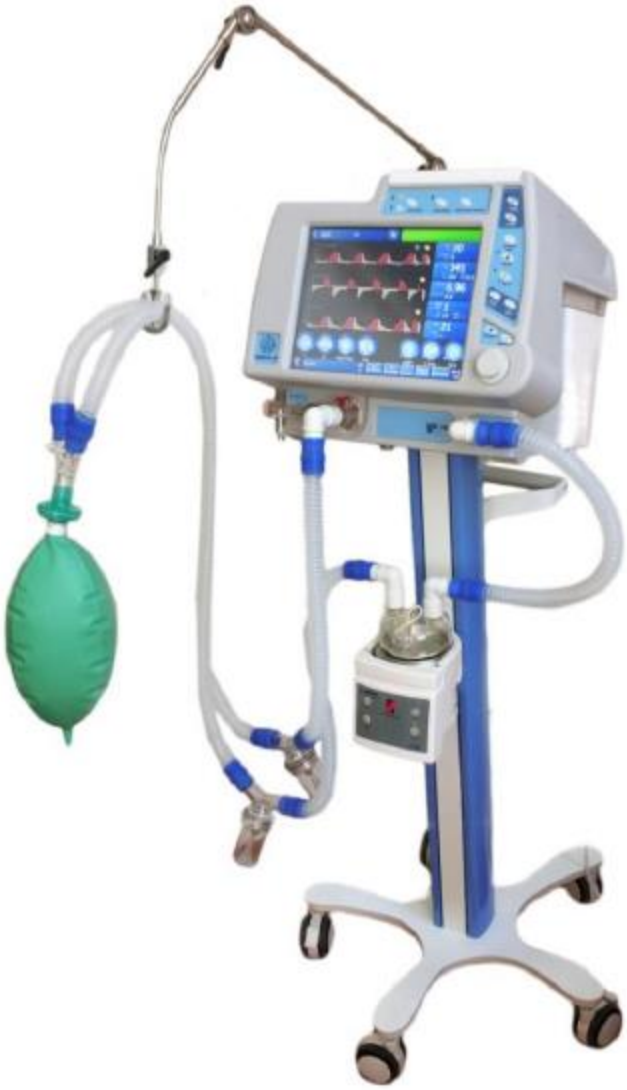
JSC Ural instrument-engineering plant
Lung ventilator
AVENTA-M

**Operator's manual**
R51.00.000RE



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Contents

# Warning and information for security

This section contains the important information for security relate to the general situations of using a lung ventilator AVENTA-M (hereinafter-ventilator). Another comments for security are in relevant sections of the present Manual.

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1. Before operation read this manual, the instruction to the additional equipment and all warning information in bold

2. Staff not younger than 18, trained and certified, who have passed the appropriate safety training, and have 1 qualification group for electrical safety, can operate the ventilator. Ventilator's operation must be supervised by a qualified medical personal who can react when an alarm occurs, who can help when the ventilator is fault or can offer alternative method of artificial ventilation.

3. Lack of alternative methods artificial ventilation such as self-inflating, hand control, reanimation device with mask can become a cause of a patient's death.

4. Non-observance of the operating rules may lead to a deterioration in the operation of the ventilator, to a disruption in its operability, a risk to patient safety, and lead to the voiding of the warranty.

5. Before operation check the condition of the ventilator and the component parts. Do not operate a defective ventilator! If a fault of the ventilator is detected, immediately switch off the ventilator from the patient and contact customer service.

6. Sternly monitor the correct assembly of the respiratory circuit. An incorrectly assembled respiratory circuit can lead to a malfunction of the ventilator and, above all, to a loss of respiratory volume.

7. Do not block intake holes of gas that lead to disruption of patient's ventilation.

8. Additional nozzle or another component, or subassembly for respiratory circuits of ventilator can change falling of pressure to the respiratory circuit. Such changes in respiratory circuit can have a negative impact to the functional characteristic of the ventilator.

9. Spraying or humidification may increase the resistance of the respiratory circuit filters. The operator must check the respiratory circuit filters as often as possible for increased resistance and blockage.

10. Prohibit to combine ventilator operation together with sources of explosive gas anesthetics.

11. Do not use the ventilator with nitrous oxide.

12. Do not use the ventilator with helium or helium mixtures.

13. Ventilator's Respiratory circuit, its parts and equipment must not contain phthalates which classified as carcinogenic, mutagenic or toxic to reproductive function.

14. Gases added by the Nebulizer`s using may affect the accuracy of the ventilator`s operation.

15. Do not cover the ventilator to avoid negative effects on the equipment operation.

16. The ventilator is a device with large flow values and must be connected to pipelines which were designed with using an uniformity ratio that takes into account the indicated high flow values in a certain number of exits to prevent an excess of the design pipeline flow, thereby minimizing the risk that the VENTILATOR will interfere with the operation of connected equipment .

17. The ventilator can be located in an optimal position for the patient, to avoid any delays, which are an integral part of a dangerous situation.

18. The ventilator must be located so as not to create difficulties when working with the separation device.

19. The operator who services the VENTILATOR must wear medical gloves and be directly in front of the display block to avoid any delay that is an integral part of a dangerous situation.

20. Maintenance should only be carried out by specially trained, highly qualified service personnel certified by the manufacturer of the device JSC Ural instrument-engineering plant (UIEP). Training must be necessary as for operators and so for a representative from a responsible organization.

21. Any interference into the ventilator`s design and ventilator's repair by third party is prohibit

22. Ventilator operator carries out an exclusive responsibility for any fault that happened in result of serving or ventilator repairing by unqualified personal.

23. If a fault appears, check that the respiratory circuit is correctly assembled, refer to the section "Possible faults and methods for their elimination" and call a service engineer if necessary.

24. Before device's serving or cleaning disconnect it from network.

25. Prohibit do any maintenance service, any repairing or regulated work before switching a devise off from a patient.

26. The ventilator is not intended for use in a pressure chamber! The pressure chamber can affect the operation of the device, that endangers the life of the patient.

27. The ventilator is not intended for use during the magnetic resonance scanning (MRI, MRT, NMR, NMI)! A source of electromagnetic waves can have an effect on the devise's operation, that endangers the life of the patient.

28. Prohibit to use a mobile phone is nearer as 10 m from the ventilator. The mobile phone can have an effect on the device's operation, that endangers the life of the patient.

29. Do not use antistatic or electricity hoses and pipes.

30. The device does not provide materials and components whose impact could lead to unacceptable risks for both the patient and the operator.
31. Keep this manual instruction next to the device and periodically review the sections according to the safety rules.

# 1. Intention of ventilator, indication and contraindication for using

The present Operation Manual will allow you to get acquainted in details with all the features, provided by the Ventilator for high quality ventilation of patients

## 1.1. Intention of the ventilator

The present Operation Manual is applicable to the lung ventilator AVENTA-M by TU 32.50.21-009-07509215-2019 (hereinafter referred to as Ventilator), for intensive therapy of adults and children.

The ventilator designed to promote controlled and support artificial lung ventilation (LV) of adults and children in weight from 3 until 150 kg., according to the Body Mass Index (IMT), in operating clauses, intensive care unit of medical facilities.

The ventilator provides the Operator with a wide choices of ventilation modes and parameters. This allows for perform high-quality lung ventilation.

The ventilator does not require an external source of compressed air and uses by means of internal turbine the ambient air entering the device through a filtration system and bacterial anti-virus protection.

The ventilator is equipped with a pneumatic oxygen drive. The ventilator uses an active exhalation valve, which allows to perform the most advanced ventilation modes and methods of delivering the gas mixture to the patient.

The ventilator has automatic control of basic and main flows by means of internal and external flow sensors.

In order to give a moisture and heat of the gas mixture, the ventilator is equipped with a humidifier with a set of consumables.

For humidification and heating of the gas mixture, the ventilator is equipped with a humidifier with a set of consumables.

The device provides monitoring of all fundamental parameters of the patient's breathing and respiratory mechanics, including monitoring the carbon dioxide content in the exhaled mixture (EtCo2) and monitoring the oxygen saturation of hemoglobin in arterial blood (SpO2).

Convenient interface with Operator is provided by the presence of high-quality high-resolution color display, a touch screen and a special encoder (shuttle) for quick

input of information.

To alert the Operator about the danger the ventilator has a three-level system of visual and sound alarm.

## 1.2. Requirement to the service personnel.

Personnel must be at least 18 years old, trained and certified, who have passed the appropriate safety training and have 1st qualification group for electrical safety, who studied the operational documentation.

The device must be operated under the supervision of qualified medical personnel who are ready to assist in the event of malfunctions in the device.

Attention! Use medical gloves when handling this machine.

## 1.3. Indication for using the ventilator.

- lack of spontaneous breathing (apnea)
- acute respiratory rhythm disturbances, pathological rhythms, agonal breathing
- respiratory rate of more than **40 per minute**, if it is not associated with hypertension (body temperature above 38.5 ℃) or severe hypovolemia;
- clinical signs of increasing hypoxemia with decreased **PaO2** below **60 mm Hg** and / or increased hypercapnia **PaCO2** if they do not disappear after conservative measures (analgesia, restoration of airway conduction, oxygen therapy, elimination of life-threatening levels of hypovolemia, gross metabolic disorders) or assisted ventilation in a "non-invasive" way.

## 1.4. Contraindication for using the ventilator

- hemodynamic instability (hypotension, cardiac arrhythmia, myocardial infarction);
- depression of the consciousness level, inadequacy of the patient;
- high risk of aspiration;
- abundant and/ or viscous sputum;

- recent surgical operation in the maxillofacial or gastroesophageal zone;
- maxillofacial injury;
- abnormal development of the nasopharynx;
- burns;
- extremely massive obesity.

## 1.5. The potential adverse effects of the ventilator

By the nature and localization of complications, side effects can be divided into four groups:

- the lungs (atelectasis, pneumonia, pneumothorax);
- the respiratory tract (stenosis of the trachea, tracheoesophageal fistula, bedsores of the mucous membrane of the trachea, tracheobronchitis);
- the cardiovascular system (lowering blood pressure, sudden cardiac arrest, vascular bleeding);
- through the fault of technical errors of the system.

In order to weaken the side effects of the use of lung ventilator, special rules have been developed at present:

- inhalation is shorter than exhalation (with manual mechanical ventilation - and pauses after it);
- do not maintain positive pressure on the breath for longer than necessary;
- respiratory resistance should be low (when exhaling, this is ensured by a drop-in pressure, in maintaining the bag in a half-bloated state (with manual ventilation), as well as the use of bronchodilators);
- create a fast gas stream by squeezing the bag smoothly, but quite energetically;
- minimize “dead space”.

The choice of ventilation parameters is not based on feedback from a specific organism and is indicative, therefore, suggests the possibility of various violations.

# 2. List of accepted abbreviation and arbitrary notations

The list of accepted abbreviations and arbitrary notations according to the text is given in table 2.1, written on the ventilator - in table 2.2, packaging - in table 2.3

Table 2.1

| **Notation** | **Definition** |
|---|---|
| A/C | Ventilation mode Assist/ Control Support/Mandatory lung ventilation, analogue of Control Mandatory Ventilation (CMV) |
| APRV | Inhalation support with the release of the pressure (APRV-airway pressure release ventilation) |
| Auto-MVG | Adaptive ventilation mode providing a set minute ventilation volume (analogue of ASV TM) |
| APNEA | Mandatory breath delivery mode |
| Cstat | Static compliance displays estimated tensile value of patient's lungs |
| CMV | Control mandatory ventilation |
| CPAP | Mode of breath support by means of Continuous positive airway pressure |
| DUAL-LEVEL | Mode ventilation that synchronizes two pressure levels with attempts of spontaneously the patient inhales (analogue of BiLevelTM) |
| BTPS | The standard conditions of environment |
| STPD | All volumes, flows and leaks connected with the breathing circuit are expressed in the STPD system (standard temperature and pressure, dry air - standard temperature and pressure, dry) |
| Esense | Expiratory sensitivity (for spontaneous breaths) |
| ET | Endotracheal tube |
| EtCO2 | Carbon dioxide content at the end of exhalation |
| EtO2 | The content of oxygen at the end of exhalation |
| f | Frequency of mandatory breaths (assigned by the Operator) |
| f_tot | Measured total frequency of the patient’s breathing |
| f_spont | Measured frequency of spontaneous patient’s breaths |

| | |
|---|---|
| **Notation** | **Definition** |
| FiCO2 | The content of carbon acid in inhaled mixture |
| FiO2 | Percent rate of oxygen content in inhaled mixture |
| F-Trig | Flow Trigger sensitivity (set by Operator) |
| I: E<br>Ti:Tie | The ratio of time inhalation and exhalation<br>The ratio of inhalation to the duration of the respiratory cycle |
| MV_tot | Minute volume |
| MV_ spont | Minute volume of spontaneous breath |
| PC | Type of mandatory inhalation with pressure control (pressure control) |
| NIV | Non-invasive ventilation (by using mask) |
| PC-VG | The type of mandatory inhalation with pressure control with a guaranteed delivery of preset volume. |
| Pmean | Average pressure in breathing circuit in the last minute |
| Ppeak | Peak (maximum) pressure in the last cycle of inhalation and exhalation. |
| PEEP | Positive pressure at the end of inhalation |
| PEEPH | High pressure level in mode DUAL-LEVEL |
| PEEPL | Low pressure level in mode DUAL-LEVEL |
| Pi | Inspiratory pressure (set by the operator for PC inhalation) |
| Ppl | Pressure plateau (measure parameters) |
| PR | PulseRate- pulse rate (measure parameters) |
| Pramp | Rise time pressure until target level (set by the Operator ) |
| PS | PressureSupport-Pressure Support<br>(type of supporting of spontaneous inhalation) |
| PS-VG | Pressure support with guaranteed delivery of preset volume (supporting type of spontaneous inhalation) |
| Psup | Pressure support of spontaneous inhalations (set by the Operator) |
| P-Trig | Sensitivity trigger according to pressure (set by the Operator) |
| Rstar | Static resistance |
| SIMV | Ventilation mode SIMV<br>Synchronous Intermittent Mandatory Ventilation |

| | |
|---|---|
| **Notation** | **Definition** |
| SPONT | Mode of spontaneous breath |
| SpO2 | Oxygenation of arterial blood hemoglobin (measured parameters) |
| Ta | Interval Apnea (set by the Operator) |
| Te | Exhalation duration |
| TH | Duration of the high-pressure phase in mode DUAL-LEVEL ( set by the Operator) |
| Ti | Time of inhalation (set by the operator) |
| TC | Compensation resistance of the incubatory tube. |
| TL | Duration of the low-pressure phase in mode DUAL-LEVEL ( set by the operator) |
| Tpl | Duration Plateau (set by the operator) |
| Trach | Tracheostomy tube |
| VC | Type of mandatory inhalation with the volume control (Volume Control) |
| PeakFlow | Peak Flow (set by the operator for VC inhalations) |
| VT | Tidal volume (set by the operator) |
| Vte | Exhalated volume (measured by the ventilator) |
| VTi | Inhalated volume (measured by the ventilator) |
| Age | Age |
| IMS (Body mass index) | Body mass index |
| MAS | Mass of a body |
| ARDS | Acute Respiratory Distress Syndrome |
| COBD | Chronic obstructive pulmonary disease |
| CSF | Intracranial hypertension |
| Hypovolemia | Dehydration or blood loss |
|  | Warning sign |

| | |
|---|---|
| **Notation** | **Definition** |
|  | Sign of execution of Operator's Manual |
|  | Sign of mandatory activities |
|  | Operator`s Manual |
|  | Symbol for security notation – nonionizing radiation |

**Table 2.2**

| **The notations on the ventilator and another equipment** | **Definitions** |
|---|---|
|  | Sign of compliance in the mandatory certification |
|  | Working part type B.<br>The symbol for notation of goods class. |
|  | Working part type BF.<br>The symbol for notation of goods class; a sensor connection place SpO2 (pulse oximeter), CO2 (capnometry) |
|  | Secondary use prohibit . |
|  | Mass of the most often using configuration of ventilator. |
|  | Utilization with domestic waste is ban |
|  | Manufacturer |
| IP21 | Degree of protection provided by coats |

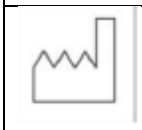
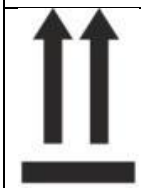
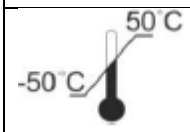
| | |
|---|---|
| **The notations on the ventilator and another equipment** | **Definitions** |
|  | Date of production |
|  <br>VP2B – 1<br>250 V<br>6.3 A | Location of fuses with name's and characteristic's indication. |
|  | Do not use if packaging is damage |
|  | Use up to… |
|  | Lot number |
|  | Catalogue's number |
|  | Serial number |
|  | Sterile |
|  | Sterilization with ethylene oxide |

**Table 2.3**

| **Notation** | **Definition** |
|---|---|
|  | Correct vertical position of the load |
|  | Unbreakable! Handle carefully during transport and during storage! |

| | |
|---|---|
|  | Protect from moisture during transportation and during storage |
|  | Transportation temperature Limits and during storage |
|  | Restrictions on longline installation during transportation and during storage |

# 3. Description of the Ventilator

## 3.1 Delivery set

The delivery set of the device is given in the DataSheet of the ventilator.

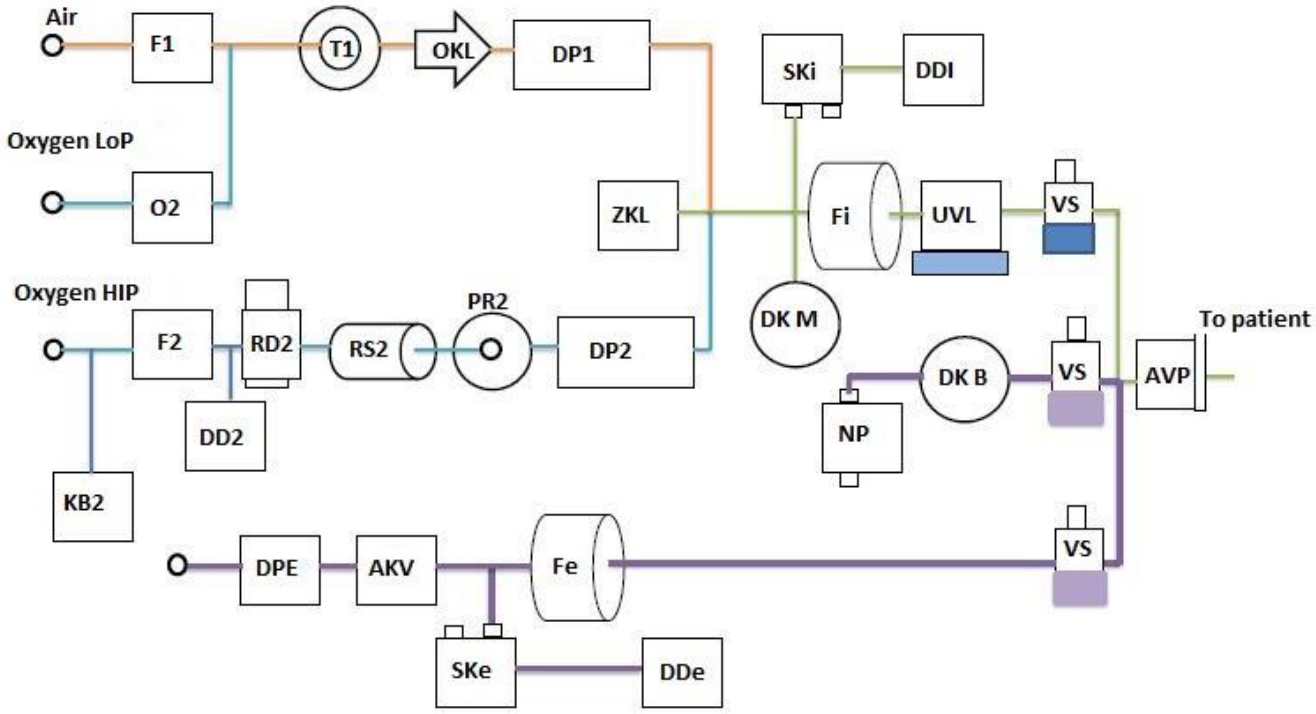
Respiratory circuit, parts and accessories are validated for use with the ventilator Incompatible parts may result in poor performance.

The responsible organization is responsible for ensuring the compatibility of the ventilator and all parts intended to be connected to the patient before use.

## 3.2 Device and principle of working

### 3.2.1 Pneumatic system of the ventilator

The general structure of the pneumatic system of the ventilator is presented on the Picture 3.1




Picture 3.1 The structure of the pneumatic system of the ventilator.

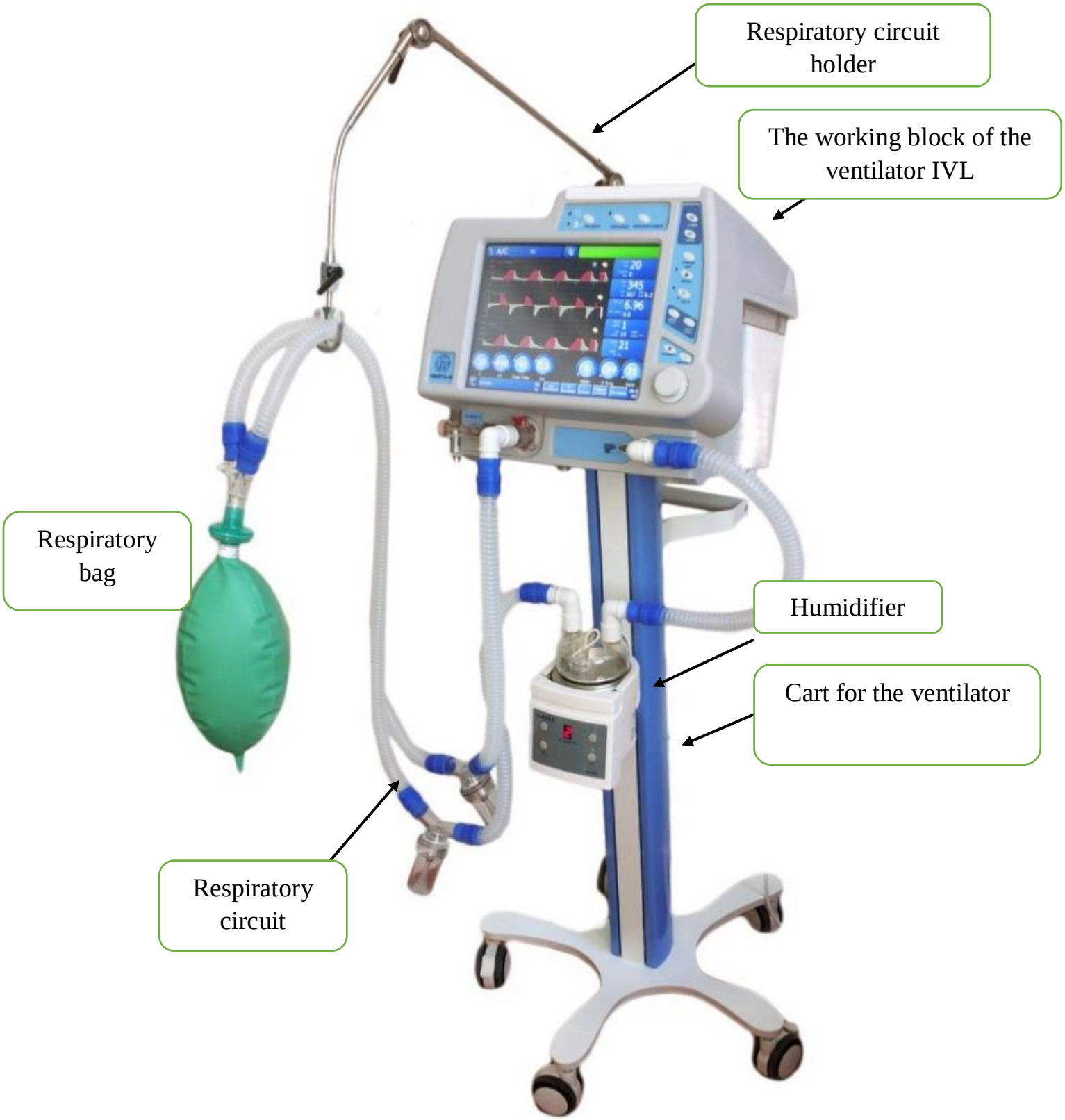
**The diagram is presented only to explain the general ideology of the ventilator.**
**The actual circuit diagram of the ventilator may differ from the diagram shown in the figure.**
**The developer and manufacturer of the device are constantly working on improving it, and therefore, in your copy of the ventilator there may be slight differences in design and information given in this manual.**
**These changes are aimed at improving the operation of the device and do not affect its characteristics and consumer properties.**

Table 3.1.

| Designation | Name | Note |
|---|---|---|
| AVP | Air outlet adapter for connecting a CO2 monitoring line | Allows sampling for analysis by the monitoring unit module |
| AKV | Active exhalation valve | Regulates exhaled flow rate. Allows you to control the level of PEEP. Allows you to implement complex ventilation modes with the possibility of spontaneous inhalation of the patient at any time. Allows you to maintain the set pressure on the inspiration even during the patient's cough. |
| VS | Moisture collector | Removing excess moisture |
| DD2 | Pressure sensor | Measures inhaled pressure of oxygen (from operator's net) |
| DDe | Pressure sensor in the exhalation | Measures the pressure in the exhalation's circuit |
| DDi | Pressure sensor in the inhalation | Measures the pressure in the inhalation's circuit |
| DK M, DK B | Oxygen sensor (slow, fast) | Serves for measuring FiO2. May not be available when using a gas exchange monitoring module with a fast oxygen sensor |
| DP1, DP2 | Flow sensors | Required for measuring air and oxygen flows when creating a mixture with specified parameters |

| | | |
|---|---|---|
| DPE | Flow sensors in the exhalation | Measures expiratory flow in the exhalation circuit |
| ZKl | Protective valve | Opens passively when pressure exceeds 90 cm H2O |
| KB2 | Security valve | Limits the maximum oxygen pressure from the consumer network |
| NP | Pumping | Air sampling from patient tee |
| O2 | Oxygen of low pressure | Connection to a low-pressure oxygen concentrator |
| OKl | Unilateral valve | It allows flow in only one direction. Eliminates leakage of exhaled flow |
| PR2 | Proportional solenoid valve | Allows you to adjust the oxygen flow to achieve the specified parameters of the mixture supplied to the patient's lungs (total mixture flow and FiO2) |
| RD2 | Pressure regulator | Reduces oxygen pressure to nominal values |
| RS2 | Receiver | Smooths oxygen pressure fluctuations |
| SKe | Solenoid valve | Serves for periodic calibration of zero expiratory pressure (relative to atmospheric) |
| Ski | Solenoid valve | Serves for periodic calibration of a zero level of inspiratory pressure (relative to atmospheric) |
| T1 | Turbine | Creates an air flow for breath |
| UVL | Respiratory mixture humidifier | Respiratory mixture humidifier |
| F1,F2 | Filter | Purify the supplied air and oxygen |
| Fi | Respiratory Gas Filter | Bacterial virus filter |
| Fe | Expiratory Gas Filter | Bacterial virus filter |

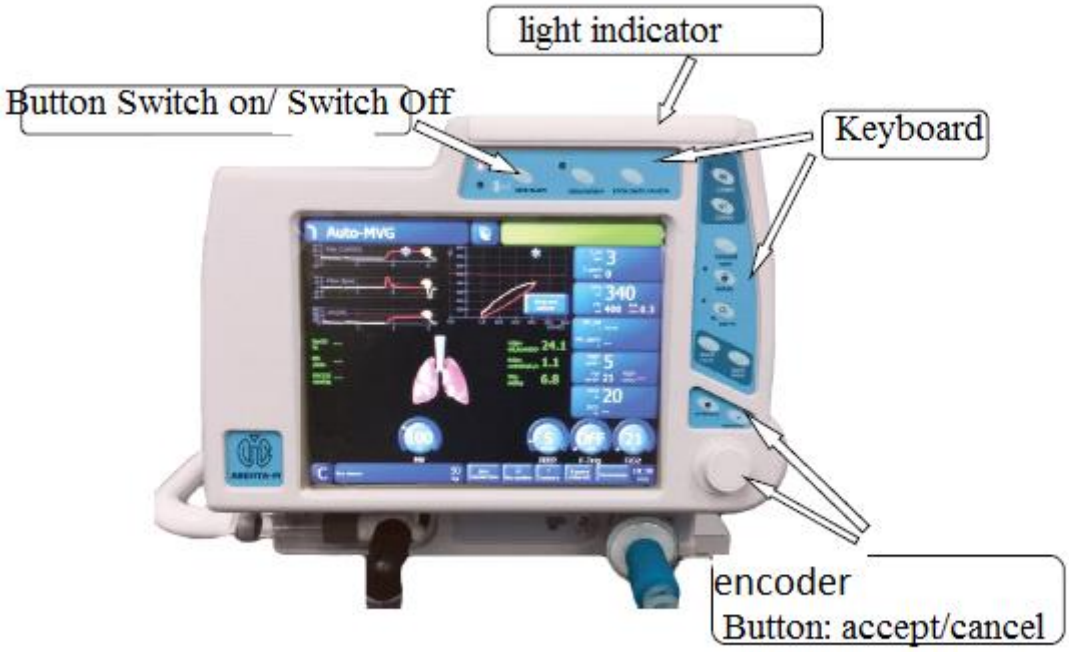
## 3.3 Overall view of the ventilator




**Picture 3.2 General ventilator's view**

## 3.4 Working block of the ventilator

**General view of the working block with the ventilator's controls is presented in Picture 3.3.**




**Picture 3.3 – General view of a display and controls**

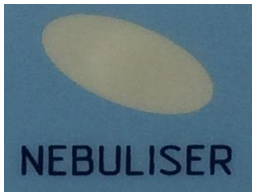
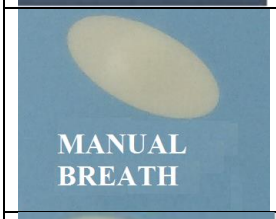
### 3.4.1 Sensory screen

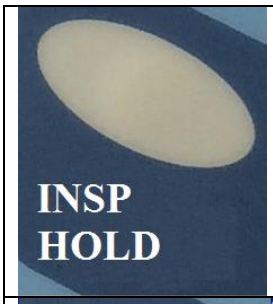
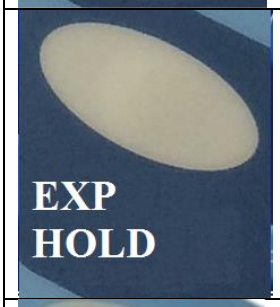
The ventilator in its composition has a display with a sensory panel. The presence of a sensory panel facilitates the management of the device settings and creates additional protection for the display from mechanical damage. The sensory screen has maximum resistance to contamination. The screen reacts to touch with any smooth solid object: hand (bare or gloved), pen, blunt end of the scalpel. The effort to press the sensory screen should not exceed 150g.

1. **Never use sharp objects to touch the sensory screen! This can damage the film and damage the screen.**

2. **Never treat the surface of the sensory screen with organic solvents, liquids containing acid or alkali.**

### 3.4.2 Control buttons

| | |
|---|---|
|  | Button **on** / **off** of the device. The light indication shows the operation of the device from a 220V network or from a battery. |
|  | Button with light indication. Includes a nebulizer. |
|  | Button lock keypad. |
|  | Button with light indication. Alarm mute button. Used to mute the sound of an alarm for 2 minutes. |
|  | Sound alarm reset button. |
|  | Mandatory hand inhalation button |
|  | Button with the light indication. Lock sensory screen. |
|  | Button with the light indication. Switch on 100% oxygen mode. At the same time, the oxygen sensor of the ventilator is calibrated. |

| | |
|---|---|
|  | Inspiratory pause button. |
|  | Expiratory pause button. |
|  | Button of cancellation of the current settings of Ventilator. |
|  | Button of acceptance of the current settings of Ventilator. |

### 3.4.3 Encoder

| | |
|---|---|
|  | To simplify changing the settings, the device includes an encoder.<br>The window of each parameter is a touch button, when clicked, the selected parameter is highlighted.<br>To increase the value of the selected parameter, rotate the encoder clockwise.<br>To decrease the value of the selected parameter, rotate the encoder counterclockwise. |

# 4. Technical feathers

## 4.1 Basic parameters and dimensions

Overall dimensions of the ventilator are no more than mm:

| | |
|---|---|
| Without the cart | 415×460×355 mm |
| With the cart | 1400× 550 × 550 mm |
| Ventilator weight, no more than kg | 20 |

Graphical display with sensory panel, input interface LVDS

| | |
|---|---|
| Diagonally display's dimension | 31cm (12 inches) |
| Resolution (number of points) | 800 ×600 |
| Number of colors | 262144 |
| Brightness | 500 |
| Contrast | 700 |
| Response time, no more than m sec | 5 |
| Interface language | English |
| Hose length with high- pressure (oxygen), m | 5.0±0.1 |
| Net cable length | 5.0±0.1 |
| Length of SpO2 sensor's cable | 3±0.1 |
| Length of Co2 sensor`s cable length, m | 3.0±0.1 |
| Patient protection type | class I |
| Patient isolation | Type B, BF |
| Software (RO) | AVENTA-M |
| Version RO (software), no more | 6.0 |
| Carrier RO (software) | Built-in energy-independent |
| Key features RO (software) | memory Applied |
| Security class RO (software) according to IEC 62304:2006 (GOST R MEK 62304) | Class B |

*Notes- - To view information about the device version, turn on the device, in the "Standby mode" screensaver, click the "Settings" button at the bottom of the display and select the "Information" tab ( Picture 11.1 section 11 " General settings and information about the ventilator ").

Change of software is made only by permit of the manufacturer. At request the Manufacturer may provide the Operator with additional options and Software version.

## 4.2 Electric parameters

| | |
|---|---|
| Supply net voltage, V | 220±22 |
| Supple net frequency, Hz | 50 |
| Rated consumption current, no more, A | 1.0 |
| Power consumption (without moisture), no more, VA | 200 |
| Fuses | VP2B-1V |
| Current, A | 6.3 |
| Voltage, V | 250 |
| Response time, no more than, s | 1 |
| The time to establish the operating mode of the ventilator, no more than, s | 30 |
| Operating time from the built-in battery *, not less than, h | 5 |
| Accumulator battery | HR1221 |
| capacity, not less than Ah | 5,5 |
| Voltage, V | 24 |
| Type | Lad-acid |
| Oxygen sensor service life, not less than, years | 1 |

*__Notes__- Operating time is specified when the battery is fully charged.

## 4.3 Parameters of pneumatic system

| | |
|---|---|
| Operating range of the oxygen pressure supplied to the input of the ventilator | from 0.15 to 0.7 MPa and an input flow rate of not more than 60 l / min; from 0.02 to 0.1 MPa and an input flow rate of not more than 5,0 l / min; |
| Oxygen input port | NIST |
| Averaged over 10 s input flow rate required by the VENTILATOR at a pressure of 280 kPa when measured at the inlet orifice O2 | should not exceed 60 l / min. |
| The maximum unsteady oxygen input flow averaged over 3 s required by the VENTILATOR at a pressure of 280 kPa | Should not exceed 200 l/ min. |

| | |
|---|---|
| The maximum flow of the gas mixture supplied to the patient | From 3 to 180 l/ min (up to 250 l/ min for spontaneous inhalations) |
| Nebulizer flow | 6± 0.5 l/min<br>10± 0.5 l/min |

### 4.4 Conditions of exploitation, storage and transportation

| | |
|---|---|
| Environment temperature | |
| during exploitation | from +10℃ to+35℃ |
| during storage | from -50℃ to +40℃ |
| during transportation | from 50℃ to +50℃ |
| Relative humidity at 25C | |
| during exploitation | from 30% to 80% (without condensate) |
| during storage | from 98% (without condensate) |
| during transportation | from 100% (without condensate) |
| Atmosphere pressure | |
| during exploitation | from 60 kPa (450mm Hg)<br>up to 107 kPa (800 mm Hg) |
| during storage and transportation | from 50 kPa (375 mm Hg)<br>up to 106 kPa (795 mm Hg) |

## 4.5 Compliance with standards

Depending on the potential risk of use, the ventilator belongs to class 2b according to GOST (State Standards) 31508.

Depending on the degree of protection against electric shock, the device belongs to class I products with working parts of type B, BF, a product with an internal power source in accordance with GOST R IEC (International Technical Commission) 60601-1. The device is designed for continuous operation.

Type of climatic modification of the device - UHL 4.2 according to GOST 15150.

The device according to perceived mechanical stress belongs to group 2 according to GOST R 50444.

The device, during transportation, is resistant to climatic factors according to GOST 15150 for the climatic modification of UHL 4.2 storage conditions 5.

The device, packed in a shipping container, remains operational after mechanical stress according to GOST R 50444.

The device, packed in a shipping container, is resistant to climatic influences for storage conditions 5 in accordance with GOST 15150.

For safety, the device complies with the requirements of GOST R ISO 80601-2-12, GOST IEC 60601-1-8, GOST ISO 9919, GOST R IEC 60601-1-6, GOST R ISO 80601-2-55 and is made in protection class I c working parts of type B, BF according to GOST R IEC 60601-1.

By the degree of protection against penetration of water and solid particles, the product complies with IP21 according to GOST 14254.

Metallic and nonmetallic inorganic coatings of the ventilator satisfy the requirements of GOST 9.301 and GOST 9.303 for the operating group according to GOST 15150.

Paint and varnish coatings of the ventilator satisfy GOST 9.401 for a group of operating conditions UHL 4 in accordance with GOST 9.104.

The outer surfaces of the ventilator have coatings of at least class III according to GOST 9.032.

The outer surfaces of the components of the ventilator are resistant to disinfection according to MU 287-113 by the chemical method (wiping with a cloth 4% hydrogen peroxide solution according to GOST 177 with the addition of 0.5% synthetic detergent according to GOST 25644).

Average service life of at least 6 years. The criterion of the limiting state is the impossibility or technical and economic inexpediency of restoring performance.

The software of the device complies with the requirements of GOST R IEC 62304 for the security class of software type B.

The ventilator AVENTA-M meets the requirements of GOST R 55954.

## 4.6 Indication of security measure

The ventilator must be used exclusively in accordance with the safety measures contained in this manual and not be used for purposes other than intended.

**ATTENTION!**

**Before assembly, setup, use and service of the ventilator, you must familiarize yourself with this manual.**

The ventilator, when used, presents a potential danger with regard to:

- danger of electric current;
- other dangers provided by GOST R IEC 60601-1.

When using the device, it is necessary to comply with safety regulations when working with electrical equipment

**ATTENTION!**

**Do not use the power cord without an earth pole or with a faulty earth pole.**

**Do not connect the device to a power outlet without a ground loop or with a faulty ground loop.**

**Do not allow liquids and objects to enter the components of the ventilator.**

**Using a power cord other than the one supplied with the device, as well as with humidifier, can lead to increased emissions of radio interference or reduced noise immunity of the device.**

**Do not leave the device in operation without supervision!**

The device uses:

- power cable (PVS-VP 2x0.75 + 1x0.75-250-01-10-1.2 GOST 28244) 5.0 ± 0.1 m long;

In terms of electromagnetic compatibility, the device meets the requirements of GOST R IEC 60601-1-2.

## 4.7 Management and declaration of manufacturer

### 4.7.1 Electromagnetic emission

**Table 4.1 -Electromagnetic emission**

The ventilator is intended for use in an electromagnetic environment as defined below. The buyer or operator must ensure its use in the specified environment.

| Hindrance emission test | correspondence | Electromagnetic environment - instructions |
|---|---|---|
| Industrial radio interference in accordance with GOST R 51318.11 (CISPR 11: 2004) | Group 1 | The device uses radio frequency energy only for internal functions. The level of emission of radio frequency interference is low and probably will not lead to malfunctions of nearby electronic equipment |
| Industrial ratio interference in according with GOST R 51318.11 (CISPR 11:2004) | Class B | The ventilator is suitable for use in all locations, including residential buildings and buildings directly connected to the distribution network supplying residential buildings |
| Harmonic components of current consumption in accordance with GOST 30804.3.2 | Class A | |
| Voltage fluctuations and flicker according to GOST 30804.3.3 | Corresponds | |

### 4.7.2 Hindrance immunity

**Table 4.2 -Hindrance immunity**

**The ventilator is intended for use in an electromagnetic environment as defined below. The buyer or operator must ensure its use in the indicated situations.**

| **Hindrance immunity test** | **Test level according to IEC 60601** | **Compliance level** | **Electromagnetic environment - instruction** |
|---|---|---|---|
| Electromagnetic discharge (ESR) according to GOST 30804.4.2 | ±6 kV -contact discharge | ±6 kV -contact discharge | The floors must be made of wood, concrete or ceramic tile. If the floors are covered with synthetic material, then the relative humidity should be at least 30% |
| | ±8 kV- air discharge | ±8 kV- air discharge | |
| Nanosecond impulse noise according to GOST 30804.4.4 | ±2kV- for electricity mains<br>±1 kV- for input-output mains | ±2kV- for electricity mains<br>±1 kV- for input-output mains | The quality of electrical energy in the building's electrical network must meet the typical conditions of a commercial or hospital conditions |
| Microsecond impulse noise of high energy according to GOST R 51317.4.5 | ±1 kV- during supply noises according scheme wire-wire | ±1 kV- during supply noises according scheme wire-wire | The quality of electrical energy in the building's electrical network must meet the typical conditions of a commercial or hospital conditions |
| | ±2 kV- during supply noises according scheme wire-ground | ±2 kV- during supply noises according scheme wire-ground | |
| Voltage dips, interruptions and voltage changing | <5% UT (voltage depression > 95% UT) during 0.5 period | <5% UT (voltage depression > 95% UT) during 0.5 period | The quality of electrical energy in the building's electrical network must meet the typical conditions of |

| | | | |
|---|---|---|---|
| | | | a commercial or hospital conditions |
| **Hindrance immunity test** | **Test level according to IEC 60601** | **Compliance level** | **Electromagnetic environment - instruction** |
| Input electricity mains according to 30804.4.11 | 40% UT (voltage depression 60% UT) during 5 periods | 40% UT (voltage depression 60% UT) during 5 periods | If the operator requires uninterrupted operation in conditions of interruption of the mains voltage, it is recommended to supply the connection of the complex from an uninterruptible power supply |
| | 70 % UT (voltage depression 30% UT) during 25 periods | 70 % UT (voltage depression 30% UT) during 25 periods | |
| | <5% UT (Voltage depression > 95% UT) during 5 s | <5% UT (Voltage depression > 95% UT) during 5 s | |
| Notes -UT- voltage level of the electrical network until the test influence | | | |

| **Hindrance immunity test** | **Test level according to IEC 60601** | **Compliance level** | **Electromagnetic environment - instruction** |
|---|---|---|---|
| Magnetic field of commercial frequency GOST R 50648 | 3 A/m | 3A/m | Magnetic field of commercial frequency must satisfy typical conditions of commercial or hospital conditions |
| | | | Distance between used mobile radiotelephone communication system and any element complex including cables must be not less recommended space diversity which calculated in according to below expression applied to transmitter frequency. Recommended Space diversity |
| Conductive noises, induced radio frequency electromagnetic noises according to GOST R 51317.4.6 | 10V from150kHz to 80MHz (at frequencies allocated to PNM VCh devices) | V2-10 (V) | $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ |
| Radiated radio frequency electromagnetic field according to GOST 30804.4.3 | 10V/m From 80 MHz to 2.5 GHz | E1-10(V/m) | $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ From 80 MHz to 800 MHz<br>$d = \left[\frac{23}{E_1}\right]\sqrt{P}$ From 800 MHz to 2.5 GHz |

| Hindrance immunity test | Test level according to IEC 60601 | Compliance level | Electromagnetic environment - instruction |
|---|---|---|---|

Where P is the maximum output power of the transmitter in watts (W) in accordance with the manufacturer's specifications, and the recommended distance in meters (m).

d- recommended spatial separation, m;

The field strength during the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic environment a), should be lower than the level of compliance in each frequency band b)

Influence of noises can have place near of equipment, marked with a sign:

a) Field strength during the propagation of radio waves from stationary radio transmitters, such as base stations of radio telephone networks (cellular / wireless) and terrestrial mobile radio stations, amateur radio stations, AM and FM broadcast transmitters, television transmitters, cannot be determined by calculation with enough accuracy. For this, practical measurements of the field strength should be carried out. If the measured values at the location of the Aventa-M lung ventilator (hereinafter referred to as the Ventilator) are higher than the applicable conformity levels, then the Ventilator should be monitored to verify its normal functioning. If during the observation process a deviation from normal functioning is detected, then additional measures must be taken, such as reorientation or relocation of the Unit.
b) Outside the frequency range from 150 kHz to 80 MHz, a field strength of less than (V1) V / m should be ensured.

Notes

1. At frequencies of 80 and 800 MHz, a larger field strength value is used.

The above expressions are not applicable in all cases. Electromagnetic propagation is affected by absorption or reflection from structures, objects, and people.

Table 4.3 - Recommended values of space diversity between portable and mobile radio frequency communications and ventilator

| | |
|---|---|
|  | The ventilator is used in electromagnetic level where control environment radiated interference. The operator of the device can avoid electromagnetic noises, ensuring minimal space diversity between portable and mobile radio frequency communications (transmitters) and ventilator, as recommended below, taking into account the maximum output power communication. |

| Nominal, maximum output transmitter's power, Watts | Space diversity, m, depend on a transmitter's frequencies | | |
|---|---|---|---|
| | 150 kHz 80 MHz (at the frequencies that dedicated for PNM VCh devices). $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ | 80 MHz 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ | 800 MHz 2.5 GHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.20 | 1.20 | 2.30 |
| 10 | 3.79 | 3.79 | 7.27 |
| 100 | 12.00 | 12.00 | 23.00 |

Notes

At the frequencies 80 and 800 MHz are used a higher value of field's voltage.

The above expressions are not applicable in all cases. For distribution electromagnetic waves are affected by absorption or reflection from structures, objects and people.

When determining the recommended values of the spatial separation d for transmitters with a rated maximum output power not specified in the table, the nominal maximum output power P in watts specified in the manufacturer's documentation the transmitter.

### 4.7.3 Ventilation parameters

The ventilator provides settings of the ventilation parameters, which are presented in Table 4.4

**Table 4.4 -Ventilation parameters**

| **Designation of parameters** | **Description of parameters** | **Units of measurement, ranges of values, step of installation, errors** |
|---|---|---|
| Ideal weight (IBW) with growth identification | Sets the ideal patient weight (excluding excess fat mass). The ventilator uses this value to set the default values of some ventilation parameters (tidal volume, peak flow), as well as to set the initial values of the alarm limits. The parameter is entered in the patient data window, which is displayed automatically when you start working with a new patient or when you click on the ideal weight display area in the main window | Value range:<br>3-150 kg<br>Installation step: 1 kg |
| Live body mass (MAS) | | Value range:<br>3-200kg<br>Setting step:<br>In range from 3 to 10 kg - 0.1;<br>In range from 11 to 200 kg - 1 kg |
| Age | Indicate the patient's age the ventilator uses this value to correct the values calculated with using the IBW parameter | Value range:<br>1-120 years<br>Setting step: 1 year |
| Patient's sex | | Male or Female |
| Patient's peculiarities | | ARDS, COPD, ICH, Hypovolemia |
| Name | | In letters |

| Designation of parameters | Description of parameters | Units of measurement, ranges of values, step of installation, errors |
|---|---|---|
| Mode | Sets the ventilation mode and sets the admissible combinations of mandatory and spontaneous breaths | Possible values: A / C, CMV, SIMV, SPONT, CPAP, APRV, DUAL-LEVEL, Auto-MVG, APNEA, HFlow, Inhalation pause, Exhalation pause, 100% oxygen ventilation, Manual inhalation, Nebulizer control.<br>Procedures: Auto-PEEP / FiO2, Suctioning tool, recruitment maneuver, PV maneuver.<br>A detailed description of ventilation modes is given in the relevant sections of this manual. |
| Type of mandatory breaths | Set the type of mandatory breaths:<br>- pressure control (PC);<br>-volume control (VC);<br>-pressure controlled volume guaranteed (PC-VG) | Possible values:<br>PC, VC, PC-VG |
| Type of spontaneous breaths | Set the type of supports spontaneous breaths:<br>Pressure support (PS);<br>Pressure support with guaranteed volume (PS-VG);<br>automatic endotracheal tube resistance compensation (TC)<br>proportional pressure support (PS-PRO) | Possible values:<br>PS, PS-VG, TC, PS-PRO |

| **Designation of parameters** | **Description of parameters** | **Units of measurement, ranges of values, step of installation, errors** |
|---|---|---|
| Trigger's type | Set the method for detecting an attempt to inhale:<br>- Flow (F-Trig);<br>- pressure (P-Trig) | F-trig, P-trig |
| Connecting type | Set the method for connecting a patient to the device:<br>- using an endotracheal tube;<br>- using a mask (non-invasive ventilation) | Possible values:<br>ET (endotracheal tube),<br>Trach (tracheostomy tube),<br>NIV (mask) |
| Breath Rate (f) | Set the minimum number of mandatory inhalations that are delivered to the patient in 1 minute. Used in AC, SIMV, DUAL-LEVEL modes | Value Range: 1 - 150 rpm<br>Installation Step: 1 min-1<br>Installation error: in the range from 1 to 59 - ± 1 min-1 from 60 to 150 - ± 2 min-1 |
| Tidal Volume (VT) | Set the volume of the gas mixture that are delivered to the patient during a mandatory inhalation with volume control (VC). Respiratory volume is delivered with taking into account the compensation of the respiratory circuit compliance and is brought to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Value range: 10 - 3000 ml<br>Installation step: in the range from 10 to 200 ml - no more than 10%<br>in the range from 200 to 3000 ml - no more than 10% |
| Duration of inhalation (TI) | Sets the duration of the mandatory inhalation with pressure control (PC). For volume controlled (VC) inhalations are not used. | Value Range:<br>0.20 - 15.00 s<br>Installation step: 0.05 s |

| **Designation of parameters** | **Description of parameters** | **Units of measurement, ranges of values, step of installation, errors** |
|---|---|---|
| Ratio of inhalation's and exhalation's duration (I:E) | Displays the ratio of inhalation duration to exhalation duration for the previous inspiration. | Value range:<br>1:99-60:1, with installation step 1.0<br>4:1 – 1:9, with installation step 0.1 |
| Plateau duration (TPL) | Sets the additional time interval of mandatory inhalation with volume control (VC), during which the flow of the gas mixture into the lungs is stopped and the exhalation valve is closed | Value range:<br>0-2.0 with installation step:<br>0.1 s |
| Peak flow (Peak Flow) | Sets the peak (maximum) flow during mandatory inhalation with volume control (VC). For pressure-controlled inhalation (PC) is not used | Value range:<br>3-200 l/min<br>Installation step:<br>In range from 3 to 10 l/min-0.1 l/min<br>In range from 11 to 200 l/min -1 l/min<br>Possible deviation is not more ±15% |
| Inspiratory pressure (Pi) | Sets the inspiratory pressure (relative to the PEEP level) during mandatory inhalation with pressure control (PC). For volume-controlled breaths (VC)is not used | Value range:<br>0-100 cm water column<br>Pi + PEEP <100 cm Hg<br>Pi + PEEP + 2 <↑ Ppeak<br>Installation step: 1 cm water st..<br>Installation error: ± (3 + 0.04 * Pi_ust) cm water st.,<br>where Pi_ust is the set value of Pi |
| Trigger sensitivity according to Flow (F-Trig) | Sets the threshold value of the flow, which is perceived by the ventilator as an attempt to inhale the patient. After the trigger is worked, the device either delivers a mandatory inhalation or supports spontaneous inhalation (depending on the mode) | Range of values: from -0.1 to -25 l / min, OFF:<br>(-0.1) ÷ (-1), installation step 0.1 (-1) ÷ (-10), installation step 0.5 (-10) ÷ (-25), installation step 1.0 |

| **Designation of parameters** | **Description of parameters** | **Units of measurement, values range, step of installation, errors** |
|---|---|---|
| Trigger sensitivity according to pressure (P-Trig) | Set the threshold value for the pressure drop (below the PEEP level), which is perceived by the ventilator as an attempt to inhale the patient. After the trigger is worked, the device either delivers a forced breath or supports spontaneous inspiration (depending on the mode) | Values range:<br>From -0.2 to -25 cm water column, OFF<br>(+1)÷ (-10), installation step 0.5<br>(-10)÷ (-25), installation step 1 |
| Flow wave (Waveform) | Set the shape of the flow for mandatory inhalations with volume control (VC). For pressure-controlled inhalations is (PC) not used. The parameter is available on the additional control parameters panel. | Values range:<br>Rectangular, descending |
| Expiratory sensitivity (ESENS) | Set the threshold value of the inspiratory flow (as a percentage of the peak flow), upon reaching which the device switches from inspiration to exhalation. The parameter is used only for spontaneous inhalations. The parameter is available on the additional control parameters panel. | Values range:<br>1-90%<br>AUTO<br>Installation step: 1% |

| **Designation of parameters** | **Description of parameters** | **Units of measurement, values range, step of installation, errors** |
|---|---|---|
| Sigh | Used for mandatory inhalations with volume control (VC and PC). The patient is delivered one and a half volumes in every hundredth inhalation, but not less than once in 7 minutes. The parameter is available on the additional control parameters panel. | Values range:<br>ON, OFF |
| Units of the plateau values installation (Tpl units) | Set the installation units for parameters Tpl | Values range: sec, % |
| Oxygen content of the respiratory mixture (FiO2) | Set the percentage of oxygen content into the gas mixture, delivered to the patient | Values range:<br>21-100% (Auto mode)<br>Installation step: 1%<br>Installation error:<br>±3% |
| Positive pressure at the end of exhalation (PEEP) | Set the positive pressure at the end of exhalation | Values range:<br>0-50 cm water column<br>0-24 cm water column (Auto mode)<br>Installation step: 1 cm water column<br>Installation error:<br>±(2+0.04 * PEEP_ust) cm water column, where PEEP_ust is setting values PEEP |
| Pressure for supporting spontaneous inhalations (PSUP) | Set the pressure (relative level to PEEP)for supporting spontaneous inhalations, when chosen type of supporting PS | Values range:<br>0-100 cm water column<br>PSUPP+PEEP < 90 cm water column<br>PSUPP+PEEP + 2<↑Ppeak<br>Installation step:1 cm water column |

Maximum systematic error and maximum linearization error:

- the maximum error of the SET VOLUME relative to the set value ± 10%;

- maximum error of the AIR LEAD-IN PRESSURE (Paw) at the end of the inspiratory phase relative to the set value of 2 cm water column.;

- maximum error PEEP relative to the set value ± (2 + 0.04 PEEP measured.);

- the maximum error in the concentration of respirable oxygen in the hole for the CONNECTION of the PATIENT relative to the set value ± 3%;

- the time required to change the concentration of O2 20s;

- accuracy of monitoring equipment for exhaled volume ± 10%.

### 4.7.4 Alarm limits

The device provides setting alarm limits for the parameters mentioned in Table 4.5.

**Table 4.5 -Alarm limits**

| **Parameters** | **Description** | **Values range** |
|---|---|---|
| Interval apnea (Ta) | Set the maximum interval for the absence of any type inhalations, after which the ventilator gives an alarm and automatically switches to ventilation mode by apnea | Values range:<br>5-75 s |
| Upper limit of peak pressure (↑Ppeak) | Set the maximum available pressure in the breathing circuit. When this value is reached in the inspiration phase, the device immediately terminates inspiration and switches to exhalation | Values range:<br>0-150 cm water column |
| Upper limit of total respiratory rate (↑f_tot) | Sets the limit for the maximum breath rate | Values range:<br>1—150$min^{-1}$, OFF |
| Low limit of general respiratory rate(↓f_tot) | Set the limit for the minimum respiration rate | Values range:<br>0-5$min^{-1}$ |
| Upper limit of general respiratory minute volume ( ↑MV_tot) | Sets the limit for the maximum value of the total minute breathing volume | Value range:<br>0-60l, OFF |

| Parameters | Description | Values range |
|---|---|---|
| Low limit general respiratory minute volume (↓MV_tot) | Set the limit for the minimum value of the general respiratory minute volume | Values range:<br>0-60 l, OFF |
| Upper limit of exhalation volume(↑VTe_mand) | Set the limit for the maximum value of the mandatory exhalation volume | Value range:<br>50-3000 ml |
| Low limit of exhalation volume(↓VTe_mand) | Set the limit for the minimum value of the mandatory exhalation volume | Values range:<br>10-3000ml |
| Upper limit of exhalation volume(↑VTe_spont) | Set the limit for the maximum value of the spontaneous exhalation volume | Values range:<br>50-3000ml |
| Low limit of exhalation volume(↓VTe_spont) | Set the limit for the minimum value of the spontaneous exhalation volume | Values range:<br>10-3000ml |
| Upper limit of concentration CO2 in the exhale mixture (↑EtCO2) | Set the limit for the maximum value EtCO2 | Values range:<br>30-120 mm Hg (0-15%) |
| Low limit of concentration CO2 in the exhale mixture (↓EtCO2) | Set the limit for the minimum value EtCO2 | Values range:<br>10-40 mm Hg (1.4-5.6%) |
| Upper limit of oxygen saturation of hemoglobin in arterial blood(↑SpO2) | Set the limit for the maximum value SpO2 | Values range:<br>90-100% |
| Low limit of oxygen saturation of hemoglobin in arterial blood(↓SpO2) | Set the limit of the minimum value SpO2 | Values range:<br>70-95% |
| Upper leak limit(↑Leak) | Set the limit for upper leak limit | Not more<br>200 ml/min at 50 cm water column;<br>Not more 50 ml/min at 20 cm water column |

When the parameter value exceeds the above alarm limits, the ventilator gives an audible alarm (in accordance with the level of danger) and the corresponding text message appears in the alarm window.

## 4.8 Monitored parameters

The ventilator provides measurement and indication on the display the patient`s respiration parameters, presented in Table 4.6.

**Table 4.6**

| **Parameters** | **Description** | **Values range** |
|---|---|---|
| Type of the patient's connection | Display the type of the patient's connection | ET, Trach, NIV |
| Type and phase of the current respiratory cycle | Display type and phase of the current respiratory cycle | C- mandatory inhalation, initiated with the ventilator |
| | The value on a light background indicates the inhalation phase. | A-mandatory inhalation initiated by a patient |
| | The value on a dark background indicates the exhalation phase. | S-spontaneous inhalation |
| Inhalation volume (Vti) | Display the volume of the gas mixture delivered to the patient. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Values range:<br>1-9999ml<br>Discreteness: 1 ml<br>Range error:<br>From 50 to 99 ml ±8%<br>From 100 to 3000 ml ±8% from measured value |
| Spontaneous inhalation volume (Vti_spont) | Displays the volume of the gas mixture delivered to the patient. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Values range:<br>1-9999 ml<br>Discreteness: 1ml<br>Range error:<br>From 50 to 99 ml ±8%<br>From 100 to 3000 ml ±8% from measured value |
| Exhalation volume (VTe) | Displays the volume of the gas mixture measured in the exhale phase of the patient`s breath. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Values range:<br>1-9999 ml<br>Discreteness: 1ml<br>Range error:<br>From 50 to 99 ml ±8%<br>From 100 to 3000 ml ±8% from measured value |

| Parameters | Description | Values range |
|---|---|---|
| Spontaneous exhalation volume (VTe_spont) | Display the volume of the gas mixture measured in the expiratory phase. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Values range:<br>1-9999ml<br>Discreteness: 1 ml<br>Range error:<br>From 50 to 99 ml – 15ml<br>From 100 to 3000 ml− ±8% from measured value |
| Total breath rate (f_tot) | Display the total number of mandatory and spontaneous inhalations for the previous minute | Value range:<br>2-200 $min^{-1}$<br>Discreteness: 1$min^{-1}$<br>Range error:<br>From 2 to 59 -±1$min^{-1}$<br>From 60 to 200 -±2$min^{-1}$ |
| Spontaneous breath rate (f_spont) | Display the number of spontaneous inhalations in the previous minute. | Values range:<br>2-200 $min^{-1}$<br>Discreteness: 1$min^{-1}$ |
| Coefficient of spontaneous breath (k_spont) | Displays the ratio of the number of spontaneous inhalations to the total number of inhalations per minute | Values range:<br>0-100% |
| Trigger window size (SIMV_tr) | Displays the trigger window size in SIMV mode | Values range:<br>0-100%<br>0-5 s |
| Total respiratory minute volume (MV_tot) | Displays the total value of all expiratory volumes (for mandatory and spontaneous inhalations) for the previous minute. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100%) | Values range:<br>0-99.9 l<br>Discreteness:0,01l |

| Parameters | Description | Values range |
|---|---|---|
| Minute volume of spontaneous inhalation (MV_spont) | Display the total value of expiratory volumes (only for spontaneous inspirations) for the previous minute. Mandatory breaths are not counted here. The volume is reduced to standard BTPS conditions (temperature 37 ° C, current atmospheric pressure, relative humidity 100 | Values range:<br>0-99.99 l<br>Discreteness: 0.01l |
| Duration of spontaneous inhalation (Ti_spont) | Display the duration of the previous spontaneous inspiration. Not used for mandatory breaths. | Values range:<br>0-10.00 s<br>Discreteness: 0.01s |
| Duration of spontaneous exhalation (Te_spont) | Display the duration of the previous spontaneous exhalations. Not used for mandatory breaths. | Values range:<br>0.10-15.00 s<br>Discreteness: 0.01s |
| Ratio between inhalation's and exhalation's duration I:E | Displays the ratio of inspiratory duration to expiratory duration for the previous breath. Used for all types of breaths (mandatory and spontaneous) | Values range:<br>1:150-150:1<br>4:1-1:10 |
| Respiratory Cycle Occupancy Rate (BCF) | Displays the ratio of inspiratory duration to the duration of the entire respiratory cycle | Values range:<br>0-100% |
| Peak pressure (Ppeak) | Displays Peak pressure (Ppeak) in respiratory circuit, measured during previous respiratory cycle | Values range:<br>0-120 cm water column,<br>Discreteness: 1 cm water column<br>Measure error:<br>$\pm$(2+0.04*Ppeak_izm) cm water column,<br>Where Ppeak_izm- Value measure Ppeak |
| Mean pressure (Pmean) | Displays the average pressure in the respiratory circuit, measured (averaged) for the previous minute | Values range:<br>-20-+130 cm water column<br>Discreteness: 1 cm water column |

| Parameters | Description | Values range |
|---|---|---|
| Pressure “Plateau” (Ppl) | Display the pressure in the respiratory circuit, measured at the end of the “inspiratory pause” is the final alveolar pressure | Values range: -20 - +130 cm water column Discreteness: 1 cm water column Measure error: ± (2 + 0.04 *Ppl_ism) cm water column, where Ppl_ism is the measured value of Pp |
| Pressure at the end of exhalation (PEEP) | Display respiratory pressure measured at the end of a previous exhalation | Values range: -20 - +130 cm water column Discreteness: 1 cm water column Measure error: ± (2 + 0.04 *PEEP measured) cm water column where PEEP_ism is the measured value of PEEP |
| Flow value at the end of inhalation (EIF) | Display the value of the flow at the time of completion of inspiration and switching to exhalation | Values range: 0-200 l/min |
| Flow value at the end of exhalation (EEF) | Display the value of the flow at the time of completion of exhalation and switching to inspiration | Values range: 0-200 l/min |
| End exhalation pressure (Pe_end) | Display final exhalation pressure. | Values range: -20-+130 cm water column Discreteness: 1 cm water column |
| Occlusive expiratory pressure (P0.1) | Display the pressure that the patient creates during the first 100 ms of a spontaneous inhalation. | Values range: 0.1 - 20 cm water column Discreteness: 0.1 cm water column |
| Respiratory Effort Index (MIP) | Displays the magnitude of the change in pressure in the respiratory circuit when a patient attempts to inhale | Value range: 0 - 50 cm. |
| Rapid Surface Respiration Index (RSBI) | “It is an indicator of the respiratory muscles' working capacity under the condition of a satisfactory state of the respiratory center and pathways” (O. E. Satishur, 2006) | Values range: 1-1000 |

| Parameters | Description | Values range |
|---|---|---|
| Normalized Index of rapid shallow breath (RSBN) | Normalized Index RSBI to the ideal weight of the patient<br>RSBN= RSBI*IBW/100 | Values range:<br>0.1-100 |
| Static compliance (Cstat) | Display the estimated value of the tensility patient's lung | Values range:<br>0-300ml/cm water column |
| Static resistance (Rstat) | Display the estimated value of the respiratory ways' resistance | Values range:<br>0-300ml/cm water column |
| Dynamic compliance (Cdyn) | Display the estimated dynamic value of the tensility patient's lung | Values range:<br>0-300ml/cm water column |
| Elasticity (El) | Display the estimated value of the patient's lung elasticity | Values range:<br>0-300cm water column/l |
| Dynamic resistance (Rdyn) | Display the estimated dynamic value of the respiratory ways' resistance | Values range:<br>0-300 cm water column/l/s |
| Time constant of inhalation (Tc_i) | Display the time constant in implementing of inhalation | Values range:<br>0-5s |
| Time consonant of exhalation (Tc_e) | Display the time constant in implementing of exhalation | Values range:<br>0-5s |
| Total work of breath (WOB_tot) | Display the total works that are spent by the ventilator and patient on the inhalation | Values range:<br>0-10J/L |
| Total work of breath (WOB_pat) | Display the total works that are spent by patient on the inhalation | Values range:<br>0-10J/L |
| Total work of breath (WOB_imp)_ | Display a work that is done by a patient for the trigger inhalation (overcoming resistance of the respiratory contour) | Values range:<br>0-10J/L |
| Oxygen content during inhalation (FiO2) | Display percentage of the oxygen content in gas mixture that is delivered to a patient during inhalation phase | Values range:<br>21-100%<br>Measure error: ±3% |

| Parameters | Description | Value range |
|---|---|---|
| Oxygen content at the end of exhalation (EtO2) | Display the percentage of oxygen content in the patient's exhaled gas mixture. Measurement is taken at the end of the exhalation phase. The parameter is optional and is available only if a quick oxygen sensor is included in the delivery. | Value range: 0-100% |
| Carbon dioxide content at inhalation (FiCo2) | Display the carbon dioxide content of the gas mixture delivered to the patient during the inhalation phase. | Value range: 0-115mm Hg (0-13%) |
| Carbon dioxide content at the end of exhalation (EtCO2) | Display the carbon dioxide content in the patient's exhaled gas mixture. Measurement is done at the end of the exhalation phase. | Value range: 0-115mmHg (0-13%) |
| Oxygen saturation of hemoglobin of arterial blood of the patient (SpO2) | Display the value measured SpO2 by two-wave pulse oximetry. | Value range: 60-100% |
| Pulse rates (PR) | Display the value of the pulse rate measured by the method of two-wave pulse oximetry | Value range: 0-240 hits/min |
| Volumetric campometry (VCO2) | Display the amount of CO2 emitted in 1 min, 30 min, 60 min | Value range: 1-1000 ml |
| Peak alveolar pressure (Palv) | | Value range: (-20)-(130) |
| Minute alveolar pressure (MValv) | | Value range: 0-99.9 |
| Pressure time product (PTP) | The value of PEEP variation in the beginning of independent inhale of the patient during the period of time | Value range:0 – 100 cm.H2O * sec |

The ventilator provides with the measurement and indication on the display patient`s parameters, presented in Table 4.7

**Table 4.7**

| **Parameters** | **Values range** |
|---|---|
| Live body mass | 3-200 kg |
| Consumable oxygen of a patient (VO2) | 0-1000 ml/min |
| Product CO2 per 1 min, 30 min, 60 min (VCO2) | 0-1000 ml/min |
| Energy expenses (EE) | 0-5000 kcal/day |
| Carbon oxidation (dCH) | 0-5000kcal/day |
| Fat oxidation (dF) | 0-5000kcal/day |
| Functional Residual Lung Capacity (FRC) | 0-5000 ml |
| Lung capacity (VC) | 0-5000ml |
| Reserve expiratory volume (ERV) | 0-5000 ml |
| Graphic image of the lungs | |
| Intraesophageal pressure (Pes) | -10 -+100 cm water column |
| Patient breathing effort | 0-50 cm water column |

# 5. Preparation of the ventilator for operation

## 5.1. The order of putting the ventilator into operation

Installation of the ventilator is to be carried out by specialists of the manufacturer JSC "UIEP"

Maintenance of the VENTILATOR during operation must be carried out by highly qualified SERVICE PERSONNEL in strict accordance with the requirements of this manual and the manual of the service engineer.

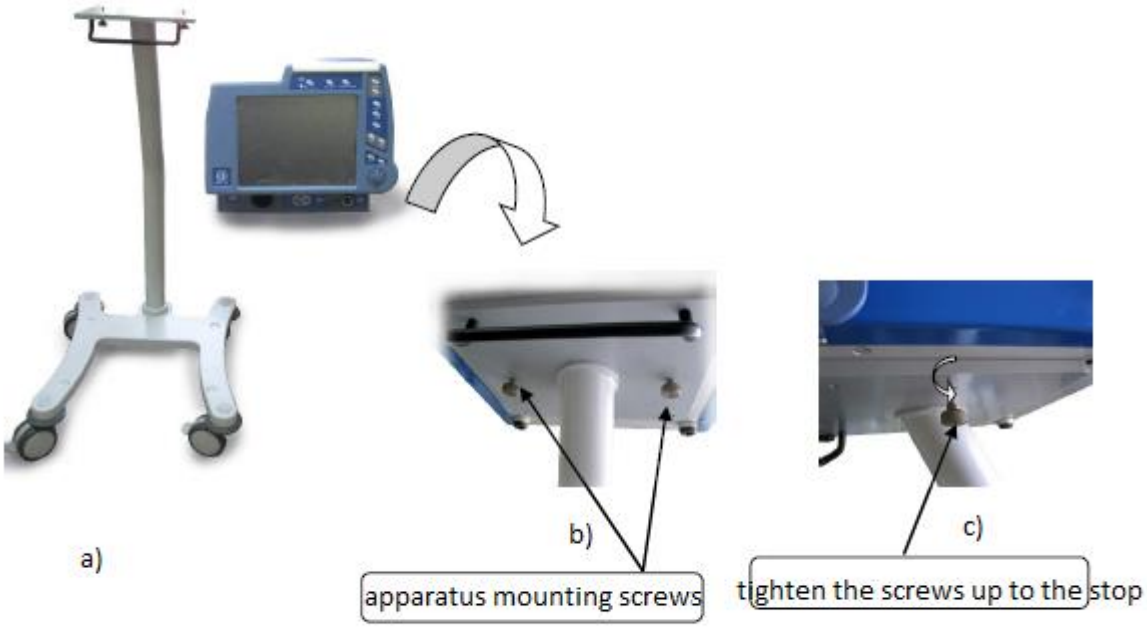
5.2. Warning and information for security during operation

| | |
|---|---|
|  | 1. Do not use the unit without grounding. The grounding of the device must comply with the requirements of the "Instructions for protective grounding of electromedical equipment."<br>2. The device must be operated in a well-ventilated area to prevent an increase in oxygen concentration.<br>3. Never use oxygen hoses with mechanical damage. Parts of the ventilator that come in contact with compressed oxygen should not show signs of grease or other flammable substances.<br>4. Operation of the device should be supervised by qualified medical personnel who are ready to provide assistance in case of malfunctions in the operation of the ventilator. |
|  | 5. The combined use of the device with sources of explosive gases of anesthetics is strictly prohibited.<br>6. Personnel must be at least 18 years old, trained and certified, who have passed the relevant safety training and have 1 qualification group for electrical safety, who studied the operational documentation, to operate the device.<br>7. The device is not intended for use in pressure chambers! The pressure chamber can affect the operation of the device, which jeopardizes the life of the patient. |

| | |
|---|---|
|  | 8. The device is not intended for operation during magnetic resonance scanning (MRI, MRT, NMR, NMI)! The source of electromagnetic waves can affect the operation of the device, which jeopardizes the life of the patient.<br>9. It is strictly forbidden to use mobile phones closer than 10 meters to the unit. Mobile phones can affect the operation of the device, which jeopardizes the life of the patient.<br>10. It is strictly forbidden to use a multi-socket outlet for supplying energy to products not included in the medical electrical system.<br>11. Use medical gloves when handling this machine. |
|  | 12. In order to avoid failure of the flow sensor, connect it with the device turned off. |

## 5.2 Installation display in the working position

The ventilator is delivered in transport packaging, the trolley in its packaging.



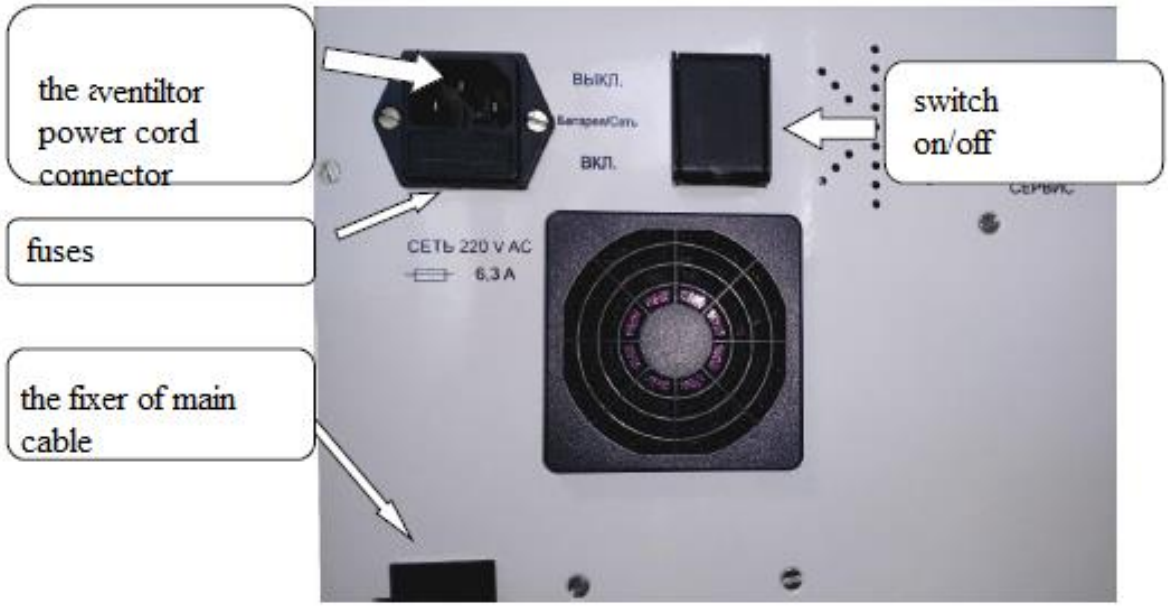

**Picture 5.1 -Installation the ventilator in the working position**

Unpack the machine and the cart from the boxes (Picture 5.1a). To assemble trolley according to the instructions of the trolley manufacturer. Set the device to trolley platform so that the mounting screws on the platform coincide with threaded holes on the bottom of the ventilator (Picture 5.1b). Wrap up fixing screws fully counterclockwise (Picture 5.1c).

## 5.3 Connection to the electro power net

| | |
|---|---|
|  | 1. Before turning on the device, make sure that the patient is not connected to the device.<br>2. Never pull the power plug of the device from the outlet by the cord. Failure to do so may result in wire breakage in the power cord and subsequent short circuit.<br>3. It is strictly forbidden to connect the device into one extension cord or socket unit together with electrosurgical devices. |

Connection is made by the power cord to the connector located on the back cover of the device (see Figure 5.2). The device is grounded using a power cord with a grounding contact; therefore, the device must be connected to a socket of type C2 according to GOST 7396.1 (Type F according to CEE) 220 V 50 Hz with a good ground loop. The device must not be plugged in without grounding or through an extension cord without grounding.




Picture 5.2 - Locations of connectors for electrical connections

The device is equipped with an internal battery, from which the device can operate when the AC mains is unavailable. The battery automatically recharges whenever the device is connected to the AC mains and the on / off switch on the back of the device is turned on (Picture 5.2).

Therefore, it is recommended that you leave the ventilator connected to AC power when not in use. This will keep the battery fully charged and ready for use at any time. Before using the device for the first time, the built-in battery must be charged. A full charge takes approximately 10 hours. In the off state, the battery circuit breaks, protecting it from discharging. The use of the ON / OFF switch is recommended for long-term storage. If the device is not used for a long time, the battery must be recharged at least 1 time per month.

When about 10 minutes remain until the battery is completely discharged, the red indicator on the top cover of the device starts blinking and the inscription "Battery is low" appears on the monitor of the device, and an audible alarm sound. Connect the machine to AC power to charge the battery. If the device is not connected to the AC mains within 10 minutes, it will turn off automatically. As the battery ages during operation, the time interval between the occurrence of a battery discharge alarm (blinking of the red LED) and turning off the device may be reduced.

## 5.4 Connection to the source of high pressure

1. It is strictly forbidden to use electrically conductive hoses to connect the device to sources of compressed gases. Conductive hoses can result in electric shock to personnel and patients.
2. Use the supplied high-pressure hoses only. Other hoses may result in poor performance.
3. When using oxygen cylinders, connect them only through a special reducer designed for medical gases.
4. The use of cylinders with compressed gases during operation of the ventilator requires strict observance of the "Rules for the design and safe operation of pressure vessels".
5. If the unit is idle for a long time, disconnect it from the gas supply systems.

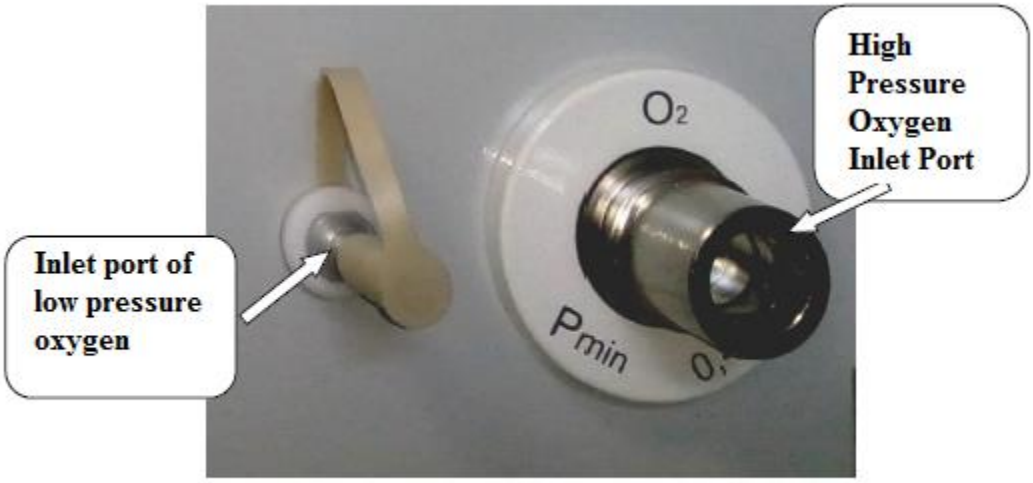
The device is equipped with a built-in automatic oxygen mixer. This means that it can be connected to sources of high-pressure gases (oxygen). Compressed gas must be dry, free from dust and oil particles.

The gas pressure in the supply system must comply with the technical characteristics of the ventilator. If the centralized power supply does not match, oxygen cylinders can be used as a source of compressed oxygen.

For additional purification of oxygen from dust and moisture, as well as pressure stabilization, the ventilator includes a special filter regulator with a glass-moisture collector. It is located inside the device and is not subject to maintenance.

## 5.4.1 Connection to the source of compressed oxygen

Connection is made by a special high-pressure hose to the port located on the rear wall of the device (Figure 5.3). The oxygen port is **NIST** compliant.




**Picture 5.3 - Ports for connecting gas sources**

The pressure supplied from the oxygen source should be in the range from 0.15 to 0.7 MPa and an inlet flow rate of not more than 60 l / min.

## 5.4.2 Connection to the source of low pressure

A low-pressure oxygen source can be an oxygen concentrator (not included in the delivery package of Aventa-M).

The low-pressure oxygen source is connected to the appropriate port (see Figure 5.3) using the hose of the supplied oxygen source.

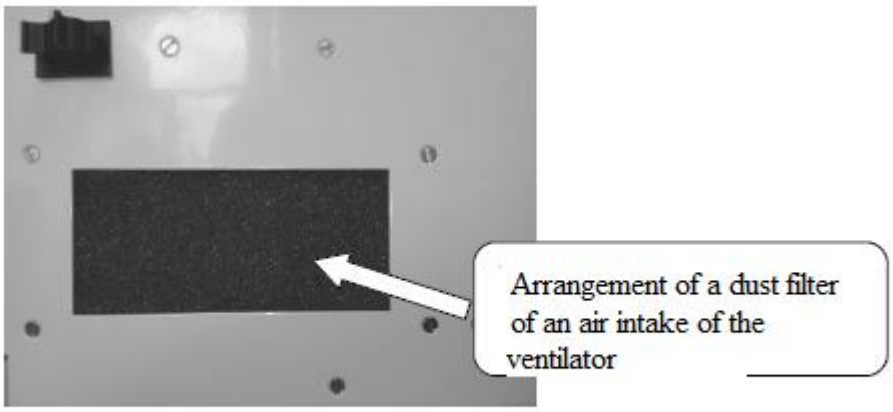
The oxygen supply through the low-pressure port should be in the range from 0.02 to 0.1 MPa (0.2 to 1.0 atm), and the input flow rate is not more than 5.0 l / min.

## 5.5 Ventilator's protection against dust and bacterial

To clean the air taken by the device, a dust filter is installed in the housing in front of the air intake (Picture 5.4).

It is recommended to periodically wash the dust filter with a 0.5% solution of detergents such as Lotus, Progress, Astra, followed by washing in running water.

You can get the dust filter by removing the protective cover.



