COROVENT

a device for emergency mechanical lung ventilation of the patients with respiratory failure in the period of lack of ventilators due to the Covid-19 pandemic

Instructions for Use

Document version 10.5h June 27, 2021 SW and HW version 1.31b

Indications for Use

The CoroVent ventilation device is intended for the emergency, invasive ventilation of adult patients greater than 21 years of age, with body weight greater than 50 kg (110 lbs), and with respiratory failure due to COVID-19. The CoroVent provides pressure-limited continuous mandatory ventilation (VC-CMV) to ventilation-dependent patients. The CoroVent is intended to be used by physicians in hospital facilities. The CoroVent is not a transport ventilator.

The CoroVent is not cleared or approved in the United States and has been granted an Emergency Use Authorization by the FDA for use during the COVID-19 pandemic.

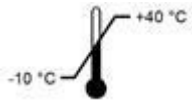
The CoroVent provides patients with emergency ventilatory support when no cleared or approved standard ventilators are available.

Device identifier: 90192000

List of Contents

1. Used symbols, markings and abbreviations

The following symbols and markings appear on the device and in the Manual:

SYMBOL	DESCRIPTION	WHERE OCCURRED
	Warning of possible danger	On the device and in the Manual
	Find relevant information in the Manual	On the device
	Attachment part of B type, comes into contact with the patient	On the rating plate of the device
	The device is assigned to the WEEE group	On the rating plate of the device and in the Manual
	Year of manufacture	On the rating plate of the device
	Manufacturer	On the rating plate of the device
	Storage temperature range	On package of the device
	Limitation of humidity	On package of the device
	Attention Fragile	On package of the device

	Keep away from rain	On package of the device
	Limited number of units during storage	On package of the device
0	OFF **Notice**: The main switch is not the power switch, i.e. it does not disconnect the device from the power network.	On the device and in the Manual
1	ON	On the device and in the Manual

The following abbreviations appear in the Manual or on the device, including its touch screen:

Abbrev.	Meaning
FiO_2	Fraction of oxygen in the inspiratory gas mixture
HF	High frequency (of electrical current or electromagnetic radiation)
HME	Filter, Heat and Moisture Exchanger Filter
MV	Minute ventilation (calculated from RR and VTe)
MV_{max}	Max. minute ventilation (can be changed in the “Alarm Setting” menu)
MV_{min}	Min. minute ventilation (can be changed in the “Alarm Setting” menu)
Pair	Air pressure at the device inlet
$Pair_{min}$	Min. air pressure value at the inlet (set by the manufacturer, cannot be changed)
Paw	Airway Pressure
PEEP	Positive End-Expiratory Pressure
$PEEP_{max}$	PEEP value for high PEEP alarm (can be changed in the “Alarm Setting” menu)
$Pindif_{max}$	Max. pressure difference of supplied gases, air and oxygen (set by the manufacturer, cannot be changed)
Plim	Inspiratory pressure limit
Pmax	Maximum Pressure (referred to as PIP, Peak Inspiratory Pressure, as well)
$Pmax_{max}$	Pmax value limit for high Pmax alarm (can be changed in the “Alarm Setting” menu)
PO2	Oxygen pressure at the device inlet
$PO2_{min}$	Min. oxygen pressure at the device inlet (set by the manufacturer, cannot be changed)
Pplat	Plateau pressure (pressure at the end of the inspiratory plateau)
RR	Respiratory Rate
RR_{max}	Max. Respiratory Rate (can be changed in the “Alarm Setting” menu)
RR_{min}	Min. Respiratory Rate (can be changed in the “Alarm Setting” menu)
UPS	Uninterrupted Power Supply
VDO	Very important circuits; uninterrupted power supply

VTe	Expiratory tidal volume
VTi	Inspiratory tidal volume
VT_{max}	Max. tidal volume (can be changed in the “Alarm Setting” menu)
VT_{min}	Max. tidal volume (can be changed in the “Alarm Setting” menu)
ZIS	Medical Isolated (Power) System
ZZ	Medical Establishment/Facility

2. Introduction

CoroVent is intended to provide continuous ventilation to adult patients requiring respiratory support.

CoroVent provides patients with emergency ventilatory support when no cleared or approved standard ventilators are available.

The CoroVent ventilator is not cleared or approved in the United States and has been granted an Emergency Use Authorization by the FDA for use during the COVID-19 pandemic.

CoroVent has been designed as the emergency device for artificial lung ventilation of the persons with respiratory failure in the course of the Covid-19 pandemic. The device is intended only and exclusively for the adult population weighing 50 kg (110 lbs) or more. It provides only the mandatory ventilation in the patients dependent on mechanical ventilation and does not allow synchronization with the patient's breathing effort. Parameters of the ventilation are adjustable in accordance with the principles of the so-called protective ventilation, based on latest evidence-based medicine.

Device identifier: 90192000.

Fig. 1: View of the CoroVent ventilator with the connected patient's circuit and the CoroQuant pressure and flow sensor.

The CoroVent ventilator has been manufactured on the basis of the CoroVent technology developed at the Czech Technical University in Prague, Faculty of Biomedical Engineering in Kladno, Czech Republic (www.ventilation.cz).

3. CoroVent device designation and features

CoroVent ventilation device:

- CoroVent is intended to provide continuous ventilation to adult patients requiring respiratory support.
- Environment of CoroVent use: hospital or clinical facility.
- Target users of CorVent: physicians and respiratory therapists. CoroVent must be operated only by professionals experienced and well trained in mechanical ventilation that have a proper qualification to provide respiratory care.
- Target patient population: adults, with body weight ≥ 50 kg (110 lbs) and body height from
  150 cm to 220 cm, both genders.
- CoroVent allows medical oxygen dosing in the range of 21 - 100%.
- CoroVent is equipped with a backup battery for at least 20 minutes of operation without any power supply source.
- CoroVent is a portable device: the ventilator is intended to be carried (but not operating) from one location to another.

WARNING!

CoroVent is not a ventilator splitter or adapter for multiplexing.
CoroVent should not be used with ventilator splitters or adapted for multiplexing.

CoroVent provides patients with emergency ventilatory support when no cleared or approved standard ventilators are available. The CoroVent is not cleared or approved in the United States and has been granted an Emergency Use Authorization by the FDA for use during the COVID-19 pandemic.

Before using CoroVent, please read **FACT SHEET FOR HEALTHCARE PROVIDERS— Emergency Use of Ventilators During the COVID-19 Pandemic** at https://www.fda.gov/media/136424/download, and **FACTSHEET FOR PATIENTS— Emergency Use of Ventilators During theCOVID-19Pandemic** at https://www.fda.gov/media/136425/download.

4. Indications for CoroVent device

CoroVent ventilation device is indicated in the following situations:

- in patients with breathing failure in the course of the Covid-19 pandemic when no other alternative FDA cleared or approved ventilators are available.
- in adults weighing 50 kg (110 lbs) and over, body height from 150 cm to 220 cm, both genders.
- is intended for artificial lung ventilation of intubated patients.

WARNING! The device cannot be used in newborns, children and adults below 50 kg (110 lbs) of body weight.

5. Contraindications to use of the CoroVent device

The CoroVent ventilation device has been designed as the emergency device for artificial lung ventilation of the patients with respiratory failure in the course of the Covid-19 pandemic. Use in the patients with other pulmonary diseases is not recommended.

Contraindications:

- invasive ventilation of children, neonates or patients with body weight less than 50 kg (110 lbs);
- non-invasive ventilation using masks, full-face masks or hoods;
- use as a transport ventilator or outside healthcare facilities.

WARNING! The device cannot be used:

- in patients weighing less than 50 kg (110 lbs)
- in patients breathing spontaneously
- as the transport ventilator

6. CoroVent device description

Components of the device are as follows:

- CoroVent main ventilation unit
- Gas connections – compressed medicinal air and compressed medicinal oxygen
- Expiratory valve

The necessary accessories for operation of the device are as follows:

- Patient's ventilation circuit
- Filter for humidifying and heating the gas mixture (HME filter)
- CoroQuant flow sensor – orifice gauge

7. These Instructions for Use

These Instructions for Use summarize functions and safety features of the CoroVent ventilation system. This manual does not replace the training how to use the device.

8. Safety regulations and requirements

Follow the hospital guidelines, when using the CoroVent ventilation device.

Other alerts appear in the entire document. Such information is preceded by the terms *Warning, Caution, Important Information*, or *Note*, where:

WARNING!
Indicates critical information about possible serious consequences for the patient or the user.

CAUTION:
Indicates instructions that have to be followed to ensure proper operation of the device.

***Important information*:** Indicates the information serving as a simple and practical aid for operation of the device or equipment connected to it.

Note: Indicates the information requiring a special attention.

9. General information

WARNING!

- The ventilation system may only be operated by the authorized staff trained in the use of this system. This system must be operated in accordance with the instructions contained in this manual.
- After unpacking, perform routine cleaning and testing of the device.
- Prior to connecting the ventilator to the patient, always test the device and check the ventilation function using a so-called artificial lung.
- The responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.
- The ventilator was designed to minimize risk of insertion of a human body or a part of the human body to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion hazard. Do not insert parts of the body to any possible trapping places.
- Fix all hoses, tubes, and cables to prevent the device from accidental fall.
- If any of the following phenomena occurs, stop using the CoroVent ventilation system immediately and contact a service technician:
    - - unknown pop-ups on the screen,
    - - unknown sounds,
    - - any unknown or unexplainable phenomenon,
    - - alarm(s) that cannot be resolved.
- Make sure the hand-held resuscitator is readily available!
- Positive pressure ventilation may be associated with the following adverse events: barotrauma, hypoventilation, hyperventilation or impaired circulation.
- If the ventilator is connected to the patient, ventilation must be started by the CoroVent ventilator operator.
- The CoroVent device has to be placed on a solid, smooth surface; do not tilt, suspend or place it on the side other than the bottom side of the device.
- Do not cover the ventilation system anyhow not to affect its functionality negatively. The display would not be readable as well.
- Neither modify nor remove any original parts, safety notices, rating plate and other information items.
- The ventilation system is not intended for use during MRI (magnetic resonance imaging).
- The ventilation system is not intended for use during radiotherapy, as the system could fail.
- The ventilation system may not be used in the hyperbaric chamber.
- Only the accessories, consumables and extra equipment recommended by the manufacturer and identified in this manual may be used with the CoroVent ventilation system. Use of other accessories, spare parts or ancillary equipment could restrict performance and safety of the system.
- Use the HME filters approved and recommended by the manufacturer for safe operation of the CoroVent ventilator. Use of active humidifiers may result in increased gas temperature, higher resistance in the filters, affected gas flow measurements, and in the overall reduced ventilation efficiency. Use of active

humidifiers is not possible.

- During humidification, the airway pressure has to be checked carefully. Increased airway pressure may be caused, for example, by a clogged filter or a faulty expiratory valve of the ventilation unit. The filter has to be replaced if the expiratory resistance rises, or if there are clear signs of filter contamination or malfunction, and/or replace the filter in conformity with the filter specification, whichever comes first.
- Service, repairs and installation may only be performed by the staff authorized by the manufacturer.
- Avoid any unauthorized modification to the device or its parts and accessories.
- The portable HF (high frequency) communication equipment (incl. peripherals, such as antenna cables and external antennas) may not be used closer than 30 cm (12 inches) from the ventilator, incl. the cables identified by the manufacturer; failure to observe this instruction may result in worsened performance of the device or its malfunction.
- Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.
- The design of the ventilator has been conducted using the risk management process (e.g. ISO 14971).

CAUTION:

- Never leave the patient unattended when connected to the CoroVent ventilation system.
- Prior to use the CoroVent ventilation system, check availability of compressed medicinal air and medicina oxygen.
- The manufacturer is not responsible for safe operation of the CoroVent ventilation system if the requirements, instructions, recommendations and warnings contained in this manual are not followed.
- If you lift or handle the ventilation system or its parts, observe the established ergonomic principles, ask for help, and adopt suitable safety precautions.
- Weight of the CoroVent ventilation device is 20 kg (44 lbs).
- Expiratory branch of the ventilation circuit and gas mixture at the expiratory valve outlet are most probably contaminated. Always use the personal protective equipment, i.e. at least the protective gloves and the airways protection of class FFP3, when handling these parts.
- The expiratory valve is disposable and can be used for 7 days as a maximum.
- The used expiratory valve has to be disposed as the infectious waste.
- During operation, the water separator must be checked regularly (if it is the integral part of the ventilation circuit) and emptied, if necessary.
- If a highly infectious patient is ventilated, use protective equipment of the highest possible class.
- Any excess fluid has to be disposed in accordance with the hospital practice and handled as infectious material.
- The complete technical documentation is available from the manufacturer's authorized staff.
- The ventilator is not suitable for use in an oxygen enriched environment

>25 % O_2.

