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NOTICE

Contoura® 880 Series Hospital Bed Frames

IMB Safety Notice: SN2011(24)

Circulation Date: 04 November 2011

MANUFACTURER/SUPPLIER

ArjoHuntleigh

TARGET GROUPS

Hospital CEOs
Risk Managers
Procurement Managers

ISSUE

ArjoHuntleigh is aware of an issue with the Contoura® 880 Series Hospital Bed Frames, whereby the CPR release arm on the backrest actuator could break during use and render the emergency CPR function inoperable.

BACKGROUND

ArjoHuntleigh issued a field safety notice (SAN/02/10/MBD) in June 2010 notifying users of an issue with the Contoura® 880 Series Hospital Bed Frames, whereby the CPR release arm on the backrest actuator could break during use and render the emergency CPR function inoperable. This field safety notice notified users that a new part had to be fitted to the CPR release mechanism to prevent this issue from re-occurring in the future.

One customer in Ireland has since reported an incident in which the CPR release on a bed with new parts fitted failed to work in an emergency situation. An investigation carried out by the manufacturer indicated that this incident occurred because the replacement CPR release arm was not installed in accordance with the instructions provided by ArjoHuntleigh.

ArjoHuntleigh issued a second field safety notice (FSN/03/2011/MBD) in October 2011. This field safety notice requests:

1. Any outstanding upgrades should be carried out by an ArjoHuntleigh technician.
2. All upgrades previously carried out by the facility's own personnel should be inspected by an ArjoHuntleigh technician to ensure correct fitting and operation.

S A F E T Y NOTICE

ACTION OR RECOMMENDATIONS

ArjoHuntleigh have been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action.

The IMB advises that users:

1. Ensure the appropriate personnel are made aware of this notice.
2. Identify the location of all affected bed frames.
3. If your institution has affected medical devices, please contact ArjoHuntleigh to arrange to carry out the required modification to the bed frame.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Rachel Dempster
ArjoHuntleigh (Ireland) Limited
EA House
Damastown Industrial Park
Mulhuddart
Dublin 15

Telephone: 01-8098960
Fax: 01-8098971
Email: complianceALIE@ArjoHuntleigh.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie