User Manual – Inspiration Ventilation System

Project Inspiration

June 2020

Contents

1 Introduction

1.1 Device description

This section provides general information about the Inspiration Ventilator System along with guidelines for appropriate use.

The Inspiration Ventilator is a low cost solution to combat the shortage of mechanical ventilators in the world during the COVID-19 pandemic. It is based on the East-Radcliffe ventilator, developed in the sixties and extensively used during the last century. The design consists of easy to manufacture and widely available parts, reducing costs. The ventilator provides adjustable pressure, volume and breathing rate for every patient and offers the possibility to connect to a humidifier.

The ventilator works together with two separate systems; a humidifier and a power system. It is recommended that the ventilator is used with all systems in place to ensure proper care for the patient. It is recommended to use an off the shelf humidifier. For the power system, a PowerWalker model VI650SH was used during testing and found sufficient. The power system should be able to work without main power for at least 20 minutes.

1.2 Device Components

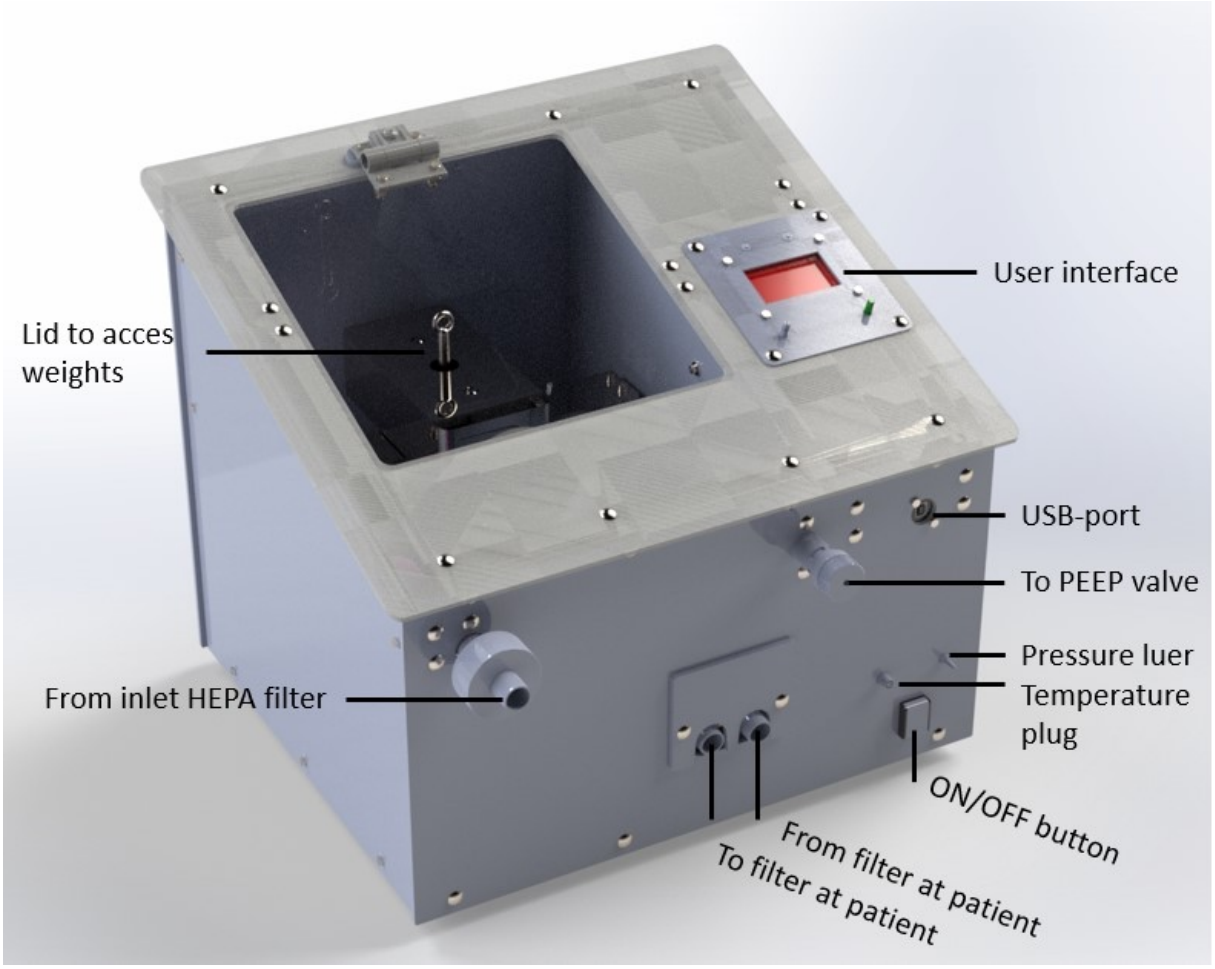

Figure 1: Overview of the user interfaces at the front

Figures 1 and 2 shows the location of the different components that users can interact with. The lid allows the weight to be moved to change pressure and ensures that the ventilator remains a closed system when pressure is set. All locations for external tubing are indicated as well. The user interface can be used to set the amount of breaths the machine provides per minute to the patient. The positive end-expiratory

