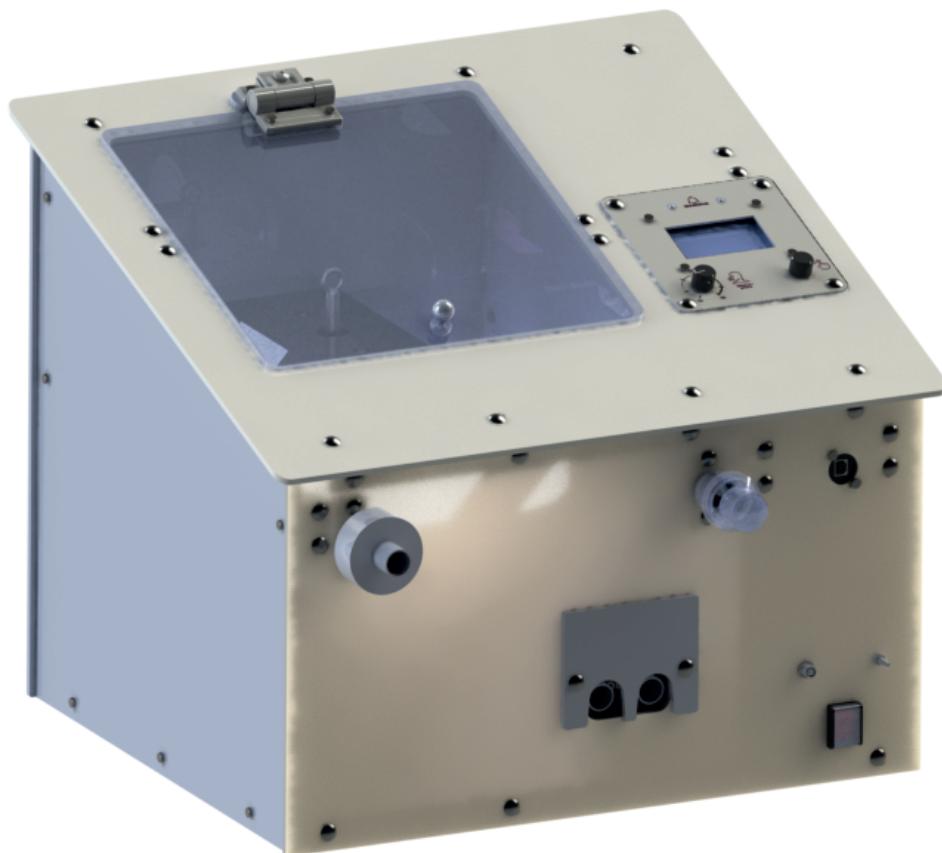


# User Manual – Inspiration Ventilation System

Project Inspiration

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[www.projectinspiration.nl](http://www.projectinspiration.nl)

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# 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 an humidifier and an Uninterruptible Power Supply (UPS). It is recommended to use an off the shelf humidifier and UPS. Besides the ventilator must be connected to the main net power with a converter to 12-24V and a minimum of 5A.

## 1.2 Device Components

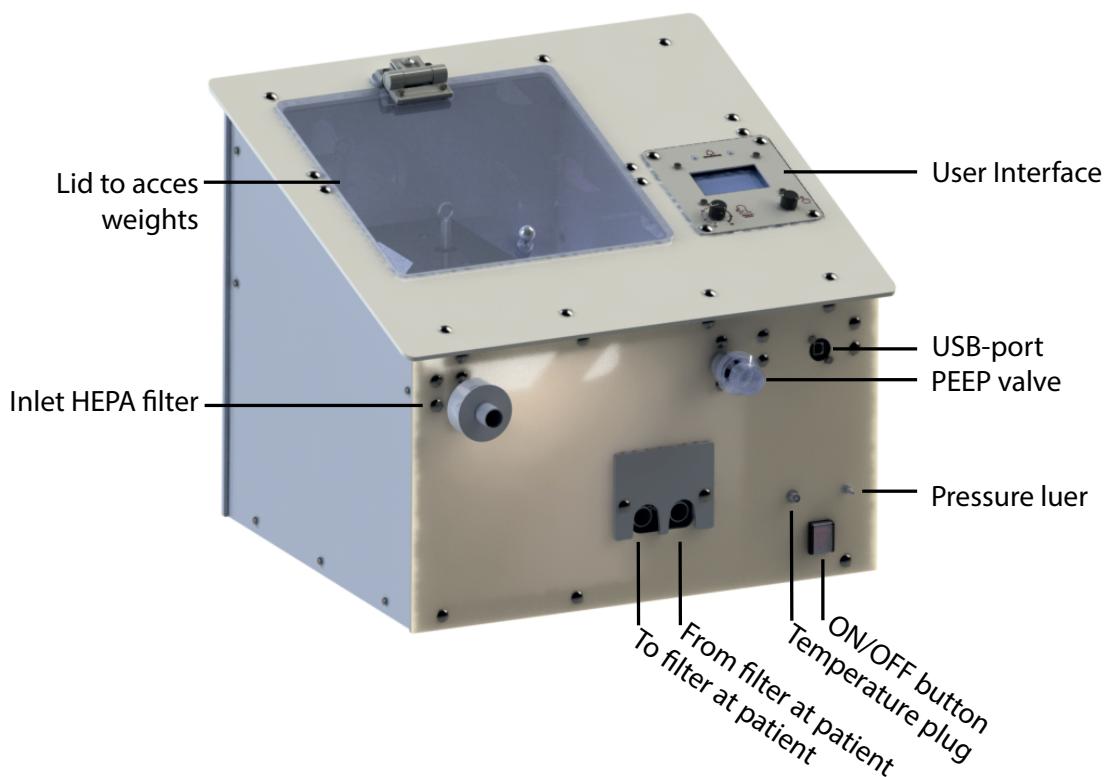


Figure 1: Overview of the front

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 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. Use the oxygen inlet for an external oxygen supply. 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

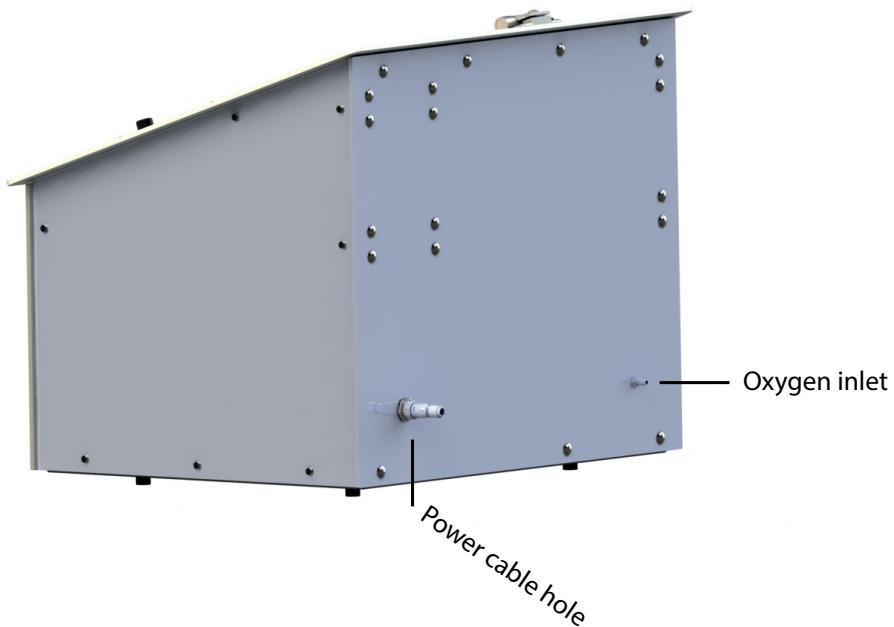


Figure 2: Overview of the back

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 devices 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

Besides the net power the Inspiration Ventilation System should be connected to a stable source that provides 12-24V with a minimum of 5A as power backup. This power source must allow the ventilator to function for at least 20 minutes when disconnected from the main power net. For example the PowerWalker model VI650SH can be used for this.

