

Use and Care Guide

For patients, caregivers and clinicians







This document may be updated, replaced or rendered obsolete by other documents at any time and without notice. Ensure that you have the latest relevant version of this documentation. Contact Fisher & Paykel Healthcare if you are in doubt, or to obtain specific revisions.

F&P[™], myAirvo[™], Optiflow[™], Optiflow Junior[™], AirSpiral[™], InfoSmart[™] and Wigglepads[™] are registered trademarks or trademarks of Fisher & Paykel Healthcare Limited. For patent information, refer to: www.fphcare.com/ip

Product or company names marked [™] or [®] are trademarks or registered trademarks of their respective owners. This includes, but is not limited to, Apple[®], Mac[®], Microsoft[®], Windows[®], and Bluetooth[®].

For more information, please contact your local Fisher & Paykel Healthcare representative.

LANGUAGE SECTION English (en) A Español (es) B Français (fr) C 繁體中文 (zht) D نالعربية (ar) E Melayu (ms) F

Before you start

- This User Manual is intended for patients and healthcare professionals.
- Read this User Manual including all warnings. Failure to do so may result in injury. Keep in a safe place for future reference.
- Before the myAirvo 2 is used for the first time, it must be set up according to the instructions in the myAirvo 2 Technical Manual. This should be carried out by a healthcare professional or medical technician. The myAirvo 2 needs special precautions regarding electromagnetic compliance (EMC) therefore must be installed and put into service according to the EMC information provided in this User Manual and the Technical Manual.

OTHER REFERENCES

- · Refer to all relevant accessory user instructions.
- Watch the training videos on the myAirvo 2 website www.fphcare.com/myAirvo
- · For troubleshooting information, please refer to the myAirvo 2 Technical Manual.
- Download the myAirvo 2 Simulator App to learn how to use the myAirvo 2. You can change settings, simulate faults and test your skills. Available from the Apple, Google Play and Windows App stores.
- Visit the Fisher & Paykel education & resources website at www.fphcare.com/education, to find self-paced online courses and local training events.
- If the unit is ever used by multiple patients, the unit must be cleaned and disinfected between patients according to instructions in the Disinfection Kit Manual (900PT600).
- For further assistance, please contact your Fisher & Paykel Healthcare representative.



Contents

Be	fore yo	bu start
1	Over	view A3
	1.1	Intended use
2	Safet	A3 A3
3	myAi	irvo 2 and accessories A4
	3.1	Patient consumables
	3.2	Replacement parts and accessories
4	Using	y your myAirvo 2 A7
	4.1	Set up the myAirvo 2
	4.2	Prepare the water chamber
	4.3	Connect the heated breathing tube
	4.4	Switch on your myAirvo 2
	4.5	Connect oxygen supply
	4.6	Connect the patient interface
	4.7	Condensate management
	4.8	Stopping therapy
5	After	use: caring for your myAirvo 2 A12
	5.1	Daily care
	5.2	Weekly care A13
	5.3	Reprocessing for multiple patient use
	5.4	Timetable for changing accessories
	5.5	Filter replacement
	5.6	Servicing
6	Alarn	ns A16
	6.1	Alarm signals
	6.2	Alarm conditions
	6.3	Alarm limits
	6.4	Checking alarm system functionality
	6.5	Auditory information signals
7	Adva	nced settings A18
	7.1	Target dew-point temperature. A18
	7.2	Target flow
	7.3	Day/Night Modes
	7.4	Compliance
	7.5	Junior Mode A19
8	Techi	nical information A20
	8.1	Product specifications
	8.2	Operating conditions
	8.3	Storage and transport conditions
	8.4	Standards and approvals
	8.5	Disposal instructions
9	Gloss	Sary A21
	9.1	Symbol definitions

1. Overview

The myAirvo 2 is a humidifier with integrated flow generator that delivers warmed and humidified respiratory gases to spontaneously breathing patients through a variety of patient interfaces.

1.1 Intended use

The myAirvo 2 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 - 60 L/min depending on the patient interface. The myAirvo 2 is for patients in homes and long-term care facilities.

USA Federal Law restricts this unit for sale by or on the order of a physician.

2. Safety information

▲ Warnings

- · The unit is not intended for life support.
- Appropriate patient monitoring must be used at all times. Loss of therapy will occur if power is lost. Loss of supplemental oxygen will
 also occur if power is lost.
- Nasal delivery of respiratory gases may generate flow-dependent dynamic positive airway pressure. This must be taken into account
 where positive airway pressure could have adverse effects on a patient.

To avoid burns:

- Use only interfaces, water chambers and breathing tubes specified in this user manual.
- Do not use accessories beyond the maximum periods of use specified in this manual.
- · Before using oxygen with the unit, read all warnings in the "Oxygen" section of this manual.
- Never operate the unit if:
 - the heated breathing tube has been damaged with holes, tears or kinks,
 - it is not working properly,
 - the case screws have ever been loosened.
- Do not block the flow of the air through the unit and breathing tube.
- · Locate the unit in a position where ventilation around the unit is not restricted.
- Never block the air openings of the unit or place it on a soft surface such as a bed or couch/sofa, where the filter area may be blocked. Keep the air openings free of lint, hair etc.

