

# TECHNICAL MANUAL



**Airvo™ 3**  
Optiflow™ high flow therapy

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# Before you start

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- 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 these instructions in a safe place for future reference.
- This 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 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.
- Fisher & Paykel Healthcare continually improves its products and reserves the right to change specifications.
- This technical manual applies to Airvo 3 with software version 1.x, where 'x' is a number indicating minor software changes that do not affect specifications.

## Additional resources

- Refer to the Airvo 3 User Manual for instructions on using the Airvo 3.
- Refer to the Disinfection Kit Manual for instructions on cleaning and disinfecting the Airvo 3 between patients using the red disinfection tube.
- Refer to the user instructions supplied with accessories for detailed information on their proper use.
- Visit the Airvo 3 website at [www.fphcare.com/airvo3](http://www.fphcare.com/airvo3) to download user instructions and user manuals.
- Watch self-paced online courses and find local training events by visiting the Fisher & Paykel Healthcare education and resources website at [www.fphcare.com/education](http://www.fphcare.com/education).
- For further assistance, please contact your local Fisher & Paykel Healthcare representative.

## 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.

# Content

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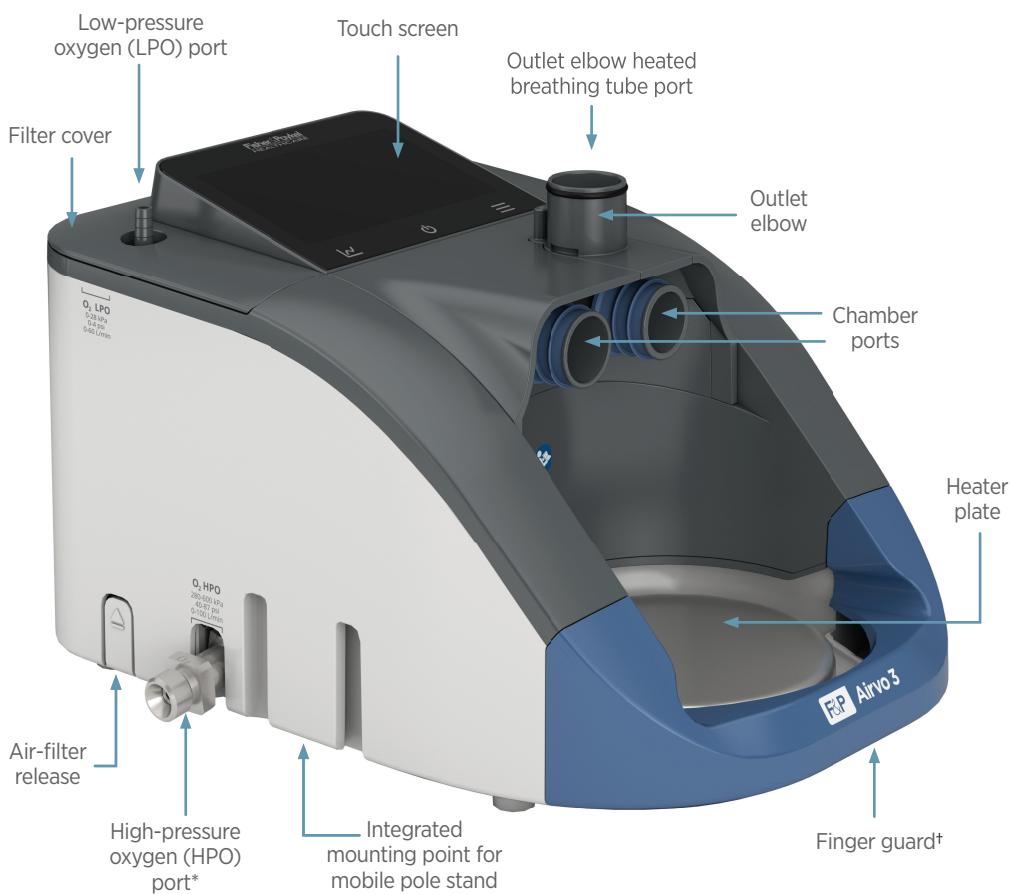
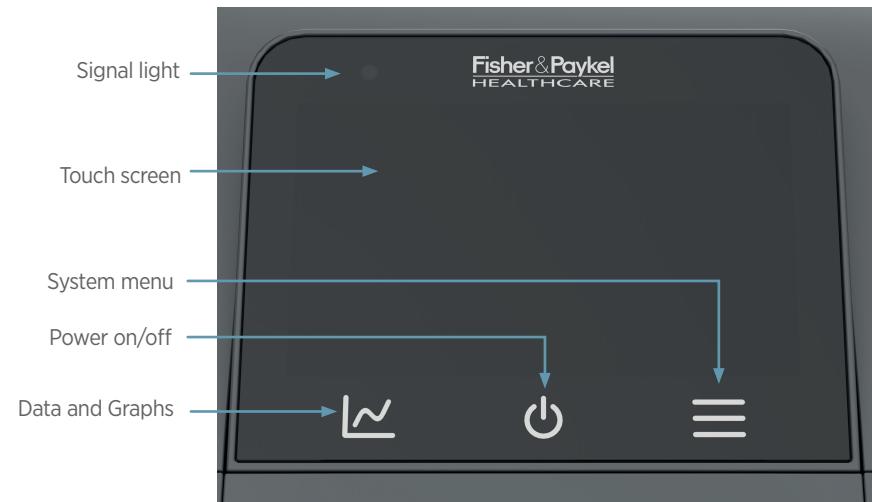
<b>Before you start</b>	<b>1</b>
<b>1 Overview</b>	<b>4</b>
1.1 Identifying device components .....	4
1.2 Packaged content .....	5
1.3 Pneumatic pathway .....	6
1.4 Essential Performance .....	6
<b>2 Set up Airvo 3 for first use</b>	<b>7</b>
2.1 Unpack Airvo 3.....	7
2.2 Place Airvo 3 on the stand.....	9
2.3 Set up supplementary oxygen supply .....	9
2.3.1 Low-pressure oxygen (LPO) supply.....	10
2.3.2 High-pressure oxygen (HPO) supply.....	11
<b>3 Commissioning</b>	<b>13</b>
3.1 Electrical safety check .....	13
3.2 Performance checks and calibration.....	13
3.3 Charge battery .....	13
3.4 Configure user settings .....	13
<b>4 Configure system settings</b>	<b>14</b>
4.1 System settings .....	14
4.2 Accessing system settings.....	15
4.3 Language settings.....	15
4.4 Sound and display settings.....	16
4.5 Oxygen settings.....	16
4.6 Pulse oximeter settings .....	16
4.7 Optiflow settings.....	17
<b>5 Servicing</b>	<b>17</b>
5.1 Changing the battery module .....	18
5.2 Replacing the power cord .....	20
5.3 Replacing the air filter .....	21
5.4 Replacing the outlet elbow .....	22
<b>6 Airvo Service Application</b>	<b>22</b>
6.1 Installation.....	22
6.2 Use of Airvo Service Application .....	22
6.3 Updating Airvo 3 software .....	23
<b>7 Device checks (optional)</b>	<b>24</b>
7.1 Physical checks (optional).....	24
7.2 Functional checks (optional) .....	25
7.2.1 General checks.....	26
7.2.2 USB port functional check .....	29

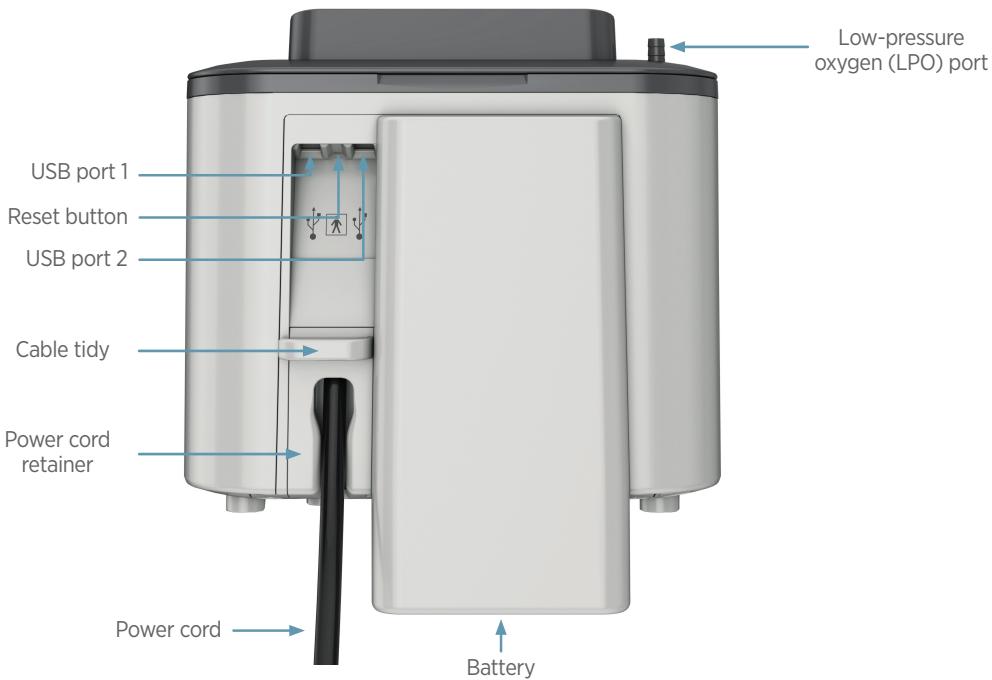
<b>8 Spare parts and accessories</b>	<b>30</b>
8.1 Power cords .....	30
8.2 Spare parts .....	30
8.3 Interface cables .....	31
8.4 High-level disinfection .....	31
8.5 Hardware/Mounting .....	32
8.6 HPO dual-input manifolds.....	33
<b>9 Third-party accessories</b>	<b>34</b>
<b>10 Pulse oximetry clinical data</b>	<b>34</b>
<b>11 EMC tables</b>	<b>35</b>
<b>12 Modem specifications</b>	<b>38</b>
<b>13 Collection and use of personal data</b>	<b>40</b>
<b>14 Error codes</b>	<b>41</b>
<b>15 Troubleshooting</b>	<b>42</b>
15.1 Power .....	42
15.2 Battery .....	42
15.3 Condensation .....	43
15.4 Other.....	43
<b>16 Specifications</b>	<b>44</b>
16.1 General.....	44
16.2 Range and accuracy of measured parameters.....	45
16.3 Pulse oximetry specifications .....	46
16.4 Standards compliance .....	47
16.5 Disposal instructions.....	47
<b>17 Glossary</b>	<b>48</b>
<b>Appendix A. Physical check results</b>	<b>49</b>
<b>Appendix B. Functional check results</b>	<b>50</b>
<b>Appendix C. User default settings</b>	<b>51</b>
<b>Appendix D. Airvo 3 service log</b>	<b>53</b>
<b>Appendix E. Fault report form</b>	<b>54</b>
<b>Appendix F. Compatible consumables and accessories</b>	<b>55</b>