- The high pressure parts of the ventilator operates at pipeline pressure.

Important information:

- The CoroVent ventilation system must be installed and put into operation in accordance with the EMC statement. The EMC parameters are listed in the Annex I of this document.
- Fix all cables, hoses, etc. securely to avoid undesirable spontaneous disconnection.
- When used, the CoroVent ventilation system must be placed on a solid, stable base.

- If the ventilation system is connected to the patient:
    - Do not handle or cover the expiratory valve.
    - Keep an eye on the set and measured parameters on the screen continuously.
    - Always use a heat and moisture exchanger filter (HME) to prevent lung tissue dehydration.

Notes:

- Do not touch the patient and any accessible contact terminal at the same time.
- Do not touch the patient and any metal part of the device at the same time.
- When determining status of the patient and the CoroVent ventilation system, consider parameters of vital functions measured by the vital signs monitor.
- A great attention has to be paid when handling tubes, connectors, and other patient circuit components.
- Contact the manufacturer when decommissioning the device.

10. Cleaning and maintenance

Refer to Chapter 23 “Care and maintenance” of these Instructions for Use.

11. Instructions for servicing

CAUTION:

Regular servicing: The ventilation system must be serviced at regular intervals by the specialists who have been specially trained and authorized by the manufacturer.

Service records: All service interventions performed on the ventilation system must be recorded in the service book in accordance with the hospital procedures and local and national regulations.

12. Disclaimer of warranty

Intervention into the device and unprofessional servicing are the main reasons for disclaimer of warranty. The manufacturer disclaims any responsibility for safety of operation of the ventilation system if the installation, service or repair works were performed by the persons having no adequate authorization from the manufacturer.

13. Network power supply

WARNING!

- The feed cable may only be connected to the properly grounded AC socket to avoid the risk of electric shock (protection class I).
- The device may only be used with the power cord delivered by the manufacturer.
- The power cable must always be plugged directly into the network power socket without using a multiple outlet. If a multiple outlet is used with other products, the total leakage current may be exceeded in case of a protective earth fault.
- Connect the device to VDO or ZIS sockets only (very important circuits, medical isolated power system).
- The device is energized even when the main power switch is off. Disconnection from the mains is performed by the mains plug.
- This ventilator relies on the integrity of the protective earth ground to reduce the risk of electrical shock. Check the integrity and verify the function of the protective earth ground of the supply mains receptacle prior to use.

- The means to reduce leakage currents according to IEC 60601-1 limits are used including the use of an isolation transformer complying IEC 61558.

CAUTION:

- **DO NOT USE** antistatic or electrically conductive ventilation circuit pipes with this system.
- Do not touch the external electrical connectors.

14. Backup battery

WARNING!

- To guarantee a reliable battery backup, the device has to be plugged in electric socket and allowed to charge for approximately 4 hours.
- A discharged or malfunctioning battery must be disposed of in accordance with the local regulations and not together with the common household waste.

Important information:

- The device is equipped with a backup lead-acid battery, which is able to cover the power failure for at least 20 minutes. Ventilator can typically work approx. 2 hours on the backup battery.
- If the device is plugged in and turned off by the main switch, the screen displays the UPS / battery charge status.
- Always charge the battery as high as possible prior to using the CoroVent device.
- To ensure the fully charged battery all the time, the ventilation system must be permanently connected to mains voltage source, even if not used and if turned off by the main switch.
- If the device is not used for a long time period, it has to be connected to the mains for 24 to 48 hours at least once every six months to recharge the battery and avoid its damage by deep discharge.
- If the backup battery is damaged (if it does not have the required capacity), the ventilator displays the relevant warning on the status screen (see sec. 20.4). The battery status and the associated warning does not prevent the patient from ventilating, when the device is on AC power.
- The battery complies with IEC 61056-1 and IEC 61056-2.

WARNING! When starting the ventilator, the main cable must be connected to the ZIS socket (medical isolated system) or the VDO socket (very important circuits). The device cannot be started fed by the battery only.

15. Fire hazard

WARNING!

- Make sure that all possible sources of ignition or potentially hazardous substances are well away from the ventilation system and oxygen hoses.
- Never use the ventilation system with the oxygen hoses that are worn, scuffed or polluted by flammable substances such as greases and oils!
- The oxygen-enriched gas promotes combustion: if you smell a burn, check the CoroVent ventilation system. In hazardous situations, stop ventilation and disconnect oxygen supply and the main power supply.
- Make sure that the power cord is accessible easily so that it can be disconnected in an emergency without undue delay.

16. Gases

The CoroVent ventilation unit is intended for operation with dry medicinal gases for treatment of the lung disease associated with the Covid-19 pandemic. Only the compressed medicinal air and medicinal oxygen may be connected to the device. Connect the ventilation unit only and exclusively by the pressure hoses delivered with the device.

WARNING!

The CoroVent ventilation system may be used neither with helium nor with any helium containing gas mixture.

CAUTION:

Measurement of numerical values through the ventilation system performed by a peripheral:

- can be inaccurate when using the equipment that has not been verified;
- if they contradict with the information on the ventilator screen, they must be invalidated.

Note:

Accessories, consumables and peripherals used by the CoroVent ventilation system must:

- be recommended by the manufacturer,
- meet requirements of EN ISO 60601-1 standards,
- meet IEC standards as a whole system.

17. Electromagnetic compatibility

CoroVent contains the necessary elements and technical solutions to ensure its electromagnetic compatibility when used with other medical devices in accordance with the requirements of technical standards for medical devices

Important information:

The ventilation system must be installed and put into operation in accordance with the electromagnetic compatibility requirements.

18. SW version and configuration

These Instructions for Use refer to version 1.31b of the CoroVent ventilation system.

19. System overview

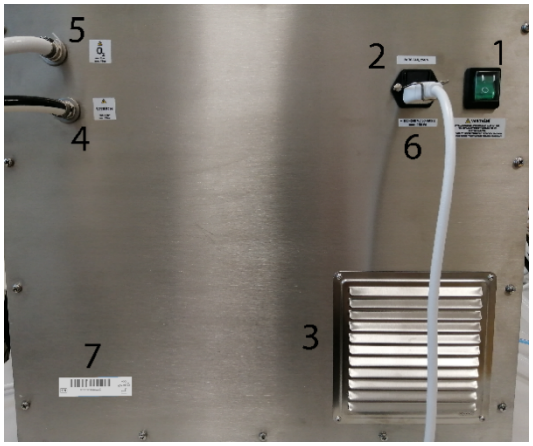
The CoroVent ventilator consists of the ventilator unit and the user interface. Air and oxygen can be supplied from the hospital gas distribution system, from the compressor modified for medicinal air or from medicinal gas pressure vessels. Make sure that the ventilator unit is placed firmly and cannot be turned over.

19.1 CoroVent ventilation unit

Front view *(Fig.2):*

1. Touch screen
2. Alarm light
3. Paw manometer
4. Manometer of inspiratory airway pressure limit (Plim)
5. Rotating inspiratory airway pressure limit controller (Plim)
6. Rotating positive end-expiratory pressure controller (PEEP)
7. Inspiratory limb outlet

Rear view *(Fig. 3):*



1. Main ON-OFF switch
2. AC power supply connector with fuses
3. Cooling fan vents with a dust filter
4. Hose for connection to compressed air source
5. Hose for connection to compressed oxygen source
6. Rating plate
7. Serial number label

Left side view *(Fig. 4):*

1. Expiratory valve
2. Expiratory valve holder
3. Outlet for connecting the pressure control hose
4. Inlet for hoses from the CoroQuant spirometer probe (sensor) - blue and white inlets

19.2 Expiratory valve

The expiratory valve, shown in Fig. 5, is a separate element representing the integral part of the expiratory limb of the patient's circuit.

Procedure of installation of the expiratory valve:

1. Insert the expiratory valve into the holder mounted on the left side of the CoroVent device. Position the valve with the pressure control hose outlet facing up. Make sure that the valve is firmly attached in the holder and that the holder does not cover the holes on the sides of the valve.
2. Connect the pressure control hose to the expiratory valve. Insert the hose into the connector and push it, by applying a moderate pressure, as far as the stop. When handling the hose, hold the valve with your other hand to avoid its sliding out of the holder.
3. Connect the expiratory limb of the patient's breathing circuit (see below) to the bottom part of the valve, via the 22M connector.

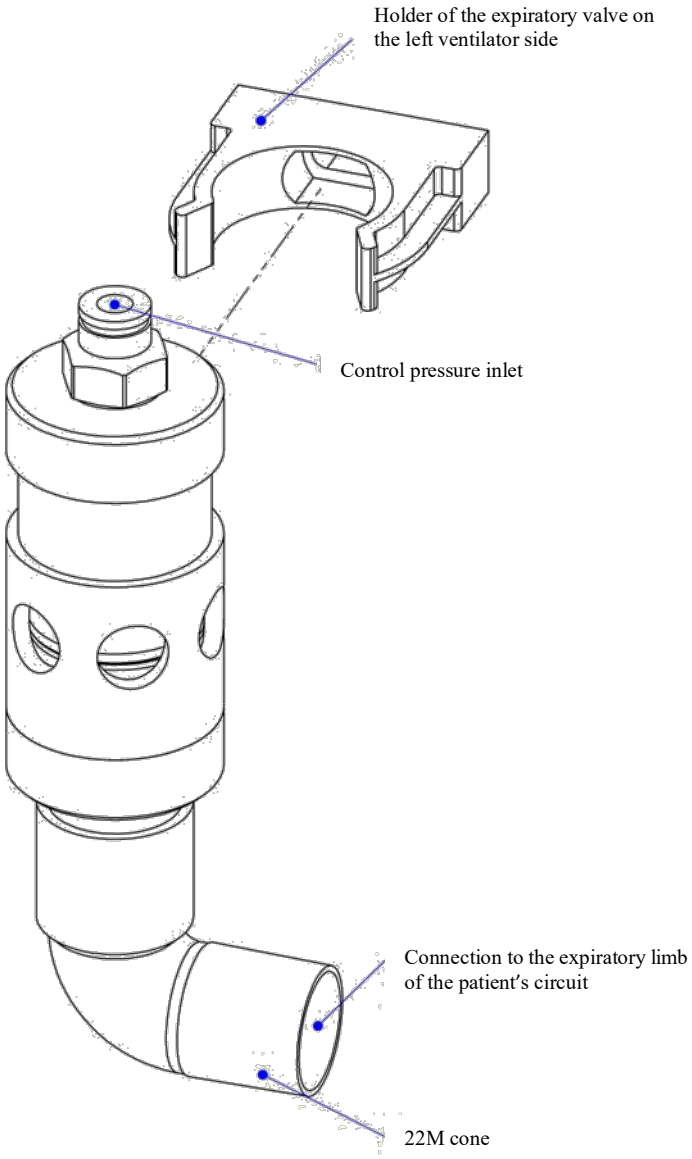


Fig. 5: Expiratory valve of the CoroVent ventilator

CAUTION:
The expiratory valve is disposable! When ventilation of one patient is completed, discard the valve in accordance with regulations of the medical facility.

19.3 Patient's circuit

A schematic diagram of the patient's circuit of the ventilator with the correct sequence of individual components can be seen in Fig. 6.