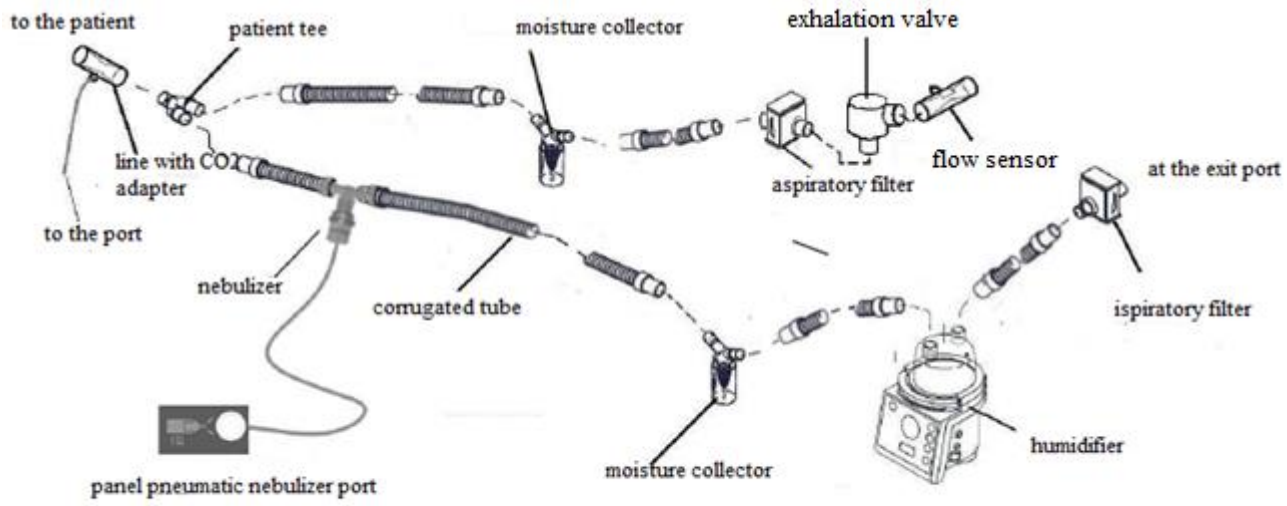

**Picture 5.4**

**A contaminated dust filter leads to hindering the operation of the turbine and, as a result, to a reduction in the volume of air supplied.**
**As a result, a frequent occurrence of anxiety about insufficient volume of inspiration or minute ventilation.**
**Further contamination of the dust filter leads to contamination of the flow sensor, as a result, to its failure and failure of the ventilator.**
**This situation is considered as removal of the device from warranty service.**
**The described situation is leveled by the installation and periodic replacement of the dust filter (see paragraph 5.5 of this document).**

## 5.6 Connection of the respiratory circuit

**1 The device and all its components are supplied non-sterile.**
**2 The use of exhalation and inspiratory filters is strictly required!**
**3 It is recommended to use only accessories specified in section 3 of the DataSheet for the Ventilator.**
**4 Connect the flow sensor with the unit turned off. Incorrect connection of the streaming sensor leads to its malfunction or malfunction of the device.**
**5 After each connection of a new circuit, as well as when changing its configuration (for example, when changing filters or when connecting a humidifier), it is necessary to test the breathing circuit.**
**6 These tests measure the compliance of the circuit, check the condition of the filters, and check the tightness of all connections.**
**7 The testing procedure is described in the section "Testing".**
**8 Failure to carry out tests may lead to improper operation of the device and harm the patient.**

The recommended respiratory contour configuration is shown in Picture 5.5.




Picture 5.5 The recommended respiratory contour configuration

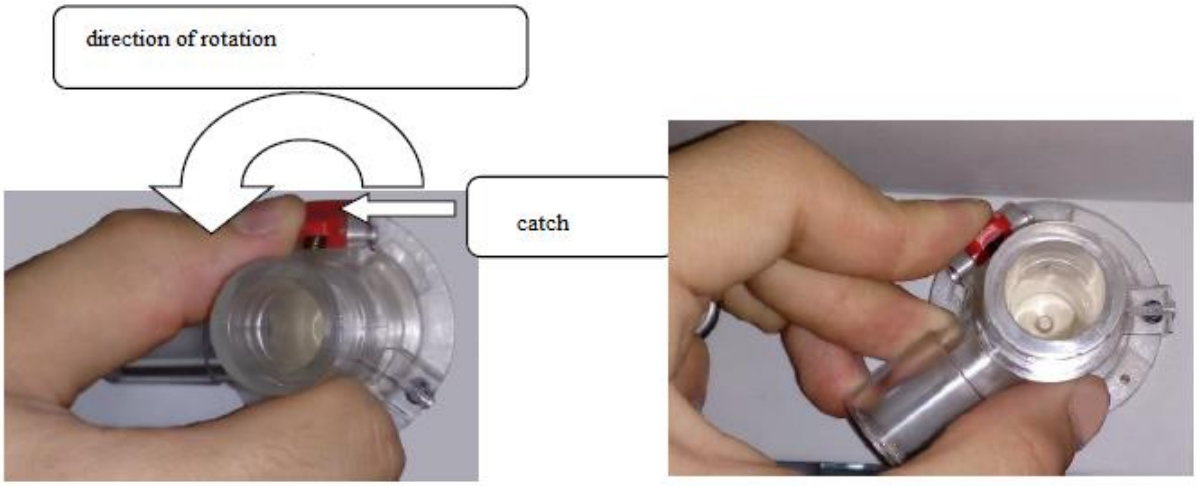
## 5.7 Operation of exhalation valve

The exhalation valve is designed to create pressure in the patient's lungs by blocking the air flow in the patient's line, regulating the residual pressure at the end of the exhalation (PEEP), and working with two phases of positive airway pressure - BiLevel (BiPAP).

The exhalation valve consists of two functional parts - electrical and pneumatic. Electrical part - an electromagnet with a running rod is located inside the ventilator and cannot be disassembled. The pneumatic part is located outside the ventilator, is removable and is subject to periodic disinfection.

The frequency of disinfection is determined by medical staff, carried out after each patient or as necessary.

The pneumatic part of the exhalation valve is detachable. To remove it, press the catch key down (Picture 5.6) and, turning the valve body counterclockwise, remove it by moving it toward you (Picture 5.7).



Picture 5.6 The location of the detachable part of the valve with a catch

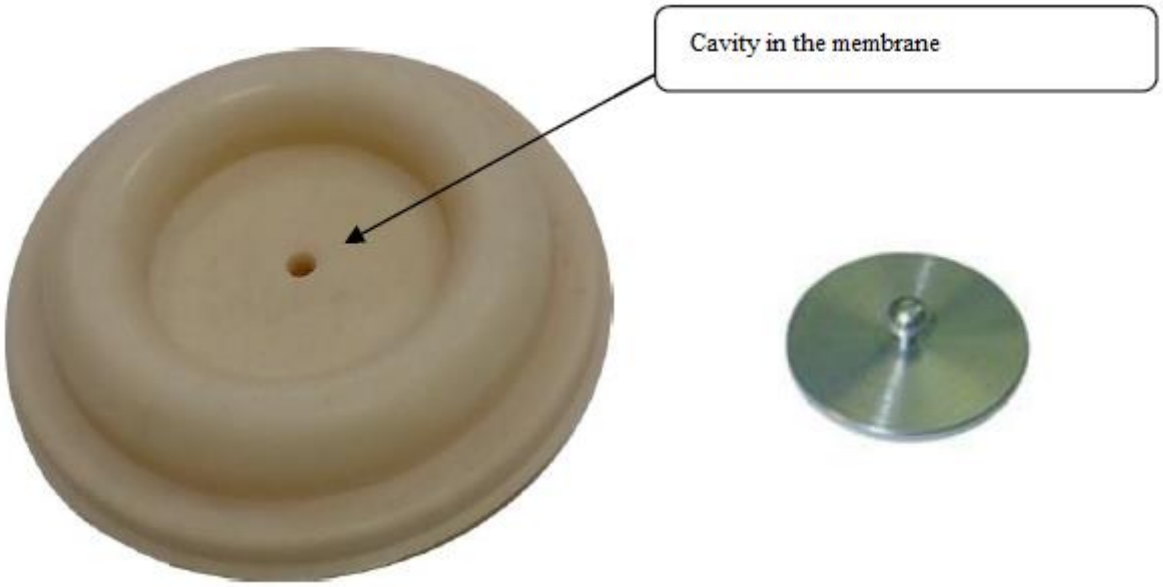
**Picture 5.7 Remove a valve**

The detachable pneumatic part of the valve consists of a body with a catch (Picture 5.8) and a shut-off valve (Picture 5.9).

Picture 5.8 Body with a catch

Picture 5.9 Pinch - off valve

The pinch-off valve consists of the rubber elastic membrane and the tough insert.



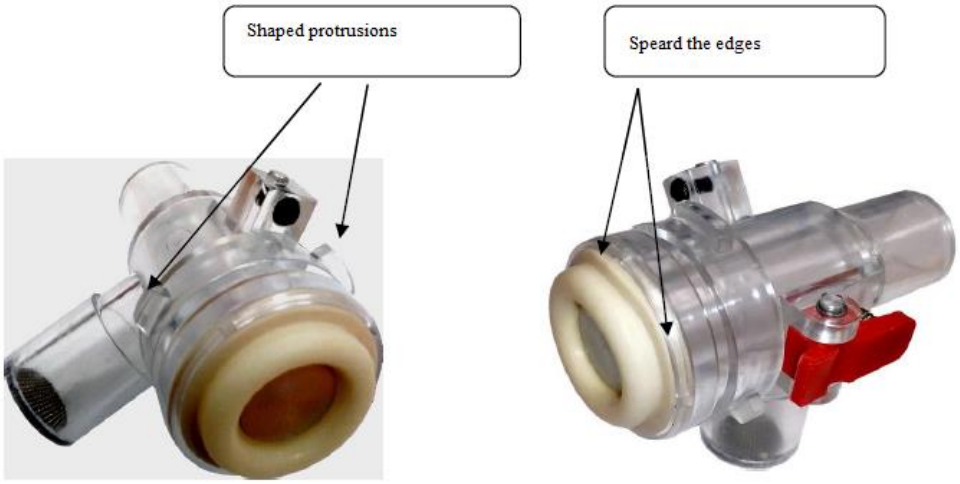

Picture 5.10- Elastic membrane and tough insert

Disinfection is carried out both the catch body itself and the pinch-off valve.
If it is needed, the pinch-off valve can be disassembled, for which a rigid insert can be taken by the edges and slightly pulled out of the elastic membrane until the fixing ball of the insert exits the recess of the membrane.
To assemble the pinch-off valve, align the fixing ball of the insert with the recess of the membrane, slightly press on the insert until it locks in the recess of the membrane (Picture 5.11) to the state shown in Picture 5.9.


**Picture 5.11 Assemblage the pinch-off valve**

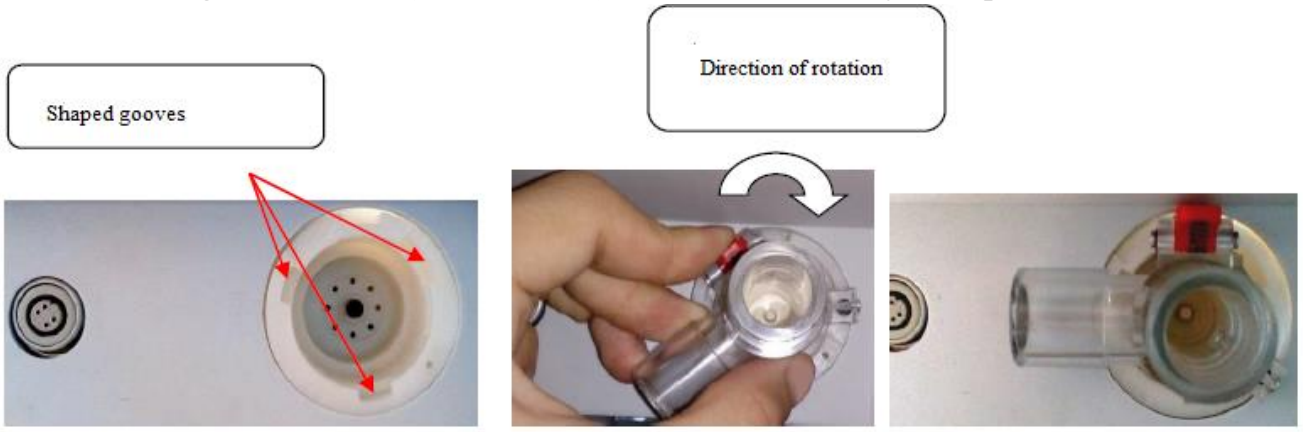
After assembling the edges of the pinch-off valve, wipe with an alcohol ball on both sides. This operation should also be performed if, when passing the mandatory test, before the ventilator is connected to the patient, a leak greater than the permissible value is displayed.

Carefully insert the assembled pinch-off valve into the body of the removable valve part. Spread the edges of the pinch-off valve evenly, avoiding kinks (Picture 5.12).



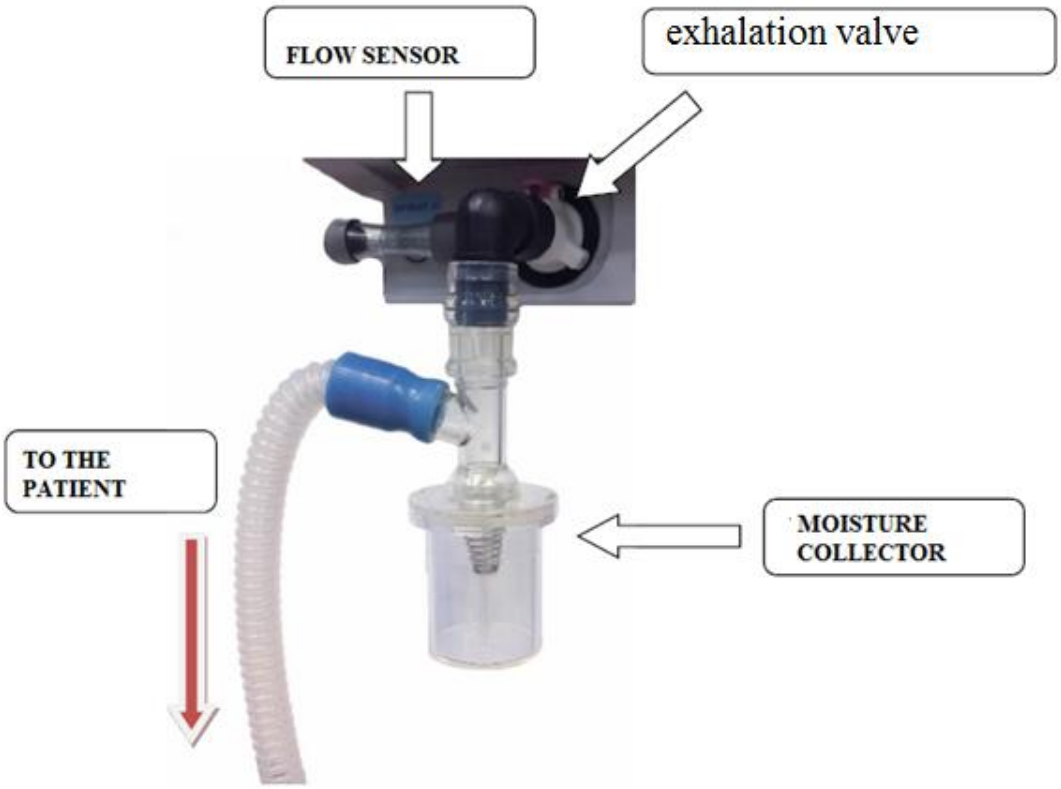

**Picture 5.12-Assembling of pneumatic valve's part**

After assembling the pneumatic part, install it in the ventilator, for which carefully align the protrusions on the removable part with the grooves on the part located on the ventilator. Press the catch key. Press the valve slightly away from you and turn clockwise until the locking latch clicks (Picture 5.13). The valve is ready for operation.




**Picture 5.13 Setting of the removable valve's part**

To the valve is connected the flow sensor- R51.20.200 (Picture 5.14)




Picture 5.14 -Placement of the flow sensor and moisture collector

To drain accumulated moisture, unscrew the removable cup, for which rotate it counterclockwise (Picture 5.15).

**Picture 5.15 Remove cup with water**

In order to better collect moisture from the patient's expiration line, a moisture collector is included in the opening of the exhalation hoses (Picture 5.16). Moisture is removed from it in the same way as on the moisture collector of the flow sensor R 51.20.200 (Picture 5.15).

**Picture 5.16 Moisture collector in the exhalation part of breathing circuit**

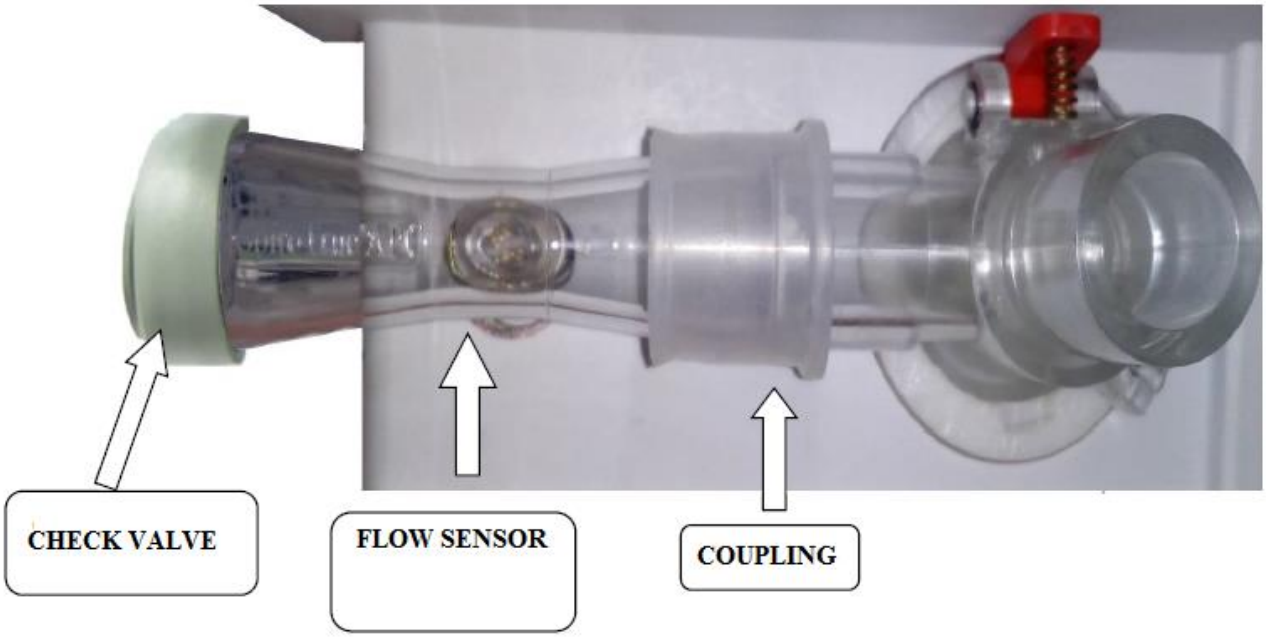
Notes: the absence of moisture collectors affects the accuracy of the flow sensor and, consequently, the occurrence of false alarms

.

## 5.8 Connection of the floe sensor to the exhalation circuit

To register the flow exhaled by the patient, it is necessary to connect a special flow sensor (supplied) to the exhalation valve through a connection sleeve (Picture 5.17).

| | |
|---|---|
| | **In order to avoid failure of the flow sensor, connect it with the ventiltor turned off.** |




**Picture 5.17 The exhalation valve with connecting the flow sensor**

Placement of the exhalation valve and the flow sensor connector are shown in Picture 5.18


**Picture 5.18 – Placement of the exhalation valve and flow sensor connector**

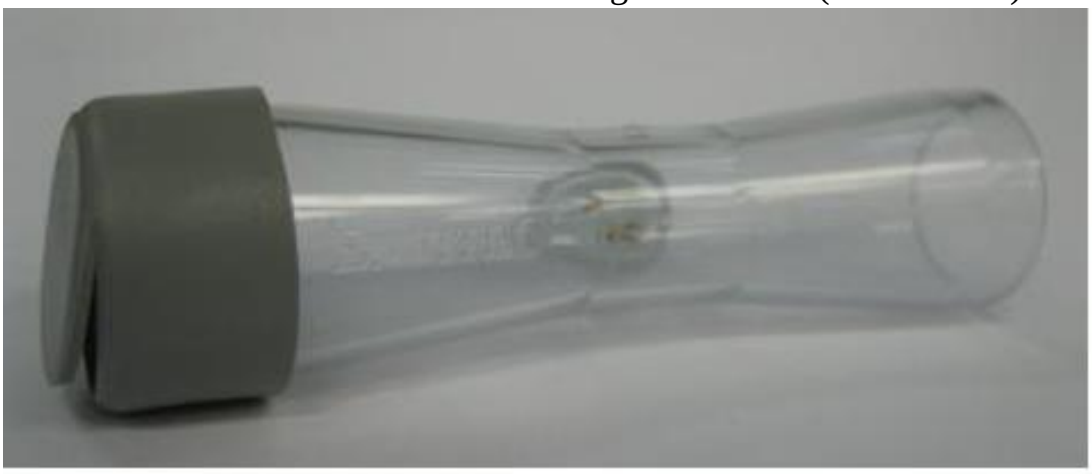
The connector for the flow sensor is located on the ventilator itself.

To connect the flow sensor, position it horizontally so that the label is readable (not upside down).

On the left side of the sensor there should be a grid (Picture 5.19).

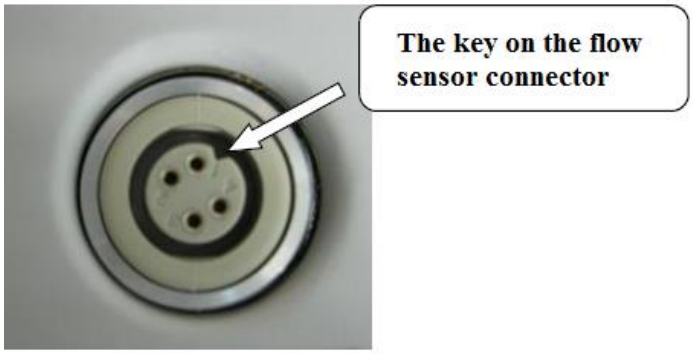
**Picture 5.19- Placement of a grid on the flow sensor**

The grid is closed the check valve which work together with it (Picture 5.20)



**Picture 5.20- Placement of the check valve on the flow sensor**

Take an attention on the location of the connector (Picture 5.21)




**Picture 5.21 -Location of the connector key**

**ATTENTION! The key on the ventilator's connector must match the key on the flow sensor's connector. Failure to match the keys leads to damage to the flow sensor.**

Slide the connector onto the right end of the flow sensor and gently push the sensor into the connector of the ventilator (Picture 5.22).

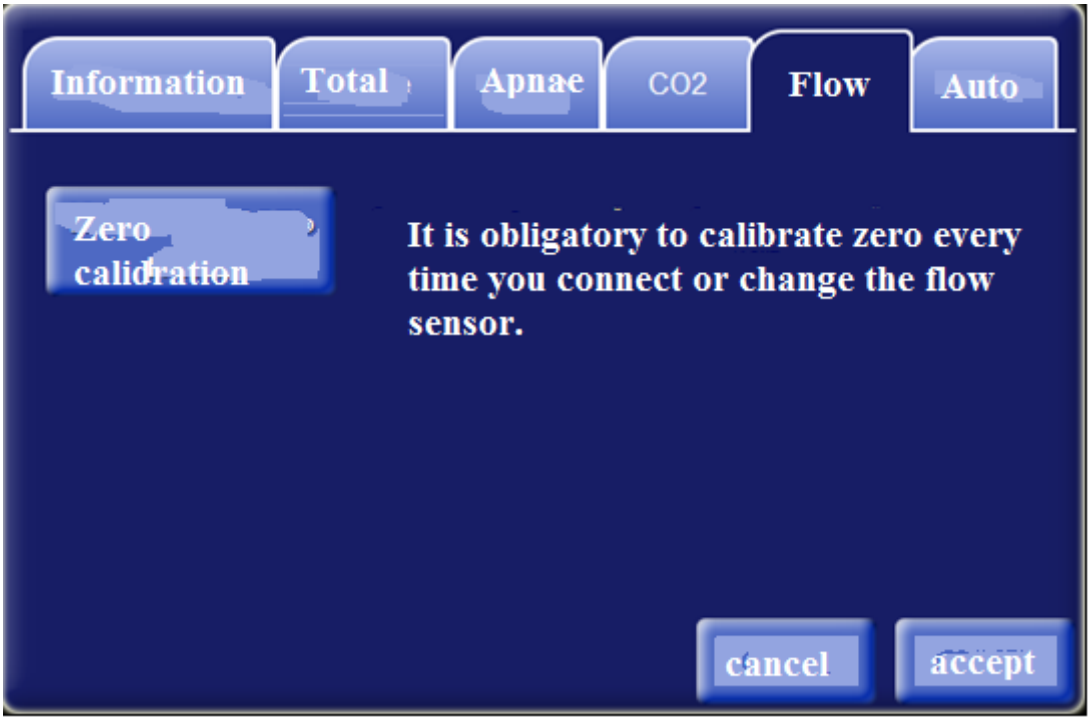
**Picture 5.22- Location of flow sensor on the ventilator**

Insert the exhalation valve into your socket.

Align the coupler so that it is fitted to both the outlet port of the exhalation valve and the flow sensor (see Figure 5.22).

The used flow sensor - P51.20.200 must be calibrated every time a sensor is connected or changed.

Zero calibration of the flow sensor is carried out in the settings window on the FLOW tab (Picture 5.23).




**Picture 5.23- Zero calibration of the flow sensor**

Before calibration, go to standby mode, open the settings window and select the "Flow" tab.

To start the calibration procedure, click the "Zero calibrate" button.

| | |
|---|---|
| | **Zero calibration of the flow sensor during ventilation is not recommended! This can lead to an inaccurate zero setting, which in turn will affect the measurement accuracy of the monitored parameters and lead to false triggers!** |

## 5.9 Installing of breathing circuit holder

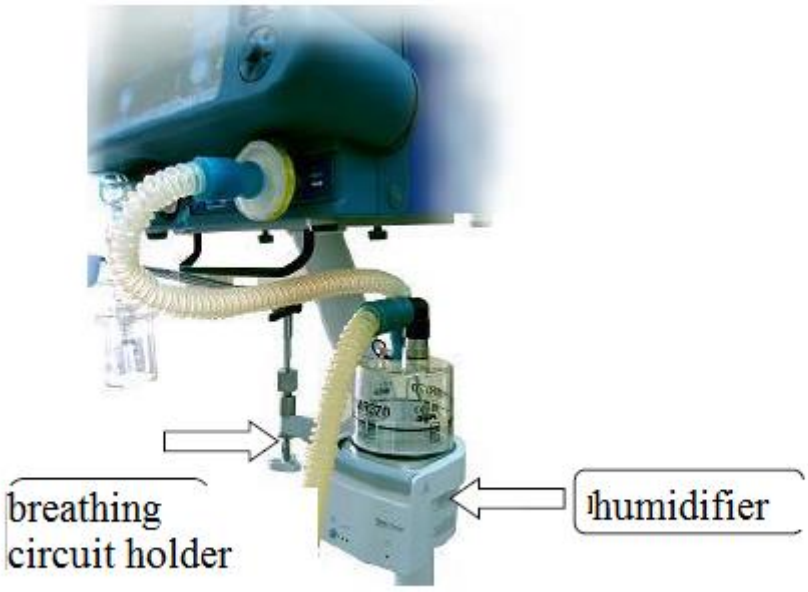
The ventilator is supplied complete with a breathing circuit holder. The breathing circuit holder is fixed on the trolley cart.

## 5.10 Installation and connection of the humidifier

The device can be delivered complete with a humidifier.

The humidifier is mounted on the bar of the cart (Picture 5.24). The humidifer is fixed in the grooves and fixed on the bracket under its own weight.

Maintenance of the humidifer, adjustment of its operation, actions in emergency situations, care, etc. described in the manual for the humidifier.




**Picture 5.24- Location of the moisture collector and contour holder**

## 5.11 Connection of the nebulizer

Nebulizers are connected to the patient's respiratory contour through a T-adapter. Connecting a nebulizer is shown in Picture 5.5.

Nebulizers synchronized with breathing are also connected to a special port of the Aventa-M ventilator (Picture7.18) located on the front panel next to the INPUT port. The operation mode of the nebulizers synchronized with breathing is set in the Aventa-M ventilator (clause 7.9.2).

## 5.12 Connection of additional equipment.

On the back panel of the ventilator there are the following connectors for connecting additional hanging equipment (Picture 5.25).


**Picture 5.25- Connectors for connection of additional equipment**

**Service** -use at the services to service the ventilator

**USB / Wi-Fi** - data transfer to the doctor's computer / when using a modem - remote access with data displayed on the monitor of the device to a remote computer
**SD-Card** - SD card slot
**Eth** - Ethernet input
**SpO2** - P56.06.600 sensor connector
**RS-232** - connector for connecting devices with a serial port
**CO2** - capnograph connector /

## 5.13 Using the ventilator`s cart

**It is strictly prohibited to move the ventilator beyond the wires, sensors, patient circuit.**
**To prevent damage to health and equipment, make sure that the ventilator is properly fixed to the cart.**
**To prevent the cart from tipping over and equipment to be damaged, follow these steps:**
**- block the wheels of the cart, leaving it in the place of temporary stay;**

**- Be careful when transporting the cart over thresholds.**

The cart's wheels are equipped with special locking mechanisms. To move the ventilator, you must unlock the locking mechanism.

And to fix the ventilator in a state position, it is necessary to lock the locking mechanisms (Picture 5.26).


**Picture 5.26-Control the ventilator blocking mechanism of the wheels**

# 6 Carry out the tests

Tests- the sequence of operations during which:

- Check flow sensors
- Checking the operation of pressure sensors
- Checking the leak in the respiratory circuit
- Respiratory circuit compliance measurement
- Respiratory circuit resistance measurement

The total time required for the tests is about 3 minutes.

1. It is obligatory to disconnect the patient from the ventilator before carrying out tests. Otherwise, running tests can harm the patient!
2. During carrying out tests, use the same circuit (with all its components) to which you will connect the patient. If you change the circuit configuration, you must run the tests again.
3. Errors may occur during tests. This means that the ventilator or the corresponding circuit elements are damaged and cannot provide ventilation. In this case, it is necessary to replace the corresponding components before starting ventilation.

## 6.1 When will the test be carry out?

| | |
|---|---|
|  | Testing recommended:<br>1. During replacing the expiratory filter<br>2. During connecting a different type of respiratory circuit<br>3. During changing the configuration of the circuit (in case of replacement of the humidifier, moisture collector, etc.).<br>4. Before connecting a new patient to the ventilator<br>It is obligatory to carry out tests: Every two weeks when the patient is disconnected from the device |

### 6.1.1 Demands to carry out the tests and necessary components

For carrying out you will need:

- respiratory circuit assembly with all components, including expiratory and inspiratory filters,

- a cap for blocking the tee from the patient.

In addition, the ventilator must be connected to oxygen sources, the pressure of which must comply with technical requirements.

| | |
|---|---|
|  | **Before starting the tests, it is needed that at least 5 minutes pass after the ventilator is turned on. This is necessary to warm up the components of the ventilator and achieve good exactness of measurements carried out in tests.**<br>**To avoid leakage errors, make sure all respiratory elements of the contour are correctly installed before starting tests.** |

### 6.1.2 The order of carrying out the tests

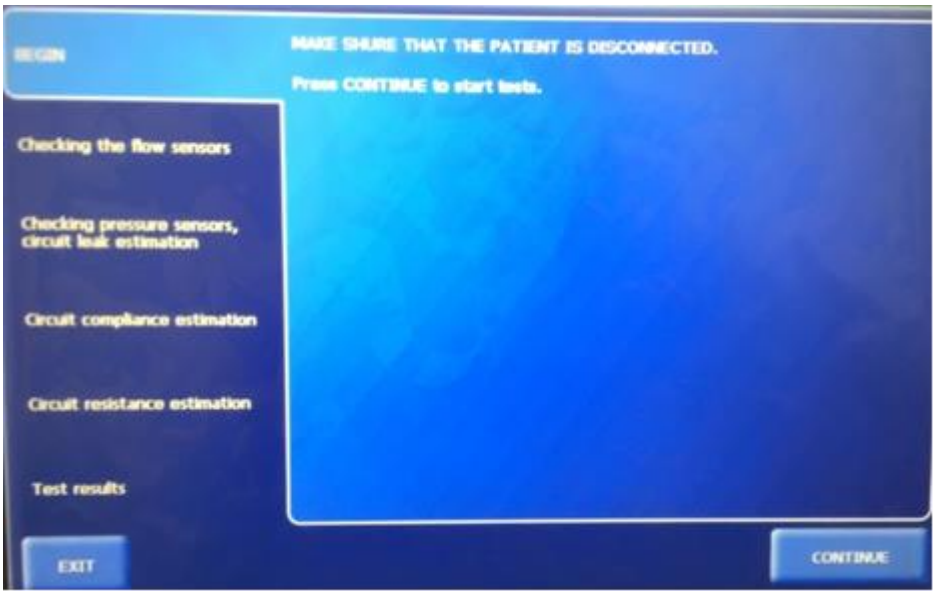
**It is obligatory to disconnect the patient from the ventilator before carrying out tests. Otherwise, running tests can harm the patient!**

For start the tests, follow these steps:

1. If the ventilator is turned on, switch to standby mode. if turned off, turn on the device.
2. Make sure that five minutes have passed after turning on the device.
3. Connect the inspiratory filter and respiratory circuit that will be used for ventilation.
4. Press the button TESTS in the standby mode window on the display of the ventilator.


**Picture 6.1 -Standby mode window**

5. The window of done tests will be appeared on the display




**Picture 6.2- Carrying out tests window - START**

6. To be sure that patient is disconnected form the respiratory ventilator. Press the button CONTINUE to start tests.

At each step, during the tests, you can exit the tests by pressing the button EXIT. In this case, the device will use the results saved during the last test, if any, otherwise the default results will be used.

After each procedure, the system displays the result of the procedure. In case of an error, the system suggests repeating the current procedure again. In the case when the result is outside the permissible limits, the system gives an appropriate warning and offers the operator the most suitable result for the corresponding procedure.

**You can accept this result only when you are sure that it will not harm the patient**.

The procedure is considered completed if the result of its execution is within acceptable limits or the operator accepted another result proposed by the system.

The list of procedures performed during the tests is shown in Table 6.1.

Table 6.1

| **Procedure description** | **Work procedure** |
|---|---|
| **Check flow sensor** | |
| 1.The device will ask you to connect the inspiratory port and the exhalation port with a short tube with filters. | Connect the inspiratory port and the exhalation port with a short tube with filters. Click the button. CONTINUE |

| | |
|---|---|
| 2. The device checks the accuracy of the installation of flows and displays the result of the verification | In case of error, follow the instructions of the ventilator.<br>To proceed to the next procedure, press CONTINUE. |
|  | Connect exactly the circuit that will be used for ventilation, including a humidifier, dehumidifiers and filters. |
| **Check pressure sensors** | |
| 1. The device will ask you to assemble and connect the respiratory circuit to the device and plug the tee from the patient's side with a stopper. | Assemble and connect the respiratory circuit to the ventilator and plug the tee from the patient side. Click the button CONTINUE |

| **Procedure description** | **Work procedure** |
|---|---|
| 2. The device checks the operability of the pressure sensors for inspiration and expiration and evaluates the leakage in the circuit and displays the estimated value. | To proceed to the next procedure, press CONTINUE. In case of an error, the transition to the next procedure will be prohibited. |
| **Appraise compliance of the respiratory circuit** | |
| 1. The device will ask you to assemble and connect the breathing circuit to the device and plug the tee from the patient's side with a stopper. | Assemble and connect the breathing circuit to the device and plug the tee from the patient side. Click the Continue button. |
| 2. The device evaluates and displays the circuit compliance value on the display. | To proceed to the next procedure, press CONTINUE. In case of an error, the transition to the next procedure will be prohibited. |
| **Appraise resistance of the respiratory circuit** | |
| 1. The ventilator will ask you to assemble and connect the breathing circuit to the device and plug the tee from the patient's side with a stopper. | Assemble and connect the breathing circuit to the device and plug the tee from the patient side. Click the "Continue" button. |

| | |
|---|---|
| 2. The ventilator will ask you to open the tee on the patient side. | Open the tee on the patient side. Click the Continue button. |
| 3. The ventilator displays the test result on the display. | Click the button Continue. In case of an error, the transition to the next procedure will be prohibited. |

After completing all the procedures, the system will display the results of the tests. To exit the tests, click the DONE button.

### 6.1.3 The results of the tests

Test results are stored in non-volatile memory and are available for viewing in the standby window by the "TEST RESULTS" button.

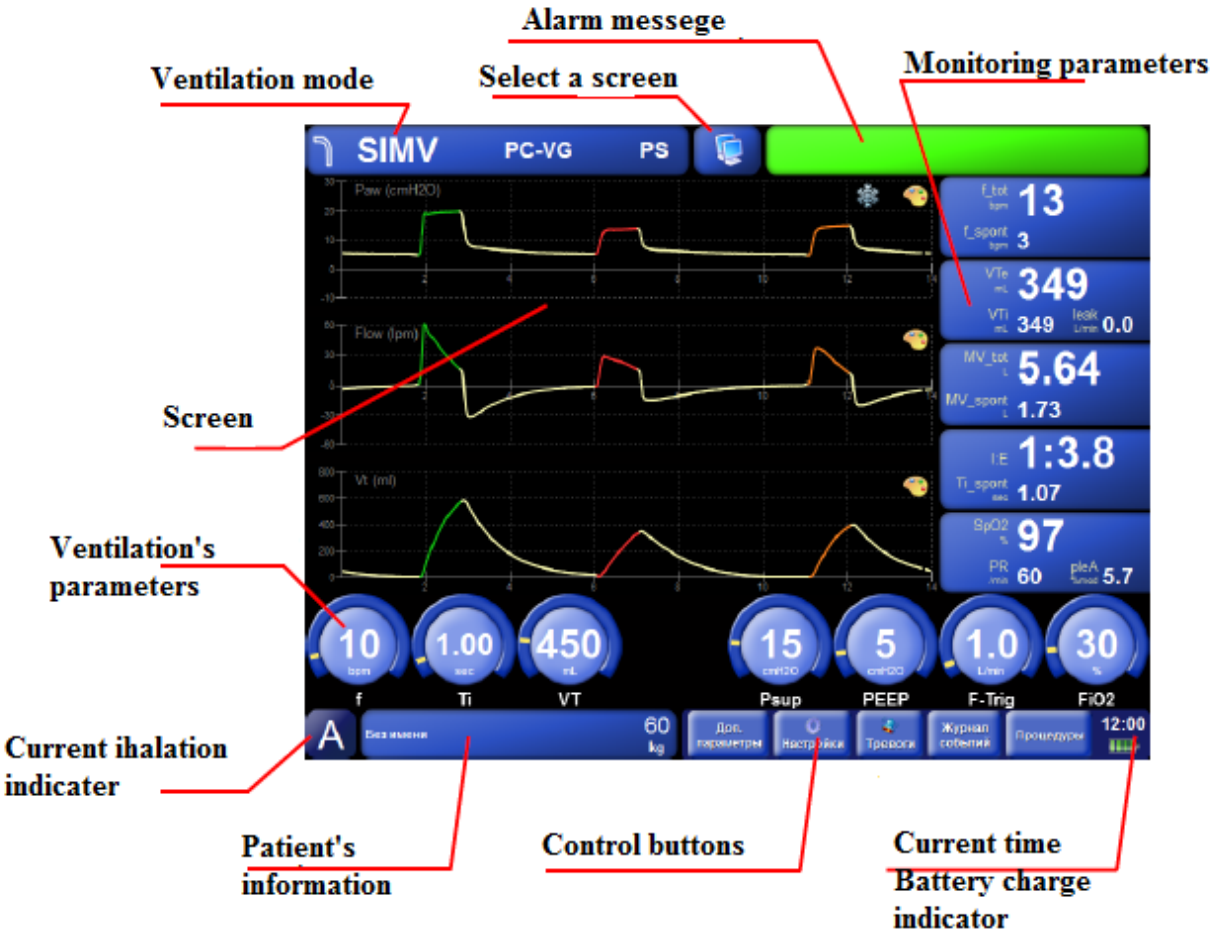
### 6.1.4 Power-on self-test

When turned on, the device performs a self-test of all ventilation controls. The result of the self-test is recorded in the event log. If an error occurs during the self-test, a message appears on the display with a comment about the following operator actions.

# 7. Control the ventilation

The ventilator is equipped with intelligent monitoring with graphical visualization of the main indicators that provides with the ventilation process in real time, the state of respiratory mechanics, the degree of patient and device involvement.

## 7.1 Total display view




**Picture 7.1- Total display view**

In the upper left corner on a dark blue background displays information about the current ventilation mode, type mandatory breaths, type of spontaneous breaths. In the center, an icon is located above, with which you can select the current display screen. In the upper right corner, there is a field on which current alarms are displayed. If now there are no alarm messages, then this field is colored green. On the right, five operator-selected parameter groups are displayed. In the center of the display, data from the current display screen is displayed. The set ventilation parameters are displayed a little lower.

In the lower left corner is the indicator of the current inspiration type. The letter indicates the type of inspiration:

- C - breath initiated and controlled by the ventilator,

- A - breath initiated by the patient and controlled by the ventilator,

- S - breath initiated and controlled by the patient (spontaneous breath).

To the right of the current inspiration indicator is a field that displays the name of the patient and his ideal weight (IBW). To the right of the patient information are the control buttons. In the lower right corner, the current time and battery indicator are displayed.

After switching on, the device is in standby mode and the following window is displayed:

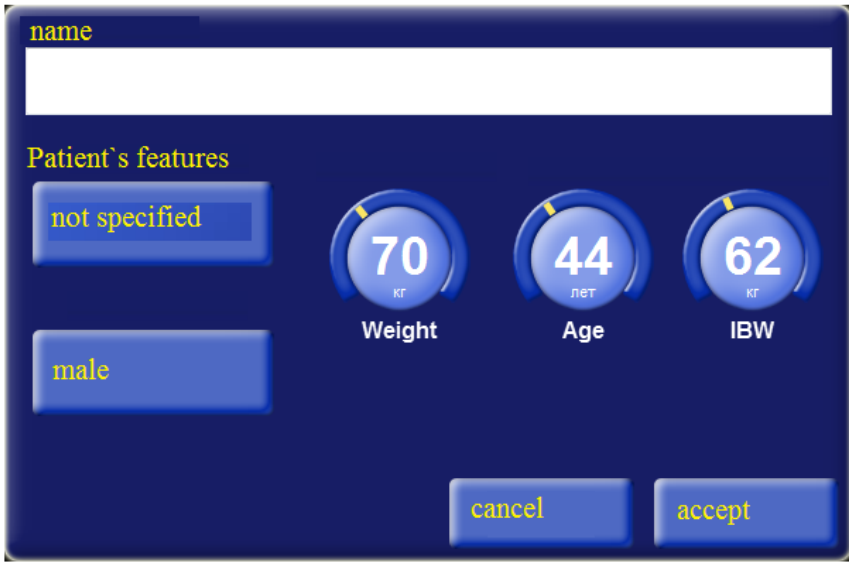

**Picture 7.2- Window of standby mode**

Also, during ventilation, you can switch to standby mode by pressing the 

button on the keypad of the device and then click the "Standby mode" button in the window that opens.

