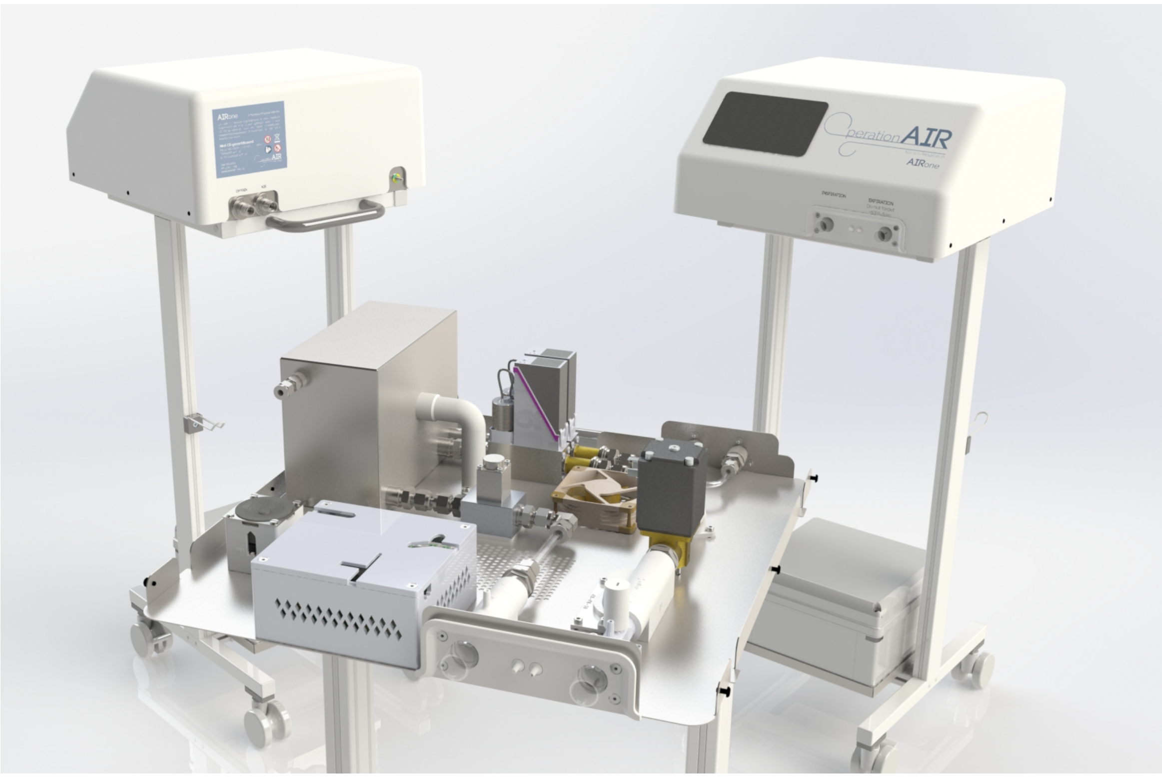
OperationAIR

Assist In Respiration

AIRone - Technical Manual

OperationAIR

Version 1.0, May 6, 2020



⚠ WARNING:

The device should only be used by trained users and these instructions should be thoroughly read before use.

Device version: 1.0
Firmware version: 1.0
Manual version: 1.0

Liability and warranty

This medical device is made available to healthcare institutions in the Netherlands which have explicitly requested this on the basis of the procedure established by the Inspection for Healthcare and Youth (IGJ) to deliver non-CE-certified medical devices or devices which have not completed the normal assessment procedure. Delivery of this medical device has happened on the request of the healthcare institution. The application of this medical device is based on the responsibility of the healthcare institution as defined in the 'Wet kwaliteit, klachten en geschillen zorg (Wkkgz)'. The manufacturer has reported the delivery of this device to the IGJ conform aforementioned procedure.

Customer support

In case of production errors or when service, assistance or recalibration is needed, please contact:

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Contents

1 Introduction

1.1 Scope

This technical manual is intended to outline the general working principle of the AIRone ventilator, and to explain the design choices and functionality for all relevant components.

1.2 Intended use

The AIRone provides positive-pressure ventilation (PPV) for emergency automatic ventilation with adjustable PEEP, I:E ratio, peak pressure, oxygen concentration(%) and breathing frequency, created for the use on adult (suspected) COVID-19 patients who need non-weaned respiratory support to bridge a longer period of time until conventional ventilation becomes available.

2 General working principle

The AIRone uses pressurized medical air and oxygen that is available in most hospitals, reduces it to the required pressure, and delivers this to the patient using a set of proportional valves that are controlled using a central microcontroller.

The physician can start up the device and use the touchscreen (GUI) to set ventilation parameters to the desired settings. Settings that can be adjusted by the user are Peak Pressure, Positive End-Expiratory Pressure (PEEP), Fraction of Inspired Oxygen (FiO_2), Inspiratory:Expiratory ratio (I:E Ratio) and breating rate. The GUI will communicate these setting to the Micro Controller Unit (MCU). The MCU then controls all valves to ventilate the patient accordingly.

