Armstrong Medical

AquaVENT® FD140i

User Manual, English

Guidance

WARNING

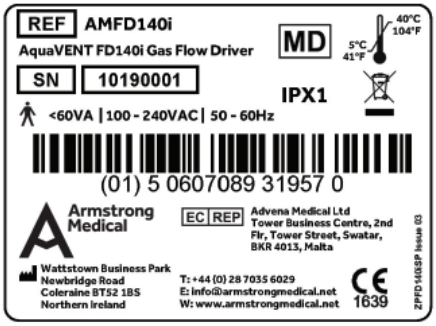
Correct operation of this device is described in this User Manual and on other documents or materials enclosed or provided by the manufacturer. It should only be assembled, operated, maintained and repaired according to such information.
The device must be checked prior to each clinical use to verify that it is operable and meets the user's requirements for delivery of therapy to patients. The device must be inspected at regular intervals by a competent person. The device must not be used if found to be defective. A defective device must be removed to a location where it is not at risk from inadvertent clinical use.
If a repair is necessary, the manufacturer and distributor recommend contacting the manufacturer or their authorised representative to arrange such works. Maintenance and repairs must only be carried out by the manufacturer or by competent persons authorised by the manufacturer to undertake such work. The user of the device shall have sole responsibility for any malfunction or damage which is due to improper use, poor maintenance, improper service, improper repairs or modifications carried out by unauthorised persons.
The device is provided with a serial number located on an identification plate at the rear of the device. The identification plate specifies the manufacturer and their contact details, the device product code and the device serial number.

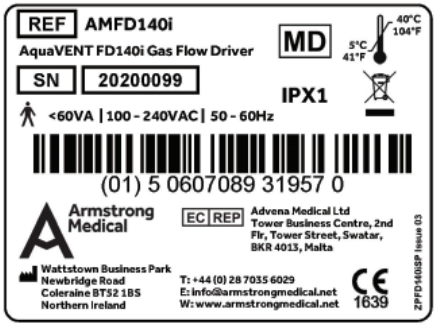
After set-up of a breathing system and prior to connection of the breathing system to the patient, verify that:

a. Gas flow is running in the breathing system.
b. Separate inspiratory and expiratory gas paths are present and functioning.

Serial number format

Example 1:	*10190001*
10190001	First "10" represents device with paramagnetic oxygen sensor option
10**19**0001	"19" represents 2019 (year of manufacture)
10190001	Last "1" represents the 1st device manufactured
Example 2:	*20200099*
20200099	First "20" represents device with oxygen fuel cell option
20**20**0099	"20" represents 2020 (year of manufacture)
2020099	Represents the 99th device manufactured





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1 Introduction

1.1 About this manual

This User Manual describes the intended use of AquaVENT® FD140i with software version 1.01.

AquaVENT® FD140i and accompanying User and Technical Manuals are available in English, French, German, Italian, Dutch and Spanish.

To ensure safe operation of AquaVENT® FD140i, the device must only be used as described in this manual. Before using AquaVENT® FD140i, the full contents of this manual must be read and understood. The AquaVENT® FD140i must only be used by qualified healthcare professionals trained in the operation of the device.

Armstrong Medical Ltd. reserves all rights to further develop and alter AquaVENT® FD140i in the interest of technical progress and patient safety.

CE 1639

AquaVENT® FD140i complies with Medical Devices Directive, provided it is operated according to the User Manual. "1639" is the identification number of the Notified Body.

MD

WARNING

- Read the entire manual before using the AquaVENT® FD140i
- AquaVENT® FD140i is for use only by trained healthcare professionals and only within a healthcare facility

- Use AquaVENT® FD140i only for the intended use as described in this manual.

1.2 Indications for use

AquaVENT® FD140i is a gas flow driver, delivering an air and oxygen mixture at 21-100%. It is a clinical respiratory therapy device which assists respiration using continuous positive airway pressure (CPAP) and high flow oxygen therapy (HFOT) in patients in a hospital setting. Such patients must be medically-indicated by a healthcare professional for the respective therapy once assessed as conscious and breathing spontaneously and not at significant risk of conditions of exacerbation caused by the therapy or at risk of a prolonged apnoeic event. AquaVENT® FD140i is not a life-support device.

Always verify that an expiratory gas path is present and functioning BEFORE commencing therapy on a patient.

CPAP therapy can be applied in different modes and delivered using a suitable breathing circuit connected to a face mask, tracheal tube or tracheostomy tube or by helmet. In the case of BUBBLE-PAP mode the circuit is connected to a nasal cannula. Furthermore, AquaVENT® FD140i can be used as a gas flow driver for High Flow Oxygen Therapy (HFOT) delivered via nasal cannula, face mask and tracheostomy tube. With the exception of CPAP Helmet therapy, we advise that all breathing circuits in use must be set-up to deliver the gas as heated and humidified.

AquaVENT® FD140i is intended for use with adults, children and new-born babies should they be medically-indicated for the therapy and should the therapy be listed as suitable for that patient group. This device is not recommended for use in a domestic environment.

AquaVENT® FD140i is equipped either with a paramagnetic oxygen sensor or a replaceable oxygen fuel cell. These sensors continuously measure O_2 delivery to the breathing circuit. This value is displayed on the screen. To ensure that hypoxemic and hyperoxic gas mixtures are not inadvertently delivered to patients, we advise that O_2 delivery is monitored at all times during therapy and that external peripheral oximetry is considered as an adjunct.

The paramagnetic oxygen sensor is maintenance-free. It should be calibrated once annually or when the device has been moved or transported – such that vibration of the device as occurred. The replaceable oxygen fuel cell has a finite usable life-time based on volume of gas flow delivered to the breathing circuit.

The device is equipped with an internal rechargeable battery with an integrated mains power failure alarm.

Clinical use of FD140i should be on mains power. Use on battery power should be restricted to short periods where mains power is not available or convenient to use, such as during patient transportation. In the event that FD140i is to be used on battery power, ensure that it is charged prior to use - preferably showing 100% remaining battery capacity on the display. Full battery charge level is associated with a solid green indicator LED. This LED is located on the bottom right corner of the front panel, above the 'ON/OFF' button.

1.3 Contraindications

This section details some, but not all conditions, which make the following therapies inadvisable:

CPAP
- Respiratory arrest or unstable cardiorespiratory status
- Reduced consciousness
- Apnoea
- Inability to protect airway
- Extremely anxious patient
- Facial trauma / burns
- Facial, oesophageal, or gastric surgery
- Low blood pressure secondary to blood loss
- Stomach surgery or bowel bleeding

Helmet CPAP
- Claustrophobic or tetraplegic patients
- Tidal volume monitoring requirement

Paediatric CPAP
- Obstruction of sinonasal polyposis (SNP) from secretions
- Pulmonary interstitial emphysema
- Pneumomediastinum
- Pneumothorax
- Decreased cardiac output (due to decreased venous return) with excessive CPAP levels
- Inadequate ventilation
- Gastric distension or feed intolerance
- Increased work of breathing due to increased airway resistance (related to diameter of SNP)

BUBBLE-PAP
- Obstruction of SNP
- Large emphysematous bullae
- Acute asthma or severe bronchospasm
- Lung abscess
- Severe fibrotic changes
- Increased work of breathing e.g. COPD or acute asthma
- Intracranial pressure >20mmHg
- Dialysis

High Flow Oxygen Therapy (HFOT)
- Pneumothorax
- Acute bullous lung disease
- Low blood pressure
- Cerebrospinal fluid leak
- Cranial surgery / trauma

POINT
- Any contraindication to CPAP
- Reduced levels of consciousness
- Extremely anxious patient patients
- Epistaxis
- Facial injury
- Airway obstruction

1.4 Adverse effects

The most common adverse effects during CPAP therapies are face mask or helmet or gas flow/pressure related. Some patients may experience claustrophobia due to the mask, nasal congestion, rhinitis or a runny nose. To minimise these adverse effects ensure that:

- Correct face mask size is used – if the mask is too small / large it may result in discomfort and air leaks.
- Mask is not overtightened – may result in mask discomfort and damage to the skin.
- Heated humidified air is used via a heater humidifier.

Helmet CPAP is predisposed to CO_2 rebreathing and could increase the patients' ventilator asynchrony.

In addition to the adverse effects stated above, Paediatric CPAP may result in congestion, dry mouth, lip bleeds or nosebleeds. Masks may cause irritation or redness of the skin. Using the correct mask size and padding can minimise pressure sores from tight contact with skin.

BUBBLE-PAP may also cause nosebleeds; humidification can often help with these symptoms. Again, heated humidified air can help to prevent nosebleeds from occurring.

Adverse effects when using HFOT can include skin irritation, skin breakdown and nasal dryness. It is important to be aware that HFOT can lead to suppression of breathing, oxygen toxicity and is a fire hazard at high oxygen concentrations.

1.5 General safety precautions

To ensure safe operation of AquaVENT® FD140i , all precautions contained within this chapter must be adhered to, in addition to all other warnings, cautions and notes dispersed throughout the User Manual.

WARNING	Alerts you to a situation which may cause patient or user injury
CAUTION	Explains measures for the effective use of the device
NOTE	Refers to important information which should be taken into consideration by the user.

WARNING

- AquaVENT® FD140i is for use only by trained healthcare professionals and only within a healthcare facility.
- Patients receiving respiratory therapy should be closely monitored by a qualified healthcare professional, trained in the use of the device.
- AquaVENT® FD140i is not intended to be operated by patients.
- Electromagnetic interference may occur if the device is not used in accordance with this User Manual. AquaVENT® FD140i has been tested and complies with BS EN 60601-1-2:2015. Information on electromagnetic compatibility can be found under Section 8.7.
- AquaVENT® FD140i must not be used in close proximity to nuclear magnetic resonance equipment. Devices in the vicinity of AquaVENT® FD140i, which generate electromagnetic fields, can affect the safe operation of the device and endanger the patient.
- Mobile telephones and any portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30cm (12 inches) of any part of AquaVENT® FD140i. This can result in improper operation of the device.
- AquaVENT® FD140i must not be used in the presence of flammable substances or in potentially explosive atmospheres.
- AquaVENT® FD140i is designed for use only within the limits of the operating environment described in Section 8.1 Technical Specification. If the temperature of AquaVENT® FD140i is higher or lower than its specified operating range then wait 1-hour to allow the device to adjust to operating temperature prior to use.
- AquaVENT® FD140i should not be positioned such that the cooling fan outlet is obstructed.
- AquaVENT® FD140i must always be disconnected from mains power before any cleaning, maintenance or repair.
- Use of this equipment, adjacent to, or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment should be observed to verify that they are operating normally. Device setup has been described in Section 3 of this manual.

CAUTION

- Use of other electrical equipment with AquaVENT® FD140i or in its vicinity should be avoided, as it can result in improper operation. If such use is necessary, AquaVENT® FD140i and other equipment must be verified prior to connecting the patient to AquaVENT® FD140i.

NOTE

- 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 from radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re- orienting the equipment.

1.6 Limitation of liability

The manufacturer shall not accept any liability for damages due to:

- Failure to adhere to this User Manual
- Use of device by untrained personnel
- Improper use / maintenance
- Unapproved modifications to the device
- Use of unapproved spare parts

1.7 Copyright

This User Manual may only be copied, photocopied, reproduced or translated in to other languages for personal use. Reproduction for disclosure to third parties is not permitted without prior written consent from Armstrong Medical Ltd.

1.8 Service life

When the device is used correctly and in-line with this User Manual, the expected service life of AquaVENT® FD140i is 10 years from the date of delivery to the hospital.

1.9 Warranty

The warranty conditions correspond with Armstrong Medical's terms and conditions at the time of purchase. Warranty will be valid for 2-years from the date of delivery to the hospital and will cover defects in parts and labour that arise when the repaired device is used correctly and in-line with this User Manual.

2 AquaVENT® FD140i Overview

2.1 Principle of operation

AquaVENT® FD140i is an electronic gas flow driver which delivers an adjustable blend of medical air and oxygen to the patient via an attached breathing circuit. The device has six preset respiratory therapies;

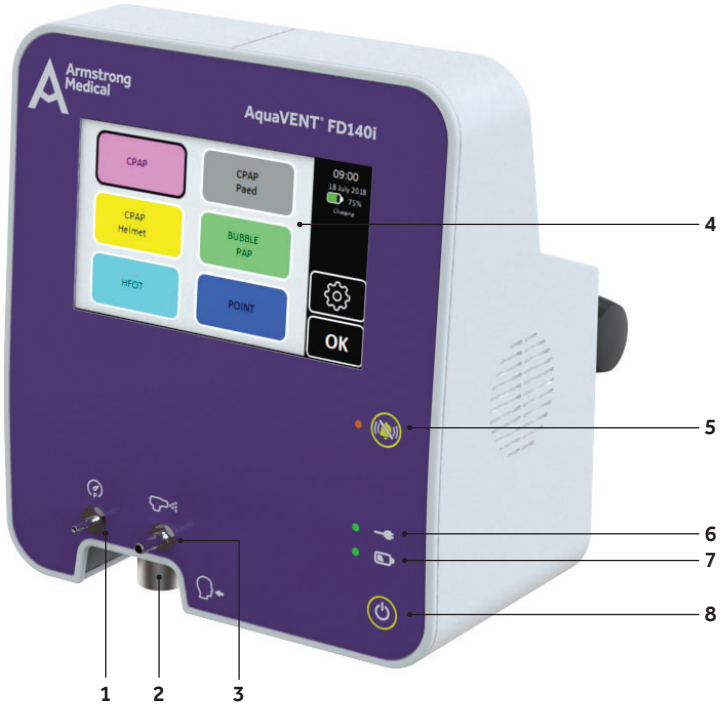
- CPAP
- CPAP Paed
- CPAP Helmet
- BUBBLE-PAP
- HFOT
- POINT®

For a description of each therapy please refer to Section 3.7 "Breathing circuit setup".

Each mode has customized settings according to the therapy characteristics. The device is also equipped with a nebuliser outlet port which supplies a flow of medical air for driving a jet nebuliser containing liquid drug suspension.

AquaVENT® FD140i incorporates a user friendly touch screen interface facilitating intuitive operation. Its sophisticated alarm system and advanced oxygen sensing technology collaborate to safeguard patient care. Additionally, the device is equipped with an internal Li-Ion battery for uninterrupted operation in the event of a temporary disconnection from the mains supply.