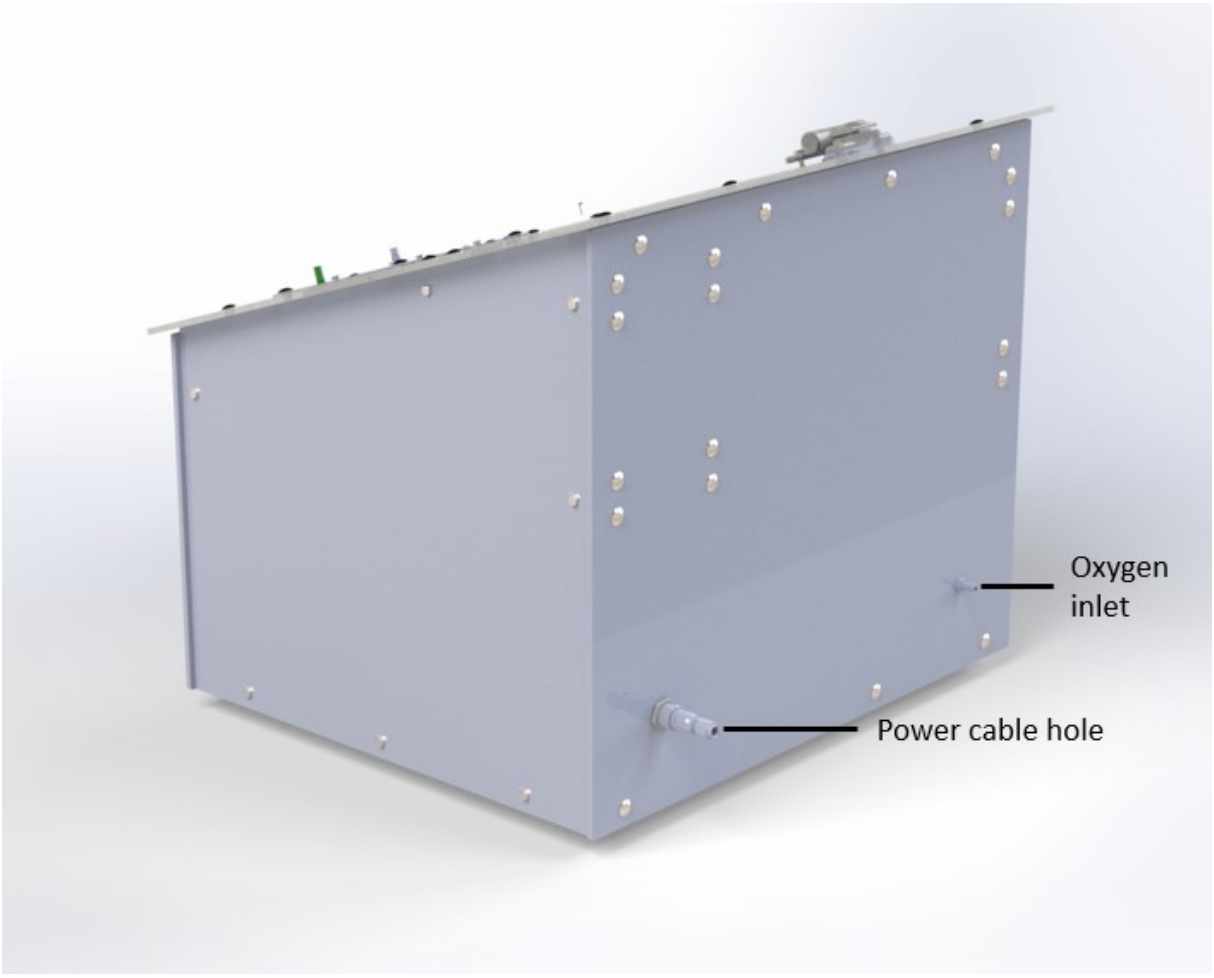

Figure 2: Overview of the user interfaces at the back

pressure inside of the patient lungs can be set with the PEEP valve. Output values of the system are displayed in the user interface, together with the alarm settings. See chapter 5 for an in-depth explanation of the user interface. The power is supplied by the cable, coming from the power cable hole. To measure the temperature of the air to the patient, a thermometer can be connected to the temperature plug, the temperature sensor is optional. If oxygen needs to be supplied the oxygen inlet can be used for connection to an oxygen tank. The USB port is for making changes to the software of the user interface or for showing graphical information. The pressure can be measured at two different locations. If it is measured at the inlet to the patient the pressure sensor needs to be connected to the pressure luer. Another option is to apply the sensor to the tubes/HEPA filter in the casing and connect it directly to the PCB. The ON/OFF button either powers on or powers off the entire ventilator, including the user interface. See chapter 4 for a detailed overview of the sensors and connections.

1.3 Intended Use

The Inspiration Ventilator System is intended for treating and monitoring patients with respiratory failure or respiratory insufficiency, directly or indirectly caused by a COVID-19 infection.

Warning: The Inspiration Ventilator System should only be used if no intensive care unit is available with a ventilator.

1.4 Intended User

The Inspiration Ventilator System should only be used by professional health care providers, that have received proper training on how to use the system and are experienced with ventilation treatment.

1.5 Intended Use Environment

The Inspiration Ventilator System should only be used in hospitals and facilities of which the primary purpose is to provide health care.

1.6 Disclaimers

The design is not certified by any official body for medical use. The design should not be used without proper validation and certification by local authorities. TU Delft provides the initial engineering design and blue prints, but holds no responsibility on the device's performance in actual clinical settings. Any future device based on the provided TU Delft design should not be used for medical purposes without complete evaluation by relevant local authorities for suitability as an emergency device. TU Delft cannot be held accountable for the performance of future device designs partially or fully based on the provided TU Delft prototype.

2 Warnings

In this part of the manual general safety guidelines are given. Throughout this document additional warnings can be found where applicable.

2.1 General

In this manual an overview of the functions and safety features of the Inspiration Ventilation System can be found, though this manual is not all-encompassing and is not an alternative to proper training.

The following instructions are of high importance and should always be pursued.

