# 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

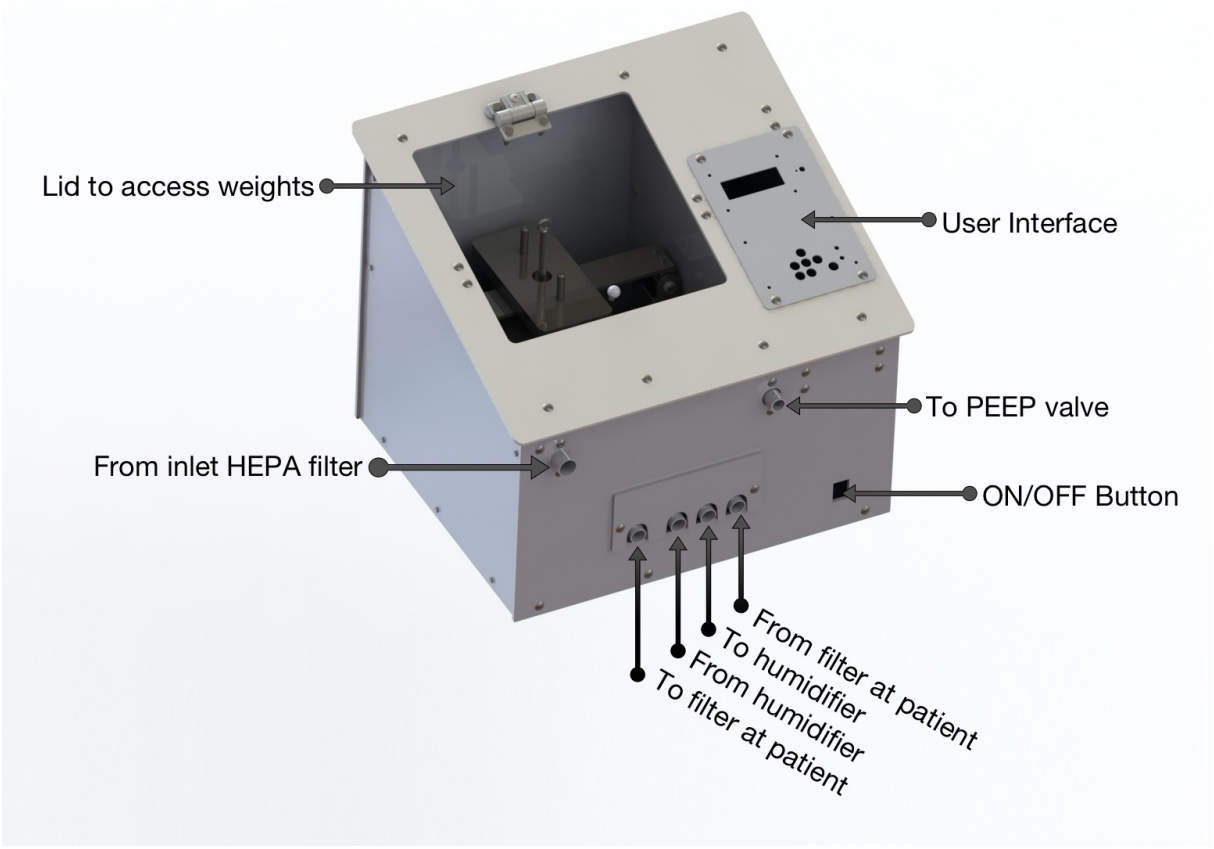


Figure 1: Overview of the user interfaces

Figure 1 shows the location of the different components that users frequently 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 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. The ON/OFF button either powers on or powers off the entire ventilator, including the user interface.

## 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 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
- Plateau Pressure 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
- PEEP pressure 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

- Plateau pressure (too high/low); adjustable limits
- PEEP (too high/low); adjustable limits
- Tidal volume (too high/low); adjustable limits
- Humidity & Temperature (too high/low); adjustable limits
- Oxygen concentration (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 current achieved PEEP
- Plateau Pressure
- FiO2
- VT and Breathing rate (BPM)
- Temperature of inspired air

## 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 2 shows all tubing connections. All connections are designed for standard 22mm connections.

