User Manual

Ventway Sparrow

Emergency and transport
ventilator

VWSP-100 Civil Model

VWSP-900 Military Model

INOVYTEC

THE POWER TO SAVE LIVES

Document Number VWSP-500-06 May 2019

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.

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Contact Information:

Inovytec Medical Solutions Ltd.
3 Hanagar St., POB 7282,
Hod-Hasharon 4501306, Israel
Tel: +972 9 779 41 35
Fax: +972 9 779 41 38
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.

Contents

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 sales@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 sales@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

Apnea	**Temporary cessation of breathing**
BPM	Breaths Per Minute
CPAP	Continuous Positive Airway Pressure
lpm	Liters per minute
Mandatory Breath	Ventilator initiated breath
MV	Minute Volume
NIV	Non-Invasive Ventilation
PC	Pressure Control
Peak Flow	Maximum volumetric flow
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
Pressure support	Preset pressure delivered to the patient, on top of the PEEP, during triggered breath
PSV	Pressure Support Ventilation
SIMV VC PS	Synchronized Intermittent Mechanical Ventilation with Volume Control and Pressure Support
T_e	Expiratory Time
T_i	Inspiratory Time
Tidal Volume	Normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied
Triggered breath	Patient initiated breath
TV_e	Expired Tidal volume
TV_i	Inspired Tidal volume

2. OVERVIEW OF SYSTEM

2.1. DESCRIPTION OF DEVICE

The Ventway is a portable ventilator, used for transport in prehospital, field hospital, and hospital settings as well as EMS and military applications.

Ventway is easy to set up, self-sufficient and lightweight, allowing the patient to be moved quickly while maintaining quality ventilation.

The ventilator is suitable for non-invasive ventilation for a full non-vented ventilation face mask or Invasive ventilation via an endotracheal tube, tracheostomy and laryngeal mask airway (LMA).

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

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), CPAP.

The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for Invasive or non-invasive ventilation presets. 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 alerting in these cases.

Note: The use of 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 unit has Class B compliance.

4.3. SAFETY INSTRUCTIONS

Warnings

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

DO NOT USE BEFORE READING THIS USER MANUAL.

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.**

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

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.

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 24 hours of continuous use.
- 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 demand valve, the oxygen enrichment level will reach a minimum of 95%.
    - When using reservoir bag, the oxygen enrichment level may vary depending on oxygen flow rate.
- 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.

Cautions

- 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 classified as Class IIb, 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.
- 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, tracheostomy and laryngeal mask airway (LMA).

Cautions

- During NIV (Non-Invasive Ventilation) the user should use a capnograph in order to monitor the CO2 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.
- 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.

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

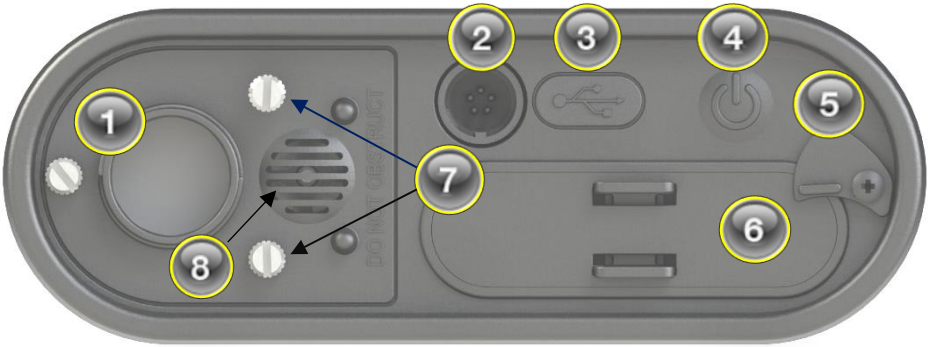
Package contents

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 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 is recommended to be placed in a horizontal position.

5.4. PATIENT CIRCUIT

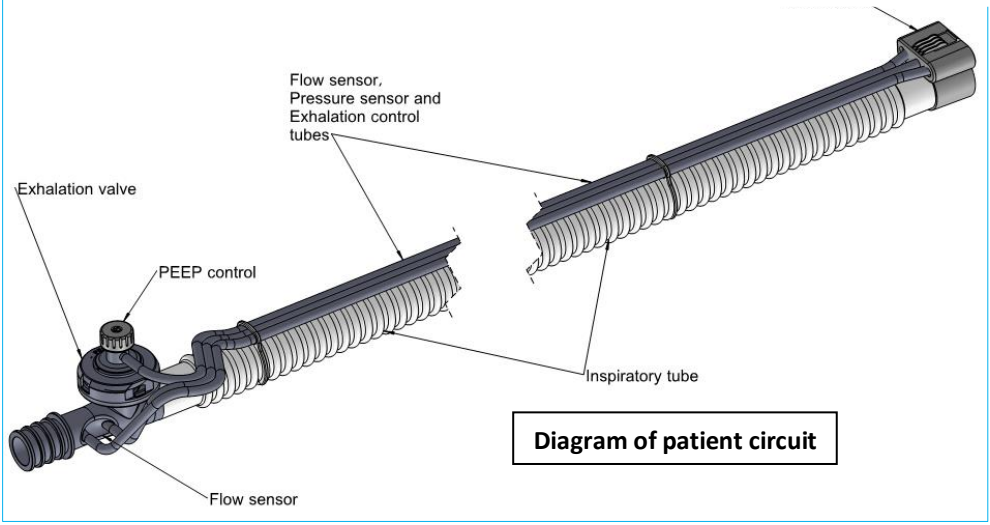


Diagram of patient circuit

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 cmH2O @ 60 lpm	5.4 cmH2O @ 30 lpm
Dead space	17 cc	16.5 cc
Circuit compliance	0.001 L/cmH2O	0.008 L/cmH2O
Corrugated tube diameter	22 mm	15 mm
Delivered tidal volumes	100 - 2000 cc	50 - 250 cc
Exhalation valve cap and knob color	Transparent	Blue

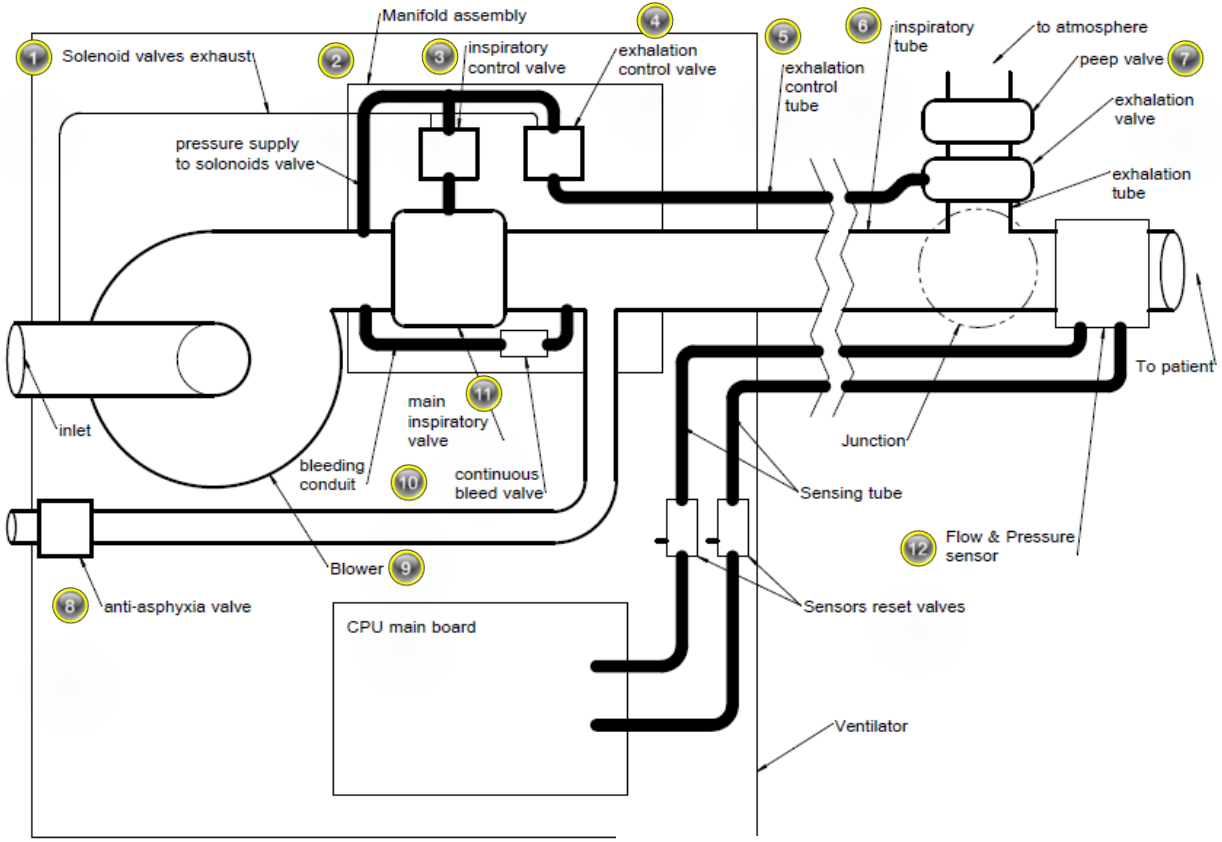
An authorized HME and anti-bacterial filter must be used at all times, in order to protect both patient and ventilator from infection.

Assemble the filter between the patient and transducer; if not possible, then between the ventilator outlet and the patient circuit 22 mm connector.

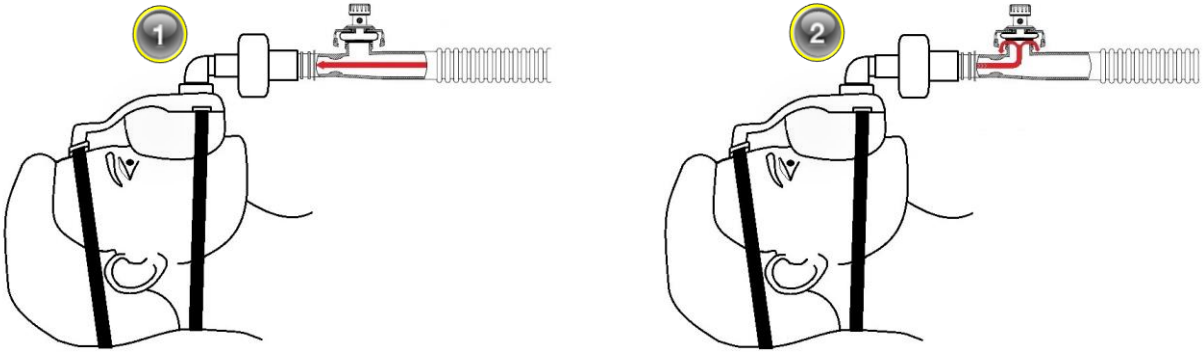
Warning: All parts of the patient circuit are single-use. Discard after use. Handle carefully to avoid cross-contamination.

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 CO2 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.