### 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<sup>1</sup> 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<sup>2</sup> 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
- Option to calibrate FiO2 and pressure
- Option to connect a temperature sensor

### 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.

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

<sup>1</sup>Officially the max. pressure is measured but is almost the same as the plateau pressure

<sup>2</sup>Officially the min. pressure is measured but is almost the same as the PEEP 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 4 shows an schematic overview for connecting the ventilator to a patient.

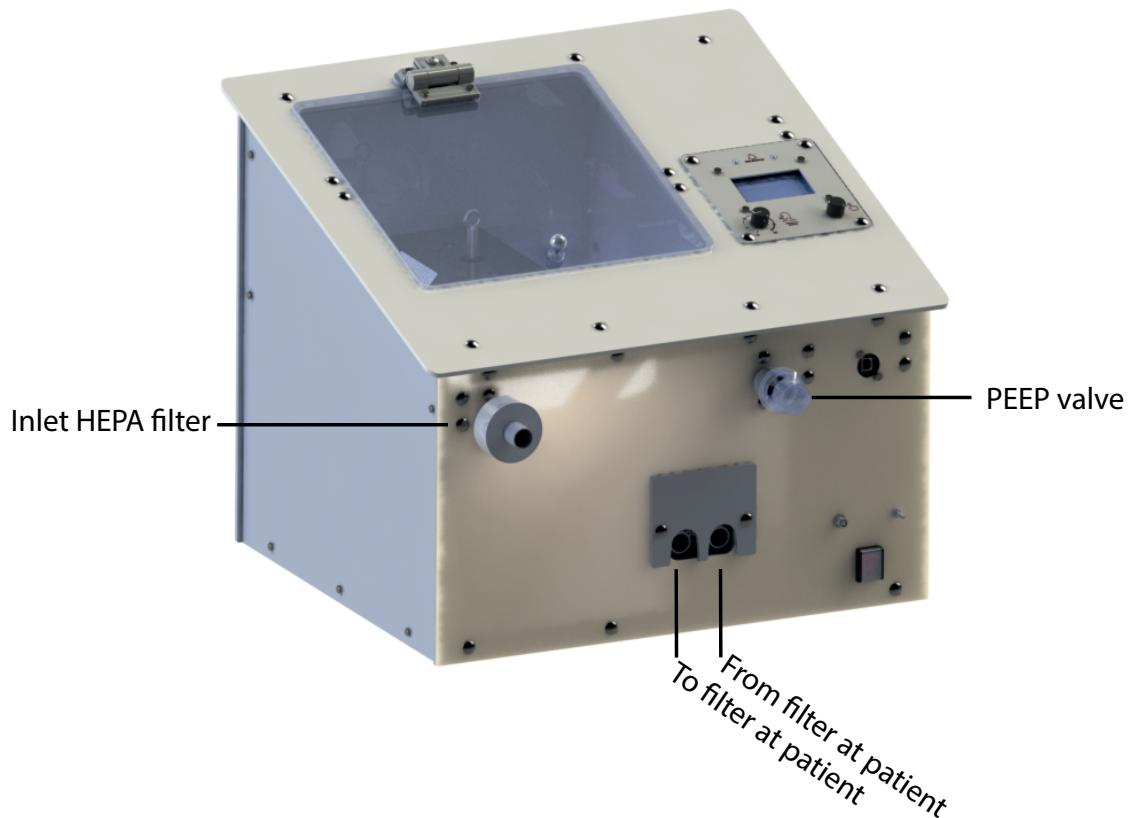


Figure 3: Air connections to ventilator



**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.

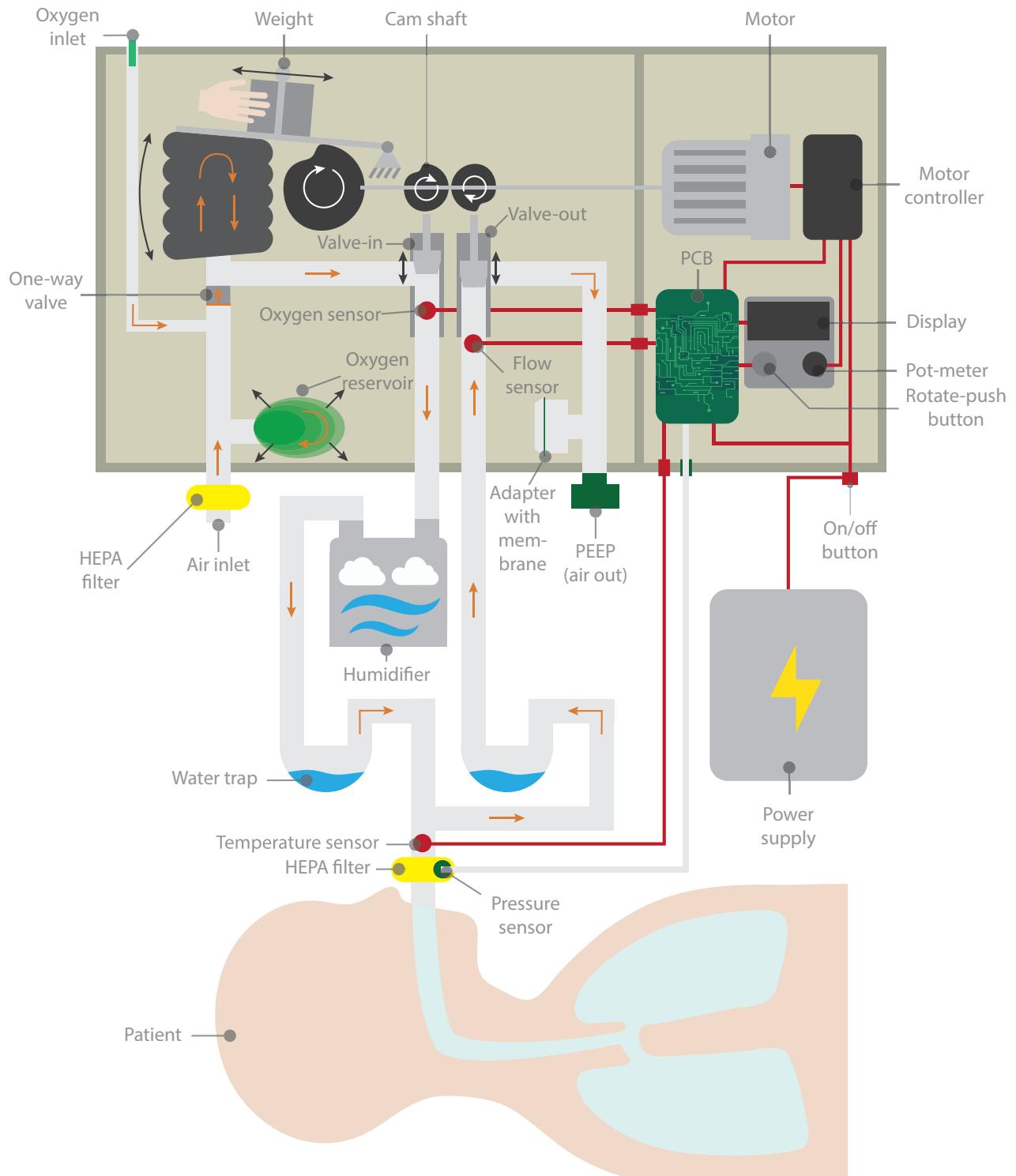


Figure 4: Schematic overview of system with pressure sensor outside the casing



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

