

1. DEVICE/EQUIPMENT:

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).

2. 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.

3. ACTION BY:

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.

4. ACTION:

- Trace all PHP198, 396, 398 and 399 pumps.
- Obtain latest maintenance instructions from Park House Healthcare Ltd.
- For pumps over three years old obtain replacement timer mechanisms and arrange for them to be fitted.
- Update local maintenance procedures to align with the latest instructions to replace the timer mechanisms on pumps when they are three years old.

5. ONWARD DISTRIBUTION TO:

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

- 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
- Community nurses
- Domiciliary care providers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to 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

Enquiries to NIAIC should quote reference number MDEA(NI)2008/075 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

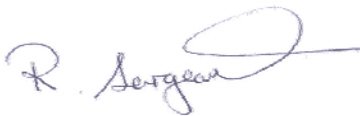
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
10th Oct 2008

Action Under Way:
7th Nov 2008

Action Complete:
9th Jan 2009



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety