

AAU Pandemic Ventilator

USERMANUAL

WARNING

- The AAU Pandemic Ventilator is only to be used if no CE-marked sufficient equipment is available.
- This device is only intended for use on adult patients.
- This device is only intended for invasive mechanical ventilation.
- Using this device is entirely the user's responsibility.

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1 Introduction

1.1 Device description

This section provides a general description of the AAU Pandemic Ventilator .

1.1 Intended use, users, and environment

The AAU Pandemic Ventilator is intended for treating patients with respiratory failure or insufficiency. The AAU Pandemic Ventilator should only be used by professional health care personal trained in using this specific ventilator. The AAU Pandemic Ventilator should only be used in hospital environments and other facilities with the primary purpose of treating respiratory complications. The AAU Pandemic Ventilator can be used for transport between or within health care facilities.

1.1 Disclaimer

The AAU Pandemic Ventilator should only be used when no CE-marked ventilator is available. The AAU Pandemic Ventilator should only be used as described above in section 1.1 and following the instructions provided in this user manual. The AAU Pandemic Ventilator only supports invasive volume control ventilation.

1.2 Warnings

Always conform to the safety guidelines and warnings of this user manual and provided on the ventilator user interface.

1.2 General

Always perform a pre-use check before connecting the ventilator to the patient. Omitting this may result in malfunction and harm to the patient.

Alarms are persistent and should not be omitted. This could seriously harm the patient.

1.2 Mechanical and gases

- Do not open the system. All controls are located at the front via the screen or at the left side (the PEEP valve).
- The system is not intended to be used with any anesthetic agents.
- The gases in the system must conform to the following standards for concentrations of water vapor and oil:
 - Air: $\text{H}_2\text{O} < 7 \text{ g/m}^3$; Oil $< 0.5 \text{ mg/m}^3$
 - Oxygen: $\text{H}_2\text{O} < 20 \text{ mg/m}^3$

1.2 Electrical

- The power cord should be connected only to a properly grounded AC electrical outlet.

1.3 Versions and configurations

These sections describe different available versions of the AAU Pandemic Ventilator system. This manual covers the following versions:

- AAU Pandemic Ventilator volume control

2 System overview

2.1 AAU Pandemic Ventilator

This section describes the overall components of the ventilator. Please refer to Figure 1: AAU Pandemic Ventilator overview. 1: Air and O₂ supply, 2: Power cord, 3: Screen and controls, 4: Inspiratory outlet, 5: Expiratory inlet, 6: PEEP adjustment. The ventilator is intended to be used as seen in the figure but will function positioned in any direction.



Figure 1: AAU Pandemic Ventilator overview. 1: Air and O₂ supply, 2: Power cord, 3: Screen and controls, 4: Inspiratory outlet, 5: Expiratory inlet, 6: PEEP adjustment.

1. Air and O₂ supply
2. Power cable
3. User interface
4. Inspiratory outlet (delivers fresh gas to patient at inspiration)
5. Expiratory inlet (expiratory gas returning from the patient)
6. Adjustment of PEEP and expiratory gas outlet.

2.2 User interface

The user interface consists of a 4-inch screen and 4 analog buttons placed below the screen, see embodiment in Figure 2. The user interface is controlled using the 4 buttons. This allows the user to change settings, measurements, alarms and to switch on and off ventilation.



Figure 2: Example of implementation of the user interface.

2.2 Setting PEEP

The Positive End Expiratory Pressure (PEEP) is adjusted directly on a mechanical valve placed on the left-hand side of the ventilator, whereas all other settings are controlled via the graphical user interface.

After manual PEEP adjustment, wait 1 minute and confirm in display if correct PEEP is measured.

2.3 User interface components

The screen is divided in to 4 areas, seen in Figure 3 and explained below. The right-hand side of the panel (1) and the bottom part (3) are static and always visible to the user. When a menu item or setting is selected, this is marked by a green dot near the item. Navigation is described in the next section, 2.4.