To continue ventilation with the previous parameters, press the “PREVIOUS PATIENT” button. In this case, the device will begin ventilation using the previous settings, as soon as it detects that the patient is connected to the circuit.

To set new ventilation parameters, press the “NEW PATIENT” button



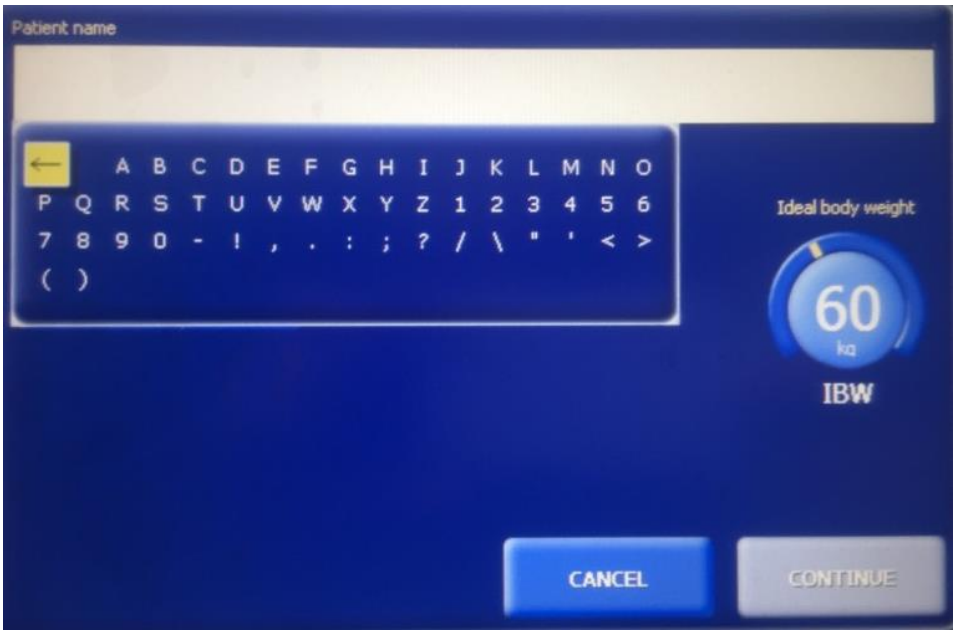

**Picture 7.3 - Patient Information Entry Window**

The display will show a window for entering patient information. In this window you must specify the name, features, ideal weight, age, live weight and gender of the patient.

Click on the image of the ideal weight parameter and set the desired value. If the ideal weight is difficult to determine, then you can focus on the growth, which is displayed on the tooltip above in the process of setting the value. When you touch the image of the parameter, the “ACCEPT” button will become available for pressing.

To enter the name of the patient, click on the white field. A panel of characters for typing appears below (Picture 7.4). Using the encoder, move the pointer to the desired character and click on the " 

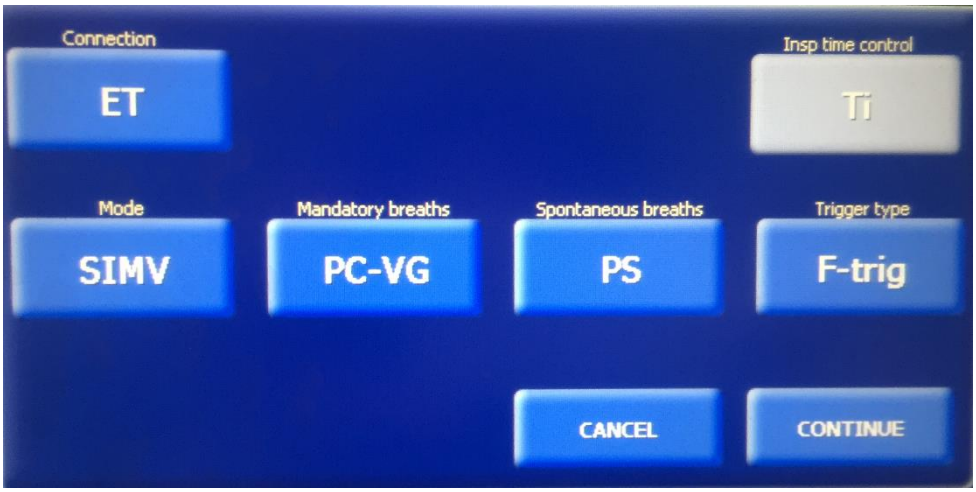
" button (near the encoder), the selected character will be added to the input line. Also, typing can be done directly by clicking on the characters displayed on the panel.




**Picture 7.4 - Patient Information Entry Window- Entry Name**

After entering the patient information, press the “ACCEPT” button or “CANCEL” to return to the previous one to go to the next window.

In the next window, you must specify the type of patient connection to the ventilator, ventilation mode, type of forced breaths (if required), type of spontaneous breaths (if required), type of trigger. Click on the appropriate button and in the context menu that opens, use the encoder to move the cursor to the desired item and click on the "apply" button near the encoder.




**Picture 7.5- Setting of ventilation parameters window**

The type of connection determines how the patient is connected to the device:

- ET - endotracheal tube,

- Trach - tracheostomy tube,

- NIV - non-invasive ventilation (mask).

The ventilation mode determines the method and sequence of delivery of breaths to the patient:

- A / C (ASSIST / CONTROL) - delivery if only mandatory breaths initiated either by time, or by the patient, or by the operator (using the button “ 

”),

- CMV - delivery of only mandatory breaths with a given frequency or initiated by the patient,

- SIMV (Synchronized Intermittent Mandatory Ventilation) - delivery of mandatory and spontaneous breaths,

- SPONT - delivery of spontaneous breaths, as well as mandatory ones initiated by the operator (using the button “ 

”),

- DUAL-LEVEL - delivery of forced and spontaneous breaths. In this mode, two pressure levels, PEEPH and PEEPL, are set.

- CPAP - support for spontaneous breaths at the level of the set base pressure,

- HFlow –support spontaneous breathing with a high flow of respiratory mixture

A detailed description of ventilation modes is given in section 18 of this manual.

The type of mandatory breaths determines the method of organizing mandatory breaths (controlled by the device):

- PC - with pressure control,

- VC - with volume control,

- PC_VG - with pressure control with guaranteed volume.

The type of spontaneous breaths determines how to support spontaneous breaths (controlled by the patient):

- PS - pressure support,

- PS-VG- pressure support with guaranteed volume,

- TC - automatic compensation of resistance of the endotracheal tube and tracheostomy tube,

The type of trigger determines the method for detecting a breath attempt:

- F-Trig – flow trigger

- P-Trig – pressure trigger,

- V-Trig – volume trigger.

Controlling inspiratory time determines how to set the mandatory inspiratory time. Depending on the selected ventilation mode, the following methods of controlling the inspiratory time are available:

- Ti – directly sets the duration of the mandatory breath,

- I: E – inspiratory duration is calculated from the values of the breath rate and from the ratio of inspiratory time to expiratory time,

- PeakFlow– inspiratory duration is calculated from the values of ventilation frequency, peak flow and flow shape.

After selecting the appropriate options, press the button “Continue”.

At the bottom of the display, control parameters that correspond to the set ventilation mode, type of mandatory and spontaneous breaths, and the selected trigger type are highlighted (Picture 7.6).


**Picture 7.6 – Panel of the control’s parameters**

The ventilator sets the values of all parameters depending on the entered ideal weight and patient characteristics. You can change the value of any of these parameters.

Press on the parameter whose value you want to change and use the encoder to set the desired value. In addition to the main control parameters, you can open a panel with additional parameters. To do this, press “Add. parameters”. After that, a panel of additional parameters will appear above the main parameters as shown in Picture7.7.


**Picture 7.7 – Panel of the control additional parameters**

Table 4.1 provides a complete list of control parameters available when controlling ventilation.

After setting all the necessary values, press the button 

on the panel next to the encoder.

| | |
|---|---|
| | The values of all parameters take effect only after pressing the button “APPLY” on the ventilator panel. |

## 7.2 Changes of ventilation`s mode

In the upper left corner of the display there is an indicator of the current ventilation mode (Picture 7.8), which constantly shows the type of connection of the patient to the device (as an image of a tube or mask), ventilation mode, types of forced and spontaneous breaths (if they are provided in the current mode ventilation).


**Picture 7.8 – The current ventilation mode indicator**

To change the ventilation settings, press the current ventilation mode indicator. The display will show the ventilation parameters settings window (see Figure 7.5), which was described above. Make the necessary changes and click the “Continue” button.

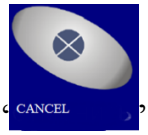
Then, set the necessary values for the ventilation control parameters and press the "


" button on the panel next to the encoder.

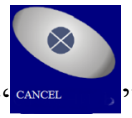
## 7.3 Changes of ventilation's parameters

You can change the values of ventilation parameters without changing the ventilation mode, types of mandatory and spontaneous breaths, etc. To do this, simply click on the image of the parameter whose value you want to change and use the encoder to set the required value. In the same way, you can change the values of any other parameters. The currently changing parameter is displayed on a green background, and parameters that have already been changed are displayed on a yellow background (Picture 7.9).

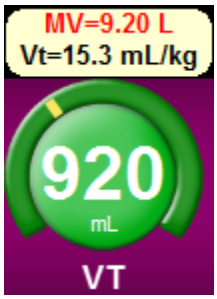

**Picture 7.9- Value changes of the control parameters**

To cancel the changes made, press the " 

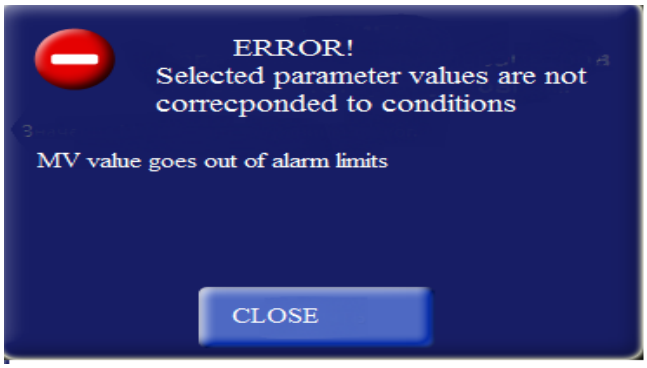

" button on the panel next to the encoder. The previous values of all parameters appear on the display, and the background illumination of the parameters disappears.

In the process of changing the values of some parameters, tooltips may appear above them that contain additional information corresponding to the displayed value of the parameter (Picture 7.10). In some cases, red hints may contain information about an invalid parameter value. In this case, if you press the " 


" button on the panel next to the encoder, a message about incorrect parameter values will appear on the display (see Figure 7.11).




Picture 7.10



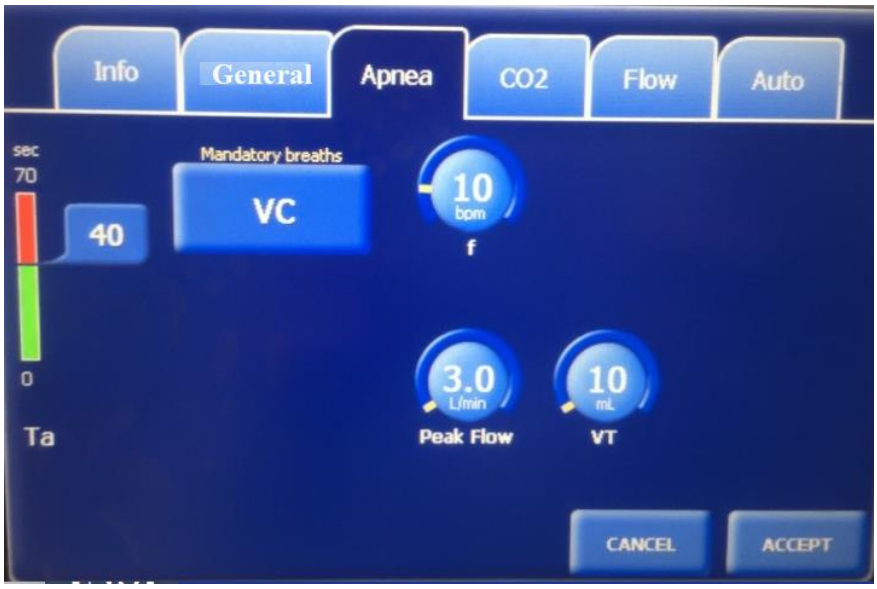

**Picture 7.11 – Error message**

When such situations are appeared, change the values of the parameters that caused the error, or change the corresponding alarm limits ( section 8 “Alarm’s system”). Then again press the “ 

” button on the panel next to the encoder.

### 7.4 Installation parameters of ventilation for APNEA mode (in case of apnea)

Ventilation parameters for the Apnea mode are set in the settings window on the Apnea tab. To call this window, click on the “Settings” button at the bottom of the main window. Then, select the Apnea tab (Picture 7.12).




Picture 7.12- Setting window – tab Apnea

On this tab, you can set the values of the following parameters:

- Apnea Interval (Ta),
- Type of spontaneous breaths,
- Breath rate (f),
- Tidal volume (Vt),
- Peak Flow
- Inhalation time (Ti).

**In "APNEA" mode with non-invasive ventilation (NIV), only mandatory breaths controlled by pressure (PC) are possible.**

To change the value of a parameter, press on the display's picture, then set the desired value by using encoder. Press on the "ACCEPT" button, if you want that parameter values are taken effect. To cancel the changes, press on the "CANCEL" button.

### 7.5 Holding breath

When you press the button 

, the ventilator waits for the completion of the current mandatory inhalation and blocks the flow of the gas mixture in the respiratory circuit, waiting for the pressure to stabilize.

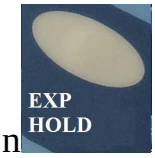
During the inspiratory pause, the pressure in the patient's lungs and the pressure in the respiratory circuit, as well as the pressure between the various departments inside the lungs are equalized.

An inspiratory pause is used to measure static compliance, airway resistance and plateau pressure, as well as pressure in the distal lungs.

Holding a breath can be done in two ways:

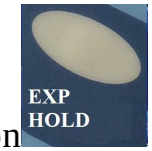
- By briefly pressing the button 

. In this case, the device automatically determines the duration of the inspiratory pause (from 0.5 to 3 seconds).

- By holding down the button 

. In this case, the duration of the expiratory pause is controlled by the operator. The expiration pause ends when you release the “Insp pause” button or after 30 seconds have elapsed since the start of the pause.

### 7.6 Holding exhalation

When you press the button 

, the ventilator continues to exhalation until the pressure in the respiratory contour is stabilized, or until the pause is completed by timeout.

During an expiratory pause, the pressure in the patient's lungs and the pressure in the respiratory contour are equalized. An expiratory pause is used to evaluate the value of internal PEEP.

Exhalation can be carried out in two ways:

- By briefly pressing the button 

. In this case, the ventilator automatically determines the duration of the expiratory pause (from 0.5 to 3 seconds).

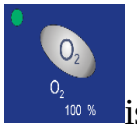
- By holding down the button 

. In this case, the duration of the expiratory pause is controlled by the operator. The aspirational pause ends when you release the button 

or after 30 seconds have elapsed since the pause began.

**After pressing the “Exp hold” button, the ventilator begins to wait for suitable conditions in the exhalation phase to begin the maneuver. The waiting time cannot exceed 60 seconds, otherwise the device will issue a corresponding message on the cancellation of the expiration pause.**
**If during the expiration pause the patient tries to inhale or there is any alarm, the device will stop the maneuver and give a message that the expiration pause has been canceled.**

### 7.7 100% oxygen ventilation

When the button 

is pressed, the device ventilates with 100% oxygen for 2 minutes from the moment the button is pressed.

At the end of the 2-minute period of ventilation with 100% oxygen, the device automatically calibrates the oxygen sensor.

### 7.8 Manual breath

A manual breath is initiated by the operator by pressing the button 

on the keypad of the device.

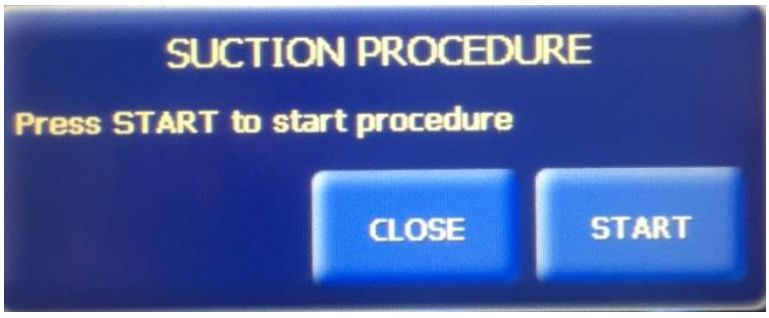
When this button is pressed, the ventilator delivers one forced (PC or VC) breath to the patient, in accordance with the current mandatory breath settings.

**Manual inhalation is carried out only at certain (permitted) time intervals.**
**For example, if during pressing the button the ventilator already delivers any breath to the patient, then the manual breath will not be delivered.**

### 7.9 Treatment

#### 7.9.1 Suctioning tool

To start the bronchial sanitation procedure, click on the "Procedures" button in the lower area of the display. Then, in the menu that opens, select the "Suction procedure" item. A window will appear on the screen as shown in Picture 7.13.

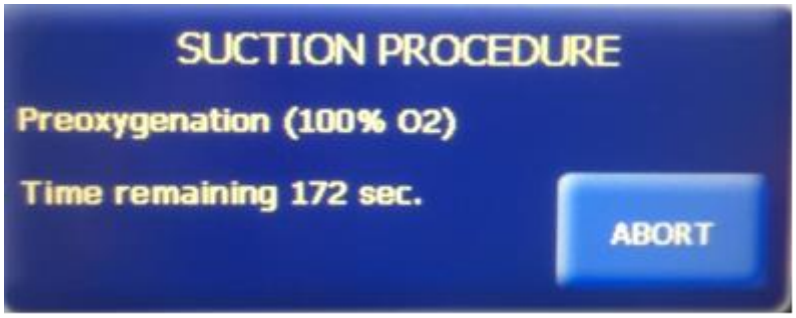



**Picture 7.13- Suctioning tool**

To start the procedure, press the START button. To cancel the procedure, press the CLOSE button.

The procedure for the rehabilitation of the bronchi consists of three stages.

The first stage is preoxygenation. At this stage, the patient is given breaths with an increased concentration of oxygen in the inhaled air mixture. The amount of concentration depends on the set patient weight (IBW). With a weight of less than 30 kg, the oxygen concentration rises by 25% relative to the current concentration, which was before the start of the procedure. With a weight of more than 30 kg, the concentration is set equal to 100%. The maximum duration of preoxygenation is 180 seconds. During this time, it is necessary to disconnect the patient from the device, after which the device will automatically switch to the next stage of the procedure.




**Picture 7.14- Suction procedure- preoxygenation**

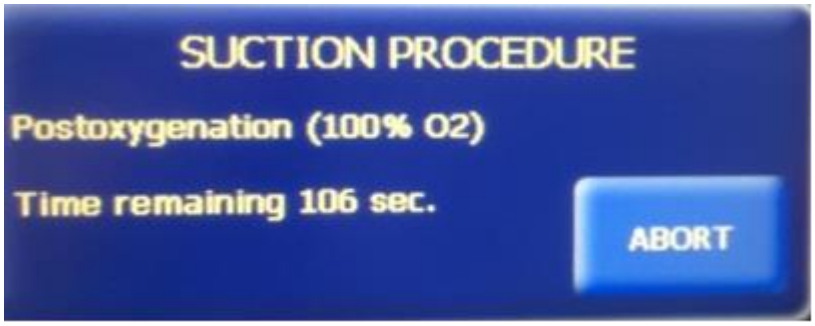
To stop the procedure, press the "INTERRUPT" button.

The second stage is the rehabilitation of the bronchi. At this stage, it is necessary within 120 seconds to carry out the rehabilitation of the bronchi and connect the patient back to the device. During the second stage, all alarms are disabled. As soon as the device detects the patient's connection, it will automatically proceed to the last step of the procedure.


**Picture 7.15 – Suction prosedure - Sanitation**

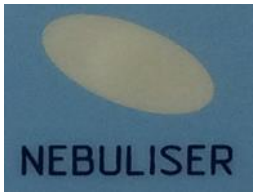
The third stage is postoxygenation. At this stage, the patient is taken in breaths with an increased concentration of oxygen in the inhaled air mixture. The concentration value is set the same as at the preoxygenation stage. The duration of the stage is 180 seconds.

The operator can forcefully complete the procedure by clicking on the “Abort” button in the procedure window.

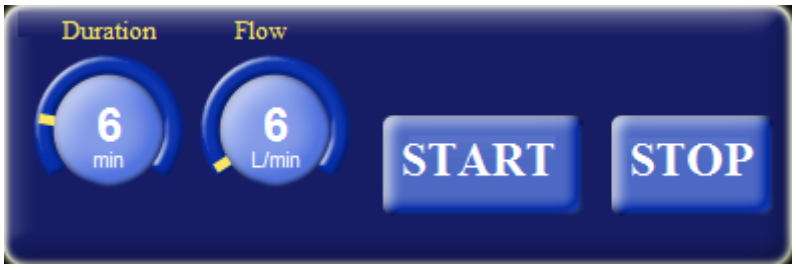



**Picture 7.16 – Bronchial remediation procedure - Postoxygenation**

### 7.9.2 Nebulizer`s operation

To control the nebulizer, you must press the 

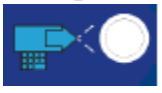
button in the main window. The nebulizer control window will open on the display (Picture 7.17).




**Picture 7.17 - Nebulizer control window**

In this window, the duration of the nebulizer is selected using the “Duration” parameter. In addition, you can set the required nebulizer flow by setting the value of the “Flow” parameter. The “START / STOP” button starts and stops the nebulizer.

The nebulizer works as follows.

After pressing the “START” button for the specified duration, an oxygen flow of 6 l / min or 10 l / min (in accordance with the selected value of the “Flow” parameter through a special port of the nebulizer located on the front panel of the device next to the nozzle “INSPECTION” and is indicated by a picture -  (Picture 7.18).


**Picture 7.18 -Pneumatic nebulizer port**

At the end of the inspiration, the flow stops, and at the next, it turns on again, and so on for the entire specified duration. The duration of the nebulizer is set in the range from 1 to 30 minutes in increments of 1 minute.

During the operation of the nebulizer, the corresponding nebulizer operation indicator appears on the inspiration indicator (in the lower left corner of the display).

After the set duration, the nebulizer automatically stops working. In addition, you can force stop the nebulizer by pressing the "STOP" button in the nebulizer control window.

### 7.9.3 Recruitment maneuver

Recruitment maneuver is used to straighten the lungs of a patient with acute respiratory distress syndrome (ARDS) at stage I. This stage of ARDS is characterized by the development of macro and microatelectases. Turning off the alveoli from gas exchange leads to a progressive decrease in arterial blood oxygenation. Often during traditional mechanical ventilation in such patients during each respiratory cycle, the opening of the alveoli by inspiration and closing by exhalation are observed. The resulting deformation of the alveoli leads to damage.

The task of the recruitment maneuver is to open the adhered alveoli and keep them open. This is achieved by a single significant increase in pressure. To further maintain the alveoli in the open state, it is enough to apply much less pressure.

Disclosure of coalesced alveoli leads to an increase in the dynamic compliance of the lungs and tidal volume, an improvement in oxygen supply and the removal of carbon dioxide.

An effective recruitment maneuver allows you to increase dynamic lung compliance by 20-30% and increase oxygenation to 99-100%.

The recruitment procedure consists of the following steps:

- Preparatory,
- Search for alveolar closure pressure (primary recruitment),
- Disclosure of the alveoli (repeated recruitment).

### 7.9.3.1 Preparatory phase

To ensure the accuracy of measurements and to prevent the patient's no synchronism with the device, sedatives are administered and, if necessary, muscle relaxants.

Before performing the maneuver, increase the rate of infusion support or doses of inotropic drugs.

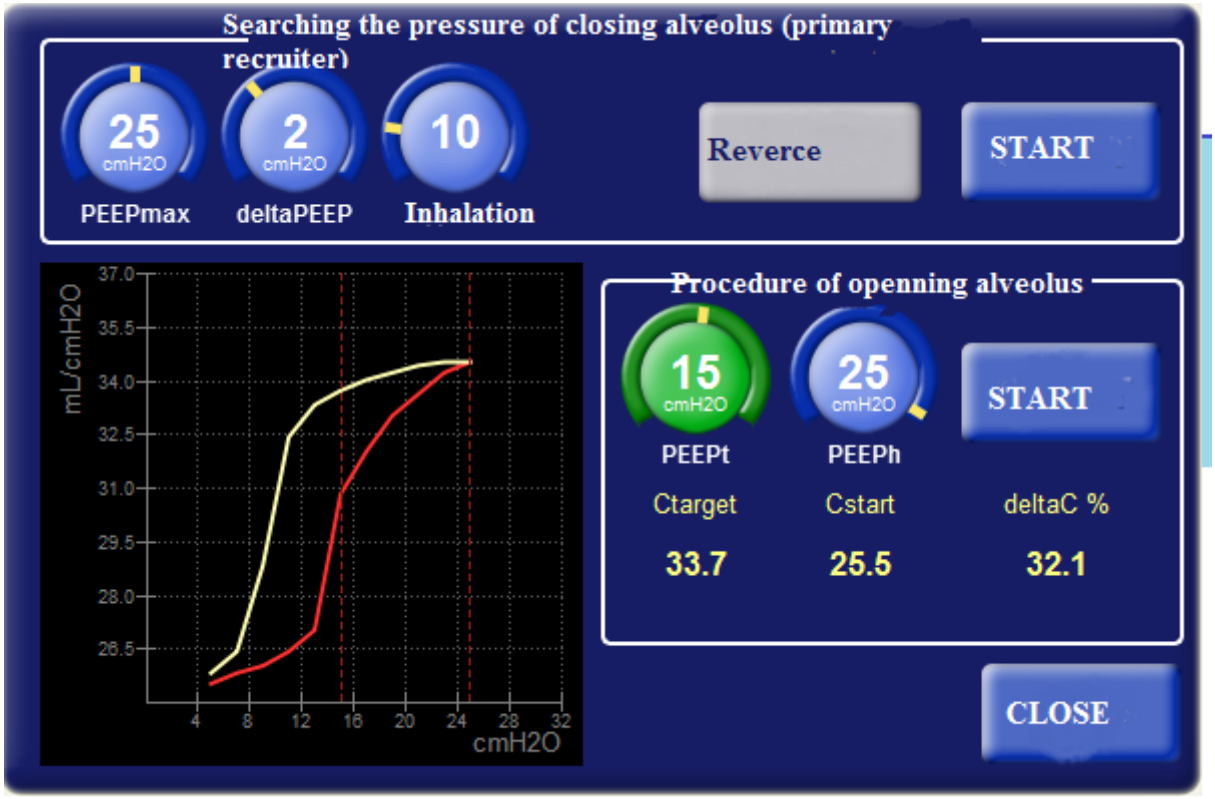
Switch the device to A / C mode with pressure-controlled forced breaths (PC), set the respiratory rate to maintain the initial MVtot, set the inspiratory to expiratory ratio 1: 1. It is also possible to maneuver in SIMV PC or DUAL-LEVEL modes.

Make sure that automatic control of PEEP and FiO2 parameters is disabled.

**CARRYING OUT RECRUITMENT-MANEUVER IS REQUIRED WITH PARTICULAR CAUTION!**
**Recruitment maneuver can harm the patient!**
**Be sure to check the following conditions:**
**The patient should be completely passive (i.e., not attempting to inhale) for at least the last minute.**
**The patient should be on invasive mechanical ventilation.**
**There are no leaks in the respiratory circuit and no occlusion**
**It is forbidden to carry out a recruitment maneuver simultaneously with other procedures (sanitation of the bronchi, P / V maneuver, etc.).**

### 7.9.3.2 Searching the pressure of closing alveolus (primary recruiter)

Press the procedure button in the lower right corner of the display and select "Recruitment" in the menu that opens. The recruitment maneuver window will open on the screen**.**




**Picture 7.19- Window of lungs recruitment**

To do primary recruitment, the following parameters are used:

- PEEPmax - maximum PEEP pressure to which the unit can rise during the maneuver.
- deltaPEEP (PEEP increment) - the value by which PEEP increases.
- Number of breaths - sets the number of breaths through which the device changes the PEEP value.

To start primary recruitment, click the START button.

Primary recruitment consists in gradually increasing PEEP pressure until a decrease in dynamic compliance of the lungs and tidal volume is noted or the maximum permitted PEEPmax value is reached. After this, the PEEP pressure gradually decreases to the initial level in order to determine the closing pressure of the alveolus.

**If there are signs of hemodynamic instability in the patient, the recruitment maneuver should be stopped immediately!**

The increment of the PEEP level is controlled by the “deltaPEEP” parameter and occurs after a certain number of breaths, which is set by the “Inhale” parameter. In the process of increasing PEEP pressure in the recruitment window, a graph of the dependence of the dynamic compliance on the red PEEP level is built. The device increases the PEEP pressure until it reaches the maximum permitted PEEPmax value or the “Reverse” button is pressed.

Then, the ventilator begins to gradually decrease the PEEP value to the initial level. In the process of reducing PEEP pressure in the recruitment window, a graph of the dependence of the dynamic compliance on the white PEEP level is built. At a certain stage, in the process of PEEP reduction, a sharp decrease in the dynamic lung compliance is observed, which in turn indicates the closure of the alveolus.

Using the constructed graph, you can visually determine the closing pressure of the alveoli. To do this, the inflection point is searched on the white chart. The pressure at this point will be the closing pressure of the alveolus.

If during the pressure build-up there is a tendency towards a decrease in dynamic compliance, and PEEP pressure has not yet reached the maximum allowed PEEPmax, press the "Reverse" button, then the device will begin to reduce pressure, which in turn will help prevent overstretching of the lungs and prevent barotrauma.

#### 7.9.3.3 Opening of the alveolus (repeated recruitment)

After the closure pressure of the alveoli has been found, repeated recruitment is performed, during which the ventilator for 10 breaths sharply increases the PEEP pressure so that the adhered alveoli open. Then, the ventilator lowers the PEEP pressure to the level of alveolar closure plus 2 - 3 cmH2O to maintain the alveoli in the open state.

The following parameters are used to perform recruitment:

- PEEPt - target PEEP pressure at which the alveoli remain open,

- PEEPh - PEEP value at which the maximum increase in dynamic compliance occurs.

PEEPt cannot exceed PEEPh minus 1 cmH2O.

To start re-recruitment, press the "START" button.

When changing the value of the PEEPt parameter, the left marker moves on the graph (vertical dashed line in red). The PEEPt value is set equal to the alveolar closure pressure plus 2–3 cm H2O.

When changing the value of the PEEPh parameter, the right marker moves on the chart. PEEPh value is chosen equal to the pressure, which corresponds to the maximum value of the dynamic compliance on the graph curve displayed in red.

The following values are displayed to the right of the graph:

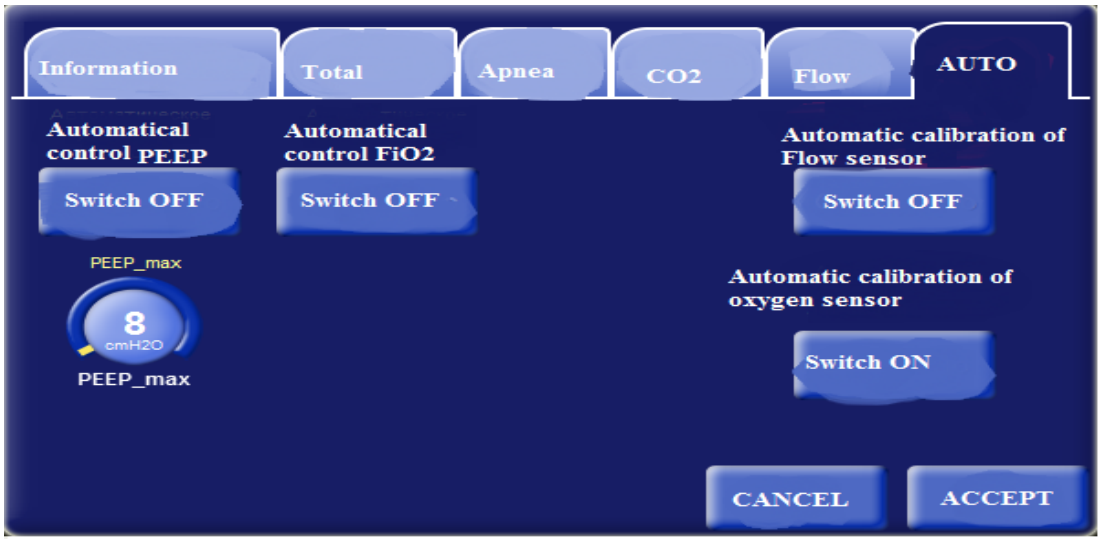
- Ctarget - the predicted value of the dynamic compliance after the maneuver,

- Cstart - value of dynamic compliance before performing a maneuver,

- deltaC - increment of dynamic compliance after the maneuver.

## 7.10 Automatic control of PEEP and FiO2

The device supports the ability to automatically control the parameters of PEEP and FiO2 during ventilation. This feature is available when the “Auto-PEEPAuto-FiO2” option is activated. Automatic control of these parameters is enabled in the settings window on the “Auto” tab (Picture 7.20).




**Picture 7.20 – Setting window tab AUTO**

On this tab, you can enable or disable automatic control of PEEP and FiO2 parameters. In addition, you can set the maximum PEEP value that the machine will not exceed during the automatic PEEP installation.

With automatic control of PEEP and FiO2 parameters, the device is guided by the readings of the pulse oximetry module. The values set by the device depend on the level of oxygen saturation of hemoglobin in arterial blood (% SpO2) and qualitative indicators of plethysmogram. The task of the device is to maintain the SpO2 value in the normal range under specific ventilation conditions. When the SpO2 value is in this range, the values of the control parameters PEEP and FiO2 are not changed. If the SpO2 value is outside the normal range, the device begins to adjust the PEEP and FiO2 values up or down, depending on which direction the saturation value deviates. In some cases, when the SpO2 value drops too low, the unit automatically sets the FiO2 value to 100%. In other cases, when adjusting the PEEP and FiO2 parameters, the device is guided by the well-known ARDSNet protocol (Table 7.1).

Table 7.1

| less PEEP/ more FiO2 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FiO2 (%) | 30 | 40 | 40 | 50 | 50 | 60 | 70 | 70 | 70 | 80 | 90 | 90 | 90 | 100 |
| PEEP (cm $H_2O$) | 5 | 5 | 8 | 8 | 10 | 10 | 10 | 12 | 14 | 14 | 14 | 16 | 18 | 18-24 |
| More PEEP/ less FiO2 | | | | | | | | | | | | | | |
| FiO2 (%) | 30 | 30 | 30 | 30 | 30 | 40 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | 100 |
| PEEP (cm $H_2O$) | 5 | 8 | 10 | 12 | 14 | 14 | 16 | 16 | 18 | 20 | 22 | 22 | 22 | 24 |

During the adjustment process, control parameters whose values are changed by the device look as shown in Picture 7.21.

The remaining time in seconds until the next change in the value is displayed above the parameter value. Rotating arrows indicate the direction of adjustment of the parameter value. If clockwise rotation occurs, the value of the parameter will be increased. When rotating counterclockwise, the value of the parameter will be reduced when the time counter reaches zero.


Picture 7.21

### 7.11 Automatic Functions

The device supports the following automatic functions:

- Automatic zero capture of the expiratory flow sensor,
- Automatic calibration of the oxygen sensor.

The device performs these procedures automatically at intervals of 8 hours. Enabling and disabling functions is carried out in the settings window on the "Auto" tab (Picture 7.20).

Upon successful execution of the function, the device makes an appropriate entry in the event log. If an error occurs, the device displays the corresponding message on the display in the alarm display area and writes information about the error to the event log.

## 7.12 Reference ventilation mode

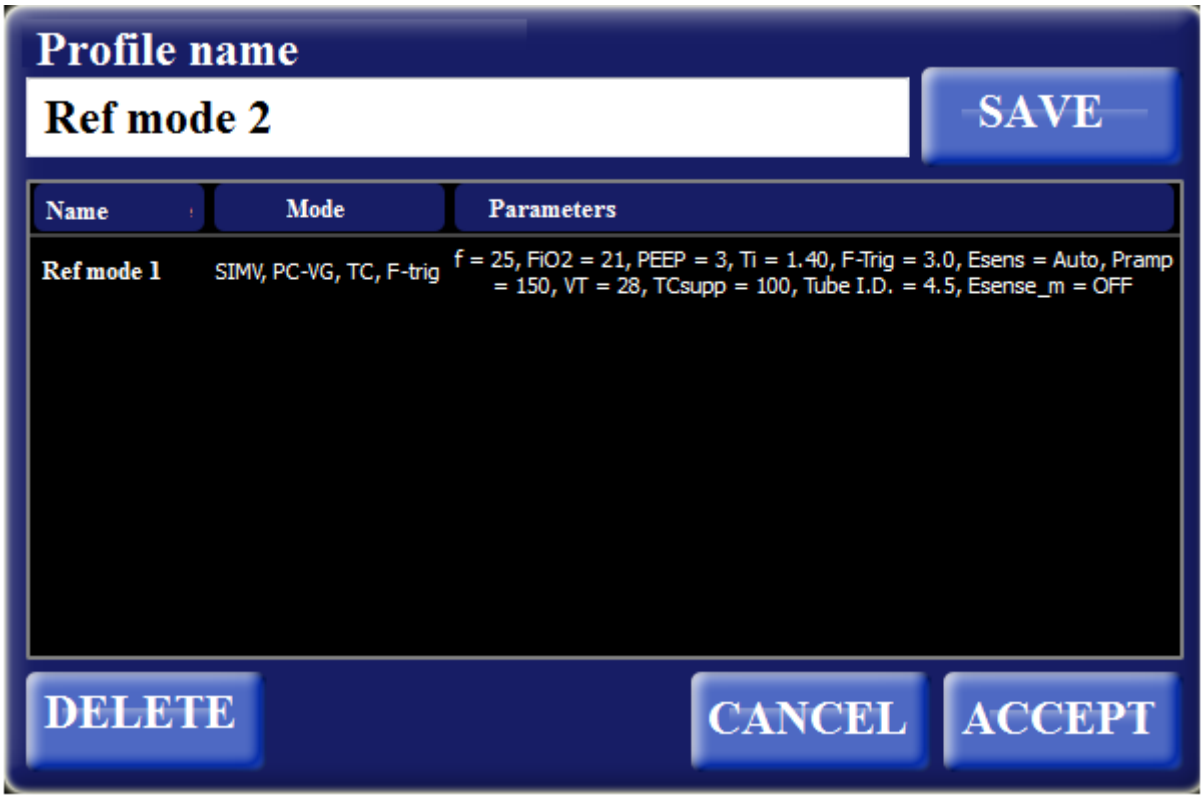
In addition to the previous settings, the device can store up to 100 different configurations of modes and values of control parameters called “Reference ventilation mode”.

Access to the templates can be obtained in the standby window or in the window for setting the ventilation mode using the “Reference ventilation mode” button. When you click on the button, the templates window opens (Picture 7.22). This window displays a table of previously saved templates, a line for entering the name of a new template, the “SAVE” button and the “DELETE” button. The table indicates:

- The name of the template,

- Ventilation mode indicating the type of forced breaths, the type of spontaneous breaths and the type of trigger,

- Values of the main control parameters for this template**.**




**Picture 7.22 - Window ventilation templates.**

To save a new template, enter the name and click the “SAVE” button. The device will save the current settings in a separate template with the specified name. It is recommended to name the template based on the specific clinical situation, so that later it is easier to remember why this template can be used.

To delete a template, select the corresponding line in the table and click on the "DELETE" button.

In order to close the window without performing any actions, click on the "CANCEL" button.

# 8. Alarm system

Information about dangerous situations (alarms) that appear is displayed in the upper right corner of the display in the form of a drop-down list. The list of alarms is opened by clicking on the field with the alarm text. All alarms in the list are arranged in a certain order, considering priority, time of occurrence and relevance. 360 degree visible alarm lamp is situated on the right upper corner of the ventilator.

Alarms associated with ventilation parameters are triggered 30s after the start of ventilation to avoid false alarms.

Alarms associated with volumetric parameters (MV_tot, VTe_mand, etc.) are triggered only if the values of the corresponding parameters go beyond the limits of the set alarms for at least three breaths in a row. The alarm system does not turn off.

When alarms with the same priority are triggered, the last alarm that was triggered is displayed on the display in the upper right corner. In this case, other active alarms (with the same or lower priority) can be viewed by clicking the “maximize” button in the upper right corner of the display.

When the device is first started, the alarm presets correspond to the factory settings that are set when the device is manufactured.

When entering the parameters of a new patient (height, weight, etc.), as well as when turning on the power of the ventilator system, the alarm pre-settings (alarm limit) are set automatically and their values are calculated depending on the given patient parameters.

WARNING! When using different default preset settings on a ventilator or similar equipment in the same intensive care unit, the potential risk increases.

**Important information:** Alarms responding must be healthcare professionals with experience in ventilation and trained in using this ventilator.

### 8.1 Alarm classification

Each hazardous situation, depending on the degree of danger to the patient, is assigned one of three priorities.