# 1. Overview

The Airvo 3 is a humidifier with integrated flow generators that deliver 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)

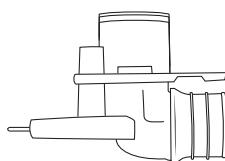
### **⚠️ Warnings**

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

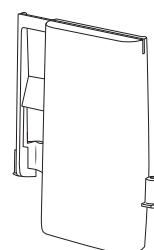
## 1.2 Packaged content



Airvo 3 device  
(PT3xx)



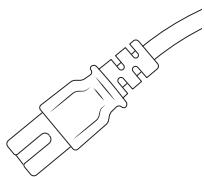
Outlet elbow (already fitted)  
(900PT930)



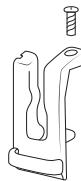
Battery (attached)  
(900957LG)



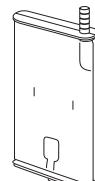
Airvo 3 User Manual



Power cord  
(attached)



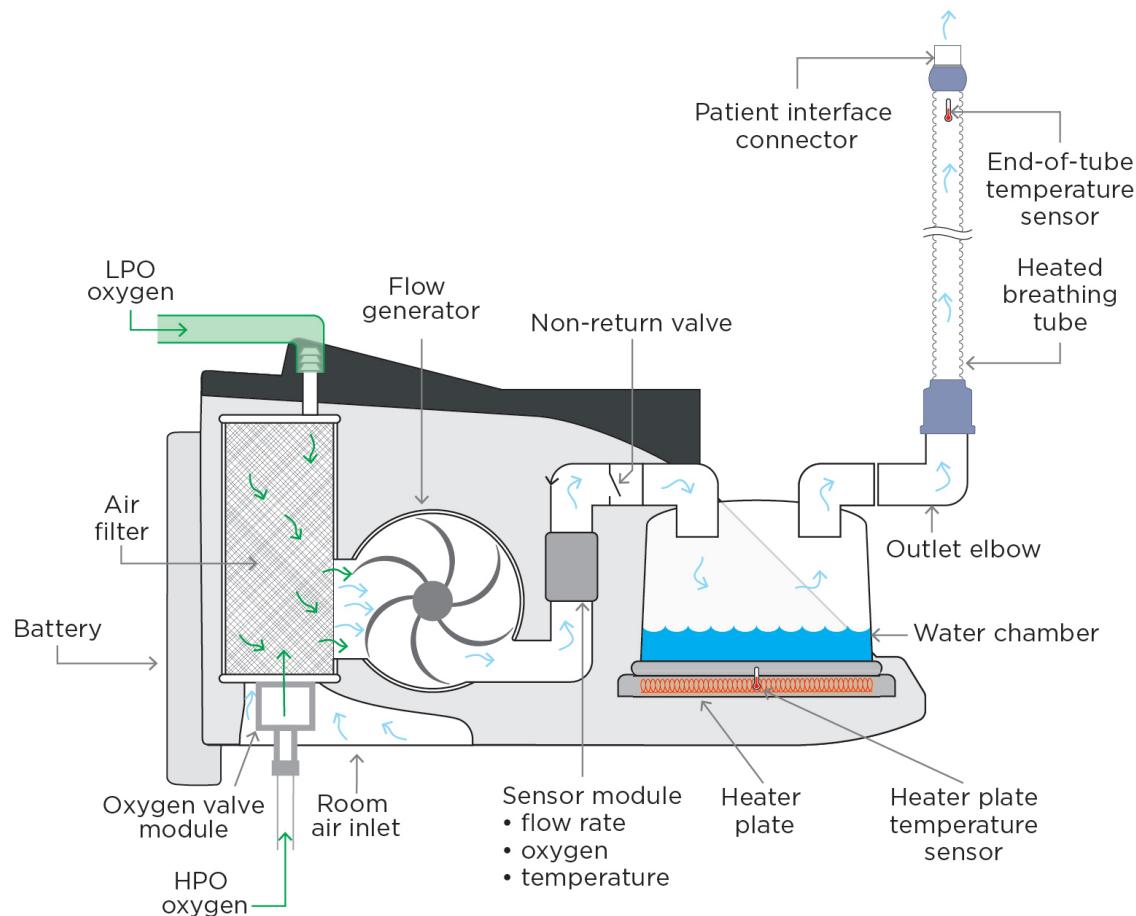
Power cord  
retainer  
(attached)



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 AC, and has an internal battery backup to provide continuity of therapy during intra-hospital transport.

## 1.4 Essential Performance

### 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.

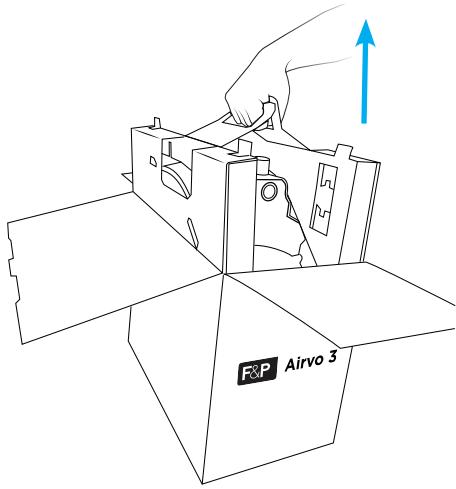
### Pulse oximetry

$\text{SpO}_2$  accuracy, pulse rate accuracy and limit alarm conditions, or generate alarm.

## 2. Set up Airvo 3 for first use

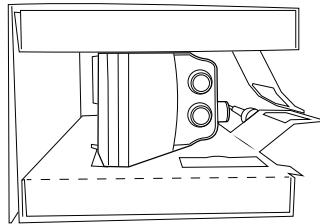
### 2.1 Unpack Airvo 3

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.

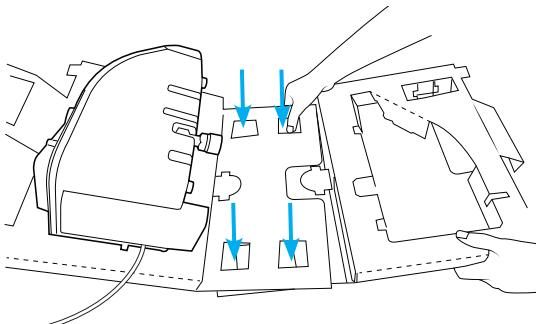


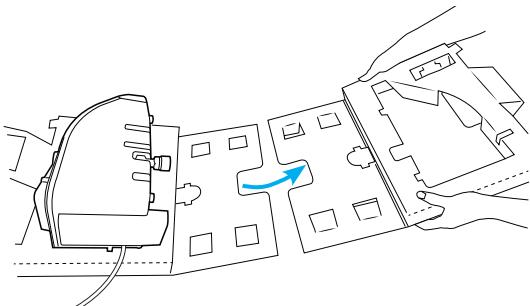
Remove the Airvo 3 from its packaging by pulling up the handle.

Place the Airvo 3 on its side.

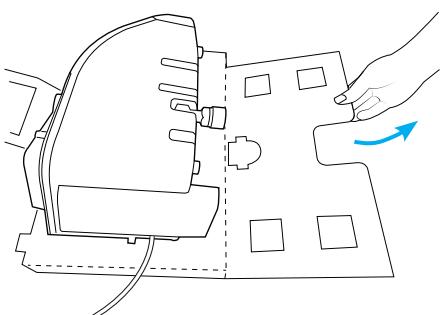


Remove half of the cardboard insert by pressing the four tabs through the square holes.

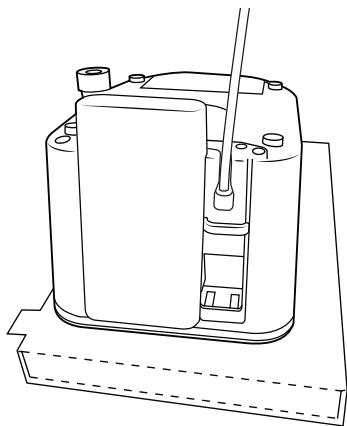




With the tabs detached, remove half the cardboard box and store in a safe place for future use.



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 7.2.4 for further details.

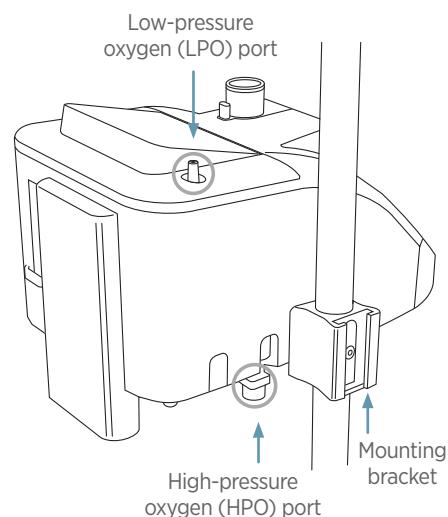
## 2.2 Place Airvo 3 on the stand

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.



### **⚠️ 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 use 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 this user manual or this 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.

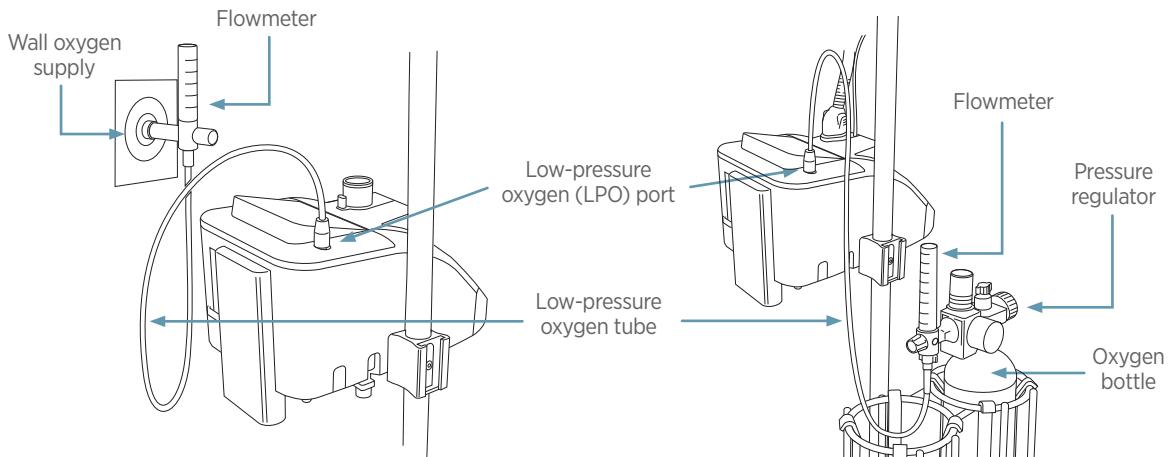
### 2.3.1 Low-pressure oxygen (LPO) supply

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.

