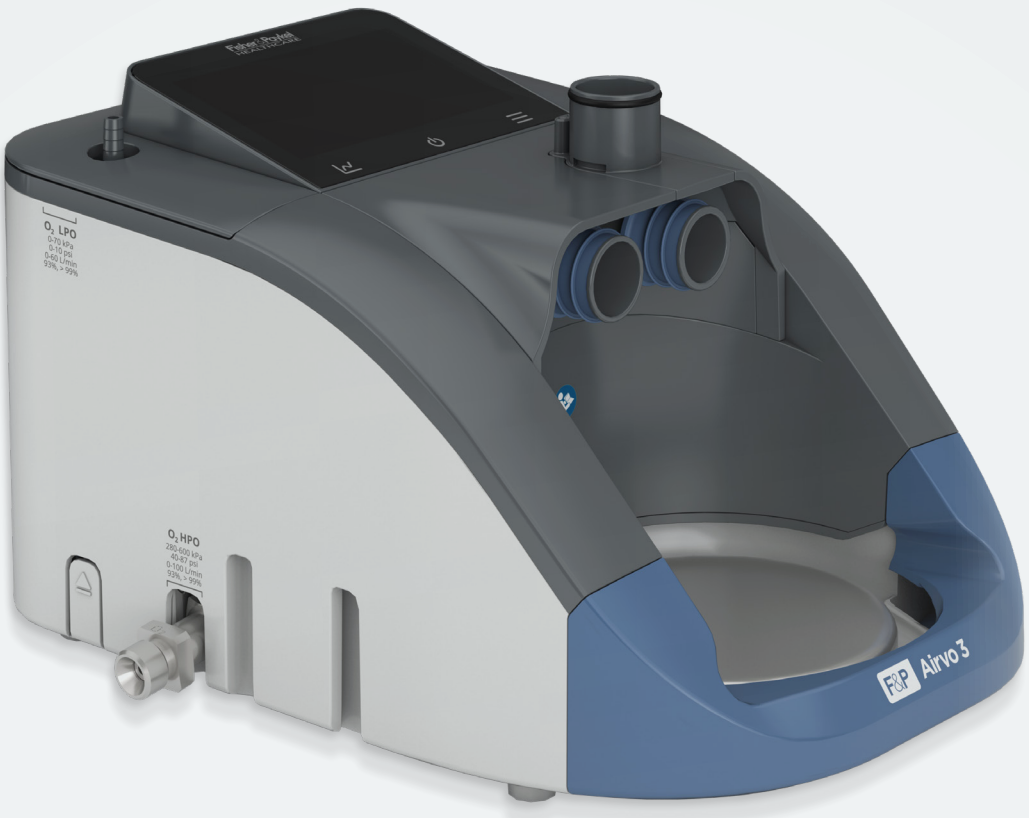
F&P Airvo 3

TECHNICAL MANUAL

Optiflow™ High Flow therapy



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Fisher & Paykel HEALTHCARE

F&P Airvo 3

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Before you start

- This technical manual is intended for clinical engineering and technical personnel. It describes the technical specifications, setup, maintenance, troubleshooting and optional device checks for the Airvo™ 3. Keep this technical manual in a safe place for future reference.
- This technical manual is intended to be used in conjunction with the Airvo 3 User Manual. Read the user manual, including all warnings and cautions, before using the Airvo 3 (including and not limited to commissioning and troubleshooting). Failure to do so may result in injury to you or your patients.
- Before the Airvo 3 is used for the first time, it must be set up according to the instructions contained in this technical manual.
- The responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.
- Some accessories may not be available in certain countries. Please contact your local Fisher & Paykel Healthcare representative for more information.

Additional resources

- Refer to the Airvo 3 User Manual for instructions on using the Airvo 3.
- If using the Disinfection Kit to reprocess the Airvo 3, refer to the Disinfection Kit Manual provided with the Disinfection Kit (900PT600).
- Refer to user instructions supplied with individual accessories for correct use and additional safety information.
- Refer to this Airvo 3 Technical Manual for initial setup, maintenance, servicing and additional troubleshooting instructions.
- Visit the Airvo 3 website at: www.fphcare.com/airvo3 to download the user manual.
- If the software on your device gets updated, please ensure you download a copy of the user manual that reflects the new software. The software number is available on your device and on the back page of this technical manual.
- For assistance from your Fisher & Paykel Healthcare representative contact us at: www.fphcare.com/contact-us.

Conventions used in this manual

WARNING

A warning alerts the user to a potential hazard with use or misuse of the device which, if not avoided, could result in death or serious injury.

CAUTION

A caution alerts the user to a potential hazard with use or misuse of the device which, if not avoided, could result in minor or moderate injury.

Note

A note emphasizes important information for using the Airvo 3 correctly.

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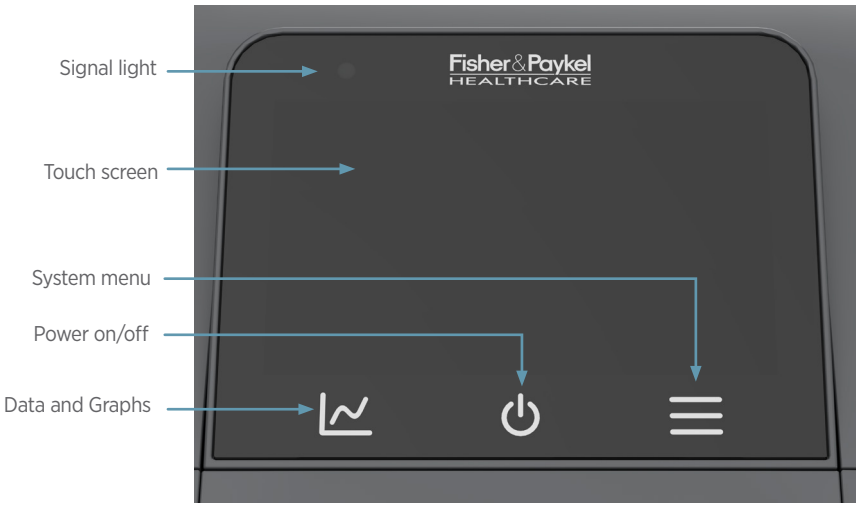
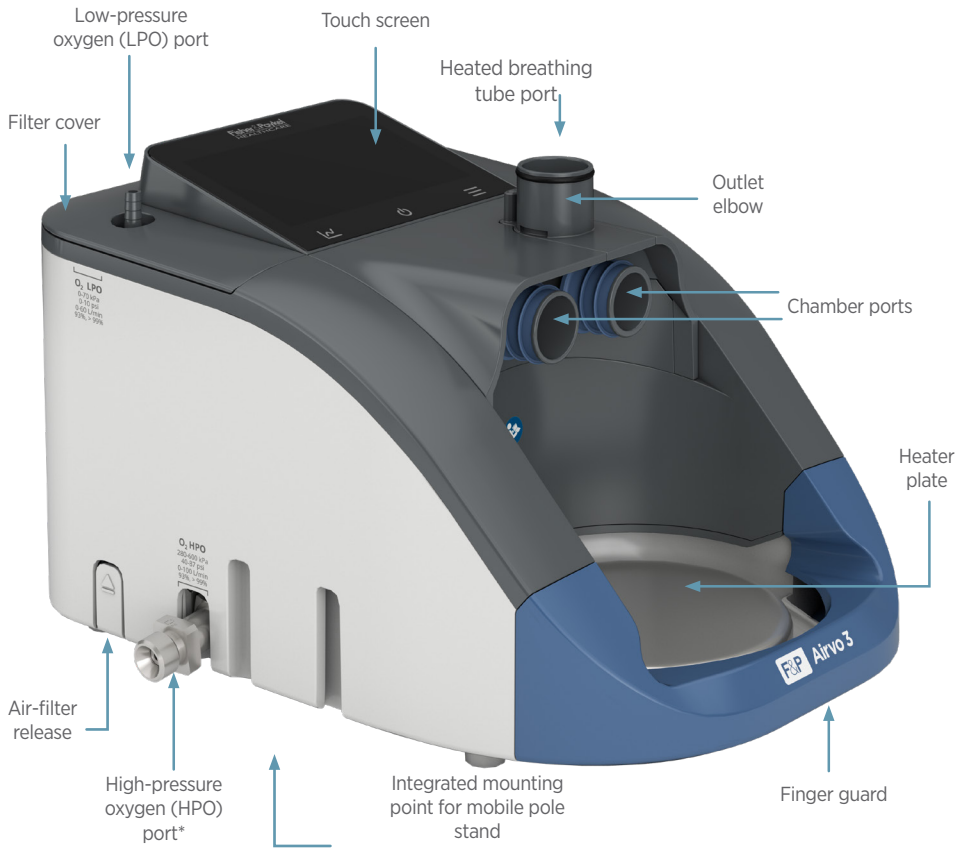
1. Overview

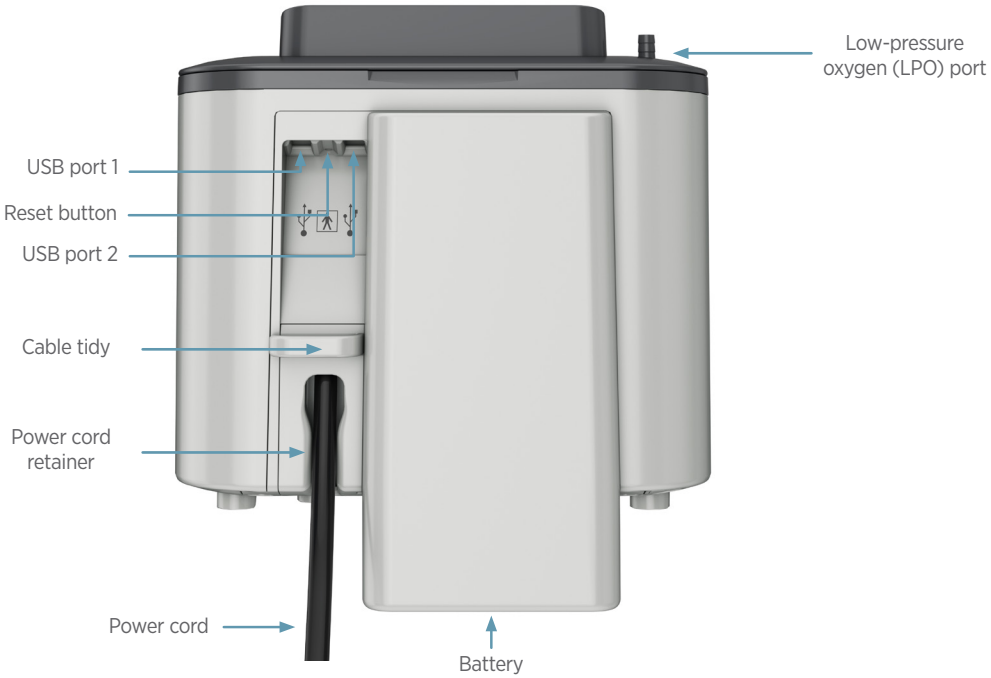
The Airvo 3 is a humidifier with integrated flow generator that delivers warmed and humidified medical gases to spontaneously breathing patients through a variety of patient interfaces. The Airvo 3 is to be used with Fisher & Paykel Healthcare breathing circuit kits, interfaces and accessories.

1.1 Identifying device components





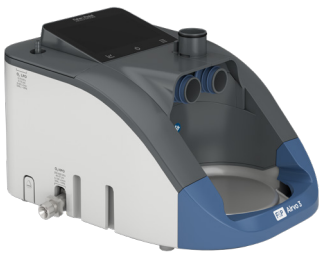
* HPO connection may vary depending on regional selection of connector type (DISS, NIST or SIS)



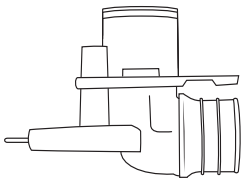
WARNING

Do not use any patient consumables, accessories or replacement parts that are not listed in this technical manual, or the Airvo 3 User Manual.

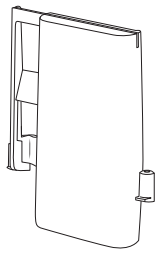
1.2 Packaged content



Airvo 3 device (PT301xx)

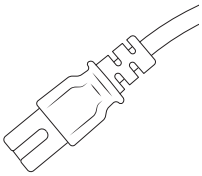


Outlet elbow (already fitted) (900PT930)

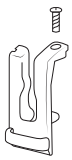


Battery (attached) (900PT957L)

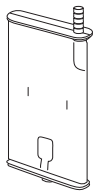
Airvo 3 User Manual



Power cord (attached)



Power cord retainer (attached)

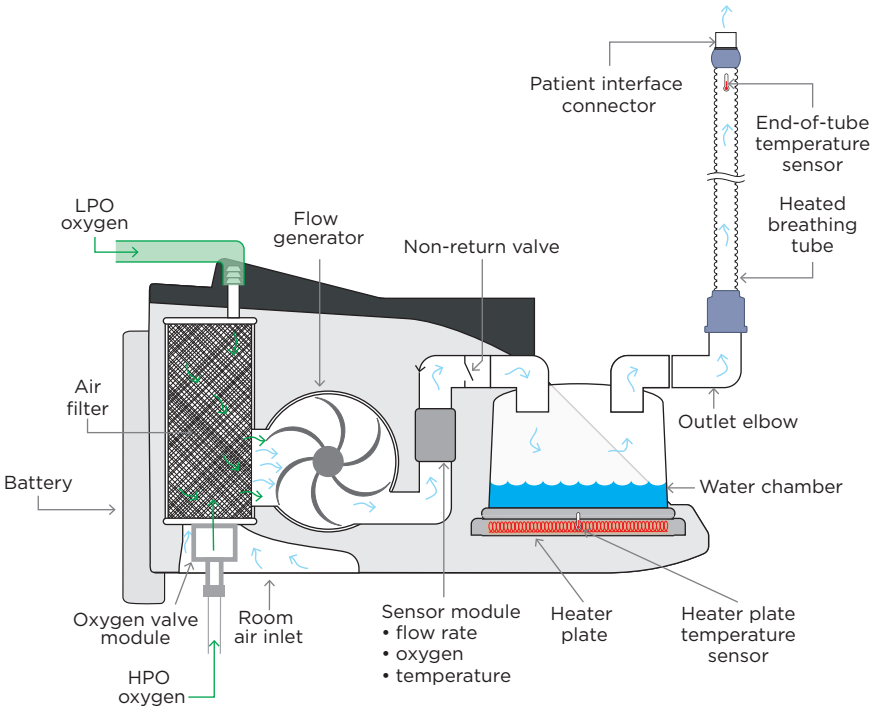


2x Air filter (900PT933) (1 x fitted, 1 x spare)

1.3 Pneumatic pathway

The schematic diagram below illustrates the Airvo 3's pneumatic pathway. A blower inside the Airvo 3 entrains flows of room air from 2 to 70 L/min, which may be mixed with oxygen from high-pressure sources (such as wall supplies or bottles) or low-pressure sources (such as oxygen flowmeters). The air-oxygen mixture is then warmed and humidified in the water chamber, before it is transported through the heated breathing tube to a patient nasal, tracheostomy or mask interface.

The Airvo 3 is powered by wall power supply, and has an internal battery backup to provide continuity of therapy during intra-hospital transport.



1.4 Essential Performance

Under a fault condition, the Airvo 3 delivers therapy within the defined performance range or raises an appropriate alarm condition. For typical performance, refer to the specifications page.

Optiflow High Flow

Delivery of humidification output and delivery of a continuous flow of gas (air/oxygen) at the patient-connection port, or generate alarm.

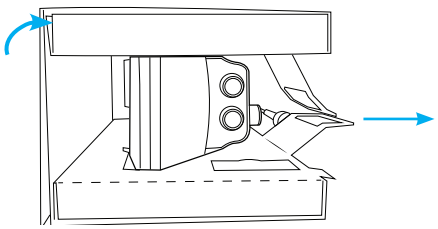
Pulse Oximetry

SpO_2 accuracy, pulse rate accuracy and limit alarm conditions, or generate alarm.

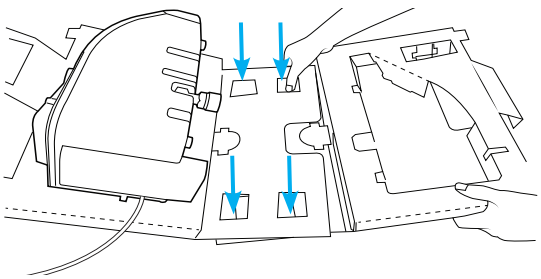
2. Set up Airvo 3 for first use

2.1 Unpack Airvo 3

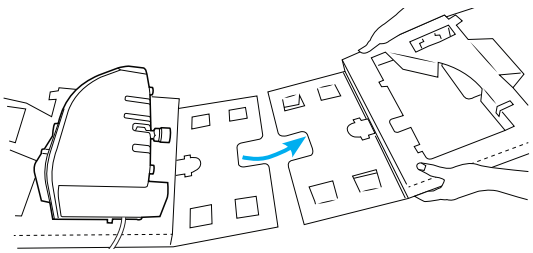
Read the Airvo 3 User Manual, including all warnings and cautions, before using the Airvo 3. Store the user manual and spare air filter in a safe place for future use.