- Always keep the ventilator upright during use
- Always keep the ventilator levelled during use
- Always keep water traps hanging vertically
- Never leave the patient unattended
- Ensure continuous monitoring of the patient, the settings and the measurements displayed by the screen
- Discontinue use of the ventilator and contact a trained technician if any of the following event occur:
  - Falling over of device
  - Nonfunctional user interface
  - Detection of leakage in any of the components
  - Any other unforeseen events that harm the device, its functionality, the patient or the users in any way

2.2 Power Supply

The Inspiration Ventilation System should only be connected to a stable source that provides 12-24V with a minimum of 5A. This power source must allow the ventilator to function for at least 20 minutes when disconnected from the main power net.

2.3 Fire Hazard

The system allows to provide a patient with oxygenated air, which is highly flammable. Therefore, at all times, keep the system and its tubing away from possible ignition sources. If ever a burning aroma is sensed, disconnect the oxygen tank immediately and turn off the ventilator completely.

3 Specifications and Limitations

This chapter describes the specifications and the limitations of the machine.

3.1 Detailed specifications

- Ventilator usable without any electronics except motor. In that case the ventilator will be less precise
- Max. Pressure/Plateau Pressure[1] regulated by sliding weight: default range from 15 to 30 cm H2O
- Emergency ventilation pressure up to 70 cm H2O possible by adding weights
- Nearly constant pressure achieved by weighted bellow flow generation
- Min. Pressure/PEEP pressure[2] mechanically adjustable: 5 cm H2O to 20 cm H2O
- Safety valve in inspiratory airway, which triggers at 70 cm H2O
- Tidal Volume: results from lung compliance, pressure setting and breathing rate
- Mechanical valve control, fixed I:E ratio: 1:2 (expiration longer than inspiration)
- Breaths per minute: adjustable between 10 and 40 breaths per minute
- Only mandatory/forced ventilation possible

3.2 Alerting

- Breathing rate (too high/low); adjustable limits
- Tidal volume (too high/low); adjustable limits
- Oxygen concentration (Too high/low); adjustable limits
- Maximal Pressure/Plateau pressure (too high/low); adjustable limits
- Minimal Pressure/PEEP (too high/low); adjustable limits
- Temperature (too high/low); adjustable limits

3.3 Monitoring

The monitoring system is able to present the things listed below. The way all the parameters are presented in the operating menus is described in section 5.1.1

- Numeric display of Minimal Pressure/PEEP
- Maximal pressure/Plateau Pressure
- FiO2
- Tidal volume and Breathing rate (BPM)
- Temperature of inspired air

[1] Officially the min. pressure is measured but is almost the same as the PEEP pressure
[2] Officially the max. pressure is measured but is almost the same as the plateau pressure

3.4 Peripheral features

- Internal operating voltage: 12V (motor control up to 50V)
- 22mm airway connections according to ISO 5356-1
- Rigid casing; disassembly/servicing possible; cleaning possible
- Sterilisation of most breath delivering components possible

3.5 Limitations

There are some limitations that the simple mechanical working principle encounters. Currently the system is designed for mandatory ventilation, the system can not be used for weaning. This means that the patient must be sedated when connected to the ventilator. Furthermore the I:E ratio is fixed on 1:2, other breathing ratios can not be set.

4 System Setup & Connections

4.1 Attachment to the Patient

Figure 3 shows all tubing connections. All connections are designed for standard 22mm connections.