The AIRone has two male NIST (Non-interchangeable screw thread) connectors, one for compressed medical air and one for oxygen. The female counterparts of these connectors should be available in the hospital and can be connected to the AIRone. The input pressure of both oxygen and compressed air may vary between 4 and 8 bar. In the device, the oxygen and air pressure is reduced to 4 bar. Two Mass Flow Controllers (MFCs) are used to control the flow of both gasses into a mixing chamber. This ensures a highly controlled mixing ratio, having a gas with the desired oxygen concentration as result. A pressure sensor in the mixing chamber gives feedback to the MFCs, adjusting their flow to keep the pressure in the chamber at 650 mbar. As a back-up, a back pressure regulator ensures the pressure in the chamber will never exceed 1 bar by blowing off air when the pressure is too high.

Downstream of the mixing chamber, a proportional valve regulates the pressure going into the patient. Generally, the valve will open at the start of inspiration and close when the pressure at the lungs is at the desired plateau pressure. Before the gas mixture flows to the patient it passes a check valve which blocks flow coming back from the patient.

During expiration, the gas is filtered by a HEPA filter. The gas then passes another check valve, and also a pressure relief valve, which opens when the pressure in the system rises above 70 cmH_20. The gas is then released to outside the system by another proportional valve that opens at the beginning of the expiration and closes at the end of the expiration.

3 Product specifications

Productspecifications	
Tidal volume	5 - 700 mL
Positive end expiration pressure (PEEP)	5-30 cmH_2O
Pressure above PEEP	5-40 cmH_2O
Maximum pressure	70 cmH_2O
Breathing-frequency	5-40 b/min
Inspiration time	0.2-5.0 sec
Expiration time	0.2-5.0 sec
Inspiration expiration ratio (I:E)	2:1 - 1:3
Peak inspiration "flow"	0-100 L/min
Pressure rise time, inspiration rise time	0.3-0.7 sec
O_2-concentration FiO_2	21-100 %
Displayed	flow and pressure

Table 1: Product specifications of the AIRone ventilator.

4 Hardware description

Overview

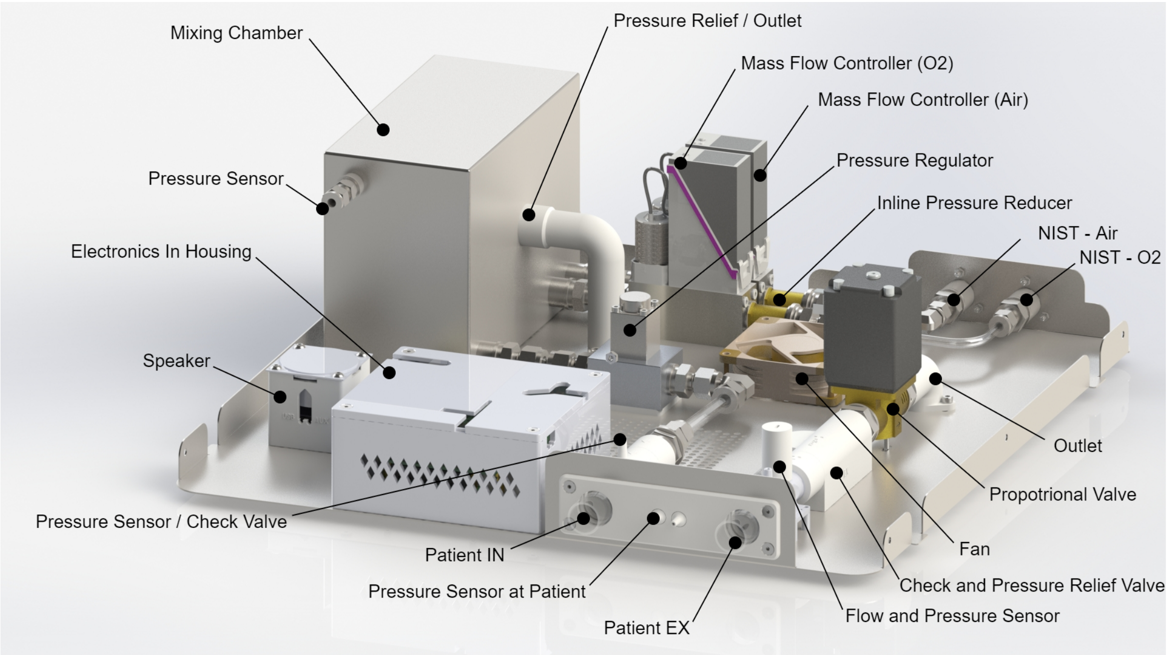

Figure 1: Rendered 3D image of the internal layout of parts

4.1 NIST connections

Essence	To connect to pressurized air and oxygen inputs without leaking, while making sure the two inputs cannot be interchanged.
Working principle	Female NIST connectors can be attached by tightening the bolts. The two connectors have different diameters to make them non interchangeable.
Specifications	Conform NEN-EN-ISO 18082:2014/A1:2017. The compatible pressure range is 4 to 14 bar. The outer diameter of both connectors is 19.7 millimeter. The inner diameter for the oxygen connector decreases from 13.5 to 4.7 millimeter, the outer diameter for the air connector decreases from 16 to 4.7 millimeter. They are connected to the bottom plate. The connector is made from stainless steel 316, which is oxygen compatible and bio-compatible.
Accuracy	Not applicable
Housing/tubing	None
Bill of materials	3.19 NIST Fitting O2, 3.20 NIST Fitting AIR

