IRISH MEDICINES BOARD

Notice Information: - Advisory
01 April 2011

Part 1. Product Information

a)	Title:	BHM Medical Inc. Hoists
b)	Product Name/Type:	BHM Medical Inc. Hoists
c)	Reference:	IMB Safety Notice: SN2011(04)
d)	Manufacturer/Supplier:	BHM Medical Inc.

Part 2. Target Audience

a) Target Audience:

- 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

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a) Background Information:

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

The manufacturer issued a field safety notice in February 2010 to advis

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.

Part 5. Action to be taken

a) Action to be taken:

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.

Part 6. Enquiries

a)	All enquiries should be made to:	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 Please Click here to download a PDF Version of the Safet

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