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NOTICE**

Pegasus Alternating Mattresses X2 Capacitor Upgrade Program

Affected pumps include Biwave, Cairwave,
Trinova and Viaclin Pumps, pre 2006

IMB Safety Notice: SN2014(10)
Circulation Date: 14 March 2014

MANUFACTURER/SUPPLIER

ArjoHuntleigh (Ireland) Limited

TARGET GROUPS

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

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.

BACKGROUND

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

S A F E T Y NOTICE

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.

The following serial numbers remain unaccounted for:

102144	BC104270	OV11949	OV8679
102926	BC104271	OV11999	OV9116
103131	BC104272	OV12016	OV9224
103595	BC104273	OV12039	OV9225
104070	BC104276	OV12275	OV9226
104392	BC104277	OV12394	OV9227
104395	BC104417	OV12399	OV9659
104637	BC104497	OV12461	OV9661
104889	BC104539	OV12531	OV9721
104891	BC104558	OV12665	OV9722
104954	BC104741	OV12902	OV9723
105114	BC104747	OV7012	OV9731
105378	BC104871	OV7013	OV9994
105384	BC104886	OV7031	TR100072
106831	BC104896	OV7035	TR100149
105791	BC104909	OV7036	TR100457
106038	BC104928	OV7046	TR101868
BC100358	BC105276	OV7047	TR101913
BC100497	OV10075	OV7056	TR102472
BC101498	OV10078	OV7127	TR102895
BC101506	OV10093	OV7197	TR102969
BC101509	OV10105	OV7202	TR102970
BC102118	OV10121	OV7203	TR103127
BC102179	OV10164	OV7430	TR103424
BC102224	OV10169	OV7542	TR103550
BC102228	OV10177	OV7585	TR103649
BC102708	OV10178	OV7598	TR103929
BC102709	OV10536	OV7769	TR103931
BC102724	OV11555	OV7796	TR103932
BC103202	OV11645	OV8032	TR103934
BC103319	OV11659	OV8256	TR104019
BC104003	OV11765	OV8257	TR104342
BC104268	OV11774	OV8258	
BC104269	OV11945	OV8676	

Further details of the corrective action can be found in the attached updated field safety notice (FSN) issued by ArjoHuntleigh.

S A F E T Y NOTICE

ACTION OR RECOMMENDATIONS

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.

ENQUIRIES

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