4.2 Inline pressure reducers

Essence	To reduce input pressures to 4 bar. The input pressure from the hospital supply ranges between 8 and 4 bar. The mass flow controllers are able to handle these pressures. In the long term, pressures above 4 bar could exhaust the internal valves in the mass flow controllers. Thus, to improve durability pressure reducers are implemented.
Working principle	It consists of a membrane with a spring that opens at a certain pressure. When the pressure downstream is below the pressure applied by the spring, the valve will increase its opening, lowering the resistance. When the pressure is above the force of the spring, it will decrease its gap and increase the resistance. The flow through the valve is matched to the input gas pressure. Pressures higher than 4 bar are compensated by an altered flow trough the valve in order to maintain a steady output pressure.
Specifications	Max input pressure 15 bar, output pressure 4 Bar, G1/4”, it is made from Brass, which is oxygen compatible but it is known that it can result in a extremely low dose of loose copper ions.
Accuracy	Not applicable
Housing/tubing	None
Bill of materials	3.16 Pressure regulator

4.3 Mass flow controller (MFC)

Essence	To control the flow of air and oxygen towards the mixing chamber and set the desired oxygen fraction in the mixture. The pressure in the mixing chamber is controlled by adjusting the volumetric flow set in the MFCs.
Working principle	Mass flow controllers measure gas flow by measuring the heat loss over a heated wire when gas flows by the wire. The flow is controlled by a proportional valve. Two MFC’s are used, one for air and one for oxygen. Based on the set FiO_2, the MFC connected to the oxygen input generates more output then the other to reach the required O_2 fraction.
Specifications	The inlet and outlet diameters are both G1/4. Input pressure 3 - 4 Bar. The MFC is made from stainless steel 316L, with standard: Viton® rings. Power input 24V. All are biocompatible and oxygen compatible.
Accuracy	Maximum output flow: 50 l/min, accuracy: ±1 %FSS.
Housing/tubing	None
Bill of materials	3.1.1 MFC AIR including cables, 3.2.2 MFC O2 including cables

4.4 Mixing chamber

Essence	The mixing chamber is used to ensure mixing of air and oxygen. Volume from the mixing chamber is extracted to deliver tidal volumes to the patient. Air and oxygen is added by the mass-flow controllers to supplement the escaped volume. The fluctuation in pressure is preferably minimized.
Working principle	The mixing chamber is a simple tank with a fixed volume. It has no active components. The higher the tank volume, the lower the fluctuation but the longer the response time to adjusted FiO_2.
Specifications	The tank is made from stainless steel 316, which is bio-compatible and can work with 100% oxygen. The volume is 3L. Inlet size: G1/4 - G1/4, outlet size: G1/4 - G1/4 and 1 G3/8 for the pressure sensor. Working pressure 650 mbar.
Accuracy	The relevant parameter is the pressure inside the chamber. The proportional valve downstream decreases the pressure as it takes gas from the chamber during inspiration. The MFCs react by increasing their flow, aiming for a constant pressure. During the expiration the proportional valve will close and pressure will build up in the chamber. The MFCs will decrease their flow accordingly. The result is a fluctuation in pressure of 50 mbar with respect to the desired pressure. The proportional valve is able to handle this fluctuation.
Housing/tubing	None
Bill of materials	3.14 Mixing chamber

4.5 Pressure sensor on mixing chamber

Essence	Measure the pressure in the mixing chamber.
Working principle	A pressure change will cause a strain in the sensor and in the buried resistors. The resistor values will change in proportion to the stress applied, which produces an electrical output, which will be amplified.
Specifications	The sensor is operated on 5V. It is a gauge sensor mounted to the PCB. Pressure range: 0 to 15 psi.
Accuracy	Total error band: 1.5%FSS, accuracy: 0.25%FSS.
Housing/tubing	None
Bill of materials	1.1.1.3 Pressure sensor 1

4.6 Safety relief valve on mixing chamber

Essence	The safety relief valve is a valve between the mixing chamber and an outlet part. As mentioned, the mixing chamber is added to provide stable pressure inlet to the proportional valve. In case of failure of the mass flow controllers to provide stable pressure input to the proportional valve, the pressure should not build up too high. The safety relief valve is the safety net for this scenario. The safety relief valve tries to maintain steady pressure upstream.
Working principle	The valve opens at an over-pressure. The release of flow is proportional to the excessive pressure. The upward flow creates counterpressure on the force applied by the a spring. Excessive pressure is vented until an equilibrium between the pressure applied by the safety relief valve and the flow from the system is reached.
Specifications	The used safety relief valve is made from brass.
Accuracy	Pressure: 1 bar, pressure range: 1 - 4 bar, blow-off: up to 200 l/min.