2.2 Device layout

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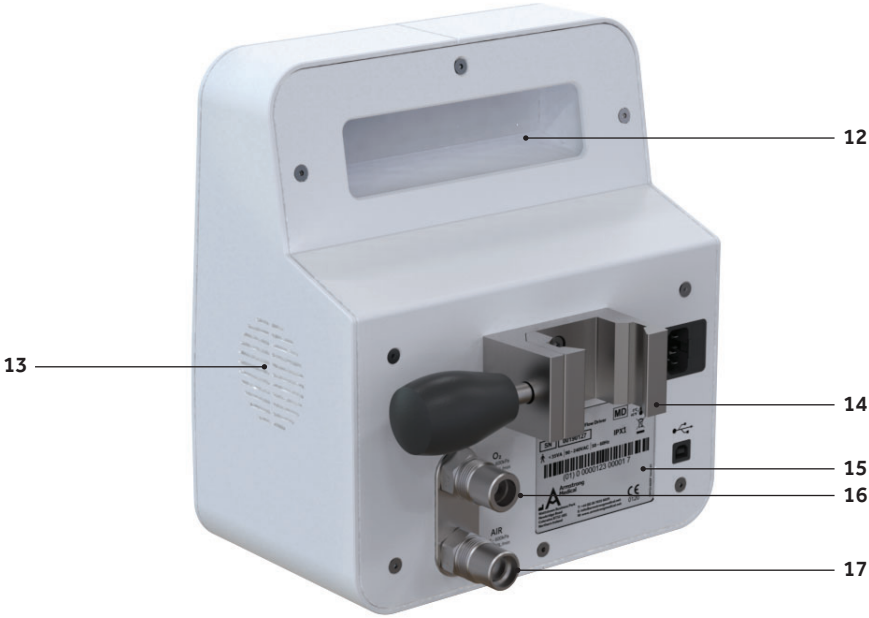
10
11
REF AMFD140i
AquaVENT FD140i Gas Flow Driver
MD
SN 00190127
IPX1
(01) 0 0000123 00001 7
Armstrong Medical
O2
270 - 600kPa
Min. 150L/min
AIR
270 - 600kPa
Min. 150L/min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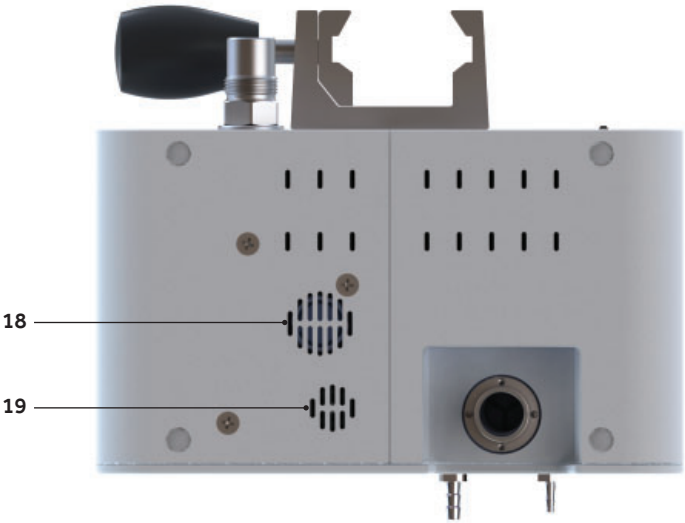


Item	Description
1	Pressure measurement port
2	Respiratory gas outlet
3	Nebuliser port
4	Touch screen
5	Alarm mute button
6	Mains power connection indicator
7	Battery status indicator
8	Power on/off button
9	Refer to instruction manual/booklet
10	Mains power inlet
11	USB connector
12	Handle
13	Fan outlet
14	Fixation claw
15	Serial plate
16	Medical Oxygen inlet
17	Medical Air inlet
18	Over pressure relief valve
19	Anti-asphyxiation entrainment valve

2.3 Therapy modes technical specification

Mode	CPAP	CPAP (Paed)	Helmet CPAP	BUBBLE-PAP	HFOT	POINT
Interface screen colour	Purple	Grey	Yellow	Green	Light blue	Dark blue
Flow range (L/min)	20-140	10-70	40-140	2-20	2-70	10-80
Default flow (L/min)	60	20	60	5	20	30
Oxygen range (%)	21-100	21-100	21-100	21-80	21-100	21-100
Default oxygen (%)	30	30	30	30	30	60
Pressure measured	Yes	Yes	Yes	Yes	No	No
Breath frequency measured	Yes	Yes	Yes	No	No	No
Nebuliser ON	Yes	Yes	No	No	Yes	Yes
Pressure alarm range (cmH_2O)	2-25 and OFF	2-25 and OFF	2-25 and OFF	2-15 and OFF	-	-
Default pressure alarm 'Low'	2	2	2	2	-	-
Default pressure alarm 'High'	12	12	12	10	-	-
Apnoea alarm range (sec)	20-60	20-60	20-60	-	-	-
Default apnoea alarm period (sec)	20	20	20	-	-	-

2.4 Device interface

Front panel icons and indicator lights

Description
1. Power source indicators
 AC mains power supply is connected when indicator light is illuminated
 Running on internal battery when indicator light is illuminated solid green
 Internal battery is charging when indicator light is flashing green
 Internal battery level is ≤ 20% charged when indicator light is illuminated solid red
2. Power on or off device
 Power on or off device
3. Alarm mute
 Alarm audio is muted when indicator light is flashing orange
 Alarm audio is sounding when indicator light is solid orange
4. Gas ports
 Respiratory gas outlet
 Patient pressure measurement connection
 Nebuliser port

Touch screen icons

Description

1. Screen lock


Screen Locked

2. Power supply and battery charge indication


Device unplugged from mains power

Internal battery level-percentage charged (alternates between battery icon and unplugged icon)
Battery level at 20% or below


Charging
Battery charging

3. General settings


General Settings Menu


Return to previous menu


Touch tone volume


Alarm volume


Screen brightness


Language selection

4. Therapy settings


Adjust flow settings


Adjust alarm settings


Select approximate value


Increase value incrementally


Decrease value incrementally


Minimum permissible value


Maximum permissible value


Therapy timer


Start therapy


Stop therapy


Nebuliser gas supply off


Nebuliser gas supply on


Respiratory gas values


In therapy icon

5. Alarms


Warning - alarm activated


Alarm silenced

3 Device Setup

3.1 Unpacking

When unpacking AquaVENT® FD140i, the following parts should be present:

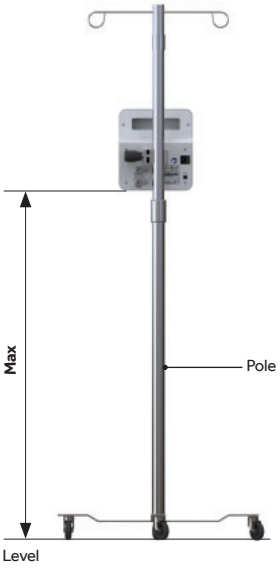
- AquaVENT® FD140i device
- Power lead
- User Manual
- Technical Manual (optional)

If all the parts listed above are not present, please contact the manufacturer.

NOTE The protective packaging containing the device should be retained for when the device is being transported back to the manufacturer for service or repair. This is to prevent damage to the device during transportation.

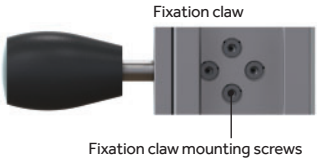
3.2 Mounting

AquaVENT® FD140i has been designed to be mounted on a pole stand such as would commonly be used with a patient on a "drip". The device should be mounted such that the touch screen can be comfortably viewed and accessed by the healthcare giver.



CAUTION

Before mounting the device on a pole stand, open the Fixation Claw fully by rotating the handle in an anticlockwise direction and ensure that the 4x M5 screws on the back of the fixation claw have been fully tightened.



WARNING

- The device should be mounted on approved pole stands only with a load capacity of at least 10Kg.
- Do not mount the device at a height greater than 1400mm measured from the base of the device to the floor.
- Ensure that the supporting pole stand is on a level floor.
- When not transporting the device, ensure that the pole stand castors are locked.
- Ensure the power lead is always readily connectable to a mains power supply. Also ensure that the device can easily be disconnected from mains power supply in the event of an emergency.

CAUTION

- The Fixation Claw handle should be positioned on the same side as the O_2 and AIR inlet connectors only.
- AquaVENT® FD140i is designed for mounting on a vertical pole stand and should not be mounted on a horizontal pole.
- The device should not be bed-mounted.
- If the device is used in conjunction with a heater humidifier it should be mounted approximately 600mm above the humidification chamber.
- When moving AquaVENT® FD140i whilst it is mounted on a pole stand, the device should be lowered down the pole in order to increase stability in motion.
- During transportation, the water bag should be removed from the pole stand in order to prevent water entering the enclosure in the event of a spillage.

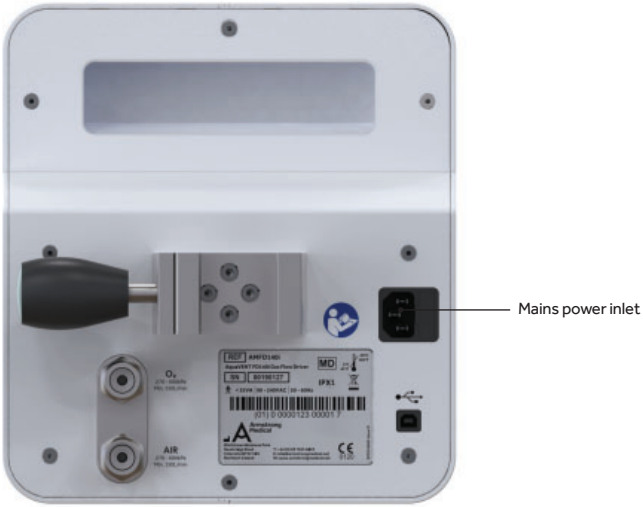
3.3 Power supply

Connecting to Mains Supply

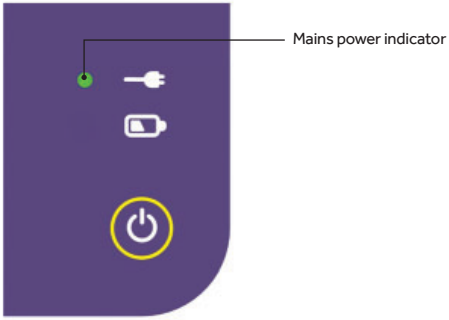
Connect the original power lead to the mains power inlet on the back of the device and plug into the mains supply. The AquaVENT® FD140i should be used with a mains supply voltage ranging from 100 - 240VAC at 50 - 60Hz only.

WARNING

- Before connecting the device to mains power, the device must be checked for visible damage. Do not use if any damage is evident on the device or power lead.
- This device must be connected to a power supply with a protective earth conductor.



When the device is connected to mains power, the Mains Power Indicator illuminates solid green.



Battery powered operation

An internal battery is included in AquaVENT® FD140i which ensures a continuous power supply when mains power is disconnected or disrupted. When fully charged, the internal battery operates for a minimum of 60 minutes under typical therapy operation. When AquaVENT® FD140i starts using the internal battery as its power source, you are notified by the battery status indicator on the front panel.

The battery status indicator provides the following indications:

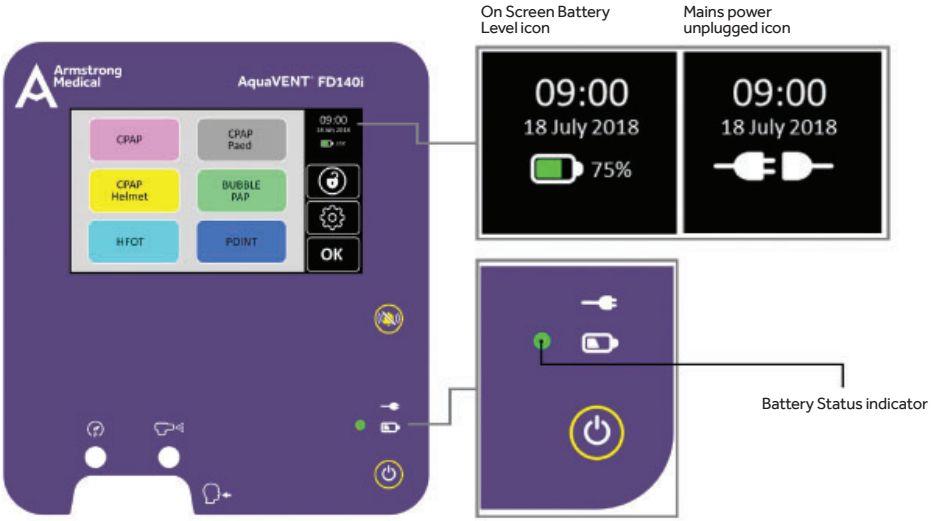
Flashing green: Battery charging in progress. The battery will charge when the mains power is connected until it reaches a fully charged state.

Solid green: Battery fully charged

Solid red: Battery level at 20% or below

The remaining time left on the battery is displayed via the on-screen battery level icon. Battery charge duration depends on the therapy settings in use. When high flow rates are selected, the load will be greater, so less time remaining will be indicated on the battery. Note that the onscreen battery level indicator alternates with the Mains Power Unplugged icon when mains power is disconnected. The Mains Power Unplugged icon serves as a reminder to connect to mains supply at earliest opportunity.

During therapy, alarms will alert the user to a low battery condition. During standby, no alarms will be announced. Please refer to Chapter 5, "Alarms and Notifications" for details.



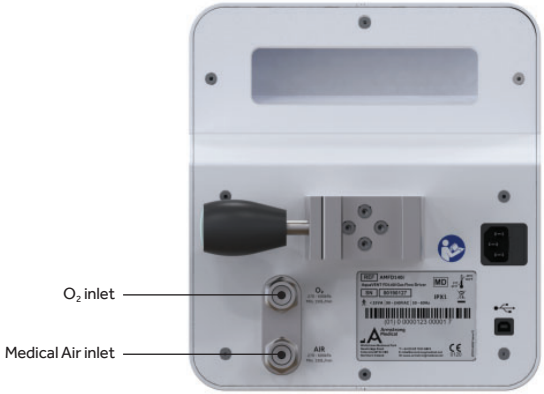
CAUTION

- The internal rechargeable Li-Ion battery has an estimated life of approximately 2-3 years.
- Li-Ion batteries gradually lose capacity to hold a charge when not in use or while in storage, therefore, the battery charge status should be routinely checked.
- Li-Ion batteries are subject to disposal and recycling regulations that vary by country and region. Always check and follow applicable regulations before disposal. Please refer to Chapter 11, "Disposal" for details.

