

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	Action
Risk of cessation of therapy due to deterioration of power cord.	Ensure that all users, including patients at home, are aware of the manufacturer's Field Safety Notice .
Action by	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.
All those involved in the purchase and use of these devices.	
CAS deadlines	Contact
Action underway: 20 October 2010 Action complete: 10 November 2010	Manufacturer Fisher & Paykel Healthcare Colin Murray Tel: 01628 626 136 Email: Colin.Murray@fphcare.co.uk

Link to full Medical Device Alert

www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON094175