User Manual

ventway SPARROW

EMERGENCY AND TRANSPORT VENTILATOR

VWSP-100 Civil Model | VWSP-100MR Civil Model
VWSP-900 Robust Model | VWSP-900 MR Robust Model

INOVYTEC
THE POWER TO SAVE LIVES

VWSP-500, Rev. 16, Last update June 2021

Important

This User Manual is subject to periodic review, update and revision.

Do not use a defective product. Do not repair this product or any of its parts. If this device does not perform properly, contact an Inovytec representative.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Inovytec Medical Solutions Ltd.

The safety, reliability, and performance of this device can be assured only under the following conditions:

- The device has been used according to the accompanying operating instructions.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by Inovytec Medical Solutions Ltd.'s authorized representatives.

Inovytec Medical Solutions Ltd. reserves the right to change or improve its products and accompanying technical literature without specific notice of changes or improvements.

This product is protected by patents listed on the Inovytec website.

Contact Information:

Inovytec Medical Solutions Ltd.
5 HaTidhar St.,
Raanana 4366507, Israel
Tel: +972 9 965 64 70
Fax: +972 9 965 64 79
E-mail: Info@Inovytec.com
Web Site: http://www.Inovytec.com

Disclaimer

Information provided by Inovytec Medical Solutions Ltd. is believed to be accurate and reliable. However, Inovytec assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of ventilators. Under this law, owners of this ventilator must notify Inovytec Medical Solutions Ltd. if this product is received; lost, stolen, or destroyed; donated or resold; or otherwise distributed to a different organization. If any such event occurs, contact Inovytec in writing with the following information:

- Originator's organization – Company name, address, contact name, and contact phone number.
- Model number, and serial number of the ventilator
- Disposition of the ventilator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number.
- Date when the change took effect.

Please address this information to Inovytec Medical Solutions Ltd. at the address given above.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM.

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Obtaining Help

If you have a ventilator problem that you cannot solve, and the ventilator was purchased **directly from Inovytec,** you may contact Inovytec at info@Inovytec.com.

If you have a ventilator problem that you cannot solve, and the ventilator was purchased **from an authorized Inovytec distributor,** please contact your distributor directly to report the problem.

Note: If this ventilator has not been purchased directly from Inovytec, please ensure that it has been purchased from an authorized distributor of Inovytec. To obtain a list of authorized distributors, contact Inovytec at info@Inovytec.com.

1. ABOUT THIS USER MANUAL

This User Manual provides the information necessary to operate and maintain the Ventway Sparrow ventilator.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM. If any part of this User Manual is not clear, contact Customer Support for assistance.

PLEASE RETAIN THIS USER MANUAL FOR FUTURE REFERENCE.

1.1 TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Manual:

Warning: A warning indicates precautions to avoid the possibility of personal injury or death.

Caution: A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.

Note: A note provides other important information.

1.2 GLOSSARY AND ABBREVIATIONS

Term	Description
Apnea	Temporary cessation of breathing
BPM	Breaths Per Minute
Breath	Period from the start of inspiratory (positive) flow to the subsequent start of expiratory (negative) flow
Cycle	Ending inspiratory time – Cycling can be patient or machine initiated
I:E Ratio	Ratio of inspiratory time to expiratory time
LPM	Liters per minute (units for flow)
Mandatory Breath	Inspiration is machine triggered or cycled independent of patient action
Manual Breath	Inspiration is operator triggered
MV	Minute Volume
NIV	Non-Invasive Ventilation - Use of mask instead of endotracheal tube
PC	Pressure control - Inspiratory pressure rise above PEEP is preset during inspiration - Applies to mandatory or spontaneous breaths
Peak Flow	Maximum inspiratory flow
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
PSV	Pressure Support Ventilation - Inspiration is pressure controlled, pressure triggered and flow cycled - Applies to spontaneous breaths only
Sensitivity	The change in airway pressure required for the patient to trigger inspiration
Spontaneous Breath	Inspiration is patient triggered and patient cycled independent of machine trigger or cycle signals
T_E	Expiratory time - The period from the start

Term	Description
	of expiratory (negative) flow to the start of inspiratory (positive) flow - May be a setting or a measurement.
T_I	Inspiratory time - The period from the start of inspiratory (positive) flow to the start of expiratory (negative) flow - May be a setting or a measurement.
Tidal Volume (VT)	The volume inhaled or exhaled during a breath
Trigger	Starting inspiratory time – Triggering can be patient or machine initiated
VC	Volume control – Tidal volume and inspiratory time are preset during inspiration - Applies to mandatory breaths only
VT_E	The maximum volume exhaled during the expiratory time
VT_I	The maximum volume inhaled during the inspiratory time
HFNC	High Flow Nasal Cannula – intended to accurately deliver high volume of oxygen therapy

2. OVERVIEW OF SYSTEM

2.1 DESCRIPTION OF DEVICE

The Ventway Sparrow is a portable ventilator, used for transport in pre-hospital, field hospital, and hospital settings as well as Emergency Medical Service (EMS) applications under the direction of a physician.

The Sparrow is easy to set up, self-sufficient and lightweight.

The ventilator is suitable for non-invasive ventilation for a full non-vented ventilation face mask or invasive ventilation via an endotracheal tube and tracheostomy.

Note: The power supply needs to be firmly and permanently secured in any EMS environment in which the ventilator is used.

Note: The Ventway Sparrow is able to work with an MR scanner at a maximum power of three tesla. As a precaution, locate the ventilator as far as possible from the coils – at least one meter. Keep a 10cm distance between the patient circuit transducer and the patient's body. The ventilator must be operated only with the internal battery.

MRI Safety Information

The Ventway Sparrow Models VWSP-100MR and VWSP-900MR are designed and shielded to ventilate the vicinity of an MRI scanner, and can be used at a magnetic field strength of 47 mT (470 G) without creating any MR image artifacts.

VWSP-100MR and VWSP-900MR may be safely used in the MR environment up to 3 Tesla.

Failure to follow these conditions may result in injury.

Do not use the Ventway Sparrow Models VWSP-100 and VWSP-900 in MR environment, as safety in MR environment has not been tested.

3. CONDITIONS FOR USE

3.1 INDICATIONS FOR USE

The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb.), who require the following types of ventilatory support: SIMV VC PS, SIMV PC PS, CPAP or HFNC.

The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for invasive (via an endotracheal tube and tracheostomy) or noninvasive (full non-vented ventilation face mask) ventilation presets. It may be used in hospitals, pre-hospital (transport) and field environments.

Models VWSP-100MR and VWSP-900MR may be used in a Magnetic Resonance (MR) environment up to 3 Tesla.

The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

3.2 CONTRAINDICATIONS

- Depending on the legal status of DNR, DNAR or DNACPR instructions in your location, use of this device may be contraindicated. Consult your legal advisor for specific guidelines in this respect.
- Acute Pneumothorax

3.3 LIMITATIONS OF USE

Clinical situations potentially affecting accuracy or performance:

- Controlling the flow in the presence of difficult airways, such as severe lung blockage and asymmetric air entrance to the lung
- Low compliance of the airways
- Asynchronization between patient and ventilator

- Barotrauma
- Behavior of the ventilator in case of barotrauma, monitoring and displaying alarms in these cases.

Note: The use of heated humidification is not recommended, due to potential blockage of control and measurement tubes.

4. SAFETY

4.1 ELECTRICAL SAFETY

The device complies with requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment:

- Class I Equipment BF type applied part
- Mode of operation: Continuous measurement
- Degree of mobility: Portable

4.2 EMC COMPLIANCE

The Ventway Sparrow is suitable for the electromagnetic environment of typical commercial or hospital settings.

During the immunity testing described below, the Ventway Sparrow continued to provide uninterrupted delivery of tidal volume, respiratory rate, PIP, and PEEP within the device specifications.

4.2.1 EMISSIONS

Electromagnetic Emissions		
The Ventway Sparrow is intended for use in the electromagnetic environment of hospitals and EMS environments . The user should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Ventway Sparrow 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 Ventway Sparrow is suitable for use in The Ventway Sparrow is suitable for use in hospitals, pre-hospital (transport) and field environments.
Harmonic emissions IEC 61000-3-2	A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Per Standard	

4.2.2 IMMUNITY

Electromagnetic Immunity		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±2, 4, 8, 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 for power supply lines	Mains power quality should be that of hospitals, pre-hospital (transport) and field environments.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of hospitals, pre-hospital (transport) and field environments.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of hospitals, pre-hospital (transport) and field environments. If the user of the Ventway Sparrow requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the Ventway Sparrow is powered from an uninterruptible power supply. Note percentages are the level of mains power during the dropout
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in hospitals, pre-hospital (transport) and field environments.

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 6 V rms in ISM and amateur radio bands 10 V/m And immunity to proximity fields from RF wireless communications equipment	The Ventway Sparrow is suitable for the electromagnetic environment of hospitals, pre-hospital (transport) and field environments.

4.3 SAFETY INSTRUCTIONS

Warnings

US Federal Law restricts the sale of this instrument only by, or on the order of, a physician.

DO NOT USE BEFORE READING THIS USER MANUAL.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ventway Sparrow System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Ventway Sparrow should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Ventway Sparrow should be observed to verify normal operation. If operation is not normal, the Ventway Sparrow or the other equipment should be moved.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.

Basic safety precautions should always be taken, including all those listed below.

Warnings

DO NOT use this device for any purpose other than specified in this manual without written consent and approval from Inovytec Medical Solutions Ltd.

In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in **patient death.**

The exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask.

The device shall not be used in a hyperbaric chamber.

The device shall not be used with nitric oxide and explosive or highly flammable gas mixtures.

The device shall not be used with helium or mixtures with helium.

The device should not be used on unattended patients.

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

If no patient weight was set, the user will not be able to change any default alarm parameters.

Cautions

If the device packaging is not intact, do not use the device.

If the device does not turn on, or is not working correctly, discontinue use. Refer servicing or replacement to qualified service personnel.

Do not disassemble any part of the system components. This system is not user-serviceable.

Do not use the equipment if it is not working properly or if it has suffered any damage, for example, by dropping the equipment or splashing water on it.

If the LCD screen is cracked or damaged, check whether the screen can be used, and if not, do not use the device.

If the power button is damaged or stuck, disconnect the patient from the device and remove the battery.

If the rotator switch does not allow changing parameters, the device cannot be used.

The Patient Circuit is single use only. If it is not removed from a new container, it may have already been used and should not be used.

The Patient Circuit should be changed after 7 days of continuous use for the same patient.

Use only the original Inovytec Patient Circuit.

Confirm that the expiration date, found on the Patient Circuit packaging bag, has not been reached.

The device should be used under medical supervision.

When using external oxygen enrichment, please note the following:

- When using Oxygen Mixer, the oxygen enrichment level will reach a maximum of 95%.
- When using oxygen enrichment kit, the oxygen enrichment level may vary depending on oxygen flow rate.

Cautions

It is the user's responsibility to retain information about the patient (by USB connection). Storage capacity may be sufficient for at least one year of ventilation.

Repairs should be undertaken only by personnel trained or authorized by Inovytec Medical Solutions Ltd. Do not modify this equipment without authorization from Inovytec Medical Solutions Ltd.

The device may not operate correctly if used or stored outside the relevant temperature or humidity ranges, as described in the performance specifications.

Strictly follow the warning instructions in this manual.

This instrument is fragile. To prevent damage, please handle with care, including while packing and unpacking.

Ensure that the system is only used by a trained person familiar with all system operating procedures. EMS personnel should complete a training program before operating the Ventway Sparrow.

User is prohibited from changing, adding, removing or disassembling any system parts. Warranty shall not apply to any defects, failure or damage caused by improper use and/or improper or inadequate maintenance and care.

The unit is continuously operated, ordinary equipment with applied part and with signal input/output parts.

The device is not intended for use in the presence of flammable substances.

To avoid damage to the screen, do not expose the instrument to direct sunlight for prolonged periods.

The system is approved for IP45 in operation mode with oxygen enrichment. To prevent damage to the instrument or patient cable, avoid liquid spillage while cleaning.

Cautions

- It is strongly recommended that all Ventway Sparrow parts be replaced with parts purchased from Inovytec Medical Solutions Ltd. or an authorized distributor. Use of other parts may damage the unit and void the warranty.
- The ventilator is suitable for non-invasive ventilation for full non-vented ventilation face mask or Invasive ventilation via an endotracheal tube or tracheostomy.
- During NIV (Non-Invasive Ventilation) the user should use a capnograph in order to monitor the CO_2 level of the patient.
- Covering the ventilator is prohibited.
- Ensure that no Latex or natural rubber parts are in patient pathways.
- When adding medication to the gas flowing into the patient by using an MDI or nebulizer, please position between mask/ETT and exhalation valve. Choose NEB set up in order to compensate for additional volume added by the use of nebulizer.
- Do not obstruct the gas intake ports.
- Discarded used or unused patient circuit is classified as clinical waste. As such, the user is responsible for complying with all local and national regulations regarding discarding of clinical waste.
- In order to keep the device waterproof, replace the USB cover in its exact original location.
- After replacing the filter, close the cover screws firmly by hand or using a tool. Be sure to close completely – if not closed properly, oxygen enrichment may be affected.

Cautions

VWSP-100MR and VWSP-900 MR can be used at the specified test location without negative impact on the image quality of the 3T MR system. However, special MR Conditional installation requirements needs to be taken into account in order to keep the device at a safe distance and acceptable spatial magnetic field gradient isocontour. Otherwise serious injuries might occur due to the device becoming accidentally a projectile hazard moving towards the magnet bore entrance where high spatial magnetic field gradients exist, causing magnetically induced displacement forces.

VWSP-100MR and VWSP-900MR may be used in a Magnetic Resonance (MR) environment up to 3 Tesla with a rechargeable battery only, without using an external power source.

Notes

Dispose of this device and used sensors in accordance with local regulations.

Use the equipment only for the purpose described in these instructions for use.

The contents of this manual are subject to change without prior notice.

The user or any technical personnel who are not formally authorized by Inovytec Medical Solutions Ltd. should not open the device under any circumstances. Opening the device could damage the unit and will void the warranty provided by Inovytec Medical Solutions Ltd.

5. SYSTEM COMPONENTS

5.1 UNPACKING THE DEVICE

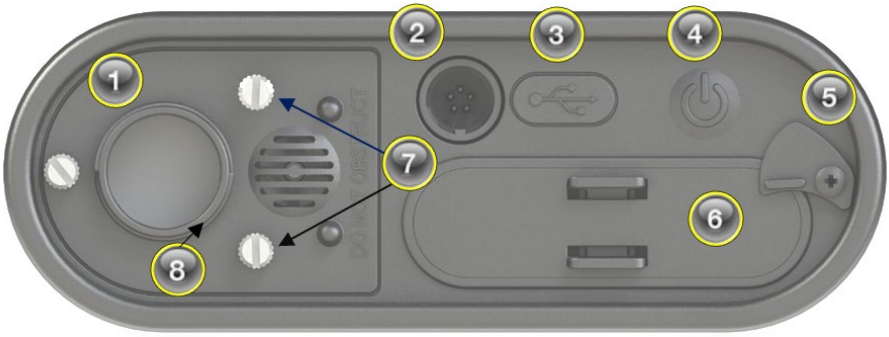
Package contents

1	Ventway Sparrow ventilator
2	Battery pack - Inside ventilator battery compartment
3	User Manual and device documentation
4	Power supply

5.2 VENTILATOR – FRONT PANEL

Front Panel: ***(1)*** *control knob,* ***(2)*** *display,* ***(3)*** *control and sensing tubes port,* ***(4)*** *patient circuit port*

5.3 VENTILATOR – REAR PANEL



Rear Pane: ***(1)*** *Air/Low pressure oxygen inlet,* ***(2)*** *Power supply connector,* ***(3)*** *USB connector,* ***(4)*** *Power On/Off button,* ***(5)*** *Battery pack lock, (6) Battery pack,* ***(7)*** *Filter compartment screws,* ***(8)*** *Anti asphyxia valve*

⚠ **Warning:** Do not block item **(1)**, the air/oxygen inlet.

5.3.1 VENTILATOR – USE CONFIGURATION

During transport, the ventilator should be placed in a horizontal position.

