INTENSIVE CARE VENTILATOR

MV200, MV300

USER MANUAL

TESM.941144.001-01 UM

1st edition, 03/2020

CONTENT

1 INTRODUCTION

1.1 Intended use

Intensive care ventilator, versions MV200, MV300 (hereinafter – device, ventilator) is intended for carrying out controlled and assisted artificial ventilation of lungs for all patient groups with tidal volume from 10 ml dependent on artificial ventilation in resuscitation units, surgery and intensive care departments of professional medical facilities, and also at transportation within professional medical facilities.

Ventilation modes of device are in detail described in it. 4.1 and the Appendix 1.

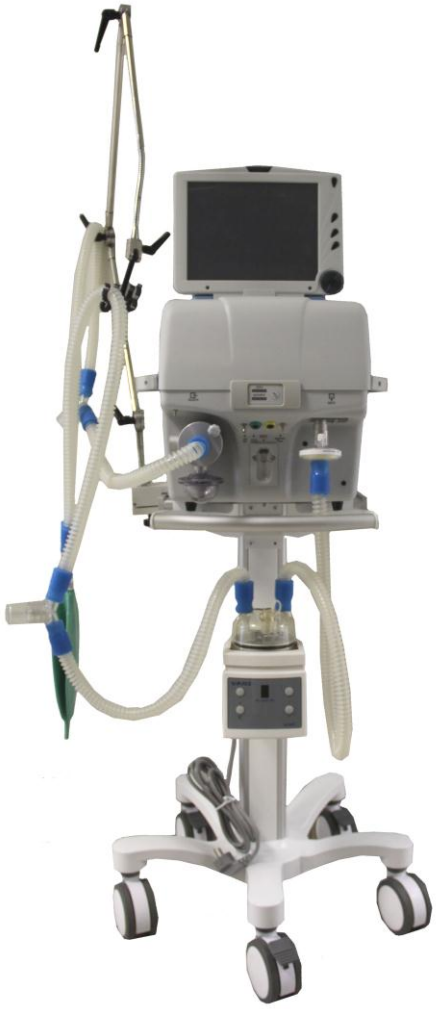

Figure 1.1 - Appearance of the device

Simplicity of control, functional design of the device, graphical display module allowing to set it under the optimum angle provide convenience of operation.

The device is equipped with the built-in respiratory mixture flow generator (analogue of the turbine) and does not need sources of the compressed air. For connection to the high pressure oxygen line the device is equipped with the pneumatic socket. The built-in oxygen sensor measures oxygen concentration in the respiratory mixture and allows controlling operation of the air-oxygen mixer of the device.

The device can have the version allowing operation with sources of low pressure oxygen. In this case it has the special low pressure oxygen input.

At emergency case (absence of oxygen) the device provides ventilation only with air. Due to its design the device can operate even at the minimum pressure in oxygen system of the hospital, taking away all possible oxygen from the line. Therefore deviations in FiO_2 regulation are possible.

Depending on the version, the device is equipped with a 12.1”color touch-screen display (MV200 version) or 15” (MV300 version), which displays the measured data in the form of numbers and graphs (waveforms and loops), as well as all the information necessary for control modes.

Special fastening of the display on the electronic unit surface allows to change the viewing angle and fully fold the display (so the operating surface of the display lies on the plane of the base unit) during storage and transportation of the device in order to avoid mechanical damage.

Controls of the device are the rotated regulator (encoder), the touch screen and functional control buttons. They provide fast and convenient access to the control parameters, registered monitoring information (trends). Control buttons are made using touch technology (“touch-screen”). In particular, set parameters of the current mode of ventilation are touch control buttons, they become active by pressing.

To avoid the accidental or inadvertent change of ventilation parameters in the device are applied:

- The three-stage scheme of applying of changes (activation, change, and confirmation). It is necessary to confirm with special action application of the changed parameter;
- Function of the screen blocking that can be operatively switched on by the user.

For warming and moistening of the respiratory mixture the humidifier with the set of consumables is needed. Please pay attention that humidifier is not included in the basic delivery set.

If necessary artificial ventilation of lungs can be carried out with the heat and moisture exchanging filter that also is the part of the device delivery kit. The temperature of the respiratory mixture is displayed on the humidifier; ways of displaying depends on the humidifier model.

The delivery kit of the device can contain adult, child reusable and/or disposable breathing circuits.

The device is equipped with the expiration valve with the electromagnetic mechanism operated by the ventilation controller. The expiration valve has the small lag effect that does not exceed 5 ms and provides necessary dynamics of pressure maintenance in the breathing circuit. The expiration valve has the removable part containing flow sensor and transmitting system of measured pressure to the device.

The membrane and the removable part of the expiration valve with the flow sensor have direct contact with air exhaled by the patient, except the breaching circuit. These elements shall be sterilized before using on the new patient. The membrane and the expiration valve are made from the materials allowing sterilization by autoclaving.

The device kit contains the circuit holder (supporting arm) that provides a big range of attitudes and allows to place conveniently the breathing circuit.

The device can be equipped with the mainstream CO_2 sensor, its connection to the circuit is made via the special airway adapter connected as close as possible to the endotracheal tube.

The device with the mainstream CO_2 sensor can have optional function of the volume capnometry. This function allows to measure amount of carbon dioxide exhaled by the patient, and also to define volume of the functional dead space and volume of alveolar ventilation.

Optionally the device can be equipped with the built-in module of the metabolism parameters assessment, operating on methods of the sidestream oximetry and mainstream capnometry.

The device can incorporate two oxygen sensors. One quite slow measures oxygen concentration in the inspiratory flow (always exists) and the second is special high-speed sensor for the assessment of the oxygen concentrations gradient at the inspiration and the exhalations.

The device has function of the automatic calibration of the main oxygen sensor without stopping ventilation. Also 2 precision flow sensors are used in addition for measurement and control of concentration O_2 in the inhaled gas mixture.

Electrochemical oxygen sensor is used as the main.

Pulse oximeter also can be the part of the device. In this case the delivery kit contains the pulse oximetry sensor of clip type (or another on special order).

Flow and pressure sensors are placed inside the device and do not need any special lines for the operation. Inspiratory flow sensors are separate for air and oxygen that allows managing oxygen concentration independently of the technical condition of oxygen sensors. The expiratory flow sensor is structurally placed in the expiration valve behind the membrane. Calibration of the expiratory flow sensor is carried out without stopping of ventilation. Pressure measurement in respiratory ways is made by means of two independent pressure sensors embedded in electronic unit.

The device can contain the additional pressure measurement channel where the measurement catheter can be connected, for example, catheter for the pressure measurement in the trachea or in the esophagus.

The transport cart (mobile trolley) with the handle for movement is the part of the basic kit. The wheels of the cart have clamps. Standard way of use of the device is installation of the electronic unit and the humidifier on the transport cart. However, operation without the transport cart is also possible. The electronic unit of the device is equipped with handles for its carrying, at removal from the transport cart.

1.2 General guidance

The current User manual is a component of the device and the mandatory part of the delivery set. This document is provided only for information purposes, it is prohibited to copy, reproduce, translate it into other language, to keep in the information retrieval system, to transmit in any form or by any means or to transform to a form suitable for storage on electronic data carriers without the prior written permission of the manufacturer. Information contained in this document can be changed without notice.

Before starting of operation with the device attentively read current manual. Remember that mishandling can cause performance deterioration of the device, its malfunction and safety hazard for the patient.

At malfunction or unstable operation of the device, firsty it is necessary to address to the list of possible malfunctions and methods of their elimination (see Section 7), and also to appropriate sections of the present User manual.

In the current User manual the following designations are used:

This information is necessary to know to avoid injuries of patient or personnel.

This information is necessary to know for proper and efficient use of the device and to avoid its damage.

The Triton Electronic Systems Ltd. holds responsibility for reliability and operational characteristics of the device only if:

- service and installation of the device are carried out by specialists of Triton Electronic Systems Ltd or personnel passed special training and authorized by Triton Electronic Systems Ltd on carrying out of these works;
- the mains power meets the requirements of national standards;
- ventilator is used in accordance with current User Manual.

Reusable consumables have limited service life. Various operation conditions, cleaning, disinfection and sterilization can lead to the deterioration and the corresponding reduction of their service life. At appearing of visible signs of deterioration (cracks, deformation, decolouration, paint detachment etc.) it is necessary to replace the consumables with the new.

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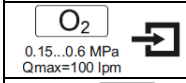
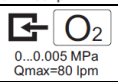
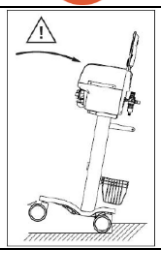
1.3 Symbols and references

The symbols used on the enclosure of the device	
	Caution!
	Refer to accompanying documents!
	Applied part of BF type
	Applied part of B type
	Mark of conformity of the Directive 2012/19/EU
	Serial number
	Date of manufacture
	Manufacturer
	Authorized representative in EU
IP 21	Type of enclosure protection from ingress of water and solid particles
	General sign of prohibition
	Alternative current
	Mains power switch
	The button calling the delayed alarms log
	The button calling the menu window, cancellation of parameter set, menu exit etc.
	The button calling the menu of additional functions as well as turning on the nebulizer
	The button saving the current screen image – screenshot (MV300)
	Audio paused button
	Oxygen inlet, necessary operating pressure 0.15…0.6 MPa
	Additional oxygen inlet for connection to the low-pressure oxygen source (optional)
	Outlet of the exhausted gas mixture
	Port for connection of the inspiratory line of the breathing circuit
The symbols used on the enclosure of the device	

Exp	Port for connection of the expiratory line of the breathing circuit
	Equipotentiality
CO_2	Port for connection of the mainstream CO_2 sensor
Ethernet	Connector for the local information network by the standard Ethernet protocol
	Connector for USB Flash memory devices
T2.0AL/250V	Mains power fuse
SpO_2	Connector for the pulse oximetry sensor
	Connector for the pneumatic nebulizer
Paux	Port for connection of the catheter for auxiliary external pressure monitoring
REE	Port for connection of water trap and sampling line of metabolism module
REE OUTLET	Output port of metabolism module (is used for elimination of the gas sample to the atmosphere)
Symbols on the transport cart	
	Symbols warning of the overturning danger (see p. 3.2)
Symbols and icons on the ventilator screen	
General and patient symbols	
	Battery condition symbol (level of filling is proportional to the energy, green - at a charge, yellow - at a discharge, red blinking - at the faulty accumulator)
	Indicator of patient's spontaneous inspiration attempts
	Measurement of a compliance and resistance button
adult	"Adult" type of patient
child	"Child" type of patient
IBW	Ideal body weight
ET (TST)	Endotracheal (tracheostomy) type of tube
Icons	

	Audio paused
	Oxygenation
	Standby mode
	Alveolar recruitment maneuver
	Suction
	Leak compensation
	Manual breath (manual ventilation)
	“Freezing”/ analysis of graphs
	Screen lock
	Display brightness control
	Saving the current screen image (screenshot)
Graphs	
Flow	Flow graph
iSV	Graph of iSV mode
Paux	Auxiliary external pressure graph
Paw	Airway pressure graph
PCO_2	Capnogram
PO_2	Oxigram for operating with the metabolism module (calculated as the difference FiO_2 - EtO_2)
REF	Reference loop
SpO_2	Photopletismogram
VCO_2	Volume capnography graph
Vol	Volume waveform
V-F	Volume/ Fow loop
V-P	Volume/ Pressure loop
F-P	Flow/ Pressure loop
V-Paux	Volume / Auxiliary pressure loop

1.4 Information about resource of the main functional units of the device

The device has the built-in flow generator providing its independence from sources of compressed air. The design and completing units provide guaranteed operability of the built-in flow generator during at least 40 000 operating hours, or during the whole period of operation of 10 years (the smallest parameter is chosen). Operability of the built-in flow generator is guaranteed only at following operating and service conditions stated in the present document.

For the monitoring of oxygen concentration in the inhaled air the device has the built-in electrochemical oxygen sensor with the operation resource at least 10 thousand hours.

For the service control the device has the special operating time counter. After 6 000 operating hours the message appears at the screen of the device “Carry out maintenance”. The engineer who has carried out maintenance should enter the command in the service menu “Reset time after maintenance” then the time counter will return to the starting position.

1.5 Revision history

Every version of User manual has its number and date of issue. Version number is changed with the significant technical changes of the device. When issuing new version, date of version is also changed. Insignificant amendments and additions that don’t influence on the modes, functions and parameters of ventilator, don’t cause the change of version date.

2 DESCRIPTION OF DEVICE

2.1 Basic parameters and characteristics

No	Parameter	Value (description)
1	**General features**	
1.1	Intended use	Controlled and assisted artificial ventilation of lungs for all patient groups with tidal volume from 10 ml dependent on artificial ventilation in resuscitation units, surgery and intensive care departments of professional medical facilities, and also at transportation within professional medical facilities.
1.2	Modes of operation	Adult, pediatric
1.3	Display	Touch, color, MV200 – 12.1 inches MV300 – 15 inches
1.4	Electrical power Mains Built-in accumulator	 100 - 250 V, 50/60 Hz 10-27 V
1.5	Maximum power consumption	not more than 300 VA
1.6	Operation mode setup time	Maximum 15 sec
1.7	Time of full ventilation when powered on internal accumulator at mains power failure	Not less than 240 minutes at any ventilator settings
1.8	Dimensions of enclosure, width x depth x height electronic unit - MV200 - MV300 electronic unit installed at the mobile trolley - MV200 - MV300	 maximum 450x460x620 mm maximum 450x460x660 mm maximum 600x600x1465 mm maximum 600x600x1495 mm
1.9	Weight electronic unit electronic unit installed at the mobile trolley	 maximum 25 kg maximum 35 kg
1.10	Input oxygen pressure Operation from a high pressure oxygen sources	0.15 - 0.6 MPa (1.5 - 6 bar)
1.11	Operation from a low pressure oxygen sources	0 - 0.005 MPa (0 - 0.05 bar)
1.12	Accuracy of the mixer when regulating the oxygen concentration in the gas mixture - in the range 21-60% - in the range 61-100%	 3 % 6%
1.13	Trigger system of the device	Flow and pressure triggers
1.14	Function of saving and viewing of trends of the main monitoring parameters. The duration of trend	Available 240 hours
1.15	Humidifier	External: provide humidification and heating of respiratory gas mix
1.16	Nebulizer	Built-in, pneumatic Optional: external, ultrasonic micro-pump

No	Parameter	Value (description)
1.17	The synchronization of the nebulizer with the beginning of the patient's inspiration	Available
1.18	Noise level at operation of the device Corrected sound power level	up to 43 dBA up to 51 dBA
1.19	Force for propulsion the device on the transport cart	maximum 30 N
1.20	Ranges of equivalent sound pressure levels for alarms. • at maximum sound volume: - high priority - medium priority • at minimum sound volume: - high priority - medium priority	 maximum 55 dBA maximum 54 dBA maximum 47 dBA maximum 41dBA
2	**Ventilation modes**	
2.1	Continuous mandatory ventilation with the controlled volume of inspiration (synchronized ventilation with volume control)	CMV/VCV
2.2	Continuous mandatory ventilation with the controlled pressure of inspiration (synchronized ventilation with pressure control)	CMV/PCV
2.3	Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with volume control with pressure support of spontaneous breaths (PS)	SIMV/VC
2.4	Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with pressure control with pressure support of spontaneous breaths (PS)	SIMV/PC
2.5	Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with double control with pressure support of spontaneous breaths (PS)	SIMV/DC
2.6	Spontaneous breathing with continuous positive airway pressure with pressure support of spontaneous breaths (PS)	CPAP+PS
2.7	Spontaneous breathing with two levels of continuous positive airway pressure with pressure support of spontaneous breaths (PS)	BiSTEP
2.8	Airway pressure release ventilation	APRV
2.9	Pressure controlled ventilation with guaranteed respiratory volume	PCV-VG
2.10	Non-invasive ventilation of lungs	NIV
2.11	Intellectual support ventilation (option)	iSV
2.12	Automatic backup ventilation mode in cases of pressure and volume apnea.	APNEA
3	**Ventilation parameters**	
3.1	Tidal volume, Vt Acceptable deviation: In range 10-100 ml In range 100-3000 ml	10 - 3000 ml ±(2+0.05Vt) ml abs ±8 % rel

No	Parameter	Value (description)
3.2	Minute volume, MV Acceptable deviation: In range 0-3 lpm In range 3-60 lpm	0 - 60 lpm ±0,24 lpm ±8 % rel
3.3	Rate of breathing / respiratory rate (controlled respiratory cycles), RB: Acceptable deviation	1 - 120 1/min ±(1,0+0,05$F_{изм}$) 1/min
3.4	Frequency of mandatory breaths at synchronized intermittent assisted ventilation, RB Acceptable deviation	1 - 60 1/min ±(1,0+0,05$F_{изм}$) 1/min
3.5	Waveform of the gas flow in the ventilation modes with volume control, FormFlow	Rectangular, descending
3.6	Periodic enhanced inspiration	Available
3.7	I:E ratio Acceptable deviation	1:99 - 60:1 ±10% rel
3.8	Plateau time, Tplat Acceptable deviation	0 - 5 s 0 - 70 % from inspiratory time ±15% rel
3.9	Support pressure of spontaneous breath, PS Acceptable deviation	0 - 80 cmH_2O (mbar) ±2,0 cmH_2O (mbar)
3.10	Positive end-expiratory pressure, PEEP Acceptable deviation	0 - 50 cmH_2O (mbar) ±2 cmH_2O (mbar)
3.11	Inspiratory pressure, Pi Acceptable deviation	0 - 100 cmH_2O (mbar) ±2 cmH_2O (mbar)
3.12	Inspiratory time, Tinsp Acceptable deviation	0.2 - 10 s ±0,05 s
3.13	Trigger window, TrigWnd	0 - 100 % 0.5 - 4 s
3.14	Flow trigger sensitivity, Ftrig Acceptable deviation	0.5 - 20 lpm ±(1,0+0,1$F_{изм}$), lpm
3.15	Pressure trigger sensitivity, Ptrig Acceptable deviation	0.5 -20 cmH_2O (mbar) ±(1,0+0,1$P_{изм}$) cmH_2O (mbar)
3.16	Expiration trigger sensitivity, ETS Acceptable deviation	5 - 80 % ±25 % rel
3.17	Periods of low pressure and high pressure Acceptable deviation	0.5 - 30 s, 0 -35 cmH_2O (mbar) 1 - 30 s, 0 -70 cmH_2O (mbar) ±(2+0,1$T_{изм}$), s; ±(1+0,1$P_{изм}$), cmH_2O (mbar)
3.18	Gas leakage from the breathing circuit - at the pressure of 50 cmH_2O (mbar) - at the pressure of 40 cmH_2O (mbar) - at the pressure of 20 cmH_2O (mbar)	 Up to 0,2 lpm Up to 0,1 lpm Up to 0,05 lpm
3.19	Fractional concentration of inspired oxygen, FiO2	21 - 100 %
3.20	Maximum acceptable inspiratory pressure, Pmax Acceptable deviation	105 cmH_2O (mbar) ±5 cmH_2O (mbar)
3.21	Time of transition to the apnea mode, Tapnea Acceptable deviation	10 - 60 s ±1 s
3.22	Pressure drop of the device in passive exhalation line	Up to 2 cmH_2O (0,2 kPa)

No	Parameter	Value (description)
3.23	When the device is switched off the possibility of spontaneous breathing of the patient through the device is provided.	Available
4	**Parameters of basic respiratory monitoring**	
4.1	Peak inspiratory pressure indication range 0-100 cmH_2O (0-10 kPa)	PIP
4.2	Positive end-expiratory pressure (the minimum pressure in the circuit) indication range 0-50 cmH_2O (0-5 kPa)	PEEP
4.3	Minute volume of breathing indication range 0-60 lpm	MV
4.4	Expiratory volume indication range 0-6000 ml	Vexp
4.5	Inspiratory volume indication range 0-6000 ml	Vinsp
4.6	Respiratory rate indication range 0-120 1/min	RB
4.7	Inspiratory:expiratory ratio indication range 1:99 ÷60:1	I:E
4.8	Fractional concentration of inspired oxygen indication range 0-100 %	FiO2
4.9	Static compliance (ml/cmH_2O) indication range: - lower value maximum 10 upper value minimum 90	Cst
4.10	Static resistance (cmH_2O/l/s) indication range: - lower value maximum 0 upper value minimum 200	Rst
4.11	Concentration (partial pressure) of CO2 in the inhaled and exhaled gas mixture (option) indication range 0-15 % (0-115 mm Hg)	FiCO2, EtCO2
4.12	Oxygen saturation of arterial blood hemoglobin (option) indication range 10-100 %	SpO_2
5	**Alarms**	
5.1	Three levels of alarm with visual and audible alarm	Automatic detection of alarm conditions. Sound and visual form, explanatory text message with the alarm priority (high, medium, low)
5.2	Disconnection of the patient	Available
5.3	Apnea	Available
5.4	Occlusion	Available
5.5	High/low Vexp	Vexp max 0 – 6000 ml Vexp min 0 – 6000 ml
5.6	High/low minute volume	MVmax 1 – 60 lpm MVmin 0 – 59 lpm
5.7	Low accumulator charge	Available
5.8	Low/high O_2 concentration	1 - 50 % from the set value
5.9	Pmax is reached	Pmax: 10 -105 cmH_2O (mbar)

No	Parameter	Value (description)
5.10	Low/high respiratory rate RB	RB max 2 - 120 ^{1}/min RB min 1 - 119 ^{1}/min
5.11	Low O_2 pressure	Available
5.12	No mains voltage	Available
5.13	Low/high $EtCO_2$	2 - 12 % (15 - 100 mmHg)
5.14	Low/high SpO_2	60 - 95 % / 90 - 100 %
5.15	Low/high PR	15 - 100 ^{1}/min / 80 - 350 ^{1}/min
5.16	High PEEP	1-50 cmH_2O (mbar)
Classification		
The device is designed for continuous operation in accordance with IEC 60601-1. Regarding safety the device complies with IEC 60601-1, IEC 60601-1--8, ISO 80601-2-12, ISO 80601-2-55, ISO 80601-2-61. The device is classified as class I type of protection (when powered from mains)/from internal power supply (in the absence of connection to the mains) with applied part of type B and applied part of type BF (pulse oximetry sensor). According to electromagnetic compatibility the device complies with IEC 60601-1-2. The enclosure of device has degree of protection against penetration of water and solids particles IP21 (enclosure is protected against ingress of particles with a diameter of at least 12.5 mm and falling drops of water falling vertically). The device has the parts and accessories to be autoclaved by steam (see Section 3.5).		

Note:

Control ranges of some ventilation parameters in certain modes of ventilation and with "child" type of the patient may differ from the written above.

ATTENTION!

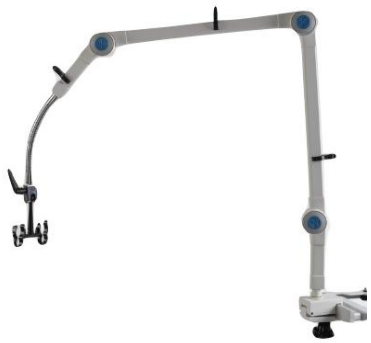
Functional characteristics and parameters of the device depend on delivery specification.

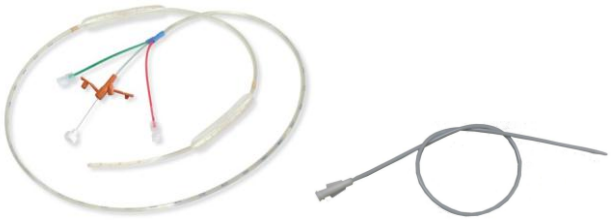
ATTENTION!

The list of additional parameters and characteristics is presented in Appendix 7.

2.2 Configuration of device

1 Electronic unit a) MV200 - TESM.230001 b) MV300 - TESM.230002	 a) b)
2 Filter-regulator TESM.186143 for connection of the device to the compressed oxygen.	
3 Mobile trolley (transport cart) TESM.186307-01 for installation and transportation of the electronic unit. a) TESM.186307-01 b) TESM.186307	 a) b)
4 Oxygen hose TESM.046002-01 for connection of the unit to the cylinder or the distribution system of compressed oxygen of medical facility.	
5 Basket TESM.189014 for storage of the accessories. Mounted on transport cart (option).	

6 Supporting arm for the breathing circuit TESM.189015 for fixing of the breathing circuit. Mounted on the transport cart.	
7 Humidifier of breathing mixtures for ventilators with accessories (available on request)	 
8 Breathing circuit (patient circuit) Adult, pediatric (including by special order silicone, coaxial, disposable or reusable)	
9 Respiratory (virus-bacterial) heat and moisture exchanging filter, 22F (HME filter) for assembling of the breathing circuit	 
10 Respiratory filter (virus-bacterial), Luer-Lock used during measuring the auxiliary external pressure (option)	
11 Breathing bag (test lung), 3L, 22F or 0.5 L 10(15)F for functional test of device before connection to the patient	
12 Sidestream airway adapter for the connection of metabolism module with a breathing circuit **Monitoring line** with Luer-Lock for the connection of the oximeter channel of metabolism module with the breathing circuit. Also used during measuring the auxiliary external pressure	 

13 Mainstream CO_2 module including: • mainstream CO_2 sensor TESM.506001; • airway adapter adult/pediatric TESM.706020; • airway adapter pediatric/neonatal TESM.706021	
14 Pulse oximetry sensor a) RM501.00.124-01 (finger, clip) b) RM501.00.004-01 (neonatal, universal) (option)	 a) b)
15 Nebulizer (sprayer of inhalation solutions)	
16 Mask for non-invasive ventilation (available on request)	
17 Catheter for measurement of auxiliary pressure in trachea (TESM.046502) and esophagus (stomach)	
18 Power cable for connection of the ventilator to the mains power	
19 Spare parts:	

19.1 Fuse T2.0AL/250V 5×20 mm (2 pieces) to replace the fuse in the power plug in case of their failure.	
19.2 Microfilter TESM.189017 for the replacement in the filter - oxygen pressure regulator	
19.3 Membrane TESM.236501 for the replacement in the expiration valve	
19.4 Dust filter TESM.009926 for the replacement in the cooling fan and fresh gas intake fan	
19.5 Water trap for the replacement in the oximeter channel of the metabolism module	
19.6 Ring TESM.049124 for the replacement in the screwed cap of filter-regulator for connection to the "O_2" inlet port.	

ATTENTION!

Some items may be optional, depending on the functional configuration of the device and the supply agreement. Check the delivery kit of your device according to the packing list.