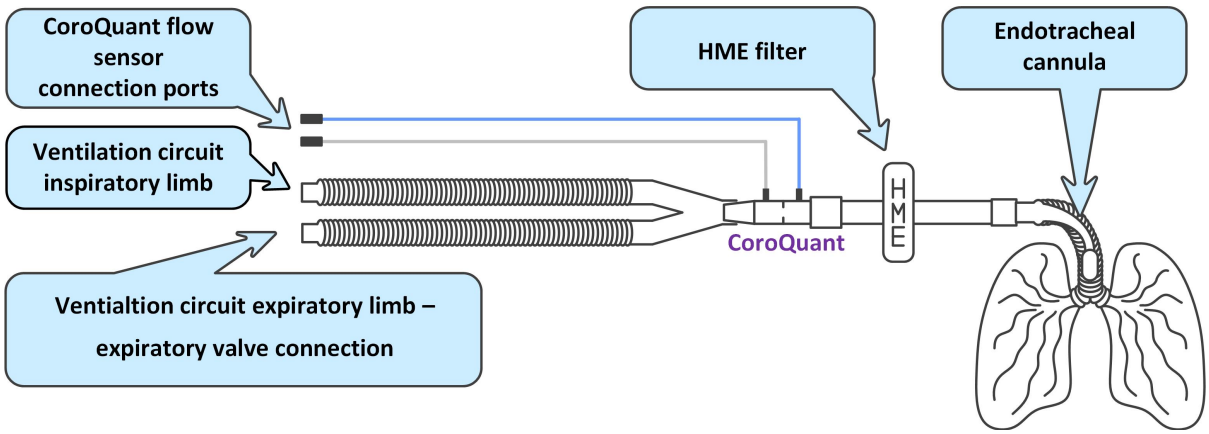


Fig. 6: Patient's ventilation circuit diagram.

The breathing system with the patient Y-coupling and two wrapped hoses is the preferred patient's circuit.

WARNING!
Use of the coaxial patient's circuit is impossible.

Connection of nebulization is possible with an external source of propellant gas (oxygen, air) only. The CoroVent device does not have a special port for nebulization. During nebulization, the alarm caused by the difference between the inspiratory and expiratory tidal volume (alarm E19 according to the Table 4) will be triggered. Its software compensation is out of scope of the device.

WARNING!
Use of the HME filter is inevitable!

CAUTION:

The patient circuit with active humidifying cannot be used.

Measurement of the expiratory carbon dioxide concentration ($ETCO_2$) is possible by means of an external device, by connecting the capnometry hose to the HME filter port, which allows this.

In order to prevent excessive CO_2 rebreathing, the dead space of the bi-directional gas flow parts must be reduced. Do not use excessive parts of the patient's circuit that may increase the dead space.

19.4 CoroQuant spirometer sensor

The CoroQuant spirometer sensor is used to measure pressures and flows in the patient circuit (Paw and Qaw). It is inserted between the patient's circuit Y-coupling and the HME filter. The color-coded hoses, one ends of which are connected to the probe in the patient's circuit (blue and white), are connected by their other ends to the CoroVent device on the left side of the device – to the pins of the corresponding colors (blue to blue and white to white).

WARNING!
The CoroQuant spirometer sensor is a disposable consumable. Use a new probe for each patient. **Service life time of the probe is 7 days.**

19.5 Internal structure and functions of the CoroVent ventilator

Diagram of the pneumatic part of the ventilator can be seen in Fig. 7.

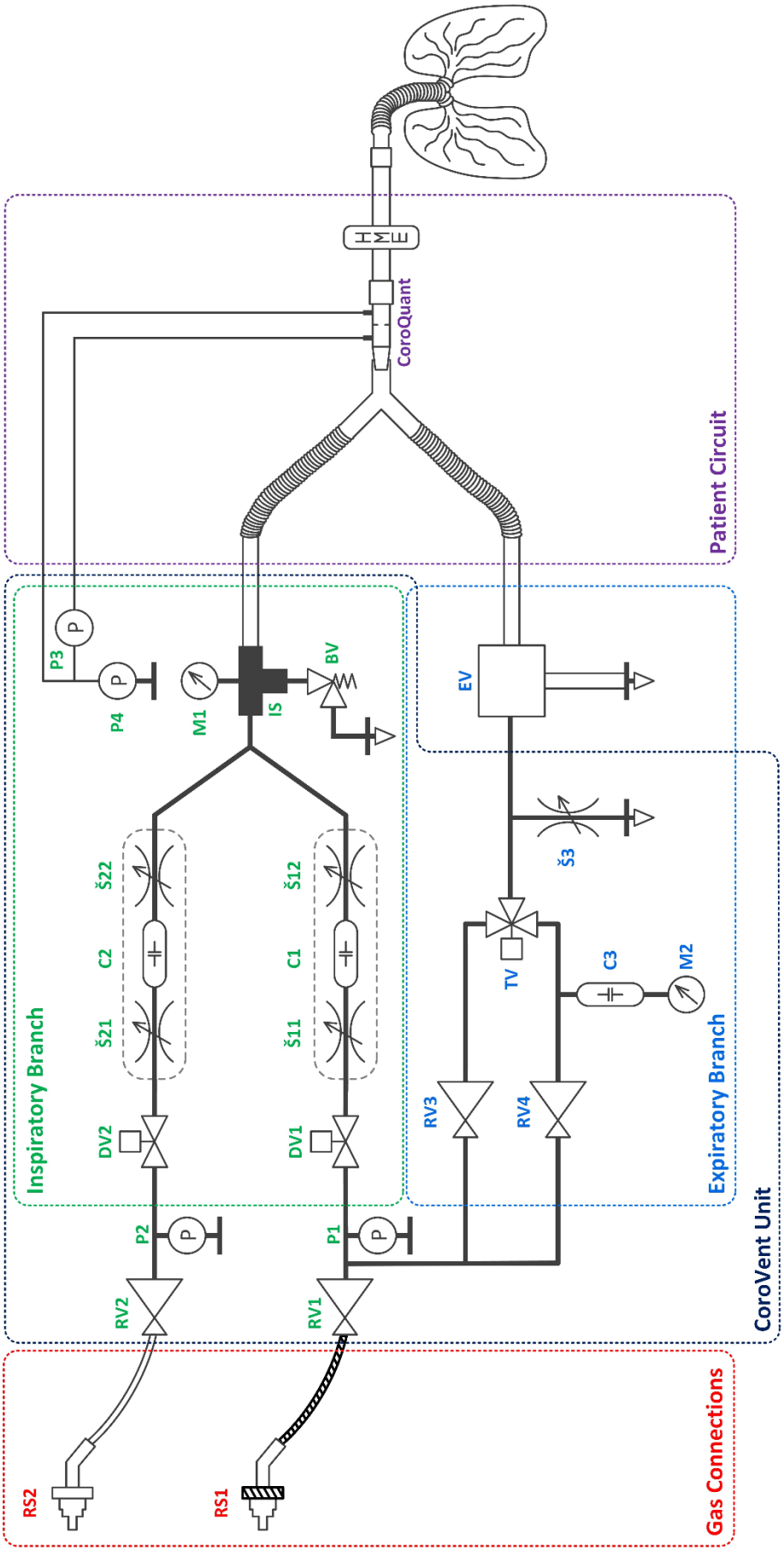


Fig. 7: Layout of individual functional components of the pneumatic part of the CoroVent ventilator.

List of components:

RS1 medicinal air quick coupling
RS2 medicinal oxygen quick coupling
RV1 air reducing valve
RV2 oxygen reducing valve
DV1 two-state electrically controlled air valve
DV2 two-state electrically controlled oxygen valve
Š11 primary air throttle valve
Š12 secondary air throttle valve
Š21 primary oxygen throttle valve
Š22 secondary oxygen throttle valve
C1 compliance in the air branch
C2 compliance in the oxygen branch
M1 pressure gauge for patient circuit pressure measurement (Ppo, Paw approximation)
BV safety relief valve
IS inspiratory coupling with the port for connection of the patient's circuit
EV expiratory valve
RV3 pressure-reducing valve for PEEP pressure control
RV4 pressure-reducing valve for Plim pressure control
M2 manometer for indication of Plim setting
C3 compliance for M2 manometer stabilization
TV three-way electrically controlled valve
Š3 throttle valve

Description of the structure and internal ventilator function

The basic structure and internal function of the CoroVent ventilator is described here. Individual parts of the ventilator are colour coded in accordance with the diagram in Fig. 7.

Gas connections

Connecting hoses are used to connect the ventilator to the hospital air and oxygen distribution system. Pressure in the hospital distribution system can be about 4 to 5 bar. If CoroVent is used with the pressure cylinders, a standard medical pressure-reducing valve must be installed on the cylinder.

Air inlet: The air branch starts with a medical quick coupling for connection to the air distribution system (EN ISO 7396-1), which an air hose (black and white colour according to EN ISO 7396-1) is connected to, and which leads to the ventilator itself.

Oxygen inlet: is designed in the same way like the air inlet. The oxygen quick coupling, the hose is white (again according to EN ISO 7396-1), other materials are compatible with oxygen.

Pressure reducing valves: The inlet hoses are connected to the pressure reducing valves inside the ventilator. They reduce pressure from the hospital distribution system to the working pressure of the ventilator; the recommended value of this working pressure is 0.2 MPa at the flow rate of 50 L/min for both air and oxygen.

Inspiratory arm

Distribution lines inside the ventilator are, unless otherwise stated, made by the hoses and screw joints for the hose, OD 6 mm.

Two quick electrically controlled two-state valves DV1 and DV2 are used to control inspirium. Both valves utilize the pulse width modulation (known rather from electronics) to generate the inspiratory flow while controlling the oxygen fraction in the ventilation mixture. At the same time, by interrupting this flow, they are able to control the inspiration time and the number of breaths per minute. An example of flow control and at the same time oxygen fraction control during inspirium are shown in Fig. 8.

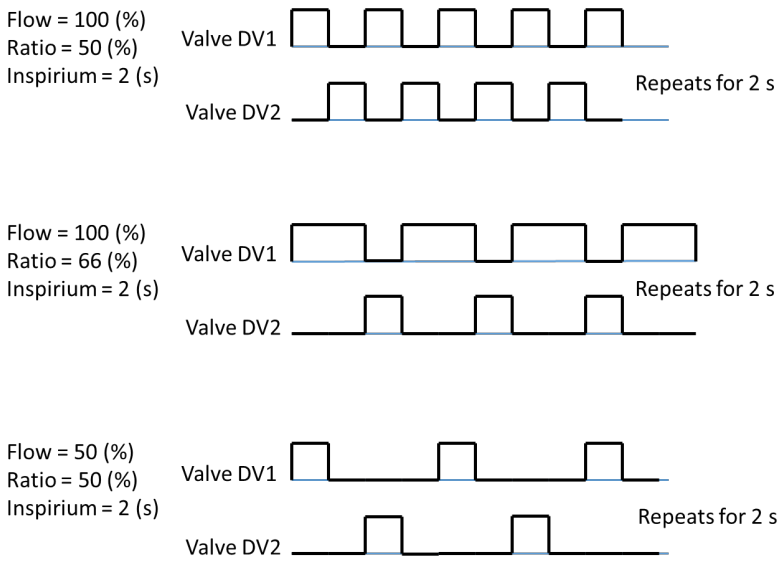


Fig. 8: Example of the pulse control of inspiratory valves to generate the defined flow rate (as a percentage of the maximum possible flow with the valve fully open) while creating the desired air / oxygen mixture. Note: In the Figure, the "Ratio" parameter means the air to oxygen ratio in the range of 0-100%, whereby the resulting fraction of FiO_2 oxygen ranges 21- 100%, which is calculated in the ventilator SW afterwards.

Working pressure sensors P1 and P2, located downstream the pressure-reducing valves in both branches, monitor the working pressure downstream the pressure-reducing valves. Based on the sensor data, the following alarms are triggered: low air or oxygen pressure, high working pressure difference of both gases and malfunction of any of the two-state valves.

The two-state electrically controlled valves are used to control the oxygen fraction in the ventilation mixture, the tidal volume, the respiratory rate and the inspiratory / expiratory time

ratio.

The pulse filters located in both branches serve for smoothing the inspiratory flow. They consist of two throttle valves (primary and secondary) and compliance between them.

The air and oxygen branch connection (IS) ensures connection of the air and oxygen branch together and at the same time includes a port for connection of the patient circuit inspiratory branch to the ventilator. This metal port is ended with a 22 mm M medical cone (according to ČSN EN ISO 5356- 1:2015). The IS coupling interconnects pneumatic circuits of inspirium control with the patient circuit and also with the BV safety relief valve.

The safety relief valve (BV) serves for protection of the patient from the airway pressure higher than 6.5 kPa (65 cm H_2O); 6.5 kPa was selected from the max. limit of 12.5 kPa (125 cm H_2O) as required by sec. 51.102 of ČSN EN 894-1+A2:2009 standard). The valve is installed here for the case of failure, total occlusion of the expiratory arm of the patient circuit, or presence of another undesirable status.