To avoid electric shock:

- Do not store or use the unit where it can fall or be pulled into water. If water has entered the unit enclosure, disconnect the power cord and discontinue use.
- Never operate the unit if:
 - it has been dropped or damaged,
 - it has a damaged power cord or plug,
 - it has been dropped into water.
- Avoid unnecessary removal of the power cord from the rear of the device. If removal is necessary, hold the connector during removal. Avoid pulling on the power cord.
- · Return the unit to an authorized service center for examination and repair, except as outlined in this manual.
- To avoid choking, or inhalation of a foreign object:
- Ensure an air filter is fitted when operating your unit.
- Never drop or insert any object into any opening or tube.

Miscellaneous:

- Prior to each patient use, ensure that the auditory alarm signal is audible by conducting the alarm system functionality check described in the Alarms section.
- Humidity output will be compromised below 18°C (64°F) and above 28°C (82°F).
- To prevent disconnection during use, especially during ambulatory use, use only heated breathing tubes specified in this manual.
- The unit is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.
- The myAirvo 2 is not a sealed system. Follow hospital infection control guidelines to reduce risk of cross-contamination.
- Use of accessories or power cables not specified by Fisher & Paykel Healthcare could result in increased electromagnetic emissions, decreased electromagnetic immunity and/or improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it 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. California residents please be advised of the following, pursuant to Proposition 65:
- This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more
 information, please visit: www.fphcare.com/prop65

3. myAirvo 2 and accessories



Some products may not be available in your country. Please contact your local Fisher and Paykel Healthcare representative.



myAirvo 2 Set up



Reusable chamber



Auto-fill chamber

3.1 Patient consumables

The patient interfaces and accessories shown in the table below have been tested for use with the myAirvo 2. Take care to follow the user manual supplied with all patient interfaces and accessories.

All patient interfaces are Type BF applied parts.

Description	Part number	Size	Pack size
Optiflow+ nasal cannula 2-pack	MYOPT9SMALL MYOPT9MEDIUM MYOPT9LARGE	Small Medium Large	2 2 2
Optiflow+ nasal cannula	OPT942E OPT944E OPT946E	Small Medium Large	1 1 1
Optiflow Junior 2 nasal cannula	OJR416HM OJR418HM	L XL	5 5
Optiflow Junior nasal cannula	OPT316 OPT318	Infant Pediatric	20 20
Optiflow+ Tracheostomy interface 2-pack	MYOPT9TRACHE	15 mm tracheostomy direct connection	2
Tracheostomy interface	OPT970E	15 mm tracheostomy direct connection	1
Optiflow+ Mask interface adapter 2-pack	MYOPT9MASK	22 mm mask interface adapter	2
Optiflow+ Mask interface adapter	OPT980E	22 mm mask interface adapter	1
Tube and chamber kits			
AirSpiral tube and auto-fill chamber kit	MYAIRVOKIT1	n/a	1
AirSpiral tube, MR290 auto-fill chamber and adapter	900PT561	n/a	10
Heated breathing tube, MR290 auto-fill chamber and adapter	900PT501	n/a	10
Junior heated breathing tube, MR290 auto-fill chamber and adapter (for use with OPT316/ OPT318 only)	900PT531	n/a	10
Tube kits			
AirSpiral tube kit	MYAIRSPIRAL	n/a	1
AirSpiral tube kit	900PT560E	n/a	1
AirSpiral tube kit	900PT560	n/a	10
Heated breathing tube	900PT500E	n/a	1
Heated breathing tube	900PT500	n/a	10
Water bag	900PT401	n/a	2
Reusable water chamber	MYAIRVOCHAMBER1	n/a	1
Reusable water chamber	HC360	n/a	1
Wigglepads 2	WJR112	n/a	2*20-pack = 40 ea
Wigglepads	OPT012	n/a	2*20-pack = 40 ea

3.2 Replacement parts and accessories

Description	Part number	Pack size
Compact stand	900PT400	1
Air filter	900PT913	2
Disinfection kit	900PT600	1

4. Using your myAirvo 2

At the start of each therapy session you will need to prepare your myAirvo 2.

4.1 Set up the myAirvo 2



Before you begin

Place the unit on a low shelf or near the floor beside your bed. It must be placed below head height and flat. Position the device so the power cord connection to the power supply is easily accessible and able to be disconnected.

4.2 Prepare the water chamber

The respiratory gases are warmed and humidified inside the water chamber.

There are two types of water chamber available for the myAirvo 2, the:

- reusable water chamber, and
- auto-fill water chamber.

Follow the steps in the user manual included with your chamber or tube and chamber kit to set up your chamber.

The table below shows approximately how long a full water chamber or water bag will last on the myAirvo 2 at different flow rates.



