IRISH MEDICINES BOARD

Notice Information: - Advisory
14 March 2014

Part 1. Product Information

a)	Title:	Pegasus Alternating Mattresses X2 Capacitor Upgrade Program
b)	Product Name/Type:	Pegasus Alternating Mattresses X2 Capacitor Upgrade Program
c)	Reference:	SN2014(10)
d)	Manufacturer/Supplier:	ArjoHuntleigh (Ireland) Limited

Part 2. Target Audience

a) Target Audience:

- Hospital CEOs
- Risk Managers
- Procurement Managers
- Loan Store Managers
- Biomedical Engineers
- Nursing Managers
- Nursing Staff
- HSE Offices
- Community Care Centres
- Community Care Managers
- Health Visitors
- Nursing Homes
- Carers

Part 3. Problem/Issue

a)	Problem/Issue:	ArjoHuntleigh received a recent report of a failure of an internal component causing the power management unit to fail due to overheating of the component. This resulted in the evacuation of a healthcare facility as a result of smoke generated when the component failed.

Part 4. Background Information

a)	Background Information:	In June 2010, ArjoHuntleigh initiated a field safety corrective action to upgrade Pegasus Alternating Mattresses with Biwave, Cairwave, Trinova and Viaclin pumps, pre-2006. This upgrade was introduced following a number of incidents relating to failure of an internal component causing power management unit failure due to overheating of a component, which could result in loss of therapy when the air pump stops and where non-toxic smoke can be emitted as the component fails. ArjoHuntleigh has been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action. A recent incident in Ireland of this type of failure resulted in a facility evacuation as a result of smoke generated when the component failed. There are 134 affected pumps on the Irish market, requiring an upgrade, which cannot be located. Please see the PDF version of this Safety Notice for a least of the remaining serial numbers which remain unaccounted for. Further details of the corrective action can be found in the attached updated field safety notice (FSN) issued by ArjoHuntleigh.

Part 5. Action to be taken

a)	Action to be taken:	The IMB recommends that users: (1) Forward this safety notice to all those who need to be aware of this action within your organisation, including those who maintain pumps and to any other persons/organisations where these devices have been transferred. (2) Identify the location of all affected pumps. (3) If you / your institution have any affected pumps, please follow the manufacturer's recommendations as outlined in the attached FSN and contact ArjoHuntleigh.

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the manufacturer should be addressed to: Rachel Dempster ArjoHuntleigh (Ireland) Limited EA House Damastown Industrial Park Mulhuddart Dublin 15 Phone: 01-8098960 Fax: 01-8098971 Email: rachel.dempster@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 Please click here to view a copy of FSN 2010 Pleas

Please click here to view a copy of FSN 2010

Please click here to view a copy of FSN 2014

Please click here to view a PDF version of the Safety Notice