

Field Safety Notice - FSN201002



STATIC MATTRESSES Modifications to user instructions

Date: 6th October 2010

Telephone: 0845 0600 333
Fax: 0845 0600 334
Email: info@parkhouse-hc.com
Web: www.parkhouse-hc.com

Attention: Community Stores, Service Centres, PCTs, Acute Hospitals, Nursing Homes, Hospices and Service / Maintenance Engineers.

Details on affected devices:

This notice relates to our "Guide to Correct Mattress Use" for static mattresses.

Description:

We would like to bring your attention our updated "Guides to correct mattress use". Mattress inspection instructions have been printed on covers since December 2009, however customer with static mattresses older than this may not be aware of the correct method to inspect mattresses. This updated guide to mattress use advised how to complete this correctly.

Advice on action to be taken:

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the mattresses are used. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this action.

A complete copy of this guide is included with this Field Safety Notice.

Park House Healthcare Ltd confirms that the relevant authorities have been informed of this Field Safety Corrective Action.

Contact reference person:

Roy Smith – Operations & QA Manager

Park House Healthcare Ltd, Whitehall 26 Business Park, 1 Heathfield Lane, Birkenshaw, West Yorkshire. BD11 2HW

FAX BACK FORM

FSN201002

Telephone: 0845 0600 333
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Email: info@parkhouse-hc.com
Web: www.parkhouse-hc.com

Update to our “Guide to correct mattress use”.

As part of the MHRA vigilance and reporting structure, we are required to feed back that the FSN has been acknowledged and the appropriate actions have taken place. In this case, the updated instructions for use amendments have been noted and that they have been passed on to all users and relevant personnel for whom they may effect.

We would be grateful if you could **sign** and either e-mail or fax this form back to:

Roy Smith – Operations & QA Manager Fax Number: 0845 344 2648 e-mail: roy.smith@parkhouse-hc.com

Organisation Name:

Organisation Address:

Name:

Position:

Signed:

Date:

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A GUIDE TO CORRECT STATIC MATTRESS USE

Park House Healthcare recommend that mattresses should be used and maintained in accordance with the following guidelines:

1. INSTRUCTIONS FOR USE

- Check if the mattress is a replacement or an overlay (see section 5. Mattress Specifications)
 - If it is a replacement mattress it should be placed directly on to the bed frame
 - If it is a mattress overlay it should be placed on top of the existing mattress
- Check that the safe working load of the mattress is suitable for the intended user (see section 5. Mattress Specifications). **Do not exceed the safe working load of the mattress**
- Check that the Risk Factor is suitable for the intended user (see section 5. Mattress Specifications). **To help prevent pressure damage it is important that patients reposition themselves, or are repositioned regularly**
- Mattresses are delivered in plastic covers for protection; these covers must be fully removed before use
- When being used for the first time allow 1 hour before placing the patient on the mattress (depending on the room temperature)
- With the exception of bed sheets avoid using any additional covers/padding between the patient and the support surface, as this may affect its pressure reducing qualities

2. MATTRESS DAMAGE PREVENTION

General Use

Take extra care not to puncture the cover as this will allow fluid ingress to contaminate the foam core. To prevent the cover from being punctured and/or damaged:

- Do not place sharp objects such as hypodermic needles, scalpels, etc, on the mattress,
- Avoid wearing protruding jewellery i.e. rings with large stones,
- Take extra care when using medical equipment such as monitors, drip stands, side rails, transfer boards, etc

Storage

For ease of storage mattresses can be stacked on top of one another. To prevent mattresses becoming contaminated and/or damaged during storage:

- Mattresses should be stored flat,
- Mattresses should be stored within a plastic cover/bag,
- Do not store other objects such as side rails or bed ends on top of mattresses,
- Allow adequate space for the stored mattresses to be manoeuvred by two people

Moving and Handling

Where possible, mattresses should be stacked flat and transported on a bed base. Mattresses should be handled by two people at either end of the mattress. **Do not drag or pull mattresses by their cover**

3. MATTRESS CLEANING AND CARE

Mattresses are fully encased in a protective waterproof, multi stretch PU cover to help prevent fluid ingress from damaging the foam core. **The mattress cover should be cleaned regularly in accordance with your organisations' disinfection protocol.**

Park House Healthcare recommend the following cleaning procedures **for mattress covers only**:

General Cleaning

Before cleaning, mattress covers should be completely removed; the foam core should not be cleaned. **If the foam core is contaminated in any way, the mattress should be removed from use immediately.**

Using a single use wipe, clean the mattress cover with a solution of neutral detergent and hot water. Rinse thoroughly with clean water and a damp single use wipe. Make sure the cover is completely dried before re-fitting to the mattress.

Disinfecting the cover

If the cover is heavily soiled or has been exposed to bodily fluids such as blood, it will require a more thorough cleaning procedure:

Wipe the cover using a single use wipe and a 0.1% Chlorine Solution (1,000ppm). If required a 1% Chlorine Solution (10,000ppm) can be used. Rinse thoroughly with clean water and a damp single use wipe. Make sure the cover is completely dried before re-fitting to the mattress.

Laundering

Where required all mattress covers can be removed and laundered as follows:

Pre wash	80°C + 15 minutes
Main wash	80°C + 15 minutes

This should be followed by a cold rinse and extraction.

Drying

Mattress covers should be hung from a line or bar and drip dried in a clean indoor environment. Covers must be completely dried before re-fitting to the mattress.

Tumble drying

Mattress covers can be tumble dried on a low heat setting for 90 minutes. **Drying temperature must not exceed 40°C. Exceeding this temperature can cause significant damage to the mattress cover.**

4. MATTRESS INSPECTION RECOMMENDATIONS

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.

