COVIDAIR

Non-invasive ventilation device developed in the context of the global COVID-19 pandemic

Reference Manual

⚠ WARNING

• The COVIDAIR device must always be used under the supervision of a doctor or a member of the medical profession trained in ventilation

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1. Introduction

The COVIDAIR device provides mechanical ventilation to patients who are not dependent on a ventilator. It delivers pressure ventilation through a leakage circuit and is compatible with a whole range of accessories designed to meet specific applications.
The information in this guide applies to the COVIDAIR device.

⚠ WARNING

- Read the entire manual before using the COVIDAIR.
- Use COVIDAIR only as directed by your doctor or healthcare provider.
- Use COVIDAIR only for its intended use as described in this manual. The advice given in this manual does not replace the instructions of the attending doctor.
- Install and configure the COVIDAIR device according to the instructions provided in this guide.

1.1. Indication of use

The COVIDAIR device provides continuous or intermittent ventilation to patients who weigh more than 30 kg requiring mechanical ventilation. The COVIDAIR device is designed for use in hospitals / healthcare facilities and at home; it can only be used for non-invasive ventilation.

⚠ WARNING

COVIDAIR device is not intended for use as an emergency ventilator

1.2. Contraindications

The COVIDAIR device is contraindicated in patients with the following pre-existing conditions:
- Pneumothorax or pneumomediastinum
- Pathologic hypotension, especially if associated with intravascular volume depletion
- Leaking cerebrospinal fluid, recent head trauma, or head surgery
- Severe bulbar lung disease
- Dehydration

1.3. Side effects

Patients should tell their doctor if they experience unusual chest pain, severe headache, or increased dyspnea. The following side effects may occur during treatment with the device:
- Dry nose, mouth or throat
- Nose bleeds
- Bloating
- Discomfort in the ear or sinuses
- Eye irritation
- Skin rash

1.4. General warnings and precautions

The following warnings and cautions are general. Other warnings, cautions and specific notes are given in the manual alongside the instructions to which they relate. A warning warns you of the risk of injury.

⚠ WARNINGS

• Stop using the device and call your healthcare provider if you experience any unexplained changes in function, unusual or harsh noises, or if the device or power supply is dropped or mishandled.
• Ventilator dependent patients should always have auxiliary ventilation equipment such as a back-up ventilator, manual resuscitator, or similar device available. Failure to comply with this instruction may cause injury to the patient, or even death.
• The COVIDAIR device is a limited-use medical device intended for use by suitably qualified and trained personnel under the direction of a physician. Clinical supervision is required in the critical / intensive care unit.
• Ventilated patients should be monitored continuously by trained personnel or caregivers. These personnel and caregivers must be able to take the necessary corrective actions in the event of an alarm or ventilator failure.
• The COVIDAIR device is not intended for use by persons (including children) with impaired physical, sensory or mental capacities without the proper supervision of a person responsible for the safety of the patient.
• The COVIDAIR device is not intended for use by patients unless a person responsible for patient safety has given them adequate instructions on the operation of the device.
• The COVIDAIR machine should not be used near an MRI machine.
• The effectiveness of ventilation and alarms should be checked, including after any change to ventilation and alarm settings, after any change in circuit configuration, or after a change in concomitant therapy (eg, nebulization, oxygen flow).
• The COVIDAIR device and the AC power supply may become hot during operation. To avoid possible skin damage, do not leave the COVIDAIR device or the AC power supply in direct contact with the patient for an extended period of time.
• The device is not designed for ventilator-dependent patients. The ventilation mode, type of circuit and alarm strategies should be selected after clinical assessment of the needs of each patient.
• The device must not be used outside the temperature range of 15 to 35 ° C.
• To reduce the likelihood of the fan being unplugged and to avoid undesirable fan performance, use only accessories that are compatible with the fan. Compatibility is determined by reviewing these instructions for using the ventilator or accessories.
• The COVIDAIR device does not contain a battery. If you are unsure of the power supply, please use an additional uninterruptible power supply (UPS)

⚠ WARNING

• Repairs and maintenance of the device should be carried out by an authorized technician only.
• The temperature of the respiratory air flow produced by this device can be a maximum of 6 ºC above the ambient temperature of the room. Special care should be taken when the ambient temperature is above 35 ° C.
• Ne pas exposer l'appareil à des forces excessives, des chutes ou des vibrations

A **note** informs you about specific characteristics of the product.

Note :
• For assistance and to report problems associated with the COVIDAIR device, contact your health care provider or authorized reseller.

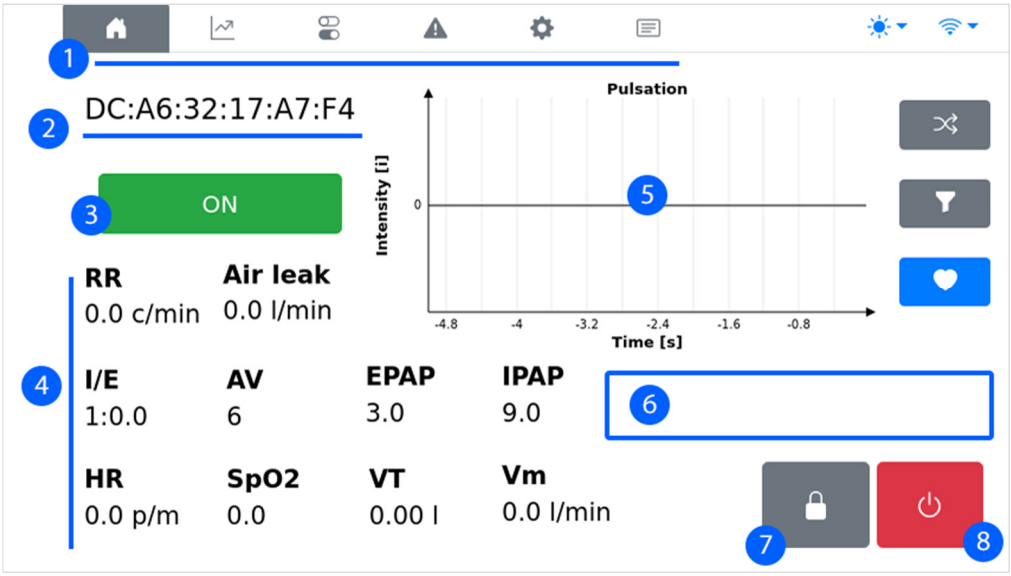
2. Description

The following images describe the components of the COVIDAIR S/T device.

1 Handle
2 Patient Inspiratory port.
3 On / off button.
4 Touchscreen.
5 Humidification system (Option not deliverable)
6 Humidification output port.
7 Humidification input port.
8 SpO2 sensor connector.
9 USB connectors (maintenance service only).
10 Ground connector.
11 Power connector.
12 Low flow oxygen inlet and inlet filter.
13 Nameplate.

2.1. COVIDAIR interface and Touch screen

The COVIDAIR device interface includes several features, which are described in the following image.



1. The upper tabs provide access to the various menus described later in this document.
2. Unique identification number of the COVIDAIR device.
3. Ventilation start and stop button.
4. Display of main machine and patient parameters.
5. Graphic area to display the flow, pressure or heart rate.
6. Display area for the various device messages.
7. Screen lock button
8. Device shutdown button.

3. Modes of operation

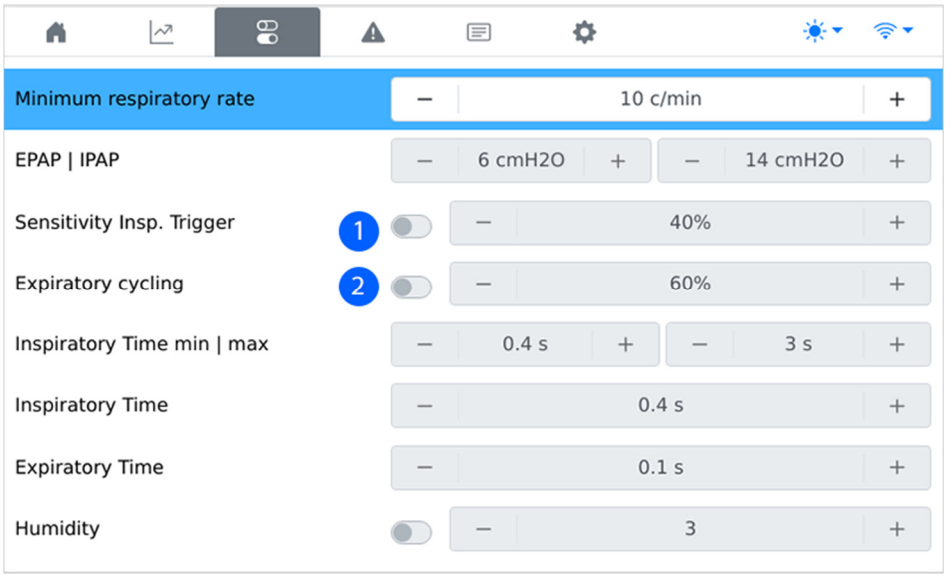
The COVIDAIR device provides pressure-controlled ventilation to patients requiring non-invasive ventilation. Pressure-controlled ventilation delivers the prescribed pressure to the patient in accordance with the settings for respiratory rate and inspiration time. This means that each breath is controlled so that a prescribed level of pressure is delivered to the patient.
The device delivers assistance at two pressure levels. An IPAP is delivered during inspiration and a lower EPAP is delivered during expiration.

3.1. Types of breathing

The three applicable breathing types are assisted breathing, compulsory breathing, and spontaneous / timed breathing (S / T)

3.1.1. Mandatory breathing

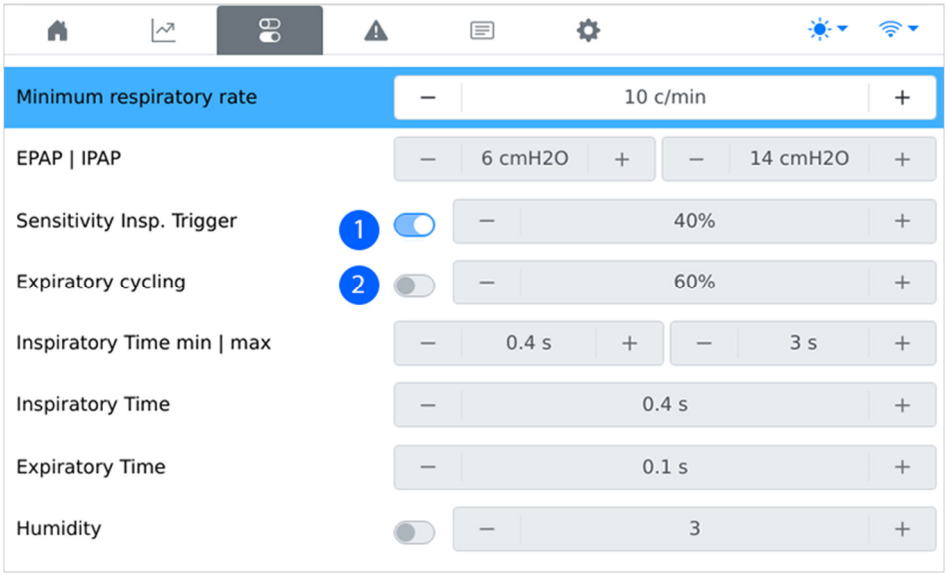
Mandatory (or device-triggered) breathing is breathing that is fully controlled by the ventilator. The ventilator controls both the start and the end of the inspiratory phase. For this mode to be active, the trigger sensitivity (1) and expiratory cycling (2) sliders must be OFF:



See chapter "4.6.3 Parameter screen" for details of display and settings.

