Fisher & Paykel Healthcare Pty Ltd
19-31 King Street
Nunawading, Melbourne
Victoria, 3131 Australia
PO BOX 159 Mitcham,
Victoria 3132, Australia

Telephone: +61-3-9871 4900
Facsimile: +61-3-9871 4998
Website: www.Fphcare.com

DD MMM YYYY

[Appropriate personnel title e.g. Chief Executive Officer]
[Company Address]

Attention: [Head of appropriate department e.g. Chief Biomedical Engineer, Clinical Investigator, Director of Nursing, Risk Manager, Home Care Company / DME (Durable Medical Equipment)]

Urgent Medical Device Recall

Fisher & Paykel Healthcare PT101XX Airvo 2 and PT100XX myAirvo 2

F&P Recall Reference: FA-2024-001

Fisher & Paykel Healthcare (F&P) is initiating a voluntary limited recall of batches of Airvo 2 and myAirvo 2 devices manufactured before 14 August 2017.

AFFECTED PRODUCT DETAILS

PRODUCT NAME	PART NUMBER / MODEL	SERIAL NUMBER RANGE
Airvo 2	PT101XX *Note: XX represents the various model number country suffixes.*	120521YYYYYY - 170813YYYYYY
myAirvo 2	PT100XX *Note: XX represents the various model number country suffixes.*	

DEVICE USE

Airvo 2 and myAirvo 2 devices are used to deliver high flow respiratory therapy to patients. The Airvo 2 and myAirvo 2 devices are not intended for life support. Patient monitoring is required at all times.

[F&P Consignee Number]

REASON FOR RECALL

The reason for the voluntary limited recall relates to a speaker configuration in Airvo 2 and myAirvo 2 devices manufactured before 14 August 2017.

The speaker in the Airvo 2 and myAirvo 2 devices is intended to provide the user with auditory alerts and alarms under certain conditions. In devices manufactured before 14 August 2017, the speaker configuration may result in distorted, intermittent or inaudible alarm sound levels.

This does not affect the therapy delivered by the Airvo 2 and myAirvo 2 device. The device will otherwise perform as intended. The visual alarm on the display will continue to function and notify the user of the alarm state. However, in the absence of an audible alarm, if there is an interruption to therapy, a patient may experience oxygen desaturation.

Beginning 14 August 2017, a new speaker configuration from a different supplier was implemented into the manufacturing of Airvo 2 and myAirvo 2 devices.

Airvo 2 and myAirvo 2 devices manufactured on or after 14 August 2017 are not subject to this recall.

ACTIONS BEING TAKEN BY F&P

F&P is taking steps to remove and replace products affected by the recall (Affected Product).

Affected Product will be [removed and returned to your local F&P Regional Office].

ACTIONS REQUIRED FROM YOU

Please follow the steps below to support this recall.

Actions for Affected Product in your inventory

Step 1

a. Identify any Affected Product in your inventory by checking the Reference (REF) and Serial Number (SN) on the product label underneath the base of the unit or the label on the box (see Figure 1).
b. Place the Affected Product in quarantine.

Figure 1: Examples of Airvo 2 labels

Step 2
Complete **Section A – Inspection of Stock** on the **Medical Device Recall Response Form** attached and return as specified on the form.

Step 3
Contact your F&P representative [insert contact details] OR F&P Regional Office [insert contact details] to arrange the collection of the Affected Product and to obtain replacement product.

Actions for Affected Product you may have distributed

Step 1

a. Review your sales records and identify if any Affected Product has been distributed to your customers and complete **Section B – Notification to Customers** in the **Medical Device Recall Response Form** attached.

b. Sign the completed **Medical Device Recall Response Form** attached and return it to your F&P Representative [insert contact name] or F&P Regional Office [insert contact details].

Step 2
If you identify that any of the Affected Product has been distributed to your customers, create a list of affected customers for tracking purposes using the **Second Consignee Spreadsheet** provided in the email.

Step 3

a. Create a **Medical Device Recall Letter** and **Medical Device Recall Response Form** for each customer.
b. Use the templates listed below and edit only the text in **red:**
   - Second Consignee_Medical Device Recall_Initial Letter
   - Second Consignee_Medical Device Recall_Response Form

Step 4
Send the **Medical Device Recall Letter** and **Medical Device Recall Response Form** to all affected customers within **5 business days** of receiving this letter, using a courier service

(with track and trace). Should a patient need to continue to use the device, the patient is instructed to contact their physician.

Step 5
Update the relevant information on **The Second Consignee Spreadsheet.**

Note: The Second Consignee Spreadsheet and **all Response Forms** must be kept and sent to your F&P Representative [insert contact name].

Step 6

a. Where a customer fails to respond to the **Medical Device Recall Letter** within **5 business days** of initial contact via letter, please **follow up a minimum of three times** via courier with a **Reminder Letter** once every subsequent **5 business days**.
b. Create the Reminder Letter using the **Second Consignee_Medical Device Recall_Reminder Letter** template. Enter the type of reminder letter (First, Second or Final) and the date on which you will send the Reminder Letter.
c. Enter the date and summary of letters sent and contact attempts in **The Second Consignee Spreadsheet**.

Note: Reminder Letters must be sent within 5 business days of the last letter's date.

INFORMING OTHERS OF THIS RECALL

Please inform anyone within your organisation who needs to be aware of this recall.

If you have distributed Affected Products to any other customer or organisation, please notify them within 5 business days of receiving this notice.

If you have any questions, please contact your F&P representative OR F&P Regional Office via email at [email@Fphcare.com] or directly at [enter telephone details].

Yours sincerely,

[Signature]
[Insert sponsor name, position details]