#### **⚠️ Warnings**

Do not connect more than 60 L/min O<sub>2</sub> 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<sub>2</sub> 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.

## 2.3.2 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  $\text{FiO}_2$  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.

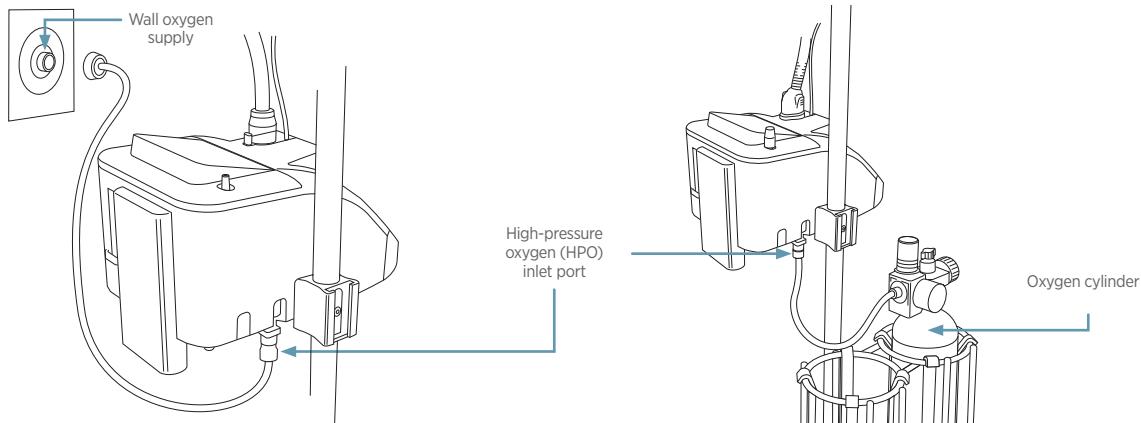
The line pressure of an oxygen source connected to the HPO inlet port must be between 280 kPa and 600 kPa. The Airvo 3 will draw up to 100 L/min.

### 2.3.2.1 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  $\text{FiO}_2$  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.

### 2.3.2.2 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 (~2 feet)
  - 1 x ~3 m (~10 feet)
- 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.

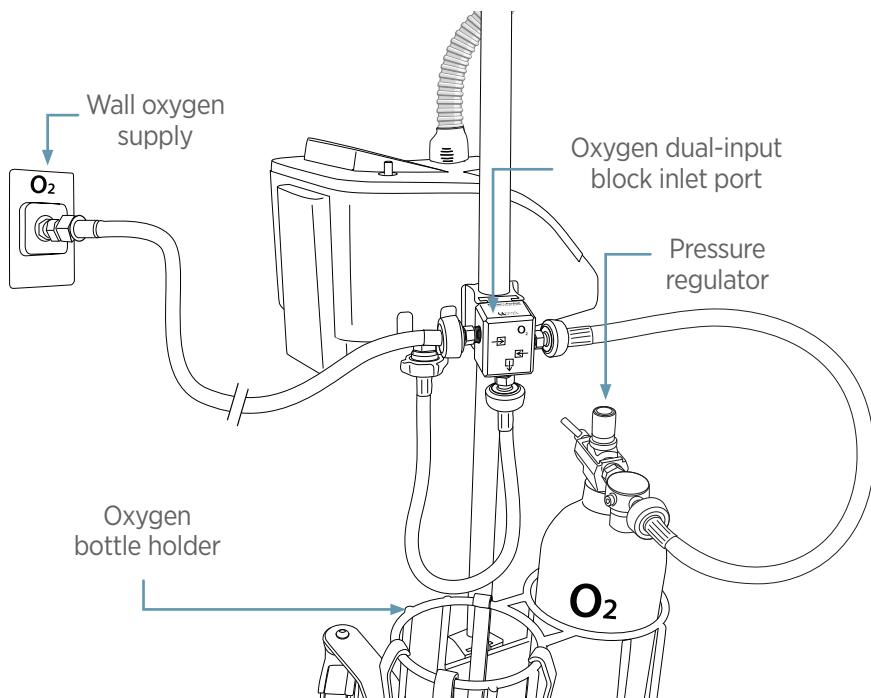
See Section 9.6 for a list of HPO dual-input manifolds.

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.

The Airvo 3 has an in-built wireless modem, ensure that the device is placed at least 20 cm (8 in.) away from your body while in use.

### 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.

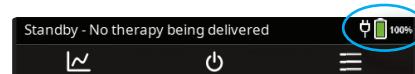
Fisher & Paykel Healthcare carries out stringent testing on every manufactured Airvo 3 to ensure it meets strict quality and patient safety standards. The temperature, flow, pressure and oxygen sensors inside each unit have been calibrated and tested in our controlled environment.

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 AC power supply.



Leave the Airvo 3 plugged into AC 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.

Settings can be changed in two ways.

1. Directly on the Airvo 3 (see Section 4).
2. Using the Airvo Service Application (see Section 6).

### 3.4.1 Record device setup in service log

Record the date the Airvo 3 enters service in your service 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 service log template in Appendix D.

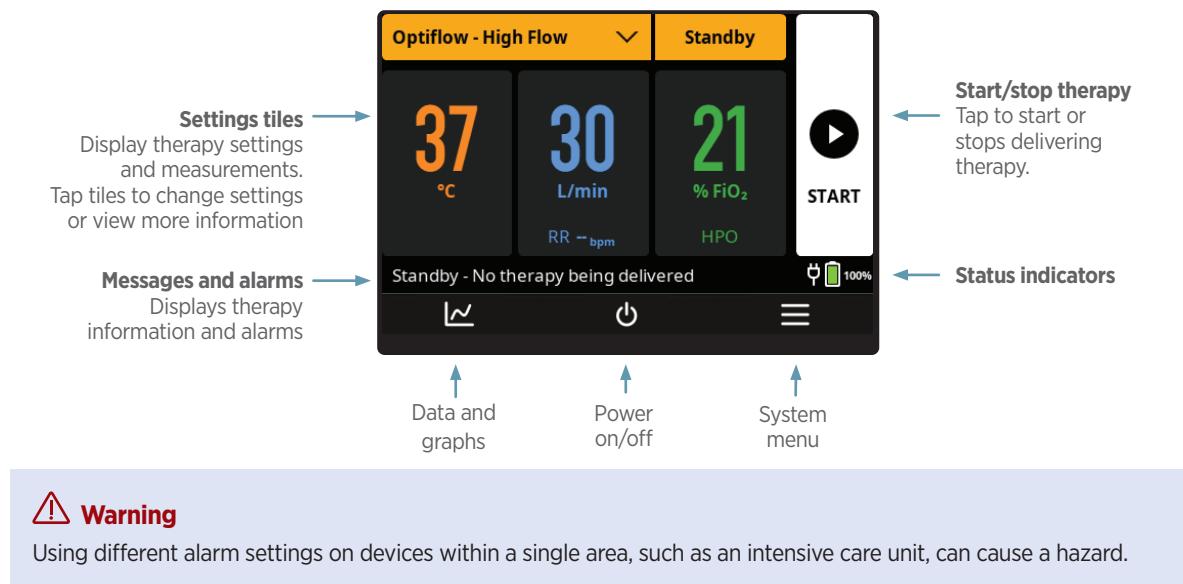
## 4. Configure system settings

### 4.1 System settings

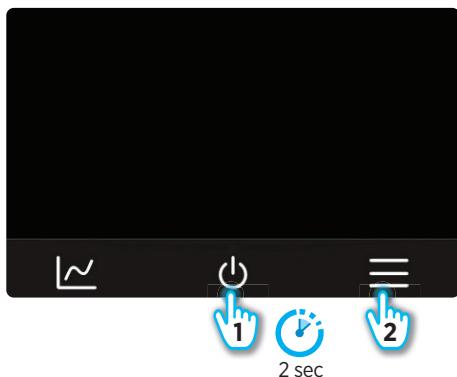
System settings allow clinical engineering/technical personnel to configure the Airvo 3 to suit the clinical environment where it will be used. This involves configuring:

- language
- sound and display
- oxygen
- pulse oximeter
- 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.



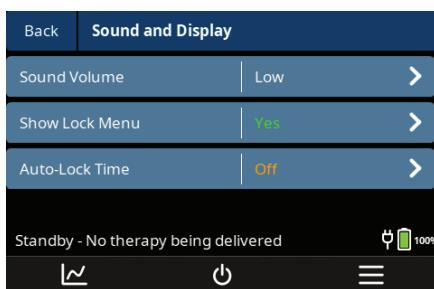
## 4.2 Accessing system settings



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 personal identification number (PIN) 35278. This PIN can be changed by accessing System Settings menu and selecting Change Pin.

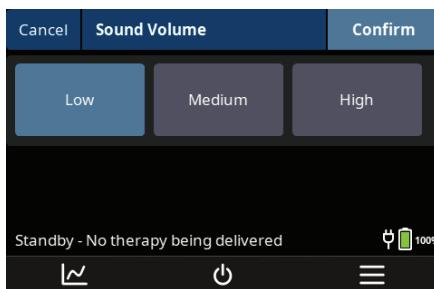
Note: Pin must contain five digits.



To review and/or change settings:

1. Select the desired group (e.g. Sound and Display).
2. Select the desired setting (e.g. Sound Volume).
3. Tap the desired option.
4. 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 Language settings

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

(da) Danish	(de) Deutsch	(en) English	(es) Español	(fi) Suomi
(fr) Français	(frca) Français Canadien	(it) Italiano	(ms) Malay	(nl) Nederlands
(no) Norsk	(pt) Português	(sv) Svenska	(zh) 简体中文	(zht) 繁體中文

## 4.4 Sound and display settings

Label	Options	Default	Description
<b>Sound Volume</b>	Low, Medium, High	Medium	Volume of alarms and information sounds.  <b>⚠️ Warning</b> Ensure that the Sound Volume is loud enough so that operators will hear alarms in the environment where the Airvo 3 will be used.
<b>Show Lock Menu</b>	Yes, No, Auto-lock Time	Yes	Lock option in the system menu (≡). The touchscreen lock can prevent accidental changes to settings.