- **High** - the alarm is displayed on a red background with three exclamation points and is accompanied by a sound signal consisting of a sequence of six notes. The sound signal is repeated at intervals of 10 seconds.
- **Medium** - the alarm is displayed on a yellow background with two exclamation points and is accompanied by a sound signal consisting of a sequence of three notes. The sound signal is repeated with a frequency of 15 seconds.
- **Low** - the alarm is displayed on a yellow background with one exclamation mark and is accompanied by a sound signal consisting of a sequence of two notes. The sound signal is reproduced at the time of a dangerous situation and is not repeated.

- The sound pressure level is between 65-85 dBA.

- The interval between pulses is 200 ms between the 1st and 2nd, 2nd and 3rd, 4th and 5th pulses, 400 ms between the 3rd and 4th pulses.

- The rise and fall time of the pulse is 10%.

- The flashing frequency of the light alarm must be 1 Hz.

Table 8.1 lists the alarms issued by the device during operation.

**Table 8.1**

| **Alarm name** | **Priority** | **Designation** |
|---|---|---|
| No connection with control unit | high | There is no data from the control unit. Further operation of the ventilator is impossible, contact customer service |
| No connection with power unit | high | There is no data from the power unit. Further operation of the ventilator is impossible, contact customer service. |
| No connection with measurement unit | high | There is no data from measurement unit. Further operation of the device is not possible, contact customer service |
| Low O2 inhale pressure | high | Low inhale O2 pressure. It is possible some installation errors. |

| Alarm name | Priority | Designation |
|---|---|---|
| High oxygen pressure | High | High inlet oxygen pressure in the network. It is required to reduce the pressure in the network or disconnect the device from the network with oxygen in order to avoid the failure of the ventilator |
| Error supplying oxygen to the circuit | High | Setting value of the oxygen flow does not correspond to the measured value. |
| Battery discharge in less 10 min | High | The battery is fully discharged, further operation is not possible. It is required to connect the device to the network |
| Error calibration oxygen sensor | Low | Can not calibrate a sensor with oxygen 100% |
| Error calibrate valve at the inhalation | High | The battery is fully discharged, further operation is not possible. It is required to connect the device to the network |
| Error calibrate valve at the exhalation | High | The battery is fully discharged, further operation is not possible. It is required to connect the device to the network |
| Error of atmosphere pressure sensor | Average | Measurement value of atmosphere pressure goes out possible limits |
| Low frequency ventilation rotation | Low | Low speed of ventilation rotation or it stop fully or can't determine frequency of ventilation rotation. |
| Depressurization | High | Depressurization of respiratory patient's contour is disconnected |
| Occlusion | High | Respiratory contour elements are clogged |
| Apnea | High | No breaths for a given apnea interval |

| Alarm name | Priority | Designation |
|---|---|---|
| High pressure in the circuit | High | Circuit pressure exceeded Ppeak maximum alarm limit |
| Low concentration O2 on inhalation | High | The measured oxygen concentration is less than 7% of the set value of FiO2 |
| High concentration O2 on inhalation | High | The measured oxygen concentration is less than 7% of the set value of FiO2 |
| Low minute volume | Average | The measured value of the minute volume is less than the set lower alarm limit |
| High minute volume | Average | The measured value of the minute volume is less than the set high alarm limit |
| High breath rate | Average | The measured value of f_tot is more than the set higher alarm limit |
| Low breath rate | Average | The measured value of f_tot is less than the set lower alarm limit |
| Low exhalation volume | Average | The measured value of the exhalation volume is less than the set lower alarm limit |
| High exhalation volume | Average | The measured value of the exhalation volume is more than the set higher alarm limit |
| Operation from battery | Low | The ventilator switched to work from the built-in battery |
| Low level SpO2 | Average | SpO2 measured value less than the set lower alarm limit |
| Low EtCO2 | Average | The measured EtCO2 value is less than the set lower alarm limit. |
| High EtCO2 | Average | The measured EtCO2 value is more than the set high alarm limit. |
| Sensor SpO2 is not connected | Average | SpO2 sensor is not connected to the ventilator. Check sensor connection |
| No finger in SpO2 sensor | Average | There is no finger in the SpO2 sensor. Check for a patient's finger in the sensor |
| No pulse | High | There is no pulse in the finger that is inserted into the SpO2 sensor |
| Occlusion CO2 | average | Clogged CO2 outlet (tube) |
| Apnea in canal | High | No breath detected in CO2 channel |

## 8.2 Tuning of alarm's limits

**Attention! Always check tuning of alarm after connecting to a new patient.**

The alarm tuning panel is opened by pressing the **"ALARMS"** button (at the bottom of the display). In this panel one can tune the alarm's bounds for the monitored parameters, as well as tune the volume of the audible alarm. The monitored parameters in the tuning of the alarm's bounds are divided into two groups: the first includes breathing mechanics parameters, and the second includes gas exchange parameters (**$SpO_2$ and $EtCO_2$**).

To change the upper or lower bound of the parameter, click on the corresponding marker image and use the encoder to set the necessary value. To apply the settings, click the button **"ACCEPT"**, to cancel the changes made, click **"CANCEL"** (see Figure 8.1).


**Figure 8.1. – Tuning of alarm window – group 1**

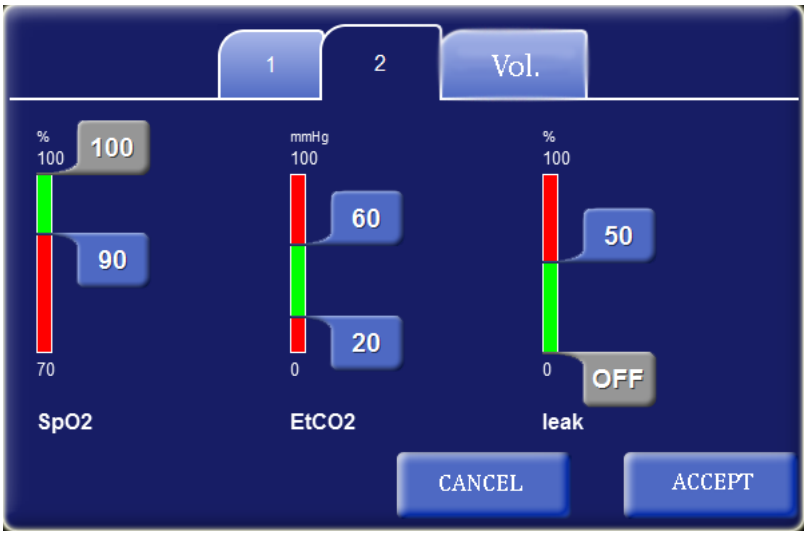



**Figure 8.2. – Tuning of alarm window – group 2**

To set the volume of alarm or set the alarm delay in NIV mode, choose the tab **"Control".**

Press the **"Alarm loudness"** parameter and set the desired volume level from 1 to 10. To check the set level, press the button **"TEST"**.


**Figure 8.3. – Tuning of alarm window – volume**

| | |
|---|---|
|  | Setting the alarm volume to zero is prohibited! |

### 8.3 Muting of alarm for 2 minutes

To mute the sound signals for two minutes, press the button “ 

” on the keypad of the ventilator.

### 8.4 Fault of alarms

After viewing the list of alarms, there may be reset irrelevant alarms. To do this, press the button “ 

” on the keypad.

| | |
|---|---|
|  | Reset alarms are deleted only from the alarm list, and not from the alarm logging. |

### 8.5 Event logging

Any dangerous situation is recorded in the event logging at the time of its occurrence. The event logging keeps up to 5000 of the latest alarms and events associated with changes of settings. The logging can be displayed by pressing the button “event log” at the bottom of the main panel.

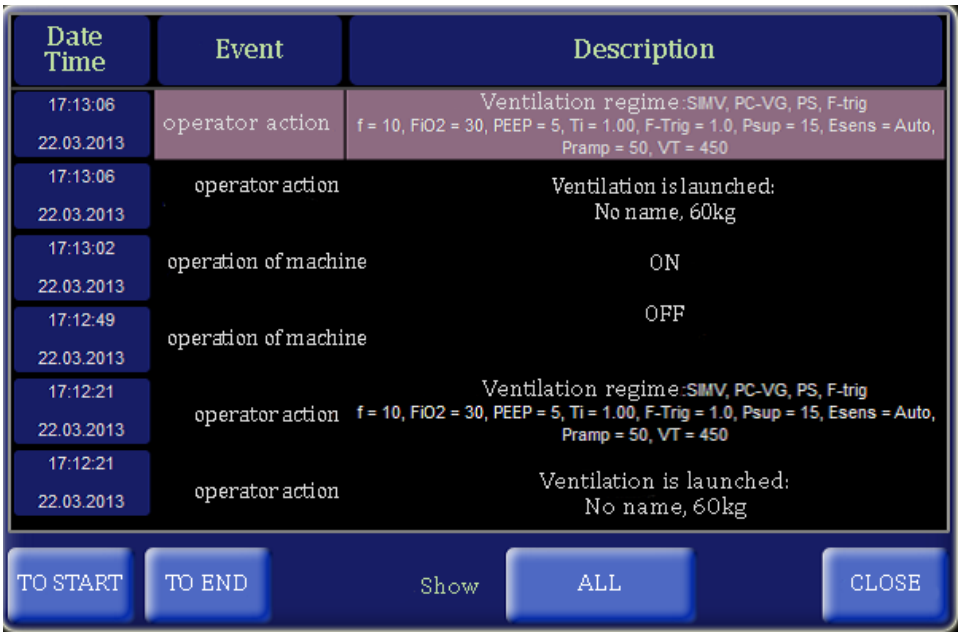



**Figure 8.4. – Event logging panel**

Dangerous situations in the logging are displayed in the order in which they occur, that is, the last alarm is always at the very top. Apart from dangerous situations, the logging also stores other events, such as starting/stopping ventilation, connection of a new patient, and other operator actions.

Navigation through the logging is carried out with the encoder by moving the line marker, as well as with the buttons **“START”** and **“END”.**

If necessary, one can set the event filter:

- show only alarms,

- show only manipulations,

- show everything.

### 8.6 Audit of the functioning of the alarm`s system

Check the functioning of the alarm system every time the ventilator is turned on, before testing.

Turn the ventilator into operation in the 220 V network in any mode by connecting the lung model (rubber bag).

#### 8.6.1.1 Low priority alarm test

Disconnect the ventilator from 220 V network, when the ventilator is turned on, a low priority alarm should be activated and the **“Battery power”** alarm is displayed in the

**“Alarm messages”** panel (see Figure 7.1) **against a yellow background** with one exclamation mark and is accompanied by a sound signal consisting of a sequence of **two notes**.

#### 8.6.1.2 Medium priority alarm test

On a running ventilator, cover the flow sensor with your hand. An alarm of medium priority should be activated – the alarm “High resistance in the exhalation circuit” – the alarm is displayed **on a yellow background** with two exclamation marks and is accompanied by a sound signal consisting of a sequence of **three notes**.

The sound signal is repeated at intervals of 25 seconds.

#### 8.6.1.3 High priority alarm test

On a running ventilator, disconnect the inspiration line from the ventilator. An alarm of high priority should be activated – the alarm “Depressurization of the circuit” – the alarm is displayed **on a red background** with three exclamation maks and is accompanied by a sound signal consisting of a sequence of **five notes**.

The sound signal is repeated at intervals of 10 seconds.

In medium and high priority alarms, the light signaling in the “Alarm messages” window (see Figure 7.1) is duplicated on the remote light indicator for viewing the alarm signal from anywhere in the patient romm (see Figure 3.3).

#### 8.6.1.4 Automatic alarm check

Checking the absence of oxygen supply to the VENTILATOR is performed automatically.

- The alarm settings that are set before the power is off for 30s or less are automatically restored.

- The alarm system and alarm settings do not change for any duration of loss of electrical power.

- At switching to a backup power source, the green indicator on the display unit turns off, the red indicator lights up and the low-priority alarm “Battery power” is activated.

- While adjusting any alarm limit or pre-setting the alarm, the alarm system should continue to operate in normal mode.

Only specialists – qualified medical personnel authorized to operate the ventilator may be allowed to change or save changes to the specified settings of the alarm system (the fact of admission to operation must be recorded (see Table 6, DataSheet for the ventilator).

# 9 Control

Parameters measured during ventilation are displayed on the right side of the display (see Figure 7.1). The monitored parameters are grouped into separate groups. At the same time, up to 5 different groups of parameters selected by the operator can be displayed.

### 9.1 Selection of the group's parameter for display

The list of displayed parameter groups is set by the operator. In order to display a specific group of parameters in the right place, click on the place where you want to place this group. The current group of parameters is highlighted in bright color (see Figure 9.1).

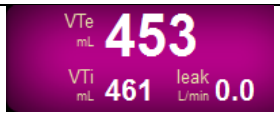



**Figure 9.1**

Then, in the menu that opens next to it (Figure 9.2), use the encoder to select the required group of parameters and press the button " 

" near the encoder knob. In place of the previous parameter group, a new parameter group will be displayed, which was selected in the menu. Similarly, one can set the remaining groups of parameters that will constantly be displayed on the screen during ventilation.


Figure 9.2

The list of displayed parameter groups is stored in non-volatile memory and the next time the ventilator is turned on, the display shows the same parameter groups that were before turning off.

# 10 Display screens

Most of the display is occupied by the display screen.

In the panel **“Settings” - “General” – “Interface mode”** for the convenience it is possible to select the mode **“Day”** or **“Night”**.

## 10.1 Selection of screen

To switch the screen, click on the screen image located at the top of the display.

Using the encoder in the drop-down menu, select the screen that you want to display. At the same time, one of the screens of the screen selection menu is displayed (Figure 10.1).

| |
|---|
| Curves |
| Loops |
| Parameters |
| Graphical trends |
| Tabular trends |
| Ventilation map |
| Metabolism |
| Multiscreen |
| P/V maneuver |
| Print screen |

**Figure 10.1. Selection of screen menu**

## 10.2 Screen curves

The Curves screen is shown in Figure 10.2.

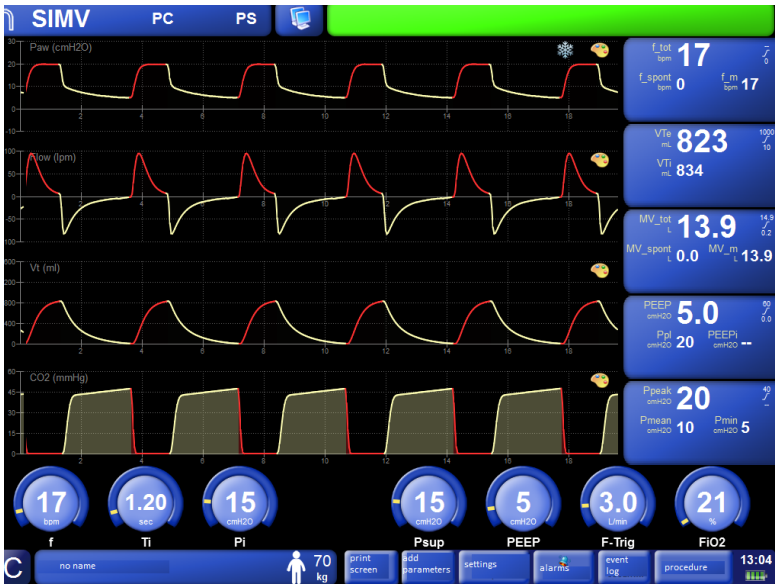



**Figure 10.2. - Screen curves**

Up to four different curves from the following list can be displayed on this screen simultaneously:

- **Paw** (pressure curve),
- **Flow** (flow curve),
- **Vt** (volume curve),
- **Ple** (photoplethysmogram),
- **$CO_2$** (capnogram).

In order to display a specific curve in the right place, touch the name of the curve and use the encoder in the drop-down menu to select the necessary curve.

### 10.2.1 Scale setting of curves

The scale of the curves can be set in two ways, either manually or automatically. To enable or disable automatic scaling of curves, set the corresponding item in the panel **"Settings"** on the tab **"General"** tab (see p.11).

In case of manual setting of the axis scale, click on the axis image on the display. The axis is highlighted in blue. Using the encoder, set the necessary scale and press the encoder knob.

The set scales of the curves are stored in non-volatile memory and the next time the ventilator is turned on, the curves are displayed at the same scales that were set before turning off.

The scales of the axes of the curves are related to the corresponding scales of the axes in the loops. Therefore, when changing the scale of the curve, the scale of the corresponding axis in the loops will change.

### 10.2.2 Speed setting of the sweep's curves

The operator can set one of three speeds of the sweep's curves: 6, 12 or 25 mm/sec. To set the sweep speed of the curves, click on the image of the time axis on the display. All three axes are highlighted in blue. Using the encoder, set the necessary sweep speed of the curves and press the encoder knob.

### 10.2.3 Parameters setting of the drawing curves

Curves can be displayed in two ways:

- each curve has its own color and degree of filling,
- on all curves, the breath is displayed in one color, and the exhale is displayed in another.

The way of drawing curves is configured in the settings window in the tab "General".

To change the curve drawing parameters, click on the palette image  in the area of the curve whose drawing parameters you want to change. The following window will appear on the display (see Figure 10.3). To change the degree of filling the curve, click on the image of the degree of filling. The value is highlighted in green. Use the encoder to set the necessary degree of transparency. To change the color of the curve drawing, click on the colored rectangle, after which the window will take the following form (see Figure 10.4)


**Figure 10.3**


**Figure 10.4**

Use the encoder to set the necessary color for drawing the curve.

### 10.3 Loop Paw-V(pressure/volume), Flow-V(flow/volume), Paw-Flow (pressure-flow)

When selecting the screen “Loops” (see Figure 10.5), either two loops are displayed simultaneously, or one of the loops, selected by operator **Pressure/Volume** or **Flow/Volume** or **Pressure/Flow**. Each loop is drawn in one respiratory cycle. Before starting a new cycle, the current loop is erased from the screen and drawing a new loop begins.

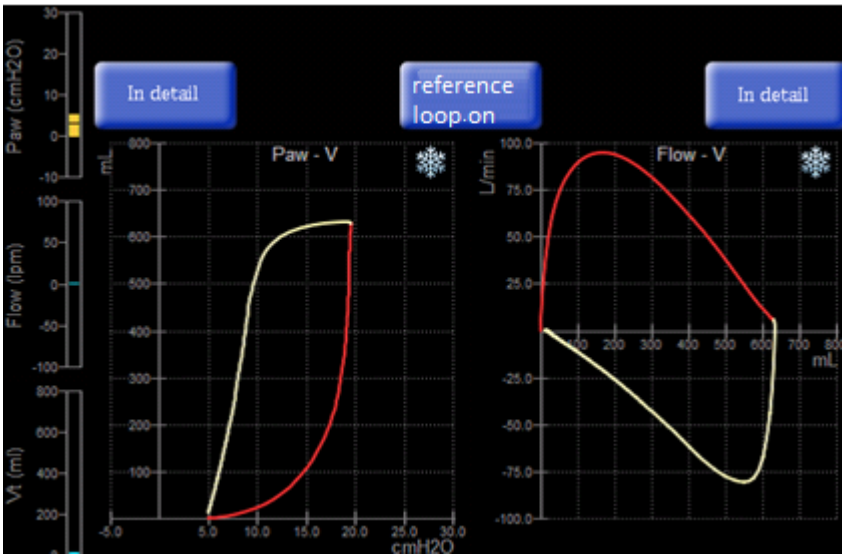



**Figure 10.5. – Loop Pressure/Volume and Flow/Volume**

The left side of the screen displays the current values of the curves that were selected in the screen **“Curves”** in the form of columns.

For a detailed display of one loop on the screen, press the button **“Details”** above the corresponding loops.

#### 10.3.1 Reference loop

During ventilation, at any time, you can remember the current loop and then use it as a template to track changes.

To fix the current loop as a template, press the button **“Reference loop on”.** When a new breath begins, the current loop will be fixed and will be displayed in gray against the background of the new loop, and the countdown from the moment the loop is fixed will begin above the button (see Figure 10.6).

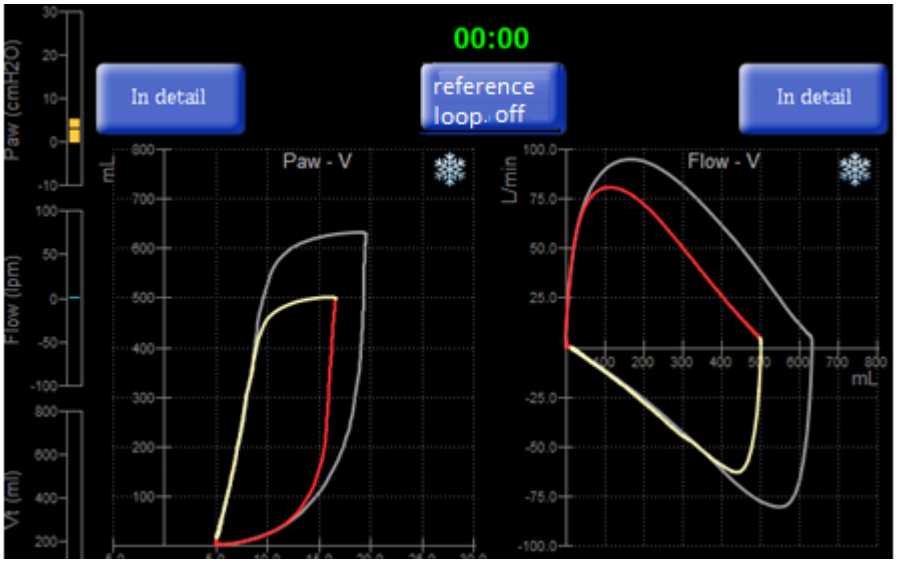



**Figure 10.6. – Reference loop**

In order to disable the template, click on the button **“reference loop off”**. Before fixing a new template, you must first disable the current one.

### 10.3.2 Setting of the color for drawing a loop

The loop color setting is available only if the setting “highlighting breath on curves and loops” is disabled.

In order to change the color of the loop drawing, click on the palette image  in the upper right corner of the screen. The following window will appear on the display:

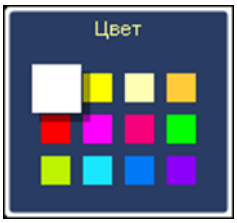



Figure 10.7

Use the encoder to set the necessary loop drawing color.

## 10.4 Graphical trends

A general view of the main window with the screen of graphical trends is presented in Figure 10.8.

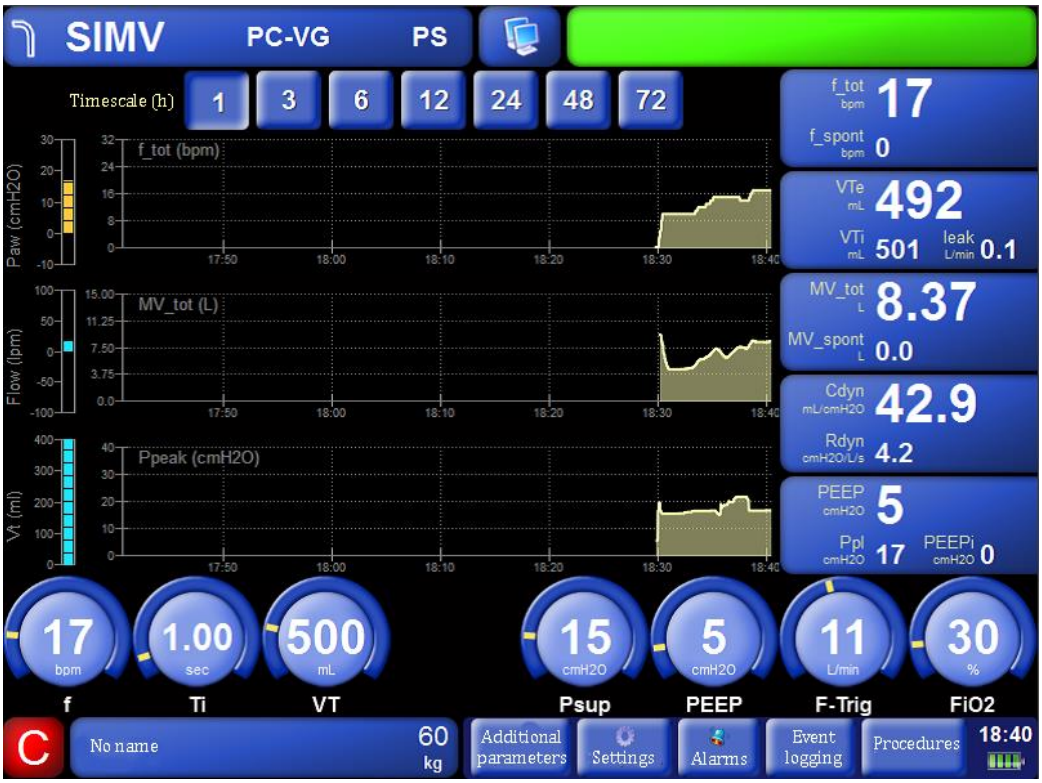



**Figure 10.8**

Trend recording is carried out continuously with an interval of 60 seconds for all monitored parameters.

On the graphical trends screen, up to three trend graphs of monitored parameters can be displayed simultaneously.

To select a graph to be displayed, click on the graph name on the display and select the necessary graph in the drop-down menu.

The selection of the vertical scale of the graph is carried out in the same way as when selecting the scale of the curve (see p. 10.2).

At the top of the graphical trends screen there are buttons for selecting the time scale of the charts.

## 10.5 Tabular trends

A general view of the main window with the screen of graphical trends is presented in Figure 10.9.

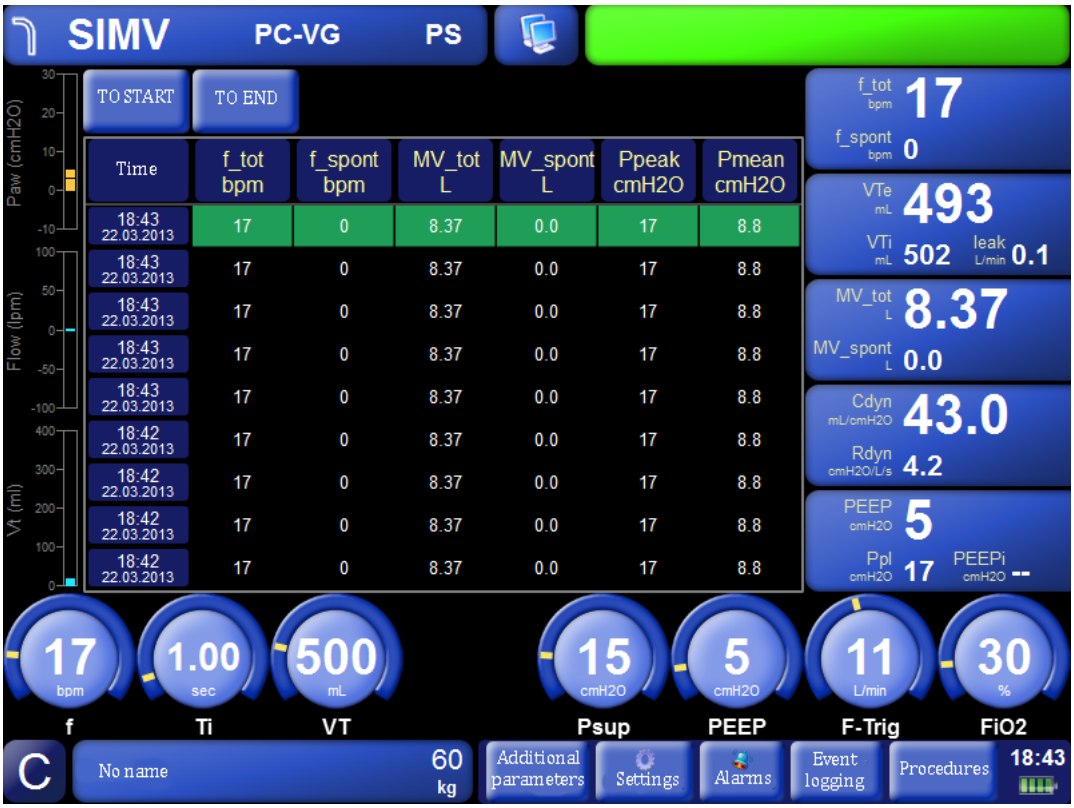



**Figure 10.9. – Tabular trends**

At the selection of the operator, up to six parameters can be displayed simultaneously on the tabular trends screen.

To select the necessary parameter, click on the column heading of the table and in the menu that opens, select the parameter whose values you want to display in this column.

Navigating the table is carried out using the encoder by moving the line marker, as well as using the buttons **“START”** and **“END”.**

### 10.6 Screen Parameters

A general view of the main window with the trend parameters screen is presented in Figure 10.10.


**Figure 10.10 – Screen Parameters**

The screen **"Parameters"** displays the current values of the monitored parameters. This screen is designed to monitor all parameters simultaneously.

### 10.7 Ventilation map

When you select the screen **"Ventilation map"** (see Figure 10.11), three graphs are displayed:

- Ventilation,
- Oxygenation,
- Spontaneous activity.

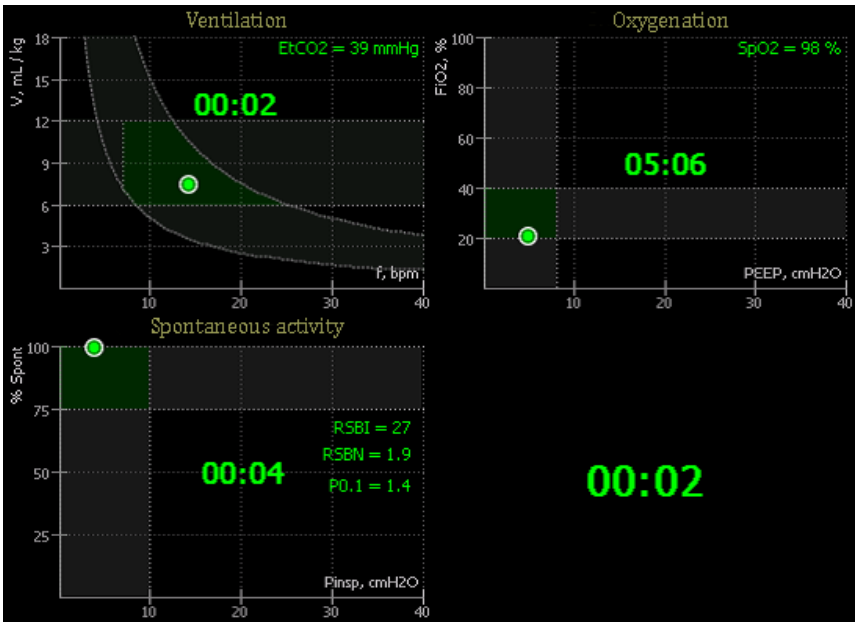



**Figure 10.1 – Screen Ventilation map**

Markers are displayed on the graphs of the scheme of ventilation. The position of each marker displays the current state of the patient. Depending on the measured values, markers can be painted over in one of three colors:

- **green** means the normal value of the parameters,
- **yellow** shows a slight deviation from normal values,
- **red** means a large deviation from normal values.

On the plane of the graph **"Ventilation"**, a marker is displayed whose position corresponds to the values of the respiratory volume and ventilation frequency. The dark gray area bounded by horizontal lines shows the normal range of respiratory volume values. The curved dark gray area shows the normal range of values for the minute ventilation volume for a given **IBW**. The green area indicates the normal range for the marker for a given **IBW**. If the current value of **$EtCO_2$** is measured, then the marker, depending on this value, is filled with color from the following set:

- **green**, with an **$EtCO_2$** value from **35** to **45 mm Hg**,
- **yellow**, with an **$EtCO_2$** value from **30** to **35** and from **45** to **50 mm Hg**,
- **red**, with an **$EtCO_2$** value of less than **30** or more than **50 mm Hg**.

When the marker is in the green area, the time in which the marker is in the normal range (in the format hh:mm) is displayed in the center of the graph.

On the **"Oxygenation"** graph, a marker is displayed whose position corresponds to the values of the control parameters **PEEP** and **$FiO_2$**. As in the **"Ventilation"** graph, the areas of normal values for the **PEEP** and **$FiO_2$** parameters are colored in dark gray, and the area of normal values for the marker is green. If the ventilator is equipped with a pulse oximetry module and the **$SpO_2$** value is measured, then the marker, depending on this value, is filled in one of the following colors:

- **green**, with a $SpO_2$ value from 93 to 100%,
- **yellow**, with a $SpO_2$ value from 88 to 92%,
- **red**, with a $SpO_2$ value of less than 88%.

When the marker is in the green area, the time in which the marker is in the normal range (in the format hh:mm) is displayed in the center of the graph.

On the **"Spontaneous Activity"** graph, a marker is displayed whose position corresponds to the values of the **Pinsp** and **% Spont** control parameters.

The **Pinsp** parameter displays the inspiratory pressure averaged over 30 seconds, which is equal to the difference between the average inspiratory pressure and the **PEEP** pressure.

The **%Spont** parameter shows the ratio of the value of the **MV_spont** parameter to the value of the **MV_tot** parameter and is displayed as a percentage.

As well as in other graphs, the areas of normal values for the **Pinsp** and **%Spont** parameters are colored in dark gray, and the area of normal values for the marker in green. If the **%Spont** value exceeds **75%,** then the values of the **RSBI** and **RSBN** parameters are calculated and, depending on the **RSBN** value, the marker is colored in one of the following colors:

- **green**, with an **RSBN** value less than **5**,
- **yellow**, with an **RSBN** value from **5** to **7**,
- **red**, with an **RSBN** value of more than **7.**

When the marker is in the green area, the time in which the marker is in the normal range (in the format hh:mm) is displayed in the center of the graph.

In the case when all three markers on the graphs fall into their green areas, in the lower right corner of the scheme of ventilation, the total time starts to be counted, during which all the markers are in their areas of normal values.

**The scales of the axes of the curves are related to the corresponding scales of the axes in the loops. Therefore, when changing the scale of the curve, the scale of the corresponding axis in the loops will change.**

### 10.8 P/V maneuver

**P/V maneuver** is a special procedure designed to build a static Pressure/Volume loop, and calculate the static lung compliance on this loop and determination of the optimal **PEEP** value.

When you select the screen **"P/V maneuver"**, the display shows a window that contains a list of conditions and restrictions that must be met before the maneuver begins (see Figure 10.12).

Attention! This maneuver may harm the patient. Be sure to comply with the following requirements:
- The patient must be completely passive;
- The patient must have stable hemodynamics;
- The preset maximum pressure and volume must be safe for the patient;
- Before carrying out the maneuver, make sure that there are no leaks in the circuit;
- Maneuver is possible no earlier than 1 minute after the completion of the nebulizer;
- A second maneuver is possible no earlier than 1 minute after the completion of the current one.

**Figure 10.12 - Warnings before performing a P/V maneuver**

**Perform the maneuver with extreme caution, observing all the requirements and limitations of this procedure!**

**Do not attempt to maneuver on spontaneously breathing patients!**

**Some alarms are disabled for the duration of the maneuver.**

The general view of the screen **"P/V maneuver"** is presented in Figure 10.13.

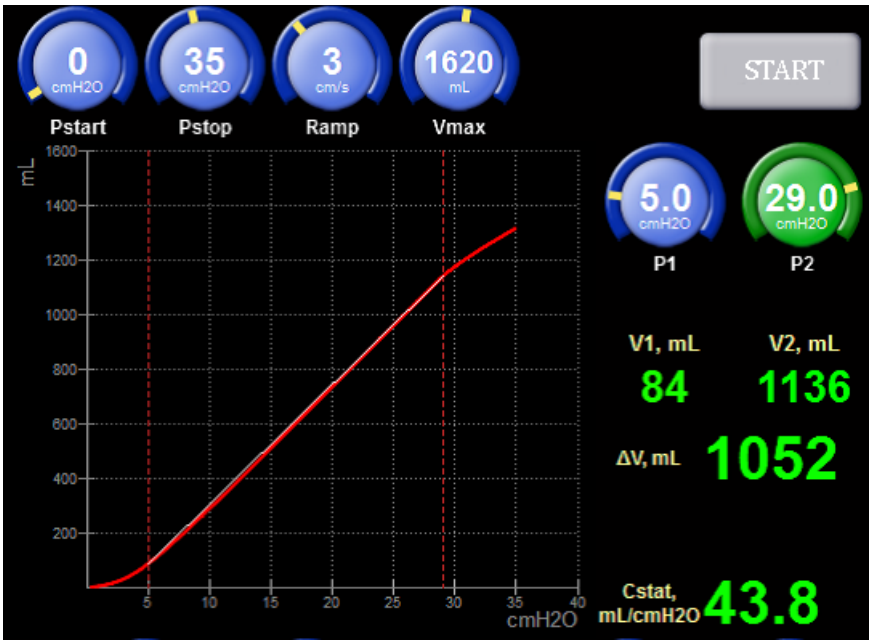



**Figure 10.13 – Screen "P/V maneuver"**

The following parameters are used to control the maneuver:

- **Pstart** – initial pressure loop pressure/volume,

- **Pstop** – final pressure loop pressure/volume,

- **Ramp** – rate of increase in pressure during the maneuver,

- **Vmax** – the maximum allowable volume pumped into the patient.

To start the maneuver, set the required parameter values and press the button **"START"**. The button **"START"** is not available in the following cases:

- Set ventilation mode SPONT,

- With non-invasive ventilation (MASK),

- Occlusion is detected in the patient's breathing circuit,

- Depressurization of the breathing circuit is detected,

- Less than 1 minute has passed since the nebulizer's operation,

- Less than 1 minute has passed since the previous maneuver,

- Patient activity detected.

After completing the maneuver, the graph shows the ascending part of the pressure/volume loop and two pressure markers. Markers can be moved by changing the values of the parameters **P1** and **P2**, respectively.

Below these parameters are displayed the corresponding values of volumes **V1** and **V2**, their difference **ΔV** and the value of the static compliance **Cstat**.

Marker **P1** should be installed at the lower inflection point of the loop, which corresponds to the pressure at which the alveoli begin to open. This point corresponds to the optimal **PEEP** for this patient.

Marker **P2** should be installed at the upper inflection point of the loop (where its slope changes), which corresponds to the maximum effective respiratory volume of the lungs.

The rate of increase in pressure during the maneuver can be set in the range from **2** to **5 cm $H_2O$/s**.

In most situations, a **3 cm $H_2O$/s** slew rate is optimal.

For patients with obstructive pulmonary pathologies (**COPD**, **Asthma, and others**), it is recommended to set a low slew rate (**2 cm $H_2O$/s**) to reduce the effect of high airway resistance on the measurement result.

For patients with restrictive pathologies (**ARDS, and others**), as well as for patients without pulmonary pathologies, the growth rate can be up to **5 cm $H_2O$/sec.**

### 10.9 Multiscreen

When you select the screen **"Multiscreen"** (see Figure 10.14), the display simultaneously shows curves, loops, trends and animated lungs.


**Figure 10.14 – Multiscreen**

The display of several screens at the same time allows you to get maximum information about the ventilation process of the current state of the patient.

Three types of multiscreen are available:

- Curves, loops, lungs (Figure 10.15),
- Curves, loops (Figure 10.16),
- Curves, trends (Figure 10.17).