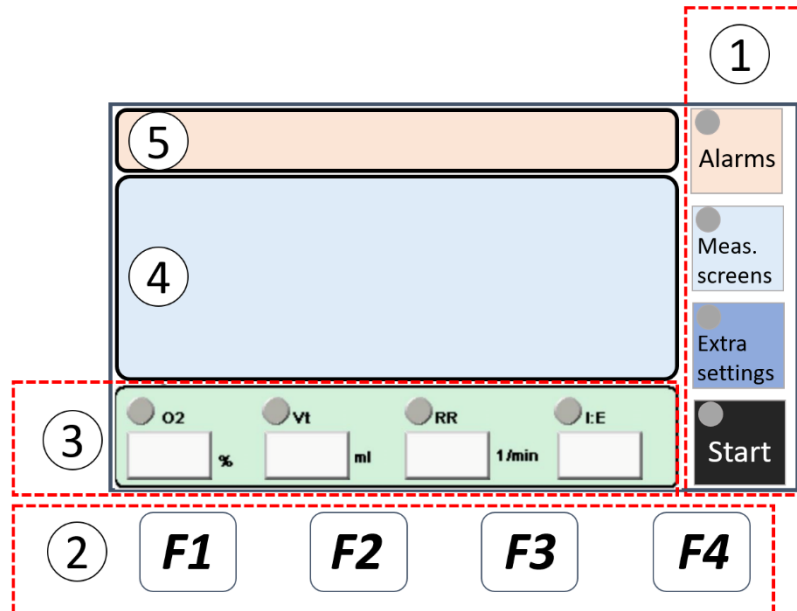






Figure 3: User interface components and buttons for control

1. Navigable menu. The right-hand side of the screen shows which menu item is selected and the available action for the ventilator, based on its status.
 - a. When the ventilator is in stand-by mode, bottom right corner shows 'Start' (as seen in Figure 3 above).
 - b. When the ventilator is turned on and ventilating, bottom right hand corner shows 'Stop' (displays an additional menu where the user needs to confirm this action, see Figure 7.)
2. Analog buttons for navigation. Explained in detail in section 2.4.
3. Ventilator main settings. Displays the current settings for:
 - a. inspired oxygen in percent (%).
 - i. Range 21% to 100% in steps of 10%. Default 40%.
 - b. tidal volume in milliliters (ml).
 - i. Range 250ml to 600ml in steps of 50ml. Default 350ml.
 - c. respiratory rare in times per minute (min-1).
 - i. Range 12 to 35 breath per minute in steps of 1. Default 15.
 - d. I:E ratio.
 - i. Can be changed between 1:2, and 1:3. Default 1:2.
4. Measurement and settings screen. Shows measurements or extra settings depending on selection in the right-hand side menu (#1).
5. Description of and number of alarms.

2.4 Navigating the user interface

The user interface is navigated using the 4 analog buttons below the screen, see Figure 3 number 2. A green indicator light shows which element is active on the screen. In summary, the main functions of the buttons and their icons:

- 
F1: Toggle between main setting (Panel 3, Figure 3). Pressing this button once will at any-time select the last used setting (O₂, inspiratory oxygen at start-up). Additionally, pressing the button cycles through the 4 settings going from left to right, e.g selecting respiratory rate (RR) is achieved by pressing **F1** three times.
- 
F2: Increment (+) in the selected setting. If Vt is chosen and **F2** is pressed, Vt is incremented by 50 ml. This is seen in Figure 4: Increasing tidal volume (Vt) by 50 ml. Left: F1 is pressed twice to select Vt as indicated by the green dot. Right: F2 is pressed once to increase the highlighted setting. Vt increases in steps of 50ml resulting in 400ml..
- 
F3: Decrease (-) the selected setting or activate (Enter) buttons on digital screen.
- 
F4: Toggle between items in digital screen (except main settings which are accessed by **F1**).

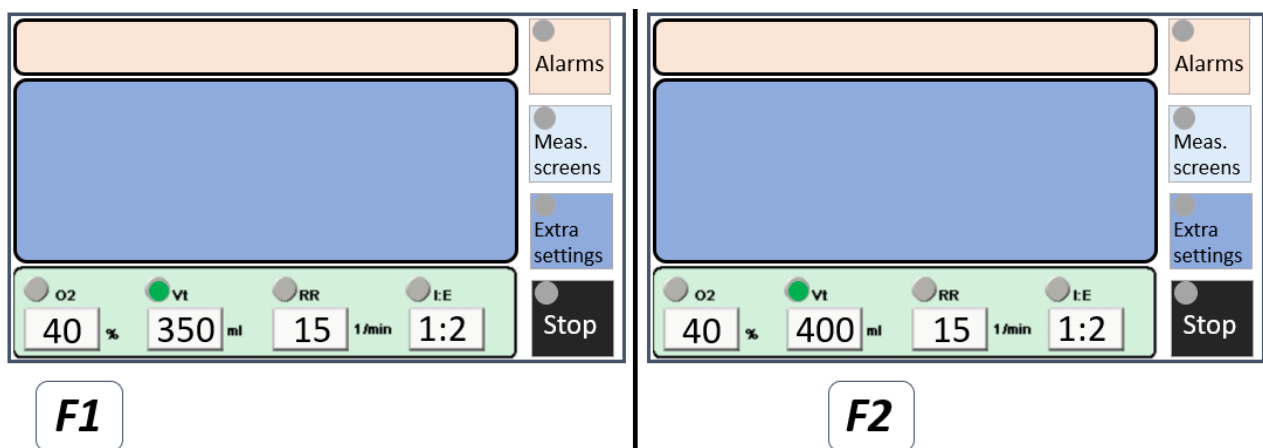


Figure 4: Increasing tidal volume (Vt) by 50 ml. Left: F1 is pressed twice to select Vt as indicated by the green dot. Right: F2 is pressed once to increase the highlighted setting. Vt increases in steps of 50ml resulting in 400ml.

2.4 Accepting changes

After a setting has been changed (as exemplified in Figure 4: Increasing tidal volume (Vt) by 50 ml. Left: F1 is pressed twice to select Vt as indicated by the green dot. Right: F2 is pressed once to increase the

highlighted setting. Vt increases in steps of 50ml resulting in 400ml.) the new setting is automatically adjusted by the ventilator following the next inspiration/expiration cycle. The green indicator light and the ability to adjust settings/select menu items using **F2** or **F3** is turned off after a short time period.

2.5 User interface views

2.5 Measurements

Measurements are shown in the middle of the screen with the possibility to change the view between two different screens. By default, when the ventilator is in standby mode, the first measurement screen is displayed although no values are present.

When ventilation is active, measurements will update following each breath. Using **F4** to navigate the right-hand side menu and selecting Meas. Screens using **F3** will switch between measurement screen 1 and two. The two measurement screens are seen in Figure 5: Measurement screens 1 and 2 during ventilation.

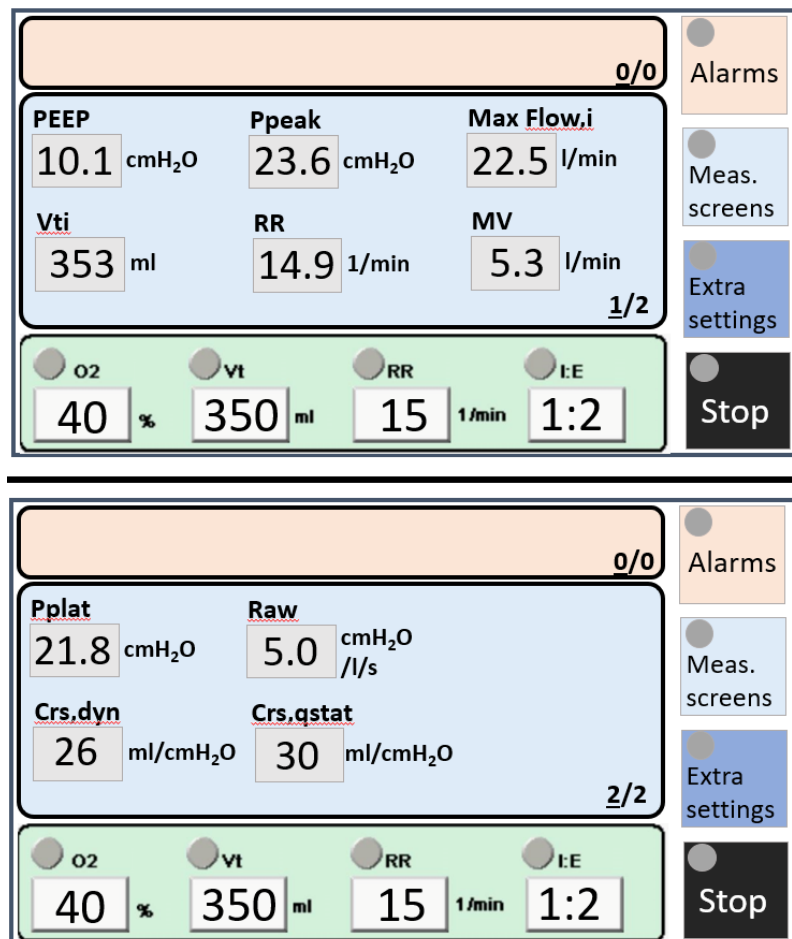


Figure 5: Measurement screens 1 and 2 during ventilation.

All available measurements are described in section 5.1.

2.5 Extra settings

In the extra settings menu, the user has the possibility to adjust additional settings affecting ventilation. Extra settings are seen in Figure 6.

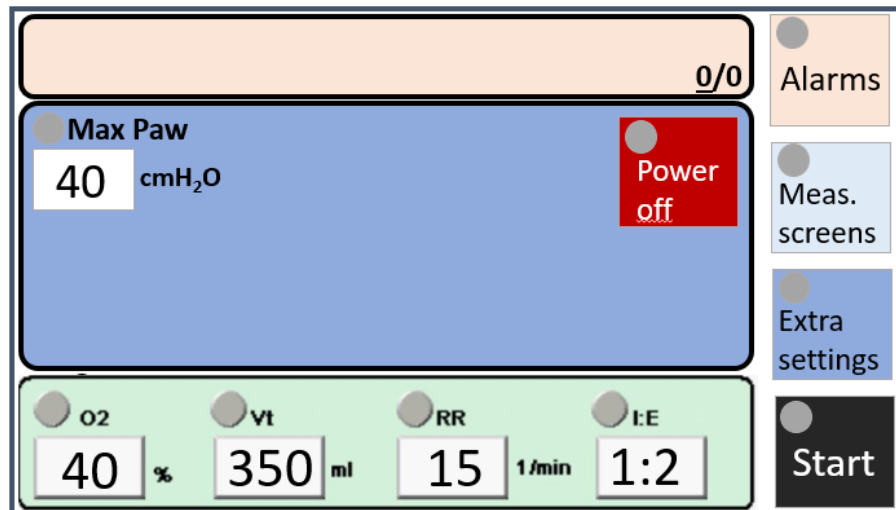


Figure 6: Center of user interface showing Extra settings screen.

2.5 Alarm display

When alarms occur, they are displayed in the top most part of the user interface. When multiple alarms are active, the latest alarm will be displayed. Selecting Alarms in the right-hand side menu allows the user to toggle through active alarms. Alarms are listed and described in section 5.3.

