Assembly Manual – Project Inspiration

PI

October 2020

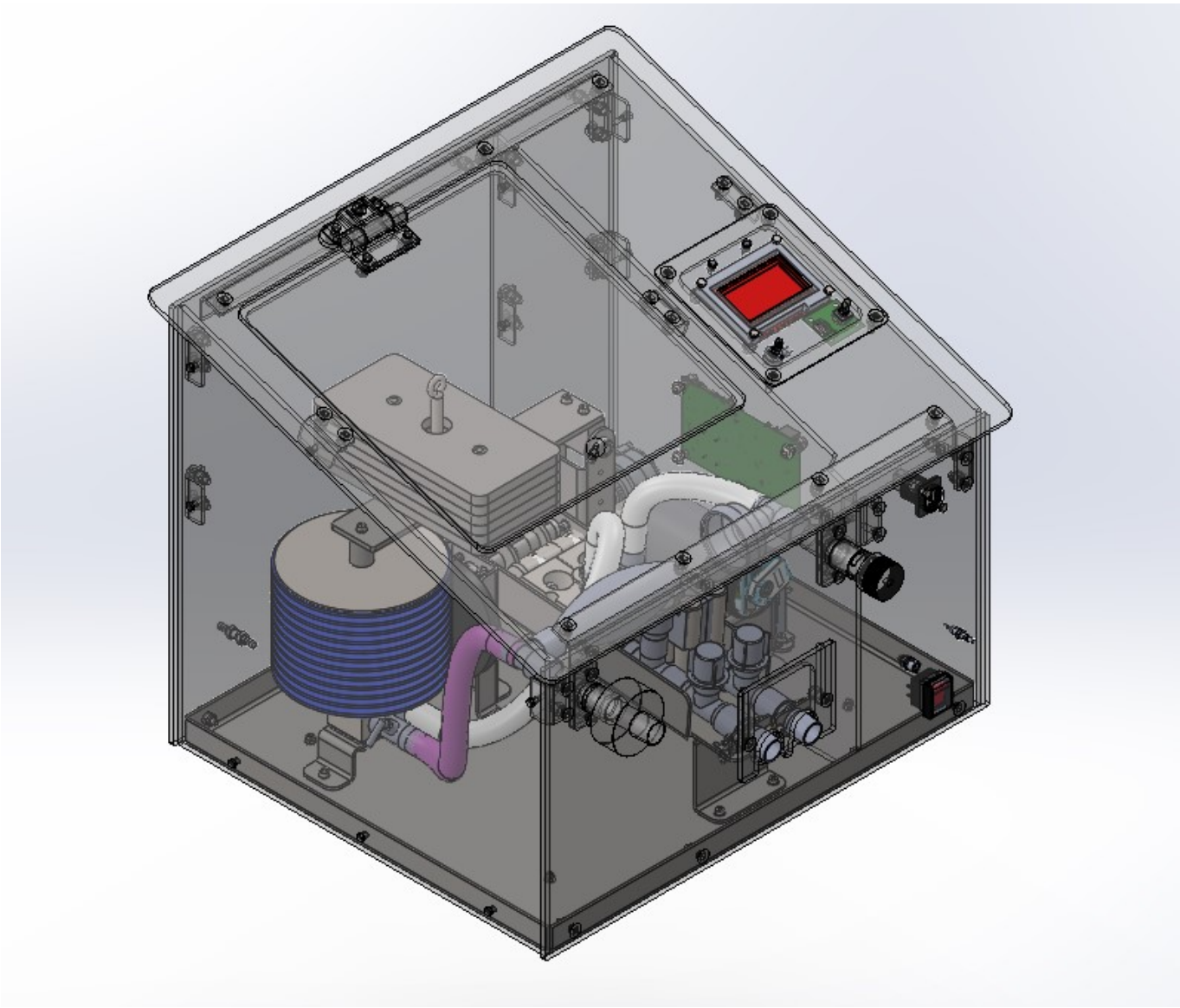

Figure 1: Isometric view of the device, for viewing purpose the housing is made transparent

Contents

1 Introduction

1.1 Device Description

This manual describes how the ventilator from Project Inspiration can be assembled. This is not a medically certified machine and medical use may only be done if local authorities certify the device for intended use. Project Inspiration provides this manual as guideline for building a ventilator, but using the device is at a user's own responsibility.

1.2 Safety

The following safety guidelines should be used during assembly.

- Personal safety equipment according to local standard
- Environmental requirement according to local standard

Figure 2 shows a systematic layout of the ventilator and divides the assembly into multiple sub-sections.

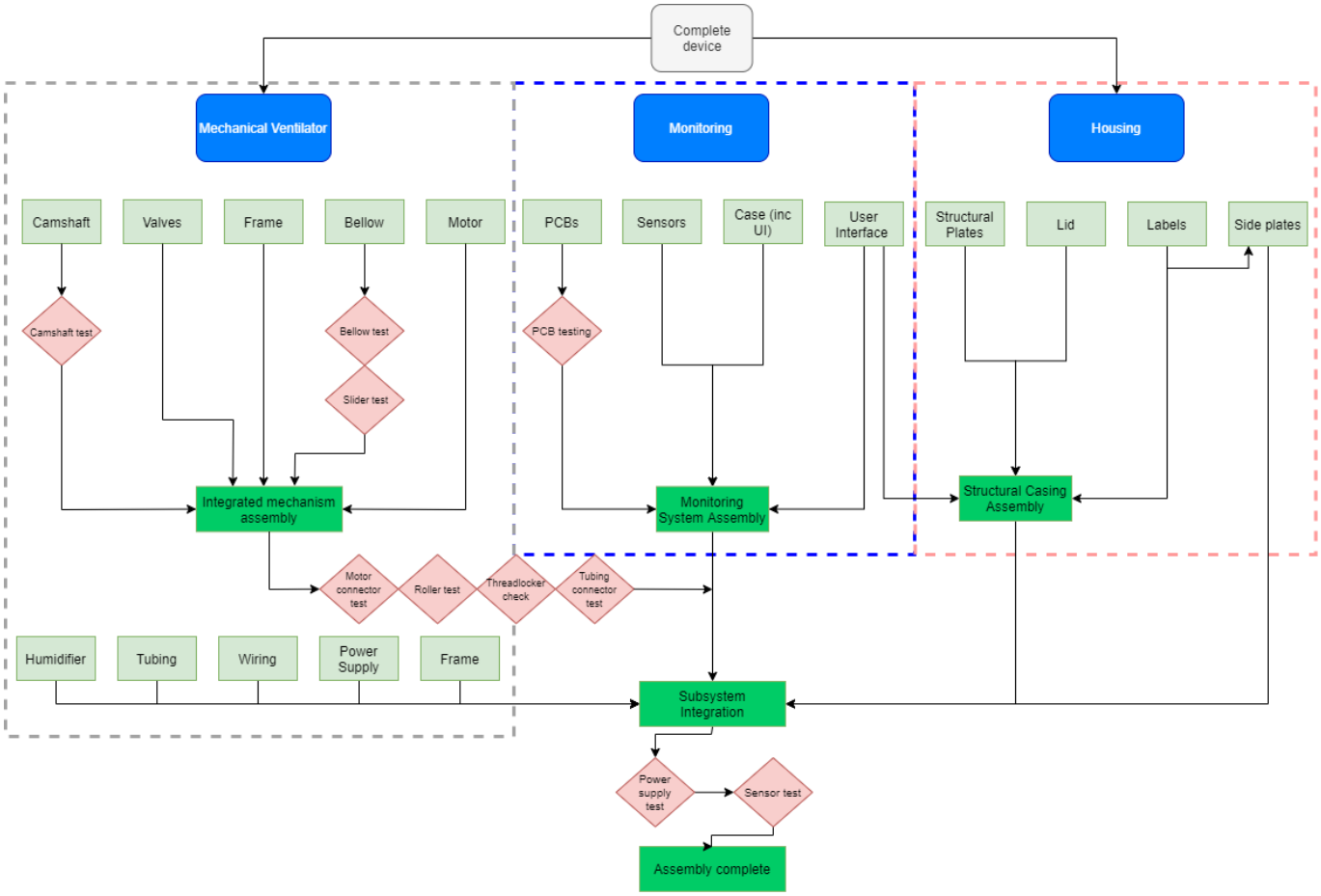

Figure 2: Assembly overview

2 Mechanical Ventilator

The mechanical components of the ventilator can be assembled with the following set of tools. See the figures below for examples.

- Torque wrench (Figure 3)
- Allen key insert size 3 (Figure 4)
- Allen key insert size 5 (Figure 4)
- Allen key size 2 (Figure 5)
- Allen key size 5 (Figure 5)
- Hand press (Figure 6)
- Wrench size 7 (Figure 7)
- Wrench size 10 (Figure 7)
- Socket 7mm (Figure 8)
- Pliers (Figure 9)

Figure 3: Torque wrench

Figure 4: Allen key insert

Figure 5: Allen key

Figure 6: Hand press

Figure 7: Wrench

Figure 8: Socket

Figure 9: Pliers

Every bolt that is not fastened with a lock-nut, but with an internal thread, must be locked with a type of thread locker. This prevents bolts from loosening due to vibrations. A small droplet must be applied to every bolt. It's important to note that thread locker should not be applied excessively and that excess fluid should be removed to prevent contamination. Washers should be applied to every bolt and nut. A torque wrench should be used to fasten every bolt with a properly set torque. The standard torque setting is 2 Nm

and 6 Nm for M4 and M6 bolts respectively. These settings should always be used if not specified otherwise. The wrenches are merely used to hold the nut in place during fastening. Set screws may be fastened with an Allen key. Proper fastening must be ensured. All plain bearings can be inserted into the holes with a hand press.

