

Medical Device Alert

Ref: MDA/2011/091 Issued: 18 August 2011 at 14:00

Device

All telescopic bed rails (model numbers HCS100, HCS105, HCS106 and HCS107) manufactured by Harvest Healthcare Ltd.



Problem

The manufacturer issued a [Field Safety Notice \(FSN\) for this device on 19 January 2011](#), but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action by

All those using, managing and maintaining hospital beds. In particular: care staff, nurses, maintenance staff and contractors.

CAS deadlines

Action underway: 19 September 2011

Action complete: 18 November 2011

Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

Contact

Manufacturer
Andy Robinson
harvest healthcare Ltd

Tel: 01709 377 172

Fax: 01709 377 173

Email: andy.robinson@hhlttd.biz

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Health and Safety Executive
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All wards and clinical departments
- Adult intensive care units
- All wards
- Day surgery units
- EBME departments
- Equipment store managers
- Intensive care units
- Maintenance staff and contractors
- Medical directors
- Nursing executive directors
- Risk managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Community nurses
- Equipment store managers
- Maintenance staff and contractors
- Risk managers

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Equipment store managers
- Maintenance staff and contractors
- Risk managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Andy Robinson
harvest healthcare Ltd
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham
S60 1 BW
Tel: 01709 377172
Fax: 01709 377173
Email: andy.robinson@hh ltd.biz

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/091** or **2011/001/007/401/013**

Jonathan Smith or David Small
Medicines & Healthcare products Regulatory Agency
Centre for Assistive Technology
241 Bristol Avenue
Bispham
Blackpool FY2 0BR
Tel: 01253 596 000
Fax: 01253 596 177
Email: bav@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ
Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix



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Urgent Field Safety Notice

Harvest Telescopic Bed Rails Hospital Type
Harvest Telescopic Bed Rails Divan Type

Modification To User Instructions

Date: 19th January 2011

Attention:

Community Stores, Service Centres, PCTs, Acute Hospitals, Nursing Homes,
Hospices and Service / Maintenance Engineers and Distributors

Details on affected devices:

This notice relates to User Manuals / Instructions for use of Telescopic Bed Rails, Product code. HCS100, HSC105, HCS106, HCS107.

Advice on action to be taken:

The Installation & Operation section of the instruction for use has been reviewed and rewritten to inform users how to install and use the bed rails safely. A complete copy of these instructions is included with this Field Safety Notice.

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 potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this action.

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



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INSTRUCTIONS FOR USE TELESCOPIC BED RAILS

Hospital Type

Hospital bedrails are fitted to the bed frame by means of 2 pairs of metal frame clamps with spring loaded mounting blocks attached.

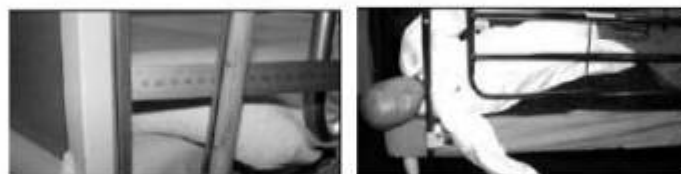
Installation & Operation

1. Examine the bed clamps with the blocks facing towards you and the large hand screw facing downwards. The block should be rotated so that the black release black spring loaded knob is the lower part of the block, and the open hole that will receive the cot side is vertical. The LH clamp has a black release knob on the left, and the RH clamp has a black knob on the right

2. Fit a left and right hand clamp to each side of the bed and lightly tighten the hand screws.
3. Slide the bedrails into the vertical holes of the mounting blocks, noting that the white button stops must face outwards to avoid patient injury.

Ensure that the bedrails are safely locked in the UP position by means of the spring loaded release knobs.

4. Now EXTEND the telescopic bed rails to suit the length and the area of the patient protection required and tighten the four clamps by hand. Once fitted, ensure that all gaps are in accordance with the MHRA Device Bulletin DB2006 (06) – Safe Use of Bed Rails. **NB: Ensure the vertical bar is positioned 60mm or less from the headboard**



5. The bedrails are lowered by retracting the release knobs



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Safety

For your safety and the efficient performance of these bed rails the following precautions should be observed:

1. The bed rails must not be used to move the bed
2. Do not allow the patient to pull themselves up using the bed rails
3. Lower the rail slowly and do not allow it to drop
4. When not in use the rail must be stored in a safe place so as to avoid damage to the pivots and clamps
5. Entrapment hazards exist with these bed rails so a full risk assessment of the patients needs should be undertaken prior to the use of any bed rails to see if they are actually required. Periodic risk assessments should then be carried out to ensure any risks are minimised.
6. Do not fit to a paediatric bed

Further reference to the safe use of bed rails can be found in the MHRA Device Bulletin – DB 2006 (06) December 2006

Maintenance

1. Check the chrome rails have not become deformed
2. Check quick release catch moves freely and locks correctly
3. Check hand screws on clamps are free from damage and tighten correctly

Cleaning

General cleaning of the bed rails may be carried out by using a cloth dampened with a mild detergent and water solution. If rails have become contaminated then they should be wiped down using a sodium hypochlorite solution diluted to 1000 ppm, or similar cleaning agent.

Do not use any abrasive compounds or cleaning pads



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INSTRUCTIONS FOR USE TELESCOPIC BED RAILS

Divan Type

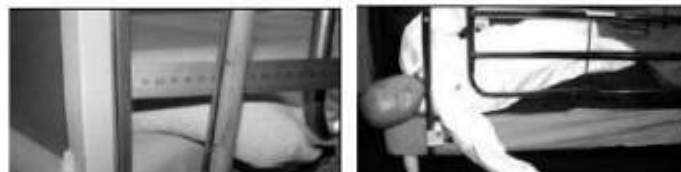
bedrails are fitted to a Divan bed by means of 2 telescopic cross rails which pass over the bed base, below the mattress.

Installation & Operation

1. Adjust the cross rails to the width of the bed, to suit standard widths from 2'6" (762mm) to 4'6" (1372mm) by means of the slide clip system.
2. The cross rails have flat end plates, that fit snugly over the bed base. The block should be rotated so that the black release black spring loaded knob is the lower part of the block, and the open hole that will receive the cot side is vertical. The LH clamp has a black release knob on the left, and the RH clamp has a black knob on the right
3. Slide the bedrails into the vertical holes of the mounting blocks noting that the white button stops must face outwards to avoid patient injury.

Ensure that the bedrails are safely locked in the UP position by means of the spring loaded release knobs.

4. Now EXTEND the telescopic bed rails to suit the length and the area of the patient protection required. Once fitted, ensure that all gaps are in accordance with the MHRA Device Bulletin DB2006 (06) – Safe Use of Bed Rails. **NB: Ensure the vertical bar is positioned 60mm or less from the headboard**



5. The bedrails are lowered by retracting the release knobs



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Safety

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2. Do not allow the patient to pull themselves up using the bed rails
3. Lower the rail slowly and do not allow it to drop
4. When not in use the rail must be stored in a safe place so as to avoid damage to the pivots and clamps
5. Entrapment hazards exist with these bed rails so a full risk assessment of the patients needs should be undertaken prior to the use of any bed rails to see if they are actually required. Periodic risk assessments should then be carried out to ensure any risks are minimised.
6. Do not fit to a paediatric bed

Further reference to the safe use of bed rails can be found in the MHRA Device Bulletin – DB 2006 (06) December 2006

Maintenance

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General cleaning of the bed rails may be carried out by using a cloth dampened with a mild detergent and water solution. If rails have become contaminated then they should be wiped down using a sodium hypochlorite solution diluted to 1000 ppm, or similar cleaning agent.

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FAX BACK FORM

Modifications to the Instructions for use for Harvest Healthcare Telescopic Bed Rails.

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:

Andy Robinson–Sales / QA : Fax Number : 01709 377173 e-mail: andy.robinson@hh ltd.biz

Organisation Name:.....

Organisation Address:.....

.....

Signed:

Print:

Position:.....

Date:



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