5.4 PATIENT CIRCUIT

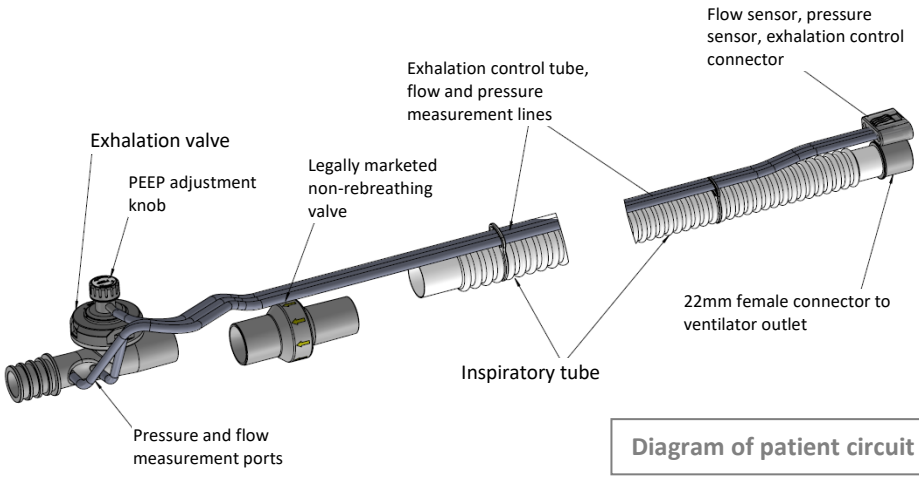


Diagram of patient circuit

Patient circuits specifications	Adult	Pediatric
Nominal overall length	180 / 240 cm	180 / 240 cm
Internal volume	690 / 920 CC	318 /424 CC
Inspiratory Resistance to flow	2.7 cm H_2O @ 60 LPM	5.4 cmH_2O @ 30 LPM
Dead space	17 mL	16.5 mL
Circuit compliance	0.001 L/cmH_2O	0.0008 L/cmH_2O
Corrugated tube diameter	22 mm	15 mm
Delivered tidal volumes	100 - 2000 mL	50 - 250 mL
Exhalation valve cap and knob color	Transparent	Blue

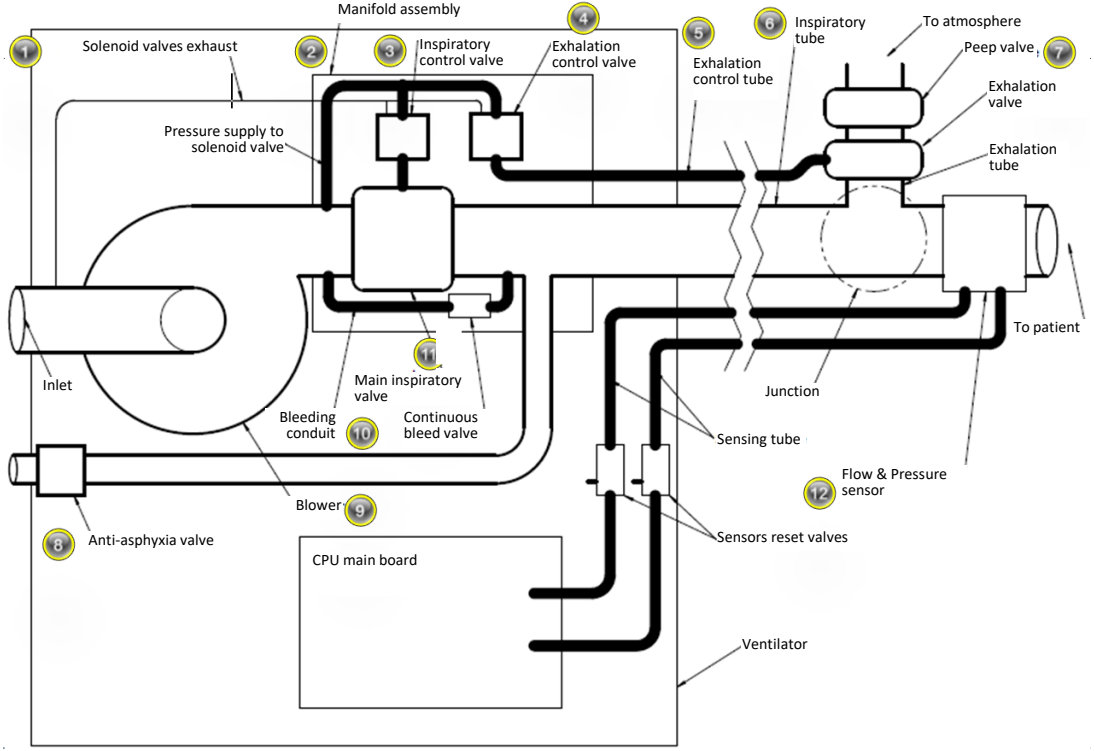
An authorized HME and anti-bacterial filter must be used at all times, in order to protect both patient and ventilator from infection.
Assemble the filter between the patient and transducer; if not possible, then between the ventilator outlet and the patient circuit 22 mm connector.

A legally marketed non-rebreathing valve 22mm O.D. inlet x 22mm I.D. outlet, resistance < 0.5 cmH2O must be used with the flow direction from the ventilator to the exhalation valve, both for adult and pediatric circuits.

Warning: All parts of the patient circuit are single-use. Discard after use. Handle carefully to avoid cross-contamination.

Warning: Do not use antistatic or electrically conductive hoses or tubing in the ventilator breathing system.

5.5 PNEUMATIC SECTION – THEORY OF OPERATION



Explanation of Diagram	
1	**Solenoid valves exhaust** – scavenging of gas residue from the solenoids, passed to inlet to prevent oxygen buildup inside the enclosure.
2	**Manifold assembly** – encapsulates all electromechanical control elements, membranes, valves and air tubes in one compact element. This design eliminates the use of air tubes and pneumatic connectors.
3	**Inspiratory control valve** – controls the main inspiratory valve.
4	**Exhalation control valve** – controls the patient exhalation valve membrane, located in the patient circuit transducer.
5	**Exhalation control tube** – transferring pressure from the exhalation control valve to the exhalation valve membrane. It is a part of the patient circuit.
6	**Inspiratory tube** – a 15 mm or 22 mm tube, connecting the ventilator and the patient. Used for delivering the gas mixture to the patient's airways.
7	**PEEP valve** – Spring activated membrane (same membrane used for exhalation control). Adjustable by rotating a knob.
8	**Anti-asphyxia valve** – designed to allow the patient to inhale through an emergency intake port separated from the regular inlet, in case of failure of the ventilator.
9	**Blower** – A radial blower, referred to sometimes as "turbine". Intended to generate pressure and flow of gas mixture either from the ambient air or from a mixture of air and oxygen.
10	**Bleeding conduit and continuous bleed valve** – orifice used for passing small amounts of flow, compensating for any leaks that may occur in the patient circuit, and removing any CO_2 from the patient circuit.
11	**Main inspiratory valve** – normally open valve. Main valve designed to allow passage of gas from the blower to the patient.
12	**Flow and pressure sensor** – a part of the patient circuit. A constant orifice sensor used for acquiring the flow and pressure in the patient's airways and passing them to pressure sensors located in the ventilator's electronic unit.

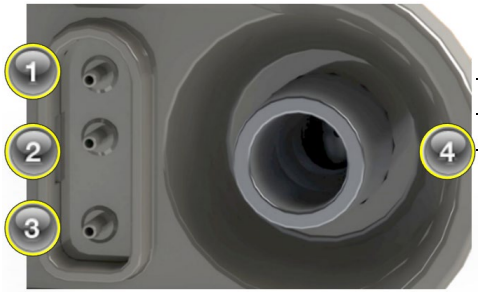
Inspiratory (1) vs. Expiratory (2) cycle

During the inspiratory phase, the exhalation valve membrane is closed, allowing the gas from the ventilator to be diverted to the patient. Once inspiration is complete, the membrane opens, allowing the gas from the patient to be exhaled through the exhalation valve.

The expiratory gas passes through the membrane which is constantly supported by a spring, creating the preset PEEP value. During expiratory time, a continuous low flow is delivered into the patient circuit, in order to prevent any re-breathing and to compensate for small leaks that may exist in the various circuit components or facemasks.

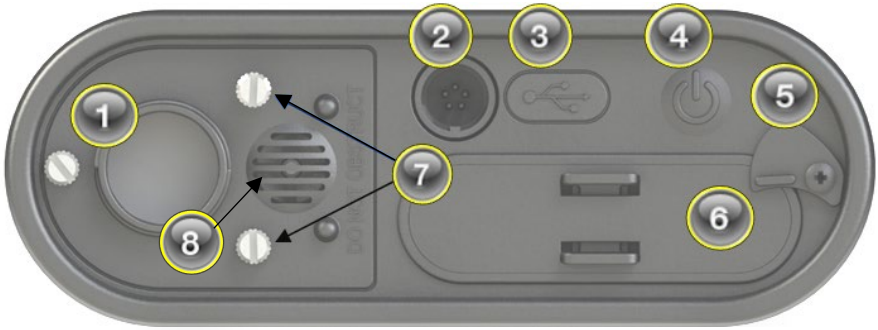
6. CONNECTING THE VENTILATOR

6.1 FRONT PANEL CONNECTIONS



1 Pressure and flow measurement port
2 Pressure measurement port
3 Expiratory valve port – control tube
4 Ventilator gas outlet

6.2 REAR PANEL CONNECTIONS



1. **Air inlet/Oxygen supply connector –** Air inlet/ oxygen connector to Oxygen Mixer (see Section *12.2.1.1 Connecting the Air Inlet to the Oxygen Mixer*).
2. **DC Power connector –** Connect power line (AC/DC or DC/DC power supply)

> **Caution:** Insert the three-conductor plug into a properly wired, three-wire, grounded, hospital grade receptacle. If a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code. Do not under any circumstances remove the grounding connector from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

3. **USB connector –** This connector is intended for technicians who require access to the logbook and device software.

4. **Power On/Off button**
5. **Battery safety lock**
6. **Battery pack**
7. **Filter compartment screws**
8. **Anti asphyxia valve**

6.3 SECURING THE VENTILATOR FOR USE IN THE MRI ENVIRONMENT

Once in the MRI environment, be sure the ventilator is safely secured and positioned.

To ensure safe and secure attachment of the ventilator to the mounting surface, the following requirements must be met:

- Ensure the ventilator is securely attached as described here.
- Use only 1/4"-20 UNC, 304 stainless steel, button head socket cap bolts screws, Allen hex drive.
- Choose an appropriate screw length that ensures that between 6 to 8 mm of the screw are fastened inside the ventilator

To attach the ventilator to a shelf or table:

1. Drill the required screw hole (6.5 to 7.0 mm diameter required) into the surfaces as needed.
2. Insert and tighten the screws.
   Ensure that 6 to 10 mm of each screw extends into the ventilator.
3. Pull up gently on the ventilator to ensure it is securely attached.

7. POWER ON/OFF AND DISPLAY STARTUP SCREEN

7.1 NORMAL START

To start the system, press and hold the **Power On/Off** button on the back panel for 3 seconds.

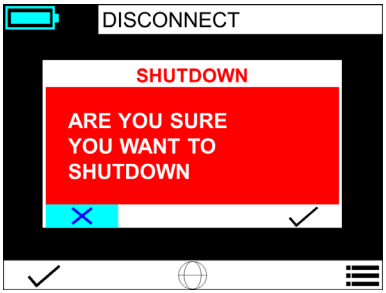
Back panel indicating the Power On/Off button

7.2 SHUTTING DOWN THE SYSTEM

To shut down the system, press and hold the **Power On/Off** button on the back panel for 3 seconds.

Back panel indicating the Power On/Off button

A confirmation screen will display, allowing the user to confirm the shutdown request:

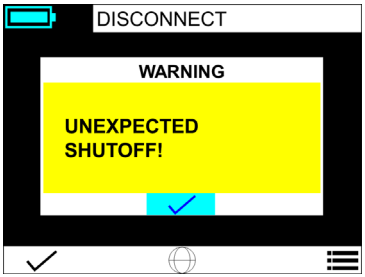


Confirmation screen for shutdown request

Press the check mark to confirm shut down. A constant beep will sound until final confirmation.

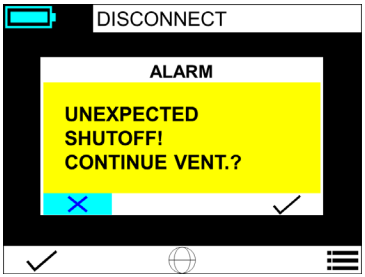
7.3 STARTUP DURING VENTILATION

If power is lost during ventilation and the ventilator is turned on **within 2 minutes,** it will automatically start with ventilation, and a DISCONNECT alarm of unexpected shutoff will be displayed on the screen.



Unexpected shutoff screen

If power is lost during ventilation and the ventilator is turned on **after more than 2 minutes,** the operator will be asked if he wants to continue ventilating using the previous parameters.



Unexpected shutoff screen

8. NAVIGATING THE GUI SCREENS

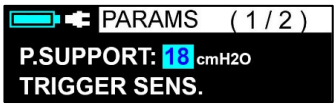
8.1 SELECTING SCREEN OPTIONS

To navigate between the screen options, turn the control knob on the left side of the device. When the desired option has been marked by positioning the marker on its location, press the knob to select the option.

Control knob

8.2 EDITING FIELDS

While turning the control knob, fields that can be modified are highlighted. To edit a field, press the control knob when positioned on the field. The field will change color. Rotate the control knob to view different values for the field, and press the knob to select a value.

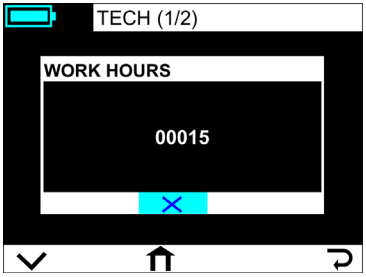


Pressure Support highlighted

Note: When the field changes to red, it means that the selection exceeds the normal setup related to the patient weight or type.

8.3 NAVIGATING BETWEEN SCREENS

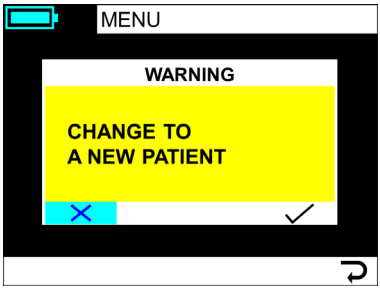
Navigate between screens as follows:



Press the Back button (↩) to return to the previous screen. Press the Next Screen button (﹀) to continue to the next screen.

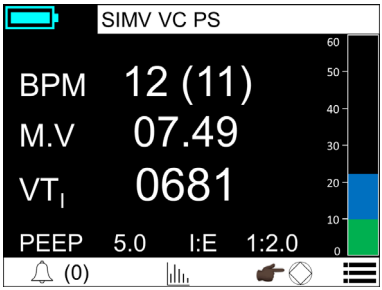
8.4 CONFIRMING OR CANCELLING A MESSAGE

When a message is displayed by the system that allows a confirm or cancel response, you can reject or confirm it:



Press Cancel (✕) to reject the action, or press Confirm (✓) to accept the action.

Pressing the Home button will automatically change the screen to the Home screen:



Home screen

The definition of which screen is the Home screen will change depending on how the device is used, as follows:

1. Upon Startup, the Home screen is defined as the DISCONNECT screen.
2. After the Run screen is displayed, the Home screen is defined as the Run screen.
3. Once a new patient has been confirmed, the Home screen is once again defined as the DISCONNECT screen.

8.5 SYMBOLS USED IN THE SYSTEM

	Back
	Next screen
	Language
	Graphs (Flow / Pressure)
	Confirm
	Cancel
	Silence an alarm for two minutes
	Manual breath
	Main Menu
	Home Button

8.6 SYSTEM INDICATORS

The top left corner of the display shows battery status and system indicators.

