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

Urgent FIELD SAFETY NOTICE

Fisher & Paykel Healthcare PT100 myAIRVO & PT101 AIRVO Humidifier

REF: FA-2011-006

Product Recall/ Corrective Action

[Date]

Attention: [Name]

DETAILS ON AFFECTED DEVICES:

The following details can be found on the underside of each unit as shown in Figure 1

Product ID:

- Fisher & Paykel Healthcare PT100 (myAIRVO) & PT101 (AIRVO) units

PART NUMBERS:

- PT100 [UK/EW/EE]
- PT101 [UK/EW/EE]

LOT NUMBERS:

- 080101-110420

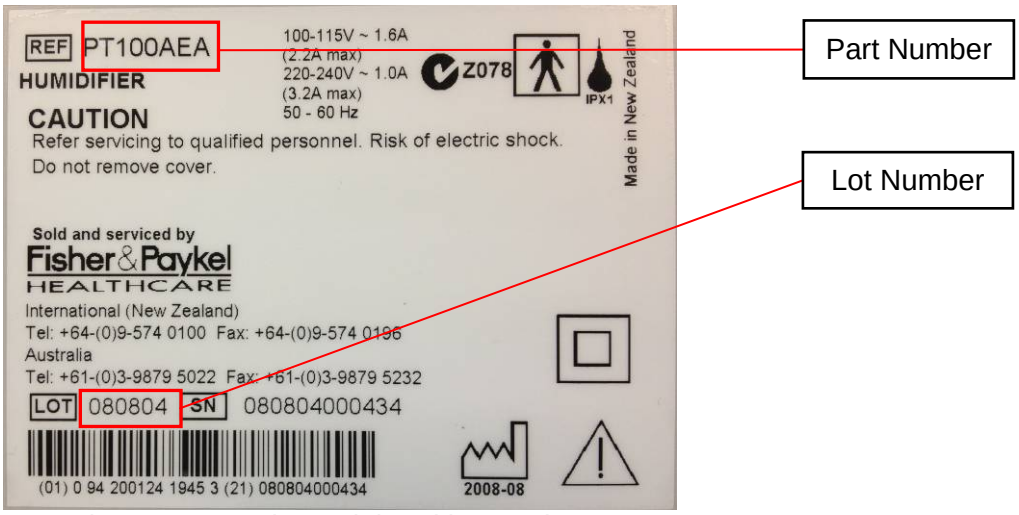

Figure 1. Sample model and lot numbers.

DESCRIPTION OF THE PROBLEM:

Fisher & Paykel Healthcare has become aware that the power cords supplied with certain models of PT100 (myAIRVO) & PT101 (AIRVO) units may be susceptible to deterioration (Refer to previous page for affected product details).

ACTIONS BEING TAKEN:

Fisher & Paykel Healthcare is replacing power cords on all affected PT100 (myAIRVO) & PT101 (AIRVO) units with alternative replacement power cords [(Part# 095542172 – UK model, Part# 095542173 – EW/EE models)] as shown below.

Figure 2. AIRVO unit with old power cord.

Figure 3. AIRVO unit with new power cord.

ADVISE ON ACTION TO BE TAKEN BY THE USER:
A Fisher & Paykel Healthcare representative will be contacting your facility to arrange a personal visit in the coming weeks to provide your facility with the replacement power cords as shown in Figure 3.

At this time please check the power cord on any affected units in your possession for signs of deterioration (Exposed wires, Damaged cable)

- If there are no signs of deterioration continue to use your AIRVO or myAIRVO unit until a replacement power cord is provided.

- If the cord is damaged, please quarantine the unit until a replacement power cord is provided.

Please be advised that Fisher & Paykel Healthcare has notified all appropriate Regulatory Agencies of this field action as required. If you have any questions relating to the above actions, do not hesitate to contact either your Fisher & Paykel Healthcare Representative [insert name here] or myself (using the details below).

Yours Sincerely,

[FPH UK/FRANCE Representative contact details]