The sections below dictate the order of operations and list the sub-assemblies that can be assembled independently for every part of the ventilator. Required tools for every sub-assembly are listed and some additional information is provided. Section 2.7 describes how the sub-assemblies can be integrated and in what order this should be done. The PI.XX.XX.XX.XX numbering refers to the drawing names. Numbering refers to the bill of materials in the corresponding drawing.

2.1 Frame

Required tools:

- Torque wrench
- Allen key insert size 3mm
- Allen key insert size 5mm
- Wrench size 7
- Hand press

2.1.1 Baseplate PI.01.06.00.00

Look at assembly drawing PI_01Frame_06BasePlate_00_00Assembly.pdf

2.2 Camshaft

2.2.1 Camshaft and valve structure PI.02.00.00.00

Look at assembly drawing PI_02Camshaft_00_00_00Assembly.pdf
For this assembly, the assembly PI.01.04.00.00 is necessary.

Required tools:

- Torque wrench
- Allen key insert size 3mm
- Allen key insert size 2mm

2.3 Bellow

2.3.1 Bellow Pump Clamping PI.03.01.04.00

Look at assembly drawing PI_03Bellow_01Pump_04Clamping_00Assembly.pdf

- Double check if there are no sharp edges
- Discs must be visually centered in the bellow

Required tools:

- Torque wrench
- Allen key insert size 3mm
- Socket 7mm
- Pliers

2.3.2 Bellow Lever Arm PI.03.02.01.00

Look at assembly drawing PI_03Bellow_02Lever_01Arm_00Assembly.pdf

- Holes can be used as a reference to place the sticker
- Setscrews are added later when assembled in main assembly

Required tools:

- Torque wrench
- Allen key insert size 3mm

2.3.3 Bellow Weight PI. 03.02.02.00

Look at assembly drawing PI_03Bellow_02Lever_02Weight_00Assembly.pdf

- Thumb screw (PI.03.02.02.03) can be loosely inserted

Required tools:

- Torque wrench
- Allen key insert size 5mm
- Pliers

2.3.4 Bellow Lever Wheel PI.03.02.03.00

Look at assembly drawing PI_03Bellow_02Lever_03Wheel_00Assembly.pdf
Required tools:

- Hand press

2.4 Valves

2.4.1 FollowerValve PI.04.01.00.00

Look at assembly drawing PI_04Valves_01FollowerValve_00_00Assembly.pdf

- Hose connection(20) may be inserted by hand, no press required
- The two valves are identical
- Pin for roller must be guided by two FollowerBusses

Required tools:

- Torque wrench
- Allen key insert size 3
- Wrench size 7
- Hand press
- Pliers

2.4.2 Valve main Assembly PI.04.00.00.00

Look at assembly drawing PI_04Valves_00_00_00Assembly.pdf

- Valve position has to be set with respect to cams. They have to touch when in closed position.
- This positioning is done during final assembly

Required tools:

- Torque wrench
- Allen key insert size 3
- Wrench size 7

2.5 Motor PI.05.00.00.00

Look at assembly drawing PI_05Motors_00_00_00Assembly.pdf

- Check motor mounting holes for M4 or M5 bolts

Required tools:

- Torque wrench
- Allen key insert size 3
- Allen key size 2

2.6 Humidifier

Users should procure their own humidifier depending on advice from a medical expert. If no humidifier can be found, contact Project Inspiration for an alternative solution.

2.7 Assembly Integration

2.7.1 Main assembly PI.00.00.00.00

Look at assembly drawing PI_00Main_00_00_00
Required Tools:

- Torque wrench
- Allen key size 2
- Allen key insert size 3
- Wrench size 7

The integrate all the sub-assemblies that have been addressed in this section, the right assembly order must be maintained. The list below provides a step by step approach.

1. Connect the camshaft/valvestructure assembly to the base plate
2. Add motor assembly to the base plate by sliding the shaft connectors together and fastening the bolts to the baseplate
3. Connect the bellow pump to the base plate
4. Connect the bellow wheel to lever arm.
5. Connect the lever arm to the frame and bellow

- A support frame for the baseplate is recommended to ease assembly

2.8 Quality Control

Table 1 provides a list of tests that should be conducted on the final mechanical assembly.

Test Number Check	Description	Passed if
1	Motor connector test	The bellow cam can not be rotated
2	Camshaft test	Cams can not be moved axially
3	Slider test	The slider can easily be moved by hand when unlocked
4	Threadlocker check	Make sure threadlocker is applied to every internal thread
5	Tubing connector test	All connectors are inserted at least 5mm
6	Bellow test	The bellow generates airflow when moved up and down
7	Roller test	The roller on the lever arm is aligned properly as prescribed in the assembly drawing

Table 1

3 Housing & Electronics

In this part of the assembly manual the housing and some placement of electronic components will be discussed. In figure 10 an overview of the complete housing sub-assembly is given. Furthermore, table 2 gives an overview of all the parts necessary. For an overview of all the parts and their technical drawings, see the GitHub on www.projectinspiration.nl. It is suggested to assemble the housing with only one person at a table and the tools required are:

- Wrench (7 & 8 mm)
- Socket wrench (7 & 8 mm)

