User Manual

Ventway Sparrow

Emergency and transport
ventilator

INOVYTEC

THE POWER TO SAVE LIVES

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Important

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

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

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

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

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

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

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

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

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Obtaining Help

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

If you have a ventilator problem that you cannot solve, and you purchased your ventilator **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.

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
Peak Flow	Maximum volumetric flow
PEEP	Peak 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, PS	Synchronized Intermittent Mechanical Ventilation with pressure support
Te	Expiratory Time
Ti	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
Tve	Expired Tidal volume
Tvi	Inspired Tidal volume

2. OVERVIEW OF SYSTEM

2.1. DESCRIPTION OF DEVICE

The Ventway is an emergency portable ventilator, used for transport, EMS and military applications.

The situations for which it is intended are characterized by attendance of first responders with limited triage capabilities, requiring a simple yet highly effective ventilator, that is self-sufficient and lightweight.

The ventilator is suitable for noninvasive ventilation for a full non-vented ventilation face mask.

3. CONDITIONS FOR USE

INTENDED USE

The Ventway Sparrow ventilator supports adult and pediatric patients weighing at least 5 kg (11 lb.) in patient transport, and emergency response with invasive or noninvasive ventilation presets. These settings can be easily refined using the single rotator/push button and easy read display.

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. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg, who require the following types of ventilatory support:

- SIMV Volume Control (VC) with pressure support (PS). The ventilator is suitable for use in institutional or transport settings.

- CPAP – Continuous Positive Airway Pressure Ventilation with pressure support, delivered invasively (via endotracheal tube or tracheostomy tube) or non-invasively (via nasal/full face mask).

3.2. CONTRAINDICATIONS

- Patient instructions regarding performing ventilation or any use of life support equipment
- 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.

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 always should 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.

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.

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

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 can be used for the same patient up to five days.
- Do not use a Patient Circuit that is not the original Patient Circuit of the device.
- 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, it will reach min. 90%.
    - When using reservoir bag, it may vary depending on oxygen flow rate.

Cautions:

- It is the user's responsibility to retain information about the patient (by USB connection), otherwise the information will be lost.
- 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.

Cautions:

- It is strongly recommended that all Ventway Sparrow parts be replaced with parts purchased from Inovytec Medical Solutions Ltd. or an authorized distributor. Use of other parts may damage the unit and void the warranty.
- The ventilator is suitable for noninvasive ventilation for full non-vented ventilation face mask.
- During NIV (Non-Invasive Ventilation) the user must use a capnograph in order to monitor CO2 level of the patient.
- Covering the ventilator is prohibited.
- Ensure that no Latex or natural rubber parts are in patient pathways.
- Do not obstruct the gas intake ports.

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

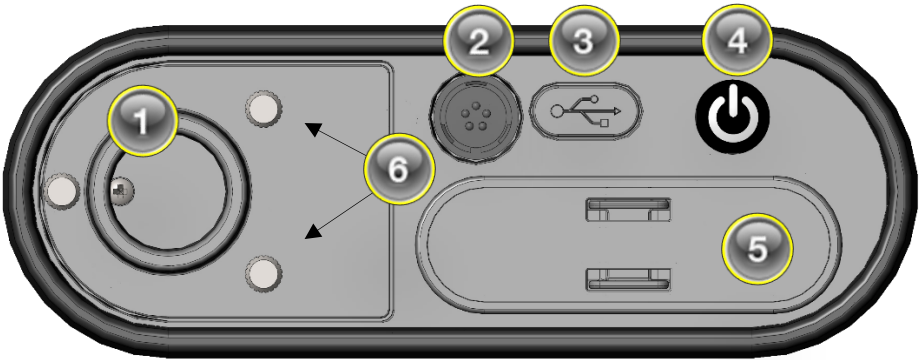
Package contents

1	Ventway Sparrow ventilator
2	User Manual and device documentation
3	Power supply

5.2. VENTILATOR – FRONT PANEL

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

5.3. VENTILATOR – REAR PANEL



*Rear Panel, indicating **(1)** Air/Low pressure oxygen inlet, **(2)** Power supply connector, **(3)** USB connector, **(4)** Power On button, **(5)** Battery pack, (**6**) Filter compartment screws*

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

Note: Item **(2)**, the power supply connector, can accept an external voltage of 18 to 28 volts, regulated.

5.4. VENTILATOR – USE CONFIGURATION

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

5.5. PATIENT CIRCUIT

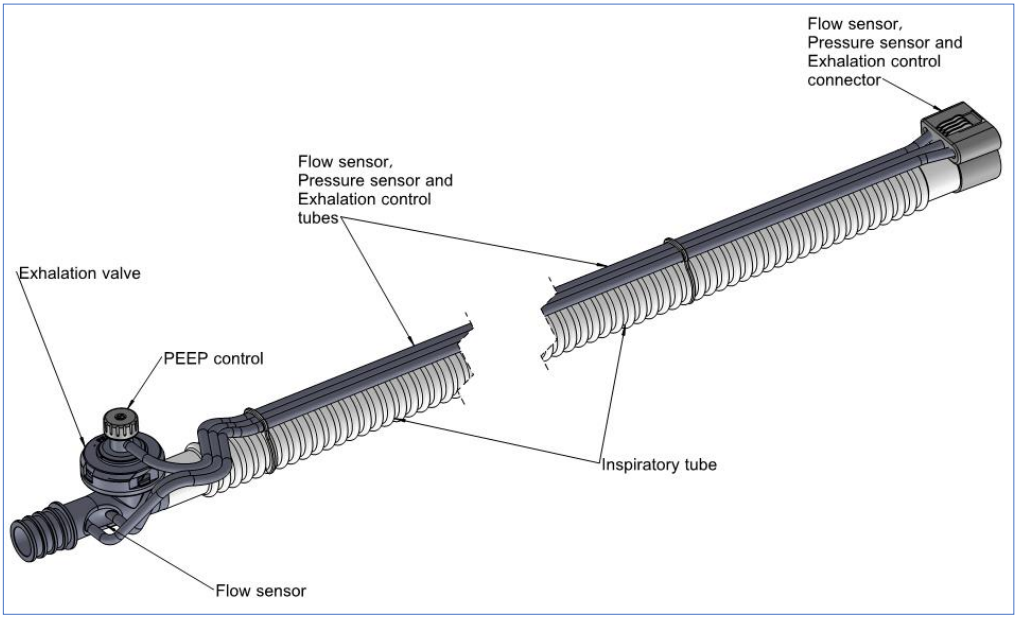


Diagram of patient circuit

Please note that an authorized HME and anti-bacterial filter must be used at all times, in order to protect both patient and ventilator from infections.