3.4 Connecting to gas supply

Medical Oxygen (O_2) and Medical air (AIR) is connected to the device via the NIST connectors positioned on the back of the device.

NOTE: Prior to commencing patient therapy the user must verify that peak flows of up to 140L/min for both Air and Oxygen can be achieved with a supply pressure ranging from 270 to 600 kPa.



WARNING

- Use approved medical gas hoses only.
- Check O_2 and Air supply connections for leaks prior to commencing therapy.
- AquaVENT® FD140i should be operated on medical grade Air and Oxygen only.

3.5 Gas supply failure

In the event of an O_2 gas supply failure the device will present an alarm notification informing that O_2 gas supply has failed accompanied by a notification requesting confirmation prior to continuing therapy with air supply only. If O_2 gas supply fails the device automatically sets FiO_2 to a value of 21%.

In the event of a loss of AIR supply, the device automatically sets FiO_2 to a value of 100%. The device will present an alarm notification informing that Air supply has failed accompanied by a notification requesting confirmation prior to continuing therapy with Oxygen supply only. Please refer to Chapter 5 Alarms and Notifications for details of the associated alarms. Please also note extensive contraindications of delivering 100% Oxygen to certain patients.

3.6 Single gas operation

AquaVENT® FD140i can be operated with a single gas supply. If an AIR supply is not connected, the FiO_2 will automatically set at 100%. If an O_2 supply is not available the FiO_2 will automatically adjust to 21%. Please refer to Chapter 5 "Alarms and Notifications" for details of the associated alarms.

3.7 Breathing circuit set-up

AquaVENT® FD140i should be used with Armstrong Medical breathing circuits and components. For more information refer to Appendix 2, "Accessories". For specific therapy mode flow and pressure ranges please refer to "Therapy Mode Technical Specifications" table in Chapter 8.

Before connecting a breathing circuit remove the port caps covering the respiratory gas outlet, Oxygen inlet and Medical air inlet.

NOTE: The port caps should be retained for when the device is being transported for service or repair. This is to prevent dust and dirt ingress during transportation.

CAUTION

Ensure that the patient circuit respiratory limbs are not kinked or otherwise obstructed. Failure to do so may introduce pressure build-up within the device.

Nebulised drug delivery

For instructions in using the AquaVENT® FD140i nebuliser function, please refer to Section 4.13 "Using with a nebulising system".

3.8 Using a heater humidifier

Active humidification should be used in all breathing circuits, other than for therapy mode Helmet CPAP. The AquaVENT® FD140i can be used with any heater humidifier known to the manufacturer.

WARNING

To prevent water from the humidification chamber from entering AquaVENT® FD140i, the following instructions must be observed:

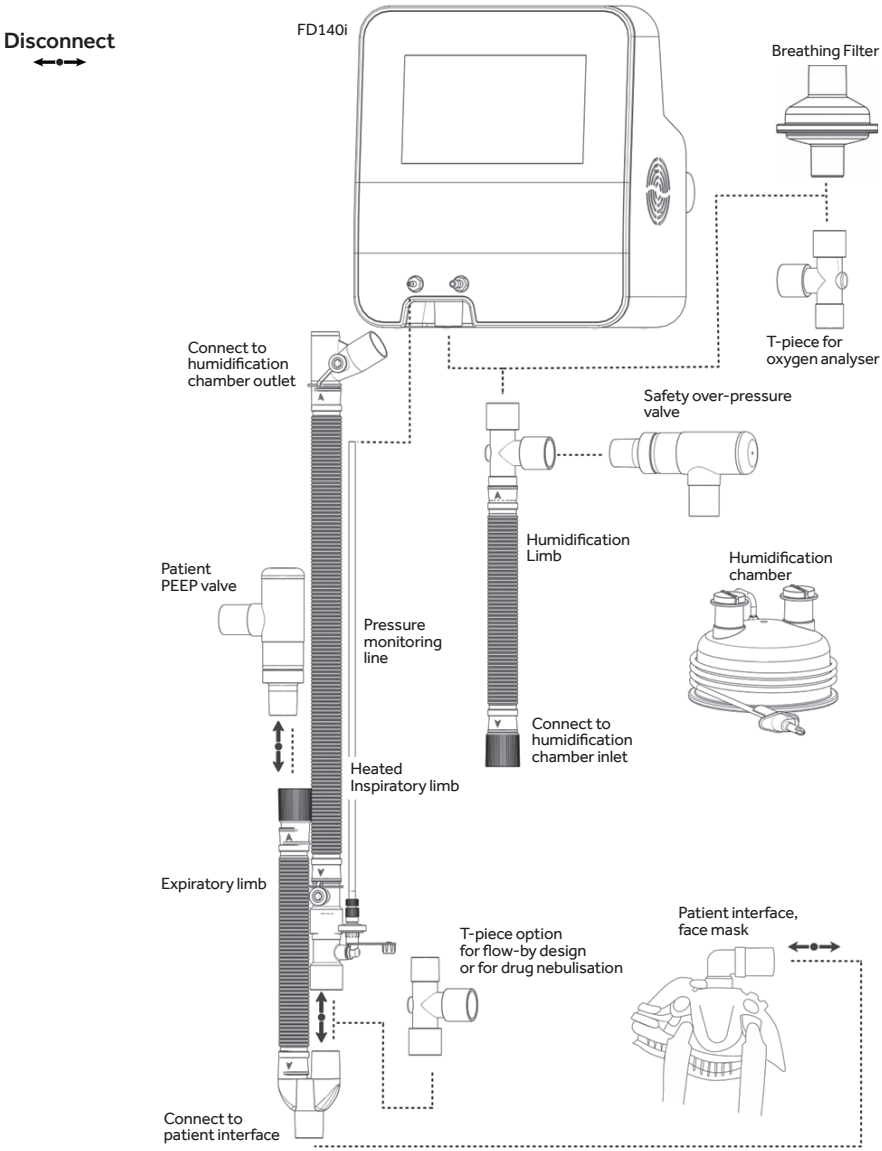
- The heater humidifier should be placed approximately 600mm below AquaVENT® FD140i.
- When removing the active humidifier from the breathing circuit, first disconnect the tube from AquaVENT® FD140i.

AquaVENT® FD140i has six available modes; CPAP, CPAP Paed., CPAP Helmet, Bubble-PAP, HFOT and POINT®. Breathing circuit arrangements for each mode are outlined in this chapter.

CPAP

Continuous Positive Airway Pressure (CPAP) therapy maintains a target positive airway pressure during inspiration and expiration in the spontaneous breathing patient.

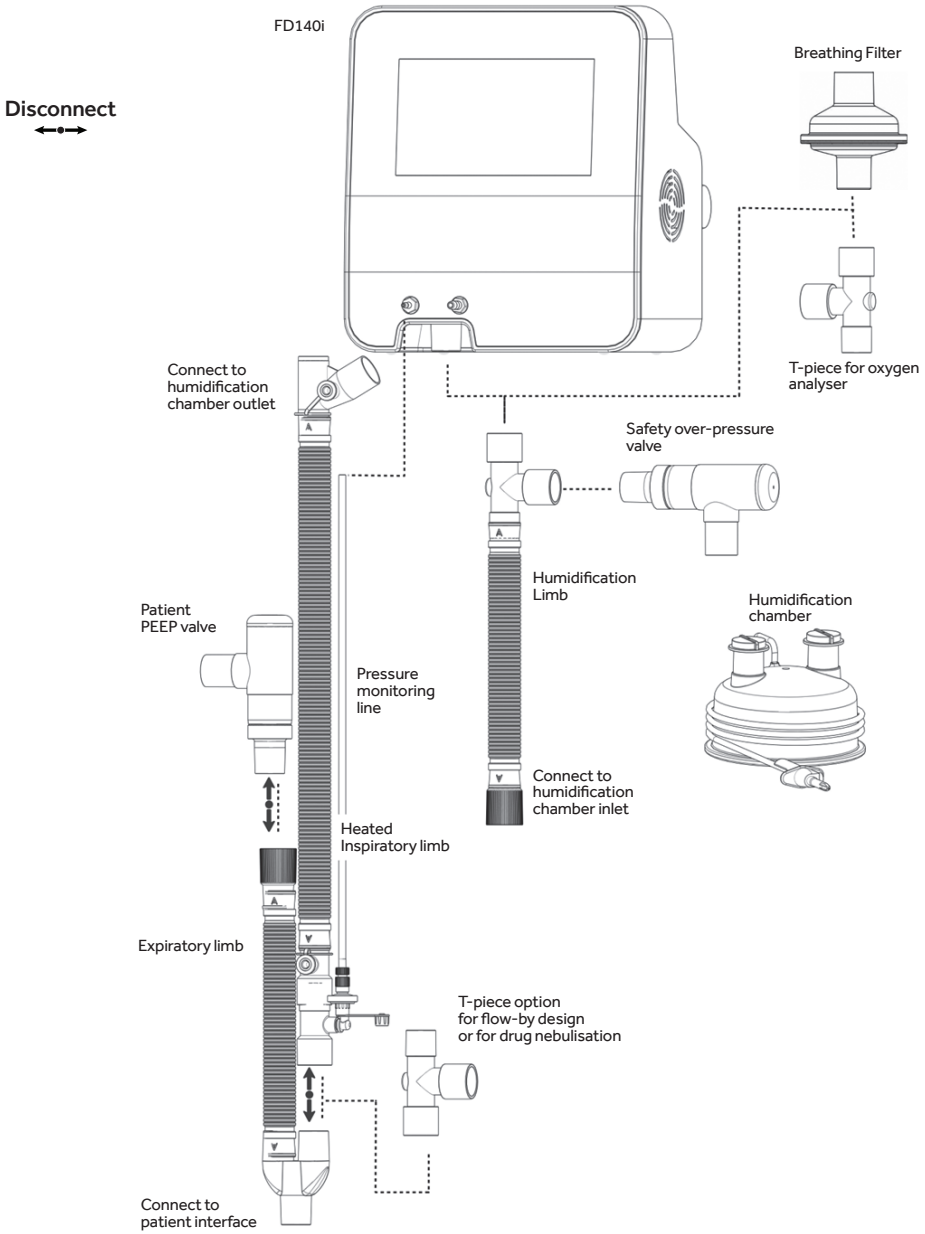
Suggested assemblies of the CPAP breathing system:



CPAP Paed.

The CPAP Paediatric mode is, in principle, the same as adult CPAP but delivers gas flow within a suitable range for paediatric patients.

Suggested assemblies of the CPAP breathing system:

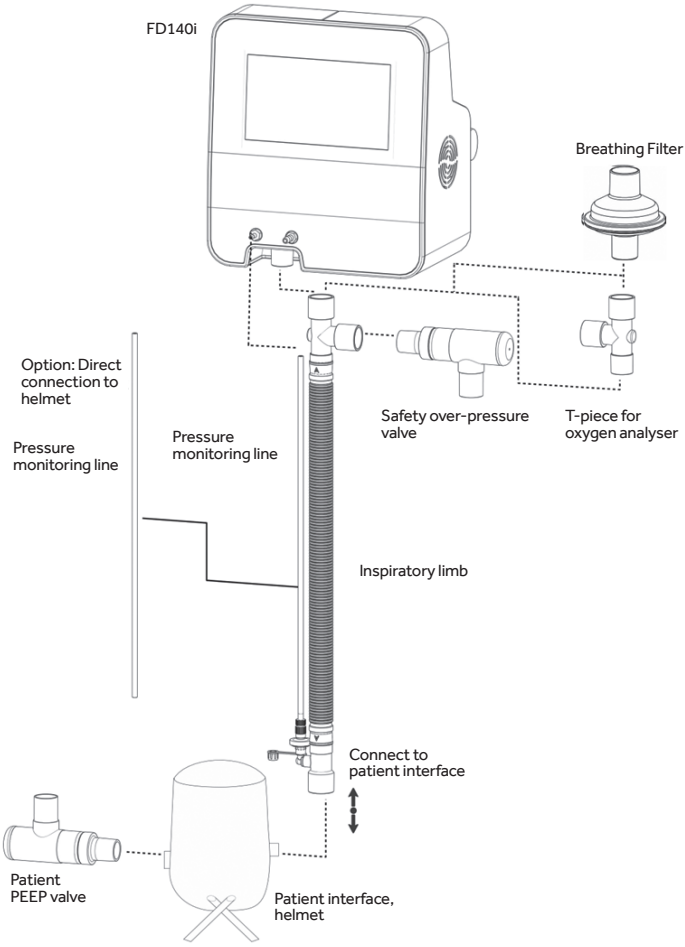


Helmet CPAP

AquaVENT® FD140i supports non-invasive ventilation by means of a CPAP helmet.