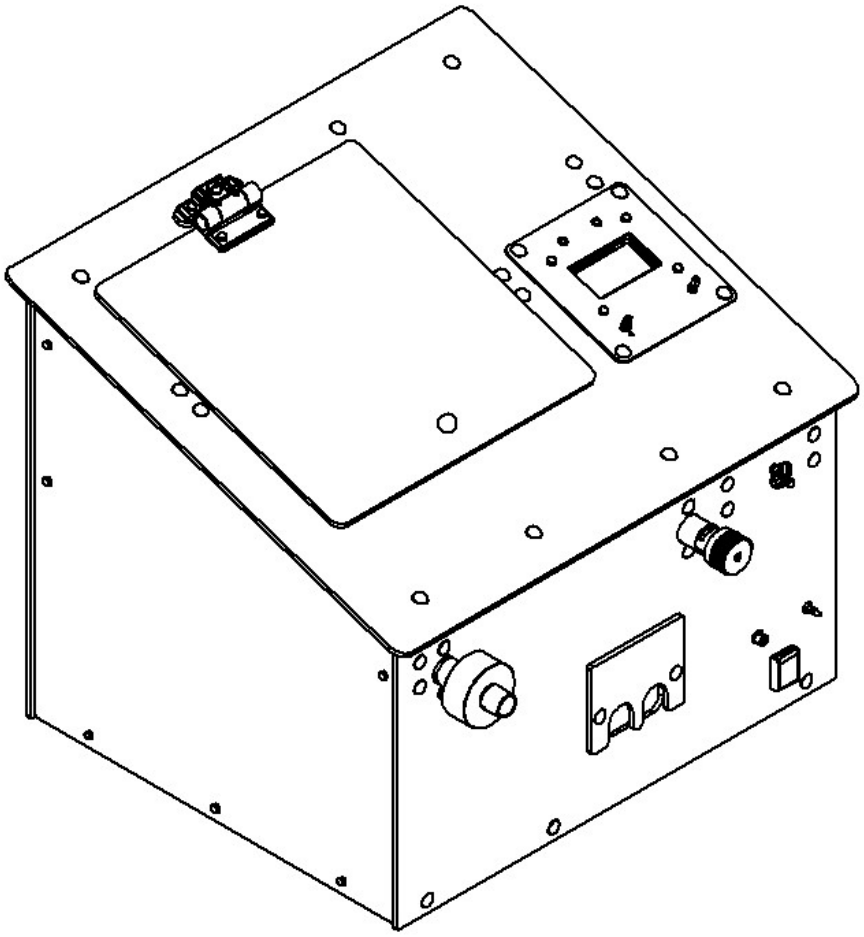

Figure 10: Overview of the Complete Housing Assembly

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
H1	PI_10Housing_01Top_00_01TopPlate	PI.10.01.00.01	1
H2	PI_10Housing_00_00_06ConnectorSharp	PI.10.00.00.06	1
H3	PI_10Housing_00_00_07ConnectorSmall	PI.10.00.00.07	12
H4	PI_10Housing_01Top_00_02Lid	PI.10.01.00.02	1
H5	PI_10Housing_01Top_00_05Hinge	PI.10.01.00.05	1
H6	PI_10Housing_01Top_00_06Handle	PI.10.01.00.06	1
H7	PI_10Housing_01Top_00_03Riser	PI.10.01.00.03	1
H8	PI_10Housing_00_00_02Back	PI.10.00.00.02	1
H9	PI_10Housing_00_00_04InternalWall	PI.10.00.00.04	1
H10	PI_10Housing_02Front_00_01Front	PI.10.02.00.01	1
H11	PI_10Housing_00_00_05ConnectorBlunt	PI.10.00.00.05	1
H12	PI_10Housing_02Front_00_02ConnectorBracket	PI.10.02.00.02	4
H13	31Intersurgical_22M-22M	PI.00.00.00.31	1
H14	32Intersurgical_22M-22F	PI.00.00.00.32	1
H15	PI_10Housing_02Front_00_03FrontSensorCover	PI.10.02.00.03	1
H16	PI_01Housing_00_00_001SideLeft	PI.10.00.00.01	1
H17	PI_10Housing_00_00_03SideRight	PI.10.00.00.03	1
H18	ISO 8677 - M5 x 20 - 16-N		56
H19	ISO 7040 - M5 - N		56
H20	ISO 4017 - M4 x 16-N		24
H21	ISO 4017 - M6 x 25-N		4
H22	ISO 7040 - M6 - N		4
H23	ISO 7040 - M4 - N		6
H24	ISO 10673 - M4 - W		4
H25	ISO 10673 - M5 - W		4
H30	PI_20Monitoring_02PCB_00_01Main	PI.20.02.00.01	1
H31	PI_20Monitoring_04PanelMounts_00_07USBConnector	PI.20.04.00.07	1
H32	PI_20Monitoring_04PanelMounts_00_01OnOffSwitch	PI.20.04.00.01	1
H33	PI_20Monitoring_04PanelMounts_00_04TemperaturePlug	PI.20.04.00.04	1
H34	PI_20Monitoring_04PanelMounts_00_05PressureLuer	PI.20.04.00.05	1
H35	PI_20Monitoring_04PanelMounts_00_02PanelMountPlug	PI.20.04.00.02	1
H36	PI_20Monitoring_04PanelMounts_00_03CableMountReceptacle	PI.20.04.00.03	1
H37	PI_20Monitoring_04PanelMounts_00_06OxygenFitting	PI.20.04.00.06	1
H38	PI_20Monitoring_01UIPanel_00_01RotarySwitch	PI.20.01.00.01	1
H39	PI_20Monitoring_01UIPanel_00_02Display	PI.20.01.00.02	1
H40	PI_10Housing_01Top_00_04UIPlate	PI.10.01.00.04	1
H41	PI_05Motors_01Drivetrain_00_04PotMeter	PI.05.01.00.04	1
H42	PI_20Monitoring_01UIPanel_00_03LED	PI.20.01.00.03	1
H43	PI_20Monitoring_01UIPanel_00_04LEDMountingClip	PI.20.01.00.04	1
H44	PI_20Monitoring_01UIPanel_00_05DisplaySpacer	PI.20.01.01.05	1
H45	40PEEPValve	PI.00.00.00.40	1
H46	41HEPAFilter	PI.00.00.00.41	1
H47	PI_07Tubing_00_00_01MembraanAdapter	PI.07.00.00.01	1
H48	PI_07Tubing_00_00_02ConicalRing	PI.07.00.00.02	1
H49	34Intersurgical_22M-22F-22F	PI.00.00.00.34	1

Table 2: Overview of all the parts of the housing sub-assembly

3.1 HA1. Top Plate Assembly

For this assembly the following parts are needed: H1, H2, 3x H3, H4, H5, H6, H7, 8x H18, 8x H19, 1x H20, 4x H21 and 4x H22.

1. Orientate the H1 Top Plate as illustrated in figure 11.
2. Position the H2 and the three H3 Connectors onto the plate and fasten them with 8x H18 bolts and H19 nuts. Make sure their orientation resembles figure 11.
3. Place the H5 Hinge onto the H4 Lid and connect with 2x H21 bolts and H22 nuts.
4. Bolt the H6 handle to the Lid with a H20 bolt.
5. Flip the Top Plate and position the H7 Riser between the Top Plate and the Hinge as illustrated in detailed view of figure 11.
6. Align the holes in the three stacked parts and connect them with 2x H21 bolts and H22 nuts to mount the Lid Assembly to the Top Plate.

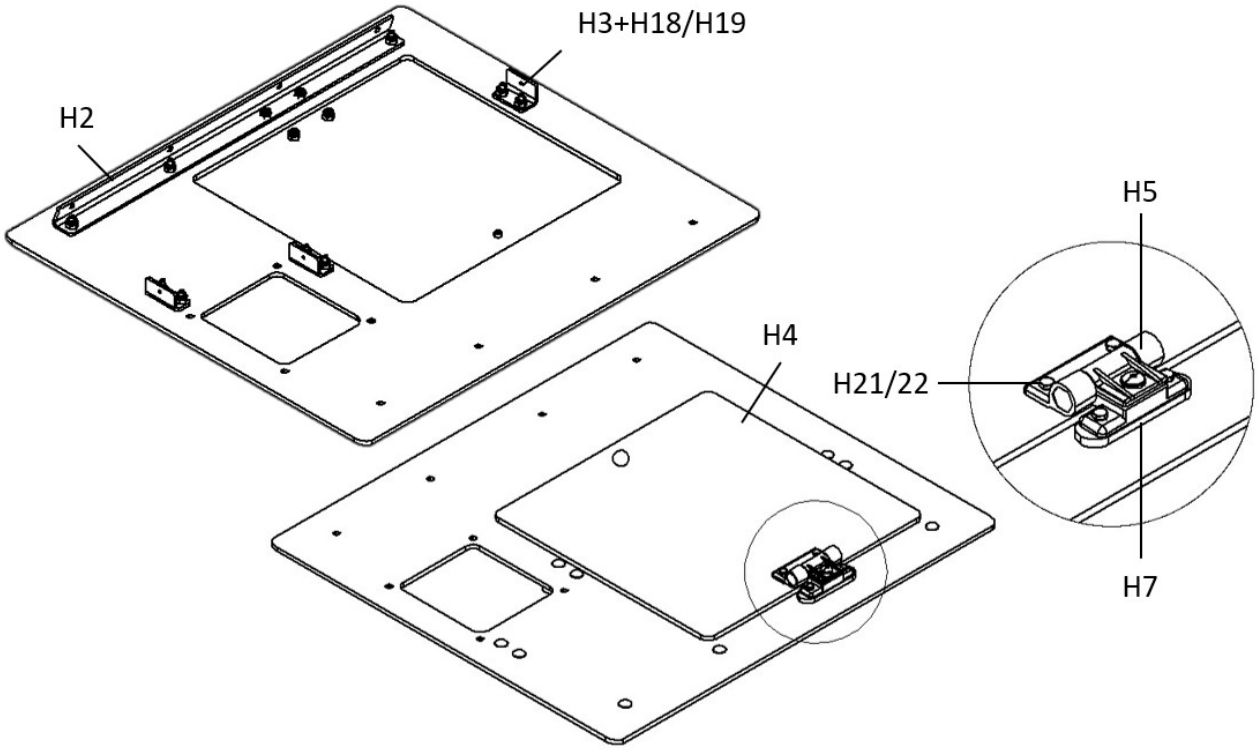

Figure 11: Overview of the Top Plate Assembly

3.2 HA2. Back Plate Assembly

For this assembly the following parts are needed: H8, H9, 6x H3, 12x H18, 12x H19, 6x H20, H30, 4x H23 and 4x H24.

1. Orientate the H8 Back Plate as illustrated in figure 12.
2. Position the 6x H3 Connectors onto the plate. Make sure their orientation resembles figure 12. Fasten the connectors with 12x H18 carriage bolts and H19 nuts.
3. Position the H9 Internal Wall perpendicular to the Back Plate and fasten it with 2x H20 hex bolts as can be seen in the detailed view of figure 12.
4. Position the H30 PCB on the Internal wall and fasten it with the 4x H20 bolts and H23/H24 washer and nut.

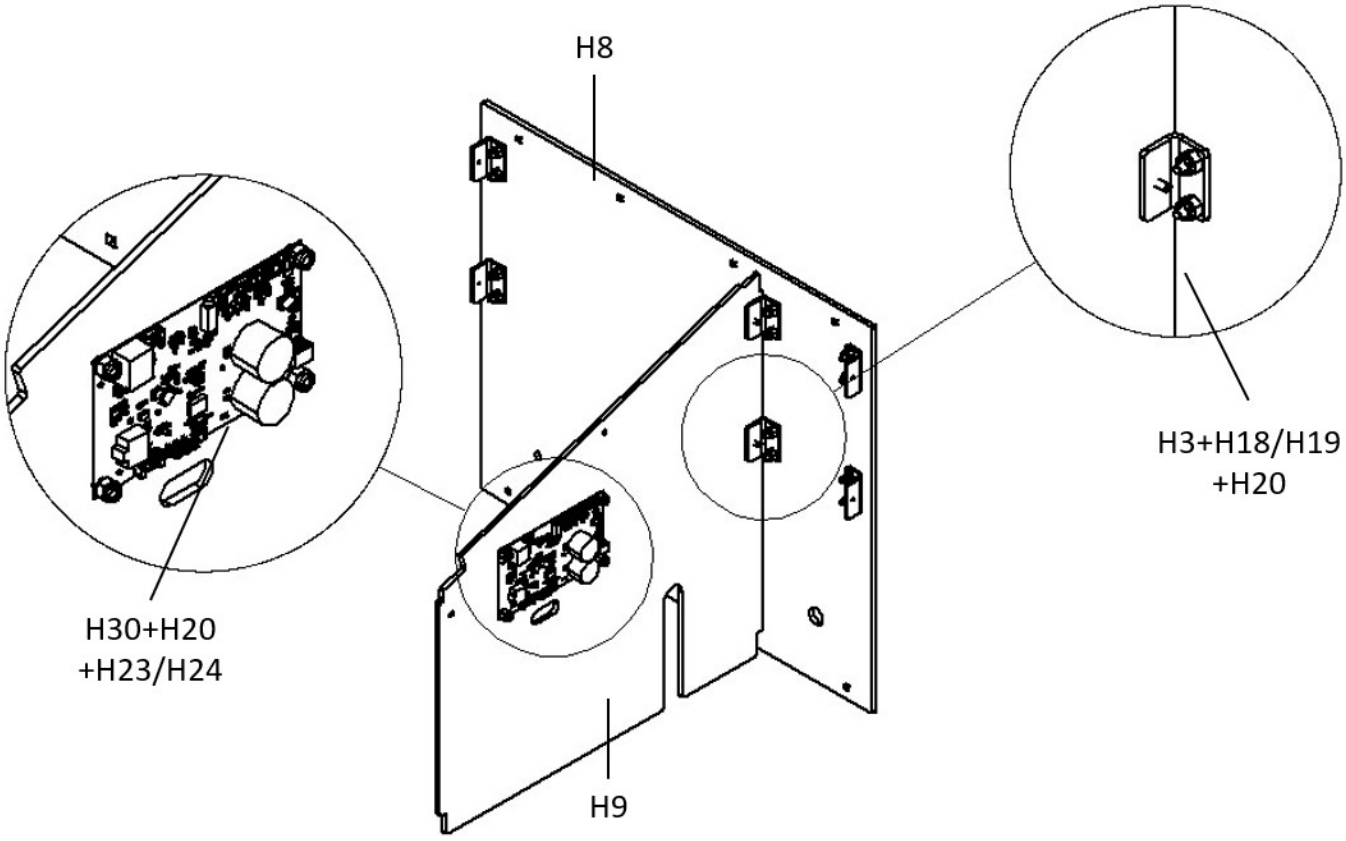

Figure 12: Overview of the Back Plate Assembly

3.3 HA3. Front Plate Assembly

For this assembly the following parts are needed: H10, H11, 3x H3, H31, H32, H33, H34, 4x H12, 2x H13/H14, 14x H18, 14x H19, 2x H20 and 2x H23. Note: the required Intersurgical tube connector type depends on the available PEEP-valve and HMEF-filter. Thus, either H13 Intersurgical 22M-22M andor H14 Intersurgical 22M-22F should be used.

1. Orientate the H10 Front Plate as illustrated in figure 13.
2. Position the H11 Connector Blunt and the 3x H3 Connectors Small onto the plate. Make sure their orientation resembles figure 13. Fasten the connectors with 10x H18/H19 carriage bolts and nuts.
3. Hook two H12 Connector Brackets onto both tube connectors of the type H13 Intersurgical 22M-22M and/or H14 Intersurgical 22M-22F.
4. Place the tube connectors through the two round holes in the Front Plate as illustrated in figure 13 and fixate their Connector Brackets to the Front Plate with 4x H18 carriage bolts and H19 nuts.
5. Position the H31 USBConnecter on the H10 Front Plate and fasten it with 2x H20 and H23 bolts and nuts.
6. Place the H22 OnOffSwitch, H33 Temperature Plug and the H34 Pressure Luer as illustrated in figure 13.

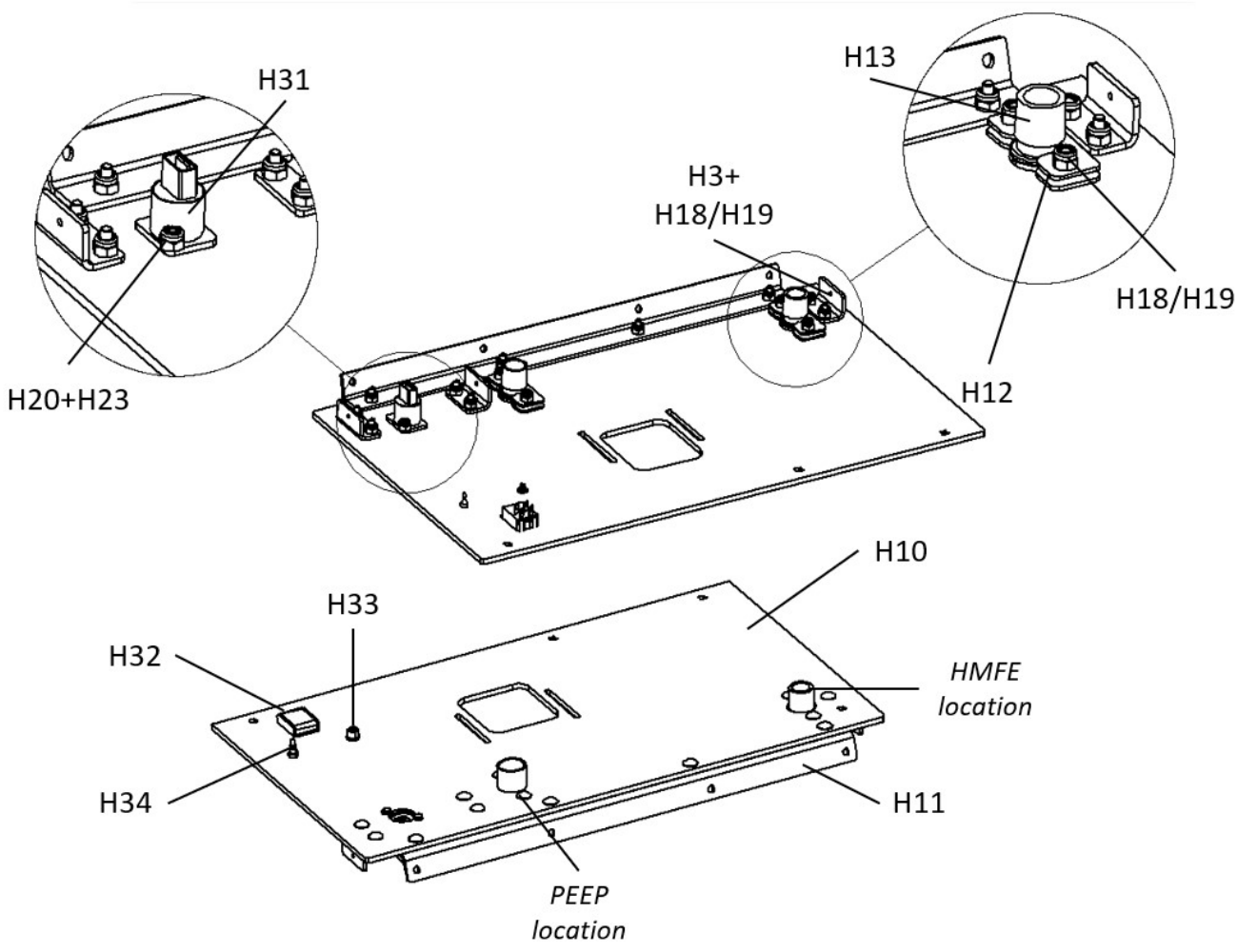

Figure 13: Overview of the Front Plate Assembly

3.4 HA4. Mounting HA2 & HA3 on Main Assembly

For this assembly the following parts are needed: Main Assembly, HA2, HA3, H15, H35, H36, H37 8x H18 and 8x H19.

1. Connect the HA2 Back Plate Assembly to the Frame with 3 H18 Carriage Bolts and H19 Nuts.
2. Connect the HA3 Front Plate Assembly to the Frame with 3 H18 Carriage Bolts and H19 Nuts as depicted in figure 14.
3. Bolt the H9 Internal Wall to the H3 Connector Small on the H10 Front Plate with a H20 Hex Bolt.
4. Bolt the H15 Front Sensor Cover with 2x H18 Carriage Bolts and H19 Nuts on the H10 Front Plate as shown in figure 14
5. Insert the H35 MountPlug to the back plate and insert the H36 CableMountReceptacle to this Mountplug.
6. Connect the H37 OxygenFitting to the backplate.

