

Urgent Field Safety Notice

Fisher & Paykel Healthcare SleepStyle™ Series CPAP Power Cord Product Replacement

ATTN: Dealer Name

DESCRIPTION OF CORRECTION:

Fisher & Paykel Healthcare is replacing the power cords supplied with affected SleepStyle™ series CPAPs as, under certain conditions, the power cords may be susceptible to deterioration.

PART NUMBER:

Fisher & Paykel Healthcare CPAP part numbers:

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

(Where X is a number)

Associated power cord part numbers:

- 095542068 (for AEK models)

AFFECTED LOT NUMBERS:

- HC230, HC240, HC250 and HC600 series AEK and MEK CPAPs with lot numbers through 091122

DEPTH AND TYPE OF FIELD ACTION:

(To be updated according to the relevant regulations)

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INSTRUCTIONS:

1. Please inspect your stock of SleepStyle™ CPAPs that have the lot numbers listed above and quarantine the affected units.



Model number

REF HC604AEA	100-115V~ 1.5A (1.7A max)		
CPAP HUMIDIFIER	220-240V~ 1.0A (2A max) 50 - 60 Hz		
CAUTION Refer servicing to qualified personnel. Risk of electric shock. Do not remove cover. Suitable for use with a D.C. Inverter. 115V - 200W / 300W surge 230V - 300W / 500W surge.			
Sold and serviced by Fisher & Paykel HEALTHCARE 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand Tel: +64-(0)9-574 0100 Fax: +64-(0)9-574 0158 Australia Tel: +61-(0)3-9879 5022 Fax: +61-(0)3-9879 5232			
LOT 070131	SN 070131003290		
(0) 0 84 200124 1595 0 (21) 070131003290		2007-01	

Lot number

2. Please send out the attached customer letter to your customers who may have purchased an affected unit.

Note: Please instruct your customers to phone the number listed in the customer letter to arrange for a replacement power cord to be sent to them.

3. Please complete the attached response form and return it to [address/fax number/e-mail address](#) so that we may arrange for replacement power cords to be sent to you. Please complete the reply form even if you have no stock subject to this product replacement.

ENCLOSED CONTENTS:

- A customer notification letter advising customers of the power cord replacement.
- A response form to acknowledge your receipt of this notification letter and to indicate distribution of the customer letter to affected customers.

If you have any questions relating to the above actions please do not hesitate to contact me at the details provided below.

Sincerely,

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[name]

Medical Device Correction Response Form

Please complete all of the details below and return this form to us, ATTN:Colin Murray, by fax to [fax number], by e-mail to [e-mail address] or by post to [address] to indicate that you have been advised of the Fisher & Paykel Healthcare SleepStyle™ Series CPAP Power Cord Product Replacement.

Note: A response is requested even if you do not have or have not distributed any affected CPAP units.

Business Name: _____

FPH Account No: _____

Contact Name: _____

Address: _____

Fax: _____ Phone: _____

E-mail address: _____

I, _____, have received and acknowledge the notification of the Fisher & Paykel Healthcare SleepStyle™ Series CPAP Power Cord Product Replacement. I confirm that the information in this response form is complete and accurate, to the best of my knowledge, and I:

Have quarantied the affected CPAP units from my stock

Please indicate the total quantity of affected CPAP units that you have in stock: _____

-AND-

Have distributed recall advisory letters to all customers who may have purchased an affected CPAP unit

Please indicate the total quantity of affected CPAP units that you have distributed: _____

-OR-

Do not have and have not distributed any affected CPAP units

Signed: _____

Position: _____

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Date: _____

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