F&P Airvo 3

USER MANUAL

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Fisher & Paykel HEALTHCARE

F&P Airvo 3

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For patent information refer to: www.fphcare.com/ip

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Compatible third-party products:

Masimo

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Masimo SET is the pulse oximetry technology proven to provide accurate measurements under the challenging monitoring conditions of low perfusion and patient motion as supported by over 100 clinical studies.

Medtronic/Nellcor™

Nellcor™ SpO_2 technology from Medtronic

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The Nellcor OxiCable is based on Covidien Sales' proprietary technology and should only be used with Nellcor branded sensors for proper operation and performance.

Nonin

Nonin®, Xpod®, PureLight®, PureSAT®, FlexiWraps®, Flexi-Form® are trademarks of Nonin Medical Inc.

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Using any sensors other than Nonin-branded PureLight® sensors with the Nonin Xpod USB connector may result in inaccurate performance (of the Airvo™ 3 and/or Nonin products) and will void the Nonin product warranty.

Before you start

- This user manual is for instructions on using the Airvo 3.
- This user manual is intended for healthcare professionals. While the information provided is believed to be accurate, it is not a substitute for exercising professional judgement.
- Read this user manual, including all warnings, before using the Airvo 3.
- Before the Airvo 3 is used for the first time, it must be set up according to the instructions in the Airvo 3 Technical Manual.
- Some accessories may not be available in certain countries. Please contact your local Fisher & Paykel Healthcare representative for more information.
- If any device or accessory label is damaged or unreadable, contact your Fisher & Paykel Healthcare representative for a replacement.

Additional resources

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

Conventions used in this manual

WARNING

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

CAUTION

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

Note

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

Contents

1. Introduction

The Airvo 3 is designed to deliver Optiflow™ high flow therapy to spontaneously breathing patients.

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

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

1.1 Intended use/indications for use

The Airvo 3 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 70 L/min depending on the patient interface. The Airvo 3 is for patients in hospitals and subacute facilities.

The Airvo 3 can deliver these high flow gases through nasal cannula to augment the breathing of spontaneously breathing neonate, infant, child, adolescent and adult patients suffering from respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 is not intended to provide total ventilatory requirements of the patient and is not for use during field transport.

1.2 Contraindications

Contraindications are therapy-specific. Refer to instructions of patient interfaces and/or tube and chamber kits for contraindications.

1.3 Side-effects

Side-effects are therapy-specific. Refer to instructions of patient interfaces and/or tube and chamber kits for side-effects.

2. Safety information

The Airvo 3 and accessories are to be operated by, or under the supervision of, qualified personnel only. Read this manual, particularly all warnings, cautions and notes, and the instructions for use supplied with all accessories before using the Airvo 3.

2.1 General

WARNINGS

- The Airvo 3 is not intended for life support. Do not use Airvo 3 on patients who cannot tolerate a brief interruption of therapy.
- Appropriate patient monitoring is required for all patients using the Airvo 3.
- Delivery of respiratory gases may generate positive airway pressure. This must be considered where positive airway pressure could have adverse effects on a patient. To avoid serious injury, appropriately monitor the patient for risk factors of airway and lung pressure injury.
- Anybody connecting patient consumables, accessories or spare parts to the Airvo 3 is accountable for the compatibility of the device and those patient consumables, accessories and/or spare parts.
- Do not use any patient consumables, accessories or spare parts that are not listed in this user manual, or the Airvo 3 Technical Manual. Incompatible consumables, parts or accessories could affect the quality of therapy, injure the patient, decrease electromagnetic immunity or increase electromagnetic emissions.
- Use only patient interfaces, heated breathing tubes, water chambers and filters specified in this manual to prevent disconnection during use, especially when moving the Airvo 3.
- Do not use antistatic or electrically conductive patient breathing circuits with the Airvo 3.
- Do not connect the Airvo 3 to the battery of a battery-powered wheelchair, which may compromise device performance and therapy delivered.
- Do not start or operate the Airvo 3 unless the device setup, including all accessories, is verified to be correct.
- Carefully route accessories, cords and cables, including the breathing tube, to reduce the possibility of patient entanglement or strangulation.
- Visually inspect the Airvo 3 and accessories before use and replace if damaged or suspected to be damaged. Using a damaged device or accessories may impair performance and/or compromise safety.
- Make sure the auditory alarm signal is audible to the operator who will respond to alarms by following the instructions in section 7.5 to test the alarm before starting therapy.
- Do not use an Airvo 3 on more than one patient at any one time.
- Do not use accessories beyond the maximum period of use specified in this manual. Exceeding the maximum use period can result in serious injury, including infection.
- Do not expose the Airvo 3 battery to water, fire or excessive heat. Do not crush, disassemble or puncture the battery, or short-circuit the connector terminals.

- Do not use the Airvo 3 as an apnea monitor.
- Do not use the Airvo 3 for arrhythmia analysis.
- In the event of a battery leaking, 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 a battery has been swallowed.
- Changes or modifications not expressly approved by Fisher & Paykel Healthcare voids the user's authority to operate the device.
- The therapy delivered to the patient can be impacted by the use of a pneumatic/jet nebulizer. Refer to compatible accessories and drug manufacturer instructions for correct usage.
- Do not use any solutions, suspensions, emulsions, anesthetic or respirable gases that are not identified in these user instructions. They may not be compatible with the patient consumables, device or accessories.
- Use only genuine F&P replacement battery modules to prevent damage to the Airvo 3, excessive temperatures, fire or explosion.

Operating environment

- Do not use the Airvo 3 at an altitude or temperature outside the rated range listed in the specifications section of the manual. Using outside of these ranges can compromise the equipment performance which consequently can result in degradation of the health of the patient.
- Do not use the Airvo 3 when outside the operating conditions listed in the specifications section. Therapy may be compromised outside this range.
- Do not use the Airvo 3 in a magnetic resonance imaging (MRI) environment.
- Do not use the Airvo 3 with, or in the presence of, a flammable anesthetic mixture with air or oxygen.
- Do not use the Airvo 3, or accessories, during defibrillation.
- Do not use the Airvo 3, or accessories, near any ignition source, including electrosurgery, electrocautery, or laser surgery instruments. Exposure to oxygen increases the risk of fire that may result in patient injury.
- Do not use the Airvo 3, or accessories during electrocautery.
- Explosion hazard: Do not use the Airvo 3 in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- Do not use the Airvo 3 in a hyperbaric chamber.
- Avoid using the Airvo 3, or accessories, adjacent to, or stacked with, other equipment, which could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The Airvo 3 is not designed for use in the home.

CAUTIONS

- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

To avoid burns

- Do not touch the hot surface of the heater-plate or chamber base.
- Never operate the Airvo 3 if:
  - the heated breathing tube has been damaged in any way including holes, tears or kinks,
  - it is not working properly, or
  - water has entered the device.
- Do not restrict ventilation around the Airvo 3, which may cause it to overheat.
- Do not block the flow of air through the Airvo 3 or breathing tube.

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.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- 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 Airvo 3 Technical Manual for instructions to replace a damaged power cord.
- Do not attempt to adjust, repair, open, disassemble or modify the Airvo 3, pulse oximeter equipment, or accessories except as described in this user manual or the Airvo 3 Technical Manual. Return the Airvo 3 to your Fisher & Paykel Healthcare representative for servicing, if necessary.

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

Note

- If a serious incident has occurred while using this device please inform your local Fisher & Paykel Healthcare representative and Competent Authority in your country.

2.2 Supplementary oxygen

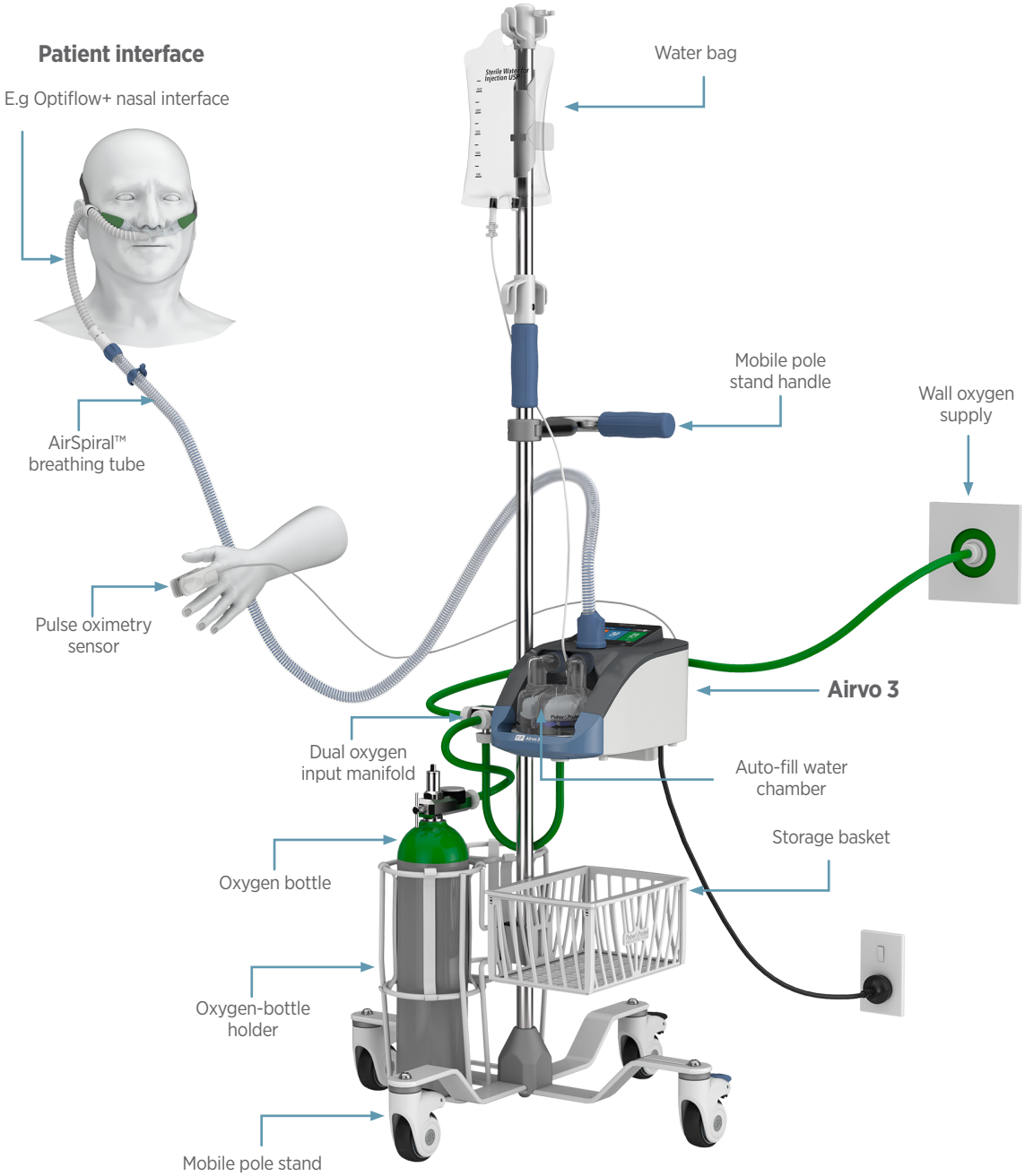
WARNINGS

- 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.
- A spontaneous and violent ignition may occur if oil, grease or greasy substances contact oxygen under pressure. Keep these substances away from all oxygen equipment.
- The Airvo 3 is a high flow device. Ensure the oxygen supply is designed to provide enough oxygen flow for all connected equipment, particularly when the supply is shared by multiple devices.
- Only connect pure oxygen to the oxygen inlet ports on the Airvo 3. The oxygen concentration displayed will be wrong if any other gas, or mixtures of gases, is connected.
- Only use lotions and/or salves that are labeled as oxygen-compatible to avoid the risk of fire and burns.

3. Overview

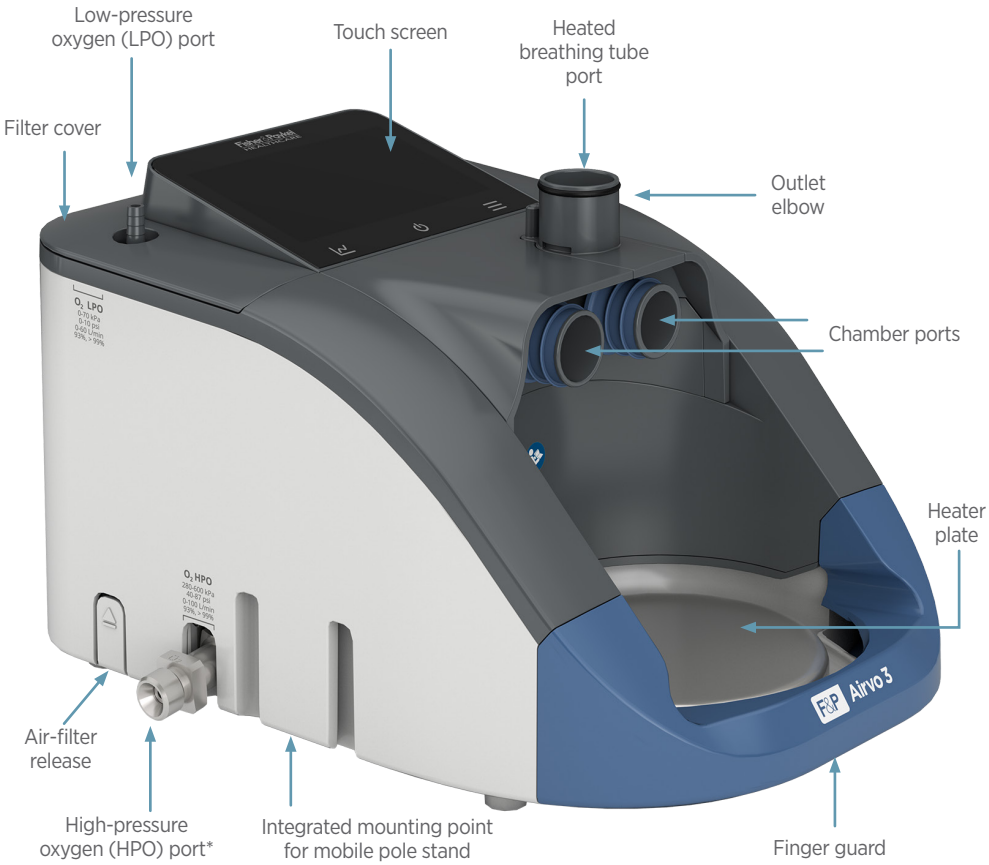
This section shows the Airvo 3 system and compatible accessories.