Reusable water chamber



Auto-fill water chamber

	myAirvo 2 water use time in hours						
Flow, L min ⁻¹	Reusable chamber (HC360 / MYAIRVOCHAMBER1)	Auto-fill chamber and water bag (MYAIRVOKITI and 900PT401)					
	(560 mL)	(1000 mL)					
2	72	129					
5	33	60					
10	17	31					
15	11	21					
20	9	16					
25	7	12					
30	6	10					
35	5	9					
40	4.5	8					
45	4	7					
50	3.5	6.5					
55	3	5.5					
60	3	5					

/!\ Warnings

To avoid burns:

- Do not fill the water chamber with hot water.
- · Do not start the unit without the water chamber in place.
- Do not touch the heater plate, water chamber or chamber base during use.
- The water in the chamber becomes hot during use. Exercise caution when removing and emptying the chamber.

To avoid electric shock:

- Always remove the water chamber to fill it and always fill with enough water to prevent it running out.
- When handling the unit with the water chamber in place, avoid tilting the machine to prevent any chance of water entering the unit enclosure.
- Empty all the water from the water chamber before transporting the unit.

A Cautions

• Adding substances other than water can adversely affect the humidifier and delivered therapy.

- To ensure optimal therapy (auto-fill water chamber only):
- · Do not use the auto-fill water chamber if it has been dropped or been allowed to run dry, this could lead to the chamber over filling.
- Do not use the auto-fill water chamber if the water level rises above the maximum water level line as this may lead to water entering the patient's airway.

4.3 Connect the heated breathing tube

The heated breathing tube carries the breathing gases generated by your myAirvo 2 to your nasal, tracheostomy, or mask adapter interface. It is warmed to help prevent condensation building up inside the breathing tube.

Only use compatible breathing tubes that are specified in the patient consumables list.

Follow the steps in the user manual included with your heated breathing tube or AirSpiral tube and chamber kit to set up your heated breathing tube.

Warnings

To avoid burns:

- Do not modify the breathing tube or interface in any way.
- Do not allow the breathing tube to remain in direct contact with skin for prolonged periods of time. The healthcare professional shall assess the conditions for safe contact, such as duration and skin condition.
- Do not 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.
- Do not use an insulating sleeve or any similar accessories which are not recommended by Fisher & Paykel Healthcare.

🕂 Caution

 Position the heated breathing tube away from any electrical monitoring leads (EEG, ECG/EKG, EMG, etc), to minimize any possible interference with the monitored signal.

4.4 Switch on your myAirvo 2



Plug the unit's power cord into the mains/utility power socket. The connector at the other end of the power cord should be well secured to the rear of the unit.

/!\ Warning

To avoid electric shock:

• Ensure that the unit is dry before plugging into the mains/utility power socket.



Switch on the unit by pressing the On/Off button for 5 seconds.



The myAirvo 2 will begin warming and humidifying the breathing gases when it is turned on. The warm-up symbol is shown on the screen while the myAirvo 2 is warming up.

4.5 Connect oxygen supply



You can connect up to 15 L/min of supplementary oxygen from a regulated supply to the myAirvo 2. Connect the output from the oxygen source to the oxygen inlet port on the side of the unit. Make sure you push the oxygen tube firmly onto this connection port.

The fraction of oxygen you breathe with this air/oxygen mixture is determined by the airflow setting on the unit and the oxygen flow connected to the unit's oxygen inlet port.

The following table shows the approximate oxygen fraction delivered for the range of unit and oxygen airflows (at sea level). The oxygen fractions given assume that the oxygen source is a home oxygen concentrator. These values will be higher if the oxygen source is bottled oxygen. At flows less than 10 L/min, the oxygen fraction delivered varies significantly with small changes in input oxygen flow. Oxygen flow settings should be titrated according to blood saturation levels.

_	:0				r	nyAirvo 2	Target Flo	w Setting	in L min ⁻¹	(Set BTPS)		
	10 ₂	5	10	15	20	25	30	35	40	45	50	55	60
	1	37	29	26	25	24	24	23	23	23	23	22	22
ନ୍ଦି	2	53	37	32	29	27	26	26	25	25	24	24	24
STF	3	68	45	37	33	31	29	28	27	26	26	25	25
in ⁻¹	4	82	53	42	37	34	32	30	29	28	27	27	26
Ē	5	93	60	47	41	37	34	32	31	30	29	28	28
e in	6	-	68	53	45	40	37	35	33	32	31	30	29
/ rat	7	-	75	58	49	43	40	37	35	33	32	31	30
flow	8	-	82	63	53	46	42	39	37	35	34	33	32
Jen	9	-	90	68	56	50	45	42	39	37	35	34	33
ōXXc	10	-	93	73	60	53	47	44	41	39	37	36	34
tor	11	-	-	78	64	56	50	46	43	41	39	37	36
ntra	12	-	-	82	68	59	53	48	45	42	40	38	37
nce	13	-	-	87	71	62	55	50	47	44	42	40	38
ပိ	14	-	-	92	75	65	58	53	49	46	43	41	40
	15	-	-	93	79	68	60	55	51	47	45	43	41

It is important that the physician prescribing your oxygen therapy approves both the flow and oxygen settings and that you do not adjust these prescribed settings without consulting them.