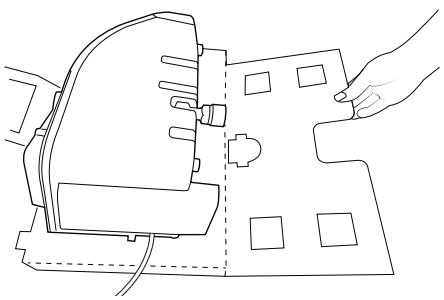
Place the Airvo 3 on its side and remove from packaging using the handle on top of the box.



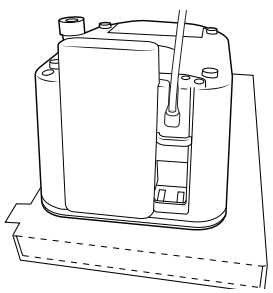
Remove half of the cardboard insert by pressing the four tabs through the square holes.



With the tabs detached, remove half the cardboard box and store in a safe place for future use.



Remove the extra piece of cardboard that has the four square holes and discard.



Turn the Airvo 3 upside down into the gap of the cardboard insert.

The high-pressure oxygen (HPO) port and USB ports are now easily accessible.

Connect the oxygen hose to the HPO port, if required. See Section 2.3.2 for further details.

Connect the pulse oximeter USB connector cable to the Airvo 3 USB port, if required. See Section 7.2.2 for further details.

Peel the screen protector film off the Airvo 3 touchscreen.

WARNINGS

You must take special care when using supplementary oxygen to reduce the risk of fire. Keep all sources of ignition away from the Airvo 3 and, preferably, not in the same room as the Airvo 3 during use.

Do not use supplementary oxygen while smoking, near sparks or open flames.

When using bottled oxygen, ensure the volume remaining in the bottle is sufficient for the planned therapy.

Connect only pure oxygen gas to the oxygen inlet ports on the Airvo 3. The oxygen concentration displayed will be wrong if any other gas, or mixtures of gases, are connected.

The oxygen concentration delivered to the patient can be affected by changes to the oxygen setting, patient interface or obstructions in the air path.

To avoid the risk of fire and burns, only use lotions/salves that are labeled as being oxygen-compatible.

Appropriate patient monitoring must be used at all times.

Make sure that all oxygen connectors are tightened sufficiently to prevent leaks.

As the low-pressure oxygen (LPO) inlet port uses an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur with a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks.

Do not connect an oxygen supply with pressure greater than 600 kPa (87 psi) to the high-pressure oxygen inlet port.

Only add oxygen through either the LPO or HPO inlet ports of the Airvo 3. Do not connect oxygen to both ports at the same time.

To avoid electric shock

Do not store or use the Airvo 3 where it can fall, or be pulled, into water. Disconnect the power cord and stop using the Airvo 3 if water has entered the case.

Never operate the Airvo 3 if it has, or is suspected of having:

- been dropped or damaged,
- a damaged power cord or plug, or
– been dropped into water.

See the Servicing section for instructions to replace a damaged power cord.

Do not attempt to adjust, repair, open, disassemble or modify the Airvo 3 except as described in the user manual or this Product Technical Manual. Return the Airvo 3 to your Fisher & Paykel Healthcare representative for servicing, if necessary.

Do not touch the patient at the same time as any conductive parts of the device, such as USB ports.

The Airvo 3 is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high-flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the humidifier interferes with the operation of adjacent equipment.

There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near sparks or open flames.

Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room as the equipment or any oxygen-carrying accessories. If the patient intends to smoke, always turn the equipment off, remove the cannula and leave the room where the equipment is located. If unable to leave the room, wait 10 minutes after the equipment has been turned off.

Do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns.

Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the device is turned on, but not in use; the oxygen will make the materials more flammable. Turn the device off when not in use to prevent oxygen enrichment.

It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the equipment and indicated in the instructions for use as this can affect the performance of the equipment or pipeline system that can consequently result in serious deterioration of health.

Open flames during Optiflow high flow therapy are dangerous and are likely to result in fire or death. Do not allow open flames within 2 m of the equipment or any oxygen-carrying accessories.

The therapy delivered to the patient can be impacted by the use of a pneumatic/jet nebuliser. Refer to compatible accessories and drug manufacturer instructions for correct usage.

WARNINGS

Do not connect more than 60 L/min O_2 to the LPO inlet port. Read the information on oxygen in the Airvo 3 User Manual before using supplementary oxygen with the Airvo 3.

You must take special care when using supplementary oxygen to reduce the risk of fire. Keep all sources of ignition away from the Airvo 3 and, preferably, not in the same room as the Airvo 3 during use.

Do not restrict ventilation around the Airvo 3 at any time, particularly when a supplementary oxygen supply is connected to either the LPO or HPO inlet port.

Make sure the air filter is installed correctly before connecting supplementary oxygen.

During Optiflow high flow therapy, the fraction of oxygen inspired by the patient will be lower than the value displayed on the FiO_2 tile if the patient's peak inspiratory demand exceeds the flow delivered.

Turn off the low-pressure oxygen source whenever the Airvo 3 is not delivering therapy to ensure that oxygen does not build up inside the device.

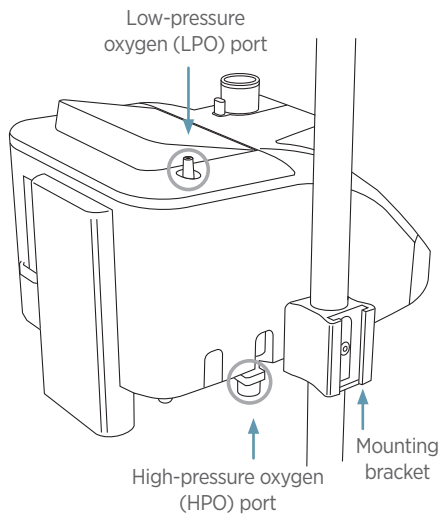
2.2 Place Airvo 3 on the stand

Follow the assembly instructions of the mobile pole stand (900PT421) and mount the Airvo 3 securely on the mounting bracket.

2.3 Set up supplementary oxygen supply

The Airvo 3 provides two options for connecting supplementary oxygen:

1. A low-pressure oxygen (LPO) inlet port, and
2. A high-pressure oxygen (HPO) inlet port:
   a) single HPO supply.
   b) dual HPO supply.



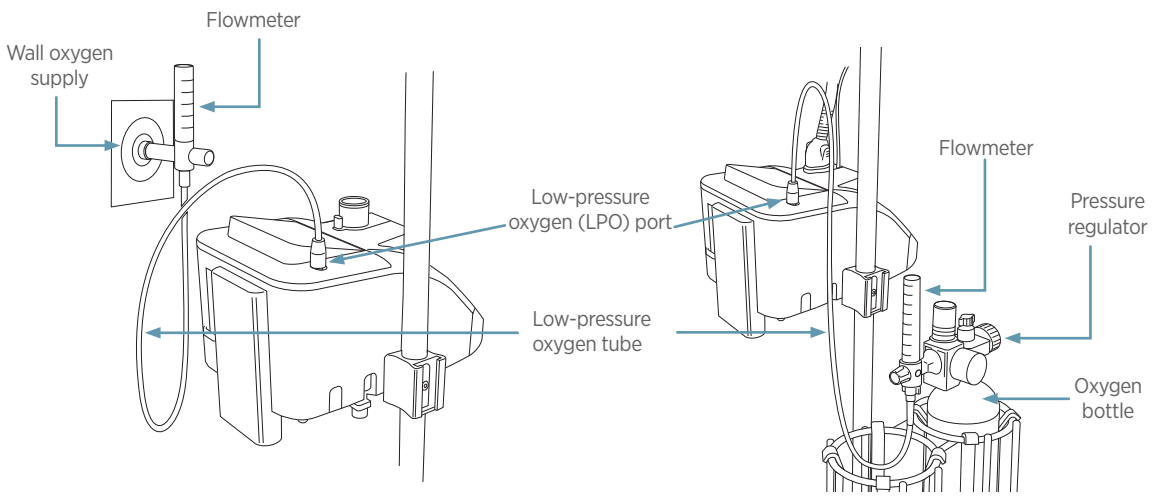
2.3.1 Low-pressure oxygen (LPO) supply

The LPO inlet port connects to an oxygen external flowmeter via a low-pressure oxygen tube.
During use, the user must adjust the oxygen flow rate manually to achieve the prescribed oxygen concentration at the set flow rate.

The LPO inlet port can be connected to:

- an oxygen flowmeter (connected to the wall oxygen supply).
- an oxygen bottle with a pressure regulator and flowmeter.

No additional setup is required to use the LPO inlet port.
See Supplementary Oxygen in the Airvo 3 User Manual for details.



2.3.2 High-pressure oxygen (HPO) supply

When oxygen is connected to the HPO port, the Airvo 3 directly controls the oxygen input to meet the target FiO_2 setting.

The Airvo 3 provides two options for connecting to high-pressure oxygen (HPO).

1. Single HPO supply.
2. Dual HPO supply.

WARNING
Oxygen gas hoses used with Airvo 3 should be compliant with ISO 5359:2014.

Note
If the Airvo 3 is used in transporting patients, we recommend the HPO dual-input oxygen manifold.
See the next section for more details.

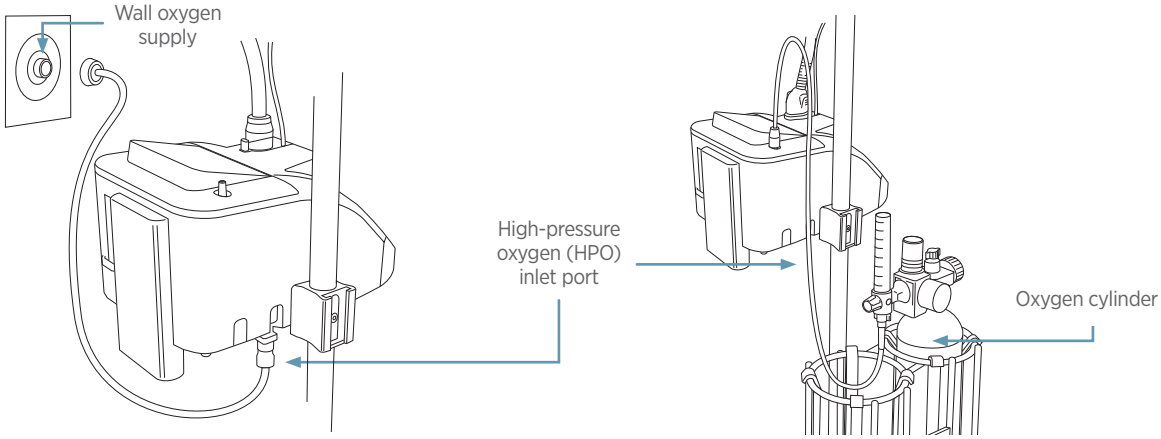
The line pressure of an oxygen source connected to the HPO inlet port must be between 280 kPa and 600 kPa.
The Airvo 3 will draw up to 100 L/min.

2.3.3 Single HPO supply setup

The HPO inlet port connects to a single HPO supply source via an oxygen hose. This allows the user to set a prescribed FiO_2 on the device.

The HPO inlet port can be connected directly to:

- a wall oxygen supply for bedside therapy.
- an oxygen cylinder for mobile use.



If not done already from section 2.1, screw the oxygen hose to the Airvo 3 HPO inlet port.
Connect the oxygen hose to the HPO supply (wall or bottle). If using an oxygen bottle, follow the bottle supplier's instructions to fit the connector correctly.

2.3.4 Dual HPO supply setup

The HPO inlet port connects to two HPO supply sources via the HPO dual-input manifold. This allows the user to change from one HPO source to the other without interruption to therapy. This configuration is recommended when Airvo 3 is intended for use while transporting patients.

You will need:

- HPO dual-input manifold (900PT460x)
- three oxygen hoses
  - 2 x ~0.5 m
  - 1 x ~3 m
- an oxygen bottle holder (900PT427 or 900PT427L)
- at least one oxygen bottle with pressure regulator of a size that fits in the oxygen bottle holder.

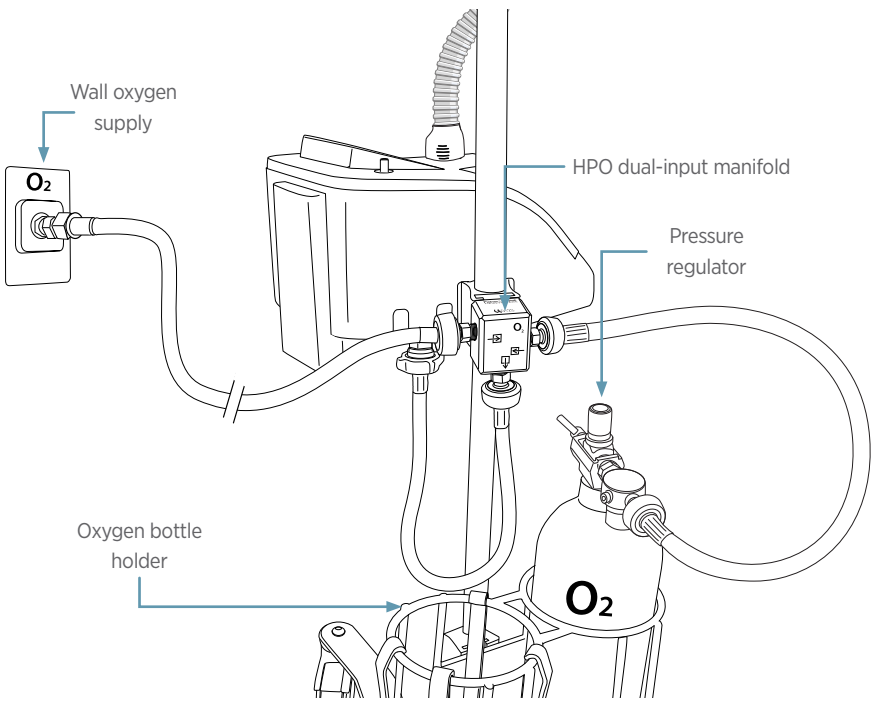
See Section 8.6 for a list of HPO dual-input manifolds.

Begin by mounting the HPO dual-input manifold on the top mounting bracket next to the Airvo 3 and the oxygen bottle holder on the bottom bracket of the Mobile Pole Stand. Place the oxygen bottle into the oxygen bottle holder.

Connect the oxygen hoses:

1. ~0.5 m hose: connect from the high-pressure inlet port on the Airvo 3 to the fitting on the bottom of the HPO dual-input manifold.
2. ~0.5 m hose: connect from the pressure regulator on the oxygen bottle to the fitting on the side of the HPO dual-input manifold.
3. ~3 m hose: connect from the fitting on the end of the HPO dual-input manifold to the wall supply.

Attach each fitting firmly to the connector so that it does not become loose during use. Do not exert excess force on the HPO inlet port - this may damage the Airvo 3.



If there are no available mounting points on the mobile pole stand, use a C-Clamp (900PT428) attached just beneath the Airvo 3 mounting bracket to mount the HPO dual-input manifold.

Note

The HPO port connector type will vary depending on region.

3. Commissioning

3.1 Electrical safety check

The Airvo 3 and associated accessories should be tested to the current local medical electrical standards for in-house testing. For example, refer to AS/NZS 3551 for Australia and New Zealand.

The Airvo 3 is an IEC-60601-1 Class II medical device so a ground connection test of the device is not required.

WARNING
Failure to complete an electrical safety check may result in electrocution.

Notes

The heater plate cannot be used as a ground reference - this may lead to corrosion.
Permanent damage to the Airvo 3 may occur if the USB port is used as a ground point during electrical safety testing.
Do not scratch the heater plate surface - this may lead to corrosion.
Electrical safety testing should only be carried out by a qualified person.

3.2 Performance checks and calibration

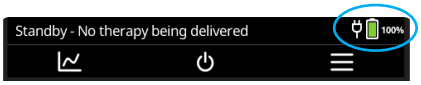
The Airvo 3 does not require initial or regular performance checks or calibration. There is no manufacturer's requirement to test, calibrate or verify the Airvo 3 as it carries out regular self checks during normal use, comparing sensor readings against expected values. It will generate alarms if conditions of operation are outside of the norm.

Fisher & Paykel Healthcare carries out stringent testing on every manufactured Airvo 3 to ensure it meets strict quality and patient safety standards. The temperature, flow, pressure and oxygen sensors inside each unit have been calibrated and tested in our controlled environment.

Do not perform external tests of internal sensor accuracy. Limitations of external test environments and equipment often produce erroneous measurements of the temperature, humidity and/or flow rates of the gases delivered by the Airvo 3.

If device checks are still required to meet hospital requirements, please see Device Check and Functional Checks in Section 7. Contact your Fisher & Paykel representative if you require a certificate of acceptance (CoA).

3.3 Charge battery



The integrated battery must be fully charged before first use. The battery will charge automatically when the Airvo 3 power cord is plugged into the wall power supply.
Leave the Airvo 3 plugged into wall power supply until the battery is fully charged.
The battery charge state is indicated in the message bar (see the Airvo 3 User Manual). It may take up to 6 hours to fully charge the battery. You can continue setting up the Airvo 3 while the battery is charging.