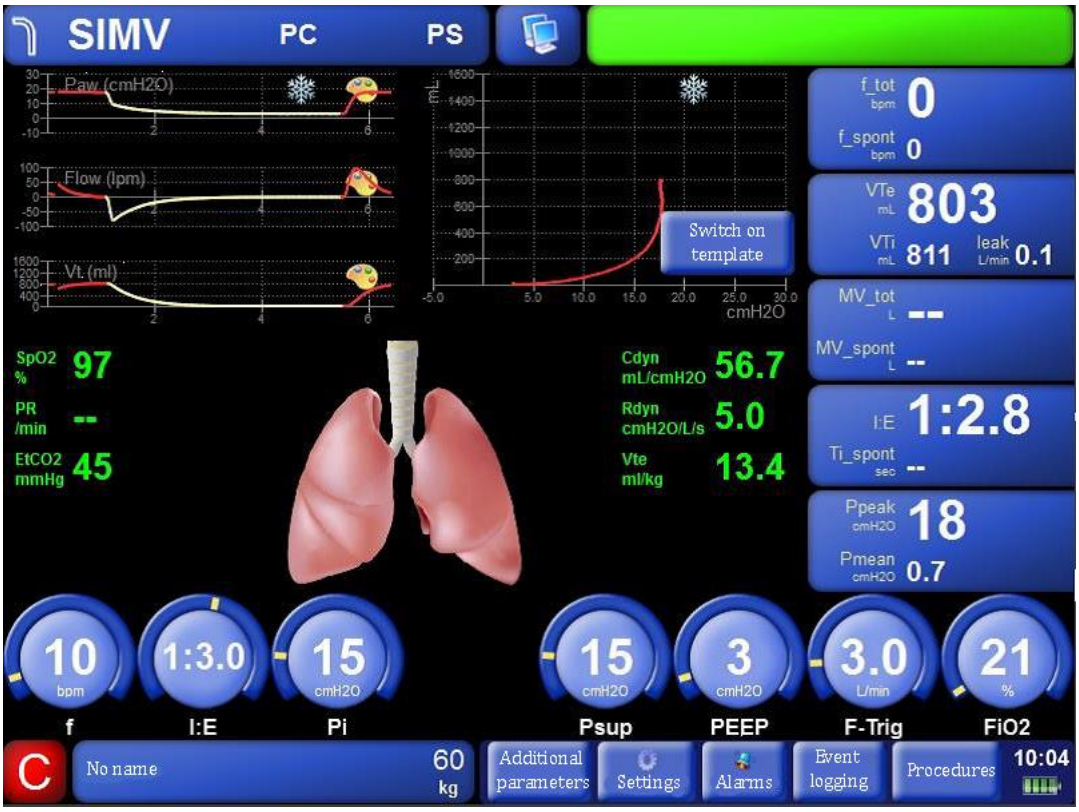



**Figure 10.15 – "Multiscreen – curves, loops, lungs"**

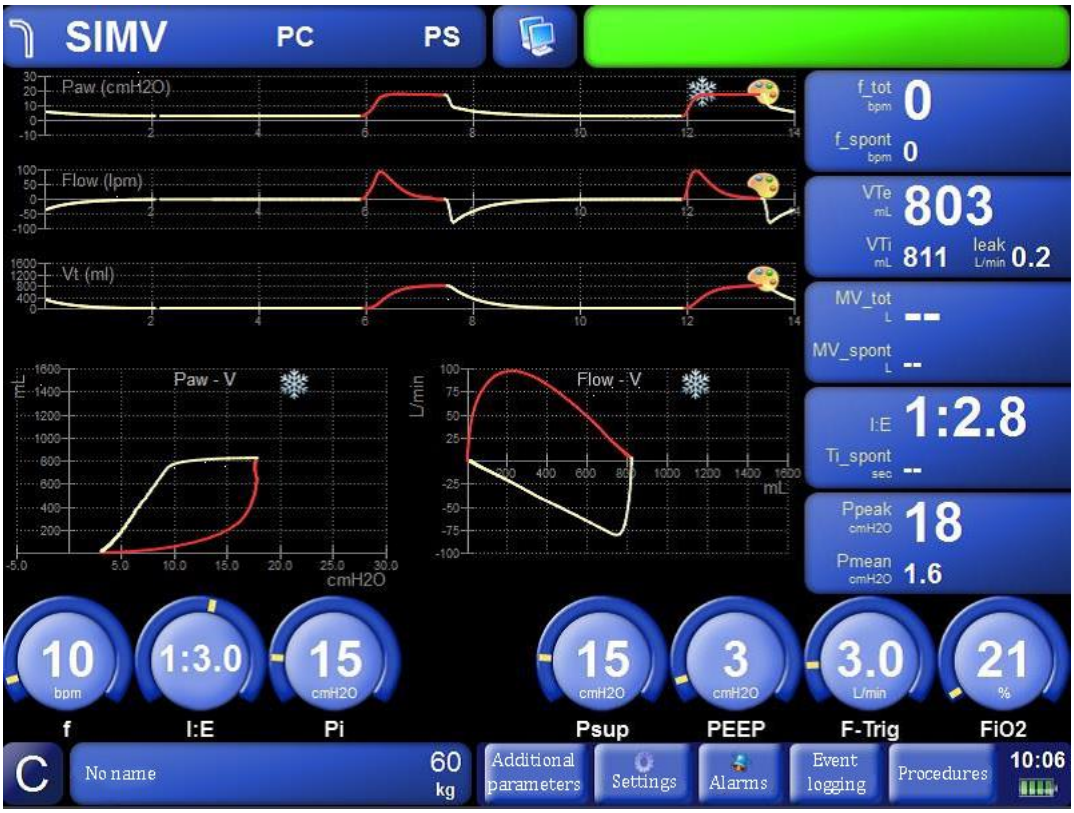



**Figure 10.16 – "Multiscreen – curves, loops"**

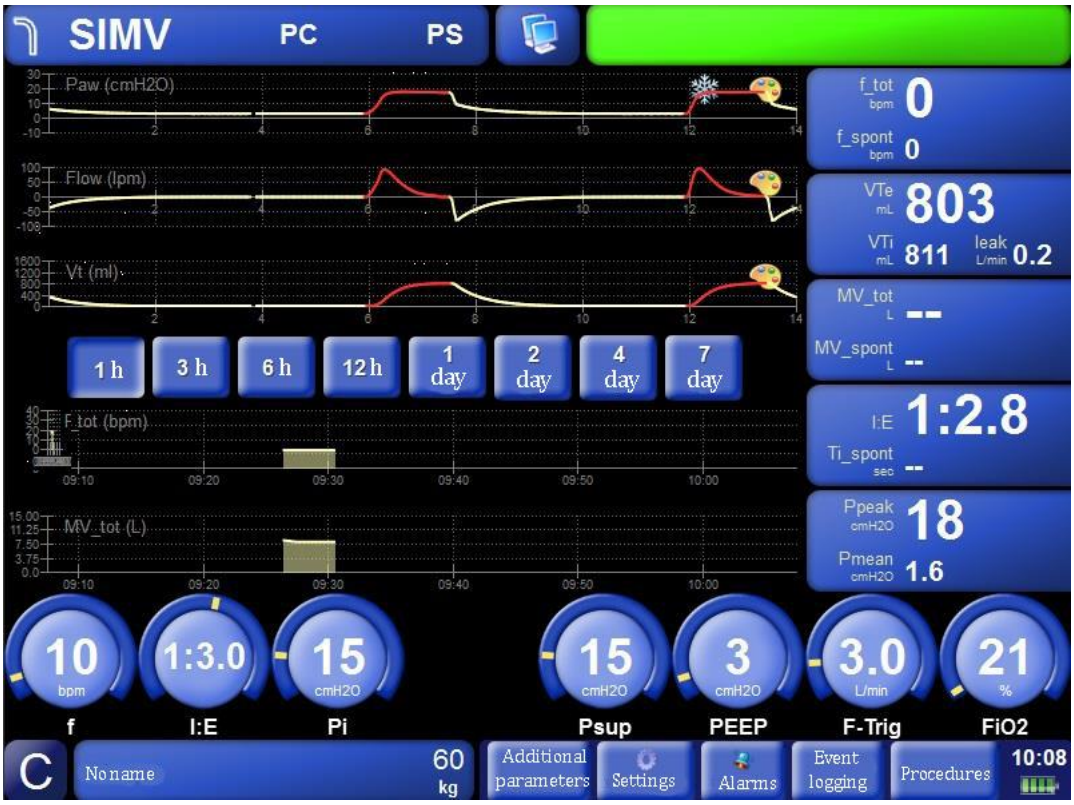



**Figure 10.17 – "Multiscreen – curves, graphical trends"**

### 10.10 Print screen

While the ventilator is in any mode, you can take a shot of screen. To do this, click on the button **"Print screen"** at the bottom of the display. After that, the ventilator will save everything that is displayed on the screen at the time of the picture.

To view and upload the taken pictures, you need to click on the button "screens" (in the middle, at the top of the display) and select "Shots of screen" in the drop-down menu. Then the image management screen will appear on the display (see Figure 10.18).


**Figure 10. 18 – "Print Screen"**

Using the **"<-"** and **"->"** buttons, you can switch between previously taken shots of screen.

By clicking on the button **"UPLOAD"**, you can upload the displayed image to a USB device. The saved file will have a name containing the date and time of this screenshot.

In total, the ventilator can store up to 100 pictures at a time. Subsequent pictures will overwrite the very first ones.

### 10.11 Metabolism

When you select the screen **"Metabolism"**, the DO-$CO_2$ loop and volumetric capnometry parameters are displayed (see Figure 10.19).

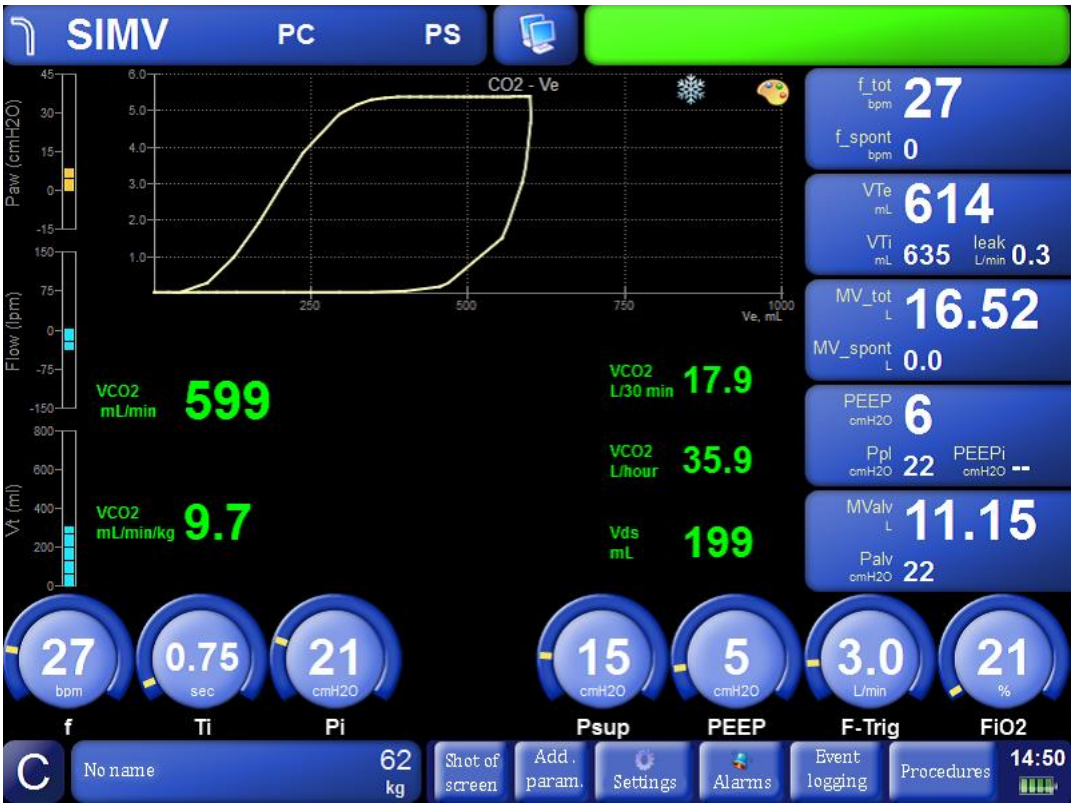



**Figure 10.19 – "Screen Metabolism"**

Volumetric capnography (DO-$CO_2$ loop) allows to get additional information compared to a temporary capnogram. Using this loop, a number of parameters are calculated:

$VCO_2$ (mL/min) – volume of exhaled carbon dioxide per minute

$VCO_2$ (mL/min / kg) – volume of exhaled carbon dioxide per minute per kilogram of body weight

$VCO_2$ (L/30min) – volume of exhaled carbon dioxide in 30 minutes

$VCO_2$ (L/hour) – volume of exhaled carbon dioxide per hour.

Vds (mL) – anatomically dead space.

Based on these data, the doctor can establish the optimal ventilation parameters for a particular patient, as well as select the necessary composition of artificial nutrition.

# 11. General settings and information about ventilator

General settings and information about the ventilator are in the settings window. To view information about the ventilator, press the button **“Settings”** at the bottom of the display and select the tab **“Information”** (see Figure 11.1).

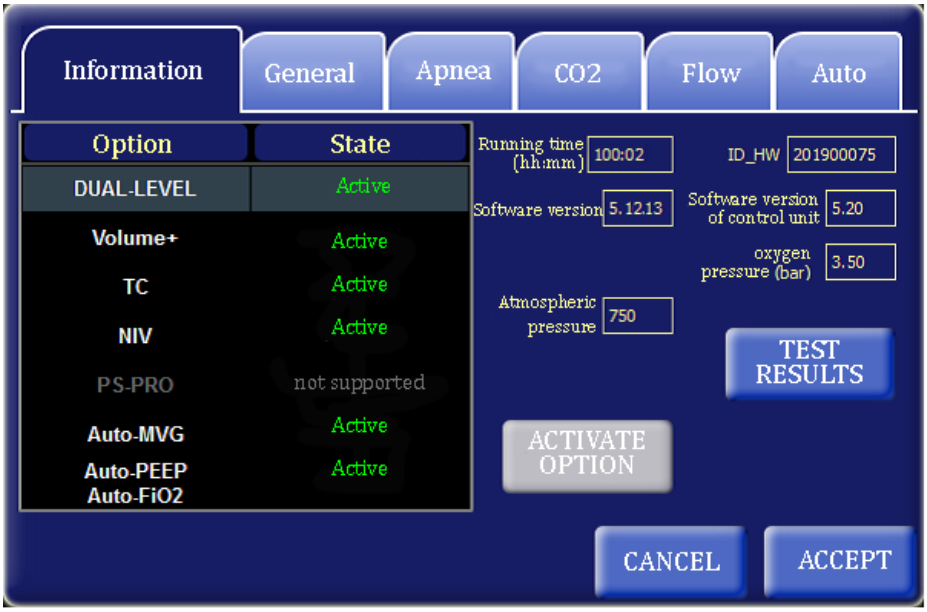



**Figure 11.1 – Control box – tab “Information”**

The following information is displayed on this tab:

- Options table,
- Operating time,
- Software version,
- Software version of the control unit,
- ID_HW (identification number of the control unit),
- Inlet air and oxygen pressure,
- Atmospheric pressure.

By clicking on the button **“TEST RESULTS”**, you can see the latest test results without interrupting ventilation.

**Operating time is the total amount of time during which the ventilator was turned on, regardless of whether ventilation was carried out at that time or not.**

The options table displays the optional features of the ventilator. Each option can have one of the following states:

- Active
- Inactive (trial period has expired),
- Trial period,
- Not supported (the ventilator does not support this option).

The device can initially be equipped with some set of options. In this case, these options immediately become active, the remaining options (which the device supports) are valid for the trial period. The trial period is one for all options and is 1000 hours.

To continue the option after the trial period has expired, it must be activated. Activation is carried out by entering a special activation code. To do this, move the table marker to the necessary option and click the button **"ACTIVATE OPTION"**. Instead of a table, a description of the selected option will appear, and a field for entering an activation code (see Figure 11.2).

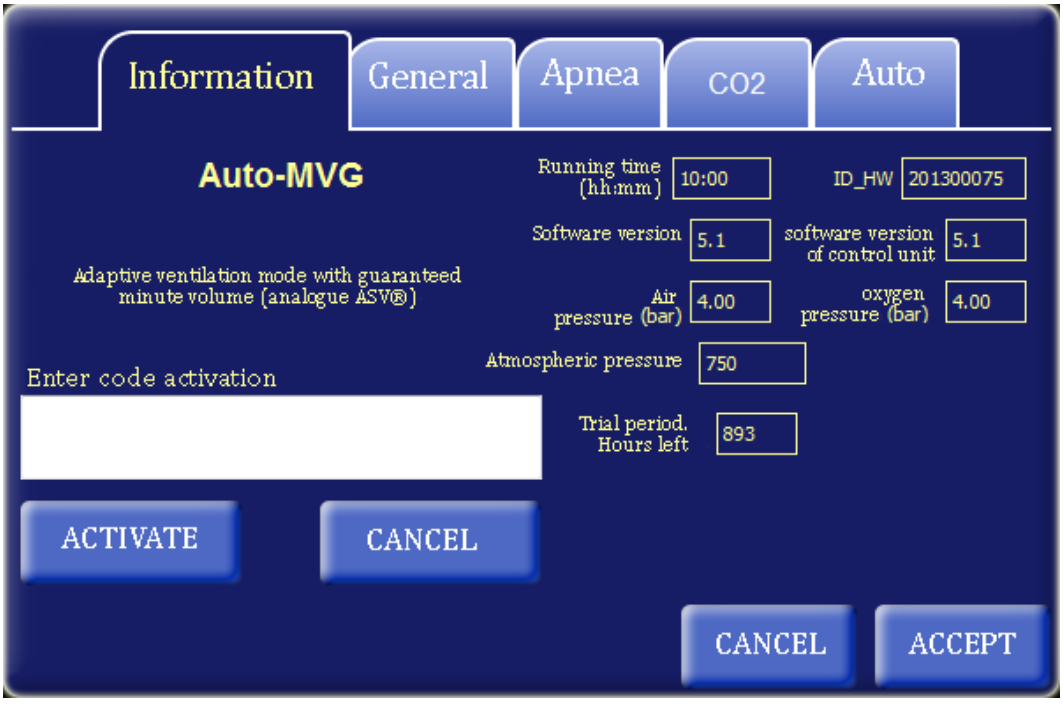



**Figure 11.2 – Control box – tab "Information" – entering activation code of option**

Click on the field to enter the activation code. In the pop-up window, use the encoder to enter the code, then, click the button **“Activate”**.

If the code is entered correctly, a table with options will again appear on the information tab, in which this option will have an active state (see Figure 11.1), otherwise, if the activation code is incorrect, an error message will be displayed.

On the tab “General” (see Figure 11.3), the following settings are set:

- BTPS Compensation,
- Remote control,
- Highlighting inspiration with color on curves and loops,
- Date/Time,
- Leakage compensation,
- Auto scale of curves,
- Work from a source of low oxygen pressure,
- Interface mode,
- Pressure units.

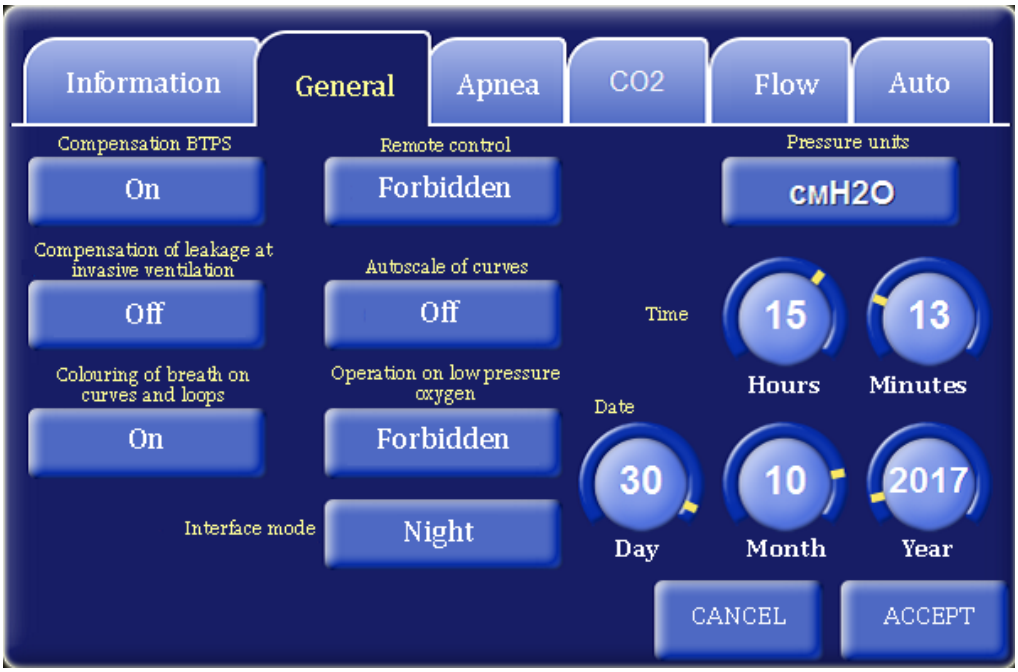



**Figure 11.3 – Control box – tab “General”**

**BTPS** compensation is used to bring the volume of the inhaled and exhaled gas mixture to the same standard conditions:

- temperature 37° C (body temperature),
- current atmospheric pressure,
- humidity 100%.

If the ventilator is connected to the central station, the "remote control" tune-up allows you to enable or disable changing the ventilation mode and the values of the control parameters of the ventilator.

Highlighting inspirations with color on curves and loops determines how curves and loops are displayed. If this setting is enabled, then on all curves and loops the inspiration is highlighted in one of the following colors, depending on the type of inspiration:

- **Red** is for the breaths initiated and controlled by the device (**Controlled**),
- **Yellow** is for the breaths initiated by the patient and controlled by the ventilator (**Assisted**),
- **Green** is for the breaths initiated and controlled by the patient (**Spontaneous**).

The setting **"Leakage compensation during invasive ventilation"** can be enabled if there are large leakages that occur at the junction of the endotracheal tube with the patient.

**It is not recommended to use the setting "Leakage compensation during invasive ventilation" if there are leakages in the patient's breathing circuit; instead, it is necessary to eliminate the leakage or replace the breathing circuit.**

The setting **"Autoscale of curves"** allows you to choose how to set scales on curves and loops.

If this setting is enabled, then the scales will be automatically adjusted each time the drawing of the current curves screen is completed and a new one begins, i.e. when the current curve drawing position moves from the far right to the far left.

Otherwise, scaling must be done manually.

**To control the brightness of the display**, there is a operator interface switching function:

- day,
- night.

For convenience, the ventilator provides the **possibility to change pressure units**. In the settings window on the tab “General” the operator can select the following pressure units:

- cm $H_2O$,
- mbar.

## 12 Setting $CO_2$

**$CO_2$** settings are in the settings window on the tab **"CO2"**. To view or change the settings, press the button **"Settings"** at the bottom of the display and select the tab **"CO2"** (see Figure 12.1).

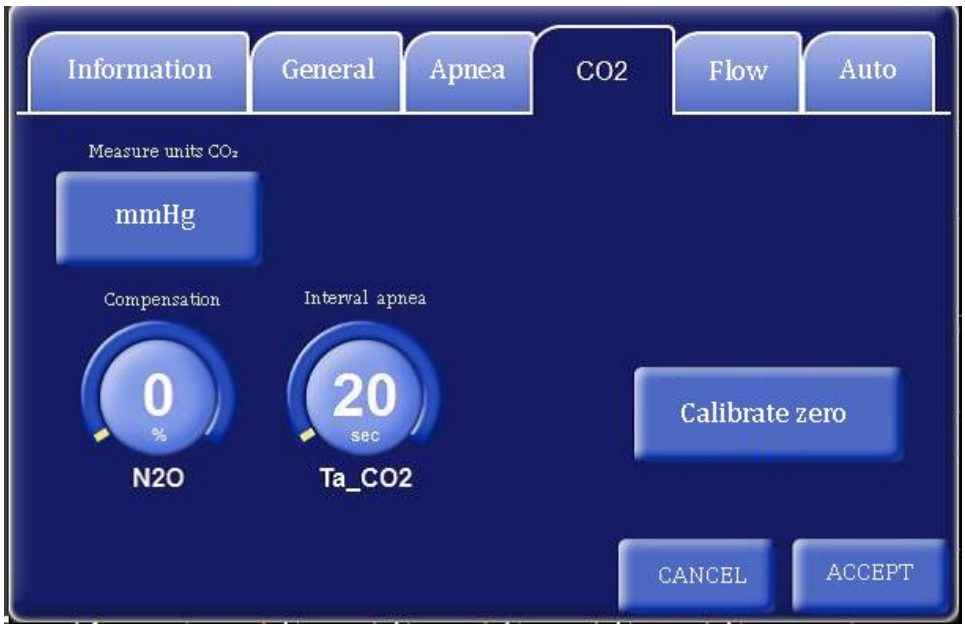



**Figure 12.1 – Control box – tab "$CO_2$"**

The measurement units of **$CO_2$** determine in which units the graphical and digital **$CO_2$** parameter data should be displayed.

To calibrate the zero level of **$CO_2$** concentration, use the button **"Calibrate Zero"**. For a detailed description, see 18.15.1.

Set the **$N_2O$** value to compensate for interference when measuring **$EtCO_2$** values.

The **Ta_$CO_2$** parameter sets the apnea interval for the **$CO_2$** channel. If during a given period of time no breath is detected by the **$CO_2$** sensor, the ventilator will display the **"Apnoe in the $CO_2$ channel"** alarm.

# 13 Ventilator `s operation shout down

To complete the operation of the ventilator, you must press the button  on the keypad. The following window will appear on the display:


**Figure 13.1**

Press the button **“OFF”**. The ventilator will stop ventilation and turn off.

**If the ventilator has faults, and it does not turn off according to the procedure described above, emergency shutdown of the ventilator is allowed.**

**To do this, press and hold the button**  **on the keypad for 5 seconds. After turning off the ventilator, release the button.**

**It is also possible to use the ON/OFF switch on the rear panel of the ventilator (see Figure 5.2).**

## 14 Possible faults and methods for their elimination

The list of possible faults is given in table 14.1.

**Table 14.1**

| **Form of fault** | **Probable reason** | **Remedy** |
|---|---|---|
| The ventilator is connected to an electrical network of 220 V 50 Hz, the NETWORK indicator does not light, the device operates on the built-in battery (the BAT indicator is on) | There is no supply voltage of 220 V | Check the ventilator's connection to the network, check the value of the supply voltage in the outlet, the fuses in the mains |
| The ventilator does not work on the battery, it gives an alarm "the battery is low" | Low battery | Charge the battery by connecting the ventilator to the 220 V network for at least 14 hours |

# 15 Ventilation and monitoring

## 15.1 Breath initiation

The ventilator can initiate a new breath when any of the following events occurs:

- the trigger threshold for the flow is exceeded (**F-Trig**),

- pressure threshold of trigger is exceeded (**P-Trig**),

- the time period of the breathing period (**set frequency f**) has expired,

- the operator pressed the button **"MANUAL INHALE"** on the keyboard of the ventilator.

## 15.2 Flow trigger

In order to detect an attempt of a new inhalation, the ventilator in the final phase of exhalation includes a small constant flow, called the base flow. The value of the basic flow is automatically set by the device 2 l/min more than the set sensitivity of the flow trigger (**F-Trig**).Using flow sensors, the ventilator continuously measures the values of the supplied flow (**Fi**) and the flow in the exhalation circuit (**Fe**).

Knowing the values of these flows, the ventilator continuously evaluates the flow in the patient (**Fp**) using the following formula:

**Fp = Fi - Fe** **(1)**

Until the patient begins an attempt to inhale, the values of **Fi** and **Fe** remain equal to each other and the flow in the patient **Fp** remains equal to zero. The entire base flow goes directly into the exhalation circuit, bypassing the patient.

But as soon as the patient begins an attempt to inhale, part of the underlying flow begins to branch into the patient. The **Fe** value in this case begins to decrease and, accordingly, the flow into the patient (**Fp**) begins to increase.

Detection of an attempt to inspire occurs at the moment when the **Fp** value exceeds the operator-defined value of the sensitivity of the trigger by flow (**F-Trig**).

In fact, the patient begins to receive the flow of the gas mixture, starting from the very beginning of the attempt to inhale (within the magnitude of the base flow).At the moment the trigger is activated, the ventilator starts the active part of the inspiration according to the set inspiration parameters.

**Figure 15.1 illustrates the process of detecting an attempted inhalation using a flow trigger.**

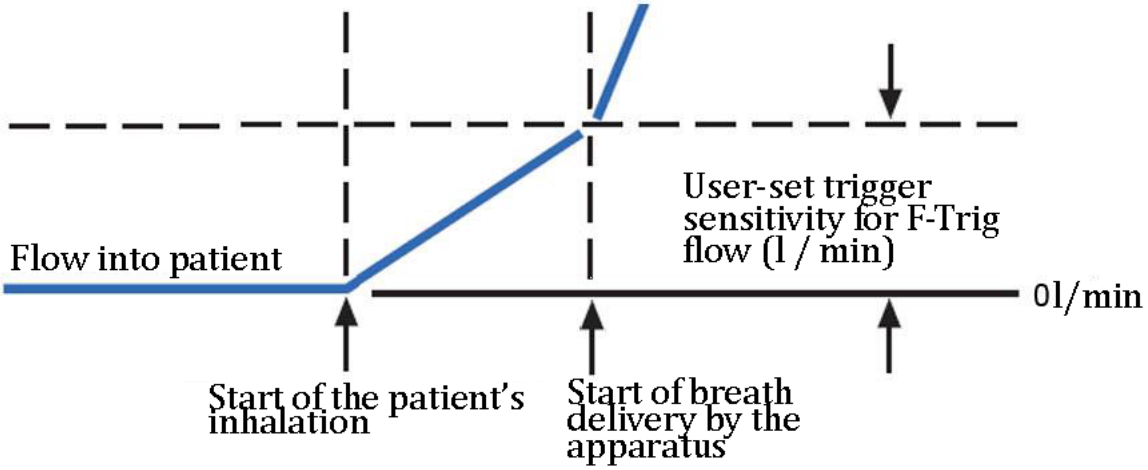



**Figure 15.1 – Breath initiation using a flow trigger**

The response time of the device from the moment the patient begins the attempt to inhale to the start of the actual delivery of the breath (trigger time) depends on the following factors:

- Flow trigger sensitivity. The lower the set **F-Trig** value, the faster it will be reached and the faster inspiration delivery will begin.

- Aggressiveness of inspiration by the patient. The more aggressive the inhalation attempt, the faster the **F-Trig** threshold will be reached and inspiration delivery will begin.

| | |
|---|---|
|  | **The ventilator has special measures to reduce the likelihood of false triggers (called auto-triggers). However, in some situations (for example, if there is a leakage of the gas mixture from the circuit, during active patient movements, etc.), when the trigger sensitivity is set too high, false triggers positives are still not completely ruled out.**<br>**Whenever possible, try not to use F-Trig values <1.5 l/min.**<br>**Use them only if necessary. If false triggers occur, increase the F-Trig value.**<br>**The value of F-Trig = 3 l/min, set by the ventilator by default for a new patient, provides normal sensitivity for most patients and almost completely eliminates the possibility of false triggers.** |

## 15.3 Pressure trigger

When using a pressure trigger, the ventilator continuously monitors the pressure in the patient circuit. Two pressure sensors are used for this, one of which is installed in the inspiration circuit, and the second in the exhalation circuit. The pressure in the patient circuit is automatically evaluated by a special algorithm from two measured pressure values – on inspiration (**Pi**) and on exhalation (**Pe**).

At the end of exhalation, the ventilator sets the pressure at the level of the operator-set **PEEP** value.

As long as there are no attempts of the patient to inhale, the pressure is constantly maintained at the **PEEP** level.

But as soon as the patient begins an attempt to inhale, a vacuum is created in the circuit and the pressure begins to drop below the **PEEP** level.

Detection of an inhalation attempt occurs at a point in time when the pressure drops below the **PEEP** level by the operator-specified pressure trigger sensitivity (**P-Trig**).

Figure 15.2 illustrates the process of detecting an attempted inhalation using a pressure trigger.

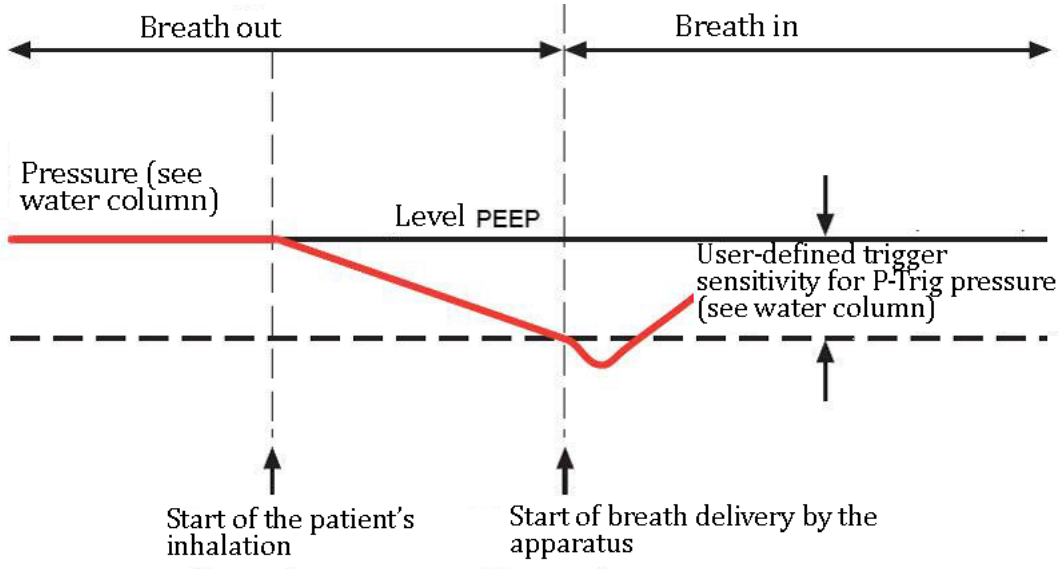



**Figure 15.2 – Breath initiation using a trigger for pressure**

The response time of the ventilator from the moment the patient begins the attempt to inhale to the start of the actual delivery of the breath (trigger time) depends on the following factors:

- Pressure trigger sensitivity. The lower the set **P-Trig** value, the faster it will be reached and the faster inspiration delivery will begin.

- Aggressiveness of inspiration by the patient. The more aggressive the inspiration attempt, the faster the **P-Trig** threshold is reached and inspiration delivery begins.

**The ventilator has special measures to reduce the likelihood of false triggers (called auto-triggers). However, in some situations (for example, if there is a leakage of the gas mixture from the circuit, during active movements of the patient, etc.), when the trigger sensitivity is set too high, the appearance of false alarms is still not completely ruled out.**

**Whenever possible, try not to use P-Trig values <1 cm Hg. Use them only if necessary.**

**If false triggers occur, increase the P-Trig value.**

**P-Trig value = 2 cm water column, set by default by the ventilator for a new patient, provides normal sensitivity for most patients and almost completely eliminates the likelihood of false triggers.**

### 15.4 Completion of breath and start of exhalation

The device completes the inhalation and switches to exhalation when any of the following events occurs:

- the set inspiration time has expired,
- inspiratory flow decreased below a threshold value,
- airway pressure exceeded the threshold value.

In any ventilation mode, the ventilator controls the minimum expiration time, which cannot be less than 500 ms.

### 15.4.1 Completion of breath according to time

This method is used for delivery of forced breaths, controlled both by pressure (**PC, PC-VG**) and by volume (**VC**).

For pressure-controlled inspirations (PC and PC-VG), inspiratory duration (Ti) is set directly by the operator.

For breaths controlled by volume (VC), the duration of the breath is determined by the ventilator automatically based on the operator-set inspiratory volume (Vt), peak flow (PeakFlow), flow shape (FlowPattern) and the duration of the "plateau".

After the set (or calculated) inhalation time has passed, the device completes the inhalation and switches to exhalation.

For spontaneous breaths, completing a timed breath is a protective method. If for some reason a spontaneous inhalation does not end within the maximum allowed time, the ventilator automatically completes the inhalation and switches to exhalation.

The maximum allowed duration of spontaneous inspiration is calculated by the ventilator automatically based on the ideal patient weight (IBW) specified by the operator.

With an increase in IBW, the maximum permitted duration of spontaneous inspiration also increases.

### 15.4.2 Completion of breath according to criterion of the reduction inspiratory flow

This method is the main method for completing spontaneous breaths supported by pressure (PS, PS-VG).

In the process of supporting spontaneous inspiration, the ventilator continuously monitors the value of the flow of the gas mixture delivered to the patient. At the same time, the device must maintain the pressure in the patient circuit at a constant level (PEEP + PS). To perform this task, in the process of filling the lungs with a gas mixture, the ventilator is forced to continuously reduce the flow delivered to the patient.

At the point in time (at the end of the inhale), when the flow into the patient decreases below the threshold level, the ventilator completes the inhalation and begins to exhale. The value of this threshold level is set as a percentage of the peak inspiratory flow by the Esense parameter.

Thus, the duration of spontaneous inspiration is determined by two factors:

- The value of the Esense parameter specified by the operator. The higher the Esense value, the earlier the breath ends.

- Patient activity during inspiration. The patient himself controls the duration of spontaneous inspiration. As soon as the patient stops inhaling, the ventilator detects this (by reducing the flow to a threshold level) and immediately begins to exhale.

**Setting the expiratory sensitivity too low (Esense <10%) may in some situations lead to a situation where spontaneous inhalation cannot be completed (the condition for the completion of inspiration will never be fulfilled)!**

**In this case, other protective mechanisms for completing the inspiration will work (according to the maximum permissible duration of inspiration, pressure, etc.).**

**Try not to use too small Esense values and always control the duration of the patient's spontaneous breaths (monitored parameter Ti_spont).**

### 15.4.3 Completion of inspiration when threshold pressure is exceeded

Completion of inspiration by exceeding the threshold pressure is a protective method for inspirations of any type.

During each breath, the ventilator continuously monitors the pressure in the circuit. As soon as the pressure exceeds the allowable threshold value, the ventilator immediately completes the inhalation and begins to exhale.

For all types of breaths (mandatory and spontaneous), the threshold value is set by the ventilator at the level of the upper limit of the peak pressure alarm (↑**Ppeak**) set by the operator.

In addition, for spontaneous inspirations with pressure support (**PS, PS-VG**), there is another threshold value Pspontmax, which the ventilator calculates as follows:

$$\mathbf{P\ spont\ max = PEEP + PS + \Delta P,} \qquad \mathbf{(2)}$$

where ΔP is the allowable excess pressure above the target value. ΔP is automatically selected by the ventilator during inspiration in the range from 2 to 8 cm water column.

Such an algorithm allows avoiding large deviations of the pressure in the circuit from the target value even in emergency situations (for example, when for some reason the main method of completing spontaneous inspiration does not work according to the criterion for reducing the inspiratory flow).

# 16 Mandatory breaths

Mandatory breaths are of the following types (by delivery method):

- with volume control (VC),
- with pressure control (PC),
- with pressure control with guaranteed volume (PC-VG).

Table 16.1 shows the comparative characteristics of the breaths of **PC, PC-VG** and **VC**.

**Table 16.1**

| **Characteristics** | **PC, PC-VG** | **VC** |
|---|---|---|
| **Initiation of breath** | The breath can be initiated by one of the following events:<br>- upon detection of an attempt of inhale of the patient (trigger for flow or pressure was on),<br>- upon expiration of the time interval corresponding to the set ventilation frequency,<br>- by pressing the button **"MANUAL INHALE"** | |
| **Pressure/flow during inspiration** | The ventilator automatically regulates the flow of the gas mixture into the patient in such a way as to achieve the target pressure **Ptarget** and keep it at this level throughout the entire inhalation time. The **Ptarget** value is defined as the sum of **PEEP + Pi**, where **Pi** is the inspiratory pressure.<br>For **PC** breaths, the **Pi** value is set by the operator.<br>For **PC-VG** breaths, the optimal **Pi** value is automatically selected by the device using a special adaptive algorithm. This value depends on the target **VT** volume set by the operator, as well as on the parameters of the patient's respiratory mechanics (airway resistance and lung distensibility). The rise time of the pressure to the target value is determined by the parameter **Pramp.** | The operator sets the necessary peak flow value and the flow shape (rectangular or downward).<br>The resulting shape of the pressure curve in the circuit depends on the parameters of the patient's respiratory mechanics (airway resistance and lung extensibility) |
| **Exhalation valve status during inspiration** | The exhalation valve is continuously adjusted to keep the pressure at the target value. | Exhalation valve closed |

| | | |
|---|---|---|
| **Completion of inspiration and the beginning of exhalation** | Inhalation ends when the operator-defined time interval **Ti** elapses. In addition, inspiration may end prematurely if the pressure in the circuit exceeds a threshold **↑Ppeak** set by the operator. Exhalation begins immediately after completion of inspiration. | Inhalation ends when the operator-defined volume of the gas mixture (**Vt**) is delivered to the patient's lungs. In addition, the inspiration may end prematurely if the pressure in the circuit exceeds the threshold **↑Ppeak** set by the operator. After inhalation is completed, the "plateau" time interval is maintained (at zero flow) and exhalation begins |
| **Pressure/flow during exhalation** | Pressure is adjusted to the **PEEP** target value set by the operator. At the end of exhalation, the base flow begins to flow into the patient to detect his attempts to inhale (if selected the trigger for flow) | |
| **Exhalation valve status during exhalation** | The exhalation valve is continuously adjusted to maintain the pressure at the level set by the operator value **PEEP** | |

## 16.1 Compliance compensation of the respiratory circuit for volume controlled breaths (VC)

When the gas mixture flows from the ventilator to the patient, unfortunately, not all of the volume enters the patient's lungs. Part of the volume remains in the tubes of the breathing circuit. The greater the total length of all the tubes, the greater the compliance of the breathing circuit and the greater the volume does not reach the patient. When using a humidifier, bacterial filters and moisture collectors, additional volume is also lost in them.

In this case, the operator, setting the necessary value of the inspiratory volume (**Vt**), believes that the entire specified volume should be delivered to the patient without loss.

To achieve this goal, the ventilator has a special compensation algorithm for the compliance (stray volume) of the breathing circuit. The ventilator actually delivers a volume equal to the sum

where **Vt** is the operator-defined respiratory volume,

**Vc** is the volume lost in the tubes of the breathing circuit.

In this case, when a part of the volume is lost in the tubes of the breathing circuit (**Vc**), it is precisely the volume set by the operator (**Vt**) that will reach the patient.

In order for the ventilator to accurately assess the lost volume (**Vc**), it is necessary to know the magnitude of the breathing circuit compliance. For this, a special test **"Measurement of the breathing circuit compliance"** is provided in the ventilator. This test can be started, select the menu position **"Tests"** when you turn on the ventilator.

**1 Measure the breathing circuit compliance (Ct) immediately before connecting the patient to the ventilator, as well as when changing the breathing circuit or its parts (including humidifier, filters, and moisture collectors). Measure Ct exactly in the configuration of the breathing circuit in which you plan to use it when connecting the patient to the ventilator! This will significantly improve the accuracy of the volumes of the gas mixture delivered to the patient.**

**2 When ventilating patients with a small ideal weight (IBW <15 kg), as well as patients with reduced lung compliance (Cstat <10 ml/cm Hg), the error of the actually delivered volume of the gas mixture to the patient (as a percentage of the set value) without compensation of the he compliance of the breathing circuit can be very large! Be sure to measure the compliance of the breathing circuit before using the ventilator with such patients!**

## 16.2 Compensation BTPS for volume controlled breaths (VC)

The primary goal of volume-controlled ventilation (**VC**) is to deliver a given volume of gas mixture to the patient's lungs.

But from the laws of physics it is known that the volume of gas directly depends on temperature, pressure and humidity.

To avoid discrepancies in the interpretation of volume values (for example, when changing temperature or humidity), the device automatically leads them to standard conditions:

- temperature 37° C (body temperature),
- current atmospheric pressure,

- humidity 100%.