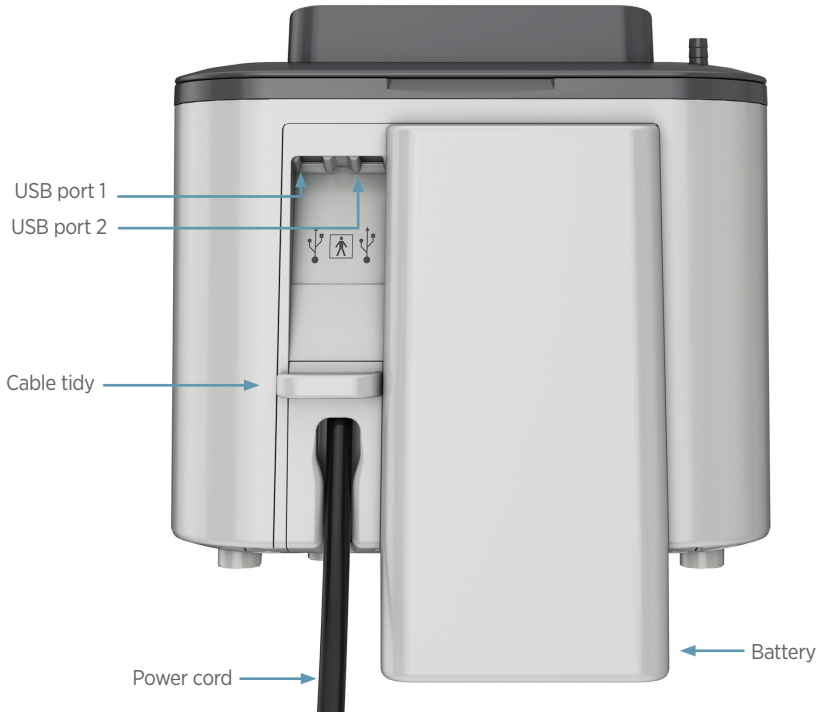
3.1 Identifying system components



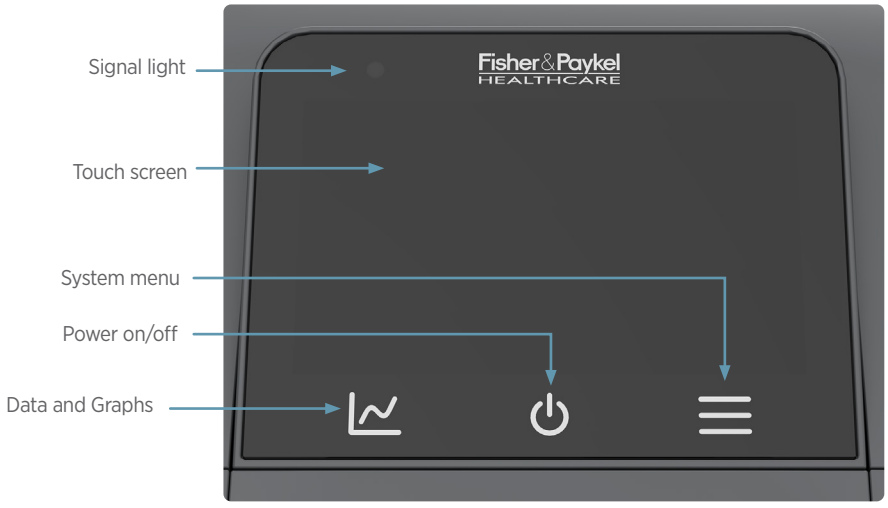
The Airvo 3 System

3.2 Identifying device components





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

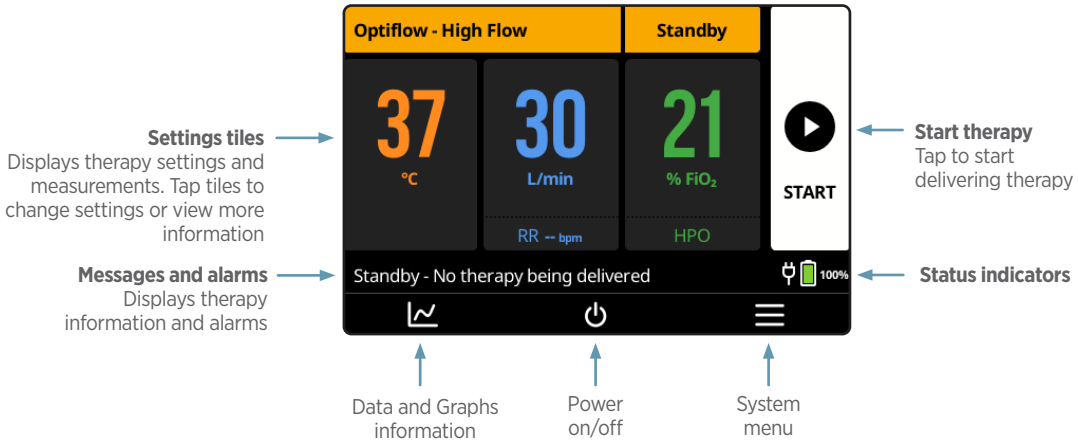


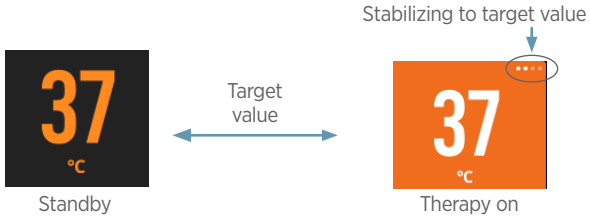
3.3 Navigating the user interface

The Airvo 3 touch screen provides access to therapy and device status, settings and alarms. You interact with the user interface by:

- touching elements on the screen to open setting screens, make selections and change values, and
- swiping up/down to scroll through menus that are only partly displayed.

3.3.1 Home screen





WARNING

To ensure responsiveness keep the Airvo 3 touchscreen clean and dry. Performance may be reduced if the screen is allowed to become wet.

3.3.2 Message bar

The Message bar shows the current state of therapy delivery, confirms settings changes and displays alarms. Example messages are shown in the table below.

Message bar	Description
	Breathing gases are not being delivered to the patient. Tap the Start button to begin therapy.
	Breathing gases are being delivered. Tap the Stop button, then confirm action to return to standby mode.
	Active alarms are displayed on top of other messages. Tap the alarm for details or press to temporarily pause the alarm audio. See section 7 for troubleshooting alarms.

3.3.3 Status indicators

The following icons may be displayed in the Message bar.

Icon	Description
	Audio pause
	The Airvo 3 is being powered from the wall power supply
100%	Status of the internal battery
50%	50% of the battery charge is remaining
50%	Battery is charging and 50% of the charge is remaining
50%	Battery is not charging properly*
	Battery is missing or faulty*
	Battery is due for replacement*
	Touch display is locked to prevent accidental changes
	An Airvo 3 USB device is connected to one of the USB ports

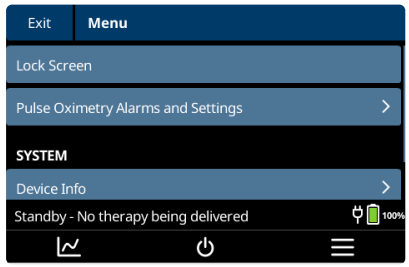
*Check the battery is properly installed. Replace the battery if the problem persists.

3.3.4 Signal light

The signal light flashes when any alarm is active. Its color indicates the highest priority alarm that is active. See section 7 for troubleshooting alarms.

3.3.5 System menu

The system menu provides access to additional settings and information.
Tap ☰ to open the system menu when the Home screen is displayed.



Menu item	Description
Lock Screen	The lock screen can prevent accidental settings changes
Pulse Oximeter Alarms and Settings	Configure the pulse oximetry settings including SpO_2 alarms
Device Info	Displays the version, disinfection, filter and battery information
System Settings	Change advanced Airvo 3 settings, limits and behaviors. Refer to the Airvo 3 Technical Manual for more information

3.3.6 Data and Graphs screen

The Data and Graphs screen displays current and previous measurements and settings for the current patient.

Tap 📈 to open the Data and Graphs screen when the Home screen is displayed.

4. Preparing the Airvo 3

Review the safety information in section 2 before proceeding. Refer to appendices 1 – 3 for a list of consumables and accessories that have been validated for use with the Airvo 3.

4.1 Equipment required

You will need:

- Airvo 3 attached to a mobile pole stand,
- clean and disinfected outlet elbow,
- bag of USP sterile/distilled water for inhalation (or equivalent).

Outlet elbows can be processed in two different ways:

Disinfection kit (900PT600)

For hospitals using the disinfection kit for reprocessing: A clean and disinfected outlet elbow will already be installed in the Airvo 3. Remove the clean storage cover and/or the red disinfection tube before use.

Washer-disinfector

For hospitals using a washer-disinfector for reprocessing: obtain a clean and disinfected outlet elbow, e.g. from your Central Sterile Services Department (CSSD) system.

If supplementary oxygen is prescribed for your patient, you will need either:

- high-pressure oxygen hoses to connect the Airvo 3 to the wall oxygen supply or an oxygen-bottle regulator, or
- low-pressure oxygen tubing to connect the Airvo 3 to a flowmeter.

WARNING

Only use patient consumables and accessories that are compatible with the Airvo 3 (see Appendix 1-3).
Do not modify patient consumables or accessories in any way.

4.1.1 Optiflow high flow therapy

To provide Optiflow high flow therapy, you will need a:

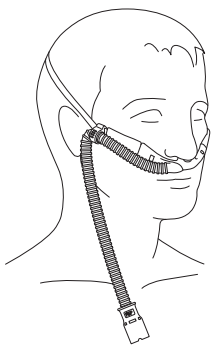
1. Breathing tube and chamber kit.
2. Optiflow patient interface.

Refer to Appendix 1 for a list of compatible consumables.

Note

The Airvo 3 is compatible with delivering specified nebulized medications. See the user instructions for the 900PT562 for more information (including warnings and cautions).

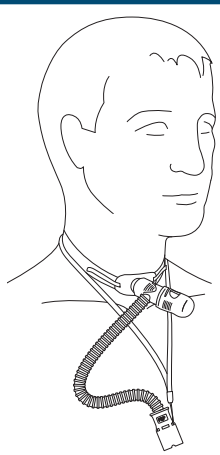
Nasal interface



Optiflow+
Optiflow 3S
Optiflow+ Duet

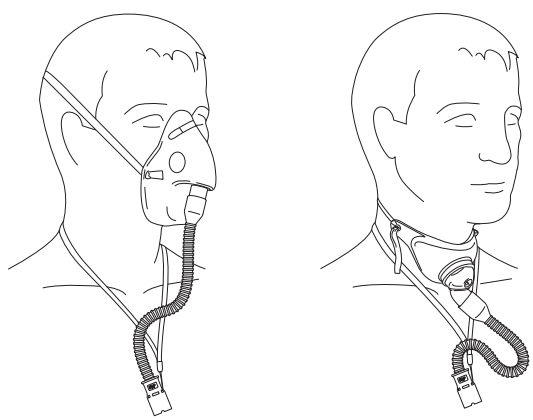
Optiflow Junior 2
Optiflow Junior 2+

Tracheostomy interface



Optiflow+ tracheostomy interface

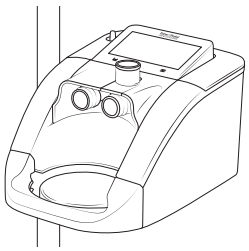
Mask interface adapter



Optiflow+ mask interface adapter

4.2 Airvo 3 setup

Standard aseptic techniques should be followed to minimize contamination when handling the Airvo 3 and accessories.



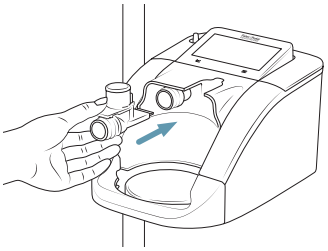
1. Check Airvo 3 height

Check that the Airvo 3 is attached securely to the mobile pole stand and is below the patient's head height.

Position the Airvo 3 so that the power cord connection to the wall power supply is easily accessible and can be disconnected if necessary.

CAUTION

Do not place the Airvo 3 where controls can be changed by the patient.



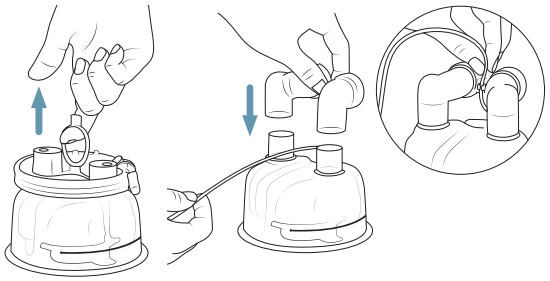
2. Connect the outlet elbow (if applicable)

This step applies if your hospital uses a washer-disinfector to clean and disinfect the outlet elbow. This step does not apply if your hospital uses the disinfection kit (900PT600).

Insert the clean, disinfected outlet elbow into the slot on the top of the Airvo 3.

WARNING

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

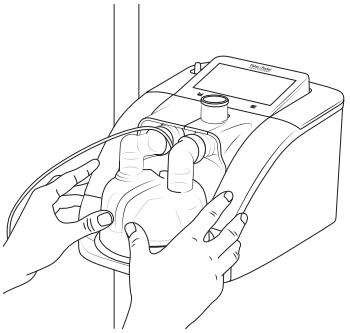


3. Assemble the water chamber

Open the tube and chamber kit and remove the MR290 auto-fill water chamber and chamber adapter.

Remove the blue port caps from the chamber by pulling the tear tab upwards then remove the bracket holding the water supply tube.

Fit the supplied adapter over the two vertical ports on the chamber and push on fully then clip the water supply tube into position.



4. Insert the water chamber

Fit the water chamber to the Airvo 3, sliding the chamber past the finger guard onto the heater-plate. Take care to align the port adapter with the blue ports on the Airvo 3.

Ensure the water chamber is fully inserted by pushing firmly on the front of the chamber until it slides past the finger guard.

To remove the water chamber, grip the port adapter and pull the chamber away from the Airvo 3.

WARNINGS

To avoid burns:

Do not start therapy without the water chamber in place.

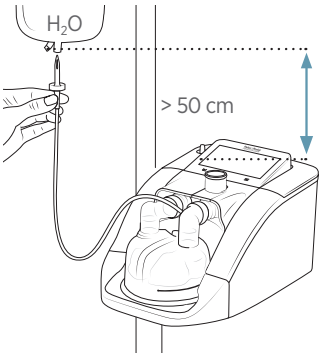
Do not touch the heater-plate, water chamber or chamber base during use.

Exercise caution when removing the chamber.

To avoid electrical shock:

When handling the Airvo 3 with the water chamber in place, avoid tilting the device to prevent any chance of water entering the unit enclosure.

Do not use the MR290 auto-fill water chamber if it has been dropped, allowed to run dry or damaged in any way. This could lead to the chamber overfilling.



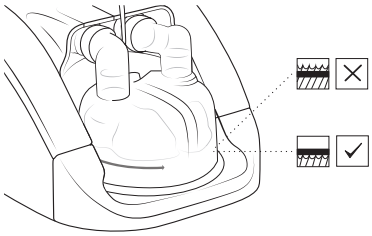
5. Connect the water bag

Attach the sterile water bag to the hanging bracket 50 cm above the Airvo 3. Remove the spike from the chamber bracket and push the bag spike into the fitting at the bottom of the bag.

Open the vent cap on the side of the bag spike.

CAUTION

Only use USP sterile/distilled water, suitable for inhalation, to fill the water chamber. Adding other substances can adversely affect the humidifier and therapy delivered.



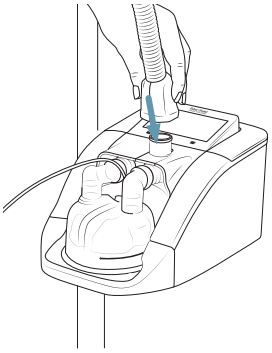
6. Check the water level

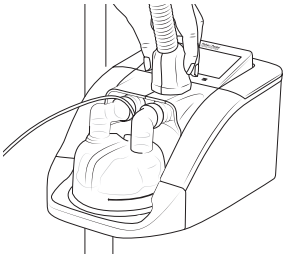
Check that water flows into the chamber and remains below the maximum water-level line.

The chamber will automatically maintain the correct water level until the water bag is empty.

CAUTION

Do not use the MR290 auto-fill chamber if the water level rises above the maximum water-level line. This may lead to water entering the patient's airway.





7. Install the breathing tube

Connect the breathing tube by lining up the pins on top of the Airvo 3, pushing down until you hear a click and the tube locks into place.

To remove the breathing tube, squeeze the sides of the connector and pull up.

WARNING

To avoid burns:

Do not use an insulating sleeve or any similar accessories which are not recommended by Fisher & Paykel Healthcare.

Note

Make sure the outlet elbow is installed in the Airvo 3 before attaching the heated breathing tube.

See step 2 "Connect the outlet elbow (if applicable)" above.

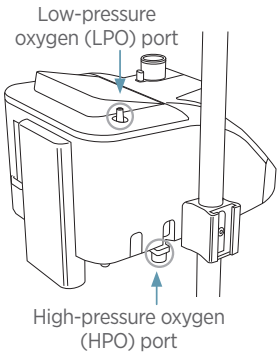
4.3 Supplementary oxygen

The Airvo 3 provides two options for connecting supplementary oxygen:

1. A high-pressure oxygen (HPO) inlet port, and
2. A low-pressure oxygen (LPO) inlet port.

The high-pressure oxygen inlet port is connected to the wall oxygen supply or to the pressure regulator on an oxygen bottle. The ability of the Airvo 3 to provide the target FiO_2 is limited by the line pressure of the high-pressure inlet port (HPO).

If the Airvo 3 is unable to maintain the target FiO_2, the device will generate a "FiO_2 Below Target" alarm. The low-pressure oxygen inlet port is connected to an external flowmeter, typically a rotameter.



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 therapy planned.

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, is 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.

Only use lotions and/or salves that are labeled as oxygen-compatible to avoid the risk of fire and burns.

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.

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

The Airvo 3 is a high-flow device. Connect it only to a pipeline designed to handle its flow rate. Not doing so may disrupt nearby equipment. Ensure proper installation to avoid issues.

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

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

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

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

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

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

CAUTION

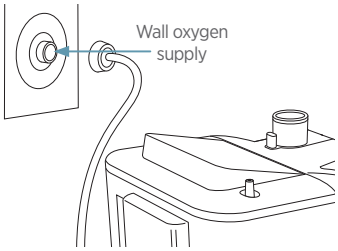
Do not connect an oxygen supply to both the high-pressure oxygen inlet port and the low-pressure oxygen inlet port at the same time. Using the low-pressure inlet at the same time as the high-pressure inlet may cause incorrect oxygen delivery and a FiO_2 Above Target alarm.

Note

The built-in oxygen analyzer uses ultrasonic measurement technology. It does not require in-field calibration.

4.3.1 High-pressure oxygen (HPO) source

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



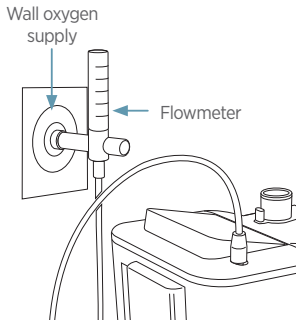
4.3.2 Low-pressure oxygen (LPO) inlet port

When using the LPO port, the amount of oxygen taken in by the Airvo 3 is controlled by an external flowmeter. Connect a tube from the external flowmeter to the LPO port. Make sure that the flowmeter is turned off whenever the Airvo 3 is not delivering therapy.

When using the low-pressure oxygen inlet port, monitor the oxygen concentration displayed on the Home screen. The flowmeter must be adjusted manually to maintain the prescribed oxygen concentration when changing the respiratory gas flow rate.

Clinicians may configure a High FiO_2 alarm to discourage use of high FiO_2 values in particular clinical environments.

The High FiO_2 alarm can be disabled or a threshold between 30% and 95% can be selected when the Airvo 3 is initially set up for your environment (see Oxygen high alarm threshold, Airvo 3 Technical Manual). The alarm threshold is displayed on the Titrate FiO_2 screen, if enabled. Tap the FiO_2 tile to open the Titrate FiO_2 screen.