3.4 Configure user settings

Settings on the Airvo 3 can be configured to restrict therapy settings and features that the operator has access to in the user menu Configurations should be developed in consultation with clinicians and operators and applied to Airvo 3 devices before they are used in your clinical environment. Apply settings consistently to all devices within a clinical environment to avoid confusion. Configured default values are applied when the operator selects New Patient upon starting up or when using the disinfection kit.

3.4.1 Record device setup in maintenance log

Record the date the Airvo 3 enters service in your maintenance log. Plan to replace the battery and air filter within the maximum use period listed in the device user manual. See an example of a maintenance log template in Appendix D.

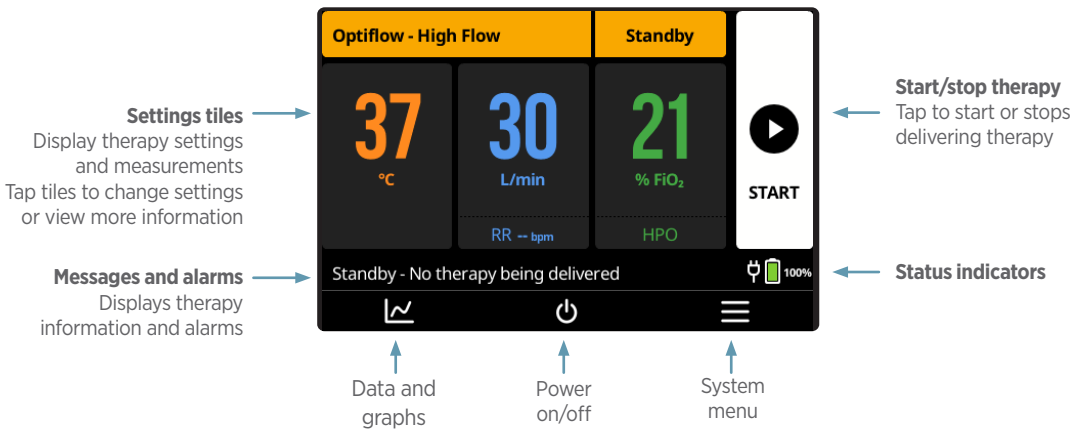
4. Configure system settings

4.1 System settings

System settings allow clinical engineering/technical personnel to configure the Airvo 3 to suit the clinical environment where it will be used. This involves configuring:

- language
- sound and display
- oxygen
- pulse oximeters
- therapy settings
- alarm settings

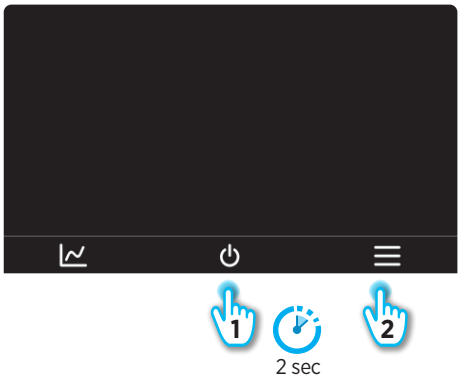
Configurations should be developed in consultation with clinicians and operators and applied to Airvo 3 devices before they are used in your clinical environment. Apply settings consistently to all devices within a clinical environment to avoid confusion. Space is provided in Appendix C to record the customized values for your clinical environment.



WARNING

Using different alarm settings on devices within a single area, such as an intensive care unit, can cause a hazard.

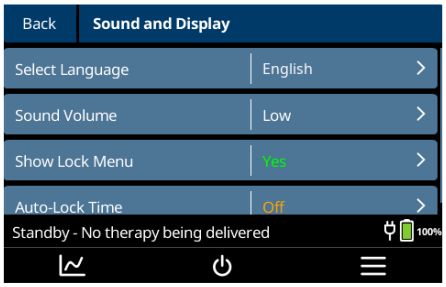
4.2 Accessing system settings

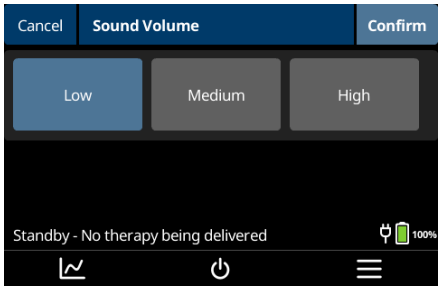


To access the system settings:

1. Turn on the Airvo 3 by holding down the Power on/off button for two seconds.
2. Open the system menu by tapping ☰.
3. Select System Settings.
4. Enter the re-settable personal identification number (PIN) 48643. This PIN can be changed by accessing System Settings menu and selecting Change Pin.

Note: Pin must contain five digits.





To review and/or change settings:

3. Select the desired group (e.g. Sound and Display).
4. Select the desired setting (e.g. Sound Volume).
5. Tap the desired option.
6. Tap 'Confirm' to apply changes or 'Cancel' to discard changes, and then return to the System Settings menu.

When you have finished making changes, tap the Back button to return to the Home Screen.

4.3 Sound and display settings

Label	Options	Default	Description
Sound Volume	Low, Medium, High	Medium	Volume of alarms and information sounds. **WARNING** Ensure that the Sound Volume is loud enough so that operators will hear alarms in the environment where the Airvo 3 will be used.
Show Lock Menu	Yes, No,	Yes	Lock option in the system menu (☰). The touchscreen lock can prevent accidental changes to settings.
Auto-lock Time	1-15 Minutes	Off	The touchscreen will automatically lock after exceeding the set Auto-lock Time.

Note

Alarms and priorities are listed in accordance with the intended operator's position of 2 meters from the device.

4.3.1 Select language

The language setting selects the language used for all text shown on the Airvo 3 touchscreen.

(da) Dansk	(de) Deutsch	(el)Ελληνικά	(en) English	(es) Español (España)
(esla) Español (LatAm)	(fi) Suomi	(fr) Français (France)	(frca) Français (Canada)	(id) Bahasa Indonesia
(it) Italiano	(ko) 한국의	(nl) Nederlands	(no) Norsk	(po) Polski
(pt) Português (Portugal)	(ptbr) Português (Brasil)	(ru) русский	(sv) Svenska	(zht) 繁體中文
(zh) 简体中文	(ms) Malay	(ja) 日本語	(cs) čeština	(tr) Türkçe
(vi) Tiếng Việt	(ro) Română			

4.4 Oxygen settings

Label	Options	Default	Increment	Description
Oxygen Concentration	93%, 100%	100%	-	The concentration of the oxygen supply connected to the LPO and HPO inlet ports (i.e., 93% for oxygen concentrators).
High FiO_2 Alarm	Off, 30 – 95%	Off	5%	The High Oxygen Alarm will be activated if the FiO_2 exceeds this threshold. Note: The Airvo 3 will not prevent the operator setting a higher FiO_2 using the built-in oxygen controller or an external oxygen flowmeter.

WARNING

Select the correct type of oxygen supply that will be connected to the Airvo 3. The oxygen concentration displayed by the Airvo 3 will be inaccurate if you do not select the correct source.

4.5 Pulse oximetry settings

Label	Options	Default	Increment	Description
Show Pulse Rate	Yes, No	Yes	-	Display of pulse rate on the Home Screen when a compatible pulse oximeter is connected.
SpO_2 Low % Limit	20 – 98%	20%	1%	Minimum value for the SpO_2 Low alarm.
Default Low SpO_2 Alarm*	20 – 98%	85%	1%	Default threshold for the SpO_2 Low alarm.
Default High SpO_2 Alarm*	Off , 21 – 98%	Off	1%	Default threshold for the SpO_2 High alarm.
Pulse Oximeter - Masimo				
Default Averaging Time	2 – 16 seconds	8 Seconds	2-4, 4-6, 8, 10, 12, 14, 16 seconds	The default averaging time for pulse oximeter parameters.
Default Sensitivity Mode	Normal, APOD, Max	APOD	-	The default sensitivity mode. Refer to the Airvo 3 user manual for details on sensitivity modes.
Default Alarm Delay	0 – 15 seconds	15 seconds	5 seconds	Default delay before audible SpO_2 Low or SpO_2 High alarm.

Pulse Oximeter - Nellcor				
Response Mode	Normal, Fast	Normal	-	The default response mode. Refer to the Airvo 3 user manual for details on response modes.
SatSeconds Limit	Delay before audible Low SpO_2 or High SpO_2 alarm	10 SatSeconds	Off, 10, 25, 50, 100	Default SatSeconds delay before audible SpO_2 Low or SpO_2 high alarm. Refer to the Airvo 3 User Manual for more information on SatSeconds.
Pulse Oximeter - Nonin				
Averaging Time	4 beats, 8 beats	8 beats	4 beats	The number of pulses used in the average of SpO_2 and pulse rates reported.
SpO_2 Alarm Delay	0 – 15 seconds	15 seconds	5 seconds	Default delay before audible SpO_2 Low or SpO_2 High alarm.

* The high alarm threshold cannot be set below the low alarm threshold.

4.6 Optiflow settings

Label	Options	Default	Increment	Description
Humidity Min	31 – 37 °C	31 °C	1 °C	Minimum target humidity that the operator can select.
Default Humidity	31 – 37 °C	37 °C	1 °C	Default target humidity for Optiflow high flow therapy.
Flow Min	2 – 70 L/min	2 L/min	1 L/min	Minimum target flow that the operator can select.
Flow Max	2 – 70 L/min	70 L/min	1 L/min	Maximum target flow that the operator can select.
Default Flow	2 – 70 L/min	30 L/min	1 L/min	Default target flow.
Allow Expiratory Relief	Yes, No	No	-	Enable/Disable expiratory relief. If enabled, off, 10%, 20% and 30% are available to users.
Show RR	Yes, No	Yes	-	Patient respiratory rate displayed on the Target Flow tile during Optiflow high flow therapy.

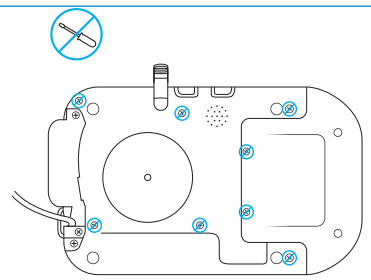
4.7 Disinfection method

Label	Options	Default	Description
Disinfection Kit Only	Yes, No	No	Set whether Airvo 3 can be disinfected without using the disinfection kit.

5. Servicing

WARNING

Do not open the Airvo 3 or loosen any of the eight fastening screws that hold the case together. Opening the device, or loosening the case screws, will affect internal oxygen seals and will compromise device safety.



Calibration and/or servicing of sensors is not required. See Section 3.2 for more details.

The following items require replacement in accordance to the guidance detailed in the table below.

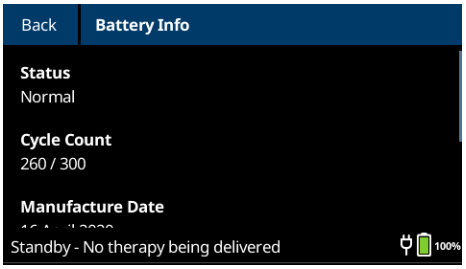
Spare Parts	Replacement schedule
Inlet Filter (900PT933)	3 months or 1,000 hours or when discolored (whichever comes first)
Outlet Elbow (900PT930)	50 washer-disinfector cycles or 5 years (whichever comes first)
Battery Module (900PT957L)	300 discharge cycles or 2 years from first use (whichever comes first)

5.1 Changing the battery module

All batteries lose capacity as they age. The integrated battery should be replaced after 300 discharge cycles or 2 years from first use (whichever comes first).

To access information regarding the battery:

1. Turn on the Airvo 3 by holding down the Power on/off button for two seconds.
2. Open the system menu by tapping ☰.
3. Scroll down the system menu and select Device Info and then Battery Info.



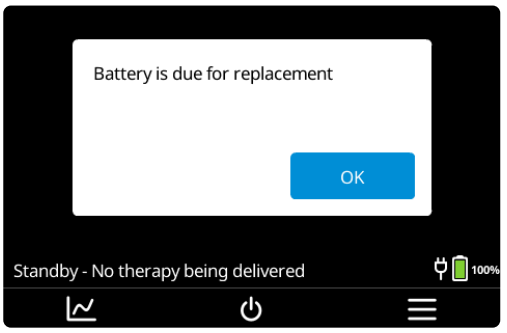
The table below shows the potential device information for the Airvo 3 battery:

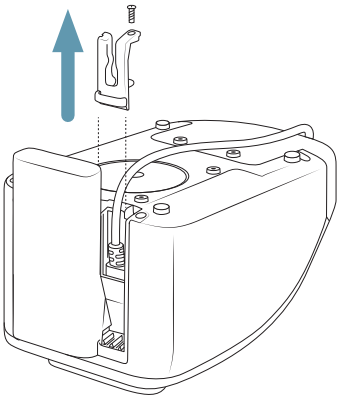
Label	Description
Normal	Battery is operating correctly and does not need to be changed.
Unsupported	An unsupported battery is being used and may not perform as intended.
Faulty: Replace Now	The battery has permanently failed and the device will turn off and not deliver therapy if disconnected from wall power.
Replace Soon	The battery is due for replacement.
Replace Now (Expired)	The battery has expired (300 discharge cycles or 5 years after date of manufacture of the battery) and needs replacing.
Replace Now (Low Capacity)	The battery has low capacity and needs replacing.
Faulty: Restart Device	Battery has a charge/discharge fault.
Initializing	Communications between battery and device has not yet been established.

When it is time to replace the battery, a message will be displayed when you start up the device (see picture, right).

You will need:

- a replacement battery module comprising of a battery, battery cover, and screws (900PT957L)
- a Phillips #1 or #2 screwdriver.





1. Remove the power cord

Turn off the Airvo 3 device and unplug from the wall power supply.

Remove the water chamber from the Airvo 3.

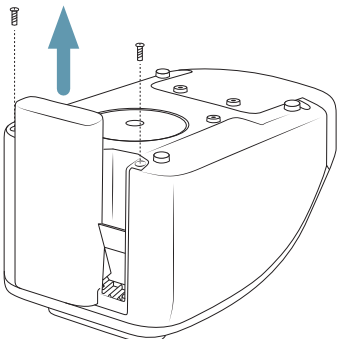
Disconnect all USB connections from the Airvo 3 USB ports.

Disconnect from HPO or LPO supply.

Remove the retaining clip by loosening the screw holding the clip in place on the bottom of the Airvo 3.

Slide the retaining clip up and away from the Airvo 3 body to remove it.

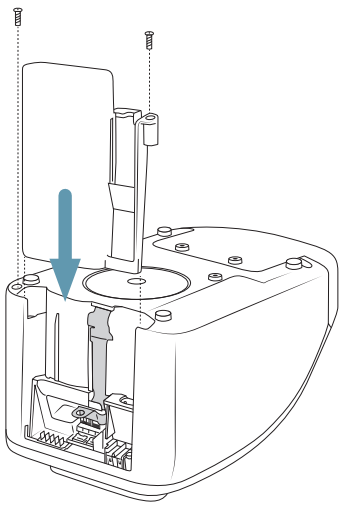
Remove the power cord.



2. Remove the battery module

Remove the battery module by loosening the two screws on the bottom of the Airvo 3 that holds the battery module in place.

Carefully slide the battery module up until it comes free of the device.

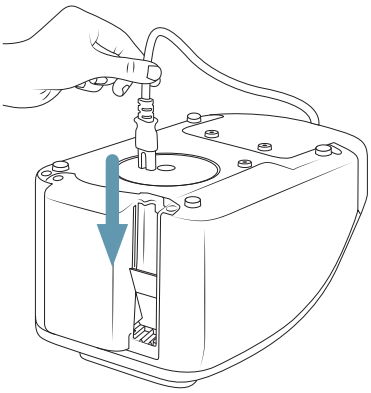


3. Install the new battery module

Install the new battery module by sliding it into the slot on the back of the Airvo 3 until the top of the wings containing the recessed screw holes are flush with the bottom of the Airvo 3 case.

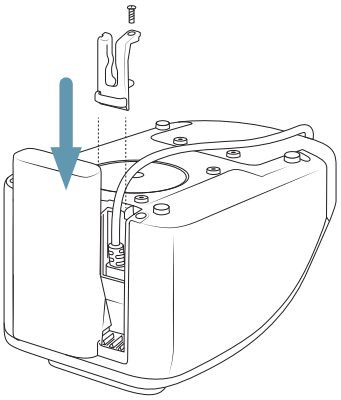
Secure the battery module in place with the two screws. Do not overtighten the screws. Apply a maximum torque of 1 Nm if using a power tool.

Take care not to damage the internal wiring when you install the new battery module.



4. Install the power cord

Insert the plug on the end of the power cord into the power socket on the back of the Airvo 3.



5. Secure the cord with the retaining clip

The retaining clip prevents the power cable from being removed accidentally during use.

Slide the retainer over the power cord and secure it in place with the screw. Do not overtighten the screw. Apply a maximum torque of 1 N m if using a power tool.

Ensure the top of the retainer is flush with the body of the Airvo 3.

6. Record the replacement date in your maintenance log

An example of a maintenance log template can be found in Appendix D.

WARNINGS

Use only a genuine Fisher & Paykel Healthcare replacement battery module to prevent damage to the Airvo 3.

Dispose batteries in accordance with local guidelines to help preserve the environment for future generations.

Do not dispose of the battery in a fire - it could catch fire and explode.

Do not expose the Airvo 3 battery to water, fire or excessive heat. Do not crush, disassemble, puncture or short-circuit the connector terminals of the Airvo 3 battery.