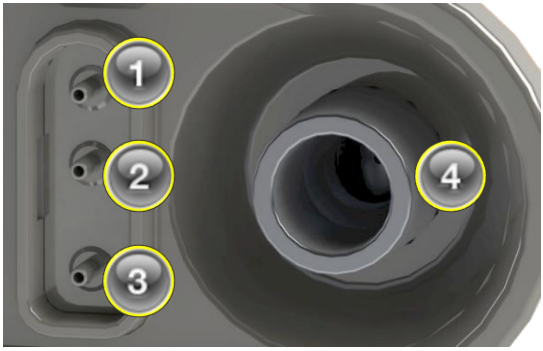
This filter must be assembled between the patient and transducer, or if not possible then between the ventilator outlet and patient circuit 22 mm ID connector.

⚠ **Warning:** All parts of the patient circuit are single-use only and must be discarded after use.

⚠ **Warning:** Antistatic or electrically conductive hoses or tubing are not to be used in the ventilator breathing system.

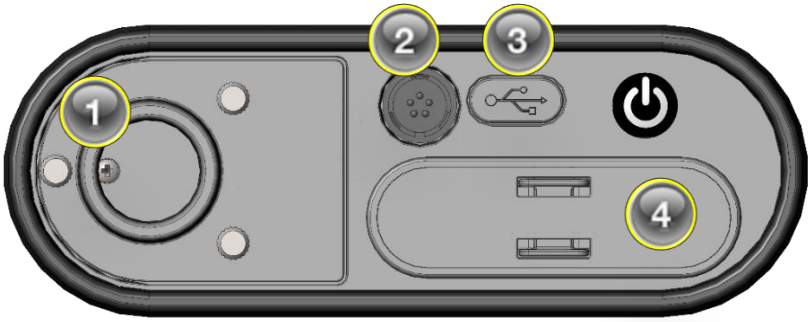
6. CONNECTING THE VENTILATOR

6.1. FRONT PANEL CONNECTIONS



1. **Patient pressure/flow sensor port 1 –** Connect control tube
2. **Flow sensor port 2 –** Connect control tube
3. **Expiratory valve port –** Connect control tube
4. **Patient port**

6.2. REAR PANEL CONNECTIONS

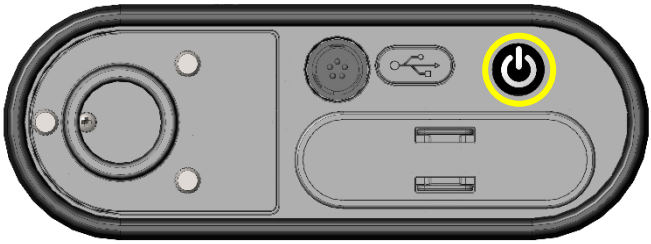


1. **22mm OD connector –** Air inlet and oxygen connector to demand valve (see Section ***9.1.1.1. Connecting the Air Inlet to the Demand Valve***)
2. **DC Power connector –** Connect power line (AC/DC or DC/DC power supply)
3. **USB connector –** This connector is intended for technicians who require access to the logbook and device software
4. **Battery pack compartment**

7. OPERATING THE VENTILATOR

7.1. POWER ON AND DISPLAY STARTUP SCREEN

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

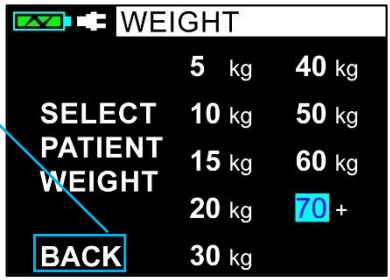


Back panel, indicating the Power On button

7.2. NAVIGATING THE GUI SCREENS

To navigate between the screen options, turn the knob on the left side of the device. When you have navigated to the desired option, press the knob to select the option.

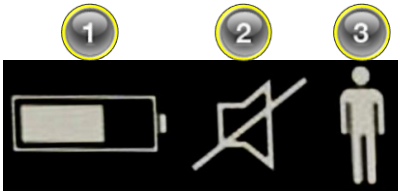
Press **BACK** to return to the previous screen.



Example of a screen with the BACK button

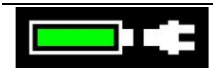
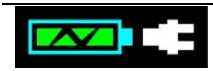
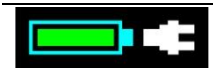
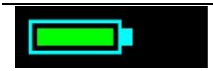
7.3. SYSTEM INDICATORS

The top left corner of the display shows the system indicators.



1. Battery level
2. Alert silence
3. Patient pressure trigger

7.3.1. BATTERY LEVEL

	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

7.3.2. ALERT

Caution: It is the user's responsibility to ensure that the alerts are working properly. See Section ***21. 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.
	Patient trigger icon

7.4. SYSTEM STARTUP – LOGO SCREEN

Note: You should hear a system alert sound during system startup, indicating a valid Circuit Verification test.

The first screen that appears with the logo allows you to identify whether the display is working properly:

Logo screen

7.5. DISCONNECT PATIENT

Initial screen

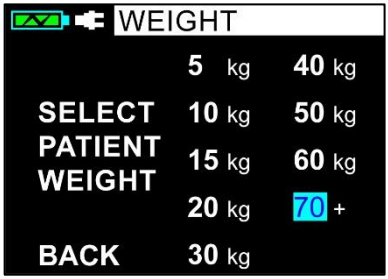
Normal procedure after turning on the device is to disconnect the patient from the device and then press **OK** on this initial screen. The system will activate the blower to test and verify the correct operation of the device.

For details on the **Menu** option, see Section ***7.9. Menu***.

Note: If you select **Menu** instead of **OK**, the **START** option will be unavailable, since the weight of the patient is unknown and ventilation parameters are not set. If you then press **START**, a message displays asking you to set ventilation parameters.