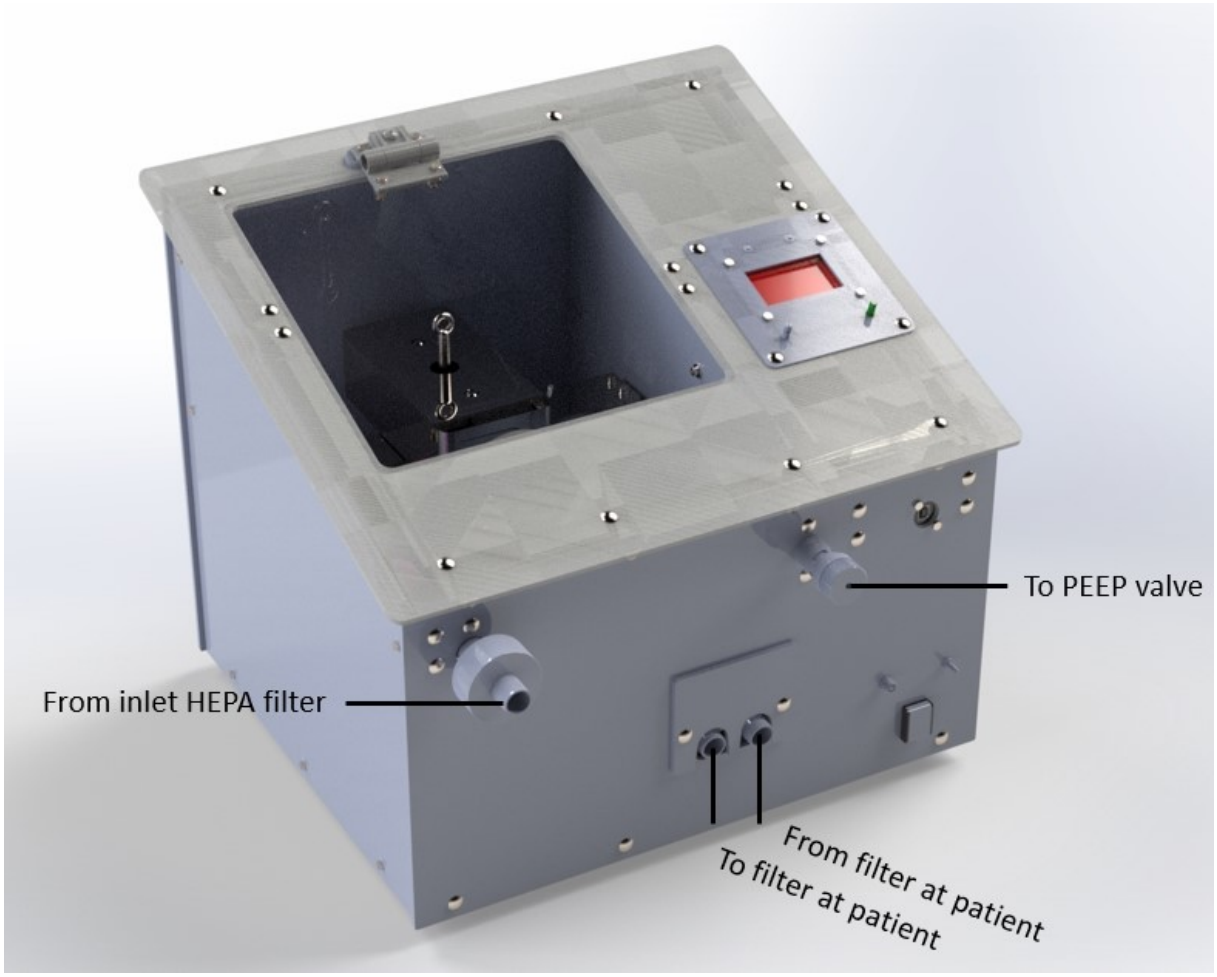

Figure 3: Air connections to ventilator

Warning: All in- and outgoing connections of the ventilator must be connected to a HEPA filter.

Warning: All HEPA filters must be connected before turning machine on.

Warning: None of the tubes and cables that go to the ventilator may be under tension.

Figure 4 shows the schematic overview of the system.

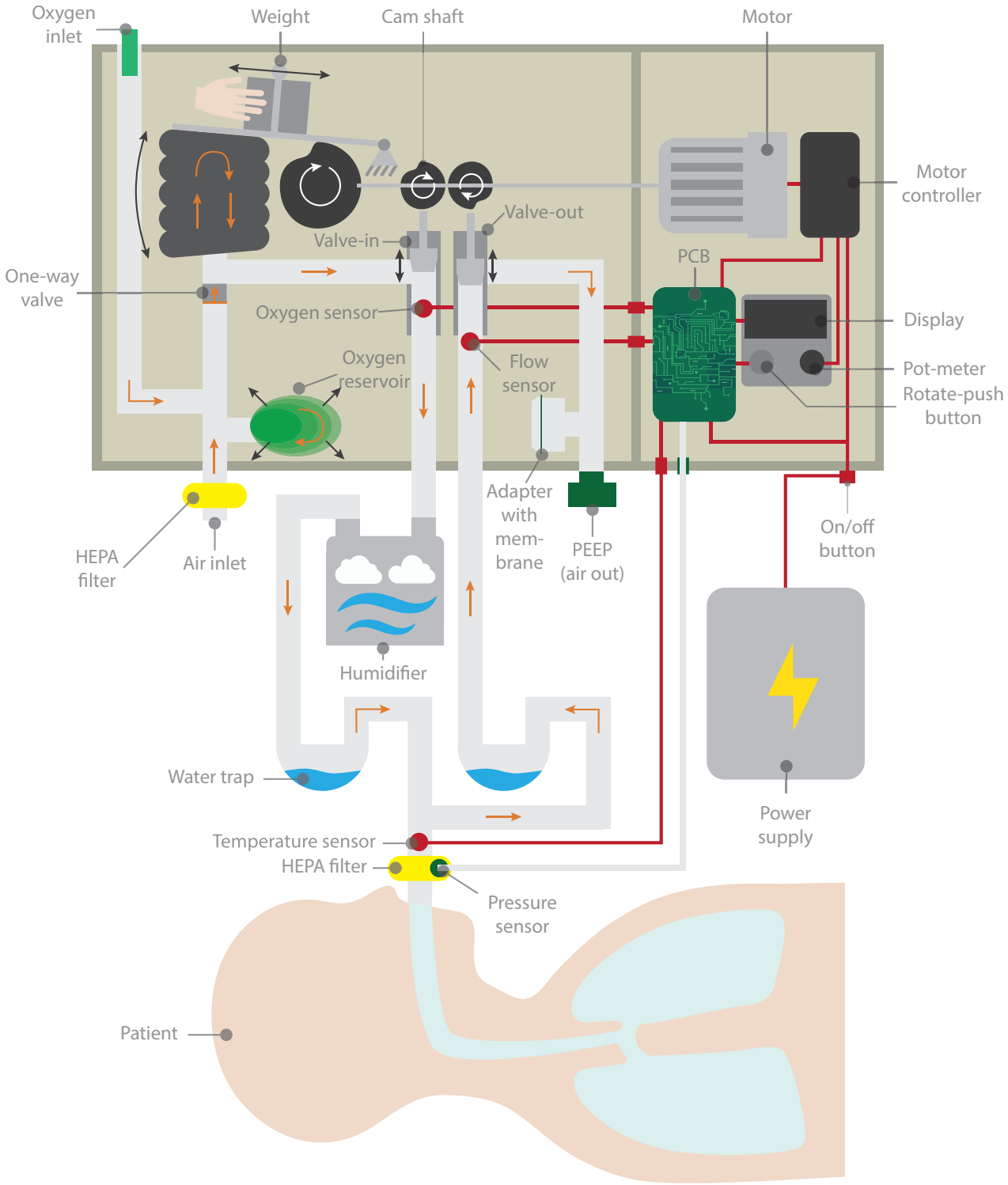

Figure 4: Schematic overview of system with pressure sensor outside the casing

Info: The humidifier with water traps and the temperature sensor are optional.