3.1.2. Assisted breathing

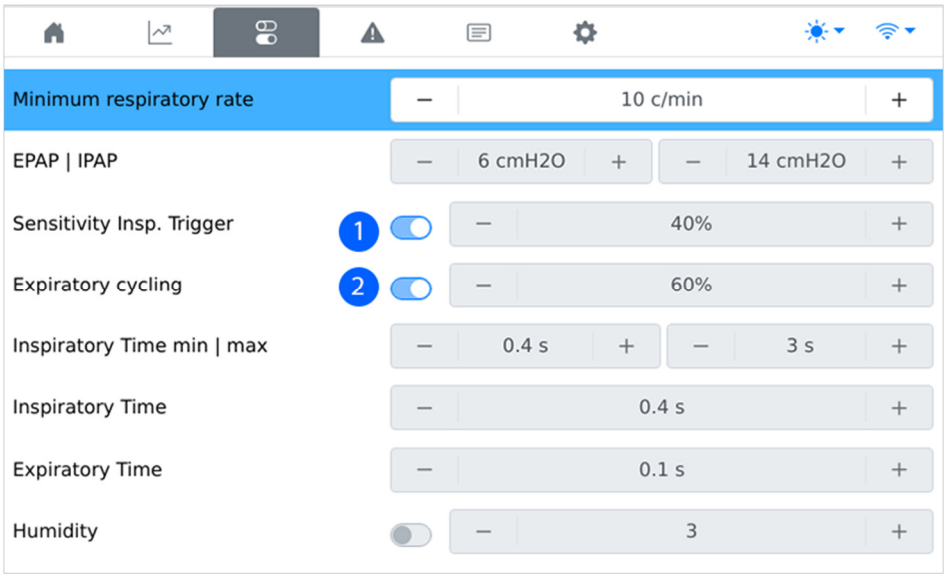
Assisted breathing is breathing controlled by both the patient and the ventilator. Breaths are triggered by patient effort and the air supply is controlled by the current pressure settings. Pressure assisted breathing delivers the prescribed inspiratory pressure. The breaths end when the inspiratory time setting is reached. For this mode to be active, the trigger sensitivity sliders (1) must be ON and the expiratory cycling slider (2) must be OFF:



See chapter "4.6.3 Parameters screen" for details of the display and settings.

3.1.3. Spontaneous / Timed Mode (S / T)

In Spontaneous / Timed (S / T) mode, the device delivers spontaneous breaths and mandatory breaths. Compulsory breathing is delivered if the patient does not breathe spontaneously at the prescribed respiratory rate setting. This ensures that the patient receives a minimum number of breaths per minute. The duration of spontaneous breathing is determined by the patient's effort. The duration of a forced breath is determined by the minimum inspiratory time setting. For this mode to be active, the trigger sensitivity (1) and expiratory cycling (2) cursors must be ON:



See chapter "4.6.3 Parameter screen" for details of display and settings.

4. Use of the COVIDAIR device

⚠ WARNING

• Do not cover the fan, make sure that the area around the appliance is dry and clean, free of bedding, clothing or other objects that could obstruct the air inlet. Blocking the air inlet can cause injury to the patient.
• Always place the appliance flat in its operating position. Any other position could alter its function and cause injury to the patient.

⚠ CAUTION

• To avoid any risk of damaging the fan, place it on a stable and level surface..
• Make sure the device is protected against water

4.1. Initial use of the COVIDAIR device

When using the COVIDAIR device for the first time, it is recommended to perform a functional test. Performing a functional test ensures that the device is in good working order before starting treatment. You can find information to help you resolve problems in the Troubleshooting section.

⚠ CAUTION

If any of the following checks fail, contact your healthcare provider for assistance.

To perform a functional test:

1. Turn off the device by pressing the power off button on the touchscreen.
2. Check the the device and accessories. Damaged components must not be used
3. Check the configuration of the patient circuit.
4. Check the integrity of the patient circuit (device and accessories not supplied) and check the condition of the connections.
5. Switch on the device and test the alarms

⚠ WARNING

If no alarm is triggered, do not use the ventilator.

6. Check the pulse oximeter sensor (if used).
7. Check the oxygen connection (if used). Check the tubing for damage and leaks. Check the remaining capacity of the oxygen cylinders.

4.2. Switching the device ON

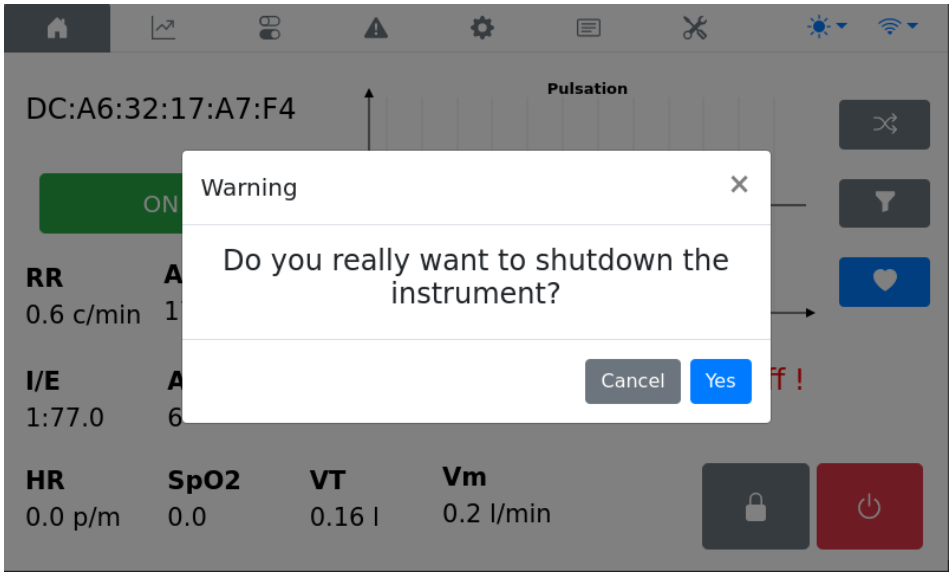
The COVIDAIR device starts up as soon as the external power supply is connected. The push button flashes slowly (1 Hz) to signify that the device has started.

If the device has been switched off displaying the graphical interface and the mains supply has not been disconnected, press the push button to start it again

The device is ready to use when the touch screen displays the main screen. The turbine blows at idle (0.5l/s) to indicate that it is working properly.

4.3. Switching the device OFF

To switch off the COVIDAIR device, press the button  on the main screen. A message will ask for confirmation of the action. The push button flashes quickly (5 Hz) to indicate that the device has switched off.



⚠ WARNING

• Always turn off the COVIDAIR device via the interface before disconnecting the external power supply.

4.4. Start and Stop ventilation

Start and stop via the Touchscreen:

Press the button ON to start ventilation.

➔ The ventilation starts with the parameters saved in the "Parameters" and "Alarms" tabs.

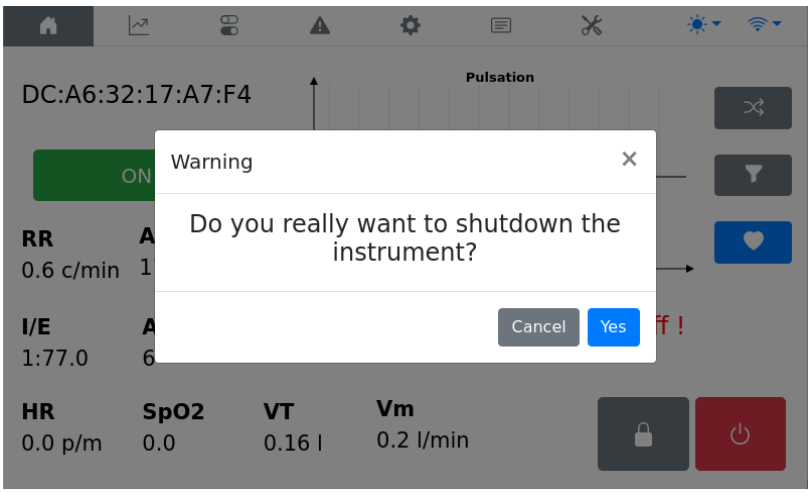
➔ The message "Ventilation activated" is displayed and the main button flashes each time the patient breathes.

Press the button OFF to stop the ventilation, a message then asks for confirmation of the stop and the message "Ventilation stopped" is displayed.

Start via the main push button:

Press the main push button to start ventilation.
The ventilation starts with the parameters saved in the "Parameters" and "Alarms" tabs.
The message "Ventilation activated" is displayed and the main button flashes each time the patient breathes.
Press the main push button again to stop the ventilation, a message then asks for confirmation of the stop. The message "Ventilation stopped" is displayed.

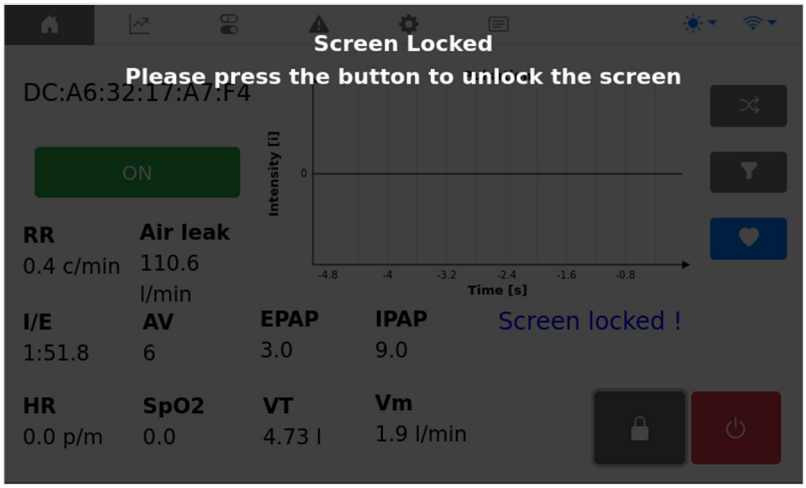
NOTE:
The ventilation start function using the main button works even if the device screen has not yet started. It is therefore possible to start ventilation quickly with the last parameters saved!



4.5. Locking and unlocking the touch screen

It is possible to lock the touch screen to avoid unwanted manipulation. This function is only available from the main screen.

To lock the touch screen, press the padlock button  on the main screen. Once the screen is locked, the following message is displayed:



To unlock the screen, press the main push button.