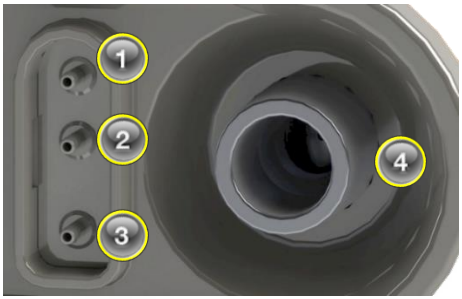
Inspiratory (1) vs. Expiratory (2) cycle

During the inspiratory cycle, the exhalation valve membrane is closed, allowing the gas from the ventilator to be diverted to the patient. Once the inspiration cycle 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 flow, 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, facemask or LMA (Laryngeal Mask Airway).

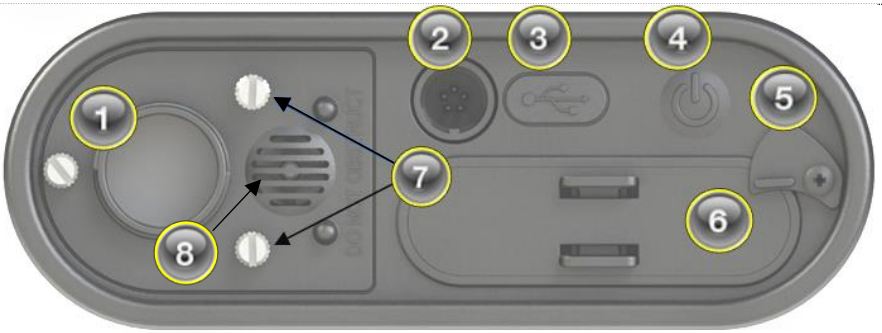
6. CONNECTING THE VENTILATOR

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 demand valve (see Section ***12.1.1.1. Connecting the Air Inlet to the Demand Valve***).
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**

7. POWER ON/OFF AND DISPLAY STARTUP SCREEN

7.1. NORMAL START

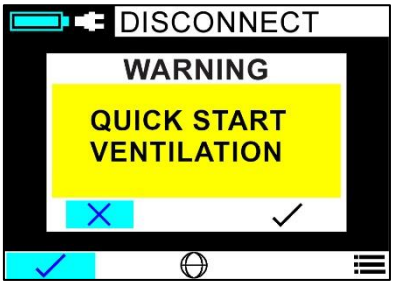
To start the system, press and hold the **Power On/Off** button on the back panel for 3 seconds.

Back panel indicating the Power On/Off button

7.2. QUICK START

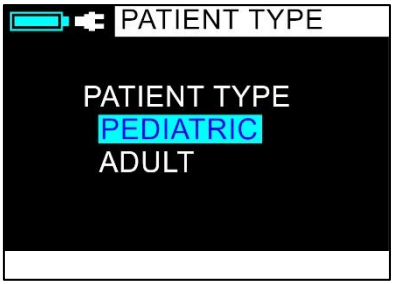
In an emergency situation, Quick Start allows you to start the ventilator immediately, using preset default options.

To perform a **Quick Start,** press and hold the Power On button for ten seconds. The following screen will display:



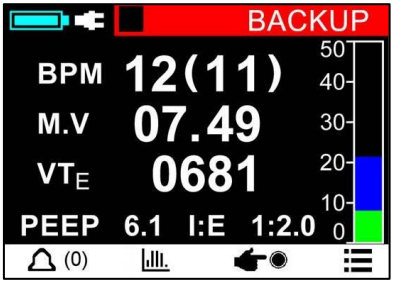
Quick Start initial screen

After you confirm by selecting the check mark and pressing the control knob, specify the Patient Type:



Patient Type screen

Now the ventilator will operate in Backup mode:



Ventilator running after Quick Start

For information on Backup Mode, see Section ***15.4. Backup Ventilation Mode.***

7.3. SHUTTING DOWN THE SYSTEM

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

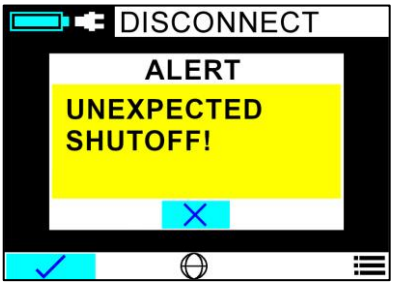
Back panel indicating the Power On/Off button

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

Confirmation screen for shutdown request

7.4. STARTUP DURING VENTILATION

If power is lost during ventilation and the ventilator is turned on **within 2 minutes,** the ventilator will automatically continue ventilation using the previous working parameters. An alert for an 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

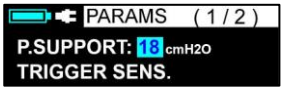
8. NAVIGATING THE GUI SCREENS

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.

8.2. EDITING FIELDS

While turning the control knob, fields that can be modified are highlighted.



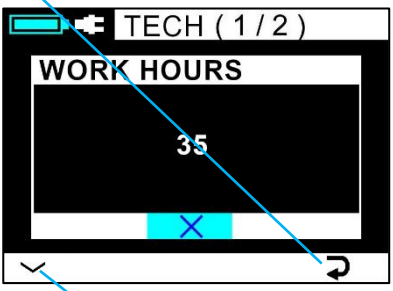
Pressure Support highlighted

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.

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

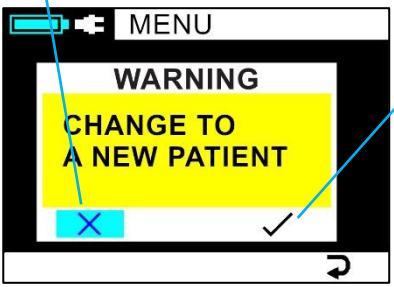
Press the Back button (↩) to return to the previous screen.



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



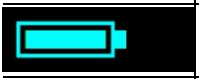
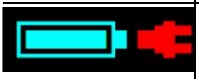
8.5. SYMBOLS USED IN THE SYSTEM

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

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 alerts indicator.

8.6.3. ALERTS

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

	Normal operation
	Alert is silenced. **Note:** While the alert is silenced (maximum 120 seconds) this indicator is displayed, and the number of active alerts 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 alerts, ordered by priority.

9. GETTING STARTED WITH VENTWAY SPARROW

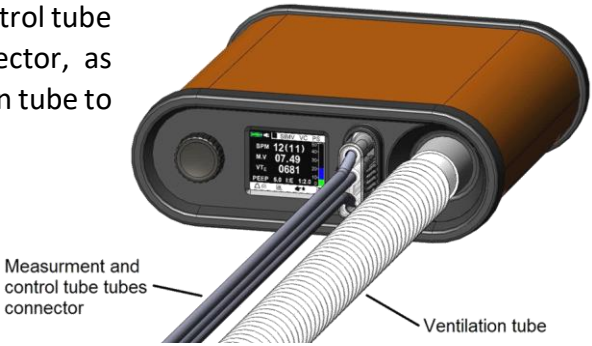
The initial set of screens allow you to start the ventilator and specify settings such as patient weight, ventilation type, and other basic parameters.

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

Note: An emergency quick start can be performed if necessary. See Section ***7.2. Quick Start***.

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. CONNECTING VENTILATOR, PATIENT CIRCUIT, ENDOTRACHEAL TUBE/LMA/FACEMASK

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

First connect the ventilator tube to the ventilator gas outlet:


Insert ventilator tube into ventilator gas outlet

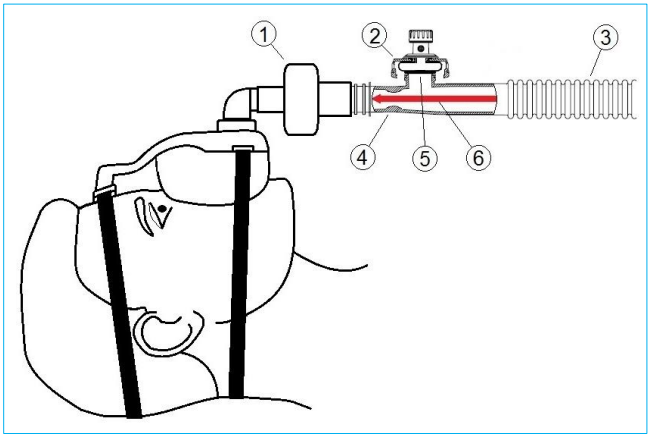
Then connect the tube connector of the measurement and control tubes to the port on the left of the ventilator gas outlet:


Insert 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 humidity and moisture exchanger (HME) filter between the patient and the patient circuit, as shown below.



1. HME (Humidity and Moisture Exchanger) filter
2. Exhalation valve cover
3. Ventilation tube
4. Flow meter
5. Exhalation valve – showing closed position (inspiratory cycle)
6. Flow direction

Connecting the Patient Circuit

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 LMA/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 ***12.1.3. 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 ***9.2. Disconnect patient***).

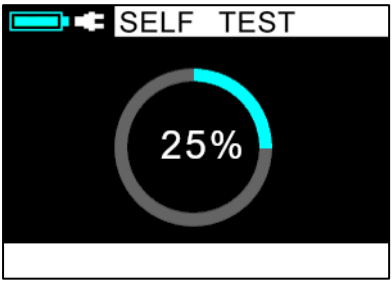
The patient may be ventilated by an endotracheal tube, LMA or facemask (non-invasive ventilation). See Section ***12.1.3. Additional recommended legally marketed components / accessories*** for recommended legally marketed endotracheal tubes, LMAs and facemasks.

9.2. 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 8 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***.

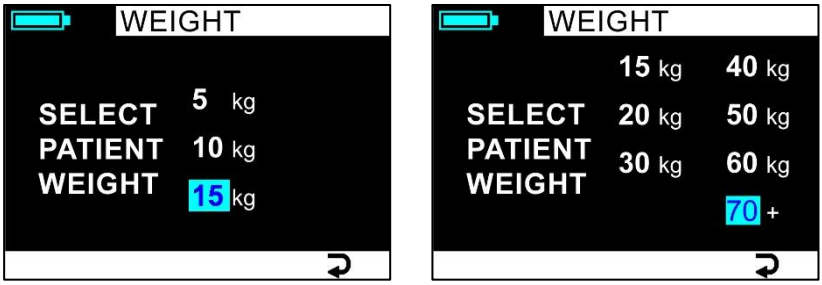
Note: If the self test is performed at an altitude that exceeds 4,000 meters (13,123 feet) the caregiver is asked if the patient circuit being used is adult or pediatric.

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

- No oxygen demand valve connected to the ventilator
- No oxygen reservoir
- 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

9.3. PATIENT WEIGHT

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

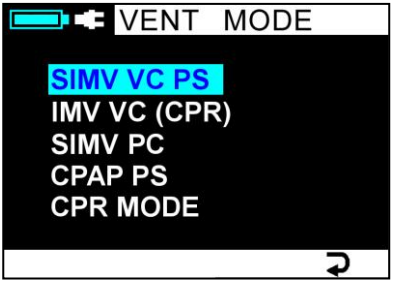


Pediatric and adult weight selection screens

Note: Setting patient weight will automatically set all ventilation parameters.

9.4. VENTILATION MODE

Select the initial choice of ventilation mode. This can be changed later. See Section ***15. Ventilation Methods*** for details about each ventilation mode.