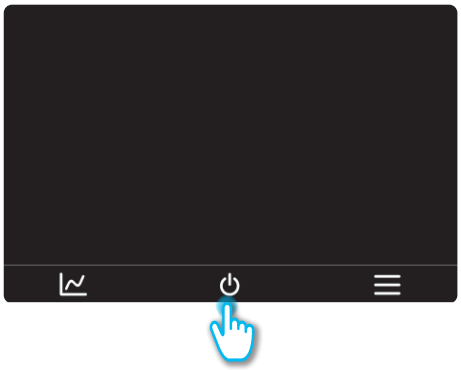


WARNING

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.

5. Using the Airvo 3

5.1 Getting started



Turn on the Airvo 3

Plug the Airvo 3 power cord into the wall power supply.

Lock the wheels of the mobile pole stand to prevent the Airvo 3 from moving.

Turn on the Airvo 3 by holding down the Power on/off button for 2 seconds.

WARNINGS

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

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

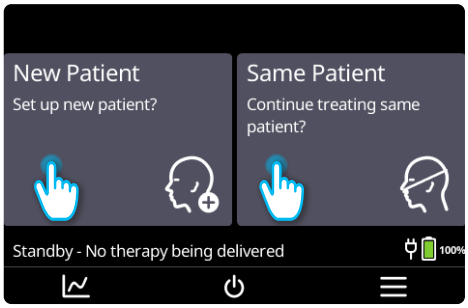
Note

If the Airvo 3 has been unused and disconnected from the wall power supply for some time, the device will not power on without being plugged in.

WARNINGS

The Airvo 3 must be cleaned and disinfected between patients. Refer to section 8 for the steps required to reprocess the Airvo 3 between patients.

Do not exceed the maximum use period for single-patient-use accessories and consumables (see section 8.3 for the schedule for changing accessories).



Review disinfection state

The Airvo 3 will ask you if it will be used on:

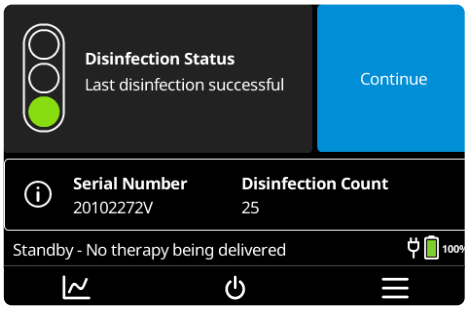
the same patient who last used the device (tap Same Patient)

OR

a new patient (tap New Patient).

For a new patient, check that:

1. The outlet elbow has been cleaned and disinfected.
2. A new tube and chamber have been installed.



Review disinfection state
(if the disinfection method is set to disinfection kit only)

For a new patient, check that:

1. The outlet elbow has been cleaned and disinfected.

The Airvo 3 will indicate the outcome of the last disinfection cycle:

Green: The previous disinfection cycle was completed successfully.

Orange: A successful disinfection cycle has not been performed. Please run a successful disinfection cycle before use on a new patient.

Red: The previous disinfection cycle failed to complete. Please run a successful disinfection cycle before use on a patient.

The number of successful disinfection cycles completed by the Airvo 3 is displayed in the lower left hand corner under 'Disinfection count'.

2. A new tube and chamber have been installed.

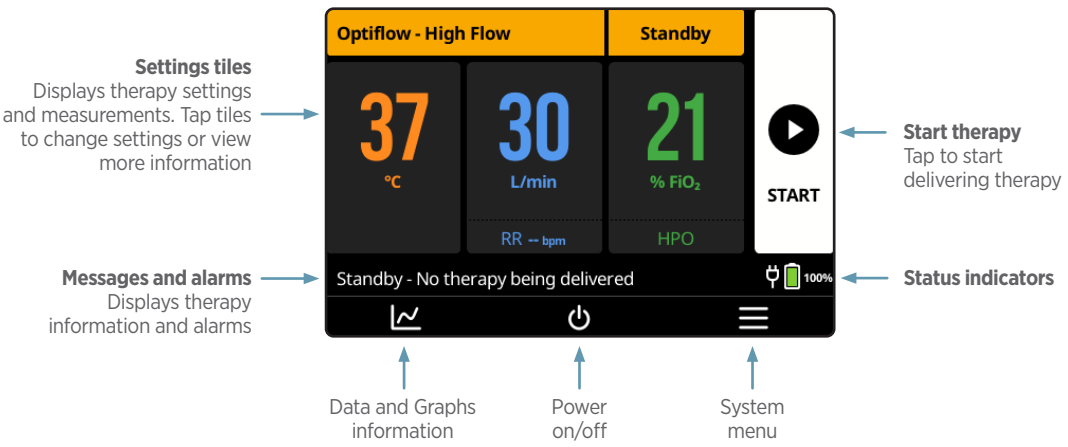
5.2 Optiflow high flow therapy settings

The default range of Optiflow high flow therapy settings is shown below. Some settings may have been limited, or disabled, when the device was initially set up for its intended clinical environment. Refer to the Airvo 3 Technical Manual for details.

Settings are persistent and will retain their previous value when the Airvo 3 is turned on. Selecting New Patient when reviewing the disinfection state (see section 5.1 above) applies the default values for its intended clinical environment to all settings.

Setting	Range	Description
Target humidity	31 – 37 °C	Target humidity for the respiratory gas supplied to the patient interface
Target flow	2 – 70 L/min	Flow rate of the respiratory gas supplied to the patient
FiO_2	21 – 100%	Target oxygen concentration for the breathing gases when an external oxygen supply is connected to the high-pressure oxygen inlet port
Expiratory relief (Target flow tile)	Off, 10%, 20%, 30%	This setting is disabled by default, and only available when the set flow is greater than 25 L/min refer to the Airvo 3 Technical Manual for details. Expiratory relief automatically reduces the respiratory gas flow rate during exhalation and returns it to normal during inhalation. Indicative flow rates are displayed on the settings screen. These may differ depending on the method and strength of the patient's breath

Tiles on the Home screen show current Optiflow high flow therapy settings and measurements. Only tiles relevant to connected accessories are shown.



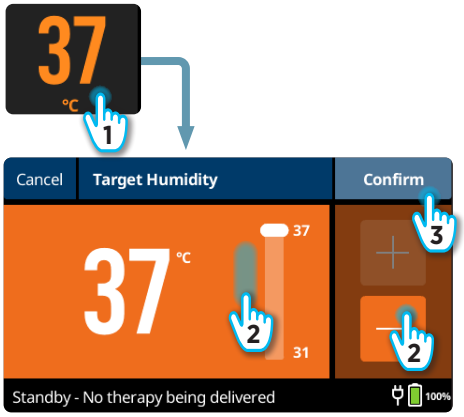
* The FiO_2 tile shows the breathing gas oxygen concentration setting when supplementary oxygen is connected to the high-pressure oxygen (HPO) inlet port and measured oxygen concentration when connected to the low-pressure oxygen (LPO) inlet port. Measured oxygen concentration is not available in standby mode.

† "--" is displayed when a value is not available; values are gray when signal quality is poor.

‡ The SpO_2 tile is displayed automatically when a compatible pulse oximeter is connected.

5.3 Starting Optiflow high flow therapy

Follow the steps below to start delivering Optiflow high flow therapy. Some settings may have been limited, or disabled, when the device was initially set up for your clinical environment. Refer to the Airvo 3 Technical Manual for details.



Adjust target humidity

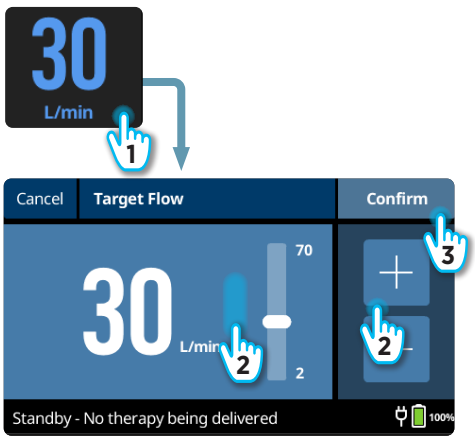
1. Tap the target humidity tile to open the Target Humidity screen.
2. Use the + / – buttons or slider to select a desired target humidity.
3. Tap Confirm to apply the change and return to the Home screen. Tap Cancel to discard any changes.

WARNING

Airvo 3 is classified as a Category 1 humidifier for patients with bypassed airways (tracheostomies) in the following modes only: 37 °C and 10-60 L/min. Do not use any other mode for patients with bypassed airways (tracheostomies).

Note

Patients using face masks may find high temperatures uncomfortable. Consider a target temperature of 31 °C.



Adjust target flow

1. Tap the target flow tile to open the Target Flow screen.
2. Use the + / – buttons or slider to select the desired flow.
3. Tap Confirm to apply the change and return to the Home screen. Tap Cancel to discard any changes.

An appropriate flow rate for your patient should be prescribed following hospital protocols.

Note

Refer to the patient interface user instructions for details.

The table below shows the target flow* settings able to be used with compatible interfaces

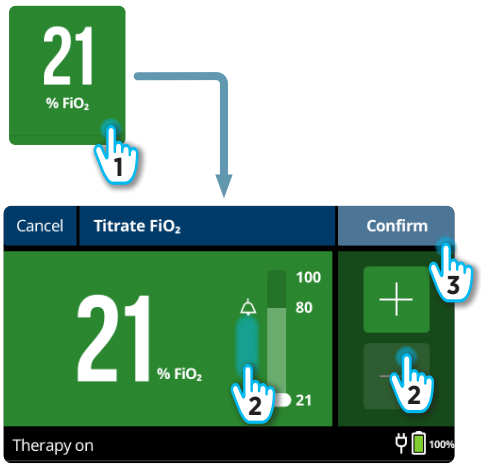
PATIENT INTERFACE		L/min: 2 3 4 5 6 7 8 9 10 15 20 25 ... 50 55 60 65 70
Optiflow Junior 2	OJR414 **M**	2 – 7
	OJR416 **L**	2 – 20
	OJR418 **XL**	2 – 25
	OJR520 **XXL**	10 – 50
Optiflow Interfaces	OPT942/OPT962/OPT1042 **(S)**	10 – 60
	OPT944/OPT964/OPT1044 **(M)**	10 – 70
	OPT946/OPT966/OPT1046 **(L)**	10 – 70
Trache	OPT970	10 – 60
Mask Adapter	OPT980	10 – 60

*The rated flow rate depends on the device, breathing circuit and patient interface. These flow rates are an indication of the achievable range, however, the rated flow rates in the breathing circuit and patient interface user instructions need to also be considered. The smallest range across these instructions is applicable. For any inconsistencies please refer to your FPH representative to confirm the rated flow rate of your system configuration.

Start therapy

Check that the breathing tube is assembled correctly and all connections are secure. Check the alarms are operating properly according to the instructions in section 7.5.

1. Tap the START button to begin therapy. After warming up, the Airvo 3 will play a short melody and display the message “Therapy on”.



Adjust supplementary oxygen (optional)

WARNINGS

Use continuous SpO_2 monitoring on patients who would desaturate significantly if their oxygen supply is disrupted.

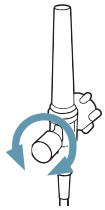
The FiO_2 control limits should be prescribed based on patient condition, hospital policies and clinical judgement for Optiflow nasal high flow therapy.

Oxygen connected to the high-pressure inlet port (HPO)

1. Tap the FiO_2 tile to open the Titrate FiO_2 screen.
2. Use the + / – buttons or slider to select the desired FiO_2.
3. Tap Confirm to apply the change and return to the Home screen. Tap Cancel to discard any changes.

The Airvo 3 will automatically adjust oxygen flow to maintain the selected FiO_2.

Oxygen connected to the low-pressure inlet port (LPO)



The Airvo 3 does not directly control FiO_2.
Use an external flowmeter to adjust FiO_2 to the prescribed level.
The oxygen tile displays measured FiO_2

Note

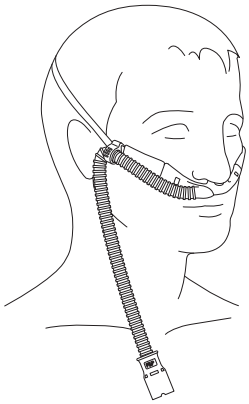
It may take a few minutes for the oxygen measurement to stabilize.

The external flowmeter will need to be readjusted following changes to Airvo 3 target flow.

High FiO_2 alarm

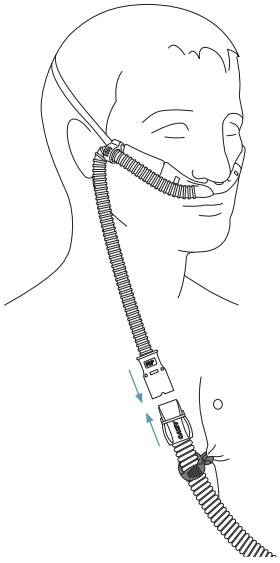
Clinicians may configure a High FiO_2 alarm to discourage the use of high FiO_2 values in particular clinical environments. See the Airvo 3 Technical Manual for setup details.

If the alarm is enabled, the alarm threshold is displayed on the Target FiO_2 screen.



Fit the patient interface

Fit the patient interface to your patient following the user instructions supplied with the interface.
Take care to follow all warnings and cautions.



Connect to the patient interface

Connect the patient interface to the connector at the end of the breathing tube.

The patient may be connected to the heated breathing tube immediately. When therapy initiation is not urgent, it is recommended to wait until the Airvo 3 plays a short melody and displays “Therapy On” in the Message bar.

Attach the breathing tube clip to the patient’s clothing.

CAUTION

Keep the heated breathing tube away from electrical monitoring leads (e.g. EEG, ECG/EKG, EMG, pulse oximeter) to reduce the risk of interference with the signal monitored.

Note

The air may feel warm when your patient starts using the Airvo 3. This is normal. The patient should continue to breathe normally.

WARNINGS

Do not allow the breathing tube to remain in direct contact with the patient’s skin for long periods of time to avoid the risk of burns. The healthcare professional shall assess the conditions for safe contact, such as duration and skin condition.

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, as this can affect the quality of the therapy or injure the patient.

Do not use sealed patient interfaces with Optiflow high flow therapy, to avoid the risk of suffocation or barotrauma.

Ensure a sufficient intended leakage between the breathing system and the patient to allow the patient to exhale.

5.4 During therapy

Monitor the patient following hospital protocols and clinical judgement. Ensure you can hear and respond to any device alarms.

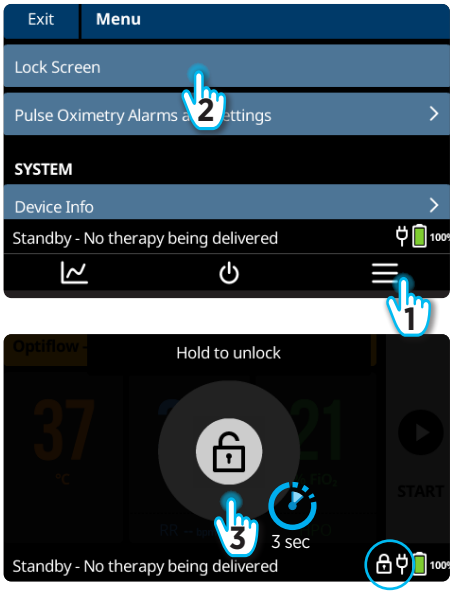
If there is an interruption to the power supply, and the battery is depleted, the Airvo 3 will raise a Power Out alarm, turn off, and not deliver any therapy to the patient. The power out alarm will sound once every 10 seconds for a minimum of 120 seconds, and the signal light above the touch screen will flash. Once power is restored the Airvo 3 can be restarted and will retain the previous therapy and alarm settings.

WARNING

If using the battery as the power source, periodically check the battery status to ensure the battery does not become depleted while therapy is being delivered.

5.4.1 Lock Screen (optional)

The lock screen can prevent accidental settings changes.



To enable the lock screen:

1. Tap ☰ to open the system menu.
2. Select Lock screen from the system menu.

   The symbol 🔒 is shown in the Message bar.

To disable the lock screen:

3. Touch the screen while it is locked, then hold the Unlock icon for three seconds.

5.4.2 Monitor and adjust settings

Adjust settings as needed. Most changes take effect after pressing the confirmation button but it may take a few minutes for some settings, such as target humidity, to respond to changes. Tiles show an animated ellipsis symbol (...) to indicate that a therapy setting has not yet reached its target.

5.4.3 Manage condensation

Drain excess condensate from the breathing tube by:

1. Disconnecting the breathing tube from the patient interface, and

2. Lifting the patient end of the tube so the condensate runs into the water chamber.

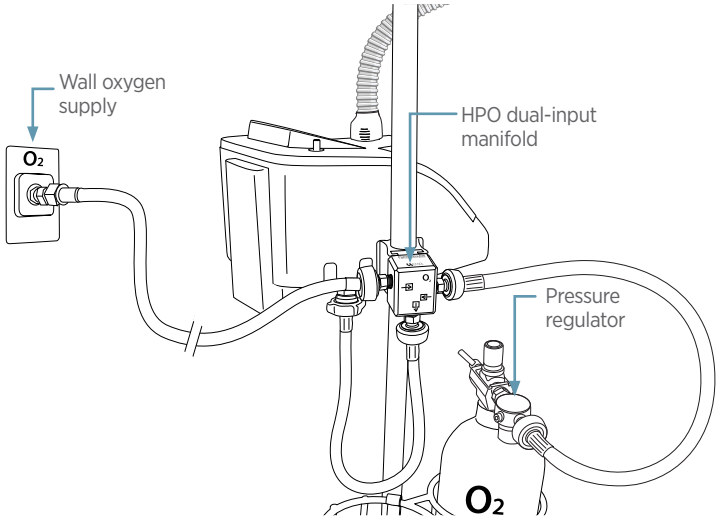
Reduce the flow rate below 30 L/min if the condensate does not run freely into the water chamber. Return the flow rate to the prescribed setting after draining the breathing tube.

