drive

DeVilbiss HEALTHCARE

Pressure Care Cushion

Instructions for use

Drive DeVilbiss Healthcare Ltd. 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 Ltd. meet the requirements of EN ISO 13485, EN ISO 9001 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. This user manual should be read carefully before using the cushion. Please ensure that you understand all instructions. If you have any questions concerning the operation or maintenance of the cushion, please contact your local distributor or Drive DeVilbiss Healthcare Ltd.

Contact Information

For any service, warranty, sales or customer service information on this product please contact your local distributor or if in doubt contact Drive DeVilbiss Healthcare Ltd. at the following address.

Drive DeVilbiss Healthcare Ltd.
Sidhil Business Park,
Holmfield,
Halifax,
West Yorkshire,
HX2 9TN,
United Kingdom.

Tel: +44 (0) 845 0600 333
Fax: +44 (0) 845 0600 334

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

Users with visual, reading or cognitive disabilities should seek advice from their provider or a professional care provider for an appropriate format. For the latest version of this document, contact Drive DeVilbiss Healthcare Ltd using the details below, or check our website.

If a serious incident occurs in relation to the product, reports should be forwarded to Drive DeVilbiss Healthcare Ltd and the MHRA or local competent authority. Please reference the product name and serial number.

For Service & Support outside the UK, 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.

2. Fire Warning

2.1 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 cushion. This is a common cause of fatal fires. A cigarette could burn a hole in the cushion surface and cause damage. Patient clothing, upholstery 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.
- Keep the cushion away from sources of heat and naked flames - close proximity to flames and heat sources could damage the cushion cover and / or could cause the cover / clothing to catch fire.
- DO NOT - use candles on or around the cushion.
- DO - keep hot equipment off and away from the cushion surface, e.g. hair dryer, curling tong, etc.
- DO - keep heaters away from the cushion.
- 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.

3. Symbol Definition


Attention, instructions to be read

Product code


Date of Manufacture


Manufacturer


Keep out of direct sunlight

Maximum Washing Temperature


Tumble dry on low heat - do not exceed 40 ° C


Drip dry


Do not dry clean


Do not iron


Resistant to ignition source: match flame equivalent


Resistant to ignition source: smouldering cigarette equivalent

Batch code


Resistant to ignition source

Medical device


Maximum user weight


Zip location


Safe working load


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


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

4. Product Information

4.1 Product Information

Contact your distributor if a datasheet or further information is required to identify the specific properties of your cushion.

4.2 Environment

Your pressure area care cushion is intended for use in the following environments:

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

Before use, a comprehensive risk assessment should be carried out to ensure the cushion is suitable for the patient, support platform and care environment.

4.3 Intended Use

The intended use of the cushion is to support the weight of the patient whilst sitting, and to assist the user with pressure redistribution as part of an overall plan of care.

4.4 Indications

To assist as part of an overall plan of care when reactive load distribution through non-mechanical means is required.

4.5 Contraindications

Exceeding the maximum patient weight of the cushion is a contraindication.

4.6 Patient Weight

The maximum patient weight can be located on the top cover as well as the information label located within the cover. The minimum user weight for this cushion will depend on a combination of the support platform the cushion is used on, the physical size of the user and the treatment program in place for the user. A risk assessment must be conducted by clinical staff to ascertain that the combinations of products are suitable for all users, but especially for low weight & bariatric users.

4.7 Storage & Operational Conditions

For ease of storage, cushions should be stacked on top of one another. To prevent damage during storage:

- Do not fold or roll.
- Ensure cushion is cleaned before storing.
- Store in a polythene cover/bag.
- Do not store heavy objects on top of the cushions.

For optimal performance, Drive DeVilbiss Healthcare recommend that the cushion is not exposed to temperatures exceeding 40°C and/or high humidity environments.

Covers may be hot to touch if exposed to direct sunlight or extreme room temperatures.

4.8 Cushion Disposal

When the cushion has come to the end of its useful life, contact your provider or Drive DeVilbiss Healthcare Ltd. to arrange for collection, or follow local recycling and disposal policies.

Any components should be recovered and reused / recycled where possible. The cushion cover is to be disposed in general municipal waste. The cushion foam and the plastic polyethylene bag supplied with the cushion can both be recycled at recycling centres that offer suitable PU foam and plastic recycling programs.