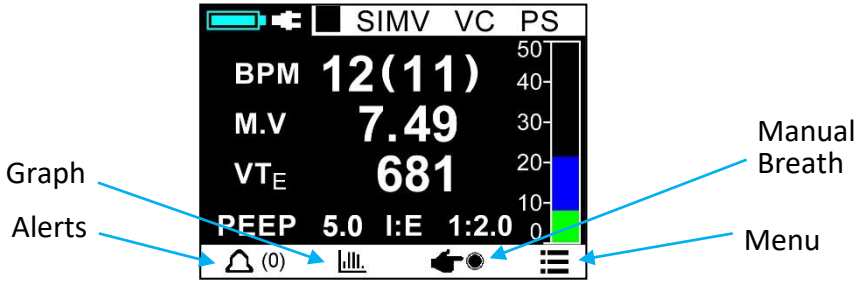
Ventilation Mode screen

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

You will be prompted to connect the patient:

9.5. 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 **VTe** to change the desired VTi.
- Select **ALERTS** to view the current active (silenced) alerts.
- Select **GRAPH** to display the Pressure or Flow graphs – see Section ***9.7. 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.***

9.6. 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.

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 negative (expiratory) tidal volume and minute volume are displayed to the user. The positive 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, VTe and VTi may vary substantially. Nevertheless, in non-invasive mode, a correction to leaks 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.

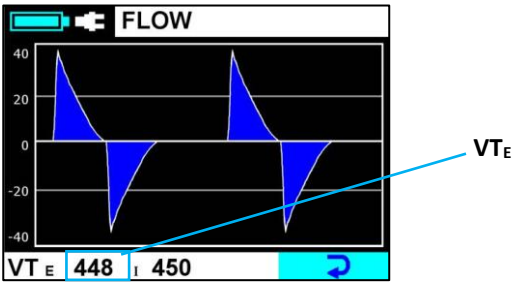
The latest **PEEP** is displayed to the user, and is updated per each breath, as the pressure measured at the end of expiration.

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

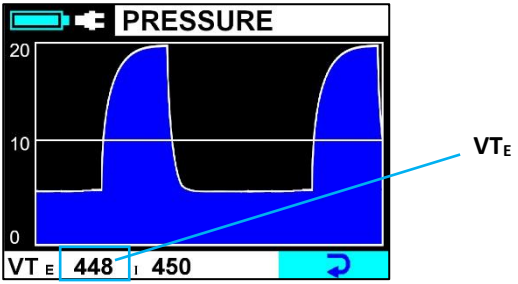
9.7. PRESSURE AND FLOW GRAPHS

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.

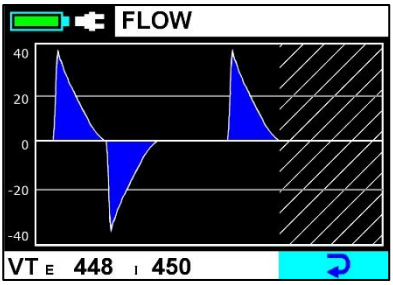


Flow Graph screen



Pressure Graph screen

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

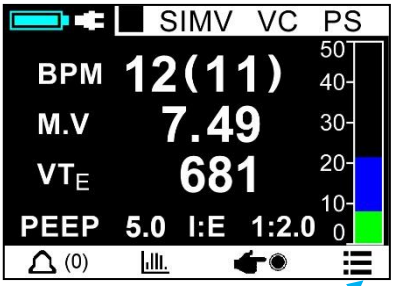


Flow graph screen during sensor zeroing

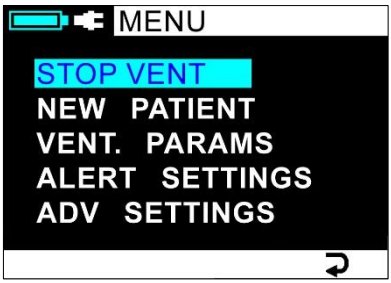
10. MAIN MENU

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***.

ALERT SETTINGS

Set the thresholds at which the alerts will be displayed. See Section ***10.3. MAIN MENU/Alert settings.***

ADV SETTINGS

Set advanced settings, such as technician mode, self test, brightness and language. See Section ***10.4. Main Menu/Advanced Settings***.

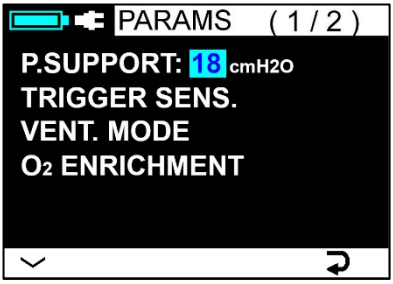
10.1. MAIN MENU/NEW PATIENT (DISCONNECT PATIENT SCREEN)

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

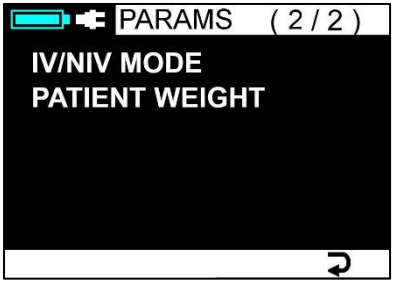
Disconnect Patient screen

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

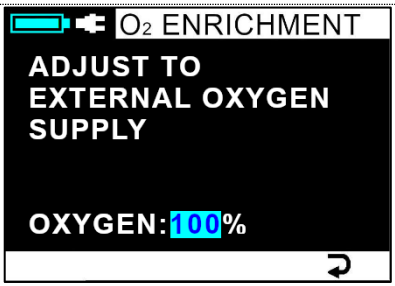
Caution: When closed suction catheterization is performed, patient trigger sensitivity must be turned to "off".

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 ***9.4. 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.

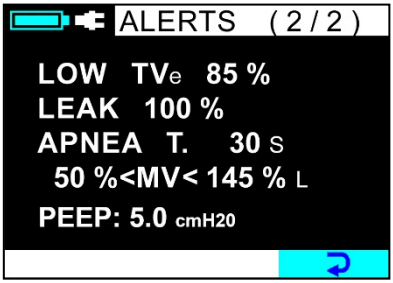
10.2.4. MAIN MENU/VENT PARAMS/PATIENT WEIGHT

The patient weight was set initially when the device was turned on. See Section ***9.3. Patient Weight*** to change the patient weight.

10.3. MAIN MENU/ALERT SETTINGS

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

Alert Param. screen (page 1)

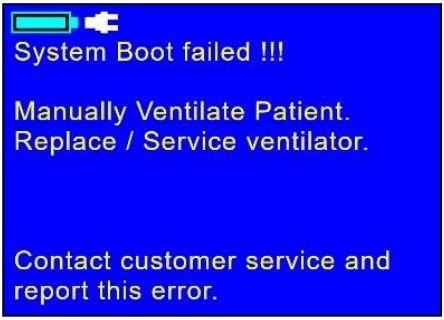


Alert Param. screen (page 2)

See also Section ***11. Warnings and Alerts*** for more information about warning and alert messages.

Caution: Boot Fail Alert

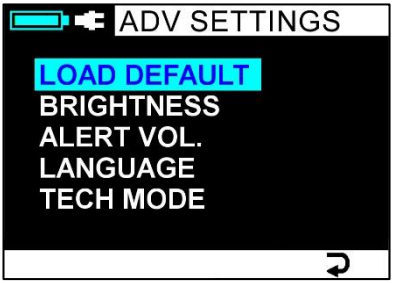
The Boot Fail screen appears if the system experiences an error when starting. Replace ventilator and contact Inovytec support.



Boot Fail screen

10.4. MAIN MENU/ADVANCED SETTINGS

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

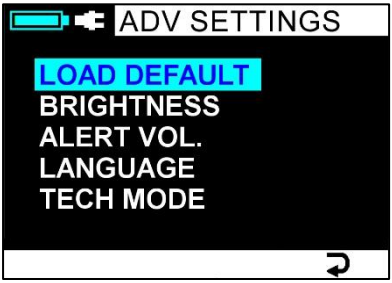


Advanced Settings menu

These options are explained in the following sections.

10.4.1. MAIN MENU/ADV SETTINGS/LOAD DEFAULT

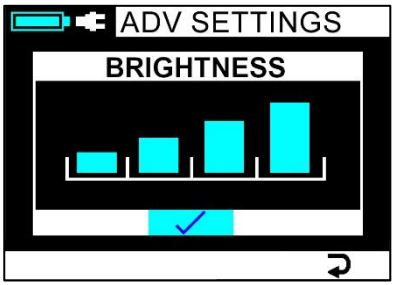
Set all parameters to their default values by the set weight.



The Load Default screen

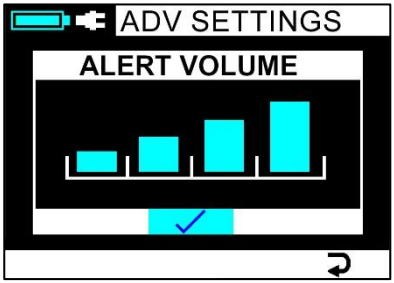
10.4.2. MAIN MENU/ADV SETTINGS/BRIGHTNESS

Change the brightness of the display.



10.4.3. MAIN MENU/ADV SETTINGS/ALERT VOLUME

Change the volume of all sound cues of the system.

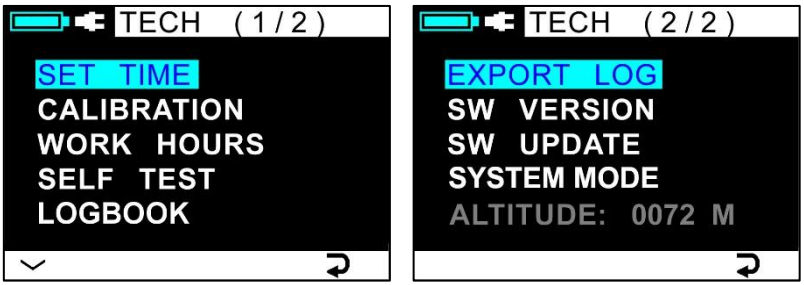


10.4.4. MAIN MENU/ADV SETTINGS/LANGUAGE

Change the system display language.

10.4.5. MAIN MENU/ADV SETTINGS/TECH MODE

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



Tech Mode screens

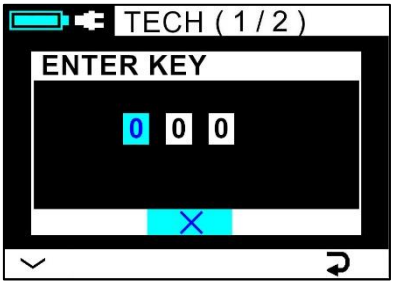
10.4.5.1. MAIN MENU/ADV SETTINGS/TECH MODE/SET TIME

Set the system date and time.