## 4.2 Starting the Ventilator

Before starting the ventilator check the following:

- Make sure no additional weight is added to the lever of the ventilator (inside the ventilator). Figure 5 shows how this should look like
- Make sure that inside the ventilator the oxygen reservoir, adapter with membrane and all tubes are connected correctly (see Figure 4)
- Make sure that everything outside the ventilator is connected correctly (see Figure 4, Figure 3 and Figure 6. Make also sure that the oxygen is connected to the back if that is needed, see Figure 2).

Push after those checks the ON/OFF button to start the ventilator. When the ventilator is started do the following on the user interface:

1. Suppress the alarm, see Section 5.1.2 for more information
2. Choose the option Previous Limits or Custom Limits, see Section 5.1.4

The next chapter will explain how to use the monitor and how to change settings.

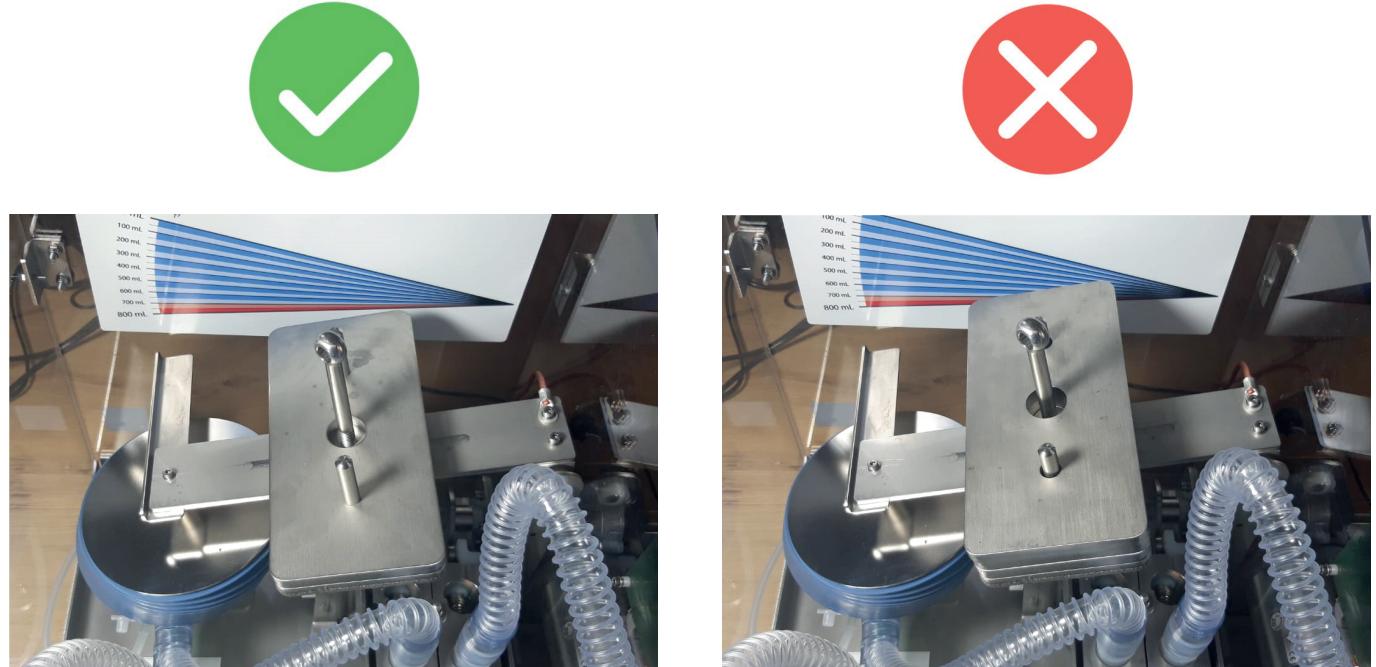


Figure 5: Left image: No extra weights are applied. Right image: Extra weights are applied