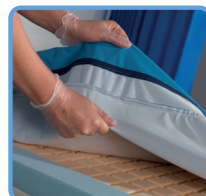
Park House Healthcare recommend that a thorough inspection of both the interior (foam core) and exterior (cover) of the mattress is carried out weekly, or each time a new patient is placed on the mattress. Visual checks should be carried out daily to identify any significant signs of damage or infection risk.

How to check a mattress

Condition of the foam and cover - what to look for:

Daily/weekly checks:

1. Check for any signs of staining
2. Check for any signs of tearing and/or punctures
3. Check all the seams for signs of splitting
4. Check the zip(s) for any signs of damage
5. Unzip, and inspect the cover internally for any signs of fluid ingress/staining
6. Ensure that the cover is suitable for the type of mattress in use
7. Check the foam core for any signs of fluid ingress/staining



If any signs of contamination are identified on the cover, the mattress should be withdrawn from use immediately until the cover is replaced.

If the foam and the cover are both showing signs of contamination the mattress should be removed from use immediately and the entire mattress should be replaced. **Failure to do so will pose significant risk of infection to both the patient and the carer.**

NOTE: the top, bottom and all four sides of the mattress must be checked

Condition of the foam - Mount Vernon Test:

The Mount Vernon Test should be performed at least once monthly to ensure the foam has not bottomed out and the mattress is still delivering adequate support and pressure reduction for the patient.

How to perform the Mount Vernon Test:

1. Make sure the mattress is level with your trochanter (hip bone) and the cover is in place.
2. Stand at the side of the bed and link your hands to form a fist (Fig.1)
3. Keeping your elbows straight, lean forward and push the fist into the mattress along the seven points indicated below (Fig.2):



Fig.1

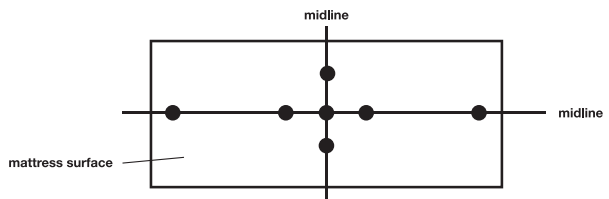


Fig.2

If the base of the bed can be felt at any point then the mattress has bottomed out and should be removed from use immediately. **Failure to do so will pose significant risk of pressure damage to the patient.**

5. MATTRESS SPECIFICATIONS

Air-Layer Replacement Mattress

Weight Limit - 39 stones/247.7 kgs
Very High Risk
Mattress Weight - 16 kgs
Non turn

Memaflex Replacement Mattress

Weight Limit - 39 stones/247.7 kgs
High Risk
Mattress Weight - 16 kgs
Non turn

Permafex Plus Replacement Mattress

Weight Limit - 39 stones/247.7 kgs
High Risk
Mattress Weight - 14 kgs
Non turn

Permafex Non-turn Replacement Mattress

Weight Limit - 39 stones/247.7 kgs
High Risk
Mattress Weight - 13 kgs
Non turn

Permafex Replacement Mattress

Weight Limit - 26 stones/165 kgs
Medium Risk
Mattress Weight - 13 kgs
Four way turn

Duraflex Mattress (zipped cover only)

Weight Limit - 39 stones/247.7 kgs
Medium to High Risk
Non turn

Community Replacement Mattress

Weight Limit - 22 stones/140 kgs
Medium Risk
Mattress Weight - 12 kgs
Four way turn

Air-Layer Mattress Overlay

Weight Limit - 18 stones/114 kgs
Medium Risk
Mattress Weight - 6 kgs
Non turn

Memaflex Mattress Overlay

Weight Limit - 18 stones/114 kgs
Medium Risk
Mattress Weight - 6 kgs
Non turn

Permapad Mattress Overlay

Weight Limit - 17 stones/108 kgs
Medium Risk
Mattress Weight - 4 kgs
Non turn

Newlife Birthing Mattress

Weight Limit - 39 stones/247.7 kgs
High Risk
Non turn

ISO Certificate No: 8019
CE Certificate No: CA001810
Master Indemnity Assurance No: IFA2433 0451 CCI

Due to its policy of continued development and improvement, Park House Healthcare Ltd reserves the right to amend any details and specifications without notice.

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New Corporate Headquarters opened in October 2006

The Company

Founded in 1984, Park House Healthcare Ltd is recognised as one of the leading manufacturers of specialist pressure relieving and pressure reducing equipment in the U.K.

Park House Healthcare Ltd has an extensive product portfolio and the facility to customise products to suit customer needs whilst offering solutions in pressure care, postural management and moving and handling.

Employing over 100 full time staff at our 60,000 sq. ft state of the art Corporate Headquarters in West Yorkshire, Park House Healthcare are proud to offer in-house manufacturing, a full product audit and decontamination service and a network of distribution centres as part of our continued commitment to Customer Care.

24 hour care, 365 days a year dedicated internal personnel manage specific regions and divisions ensuring one on one personal customer service at all times. With distributors in over 25 countries, Park House Healthcare are a truly international company and we place important emphasis on providing high levels of customer care to ensure we exceed customer expectations at all times.

Additional support nationwide is available through our service centres situated strategically around the country.

Park House Healthcare Ltd is a respected member of the British Healthcare Trade Association and has BS EN ISO 9001 and EN46002 accreditation which is the specific quality standard for Medical Devices. All products are CE marked in accordance with the European Directive 93/42/EEC.



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UM-STATICS


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