The Set Time screen

10.4.5.2. MAIN MENU/ADV SETTINGS/TECH MODE/CALIBRATION

Under Tech mode, the user may perform volume calibration by choosing the calibration screen. The Calibration screen requires a device key to be entered:

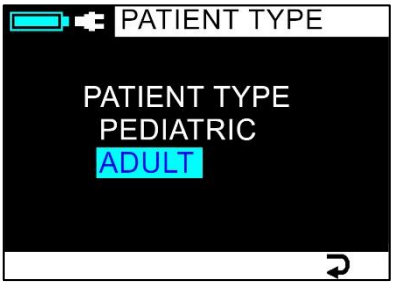


Enter key for Calibration screen

The Calibration screen will display:

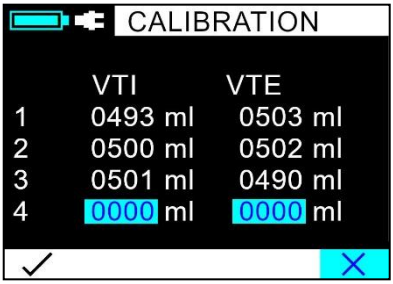
Calibration screen

Then the Patient Type screen displays:



Choose the patient type, before calibrating

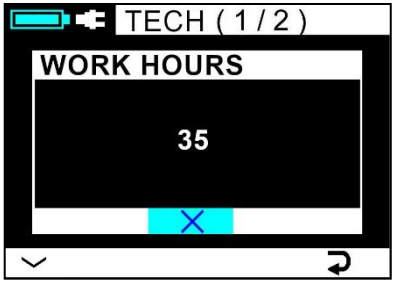
The use of a fixed volume 500 cc syringe provides an easy and accurate solution for volume calibration. The user must move the syringe handle, completing a cycle in one to two seconds, resulting in an average flow of 15 to 30 lpm. The calculated tidal volume is displayed for each stroke, and once the tidal volumes (VTi and VTe) are between 490 to 510 cc, the user may finish the calibration process by pressing the scroll knob.



Volume Calibration screen

The ventilator compensates for each stroke for tidal volume inaccuracies. The tidal volume per stroke becomes closer to 500 cc, once it is automatically multiplied by a correction factor. At the beginning of each stroke, the ventilator generates a sound, instructing the user to start moving the syringe handle.

10.4.5.3. MAIN MENU/ADV SETTINGS/TECH MODE/WORK HOURS



Work Hours screen

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

10.4.5.4. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST

When you select the Self Test option, the following screen appears:

Warning screen preparatory to Self Test

After you disconnect the patient, press ✓ to continue:

Self Test screen (press on ⌄ to see SCREEN TEST option)

The Self Test screen allows the following tests:

FLOW AND PRESS – see Section:

10.4.5.4.1. MAIN MENU/ADV SETTINGS/TECH MODE/Self Test /Flow and Pressure

CVT (circuit verification test) – see Section:

10.4.5.4.2. MAIN MENU/ADV SETTINGS/TECH MODE/Self Test /CVT

VVT (ventilator verification test) – see Section:

10.4.5.4.3. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /VVT

BLOWER TEST – see Section:

10.4.5.4.4. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /Blower Test

SOLENOID TEST – see Section:

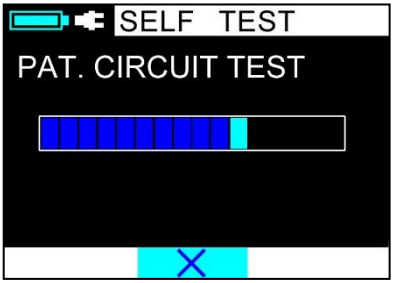
10.4.5.4.5. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /SOLENOID Test

SCREEN TEST – see Section:

10.4.5.4.6. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /SCREEN Test

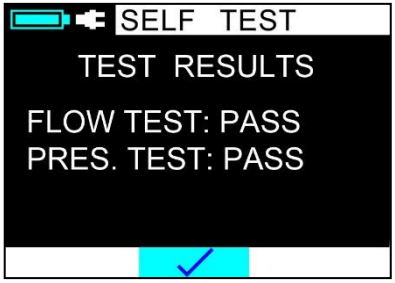
10.4.5.4.1. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /FLOW AND PRESSURE

While the test is in progress, a progress bar displays:



Self test progress bar

When the test is complete, a test result screen displays:

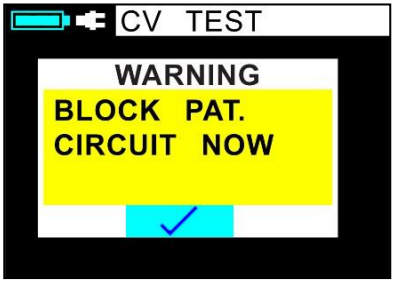


Self test results screen

In this example, the test results indicate that the ventilation circuit is ready for use, and the ventilator pneumatic and electrical systems are in order.

10.4.5.4.2. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /CVT

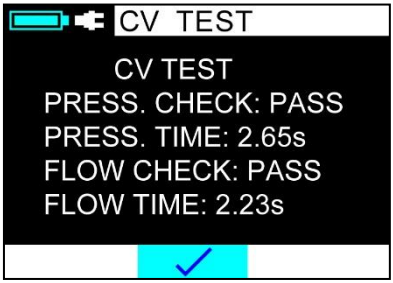
Follow the instructions on the screen for the Circuit Verification Test:



CVT screen

Use a cap to seal off the patient transducer valve:

- Press the navigation knob on the ventilator front panel to begin the test. A pop-up appears, indicating the test has begun.
- After several seconds, another pop-up will direct the user to remove the cap blocking the transducer.
- After the ventilator does further testing, the test results will display.
- Press the control knob to complete the C.V.T.



CVT Results screen

The following information is displayed:

- **PRESS. CHECK:** Pressure is over 60 [cmH2O]
- **PRESS. TIME:** Time to reach pressure of 40 [cmH2O].
- **FLOW CHECK:** Flow is over 120 [lpm].
- **FLOW TIME:** Acceleration time of blower to 100 [lpm].

10.4.5.4.3. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /VVT

Follow the instructions on the screen for the Ventilator Verification Test:

VVT screen

The manometer should be attached with the outlet blocked.

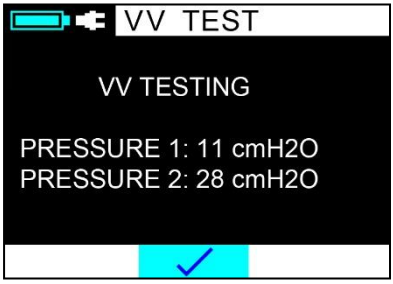
In the VVT process, the ventilator is checked for:

- System alert – audio
- Patient pressure measurement and pressure performance
- Blower pressure measurement
- Transducer tubes leak
- Motor speed measurement
- Two solenoid valves
- Solenoid safety release mechanism
- Flow performance and flow zeroing accuracy
- Watchdog safety device

The user specifies two pressure values, while the patient circuit is connected to a manometer. After the user dials in the first pressure value, the blower increases the pressure and the user dials in the second pressure value.

Manometer attached for VV test

The values will be used to calibrate the pressure sensor:



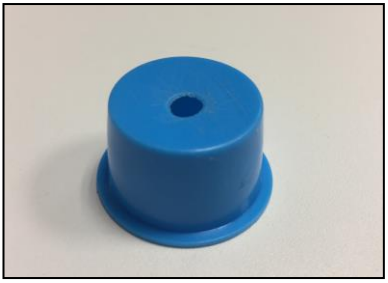
VVT pressure calibration screen

10.4.5.4.4. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /BLOWER TEST

This option turns on the blower and allows changing its speed using the rotator. Pressing the knob will stop the blower.

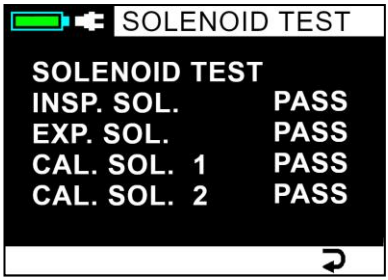
10.4.5.4.5. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /SOLENOID TEST

This option runs a series of tests that check that all solenoids used in the device are working properly. The user is instructed to place a pierced cap on the transducer and after confirmation the ventilator starts running the tests.



A pierced cap used on the transducer

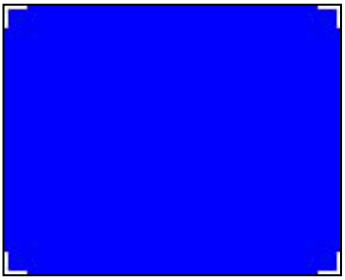
The expected result is that all solenoids are working properly, as shown below:



Solenoid test result screen

10.4.5.4.6. MAIN MENU/ADV SETTINGS/TECH MODE/SELF TEST /SCREEN TEST

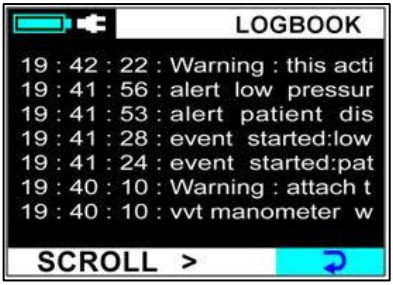
The screen will switch colors between red, green and blue with white markers for the edges of the screen. Pressing the knob will exit the test.



Screen test screen

10.4.5.5. MAIN MENU/ADV SETTINGS/TECH MODE/LOGBOOK

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



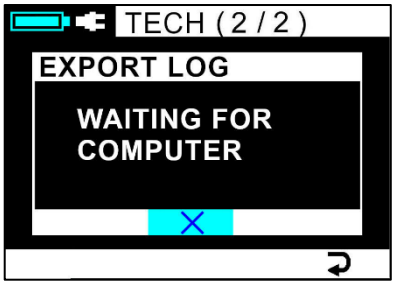
Example of an alert

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.

10.4.5.6. MAIN MENU/ADV SETTINGS/TECH MODE/EXPORT LOG

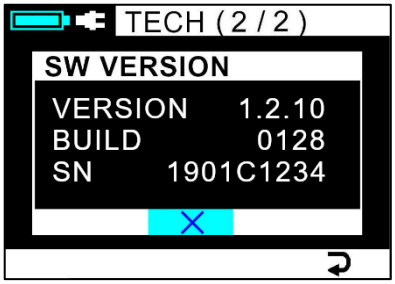
This screen allows exporting log files to a Windows PC, using a program provided by Inovytec called “Ventway Manager”.



Export log screen

10.4.5.7. MAIN MENU/ADV SETTINGS/TECH MODE/SW VERSION

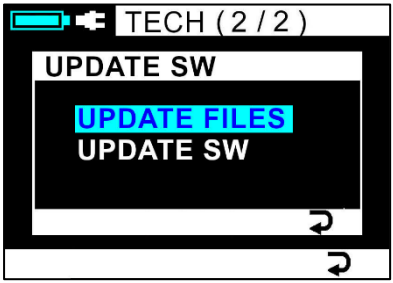
This screen shows the current software version installed on the ventilator. The serial number is also shown on this screen.