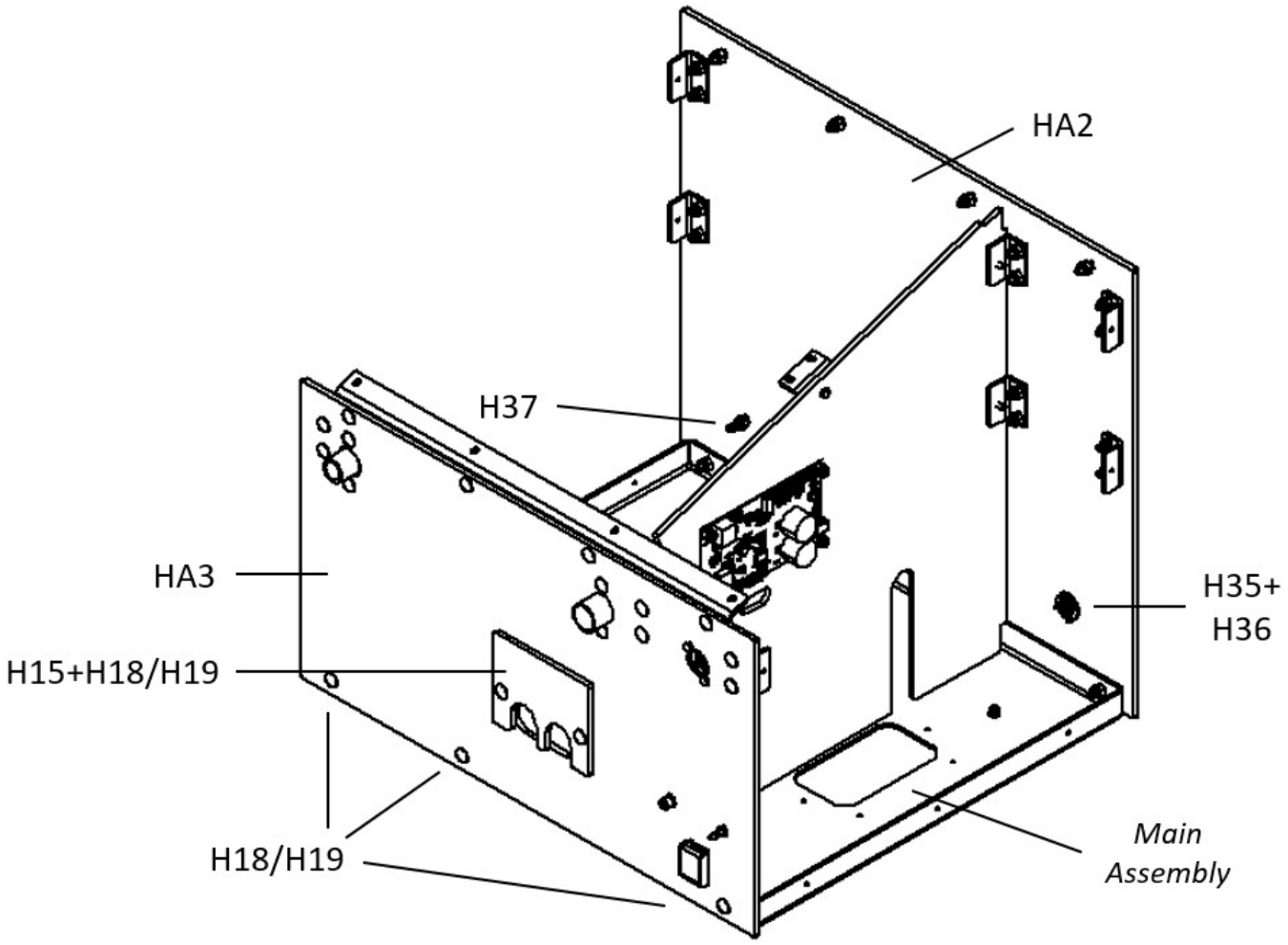

Figure 14: Mount Front and Back Plate Assembly to Main Assembly

3.5 HA5. Mounting HA1 to HA4

For this assembly the following parts are needed: HA1, HA4, 10x H18 and 10x H19.

1. Place HA1 onto HA4 as illustrated in figure 18 and fasten it with 4x H18 Carriage Bolts and H19 Nuts at the front and 4x H18 Carriage Bolts and H19 Nuts at the back.
2. Connect the H3 Connector Small (which is connected to the H9 Internal Wall) to the HA1 Top Plate assembly with 2x H18 Carriage Bolts and H19 Nuts.

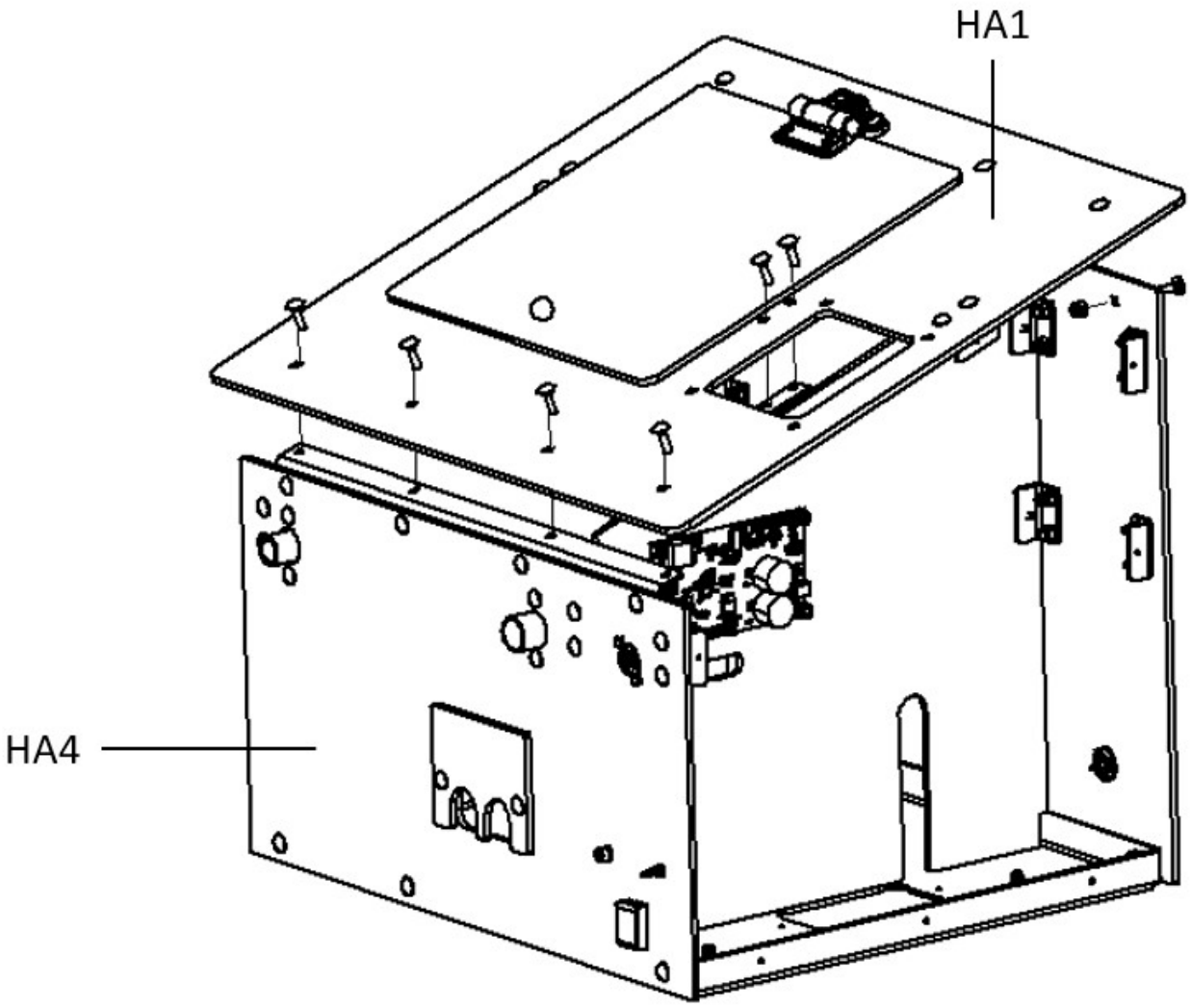

Figure 15: Mount Top Plate Assembly to Main Assembly

3.6 HA6, User Interface Assembly

For this assembly the following parts are needed: 4x H20, 4x H23, H38, H39, H40, H41, 2x H42, 2x H43 and H44. Also the PI_10Housing_00_00_15StickerUserInterface is needed (PI.10.00.00.15).

1. Place the Sticker on the H40 UIPlate. The holes indicates the position.
2. Assembly the H39 Display by placing it on the H44 DisplaySpacer as shown in figure 16. Position both on the H40 UIPlate as shown and mount it with the 4x H20 bolts and 4x H23 nuts. Do not over tighten the bolt and nuts.
3. Use the 2x H43 LEDMountingClips and the 2x H42 LED to push them both in the H40 UIPlate.
4. Fasten the H38 RotarySwitch and the H41 Potmoter as shown. Make sure it looks like figure 17.