2.3 Front panel

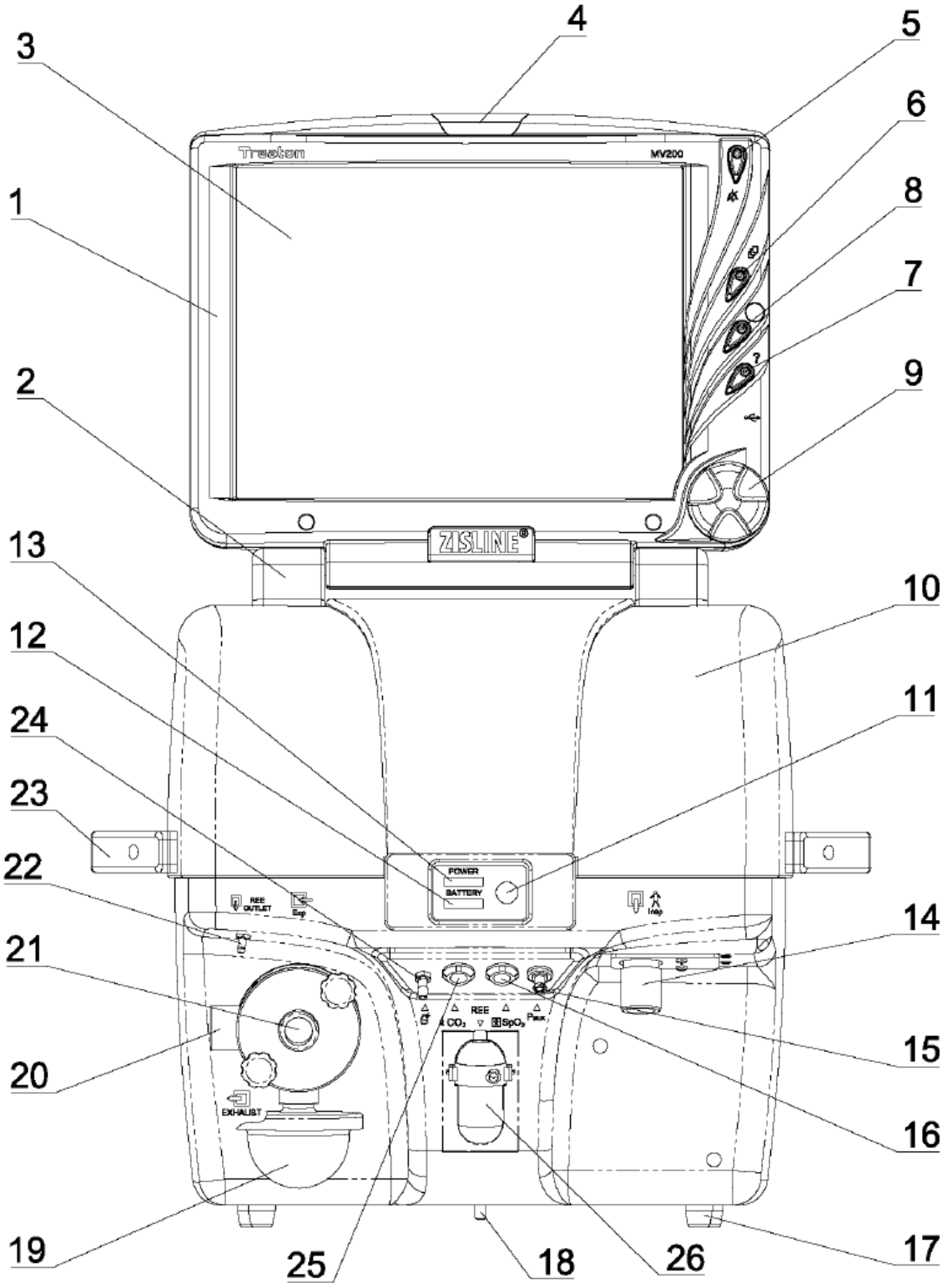


Figure 2.1 a – Front view of the electronic unit (MV200)

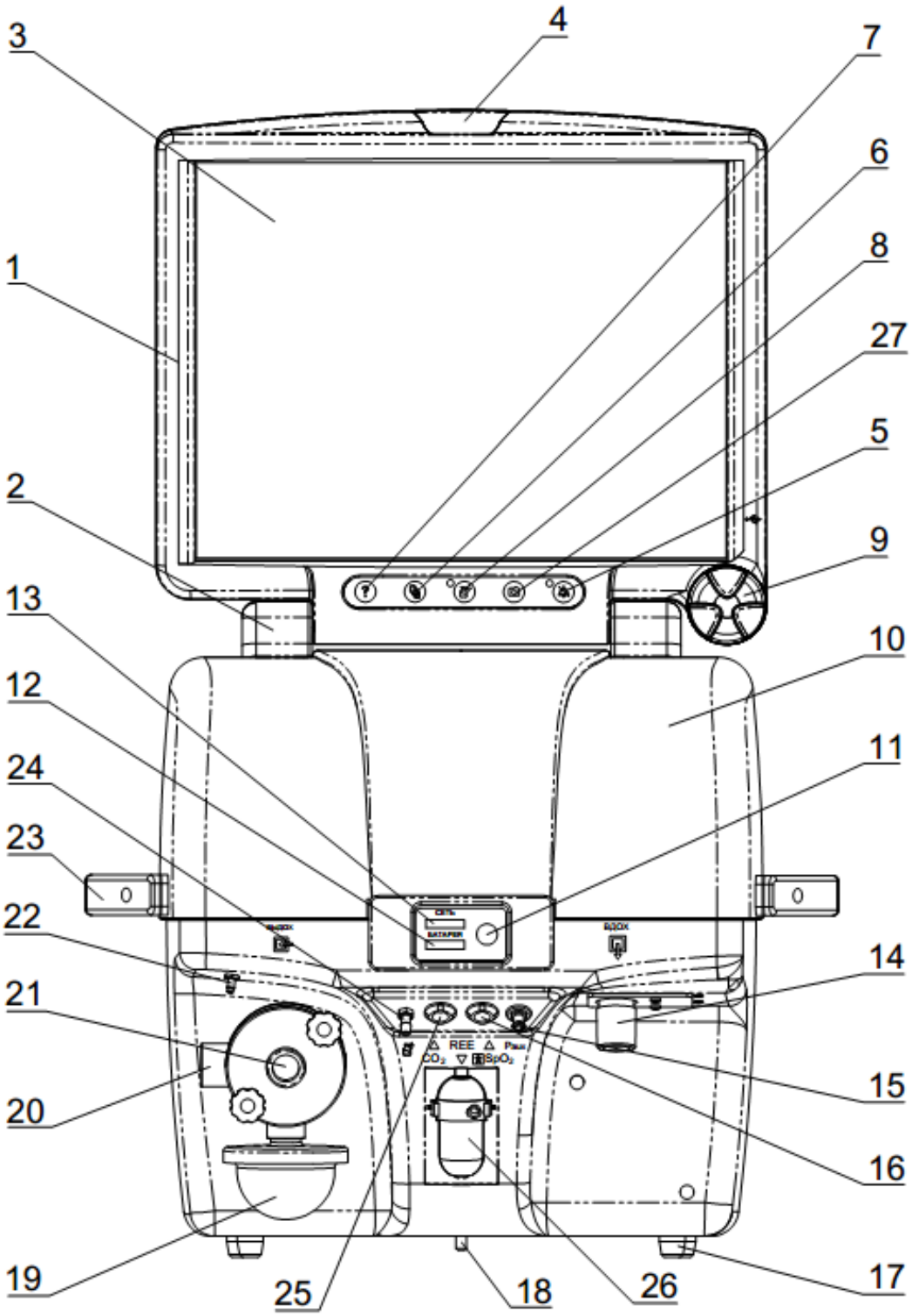


Figure 2.1 b – Front view of the electronic unit (MV300)

1. *Swivel panel*

2. *Swivel panel support*

3. *Touch screen*

4. *"Alarm" indicator is used for additional attraction of attention. It flashes red when the alarm is triggered.*

5. *Button of temporarily mute of the audible alarm. Green LED means that audible alarm is off.*

6. *Button "Menu" in intended for entering the device's control menu.*

7. *Button "?" is intended for displaying of delayed alarms window.*

8. *Button*  *("Functions") is intended for displaying of the menu of additional functions, as well as turning on the nebulizer.*

9. *Manipulator (encoder) for the control of the device.*

10. *Bottom part of the device.*

11. *Turn on/off button (to turn off – hold down for 3-5 seconds).*

12. *"Battery" LED. It indicates the condition of the accumulator charger:*

- *green - accumulator is being charged;*
- *off – the accumulator is fully charged;*
- *flashing yellow – less than 10 minutes left of operation from the accumulator;*
- *red – charger malfunction.*

13. *"Power" LED. It indicates the power supply:*

- *green – device is connected to the mains*

14. *"Insp" port is intended for connection of the inspiratory line of the breathing circuit.*

15. *"Paux" port for connection of external auxiliary pressure monitoring catheter.*

16. *"SpO_2" connector for the pulse oximetry sensor.*

17. *Rubber legs of the device.*

18. *Fixing bolt of the electronic unit to the transport cart.*

19. *Water trap for the removing of fluid from the exhaust valve.*

20. *"EXHAUST" port for the elimination of the patient's exhaled gas to the atmosphere.*

21. *"Exp" port for connection of the expiratory line of the breathing circuit.*

22. *Output port of metabolism module for elimination of the gas sample to the atmosphere.*

23. *Handles for carrying of the device.*

24. *Port for connection of the line from pneumatic nebulizer.*

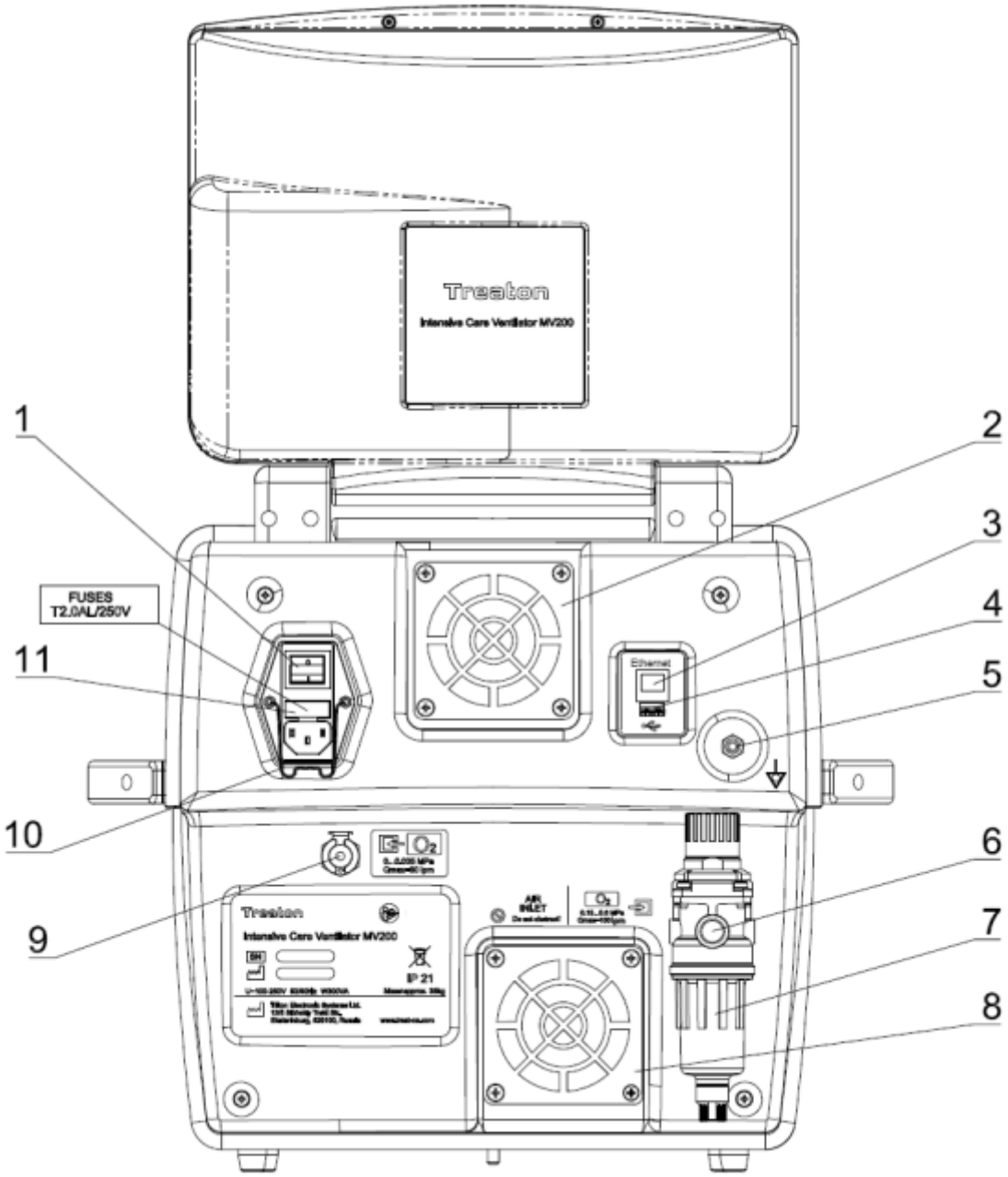
25*. "CO_2" connector for the mainstream capnometer*

26. *Water trap for connection of sampling line for metabolism module (optional)*

27 *The button saving the current screen image (screenshot)*

The surface of the liquid crystal display of device should be protected from impacts and other mechanical effects in order to avoid the appearance of unevenness, scratches, and damage of the touchscreen and display.

2.4 Rear panel



1. *Power switch (in "O" position fully disconnects the device from the mains supply voltage)*

2. *Cooling fan filter*

3. *Communication interface socket (Ethernet)*

4. *USB-port for connecting of the external USB-flash memory*

5. *Equipotential terminal (potential balancing)*

6. *Filter-regulator with the port for connection of the device to the oxygen source*

7. *Water trap of the filter-regulator*

8. *Fresh gas intake filter*

9. *Connector for the low pressure oxygen line*

10. *Metal bracket for prevention of accidental disconnection of the power cord*

11. *Mains fuses holder*

Figure 2.2 – Back view of the ventilator

2.5 Transport cart (mobile trolley)

Since some details (the panel, handle, wheels) are transported in the disassembled state, before using assemble it according to the Figure 2.3.

a) *b)*

1. *Installation table*
2. *Bracket for fixing of the supporting arm (circuit holder)*
3. *Handle*
4. *Panel for installation of the additional equipment*
5. *Mounting bracket for humidifier*
6. *Chassis*
7. *Swivel wheel with brake*
8. *Swivel wheel*
9. *Openings for installation (1 pc.) and fixing (2 pcs.) of the electronic unit.*
10. *Basket* for storage *of the accessories (the balloon holder can be mounted instead)*

Figure 2.3 – Transport cart a) TESM.186307-01, b) TESM.186307

ATTENTION!

At installation of the transport cart it is necessary to use all three screws to secure the electronic unit to the ventilator's installation table to prevent the electronic unit from falling in case of careless transportation.

Do not use the cart if damage is found. Contact your service representative for assistance.

For your notes

3 PREPARING FOR OPERATION

3.1 Operating conditions

- Ambient air temperature +10…35 ºC.
- Relative humidity 40…80 % (at the air temperature +25 ºC).
- Atmospheric pressure 425... 800 mmHg.
- Placement of the device is selected in accordance with connections to the mains and to the patient. The distance from the rear panel of the device to the wall or any other large obstruction should be at least 10 cm.
- Install the device so that the data on the display are clearly visible to the operator and the controls are easily accessible
- Connect the device only to the three-pole mains power outlet with the operating protective grounding. It is not allowed to switch the device into the wall outlet without grounding.
- In the case of joint operation of device with electrosurgical instruments for stable operation connect the potential equalization wire to the potential equalization terminal - see Figure 2.2, position 5. It is not allowed to switch the device simultaneously with other electrical devices in one multi-outlet power connector.
- The device must be connected to the high pressure source of the compressed oxygen (cylinder with reducer or distribution system of medical facility) with pressure 0.15 - 0.6 MPa and capacity at least 100 lpm. In the optional version (supplied by special order) device can be connected to the low pressure oxygen source.

3.2 Safety precautions

- Concerning safety, the device complies with IEC 60601-1, IEC 60601-1-8, ISO 80601-2-12, ISO 80601-2-55, ISO 80601-2-61. The device belongs to protection class I when powered from mains/with internal power supply (in the absence of connection to the mains) with applied parts of B type and pulse oxymetry channel of BF type.
- Concerning electromagnetic compatibility (EMC), the device meets the requirements of IEC 60601-1-2. The device is intended for use in the electromagnetic environment specified in Appendix 3. During operation it is strongly recommended to use of the device in the specified electromagnetic environment. Use the power cord supplied with the device.
- The room where the device is installed must be equipped with a ground circuit and socket outlets with ground terminal.
- In the absence of operational grounding circuit at the workplace the device should be operated from the internal power supply in order to avoid injury of the personnel by electrical shock in case of emergency breakdown on the enclosure.
- Usage of the device is allowed by personnel older than 18 years old, appropriately trained and certified, underwent the safety briefing. A prerequisite for admission to operation with the device is preliminary detailed study of the current manual.
- Do not place the device near curtains. It may hinder the cooling air flow intake into the device.
- Do not block the fresh gas input, it can cause abnormal patient ventilation.
- Do not use the device in the hyperbaric chambers, it can affect the operation parameters of the device and have the negative influence on the patient.
- The device is not intended for the administering of the inhaled anesthetics during anesthesia.
- The device is not intended for the administering of the helium or gas mixtures containing helium.

- The operation of the device is allowed only under the supervision of qualified medical personnel able to provide immediate care to the patient and, if necessary, to ensure alternative methods of ventilation in case of device's malfunction!
- During ventilation always use a bedside monitor providing a complete and independent control of the vital parameters of the patient. Leaving the patient unattended be sure that the sound alarm the device is enabled.
- While using the device on the patient keep ready the alternative means of ventilation (for example, the spare ventilator).
- While using the device on the patient periodically check the patient condition and proper ventilator function, e.g. on-time data updating on the screen.
- Ventilation with dry gas after 10 minutes can cause damage of the ciliary epithelium of the trachea and bronchi and subsequent evaporation from the surface of the alveoli. Do not allow prolonged ventilation without heating and moistening the gas supplied to the patient.
- In case of any emergency situation during of the operation (fire, short circuit, etc.), immediately disconnect the device from the patient and continue to ventilate the patient in other ways. Pull out the power cord from the wall outlet or turn off the device by power switch (see Figure 2.2, position 1). Disconnect the pressure of compressed oxygen.
- On the rear panel of the device in the mains block there are fuses of T2.0AL/250V type (2 pcs.). Do not replace the fuse without disconnecting the device from the mains.
- Operation of the device at the removed cover powered from mains is prohibited.
- Disinfection of the switched on device is prohibited (the power plug must be removed from the socket).
- Immersion of electrical connectors of sensors, cables etc. into liquid disinfectant solutions is prohibited**.**
- The operation the device may affect equipment in the vicinity, for example, high-frequency electrosurgical devices, shortwave therapy equipment, cell phones. Do not use the device in the operating conditions of the nuclear magnetic resonance equipment.
- The barometric pressure is compensated by ventilator during measurements with mainstream CO_2 sensor and metabolism measure module.
- During operation high oxygen concentration are used, so it is necessary to perform the following safety rules:
    - Use only the breathing circuits intended for use in the enriched oxygen environment. Do not use antistatic or conductive hoses and tubes in the breathing circuit.
    - Connection to the oxygen line is allowed only through regular oxygen filter-regulator supplied with the device and mounted on the rear of the cap nut with seal.
    - Do not allow oxygen leakage in the place of connection of the filter-regulator to the compressed oxygen source.
    - Do not use the device together with the explosive anesthetics.
    - Do not use the device near equipment containing industrial oils.
    - Do not use the device if the oxygen hose is damaged or contaminated with industrial oils.
    - Periodically inspect the filter located in the water trap reservoir of the oxygen regulator. If contaminated immediately replace it with the supplied spare filter.
    - Remove the condensate from the water trap through the valve at the bottom part of the regulator. Do not disassemble the regulator under pressure!!!
    - When handling with oxygen cylinders comply with the local safety regulations. Always check the status of the gas cylinders before using.

- Multiple cleaning or sterilization and re-use of disposable accessories are prohibited. This can cause equipment malfunction and harm to the patient.
- Dispose the packing materials from accessories including packing from disposable accessories according to your national standards and your facility's guidelines for waste disposal.
- During operation the ventilator should be securely fixed on the cart in three points with supplied bolts and nut.
- When placing the device on the transport cart increased tilting danger in case of:
  - placing or moving the cart on sloped floors;
  - pulling the cart over obstacles like doorsteps;
  - heavy items leaning against the cart;
  - equipment and accessories mounted outside the center of gravity.
- Do not lean against the cart.
- When placing the device with the transport cart on an inclined plane, swivel wheels with brakes must be located from below to prevent the device from sliding.
- Be careful during transportation the device on the transport cart. Hold the cart handle with both hands when moving to prevent tipping.

Modification of this device without the permission of the manufacturer is not allowed!

3.3 Preparing for operation

ATTENTION!

After transportation or storage at the low temperatures it is necessary to sustain the device at room temperature for at least 12 hours in the unpacked state before its switching on.

3.3.1 Preparing of the device and accessories

- Unpack the device and accessory kit. Make visual inspection and ensure that there are no external damages and moisture.

CAUTION!

The device is supplied non-sterile.

- Before putting into operation clean and disinfect the device and its components in accordance with it. 3.5.

3.3.2 Installation of the electronic unit and the supporting arm

- Install the electronic unit on the table of the cart. Pin in the bottom part of the block should coincide with the hole on the cart (see Figure 2.3, position 9).

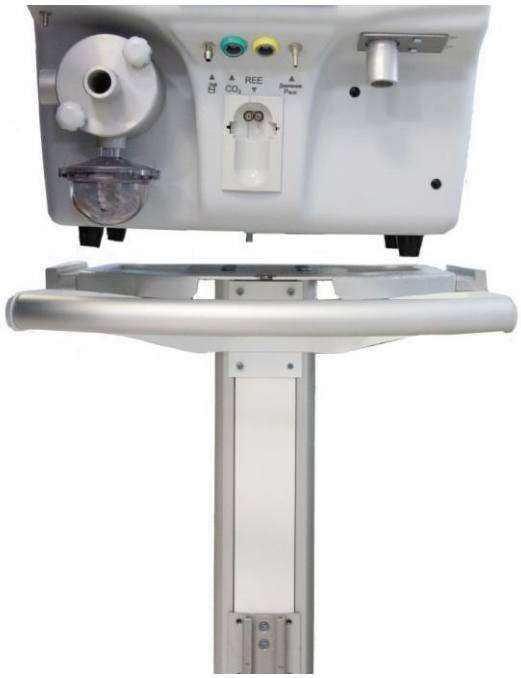


Figure 3.1 – Installation of the electronic unit on the table of the cart

Secure the electronic unit to the cart with the supplied butterfly nut and additional attachments on the other side (Figure 3.2).

Figure 3.2 - Securing the electronic unit on the transport cart

CAUTION!	**Make sure that the ventilator is properly fixed on the cart in three points to prevent injuries of the patient caused by falling of electronic unit from the cart.**
CAUTION!	**After preparing the device for use, lock the cart wheels to prevent injuries of the patient and personnel, and damage of the device.**

- Install the supplied supporting arm (the circuit holder) on either side of the cart according to Figure 3.3. Place breathing circuit on the supporting arm in a form convenient for use.

Figure 3.3 – Installation of the supporting arm (circuit holder)

- The arm is equipped with self-locking buttons (see Figure 3.4) for changing the segments position. For the arm folding, press and hold the button to unlock the segment, select the desired segment position, then release the button to lock it. It is not necessary to press the button for the arm lifting, just pull the segment upward.

Figure 3.4 – Self-locking button for changing the segments position

3.3.3 Installation of humidifier

- Install the humidifier into vertical slots of the holder and secure on the bracket (see Figure 3.5).

Figure 3.5 – Installation of humidifier

- Fill the humidifier chamber with distilled water and prepare humidifier for operation in accordance with its operating manual supplied.

***Note**:*

1. Use humidifiers recommended by the manufacturer.

2. When using the humidifier follow the its operation manual.

3. When using the humidifier the active humidification method is applied.

ATTENTION! **For the operation of the humidifier use only distilled water.**

3.3.4 Assembling of the breathing circuit

- Prepare elements of the breathing circuit, filters, breathing bag (test lung), and water trap of oximeter channel of metabolism module from the delivery kit. Depending on circuit type assemble it as shown in Figures 3.6 – 3.9. For connection of the coaxial breathing circuit refer to Figure 3.12. Assembly diagram of the breathing circuit with the mask for NIV (optional) is shown in Figure 3.10.

ATTENTION! **The reusable circuits are supplied nonsterile. Reprocess the circuit before the first use in accordance with it. 3.5.2.**

- Through the inlet port (“Insp” fitting) gas is supplied under breathing pressure through the inspiration line to the patient connection port. Through the outlet port (“Exp” fitting) breathing gas is returned under breathing pressure through the exhalation line from the patient connection port. Through the EXHAUST port gas is discharged directly into the atmosphere.

• To choose appropriate breathing circuit for certain humidifier use the information in Table 3.1.

Table 3.1. The list of recommended circuits for different types of humidifiers

Breathing circuit	Circuit type	Figure			
		w/o humidifier.	Humidifier VADI Medical Technology Co. Ltd, Taiwan	Humidifiers MR810, MR850 Fisher & Paykel Healthcare Ltd, New Zealand	
			VH-2000	MR810	MR850
Adult/Pediatric					
KD-“MS-1” Medsilicon Ltd, Russian Federation patient circuit, reusable, adult / pediatric	reusable	3.7	3.9	-	-
Adult					
038-01-155B Flexicare Medical Ltd, UK	disp.	3.7	3.9	-	-
5009 Intersurgical Ltd, UK	disp.	3.7	3.9	-	-
RT206 Fisher & Paykel Healthcare Ltd, New Zealand	disp.	-	-	3.8	3.6
038-31-768 Flexicare Medical Ltd, UK	disp.	-	-	3.8	3.6
RT105 Fisher & Paykel Healthcare Ltd, New Zealand	disp.	-	-	3.8	3.6
038-01-163 Flexicare Medical Ltd, UK	disp.	-	-	3.8	3.6
900MR784 Fisher & Paykel Healthcare Ltd, New Zealand	reusable	-	-	3.8	3.6
Pediatric					
038-02-155B Flexicare Medical Ltd, UK	disp.	3.7	3.9	-	-
5513 Intersurgical Ltd, UK	disp.	3.7	3.9	-	-
4504810 Intersurgical Ltd, UK	disp.	-	-	3.8	3.6
5504810 Intersurgical Ltd, UK	disp.	-	-	3.8	3.6
Neonatal					
038-03-315 Flexicare Medical Ltd, UK	disp.	3.7	3.9	-	-
4510 Intersurgical Ltd, UK	disp.	3.7	3.9	-	-
RT225 Fisher & Paykel Healthcare Ltd, New Zealand	disp.	-	-	3.8	3.6
038-03-304C Flexicare Medical Ltd, UK	disp.	-	-	3.8	3.6

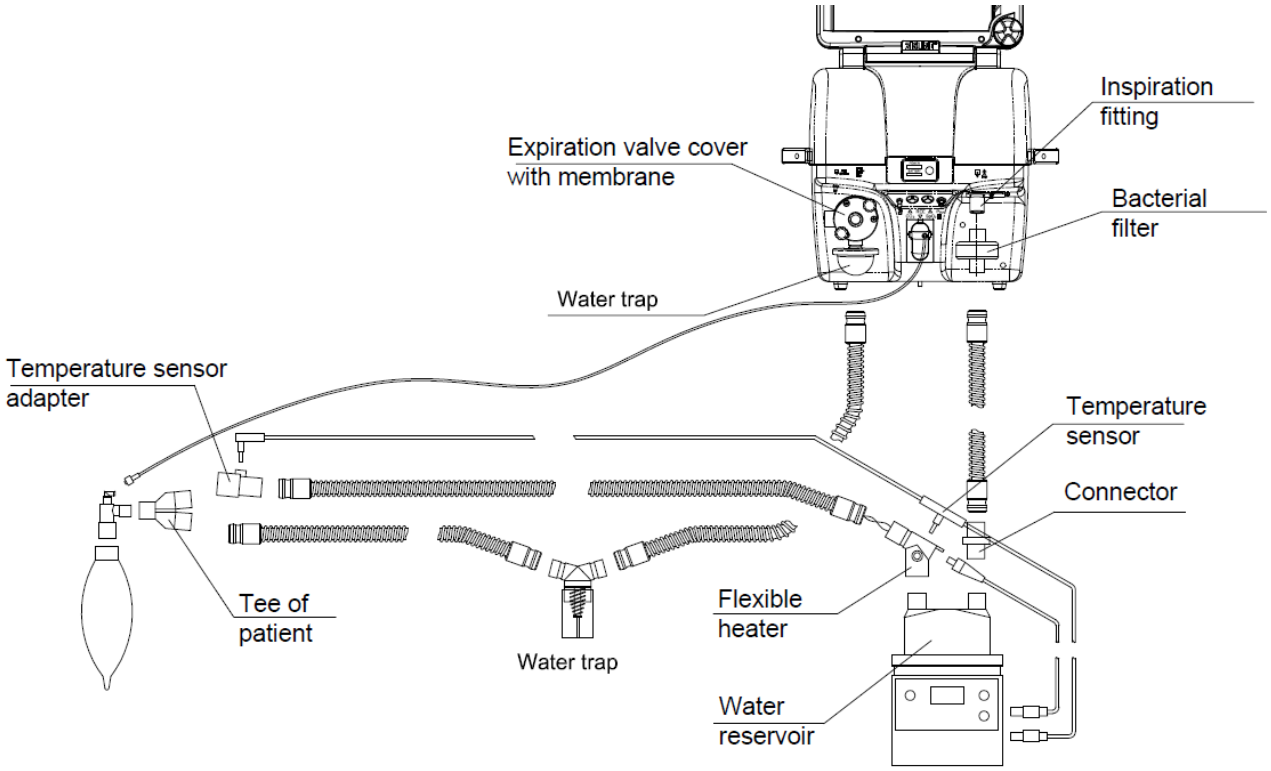


Figure 3.6 – Assembly of the disposable or reusable breathing circuit with humidifier MR850 with the heated hose and temperature sensor

Note:

At the extreme necessity at the discretion of the physician the short-term operation without the humidifier is allowed. In this case assemble circuit according to the Figure 3.7. Use the passive humidifier, i.e. recommended heat-moisture exchange (HME) filter.