Direct cold air away from the heated breathing tube where possible. Air conditioners, fans, open windows and other sources of cold air may increase condensation.

Consider reducing the target humidity if condensation persists.

5.5 Mobility and battery operation

The HPO (High Pressure Oxygen) dual-input manifold and internal rechargeable battery provide continuity during intra-hospital transport. Reduced humidity will be delivered when the Airvo 3 is being powered only by the battery; for more details see Appendix 4.
The HPO dual-input manifold uses the oxygen supply with the highest pressure.

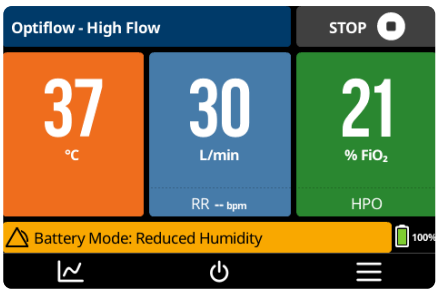


When transporting the Airvo 3 with your patient:

1. Ensure the Airvo 3 is affixed to the mobile pole stand.
2. Adjust therapy settings as necessary for intra-hospital transport.
3. If using supplementary oxygen:
   - Check that the oxygen bottle contains enough oxygen for your journey.
   - Turn on the oxygen-bottle pressure regulator.
   - Disconnect the oxygen hose from the wall supply. Either attach it to a second oxygen bottle for longer trips or hook it over the Airvo mobile pole stand if additional oxygen is not required.

The HPO dual-input manifold will use the oxygen-bottle supply automatically. Check the battery contains enough charge for intra-hospital transport. A new battery will provide therapy for approximately 50 minutes when fully charged. A Low Battery alarm will occur when 35% of the battery is remaining (no changes to the device or therapy). A Critically Low Battery alarm will occur when 20% of the battery is remaining (humidity is turned off, oxygen and flow continue to be delivered). When the battery is fully depleted, the Airvo 3 will interrupt therapy and produce a Power Out alarm.

4. Unplug the Airvo 3 from the wall power supply.
5. The Airvo 3 will display a Battery Mode: Low Humidity alarm.
6. When you reach your destination:
   - Reconnect the Airvo 3 to the wall power supply and the wall oxygen supply.
   - Turn off the oxygen bottle pressure regulator to avoid draining the oxygen bottle and switch to the wall oxygen supply.



If you are not using the HPO dual-input manifold, connect an oxygen bottle (if required) to one of the oxygen inlet ports when transporting your patient. Ensure any oxygen supply connected to the low-pressure oxygen (LPO) inlet port is turned off when the device is in standby mode, not delivering therapy.

WARNINGS

Only transport the Airvo 3 when it is affixed to the mobile pole stand. If the Airvo 3 ever needs to be removed from the mobile pole stand, empty all the water from the water chamber.

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

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

Loss of power will result in loss of therapy. In the event of a Critically Low Battery alarm, promptly connect the Airvo 3 to the wall power supply to avoid loss of therapy due to the battery becoming depleted.

Contact technical personnel to remove the battery from the device if it is not likely to be used for an extended period of time.

5.6 Stopping therapy

When therapy is finished:

1. Remove the patient interface from your patient.
2. If oxygen is provided through the low-pressure oxygen inlet port on the top of the Airvo 3, turn off and disconnect the oxygen supply.

Note

The Airvo 3 will automatically stop oxygen provided through the high-pressure oxygen inlet port. You do not need to disconnect it.

1. Tap the STOP button to end therapy.
2. Review any warnings, then tap Yes to confirm and enter standby mode or No to continue therapy.
3. Turn the Airvo 3 off by holding down the Power button for 2 seconds.
4. Tap Yes to power down the device.

The Airvo 3 must be cleaned and disinfected between patients. Follow the reprocessing instructions if your patient has finished using the device.

WARNINGS

To avoid burns, do not touch the heater-plate or the bottom of the water chamber. The water in the chamber and the heater-plate beneath the chamber become hot during use.

Turn off the low-pressure oxygen source before stopping therapy. The oxygen flow must be turned off when the Airvo 3 is not delivering therapy to ensure oxygen does not build up inside the device.

6. Monitoring data

WARNING

In line with the indications for use of the Airvo 3, the monitoring functionality of the Airvo 3 is intended for use on spontaneously breathing patients and not intended for patients requiring life support. It is the responsibility of the clinician to select the appropriate level of monitoring for their patient and to be prepared to deal with alarms and equipment malfunction. Additional, independent monitoring equipment may be necessary.

The Airvo 3 is not designed to collect identifiable information about end-users. To function effectively, Airvo 3 will collect and store limited therapy data. The therapy data will be securely stored on the Airvo 3 device.

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

For more information about what type data is involved in these activities, refer to the Airvo 3 Technical Manual.

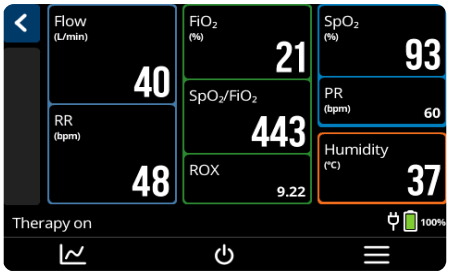
Please refer to the T&Cs for your data protection and privacy obligations. Alternatively, refer to our Global Privacy Statement on our website for more on how we handle personal information.

6.1 Data and Graphs

The Airvo 3 records up to 24 hours of data for review on the Data and Graphs screen, accessible by tapping the Data and Graphs information button from the Home screen. Data and Graphs data will be lost if power from the battery and from the wall power supply is lost. Refer to the Airvo 3 Technical Manual for detailed information on data handling.

6.2 Patient data

The values displayed in the patient data screen are described below. Measurements that are not available are shown as "--". Measurements may not be available when the Airvo 3 is in standby mode or the device has not collected enough data for a reliable measurement.

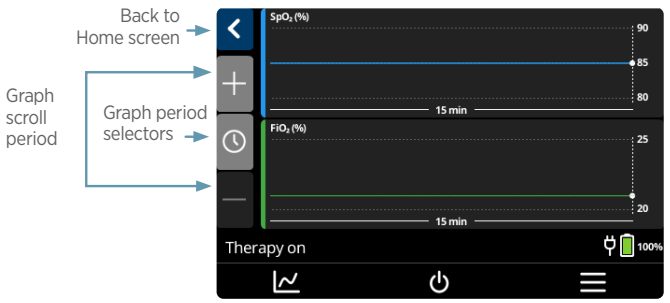


Label	Unit	Description
Flow	L/min	The current flow rate of breathing gases supplied to the patient
RR	BPM	The patient's respiratory rate (breaths per minute), averaged over the last 90 seconds
Humidity	°C	The current humidity of the breathing gases supplied to the patient interface
FiO_2	%	The current fraction of oxygen in the breathing gases supplied to the patient
SpO_2/FiO_2*		Ratio of SpO_2 and FiO_2
ROX*		SpO_2 divided by FiO_2 and respiratory rate
SpO_2*	%	Peripheral blood oxygen saturation measured by pulse oximeter
PR*	BPM	Pulse rate measured by pulse oximeter (beats per minute)

6.3 Long term graphs

Airvo 3 Data and Graphs show measurements plotted against time for up to 24 hours. New measurements are added to the right side of the graph. Prior data will scroll to the left as new measurements are added. Gaps will appear in the plotted data if therapy is stopped or measurements are missing due to poor signal quality.

The graphs available are described in the table below.



Label	Unit	Description
Target flow	L/min	The target flow rate of breathing gases supplied to the patient
RR	BPM	The patient's respiratory rate (breaths per minute), averaged over the last 90 seconds
FiO_2	%	The fraction of oxygen in breathing gases supplied to the patient
SpO_2/FiO_2*		Ratio of SpO_2 and FiO_2
ROX*		SpO_2 divided by FiO_2 and respiratory rate
SpO_2*	%	Peripheral blood oxygen saturation measured by pulse oximeter
PR*	BPM	Pulse rate measured by pulse oximeter (beats per minute)

*Only available if connected to a pulse oximeter

7. Troubleshooting

This section describes common causes, and solutions to, problems and alarms that you may encounter while using the Airvo 3. The Airvo 3 Technical Manual contains additional information that may be helpful in resolving more advanced problems.

7.1 Alarms

The Airvo 3 has visual and auditory alarms to notify users about interruptions to a patient's treatment. These alarms are generated by an intelligent alarm system, which processes information from sensors and target settings of the device and compares this information with pre-programmed limits. Changes to alarm settings will be preserved during or after any power loss.

The signal light flashes and troubleshooting information is displayed on the Airvo 3 touch screen when any alarm is active. The color of the signal light indicates the highest-priority active alarm condition.

7.2 Alarm priority

Alarms are grouped by urgency and severity into three priority levels: low, medium, high. When multiple alarms are active, the audible alert, signal light and Message bar background color will signal the highest-priority alarm active.

- A response is needed for all alarms.
- A prompt response is required for all medium-priority alarms.
- An immediate response is required for all high-priority alarms.

Priority	Message bar, signal light color	Audible alert
Low	Solid yellow	High then low-pitched beep
Medium	Flashing yellow	3 beeps every 9 seconds
High	Flashing red	10 beeps every 5 seconds

WARNING

Audible alarms may not be heard if the alarm volume is set lower than ambient noise. Missed alarms may lead to patient injury. Refer to the Airvo 3 Technical Manual to review and set the alarm volume.

7.3 Auditory information signals

The informative sounds made by the Airvo 3 are:

Melody	Meaning
Ascending sequence of 5 tones	The breathing gas has warmed up
Single tone	A touch on the display has been registered
Single low then high tone	All active alarms have been resolved
High note followed by 2 (identical) lower notes, repeated every 10 seconds	The Power Out alarm is active. The wall power supply has been disconnected or turned off and the battery is depleted
Descending sequence of 3 tones	The device has completed the power off process
Sequence of 3 tones with high, low then middle pitch	The device has been turned on

7.4 Viewing alarm details

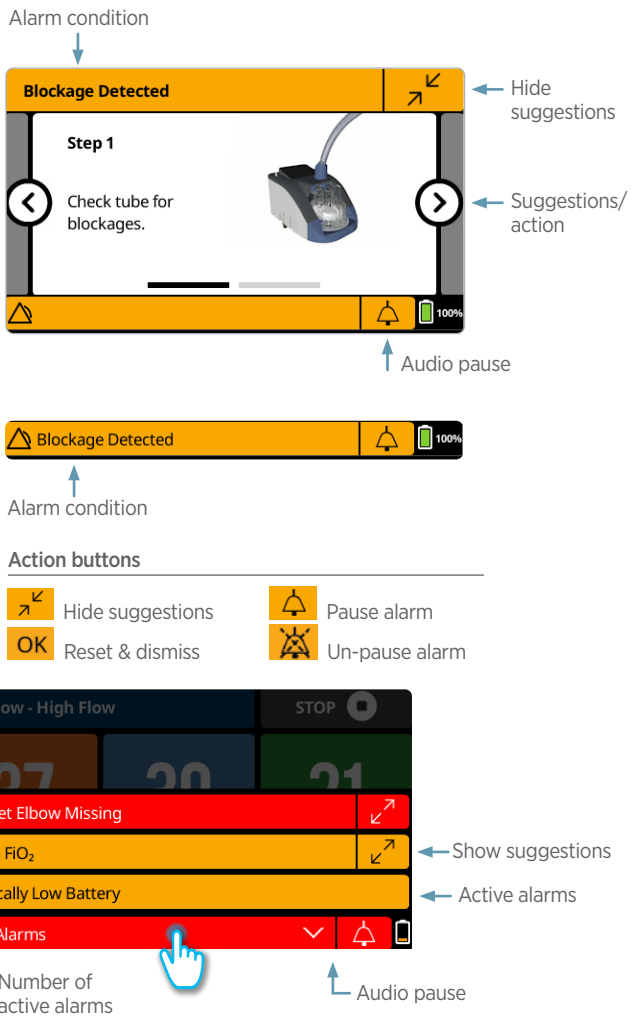
Alarms are displayed with suggestions and action buttons for managing the alarm information:

- Tap the Audio Pause button to silence the alarm for 120 seconds. The Audio Pause button will change to when audible alarms are silenced.
- Use 〈 〉 to scroll through multiple suggestions. Some alarms have only one suggested resolution.
- Tap Hide suggestions to collapse the alarm information to the Message bar. Restore suggestions by tapping the alarm condition on the Message bar.

The alarm condition and action button are displayed on the Message bar when alarm information is collapsed.

The Message bar cycles through each alarm condition when multiple alarms are active. Tapping the Message bar displays a list of active alarm conditions, from highest priority to lowest priority and they are ordered from when they occurred.

Alarm signals always indicate the highest-priority active alarm condition.



7.5 Checking the alarm system

To test the alarm system:

1. In standby mode, disconnect the breathing tube then press “Start”.
2. Verify that the “Check tube” visual alarm appears on screen.
3. Verify that the signal light flashes yellow.
4. Verify that the auditory alarm signal can be heard.

Do not use the Airvo 3 if it fails this test. Contact your Fisher & Paykel Healthcare representative.

7.6 Airvo 3 alarms

The intelligent alarm system of the Airvo 3 prioritizes the most relevant alarms to the user. As part of this, if there are high or medium priority alarms on-screen then any low priority alarms are not displayed until the higher priority alarms are resolved.

The table below shows all the alarms you may encounter while using the Airvo 3 as well as common causes, resolutions, and any delays inherent in determining alarm conditions. The design of the alarm system is based on an intended operator’s position of 2 meters from the device.

Alarm condition	Priority	Delay	Meaning
Faults			
Device Fault [Fault X.X.X]	High	-	A technical fault has occurred, and the patient may need immediate attention. Restart the device to clear the fault condition. If the issue persists, contact your service representative
Device Fault [Fault X.X.X]	Med.	-	A technical fault has occurred, and the patient may need prompt attention. Restart the device to clear the fault condition. If the issue persists, contact your service representative.
Power system alarms			
Power Out	High	≤ 5 s	The Airvo 3 has been disconnected from the wall power supply and the internal battery is depleted. The auditory alarm will sound once every 10 seconds for 120 seconds and the signal light above the touch screen will flash. The touch screen is off during the Power Out alarm. The Airvo 3 will shut down after signaling the Power Out alarm but will restart automatically if power is restored before it shuts down.

Alarm condition	Priority	Delay	Meaning
Unsupported Battery	Med.	≤ 5 s	The device is running off the battery and either an incorrect battery type is connected or communications with the battery could not be established. Charging is disabled. During battery use the behaviour is the same as the Critically Low Battery alarm.
Critically Low Battery	Med.	≤ 5 s	The Airvo 3 battery level is critically low and indicates at least 5 minutes left for complete loss of battery power. The humidification is turned-off to maintain operation of the blower and oxygen supply. Connect to wall power supply to continue therapy as normal.
Low Battery	Low	≤ 5 s	The Airvo 3 battery level is low and indicates at least 10 minutes left for complete loss of battery power. Connect to wall power supply to continue therapy as normal.
Battery not functional	Low	≤ 5 s	The Airvo 3 has detected a battery failure. Replace the battery.
Battery Mode: Reduced Humidity	Low	≤ 5 s	The Airvo 3 has been disconnected from the wall power supply and the device is now running off the battery. The delivered humidity may be reduced.
Battery Charger Fault	Low	≤ 30 s	The battery charger is not functioning correctly and has been disabled. Restart the device to resolve the fault. If the issue persists, contact your service representative.
Therapy alarms - tube			
Outlet Elbow Missing	High	≤ 15 s	The Airvo 3 outlet elbow has been removed from the device during therapy. Check that the outlet elbow is fully inserted into the Airvo 3. If the issue persists, replace the outlet elbow.
Check Tube	Med.	≤ 5 s	The Airvo 3 cannot detect the heated breathing tube. Check that the heated breathing tube is not damaged and is plugged in correctly. Replace the heated breathing tube if the problem persists.
Wrong Tube	Med.	≤ 5 s	The heated breathing tube is not suitable for the selected therapy, or is damaged. Connect a suitable heated breathing tube. Replace the breathing tube if the problem persists.
Outlet Elbow Fault	Med.	≤ 5 s	A fault has been detected with the outlet elbow. Check that the outlet elbow is fully inserted into the Airvo 3. If the issue persists, replace the outlet elbow.
Outlet Elbow Too Warm	Med.	≤ 5 s	The outlet elbow is too warm to run start up checks. Wait for the outlet elbow to cool down. If the issue persists, replace the outlet elbow.
Therapy alarms – high flow			
Chamber Leak Detected	Med.	≤ 30 s	The water chamber has been removed. Ensure the water chamber is correctly inserted into the Airvo 3. If the issue persists, contact your service representative.
Leak Detected	Med.	≤ 30 s	When used with the Optiflow Junior 2 patient interfaces, the Airvo 3 has detected a reduction in the resistance to flow of the breathing circuit. Check: • the water chamber has not been removed and is properly installed, • the heated breathing tube is plugged in correctly or is not damaged, • the patient interface has not been disconnected, and • the air filter is fitted correctly. If the issue persists, replace the consumables.
Blockage Detected	Med.	≤ 15 s[†]	The Airvo 3 has detected a blockage. Check: • for blockages in the heated breathing tube, patient interface and inlet air filter, • the patient interface is the correct size for the patient, and • the target flow rate is within the rated range of the interface. If the issue persists, replace the consumables.
Flow Below Target	Med.	≤ 2 min	The Airvo 3 flow rate is lower than the target flow rate. Check: • for blockages in the heated breathing tube, patient interface and inlet air filter, • the patient interface is the correct size for the patient, and • the target flow rate is within the rated range of the interface. If the issue persists, replace the consumables.