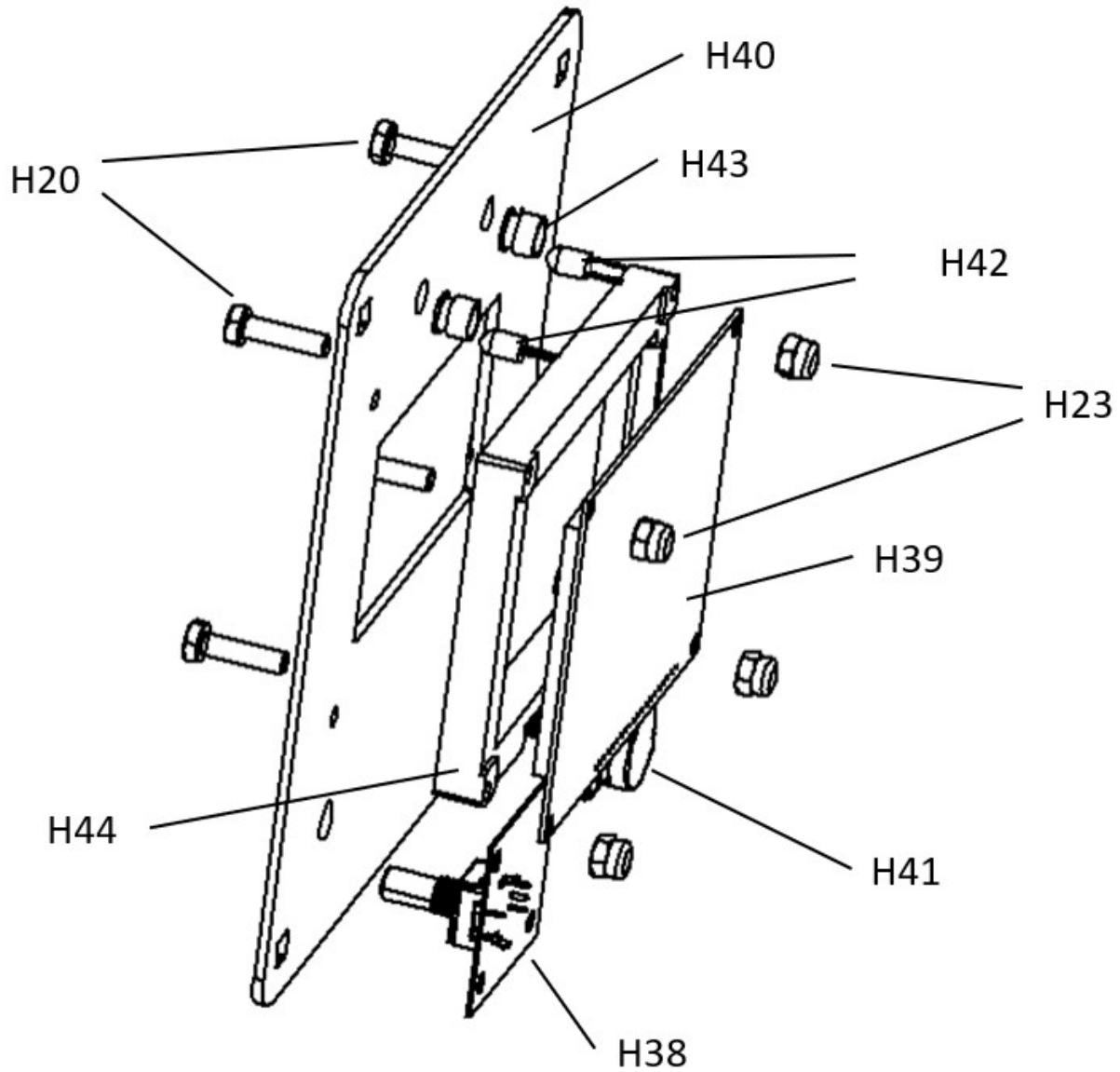

Figure 16: Exploded view of the User Interface Assembly

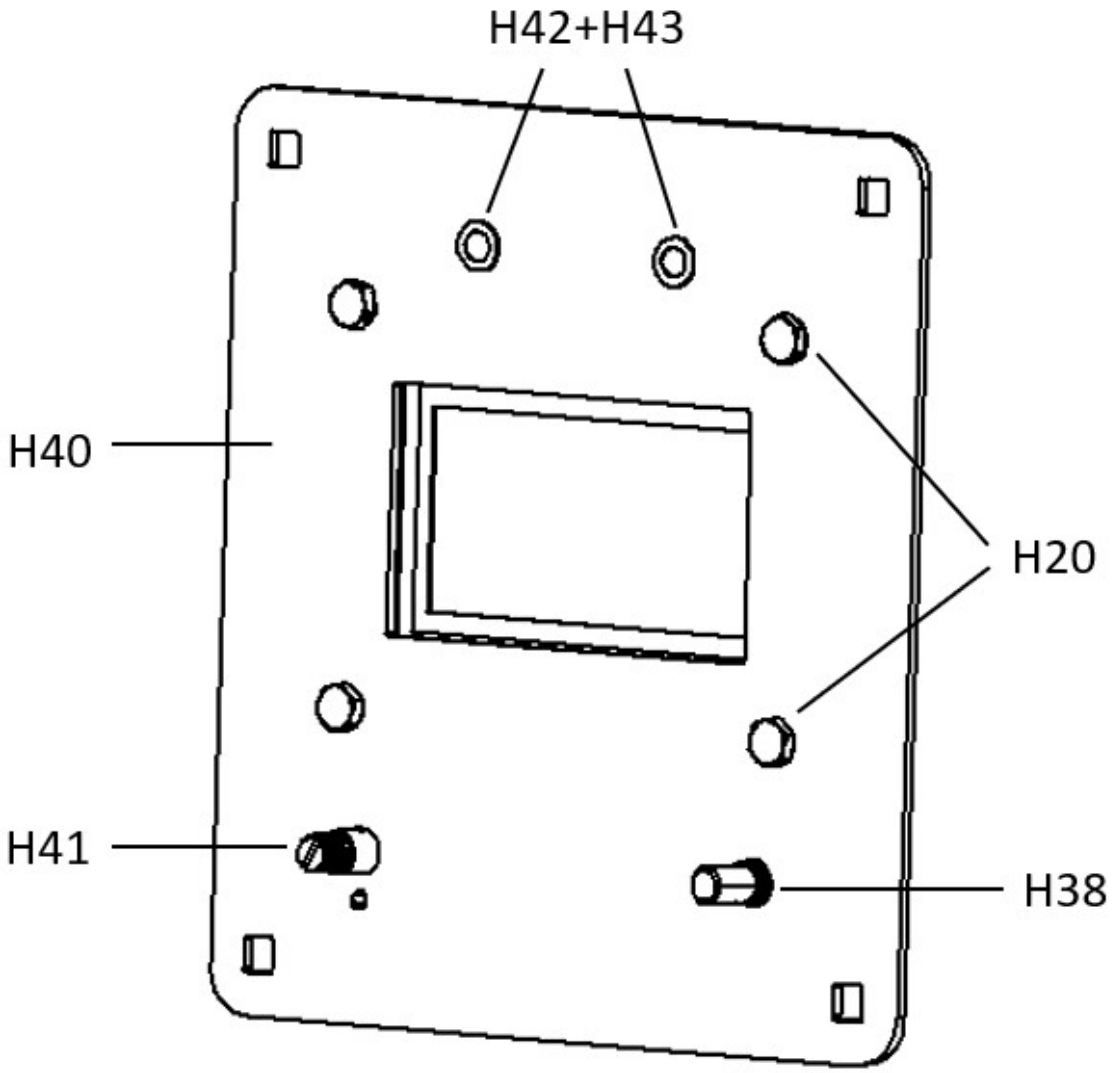

Figure 17: Front view of the User Interface

3.7 HA7. Mount HA6 to HA5

For this assembly the following parts are needed: HA5, HA6, 4x H18, 4x H19 and 4x H25.

1. Position the Monitoring Panel onto the opening in the Top Plate as shown in figure 18.
2. Use 4x H18 Carriage Bolts, 4x H19 Nuts and 4x H25 Washers to mount the User Interface.

   Note: All electronic connections can be made now. Make sure everything is connected correctly before going to the next step.

