Medical Device Alert

Action

Ref: MDA/2010/076 Issued: 29 September 2010 at 15:00

Device

SleepStyle CPAP devices.

Manufactured by Fisher & Paykel Healthcare.

Specific model and lot numbers are affected.

Problem

Risk of cessation of therapy due to deterioration of power cord.

Action by

All those involved in the purchase and use of these devices.

Action

Ensure that all users, including patients at home, are aware of the manufacturer's Field Safety Notice.

Identify affected devices. The model number and lot number are located on the bottom of the CPAP device. Remove the water chamber or empty it before viewing the bottom of the device.

Contact the manufacturer to arrange for a replacement power cord. In the interim users should continue with their CPAP therapy.

CAS deadlines

Action underway: 20 October 2010

Action complete: 10 November 2010

Contact

Manufacturer
Fisher & Paykel Healthcare
Colin Murray
Tel: 01628 626 136
Email: Colin.Murray@fphcare.co.uk

Device

This device is used for the treatment of obstructive sleep apnoea and delivers continuous positive airway pressure (CPAP) to assist with a patient's breathing during sleep. The device is for use by adult patients at home or in a sleep laboratory.

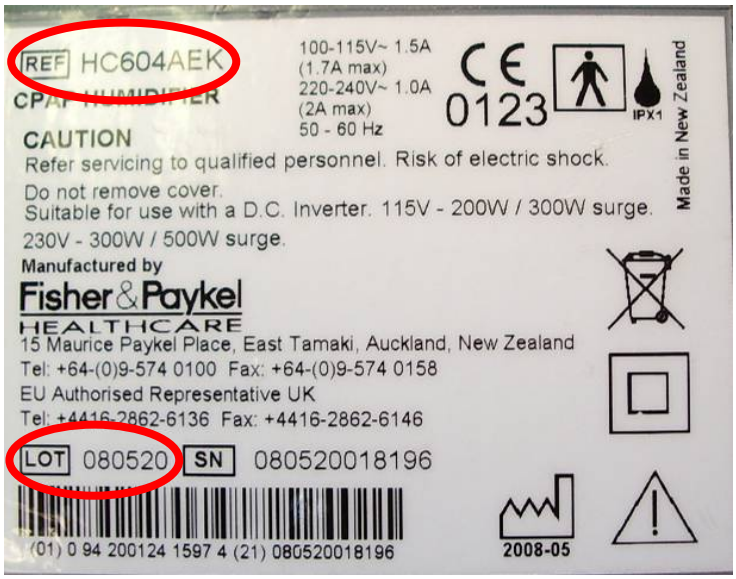
The model numbers of affected devices are:

- HC23XAEK and HC23XMEK
- HC24XAEK and HC24XMEK
- HC254AEK and HC254MEK
- HC60XAEK and HC60XMEK

(Where X is a number)

The relevant LOT numbers are those up to and including **091122**.

The image below shows where the model and lot number are located on the device label.



CPAPs manufactured with lot numbers higher than 091122 have a different power cord and are not subject to this product replacement.

Problem

Fisher & Paykel Healthcare has received reports of deterioration in the connectors of power cords supplied with their CPAP flow generators.

A power cord that deteriorates will stop working because of a disconnection in the internal wiring, which may lead to arcing and ultimately could cause a melt or breach of the outer cord sheath (insulation); this may arise near the connector that plugs into the CPAP unit.

Distribution

This MDA has been distributed to:
NHS trusts in England (Chief Executives)

- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward 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 and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Chest physicians
- Clinical governance leads
- EBME
- ENT surgeons and sleep laboratories
- Equipment stores
- Health and safety managers
- Medical directors
- Nursing executive directors
- Physiotherapists
- Purchasing managers
- Respiratory medicine, department of
- Respiratory nurse specialists
- Risk managers
- Sleep apnoea clinics
- Sleep laboratories

Establishments registered with the Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Private clinics

Primary care trusts to:

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

- Community hospitals
- Community nurses
- District nurses
- Equipment libraries and stores

Contacts

Manufacturer
Fisher & Paykel
Colin Murray
Unit 16, Cordwallis Park
Clivemont Road
Maidenhead
Berkshire SL6 7BU

Tel: 01628 626 136
Email: Colin.Murray@fphcare.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/076** or **2010/005/019/081/010.**

Please note that telephone numbers for the MHRA contacts below will change on 25 October 2010. From that date please contact the MHRA Central Enquiry Point on 020 7084 2000 and ask for the person by name.

Technical aspects
Dr Louise Mulroy and Mr Graham Nash
Medicines & Healthcare products Regulatory Agency

Tel: 020 7084 3344 / 3125 Email: louise.mulroy@mhra.gsi.gov.uk
graham.nash@mhra.gsi.gov.uk

Clinical aspects
Mr Jonathan Plumb
Medicines & Healthcare products Regulatory Agency

Tel: 020 7084 3128 Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk
http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed 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
Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922
Email: Haz-Aic@wales.gsi.gov.uk