

HAZARD NOTICE

By arrangement with the Scottish Executive Health Department



HAZ(SC)07/14
05 SEP 2007
Medical Devices
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HILL-ROM TOTALCARE® DUO 2® PRESSURE RELIEVING HOSPITAL BEDS: RISK OF CROSS INFECTION

SUMMARY

Hill-Rom has supplied TotalCare® Duo 2® pressure relieving hospital beds without instructions for checking, cleaning and disinfection. Action is required to prevent cross infection.

BACKGROUND

1. Hill-Rom manufactures and supplies the TotalCare® Duo 2® pressure relieving hospital bed (see Figure 1, page 2). The mattress is fully enclosed in a waterproof cover manufactured from Protex™ (polyurethane covered in knitted nylon).
2. The Instructions For Use for this bed should have included instructions for checking, cleaning and disinfection of the mattress and Protex™ cover. However, they are contained in a separate document which was not supplied with the beds.
3. The Medicines and Healthcare products Regulatory Agency (MHRA) has received reports of two incidents in which damage to mattress covers enabled body fluids to soak into the mattress resulting in a risk of cross infection for subsequent bed occupants.

ACTION

4. This notice should be brought to the attention of all appropriate managers and staff.
5. All Hill-Rom TotalCare® Duo 2® pressure relieving hospital beds should be identified. Hill-Rom should be contacted (see Enquiries) to arrange for the provision of the instructions for checking, cleaning and disinfection (Cleaning and Disinfection Instructions, Ref. W13001uks rev2).

At the next available opportunity

6. All mattress covers should be unzipped to check for:
 - a) holes in the mattress cover,
 - b) signs of fluid contamination inside the cover or on the mattress.(Precautions should be taken to protect staff from any contamination that may be present).
7. Contaminated mattresses and mattress covers should be removed from use until they have been cleaned and disinfected in accordance with the manufacturer's instructions.

<i>Suggested Distribution</i>	Care Home Services	Community Care	Estates/Facilities
Health & Safety	Hospices	Infection Control Staff	Intensive Therapy Units
Loaned Equipment Stores	Maternity	Medical Physics	Nursing
Risk Management	Stores	Supplies/Procurement	Wards



SCOTTISH HEALTHCARE SUPPLIES

Gyle Square Edinburgh EH12 9EB

A Division of the National Service Scotland for NHSScotland

CONTACT EMAIL: iric@shs.csa.scot.nhs.uk

WEBSITE: http://www.nhsscotland.com/shs/hazards_safety/adverse_p.html

FAX: 0131 314 0722

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Ongoing action

8. The manufacturer's instructions for checking, cleaning and disinfection should be followed between each patient use. Damaged covers should be disposed of appropriately¹.
9. Replacement mattresses and mattress covers are available from Hill Rom (see Enquiries).

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Diane Pitchford
Hill-Rom
Clinitron House
Ashby Park
Ashby de la Zouch
Leicestershire LE65 1JG

Tel: 01530 562 167 (enquiries and requests for instruction documents)
01530 411 000 (orders for mattresses and mattress covers)
Fax: 01530 562 029
E-mail: uk.customer.care@hill-rom.com

REFERENCES

1. Device Bulletin DB 2006(05), *Managing Medical Devices*, Medicines and Healthcare products Regulatory Agency, November 2006 ([website only](#)).



Figure 1



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