8.6.1 BATTERY STATUS

	No battery, external power source used
	Non-rechargeable battery, no external power source
	Non-rechargeable battery, external power source connected
	Rechargeable battery, external power source connected (charging)
	Rechargeable battery, external power source connected (fully charged)
	Rechargeable battery, no external power source connected
	Rechargeable battery, not charging due to battery temperature protection or faulty battery

Battery charge level is indicated by the following signs:

	Battery full
	Medium energy level
	Low energy level
	Battery in critical energy level

8.6.2 INDICATORS

T	Patient trigger detected
C	Patient cough detected **Note:** If a cough is detected, the ventilator will ignore patient triggers for one second.
Z	Pressure sensors are currently being zeroed **Note:** While zeroing sensors, the ventilator will not detect patient triggers.

The bottom left corner of the display shows the active alarms indicator.

8.6.3 ALARMS

Caution: It is the user's responsibility to ensure that the alarms are working properly. See Section *23 Appendix – Test Alarms* for instructions on testing the alarms.

	Normal operation
	Alarm is silenced. **Note:** While the alarm is silenced (maximum 120 seconds) this indicator is displayed, and the number of active alarms is displayed in parentheses next to the icon. **Note:** The icon serves as an activation button. Pressing it will open a list of up to five active alarms, ordered by priority.

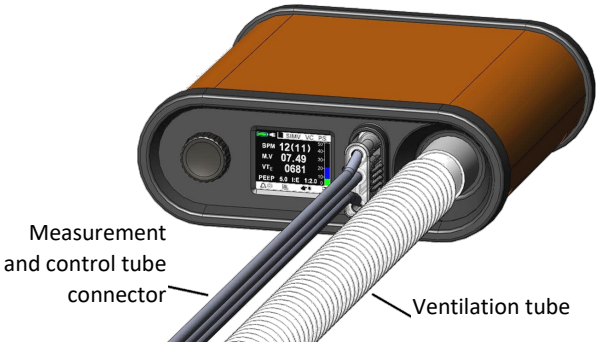
9. GETTING STARTED WITH VENTWAY SPARROW

The initial set of screens allow you to start the ventilator and specify settings such as patient weight, ventilation type, and other basic parameters.

Note: A system alarm sound is activated during system startup, indicating a valid Circuit Verification test.

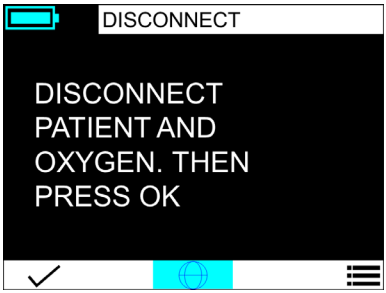
The first screen showing the Ventway Sparrow logo allows the user to identify whether the display is working properly.

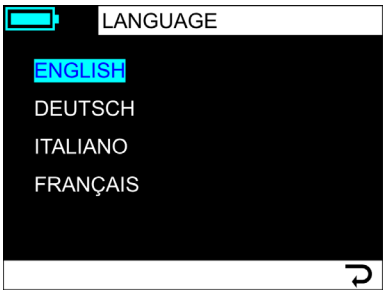
Connect the measurement and control tube adapter to the front panel connector, as shown here. Connect the ventilation tube to the ventilator outlet.



9.1 LANGUAGE SETTING

Ventway Sparrow operates in multiple languages, to change the default English language, rotate the scroll knob to the Language symbol, press it and select the required language:





9.2 CONNECTING VENTILATOR, PATIENT CIRCUIT, ENDOTRACHEAL TUBE/FACEMASK

Note: The following procedures are identical for both Adult and Pediatric use.

First connect the ventilator tube to the ventilator gas outlet:

Then connect the tube connector of the measurement and control tubes to the port on the left of the ventilator gas outlet:

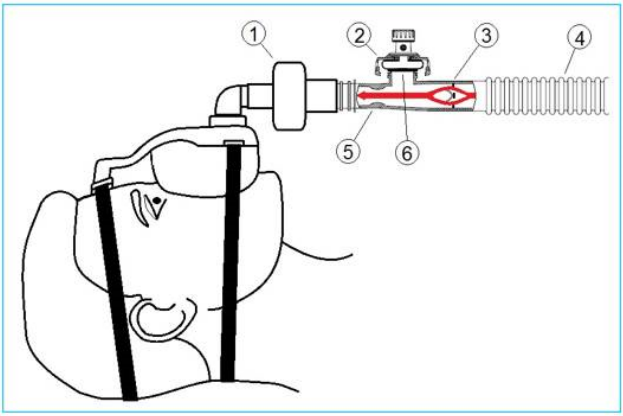
Insert ventilator tube into ventilator gas outlet

Insert the connector of the measurement and control tubes

Connectors fully inserted

Warning: Verify that each connector is secure by pulling gently on the connector.

Always use an anti-bacterial heat and moisture exchanger (HME) filter between the patient and the patient circuit, as shown below.



Connecting the Patient Circuit

1. HME (Heat and Moisture Exchanger) filter
2. Exhalation valve cover
3. One-way directional valve
4. Ventilation tube
5. Flow meter
6. Exhalation valve – showing closed position (inspiratory cycle)

Warning: Read carefully the Instructions For Use of patient circuit, attached inside the patient circuit pack.

Note: The patient-side connector is standard 22 mm outer diameter and 15 mm inside diameter. It must be connected to the female side of an HME which then connects to an endotracheal device/facemask or other airway management device that is in direct contact with the patient. When connecting the airway management device to the patient, follow the instructions for use provided with the device.

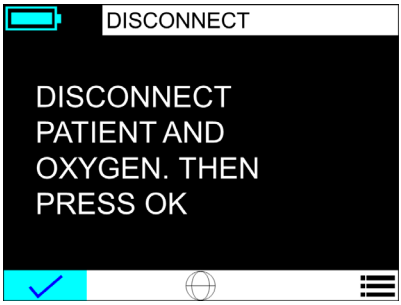
See Section *12.2.3 Additional recommended legally marketed components / accessories* for recommended legally marketed filters.

After connecting the patient circuit to the ventilator, verify that no caps are installed on the patient connection port. Perform circuit testing by following the instructions on the screen (see Section *9.3 Disconnect patient*).

The patient may be ventilated by an endotracheal tube or facemask (non-invasive ventilation). See Section *12.2.3 Additional recommended legally*

marketed components / accessories for recommended legally marketed endotracheal tubes and facemasks.

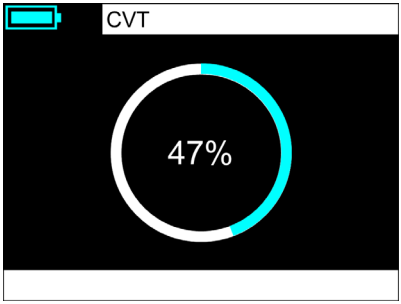
9.3 DISCONNECT PATIENT



Initial screen

Normal procedure after turning on the ventilator is to verify that the patient is disconnected, then press **OK** on this initial screen. The system will activate the blower to verify the correct operation of the device and various components (e.g. patient circuit, sensors and electrical components).

The self-test screen will display for about 15 seconds.



Self Test screen

Note: If the Main Menu is selected instead of **OK**, the **START** option will be unavailable, since the weight of the patient is unknown and ventilation parameters are not set. For details on the Main Menu option, see Section *10. Main Menu.*

Note: If the self test is performed at an altitude that exceeds 4,000 meters (13,123 feet) the caregiver is asked if the patient circuit being used is adult or pediatric.

If the self test fails, the user is advised to check the following:

- No Oxygen Mixer connected to the ventilator
- No Oxygen enrichment kit
- Dirty/obstructed inlet filter
- Pressure and control tube connected properly (kinks, disconnection or rupture of the tubes)
- No HME or filter are connected to the exhalation valve
- Patient is not connected

9.4 QUICK START

When quick start is activated, symbol will appear in the weight selection screen:

Weight selection screen

Once selected, ventilation will start according to predefined parameters.

Note: Setting parameters is performed by a qualified person under a direction of a physician. See section *10.4.6 MAIN MENU/Adv Settings/FF config*

9.5 PATIENT WEIGHT

Rotate the scroll knob to select the weight of the patient:

The patient circuit type will be identified automatically, and the appropriate weight screen (Pediatric/Adult) will be displayed.

Pediatric and adult weight selection screens

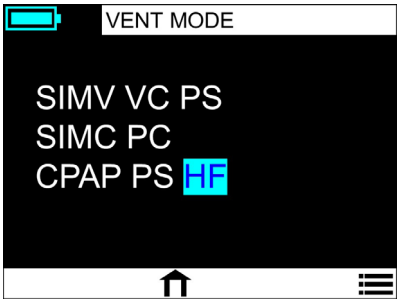
Note: Setting patient weight will automatically set all ventilation parameters

9.6 VENTILATION MODE

Term	Classification*	Description
SIMV PC PS	PC-IMV(1)s	Pressure Control Synchronized Intermittent Mandatory Ventilation with pressure support ventilation - Mandatory breaths are pressure controlled and spontaneous breaths are pressure supported
SIMV VC PS	VC-IMV(1)s	Volume Control Synchronized Intermittent Mandatory Ventilation with pressure support ventilation - Mandatory breaths are volume controlled and spontaneous breaths are pressure supported
CPAP PS	PC-CSVs	Continuous Positive Airway Pressure
CPAP PS HF	PC-CSVs	Continuous Positive Airway Pressure

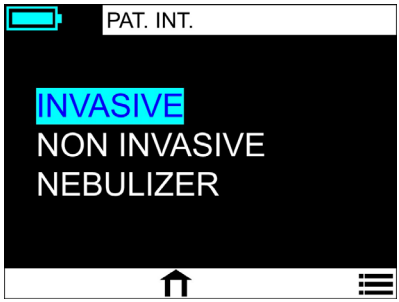
Chatburn RL et al. A Taxonomy for Mechanical Ventilation. Respir Care 2014;59(11):1747–1763.

Select the initial choice of ventilation mode. See Section *15. Ventilation Methods* for details about each ventilation mode.



Ventilation Mode screen

After ventilation mode is selected, select Invasive, Non-invasive or Nebulizer Mode:



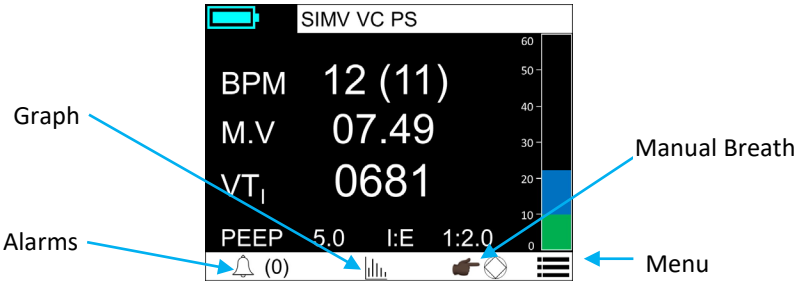
Note: After selecting "Nebulizer", you will be required to set nebulizer flow rate.

Note: When using nebulizer, HME filter should be removed.

You will be prompted to connect the patient:

9.7 VENTILATION PARAMETERS

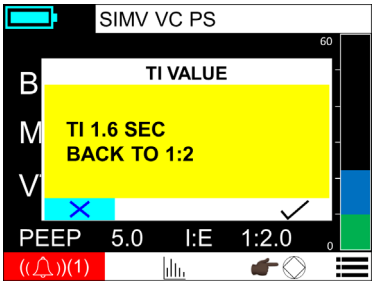
The Ventilation Parameters screen displays the relevant patient information, updated on a real-time basis:



Ventilation Parameters screen

- Select **BPM** to change the breaths per minute delivered.
- Select **VT_E** to change the desired VT_I - when scrolling to VT_E, the display automatically changes to VT_I.
- Select **I:E** to change the default T_I.
- Select **ALARMS** to view the current active (silenced) alarms.
- Select **GRAPH** to display the Pressure or Flow graphs – see Section *9.9 Pressure and flow graphs.*
- Select **MANUAL BREATH** to give one breath to the patient using the current parameters.
- Select **MENU** to display the Menu screen – see Section *10. Main Menu.*

Note: The possible range of TI is a minimum of 0.3 seconds and maximum of 4 seconds. In case that TI will exceed I:E ratio, an alert will be triggered.



9.8 NUMERICAL REPRESENTATION OF BREATH PARAMETERS

The measured and computed values that are displayed in the system are calculated using the filtering and smoothing techniques described below.

Patient pressure is displayed to the user by a bar (graphic refreshing frequency is 10 Hz). The sample rate of the pressure value is 500 Hz. The Peak Inspiratory Pressure is displayed as a blue background, remaining throughout the current breath, while the current pressure is displayed in green.

Altimeter input is averaged per second and linearly interpolated.

Oxygen percentage correction factor for density correction is taken from a table. Oxygen value is determined by the user.

Oxygen level is determined by the external Oxygen Mixer. However, the user is required to determine the oxygen correction factor (determined in the O_2 enrichment screen) in accordance with the actual oxygen level given**.**

Flow correction factor is taken from the last performed volume calibration.

Real time flow values are calculated using linear interpolation and corrected by the oxygen percentage, altitude (atmospheric pressure) and calibration correction factors.

Inspiratory and expiratory tidal volumes are calculated by integrating the positive and negative flows over time. The expired tidal volume and minute volume are displayed to the user. The inspired tidal volume is used to determine timing of the current breath termination and for blower speed corrections.

Please note that due to possible leaks when using non-invasive ventilation, VT_E and VT_I may vary substantially. Nevertheless, in non-invasive mode, a leak correction is performed by the ventilator.

BPM is calculated as one minute divided by the latest breath length.

Minute volume is calculated as the latest BPM multiplied by the latest expiratory tidal volume.

I:E is displayed to the user and is calculated per each breath as the inspiration time divided by the expiration time.

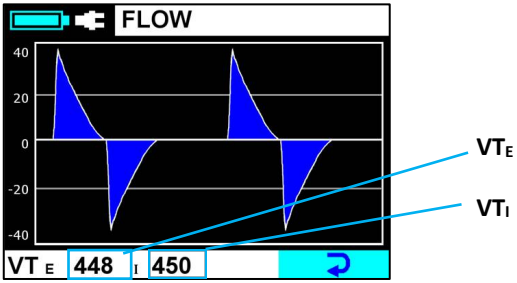
The latest **PEEP** is displayed to the user, and is updated per each breath, as the pressure measured at the end of expiration.

PIP is displayed to the user by a bar graph. It is the highest level of pressure applied to the lungs during inhalation.

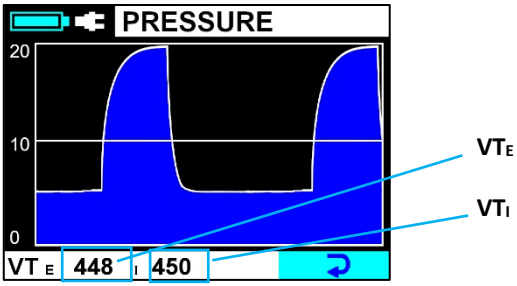
9.9 PRESSURE AND FLOW GRAPHS

This display shows the graphs of the pressure (in units of cm H2O) over time, and flow (in units of LPM) vs. time.

Rotation of the knob will switch between flow and pressure graphs.

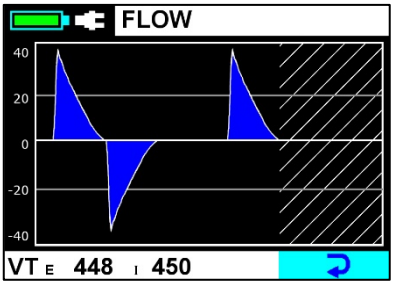


Flow Graph screen



Pressure Graph screen

During sensor zeroing, diagonal lines are drawn on the graph to indicate no input from the sensors.

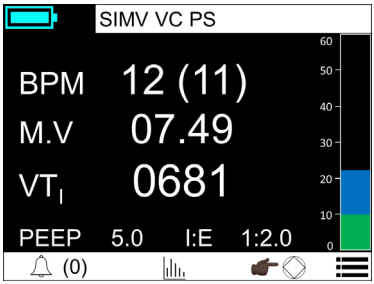


Flow graph screen during sensor zeroing

10. MAIN MENU

The Main Menu screen allows the user to view and set various system values.

The Main Menu is accessed by selecting on the bottom of the screen:



Access the Main Menu

Main Menu screen

Options on the Main Menu:

STOP VENT/START VENT
Stop or start the respiratory function of the device.