Check that suitable blood saturation levels are achieved at the prescribed flow.

Use continuous oxygen monitoring on patients who would desaturate significantly in the event of disruption to their oxygen supply.

/!\ Warnings

Before using oxygen with the unit, read all of the following warnings:

- The use of oxygen requires that special care be taken to reduce the risk of fire.
- Accordingly, for safety it is necessary that all sources of ignition be kept away from the unit and preferably out of the room in which it is being used. Oxygen should not be used while smoking or in the presence of an open flame. The unit should be located in a position where ventilation around the unit is not restricted.
- A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from all oxygen equipment.
- Ensure that the myAirvo 2 is switched on before connecting oxygen.
- Oxygen must only be added through the special oxygen inlet port on the back of the unit. To ensure that oxygen enters the unit correctly, the oxygen inlet port must be fitted properly to the filter holder and the filter holder must be fitted properly to the unit. The power cord connector should also be well secured.
- Ensure that the myAirvo 2 target flow rate is higher than the supplementary oxygen flow rate, to avoid excess oxygen being vented into the surroundings.
- Do not connect more than 15 L/min of supplementary oxygen to the myAirvo 2.
- The oxygen concentration delivered to the patient can be affected by changes to the flow setting, oxygen setting, patient interface or if the airpath is obstructed.

4.6 Connect the patient interface



When the "Ready for Use" symbol appears on the display, connect the patient interface to the heated breathing tube. When you first use the unit, the air will feel warm. Continue to breathe normally.

The myAirvo 2 can be used with a variety of patient interfaces. Read the separate user instructions for the patient interface that will be used, including all warnings.



/ Warnings

To avoid burns:

- Do not modify the breathing tube or interface in any way.
- Do not use any patient interfaces not listed here.

All patient interfaces are Type BF applied parts.

The following table shows the target dew-point temperature settings and target flow settings able to be used with these interfaces.

			°C			L min	1 ⁻¹								
PATIENT INT	ERFACE		31	34	37	25	10	15	20	25		50	55	60)
Optiflow	OPT316					2		20							
Junior	OPT318					2			25						
Optiflow	OJR416HM					2		20	ĺ –						
Junior 2	OJR418HM					2			25						
Optiflow+	MYOPT9SMALL/OPT942E	S					10				Ę	50			
	MYOPT9MEDIUM/OPT944E	M					10							60	
	MYOPT9LARGE/OPT946E	L					10							60	
	MYOPT9TRACHE/OPT970E						10							60	
	MYOPT9MASK/OPT980E						10							60	

Low temperature ambient conditions may prevent the unit from reaching a target temperature setting at high target flow settings. In these cases, consider decreasing the target flow setting.

At altitude, the maximum flow rates achievable may be lower than those in the above table, by approximately 5 L/min per 1000 m (3000 ft).

4.7 Condensate management



The unit must be placed below head height and flat. This allows condensate to drain towards the water chamber, away from the patient.

If excess condensate accumulates in the heated breathing tube, disconnect the patient interface from the heated breathing tube, drain the condensate by lifting the patient end of the tube, allowing the condensate to run into the water chamber.

At higher target flow rates, it may be necessary to first reduce the target flow rate to 30 L/min or below, to ensure the condensate drains into the water chamber.

Minimize local sources of cooling acting on the heated breathing tube, such as a fan to cool the patient or an air-conditioning unit/vent.

If condensate persists, consider turning the target temperature down. A lower target temperature will decrease the humidity output of the unit, decreasing the level of condensation.

The temperature and humidity level delivered to the patient will also be reduced.

4.8 Stopping therapy

4.8.1 Disconnect oxygen



When finished, turn off the oxygen source. Remove the output of the oxygen source from the oxygen inlet port on the back of the unit.

/ Warning

To avoid burns:

• The oxygen flow must be turned off when the unit is not operating, so that oxygen does not build up inside the device.

4.8.2 After use



When you have finished using the unit, remove your interface and drain any excess condensate in the breathing tube by lifting the patient end of the tube, and allowing the condensate to run into the water chamber.

4.8.3 Drying mode



Then press and hold the On/Off button for 3 seconds until a melody sounds. The unit will automatically enter Drying Mode and dry the tube so it is ready for you to use next time. Drying Mode runs for 99 minutes. The unit will automatically turn off when it is finished.

/!\ Warnings

To avoid burns:

- Do not wear the interface during Drying Mode. The air is hot and dry and may cause injury.
- Do not remove the water chamber until drying mode has been completed.

To switch the unit off without completing Drying Mode (this is not recommended), hold down the On/Off button for 5 seconds.

If you unplug the unit's power cord from the mains/utility power socket while the unit is still running, the "Power Out" alarm will sound. Press the "Audio Pause" button to silence this alarm.

5. After use: caring for your myAirvo 2

It is important to carefully follow the instructions in this section, to keep the device clean and safe for use and to extend the life of the consumables.

The following instructions are for single-patient home use. If the unit is ever used by multiple patients, refer to "Reprocessing for multiple patient use".

