

Technical Manual







BEFORE YOU START

This Technical Manual is intended for clinical engineering / technical personnel. It defines the technical specifications, as well as setup and servicing information, for the AIRVO 2 humidifier. It applies to all lot numbers from 130621 and above.

OTHER REFERENCES

- Refer to the AIRVO 2 User Manual for detailed instructions for use, and watch the included instructional DVD.
- 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.

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1. GENERAL INFORMATION

The AIRVO 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.

PACKAGE CONTENTS



AIRVO 2 humidifier (PT101xx)



AIRVO 2 User Manual



AIRVO 2 Swingtag



AIRVO 2 DVD



Oxygen inlet extension kit (900PT422)



Disinfection Kit (900PT600)



Air filter (x2) (900PT913)



Power cord (900PT410xx)

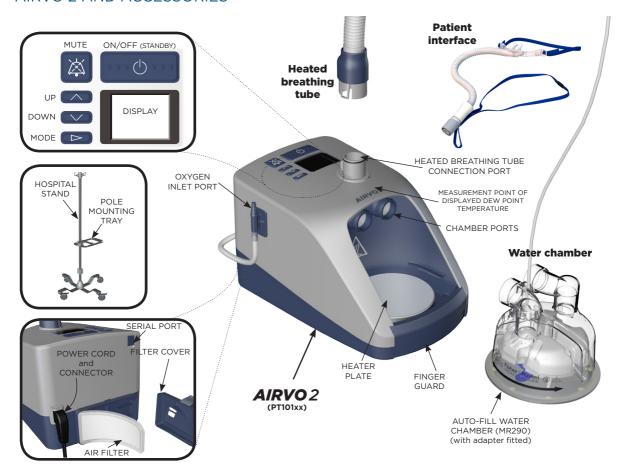
WARNING

UNDER NO CIRCUMSTANCES SHOULD THE AIRVO 2 BE OPENED OR ANY OF THE SIX FASTENING SCREWS ON THE UNDERNEATH SIDE OF THE DEVICE BE LOOSENED.

OPENING THE UNIT WILL AFFECT THE OXYGEN SEALS INSTALLED INSIDE, WHICH WILL COMPROMISE THE SAFETY OF THE DEVICE.



AIRVO 2 AND ACCESSORIES



2. SETTING UP AIRVO 2 FOR FIRST USE



1. REMOVE THE AIRVO 2 FROM ITS PACKAGING

Place the AIRVO 2 on the 900PT405 pole mounting tray, on the 900PT421 hospital stand.



2. CONNECT THE POWER CORD

For PT101AZ, PT101EE, PT101EW, PT101UK:

Plug the power cord connector into the socket on the back of the $\mbox{\sc AIRVO}$ 2.



For PT101US:

Use the cable tie in the Oxygen Inlet Extension Kit (900PT422) to secure the power cord connector.



3. ATTACH THE OXYGEN INLET EXTENSION KIT

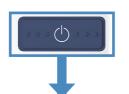
Refer to the instruction sheet included with the kit itself.



4. ATTACH WATER CHAMBER AND HEATED BREATHING TUBE

The water chamber and heated breathing tube must be connected to carry out the following setup and testing procedures.

If you have not been supplied with a reusable HC360 water chamber, you can use an MR290 chamber instead.



5. SWITCH ON UNIT

Switch on the unit by pressing the On/Off button.



6. WARM-UP

The unit will begin to warm up.



"Warm-up" symbol



7. READY FOR USE

The "Ready for Use" symbol means that the system is ready for the patient to use.



"Ready for use" symbol



ADVANCED SETTINGS

When you see the "Warm-up" or "Ready for use" symbols, hold a combination of three buttons (Up, Down and Mute) for 5 seconds, to view and change advanced settings.

This button combination is for use by clinical engineering / technical personnel only.



AIRVO 2 / myAIRVO 2 MODE

You can change the unit from "AIRVO" (hospital) mode to "myAIRVO" (home / long-term care) mode, eg. for patients going home.