Software version screen

10.4.5.8. MAIN MENU/ADV SETTINGS/TECH MODE/SW UPDATE

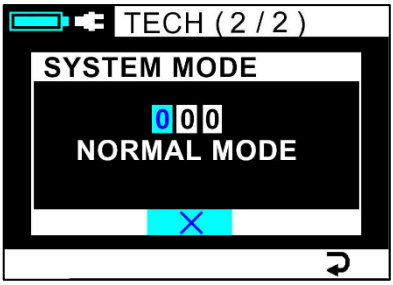
This screen allows updating the software of the ventilator using a Windows PC program provided by Inovytec called “Ventway Manager”.



Software update screen

10.4.5.9. MAIN MENU/ADV SETTINGS/TECH MODE/SYSTEM MODE

This screen sets a system mode for the ventilator. This field shouldn't be changed unless instructed to do so by Inovytec.



System mode screen

10.4.5.10. 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 ALERTS

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

11.1. SUMMARY OF ALERT TYPES

The following table summarizes the various types of alerts.

Alert type	Value	Range/Display
User Adjustable	Respiratory rate	High: 12-60 bpm Low: 1-20 bpm
	Inspiratory pressure	Limit: 10-60 cmH_2O Alert: 10-55 cmH_2O
	Apnea	5-120 seconds
	Leak	0-100%
	Low Tidal Volume Delivered	Off or 15%-85%
	Inverse I:E Ratio	ON/OFF
	Alert Volume	1-4
	Pressure limit	11-60 cmH_2O
	Pressure alert limit	10-55 cmH_2O
Additional	Low Battery	Estimated battery energy level + Alert
	Empty Battery	Screen Icon + Alert
	Battery Disconnect	Screen Icon (swapping)
	Check Sensor tubes	Alert
	Tube Disconnect	Alert
	High PEEP	Alert
	Service Notice	Alert
	System Boot Failed	Alert
	AC Power Disconnect	Screen icon and an audio que

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

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

11.2. SUMMARY OF ALERT LEVELS

Alerts 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 alerts.

Alert category	Alert
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
	Battery low
	High temperature
	Expiratory valve blocked
	High PEEP
	Low PEEP

Alert category	Alert
Medium level	High respiratory rate
	Low tidal volume
	Low pressure
Low level	Replace filter
	Service needed
	Altitude out of range
	External power connected/disconnected (icon instead of popup message)
	Battery charge protection active

11.3. WARNING EXAMPLE

Here is an example of a warning message:

Warning message

11.4. ALERT EXAMPLE

A typical alert appears as follows:

Example of an alert

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

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

High PEEP alert

12. DEFAULT PARAMETERS

12.1. START VOLUME VENTILATION

Patient Weight	Rate	Tidal Volume	Max. Pressure
(Kg)	(bpm)	(ml)	(cm H2O)
5	35	50	30
10	30	70	30
15	25	100	30
20	20	120	30
30	18	180	40
40	16	240	40
50	14	300	40
60	12	360	40
70+	12	450	40

12.1.1. OXYGEN SUPPLY

When a high-pressure oxygen source that is connected to a demand valve is not available, the Ventway Sparrow ventilator can accept oxygen from a low-pressure oxygen source such as a reservoir bag 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 flow of oxygen to reach the desired value of FiO_2. Select the "O2 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 demand valve 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 ***12.1.3. Additional recommended legally marketed components / accessories*** for recommended legally marketed reservoirs.

12.1.1.1. CONNECTING THE AIR INLET TO THE DEMAND VALVE

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

Connecting the oxygen demand valve to the air inlet connector

The demand valve/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 demand valve.

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

12.1.2. 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.

12.1.3. 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	TELEFLEX MEDICAL	HUMID-VENT 1 HEPA
LMA	TELEFLEX MEDICAL	LMA® Supreme™ Airway
LMA	INTERSURGICAL, INC.	i-gel, supraglottic airway
Endotracheal tube	TELEFLEX MEDICAL	SHERIDAN® Endotracheal Tube
Endotracheal tube	Kimberly-Clark	MICROCUFF Endotracheal Tube
Face Mask	Intersurgical Ltd	Varifit, FaceFit Non Vented face masks
Face Mask	Hans Rudolph, inc.	Non Vented face masks Model 6500
Face Mask	AMBU, INC.	Ambu®Disposable Face Masks
Reservoir	INSTRUMENTATION INDUSTRIES, INC.	OXYGEN ENRICHMENT KIT, MODELS SG 066, SG 067

12.2. ALERT DEFAULT PARAMETERS: 5 KG TO 70+ KG

Alert Parameter	Weight								
	5kg	**10kg**	**15kg**	**20kg**	**30kg**	**40kg**	**50kg**	**60kg**	**70+ kg**
Pressure Alert (cm H_2O)	21	23	25	30	33	35	40	40	40
Pressure Limit (cm H_2O)	25	28	30	35	40	42	47	50	50
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)	2.5	4.2	5.3	5.6	7.6	9	9.8	10.1	12
Low Min Vol. (LPM)	1	1	1	2	2	3	3	4	4

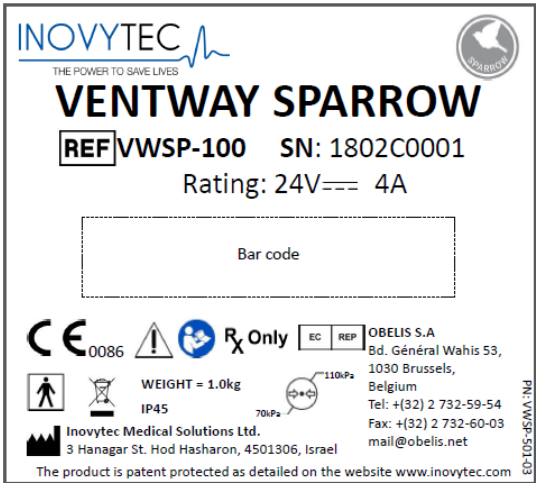
12.3. ALERT DEFAULT PARAMETERS: ALL PATIENT WEIGHTS

PEEP	**> 2.5 cm H_2O from set value**
Low pressure	5 cm H_2O
Leak (%)	100% (off)
Inverse I:E Ratio	ON
Low Tidal Volume Alert Range	85% of set volume

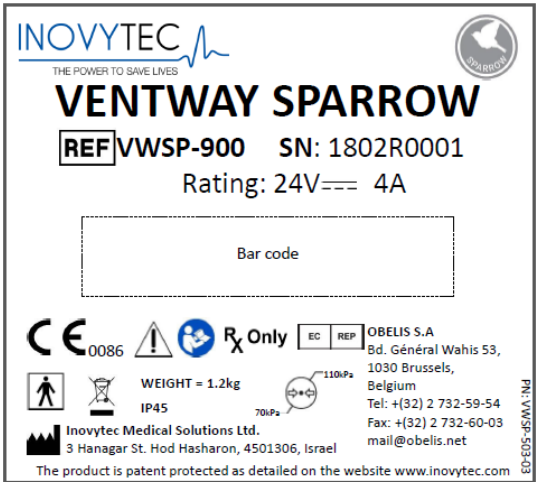
13. LABELS AND SYMBOLS

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.



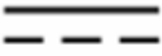
VWSP-100 Civil Model



VWSP-900 Military Model

13.2. SYMBOLS

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

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

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

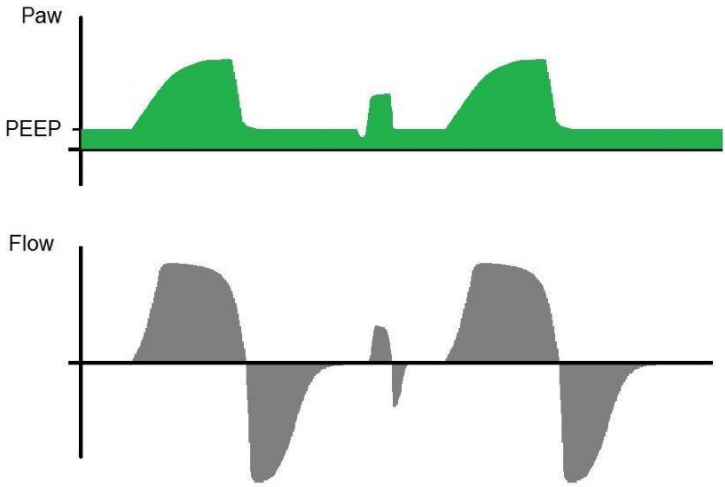
15.1. SIMV-VC (PS) FLOW CHART

In SIMV-VC, the patient is supplied with the set tidal volume VT during the mandatory breaths. The mandatory breaths are synchronized with the patient's own breathing attempts. Mandatory breaths are prevented from being applied during spontaneous expiration, by providing that a patient-triggered mandatory breath can only be triggered within a trigger window.

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 number of mandatory breaths. If no independent breathing attempt is detected during the trigger window, the machine-triggered mandatory breaths are applied. Thus, the minute volume MV remains constant over time. If the breathing attempts of the patient are insufficient to trigger the mandatory breath, the machine-triggered mandatory breaths are applied. The patient can breathe spontaneously at PEEP level during the expiration phase. During spontaneous breathing at PEEP level, the patient can be pressure-supported using PS.

Please note:

