

**FIRST CONSIGNEE (DISTRIBUTOR) URGENT FIELD SAFETY NOTICE NOTIFICATION
LETTER**



Fisher & Paykel Healthcare Limited
Stewart Building
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

[Date]

Chief Executive Officer

[Facility Address]

Attention: [head of appropriate department e.g. Chief Biomedical Engineer]

Urgent Field Safety Notice
Fisher & Paykel Healthcare 400HC212 (Lot 130820) & 400HC214 (Lot 130823)

FPH FSCA Identifier: FA-2013-004

Type of Action: Recall

DEPTH OF RECALL:

- Consumer

AFFECTED PRODUCT DETAILS

The 400HC212 and 400HC214 are spare elbow kits used with Fisher & Paykel Healthcare HC431 Flexifit Full Face NIV Mask and HC452 Oracle NIV Oral Mask.

NAME OF PRODUCTS:

- 400HC212: HC431 NIV Elbows Non-Vented & Vented
- 400HC214: HC452 NIV Elbow Non-Vented & Vented

TYPE OF DEVICE:

- Spare elbow kit

PART NUMBERS / MODEL:

- 400HC212
- 400HC214

LOT NUMBER / SERIAL NUMBER:

- 400HC212: Lot number 130820 only.
- 400HC214: Lot number 130823 only.

PACK SIZE:

- Each elbow kit contains one non vented (blue) elbow and one vented (clear) elbow.

REASON FOR RECALL:

The 400HC212 and 400HC214 Elbow Kits are spare elbows to be used with the HC431 Flexifit NIV masks and Oracle NIV Oral masks. Fisher & Paykel Healthcare (FPH) has become aware that the vented elbows from 400HC212 Lot 130820 and 400HC214 Lot 130823 have potentially been incorrectly assembled. They may have been assembled with a swivel instead of a Non-rebreathing Valve (See Figure 2 below). This still allows the mask base to be connected to the breathing tube and still allows the delivery of CPAP therapy. However, the absence of a NRV will not allow adequate CO₂ flushing in the event of a CPAP/Ventilator failure or tube disconnection if used in conjunction with a Full Face Mask or an Oral Mask with nasal plugs.

ACTIONS BEING TAKEN BY FISHER & PAYKEL HEALTHCARE:

FPH would like to replace any existing affected products that you have been provided.

ACTIONS REQUIRED FROM YOU:

FPH requires you to destroy and dispose of all affected products in your inventory. FPH also requires your assistance in contacting your customers if affected products have been distributed. This will ensure all distributed products are destroyed accordingly.

Part A: Product in your inventory

If packaging is available:

Using example labels in Figure 1 below, identify any 400HC212 Lot 130820 and 400HC214 Lot 130823. For any affected product please destroy the vented elbow by disconnecting the 90° elbow from the swivel and immediately disposing of the two parts as per Figure 2 below. Please complete Section A 'Inspection of Stock' on the Urgent Field Safety Notice Response Form.

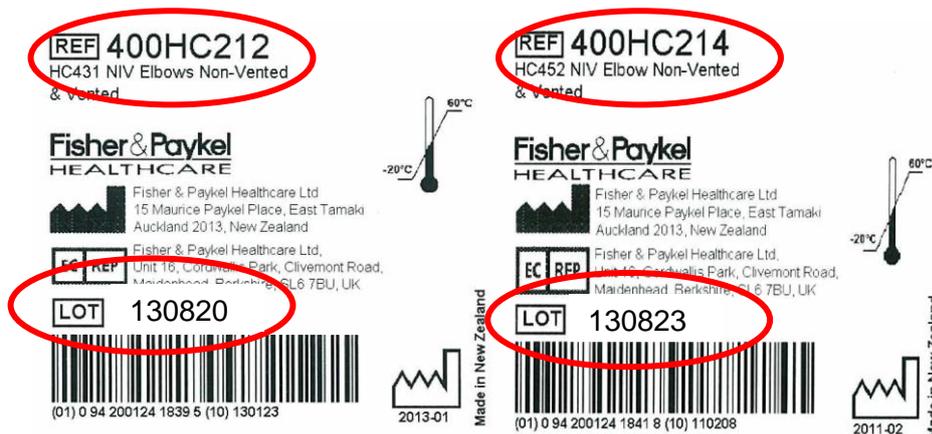


Figure 1: Product labels



Figure 2: Separated assembly for disposal

If packaging is not available:

Inspect the vented elbow assembly for the presence of an NRV valve as per Figures 3 and 4 below. For any identified product please destroy the vented elbow by disconnecting the 90° elbow from the swivel and immediately disposing of the two parts as per Figure 5. Please complete Section A 'Inspection of Stock' on the Urgent Field Safety Notice Response Form.