These standard conditions are called BTPS (Body Temperature and Pressure, Saturated).

They are as close as possible to the conditions in which the gas mixture is in the patient's lungs.

Thus, all set and displayed values of the volumes and flows of the gas mixture are automatically brought to the **BTPS** conditions by the ventilator.

# 17 Spontaneous breaths

The main difference between spontaneous breaths and mandatory ones is that during a spontaneous breath the patient independently "controls" the breathing process (breathing duration).

Spontaneous breaths are only possible in ventilation modes **SIMV, SPONT (CPAP) and DUAL-LEVEL.**

In A/C mode, all breaths are only mandatory.

Spontaneous breaths are of the following types (by way of support):

- with pressure support (**PS**),
- with pressure support with guaranteed volume (**PS-VG**),
- with automatic compensation of tube resistance (**TC**),
- with proportional pressure support (**PS-PRO**).

Table 17.1 shows the characteristics of spontaneous breaths of **PS** and **PS-VG.**

**Table 17.1**

| **Characteristics** | **PS, PS-VG** |
|---|---|
| **Initiation of breath** | Inhalation can only be initiated if an attempt to inhale of a patient is detected (trigger for flow or pressure was on) |
| **Pressure/flow during inhalation** | The ventilator automatically regulates the flow of the gas mixture into the patient in such a way as to achieve the target pressure **Ptarget** and keep it at this level throughout the entire inhalation time. The **Ptarget** value is defined as the sum of **PEEP + PS**, where **PS** is the support pressure.<br>For **PS** breaths, the **PS** support pressure value is set by the operator. For **PS-VG** breaths, the optimal **PS** support pressure value is automatically selected by the ventilator using a special adaptive algorithm. This value depends on the target **VT** support volume set by the operator, as well as on the parameters of the patient's respiratory mechanics (airway resistance and lung distensibility). The rise time of the pressure to the target value is determined by the parameter **Pramp.** |
| **Exhalation valve status during inspiration** | The exhalation valve is continuously adjusted to keep the pressure at the target value. |

| | |
|---|---|
| **Completion of inhalation and the beginning of exhalation** | Inhalation is completed when any of the following conditions is met:<br>The flow of the gas mixture into the patient falls below the threshold expiratory sensitivity (**Esense**).<br>The **Esense** value is set by the operator as a percentage of the peak inspiratory flow value.<br>Airway pressure exceeded the target **Ptarget** (**PEEP + PS**) by 10 cm water column.<br>The duration of inspiration exceeded the maximum permissible value, which is calculated automatically by the device depending on the ideal patient weight (**IBW**) set by the operator.<br>The pressure in the circuit has exceeded the threshold ↑**Ppeak** set by the operator.<br>Exhalation begins immediately after completion of inspiration. |
| **Pressure/flow during exhalation** | Pressure is adjusted to the **PEEP** target value set by the operator. At the end of exhalation, the base flow begins to flow into the patient to detect his attempts to inhale (if selected trigger for flow) |
| **Exhalation valve status during exhalation** | The exhalation valve is continuously adjusted to maintain the pressure at the level set by the operator value **PEEP** |

### 17.1 Spontaneous breaths with proportional support of pressure PS-PRO

**PS-PRO** is a new type of spontaneous breathing in which the support pressure is proportional to the effort to inhale of the patient.

**PS-PRO** is an analogue of the **PAV**® (Proportional Assist Ventilation®) mode implemented in the **PB-840** (Puritan Bennett).

The control parameters for the PS-PRO breaths are presented in table 17.2.

**Table 17.2 - The control parameters for the PS-PRO breaths**

| Parameter | Description |
|---|---|
| **% Support** | **Support level**. It is set in percent (**from 5 to 90%)** and determines the degree of compensation of the patient's effort necessary for inspiration. For example, the value **% Support = 70%** means that the device carries out **70%** of the entire work of breathing (effort), and the patient has only **30%** of all work. |
| |  When setting the %Support parameter value, follow these rules:<br>1 Do not change the value of the parameter earlier than after 10 – 15 breaths from the moment of setting the previous value. Such a number of breaths is necessary to stabilize the patient's response to a new level of support.<br>2 Too much support may be uncomfortable for the patient, especially if the patient has a lot of respiratory activity. Be especially careful when setting the support value to more than 80%. |
| | By default, 50% of support is set for a new patient |
| **Esense** | **Expiratory sensitivity.** Unlike other types of spontaneous breaths, the **PS-PRO** uses an absolute flow value (**Esense**) of l/min. The value of this parameter is set by the doctor in the range from 1 to 10 l/min. By default, the ventilator sets the **Esense** value to 3 l/min for the new patient. |
| **Vt_max** | **The maximum allowable volume of inhalation.** Set in milliliters per kilogram of patient weight. Value Range: **from 5 to 30 ml/kg** |
| **Tube I. D** | **The diameter of the endotracheal tube.** Range of values: **from 6 to 10 mm.** |
| |  **The set value of the Tube I.D parameter must strictly correspond to the actual diameter of the endotracheal tube. Otherwise, in some situations, excessive or insufficient proportional support is possible, which in turn will cause patient discomfort.** |

**PS-PRO** inhalations provide maximum comfort for the patient, since in this case the patient fully controls the entire process of inhalation and receives the level of support that he needs at any given time.

The ventilator continuously adapts to the needs of the patient, evaluating in real time all the basic parameters of respiratory mechanics and using them to provide the necessary level of support.

The main differences between **PS-PRO** breaths and regular **PS** breaths are as follows:

- For **PS** breaths, support pressure is set by the physician. It is a constant and does not change during inhalation, or from inhalation to inhalation.

- For **PS-PRO** breaths, the support pressure changes both during inhalation and from inhalation to inhalation. The amount of support is not set by the doctor, but directly depends on the inspiratory effort of the patient, i.e. the patient himself forms the necessary level of support for himself. Moreover, support is provided precisely at those moments when it is required by the patient. This type of breathing is as comfortable and physiological as possible for the patient.

The task of **PS-PRO** is to compensate the patient for breathing (respiratory effort). The doctor only sets the degree of compensation for this effort with the **%Support** parameter.

To provide proportional support for spontaneous breaths, the ventilator constantly assesses the airway resistance and the lungs compliance of the patient's lungs, as well as continuously monitors the inspiratory flow and volume in the lungs during the whole breath. Based on these data, the device calculates the required instantaneous value of the support pressure in the patient's tee at each moment of time throughout the inspiration (at least 100 times per second).

**To use the proportional support of spontaneous breaths, the following conditions must be met:**

**1 The patient should be intubated with an endotracheal (ET) or tracheostomy (Trach) tube with a diameter of 6 to 10 mm.**

**2 The patient should breathe spontaneously. The patient's inspiratory effort should be adequate to provide the necessary minute ventilation.**

**3 The ideal patient weight (IBW) should be at least 25 kg.**

**4 There should be no leakage in the breathing circuit, otherwise incorrect compensation may occur.**

**When replacing the breathing circuit, be sure to test it.**

### 17.1.1 Setting of spontaneous breaths PS-PRO (option)

To set the type of spontaneous breaths **PS-PRO** do the following:

- open the ventilation mode settings window,

- click on the button **"Mode"** and select the **SPONT (CPAP)** mode in the menu that opens,

- click on the button **"Spontaneous breaths"** and in the menu that opens, select the type of spontaneous breaths **PS-PRO**,

- set the values of the control parameters,

- click the button **"Apply"** on the keypad of the ventilator.

Other parameters (**PEEP, FiO2, etc.)** are set similarly to other ventilation modes, depending on the clinical situation.

### 17.1.2 Principle of working PS-PRO

Before starting to provide proportional support for spontaneous breaths, the ventilator performs several test spontaneous breaths with constant support pressure. During these inspirations, the respiratory mechanics parameters necessary for the implementation of **PS-PRO** inspirations are automatically evaluated.

After that, the ventilator begins delivery of spontaneous breaths **PS-PRO**.

To calculate the required level of support, the ventilator uses the estimated values of the resistance of the airways and lung compliance. Since the parameters necessary for the high-quality implementation of **PS-PRO** breaths can change over time, the device periodically (once in several breaths) carries out special maneuvers on the breath for their qualitative assessment. The maneuvering moments are randomly selected by the device so as not to cause the patient to get used to the same breathing pattern.

### 17.1.3 Weaning the patient from the ventilator

The patient's weaning from the ventilator is reduced to a smooth "transferring" of the work (effort) of breathing from the ventilator to the patient. In **PS-PRO** mode, this is done by smoothly decreasing the support level with the **%Support** parameter.

For example, with **%Support = 80%,** the ventilator performs 80% of all breathing work.

In this case, the patient performs only 20% of the work.

And with **% Support = 5%,** the patient will have to do 95% of the work of breathing.

So, most of the work will already be transferred to the patient.

If in this case adequate ventilation parameters are provided for a long time, normal oxygenation level with minimum **PEEP** (**less than 8 cm $H_2O$**) and **FiO2 (less than 40%),** then this is a good forecast for successful extubation.

# 18 Ventilation mode

## 18.1 Mode Assist/Control (A/C)

In **A/C** mode, all breaths delivered by the ventilator are mandatory. This means that the entire process of inhalation is completely controlled by the ventilator in accordance with the established parameters of inhalation. In this case, mandatory breaths are divided into two classes according to the criterion of their initiation:

- breaths initiated by the patient (in case of the trigger for flow or pressure), such breaths are also called **Assisted**;

- breaths initiated by the ventilator (when there are no attempts to inhale by the patient), such breaths are also called **Controlled**.

When the ventilator detects an attempt to inhale the patient, he immediately gives him a mandatory **Assisted**-breath. If an attempt to inhale is not registered by the ventilator, it delivers mandatory **Controlled**-breaths at intervals corresponding to the set ventilation frequency (**f**).

## 18.2 Delivery of breath in mode A/C

In **A/C** mode, the ventilator calculates the period of inhalation following the given ventilation frequency according to the formula:

$$\mathbf{T = 60/f,} \qquad \mathbf{(4)}$$

where: T – the period of following breaths (s),

f - operator-defined ventilation frequency ($min^{-1}$).

The duration of the inspiratory phase is determined by the inspiration parameters set by the operator. For pressure-controlled breaths (**PC**), the inspiratory phase time is set directly by the operator. And for inhalations with volume control (**VC**), the duration of the inspiratory phase is determined by the operator-set values for inhalation volume (**Vt**) and peak flow (**PeakFlow**) and flow form. The duration of the expiratory phase is calculated by the ventilator according to the following formula:

$$\mathbf{Te = T - Ti,} \qquad \mathbf{(5)}$$

where: Te is the duration of the expiratory phase (s),

Ti is the duration of the inspiratory phase (s),

T - the period of following breaths (s).

The figures below illustrate the mechanism for delivering breaths in **A/C** mode in various situations (in there are attempts of inhalation of the patient and in the case of their absence).

It can be seen from the figures that in **A/C** mode the actual ventilation frequency can be greater than or equal to the frequency set by the operator.

In the case when the patient initiates **Assisted-breaths** before the expiration of the breath period, the actual ventilation frequency becomes higher than the frequency set by the operator.

The actual frequency will be equal to the frequency set by the operator only if there are no attempts of inhalation of the patient, i.e. when all the breaths delivered by the device will be **Controlled-breaths**.

Figure 18.1 illustrates the mechanism for delivering breaths in **A/C** mode when there are no attempts of inhalation of the patient. In this case, the ventilator delivers **Controlled-breaths (C)** with a period of **T**.

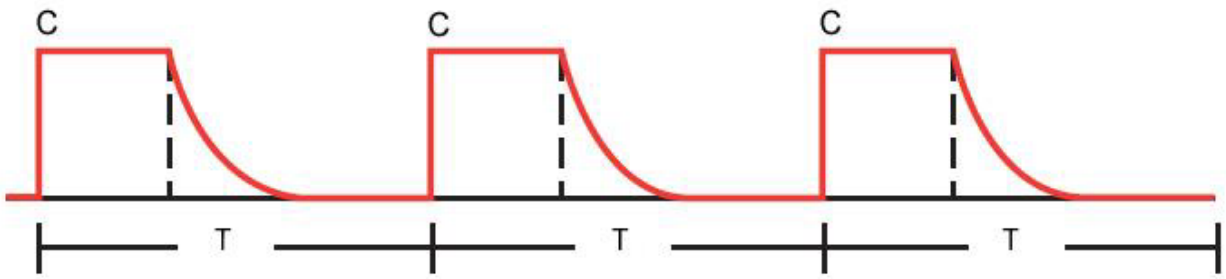



**Figure 18.1 – A/C mode, there are no attempts of inhalation of the patient**

Figure 18.2 illustrates the mechanism for the delivery of breaths in the case when the ventilator detects attempts of inhalation of the patient, i.e. when the trigger works (for flow or pressure, depending on the type of trigger selected). In the situation shown in this figure, all breaths are initiated by the patient, i.e. **Assisted-breaths (A).**

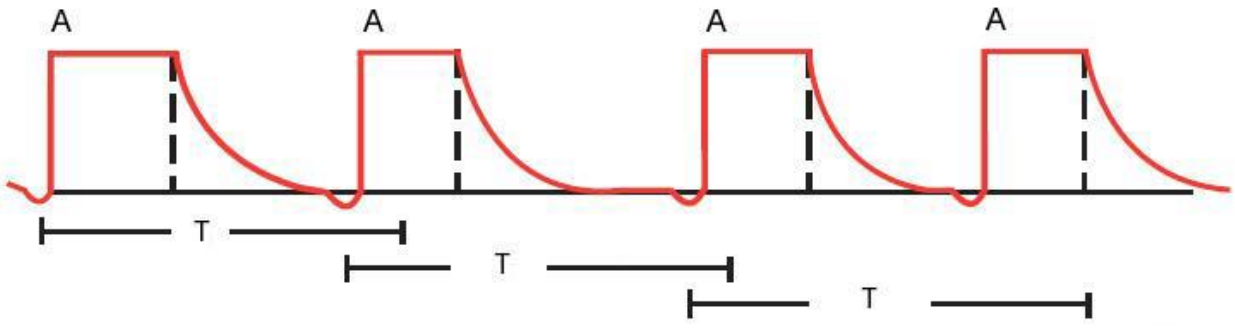



**Figure 18.2 - A/C mode, all breaths initiated by the patient**

Figure 18.3 illustrates the mechanism for delivering breaths when there are breaths initiated by both the patient and the ventilator.

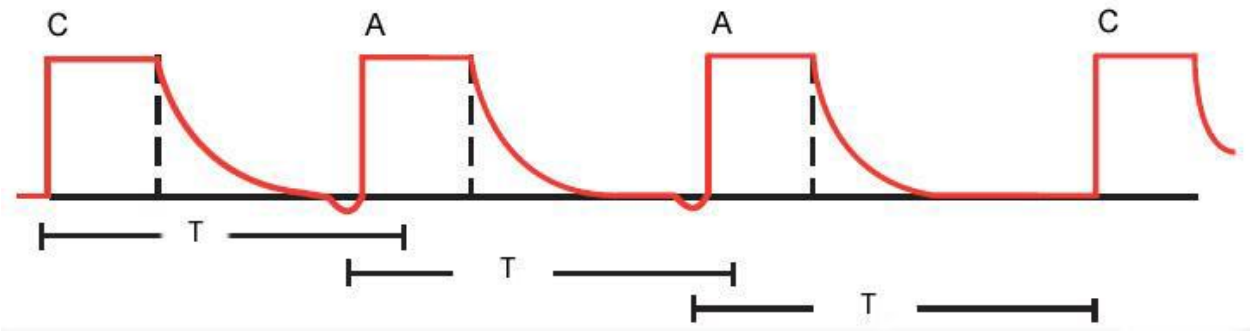



**Figure 18.3 - A/C mode, breaths are initiated by both the patient (A) and the device (C)**

### 18.3 Mode SIMV (Synchronize, Intermittent, Mandatory Ventilation)

**SIMV** is a mixed ventilation mode in which breaths can be either mandatory or spontaneous. The ability to perform spontaneous breaths is the main difference between **SIMV** mode and **A/C** mode.

Mandatory breaths in the **SIMV** can be either volume control **(VC)** or pressure control (**PC**).

Spontaneous breaths can be carried out both with pressure support (**PS**), and with automatic compensation of resistance of the endotracheal tube (**TC**).

To detect attempts of inhalation of the patient, any of the triggers (for flow or pressure) can be selected.

In **SIMV** mode, one mandatory breath is guaranteed for one breathing period, which is determined by the ventilation frequency set by the operator.

Mandatory breaths can be initiated both by the patient (**Assisted-breaths**), and by the ventilator (**Controlled-breaths**) in the case when an attempt of inhalation of the patient is not detected during the period of breathing.

### 18.4 Delivery of breath in mode SIMV

In **SIMV** mode, the ventilator, similarly to **A/C mode**, calculates the duration of the breathing period:

$$T = 60 / f, \quad (6)$$

where f is the operator-defined ventilation frequency (1/min),

T– SIMV respiration period (s).

Each breathing period in **SIMV** mode is divided into two time intervals:

$$T = Tpr + Tspont, \quad (7)$$

where **Tpr** is the time interval reserved for mandatory breaths,

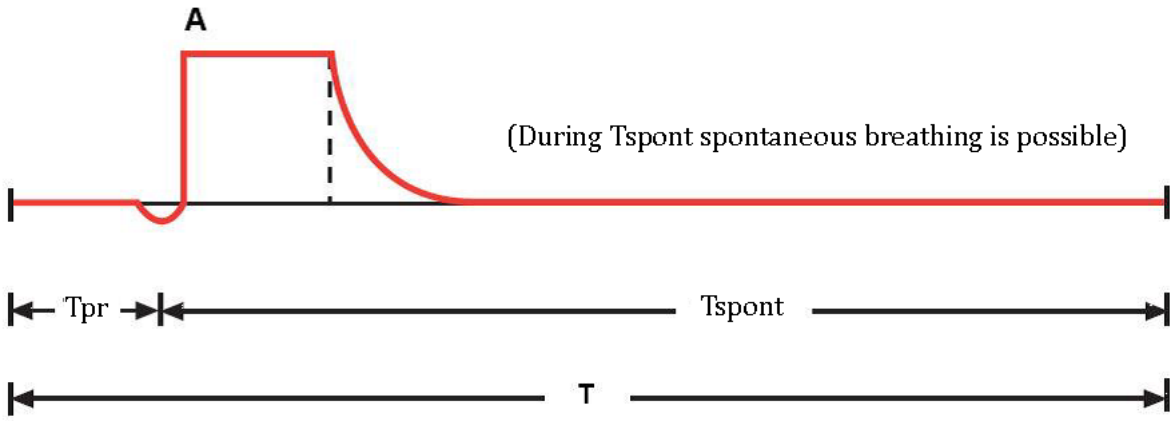
**Tspont** – a time interval reserved for spontaneous breaths.

During the time interval Tmp, the ventilator expects an attempt of inhalation from the patient.

Upon detection of this attempt (**if the trigger worked**), the ventilator immediately delivers one mandatory **Assisted-breath** in accordance with the established inhalation parameters. In this case, the interval **Tpr** ends and the ventilator switches to the interval **Tspont**, during which the ventilator allows breathing spontaneously until the expiration of the breathing period **T**.

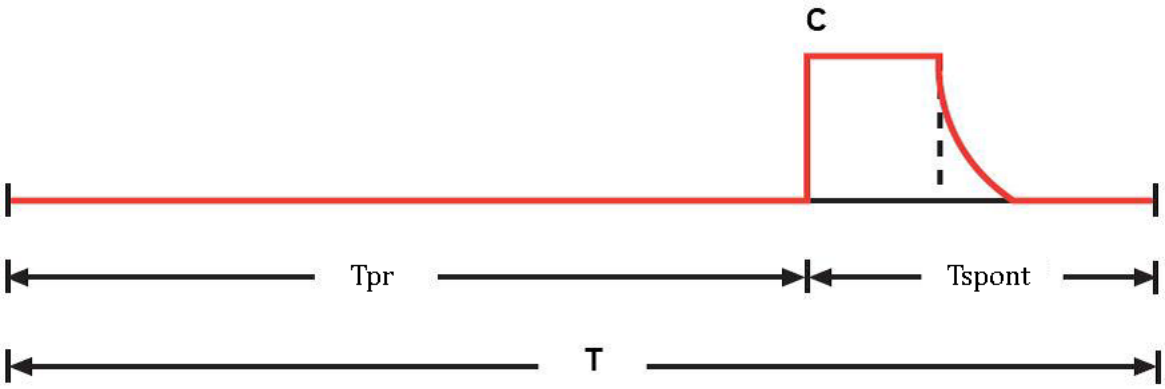
If an attempt to inhale was not detected during the time interval **Tpr** (i.e., the maximum time for waiting for an attempt to inhale has expired), the ventilator makes one mandatory **Controlled-breath** and also switches to waiting for spontaneous breaths, i.e. begins the interval **Tspont**. After a period of respiration **T**, the entire process described above is repeated cyclically.

Figure 18.4 and Figure 18.5 explain the structure of the **SIMV** respiration period in various situations.




(During Tpr, an attempt was made to inhale by the patient and one Assisted-breath was delivered (A). After that, the ventilator switched to Tspont)

**Figure 18.4 – Period of breathing SIMV**




(No attempt to inhale by the patient was detected during Tpr. After Tpr one Controlled-breath was delivered (C). After that, the ventilator switched to Tspont).

**Figure 18.5 - Period of breathing SIMV**

### 18.5 Mode features SIMV

- In **SIMV** mode, the ventilator is guaranteed to deliver one mandatory breath in one breathing period. Mandatory breaths are delivered in accordance with the parameters set by the operator and can be controlled both by volume (**VC**) and pressure (**PC, PC-VG**).

- The maximum waiting time for forced breaths Tpr max is determined according to the following rule:

**Tpr max = 0.6 * T (but not more than 10 s).** **(8)**

- During the time interval Tspont, the patient can take an unlimited number of spontaneous breaths. All spontaneous breaths can be accompanied by any support method (**PS, PS-VG, TC**).

- In cases where a spontaneous breathing begins before the end of the respiration period T, the ventilator automatically prolongs this interval until the end of the spontaneous exhalation. So, the ventilator is guaranteed to complete the started spontaneous breath and exhale of the patient. After completion of spontaneous exhalation, the ventilator returns to the usual logic of forming time intervals.

- In **SIMV** mode (unlike **A/C**), a short-term decrease in the ventilation frequency below the set f value is possible. For example, if a patient initiates a mandatory breath at the moment of the beginning of the breathing cycle, and the next breath does not initiate until the maximum interval Tpr max has elapsed, then the monitored value of the ventilation frequency may be less than the value set by the operator.

Thus, in **SIMV** mode, the actual mandatory-breath rate may be less than or equal to the set frequency.

### 18.6 Mode SPONT

**SPONT** mode is the patient's spontaneous breathing mode. Most breaths in this mode are initiated and controlled by the patient.

To detect attempts of inhalation of the patient, any of the triggers (for flow or pressure) can be selected.

#### 18.6.1 Delivery of breath in mode SPONT

When an attempt of inhalation is detected, the ventilator immediately begins to support it.

The type of support is determined by the current settings of the ventilator (**PS, PS-VG or TC**).

If pressure support (**PS**) is selected, the delivery of breath to the patient is determined by the values of the following parameters:

- **PEEP** (positive pressure at the end of expiration),

- **Psupp** (support pressure relative to **PEEP** level),

- **Pramp** (support pressure rise time),

- **Esense** (expiratory sensitivity).

If pressure support with guaranteed volume (**PS-VG**) is selected, the delivery of breath to the patient is determined by the values of the following parameters:

- **PEEP** (positive pressure at the end of expiration),

- **VTsupp** (volume of support),

- **Pramp** (support pressure rise time),

- **Esense** (expiratory sensitivity).

If endotracheal tube (**TC**) resistance compensation is chosen as inspiration support, the delivery of breath to the patient is determined by the following parameters:

- **Tube Type (type of tube)**

- **TubeI.D.** (tube diameter)

- **% Supp** (degree of compensation),

- **Esense** (expiratory sensitivity).

### 18.6.2 Mode features SPONT

- Use **SPONT** mode only for patients with stable spontaneous breathing! The absence of attempts of inhalation of the patient will lead to the termination of the delivery of breaths to the patient (apnoe). When apnoe occurs, the ventilator will immediately emit a high priority alarm sound and automatically switch to **APNOE** ventilation mode.

- Most **SPONT** breaths are spontaneous. However, the list of adjustable ventilation parameters for this mode also contains mandatory breath parameters. Mandatory breaths in **SPONT** mode are only breaths initiated by the operator by pressing the button “ 

” on the keyboard of the ventilator. Accordingly, all mandatory breath settings in **SPONT** mode apply only to breaths initiated by the operator by pressing the button “ 

”.

### 18.7 Mode CPAP

CPAP – "Continuous Positive Airway Pressure" is a mode that supports the patient's spontaneous breathing at the level of the established positive pressure at the end of exhalation (PEEP). The level of positive pressure at the end of exhalation (PEEP) is determined by the doctor. It is used to prevent the decline of alveoli, atelectasis.

### 18.8 Mode HFlow

HFlow is a mode of supporting unassisted breathing with a high (up to 15 - 65 l/min and higher) flow of the respiratory mixture with an adjustable oxygen content and conditioning of the flow, using specially produced nasal air ducts (cannulas) connected to the tee of the breathing circuit. It is used to prevent hasty tracheal intubation in cases when, with significant respiratory failure, the patient is compensated (subcompensated) for other vital functions.

### 18.9 Mode DUAL-LEVEL

The **DUAL-LEVEL** mode (similar to the **BIPAP®** and **BiLevelTM** modes) is classified as a mixed ventilation mode, combining the possibilities of mandatory and spontaneous breathing.

Mandatory breaths in **DUAL-LEVEL** mode are always performed with pressure control **(PC**), and spontaneous breaths can be performed with pressure support (**PS**).

In the absence of spontaneous breathing of the patient, mandatory breaths in the **DUAL-LEVEL** mode are similar to pressure-controlled (**PC**) breaths in the **A/C** mode. The only difference is that in the **DUAL-LEVEL** mode the patient can initiate spontaneous breaths both at a low pressure level ($\mathbf{PEEP_L}$) and at a high level ($\mathbf{PEEP_H}$).

**DUAL-LEVEL** mode can be considered as a mode with two levels of **PEEP**.

The duration of the interval of each of the levels ($\mathbf{T_L}$ and $\mathbf{T_H}$) is set by the operator. After the current time interval ($\mathbf{T_L}$ or $\mathbf{T_H}$), the ventilator automatically switches to another pressure level ($\mathbf{PEEP_H}$ or $\mathbf{PEEP_L}$).

An important feature of the **DUAL-LEVEL** mode is that the ventilator constantly tries to synchronize the moments of switching pressure levels with attempts of spontaneous

breaths of the patient. For this, at the end of each of the intervals ($\mathbf{T_L}$ or $\mathbf{T_H}$), a time interval is called a synchronization interval. During this interval, the ventilator expects another attempt of spontaneous inhalation of the patient (or the beginning of exhalation). If an attempt is detected, the ventilator immediately switches to a different pressure level in synchronization with the attempt to inhale (or exhale) the patient. This strategy allows you to provide maximum comfort for the patient when switching from one pressure level to another.

Figure 18.6 illustrates the process of switching between $\mathbf{PEEP_L}$ and $\mathbf{PEEP_H}$ levels.

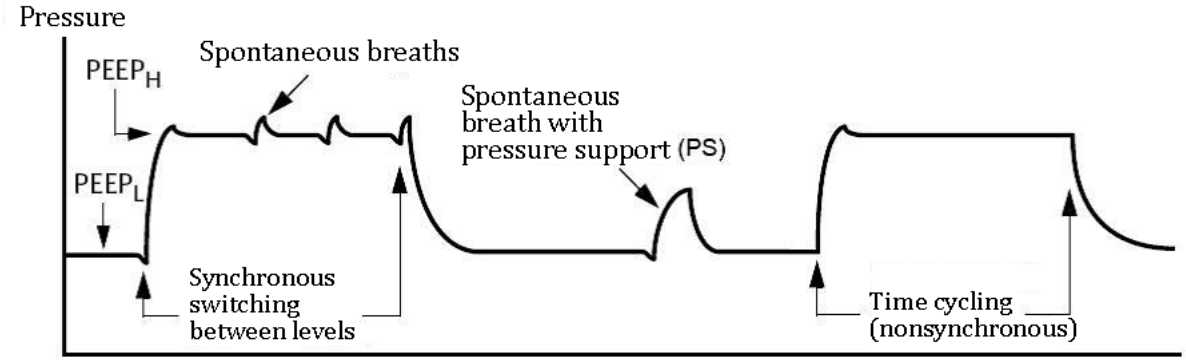



**Figure 18.6 - Switching pressure levels in DUAL-LEVEL mode**

### 18.9.1 Using the support pressure (PS) of spontaneous breaths in mode DUAL-LEVEL

Pressure support (**PS**) in **DUAL-LEVEL** mode is performed in accordance with the following rules (see Figure 18.7):

- A operator-defined value for the support pressure (**Psupp**) is always calculated at a relatively low pressure level ($\mathbf{PEEP_L}$). Based on the operator-defined support pressure (**Psupp**), the ventilator automatically calculates the target pressure (**Ptarget**) according to the formula:

$$\mathbf{Ptarget = PEEP_L + Psupp} \qquad \mathbf{(9)}$$

- At a low level ($\mathbf{PEEP_L}$), all spontaneous breaths are maintained by pressure. The support pressure in this case is equal to **Psupp.**

- At a high level ($\mathbf{PEEP_H}$), spontaneous breaths supported with pressure when the condition **Psupp**> ($\mathbf{PEEP_H}$-$\mathbf{PEEP_L}$) is met, where **Psupp** is the operator-specified support pressure. The support pressure in this case is **Psupp** - ($\mathbf{PEEP_H}$-$\mathbf{PEEP_L}$).

If the condition **Psupp**> (**$PEEP_H$-$PEEP_L$**) is not performed, spontaneous breaths at a high level (**$PEEP_H$**) are not supported by pressure!

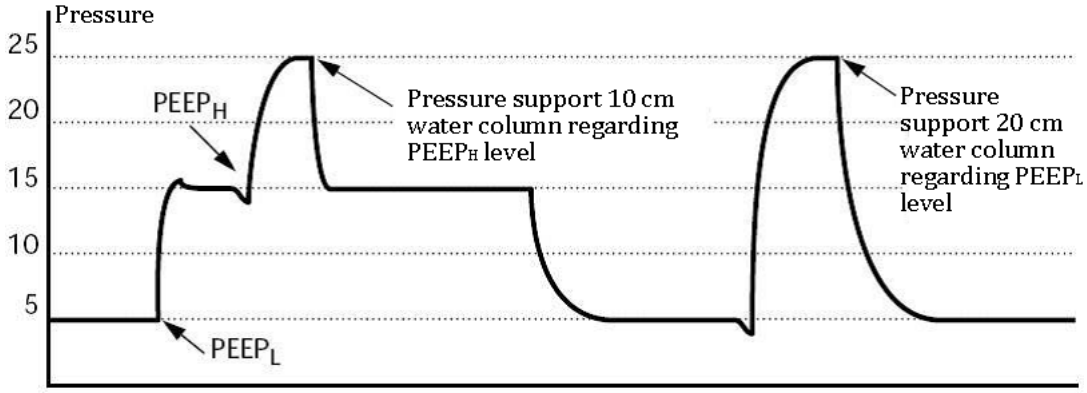



**Figure 18.7 - Support pressure (PS) in mode DUAL-LEVEL**

### 18.10 Mode Auto-MVG

**Auto-MVG** mode (analogous to **ASV®** mode) is classified as adaptive mode, which provides a operator-defined minute volume of ventilation regardless of the state of the respiratory system and spontaneous activity of the patient.

The ventilator sets all basic parameters (frequency of mandatory breaths, respiratory volume, inspiratory/expiratory time, I: E, etc.) automatically depending on the current state of the patient.

In **Auto-MVG** mode, the ventilator continuously (with each breath) adjusts the main ventilation parameters to optimize the ventilation process. The main task of the ventilator in this mode can be formulated as follows:

- ensure the delivery of the target (operator-defined) minute volume of ventilation,
- strictly comply with all requirements of the concept of lung protection (exclude the possibility of causing a patient barotrauma),
- take into account the presence (or absence) of spontaneous breaths of the patient,
- prevent the occurrence of **AutoPEEP**,

- prevent **tachypnoe**,

- take into account the “dead volume” of the patient,

- provide adequate ventilation during the entire period the patient is on the ventilator (from fully mandatory ventilation to extubation),

- comply with all of the above requirements in a fully automatic mode with the minimum possible work of breathing (**WOB**), which corresponds to the maximum comfort for the patient.

### 18.10 Operation of Auto-MVG mode

**Step 1. Before connecting the patient to the device...**

Prepare the ventilator for work, conduct tests of the breathing circuit and be sure that all connections are secure and free of leakages!

**Step 2. Initial start of Auto-MVG mode.**

1. Set the upper limit of the airway pressure alarm ↑Ppeak:

- **45...50 cm $H_2O$** – for patients with obstructive pathologies **(COPD, Asthma**);

- **40 cm $H_2O$** – for other patients.

During operation, the maximum airway pressure will be limited by ↑ **Ppeak - 5 cm $H_2O$** (but not higher than **40 cm $H_2O$**). On the airway pressure curve, this area is displayed as a red bar.

Avoid too small ↑**Ppeak** values. Otherwise, in some situations, the ventilator will not be able to provide the required respiratory volume. The ↑**Ppeak** value must be at least **25 cm $H_2O$** above the specified **PEEP** level.

2. Set the Auto-MVG mode in the ventilation mode settings window. When you click Continue, the **Auto-MVG** mode settings window opens automatically.

3. Set the basic parameters for **Auto-MVG** mode:

- **% MV** (desired minute ventilation volume). This is the main parameter for **Auto-MVG** mode. Set as a percentage of the "norm" for a given ideal patient weight (**IBW**).

The value of **0.1 l/kg IBW/min** is taken as the "norm" for an adult.

For example, for a patient with IBW = 60 kg: % MV = 100% - corresponds to a minute ventilation of 6 l/min. % MV = 150% - corresponds to a minute ventilation of 9 l/min.

If there is no information about the patient's needs (first connection to the ventilator), MV = 100% for most patients without revealed pathologies of the lungs, 120% for patients with restrictive pathologies (**ARDS**) and 90% for patients with obstructive parameters can be set as the initial value pathologies (**COPD, Asthma**). If the patient's body temperature is high (greater than 38.5° C), add an additional 20% to these values (for all patients).

- **Vt_max** (maximum allowable inspiratory volume). It is set in milliliters per kilogram of IBW. During the automatic adjustment of the inspiratory volume, the ventilator will never exceed this preset value and will not pump the volume into the patient above the permissible level, even if a larger volume is required for optimal ventilation.

- Pramp, Esens, PEEP, F-Trig/P-Trig, $FiO_2$. These parameters are set according to the clinical situation similar to other ventilation modes.

4. Confirm your settings. The unit will start ventilation in Auto-MVG mode.

**Step 3. Ventilation in Auto-MVG mode. Adjustment of the% MV parameter.**

In **Auto-MVG** mode, the ventilator automatically adjusts the most of ventilation parameters (mandatory respiratory rate, inspiratory volume, inspiratory pressure, inspiratory time, I: E ratio, etc.) depending on the current state of the patient's respiratory system and its spontaneous activity, are selected automatically by the ventilator. The purpose of the ventilator is to provide a given minute volume (**%MV**) with the minimum possible work of the patient's breathing, i.e. with maximum comfort for the patient.

Thus, in **Auto-MVG** mode, the ventilator continuously (with each breath) performs all the routine work of adjusting most of the ventilation parameters, while leaving the doctor the only and main task – to monitor the patient's condition and adjust the minute ventilation as necessary (adjusting only one parameter **%MV**) depending on the current needs of the patient.

To monitor the patient's condition, the ventilator has a large list of monitored parameters, including respiratory mechanics, capnography and pulse oximetry.

In addition, it is necessary to take into account the general clinical condition of the patient, as well as the indicators of **ACS**.

Examples of **%MV** adjustment for some patient conditions are shown in table 18.1:

Table 18.1

| **Condition of patient** | **Regulation % MV** | **Note** |
|---|---|---|
| High **$PaCO_2$ ($EtCO_2$)** | Increase % **MV** | Control **Ppeak** |
| Low **$PaCO_2$ ($EtCO_2$)** | Reduce % **MV** | Control **$SpO_2$** |
| Frequency and effort of spontaneous breaths are too high | Increase % **MV** | If necessary, use sedatives |
| There are no spontaneous breaths (the patient does not show spontaneous activity) | Reduce % **MV** (not lower 70 %) | Only under the condition **$PaCO_2$** <45 mm Hg |
| Positive clinical dynamics (decrease in body temperature, decrease in signs of an inflammatory reaction, etc.) | Reduce % **MV** (not lower 70 %) | Control **$PaCO_2$ ($EtCO_2$)** and oxygenation |
| Signs of inadequate ventilation (anxiety, tachypnea, sweating, hypoxemia, etc.) | Increase % **MV** | Control **Ppeak**. Increase **$FiO_2$** if necessary |
| The patient is "stable" and his "weaning" from mechanical ventilation is planned. | Reduce % **MV** gradually | To control the process of "weaning" |

**Step 4. Monitoring in Auto-MVG mode.**

In **Auto-MVG** mode, the ventilator continuously adapts (adjusts) to the current state of the patient. When changing the respiratory mechanics or spontaneous activity of the patient, the ventilator immediately adjusts the ventilation parameters to ensure maximum comfort to the patient.

It is very convenient to observe this adaptation process in the **"Ventilation"** window when viewing the **"Scheme of Ventilation"** (see Figure 18.8).


**Figure 18.8**

Target (optimal for the current state of the patient at a given % **MV**) values of the respiratory rate and respiratory volume are displayed with a marker in the form of a **"cross"**. This **"cross"** automatically moves when the operator changes the % **MV** value, as well as when the respiratory mechanics of the patient (in particular, the expiratory time constant **RCe**) changes.

The current actually measured values of these parameters are marked as a painted **"circle"**. The task of the ventilator is to achieve the target values, i.e. it is constantly trying to combine the circle with a cross to ensure "optimal" ventilation. This adaptation process can be observed in real time.

The red frame in this window displays the bounds of safe parameter values for the current state of the patient. When the patient's state changes, this frame can change (expand, narrow, move). The target value ("cross") is always inside this frame, i.e. the ventilator never sets ventilation parameters that go beyond safe bounds.

**Step 5. "Weaning" of the patient from the ventilator.**

Weaning of the patient from the ventilator is a complex procedure that requires certain knowledge and experience from the staff. **Auto-MVG** mode greatly facilitates the process of "weaning".

The doctor's actions in the process of "weaning" consist only in a gradual decrease in the value of minute ventilation (% **MV**). In this case, a gradual shift in the work of breathing from the ventilator to the patient occurs.

The **Auto-MVG** algorithm automatically "stimulates" the patient's spontaneous breathing. When spontaneous breaths appear, the ventilator automatically reduces the number of mandatory breaths, allowing the patient to take independent (spontaneous) breaths.

With adequate spontaneous activity of the patient, the frequency of forced breaths decreases to zero and the patient's breathing becomes completely spontaneous.

In addition, with increased spontaneous activity and improved respiratory mechanics, the algorithm automatically reduces the level of pressure support (**Pinsp**) to provide the target minute volume.

Thus, in **Auto-MVG** mode, the transition from fully mandatory (ventilator) ventilation to completely spontaneous breathing with a decrease in the level of support occurs completely in automatic mode.

In the process of "weaning", in the absence of signs of hypoventilation, hypoxia and fatigue of the respiratory muscles, % **MV** is gradually reduced up to 50-70%. If at the same time spontaneous ventilation (percentage of spontaneous breaths) and oxygenation (**$SpO_2$**) remain adequate with minimal pressure support (**Pinsp <10 cm $H_2O$**) and with minimal **$FiO_2$ (<40%),** then this is a sign of the patient's readiness to disconnect from the ventilator.

A generalized block diagram of the algorithm of the doctor's actions in the process of ventilation of the patient in the **Auto-MVG** mode is shown in Figure 18.9.