Standard aseptic techniques to minimize contamination should be followed when handling the unit and accessories. This includes proper hand-washing, avoiding hand contact with connection ports, safe disposal of the used consumables and suitable storage of the unit after cleaning and disinfection.

5.1 Daily care

Run Drying Mode / Rinse the patient interface and water chamber

Allow Drying Mode to run after use (refer to the "Using your myAirvo 2" - "Drying Mode").









Follow these steps, immediately after stopping therapy, every time that you use the myAirvo 2. Carry out these steps while Drying Mode is running.

- 1. Drain any excess water from the breathing tube by lifting the end attached to the patient interface so the water runs into the water chamber.
- 2. Disconnect the patient interface from the heated breathing tube.

Leave the heated breathing tube connected and the water chamber installed in the myAirvo 2.

You do not need to empty the water chamber during Drying Mode.

3. If using an Optiflow+ interface, rinse your patient interface in drinking-quality tap water.

If using the Optiflow Junior Nasal Cannula, do not soak or sterilize this product. Avoid contact with chemicals, cleaning agents, or hand sanitizers. Secretions on the cannula and the prongs can be removed by gently wiping with a damp cloth.

- Reconnect the patient interface to the heated breathing tube while the myAirvo 2 is still in Drying Mode.
- 5. Follow the Weekly care instructions below once a week.
- 6. After Drying Mode:

If using the Reusable water chamber (MYAIRVOCHAMBER1 / HC360):

Check the user manual that accompanies your water chamber and follow the daily care instructions.

If using the Auto-fill water chamber:

Do not wash or remove this chamber.

5.2 Weekly care

Clean the patient interface, water chamber and myAirvo 2

1. Switch off the unit and unplug from the mains/utility power socket.

2. Remove the heated breathing tube and drain any excess condensate.











 Remove the interface from the heated breathing tube, wash it in warm water with mild dishwashing detergent added, rinse it in drinking-quality water, then reconnect it to the heated breathing tube.

If using the Optiflow Junior Nasal Cannula, discard after a maximum of seven days. Replace earlier if necessary.

4. Remove the water chamber.

If using the **Reusable chamber (MYAIRVOCHAMBER1 / HC360)**: Check the user manual that accompanies your water chamber and follow

Check the user manual that accompanies your water chamber and follow the weekly care instructions.

If using the Auto-fill water chamber:

Do not wash this chamber. Carefully put the chamber aside.

- Thoroughly wipe the inside of the heated breathing tube connection port with a clean, low-lint cloth dipped in warm water with mild dishwashing detergent added.
- 6. Wipe the exterior of the unit with a clean, damp (not wet) cloth dipped in warm water with mild dishwashing detergent added. Do not use harsh abrasives or solvents, as these may damage the unit.
- 7. Reassemble your myAirvo 2 so that it is ready for your next therapy session (refer to the "Using your myAirvo 2" section).

5.3 Reprocessing for multiple patient use

The unit must be cleaned and disinfected between patients according to instructions in the Disinfection Kit Manual (900PT600). Single-patient use accessories must be disposed of between patients to prevent cross-contamination.

Supplies required for reprocessing the external surfaces of the myAirvo 2:

- Mild detergent
- 70% alcohol solution or 70% alcohol wipes
- Clean, disposable, lint-free cloths
- · Protective gloves

/!\ Warning

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 myAirvo 2 include: ammonia, ammonium hydroxide, caustic soda, iodine, methanol, methylated spirits, turpentine and alkaline bleaches such as sodium hypochlorite. Use of any of these products will damage the myAirvo 2.



Clean the outside surfaces of the myAirvo 2 (including the outlet elbow) with a cloth dipped in a solution of warm water and mild detergent. Use a clean, damp, disposable lint-free cloth to remove any residue.

Use an alcohol wipe or apply alcohol solution to a clean, disposable lint-free cloth to wipe the outside surfaces of the myAirvo 2. Allow to air dry.

5.4 Timetable for changing accessories

The accessories for the unit must be changed frequently to avoid the risk of infection. Parts should be replaced immediately if they are damaged or discolored; otherwise they must be replaced within the periods shown in the following table. These periods assume that the correct daily and weekly cleaning procedures and maintenance schedule described above are adhered to. If these procedures and schedules are not followed, the maximum periods of use will change to those stated in the AIRVO 2 manual. These accessories are for single-patient use only.