5 Controls & User Interface

In this section the controls and user interface will be discussed. First the layout of the machine will be explained. In the next section the use of the monitor will be elaborated. At last, it will be explained how to set all the operating parameters.

5.1 Electronic User interface

The user interface can be seen in Figure 5. This interface will be discussed below.

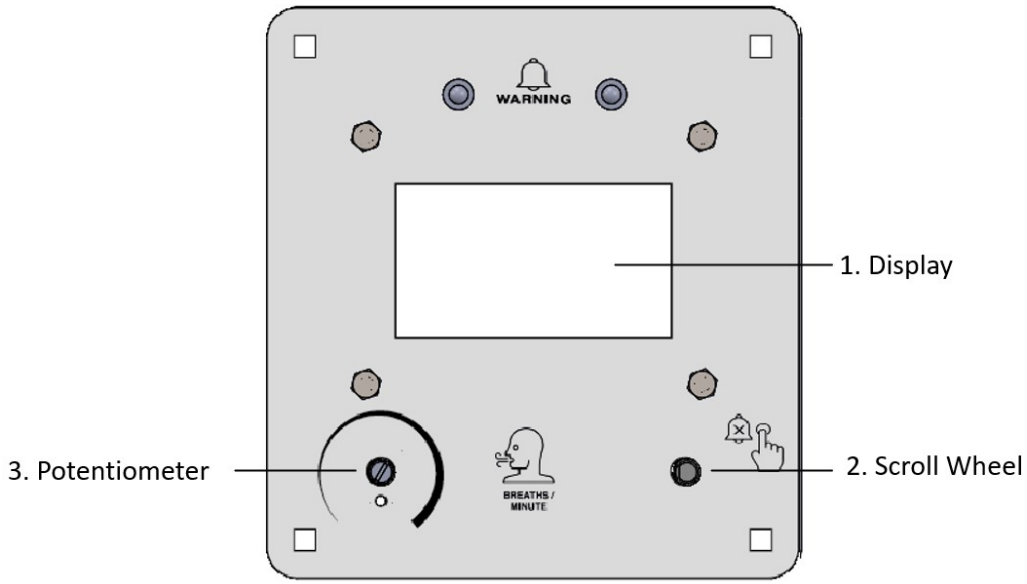

Figure 5: User interface

5.1.1 Respiratory Information

The primary display (**1**) features several screens. The primary screen displays operating data. In particular, six values are displayed (i) achieved breathing rate, (ii) lung tidal volume, (iii) fraction of inspired oxygen (FiO2), (iv) maximal pressure, (v) minimal pressure and (vi) the temperature of the inspired air. These values are displayed intermittently. It is also possible to scroll through the values in the primary screen by using the Scroll Wheel (**2**). The exact meaning of each value is elaborated in Table 1.

With the Potentiometer (**3**) the Breathing Rate can be controlled. Rotating clockwise and counterclockwise results in respectively a higher and lower breathing rate.

5.1.2 Use of Monitor and Editing Settings

By pressing or rotating the Scroll Wheel (**1**), the user may access the primary screen. Upon inactivity, or by going back, the primary screen is displayed again. The primary screen lists all the parameters and the current selected setting is displayed with a darker background. The user must use the Scroll Wheel to navigate the menu and can push on the Scroll Wheel to edit the currently selected setting. Rotating the Scroll Wheel clockwise or counterclockwise results respectively in going down and going up in the menu. An example of the primary screen is given in figure 6.

When editing, the edit screen is displayed, and the user can use the Scroll Wheel to alter the current value. Push on the Scroll Wheel to change the selected setting, rotate the Wheel to change the value and push again to confirm the selection. Pressing on back leads the user back to the primary screen.

Display	Unit	Provenance
`Breathing rate`	Breaths per Minute (BpM)	Moving average of the breathing rate of four breaths. Each breathing rate is extrapolated from the length of the intervalues of consecutive breath.
`Tidal volume`	mL	Moving average of the lung tidal volume of the last four breaths. The Tidal volume is calculated as the integrated expiratory mass flow over the duration of expiration, corrected for the expiratory gas pressure.
`FiO2`	%-molar	Moving average of molar fraction of inspired oxygen during the last five seconds.
`Min. pressure`	cmH2O	Moving average of minimal pressure/PEEP of the last four breaths.
`Max. pressure`	cmH2O	Moving average of the maximal pressure/plateau pressure during the last four breaths. Plateau pressure is calculated as the maximal pressure value calculated with a 50Hz lowpass filter.
`Temperature`	degrees Celsius	Temperature of the currently inspired air to the patient.

Table 1: Respiratory information as displayed on the primary screen.

When a threshold is exceeded the display will show a severe caution screen and the buzzer sounds at 1HZ with a duty cycle of 50%. Pushing on the Scroll Wheel will suppress the alarm for 10 seconds and the interface can be used as usual in that time. A blinking block around the parameter(s) indicates the value(s) that exceeds the thresholds. When needed an individual threshold can be changed.

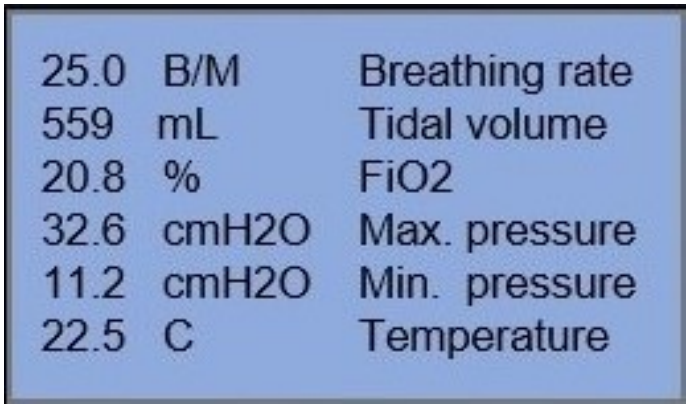

Figure 6: An example of the primary screen.