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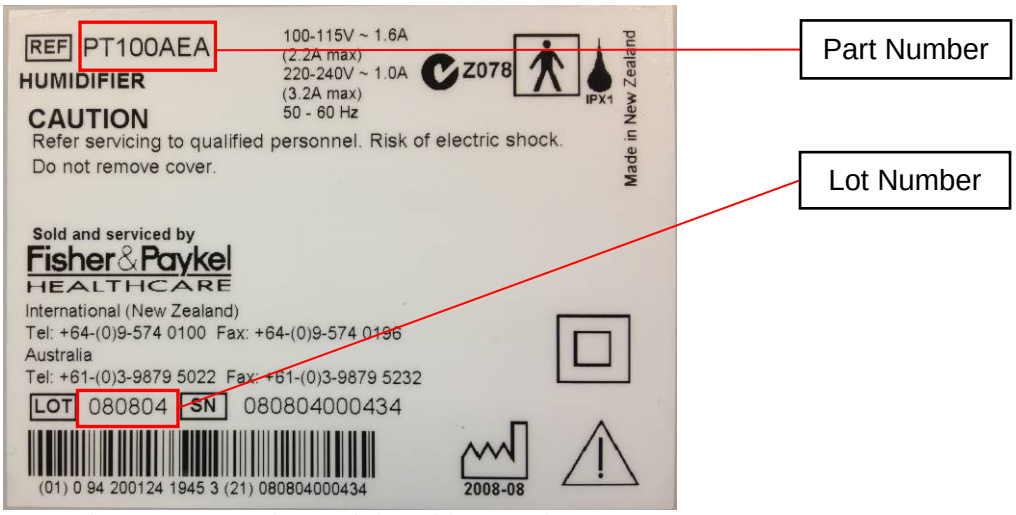

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Figure 2. AIRVO unit with old power cord.

Figure 3. AIRVO unit with new power cord.

ADVISE ON ACTION TO BE TAKEN BY THE USER:
Please note that the amount of power cords we have supplied you is an estimate based on our sales records. If you need additional replacement power cords or were sent too many replacement power cords, please contact your local Fisher & Paykel Healthcare representative.

Step 1: Locate any affected products at your facility (Affected product details listed on page 1).

Step 2: Turn off your AIRVO device.

Step 3 Remove the water chamber from your AIRVO device.

Step 4: Check the part and lot numbers of your device. This information can be found at the underside of your device (see Figure 1).

Step 5: If you have an affected power cord, as shown in the Figure 2, please unplug the power cord from the wall outlet.

Step 6: Locate the cable tie that is connected to the power cord connector on the back of your AIRVO unit (See Figure 2) and cut the cable tie using scissors or a wire cutter. If a cable tie is not present, please proceed to Step 7.

Step 7: Unplug the power cord from the back of your AIRVO device and replace the old power cord (See Figure 2) with the new power cord (See Figure 3) that has been supplied to you. Please then discard and destroy the old power cord.

Step 8: Please complete and return the enclosed urgent **Field Safety Notice Response Form** to the address indicated on the form, even if you have not received or distributed any devices affected by this Field Action.

TRANSMISSION OF THIS MEDICAL DEVICE RECALL NOTIFICATION:
Please transfer this notice to all those who need to be aware within your organisation. If affected product has been distributed to any other organisation or patients/users, please follow the instructions below to notify them regarding this product recall and arrange the replacements of power cords:

1. Use the enclosed “Sample Field Safety Notice Letter Template” to create notification letters with your contact information and send the letters to patients/users with affected products.
2. Contact either your Fisher & Paykel Healthcare Representative [insert name here] or myself to obtain the replacement power cords as required. You will be required to supply records of how many units were affected that had the power cords replaced.

ENCLOSED CONTENTS:

- “Field Safety Notice Response Form”
- “Sample Field Safety Notice Letter Template”
- One replacement power cord for every affected AIRVO unit sold to you (please advise us if more units are required)

Please be advised that Fisher & Paykel Healthcare has notified all appropriate Regulatory Agencies of this field action as required. If you have any questions relating to the above actions, do not hesitate to contact either your Fisher & Paykel Healthcare Representative [insert name here] or myself (using the details below).

Yours Sincerely,

[FPH UK/FRANCE Representative contact details]

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[Date]

Field Safety Notice Response Form

Field Action – PT100 myAIRVO & PT101 AIRVO Humidifier

REF: FA-2011-006

Product Recall / Corrective Action

Please complete all of the details below and return this form to your Fisher & Paykel Healthcare area manager using the details below:
Note: A response is required even if you do not have or have not distributed any affected product.

Email: [areamanager@fphcare.co.nz]

Fax: [+xxxxx (Attention: Area Manager)]; or

Post: Fisher & Paykel Healthcare
Attention: [Area manager]
[Area Manager address]

Business Name: _____

Address: _____

_____

Fax: _____

Phone: _____

E-mail address: _____

I, _____ have received, read and understood the Field Safety Notice issued by Fisher & Paykel Healthcare (FPH) regarding the AIRVO Power Cord Replacement. I have _____ affected unit(s) in my possession and I will replace the old power cord(s) of the affected unit(s) with the replacement power cord(s) provided by FPH, and:

☐ I have distributed the affected products to other facilities and/or patients. I will notify facilities and/or patients regarding this medical device recall and arrange the replacements of power cords to all facilities and/or patients who are in possession of the affected products within 30 calendar days of receiving the Field Safety Notice.

- ❖ Total number of affected products distributed to other facilities and/or patients identified

  _____

OR

☐ I have not distributed any affected products.

Note: Please return this form even if you have not distributed any affected product.

Signed: _____

Position: _____

Date: _____