

DD MMM YYYY

Dear [Name of First Consignee]

Urgent: Field Safety Notice

Fisher & Paykel Healthcare Airvo™ 3 NIV

F&P Reference: FA-2024-002

Fisher & Paykel Healthcare (F&P) is initiating a field safety corrective action to update Airvo 3 NIV devices that have software version 1.5.1 or earlier installed.

AFFECTED PRODUCT DETAILS

Product Name	Part Number / Model	Manufacturing Date Range (YYYY-MM-DD)	Software Version(s)
Airvo 3 NIV	PT311EW	2021-03-17 – 2024-03-14	1.2.0 – 1.5.1



PT311EW

REASON FOR FIELD SAFETY CORRECTIVE ACTION

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

When this happens in Airvo 3 NIV 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.

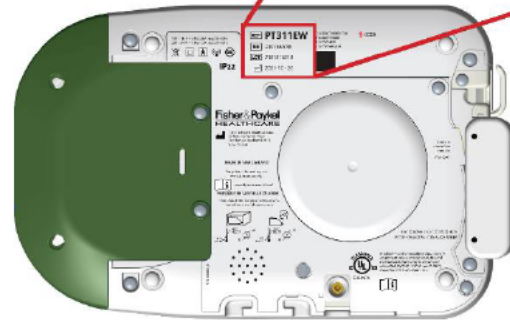
Software version 1.5.2 updates the software algorithm and ensures the target therapy continues in the event that this alarm occurs.

ACTIONS REQUIRED FROM YOU

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, and confirm it is within the affected product range.
 - a. Model Number reference (REF)
 - b. Serial Number (SN)
 - c. Manufacturing Date (YYYY-MM-DD)



REF	PT311EW
SN	21076NY46
LOT	2101816218
	2021-10-26

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.

CONTINUING USE OF THE AIRVO 3 NIV DEVICE

Until the software is updated, you may continue to use the Airvo 3 NIV device. When using the device, all instructions, including warnings and cautions in the Airvo 3 NIV 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 [\[email@fphcare.com\]](mailto:email@fphcare.com) or directly at [\[enter telephone details\]](#).

Thank you in advance for your prompt attention.

[Signature]

[Title]