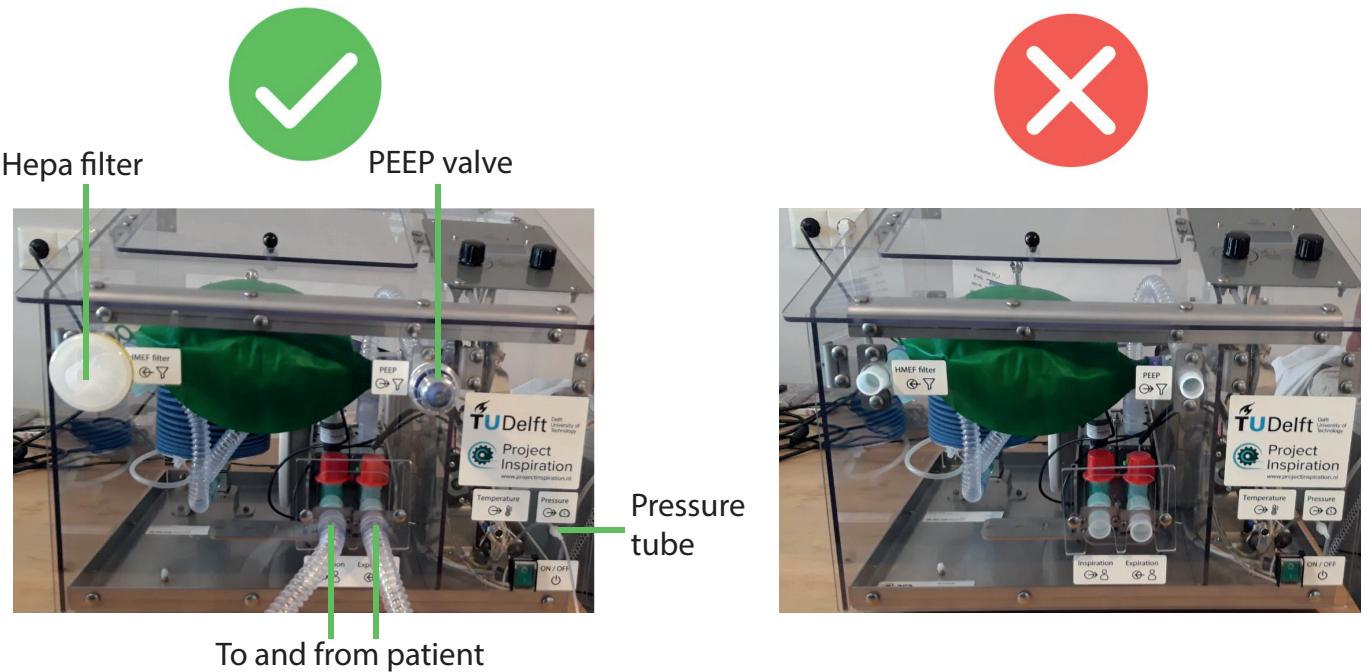


Figure 6: Left image: Picture of how the PEEP valve, Hepa filter and inspiratory and expiratory tubes must be connected. Right image: No Hepa filter, PEEP valve and in-and expiratory tubes are connected.

## 5 Monitoring & Settings

The user interface will be discussed in this section. The user interface is mainly for set up alarms and for reading out values (monitoring). The layout of the interface is first described. After that the use of the monitor will be elaborated. At last the adjustment of the breathing rate, PEEP and max. pressure is explained.

### 5.1 Electronic User interface

Figure 7 shows the user interface. This interface will be discussed below.

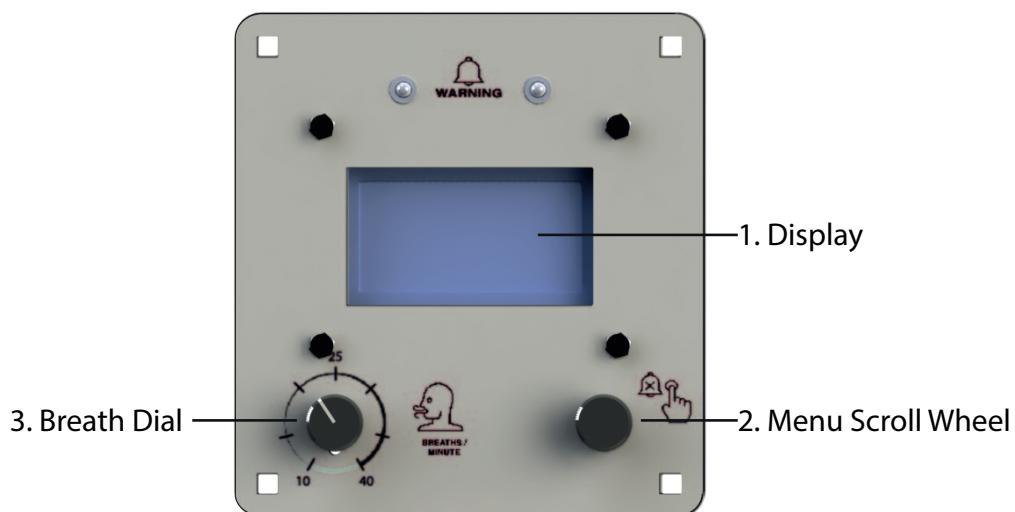


Figure 7: The user interface

The display (1) shows initially the main menu which displays the following six values: (i) achieved breathing rate, (ii) lung tidal volume, (iii) fraction of inspired oxygen (FiO<sub>2</sub>), (iv) maximal pressure, (v) minimal pressure and (vi) the temperature of the inspired air. Table 1 shows the exact meaning of all the six values. Figure 8 shows an example of the display with the main menu.

The menu scroll wheel (2) is for going through the menu (rotating the wheel) and for selecting items (pressing the wheel). The current selected item is displayed with a black or white background (different per device).

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



**Info:** The Display is not for changing settings (Breathing rate, PEEP or Max. pressure).

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 interval values 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.

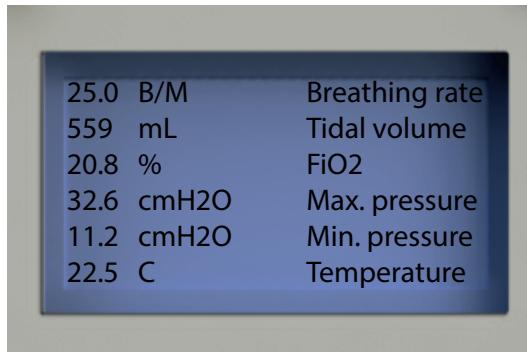


Figure 8: An example of the main menu.

### 5.1.1 Edit a threshold

Take the following steps to change a threshold:

1. Scroll through the six values and select the parameter that needs to be changed (e.g. Tidal Volume) by pushing the menu scroll wheel
2. The setting menu appears
3. Select the threshold that needs to be changed (e.g. Minimum)
4. Rotate the menu scroll wheel to change the threshold to the desired value
5. Push on the menu scroll wheel to edit the threshold

The display shows now the new threshold. Pressing on back shows the main menu again. An illustration of changing the threshold of the minimum of the Tidal Volume from 250 mL to 200 mL is shown in Figure 9.