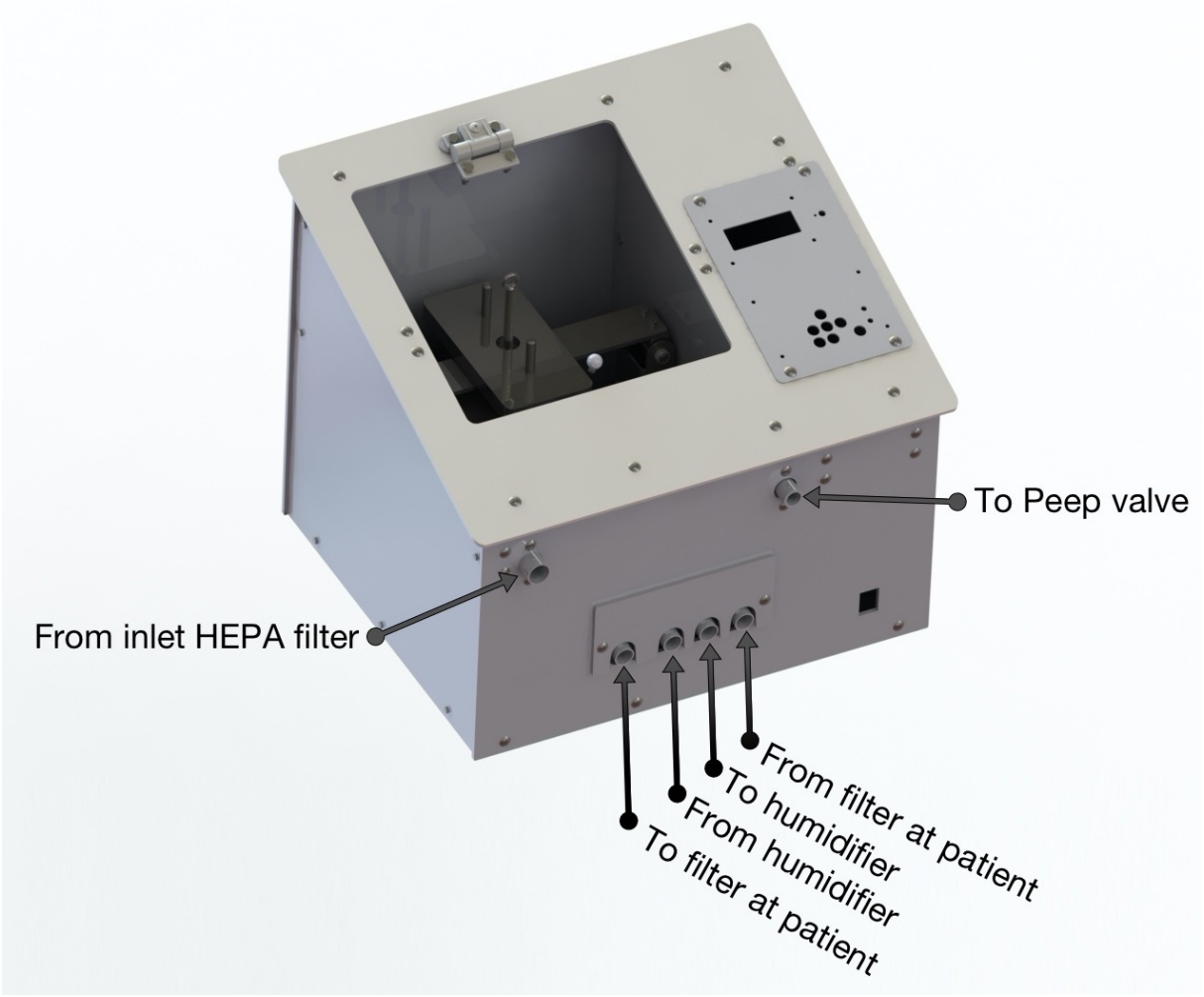


Figure 2: Air connections to ventilator

**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 3 shows the schematic overview of the system.

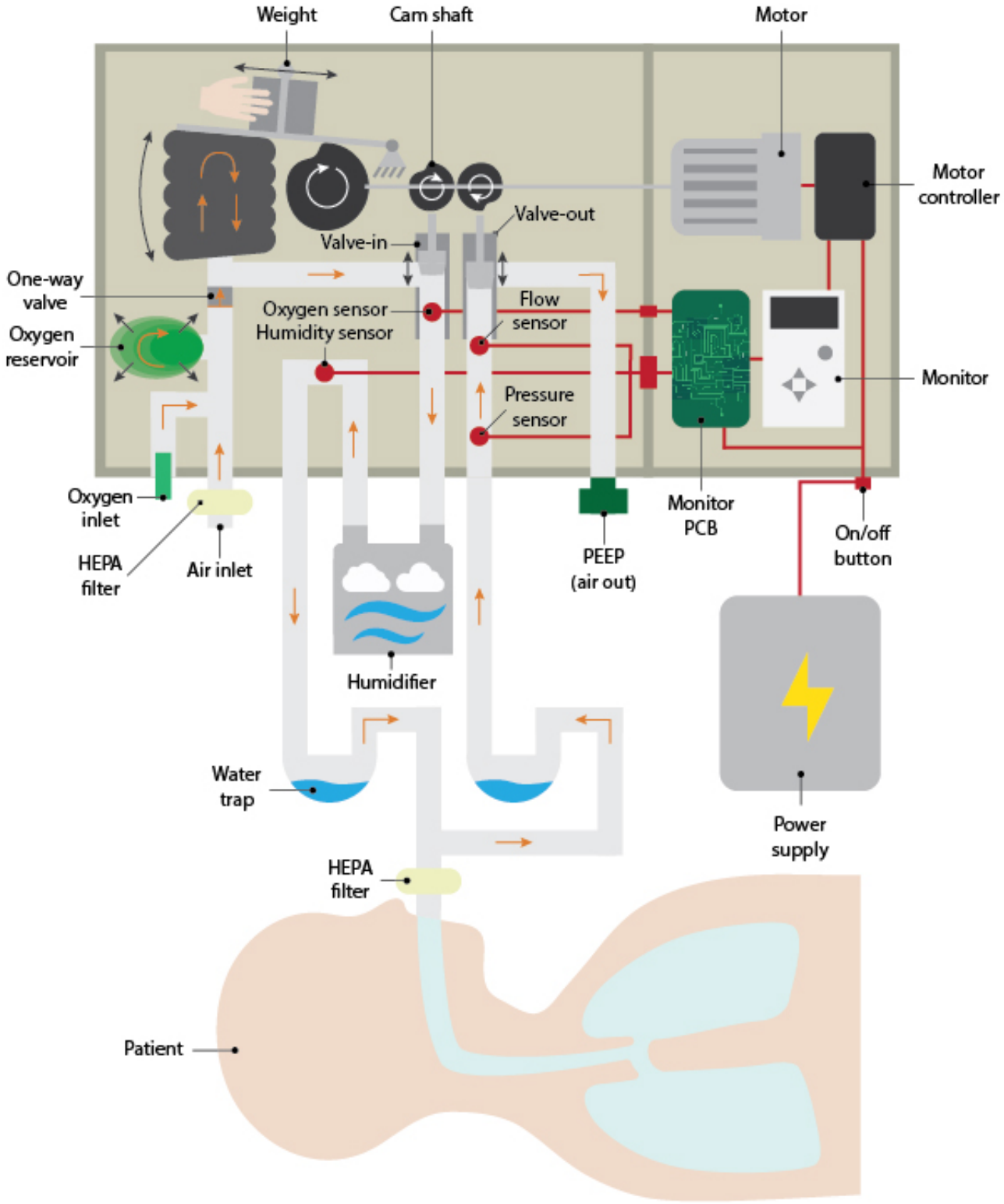


Figure 3: Schematic overview of system - PRELIMINARY! NEW VERSION WILL FOLLOW SHORTLY

# 5 Controls & User Interface

In this section the controls and user interface will be discussed. First the layout of the machine and all the graphical alerts 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 4. This interface will be discussed below.

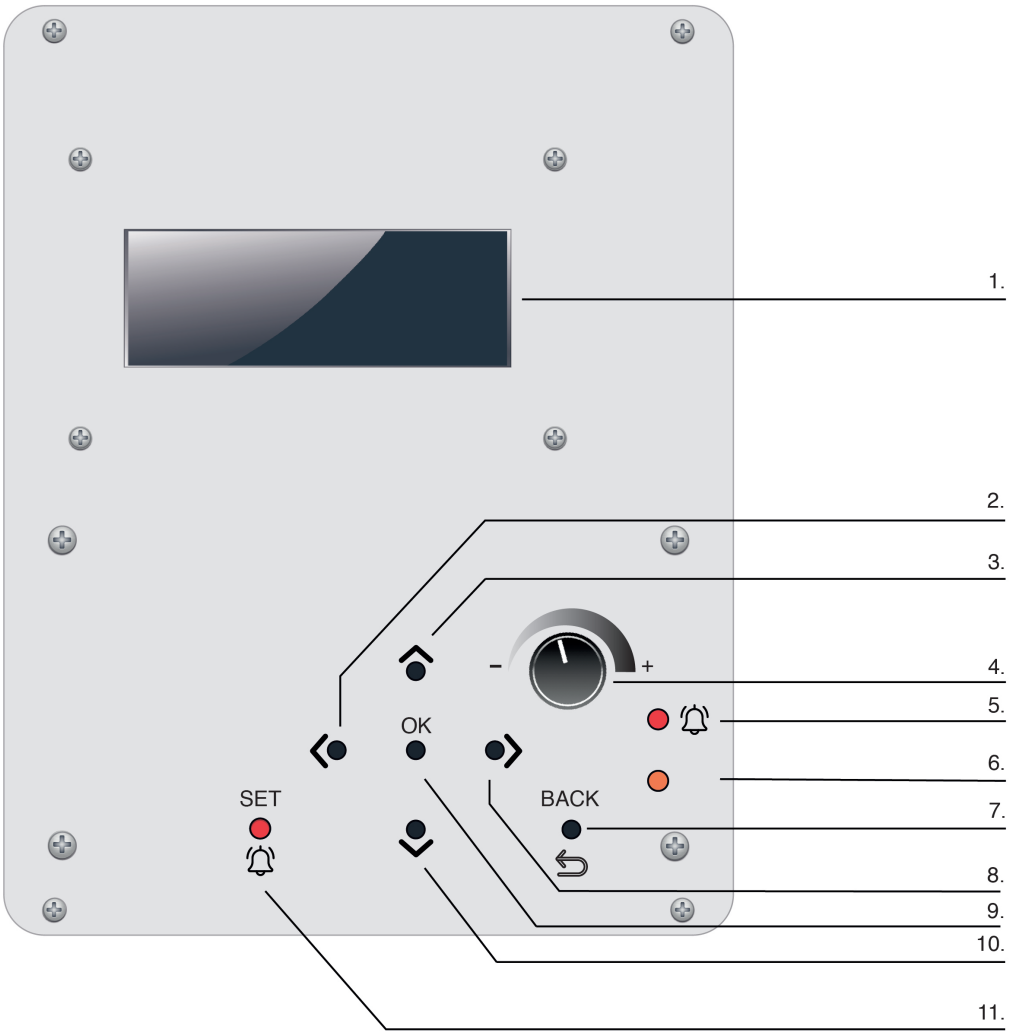


Figure 4: User interface

1. Display
2. Left button
3. Up button
4. Scroll wheel
5. Severe caution LED (red)
6. Warning LED (orange)
7. Back button
8. Right button
9. OK button
10. Down button
11. Alarm set button

### 5.1.1 Respiratory Information

The primary display (**1**) features several screens. The primary screen displays operating data. In particular, five values are displayed (i) achieved breathing rate, (ii) lung tidal volume, (iii) achieved minimal PEEP (iv) approximate plateau pressure, and (v) fraction of inspired oxygen (FiO2). These values are displayed intermittently. It also possible to scroll through the values in the primary screen by using the Scroll Wheel (**4**). The exact meaning of each value is elaborated in Table 1.

| Display | Unit | Provenance |
|---|---|---|
| `PEEP` | cmH2O | Moving average of PEEP of the last four breaths. |
| `FiO2` | %-molar | Moving average of molar fraction of inspired oxygen during the last five seconds. |
| `Plat` | cmH2O | Moving average of the plateau pressure during the last four breaths. Plateau pressure is calculated as the maximal pressure value calculated with a 50Hz lowpass filter. |
| `Tidal` | 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. |
| `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. |

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

### 5.1.2 Editing Settings and Alarms

By pressing the OK button (**9**), the user may access the settings screen. Upon inactivity, or by pressing the Back button (**7**), the primary screen is displayed again. The settings screen lists all the settings and the current selected setting is displayed with an arrow. The user may use the Scroll Wheel or the Up and Down buttons (**3, 10**) to navigate the menu and can use the OK button to edit the currently selected setting.

When editing, the edit screen is displayed, and the user can use the up/down buttons, the Left/Right buttons (**2, 8**), and the scroll wheel to alter the current value. Use the OK button to confirm the selection, or use the Back button to abort changing the setting restore the original value. Pressing back leads the user back to the settings screen.

Figure 5 displays the functionality of the menu in a diagram, including examples of what the screen will show during the editing process.

### 5.1.3 Enabling, Disabling, and Suppressing Alarms

When the respirator starts up, threshold alarms are initially disabled. The primary screen then indicates `"Alarms off"`. Additionally, the Severe Caution LED (**5**) is continuously illuminated and a buzzer sounds for 0.5 seconds at a frequency 0.2Hz (once every five seconds). When in the primary screen, the user can enable (arm) threshold alarms using the Alarms Set button (**11**), or by editing the `"Alarms"` setting in the settings screen. When alarms are armed, and not triggered, the the Severe Caution LED is off. It is not possible to enable or disable individual threshold alarms, they can only be enabled and disabled together.

When a threshold is exceeded while alarms are armed, the alarm is displayed on the primary screen. For example, the primary screen may indicate `"PEEP prs. low"`, which indicates that the PEEP minimum was exceeded. The relevant operating value also blinks on the primary screen. Additionally, the Severe

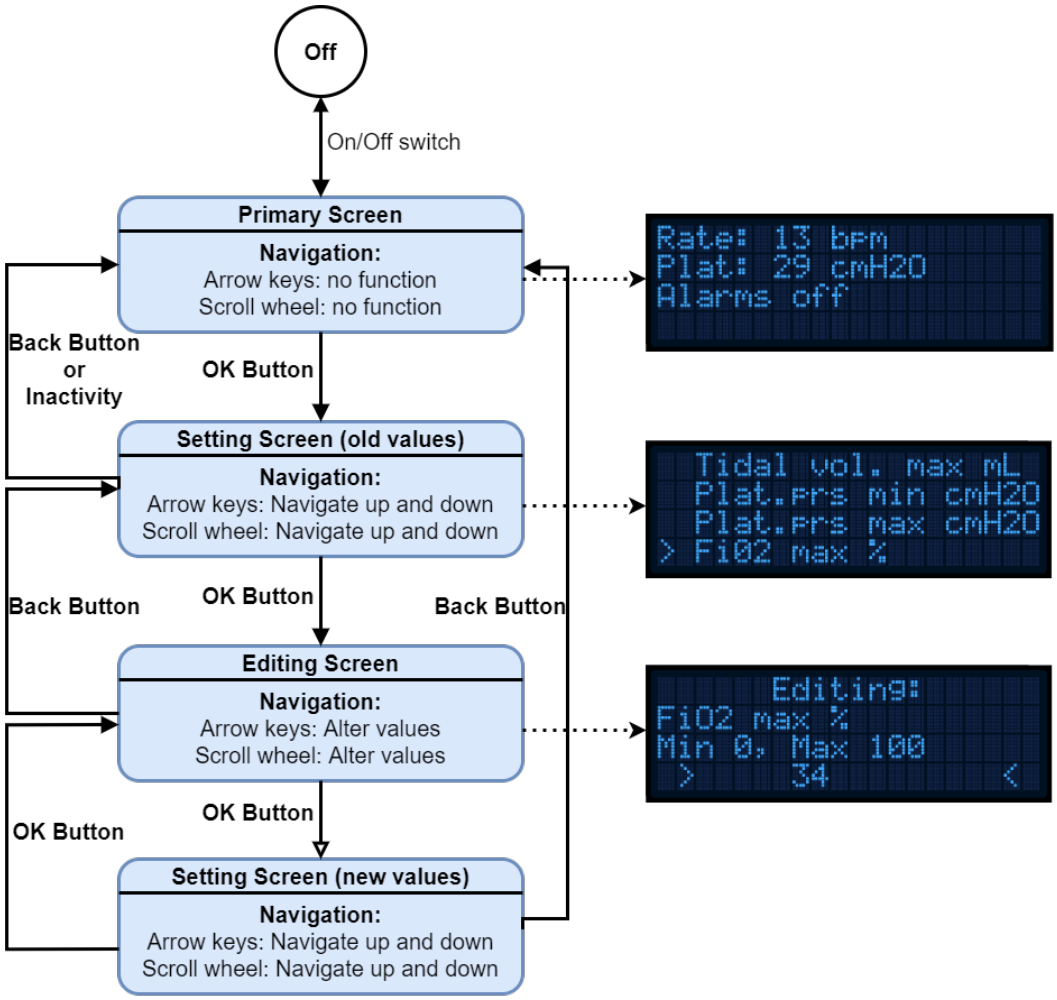


Figure 5: Editing Settings and Alarms Diagram

Caution LED blinks at a frequency of 2Hz (twice per second) and a buzzer sounds at 1Hz with a duty cycle of 50%. Once an alarm is triggered, it is active until the alarm is suppressed or alarms are turned off. Other (subsequent) alarms can not be activated while an alarm is active.

The user may suppress the alarm by again pressing the Alarm Set button. Suppressing the alarm illuminates the Severe Caution LED continuously and blinks the Warning LED at 2Hz. Buzzers are not audible when alarms are displayed, the alarm is still displayed on screen. Pressing the Alarm Set button again turns off alarms.

Figure 6 displays how the alarm can bet enabled, disabled and suppressed in a diagram.

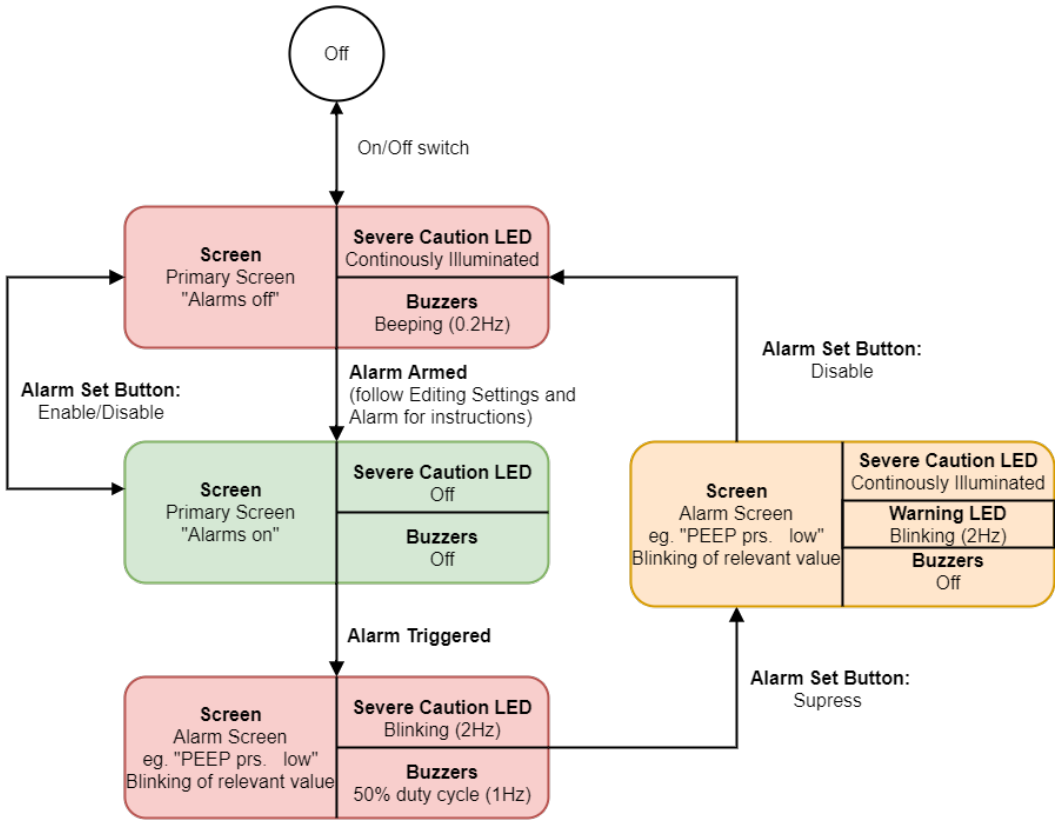


Figure 6: Enabling, Disabling and Suppressing Alarms Diagram

## 5.2 Adjustment of Plateau Pressure

The plateau pressure that needs to be delivered to the lungs can be adjusted by changing the position of the weight on the lever. The plateau pressure can be adjusted between a minimum value of 15 cm H2O and a maximum value of 30 cm H2O. The scale on the lever indicates the target pressure as shown in figure 7. The target pressure can be obtained by reading the value on the scale that coincides with the side of the weight. 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 counter clock-wise to unlock the weight. Subsequently the slider can be moved gently to the target pressure. The fastener must be rotated clock-wise firmly to lock the weight in place. Plateau pressure must be validated in the display if the pressure is too far off. Tightening and loosening of the fastener must be done gently and force exerted on the lever must be minimised.