NEW PATIENT
View the Disconnect Patient screen and reset all selected parameters. See Section *10.1 Main Menu/New Patient (Disconnect Patient Screen)*.

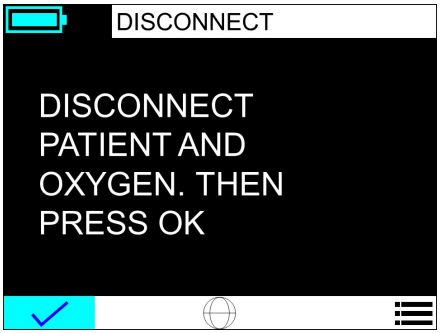
VENT. PARAMS
View patient weight, ventilation mode, and other parameters.
See Section *10.2 Main Menu/Vent Params*.

ALARM SETTINGS
Set the thresholds at which the alarms will be displayed. See Section *10.3 MAIN MENU/Alarm settings.*

ADV SETTINGS
Set advanced settings, such as technician mode, self test, brightness and language. See Section *10.4 MAIN MENU/ADVANCED SETTINGS*.

10.1 MAIN MENU/NEW PATIENT (DISCONNECT PATIENT SCREEN)

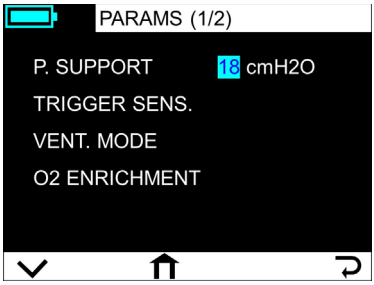
This screen allows the user to restart existing ventilation parameters, e.g. when ventilating a new patient.



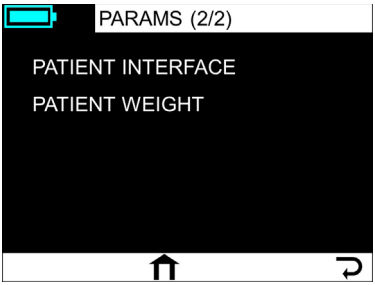
Disconnect Patient screen

10.2 MAIN MENU/VENT PARAMS

These screens allow the user to set the patient weight, ventilation mode, and other ventilation parameters.



Vent. Param. screen (1 of 2)



Vent. Param. screen (2 of 2)

10.2.1 MAIN MENU/VENT PARAMS/TRIGGER SENSITIVITY

Set the trigger sensitivity for the pressure measurements.

Trigger Sensitivity screen

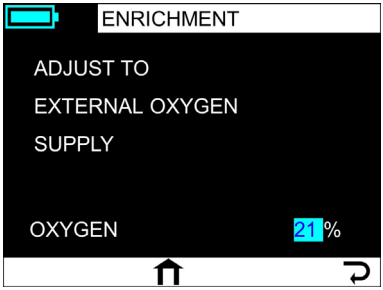
Caution: When closed suction catheterization is performed, patient trigger sensitivity must be turned to "off".

Caution: During transport ventilation, when the patient is often moved and subject to abrupt bumps, it is recommended to decrease pressure triggers sensitivity, in order to avoid auto triggers (e.g. -5 instead of -2).

10.2.2 MAIN MENU/VENT PARAMS/VENT MODE

The ventilation mode was set initially when the device was turned on. See Section *9.6 Ventilation Mode* to change the ventilation mode.

10.2.3 MAIN MENU/VENT PARAMS/O_2 ENRICHMENT



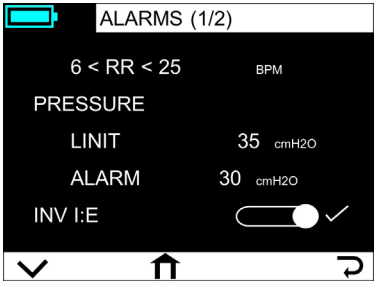
This screen allows adjustment to the volume calculation, according to the delivered mixture to the ventilator.

10.2.4 MAIN MENU/VENT PARAMS/PATIENT WEIGHT

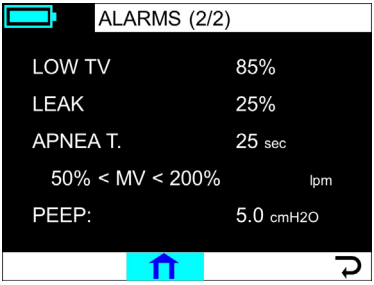
The patient weight was set initially when the device was turned on. See section *9.5 Patient Weight* to change the patient weight.

10.3 MAIN MENU/ALARM SETTINGS

The Alarm Settings screens allow the user to set the threshold value for each type of ventilation parameters alarm.



Alarm Param. screen (page 1)



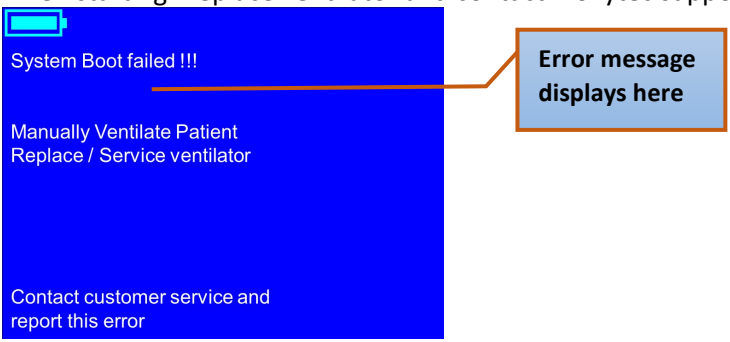
Alarm Param. screen (page 2)

See also Section *11 Warnings and Alarms* for *more* information about warning and alarm messages.

10.3.1 BOOT FAIL ALARM

Caution: Boot Fail Alarm

The Boot Fail screen appears if the system experiences an error when starting. Replace ventilator and contact Inovytec support.

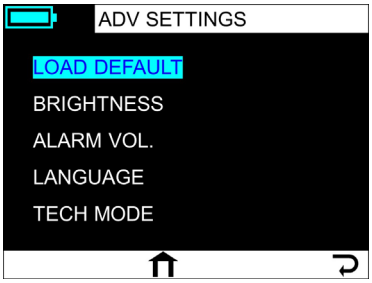


Example of Boot Fail Alarm

A summary of Boot Fail alarms is shown in Section *11.1 Boot Fail Alarms.*

10.4 MAIN MENU/ADVANCED SETTINGS

The **Advanced Settings** menu screen is shown below.

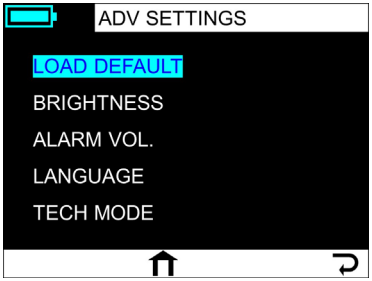


Advanced Settings menu

These options are explained in the following sections.

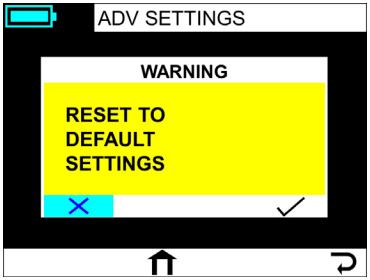
10.4.1 MAIN MENU/ADV SETTINGS/LOAD DEFAULT

Set all parameters to their default values by the set weight.



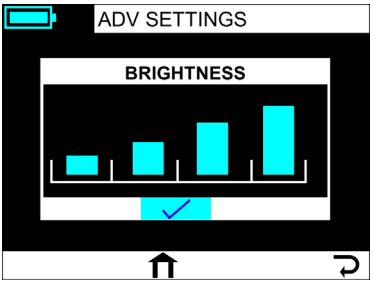
The Load Default screen

After pressing LOAD DEFAULT, a warning display will appear.



10.4.2 MAIN MENU/ADV SETTINGS/BRIGHTNESS

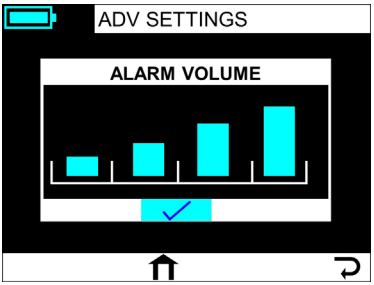
Change the brightness of the display.



In Robust mode there is an option to lower brightness and volume.

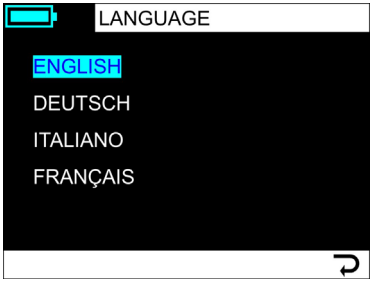
10.4.3 MAIN MENU/ADV SETTINGS/ALARM VOLUME

Change the volume of all sound cues of the system.



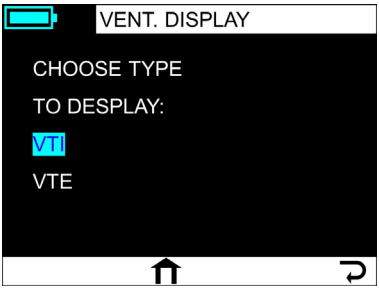
10.4.4 MAIN MENU/ADV SETTINGS/LANGUAGE

Change the system display language.



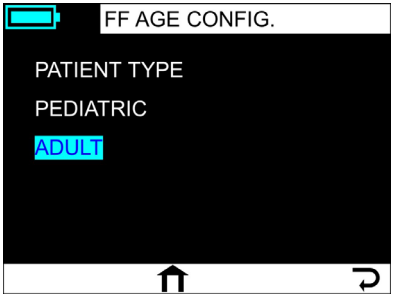
10.4.5 MAIN MENU/ADV SETTINGS/VENT DISPLAY

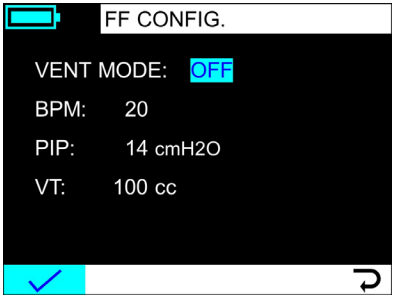
Change ventilation parameters display.



10.4.6 MAIN MENU/ADV SETTINGS/FF CONFIG

Set quick mode parameters for adult and pediatric patients:





Set ventilation mode: VC – Volume control or PC – Pressure Control.

For Volume Controlled ventilation set default BPM and TV.

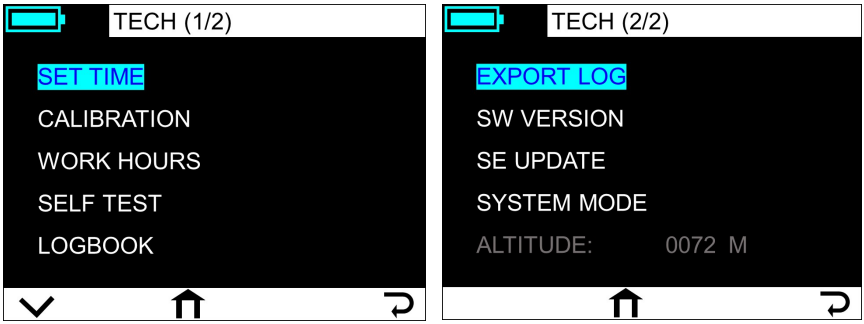
For Pressure Controlled ventilation set default BPM and PIP.

Allowable limits for quick start parameters		
	Adult	Pediatric
BPM	10 - 16	15 – 25
PIP	14 – 20 cmH_2O	12 – 20 cmH_2O
VT	350 – 600 cc	50 – 150 cc

Note: The rest of the parameters are set automatically. See section *12 Default Parameters*.

10.4.7 MAIN MENU/ADV SETTINGS/TECH MODE

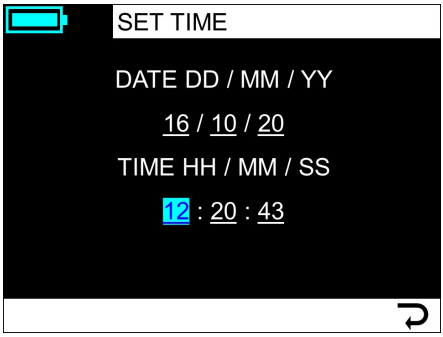
Tech mode allows the setting of the time, total hours of operation, and provides a system self-test function.



Tech Mode screens

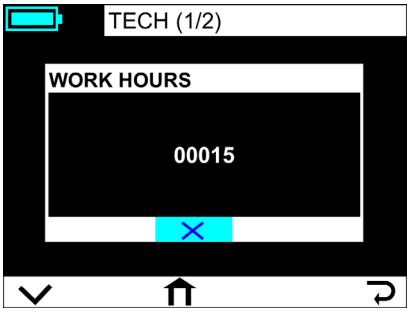
10.4.7.1 MAIN MENU/ADV SETTINGS/TECH MODE/SET TIME

Set the system date and time.



The Set Time screen

10.4.7.2 MAIN MENU/ADV SETTINGS/TECH MODE/WORK HOURS

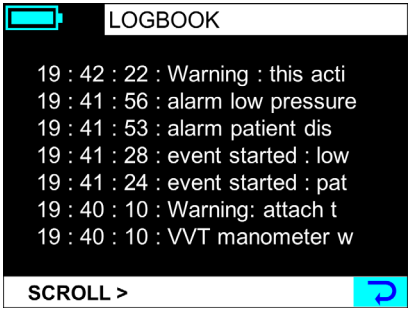


Work Hours screen

This screen shows the total ventilation hours performed by the ventilator.

10.4.7.3 MAIN MENU/ADV SETTINGS/TECH MODE/LOGBOOK

The Logbook screen shows alarms, indications and user interaction with the ventilator:



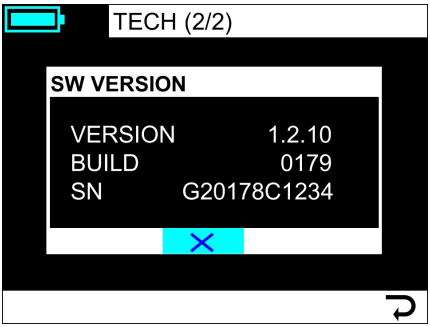
Example of an alarm

Note: The logbook is displayed in technician mode. Download is possible only in technician mode.

Note: Press **BACK** to exit log or **SCROLL** the rotator knob to continue viewing the log.

10.4.7.4 MAIN MENU/ADV SETTINGS/TECH MODE/SW VERSION

This screen shows the current software version installed on the ventilator. The serial number is also shown on this screen.



Software version screen

10.4.7.5 MAIN MENU/ADV SETTINGS/TECH MODE/ALTITUDE

The altitude above sea level is shown on the bottom of the second Tech Mode submenu.

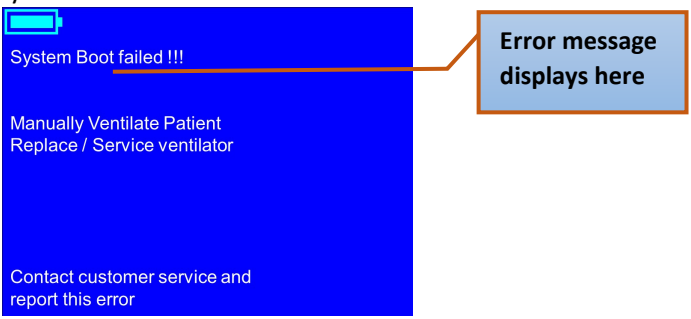
Example of altitude display: 72 meters

11. WARNINGS AND ALARMS

This section provides information about alarms, and examples of typical system messages.

11.1 BOOT FAIL ALARMS

A Boot Fail alarm is displayed on a blue screen and indicates that the device has not started properly.



Example of Boot Fail alarm

The specific error message is displayed in the part of the screen indicated above.

The following Boot Fail alarms can be fixed by the manager:

- Error in Flash checksum- installed software is problematic
- Error in SD card validity – missing or corrupted specific SD card files

For the following Boot Fail alarms, contact customer service and report the error:

- Voltage not in range – knob voltage is not up to appropriate range levels

11.2 SUMMARY OF ALARM TYPES

The following table summarizes the various types of alarms.