The Paw manometer indicates the pressure at the patient circuit inlet. This pressure is very similar to the pressure that is measured in the patient Y-coupling of the patient circuit and can therefore be designated (with a certain error) as Paw. Exact values of the actual pressure Paw are shown on the ventilator screen. The manometer informs the ventilator operator about the pressure curve during the whole breath cycle and is understood an additional modality.

Patient's circuit

The standard patient's circuit is a consumable to the ventilator. CoroVent has been designed to be compatible with conventional patient circuits with the Y-coupling and two separate hoses for the inspiratory and expiratory arms. CoroVent is not intended for use with a coaxial patient circuit.

The standard patient circuit is a consumable replaced for each new patient at the latest. In case of insufficient number of patient circuits, the medical Y-coupling with the medical cone of 22 mm M (external) and 15 mm F at all three ends can be used. The typically wrapped 160 cm hoses (creating the inspiratory and expiratory arms) are inserted on two Y-coupling ends, and the CoroQuant measuring orifice is attached to the third end.

CoroQuant measuring orifice is a measuring pressure element at the inlet into the patient airways (Paw) and flow into the patient (Qaw). The whole unit works as an obstructive diaphragm, on which the pressure loss is generated when the gas flows through the obstacle; the pressure loss is measured by the differential pressure sensor P3. CoroQuant is equipped by two measuring pins (one upstream and the other downstream the obstacle) for
2.5 mm ID hose. Using the hoses set on the measuring pins, pressure from the pins is transmitted into the ventilator, where it is brought onto the differential pressure sensor P3 (for Qaw) and the P4 sensor measuring overpressure compared with the ambient air (for Paw). The hoses for interconnection of the CoroQuant unit and the ventilator are factory-mounted to the CoroQuant body and are colour-coded (clear and blue colours). Pins on the ventilator are marked by the same colours, thanks to which the CoroQuant unit cannot be connected in the wrong, i.e. in the opposite direction.

Expiratory branch

Expiratory valve is the element that closes the expiratory arm of the patient circuit during inspirium and opens the arm during expirium. During inspirium, it works as a pneumatically controlled pressure relief valve, allowing to limit the max. inspiratory pressure (Plim) in the patient circuit. In expirium, it acts as a pneumatically controlled flow resistance, through which it is possible, together with expiration time setting, to control the positive end- expiratory pressure (PEEP). This valve design enables (during expirium) to compensate the additional flow resistance of the expiratory filter incorporated between the patient circuit and the expiratory valve. The control pressure setting the maximum inspiratory pressure in the patient circuit, and PEEP is brought (during expirium) into the valve from the pneumatic circuits of the expiratory valve control through the fitting with a 6 mm outside diameter hose.

Pressure-reducing valve form Plim control - by its outlet pressure, the max. possible pressure in the patient circuit (Plim) is controlled. The Plim value can be set by the user from the PEEP value up to 45 cmH_2O, using the control button labelled “Plim” on the front panel of the ventilator.

The compliance (C3) compensates short-time pressure losses in the outlet pneumatic line from the pressure-reducing valve for Plim control, and at the same time serves as the low-pass filter, filtering pressure oscillations measured by the M2 manometer, according to which the Plim pressure is set by the operator of the ventilator.

The pressure-reducing valve for PEEP control provides pressure to control the expiratory valve resistance, i.e. de facto PEEP, during expirium. This pressure can be changed by the user by the control button labelled "PEEP" on the front panel of the ventilator.

The three-way valve (TV) is an electrically controlled pneumatically driven valve. This valve switches the pressure branch of the expiratory valve between the pressures at the pressure-reducing valve outlet for PEEP and for Plim. The valve utilizes compressed air for its feeding. To ensure correct function of the three-way valve for its control pressure cycling, the circuit incorporates the throttle valve to relieve the pressure in the control branch of the expiratory valve (Š5). Function of this throttle valve is to relieve pressure from the control branch of the expiratory valve by a low flow (L/min).

20. Operation of CoroVent ventilator

1. Prior to start the ventilator, check that the device, its accessories, and the cables and connections to the medicinal gases are not damaged.
2. Connect the CoroVent ventilation unit to the source of medicinal gases and electricity.
3. Check the battery condition after connecting the power.
4. By pressing the button “Run the Test of the Alarm Signals of the Device?” perform the test of audible and visual alarm signaling (see sec. 20.1).
5. Turn the CoroVent ventilation unit on by the main ON-OFF switch on the rear side of the ventilator.
6. Connect the expiratory valve to the CoroVent ventilation unit on the left side of the device, connect the expiratory valve pressure control hose.
7. Connect the patient’s circuit, including the HME filter, to the ventilation unit.
8. Incorporate the CoroQuant flow sensor between the patient’s circuit Y-coupling and the HME filter, and calibrate the sensor via the “Setup” - “Reset” menu.
9. Connect an artificial lung to the patient’s circuit to test ventilator settings.
10. Set the ventilation mode parameters.
11. Check and, when necessary, adjust alarm limits.
12. Start ventilation of the so-called artificial lung. If there is no complication, proceed to the next point.
13. Connect the ventilation system to the patient.
14. Adjust the alarm limits or modify the ventilation parameters if necessary.
15. Terminate the ventilation, if necessary.
16. After ventilation, disconnect the ventilation system from the patient.
17. Close the gas supply and switch off the device with the ON / OFF button.
18. Disconnect all tubing, filters, and other medical supplies from the device and perform their cleaning, disinfection or disposal in the prescribed manner.
19. Clean the ventilation system to the extent necessary for its further use in accordance with article 23.4.

WARNING!
To switch on the device, it is necessary to connect the device to the mains power supply socket. The device cannot be started without the power cable connected.

WARNING!

- Always test the device prior to connecting the ventilator to the patient.
- If any fault persists, do not connect the ventilation system to the patient.

Important information:

- The internal volume of the patient’s circuit should be the same during the device test as during the ventilation itself.

- If you change the patient's circuit after the completed device test, perform a new test of the device.
- The pre-use inspection must be performed to ensure proper system functionality, optimal performance and patient safety.

When the CoroVent device is connected to the power supply source via the mains cable, the main screen of the switched-off device (Fig. 9) appears with the information concerning **status of UPS** (uninterruptible power supply) **charging**.

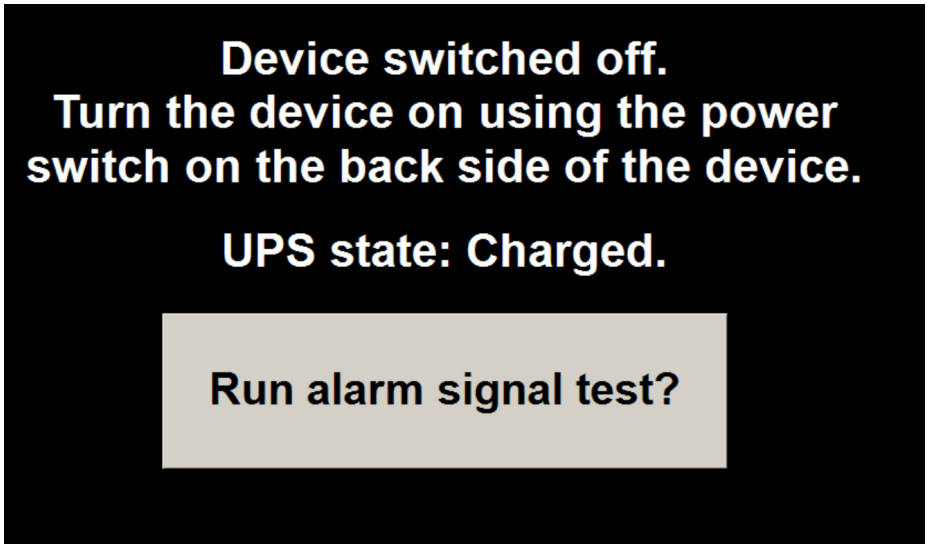


Fig. 9: Screen of the switched off device after plugging the power cable.

From the switched off screen of the device it is possible to move to the menu of Alarm Signal Testing – for greater details, see sec. 20.1.

20.1 Test of alarm signals

Before switching on the ventilator, test both the audible and the visual signaling of the alarm system.

Start the test by pressing the button **"Run the test of the alarm signals of the device?"** on the switched off device screen.

1. In the first dialog box you will be asked: "**Is the visual alarm signaling on**?" Check the visual signaling on the front panel of the device. If the bright red pilot lamp labelled "Alarm" is lit, confirm in the dialog box by pressing the button "Yes".

2. Then the following question appears in the next box "**Is the audible alarm signaling active?**" Confirm its function (in case of a loud audible alarm), by pressing the button "Yes".if the

function of the alarm message signaling works correctly, the confirmation message "**Test of alarm signals of the device completed**" appears on the screen; confirm by pressing "OK".

In case of malfunction of one or both modalities, the following message appears "**Faulty optical (audible) alarm signaling! Service required!**" By pressing the button "**Continue using the ventilator**", you will be returned back to the switched off device screen.

Important information:
In case of malfunctioned alarm signaling system, patient ventilation can be continued, but the "**Error of audible (and/or visual) alarm - service**" message remains permanently on the main ventilator screen**"**.

WARNING: In case of malfunction of the audible (or visual) alarm signaling, the device can still be operated, but must be kept under permanent supervision – the alarm messages are displayed in the information field on the main ventilator screen, but the user is not notified of their presence by audible (or visual) signals.

20.2 Calibrating the CoroQuant flow sensor

Calibrate the CoroQuant sensor before ventilating the patient. Zeroing of pressure and flow sensor CoroQuant flow sensor is started in the "Settings" menu by selecting "Calibration" (see also chapter 20.5, fig. 23). This calibration resets the Paw pressure and the Qaw flow at the inlet into the patient circuit. It is not necessary to disconnect the CoroQuant sensor from this operation patient circuit and there is no interruption of artificial lung ventilation. Another reset CoroQuant spirometric probes run automatically with a period of several minute.

WARNING!
It is not possible to measure ventilation parameters while resetting the CoroQuant sensor!
Ventilation of the patient during the resetting of the CoroQuant sensor is as before set parameters.

20.3 Ventilation mode setting

The ventilator contains only one ventilation mode: the volume-controlled, pressure-limited ventilation. The mode of ventilation can be characterized as:

CONTROL VARIABLE: Volume
BREATH SEQUENCE: Continuous mandatory ventilation
TARGETING SCHEME: Dual
MODE NAME: CMV + pressure limited

The ventilator works as a constant pressure source in inspirium. The course of pressure and flow during ventilation, and significance of individual ventilation parameters can be seen in Fig. 10. The expirium is controlled by a pneumatic valve, which maintains the required PEEP and also serves as a safety valve not to exceed the maximum Plim pressure setting that may occur in the patient circuit, thus realizing the pressure limitation. The inspiratory plateau is created by appropriate timing of the expiratory valve with respect to the inspirium.