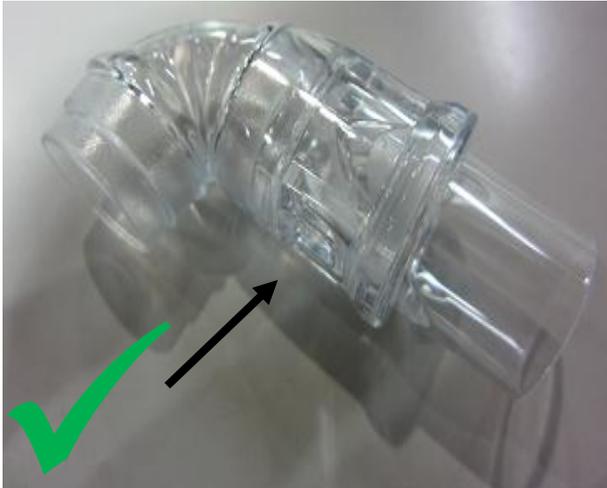


Figure 3: Correctly assembled vented elbow

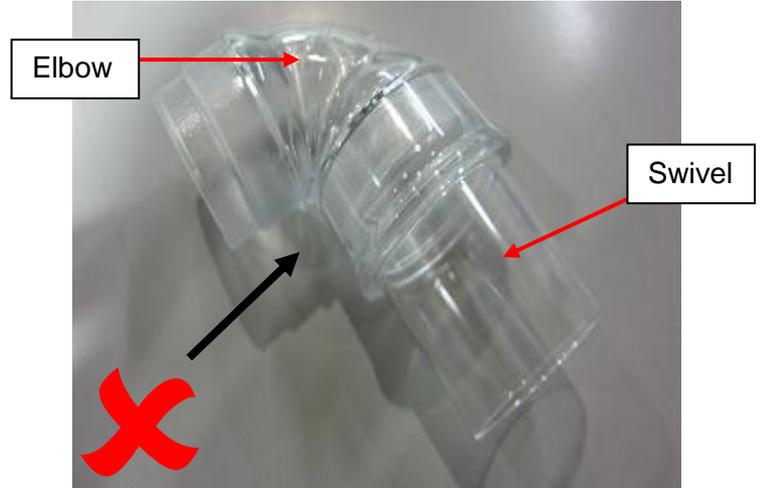


Figure 4: Incorrectly assembled vented elbow with missing NRV valve



Figure 5: Separated assembly for disposal

Part B: Identification of distributed product

- Step 1: Please review your sales records and identify if any affected product has been distributed to your customers and complete Section B 'Notification to Customers' on the Urgent Field Safety Notice Response Form.
- Step 2: If you identify that the affected product has been distributed to your customers then create a list of affected customers for tracking purposes using the tracking sheet provided on the CD for your convenience. If the affected product **has not** been distributed please move to Step 8.
- Step 3: Upon receipt of this notification notify your customers immediately, advising them to check if they have any 400HC212 Lot 130820 and 400HC214 Lot 130823 and arrange for a replacement. Inform them that further written instructions will follow.
- Step 4: Identify if each customer is a distributor, hospital, or end user and create a customer Urgent Field Safety Notice notification letter and response form using the templates provided on the CD and edit the text in red.

Step 5: Send the Urgent Field Safety Notice letter and response form to all affected customers within **five business days** of receiving this notification, using a courier system (with track and trace).

Step 6: Update the following fields on the Customer Tracking Sheet:

- Date the customers were sent the Urgent Field Safety Notice notification and follow up letters
- The date each completed response form is received
- Tracking numbers of notification and follow up letters sent to the customers

Note: All response forms must be kept and sent to Fisher & Paykel Healthcare Representative **[insert contact name]**.

Step 7: Where a customer fails to respond to the Urgent Field Safety Notice notification letter within **10 business days** of initial contact, please follow up a minimum of **three times** via courier with a follow up notification. Create a follow up notification using the Follow Up Letter template provided on the CD. Enter the type of follow up (First, Second or Final) and the date on which you will send the letter.

- The follow up is to be conducted within 10 business days from the last date of attempt. Please document the date and summary of the attempts made in the customer tracking sheet for records.

Step 8: Arrange to provide replacements for affected products free of charge. Should you require replacement products, please contact your Fisher & Paykel Healthcare Representative **[insert contact name]**.