Contact Fisher & Paykel Healthcare for a myAIRVO 2 User Manual.



To change the mode:

Hold the Up and Down buttons for 3 seconds to "unlock" the setting.

Use the Up button to select myAIRVO 2.



Press the Mode button to confirm the change and/or move on to the next screen. Note that the unit will reset itself if it is switched between AIRVO 2 and myAIRVO 2 modes.

LANGUAGE

You can set the AIRVO 2 / myAIRVO 2 to one of 15 language settings:



Nederlands nl
Português pt
Dansk da
Suomi fi



To change the language:

Hold the Up and Down buttons for 3 seconds to "unlock" the setting.

Use the Up and Down buttons to select the desired language. $\,$



Press the Mode button to confirm the change and/or move on to the next screen.



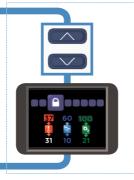
ENVIRONMENT SETTINGS (FOR DEFAULT MODE)

A clinician may change the "Environment Settings", to customise individual AIRVOs for different environments (eg. intensive care, general care areas, emergency departments). The "Environment Settings" chosen will put limits on the "Patient Settings" that the operator can choose when in normal use.

This screen defines the "Environment Settings" for the AIRVO 2 when in Default Mode (ie. non-"Junior Mode").

Minimum dew-point temperature (°C)	The lowest target dew-point temperature that the operator will be able to select. Possible Settings: 31, 34, 37 °C If this is set to 31, the operator can select a target dew-point temperature between 31 and 37. ie. 31, 34 or 37 (°C). If the patient is tracheostomised, a clinician may wish to set this value to 37, so that the operator can only select a target dew-point temperature between 37 and 37, ie. only 37 (°C). Note: The maximum dew-point temperature setting is always 37 °C in Default Mode.
Minimum flow (L/min)	The lowest flow that the operator will be able to select. Possible Settings: 10 to 60 in increments of 5 or 1 L/min, always less than or equal to Maximum Flow setting. Example: If this is set to 10, the operator will be able to select flows down to 10 L/min. If this is set to 25, the operator will be able to select flows down to 25 L/min.
Maximum flow (L/min)	The highest flow that the operator will be able to select. Possible Settings: 10 to 60 in increments of 5 or 1 L/min, always greater than or equal to Minimum Flow setting. Example: If this is set to 60, the operator can select flows up to 60 L/min. If this is set to 35, the operator can select flows up to 35 L/min.
Maximum oxygen fraction (%)	The highest oxygen fraction that the operator may set the unit to. Possible settings: 30 - 100% in increments of 5% O2. The unit will alarm if the measured oxygen fraction exceeds this value.
Minimum oxygen fraction (%)	The lowest oxygen fraction that the operator may set the unit to. Possible settings: 21 or 25% O2. When set to 25% the unit will alarm if the measured oxygen fraction is below this value. This allows detection of oxygen being disconnected.

Note that, for Oxygen display, this is a measurement only, not a control setting. The operator changes the measured oxygen fraction by altering the AIRVO 2 target flow setting and the flow of oxygen connected to the unit (e.g. from a flowmeter) - there is no closed-loop control.



To change the environment settings:

Hold the Up and Down buttons for 3 seconds to "unlock" the first setting.

Use the Up and Down buttons to change the setting, then press the Mode button to progress to the next setting.



