DD MMM YYYY

Dear [Name of First Consignee]

Urgent: Field Safety Notice

Fisher & Paykel Healthcare Airvo™ 3

F&P Reference: FA-2024-003

Fisher & Paykel Healthcare (F&P) is initiating a field safety corrective action to update Airvo 3 devices that have software version v1.5.1 or earlier installed.

AFFECTED PRODUCT DETAILS

Product Name	Part Number / Model	Manufacturing Date Range (YYYY-MM-DD)	Software Version(s)
Airvo 3	PT301EW	2021-03-17 – 2024-03-14	1.2.0 – 1.5.1

PT301EW

REASON FOR FIELD SAFETY CORRECTIVE ACTION

This field safety corrective action relates to specific versions of software of the Airvo 3, and how the device responds when flow alignment alarm 3.2.2 occurs.

When this happens in Airvo 3 devices set up with High Pressure Oxygen (HPO) and running software version 1.5.1 or earlier, the device will deliver room air only. If this happens, a patient may experience oxygen desaturation that could lead to hypoxia.

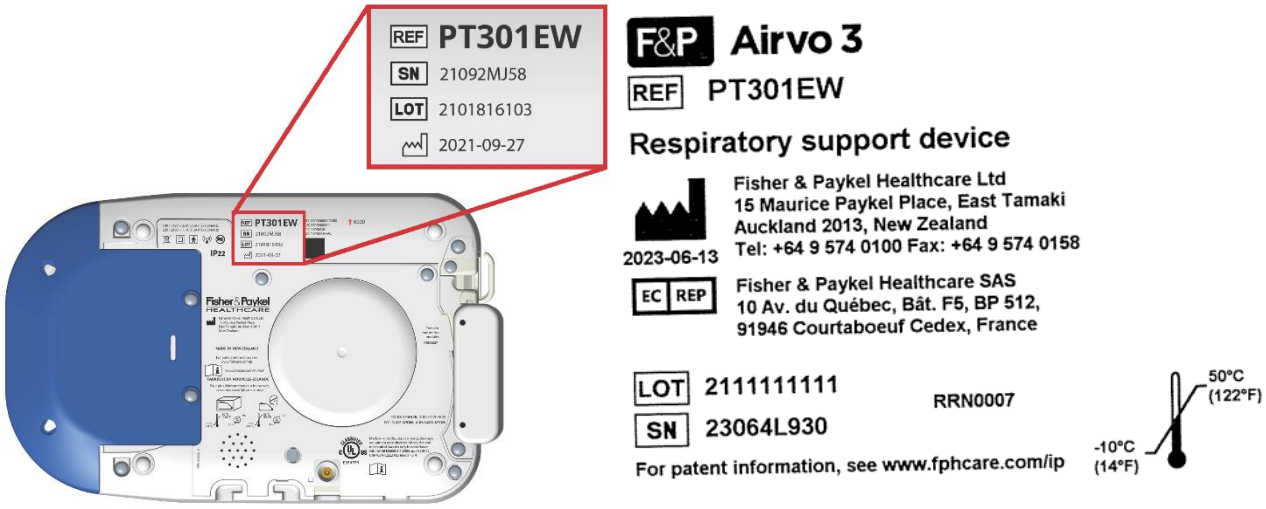
Software version 1.5.2 updates the software algorithm and ensures the target therapy continues in the event that this alarm occurs.

ACTIONS REQUIRED FOR AFFECTED PRODUCT IN YOUR INVENTORY

Please immediately follow these steps to support this field safety corrective action.

Step 1: Identify Affected Product

a. Check the following on the product label underneath the base of the device or the label on the box, and confirm it is within the affected product range.
   i. Model Number reference (REF)
   ii. Serial Number (SN)
   iii. Manufacturing Date (YYYY-MM-DD)



b. If the device is still within your inventory, please put the product in quarantine to prevent ongoing distribution until we have contacted you with next steps.

Step 2: Complete and return the attached response form.

a. Complete the **Field Safety Notice Response Form** attached to this letter.
b. Return the form to your F&P Regional Office / F&P Representative. (Contact details are on the form).

Step 3: Await instructions from your F&P Representative.

a. After we receive your response form, an F&P Representative will contact you regarding the update of your software.

ACTIONS FOR AFFECTED PRODUCT YOU MAY HAVE DISTRIBUTED

Step 1: Identify Distributed Product

a. Review your sales records and identify if any Airvo 3 devices manufactured prior to 14 March 2024 have been distributed to your customers.

Step 2: Complete and return the attached response form.

a. Complete the **Field Safety Notice Response Form** attached to this letter.
b. Return the form to your F&P Regional Office / F&P Representative. (Contact details are on the form).

Step 3: Create list of affected customers.

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

Step 4: Notification Letter and Response Form.

a. Create a **Field Safety Notice Letter** and **Field Safety Notice Response Form** for each customer.
b. Use the templates listed below and edit only the text in red:
    i. Second_Consignee_Field Safety Notice_Initial Letter
    ii. Second_Consignee_Field Safety Notice_Response Form
a. Send the **Field Safety Notice Letter** and **Field Safety Notice Response Form** to all affected customers within 10 business days of receiving this letter via email.

Step 5:

a. 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 Regional Office.

Step 6: Follow-Up

a. Where a customer fails to respond to the **Field Safety Notice Letter** within **10 business days** of initial contact via email, please **follow up minimum of three times**, with a **Reminder Letter** once every subsequent 10 business days.
b. Create the Reminder Letter using the **Second Consignee_Field Safety Notice_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**

CONTINUING USE OF THE AIRVO 3 DEVICE

Until the software is updated, the Airvo 3 device can continue to be used by your customers. When using the device, **all** instructions, including warnings and cautions in the Airvo 3 User Manual must be followed, particularly those in Sections 1 and 2.

If alarm 3.2.2 occurs, follow the onscreen instructions.

INFORMING OTHERS OF THIS FIELD SAFETY CORRECTIVE ACTION

Please inform anyone at your facility who needs to be aware of this field safety corrective action.

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your F&P Regional Office / F&P Representative via email at [email@fphcare.com] or directly at [enter telephone details].

Thank you in advance for your prompt attention.

[Signature]

[Title]