Note:
Alarms have priority over screen locking. If one of them sounds while the screen is locked, it will unlock and show the alarm in a visible way.

Navigation in menus and settings

Navigation in the page and settings is carried out using the tabs at the top of the display. The tabs are visible in each menu


: Main page (Cockpit)


: Graphic Display page


: Ventilation parameter page


: Alarms page


: Advance parameter page

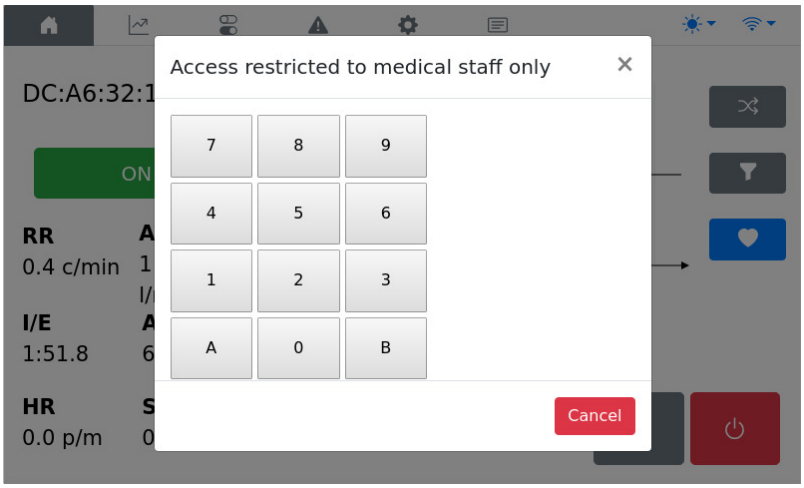

: History page


: Maintenance (Trained user only)


: Brightness setting

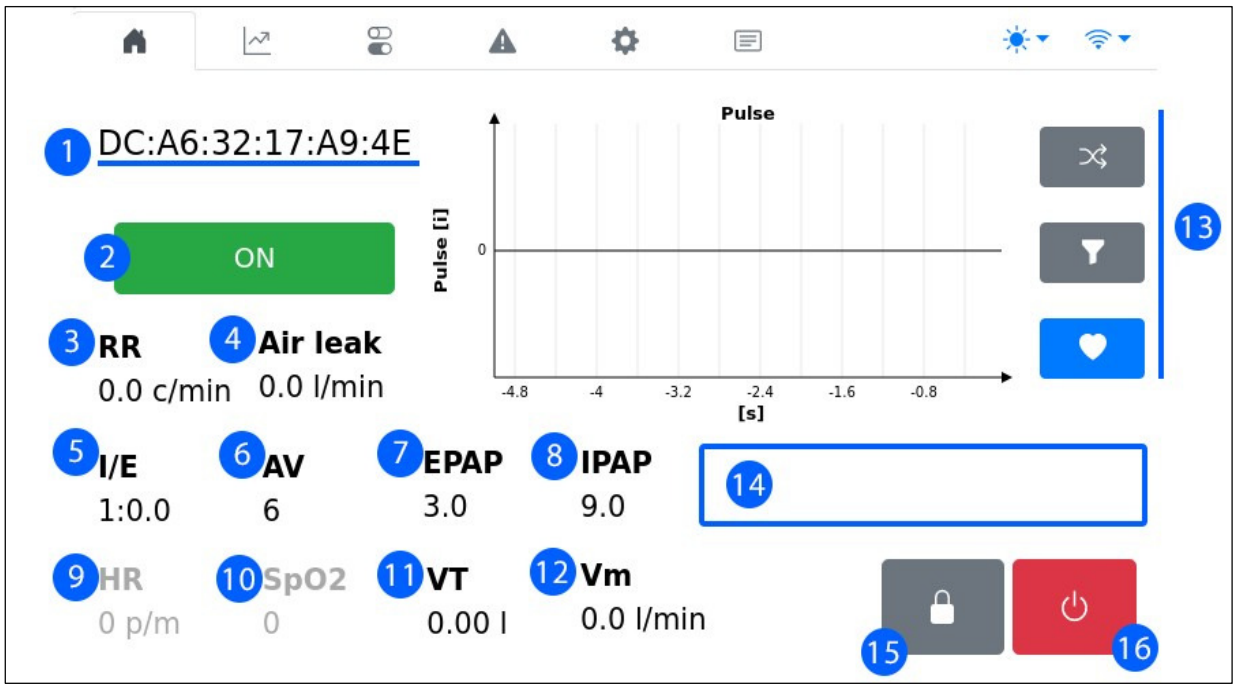

: Network Settings

Some screens are accessible only with a password. In this case, during the selection, the following screen is displayed:



The default password is “0000”. Once entered, the relevant screen is accessible for 5 minutes. As soon as the time has passed, you must re-enter the password.

4.5.1. Cockpit Pagel

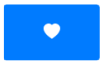


1. Unique identification number of the COVIDAIR device.
2. Ventilation start and stop button.
3. **RR:** Respiratory Rate in cycles per minute
4. **Leak: E**stimated leak in liters per minute.
5. **I/E:** Inspiratory /Expiratory time ratio.
6. **AV:** Inspiration Assist (IPAP-EPAP).
7. **EPAP** or **PEP**: Expiratory Positive Airway Pressure in cmH2O.
8. **IPAP:** Inspiratory Positive Airway Pressure in cmH2O.
9. **HR:** Heart rate indicator in beats per minute (only if the pulse oximeter is used).
10. **SpO_2**: Oxygen saturation indicator in % (only if the pulse oximeter is used). Validity from 90 to 100%
11. **VTt**. Expiratory tidal volume, with leakage correction.
12. **MV:** Current Patient Volume in liters per minute.
13. Graphic area with multiple displays:

The selection of the type of graph is done by a simple press of the buttons listed below:

 Display the flow curve (last 15 seconds)

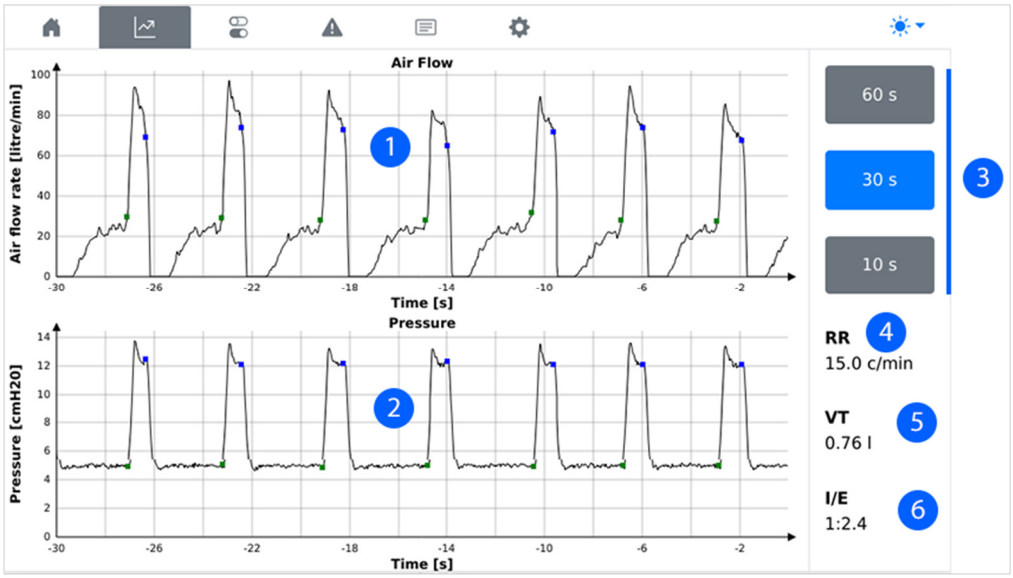
 Display the pressure curve (last 15 seconds)

 Display the heart rate curve, if the pulse oximeter is used (last 5 seconds)

14 Display area for various devices messages.
15 Screen lock button.
16 Device shutdown button.

4.5.2. Graphic page

The graphics display shows real-time pressure airflow graphs.



1. Flow rate in liters per minute.
2. Pressure (Paw) in cmH_2O
3. Time scale. It is also possible to zoom directly on the graphics with two fingers

Displays the 60 last seconds

Displays the last 30 seconds

Displays the last 10 seconds

4. **RR:** Respiratory Rate per minute
5. **VTe**: Expiratory tidal volume, with leakage correction.
6. **I/E**: Inspiratory /Expiratory time ratio

The green point on the graph indicates the time and the trigger level of the trigger. It is related to the "Trigger sensitivity" parameter described in chapter 4.6.3.

The blue dot on the graph indicates the time and level of end of cycle detection. It is related to the "Respiratory cycling" parameter described in chapter 4.6.3.

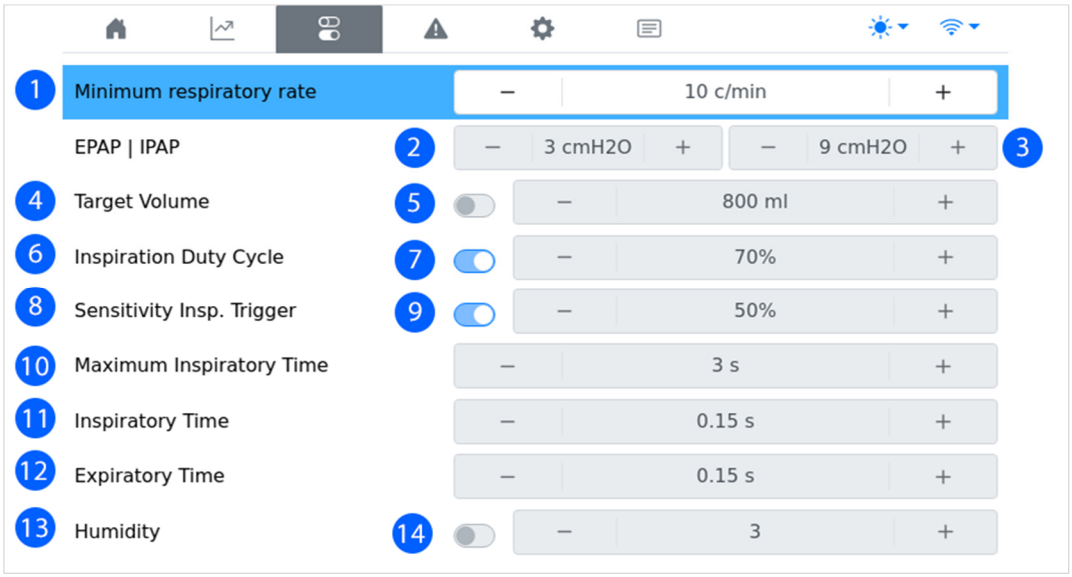
4.5.3. Ventilation Parameter Page

The parameters menu will determine the COVIDAIR ventilation parameters. All parameters can be changed during ventilation. This menu is only accessible with a password. The default password 0000.

WARNING

The adjustment and modification of the parameters must be carried out under the supervision of a doctor or a member of the medical profession trained in ventilation.