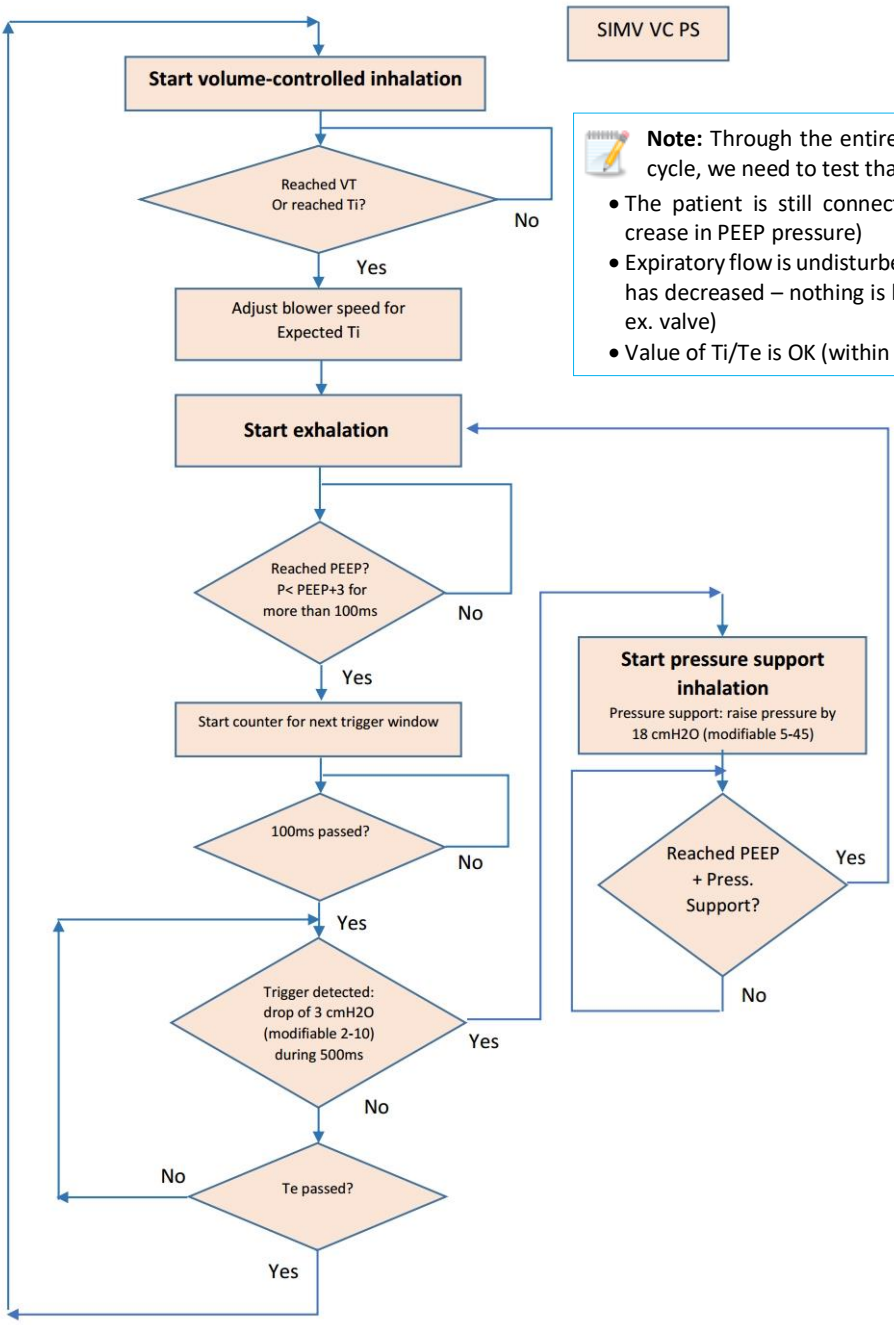
1. The number of breaths is set by the patient weight (more weight = less breaths/minute). BPM=mandatory breaths.
2. It is volume controlled (although pressure is constantly being monitored).
3. Either the machine or patient can trigger the breath.
4. Trigger definition: If the patient reaches -2 cm H_2O in less than 300 msec then a trigger breath is initiated.
5. Trigger activation window: 300 msec after termination of breath until initiation of new breath.
   If no independent breathing attempt is detected during the trigger window, the machine-triggered mandatory breath is applied.



6. If no spontaneous breathing attempt is detected during the inspiratory trigger window, the machine-triggered mandatory breath is applied.

The mandatory tidal volume (VT) results from the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. Pinsp is the inspiratory pressure (pressure in the lung throughout the inspiratory cycle). If the lung mechanics change (pressure, water in the lungs etc.) the ventilation will not change the volume, and the only change may be the PIP (within the safety/alert pressure values).

Note: In non-invasive ventilation the ventilator is programmed to compensate for the loss of volume due to leaks from the facemask or LMA. Actual delivered tidal volume can only be interpolated, and is not displayed.



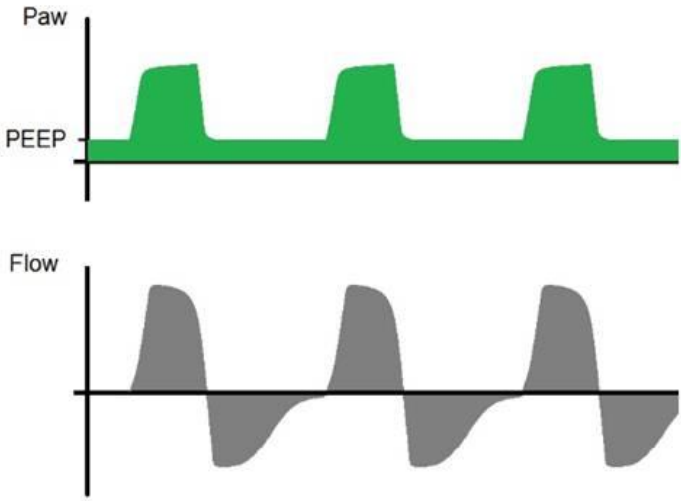
Note: Through the entire ventilation cycle, we need to test that:

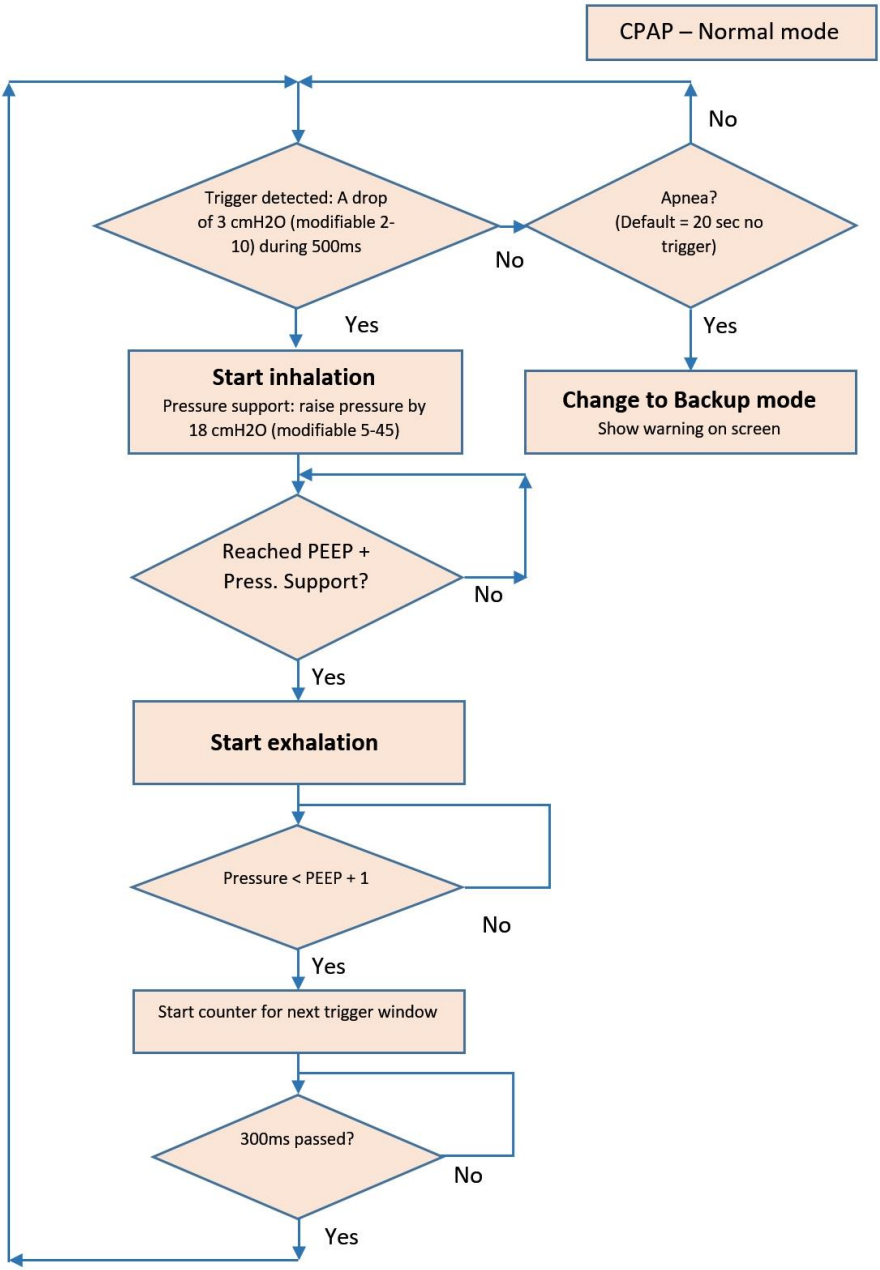
- The patient is still connected (no decrease in PEEP pressure)
- Expiratory flow is undisturbed (pressure has decreased – nothing is blocking the ex. valve)
- Value of Ti/Te is OK (within the norm).

15.2. CPAP – SPONTANEOUS BREATHING MODE

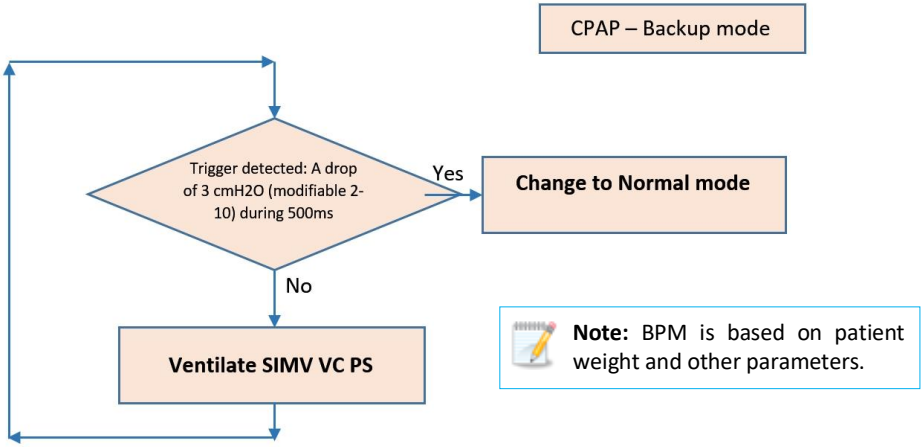
During the spontaneous ventilation modes, the patient carries out the majority of the breathing effort. The pressure support ventilation level PS can be adjusted. The default **PSV** level is 18 cm H_2O.

As long as the patient's airways are below the PEEP + PSV level, the ventilator will perform ventilation support. This setting directly affects the flow and thus the supplied tidal volume (VT_I).




CPAP – Normal mode
Trigger detected: A drop of 3 cmH2O (modifiable 2-10) during 500ms
No
Apnea? (Default = 20 sec no trigger)
No
Yes
Yes
Start inhalation
Pressure support: raise pressure by 18 cmH2O (modifiable 5-45)
Change to Backup mode
Show warning on screen
Reached PEEP + Press. Support?
No
Yes
Start exhalation
Pressure < PEEP + 1
No
Yes
Start counter for next trigger window
300ms passed?
No
Yes

CPAP Backup ventilation



Note: BPM is based on patient weight and other parameters.

15.3. SIMV-PC

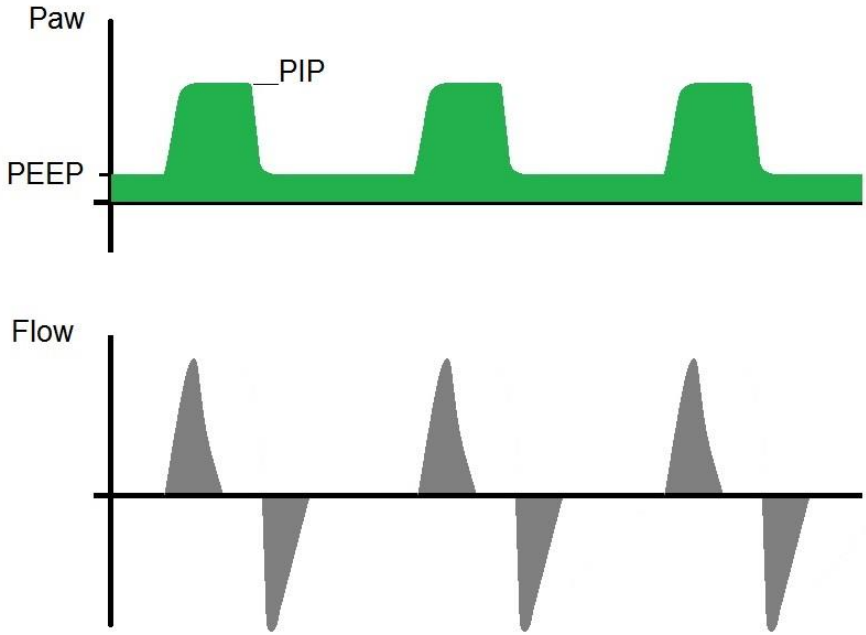
In SIMV-PC (Pressure Control ventilation), the patient's tidal volume is determined by setting upper and lower pressure levels, and is dependent upon overall pulmonary compliance and resistance.