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

4.9 Biocides

Foam cushions contain a biocide anti-fungal agent to control microbial deterioration. The active ingredient is Folpet (CAS number 133-07-3). The product does not contain any nano-materials.

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

Foam cushion products are free from natural rubber latex.

5. General Information

5.1 General Instructions

- Remove all packaging materials and allow the cushion to lie flat at ambient temperature for a minimum of 2 hours before use. This will allow the foam to condition.
- Assess the cushion for any damage which may have been caused during transit.
- Memory foam (visco-elastic) cushions are heat sensitive. In rooms where the temperature is below 18°C, the cushions may initially feel firmer than expected. The cushion will adjust when absorbing body heat.
- The cushion may have a slight odour when first unpacked; this is normal and will not cause harm. This odour will dissipate over the course of a few days.
- Ensure the cushion is suitable for the product combination (seat, wheelchair, etc.).
- Ensure the cushion is suitable for the intended patient and maximum patient weight.
- To ensure the most appropriate pressure prevention, 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.
- Avoid using additional covers or padding between the seat and the patient as this may affect the pressure redistributing qualities.

To ensure the most appropriate pressure prevention, it is important the patient can either reposition themselves or are repositioned on a regular basis; please follow local policy.

- Incompatible seats can create stability / safety hazards.
- If the cushion is located in an environment which is at an elevated temperature, the risk of developing a pressure-related injury may increase due to a potential moisture build-up between the cushion and patient — Regular skin checks must be carried out.
- Any serious incident that occurs in relation to the device should be reported to the manufacturer immediately.

5.2 Damage Prevention

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

- Do not place sharp objects such as hypodermic needles or scalpels onto the cushion.
- Avoid wearing protruding jewellery, such as rings with large stones or watches.
- Take extra care when using medical devices such as drip stands.

5.3 Transporting

Where possible, it is recommended the transport of multiple cushions should be carried out on a flat based trolley. Do not throw the cushions. Please follow local moving and handling policies and guidelines.

6. Cushion Inspection

Cushions and seating support surfaces should be assessed on a regular basis to ensure they are fit for purpose, clinically effective and pose no risk of cross infection to the patient or care provider.

Drive DeVilbiss Healthcare Ltd. recommend a thorough inspection of both the interior and exterior of the cushion is carried out on a weekly basis, and prior to a new patient being placed onto the cushion. Visual checks should be carried out daily for signs of damage to reduce the risk of cross infection.

If there are any signs of contamination or damage to the foam or cover, the cushion should be withdrawn from use immediately and a replacement part or product sourced. Failure to do so could put patients and carers at risk.

How to assess the cushion:

- Ensure the cover is suitable for the type of cushion in use.
- Ensure screen print on top cover is in good condition and readable.
- Check the foam core for any signs of fluid ingress/staining.
- Check for any signs of tearing and/or punctures.
- Check seams for signs of splitting.
- Check the zips for any signs of damage.
- Unzip the cover and assess the white inner substrate for any signs of ingress or staining.
- Ensure the top, base and all four sides of the cushion are assessed.
- Ensure any support surfaces (chairs, wheelchairs etc.) are inspected according to the manufacturer's recommendations.
- Ensure foam shows no signs of permanent deformation or compression.

7. Cleaning and Decontamination

- Personal protective equipment must be worn during the entire cleaning process to prevent the risk of infection.
- Regular cleaning and disinfection of the cushion will help to prevent the risk of infection to the occupant and/or carer.
- Prior to transferring the cushion to another user, ensure it has been cleaned and disinfected using the method as detailed to help prevent the risk of cross contamination.
- Deviating from the specified cleaning and decontamination instructions could cause a biological hazard and adversely affect the life and efficiency of the product.

It is critical to take note of the orientation of the internal foam in relation to the cushion cover before removing the cover. This is vital for the correct reassembly of the cushion after cleaning.

7.1 Inspection

Before attempting to clean the cushion, covers are 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 and to the foam and inspecting the foam for dampness.

- Replace the cover if strike-through is evident – Risk of cross contamination.
- Replace the cover if there are any signs of damage (tearing, punctures, abrasion, damaged seams etc.)
- If the foam core has been contaminated in any way, the cushion must be removed from use immediately – Risk of cross infection.