The adjustment and modification of the parameters must be carried out under the supervision of a doctor or a member of the medical profession trained in ventilation.



1. Setting the minimum respiratory rate per minute imposed on the patient. The value of the respiratory rate is between 3 and 30 with steps of 1 breath per minute.
2. Adjustment of the EPAP expiratory pressure in cmH_2O. The value of the expiratory pressure is between 2 and 40 cmH_2O it 1 cmH_2O increments, but it cannot be greater than the IPAP value. If IPAP and EPAP are equal the device functions as CPAP.
3. Adjustment of the IPAP inspiratory pressure in cmH_2O.
4. Tidal volume adjustment. WARNING: This value did not take care of leaks. It is not recommended to use this value for ventilation system with leak.
   The tidal volume value is between 200 and 4000 milliliters with 50ml increments.
5. Tidal volume activation slider (see its meaning and use at the end of the chapter)
6. Respiratory Rate adjustment in %. The end of the inspiratory cycle is reached when the flow rate drops to X % of the peak flow rate. This value can be set between 15% and 99% in 1% increments.
7. Respiratory Rate cycling activation slider (see its meaning and use at the end of the chapter)
8. Adjustment of the sensitivity of the inspiratory trigger in%. The higher the %, the more sensitive the trigger. If the trigger is too sensitive (too high) there is a risk of self-trigger.
9. Inspiratory trigger sensitivity activation slider (see its meaning and use at the end of the chapter)
10. Setting the maximum inspiration time in seconds. The value of the inspiration time is between 0.1 and 3 by 0.1s increments

11. Setting the rise time in seconds. The value of the rise time is between 0.1 and 1 in 0.05s increments. A short rise time (< 0.3 seconds) can lead to an overshoot).
12. Setting the drop time in seconds. The value of the descent time is between 0.1 and 1.45 in 0.05s increments.
13. Setting the humidity. The humidity value is between 1 and 5 in 1 increment. Do not use this setting if the humidifier is not used.
14. Humidity activation slider (see its meaning and use at the end of the chapter)

For each setting instruction, the "-" button allows you to decrease the value while the "+" button allows you to increase the value by the indicated steps. It is also possible to let your finger pressed in order to reach the settings faster.

The sliders in front of certain parameters allow you to activate or not the taking into account of the adjusted parameter. A simple press on the cursor changes its value.

When the cursor is ON, the parameter is active

When the cursor is OFF, the parameter is not active..

⚠ CAUTION

If the parameter cursor is OFF, changing the parameter has no influence on the actual ventilation.

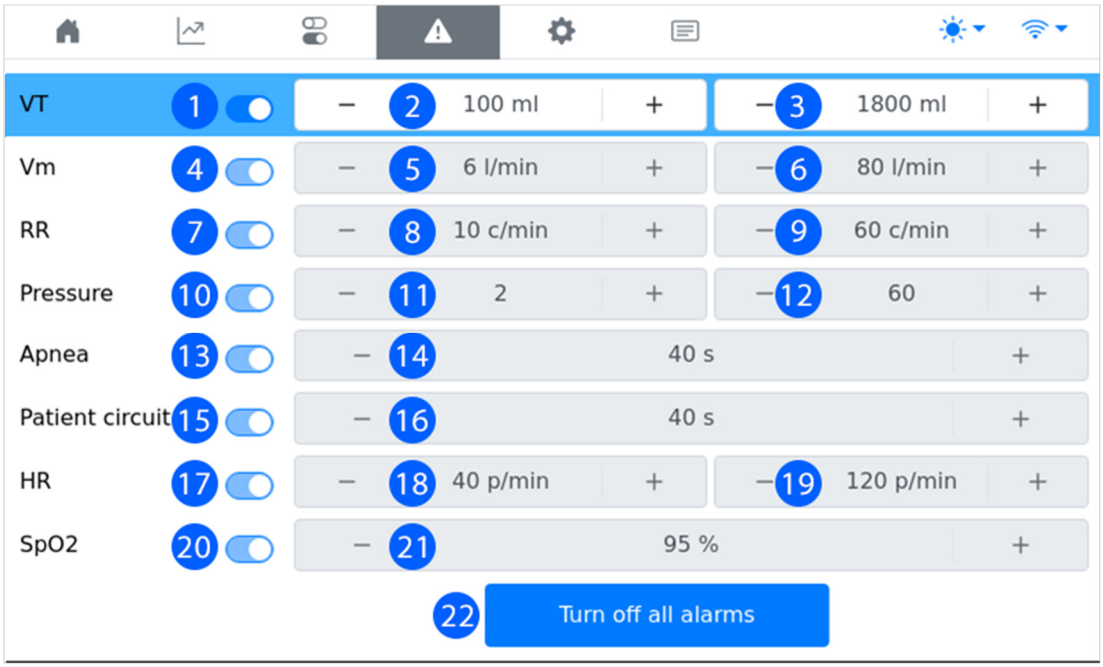
4.5.4. Alarm Page

The “Alarms” page is used to activate or deactivate the alarms, as well as to set the alarm limits. This menu is only accessible with a password. The default password is 0000.

WARNING

The adjustment and modification of alarm parameters must be carried out under the supervision of a doctor or a member of the medical profession trained in ventilation.

Changing an alarm setting is only possible if the row is highlighted. The highlighting is activated by pressing once on the description of the alarm setting you want to change.



1. Activation slider for the "Total expired volume" (VTe) alarm (see its meaning and use at the end of the chapter).
2. Setting the lower limit for the alarm "Total expired volume” (VTe) in milliliters.

The value of the lower limit for "Total expired volume" is between 40 and 1300 by 5ml. increments.

3. Setting the upper limit for the alarm "Total expired volume" (VTe) in milliliters.
4. Activation slider for the "Volume per minute" (MV) alarm (see its meaning and use at the end of the chapter).
5. Setting the low limit for the "Volume per minute" (MV) alarm in liters per minute.

The value of the lower limit for the "Volume per minute" is between 0.2 and 25 by 0.1 l. increments.

6. Setting the upper limit for the "Gaz volume per minute" (MV) alarm in liters.

The upper limit value for "Volume per minute" is between 1 and 99 by 0.1 l/min. increments.

7. Activation slider for the "Respiratory Rate" alarm (RR) (see its meaning and use at the end of the chapter).
8. Setting the lower limit for the " Respiratory Rate " (RR) alarm in cycles per minute.

The value of the lower limit for the " Respiratory Rate " (RR) is between 4 and 52 by 1 cycle/min. increments.

9. Setting the upper limit for the " Respiratory Rate " (RR) alarm in cycles per minute.

The value of the upper limit for the " Respiratory Rate " (RR) is between 40 and 80 by 1 cycle/min. increments.

10. Activation slider for the "Pressure" alarm (Pressure Paw) (see its meaning and use at the end of the chapter).
11. Adjustment of the low limit for the "Pressure". alarm (Pressure Paw) in cmH2O.

Setting the low limit for the "Pressure" alarm (Pressure Paw) in cmH2O.
The value of the low limit for the "Pressure" alarm (Pressure Paw) in cmH2O. The value of the low limit for the " Pressure " alarm is between 0 and 20 by 1 cmH2O increments.
12 Adjustment of the upper limit for the "Pressure". alarm (Pressure Paw) in cmH2O.
The value of the upper limit for the " Pressure alarm " is between 40 and 80 by 1 cmH2O increments.
13. Activation slider for the "Apnea Time" alarm (Apnea) (see its meaning and use at the end of the chapter)
14. Setting the time limit for the "Apnea time" (Apnea) alarm in seconds. The countdown begins after 3 missed respiratory cycles. The limit value for " Apnea time" is between 10 and 60 by 5s increments.
15. Activation slider for the "Allowable leak time" (Leak) alarm (see its meaning and use at the end of the chapter)
16. Setting the time limit for the "Allowable leak time" (Leak) alarm in seconds. The count begins at the start of the leak. The limit value for the "Allowable leakage time" is between 5 and 60 by 5.s increments.
17. Setting the low limit for the "Heart rate" (Fc) in beats per minute alarm, can only be changed if the pulse oximeter is used.
18. The value of the low limit for the "Heart rate" (Fc) is between 40 and 80 by 1 pulse per minute increments.
Setting of the upper limit for the "Heart rate" (Fc) in pulses per minute alarm, which can only be modified if tthe pulse oximeter is used.
The value of the upper limit for the "Heart rate" (Fc) is between 50 and 200 in 1 pulse per minute increments.
19. Activation slider for the "Oxygen saturation" (SpO2) alarm, which can only be modified if the pulse oximeter is used. (see its meaning and use at the end of the chapter)
20. Setting the time limit for the "Oxygen saturation" (SpO2) alarm in percent, only modifiable if the pulse oximeter is used.
21. Setting the time limit for the "Oxygen saturation" (SpO2) alarm in percent, only editable if the pulse oximeter is used.
22. Button for deactivating all alarms. By default, all alarms are enabled. It is possible to deactivate them all with this button. A confirmation message will be requested.
23. Alarm test button. See chapter 8.1.3 "Testing the display and horn" for details of its operation.

For each adjustment setpoint, the "-" button is used to decrement the value and the "+" button is used to increase the value by the steps indicated. The maximum values can be equal to or greater than the minimum values and the minimum values can be equal to or less than the maximum values for a parameter.

The cursors in front of certain parameters enable or disable the taking into account of the parameter set.
A simple press on the cursor changes its value.


The cursor is on ON, the alarm is taken into account.


The cursor is on OFF, the alarm is not taken into account.

Note:
• Alarms take precedence over the screen lock or-any other displayed menus. If one alarm activates, it is displayed in priority.

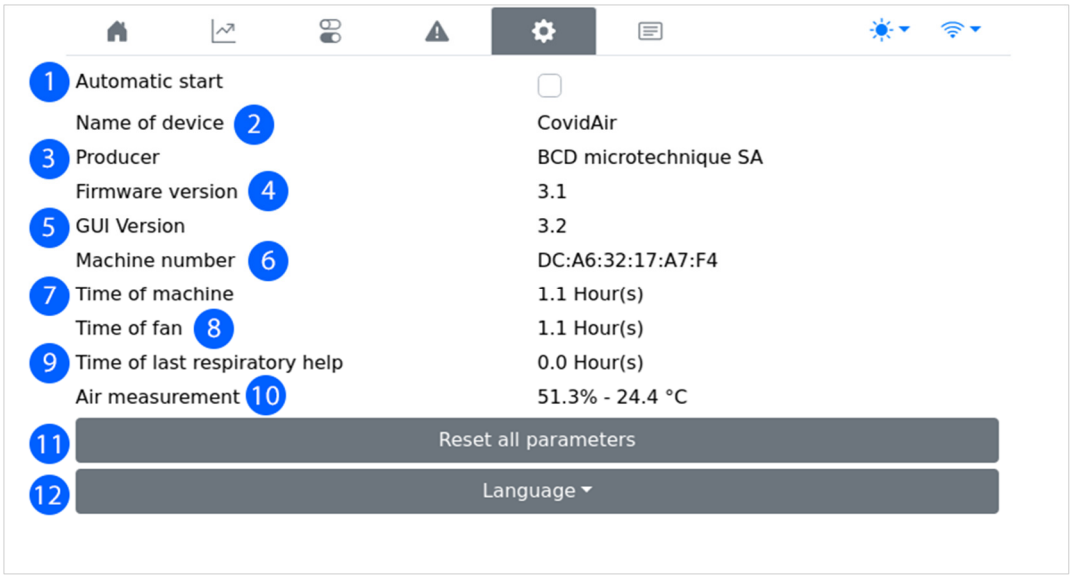
See also the "Alarms" chapter earlier in this document for details on viewing and managing current alarms.