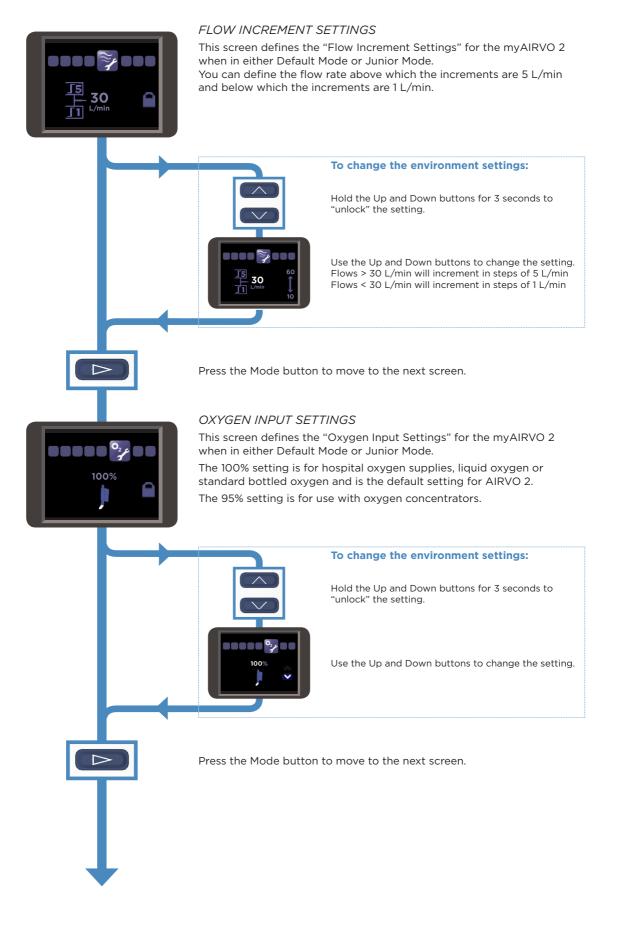
Press the Mode button to move to the next screen.

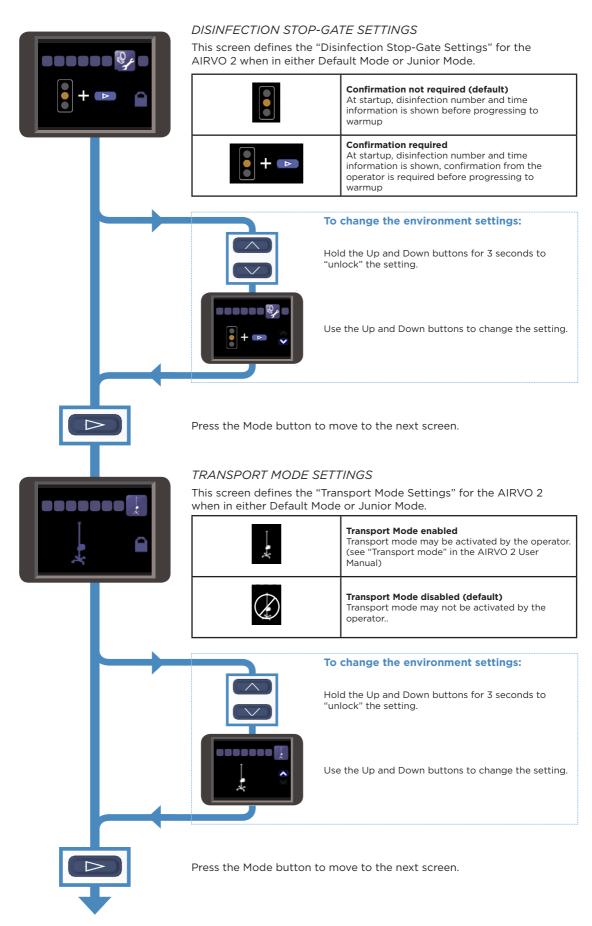


ENVIRONMENT SETTINGS (FOR JUNIOR MODE)