7.2 General Cleaning

After each patient use the cushion must be cleaned. Drive DeVilbiss Healthcare Ltd. recommend the following cleaning instructions for cushion covers only:

- Using a clean, moistened, single-use wipe, clean the cushion with mild detergent 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 dry fully before putting back into use.
- Ensure the internal foam is orientated correctly to the cushion cover when reassembling.

Do not steam clean or use in a autoclave.

7.3 Decontamination

If the cushion cover is heavily soiled or has been exposed to bodily fluids, follow your organisation's decontamination procedure.

Alternatively:

- Mop up any fluid with paper towels.
- Rinse the cover 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) can 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 dry fully before putting back into use.
- Ensure the internal foam is orientated correctly to the cushion cover when reassembling.

- Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the cushion.
- Do not use alcohol, biological or phenol based cleaning solutions.
- Do not use any abrasive compounds or cleaning pads.

7. Cleaning and Decontamination

7.4 Laundering

Decontamination of the cushion cover may be achieved by laundering; launder as per your organisation's decontamination policy.

Alternatively:

- Remove cushion cover.
- 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.

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

7.5 Drying

To increase the longevity of the covers, it is recommended the covers are drip dried. However, cushion covers can be tumble dried on a low heat setting for 90 minutes. Drying temperature must not exceed 40°C.

- Exceeding this temperature could cause significant damage to the cushion cover.
- Covers must be completely dried before refitting to the cushion foam.

8. Specification

8.1 Risk Factors

The Drive DeVilbiss Healthcare range of pressure care cushions are intended to assist the user with pressure redistribution, as part of an overall plan of care. It is the care providers responsibility to perform a risk assessment to ensure that the cushion selected is appropriate for the user.

At Risk

Patients considered to be 'at risk' of developing a pressure injury are those who, after assessment using clinical judgement and/or a validated risk assessment tool, are considered to be at risk of developing a pressure injury.

At High Risk

Patients considered to be 'at high risk' of developing a pressure injury usually have multiple risk factors (for example, significantly limited mobility, nutritional deficiency, inability to reposition themselves, significant cognitive impairment) identified during risk assessment, with or without a validated risk assessment tool.

For more information visit:
www.nice.org.uk/guidance

8.2 Technical Information

Technical information including the; cushion dimensions, maximum patient weight and product weight, can be found on the product labels inside the cushion covers.

All Drive DeVilbiss Healthcare foam cushions are Class 1 medical devices.

For the full range of Drive DeVilbiss Healthcare Ltd. cushions and products, please visit:
www.drivedevilbiss.co.uk

9. Warranty

Warranty

The range of Drive DeVilbiss Healthcare Ltd. foam cushions are covered by a comprehensive manufacturer's warranty covering manufacturing defects arising from poor workmanship, materials or assembly. The warranty starts from the date the products are delivered and remains in place for the identified warranty period specific to the product you have purchased; please check your specific products information label to identify the associated warranty period.

Drive DeVilbiss Healthcare Ltd. maximum liability is to replace the product free of charge should the product fail under warranty, provided that written details of the said defect are sent to Drive DeVilbiss Healthcare Ltd. and proof of purchase is provided. Drive DeVilbiss Healthcare Ltd. reserves the right to request the return of the product for inspection. Drive DeVilbiss Healthcare Ltd. do not accept any claims for consequential losses resulting from any failure of a product under warranty.

Warranty will not apply if:

- The product has been used other than for its specified use,
- Cleaning and decontamination has not been carried out in line with the manufacturers recommendations,
- The product has not been stored correctly,
- Alterations to the cushion have been made,
- Notice of defects have not been highlighted to supplier within the warranty time period,
- The product has suffered malicious damage,
- The product has been affected by strikethrough,
- Due to expected wear and tear.

Notes

CONTACT INFORMATION
Tel: +44 (0) 845 0600 333 Fax: +44 (0) 845 0600 334
Email: info@drivedevilbiss.co.uk
www.drivedevilbiss.co.uk
Drive DeVilbiss Healthcare Ltd., Holmfield, Halifax,
West Yorkshire, HX2 9TN, United Kingdom

A member of the Drive DeVilbiss Group of Companies

ORIGINAL INSTRUCTIONS
INSTRUC/STATIC/CUSH, 2023/03 — Rev3