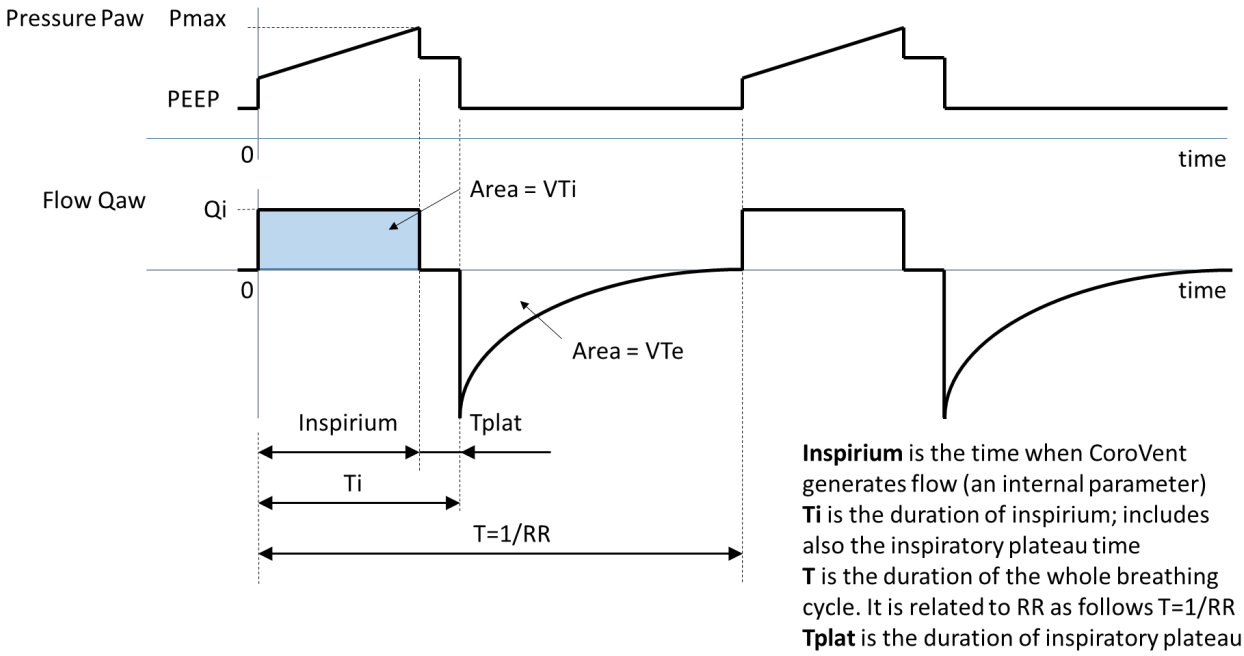


Fig. 10: Significance of individual, controlled breath parameters

The following items are intended to set the ventilation parameters:

1. Rotating controllers on the front panel of the device (Fig. 11) - used to set PEEP and Plim
2. Touch screen – serves for setting other ventilation parameters and access to alarms, etc.

WARNING! When starting the ventilator, the power cable must be connected to the ZIS socket (medical isolation system) or the VDO socket (very important circuits). The device cannot be switched on with the battery only.

CAUTION:

The rotating controllers for PEEP and Plim setting are equipped with arrest. By pulling the controller, the requested value can be set, by pressing it, the arrest is activated.

Plim represents the pressure limitation of the ventilation mode “pressure limited volume controlled continuous mandatory ventilation”. This is a pressure value, which may appear as the maximum in the patient circuit during a regular operation and ventilation. The minimum adjustable value is 15 cmH_2O and the maximum adjustable value is 45 cmH_2O.

Fig. 11: Rotating controllers for ventilation parameter setting – Plim (left) and PEEP.

The basic adjustable ventilation parameters and their range is given in Tab. 1.

Table 1: Basic ventilation parameters adjustable on the CoroVent device and their layout on the user interfaces.

User interface	Adjustable ventilation parameter	Setting range
Touch display	Tidal volume (VT) at RR: 20 breaths per minute and I:E 1:2	200–800 mL
	Respiratory rate (RR)	5–45 breaths per minute
	Inspirium to expirium ratio (I:E)	1:1–1:4
	Oxygen fraction in inspiratory mixture (FiO2)	21–100 %
Rotating controllers	Positive end-expiratory pressure (PEEP)	0–30 cmH2O
	Limit (inspiratory) pressure (Plim)	15–45 cmH2O

CAUTION:

The device allows only mandatory ventilation without the possibility of triggering by the patient's breathing effort).

The measured basic pressure and volume parameters are displayed continuously during ventilation (see Tab. 2). These data are obtained from the CoroQuant spirometer sensor.

Table 2: The parameters measured with the CoroQuant spirometer sensor and displayed continuously on the basic CoroVent device scree

Measure parameter	Unit
Inspiratory tidal volume (VTi)	mL
Expiratory tidal volume (VTe)	mL
Positive end-expiratory pressure (PEEP)	cm H_2O
Maximum pressure during inspirium (Pmax)[1]	cm H_2O
Plateau pressure (Pplat)	cm H_2O
Respiratory rate (RR)	Number of breaths per minutes
Inspiratory time to the total breath cycle time ratio	– (decimal)

[1]Note: The presence of HME filter causes an increase in measured Pmax value by units of cm H_2O. The real Pmax in the patient's respiratory system is always lower than the measured and displayed Pmax value.

To set the ventilation:

1. When the device is in ventilation off mode, turn on the device by the main ON-OFF switch on the rear panel of the device. The basic Standby mode screen appears (Fig. 12).
2. Set PEEP to 0 cmH2O: at first unlock the rotating controlled by pulling and then turn the controlled counterclockwise (in the "-" minus direction) as far as the stop.
3. Set the limit pressure (Plim) by the rotating controller to 25 cmH2O (the set value can be read on the pressure gauge labelled Plim above the rotating controller)
4. Na Select "**Start new patient ventilation**" on the touch screen**".**
5. The initial tidal volume (VT) is set to low, therefore set VT to the desired volume depending on the needs of a specific patient using the **"+ VT**" button, observe the current tidal volume on the ventilator display.
6. Set the desired RR respiratory rate and the I:E inspirium to expirium ratio.
7. Finally set PEEP to the desired value, while adjusting, observe the achieved value at the end of expiration on the Paw gauge to the right of the display and numerically on the display.
8. After setting the PEEP value, adjust the tidal volume value, which may change by changing the PEEP.

WARNING!

- The CoroVent device allows the mandatory ventilation only; there is no option for supported ventilation with a user-adjustable trigger. The patient connected to this ventilator has to be sedated adequately or even relaxed pharmacologically.
- Before starting ventilation, make sure that the PEEP pressure-reducing valve is set to 0 cmH_2O (fully turned in the "minus" direction").

WARNING!
Signaling of the alarm status is not activated for 3 breaths after start of the ventilation.

CAUTION:

- The abdominal patient position (so-called pronation position) is not considered contraindication to use of the CoroVent device.
- Before starting ventilation, check alarm settings (see sec. 20.6), using the "Setup" -> "Alarm Setup" option.

20.4 How to set ventilation parameters using the touch screen

When the CoroVent device is connected to the power supply source by a mains cable, screen of the switched off device appears (see Fig. 9). To activate the device in the Standby mode, turn on the device with the main ON-OFF switch on the rear side of the device. The Standby screen appears (Fig. 12).

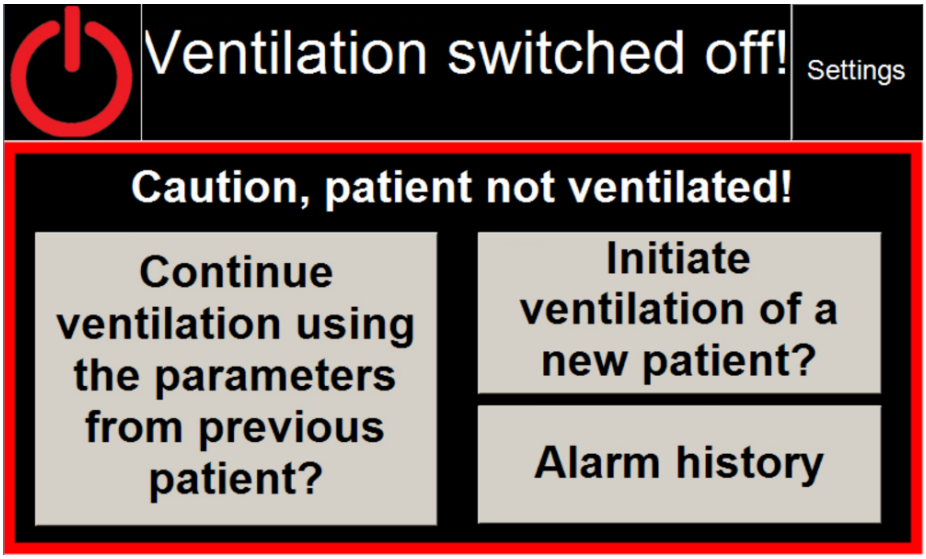


Fig. 12: Standby mode screen.

Activation and deactivation of the Standby mode is performed by pressing the symbol showing the current Standby mode status (see Fig. 13). Deactivation of the Standby mode starts ventilation. Activation of the Standby mode stops ventilation. Another option to deactivate the Standby mode and start ventilation is to select the option "**Start ventilation of a new patient?**" on the Standby mode screen.

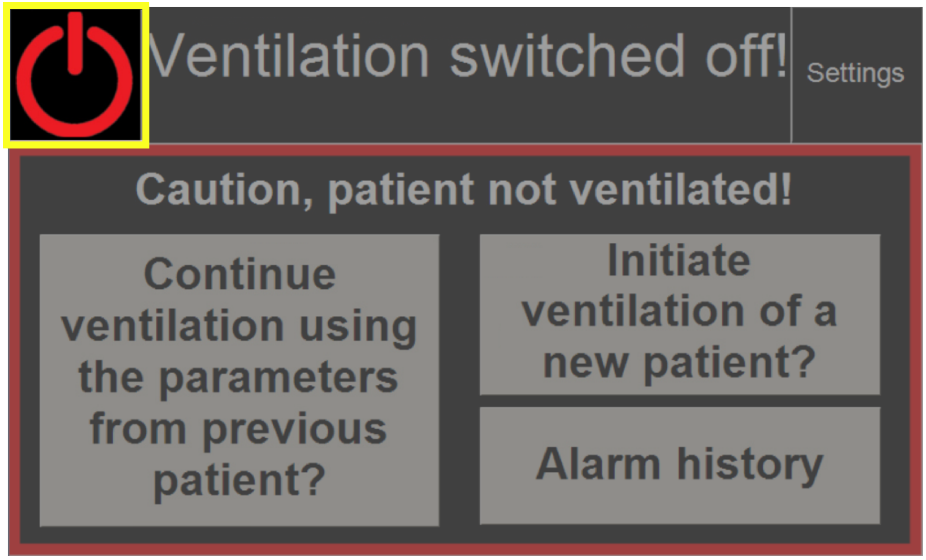


Fig. 13: Layout of the Standby mode control.

When the ventilation is off, the Standby mode is active and a red symbol is displayed in the upper left corner of the screen (Fig. 14):

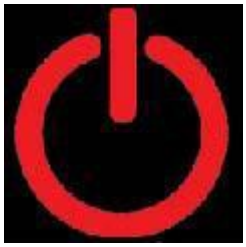


Fig. 14: Symbol at switched off ventilation - active Standby mode.

When clicking on the switched off ventilation symbol (Fig. 14), the dialog box for confirming the switched on ventilation, as shown in Fig. 15, will be displayed. After confirming that the ventilation is switched on by clicking “OK”, the ventilation will be started. By clicking on “Cancel”, the dialog box will be closed and ventilation will not be started.

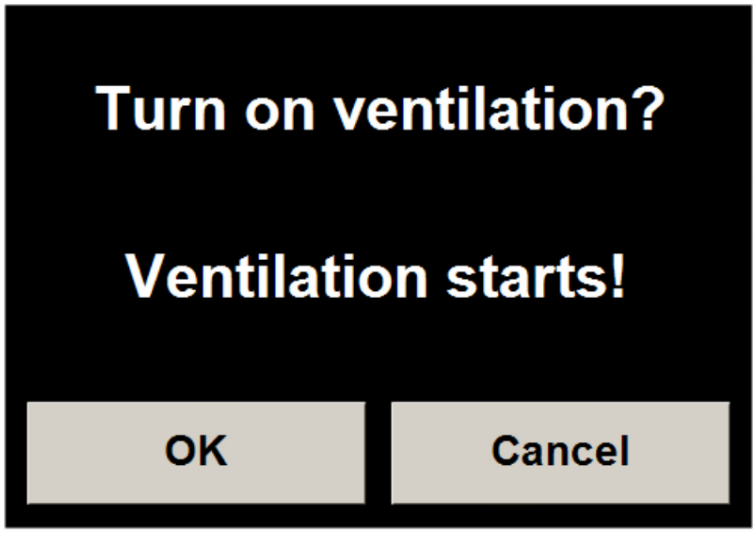


Fig. 15: Dialog box for start of ventilation

With the ventilation on, the Standby mode is deactivated and the white symbol shown in Fig. 16 is displayed in the upper left corner of the screen.

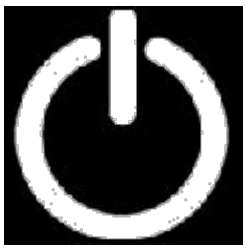


Fig. 16: White symbol when the ventilation is on.

Ventilation can be started on the main Standby mode screen (Fig. 12). After clicking on "**Continue ventilation with parameters of the previous patient?**", ventilation with the previous patient's settings will be started, including alarm limit settings. After clicking on "**Start ventilation of a new patient?**", ventilation will be started with the factory default settings.