Maximum period of use	Part number	Product description
7 days per cannula	Optiflow Junior interfaces OJR416HM OJR418HM OPT316 OPT318	Optiflow Junior 2 Home Nasal Cannula - L Optiflow Junior 2 Home Nasal Cannula - XL Nasal Cannula - Infant Nasal Cannula - Pediatric
30 days per interface	Optiflow interfaces MYOPT9SMALL / OPT942E MYOPT9MEDIUM / OPT944E MYOPT9LARGE / OPT946E MYOPT9TRACHE / OPT970E MYOPT9MASK / OPT980E	Optiflow+ Nasal Cannula - Small Optiflow+ Nasal Cannula - Medium Optiflow+ Nasal Cannula - Large Tracheostomy Interface Mask Interface Adapter
60 days per kit	All tube & chamber kits MYAIRVOKIT1 / 900PT561 MYAIRSPIRAL / 900PT560 / 900PT560E 900PT501 900PT531 900PT500 / 900PT500E 900PT290E	AirSpiral tube and auto-fill chamber kit AirSpiral heated breathing tube Heated breathing tube, MR290 auto-fill chamber and adapter Junior heated breathing tube, MR290 auto-fill chamber and adapter Heated breathing tube MR290 auto-fill chamber and adapter
60 days per bag	900PT401	Water bag
3 months or 1000 hours (or more often if significantly discolored)	900PT913	Air filter
Reusable (2 years)	MYAIRVOCHAMBER1 HC360	Reusable water chamber
As required	WJR112 OPT012	Wigglepads 2 Wigglepads

Some products may not be available in your country. Please contact your local Fisher and Paykel Healthcare representative.

5.5 Filter replacement

After the myAirvo 2 has been switched on for a total of 1000 hours, a prompt will appear indicating that an air filter change is due. Follow the steps below if filter change is due:



- 1. Take the filter holder from the back of the unit and remove the filter.
- 2. Replace the old filter with a new one.
- 3. Reattach the filter holder to the unit (clip the bottom of the filter holder in first, then rotate it upwards until the top clips into place).
- 4. Press the Mode button to move on to the "Replace now" screen.
- 5. Press the Up button to select "Now".
- 6. Press the Mode button to confirm. The hours counter will be reset to zero.

If you choose the "Later" option, the prompt will continue to appear whenever the unit is switched on.

5.6 Servicing

This device contains no internal serviceable parts.

Refer to the myAirvo 2 Technical Manual for a list of external spare parts.

6. Alarms

The myAirvo 2 has visual and auditory alarms to warn you about interruptions to your treatment. These alarms are generated by an intelligent alarm system, which processes information from the sensors and target settings of the unit and compares this information to pre-programmed limits.

6.1 Alarm signals



6.2 Alarm conditions

All of the alarms listed below have been assessed as "Medium Priority". These priorities have been allocated for an operator's position within 1 meter of the device. The unit also uses an internal priority-ranking system. If multiple alarm conditions occur simultaneously, the unit will display the highest-priority alarm.

The following table lists all of the alarm conditions from highest-priority to lowest priority, their causes, possible solutions and delays. Alarm conditions that affect oxygen delivery require an immediate response to assess the patient's saturation levels. Alarm conditions that affect humidity delivery require a prompt response to assess potential drying of mucus and associated blockages.

The following alarm delays assume operation in "Ready for use" mode.

Message	Meaning	Affects delivery of:	Delays
Fault (E###)	<i>The unit has detected an internal fault.</i> Switch the unit off and then restart. If the problem persists, note the fault code and contact your Fisher & Paykel Healthcare representative.	Oxygen, humidity.	< 5 seconds
Check tube	The unit cannot detect the heated breathing tube. Check that the heated breathing tube is not damaged and that it is plugged in correctly. If the problem persists, then change the heated breathing tube.	Oxygen, humidity.	< 5 seconds
Check for leaks	The unit has detected a leak in the system. The most likely cause is that the water chamber has been removed or has not been pushed into place correctly. Check that the heated breathing tube is not damaged and that it is plugged in correctly. Check that the filter is fitted.	Oxygen, humidity.	< 120 seconds
Check for blockages	The unit has detected a blockage in the system. Check the heated breathing tube or patient interface for blockage. Check the air filter and filter holder for blockage. Check whether the unit should be in Junior Mode. If the patient will be using an Optiflow Junior nasal cannula (OPT316/OPT318/OJR416HM/OJR418HM), you must activate Junior Mode.	Oxygen, humidity.	< 10 seconds
O ₂ too low	The measured oxygen level has fallen below the allowed limit. Check that the oxygen source is still operational and is correctly connected. Adjust the level of oxygen from the oxygen source as necessary.	Oxygen	< 20 seconds
O ₂ too high	<i>The measured oxygen level has exceeded the allowed limit.</i> Check that the myAirvo flow rate is set correctly. Adjust the level of oxygen from the oxygen source as necessary.	Oxygen	< 20 seconds