2.5 Termination of ventilation

When the user wishes to terminate ventilation and return to stand-by mode, an additional acknowledgement is required. Upon selecting Stop in the right-hand side menu (Using **F4** and **F3**) a pop-up screen as seen in Figure 7 will be displayed, requiring the user to push **F1** to terminate. This two-stage process is implemented to avoid accidentally terminating ventilation while navigating menus.

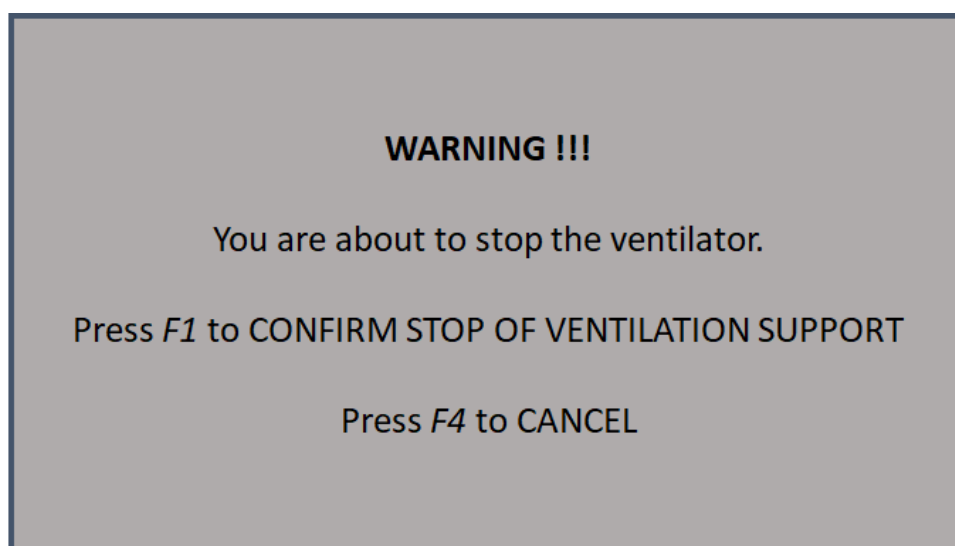


Figure 7: Termination of ventilation is a two-step process which requires the user to confirm the action by pressing F1.

2.6 Respiratory unit

The respiratory unit of the ventilator ensures proper mixing of inspiratory gas, delivery of selected volume, measurements (and control) of pressure and flow, and expiration at elevated pressure (PEEP). A schematic drawing of the main components is shown in Figure 8.

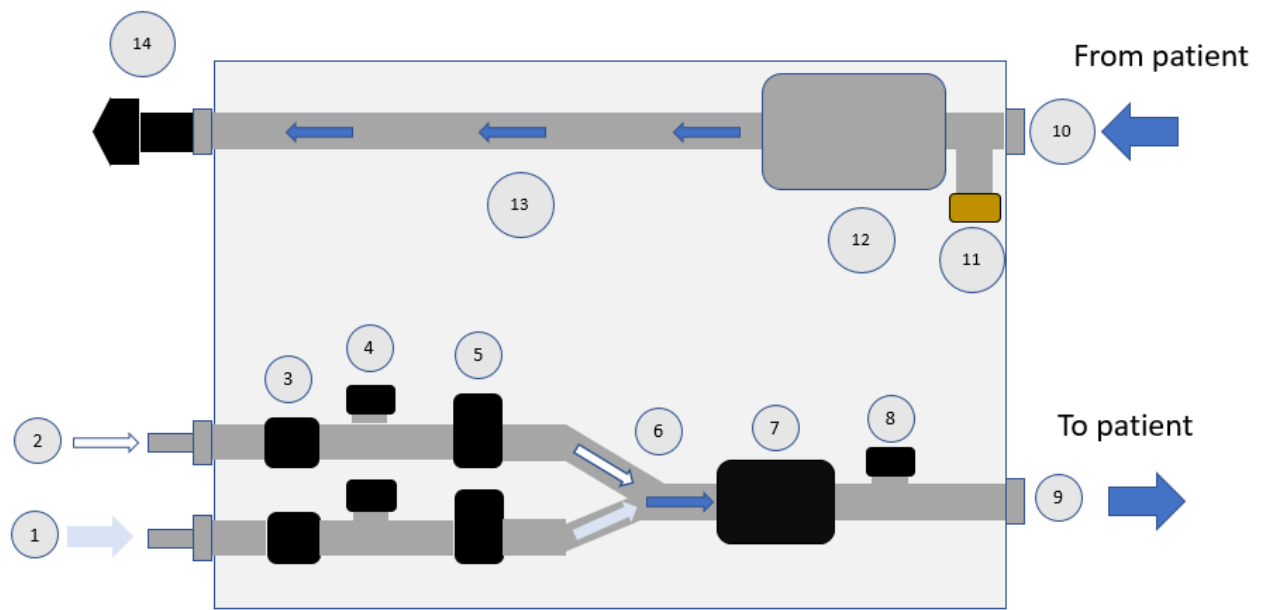


Figure 8: Respiratory unit of the ventilator. 1: Air inlet. 2: O₂ inlet. 3: pressure reduction valves. 4: High pressure sensor. 5: inspiratory valve. 6: Gas mixing manifold. 7: Inspiratory flow tube. 8: Low pressure measurement. 9: Inspiratory port. 10: Expiratory port. 11: Safety relieve valve. 12: Expiratory valve 13: Expiratory gas tube 14: PEEP valve and expiratory gas outlet.

3 Power supply

The ventilator is equipped with an AC power supply than can be operated using either 100-120V or 220-240V, both AC. All internal components and the user-interface screen are supplied by 24V or 5V. A battery pack is installed in the ventilator, allowing continuous use for ≥ 20 minutes.

It is recommended that the ventilator is plugged in to a reliable power source whenever possible as this keeps batteries charged at all times.

3.1 Power supply safety

Whenever the ventilator is turned on (in standby mode or active ventilation) an alarm will sound and display if the main plug is disconnected and the system runs on battery.

Warning: When the ventilator is running on batteries it will eventually shut down as batteries become fully discharged. Make sure a power plug is connected whenever possible.

4 Operating the ventilator

This section describes normal use of the ventilator, including how to connect the ventilator to a patient. Pre-use setup and routine checks are also described.

4.1 Connections and hoses (for technical staff)

All gas connectors and hoses comply with BS EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017 and BS 2050: 1978 Electrical Conductivity.

Warning: Please check that connectors and hoses comply with local requirements.

4.2 Powering on the ventilator

When the ventilator is connected to main power supply, and the on button is pressed, an alarm will sound. This is due to a lag in PLC boot, and the sound will stop after 40 seconds. In these 40 seconds, no values are showed on the screen. This is not a fault and will not affect the functioning of the ventilator.

4.3 Pre-use setup

Before operating the ventilator for the first time, make sure that a proper power cord and plug is installed. This should comply with local standards for electrical equipment.

Oxygen (O₂) and air supply needs proper hosing. By default, 5-metre hoses with special connectors for O₂ and air are installed on the ventilator. Both hoses are for medical grade use and are fixed to the ventilator.

Warning: If hoses for O₂ and air are replaced make sure new ones are attached correctly and that they are not interchangeable. The ventilator will not function correctly if O₂ and air supply is switched. The ventilator is not capable of measuring O₂ fraction and can thus not check if hoses are attached correctly.

4.4 Pre-use check

Every time the system is powered on and before ventilating a patient, it is recommended to run a pre-use check. This is also recommended if the ventilator is swapped to a new patient.

The ventilator will function without running a pre-use check and can be used immediately after power-up. An alarm will indicate if a pre-use check has not been performed. If the last pre-use check was failed the ventilator will not be allowed to start before a new pre-use check has been passed.

The pre-use check includes tests and measurements of:

- O₂ and Air supply pressures
- O₂ and Air flows
- Inspiratory valves

During the pre-use test, the ventilator will ask the user to connect a hose connecting the inspiratory outlet and the expiratory inlet. This allows test and measurement of:

- Internal leakage
- Safety valve
- PEEP value.
- Expiratory valve

If the ventilator detects a hose connecting the inspiratory outlet and the expiratory inlet, a full pre-use check is performed, else only the three first points are tested and measured.

4.4 Initiating Pre-use check

Disclaimer: the pre-use check can be aborted by pressing F2 at certain steps as indicated on the screen.

Connect the ventilator to main power supply

The ventilator turns on

Make sure no filters or hoses are connected to the ventilator

Press F3 to start the pre-use check (supply air pressure)

The pre-use check will iterate through various steps automatically

After this test phase, following reports will appear on the screen:

O2 inlet

O2 flow

Air inlet

Air flow

If reports are not OK– see pre-use check trouble shooting

If all reports are OK, press F3 to continue

Connect test tube from inspiratory port to expiratory port and press F3 continue the pre-use check

Safety valve, leakage and PEEP check will run automatically

If parts of the pre-use check is not OK - see Pre-use check trouble shooting

If all checks are OK, the ventilator is ready for ventilation

4.4 Pre-use check trouble shooting

Alarm text	Action
<i>Please connect to mains to perform pre-use check</i>	Connect the ventilator to main power supply and press F3.
<i>Pre-use check failed! System leakage failure Ventilator not able to generate sufficient pressure to finish pre-use check</i>	Open the lid and check the ventilator for leakage during operation. Contact manufacturer if leakage persists.
<i>Pre-use check failed!</i>	The ventilator is not suitable for ventilation!

<i>Ventilator will not be allowed to start until a pre-use check has been passed or passed with exceptions.</i>	Inspect which report is faulty and if it is not possible to fix the problem, contact the manufacturer.
<i>Pre-use check passed with exceptions. Ventilator will be allowed to start but should be done so with caution as pre-use check resulted in one or more pass with exception results.</i>	The ventilator is suitable for ventilation, but inspection of faulty reports and solutions to the problems should be perused. It is strongly recommended to fix the issues before connecting to a patient.

4.5 Connecting a patient

Before connecting hoses to ventilator and patient make sure that all appropriate filters, HME and water traps are connected.

Connecting the ventilator to a patient requires a standard issue y-hose as seen below in Figure 9.

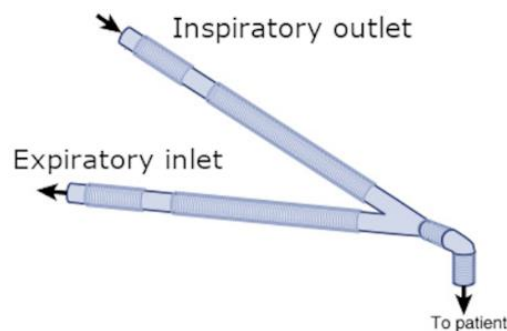


Figure 9: Y-hose connecting ventilator to patient.

Antibacterial filters should be changed on a regular basis and y-hose when a new patient is connected.

Below is a list describing the above:

- Make sure an empty water trap is connected to the expiratory inlet.
- Connect antibacterial filters to respiratory circuit at inspiratory and/or expiratory valve and/or at patient end of y-piece of hose. (In e.g. COVID-19 patients it has been advised to insert a high-efficiency particulate air (HEPA) filter on every oxygenation interface including endotracheal tube and respiratory circuit)
- Connect y-hose to expiratory inlet.
- Connect y-hose to inspiratory outlet
- Optionally, connect Heat-moisture exchanger (HME) at patient end of y-piece of hose. (This has been advised in e.g. COVID-19 patients)
- Connect hose to patient

Warning: All items connected between ventilator and patient, such as hoses, HMEs and filters, are single-use items, and must be replaced between use of the ventilator on different patients.

4.6 Ventilation mode

The ventilator operates in one mode – volume control ventilation (VCV). This is a time-cycled and flow-controlled mode of ventilation for patients with no respiratory drive.

The ventilator does not support patient initiation of ventilation.

Warning: In a patient with respiratory drive intact or recovering, serious patient-ventilator asynchrony may occur. It is therefore important to monitor patient to detect signs of active breathing efforts and sedate as appropriate.

4.7 Breath cycle and flow delivery in VCV

A breath in VCV contains in this order:

1. An inspiratory rise period where flow increases
2. A constant flow period, which with the inspiratory rise period delivers the specified volume
3. An inspiratory pause period with all valves closed
4. A passive expiration period where inspiratory valves are closed and expiratory valve is open

The settings and constants used for defining breath cycle and flow delivery are specified in section 5.2.

4.8 Ventilation startup and management

When the patient is properly connected and appropriate settings are selected, ventilation is started by selecting Start at the user interface. This is seen in Figure 10: Standby mode with Start selected in the right-hand side menu, but before first breath. When Start is selected (using F4) and confirmed (using F3) the ventilator immediately starts ventilation of the patient.

Note: Level of PEEP is not selected using the graphical user interface but needs to be adjusted manually using a mechanical valve at the ventilators left-hand side. For further instructions, see section 2.2 Setting PEEP.

After starting ventilation, the user of the system should always control the level of PEEP measured by the ventilator and assure peak pressure is not too high.

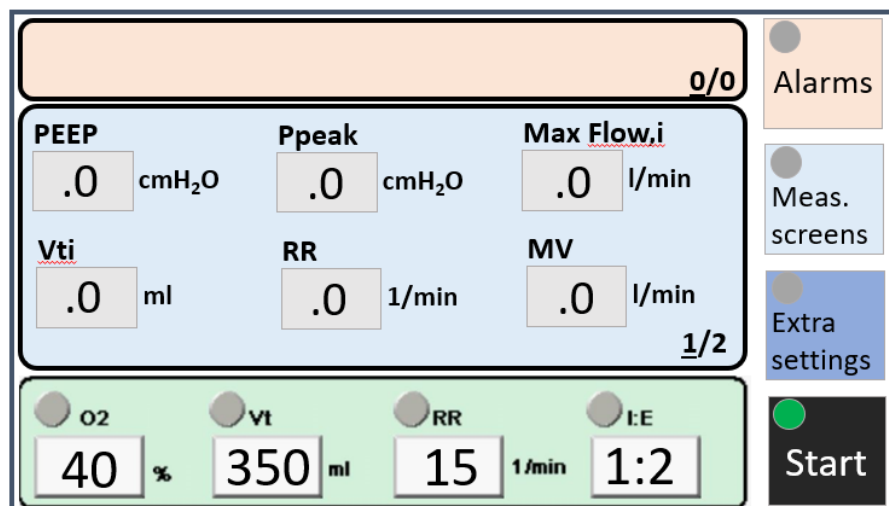


Figure 10: Standby mode with Start selected in the right-hand side menu, but before first breath.

Ventilator settings and constants used for controlling breaths are listed and described in section 5.2.

5 Measurements, settings and alarms

As described earlier, the user interface displays measurements, settings and alarms which can be navigated, selected and changed using the buttons **F1** to **F4**. This section describes the available measurements, settings and correspondent alarms.

