FLIGHT MEDICAL INNOVATIONS LTD.

Ventoux Ventilator

Operator's Manual

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Legal Notice

Disclaimer

FLIGHT MEDICAL INNOVATIONS LTD. (FLIGHT MEDICAL) provides this Operator's Manual in its commitment to help reduce patient risk and injury. However, this manual is not intended to in any way replace or substitute duty of care to a patient, professional responsibility, or professional judgment, nor is it intended to provide any warranty, promise, guarantee, assumption of risk or duty, release, or indemnity. Physicians shall at all times maintain responsibility for patient treatment and outcomes, and FLIGHT MEDICAL further assumes no liability for patient treatment or outcome or for operator's negligence, breach of duty of care, or malpractice.

The Ventoux Ventilator operator is solely responsible for selecting the appropriate level and method of patient monitoring. Product modification or misuse can be dangerous. FLIGHT MEDICAL disclaims all liability for the consequences of product alterations or modifications (including the use of spare parts and batteries that were not manufactured by Flight Medical), as well as for the consequences which might result from the combination of this ventilator with other products, whether supplied by FLIGHT MEDICAL or by other manufacturers, unless such a combination has been specifically endorsed by FLIGHT MEDICAL.

The design of VENTOUX Ventilator, the Operator's and Service Manuals, and the labeling on the ventilator, take into consideration that the purchase and use of the equipment is restricted to trained professionals, and that certain inherent characteristics of the ventilator are known to the operator. Instructions, warnings, and caution statements are therefore limited to the specifics of the VENTOUX Ventilator.

Federal law (US) restricts this device to sale by or on the order of a physician.

This Operator's Manual excludes references to various hazards which are obvious to medical professionals and operators of this equipment, to the consequences of product misuse, and to potential adverse effects in patients with abnormal conditions.

When the VENTOUX Ventilator is used in sub-acute environments, only properly trained personnel should operate the ventilator. The VENTOUX Ventilator is a restricted medical device designed for use by respiratory therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

Transport of patients with the VENTOUX Ventilator requires that medical staff have a good working knowledge of the ventilator's use and problem resolution. Proper emergency backup equipment must be immediately available during transport.

VENTOUX Ventilator operators must recognize their responsibility for implementing safety monitoring mechanisms which supply appropriate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of means, such as electronic surveillance of equipment performance and patient condition. However, equipment surveillance should not replace direct observation of clinical signs.

The liability of FLIGHT MEDICAL is subject to and limited to the exclusive terms and conditions as set forth herein. Said liability is limited whether arising out of, or related to, the manufacture and sale of goods, their installation, demonstration, sales representation, use, performance, or otherwise. Any liability based upon product warranty is limited regardless of any fault attributable to FLIGHT MEDICAL and the nature of the action (including breach of warranty, negligence, and strict liability).

The written warranties are in lieu of all other warranties, expressed or implied, including, without limitation, warranties of merchantability, fitness for any purpose, or non-infringement.

FLIGHT MEDICAL shall not be liable for any special incidental or consequential damages incurred by the buyer to a third party. The buyer shall not be entitled to make liability recoveries from FLIGHT MEDICAL due to such situations.

Warranty

The VENTOUX Ventilator warranty does not apply for/ in case of:

- Defects caused by misuse, mishandling, tampering, or by modifications not authorized by FLIGHT MEDICAL or its representatives.
- Rubber and plastic components and materials, which are guaranteed to be free of defects at time of delivery.

Any product which proves during the warranty period to be defective in workmanship or material, will be replaced, credited, or repaired. FLIGHT MEDICAL retains the discretion to select the most suitable of these options. FLIGHT MEDICAL is not responsible for deterioration, wear, or abuse. In all cases, FLIGHT MEDICAL will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

- FLIGHT MEDICAL or its authorized representatives must be promptly notified upon detection of the defective material or equipment.
- Defective material or equipment must be returned to FLIGHT MEDICAL or its authorized representative.
- Examination by FLIGHT MEDICAL or its authorized representatives must confirm that the defect is covered by the terms of this warranty.

The above is the sole warranty provided by FLIGHT MEDICAL. No other warranty, expressed or implied, is intended. Representatives of FLIGHT MEDICAL are not authorized to modify the terms of this warranty.

In no way does this or any of FLIGHT MEDICAL's policies, training materials, guidelines, or instructions create an obligation for FLIGHT MEDICAL to perform any services.

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1 Introduction

The VENTOUX Ventilator is an electrically powered, microprocessor-controlled multi-parameter ventilator, which can be: Time, Pressure, Flow or Volume triggered; Volume or Pressure controlled; Time or Flow cycled.

Manual inflation is allowed, and the Ventoux supports the emergency intake of ambient air which permits the patient to pull ambient air into the breathing circuit in the event of a complete loss of air/gas supply.

Volume triggered is based on Inspiratory trig response time ≤100 ms from pressure drop/flow rise to PEEP level.

The inspiratory and expiratory gas pathway resistance is validated over a range of 5 to 200 cm H20/l/s and the compliance over a range of 3 to 100 ml/cm H2O.

Ventilation is possible in both Invasive and Noninvasive settings.

The system can be expanded to include additional parameter monitoring to allow for SpO_2, $etCO_2$ and Cuff Pressure Control.

The Ventoux can be powered by external power (100 – 240 VAC, 50-60 HZ or 10 – 30 VDC) and/or by its two swappable internal Li Ion rechargeable batteries, which provide full operating power the to the ventilator for a minimal operating time of 5 hours when operating on standard ventilation parameters.

The ventilator maintains accuracy of controlled and displayed under an array of pressure transducers, monitoring the airway & O_2 pressure and flow variables continuously. This includes periodic zeroing of the flow sensor and periodic purging. In addition, an FiO_2 sensor is integrated within the system. The active control is performed both via the Ventilator's turbine blower, and groups of solenoids which control gas pressure and flow.

Zeroing and Purge operations are performed automatically to keep the relevant sensors aligned.

The periodic auto zero function compensates for drifts in sensors. Barometric measurement is continuously monitored and corrected in real-time for flow and Oxygen. This automatic process eliminates variances that might otherwise cause measurement drift. Therefore, the module does not exhibit drift

The input flow for the oxygen is control by a solenoid valve, and for the air is controlled by a turbine engine. The maximal air flows of the Ventoux for air and O_2 are: Air – 220 l/min at free flow and O_2 – 110 l/min at free flow.

Maximal turbine RPM, combined with complete occlusion of the exhalation valve membrane is the means by which maximum working pressure is ensured.

	When assembling the breathing system, the User should pay special attention to any restrictions on the positioning of components within the ventilator breathing system.
	Transport of patients with the VENTOUX Ventilator requires that medical staff have a good working knowledge of the ventilator's use and problem resolution. Proper emergency backup equipment must be immediately available during transport.

This Operator's Manual contains information intended to ensure safe and effective use of the VENTOUX Ventilator.

1.1 Intended Use

The VENTOUX Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Ventoux is applicable for adult, and pediatric (i.e., infant, child, and adolescent) patients who weigh at least 5 kg.

The Ventoux Ventilator provide auto-leak compensation up to 100L/min allowing acute non- invasive ventilation.

The VENTOUX Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospitals, sub-acute emergency rooms, and emergency response applications.

Ventoux is intended for use on one patient at a time and is not intended to ventilate multiple patients at once.

1.2 Symbols

Symbol	Description
	**On/Off**
	**Mute**
	**Caution; consult accompanying documents (check symbol)**
	**Type BF applied part**

Symbol	Description
	**Double Isolation**
	**Temperature limitation**
	**Humidity limitation**
	**Atmospheric pressure limitation**
	DC – Direct Current
	**AC – Alternating Current**
	**USB – Universal Serial Bus**
	**LAN – Local Area Network**
O2 Vmax 15 l/min	**Low-Flow Oxygen Port**
O2 2.4 – 6.2 BAR 35 – 90 PSI	**High Pressure Oxygen Port**
	**MR unsafe – keep away from magnetic resonance imaging (MRI) equipment**
	**Dispose of according to standard local regulation requirements for electronic components**
	**EC Notified Body Approval**
	**Manufacturer address of device**

2 Safety Instructions

At all times, strictly follow this manual. The safe use of the VENTOUX Ventilator requires full understanding of its operation, and adherence to the manual's instructions. The equipment is only to be used for the purpose specified in Section 1.1. Observe all of the WARNINGS and CAUTIONS posted in this manual, and on buttons found on the VENTOUX Ventilator and associated accessories.

Notice: Any incident with the device leading to serious patient injury, death, or a potential threat to public health must be reported to the manufacturer and the relevant authorities.

2.1 General Warning

External power connection: The Ventoux is specially designed for 2-prong home use electrical, floating-ground, AC power connection. Always disconnect the external power supply prior to servicing.

Do not position next to a curtain that blocks the flow of cooling air, thereby causing the ventilator to overheat.

To prevent possible personal injury and equipment damage, including tipping:

– Lock the trolley’s wheels when parking the ventilator.

– Take care when crossing thresholds.

To prevent accidental extubation, check the patient tubing support arm joints and secure as necessary.

All settings and adjustments in the different ventilation modes must be made in accordance with a physician's prescribed therapy.

There is a risk of explosion if used in the presence of flammable anesthetics.

To prevent cross-contamination, always use a clean, disinfected patient circuit.

Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as pulse oximeter and/or capnography) when the Ventilator is in use on a patient.

In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death. If a fault is detected in the ventilator and its life support functions are in doubt, immediately discontinue use; use an alternative method of ventilation until the fault has been corrected and contact your provider or FLIGHT MEDICAL immediately.

Adding attachments, other components or sub-assemblies to the ventilator breathing system can change the pressure gradient across the breathing system which can adversely affect the ventilator performance.

The ventilator is ready for operation only when it is completely assembled.

Constant attention by qualified medical personnel is recommended whenever a patient is ventilated with the VENTOUX Ventilator.

Failure to identify and correct alarm violations may result in patient injury.

Ensure that the oxygen source is not empty before and during the use of the optional Air/Oxygen Entrainment Mixer.

When the "Batteries empty" alarm is issued, only a limited amount of battery power remains, and an alternate power source should be found immediately.

Only a FLIGHT MEDICAL approved patient circuit can be used when ventilating with a single limb patient circuit

To prevent patient contamination, always use a bacteria filter or HMEF between the patient and the inspiratory port.

Do not use unapproved / antistatic or electrically conductive patient circuits with the Ventoux.

For pediatric ventilation, ensure that the patient circuit type is suitable for pediatrics ventilation. The Ventoux Flow Sensor's dead-space is 19cc; consider using a Flow Sensor Pediatric Adaptor to reduce dead-space when ventilating pediatric patients.

Ensure that all of the components of the breathing circuit set, including but not limited to flow sensor, humidifier, and other accessories, match the associated intended use for the target patient group.

Only a FLIGHT MEDICAL approved exhalation valve can be used with the VENTOUX Ventilator

Always ensure that the Power LED is illuminated after connecting the ventilator to an external AC or DC power source. If the LED is not illuminated, check all power connections, and resolve any problems.

To avoid the risk of cross contamination, the disposable patient circuit must be discarded in a responsible manner according to local state procedures. The user should not clean, disinfect or sterilize the circuit for reuse.

Only an authorized FLIGHT MEDICAL factory-trained technician can service or perform repairs on the VENTOUX Ventilator.

MR unsafe – keep away from magnetic resonance imaging (MRI) equipment.

The Ventilator shall not be used with inlet gases, which are not specified for use such as nitric oxide or with helium or mixtures with helium. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.

The Ventilator accuracy can be affected by the gas added by use of a nebulizer

Nebulization or humidification can increase the resistance of breathing system filters and should be monitored frequently for increased resistance and blockage

Close suction catheter should always be used with proximal patient circuit connection

The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.

This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury."

2.2 Cautions

Only use medical grade oxygen with the high and low pressure ports.

As Lithium Ion batteries are charged and discharged over time, their ability to hold a charge is decreased with use. This can shorten the length of time the ventilator can function while on battery power.

The batteries should be replaced when they no longer meet the needs of the user. This depends on several factors including settings and usage patterns.

When the VENTOUX Ventilator is used for transport applications, ensure that the internal batteries are fully charged prior to use.

The flow resistance of the air inlet filter, located at the rear of the ventilator, is likely to increase with repeated use. Ensure that the filter is checked and changed regularly.

CAUTION

If you place an additional component, such as an HMEF, between the flow sensor and the patient, the additional resistance limits the ventilator's ability to identify disconnection at the patient. To correctly identify a patient disconnection, be sure to appropriately set the lower limit of the Pressure alarm, as well as the Volume alarm limits, and carefully monitor the patient's SpO2 and, if available, etCO2 values.

CAUTION

Do not cover the ventilator nor place liquid containers in the immediate vicinity or on top of the ventilator. Liquids that get into the ventilator can cause equipment malfunction and damage.

CAUTION

Do not open the ventilator or perform service on an open unit while connected to external power.

CAUTION

Use standard antistatic techniques while working inside the ventilator or handling any electronic parts.

CAUTION

To prevent cross-contamination, clean all external parts of the ventilator prior to servicing.

CAUTION

Water in the oxygen supply can cause equipment malfunction and damage.

CAUTION

When the ventilator is not likely to be used for a long period of time, remove the batteries.

CAUTION

Batteries contain Li-Ion. Do not discard them in an incinerator or force them open. Batteries should be disposed of according to WEE and not be disposed of with normal waste.

Review VENTOUX Ventilator Service Manual before servicing the ventilator.

	Use the tools and equipment specified in this manual to perform specific procedures.
	Charge the batteries for a minimum of three hours before powering the ventilator from the batteries. This provides fully charged batteries
	During storage, charge the batteries for a minimum of three hours every 30 days. This provides charged batteries.
	As good practice, always plug the VENTOUX Ventilator into an AC power supply source when not in use, to ensure best battery performance.

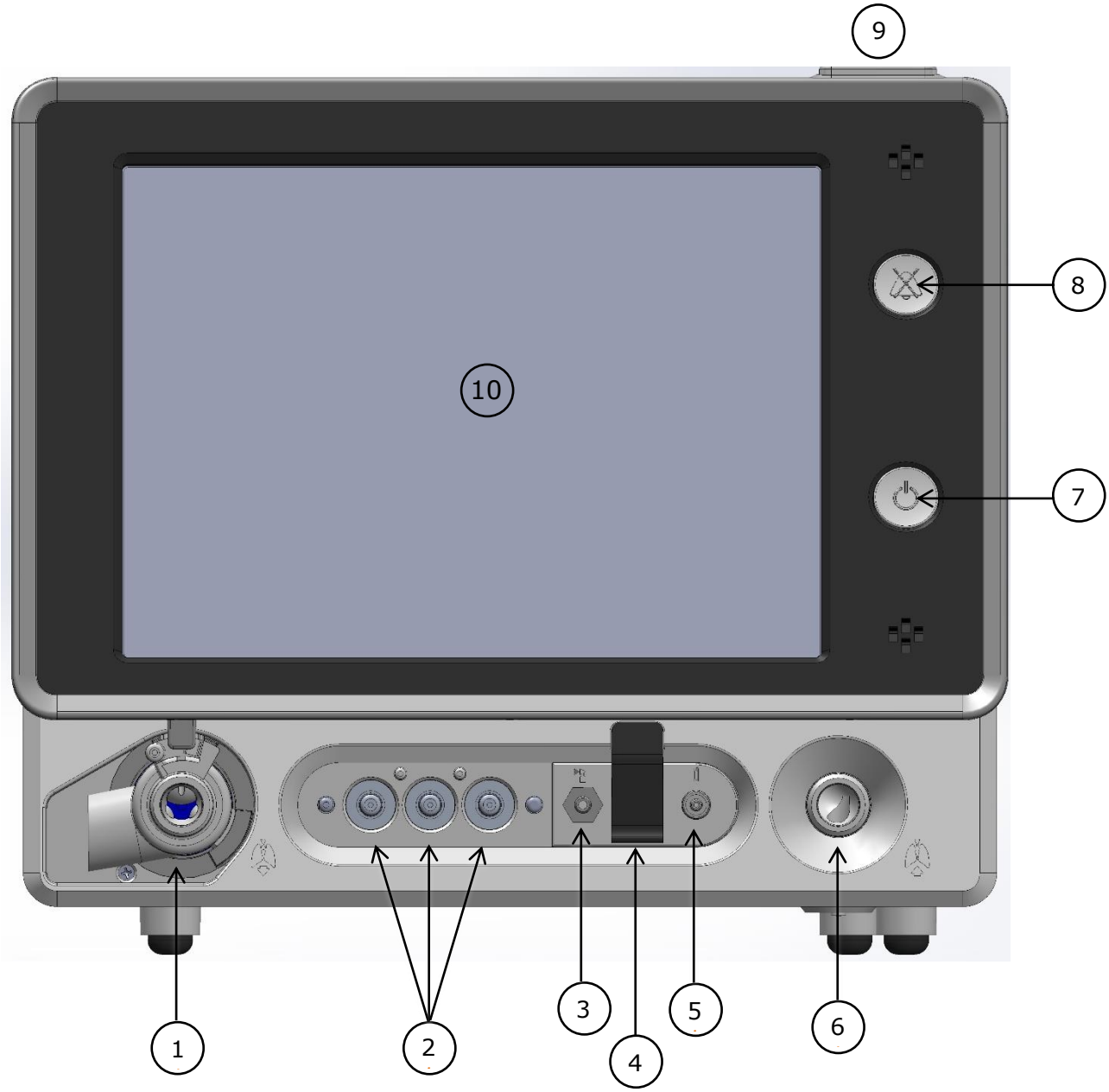
2.3 Contraindications

- The Ventoux is not intended for patients who weigh less than 5 kg
- To prevent possible patient injury, do NOT use noninvasive ventilation on patients with no or irregular spontaneous breaths. Noninvasive ventilation is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.
- To prevent possible patient injury, do NOT attempt to use noninvasive ventilation on intubated patients.
- Using noninvasive ventilation is contraindicated if any of the following conditions are met:
  a. The patient does not have the drive to breathe
  b. Partial or complete airway obstruction
  c. Gastrointestinal bleeding
  d. Anatomic or subjective intolerance of NIV interface
  e. Patient is unable to cooperate or protect Airway

3 Ventilator Description

3.1 Front Panel Features

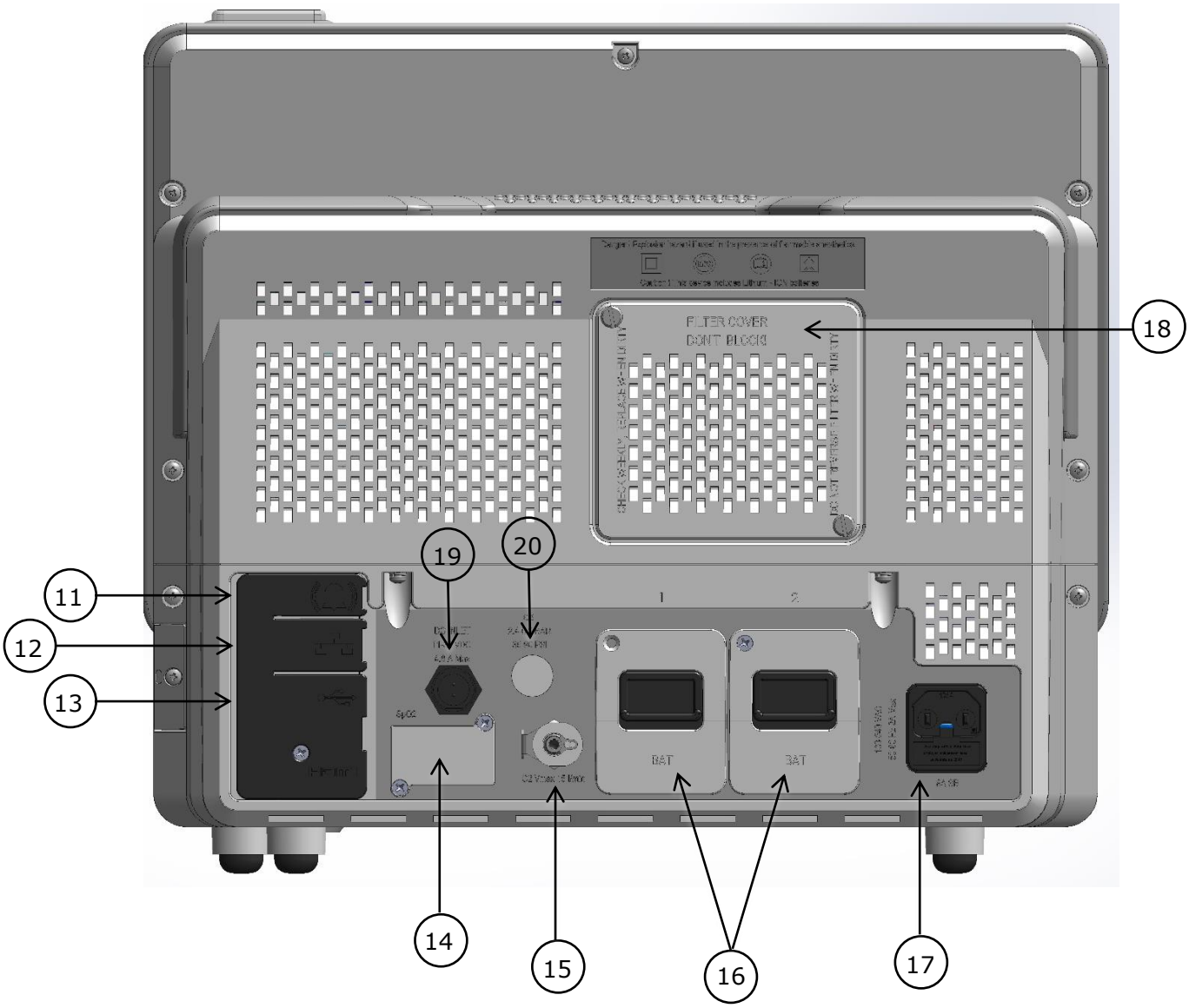
The front panel contains visual indicators, display screen, and patient circuit connection.



Front Panel

Item No.	Name	Description
1	Dual Limb Exhalation Valve	Connects the patient circuit expiratory limb.
2	Proximal Connection Ports	For Connecting to the patient circuit if a proximal flow sensor is used or single limb patient circuit is used
3	Nebulizer Port (optional)	For connecting to a pneumatic nebulizer.
4	Capnography CO_2 Port (optional)	For connecting to a Capnography Filter line
5	Cuff Port (optional)	For connecting to the patient Cuff tube
6	Patient Circuit Connector	Gas outlet, connects the patient circuit inspiratory limb.
7	On/Off button	Turns the ventilator on and stops ventilation. A green LED on the button indicates connection to an external electric power.
8	Mute	When pressed temporarily silences the audible alarm for 2 minutes; when repressed during alarm silence - resets silence status. When alarms are muted the LED indicator of the mute button is lit.
9	360° Alarm LED	Flashes red or yellow to indicate there is an alarm.
10	Display touch screen	Enables the user to modify the ventilation, alarm, and technical settings, and to view real time patient data, alarms, battery status and logs.

3.2 Back Panel Features



Back Panel

Label	Name	Description
11	COM1 (RJ11)	Remote alarm/ Nurse call connector
12	LAN (RJ45)	LAN for network logging ( )
13	USB 1, USB 2	USB ports for SW loading to the ventilator or for log files exportation. For authorized and qualified service technicians only
14	SpO_2 port (optional)	Connects to SpO_2 finger probe
15	Low Flow Oxygen Port	Low flow oxygen enrichment source (up to 345 kPa, 0 – 15 L/min)
16	Detachable Batteries	Li-Ion 22.2 VDC
17	AC Inlet with Fuse	100 – 240 V AC, 50 – 60 Hz, Fuse 8A (SB or TL)
18	Air Intake with Filter	Enables the patient to pull ambient air into the patient circuit. Acts as emergency air inlet in the event of complete system failure.
19	DC Inlet	10 – 30 VDC
20	High Pressure O_2 Port (optional)	Connects to high pressure O_2 (240 – 620 kPa, 21% - 100%)

Due to cyber security issues, the device must be connected to the intra-hospital network only! Blocking all remote access to the device is under the responsibility of the hospital's information security department.

Do not obstruct any of the Air Intake point! Any impediment can result in deterioration in the operation of the unit and affect patient treatment.

3.3 Main Screen

Label	Name	Description
1	Alarms bar	Display of signaled alarms
2	Ventilation mode selector	Button for ventilation mode change
3	Indicators bar	Batteries status DC/AC external connection Oxygen supply connection Time and date/alarm mute counter Network connectivity – WiFi /Wire
4	Main Monitoring Parameters	Display of 6 constant main breathing parameters
5	Graphic Display	Display of graphical data
6	Operational control bar	Operating of additional features (see clause 5.7)
7	Controllers lines selectors	Used for controllers' lines selectors

Label	Name	Description
8	Main Controllers	Controllers for changing ventilation parameters

3.4 Configuration Identification

The configuration of the Ventoux is indicated as part of the Product Description code printed on the bottom Identification Plate of the Ventoux. To read the configuration (which is given in the example form VX-12-1-MN1), see below:

Code form: VX-A-B-CDE

Where: VX – Indicates Ventoux Ventilator

A – Indicates either 8 inch or 12 inch display screen

B – Indicates if with internal mixer (1) or without internal mixer (0)

C – Indicates if with Capnography, this can be either:
(0) no capnography, (M) Oridion Sidestream, (P) Philips ready

D – Indicates if with SpO_2 this can be either: (0) without SpO_2, or (N) with Nellcor SpO_2

E – Indicates if with Cuff Control, this can be either:
(0) without Cuff Control, or (1) with Cuff Control

For the example given above: VX-12-1-MN1, this can be read as: with 12 inch screen, with internal mixer, with Capnography (Oridion Sidestream), with SpO_2 (Nellcor) and with Cuff Control.

4 Installation

4.1 Introduction

Familiarize yourself with the instructions in this section prior to installing the ventilator. Following all of the listed steps is essential for ensuring the safest possible operation of the ventilator. Use the information in this section in conjunction with established hospital protocols.

Only properly trained personnel should install the ventilator.

4.2 Removing the Ventilator Parts from the Box

Before installing the ventilator, familiarize yourself with the various components. Remove all of the items from the shipping box and inspect each part and component for completeness and verify that there is no shipping damage.

The complete assembly consists of the following parts:

- VENTOUX Ventilator
- AC Power Cord (configured to local standard)
- Patient Circuit – Dual Limb Patient Use
- Air Inlet Filter (pk. of five filters)
- Two lithium-ion rechargeable swappable Batteries

4.3 Mounting the Ventilator

To mount the ventilator:

1. Mount the ventilator on a stable surface (e.g., bedside table or the Roll Stand Assembly).
2. To mount the ventilator on the Roll Stand Assembly, follow the instructions provided with the assembly; position the ventilator on a pedestal mount and then secure it using the screws provided.

4.4 Installing the Detachable Batteries

To install the detachable batteries:

Insert BAT1 (item 17) battery into the ventilator until it is locked in place.

Insert BAT2 battery into the ventilator until it is locked in place and secure with screw (item 22).

If external power is not connected to the ventilator, batteries will start to deplete.