(continued) Message	Meaning	Affects delivery of:	Delays
Cannot reach target flow	The unit cannot reach the target flow setting. Check the heated breathing tube or patient interface for blockage. Check whether the target flow setting is too high for the patient interface being used (refer to the "Using your myAirvo 2" - "Connect the patient interface"). You will be prompted for acknowledgement.	Oxygen	< 120 seconds
	Warning The oxygen concentration delivered to the patient can be affected by changes to the flow setting. Adjust the level of oxygen from the oxygen source as necessary.		
Check water	The chamber has run out of water. If using the reusable water chamber : Remove the chamber and refill. If using the auto-fill water chamber : When a chamber runs dry, the chamber float may be damaged. Replace the chamber and water bag. To ensure continual humidification, always ensure that the water chamber and/or water bag are not allowed to run out of water.	Humidity	< 30 minutes
Cannot reach target temperature	The unit cannot reach the target temperature setting. You will be prompted for acknowledgement. The most likely cause for this is that the unit is operating at a high flow rate in low ambient conditions. Consider increasing ambient conditions to match the recommended operating conditions or decreasing the target flow setting.	Humidity	30 +/- 3 minutes
	Warning The oxygen concentration delivered to the patient can be affected by changes to the flow setting. Adjust the level of oxygen from the oxygen source as necessary.		
Check operating conditions	The unit has detected that it is operating in unsuitable ambient conditions. This alarm may be caused by a sudden change in ambient conditions. Leave the unit running for 30 minutes. Switch the unit off and then restart.	Humidity	60 +/- 6 seconds
[Power out]	The unit has been disconnected from the mains/utility power socket. No visual alarm. The auditory alarm will sound for 120 seconds. If power is reconnected in this time, the unit will automatically restart.		~ 5
	Appropriate patient monitoring must be used at all times. Loss of therapy will occur if power is lost.	humidity.	seconds

6.3 Alarm limits

Most alarm limits are pre-programmed. The exceptions are listed below. These alarm limits may be changed to other values by authorized personnel. Changes will be preserved during or after any power loss.

Alarm condition	Factory-set alarm limit	Possible preset values
O ₂ too low	21% O ₂	21 or 25% O ₂
O ₂ too high	90% O ₂	30 – 90% O ₂ in 5% increments

/!\ Warnings

- · A hazard can exist if different alarm presets are used on different units within any single area, eg. long term care facility
- Alarm limits set to extreme values can render the alarm system useless.

6.4 Checking alarm system functionality

The functionality of the alarm system can be checked at any time when the unit is turned on. Remove the heated breathing tube. You should see the "Check tube" visual alarm signal and hear the auditory alarm signal. If either alarm signal is absent, do not use the unit. Contact your Fisher & Paykel Healthcare representative.

6.5 Auditory information signals

In addition to auditory alarm signals, auditory information signals are provided. These are described below.

Melody	Meaning
Ascending sequence of 5 tones	The "Ready for use" symbol has appeared
Ascending sequence of 3 tones	Activation/deactivation of Junior Mode
Descending scale of 3 tones (within 2 seconds)	Drying Mode has been activated
Single tone every 5 seconds	Measured oxygen level ≥ 33% at turn-off
Single tone every 30 seconds	Measured oxygen level > 95%

7. Advanced settings

-	
>	
-	

When you see the "Warm-up" or "Ready for use" symbols, you can press the Mode button to view and change advanced settings.

7.1 Target dew-point temperature



You can set the myAirvo 2 to three target dew-point temperature settings:

- 37°C (98.6°F)
- 34°C (93°F) [if compliance at 37°C is a problem]
- 31°C (88°F) [for face masks only].
- You may not have access to all settings, if:
- the unit is in Junior Mode (limited to 34 °C),
- the unit was initially set up with tighter limits.

The myAirvo 2 will remember its target dew-point temperature setting when you switch it off.

To change the target dew-point temperature setting:



1. Press the Up and Down buttons to choose the new setting.





- The large number in the center of the screen shows your chosen setting.
- The small numbers near the arrow show the minimum and maximum accessible settings.

You can set the myAirvo 2 to flows between 10 L/min and 60 L/min, in increments of 1 L/min



2. Press the Mode button to move on to the next screen.

(10-25 L/min) and 5 L/min (25-60 L/min). You may not have access to all settings, if:

• the unit was initially set up with tighter limits.

7.2 Target flow



To change the target flow setting:







• The large number in the center of the screen shows your chosen setting.

• the unit is in Junior Mode (limited to 2 - 25 L/min in increments of 1 L/min)

The myAirvo 2 will remember its target flow setting when you switch it off.

- The small numbers near the arrow show the minimum and maximum accessible settings.
- 2. Press the Mode button to move on to the next screen.

7.3 Day/Night Modes



You can set the myAirvo 2 to "Day" mode or "Night" mode.

In "Night" mode, some of the myAirvo 2 sounds will be made quieter. The display will become dimmed. Alarms will be unaffected.

"Night"

The myAirvo 2 will remember its Day/Night setting when you switch it off.

To change the Day/Night setting:



1. Press the Up and Down buttons to choose the new setting.



 \sim

7.4 Compliance



2. Press the Mode button to move on to the next screen.

"Day"

This screen displays three pieces of compliance data:

Total hours used	Displays the total number of hours that the unit has been switched on.
Hours per day	Displays the average number of hours that the unit has been used per day.
Checksum	Displays usage information for the medical practitioner.

Press the Mode button to return to the "Warm-up"/"Ready for use" screen.

7.5 Junior Mode

If the patient will be using an Optiflow Junior nasal cannula (OPT316/OPT318/OJR416HM/OJR418HM), you must activate Junior Mode. Do not use Junior mode for other patient interfaces.

Junior Mode limits the target settings to: 34 °C and 2 - 25 L/min, in increments of 1 L/min.

To activate Junior Mode:



To deactivate Junior Mode:



You must be able to see the "Warm-up" symbol or the "Ready for use" symbol to activate Junior Mode.

