IRISH MEDICINES BOARD
SAFETY NOTICE

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BHM Medical Inc. Hoists

IMB Safety Notice: SN2011(04)
Circulation Date: 1 April 2011

MANUFACTURER/SUPPLIER
BHM Medical Inc.

TARGET GROUPS
Health Board CEOs
Community Care Managers
Community Therapists
Health Visitors
Carers of the Elderly
Risk Managers
Loan Store Managers
Children's Disability Services
Educational Establishments
Theatre and Nursing Staff
Procurement Managers
Nursing Managers
Clinical / Biomedical Engineers

ISSUE
BHM Medical Inc. has become aware that a number of hoists may have been fitted with an incorrect power cable on the control box.

BACKGROUND
BHM Medical Inc. has confirmed that a number of hoists manufactured from May 2004 to March 2006 inclusive may have been fitted incorrectly with a single insulated power cable which increases the risk of premature failure. A power cable failure may result in the hoist structure becoming live when the hoist is connected to the mains supply for battery charging and could expose the caregiver or patient to a risk of electrical shock.

The following hoists are potentially be affected by this issue:

- Cricket – 3
- Cypress – 2
- Ergolift
- Ergolift 600
- ErgoStand
- Explorer
- Explorer 600
- Graduate
- Junior
- Medilifter-IV
- Mezzo
- Ministand
- ML-4
- Primo
- Sherpa
- SSL-2
- Standup
- Trekker
- Xtreme

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The manufacturer issued a field safety notice in February 2010 to advise users how to identify the affected cables. The affected cables are to be replaced with double insulated cables.

ACTION OR RECOMMENDATIONS

The manufacturer and the distributors of this device in Ireland have been unsuccessful in their attempts to locate all hoists affected by this field safety corrective action (FSCA).

The IMB advises that users:

- Follow the manufacturer's recommendations as outlined in the attached field safety notice.
- Identify the affected hoists in your facility and contact the manufacturer to arrange for a power cable replacement.
- Remove any affected devices from service pending installation of the new power cable.

ENQUIRIES

Enquiries to the manufacturer / European authorised representative should be addressed to:

Mr. Paul Lovell
Group Regulatory Approvals Manager
ArjoHuntleigh
310-312 Dallow Road
Luton Bedfordshire
LU1 1TD
United Kingdom

Tel: +44 (0)1582 745891
Email: paul.lovell@huntleigh-technology.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