The color of the battery symbol on the screen indicates the battery charging level:

color	Charging level	Symbol
Green	Above 80%	
Orange	below 80%, above 20%	
Red	below 20%	 or 

While the ventilator is connected to an external power source (AC or DC) a charging symbol will appear: 

The ventilator performance is not affected during the recharging of the batteries.

When the ventilator is not connected to an external power "Time to empty" (of both batteries together) is shown instead of charging level

4.5 Connecting the Power Cord (for AC)

To plug in the power cord:

Insert the AC power cord into the power entry connector on the Ventilator and then plug the cord into a proper AC outlet.

Note: The AC indicator LED of the ON/OFF button and the indicator  turn ON and the batteries begin recharging.

4.6 Connecting the Patient Circuit

FLIGHT MEDICAL and most Universal Dual Limb patient circuits can be used with the Ventoux ventilator. The Ventoux ventilator accurately measures flow, volume, and

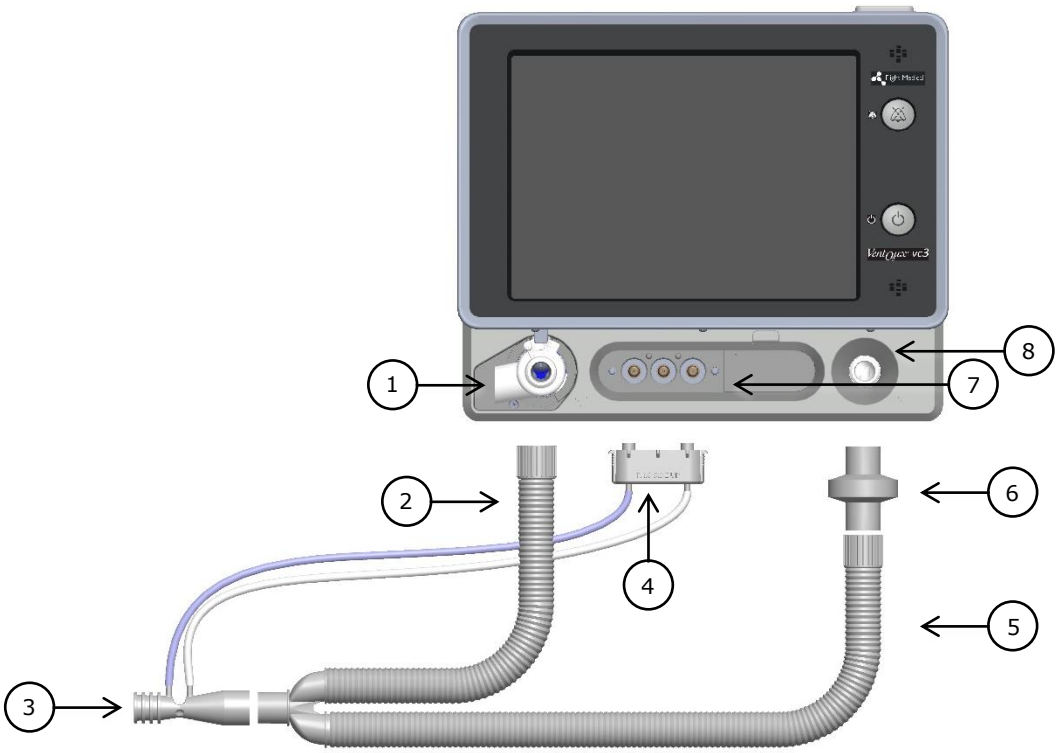
pressure in the patient's airway both with and without the FLIGHT MEDICAL flow sensor.

4.6.1 Gas flow monitoring with proximal flow sensor

The proximal flow sensor ensures high flow trigger sensitivity (response time<100 msec) and fast response time which helps the patient to minimize the breathing effort as well as providing high patient-ventilator synchronization.

4.6.1.1 Connecting a dual limb patient circuit (proximal connection):

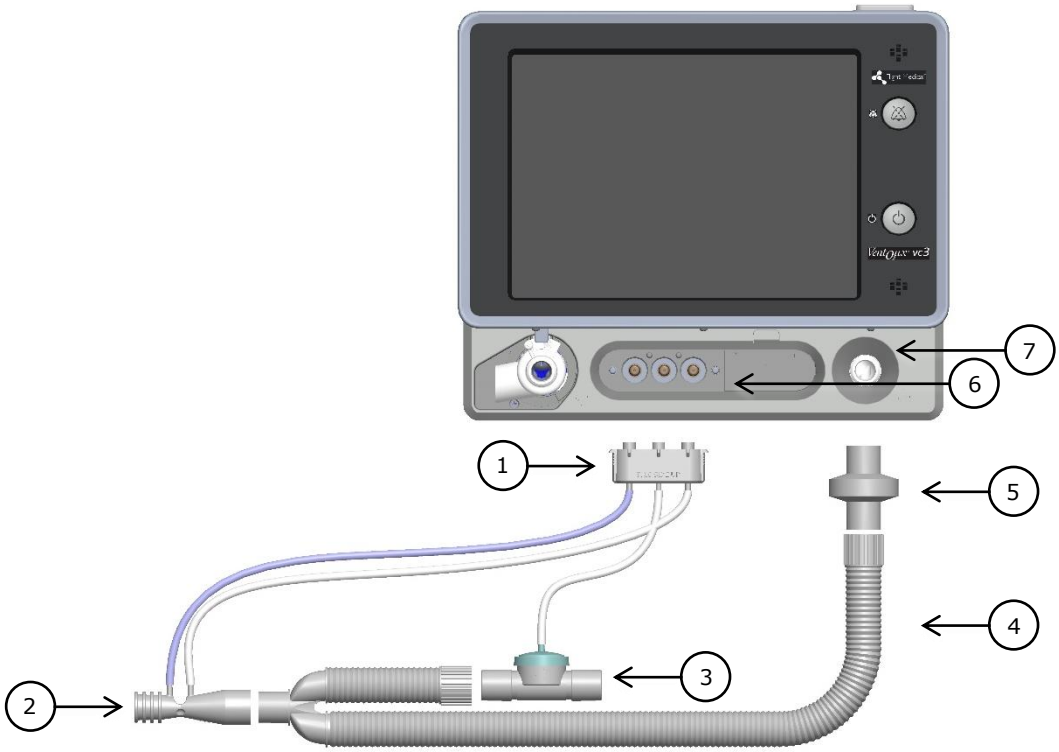
1. Connect the patient circuit quick connector to the ventilator proximal connection ports on the front panel and ensure that it is properly secured by the connector side snaps (a dual limb flow sensor consist of 2 silicon tubes).
2. Connect the inspiratory limb to the outlet on the front panel.
3. If using with an HME, attach the HME at the outlet port.
4. Connect the expiratory limb to the exhalation valve on the front panel.
5. Perform circuit test (make sure the end of the circuit is open, otherwise circuit test will fail).
6. Ensure the massage "Dual limb proximal connection detected" appears.



1	Exhalation valve	**4**	Flow sensor Quick connector	**7**	Proximal connection port
2	Expiratory limb	**5**	Inspiratory limb	**8**	Outlet
3	Flow sensor	**6**	HME Filter		

4.6.1.2 Connecting a single limb patient circuit (proximal connection):

1. Connect the patient circuit quick connector to the ventilator proximal connection ports on the front panel and ensure that it is properly secured by the connector side snaps (a single limb flow sensor consist of 3 silicon tubes).
2. Connect the inspiratory limb to the outlet on the front panel.
3. If using with an HME, attach the HME at the outlet port.
4. Perform circuit test (make sure the end of the circuit is open, otherwise circuit test will fail).
5. Ensure the massage "Single limb proximal connection detected" appears.



1	Flow sensor Quick connector	**4**	Inspiratory limb	**7**	Outlet
2	Flow sensor	**5**	HME Filter		
3	Exhalation valve	**6**	Proximal connection port		

WARNING

Ventilation with a volume smaller than 200 ml requires the use of a pediatric patient circuit.

WARNING

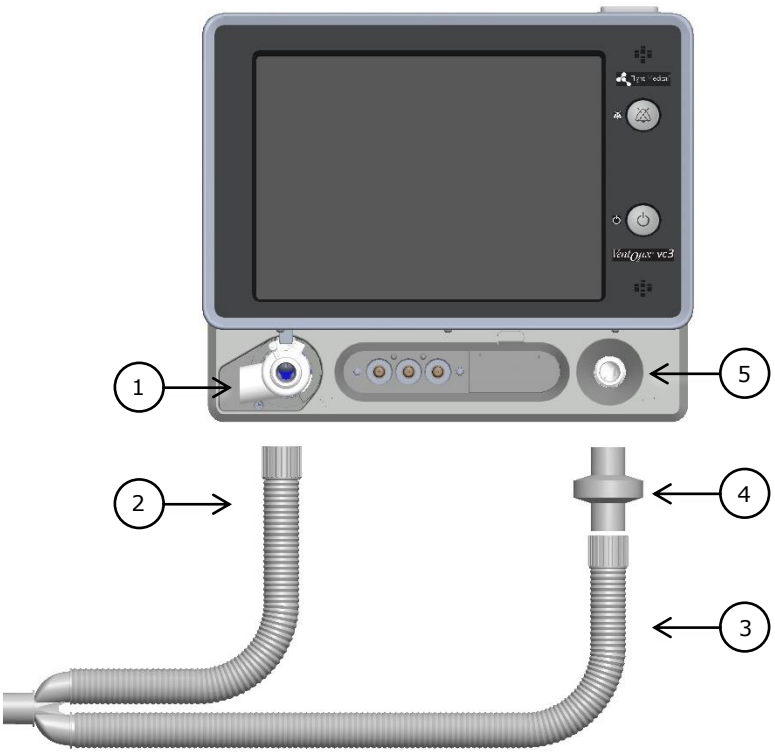
Pediatric ventilation is only allowed with FLIGHT MEDICAL patient circuit with a proximal flow sensor.

4.6.2 Gas monitoring without proximal flow sensor (universal circuit, distal connection)

The Ventoux can also ventilate without the proximal flow sensor (distal connection). Using this configuration may increase the patient's breathing effort.

4.6.2.1 Connecting a dual limb patient circuit (distal connection):

1. Connect the inspiratory limb to the outlet on the front panel.
2. If using with an HME, attach the HME at the outlet port.
3. Connect the expiratory limb to the exhalation valve on the front panel.
4. Perform circuit test (make sure the end of the circuit is open, otherwise circuit test will fail).
5. Ensure the massage "Dual limb distal connection detected" appears.



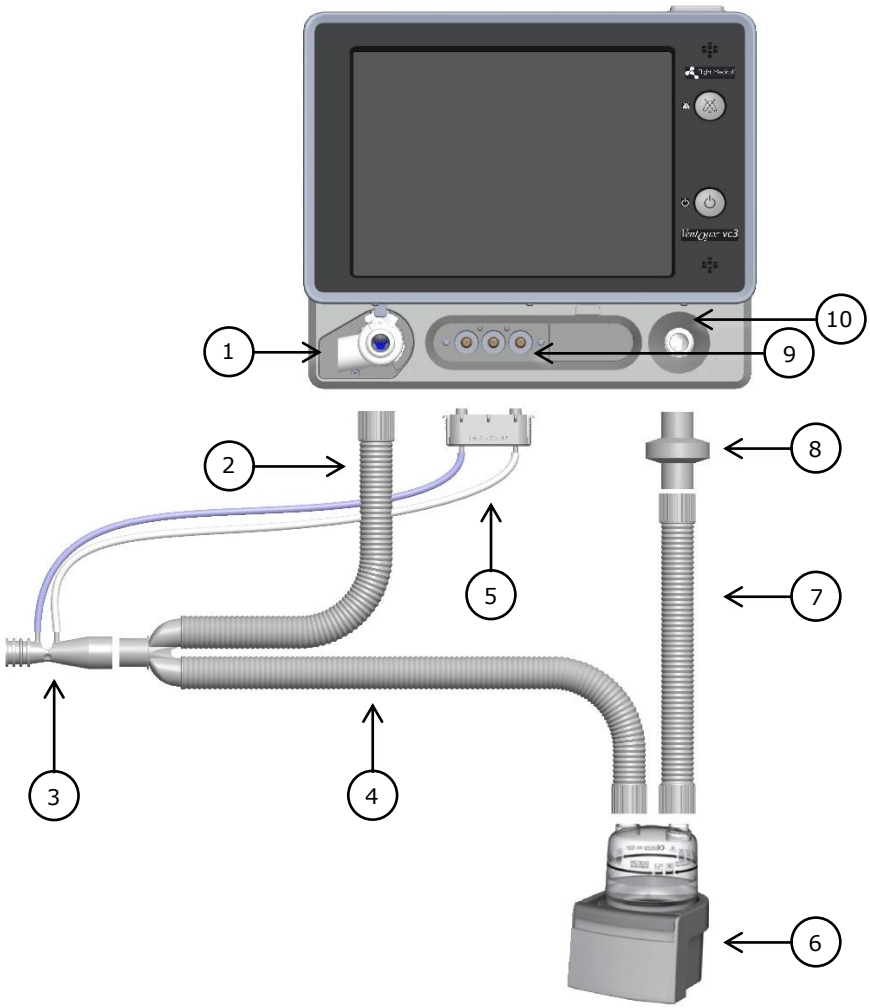
1	Exhalation valve	**4**	HME Filter
2	Expiratory limb	**5**	Outlet
3	Inspiratory limb		

It is not allowed to ventilate pediatric using universal circuit.

4.6.3 Heated wire circuit with a Humidifier

When ventilating with a heated circuit and a humidifier, it is recommended to add the Flight Medical flow sensor kit for a more accurate measurement.

1. Connect the non-heated circuit to the ventilator outlet and to one of the humidifier ports.
2. If using with an HME, attach the HME at the outlet port.
3. Connect the flow sensor quick connector to the ventilator proximal connection ports on the front panel and ensure that it is properly secured by the connector side snaps.
4. Connect the inspiratory limb of the heated wire circuit to the second humidifier port.
5. Connect the expiratory limb of the heated wire circuit to the exhalation valve on the front panel.
6. Connect the temperature probe according to the specific humidification system's instructions.

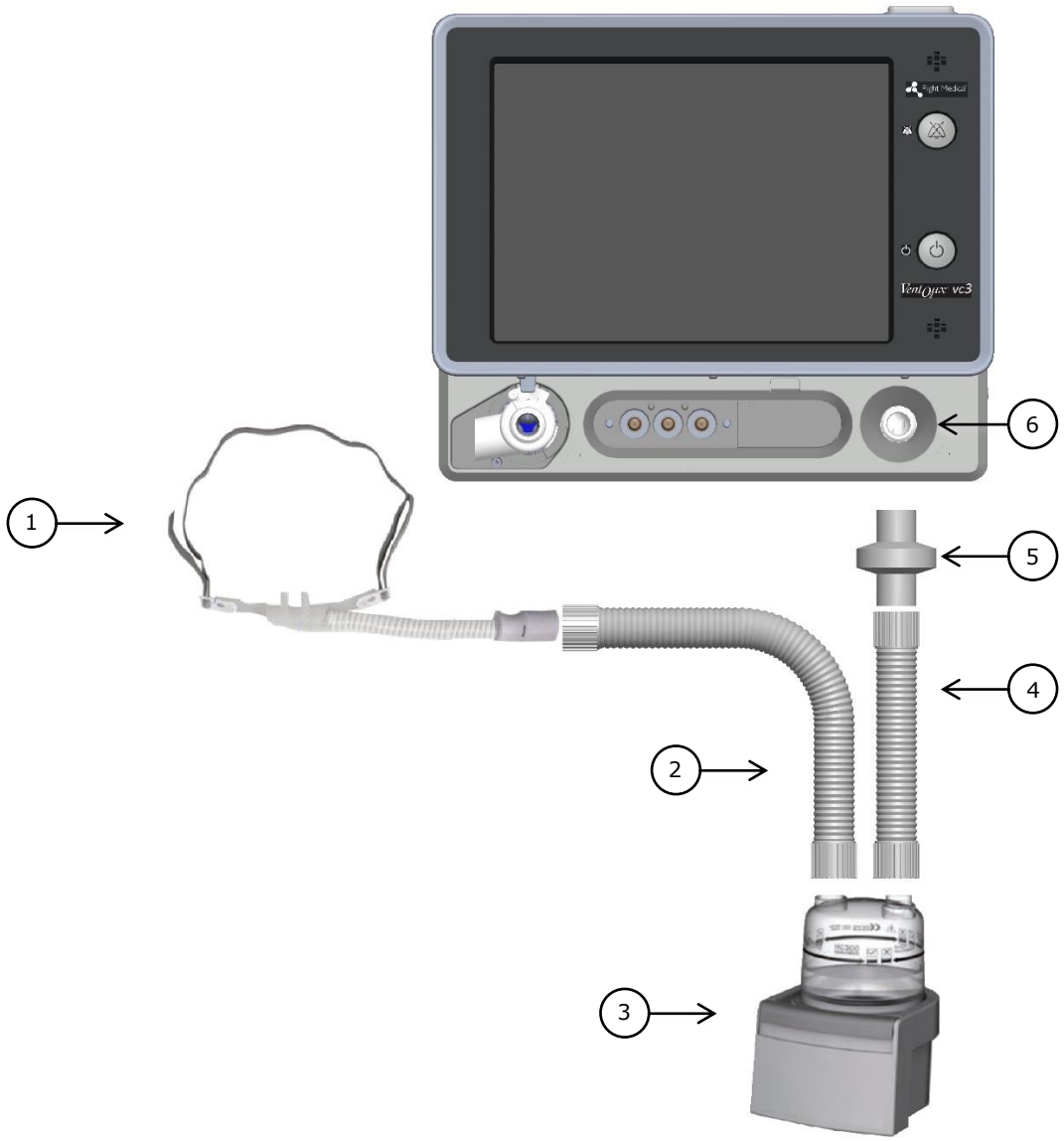


1	Exhalation valve	**5**	Flow sensor Quick connector	**9**	Proximal connection port
2	Heated expiratory limb	**6**	Humidifier	**10**	Outlet
3	Flow sensor	**7**	Inspiratory limb to humidifier		
4	Heated inspiratory limb with temperature sensor, to patient	**8**	HME Filter		

4.6.4 HFOT (High Flow Oxygen Therapy) Setting

1. Connect the non-heated circuit to the ventilator outlet and to one of the humidifier ports.
2. If using with an HME, attach the HME at the outlet port.
3. Connect the heated circuit to the second humidifier port and to the High Flow Nasal Cannula (HFNC)/ tracheostomy tube.

4. Do not connect the patient circuit to the ventilator's exhalation valve.



1	HFNC	**4**	Inspiratory limb to humidifier
2	Heated inspiratory limb with temperature sensor, to patient	**5**	HME Filter
3	Humidifier	**6**	Outlet

4.7 Connecting the Oxygen Supply

Oxygen enrichment can be reached using a high- or low-pressure source with the following options:

- Internal O_2 Mixer (high pressure – item 20)

- Low Flow Oxygen connector (low pressure – item 15)

Ensure that there is sufficient oxygen source available before and during oxygen enrichment.

A safety fan is installed inside the ventilator to remove oxygen in case of a leakage. In the case of a safety fan malfunction an alarm will be issued and the oxygen supply may be cut off for safety reasons. See section 7.4.3 for all technical alarms related to safety fan.

4.7.1 Internal O_2 Mixer

Use a high-pressure hose to connect the ventilator to a high-pressure oxygen source. Attach the hose to the High Pressure O_2 Port located at the rear panel of the ventilator (item 20).

Feature	Specification
Connector Type	DISS
Input Pressure – Oxygen	35-90 psig/240-620 kPa
FiO_2	21% to 100%
Accuracy	±5%
21% to 90% FiO_2 Response Time	Up to 20 seconds
Max input and transient flow rate	at 280 kPa is 60 l/min

When high-pressure oxygen source is connected the blue O_2 supply indicator  is on. If the external oxygen supply pressure is low, the O_2 supply icon will turn red.
If external oxygen supply is not connected and FiO_2 controller set is above 21%, a yellow warning triangle will appear on the controller. Once ventilation starts, an O_2 supply failure alarm will be displayed.

4.7.2 Low-Flow Oxygen Port

When using low-flow oxygen, connect the oxygen source to the built-in low pressure (low flow, item 15) oxygen port using the Oxygen Hose Connector provided with the device.

Low flow oxygen source can provide oxygen concentration up to 60%.

Changes in the pressure within the patient circuit may cause oxygen concentration to vary. Actual oxygen concentration varies with changes in flow in the patient circuit. The following control parameters may impact the oxygen concentration:

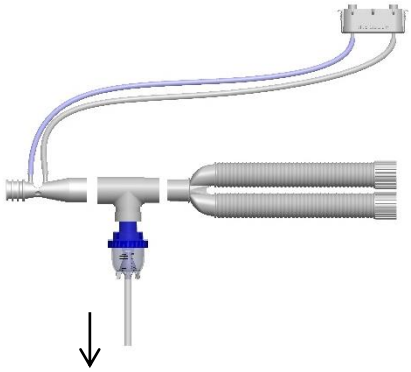
- Volume or Pressure settings
- PEEP settings
- Respiratory Rate settings
- Peak Inspiratory Flow
- Flow Waveform
- I:E Ratio
- Leak Rate
- Low Pressure Oxygen Flow Rate

 WARNING	When oxygen is administrated with a low flow source the actual delivered oxygen concentration will vary. Substantial leaks may reduce the inspired oxygen concentration. FiO_2 should be monitored, and appropriate alarm settings should be used.
 WARNING	The oxygen flow into the ventilator must not exceed 15 Liters Per Minute (LPM) and pressure must be below 50 psig.
 WARNING	This ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment oxygen is administrated with a low flow source the act
 WARNING	It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen

concentration as marked on the ventilator as this can affect the performance of the ventilator

4.8 Connecting the Nebulizer

Connect the nebulizer between the Y piece of the patient circuit and the flow sensor in order to keep the proximal flow measurement.

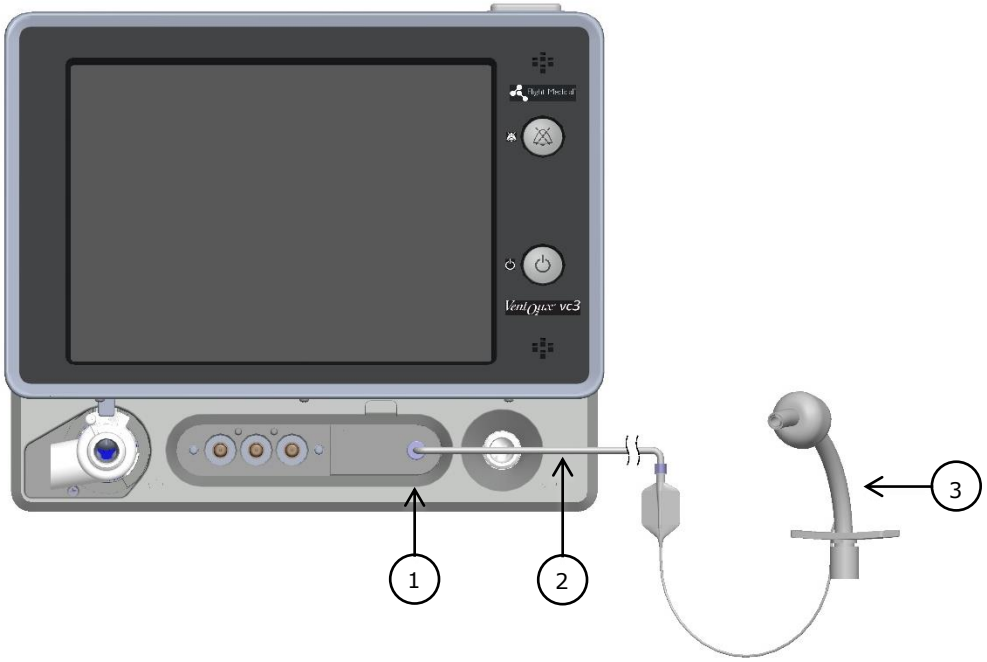


To ventilator nebulizer port

4.9 Connecting the Cuff pressure tube (optional)

The following procedure describes how to attach the cuff pressure tube to the ventilator.

1. Attach the cuff connector the ventilator cuff port on the front panel and ensure that it is properly connected.
2. If necessary, use an extension tube.
3. Inflate the cuff pressure only after intubation.
4. For operational information go to 6.6.6. Cuff pressure control (optional)



1 Cuff Port

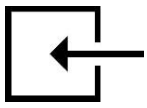
2 Cuff extender (FLM-0030)

3 Cuff tube (ETT)

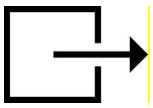
4.10 Connecting the Microstream etCO2 capnography sample line (optional)

Before monitoring a patient with capnography, the appropriate FilterLine must be connected to the ventilator and to the patient.

Gas exchange symbols appear next to the CO2 gas input connector and the gas outlet.



Gas input symbol

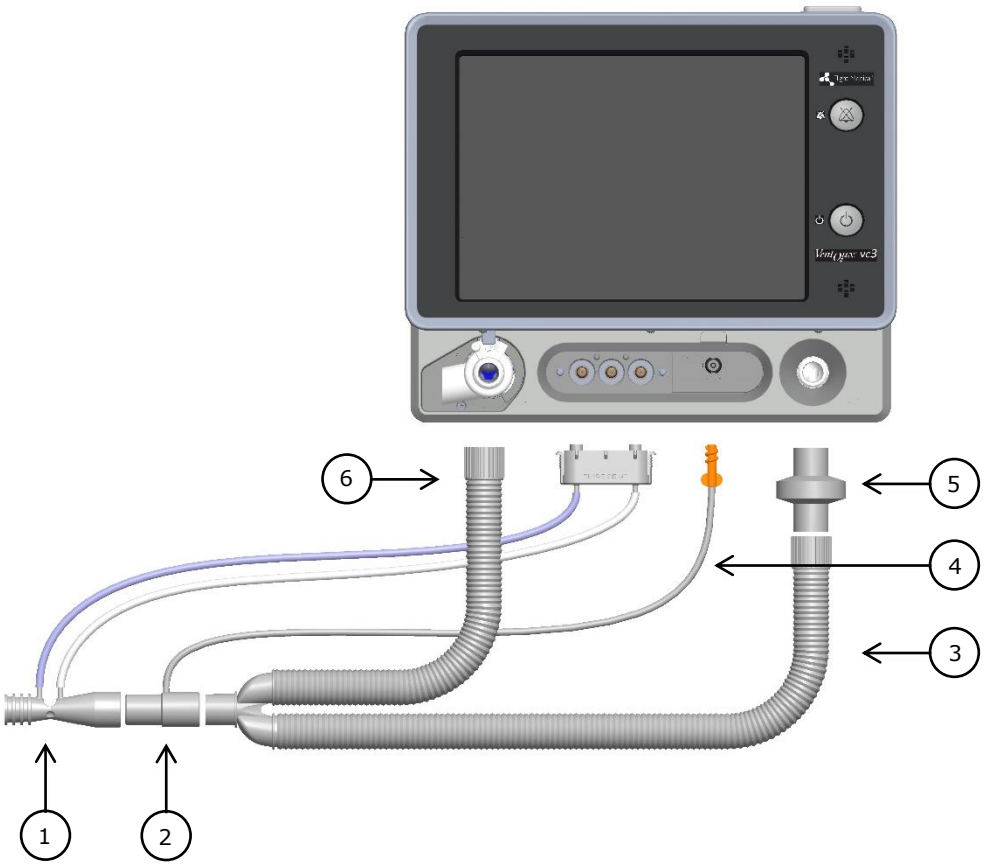


Gas output symbol

The following procedure describes how to attach the Microstream etCO2 sample line

1. Lift-up the FilterLine **input** connector silicon cover and connect the appropriate FilterLine. Screw the FilterLine connector into the ventilator capnography port clockwise until it can no longer turn.
2. Connect the FilterLine to the patient circuit between the Y piece and the flow sensor.

3. For operational information go to 6.6.7 Pulse Oximetry and Capnography (optional)
4. When the capnography module is turned on and the FilterLine is connected, the ventilator will immediately begin to search for breaths, but it will not indicate a "No Breath" condition before any valid breaths have occurred.



1	Flow Sensor	**4**	CO2 Filterline connector
2	CO2 Filterline adaptor	**5**	HME Filter
3	Inspiratory limb	**6**	Expiratory limb

WARNING

When using the system with anesthetic gases, attach tubing to connect the exhaust connector to a scavenging system, so that the exhausted gas is not exhausted into the ambient air.

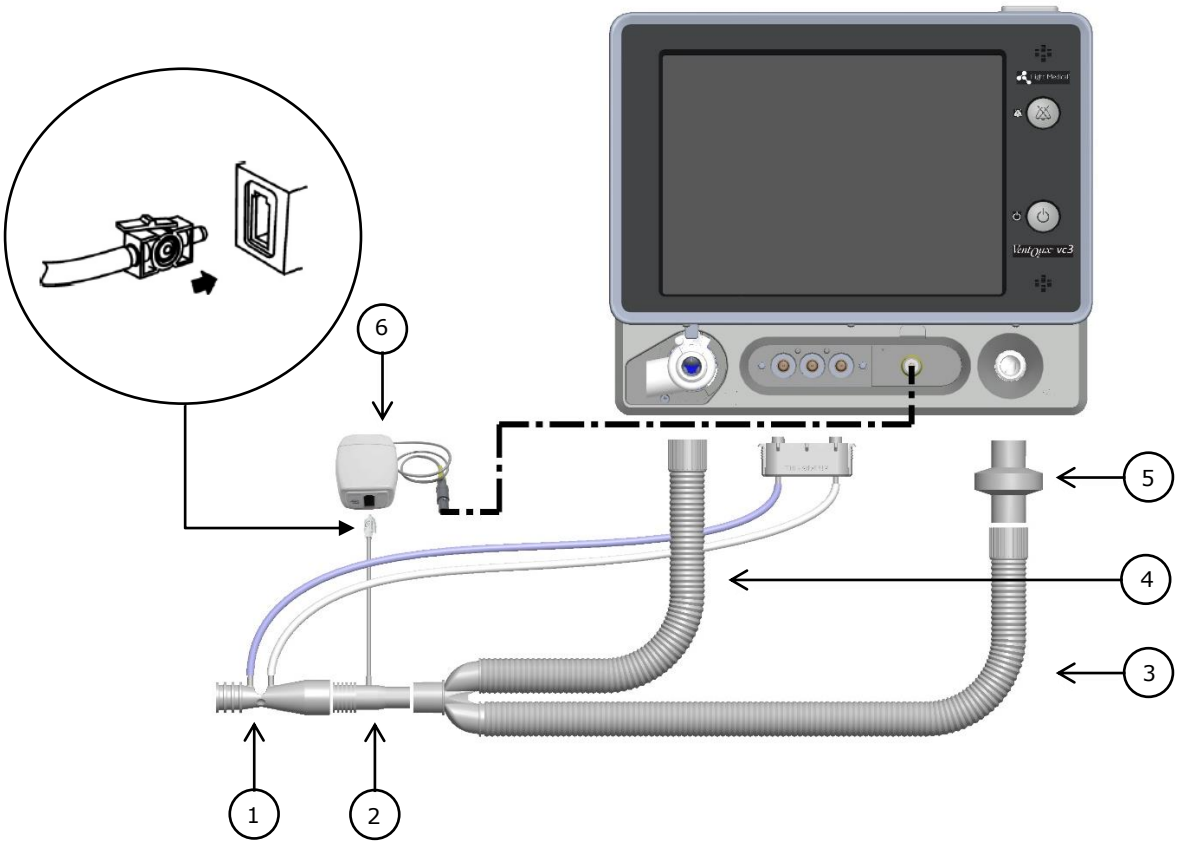
Microstream capnography connector and exhaust connector

For more information read section ***10.2 capnography monitoring***

4.11 Connecting the Philips capnography (optional)

4.11.1 Loflo C5

1. Insert the sample cell into the sample cell receptable of the LoFlo CO_2 module. A 'click' will be heard when the sample call is properly inserted
2. Inserting the sample cell into the receptable automatically starts the sampling pump. Removal of the sample cell turns the sample pump off.
3. To remove the sampling kit sample cell from the sample cell receptacle, press down on the locking tab and pull the sample cell from the sample cell receptacle.
4. Connect the LoFlo module to the CO_2 port ventilator

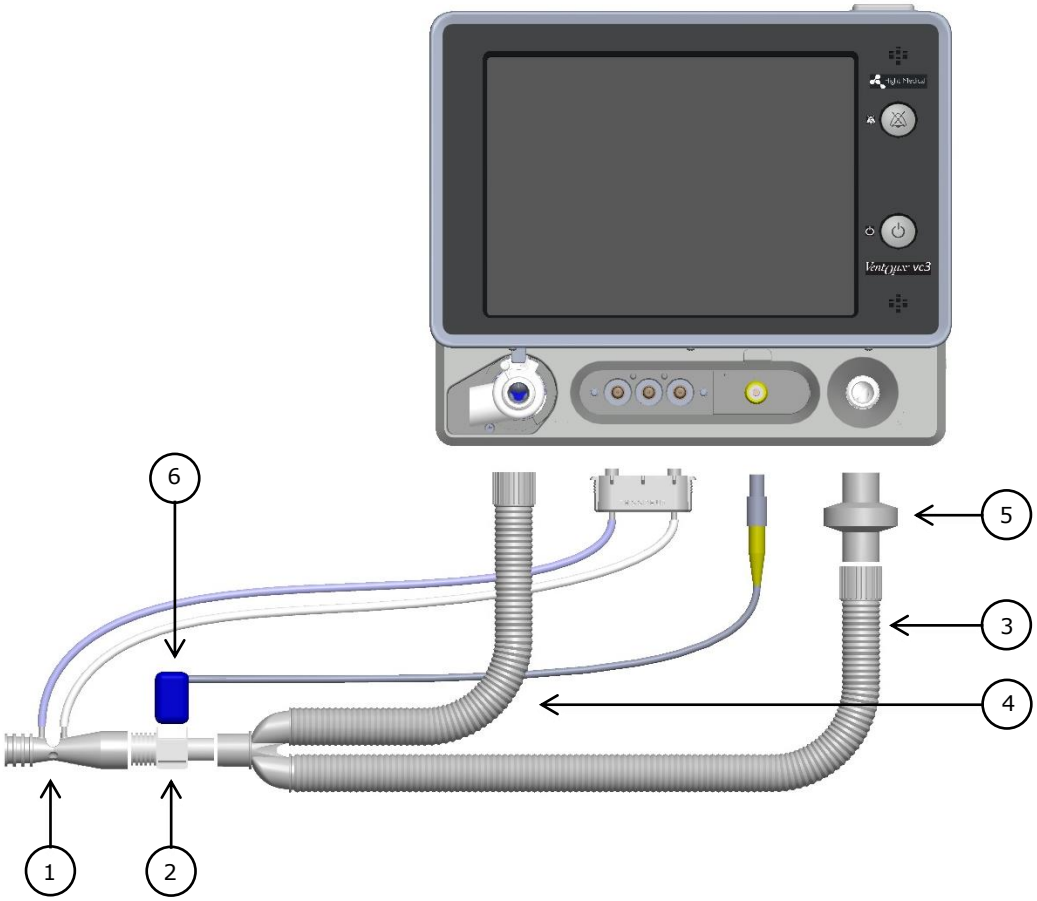


1	Flow Sensor	**4**	Expiratory limb
2	Airway Adapter Kit	**5**	HME Filter
3	Inspiratory limb	**6**	LoFlo Sidestream CO2 Module

4.11.2 CAPNOSTAT 5

The following procedure describes how to attach the CAPNOSTAT 5 (mainstream) to the Ventoux ventilator:

1. Insert the CAPNOSTAT 5 CO_2 sensor connector into the CO_2 port.
2. Make sure the arrows on the connector are at the top of the connector and line up the two keys of the connector with the receptacle and insert.
3. To remove the connector, grasp the body portion of the connector back and remove.



1	Flow Sensor	**4**	Expiratory limb
2	Airway Adapter	**5**	HME Filter
3	Inspiratory limb	**6**	Capnostat 5 Mainstream Sensor

	Do not remove the connector by pulling cable.
	For monitoring CO2, select an airway adapter based on the patient and monitoring situation

For more operational information, read section ***10.2 capnography monitoring***

For more information on the module specifications refer to the LoFlo C5 or the CAPNOSTAT 5 user guides.

4.12 Connecting the Nellcor pulse oximetry (optional)

The Nellcor Pulse Oximetry System provides noninvasive and continuous information of changes in oxygen saturation of arterial blood. The measurement takes place in real time, providing an indication of a change in the critical balance of oxygen delivery and oxygen consumption.

The following procedure describes how to attach the pulse oximetry sensor to the Ventoux ventilator:

1. For monitoring pulse oximetry parameters, select a sensor based on the patient and monitoring situation.
2. Connect the sensor connector to the Nellcor port to the Ventoux back panel (item 14)
3. Connect the sensor to the patient according to Nellcor user guide.

5 Basic Operation

Familiarize yourself with the instructions in this section prior to ventilating patients with the VENTOUX Ventilator. Following all the listed steps is essential for ensuring the safest possible operation of the ventilator. Use the information in this section in conjunction with established hospital protocols.

Only professionally trained personnel should operate the ventilator. The VENTOUX Ventilator is a restricted medical device designed for use by Respiratory Therapists or other professionally trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

5.1 Powering on the Ventilator

Review all the General Warnings and Cautions in Chapter 2 prior to using the ventilator.

The VENTOUX Ventilator can be used either with an AC, DC or internal batteries as power source.

DC charging is only allowed with Flight Medical proprietary DC cable, P/N V60-60040-60. Using a different cable may cause damage

There is no change in the behavior of the ventilator after a switchover in power supply nor when performing recharging of the batteries.

Operating time from an external DC power source depends on the level of power consumption by the ventilator. Nominal power consumption for the Ventoux ventilator is approximately 48 WH. When charging the internal batteries the nominal consumption is approximately 120 WH.

The applicable power source is shown in the indicators area: 

or 

Before using the ventilator, **either with AC or DC** power source, ensure that the internal batteries are sufficiently charged.

To turn the ventilator on:

1. Connect the patient circuit.
2. Press the **"On/Off"** hard button.

Patient circuit must be **open** at its end, otherwise the circuit test fails.

The ventilator performs a brief self-test to ensure proper microprocessor function, and a circuit test.

If the self-test passed successfully, the Standby window is shown. Otherwise, a warning message is shown.

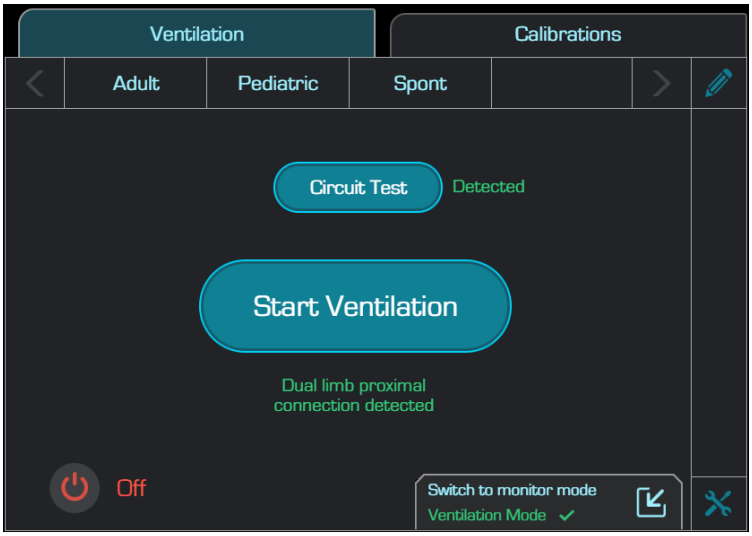
In the standby window, there are two tabs:

1. Ventilation tab
2. Calibrations tab

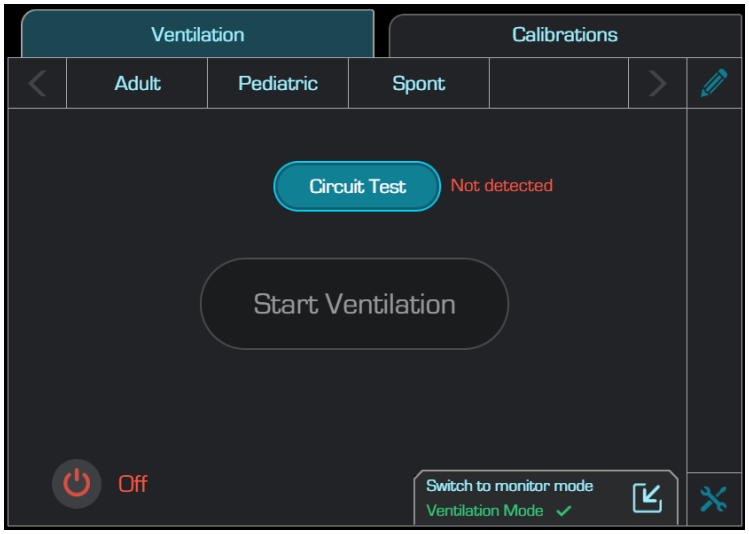
5.2 Ventilation Tab

In the ventilation tab, the following actions are available:

- To perform circuit test.
- To start new ventilation.
- To turn the ventilator off.
- To load or change presets' parameters.
- To switch to monitor mode.
- To enter service screen.



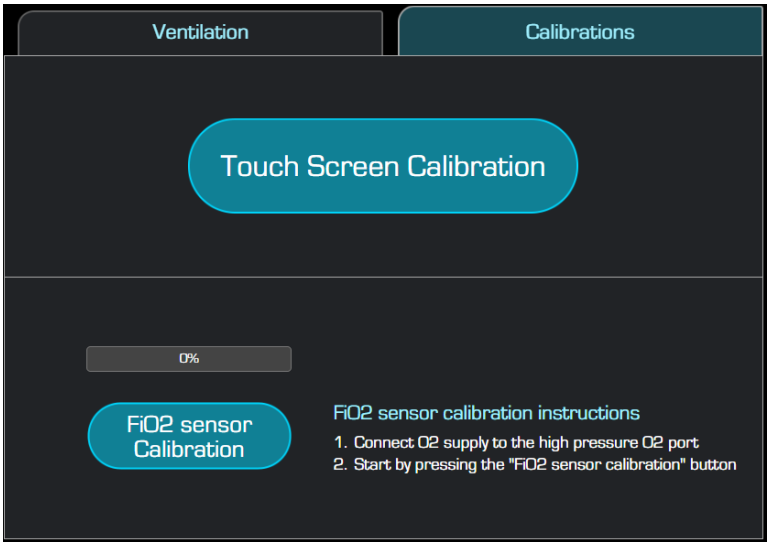
The result of the circuit test and the circuit type detected is shown on the screen. If the circuit test fails, the "Start Ventilation" button is disabled.



5.3 Calibrations Tab

In the Calibrations tab, the following calibrations are available:

- Touch screen calibration
- FiO2 sensor calibration



5.3.1 Touch screen calibration

Tapping the touch screen calibration opens a white screen and the user is required to touch the 4 indicated "+" signs.

CAUTION

In case calibration has failed in such a way that pressing the "Touch Screen Calibration" button to recalibrate is impossible, connect a "mouse" to one of the USB ports and re-calibrate.

5.3.2 FiO2 sensor calibration

Tapping the "FiO2 sensor calibration" button will start the calibration process. In order to perform FiO2 sensor calibration the ventilator must be connected to O2 supply otherwise the process will fail. The calibration date is recorded in the service screen.

5.4 Monitor Mode

When pressing ""Switch to Monitor Mode" the system enters monitor mode. In monitor mode the system can sample values according to the system configuration (SpO_2 and $etCO_2$). For activating monitoring options see section 6.6.7.
When pressing "Switch to Ventilation Mode" the system exits monitor mode and the standby window re-opens.

5.5 Initiating / Resume Ventilation

After setting all the required parameters, checking all alarm limits and control settings to ensure that they are appropriate for the patient to be ventilated, ventilation can be initiated.

To start ventilation press the "Start ventilation" button

To resume ventilation:

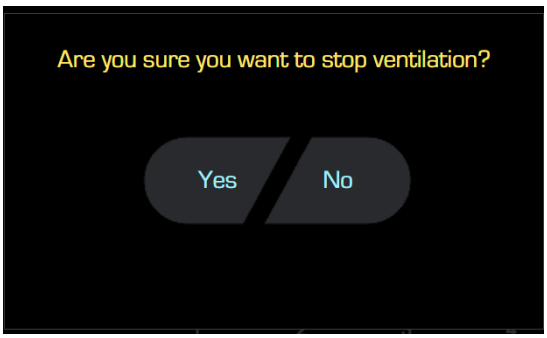
1. On the ventilator screen, press the "Start ventilation".

> After pressing "Start ventilation" the Ventoux ventilator continues ventilation according to the most recent patient settings.

5.6 Standby/Stopping Ventilation

To standby/stop ventilation:

1. During ventilation press the ON/OFF hard button. The screen will display the following message:

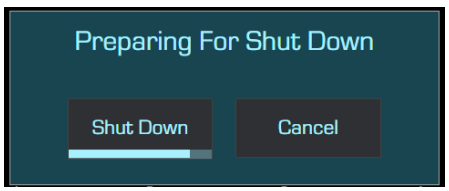


2. Confirm stop of ventilation.
3. Confirmation will activate standby mode and stop the ventilation.

5.7 Turning Off the Ventilator

To shut down the ventilator:

1. Press the "Off" button in the standby window screen.
2. Shut down timer window will appear



3. Choose "Shut Down" for immediate shut down or cancel.
4. If no option is chosen, the Ventilator will shut down after 5 seconds.

It is not possible to turn off the ventilator during ventilation

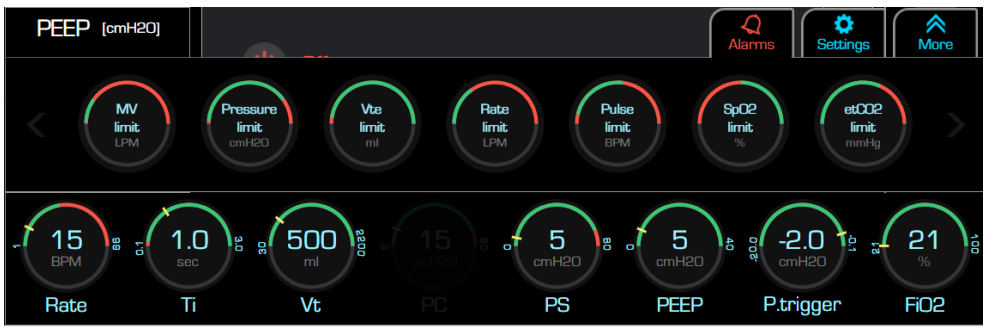
5.8 Setting Control Values

There are 4 different controllers' rows: Main, Alarms, Settings and More.

The Main controllers are always displayed at the bottom of the screen:

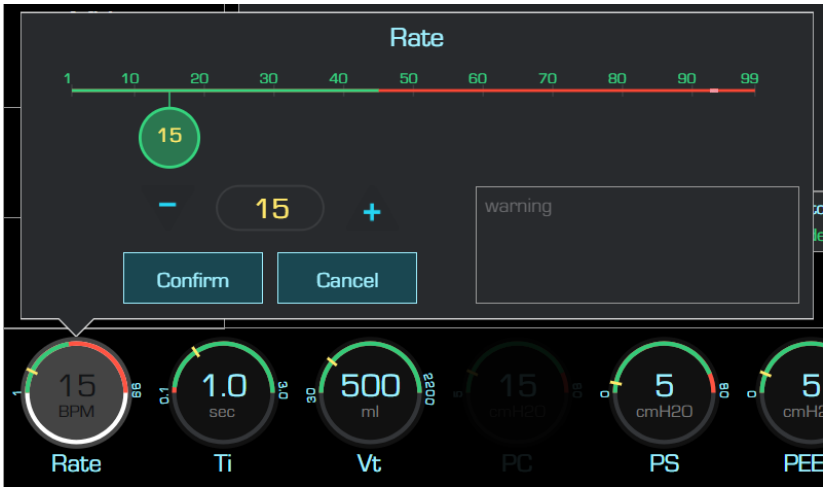
To access one of the additional rows:

1. Press the Alarm/settings/More tab.
2. An additional row will open above the main row with the corresponding controllers.



To adjust numeric control values:

1. Select the parameter by pressing the relevant control button:



2. Adjust the numeric value using the +/- in the displayed bar or by dragging the value indicator over the displayed bar.
3. Accept the value by pressing the confirm button or cancel by pressing the cancel
4. Any warning or message related to the setting will appear in a box in the lower right side.
5. Once a parameter is changed it is highlighted in yellow for the next 5 seconds 

.

To adjust non numeric control parameters:

1. Select the parameter by pressing the relevant control button (for example wave form or sigh).
2. Choose the desired option in the displayed bar.
3. Confirm by pressing the confirm button or cancel by pressing the cancel.

If there are setting limitations, the displayed bar will display the limits in red.

It is not possible to set a value out of limits.

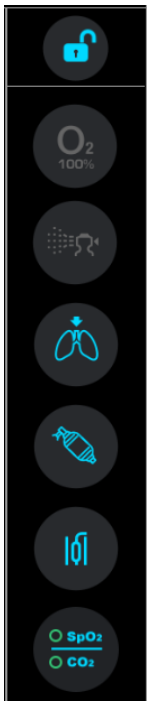
5.8.1 Default and Saved Values

When the device is operated for the first time, it uses a set of default parameters and setting values. When these values are then changed according to the user's requirements, they are saved in the system's nonvolatile memory for further usage.

5.9 Operational Control Bar

The Operational Control Bar has the following features:

1. Screen lock
2. 100% O_2 for 2 min (enabled only when the ventilator is connected to an oxygen source)
3. Nebulizer (enabled only when the ventilator is connected to an oxygen source)
4. Maneuvers
5. Manual Breath
6. Cuff Pressure (optional)
7. Pulse oximetry/capnography (optional)



For more information see clause 6.6

Cuff pressure and SpO_2/CO_2 are available also during monitor mode. Other controllers are disabled.

5.10 Presets

5.10.1 Choose a preset

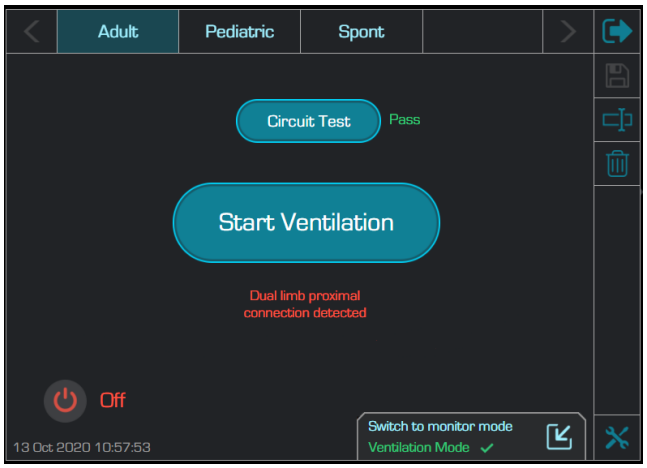
The user has the option to choose a pre-save set from a factory default set list (Adult, Pediatric, Spont), or create his own proprietary presets.

1. Scroll the presets row with the right/left arrow and chose the required preset.
2. Once a preset is chosen it will be highlighted.
3. Once any of the preset parameters is changed, the preset is turned off.

5.10.2 Edit a preset

The user has the option to edit presets.

1. Press the  icon
2. Enter password '1734'
3. A bar with the following options will be displayed:
    a. Exit preset 
    b. Save 
    c. Rename 
    d. Delete 



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5.10.3 Exit

To exit "edit preset" press the  icon. Exiting the "edit preset" will load the last edited mode.

5.10.4 Save changes or new preset

User has the option to change existing presets or add new ones.

1. Set the desired parameters
2. Press the  icon which is now enabled.
3. A keyboard is displayed on the screen.
4. The default set name is the last loaded preset.
5. If the name is identical to an existing preset name, a message is displayed: "XXX set already exist. Do you want to replace it?".
6. Once the user confirms, the preset is replaced with the new set.
7. In case a new name is typed, it is saved as an additional new preset.

5.10.5 Rename

User has the option to change preset name.

1. Chose the required preset
2. Press the  icon
3. A keyboard is displayed on the screen
4. Type the new preset name

If the name is identical to an existing preset name, it will not be possible to save it.
A message "The set name is already used" will be display.

5. Confirm
6. The uploaded preset is renamed

5.10.6 Delete preset

User has the option to delete preset.

1. Chose the required preset
2. Press the  icon
3. Confirm the message: Are you sure you want to delete XXX?

6 Ventilator Settings

6.1 Modes of ventilation

AC PC/VC/PRVC	Assist/Control Mandatory Ventilation operation mode
SIMV PC/VC/PRVC	Synchronized Intermittent Mandatory Ventilation operation mode
CPAP/PSV	Spontaneous Ventilation operation mode
VG	Volume Guarantee Ventilation operation mode
APRV	Airway Pressure Release Ventilation operation mode
NIV	Non-Invasive Ventilation (available for all modes except HFOT)
HFOT	High Flow Oxygen Therapy

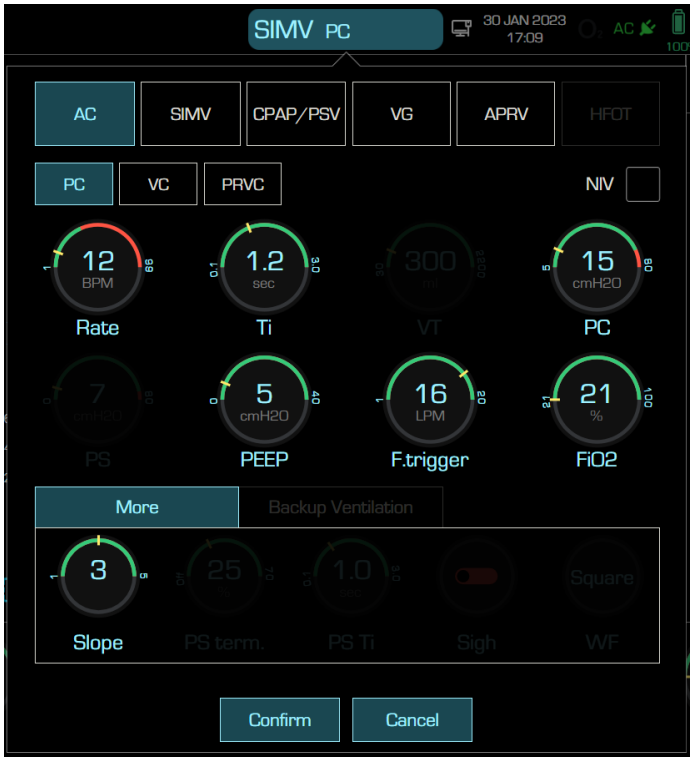
6.1.1 Set mode of ventilation

To set mode of ventilation:

1. Press the mode control area 

2. Select the required mode of ventilation
3. For non-invasive ventilation check the NIV box

The controllers will be updated according to the chosen mode



6.2 Main controllers

This is the default for the displayed controllers in standby and ventilation modes (a certain controller is only displayed only if it is relevant to the current ventilation mode).