5.1.3 Bootloader

If you are using the ventilator you should not enter the bootloader menu. The bootloader menu can be started by pressing the Scroll Wheel when starting the machine. If that happened the LED's will blink as indication that the machine is in bootloader mode. Shut the machine down and restart the machine to go back to the normal mode.

Warning: Do not press the Scroll Wheel when starting the machine.

Warning: Shut the machine down if the LED's on the User Interface are blinking and restart the machine.

5.1.4 Initialize Settings

When the respirator starts up, threshold alarms are initially disabled. The screen will show the Severe Caution Screen and the buzzer sounds. Pushing on the Scroll Wheel will suppress the alarm for a short time. After that the user can set the alarm limits by two different options, using the previous limits or make custom limits. When choosing the previous limits the Severe Caution Screen and the buzzer will sound for a short time due to the measuring time. After that the user can use the interface as normal. When choosing the custom limits all thresholds needs to be initialized. The interface shows all parameters that needs to be set. A cross before the parameter indicates that the parameter still needs to be set. Selecting the parameter and pressing on the Scroll Wheel enters the setting screen, the limits can be set as wanted. A check mark appears before the parameter that is set. After initializing all values, the interface is ready to use as normal.

5.1.5 Calibrate FiO2 and Enable/Disable Temperature Sensor

The FiO2 (molar fraction of inspired oxygen) has an extra calibration option. The molar fraction is 21% if the machine works normal, without supplied oxygen, in normal dry air. Selecting calibrate will set that 21% as value for the currently measured value.

Warning: Calibrate only if the molar fraction is known to be 21%.

The temperature sensor is optional for use. Make sure that when the ventilator starts the temperature sensor is enabled or disabled in the temperature menu. When the temperature sensor is not connected at the start of the ventilator and the temperature sensor is enabled in the menu the alarm sounds. When the sensor is then connected the temperature sensor needs to be disabled and enabled again to work properly. The temperature sensor can be disconnected when the ventilator is running by disabling the sensor in the menu and after that disconnecting the sensor from the machine. An example of how the primary screen should look like when the temperature sensor is disabled is shown in figure 7.

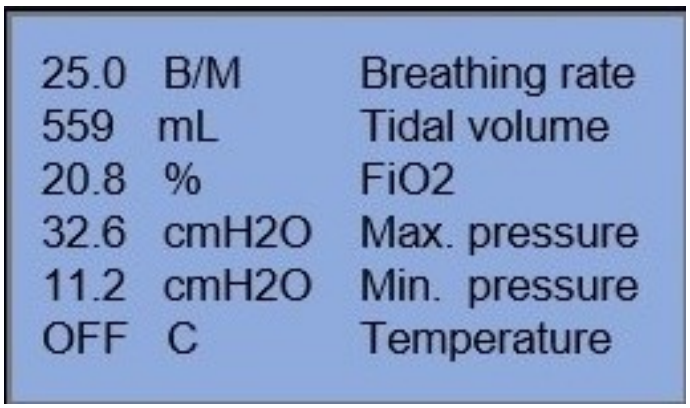

Figure 7: An example of the primary screen when temperature sensor is disabled.

5.2 Adjustment of Plateau Pressure

The max. pressure/plateau pressure that needs to be delivered to the lungs can be adjusted by changing the position of the weight on the lever, as shown in figure 8. The plateau pressure can be adjusted between a minimum value of 15 cmH2O and a maximum value of 26 cmH2O without increased weight. The scale on the lever without the mass icon indicates the target pressure without increased weight. The target pressure can be obtained by reading the value on the scale that coincides with the side of the weight. The scale is made with a breathing rate of 20 B/M and a PEEP of 5 cmH2O. It is different for other BPM and PEEP values. This scale is only for reference and the desired plateau pressure should always be validated on the display. If the pressure must be changed, the fastener can be rotated counterclockwise to unlock the weight. Subsequently the slider can be moved gently to the target pressure. The fastener must be rotated clockwise firmly to lock the weight in place. Tightening and loosening of the fastener must be done gently and force exerted on the lever must be minimised. The other side of the scale (with the picture of the mass) is for an increase of one weight. With this side a range of 17 to 29 cm H2O can be reached.

When medically necessary, the plateau pressure can be increased to a maximum of 70 cm H2O. To do this, the set of four extra weights can be gently placed on top of the slider. With this, the standard scale for weight is no longer usable.

Warning: Increasing the plateau pressure above 30 cm H2O can have life-threatening effects for the patient.

The lever must never be touched for other purposes than moving the weight when the ventilator is turned on. The weight that sets the pressure is predetermined and may never be altered. When the ventilator is turned off, the weight may not move. Manually lift the lever and move the weight if this occurs.