4.5.5. Advance Parameter Page

The menu "Advanced settings" is accessible by password. It contains technical information about the device as well as general configuration parameters. The default password is 0000.

WARNING

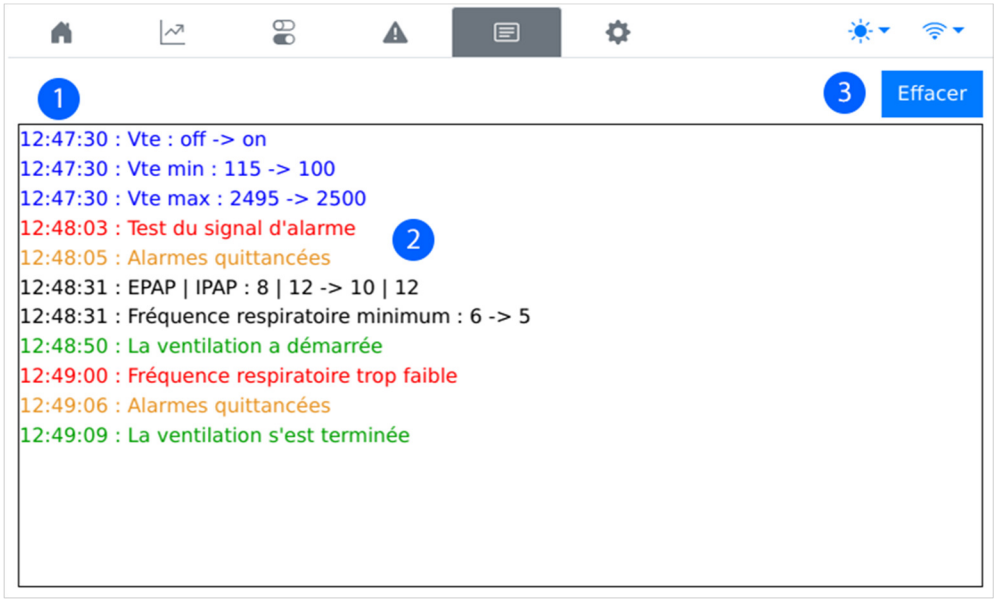
Adjustment and modification of the parameters in this menu must only be carried out under the supervision of an authorized technician.



1. Option to automatically start ventilation at power on.
2. Name of the device
3. Manufacturer
4. Firmware revision
5. Graphic user interface revision
6. Device MAC address
7. Total operating time
8. Total turbine time
9. Last ventilation operating time or time since the last ventilation operating time
10. Air humidity, temperature and atmospheric pressure indicator supplied by the device. The humidity is in % and the temperature is in ° C and the atmospheric pressure is in hPa.
11. Button for resetting the operating and alarms parameters to the default values. (Confirmed action with a nodal box)
12. Language selection.

4.5.6. History Page

The 'History' menu displays the history of events that occurred during each ventilation cycle.



1. Time of triggering of the event.
2. Event type :

In RED :	Alarm
In Orange:	Alarm cleared
In blue:	Alarm setting changed
In black:	Ventilation parameter changed

3. Clear history button. If you want to clear the history, you must press this button. A confirmation message will be requested.

⚠ WARNING

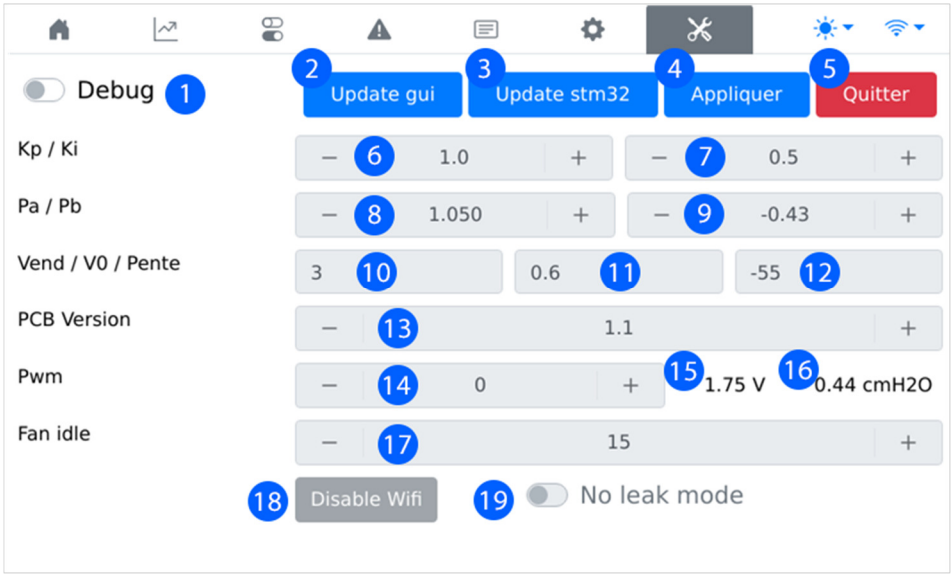
If the device is not connected to a WIFI network, the displayed time corresponds to the length of time that has elapsed since the device was started..

4.5.7. Service page

The maintenance screen is not visible in standard use. You have to press "BCD microtechnique SA" three times in the "Advanced settings" screen for it to appear. It is accessible by password. It displays the device's settings as well as the device's remote update functions. **All the settings in this menu can only be accessed during production of the device and are subsequently deactivated..**

⚠ WARNING

The setting and modification of the parameters in this menu should only be carried out under the supervision of an authorized technician.



1. Activation slider for the "Debug" function (see its meaning and use at the end of the chapter).
   This slider is used to display machine control information in the "History" menu, this is used during production and must remain disabled when used on a patient.
2. Update user interface button
3. Ventilation control system update button
4. Button for applying and saving device settings parameters.
5. Button to exit the menu and remove it from the standard user window
6. Adjustment of the KP of the turbine regulation.
   The value of "KP" is between 0 and 100 with steps of 0.1
7. Adjustment of the KI of the turbine regulation.
   The value of "KP" is between 0 and 100 with steps of 0.1
8. Setting for the "5V" supply voltage in volt.
   The value of "5V" is between 4.5 and 5.5 with steps of 0.05 volt.
9. Setting for the "10V" supply voltage in volts.
   The value of "10V" is between 9.5 and 10.5 with steps of 0.05 volt.
10. Adjustment of the "Vend" parameter for the calibration of the turbine flow rate.
    The value of the “Sell” is between -40 and 60 with steps of 0.001..
11. Adjustment of the "V0" parameter for the calibration of the turbine flow rate.
    The value of “V0” is between -40 and 60 with steps of 0.001.
12. Adjustment of the "Slope" parameter for the calibration of the turbine flow rate.
    The value of the "Slope" is between -40 and 60 with steps of 0.001
13. Adjustment of the "PCB Version" parameter. It allows you to know the material used in the device.

14. Adjustment of the "PWM" parameter of the turbine. It is used during production testing.
15. Flow indicator measured in volts.
16. Flow indicator measured in cmH2O.
17. Fan idle
18. WIFI deactivation button.
19. Leak-free mode engagement.

For each adjustment setpoint, the "-" button is used to decrease the value and the "+" button is used to increase the value by the steps indicated. **All the settings in this menu are accessible during production of the device and are subsequently deactivated.**

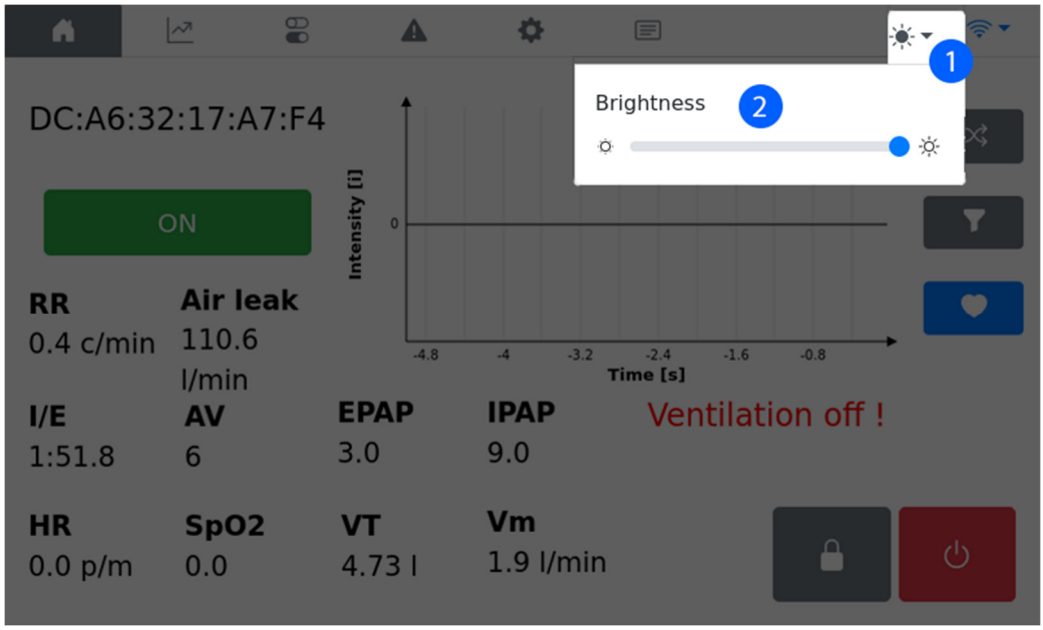
A simple press on the cursor changes its value.

The cursor is on ON, the parameter is taken into account.

The cursor is on OFF, the parameter is not taken into account.