7.6. WEIGHT

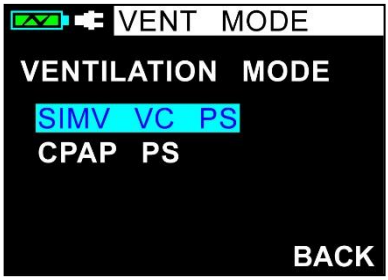
Rotate the scroll knob to select the weight of the patient:



Weight Selection screen

7.7. VENTILATION MODE

Select your initial choice of ventilation mode. You may change the ventilation mode later if desired. See Section ***12. Ventilation Methods*** for details about each ventilation mode.

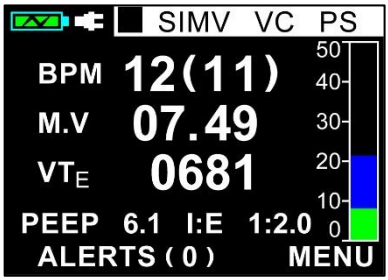


Ventilation Mode screen

If you select ventilation mode SIMV VC-PS, the Ventilation Parameters screen will display.

7.8. VENTILATION PARAMETERS

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



Ventilation Parameters screen

Select **ALERTS** to view the current active (silenced) alerts.
Select **MENU** to display the Menu screen, as shown in Section ***7.9. Menu***.

7.8.1. 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. The sample rate of the pressure value is 10Hz. The pressure is used to determine the end of the current breath in pressure support mode.

Altimeter input is averaged per second and linearly interpolated.

Oxygen percentage correction factor for density is taken from a table.

Flow correction factor is taken from the last performed 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 minute volume is displayed to the user and the value is used for blower speed corrections.

The positive minute volume is used to determine timing of the current breath termination.

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.

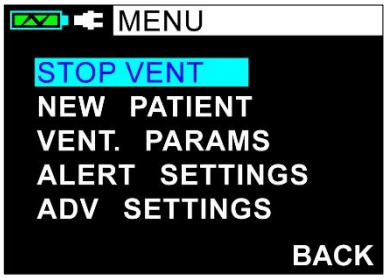
I:E is displayed to the user and is calculated per every breath as the inspiration time divided by the expiration time.

The latest **PEEP** is displayed to the user, and is updated every breath, as the minimum pressure measured during that breath.

PIP is displayed to the user by a bar graph. It is the maximum pressure measured during that breath.

7.9. MENU

The Menu screen allows you to view and set various system values:



Menu screen

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 ***7.10. New Patient (Disconnect Patient Screen)***.

VENT. PARAMS

View patient weight, ventilation mode, and other parameters.

See Section ***7.11. Vent. Params***.

ALERT SETTINGS

Set the thresholds at which the alerts will be triggered. See Section ***7.12. Alert settings.***

ADV SETTINGS

Set advanced settings, such as trigger sensitivity and technician mode. See Section ***7.15. Advanced Settings***.

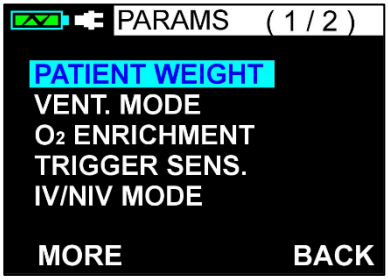
7.10. NEW PATIENT (DISCONNECT PATIENT SCREEN)

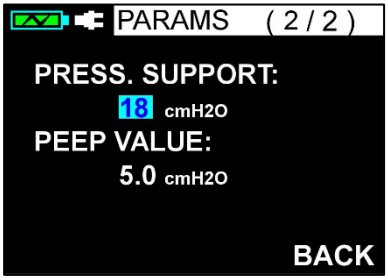
This screen allows you to disconnect an existing patient and reset parameters in preparation for a new patient.

Disconnect Patient screen

7.11. VENT. PARAMS

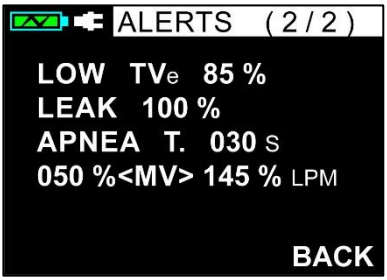
These screens allow you to set the patient weight, ventilation mode, and other parameters.





7.12. ALERT SETTINGS

The Alert Settings screens allow you to set the threshold values for each type of alert.



See also Section ***8. Warning, Alert and Logbook screens*** for examples of warning and alert messages.

7.13. SUMMARY OF ALERT TYPES

The following table summarizes the various types of alerts.

Alert type	Value	Range/Display
User Adjustable	Respiratory rate	High: 4-60 bpm Low: 1-55 bpm
	Inspiratory pressure	High: 4-60 cmH_2O Low: 1-50 cmH_2O
	Apnea	5-120 seconds
	Leak	0-100%
	Low Tidal Volume Delivered	Off or 15%-85%
	Volume Limit Reached	70-2200 mL
	Inverse I:E Ratio	ON/OFF
	Patient Circuit Disconnect (AB-Level mode, for other modes – optional)	ON/OFF
	Alert Volume	0 (off) 1-3
	Pressure limit	10-60 cmH_2O
	Pressure alarm	10-55 cmH_2O
Additional	AC Power Disconnect	Alert silence icon and timer
	Low Battery	Estimated battery energy level
	Empty Battery	Timer off
	Battery Disconnect	Screen Icon (swapping)
	Check Sensor tubes	Screen Icon
	Tube Disconnect	Screen Icon
	High PEEP	Screen Icon
	Service Notice	Screen Icon

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

7.14. SUMMARY OF ALERT LEVELS

Alerts are defined with four levels of importance:

- **Critical**: one beep per second
- **High**: three beeps every five seconds
- **Medium**: one beep every five seconds
- **Low**: one beep one time only. Not shown in list of active alerts.

