



رقم المحفوظات: ٣٨٢٥  
رقم الصادر: ١٣/١٤٩٦  
بيروت، في:  
٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Bath and aids, non integral seating, Non integral seating – University bath hoist and University bath hoist transporter

الجهاز المعنى بالمتابعة:

- Bath and aids, non integral seating, Non integral seating – University bath hoist and University bath hoist transporter
- Trade Mark: Unihost Ltd.
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة التي تحذر فيه من استعمال الصنف المذكور أعلاه نظراً لوجود خلل في التصنيع ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة  
د. وليد عمار



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EMAIL: [unihoistltd@btconnect.com](mailto:unihoistltd@btconnect.com)

WEB: [www.unihoist.co.uk](http://www.unihoist.co.uk)

### Important – Urgent Field Safety Notice

FSN Reference: 00002 Unihoist Rev 01

**Date: 28 January 2013**

**Column (pedestal) replacement on University Bath Hoist – All Models. Affected Serial numbers from 2053 to 2093 and 2335 to 2339.**

**Attn:** All distributors, installers, therapists, carers and users of University Bath Hoist and University Bath Hoist Transporter bathing lifts.

**REF: University Bath Hoist and University Bath Hoist Transporter.**

In the interests of safety and patient welfare, please be advised of the following:

#### **Description of the problem:**

This FSN is being issued following an in-house investigation of a manufacturing fault found on the column support. There have been no incidents in the field and we have traced the fault to the batch of columns used on the above serial numbers only.

We have discovered a potential risk of the column support breaking, which could cause the column to fall sideways/forward at an angle, potentially allowing the patient to fall out of the seat (if not wearing a lap belt) and risking serious injury and also serious injury to the carer.

**Unihoist Ltd will replace the columns on the affected hoists and we are contacting all our customers in regards to this FSN.**

#### **Action to be taken by the therapist/carers/user**

- ✓ Identify the Bath Hoist from the serial numbers given above and quarantine the device if applicable.
- ✓ A representative from your distributor/supplier or Unihoist Customer Service Department will contact you in regards to the removal and replacement of the column. If this has not been done within 1 month please contact us on the contact details given in this FSN

To confirm your understanding and compliance to this FSN, complete the FSN receipt form and return it to Unihoist customer services department as instructed.

Directors: S Hudson Company Secretary: A. Nockels  
Reg No. 03645045



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#### Transmission of this FSN

This notice needs to be passed onto all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. This includes a copy of the FSN receipt form.

Please maintain awareness of this notice and any resulting action for an appropriate period to ensure effectiveness of the corrective action.

#### Contact Reference:

Stanley Hudson  
Managing Director  
Unihoist Ltd  
Tel: 01865 881881  
Fax: 01865 883434

Donna Graham  
Office Manager  
Unihoist Ltd  
Tel: 01865 881881  
Fax: 01865 883434

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

This FSN will be made available on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk))

Additional contact information: Unihoist Customer Services Department 01865 881881 or via email: [unihoistltd@btconnect.com](mailto:unihoistltd@btconnect.com) or [sales@unihoist.co.uk](mailto:sales@unihoist.co.uk).

Stanley Hudson  
Managing Director

Directors: S Hudson      Company Secretary: A. Nockels  
Reg No. 03645045