

# MEDICAL DEVICE ALERT

Issued: 07 October 2008 at 11:30

Ref: MDA/2008/071

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

<b>Device:</b> Alternating air mattress pumps models PHP198,396, 398 and 399 supplied by Park House Healthcare Ltd.	► Page 2		
<b>Problem:</b> Failure of timer mechanisms leading to the loss of pressure relief.	► Page 2		
<b>Action by:</b> All those involved in the use, provision and maintenance of alternating air mattresses that use the PHP198, 396, 398 and 399 pumps. In particular: equipment managers, maintenance staff and contractors.			
<b>Action:</b> <ul style="list-style-type: none"> <li>- Trace all PHP198, 396, 398 and 399 pumps.</li> <li>- Obtain latest maintenance instructions from Park House Healthcare Ltd.</li> <li>- For pumps over three years old obtain replacement timer mechanisms and arrange for them to be fitted.</li> <li>- Update local maintenance procedures to align with the latest instructions to replace the timer mechanisms on pumps when they are three years old.</li> </ul>	► Page 2		
<b>Distributed to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;">           NHS trusts in England            Commission for Social Care Inspection (CSCI)            Healthcare Commission (CHAI)            Primary care trusts in England            Social services in England            NHS Boards in Scotland         </td> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> <li>- Chief Executives*</li> <li>- Headquarters</li> <li>- Headquarters</li> <li>- Chief Executives*</li> <li>- Directors*</li> <li>- Chief Executives</li> </ul> </td> </tr> </table> <p style="text-align: right; margin-right: 20px;">* via CE Bulletin</p>	NHS trusts in England Commission for Social Care Inspection (CSCI) Healthcare Commission (CHAI) Primary care trusts in England Social services in England NHS Boards in Scotland	<ul style="list-style-type: none"> <li>- Chief Executives*</li> <li>- Headquarters</li> <li>- Headquarters</li> <li>- Chief Executives*</li> <li>- Directors*</li> <li>- Chief Executives</li> </ul>	► Page 2
NHS trusts in England Commission for Social Care Inspection (CSCI) Healthcare Commission (CHAI) Primary care trusts in England Social services in England NHS Boards in Scotland	<ul style="list-style-type: none"> <li>- Chief Executives*</li> <li>- Headquarters</li> <li>- Headquarters</li> <li>- Chief Executives*</li> <li>- Directors*</li> <li>- Chief Executives</li> </ul>		
<b>Contacts:</b> Details of manufacturer contacts and contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	► Pages 2-3		

## Action deadlines for the Central Alerting System (CAS)

Deadline (action underway): 07 November 2008

Deadline (action complete): 07 January 2009

This notice is also on our website: <http://www.mhra.gov.uk>

## Device:

PHP198, 396, 398 and 399 pumps supplied by Park House Healthcare Ltd that are over three years old. These pumps are used with a wide range of Park House mattresses and may have been supplied with a new mattress or as a replacement pump. Each pump is labelled with a unique serial number. The first four digits of the number specify the year and month of manufacture (e.g. 0801... is January 2008).

## Problem:

The MHRA has received reports of the pump timer mechanism failing in use (on pumps over three years old). Failure of this timer mechanism results in a loss of the pressure relief characteristics as the cells of the mattress do not alternate correctly. This increases the risk of the patient developing pressure ulcers if a replacement pump is not readily available.

Park House Healthcare Ltd has now revised the maintenance instructions for the PHP198, 396, 398 and 399 pumps to include replacement of the timer mechanism when they are three years old. The maintenance instructions include details for replacing the timer.

Park House Healthcare Ltd has issued a Field Safety Notice to inform existing users of the need to change the timer mechanism when they are three years old. However, they do not have full traceability for all pumps especially where they have been passed on to second or subsequent users.

## Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

### Trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Biomedical engineering staff
- Equipment stores
- Health and safety managers
- Maintenance staff and contractors
- Medical physics departments
- Nursing directors
- Nursing staff
- Occupational therapists
- Risk managers
- Tissue viability staff

### Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Community nurses
- Equipment stores managers
- Maintenance staff and contractors
- Occupational therapists
- Risk managers
- Tissue viability staff

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector

### Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care
- Care homes providing personal care
- Domiciliary care providers
- FECs registered as care homes

### Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care management team managers
- Equipment stores managers
- In-house residential care homes
- Occupational therapists

## Contacts:

**Enquiries to the manufacturer should be addressed to:**

Roy Smith  
Park House Healthcare Ltd  
Whitehall 26 Business Park  
1 Heathfield Lane  
Birkenshaw  
West Yorkshire BD11 2HW

Tel: 0845 0600 333

Fax: 0845 0600 334

E-mail: roy.smith@parkhouse-hc.com

## Contacts (continued):

Enquiries to the MHRA should quote reference number **MDA/2008/071** or **2008/001/010/401/007** and be addressed to:

### Technical aspects:

Brian Mather or Jonathan Smith  
Medicines & Healthcare products Regulatory Agency  
Centre for Assistive Technology  
241 Bristol Avenue  
Bispham  
Blackpool FY2 0BR  
Tel: 01253 596 000  
Fax: 01253 596 177  
E-mail: [brian.mather@mhra.gsi.gov.uk](mailto:brian.mather@mhra.gsi.gov.uk)  
[jonathan.smith@mhra.gsi.gov.uk](mailto:jonathan.smith@mhra.gsi.gov.uk)

### Clinical aspects:

Chris Earl  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ  
Tel: 020 7084 3128  
Fax: 020 7084 3111  
E-mail: [chris.earl@mhra.gsi.gov.uk](mailto:chris.earl@mhra.gsi.gov.uk)

### Enquiries for Scotland should be directed to:

Incident Reporting and Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh EH12 9EB  
Tel: 0131 275 7575  
Fax: 0131 314 0722  
E-mail: [iric@shs.csa.scot.nhs.uk](mailto:iric@shs.csa.scot.nhs.uk)

### Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit  
St Nicholas Building  
St Nicholas Street  
Newcastle-upon-Tyne NE1 1NB  
Tel: 0845 015 0120  
E-mail: [enquiries@csci.gsi.gov.uk](mailto:enquiries@csci.gsi.gov.uk)

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London EC1Y 8TG  
Tel: 020 7448 0842  
E-mail: [contacts@healthcarecommission.org.uk](mailto:contacts@healthcarecommission.org.uk)

## How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Telephone 020 7084 3080 or Fax 020 7084 3109  
or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

MHRA is an executive agency of the Department of Health  
© Crown Copyright 2008

Addressees may take copies for distribution within their own organisations