Suggested assemblies of the Helmet CPAP breathing system:

Disconnect



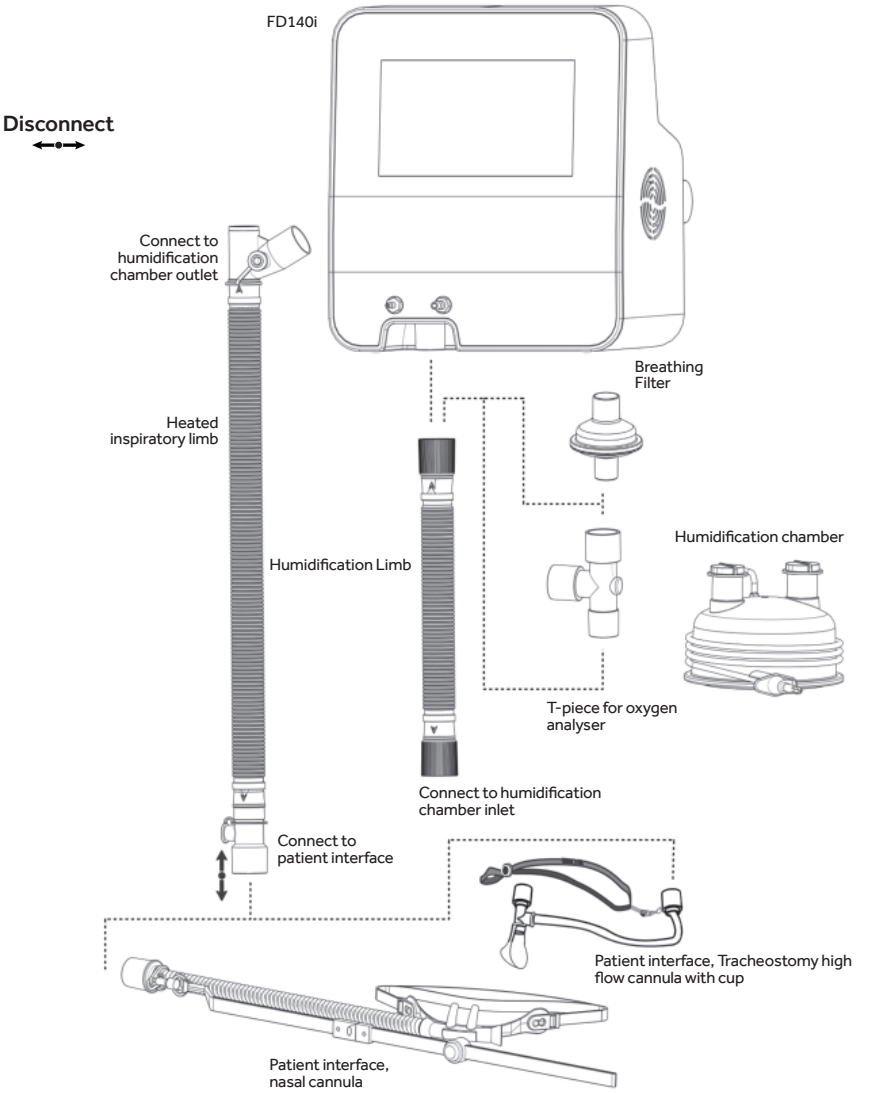
WARNING

- To prevent CO_2 rebreathing, adjust the required flow according to the instructions provided by the manufacturer of the CPAP helmet.
- When using CPAP helmets with hypercapnic patients, close monitoring is recommended when making flow adjustments to avoid CO_2 rebreathing .
- CPAP helmets may require a minimum operating pressure. Refer to the CPAP Helmet manufacturer's Instructions For Use. For more information on approved CPAP helmets refer to Section 11.2 "Appendix 2 – Accessories".

High Flow Oxygen Therapy (HFOT)

High Flow Oxygen Therapy is a form of respiratory support where high flow rates (20-70 l/min) of Oxygen/Air mixture is delivered to the patient.

Suggested assemblies of the HFOT breathing system:



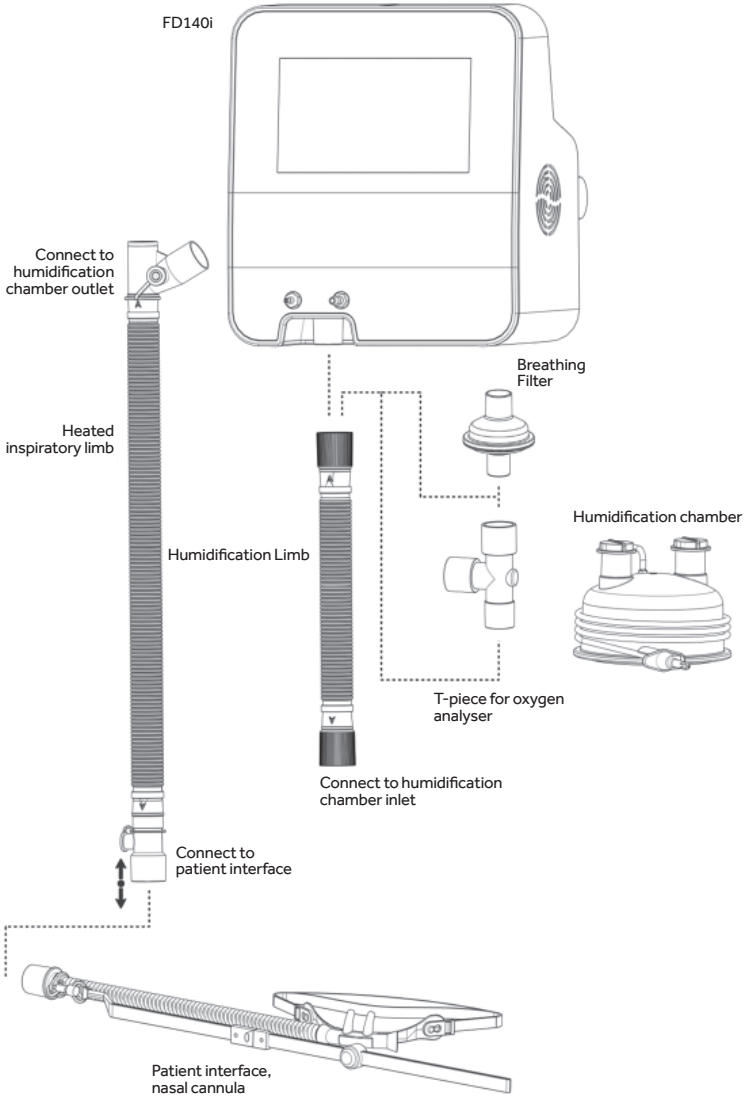
WARNING

To avoid accidental pressure peaks, adjust the required flow rate according to the instructions provided by the manufacturer of the nasal cannula.

POINT®

POINT® (Peri-Operative Insuffiatory Nasal Therapy) delivers humidified high flow nasal therapy to support the patient during the peri-operative period.

Suggested assemblies of the POINT® breathing system:



WARNING

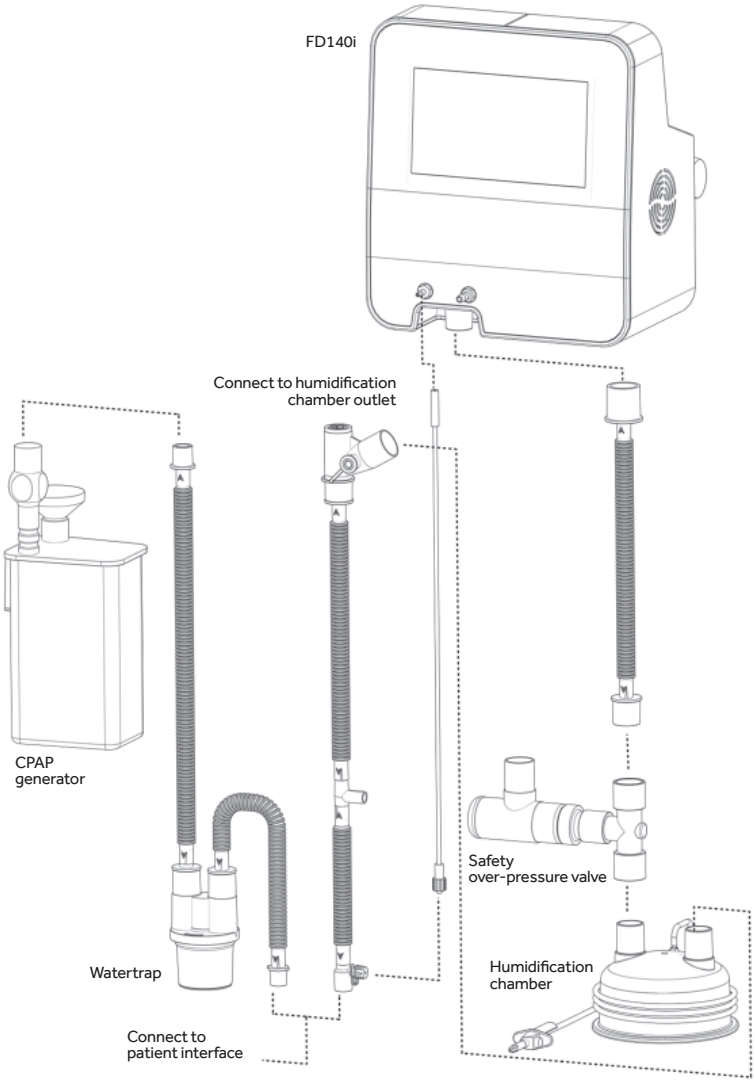
To avoid accidental pressure peaks, adjust the required flow rate according to the instructions provided by the manufacturer of the nasal cannula.

Bubble-PAP

Bubble-PAP provides a safe, consistent and accurate method of delivering humidified respiratory support to spontaneously breathing patients from birth weight up to 10kg. The therapy prevents airway closure and maintains functional residual capacity.

Suggested assembly of the Bubble-PAP breathing system:

Disconnect



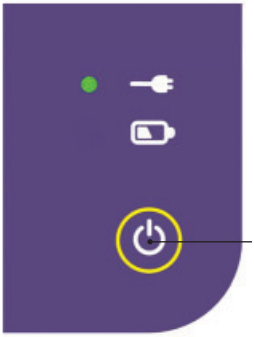
WARNING

- To avoid accidental pressure peaks, adjust the required flow rate according to the instructions provided by the manufacturer of the nasal cannula.
- Device must be connected to air and oxygen during the use of BUBBlE-PAP mode.

4 Using the AquaVENT® FD140i

4.1 Powering on the device

AquaVENT® FD140i can be powered on by pressing the ON/OFF button.



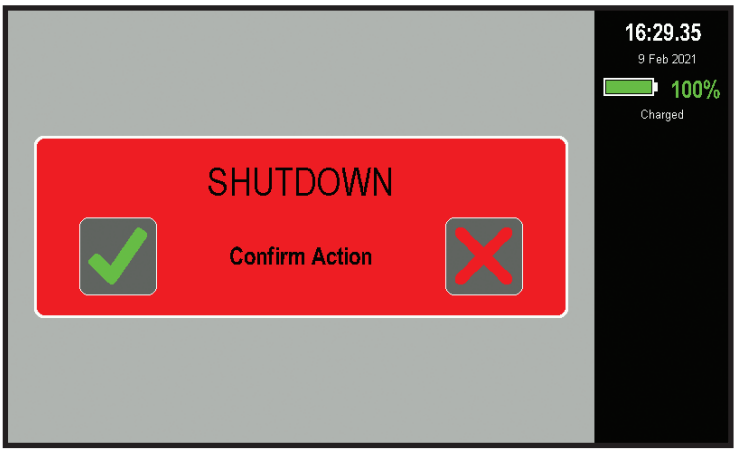
NOTE: The device runs an automatic system test each time it is switched on. Please refer to "Self Check" section for details.

WARNING

Do not power on the device if a patient is already connected to an attached breathing circuit. The patient should be connected to the device only after the system test has been carried out and the required therapy settings have been selected.

4.2 Powering off the device

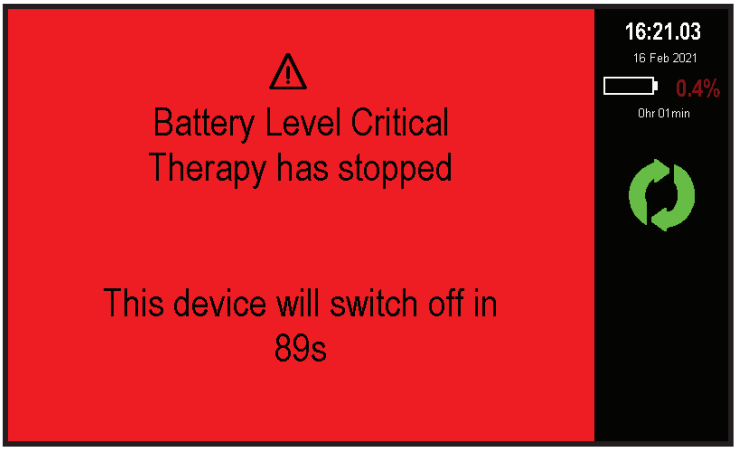
AquaVENT® FD140i can be powered off by pressing the On/Off button and confirming the command by touching the Tick icon. If "X" icon is selected you will return to the previous screen. The AquaVENT® FD140i can be powered off by pressing and holding the On/Off button for approx. 5 seconds.



NOTE: AquaVENT® FD140i can be powered off whilst in therapy mode. Press the ON/OFF icon and a Shutdown confirmation message appears. Confirm to continue with shutdown or 'X' to cancel shutdown request. For further information about terminating the therapy mode, please refer to Stopping therapy section.

4.3 Automatic switch-OFF due to discharged battery

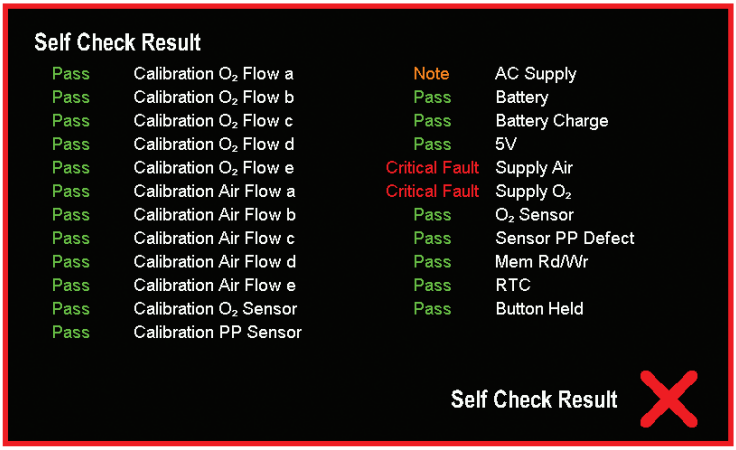
To avoid damage to the internal rechargeable battery by deep discharging, when reaching the power off threshold (battery level indicator at 0%) the device powers off all electric and pneumatic functions and displays the following message for 120 seconds:



During this 2 minute period, you can reconnect AquaVENT® FD140i to mains power and continue operation with all functions, or you can power the device off with the On/Off button. Otherwise, AquaVENT® FD140i powers off automatically at the end of the 2-minute period.

4.4 Self check

The system test starts automatically after the ON/OFF button is pressed and lasts for approximately 10 seconds. During this period an Armstrong Medical logo is presented whilst the system test is running in the background. If there are any issues/faults the Self Check Results screen is shown. If there are no issues/ faults found during the system test the device will present the "OXYGEN Sensor Calibration" menu. The system tests check the integrity of the operating software and of the electronic and pneumatic modules.