This screen defines the "Environment Settings" for the AIRVO 2 when in Junior Mode.					
Junior Mode Enable/Disable	When this option is enabled (default), the operator can enter Junior Mode from the Home Screen, by holding the Mode button for 5 seconds. When this option is disabled, entering Junior				
0 Disabled	mode is not possible. Consider disabling this option if the unit will never be used on pediatric patients.				
Dew-point temperature (°C)	The only dew-point setting in Junior Mode is 34 °C.				
Minimum flow (L/min)	The lowest flow that the operator will be able to select. Possible Settings: 2 to 25 in increments of 5 or 1 L/min, always less than or equal to Maximum Flow setting. If this is set to 10, the operator will be able to select flows down to 10 L/min.				
Maximum flow (L/min) 25	The highest flow that the operator will be able to select. Possible Settings: 2 to 25 in increments of 5 or 1 L/min, always greater than or equal to Minimum Flow setting. If this is set to 15, the operator can select flows up to 15 L/min.				
Maximum oxygen fraction (%)	The highest oxygen fraction that the operator may set the unit to. Possible settings: 30 - 100% in increments of 5% O2. The unit will alarm if the measured oxygen fraction exceeds this value.				
Minimum oxygen fraction (%)	The lowest oxygen fraction that the operator may set the unit to. Possible settings: 21 or 25% O2. When set to 25% the unit will alarm if the measured oxygen fraction is below this value. This allows detection of oxygen being disconnected.				
operator changes the measured	his is a measurement only, not a control setting. The d oxygen fraction by altering the AIRVO 2 target gen connected to the unit (e.g. from a flowmeter) l.				
То	change the environment settings:				
	ld the Up and Down buttons for 3 seconds to llock" the first setting.				
the	e the Up and Down buttons to change the setting, en press the Mode button to progress to the next ting.				

Press the Mode button to move to the next screen.



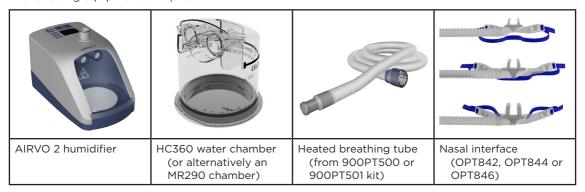


3. ACCEPTANCE/PERFORMANCE CHECKS

This section contains performance checks which can be carried out on the AIRVO 2, however there is no manufacturer requirement to carry out these checks on a routine basis. These checks test the basic functioning of the unit, the operation of the flow sensor as well as the audible alarm signal.

They should be conducted under the following ambient conditions: Temperature: $22 \pm 2^{\circ}$ C, Humidity: $50 \pm 5\%$ RH.

The following equipment is required:



HEATERPLATE TEST

- 1. Add 200mL of room temperature (not hot) water to the water chamber and fit the chamber onto the heater plate of the device. Fit the chamber tightly on to the chamber ports.
- 2. Connect the heated breathing tube to the Heated Breathing Tube Connection port. Connect the nasal cannula interface to the heated breathing tube.
- 3. Turn on the device, by pressing the power button for 2 seconds. Warm-up bars will be displayed as the unit warms up. Ensure the flow is set to 20 L/min.
- 4. Check that the "Ready for use" symbol (a "tick" or "check") is displayed within 30 minutes.

"CHECK FOR LEAKS" TEST

After the "Ready for use" symbol is displayed, the "Check for leaks" sensor test can be tested as follows:

- 1. Remove the chamber.
- 2. Check that the display shows the "Check for leaks" error (in the appropriate language) and that the audible alarm sounds, within 60 seconds.
- 3. Reconnect the chamber and check that this flashing display disappears, the audible alarm stops and the display reverts back to the Warm-up/Ready-for-use screen.

"CHECK FOR BLOCKAGES" TEST

After completing the "Check for leaks" test, the "Check for blockages" test can be tested as follows:

- 1. Disconnect the cannula from the Heated Breathing Tube.
- 2. Block the end of the Heated Breathing Tube with your hand.
- 3. Check that the display shows the "Check for blockages" error (in the appropriate language) and that the audible alarm sounds, within 30 seconds.
- 4. Unblock the end of tube and check that this flashing display disappears, the audible alarm stops and the display reverts back to the previous display.
- 5. Reconnect the cannula to the Heated Breathing Tube.