## 4.5 Oxygen settings

Label	Options	Default	Increment	Description
<b>Oxygen Supply Concentration</b>	93%, 100%	100%	-	The concentration of the oxygen supply connected to the LPO inlet port (i.e. 93% for oxygen concentrators).
<b>High Oxygen Alarm</b>	Off, 30 – 95%	95%	5%	The High Oxygen Alarm will be activated if the FiO <sub>2</sub> exceeds this threshold.  Note: The Airvo 3 will not prevent the operator setting a higher FiO <sub>2</sub> 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.

## 4.6 Pulse oximeter settings

Label	Options	Default	Increment	Description
<b>Show Pulse Rate</b>	Yes, No	Yes	-	Display of pulse rate on the Home Screen when a compatible pulse oximeter is connected.
<b>SpO<sub>2</sub> Low % Limit</b>	1 – 98%	1%	1%	Minimum value for the SpO <sub>2</sub> Low alarm.
<b>Default Low SpO<sub>2</sub> Alarm<sup>†</sup></b>	1 – 98%	85%	1%	Default threshold for the SpO <sub>2</sub> Low alarm.
<b>Default High SpO<sub>2</sub> Alarm<sup>†</sup></b>	Off , 2 – 99%	Off	1%	Default threshold for the SpO <sub>2</sub> High alarm.
<b>Default Alarm Delay</b>	0 – 15 seconds	15 seconds	5 second	Default delay before audible SpO <sub>2</sub> Low or SpO <sub>2</sub> High alarm.
<b>Default Averaging Time (Nonin)</b>	4 beats, 8 beats	8 beats	-	Default period for averaging all pulse oximeter measurements.

<sup>†</sup> The high alarm threshold cannot be set below the low alarm threshold.

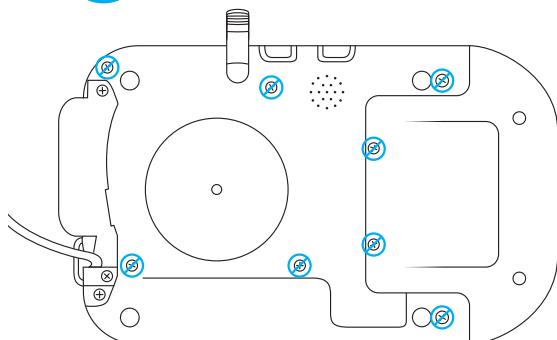
## 4.7 Optiflow settings

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

## 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.

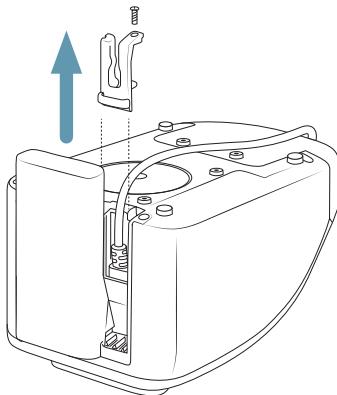
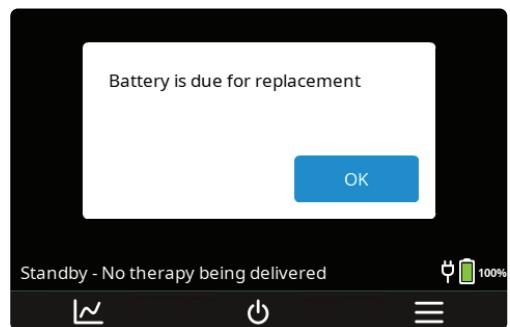
Accessory	Replacement schedule
<b>Inlet Filter (900PT933)</b>	3 months or 1,000 hours or when discolored (whichever comes first)
<b>Outlet Elbow (900PT930)</b>	50 washer-disinfector cycles or 5 years (whichever comes first)
<b>Battery Module (900PT957L)</b>	300 discharge cycles or 2 years from the date of manufacturer (whichever comes first)

## 5.1 Changing the battery module

All batteries lose capacity as they age. The integrated battery should be replaced after 300 charge/discharge cycles or two years from the date of manufacture, to ensure reliable operation. 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
- 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.

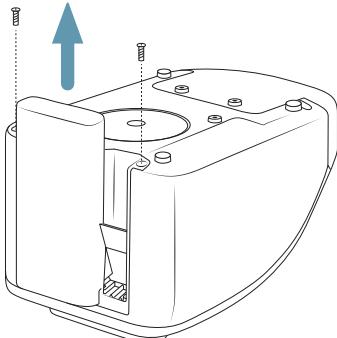
Disconnect all USB connections from the Airvo 3 USB ports.

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.

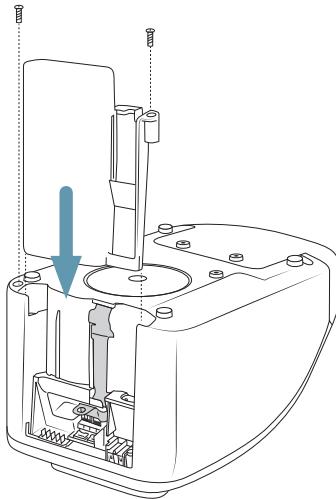
Remove the power cord.



### 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.

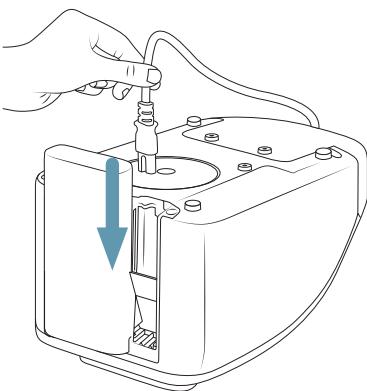


### 3. Install the new battery module

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.

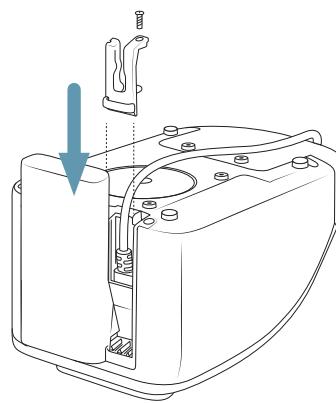
Secure the battery module in place with the two screws. Do not overtighten the screws. Apply a maximum torque of 1 N m if using a power tool.

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 service log

An example of a service 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.

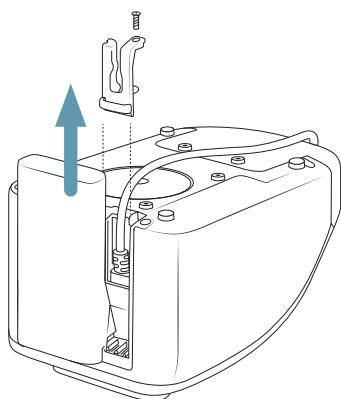
Remove the battery from the device if it is not likely to be used for an extended period of time

## 5.2 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 9 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.

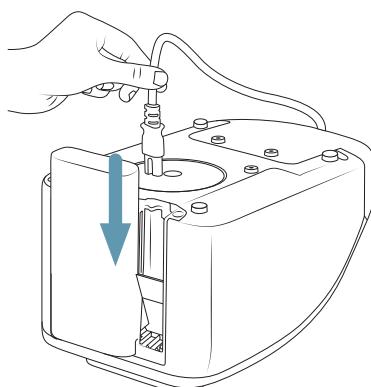
Disconnect all USB connections to the Airvo 3 USB ports.

Disconnect from HPO and/or LPO supply.

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

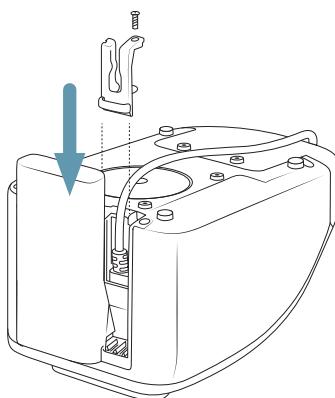
Remove the retaining clip by loosening the one screw on the bottom of the Airvo 3 holding the clip in place. Slide the retaining clip up and away from the Airvo 3 body to remove it.

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.

## 5.3 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.

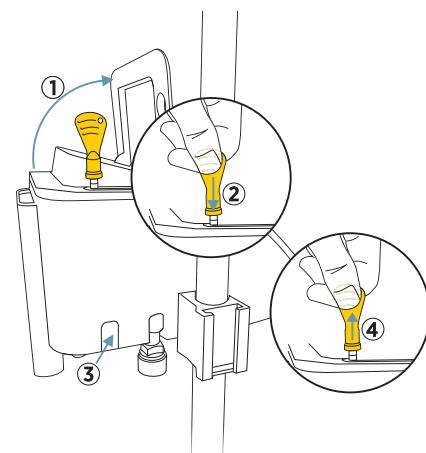
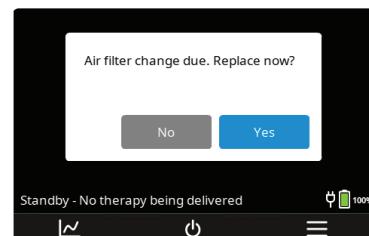
Choose:

- **New** if the air filter is replaced. This will reset the air filter-use timer, or
- **Later** to continue with therapy if the air filter was not replaced.

Begin by removing the old filter:

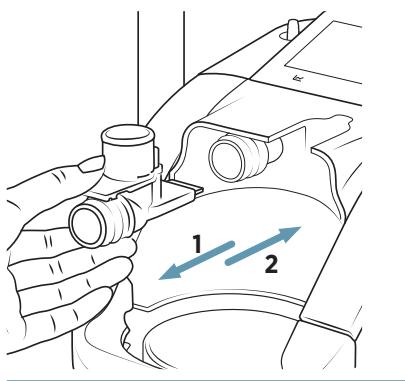
1. Raise the filter cover.
2. Push the filter removal tool down firmly onto the low-pressure oxygen inlet port to get the removal tool to grip.
3. Hold down the air filter-release button on the side of the Airvo 3.
4. Pull up on the filter removal tool to remove the filter.

Insert the new filter by pushing down on top of the filter until it clicks into place. Lower the filter cover.



## 5.4 Replacing the outlet elbow

The outlet elbow should be replaced after 50 washer-disinfector cycles, or whenever 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. Airvo Service Application (900OPT475)

### 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 Airvo Service Application is a program for managing and conducting 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 preventative maintenance.

### 6.1 Installation

To install the free Airvo Service Application you will need:

- a computer running Microsoft Windows 7 or later, and
- an internet connection.