Do not remove the battery from its original packaging until required for use.

In the event of a leaking battery, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

Seek medical advice immediately if a cell or battery has been swallowed.

Only charge the Airvo 3 battery with the Airvo 3 device.

Only use the Airvo 3 battery with the Airvo 3 device.

Remove the battery from the device if it is not likely to be used for an extended period of time.

Do not use the Airvo 3 at an altitude level or outside of temperature listed in the specifications section of the manual. Using outside of these ranges can result in degradation of the health of the patient.

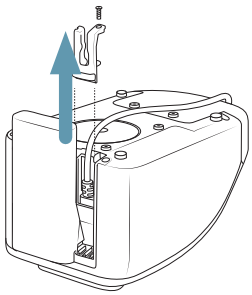
5.2 Removing the battery

The battery must be replaced or removed if it appears damaged. To remove the Airvo 3 battery you will need:

- a Phillips #1 or #2 screwdriver.
- Labels (Please contact your Fisher & Paykel Healthcare representative if you require these labels).

i) "No battery" labels (x2) REF 631661

ii) "Loss of power" label (x1) REF 631662



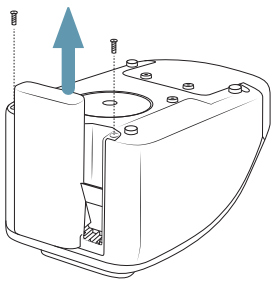
1. Remove the power cord

Turn off the Airvo 3 device and unplug from the wall power supply. Remove the water chamber from the Airvo 3. Disconnect all USB connections from the Airvo 3 USB ports. Disconnect from HPO or LPO supply.

Remove the retaining clip by loosening the screw holding the clip in place on the bottom of the Airvo 3.

Slide the retaining clip up and away from the Airvo 3 body to remove it.

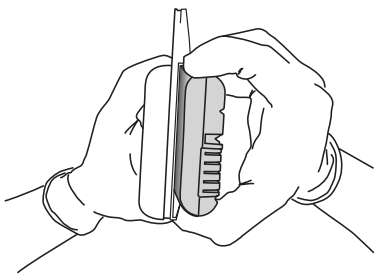
Remove the power cord.



2. Remove the battery module

Remove the battery module by loosening the two screws on the bottom of the Airvo 3 that holds the battery module in place.

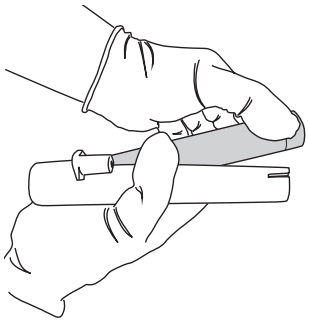
Carefully slide the battery module up until it comes free of the device.



3. Dislodge the battery from the battery cover

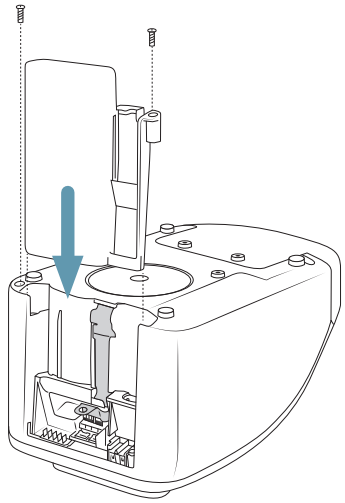
Pull very firmly to dislodge the battery from the battery case.

A soft non-metallic lever may assist.



4. Remove the battery from the battery cover

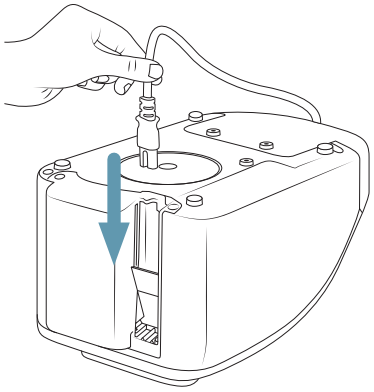
While keeping the battery and battery cover dislodged, slide the battery out as shown.



5. Install the empty battery cover

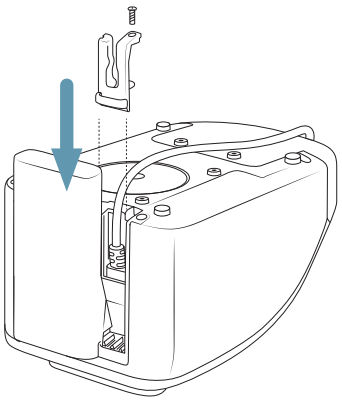
Install the empty battery module by sliding it into the slot on the back of the Airvo 3 until the top of the wings containing the recessed screw holes are flush with the bottom of the Airvo 3 case.

Secure the battery module in place with the two screws. Do not overtighten the screws. Apply a maximum torque of 1 Nm if using a power tool.



6. Install the power cord

Insert the plug on the end of the power cord into the power socket on the back of the Airvo 3.



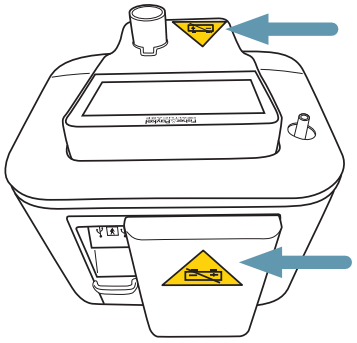
7. Secure the cord with the retaining clip

The retaining clip prevents the power cable from being removed accidentally during use.

Slide the retainer over the power cord and secure it in place with the screw.

Do not overtighten the screw. Apply a maximum torque of 1 Nm if using a power tool.

Ensure the top of the retainer is flush with the body of the Airvo 3.



8. Apply "No battery" labels

These labels will indicate to users that there is currently no battery in the device.

Clean and dry the areas where the "no battery" labels will be placed.

Apply 1 label on the top surface of the Airvo 3.

Apply 1 label on the surface of the empty battery case.

9. Apply the "Loss of power" label to the power cord

This label will indicate to users that disconnecting the Airvo 3 from the mains supply will lead to loss of therapy.

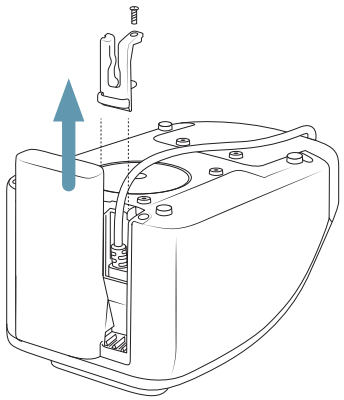
Refer to the instructions on the back of the label for directions on applying to power cord.

5.3 Replacing the power cord

The power cord should be replaced if it appears damaged or does not pass electrical safety tests.

You will need:

- a new power cord. See Section 8 for part numbers.
- a Phillips #1 or #2 screwdriver.



1. Remove the old power cord

Unplug the Airvo 3 device from the wall power supply.

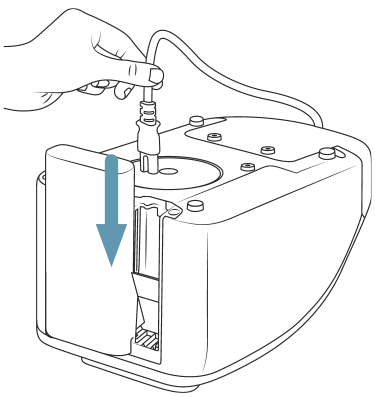
Disconnect all USB connections to the Airvo 3 USB ports.

Disconnect from HPO and/or LPO supply.

The power cord is held in place by a retaining clip.

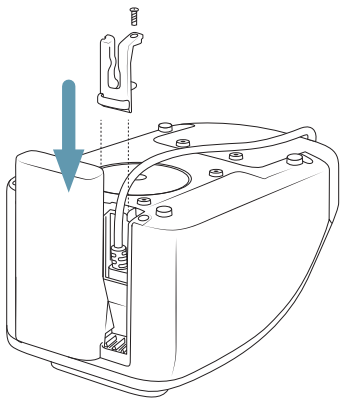
Remove the retaining clip by loosening the one screw on the bottom of the Airvo 3 holding the clip in place. Slide the retaining clip up and away from the Airvo 3 body to remove it.

Tilt the power cord towards the rear of the unit. Grip the connector to remove the power cord. Do not pull on the power cord.



2. Install the new power cord

Insert the plug on the end of the new power cord into the power socket on the back of the Airvo 3.



3. Secure the cord with the retaining clip

The retaining clip prevents the power cable being removed accidentally during use.

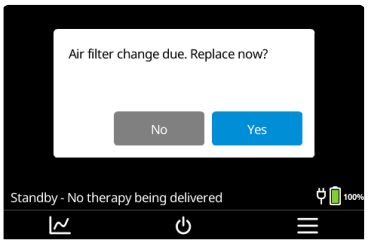
Slide the retainer over the power cord and secure it in place with the screw. Do not overtighten the screw. Apply a maximum torque of 1 N m if using a power tool.

Ensure the top of the retainer is flush with the body of the Airvo 3.

WARNING

To avoid electrical shock from the power cord coming loose, use only genuine Fisher & Paykel Healthcare power cords and the retaining clip supplied with the cord.

5.4 Replacing the air filter



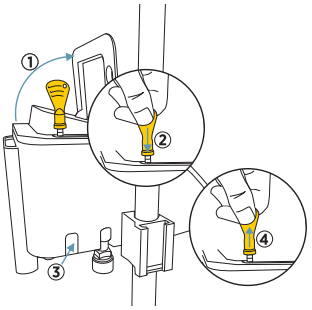
The air filter should be replaced after 1,000 hours of use or if it is discolored. The Airvo 3 will display a message when the air filter is due for replacement.

Choose:

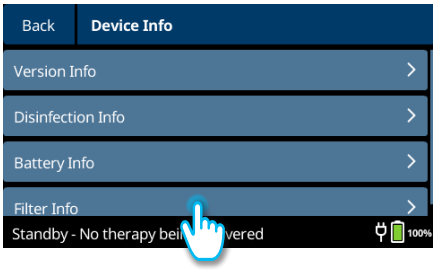
- **Yes** if the air filter is replaced. This will reset the air filter-use timer, or
- **No** to continue with therapy if the air filter was not replaced.

Begin by removing the old filter:

1. Raise the filter cover.
2. Push the filter removal tool down firmly onto the low-pressure oxygen inlet port to get the removal tool to grip.
3. Hold down the air filter-release button on the side of the Airvo 3.
4. Pull up on the filter removal tool to remove the filter.
5. Insert the new filter by pushing down on top of the filter until it clicks into place.
6. Lower the filter cover.

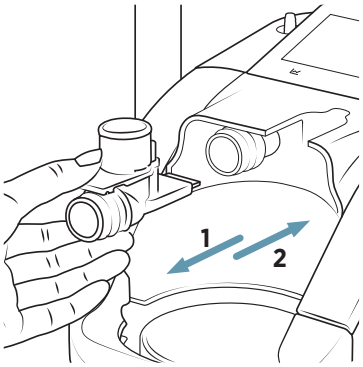


If the filter is replaced before the 1,000 hours of use, the filter use timer can be reset.



5.5 Replacing the outlet elbow

The outlet elbow should be replaced after 50 washer-disinfector cycles, 5 years, or if it is damaged. To replace the outlet elbow:



1. Remove the outlet elbow from the Airvo 3

Firmly grab the rubber-port seal on the outlet elbow, push down on the outlet elbow removal tab with your thumb and pull the outlet elbow towards the front of the Airvo 3.

2. Install a new outlet elbow

Slide the new outlet elbow into the slot above the water chamber area on the Airvo 3.

Push firmly until the elbow locks into place.

6. Fisher & Paykel Healthcare Device Manager (900PT475)

WARNING

Prior to connecting the Airvo 3 to any IT-network, the healthcare provider should identify, analyze, evaluate and control any risks to patients, users or third parties. Risks should be reassessed when changes are made to the connected IT-networks or the Airvo 3 itself.

The Fisher & Paykel Healthcare Device Manager is a program for managing and conducting Planned Preventative Maintenance tasks on the Airvo 3. This application is intended for qualified technical and clinical engineering personnel.

The application can:

- transfer firmware updates, and
- guide the user through Planned Preventative Maintenance.

6.1 Installation

To install the free Fisher & Paykel Healthcare Device Manager you will need:

- a computer running Microsoft Windows 10+ or later, and
- an internet connection.

To download the Fisher & Paykel Healthcare Device Manager, please contact your local Fisher & Paykel Healthcare representative.

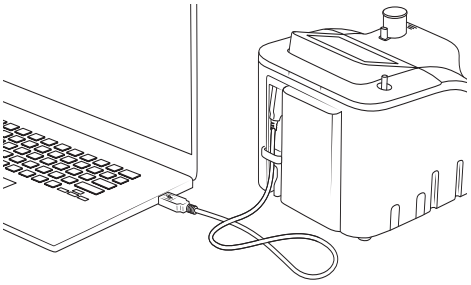
6.2 Using the Fisher & Paykel Healthcare Device Manager

To use the Fisher & Paykel Healthcare Device Manager to manage your Airvo 3, you will need:

- the Fisher & Paykel Healthcare Device Manager installed on your computer,
- an Airvo 3 USB Service Cable (900PT474), and
- an Airvo 3 device.

1. Start the Fisher & Paykel Healthcare Device Manager

Click the Fisher & Paykel Healthcare Device Manager on the Windows Start menu to open the program.



2. Connect the Airvo 3 to your computer

Plug one end of the Airvo 3 USB Service Cable into either USB port on the back of the Airvo 3.

Connect the other end of the USB cable to a free port on your computer.

3. Turn on the Airvo 3

Plug the Airvo 3 into the wall power supply and turn it on by holding down the Power on/off button for 2 seconds.

The Fisher & Paykel Healthcare Device Manager will detect the Airvo 3 and connect to the device automatically.

Select 'Help' from the application menu and follow the instructions on using the Fisher & Paykel Healthcare Device Manager.

6.3 Updating Airvo 3 software

The Fisher & Paykel Healthcare Device Manager automatically checks for Airvo 3 software updates.

To update the software of your Airvo 3:

1. Ensure your Airvo 3 is connected to the Fisher & Paykel Healthcare Device Manager by verifying the application displays a connected status.
2. Navigate to ‘Device Dashboard’ from the application’s Device menu. power while updating the software.
3. If the application indicates a software update is available under the Firmware section, click the Update button to begin and follow the steps shown.

Your Airvo 3 will automatically restart to complete the software update.
Please keep your Airvo 3 connected to the Fisher & Paykel Healthcare Device Manager until the process has completed to accurately record the update.
Refer to your Fisher & Paykel Healthcare Device Manager user instructions for completing a software update using your version of the application.

Notes

Do not remove the Airvo 3 USB Service Cable during data transfer.

Use a computer with up-to-date antivirus software installed.

Do not plug an Airvo 3 USB Service Cable into unsupported devices.

7. Device checks (optional)

The Airvo 3 does **not** require regular maintenance. Fisher & Paykel Healthcare carries out stringent testing on every Airvo 3 manufactured to ensure it meets our strict quality and patient safety standards. The temperature, flow, pressure and oxygen sensors inside each unit have been calibrated and tested in our controlled environment. The Airvo 3 automatically carries out the self-test of various flow, pressure, temperature, and oxygen sensors during use and does not require ongoing calibration. The Airvo 3 does not require ongoing calibration.

Do not perform external tests of internal sensor accuracy. Limitations of external test environments and equipment often produce erroneous measurements of temperature, humidity and/or flow rates of the gases delivered by the Airvo 3.

The device checks described in this section are to:

- meet hospital device Planned Preventative Maintenance requirements, and/or
- verify the Airvo 3 performance as part of product acceptance testing.

These checks test the basic functions of the unit and the operation of the sensors and alarms. The Device check results form in Appendix A can be used to record the test results.

WARNINGS

Do not perform acceptance/performance checks while the Airvo 3 is in use on a patient. This may result in serious harm.

Disconnect the wall power supply from the Airvo 3 before carrying out a physical check. Carrying out the physical check while the Airvo 3 is plugged into the wall power supply may result in serious harm.

7.1 Physical checks (optional)

Inspect the Airvo 3 following the steps below. Record results in the form provided in Appendix A.

If any part of the Airvo 3 is damaged, remove the device from service and contact your Fisher & Paykel Healthcare representative.

1. Check the power cord and retainer for damage including cuts, stretching, wear and bent pins. If the power cord or retainer is damaged, follow the steps in Section 5.2 to replace the damaged component.
2. Check that the battery and power-cord retainer fixing screws are present and not loose.
3. Check the air filter for damage, including discoloration, broken low-pressure oxygen inlet port and dirt. If the air filter is damaged, follow the steps in Section 5.3 to replace the air filter. Ensure the air filter is fully inserted and not loose.
4. Check the heated breathing tube port and electrical connector of the removable elbow for damage and signs of corrosion. Follow the steps in Section 5.4 to replace the outlet elbow if it is damaged.
5. Check the Airvo 3 case for damage.
6. Check the screen and the surrounding bezel (the area outside the screen) for damage. Ensure the screen is secure and not cracked.
7. Check that the 'Hot Surface' symbol is present in the water chamber cavity.
8. Check the heater plate for excessive damage, including deep scratches or heavy corrosion.
9. Check that the finger guard springs back into place when pushed down and released.
10. Check that the Airvo 3 is attached securely to the mobile pole stand and the mounting point for the stand is not cracked or broken.