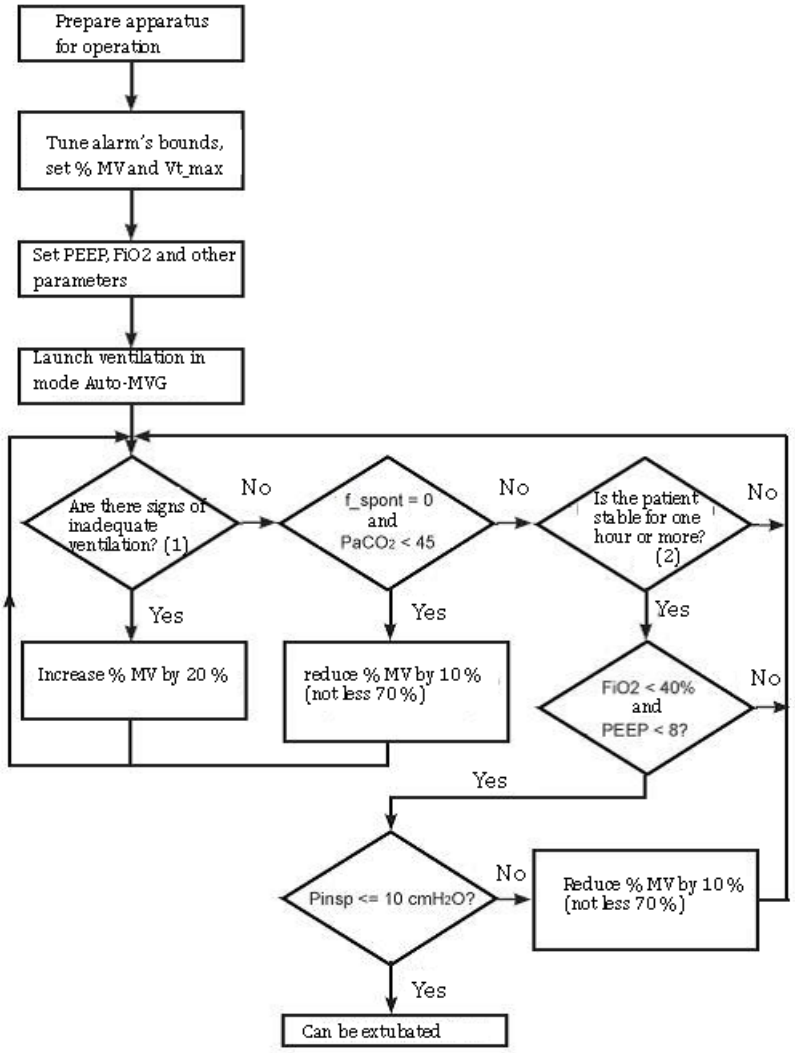



**Figure 18.9 – Algorithm of clinical use of the mode Auto-MVG**

Notes Signs of inadequate ventilation (any of the following):

- high frequency of spontaneous breaths (exceeds the target frequency by 10 breaths/min or more);

- $PaCO_2$> 45 mm Hg;

- P0.1> 3 cm water column

2. The patient is considered to be “stable” when all of the following conditions are met:

- breathing is completely spontaneous;
- $PaCO_2$ <45 mm Hg (50 mmHg for COPD);
- P0.1 <3 cm water column;
- $SpO_2$ and hemodynamics are normal.

### 18.11 Non-invasive ventilation

With non-invasive ventilation (NIV), the patient is connected to the ventilator with a special mask.

**Non-invasive ventilation should only be carried out under the supervision of highly qualified personnel.**

**During non-invasive ventilation, you should always be prepared to intubate the patient and start invasive ventilation.**

**Using a mask increases anatomically dead space. Therefore, always follow the manufacturer's instructions for the mask you use for non-invasive ventilation.**

**Use only special masks designed specifically for non-invasive ventilation. Do not try to use anesthetic masks for NIV!**

**Do not attempt to use NIV on intubated patients.**

**During NIV, it is highly desirable to monitor the main vital parameters of the patient ($SpO_2$, PE, BP, etc.)**

Non-invasive ventilation is allowed only if the following requirements are met:

- The patient should not be intubated.
- The patient must be conscious.
- The patient should independently carry out regular and adequate attempts at breathing.
- The mask should fit well on the patient's face.
- When choosing a mask for **NIV**, be guided by the following rules:
- Always try to use the mask supplied with the ventilator or recommended by the supplier of the ventilator.

- Always use a mask with a port (“Ported”, “Vented”). This provides maximum comfort for the patient.

- The size of the mask should match the size of the patient’s head.

- The mask should be easy to remove and put on the patient’s face and should not be displaced when the patient’s head is moved.

### 18.11.1 Compensation of leakage

Non-invasive ventilation suggests a leak of the gas mixture through the mask.

To compensate for the leak in the ventilator, a special algorithm is implemented that continuously in real time (**with each breath**) estimates the current level of leakage and compensates for it by supplying an additional stream of the gas mixture both during inhalation and during exhalation.

During the respiratory cycle, the level of leakage varies depending on the current airway pressure. The higher the pressure, the greater the leakage. Accordingly, the additional flow to compensate for leakage is also continuously adjusted by the ventilator during the respiratory cycle. To ensure patient safety, the maximum flow to compensate for leakage is limited to **100 l/min.**

To control the level of leakage, the ventilator has a special parameter **Leak** (l/min), or as a percentage of the inspiratory volume, **%DO**.

It represents the average leakage over the last few respiratory cycles. The higher the value of this parameter, the higher the leakage. Normal leakage values when using a mask with a port are not more than 35 l/min. In case of too high leakage values (**more than 40 l/min**), it is necessary to check the quality of applying the mask to the patient's face.

In addition, there is another parameter **% Leak**, which displays the level of leakage as a percentage of the volume of the injected mixture during inspiration.

### 18.11.2 Modes and types of breaths for NIV

When choosing **NIV**, only breaths with pressure control (**PC**) can be used. Inhalation with volume control (**VC**) and double control (**PC-VG**) when using **NIV** is prohibited, as it can be potentially dangerous for the patient!

Allowed ventilation modes for **NIV** are **A/C, SIMV** and **SPONT**.

### 18.11.3 Trigger's settings

During **NIV**, the flow signal used for work of the trigger is automatically compensated for leakage. Therefore, the trigger settings in **NIV** are completely similar to the settings for invasive ventilation. However, with very large leakages, situations are possible where the leakage cannot be fully compensated.

The reason for such situations (with a very high level of leakages), as a rule, is the poor quality of applying the mask to the face. In such cases, it is necessary to adjust the sensitivity of the trigger so that there are no false positives (**auto-triggering**).

### 18.11.4 NIV Advantages

Non-invasive ventilation has several significant advantages:

- Risks associated with intubation of the patient are excluded;
- Improves gas exchange;
- Reduces the patient's breathing;
- Increases patient comfort.

### 18.11.5 Contraindication to using NIV

As contraindications, the following can be distinguished:

- Intolerance to the patient's face mask;
- Inability to make adequate spontaneous attempts to inhale;
- Recently transferred operations on the upper respiratory tract;
- Unstable hemodynamics of the patient.

## 18.12 Mode APNOE

**APNOE** mode is not the usual mode for prolonged ventilation of the patient.

**APNOE** is a mode for protecting the patient in case of apnoe.

### 18.12.1 Detection APNOE

The ventilator detects APNOE if not a single breath (initiated by the patient, ventilator, or operator) was delivered to the patient within the specified apnoe interval (**Ta**). The apnoe interval **Ta** is set by the operator in the range of **15 to 60** s.

The default **Ta** for the new patient is **20 s**.

### 18.12.2 Enter to mode APNOE

When **APNOE** is detected, the ventilator gives an audible alarm of the highest priority and automatically switches to **APNOE** ventilation mode.

Delivery of breaths to the patient in the **APNOE** mode is performed using the following rules:

- All breaths in the **APNOE** mode are mandatory.

- The detection of attempts of inhalation of the patient is made in accordance with the current trigger sensitivity settings (flow or pressure).

- All breaths are delivered with volume control (**VC**).

- The value of the inspiratory volume delivered to the patient (**VT**) is set by the operator. The default **VT** value offered by the ventilator is calculated based on the ideal patient weight (**IBW**) according to the formula:

**VT (ml) = 7.25 (ml / kg) * IBW (kg).** **(10)**

- The ventilation frequency (**f**) is set by the operator. The ventilator offers a default **f** value based on the ideal patient weight (**IBW**).

### 18.12.3 Exit from mode APNOE

During ventilation in the APNOE mode, the ventilator continuously monitors the presence of attempts of inhalation of the patient and his exhaled volume. If two attempts are made to inhale the patient in a row and provided that the expiratory volume exceeds 50% of the inspiratory volume, the ventilator automatically exits the **APNOE** mode and returns to the mode in which ventilation was performed before entering the **APNOE** mode.

Exhaled volume control eliminates false premature exits from the **APNOE** mode due to false working of the trigger (for example, due to a large leakage of the gas mixture from the circuit).

**Operator initiated exit.**

The operator at any time can choose a different ventilation mode that does not require attempts to inhale the patient (**A/C or SIMV**),

or simply increase the minimum frequency of mandatory breaths (**f**) so that the duration of the pause between breaths does not exceed the set apnoe interval (**Ta**).

**1. Before starting ventilation in any of the modes, be sure to set the correct ideal patient weight (IBW). This will avoid the installation of incorrect VT values in the event of an automatic transition to the APNOE mode.**

**2. Always check that the ventilation parameters are correctly set in the APNOE mode (apnoe interval Ta, ventilation frequency f and respiratory volume VT). The default values of these parameters set by the ventilator are not always optimal for a particular patient!**

### 18.13 Detection occlusion (obstruction) and pressure loss in breathing circuit

In order to ensure maximum patient safety, the ventilator continuously monitors the state of the breathing circuit during ventilation.

The ventilator implements special algorithms for detecting occlusion and depressurization of the breathing circuit.

#### 18.13.1 Occlusion (obstruction)

The ventilator detects occlusion in the following situations:

- Any of the tubes in the inspiratory or expiratory circuit is blocked. The reasons can be any: clamping or bending of the tubes, accumulation of condensate and/or secretion from the patient, etc.

- The expiratory port of the ventilator or the flow sensor connected directly to this port is blocked (clogged).

- The exhalation valve is blocked in the closed state (technical fault).

- The ventilator checks the breathing circuit for occlusion in all ventilation modes in each inhalation/exhalation cycle.

- When occlusion is detected, the ventilator acts in such a way as to minimize possible risks for the patient, namely:

- Cancels muting of sound alarms (if there was one).

- Initiates an alarm of maximum priority “Occlusion”.

- It stops the current ventilation mode and automatically switches on the patient-safe ventilation mode with the following parameters:

- PEEP = 0,

- Pi = 15 cm water column;

- Ti = 2 s,

- FiO2 = 100%,

- f = 10 min-1.

During each breath, the ventilator analyzes the state of the breathing circuit.

If occlusion disappears, the ventilator automatically returns to the ventilation mode and parameters that were set before the occlusion.

### 18.13.2 Pressure loss in breathing circuit

The ventilator uses various strategies to detect depressurization of the breathing circuit (depending on the established ventilation mode and types of breaths).

The main ones are listed below:

- The values of the measured pressure and expiratory flow are close to zero during the first 200 ms from the start of exhalation.

- The volume of the gas mixture exhaled by the patient is significantly lower than the delivered volume by the ventilator for three consecutive breaths.

When a depressurization is detected, the ventilator initiates an alarm of the highest priority **"Pressure loss"**, stops the current ventilation mode, switches on the base flow, opens the exhalation valve and expects operator intervention to eliminate the cause of depressurization.

The ventilator automatically detects the moment the depressurization disappears and after that it automatically returns to the ventilation mode that was set before the depressurization occurred.

## 18.14 Monitoring $CO_2$ (Capnometry)

The device uses infrared (**IR**) spectroscopy technology for continuous measurement of carbon dioxide (**$CO_2$**) at the end of expiration (**$EtCO_2$**) and during inspiration (**$FiCO_2$**).

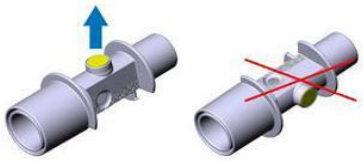
For monitoring **$CO_2$**, a capnographic sensor P51.18.100 is used, which is connected to the gap of the patient's breathing circuit between the tee and endotracheal tube using the sensor adapter P56.06.950 (for adults and children). Thus, the measurement process takes place in the "main flow", which ensures maximum accuracy of the measured values.

**Used capnographic sensor adapters (hereinafter referred to as the sensor adapter) must be disposed of in accordance with medical waste disposal requirements.**

**The sensor must not be located near mobile or radio transmitting devices.**

**Do not place the sensor adapter between the endotracheal tube and the angled connector. Such a connection may result in sputum entering the adapter window, and the sensor will measure false readings.**

**To avoid the accumulation of sputum on the adapter windows, always position the adapter so that the connected sensor is directed up by the LED.**



**Do not use the adapter with a working nebulizer. This may cause distortion in the measured signal.**

**If condensation forms inside the adapter, replace the adapter.**

**Use only the patient adapter P56.06.950.**

**Do not use adapters for newborns (they can be included in the set of IVL devices for newborns, for example, in the Aventa-U ventilation ventilator), as this can lead to a significant increase in breathing circuit resistance.**

### 18.15 Operation of capnography sensor

When working with the sensor, be sure to comply with all the requirements set forth in these operating instructions. Before you start using the capnographic sensor, carefully read the following instructions.

1. Connect the sensor to the connector of the ventilator, then turn on the ventilator.

**It is forbidden to connect the sensor to the ventilator which is turned on!**

2. Insert the sensor into the patient adapter (see Figure 18.10). If connected correctly, a click should sound.

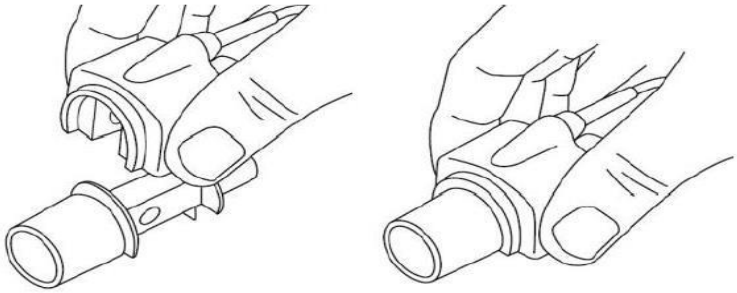


**Figure 18.10 – Connection of sensor to adapter**

3. After connecting to the patient adapter, the green LED on the sensor should light up.

**Figure 18.11 – Properly connected sensor**

4. Wait until the zero calibration procedure is completed (see section 18.15.1). Then connect the adapter to the patient's tee (see Figure 18.12).

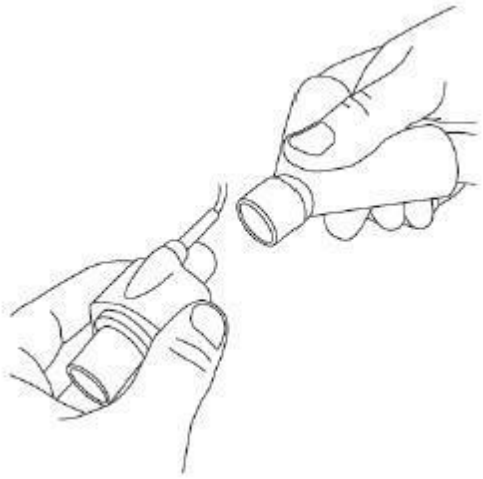


**Figure 18.12 – Connection to tee-connector of patient**

5. Connect the other end of the adapter to the endotracheal tube (see Figure 18.13).

**Figure 18.13 – Connection to endotracheal tube**

You can also use an **HME** filter between the adapter and the handset (see Figure 18.14). In this case, the **HME** filter will protect the adapter from the penetration of sputum and water vapor, which will significantly increase its service life.

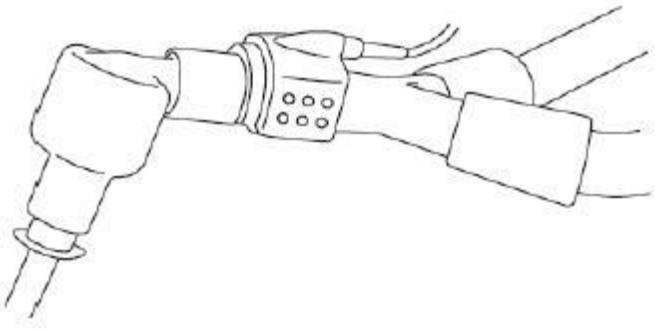


**Figure 18.14 – Use of HME filter**

When the P51.18.100 sensor is not protected by an **HME** filter, it should be positioned so that the LED is pointing up (see Figure 18.15)

**Figure 18.15 – Location of sensor**

When connecting the sensor to the patient's breathing circuit, direct contact between the sensor and the patient's body must be avoided. If for any reason it is not possible to prevent direct contact of the sensor with the patient's body, it is necessary to lay insulation material between the sensor and the patient's body.

| | |
|---|---|
|  | **The capnographic sensor is not intended for direct contact with the patient's body!** |

Before connecting the adapter to the patient's breathing circuit, always check the **$CO_2$** curve on the ventilator's display.

After connecting the adapter to the patient's breathing circuit, make sure the connection is tight.

### 18.15.1 Zero calibration

Zero calibration **$CO_2$** concentration is carried out every 5 seconds after the green LED on the sensor is ignited, after the sensor is connected to the patient's adapter. During calibration, the LED on the sensor flashes green for approximately 5 seconds. In addition, zero calibration can be performed by clicking the button "Calibrate Zero" in the settings window on the tab "**$CO_2$**".

Zero calibration must be performed when there is a displacement of the capnogram (**$CO_2$** curve) during inspiration.

**Zero calibration must be performed strictly under the following conditions:**

**1 The adapter should not be connected to the patient's breathing circuit.**

**2 Do not breathe near the ends of the patient adapter.**

**The composition of the air in which the adapter with the sensor is located must have an oxygen concentration of 21% and a carbon dioxide concentration of 0%.**

If an error occurs during the zero calibration process, the ventilator will display the "**$CO_2$ calibration error**" alarm. In this case, it is necessary to repeat the zero calibration, namely, disconnect the capnographic sensor with the patient adapter and reconnect. If the error persists after recalibration, replace the patient adapter and try again.

**Failure to fulfill the required conditions during the zero calibration procedure will lead to false sensor readings!**

### 18.15.2 Capnometry alarm

The ventilator generates alarms related to **$CO_2$** monitoring, presented in table 18.2.

Table 18.2

| Message on display | Priority | Description |
|---|---|---|
| "Error in $CO_2$ calibration" | High | An error occurred while performing the zero calibration procedure. |
| "Apnoe in channel $CO_2$" | High | The **IRMACO₂** sensor does not detect the patient's breathing. |
| "Low value $EtCO_2$" | Medium | The measured **EtCO₂** value fell below the set lower alarm limit ↓**EtCO₂** |
| "High value $EtCO_2$" | Medium | The measured value of **EtCO₂** exceeded the set upper alarm limit ↑**EtCO₂** |
| "High value $FiCO_2$" | Medium | The measured value of **FiCO₂** exceeded the set upper alarm limit ↑**FiCO₂** |

### 18.15.3 Cleaning and disinfection

Before cleaning the capnographic sensor, disconnect it from the patient adapter.

**The patient adapter is not sterilizable.**

**Sterilization destroys the surface of the adapter, making it unsuitable for further use.**

The sensor can be wiped with a cloth moistened with ethyl or isopropyl alcohol with a concentration of not more than 70%.

**The capnographic sensor must not be sterilized or immersed in liquid!**

**Figure 18.16 – Location of sensor on ventilator**

## 18.16 Monitoring $SpO_2$

This ventilator uses a **sphygmic oxymeter** module, which allows qualitative measurements of oxygen saturation of hemoglobin of the patient's arterial blood (**$SpO_2$**) and its pulse rate (**PR**) even under conditions of artifacts of patient movement and weak peripheral circulation.

**$SpO_2$** monitoring allows you to control the level of patient oxygenation during ventilation. The measured value of **$SpO_2$** helps the operator to correctly choose the level of oxygen content in the gas mixture (**$FiO_2$**) required by a particular patient at any time.

### 18.16.1 Using of Spo2 sensor

Connect the **Spo2** sensor supplied with the ventilator to the **"$SpO_2$"** connector of the ventilator.

Always install the sensor so that the light emitting diode is located on the nail side of the finger. If you need to fix the sensor, place the adhesive tape on the cable (near the sensor). At the same time, remember that too tight winding of the tip of the finger with adhesive tape will lead to a decrease in blood flow, which will significantly reduce the amplitude of the plethysmographic signal.

If possible, do not place the **$SpO_2$** sensor on the same arm as the cuff for measuring blood pressure.

If necessary, select the **$SpO_2$** and **PR** parameters to be displayed on the ventilator's display in one of the monitored parameters windows.

**This ventilator measures functional saturation: oxygen-rich hemoglobin is expressed as a percentage of hemoglobin, which can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. Laboratory hemoximeters, on the other hand, measure fractional saturation: oxygen-rich hemoglobin is expressed as a percentage of all hemoglobin measured.**

**Sphygmic oxymeter parameters are only an addition to other methods of examining a patient and should be used in combination with other clinical signs and symptoms.**

**Unauthorized replacement of the sphygmic oxymeter sensor can lead to a decrease in the accuracy of measurements and the degree of protection of patients, and can also cause damage to the ventilator.**

**Do not use damaged sensors or sensor extension cables. Do not use sensors with unprotected optical elements.**

**Long-term use of a clothespin-type sphygmic oxymeter sensor can cause skin irritation or necrosis due to squeezing. Check the installation location of the sensor every 2-4 hours. If skin irritation occurs, the installation location of the sensor should be changed.**

**Do not use the $SpO_2$ sensor at an ambient temperature above 37° C, as long-term measurements can cause burns.**

**Injection of dyes such as methylene blue or intravascular dyshemoglobin (e.g. methemoglobin) may reduce the accuracy of $SpO_2$ measurements.**

**If the patient has a high temperature, or insufficient peripheral circulation, the sensor can cause a slight burn, as it causes an increase in skin temperature by 2-3 degrees. If the patient has an abnormal increase in oxyhemoglobin or methemoglobin, then $SpO_2$ measurements will be incorrect.**

### 18.16.2 Alarm of Spo2

The ventilator generates the following alarms associated with monitoring Spo2:

Table 18.3

| **Message on display** | **Priority** | **Description** |
|---|---|---|
| "Sensor **$SpO_2$** is not connected" | Low | **$SpO_2$** sensor is not connected to the ventilator connector |
| "There is no finger in sensor **$SpO_2$**" | Medium | The **$SpO_2$** sensor is connected, but there is no finger in it. Put the sensor on finger to continue monitoring |
| "No signal of pulse" | High | The patient does not have a pulse signal or the signal is very weak. The patient may have a spasm of the peripheral vessels of the finger |
| "Low value of **$SpO_2$**" | High | The measured value of **$SpO_2$** fell below the set lower alarm limit ↓ **$SpO_2$** |
| "High value of **$SpO_2$**" | Medium | **$SpO_2$** measured value exceeded the set upper alarm limit ↑ **$SpO_2$** |

# 19 Maintenance service

Preventive maintenance should be performed by certified technicians at least once a year or after every 5000 hours of operation. The list of maintenance work and the recommended frequency are specified in the Service Engineer's Manual P51.00.000IS.

Maintenance, repair and installation may only be carried out by personnel authorized by JSC “UPZ”.

Before requesting maintenance, disinfect the exterior of the ventilator, exhalation valve, flow sensor, parts of the breathing circuit.

Preventive maintenance provides for a full functional check of the ventilator to control the correctness of the control settings.

Maintenance mode and settings can be applied only when the patient is not connected to the ventilator.

**Regularly during the operation of the ventilator, replace the bacterial filters, clean the grill and fan filter from dust, clean the filter regulators, clean the protective nets on the flow sensor.**

**1 Before starting maintenance, unplug the power cable from the outlet.**

**2 Cleaning and maintenance is carried out in accordance with 19.1, 19.2, 19.3.**

**3 Use original accessories and spare parts specified in the passport for the ventilator.**

**4 For all issues related to the warranty, you should contact the service department of the manufacturer of JSC “UPZ” by tel/fax: +7 (343) 359-94-20, e-mail: service@upz.ru**

## 19.1 Cleaning and disinfection

Disinfection, pre-sterilization cleaning and sterilization of medical devices is aimed at the prevention of nosocomial infections in patients and medical personnel.

Cleaning and disinfection are carried out in accordance with GOST R ISO 17664 “Sterilization of medical devices” and guidelines No. MU-287-113 of 12/30/1998, “Methodological instructions for disinfection, pre-sterilization cleaning and sterilization of medical devices”.

**To avoid electric shock, disconnect the ventilator from the power source before cleaning and disinfecting.**

**DO NOT reuse disposable bacterial filters, flow sensors, or other accessories with the mark. After use, they must be disposed of. Dispose of components according to procedures approved by your healthcare provider.**

**Reuse, disassembly, cleaning, disinfection or sterilization of disposable components may adversely affect their functionality and system performance, resulting in a risk of negative consequences for the operator or patient.**

**The use of chlorine-based products is strictly prohibited!**

**It is strictly forbidden to treat the surface of the touch screen with organic solvents, liquids containing acid or alkali.**

**Never immerse the sphygmic oxymeter sensor and its connector in any liquid. This may cause damage to the sensor.**

**Do not use abrasive detergents to clean the ventilator. Abrasive cleaners can damage the unit, removable parts and sensors.**

During the operation of the ventilator and under the condition of a single violation, the most contaminated body fluids and exhaled gases are the breathing circuit, both the exhalation line and the inhalation line, masks, connectors, bactericidal filters, including a humidifier, an exhalation valve connector.

**Before the first use** of the ventilator, it is recommended to disinfect its surface by wiping with a gauze swab moistened with 4% hydrogen peroxide solution with the addition of a 0.5% detergent solution.

**During operation**, the external surfaces of the ventilator, breathing circuit holder, expiratory valve connector, patient breathing circuit, moisture collectors, masks, humidifier chamber, flow sensor, $SPO_2$ and $CO_2$ sensors, gas supply hoses and connector are subject to cleaning and disinfection.

1. Disinfection of removable parts of the ventilator is carried out by immersion in a container with a solution that is approved for use with subsequent drying and blowing with compressed air of all channels.

Examples of chemical disinfection methods:

- in a 4% hydrogen peroxide solution with the addition of a 0.5% solution of Lotus detergent or other approved chlorine-free products (for example, Anasept, Polidez, Slavin) for 90 – 180 min;

- in a 4% solution of HYDROGEN PEROXIDE for 90 minutes;

- in a 10% GIGASEPT solution for 60 minutes;

- in a 0.75% solution of Lysoformin 3000 for 60 minutes;

- rubbing with a cloth dampened with ethyl alcohol (70%).

After disinfection, it is necessary to clean the parts under running water, using a soft brush, from the remnants of disinfectants and organic matter.

2. Disinfection of medical ventilator is carried out using one of the methods of steam sterilization in special rooms:

- at a temperature of 110 ± 2 ºC, overpressure of 0.05 MPa, holding time 20 ± 5 min; 121 ± 2 ºC;

- at a temperature of 121 ± 1 ºC, vapor pressure 0.10 ± 0.003 MPa, holding time 30 ± 5 min;

- at a temperature of 120 ± 2 ºC, at an overpressure of 0.96 kPa, holding time 15 min;

- at a temperature of 134 ± 1 ºC for 20 min and a drying cycle.

**Cleaning and disinfecting the external surfaces** of the ventilator and the electrical connectors of the sensors is carried out by wiping with a gauze swab moistened with 4% hydrogen peroxide solution with the addition of a 0.5% detergent solution.

**Make sure that no liquid enters the openings of the ventilator.**

Use a clean and soft, non-fibrous cloth to clean the screen. Using napkins and paper towels may scratch the surface of the display.

When cleaning and disinfecting the ventilator and replacement parts, it is also necessary to comply with the hygiene rules in force within the walls of a medical institution.

The humidifier, nebulizer and atomizer are cleaned and disinfected in accordance with the instructions in the accompanying documentation or on the packaging.

The recommended frequency, the treatment method is given in table 19.1 and is valid for the recommended breathing circuit of the patient.

Table 19.1

| **Component** | **Recommended periodicity of processing** | **Procedure** |
|---|---|---|
| Ventilator, loop holder | For every patient | Disinfection (wiping) with 4% hydrogen peroxide solution with the addition of 0.5% detergent |
| High pressure hoses, power cord | Every month | Disinfection (wiping) with 4% hydrogen peroxide solution with the addition of 0.5% detergent |
| Patient circuit tubes | For every patient | Reusable - sterilized. Disinfection method: in a 4% hydrogen peroxide solution for 90 minutes Steam sterilization at (132 ± 2) ºC for 20 min under pressure (0.2 ± 0.02) MPa. Disposable - disposed of after use |
| Removable expiratory valve, expiratory valve membrane | For every patient (weekly using an expiratory filter) | Disinfection method: in a 4% hydrogen peroxide solution for 90 minutes Steam sterilization at (132 ± 2) ºC for 20 min under pressure (0.2 ± 0.02) MPa |
| Flow sensor | For every patient | Disinfection method: in a 0.75% solution of Lysoformin 3000 for 60 minutes Steam sterilization at (110 ± 2) ºC for 20 min under pressure (0.05 ± 0.02) MPa |
| Tee of the patient, moisture collectors | For every patient | Disinfect by immersion in a 4% solution of HYDROGEN PEROXIDE, exposure 90 min. |

| | | |
|---|---|---|
| Sensor adapter $CO_2$ | For every patient | Disposed of after use |
| Inspiratory, expiratory filters | For every patient | Reusable are sterilized. Disposable after disinfection |
| Humidifier | For every patient | The heating system must be cleaned by wiping with isopropyl alcohol and a washing solution. The method of disinfection of the chamber is carried out according to the method established by the manufacturer: autoclaving at a temperature of 120º C, under an excess pressure of 96 kPa, holding time 15 min |

The table shows only the recommended dates. The orders of persons responsible for maintaining hygiene within the walls of a medical institution have higher priorities.

### 19.2 General cleaning recommendation

**To avoid damage to the ventilator and its components, DO NOT use hard brushes, sharp tools, or rough materials. Residues of cleaning and disinfecting agents can damage the surface or lead to the formation of small cracks (components that are exposed to elevated temperatures during sterilization are especially dangerous). An improper concentration of sterilization agent or an inappropriate treatment time can lead to bacterial resistance. Using rinse aid shortens the life of the product.**

### 19.3 Cleaning of the device components

Disassemble the components. Breathing circuits must be disassembled completely.

Wash components in warm water with soap or a suitable, non-concentrated detergent solution.

Dry the components in air.

Inspect all components and replace if necessary.

If you need to sterilize or sanitize a component, follow the appropriate procedure described in the product documentation.

If sterilization or disinfection of the component is not planned, reassemble and install the components (if necessary), and then perform the required tests.

### 19.4 Replacement of oxygen sensors

**Replacement of the oxygen sensor can only be done by a qualified technician.**

The approximate life of the oxygen sensor is 2 years. But depending on the operating conditions of the device, the service life may vary.

After 2 years of operation of the sensor (or earlier when the ventilator displays the message "**Sensor Error $O_2$**"), the sensor must be replaced with a new one.

The oxygen sensor is located on the left side of the ventilator (rear view) under the housing element (hereinafter – the Cover). Figure 19.1 shows the location of the oxygen sensor.

Figure 19.2 shows an oxygen sensor mounted on the inspiratory nozzle.

Sensor replacement is carried out in the following sequence:

Unscrew the two screws securing the Cover to the front panel of the casing and two screws securing to the top cover of the device, then unscrew the three screws, removing the plugs from them on the left side of the ventilator, remove the Cover of the ventilator.

Disconnect the cable from the oxygen sensor.

Unscrew the oxygen sensor from the inhalation pipe by turning the sensor counterclockwise.

Install a new oxygen sensor by turning it clockwise.

Connect the cable to the new oxygen sensor. Replace the handle and tighten the screws. Replace the plugs.

**After installing a new oxygen sensor, it is necessary to maintain it at room temperature for at least 30 minutes and then be sure to calibrate it.**

oxygen sensor under cover

turn four screws back

remove three blinds, turn screws back

**Figure 19.1 – Access to oxygen sensor**

oxygen sensor

**Figure 19.2 – Location of oxygen sensor**

## 20 Marking, filling and packing

On the outer surfaces of the ventilator should be indicated:

- name or trademark of the manufacturer;
- name of the ventilator and model;
- designation of technical conditions;
- manufacturer's address;
- serial number and year of manufacture;
- voltage and frequency of power supply;
- rated value of current consumption or power consumption;
- certification mark;
- the working part of type B, BF;
- marking of gas-specific inputs (gas name);
- marking the pressure range supplied to the inlet;
- marking the direction of flow on flow-dependent components;
- the sign “the implementation of the operating instructions”;
- general warning sign.

### 20.1 Items marking

Packaging of reusable respiratory goods must have clearly distinguishable markings for the following:

- the words “Reusable”;
- name of the product indicating the mark/model;
- an identifier with a batch, type or serial number;
- name of the manufacturer;
- manufacturer's address;
- disinfection method, packing date.

### 20.2 Packing of disposable respiratory goods

The packaging of disposable respiratory goods must have clearly distinguishable markings for the following:

- content description;
- the symbol “Prohibition of reuse”, or the text “One-time use” or “Do not reuse”;
- if applicable, the word “sterile”;
- an identifier with a batch, type or serial number;
- name of the manufacturer;
- manufacturer's address;
- name of the good indicating the mark/model;
- date of production;
- date “use until”;
- inadmissibility of use in case of violation of the integrity of the individual packaging.

The following must be marked on the transport packaging:

- name or trademark of the manufacturer;
- name or designation of the model of ventilator;
- year and month of packaging;
- gross mass;
- net weight;
- overall dimensions of the package;
- name of destination;
- handling signs corresponding to the values: “Fragile. Caution”, “Top”, “Keep away from moisture”.

Marking is applied on a paper label. The variable data on the label can be filled in clearly and legibly by hand.

Handling signs must be stenciled or stamped with black waterproof paint. The designation of storage conditions and other additional inscriptions must be applied to the container or label in places free of transport marking.

### 20.3 Packing

During storage and transportation in the process of operation (including when sent for repair), the units of the ventilator are packed in plastic bags, placed in the nests of the respective lodges made of foamed polyethylene and placed in a packing box.

The manufacturer carries out the sealing of the ventilator body with the help of a destructible sticker on which the trademark of the manufacturer is printed.

**Removal of the seal is carried out by the repair organization, after repair and verification, it is sealed again by the verification organization.**

Corrugated cardboard or other cushioning material is laid between the ventilator and the walls of the packing box, which ensures reliable fixation of the ventilator and the components supplied with the kit, relative to the walls of the box and to each other.

The ventilator should be located in a drawer only in an upright position.

## 21 Transportation and storage

The ventilator must be transported in the packaging of the manufacturer.

The ventilator should be transported by all types of vehicles in covered vehicles in accordance with GOST R 50444 and the transport rules applicable to this type of transport. Transportation conditions must comply with storage conditions 5 in accordance with GOST 15150:

- at a temperature from -50 °C to +50 °C,

- at relative humidity up to 100%.

The ventilator in the manufacturer's packaging must be stored in closed rooms with natural ventilation without artificially controlled climatic conditions in storage conditions 2 in accordance with GOST 15150:

- at a temperature from -50 °C to +40 °C,

- at relative air humidity up to 98%.

The ventilator must be preserved by static dehumidification of air in an insulated packaging volume using selicogel in case of long-term storage.

After transportation and storage at low temperatures, the ventilator must be kept in a shipping container in normal climatic conditions according to GOST 15150 (operating conditions) for at least 12 hours.

The shelf life of the ventilator in the package is no more than 2 years.

## 22 Utilization

At the end of the service life (exploitation), the ventilator is disposed of in accordance with SanPiN 2.1.7.2790-10 as waste of class B.

To dispose of and recycle batteries, essential components of a medical device, and accessories, follow applicable local regulations and regulations for disposal in an environmentally friendly manner. If WEEE (Directiveon Waste Electricaland Electronic Equipment – EU Directive on Electrical and Electronic Equipment Waste) rules apply, do not dispose of batteries and electronic components in unsorted municipal waste. Do not dispose of battery modules with normal waste.

Disposal of the system and its electrical components with household waste is not allowed! Disposal must be carried out in accordance with sanitary standards and the requirements of the relevant regulatory documents in the country of use.

## 23 Advermation

An advermation may be brought on issues that were not the subject of acceptance of goods made in accordance with the terms of the contract.

The manufacturer shall not be liable to the consumer if the good's defects are the result of force majeure circumstances or arising from a violation by the consumer of the rules and operating conditions.

For all matters related to advermation, you should contact the service department of the manufacturer of JSC "UPZ" by tel/fax: +7 (343) 359-94-20, e-mail: service@upz.ru.

## 24 Preparation for shipment for warranty repair

Warranty service (repair) of the ventilator is carried out by the manufacturer under the conditions of operation, storage and transportation during the entire warranty period (12 months from the date of sale, but no later than 18 months from the date of release of the ventilator from the manufacturer).

Before sending it for repair, the ventilator must be packed in accordance with the requirements of this manual (see section 20). The transport packaging is marked “Fragile. Caution”, “Top”, “Keep away from moisture”.

The ventilator must only be transported in an upright position.

## 25 Referential regulations

**Table 25.1 – Referential regulations**

| Reference | Name of document |
|---|---|
| GOST 9.032-74 | Unified system of corrosion and aging protection. Paints and varnishes. Groups, specifications and designations |
| GOST 9.104-79 | Unified system of corrosion and aging protection. Paints and varnishes.Environmental groups |
| GOST 9.301-86 | Unified system of corrosion and aging protection. Metallic and non-metallic inorganic coatings. General requirements |
| GOST 9.303-84 | Unified system of corrosion and aging protection. Metallic and non-metallic inorganic coatings. General selection requirements |
| GOST 9.401-91 | Unified system of corrosion and aging protection. Paints and varnishes. General requirements and methods of accelerated tests for resistance to climatic factors |
| GOST 177-88 | Hydrogen peroxide. Technical specifications |
| GOST 7396.1-89 (IEC 83-75) | Electrical plug connectors for household and similar use. Main dimensions |
| GOST ISO 9919-2011 | Medical electrical products. Particular safety requirements and basic characteristics of sphygmic oxymeters |
| GOST 14254-2015 (IEC 60529: 2013) | Degrees of Protection Provided by Enclosures (IP Code) |
| GOST 15150-69 | Machines, devices and other industrial products. Modifications for different climatic regions. Categories, operating, storage and transportation conditions as to environment climatic factors |
| GOST R ISO 17664-2012 | Sterilization of medical devices. Information to be provided by the medical device manufacturer for re-sterilization of medical devices |
| GOST 25644-96 | Synthetic powder detergents. General technical requirements |
| GOST 28244-96 | Reinforced wires and cords. Technical specifications |
| GOST 30804.3.2-2013 (IEC 61000-3-2: 2009) | Electromagnetic compatibility. Emission of harmonic current components by technical means with a current consumption of not more than 16 A (in one phase). Standards and test methods |
| GOST 30804.3.3-2013 | Electromagnetic compatibility. Limiting voltage changes, voltage fluctuations and flicker in low-voltage general-purpose power supply systems. Technical equipment with a current consumption of not more than 16 A (in one phase), connected to the electrical network if certain connection conditions are not met. Standards and test methods |
| GOST 30804.4.2-2013 (IEC 61000-4-2:2008) | Electromagnetic compatibility. Resistance to electrostatic discharges. Requirements and Test Methods |

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|---|---|
| GOST ГОСТ 30804.4.3-2013 (IEC 61000-4-3:2006) | Electromagnetic compatibility. Immunity to radio frequency electromagnetic field. Requirements and Test Methods |
| GOST 30804.4.4-2013 (IEC 61000-4-4:2004) | Electromagnetic compatibility. Immunity to nanosecond impulse noise. Requirements and Test Methods |
| GOST 30804.4.11-2013 (IEC 61000-4-11: 2004) / GOST R 51317.4.11-2007 (IEC 61000-4-11: 2004) | Electromagnetic compatibility. Resistance to failures, short interruptions and changes in voltage supply. Requirements and Test Methods |
| GOST 31508-2012 | Medical Products. Classification according to potential risk of use. General requirements |
| GOST P 50444-92 / GOST 20790-93 | Medical devices and equipment. General specifications |
| GOST P 50648-94 (IEC 1000-4-8-93) | Electromagnetic compatibility. Resistance to magnetic field of industrial frequency. Technical requirements and test methods |
| GOST P 51317.4.5-99 (IEC 61000-4-5-95) | Electromagnetic compatibility. Resistance to microsecond impulse noise of high energy. Requirements and Test Methods |
| GOST P 51317.4.6-99 (IEC 61000-4-6-96) | Electromagnetic compatibility. Immunity to conducted noise induced by radio frequency electromagnetic fields. Requirements and Test Methods |
| GOST P 51318.11-2006 (CISPR 11: 2004) | Electromagnetic compatibility. Industrial, scientific, medical and household high-frequency devices. Radio interference industrial. Norms and methods of measurements |
| GOST P 55954-2018 | Medical Products. Devices of artificial ventilation. Technical Requirements for Public Procurement |
| GOST R IEC 60601-1-2010 | Medical electrical products. Part 1. General safety requirements taking into account the basic functional characteristics |
| GOST R IEC 60601-1-2-2014 | Medical electrical products. Part 1-2. General safety requirements, taking into account the basic functional characteristics. Parallel standard. Electromagnetic compatibility. Requirements and Tests |
| GOST R IEC 60601-1-6-2014 | Medical electrical products. Part 1-6. General safety requirements, taking into account the basic functional characteristics. Additional standard. Serviceability |
| GOST IEC 60601-1-8-2011 | Medical electrical products. Part 1-8. General safety requirements. General requirements, tests and guidelines for the use of medical electrical devices and medical electrical systems alarm systems |
| GOST R IEC 62304-2013 | Medical Products. Software. Life cycle processes |

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|---|---|
| GOST R ISO 80601-2-12-2013 | Medical electrical products. Part 2-12. Particular safety requirements, taking into account the basic functional characteristics of mechanical ventilation ventilator for intensive care |
| GOST R ISO 80601-2-55-2015 | Medical electrical products. Part 2-55. Particular safety requirements taking into account the basic functional characteristics of respiratory mixture monitors |
| SanPiN 2.1.7.2790-10 | Sanitary and epidemiological requirements for the management of medical waste |
| MU 287-113 | Guidelines for disinfection, pre-sterilization cleaning and sterilization of medical devices |

**For all questions, contact the manufacturer:**

| **Telephone/fax** | **Address for correspondence** | **Internet** |
|---|---|---|
| (343) 359-97-96<br>(343) 359-93-85<br>(343) 359-94-20 | Russia,<br>624000, Sverdlovsk region, Sysertsky area, 25 km of the Chelyabinsk path,<br>JSC "Ural Instrument-engineering plant". | http://www.upz.ru<br>KVMT@mail.upz.ru<br>service@upz.ru |