Button	Description
Rate	Used to set the frequency of breaths. In AC mode, it determines the number of time-triggered breaths; in SIMV mode, it determines the total number of mandatory breaths. If the selected Rate setting results in an inverse I:E Ratio (i.e. the ratio between the length of inspiratory and exhalation phase of the breath), the system displays an "Inverse I:E" message in the massage box to alert the user. It is possible to increase the rate value up to an I:E Ratio of 3:1. Range: 1 to 99 b/min Resolution: 1 b/min

Button	Description
Ti	Used to set the inspiratory time for mandatory breaths (volume or pressure controlled). If the selected Ti setting results in an inverse I:E Ratio, the system displays an "Inverse I:E" message in the massage box. Increasing the Ti value up to an I:E Ratio of 3:1 is possible. Range: 0.1 to 3.0 seconds Resolution: 0.1 seconds
Vt	Used to set the mandatory tidal volume for the AC-VC, AC-PRVC, SIMV-VC, SIMV-PRVC and VG modes. Range: 30 to 2,200 ml Resolution: 10 ml
PC	Used to set the target pressure **above PEEP** for the AC-PC and SIMV-PC modes. Range: 5 to 80 cmH_2O/mbar Resolution:1 cmH_2O/mbar The total set value of the PC and PEEP cannot exceed 80 cm H_2O/mbar.
PS	Used to determine the level of support **above PEEP** in pressure during inspiration, for patient triggered spontaneous breaths in SIMV, CPAP/PSV and APRV modes. Breaths are normally terminated when any of the following conditions exists: ■ The flow to the patient drops to the "PS term" percentage setting for the breath peak flow. ■ The PS Ti has elapsed. Maximum airway pressure never exceeds the High-Pressure alarm limit setting. Range: 0 to 80 cmH_2O/mbar Resolution: 1 cmH_2O/mbar The total value of set PS and PEEP cannot exceed 80 cmH_2O/mbar. If both PS and PEEP values are 0, warning signs are displayed near the corresponding controllers: 

Button	Description
PEEP	Used to establish a baseline positive airway pressure in the patient circuit during the exhalation phase. Range: 0 to 40 cmH_2O/mbar Resolution: 1 cmH_2O/mbar If PEEP value is set above 15 cmH_2O the triangle warning sign is also displayed 
P.trigger	Used to determine the pressure trigger level (trigger sensitivity) in terms of how far the airway pressure must drop below the set baseline pressure in order for a patient's spontaneous efforts to be detected. The graph color is changed to green for a patient triggered breath. Range: -20.0 to -0.1 cmH_2O/mbar Resolution: 0.1 cmH_2O/mbar It is recommended to set P.trigger as close to -0.1 cmH_2O as possible without auto triggering, in order to maximize triggering synchrony.
F.trigger	Ventoux provides both pressure- and flow-based triggering. The trigger mode can be changed in the trigger setting bar. Used to determine the patient's inspiratory flow that triggers the ventilator to deliver a breath. The graph color is changed to green for a patient triggered breath. Range: OFF, 1 to 20 LPM Resolution: 1 LPM

Button	Description
FiO_2	Used to set O_2 enrichment level. Relevant to all the modes. Range: 21 to 100% Resolution: 1% If FiO_2 value is set above 21% and no oxygen is supply is connected, warning sign is displayed near FiO_2 controller: 
PS min	Volume Guarantee control, used to set the minimum pressure that can be applied. Range: 0 to 80 cmH_2O/mbar Resolution:1 cmH_2O/mbar The total set value of the PS min and PEEP cannot exceed 80 cmH_2O/mbar.
PS max	Volume Guarantee control, used to set the maximum pressure that can be applied. Range: 5 to 80 cmH_2O/mbar Resolution:1 cmH_2O/mbar The total set value of the PS max and PEEP cannot exceed 80 cmH_2O/mbar.
P Low	APRV control, used to set the low-pressure baseline. Range: 0 to 40 cmH2O/mbar Resolution:1 cmH2O/mbar The value of P Low plus PS above peep cannot exceed 80 cmH_2O/mbar. The value of P Low cannot exceed the P High – 5cmH2O value.
P High	APRV control, used to set the high-pressure baseline. Range: 5 to 80 cmH2O/mbar Resolution:1 cmH2O/mbar The total set value of the P High and PS cannot exceed 80 cmH_2O/mbar. The value of P High cannot be lower than the P Low + 5cmH2O value
T Low	APRV control, used to set the low-pressure baseline period. Range: 0.5 – 5.0 seconds Resolution: 0.1 second

Button	Description
T High	APRV control, used to set the high-pressure baseline period. Range: 1 – 15.0 seconds Resolution: 0.5 second
Flow	HFOT control, used to set the flow for HFOT mode Range: 10-60 LPM Resolution:1 LPM

6.3 "More" controllers

The following alarms are available in the alarms tab 

(a certain controller is displayed only if it is relevant to the current ventilation mode):

Button	Description
Slope	Used to set pressure rise profile. Available levels are **1** (fastest) to **5** (slowest). Relevant to all the modes besides AC-VC mode and HFOT.
PS Term.	Used to set the expiratory trigger from 10% to 70% of the peak flow or OFF. Enabled in all modes with PS breaths. When "PS Term" is set to "OFF" the length of the pressure support breath is the "PS Ti" set value.
PS Ti	Used to control and limit the inspiratory time in Pressure Support Ventilation from 0.1 to 3 seconds. Enabled in all modes with PS breaths.
SIGH	ON/OFF – Used to activate SIGH feature: once every 100 volume-controlled breathes 150% of the set VT will be delivered
Waveform	Used to select the type of flow waveform in volume controlled breathes: **Square** / **Descend** Enabled only in AC-VC and SIMV-VC modes

6.4 Alarm controllers

Make sure that the alarm limits are within clinical parameters

The following alarms are available in the alarms tab 

:

When there are more than 7 alarms to be set, use the arrows to scroll between them.

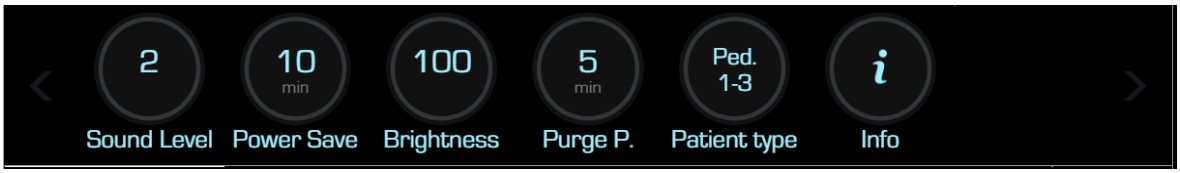
Button	Description
MV limit	Used to set the minimum and maximum allowed minute volumes. Corresponding alarms: Low MV and High MV. Range: 0 to 50 Resolution: 1 L
Pressure limit	Used to set the minimum and maximum allowed pressure of a mandatory breath. Corresponding alarms: Low Pressure and High Pressure. Range: 3 to 99 cmH_2O /mbar. Remark: High Pressure limit could not be set below 5 cmH2O above target pressure (for example, < PC+PEEP+5 or < PS + Phigh + 5, etc.) Resolution:1 cmH_2O/mbar
VTe limit	Used to set the minimum and maximum allowed exhaled tidal volume of a breath. Corresponding alarms: Low VTe and High Vte. Range: OFF, 10 to 2,200 ml Resolution: 10 ml
Apnea interval	Used to set the time for apnea detection and backup ventilation initiation (available only in CPAP/PSV and VG modes) Range: 10 to 60 sec Resolution: 10 sec
Rate limit	Used to set the minimum and maximum allowed rate of breath. Corresponding alarms: Low Rate and High Rate. Range: 0 to 99 bpm Resolution: 1 bpm
Block P.	Used to set the maximum allowed pressure measured during HFOT. Corresponding alarm: Low Flow. Range: 10 to 60 cmH2O Resolution: 10 H2O
Pulse limit	Used to set the minimum and maximum allowed measured patient pulse rate. Corresponding alarms: Low Pulse Rate and High Pulse Rate Range: 20 to 300 bpm Resolution: 1 bpm

Button	Description
SpO2 limit	Used to set the minimum and maximum allowed SpO_2. Corresponding alarms: Low SpO_2 and High SpO_2 Range: 70 to 100% SpO_2 Resolution: 1 % SpO_2
etCO2 limit	Used to set the minimum and maximum allowed $etCO_2$. Corresponding alarms: Low $etCO_2$ and High $etCO_2$ Range: 0 to 150 mmHg Resolution: 1 mmHg

6.5 Setting controllers

The following alarms are available in the alarms tab 

:



Button	Description
Sound Level	Used to set the alarm buzzer volume. Range: minimum sound level (1) to maximum sound level (10) Resolution: 1 Maximum Alarm Sound Level (10) corresponds to 80 dB(A). CAUTION: Make sure that the sound level alarm is not less than the ambient sound levels
Power Save	Used to activate power save mode. Range: OFF, 1 to 10 min. Resolution: 1 min. The screen is turned ON automatically in case of an alarm or if any key is pressed.
Brightness	Used to set the brightness of the display Range: 20 to 100 points Resolution: 1

Button	Description
Purge period	Used to set purge period Range: OFF to 10 min Resolution:1 min.
Patient type	Used to choose patient age range for the IPI parameter (available only if both SpO2 and Oridion capnography are present) **Adult/Pediatric 1-3 years/Pediatric 3-6 years/Pediatric 6-12 years**
Info	Gives the system information: - Unit serial number - SW version - Turbine working hours - Unit working hours - Altitude - Network - IP address

While nebulizer is working it is not recommended to put purge period on "OFF"

6.6 Operational Control Bar

6.6.1 Screen lock

Screen lock button locks the touch screen.

Tapping the screen lock button opens a dialog box:

Once tapping "Yes" the screen is locked. When trying to tap the screen the lock symbol will appear:

To unlock the screen, tap the screen lock button again and tap "Yes" in the opened dialog box.

6.6.2 100% O_2

Switching on the 100% O_2 function activates 100% O_2 procedure: increases the oxygen concentration delivered to the patient to 100% for 2 minutes. If the 100% O_2 function is switched OFF within the 2 minutes' period, the ventilator returns to the prior O_2 settings.

> Oxygen alarms are disabled during the 100% O_2 procedure.

To set 100% O_2:

1. Tap the **100% O_2** control button
2. The control button displays a counter showing time left for the O_2 enrichment

3. To deactivate the 100% O_2, tap the control button again.

6.6.3 Nebulizer

Switching on the Nebulizer function activates the nebulization feature.

The nebulization feature provides a synchronized flow of 6-9(LPM) to power a pneumatic nebulizer connected to the nebulizer outlet.

The in-line nebulizer is powered by 100% O_2 and synchronized with the patient inspiratory phase of each breath and can be adjusted in increments of 5 minutes for maximum of 60 minutes.

The ventilator volume ventilation algorithm compensates for the additional in-line volume.

The nebulizer should be connected to the inspiratory limb per the institution's policy and procedures. Connecting the nebulizer between the flow sensor and the endotracheal tube increases the dead space ventilation.

WARNING

The Ventilator accuracy could be affected by the gas added by use of a nebulizer.

WARNING

Nebulization affects the oxygen level delivered to the patient and should be taken into consideration.

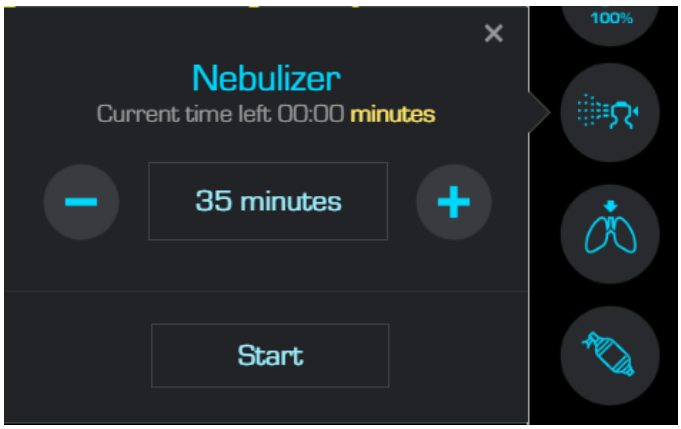
WARNING

Nebulization or humidification can increase the resistance of breathing system filters and should be monitored frequently for increased resistance and blockage.

Nebulization feature is disabled while ventilating with set volume under 200 ml and with distal patient circuit connection.

To set up the nebulizer:

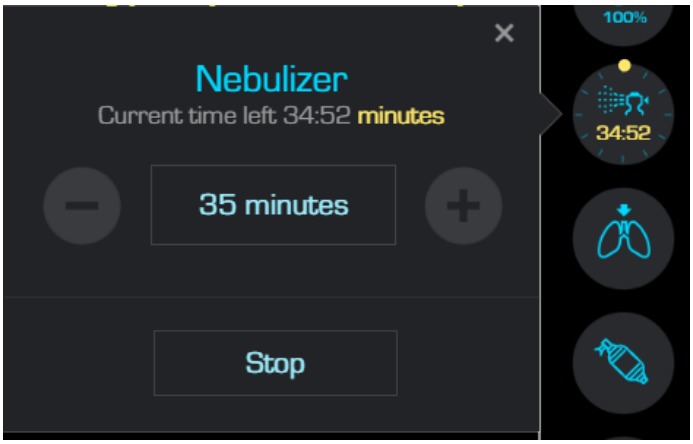
1. Securely attach the nebulizer to the port on the front panel.
2. Tap the nebulizer control button.
3. Set the nebulizer time with "+" and "-".



4. Tap on Start for nebulizer activation.

5. The control button displays a counter showing time left for the nebulizer activation.

6. To deactivate the Nebulizer re-tap the control button and tap "stop"



6.6.4 Maneuvers

The following lung mechanics monitoring parameters can be measured with the Ventoux:

Parameter (unit)	Definition	Exceptions
Dynamic Compliance - "Cdyn" (L/cmH_2O)	Dynamic compliance of the lung and chest wall.	
Inspiratory hold		
Plateau Pressure (cmH_2O)	The pressure applied to the small airways and alveoli. Without lung disease, peak inspiratory pressure is only slightly above the plateau pressure.	**Error** - the measured plateau pressure is negative
Static Compliance – "Cstat" (L/cmH_2O)	Static (during zero flow maneuver) compliance of the lung and chest wall. With "Cstat" changes of the elastic characteristics of the patient's lungs can be detected.	**Error** - the calculated static compliance is below 0.0005 or above 0.2 [L/cmH2O].

Resistance – "Rinsp" ($cmH_2O/(L/sec)$)	The resistance of the respiratory tract to airflow during inspiration	**Error** - the calculated value is below 0.5 or above 300 [cmH2O/(L/sec)].
Expiratory hold		
Auto PEEP (cmH_2O)	The difference between the set PEEP and the total PEEP in the lungs. The abnormal pressure cause by air trapped in the alveoli due to inadequate lung deflation.	**AutoPEEP = 0** means that there is no autoPEEP. The measured pressure difference could be negative or zero.

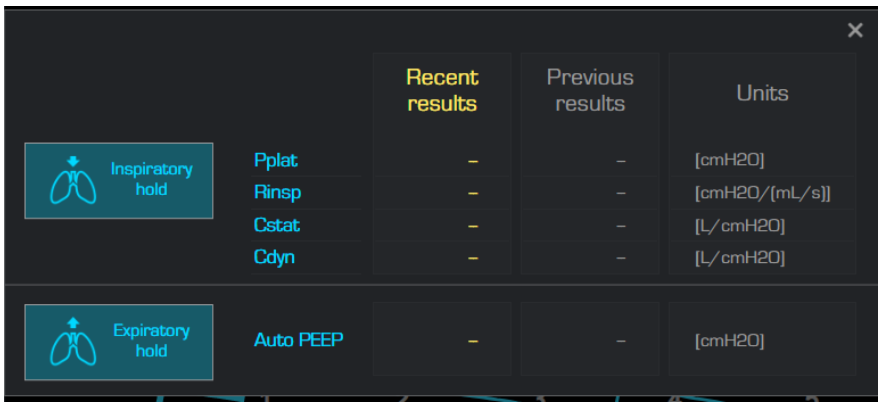
In order to monitor Plateau Pressure, Static Compliance and Resistance an ***Inspiratory Hold*** should be performed.

In order to monitor Auto PEEP an ***Expiratory Hold*** should be performed.

Actively breathing patients can create artifacts or noise, which can affect the accuracy of the lung mechanics calculations.

Performing Inspiratory and Expiratory Hold maneuvers

Pressing on the lung mechanic icon  open the following window:



To activate maneuver:

1. Press the maneuver icon.
2. Select the maneuver you would like to perform.

The selected maneuver will be performed automatically in the next inspiratory or expiratory phase respectively. The Maneuver is 3 seconds Length.

After the maneuver was performed, the monitored parameters will be updated and displayed.

One subset of the parameters is updated only in inspiratory maneuver, another – only in expiratory maneuver.

6.6.5 Manual Breath

Pressing the **Manual Breath**  button performs the same type of breath as the patient triggered breath (depends on the operation mode).

.

Manual Breath will be initiated only if the button was pressed during the exhalation phase

6.6.6 Cuff pressure control (optional)

The Cuff Control device is intended to continuously measure and automatically maintain the user set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation. The device is to be used during ventilation of adults, and pediatrics, who are intubated with ETT or TT.

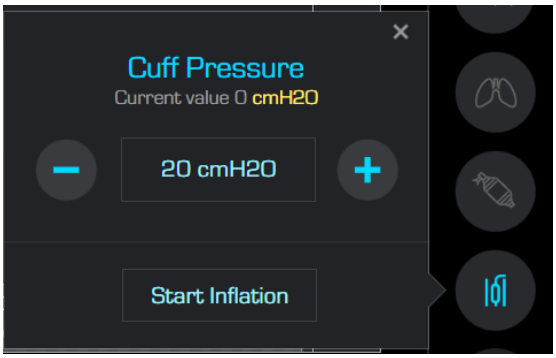
The integrated automatic cuff pressure controller provides an automatic cuff pressure in tracheal tubes and tracheostomy tubes according to an adjustable target pressure. The cuff can be either inflated or deflated.

	Use only FLIGHT MEDICAL tubing. Check tubing regularly. Bent or kinked tubes can provide incorrect monitoring information.
	Before taking out the ETT a full deflation according to hospital protocol must be performed.

	The feature is available only if the ventilator has a cuff pressure control module
	The cuff is fully deflated when turning ON the ventilator
	The cuff pressure controller is available during standby mode. Inflation and deflation are available during non-ventilation.
	Cuff pressure controller continues to function if ventilation is stopped.

To inflate the cuff pressure:

1. Press the Cuff control icon  .
2. Set the target cuff pressure adjusting with "+" and "-".
3. Tap on Start inflation



Inflation will start immediately.

The measured Cuff pressure is displayed in the Cuff pressure window and on the Cuff pressure button.

While inflation is active, changing the target pressure will automatically change the cuff pressure.

The default Cuff pressure target value is the last set value.

WARNING

Set the cuff pressure carefully to avoid damages of the trachea as well as airway leak or aspiration which can increase the risk of ventilator associated pneumonia.
Use the inflating tube of the tracheal tube or tracheostomy tube to verify that the cuff pressure controller is generating pressure and reacts immediately on squeezing the pilot balloon.

High priority alarm is displayed if the target pressure is not reached within 10 seconds.

To deflate the cuff pressure:

1. Press the Cuff control icon  .

2. Tap the Deflation button.

3. Confirm deflation

Confirmation helps avoid unintentional deflation and loss of pressure by accidentally pressing Deflation.

4. The cuff will be deflated immediately, the pressure value will continue to display until it reaches 0 cmH2O.

6.6.7 Pulse Oximetry and Capnography (optional)

This controller is displayed only if pulse oximeter and/or capnography modules are available.

A full green circle means that the module is on 

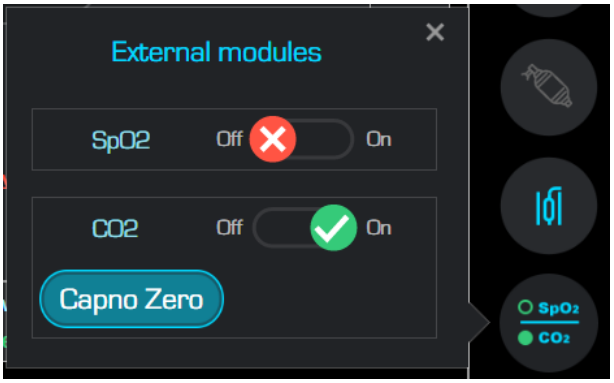
An empty green circle means that the module is available but is off 

If one of the modules is not available, it will not appear at all 

In order to turn on/off SpO_2/$etCO_2$ module:

1. Press on the 

icon.
2. Choose ON/OFF on the relevant module.



Philips capnography modules (Both LoFlo and Capnostat 5) require warm up when turned on. It takes around 30 sec. before actual measurements begin.

"Capno Zero" button is only available for Philips capnography modules (see section 10.2.2)

7 Ventilator Alarms and Backup Ventilation

The Ventoux Ventilator comes with an intelligent alarm system, which warns the user of problems with the ventilator.

The Ventoux Ventilator alarm system includes variable and automatic alarms (ventilation and technical).

These alarms can be either audible or visual.

This chapter describes:

- Audible Alarm Signals (see Section 7.1)
- Visual Alarms Signals (see Section 7.2)
- Alarm Log (see section 7.3)
- Alarms Specifications (see Section 7.47.4)

- Apnea Backup VentilationApnea Backup Ventilation (see Section 7.5)
- Muting audible alarms (see Section 7.6)
- Setting Up a Remote Alarm (see Section 7.7)

7.1 Audible Alarm Signals

The Ventoux alarm system has four distinguished audible alarm types:

- **Informative Alarm-** Operator awareness is required. These alarms alert to a change in the ventilator status and can be acknowledged by the operator.
- **Low Priority Alarm** - Operator awareness is required. These alarms alert you to a change in the ventilator status.
- **Medium Priority Alarm** – Requires the operator's response.
- **High Priority Alarm** – Require the operator's immediate response.

Audible Indicators:

- **High Priority Alarms** – When a high priority alarm is detected a 10- beep sound is repeated. The sound continues until the alarm cause is corrected.
- **Medium Priority Alarms** - When a medium priority alarm is detected a 3-beep sound is repeated. The sound continues until the cause of the alarm is corrected.
- **Low Priority Alarms** - When a low priority alarm is detected a 2-beeps sound in repeated. The sound continues until the cause of the alarm is corrected.
- **Informative Alarms** - When an informative alarm is detected a 2-beeps sound in repeated. The sound continues until the cause of the alarm is corrected **or** until the alarm is acknowledged by pressing the alarm message.

Auditory alarm signal pressure levels, which are less than ambient levels, can impede operator recognition of alarm condition and the alarm system provides a restricted minimum and maximum alarm level.

7.2 Visual Alarm Signals

The visual alarm system is composed of:

- One major visual alarm signal – Flashing red/yellow led to indicate that there are alarms in the system.

  Type of flashing indication:

- **High Priority Alarms** – When a high priority alarm is detected the indicator flashes red with high frequency and continue until the alarm cause is corrected.
- **Medium Priority Alarms** - When a medium priority alarm is detected the indicator flashes yellow with a low frequency and continue to flash until the cause of the alarm is corrected.
- **Low Priority Alarm** - When a low priority alarm is detected the indicator is constantly yellow until the cause of the alarm is corrected.
- **Informative Alarm** - When an informative alarm is detected the indicator is constantly yellow until the cause of the alarm is corrected **or** until the alarm is acknowledged by pressing the alarm message.

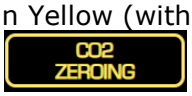
■ An Alarm Message display:

- **High Priority Alarms** – Displayed in red: 

- **Medium Priority Alarms** – Displayed in Yellow: 

- **Low Priority Alarms**– Displayed in Yellow: 

- **Informative Alarms** – Displayed in Yellow with an "x" in the left upper corner of the message: 

- **Message Alarms –** displayed in Yellow (with no flashing indication or audible alarm): 

Once an alarm goes on the matching parameter blinks in red (when applicable)

If multiple alarms occur at the same time, the three most important alarms are displayed according to their internal priority, left to right from the highest to the lowest priority. Every time a new alarm is activated, the system recalculates the correct order of the alarms and displays the three most important ones.
A numeric indicator on the left upper corner of the screen indicates the number of active alarms (

).

Alarm settings are permanently saved in flash-memory and are available even after power interruption.

WARNING

The operator should check to ensure current alarm pre-set is appropriate prior to use on each patient.

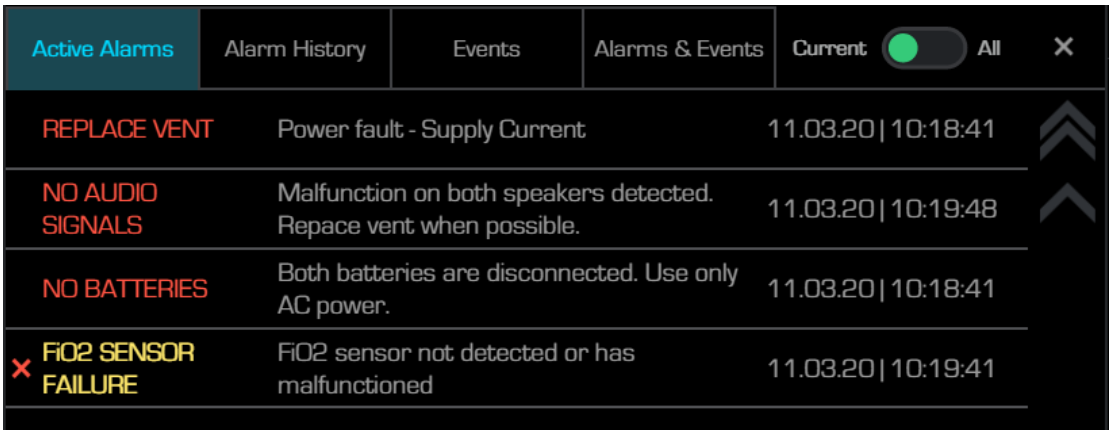
7.3 Logs

The user can open the logs window in two ways:

1. Pressing the alarm bar area (including the alarms numeric indicator or one of alarm massages opens the logs window.
2. Choosing the logs layout  in the layout window (see section 8.1).

