

URGENT: Field Safety Notice21st June 2010

ArjoHuntleigh Reference: PEG TAN A/018D/04

Dear Customer,

Following an investigation by the manufacturer into a limited number of incidents relating to the failure of an internal component, an upgrade programme was initiated to replace an ECU within the pump unit of the product range detailed below (page 2).

Please see below the actions required to assist with this programme.

	Further Information
DEVICE: ArjoHuntleigh alternating pressure therapy systems.	▶
PROBLEM: Loss of therapy due to power management unit failure, caused by overheating of an internal component.	▶
ACTION BY: All those involved in the supply, maintenance or use of these devices.	
ACTION: <ul style="list-style-type: none"> • Identify whether device is affected (check serial number) • Contact ArjoHuntleigh to arrange modification of power management unit. 	▶
DISTRIBUTED to: All listed customers of affected products	▶
CONTACTS: Details of manufacturer contacts, IMB contacts for technical and clinical aspects.	▶
FEEDBACK REQUIREMENTS: Complete and return the Customer Response form	▶

▶ Further information supplied in the following pages.

DEVICE:

ArjoHuntleigh alternating pressure therapy systems as follows:

Model	Serial numbers affected	
Bi-Wave Plus	All units	
Bi-Wave Carer	BC100000	to BC105142
Cairwave	100000	to 106901
Trinova	TR100000	to TR104379
Viaclin	OV7000	to OV12761

The affected part is a component within the power management unit. The power management unit, could be connected to a mattress, but might instead be connected to an alternating pressure cushion which is sold as an accessory.

The serial number is located on the back of the power management unit.

PROBLEM:

ArjoHuntleigh is aware of several incidents involving failure of a component within the power management unit. Overheating of this internal component has caused the air pump to stop and, in some cases, non-toxic smoke to be emitted.

ArjoHuntleigh have informed IMB that in the event of such a failure the unit's alarm will activate, and mattress deflation will take several hours.

Since the original upgrade programme to fit a varistor loom, initiated in 2004, was upgraded in 2005 to replace the ECU, ArjoHuntleigh has experienced delays in contacting all end users affected by this issue. Improvements have been put in place to improve the supply of new ECU's and a dedicated Corrective Action engineer has been recruited to complete Corrective Actions on customer product in Ireland in a timely manner.

Scheduled monthly FSCA Management Reviews have been implemented to monitor and track progress.

ArjoHuntleigh have identified the cause of the failure, and have replacement power management units ready for installation within the affected units.

ACTION:

- Customers will receive a Customer Response form (V1408/A/018D/04JS) containing the associated serial numbers as supplied to you (the customer).
- Please complete and return the Customer Response form, no later than 31st July 2010, to ArjoHuntleigh Service Department (contact details given below).
- On receipt of your response ArjoHuntleigh Service Department will arrange for a service engineer to call and modify all affected pump units. This upgrade is free of charge.
- If you are no longer the holder of this equipment, please advise us so we can update our database accordingly.
- Inform ArjoHuntleigh Service Department of any affected devices that are used in settings where there may not be anyone to respond to a failure, as these will be given priority.
- ArjoHuntleigh have advised IMB that affected devices do not need to be taken out of service whilst awaiting this modification, but if failure occurs, mattresses should be set to transport mode and disconnected from the power management unit. Failed power management units should be withdrawn from service immediately.

We would like to reassure you that only devices listed above are affected by this action.

Ian Clinch

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