Alarm type	Value	Range/Display
User Adjustable	Breath rate	High: 12-70 bpm Low: 1-20 bpm
	Apnea	10-120 seconds
	Leak	10-100%
	Low Tidal Volume Delivered	Off or 15%-85%
	Inverse I:E Ratio	ON/OFF
	Alarm Volume	1-4
	Pressure limit	11-60 cmH_2O
	Pressure alarm limit	10-55 cmH_2O
Additional	Low Battery	Estimated battery energy level + Alarm
	Empty Battery	Screen Icon + Alarm
	Battery Disconnect	Screen Icon (swapping)
	Sensor tube disconnected	Alarm
	Tube Disconnect	Alarm
	Patient Disconnect	Alarm
	High PEEP	Alarm
	Service Notice	Alarm
	System Boot Failed	Alarm
	Low PEEP	Alarm
	AC Power Disconnect	Screen icon and an audio que

Note: Minimal alarm sound level is 80 dB at a distance of one meter from the ventilator.

11.3 SUMMARY OF ALARM LEVELS

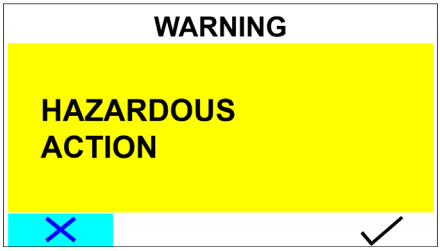
Alarms are defined with three levels of importance:

- **High**: Five beeps every two seconds
- **Medium**: Three beeps every five seconds
- **Low**: One beep one time only. Not shown in list of active alarms.

Alarm category	Alarm
High level	Blower malfunction
	Tube Disconnect
	Patient Disconnect
	Apnea
	System recovered from a crash
	Battery empty
	Sensor disconnect
	Low respiratory rate
	High minute volume
	Low minute volume
	High inspiratory pressure
	Low inspiratory pressure
	Leak
	Inverse I:E ratio
	High temperature
	Expiratory valve blocked
	High PEEP
	Low PEEP
Medium level	High breath rate
	Tidal Volume Limit Reached
	Low tidal volume
	Low pressure
	Battery low
	High Voltage
Low level	Replace filter
	Service needed
	Altitude out of range
	Unexpected Restart

11.4 WARNING EXAMPLE

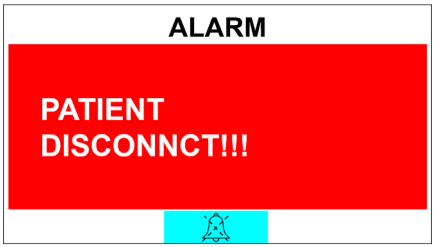
Here is an example of a warning message:



Warning message

11.5 ALARM EXAMPLE

A typical alarm appears as follows:



Example of an alarm

Note: Press the **Silence alarm sign** to acknowledge the message and silence the alarm.

In some alarms like the High PEEP alarm the user may choose to accept the out of bounds value, if it was intentionally changed. This action saves valuable time adjusting the alarm in the alarm settings screen.

High PEEP alarm

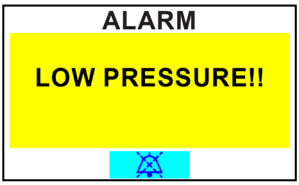
11.6 CHARACTERISTICS OF ALARM INDICATOR LIGHTS

High level alarm appears as follows:

Indicator color for high level alarm is red.
Flashing frequency = 2 Hz.
Duty cycle = 50%

Example of high level alarm

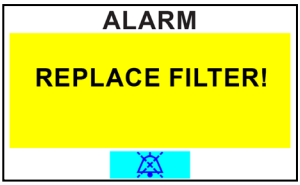
Medium level alarm appears as follows:



Indicator color for medium level alarm is yellow.
Flashing frequency = 0.45 Hz.
Duty cycle = 50%

Example of medium level alarm

Low level alarm appears as follows:



Indicator color for low level alarm is yellow.
Flashing frequency is constant (on).
Duty cycle = 100%

Example of low level alarm

11.7 ALARM SIGNAL SOUND PRESSURE LEVEL RANGE

Alarm level	Volume	Sound level (dB)
High	High	76.8
	Low	73.3
Medium	High	69.8
	Low	67.1
Low	High	66.2
	Low	65.1

Note: When multiple alarms appear they are visually seen on screen (each at appearance order).
If a high level alarm appears first, and then medium level alarm, order of audiovisual sequence is as follows:

1) High level alarm audio + visual alarm on screen (!!!)
2) Medium level alarm visual (!!) yet audio of high level alarm is in the background.

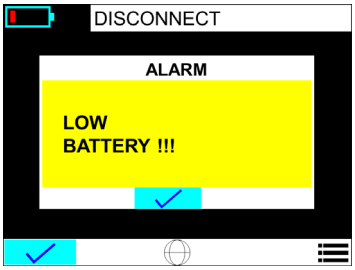
Warning: If an alarm system has a high level alarm condition and an operator adjustable auditory alarm signal sound pressure level, the auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions and the alarm system provides:

1. Only authorized personnel can configure the minimum operator-adjustable auditory alarm signal sound pressure level by using a password.
2. A blinking icon appears on the screen in a situation that a current sound pressure level might be inaudible when the auditory alarm signal sound pressure level is below a threshold that is configured.

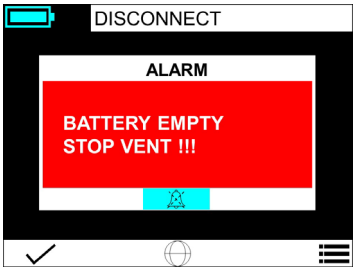
Caution: Setting alarm limits to extreme values can render the alarm system useless.

11.8 BATTERY STATUS ALARMS

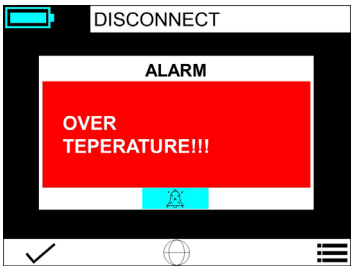
Low battery:



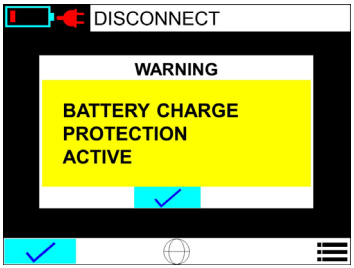
Battery empty:



Over temperature:



Battery charge protection:



12. DEFAULT PARAMETERS

12.1 START VOLUME VENTILATION

Ideal Body Weight	Rate	Tidal Volume	I:E	FiO2	PEEP
(Kg)	(bpm)	(mL)		(%)	(cmH2O)
5	35	50	1:2	21%	5
10	30	70	1:2	21%	5
15	23	100	1:2	21%	5
20	20	120	1:2	21%	5
30	18	180	1:2	21%	5
40	16	240	1:2	21%	5
50	14	300	1:2	21%	5
60	12	360	1:2	21%	5
70+	12	450	1:2	21%	5

12.2 START PRESSURE VENTILATION

Ideal Body Weight	Rate	Inspiratory Pressure	I:E	FiO2	PEEP
(Kg)	(bpm)	(cmH2O)		(%)	(cmH2O)
5	35	15	1:2	21%	5
10	30	15	1:2	21%	5
15	23	15	1:2	21%	5
20	20	20	1:2	21%	5
30	18	20	1:2	21%	5
40	16	20	1:2	21%	5
50	14	20	1:2	21%	5
60	12	20	1:2	21%	5
70+	12	20	1:2	21%	5

12.2.1 OXYGEN SUPPLY

When a high-pressure oxygen source that is connected to an Oxygen Mixer is not available, the Ventway Sparrow ventilator can accept oxygen from a low-pressure oxygen source such as a oxygen enrichment kit connected to a flow meter.

To do this, use an optional low-pressure oxygen enrichment system attached to the ventilator air inlet port through an optional Ventway adapter.

Adjust the "O_2 coefficient" parameter on the device through the O_2 enrichment screen, which can be found under the **VENT. PARAMS** screen, so that the coefficient is aligned with the actual FiO_2 value given to the patient. Select the "O_2 ENRICHMENT" option in the **VENT. PARAMS** menu. **The FiO_2 value must be measured with a calibrated external oxygen analyzer.**

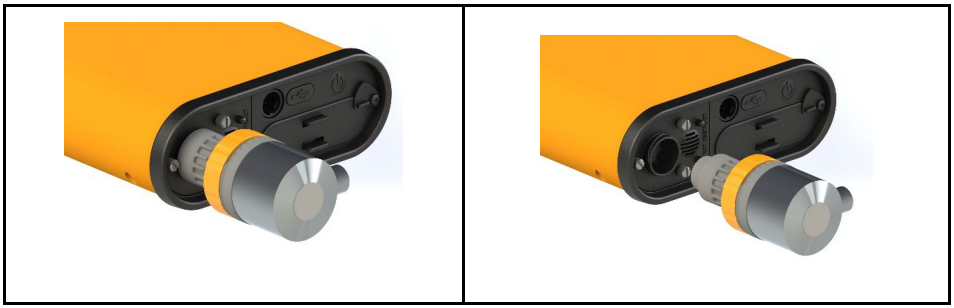
If a high-pressure oxygen source is available, an Inovytec-approved Oxygen Mixer can be used to connect to the air inlet port, delivering between 30% to 95% FiO_2 to the patient. **Measure FiO_2 with a calibrated external oxygen analyzer.**

The oxygen supply pressure shall be according to manufacturer specifications (usually 40-60 psi).

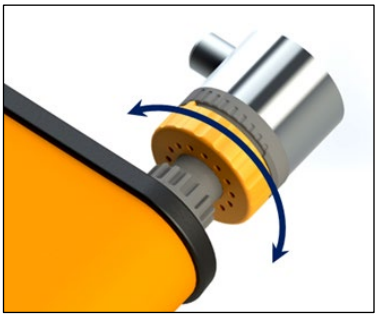
See Section *12.2.3 Additional recommended legally marketed components / accessories* for recommended legally marketed reservoirs.

12.2.1.1 CONNECTING THE AIR INLET TO THE OXYGEN MIXER

The Oxygen Mixer is connected to the device as shown below. The Oxygen Mixer connector is specially threaded to fit securely on top of the air/oxygen inlet.



Connecting the Oxygen Mixer to the air inlet connector



The Oxygen Mixer may be adjusted to mix atmospheric air and oxygen in ratios between 30% to 95%. The user may change the oxygen percentage of the gas mixture by rotating a knob at the base of the Oxygen Mixer.

The high pressure connection to the Oxygen Mixer should be performed using a standard female DISS connector.

12.2.2 RECOMMENDED DEVICES FOR MONITORING OF OXYGEN

Company Name	Product Model
Precision Medical	PM5900 Oxygen Monitor
Maxtec	$MaxO_2$ ME®
ENVITEC	MySign®O

Caution: Use of the low-pressure oxygen system at concentrations above 60% is NOT recommended, as higher values combined with varying minute volume due to spontaneous breathing of the patient may cause inadvertent PEEP.

Caution: Please read the manufacturer's instructions before using the oxygen monitoring device.

Caution: Oxygen enrichment delay time until reaching 95% oxygen at the patient port: 45 [S].

Caution: Measurement of oxygen should be performed using an external oxygen sensor. The location of the sensor should be at the outlet of the ventilator between the ventilator and the patient circuit.

12.2.3 ADDITIONAL RECOMMENDED LEGALLY MARKETED COMPONENTS / ACCESSORIES

Please use these recommended components / accessories or any other equivalents.

Component / Accessory	Company Name	Product Model
Antibacterial and HME filter	INTERSURGICAL, INC.	CLEAR-THERM MICRO HME, MODEL Mini 1831, Midi 1641, Angled & Plus 1541
Antibacterial and HME filter	INTERSURGICAL, INC.	Clear-Therm™ 3 HMEF with luer port and retainable cap , MODEL 1541000
Antibacterial and HME filter	INTERSURGICAL, INC.	Clear-Therm Mini HMEF with luer port, MODEL Mini 831000

12.3 ALARM DEFAULT PARAMETERS: 5 KG TO 70+ KG

Alarm Parameter	Ideal Body Weight								
	5kg	**10kg**	**15kg**	**20kg**	**30kg**	**40kg**	**50kg**	**60kg**	**70+ kg**
Pressure Alarm (cm H_2O)	21	23	25	30	30	30	30	30	30
Pressure Limit (cm H_2O)	25	28	30	35	35	35	35	35	35
High Rate (BPM)	45	40	35	30	30	30	30	25	25
Low Rate (BPM)	12	10	10	10	8	6	6	6	6
High Min. Vol. (LPM)	3.5	4.2	4.6	4.8	6.4	7.6	8.4	8.6	10.8
Low Min Vol. (LPM)	0.9	1	1.1	1.2	1.6	1.9	2.1	2.1	2.7

12.4 ALARM DEFAULT PARAMETERS: ALL PATIENT WEIGHTS

PEEP	> 2.5 cm H_2O from set value
Low pressure	5 cm H_2O
Leak (%) non invasive	100% (off)
Leak (%) invasive	25% default (adjustable)
Inverse I:E Ratio	ON
Low Tidal Volume Alarm Range	85% of set volume

13. LABELS AND SYMBOLS

13.1 LABELS

A number of internationally recognized symbols are found on the labels. These relate to safety requirements and standards and are described below.

Note: Labels are for reference only

VWSP-100 Civil Model

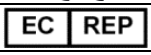
VWSP-900 Robust Model

VWSP-100MR Civil Model

VWSP-900 MR Robust Model

13.2 SYMBOLS

The following table explains the meaning of each symbol on the label.

Symbol	Meaning
	Consult instructions for use
	Manufacturer
	European approval mark
	Authorized representative in the European Community
	Serial Number
	Catalogue Number
	Batch code
	Direct current
	Do not dispose of, contact for recycling
	FCC Symbol
	Caution: Law prohibits dispensing without prescription
	Caution: Consult accompanying documents
	Type BF Applied Part
	MRI Symbol

14. CLEANING AND DISINFECTING

Caution: The system is approved for IP45 in operation mode with oxygen enrichment. To avoid damage to the instrument or patient cable, be careful of liquid spillage while cleaning.

Caution: Do not expose the instrument, patient cable or sensors to sprays, or any other type of solvents.

Caution: Be sure to turn the power off and disconnect the AC power cord from the power source before performing cleaning procedures.

This instrument requires routine cleaning, which includes removal of any soil or dirt from the external surfaces. A soft cloth dampened lightly with water may be used.

Spray the entire surface of the device with 70% alcohol.

Leave the alcohol on the device for an exposure time of 2-3 minutes.

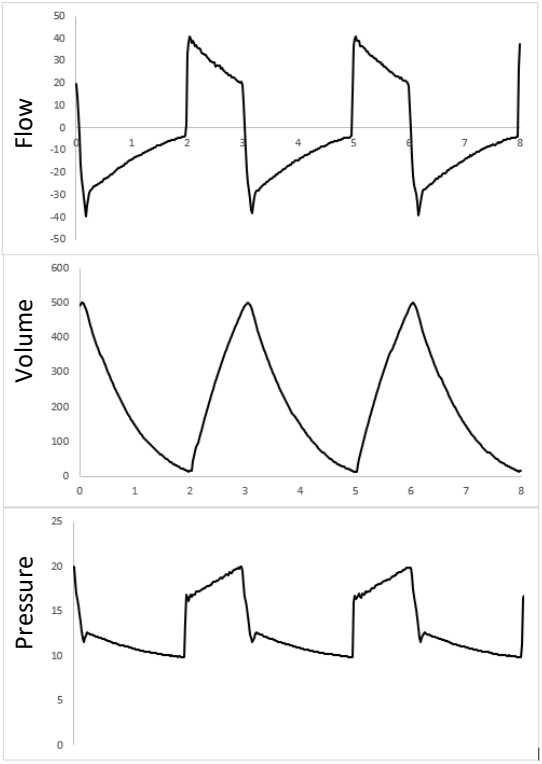
Wipe the surface of the device with Pharma-Wipes 70% alcohol.