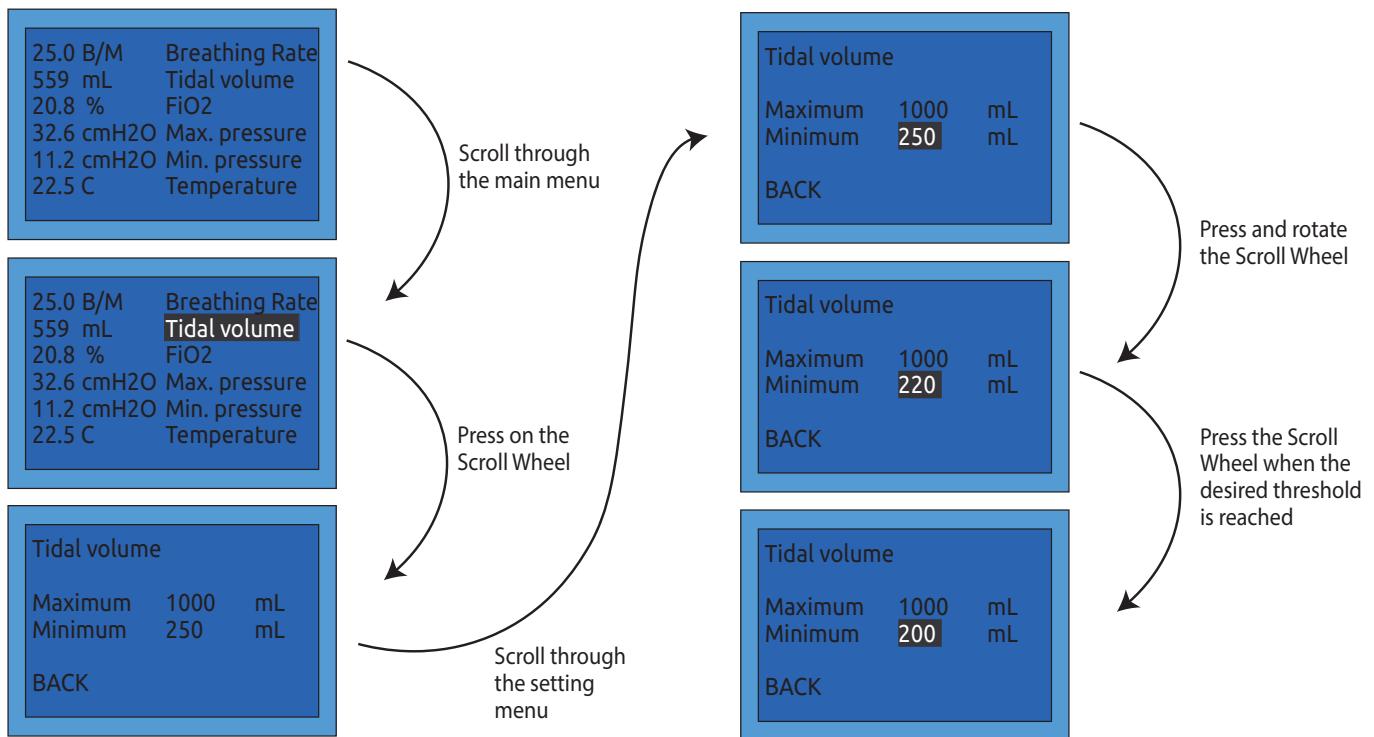


Figure 9: Example of changing a threshold

### 5.1.2 Alarm

When a threshold is exceeded the display will show a warning screen and the buzzer sounds at 1HZ with a duty cycle of 50%. Figure 10 shows the warning screen. Pushing on the menu scroll wheel will suppress the alarm for 10 seconds and the interface can be used as usual. A blinking block around the parameter(s) indicates the value(s) that exceeds the thresholds. If necessary change an individual threshold as described in the previous section.



Figure 10: The warning screen

### 5.1.3 Bootloader

The software of the ventilator has a bootloader which is a special operating system software that loads into the working memory of a system. The bootloader is only intended for software updates and must not be used by the user. To start the bootloader menu, press the menu scroll wheel when starting the ventilator. The LED's will blink when the ventilator is in bootloader mode. Shut the machine down and restart the machine to go back to the normal mode. Never use the ventilator for patients if the LED's are blinking.



**Warning:** Do not press the menu 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 Alarms

Figure 11 shows the display when the ventilator is starting. The Firmware version can be different for the ventilator. After the starting screen the threshold must be set. Figure 12 displays the options to choose from, namely previous limits and custom limits. The easiest way to set the threshold is by choosing previous limits. The ventilator uses the threshold that was used before turning off the ventilator. The custom limits lets the user set all thresholds.

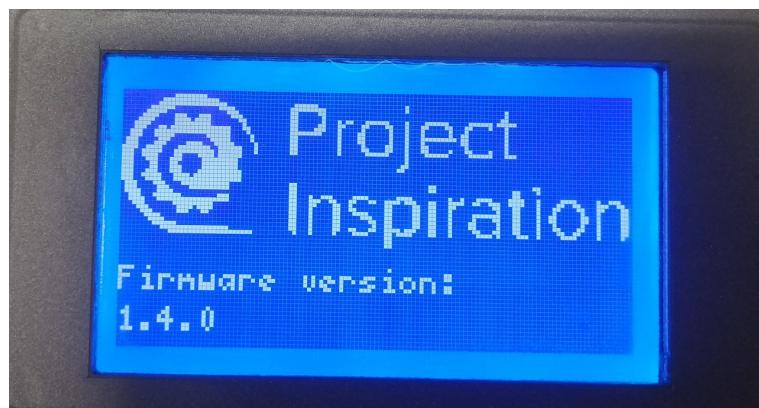


Figure 11: Starting screen.

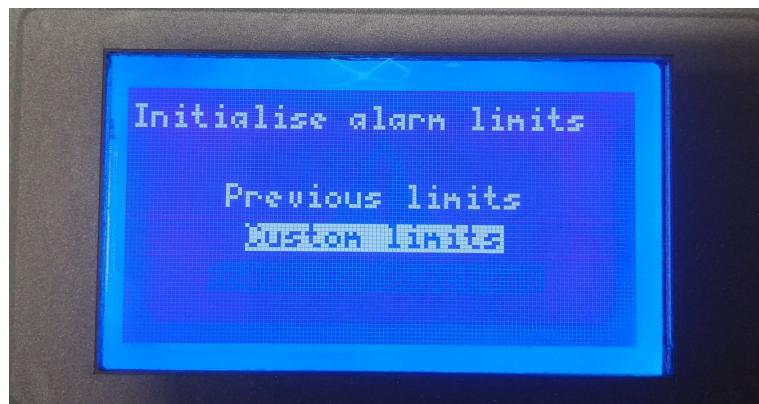


Figure 12: Threshold initializing options.

**Previous limits** Follow the next steps to set the thresholds by previous limits:

1. Select previous limits and press the menu scroll wheel
2. The alarm sounds and the warning screen is displayed
3. Wait a few seconds for the alarm to turn off
4. The thresholds are set



**Info:** It is possible to use previous limits and change some thresholds afterwards.

**Custom limits** Follow the next steps to set the thresholds by custom limits:

1. Select custom limits and press the menu scroll wheel
2. The display shows all parameters that needs to be set with a cross before the parameter. Figure 13 shows this screen. The cross before the parameters indicates that this threshold still needs to be set.
3. Select a parameter with a cross before it (e.g. Max. pressure)
4. Select a threshold and push on the menu scroll wheel (e.g. Maximum)
5. Rotate the menu scroll wheel to get the desired value and push again on the wheel
6. Repeat step 4 and 5 for the other threshold (e.g. Minimum)
7. A check mark appears before this parameter
8. Repeat step 3-7 till every cross is replaced by a check mark
9. Wait a few seconds for the alarm to turn off
10. The thresholds are set

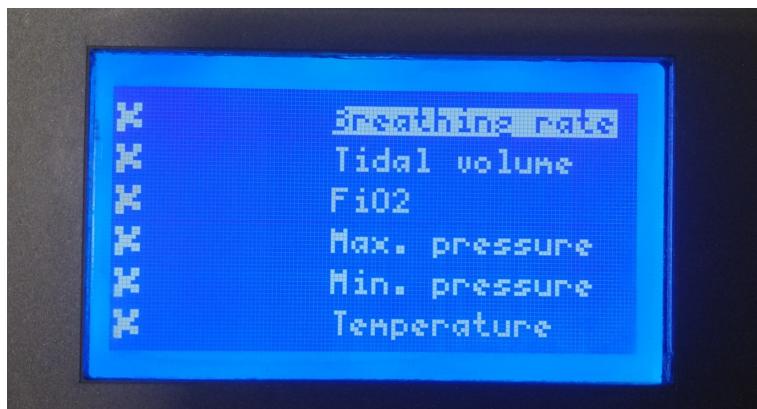


Figure 13: Displaying the thresholds that needs to be set.