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 be not be able to move. Manually lift the lever and move the weight if this occurs.

## 5.3 Interpreting the Mechanical Volume Gauge

There are two ways to read the flow of air that's delivered by the patient. Using the display is the preferred option. Alternatively, the tidal volume can be determined by using the mechanical volume gauge. The scale

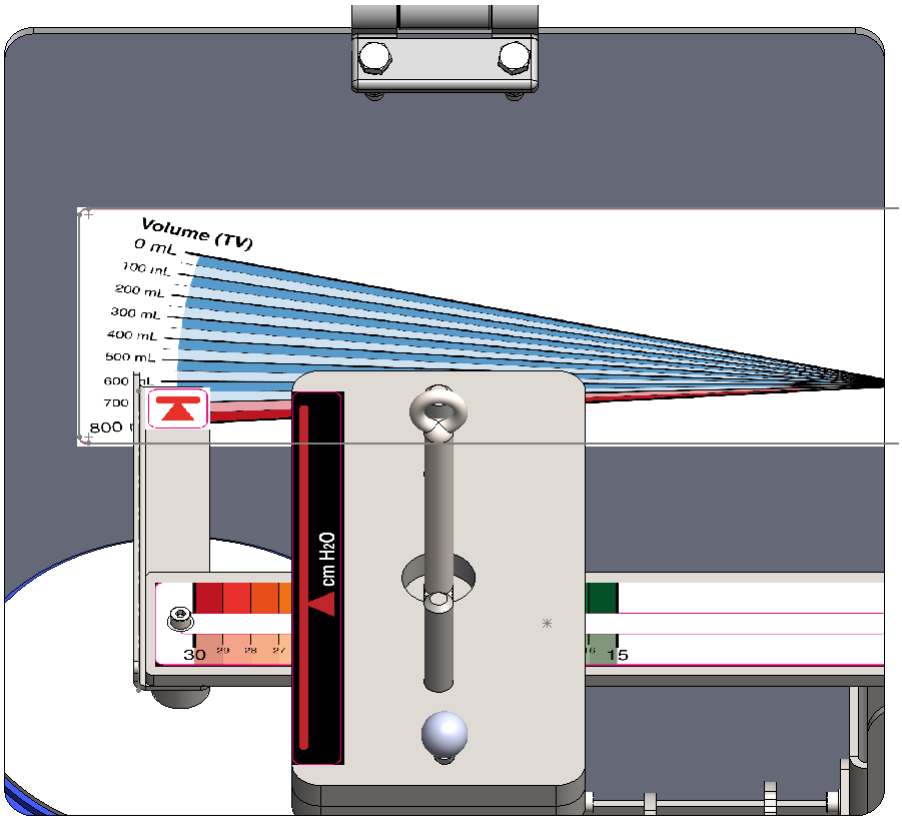


Figure 7: The pressure adjusting mechanism with stickers indicating pressure and volume

in figure 7 indicates the volume of air that's inhaled by the patient in milliliters. The tidal volume can be determined by reading the indicator on the on casing at it's lowest point. In contrary to the tidal volume on the display. The mechanical volume gauge does not measure a volume that is averaged over four breath cycles.

# 6 Alerts & Appropriate Responses

| Alerts | Alerting Mechanisms | Appropriate Response |
|---|---|---|
| Plateau Pressure (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "Plateau Pressure high/low"<br>**Value:** Blinking | Check if plateau pressure range is set correctly.<br>If correct, check for leakage or blocking in air system.<br>If problem can't be solved, repair machine with certified technician. |
| PEEP (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "PEEP high/low"<br>**Value:** Blinking | Check if PEEP is set correctly.<br>If correct, check for leakage or blocking in air system and PEEP valve.<br>If problem can't be solved, repair machine with certified technician. |
| Tidal Volume (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "Tidal Volume high/low"<br>**Value:** Blinking | Check if Tidal Volume range is set correctly.<br>If correct, check for leakage or blocking in air system<br>To increase tidal volume, increase plateau pressure.<br>To decrease tidal volume, decrease plateau pressure.<br>If problem can't be solved, repair machine with certified technician. |
| Humidity (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "Humidity high/low"<br>**Value:** Blinking | Check if Humidity is set correctly.<br>If correct, check for leakage or blocking in air system.<br>Also check humidifier functionality.<br>If problem can't be solved, repair machine with certified technician. |
| Temperature (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "Temperature high/low"<br>**Value:** Blinking | Check if temperature is set correctly.<br>If correct, check for leakage or blocking in air system.<br>If problem can't be solved, repair machine with certified technician. |
| FiO2 (too high/low) | **Severe Caution LED:** Blinking (2Hz)<br>**Warning LED:** Off<br>**Buzzers:** 50% duty cycle (1Hz)<br>**Screen:** "FiO2 high/low"<br>**Value:** Blinking | Check if oxygen percentage is set correctly.<br>If correct, check for leakage or blocking in air system.<br>If problem can't be solved, repair machine with certified technician. |
| Alarm Suppressed | **Severe Caution LED:** Continuously Illuminated<br>**Warning LED:** Blinking (2 Hz)<br>**Buzzers:** Off<br>**Screen:** eg. "PEEP high/low"<br>**Value:** Blinking | Disable Alarm by clicking the "Alarm Set Button" |
| Alarm Disabled | **Severe Caution LED:** Continuously Illuminated<br>**Warning LED:** Off<br>**Buzzers:** Beeping (0.2Hz)<br>**Screen:** "Alarms off"<br>**Value:** Continuously Illuminated | Arm the alarm by following "Editing Settings and Alarms" |