Alert category	Alert
Critical	Blower malfunction
	Tube disconnect
	Patient disconnect
	Apnea
High level	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
	Volume limit reached
	Low tidal volume
	Low pressure
Low level	Replace filter
	Service needed
	Altitude out of range
	External power connected/disconnected (icon instead of popup message)

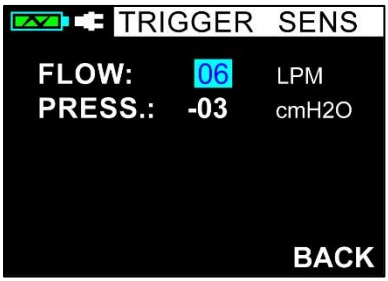
7.15. ADVANCED SETTINGS

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

Advanced Settings screen

7.15.1. TRIGGER SENSITIVITY

Set the trigger sensitivity for the flow and pressure measurements:

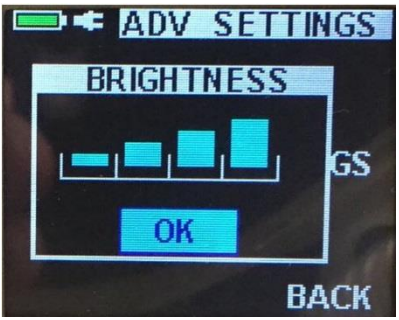


Trigger Sensitivity screen

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

7.15.2. BRIGHTNESS

Change the brightness of the display.

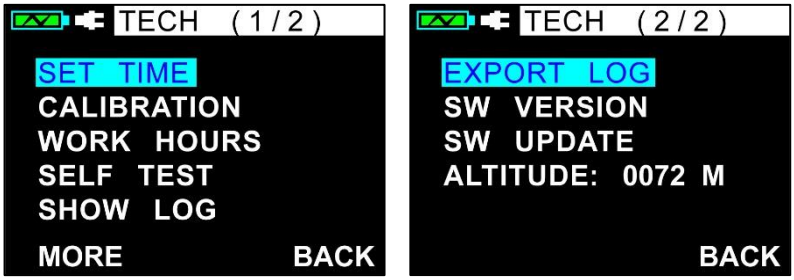


7.15.3. DEFAULT PARAM

Set all parameters to their default values.

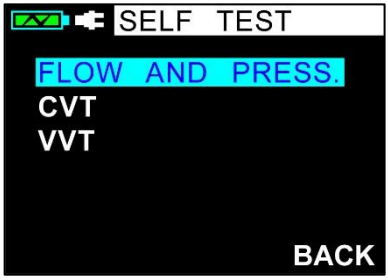
7.15.4. TECH MODE

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



Tech Mode screens

7.15.5. SELF TEST



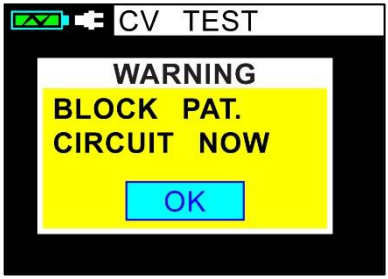
Self Test screen

The Self Test screen allows two tests:

- **FLOW AND PRESS** – See Section ***7.5. Disconnect patient***
- CVT (circuit verification test), see Section ***7.15.6. CVT – Circuit Verification Test***
- VVT (ventilator verification test), see Section ***7.15.7. VVT – Ventilator Verification Test***.

7.15.6. CVT – CIRCUIT VERIFICATION TEST

Follow the instructions on the screen:



CVT screen

Use the plastic caps to seal off the patient transducer and the exhalation valve:

- Press the knob to begin the test. A pop-up appears, indicating the test has begun.
- After several seconds, another pop-up directs you to remove the cap on the exhalation valve, leaving the cap on the patient transducer.
- After the ventilator performs further testing, it will sound an alert. If you can hear the alert, press the control knob to complete the O.V.T.

7.15.7. VVT – VENTILATOR VERIFICATION TEST

Follow the instructions on the screen:

VVT screen

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
- Solenoid valves (two)
- Solenoid safety release mechanism
- Flow performance
- Flow zeroing accuracy
- Battery status
- Watchdog safety device

8. WARNING, ALERT AND LOGBOOK SCREENS

This section provides examples of typical system messages.

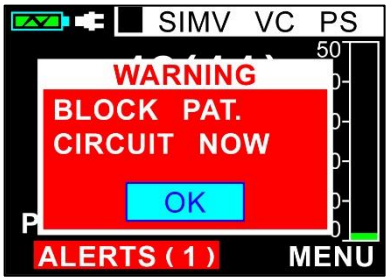
8.1. WARNING

Here is an example of a warning message:

Warning message

8.2. ALERT

A typical alert appears as follows:

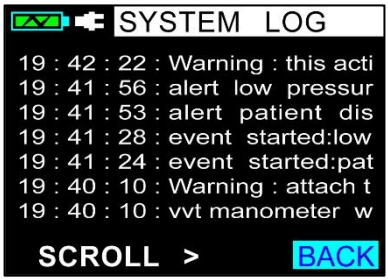


Example of an alert

Note: Press **OK** to acknowledge the message and cancel the alert.

8.3. LOGBOOK

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



Example of an alert

Note: The logbook can be displayed during ventilation. Download is possible only in technician mode.

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

9. DEFAULT PARAMETERS

9.1. START VOLUME VENTILATION

Patient Weight	Rate	Tidal Volume	Max Tidal	Min Tidal (*)	Max. Pressure
(Kg)	(bpm)	(ml)	Vol. (ml)	Vol. (ml)	(cmH2O)
5	35	50	70	30	21
10	30	100	140	60	23
15	25	150	210	90	25
20	20	200	280	120	30
30	18	300	420	280	33
40	16	400	560	240	35
50	14	500	700	300	40
60	12	600	840	360	40
70+	12	700	980	520	40

***Note:** Min tidal volume is relevant only in cases where there are patient trigger breaths, or the pressure limit is reached before nominal tidal volume was delivered.

9.1.1. 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.

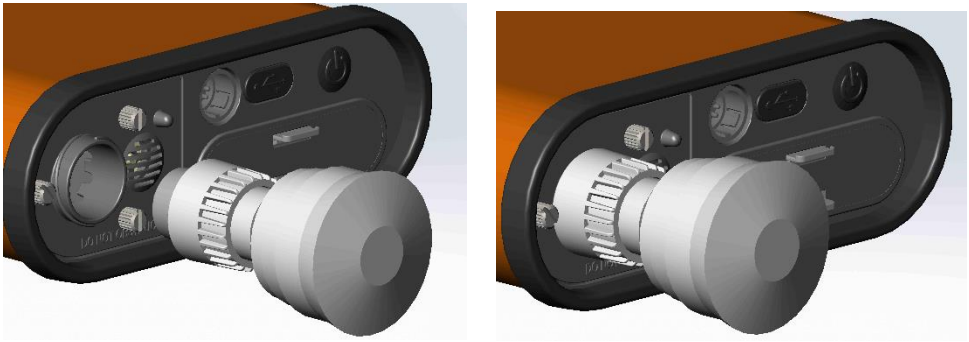
Adjust the flow of oxygen to reach the desired value of FiO_2. Select the "O2 ENRICHMENT" option in the **VENT. PARAMS** menu. The FiO_2 value must be measured with a calibrated external oxygen analyzer.