### 5.1.5 Calibration of the Pressure

The pressure sensor has a calibration option for removing the offset of the pressure while the ventilator is still working. To calibrate the pressure follow the next steps:

1. Remove the pressure tube from the sensor, Figure 4 shows the position of this tube
2. Select Min. or Max. Pressure (will work the same) and push on the menu scroll wheel
3. Select calibrate and push on the menu scroll wheel
4. Make sure that the pressure tube is removed and push again
5. The display shows succeeded or failed. Try again all the steps if the calibration failed.

### 5.1.6 Calibration of FiO2

The FiO2 (molar fraction of inspired oxygen) has also a calibration option. The molar fraction is 21% if the machine works normal, without supplied oxygen and in normal dry air. Calibration will set 21% as value for the currently measured value.

Follow the next steps to calibrate the FiO2:

1. Make sure the oxygen supply is closed and make sure that there is only fresh ambient air left in the machine.
2. Select FiO2 in the main menu and press the menu scroll wheel
3. The FiO2 setting menu is displayed as shown in Figure 14
4. Select calibrate and press the menu scroll wheel if the molar fraction is 21%
5. The FiO2 is now set to 21%

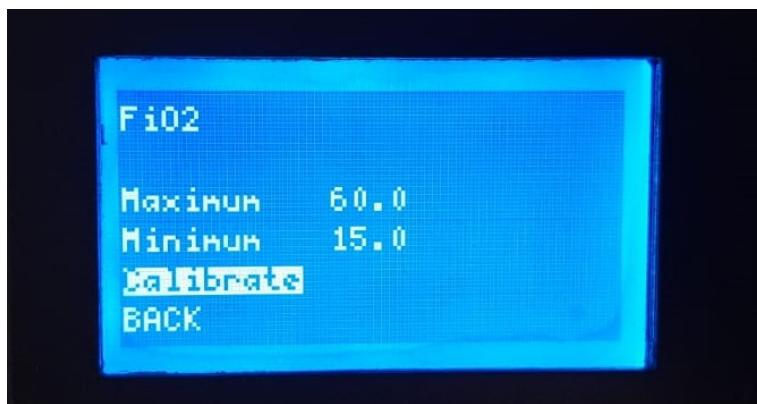


Figure 14: FiO2 setting menu.



**Warning:** Calibrate only if the molar fraction is known to be 21% (fresh ambient air).

### 5.1.7 Enable & Disable temperature sensor

The temperature sensor is optional and can be plugged in or out at the temperature plug. However the sensor must also be enabled or disabled in the user interface. The main menu shows an temperature if the sensor is enabled or shows OFF if the sensor is disabled. Figure 15 shows an example of the main screen if the sensor is disabled.

Also the temperature settings menu displays whether the sensor is enabled or disabled. Figure 16 shows an example of the temperature setting menu when the sensor is enabled. If the sensor is disabled the interface shows an OFF after enabled in the menu.

**Disable** Follow the next steps to disable the temperature sensor when the ventilator is running:

1. Select temperature in the main menu
2. Push on the menu scroll wheel to enter the temperature settings menu, the value will be set to OFF in the main menu, this should look like Figure 16
3. Select Enabled and push the menu scroll wheel
4. Disconnect the sensor from the temperature plug
5. Check the main screen to see if it looks like Figure 15

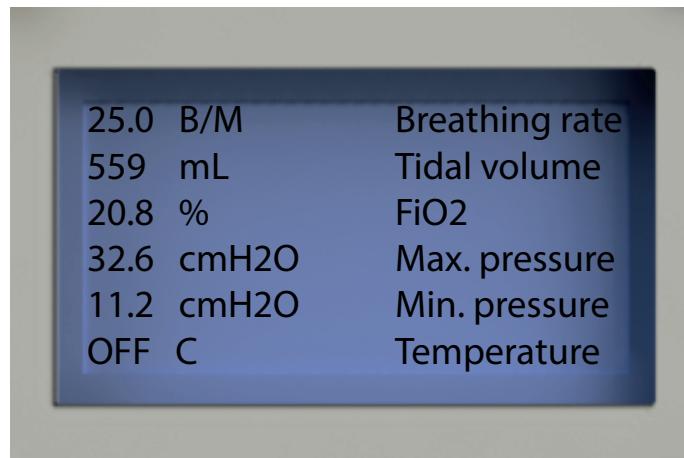


Figure 15: An example of the main screen when the temperature sensor is disabled.

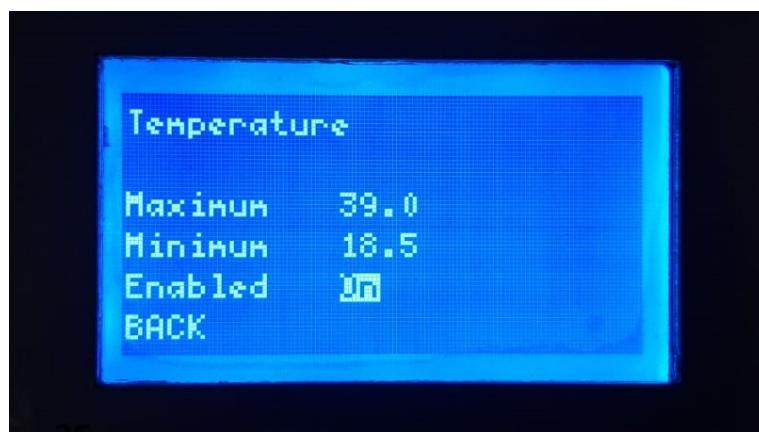


Figure 16: Temperature settings menu when the sensor is enabled

**Enable** Follow the next steps to enable the temperature sensor when the ventilator is running:

1. Connect the sensor to the temperature plug
2. Select temperature in the main menu
3. Push on the menu scroll wheel to enter the temperature settings menu
4. Select Enabled and push the menu scroll wheel
5. Check the main screen to see if a temperature value is displayed, see Figure 8 for an example

Starting the ventilator without a temperature sensor and with the sensor enabled in the menu, results in an alarm. Follow the next steps to connect the temperature sensor when this happens:

1. Connect the sensor to the temperature plug
2. Select temperature in the main menu
3. Press the menu scroll wheel to enter the temperature settings menu
4. Select Enabled and push the menu scroll wheel
5. Repeat step 2, 3 and 4
6. Check the main screen to see if it looks like normal, see Figure 8

## 5.2 Setting Device

This subsection explains how to adjust the breathing rate, the PEEP and the Plateau pressure.

### 5.2.1 Changing Breathing Rate

To set a higher or lower Breathing Rate rotate the breath dial (see Figure 7) respectively clockwise or counterclockwise and check the display if it is set properly.

### 5.2.2 Changing the PEEP

The PEEP can be set between 5 cmH<sub>2</sub>O and 20 cmH<sub>2</sub>O. To change the PEEP carefully rotate the knob of the PEEP valve (see figure 17) and check the display to see if the desired value is reached.