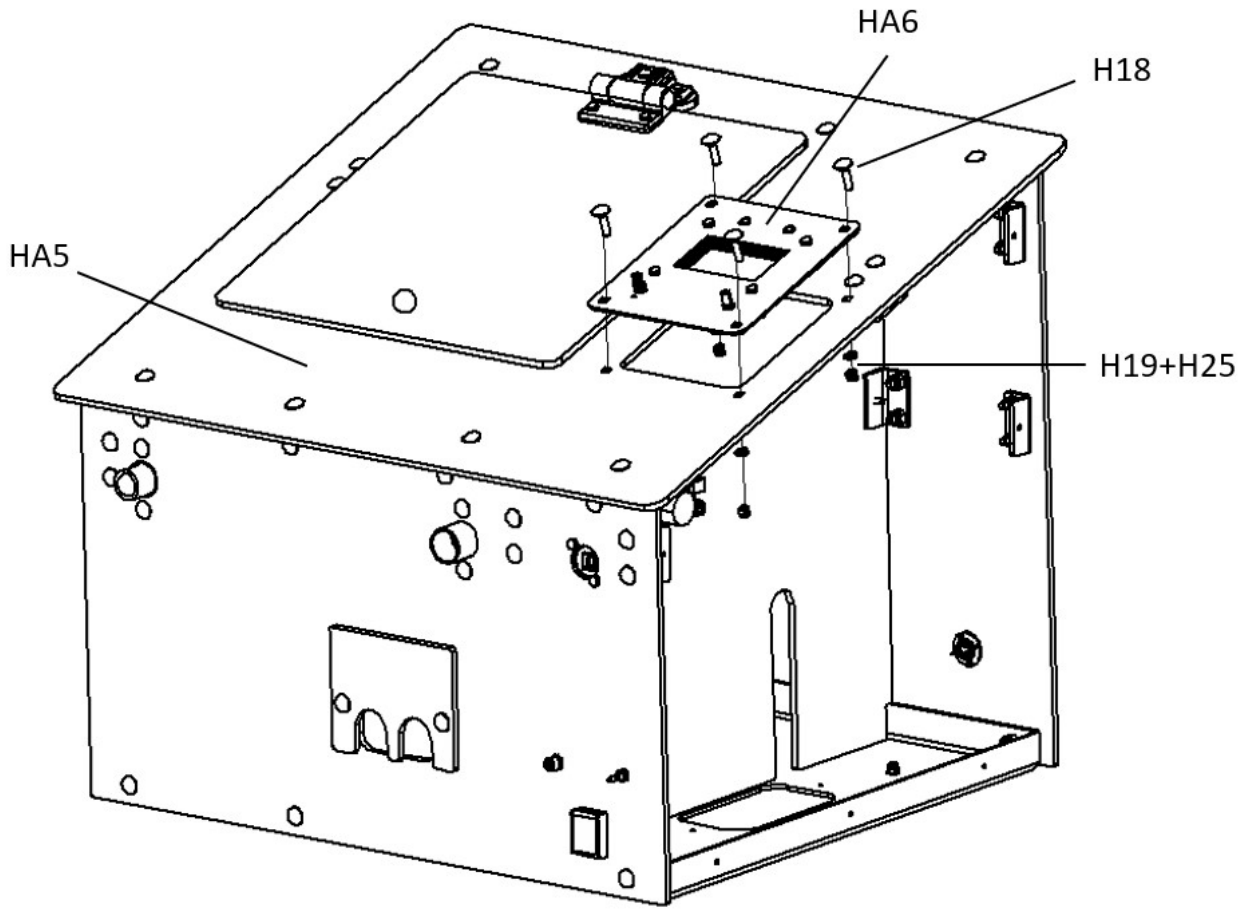

Figure 18: Mount User Interface to Top Plate

3.8 HA8. Mount Side Panels on HA5 and Main Assembly

For this assembly the following parts are needed: HA7, H16, H17, 12x H20. Note: Before this assembly step, all internal components should be placed and necessary testing should be done.

1. Mount the H16 Side Left and H17 Side Right plates to the Main Assembly with 6x H20 Bolts on either side as pictured in figure 19.

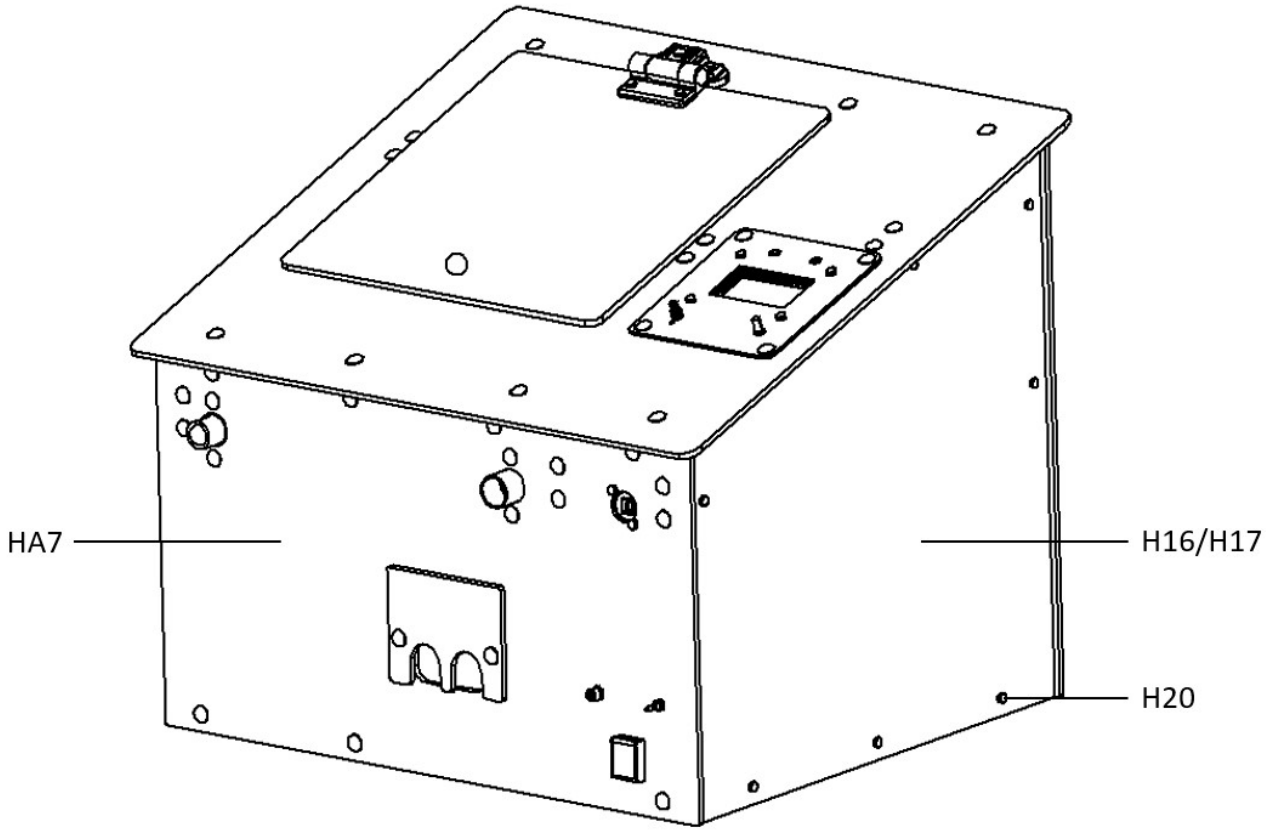

Figure 19: Mount Left and Right Side Panel to Main Assembly

3.9 HA9. Membrane Adapter Assembly

For this assembly the following parts are needed: H47, H48, H49 and a piece of rubber like material. The material tested is a piece of a surgical balloon like the oxygen reservoir.

1. Put the pieces together as shown in figure 20. The balloon piece needs to cover the whole opening of the H47 MembraneAdapter.

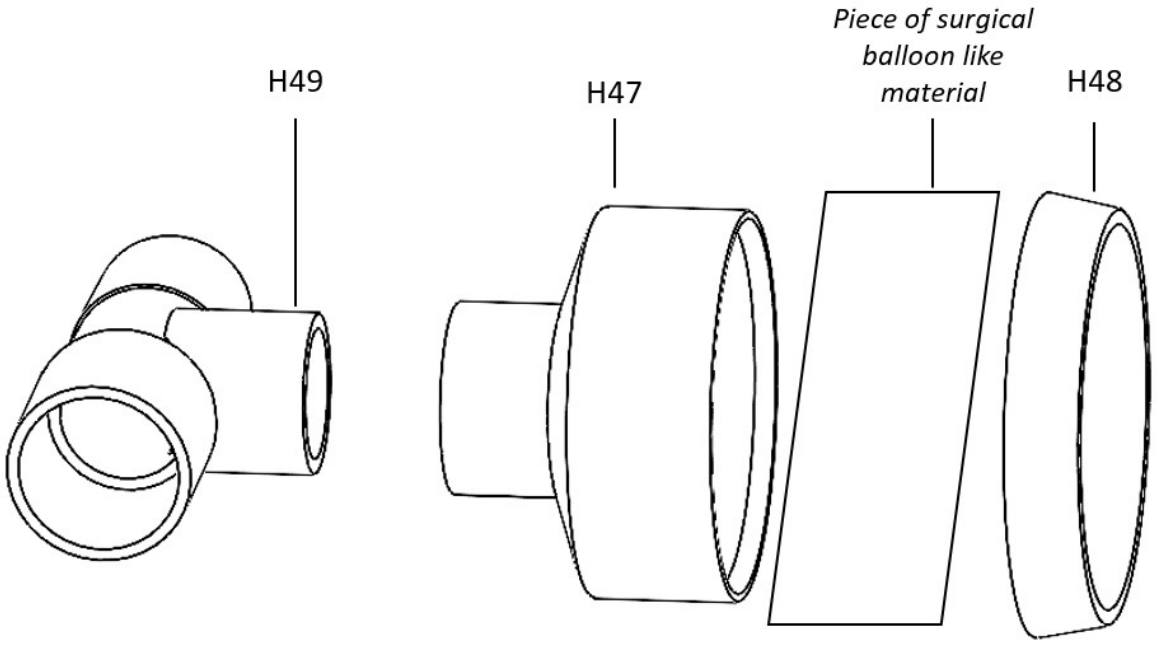

Figure 20: Assembly of Membrane Adapter

3.10 HA10. Mount Membrane Adapter, HEPA filter and PEEP Valve

For this assembly the following parts are needed: HA8, HA9, H45 and H46.

1. Place the H45 PEEP valve and the H46 HEPA filter as shown in figure 21.
2. Place the HA9 Membrane adapter inside the ventilator. It is on the other side of the Front Plate as the PEEP valve as shown in the figure.