Self Check Results Screen

If the Self Check Results screen presents any critical faults apart from a failure of Supply AIR or Supply O_2, the device will not start up until all critical faults have been rectified.

NOTE:

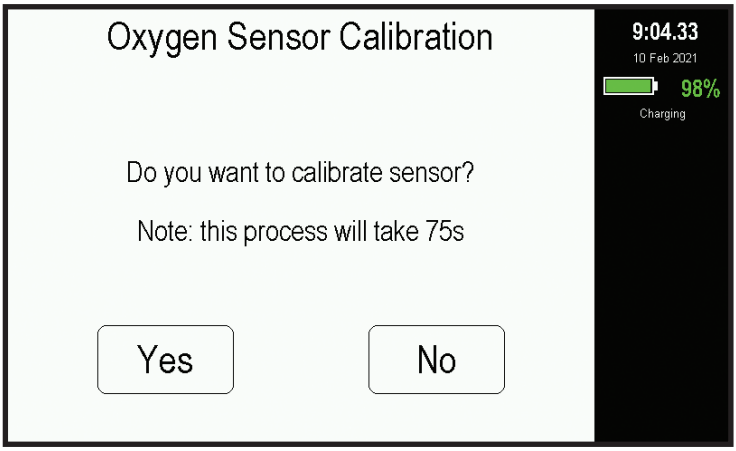
- If a critical fault is identified for both Supply AIR or Supply O_2, reconnection of one or both gas supplies will enable start-up.
- The device can start up on internal battery power if AC supply is disconnected.

CAUTION

Repair should be carried out by an authorised service technician only.

4.5 Oxygen sensor calibration

After the self check the following "OXYGEN Sensor Calibration" menu is presented. If calibration of the O_2 sensor is required, press "Yes", if not required select "No". The device's paramagnetic O_2 sensor is sensitive to movement. The manufacturer recommends calibrating the O_2 sensors after transportation of the device or if it has been subject to any form of rough handling.



The calibration procedure takes 75 seconds. An on screen count down timer indicates time left until completion of the calibration procedure.

The calibration process requires a supply of both AIR and O_2 gas. If either gas supply is not available when calibration is initiated, the "Calibrate Failure" message will be presented on screen.

WARNING

Before starting the calibration routine, ensure that the patient is disconnected from the device.

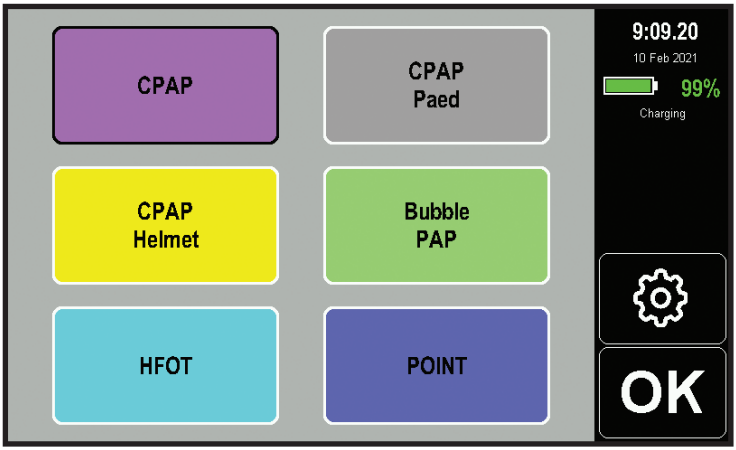
CAUTION

- Do not disconnect the mains power plug during the O_2 calibration.
- After starting the calibration the touch screen is disabled until the calibration procedure is complete.

NOTE: Ambient air may influence O_2 sensor calibration, to prevent this, connect a tube to the gas output port.

4.6 Therapy mode selection menu

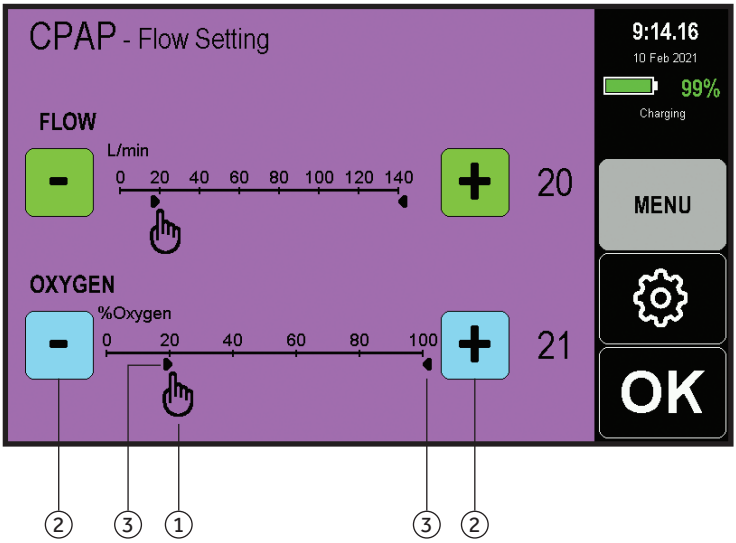
The "Therapy Mode Selection" menu presents the six therapy modes available. These modes are CPAP, CPAP Paed., CPAP Helmet, BUBBLE-PAP, HFOT and POINT®. Select the desired mode by touching the relevant Therapy Mode Button and press OK to proceed. In the example shown below CPAP has been selected.



For further information on therapy modes specifications, refer to Section 8.2 "Therapy Modes Technical Specification"

4.7 Flow settings menu

The flow settings menu allows you to set the medical air flow rate and the concentration of oxygen delivered to the patient. CPAP mode is used as an example.



Flow rates are selected using the pointer icon (1) and the +/- (2) buttons for fine adjustment. The maximum and minimum values, for the selected therapy, are indicated with the triangular markers (3).

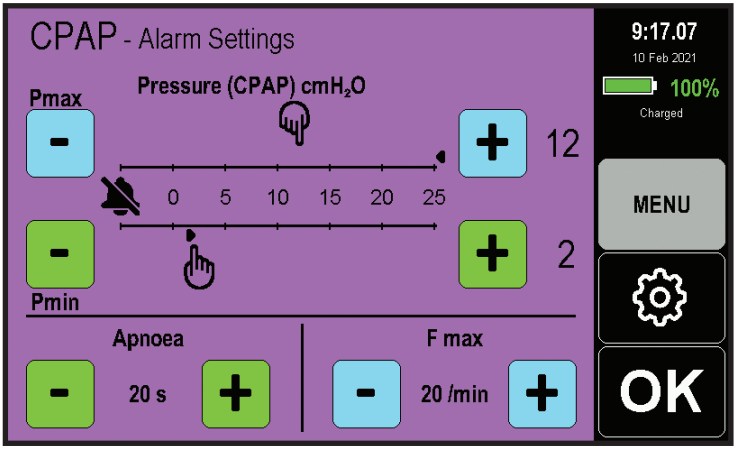
NOTE: Maximum and minimum flow rates and oxygen concentration return to pre-set default values when the therapy mode is exited. When flow rates are set, press OK to proceed.

4.8 Alarm settings menu

The alarm settings menu allows the user to specify when patient alarms will activate. Using the pointers and +/- buttons the user can set the alarms to the desired setting for:

- CPAP pressure
- Apnoea delay
- Maximum respiratory rate

CPAP mode is used as an example.



CPAP pressure

The top scale is used to select the high pressure alarm setting and the lower scale adjusts the low pressure alarm setting. Pressure can be altered in increments of 1cmH_20. High and low pressure alarms can be turned-off by positioning the pointer at the "off" position.

Apnoea

Monitoring apnoea events proceeds in three phases: Settling period, Delay period and Normal breathing.

The apnoea alarm will not activate during the first 60 seconds of therapy (Settling period). If there is an apnoea event within the last 12 seconds of the settling period then the alarm will be reported and activated at the 60 second mark (in such cases, there is no subsequent delay period). Activation of the apnoea alarm can be delayed, after the 60 second settling period, by a further 20 to 60 seconds in increments of 1 second by adjusting the +/- buttons (Delay period). If an apnoea event occurs in the last 12 seconds of the delay period it will be reported at the end of the delay period and the apnoea alarm will be activated. The delay period is followed by the normal breathing phase (Normal breathing). During the normal breathing phase, the apnoea alarm notifies that a breath has not been detected for a period of 12 seconds or greater during active therapy.

F Max

The respiratory rate is adjusted with the +/- buttons in increments of 5 seconds from "Off" to 60 breaths per minute. When the appropriate alarms settings have been set, proceed by pressing the OK button.

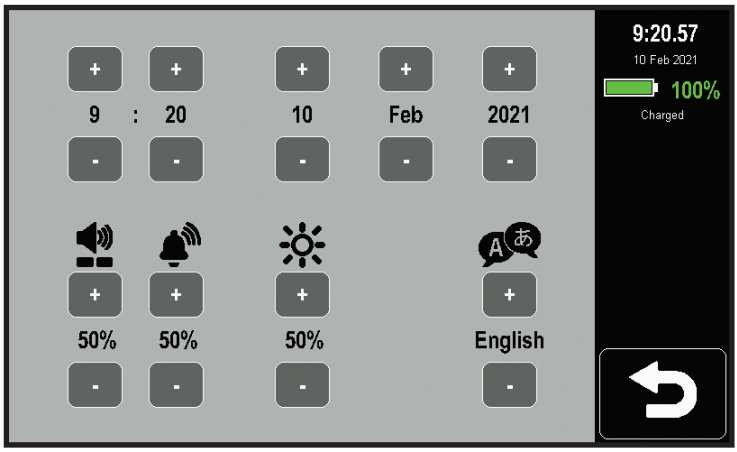
4.9 General settings menu

The general settings menu can be accessed via the general settings button. Use the return button to return to the previous menu.

General Settings Button

Return Button

The General Settings Menu allows adjustment to time, date, alarm volume, touch tone volume, screen brightness and language settings.



Touch tone volume

Adjust volume of touch screen with + and - buttons as required

Alarm volume

Adjust alarm volume with + and - buttons as required.
Note: On device restart, alarm and touch tone volumes reverts to default value of 50%.

Screen brightness

Adjust screen brightness with + and - buttons as required.
Note: On device restart screen brightness retains previous setting.

Language selection

Select language with + and - buttons.
Available languages: English, French, German, Spanish, Dutch and Italian.

Time and Date

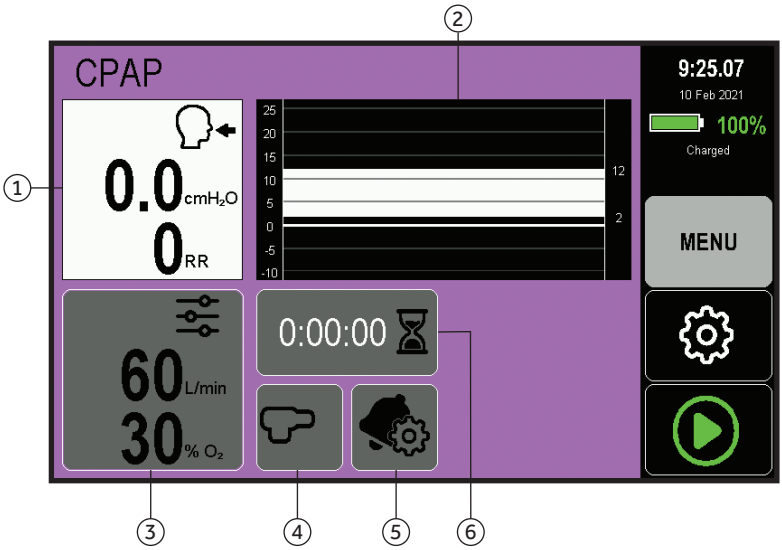
Use + and - keys to adjust as required

4.10 Therapy menu

The Therapy menu allows the user to:

- Monitor the patient's respiratory activity in real time
- View selected flow levels and access flow settings
- Switch on or off the nebuliser gas flow
- Time therapy duration
- Monitor active alarms

CPAP mode is used as an example.



Item	Description
1	Patient respiratory rate and CPAP pressure display window
2	Patient respiratory wave form
3	Patient gas flow and oxygen settings button
4	Nebuliser function button
5	Alarm settings button
6	Therapy timer button

NOTE: AquaVENT® FD140i user interface screen buttons for accessing settings have rounded corners e.g. Item 3 and windows which display information only have sharp corners, e.g. item 1.

Patient respiratory rate and CPAP pressure display window

The CPAP pressure displayed in (item 1) is the average Patient Pressure over a 7 seconds period and displayed in cmH_2O.

The RR is an average value of the previous 3 calculated RR rates. (If no breath is detected for 10 seconds, the RR value will start to be updated to reflect the low RR as a live calculated value.)

The patient respiratory live trace (item 2) presents CPAP pressure and respiratory rate in real time over 7.1 seconds. The selected alarm settings for low and high pressure are denoted on the right-hand side of the graphical trace and by the white band across the graph. The amplitude of the trace (Y-axis) indicates the air pressure and the period of the wave (X-axis) indicates the respiratory rate.

Therapy flow settings button

Flow settings can be adjusted from the therapy menu. To adjust the flow settings, press the patient flow settings button which will open the flow settings menu. Make the required change and press OK to return to the therapy menu page.

Nebuliser gas ON/OFF button

To switch on the nebuliser air flow press the nebuliser button. Note that when switched on the nebuliser icon turns green. For more information ion the nebuliser function refer to section 4.13.

Alarm Settings Button

To adjust alarm settings from the therapy menu press the alarm settings button (item 5), which will open the alarm settings menu. Make the required change and press OK to return to the therapy menu page.

Therapy Timer button

The therapy timer button displays the duration that the selected therapy has been active, less any periods during which the timer was paused or reset. The timer will stop when therapy stops and will start again if therapy is recommenced, displaying the cumulative therapy duration, less any periods during which the timer was paused or reset. To pause the timer, press the therapy timer button once.
To then un pause the timer, press the therapy timer button once. To reset the timer, press and hold for two seconds. It will reset to zero. Note that the timer will automatically reset to zero when an alternative therapy is selected from the therapy mode selection menu. If the flow or oxygen concentration settings are changed, but the mode has not changed, the timer function is unaffected, and will continue as normal without a reset.