"CHECK TUBE" TEST

After completing the above flow tests, the Tube Missing alarm can be tested as follows:

- 1. Remove the Heated Breathing Tube (pull the blue sleeve up first).
- 2. Check that within 10 seconds the display flashes the Breathing Tube symbol and the alarm sounds.
- 3. Refit the Heated Breathing Tube, check the alarm stops and that the display reverts back to the previous display.

4. SERVICING

AIRVO 2 and myAIRVO 2 humidifiers do NOT require routine servicing or calibration.

The only checks that can be carried out are the Acceptance/Performance Checks in the previous section, and the Electrical Safety Test detailed below.

WARNING

UNDER NO CIRCUMSTANCES SHOULD THE AIRVO 2 BE OPENED OR ANY OF THE SIX FASTENING SCREWS ON THE UNDERNEATH SIDE OF THE DEVICE BE LOOSENED. OPENING THE UNIT WILL AFFECT THE OXYGEN SEALS INSTALLED INSIDE, WHICH WILL COMPROMISE THE SAFETY OF THE DEVICE.



ELECTRICAL SAFETY TESTS

To test for electrical safety perform the following electrical safety tests and any others required by local regulations.

Inspection	Check the power cord for damage - cuts, stretching, wear, adequate cable restraint, bent pins. Replace with F&P approved cord if necessary.
Insulation Resistance	Use a 500 VDC insulation tester to measure the resistance between the mains plug phase pin and the heaterplate* - it should be > 10 Mohm. Repeat test from the mains plug neutral pin to the heaterplate*. * Note: The exposed surface of the heaterplate is anodised (high resistance). Contact MUST be made to the bottom lip of the heaterplate at the front of the device to make proper connection - depress the finger guard and slip the tester probe beneath the heaterplate to ensure contact to unanodised aluminium.

SPARE PARTS

Power Cord (Aus/NZ)	900PT410AZ	
Power Cord (European)	900PT410EW	
Power Cord (UK)	900PT410UK	
Power Cord (US/Canada)	900PT410US	
Filter Cover	900PT912	

STORAGE AND DISPOSAL

Refer to AIRVO 2 User Manual.

APPENDIX A: IEC60601-1-2 EMC TABLES

Guidance and manufacturer's declaration - electromagnetic emissions

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

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

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance		
Electrostatic discharge (ESD)	±2kV ,±4kV, ±6kV contact	±2 kV,±4kV, ±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the		
IEC61000-4-2	±2 kV ,±4kV, ±8 kV air	±2 kV ,±4kV, ±8 kV air	relative humidity should be at least 30%.		
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV	Mains power quality should be that of a typic		
IEC61000-4-4	±1 kV for input/output lines	See note 2 below	commercial or hospital environment.		
Surge	±1 kV differential mode	±1 kV			
IEC 61000-4-5	±2 kV common mode	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.		
	<5 % <i>U</i> T	<5 % U _T			
	(>95 % dip in UT)	(>95 % dip in UT)			
Voltage dips, short interruptions and	for 0.5 cycle	for 0.5 cycle			
voltage variations on power supply	40 % <i>U</i> T	40 % <i>U</i> T			
input lines	(60 % dip in UT)	(60 % dip in UT)	Mains power quality should be that of a typical		
	for 5 cycles	for 5 cycles	commercial or hospital environment. If the user of the device requires continued operation during		
	70 % <i>U</i> T	70 % <i>U</i> T	power interruptions, it is recommended the device be powered from an uninterruptible power supply		
IEC 61000-4-11	(30 % dip in UT)	(30 % dip in U _T)	or a battery.		
	for 25 cycles	for 25 cycles			
	<5 % <i>U</i> T	<5 % <i>U</i> T			
	(>95 % dip in U _T)	(>95 % dip in U _T)			
	for 5 sec	for 5 sec			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		

NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.