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 90% and 100% 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).

9.1.1.1. CONNECTING THE AIR INLET TO THE DEMAND VALVE

The oxygen demand valve is connected to the device as shown below.



Connecting the oxygen demand valve to the air inlet connector

9.1.2. 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 90% Oxygen at the patient port: 45 [S] 4[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.

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

Alert Parameter	Weight								
	5kg	10kg	15kg	20kg	30kg	40kg	50kg	60kg	70+ kg
Pressure Alert (cmH_2O)	21	23	25	30	33	35	40	40	40
Pressure Limit (cmH_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

9.3. 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

10. LABELS AND SYMBOLS

10.1. 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

10.2. 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
	Type BF Applied Part
	Direct current
	Do not dispose of, contact for recycling
FC	FCC Symbol
Rx	Caution: law prohibits dispensing without prescription
	Caution, consult accompanying documents

11. 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.

To disinfect the ventilator, clean with 70% medical grade alcohol using a dampened soft towel or wipe for two minutes.

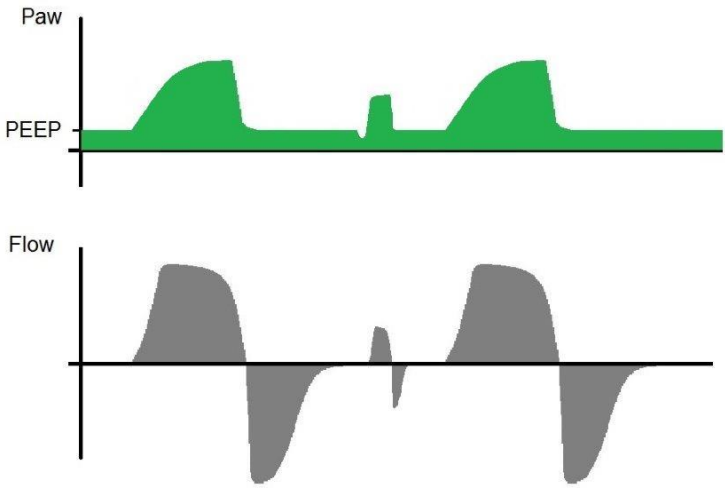
12. VENTILATION METHODS

12.1. SIMV-VC (PS)FLOW CHART

In VC-SIMV, 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.

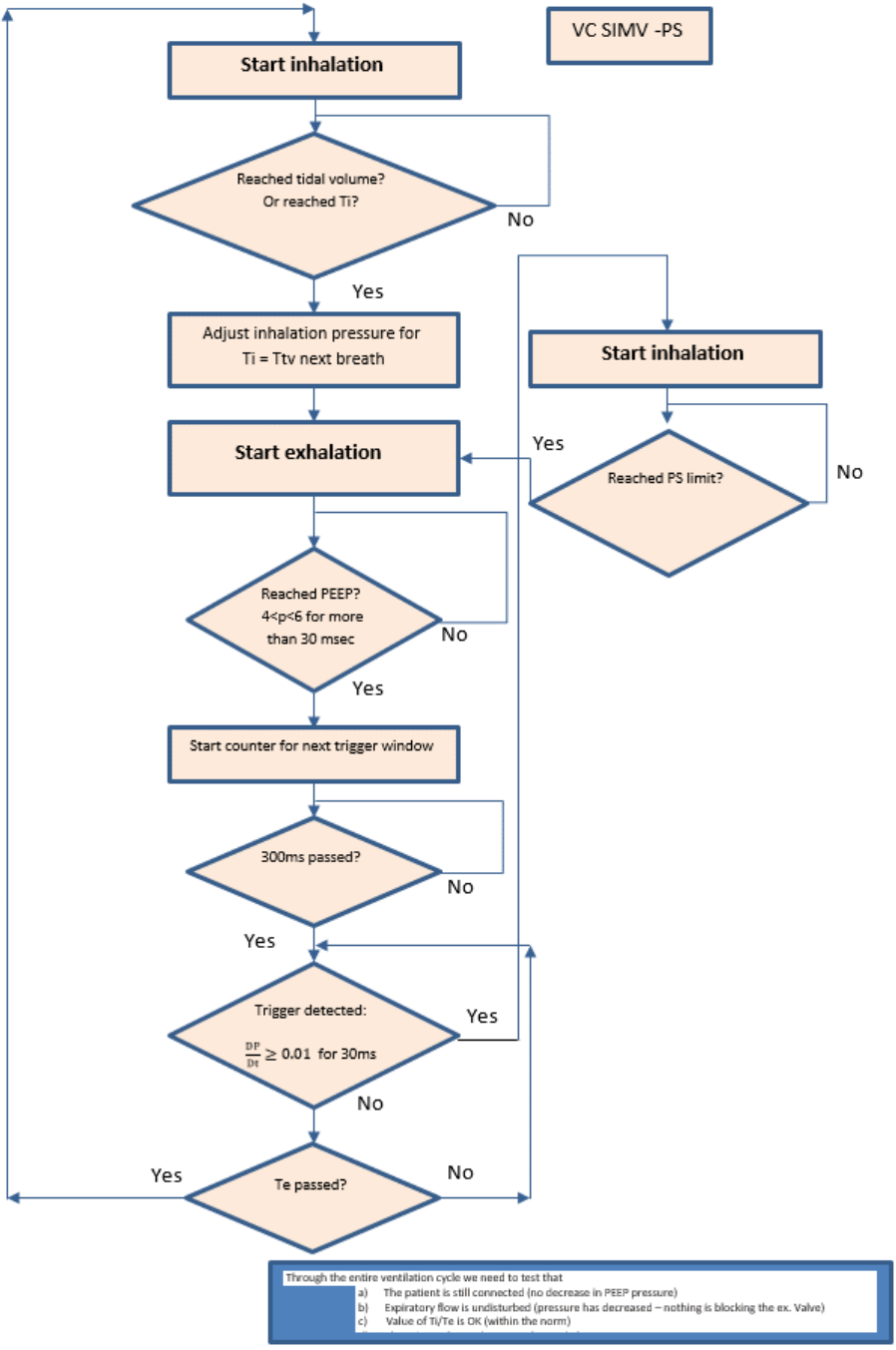
Please note:

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.