Alarm condition	Priority	Delay	Meaning
Flow Above Target	Low	≤ 2 min	The Airvo 3 flow rate is higher than the target flow rate. Check: • for leaks in the water chamber, heated breathing tube and patient interface, • the inlet air filter is inserted correctly, and • the target flow rate is within the rated range of the interface. If the issue persists, replace the consumables.
Therapy alarms – other			
Target Flow Too High	Med.	≤ 60 s†	The Airvo 3 has exceeded an internal temperature limit. Continued operation in the current configuration may result in a device fault and reduced therapy. Check: • for blockages in the heated breathing tube, patient interface and inlet air filter, • the patient interface is the correct size for the patient, • the target flow rate is within the rated range of the interface, and • the ambient temperature is within the rated range of the device. This alarm will resolve when the internal temperature is within the expected range.
Check Water	Med.	≤ 30 min	The water chamber has run out of water. Replace the water bag to resume normal operation. Ensure that the water chamber and/or water bag are not allowed to run out of water to ensure continuous humidification of the breathing gases.
Humidity Below Target	Med.	≤ 30 min†	The Airvo 3 cannot reach the target humidity. Check the water chamber contains water and the chamber base is not damaged. Consider reducing the target humidity or flow rate, if appropriate. If the issue persists, replace the water chamber.
Check Operating Conditions	Low	≤ 1 min†	The Airvo 3 has detected ambient conditions that are not suitable. Do not use the Airvo 3 when the ambient temperature is below 18 °C or above 28 °C. Move the device to a suitable environment.
Oxygen alarms			
No O_2 Pressure at HPO Port	Med.	≤ 5 s	There is no oxygen being supplied to the high-pressure (HPO) inlet port during therapy. Check that the oxygen supply is working. If using an oxygen bottle, check the bottle is not empty. If switching to the low-pressure (LPO) inlet port or stopping oxygen delivery, set the FiO_2 target to 21 %.
FiO_2 Below 25%	Med.	≤ 30 s†	The oxygen being supplied to the LPO port has fallen below 25% during therapy. Check if the oxygen supply has been disconnected.
FiO_2 Below Target	Med.	≤ 2 min	The oxygen concentration being delivered is lower than the FiO_2 target setting. Check the oxygen supply is properly connected to the HPO inlet port and there are no leaks at any oxygen hose connections. Make sure the number of connected devices does not exceed the capacity of the oxygen supply. Consider using the LPO connection if the oxygen supply has insufficient capacity.
FiO_2 Above Target	Med.	≤ 2 min	The oxygen concentration being delivered is higher than the FiO_2 target setting. Check an oxygen supply is not connected to the low-pressure oxygen inlet port. Only one oxygen source should be used at a time. Check the oxygen supply is properly connected to the high-pressure oxygen inlet port and that there are no leaks at the oxygen hose connections.
High FiO_2 (LPO)	Med.	≤ 20 s	The FiO_2 supplied by the LPO port is above the selected High Oxygen Alarm threshold for its intended clinical environment (range 30-95% or Off, default: Off, see Airvo 3 Technical Manual). Check FiO_2 is appropriate for the patient's condition. Reduce FiO_2 to the normal range when it is appropriate to do so.
Unexpected O_2	Med.	≤ 15 min†	Oxygen is being supplied to the Airvo 3 while in standby. Check all oxygen supplies are turned off and disconnected. If the issue persists, contact your service representative.
High FiO_2 (HPO)	Med.	≤ 5 s	The FiO_2 target is above the selected High Oxygen Alarm threshold for its intended clinical environment (range 30-95% or Off, default: Off, see Airvo 3 Technical Manual). Check FiO_2 is appropriate for the patient's condition. Reduce FiO_2 to the normal range when it is appropriate to do so.

Alarm condition	Priority	Delay	Meaning
Pulse oximetry alarms			
Pulse Ox Communication Failure	Med.	≤ 10 s	The Airvo 3 is unable to communicate with the pulse oximeter. Check that the USB connector cable, sensor adapter cable and sensor cables are all properly connected. Replace the sensor cable, adapter cable then USB connector cable if the problem persists.
Pulse Ox Not Recognized	Med.	≤ 10 s	The selected pulse oximeter has not been recognised. Please remove or change oximeter.
Pulse Ox Disconnected	Med.	≤ 5 s	The pulse oximetry USB connector cable has become disconnected. Reconnect pulse oximetry USB connector cable.
No Pulse Ox Sensor Connected	Med.	≤ 5 s*	A pulse oximetry sensor cable was not detected or is inoperable. Check that the sensor cable is properly connected to the USB connector cable or replace the sensor cable if necessary.
Pulse Ox Sensor Off Patient	Med.	≤ 5 s*	The pulse oximeter is no longer receiving SpO_2 measurements from the patient. Check that the sensor is properly attached to a suitable measurement site on the patient.
No SpO_2 Reading	Med.	≤ 5 s* (Masimo and Nellcor) ≤ 16 s* (Nonin)	The pulse oximeter is not sending valid SpO_2 measurements. Check the sensor, cable and USB interface. Try replacing each component in turn until the problem is resolved.
No Pulse Rate Reading	Med.	≤ 5 s* (Masimo and Nellcor) ≤ 16 s* (Nonin)	The pulse oximeter is not sending valid Pulse Rate measurements. Check the sensor, cable and USB interface. Try replacing each component in turn until the problem is resolved.
Check Pulse Ox Cable/Sensor	Med.	≤ 5 s*	**Masimo only.** The pulse oximetry USB connector cable and/or the pulse oximetry sensor cable is not functioning correctly. Please remove and reconnect the accessory and if the problem persists replace the accessory.
Incompatible Pulse Ox Cable	Low	≤ 5 s*	**Masimo only.** The pulse oximetry USB connector cable is incompatible. Please disconnect it from the device.
Incompatible Pulse Ox Sensor	Low	≤ 5 s*	**Masimo only.** The pulse oximetry sensor cable is incompatible. Please disconnect it from the device.
Pulse Ox Cable Near Expiration	Low	≤ 5 s*	**Masimo only.** The pulse oximetry USB connector cable is nearing expiration.
Pulse Ox Sensor Near Expiration	Low	≤ 5 s*	**Masimo only.** The pulse oximetry sensor cable is nearing expiration.
Pulse Timeout	High	≤ 5 s*	**Nellcor only**. The pulse oximetry USB connector cable is reporting the loss of a patients pulse signal. Check the condition of the patient.
SpO_2 Measurement Delayed	Low	≤ 5 s*	**Nellcor only.** The pulse oximeter is indicating that its dynamic averaging time has exceeded 25 seconds for the SpO_2 measurement.
Pulse Rate Measurement Delayed	Low	≤ 5 s*	**Nellcor only.** The pulse oximeter is indicating that its dynamic averaging time has exceeded 25 seconds for the pulse rate measurement.
Pulse Ox Board Failure	Med.	≤ 5 s*	**Masimo and Nellcor only**. The pulse oximetry USB connector cable has failed. Please remove and reconnect the cable and if the problem persists replace the cable.
Check Pulse Ox Sensor	Med.	≤ 5 s*	**Masimo and Nellcor only.** The pulse oximetry sensor cable is not functioning correctly. Please remove and reconnect the cable and if the problem persists replace the cable.
Replace Pulse Ox Cable	Med.	≤ 5 s*	**Masimo and Nellcor only.** There is a fault with the pulse oximetry USB connector cable and it needs replacement.

Alarm condition	Priority	Delay	Meaning
Replace Pulse Ox Sensor	Med.	≤ 5 s*	**Masimo and Nellcor only.** There is a fault with the pulse oximetry sensor cable and it needs replacement.
Pulse oximetry physiological alarms			
Low SpO_2	High	User Set†	Check your patient. The SpO_2 measurement has decreased below the Low SpO_2 alarm threshold. Check that the alarm setting is appropriate for your patient (Range: 20-98%, default 85%, see Airvo 3 Technical Manual).
High SpO_2	Med.	User Set†	Check your patient. The SpO_2 measurement has exceeded the High SpO_2 alarm threshold. Check that the alarm setting is appropriate for your patient (Range: 21-99% or Off, default Off, see Airvo 3 Technical Manual).
Disinfection alarms			
Disinfection Failed to Hold Temperature	Med.	≤ 3 min	The Airvo 3 cannot heat up to the required disinfection temperature. Check: • the disinfection tube blue connector is connected to the top of the outlet elbow, • the disinfection tube red end is connected to the left hand chamber port, • the disinfection filter is connected to the right hand chamber port, Then restart the device. If the problem is not resolved, replace the disinfection tube and outlet elbow in turn. If the issue persists, contact your service representative.
Over Temperature Detected	Med	≤ 5 s	The Airvo 3 detected higher than expected temperatures during the disinfection cycle. Check: • the disinfection tube blue connector is connected to the top of the outlet elbow, • the disinfection tube red end is connected to the left hand chamber port, • the disinfection filter is connected to the right hand chamber port, Then restart the device. If the problem is not resolved, replace the disinfection tube and outlet elbow in turn. If the issue persists, contact your service representative.
Check Tube	Med.	≤ 5 s	The Airvo 3 cannot detect the disinfection tube. Check that the disinfection tube is not damaged and is plugged in correctly, then restart the device. If the problem is not resolved, replace the disinfection tube and outlet elbow in turn. If the issue persists, contact your service representative.
Leak Detected	Med.	≤ 35 s	The Airvo 3 has detected a leak in the disinfection circuit. Check: • The disinfection tube blue connector is connected to the top of the outlet elbow, • The disinfection tube red end is connected to the left hand chamber port, • The disinfection filter is connected to the right hand chamber port, Then restart the device. If the problem is not resolved, replace the disinfection tube and outlet elbow in turn. If the issue persists, contact your service representative.
Blockage Detected	Med	≤ 10 s	The Airvo 3 has detected a blockage. Check that the disinfection tube is not blocked and that the disinfection filter is not wet, then restart the device. If the problem is not resolved, replace the disinfection tube and outlet elbow in turn. If the issue persists, contact your service representative.
Check Operating Conditions	Med.	≤ 1 min†	The Airvo 3 has detected ambient conditions that are not suitable. Do not use the Airvo 3 when the ambient temperature is below 18 °C or above 28 °C. Move the device to a suitable environment, then restart the device. If the issue persists, contact your service representative.
Wall Power Disconnected	Med.	≤ 5 s	The power cable has been removed and device is unable to perform a disinfection cycle. Connect device to wall power, then restart the device. If the issue persists, contact your service representative.
Unexpected O_2	Med.	≤ 1 min	Oxygen is being supplied to the Airvo 3 while in disinfection mode. Check all oxygen supplies are turned off and disconnected. If the issue persists, contact your service representative.

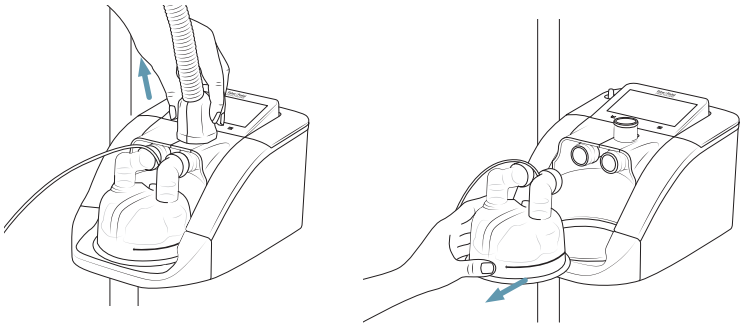
* The quoted delays account for the Airvo 3 alarm generation delay only. Quoted delays do not account for third party pulse oximeter module algorithm delay which will vary.

† An additional alarm signal generation delay of 2 s applies

8. Reprocessing

Standard aseptic techniques should be followed to minimize contamination when handling the Airvo 3 and accessories. The patient interface, heated breathing tube, water chamber and outlet elbow may become contaminated during use. As soon as possible after using the Airvo 3:

1. Remove the single-use accessories from the Airvo 3 and dispose of them in accordance with local laws, regulations and hospital protocols for disposing of contaminated products.
   - Squeeze the sides of the breathing tube connector and lift to remove it from the Airvo 3.
   - Grip the port adapter and pull the water chamber away from the Airvo 3 to remove it.



2. Reprocess the Airvo 3 device exterior by following the instructions in section 8.1.
3. Clean and high-level disinfect the Outlet Elbow by following the instructions in section 8.2.
4. Replace accessories within the maximum use period shown in section 8.3 (schedule for changing accessories).
5. Clean and disinfect pulse oximetry accessories (including reusable sensors) in accordance with the manufacturer's instructions.

WARNINGS

Do not clean and/or disinfect the Airvo 3 while it is being used by a patient.

Do not submerge the Airvo 3 or accessories in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

8.1 Airvo 3 device exterior reprocessing

8.1.1 Device exterior cleaning

Equipment

- Mild detergent and clean water
- Clean lint-free cloths
- Protective gloves

Instructions

1. Mix a solution of warm clean water and mild detergent (refer to the detergent manufacturer's instructions for use).
2. Dampen a clean cloth with the cleaning solution.
3. Thoroughly wipe all outside surfaces of the device (including the Outlet Elbow) for at least one minute to remove any visible soil. Use the corner/edge of the cloth to clean all crevices of the device.
4. Dampen a clean cloth with clean water.
5. Thoroughly wipe all outside surfaces of the device with the damp cloth to rinse and remove any detergent residue.
6. Thoroughly wipe all outside surfaces of the device with a dry cloth until it is visibly dry.
7. Allow to air dry until completely dry.

8.1.2 Device exterior disinfection

Perform disinfection only after all cleaning steps are complete

Equipment

- Disinfectant wipes
- Clean lint-free cloths
- Clean water
- Protective gloves

Instructions

1. Use pre-soaked disinfectant wipes, thoroughly wipe all outside surfaces of the device (including the Outlet Elbow).
2. Ensure that these surfaces remain visibly wet as directed by the manufacturer of the disinfectant wipes. Use additional wipes as needed to ensure that these surfaces remain wet for the required length of time.
3. Dampen a clean cloth with clean water.
4. Thoroughly wipe all outside surfaces of the device with the damp cloth to remove any disinfectant residue.
5. Thoroughly wipe all outside surfaces of the device with a dry cloth until it is visibly dry.
6. Allow to air dry until completely dry.

WARNINGS

Other cleaning agents may be used if they are: non-abrasive, non-toxic, and non-corrosive. Do not use any cleaning agents that are not compatible with polycarbonate plastic.

Cleaning agents that are not suitable for use with the Airvo 3 include: ammonia, ammonium hydroxide, caustic soda, iodine, methanol, methylated spirits, turpentine, and alkaline bleaches such as sodium hypochlorite. The use of any of these products will damage the Airvo 3.

Turn off and disconnect the Airvo 3 from the wall power supply before cleaning to reduce the risk of electric shock.

Do not submerge the device in liquid of any kind.

Do not spray liquid directly onto the device.

Do not use rinse aids as these may cause damage to the outlet elbow.

These instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing achieves the desired results, by using the correct equipment, materials, and personnel in the processing facility. This requires routine monitoring of the process.

8.2 Outlet elbow reprocessing

The Outlet Elbow requires cleaning and high-level disinfection. The Outlet Elbow can be reprocessed in two different ways.

8.2.1 Outlet elbow reprocessing via the Disinfection Kit (900PT600)

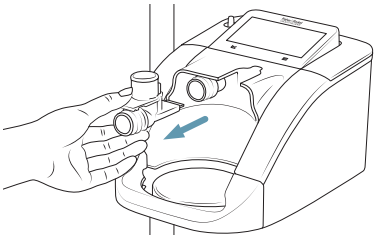
Disinfection Kit 900PT600 (see instructions in 900PT600).

8.2.2 Outlet elbow reprocessing via washer disinfector

The outlet elbow can be removed from the Airvo 3 for reprocessing by your central sterile services or reprocessing department. Reprocessing the outlet elbow must be performed in a washer-disinfector that complies with and is maintained, checked and validated to ANSI/AAMI ST15883-1:2009 (USA) and ISO 15883-1:2006 (outside USA).

Disassembly

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



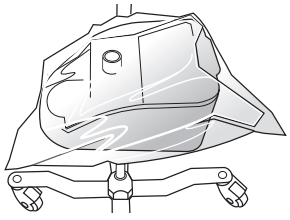
Transportation

Follow hospital infection control protocols to package the outlet elbow for transport. Protect the outlet elbow from mechanical damage during transport.

Using the storage cover

It is important that the Airvo 3 is stored properly after reprocessing. Store the Airvo 3 in a clean, dry and dust-free location that is suitable for medical devices.
Cover the Airvo 3 with the storage cover so that it remains clean during storage:

- Wrap the Airvo 3 in a storage cover (900PT603) so that the identification label on the cover sits prominently above the display of the Airvo 3.
- Seal the cover with the adhesive tabs on the storage cover.