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

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test IEC60601 test level		Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
IEC 01000-4-3	80 WHZ to 2,5 GHZ		$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:
			$((\overset{\bullet}{\blacktriangle}))$

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

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

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

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

	Separation distance according to frequency of transmitter m			
Rated maximum output power	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
of transmitter W	d = 1.2 √P	d =1.2 √P	$d=2.3 \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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

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

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

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

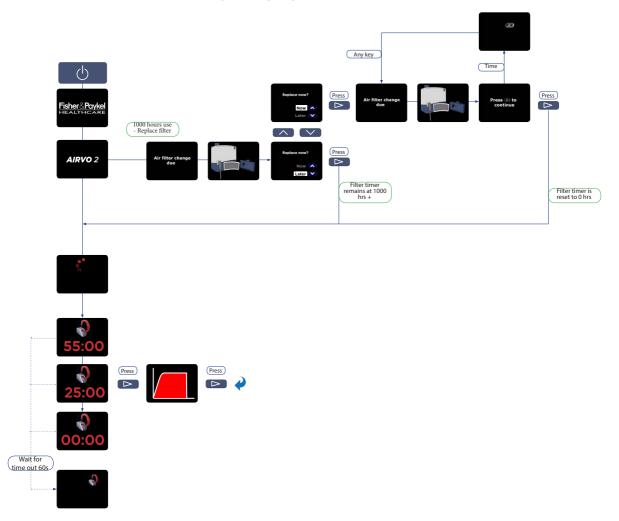
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