4.11 Starting therapy

When the user is satisfied with the therapy setup, start therapy by pressing the Start therapy button, located on the side bar menu. CPAP mode is used as an example.

Start therapy button

When the Start therapy button is pressed the user must confirm that it is their intention to start therapy via the confirm action window.

WARNING

- Before starting therapy ensure that all therapy settings are appropriate for the patient.
- Do not connect the patient to the breathing circuit until gas flow has started.

4.12 Stopping therapy

To stop therapy press the Stop therapy button, located on the side bar menu. CPAP mode is used as an example.

Stop therapy button

When the Stop therapy button is pressed the user must confirm that it is their intention to stop therapy via the confirm action window.

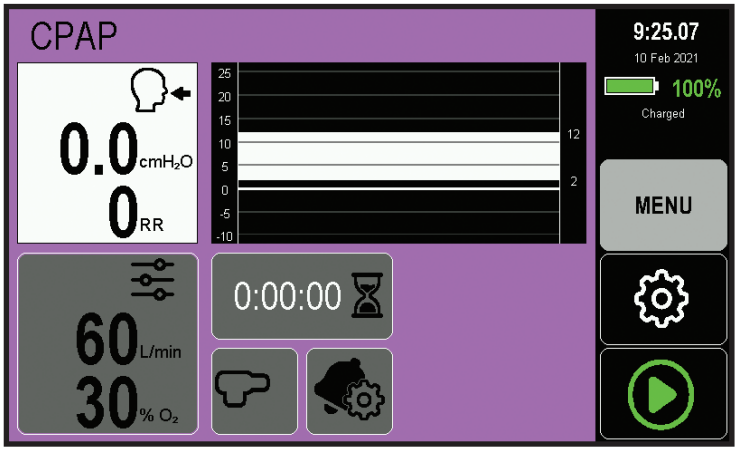
4.13 Using with a nebulising system

AquaVENT® FD140i can be used in conjunction with a jet nebuliser to add medical aerosol to the breathing circuit during therapy. The nebuliser function cannot be used when therapy is not active. For more information on approved nebulisers refer to section 11.2 Appendix 2,"Accessories". The nebuliser delivers 6L/min +/- 2L/min of compressed air.

The nebuliser function can be pre-selected during therapy set-up or alternatively, activated after therapy has commenced. The nebuliser button (1) is used to switch on and off the nebuliser gas flow. The nebuliser icon turns green when nebulisation is active.

CPAP mode is used as an example.

NOTE: The nebuliser function is not available in Helmet CPAP and Bubble-PAP modes.



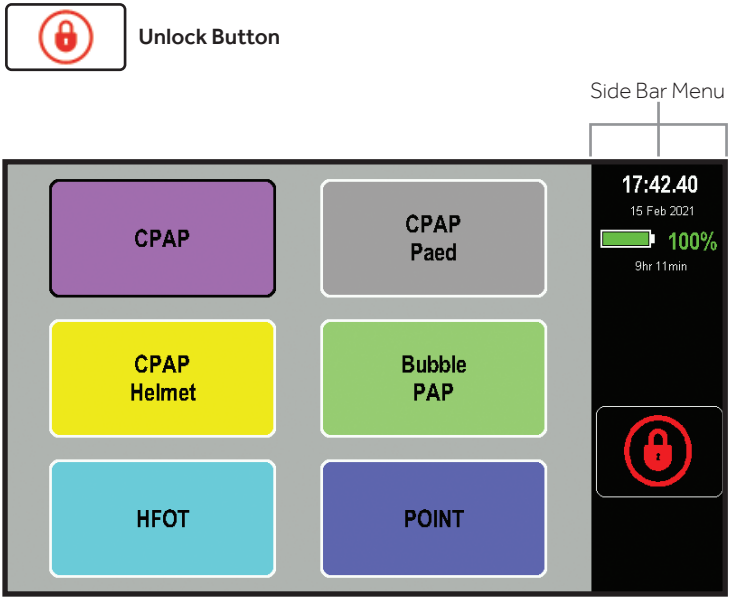
Nebuliser function off

Nebuliser function on

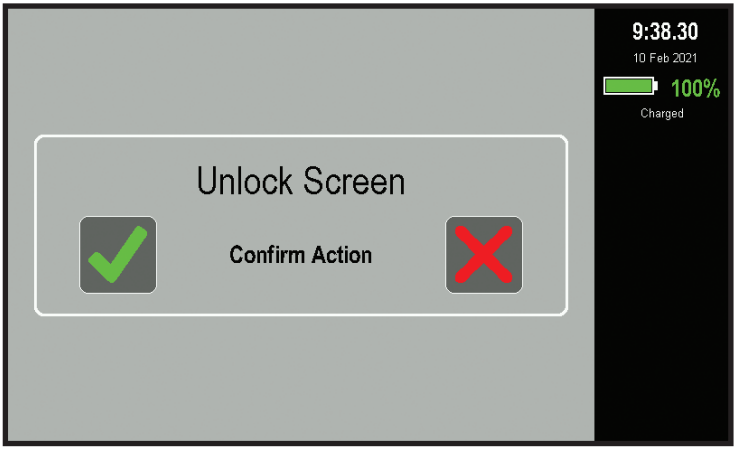
When active, the nebuliser function adds medical air to the breathing circuit. Consequently, to provide the patient with the selected O_2 concentration, the gas mixer settings adjust automatically when the nebuliser function is switched on. The nebuliser requires a therapy gas flow rate of at least 10L/min to operate.

4.14 Touch screen unlock

When the screen has not been touched for 30 seconds the screen will lock and the unlock button will appear on the side bar menu.



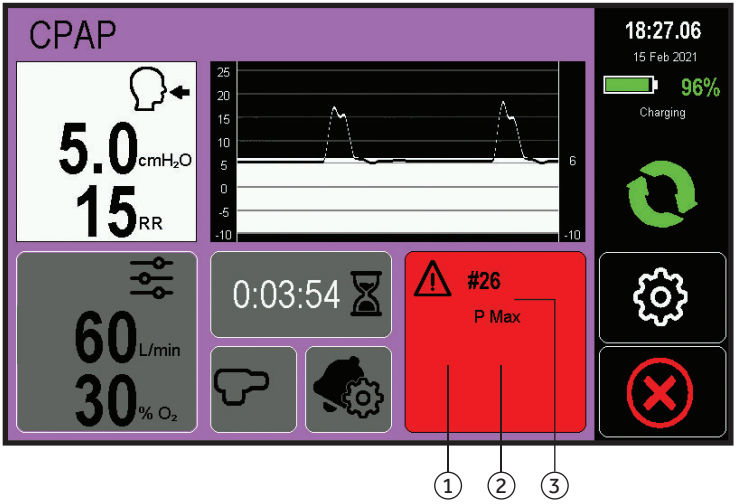
To unlock the screen press the Unlock Button then confirm action by selecting the confirm button.



5 Alarms and Notifications

5.1 Alarm indicator button

When an alarm is active the Alarm Indicator Button (1) appears on the touch screen .The colour of the Alarm Indicator Button indicates the alarm priority; red is for medium priority alarms and yellow is for low priority alarms. Example for CPAP mode:



Low Priority Alarm Indicator Button

Medium Priority Alarm Indicator Button

A description of the active alarm (2) and a corresponding Alarm Identification Number (3) are also contained within the Alarm Indicator Button. If multiple alarms are active simultaneously , the Alarm Indicator Button will cycle through the alarms, displaying each alarm description and associated indicator number for 2 seconds.

NOTE: In the event that an alarm should sound when navigated away from Therapy Menu e.g. if adjusting flow or alarm settings when therapy is active please return to the active Therapy Menu to identify the alarm condition.

5.2 Alarm acknowledgement

If the alarm condition is removed, the alarm audio will stop and the indicator button will display the message "Acknowledge Alarm" . See opposite. Acknowledge the alarm by pressing the alarm indicator button.

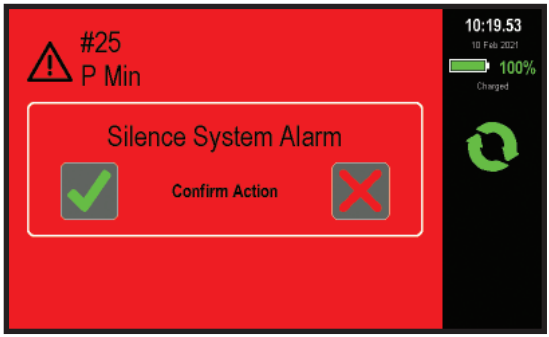
NOTE: If multiple alarms are simultaneously active, pressing the alarm indicator button at any stage throughout the cycle of alarm notifications will acknowledge all alarms related to alarm conditions which have been removed.

Alarm Indicator Button Acknowledge Alarm

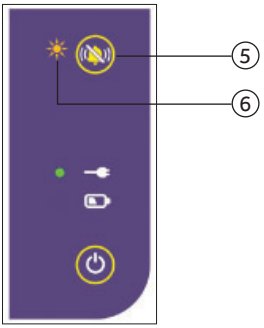
5.3 Muting alarm audio

In therapy alarm

Alarm audio is muted by pressing the Alarm Audio Mute Button on the device front panel (5). Pressing this button will activate a confirmative action window. When this action is confirmed, the alarm audio will mute for two minutes.



Alarm mute confirmative action

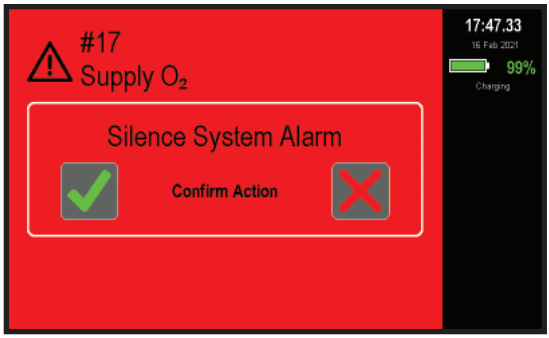


Front panel Alarm Mute Button and Alarm Mute Indicator

When an alarm is muted the on-screen Alarm Indicator Button will display the alarm mute symbol and a two minute count down timer. (figure). Additionally, the Alarm Mute Indicator Icon (6) on the device front panel will flash orange when an alarm is muted.

If the alarm condition is not resolved within a 2 minute period, the alarm audio will reactivate. Each alarm can be muted a total of 10 times, after the 10th time the audible alarm cannot be muted again.

Alarm Indicator Button with mute activated



Out of therapy alarm

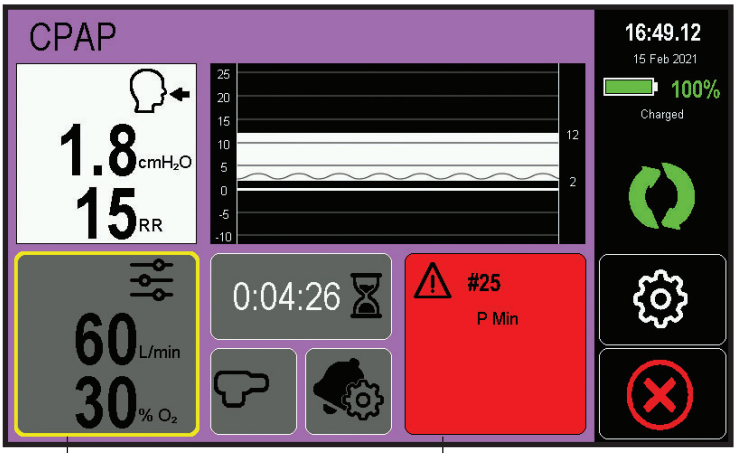
Alarm window will appear automatically and the "✓" button on the screen will clear the audio. The "✖" will clear the alarm briefly.

5.4 Alarm volume adjustment

Alarm volume can be adjusted to user preference refer to Section 4.9 "General Settings Menu" for more information.

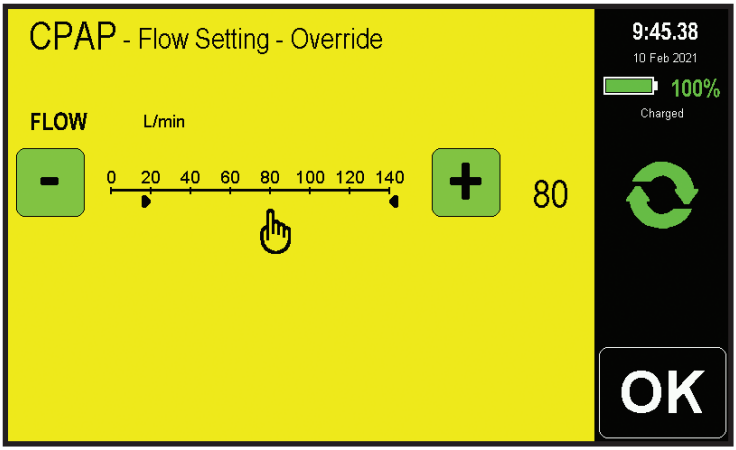
5.5 CPAP Low Pressure Alarm (P Min) flow settings override

In the event of a Low Pressure Alarm (P Min) in CPAP mode, the flow override function becomes available. This is indicated by a yellow border around the flow settings button.

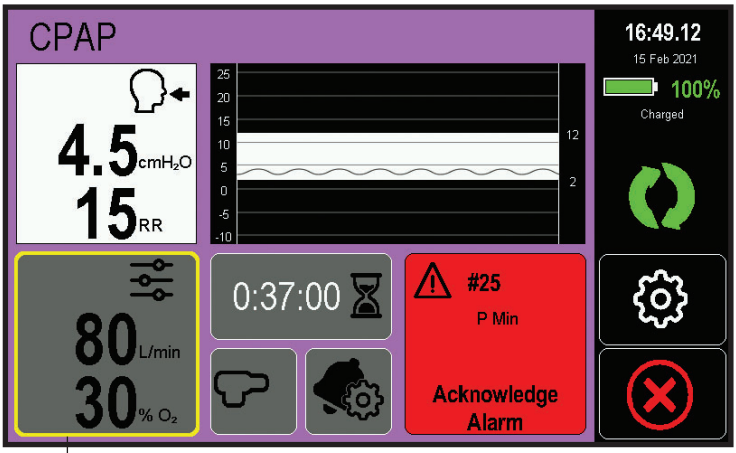


If the flow settings button is pressed when the yellow border is present , the CPAP Flow Setting Override Menu is presented. Increase the flow rate as required and press OK. When prompted, confirm this action.