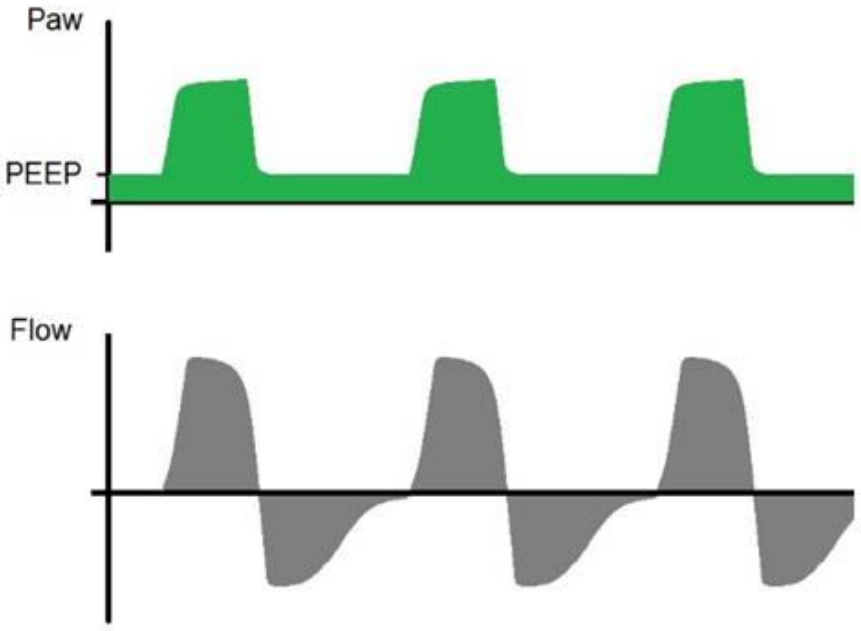
The mandatory tidal volume (VT) results from the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. Pinsp is the inspiratory pressure (pressure in the lung throughout the inspiratory cycle). If the lung mechanics changes (pressure, water in the lungs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

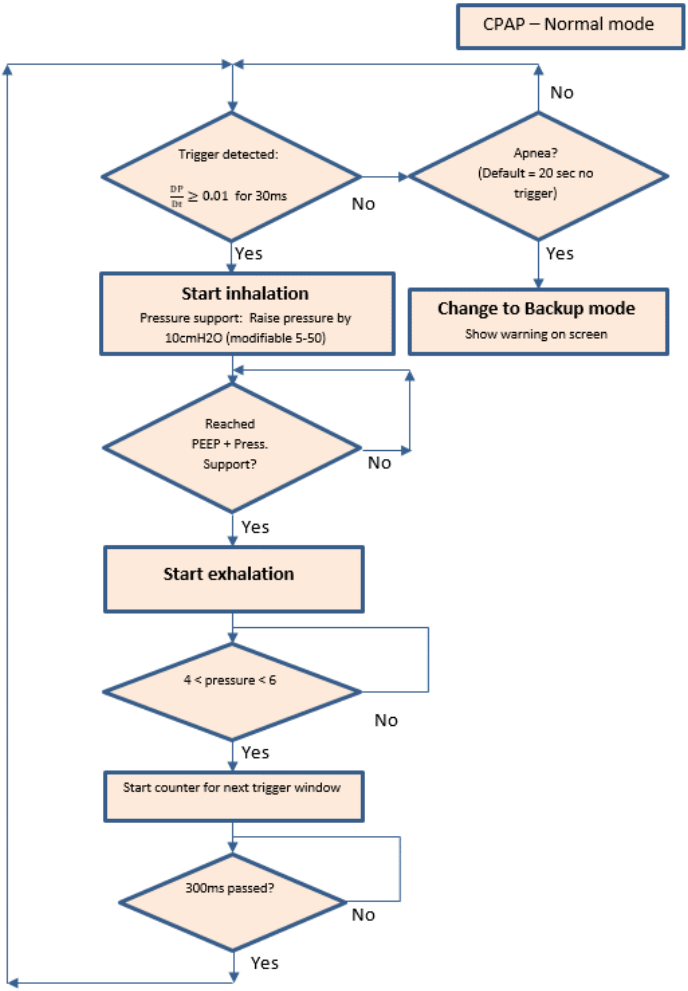

VC SIMV -PS
Start inhalation
Reached tidal volume?
Or reached Ti?
No
Yes
Adjust inhalation pressure for
Ti = Ttv next breath
Start exhalation
Reached PEEP?
4<p<6 for more
than 30 msec
No
Yes
Start counter for next trigger window
300ms passed?
No
Yes
Trigger detected:
$\frac{DP}{Dt} \geq 0.01$ for 30ms
Yes
No
Yes
Te passed?
No
Start inhalation
Yes
Reached PS limit?
No
Through the entire ventilation cycle we need to test that
a) The patient is still connected (no decrease in PEEP pressure)
b) Expiratory flow is undisturbed (pressure has decreased – nothing is blocking the ex. Valve)
c) Value of Ti/Te is OK (within the norm)