Cleaning and disinfection

Washer-disinfector supplies required for reprocessing of the Airvo 3 outlet elbow are:

- Mildly alkaline cleaning agent such as neodisher® MediClean forte (0.2% v/v)

Place the outlet elbow in a washer-disinfector and orient the outlet elbow such that washing fluid can contact all internal surfaces and allow for draining. Run a cleaning and thermal high-level disinfection cycle:

- Pre-cleaning: Cold rinse for at least 1 minute
- Cleaning: Wash at 55 °C for at least 5 minutes with a mildly alkaline cleaning agent as per manufacturer's instructions (e.g. neodisher® MediClean forte, 0.2 % v/v)
- Neutralisation: Cold rinse for at least 1 minute
- Rinsing: Cold rinse for at least 1 minute
- Thermal disinfection: 90 °C for 5 minutes
- Drying: 90 °C for 25 minutes

Note

Do not exceed the maximum use period for the outlet elbow.

Follow the manufacturer's instructions and warnings for all cleaning products.

Visual inspection

Visually inspect the outlet elbow for mechanical damage or discoloration of the chamber seal. If the seal or elbow appear damaged or discolored, replace the outlet elbow.

WARNING

Do not use the outlet elbow if the seal or elbow appear damaged or discolored. A damaged outlet elbow may affect therapy delivery.

Storage and transport

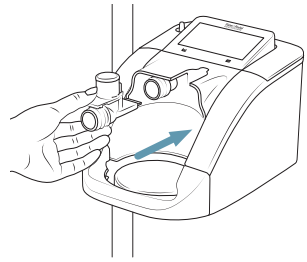
It is important that the outlet elbow is stored properly after reprocessing. Store the outlet elbow in a clean, sealed plastic bag labeled with the disinfection process details. Follow your hospital protocol for storage of high-level disinfected devices. Protect the outlet elbow from mechanical damage during transport. Store the outlet elbow in a clean, dry and dust-free location that is suitable for medical devices. The outlet elbow can alternatively be inserted back into the Airvo 3 then covered with the storage cover until the next use.

Reassembly

When setting up the Airvo 3 for the next use follow the reassembly steps below. If reassembly occurs prior to the next use, cover the Airvo 3 with the outlet elbow assembled with the clean storage cover.

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

Push firmly on the front of the elbow until the elbow locks into place.



Note

Make sure the outlet elbow is installed in the Airvo 3 before attaching the heated breathing tube.

8.3 Schedule for changing accessories

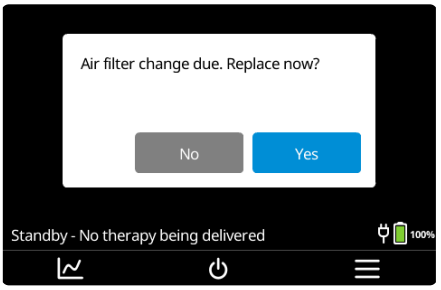
The Airvo 3 accessories must be changed according to the schedule below. All single-patient-use accessories must be disposed of after the patient's therapy to prevent cross-contamination. Replace accessories within the period shown below, or immediately if they are damaged or discolored.

Accessory	Maximum use
Optiflow Junior interfaces	1 week, or 1 patient (whichever comes first)
Optiflow+ / Optiflow+ Duet interfaces **Optiflow 3S interfaces** **All AirSpiral tube and chamber kits**	14 days (7 days when using a nebulizer), or 1 patient (whichever comes first)
Air filter	3 months or 1000 hours use (whichever comes first)
Outlet elbow	5 years or 50 washer-disinfector cycles (whichever comes first)
Battery*	300 cycles or 2 years from first use (whichever comes first)
Pulse oximetry accessories	Refer to instructions for use supplied with device

* See Airvo 3 Technical Manual for instructions to change the battery.

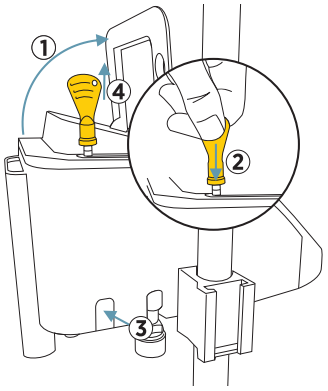
8.4 Replacing the air filter

The Airvo 3 will display a message on startup when the air filter is due to be 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.
4. Pull up on the filter removal tool to remove the filter.
5. Insert the new filter and push down on top of the filter until it clicks into place.
6. Lower the filter cover.



8.5 Servicing

The Airvo 3 does not require regular maintenance and contains no user serviceable parts. If the Medical Equipment system is modified from the specification of the manufacturer, evaluation to the requirements of 60601-1 standard is required. Refer to the Airvo 3 Technical Manual for product acceptance checks, functional tests and spare parts. Contact your Fisher & Paykel Healthcare representative if a fault develops or you are concerned the Airvo 3 is not operating correctly.

9. Pulse oximetry

The Airvo 3 supports the following pulse oximeter accessories:

- The Masimo SET uSpO_2 Pulse Oximetry Cable (3412)
- The Medtronic Nellcor OxiCable (PMC10N-SF)
- The Nonin Xpod 3012LP USB (6703-001)
- The Nonin Xpod 3012HR USB Connector Cable (114403-001)

Pulse oximeters primarily measure the oxygen saturation of blood and pulse rate. Oxygen saturation or SpO_2 is the percentage of hemoglobin in the blood that is saturated with oxygen. Hemoglobin is a protein in the red blood cells that carries oxygen from the lungs to the rest of the body. Pulse rate is the number of heart beats per minute.

A pulse oximeter operates by emitting two different wavelengths of light, typically red and infrared, into a perfused tissue site such as a fingertip or earlobe. The emitted light passes through the tissue, and a photodetector in the sensor measures the intensity of the transmitted or reflected light. By comparing the absorption of red and infrared light, the pulse oximeter calculates the ratio of oxygenated to total hemoglobin in the blood, which is used to determine the oxygen saturation level. Additionally, the device analyzes the variations in the light intensity to measure the patient's pulse rate.

9.1 Pulse oximetry warnings, cautions, and notes

WARNINGS

- In line with the indications for use of the Airvo 3, the monitoring functionality of the Airvo 3 is intended for use on spontaneously breathing patients and not intended for patients requiring life support. It is the responsibility of the clinician to select the appropriate level of monitoring for their patient and to be prepared to deal with alarms and equipment malfunction. Additional, independent monitoring equipment may be necessary.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.
- Using different alarm settings on devices within a single area, such as an intensive care unit, can cause a hazard.
- Periodically reposition the sensor to help prevent ischemia.
- If any measurement seems questionable, first check the patient's vital signs by alternate means. Then check the pulse oximeter USB connector, adapter, sensor, and Airvo 3 for proper operation.
- Carefully route cabling to reduce the possibility of patient entanglement or strangulation.
- Do not use single-patient-use pulse oximeter sensors on more than one patient to avoid cross-infection and/or contamination.
- Refer to the third party pulse oximeter sensor instructions for information on the risks of re-using a single use sensor.
- Follow the user instructions supplied with multi-use pulse oximeter sensors, adapters and USB connector cables to clean and disinfect these devices between patients to avoid cross-infection and/or contamination.
- Tissue damage may be caused by incorrect application of the sensor, e.g. by wrapping the sensor too tightly. Follow the instructions supplied with the sensor for correct application.
- Use only compatible oximetry sensors and accessories for SpO_2 and pulse rate measurements. Verify compatibility before use to avoid incorrect operation of your Airvo 3, inaccurate measurements and/or patient injury. See Appendix 3 for a list of compatible accessories.
- Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.
- Explosive hazard: Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.

Nellcor:

- Do not rely solely on the Nellcor OxiCable for patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Avoid spilling liquids into the Nellcor OxiCable.
- Refer to the OxiCable PMC10N-SF instructions for use for a complete list of warnings and more information when using the Medtronic OxiCable with the Airvo 3.

Nonin:

- Operation of the Nonin Xpod USB connector below the minimum amplitude of 0.3% modulation may cause inaccurate results.

CAUTIONS

- Before cleaning the pulse oximetry accessories, disconnect the device from the Airvo 3 to avoid electrical shock and flammability hazards.
- Do not place the pulse oximetry accessories on electrical equipment that may affect the device, preventing it from working properly.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter equipment.
- Do not place the Airvo 3 where controls can be changed by the patient.
- The accuracy of the SpO_2 measurement may be affected if the total sensor cable length (including extension cables) is greater than 3 meters.

- Setting extreme alarm thresholds can render alarms useless and may lead to patient injury.
- Check that the pulse oximetry alarm limits are appropriate for the patient being monitored every time pulse oximetry is used.
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape sensors if the patient exhibits an allergic reaction to the adhesive material.

Masimo:

- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a "Replace Pulse Ox Sensor" and/or "Replace Pulse Ox Cable", or a persistent poor signal quality message (such as "Low Signal I.Q") is displayed on the Airvo 3. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Replace the cable or sensor when a "replace sensor" or when a "low SIQ" message is consistently displayed while monitoring consecutive patients after completing the troubleshooting steps listed in this manual.
- Please refer to the instructions for use provided with the Masimo uSpO$_2$ Pulse Oximetry Cable for additional warnings, cautions, and notes.
- The Masimo SET uSpO$_2$ Pulse Oximetry Cable (Oximetry Cable) must be connected to the Airvo 3 for power, communication, display and alarm management.

Nonin:

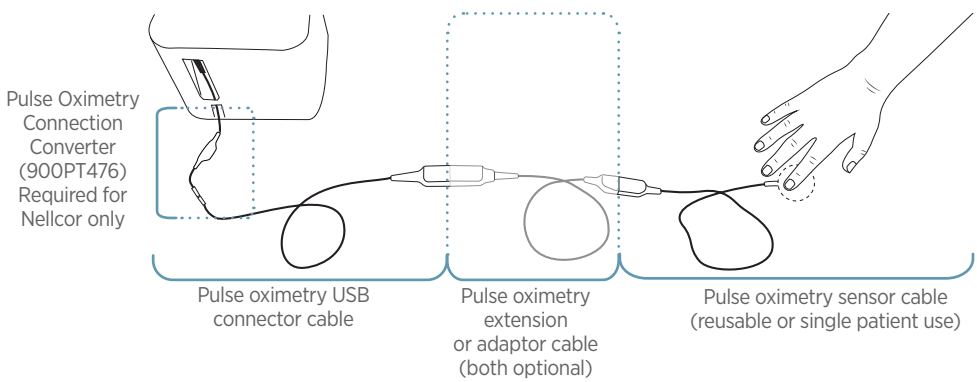
- The Nonin Xpod USB connector has motion tolerant software that minimizes the likelihood of motion artefact being misinterpreted as good pulse quality. In some circumstances, however, this device may still interpret motion as good pulse quality. This covers all available outputs (i.e. SpO$_2$, PR, PLETH, PPG).

Note

- The accuracy of pulse oximeter sensors, adapters and patient cables cannot be assessed using a functional tester.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- For more information about required safety and regulatory requirements for pulse oximeters, refer to ISO 80601-2-61, and IEC 60601-1. Additional safety information can be found in the labelling provided with each sensor.
- Do not loop the pulse oximetry cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the sensors compatible with the Airvo 3 pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use.
- Masimo cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor directions for use for the specified duration of the patient monitoring time.
- Each specific sensor comes with manufacturer-supplied instructions for its use. Please refer to these for further details, including Bland Altman plots.

9.2 Setup for pulse oximetry

Connect the pulse oximetry USB connector cable to either USB port on the back of the Airvo 3. Clip the cable into the cable tidy so that it is not pulled out accidentally. The Airvo 3 will automatically detect a compatible pulse oximeter.



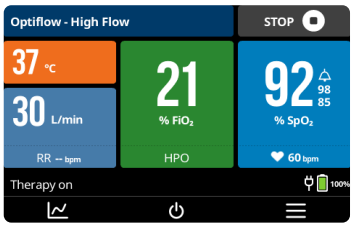
9.2.1 Pulse oximetry accessories

When compatible pulse oximetry accessories are connected, the Airvo 3 can display:

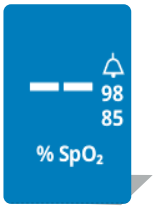
- functional oxygen saturation (SpO_2),
- pulse rate (no pulse rate alarms are included in the Airvo 3),
- perfusion index (Masimo only),
- plethysmograph, and
- signal quality indicators

9.3 During therapy

The Pulse Oximetry tile will be automatically displayed on the Home screen when a compatible pulse oximetry USB connector cable is connected to the Airvo 3.

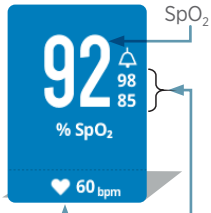


Pulse oximetry measurements and status are shown as follows:



Pulse oximetry is connected to the Airvo 3, but no measurements are available.

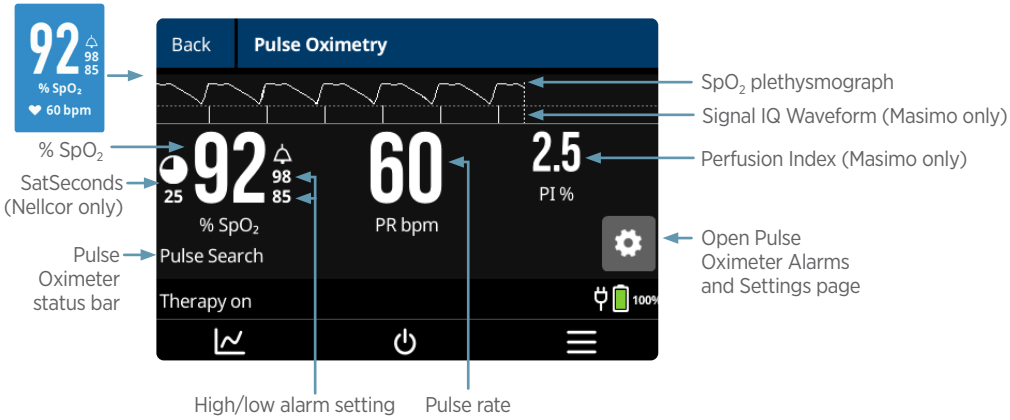
Poor signal quality (see section 7 for troubleshooting).

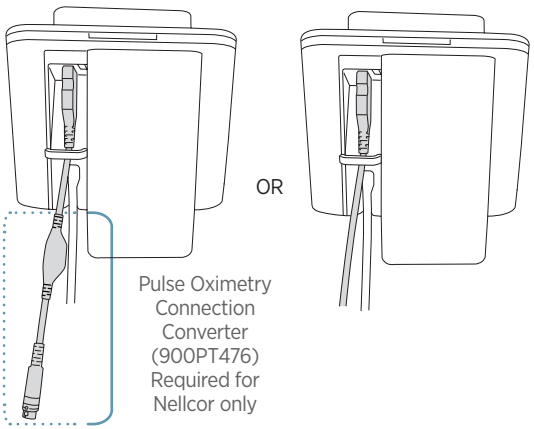


Pulse rate

High/low SpO_2 alarm threshold ("--" if disabled)

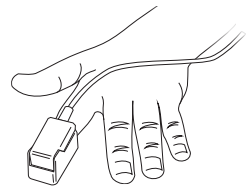
Tap the Pulse Oximetry tile to open the Pulse Oximetry screen.





Connect the USB connector cable to the to Airvo 3

Connect the pulse oximeter USB connector cable to the USB port on the back of the Airvo 3. The Airvo 3 will automatically detect compatible devices. Connect the pulse oximetry sensor cable to the other end of the USB connector cable.



Attach sensor to patient

Carefully select a pulse oximetry sensor based on the patient's age, weight and intended sensor application site. More information can be found in the instructions supplied with each sensor.

WARNINGS

Inaccurate SpO_2 and/or pulse-rate readings may be caused by:

- Improper sensor application and placement.
- Elevated levels of Carboxyhemoglobin (COHb) or methaemoglobin (MetHb): High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (COOximetry) of a blood sample should be performed.
- Elevated levels of bilirubin.
- Elevated levels of dyshemoglobin.
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease.
- Hemoglobinopathies and synthesis disorders such as thalassemia, Hb s, Hb c, and sickle cell, etc.
- Hypocapnic or hypercapnic conditions.
- Severe anemia.
- Very low arterial perfusion.
- Extreme motion artifact.
- Abnormal venous pulsation or constriction.
- Severe vasoconstriction or hypothermia.
- Arterial catheters and intra-aortic balloon.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers etc.
- Skin color disorders.
- Excessive ambient light.
- Excessive motion.
- Electrosurgical interference.
- Blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.).
- Moisture in the sensor.
- Improperly applied sensor.
- Incorrect sensor type.
- Poor pulse quality.
- Venous pulsations.
- Low hemoglobin concentrations.
- A sensor not at heart level.

Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.

The oximeter sensor may not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation or reposition the sensor.

Inaccurate readings can result due to residue (e.g. dried blood) in light path or degradation of optical characteristics of sensor components. Refer to cleaning instructions supplied with the pulse oximetry accessories.

False high readings can result if SpO_2 is low due to dysfunctional hemoglobin (e.g. carboxyhemoglobin or methemoglobin).