To download the Airvo Service Application, please contact your local Fisher & Paykel Healthcare representative.

### 6.2 Use of Airvo Service Application

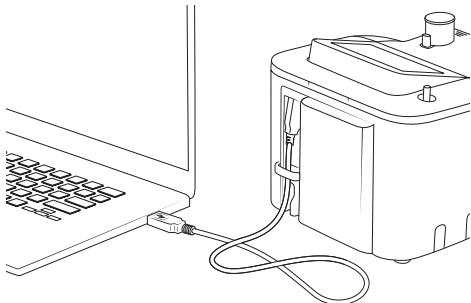
To use the Airvo Service Application to manage your Airvo 3, you will need:

- the Airvo Service Application installed on your computer
- an Airvo 3 USB Service Cable (900OPT474), and
- an Airvo 3 device.



### 1. Start Airvo Service Application

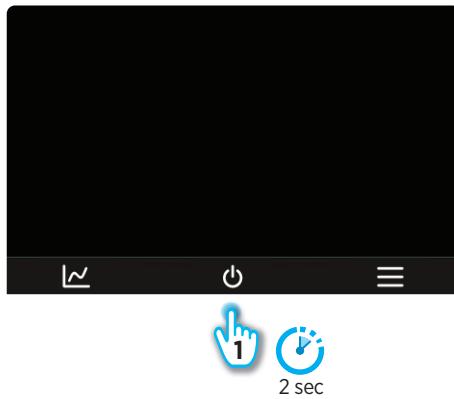
Click the Airvo Service Application icon on the Windows Start menu to open the program.



### 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

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.

The Airvo Service Application will detect the Airvo 3 and connect to the device automatically.

Select 'Help' from the application menu and follow the instructions on using the Airvo Service Application.

## 6.3 Updating Airvo 3 software

The Airvo Service Application automatically checks for Airvo 3 software updates.

To update the software of your Airvo 3:

1. Ensure your Airvo 3 is connected to the Airvo Service Application by verifying the application displays a 'Connected' status.
2. Navigate to Planned Preventative Maintenance, from the application's Device menu.
3. Click on the Enter Service Mode button to authorize Service Mode.
4. Enter the PIN displayed on the screen of your Airvo 3 and click on Submit.
5. Expand the Firmware task by clicking on the Firmware heading.
6. If the application indicates a software update is available, click on Update to transfer the software update to your Airvo 3.
7. Once transfer is complete, your Airvo 3 will automatically restart and apply the software update.

### ! 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 regular self checks during normal use to verify sensor performance. 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 7.2 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 7.3 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 7.4 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' image 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 regular self checks during normal use to verify sensor performance. 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 3.2 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 <sup>1</sup>	900PT930
Air filter <sup>2</sup>	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.

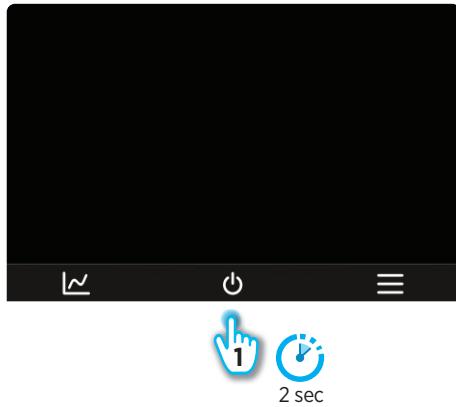
Do not use chambers or breathing tubes that have been used on patients for testing.

## 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.



### 1. 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.

#### Warning

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



### 2. Select patient type

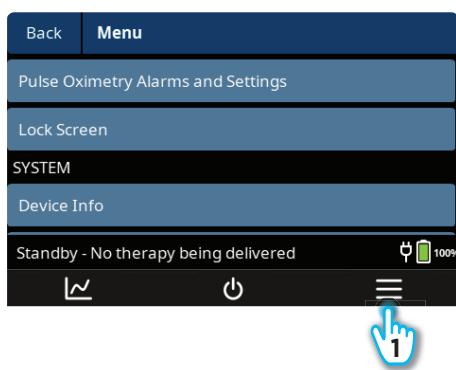
1. Select New Patient for all tests. Check that a clean, disinfected outlet elbow is installed, then
2. Tap Confirm to continue.

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

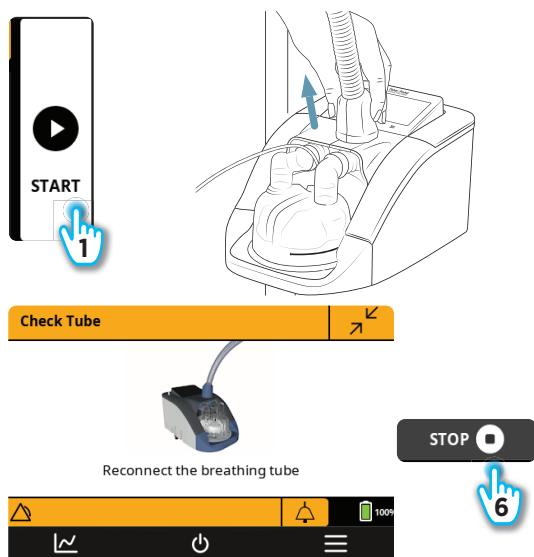
Make sure the Airvo 3 is turned off when connecting the outlet elbow.



### Language

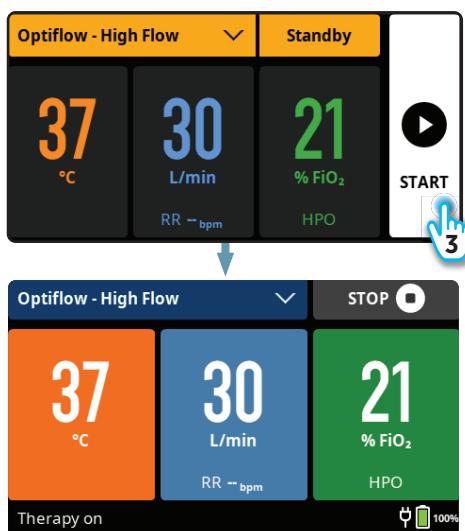
1. Tap to open the System menu.

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.

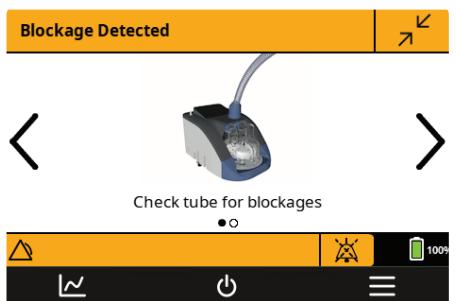
### Power out response

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 the Power Out alarm is displayed within 10 seconds of the wall power supply being disconnected.
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 30 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 the critically low battery alarm and record the time. This should trigger > 20 minutes.
5. Wait for the Power Out alarm and record the time.
6. Wait for at least 120 seconds, (but typically longer) from when the Power Out alarm occurs. The device will shut down.
7. Plug the Airvo 3 into the wall power supply to recharge the battery before it is used to deliver therapy (may take up to 6 hours).

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.

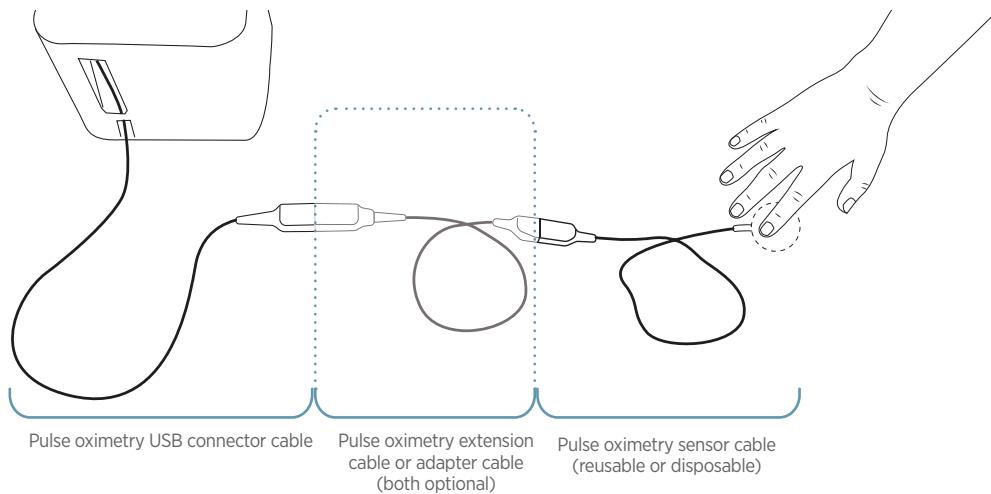
## 7.2.2 USB port functional check

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.

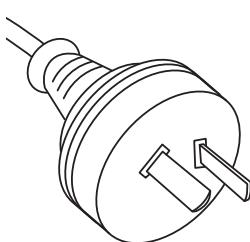


### To check the USB port and pulse oximeter:

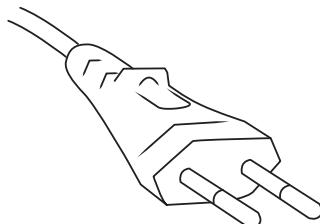
1. Connect the pulse oximetry USB connector cable into one of the USB ports on the back of the Airvo 3.
2. Connect the pulse oximeter sensor cable to the pulse oximetry USB connector cable. A pulse oximeter extension cable or adapter cable may be required.
3. Attach the pulse oximeter sensor to a suitable measurement site on your body, e.g. index finger.
4. For first-time use, a prompt will appear on the Airvo 3 screen. Select the correct pulse oximeter supplier/model.
5. Check that the pulse oximeter tile appears on the Airvo 3 Home Screen.
6. Check that SpO<sub>2</sub> measurements are displayed. SpO<sub>2</sub> should be above 90% for a healthy person.
7. 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

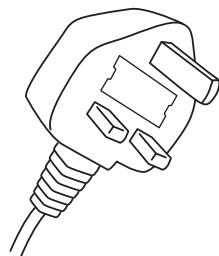
### 8.1 Power cords



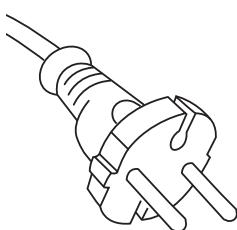
Type I  
(900PT412AN)



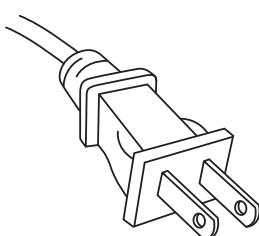
Type C  
(900PT412EW)