If the ventilation is on, the main screen is displayed (Fig. 17). The values shown in green are the ventilation parameters that can be changed by clicking omn the appropriate box. The following parameters can be set:

- FiO_2 oxygen fraction in inspiratory mixture (%)
- VT tidal volume (its increase or decrease by one step)
- RR Respiratory rate (bpm)
- I:E inspirium to expirium ratio

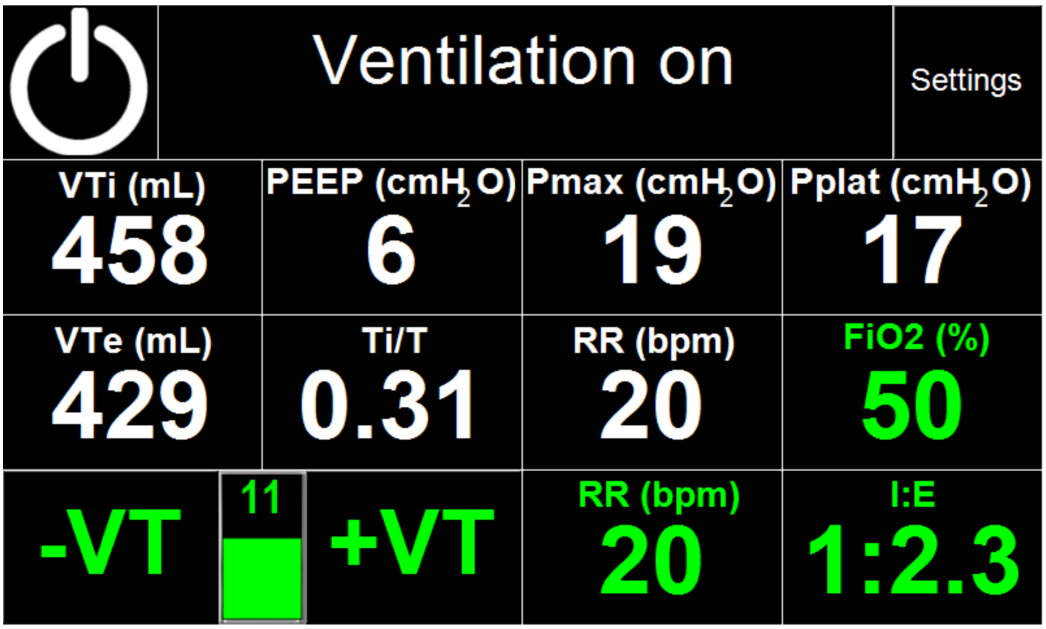


Fig. 17: Main screen when the ventilation is on

When clicking on FiO2, I:E and RR, a dialog box will be displayed where you can change values of these parameters. The procedure for changing the values will be described below.

The VT tidal volume is set by clicking on **"–VT**" (to decrease the ventilation volume) and by clicking on **"+VT**" (to increase the ventilation volume). The VT level is expressed by a power value (number between 1 and 19, see Fig. 17) and the ventilation volume indicator shown in Fig. 18, including the maximum and minimum values.

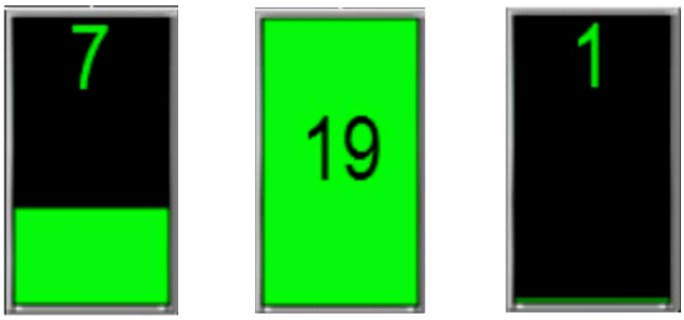


Fig. 18: Indicator of the set tidal volume – just set (left), maximum (centre) and minimum (right).

To set the values, use the dialog box in Fig. 19. By clicking on the horizontal slider path, the desired value is set. By clicking on the "**MIN**" field, the lowest possible value of the parameter is set (displayed in this field). By clicking on the "**MAX**" field, the highest possible value of the parameter is set (displayed in this field). It is also possible to decrease the value by clicking on the box marked with the **- (minus)** symbol. It is also possible to increase the value by clicking on the **+ (plus)** field. If you do not want to change the settings, press "**Cancel**" to return to the main screen. If the setting is not confirmed by pressing "**OK**", the parameter remains at the last confirmed value.

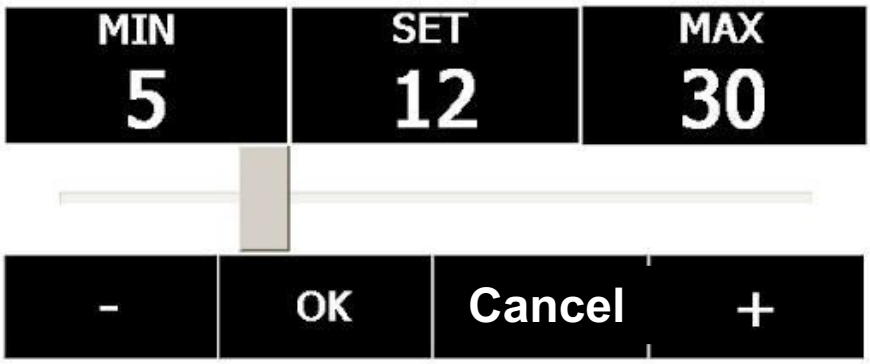


Fig. 19: Dialog box for setting values.

The values, displayed in white on the main screen, are the measured values and cannot be changed by pressing.

Measured values:

- Inspiratory tidal volume VTi (mL)
- Expiratory tidal volume VTe (mL)
- Positive end-expiratory pressure PEEP (cmH_2O)
- Maximum pressure in inspirium Pmax (cmH_2O)
- Plateau pressure Pplat (cmH_2O)
- Inspiratory time to breath cycle duration ratio Ti/T
- Respiratory rate RR (bpm).

CAUTION:

- The PEEP value can be changed using the rotating controller, but cannot be changed on the touch screen - only the measured PEEP value is displayed here).
- You can change the respiratory rate on the main screen by pressing the green RR button. The white RR value is the actually measured respiratory rate.

The status screen displays the current status of the CoroVent device. Its layout is yellow framed in Fig. 20. The current status depends on whether the ventilation is on or off and whether or not any of the possible alarms is active.

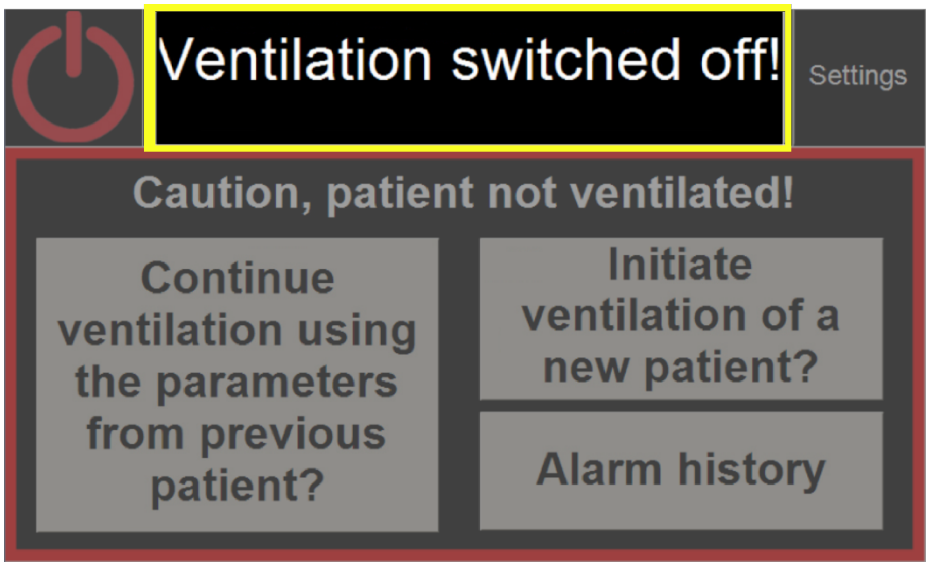


Fig. 20: Layout of the status screen.

If one or more alarms are active, the alarm table is displayed on the status screen. When the cause of the activated alarm is eliminated and the alarm silence button pressed, the corresponding alarm will be removed from the table.

The table is able to display four active alarms simultaneously as a maximum. If all active alarms do not fit in the table, you can scroll through the table using the scroll bar located on the right side of the table (see Fig. 21).

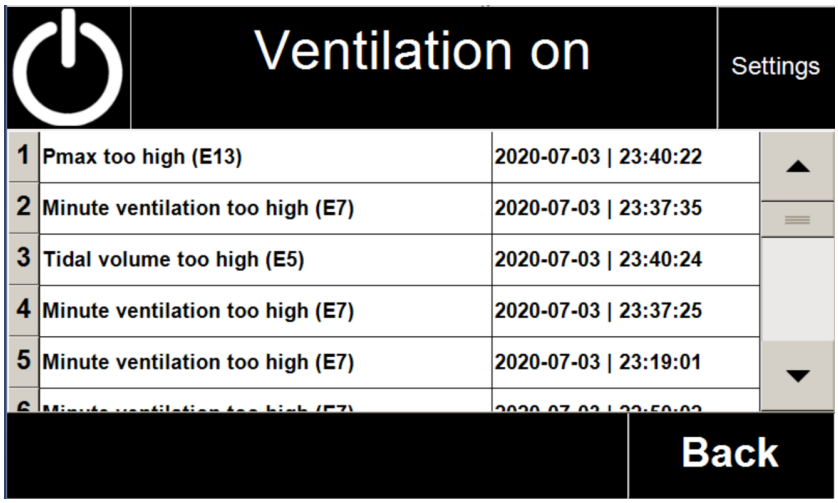


Fig. 21: More alarms displayed using a scroll bar.

To stop the ventilation, press the white symbol to activate the Standby mode (see Fig. 16). A dialog box asking "**Stop ventilation? Ventilation will be stopped!**" will be displayed. Confirm the end of ventilation by pressing "OK". Select "Cancel" to continue patient ventilation".

20.5 Setup menu

When clicking on the "**Settings**" button shown in Fig. 22, a menu for device setting will be displayed on the main screen (Fig. 23).

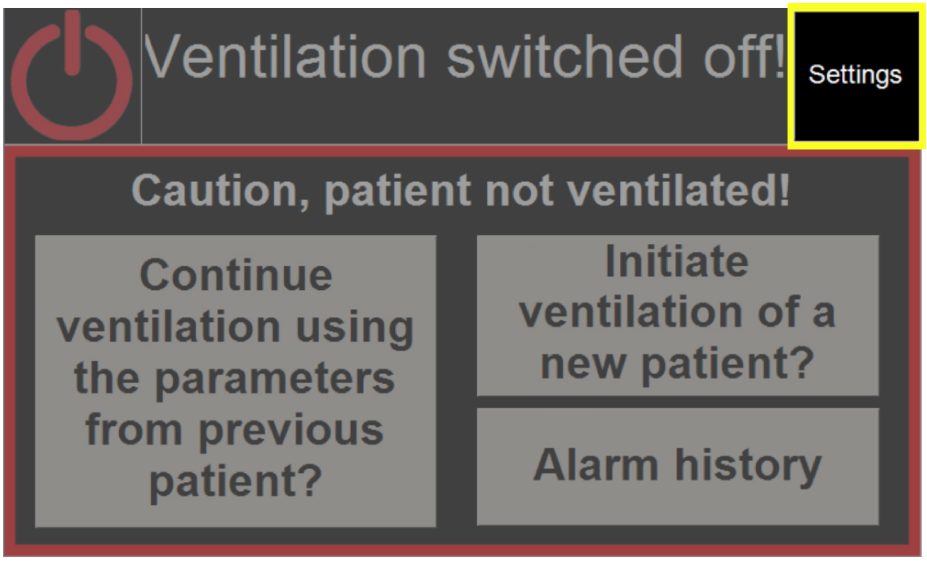


Fig. 22: Layout of the button for entering the Setup menu.

To return back to the main screen, press the button **“Back”**.