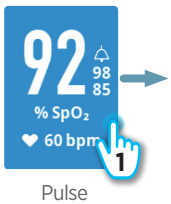
Read the instructions supplied with the pulse oximetry accessories for additional safety information (including any potential risks or adverse effects from sensor materials), measurement site selection, detailed sensor setup, maximum sensor application time at a single site before repositioning, cable lifetime, sensor lifetime, factors that can interfere with measurement, troubleshooting and maintenance instructions.

9.4 Description of measurements

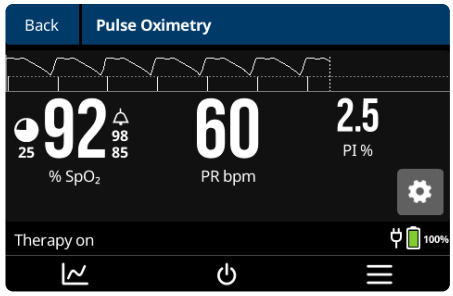
Pulse oximetry measurements are displayed on the Pulse Oximetry tile, the Pulse Oximetry screen and the Data and Graphs screen. Measurements are updated every second.

Tap the Pulse Oximetry tile to open the Pulse Oximetry screen and to open the Data and Graphs screen.

Tapping on the Pulse Oximetry screen provides a shortcut to the pulse oximetry alarms and settings.



Pulse Oximetry tile



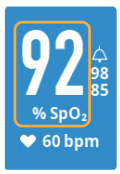
Pulse Oximetry screen

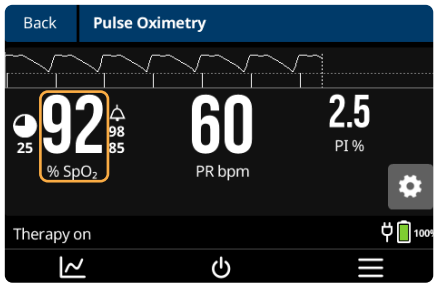
CAUTION

If any measurement seems questionable, check the patient's vital signs by another method. Then check the pulse oximetry accessories and Airvo 3 are set up, configured and working correctly.

9.4.1 SpO_2

The Airvo 3 is calibrated to display functional oxygen saturation (SpO_2) as a percentage. The SpO_2 value displayed is an average of measurements over a user selectable period (see Averaging Time in section 9.5 below). A long averaging period will generally produce more stable values but the SpO_2 displayed will respond more slowly to rapid changes in arterial blood oxygen saturation (SaO_2).





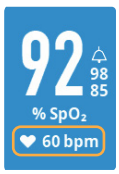
Stability of the SpO_2 measurements displayed may provide a good indication of a valid signal. Though stability is a relative term, experience with the device and patient observations will help you separate physiological effects from artifacts caused by a poorly-placed sensor or excess patient motion.

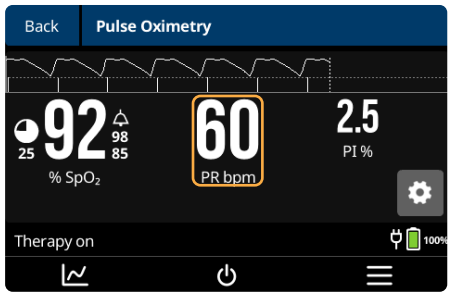
Inconsistencies between SpO_2 displayed on the Airvo 3 and arterial blood gas analysis or clinical assessment may be caused by:

- poor signal quality,
- low perfusion,
- improperly-placed sensors or cables, and/or
- the patient's condition.

9.4.2 Pulse rate

Pulse rate (♥, PR) measurements are based on optical detection of pulsatile peripheral blood flow by the pulse oximeter sensor. The pulse rate displayed, in beats per minute (bpm), is an average of measurements over a user-selectable period.



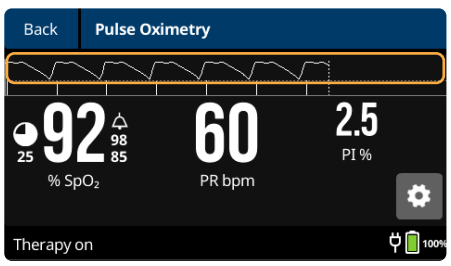


Small differences in the pulse rate displayed by different equipment may be caused by different approaches to averaging. Small discrepancies between cardiac electrical activity and pulse rate obtained from peripheral measurements can also arise. Large discrepancies between equipment may be caused by:

- poor signal quality,
- low perfusion,
- improperly placed sensors or cables, and/or
- the patient's condition.

9.4.3 Plethysmograph

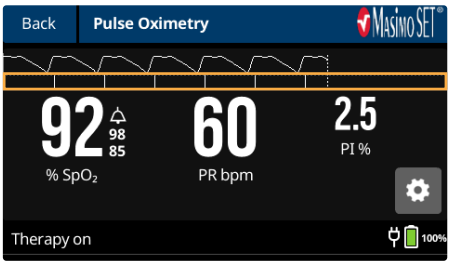
A plethysmograph (or photo-plethysmograph) provides a non-normalized indication of the change in blood volume measured by the pulse oximeter sensor. The shape of the plethysmograph may change between patients, between measurement sites and for different sensor models.
The plethysmograph provides an indication of signal inadequacy. A low amplitude or variable plethysmograph may indicate poor/inadequate signal. The plethysmograph is displayed on the Pulse Oximetry screen.



9.4.4 Signal IQ Waveform (Masimo)

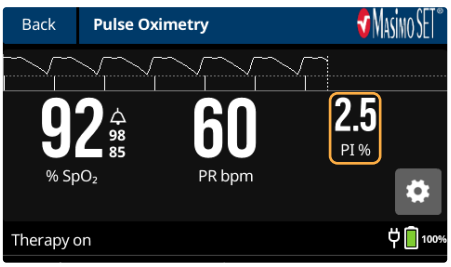
The Signal IQ waveform shows the measurement confidence and timing of each detected pulse relative to the plethysmograph waveform. The height of the vertical bars indicate the relative confidence of the measurement. A high bar corresponds to higher confidence. In addition, the bars should visually correlate to the peak of the plethysmograph waveform. This along with perfusion index provides a better tool for assessing potential problems such as blood flow obstructions, poor sensor placement, artifacts or interference.

If Signal IQ is low an indication will occur with the status message "Low SpO_2 Signal IQ" displayed. During this time the SpO_2 and pulse rate numbers will be grayed out.



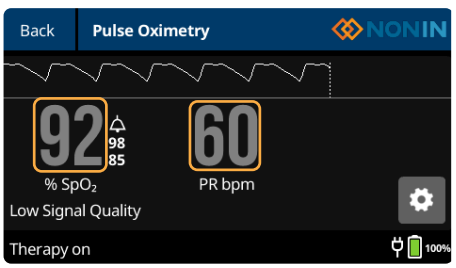
9.4.5 Perfusion Index (Masimo)

The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Perfusion index represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.



9.4.6 Signal quality indicators (Nonin)

Nonin pulse oximetry equipment indicate signal quality based on the perfusion of the patient. There are three states: green, yellow, and red corresponding to high, low/marginal, and low/poor signal quality respectively. During these periods of low signal quality (signal inadequacy) pulse oximetry values displayed may be incorrect. The Airvo 3 indicates low signal quality by graying out the SpO_2 and Pulse rate numbers.



9.5 Description of settings and alarms

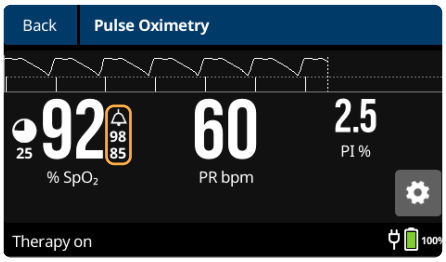
This section describes the behavior of pulse oximetry settings and alarms. See the Alarms and measurement section (9.6) on how to make changes to the alarm thresholds and settings.

9.5.1 Patient alarm thresholds

The following alarms can alert you to changes in your patient's condition:

- SpO_2 Low alarm
- SpO_2 High alarm

The corresponding alarm will be raised when a measurement is lower or higher than the alarm threshold. SpO_2 alarm thresholds are displayed on the Pulse Oximeter tile and Pulse Oximeter screen.



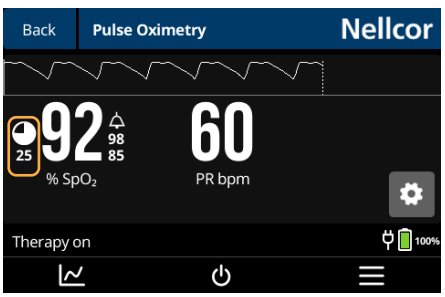
9.5.2 SpO_2 Alarm Delay (Masimo and Nonin)

The SpO_2 Alarm Delay setting defers the Low SpO_2 and High SpO_2 alarms for up to 15 seconds.
This delay helps reduce non-actionable alarms for short desaturations. The alarm will start, if the alarm condition remains, after the delay.

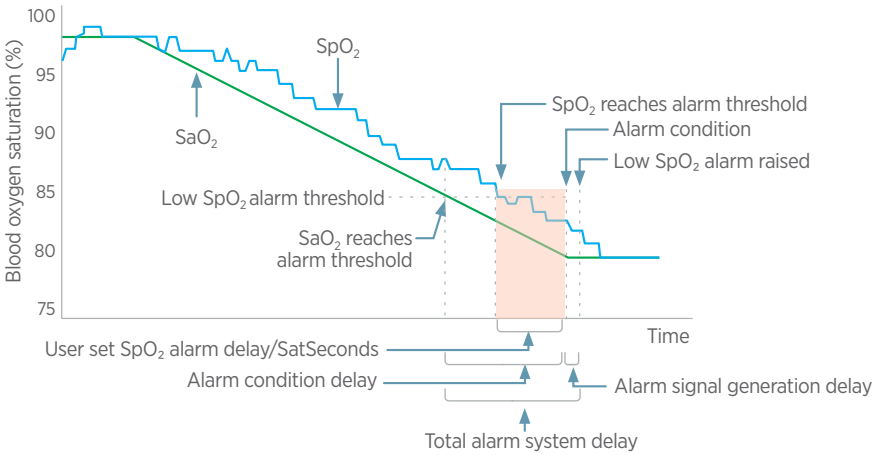
9.5.3 SatSeconds™ Limit (Nellcor)

The SatSeconds™ feature provides alarm management for mild or brief SpO_2 limit violations. SatSeconds monitors both the degree and duration of desaturation as an index of desaturation severity. This means that when more significant desaturations occur the alarm will activate quicker than when minor desaturations occur. When the SatSeconds feature is enabled, the SatSeconds icon fills in the clockwise direction as the SatSeconds alarm management system detects SpO_2 readings outside of the limit settings. The SatSeconds icon empties in the counterclockwise direction when SpO_2 readings are within limits. When the SatSeconds icon reaches full, a High or Low SpO_2 alarm will be raised.

Refer to Appendix 5: SatSeconds Alarm Management Feature for additional detail on the SatSeconds functionality.



9.5.4 Alarm response time



Pulse oximeter physiological audible and visual alarms are subject to an alarm response delay. These are defined in ISO 80601-2-61 as:

1. Alarm condition delay: the duration for a physiological change to be recognized by a pulse oximeter. This can be attributed to signal processing and averaging of the signals from the pulse oximeter. This also includes the user set SpO_2 delay/SatSeconds.
2. Alarm signal generation delay: the period between detecting an alarm condition and signaling the alarm and is made up of inherent delays in the alarm system and communication time.
3. Overall alarm system delay: the period between the physiological change in the patient being monitored and reporting the alarm to the user.

Measurement averaging will affect the alarm condition delay: a larger averaging time will increase the alarm condition delay. These delay concepts are illustrated on the graph for a decrease in SaO_2 leading to a SpO_2 Low alarm as an example. The illustration does not reflect the actual length of delays. Refer to ISO 80601-2-61 for more information about alarm response delay.

9.5.5 Averaging time

The SpO_2 averaging time can be adjusted depending on patient acuity and area of care. This is the time, in seconds for Masimo, and heart beats for Nonin that measurements are averaged over. Shorter averaging times are sometimes preferred in, for example, sleep testing while longer averaging times are more suited to telemetry and neonates.

9.5.6 Sensitivity modes (Masimo)

There are three sensitivity modes. Normal sensitivity is recommended for patients who are experiencing some compromise in blood flow or perfusion. These patients are usually observed frequently such as in the intensive care unit. Adaptive Probe Off Detection (APOD) sensitivity is recommended when there is a higher probability of the sensor becoming detached. It is also the recommended mode for areas where patients are not visually monitored continuously. It provides enhanced protection against erroneous pulse rate and SpO_2 readings when the sensor becomes inadvertently detached from a patient due to excessive movement. Maximum sensitivity (MAX) is recommended for patients with weak signals, useful during procedures or when clinician contact is continuous such as high acuity areas.

9.5.7 Response mode (Nellcor)

The Nellcor OxiCable utilizes the OxiMax algorithm which automatically extends the dynamic averaging time for measuring SpO_2 depending on measurement conditions. There are two response modes available, Normal and Fast. In Normal Mode, the SpO_2 averaging time is six to seven seconds and in Fast Mode, the SpO_2 averaging time is approximately three seconds. The Pulse rate averaging time is approximately five seconds, independent of response mode.

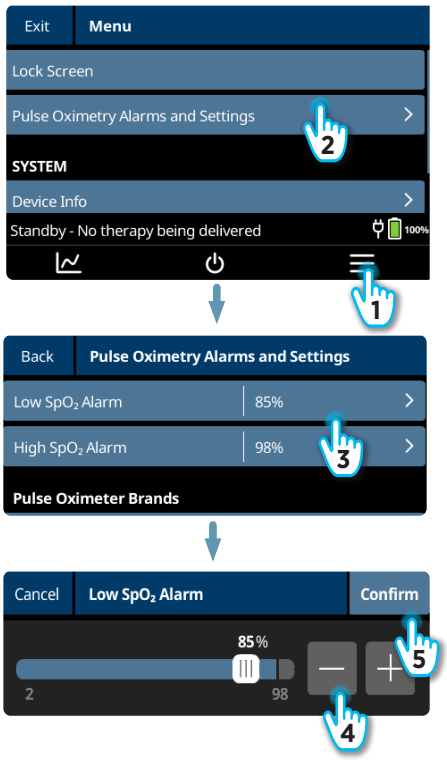
9.6 Alarm and measurement settings

To change pulse oximetry alarm thresholds and settings:

1. Tap ☰ to open the system menu,
2. Select Pulse Oximeter Alarms and Settings,
3. Tap the desired setting, scrolling if necessary,
4. Use the + / – buttons to select the required value,
5. Tap Confirm to apply the change or Cancel to discard any changes and return to the settings list.

Tap Back twice to return to the Home Screen when you have finished making changes.

All settings are persistent and will retain their previous value when the Airvo 3 is turned on and Same Patient is selected. Selecting New Patient when reviewing the disinfection state applies the default values for its intended clinical environment to all alarm and measurement settings. Refer to the troubleshooting section for troubleshooting SpO_2 measurements and general device alarms.



Label	Description	Factory default	Range
Low SpO_2 Alarm*†	Threshold for SpO_2 Low alarm	85%	20 – 98%‡
High SpO_2 Alarm†	Threshold for SpO_2 High alarm	Off	Off, 21 – 99%‡
SpO_2 Alarm Delay (Masimo and Nonin)	Delay before audible Low SpO_2 or High SpO_2 alarm	15 seconds	0, 5, 10, 15 seconds
SatSeconds Limit (Nellcor)	Delay before audible Low SpO_2 or High SpO_2 alarm	10 SatSeconds	Off, 10, 25, 50, 100
Averaging Time	Masimo: The length of time to average over Nonin: The number of pulses to average over	8 seconds 8 beats	2 – 4, 4 – 6, 8, 10, 12, 14, 16 seconds 4 or 8 beats
Sensitivity Mode	Masimo Only	APOD	Normal, APOD, Max§
Response Mode	Nellcor Only	Normal	Normal, Fast

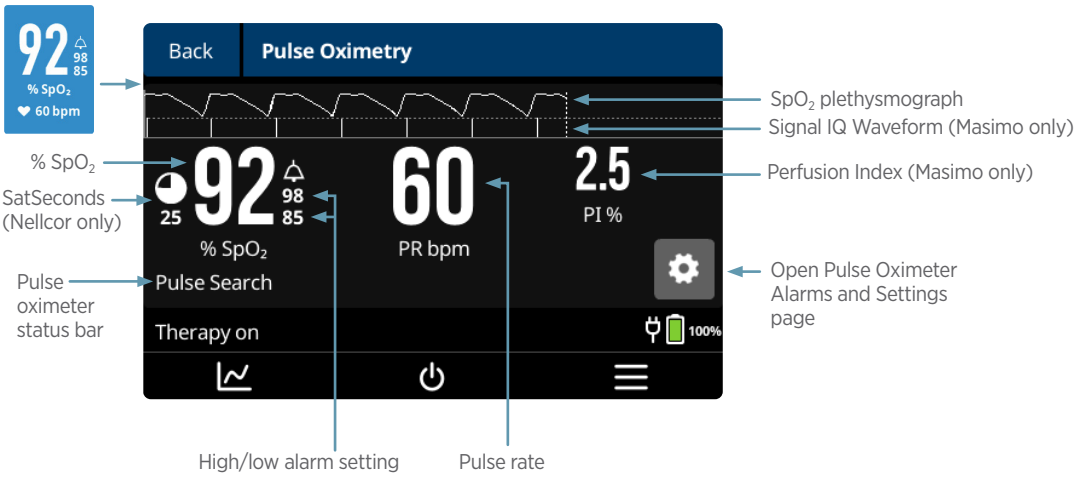
* The minimum threshold may be set when the device is set up for its intended clinical environment. Refer to the Airvo 3 Technical Manual for details.