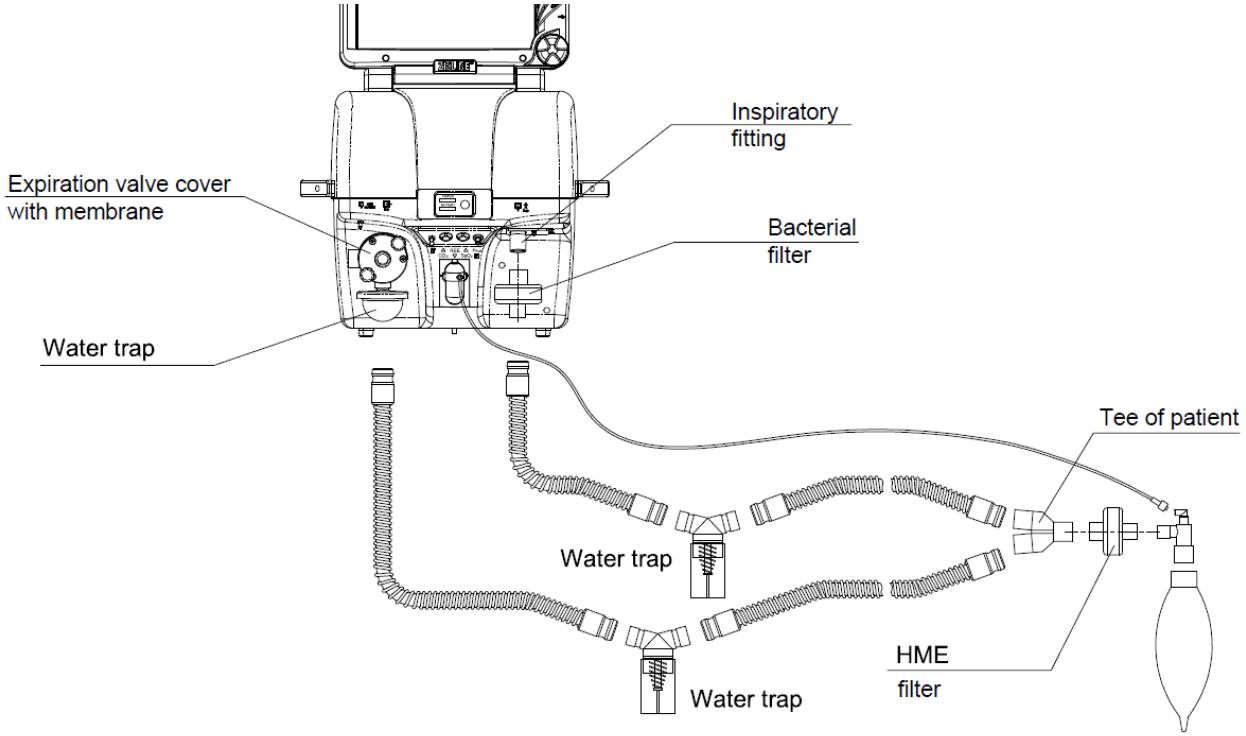


Figure 3.7 – Assembly of the breathing circuit without the humidifier

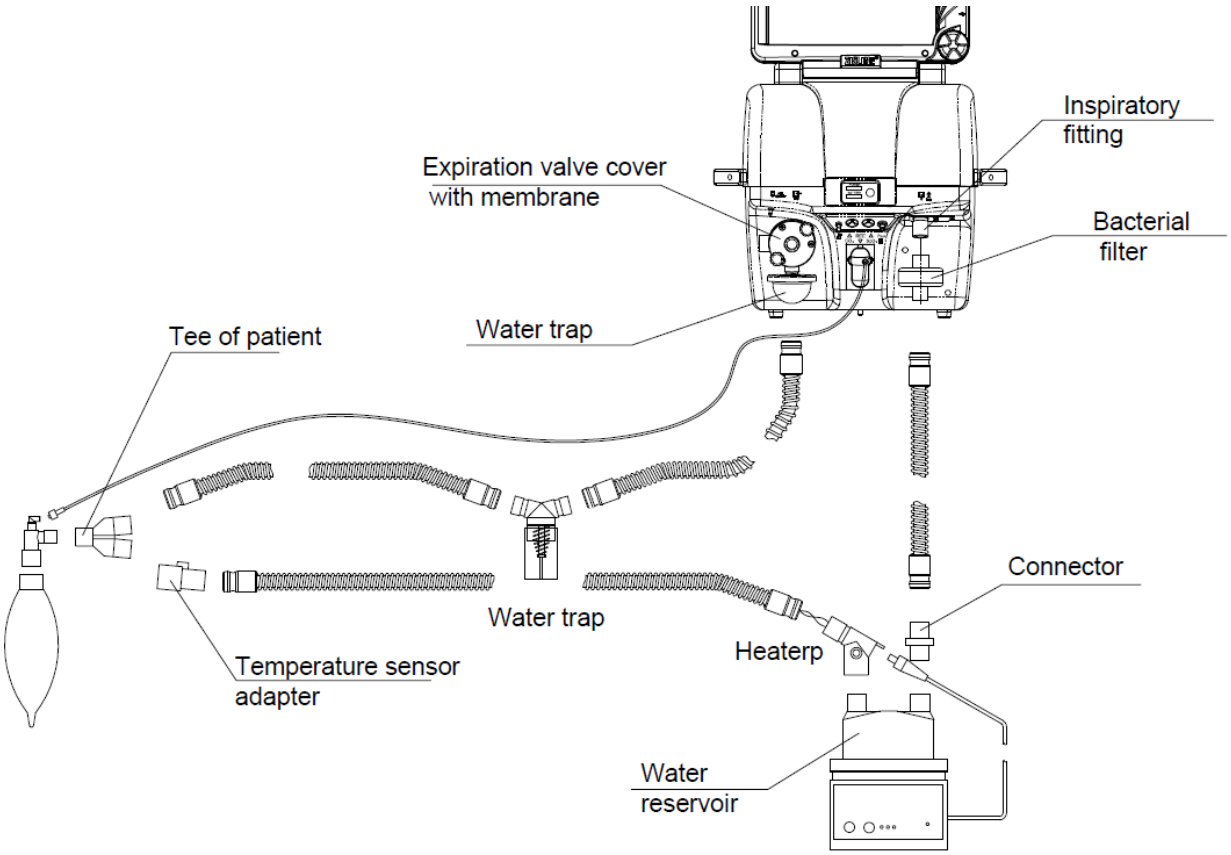


Figure 3.8 – Assembly of disposable or reusable breathing circuit with humidifier MR810

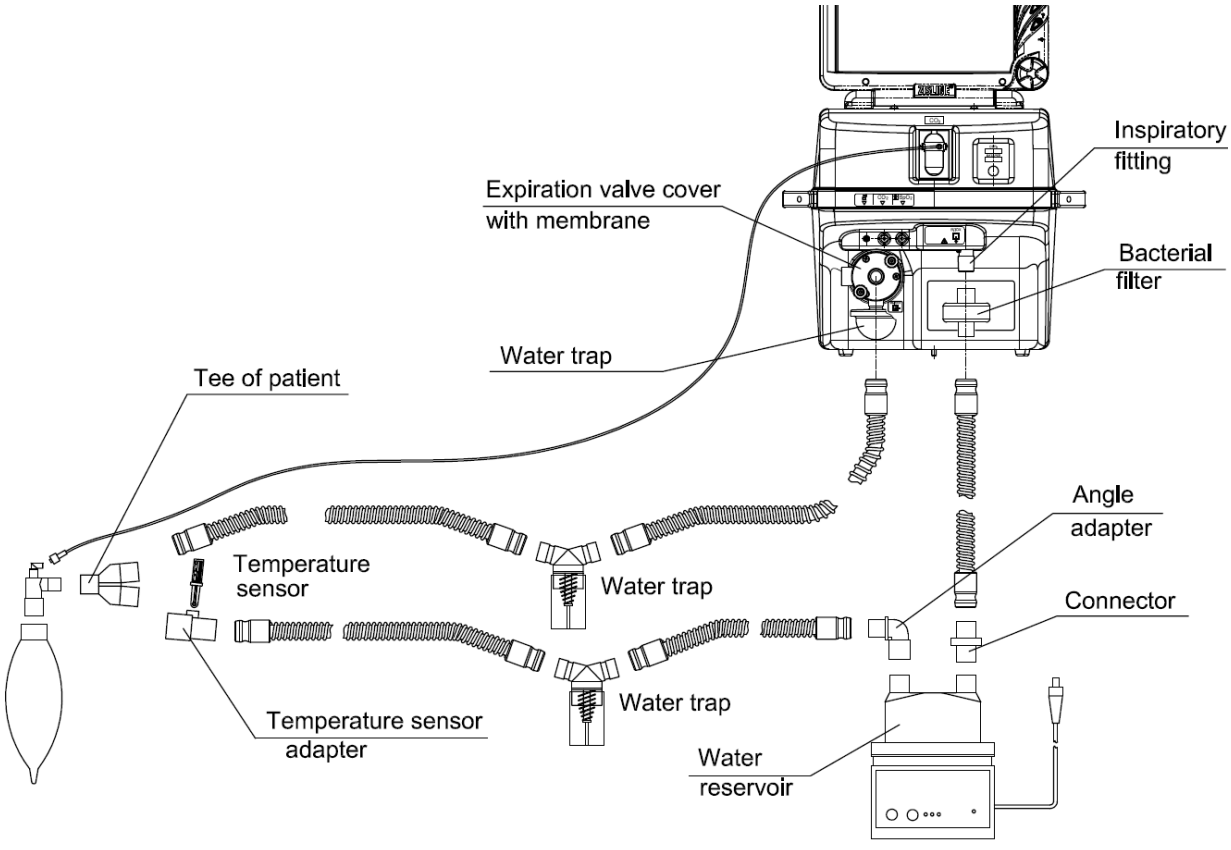


Figure 3.9 – Assembly of disposable or reusable breathing circuit with humidifier VADI VH-2000

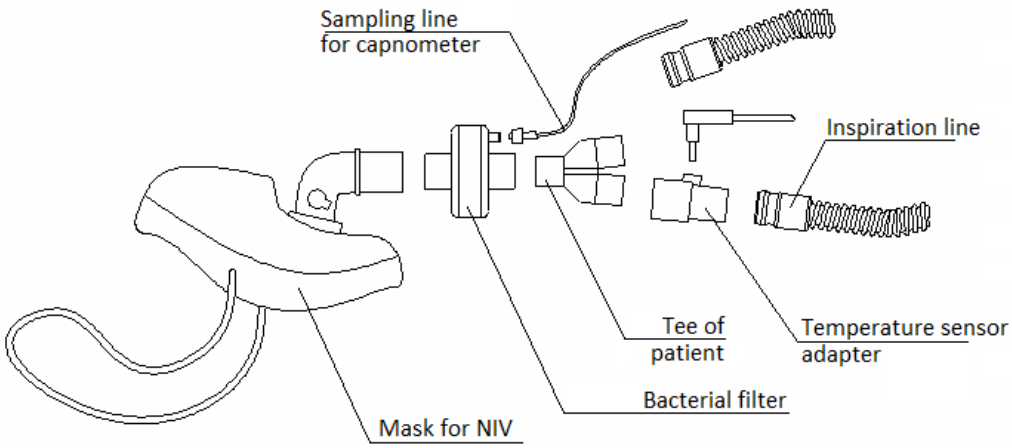


Figure 3.10 – Assembly of the breathing circuit with the mask for NIV (optional)

ATTENTION!

For connection of the masks manufactured by BMC Medical or Intersurgical with breathing circuit use connector 22F-22F REF1967 Intersurgical Ltd, UK.

ATTENTION!

Breathing circuit should contain virus-bacterial filter.

Breathing circuit should contain at least one water trap in the expiration line. Otherwise the manufacturer is not liable for the consequences of the device malfunctioning.

ATTENTION!

When using heat-moisture exchange filters it is necessary to consider the features of their operation (see it. 4.19).

ATTENTION!

During the ventilation it is necessary to monitor the level of liquid in the water trap chamber at the bottom part of the expiration valve and if necessary to empty it as shown in Figure 3.11.

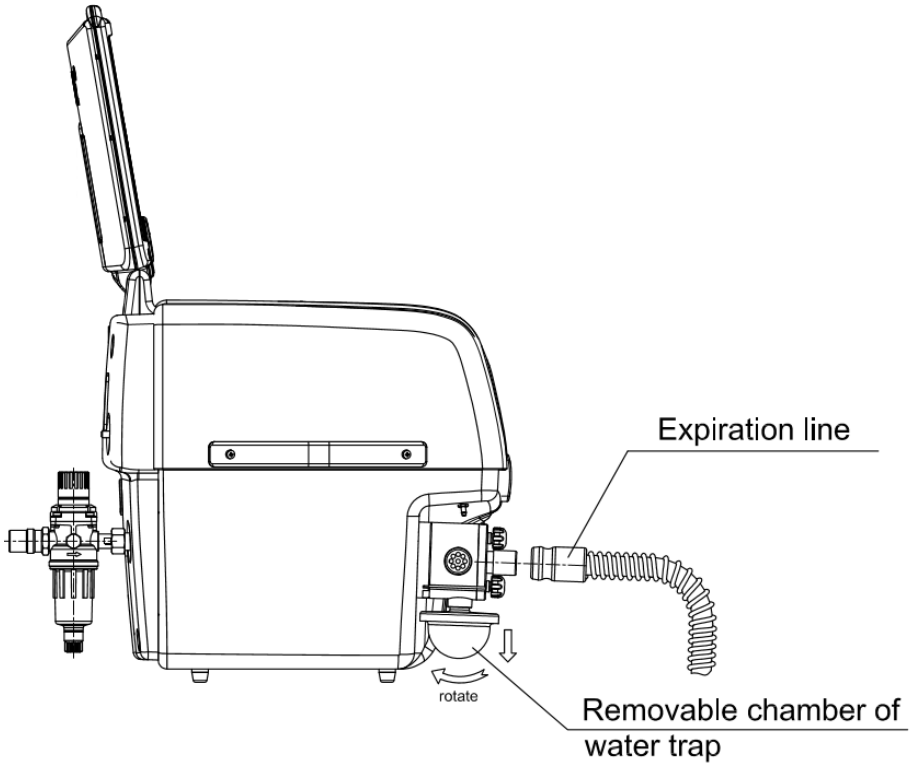


Figure 3.11 – Removing of the liquid from the removable water trap chamber

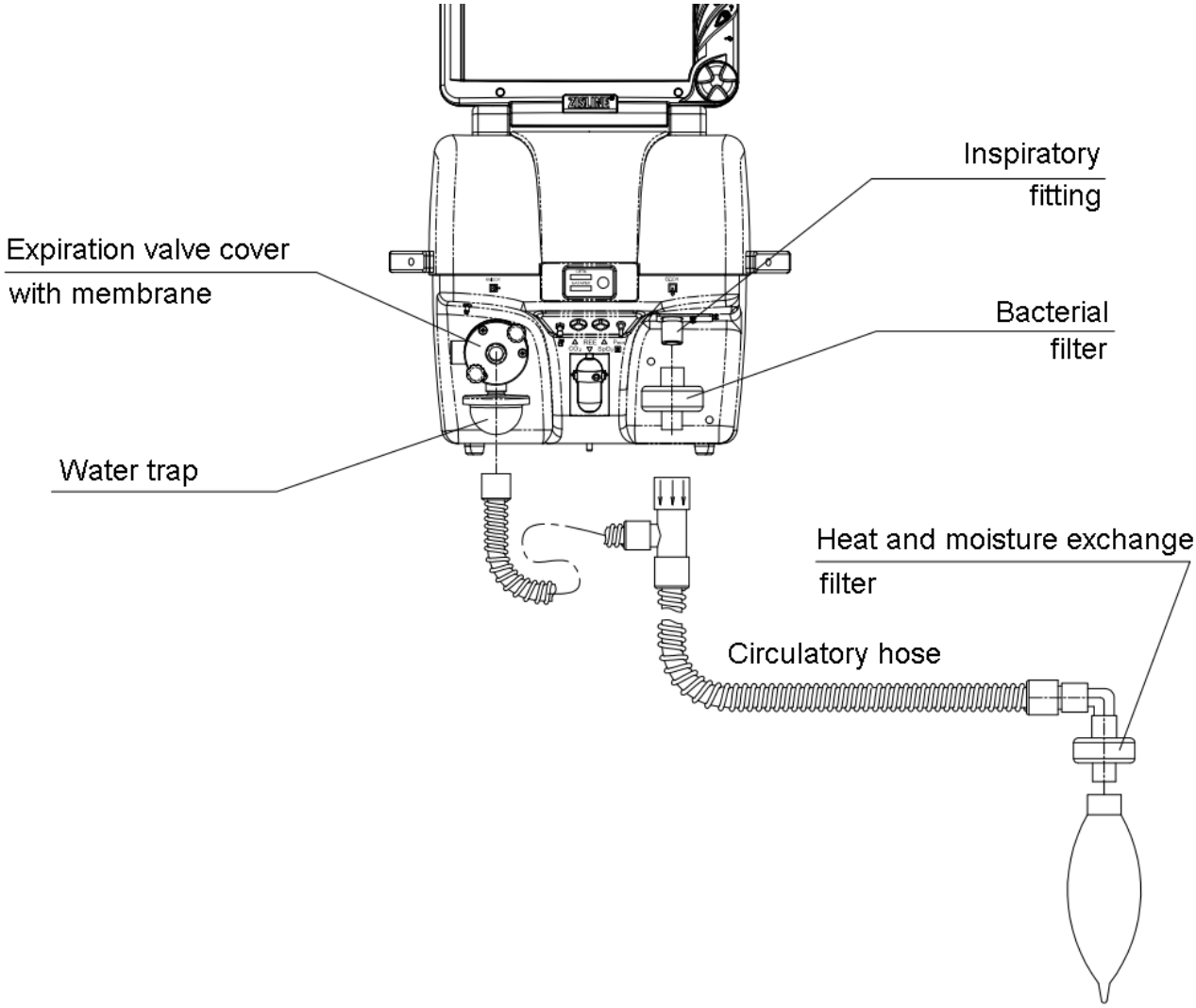


Figure 3.12 – Connection of the coaxial breathing circuit

ATTENTION!

Using of the coaxial (or dual chamber) breathing circuit is recommended for short-term ventilation without humidifier and with HME filter.

When using the humidifier because of design features of such circuits gradual accumulation of moisture and occlusion of the breathing circuit can occur.

3.3.5 Connecting to the oxygen source

The device can be connected to oxygen sources of various types (main gas supply, cylinders, oxygen concentrators). For connection to oxygen sources the low pressure oxygen hose comply with EN ISO 5359 is used. For connection make the follows:

- Connect the filter-regulator from the delivery kit to the "O_2" inlet on the rear panel of the electronic unit using the cap nut with the seal (see Figure 3.13 a).
- Connect the supplied oxygen hose with NIST connector to the filter-regulator on the rear panel of device. Insert NIST connector nipple into filter-regulator threaded inlet and secure by turning the nut as shown in Figure 3.13 b.

a) *b)*

Figure 3.13 – Connecting the filter-regulator (a) and oxygen hose (b) to the device

ATTENTION!

When installing the filter regulator, hold it by the housing vertically, with the other hand tighten the union nut until it stops (see Figure 3.13a). The nut must not be tightened with a wrench due to possible damage to the o-ring and loss of tightness.

ATTENTION!

Connection to the oxygen line is allowed only with the regular oxygen filter-regulator supplied with the device.

CAUTION!

During operation of device oxygen of the high concentration is used, so it is necessary to follow safety rules according to the it. 3.2.

- Connect the other end of the oxygen hose to the quick-release valves of the gas supply line (for oxygen) using the connector DIN 13260-2 (or DISS on special order), that is part of the hose.

Figure 3.14 - Connection to the central gas supply system of the hospital

- On special order the hoses can be equipped with other adapters for connection to the main gas supply of the medical facility.
- The filter regulator is set to maintain the input pressure of the ventilator up to 2 kgf / cm^2 (bar). If the pressure is less than 2 kgf / cm^2 (bar), it is transmitted to the input of the device without changes. The filter regulator at the bottom part has a semi-automatic valve for periodic, when necessary, draining condensate.

Adjusting of filter regulator is prohibited.

The recommended operating range of the oxygen source pressure is 1.5 - 6 kgf / cm^2 (bar). It is allowed to use low-pressure oxygen sources with a pressure range of 0.5 - 1.5 kgf / cm^2 (bar), taking into account the following features:

- The mixer is designed to try to create the required oxygen flow at any input pressure. If the oxygen flow is less than required, a lack of oxygen is replaced by air and the FiO_2 parameter in the range of values greater than 50 – 60 % with values of a minute respiration volume greater than 20 - 30 lpm may differ from the set one. To eliminate the alarms for the FiO_2, the FiO_2 limit should be set to 40 %
- When operating with oxygen concentrator, at the time of the maximum inspiratory flow the oxygen pressure can vary greatly, however, a significant change in FiO_2 does not occur due to the capacity of the oxygen line. To avoid low oxygen pressure alarms (pressure drops during inspiration), turn off the low oxygen pressure alarm.
- When operating from an oxygen concentrator, its output capacity should be at least 10 lpm.

Optionally the device can be connected to a low-pressure oxygen source of less than 0.5 kgf / cm^2 (bar). For more details, see it. 5.8. For this purpose at the factory the manufacturer installs an additional inlet oxygen fitting on the rear panel of the device.

3.4 Device turning on and off

CAUTION!

At the turning on the device and adjustment of the parameters, the patient shall NOT be connected to the device. Adjustment of parameters shall be carried out on the test lung supplied.

- If the device is powered from the mains, connect the power cord to the socket on the rear panel of the device. Insert the power cord plug to three-pole power outlet with grounding contact and turn the power switch on the rear panel to position "I" (on). "POWER" indicator on the front panel is lit green.
- When the device is connected to the mains power, "battery" indicator lights green, it means that accumulator is charging. During the charge, towards the end of the charge, the indicator may off for a while and then is lit green again.

ATTENTION!

If the "Battery" indicator is lit red (indicating the accumulator or charger failure), the usage of the ventilator is prohibited, as it does not provide the ability to work in violation of the mains supply.

- In the absence of mains supply it is allowed to operate from the backup internal or external power supply in accordance with it. 4.2.
- If the external pressure monitoring function is available, make sure that monitoring line for pressure measurement disconnected from the “Paux” fitting (Figure 2.1, position 15).
- To turn on the device shortly press button. The adjacent LEDs will be lit green.
- At device turning on graphical splash screen appears on the display (for 8 - 10 seconds), start testing (initialization) of all components and electronic units is performed and short beep signal is issued indicating the correct operation of the sound module.

Figure 3.15– Start testing window of the device

ATTENTION!

Safe operation of the device is guaranteed by the manufacturer only if start testing completed without error messages.

- After start testing, the display shows the start screen intended for the setting of the ventilation modes and parameters. Detailed procedure for the beginning of ventilation is described in it. 4.4.
- Device control is described in details in Section 4.
- At the first turning on or after a long break in the operation test the device in turned off condition without mains power. To do this for 4 - 5 seconds turn the power switch on the rear panel to the position "0" (off). If during the test the device turns off, stop using the device and contact customer service.
- At the accumulator malfunction the device can continue ventilation if there is power supply. In this case at the start the menu window with a warning appears. If you select "Continue", the device will continue its operation as in the normal mode, and the accumulator indicator will flash red to symbolize the accumulator problem.

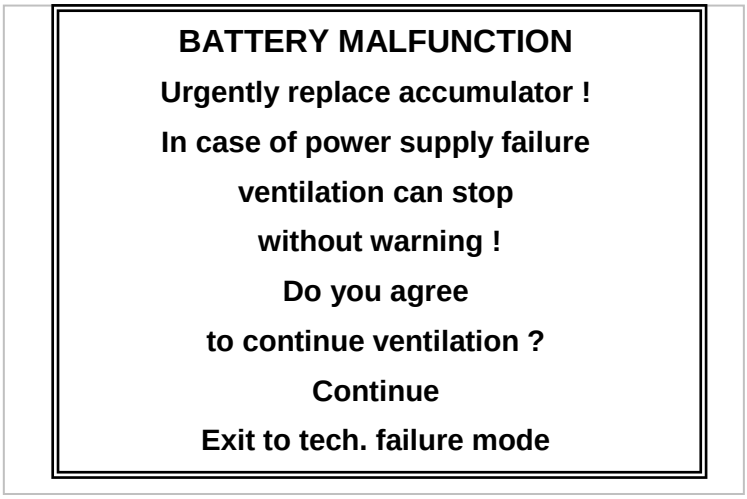


Figure 3.16 – Message window about rechargable battery malfunction

If user selects "Exit to tech. failure mode" line, window with the status of the modules will be opened. Inform the technical experts about the information in this window for all modules of the device.

CAUTION!

At the operation with a faulty accumulator, failures of the mains power can cause shutdown of the device and the termination of ventilation without any notice. The responsibility for the negative consequences of operation of the device with defective accumulator lies on the hospital medical staff.

- To turn the device off press the button during 5 - 6 seconds (it is protecting measure from accidentally pressing).
- Turning the device off is accompanied by the audible signal and the characteristic sound of the flow generator, operating for about 4 - 5 seconds at the high speed. This is done for replacement of oxygen mixture to the air in the breathing circuit, allowing to extend the service life of the oxygen sensor. Overpressure in the circuit is not created.

At operating in child mode due to increased pneumatic resistance of pediatric and especially neonatal circuits during purging of the O_2 sensor, the pressure in the tee can greatly increase, that is dangerous for the patient. In the child mode it is necessary to disconnect the circuit from the patient and only after fixing of the disconnection to perform a purge and turn off the power.

3.5 Cleaning, disinfection and sterilization

3.5.1 Cleaning, disinfection of ventilators external parts and non-sterilized components

CAUTION!	**Cleaning and disinfection of the device shall be carried out after each use as well as before putting into operation, maintenance or sending for repair to the manufacturer.**
CAUTION!	**Avoid spilling of any liquids on the body of the device and the swivel display during operation or at the disinfection.**

ATTENTION! **Application of high temperatures and chemical sterilization techniques, involving immersion of external parts and sensors (pulseoximetry and CO_2) into liquid for disinfection is strictly prohibited!**

ATTENTION! **Warranty service of the sensors failed because of incorrect operation is performed.**

ATTENTION! **Do not expose pins of the sensor (pulseoximetry and CO_2) connector to liquids; it could lead to its failure.**

ATTENTION! **When disinfecting the sensor (pulseoximetry and CO2) cable by wiping do not apply excessive tensile forces to the cable.**

Clean and disinfect the external surfaces and sensor, which are not intended for sterilization, only by wiping using gauze swab or soft cloth moistened in cleaning and disinfectant solution. Squeeze the cloth before wiping to prevent penetration of solution into the device. Use only distilled water for cleaning and disinfection solution preparation.

Recommended cleaners and disinfectants

- Hydrogen peroxide solution 3% with ionic surface-active substance solution 0.5%
- Alcohol solution (ethyl or isopropyl alcohol) 70 %
- Chlorhexidine gluconate solution 0.5%

It is possible to use other certificated cleaners and disinfectants acceptable for medical use with similar active components in proper concentration.

Cleaning and disinfection procedure

Clean the component using a gauze swab or soft cloth moistened in the mentioned above cleaning and disinfectant solution. Follow the recommendations stated in the manufacturer's cleaner and disinfectant manual.

Refer to *Table 3.2* for detailed information on cleaning and disinfection of ventilator's external parts and certain components which could be cleaned and disinfected.

For detailed description of cleaning and disinfection procedures of components manufactured by third party (humidifier and accessories, nebulizer, etc.) refer to manual supplied with component.

Table 3.2 Recommended methods for cleaning and disinfection of external parts and certain components

Component	Procedure	Comment
External parts	Before cleaning and disinfection turn off the ventilator and disconnect the power cord from mains socket. Follow the procedures mentioned above.	Ensure that ventilator is completely dry before connecting to mains socket and switching on.
Touch screen panel	Clean the touch screen with soft cloth moist with neutral detergent and then dry it with soft cloth.	Do not use rough materials with abrasive components for wiping. Do not apply an excessive effort when wiping the touch screen, you can damage it.
Mainstream CO_2 sensor	Disconnect connector of the sensor from the ventilator; disconnect the airway adapters from the sensor. Clean and disinfect the external surfaces of the sensor including optical windows according to procedures mentioned above. For reprocessing of reusable airway adapters refer to p. 3.5.2.	Before start the monitoring ensure that optical windows of the sensor are completely dry and clean, no stains from solution or water drops.
Pulseoximeter sensor	Disconnect the connector of sensor from the ventilator. Clean and disinfect the external surfaces of the sensor according to procedures mentioned above.	

3.5.2 Reprocessing of sterilized components

Reprocessing of certain components shall be carried out after each use as well as before putting into operation of the ventilator.

The recommendations on reprocessing methods (cleaning, disinfection and sterilization) of sterilized components are stated below. Use only distilled water for solution preparation. The *Table 3.4* contains a list of sterilized components and special conditions of reprocessing.

Do not sterilize disposable accessories with corresponding labeling. Utilize disposable accessories after use in accordance with national standards and your facility's guidelines for medical waste disposal

Reusing, dissembling, cleaning, disinfection and sterilization of disposable accessories could negatively affect functional and safety characteristics of the ventilator. This may cause serious negative subsequences for medical personnel and patient.

ATTENTION!

Do not use rough brushes, sharp tools and abrasive materials for manual cleaning!

Reprocessing procedure

1. Remove the component from the ventilator and dissemble it if it is possible.
2. Clean and disinfect the component in accordance with recommendation below.
3. Check the component for defects.
4. Assemble the component according to assembling scheme.
5. Put the component into special package for autoclaving.
6. Sterilize the component in autoclave in accordance with recommendation below.
7. Ensure that packaged component is completely dry after sterilization.
8. Store the component into the package. The hold time after sterilization depends on used packing, refer to packing manual.
9. After connecting the component to ventilator make all necessary testing and calibration.

Cleaning and disinfection

a) Manual cleaning and disinfection

Recommended cleaners and disinfectants

Cleaners:

- Ionic surface-active substance solution 0.5%

- Neutral soap solution

- Neodisher Mediclean forte 1 %, manufactured by Dr. Weigert

Disinfectants:

- Lysetol AF и Gigasept FF, manufactured by Schülke & Mayr;

- Sekusept PLUS, manufactured by Henkel-Ecolab;

- CIDEX, manufactured by Johnson & Johnson or gluteraldehyde solution with concentration ≤ 3.6 %;

- Hydrogen peroxide solution 3%;

- Alcohol solution (ethyl or isopropyl alcohol) 70 %.

It is possible to use other certificated cleaners and disinfectants acceptable for medical use with similar active components in proper concentration.

Cleaning

1. Remove the component from the ventilator and dissemble it if it is possible.
2. Wash and soak the component in warm solution (temperature below 40°C) of the recommended cleaner. Use the clean tray for soaking. Make sure that component is fully soaked into solution; there are no air bubbles in holes and cavities of the component. Use soft plastic brush for removing solid pollution from components surface. Soaking time and cleaning method depends on used cleaner; follow the manufacturer’s manual of cleaner.
3. Wash the component under the stream of clean water or follow the manufacturer’s recommendation of the cleaner.