4.5.8. Display Brightness

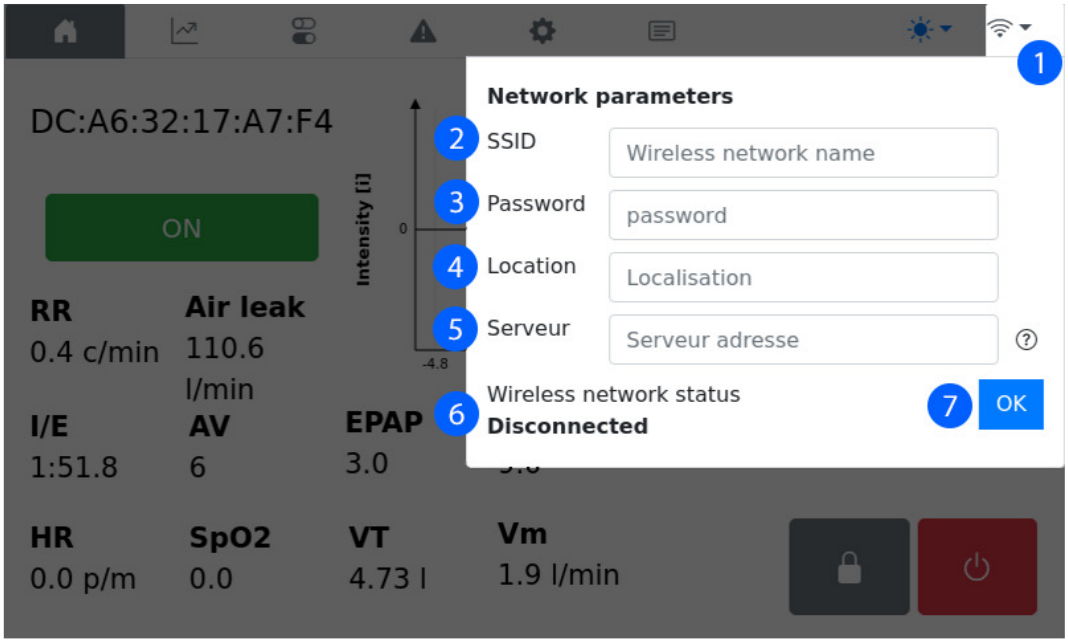
The display brightness is adjustable at all times via the button .



1. The menu opens when the button is pressed. .
2. Slide from left to right in order to adjust the brightness for visual comfort.

4.5.9. Wifi Parameters

Si If connection to the local network is required, the configuration of the WiFi network is done via the button
In order to be able to fill in the parameter's fields, it is necessary to connect a USB keyboard+mouse to the dedicated connector on the back of the device.



1. The menu opens when the button is pressed.
2. **SSID**: Wireless network name
3. Wireless network Password
4. Location: Location of the COVIDAIR device (useful during operation with supervision). (Example: HUG GENEVA room 1822/P1)
5. Server address: Dedicated server for remote supervision (IP or domain name)
6. Status of the network (Connected / not connected)
7. Button for validating and saving the network parameters.

Note :
If the device is intended for use with remote supervision, network connection is mandatory.

5. Inlet air filter

⚠ WARNING

• The COVIDAIR device must always be equipped with a compatible inlet air filter to ensure proper operation of the COVIDAIR device and patient protection

For the treatment of COVID-19, it is strongly recommended to mount an antibacterial filter at the inlet of the device.

⚠ WARNING

• The antibacterial filter should be used and replaced according to the manufacturer's specifications.
• Use only bacteria filters that comply with applicable safety standards, including ISO 23328-1 and ISO 23328-2.

To mount an antibacterial filter, simply adapt it to the inlet of the device.

If antibacterial filters are not available for the inlet, the air filter supplied with the machine must be mounted on the inlet. It is fixed using the silicone tube provided.

Inspect the condition of the air filter regularly and determine if it is clogged with dirt or dust. In normal use, the air filter should be replaced every six months (or more often in a dusty environment). (See chapter replacing the inlet air filter).

6. Connection of the breathing circuit

⚠ WARNING

• The COVIDAIR device does not support monitoring of expired volumes.
• The breathing circuit must be arranged so as not to restrict movement or present a risk of strangulation.
• Do not add any intermediate parts or accessories to the ventilator that are not intended to be used in conjunction with the ventilator, as indicated in the operating instructions for the ventilator or accessory, otherwise the ventilator may not work. correctly and pose a risk of deterioration of the patient's state of health.
• Use only circuit components that comply with applicable safety standards, including ISO 5356-1 and ISO 5367.

6.1. Connection of a single circuit with intentional leakage

An intentional leak can be built into the circuit using a built-in leak valve or intentional leak mask.

⚠ WARNING

• At low pressures, the flow rate at the mask ventilation holes may be insufficient to remove all exhaled gas, which may result in rebreathing when using a single circuit with intentional leakage.
• Check that the ventilation holes in the mask or at the leak valve are not blocked. Make sure the area around the ventilation holes is free of bedding, clothing, or other objects and that the holes are not facing the patient.

1. The COVIDAIR device must be switched on and ventilation ready to start.
2. Connect the antibacterial filter to the inspiratory outlet of the device.
3. Connect the hose to the outlet of the antibacterial filter.
4. Connect the mask with controlled leakage to the hose.
5. Check that the humidifier bypass is in place.
6. Perform the alarm test.Contrôler les paramètres de ventilation.
7. Place the mask on the patient and begin ventilation.

6.2. Connecting the antibacterial filter

⚠ WARNING

• Regularly check the bacteria filter and exhalation valve to make sure that they are free of moisture and other contaminants, especially during humidification. Failure to do so may result in increased resistance to the respiratory system and / or inaccurate measurements of exhaled gas.
• Use only bacteria filters that comply with applicable safety standards, including ISO 23328-1 and ISO 23328-2.

⚠ CAUTION

The antibacterial filter should be used and replaced according to the manufacturer's specifications.

To attach the antibacterial filter:

1. Fit the antibacterial filter to the inspiratory outlet of the device.
2. Connect the breathing circuit to the other side of the filter.
3. Attach the patient interface to the free end of the breathing circuit.

⚠ WARNING

• To prevent cross-contamination, an antibacterial filter is required if the device is used in more than one patient.
• In case of nebulization or humidification, it is required to replace the bacteria filter more frequently to prevent an increase in resistance or blockage.

6.3. Addition of oxygen

Oxygen may be prescribed.
The COVIDAIR is designed to be used with the addition of oxygen in the inlet opening of the machine. Two assemblies were tested. The first delivers up to 50% oxygen to the patient and the second delivers up to 80% oxygen to the patient.

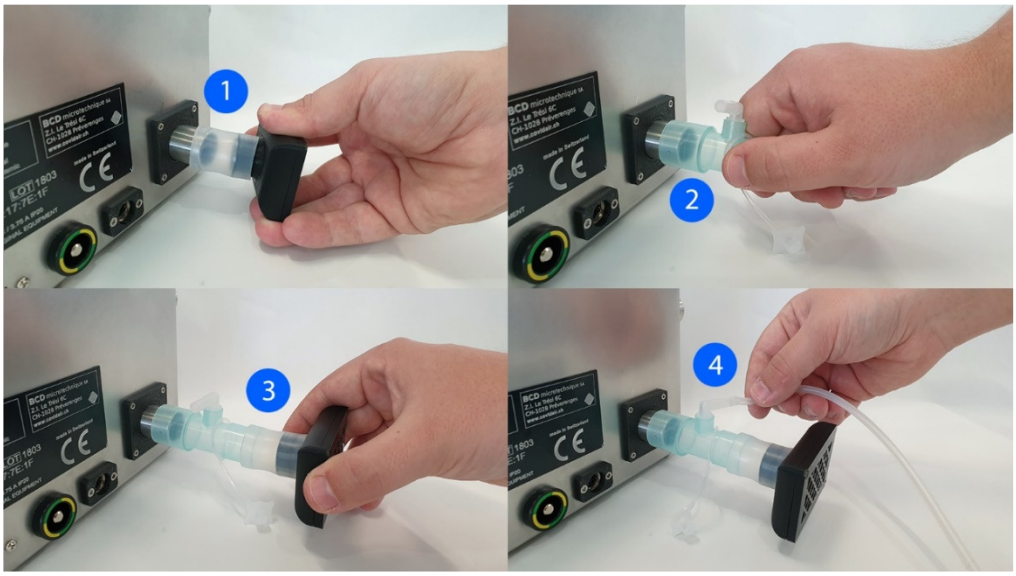
When supplemental oxygen is delivered at a fixed rate, the concentration of inhaled oxygen will vary depending on the ventilation mode and settings, the patient's breathing pattern, mask, and leak rate.

⚠ WARNING

• Use only medical grade oxygen sources.
• Always verify that the device is ventilating before turning on the oxygen supply.
• The oxygen flow should be closed when the device is not ventilating to prevent the buildup of unused oxygen in the device housing.
Explanation: Accumulation of oxygen presents a fire hazard. This applies to most types of fans.
• Oxygen is combustible. Do not smoke or bring a flame near the device when using oxygen. Addition of oxygen should only take place in well ventilated rooms.
• Oxygen should be added at the COVIDAIR suction port, located on the back of the device. Any arrival of oxygen at another location, such as in the air tubing through a side port or at the mask, can potentially interfere with the initiation of inspiration and the accuracy of therapy, monitoring, and alarms (the alarm leakage or the non-leak mask alarm, for example).
• The breathing circuit and the source of oxygen must be kept at a minimum distance of 2 m from sources of combustion.
• Monitor oxygen supply with the pulse oximeter sensor attached to the patient.

• COVIDAIR is not intended for use with heliox, nitric oxide, or anesthetic gases.
• COVIDAIR is not intended for use with heliox, nitric oxide, or anesthetic gases.
• Do not place the COVIDAIR device on its side.

Assembly 1 - for an addition of oxygen up to 50%:



1. Remove the filter
2. Add a tee fitting.
3. Fit the filter to the tee fitting.
4. Connect the oxygen to the tee fitting.
5. Switch on the ventilation.
6. Turn on the oxygen.

Before removing supplemental oxygen from the device, verify that the oxygen source has been turned off.

To remove the added oxygen:

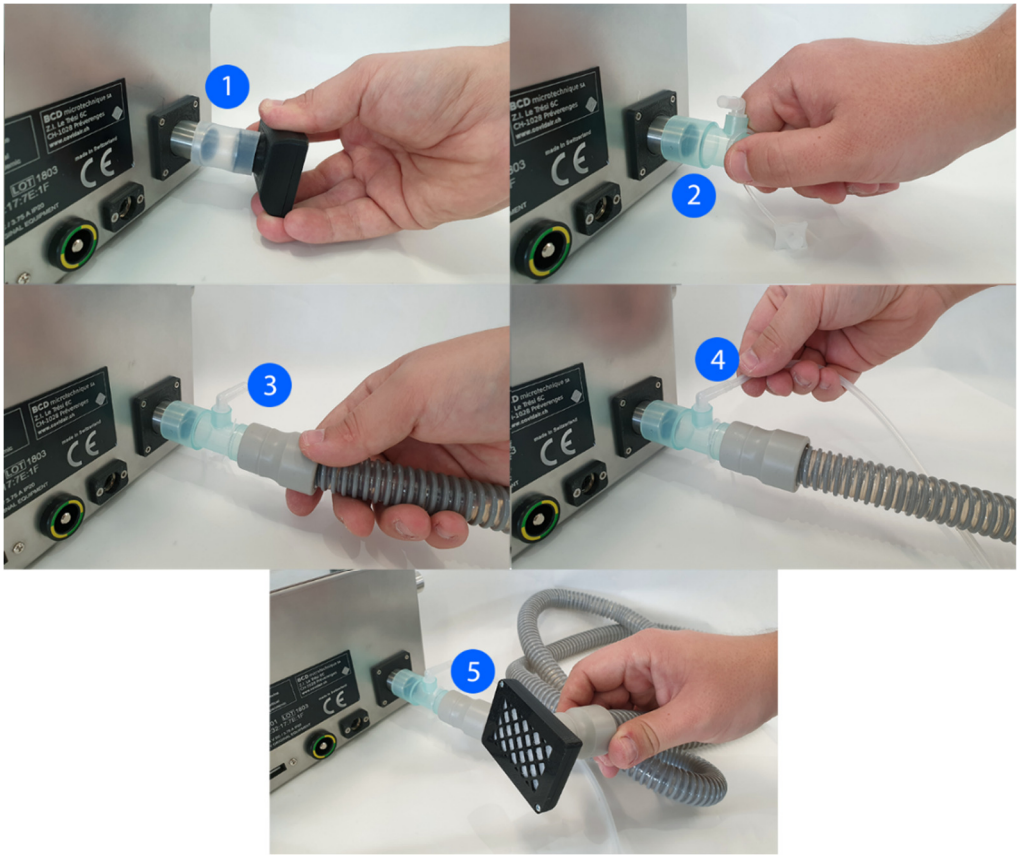
1. Shut off the oxygen source
2. Remove the tee.
3. Reassemble the filter on the inlet of the device.