7.3.1 Active Alarms

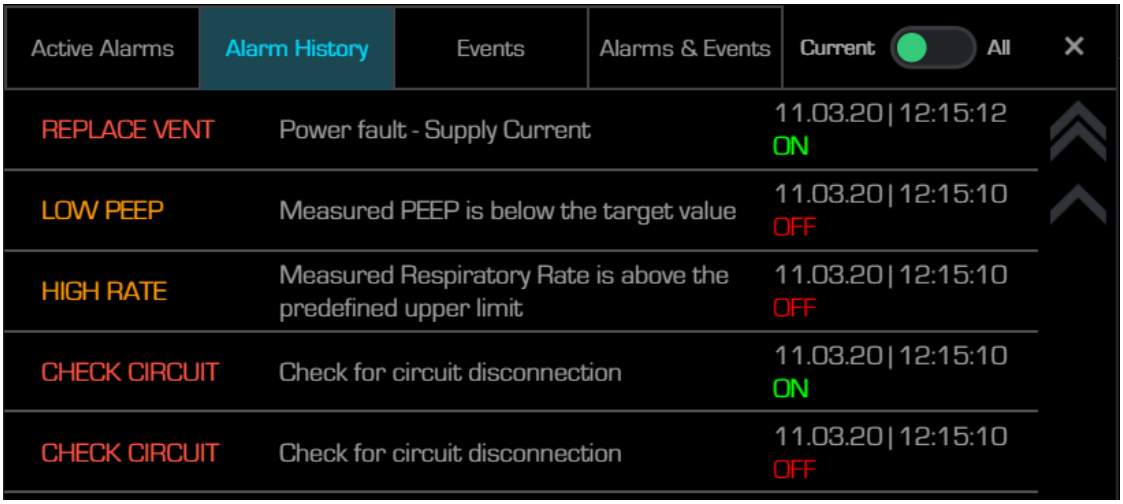
Shows the current system alarms, once the alarm cause is resolved it disappears from the list.



Acknowledged informative alarms remain in the alarms' logs until the cause of the alarm is resolved

7.3.2 Alarm history

Shows all system alarms, current and resolved. Alarm history is saved for a least 72 hours.



7.3.3 Events

Shows prescription changes (parameters, modes and alarm limits), and also events like start/stop ventilation and BUV.

The user can choose to see current session events or all events.

Current session is defined from turning on the ventilator or from the end of last ventilation session, to the end of the current ventilation session.

the parameters of the ventilation can be opened and closed by tapping the arrow.

7.3.4 Alarms and Events

Combines Alarm history and events. In this tab the user can also choose current session or all.

7.4 Alarms Specifications

This section describes the specifications for the Ventoux Ventilator:

- Power alarms
- Ventilation alarms
- Monitoring alarms
- Automatic technical alarms

7.4.1 Power Alarms

Power Alarms		
Alarm	**Description**	**Priority**
No external power	AC or external DC is disconnected	Info
Batteries below 30%	Total capacity of both batteries is less than 30% and greater than 15%	Info
One battery only	One of the batteries is disconnected	Info
Low Batteries	Total capacity of both batteries is less than 15% and greater than 10%	Medium
Batteries empty	Total capacity of both batteries is less than 10%, at least one of batteries is connected, AC supply is connected	Info
Batteries empty	Total capacity of both batteries is less than 10%, at least one of batteries is connected, no AC supply	High
No Batteries	Both batteries are disconnected	High

7.4.2 Ventilation Alarms

Ventilation alarms		
Alarm	**Description**	**Priority**
Low cuff pressure	Cuff under inflation: For target pressure ≤20 cmH2O: measured pressure < (target pressure – 3) For target pressure >20 cmH2O: measured pressure is less than 85% of target pressure	Medium
High cuff pressure	Cuff over inflation: For target pressure ≤20 cmH2O: measured pressure > (target pressure + 3) For target pressure >20 cmH2O: measured pressure is more than 115% of target pressure	High
CUFF deflation timeout	after 1 minute from deflation the CUFF pressure is above 1 cmH2O for more than 2 second	Medium
High FIO2	Measured FiO_2 is 10% above the set value	Medium
Low FIO2	Measured FiO_2 is 10% below the set value	Medium
FiO2 < 18%	Measured FiO2 is below 18%	High
No O2 supply	Measured oxygen pressure at the mixer entry is too low	High
Low VTe	Actual VTe is below the minimum VTe set	Medium
High VTe	Actual VTe is above the maximum VTe set	Medium
High MV	Actual MVe is above the maximum MV set	Medium
Low MV	Actual MVe is below the minimum MV set	High
Low rate	Actual Rate is below the minimum Rate set. When capnography module is available, the alarm should be available also during monitor mode and initiated by the module	Medium
High rate	Actual Rate is above the maximum Rate set. When capnography module is available, the alarm should be available also during monitor mode and initiated by the module	Medium
Low PEEP	Actual PEEP is at least 3 cmH2O below the set PEEP value	Medium
Partial occlusion	Partial exhalation occlusion is detected: actual PEEP is greater than 8 cmH2O above set PEEP value	Medium
Circuit occlusion	Critical Occlusion is detected: actual PEEP is greater than 15 cmH2O above set PEEP value	High
Check circuit	Possible kink in the tubing	High
Check circuit	Possible proximal line disconnection	High
Check circuit	Possible exhalation tube disconnection	High
Check circuit	Possible patient disconnection	High
Check circuit	Possible circuit disconnection	High
Low pressure	Peak inspiratory pressure is below the minimum Pressure set	High
High pressure	Maximum Pressure is reached	High
PC not reached	Peak inspiratory pressure is below the PC target value	Medium
VT not reached	Tidal volume is below the VT target value	Medium
VT exceeded	Tidal volume is above the VT target value	Medium
Apnea	When Capnography module is available, the alarm is available during monitor mode and initiated by the module	Medium
Apnea BUV	Apnea is detected: no breathes during the predefined interval. Back up ventilation due to apnea is processing	High
Apnea event ended	Backup mode was reset, and device is again ventilating in its original support (pre-apnea) mode.	Info
Low Flow	Measured flow during HFOT is below 90% of the target flow	Medium
Flow Blockage	Measured pressure is over maximum Block P. set	High

7.4.3 Technical Alarms

Technical alarms		
Alarm	**Description**	**Priority**
Calibration needed	Flow sensors calibration needed.	Info
Calibration needed	O_2 flow sensors calibration needed.	Info
Calibration needed	FiO_2 sensor calibration needed.	Info
Calibration needed	Pneumatic system calibration needed.	Info
Battery #1 Fault	The temperature of the battery #1 is greater than 50 degrees.	Medium

Alarm	Description	Priority
	The battery's removal is recommended.	
Battery #2 fault	The temperature of the battery #2 is greater than 50 degrees. The battery's removal is recommended.	Medium
High motor temperature	Motor temperature is greater than 85 degrees. The ventilator's replacement is recommended.	Medium
High internal temperature	One of the following happens: • Power board temperature is above 80 degrees. • Motor temperature is above 80 degrees. • SOM processor temperature is above 85 degrees. • Barometer temperature is above 60 degrees.	Medium
Led malfunction	Alarm led functionality cannot be verified	Info
One speaker only	Just one of the speakers is working	Info
No audio signals	Malfunction of both speakers	High
Cooling fan is off	One or both cooling fans are off	Info
Safety fan is off	Malfunction of safety fan	Low
O2 pressure sensor failure	O2 pressure sensor failure	Low
Do not connect O2	Safety fan malfunction detected; AC cable is connected. Do not connect oxygen supply.	Low
Do not connect AC	Safety fan malfunction detected; oxygen is supplied. Do not connect AC power.	Low
Disconnect O2 supply	Safety fan malfunction detected, both AC power connected, and oxygen is supplied, but ventilation is without oxygen. Disconnect O_2 supply immediately.	High
Disconnect AC	Safety fan malfunction detected, both AC power connected, and oxygen is supplied, and ventilation is with oxygen. Disconnect AC power immediately.	High
O2 supply will shut off	The safety fan is off, the oxygen supply will be off in 5 minutes	High
O2 supply is off	The safety fan is off, the oxygen supply is off	High
O2 Mixer failure	O_2 supply is disabled due to O_2 mixer failure	High
FiO2 sensor maintenance	Replace FiO2 sensor as part of periodic maintenance.	Info
FiO2 sensor failure	FiO_2 sensor is not detected, ventilation is without oxygen	Info
FiO2 sensor failure	FiO_2 sensor is not detected, ventilation is with oxygen	Medium
Calibrate FiO2 sensor	FiO_2 sensor requires calibration	Low
Barometer fault	Barometer malfunction detected	Info
Display is disconnected	Display cable is disconnected	High
Replace vent	External DC is over/under voltage	High
Replace vent	Batteries chargers are over/under voltage	High
Replace vent	No battery charging	High
Replace vent	Measured power supply voltage is over 26V	High
Replace vent	Power fault: current is too high or no current detected	High
Replace vent	Power board temperature is over 90 degrees.	High
Replace vent	Motor voltage is over 28.5V	High
Replace vent	Motor temperature is over 85 degrees.	High
Replace vent	Motor does not rotate	High
Motor maintenance	Replace motor as part of periodic maintenance	Info

7.4.4 Monitoring Alarms

7.4.4.1 Common capnography alarms

Capnography Alarms		
Alarm	**Description**	**Priority**
High etCO2	Measured $etCO_2$ is above the maximum $etCO_2$ set	Medium
Low etCO2	Measured $etCO_2$ is below the minimum $etCO_2$ set	Medium
CO_2 zeroing	Capnography sensors zeroing in progress. Sent from the module.	Silent message

7.4.4.2 NanoMediCO2 capnograph alarms

NanoMediCO2 Alarms		
Alarm	**Description**	**Priority**
CO_2 occlusion	Occlusion in gas input line. Sent from the module.	Low
CO_2 fault	Blocked exhaust, or it may be a problem internal to the NanoMediCO2 module. Sent from the module.	Low
CO_2 Calibration required	CO_2 calibration is required. Sent from the module.	Silent message
CO_2 line disconnected	CO_2 Filterline is disconnected. Sent from the module.	Low
CO2 blockage	Capnograph blockage detected	Low

7.4.4.3 Philips capnograph alarms

Philips Alarms		
Alarm	**Description**	**Priority**
Check CO_2 adapter	Airway adapter is removed from the Capnostat or optical blockage on the windows of the airway adapter. Sent from the module.	Low
CO_2 out of range	CO_2 value is out of range. Sent from the module.	Low
CO_2 Sensor fault	CO_2 sensor fault detected. Sent from the module.	Low
Capnostat not initialized	Capnostat is not initialized. Sent from the module.	Silent message
CO_2 sidestream is not connected	CO_2 sidestream adapter is disconnected. Sent from the module.	Low
CO_2 check sampling line	Check CO_2 sampling line for occlusion. Sent from the module.	Low
CO_2 pump life exceeded	CO_2 pump life is exceeded. Perform maintenance. Sent from the module.	Info
CO_2 Sensor over temp	Philips sensor is over temperature	Silent message

7.4.4.4 Oxymetry alarms

Oximetry Alarms		
Alarm	**Description**	**Priority**
SpO2 poor signal	Poor SpO2 signal is detected. Adjust probe.	Low
Low SpO2	SpO2 is below the minimum SpO2 set	Medium
High SpO2	SpO2 is above the maximum SpO2 set	Medium
Low pulse rate	Measured pulse rate is below the minimum Pulse rate set	Medium
High pulse rate	Measured pulse rate is above the maximum Pulse rate set	Medium
SpO2 INOP	Malfunction has been detected compromising SpO2 integrity. Sent from the module	High
SpO2 sensor failure	Sent from the module	Low
SpO2 disconnection	One or more junctions of the sensor SpO2 cabling is disconnected. Sent from the module	Low
SpO2 off the patient	Sensor is off the patient. Sent from the module.	Low
Pulse search	SpO2 pulse search is in process. Sent from the module	Info
Pulse timeout	Signal is lost. Sent from the module	High
SpO2 extended update	The SpO2/ pulse rate data update exceeded 25 seconds. Sent from the module	Low

When an alarm message is generated or powered down, it is recorded in the alarms log with its accurate time and date.

Comment:

- All logs are available after unexpected power loss.
- Once the logs capacity is full, new logs will delete the old logs.

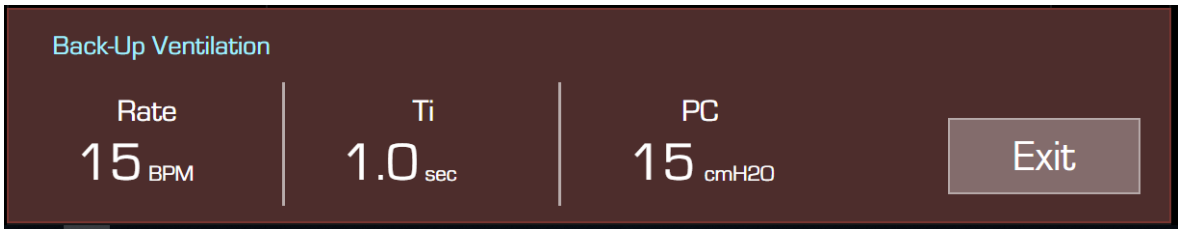
7.5 Apnea Backup Ventilation

Ventoux provides apnea backup ventilation (BUV) when no inspiratory efforts are detected for the set Apnea Interval.

When setting the ventilation parameters, the user has to set the parameters for the backup ventilation in the Backup Ventilation tab in the modes window.

During back up ventilation:

- Apnea BUV alarm is issued
- The controllers' area of the display is locked, and the following window appears:



7.5.1 Termination of Backup Ventilation

BUV mode ends in one of the following cases:

- By the patient: There are two patient-triggered breaths during the Apnea interval time
- By the operator: Pressing Exit on the backup ventilation window.

7.5.2 After exiting Backup Ventilation

- Apnea BUV alarm is cleared, audible and visual alarms stop.
- The backup ventilation window is removed from the display.
- The ventilation is back to the previous mode with the previous set of parameters

	Pressing Exit to stop the Apnea BUV alarm does not cancel other alarms.

	Backup Ventilation is not active for the Apnea preset time after the user resets the BUV alarm.

7.6 Muting Audible Alarms

The user can mute all active alarms for 2 minutes.

To mute audible alarms and cautions:

1. On the ventilator front panel, press the **Mute** hard button.

   The system enters silence mode. The led indicator on the mute hard button is illuminated and a mute indicator with a counter showing the time left for the silence mode are displayed on the main screen (replacing the time and date indicator):

   All alarms, except fault Alarm, are muted for 2 minutes.

The user can cancel the silence mode before the 2 minutes are up by pressing the **Mute** hard button again.

7.7 Setting Up a Remote Alarm

The remote alarm feature enables monitoring device alarms from a distant station. When connected to a remote alarm system, all visible and audible alarms on the device are transmitted as an electronic signal to the remote

alarm station with a 1 ms interrupt delay. Other conditions, such as system shutdown (or power down) can also be detected by the remote alarm system.

The Ventoux device can be connected to a third-party remote alarm system in several configurations. In order to connect the device to a remote alarm system, a special cable must be fitted to the system and integration must be conducted between the device and the remote alarm system.

Before attempting any connection, contact your provider or FLIGHT MEDICAL. Technical Support for details.

DO NOT rely solely upon the remote alarm!

Take precautions that PATIENT safety is not compromised!

A hazard can exist if different alarm presets are used for the same or similar equipment in any single area,

8 Monitoring

Monitoring parameters are displayed at all times to ensure continuous monitoring of the patient during ventilation.

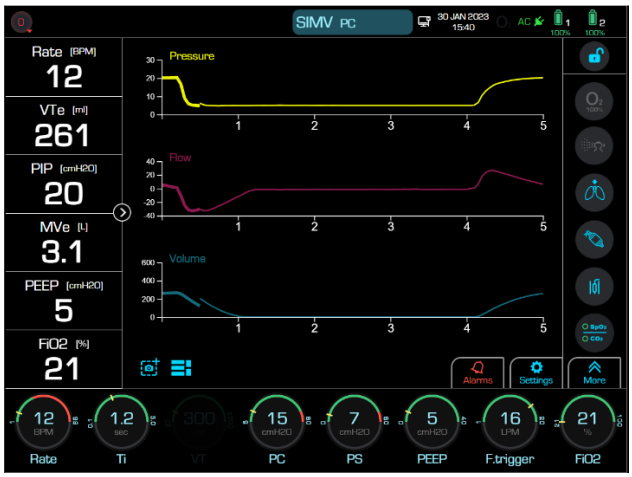
The Ventoux provides two kinds of displayed data: Graphical and Numeric.

8.1 Layouts

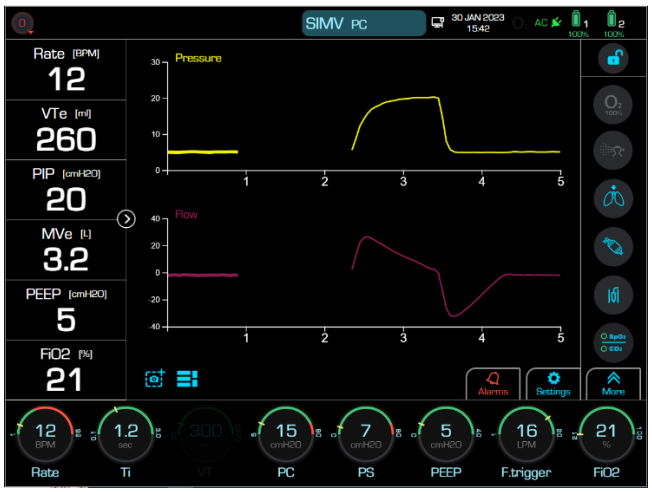
Tapping the layout icon  opens the following menu:

The user can choose between 6 layouts:

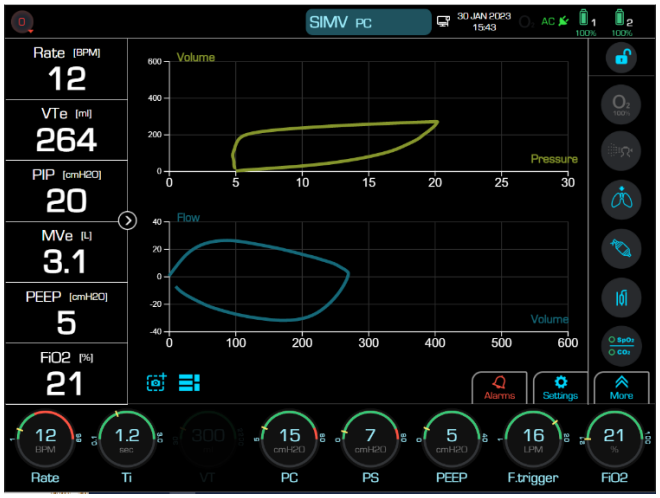
1.  Numeric display and 3 graphs



2.  Numeric display and 2 graphs



3.  Numeric display and loops



4.  Numeric display only (of the 6 main parameters)

5.  Logs window (see section 7.3)

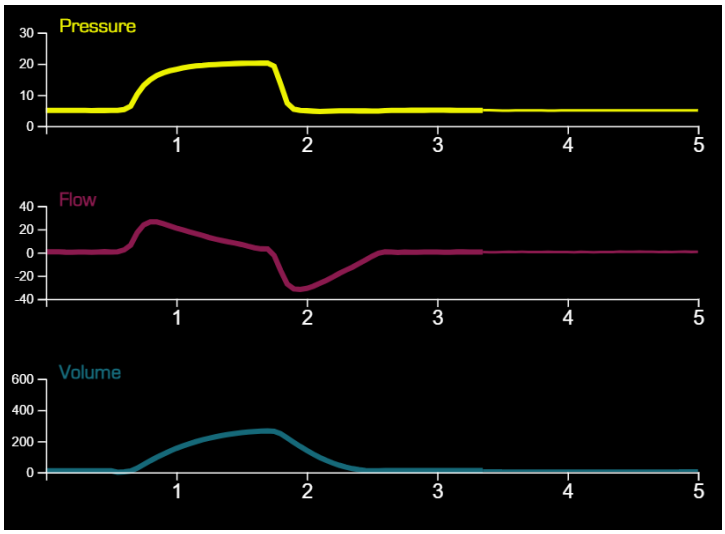
6.  Trends window (see section 8.2.4)

8.2 Graphical data

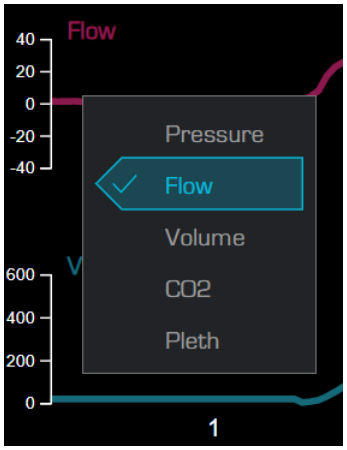
8.2.1 Types of graphs

The Ventoux plots pressure, flow, volume, CO_2 and plethysmograph data ("Pleth") against time.

The default configuration displays Pressure, Flow and Volume) graphs.

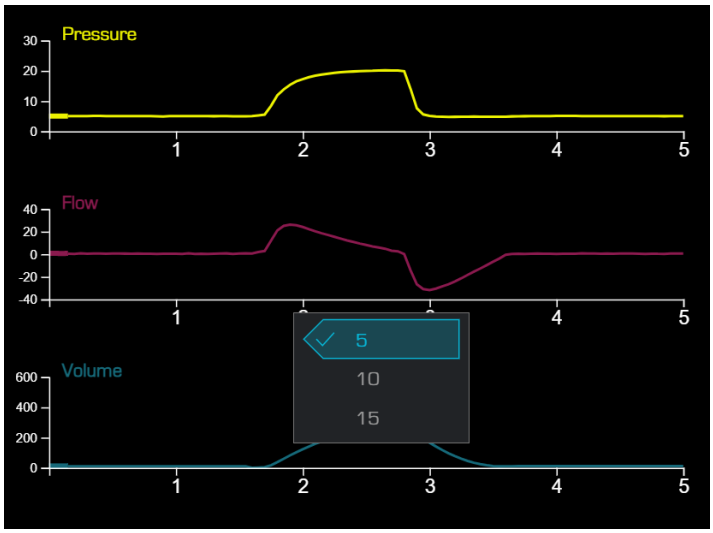


User may define the graphs to be displayed by tapping the Y scale area and choose the type from the opened list:



8.2.2 Graphs scale

The user can choose between a graph scale of 5, 10 or 15 seconds by tapping the time scale area and choose the scale from the opened list (the scale chosen applies to all the displayed graphs):



8.2.3 Graphs colors

Each graph has a different color:
Pressure - yellow; Flow - purple; Volume - blue; CO_2 – blue; Pleth - blue.

Patient triggered breaths and manual breaths are marked with a green pressure line.

WARNING

The ventilator uses an auto-scaling function – scales of each waveform or loop may differ based on the actual range of values to be displayed.

8.2.4 Loops

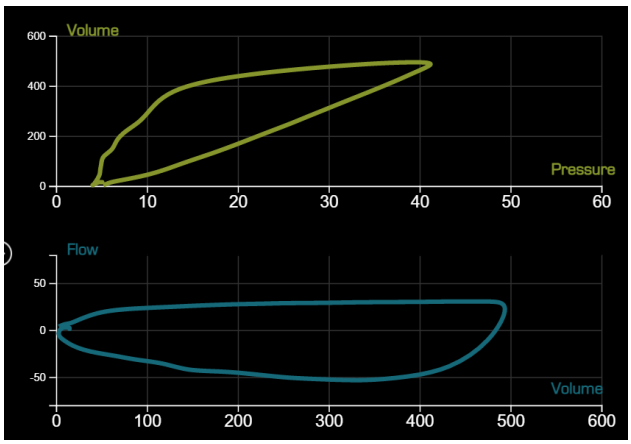
The Ventoux can display a dynamic loop based on the following parameter combinations:

Pressure/Volume

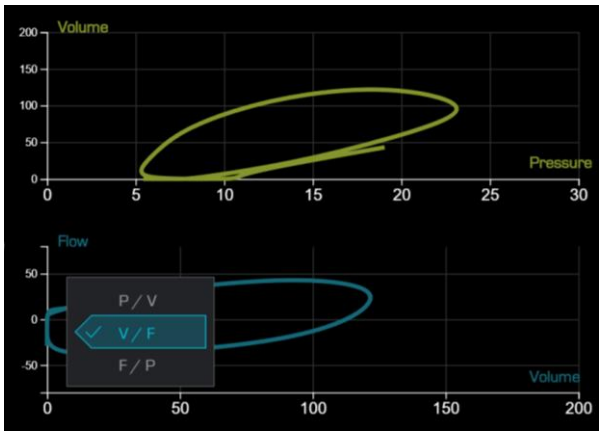
Volume/Flow

Flow/Pressure

To see the loops, choose the loops layout option in the layouts menu (see section 8.1)



User may define the loops to be displayed by tapping the Y scale area and choose the type from the opened list:



loops ranges:

Parameter	Range
Loops	
Pressure/Volume	x: 0 to 90 cmH_2O y: 0 to 2,000 ml
Volume/Flow	x: 0 to 2,000 ml y: -150 to 150 l/min
Flow/Pressure	x: -150 to 150 l/min y: 0 to 90 cmH2O

The ventilator uses an auto-scaling function – scales of each waveform or loop may differ based on the actual range of values to be displayed.

8.2.5 Trends

Every monitored parameter can be trended up to 72 hours.

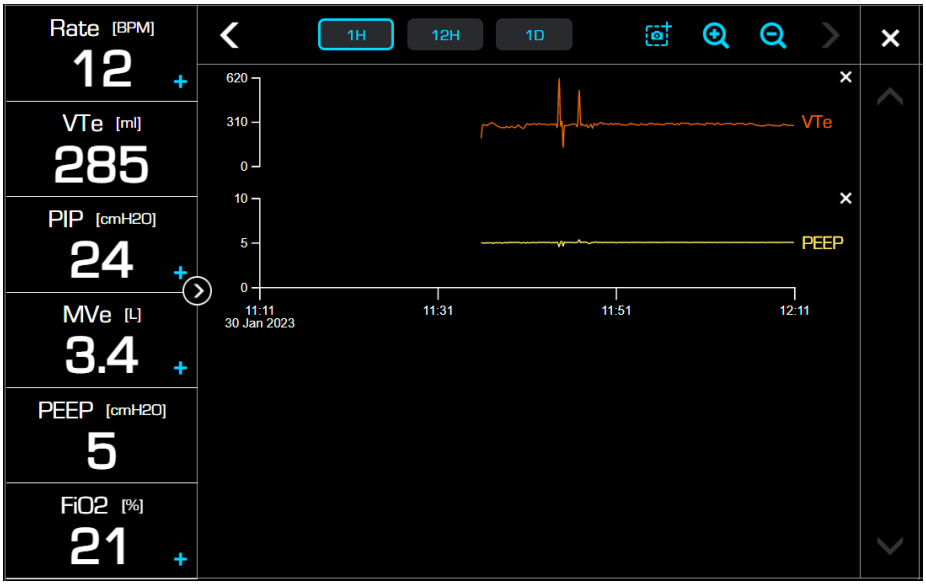
All the data of monitored parameters is available after unexpected power loss.