7.2 Functional checks (optional)

The Airvo 3 does **not** require regular maintenance. Fisher & Paykel Healthcare carries out stringent testing on every Airvo 3 manufactured to ensure it meets our strict quality and patient safety standards. The temperature, flow, pressure and oxygen sensors inside each unit have been calibrated and tested in our controlled environment. The Airvo 3 automatically carries out the self-test of various flow, pressure, temperature, and oxygen sensors during use and does not require ongoing calibration. The Airvo 3 does not require ongoing calibration.

Do not perform external tests of internal sensor accuracy. Limitations of external test environments and equipment often produce erroneous measurements of the temperature, humidity and/or flow rates of the gases delivered by the Airvo 3.

The Airvo 3 does not require regular testing or calibration (see Section 3.2). The tests described in this section may be used as part of product acceptance testing or ongoing functional testing to comply with hospital policies.

The Airvo 3 should be plugged into the wall power supply (unless otherwise stated) for all tests. Before you begin, fully charge the battery by connecting the Airvo 3 to the wall power supply until the battery indicator on the display shows 100%. Fully charging the Airvo 3 can take up to 6 hours.

If required, refer to the instructions in Section 4.2 to change the Airvo 3 system settings.

Should any of the tests fail, please contact your Fisher & Paykel Healthcare representative and fill in the Fault report form.

WARNINGS

Do not place the device into service if any of these tests fail. Contact your Fisher & Paykel Healthcare representative.

Do not carry out these tests when the Airvo 3 is being used to deliver therapy to a patient.

Functional test equipment

The table below shows the test equipment required for the Airvo 3.

Equipment	Part number
Airvo 3	PT301xx*
Clean and disinfected outlet elbow[1]	900PT930
Air filter[2]	900PT933
AirSpiral tube and chamber kit	900PT561
USP Sterile Water (or equivalent)	-

* xx refers to country-specific product code

1. A clean and disinfected outlet elbow is supplied with the Airvo 3.
2. A clean air filter is already placed in the Airvo 3 and a spare is supplied.

WARNINGS

Before testing, make sure the Airvo 3 and outlet elbow have been cleaned and disinfected if the device has been used on patients. Follow the reprocessing instructions in the Airvo 3 User Manual to clean and disinfect the Airvo 3.

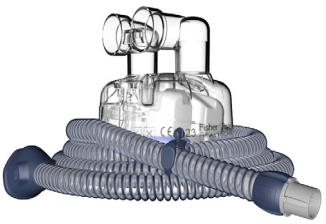
Do not use chambers or breathing tubes that have been used on patients for testing.

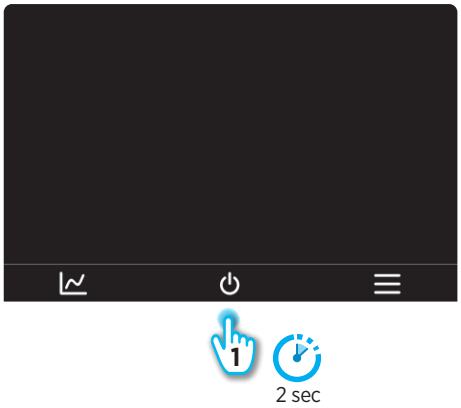
7.2.1 General checks

To prepare for the tests:

- Set up an Optiflow high flow circuit 900PT561 (refer to the Airvo 3 User Manual).

Note: A patient interface is not required for these tests.





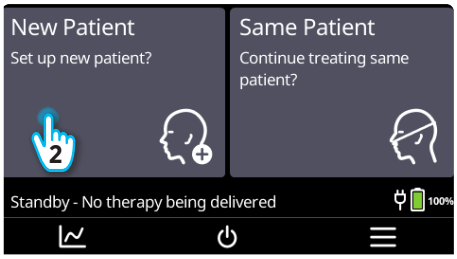
Switch on the Airvo 3

1. Plug the Airvo 3 into the wall power supply and turn it on by holding down the Power on/off button for 2 seconds.

WARNINGS

Make sure the Airvo 3 is dry before plugging it into the wall power supply to avoid a potential electric shock.

It is critical that nothing obstructs the gas intake surrounding the HPO port; this includes items like bedding. Blocking this area can disrupt the patient's therapy.



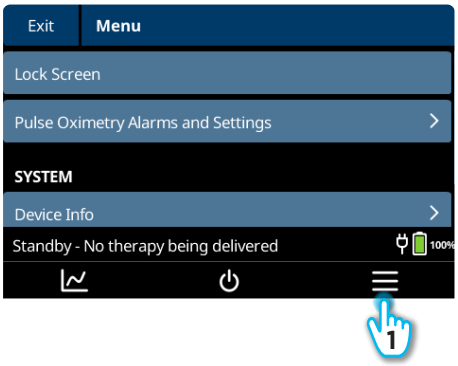
Select patient type

1. Select New Patient for all tests. Check that a clean, disinfected outlet elbow is installed, then
2. Tap Confirm to continue.

If the outlet elbow is missing or has not been cleaned and disinfected, turn the Airvo 3 off and replace the outlet elbow before continuing.

WARNING

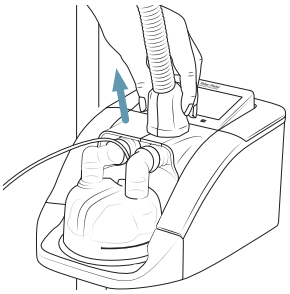
Make sure the Airvo 3 is turned off when connecting the outlet elbow.



Language

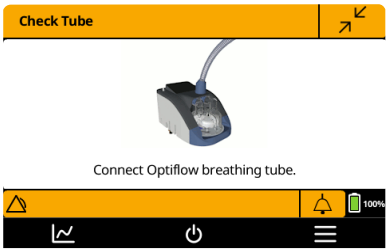
1. Tap ☰ to open the System menu.

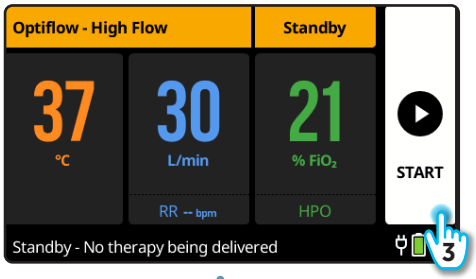
Confirm the menu entry text is displayed in a language that will be understood by operators in the clinical environment where the Airvo 3 will be used.

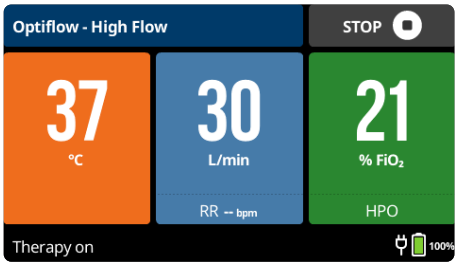


Alarm sound and tube check

1. Tap the START button on the Home Screen to start therapy.
2. Disconnect the breathing tube from the Airvo 3.
3. Confirm that the 'Check tube' alarm is displayed on the Airvo 3 screen within 5 seconds.
4. Check that the alarm sound is audible.
5. Reconnect the heated breathing tube to the Airvo 3 to resolve the alarm.
6. Tap the STOP then YES buttons to stop therapy.







Heater plate test

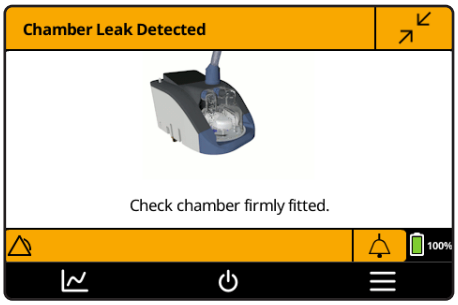
This test checks that the heater plate is functioning correctly.

1. Ensure there is water in the water chamber.
2. Apply the following settings:
   i) Flow rate: 30 L/min
   ii) Dew point temperature: 37 °C
3. Tap the START button to begin therapy.
4. Check that the Message Bar text changes from 'Therapy On – warming up' to 'Therapy On' within 30 minutes.

The Airvo 3 will play a short melody.

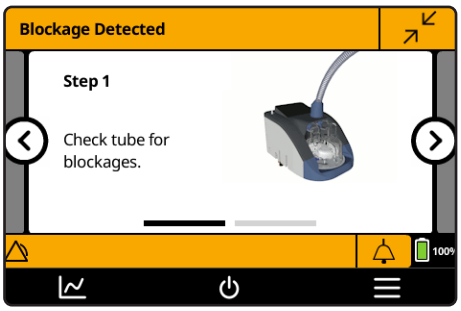
Power out response

1. Carry out the heater plate test above so that the Airvo 3 is delivering therapy and has completed warmup.
2. Check that the battery is charged by confirming the battery indicator on the Airvo 3 display is showing at least 10%.
3. Disconnect the Airvo 3 from the wall power supply.
4. Check that you hear an audible alarm and that one of the following alarms is displayed within 5 seconds of the wall power supply being disconnected:
   - Battery Mode: Reduced Humidity
   - Low Battery
   - Critically Low Battery
5. Confirm that the Airvo 3 continues delivering respiratory gases by checking for air flowing out of the breathing circuit.
6. Reconnect the Airvo 3 to the wall power supply.



Flow leak test

1. Ensure the Airvo 3 has completed warmup.
2. Remove the water chamber from the Airvo 3.
3. Check that you hear an audible alarm and the Chamber Leak Detected alarm is displayed within 30 seconds of removing the chamber.
4. Reconnect the water chamber to the Airvo 3. Confirm that the Chamber Leak Detected alarm disappears, and the audible alarm stops.



Flow obstructed test

This test confirms the sensor that detects blockages is operating correctly.

1. If connected, disconnect the nasal interface from the heated breathing tube.
2. Completely block the end of the heated breathing tube with your hand.
3. Check that you hear an audible alarm and the Blockage Detected alarm is displayed within 15 seconds of blocking the heated breathing tube.
4. Unblock the heated breathing tube. Confirm that the Blockage Detected alarm disappears, and the audible alarm stops.

Battery operating time

This test checks the operating time of the Airvo 3 on battery power.

1. Ensure the battery is fully charged (may take up to 6 hours).
2. Disconnect the Airvo 3 power plug from the wall power supply.
3. Record the current time.
4. Wait for critically low power alarm.
5. Make sure the device continues running for 20 minutes.
6. Remove the battery from the device.
7. Make sure a power down alarm is produced and that it lasts for longer than 120 seconds.

Replace the internal battery if the operating time is less than 20 minutes from step 4 above.

WARNING

Always set all settings to standard values for your hospital after completing the tests to reduce the risk of patient injury.

WARNING

Use only compatible oximetry sensors and accessories for SpO_2 and pulse rate measurements. Verify compatibility before use to avoid incorrect operation of your Airvo 3, inaccurate measurements and/or patient injury.

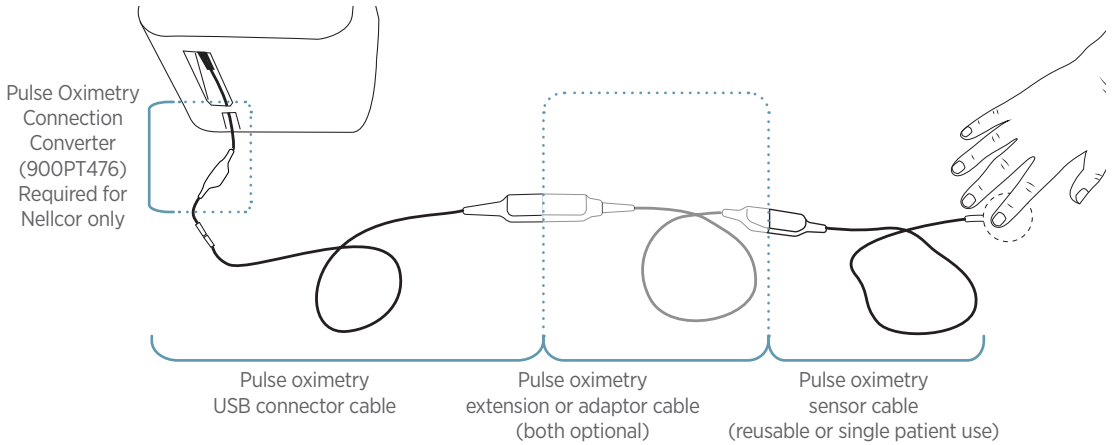
7.2.2 USB port functional check

To prepare for the tests, you will need:

- a third party pulse oximetry USB connector cable.
- a third party pulse oximeter extension cable or adapter (optional).
- a pulse oximetry sensor cable.

See Appendix F for the full list of accessories.

This test checks that the Airvo 3 can communicate with compatible pulse oximeter accessories. The pulse oximeter connects to either USB port on the back of the Airvo 3. Perform this test separately for each USB port.

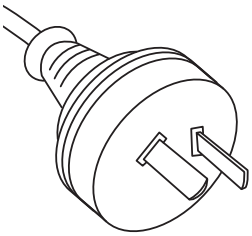


To check the USB port and pulse oximeter:

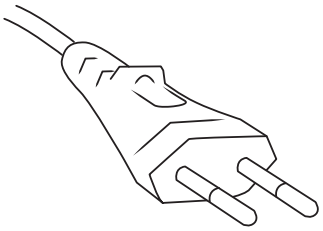
1. Connect the pulse oximetry USB connector cable into one of the USB ports on the back of the Airvo 3.
2. Connect the pulse oximeter sensor cable to the pulse oximetry USB connector cable. A pulse oximeter extension cable or adapter cable may be required.
3. Attach the pulse oximeter sensor to a suitable measurement site on your body, e.g. index finger.
4. Check that the pulse oximeter tile appears on the Airvo 3 Home Screen.
5. Check that SpO_2 measurements are displayed. SpO_2 should be above 90% for a healthy person.
6. Unplug the pulse oximetry USB connector cable from the Airvo 3 and then repeat the test using the second USB port on the Airvo 3.

8. Spare parts and accessories

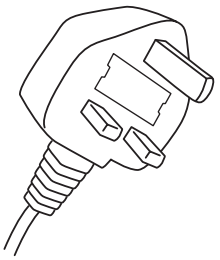
8.1 Power cords



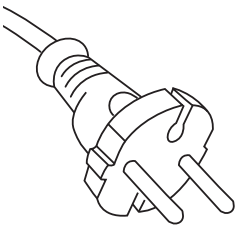
Type I
(900PT412AN)



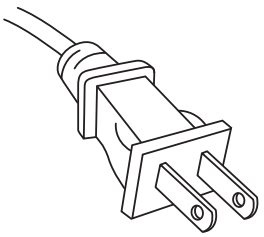
Type C
(900PT412EW)



Type G
(900PT412UK)

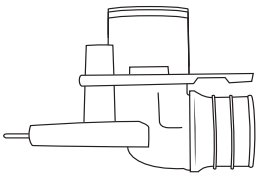


Type F
(900PT412EU)

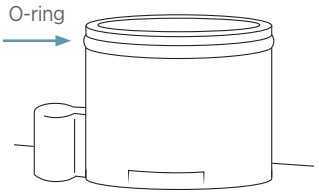


Type A
(900PT412US)

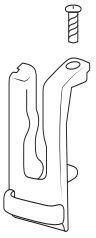
8.2 Spare parts



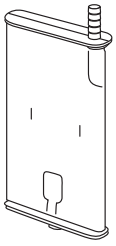
Outlet elbow
(900PT930)



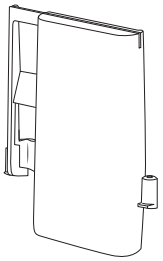
O-ring (10-pack)
(900PT408)



Power cord retainer (900PT956)
(5 x power cord retainer,
10 x retainer screws)



Air filter (900PT933)



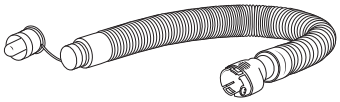
Battery module
(900PT957L)

8.3 Interface cables

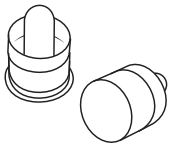
Airvo 3 USB Service Cable
(900PT474)

Airvo 3 Data Port Adapter
(900PT473)

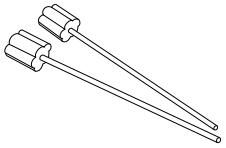
8.4 High-level disinfection



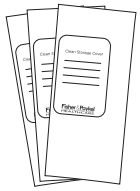
Disinfection kit
(900PT600)



Disinfection filter
(2-pack) (900PT601)



Cleaning sponge stick
(20-pack) (900PT602)



Disinfection storage cover
(20-pack) (900PT603)

Note: Not all accessories are available in all markets. Check with your Fisher & Paykel Healthcare representative.