Housing/tubing	With SLS printing an outlet part is made. It is an elbow piece pointing downwards that guides gas out of the mixing chamber when the pressure inside becomes too high. It is connected to the mixing chamber with a conical fit and is mounted to the bottom plate.
Bill of materials	3.6 Safety Valve, 3.8.7 SLS 3D prints - TankOut

4.7 Proportional valve (inspiratory)

Essence	The proportional valve opens during inspiration to release air towards the patient, and closes when the required pressure is reached.
Working principle	The proportional valve is regulated by applying a voltage over the internal coil, creating a magnetic field. The created magnetic field pulls the magnet out, opening the valve and allowing flow to pass through. The valve will open or close more or less based on the voltage given to the coil.
Specifications	It is a 2-way normally closed valve, operating on 24V and made from stainless steel 316. The orfice is 4.5mm. It works on a pressure range from 0 - 70 bar, with a flow of 300 l/min at 10 bar.
Accuracy	Hysteresis: <0.2% FS, repeatability: <0.2% FS.
Housing/tubing	None
Bill of materials	3.15 Proportional Inhalation Valve

4.8 Check valve (inspiratory)

This valve and the housing is the same as *Check valve (expiratory)*.

Essence	This non-return valve allows air to flow through it in only one direction. This prevents expiratory air from entering the device.
Working principle	An umbrella shaped membrane is held in place by a small hole, which is surrounded by six additional holes. When a sufficient positive pressure difference is reached at the back of the umbrella, it flips open and lets air through. When the pressure difference is negative, the umbrella is firmly pushed against a rim, creating an airtight sealing.
Specifications	The valve is made from ML-151 Transparent Silicone. Not pre-loaded. Opening pressure of <1 mbar.
Accuracy	Not applicable.
Housing/tubing	The rim is made with SLS printing and keeps the umbrella valve in place. Via a conical connection the rim is connected to the housing for the *Pressure sensor (inspiratory)*. To ensure a good connection, a bio-compatible glue is used. For more information, see *SLS printing*.
Bill of materials	3.7 Umbrella valve, 3.8.3 SLS 3D prints - Check valve mount

4.9 Pressure sensor (inspiratory)

This sensor is the same sensor as *Pressure sensor (expiratory)*. The housing is different.

Essence	To measure the pressure in the inspiratory airflow system.
Working principle	The gauge sensor uses a differential sensing element on an integrated silicon chip to put out a different voltage based on the pressure on the sensor.
Specifications	Operating voltage 3.3V, sample frequency 0.21kHz.
Accuracy	Pressure range: 0 - 1 psi, total error band after customer zero: 1.5% FSS, accuracy: 0.25% FSS.

Housing/tubing	With SLS printing a housing is made in which the pressure sensor is kept in place in such a way that the sensor does not interrupt the flow. The housing is connected to the output part to the patient via a conical connection. The housing is mounted to the bottom plate via a pedestal to keep the right height.
Bill of materials	1.1.1.2 Pressure sensor 2, 3.8.1 SLS 3D prints - Patient IN

4.10 Output parts

Essence	The outlet parts connect the input and output of the device with the airway tubes from the patient. The housing keeps the connectors in place.
Working principle	Not applicable
Specifications	Both outlets for the inspiratory and expiratory gas tubes are 22 millimeter Polypropylene non-sterile straight male connectors. These are compatible with standard 22 millimeter tubing. They are bio-compatible and safe for use with 100% oxygen.
Accuracy	Not applicable
Housing/tubing	With FDM printing 2 parts are made: a cover and a doublemount. The output connectors are placed in the doublemount on the inside of the device. The cover is placed on the outside of the device and is connected with bolts to the doublemount, to ensure that the output parts are kept in place.
Bill of materials	3.21 22mm-22mm connector, 3.17.1 FDM 3D printing - Tube doublemount, 3.17.7 FDM 3D printing - Cover

4.11 Pressure sensor at patient

⚠ This sensor is not yet used and weaning is not possible with the AIRone.

Essence	The pressure sensor on the outlet parts can be attached to 2 pressure tube from the patients mouth. This measures spontaneous breathing and makes the process of weaning possible.
Working principle	The sensor uses a differential sensing element on an integrated silicon chip to put out a different voltage based on the pressure on the sensor.
Specifications	It is a gauge sensor, operating on 5V and has an analog output.
Accuracy	Pressure range: 0 - 15 psi, total error band: 1.5% FSS, accuracy: 0.25% FSS.
Housing/tubing	With SLS printing a connector part is made that can be placed in the doublemount of the *Output parts*.
Bill of materials	1.1.1.3 Pressure sensor 3, 3.8.4 SLS 3D prints - Pressure tubes

4.12 Flow sensor (expiratory)

Essence	Measure the flow going out of the patient.
Working principle	The sensor heats a variable resistance. Based on the flow speed across the sensor there is a heat drop over the two connection points. Based on this heat drop, the flow is calculated.
Specifications	It is a differential sensor, operating on 10V and has an analog output.
Accuracy	Flow range: 0 - 200 SLPM, pressure drop: 2.74 mbar, repeatability: 0.5% reading max.
Housing/tubing	The housing consists of 2 parts. With SLS printing, a tube is made which connects to the *Output parts* and the *Check valve (expiratory)*. This tube is smaller in diameter than the housing of the *Pressure sensor (inspiratory)* to ensure good measurements from the flow sensor. A second part is made with FDM printing and connects to the outside of the tube. This part mounts to the bottom plate.