Type G  
(900PT412UK)

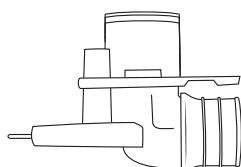


Type F  
(900PT412EU)

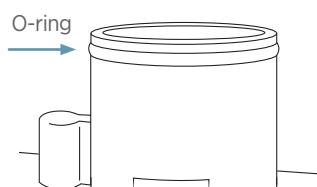


Type A  
(900PT412CA/US)

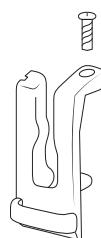
### 8.2 Spare parts



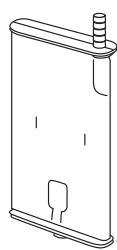
Outlet elbow  
(900PT930)



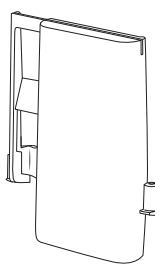
O-ring (10-pack)  
(900PT408)



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



Air filter (900PT933)



Battery module  
(900PT957L)

## 8.3 Interface cables

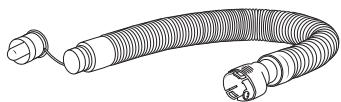


Airvo 3 USB Service Cable  
(900PT474)

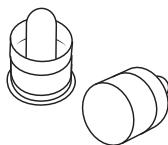


Airvo 3 Data Port Adapter  
(900PT473)

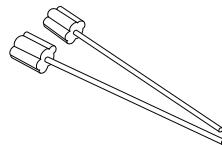
## 8.4 High-level disinfection



Disinfection kit  
(900PT600)



Disinfection filter  
(2-pack) (900PT601)



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



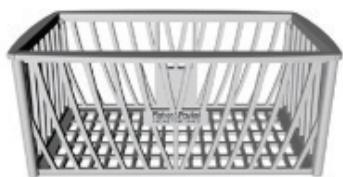
Disinfection storage cover  
(20-pack) (900PT603)

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

## 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)

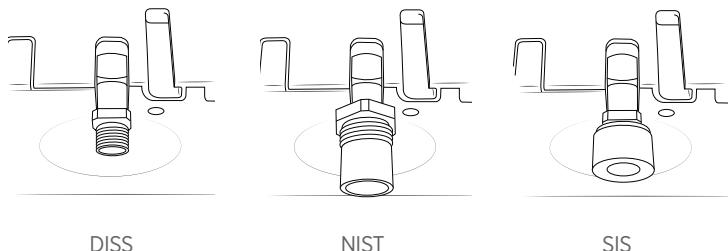
## 8.6 HPO dual-input manifolds

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	ISO/USA	Part number
<b>HPO dual-input manifold with DISS fittings</b>	DISS	N/A	900PT460D

### NIST

Description	Source-end connector	ISO/USA	Part number
<b>HPO dual-input manifold for NIST fittings</b>	NIST	N/A	900PT460N
<b>DISS to NIST connection adapter</b>	NIST	N/A	900PT462DN

### SIS

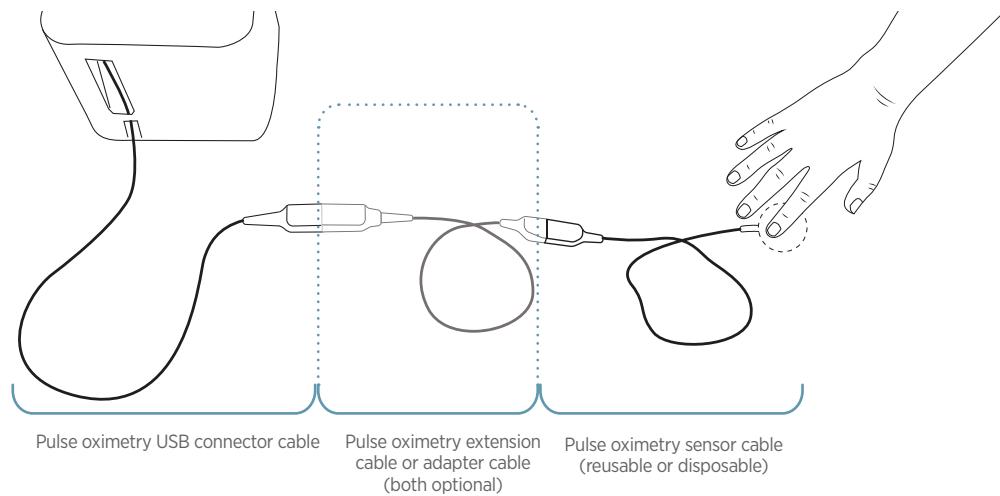
Description	Source-end connector	ISO/USA	Part number
<b>HPO dual-input manifold with SIS fittings</b>	SIS	N/A	900PT460S

## 9. Third-party accessories

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.

### Pulse oximetry



## 10. Pulse oximetry clinical data

For SpO<sub>2</sub> accuracy tables and graphs, please refer to each sensor user instruction, which are available upon request to your local Fisher & Paykel Healthcare representative.

## 11. 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
<b>RF emissions</b> <b>CISPR 11</b>	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.
<b>RF emissions</b> <b>CISPR 11</b>	Class A	Applicable for countries with 100-115V and 220-240V mains voltage.
<b>Harmonic emissions</b> <b>IEC 61000-3-2</b>	Class A	
<b>Voltage fluctuations/</b> <b>Flicker emissions</b> <b>IEC61000-3-3</b>	Complies	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.

### 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
<b>Electrostatic discharge (ESD)</b>	±8kV contact	±8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
<b>IEC61000-4-2</b>	±15kV air	±15kV air	Mains power quality should be that of a typical residential, commercial, professional healthcare facility, or hospital environment.
<b>Electrical fast transient/burst</b>	±2 kV for power supply lines	±2 kV	
<b>IEC61000-4-4</b>	±1 kV for input/output lines	See note 2 below	
<b>Surge</b> <b>IEC 61000-4-5</b>	±1 kV line to line	±1 kV	Mains power quality should be that of a typical residential, commercial, professional healthcare facility, or hospital environment.
<b>Voltage dips, short interruptions and voltage variations on power supply input lines</b>	<b>Voltage dips:</b> 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle  70 % UT (30 % dip in UT) for 25/30 cycles  Single phase at 0°	<b>Voltage dips:</b> 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle  70 % UT (30 % dip in UT) for 25/30 cycles  Single phase at 0°	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.
<b>Power frequency (50/60 Hz) magnetic field</b> <b>IEC 61000-4-8</b>	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
<b>Conducted RF</b>	3 Vrms, 6 Vrms (ISM) 150 kHz to 80 MHz	3 Vrms, 6 Vrms (ISM) 150 kHz to 80 MHz	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. <b>Recommended separation distance:</b> $d = 1.2 \sqrt{P}$
<b>IEC 61000-4-6</b>			
<b>Radiated RF</b>	3 V/m 80 MHz - 2700 MHz	3 V/m 80 MHz - 2700 MHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
<b>IEC 61000-4-3</b>			$d = 2.3 \sqrt{P}$ 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, <sup>a</sup> should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
<b>Proximity fields from RF wireless Communications equipment</b>	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
<b>IEC 61000-4-3</b>			

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.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	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.

## 12. Modem specifications

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### Note

Bluetooth and WiFi functionalities are disabled and not accessible to the user.

### Cellular for PT301AN (HL7650) (Australia and New Zealand)

Reception band	Reception channel bandwidth	Transmission band	Transmission channel bandwidth	Modulation	Maximum transmission power
<b>1805 - 1880 MHz</b>	20 MHz	1710 - 1785 MHz	20 MHz	LTE B3	23 dBm ± 2 dBm
<b>869 - 894 MHz</b>	10 MHz	824 - 849 MHz	10 MHz	LTE B5	23 dBm ± 2 dBm
<b>925 - 960 MHz</b>	10 MHz	880 - 915 MHz	10 MHz	LTE B8	23 dBm ± 2 dBm
<b>758 - 808 MHz</b>	20 MHz	703 - 748 MHz	20 MHz	LTE B28	23 dBm ± 2 dBm
<b>2110 - 2170 MHz</b>	5 MHz	1920 - 1980 MHz	5 MHz	UMTS B1	24 dBm +1 / -3 dBm
<b>869 - 894 MHz</b>	5 MHz	824 - 849 MHz	5 MHz	UMTS B5	24 dBm +1 / -3 dBm
<b>925 - 960 MHz</b>	5 MHz	880 - 915 MHz	5 MHz	UMTS B8	24 dBm +1 / -3 dBm

## Celluar for PT301 Global (HL7800)

Reception band	Reception channel bandwidth	Transmission band	Transmission channel bandwidth	Modulation	Maximum transmission power
<b>1920 - 1980 MHz</b>	1.4 MHz	2110 - 2170 MHz	1.4 MHz	LTE B1	23 dBm ± 1.5 dBm
<b>1850 - 1910 MHz</b>	1.4 MHz	1930 - 1990 MHz	1.4 MHz	LTE B2	23 dBm ± 1.5 dBm
<b>1710 - 1785 MHz</b>	1.4 MHz	1805 - 1880 MHz	1.4 MHz	LTE B3	23 dBm ± 1.5 dBm
<b>1710 - 1755 MHz</b>	1.4 MHz	2110 - 2155 MHz	1.4 MHz	LTE B4	23 dBm ± 1.5 dBm
<b>824 - 849 MHz</b>	1.4 MHz	869 - 894 MHz	1.4 MHz	LTE B5	23 dBm ± 1.5 dBm
<b>880 - 915 MHz</b>	1.4 MHz	925 - 960 MHz	1.4 MHz	LTE B8	23 dBm ± 1.5 dBm
<b>699 - 716 MHz</b>	1.4 MHz	729 - 746 MHz	1.4 MHz	LTE B12	23 dBm ± 1.5 dBm
<b>777 - 787 MHz</b>	1.4 MHz	746 - 756 MHz	1.4 MHz	LTE B13	23 dBm ± 1.5 dBm
<b>788 - 798 MHz</b>	1.4 MHz	758 - 768 MHz	1.4 MHz	LTE B14	23 dBm ± 1.5 dBm
<b>704 - 716 MHz</b>	1.4 MHz	734 - 746 MHz	1.4 MHz	LTE B17	23 dBm ± 1.5 dBm
<b>815 - 830 MHz</b>	1.4 MHz	860 - 875 MHz	1.4 MHz	LTE B18	23 dBm ± 1.5 dBm
<b>830 - 845 MHz</b>	1.4 MHz	875 - 890 MHz	1.4 MHz	LTE B19	23 dBm ± 1.5 dBm
<b>832 - 862 MHz</b>	1.4 MHz	791 - 821 MHz	1.4 MHz	LTE B20	23 dBm ± 1.5 dBm
<b>1850 - 1915 MHz</b>	1.4 MHz	1930 - 1995 MHz	1.4 MHz	LTE B25	23 dBm ± 1.5 dBm
<b>814 - 849 MHz</b>	1.4 MHz	859 - 894 MHz	1.4 MHz	LTE B26	23 dBm ± 1.5 dBm
<b>807 - 824 MHz</b>	1.4 MHz	852 - 869 MHz	1.4 MHz	LTE B27	23 dBm ± 1.5 dBm
<b>703 - 748 MHz</b>	1.4 MHz	758 - 803 MHz	1.4 MHz	LTE B28	23 dBm ± 1.5 dBm
<b>1710 - 1780 MHz</b>	1.4 MHz	2110 - 2200 MHz	1.4 MHz	LTE B66	23 dBm ± 1.5 dBm

## 13. Collection and use of personal data

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Airvo 3 is not designed to collect identifiable information about end users. To function effectively, Airvo 3 will collect and store limited therapy and device performance data.

