

Our Ref : Re-Issue PEG TAN A/018D/04

14 March 2014

Customer
Address 1
Address 2
Address 3
Address 4

FOR THE ATTENTION OF MAINTENANCE MANAGER/RISK MANAGER

Dear Customer

**PEGASUS ALTERNATING MATTRESSES X2 CAPACITOR UPGRADE PROGRAM
PRODUCTS AFFECTED : BIWAVE, CAIRWAVE, TRINOVA AND VIACLIN PUMPS – PRE 2006**

Back in 2010 we wrote to you in relation to the above upgrade program which was part of a Field Safety Corrective Action PEG TAN A018D/04. Despite previous contact attempts a response HAS NOT been received and our records show that your systems may not have been upgraded in line with the Field Safety Notice.

This upgrade was introduced following a manufacturer investigation into a limited 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.

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, this has required us to contact you again to establish if you still have any systems in use and to complete the upgrade on any systems outstanding.

Please find attached a copy of the original Field Safety Notice and Customer Reponse Form issued in relation to the above products. The Customer Response provides details of the product serial numbers that we have on record. If you are not the appropriate contact for your facility, please direct it accordingly. Please complete the Customer Response as soon as possible and return to us on or before 30/03/2014.

On receipt of your response ArjoHuntleigh will arrange for a Service Engineer to call and inspect and where appropriate modify affected pump units. This upgrade is entirely free of charge.

If you are no longer the holder of this equipment, or the equipment is no longer in use, please advise using the response form so that we can update our records accordingly.

We are working closely with the IMB to manage completion of this action and will provide feedback to them on progress to facilitate closure of the Field Action.

ArjoHuntleigh (Ireland) Ltd.
EA House,
Damastown Industrial Park,
Mulhuddart, Dublin 15,
Ireland
Phone: 01 809 8960
Fax: 01 809 8971
Email: dublin@ArjoHuntleigh.com

www.ArjoHuntleigh.com

Our total commitment to high quality products ensuring the safety of users and patients is always paramount.

If you have any queries please do not hesitate to contact me or Rachel Dempster our Compliance Administrator.

Thank you in advance for your co-operation.

Yours faithfully



Julie Stranaghan
Business Support Manager

ArjoHuntleigh

UK & Ireland GETINGE GROUP

T: +44 (0)28 9050 2000 / +353 (0) 1 809 8960

DDI: +44 (0)28 9050 2013 / 048 9050 2013

F: +44 (0)28 9050 2001 / +353 (0)1 809 8971

M: +44 (0)7817 279667

W: www.arjohuntleigh.com

MEMBER OF THE GETINGE GROUP

ArjoHuntleigh (Ireland) Ltd.

EA House,
Damastown Industrial Park,
Mulhuddart, Dublin 15,
Ireland
Phone: 01 809 8960
Fax: 01 809 8971
Email: dublin@ArjoHuntleigh.com

www.ArjoHuntleigh.com

Registered Office: ArjoHuntleigh (Ireland) Ltd, EA House, Damastown Industrial Park, Mulhuddart, Dublin 15. VAT No: IE82380340
Registered in Ireland No: 238034 • Directors: W Dorrian (British), A Khakhar (British), K Ibrahim (British)

FIELD SAFETY NOTICE - PEGASUS X2 CAPACITOR UPRGRADE PROGRAM

CUSTOMER RESPONSE FORM

PLEASE COMPLETE AND RETURN THIS FORM ASAP BUT NO LATER THAN 30 MARCH 2014

Email: rachel.dempster@arjohuntleigh.com

Tel : 01 809 8960 Fax : 01 809 8971

Product: Biwave, Cairwave, Trinova & Viaclin Alternating Mattress Systems

Affected Devices: Pre 2006 Pumps

Please fill in the tables below, including current location of pump unit.

If the product is no longer in service, or cannot be located, please tick the NOT LOCATED box.

Facility Name:	
Address:	
Contact Name:	
Contact Telephone No:	
Contact Email address:	

PRODUCT	SERIAL NO	LOCATION	NOT LOCATED
<i>Eg Trinova</i>	<i>TR104378</i>	<i>Ward 7, Surgical</i>	<input type="checkbox"/>
<i>Eg Biwave</i>	<i>BC123456</i>	<i>Condemned-out of service</i>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

Print Name:	Signature:
Position:	Date:

ArjoHuntleigh (Ireland) Ltd.
 EA House,
 Damastown Industrial Park,
 Mulhuddart, Dublin 15,
 Ireland
 Phone: 01 809 8960
 Fax: 01 809 8971
 Email: dublin@ArjoHuntleigh.com

www.ArjoHuntleigh.com