4. Dry component on the air
5. Inspect the component and dispose the defective one.

Disinfection

6. Disinfect the component by means of soaking in disinfection solution. Remove the component from the ventilator and dissemble it if it is possible. Use the clean tray for soaking. Make sure that component is fully soaked into solution, there are no air bubbles. The soaking time and disinfection method depend on used disinfectant, follow the disinfectant's manual.
7. Dry component on the air. Do not wipe the component during drying.

b) Automated cleaning and disinfection

For automated cleaning and disinfection use the washing machine comply with ISO 15883. As cleaning agent use Neodisher FA®, as neutralizer - Neodisher Z®, both manufactured by Dr. Weigert. Follow the operation manual of machine and detergent as well. Recommended regimes are stated in Table 3.3.

Table 3.3. Recommended stages for automated cleaning and disinfection

Stage	Temperature	Duration
Prerinsing	Cold water	3 min
Cleaning	65°C	5 min
Neutralizing	Hot water	1 min
Rinsing	Cold distilled water	3 min
Thermal disinfection	93 °C	44 min
Drying	120 °C	12 min

Packing

After cleaning and disinfection assemble and put the component into the sterilization pocket. The sterilization packing should comply with ISO 11607 standard.

Sterilization

- Sterilize the components in hot steam sterilizer at 134°C and 0.21 MPa. Duration of sterilization is to be not less than 3 minutes and not more than 14 minutes, unless other condition indicated in Table 3.4.

Table 3.4. Recommended methods for reprocessing of sterilized components

Component	Procedure	Comment
Expiration valve components		
Disconnect the expiration valve housing from the ventilator, see it. 6.6. Clean and disinfect all components of expiration valve housing (removable part, membrane, water trap) separately. After cleaning and disinfection insert the membrane to removable part and assemble the water trap. Sterilize the removable part with membrane and water trap separately. Assemble the expiration valve housing by connecting the water trap to removable part with membrane before connection to ventilator. After connection the expiration valve housing to ventilator perform the calibration, see it. 4.16.3.		

Component	Procedure	Comment
Removable part of expiration valve	Disconnect the water trap and membrane from removable part. Reprocess according to Reprocessing procedure mentioned above.	Before sterilization make sure that all ports and holes are cleaned properly.
Membrane	Before processing carefully separate the membrane from the expiration valve seat with the uncut long object (inverse part of the tweezers) through the hole "Expiration" of the valve. Reprocess according to Reprocessing procedure mentioned above.	The number of cycles is not less than 100 (excluding damages during operation). After cleaning and disinfection of the membrane ensure that metal disk is tightly and properly sealed into membrane. Replace the membrane with new one in case of defect detection.
Water trap reusable	Disassemble the water trap (see Figure 3.11) by disconnection of water trap chamber before reprocessing. Dispose the water from water trap chamber. Clean and disinfect all components of water trap separately. Assemble the water trap before sterilization. Reprocess according to Reprocessing procedure mentioned above.	The number of cycles is not less than 100 (excluding damages during operation). Replace the water trap with new one in case of defect detection.
Patient circuit components		
Disassemble the patient circuit completely. Disassemble the water traps, dispose the water. Clean and disinfect the components of water trap separately. The general recommendations on reusable circuit reprocessing are stated below, for more details follow the manual supplied with circuit.		
Patient circuit tubes reusable	Autoclave at 134 °C and 0.21 MPa for 30 minutes.	Roll the tubes on big diameter circles. Avoid kinking and over twisting of the tubes. Before sterilization make sure that tubes are completely dry.
• Patient circuit connectors • Reusable patient tee • Water trap	Autoclave at 120 °C and 0.11 MPa for 45 minutes.	Replace the component with new one in case of defect detection.
Reusable airway adapters for mainstream CO_2 sensor		

Component	Procedure	Comment
Reusable airway adapters for mainstream CO_2 sensor	Disconnect the airway adapter from mainstream CO_2 sensor. Reprocess according to Reprocessing procedure mentioned above.	The number of cycles is not less than 100 (excluding damages during operation). After reprocessing ensure that adapter's windows are clean and dry.

For your notes

4 DEVICE CONTROL

4.1 Main features of device

Device provides respiratory assistance in the following ventilation modes:

- Continuous mandatory ventilation with the controlled volume of inspiration CMV/VCV;
- Continuous mandatory ventilation with the controlled pressure of inspiration CMV/PCV;
- Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with volume control SIMV/VC with pressure support of spontaneous breaths (PS);
- Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with pressure control SIMV/PC with pressure support of spontaneous breaths (PS);
- Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with double control SIMV/DC with pressure support of spontaneous breaths (PS);
- Spontaneous breathing with continuous positive airway pressure CPAP with pressure support of spontaneous breaths (PS);
- Spontaneous breathing with two levels of continuous positive airway pressure BiSTEP with pressure support of spontaneous breaths (PS) (analog of BiPAP[1] mode);
- Mandatory ventilation with guaranteed delivery of target respiratory volume at minimum possible pressure with pressure control PCV-VG with pressure support of spontaneous breaths (PS);
- Non-invasive ventilation of lungs (unassisted breath through the mask with continuous positive airway pressure and pressure support of spontaneous breaths) NIV;
- Airway pressure release ventilation APRV;
- Intellectual support ventilation iSV;
- APNEA ventilation (emergency mode, it is triggered if respiratory standstill – apnea – is detected).

Note:

Accessible ventilations modes are defined by functional equipment of the device. The detailed description of ventilation modes is provided in the Appendix 1.

In the NIV mode parameters of the APNEA ventilation are displayed in the edit line and can be changed by the user.

The device displays on the screen real data of respiratory monitoring in the form of figures and waveforms. Graps of pressure, flow and tidal volume, the capnography and photoplethysmography waveform (if capnometer and pulse oximeter are connected) are displayed in real time, and also volume capnography waveform and auxiliary pressure graphs can be displayed.

The device allows the user to set the alarm thresholds for the main parameters of patient ventilation monitoring, and also provides the alarm at the events breaking normal ventilation (disconnection, occlusion, absence of mains voltage etc.).

Ergonomic design of the device, including the big touch display, one rotating control handle (encoder) allow the user to get fast and easy access to the control parameters, and registered monitor information (trends).

[1] *Hereinafter BiPAP® is a registered trademark of "Respironics Inc"*

The built-in accumulator allows the device to operate without interruption (at the total charge) not less than 4 hours in case of absence of the centralized power supply at any ventilations parameters. At the minute ventilation volume of 10 lpm the device operates from the accumulator not less than 6 hours.

The transport cart (mobile trolley) allows to move quickly the device to the necessary place, and also to provide ventilation of the patient during intrahospital transportation.

The device can be used also without the transport cart.

The device operates with the open circuit - gas exhaled by the patient is not used repeatedly.

At installation in the breathing circuit up to 3 virus-bacterial filters pressure in the patient tee changes no more than on 3 cmH_2O, at the flow 60 lpm in case of timely replacement of filters at their remoistening.

The device provides possibility of independent breath of the patient if normal ventilation is impossible because of troubles with electro - and pneumo supply. Pressure drop in the inspiration and exhalation lines, measured in the patient connection port does not exceed 6 cmH_2O.

The device can operate with oxygen sources of high and low pressure, for example with oxygen concentrators. The device supports the declared accuracy of FiO_2 only if operates from high pressure oxygen sources. At operation from low pressure oxygen source, accuracy of FiO_2 is defined by the low pressure oxygen source.

4.2 Reserve power supply

4.2.1 Built-in accumulator

In case of sudden shutdown of mains supply the device has the reserve power supply - 2 built-in accumulators. These are the pressurized, explosion-proof acid rechargeble accumulators that don't need any maintenance. Capacity of each accumulator is 7.2 A/h at the 12 V.

ATTENTION!

In case of sudden shutdown of mains supply the device will automatically operate from the reserve power supply.

Due to the built-in flow generator, mode of ventilation will not be changed.

At operation of the device from the built-in accumulator light indicator "POWER" is switched off, and the graphic symbol of accumulator condition on the display (see Figure 4.4, position 4) changes the color from green to yellow. Furthermore, alarm signal of low priority "No mains voltage" is activated.

The device can operate when powered from the new completely charged accumulator not less than 4 hours. In average conditions, at respiratory rate 15 - 20 ^{1}/min and tidal volume 500 - 700 ml (minute volume of ventilation about 10 lpm), the device can operate from completely charged accumulator not less than 6 hours.

Level of charge of the built-in accumulator can be controlled by the graphic symbol on the device display (see Figure 4.4, position 4). The figure in the center of the symbol shows the level of the remained charge (the maximum value 100 corresponds to completely charged accumulator).

If charge of accumulator is close to discharging, the medium priority alarm signal "Low battery" is activated.

CAUTION!

At activation of the medium priority alarm signal "Low battery" try to restore mains supply, if it is impossible, immediately prepare other means for the patient ventilation and be ready to use them.

If charge of accumulator provides less than 10 minutes of device operation, the high priority alarm signal "< 10 min left" is activated and the graphic symbol of the accumulator becomes blinking red.

At restoration of the mains supply the device automatically changes operation to it and ventilation modes do not change. The charge of the built-in accumulator also starts automatically, and indicator "BATTERY" changes its color to green. The microprocessor control system of the charger chooses the optimum current of the accumulator charge. If device is completed with the accumulators with the charge current not less than 2.9 A, the charge of the accumulator proceeds about 3 hours if initially it is completely discharged.

If the built-in accumulator is fully charged, indicator "BATTERY" is switched off.

When the unit is powered from external DC source, the built-in accumulator does not charge.

4.2.2 Features of reserve power supply operation

Table 4.1. Reserve power supply conditions

Reserve power supply condition	Light indicator “BATTERY”	Graphical symbol on the display	Alarm priority	Message
Charge from the mains	Green	Green	-	-
Fully charged	Off	Green	-	-
Discharge	Yellow	Yellow	Low	No mains voltage
Fully discharged	Blinking yellow	Red	Medium	Low battery
		Blinking Red	High	< 10 min left
Charge from the mains	Red	Blinking Red	High	Accumulator malfunction

Fully charge built-in accumulator before every using of ventilator with the connection to the patient.

Presence of the accumulator in the device demands considering features of its operation (see below).

- Device operating time in the independent mode depends on the accumulator capacity, its previous charge level and time passed after that, quality of the accumulator, terms of its operation, and also from the operating mode of the device.
- During long-term operation or storage there can be reduction of accumulator capacity, therefore time of independent operation of the device can be reduced. That can not be a reason for claims to the manufacturer.
- For the maintenance of capacity and increasing of the service life of the accumulator it is necessary to conduct periodically its training (at least once a half a year) (see Section 6).

If the device is connected to the mains power, but the indicator “accumulator” is red, it means that charging device and/or the accumulator are faulty and need repair. Operation of such device is forbidden, because it does not provide possibility of operation at interruptions of power supply.

In some cases, at malfunction of the accumulator, the device can continue ventilation in the presence of mains supply. Also at the detection of the accumulator failure during the device operation, ventilation does not stop, but the accumulator indicator on the screen blink with red color.

In this situation it is necessary to prepare immediately other means for the patient ventilation and be ready to use them. When operating with the faulty accumulator, power supply interruptions can cause switching off the device and the ventilation termination without any warnings.

Responsibility for negative consequences of operation of the device with the faulty accumulator lies on medical staff of the medical facility.

4.3 Controls

Power control buttons:

- Button  on the rear panel provides external mains power supply to the device and charger with accumulator.
- Button  on the front panel of the device is used for switching on and off the device.

Control buttons on the front panel of the device:

- Audio paused  button – switches off sound alarm for 2 min.

The button is duplicated by the icon  on the touch screen.

If at the moment of pressing there are no alarms of medium and/or high priority, the pressing the button will lead to disabling of sound alarm for 2 minutes, even if during this time there will be new alarms. The icon will have red-yellow color.

If at the moment of pressing there are alarms of medium and/or high priority, the pressing the button will lead to disabling of sound alarm for 2 minutes, or before appearing of new alarm. The icon thus will have blue-white color.

- Menu button  - call of menu window, cancellation of parameter setting, exit from the menu etc.
- Button  - call of menu of additional functions, as well as turning on the nebulizer.
- Button  - call the list of delayed alarms on the log screen. The list contains earlier alarms which reasons are eliminated. If the reason of alarm was eliminated, the sound alarm signal disappears, however the light signal remains and demands from the user to enter into the delayed alarm log and to familiarise with them. After that the delayed alarm log is automatically cleared and the light alarm signal is switched off.
- Encoder  – navigation on the menu items, moving of the marker on the trends, navigation in the alarm log, parameter change (handle rotation); parameter choice/fixing, activation of the menu item (pressing of the encoder handle).

4.4 Starting window. Beginning of ventilation

4.4.1 Starting window

After turning on of the device on the screen there is the starting window offering a choice of the new patient or continuation of the ventilation with parameters of the previous patient:

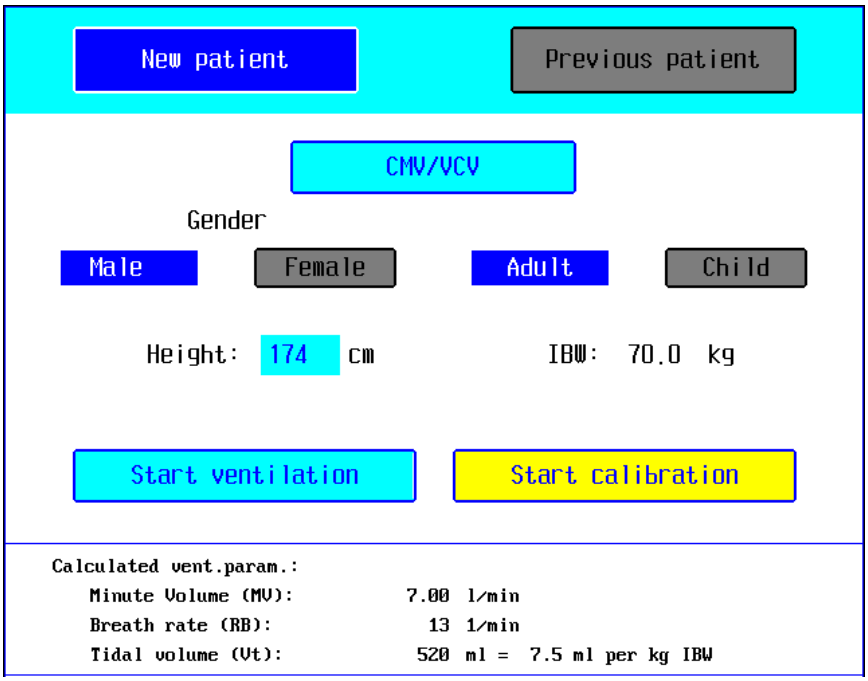


Figure 4.1 – Starting window of the ventilator

** - For modes with pressure control, instead of tidal volume Vt, target inspiratory pressure Pi is specified.*

The starting window is by default set in the position "New patient". Buttons of selection of the mode, gender, type, height of the patient and "Start ventilation" button are active. In the bottom rectangle starting calculated parameters are shown.

The "Previous patient" button is also active, it opens the window with data of the previous patient: the mode, gender, type, height and ideal weight, but these buttons are not active, only "Start ventilation" button is active. Starting calculated parameters for the previous patient are not shown.

Default parameters for the new patient:

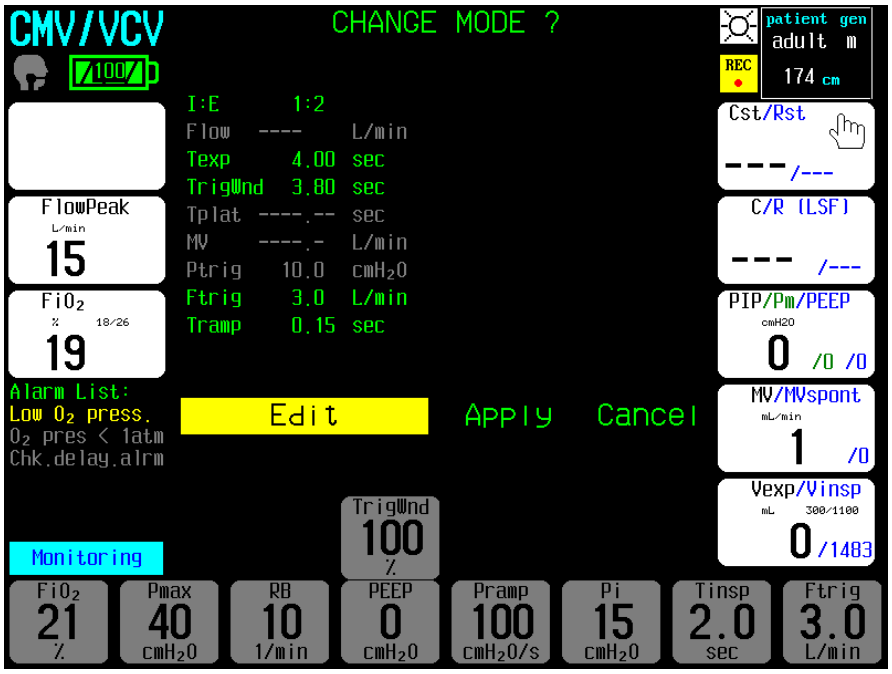
- Adult - man, height 174 cm. Child - man, height 70 cm.
- Height control range in the pediatric mode: from 57 to 150 cm (with step of 1 cm to 100 cm, 2 cm to 150 cm).
- Weight control range in the child mode (at height < 57 cm): from 2.0 to 5.0 kg (with step of 0.1 kg).
- Height control range in the adult mode: from 130 to 250 cm (with step of 2 cm).

Height of the patient is corrected by the encoder. According to the height of the patient the ideal body weight (IBW) is calculated. Value of ideal body weight (IBW) is the evaluated depending on height and gender of the patient and can not be adjusted directly. The calculation procedure of ideal body weight (IBW) is given in the Appendix 2.9. The ideal body weight (IBW) is the average value, function of height and gender and does not depend on real weight of the patient. It is used for the estimation of target MV, inspiration volume and respiratory rate. In concept of ideal weight there is important physiological value - people of different weight, but identical height statistically have the close sizes of lungs. The optimum volume of the inspiration correlates more with human height, than with its weight.

"Start calibration" button is used to start the calibration procedure for the expiration valve. It shall be performed every time after the replacement or sterilization of the removable part of the expiration valve (for detailed description see 4.16.3).

4.4.2 Window of associated parameters

After pressing of "Start ventilation" button the main screen appears, and in the central part of the screen there is the window of the ventilation associated parameters and the window of Apnea parameters (for those ventilation modes where there is support of spontaneous breath of the patient, see it. 4.8.2):



where:

I:E	*- Inspiratory:expiratory ratio*
Flow	*- Initial flow*
Texp	*- Expiratory time*
TrigWnd	*- Trigger window*
Tplat	*- Plateau time*
MV	*- Minute volume*
Ptrig	*- Pressure trigger sensitivity*
Ftrig	*- Flow trigger sensitivity*
Tramp	*- Pressure rise time relatively to Tinsp*

Figure 4.2 – Window of associated parameters

Ventilation begins after pressing of the graphic button "Apply" or through 10 s, if it there are no actions on editing of ventilation parameters.

After pressing of the corresponding "Edit" button ventilation parameters located in the bottom line of the main screen and parameters of the apnea become available for editing. When ventilation parameters are adjusted, corresponding associated parameters also are changed. In case of the conflict of parameters conflicting parameters are designated by red or yellow color.

Adjustment of ventilation parameters for each ventilation mode is described more detailed in it. 4.7.

4.4.3 Automatic calculation of initial ventilation parameters

According to the entered data in starting window (height and gender of the patient) the device ventilation automatically calculated starting parameters for all provided modes.

MV for adults and children differs and is calculated in liters per kg of ideal weight (IBW):

- For the adult patients MV = 0.1 liter per kg IBW,
- For the children with weight more than 30 kg MV = 0.1 liter per kg IBW,
- For the children with weight up to 5 kg inclusive MV = 0.3 liter per kg IBW,
- For the children with weight from 5 to 30 kg MV = (–0.008×IBW+0.34) × IBW.

The above described calculations are visually presented on graphics.

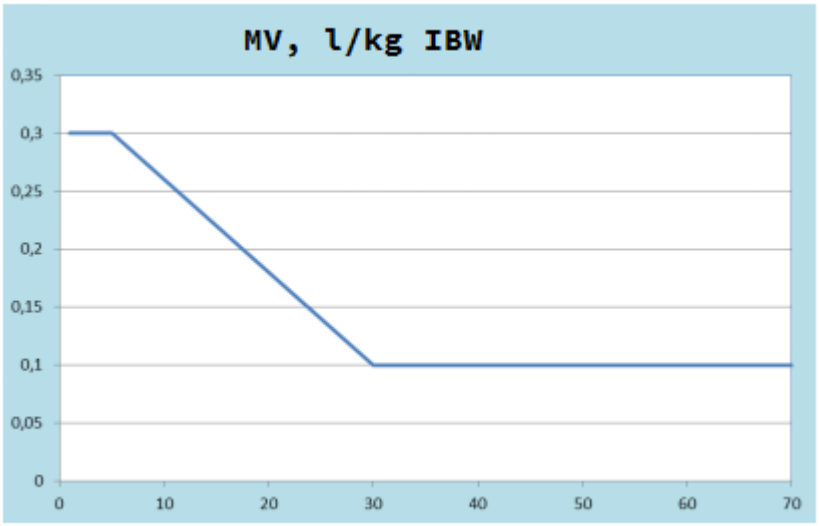


Figure 4.3 – Automatic MV calculation for adults and children

These calculations are real for a resting condition (without physical activity) for conditionally healthy person. At the increased physical activity, at the increased body temperature, at the raised metabolism, at the expressed pain syndrome minute ventilation can increase many times. At the same time in the condition of the lowered metabolism (for example, under anesthesia, etc.), minute ventilation can decrease noticeably. Further correction of minute volume during ventilation is carried out by the doctor, according to the information of gas composition of blood, $EtCO_2$ and clinical condition of the patient.

Values of calculated starting ventilation parameters are given below. These parameters are starting, guaranteeing the safe start of ventilation.

Table 4.2. Values of the calculated starting ventilation parameters for the new patient

Parameter	Value	Notice
MV	0.1 liter per kg IBW	adults and children with weight more than 30 kg
	0.3 liter per kg IBW (–0.008×IBW+0.34) liter per kg IBW	children with weight up to 5 kg children with weight from 5 to 30 kg
Vt	7.5 ml/kg × IBW	standard value of 7.5 ml/kg is available to adjust in the [Menu] → [Ventilation parameters] → [Patient's parameters] in the range 6 … 9 ml/kg IBW with the step 0.5 ml

Parameter	Value	Notice
RB	MV/Vt	calculated values of MV, Vt
Pi	15 cmH_2O 15 cmH_2O 18 cmH_2O 20 cmH_2O previous value	children with IBW from 3 to 30 kg adults with IBW from 30 to 89 kg adults with IBW from 90 to 99 kg adults with IBW above 100 kg in BiStep, APRV modes
I:E	1:2 1:2.5 1:2	adults (except APRV) children (except APRV) in APRV and APNEA modes
FiO_2	40 %	
PEEP	5 cmH_2O	
Tapnea	15 s 20 s	children adults
Pramp	100 cmH_2O/s 50 $смH_2O$/s	patients over 50 kg patients up to 50 kg
TrigWnd	100 %	
Ftrig	2 lpm pediatric mode 3 lpm adult mode	sensitivity of the trigger
Pmax	35 cmH_2O 40 cmH_2O	children adults
%MV	100 %	
Plow BiStep	5 cmH_2O	
Phigh BiStep	7 cmH_2O	
Tlow BiStep	5 s	
Thigh BiStep	7 s	

4.4.4 Initial alarm settings

Alarm thresholds MV for the new patient are set automatically at the start of ventilation: MV max = 1.5 MV, MV min = 0.7 MV.

Default value of the bottom alarm threshold Vt min = 4.4 ml/kg IBW for all modes. Default value of the top alarm threshold Vt max - 16 ml/kg of IBW.

During operation at regulation of parameters, limits of alarms do not change. If %MV changes, the bottom threshold 0.7 MV from 100%MV always remains constant, also as well as the top threshold of 1.5 MV at setting of %MV in the range from 25 to 100 %. At the setting %MV more than 100 %, the top alarm threshold is increasing on the corresponding value. For example, if %MV is set to 200 %, the top alarm threshold is set to 250 %, if %MV is set to 220 % - the alarm threshold is set to 270 %. If adaptation is enabled, the top alarm threshold is set to 250%MV.

ATTENTION!

Before starting the ventilation, make sure that the preset alarm thresholds are appropriate for the patient.

4.4.5 Calibration procedure before the beginning of operation

In some cases before the beginning of operation it is necessary to carry out the calibration.

Absence of calibrations can cause the decrease of measurement accuracy of some parameters of the device.

- At the replacement of a breathing circuit (application of circuit of other type or manufacturer) obligatorily carry out the calibration of the breathing circuit: [Menu] → [Service menu] → [Calibration] → [Breathing circuit calibration].
- At conducting of breathing circuit calibration compliance and resistance of the current circuit is defined and then used for more exact calculation of inspiration pressure and target tidal volume. This is especially important for ventilation of children. When using one type of breathing circuit without autoclaving, the circuit calibration is generally not required. Calibration procedure of the breathing circuit is described in it.4.16.5.
- After disassembling (disinfection) or replacement of the removable part of the expiration valve it is recommended to carry out exhalation flow sensor calibration:

  [Menu] → [Service menu] → [Calibration] → [CIVL] → [Exp. flow sens. calibr.]

Calibration provides more precision measurement of tidal volume V_T and positive end-expiratory pressure PEEP. Calibration procedure is described in it. 4.16.3

4.5 Main window

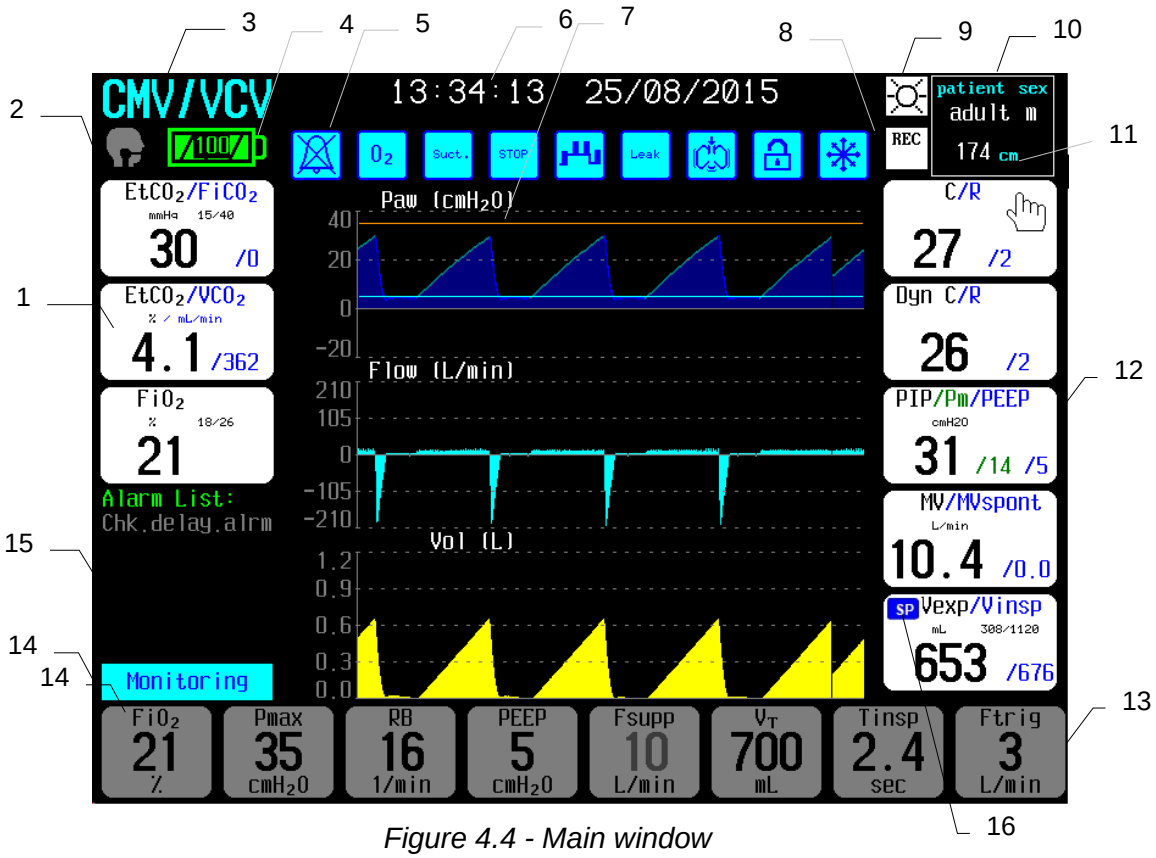


Figure 4.4 - Main window

1	Monitoring parameters indication area (fields 1-3)	Selection of parameters displayed in the rectangle is made in [Menu] → [Display settings] → [Choose measured par. blocks]. Some indication rectangles at the same time are also touch-sensitive buttons allowing to adjust the alarm thresholds.
2	Symbol of patient's spontaneous breaths	Graphical symbol of head is highlighted by the bright white color at the moment of patient's breathing attempt.
3	Set ventilation mode	At the same time it is a touch button opening the "Ventilation modes" submenu window.
4	Accumulator condition symbol	See it. 4.2.
5	Line of icons of additional functions	Icons are used for the quick access to additional features and displaying of their status. Depending on the completeness of the device the following icons can be displayed:

Icon	Additional functions	Notice
	Audio paused	Up to 120 s
	Oxygenation	it. 4.11.2
	Suction	it. 4.11.3
	Standby mode	it. 4.11.4

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>  </td><td>Alveolar recruitment maneuver</td><td>it. 4.11.1</td></tr>
<tr><td>  </td><td>Leak compensation</td><td>it. 4.11.5</td></tr>
<tr><td>  </td><td>Manual breath (manual ventilation)</td><td>it. 4.11.6</td></tr>
<tr><td>  </td><td>"Freezing"/analysis of graphs</td><td>it. 4.11.8</td></tr>
<tr><td>  </td><td>Screen lock</td><td>it. 4.11.7</td></tr>
</table>
Enabling of the function is accompanied with a change of icon’s color and with the indicator “on” above it. If the function is active within a certain time, timer of operation of the function is displayed in the indicator field. If clicking on the icon does not result in its activation, this means that the necessary conditions for enabling are not fulfilled. These conditions are described in the relevant sections for each function. Some icons in the active mode have a red color of frame and letters, and yellow background. These icons correspond to the functions that require high degree of attention.
</td></tr>
<tr><td>6</td><td>Area (section) of indication of date/ time or messages</td><td>

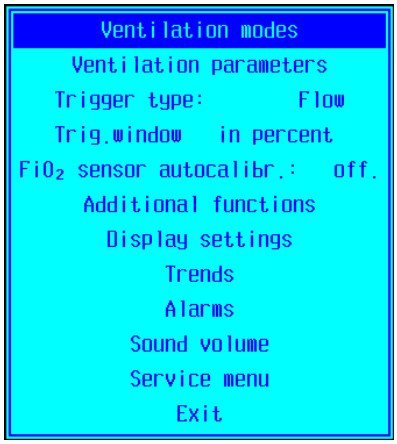
high priority alarm messages (in the main mode);
name of menu window (in the menu mode);
warning about the impossibility of changing the parameter (in the mode of parameter setting).