Figure 8: The pressure adjusting mechanism with a sticker indicating pressure

6 Alerts & Appropriate Responses

Alerts	Alerting Mechanisms	Appropriate Response
Breathing rate (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around Breathing rate	Check if breathing rate range is set correctly. If correct, check for leakage or blocking in air system. Check also if the engine works properly. To increase breathing rate, rotate potentiometer clockwise. To decrease breathing rate, decrease plateau pressure. If problem can't be solved, repair machine with certified technician.
Tidal Volume (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around Tidal Volume	Check if Tidal Volume range is set correctly. If correct, check for leakage or blocking in air system To increase tidal volume, increase max. pressure. To decrease tidal volume, decrease plateau pressure. If problem can't be solved, repair machine with certified technician.
FiO2 (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around FiO2	Check if oxygen percentage is set correctly. If correct, check for leakage or blocking in air system. If problem can't be solved, repair machine with certified technician.
Max. Pressure (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around Max. Pressure	Check if max. Pressure/plateau pressure range is set correctly. If correct, check for leakage or blocking in air system. If problem can't be solved, repair machine with certified technician.
Min. Pressure (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around: Min. Pressure	Check if min. pressure/PEEP is set correctly. If correct, check for leakage or blocking in air system and PEEP valve. If problem can't be solved, repair machine with certified technician.
Temperature (too high/low)	**Severe Caution Screen:** Blinking (2Hz) **Buzzers:** 50% duty cycle (1Hz) **Primary screen:** Blinking block around Temperature	Check if temperature is set correctly. If correct, check for leakage or blocking in air system. If problem can't be solved, repair machine with certified technician.

7 Likely Failure Modes & Appropriate Responses

Failure Mode	**Response**
Forgotten HEPA filter	Remove device from use Clean airways thoroughly with appropriate cleaning method
Device delivers shocks to operator	Remove device from use Technician should check device for grounding
Device falls over	Remove device from use Technician should check all device functionality before next patient
Water traps are full	Empty water traps
User interface unresponsive	Remove device from use Technician should repair or replace electronics

8 Cleaning and Maintenance Instructions

The following section contains preliminary work and will only help by the Cleaning and Maintenance. Always listen to local standards of cleaning and maintenance.

8.1 Mechanical Maintenance

The machine must regularly be inspected on wear throughout it's lifetime. The mechanical parts such as the bearings will wear out and that can have dangerous effects.

8.1.1 Visual Inspection

The list below specifies all components that must be inspected, figure 9 shows these components.

1. Bellow
2. Check Valve
3. Bellow cam
4. In/out cams
5. Cam followers

Inspection must be done by disassembling the components and assessing the wear on the components. If excessive wear is found, the components must be replaced by a new one. Wear is excessive if the machine operation may be compromised because of it. This inspection must be done by a mechanical experts that has experience with the ventilator.

8.1.2 Testing

After inspection and due maintenance, a leakage test must prove that the system is able to continue operation. The first step of the leakage test is connecting a manometer to the tubing between the check valve and the cam that triggers the patient's inhalation. Position the camshaft in such a way that air can flow from the bellow through the inspiratory valve. Lift the bellow until the bellow has a stretched length of 120mm. If a pressure drop of less than 5 mbar per minute is detected, the device is alright. If a larger pressure drop is detected, the origin of the leak must be found and mitigated by a mechanical expert.

8.2 Cleaning the Machine During Use

While a patient is connected to the device frequent cleaning of the housing of the system is recommended. Primarily this includes cleaning the housing and the user interface. Wiping must be done with a damp cloth immersed in compatible disinfectant such as alkalescent detergent or an alcohol solution. After that the cleaned surfaces should be wiped off with a dry lint free cloth. Optionally the power cord, oxygen supply hose and any other components that are continuously exposed are to be cleaned in a similar fashion.

Warning: Do not rotate the potentiometer when cleaning the interface.

8.3 Elaborate Cleaning Methods

It is not necessary to subject the inner components of the system to per-patient cleaning as these parts are not exposed to the patient or the patient's respiratory secretions. Also all inlets are connected to HEPA filters. However, if possible it is recommended that the expiratory side of the inner tubing is cleaned as necessary. This includes the sensor tube that houses the pressure and mass flow sensor, the out valve, the