Inspect the device for residual debris. Should any debris remain, repeat the entire cleaning procedure until all debris is removed.

15. VENTILATION METHODS

15.1 SIMV VC PS FLOW CHART

In SIMV-VC, the patient is supplied with the set tidal volume during the set inspiratory time at the set breath rate for mandatory breaths. The inspiratory flow waveform is variable, depending on ventilator settings and the load effect (ie, impedance of the lungs and chest wall and patient inspiratory effort) on the blower, but the mean inspiratory flow remains constant (at steady state) to provide VC. The ventilator makes minor changes in blower output between breaths to keep the tidal volume on target with varying load effects.



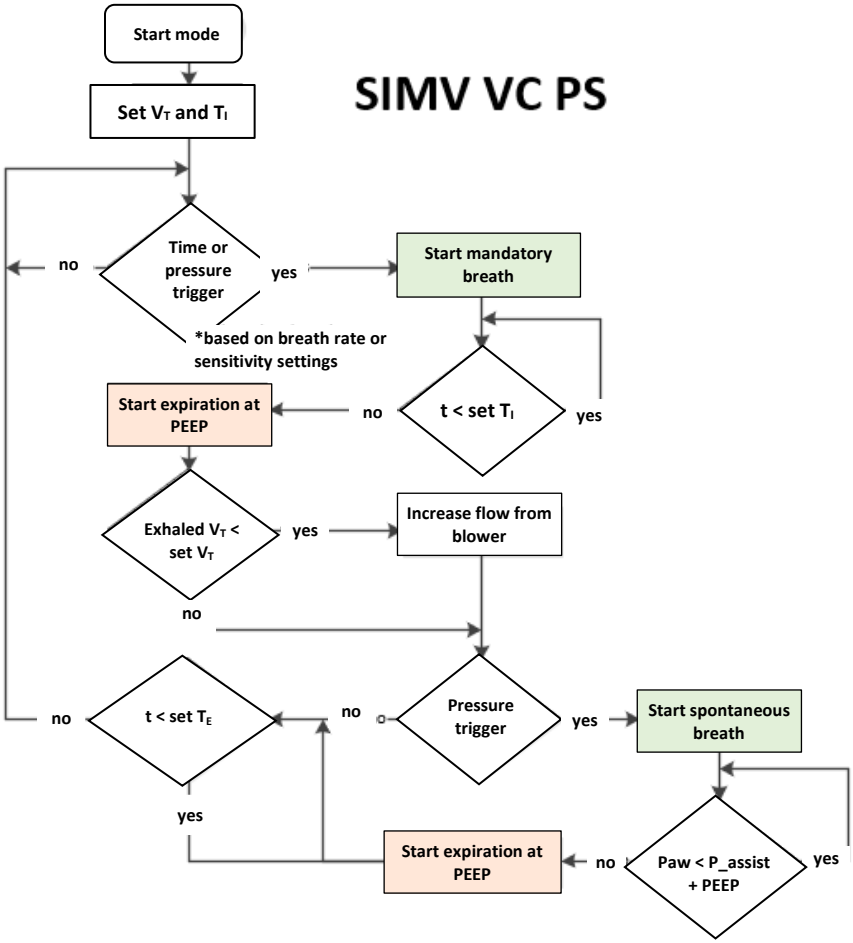
The triggering of mandatory breaths is synchronized with the patient's inspiratory efforts. A patient-triggered mandatory breath can only occur within a short trigger window prior to the scheduled machine trigger (according to the set mandatory breath rate). If the expiratory time between two mandatory breaths is shortened due to synchronization, the next expiratory period will be extended. This adaptation prevents a change in the set frequency of mandatory breaths. If no patient inspiratory effort is detected during the trigger window, the machine-triggered mandatory breaths are applied. Thus, the minute volume of mandatory breaths remains constant over time.

Patient triggered spontaneous breaths may occur outside the trigger window. Spontaneous breaths between mandatory breaths will be assisted if the Pressure Support level is set above zero.

Please note:

1. The default frequency of mandatory breaths is determined by the patient ideal body weight (more weight = less breaths/minute). BPM = mandatory breaths.
2. Mandatory breaths are volume controlled, meaning the tidal volume and inspiratory time are preset and airway pressure depends on lung mechanics (resistance, compliance and breathing effort).
3. Mandatory breaths are pressure or time triggered and time cycled. Spontaneous breaths are pressure triggered and flow cycled.
4. If no patient inspiratory effort is detected during the inspiratory trigger window, the machine-triggered mandatory breath is applied.

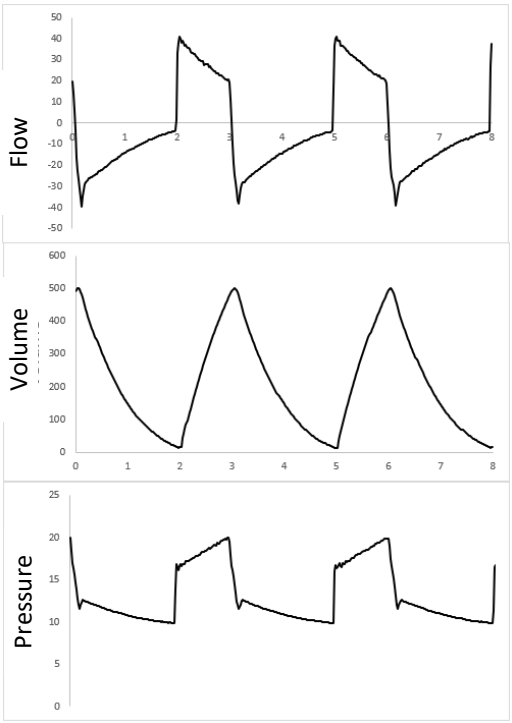
	**Note:** In non-invasive ventilation the ventilator is programmed to compensate for the loss of volume due to leaks from the facemask. Actual delivered tidal volume can only be interpolated, and is not displayed.
	**Note:** In this operation mode you will be required to enter patient ideal body weight and ventilation parameters will be set automatically according to section *12.1 Start Volume Ventilation*.



Note: Through the entire ventilation cycle, we need to test that:

- The patient is still connected (no decrease in PEEP pressure)
- Expiratory flow is undisturbed (pressure has decreased – nothing is blocking the ex. valve)
- Value of Ti/Te is OK (within the norm).

15.2 SIMV PC PS

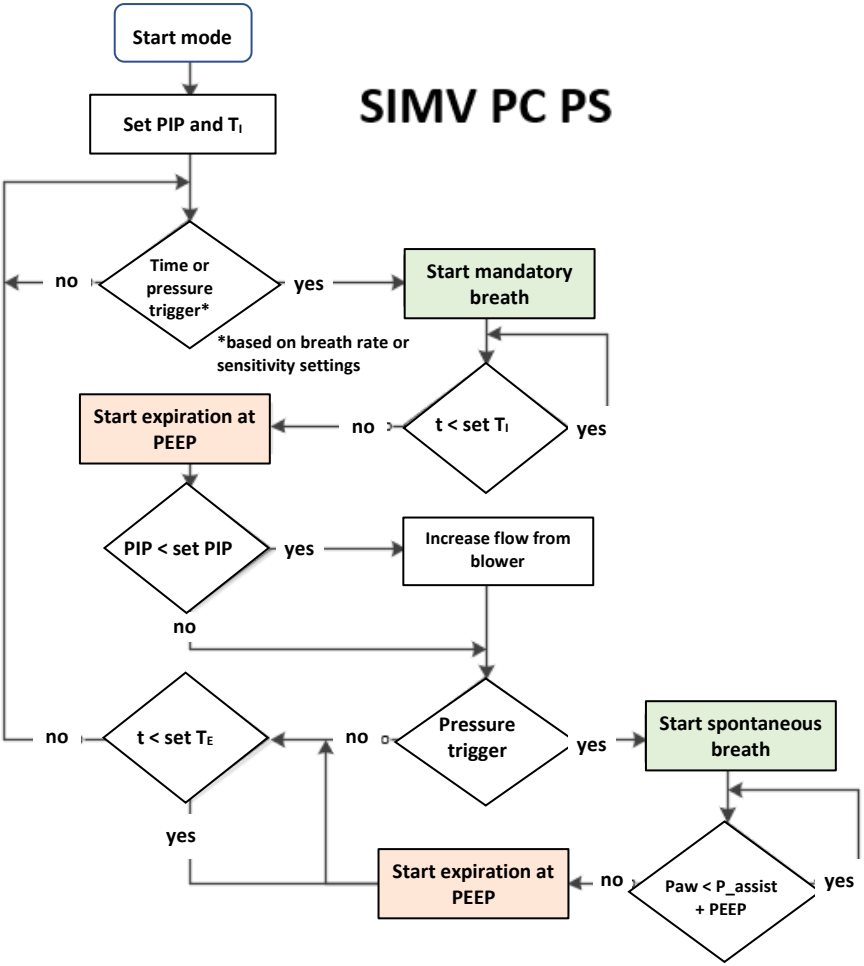


In SIMV-PC, the patient is supplied with the set inspiratory pressure during the set inspiratory time and breath rate for mandatory breaths. The inspiratory flow and tidal volume are variable, depending on ventilator settings and the load effect (i.e., impedance of the lungs and chest wall and patient inspiratory effort) on the blower, but the peak inspiratory pressure remains constant (at steady state) to provide PC.

The triggering of mandatory breaths is synchronized with the patient's inspiratory efforts. A patient-triggered mandatory breath can only occur within a short trigger window prior to the scheduled machine trigger (according to the set mandatory breath rate). If the expiration phase (and with it the spontaneous breathing time) is shortened on account of synchronization, the next expiration phase will be extended. This adaptation prevents a change in the set frequency of mandatory breaths. If no patient inspiratory effort is detected during the trigger window, the machine-triggered mandatory breaths are applied. Thus, the minute volume MV of mandatory breaths remains constant over time.

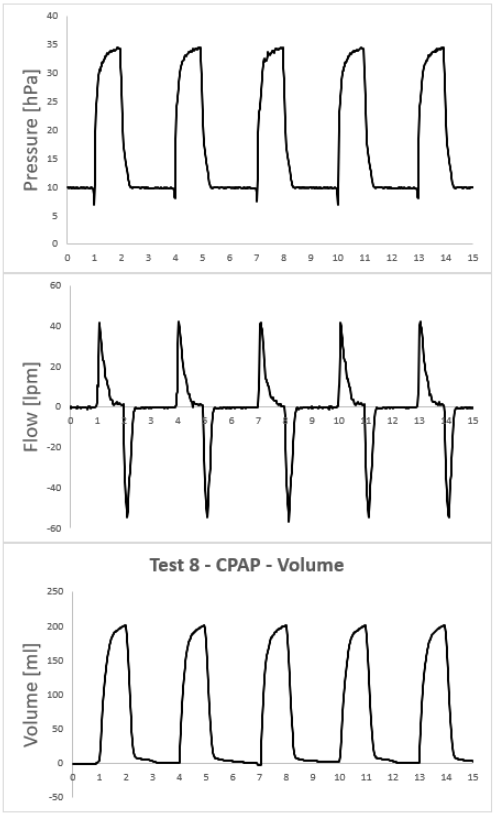
Patient triggered spontaneous breaths may occur outside the trigger window. Spontaneous breaths between mandatory breaths will be assisted if the Pressure Support level is set above zero. The default inspiratory pressure for spontaneous breaths is identical to the initial PIP value for mandatory breaths, and may be modified.

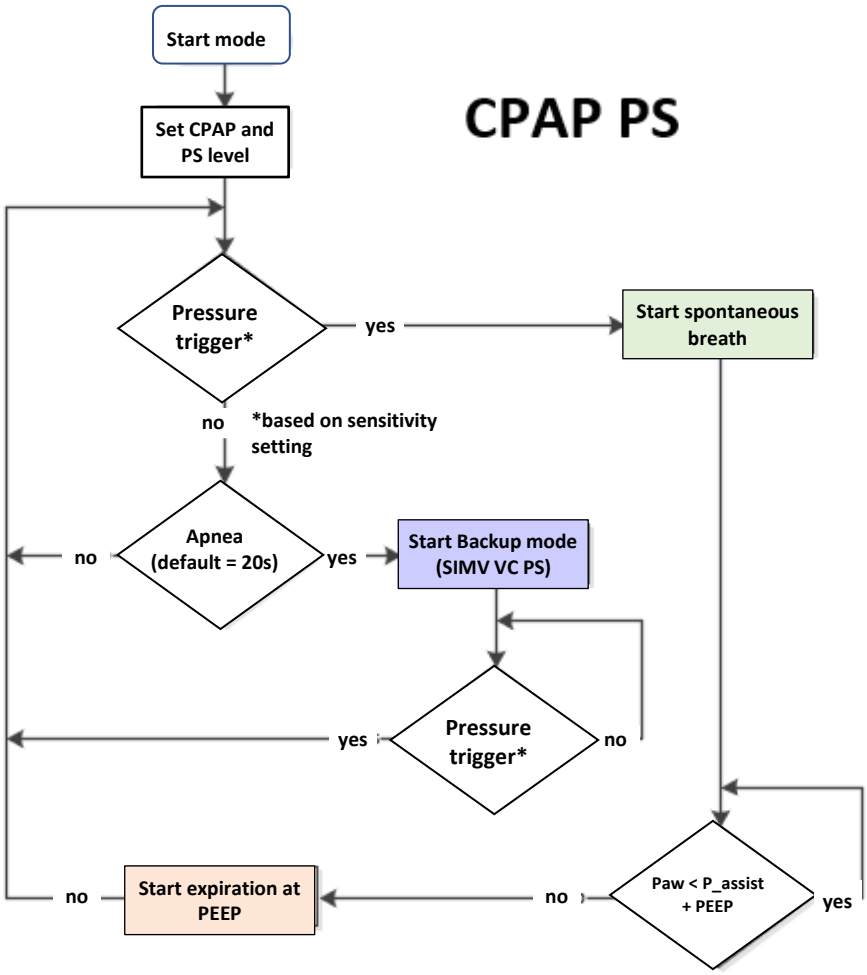
	Note: In this operation mode you will be required to enter patient ideal body weight and ventilation parameters will be set automatically according to section *12.2 Start pressure Ventilation.*



15.3 CPAP PS MODE

In CPAP PS, the ventilator attempts to maintain a stable baseline pressure and breaths are assisted with PSV at an inspiratory pressure of at least 5 cm H_2O (inspiratory pressure is adjustable from 5-50 cm H_2O). Spontaneous breaths are pressure triggered, pressure controlled, and flow cycled. The default inspiratory pressure level is 18 cm H_2O. In the event of apnea, the backup mode is SIMV VC PS.




CPAP PS
Start mode
Set CPAP and PS level
Pressure trigger*
yes
Start spontaneous breath
no
*based on sensitivity setting
Apnea (default = 20s)
no
yes
Start Backup mode (SIMV VC PS)
Pressure trigger*
yes
no
Paw < P_assist + PEEP
no
yes
Start expiration at PEEP
no

15.4 HIGH-FLOW NASAL CANNULA (HFNC)

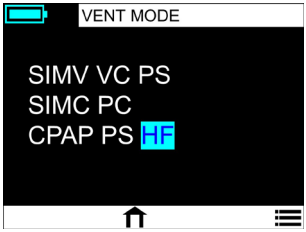
High-flow nasal cannula (HFNC) therapy is an oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a flow rate of up to 60 liters per minute. All settings are controlled independently allowing for greater confidence in the delivery of supplemental oxygen as well as better outcomes when used. In addition to greater control over the delivery of FiO2, there are several benefits to using a high-flow nasal cannula.

Note: This mode is not available in the US.

