positioned on the mattress.
3. Ensure the patient is suited to the maximum rating of the mattress.

17.4 Pump Failure

The alternating system has a 1 in 2 cycle, meaning that every other cell will be deflated at a given time.

1. Turn off the control unit.
2. Disconnect the feed pipes to reduce cell pressure.
3. Reconnect the feed pipes.
4. Turn on the control unit.
5. If alternating mode is still inoperable turn off at the mains and contact your approved service provider.

17.5 Noisy Pump

1. Tightly secure the bed hooks to the bed frame or reposition the pump to reduce vibration and limit noise.
2. Ensure air pipes are not kinked.
3. If fault still continues contact your approved service provider.

18. Electromagnetic Compatibility (EMC)

18.1 EMC

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

Interference can be received from fixed transmitters (e.g. commercial radio and television towers) and portable / mobile RF communications equipment (e.g. mobile phones). Due to the increasing number of mobile phones and other wireless devices the possibilities of interference to the control unit and other surrounding equipment results in the need for special precautions to be taken regarding EMC.

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 Hybrid-Power mattress 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.

Only the Drive DeVilbiss Healthcare Ltd. approved mains cable for the Hybrid-Power control unit is to be used.

The use of an unapproved cable could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- The Hybrid-Power control unit should not be used adjacent to or stacked with other equipment where possible, if adjacent or stacked use is necessary the Hybrid-Power should be observed to verify normal operation in the configuration in which it is to be used.
- Portable RF communications equipment (e.g. mobile/cordless phones) should be used no closer than 30 cm (12”) to the Hybrid-Power control unit or its mains cable, otherwise degradation of the performance of this equipment could result.

19. 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 5 years for the mattress and 2 years for the pump (full parts and labour) from the date of purchase from Drive DeVilbiss Healthcare Ltd. and its subsidiary companies.

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:

1. damaged by lightning, water, or power surges,
2. neglected, altered, abused, or used for a purpose other than the purpose for which they were designed,
3. repaired by you or any other party without Drive DeVilbiss Healthcare Ltd. prior written authorisation,
4. used in conjunction with a third party product or products not approved in advance by Drive DeVilbiss Healthcare Ltd.,
5. damaged or failed by or attributes to acts of God,
6. damaged, caused by failure to follow instructions, or
7. 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;

1. correct the defect by product repair within the terms of the warranty
2. replace the product with one of the same or similar design or
3. 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 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.

Notes

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