Bill of materials	3.13 Flow sensor, 3.8.5 SLS 3D prints - Flow sensor holder, 3.17.8 FDM 3D prints - Flow sensor basket

4.13 Check valve (expiratory)

This valve and the housing is the same as *Check valve (inspiratory)*.

Essence	This non-return valve allows air to flow through it in only one direction. This prevents expirated air flow flowing back to the patient.
Working principle	An umbrella shaped membrane is held in place by a small hole, which is surrounded by six additional holes. When a sufficient positive pressure difference is reached at the back of the umbrella, it flips open and lets air through. on the other hand, when the pressure difference is negative, the umbrella is firmly pushed against a rim, creating an airtight sealing.
Specifications	Valve made from ML-151 Transparent Silicone, housed in a 3D printed seating. Not pre-loaded. Opening pressure of <1 mbar.
Accuracy	Not applicable.
Housing/tubing	The rim is made with SLS printing and keeps the umbrella valve in place. Via a conical press fit on both sides the rim is placed between the housing for the *Flow sensor (expiratory)* and the *Pressure sensor (expiratory)*. Between the pressure sensor and the check valve, a glue is needed to ensure a tight fitting. For more information, see *SLS printing*.
Bill of materials	3.7 Umbrella valve, 3.8.3 SLS 3D prints - Check valve mount

4.14 Pressure sensor (expiratory)

This sensor is the same sensor as *Pressure sensor (inspiratory)*. The housing is different.

Essence	To measure the pressure in the expiratory airflow system.
Working principle	The gauge sensor uses a differential sensing element on an integrated silicon chip to put out a different voltage based on the pressure on the sensor.
Specifications	Operating voltage 3.3V, sample frequency 0.21kHz.
Accuracy	Pressure range: 0 - 1 psi, total error band after customer zero: 1.5% FSS, accuracy: 0.25% FSS.
Housing/tubing	With SLS printing the housing is made in which the pressure sensor is placed and mounted to the bottom plate. It connects to the *Check valve (expiratory)* and the *Proportional valve (expiratory)* both with a conical press fit. The pressure sensor is placed in the same way in the tubing as the *Pressure sensor (inspiratory)*. On the bottom of the tubing a hole is made in which the *Fail safe* is placed.
Bill of materials	1.1.1.2 Pressure sensor 2, 3.8.2 SLS 3D prints - Patient OUT

4.15 Fail safe

Essence	The fail safe ensures the input pressure never exceeds 70 millibar to protect the patient. The fail safe sets an absolute maximum pressure with a pressure relief valve.
Working principle	The pressure relief valve uses a spring to pull a plunger with an O-ring seal against a sealing face. If an overpressure exists, this will work against the spring which will push the plunger up so the pressure is released from the system.
Specifications	The fail safe is made from stainless steel 304, the seal is made of Viton, which is biocompatible. The nominal width is 40 mm. The spring is ISO-K preloaded. The maximum orifice in case of overpressure is 113.1 mm^2.

Accuracy	Specified leak rate: 1 *10^{-7} mBar*l/s, opening pressure: 70 mbar, opening pressure range: 70 - 270 mbar.
Housing/tubing	The valve is placed in the bottom of the housing for the *Pressure sensor (expiratory)*. To keep the fail safe in place, an FDM printed part is placed around the fail safe and mounted to the bottom plate.
Bill of materials	3.5 Spring loaded overpressure relief valve, 3.17.3 FDM 3D prints - Pressure relieve print

4.16 Proportional valve (expiratory)

Essence	The proportional valve is needed to build up pressure during inspiration (peak pressure) and maintain pressure during expiration (PEEP). The valve is positioned at the end of the expiratory tract and ends up into the expiratory outlet. From here the expirated gas is moved out of the device.
Working principle	The proportional valve is regulated by applying a voltage over the internal coil, creating a magnetic field. The created magnetic field pulls the magnet out, opening the valve and allowing flow to pass through. The valve will open or close more or less based on the voltage given to the coil.
Specifications	It is a 2-way normally closed valve, operating on 24V and made from brass. The orifice is 8mm. It works on a pressure range from 0 - 25 bar, with a nominal pressure of 2 bar and a maximal differential pressure of 1 bar.
Accuracy	PWM frequency: 900 Hz, hysteresis: <5%, repeatability: <0.5% FS, sensitivity: <0.25% FS, span: 1:200, response time: 25 ms.
Housing/tubing	The output part is a SLS printed elbow part pointing downwards which is mounted to the bottom plate. It is connected to the proportional valve via a conical fit.
Bill of materials	3.15 Proportional Inhalation Valve, 3.8.6 SLS 3D prints - EndTube

