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16 SEP 2025

Urgent: Product Correction

Fisher & Paykel Healthcare Airvo™ 2 and myAirvo™ 2 Disinfection Kit User Manual Update

F&P Reference: FA-2025-001
TGA Reference: RC-2025-RN-00782-1

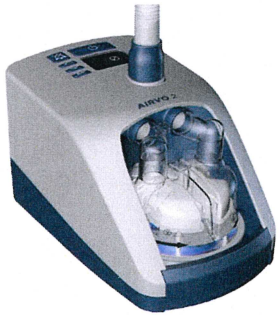
Fisher & Paykel Healthcare (F&P) is initiating a Product Correction informing you of an update to the Disinfection Kit User Manual for Airvo 2 and myAirvo 2 devices.

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. Appropriate patient monitoring must be used at all times.

AFFECTED PRODUCT

Disinfection Kit User Manual	Product Name	Part Number / Model	Device Identifier
UI-185043723 rev P	myAirvo 2	PT100AN	09420012447319
	Airvo 2	PT101AN	09420012447333



Airvo 2 / myAirvo 2

REASON FOR NOTICE

This notice is to inform you of an update to the Disinfection Kit User Manual for maintaining your Airvo 2 and myAirvo 2 device throughout its expected service life[1]. The Airvo 2 and myAirvo 2 have an audible alert that sounds for at least 120 seconds when the unit is unintentionally disconnected from a power source. The Disinfection Kit User Manual has been updated to include a regular test of this alert, to be carried out in between patient uses.

This update has been made due to reports of the audible alert sounding for less than 120 seconds, which may delay user awareness to reconnect power.

There have been no events with serious injuries or death related to this issue.

ACTIONS TAKEN BY F&P

F&P has updated the Disinfection Kit User Manual with a step to check the audible alert.

Please see the update below:

> **7a: Perform 'Power-Out Alarm' test (Airvo 2 and myAirvo 2 only)**
> Ensure steps 1-6 have been carried out, so that the alarm circuit is charged.
> Unplug the unit from the mains/utility power socket.
> Check that the audible alarm sounds for at least 120 seconds.
> The unit is now ready for storage.

CONTINUING USE OF YOUR DEVICE

You may continue to use Airvo 2 and myAirvo 2 devices with appropriate patient monitoring as per the User Manual. When using the device, **all** instructions, including warnings and cautions in the User Manual must be followed, particularly those in Section 1.

[1] Please note, as per the 'Technical Information' section of the Product Technical Manual and the User Manual, the expected service life is 5 years.

ACTIONS REQUIRED FROM YOU

Prior to use on a new patient, follow the instructions of the updated Disinfection Kit User Manual.

Please acknowledge receipt of this notice by following these steps:

1. Enter your organisation and contact information on the response form.
2. Acknowledge and sign that you have read and understood this notice.
3. If you have distributed Airvo 2 or myAirvo 2 devices, notify your customers and include a copy of this notice.

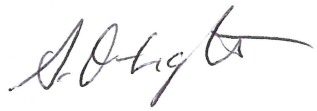
INFORMING OTHERS OF THIS NOTICE

Please inform anyone at your facility who needs to be aware of this notice.

This notice has been reported to all applicable regulatory authorities. Please report all device-related incidents to F&P, your distributor or local representative, and the Therapeutic Goods Administration (TGA) if appropriate.

If you have any questions, please contact your F&P Regional Office via email at FieldActionAU@fphcare.com.au or directly at (03) 9871 4900 (Fisher & Paykel Australia Customer Care).

Thank you in advance for your prompt attention.



Sharon Ortenburg-Light

Quality and Regulatory Manager

Fisher & Paykel Healthcare Pty Ltd