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 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
<b>1.2.x-1.3.x</b>	<b>Communication and audio</b>	Restart the Airvo 3 and check the system settings for audio alarm configuration.
<b>2.1.x – 2.2.x</b>	<b>Software</b>	Restart the Airvo 3 and ensure the correct consumables are connected to the device.
<b>2.3.x</b>	<b>Voltage</b>	Restart the Airvo 3 and ensure the power supply meets the specifications outlined in the user manual.
<b>2.4.x – 2.5.x</b>	<b>Heater plate</b>	<ol style="list-style-type: none"> <li>1. Turn off the Airvo 3.</li> <li>2. Check that the water chamber is fitted correctly.</li> <li>3. Check the power supply is stable.</li> </ol>
<b>2.6.x – 2.7.x</b>	<b>Heated breathing tube</b>	<ol style="list-style-type: none"> <li>1. Check that the tube is connected correctly.</li> <li>2. Restart the Airvo 3.</li> <li>3. If the problem persists, repeat the steps above with a new tube.</li> </ol>
<b>2.8.x – 2.9.x, 4.x.x</b>	<b>Motor</b>	Turn off the Airvo 3 and wait for at least 30 minutes before restarting.
<b>2.10.x, 3.3.x – 3.4.x</b>	<b>Pressure</b>	Ensure that operating conditions are within the specified range in the user manual.
<b>2.11.x, 3.8.x</b>	<b>Oxygen related</b>	<ol style="list-style-type: none"> <li>1. Turn off the Airvo 3.</li> <li>2. Check that the HPO port is securely connected.</li> <li>3. Check the oxygen source (wall or cylinder).</li> <li>4. Turn on the Airvo 3.</li> </ol>
<b>2.12.x</b>	<b>Ambient conditions</b>	Ensure that the Airvo 3 is used under the specified operating conditions outlined in the user manual. Restart the Airvo 3.
<b>2.13.x</b>	<b>Disinfection</b>	<ol style="list-style-type: none"> <li>1. Ensure the operating conditions are used within the specified range.</li> <li>2. Check that the disinfection tube and disinfection filter are connected properly.</li> <li>3. Check that any supplementary oxygen supply is turned off and disconnected from the Airvo 3.</li> <li>4. Make sure the Airvo 3 is connected to the wall power supply.</li> <li>5. Check that the air filter is inserted correctly.</li> <li>6. Restart the Airvo 3.</li> <li>7. If the problem persists, repeat the steps above with a new disinfection tube and then a new unit elbow.</li> </ol>
<b>3.x.x</b>	<b>Internal sensors</b>	<p>Ensure that the Airvo 3 is used in the operating conditions specified in the user manual.</p> <p>Restart the Airvo 3.</p>

## 15. Troubleshooting

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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.

#### **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 5.1

#### **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 2 years from the date of manufacture, whichever comes first.

#### **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 is after 2 years, a prompt will be generated at every start up. Follow Section 5 Servicing on instructions on changing the battery.

## 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 (64 °F) 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.

If using an incubator/radiant warmer, you will need an AirSpiral tube and chamber kit with the incubator/warmer tube. Remove the incubator/warmer tube when not in an incubator/radiant warmer.

#### 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 or <5 cmH<sub>2</sub>O 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 or pressures 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. A prompt will appear on the screen.
5. Ensure the correct supplier is selected.

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

# 16. Specifications

## 16.1 General

<b>Dimensions</b>	205 mm x 295 mm x 190 mm
<b>Weight including battery</b>	4.45 kg
<b>Supply voltage/current</b>	100 – 115 VAC, 2.4 A (2.6 A max <sup>1</sup> ) 220 – 240 VAC, 1.1 A (1.3 A max <sup>1</sup> )
<b>Supply frequency</b>	50 – 60 Hz
<b>USB port sourcing (1 and 2)</b>	5 V, 0.35 A (maximum each port)
<b>Auditory alarm</b>	
<b>Sound pressure level</b>	> 40 dBA @ 1 m
<b>Audio pause duration</b>	120 seconds
<b>Ingress protection</b>	IP22 <sup>2</sup>
<b>Expected service life</b>	5 years <sup>3</sup>

## Operating conditions

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

## Storage and transport conditions

<b>Ambient temperature<sup>5,6</sup></b>	-10 – 50 °C
<b>Humidity (non-condensing)</b>	10 – 95% relative humidity

## Battery (900PT957L)

<b>Chemistry</b>	Lithium Ion (Li-Ion)
<b>Voltage</b>	14.4 VDC
<b>Capacity, power output</b>	99.4 Wh, 80 W
<b>Battery life</b>	300 charge/discharge cycles or 2 years from the date of manufacture (whichever comes first)
<b>Recharge time</b>	6 hours (maximum)
<b>Storage life</b>	1 year
<b>Operating time</b>	
<b>Typical</b>	40 minutes
<b>Worst case<sup>7</sup></b>	20 minutes

## Supplementary oxygen

<b>Oxygen sensor start-up time</b>	< 30 s
<b>Oxygen delivery response</b>	< 60 s
<b>High-pressure oxygen (HPO) inlet port</b>	
<b>Line pressure</b>	280 – 600 kPa (40 – 87 psi)
<b>Maximum flow rate (3s &amp; 10s)</b>	100 L/min (SLPM <sup>8</sup> ) NHF
<b>Low-pressure oxygen (LPO) inlet port</b>	
<b>Line pressure</b>	0-70 kPa (0-10 psi)
<b>Maximum flow rate</b>	60 L/min (SLPM <sup>8</sup> )

## Optiflow high flow therapy<sup>9</sup>

<b>Target humidity range</b>	31 – 37 °C
<b>Target flow range<sup>10</sup></b>	2 – 70 L/min
<b>Maximum limited pressure<sup>12</sup></b>	60 cmH <sub>2</sub> O
<b>Oxygen concentration</b>	21 - 100% FiO <sub>2</sub>
<b>Humidity<sup>4,13</sup></b>	
<b>Wall power</b>	> 33 mg/L at 37 °C target humidity, 10 – 60 L/min target flow > 12 mg/L for all other settings

<b>Warm-up time<sup>11</sup> (MR290 chamber)</b>	
<b>23 ± 2 °C to 37 °C (73 °F to 98.6 °F)</b>	< 20 min

1. Inrush current may reach 50 A.
2. The device is protected against harmful effects of dripping water when tilted by up to 15° and/or incursion of fingers or similar-sized objects.
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. Worst-case operating time applies to a fully charged battery at 25 °C that has experienced 300 charge/discharge cycles followed by 1 year of storage.
8. Volumetric flow rate is expressed in SLPM (standard litres per minute at STP).
9. Values are expressed in body temperature, pressure and saturated (BTPS) unless otherwise stated.
10. Maximum achievable flow rate depends on the patient interface selected.
11. Applies when the device is connected to a wall power supply for warmup.
12. In accordance with ISO 80601-2-90.
13. For humidity performance under battery use, see Appendix 4.

## 16.2 Range and accuracy of measured parameters

### 16.2.1 Range and accuracy of measured parameters (Optiflow)

Measurement	Symbol	Displayed Range	Accuracy
<b>Humidity</b>	Temp	25 – 37 °C	not specified
<b>Flow rate</b>	Flow	2 – 70 L/min	± (1 + 5% of reading) L/min
<b>Oxygen concentration<sup>†</sup></b>	FiO <sub>2</sub>	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
<b>Respiratory rate</b>	RR	4 – 70 BPM	RMS error of 3 BPM <sup>‡</sup>
<b>Peripheral blood oxygen saturation</b>	SpO <sub>2</sub>	1 – 100%	See Nonin pulse oximetry specifications below
<b>Pulse rate</b>	PR / 	18 – 321 BPM	See Nonin pulse oximetry specifications below

<sup>†</sup> Oxygen measurements are automatically compensated for changes in barometric pressure.

<sup>‡</sup> 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

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)	
<b>SpO<sub>2</sub> Accuracy (A<sub>rms</sub> **)</b>	70 to 100%	
<b>No Motion</b>	<b>Adults/Pediatrics***</b>	<b>Neonates</b>
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
<b>Motion</b>		
Reusable		
8000AX Series:	± 2 digits	N/A
800XJ Series:	± 3 digits	N/A
8000SX Series:	± 3 digits	N/A
<b>Low Perfusion****</b>	± 2 digits	± 3 digits
<b>Pulse Rate Accuracy</b>	<b>Adults/Pediatrics***</b>	<b>Neonates</b>
<b>No Motion (18 - 300 BPM)</b>		
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
<b>Motion (40 - 240 BPM)</b>		
Reusable		
8000AX Series:	± 5 digits	N/A
800XJ Series:	± 5 digits	N/A
8000SX Series:	± 5 digits	N/A
<b>Low Perfusion (40 - 240 BPM)****</b>	± 3 digits	± 3 digits

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

\*\* ± 1 A<sub>rms</sub> 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<sub>2</sub> 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<sub>2</sub>) of the sensors is compared to arterial hemoglobin oxygen (SaO<sub>2</sub>) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples is measured over the SpO<sub>2</sub> 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<sub>2</sub> Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO<sub>2</sub> levels. The module must maintain accuracy in accordance with ISO 80601-2-61, formerly ISO 9919, pulse rate and SpO<sub>2</sub> at the lowest obtainable pulse amplitude (0.3% modulation).

