

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/14

Issued: 8 February 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Fisher and Paykel Healthcare re-usable CPAP respiratory masks and connectors for obstructive sleep apnoea.</p>	▶ ①
<p>Problem: Plastic tabs incorporated into the re-usable CPAP mask connectors may break off when in use with the possibility of components entering the patient's airways. The affected connectors are found in most Fisher and Paykel CPAP face, nasal and oral mask kits, and various tubing kits. Fisher and Paykel have now redesigned this connector (available since April 2006) and are recalling all face mask kits with the previous version; the recall notice and fax back form are appended to this alert.</p>	▶ ②
<p>Action by: All those involved in the purchase and use of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure all relevant staff are aware of this recall; customer letter and recall fax back form are appended to this alert. • Identify devices currently in use and arrange for alternatives to be provided. • Identify and remove all unused affected stock. • Contact the manufacturer to arrange collection and replacement of stock. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Fisher and Paykel Healthcare re-usable CPAP respiratory masks and connectors for obstructive sleep apnoea.

2. PROBLEM:

Plastic tabs incorporated into the re-usable CPAP mask connectors may break off when in use with the possibility of components entering the patient's airways. The affected connectors are found in most Fisher and Paykel CPAP face, nasal and oral mask kits, and various tubing kits. Fisher and Paykel have now redesigned this connector (available since April 2006) and are recalling all face mask kits with the previous version; the recall notice and fax back form are appended to this alert.

3. ACTION BY:

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

4. ACTION:

- Ensure all relevant staff are aware of this recall; customer letter and recall fax back form are appended to this alert.
- Identify devices currently in use and arrange for alternatives to be provided.
- Identify and remove all unused affected stock.
- Contact the manufacturer to arrange collection and replacement of stock.

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:

- Clinical governance leads
- ENT surgeons and sleep laboratories
- Equipment stores
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Medical directors
- Nursing executive directors
- Purchasing managers
- Respiratory medicine, department of
- Respiratory nurse specialists
- Risk managers
- Sleep apnoea clinics

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Mr Colin Murray
Quality Manager
Fisher and Paykel Healthcare Ltd
Unit 16, Cordwallis Park
Clivemont Road
Maidenhead
Berkshire SL6 7LB

Tel: 01628 626 136

Fax: 01628 626 146

E-mail: Colin.Murray@fphcare.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2007/14 and be addressed to:

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

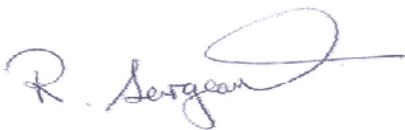
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



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)2006/01. 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

Fisher & Paykel Healthcare Ltd
Unit 16, Cordwallis Park
Clivemont Road
Maidenhead
Berkshire SL6 7BU

6th December 2006

United Kingdom
PHONE: (+44) 1628 626 136
FAX: (+44) 1628 626 146

Voluntary Recall : Fisher & Paykel Healthcare CPAP Masks and Connectors

Fisher & Paykel Healthcare has become aware that a connector component used in a previous version of its CPAP masks may fail prematurely if improperly cleaned. Plastic tabs incorporated into the connector components of these CPAP masks may break off if they are not cleaned in accordance with our Instructions for Use. In the unlikely event of a tab breaking off, it may enter the CPAP system air path.

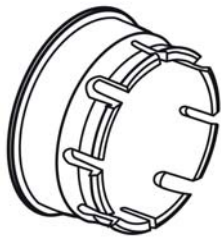


Figure 1: Tab Connector



Figure 2: New (no tab) Connector

As a precautionary measure, Fisher & Paykel Healthcare has decided to conduct a retail level recall of CPAP masks and connectors with tabs (Figure 1) and replace them with our current no tab design (Figure 2). This will ensure that any replacements you provide will be CPAP masks or connectors using the new no tab design. See the attached fax back form for CPAP Mask models, spare part numbers and lot numbers that are affected by this voluntary recall.

Masks manufactured since April 2006 have a new connector instead of a tab connector. These masks are not subject to this voluntary recall.