12.2. CPAP – SPONTANEOUS BREATHING MODE

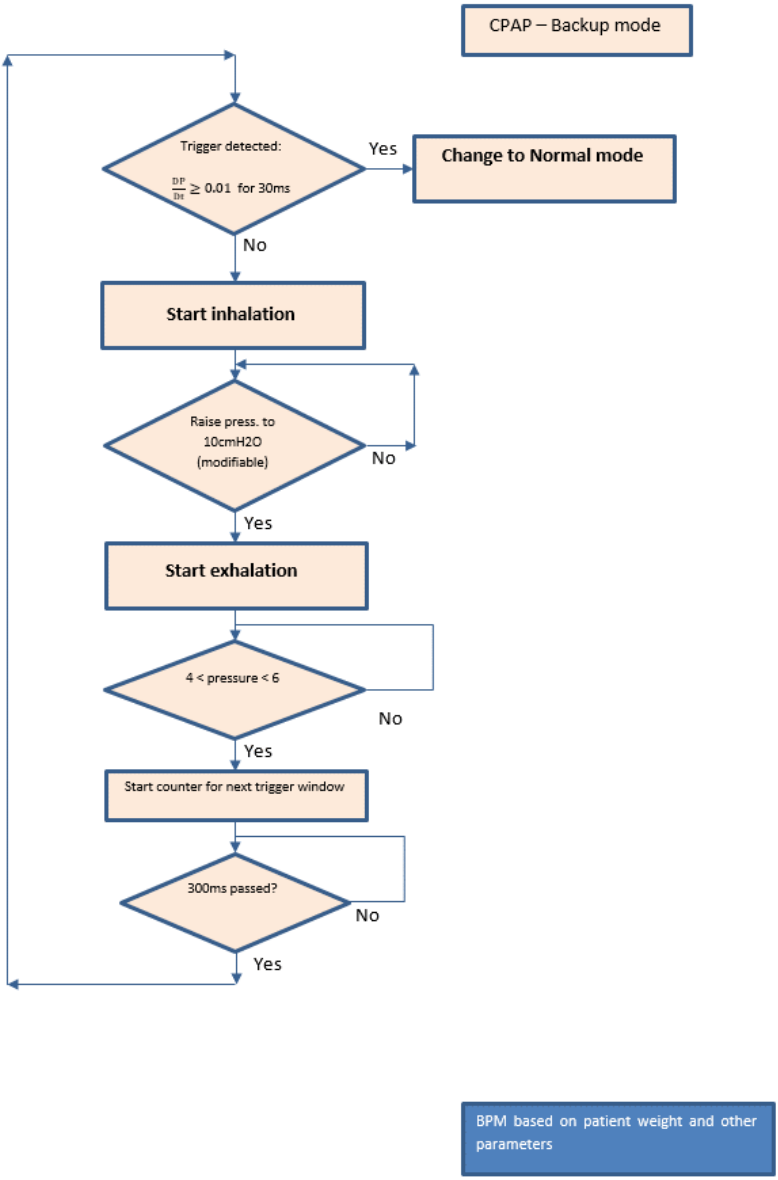
During the spontaneous ventilation modes, the patient carries out the majority of the breathing effort. The pressure support ventilation level PS can be adjusted. The default PSV level is 10 cm H_2O.

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 (V_{TI}).




CPAP – Normal mode
No
Trigger detected:
$\frac{DP}{Dt} \geq 0.01$ for 30ms
No
Apnea?
(Default = 20 sec no trigger)
Yes
Yes
Start inhalation
Pressure support: Raise pressure by 10cmH2O (modifiable 5-50)
Change to Backup mode
Show warning on screen
Reached PEEP + Press. Support?
No
Yes
Start exhalation
4 < pressure < 6
No
Yes
Start counter for next trigger window
300ms passed?
No
Yes

CPAP Backup ventilation



12.3. 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. Patient is ventilated in CPAP mode and does not initiate any spontaneous breaths for more than 30 seconds.
2. Patient is connected to the ventilator, and for some reason, the user did not start ventilation after connecting the patient.
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.

1. Backup Ventilation in CPAP

If during CPAP ventilation, the patient stops initiating spontaneous breaths for more than 20 seconds--> Apnea alert appears. If the patient does not initiate a spontaneous breath for an additional 10 seconds (total of 30 seconds), then backup ventilation is initiated:

-Screen displays an alert: "Backup Ventilation Started" and "OK" button for user approval appears. Ventilation will start even if user has not pressed **OK**. Alert will appear on screen for 10 seconds while audio prompt is activated.

- BPM = patient weight based
- 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.
- Every 30 seconds an alert is issued "Backup ventilation active"-- "OK".

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 (pressure -2.5 cm H_2O or -5 lpm or greater) was sensed.

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

- "Backup ventilation mode" alert is activated - "OK" appears on screen. User approval does not prevent going into backup mode.
- " Backup ventilation mode" icon appears on top of screen after 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 cmH_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]
50-70	5
71-140	10
141-210	15
211-280	20
281-420	30
421-560	40
561-700	50
701-840	60
Over 841	70+

5. Evaluating patient weight will establish the other ventilation parameters as per a more complete table given in the URS/SRS, including max. TV, BPM etc.

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.

- Every 30 seconds 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 issued 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".

13. 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 does not require maintenance or service on a routine basis, except as suggested in this User Manual. Service should only be provided by an authorized Inovytec Medical Solutions Ltd. representative.

13.1. DEVICE CALIBRATION AND SOFTWARE UPGRADES

Calibration and upgrade of the software are performed by the factory, or in technician mode using a password provided by Inovytec.

14. 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

15. SPECIFICATIONS

15.1. DIMENSIONS AND WEIGHT

Width	165 mm
Length	167 mm
Height	60 mm
Weight	Civilian version: 1 kg with batteries
	Military version: 1.2 kg with batteries

15.2. ENVIRONMENTAL SPECIFICATIONS

Operating Temperature	-15 °C to 50 °C (5 °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	IP IP45 (with oxygen enrichment)
Atmospheric Pressure	700 hPa to 1060 hPa
Altitude	-370 meters to 4500 meters
Total External Sound Level	54 dBa at 0.6 meter distance

15.3. POWER SUPPLY

External AC-DC Adapter	Input 100 to 264 VAC, 50-60 Hz, max 1.6 A Output 16-24 VDC , 120 W
External DC-DC Car adapter	Input 10 to 32 VDC Output 16-24 VDC , 90W
Internal Battery	8 x CR123 cells for 12VDC configuration (2 x 4S1P)
	4 x 18650 Li-Ion for 14.8VDC rechargeable configuration (4S1P)
Recharge Time	6 hours
Operating Time (internal battery)	4 hours

15.4. VENTILATION PERFORMANCE

Respiratory Rate	1 – 12 ±1, 12 – 50 ± 2 bpm
Tidal Volume	50-1800 mL
Accuracy of Respiratory Volume Measurement	±15% + 4 ml
Inspiratory Pressure Limit	5 to 65 cmH_2O
Inspiratory Time	0.3 to 3 ±10% sec
Peak Flow (PIF)	150 ±10% L/min Spontaneous to 180 ±10% L/min
Oxygen Mix (FiO_2)	21% to 95% ±5% O_2
PEEP	5 to 10 cmH_2O ±1,
Trigger Sensitivity	-2.5 to 10 cmH_2O Pressure, Off
PS	5 to 50 cmH_2O
Controlled Pressure	5 to 65 cmH_2O
FiO_2 low pressure enrichment	21% to 100% (low and high pressure oxygen source)

15.5. STANDARDS AND SAFETY REQUIREMENTS

The Ventway Sparrow meets or exceeds 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
ISO 80601-2-12	Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
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
RTCA DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment
EN 1789	Medical vehicles and their equipment. Road ambulances

16. CLEANING AND ROUTINE MAINTENANCE

Part	Procedure	Comments
Ventilator	Wipe exterior clean with a damp cloth and mild detergent.	Do not allow liquid to penetrate into the ventilator.
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.