4.17 Printed circuit board

Essence	Reading all sensors (pressure and flow) and controlling the actuators (valves and mass flow controllers). The PCB (Printed Circuit Board) contains a LPC11U37 MCU (Microcontroller Unit) which can be programmed in order to ventilate a patient correctly.
Working principle	Custom built PCB containing all components to satisfy the essence as discussed above.
Specifications	Input voltage 24V, maximum 10 Watt. Output depending on the specifications of the sensors and actuators.
Accuracy	Not applicable.
Housing/tubing	With FDM printing a housing for the PCB and the *Raspberry Pi* is made. It consists of 2 parts: a cover and a roof. On the cover text is placed to indicate which cables belong where. On both parts holes are added to ensure an outflow of air to cool the PCB and Raspberry Pi and ensure cables run smoothly out of the PCD.
Bill of materials	1.1.2 PCB printing parts, 1.1.3 PCB Base Plate, 3.17.4 FDM 3D printing - Electronics cover, 3.17.5 FDM 3D printing - Electronics roof

4.18 Raspberry Pi

Essence	To provide an interface for users to display and set the ventilation parameters.

Working principle	Raspberry pi which runs on Linux connected to a touchscreen to display the user interface. This interface will visualise volume, pressure and flow curves and values. Alarms will go of when the sensor detect values outside the set ranges. Memory is handled via a micro SD card.
Specifications	Raspberry Pi 3: 5V, 2.5A, micro USB connector, 24h memory (micro SD), Quad Core 1.2GHz Broadcom BCM2837 64bit CPU, 0-50°, 7' inch touch-screen. SD card: 16 GB MicroSDHC Card Class 10, UHS-1 U1
Accuracy	Not applicable.
Housing/tubing	The Raspberry Pi is placed in the same housing as the *Printed circuit board.*
Bill of materials	1.2 Raspberry Pi, 1.3 Raspberry Pi Touchscreen Display, 1.4 Micro-SD card

4.19 Ventilator

Essence	The ventilator blows air out of the machine to keep the internal temperature low.
Working principle	A ventilator rotates to create an airflow from inside the casing to outside. Air warmed up by the internal parts is in this way moved out of the device. The ventilator is powered via a USB port on the Raspberry Pi.
Specifications	RPM: 2200, maximum flow: 15.4 l/s, static pressure: 2.37 mmH2O, maximum volume: 17.7dB.
Accuracy	Not applicable.
Housing/tubing	None.
Bill of materials	3.18 Ventilator

4.20 Speaker

Essence	The speaker ensures the audio output and are placed inside the device.
Working principle	The speaker is connected to the GUI by USB for power input and an auxiliary connector for audio input.
Specifications	Input voltage: 5V, 500 mA, given via USB 2.0. The output is 4W RMS.
Accuracy	Not applicable.
Housing/tubing	With FDM printing a housing is made in which the speaker is placed and can be mounted to the bottom plate. Holes in the housing are for the cables and the volume slider.
Bill of materials	1.11 Speaker, 3.17.6 FDM 3D printing - Speaker print

4.21 Gas flow tubes & connectors

Essence	The hoses and connectors inside the device will connect the parts and will maintain pressure and flow.
Working principle	Not applicable.
Specifications	All the hoses are made from perfluoroalkoxy alkane (PFA), which is semi-biocompatible and oxygen compatible, with a nominal wall thickness of 0.062 inch. Two diameters are used: 3/8 and 1/4 inch, which can reach up to 10.6 and 7.9 bar working pressure at 37°C respectively. The connectors are all made from stainless steel 316. 11 different connectors are used, please look at the design schematics for more information.
Accuracy	Not applicable.
Housing/tubing	None.
Bill of materials	3.2 Gas pipe fittings, 3.3 PFA Tubing

4.22 Power supply

Essence	The device is powered at all times by the Uninterruptible Power Supply (UPS).
Working principle	It consists of a 24V transformer, UPS module, and two VRLA batteries. The power adapter can be connected to the mains power, which is then transformed to 24V by the transformer. This is used to power the electrical components of the device and simultaneously charge the batteries. When disconnected from the mains power supply, the UPS module immediately toggles power supply from the batteries.
Specifications	Input 220-230VAC, 50-60 Hz. Output 25.2 V DC, C14 cable. The power adapter is IEC 60601-1-2 certified. The UPS has a maximum nominal power of 48W and can power the device for 30 minutes with this power. Battery capacity is 55.2 Wh, 27.6 Wh each.
Accuracy	Not applicable.
Housing/tubing	Glass fibre reinforced polycarbonate body, polycarbonate lid, silicone sealing. It is IP67 rated. Dimensions: 300 x 300 x 180 mm. Maximum temperature it can withstand is 80°C. It can be cleaned with standard cleaning equipment (alcohol 70%, isopropylalcohol, alcohol with 1.5% chlorhexidine).
Bill of materials	1.13 Power supply