## 16.4 Standards compliance

Designed to conform to the following standards:

IEC 60601-1:2005 + A1:2012 (ed 3.1)

IEC 60601-1-2: 2014

IEC 60601-1-8:2006 + Amd 1 2012

ISO 80601-2-61: 2017

ISO 80601-2-74:2017

Do not place any part of the device or accessories within 30 cm (12") 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.

### FCC compliance

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reposition or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult your healthcare provider or your Fisher & Paykel Healthcare representative for help.

Accessory equipment connected to 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 the 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](http://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 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](http://www.fphcare.com/certifications).

## 16.5 Disposal instructions

### Device disposal instructions



This device contains electronics and a lithium battery. Please do not discard as regular waste. Return to Fisher & Paykel Healthcare or dispose according to local guidelines for disposing of electronics. In the European Union, return to Fisher & Paykel Healthcare for disposal.

### 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 a contaminated product.

## 17. Glossary

			
For safety reasons, refer to the instructions for use	Warning, hot surface	Consult instructions for use for detailed information	Warning: a potential hazard which, if not avoided, could result in death or serious injury
			
Caution: a potential hazard which, if not avoided, could result in minor or moderate injury	Note: emphasizes information important for using the Airvo 3 correctly	Power on/off button	System menu button
			
Touch lock enabled	Data and Graphs information button	Pulse rate	USB port and Compatible USB device detected
			
Alarm symbol	Audible alarm paused	Battery status	Wall power supply
			
Alarm limits	Class II equipment (double insulated)	Do not use if package is damaged	Type BF applied part (body floating)
			
Temperature range	Humidity range	Operating conditions	Storage and transport conditions
	<b>IP22</b>		
Manufacturer	Protected against ingress of small objects and water drops	Magnetic Resonance (MR) Unsafe	Non-ionizing electromagnetic radiation
<b>REF</b>	<b>SN</b>	<b>LOT</b>	<b>EC REP</b>
Catalog number	Serial number	Batch code	EU representative
		<b>CE 0123</b> Conforms with medical device directive 93/42/EEC	
Do not discard as regular waste	Discard as regular waste	Conforms with medical device directive 93/42/EEC	Regulatory compliance mark (RCM)

## 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.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	The battery and power-cord retainer fixing screws are all present and not loose.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
The air filter is not damaged or discolored.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	The 'Hot Surface' warning sticker is present in the water chamber cavity.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
The heated breathing tube port is not damaged, and the electrical connector shows no sign of corrosion.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	The heater plate is not badly scratched or corroded.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
The Airvo 3 case is not damaged.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	The finger guard springs back into place when pushed down and released.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
The screen and bezel are not damaged or cracked.	<input type="checkbox"/> Pass <input type="checkbox"/> 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.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

### Electrical safety test results

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

Test	Result	Test	Result
The device meets the local medical electrical standard for in-house testing.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	Resistance between the bottom lip of heater plate and power plug phase pin is greater than 500 MΩ.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Resistance between the bottom lip of heater plate and power plug phase pin is greater than 500 MΩ.	<input type="checkbox"/> Pass <input type="checkbox"/> 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
<b>Heater plate</b>	Warmup completed.	< 30 minutes	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
<b>Check for Leaks</b>	The check for Leaks alarm is generated when the water chamber is removed.	< 30 seconds	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
<b>Check for Blockages</b>	The check for Blockages alarm is generated when the heated breathing tube is blocked.	< 30 seconds	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
<b>Check Tube</b>	The Check Tube alarm is generated when the heated breathing tube is disconnected.	< 5 seconds	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
<b>Power Out</b>	The Power Disconnected message is displayed when the wall power supply is disconnected. Therapy delivery continues with battery power.	< 10 seconds	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

## Appendix C. User default settings

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Airvo 3 serial number:

---

Hospital/Department:

Asset number:

---

### System settings

Label	Options	Default	Customized hospital-specific setting (if different)
<b>Sound and display</b>			
<b>Sound volume</b>	Low, medium, high	Low	
<b>Show lock menu</b>	Yes, No	Yes	
<b>Oxygen settings</b>			
<b>Oxygen supply concentration</b>	93%, 100%	100%	
<b>Oxygen Disconnect Alarm</b>	Off, 30 - 90%	95%	
<b>FiO<sub>2</sub> High Oxygen Alarm</b>	30 – 95%, off (5% increments)	95%	
<b>Pulse oximeter settings</b>			
<b>Show pulse rate</b>	Yes, No	Yes	
<b>SpO<sub>2</sub> Low % Limit</b>	1 – 98%	1%	
<b>Default Low SpO<sub>2</sub> Alarm<sup>†</sup></b>	1 – 98%	85%	
<b>Default High SpO<sub>2</sub> Alarm<sup>†</sup></b>	Off, 2 – 99%	Off	
<b>Default Alarm Delay</b>	0 – 15 seconds	15 seconds	
<b>Default Averaging Time</b>	4 beats, 8 beats	8 beats	

<sup>†</sup> The high alarm threshold cannot be set below the low alarm threshold.

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## Optiflow settings

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

## Appendix D. Airvo 3 service 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 (900PT9330):

**Maximum use: 3 months or 1000 hours or when significantly discolored (whichever comes first)**

## **Battery (900PT957L):**

**Maximum use: 300 discharge cycles or 2 years from the date of manufacture (whichever comes first)**

## 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

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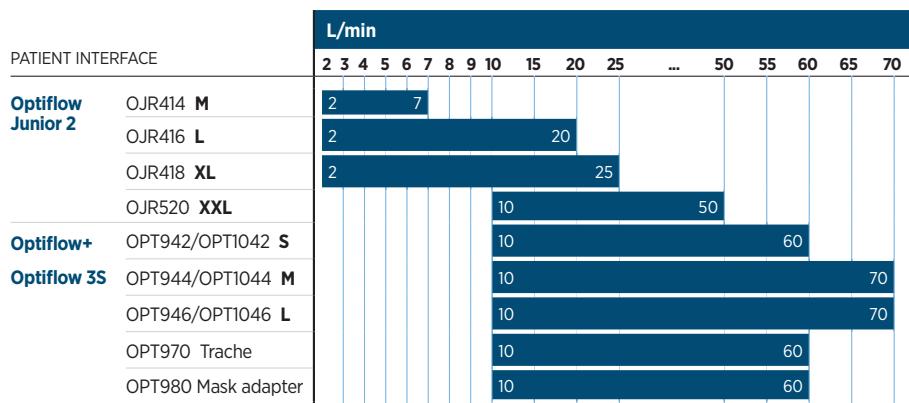
## Appendix F. Compatible consumables and accessories

### Optiflow high flow therapy

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

<sup>†</sup> Wigglepads part numbers are shown in parentheses.

<sup>‡</sup> The mask interface adapter is designed for vented masks only. Do not use sealed masks with Optiflow high flow therapy.



## Accessories

Description	Part number	Description	Part number
<b>Mobile pole stand</b>	900PT421	<b>HPO Dual-Input Manifold (DISS, NIST, SIS)</b>	900PT460D 900PT460N 900PT460S
<b>Mobile pole stand handle</b>	900PT445		
<b>Mobile pole stand clamp</b>	900PT428	<b>HPO adapter (DISS to NIST)</b>	900PT462DN
<b>Oxygen-bottle holder</b>	900PT427 900PT427L	<b>Airvo 3 USB service cable</b>	900PT474
<b>Storage basket</b>	900PT426	<b>Airvo 3 data port adapter</b>	900PT473
<b>Airvo 3 service app</b>	900PT475	<b>Storage cover</b>	900PT603
<b>Disinfection kit<sup>†</sup></b>	900PT600		

<sup>†</sup> 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.

## 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.

### Nonin:

#### Part numbers of compatible Nonin pulse oximetry USB connector cables

Description	Nonin part number (cable length)
Xpod® 3012 LP with USB Connector	6703-001 (1m, 3ft)

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

Sensor description	Nonin part number (cable length) (other information)
<b>8000SS reusable soft sensors, small</b>	6837-000 (1m, 3ft), 6837-300 (3m, 10ft)s
<b>8000SM reusable soft sensors, medium</b>	6836-000 (1m, 3ft), 6836-300 (3m, 10ft)
<b>8000SL reusable soft sensors, large</b>	6835-000 (1m, 3ft), 6835-300 (3m, 10ft)
<b>8000AA adult reusable finger clip sensors</b>	3278-001 (1m, 3ft), 3278-006 (2m, 6ft), 3278-003 (3m, 10ft)
<b>8000AP pediatric reusable finger clip sensors</b>	2360-000 (1m, 3ft), 2360-003 (3m, 10ft)
<b>8000Q2 ear clip sensor</b>	6455-000 (1m, 3ft)
<b>8000R reflectance sensor</b>	0487-000 (1m, 3ft)
<b>8000J adult semi-reusable Flex Sensor</b>	0741-000 (1m, 3ft), 2353-002 (3m, 10ft) (includes x25 8000JFW FlexiWraps®)
<b>8008J infant semi-reusable Flex Sensor</b>	0740-000 (1m, 3ft) (includes x25 8008JFW FlexiWraps)
<b>8001J neonatal semi-reusable Flex Sensor</b>	0739-000 (1m, 3ft) (includes x25 8001JFW FlexiWraps)
<b>6000CA adult cloth disposable sensors</b>	7426-001 (1m, 3ft) (24 pack)
<b>6000CP pediatric cloth disposable sensors</b>	7426-002 (1m, 3ft) (24 pack)
<b>6000CI infant cloth disposable sensors</b>	7426-003 (1m, 3ft) (24 pack)
<b>6000CN neonatal cloth disposable sensors</b>	7426-004 (1m, 3ft) (24 pack)
<b>7000A adult Flexi-Form® III disposable sensors</b>	7427-001 (1m, 3ft) (24 pack)
<b>7000P pediatric Flexi-Form III disposable sensors</b>	7427-002 (1m, 3ft) (24 pack)
<b>7000I infant Flexi-Form III disposable sensors</b>	7427-003 (1m, 3ft) (24 pack)
<b>7000N neonatal Flexi-Form III disposable sensors</b>	7427-004 (1m, 3ft) (24 pack)
<b>8000JFW adult FlexiWraps</b>	4097-000, (25 pack), for use with 8000J
<b>8008JFW infant FlexiWraps</b>	4774-000, (25 pack), for use with 8008J
<b>8001JFW neonatal FlexiWraps</b>	4777-000, (25 pack), for use with 8001J
<b>8000H reflectance sensor holder pack</b>	0616-000, (10 caps & 20 adhesive stickers) for use with 8000R
<b>Sensor Clip for LP Xpod External Pulse Oximeter</b>	7504-001

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