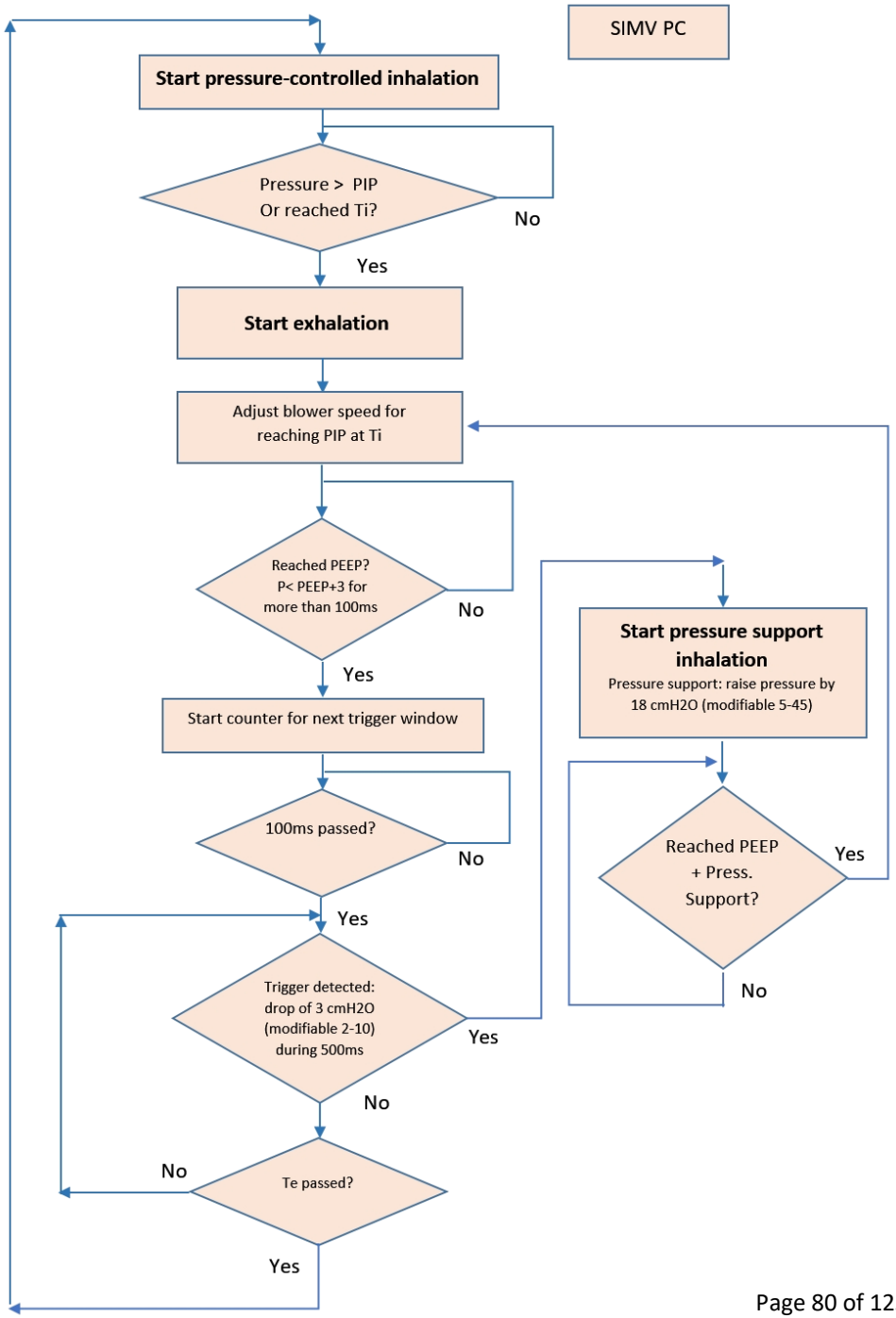
The user defines a number of mandatory breaths in which the ventilator provides a constant pressure set during the inspiratory phase. The inspiratory pressure, inspiratory time, rate and maximum delivered tidal volume values are set by the operator (by selection of patient weight or modification of parameters setup). A pressure control breath can be initiated both by the ventilator (mandatory pressure control breath) and by the patient (assist pressure control breath), during the complete breathing cycle.

The mandatory breaths are synchronized with the patient's own breathing attempts. A patient-triggered mandatory breath can only be triggered within a trigger window. 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 number of mandatory breaths (RR). If no independent breathing attempt is detected during the trigger window, the machine-triggered mandatory breath is applied. The mandatory tidal volume (VT) results from the pressure difference between PEEP and PIP (Peak Inspiratory Pressure), the lung mechanics and the breathing effort of the patient. If the Resistance (R) or Compliance (C) of the lung changes during the ventilation treatment, the supplied tidal volume (VT) and thus the minute volume (MV) also vary. These values may exceed the predefined TV (Tidal Volume) and MV (Minute Volume) settings initially performed by the user.

During spontaneous breathing at PEEP level, the patient can be supported using PS (Pressure Support).

Default PS level is identical to the initial PIP value, and may be modified. Changing PS value will change the Tidal Volume supplied by the ventilator during spontaneous breathing.


Paw
PIP
PEEP
Flow


SIMV PC
Start pressure-controlled inhalation
Pressure > PIP
Or reached Ti?
No
Yes
Start exhalation
Adjust blower speed for
reaching PIP at Ti
Reached PEEP?
P< PEEP+3 for
more than 100ms
No
Yes
Start counter for next trigger window
100ms passed?
No
Yes
Trigger detected:
drop of 3 cmH2O
(modifiable 2-10)
during 500ms
Yes
No
Te passed?
No
Yes
Start pressure support
inhalation
Pressure support: raise pressure by
18 cmH2O (modifiable 5-45)
Reached PEEP
+ Press.
Support?
Yes
No

15.4. BACKUP VENTILATION MODE

Note: Backup will not occur when the user inserts weight, selects a ventilation mode and does not press **OK**. In this situation, a trigger is received from the patient and the respiration is performed according to the ventilation mode.

Backup mode is an alternative ventilation method taking place when the ventilator patient circuit is connected to the patient in these situations:

1. 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 alert appears.
2. Patient is connected to the ventilator, and for some reason, the user did not start ventilation after connecting the patient. The backup starts after three breaths.
3. Patient is connected to the ventilator, and user has paused ventilation. In this case when trigger is sensed by the ventilator, the ventilation will automatically resume.

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.

15.4.1. 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 alert appears.

Then backup ventilation is initiated:

The screen displays an alert: "Backup Ventilation Started" and the "OK" button for user approval appears. Ventilation will start even if user has not pressed **OK**. Alert will appear on the screen while audio prompt is activated.

- Volume, Pressure, MV and all other alerts 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 (will alert on screen: "CPAP ventilation resumed - OK"), or user switching back to CPAP or SIMV - VC - PS manually, through the "MENU" option on the main screen.
- All alerts and user inputs will be logged in logbook.
- An alert is issued "Backup ventilation active" -- "OK".

15.4.2. BACKUP VENTILATION BEFORE STARTING PATIENT VENTILATION

If patient is connected to the ventilator, the following conditions may also initiate backup ventilation:

a) Ventilation has not started yet, but ventilator is turned on (either patient weight, ventilation method or start command was not chosen by the user).

b) Patient trigger sensed.

If conditions a) and b) above were met, then backup ventilation starts.

- "Backup ventilation mode" alert is activated - "OK" displays.
  - If the user approves, the Patient Type window appears, and then the backup starts.
  - If the user does not approve, the action is canceled and the ventilation **does not** start.
- The "Backup ventilation mode" icon appears on top of the screen after the last alert was either accepted or discarded.

If Patient weight was entered, the device ventilates according to the given weight parameters.

If Patient weight was not entered:

1. Initial pressure support value is set to PS=10 cm H_2O.
2. Tidal volume is calculated during ventilation.
3. 3 breaths are given to the patient at identical parameters (PS=10 cm H_2O) at 10 BPM rate.

4. After 3 breaths, the patient weight is evaluated by using TV average of the last 3 breaths:

TV[cc]	Patient weight [kg]
Below 50	5
50-69	10
70-99	15
100-119	20
120-179	30
180-239	40
240-299	50
300-359	60
Over 359	70+

5. The table shown above shows the estimated patient weight, based on the volume reached during quick mode method.

If Patient weight and ventilation mode were entered, ventilation will start in selected mode and will issue an alert “Ventilation started – OK”.

If patient trigger is sensed, then spontaneous breath is initiated with the same ventilation parameters.

- An alert appears: "Backup ventilation active -- OK".
- User may change the ventilation parameters by entering MENU and selecting new ventilation parameters.

If the ventilator did not complete the initial verification, an alert will be activated 15 seconds after starting backup ventilation: "Initial ventilator verification needed -- OK". This alert will appear only once.

3. Backup Ventilation in Pause mode

In case the user chose to pause the ventilation for any reason, and patient trigger (pressure -2.5 cm H_2O or -5 lpm or greater) was sensed, then ventilation is resumed with the exact same parameters as set by the user. The alert is issued: "Ventilation is resumed -- OK".

15.5. IMV VC (CPR)

In SIMV-VC (CPR), as in the normal SIMV-VC (PS), the patient is supplied with the set tidal volume VT during the mandatory breaths.

The only difference in this setup, is that patient triggering is switched to OFF. This is very useful during cardiopulmonary resuscitation combining chest compressions.

Chest compression is known to activate undesirable patient triggers causing the ventilator to continue delivering spontaneous breaths at a high rate (uncontrolled auto triggering).

By turning off the triggers, the ventilator will not alert due to high minute volume, breath rate or inadequate I:E ratio.

15.6. CPR

This setup delivers constant pressure into the patient airways. The pressure can be adjusted by changing the turbine power level field (values range from 1 to 4) and by adjusting the external PEEP control knob on the patient transducer. See ***Section 15.7. Setting the PEEP Value*** for instructions for setting the PEEP.