# 7 Likely Failure Modes & Appropriate Responses

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

# 8 Cleaning and Maintenance Instructions

*DISCLAIMER: The following section contains preliminary work and will be elaborated and reviewed in collaboration with medical professionals*

## 8.1 Mechanical Maintenance

Every machine must be inspected and tested at several stages throughout it's lifetime. The first inspection during use must take place after 14 days of continuous operation or equal. After this the machine must be inspected every 7 days of continuous operation.

### 8.1.1 Visual Inspection

The list below specifies all components that must be inspected, figure 8 shows these components.

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

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 connection a manometer to the tubing between the check valve and the cam that triggers that 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 ok. 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. If wiping is used as cleaning method this should be done with a damp cloth immersed in compatible disinfectant such as alkalescent detergent or an alcohol solution. The cleaned surfaces should then 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.

## 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. 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 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

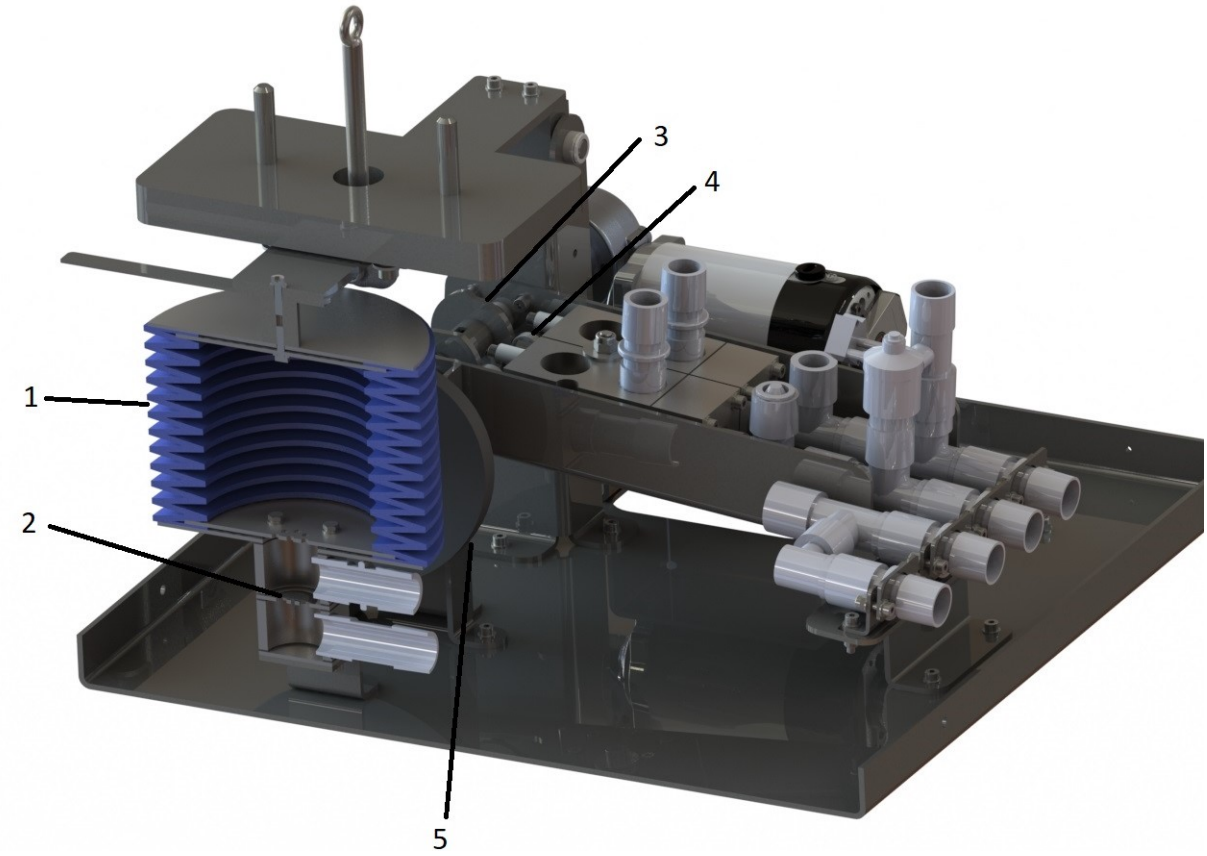


Figure 8: Components that require periodic visual inspection

on the part's ability to undergo disinfection and sterilisation methods (see table 2). 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. The procedure to remove this from the machine is illustrated in figure 9 and 10. 11 shows how the complete casing is removed for internal wiping in the case of spillage or for ultraviolet radiation treatment .