</td></tr>
<tr><td>7</td><td>Area (section) of indication of graphs, menu windows, trends (depending on the selected mode)</td><td>Changing of the mode of graphs displaying is made in [Menu] → [Display settings] → [Graphs]. Changing of the mode of trends displaying is made in [Menu] → [Trends].</td></tr>
<tr><td>8</td><td>Touch button "screenshot"</td><td>Saving the current state of the screen to a file on removable USB-Flash connected to the USB-port. Saving is made to the file scr0000.bmp (number changes with increasing number of file) in the SCREEN directory.
 
During screen saving that can take up to 40 seconds, the operation with the interface (touchscreen, buttons and encoder) is blocked, and the content of the screen is not updated. This condition is indicated by the symbol  . Ventilation is not interrupted, and the rest of the algorithms of the device are carried out normally.</td></tr>
<tr><td>9</td><td>Touch button of changing brightness</td><td>Day/night mode (see it. 4.11.9).</td></tr>
<tr><td>10</td><td>Patient parameters</td><td>At the same time it is a touch button that opens the "Patient parameters" submenu.</td></tr>
<tr><td>11</td><td>Indicator of "Patient height" parameter</td><td></td></tr>
</table>

12	Field of indication of monitoring parameters (fields 4-8)	Selection of parameters displayed in the rectangle is made in [Menu] → [Display settings] → [Choose measured par. blocks]. These rectangles are also touch-sensitive buttons, clicking on them user can adjust the alarm thresholds.
13	Field of indication of the set ventilation parameters	It consists of the constantly displayed bottom row (8 parameters) and of top row that appears in the setting mode. Each ventilation mode corresponds to a specific set of defined parameters, for details see it. 4.7. The window of each parameter is the touch button.
14	Icon of enable/ disable windows of extended respiratory monitoring and window of metabolic parameters	Respiratory monitoring - RESP2, RESP3 (see it. 4.18), window of metabolic parameters see it. 5.5.
15	Area (section) of alarm list indication	Up to 6 lines
16	Symbol “SP” - spontaneous	There is separate indication for spontaneous and mandatory breaths. . Symbol  appears, when displaying the volume of a patient's spontaneous breaths with pressure support

4.6 Main menu

To enter the main menu press "Menu" button on the front panel (see Figure 2.1, position 6).



Each line of the menu is the touch button. For quick access to the menu item press the appropriate line by your finger. Navigating in the menu is also made by rotation of encoder knob, the selection of menu item is made by pressing the encoder knob. To cancel and exit from the menu repeatedly press the "Menu" button or select "Exit".

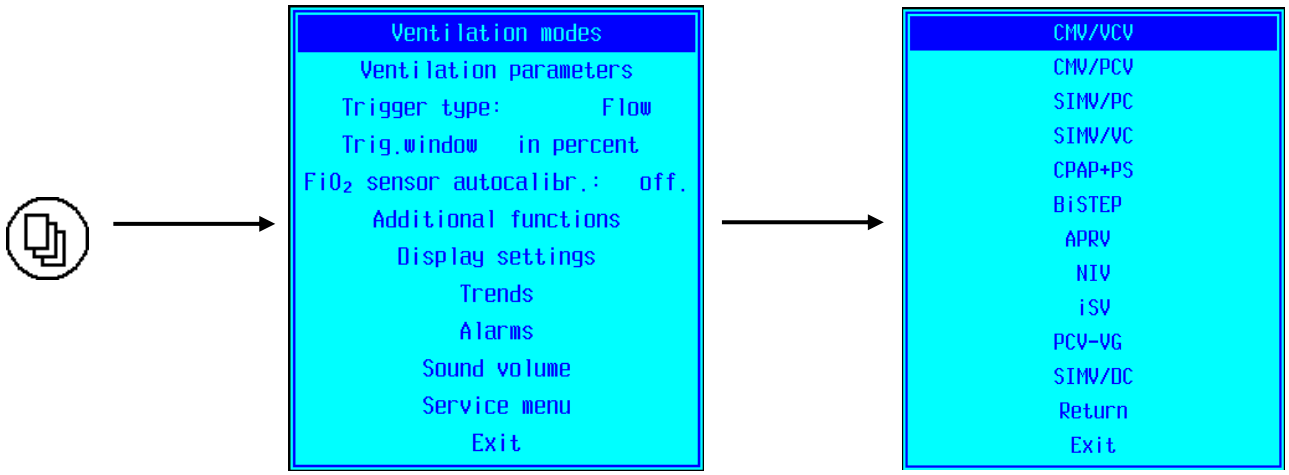
If within 30 seconds no pressing or turning the encoder was detected, exit from the menu to the previous menu and then to the main screen window is made automatically.

Table 4.3. Main menu parameters

Parameter	Function	Description
Ventilation modes	Parameter calls menu of ventilation mode setting.	it. 4.7
Ventilation parameters	Parameter calls the menu of general ventilation parameters setting and selection of patient's type.	it. 4.8
Trigger type	Parameter allows to set type of the inspiration trigger - pressure or flow one.	it. 4.9
Trig.window	Parameter allows to set the duration of the trigger window in percent or seconds. Selecting the units of the trigger window - in percent or in seconds.	---
FiO_2 sensor autocalibr.	Parameter provides the possibility to measure FiO_2 accurately at changing of external conditions.	it. 4.10
Additional functions	Parameter calls the additional functions menu.	it. 4.11
Display settings	Parameter calls menu of settings of graphs and measured parameters rectangles.	it. 4.12
Trends	Parameter calls the menu of viewing trends and alarm log.	it. 4.13
Alarms	Parameter calls the menu of alarm thresholds setting.	it. 4.14
Sound volume	Parameter calls the menu of setting the volume of alarms and spontaneous breath signal.	it. 4.15
Service menu	Technical menu for the service personnel.	it. 4.16
Exit	Return to the main window.	---

4.7 Setting of ventilation modes and parameters

4.7.1 Ventilation mode selection



Selection of ventilation mode is made by encoder or touch buttons (menu rows).

Table 4.4. Ventilation modes menu

Parameter	Function	Description
CMV/VCV	Continuous mandatory ventilation with the controlled volume of inspiration	Appendix 1.1
CMV/PCV	Continuous mandatory ventilation with the controlled pressure of inspiration	Appendix 1.2
SIMV/PC (SIMV/VC)	Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with pressure (volume) control with pressure support of spontaneous breaths (PS)	Appendix 1.3
SIMV/DC	Synchronized intermittent mandatory ventilation with flow trigger or pressure trigger with double control with pressure support of spontaneous breaths (PS)	Appendix 1.3
CPAP+PS	Spontaneous breathing with continuous positive airway pressure with pressure support of spontaneous breaths (PS)	Appendix 1.4
BiSTEP	Spontaneous breathing with two levels of continuous positive airway pressure with pressure support of spontaneous breaths (PS)	Appendix 1.6
APRV	Airway pressure release ventilation	Appendix 1.8
NIV	Non-invasive ventilation of lungs	Appendix 1.7
PCV-VG	Mandatory ventilation with pressure control and guaranteed delivery of target respiratory volume at minimum possible pressure with pressure control, with pressure support of spontaneous breaths (PS)	Appendix 1.9
iSV	Intellectual support ventilation	Appendix 1.10

After selecting of the desired mode, ventilation associated parameters window (see it.4.4.2) and apnea parameters window (for ventilation modes with the support of the spontaneous breathing) (see it. 4.8.2) will appear in the center of the display.

By clicking on the graphical button "Edit" user can change the ventilation parameters at the bottom part of the main screen (see Figure 4.4, position 13), and apnea parameters (if available in the current ventilation mode).

Start of the ventilation in the new mode occurs only by pressing the touch button "Apply" with the set cursor on it or by pressing the encoder knob. This provides protection against unintended changes of modes and settings of the ventilation.

If no attempts to edit the parameters were detected within 30 seconds or after pressing the "Cancel" button the ventilator returns to the previous mode of the ventilation.

4.7.2 Changing of parameters. Conflict of parameters

Changing of ventilation parameters:

- There are up to 8 windows of parameters in the bottom row and additional windows in the top row (if necessary) for setting ventilation parameters. The top row is only available in “Edit” mode. In some modes of ventilation only a part of windows can be used. In this case the name of the parameter in this window is displayed in gray color of low contrast or is not displayed.
- Selection of ventilation parameter for its setting is made by pressing the window (graphic touch button) of the appropriate parameter. Window of the set parameter changes background color to blue one.
- Rotate or press the encoder to change or confirm changing of parameter.
- While parameter is adjusted, new value of parameter is not applied by ventilator. The device detects (but not apply) new parameter value only after its confirmation (pressing the touch button or encoder). Background of parameter window changes its color to grey (white).
- At the each step of parameter changes, all related parameters are recalculated and instantly change on the screen. At recalculation there is a check for conflict settings.
- If at parameter changes, any related parameters exceed their limits, they are highlighted with red color. If user tries to apply incorrect parameters, "Apply" button is blocked until the conflict is resolved.
- Parameter comes into effect by pressing the encoder when the cursor is on the "Apply" button, or by pressing "Apply" touch button.
- If there was no confirmation of changes, the ventilator exits parameter setting mode in 30 seconds and returns to the previous parameter value.
- View of the ventilation parameters row for the each mode is shown in it. 4.7.3.
- Description of the ventilation parameters is in the it. 4.7.4.

Parameter setting in the apnea mode:

- At the apnea ventilation mode with volume control respiratory rate (RB) and tidal volume (Vapnea) are set automatically but can be corrected by the user.
- At the apnea ventilation mode with pressure control respiratory rate (RB) is set automatically by the same rules depending on the patient's weight. The target inspiratory pressure in the apnea ventilation mode with pressure control (Piapnea) is set by user.
- In the NIV mode only apnea ventilation with pressure control is available.

Conflict of parameters:

- At the change of ventilation parameter, conflict with other parameters in the edit row or associated parameter window can occur. Test of parameter correctness is made on the each step of setting. For instance, increasing of respiratory rate can lead to situation when I:E is out of allowable range with the same inspiratory time.
- The type of conflict is reflected by the color of conflicting parameter.
- Yellow color indicates a medium priority conflict. The device can take this parameter for execution, but warns about incorrect parameter. This situation occurs when the sensitivity of the inspiratory pressure trigger exceeds PEEP. This means that the trigger will be activated at the negative pressure in the circuit. Also problem can occur when user selects the decreasing flow waveform and large flows during inspiration - because of the limitation of the peak flow in the volume modes at 100 lpm flow waveform may differ from descending, approaching to the rectangular.
- Red color indicates a high priority conflict. The values of various parameters are mutually exclusive. The device can not take this parameter for execution. The user must resolve the conflict to change the mode. All ventilation modes have the same algorithm for informing about conflict.

4.7.3 View of parameter setting line in the different ventilation modes

Parameter setting line in the CMV/VCV mode

CMV/VCV	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				Tplat	TrigWnd			
Bottom line	FiO_2	Pmax	RB	PEEP	FormFlow	V_T	Tinsp	Ptrig

Parameter setting line in the CMV/PCV mode

CMV/PCV	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				TrigWnd				
Bottom line	FiO_2	Pmax	RB	PEEP	Pramp	Pi	Tinsp	Ptrig

Parameter setting line in the SIMV/PC mode

SIMV/PC	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				TrigWnd	Pramp	Piapnea		
Bottom line	FiO_2	Pmax	RB	PEEP	PS	Pi	Tinsp	Ptrig

Parameter setting line in the SIMV/VC mode

SIMV/VC	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line			Pramp	Tplat	FormFlow	TrigWnd		
Bottom line	FiO_2	Pmax	RB	PEEP	PS	V_T	Tinsp	Ptrig

Parameter setting line in the SIMV/DC mode

SIMV/DC	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				Piapnea	Pramp	TrigWnd		
Bottom line	FiO_2	Pmax	RB	PEEP	PS	V_T	Tinsp	Ptrig

Parameter setting line in the CPAP+PS mode

CPAP+PS	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				Fsupp	Piapnea			
Bottom line	FiO_2	Pmax	PS	PEEP	Pramp	ETC	Tapnea	Ptrig

Parameter setting line in the BiSTEP mode

BiSTEP	Windows of parameters							
	1	2	3	4	5	6	7	8
Bottom line	FiO_2	Phigh	Plow	PS	Pramp	Thigh	Tlow	Ptrig

Parameter setting line in the APRV mode

APRV	Windows of parameters							
	1	2	3	4	5	6	7	8
Bottom line	FiO_2	Phigh	Plow	PS	Pramp	Thigh	Tlow	Ftrig

Parameter setting line in the NIV mode

NIV	Windows of parameters							
	1	2	3	4	5	6	7	8
Bottom line	FiO_2	PEEP	PS	Facc	Piapnea	RBapnea	Tapnea	Ptrig

Parameter setting line in the PCV-VG mode

PCV-VG	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line						TrigWnd		
Bottom line	FiO_2	Pmax	RB	PEEP	Pramp	V_T	Tinsp	Ptrig

Parameter setting line in the iSV mode

iSV	Windows of parameters							
	1	2	3	4	5	6	7	8
Top line				Pmin				
Bottom line	FiO_2	Plimit	PEEP	%MV	Ftrig	Pramp	ETS	Adapt.MV

4.7.4 Description of ventilation parameters

This section describes the ventilation parameters available for control in the lower lines of the main screen. Some parameters common for the all ventilation modes are described in it. 4.8 (menu of the general parameters).

- **FiO_2** – fractional concentration of inspired oxygen. The device automatically maintains the set oxygen concentration. The measured value of the oxygen concentration is displayed in the field of monitored parameters.
- **Pmax** – maximum acceptable inspiratory pressure. Pmax parameter is used in all modes to limit the pressure in the patient breathing circuit and to prevent barotrauma. If the pressure in the patient breathing circuit for some reason has become equal to or higher than Pmax, the device immediately opens the exhaust valve and begins expiration. At any ratio of parameters the device ensures that Pmax greater or equal to (Pi + PEEP + 5 cmH_2O) or (PS + PEEP + 5 cmH_2O), or "APPLY" touch button for confirmation of changes will be blocked. Pmax control limit is determined by the selected patient type (adult/child) and for some ventilation modes can be set in [Menu] → [Ventilation parameters] → [Pmax limit].
- **RB** – respiratory rate (CMV/VCV, CMV/PCV, PCV-VG modes). At changes of RB parameter, parameters associated with it (MV, I:E, Texp) recalculate automatically. Tidal volume V_T is not changed; respectively the minute volume MV is changed proportionally to the frequency change. inspiratory time Tinsp remains unchanged. Changing of frequency and period of respiratory cycle is made due to the change of expiratory time and I:E parameter (inspiration to expiration ratio).
- **RB** – respiratory rate, frequency of mandatory breaths (SIMV/VC, SIMV/PC modes). It is regulated similarly to RB in automatic mandatory ventilation modes. The only difference is

that the time of expiration can be significantly longer than the time of inspiration. There is no limitation of the expiratory time regarding the minimum I:E ratio, it can reach a value of 1:99.

- **PEEP** – positive end-expiratory pressure. In BiSTEP and APRV modes Plow parameter functionally corresponds to the PEEP parameter.
- **V_T** – tidal volume. At changing of V_T minute volume MV and initial flow Flow are changed simultaneously. Other parameters (respiratory rate, inspiration and expiratory time) are not changed.
- **Tinsp** – inspiratory time. Changing of the Tinsp parameter is made due to expiratory time Texp and I:E ratio and does not change the respiratory rate. Control limit of Tinsp for some modes can be changed in [Menu] → [Ventilation parameters] → [Tinsp limit].
- **Tplat** – plateau time is duration of the plateau relative to inspiratory time. It is set in percent or seconds depending on the setting of parameter [Menu] → [Ventilation parameters] → [Plateau time].
- **FormFlow** – flow waveform (rectangular or decreasing).
- **Ftrig (Ptrig)** – flow (pressure) trigger sensitivity. Trigger sensitivity determines the minimum value of the patient's respiratory effort required to run the algorithm of spontaneous inspiration support. In the flow trigger [Menu] → [Ventilation parameters] there is an additional criterion “Trigger Vinsp 25ml”, which eliminates missing of breaths with very low rate of the flow increasing. Breath is activated by the accumulation of 25 ml tidal volume during 0.5 s.

Do not set without a special reason very high sensitivity of the inspiratory trigger (Ftrig < 3 lpm or Ptrig < 3 cmH2O) because it increases the probability of autotriggering or false triggering due to movements of the circuit, acoustic noise, patient’s movements, etc. In this case triggering will be initiated by the system itself, and not by the patient.

- **PS** – support pressure of spontaneous breath. If the newly set inspiration support pressure plus PEEP exceeds the maximum allowable pressure Pmax, then the PS and PEEP background will be painted in red and the application of parameters will be forbidden. In the BiSTEP mode PS parameter is used to support spontaneous breaths only on the low pressure phase Plow. At high pressure phase support pressure is fixed at 5 cmH_2O to prevent barotrauma.
- **Pi** – inspiratory pressure. If the newly set inspiratory pressure plus PEEP exceeds the maximum acceptable pressure Pmax, then Pi background will be painted in red and the application parameters will be forbidden.
- **Vapnea** – tidal volume in the apnea mode. It is regulated similarly to V_T.
- **Tapnea** – time of transition to the apnea mode after detection of the respiratory arrest.
- **Piapnea** – inspiratory pressure above apnea PEEP level in the apnea mode.
- **RBapnea** – respiratory rate in the apnea mode.
- **Phigh (Plow)** – pressure value in the high (low) pressure phase (in the BiSTEP, APRV modes).
- **Thigh (Tlow)** – time of the high (low) pressure phase (in the BiSTEP, APRV modes).
- **Fsupp** – support flow (base flow).
- **ETS** – expiration trigger sensitivity - percentage of peak inspiratory flow at which the device switches from inspiration to expiration in the respiratory cycle with pressure support. Increasing of parameter results in the earlier termination of inspiration and allows to complete breath normally when there is a leakage in the circuit.

- **TrigWnd** – trigger window or a part of the expiratory time when spontaneous breath is expected. The expiration is divided by trigger window into two parts: 1) the time period at the end of that hardware breath should happen, if there were no spontaneous inspiration attempts, 2) the time period during that the spontaneous inspiratory efforts are expected and maintained. The duration of the trigger window can be set in percent or seconds, depending on the setting of [Menu] → [Trig.window].
- **ETC** – endotracheal tube compensation.
- **%MV** – factor of increasing/decreasing of target MV in the iSV mode.
- **Adapt.MV** – function of MV adaptation in the iSV mode.
- **Pramp** – rate of the pressure rise. This value determines the time of reaching of the target pressure in the pressure control mode and at spontaneous inspiration support. Control range 5…200 cmH_2O/s. At changing of the rate of pressure rise, the ventilator automatically calculates the specific amount of inspiratory time that takes the phase of pressure rise and displays it in the associated parameters window in %.

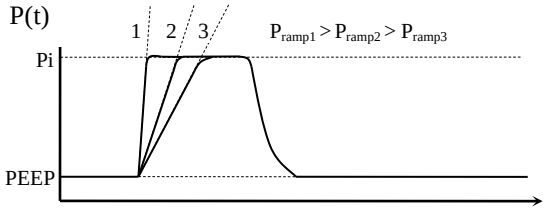


Figure 4.5 – Pramp adjustment

At using endotracheal or tracheostomy tubes of small diameter try to avoid high values Pramp. Due to inadequate large initial flow and high tube resistance inspiratory pressure in the breathing circuit can be achieved untimely. As a result due to the activation of the expiratory trigger, the pressure support of spontaneous inspiration (PS) can be prematurely interrupted.

Pramp parameter determines the time when the target pressure will be reached. Optimal value of Pramp can be determined by the shape of the inspiration pressure curve, see Figure below.

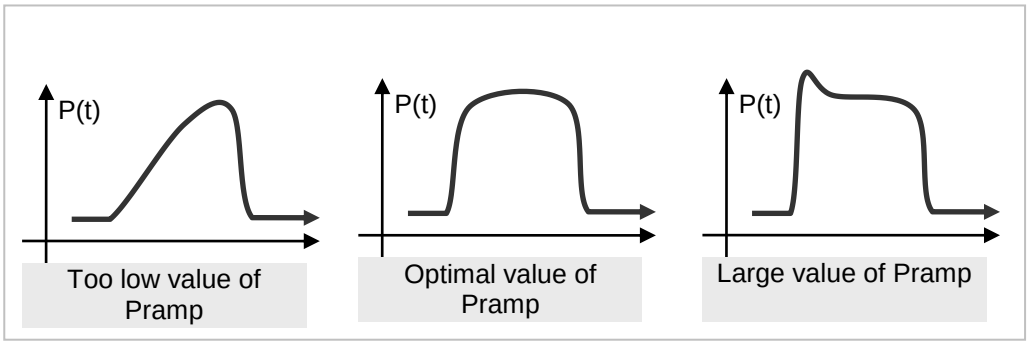


Figure 4.6 – Influence of Pramp to the inspiration pressure waveform

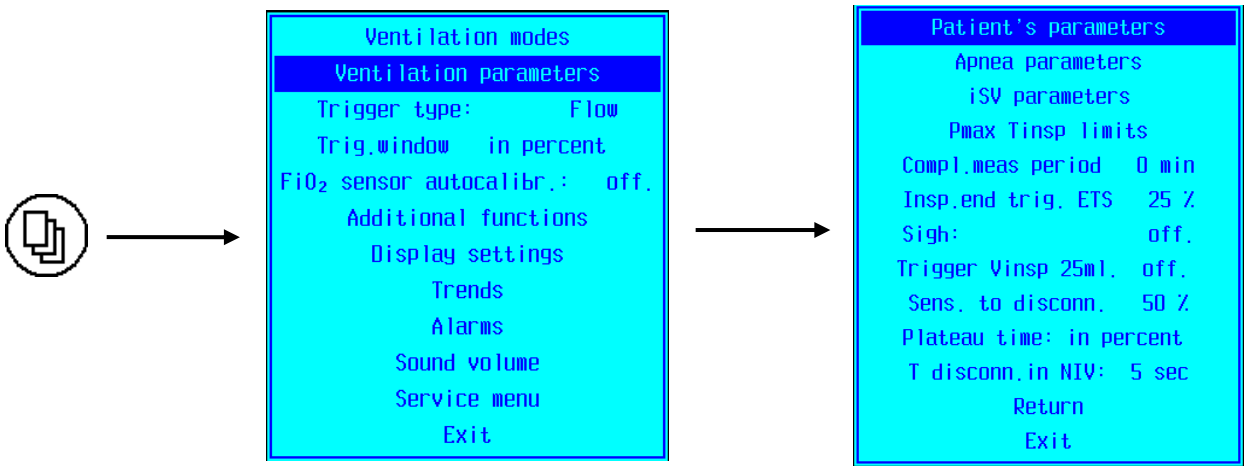
Proper selection of this parameter is essential for optimal inspiration and increases patient's respiratory comfort. Because of inadequate high pressure rise rate and high tube resistance, inspiratory pressure in the breathing circuit can be achieved untimely. As a result inspiration can be prematurely interrupted at the pressure support (PS) of spontaneous breath. Excessive small value of Pramp can cause the patient's feeling of the lack of air. When using endotracheal or tracheostomy tubes of small diameter try to avoid high values of Pramp.

- **Facc** – Determines the rate of the initial inspiratory flow change. Parameter is used only in NIV mode (instead of Pramp). Control range is 10…100 %.
- **Plimit** – value of pressure limitation in the breathing circuit in the iSV mode.
- **Pmin** – minimum support pressure, sets the minimum allowable value of the support pressure of the spontaneous breathing by ventilator.

4.8 Menu of general ventilation parameters setting

4.8.1 Description of general ventilation parameters

To enter the menu press:



This menu is used to set the ventilation parameters that are rarely changed: Selection of parameters is performed by the encoder or the touch buttons (menu bar).

Table 4.5 - Parameters of ventilation modes menu:

Designation of parameter	Description of parameter	Values
Patient's parameters	Type of the patient	adult, child
	Gender	male, female
	Height Weight[1]	57…250 cm 2.0…5.0 kg
	IBW (ideal body weight)	
	Tube parameters: Type (endotracheal, tracheostomy) Diameter (variation range is defined by IBW, see it.5.6)	 ET, TST 4.5…10.0 mm
Apnea parameters	Calls the window of apnea parameters	see it.4.8.2
iSV parameters	Calls the window of iSV parameters	see it.4.8.3
Pmax, Tinsp limits	Allows in some modes to increase the upper limits of the adjustment of Pmax, Tinsp	see it.4.8.4
Compl.meas period	Determines time between compliance and resistance measurement cycles.[2]	0…10 min
Insp.end trig. ETS	Trigger of the end of inspiration ETS - percentage of peak inspiratory flow at that the ventilator switches from inspiration to expiration in the respiratory cycle with pressure support. Increasing the parameter results in earlier termination of inspiration and allows to complete breath normally at the leakage in the circuit. The NIV mode uses its own copy of the ETS parameter that does not affect other modes.	5…80 %

Designation of parameter	Description of parameter	Values
	After exit from the NIV mode the old value of ETS is restored. ETS in NIV is measured in lpm.	
Sigh	Mode of the periodic deepen sigh.[3]	on, off
Trigger Vinsp 25ml	Additional criterion of activation of the inspiratory trigger, when inspiratory volume exceeds 25 ml. That provides the triggering at the slow spontaneous inspirations.	on, off
Sens. to disconn.	Sensitivity threshold of device to the "Disconnection" alarm. It is defined as the inspiration to expiration volume ratio expressed in percent. Alarm "Disconnection" will be formed when the inspiration to expiration volume ratio is below the sensitivity to disconnection.	0…50 % (step 5 %)
Plateau time	Selecting of the parameter unit	%, s
T disconn.in NIV	Delay time of disconnection alarm triggering in the NIV mode. Default parameter value is 5 seconds.	0…60 s

1 – If user tries to enter a patient's height <57 cm, the ventilator goes into the patient's weight editing mode (to the minimum value of 2 kg). The reverse transition occurs when user enters a weight > 5 kg. At weight values between 2.0 and 5.0 kg, the iSV mode becomes unavailable

2 – Applied method of calculation of compliance and resistance is described in Appendix 2.1. To measure compliance immediately, press the compliance window on the device's display. That is sensor button at the same time.

3 – Parameters of the periodic deepen sigh mode: periodicity - every 50 respiratory cycles (inspiration), tidal volume - 1.5 times more than set one (for ventilation modes with volume control), maximum pressure – on 5 cmH_2O more than the set one (for ventilation modes with the pressure control).