Example of increase from 60L/min to 80L/min is shown below.



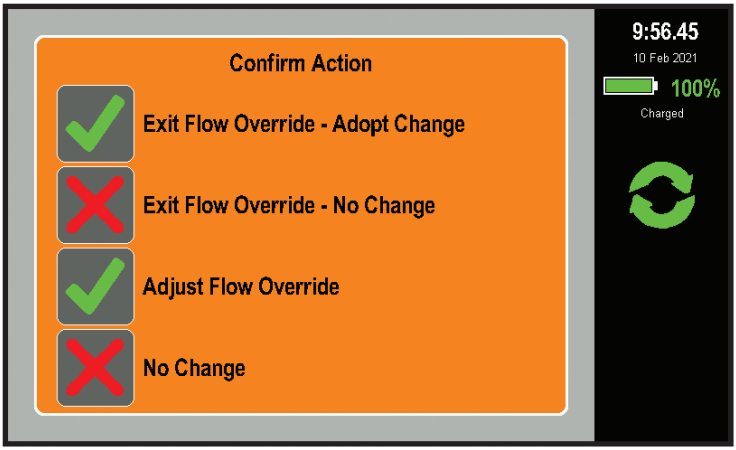
When the flow override function is active the yellow border around the flow settings button will flash.



Yellow border-flashing

NOTE: If the increased flow removes the P Min alarm condition , the "Alarm Acknowledge" P Min Alarm notification appears at the indicator button.

To return to the original settings from the flow override or adjust override settings to another value, press the flow settings button and confirm the selected action.



5.6 Alarm types

The following table identifies all alarm types included in the AquaVENT® FD140i along with alarm condition and corresponding corrective action. Alarm identification numbers (ID) and alarm priorities are also listed.

Alarm Message	Alarm ID No.	Alarm Priority	Alarm Condition	Corrective Action	Notes
Mem Rd/Wr	0	Medium	FLASH memory has failed	Restart system. If fault continues, return to approved service centre	-
RTC	1	Low	The device's internal clock is no longer working correctly	Return to approved service centre	-
Calibration O_2 Flow a	2	Medium	Oxygen 0 - 10 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration O_2 Flow b	3	Medium	Oxygen 10 - 30 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration O_2 Flow c	4	Medium	Oxygen 30 - 80 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration O_2 Flow d	5	Medium	Oxygen 80 - 120 L/ min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration Air Flow a	6	Medium	Air 0 - 10 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration Air Flow b	7	Medium	Air 10 - 30 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration Air Flow c	8	Medium	Air 30 - 80 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration Air Flow d	9	Medium	Air 80 - 120 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration O_2 Sensor	10	Medium	Oxygen concentration sensor calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre

Alarm Message	Alarm ID No.	Alarm Priority	Alarm Condition	Corrective Action	Notes
Calibration PP Sensor	11	Medium	Patient Pressure sensor calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Battery Fault	13	Medium	Battery not fitted or faulty battery installed	Have device serviced by authorised technician	-
5V	14	Medium	5V supply to device is greater than +/- 20%	Restart system. If fault continues, return the device to an approved service centre	-
Supply AIR	16	Medium	No AIR supply connected	Connect AIR supply	When air supply is disconnected, FiO_2 is automatically set to 100%
Supply O_2	17	Medium	No O_2 supply connected	Connect O_2 supply	When oxygen supply is disconnected, FiO_2 is automatically set to 21%
AC Supply	18	Low	AC Supply disconnected	Connect device to AC supply	Single Alert Alarm
O_2 Sensor	19	Medium	O_2 sensor defect	Have device serviced by authorised technician	-
Patient Pressure Sensor defect	20	Medium	Device fails to sense AIR or O_2 Flow and/or patient pressure	Have device serviced by authorised technician	-
Touch Held	21	Low	Touch screen held for more than 20 seconds	Release touch screen	-
Button Held	22	Low	Front panel button held for more than 5.5 seconds	Release button	-
Battery Charge	23	Medium	Battery charge level at 20% or below	Connect device to AC supply	Single Alert Alarm
O_2 Calibration	24	Medium	O_2 sensor not calibrated	Calibrate oxygen sensors; refer to section 4.5 "Oxygen sensors calibration"	Single Alert Alarm Following calibration of O_2 sensor, If the O_2 sensor fails at start up the alarm will be activated once

Alarm Message	Alarm ID No.	Alarm Priority	Alarm Condition	Corrective Action	Notes
P Min	25	Medium	Patient pressure is less than applied P Min alarm limit	Evaluate low pressure alarm settings and increase pressure setting if appropriate	P Min alarm does not activate in HFOT or POINT
P Max	26	Medium	Patient pressure is more than applied P Max alarm limit	Evaluate high pressure alarm settings and reduce pressure setting if appropriate	P Max alarm does not activate in HFOT or POINT
Apnoea	27	Medium	No respiration detected for a period greater than 12 seconds	Check patient and evaluate apnoea alarm settings	-
F Max	28	Low	Respiratory rate is greater than applied F Max alarm limit	Evaluate F Max alarm settings and increase F Max alarm value if appropriate	-
P Limit	29	Medium	Patient pressure greater than 25cmH_2O for CPAP, CPAP Paed and Helmet Patient pressure greater than 15cmH_2O for BUBBLE PAP	Evaluate High Pressure Alarm settings and reduce pressure setting if appropriate	P Min alarm does not activate in HFOT or POINT
FiO_2 High	30	Low	Detected FiO_2 level is >5 percentage points higher than the set value	Wait 10 seconds, if alarm clears proceed with use. If alarm has not cleared, consider increasing flow by 1 or 2L/min. If alarm persists, stop the therapy session and restart it from the mode menu screen. If alarm does not clear calibrate oxygen sensors; refer to section 4.5 "Oxygen sensors calibration". If calibration does not clear the alarm, return the device to an approved service centre	Following adjustment of O_2 percentage, FiO_2 low alarm is deactivated for 30 seconds
FiO_2 Low	31	Low	Detected FiO_2 level is >5 percentage points below the set value or less than 18%	Wait 10 seconds, if alarm clears proceed with use. If alarm has not cleared, consider increasing flow by 1 or 2L/min. If alarm persists, stop the therapy session and restart it from the mode menu screen. If alarm does not clear calibrate oxygen sensors; refer to section 4.5 "Oxygen sensors calibration". If calibration does not clear the alarm, return the device to an approved service centre	Following adjustment of O_2 percentage, FiO_2 low alarm is deactivated for 30 seconds

NOTE: Single Alert Alarms do not repeat audio alarm after alarm mute has been activated.

Alarm Message	Alarm ID No.	Alarm Priority	Alarm Condition	Corrective Action	Notes
Fan Defect	34	Medium	Technical failure	Have device serviced by authorised technician	-
Sensor AIR Defect	36	Medium	Technical failure	Restart therapy. If fault continues, recalibrate device or return the device to an approved service centre	-
Sensor O_2 Defect	37	Medium	Technical failure	Restart therapy. If fault continues, recalibrate device or return the device to an approved service centre	-
Calibration O_2 Flow e	38	Medium	Oxygen 120 - 140 L/ min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre
Calibration Air Flow e	39	Medium	Air 120 - 140 L/min calibration cannot be retrieved	Recalibrate device	If recalibration does not clear the alarm, return the device to an approved service centre

5.7 Alarms settling period

At the commencement of therapy (on any mode), alarms are de-activated for a set period of time depending on the alarm type. We refer to this as the 'settling period'. Although an alarm condition may exist during the settling period, it will not be reported on the screen until after the settling period has ended. The settling period is provided to allow the user to finalise the therapy set-up and its function. Often this involves adjusting the patient interface or further adjusting gas flow rate or oxygen % to the desired values. Within a settling period or at anytime thereafter, if the therapy settings are adjusted in any way, a new settling period is initiated.

In respect of flow rate, apnoea alarm, Pmax and Pmin alarms, respiratory rate alarm, nebuliser ON and nebuliser OFF – changes to these settings creates a settling period of 60secs during which pre-existing alarms that had been present on the screen are cleared - even if the cause of the alarm condition is not resolved. During the settling period that follows, alarm conditions that arise during the settling period will be held from view until after the settling period has ended – whereupon they will appear on the screen, prompting the user to address the alarm condition (s). In respect of FiO_2 alarms, the same applies but the settling period is 180secs. Other alarm conditions may be subject to a short period of de-activation following commencement of therapy.

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6 Maintenance and Repair

6.1 Repair

Maintenance and Repair

AquaVENT® FD140i is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by the manufacturer. If any irregularity becomes apparent, you should exercise caution and have the device inspected by an authorised service centre.

6.2 Servicing Schedule

With regular servicing, the expected service life of an AquaVENT® FD140i is 10 years. For more information about maintenance, please refer to AquaVENT® FD140i Technical Manual.
The AquaVENT® FD140i should be serviced by an authorised Armstrong Medical service centre according to the following schedule from the first date of use:

Recommended service interval	Conducted by	Instructions
Every Six months	Armstrong Medical	Replacement/Service of AEC0355 Oxygen sensor if it is used
Every year	Armstrong Medical	Check for depletion and requirement for replacement of oxygen fuel cell, if present
Every year	Armstrong Medical	Replace Cone Filters in the NIST fittings – N2185/06
Every year	Armstrong Medical	Replace the Free Breathing Valve – AMCAEM1000-110
Every year	Armstrong Medical	Replace the O ring at the 1/8" screw joint of the NIST fittings
Every year	Armstrong medical	Replace the O-ring at the Nebuliser gas outlet port
Every year	Armstrong Medical	Replace the O-ring at the Patient pressure gas inlet port
Every year	Armstrong Medical	Replace the O-ring at the 22mm gas outlet port
Every Two years	Armstrong Medical	Replace the Sintered Flow Discs within the manifold – AEC1221
Every Two years	Armstrong Medical	Replace the device battery
Every Three years	Armstrong Medical	Replace the Real Time Clock battery
Every Six Years	Armstrong Medical	Replace the O_2 pressure regulator
Every Six Years	Armstrong Medical	Replace the Air pressure regulator
Every Six Years	Armstrong Medical	Replace the 2 proportional (flow sensor) valves
Every Ten Years	Armstrong Medical	It is necessary to replace all active internal components of AquaVENT® FD140i for safety reasons during maintenance after 10 years.

AquaVENT® FD140i Servicing schedule from the date of first use.

7 Cleaning and Decontamination

7.1 Cleaning

Cleaning and Decontamination

Before cleaning, ensure that the device is powered OFF and that the mains power lead is removed and kept separate from cleaning solutions. Use only mild disinfectant detergents applied to a soft cloth. Wipe only the external surfaces of the device.

Such detergents are those suitable for cleaning external surfaces of equipment common to critical care areas of hospitals. Surfa® Safe (Laboratoires Anios) and Clinell® (Gama Healthcare) are suitable detergents. A list of specific approved detergents is available upon request.

After cleaning and before powering the device on, check that the external surfaces are completely dry.

7.2 Decontamination

Before returning AquaVENT® FD140i to the manufacturer for repair/service, the decontamination status should be assessed by competent hospital personnel as either requiring decontamination or not requiring decontamination due to the risk of contamination being low enough to be deemed acceptable.

WARNING

- Wear protective gloves and safety goggles.
- Do not inhale fumes.
- If liquids have entered the housing, remove AquaVENT® FD140i from service. Notify an authorised service technician to clean the device.

NOTE: Refer to the Material Safety Data Sheets of the cleaning solutions before use.

8 Technical Specifications

8.1 Technical specifications

Gas supply	
Oxygen supply (O_2) pressure range	270 to 600 kPa (40 to 87 PSI)
Oxygen supply (O_2) max. over pressure	1000 kPa (145 PSI)
Oxygen supply (O_2) flow rate	140L/min maximum
Oxygen supply (O_2) quality	Medical oxygen, dry, oil-free and particle-free
Oxygen supply (O_2) connection	NIST
Air supply pressure range	270 to 600 kPa (40 to 87 PSI)
Air supply max. over pressure	1000 kPa (145 PSI)
Air supply flow rate	140L/min maximum
Air supply quality	Medical compressed air, dry, oil-free and particle-free
Air supply connection	NIST
Power Supply	
Mains power	100 - 240VAC, 50 -60Hz
Power consumption	< 35VA
Internal Battery	11.1V Nominal, 2600 mAh Nominal
Type	Rechargeable Li-Ion
Operating time	≥ 60 minutes with fully charged battery
Power Inlet Fuses	F 1A, 250V, Breaking Capacity Current AC: 35A
Environmental Conditions	
Operating temperature	+5°C - +40°C
Operating humidity	<90%
Operating atmospheric pressure	50 kPa-110kPa
Storage and transport temperature	0°C - +40°C
Storage and transport relative humidity	<90%
Storage and transport atmospheric pressure	50 kPa-110kPa
Ingress protection rating	IPX1, Protected against vertically dripping water
Restricted environments	Not suitable for use in the presence of flammable anaesthetic mixture. Not for home care, helicopter or submarine use
Dimensions (Width x Depth x Height)	W236 x D138.5 x H260 mm
Weight	4.8kg +/- 0.5kg (varying on specification)
Electromagnetic compatibility	Tested according to: BS EN 60601-1-2, according to Directive 2014/30/EC
Classification	
Applied Part - Class B	Breathing Circuits/ Respiratory system (For more information refer to section 11.2 Appendix 2 - Accessories)
Device class according to Directive 93/42/EEC, Annex IX:	IIb
Protection class, electrical hazard:	I (protective earth)
Mode of operation (duration of application)	Continuous short-term application
Languages	English, French, German, Spanish, Dutch, Italian.