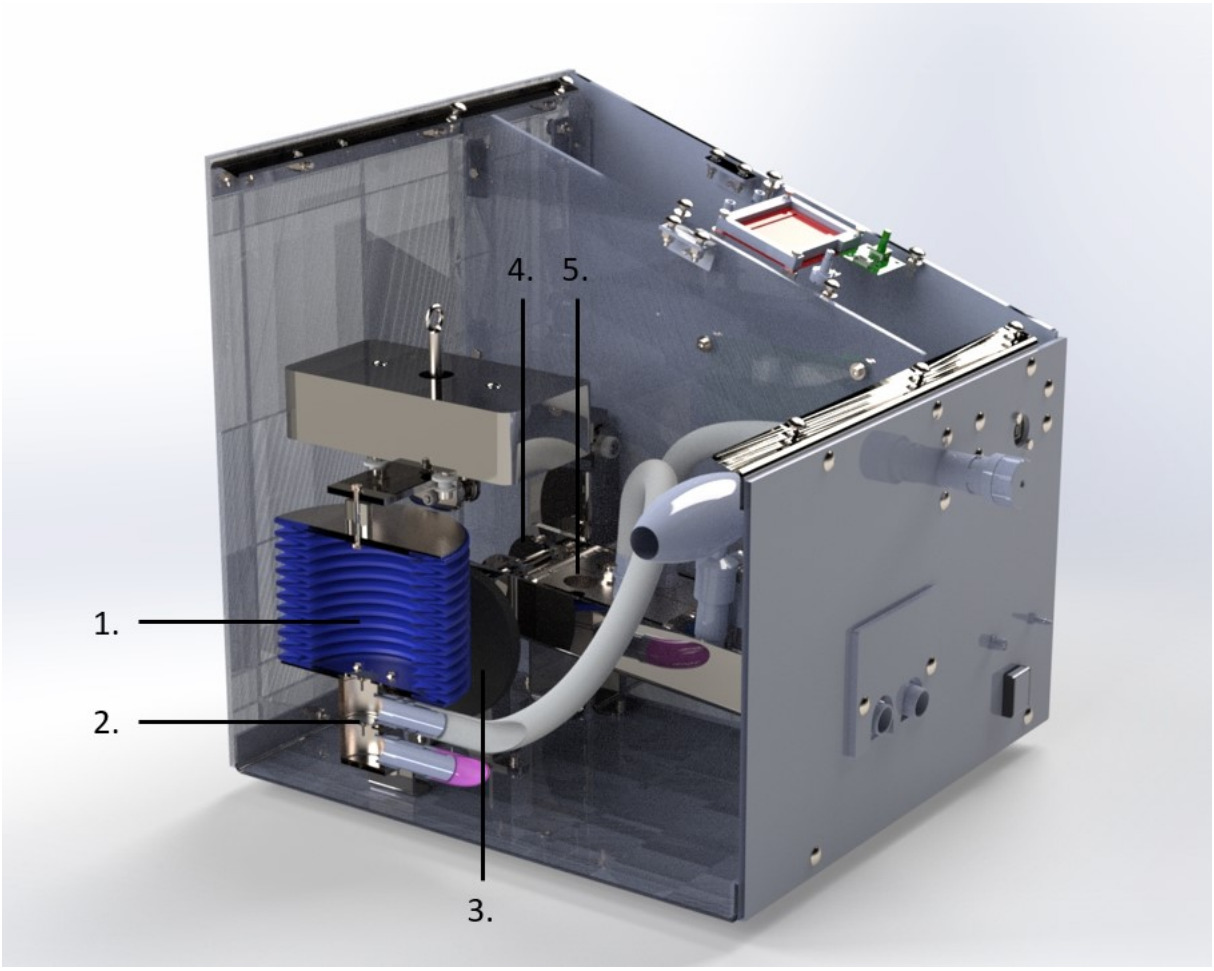

Figure 9: Components that require periodic visual inspection

tubing from the exhalation valve to the PEEP valve and the PEEP valve. In summary these parts should be disassembled and cleaned with a detergent and rinsed clean. Subsequently the parts should be subjected to high-level disinfection or sterilisation depending on the part's ability to undergo disinfection and sterilisation methods. Parts should be dried to prevent microbial growth and dilution of chemical disinfectants. Either air-dry the parts or dry them using a, preferably single use, clean non-linting cloth. The stainless steel parts should be dried immediately to prevent spotting. The optional storage of parts should be in closed dry packages.

The system is made in such a way that the sensor tubes and the main valves can be removed in one piece out of the machine so it can be cleaned. For that the left side needs to be removed (figure 10. The second step is to removing the bolts indicated in figure 11.

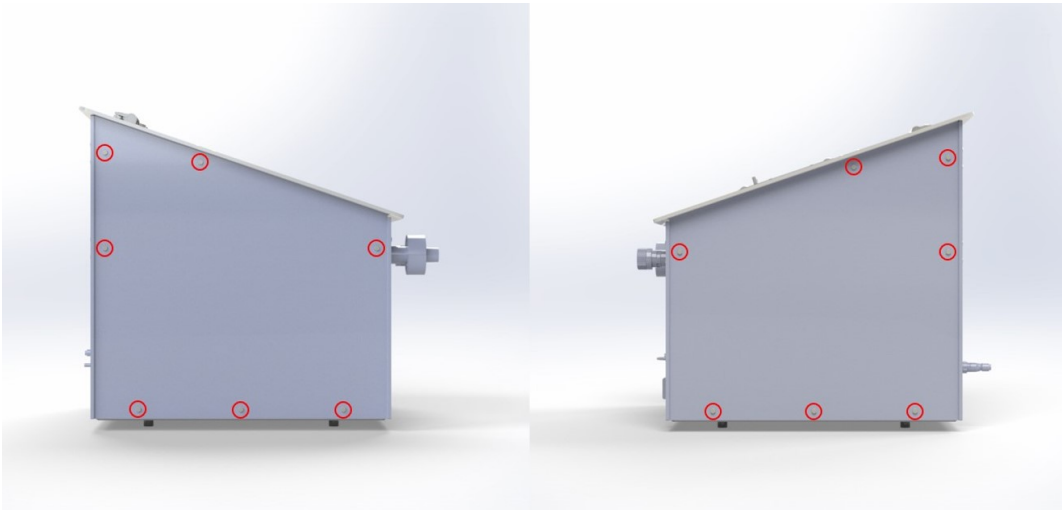

Figure 10: Remove the bolts in the red circles to remove the sides of the panel

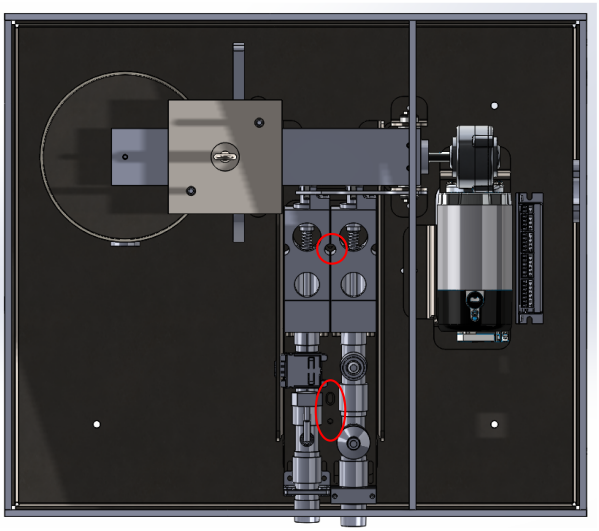

Figure 11: Remove the sensor tubes and main valve assembly by removing the bolts indicated in red

Warning: Do not use harsh cleaning agents for the housing and user interface.