The user can open the trends window in two ways:

1. A long press on one of the monitored parameters.
2. Choosing the trends layout  in the layout window (see section 8.1).

8.2.5.1 Selecting Trended Parameters

Once the trends window is open a blue ”plus” sign will appear on the monitored parameters, tapping it will add the parameter to the trends window (the ”plus” sign disappears once the parammeter is already open). . Up to 4 graphs can be displayed simultaneously. Every additional parameter will "push" the first one up. The user can scroll between the graphs using the arrows on the right. Each graph can be closed separately from its "x", closing the last graph will close the trend window.



8.2.5.2 Time Scale Adjustment

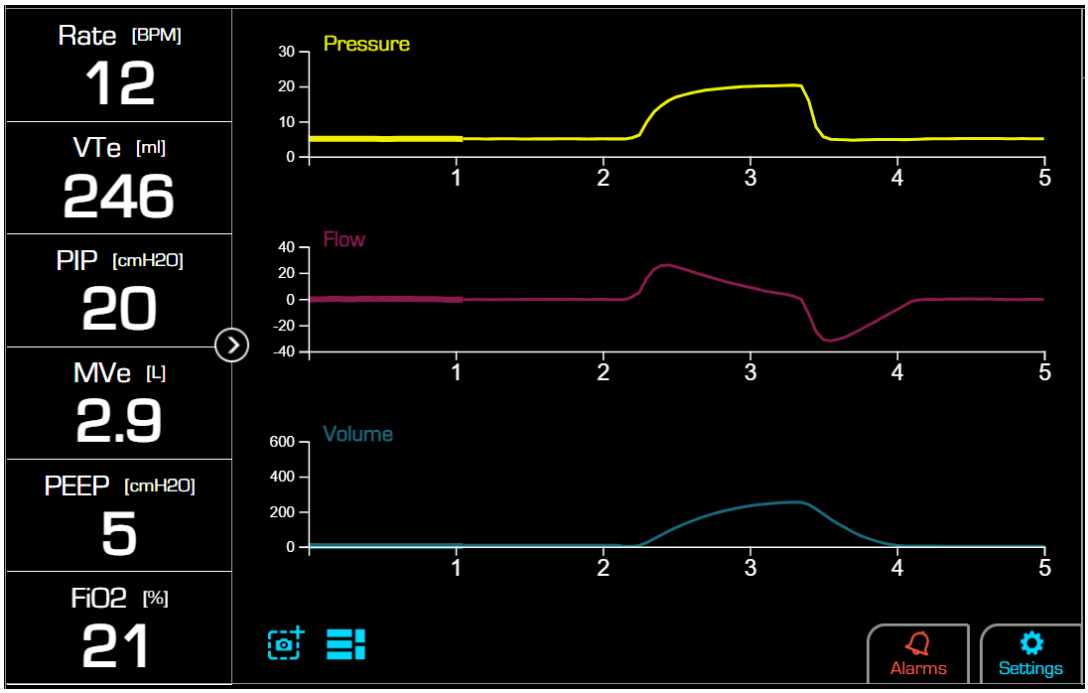
The user can choose between a time scale of 1H, 12H and 1D (24H), and scroll back and forth in time using the arrows on the top.

Zoom in and out is also available  .

8.3 Numeric Display

The Ventoux displays continuously numerical parameters.

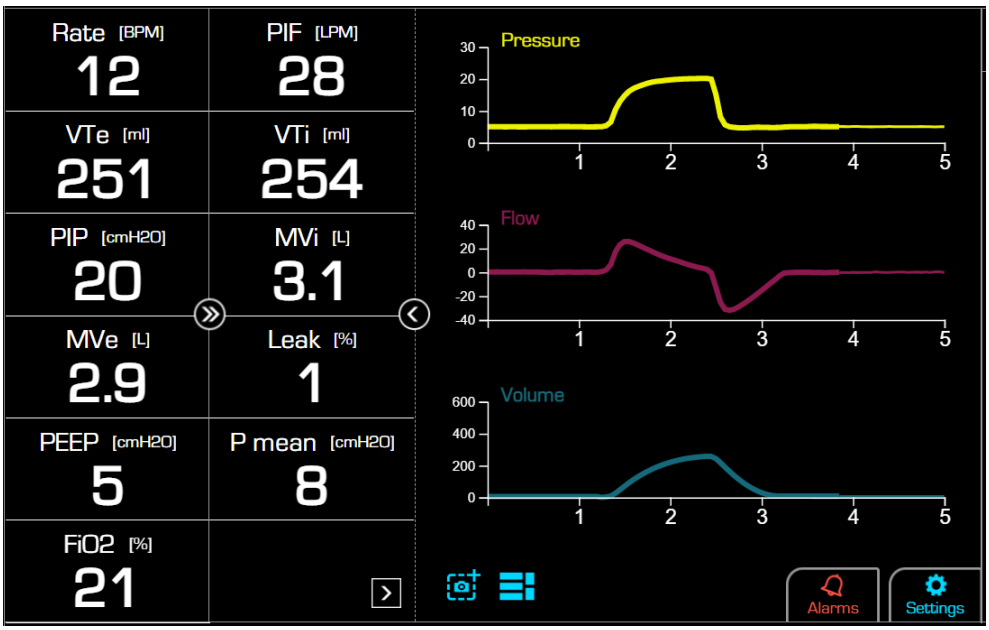
6 main default parameters are constantly displayed on the left side of the screen:



The following 6 parameters are constantly displayed on the left area:

Rate	Total number of patient or time activated breaths	99 b/min	1 b/min	Breath by breath
VTe	Expiratory Tidal Volume	0 to 7500 ml	10 ml	Breath by breath
PIP	Peak Inspiratory Pressure	0 to 120 cmH_2O	1 cmH_2O	Breath by breath
MVe	Expiratory Minute Volume	0 to 99 L	1 L	10 seconds rolling average
PEEP	Baseline airway pressure at the end of expiration	0 to 99 cmH_2O	1 cmH_2O	Breath by breath
FiO2	Fraction of Inspired Oxygen	18% to 100% O_2	1%	Every 10 seconds

Tapping the arrow  on the right of the numeric display will open secondary numeric display column:



The user can scroll between 3 columns of secondary parameters with the arrow  at the bottom:

The following 5 parameters are displayed in the first secondary column:

PIF	Peak Inspiratory Flow	1 to 120 L/min	1 L/min	Breath by breath
VTi	Inspiratory Tidal Volume	0 to 7500 ml	10 ml	Breath by breath
MVi	Inspiratory Minute Volume	0 to 99 L	1 L	10 seconds rolling average
*Leak	(1-VTe/VTi) *100	0% to 100%	1%	Breath by breath
P mean	Mean airway pressure	0 to 99 cmH_2O	1 cmH_2O	Breath by breath

*Leak is presented only in noninvasive ventilation (when NIV box is checked)

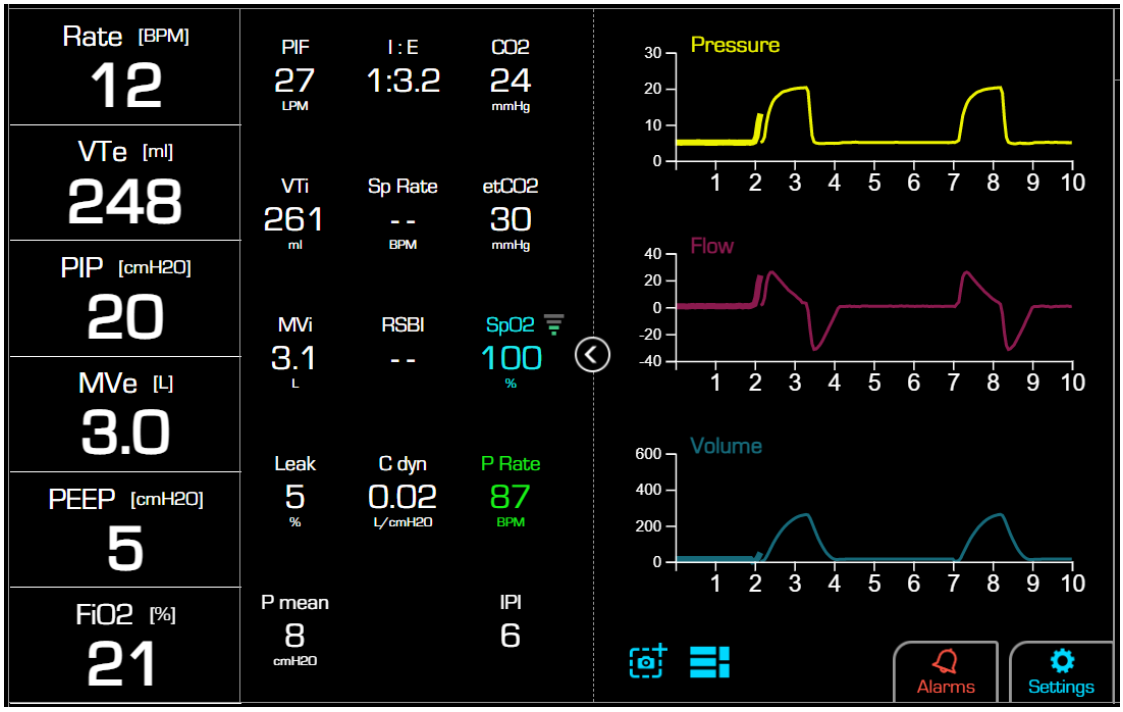
The following 4 parameters are displayed in the second secondary column:

I:E	Ratio between inhalation and exhalation period **Note:** If the expiratory time is longer than the inspiratory time, the display format is 1: X.X. If the expiratory time is shorter than Ti, the display format is X.X:1.	1:99 to 3:1		Breath by breath
Sp Rate	Rate of patient triggered breathes (spont. rate includes also manual breaths given by the operator)	99 b/min	1 b/min	Breath by breath
RSBI	rapid shallow breathing index The Rate of pressure support breaths divided by the average exhaled tidal volume. * RSBI considers only pressure support breaths.	0-200 breathes/min*L	1 breathes/min *L	Breath by breath
C dyn	Dynamic compliance of the lung and chest wall.	0.00-0.30 L/cmH_2O	0.01 L/cmH_2O	Breath by breath

The following 5 parameters are displayed in the third secondary column (only if capnography and oximetry modules are installed):

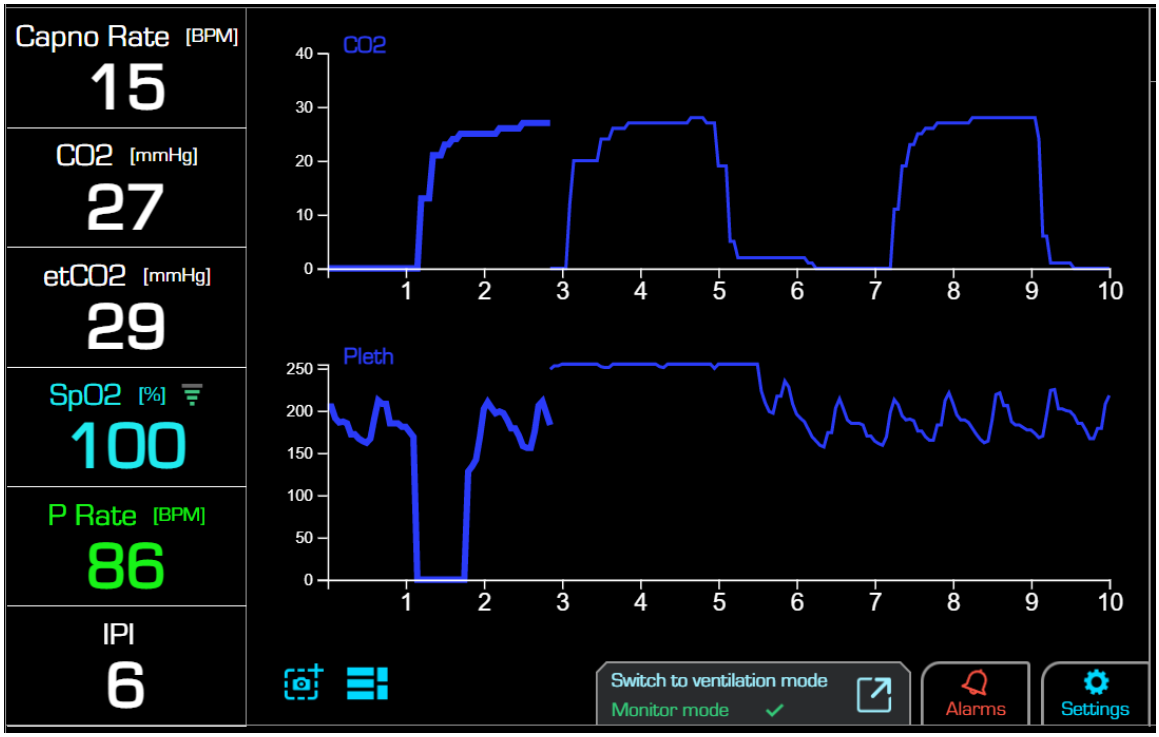
CO_2	amount of CO2 during every breath	0 to 150 mmHg	1 mmHg	Breath by breath
etCO_2	amount of CO2 present at the end of exhalation	0 to 150 mmHg	1 mmHg	Breath by breath
SpO_2	Saturation of O_2 in blood after 1 breath	1% to 100%	1%	Breath by breath
Pulse Rate	Average pulse rate during the breath	20 – 300 Bpm	1 Bpm	Breath by breath
IPI (only if both SpO_2 and Oridion capnography are present)	Integrated Pulmonary Index	1 - 10	1	Unit less

Tapping the arrow  will close the secondary column, tapping the double arrow  will display all monitored parameters together:



In monitor mode the ventilator will automatically display the following default parameters (depending on the modules installed):

Capno Rate	Total number of patient or time activated breaths	0 to 150 b/min	1 b/min	Breath by breath
CO_2	amount of CO2 during every breath	0 to 150 mmHg	1 mmHg	Breath by breath
$etCO_2$	amount of CO2 present at the end of exhalation	0 to 150 mmHg	1 mmHg	Breath by breath
SpO_2	Saturation of O_2 in blood after 1 breath	1% to 100%	1%	Breath by breath
Pulse Rate	Average pulse rate during the breath	20 – 300 Bpm	1 Bpm	Breath by breath
IPI (only if both SpO_2 and Oridion capnography are present)	Integrated Pulmonary Index	1 - 10	1	Unit less



8.4 Screen Capture

Tapping the  icon creates a screen capture that is saved in the internal storage of the ventilator. The screen captured photos can be accessed from the Ventoux Remote Screen application (a standalone application).

9 Ventilation Modes

- **AC** (Assist/Control Mandatory Ventilation) VC/PC/PRVC
- **SIMV** (Synchronized Intermittent Mandatory Ventilation) VC/PC/PRVC
- **CPAP/PSV** (Spont)
- **VG** (Volume Guarantee)
- **APRV** (Airway Pressure Release Ventilation)
- **HFOT** (High Flow Oxygen Therapy)

9.1 AC Mode (Assist Control Mandatory Ventilation)

In AC mode, time activated (mandatory) breaths are delivered in accordance with the Rate setting. Patients can trigger mandatory breaths in addition to, or in place of, time activated (mandatory) breaths, if the effort that they generate causes airway pressure to meet the P.trigger or F.trigger setting. Each such patient effort results in a mandatory breath.
The breath can be volume or pressure controlled. PEEP may be added. Tidal volume is determined by the target pressure, Ti, patient respiratory mechanics in Pressure Control, and by the tidal volume setting in Volume Control.

9.1.1 VC/PC/PRVC

In AC mode the ventilator can work in either of three sub-modes:

- **Volume Control** (VC)
- **Pressure Control** (PC)
- **PRVC** – Pressure Regulated Volume Control

9.1.1.1 Volume Control Ventilation (VC)

The VC mode delivers volume-controlled breaths as mandatory breaths. The user can set the volume. The tidal volume delivered to the patient is limited by the minimal and maximal flow of the system.

If the Volume Control setting causes the flow rate to reach the maximum or minimum level of the flow specification, adjustment of Volume Control ceases, and a setting limitation message appears in the warning window at the right bottom of the adjustment window.

The system supports two modes of flow waveform:

- **Square** – The flow is constant during the inspiratory phase.
- **Descend** – The flow decreases gradually during the inspiratory phase.

During Volume Control ventilation, tidal volume can be set for mandatory breaths. If a volume setting is changed while the ventilator is operating, the change takes place in increments over a series of breaths.

To set the target volume:

1. Tap the **VT** control button.
2. Adjust the VT value (tidal volume), using the displayed bar.
3. Confirm the change.

9.1.1.2 Pressure Control Ventilation (PC)

The PC mode delivers pressure-controlled breaths as the mandatory breaths. Breath termination occurs when one of the following conditions exists:

- The set Ti elapses.
- Maximum airway pressure exceeds the user set High pressure alarm limit setting.

Both time and patient triggered mandatory breaths can be delivered in AC and SIMV Pressure Control operation. During SIMV Pressure Control operation, patients can breathe spontaneously between mandatory breaths with or without pressure support.

When Pressure Control is first initiated or the setting is changed, the first few breaths may cycle off early until the rise profile is optimized. If early cycling off continues, reevaluate the patient circuit configuration and lengthen the tubing as necessary.

The minimum target airway pressure is 5 cmH_2O(mbar) above the set baseline pressure (PEEP).

To set the target pressure:

- Tap the **PC** control button.
- Adjust the PC value (the target pressure), using the displayed bar.
- Confirm the change.

9.1.1.3 Pressure Regulated Volume Control (PRVC)

In PRVC, breaths are pressure control while the pressure level is automatically adjusted in order to achieve the preset target volume.
The maximum airway pressure never exceeds the user set High pressure alarm limit setting.
The following primary breath controls are required for PRVC mode:

- VT – The target tidal volume.
- Rate – Breath rate.
- Ti – Inspiratory time

9.2 SIMV Mode (Synchronized Intermittent Mandatory Ventilation)

SIMV stands for synchronized intermittent mandatory ventilation. In SIMV mode, the ventilator delivers volume or pressure controlled mandatory breaths which can be alternated with pressure supported spontaneous breaths.
SIMV mode guarantees volume/pressure delivery, with one or more breaths delivered within an interval determined by the set Rate.
Each SIMV breath interval includes mandatory time and spontaneous time.
If the patient triggers during spontaneous time, the ventilator delivers a pressure supported breath.

During mandatory time, the ventilator waits for the patient to trigger a breath:

- If the patient triggers a breath, the ventilator immediately delivers a mandatory breath. All following breaths during spontaneous time will be flow-cycled, pressure supported.
- If the patient does not trigger a breath, the ventilator automatically delivers a mandatory breath at the end of mandatory time.

The mandatory time is set to be 25% of the total SIMV breath interval minus Ti.

In SIMV mode, the ventilator can work in either of three sub-modes:

- **Volume Control** (VC)
- **Pressure Control** (PC)
- **PRVC** – Pressure Regulated Volume Control

The sub-modes are detailed in section 9.1.1.

9.3 CPAP/PSV Mode (Continuous and Pressure Support Ventilation)

Pressure support ventilation is patient-triggered mode of ventilation, allowing the patient to actively control the start of each breath. Mandatory breaths are not delivered.

The caregiver can adjust both PEEP and PS (pressure support) levels.
The patient has control of each breath.

Backup Ventilation is activated if the Apnea alarm limit is violated.

9.4 VG (Volume Guarantee)

VG is a volume target mode, with pressure supported (PS) breaths. The VG mode changes the pressure support level in order to achieve a targeted tidal volume. Each breath is a pressure supported breath triggered by the patient.

The following controls are required for VG mode:

- VT – The target tidal volume.
- PS min – The minimum pressure that can be applied.
- PS max – The maximum pressure that can be applied.
- Slope – The pressure rise profile.
- PS Term. – PS breath expiratory trigger (can be set from 10% to 90% of the peak flow).
- PS Ti – PS breath inspiratory time.

9.5 APRV Mode

APRV stands for Airway Pressure Release Ventilation. APRV is a time-cycled pressure mode. The ventilator cycles between two different baseline pressures

based on time. This mode allows unrestricted, spontaneous breathing throughout the entire ventilator cycle.

Pressure support can be set to assist spontaneous breaths whether they occur at the P low or P high.

Pressure support is set relative to (above) current level of pressure.

The following controls are required for APRV mode:

- P low – the low-pressure baseline.
- P high – the high-pressure baseline.
- T low – the low-pressure baseline period.
- T high – the high-pressure baseline period.
- PS – the pressure support level.

9.6 NIV (Non-Invasive Ventilation) Sub Mode

Non-invasive ventilation is available for all ventilation modes (except HFOT). Ventoux provides auto-leak compensation up to 100 L/min in all modes of ventilation.

Potential adverse reactions:

- Aspiration, gastric insufflation
- Increase of intracranial pressure (ICP)
- Decrease of arterial pressure
- CO2 rebreathing
- Claustrophobia
- Discomfort
- Dyssynchrony
- Skin or conjunctiva lesions

- Carefully observe the patient/ventilator interaction.
- Significant leakage may prevent reaching the set PEEP/PS (an alarm will be generated).
- Always monitor the "Leak" value. In case of extensive leak, check the mask fit.
- The exhaled volume from the patient can differ from the measured exhaled volume due to leaks around the mask.

- Peak pressures exceeding 33 cmH2O may increase the risk of aspiration due to gastric insufflation. When ventilating with such pressures, consider using an invasive mode.

When NIV box is checked the following alarms are disabled: "Check Circuit", "Low VTe", "Low MV"

9.7 HFOT

Note: HFOT is not yet an approved mode of operation and is pending CE approval

HFOT stands for High Flow Oxygen Therapy. This mode provides a continuous flow of oxygen and air to the patient.

- HFOT mode must be used with a heated patient circuit and an active humidifier.
- Do not use Flight Medical flow sensor when using HFOT mode.
- Do not connect the patient circuit to the exhalation valve.
- Excessive high flows through the nasal cannula could lead to adverse clinical events such as barotrauma or pneumothorax.
- Do not use high flow oxygen therapy (HFOT) during intrahospital transport.

The following controls are required for HFOT mode:

- HFOT Flow - the target flow
- FiO_2 – the oxygen concentration

Switching between HFOT and other modes in not possible during ventilation. To switch from HFOT to other ventilation modes or vice versa the user must go through the standby window

Be sure to use the appropriate cannula size for the patient

The Ventoux ventilator HFOT mode has an overpressure protection of (60 cmH2O). The actual maximum flow that can be achieved in practice, using a specific cannula, depends on the backpressure it generates.

Capnography modules (both Oridion and Philips) cannot be used during HFOT

Overview of HFOT in Ventoux

High Flow Oxygen Therapy (HFOT) is a mode of ventilation in which the Ventoux provides continuous air flow with Oxygen. When selected internally according to pre-set values for flow rate and FiO_2, the turbine is controlled for overall flow, while the O_2 solenoid controls the oxygen flow using the feedback from flow sensors, and FiO_2sensor.

HFOT is a non-invasive therapy, intended for spontaneously breathing patients. Therapy is delivered via the Nares or tracheostomy site.

Intended Use:

HFOT is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 10 – 60 L/min depending on the patient interface. The HFOT mode is for patients in hospitals and long-term care facilities.

User Interface:

When selected it is not possible to switch to any other mode without placing the system in Standby mode (and vise verse, it is not possible to select HFOT during ventilation in other mode).

The following parameter controllers are available in this mode: "HFOT Flow" for target flow (10 – 60 LPM), "%O_2" for FiO2 (21 – 100%) and "100% O_2" for 2-minutes full oxygenation.

Alarms – HFOT has the following alarms: "Low FiO_2", "High FiO_2", "High Pressure" and "Low Flow" alarms.

Use of Humidifier and Heated Patient Circuit with HFOT

When setting up the Ventoux for use with HFOT mode, the ventilator must be used with a heated patient circuit and an active humidifier. Flight Medical has verified the use of the Ventoux on an active humidifier. Should the user wish to verify their humidifier in use, please go to appendix B.

Warnings:

- Nasal delivery of respiratory gases generates flow-dependent positive airway pressure (PAP). This must be taken into account where PAP could have adverse effects on a patient. It could also be delivered via tracheostomy site.
- HFOT is not intended for life-support.
- To avoid burns, the type of interface, water chamber and breathing circuit used should be taken into consideration.

Contraindications

Patient must not be obtunded and should be spontaneously breathing.

Contraindications to HFOT include abnormalities or surgery of the face, nose, or airway that preclude an appropriate-fitting nasal cannula. Complications are rare and include abdominal distension, aspiration, rarely barotrauma and facial burns.

10 Additional Features (optional)

10.1 SpO_2 Monitoring

When performing SpO_2 monitoring with the Ventoux, the following information is relevant:

The user must always refer to the instructions for use that accompany the pulse oximetry probe designed for use with the Ventoux, before using it for SpO_2monitoring.

The user should pay special attention to the recommended intended use and maximum application time given for the pulse oximeter probe at a single site.

The SpO_2 monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Specific pulse oximeter probes and extenders are suitable for use with the Ventoux SpO2 monitoring system. Probes that are not specifically indicated for use with the Ventoux should not be used.

The responsible organization and/or operator needs to verify the compatibility of the probe, and cable before use, otherwise patient injury can result

The user must select the specific type of oximeter probe and extender cable for the intended use. There are different probes and extenders for adult and pediatric, and for short-term and long-term use, and for re-use and single-use.

Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen

Incorrect application or inappropriate duration of use of a sensor can cause tissue damage. Inspect the sensor site as directed in the Instructions for Use

Failure to cover the sensor site with opaque material when operating under high ambient light conditions may result in inaccurate measurements. Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions.

The recommended operating range for SpO_2 monitoring is limited up to 40 °C.

1. For a list of the pulse oximetry probes and extenders which the pulse oximetry monitor has been validated and tested for compliance with this International Standard, please consult your nearest Flight Medical representative.
    - Use DOC-10 Extender Cable
2. The Ventoux SpO_2 monitoring alarm system does not include the capability to detect an SpO_2 or pulse rate physiological alarm condition
3. Displayed ranges of SpO_2 and pulse rate: SpO_2 (0% to 100%), Pulse Rate: (20 to 300 bpm)
4. The adjustable range for the SpO_2 alarm limit range is 70% to 100%.
5. The pulse oximeter is calibrated to display functional oxygen saturation.
6. Note: a functional tester cannot be used to assess the accuracy of a pulse oximetry probe or pulse oximeter monitor.
7. The range of the peak wavelengths and maximum optical output powers of the light emitted by the pulse oximeter probes are, as follows:
    a. Red Light Wavelength Approximately 660 nm
    b. Infrared Light Wavelength Approximately 900 nm
    c. Optical Output Power Less than 15 mW
    d. Power Dissipation 52.5 mW

Note: information about wavelength range can be especially beneficial to clinicians.

8. Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a

combination of these factors, which results in an increase in the dynamic averaging.

The Data Update Period is once per breath.

Alarm Condition - this is based on the once per breath update, where the value is read and compared to the Upper and Lower limits. If out of the predefined limit, the alarm is issued. This is the same for the High and Low Pulse Rate.

9. Signal inadequacy is displayed as (- -) on the display SpO_2 reading.

10.2 Capnography Monitoring

Capnography is a non-invasive method for monitoring the level of carbon dioxide in exhaled breath ($etCO_2$) to assess a patient's ventilatory status.