WARNINGS

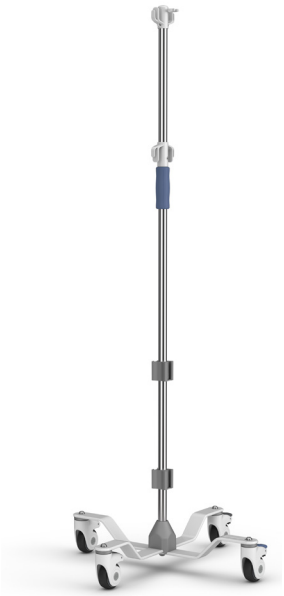
Equipment connected to the Airvo 3 via the Data Port Adaptor (900PT473) must be certified according to IEC 60950-1 or IEC 60601-1. All combinations of equipment must be in compliance with IEC 60601-1 requirements for medical electrical systems. Any person who connects additional equipment has now configured a medical system and is therefore responsible for ensuring that the system complies with the requirements of IEC 60601-1. Consult a technical specialist in your hospital for more information.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Airvo 3.

All data transferred from the Airvo 3 is intended for information only and must not be used as the sole basis for diagnostic or therapeutic decisions.

Anybody connecting patient consumables, accessories or spare parts to the Airvo 3 is accountable for the compatibility of the device and those patient consumables, accessories and/or spare parts.

8.5 Hardware/Mounting



Mobile pole stand
(900PT421)

Accessory basket
(900PT426)

Large and small oxygen bottle holder
(900PT427, 900PT427L)

Mobile pole stand handle
(900PT445)

C-clamp for Mobile pole stand
(900PT428)

Hook for mobile pole stand
(900PT450)

Braked castor wheel and fasteners
(900PT448)

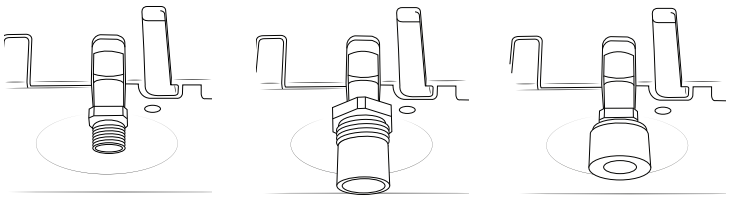
Steering castor wheel and fasteners
(900PT449)

8.6 HPO dual-input manifolds

The HPO dual-input manifold is available for three different connector systems: DISS, NIST and SIS. A set of hoses with corresponding connector types connect the HPO dual-input manifold to the Airvo 3, a source of bottled oxygen and the wall oxygen supply.

The HPO inlet port connector on the Airvo 3 is market dependent. Use the diagram below to identify the HPO inlet port connector on your device.

HPO dual-input manifold with DISS fittings



DISS NIST SIS

DISS

Description	Source-end connector	Part number
HPO dual-input manifold with DISS fittings	DISS	900PT460D

NIST

Description	Source-end connector	Part number
HPO dual-input manifold for NIST fittings	NIST	900PT460N
DISS to NIST connection adapter	NIST	900PT462DN

SIS

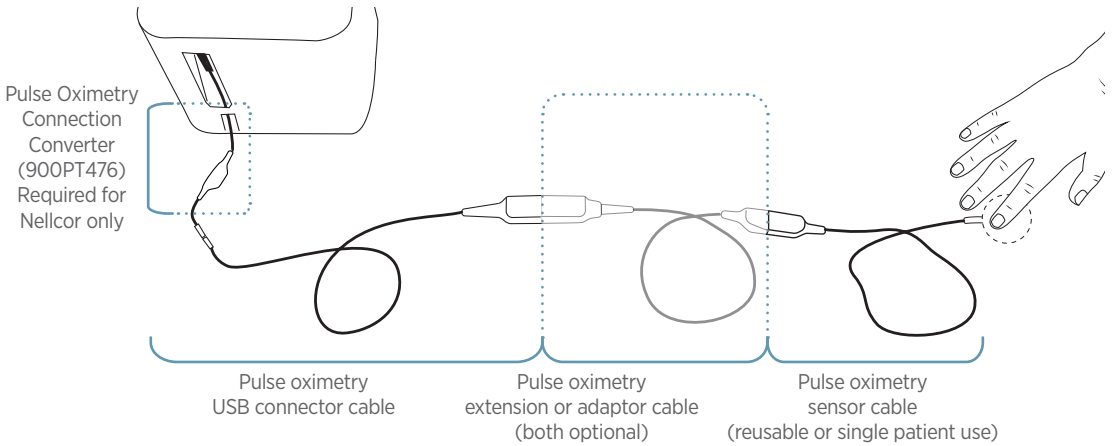
Description	Source-end connector	Part number
HPO dual-input manifold with SIS fittings	SIS	900PT460S

9. Third-party accessories

Pulse oximetry

Refer to the user instructions of the third-party accessory for correct operation, use, maintenance and servicing.
The instructions in this section are for Fisher & Paykel Healthcare approved third-party accessories only and they do not substitute instructions from the manufacturer.

For a full list of compatible sensors, see Appendix F.

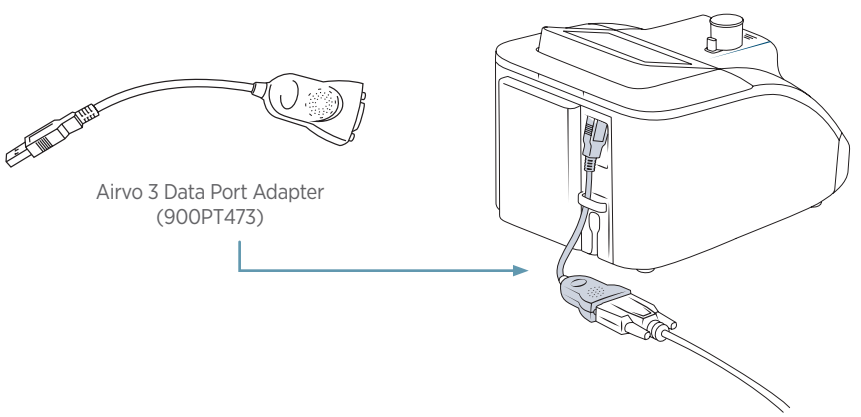


10. Pulse oximetry clinical data

For SpO_2 accuracy tables and graphs, please refer to each sensor user instruction, which are available upon request to your local Fisher & Paykel Healthcare representative.

11. Airvo 3 connectivity

When the Data Port Adapter (900PT473) is connected to the Airvo 3 it allows therapy and device data to be transmitted to other third-party devices and hospital systems, such as electronic health records, bedside monitors and centralised monitoring systems. The data is output in a CSV format every second. For a copy of the Airvo 3 CSV Data Format or a list of supported third-party devices, please contact your Fisher & Paykel Healthcare representative.



12. EMC tables

Electromagnetic emissions: Manufacturer's declaration and guidance

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Applicable for countries with 100-115V and 220-240V mains voltage.
Harmonic emissions IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	

Electromagnetic immunity: Manufacturer's declaration and guidance

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV See note 2 below	Mains power quality should be that of a typical residential, commercial, professional healthcare facility, or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line	±1 kV	Mains power quality should be that of a typical residential, commercial, professional healthcare facility, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	**Voltage dips:** 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle	**Voltage dips:** 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle	Mains power quality should be that of a typical residential, commercial, professional healthcare facility, or hospital environment. If the user of the device requires continued operation during power interruptions, it is recommended the device be powered from an uninterruptible power supply or a battery.
	70 % UT (30 % dip in UT) for 25/30 cycles	70 % UT (30 % dip in UT) for 25/30 cycles	
	Single phase at 0°	Single phase at 0°	
	Voltage interruptions: 0% UT for 250/300 cycle	**Voltage interruptions:** 0% UT for 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical residential, commercial, professional healthcare facility, or hospital environment.

Note 1. UT is the AC mains voltage prior to application of the test level.

Note 2. This testing is not necessary for the safe operation of the device.

Electromagnetic immunity: Manufacturer's declaration and guidance

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF **IEC 61000-4-6**	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	d = 1.2 √P
	6 Vrms ISM bands from 150 kHz to 80 MHz	6 Vrms ISM bands from 150 kHz to 80 MHz	
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz - 2700 MHz	3 V/m 80 MHz - 2700 MHz	d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless Communications equipment **IEC 61000-4-3**	9 - 28 V/m, 15 Radio Service Bands at 385 MHz – 5785 MHz	9 - 28 V/m, 15 Radio Service Bands at 385 MHz – 5785 MHz	d = 30 cm
Radiated fields in close proximity. **IEC 61000-4-39**	65 A/m (134.2 kHz) 7.5 A/m (13.56 mHz)	65 A/m (134.2 kHz) 7.5 A/m (13.56 mHz)	

Note 1. At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer.

Note 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13. Collection and use of personal data

Airvo 3 is not designed to collect identifiable information about end users. To function effectively, Airvo 3 will collect and store limited therapy data. The therapy data will be securely stored on the Airvo 3 device for 24 hours or until it is powered off.

Limited Airvo 3 device information may be collected by F&P Healthcare to monitor medical device performance, including device identifiers. This is to monitor medical device effectiveness, and improvement opportunities (e.g. firmware). Information is stored and used securely by F&P Healthcare and does not include any therapy data or data relating to your personal information.

Engineering and performance data to support medical device effectiveness and improvement (available to F&P):

- Device identifier / serial number
- Device usage data
- Device performance metrics
- Device sensor measurements
- Firmware update status

Please refer to the T&Cs for your data protection and privacy obligations. Alternatively, refer our Global Privacy Statement on our website for more on how we handle personal information.

Read and accept the privacy statement which is available from: https://www.fphcare.com/nz/our-company/about-us/privacy-statement/

Note

Prior to connecting the Airvo 3 to any IT-network, the healthcare provider should identify, analyze, evaluate and control any risks to patients, users or third parties. Risks should be reassessed when changes are made to the connected IT-networks or the Airvo 3 itself.

14. Error codes

The Airvo 3 continuously monitors critical internal components during use. The following provides troubleshooting advice for error codes that may appear. During the fault condition, the audible alarm will sound and the Airvo 3 will, in some instances, stop therapy.

Error codes will be displayed as 'E.x.x.x' where 'x' is a number. If the problem persists, contact your F&P representative.

Error codes	Error type	Troubleshooting steps
1.2.x-1.3.x	**Communication and audio**	Restart the Airvo 3 and check the system settings for audio alarm configuration.
2.1.x – 2.2.x	**Software**	Restart the Airvo 3 and ensure the correct consumables are connected to the device.
2.3.x	**Voltage**	Restart the Airvo 3 and ensure the power supply meets the specifications outlined in the user manual.
2.4.x – 2.5.x	**Heater plate**	1. Turn off the Airvo 3. 2. Check that the water chamber is fitted correctly. 3. Check the power supply is stable.
2.6.x – 2.7.x	**Heated breathing tube**	1. Check that the tube is connected correctly. 2. Restart the Airvo 3. 3. If the problem persists, repeat the steps above with a new tube.
2.8.x – 2.9.x, 4.x.x	**Motor**	Turn off the Airvo 3 and wait for at least 30 minutes before restarting.
2.10.x, 3.3.x – 3.4.x	**Pressure**	Ensure that operating conditions are within the specified range in the user manual.
2.11.x, 3.8.x	**Oxygen related**	1. Turn off the Airvo 3. 2. Check that the HPO port is securely connected. 3. Check the oxygen source (wall or cylinder). 4. Turn on the Airvo 3.
2.12.x	**Ambient conditions**	Ensure that the Airvo 3 is used under the specified operating conditions outlined in the user manual. Restart the Airvo 3.
3.x.x	**Internal sensors**	Ensure that the Airvo 3 is used in the operating conditions specified in the user manual. Restart the Airvo 3.

15. Troubleshooting

Carefully follow each step outlined below. Where possible, confirm that a second device operates as expected. If the problem persists, please contact your local Fisher & Paykel Healthcare representative.

A comprehensive guide for alarm conditions, such as therapy, power, pulse oximetry and oxygen alarms, can be found in the user manual.

15.1 Power

Airvo 3 does not turn on (mains power)

- Ensure the Airvo 3 is plugged into the wall power supply and the wall power switch is turned on.
- Press and hold the power button for at least 2 seconds. You should hear a melody and the screen will display the Fisher & Paykel Healthcare logo.
- Connect the Airvo 3 to another power outlet and repeat steps above.
- Check the power cord for visible damage. If the power cord is damaged, immediately turn off the power supply at the wall. Replace the damaged cord. See Section 5.2 to replace the power cord. Discard the faulty cord in accordance with local guidelines and regulations.
- The power cord may be damaged internally. Consider replacing the power cord, as described above.
- Ensure the touch screen is clean and dry, and not in contact with any objects, tubes, or wires.

Airvo 3 does not turn on (battery power)

- Press and hold the power button for at least 2 seconds. You should hear a melody and the screen will display the Fisher & Paykel Healthcare logo.
- Confirm the Airvo 3 operates when connected to the wall power supply. Follow the steps in Section 15.1 above.
- Check the battery is charged. To protect the battery, the Airvo 3 will not turn on if the battery level is below 10%.
- Plug the Airvo 3 into the wall power supply to charge the battery for at least 6 hours, then disconnect the power and hold down the power button for at least 2 seconds.
- Check the battery has not reached the end of its working life. Follow battery replacement instructions in Section 5.

Black screen (power out)

- The audible alarm will sound for at least 120 seconds and the signal light above the touchscreen will flash.
- The most likely cause is a depleted battery or a loose or disconnected power cord. Follow the steps in Section 5.1 and 5.2.

Restarting the Airvo 3

Perform the following steps when instructed to restart the Airvo 3.

1. Turn off the Airvo 3 and disconnect it from the wall power supply.
2. Wait 5 seconds.
3. Plug the Airvo 3 into the wall power supply and turn it on again.

15.2 Battery

The Airvo 3 battery is due for change after 300 cycles or 5 years after date of manufacture of the battery.

Battery change prompt

A prompt is generated prior alerting the user that a change is due. Once the battery has reached either 300 cycles or it has been 5 years since date of manufacture, a prompt will be generated at every start up. Follow Section 5 Servicing on instructions on changing the battery.

Note

The Airvo 3 can only turn on from battery power for a limited time after being unplugged to preserve battery life.

15.3 Condensation

The Airvo 3 series is a humidifier that delivers up to 37 °C dew point to the patient. The AirSpiral breathing tube is heated and insulated to minimize condensation. Condensation may still arise in some situations. Manage condensation in the breathing tube when it cannot be prevented.

Ensure the Airvo 3 is placed below the height of the patient's head. This will allow any condensation to drain towards the water chamber and away from the patient. Refer to the Airvo 3 User Manual for more detailed set-up instructions.

Preventing excessive condensation

Condensation is more likely to occur when the Airvo 3 is used in environments where the temperature is below 18 °C or if there are external sources of cooling.

A fan, air conditioner, vent or open window that cools the heated breathing tube may cause condensation to form. Redirect, minimize or place a barrier between sources of cooling and the breathing tube. Do not cover the heated breathing tube.

WARNING

Do not cover or add heat above ambient levels to any part of the breathing tube or interface (e.g. by covering with a blanket or by heating with infrared radiation, an overhead heater or an incubator).

Condensation management

If you are unable to prevent excessive condensation in the heated breathing tube, implement a process to regularly check the heated breathing tube for condensation as part of your routine patient monitoring.

When condensation is observed in the heated breathing tube, drain it back into the water chamber:

1. Disconnect the heated breathing tube from the patient interface (if possible).
2. High target flow rates or pressures may prevent the condensate from draining back into the water chamber. Reduce the flow rate to < 30 L/min to ensure condensate drains into the water chamber (if possible).
3. Drain the tube by lifting the patient end of the tube so the condensate runs back into the water chamber.
4. Restore the target flow rate to the setting prescribed for the patient.
5. Reconnect the heated breathing tube to the patient interface.

Consider reducing the dew-point temperature setting if condensation persists. Reducing the dew-point temperature will decrease the amount of water vapor and condensate in the breathing tube. The temperature and humidity of the respiratory gases delivered to the patient will also be reduced.

15.4 Other

Third party accessories

Only use approved third party accessories. If a warning is generated for pulse oximeter incompatibility, conduct the following steps:

1. Disconnect the pulse oximetry USB connector cable from the back of the Airvo 3 USB port.
2. Ensure only approved accessories are used as per Appendix F.
3. Reconnect the pulse oximetry USB connector cable to the back of the Airvo 3.
4. The accessory will be automatically detected.

If problems persist, please contact your local Fisher & Paykel Healthcare representative.

Airvo 3 screen is non-responsive

There is a reset button at the rear of the device, between the two USB-A ports, that can be accessed with a small, narrow object (like a paper clip). Perform a short press (long enough for the screen to turn off, about 1 second).

Note: This only resets the screen, therapy will not be interrupted.