HFNC Configuration:

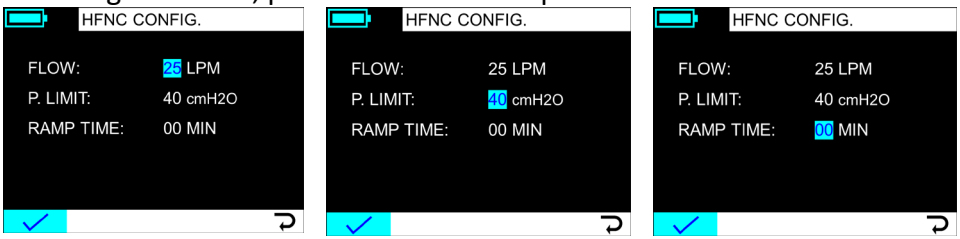
Flow	10 – 60 ± 1 lpm
Pressure Limit	20 – 60 cm H_2O
Ramp Time	0 – 20 min
FiO2	21 – 100 %

To select HFNC ventilation, select HF in Ventilation Mode screen:



Ventilation Mode screen

To change the flow, pressure limit or ramp time use the control knob:



HFNC configuration screen

15.5 BACKUP VENTILATION MODE

Backup mode is an alternative ventilation method taking place when the ventilator patient circuit is connected to the patient during CPAP ventilation, the patient stops initiating spontaneous breaths from more than 10 seconds for pediatric (5KG) and more than 25 seconds for an adult (70+ KG), an Apnea alarm appears.
The result of using this backup mode is that the patient will be ventilated in case of losing the ability to initiate spontaneous breaths in CPAP mode, or if an emergency or user error has occurred in the preliminary stages of ventilation setup, or when pausing the ventilator for some reason without resuming ventilation.

15.5.1 BACKUP VENTILATION IN CPAP

If during CPAP ventilation, the patient stops initiating spontaneous breaths from more than 10 seconds for pediatric (5KG) and more than 25 seconds for an adult (70+ KG), an Apnea alarm appears.

Then backup ventilation is initiated:

The screen displays an alarm: "Apnea Detected" and the "OK" button for user approval appears. Ventilation will start even if user has not pressed **OK**. Alarm will appear on the screen while audio prompt is activated.

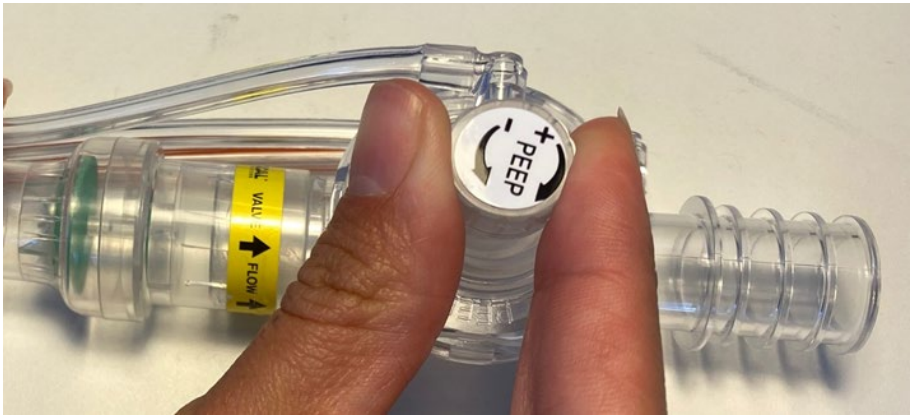
- Volume, Pressure, MV and all other alarms which are patient weight-based remain unchanged.
- Ventilation method is changed to SIMV - VC - PS with the last patient weight parameters dialed in.
- BPM value is patient weight-based.
- Resuming to CPAP ventilation will be possible either by patient trigger, or user switching back to CPAP or SIMV - VC - PS manually, through the "MENU" option on the main screen.
- All alarms and user inputs will be logged in logbook.
- An alarm is issued "Backup ventilation active" -- "OK".

15.6 SETTING THE PEEP VALUE

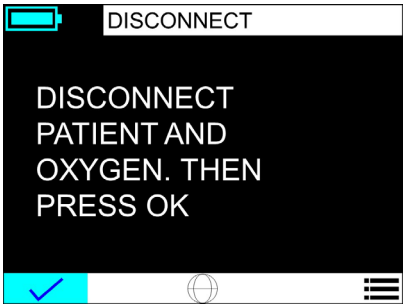
When setting the PEEP value, make sure that there are no kinks in the three tubes:

Tubes are free of kinks

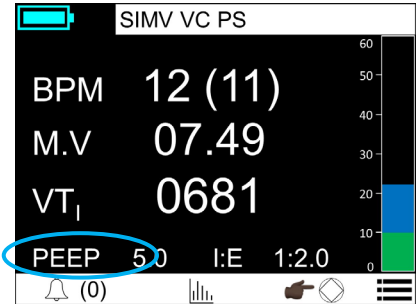
The PEEP value will be preset to 5 millibar, but this must be verified by the value shown on the ventilator screen (see final display below).



Follow the on-screen instructions and press OK:



Note that the PEEP value will appear on the display:



Caution: PEEP value may be influenced by the oxygen enrichment method in extreme cases when ventilation operation is stopped and re-started.

For example, if we connect an Oxygen Mixer for O_2 enrichment, the PEEP may decrease at 3-4 cm H_2O. Although the ventilator will issue an alarm, the user may have to readjust the PEEP by rotating the PEEP knob.

16. SERVICE AND MAINTENANCE

Note: The user or any technical personnel who are not formally authorized by Inovytec Medical Solutions Ltd. must not open the Ventway Sparrow device under any circumstances. Opening the Ventway Sparrow device may damage the unit and will void the warranty provided by Inovytec Medical Solutions Ltd.

The system requires maintenance on a routine basis in accordance with Ventway Sparrow Service Manual.

Service should only be provided by an authorized Inovytec Medical Solutions Ltd. representative.

17.1. TROUBLESHOOTING

The following table lists some typical conditions that may occur when using the system.

Condition	Possible Cause	Recommended Action
Battery disconnected	Not inserted properly	Firmly insert battery in its place
DC connector connected and no sign of charging	Power supply not connected to power source or DC connector	Check connection to ventilator and power source
Patient circuit verification failed	Accessories or patient connected, control tube connector disconnected	Check patient circuit connections

18. SPECIFICATIONS

18.1 1.1. DIMENSIONS AND WEIGHT

Dimension	Measurement
Width	165 mm
Length	167 mm
Height	60 mm
Weight	Civilian version: 1 kg with batteries
	Robust version: 1.3 kg with batteries
	MR version: 1.3 kg with batteries

18.2 1.2. ENVIRONMENTAL SPECIFICATIONS

Operating Temperature	-18 °C to 50 °C (0°F to 122 °F)
Storage Temperature	-40 °C to 70 °C (-40 °F to 158 °F)
Relative Humidity	10% to 90%
Water and Dust Resistance	IP45 (with oxygen enrichment) IP20 (when using power supply) **Note:** First digit (“4” In IP45, or “2” in IP20) relates to object size protection (<1 mm). Second digit (“5” in IP45 or “0” in IP20) indicates protection from water jets from any direction.
Atmospheric Pressure	376 hPa to 1060 hPa
Altitude	-370 to 7620 meters (-1,200 to 25,000 feet)
Total External Sound Level	54 dBa at 0.6 meter distance
Max acoustic energy level	55 [dBa]

18.3 HARSH ENVIRONMENTAL CONDITIONS

The Ventway Sparrow is designed to operate in extreme environments, such as ground and transport. The Ventilator continuously monitors the ambient pressure, temperature and other parameters, and compensates for these changes.

Although the unit may activate a low priority alarm that indicates exceeding regular operation conditions, please remember that these alarms are advisory, and the unit will continue to operate normally.

18.3.1 OPERATION IN EXTREME HIGH / LOW TEMPERATURES

During high temperature operation, the ventilator may prompt an alarm regarding its high temperature charge limit. The battery protection circuit will stop charging below 0°C and over 50°C, as measured inside the battery pack.

Normal ventilator operation may create heat in the battery compartment. When operating in a hot environment you should remove the ventilator padded case, increasing heat dissipation into the environment.

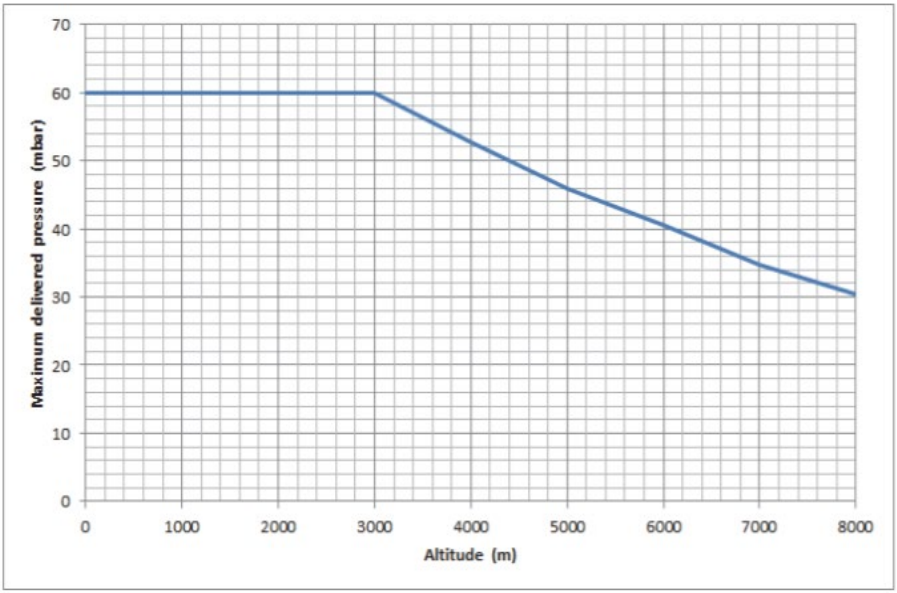
During low temperature operation, it is recommended to use the ventilator padded case. This will insulate the unit from the outside temperature and retain the internal heat created by the blower motor and other electrical heat-generating components.

18.3.2 OPERATION IN HIGH OR LOW ALTITUDE

The Ventway Sparrow is designed to operate at an altitude of -370 to 7620 meters (-1,200 to 25,000 feet). An internal altimeter measures the ambient pressure, allowing the ventilator to compensate the flow calculations for the changes in density and pressure.

If the operation altitude is outside of the specified values, a low priority alarm will be activated. In this case the user should monitor the Peak Inspiratory Pressure (PIP) and adjust the tidal volume so the same PIP is achieved. It is also advised to monitor the breathing sounds and chest excursion to assure the unit maintains adequate ventilation.

Note that at higher altitudes the ventilator performance may be limited. If set pressure is not reached, a “LOW PRESSURE” alarm will be activated.



Altitude vs. Maximum Pressure possible

18.3.3 AIRBORNE PARTICULATES

The inlet filter of the Ventway Sparrow provides protection of gas flow paths through the inlet and emergency intake ports. However, in areas where fine dust is present, it is recommended to use a disposable bacterial/viral filter.

This may prolong the lifetime of the internal filter. Visually inspect the filter for dust and dirt buildup for extended operation in dusty environments.

If the filter becomes dirty, it must be replaced. Circuit Verification Test (CVT) must be performed without the filter attached to the ventilator, since it may cause a pressure drop that will result in not passing the test.

18.4 POWER SUPPLY

External AC-DC Adapter	Input 100 to 264 VAC, 50-60 Hz, max 1.6 A Output 24 VDC, 120 W
Internal Battery	8 x CR123 cells for 12VDC configuration (2 x 4S1P)
	4 x 18650 Li-Ion for 14.8 VDC rechargeable configuration (4S1P)
Recharge Time	4 hours
Operating Time (internal battery)	4 hours

Note: The time required for the ventilator to warm up from the minimum storage temperature between uses until it is ready for intended use, is 20 minutes in standard temperature and pressure conditions.

Note: The time required for the ventilator to cool down from the maximum storage temperature between uses until it is ready for intended use, is 30 minutes.

18.5 VENTILATION PERFORMANCE

Note: If temperature exceeds 85°C, a temperature alarm may be activated. This may result in breath parameters inaccuracies that exceed the tolerances specified below.

Note: If humidity exceeds 95% and condensation occurs, it may lead to water droplet buildup in the sensing tubes.

Note: If the ventilator is exposed to altitudes outside of the defined values, the ventilator may be unable to accurately compensate for volume and pressure deviations.

Respiratory Rate	1 – 60 ± 1 bpm
Tidal Volume	50-2000 mL ±10% + 4 mL
Inspiratory Pressure Limit	11 to 60 cm H_2O ± 2 cm H_2O or 10% whichever is greater
Inspiratory Time	0.3 to 4 ± 10% sec
I:E Ratio	1:4 to 4:1
Peak Flow (PIF)	Mandatory breaths: 135 L/min (-5% to +10%) Spontaneous breaths: 160 L/min ± 10%
Oxygen Mix (FiO_2)	21% to 95% ± 5% O_2
PEEP	0 to 20 cm H_2O ± 1, (externally adjusted)
Trigger Sensitivity	-0.25 to -10 cm H_2O Pressure, Off
Pressure Support Limit	11 to 50 cm H_2O above PEEP ± 2 cm H_2O
Pressure Alarm Limit	10 to 55 cm H_2O above PEEP ± 2 cm H_2O
FiO_2 low pressure enrichment	21% to 100% (low and high pressure oxygen source)

18.6 STANDARDS AND SAFETY REQUIREMENTS

The Ventway Sparrow meets the requirements of the following international standards:

IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
IEC 60601-1-12	Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
ISO 80601-2-12	Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 10651-3	Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators
EN 794-3	Lung ventilators. Particular requirements for emergency and transport ventilators
AIM 7351731	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
RTCA DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment - Rotary wing aircrafts – Helicopters
EN 1789	Medical vehicles and their equipment. Road ambulances
MIL-STD-810G	Department of defense test method standard: Environmental engineering considerations and laboratory tests
MIL-STD-461G	Department of defense interface standard: Requirements for the control of electromagnetic interference characteristics of subsystems and equipment

MIL-STD-1275	Department of defense interface standard: Characteristics of 28 volt DC input power to utilization equipment in military vehicles
ASTM F2119 - 3 Tesla	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

18.7 CLEANING AND ROUTINE MAINTENANCE

Part	Procedure	Comments
Ventilator	1. Spray entire surface with 70% Alcohol 2. Do not wipe device for 1 min. 3. Wipe device with pharma wipes 70% alcohol	Do not allow liquid to penetrate into the ventilator. Inspect for residual debris.
Air Inlet Filter	Replace every 300 hours (or 1 month) of operation, or as necessary.	Do not attempt to clean or reuse the air inlet filter.

19. BATTERIES

The Sparrow can be configured with two battery options: an internal, re-chargeable battery pack, and an internal non-rechargeable battery pack. The battery should be charged or replaced when not in use. For long storage periods, the battery should not be inserted into the battery compartment of the ventilator. It is possible to switch between these two battery options.

19.1 BATTERY MAINTENANCE

Rechargeable batteries

The internal battery pack is charged from the external device connector, using the supplied 18-24 volt regulated power supply.

Caution: If the batteries do not charge, replace the charger or the batteries.

Caution: Battery failure may occur if maintenance is not performed on time and according to instructions.

Note: If charging at temperatures over 35°C (95°F), charging time may be extended, and battery thermal protection may be activated preventing the battery charge.

Shelf life: 4 years. First time charging: 6 hours.
Permissible battery pack charging temperature range: 0°C to 50°C (32°F to 122°F)
Permissible temperature range for long-term storage: 10°C to 35°C (50°F to 95°F)
Charge Interval: 6 months in standard temperature and pressure
Shelf life: 4 years or 500 cycles at 25°C (77°F). A cycle is defined as one charge and one discharge.
Max discharge current: 8.25[A]
Storage temperature for shipping state (about 40% capacity of fully charged state):

1 month	45°C to 60°C (113°F to 140°F)
3 month	-25°C to 45°C (-13°F to 113°F)
1 year	-20°C to 25°C (-4°F to 77°F)

Non-Rechargeable batteries

Shelf life: 5 years. Long term storage: -20°C to 35°C (-4°F to 95°F)

20. PARTS AND ACCESSORIES

This section outlines information for ordering and shipment of replacement parts for the Ventway Sparrow.

Main Accessories:

Part Number	Description
Inlet Filter	VWSP-810
Patient Circuit Adult / Pediatric	VWSP-450F / VWSP-550F
Oxygen Mixer	VWSP-580
Rechargeable Battery	VWSP-420
Non-Rechargeable Battery	VWSP-430
Oxygen Enrichment Kit	VWSP-304

User supplied component: Legally marketed Nonrebreathing Valve 22mm O.D. inlet x 22mm I.D. outlet, resistance < 0.5 cmH2O both for adult and pediatric circuits.