Notes :
• The assembly is identical with an antibacterial filter.

Assembly 2 - for an addition of oxygen up to 80%:

The difference with the first assembly is the addition of a tank of approximately 0.6 liter between the filter and the tee fitting. This reservoir will fill up during the expiratory phase and empty during the inspiratory phase by increasing the oxygen supply. The tank must not be waterproof and it must support the mounting of a filter.
In this arrangement, the recommended reservoir is a fan tube with a diameter of 20 millimeters and a length of 2 meters, which gives a volume of 0.63 liters.

This arrangement is effective only if the available oxygen flow can be greater than the leakage flow.



1. Remove the filter
2. Fit a tee fitting.
3. Fit the Ø22 mm x 2 meter tube on the tee fitting
4. Connect the oxygen to the tee fitting.
5. Mount the filter on the tube
6. Switch on the ventilation.
7. Turn on the oxygen.

Before removing supplemental oxygen from the device, verify that the oxygen source has been turned off.

To remove the added oxygen

1. Shut off the oxygen source
2. Disassemble the tee and the tube.
3. Reassemble the filter on the inlet of the device.
4.

Notes :

• The assembly is identical with an antibacterial filter.

6.4. Connection of the pulse oximeter

⚠ WARNING

• Use only compatible pulse oximeters.
• Do not use pulse oximeter sensors with excessive pressure for prolonged periods of time, as this can cause pressure-related injury to the patient.
• The compatibility of the COVIDAIR device with the pulse oximeter sensor and the cable should be verified, as this may cause injury to the patient.

⚠ CAUTION

Factors that may affect the performance of the pulse oximeter or affect the accuracy of the measurement may be: excessive ambient light, excessive movement, electromagnetic interference, restrictions in blood flow (arterial catheters, blood pressure monitors, blood pressure lines, transfusion, etc.), moisture in the sensor, incorrect application of the sensor, wrong type of sensor, poor pulse quality, venous pulsations, anemia or low levels of hemoglobin, indocyanine green or other intravascular coloring agents, carboxyhemoglobin, methemoglobin, hemoglobin dysfunctional, artificial nails or nail polish, or incorrect positioning of the sensor.

Connect the pulse oximeter

1. Connect the oximeter plug to the back of the device.
2. The red light on the sensor should be on.
3. Secure the sensor to a patient's finger with a gas band or bandage.
4. Pulse and SpO2 readings are displayed after 5 seconds.

Notes :
• If the measurement does not start, check that the red light of the sensor is on. If so, check the positioning of the sensor on the patient's finger. Too much pressure from the sensor on the finger can also prevent the measurement.

7. Power Supply

⚠ WARNING

• Risk of electric shock. Do not immerse the device, the power supply unit or the power cable in water.
• Check that the power cable and plug are in good condition and that the equipment is not damaged.
• Keep the power cable away from any hot surface.
• Explosion Hazard — Do not use near flammable anesthetics.
• Always use the power supply supplied with the COVIDAIR device. Replacing it could seriously damage the integrity of the device.
• Do not connect the ventilator to a wheelchair battery as this may impair the ventilator performance and consequently lead to deterioration of the patient's health.

The COVIDAIR device is supplied with a 24V - 3.75A power supply.

7.1. Connection to the mains supply

⚠ WARNING

• Check the power cable for tripping or strangulation.
• Check the orientation of the pin on the plug when inserting it into the device.
• Insertion is difficult, check that the plug is correctly oriented and in place.
• The connector on the back of the COVIDAIR has a lock. The disconnection of this one must be done carefully.
• When disconnecting the mains power and the COVIDAIR device, **NEVER** pull on the cords.

To connect the mains power:

1. Connect the DC plug of the supplied external power supply to the back of the COVIDAIR.
2. Plug the other end of the power cable into a power outlet.

To disconnect the mains power:

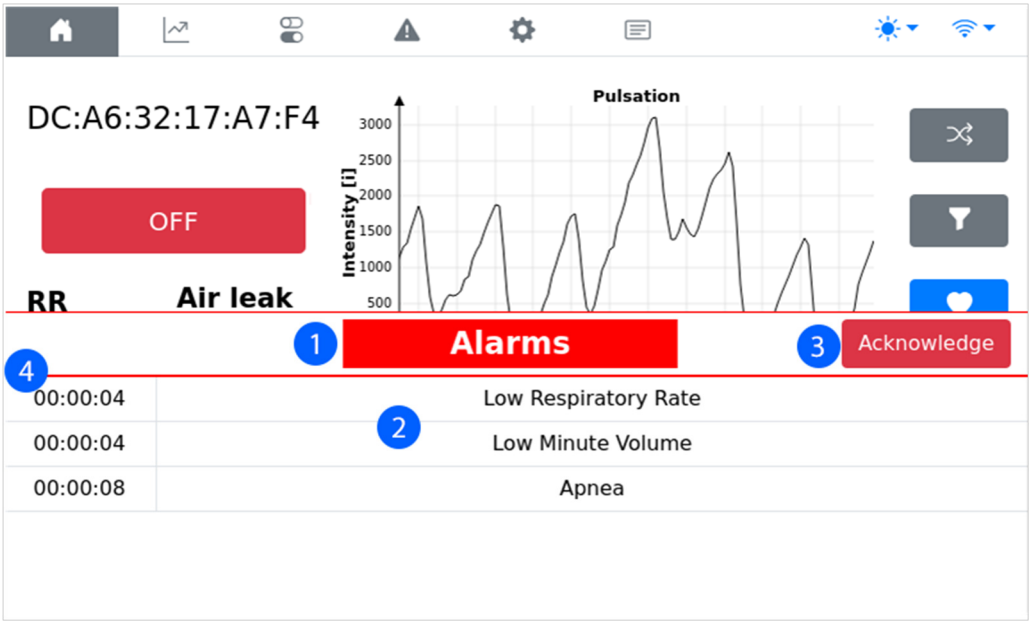
1. Disconnect the plug from the COVIDAIR device.
2. Unplug the power cable from the power outlet.

8. Alarms

The COVIDAIR device activates alarms to alert you to conditions that require intervention to ensure patient safety. When an alarm is activated, the COVIDAIR device provides audible and visual alerts, and displays an alarm message superimposed on the touchscreen.

Once the activation condition is met, the COVIDAIR device provides audible and visual alerts without delay.

The display of alarms has priority over locking the screen as well as over the menus during consultation.



1. Alarm display
2. List of current alarms.
3. Alarm acknowledgment button
4. Time since the occurrence of the alarm

8.1. List of alarms

The COVIDAIR device with 2 types of alarms. The first type: Functional alarms is related to the control of the respiratory aid. These alarms are defined and activated in the "Alarms" menu, they can be acknowledged by the medical staff and they will reactivate if the problem persists, otherwise they will stop as soon as the measured values are within the set values. The second type: Alarms related to device components. They are active all the time and indicate a failure of a component of the device. These alarms do not stop until the problem with the device is resolved.

⚠ WARNING

• If a hardware alarm persists, please shut down the device and contact the maintenance department.

8.1.1. Functional alarms

1. Leakage too low
   This alarm occurs when the total leak does not exceed 13l / min.
2. Circuit disconnected
   This alarm occurs when the total leak exceeds 160l / min. This can happen when no hose or mask is connected to the device.
3. Volume too low
   This alarm occurs when the total exhaled volume is less than the limit set in the “Alarms” menu.
4. Volume too high
   This alarm occurs when the total expired volume is greater than the limit set in the “Alarms” menu.
5. Minute volume too low
   This alarm occurs when the air volume per minute is less than the limit set in the "Alarms" menu.
6. Minute volume too high
   This alarm occurs when the air volume per minute is greater than the limit set in the "Alarms" menu.
7. Respiratory rate too low
   This alarm occurs when the respiratory rate is lower than the limit set in the “Alarms” menu.
8. Respiratory rate too high
   This alarm occurs when the respiratory rate is greater than the limit set in the “Alarms” menu.
9. Freediving
   This alarm occurs when the device does not detect any breathing from the patient for the time set in the "Alarms" menu.
10. Heart rate too low
    This alarm occurs when the heart rate is lower than the limit set in the “Alarms” menu. This alarm is not reported if the pulse oximeter is unplugged.
11. Heart rate too high
    This alarm occurs when the heart rate is higher than the limit set in the “Alarms” menu. This alarm is not reported if the pulse oximeter is unplugged.
12. Oxygenation too low
    This alarm occurs when the patient's oxygen saturation is lower than the limit set in the "Alarms" menu. This alarm is not reported if the pulse oximeter is unplugged.
13. Pressure level not reached
    This alarm occurs when the pressure level is not reached.
14. Low pressure
    This alarm occurs when the pressure is lower than the limit defined in the “Alarms” menu.
15. High pressure
    This alarm occurs when the pressure is greater than the limit defined in the “Alarms” menu.