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

‡ The alarm threshold can be changed in 1% steps.

§ Max sensitivity mode does not persist through an Airvo 3 power cycle. Once powered back up the sensitivity setting reverts to the current default setting.

9.7 Troubleshooting



To help ensure successful monitoring of your patient's SpO_2:

- Apply the pulse oximeter sensor to a well-perfused site.
- Select a measurement site that has unrestricted blood flow.
- Follow all the instructions supplied with the pulse oximetry sensor to ensure the device is correctly applied.

The pulse oximeter status bar displays the status of the pulse oximeter. Tap the pulse oximeter tile to open the pulse oximetry screen and view the status. Possible status messages and warnings are described below.

Message	Cause/remedy
Low SpO_2 Signal IQ	**Masimo only.** The pulse oximeter is indicating low signal confidence in the values displayed due to poor signal strength. The parameters displayed are grayed out while in this state. The patient should be assessed and the sensor should be checked for correct application.
Low Signal Quality	**Nonin only.** The pulse oximeter is indicating low signal quality. The parameters are displayed in gray while in this state. These low signal quality states may be caused by excess motion, low perfusion, a long/blocked light path, or a damaged or incorrectly fitted sensor. • Follow the sensor's user instructions to check it is the correct type and that it has been correctly applied to the patient. • Reduce or eliminate motion at the monitoring site. • Consider an adhesive sensor. • Check that the sensor's emitter and detector are properly aligned, particularly when using an adhesive sensor. • Consider a different measurement site. • Check that blood flow to the measurement site is not restricted. • See the pulse oximetry section for physiological conditions that may affect pulse oximetry measurement accuracy and consider an alternative method if indicated. • Remove excessive fingernail polish or artificial nails. • Replace the sensor.
Replace Cable Next Patient	**Masimo only.** The pulse oximetry USB connector cable is defective or has expired and should be replaced after the current patient.
Replace Sensor Next Patient	**Masimo only.** The pulse oximetry sensor cable is defective or has expired and should be replaced after the current patient.
Sensor Initialising	**Masimo only.** The pulse oximetry sensor is initialising. If values are not displayed within 30 seconds disconnect and reconnect the sensor. If the problem persists replace the sensor.
Low Perfusion Index	**Masimo only.** The pulse oximeter is indicating that the perfusion index of the patient is low. Please move the sensor to a better perfused site.
Demo mode	**Masimo only.** The pulse oximeter is indicating that it is running in demonstration mode. If this is unintentional please remove and replace the oximetry equipment.

Message	Cause/remedy
SpO_2 Only Mode	**Masimo only.** The pulse oximeter is indicating that it is running in SpO_2 only mode. No pulse rate is available. Check the sensor placement referring to the directions for use provided with the sensor.
Pulse Search	**Masimo and Nellcor only**. The pulse oximeter is performing a pulse search. For Nellcor a continuous message indicates a loss-of-pulse while a flashing message indicates searching. If values are not displayed within 30 seconds, disconnect and reconnect the sensor. If the problem persists replace the sensor.
Interference Detected	**Masimo and Nellcor only.** The pulse oximeter is indicating that interference has been detected. Check that the sensor is correctly applied and if necessary cover the sensor site with an opaque material.
Patient Missing	The pulse oximeter cannot detect a patient. Check that the sensor is properly fitted by following the user instructions supplied with the sensor.
Sensor Disconnected	The pulse oximeter is indicating that there is no sensor currently connected. If there is remove and reconnect. If the problem persists please replace the oximeter accessories.

Nellcor recommends the following actions if there are any issues with their oximetry:

- Reposition sensor,
- Ensure the sensor is not too tight,
- Try an alternative sensor placement sight,
- Optically cover the sensor sight,
- Use an adhesive sensor,
- Use an ear, nasal, or forehead sensor,
- Use a headband with the forehead sensor,
- Check the assembly,
- Remove any nail polish from nail beds,
- Check for and eliminate external interference,
- Clean the sensor site,
- Secure the sensor cable.

If pulse oximeter measurements do not correlate with clinical assessment and/or arterial blood gas measurements:

- check the pulse oximeter status, as described above,
- check the pulse oximeter sensor is fitted correctly, following the user instructions supplied with the sensor,
- review the pulse oximetry section for conditions that may affect pulse oximetry measurement accuracy and consider an alternative method if indicated, and/or
- try a different measurement site.

If the Airvo 3 loses mains power, the system will automatically switch over to use the internal battery and pulse oximetry functionality will be maintained including patient settings and trend data.

If mains power is lost and the battery is depleted, pulse oximetry functionality will be lost. It will be restored once power is restored to Airvo 3 maintaining patient settings but trend data will be lost.

Specifications

General

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

Operating conditions

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

Storage and transport conditions

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

Battery (900PT957L)

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

Supplementary oxygen

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

Optiflow high flow therapy[9]

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

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

Range and accuracy of measured parameters

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

* Test equipment and methods are selected and controlled to ensure the uncertainty coverage is no more than 30% of the disclosed tolerance.
† Oxygen measurements are automatically compensated for changes in barometric pressure.
‡ An RMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

Pulse oximetry specifications (Masimo)

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

Data update period	< 30 sec
Measurement wavelengths and Output Power	Radiant power with a 50mA pulsed LED is less than 15mW. Masimo's RD SET and LNCS sensors use red and infrared light emitting diodes. The wavelengths for all sensors except TC-I and TF-I sensors are 660 Nanometres (nm), and 905nm for red and infrared respectively. TC-I: 653nm and 880nm for red and infrared respectively. TF-I: 660nm and 880nm for red and infrared respectively. This information is especially useful for clinicians performing photodynamic therapy.
Accuracy (see notes 1-12 below)	
Saturation (%SpO_2) – During No Motion Conditions	
Adults/Pediatrics	70 – 100% ± 2 digits 0 – 69% unspecified
Neonates	70 – 100% ± 3 digits 0 – 69% unspecified
Saturation (%SpO_2) – During Motion Conditions	
Adults/Pediatrics	70 – 100% ± 3 digits 0 – 69% unspecified
Neonates	70 – 100% ± 3 digits 0 – 69% unspecified
Pulse Rate (bpm) – During No Motion Conditions	
Adults, Pediatric, Neonates	25 to 240 ± 3 digits
Pulse Rate (bpm) – During Motion Conditions	
Adults, Pediatric, Neonates	25 to 240 ± 5 digits

Resolution	
Saturation (%SpO_2)	1%
Pulse Rate (bpm)	1
Low Perfusion Performance	
Pulse Amplitude	± 2 digits
% Transmission	5%
Saturation (%SpO_2)	± 2 digits
Pulse rate	± 3 digits

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

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

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

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

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

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

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

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

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

10 The Trauma and Newborn sensors are for use only with instruments containing Masimo SET oximetry (Version 4.1.0.1 or higher) or monitors licensed to use specialty sensors.

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

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

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

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

Pulse oximetry specifications (Nellcor)

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

Pulse oximetry specifications (Nonin)

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

Nonin:

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

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

† ± 1 Arms represents approximately 68% of measurements.

‡ Includes Infant patients

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

Notes:

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

Standards compliance

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

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

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

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

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

Device disposal instructions

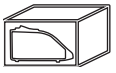
This device contains electronic components and a lithium-ion battery. Regulations in your country may require them to be collected for waste recovery and recycling to reduce the environmental impact. Please dispose of this device in accordance with local regulations.

Disposal of accessories, spare parts and packaging

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

Glossary

Symbols

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

**symbol seen on select models*

Appendix 1. Patient consumables

The patient interfaces and accessories shown in the tables below are approved for use with the Airvo 3. Carefully read the user instructions, including all warnings and cautions, supplied with each device before use.

Some accessories may not be available in certain countries. Contact your Fisher & Paykel representative for the latest information on patient interfaces available for the Airvo 3. All patient interfaces are Type BF applied parts.

Optiflow high flow therapy

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

* Wigglepads part numbers are shown in parentheses.

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

Appendix 2. Parts and accessories

Some accessories may not be available in certain countries. Please contact your local Fisher & Paykel Healthcare representative for more information.

Accessories

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

* The data port adapter allows for data to be transferred from the Airvo 3 to patient monitoring and hospital computer systems. Integration is required to enable functionality. For more informtation please contact your local Fisher & Paykel Healthcare representative.

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

Spare parts

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

WARNINGS

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

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

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

Appendix 3. Pulse oximetry accessories

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

Masimo:

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

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

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

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

Masimo:

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

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

Nellcor:

Adaptors and extension cables

Description	Part number
Pulse Oximetry Connection Converter 1	900PT476 (0.3 m)
Medtronic/Nellcor™ OxiCable	PMC10N-SF (2.8 m)

Part numbers of validated Nellcor pulse oximetry sensor consumables

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

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Nonin:

Part numbers of validated Nonin pulse oximetry USB connector cables

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

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

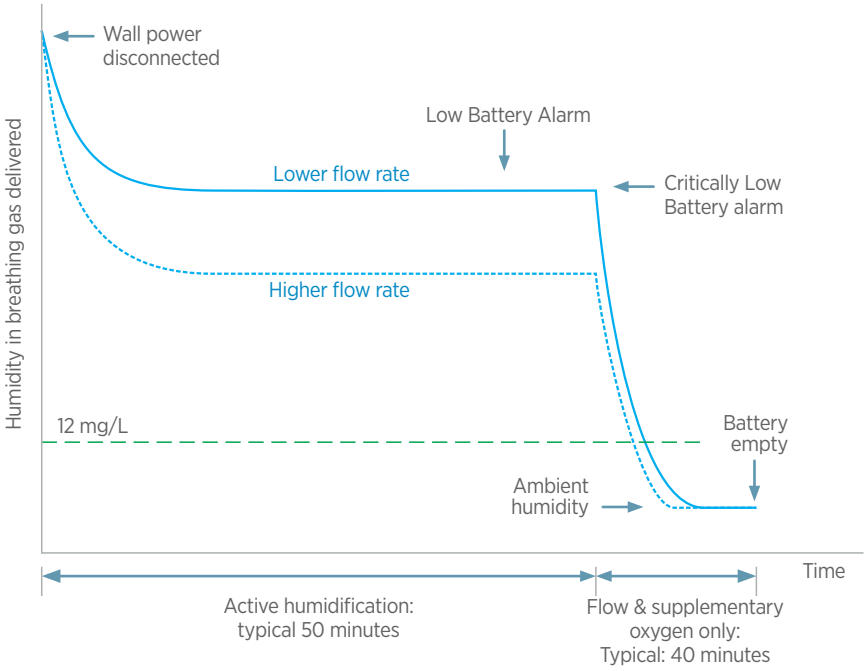
Sensor description	Nonin part number (cable length) (other information)
8000SS reusable soft sensors, small	6837-000 (1 m), 6837-300 (3 m)
8000SM reusable soft sensors, medium	6836-000 (1 m), 6836-300 (3 m)
8000SL reusable soft sensors, large	6835-000 (1 m), 6835-300 (3 m)
8000AA adult reusable finger clip sensors	3278-001 (1 m), 3278-006 (2 m, 6.6 m), 3278-003 (3 m)
8000AP pediatric reusable finger clip sensors	2360-000 (1 m), 2360-003 (3 m)
8000Q2 ear clip sensor	6455-000 (1 m)
8000R reflectance sensor	0487-000 (1 m)
8000J adult semi-reusable Flex Sensor	0741-000 (1 m), 2353-002 (3 m) (includes x25 8000JFW FlexiWraps®)
8008J infant semi-reusable Flex Sensor	0740-000 (1 m) (includes x25 8008JFW FlexiWraps)
8001J neonatal semi-reusable Flex Sensor	0739-000 (1 m) (includes x25 8001JFW FlexiWraps)
6000CA adult cloth disposable sensors	7426-001 (1 m) (24 pack)
6000CP pediatric cloth disposable sensors	7426-002 (1 m) (24 pack)
6000CI infant cloth disposable sensors	7426-003 (1 m) (24 pack)
6000CN neonatal cloth disposable sensors	7426-004 (1 m) (24 pack)
7000A adult Flexi-Form® III disposable sensors	7427-001 (1 m) (24 pack)
7000P pediatric Flexi-Form III disposable sensors	7427-002 (1 m) (24 pack)
7000I infant Flexi-Form III disposable sensors	7427-003 (1 m) (24 pack)
7000N neonatal Flexi-Form III disposable sensors	7427-004 (1 m) (24 pack)
8000JFW adult FlexiWraps	4097-000, (25 pack), for use with 8000J
8008JFW infant FlexiWraps	4774-000, (25 pack), for use with 8008J
8001JFW neonatal FlexiWraps	4777-000, (25 pack), for use with 8001J
8000H reflectance sensor holder pack	0616-000, (10 caps & 20 adhesive stickers) for use with 8000R
Sensor Clip for LP Xpod External Pulse Oximeter	7504-001

Appendix 4. Humidification behavior during battery operation

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

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

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

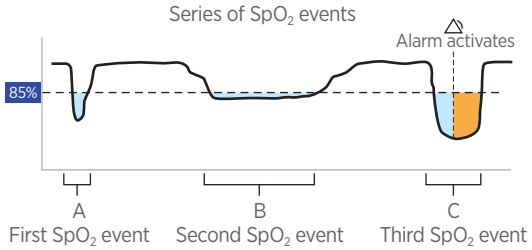


The Airvo 3 delivers reduced humidity in the breathing gas during Optiflow high flow therapy until the battery is nearly depleted, where humidity is turned off to maintain the delivery of flow and oxygen.

Appendix 5. SatSeconds alarm management feature

SatSeconds is an additional function available when using the Medtronic Nellcor OxiCable solution. SatSeconds differs from traditional alarm management in that it monitors both degree and duration of desaturation as an index of desaturation severity helping to distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

Consider a series of events leading to a violation of the clinician set SatSeconds alarm limit (right). An adult patient experiences several minor desaturations, then a clinically significant desaturation.

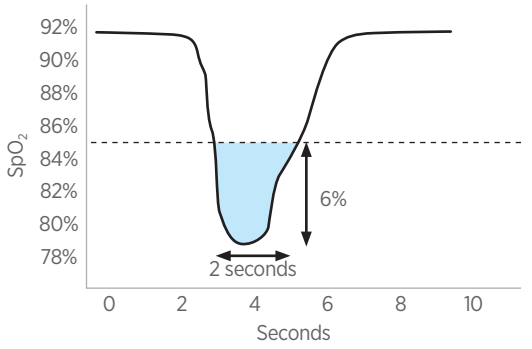


A5.1 First SpO_2 event

Consider the first event. Suppose the SatSeconds alarm limit is set to 25. The patient's SpO_2 drops to 79% and the duration of the event is 2 seconds before the saturation again exceeds the lower alarm threshold of 85%.

In this situation there is a 6% drop below the low alarm threshold multiplied by a 2 second duration which equals a SatSeconds of 12.

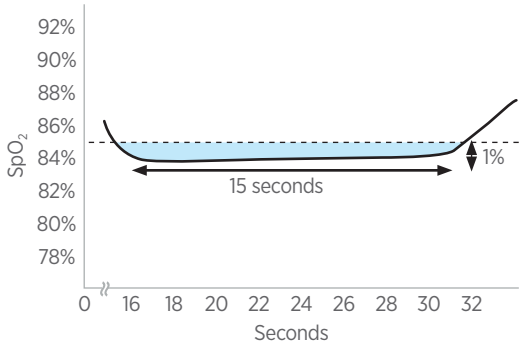
Because the SatSeconds alarm limit is set to 25 and the actual number of SatSeconds equals 12 there is no alarm activated.



A5.2 Second SpO_2 event

Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO_2 drops to 84% and the duration of the event is 15 seconds before the saturation again exceeds the lower alarm threshold of 85%.

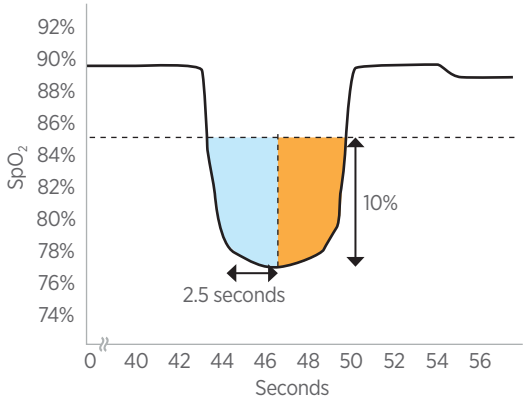
In this situation there is a 1% drop below the low alarm threshold multiplied by a 15 second duration equals 15 SatSeconds. Because the SatSeconds alarm limit is set to 25 and the actual number of SatSeconds equals 15 there is no alarm activated.



A5.3 Third SpO_2 event

Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO_2 drops to 75%, which is 10% below the lower alarm threshold of 85%. At this level of saturation the event cannot exceed 2.5 seconds without invoking the SatSeconds alarm (10% x 2.5 seconds = 25 SatSeconds).

Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds the low SpO_2 alarm is activated.



A5.4 The SatSeconds Safety Net

The SatSeconds "Safety Net" is for patients with saturation levels frequently below the limit, but not staying below the limit long enough for the SatSeconds time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds even if SatSeconds time setting has not been reached.

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