**Info:** The disassembly of the casing for the cleaning procedure requires a 3mm allen key and 7mm wrench.

| Part | Frequency | Preferred cleaning method |
|---|---|---|
| `Housing` | daily/weekly | Wiping using a compatible disinfectant |
| `Housing` | Optional / every four weeks | 30-60 minutes of Ultraviolet radiation after complete removal of the housing |
| `User Interface` | daily | Wiping using a compatible disinfectant |
| `Expiratory sensor tube` | Every four weeks / if needed | Immersion in detergent |
| `Exhalation valve` | Every four weeks / if needed | Gas sterilisation, Immersion in detergent or autoclave |
| `PEEP tube` | Every four weeks / if needed | Disposal or Immersion in detergent |
| `PEEP valve` | Every four weeks / if needed | Disposal |
| `Humidifier` | after every patient | Gas sterilisation, Autoclave or Immersion in detergent |

Table 2: Cleaning per part

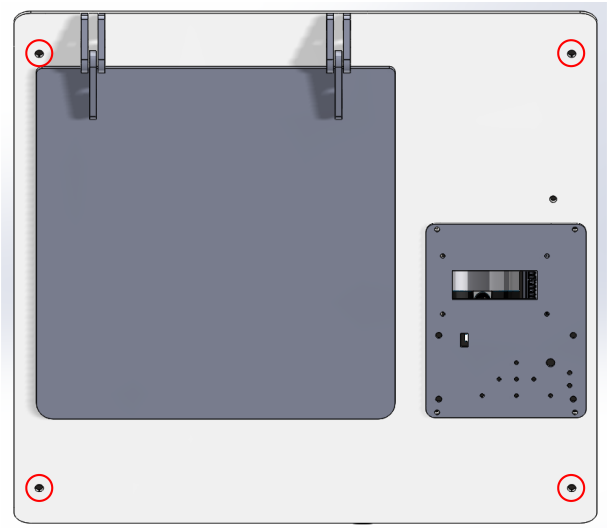

Figure 9: Remove bolts in the red circle to remove the top cover

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

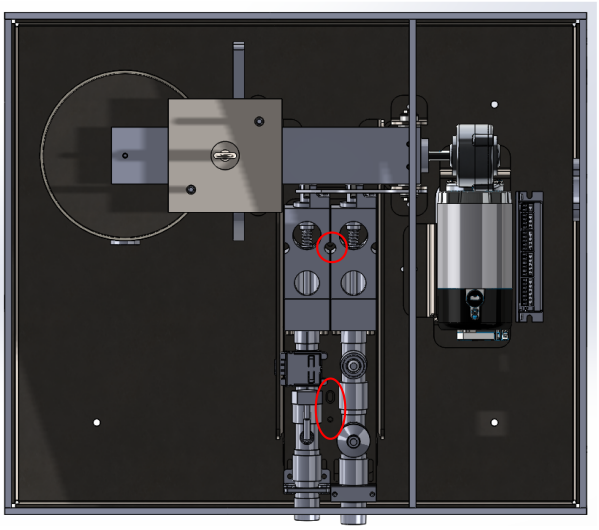

Figure 10: Remove the sensor tubes and main valve assembly by removing the bolts indicated in red

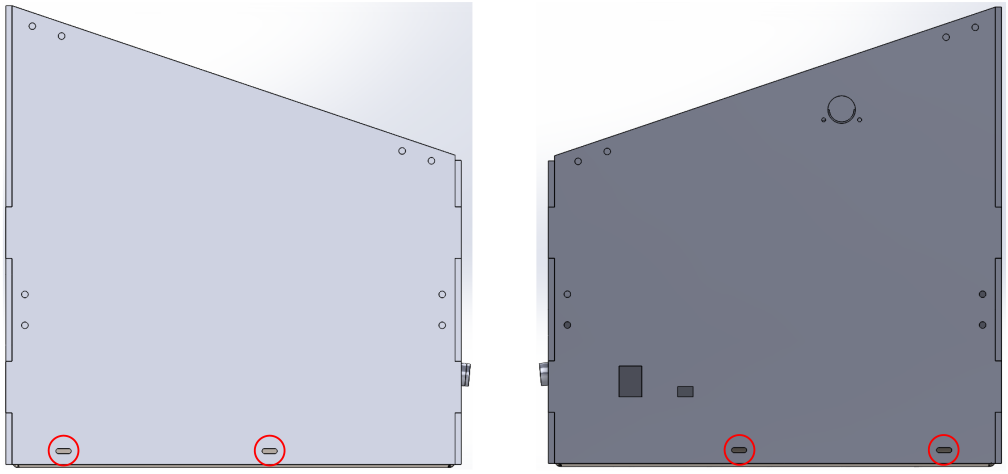

Figure 11: Remove the bolts in the red circles to remove the entire casing