4.8.2 Menu of apnea parameters

Menu of apnea parameters is available when the device switches on (or ventilation mode is changed) – for ventilation modes that support spontaneous breathing, and also through the main menu:

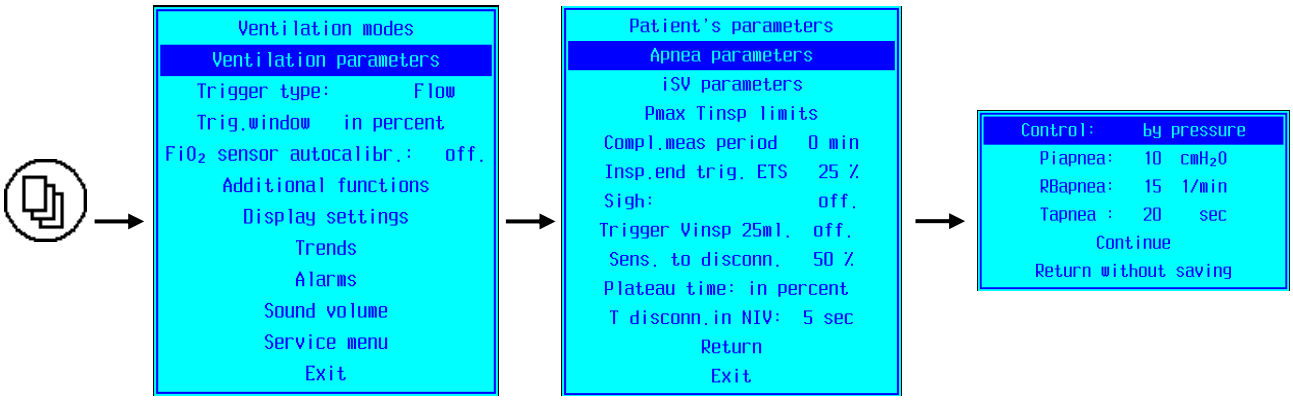
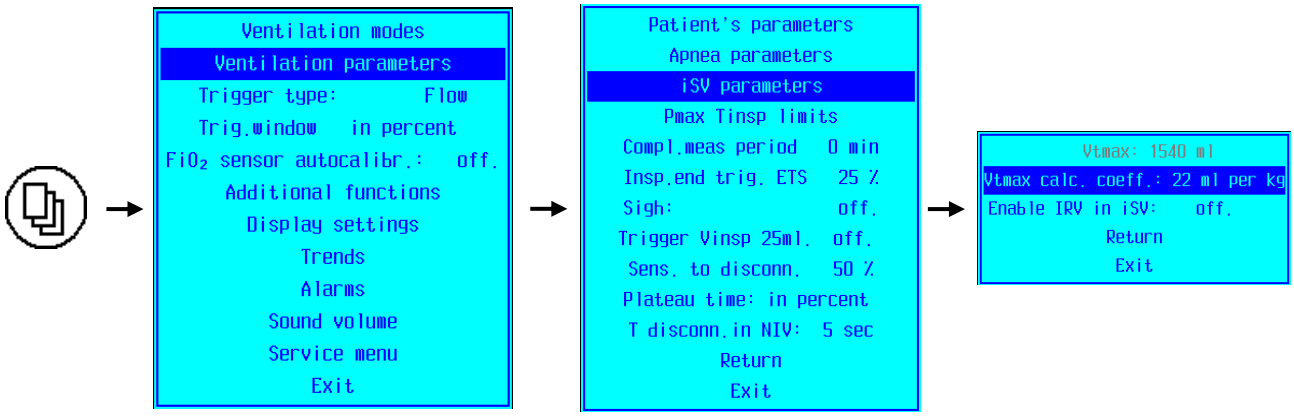


Table 4.6. Parameters of apnea ventilation

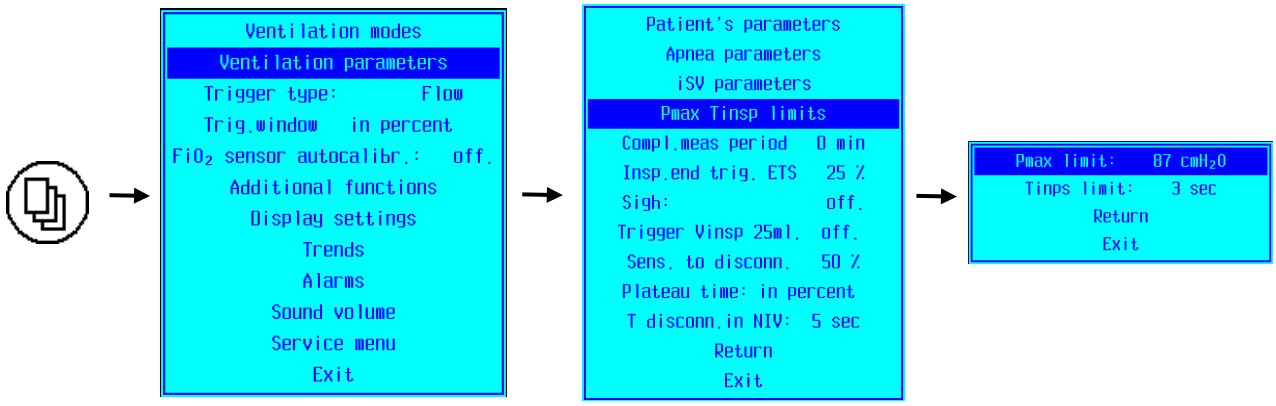
Designation of parameter	Description of parameter	Values
Control	Controlled ventilation with volume or pressure control	by volume, by pressure
Piapnea	Inspiratory pressure above apnea PEEP level in the apnea mode: - child mode - adult mode	 10 - 25 cmH_2O 10 - 80 cmH_2O
Vapnea	Tidal volume in the apnea mode: - child mode - adult mode	 10 - 400 ml 200 - 2000 ml
RBapnea	Respiratory rate in the apnea mode: - child mode - adult mode	 15 - 60 ^{1}/min 8 - 60 ^{1}/min
Tapnea	Time of transition to the apnea mode after detection of apnea: - child mode - adult mode	 10 - 20 s 10 - 60 s

4.8.3 Menu of iSV mode parameters



Designation of parameter	Description of parameter	Values
Vtmax calc. coeff.	Sets the level of inspiratory volume limitation Vtmax, at that Vtmax is calculated automatically Vtmax = Vtmax calc. coeff. x IBW, where IBW – ideal body weight (see it.4.8.1). (default value 22 ml per kg)	7 - 30 ml per kg
Enable IRV in iSV	Enable/disable of the inverse mode of ventilation when inspiration is longer than expiration (default value off).	off/on

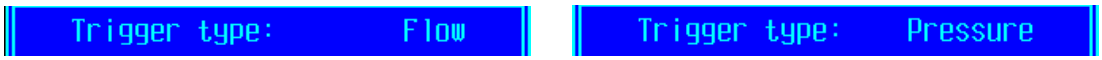
4.8.4 Menu of Pmax, Tinsp limits



Designation of parameter	Description of parameter	Values
Pmax limit	Allows to increase the upper limit of Pmax to 105 cmH_2O (line is available only in the CMV/VCV, CMV/PCV, SIMV/VC, SIMV/PC, SIMV/DC, PCV/VG modes at the adult type of patient)	87, 105 cmH_2O
Tinsp limit	Allows to increase the upper limit of inspiratory time Tinsp to 10 s (line is available only in the CMV/VCV, CMV/PCV, SIMV/VC, SIMV/PC, SIMV/DC, PCV/VG modes at the adult type of patient)	3, 10 s

4.9 Setting of the type of inspiration trigger

The ventilator has two types of inspiration triggers - flow and pressure.



The trigger is intended for activation of the inspiration process when it detects patient's attempts to spontaneous breathing. Flow trigger is triggered, if it detects that inspiratory flow of the patient is greater than the threshold value. The pressure trigger is started when pressure drop in the circuit caused by inhalation of the patient is greater than the threshold value.

Trigger flow is preferable because it usually allows the patient to breathe with less effort. An additional criterion of flow triggering is the excess of the inspiration volume of 25 ml that provides triggering at the slow spontaneous breaths.

Enter the main menu of device to set type of the inspiration trigger (see it. 4.6). This automatically sets the correct sensitivity parameter Ftrig or Ptrig, which is displayed in the right window of the set parameters area (see Figure 4.4, position 13).

Designation of parameter	Description of parameter	Values
Ftrig	Flow trigger sensitivity: - child mode - adult mode	 0.5 …10 lpm 1…20 lpm with step of 0.5 lpm*
Ptrig	Pressure trigger sensitivity	0.5 …20 cmH_2O with step of 0.5 cmH_2O

** - in the range up to 3.0 lpm –with step of 0.1 lpm*

The sensitivity of the trigger is a parameter that determines the minimum value of the patient's respiratory effort required to run the spontaneous inspiration support algorithm.

In the NIV mode flow trigger is not used because its operation is impossible in the presence of leak. The algorithm of the inspiratory trigger in NIV has two simultaneous criteria:

- The first one is similar to the pressure trigger of other modes (Ptrig is limited to 10 cmH_2O).
- The second one is unique for the NIV and applies only in the NIV mode. The ventilator compares the flow of the patient with the same flow but delayed for 0.3 seconds. This operation is performed by control microprocessor of the ventilator.

If the difference between the flows reachs 10 lpm, device makes a decision about detection of spontaneous inspiration. This criterion is not susceptible to leakage and allows the device to work reliably at unpressurized breathing circuit (mask).

An additional criterion of activation of the inspiratory trigger is excess of the inspiratory volume of 25 ml. That allows the triggering at the slow spontaneous breaths.

In the CMV / VCV, CMV / PCV and PCV-VG modes, the flow and pressure triggers can be disabled (has Off position).

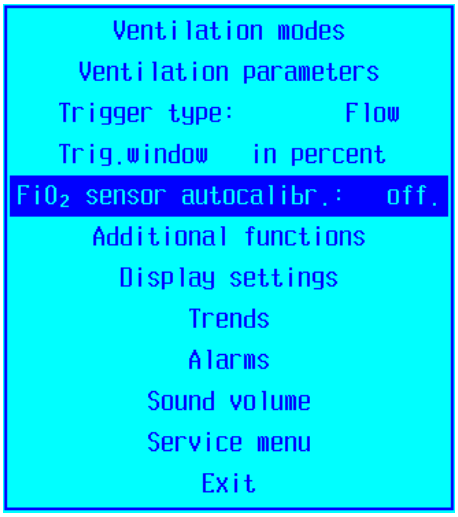
ATTENTION!

Do not set high trigger sensitivity of 1 - 2 lpm (1 cmH_2O) without necessity. It can cause false triggering because of different kinds of noise of auto triggering.

4.10 Automatic calibration of the oxygen sensor

The "Automatic calibration of the oxygen sensor" function provides the ability to accurately measure of FiO_2 at the changing of the external conditions: temperature, pressure or aging of oxygen sensors.

Auto calibration of oxygen sensor is switched on in the main menu:

Enter the menu:  

When the function is on, periodic monitoring of mismatch between the sensor readings of FiO_2 and set value of FiO_2 is conducted. If the mismatch is greater than the absolute value of 3 %, the FiO_2 sensor is automatically calibrated. The display shows message about the oxygen sensor calibration. Calibration is performed without stopping of ventilation with the O_2 level of 21 %, so there is short-time (about 1 min) decreasing of FiO_2 to 21 %. Upon completion of the calibration, FiO_2 value is restored and message about the results of the calibration is displayed.

The set parameter of oxygen sensor automatic calibration is retained at the change of mode, patient type, switching off the device.

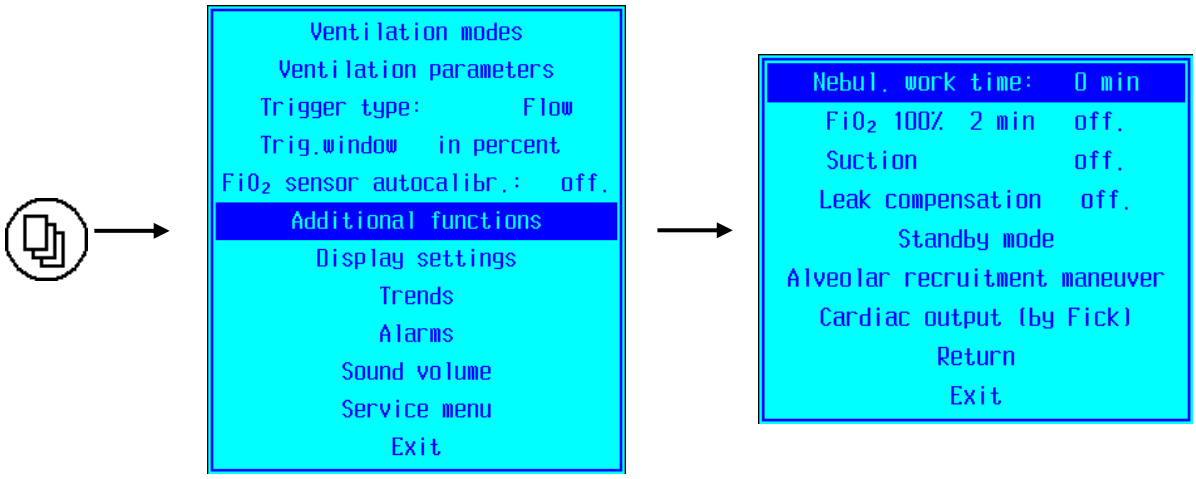
4.11 Additional functions

Additional functions of the ventilator include:

- Alveolar recruitment maneuver;
- Oxygenation;
- Suction;
- Standby mode;
- Leak compensation;
- Manual breath (manual ventilation);
- Screen lock;
- "Freezing" / analysis of graphs;
- Display brightness control (night or day mode).

Selection of the desired additional function is performed by the corresponding icon on the main screen of the device (see Figure 4.4, position 5).

Enabling of some additional functions is available through the submenu of additional functions (entrance through the main menu or with the button on the front panel of the ventilator):



4.11.1 Alveolar recruitment maneuver

Current procedure is active only in CMV/PCV and CMV/VCV modes, with the type of patient "Adult".

Activation of the function is available through [Menu] → [Addtitional functions] → [Alveolar recruitment maneuver] or icon on the main screen.

Enabling of function is impossible in the following cases:

- If the type of patient «Child»;
- if set PEEP exceeds 22 cmH_2O;
- at non-compliance with the condition Pmax – PEEP – Pi – 5 ≥ 3 cmH_2O;
- at active ventilation modes other than CMV/VCV, CMV/PCV;
- if the "Sigh", "Leak compensation" or "Suction" function is enabled.

PEEP increment value is set in the menu. It can be changed in the range from 3 to 25 cmH_2O. By clicking on the "Start" row, the maneuver starts and the icon changes its color to indicate the activation of the mode.

When the procedure "Alveolar recruitment maneuver" is enabled by the operator or automatically by time, the following occurs:

- After the next inspiration new PEEP value is set equal to PEEP + PEEP incr.;
- 2 breaths are performed. Inspiration pressure in the CMV/PCV mode is equal to Pi + PEEP incr., in the CMV/VCV mode inspiration volume is not changed;
- Returning to the initial ventilation settings. The procedure is repeated automatically after 3 minutes. Alveolar recruitment maneuver is turned off at the activation of the functions "Sigh", "Leak compensation", "Suction".

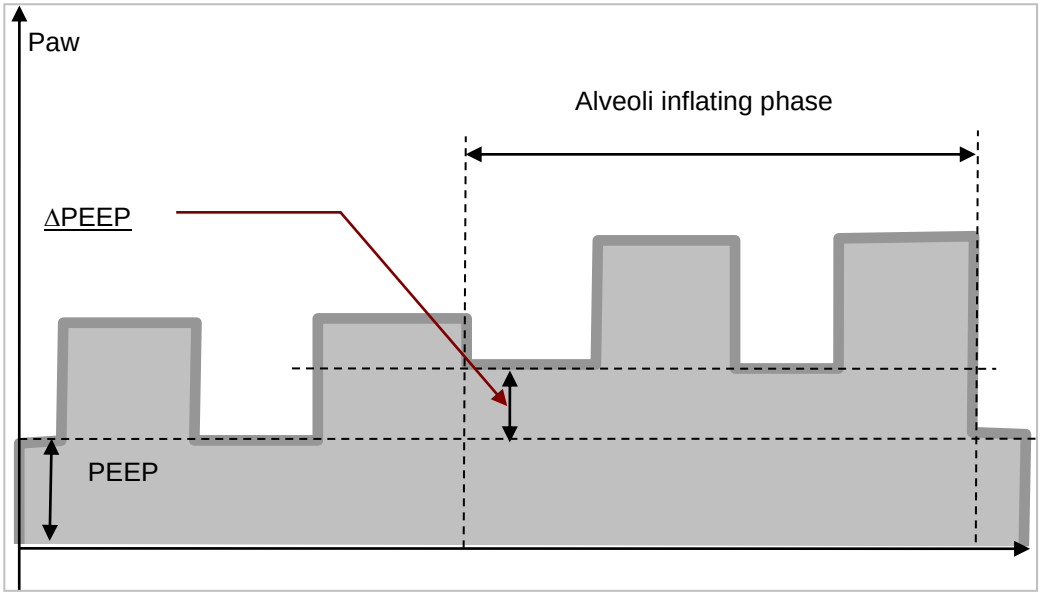
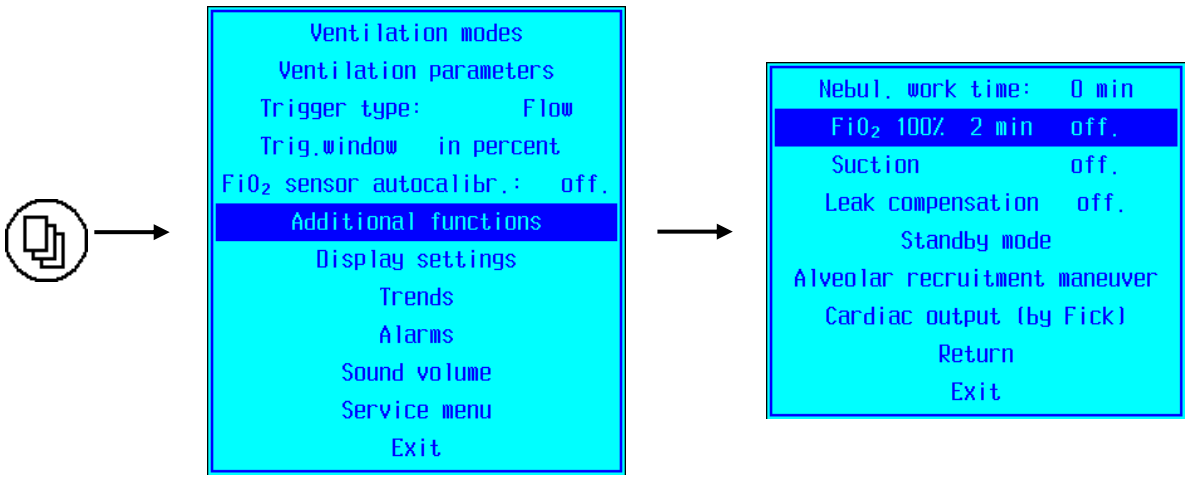


Figure 4.7 – Paw waveform at the active phase of the alveolar recruitment maneuver

To disable the maneuver click on the "Stop" row (during procedure it replaces the row “Start”) in the "Alveolar recruitment maneuver" submenu, the icon will change color to indicate that mode is off. The device automatically disables the alveolar recruitment maneuver at the transition to another ventilation mode. At the occlusion, disconnection or apnea deactivation also occurs with subsequent recovery at the returning to the initial mode of ventilation.

4.11.2 Oxygenation

Activation of the function is available through [Menu] → [Additional functions] → [FiO_2 100% 2 min] or [O_2] icon on the main screen.



In the oxygenation mode 100 % oxygen is provided for 2 minutes. Field of oxygen concentration setting in supplied breathing mixture becomes yellow and contains the countdown timer that shows the time left before the end of oxygenation. At clicking on this field or icon [O_2] oxygenation is disabled.

4.11.3 Suction

Activation of the function is available through [Menu] → [Additional functions] → [Suction] or icon [Suct.]

After activation of the function for 3 minutes "Oxygenation" is performed (see it.4.11.2). At this time the ventilator waits for disconnecting of the patient. If the disconnection does not occur, the device returns to the previous mode, the "Suction" function is switched off.

If disconnection occurs, the device stops ventilation. Window with the message of disconnection and with timer showing time of its beginning appears. Operation with the interface and alarms are blocked. The ventilator is waiting for connection of patient after suction. If connection does not occur within 2 minutes, the device activates sound alarm.

After connection device resumes ventilation. Oxygenation is swiching for 2 minutes.

Suction can be stopped during operation by disabling "Suction" or "Oxygenation" function through the menu or through the icon.

4.11.4 Standby mode

Activation of the function is available through [Menu] → [Additional functions] → [Standby mode] or through the icon STOP on the main screen.

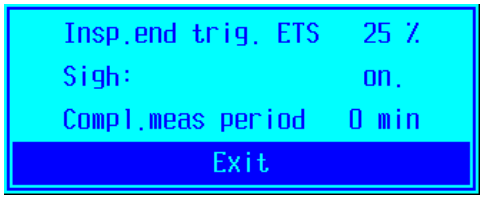
Enabling of this mode leads to:

- Stopping the ventilation;
- Blocking of all alarms;
- Blocking of the operation with the interface except encoder, button "Start" and “Vent.param”;
- Reset (cancellation) of all selected additional functions.

To resume the ventilation press the encoder or "Start" button.

To edit or save ventilation parameters press the button "Vent. param".

At the clicking on this button "Parameters" menu appears:



Menu allows to change the indicated ventilation parameters. At the clicking on the "Exit" item, menu closes and the screen shows information window of standby mode.

4.11.5 Leak compensation

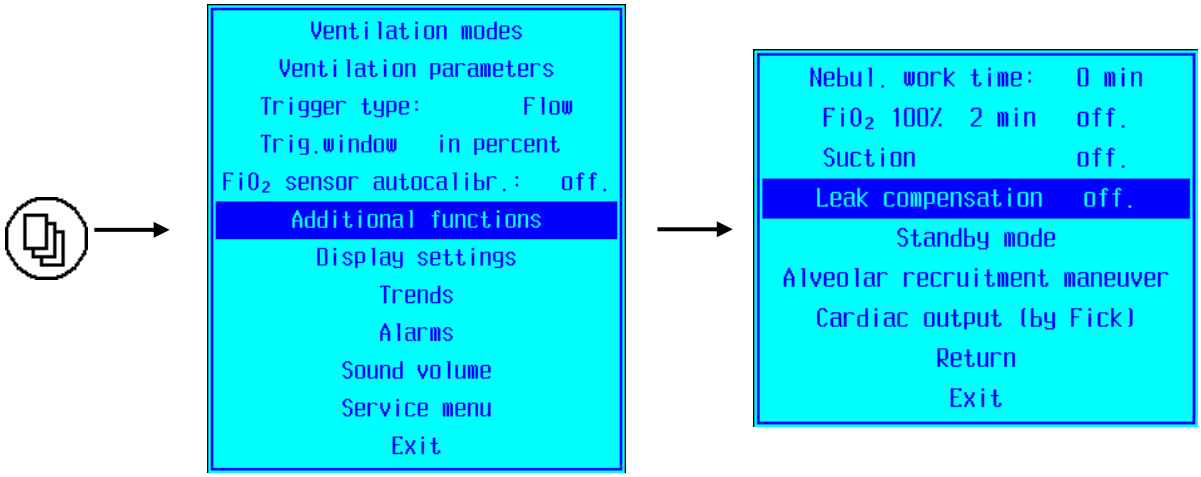
This function is used for ventilation in the conditions when the tightness of the breathing circuit can not be ensured. However, the capabilities of the device to compensate the leakage are not unlimited and operator should take measures to decrease it as much as possible.

In presence of leakage it is recommended to set one of the pressure-controlled modes. In modes with volume control or double control the accuracy of tidal volume is lower.

Leakage compensation is provided in all modes of ventilation.

In BiSTEP, ARPV, NIV, CPAP+PS modes leakage compensation is provided automatically by pressure control. As the ventlator tries to achieve the inspiratory pressure set by physician, the measured expiratory volume reflects the tidal volume received by the patient.

In other modes activation of the leakage compensation is available through [Menu] → [Additional functions] → [Leak compensation] or through the Leak icon on the main screen.



When the leakage compensation function is active, the device performs the following actions:

- tidal volume is increased by the level of leakage;
- base flow (support flow) in the phase of PEEP maintenance is increased so that despite the leakage, PEEP remains at the predetermined level.

In the ventilation modes with volume control the device adds a measured amount of leakage to the inspiration volume set by the user V_T. However, the addition can not exceed 100 % of V_T. This limitation minimizes the risk of harm to the patient in case of errors in the leakage determination due to technical failures or any other reasons.

When leakage compensation is disabled, base flow (support flow) of device is 10 lpm. It is necessary for the PEEP maintenance and operation of the flow trigger.

Activation of leakage compensation function automatically increases the base flow so that base flow through the expiration valve is 10 lpm. This mechanism ensures the maintenance of PEEP with presence of leakage and allows the normal operation of the inspiratory triggers.

The device can successfully operate up to the value of the base flow of 25 lpm with PEEP of 20 cmH_2O. It allows to compensate for significant leakage. If leakage is greater, deviation from the set level of PEEP or false activation of inspiratory trigger can occur. If this happens, check the breathing circuit and eliminate the cause of the leakage, or fix the position of the endotracheal tube or reduce the sensitivity of the inspiratory trigger.

Significant leakage can lead to the retention of spontaneous inspiration, due to the fact that the inspiratory flow will not fall to the level of activation of the expiratory trigger (the trigger of the end of inspiration). To normalize the situation set the expiratory trigger level higher than leakage.

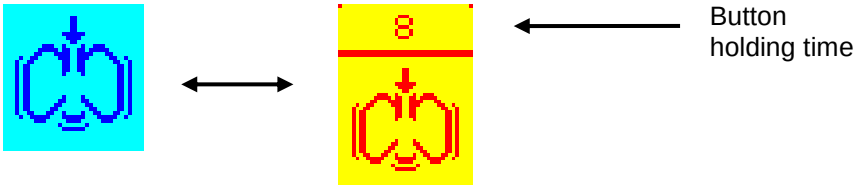
If necessary operator can use the face mask (mask for non-invasive ventilation) instead of the endotracheal tube in all modes of the ventilation with leakage compensation, as the step of separation of the patient from the device. A feature of this mode unlike the NIV mode is presence of the hardware breaths.

4.11.6 Manual breath (manual ventilation)

The "Manual breath" function (single mandatory breath) is intended to accelerate the start of ventilation at the suction, especially in conditions of spontaneous breathing, for lung recruitment maneuvers, for diagnostic (X-rays) and treatment (synchronization with aerosol administration of dose of medicines) procedures.

View of manual breath activation button:

Button is located in the row of icons. View of inactive and active button of activation of the manual breath is shown below.



Running the function:

The function is running at pressing the appropriate button by the user. If the function is initialized by the operator in the inspiratory phase - the phase is extended until the button is released, but not more than 15 seconds.

If the function is initialized by the operator in the expiratory phase - expiration is interrupted, extraordinary breath with the current settings is started. Inspiraiton lasts until operator releases the button, but not more than 15 seconds, or at the end of the current criterion of inspiration, if the button is released before.

If the pressing is in forbidden phase of the expiration - activation of an extraordinary inspiration begins at the end of the forbidden expiratory phase. Additionally the inspiration is delayed, if pressing coincided with forbidden phases in BiSTEP or APRV mode.

If the button is pressed more than 15 seconds, then at the end of 15 seconds the inspiration is interrupted and ventilation with the current settings begins. Pressing the button is ignored. To reactivate the function, firstly release the button.

Timer shows the holding time of the button. Through 15 seconds the counter stops. When user releases the button, the counter disappears.

If the nebulizer is active, at clicking "Manual breath" button it begins operation, and continues during the set by physician inspiratory time or until the beginning of the formation of the plateau.

Running of the manual breath in different modes:

In CMV, PCV-VG modes manual breath is performed as a hardware breath with the current parameters. Inspiratory volume should correspond to the set V_T. If the button is held longer than Tinsp, in modes with volume control flow must be stopped at the moment of Tinsp.

In the PCV-VG mode (similar to SIMV/DC), if the previous PCV breath is incorrect, manual breath will be performed as a test one.

In the SIMV mode manual breath is performed as hardware breath with the current parameters. Inspiratory volume in the volumetric modes should correspond to the set V_T. If the button is held longer than Tinsp, flow must be stopped at the moment of Tinsp.

In the CPAP+PS and NIV modes manual breath is performed as hardware breath with pressure control with pressure Pi = PS with the current rate of pressure rise. If the button is released

before the end of inspiration, inspiration continues to the activation of the expiratory trigger. Otherwise inspiration ends when the button is released or time is passed.

In the BiSTEP mode manual breath on the Plow phase is performed as hardware breath with pressure control with pressure Pi = PS with the current rate of pressure rise.

On the Phigh phase, if Phigh ≥ Plow + PS manual breath is not performed. If Phigh < Plow + PS manual breath is performed by the usual rules with transition to the expiration by an algorithm similar to CPAP+PS.

On the Plow phase manual breath is performed similarly to the CPAP+PS mode.

In the APRV mode on the Plow phase manual breath is not performed. If the button remains pressed, at the transition to Phigh, inspiration to pressure Phigh + PS is performed.

In the APRV mode on the Phigh phase, manual breath is performed to the pressure Phigh + PS, with transition to the expiration by an algorithm similar to CPAP+PS.

In iSV mode function “Manual Breath” is not available.

Running of "Manual breath" function together with compliance measurement maneveur and AutoPEEP

If at the inspiratory phase procedure of compliance plateau formation was performed and duration of inspiratory phase was more than (set inspiratory time + maximum compliance plateau duration), measurement of compliance and resistance will be not performed.

If manual breath is activated at the moment of formation of AutoPEEP measurement procedure, procedure will be immediately stopped, AutoPEEP will be not measured and previously measured AutoPEEP value will be displayed.

AutoPEEP measurement procedure will not be called if manual breath is initiated.

Manual ventilation

If necessary the physician can perform manual breaths with the desired frequency, thereby performing the manual ventilation.

4.11.7 Screen lock

Screen lock function is used for protection against inadvertent changes of parameters. Enabling is performed via icon  on the main screen. At the same time:

- The whole touch screen is locked, in the bottom part of the screen yellow message "Touch screen is locked" is displayed.
- Data output continues as usual. Alarms are not blocked.
- Encoder and button of temporarily disabling of the audible alarm is not blocked.

Press the encoder to unlock the screen. At pressing the menu "Unlock touch screen? Yes. No." is shown. If user selects "Yes" line by encoder handle the lock is released. If user selects the line "No" lock retains.