17. BATTERIES

The Sparrow can be configured with two battery options: an internal, re-chargeable, non-removable battery pack, and a removable battery pack. The battery should be charged or replaced when not in use.

17.1. 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.

Note: If charging at temperatures over 30°C, charging time may be extended.

Shelf life: 4 years. First time charging: 6 hours
Permissible charging temperature range: -20°C to 50°C (-4°F to 122°F)
Permissible temperature range for long-term storage: 10°C to 30°C (50°F to 86°F)

Charge Interval: 6 months in standard temperature and pressure
Shelf life: 4 years or 1000 cycles at 25°C (77°F). A cycle is defined as one charge and one discharge.
Max discharge current 10[A]
Permissible charge temperature range: -10°C to 45°C (14°F to 113°F)
Permissible discharging temperature range: -20°C to 60°C (-4°F to 140°F)
Storage temperature for shipping state (about 40% capacity of fully charged state):

1 month	-30°C to 60°C (-22°F to 140°F)
3 month	-20°C to 45°C (-4°F to 113°F)
1 year	-20°C to 20°C (-4°F to 68°F)

Non-Rechargeable batteries

Shelf life: 5 years. Long term storage: -20°C to 30°C (-4°F to 86°F)

18. 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 distributor. For a list of Inovytec Medical Solutions Ltd. distributors please visit our web site at sales@Inovytec.com.

When ordering parts, specify the serial number of your unit and the part number of the item(s) you are ordering. A schedule of part numbers may be found in the Equipment and Accessory Inventory list 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

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.

19. REGULATORY

Manufacturer:

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 0086

20. 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 you need to ship the device, 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.

21. 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.

21.1. BACKUP VENTILATION

Step	Procedure Action	Expected Results
1	Start a new patient via the menu. Set the lung simulator simulated weight to 50 kg.	Message requesting to disconnect the patient.
2	Generate inhalation trigger.	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. 50 kg. The software keeps indicating that it is in backup ventilation mode. The software instructs the user to perform patient circuit test (via the menu).
6	Stop ventilation.	Ventilation stops.

21.2. START BACKUP VENTILATION WITH UNKNOWN WEIGHT

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 inhalation trigger.	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. The software instructs the user to perform patient circuit test (via the menu).
6	Stop ventilation.	Ventilation stops.

21.3. 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 **Te** 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 after PEEP reached, generate inhalation trigger.	Trigger is detected & inhalation phase starts (Inspiratory control valve opens and exhalation valve closes). The software switches back to CPAP normal mode.

21.4. 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.	Mode is set. The blower starts. The software switches to running ventilation, in CPAP mode.
3	Decrease PEEP to PEEP -2.	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.

21.5. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Increase PEEP above the limit.	The software indicates to the user that PEEP is above the PEEP limit.
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.

21.6. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease the expiratory flow.	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.

21.7. 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 inspiration 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 inspiration 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.

21.8. 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.

21.9. 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.

21.10. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Slowly decrease the Tidal volume (TV) to 70%.	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.	TV is disabled.
7	Slowly decrease the Tidal volume (TV) to 50%.	Alarm is not set.

21.11. 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.	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.	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.	The software doesn’t issue an alert.

21.12. 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.	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.

21.13. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Disconnect the ventilator from the power.	The software indicate Power is disconnected.
4	Inspect the battery level.	Battery level is indicated to the user.
5	Reconnect the ventilator to power.	The software indicate Power is connected.

21.14. 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.	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 indicate *CriticallyLowBattery* level.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

21.15. BATTERY TYPE 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	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.

21.16. 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.	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 indicate Power is below range (“Low Voltage” alert), and switches to battery power.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

21.17. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Simulate a Device temperature above *MaxAllowedTemperature*.	The software indicate that the temperature is above range.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

21.18. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Disconnect the tube.	The software indicate that the tube is disconnected.
4	Silence the alert.	Alert indication on the screen, but alert is silenced.

21.19. SERVICE REQUIRED ALERT

Step	Procedure Action	Expected Results
1	Edit the file WH.txt on the SD-card with value 0	
2	Start up the Sparrow ventilator.	The software indicate that a service is required.
3	Silence the alert.	
4	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
5	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.
6	Open alerts option in running ventilation screen	See that there is no alert for service required.

21.20. FILTER REPLACEMENT REQUIRED

Step	Procedure Action	Expected Results
1	Edit the file WH.txt on the SD-card with value 882000.	
2	Start up the Sparrow ventilator.	The software indicate that a filter replacement is required.
3	Silence the alert.	
4	Start up the Sparrow ventilator. Complete the patient circuit test.	The software switches to the ventilation phase, weight selection screen.
5	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.
6	Open alerts option in running ventilation screen	See that there is no alert for service required.

21.21. 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.	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.
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.
6	Silence the alert.	Alert indication on the screen, but alert is silenced.
7	Change the altitude to be inside the *AltituteRange*, at the lower limit. Measure air density.	The air density is correctly compensated for the defined altitude.
8	Change the altitude to be inside the *AltituteRange*, at the upper limit. Measure air density.	The air density is correctly compensated for the defined altitude.

21.22. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Shut the device down by long press on the on/off button.	The software requires confirmation for shutting down.
4	The device starts playing a tone until an extra confirmation.	The device shuts down.

21.23. 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.	Mode is set. The blower starts. The software switches to running ventilation, in SIMV mode.
3	Put the device in standby via the menu.	The blower stops.
4	Generate inhalation trigger.	The blower starts. The software switches to the running ventilation screen, continuing the previous ventilation with the same parameters.

22. APPENDIX – MENU HIERARCHY

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