16. Specifications

16.1 General

Dimensions	205 mm x 295 mm x 190 mm
Weight (including battery)	4.45 kg
Supply voltage/current	100 – 115 VAC, 2.4 A (2.6 A max[1]) 220 – 240 VAC, 1.1 A (1.3 A max[1])
Supply frequency	50 – 60 Hz
USB port sourcing [14] (1 and 2)	USB 2.0 Type A 5 V, 0.25 A (maximum each port)
Auditory alarm	
Sound pressure level	> 40 dBA @ 1 m
Audio pause duration	120 seconds
Sound level	< 50 dBA @ 1 m
A-weighted sound power level	< 60 dBA
A-weighted sound pressure level	< 50 dBA
Ingress protection	IP22[2]
Expected service life	5 years[3]

Operating conditions

Ambient temperature	18 – 28 °C
Humidity	10 – 95% relative humidity (non-condensing)
Ambient pressure	700 – 1060 hPa
Altitude range	0 – 3000 m
Mode of operation	Continuous operation
Maximum surface temperature of applied parts[4]	44 °C
Maximum delivered dew-point temperature of respiratory gas[4]	43 °C

Storage and transport conditions

Ambient temperature[5,6]	-10 – 50 °C
Humidity (non-condensing)	10 – 95% relative humidity

Battery (900PT957L)

Chemistry	Lithium Ion (Li-Ion)
Voltage	14.4 VDC
Capacity, Power output	≤ 99.4Wh, 80 W
Battery life	300 cycles or 2 years from first use (whichever comes first)
Recharge time	6 hours (maximum)
Shelf life	3 years
Operating time[7] to 20%	
Typical	50 minutes

Supplementary oxygen

Oxygen sensor startup time	< 30 s
Oxygen response time	< 60 s
High-pressure oxygen (HPO) inlet port	
Line pressure	280 – 600 kPa
Maximum flow rate (3 s & 10 s)	100 L/min (STPD[8])
% Concentration	93%, > 99%
Low-pressure oxygen (LPO) inlet port	
Line pressure	0 – 70 kPa
Maximum flow rate	60 L/min (STPD[8])
% Concentration	93%, > 99%

Optiflow high flow therapy[11]

Target humidity range	31 – 37 °C
Target flow range[10]	2 – 70 L/min
Maximum limited pressure[11]	60 cmH_2O
Maximum operating pressure	< 45 cmH_2O
Oxygen concentration	21 – 100% FiO_2
Humidity[4, 7] Wall power	≥ 33 mg/L at 37 °C target humidity, 10 – 60 L/min target flow[12] ≥ 16 mg/L for all other settings
Static temperature stability	± 2 °C
Warm-up time[13] (MR290 chamber) 23 ± 2 °C to 37 °C	< 20 min

1. Inrush current may reach 50 A.
2. The device is protected against solid objects larger than 12 mm (e.g contact with a finger) and vertically dripping water will have no harmful effects when the enclosure is tilted at an angle of up to 15° from its standard position.
3. Assumes typical usage pattern. Actual service life may vary.
4. In accordance with ISO 80601-2-74. Tested to an accuracy of ± 1 °C or ± 1 mg/L, as appropriate.
5. Storage at temperatures above 40 °C for prolonged periods will accelerate battery degradation.
6. The device may require up to 24 hours to equilibrate to operating temperature before it is ready for use.
7. For humidity performance under battery use, see Appendix G.
8. Flow rate is expressed in STPD (standard temperature and pressure, dry) as per ISO 80601-2-74.
9. Values are expressed in body temperature, pressure, saturated (BTPS), in accordance with ISO 80601-2-74, unless otherwise stated.
10. Achievable flow range depends on the patient interface selected.
11. In accordance with ISO 80601-2-90.
12. Applies to use with bypassed airway patient interfaces only.
13. Applies when the device is connected to a wall power supply for warm-up.
14. Only connect approved devices or accessories listed as compatible in this Product Technical Manual.

16.2 Range and accuracy of measured parameters

Measurement	Symbol	Displayed Range	Accuracy
Humidity	Temp	31 – 37 °C	Not specified
Flow rate*	Flow	2 – 70 L/min	± (1 + 5% of reading) L/min
Oxygen concentration*†	FiO_2	21 – 100%	Lower of: ± 4%, or ± (2.5% + 2.5% of reading) – excluding rounding to 21% and 100%, as appropriate – provided "Oxygen concentration" setting is correct
Respiratory rate	RR	4 – 70 BPM	RMS error of < 3 BPM ‡
Peripheral blood oxygen saturation	SpO_2	1 – 100%	See the specifications sections below.
Pulse rate	PR / ♥	Masimo 25 – 240 beats/min Nellcor 20 – 300 beats/min Nonin 18 – 321 beats/min	See the specifications sections below.
Perfusion Index	PI	0.02% – 20%	Not specified (Masimo only)

* Test equipment and methods are selected and controlled to ensure the uncertainty coverage is no more than 30% of the disclosed tolerance.

† Oxygen measurements are automatically compensated for changes in barometric pressure.

‡ An RMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

16.3 Pulse oximetry specifications

Pulse oximetry (Masimo)

Specifications are tabulated for the Airvo 3 and all compatible sensors unless otherwise stated.

Masimo:

Data update period	< 30 sec
Measurement wavelengths and Output Power	Radient power with a 50mA pulsed LED is less than 15mW. Masimo's RD SET and LNCS sensors use red and infrared light emitting diodes. The wavelengths for all sensors except TC-I and TF-I sensors are 660nm, and 905nm for red and infrared respectively. TC-I: 653nm and 880nm for red and infrared respectively. TF-I: 660nm and 880nm for red and infrared respectively. This information is especially useful for clinicians performing photodynamic therapy.

Accuracy (see notes 1-12 below)

Saturation (%SpO_2) - During No Motion Conditions

Adults/Pediatrics	70-100% ± 2 digits 0-69% unspecified
Neonates	70-100% ± 3 digits 0-69% unspecified

Saturation (%SpO_2) - During Motion Conditions

Adults/Pediatrics	70-100% ± 3 digits 0-69% unspecified
Neonates	70-100% ± 3 digits 0-69% unspecified

Pulse Rate (bpm) - During No Motion Conditions

Adults, Pediatric, Neonates

25 to 240 ± 3 digits

Pulse Rate (bpm) - During Motion Conditions

Adults, Pediatric, Neonates 25 to 240 ± 5 digits

Resolution

Saturation (%SpO_2) 1%

Pulse Rate (bpm) 1

Low Perfusion Performance

Pulse Amplitude ± 2 digits

% Transmission 5%

Saturation (%SpO_2) ± 2 digits

Pulse rate ± 3 digits

1 The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

2 The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.

3 The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

5 The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

6 See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

7 The TC-I sensor is contraindicated for patients with pierced ears at the measuring site.

8 The TF-I sensor must be removed and repositioned to a different monitoring site at least every 2 hours. If extended monitoring is required, use of a single patient adhesive digit sensor is recommended.

9 The TF-I, TC-I, and DBI sensors were not validated under motion conditions.

10 The Trauma and Newborn sensors are for use only with instruments containing Masimo SET oximetry (Version 4.1.0.1 or higher) or monitors licensed to use specialty sensors.11 Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

11 Masimo M-LNCS, LNOP, RD, and LNCS sensors, cables, and adapters have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

12 For M-LNCS Blue, LNOP Blue is the predicate. Masimo SET technology with LNOP Blue sensors have been validated for no motion accuracy in human blood studies on neonatal, infant and pediatric patients with congenital cyanotic cardiac lesions in the range of 60%-100% SpO_2 against a laboratory co-oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

13 The presented 510(k) reference is based on the specific FDA clearance for the specific Masimo technology board cleared with the compatible Masimo sensor. The 510(k) reference may vary for the Masimo sensor depending on the pulse oximetry technology (i.e. Masimo SET, Masimo rainbow SET, Philips FAST, Nellcor).

Pulse oximetry specifications (Nellcor)

Please refer to the OxiCable Instructions for Use for product specifications.

Pulse oximetry (Nonin)

Specifications are tabulated for the Airvo 3 and all compatible sensors unless otherwise stated.

Nonin:

Data update period	< 30 sec	
Measurement wavelengths and Output Power*	Red: 660 nanometers @ 0.8 mW max. avg. Infrared: 910 nanometers @ 1.2 mW max avg. (using Nonin Purelight sensor)	
SpO_2 Accuracy (A_{rms} †)	70 to 100%	
No Motion	**Adults/Pediatrics‡**	**Neonates**
Reusable		
8000AX Series:	± 2 digits	N/A
800XJ Series:	± 3 digits	N/A
8000SX Series:	± 2 digits	N/A
8000R:	± 3 digits	N/A
8000Q2:	± 3 digits	N/A
Disposable		
6000CX Series:	± 2 digits	± 3 digits
7000X Series:	± 2 digits	± 3 digits
Motion		
Reusable		
8000AX Series:	± 2 digits	N/A
800XJ Series:	± 3 digits	N/A
8000SX Series:	± 3 digits	N/A
Low Perfusion §	± 2 digits	± 3 digits
Pulse Rate Accuracy	**Adults/Pediatrics‡**	**Neonates**
No Motion (18 - 300 BPM)		
Reusable		
8000AX Series:	± 3 digits	N/A
800XJ Series:	± 3 digits	N/A
8000SX Series:	± 3 digits	N/A
8000R:	± 3 digits	N/A
8000Q2:	± 3 digits	N/A
Disposable		
6000CX Series:	± 3 digits	± 3 digits
7000X Series:	± 3 digits	± 3 digits
Motion (40 - 240 BPM)		
Reusable		
8000AX Series:	± 5 digits	N/A
800XJ Series:	± 5 digits	N/A
8000SX Series:	± 5 digits	N/A
Low Perfusion (40 - 240 BPM)§	± 3 digits	± 3 digits

* This information is especially useful for clinicians performing photodynamic therapy.

† ± 1 A_{rms} represents approximately 68% of measurements.

‡ Includes Infant patients

§ Does not apply to those sensors listed as N/A under the neonate column, 8000R and 8000Q2

Notes

- SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61 formerly ISO 9919, Standard Specification for Pulse Oximeters for Accuracy.
- Pulse rate motion testing measures pulse rate accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61, formerly ISO 9919, for pulse rate during simulated movement, tremor, and spike motions.• Low perfusion testing uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels. The module must maintain accuracy in accordance with ISO 80601-2-61, formerly ISO 9919, pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).
- The Nonin Xpod has been validated for pulse rate accuracy from 18–300 bpm with no motion and from 40–240 bpm with motion. Testing was carried out using a Datrend Oxitest Plus 7 simulator.

16.4 Standards compliance

Designed to conform to the following standards:
IEC 60601-1:2005+AMD1:2012 +AMD2:2020
IEC 60601-1-2:2014+AMD1:2020
ANSI/AAMI ES 60601-1:2005 and A1:2012 and A2:2021
CAN/CSA-C22.2 NO.60601-1:14+A2:2022 (R2022)
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020
IEC 60601-1-8:2006+AMD1:2012+AMD2:2020
ISO 80601-2-61:2017
ISO 80601-2-74:2021

E354976

Medical — cardio, vascular and pulmonary equipment as to electrical shock, fire and mechanical hazards only in accordance with AAMI ES60601-1 (2005) + AMD 1 (2012), CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1-6:2010, AMD1:2013, IEC 60601-1-8: 2006 + Am.1: 2012, ISO 80601-2- 61:2017, COR1:2018, ISO 80601-2-74:2017

Do not place any part of the device or accessories within 30 cm of any portable mobile radio frequency communication equipment. The Airvo 3 complies with the electromagnetic compatibility requirements of IEC 60601-1-2. In certain circumstances the Airvo 3 may affect or be affected by nearby equipment because of electromagnetic interference. Excessive electromagnetic interference may affect the therapy delivered by the device.
If this should happen, try moving the Airvo 3 or the unit causing interference, or consult your healthcare provider.

Accessory equipment connected to the any port of the Airvo 3 must be certified to IEC 60601-1-1 or IEC 60950-1.
All configurations shall comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult your technical services department or your local Fisher & Paykel Healthcare representative.

Certain elements of the software included with product are supplied under the license terms of third parties, including elements of the software that are subject to certain open source software licenses. Where required by the terms of these licenses, Fisher & Paykel Healthcare Limited provides notices regarding such software elements on its website.
Please visit www.fphcare.com/airvo3/third-party-licenses to view these notices. Note that the notices that apply may be updated as the software included in the product is updated. The F&P Airvo 3 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.fphcare.com/certifications.

Device disposal instructions

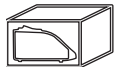
This device contains electronic components and a lithium-ion battery. Regulations in your country may require them to be collected for waste recovery and recycling to reduce the environmental impact. Please dispose of this device in accordance with local regulations.

Disposal of accessories, spare parts and packaging

Dispose of accessories, spare parts and packaging according to local guidelines. Place the breathing tube and water chamber in a waste bag at the end of use and discard with normal waste. Hospitals should discard according to their standard method for disposing of contaminated product.

17. Glossary

Symbols

 For safety reasons, refer to the instructions for use	 Warning, hot surface	 Power on/off button	 System menu button
 Alarm symbol	 Alarm limits	 USB port and Compatible USB device detected	**IP22** Protected against ingress of small objects and water drops
 Class II equipment (double insulated)	 Magnetic Resonance (MR) unsafe	 Temperature range	 Humidity range
 Do not use if package is damaged	 Type BF applied part (body floating)	 Do not discard as regular waste	 Pb Co Contains hazardous substances Pb Lead, Co Cobalt
 Operating conditions	 Storage and transport conditions	 Importer	 Distributor
REF Catalogue number	 YYYY-MM-DD Date of manufacture	 Manufacturer	 YYYY-MM-DD Manufacturer and date of manufacture
SN Serial number	MD Medical Device*	CE 0123 European conformity - TÜV SÜD*	 Regulatory compliance mark*
 UL Classified Mark Canada, USA*	EC REP EU Authorised representative		

**symbol seen on select models*

Appendix A. Physical check results (optional)

This form may be printed to record device check test results. Refer to Section 7.1 for test protocols.
Contact your Fisher & Paykel Healthcare representative if any of the tests do not pass.

Airvo 3 serial number: Software version:

Hospital/department: Asset number:

Inspection by

Name: Title: Inspection date:

Signature: Organization:

Physical check results

See Section 5.1 Physical check for instructions.

Test	Result	Test	Result
The power cord and retainer are not damaged.	☐ Pass ☐ Fail	The battery and power-cord retainer fixing screws are all present and not loose.	☐ Pass ☐ Fail
The air filter is not damaged or discolored.	☐ Pass ☐ Fail	The 'Hot Surface' warning symbol is present in the water chamber cavity.	☐ Pass ☐ Fail
The heated breathing tube port is not damaged, and the electrical connector shows no sign of corrosion.	☐ Pass ☐ Fail	The heater plate is not badly scratched or corroded.	☐ Pass ☐ Fail
The Airvo 3 case is not damaged.	☐ Pass ☐ Fail	The finger guard springs back into place when pushed down and released.	☐ Pass ☐ Fail
The screen and bezel are not damaged or cracked.	☐ Pass ☐ Fail	The Airvo 3 is attached securely to the mobile pole stand and the mounting point on the Airvo 3 is not cracked or broken.	☐ Pass ☐ Fail

Electrical safety test results

Fill in the results while completing the tests in Section 7 of the Airvo 3 Technical Manual.

Test	Result
The device meets the local medical electrical standard for in-house testing.	☐ Pass ☐ Fail

Appendix B. Functional check results (optional)

This form may be printed to record acceptance test results. Refer to Section 7.2 for test steps.
Contact your Fisher & Paykel Healthcare representative if any of the tests fail.

WARNING
To reduce the risk of patient injury, always set all settings to standard values for your hospital after completing a test.

Airvo 3 serial number:	Software version:	
Hospital/Department:	Asset number:	
Inspection by Name:	Title:	Inspection date:
Signature:	Organization:	

Optiflow high flow test results

Test	Description	Acceptance criteria	Result
Heater plate	Warmup completed.	≤ 30 minutes	☐ Pass ☐ Fail
Check for Leaks	The check for Leaks alarm is generated when the water chamber is removed.	≤ 30 seconds	☐ Pass ☐ Fail
Check for Blockages	The check for Blockages alarm is generated when the heated breathing tube is blocked.	≤ 15 seconds	☐ Pass ☐ Fail
Check Tube	The Check Tube alarm is generated when the heated breathing tube is disconnected.	≤ 5 seconds	☐ Pass ☐ Fail
Power Out	When disconnecting power (assuming a battery is present) the device displays the alarm "Battery Mode: Reduced Humidity".	≤ 5 seconds	☐ Pass ☐ Fail

Battery Operation test results

Test	Description	Acceptance criteria	Result
Battery Operating Time	Operating time of the Airvo 3 on battery power.	≥ 20 minutes	☐ Pass ☐ Fail
Power Down Alarm	An audible alarm and light signal is generated when the Airvo 3 has lost both wall power supply and batter power.	≥ 120 seconds	☐ Pass ☐ Fail

Appendix C. User default settings

Airvo 3 serial number:

Hospital/Department: Asset number:

System settings

Label	Options	Default	Customized hospital-specific setting (if different)
Sound and display			
Sound volume	Low, medium, high	Medium	
Show lock menu	Yes, No	Yes	
Oxygen settings			
Oxygen supply concentration	93%, 100%	100%	
FiO_2 High Oxygen Alarm	30 – 95%, off (5% increments)	Off	
Pulse oximeter settings			
Show pulse rate	Yes, No	Yes	
SpO_2 Low % Limit	20 – 98%	20%	
Default Low SpO_2 Alarm*	20 – 98%	85%	
Default High SpO_2 Alarm*	Off, 21 – 99%	Off	
Default Averaging Time (Masimo)	2-4,4-6,8,10,12,14,16 seconds	8 seconds	
Default Averaging Time (Nonin)	4 beats, 8 beats	8 beats	
Default Sensitivity Mode (Masimo only)	Normal, APOD, Max	APOD	
Default Response Mode (Nellcor only)	Normal, Fast	Normal	
Default SatSeconds Limit (Nellcor only)	Off, 10, 25, 50, 100 seconds	10 seconds	

*The high alarm threshold cannot be set below the low alarm threshold.