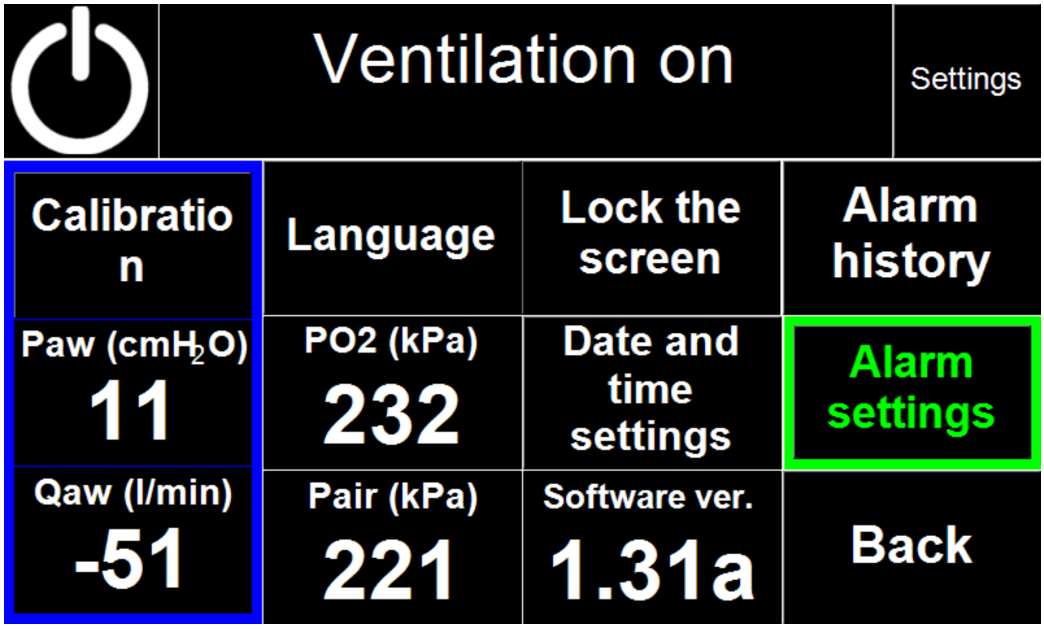


Fig. 23: Setup menu of the device.

20.6 How to set limit alarm values

Alarm limit setting is available in the "**Setup**" menu by selecting "**Alarm Setting**" (see Fig. 24). The list of the available minimum and maximum alarm limit values, including the factory presets, can be seen in the Table 3 below. The factory preset alarm limit values always appear when a new patient ventilation is initiated. The set limit values are preserved during the continuing ventilation.

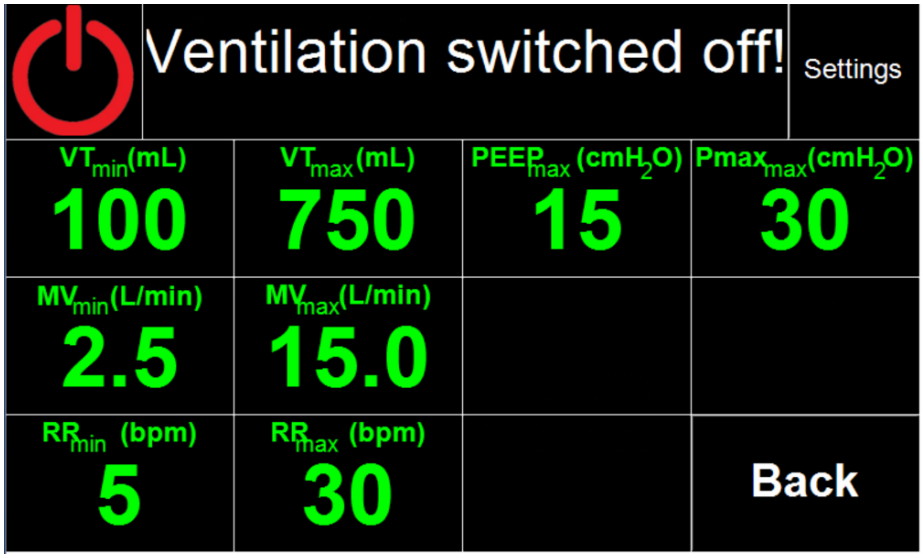


Fig. 24: Alarm setting menu.

Alarms are indicated in text on the CoroVent device display, and audible and optical signaling is activated at the same time. The activated alarm can be silenced by the button with a picture of the bell on the display (Fig. 25). The alarm message text appears in the white field on the main screen of the device (see Fig. 21). If there are more alarm messages, a scroll bar appears on the right allowing to scroll through the messages.

Fig. 25: Symbol for silencing the audible alarm signaling.

When the symbol for silencing the audible alarm signaling is pressed (Fig. 25), the audible alarm is deactivated for 120 s. If the alarm situation persists, after expiry of this time period, the alarm will be re-activated.

CAUTION:

The alarm limits can be reset to the factory presets upon start of ventilation of a new patient. Prior to use in any patient, operator of the device must check whether the set alarms are appropriate for the patient in question.

WARNING!

- Alarm limits setting to the extreme values can result in malfunction of the alarm system.
- If different alarm presets are used on the same or similar device in the same area, dangerous situations may occur.

CAUTION:

In case of power failure, the alarm system is reset to the factory-set configuration. If the power supply is interrupted for 30 seconds or less, the alarm setting is restored automatically to the state before the blackout.

Table 3: Alarm limits in the "Alarm setting" menu and their factory presets.

Parameter	Units	Factory preset	Minimum setting	Maximum Setting
VT_{min}	mL	100	100	750
VT_{max}	mL	750	250	1000
MV_{min}	L/min	2.5	0.5	10
MV_{max}	L/min	15.0	2.0	25.0
RR_{min}	bpm (breaths per minute)	5	5	25
RR_{max}	bpm (breaths per minute)	30	10	30
$PEEP_{max}$	cmH_2O	15	3	30
$Pmax_{max}$	cmH_2O	30	15	45

20.7 Language setting

The ventilator can communicate in several languages. After pressing “Language” or „Jazyk“ on the setup screen (Fig. 23), a language selection screen appears (Fig. 26.). A desired language can be selected by pressing the corresponding button.

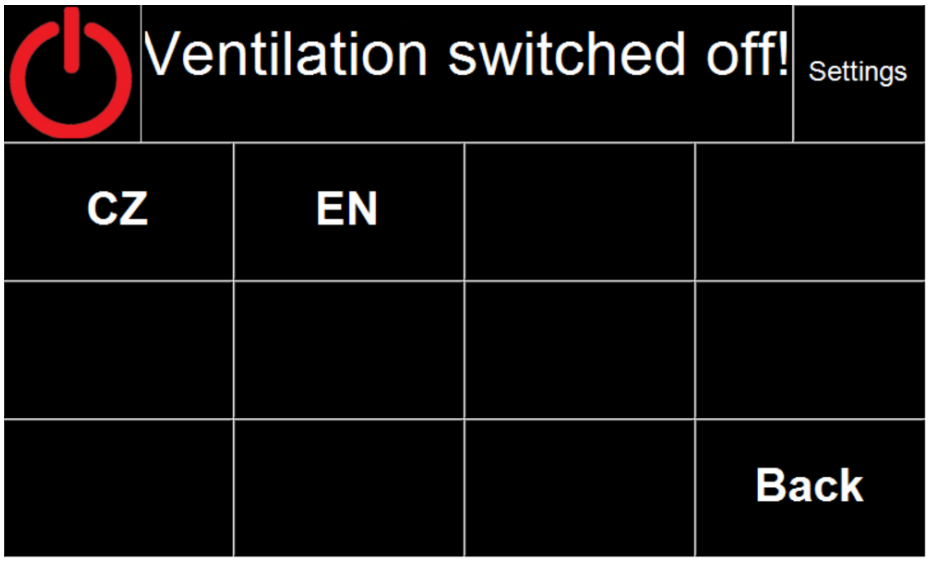


Fig. 26: Language selection screen.

20.8 Date and Time setting

By pressing “Date and time setting” on setup screen (Fig. 23), the date and time setting screen opens (Fig. 27). Setting date and time is analogous to setting of ventilatory parameters described in chapter 20.3, Fig. 19.

The time setup screen (Fig. 27) contains too the runtime of the CoroVent device. The time counting starts by the first switch on device. The counted time cannot be influenced. It contains too the production time which is intended for setting and testing.

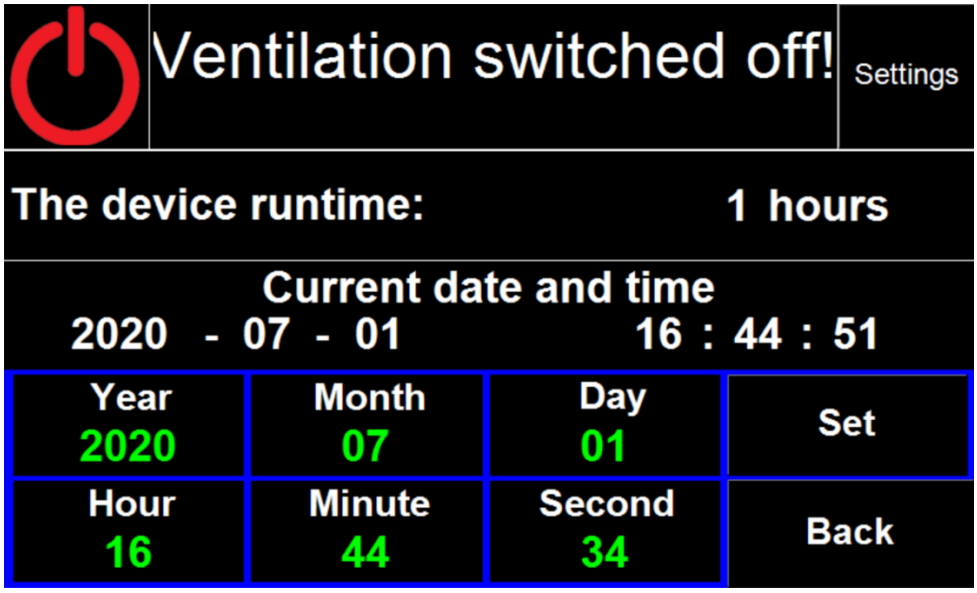


Fig. 27: Date and time setting screen.

20.9 Lock Screen function

The “**Lock screen**” function in the Setup menu deactivates the touch screen.

CAUTION:

Changes of ventilator setting cannot be performed if the screen is locked.

If the screen is locked, the display is black and the “**Click here to unlock**” message box moves across it (Fig. 28). By pressing this field twice, the system will be returned to the setup menu.

Fig. 28: Unlock field on a locked touch screen.

Use the “Lock screen” option to deactivate the screen, e.g. for wiping the touch screen or for handling the CoroVent device, which could lead to inadvertent activation of the button on the screen.

20.10 Switching off the device

To switch off the device, complete ventilation of the patient at first. Then switch off the device by the main ON-OFF switch. If you try to turn off the device with the main power switch while ventilation is still in progress, the warning message "**You have turned off the power switch. Do you really want to switch off the device? To continue ventilation, turn on the main switch on the rear side of the device**" appears. To confirm the switch off, click on the "Switch off" button.

If you do not want to switch off the device, press the main ON-OFF switch again.

21. List of system alarms and their meaning

The complete list of alarms, their trigger conditions and response of the ventilator to their activation are contained in Tab. 4.

Tab. 4: List of alarms, their trigger conditions and response of the ventilator to their activation.