4.11.8 "Freezing" / analysis of graphs

The "freezing" of graphic curves is used for detailed analysis of the respiratory cycle and viewing via the encoder of instantaneous values of the curves. The function is active when the set number of output graphs is from 1 to 3.

The activation function is performed via  icon on the main screen, at the same time:

- graphic representation of the icon becomes active (dark blue);
- current scale of the graph is saved;
- the last recorded point of the curve is drawn at the end right position;
- all previous points of the curve are drawn in proportion to the left;
- vertical marker line appears on all charts, corresponding to the time of pressing the freeze button;
- line of instantaneous values of the curves corresponding to the position of the marker line appears above graphs;
- marker line is moved to the desired position by encoder;
- at the repeated pressing the icon, "freezing" of the curves is canceled. Current cycle begins to draw from the random moment.

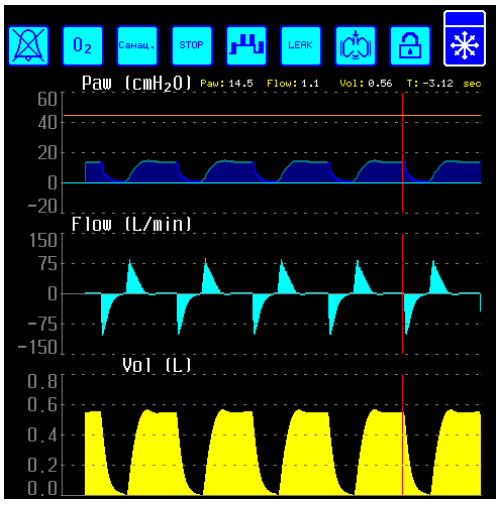


Figure 4.8 – Pressed button "Freezing"

At rotating the encoder marker line moves to the left/right and accordingly to its position instantaneous values including time are changed. Moving the marker line can also be done by touching in the certain area of graphs. Time is counted down from the moment of pressing (eg. – 3.21 s).

4.11.9 Display brightness control

The function allows to change the display brightness separately for the day and night operation mode with the icon  or  on the main screen of the device (see Figure 4.4, position 9).

Night mode of the display is switched automatically from 24 pm to 5 am.

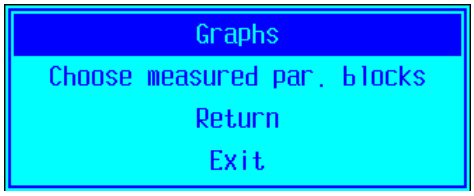
By clicking on the icon display mode is switched to the opposite (regardless of the time).

Brightness of the display can be adjusted through the [Menu] → [Service menu] → [Calibration] → [CIND] → [Day brightness] or [Night brightness]. The brightness of the day screen varies

from 100 to 50 % with 10 % step. Default value is 100 %. Brightness in the night mode varies from 100 to 30 % with 10 % step. Default value is 60 %.

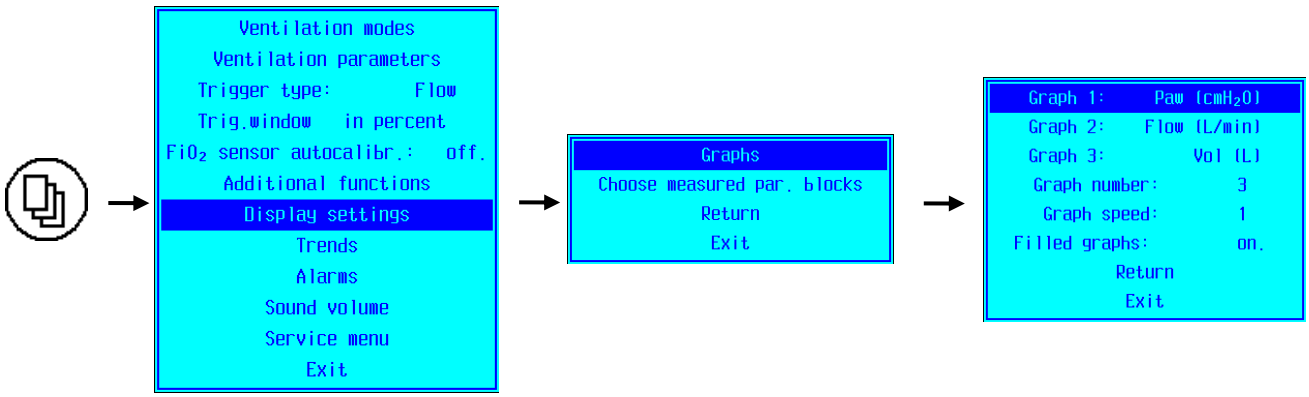
4.12 Display settings menu

Enter the menu through the main menu of device [Menu] → [Display settings] (see it. 4.6).



4.12.1 Graph setting menu

To enter the menu press:



Selection of the quantity and type of graphs

- Set "Graph number" parameter (from 1 to 4).
- Set the "Graph speed" parameter (1, 2, 4). Default value of speed for adult type of patient is 1, for pediatric one is 2.
- Select function for each graph from the following list:

Paw	Airway pressure waveform
Flow	Flow waveform
Vol	Volume waveform
Loop	Loop curves: volume/flow, volume/pressure, flow/pressure, volume/auxiliary external pressure
PCO_2, mmHg	Capnogram [mmHg]
PCO_2, %	Capnogram [%]
PO_2, %	Oxigram [%] (for metabolism measurement)
SpO_2	Photopletismogram (PPG)
iSV graph	Graph of iSV mode
Paux	Auxiliary external pressure waveform
VCO_2	Volume capnography waveform

Note: *Selection of the "Loop" graph is possible when the number of graphs is 1 or 4. Selection of iSV mode graph is possible when the number of graphs is 2 or 3.*

To select graph rotate the encoder, to select the desired graph push the encoder, to cancel press the "Menu" button.

Enable/disable filling of graphs

The function allows to select the view of the output curves in the form of outlines or filled graphs. Filled graphs have better contrast. Inspiratory phase of the respiratory cycle is highlighted with blue for the hardware and white for spontaneous breaths. In addition the start of spontaneous inspiration is shown with crimson vertical bar.

To activate the function set "Filled graphs" in the "On" position in the submenu "Graphs".

Displaying of graphs

The scale of pressure graph is selected by user of the Pmax value and in maximum case may be -20…120 cmH_2O.

The scale of the rest of the graphs is selected automatically - once for the entire period of the sweep (at the moment of the transition of the graph through the right border), if the scale change criterion works.

Pressure graph Paw shows:

- Marker of the maximum inspiratory pressure Pmax (blue line).
- PEEP marker (if PEEP > 0 cmH_2O) (light blue line).
- Pressure curve (green or blue line, depending on the inspiration/expiratory phase).

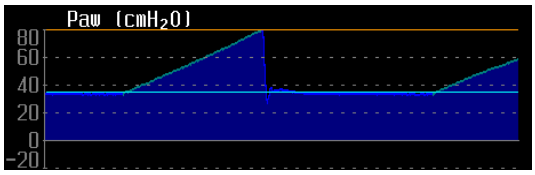


Figure 4.9 – Pressure in the patient airways (Paw)

Scale of flow rate graph is automatically selected in the range ±250 lpm, depending on the maximum flow rate in the current mode.

All graphics display instant, current values of parameters in real time and are synchronized on the common time base.

Displaying of spirometry loops

Spirometry loops are displayed in the mode of 1 and 4 graphs.

At selection of spirometric loop and displaying of 1 graph, two interactive buttons TYPE and REF are displayed. At the activation of TYPE button, menu of selection of spirometric curve type appears on the screen:

- volume/flow V-F,
- volume/pressure V-P,
- flow/pressure F-P,
- vol/pressure V-Paux (option).

Press the appropriate line to select the desired loop type. Press the TYPE button again to hide the selection of spirometry loop type.

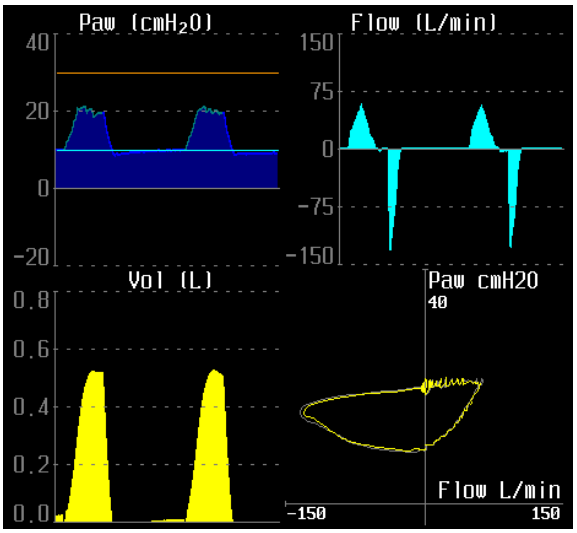
Simultaneously with the current spirometric curve, previous or reference loop is displayed on the screen in gray.

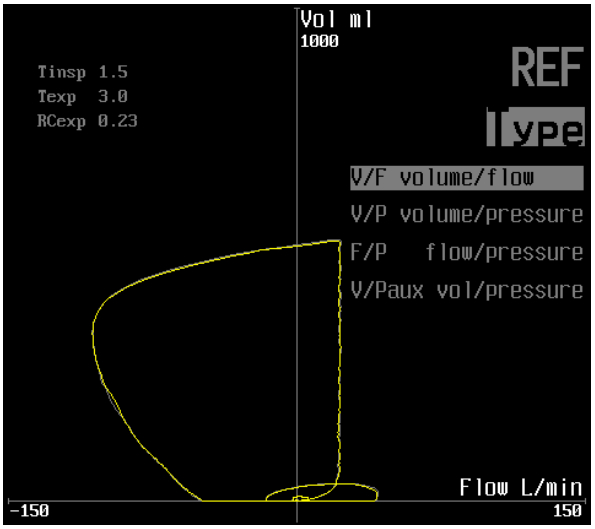
Setting of the support (reference) loop is performed by pressing the REF button. At pressing REF:

- current loop becomes the reference at the end of the respiratory cycle;
- reference loop is fixed in grey color;
- line of reference loop fixing time is displayed.

At the repeated pressing of REF, the previous loop is selected as reference. The reference loop is updated at every new cycle. Time line will be hidden.

In the mode of displaying of 4 curves the last selected reference loop is displayed.





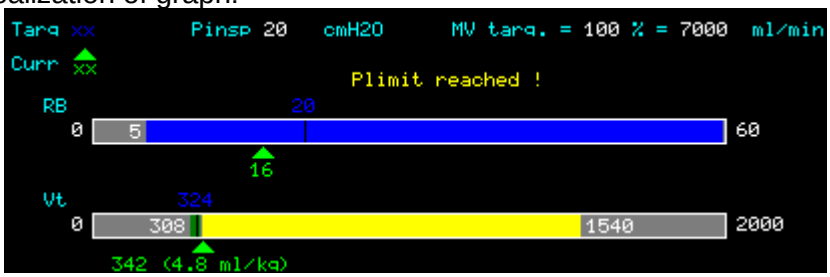
Displaying of iSV graph

iSV graph allows to estimate the optimal choice of parameters of ventilation by algorithms of current ventilation mode. The iSV graph displays the respiratory rate and tidal volume scales.

iSV graph shows:

- limits of safe ventilation by RB and Vt, top and bottom values (in graphical and numerical view);
- target values of RB and Vt (in graphical and numerical view);
- real values of RB and Vt (in graphical and numerical view);
- target minute ventilation values in % and ml/min;
- adaptation minute ventilation values in % and ml/min;
- values of the current inspiratory pressure for hardware breaths;
- values of the current support pressure for spontaneous breaths.

Example of realization of graph:

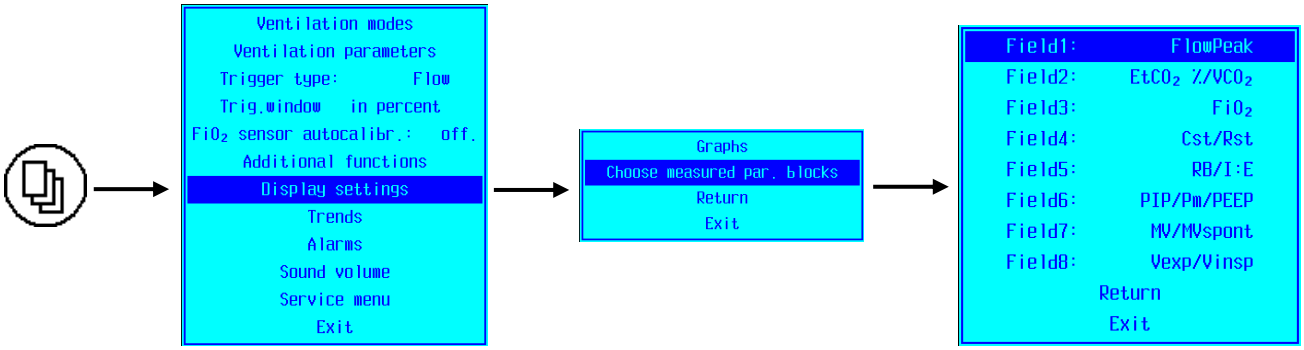


Inspiraiton volume Vtmax can be limited in [Menu] → [Ventilation parameters] → [iSV parameters].

ATTENTION!

Changing of the graph indication mode does not effect on the current lung ventilation mode.

4.12.2 Menu of settings of measuring parameter blocks



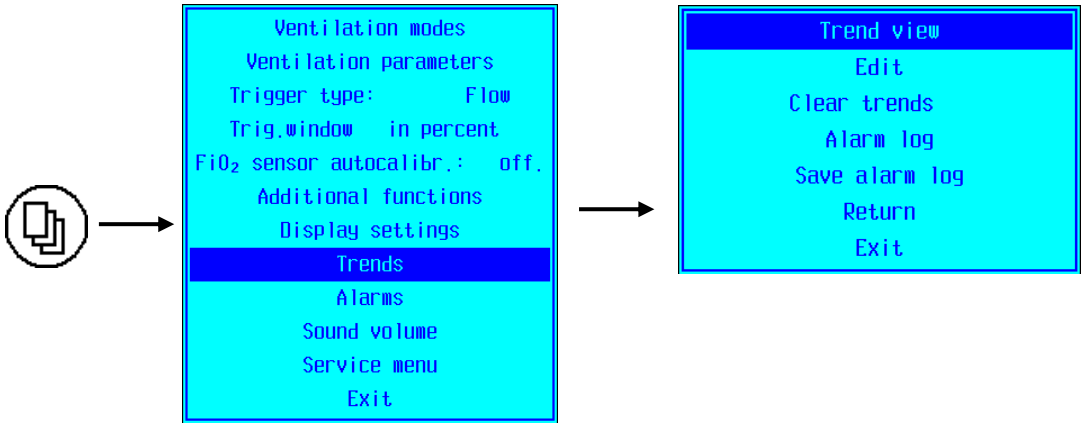
Menu allows to configure the areas of additional and the main monitoring parameters displaying (see Figure 4.4, positions 1, 12).

Table 4.7. The list of monitoring parameters that can be selected in any of the displayed fields of the screen

1.	Empty	No data
2.	AutoPEEP	Residual pressure level in lungs
3.	C/R (LSF)	Dinamic compliance/resistance
4.	Cst/Rst	Static compliance/Static resistance
5.	$EtCO_2$ %/VCO_2*	Concentration of CO_2 in the exhaled mixture / Elimination of CO_2 per minute
6.	$EtCO_2$ mmHg/$FiCO_2$	Partial pressure of CO_2 in the exhaled / inspired mixture in mmHg
7.	FiO_2	Fractional concentration of inspired oxygen
8.	fspont	Frequency of spontaneous breaths
9.	FlowPeak	Peak inspiratory flow
10.	Leak	Leakage flow from the breathing circuit
11.	MV/MVspont	Minute volume / Minute volume of spontaneous breaths
12.	MValv*/Vd*	Minute alveolar ventilation / Functional dead space
13.	Paux	Auxiliary external pressure
14.	Ptp	Transpulmonary pressure
15.	PIP/Pm/PEEP	Peak inspiratory pressure / Mean pressure for the respiratory cycle / Positive end-expiratory pressure
16.	Pplat	Plateau pressure
17.	RB/I:E	Respiratory rate / Inspiratory:expiratory ratio
18.	Valv/Vd:Vexp*	Alveolar ventilation / Functional dead space: tidal volume
19.	Vexp/Vinsp	Expiratory volume / Inspiratory volume
20.	CO/VCO_2*	Cardiac output (by Fick) / Elimination of CO_2 per minute

** - parameters of volumetric capnometry VCO_2, Valv, MValv, Vd and cardiac output (CO) by Fick are available only if device is equipped with mainstream capnometer, volume capnometry module and function of cardiac output.*

4.13 Menu of view of trends and alarm log



"Trend view" parameter

At the selection of "Trend view" parameter the device displays the trend window:

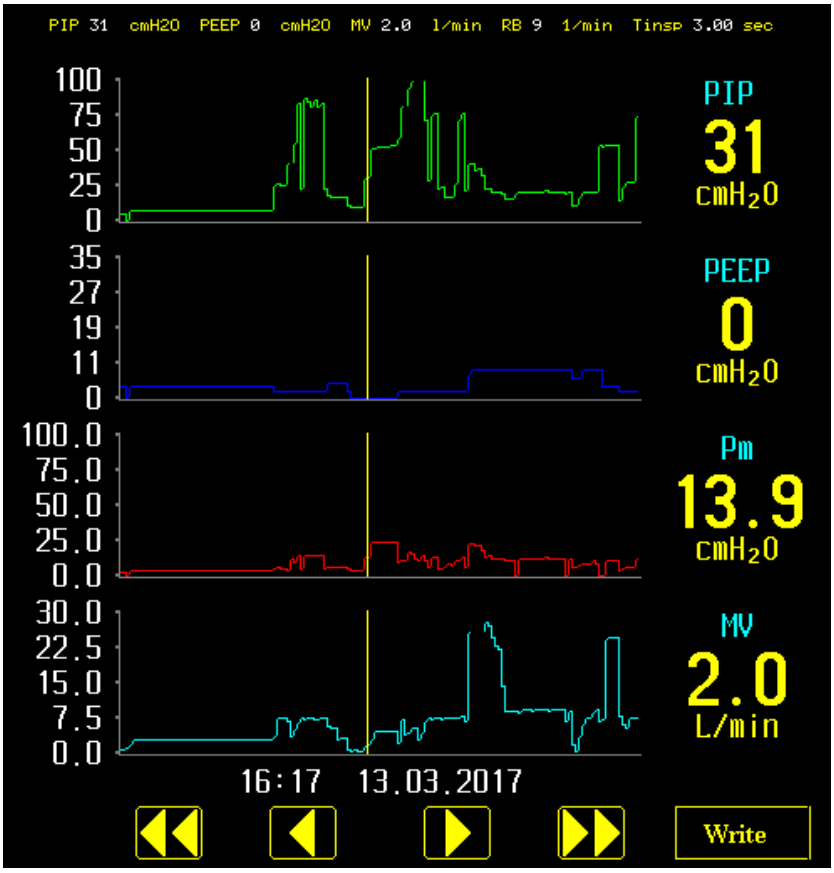


Figure 4.10 - Window of trends

In the main part of the screen from 1 to 4 trend graphs are displayed (according to the choice of user). In the top part of the screen 5 additional fixed trends associated with graphs are displayed, they are:

- PIP (peak inspiratory pressure);
- PEEP (positive end-expiratory pressure);
- MV (minute volume);
- Tinsp (inspiratory time);
- RB (respiratory rate).

All trends are synchronized and linked to the same time point selected by the cursor on the graph.

Moving the cursor is performed by rotating the encoder or by pressing the touch buttons at the bottom part of the trend window. Incorrectly measured and unmeasured parameters are displayed as gaps in the graphs and as dashes in the value field. To the right of the trend, values at the selected moment are displayed. The bottom line displays the time and date of recording.

Trends are cyclically recorded in non-volatile memory and restored when the power is turned on. Duration of trends is the last 240 hours of device's operation.

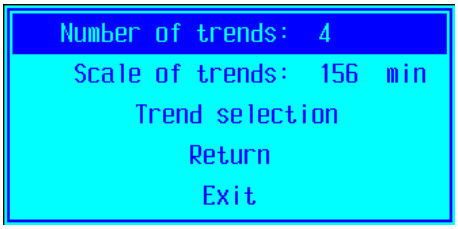
To return from the trend window to the main mode press the "Menu" button or click the encoder.

ATTENTION!

Trend review is carried out without interrupting of ventilation. Measurement and indication of the ventilation parameters are also saved.

"Edit" parameter

Using "Edit" parameter operator can set time scale of the main trends (the width of the trend window in minutes), their number:



and displayed parameters (this menu is also available by pressing on the area of displaying parameter values that is to the right of the area of displaying trends):

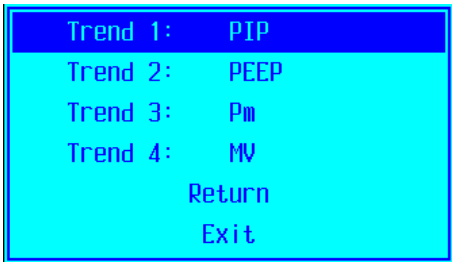


Table 4.8. List of parameters displayed in the form of trends

№	Parameter	Name	Meas.units
1	PIP	Peak inspiratory pressure	cmH_2O
2	PEEP	Positive end-expiratory pressure	cmH_2O
3	Pm	Mean pressure for the respiratory cycle	cmH_2O
4	MV	Minute volume	lpm
5	MVexp	Expiratory minute volume	lpm
6	MVspont	Minute volume of spontaneous breaths	lpm
7	Vexp	Expiratory volume	ml
8	Vinsp	Inspiratory volume	ml
9	Tinsp	Inspiratory time	s
10	RB	Respiratory rate	^{1}/min
11	Leak	Leakage flow from the breathing circuit	lpm
12	Cst	Static compliance	ml/cmH_2O
13	Rst	Static resistance	$cmH_2O{\cdot}s/l$
14	CO_2	Partial pressure of CO_2 in the exhaled mixture ($EtCO_2$)	mmHg
15	SpO_2	Oxygen saturation of arterial blood hemoglobin	%
16	PR	Pulse rate	^{1}/min
17	AutoPEEP	Residual pressure level in lungs	cmH_2O
18	RCexp (t)	Expiratory time constant	s
19	SI	Stress index	cmH_2O
20	Wvent	Work of the ventilator breathing	J/l
21	Wspont	Work of the patient breathing	J/l
22	PEEPtot	True pressure level in lungs at the end of expiration	cmH_2O
23	FiO_2	Fractional concentration of inspired oxygen	%
24	Ccirc	Compliance of the breathing circuit	ml/cmH_2O
25	Rcirc	Resistance of the breathing circuit	$cmH_2O{\cdot}s/l$
26	ExpEndFlow	Flow at the end of expiration	lpm
27	fspont	Frequency of spontaneous breaths	^{1}/min
28	RSBI	Rapid shallow breathing index	
29	I:E	Inspiratory:expiratory ratio	
30	Acc.charge	Residual accumulator capacity	%
31	VO_2	Oxygen consumption	ml/min
32	VCO_2	Elimination of CO_2	ml/min
33	RQ	Respiratiory quotient	rel. units
34	REE	Resting energy expenditure	kcal/day

"Clear trends" parameter allows the user to delete the previously stored in trends data. To activate this action enter the system password. To exit without clearing the trend press 4 times the encoder or press the "Menu" button.

"Alarm log" parameter

At the selection of the "Alarm log" device allows to view the list of alarms and events (turning the device on, switching between ventilation modes, diagnostic messages, used functions) with the name and priority of the alarm (messages are painted in different colors depending on their priority), the date and time of their occurrence and the alarm limit.

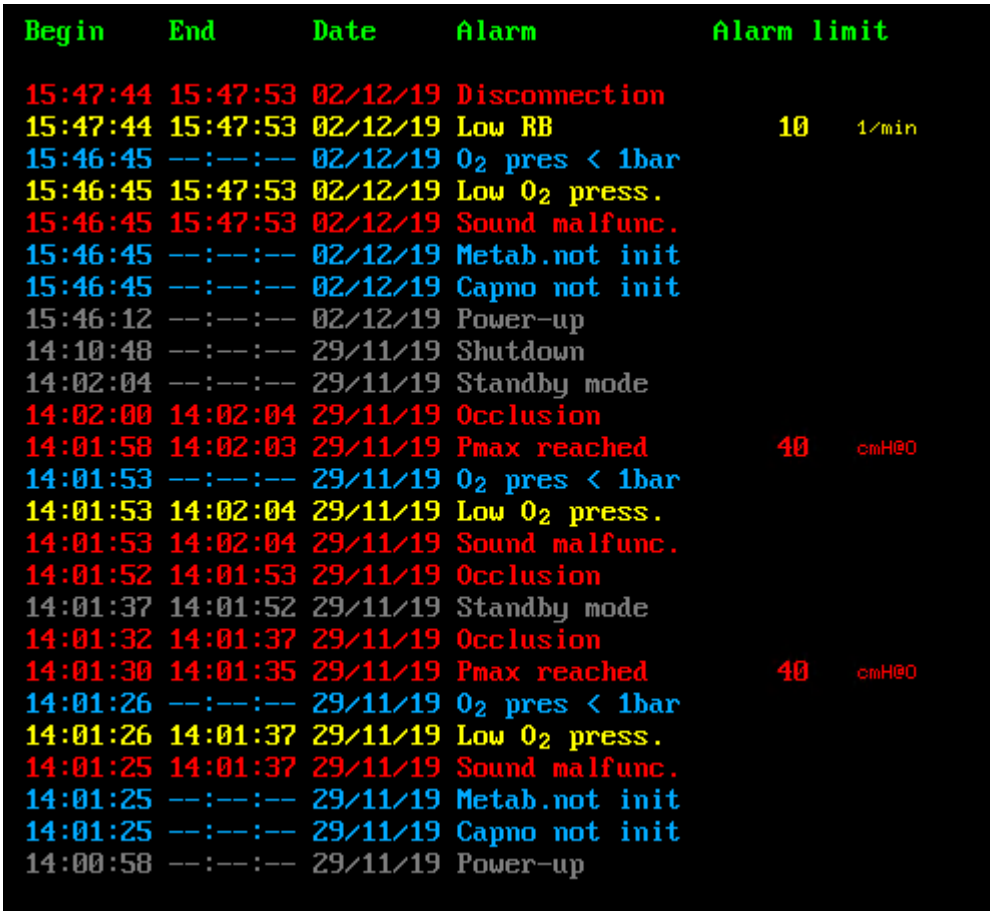


Figure 4.11 – Alarm log

Navigation in the alarm log is performed by rotating the encoder. To exit press the "Menu" button or the encoder. Alarms are logged cyclically. The log can hold at least 1 000 alarms. The log is stored in non-volatile memory.

"Save alarm log" parameter records the alarm log to removable media connected to the USB-port on the rear panel of device. Alarm log is stored in the file "AlarmJournal.csv", in csv format with the separation character ";" in CP866 coding.

4.14 Alarm settings menu

Enter the window through the main menu of ventilator (see it. 4.6).