APPENDIX B: USER INTERFACE FLOW CHARTS

AIRVO 2



DISINFECTION



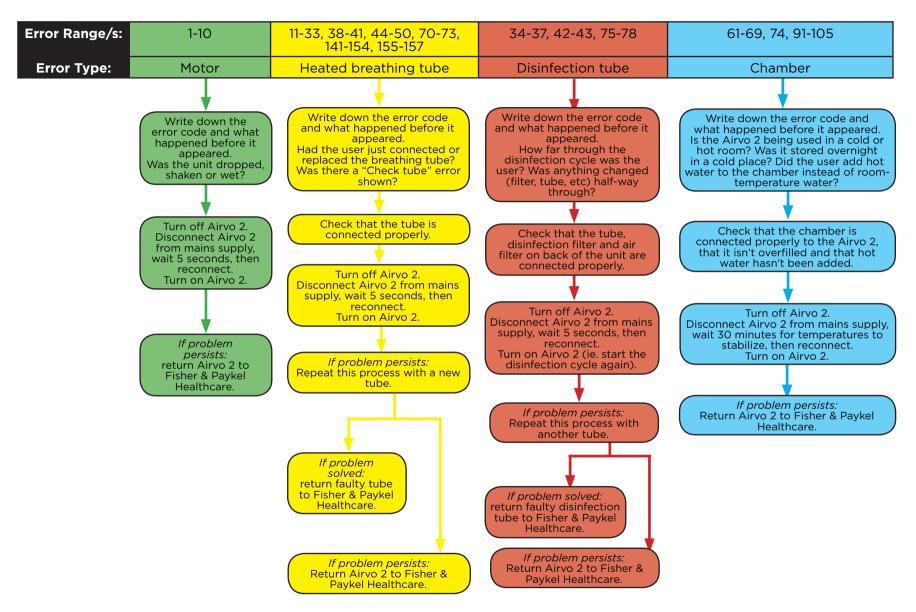
APPENDIX C: DEFAULT VALUES

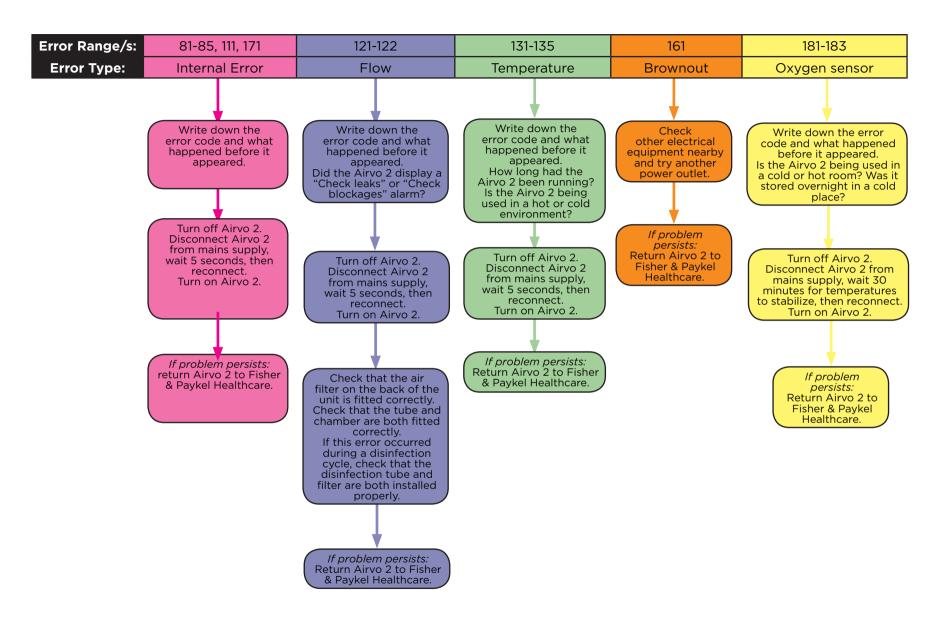
The following values are default non-alarm settings set by the factory:

Parameter	Model	Mode	Value	Unit
Default set dewpoint	AIRVO 2 or myAIRVO 2	Default	37	°C
temperature	AIRVO 2 or myAIRVO 2	Junior	34	°C
Max set dewpoint	AIRVO 2 or myAIRVO 2	Default	37	°C
temperature	AIRVO 2 or myAIRVO 2	Junior	34	°C
Min set dewpoint	AIRVO 2 or myAIRVO 2	Default	31	°C
temperature	AIRVO 2 or myAIRVO 2	Junior	34	°C
Default set flow	AIRVO 2	Default	30	L/min
	myAIRVO 2	Default	25	L/min
	AIRVO 2 or myAIRVO 2	Junior	15	L/min
Max set flow	AIRVO 2 or myAIRVO 2	Default	60	L/min
	AIRVO 2 or myAIRVO 2	Junior	25	L/min
Min set flow	AIRVO 2 or myAIRVO 2	Default	10	L/min
	AIRVO 2 or myAIRVO 2	Junior	2	L/min
Defects consequent	AIRVO 2	Default or Junior	95	%
Default upper oxygen limit	myAIRVO 2	Default or Junior	90	%
1	AIRVO 2	Default or Junior	100	%
Max upper oxygen limit	myAIRVO 2	Default or Junior	90	%
Min upper oxygen limit	AIRVO 2 or myAIRVO 2	Default or Junior	30	%
Default lower oxygen limit	AIRVO 2 or myAIRVO 2	Default or Junior	21	%
Max lower oxygen limit	AIRVO 2 or myAIRVO 2	Default or Junior	25	%
Min lower oxygen limit	AIRVO 2 or myAIRVO 2	Default or Junior	21	%
Language	AIRVO 2 or myAIRVO 2	Default or Junior	English	
Flow Increment Crossover	AIRVO 2 or myAIRVO 2	Default or Junior	25	L/min
Oxygen Input	AIRVO 2	Default or Junior	100	%
Oxygen input	myAIRVO 2	Default or Junior	95	%
Disinfection Stop-Gate	AIRVO 2	Default or Junior	Confirmation not required	
Transport Mode	AIRVO 2	Default or Junior	Disabled	
Day/Night mode	myAIRVO 2	Default or Junior	Day	

APPENDIX D: TROUBLESHOOTING

The following pages provide troubleshooting advice for fault / error / "E" codes that may appear during use of the AIRVO 2.





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

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