Alarm No.	Alarm text	Trigger condition	Response
1	Failure of the device – service – ventilation is OFF (E1)	Failure of el. circuit controlling the valves	Ventilation switching off
2	Inadequate oxygen source pressure (E2)	PO2 < $PO2_{min}$ for > 1 s	NA
3	Inadequate air source pressure (E3)	Pair < $Pair_{min}$ for > 1 s	NA
4	Too low tidal volume (E4)	VTe < VT_{min} for > 3*1 / RR after the ventilation is switched on	NA
5	Too high tidal volume (E5)	VTe > VT_{max} for time period (1)	NA
6	Too low minute ventilation (E6)	MV < MV_{min} for time period (1)	NA
7	Too high minute ventilation (E7)	MV > MV_{max} for time period (1)	NA
8	Too low respiratory rate (E8)	RR < RR_{min} for time period (1)	NA
9	Too high respiratory rate (E9)	RR > RR_{max} for time period (1)	NA
10	To high PEEP (E10)	PEEP > $PEEP_{max}$ for time period (1)	NA
12	Power supply failure. Work with backup battery (E12)	Network power supply failure. Work with backup battery for > 1 s	NA
13	High pressure in the patient (E13)	Pmax > $Pmax_{max}$ (evaluated during ventilation, not in standby mode	N A
14	Failed cooling of the device (E14)	Interrupted cooling of the device for time period > 3 s	NA
15	Failed Paw sensor (E15)	El. failure of Paw sensor	NA
16	Failed Qaw sensor (E16)	El. failure of Qaw sensor	NA
17	Failed air pressure sensor (E17)	El. failure of the Pair sensor	NA
18	Failed O2 pressure sensor (E18)	El. failure of the PO2 sensor	NA
19	Disconnection or leakage (E19)	Time of inspirium > 6 s for time period (1) and (2)	NA
20	Disconnection or leakage (E20)	VTe < (0.7*VTi) for time period (1) and (2)	NA
21	Disconnection or leakage (E21)	VTi < (0.65*SetVTi) and at the same time PEEP < 0.25*PMAX for time period (1) and (2)	NA

23	High pressure (E23)	P150 > 55 cmH_2O. P150 is the average value of Paw during the last 150 ms.	Automatic initiation of expiratory phase
24	Both gases are necessary for operation of the device (E24)	Pair < $Pair_{min}$ for > 1 s	No ventilation of a patient!
99	High oxygen and air working pressure difference - service (E99)	/Pair – PO2/ > $Pindif_{max}$	NA

Notes:

1. 3 * 1 / RR time, which is valid after the ventilation is started (when the Standby mode is deactivated). After expiry of this time, the alarm in question is checked without any delay.
2. 2 * 1 / RR, which is valid after the RR or VT requested value has been changed. After expiry of this time, the alarm in question is checked without any delay.

22. Service and settings

You can access the service settings by selecting the **Setup** option on the basic screen and then by selecting the "**Service menu**". When entering this menu, it is necessary to load the service security code using the displayed numeric keypad.

CAUTION: Changes of settings in the "Service menu" can fundamentally change the CoroVent ventilator function parameters and are intended for the authorized staff only.

Changes in the settings may only be made by a qualified person who is familiar with the internal functions of the ventilator and authorized by the manufacturer to make such changes.

The service menu is not intended for CoroVent ventilator users.

The Service menu allows setting of internal ventilator variables, diagnostics of the ventilator and its equipment. Service settings are subject to a separate *Service Manual*.

23. Care and maintenance

23.1 Transportation and storage

Do not expose the CoroVent device to extreme conditions during transportation - temperature, dust, vibrations, humidity.

The CoroVent device must be secured against tipping over during transportation.

WARNING!
After transportation, allow the unpacked device to acclimate at the room temperature for at least 30 minutes prior to its first connection to the power supply source**.**

CAUTION:
Weight of the CoroVent device is 20 kg (44 lbs) without accessories**.**

Conditions of storage of the CoroVent device are shown in Tab. 5.

Table 5: Conditions of storage of the CoroVent device.

Ambient temperature	15 –30°C
Pressure	700 – 1100 hPa (700 – 1100 cm H_2O)
Air humidity	30 – 90 %, non-condensing

23.2 CoroVent ventilator maintenance and repairs

The ventilator requires periodic safety checks and preventive maintenance every year.

The date of the manufacturing or the date of the last preventive maintenance is marked on the label, supplemented with the date of the next required preventive maintenance.

Maintenance, repairs and safety technical inspections may be performed only by the service technician trained by the manufacturer.

23.3 Battery replacement

Only a service technician trained by the manufacturer may replace the battery.

The battery can only be replaced when the 230 V power supply source is disconnected.

Replace the battery as needed, every 3 years as a maximum.

23.4 Cleaning and disinfection

This chapter provides information about maintaining the surface and accessible parts of the CoroVent lung ventilator. It describes regular preventive maintenance, cleaning, disinfection and sterilization of parts and components of the device.

CAUTION: To clean and disinfect the device, always disconnect the ventilator from the power supply source to reduce the risk of electric shock.

A. Outer surfaces

The outer surfaces of the ventilator can be cleaned with antimicrobial surface disinfectants approved for critical medical devices.

Do not use abrasive materials (such as steel wool or mechanical metal polish) to treat surfaces.

Do not spill liquids on surfaces of the device.

B. Touch screen

Touch screen cleaning is possible with neutral detergents, isopropyl alcohol and a soft cloth.

CAUTION: No chemical solvents, alkaline or acidic reagents may be used to clean the touch screen.

C. The interior of the ventilation unit

The interior of the unit is protected from microbial contamination by antibacterial filter on the patient end of the breathing circuit.

DO NOT attempt to sterilize ventilator internals. In case of contamination of interior air passway, contact the manufacturer.

Do not sterilize the ventilator as a whole, i.e. in ethylene oxide (ETO).

D. General considerations

Action of detergents and disinfectants can reduce service life of certain components, especially the plastic ones and the CoroVent ventilation unit touch screen.

Penetrating fluids into the device and immersing components into the liquid will damage the device.

DO NOT reuse antibacterial filters, flow sensors, or other disposable accessories. These parts must always be disposed safely after use. Proceed in accordance with regulations of the medical facility.

Handle antibacterial filters with care to avoid their mechanical damage and risk of bacterial infection. Dispose the filters immediately after their use. Proceed in accordance with regulations of the medical facility.

The patient circuit can be used on the disposable or re-sterilizable basis - follow local recommendations for circuit handling.

Replacement of the patient circuit is necessary every 7 days as a minimum.

The expiratory valve and spirometer probe/sensor are disposable consumables, and if a new patient is connected to the device, all these parts have to be replaced for the new ones. None of these parts is re-sterilizable.

The expiratory valve must be replaced after max. 7 days of operation.

The CoroQuant spirometer probe/sensor must be replaced after 7 days of operation.

WARNING!
To avoid microbial contamination and possible functional problems, do not clean, disinfect, or reuse disposable components intended for use in one patient only. Dispose them in accordance with the local and institutional regulations.

24. Disposal of the device

If the device has to be retired and disposed, it can be done in the way usual for this type of device, but only after removal of the lead-acid battery.

The accumulator battery must be disposed correctly, not with the household waste. The battery is the led-acid battery type.

The device does not contain any toxic materials (except the battery as above) that could cause environmental damage if disposed in the way usual for standard electrical equipment.

25. Specification of consumables

Periodic replacement of consumables is required for safe operation of the CoroVent device.

In addition to the common consumables used for the patients on invasive artificial lung ventilation, use of the following items is necessary for the CoroVent device:

1. patient circuit (with passive humidification) – a standard consumable; it shell comply with ISO 5367:2014,
2. filter with heat and moisture exchanger (HME) – a standard consumable. Any HME filter used with CoroVent shall comply with ISO 9360-1:2000 or ISO 9360-2:2001 and with the relevant requirements of ISO 23328-1:2003 and ISO 23328-2:2002.
3. expiratory valve with connection hose for pressure control (CoroExsp, MICo type, CR),
4. spirometer probe/sensor (CoroQuant, MICo type, CR).

WARNING!
For safe operation of the ventilator, the patient circuit without active humidification has to be used. It is necessary to use the HME type filter (with heat and moisture exchanger). As the CoroVent device is used in highly infectious Covid-19 patients, absence of the antimicrobial filter results in creation of a highly infectious aerosol.

CAUTION:
The expiratory valve is a disposable consumable; a new valve must be used for each individual patient.

The responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.

26. Operating conditions

Operating conditions are shown in Tab. 6.

Table 6: Specified operating conditions.

The device may only be used under the following operating conditions:	
Place of use	- designed for indoor use in health care facilities - in a dust-free environment free from aggressive vapors and gases, away from direct reach of sunlight
Ambient temperature	15–30°C
Pressure	700 – 1100 hPa (700 – 1100 cm H_2O)
Air humidity	30 – 90 %, non-condensing
Working position	horizontal
Air and oxygen pressure in the distribution line	300 – 700 kPa (3 000 – 7 000 cm H_2O) according to ČSN EN ISO 7396-1
Power supply	network 100 V – 240 V / 50 – 60 Hz ~

27. Technical parameters

Technical parameters of the CoroVent ventilator are shown in Tab. 7.

Table 7: Technical parameters of the ventilator.

Max. power input	150 VA
Dimensions: height length width	 47 cm 50 cm 20.5 cm
Weight	20 kg (44 lbs)
Noise level	max. 60 dB
Classification of the device from the point of el. safety	Class of protection I
Characteristics of the attachment part of the device	B type Patient circuit of the ventilator (inspiratory and expiratory branch connected by the patient Y-coupling and CoroQuant spirometer probe/sensor with connection hoses
Degree of protection	IP21
Accuracy of pressure measurement	±(2 hPa (2 cmH_2O) + 4 % of the real value)
Accuracy of volume measurement	±(4 mL + 15% of the real supplied volume)

Manufacturer	MICo spol. s r. o. Sycheniova 270/6 674 01 Třebíč

Annex I – EMC parameters

Electromagnetic radiation		
The device is intended for use in the electromagnetic environment specified below. User of the device must ensure that the device is really used in the specified environment.		
Radiation test	**Compliance**	**Electromagnetic environment**
High-frequency radiation CISPR 11	Group 1	The device uses high frequency energy only for their own internal functions. For this reason, the high frequency emissions are very low and it is unlikely to cause any interference to nearby electronic devices.
High-frequency radiation CISPR 11	Class B	The device is suitable for use in medical facilities.
Harmonic radiation IEC 61000-3-2	Class A	
Voltage fluctuations / flicker IEC 61000-3-3	Pass	

Electromagnetic resistance			
The device is intended for use in the electromagnetic environment specified below. User of the device must ensure that the device is really used in the specified environment.			
Test of resistance	**Test level according to IEC 60601**	**Satisfactory level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±8KV for contact ±2KV, ±4KV, ±8KV, ±15KV for air	±4KV for contact ±2KV, ±4KV, ±8KV for air	Floors in the rooms have to be: - wooden - concrete - of ceramic tiles - floors covered with synthetic material (non-antistatic linoleum) - relative humidity in the rooms must be min. 30%
Electrical fast transient / group of pulses IEC 61000-4-4	±0.5KV, ±2KV for feeding lines ±0.5KV, ±1KV, ±2KV for input /output lines	±0.5KV, ±2KV for feeding lines ±0.5KV, ±1KV, ±2KV for input /output lines	The quality of the electrical network should be of a quality typical of commercial and hospital environments.
Surge pulse IEC 61000-4-5	±1KV between the lines ±2KV between the Lines and ground	±1KV for differential mode ±2KV for common mode	The quality of the electrical network should be of a quality typical of commercial and hospital environments.

Short-term voltage drop, Short interruptions and slow voltage changes on the feeding Inlet line IEC 61000-4-11	0% Ut per 0.5 cycle (short-term blackout) 0% Ut per 1 cycle (short-term blackout) 0% Ut per 250/300 cycles (short-term blackout) 75% Ut per 25/30 cycles (short-term Ut drop)	0% Ut per 10ms (short-term blackout) 0% Ut per 20ms (short-term blackout) 0% Ut per 5s (short-term blackout) 75% Ut pera 500ms (short-term Ut drop	The quality of the electrical network should be of a quality typical of commercial and hospital environments.
Magnetic field of power line frequency (50-60Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of frequency of power networks should be at levels characteristic of commercial or hospital environments.
Radiated high Frequency IEC 61000-4-3	80 MHz - 2,5 GHz: 3 V/m 80 MHz - 2,5 GHz: Up to 28 V / m in ISM bands according to the table 9 ČSN EN 60601-1-2 ed.3	3 V/m and 28 V/m	Recommended minimum distance of portable and mobile high frequency transmitters with transmission power PEIRP from the medical devices, including his cables: 1,84m x $\sqrt{P_{EIRP}[watts]}$
high frequency interference IEC 61000-4-6	150 kHz - 80 MHz: 6 V in ISM bands 150 kHz - 80 MHz: 3 V out ISM bands	3V and 6V	Recommended minimum distance of portable and mobile high frequency transmitters with transmission power PEIRP
Ut is the AC line voltage prior to applying the test level			