All equipment and accessories are available directly from Inovytec Medical Solutions Ltd. or from an authorized local distributor. For a Inovytec Medical Solutions Ltd. local distributor please contact Inovytec email as specified below.

When ordering parts, specify the part number of the item(s) ordered. For the Equipment and Accessory list, see our website as specified below.

Forward orders to:

Inovytec Medical Solutions Ltd.
5 HaTidhar St.,
Raanana 4366507, Israel
Tel: +972 9 965 64 70
Fax: +972 9 965 64 79
E-mail: Info@Inovytec.com;
Web Site: http://www.Inovytec.com

Caution: It is strongly recommended that all Ventway Sparrow parts be replaced with parts purchased from Inovytec Medical Solutions Ltd. or an authorized distributor. Use of other parts may damage the unit and could void the unit warranty.

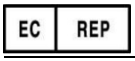
Note: Dispose of this device and of used sensors in accordance with local regulations.

21. REGULATORY

 Manufacturer:

Inovytec Medical Solutions Ltd.
5 HaTidhar St.,
Raanana 4366507, Israel
Tel: +972 9 965 64 70
Fax: +972 9 965 64 79

E-mail: Info@Inovytec.com
Web Site: http://www.Inovytec.com

 Européen Agent Information:

OBELIS S.A.
Bd Général Wahis, 53

B-1030 Brussels
Belgium
Telephone +3227325954
Fax: +3227326003
E-mail: mail@obelis.net
Website www.obelis.net

22. WARRANTY

Service Support

Repairs of the System under warranty must be made by authorized repair centers. If the device needs repair, contact Inovytec Medical Solutions Ltd. service department or your local distributor.

If shipping the device is required, pack the device and its accessories carefully to prevent shipping damage.

Duration

Inovytec Medical Solutions Ltd. will repair or replace, at its sole discretion, the product or any defective part, provided it is returned to Inovytec Medical Solutions Ltd. service within 30 days.

23. APPENDIX – TEST ALARMS

The following instructions explain how to test all the alarms that can be activated by the system, to ensure that they are working properly.

23.1 CPAP VENTILATION WITH BACKUP VENTILATION

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then CPAP ventilation mode.	Mode is set. The blower starts. The software switches to running ventilation, in CPAP mode.
CPAP – Apnea		
3	Wait for the apnea timer to run out.	The software switches to SIMV mode, backup mode is indicated.
2	Wait for the next exhalation phase and for pressure to reach PEEP value. Wait until the time has passed.	The software switches to inhalation phase: Inspiratory control valve opens and exhalation valve closes.
3	Allow for a few breaths cycles.	The software switches between phases, using SIMV ventilation mode.
4	Wait for the next exhalation phase and for pressure to reach PEEP value. After more than *Configurable delay of trigger window* time has passed after PEEP reached, generate inhalation trigger.	Trigger is detected & inhalation phase starts (control valve opens and exhalation valve closes). The software switches back to CPAP normal mode.

23.2 PATIENT DISCONNECT

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then CPAP ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in CPAP mode.
3	Disconnect patient circuit from lung	The software displays: “Patient disconnection”.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
5	Select to view active alarms via the menu.	Patient Disconnection alarm is shown.

23.3 HIGH PEEP

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Go to menu -> alarm settings, change PEEP to 5 (this appears in the second page of the alarm settings). Go back to run screen.	See the run screen.

Step	Procedure Action	Expected Results
4	Increase PEEP above the limit. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the PEEP rises to about 10 on the run screen
5	Wait a few seconds	See that a "high peep" warning pops-up, with an option to cancel and to confirm.
6	Press cancel	See that the pop-up disappears.
7	Select to view active alarms via the menu.	Alarm is shown.
8	Decrease PEEP. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the PEEP decreases to about 5 on the run screen
9	Select to view active alarms via the menu.	Alarm is not shown.
10	Increase PEEP above the limit. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the PEEP rises to about 10 on the run screen
11	Wait a few seconds	See that a "high peep" warning pops-up, with an option to cancel and to confirm.
12	Press confirm	See that the pop-up disappears and that the alarm disappears from the alarms screen.
13	Select to view active alarms via the menu.	Alarm is not shown.
14	Go to menu -> alarm settings, look at the PEEP setting in the second page	See that the PEEP setting changed to 10.

23.4 LOW PEEP

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Go to menu -> alarm settings, change PEEP to 10 (this appears in the second page of the alarm settings). Go back to run screen.	See the run screen.
4	Decrease PEEP below the limit. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the peep drops to about 5 on the run screen
5	Wait a few seconds	See that a “low peep” warning pops-up, with an option to cancel and to confirm.
6	Press cancel	See that the pop-up disappears.
7	Select to view active alarms via the menu.	Alarm is shown.
8	Increase PEEP. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the PEEP rises to about 10 on the run screen
9	Select to view active alarms via the menu.	Alarm is not shown.
10	Decrease PEEP below the limit. See Section *15.6 Setting the PEEP Value* for instructions for setting the PEEP.	See that the PEEP drops to about 5 on the run screen
11	Wait a few seconds	See that a “low peep” warning pops-up, with an option to cancel and to confirm.

Step	Procedure Action	Expected Results
12	Press confirm	See that the pop-up disappears and that the alarm disappears from the alarms screen.
13	Select to view active alarms via the menu.	Alarm is not shown.
14	Go to menu -> alarm settings, look at the PEEP setting in the second page	See that the PEEP setting changed to 5.

23.5 VALVE BLOCKED

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease the expiratory flow (block expiratory valve from all directions tightly).	The software displays: “valve blocked”.
4	Increase flow back to normal.	The alarm disappears.
5	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
6	Select to view active alarms via the menu.	Alarm is shown.

23.6 PRESSURE ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease the inspiratory pressure under the min inspiration alarm settings.	The software displays: “Low Pressure”.
4	Increase pressure back to normal.	The alarm disappears.
5	Slowly increase the inspiratory pressure above the max inspiration alarm settings.	The software displays: “High Pressure”. **Caution:** The interval from the moment that the airway pressure equals the high-pressure alarm limit, to the moment that the pressure starts to decline, must not exceed 80 ms.
6	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
7	Select to view active alarms via the menu.	Alarm is shown.

23.7 MINUTE VOLUME (MV) ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease MV under the min MV alarm settings.	The software displays: “MV Alarm”.
4	Increase pressure back to normal.	The alarm disappears.
5	Slowly increase MV above the max MV alarm settings.	The software displays: “MV Alarm”.
6	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
7	Select to view active alarms via the menu.	Alarm is shown.

23.8 LEAK ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly increase a leak in the ventilation.	After a short pause, the software displays: “Leak Alarm”.
4	Close the leak.	The alarm disappears.

23.9 TIDAL VOLUME ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease the Tidal volume (TV) to 70%, By not allowing the lung to fill up.	When TV is below 80%, the software displays: “Low Tidal Volume Alarm”.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
5	Increase TV above 80%.	The alarm disappears.
6	Change settings to disable TV. (Go to alarms settings second screen and change the low TVe value to “--”).	TV is disabled.
7	Slowly decrease the Tidal volume (TV) to 50%, By not allowing the lung to fill up.	Alarm is not set.

23.10 I:E ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Change the I:E ratio to be below 1. (cause a lot of consecutive triggers, so that after a few breaths the average of the inhalation length is longer than the average of the exhalation length)	The software displays: “I:E Alarm”.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
5	Change the settings to disable I:E Alarm.	I:E alarm is off.
6	Change the I:E ratio to be below 1, (cause a lot of consecutive triggers, so that after a few breaths the average of the inhalation length is longer than the average of the exhalation length)	The software doesn’t issue an alarm.

23.11 APNEA ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then CPAP ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in CPAP mode.
3	Wait without generating inhalation triggers.	After the set time for Apnea alarm, the software displays: “Apnea Alarm” and switches to backup ventilation mode.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
5	Select to view active alarms via the menu.	Alarm is shown.

23.12 POWER ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Disconnect the ventilator from the power.	The software indicates Power is disconnected.
4	Inspect the battery level.	Battery level is indicated to the user.
5	Reconnect the ventilator to power.	The software indicates Power is connected.

23.13 LOW BATTERY ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Wait until the battery level reaches *Critically Low Battery* level.	The software indicates *Critically Low Battery* level.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.

23.14 BATTERY TYPE ALARM

Step	Procedure Action	Expected Results
1	Disconnect AC power and insert a rechargeable battery. Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Inspect battery icon.	Battery icon is of rechargeable battery, disconnected from power.
4	Reconnect AC power.	Battery icon is of rechargeable battery, connected to power.
5	Replace the battery to non-rechargeable. Disconnect from power. Inspect the icon.	Battery icon is of regular battery, disconnected from power.
6	Reconnect the AC power.	Battery icon is of regular battery, connected to power.

23.15 VOLTAGE ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Connect the ventilator to the AC power, with voltage that is below *Voltage Range*.	The software stops indicating an AC power connection and switches to battery power.
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.

23.16 TEMPERATURE ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Simulate a device temperature above *Max Allowed Temperature*.	The software indicates that the temperature is above range (above 80 degrees).
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.

23.17 TUBE DISCONNECT ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Wait 3 breaths.	Run screen keeps running.
4	Disconnect the tube.	The software indicates that the tube is disconnected.
5	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.

23.18 ALTITUDE CHANGE ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Simulate altitude below *Altitude Range*.	The software indicates that the device is out of altitude range (lower than -381 meters).
4	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.
5	Simulate altitude above *Altitude Range*.	The software indicates that the device is out of altitude range (higher than 4572 meters).
6	Silence the alarm.	Alarm indication on the screen, but alarm is silenced.

23.19 SHUTDOWN ALARM

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Shut the device down by a long press on the on/off button.	There will be a recurring quick beeping tone while the button is 4pressed. The software requires confirmation for shutting down.
4	The device starts playing a tone until an extra confirmation is given.	The device shuts down.

23.20 VENTILATION DURING STANDBY (DUE TO PATIENT INSPIRATORY EFFORT)

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 60 kg. Select 60 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Put the device in standby by stopping the ventilation in the menu screen.	The blower stops.
4	Generate 3 inhalation triggers.	The blower starts. The software switches to the running ventilation screen, continuing the previous ventilation with the same parameters.

23.21 START-UP DURING VENTILATION

Step	Procedure Action	Expected Results
1	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
2	Set the simulator to the patient weight of 70 kg. Select 70 kg and then SIMV ventilation mode, Invasive/Non-Invasive, and confirm the patient connection.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Change the desired BPM in the run screen to 13	The ventilator starts ventilating 13 breaths per minute.
4	Change the desired Volume to 500cc.	The ventilator starts ventilating in 500cc breaths.
5	Enter the Menu -> Alarm settings	The screen title should be “ALARMS(1/2)”
6	Change all the alarm settings in both alarms settings screens.	All alarm settings are changed.
7	While ventilating, disconnect the external charger and remove the battery.	The ventilator turned off.
8	Reconnect the external charger within 2 minutes and turn the ventilator on.	The ventilator should notify “unexpected shutoff” and continue ventilating using the previous settings.
9	Check and see that all settings are the same as before the restart.	All settings should be the same as before the restart.
10	Disconnect the charger.	The ventilator should turn off.
11	Wait longer than 2 minutes, reconnect the charger and turn the ventilator on.	The ventilator should show a message for an “unexpected shutoff” and give the option to continue ventilating.
12	Select Ok	The ventilator should continue ventilating using previous settings.

Step	Procedure Action	Expected Results
13	Enter Menu -> Adv. Settings and press “Load default”.	A warning saying “Reset to default settings” should appear
14	Press ok	The warning popup should disappear
15	Go back to the alarm settings screens and see that all the values are back to the default values.	All the values should be the default values.
16	Enter the menu and press “stop vent”.	The ventilator should stop ventilating.
17	Disconnect the charger.	The ventilator should turn off.
18	Reconnect the charger and turn the ventilator on.	The ventilator should show a message for an “unexpected shutoff” without giving the option to continue ventilation.

23.22 MISCELLANEOUS ALARMS

There are two alarms which can only be tested by running the Ventway in a ventilation situation for many hours:

1) After every 300 hours of work, an alarm will pop-up with the following message “replace inlet filter”, along with two options, OK or Cancel.

   If “Cancel” is chosen the message will pop up again when the Ventway is restarted or if 24 hours have passed since “Cancel” was last chosen.

   If “OK” is chosen the message will disappear until another 300 hours of ventilation have passed.

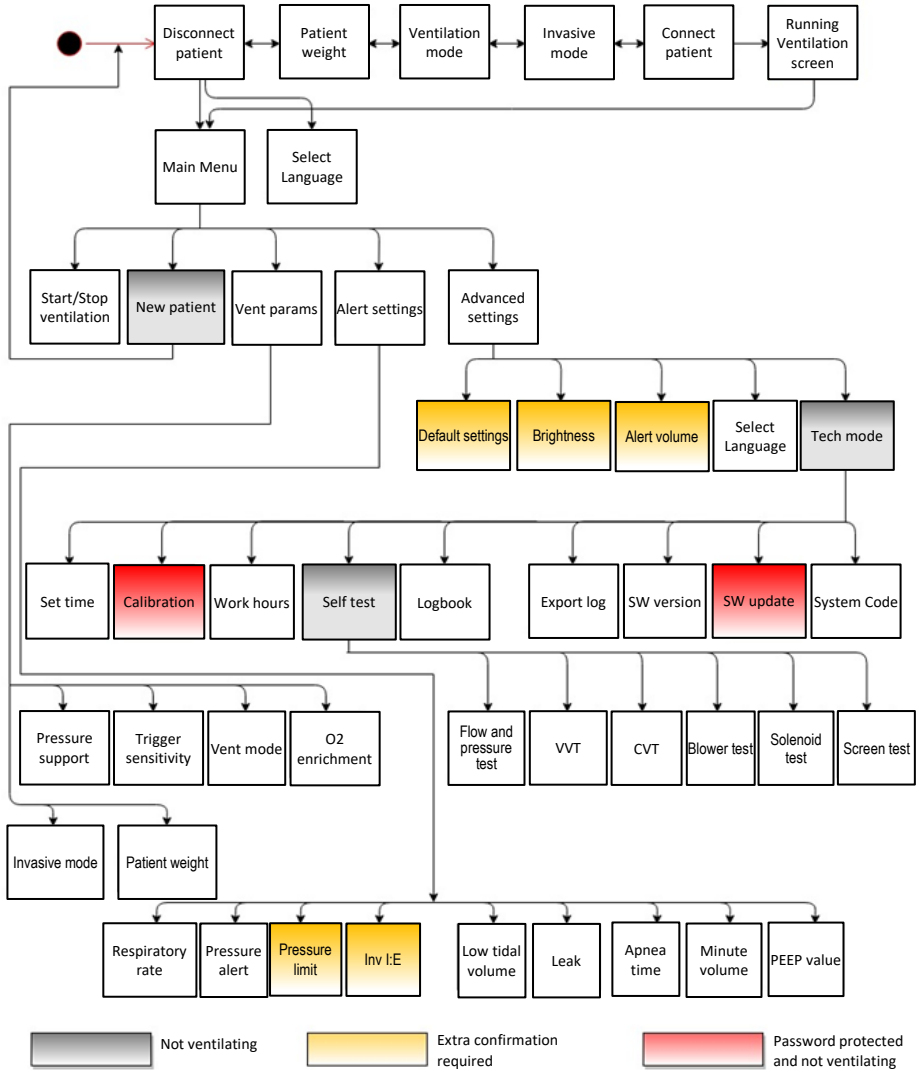
Caution: This alarm is intended for the user in order to change the filter. **Do not ignore this message. Do not press “OK” until the filter has been changed.**

2) After 15,000 hours of work, an alarm will pop up with the following message: “service needed”.

Caution: This alarm is intended for the user in order to send the Ventway back to the vendor in order to be serviced. **Do not ignore this message.**

24. APPENDIX – MENU HIERARCHY

The diagram below shows all the menus in the Ventway Sparrow system.



Ventway Sparrow menu hierarchy