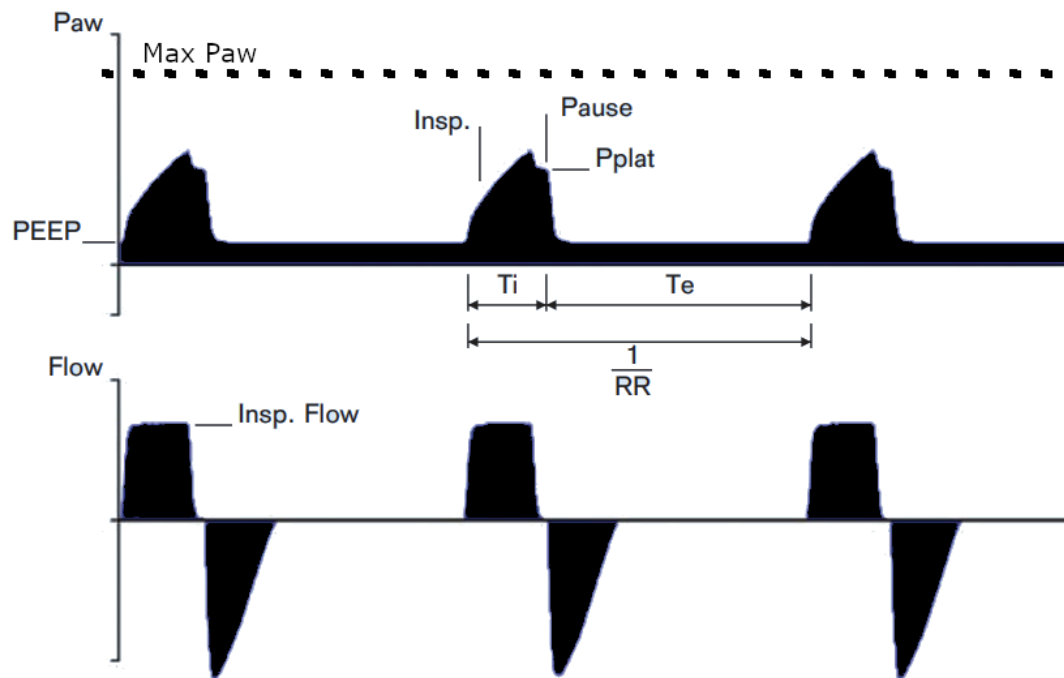


Figure 11: Pressure and flow profiles with specific measurements marked.

5.1 Setting Max Paw

Navigate to extra settings by using F4 until green indicator light is present in Max Paw. Press F2 or F3 to change maximal airway pressure.

5.2 Measurements

All measurements are presented as 1 min average of breath-by-breath measurements. See figure 10 for specification of some of these measurements during the respiratory cycle.

Value	Acronym	unit	Explanation
Positive end-expiratory pressure	PEEP	cm H ₂ O	Pressure at end-expiration preceding inspiration
Peak inspiratory pressure	Ppeak	cm H ₂ O	Highest pressure during inspiration
Maximum inspiratory flow	Max Flow _i	l/min	The maximum inspiratory flow during inspiration.
Inspiratory tidal volume	V _{ti}	ml	The actual delivered volume during inspiration
Respiratory rate	RR	1/min	The actual achieved respiratory rate
Minute ventilation	MV	l/min	The volume of gas delivered to the patient per minute (RR*V _{ti})

Dynamic compliance of respiratory system	Crs,dyn	ml/ cm H ₂ O	The compliance of the respiratory system during inspiration with flow, as measured at the inspiratory valve of the ventilator ($C_{rs,dyn} = V_{ti}/(P_{peak}-PEEP)$).
Plateau pressure	Pplat	cm H ₂ O	The plateau pressure measured at no flow during inspiratory pause, as measured at the inspiratory valve of the ventilator. NOTE: requires inspiratory pause, which is always included in VCV
Quasistatic compliance of respiratory system	Crs,qstat	ml/ cm H ₂ O	The quasistatic compliance of the respiratory system during inspiratory pause, as measured at the inspiratory valve of the ventilator ($C_{rs,qstat} = V_{ti}/(P_{plat}-PEEP)$). NOTE: requires inspiratory pause, which is always included in VCV
Airway resistance	Raw	cm H ₂ O/ l/s	The resistance of the airways ($R_{aw} = (P_{peak}-P_{plat}) / (Max\ Flow_{i/60})$). NOTE: requires inspiratory pause, which is always included in VCV.

5.3 Settings and constants

This section describes the settings available in the user interface and constants used for determining breath cycles.

Settings on user interface:

Main settings	Default [range]	Step	unit	Description
O ₂	40 [21-100]	10	%	Percentage of oxygen in inspired gas.
V _t	350 [250 – 600]	50	ml	Volume provided to patient in each breath
RR	15 [12-35]	1	1/min	Number of breaths per minute.
I:E	1:2 [1:2, 1:3]	-	-	Inspiratory to expiratory ratio. E.g. an I:E of 1:2 means expiration is twice the duration of inspiration, i.e. inspiratory time = 1/3 of total breath duration.
Additional settings	Default [range]	Step	unit	Description
Max Paw	35 [15-70]	5	Cm H ₂ O	Software pressure release and alarm limit. If inspiratory pressure > this limit, the expiratory valve will open until airway pressure < limit and an alarm will be given.