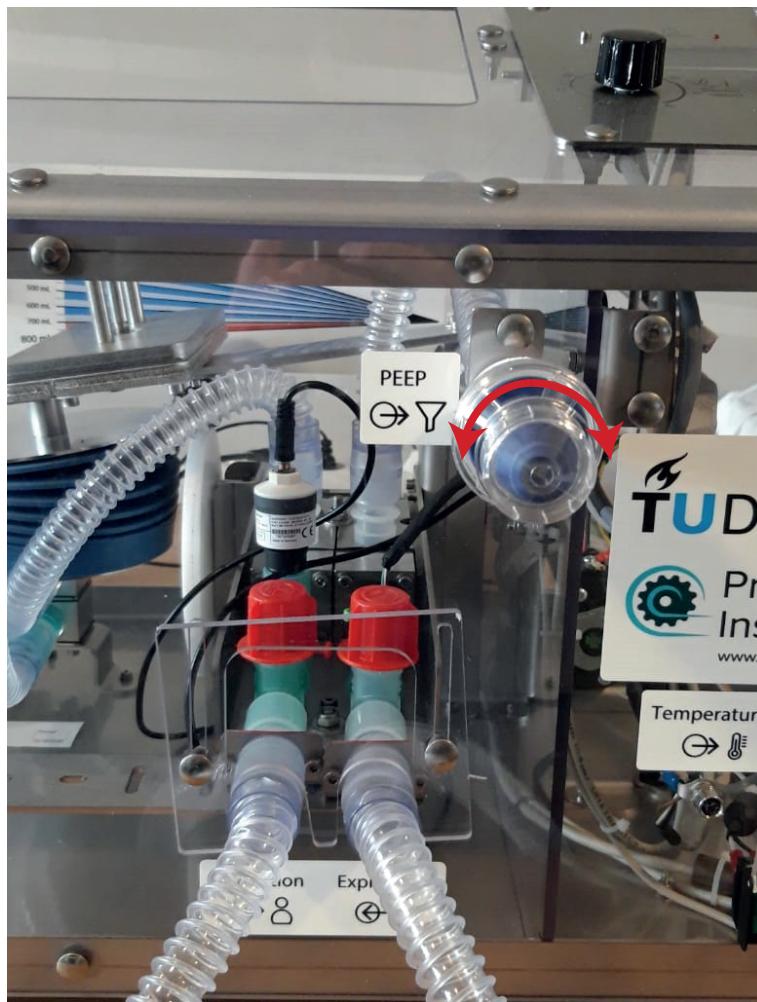


Figure 17: Changing the PEEP by rotating the knob of the PEEP valve

### 5.2.3 Changing Plateau/Max. Pressure

The max. pressure/plateau pressure that needs to be delivered to the lungs can be adjusted by changing the position of the weight(s) on the lever, as shown in figure 18. The max. pressure can be adjusted between a minimum of 15 cmH<sub>2</sub>O and a maximum of 70 cmH<sub>2</sub>O.



**Warning:** Increasing the plateau pressure above 30 cm H<sub>2</sub>O can have life-threatening effects for the patient.

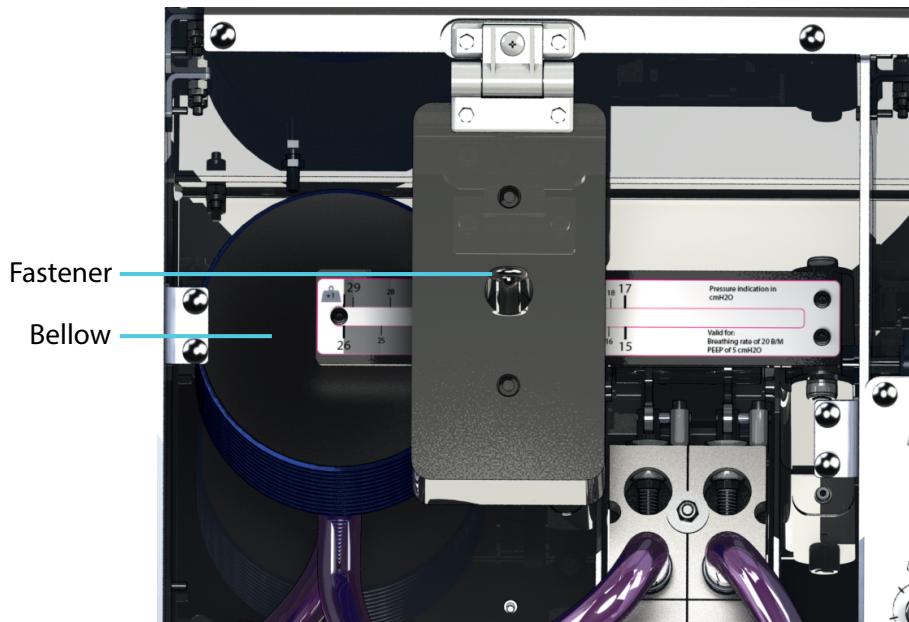


Figure 18: The pressure adjusting mechanism

**Scale** 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 that is closest to the bellow. The scale is for a breathing rate of 20 B/M and a PEEP of 5 cmH2O. It is different for other breathing rates and PEEP values. This scale is only for reference and the desired plateau pressure should always be validated on the display. The other side of the scale (with the picture of the mass) is for an additional weight. With one additional weight a range of about 17 to 29 cmH2O can be reached.



**Info:** Make sure first the breathing rate and PEEP are set before changing the max. pressure.

**Changing max. pressure** To change the max. pressure follow the next steps:

1. Check first the PEEP and breathing rate, make sure that those values are set correctly.
2. Look at the display to see whether the max. pressure needs to be set higher or lower
3. Open the lid to access the weights as shown in Figure 1
4. Make an estimate on how many weights are necessary
5. Put or remove weights if necessary
6. Look again at the display to see whether the max. pressure needs to be set higher or lower
7. Hold the weights and rotate the fastener gently counterclockwise to unlock the weights
8. Slide the resulting weights to the bellow to increase the max. pressure or slide it away from the bellow to decrease the max. pressure.
9. Rotate the fastener gently clockwise to lock the weights
10. Check the display after a few seconds to see if it is set as desired
11. If necessary repeat the steps 2-10



**Warning:** 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 H<sub>2</sub>O. To do this, the set of four extra weights can be gently placed on top of the slider. With this, the standard scale is no longer usable.

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.