4.23 Bottom plate, chassis and casing

Essence	The bottom plate is needed to ground all the electrical parts of the device and to keep all the parts in place. The bottom plate is then placed and secured to the chassis. The chassis allows maneuverability of the ventilator and offers stability. The casing is placed over the bottom plate and protects the internal structures against splashing water and physical damage.
Working principle	The chassis and casing are interconnected through the bottom plate on which the internal components are mounted. The bottom plate is has a protective earthing connector which can be connected to a protective earthing terminal. The casing can be cleaned with the standard cleaning equipment (alcohol 70%, isopropylalcohol, alcohol with 1.5% chlorhexidine) and is IP22 certified.
Specifications	Chassis: Aluminium body, bottom dimensions : 50 x 40 cm Top dimensions: 40 x 40 cm, height: 122cm. Handle on back side of chassis, wheels with brakes on front side of chassis. Casing: ABS, dimensions are 492 x 492 x 220 mm, thickness of 5 mm. The material is not fire retardant, can stand temperatures between 85°C and 100°C. Bottom plate: stainless steel 316, thickness of 1 mm. Protective earthing cable is 3 meter, green/yellow colored.
Accuracy	Not applicable.
Housing/tubing	Not applicable
Bill of materials	2.1 Metal bottom plate, 2.2 Top cap, 2.4 Chassis

5 3D printed Housing/tubing

3D printing is used for the tubing and housing of certain parts. For both goals, different techniques and standards are used to achieve the characteristics and quality needed.

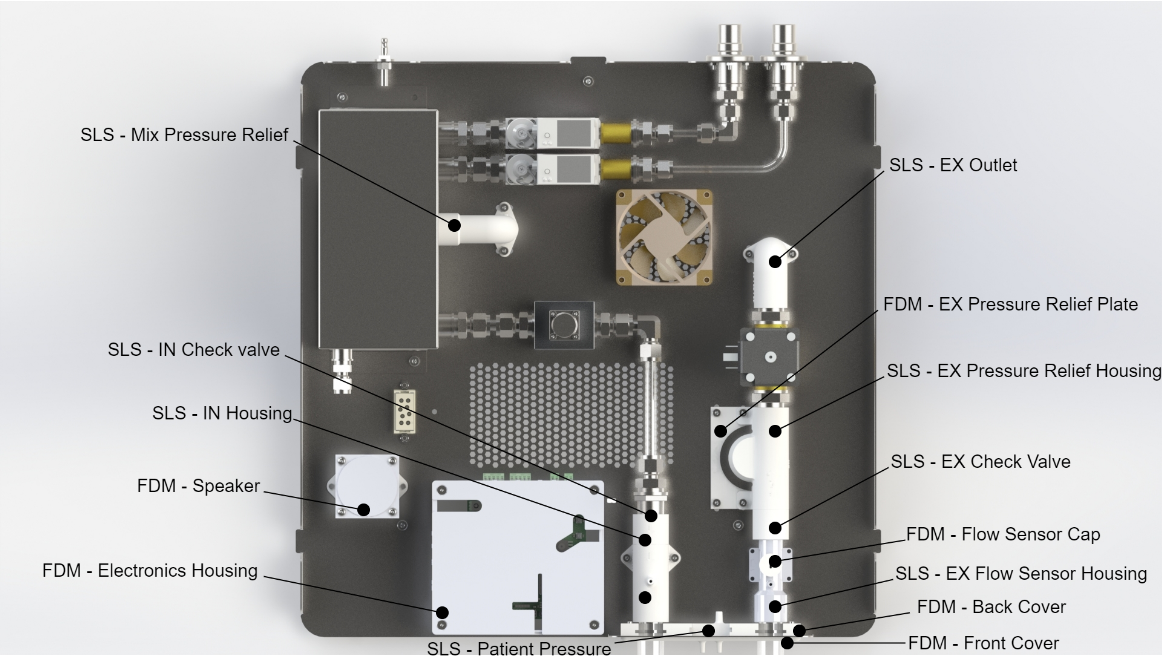

Figure 2: Rendered 3D image of the internal housing of parts

5.1 SLS printing

All the tubing is made with the SLS printing technique using polyamide 12 filament (nylon 12) under the ISO 13485 certificate. All the parts have a minimum wall thickness of 2 mm. Post processing consist of the following steps.

- The printed parts are sprayed clean.
- Then blasted with glass pearls to remove nylon dust.
- Then tumbled in ceramic particles to smoothen the surface.
- The parts are rinsed in water.
- Lastly, they are coated with an impregnation system which fills holes up to 0.1 millimeter to ensure bio-compatibility and reduce porosity.

To ensure oxygen-safety, the 3D-printed parts are designed and tested on airtightness, non-reactivity with high oxygen concentrations and having as lass as sharp edges and corners possible. Connections with other parts are in some instances glued using a bio-compatible instant-glue made of alkoxyethyl cyanoacrylate to ensure airtightness, ISO-10993 certified. All the parts are printed with the same printer, to ensure the parts fit and won't leak air. Furthermore, on every SLS part an arrow is printed to indicate the direction of the flow and the printing date. Parts can be used for 2 years and can then be replaced.

5.2 FDM printing

All the housing is made with the FDM printing technique using PLA filament. The housing parts do not come in contact with the patient or the gas. All the parts have a minimum wall thickness of 3 mm.

