

17 SEP 2025

## Urgent: Field Safety Notice

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

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**F&P Reference: FA-2025-001**

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Fisher & Paykel Healthcare (F&P) is initiating a Field Safety Corrective Action 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	Airvo 2	PT101UK	09420012422354
	myAirvo 2	PT100UK	09420012422255



*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<sup>1</sup>. 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.

<sup>1</sup> 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 National Competent Authority if appropriate.

If you have any questions, please contact your F&P Representative via email at [FieldActionASEAN@fphcare.com](mailto:FieldActionASEAN@fphcare.com).

Thank you in advance for your prompt attention.



**Chris Greville**

General Manager - Regional Sales

Fisher & Paykel Healthcare

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## Segera: Notis Keselamatan Lapangan

### Fisher & Paykel Healthcare Airvo™ 2 dan myAirvo™ 2 Kemas Kini Manual Kit Disinfeksi Pengguna

Rujukan F&P: FA-2025-001

Fisher & Paykel Healthcare (F&P) melaksanakan Tindakan Pembetulan Keselamatan Lapangan yang memaklumi anda tentang kemas kini pada Manual Pengguna Kit Disinfeksi bagi peranti Airvo 2 dan myAirvo 2.

#### PENGUNAAN PERANTI

Peranti Airvo 2 dan myAirvo 2 digunakan untuk memberikan terapi pernafasan aliran tinggi kepada pesakit. Peranti Airvo 2 dan myAirvo 2 tidak direka untuk sokongan hayat. Pemantauan pesakit yang sewajarnya mesti dijalankan pada setiap masa.

#### PRODUK YANG TERJEJAS

Manual Pengguna Kit Disinfeksi	Nama Produk	Nombor Bahagian / Model	Pengecam Peranti
UI-185043723 rev P	Airvo 2	PT101UK	09420012422354
	myAirvo 2	PT100UK	09420012422255



Airvo 2 / myAirvo 2

## TUJUAN NOTIS

Notis ini adalah untuk memaklumi anda tentang kemas kini Manual Pengguna Kit Disinfeksi bagi menyelenggara peranti Airvo 2 dan myAirvo 2 anda sepanjang hayat perkhidmatannya yang dijangkakan<sup>1</sup>. Airvo 2 dan myAirvo 2 mempunyai amaran boleh didengar yang berbunyi selama sekurang-kurangnya 120 saat apabila unit itu terputus sambungan daripada sumber kuasa secara tidak sengaja. Manual Pengguna Kit Disinfeksi ini telah dikemas kini untuk menyertakan ujian berkala bagi amaran ini, yang perlu dilakukan di antara penggunaan pesakit.

Kemas kini ini dibuat susulan laporan bahawa amaran boleh didengar berbunyi kurang daripada 120 saat, yang boleh menyebabkan pengguna lambat menyambung semula kuasa.

Tiada kecederaan serius atau kematian berlaku disebabkan masalah ini.

## TINDAKAN YANG DIAMBIL OLEH F&P

F&P telah mengemas kini Manual Pengguna Kit Disinfeksi dengan langkah memeriksa amaran boleh didengar.

Sila lihat kemas kini di bawah:

### **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.

## PENGGUNAAN BERTERUSAN PERANTI ANDA

Anda boleh terus menggunakan peranti Airvo 2 dan myAirvo 2 dengan melakukan pemantauan pesakit yang sewajarnya mengikut Manual Pengguna. Semasa menggunakan peranti, **semua** arahan, termasuk amaran dan peringatan dalam Manual Pengguna mesti dipatuhi, terutamanya yang terdapat dalam Bahagian 1.

<sup>1</sup> Sila ambil perhatian, menurut bahagian 'Maklumat Teknikal' dalam Manual Teknikal Produk dan Manual Pengguna, jangka hayat perkhidmatan yang dijangkakan ialah 5 tahun.

## TINDAKAN YANG PERLU ANDA LAKUKAN

Sebelum digunakan pada pesakit baharu, ikut arahan dalam Manual Pengguna Kit Disinfeksi yang dikemas kini.

Sila sahkan penerimaan notis ini dengan melakukan langkah-langkah ini:

4. Masukkan nama organisasi dan maklumat hubungan anda pada borang maklum balas.
5. Sahkan dan tandatangan untuk membuktikan bahawa anda telah membaca dan memahami notis ini.
6. Sekiranya anda telah mengedarkan peranti Airvo 2 atau myAirvo 2, maklumi pelanggan anda dan sertakan salinan notis ini.

## **MEMAKLUMI ORANG LAIN TENTANG NOTIS INI**

Sila maklumi sesiapa sahaja di fasiliti anda yang perlu tahu tentang notis ini.

Notis ini telah dilaporkan kepada semua pihak berkuasa kawal selia yang berkenaan. Sila laporkan semua insiden berkaitan peranti kepada F&P, pengedar atau wakil tempatan anda, dan Pihak Berkuasa Kebangsaan jika perlu.

Jika anda mempunyai sebarang pertanyaan, sila hubungi Wakil F&P anda melalui e-mel di [FieldActionASEAN@fphcare.com](mailto:FieldActionASEAN@fphcare.com).

Terima kasih diucapkan atas tindakan pantas anda.



**Chris Greville**

General Manager - Regional Sales

Fisher & Paykel Healthcare