TRANSMISSION OF THIS FIELD SAFETY NOTICE:

Please transfer this notice to all those persons within your organization who need to be aware of it.

FORTNIGHTLY STATUS UPDATES:

As part of monitoring of this Field Action, Fisher & Paykel Healthcare New Zealand requests that a fortnightly update is submitted to your Fisher & Paykel Healthcare Representative **[insert contact name]**. Please provide the following information:

- Updated Customer Tracking sheet with:
 - Date on which the customers were sent the Urgent Field Safety Notice notification, follow-up reminders (1st, 2nd, and final).
 - Any other relevant information such as any failures in delivery of the notifications and reminders.
 - Tracking numbers for each Urgent Field Safety Notice notification or follow up letters sent.
- Scanned copies of courier receipts (labeled as 'Field Safety Notice Notification', 'First follow-up', 'Second follow-up' or 'Final follow-up', as appropriate).

Please be advised that Fisher & Paykel Healthcare has notified all appropriate Regulatory Agencies of this Field Safety Corrective Action as required, including **[insert Regulatory Agencies]**.

If you have any questions relating to the above actions, do not hesitate to contact either your Fisher & Paykel Healthcare Representative **[insert name]** via email at **[email@fphcare.com]** or directly at **[enter telephone details]**.

Yours Sincerely,

[Signature]

[Insert EU sponsor name, position details & email]

**FIRST CONSIGNEE (DISTRIBUTOR) URGENT FIELD SAFETY NOTICE RESPONSE
FORM**



Fisher & Paykel Healthcare Limited
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Urgent Field Safety Notice Response Form
Fisher & Paykel Healthcare 400HC212 (Lot 130820) & 400HC214 (Lot 130823)

FPH FSCA Identifier: FA-2013-004

Type of Action: Recall

Please complete all of the details below and return this form your Fisher & Paykel Healthcare Representative via the details below:

Note: A response is required even if you do not have or have not distributed any affected product.

Email: [\[insert email address\]](#)
Fax: [\[insert fax details\]](#)
Post: [\[insert postal address\]](#)

Business Name: _____

Address: _____

Fax: _____

Phone: _____

E-mail address: _____

Please tick the appropriate box in Section A and Section B.

Section A – Inspection of stock

- I have identified and destroyed all affected stock and disposed of them;
_____ Number of 400HC212 Lot 130820 that were in my inventory that I have destroyed.
_____ Number of 400HC214 Lot 130823 that were in my inventory that I have destroyed.

Or;

- I did not have any affected stock in my inventory.

(Turn over page)

Section B - Notification to Customers

I have distributed affected products and I have read and understood my obligation to notify and provide replacement products to all of my customers who have affected 400HC212 (Lot 130820) or 400HC214 (Lot 130823) Elbow Kits.

- Number of affected customers: _____
- Number of affected products distributed: _____

Or

I have not distributed any affected 400HC212 (Lot 130820) or 400HC214 (130823) Elbow Kits.

Name: _____

Title: _____

Signed: _____

Date: _____

FIRST CONSIGNEE (HOSPITAL) URGENT FIELD SAFETY NOTICE NOTIFICATION



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[Date]

Chief Executive Officer

[Facility Address]

Attention: [head of appropriate department e.g. Chief Biomedical Engineer]

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TYPE OF DEVICE:

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FPH would like to replace any existing affected products that you have been provided.

ACTIONS REQUIRED FROM YOU:

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Step 1: Identification of affected product

If packaging is available:

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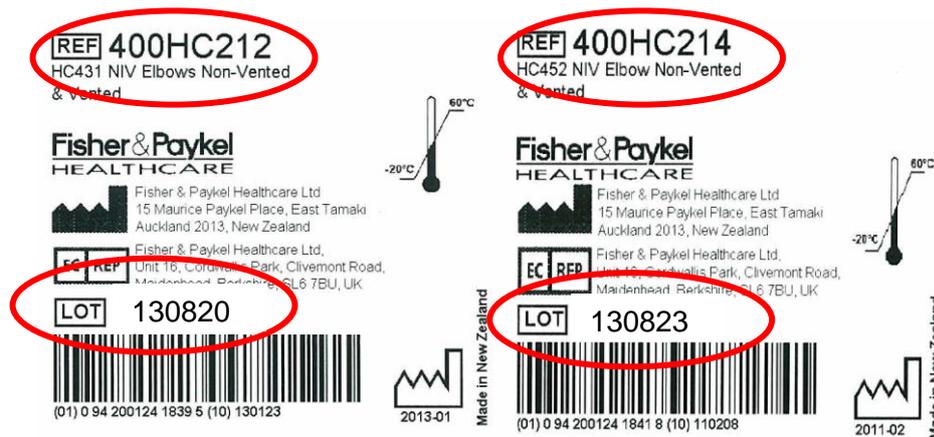


Figure 1: Product labels



Figure 2: Separated assembly for disposal

If packaging is not available:

Inspect the vented elbow assembly for the presence of an NRV valve as per Figures 3 and 4 below. For any identified product please arrange for a replacement and destroy the vented elbow by disconnecting the 90° elbow from the swivel and immediately disposing of the two parts as per Figure 5.