6 Accessories

⚠ `The accessories described here are not provided by OperationAIR and should be available in-house.`

6.1 Hoses

The hoses for connection of the oxygen and compressed air infrastructure to the AIR one consist of a female NIST connection that fits the connection in the wall of the hospital and the connection at the AIRone.

6.2 Breathing circuit

The breathing circuit consists of:

- Inspiratory tube
- Expiratory tube
- HME filter
- HEPA filter
- Endotracheal tube

The inspiratory and expiratory tubes needed for ventilation using the AIRone will be connected to the AIRone ventilator and the endotracheal tubes. The HME filter needs to be positioned between the inspiratory tube and the endotracheal tube and the HEPA filter needs to be positioned between the expiratory tube and the AIRone ventilator. The inspiratory and expiratory tubes used for testing are standard 22 millimeter tubes from Fisher Paykel.

6.3 HME filter

The heath and moisture exchanger (HME) filter humidifies and filters the air that flows into the patient. The HME filter connects to a standard endotracheal tube. The filter is positioned between the inspiratory tube and the endotracheal tube.

The filter consist of multiple layers of foam or paper embedded with a hydroscopic salt. The HME filter has a humidification efficiency of > 30mgH2O/L and a viral/bacterial efficiency of > 99.9%.

6.4 HEPA filter

The High-efficiency particulate air (HEPA) filter needs to be placed between the expiratory tube and the entry of the AIRone ventilator to filter the expiration air from the patient before entering the AIRone ventilator. The HEPA filter can trap 99.97% of dust particles with a diameter of 0.3 microns.

7 Software

7.1 General software description

The software of the AIRone consists of two main components. The GUI is responsible for all communication with the user. It displays ventilation parameters, settings and device status to the user, and is used to change several ventilation settings. It also generates visual and auditory alarms. Control of the hardware components resulting in the actual ventilation is controlled by software running on the microcontroller. This control module reads out all sensors, takes the ventilation settings from the GUI, and controls the mass flow controllers and proportional valves accordingly.

7.2 User Interface

The user interface is controlled by a raspberry pi 4 (model B) running on raspbian 2020-02-13. The user interface itself runs in Python 3.6. Communication with the microcontroller is done over UART using a custom binary protocol. Sensor data is sent from the microcontroller to the user interface, and then visualized to the user by either directly showing the value or plotting it in a graph. The following sensor values are sent to the user interface:

- Inspiratory flow
- Expiratory flow
- Inspiratory pressure
- Expiratory pressure
- Inspiratory oxygen fraction
- Inspiratory Tidal Volume
- Expiratory Tidal Volume
- Expiratory minute volume

The user can set several ventilation parameters on the user interface. This regards the following parameters:

- Peak pressure above PEEP
- PEEP
- FiO2
- breathing rate
- I:E ratio

The user interface can generate alarms based on ranges set by the user. Ranges can be set for Peak pressure above PEEP, PEEP, FiO2, and tidal volume. When a measured value is outside its set alarm range, an alarm sound is played and the relevant parameter is displayed in red on the user interface. Additionally, information regarding the status of the internal battery is sent to the user interface, so this can be displayed and an alarm can be issued when the battery is almost empty.

The user interface can also be used to trigger the inspiratory and expiratory hold manoeuvres, for which buttons are available.

7.3 Control Module

The control module is responsible for controlling the mass flow controllers and proportional valves, to create a breathing cycle with the parameters set by the user. It works with two separate control loops, one for the MFCs, and one for the proportional valves.

7.3.1 MFC control

A PID control loop is used, aiming to keep a constant pressure in the mixing chamber with the required oxygen fraction. It does so by calculating the ratio between the flows of air and oxygen that is needed to get the required oxygen fraction. The pressure in the mixing chamber is continuously measured, and when the pressure is below its threshold, the MFCs are opened to build up pressure again.

7.3.2 Valve control

Two other PID control loops are used to open and close the inspiratory and expiratory proportional valves to create the breathing cycles. The aim of this system is to follow the ideal pressure curve, based on the set Peak pressure, PEEP, I:E ratio and breathing rate, as much as possible. The pressures at the outlet of inspiratory gas and inlet of expiratory gas are measured, and the average pressure is used as the reference value for the control loop. The two PID loops alternate. One loop aims to keep pressure at the set peak pressure value. This loop is active during the inspiratory phase. The second loop aims to maintain PEEP pressure, and is active during the expiratory phase. Together these loops create the breathing cycle.

Appendices

I abbreviations

NIST	Non Interchangable Screw Thread
MFC	Mass Flow Controllers
IPR	Inline Pressure Reducer
BPR	Back Pressure Regulator
PRV	Pressure Relief Valve
PCB	Printed Circuit Board
MCU	Microcontroller Unit
GUI	Graphical User Interface
PU	Polyurethane
RMS	Root-mean square
V	Volt
W	Watt
(m)A	(milli)ampere
FSS	Full Scale Span
GUI	Graphical User Interface
ABS	Acrylonitrile butadiene styrene
psi	pound-force per square
UPS	uninterruptible power supply
SLPM	Standard litre per minute
UART	Universal asynchronous receiver-transmitter
VRLA	Valve Regulated Lead Acid
Wh	Watt-hour