1. Hold the Mode button for 5 seconds.

New target settings

The target settings for dew-point temperature and flow will be changed automatically. The colorful icons in the corners of the screen indicate that this unit is in Junior Mode.

1. Hold the Mode button for 5 seconds.

If you are unable to activate Junior Mode, it is possible that Junior Mode may not have been enabled for your device. Contact your Fisher & Paykel Healthcare representative.

8. Technical information

8.1 Product specifications

Dimensions	295 mm x 170 mm x 175 mm (11.6" x 6.7" x 6.9")	Target temperature settings	37, 34, 31 °C
Weight	2.2 kg (4.8 lb) unit only, 3.4 kg (7.5 lb) packaged in bag incl. accessories	Humidity performance	>33 mg/L at 37 °C target >12 mg/L at 34 °C target >12 mg/L at 31 °C target
Supply frequency	50-60 Hz	Maximum temperature of	43 °C (109 °F)
Supply voltage/current	100-115 V 22 A (24 A max ⁺)	delivered gas	(in accordance with ISO 80601-2-74)
	220-240 V 1.8 A (2.0 A max ⁺)	0-240 V 1.8 A (2.0 A max ⁺) Maximum surface	
Sound pressure level	Alarms exceed 45dbA @ 1 m	temperature of applied parts	(in accordance with ISO 80601-2-74)
Auditory alarm pause	115 seconds	Flow range (default)	10-60 L /min*
Expected service life	5 years		
Serial port	The serial port is used for	(Junior Mode)	2-25 L/min*
	downloading product data, using F&P Infosmart software.	Maximum oxygen input	15 L/min
Warm-up time	10 minutes to 31 °C (88 °F), 30 minutes to 37 °C (98.6 °F) using an auto-fill chamber with flow rate of 35 L/min and starting temperature 23 ± 2 °C (73 ± 3 °F)	Oxygen analyzer accuracy	< ± 4 % (within the range 25-95% O ₂) Operating conditions: 18-28 °C (64-82 °F), 30-70% RH

* Flow rates are measured in BTPS (Body Temperature/Pressure, Saturated)

⁺ Inrush current may reach 50A

8.2 Operating conditions

8.3 Storage and transport conditions

Ambient temperature	18 - 28 °C (64 - 82 °F)	myAirvo	
Humidity	10 - 95% RH	Ambient temperature	-10 - 60 °C (14 - 140 °F)
Altitude	0 - 2000 m (6000 ft)	Humidity	10 - 95% RH, non-condensing
Mode of operation	Continuous operation	Tube & chamber kits	
		Ambient temperature	-10 - 50 °C (14 - 122 °F)
		The unit may require up t	to 24 hours to warm up or cool down from

the minimum or maximum storage temperature before it is ready for use.

/!\ Warning

Do not use the unit at an altitude above 2000 m (6000 ft) or outside a temperature range of 18 - 28 °C (64 - 82 °F). Doing so may affect the quality of the therapy or injure the patient.

8.4 Standards and approvals

IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2014 ANSI/AAMI 60601-1:2005/(R) 2012 CAN/CSA-C22.2 No. 60601-1:2014 EN 60601-1:2006 + A1:2013 ISO 80601-2-74:2017

Designed to conform to the requirements of: The unit complies with the electromagnetic compatibility requirements of IEC 60601-1-2. In certain circumstances, the unit may affect or be affected by nearby equipment due to the effects of electromagnetic interference. Excessive electromagnetic interference may affect the therapy delivered by the unit. If this should happen, try moving the unit or the location of the unit causing interference, or alternatively consult your healthcare provider. To avoid potential interference, do not place any part of the device or accessories within 30 cm (12") of any portable or mobile radio frequency communication equipment.

Accessory equipment connected to the serial port of the device must be certified to either IEC 60601-1 or IEC 60950-1. Furthermore 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 the technical services department or your local representative.

8.5 Disposal instructions

8.5.1 Device disposal instructions

X

This unit contains electronics. Please do not discard with regular waste. Return to Fisher & Paykel Healthcare or dispose according to local guidelines for disposing of electronics. Dispose according to Waste Electrical and Electronic Equipment (WEEE) directive in European Union.

8.5.2 Disposal of consumables

Place the interface, breathing tube and chamber in a bag at the end of use and discard with regular waste.

9. Glossary

9.1 Symbol definitions

3	For safety reasons, refer to the instructions for use		Class II equipment
	Caution	REF	Catalogue number
ĺĺ	Consult instructions for use	SN	Serial number
	Warning, hot surface	LOT	Batch code
	Manufacturer		Humidity range
~~	Date of manufacture		Temperature range
	Date of shelf life expiry	IP22	Protected against ingress of small objects and water drops
Ŕ	Type BF applied part	EC REP	EU representative
Rx only	(USA) Federal Law restricts this device to sale by, or on the order of a physician.	CE	CE Mark
\bigtriangleup	Alarm symbol		Power on/off (standby)
苾	Alarm pause		Regulatory Compliance Mark (RCM)