10.2.1 Microstream® Capnography module (Oridion)

Microstream® capnography module uses Microstream® non–dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 during every breath, the amount of CO_2 present at the end of exhalation ($etCO_2$) and the Respiratory Rate.

Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Because the absorption is proportional to the concentration of the absorbing molecule, the concentration can be determined by comparing its absorption to that of a known standard.

The Microstream® $etCO_2$ sampling lines deliver a sample of the inhaled and exhaled gases from the ventilator circuit or directly from the patient (via an oral/nasal cannula) into the monitor for CO_2 measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO_2 waveform.

The 50 ml/min. sampling flow rate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments.

Once inside the Microstream® CO_2 sensor, the gas sample goes through a micro-sample cell (15 microliters). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO_2 readings, even at high respiration rates.

The Micro Beam IR source illuminates the micro-sample cell and the reference cell. This proprietary IR light source generates only the specific wavelengths characteristic of the CO_2 absorption spectrum. Therefore, no compensations are required when different concentrations of N_2O, O_2, anesthetic agents and water vapor are present in the inhaled and exhaled breath. The IR that passes through the micro-sample cell and the IR that passes through the reference cell are measured by the IR detectors.

The microprocessor in the board calculates the CO_2 concentration by comparing the signals from both detectors.

The Ventoux capnography monitoring system is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with pediatric and adult patients in hospitals, hospital-type facilities and intra-hospital transport.

The user must always refer to the instructions for use that accompany the Capnograph designed for use with the Ventoux, before using it for Capnography monitoring.

The Capnography monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Specific Capnography modules are designed for use with the Ventoux capnography monitoring system. Modules that are not specifically indicated for use with the Ventoux should not be used.

The responsible organization and/or operator needs to verify the compatibility of the capnograph, and cable before use, otherwise patient injury can result.

The user must select the specific type of capnography accessories and extender cable for the intended use. There are different probes and extenders for adult and pediatric, and for re-useable and single-use.

If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the Ventoux capnography monitoring system is functioning correctly.

The Ventoux capnography monitoring system should not be used as an apnea monitor.

To ensure patient safety, do not place the Ventoux ventilator in any position that might cause it to fall on the patient.

Carefully route the FilterLine to reduce the possibility of patient entanglement or strangulation.

Do not lift the ventilator by the FilterLine, as the FilterLine could disconnect from the ventilator, causing the ventilator to fall on the patient.

The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

CO_2 readings and respiratory rate can be affected by certain ambient environmental conditions, and certain patient conditions.

The ventilator is a prescription device and is to be operated by qualified healthcare personnel only.

If calibration does not take place as instructed, the Ventoux capnography monitoring system may be out of calibration. A Ventoux capnography monitoring system that is out of calibration may provide inaccurate results.

When using the Ventoux capnography monitoring system with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system.

The Ventoux capnography monitoring system is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

The FilterLine may ignite in the presence of O_2 when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.

When using a sampling line for intubated patients with a closed suction system, do not place the airway adapter between the suction catheter and endotracheal tube. This is to ensure that the airway adapter does not interfere with the functioning of the suction catheter.

Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.

Do not cut or remove any part of the sample line. Cutting the sample line could lead to erroneous readings.

If too much moisture enters the sampling line (i.e., from patient secretions), the alarm CO_2 Blockage issues

Check CO_2 and O_2 tubing regularly during use to ensure that no kinks are present. Kinked tubing may cause inaccurate CO_2 sampling or affect O_2 delivery to patient.

Do not silence the audible alarm on the monitor if patient safety may be compromised.

Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.

Before each use, verify that the alarm limits are appropriate for the patient being monitored.

Ensure that tubing is not stretched during use.

Microstream® etCO_2 sampling lines are designed for single patient use and are not to be reprocessed. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor.

CO2 sampling lines used with the monitor are marked with the upper limit of oxygen that may be provided with the sampling line. At levels of oxygen provision higher than those marked on the sampling line packaging, dilution of CO_2 readings may occur, leading to lower CO_2 values.

When monitoring with capnography during sedation, please note that sedation may cause hypoventilation and CO_2 waveform distortion or disappearance. Waveform attenuation or disappearance is an indicator that the status of the patient's airway should be assessed.

CAUTION

When monitoring patients during upper endoscopy, partial blockage of the oral airway due to endoscope positioning may cause periods of low readings and rounded waveforms. The occurrence will be more pronounced with high oxygen delivery levels.

CAUTION

If CO_2 insufflation is performed during CO_2 monitoring, the $etCO_2$ values will accordingly rise very significantly and this may result in device alarms and abnormally high waveforms until the CO_2 is evacuated from the patient.

CAUTION

Dispose of sampling lines according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

CAUTION

Use of a CO2 sampling line with H in its name (indicating that it is for use in humidified environments) during MRI scanning may cause interference. These sampling lines include CapnoLine H/Long, CapnoLine H O_2, Smart CapnoLine H/Long, Smart CapnoLine H O2, and Smart CapnoLine H Plus O_2/Long. The use of non H sampling lines is advised.

CAUTION

Before use, carefully read the Microstream® $etCO_2$ sampling lines Directions for Use.

CAUTION

Only use Microstream® $etCO_2$ sampling lines to ensure the monitor functions properly.

CAUTION

In high-altitude environments, $etCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to take this into account and to consider adjusting $etCO_2$ alarm settings accordingly.

During nebulization or suction for Intubated patients, in order to avoid moisture buildup and sampling line occlusion, the user should remove the sampling line luer connector from the monitor.

Replace the sampling line according to hospital protocol or when a blockage is indicated by the device. Excessive patient secretions or a build-up of liquids in the airway tubing may occlude the sampling line, requiring more frequent replacement.

When connecting a sampling line to the monitor, screw the sampling line connecter clockwise into the monitor CO_2 port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that measurement accuracy is not compromised.

Following connection of the CO_2 sampling line to the ventilator and patient, check that CO2 values appear on the ventilator display.

Sampling lines with H in their names include a moisture reduction component (Nafion®* or its equivalent) for use in higher humidity environments where long duration use of CO_2 sampling is required.

For a list of the capnograph accessories which the capnograph monitor has been validated and tested for compliance with International Standard, please consult your nearest Flight Medical representative.

Alarm Condition – Low and High alarms are according to user Upper and Lower limit settings. If out of the predefined limit, the alarm is issued.

The ventilator displays real time CO_2 data. The displayed data includes:

- Real time etCO_2 values
- Real time CO_2 values
- Respiration rate (RR) in breaths per minute
- CO_2 Waveform

Capnography specifications:

CO2 Units	mmHg
CO2, etCO2 Range	0-150 mmHg
CO2 Waveform Resolution	0.1 mmHg
EtCO2 Resolution	1 mmHg
CO2 Accuracy*	0-38 mmHg: ± 2 mmHg
	39-99 mmHg: ± (5% reading + 8% x (reading – 39mmHg))
	100-150 mmHg: ± (Ambient Pressure of 0.43 % + 8 % of reading), per ISO80601-2-55
Respiration Rate Range	0-150 bpm
Respiration Rate Accuracy	0-70 bpm: ±1 bpm
	71-120 bpm: ±2 bpm
	121-150 bpm: ±3 bpm
Flow Rate	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume
Waveform Sampling	20 samples/s
Initialization Time	40 s (typical, includes power-up and initialization time)
Calibration Interval	A calibration should be performed after the initial 1,200 operating hours, then once a year or after 4,000 operating hours, whichever comes first. The initial calibration should not occur before 720 hours of use. If the initial calibration is done before 720 hours of use, the module will reset to require its next calibration after 1200 hours, instead of after 4000 hours. For more information refer the Ventoux Service Manual
System Response Time	The system response time of the NanoMediCO2 in standard etCO2 mode with a standard Microstream® FilterLine of 200 cm length is specified at 3.5 seconds (typical).

Compensation	BTPS (standard correction used by Microstream capnography during all measurement procedures for body temperature, pressure, and saturation)

*

1. For breath rates above 80 bpm, the nominal, accuracy is 4 mmHg or ±12 % of reading whichever is greater.

2. For module temperature above 55°C, the nominal CO2 measurement accuracy might be reduced by 1mmHg or 2.5%, whichever is greater.

3. Accuracy is verified according to the procedures outlined in ISO80601-2-55 STD.

CO_2 accuracy in the presence of interfering gases should be as follows:

The nominal accuracy indicated in the table above, is deteriorated by not more than 4% of the reading, in the presence of interfering gases.

Notes:

- Interfering gases- as detailed in ISO 80601-2-55 clauses 201.12.1.101.3, 201.101.
- Testing method - according the procedures of ISO 80601-2-55 Capnography standard
- The gases include Heliox with up to 80% Helium and with up to 15% oxygen

The periodic auto zero function compensates for drifts between components, changes in ambient temperature, and barometric conditions. This automatic process eliminates variances that might otherwise cause measurement drift. Therefore, the module does not exhibit drift.

Storage and Transport Temperature	-40°C to 70°C
Storage and Transport Humidity	10% to 95% non-condensing
Storage and Transport Pressure	11.7kPa to 106kPa (88 mmHg to 795 mmHg)
Storage and Transport Altitude	-381m to 15,240m (-1250 feet to 50,000 feet)
Operating Temperature	0°C to 65°C
Operating Humidity	10% to 95% non-condensing
Operating Pressure	57kPa to 106kPa (430 mmHg to 795 mmHg)
Operating Altitude	-381m to 4572m (-1,250 feet to 15,000 feet)

** these are the specifications of the capnography module and should be taken into account if using a capnography module*

When using module with a ventilator, under high over pressures close to 10kPa (100cmH2O), the module may enter into a blockage mode in order to protect the module from damage. Refer to NanoMediCO$_2$ product specification for more information.

Recommended Microstream alarm limits:

Microstream Default Alarm Limits Parameter	Adult	Pediatric	Alarm/Alert Range
High EtCO2	60	60	5-150 mmHg
Low EtCO2	15	15	0-145 mmHg
High rate	30	40	5-150 bpm
Low rate	5	10	0-145 bpm
Apnea	30	20	10-60 sec

Microstream™, FilterLine™ and CapnoLine™ are trademarks of a Medtronic company.
Oridion Medical 1987 Ltd. is a Medtronic company.
The US Patents for the NanoMediCO$_2$ module are listed at US Patents:
www.covidien.com/patents

10.2.1.1 IPI - Integrated Pulmonary Index™

When both Microstream capnography and Nellcor SpO2 modules are present and active, the IPI parameter is presented. IPI is a numerical value between 1-10 which integrates four major patient parameters in order to provide a simple indication of the patient's overall ventilatory status. The integrated parameters are etCO2, RR, SpO2, and PR.

In order to get an accurate calculation the user must choose the correct "Patient type" in the settings tab (see section 6.5).

Integrated Pulmonary Index™ is a trademark of a Medtronic company.
Oridion Medical 1987 Ltd. is a Medtronic company.

10.2.2 Philips Capnography modules

10.2.2.1 Capnostat 5 Zeroing

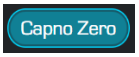
A Capnostat zeroing should be performed in the following cases:

- With the first use of the CAPNOSTAT 5 CO2 Sensor.
- Whenever the Capnostat 5 is connected to the Ventoux ventilator.

- When switching from one airway adapter type to another, such as when switching from a disposable to a reusable airway adapter (zeroing is not required when switching from the same type of airway adapter, such as a disposable airway adapter)

  Ensure that the sensor is disconnected from the patient circuit with no CO2 present in the airway adapter prior to performing the procedure.

  To perform an adapter Zeroing:

  1. Connect the CAPNOSTAT 5 CO2 Sensor to the ventilator capnography port
  2. Place the CAPNOSTAT 5 CO2 Sensor onto a clean and dry CO2 adapter that is exposed to room air and away from all sources of CO2, including the ventilator, the patient's breath and your own.
  3. Start the adapter zeroing by tapping the CO2 zeroing button 

located in the external modules window (in the operational control bar)

  The maximum time for a CAPNOSTAT zeroing is 40 seconds. The typical time for a zero is 15-20 seconds.

For best results, connect the CAPNOSTAT 5 CO2 Sensor to an adapter and wait 2 minutes before performing the Adapter Zeroing procedure.

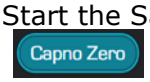
10.2.2.2 LoFlo Zeroing

- System does not allow adapter zeroing for 20 seconds after the last breath is detected.
- System does not allow adapter zeroing if temperature is not stable
- An adapter zeroing cannot be performed if a sample cell is not connected to the LoFlo CO2 Module

A Sample Cell Zeroing is not required when switching from one sampling accessory to another.

To perform a Sample Cell Zeroing:

1. Connect the LoFlo CO2 Module to the ventilator capnography port.
2. Connect a LoFlo Sampling accessory to the LoFlo CO2 Module, and make certain that the accessory is exposed to room air and away from all sources of CO2, including the ventilator, the patient's breath and your own.

3. Start the Sample Cell Zeroing by tapping the CO2 zeroing button 

located in the external modules window (in the operational control bar)

The maximum time for LoFlo zeroing is 40 seconds. The typical time for a zero is 15-20 seconds.

For best results, wait 5 minutes to allow the LoFlo CO2 Module to warm up before performing the Sample Cell Zero procedure.

10.2.2.3 Failure of zeroing process

If the zeroing process has failed, a "failed" massage will appear next to the button. There are several scenarios in which the zeroing porcess can fail (the sepcific reason is detiled in the events tab):

error:source current unstable

1. The module is not awake yet (in sleep mode) – try again in a few minutes.
2. Temperature low/high – the sensor has not warmed up yet, wait a few minutes. Or the tempareture is too high. Always make sure you operate in the specified temperature range of the device.
3. Breaths detected lately - Breaths have been detected by the Capnostat within the last 20 seconds while a Capnostat zero was attempted – make sure the patient is not connected and try again.
4. Timeout – 40 seconds have passed and therefore the zeroing process was stopped. Try again
5. faulty-sensor-error – fault in sensor
6. hardware-error – hardware error
7. source-current-error – current is not stable

11 Accessories

11.1 Flight Medical accessories

Patient Circuits			
#	**P/N**	**Description**	**Note**
1	VX64-0001	VX-DL Single Use Universal P.C.	Adult DL
2	VX64-0002	VX-DL Single Use P.C.	
3	VX64-0003	VX- DL Autoclavable P.C.	
4	VX64-0004	VX- DL Autoclavable F.S. Kit	
5	VX64-0005	VX- DL F.S. Kit	
6	VX64-0006	VX- DL Ped. Single Use P.C.	Pediatric DL
7	VX64-0007	VX- DL Ped. Autoclavable F.S. Kit	
8	VX64-0008	VX- DL Ped. F.S. Kit	
9	VX64-0009	VX- SL Single Use P.C.	Adult SL
10	VX64-0010	VX- SL Autoclavable P.C.	
11	VX64-0011	VX- SL F.S. Kit	
12	VX64-0012	VX- SL Autoclavable F.S. Kit	
13	VX64-0013	VX- SL Single Use Ped. P.C.	Pediatric SL
14	VX64-0014	VX- SL Ped. F.S., Kit	
15	VX64-0015	VX- SL Ped. Autoclavable F.S. Kit	
16	VX64-0016	VX-DL Ped.Single Use P.C. w/RD	Pediatric DL w/ RD
17	VX64-0017	VX-DL Ped.Autoclavable F.S. Kit w/RD	
18	VX64-0018	VX-DL Ped. F.S. Kit w/RD	
19	VX64-0019	VX- SL Single Use Ped. P.C. w/ RDS VX-SL Single Use Ped. P.C. w/RD	Pediatric SL w/ RD
20	VX64-0020	VX-SL Ped. F.S Kit w/RD	
21	VX64-0021	VX-SL Ped.Autoclavable F.S Kit w/RD	
Additional Accessories			

#	P/N	Description	Note
1	KIT-0011	Flight Medical Test Lung Kit	
2	KIT-0087	F60/VX Quick Release Kit	
3	KIT-0093	Oxygen Cylinder Holder Kit	
4	KIT-0095	Technician Kit for Ventoux Ventilator	
5	MEB-0094	Ventilator 3 Section Arm with Extension(P)	
6	MEB-0097	Ventilator Roll Stand For O2 Kit(P)	
7	MEB-0093	Roll Stand for Ventilator(P)	

11.2 Philips Accessories

#	P/N	Description	Note
1	1015928	Capnostat 5 Mainstream Sensor	
2	6063-00	Adult/Pediatric Airway Adapter, SPU	
3	7007-01	Adult/Pediatric Airway Adapter, Reusable	
4	1022054	LoFlo Sidestream CO2 Module	
5	3472ADU-00	Airway Adapter Kit, Adult/Pediatric, SPU	
6	3473ADU-00	Airway Adapter Kit, Adult/Pediatric, with Dehumidification tubing, SPU	
7	3468ADU-00	Nasal CO2 Sampling Cannula, Adult, SPU	
8	3468ADH-00	Nasal CO2 Sampling Cannula, Adult, with Dehumidification tubing, SPU	
9	3468PED-00	Nasal CO2 Sampling Cannula, Pediatric, SPU	
10	3468PEH-00	Nasal CO2 Sampling Cannula, Pediatric, with Dehumidification tubing, SPU	
11	1027730	LoFlo Module Mounting Bracket	

11.3 Medtronic Accessories

#	P/N	Description	Note
1	DOC10	Nellcor Pulse Oximetry Interface Cable 10 Ft (3.0 m)	
2	DS100A	Nellcor Adult SPO2 Sensor	
3	MVA	Microstream Advance Adult Oral-Nasal CO2 Filter Line	
4	MVAI	Microstream Advance Adult-Pediatric Intubated CO2 Filter Line	

12 Cleaning and Maintenance

12.1 Cleaning and Disinfecting

The VENTOUX Ventilator and associated patient circuits are shipped in clean but non sterile condition.

Associated patient circuits (as listed in section 11.1)

Only autoclavable patient circuits are required to undergo cleaning, disinfection and sterilization. The instructions for performing these processes are given in the instructions for use provided with the patient Circuits

12.1.1 VENTOUX Ventilator

Wipe clean the VENTOUX Ventilator before using on a new patient, and once a week while in use.

➔ **To clean and disinfect the ventilator:**

- Wipe clean the ventilator parts (not including the touch screen) using MEDIWIPES or equivalent (Ingredients: Ethanol + Isopropyl Alcohol 70% v/v, Chlorhexidine Digluconate 0.5%, Hydrogen Peroxide 0.45%) as follows:

  Clean each part 3 times using approved wipes as indicated above. Use a new wipe for each wipe.

  The points of concern to be cleaned include: Control Buttons, Front Frame of unit, Carrying Handle, and Top and Sides of unit.

- Wipe touch screen 2-6 times with soft microfiber cloth wetted with 70% isopropyl alcohol (IPA) and USP grade water. Use a new cloth for each wipe.

- Leave to air dry.

Do not apply the cleaning solution directly on the screen.

On the front panel display or ventilator housing, do not use agents that contain acetone, toluene, halogenated hydrocarbons, or strong alkaline.

Never ETO sterilize the VENTOUX Ventilator and its accessories. These processes will damage the VENTOUX Ventilator and accessories, rendering them unusable.

12.1.2 VENTOUX Ventilator Accessories

The instructions in this section refer to accessories manufactured by Flight Medical Innovations Ltd. only.

For accessories, which are not manufactured by Flight Medical Innovations, (as listed in sections 11.2 and 11.3) please refer to the manufacturer cleaning instructions, as detailed in their instructions for use or in the applicable section in this document.

Use the information in this section in conjunction with hospital policy and physician prescription

- **Additional Accessories (as listed in section 11.1):**

In order to avoid risk of cross infection, we recommend the following:

1. Cleaning and disinfection

   Clean by rinsing in a warm soapy solution followed by rinsing with distilled water and drying with dry Cloth.

   The use of liquid Isopropyl alcohol 70%. as a low level disinfectant is optional and may be used at the user discretion.

12.1.2.1 Exhalation Valve and Diaphragm

➔ **To disassemble the exhalation valve:**

1. Disconnect the patient circuit.
2. Press the lever and rotate the exhalation valve counter clockwise.
3. Carefully remove the diaphragm by pulling the diaphragm tip.

➔ **To clean the dual limb exhalation valve and diaphragm:**

1. Wash the dual limb valve and diaphragm with a soft brush using mild detergent (such as liquid soap).
2. Rinse the exhalation valve and diaphragm thoroughly with sterile/distilled water.
3. Shake off excess water and place it on a clean towel to air dry (do not heat or blow-dry).

➔ **To disinfect the dual limb exhalation valve and diaphragm:**

Soak valve and diaphragm in the following solution:

Approved Glutaraldehyde solution (such as Cidex [2%]) Use in accordance to Manufacturer instructions for use.

➔ To reassemble the exhalation valve:

1. Place the exhalation valve diaphragm inside the exhalation valve base with its holding tip facing forward.
2. Place the exhalation valve to its base. Rotate the exhalation valve clockwise to secure it into place. Verify the secure snap mechanism in place.

12.1.3 Philips Accessories (as stated by the manufacturer)

For the Capnostat 5 and the LoFlo sensors please refer to the instruction for use provided by Philips.

Cleaning and disinfection of reusable adapters:

1. Treat all reusable airway adapters in accordance with institutional protocol for single patient use items.
2. Clean by rinsing in a warm soapy solution followed by soaking in a liquid disinfectant (use in accordance to Manufacturer instructions for use):
   - Isopropyl alcohol 70%.
   - 10% aqueous solution of chlorine bleach.
   - Glutaraldehyde 2.4% solution such as Cidex®
   - Peracetic Acid such as Perasafe or Steris System 1®.
   - Ortho-Phthaldehyde 0.55% solution such as Cidex OPA
3. Rinse thoroughly with sterile water and dry.
4. Before reusing the adapter, ensure the windows are dry and residue free and that the adapter has not been damaged during handling or the cleaning/disinfecting process.

Autoclaving of reusable adapters (100 cycles):

- Autoclave at 134 degrees C (273 degrees F), 20 minutes, unwrapped
- Autoclave at 121 degrees C (250 degrees F), 20 minutes, unwrapped

12.2 Maintenance

12.2.1 Preventive Maintenance

It is recommended to take the following measures to maintain the VENTOUX Ventilator:

- Check the Air Inlet Filter (located behind the Filter Cover) weekly. Replace it when the majority of the filter surface area has changed from a clean white to dirty brown color. **Air Inlet Filters are not reusable.**

NEVER reverse the inlet particle filter when it is dirty.

NEVER operate the VENTOUX Ventilator without a clean inlet particle filter in place.

After replacing the filter, make sure that the two holding screws on the Filter Cover are secure. If the screws are not tight, ambient air may enter the VENTOUX Ventilator from around the inlet cover.

- Inspect the VENTOUX Ventilator power cord on a regular basis, for signs of a broken or frayed power cord.
- Inspect the exhalation valve, outlet and patient circuit flow orifice to verify that there are no cracks or damaged surfaces.
- Wipe down the surface of the ventilator housing regularly to remove any dust that might accumulate.

If service is required, contact your provider.

12.2.2 FiO_2 Sensor Maintenance

It is recommended to replace the internal FiO_2 sensor once a year. Refer to the Service Manual for details. If the monitored FiO_2 value is different than the set FiO_2 by more than 8, FiO_2 sensor calibration is required and should be performed by a certified Ventoux technician.

12.2.3 Internal Battery Maintenance

It is recommended that if the batteries are no longer meeting the time requirements of the user, they should be replaced.

➔ **To preserve the internal batteries' life:**

- Whenever possible, plug the VENTOUX Ventilator into the external power source to charge the batteries.
- Use the Auto Lighter Cable accessory to power the VENTOUX Ventilator when traveling by automobile. The batteries will be charged once the ventilator is connected.

While In storage:

1. When batteries are on the shelf over a period of more than 3 months, make sure to charge them to 40% once a year.

2. When batteries are inside the device, connect the device to an AC power supply in order to keep the batteries fully charged and ready for use at all times.

3. When batteries are inside the device and no AC power supply is available, make sure to charge the batteries to 100% every 4 months.

While In use:

Keep the device connected to an external power supply as much as possible in order to keep the batteries fully charged and ready for use.

12.2.4 25,000 Hour Maintenance

A comprehensive maintenance should be performed after 25,000 hours of operation. The 25,000-hour maintenance includes replacement of the pump assembly.

Contact your provider or FLIGHT MEDICAL for detailed information on the 25,000-hour maintenance (see Section 13.5 for contact information).

Item	Schedule	Comment
Air Filter	Check weekly	Replace it when the majority of the filter surface area has changed from a clean white to dirty brown color. Air Inlet Filters are not reusable.
Power cord	Regularly	Check for signs of a broken or frayed power cord.
Exhalation valve, outlet and patient circuit flow orifice	Regularly	Check that all parts are intact and there are no cracks. (by a technician)
Device case	Regularly	Wipe down
FiO_2 sensor	Once a year	Replace (by a technician)
Internal batteries	Whenever capacity is not meeting user requirements	Replace
Pump assembly	25,000 Hour	Replace (by a technician)

12.2.5 NanoMedico module maintenance

calibration should be performed after the initial 1,200 hours of use, and following that calibration once a year or every 4,000 operating hours, whichever comes first.

The initial calibration should not occur before 720 hours of use. If the initial calibration is done before 720 hours of use, the module will reset to require its next calibration after 1200 hours, instead of after 4000 hours

12.3 General Warnings

- Preventive maintenance work, repairs, and service may only be performed by FLIGHT MEDICAL trained or factory-authorized personnel.
- Always follow accepted hospital procedures or physician instructions for handling equipment contaminated with body fluids.
- The ventilator and its accessories must be thoroughly cleaned and disinfected after each patient use. Perform all cleaning and disinfection of external parts and accessories in accordance with established hospital procedures and physician prescription.
- Certain components of the ventilator, such as the exhalation valve and the front panel, consist of materials that are sensitive to some organic solvents used for cleaning and disinfection (such as phenols, halogen releasing compounds, oxygen releasing compounds, and strong organic acids). Exposure to such substances may cause damage that is not immediately recognizable.

13 Troubleshooting

13.1 Introduction

The VENTOUX Ventilator is used in life-support situations. As such, it is essential that all individuals using the VENTOUX Ventilator, including clinicians and support staff, have a thorough understanding of its operation. This should include a working knowledge of the ventilator's pneumatic and electronic systems.

The following practical troubleshooting section is provided as a training resource for individuals learning how to use the VENTOUX Ventilator, and as a reference tool for those already familiar with its use and operation. It should be noted that this outline is not all inclusive and is intended only as a guide.

Only properly trained personnel should operate the ventilator. The VENTOUX Ventilator is a restricted medical device designed for use by Respiratory Therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

13.2 Alarms

Problem	Potential Cause	Suggested Action
Apnea BUV	Patient did not trigger a breath for the preset Apnea interval (10 to 60 seconds).	Re-evaluate the patient and ventilator settings and provide increased ventilatory support, as needed.
	Patient efforts are not detected. Trigger level set improperly.	Use P.trigger or F.trigger to adjust the trigger level closer to the baseline pressure (0 cmH_2O) so that patient efforts are detected.
Check circuit	Humidity in the proximal line.	The ventilator purges every predefined time period in order to clean the tubes. Verify the alarm ceased after the ventilator purge.
	Proximal line disconnected or kinked.	Reconnect the proximal line or unkink the line.
	Circuit is disconnected from the patient.	Reconnect the circuit to the patient.