## 6 Alerts & Appropriate Responses

Alerts	Alerting Mechanisms	Appropriate Response
Breathing rate (too high/low)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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 Breathing Dial clockwise. To decrease breathing rate, decrease plateau pressure. If problem can't be solved, repair machine with certified technician.
Tidal Volume (too high/low)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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)	<b>Severe Caution Screen:</b> Blinking (2Hz) <b>Buzzers:</b> 50% duty cycle (1Hz) <b>Primary screen:</b> 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 its 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 19 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 Breathing Dial 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 patients 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

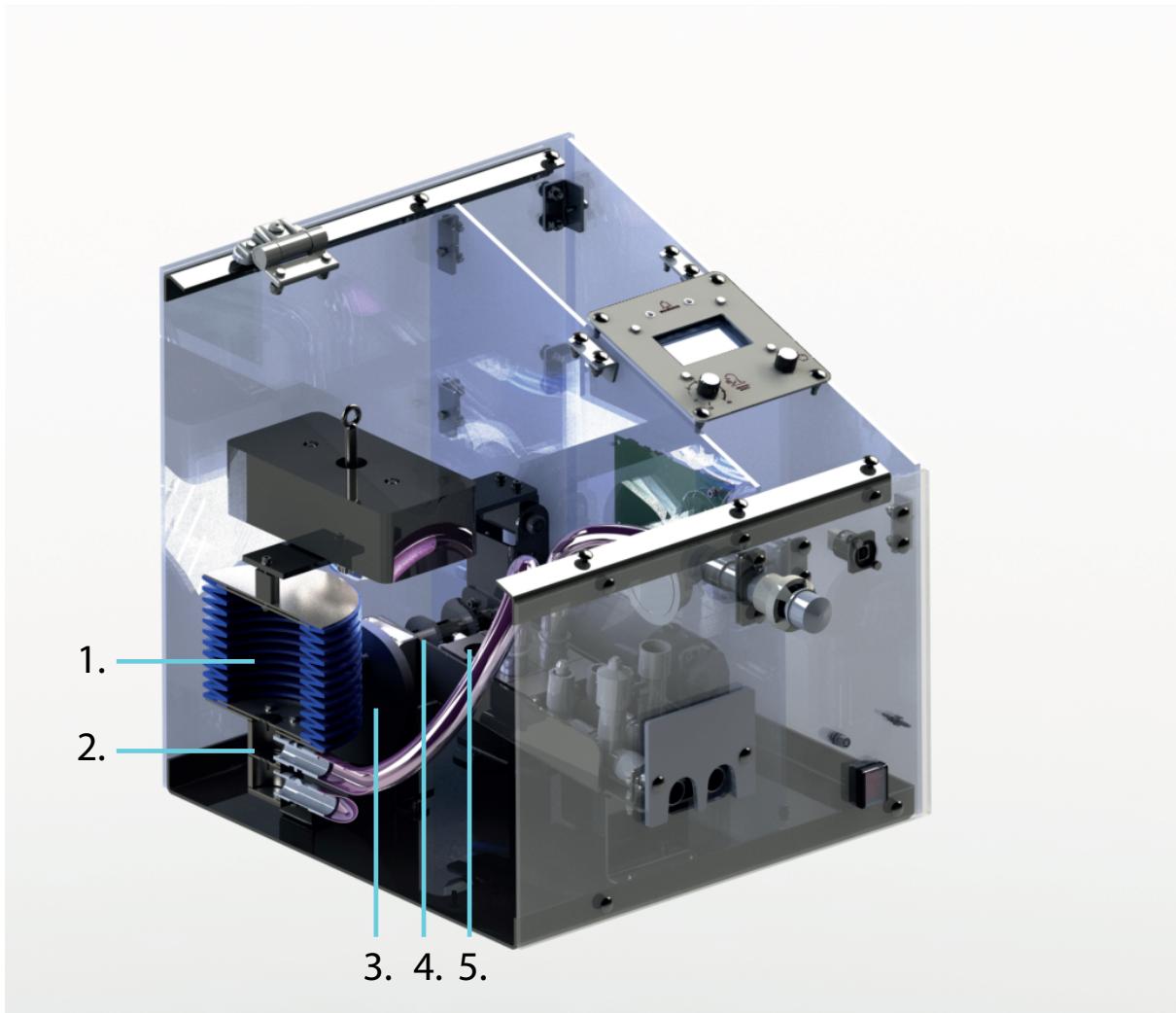


Figure 19: Components that require periodic visual inspection

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 20. The second step is to removing the bolts indicated in figure 21.



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

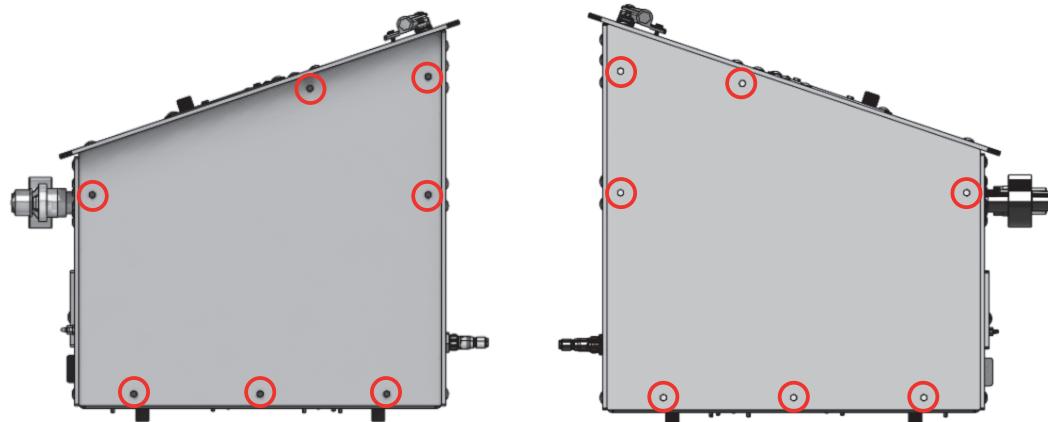


Figure 20: Remove the bolts in the red circles to remove the sides of the panel

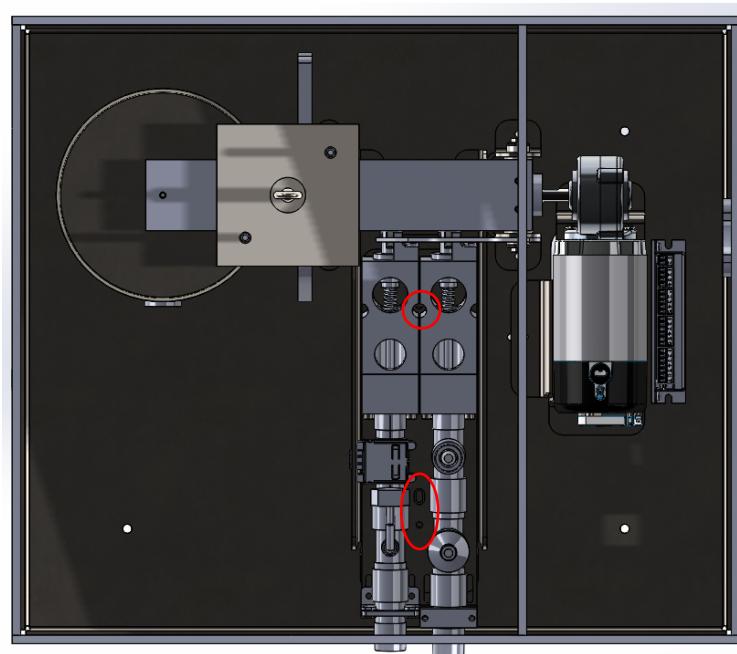


Figure 21: Remove the sensor tubes and main valve assembly by removing the bolts indicated in red