Optiflow settings

Label	Options	Default	Customized hospital-specific setting (if different)
Temperature Min	31 – 37 °C	31 °C	
Default Temperature	31 – 37 °C	37 °C	
Flow Max	2 – 70 L/min	70 L/min	
Flow Min	2 – 70 L/min	2 L/min	
Default Flow	2 – 70 L/min	30 L/min	
Allow Expiratory Relief	Yes, No	No	
Show RR	Yes, No	Yes	

Appendix D. Airvo 3 maintenance log

The Airvo 3 battery and air filter must be replaced regularly, as shown below. You can print this form to track scheduled replacements. Refer to the Airvo 3 Technical Manual for steps to change the battery and air filter.

Airvo 3 serial number

Hospital/Department

Asset number

Air filter (900PT933):
Maximum use: 3 months or 1000 hours or when significantly discolored (whichever comes first)

Date installed	Next change due date	Installed by

Battery (900PT957L):
Maximum use: 300 cycles or 5 years after date of manufacture of the battery

Date installed	Next change due date	Installed by

Appendix E. Fault report form

Please complete this page to report the problem. Tell us as much as you can to help us understand the problem. Return the completed form with the faulty component to your local Fisher & Paykel Healthcare representative.

Airvo 3 serial number

Software version

Hospital

Department where incident occurred

Contact person:

Name | Title

Signature | Organization

Date of incident | Time of incident

Error code or warning displayed

Has this problem happened before? Check all that apply:

☐ Yes (same unit) ☐ Yes (different unit) ☐ First time ☐ Unknown

Was a pulse oximeter connected when the problem occurred?

☐ No ☐ Yes ☐ Unknown

When did the problem occur? Check all that apply:

☐ Before therapy ☐ During therapy ☐ During disinfection ☐ Unknown

Additional details/comments

Appendix F. Compatible consumables and accessories

Optiflow high flow therapy

Description	Part number	Size	Pack size
Optiflow+ nasal interface	OPT942	Small	20
	OPT944	Medium	20
	OPT946	Large	20
Optiflow+ Duet interface	OPT962	Small	20
	OPT964	Medium	20
	OPT966	Large	20
Optiflow 3S nasal interface	OPT1042	Small	20
	OPT1044	Medium	20
	OPT1046	Large	20
Optiflow Junior 2 nasal interface*	OJR414 (WJR112)	M	20
	OJR416 (WJR112)	L	20
	OJR418 (WJR112)	XL	20
Optiflow Junior 2+ nasal cannula*	OJR520 (WJR114)	XXL	10
Optiflow Junior 2 WigglewiNG	WJR212	M, L, XL	10
	WJR214	XXL	10
Optiflow+ tracheostomy direct connection	OPT970	15 mm	20
Optiflow+ mask interface adapter†	OPT980	22 mm mask interface adapter	20
AirSpiral tube and chamber kit	900PT561	—	10
AirSpiral tube and chamber kit with nebulizer adapter	900PT562	—	10

* Wigglepads part numbers are shown in parentheses.

† The mask interface adapter is designed for vented masks only. Do not use sealed masks with Optiflow high flow therapy.

Carefully read the user instructions, including all warnings and cautions, supplied with each part or accessory before use. Contact your Fisher & Paykel representative for the latest information on parts and accessories available for the Airvo 3.

Accessories

Description	Part number
Water bag (2-Pack)	900PT401
Mobile pole stand	900PT421
Mobile pole stand handle	900PT445
Mobile pole stand clamp	900PT428
Oxygen-bottle holder	900PT427, 900PT427L
Storage basket	900PT426
HPO Dual-Input Manifold (DISS, NIST, SIS)	900PT460D, 900PT460N, 900PT460S
HPO adapter (DISS to NIST)	900PT462DN
Airvo 3 data port adapter*	900PT473
Airvo 3 USB service cable	900PT474
Fisher & Paykel Healthcare Device Manager	900PT475
Disinfection kit†	900PT600

* The data port adapter allows for data to be transferred from the Airvo 3 to patient monitoring and hospital computer systems. Integration is required to enable functionality.

† A disinfection kit is required when using the built-in disinfection mode to disinfect the outlet elbow. It is not required for hospitals using a washer-disinfector to clean and disinfect the outlet elbow.

Spare parts

Description	Part number
Cleaning sponge sticks	900PT602
Storage cover	900PT603
Outlet elbow	900PT930
Air Filter	900PT933
Battery module	900PT957L

WARNINGS

Equipment connected to Airvo 3 via the Data Port Adaptor (900PT473) must be certified according to IEC 60950-1 or IEC 60601-1. All combinations of equipment must be in compliance with IEC 60601-1 requirements for medical electrical systems. Any person who connects additional equipment has now configured a medical system and is therefore responsible for ensuring that the system complies with the requirements of IEC 60601-1. Consult a technical specialist in your hospital for more information.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Airvo 3.

All data transferred from Airvo 3 is intended for information only and must not be used as the sole basis for diagnostic or therapeutic decisions.

Pulse oximetry accessories

The pulse oximetry accessories listed below are compatible with the Airvo 3. Carefully read the user instructions, including all warnings and cautions, supplied with each device before use. Not all accessories are available in all markets, and some accessories may not be available from Fisher & Paykel Healthcare.

Masimo:

Part numbers of validated Masimo pulse oximetry USB connector cable, adapters, and extension cables

Description	Masimo part number (cable length)	FPH part number
Masimo SET uSpO$_2$ Pulse Oximetry Cable	3412 (1.8 m)	9516-3412
RD to LNC Adapter Cable	4089 (0.9 m)	N/A
RD to LNC Adapter Cable	4105 (0.45 m)	N/A
LNC-4-Ext	2021 (1.2 m)	N/A

Part numbers of validated Masimo pulse oximetry sensor cables and sensor consumables

Sensor description	Masimo part number (cable length) (other information)
RD SET DCI Series Adult Reusable Finger Clip Sensors	4050 (0.9 m)
RD SET DCI-P Series Pediatric Reusable Finger Clip Sensors	4051 (0.9 m)
RD SET TC-I Reusable Tip Clip Sensor	4053 (0.9 m)
RD SET YI SpO$_2$ Multisite Reusable Sensor	4054 (0.9 m)
RD SET TF-I SpO$_2$ Reusable Transflectance Forehead Sensor	4055 (0.9 m)
RD SET DB-I Reusable Soft Sensors	4052 (0.9 m)
RD SET Series Adt SpO$_2$ Disposable Sensors	4000 (0.45 m) (20 pack)
RD SET Series Pdt SpO$_2$ Disposable Sensors	4001 (0.45 m) (20 pack)
RD SET Series Inf SpO$_2$ Disposable Sensors	4002 (0.45 m) (20 pack)
RD SET Series Neo SpO$_2$ Disposable Sensors	4003 (0.45 m) (20 pack)
RD SET Series Neo Pt SpO$_2$ Disposable Sensors	4004 (0.45 m) (20 pack)
RD SET Series Neo Pt SpO$_2$ Disposable Sensors (Non-Adhesive)	4005 (0.45 m) (20 pack)
RD SET Specialty Sensor Series Adult Trauma	4011 (10 pack)
RD SET Specialty Sensor Series Newborn Neonatal	4013 (10 pack)
RD SET Specialty Sensor Series Newborn, Infant, Pediatric	4012 (10 pack)
RD SET Blue Disposible Sensor	4014 (10 pack)
RD SET Ear Sensor	4015 (0.9 m) (10 pack)
RD SET TFA-1 SpO$_2$ Disposable Transflectance Forehead Sensor	4016 (0.9 m)
LNCS DCI ADT Reusable Sensor	1863 (0.9 m)
LNCS DCIP Reusable Sensor	1864 (0.9 m)
LNCS TC-I Reusable Tip Clip Sensor	1895 (0.9 m)

Masimo:

Sensor description	Masimo part number (cable length)
LNCS YI SpO_2 Multisite Reusable Sensor	2258 (0.9 m)
LNCS TF-I Adult SpO_2 Reusable Transflectance Sensor	1896 (0.9 m)
LNCS DB-I Series Reusable Soft Sensors	2653 (0.9 m)
LNCS Adtx, Adult Adhesive Sensor	1859 (0.45 m) (20 pack)
LNCS Adtx-3, Adult Adhesive Sensor	2317 (0.9 m) (20 pack)
LNCS Pdtx, Pediatric Adhesive Sensor	1860 (0.45 m) (20 pack)
LNCS Pdtx-3, Pediatric Adhesive Sensor	2318 (0.9 m) (20 pack)
LNCS Inf, Infant Adhesive Sensor	2328 (0.45 m) (20 pack)
LNCS Inf-3, Infant Adhesive Sensor	2319 (0.9 m) (20 pack)
LNCS Inf-L, Infant Adhesive Sensor	1861 (0.9 m) (20 pack)
LNCS Neo, Neonate Adhesive Sensor	2329 (0.45 m) (20 pack)
LNCS Neo-3, Neonate Adhesive Sensor	2320 (0.9 m) (20 pack)
LNCS Neo-L, Neonate Adhesive Sensor	1862 (0.9 m) (20 pack)
LNCS NeoPt, Sensitive Skin Neonate Adehesive Sensor	2330 (0.45 m) (20 pack)
LNCS NeoPt-3, Sensitive Skin Neonate Adhesive Sensor	2321 (0.9 m) (20 pack)
LNCS NeoPT-L, Sensitive Skin Neonate Adhesive Sensor	1901 (0.9 m) (20 pack)
LNCS NeoPt-500, Neonate Non-Adhesive Sensor	2331 (0.45 m) (20 pack)
LNCS Trauma Adult Adhesive Sensor	2411 (0.9 m) (20 pack)
LNCS Specialty Sensor Series Newborn neonatal	2412 (0.9 m) (20 pack)
LNCS Specialty Sensor Series Newborn, Infant, Pediatric	2413 (0.9 m) (20 pack)
LNCS E1 Ear Sensor	2918 (0.9 m) (10 pack)
LNCS TFA-1 SpO_2 Disposable Transflectance Forehead Sensor	3858 (0.9 m) (10 pack)

Nellcor:

Adaptors and extension cables

Description	Part number
Pulse Oximetry Connection Converter 1	900PT476 (0.3m)
Medtronic/Nellcor OxiCable	PMC10N-SF (3.05m)

Part numbers of validated Nellcor pulse oximetry sensor consumables

Sensor description	Nellcor part number (cable length) (other information)
Nellcor SpO_2 Forehead Sensor	MAXFAST (0.75 m) (24 pack)
Nellcor SpO_2 Nonadhesive Sensor	SC-A/SC-NEO/SC-PR (0.9 m) (24 pack)
Nellcor Flexible SpO_2 Sensor	FLEXMAX/FLEXMAX-P (0.9 m)
Nellcor SpO_2 Adhesive Sensors	MAXA/MAXAL/MAXN/MAXI/MAXP (0.9 m) (24 pack)
Nellcor SpO_2 Adhesive Sensors Nasal	MAXR (0.45 m) (24 pack)
Nellcor Reusable SpO_2 Sensors	DS100A (1 pack), OXI-A, OXI-N, OXI-P, OXI-I (24 pack) (0.9 m)
Nellcor Reusable Multisite SpO_2 Sensors	D-YS, D-YSE, D-YSPD (0.9 m), PDSLV (replacement sleeves, 12 pack)
Nellcor Single-Patient Use Sensor Wraps	POSEY (for OXI-A/N/P/I, D-YS) (12 pack)
Nellcor Single-Patient Use Adhesive Sensor Wraps	ADH-A/N (for OXI-A/N, D-YS), ADH-P/I (for OXI-P/I, D-YS) (100 pack)
Nellcor Single-Patient Use Foam Sensor Wraps	FOAM A/N (for OXI-A/N, D-YS), FOAM P/I (for OXI-P/I, D-YS) (100 pack)
Nellcor OxySoft Neonatal-Adult SpO_2 Sensors	OXYSOFTN (24 pack)

Fisher & Paykel is an authorised distributor of Nellcor OxiCable

Nonin:

Part numbers of validated Nonin pulse oximetry USB connector cables

Description	Nonin part number (cable length)
Nonin Xpod 3012HR USB Connector Cable	114403-001 (1 m)
Nonin Xpod 3012 LP USB	6703-001 (1 m)

Part numbers of compatible Nonin pulse oximetry sensor cables and sensor consumables

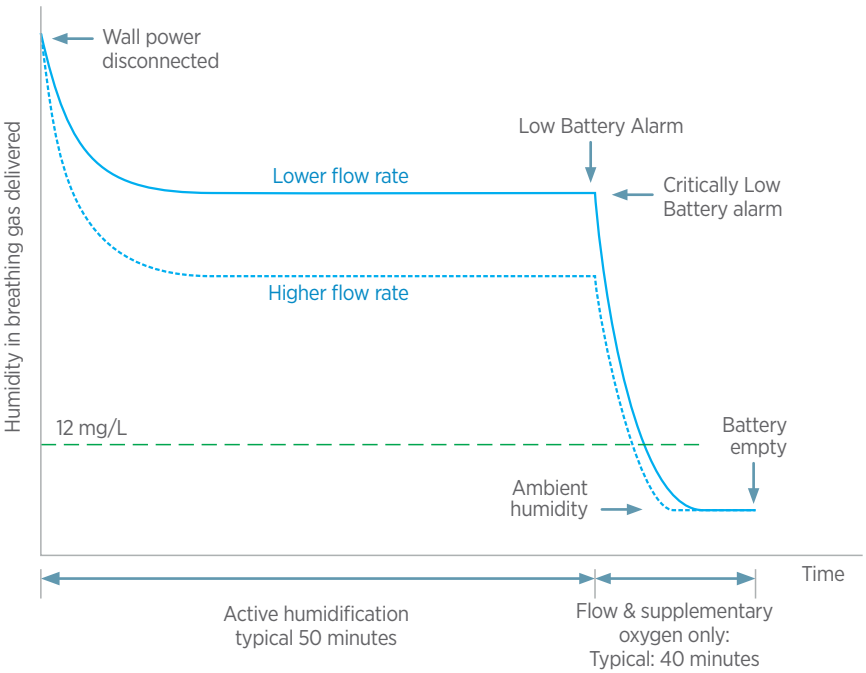
Sensor description	Nonin part number (cable length) (other information)
8000SS reusable soft sensors, small	6837-000 (1m), 6837-300 (3m)
8000SM reusable soft sensors, medium	6836-000 (1m), 6836-300 (3m)
8000SL reusable soft sensors, large	6835-000 (1m), 6835-300 (3m)
8000AA adult reusable finger clip sensors	3278-001 (1m), 3278-006 (2m), 3278-003 (3m)
8000AP pediatric reusable finger clip sensors	2360-000 (1m), 2360-003 (3m)
8000Q2 ear clip sensor	6455-000 (1m)
8000R reflectance sensor	0487-000 (1m)
8000J adult semi-reusable Flex Sensor	0741-000 (1m), 2353-002 (3m) (includes x25 8000JFW FlexiWraps)
8008J infant semi-reusable Flex Sensor	0740-000 (1m) (includes x25 8008JFW FlexiWraps)
8001J neonatal semi-reusable Flex Sensor	0739-000 (1m) (includes x25 8001JFW FlexiWraps)
6000CA adult cloth disposable sensors	7426-001 (1m) (24 pack)
6000CP pediatric cloth disposable sensors	7426-002 (1m) (24 pack)
6000CI infant cloth disposable sensors	7426-003 (1m) (24 pack)
6000CN neonatal cloth disposable sensors	7426-004 (1m) (24 pack)
7000A adult Flexi-Form III disposable sensors	7427-001 (1m) (24 pack)
7000P pediatric Flexi-Form III disposable sensors	7427-002 (1m) (24 pack)
7000I infant Flexi-Form III disposable sensors	7427-003 (1m) (24 pack)
7000N neonatal Flexi-Form III disposable sensors	7427-004 (1m) (24 pack)
8000JFW adult FlexiWraps	4097-000, (25 pack) for use with 8000J
8008JFW infant FlexiWraps	4774-000, (25 pack) for use with 8008J
8001JFW neonatal FlexiWraps	4777-000, for use with 8001J
8000H reflectance sensor holder pack	0616-000, (10 caps & 20 adhesive stickers) for use with 8000R
Sensor Clip for LP Xpod External Pulse Oximeter	7504-001

Appendix G. Humidification behavior during battery operation

The Airvo 3 reduces the energy used to humidify breathing gases when not powered from a wall power supply, to conserve battery power. In all cases, the Airvo 3 continues supplying supplementary oxygen and breathing gases until the battery is depleted.

For Optiflow high flow therapy, active humidification of the breathing gases is reduced during battery operation. If the Critically Low Battery alarm is raised, active humidification is stopped to conserve battery power.

Connect the Airvo 3 o a wall power supply before the battery is empty to automatically resume normal therapy. If the Airvo 3 battery is depleted, the device stops supplying supplementary oxygen and breathing gases, powers down and produces the Power Out alarm. To resume therapy after the device has powered down, connect the Airvo 3 to a wall power supply.



The Airvo 3 delivers reduced humidity in the breathing gas during Optiflow high flow therapy until the battery is nearly depleted, where humidity is turned off to maintain the delivery of flow and oxygen.

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F&P Airvo 3

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