Problem	Potential Cause	Suggested Action
	Quick connector is loosened.	Secure the quick connector.
	Pressure transducer is improperly calibrated or defective.	Call FLIGHT MEDICAL.
Batteries empty	Detachable and Integral batteries charge is depleted and the ventilator shutdown will occur shortly.	Immediately connect the VENTOUX Ventilator to external AC or DC power.
No external power	External power cord is disconnected.	Re-insert the power cord.
	External power source failure.	Use the batteries. Recharge the batteries when AC is available.
High pressure	Increased patient resistance or decreased patient compliance.	Evaluate the patient. The patient may need suctioning, aerosol therapy, check bacterial filter, etc.
	Increased patient circuit resistance.	Check for obstructions (kinked tubes, water in tubing, occluded filters, etc.)
	Control/alarm parameters have changed.	Re-evaluate settings.
	High Pressure alarm set incorrectly.	Re-adjust High Pressure alarm, if appropriate. Notify physician as necessary.
Partial occlusion	Airway pressure remains above the Low Pressure alarm setting at the beginning of inspiration. Indicates an occlusion in the circuit/exhalation valve or that the proximal pressure line or exhalation drive line is pinched.	Unblock the occluded area.
	Breath set rate is too high (insufficient time to exhale).	Evaluate patient and make necessary adjustments to ventilation parameters.
	Ventilator auto triggering from leak or improper trigger setting.	Fix the leak and re-adjust trigger level as needed. Change Trigger Mode to P.Trigger.
	Rapid decreasing of the PEEP value.	Gradually decrease the PEEP.
High MV	Increased spontaneous patient breathing.	Evaluate the patient. Adjust the High MV alarm setting, check trigger setting.
	Increase in trachea/airway leak.	Evaluate the leak, look for normal wake-sleep trends, and set alarms appropriately.

Problem	Potential Cause	Suggested Action
	Increased minute volume due to ventilator auto triggering from leak.	Check circuit for leak and correct.
	Increased minute volume due to ventilator auto triggering from P.trigger or F.trigger setting too low (most common with single use exhalation valve).	Reevaluate/readjust trigger setting (especially after circuit change).
	Increased minute volume due to ventilator auto triggering from loose quick connector.	Secure the quick connector.
	Increased minute volume due to ventilator auto triggering from circuit disconnected for airway care or by inadvertent disconnect.	Reconnect the circuit securely. (Allow one minute for stabilization. In order to avoid unnecessary audible alarm press the **Mute** button when reconnecting after airway care).
Batteries below 30%	When the combined charge of both batteries is less than 30%.	Plug the power cord into an external power source to charge.
Low pressure	Decreased patient resistance or increased patient compliance.	Evaluate the patient. Adjust the ventilation settings and/or Low Pressure alarm, as needed.
	Leak or disconnect in the patient circuit.	Verify that connections are tight and leak free.
	Low Pressure alarm set incorrectly.	Readjust Low Pressure alarm limit, if appropriate.
Low PEEP	Baseline pressure is below set PEEP due to airway or circuit leak, or fluid pooled in tubing.	Verify that all circuit connections are secure and leak free, and that all fluid is cleared from the tubing.
	False Low PEEP Alarm during purge.	Verify the alarm ceased after the ventilator purge. A minor Ti settings change may eliminate this alarm.
Low MV Alarm/Apnea	Patient efforts are not detected. The trigger level (P.trigger or F.trigger) is set improperly.	Check the circuit connections, and evaluate the trigger setting. Detected patient efforts are indicated by coloring pressure waveform on the screen by green.
	The Low MV alarm is set above the delivered mandatory minute volume.	Readjust Low MV alarm setting level.

Problem	Potential Cause	Suggested Action
	Patient needs suctioning or airway occlusion (pressure control / pressure support).	Suction and evaluate patient.
	Patient is breathing slowly or is not breathing.	Evaluate patient.
	Apnea interval is too short.	Evaluate the patient. Adjust the Apnea alarm.
Circuit occlusion	Exhalation valve is blocked or line is kinked.	Check the exhalation valve line. Replace the exhalation valve assembly.
	High breath rate.	Change to lower set rate, evaluate patient.
PC not reached	Gross leak in the patient circuit.	Check all patient circuit connections.
	Target pressure setting requires a flow rate that is beyond the VENTOUX Ventilator's maximal flow capability.	Reevaluate the ventilator settings and strategy.
Replace vent	Unrecoverable internal system failure.	Ventilate the patient with an alternate means of ventilation. Make note of the message in the alarm display area. Call FLIGHT MEDICAL

13.3 General/Clinical

Problem	Potential Cause	Suggested Action
Alarm volume too loud or too quiet.	Unintended setting.	Go to "Sound Level" button and adjust the buzzer volume

Problem	Potential Cause	Suggested Action
Batteries depleted too fast; not lasting up to 6 hours	Batteries are not fully charged.	Charge the batteries to their full charge level. Batteries charge in three hours from AC. Check the charge level by viewing the main and secondary battery icon level on the display. Extend the battery use time by plugging into AC when available. Suggestion: Optional accessory, Automobile 12V power cord can be used to plug the ventilator into the automobile cigarette lighter. Ensure that the green Ext. Power LED is illuminated when connected to an external AC or DC power source (it can take up to one minute). If the LED is not illuminated, check the connections and resolve any problems.
	Batteries are not in optimal condition or need to be replaced.	As the battery ages, the Low Battery caution occurs sooner. When this begins to infringe on the required battery time, the batteries should be replaced.
CO_2 rises Child's CO_2 rises dramatically when put on the ventilator	Too much dead space (re breathing) in the patient circuit. (On a single-limb circuit, the tubing on the patient side of the exhalation valve is dead space.)	On small patients, avoid using any tubing between the flow orifice and the patient. If extension tubing is a must, it should be as small as 15 mm ID and shorter than 50 mm.
Exhalation Valve Honks Exhalation valve makes honking noise	Low compliance / high resistance of circuit system.	Make sure that the patient circuit is 22 mm ID (regardless of patient size).
	The single use exhalation valve in use is not compatible with the ventilator.	Use an exhalation valve that is approved for use with the VENTOUX Ventilator.
External Power Not Working After plugging into an external AC or DC outlet, Ext. Power indicator does not light after one minute.	Power cord is not plugged far enough into the ventilator outlet.	Check that the power cord is pushed in all the way.
	AC outlet has no power.	Check for power in the AC outlet or use another AC outlet with power.
	DC Auto lighter outlet is not active with engine off.	Make sure that the auto lighter outlet is active with the engine off or turn the engine on.
PEEP Control	Faulty exhalation valve.	Replace the exhalation valve.

Problem	Potential Cause	Suggested Action
Baseline pressure during exhalation continues to slowly decrease.	Leak in the patient circuit.	Perform a leak check on patient circuit connections and eliminate any leaks found.
	Leak around ET (Endotracheal) tube/ patient interface.	Check ET tube/patient interface.
PEEP Control Monitored PEEP is less than set PEEP.	Leak in patient circuit, endotracheal tube cuff, patient interface, or other.	Find and correct the leak.
	Faulty exhalation valve.	Replace the exhalation valve.
Pressure reading Pressure does not return to zero when PEEP is set to zero.	Patient circuit resistance is caused by an occluded filter or exhalation valve, pooled water, or lodged secretions which prevent the free exit of patient exhalation.	Temporarily disconnect the patient circuit from the ventilator GAS OUTPUT gas output outlet. If the pressure reading returns to zero, the cause of the elevated baseline pressure is circuit resistance. Check for (and empty) water in the patient circuit. Check for (and replace) the clogged filter or heat moisture exchanger in the patient circuit. Check for (and clean) an exhalation valve that has become clogged with medications or patient secretions. Ensure that the expiratory drive line is not kinked.
Pressure reading Baseline pressure (PEEP) is fluctuating.	Water in patient circuit tubing.	Drain tubing.
	Leak in patient circuit.	Perform exhalation valve calibration; check/eliminate any leaks found.
	Leak in the exhalation valve.	Replace the exhalation valve.
	Bounce/rebound from test lung.	Use a test lung with better physiological performance.
Pressure Not Rising Ventilator sounds like it is delivering breaths; however, the pressure is not rising during the breath.	Massive leak in the patient circuit.	Locate the leak and fix it.
	Exhalation valve diaphragm has become unseated.	Replace the exhalation valve / patient circuit.

Problem	Potential Cause	Suggested Action
Trigger Problem Patient cannot trigger the ventilator.	Inappropriate trigger setting.	Adjust the P.trigger/F.trigger towards "-0.1"/"1" until the ventilator auto-triggers, then slowly increase the P.trigger or F.trigger setting until the auto-triggering stops.
	Baseline pressure increased inadvertently due to *Rate,* Ti, Volume control, or Pressure control change.	Check the ventilation settings; readjust if necessary.
	Baseline pressure increased inadvertently due to incomplete exhalation.	Check the ventilation settings; readjust if necessary.
	Patient lacks any spontaneous effort or has very weak effort.	Evaluate the patient.
Trigger Problem Ventilator auto-triggering	Trigger level is not set properly.	Readjust P.trigger/F.trigger level.
	Leak in patient circuit, exhalation valve, or expiratory drive line.	Check/secure the circuit connections. Change the exhalation valve.
Trigger Problem Patient double-triggers the ventilator.	In volume control, the flow is set inappropriately low.	Check the flow setting in the display. If it is too low for patient need, decrease the inspiratory time (Ti) setting until the flow is set appropriately.
	Pressure support is set too low for patient need.	Reevaluate the pressure support setting.
Monitored Tidal Volume Vte and Vti inconsistent	Circuit disconnect	Check Circuit Connections
	Quick Connect not firmly attached	Re-attach the Quick Connector
Ventilator Makes Noise When Air/Oxygen Mixer Is Connected VENTOUX Ventilator makes a loud noise when using the Air Oxygen Entrainment Mixer connected to a gas cylinder.	Cylinder is turned off or empty.	Check that the cylinder is turned on and that it is not empty.
Water in Breathing Circuit Tubing	Room temperature is cooler than the heated, humidified breathing gas in the circuit. When the gas in the circuit cools, water precipitates out.	a. Place water trap in line with the patient circuit and empty it regularly. c. Use a heated wire circuit.

13.4 Air/Oxygen Entrainment Mixture

Problem	Potential Cause	Suggested Action
Monitored FiO_2 is lower than set FiO_2 by >8%, when using Air Oxygen Entrainment Mixture	Oxygen Sensor Expired	Contact your provider or FLIGHT MEDICAL to replace the Oxygen sensor
	Filter cover is loose.	Tighten the filter cover.
	Filter cover needs to be replaced.	Contact your provider or FLIGHT MEDICAL to obtain a replacement filter cover.
	Oxygen source gas pressure is low.	Check that the oxygen source gas is not less than 50 psig.
	Oxygen source regulator is oscillating.	Check the oxygen source regulator. If the noise continues, Contact your provider or FLIGHT MEDICAL.
Mixer makes a pronounced clicking sound during normal operation.	Mixer diaphragm is leaking.	Contact your provider or FLIGHT MEDICAL.
Oxygen leaks out of Mixer when connected to 50 psig oxygen gas source.	FLT isn't screwed and sealed	Tighten the FLT screw.
	Cracks in FLT	Contact your provider or FLIGHT MEDICAL.
	Regulator O-ring is ripped	Contact your provider or FLIGHT MEDICAL.

13.5 Contact Information

Address further questions or problems to one of the FLIGHT MEDICAL offices.

FLIGHT MEDICAL INNOVATIONS Ltd.
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Obelis.a
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Tel: +32 2 7325954
Fax: +32 2 7326003
Email: mail@obelis.net

14 Technical Specifications

14.1 Physical Specifications

Physical Characteristic	Specification
Ventilator Weight	8 Inch Screen: 7.6 kg 12 Inch Screen: 8.2 kg
Ventilator Dimensions	8 Inch Screen: 34W x 26D x 25H cm 12 Inch Screen: 34W x 26D x30H cm
Single Use Patient Circuit	Single use 22 mm ID 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick connector.
Connectors	Gas Outlet: ISO 22 mm OD conical. Air/Oxygen Inlet: ISO 30 mm female fitting.
Add-ons	$etCO_2$ –monitoring of the partial pressure of carbon dioxide in exhaled breath. Cuff pressure control - provides an automatic cuff pressure in tracheal tubes and tracheotomy tubes according to an adjustable target pressure. SpO_2- monitoring of the ratio of oxy-hemoglobin to the total concentration of hemoglobin present in the blood.

14.2 Pneumatic Specifications

Item	Specification
Over Pressure Relief Valve	Limits the maximum airway pressure to 120 ± 5 cmH_2O
FiO_2 sensor	MAX 16 by MAXTEC; range from 0 to 100% oxygen. Warm up time: less than 30 minutes after replacement.

14.3 Operating Specifications

Item	Specification
Maximum error of delivered volume in relation to set value	± (4,0 ml + 15 % of the actual VT) for VT > 50ml; ±15ml for VT < 50ml
Maximum PEEP error in relation to set value	±1cmH2O for PEEP <= 5; ±2cmH2O for 5<PEEP<=20; ±10% for PEEP>20
Maximum FiO_2 error in relation to set value	± (2.5 + 2.5% of set FiO_2)
Maximum error of the airway pressure at the end of the inspiratory phase in relation to the set value	± (2 cmH2O + 4 % of the actual PIP for PC+PEEP < 40cmH2O; ±10% of the actual PIP for PC+PEEP≥ 40 cmH2O
Maximum limited gas flow	The maximal gas flow of the Ventoux for air and O_2 is: Air – 220 l/min at free flow and O_2 – 110 l/min at free flow.

14.4 Electromagnetic Emission - Guidance and Manufacturer's Declaration

IEC 60601-1-2: Table 1 – Guidance – electromagnetic emissions		
The *Ventoux* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Ventoux* should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *Ventoux* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *Ventoux* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

IEC 60601-1-2: 2014(ed4.0) Table 2 - Guidance – electromagnetic immunity			
The **Ventoux** is intended for use in the electromagnetic environment specified below. The customer or the user of the *Ventoux* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance –**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line(s) to line(s): ±0.5 kV, ±1 kV line(s) to ground: ±0.5 kV, ±1 kV, ± 2 kV	±1 kV Differential mode ± 2 kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT: 0.5 cycle At 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 cycle, and 70% UT: 25/30 cycles Single phase: at 0 degrees Voltage interruptions: 0% UT: 250/300 cycle	UT=0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, 315 degrees) UT=0%; 1 cycle UT=70% 25/30 cycles (0 degrees) UT=0%; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Ventoux** requires continued operation during power mains interruptions, it is recommended that the **Ventoux** be powered from an uninterruptible power supply or a battery*.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
* Note: The Ventoux ventilator has a battery that is locked by a screw and switching electronics that ensure the ventilator continue to function on internal power, even in the case of External power supply power problems (such as voltage dips, short interruptions or extreme voltage variations on power supply input lines). As percussion the ventilator issues an alarm in case the internal battery is disconnected or if it fails.			

IEC 60601-1-2: 2007 - Table 3 Guidance– electromagnetic immunity			
The *Ventoux* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Ventoux* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *Ventoux*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	10 V	$d = \frac{3.5}{10}\sqrt{P} = 0.35\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 V	$d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$
	10 V/m 80 MHz to 2,5 GHz	30 V/m	$d = \frac{12}{30}\sqrt{P} = 0.4\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{23}{30}\sqrt{P} = 0.77\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment  marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Ventoux* is used exceeds the applicable RF compliance level above, the *Ventoux* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Ventoux*. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

IEC 60601-1-2: 2007 Table 5

Recommended separation distances between portable and mobile RF communications equipment and the *Ventoux*

The *Ventoux* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Ventoux* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Ventoux* as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter[W]	Separation distance according to frequency of transmitter [m]			
	150 kHz to 80 MHz outside ISM bands $d = \frac{3.5}{10}\sqrt{P} = 0.35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = \frac{12}{30}\sqrt{P} = 0.4\sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{23}{30}\sqrt{P} = 0.77\sqrt{P}$
0.01	0.035	0.12	0.04	0.077
0.1	0.11	0.38	0.13	0.24
1	0.35	1.2	0.4	0.77
10	1.1	3.8	1.3	2.4
100	3.5	12.0	4.0	7.7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14.4.1 EMC statement of Essential Performance

This statement is the basis of the immunity pass/fail criteria for the EMC tests.

The essential performance is:

1. There will be no change in airway pressure, expired volume or in programmable parameters or settings
2. No changes in oxygen level ALARM CONDITIONS
3. There will be no reset to default settings
4. There will be no interruption of power supply
5. No component failures
6. Internal electrical power source is not depleted

Cables

The AC cable maximum length should be 3 meters.

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used
- The use of accessories, transducers and cables other than those specified could result in increased emissions or decreased immunity.
- The ventilator may activate an alarm while in close proximity to a strong 94-100 MHz radiating source. In such case the ventilator should be kept afar from the radiating source until the alarm is deactivated. Special care should be given while the alarm is activated in order to insure operators are alerted to other alarms, if occur, at the same time

EMC general

1. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Instruction Manual.
2. Portable and mobile RF communication equipment can affect medical equipment.

14.5 Electrical Specifications

Voltage	Frequency	Current Consumption
100 – 240 VAC	50 – 60 Hz	6 Amp MAX
10 – 30 VDC	NA	10 Amp MAX

14.6 Internal Battery Specifications

Battery Characteristic	Specification
Two swappable batteries	
Battery Type	Li-Ion
Nominal Voltage	21.6 VDC
Nominal Pack Capacity	3400 mAh
Charging Time	Three hours MAX
Average operating time	When new and fully charged, supplies power for up to 6 hours of operation under STS ventilation parameters. (VT = 500 ml, Rate = 15 BPM, Ti =-1.0 sec, PEEP = 5 cm H2O, Power Save mode ON)

14.7 Safety and Particular Standard Specifications

Standard	Specification
Safety	IEC60601-1(ed. 3.1, 2012) Medical electrical equipment general requirements for basic safety and essential performance.
	IEC60601-1-2 2 (ed. 4, 2014): General requirements for basic safety and essential performance; Collateral standard: electromagnetic compatibility.
	IEC 60601-1-8) Medical electrical equipment – Parts 1-8: general requirements for safety; Collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.
Particular	ISO 80601-2-12: 2011 Medical Electrical Equipment – Part 2-12 Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators
	ISO 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
	ISO 80601-2-55:2011 Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors -anesthetic gas monitoring, carbon dioxide monitoring, and oxygen monitoring.

Standard	Specification
	EN 794-3:1998+A2:2009: Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators (Applicable only for 8” model)
	ISO 80601-2-84 Medical electrical equipment —Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (Applicable only for 8” model)

14.8 Environmental Specifications

Condition	Range
Operating Temperature	-18 ^{O}C to 50 ^{O}C / -0.4 ^{O}F to 122 ^{O}F
Storage Temperature	-30 ^{O}C to 71 ^{O}C / -22 ^{O}F to 160 ^{O}F
Operating Pressure (Altitude)	70 kPa to 110 kPa (0 to 15000 ft)
Humidity	15% to 95% RH at 31 ^{O}C
Water Resistance	IP34 (dust/splash proof) IEC 60529
Mechanical shock	IEC 68-2-27
Free Fall	IEC 60068-2-31
Random Vibrations Wide Band	IEC 60068-2-64
A-weighted sound pressure level emitted	37.9 dB(A)
A-weighted sound power level emitted	48.9 dB(A)

*These environmental specifications are for the ventilation functionality of Ventoux ventilator. When using the Ventoux with accessories such as oximetry or capnography the environmental specifications for the specific accessory should be taken into account. (for the accessories environmental specifications please see section 10 of this manual).

14.9 Internal O_2 Mixer Specifications

Feature	Specification
Connector Type	DISS
Input Pressure – Oxygen	35-90 psig/240-620 kPa
FiO_2	21% to 100%
Accuracy	±5%

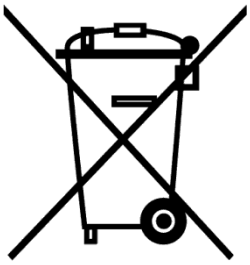
Feature	Specification
21% to 90% FiO_2 Response Time	Up to 20 seconds

14.10 Low Flow Port Oxygen Specifications

Item	Specification
Oxygen Flow	0 to 15 L/min
Oxygen Pressure	Below 50 psig

14.11 WEEE Disposal Information

EU Waste Electrical and Electronic Equipment (WEEE)



WEEE symbol – crossed out wheeled bin

EU Waste Electrical and Electronic Equipment (WEEE) Directive

In August of 2005, the European Union (EU) implemented the EU WEEE Directive 2002/96/EC and later the WEEE Recast Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE that the Producer places on the EU market after August 13, 2005. The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage re-use and recycling at the end of life.

If you have purchased Flight Medical-branded electrical or electronic products in the EU and are intending to discard these products at the end of their useful life, please do not dispose of them with your other household or municipal waste. Flight Medical has labeled its branded

electronic products with the WEEE Symbol (see above) to alert our customers that products bearing this label should not be disposed of in a landfill or with municipal or household waste in the EU.

Flight Medical Innovations Ltd. has met its national obligations to the EU WEEE Directive by registering in those countries to which Flight Medical is an importer.

For professional users in the European Union

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

For disposal in countries outside of the European Union

This symbol is only valid in the European Union (EU). If you wish to discard this product please contact your local authorities or dealer and ask for the correct method of disposal

14.12 Technical Description

If required, the following technical description of the Ventoux can be provided.

1. Summary description of the filtering and/or smoothing techniques for all measured and/or computed variables that are displayed or used for control.

2. Pneumatic diagram of the ventilator, including a diagram for operator-detachable parts of the ventilator breathing system.

3. Summary description of the means of initiating and terminating the inspiratory phase in each mode of the ventilator.

4. Description of a method for checking the function of the alarm system for each of the alarm conditions specified in this manual

5. Means of restricting access to changing or to the storage of changes.

14.13 Alarm Signals Validation

The following procedures can be used to verify the functionality of the Alarm System

1. In order to give rise to **Low priority** alarm signal:
   a. turn the vent on with AC cable connected
   b. on standby mode, pull out the AC cable

EXPECTED RESULT	PASS/FAIL
Alarm “No External Power” is displayed	
Circular sound sequence – 2 slow notes Long pause between 2 consecutive sequences	
Visual yellow alarm is ON	

Remote alarm is ON	

2. In order to give rise to **Medium priority** alarm signal:
    a. Connect the adult simulated lung (C=0.05, R=5), set the STS prescription
    b. Set FiO_2 target to 60%, but do not connect oxygen supply
    c. Start ventilation

EXPECTED RESULT	PASS/FAIL
Alarm “No O2 Supply” is displayed	
Circular sound sequence – 3 slow notes Medium pause between 2 consecutive sequences	
Visual yellow alarm is blinking slowly	
Remote alarm is ON	

3. In order to give rise to **High priority** alarm signal:
    a. Connect the adult simulated lung (C=0.05, R=5), set the STS prescription
    b. Start ventilation
    c. Disconnect the outlet tube

EXPECTED RESULT	PASS/FAIL
Alarm “Check Circuit” is displayed	
Circular sound sequence – 5 fast notes, short pause and 3 fast notes Short pause between 2 consecutive sequences	
Visual red alarm is blinking fast	
Remote alarm is ON	

15 Appendix A – Testing of Oximetry and Capnograophy Alarm Settings

15.1 APNEA alarm

1. Set APNEA limit to 20 seconds, using the corresponding button on the “Alarms” tab screen
2. Go to Monitor mode
3. Establish a display of normal breathing on the monitor
4. Once normal breathing is displayed, remove the sampling line from the test subject to create a no breath situation.
5. Wait for 20 seconds.
6. **The monitor should then display a APNEA alarm.**
7. Reconnect the sampling line in order to return normal breathing on the monitor
8. **The APNEA alarm should disappear.**

15.2 SpO2 OFF THE PATIENT alarm

1. Go to Monitor mode
2. Establish a display of normal breathing on the monitor
3. Once SpO_2 actuals values are displayed, remove the sensor from the test subject to create alarm situation.
4. **The monitor should then display a SpO2 OFF THE PATIENT alarm.**
5. Return the sensor back.
6. **The SpO2 OFF THE PATIENT alarm should disappear.**

15.3 HIGH SpO2 alarm

1. Go to Monitor mode
2. Establish a display of normal breathing on the monitor
3. Once SpO_2 actuals values are displayed, detect approximately the average of these values
4. Go to Alarms tab screen, press on SpO2 limit button and set the high limit to the value ~10 points below the measured average
5. **The monitor should then display a HIGH SpO2 alarm.**
6. Go to Alarms tab screen, press on SpO2 limit button and set the high limit to the value ~10 points above the measured average
7. **The HIGH SpO2 alarm should disappear.**

15.4 LOW SpO2 alarm

1. Go to Monitor mode
2. Establish a display of normal breathing on the monitor

3. Once SpO_2 actuals values are displayed, detect approximately the average of these values
4. Go to Alarms tab screen, press on SpO_2 limit button and set the low limit to the value ~10 points above the measured average
5. **The monitor should then display a LOW SpO2 alarm.**
6. Go to Alarms tab screen, press on SpO_2 limit button and set the low limit to the value ~10 points below the measured average
7. **The LOW SpO2 alarm should disappear.**

15.5 HIGH etCO2 alarm

1. Go to Monitor mode
2. Establish a display of normal breathing on the monitor
3. Once $etCO_2$ actuals values are displayed, detect approximately the average of these values
4. Go to Alarms tab screen, press on $etCO_2$ limit button and set the high limit to the value ~20 points below the measured average
5. **The monitor should then display a HIGH etCO2 alarm.**
6. Go to Alarms tab screen, press on etCO2 limit button and set the high limit to the value ~20 points above the measured average
7. **The HIGH etCO2 alarm should disappear.**

15.6 LOW etCO2 alarm

1. Go to Monitor mode
2. Establish a display of normal breathing on the monitor
3. Once $etCO_2$ actuals values are displayed, detect approximately the average of these values
4. Go to Alarms tab screen, press on $etCO_2$ limit button and set the low limit to the value ~20 points above the measured average
5. **The monitor should then display a LOW etCO2 alarm.**
6. Go to Alarms tab screen, press on $etCO_2$ limit button and set the low limit to the value ~20 points below the measured average
7. **The LOW etCO2 alarm should disappear.**

16 Appendix B – humidifier verification

To Verify Operations of a humidifier with the Ventoux. The User should ensure that their humidifier can provide a constant flow for at least a 4 hours operating time.

To verify a humidifier, select HFOT mode, set Flow = 40 and start ventilation. Perform HFOT for 4 hours and verify each 20 minutes using a flow analyzer such as IMT, that the Flow remains within 40 LPM ±10%. Verify that no alarms are issued.

The HFOT mode in the Ventoux ventilator was tested with:

- Medline Hudson RCI ConchaTherm Neptune Heated Humidifier, P/N HUD42500
- Medline Hudson RCI Comfort Flo Plus Nasal Cannula size S, P/N HUD241213.
- Flexicare NioFlo Cannula Pediatric size S, P/N 032-12-250.