Alarms	
Type of Alarm	Visual and Audible
Alarm volume range	45.5 dBA to 86.5 dBA
Alarm audio mute duration	120s

Noise levels	
Peak sound pressure (no alarm state)	54.5dBA
Peak sound pressure (alarm state)	86.5dBA

Display	
Screen type	Colour TFT LCD
Screen diagonal	7.0 inch
Screen Resolution	800 (RGB) x 400

Oxygen sensors	
Sensor Type: Option 1	**Paramagnetic Oxygen Sensor**
Accuracy	+/- 2 percentage points
Service	Annual
Service life	10 years
Sensor Type: Option 2	**Oxygen fuel cell**
Accuracy	+/- 2 percentage points
Service life	Depends on gas flow and usage

Safety Valve	
Free breathing valve	Upon loss of gas supply free breathing valve allows spontaneous breathing with room air
Example Flow Setting	**Expected range (L/min)**
2L/min	1.5 - 2.5
5L/min	4.0 - 6.0
10L/min	8.5 - 11.5
20L/min	18.0 - 22.0
40L/min	36.0 - 44.0
70L/min	65.0 - 75.0
110L/min	102.0 - 118.0
140L/min	130.0 - 145.0

Application	
Intended Operator	Trained healthcare professionals only
Patient categories	Adults, children and new-born babies

8.2 Therapy modes technical specification

Mode	CPAP	CPAP (Paed)	Helmet CPAP	BUBBLE-PAP	HFOT	POINT
Interface screen colour	Purple	Grey	Yellow	Green	Light blue	Dark blue
Flow range (L/min)	20-140	10-70	40-140	2-20	2-70	10-80
Default flow (L/min)	60	20	60	5	20	30
Oxygen range (%)	21-100	21-100	21-100	21-80	21-100	21-100
Default oxygen (%)	30	30	30	30	30	60
Pressure measured	Yes	Yes	Yes	Yes	No	No
Breath frequency measured	Yes	Yes	Yes	No	No	No
Nebuliser ON	Yes	Yes	No	No	Yes	Yes
Pressure alarm range (cmH_2O)	2-25 and OFF	2-25 and OFF	2-25 and OFF	2-15 and OFF	-	-
Default pressure alarm 'Low'	2	2	2	2	-	-
Default pressure alarm 'High'	12	12	12	10	-	-
Apnoea alarm range (sec)	20-60	20-60	20-60	-	-	-
Default apnoea alarm period (sec)	20	20	20	-	-	-

8.3 Parameter settings

	Increment	Min. Value	Max. Value
FiO_2	1 at 21 - 100%	21%	100%
Treatment Duration	0:00:01 (hr:min:sec)	0:00:01 (hr:min:sec)	23:59:50 (hr:min:sec) plus # days
Volume Settings	10%	10%	100%
Apnoea Duration	1s	20s	60s
Pressure Max. (Pmax)	1cmH_2O	5cmH_2O, OFF	25cmH_2O, OFF
Pressure Min. (Pmin)	1cmH_2O	2cmH_2O, OFF	22cmH_2O

8.4 Measurement functions

	Increment	Min. value	Max. value	Accuracy
FiO_2	1 at 21 - 100%	21%	100%	2%
Respiratory Rate	1/min	0/min	60/min	±2/min
Patient Pressure	1cmH_2O	0cmH_2O	50cmH_2O	±10%

8.5 Paramagnetic oxygen sensor

Accuracy	±2 percentage points
Calibration	Annual or when a defect is suspected
Service Life	10-years

8.6 External communication

WARNING

For communication with external devices, AquaVENT® FD140i has a USB Type B connection.

This connection is not intended to be accessible by a caregiver and is concealed from use by a cover that should only be removed by an authorised service technical or suitably-qualified hospital engineer.

8.7 Electromagnetic environment

AquaVENT® FD140i is intended for use in the electromagnetic environment detailed at 8.1 Technical Specifications. It is the responsibility of the user to ensure that the device is operated in such an environment.

Emissions

BS EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbance – Requirements and tests For Professional Healthcare Environment (controlled EM Environment)		
Reference Standard	Class/limit	Electromagnetic environment
Conducted and radiated RF emissions CISPR 11	Group 1	AquaVENT® FD140i uses RF energy only for its internal function. The resulted emissions are of a very low level and are not likely to cause any interference in nearby electronic equipment.
Conducted and radiated RF emissions CISPR 11	Class A	AquaVENT® FD140i is only to be used in a Professional Healthcare Environment. MODE 1 MODE 2
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Immunity

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance to the electromagnetic environment setting
Electrostatic discharge (ESD) MODE 1 IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ±8 kV contact ± 2 kV, ± 4 kV, ± 6 kV, ±8 kV, ± 15 kV air	± 4 kV contact ± 6 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. At higher levels, during normal functionality (uninterrupted therapy) it shall be permitted a temporary loss of display (blank display) which may occur due to the phenomenon of electrostatic discharge.
Electrostatic discharge (ESD) MODE 2 IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ±8 kV contact ± 2 kV, ± 4 kV, ± 6 kV, ±8 kV, ± 15 kV air	± 4 kV contact ± 8 kV air	
Electrical fast transient/ burst MODE 1 IEC 61000-4-4	± 2 kV 100 kHz burst frequency 0.75 ms duration	± 2 kV 100 kHz burst frequency 0.75 ms duration	The mains power quality should be that of a typical commercial or hospital environment. Permitted ticking sound may appear along with display altering, re-selection of functions are available within 0.01 sec, therapy mode is uninterrupted.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	< 5% U_T (> 95% dip in der U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	The mains power quality should be that of a typical commercial or hospital environment. If the user and/or operator of the AquaVENT® FD140i requires continued operation during power mains interruptions, it is recommended that the AquaVENT® FD140i be powered from an uninterruptible power supply (UPS) or a battery.
Magnetic field at the power frequency (50/60 Hz) 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: U_T is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to the AquaVENT® FD140i, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF to IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	10 V	$d = 0{,}35\ P$
Radiated RF EM fields EN 61000-4-3:2006 +A1:2008+IS1:2009+A2:2010	3 V/m 80 MHz to 2.7 GHz	3 V/m	Swept frequency testing to be performed on 4 faces of the AquaVENT® FD140i.
			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 In the vicinity of equipment marked with the following symbol, interference may occur. 
References and footnotes are explained on the following page.			

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AquaVENT® FD140i is used exceeds the applicable RF compliance level above, the AquaVENT® FD140i should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AquaVENT® FD140i

The AquaVENT® FD140i is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AquaVENT® FD140i can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AquaVENT® FD140i as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter W	**Separation distance according to frequency of transmitter m**	
	150 kHz to 80 MHz $d = 0{,}35\ P$	
0.01	0.04	
0.1	0.11	
1	0.35	
10	1.1	
100	3.5	

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

Note 1 At 80 MHz and 800 MHz, the 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.

9 European Community Declaration of Conformity

9.1 EC Declaration of Conformity

No. AML2401

Declaration of Conformity for Gas Flow Driver

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Gas Flow Driver (AquaVENT® FD140i)
Legal Manufacturer:	Armstrong Medical Ltd, Wattstown Business Park, Newbridge Road, Coleraine BT52 1BS, Northern Ireland
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	AquaVENT® FD140i is a clinical respiratory therapy device that delivers an air and oxygen mixture at 21-100%. The device assists spontaneous and natural patient respirations by providing continuous positive airway pressure (CPAP) and high flow oxygen therapy (HFOT) in patients in a professional healthcare facility. AquaVENT® FD140i is not a life-support device. It is intended for use with adults, children and new-born babies, should they be medically indicated for the therapy.
MDD Classification:	Class IIb
Notified Body:	SGS Belgium NV, CE1639, SGS House Noorderlaan 87, 2030 Antwerp, Belgium
CE Certificate Reference	GB19/964541
EU Authorised Representative	Advena Ltd, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta
MDD Conformity Assessment Route:	Full Quality Assurance in accordance with Annex II of the Medical Device Directive

Name Ciaran Magee **Position** Technical Director

Signed **Date** 06/04/2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

List of Standards including date of issue and relevant parts are listed in the Technical Documentation.

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
AMFD140i-EU	FD140i Gas Flow Driver, Complete EU	57831
AMFD140i-UK	FD140i Gas Flow Driver, Complete UK	57831

10 Disposal

10.1 Disposal

AquaVENT® FD140i must not be disposed of as general waste. It must be disposed of separately. Please adhere to applicable regulations when disposing AquaVENT® FD140i.

In the United Kingdom applicable regulations include:

The Waste Electrical and Electronic Equipment (WEEE) Regulations (2013)
The Waste Batteries and Accumulators Regulations (2009)

All countries within the European Union must comply with:

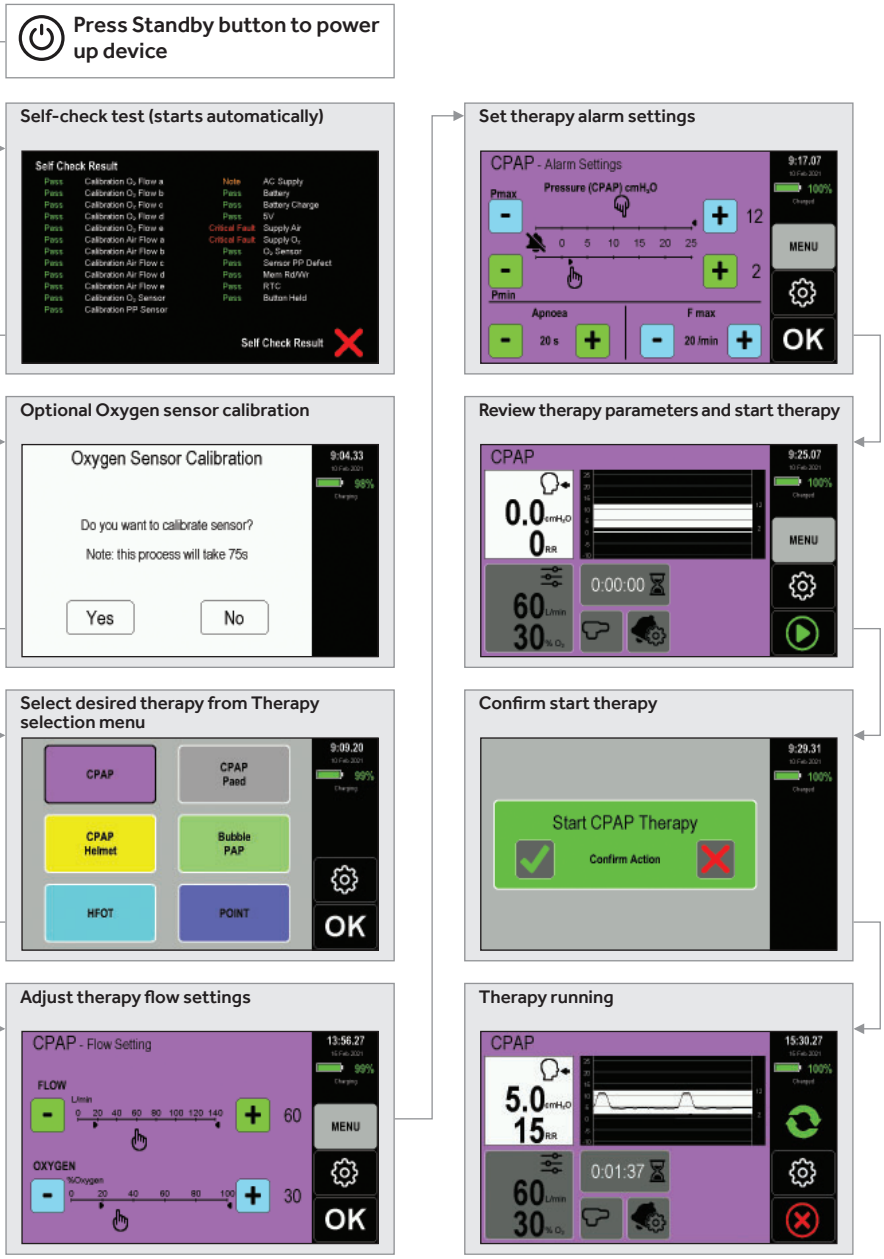
EU Directive 2011/65/EU (Restriction of the Use of Certain Hazardous Substances in Electronic and Electrical Equipment)

If you are disposing of this device outside the UK, please adhere to country-specific disposal regulations regarding electrical equipment and Li-Ion batteries.

11 Appendices

11.1 Appendix 1 - Therapy Set-up Flow Diagram

For a detailed explanation of therapy set-up and operation refer to chapter 4, "Using AquaVENT® FD140i".



11.2 Appendix 2 - Accessories

AquaVENT® FD140i is compatible with a range of accessories available from Armstrong Medical. Accessories include breathing circuits, heater humidifier, humidification chambers, PEEP valves, filters, face masks and nasal interfaces.

An extended list of compatible accessories can be accessed at www.armstrongmedical.net or by contacting Armstrong Medical via the contact details listed on the back cover of this manual.

NOTE: The manufacturer recommends the use of compatible Armstrong Medical accessories only.

11.3 Appendix 3 - Definitions

Definitions of abbreviations included in this User Manual;

AIR	Medical air
O_2	Medical oxygen
CPAP	Continuous Positive Airway Pressure
CPAP Paed	Continuous Positive Airway Pressure, Paediatric
BUBBLE-PAP	Bubble Positive Airway Pressure
HFOT	High Flow Oxygen Therapy
POINT®	Perioperative Insufflatory Nasal Therapy
PEEP	Positive end-expiratory pressure
FiO_2	Fraction of inspired oxygen
SNP	Sinonasal polyposis
F Max	Maximum respiratory rate
P Max	Maximum CPAP pressure
P Min	Minimum CPAP pressure
CO_2	Carbon dioxide
L/Min	Litres per minute
RR	Respiratory rate
cmH_2O	Centimetres of water pressure
Sec and s	seconds
NIST	Non Interchangeable Screw Thread
dBA	A-weighted decibels
LCD	Liquid Crystal Display
RGB	Red, Green, Blue colour model.

11.4 Appendix 4 - User Manual Revision History

Release Date	Issue No.	Summary of change/s
17/04/2020	01	Original
23/06/2020	02	Change of Power Supply rating to 100-240 VAC; and other editorial changes.
24/07/2020	03	General improvements to the accuracy and consistency of the displayed information
18/11/2020	04	General improvements to the accuracy and consistency of the displayed information
14/01/2021	05	Changes to reflect firmware update
05/01/2022	06	Addition of information for battery use and change of software version to 1.02

For Technical Support and Customer Service, contact Armstrong Medical Ltd.

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EC REP

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Malta

Most recent version of this manual is available on the Armstrong Medical Ltd website.

This manual documents software version 1.02

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