8.1.2. Hardware alarms

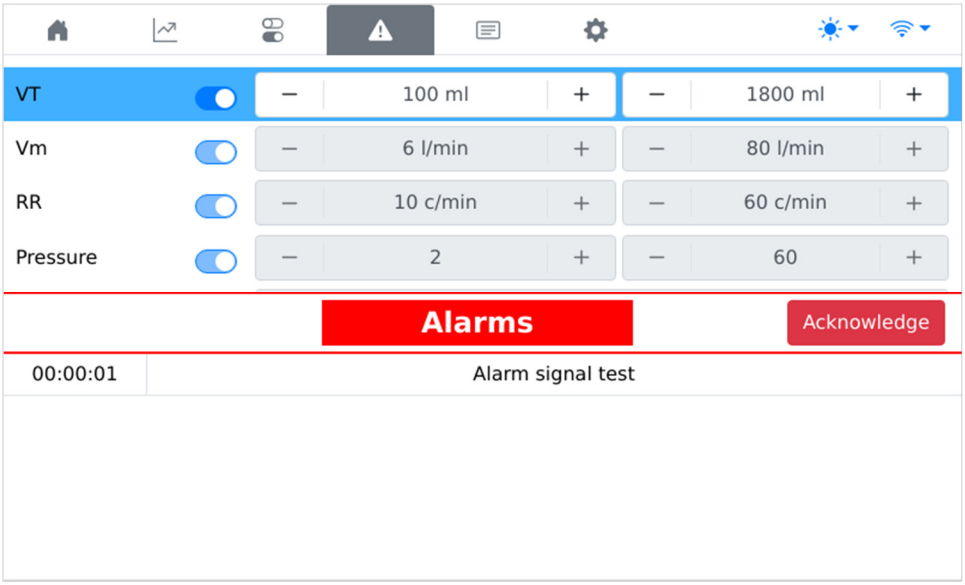
1. Heating temperature too high
   This alarm occurs when the heating temperature exceeds 80 ° C.
2. Enthalpy too high
   This alarm occurs when the enthalpy made by the humidifier exceeds 197 kJ / m3 of dry air averaged over 120s.
3. Pressure sensor error
   This alarm occurs when the measured value of the pressure sensor is no longer within the specifications of the component.
4. Heater temperature measurement error
   This alarm occurs when the measured value of the heater temperature sensor is no longer within the specifications of the component.
5. Flow measurement error
   This alarm occurs when the measured value of the flow sensor is no longer within the specifications of the component.

6. Error in humidity measurement
   This alarm occurs when the measured value of the humidity and temperature sensor is no longer connected.
7. Turbine error
   This alarm occurs when the machine fails to supply the required air.
8. 24V power supply error
   This alarm occurs when the measured value of the supply voltage is less than 90% of its nominal value.
9. Internal 5V power supply error
   This alarm occurs when the measured value of the supply voltage is less than 90% of its nominal value
10. 10V internal power supply error
    This alarm occurs when the measured value of the supply voltage is less than 90% of its nominal value

8.1.3. Display and horn test

Test the alarm periodically to confirm that it will be triggered as intended. In addition to the display, the COVIDAIR device has an audible warning device. During an alarm condition, the display coupled with the buzzer will indicate the alarm and its type. Perform the alarm test function periodically to confirm proper operation.

In the alarms screen, press the "Alarm test" button. The device should display the following message and the horn should sound 3 tones.



⚠ WARNING

• If no alarm is triggered, do not use the ventilator

9. Cleaning and maintenance

The cleaning and maintenance procedures described in this section should be performed regularly.

9.1. Cleaning the device

⚠ WARNING

• Patients treated with mechanical ventilation are highly susceptible to the risk of infection. Dirty or contaminated equipment presents a potential source of infection. Regularly clean the COVIDAIR device and its accessories.
• Always turn off and unplug the appliance before cleaning and make sure it is dry before plugging it back in.
• Do not immerse the device, pulse oximeter, or power cable in water.

⚠ CAUTION

• Clean only the external surfaces of the COVIDAIR device.
• Do not use strong detergents, abrasive cleansers or brushes to clean the device.
• Use only the methods and cleaning agents specified in this manual.

The external surface of the ventilator should be cleaned before and after each use and more often if necessary.

1. Unplug the unit and clean the front panel and exterior of the cabinet as needed with a clean cloth dampened with one of the following cleaning agents:

   - Soapy water or mild detergent
   - Hydrogen peroxide (at 3%)
   - Isopropyl alcohol (91%)
   - 10% bleach solution (10% bleach, 90% water)

2. Do not allow any liquid to get inside the fan housing. After cleaning, use a soft, dry cloth to absorb the remaining cleaning product. Be extra careful when cleaning the screen. Abrasive cleaners can scratch it.
3. Let the appliance dry completely before connecting the power cord.

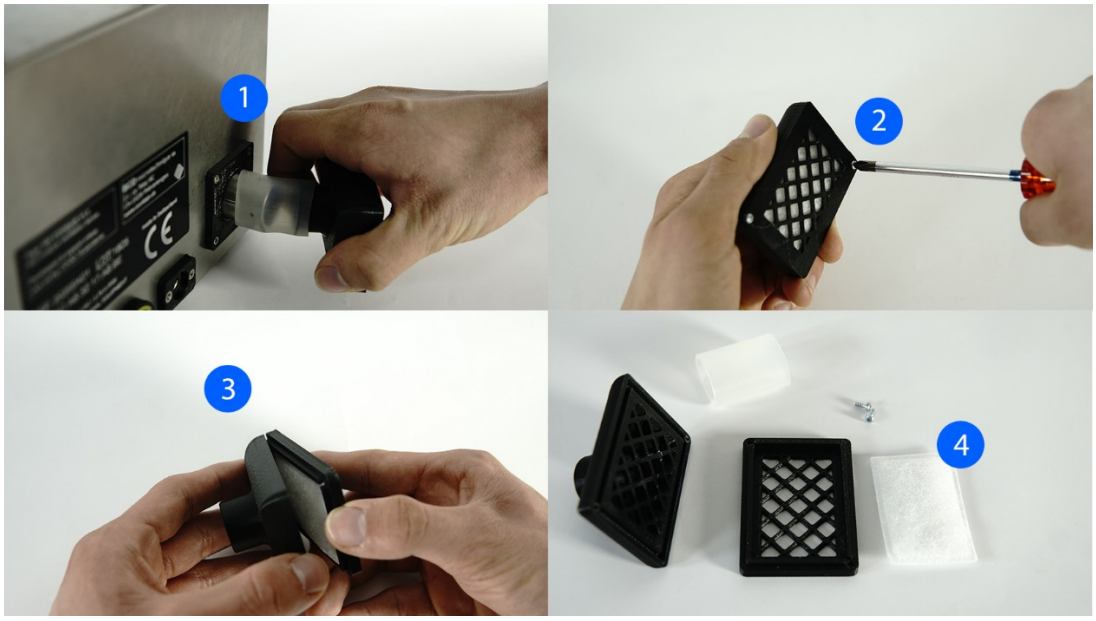
For cleaning all other parts of the respiratory aid system please follow the manufacturer's cleaning and maintenance recommendations for all circuit components.

9.2. Replacing the inlet air filter

Inspect the condition of the air filter and determine if it is clogged with dirt or dust. In normal use, the air filter should be replaced every six months (or more often in a dusty environment).

To remove and replace the air filter:

Before replacing the air filter, switch off the device and disconnect it from the power supply.



1. Separate the filter from the COVIDAIR.
2. Remove the 2 screws using a Phillips screwdriver.
3. Gently open the filter cartridge.
4. Replace the filter with a new one and perform the reverse operations to reassemble it. Tighten the screws moderately.

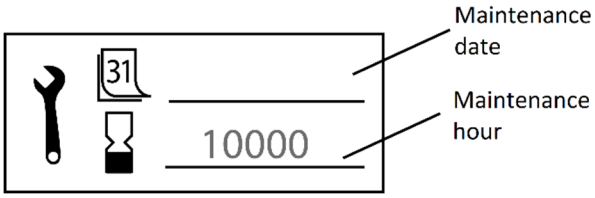
Replace the filter by a ResMed S9 air filter or equivalent.

⚠ WARNING

Do not wash the air filter. The air filter is not washable or reusable.

9.3. Device maintenance and schedule

The COVIDAIR device has a "Maintenance" label affixed to the bottom of the device. This label indicates the due date for the maintenance service. Maintenance should be performed every 10,000 hours or every 24 months, whichever comes first depending on the usage of the device.



Be sure to record the date and times on the label to maximize your interval of use. Note the date of maintenance corresponding to 24 months from the date of the first placement on a patient. Note the hours representing 10,000 hours of initial use.
Use "Total Fan Time" in the "Advanced Settings" menu to determine when the maintenance is due.

Before first use

1. Inspect the condition of the device.
2. Test the alarms; see 8.1.3 Display and horn test.

Weekly

1. Inspect the condition of the device.
2. Test the alarms; see 8.1.3 Display and horn test.

Mensuel

1. Inspect the condition of the air filter and determine if it is clogged with dirt or dust, in order to replace it. In normal use, the air filter should be replaced every six months (or more often in a dusty environment).

Every 10,000 hours or every 2 years

1. Perform a complete system check and calibration. This check must be carried out by specialized technicians trained by BCD microtechnique SA.

10. Troubleshooting

In case of a problem, try the following solutions. If the problem cannot be solved, contact your healthcare provider or an authorized technician..

10.1. Alarm troubleshooting

When triggering an alarm it is important to identify the cause before acknowledging it. The table below indicates the actions to be taken for each type of alarm.

Notes :
• The alarm actions below assume that the alarms are set correctly for the treatment of the patient. When an adjustable alarm is activated, reconfirm the alarm settings.
• If an alarm occurs multiple times and the cause is not determined, stop treatment and switch to a secondary ventilator, then return the device for service.

Functional alarm message	**Action**
Low air leak	1. Check the patient's status and airway. 2. Inspect the circuit for the presence of intentional leak.
Low tidal volume	Check the patient's status.
High tidal volume	Check the patient's status.
Low minute volume	Check the patient's status.
High minute volume	1. Check the patient's status and airway. 2. Inspect the circuit and tubing for leaks.
Low respiratory rate	Check the patient's status.
High respiratory rate	Check the patient's status.
Apnea	1. Check the patient's status and airway. 2. Inspect the circuit and tubing for leaks.
Patient disconnect	1. Check the patient's status and airway. 2. Inspect the circuit and tubing for leaks.
Low heart rate	1. Check the patient's status. 2. Check the positioning of the pulse oximeter.
High heart rate	1. Check the patient's status. 2. Check the positioning of the pulse oximeter.
Low SpO_2	1. Check the patient's status. 2. Check the positioning of the pulse oximeter.
Target pressure level not reached	Inspect the circuit and tubing for leaks.
Pressure too low	1. Check the patient's status. 2. Inspect the circuit and tubing for leaks.
Pressure too high	Check the patient's status.

⚠ WARNING

If a hardware alarm occurs, stop therapy and switch to a secondary ventilator. Then test the following actions without the ventilator connected to the patient.

Hardware alarm message	**Action**
Temperature heater too high	Stop the ventilator and let it cool. If the alarm sounds again upon restarting, return the unit for service.
Too high entalpy	This alarm turns off the heating. Stop the ventilator and let it cool. If the alarm sounds again when restarted, return the unit for service.
Pressure sensor error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Heating temperature measurement error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Flow mesurement error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Humidity measurement error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Turbine error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
24V power supply error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Internal 5V error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.
Internal 10V error	Restart the ventilator. If the alarm sounds again when restarted, return the unit for service.

11. Contact

11.1. Manufacturer

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11.2. Regional representative