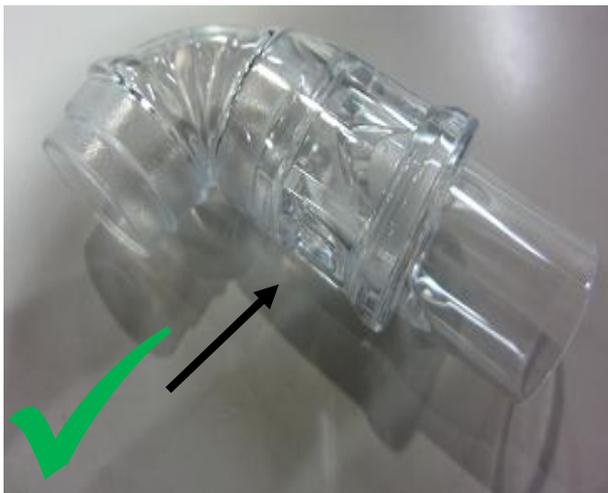


Figure 3: Correctly assembled vented elbow

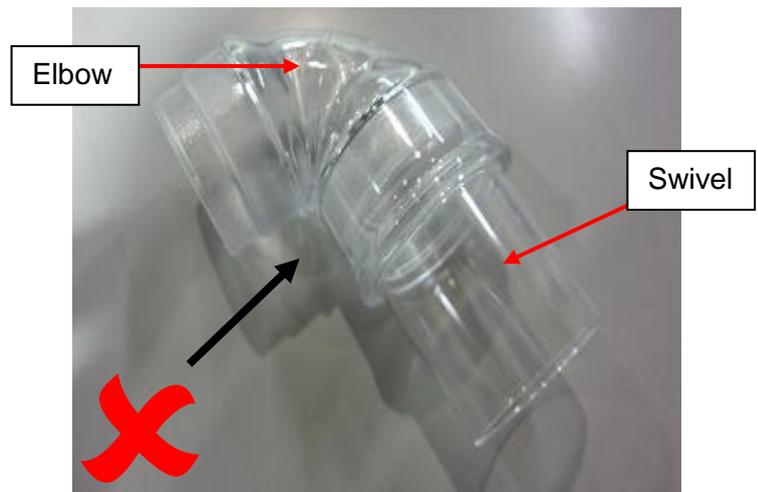


Figure 4: Incorrectly assembled vented elbow with missing NRV valve



Figure 5: Separated assembly for disposal

- Step 2: Please complete Section A 'Inspection of Stock' on the Urgent Field Safety Notice Response Form and return to your Fisher & Paykel Healthcare Representative [\[insert name\]](#)
- Step 3: Arrange to provide replacements for affected products free of charge. Should you require replacement products, please contact your Fisher & Paykel Healthcare Representative [\[insert contact name\]](#).

TRANSMISSION OF THIS FIELD SAFETY NOTICE:

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If you have any questions relating to the above actions, do not hesitate to contact either your Fisher & Paykel Healthcare Representative [\[insert name\]](#) via email at [\[email@fphcare.com\]](#) or directly at [\[enter telephone details\]](#).

Yours Sincerely,

[Signature]

[Insert EU sponsor name, position details & email]

FIRST CONSIGNEE (HOSPITAL) URGENT FIELD SAFETY NOTICE RESPONSE FORM



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FPH FSCA Identifier: FA-2013-004

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Note: A response is required even if you do not have or have not distributed any affected product.

Email: [\[insert email address\]](#)
Fax: [\[insert fax details\]](#)
Post: [\[insert postal address\]](#)

Business Name: _____

Address: _____

Fax: _____

Phone: _____

E-mail address: _____

Section A - Inspection of stock

- I have identified and destroyed all affected stock and disposed of them;
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_____ Number of 400HC214 Lot 130823 that were in my inventory that I have destroyed.

Or;

- I did not have any affected stock in my inventory.

(Turn over page)

Name: _____

Title: _____

Signed: _____

Date: _____