In order to effectively support this voluntary recall please proceed as follows:

1. Inspect your stock of CPAP masks and spare parts for items within the lot ranges specified in the attached fax back form. The lot code is included on the package label Indicated in Figure 3.
2. Quarantine affected stock.
3. Complete the table in the attached fax back form to indicate quantity of affected units in your stock.
4. Sign and date the fax back form to confirm the accuracy of information in the table and to certify the quarantine

Fax the form back to the fax number above so that we can arrange pick up of affected stock and replacement.

6. Complete the fax back form even if you have no stock which is subject to this voluntary recall, as we require this information to reconcile this process.

Please call the number above if you have any questions relating to this letter.

Fisher & Paykel Healthcare sincerely regrets any inconvenience caused.

Sincerely

Colin Murray

Quality Manager

Fisher & Paykel Healthcare Ltd

Figure 3. Lot No Indication



Fisher & Paykel
HEALTHCARE

Recall Fax Back Form

Attention: Colin Murray

Fax: (+44) 1628 626 146

Please complete all of the details below and fax this form back to Fisher & Paykel Healthcare at the fax number above.

Homecare Provider Details:

Business Name: _____

Contact Name: _____

Shipping Address: _____

Account No: _____

Fax: _____ Phone: _____

Do you have any stock affected by the recalled part? YES NO

Please indicate in the tables below the quantities of affected masks (Table 1) and spare parts (Table 2) in the lot number ranges. All affected stock needs to be **quarantined and returned to Fisher & Paykel Healthcare**. Complete this form and fax back to Fisher & Paykel Healthcare. We will contact you to arrange pick up of affected stock and replacement.

Table 1: Please indicate quantities of affected masks in your stock:

Part Number	Description	Start Lot #	End Lot #	Quantity in stock
HC401U	Aclaim® Nasal Mask	020520	060207	
900HC401X	Aclaim® Nasal mask 10 pk	020109	020524	
HC405U	FlexiFit™ 405 Nasal Mask	030922	060112	
HC406U	FlexiFit™ 406 Nasal Mask	050913	060123	
HC407U	FlexiFit™ 407 Nasal Mask	040407	060210	
HC407NIV	FlexiFit™ 407 NIV Nasal Mask	050216	060420	
HC431NIV	FlexiFit™ 431 NIV Full Face Mask	050223	060420	
HC431U	FlexiFit 431 Full Face Mask	040507	051118	
HC451U	Oracle™ 451 Oral Mask	020531	041123	
HC452NIV	Oracle™ 452 NIV Oral Mask	050216	060314	
HC452U	Oracle™ 452 Oral Mask	041018	060302	
HC481U	Infinity™ 481 Nasal Direct Mask	050601	060503	

400HC200	Elbow non-diffuser 10pk	040623	060301	
400HC200B	Elbow kit non-diffuser 407 10pk	041013	051104	
400HC202	Elbow non-diffuser holes	040802	060128	
400HC203	HC431 elbow + vented NR valve	040719	051104	
400HC205	Oracle flexitube kit	041104	051019	
400HC209	Oracle flexitube kit + vent NR valve	041108	050920	
400HC210	407NIV elbow vented + nonvented	050810	060512	
400HC212	431NIV elbow vented + nonvented	050808	060519	
400HC214	452NIV elbow vented + nonvented	050802	060310	
400HC502	HC407 mask no headgear	040825	060208	
400HC503	HC 431 mask no headgear	040830	051114	
400HC504	HC407 mask no headgear 25pk	041104	051216	
400HC505	Infinity HC481 mask base	050223	051117	
400HC506	Oracle HC452 no headgear	050713	051028	
400HC507	Infinity HC481 no headgear	051028	051104	
400HC510	HC406 mask no headgear	051007	051104	
900HC402	Aclaim mask no headgear	010918	060214	
900HC405	HC405 sleep lab mask kit	030924	031002	
900HC406	HC405 mask no headgear	031110	051104	
900HC412	Aclaim flexitube kit	020108	060224	
900HC441	Elbow diffuser and swivel	031110	060121	
900HC463	HC451 flexitube kit	020108	041204	

Note: A response is required even if you have no stock in the affected lot range.

I, _____ have received and acknowledge the details outlined in the attached letter. My signature below verifies that the above information is true and correct and I certify that all affected product has been appropriately identified.

Signed: _____

Date: _____

Fisher & Paykel Healthcare Office use only:

I confirm receipt and destruction of product above.

Signed: _____ Name: _____

Date: _____