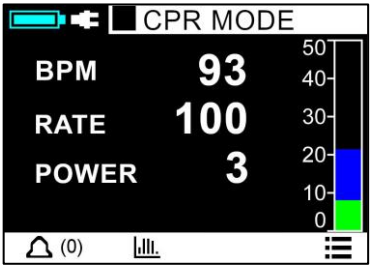
Audio prompt is played in a frequency ranging from 80 to 120 beeps per minute in order to indicate rhythm of compressions to the caregiver. After 30 beeps are sounded, the ventilator instructs the caregiver to stop giving chest compressions by sounding 5 consecutive low tone beeps and then two pressure controlled breaths are delivered to the patient. After the two breaths end, the ventilator continues to sound the audio prompt for the chest compressions.

CPR mode may be used when prolonged cardiopulmonary resuscitation (CPR) is performed. The following parameters are displayed in CPR mode:

BPM – Number of compressions sensed by the patient pressure sensor. The number may vary due to the strength, frequency of compressions, and leaks from the patient airways.

Rate – Allows changing the audio prompt frequency (range is from 80 to 120).

Power – Change the power level of the turbine, values range from 1 to 4.



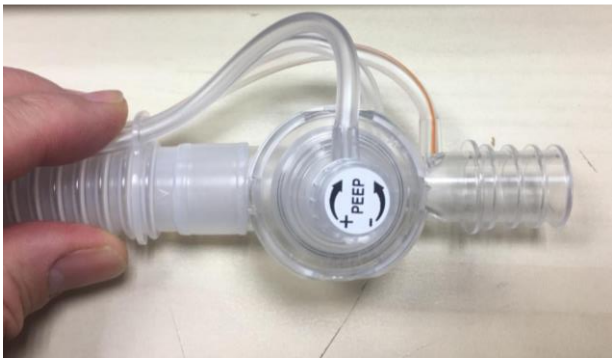
Display in CPR mode

Pressure bar graph – Pulmonary pressure is displayed on the bar graph.

Caution: If an unexpected shutoff event occurs, the ventilator will alert for the unexpected shutoff when it is next activated. If the incident occurred during patient ventilation, and the event took place no more than two minutes before, the ventilator will continue with the last ventilation parameters automatically.

15.7. SETTING THE PEEP VALUE

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

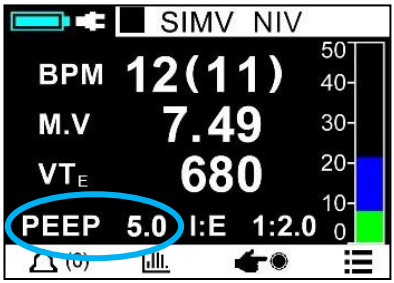


Tubes are free of kinks

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 is influenced by the oxygen enrichment method. For example, if we connect a demand valve for O2 enrichment, the PEEP may decrease at 3-4 cm H2O. Although the ventilator will issue an alert, 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 of 15,000 operation hours or three years (whichever is first). Service should only be provided by an authorized Inovytec Medical Solutions Ltd. representative.

16.1. DEVICE CALIBRATION AND SOFTWARE UPGRADES

Every three years the device needs to be calibrated (see Section ***10.4.5.2. MAIN MENU/ADV SETTINGS/TECH MODE/Calibration***).

Calibration and update of the software are performed by a certified Inovytec technician mode using software and password provided by Inovytec.

17. 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. DIMENSIONS AND WEIGHT

Width	165 mm
Length	167 mm
Height	60 mm
Weight	Civilian version: 1 kg with batteries
	Military version: 1.3 kg with batteries

18.2. ENVIRONMENTAL SPECIFICATIONS

Operating Temperature	-18 °C to 50 °C (0 °F to 122 °F)
Storage Temperature	-20 °C to 70 °C (-4 °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 7600 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 alert that indicates exceeding regular operation conditions, please remember that these alerts 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 alert 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 alert 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.

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 16-24 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: Measurement accuracy of calibration equipment may affect the respiratory parameters display by the following parameters:

- Volume calculation : +/-2% or 20 [cc]
- Inspiratory and expiratory times : +/- 0.02 [s]
- Pressure : +/- 0.75% or +/- 0.1 [mbar]

Note: If temperature exceeds the range of -18°C to 50°C, a temperature alert 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
Accuracy of Respiratory Volume Measurement	±15% + 4 ml
Inspiratory Pressure Limit	5 to 60 cm H_2O
Inspiratory Time	0.3 to 3 ±10% sec
Peak Flow (PIF)	135 (-5% to +10%)% L/min Spontaneous to 160 ±10% L/min
Oxygen Mix (FiO_2)	21% to 95% ±5% O_2
PEEP	0 to 15 cm H_2O ±1, (externally adjusted)
Trigger Sensitivity	-2 to 10 cm H_2O Pressure, Off
PS	5 to 45 cm H_2O
Controlled Pressure	5 to 60 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
RTCA DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment Rotary wing – 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

19. 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 (77°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.

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 serial number of the unit and the part number of the item(s) ordered. For the Equipment and Accessory Inventory list, see our website as specified below.

Forward orders to:

Inovytec Medical Solutions Ltd.
3 Hanagar St., POB 7282,
Hod-Hasharon 4501306, Israel
Tel: +972 9 7794135

E-mail: Info@Inovytec.com; sales@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.
3 Hanagar St., POB 7282,
Hod-Hasharon 4501306, Israel
Tel: +972 9 7794135

E-mail: Info@Inovytec.com

Web Site: http://www.Inovytec.com

EC REP 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

CE 2797

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 ALERTS

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

23.1. BACKUP VENTILATION

Step	Procedure Action	Expected Results
1	Start a new patient via the menu. Set the lung simulator simulated weight to 70 kg.	Message requesting to disconnect the patient.
2	Generate 3 inhalation triggers.	The software switches to the running ventilation screen with unknown weight, in SIMV ventilation mode. The software indicates that it is in backup ventilation.
3	Inspect the parameters on the screen.	The blower starts, with PS = *DefaultPS,* and presents the ventilation parameters.
4	Wait for two breathes.	The following ventilation parameters are automatically set according to the simulated patient weight: Alert Pressure, Minute Volume M.V., BPM, Tidal volume Vt, Ti, Te, PS, trigger sensitivity.
5	Wait for a few minutes.	Ventilation continues with parameters suitable for a patient weighing approx. 70 kg. The software keeps indicating that it is in backup ventilation mode (upper right of the screen). The software instructs the user to perform patient circuit test (via the menu).
6	Stop ventilation.	Ventilation stops.

23.2. 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.
4	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.
5	Allow for a few breaths cycles.	The software switches between phases, using SIMV ventilation mode.
6	Wait for the next exhalation phase and for pressure to reach PEEP value. After more than *MinRestDuration* 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.

23.3. 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 alerts: “Patient disconnection”.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.
5	Select to view active alerts via the menu.	Patient Disconnection alert is shown.

23.4. 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 -> alert settings, change PEEP to 5 (this appears in the second page of the alert settings). Go back to run screen.	See the run screen.
4	Increase PEEP above the limit. See ***Section 15.7. 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 alerts via the menu.	Alert is shown.
8	Decrease PEEP. See ***Section 15.7. 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 alerts via the menu.	Alert is not shown.
10	Increase PEEP above the limit. See ***Section 15.7. 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 alert disappears from the alerts screen.
13	Select to view active alerts via the menu.	Alert is not shown.
14	Go to menu -> alert settings, look at the PEEP setting in the second page	See that the PEEP setting changed to 10.

23.5. 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 -> alert settings, change PEEP to 10 (this appears in the second page of the alert settings). Go back to run screen.	See the run screen.
4	Decrease PEEP below the limit. See ***Section 15.7. 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 alerts via the menu.	Alert is shown.
8	Increase PEEP. See ***Section 15.7. 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 alerts via the menu.	Alert is not shown.
10	Decrease PEEP below the limit. See ***Section 15.7. 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.
12	Press confirm	See that the pop-up disappears and that the alert disappears from the alerts screen.
13	Select to view active alerts via the menu.	Alert is not shown.
14	Go to menu -> alert settings, look at the PEEP setting in the second page	See that the PEEP setting changed to 5.

23.6. 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 alerts: “valve blocked”.
4	Increase flow back to normal.	The alert disappears.
5	Silence the alert.	Alert indication on the screen, but alert is silenced.
6	Select to view active alerts via the menu.	Alert is shown.

23.7. PRESSURE ALERT

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 alert settings.	The software alerts: “Low Pressure”.
4	Increase pressure back to normal.	The alert disappears.
5	Slowly increase the inspiratory pressure above the max inspiration alert settings.	The software alerts: “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 alert.	Alert indication on the screen, but alert is silenced.
7	Select to view active alerts via the menu.	Alert is shown.

23.8. MINUTE VOLUME (MV) ALERT

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 alert settings.	The software alerts: “MV Alert”.
4	Increase pressure back to normal.	The alert disappears.
5	Slowly increase MV above the max MV alert settings.	The software alerts: “MV Alert”.
6	Silence the alert.	Alert indication on the screen, but alert is silenced.
7	Select to view active alerts via the menu.	Alert is shown.

23.9. LEAK ALERT

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 alerts: “Leak Alert”.
4	Close the leak.	The alert disappears.

23.10. TIDAL VOLUME ALERT

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 alerts: “Low Tidal Volume Alert”.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.
5	Increase TV above 80%.	The alert disappears.
6	Change settings to disable TV. (go to alerts 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.

23.11. I:E ALERT

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 alerts: “I:E Alert”.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.
5	Change the settings to disable I:E Alert.	I:E alert 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 alert.

23.12. APNEA ALERT

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 alert, the software alerts: “Apnea Alert” and switches to backup ventilation mode.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.
5	Select to view active alerts via the menu.	Alert is shown.

23.13. POWER ALERT

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.

23.14. LOW BATTERY ALERT

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 *CriticallyLowBattery* level.	The software indicates *CriticallyLowBattery* level.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

23.15. BATTERY TYPE ALERT

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.

23.16. VOLTAGE ALERT

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 *VoltageRange*.	The software stops indicating an AC power connection and switches to battery power.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

23.17. TEMPERATURE ALERT

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 *MaxAllowedTemperature*.	The software indicates that the temperature is above range (above 80 degrees).
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

23.18. TUBE DISCONNECT ALERT

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 alert.	Alert indication on the screen, but alert is silenced.

23.19. ALTITUDE CHANGE ALERT

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 *AltitudeRange.*	The software indicate that the device is out of altitude range (lower than -381 meters).
4	Silence the alert.	Alert indication on the screen, but alert is silenced.
5	Simulate altitude above *AltitudeRange.*	The software indicate that the device is out of altitude range (higher than 4572 meters).
6	Silence the alert.	Alert indication on the screen, but alert is silenced.

23.20. SHUTDOWN ALERT

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 pressed. The software requires confirmation for shutting down.
4	The device starts playing a tone until an extra confirmation is given.	The device shuts down.

23.21. 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.

23.22. 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 -> Alert settings	The screen title should be “ALERTS(1/2)”
6	Change all the alert settings in both alerts settings screens.	All alert 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.
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

Step	Procedure Action	Expected Results
15	Go back to the alert 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.

23.23. MISCELLANEOUS ALERTS

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

1) After every 300 hours of work, an alert 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 alert 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 alert will pop up with the following message: “service needed”.

Caution: This alert 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.