18 SEP 2025

Urgent: Medical Device Correction

Fisher & Paykel Healthcare Airvo™ 2 and myAirvo™ 2 Disinfection Kit User Manual Update related to audible alert sounding for less than 120 seconds when unintentionally disconnected from a power source

This document contains important information for the continued safe and effective use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

F&P Reference: FA-2025-001

Fisher & Paykel Healthcare (F&P) is initiating a Medical Device Correction to inform you of an update to the Disinfection Kit User Manual for Airvo 2 and myAirvo 2 devices. This update has been made due to reports of the audible alert sounding for less than 120 seconds when the unit is unintentionally disconnected from a power source. This may delay user awareness to reconnect power. A delay in reconnecting power could lead to a patient experiencing oxygen desaturation that may lead to hypoxia.

INDICATIONS FOR USE - 510(k) Number: K131895

The Airvo 2 and myAirvo 2 are for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The Airvo 2 is for patients in hospitals and long-term care facilities. The myAirvo 2 is for patients in homes and long-term care facilities.

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
All revisions before UI-185043723 rev P	Airvo 2	PT101US	9420012422347
	myAirvo 2	PT100US	9420012422248

Airvo 2

myAirvo 2

REASON FOR NOTICE

This notice is to inform you of an update to the Disinfection Kit User Manual for Airvo 2 and myAirvo 2 device due to the audible alert not sounding for at least 120s when the unit is unintentionally disconnected from a power source. This may delay user awareness of the need to reconnect power (there is no accompanying visual indicator). The Disinfection Kit User Manual has been updated to include a regular test of this audible alert, to be carried out in between patient uses.

The hazard and harm associated with the issue

A delay in reconnection of power could lead to oxygen desaturation that may lead to hypoxia.

Appropriate patient monitoring must be used at all times.

There have been 642 reports globally of the audible alert sounding for less than 120 seconds. These have been primarily identified during performance checks while the device is out of use.

There have been no reported events with serious injuries or death.

ACTIONS TAKEN BY F&P

F&P has updated the Disinfection Kit User Manual to include 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.

The User Manual can be downloaded from the following links:

Airvo 2: https://resources.fphcare.com/content/airvo-manual-uk-us-and-az-ui-185045495-h-15thmarch22.pdf

myAirvo 2: https://resources.fphcare.com/content/myairvo2-user-manual-ui-185045490.pdf

Disinfection Kit: https://resources.fphcare.com/content/airvo-2-disinfection-manual-user-instructions-ui-185043723.pdf

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 organization 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 and/or branches 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 Food and Drug Administration (FDA's) MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

If you have any questions, please contact F&P Customer Care via email at FieldActionUSCA@fphcare.com or directly at+*1 (800) 446 3908 ext 5003* or *+1 (949) 453 4000 ext 5003*.

Thank you in advance for your prompt attention.

Yours sincerely,

Diego Vargas Banuelos
Director, Quality & Regulatory