Constants included in determining breath cycle and delivery of gas:

Constant	Value	Unit	Description
Inspiratory rise time	5	%	Percentage of total breath duration where flow is increasing up to required constant flow to deliver the volume specified by set V _t . E.g. for a RR of 15 1/min, breath duration is 4 s, giving an inspiratory rise time of 0.2 s.
Inspiratory pause time	10	%	Percentage of total breath duration where all valves are closed for flow of 0 L/min at end of inspiration. E.g. for a RR

			of 15 1/min, breath duration is 4 s, with an inspiratory pause of 0.4 s. At an I:E of 1:2, inspiratory time for RR=15 1/min is 1.33 s meaning that $1.33 - 0.4 = 0.93$ s remain for rise and constant flow delivery.
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5.4 Alarms

5.4 Gas failure alarm

If wall O₂ or air pressure drops or increases above safe range an alarm will sound and alarm text will appear on alarm screen.

Warning: if “gas failure alarm” appear, ventilation might stop and cause harm or death to the patient. Check that all hoses and connectors are correctly attached and pressure range on wall air and O₂ manometers.

5.4 Electrical supply failure alarm

If electrical supply fails (i.e. power cut or the power cord is pulled from the wall) an alarm will sound and alarm text will appear on alarm screen.

Warning: If “electrical failure alarm” appears, ventilation might stop and cause harm or death to the patient.

The ventilator will by default continue running of battery. When the ventilator is running on batteries it will eventually shut down as batteries become fully discharged. Make sure a power plug is connected whenever possible.

5.4 Switch off in mandatory ventilation alarm

Whenever the ventilator is turned off during active ventilation an alarm will sound and alarm text will appear on alarm screen.

Warning: If “electrical failure alarm” appears, ventilation might stop and cause harm or death to the patient.

The ventilator will by default continue running of battery. When the ventilator is running on batteries it will eventually shut down as batteries become fully discharged. Make sure a power plug is connected whenever possible.

5.4 High inspiratory pressure alarm

If inspiratory pressure exceeds that specified by the user, an alarm will sound and alarm text will appear on alarm screen.

Warning: If “high inspiratory pressure alarm” appears, the patient is in risk of lung injury or death.

Immediately turn down the tidal volume and or PEEP valve and review if the alarm disappears. If not, switch the patient to another ventilator.

5.4 Low inspiratory pressure and/or PEEP alarm

If inspiratory pressure or PEEP is lower that specified by the user, an alarm will sound and alarm text will appear on alarm screen.

Warning: If “low inspiratory pressure alarm” appears, the patient is in risk of hypoxemia or death.

Immediately turn up the tidal volume and or PEEP valve and review if the alarm disappears. If not, switch the patient to another ventilator.

5.4 Tidal volume alarm

If tidal volume is lower or higher that specified by the user, an alarm will sound and alarm text will appear on alarm screen.

Warning: If “tidal volume alarm” appears, the patient is in risk of hypoxemia, barotrauma or death.

Immediately adjust the tidal volume accordingly and review if the alarm disappears. If not, switch the patient to another ventilator.

5.4 Battery discharge alarm

If the battery is discharged an alarm will sound and alarm text will appear on alarm screen.

Warning: If “battery discharge alarm” appears, ventilation might stop and cause harm or death to the patient.

When the ventilator is running on batteries it will eventually shut down as batteries become fully discharged. Make sure a power plug is connected whenever possible.

5.4 Shut down alarm

Whenever the ventilator is turned off during active ventilation an alarm will sound and a pop-up screen will appear to verify shut down.

Warning: If “shut down alarm” appears, ventilation might stop and cause harm or death to the patient.

The ventilator will by default continue running of battery. When the ventilator is running on batteries it will eventually shut down as batteries become fully discharged. Make sure a power plug is connected whenever possible

5.4 Tidal volume and RR mismatch alarm

If a mismatch occur between tidal volume and RR , an alarm will sound and alarm text will appear on alarm screen.

Warning: If “tidal volume and RR mismatch alarm” appears, the patient is in risk of hypoxemia, barotrauma or death.

Immediately adjust the tidal volume and/or RR accordingly and review if the alarm disappears. If not, switch the patient to another ventilator.

5.4 High peak and plateau pressure alarm

If peak pressure or plateau pressure is higher that specified by the user, an alarm will sound and alarm text will appear on alarm screen.

Warning: If “high peak and plateau pressure alarm” appears, the patient is in risk of barotrauma or death.

Immediately adjust the tidal volume and/or PEEP accordingly and review if the alarm disappears. If not, switch the patient to another ventilator.

6 Cleaning

All external surfaces must be wiped and cleaned with standard cleaning agent between each patient use. To ensure proper cleaning, detach all single use items and clean connectors etc.

The PEEP valve must be detached, disassembled into 3 parts and cleaned in hot soap water, before put in to new use.

7 Specifications

Intended use	Volume control ventilation
Weight	18 kg
Size	400 x 400 x 200 mm
Operating flows	0-100 l/min
Operating pressures	0-70 cmH ₂ O
Operating tidal volumes	0.25-0.6 l (steps of 50 ml)
PEEP	Mechanical adjustable: 2.5-20 cmH ₂ O
Electronically safety relief pressure	35 cmH ₂ O
Mechanical safety relief pressure	80-100 cmH ₂ O
FiO ₂	21%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100%