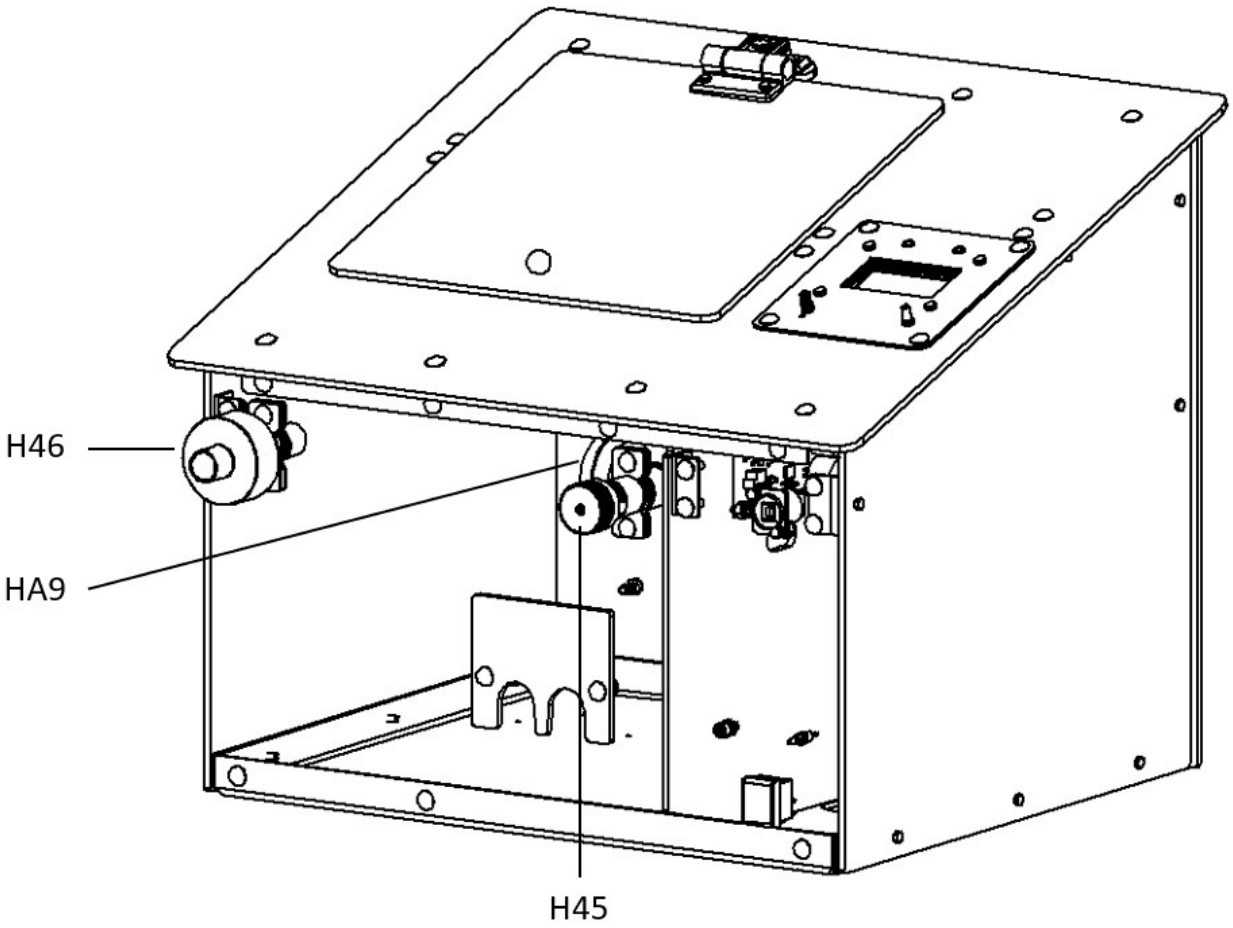

Figure 21: Mounting PEEP valve, HEPA filter and MembraneAdapter. The front is transparent to show the position of the adapter.

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
H50	PI_10Housing_00_00_10StickerFunctionPower	PI.10.00.00.10	1
H51	PI_10Housing_00_00_15StickerLocationPEEP	PI.10.00.00.15	1
H52	PI_10Housing_00_00_14StickerLocationHMEF	PI.10.00.00.14	1
H53	PI_10Housing_00_00_13StickerLocationPatientInO	PI.10.00.00.13	1
H54	PI_10Housing_00_00_09StickerLogoProject	PI.10.00.00.09	1
H55	PI_10Housing_00_00_08StickerWarningBackUp	PI.10.00.00.08	1
H56	PI_10Housing_00_00_12StickerLocationOxygen	PI.10.00.00.12	1

Table 3: Overview of all stickers of the housing sub-assembly

3.11 HA11. Placement of Stickers

This chapter is about the placement of the stickers to the housing. Table 3 gives an overview of the stickers needed.

For this assembly HA10 is needed together with the stickers.

1. Place stickers H50, H51, H52, H53 & H54 on the front plate of assembly HA7 as shown in figure 22.
2. Place sticker H56 on the back plate of assembly HA7 as shown in figure 23.
3. Place sticker H55 on the right side plate of assembly HA7 as shown in figure 24.

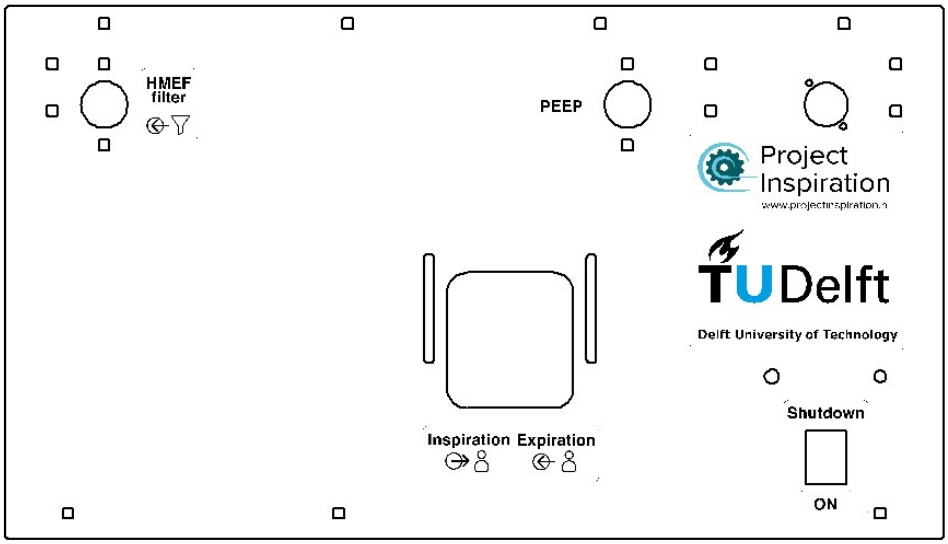

Figure 22: Placement of stickers on Front Plate

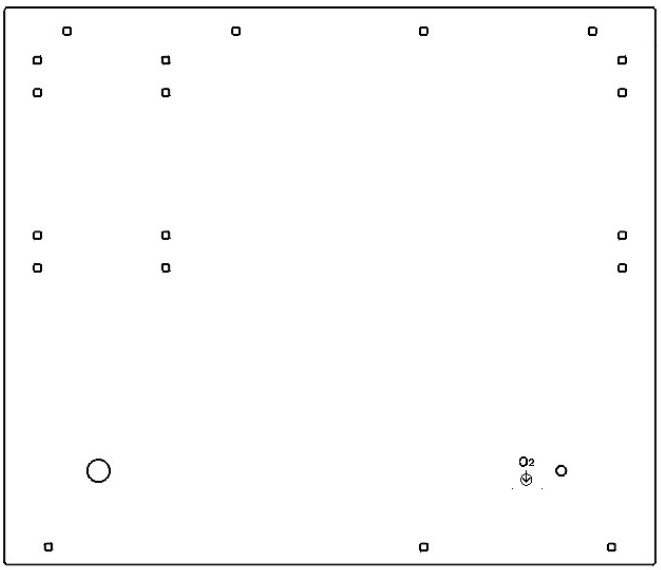

Figure 23: Placement of sticker on Back Plate

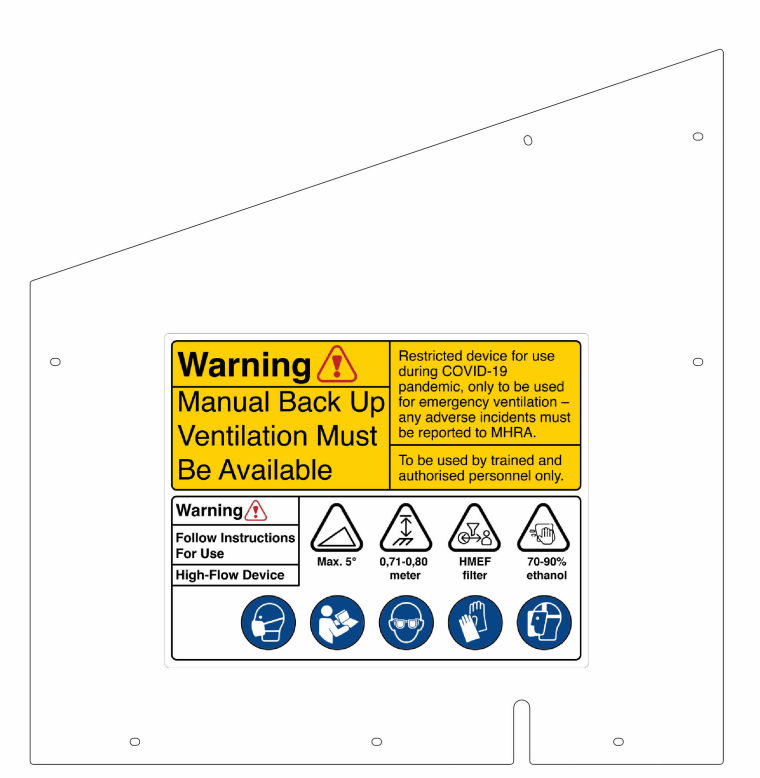

Figure 24: Placement of sticker on the right side plate