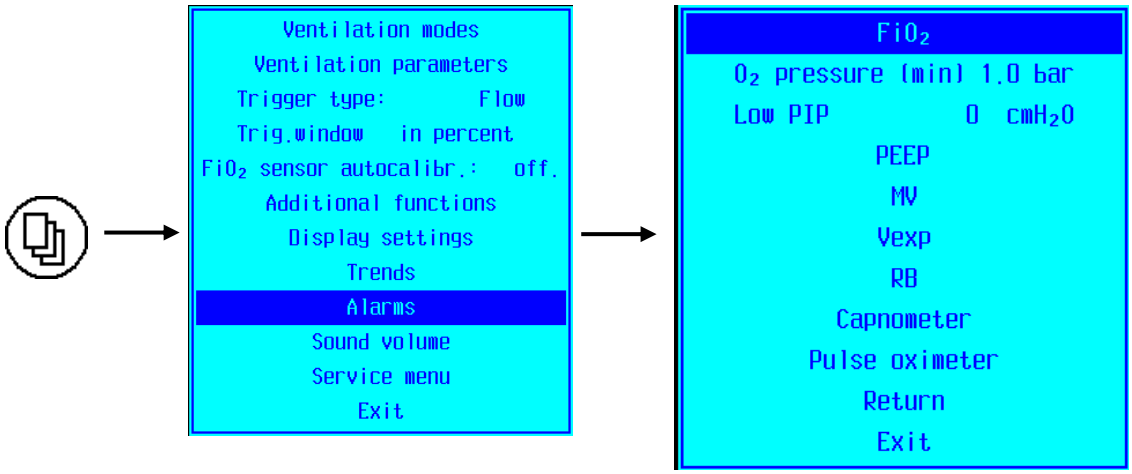


Table 4.9. Alarm threshold parameters

Line of the menu	Designation, description of parameters	Possible values	Default value
FiO_2	**FiO_2 sensor** – display of FiO_2 readings (dashes «---» are displayed in the «**off**» position)	on/off	on
	FiO_2 alarms – enable/disable FiO_2 alarms	on/off	on
	O_2 deviation – level deviation of measured concentration from set that triggers the alarm.	1…50 %, off	5 %
O_2 pressure (min)	Low oxygen pressure alarm threshold in the input line. The recommended values are 1.0, 1.5 bar (kgf/cm^2). Set "0.0" value only in case of ventilation from low pressure O_2 source or air.	0.0, 0.5, 1.0, 1.5 bar	1.0 bar
Low PIP	Low inspiratory pressure alarm threshold. "0" value means disabled alarm.	0…20 cmH_2O	0 cmH_2O
PEEP	**High PEEP** - top alarm threshold of PEEP	Low PEEP …50 cmH_2O	20 cmH_2O
	Low PEEP - bottom alarm threshold of PEEP. "0" value means disabled alarm.	0…10 cmH_2O (High PEEP)	0 cmH_2O
MV	**MV_max** – top alarm threshold of minute breathing volume.	MV_min…60 lpm	12 lpm
	MV_min – bottom alarm threshold of minute breathing volume.	0…MV_max lpm	2 lpm
Vexp	**Vexp_max** – top alarm threshold of expiratory volume.	Vexp_min… 6000 ml	6000 ml
	Vexp_min – bottom alarm threshold of expiratory volume.	0 … Vexp_max ml	0 ml
RB	**RB_max** – top alarm threshold of respiratory rate.	RB_min…120 ^{1}/min	40 ^{1}/min
	RB_min – bottom alarm threshold of respiratory rate.	1… RB_max ^{1}/min	8 ^{1}/min
Capnometer	**$EtCO_2$_max** – top alarm threshold of CO_2 partial pressure in exhaled air [mm Hg].	$EtCO_2$_min…100 mmHg	40

Line of the menu	Designation, description of parameters	Possible values	Default value
	$EtCO_2$_min – bottom alarm threshold of CO_2 partial pressure in exhaled air [mm Hg].	15… $EtCO_2$_max mmHg	15
	$EtCO_2$_max – top alarm threshold of CO_2 concentration in exhaled air [%].	$EtCO_2$_min…12 %	6
	$EtCO_2$_min – bottom alarm threshold of CO_2 concentration in exhaled air [%].	2… $EtCO_2$_max %	2
	Change measuring units – switches unit of measurement of CO_2	%, mmHg	mmHg
Pulse oximeter	**SpO_2_max** – top alarm threshold of SpO_2 – hemoglobin saturation of arterial blood by oxygen	from 90 % or from SpO_2_min to 100 %	100
	SpO_2_min – bottom alarm threshold of SpO_2 - hemoglobin saturation of arterial blood by oxygen	60... 95 % (SpO_2_max)	86
	PR_max – top alarm threshold of pulse rate	80 (PR_min)… 350 ^{1}/min	90
	PR_min – bottom alarm threshold of pulse rate	15…100 (PR_max) ^{1}/min	50
	Low pulse volume alarm	on/off	on

Changing and saving of parameters is carried out by the encoder. Values of alarm thresholds remain in non-volatile memory and are restored at power up in previous patient mode, except alarms "**FiO_2 sensor**", "**FiO_2 alarms**", "**O_2 pressure (min)**".

ATTENTION!

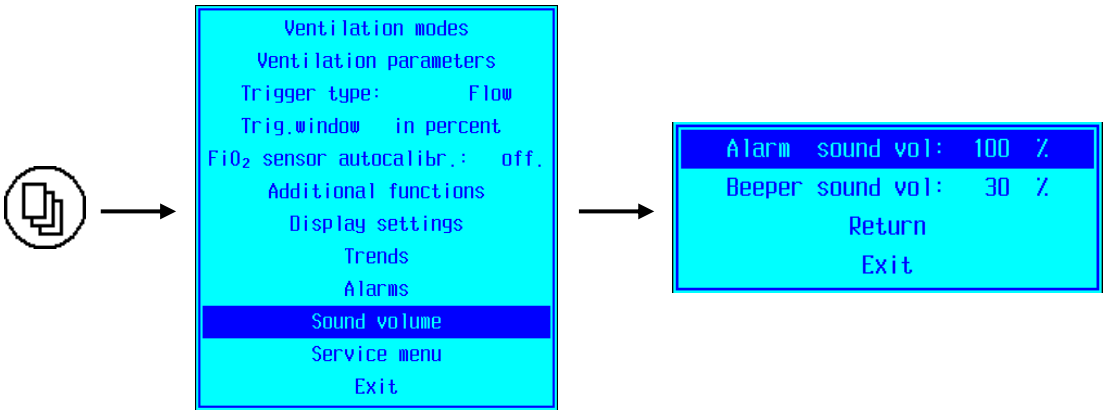
Always check that the alarm thresholds for the parameters are set correctly. Setting alarm thresholds to extreme values can make the alarm system useless.

ATTENTION!

Make sure that the preset alarm thresholds are appropriate for the patient first before starting ventilation.

4.15 Volume settings menu

Enter the menu through the main window of the device (see it.4.6):



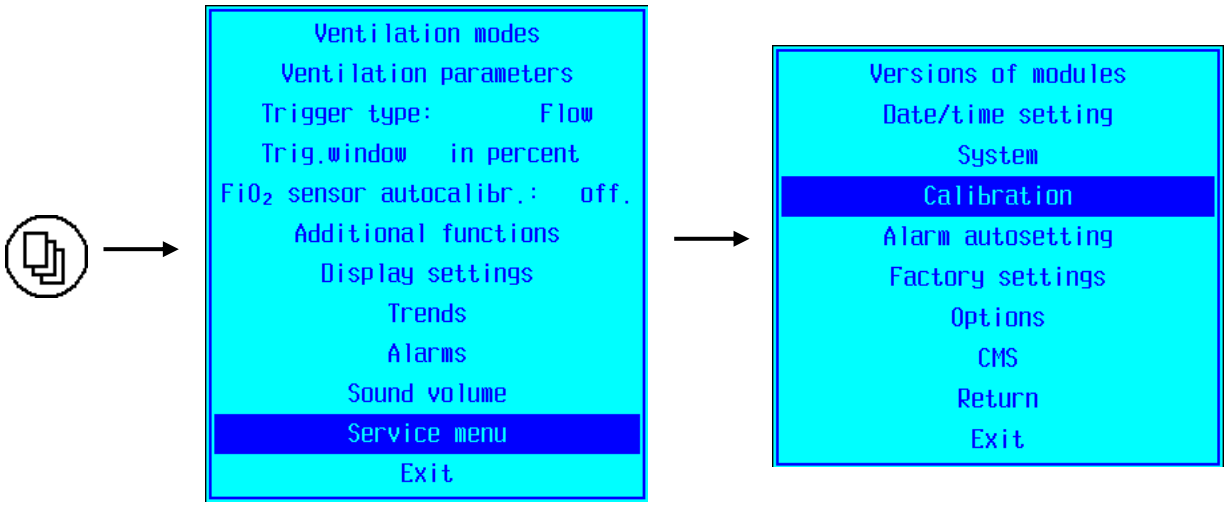
Designation	Description of parameters	Values
Alarm sound vol	Volume level of sound alarm	30…100 %
Beeper sound vol	Volume level of signal of spontaneous breaths (BEEP signal)	5…100 %

ATTENTION!

For the purposes of patient's safety user can not disable of set alarm volume less than 30 %.

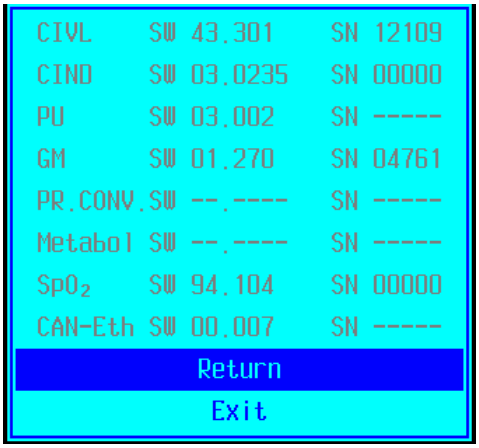
4.16 Service menu

The service menu includes functions of full internal testing (FIT) and calibration of various systems of the device. The entrance in the service menu is made through the main menu of the device (see it. 4.6). This menu is intended for the service personnel of medical equipment in medical facilities, and the staff of the service centers.

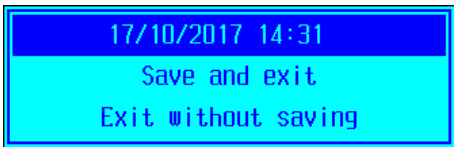


4.16.1 Function of service menu parameters

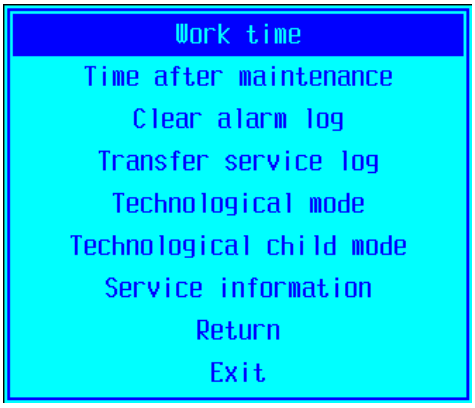
- **Versions of modules** parameter allows to see software version numbers of the units and modules which are present at the device, their serial numbers (CIVL – ventilation controller, CIND – display controller, PU – power unit, GM – gas mixer circuit, PR.CONV. – protocol converter circuit, Metabol. – metabolism module, SpO_2 – pulse oximetry module, CAN-Eth – network card.



- **Date/time setting** parameter allows to enter the menu of current time and date setting:



- **System** parameter allows to enter the submenu including the following parameters:



where:

- ***Work time*** parameter allows to see the whole operating time of the device.
- ***Time after maintenance*** parameter allows to control time after the previous maintenance of the device for the next timely maintenance. For this purpose the expert who was carrying out maintenance, should choose the “Zero time after maintenance” parameter and then the time counter returns to starting (zero) position.
- ***Clear alarm log*** parameter allows to clear information from the memory. For the activation of this action enter the system password. For exit without emptying the alarm log press the encoder for 4 times.
- ***Transfer service log*** parameter allows to make record of maintenance log to the portable data medium connected to USB-port. The maintenance log is saved in "servicelog.csv" file, in the csv format with the symbol divider ";", in the CP866 coding.
- ***Technological mode*** parameter is intended for the transfer of the device to the mode of the gas leakage test in the breathing circuit being under pressure during inspiratory time, and also test of pressure drop of the device in the passive exhalation line (the specified tests are carried out by the manufacturer and in the service centers, for these tests it is necessary to enter the system password).
- ***Technological child mode*** parameter is intended for the test of device by the manufacturer and in the service centers.
- ***Service information*** parameter is intended for technical staff (to perform the operation it is necessary to enter the system password).

- **Calibration** parameter allows to enter submenu including the following parameters:
  - CIVL
  - CIND
  - Breathing circuit calibration
  - CAPNO
  - SpO_2 module (option).

- ***CIVL*** parameter is needed for entering to the menu of calibration selection of the ventilation controller.

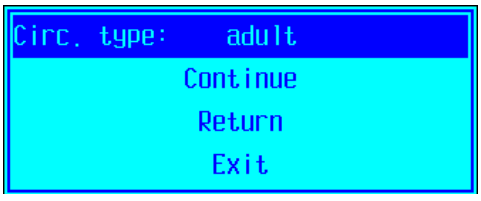
Table 4.10. CIVL calibration parameters:

Parameter	Function	Description
FiO_2 sensor calibration	Call of procedure of the oxygen sensor calibration	it.4.16.2
FiO_2 sensor replacement	Call of procedure of the oxygen sensor replacement	it.4.16.2
Exp. flow sens. calibr.	Call of procedure of expiratory flow sensor	it.4.16.3

Parameter	Function	Description
	calibration	
Insp. conditions	Selection of conditions (temperature, humidity, pressure) for the correction of inspiratory flow: ATP, ATPS, ATPD, BTPS	it.4.16.4
Exp. conditions	Selection of conditions (temperature, humidity, pressure) for the correction of expiratory flow: ATP, ATPS, ATPD, BTPS	it.4.16.4
Thresholds	Selection of the minimum and maximum available voltage on the new oxygen sensor (system password is required).	-

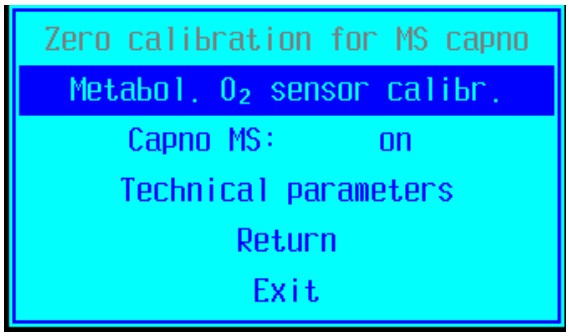
- ***CIND*** parameter is used to enter the calibration menu of the display controller:
  - ***Interface language*** allows to select language of the interface.

  - ***Touch screen calibration*** parameter is used to align the coordinates of graphical display control buttons with areas on the touch screen. In the touch screen calibration mode it is necessary to perform consistently all the instructions on the display.
  - The ***Day brightness*** and ***Night brightness*** parameters are used for changing of the display brightness during the day (05.00 - 00.00) and night (00.00 - 05.00) time in the range 50 - 100 % and 30 - 100 %, respectively. Default values are 100 % for day brightness and 60 % for night brightness.
- **Breathing circuit calibration** parameter is recommended after changing of the breathing circuit type. Before starting of the calibration select the type of the circuit (adult or child/coax.), connect the breathing circuit with filters to the device, release or close up the patient tee depending on the instructions on the display.



  During the calibration the compliance and resistance of the breathing circuit are defined, and then used for more accurately calculation of the inspiratory pressure.
- ***CAPNO*** is used to enter the setup and calibration menu of respiratory gas analysis modules available in the device (mainstream capnometer, metabolism module).

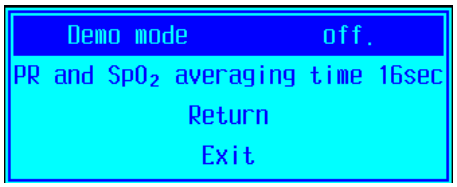
  If mainstream capnometer and metabolism module are installed (the most common variant of delivery) the menu looks as follows:



where:

- ***Zero calibration for MS capno*** parameter is used for running of mainstream capnometer zeroing routine (see it. 5.1);
- ***Metabol. O_2 sensor calibr.*** parameter is used for entering to calibration menu of built-in oxygen sensor for metabolic parameters;
- ***Capno MS*** parameter is used for enabling/disabling of mainstream capnometer*;*
- ***Technical parameters*** parameter is used for entering the metabolism module calibration menu (protected by the password).

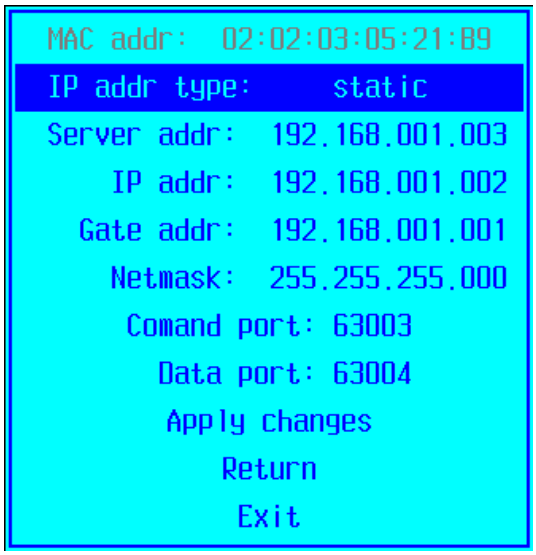
▪ ***SpO_2 module*** parameter is used for entering the control menu of built-in pulse oximeter parameters (available only if module presents in the device):



where:

- ***Demo mode*** parameter enables or disables emulation of the patient;
- ***PR and SpO_2 averaging time*** parameter allows to change the averaging time of the displayed parameters (4, 8, 16 s).

- Service menu parameter **Alarm autosetting** is used for restoring of the alarm threshold factory settings (see it. 4.14). The maximum pressure limit value Pmax (45 cmH_2O) and the corresponding alarm threshold are also recovered.
- Service menu parameter **Factory settings** allows, if necessary, reset the ventilation parameters to their default values (the operation required the system password).
- Service menu parameter **Options** allows to enable or disable optional functions of the device (the operation required the system password).
- Service menu parameter **"CMS"** allows to check the current network settings of the device for connection to central monitoring system (CMS) and to change them if necessary (protected by password). After making changes restart the device to apply network settings.



4.16.2 Calibration of FiO_2 sensor, O_2 sensor of metabolism module

Calibration of FiO_2 sensor

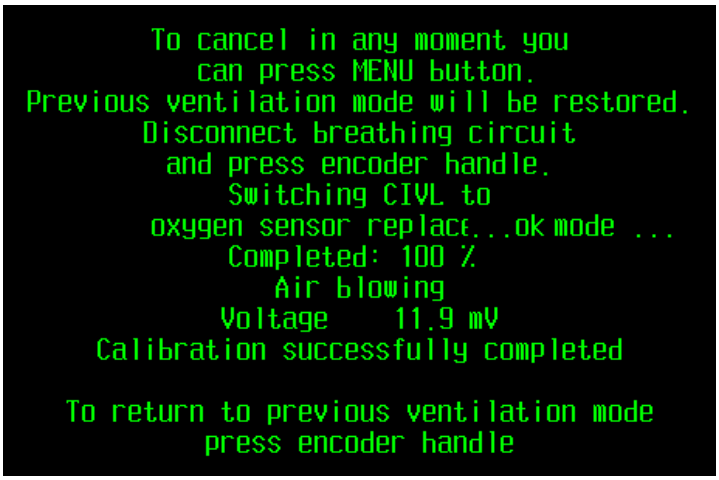
Calibration of the oxygen sensor measuring the concentration in the inspiratory gas (FiO_2) is conducted in the following cases:

- During maintenance.
- After replacement of the FiO_2 sensor.
- If the message "Check or replace the oxygen sensor" appears according to the results of the automatic performance control and calibration of the FiO_2 sensor (see it. 4.10), or at the other deviations in the FiO_2 measurement, particularly if concentration measurement error exceeds 2 % during air ventilation.

FiO_2 sensor of electrochemical type is applied in the device. Its lifetime depends on the time spent in oxygen environment and on oxygen concentration. At medium operation parameters lifetime of the FiO_2 sensor should be at least 1.5 years. Calibration of the FiO_2 sensor usually is important in the final phase of the life cycle of the sensor in order to prolong its lifetime and ensure the required accuracy characteristics.

To calibrate FiO_2 sensor:

- disconnect the device from the patient;
- enter the [Menu] → [Service menu] → [Calibration] → [CIVL] → [FiO_2 sensor calibration];
- run the calibration by pressing the encoder (sensor calibration takes about 1 minute).



After appearing of the message “Calibration successfully completed” the device is ready for operation.

At the failed calibration sensor replacement of device’s repair is required. After sensor replacement conduct calibration in [Menu] → [Service menu] → [Calibration] → [CIVL] → [FiO_2 sensor replacement].

Description of the messages with calibration results see in the Table 4.11.

Table 4.11. Description of the messages with calibration results and FiO_2 sensor replacement

No	Message	Alarm condition	Operator’s actions
1	Calibration successfully completed	Successful completion of calibration	Continue to work with the device
2	Calibration successfully completed, it is recommended to replace oxygen sensor	Successful completion of calibration, the oxygen sensor lifetime is coming to the end	Replace the oxygen sensor as soon as possible and perform the oxygen sensor replacement procedure from the menu [Menu] → [Service menu] → [Calibration] → [CIVL]
3	Could not set CIVL to oxygen sensor replacement mode	Ventilation controller don’t respond to calibration request	Contact the customer service
4	No information about atmospheric pressure or information is incorrect	Gas mixer malfunction	Contact the customer service
5	The oxygen sensor is missing or malfunctioning	Low voltage from the oxygen sensor	Install another oxygen sensor. If after oxygen sensor replacement message appears again during oxygen sensor replacement procedure, please contact the customer service.
6	Calibration cancelled	Calibration is cancelled by the user	Continue to work with the device
7	Malfunction of oxy measuring channel in CIVL	Oxygen measuring channel in ventilation controller is faulty	Contact the customer service
8	Coefficients writing error	Malfunction in the ventilation controller	Contact the customer service
9	Oxygen sensor calibration time out	No messages from ventilation controller about calibration results	Contact the customer service

Calibration of O_2 sensor of metabolism module

If the device has metabolism module, the fast oxygen sensor calibration is required. This sensor measures FiO_2 in Metabolism window and shows the difference of the oxygen concentration at the inhalation and exhalation FiO_2 - EtO_2:

- enter [Menu] → [Service menu] → [Calibration] → [CAPNO] → [Metabol. O_2 sensor calibr.], at that the device displays a brief calibration instruction;
- run the calibration by pressing the encoder (calibration lasts about 10 - 15 sec).

In the case of successful calibration the message "Calibration successfully completed" will be displayed. The device is ready for operation.

At unsuccessful calibration sensor replacement or device repair is required.

4.16.3 Expiratory flow sensor calibration

Make the procedure every time after replacement of the removable part of expiration valve.

For calling of the procedure select parameter: [Menu] → [Service menu] → [Calibration] → [CIVL] → [Exp.flow sens. calibr.]

After calling the procedure follow the instructions on the screen. Description of the messages with calibration results see in the Table 4.12.

Table 4.12. Description of messages about calibration results of expiratory flow sensor

No	Message	Alarm condition	Operator's actions
1	Calibration successfully completed	Calibration is completed successfully	Continue operation with the device
2	Time out of expiratory flow sensor calibration	No messages about calibration results from the ventilation controller	Contact the customer service
3	Calibration cancelled	Calibration is cancelled by user	Continue operation with the device
4	Could not set CIVL to expiratory flow sensor calibration mode	Ventilation controller does not respond to the calibration requests	Contact the customer service
5	Error: gas mixer failure	Malfunction of the gas mixer	Contact the customer service
6	Error: no response from gas mixer	Malfunction of the gas mixer	Contact the customer service
7	Error: non-zero flow	Ventilation controller malfunction	Contact the customer service
8	Error: incorrect data transfer rate from GM	Malfunction of the gas mixer	Contact the customer service
9	Error: high pressure in inspiratory line	Inspiratory line clogging.	Clean the inspiratory line and repeat the calibration. If the message appears again contact the customer service
10	Calculation error of approximating coeff.	User incorrectly followed the calibration instructions on the screen or malfunction of the device	Repeat the calibration. If the message appears again contact the customer service
11	Coeff. error for press.sensor in insp.line	Ventilation controller malfunction	Contact the customer service

No	Message	Alarm condition	Operator's actions
12	Incorrect coeff. for differential press. sensor	Ventilation controller malfunction	Contact the customer service
13	Error: no response from power unit	Power unit malfunction	Contact the customer service
14	Error: temperature sensor error in power unit	Power unit malfunction	Contact the customer service
15	Error: low ambient air temperature	Power unit malfunction	Contact the customer service
16	Calibration task stop	Calibration task failure	Repeat the calibration. If message appears again contact the customer service
17	Monotony error in input table	User incorrectly followed the calibration instructions on the screen or malfunction of the device	Repeat the calibration. If message appears again contact the customer service
18	Coefficients writing error	Ventilation controller malfunction	Contact the customer service
19	Incorrect coeff.for press.sensor in exp.line	Ventilation controller malfunction	Contact the customer service

4.16.4 Selection of flow correction conditions on the inspiration and the expiration

On the inspiration the device uses the flow sensors, operating on the principle of measuring the mass of the passed gas. On the expiratory flow sensor measures the volume of the passed breathing mixture. It is possible to use different types of breathing gas humidification in the device.

"Insp. conditions" and "Exp. conditions" parameters are intended for selection of conditions for the conversion of the breathing mixture mass passed through the device to the appropriate volume. Weight and volume are connected by the equation that contains the partial pressures of all gas fractions, temperature and the absolute pressure of the mixture.

Select the parameters through the menu: [Menu] → [Service menu] → [Calibration] → [CIVL] → [Insp. (Exp.) conditions].

The device provides 4 types of inspiration and expiratory flow correction:

- ATP (Ambient Temperature, Pressure) - the conversion is carried out for the 30 % relative humidity and ambient temperature of 25 °C.
- ATPS (Ambient Temperature, Pressure, Saturated – 100 % humidity), this correction is similar to ATP at 100 % relative humidity.
- ATPD (Ambient Temperature, Pressure, Dried – 0 % humidity), this correction is similar to ATP at 0 % relative humidity.
- BTPS (Body Temperature, Pressure, Saturated – ambient pressure, 100 % relative humidity).

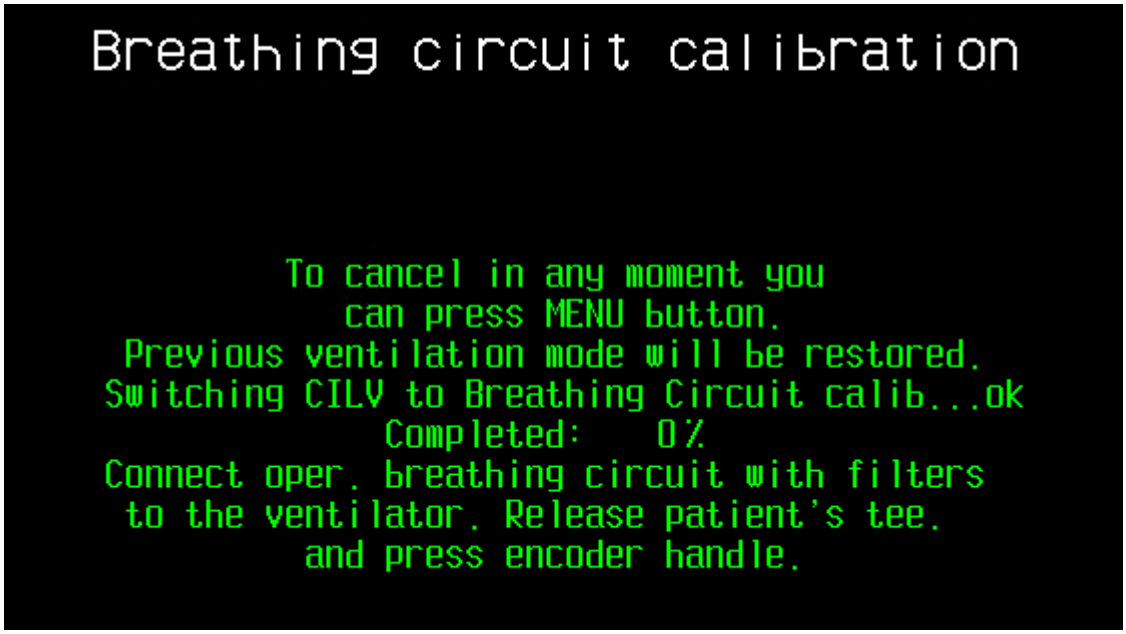
When working with the bag select ATP correction, when using the humidifier select BTPS. Incorrect type of correction would lead to the increasing of measurement errors of inspiration and expiration volume.

4.16.5 Breathing circuit calibration

Breathing circuit calibration is intended for the adaptation of the device to the breathing circuit. It is recommended to carry out when the device is switched on and especially when switching to another type of the breathing circuit.

The procedure is called through the menu: [Menu] → [Service menu] → [Calibration] → [Breathing circuit calibration].

After calling the procedure follow the instructions on the screen.



As a result of calibration particularly the compliance of the breathing circuit is measured, that is then used for its compensation. If the calibration was not carried out the effective compensation of breathing circuit compliance is impossible. Description of messages with calibration results see in the Table 4.13.

Table 4.13. Description of messages about breathing circuit calibration results

No	Message	Alarm condition	Operator's actions
1	Measuring of br.circuit param. succes.completed	Breathing circuit calibration is successful	Continue operation with the device
2	Error: insp. pressure sensor is not calibrated	Inspiration pressure sensor in not calibrated	Reset the device; restart breathing circuit calibration, if the message appears again contact the customer service.
3	Error: exp. pressure sensor is not calibrated	Expiration pressure sensor in not calibrated	
4	Error: no response from gas mixer	Gas mixer malfunction	Contact the customer service
5	Error: wrong data transfer freq. from gas mixer	Gas mixer malfunction.	Contact the customer service
6	Error: low ambient air temperature	Low ambient temperature or power unit malfunction.	If the ambient temperature is below 15 °C, the move the device to the warmer place. Otherwise contact the customer service.
7	Error: temperature sensor error in power unit	Temperature sensor malfunction.	Contact the customer service.
8	Calibration cancelled	Calibration is cancelled by user.	Continue operation with the device.

No	Message	Alarm condition	Operator's actions
9	High pressure in inspiration line	Inspiratory line clogging.	Clean the inspiratory line and repeat the calibration. If the message appears again contact the customer service.
10	Could not switch CIVL to calibration mode	Ventilation controller does not respond to the requests of breathing circuit calibration.	Contact the customer service.
11	Monotony error in input table	User incorrectly followed the breathing circuit calibration instructions on the screen or malfunction of the device.	Repeat the breathing circuit calibration. If message appears again contact the customer service.
12	Coefficients writing error	Ventilation controller malfunction.	Contact the customer service.
13	Breathing circuit calibration time out	No messages from ventilation controller about results of breathing circuit calibration.	Contact the customer service.
14	Gas mixer malfunction	Gas mixer malfunction.	Contact the customer service.
15	Power unit does not respond	Power unit does not respond to the requests of ventilation controller.	Contact the customer service.

4.17 Alarms

Alarm signals

Alarm system continuously monitors the operating parameters of the device affecting to the safety of the patient, and indicates the situation where the intervention of the staff is required.

Forms of the alarm signals:

1. Sound alarm. Volume is growing by 10 % every minute in presence of alarm situation;
2. Red indicator “Alarm” on the top side of device enclosure;
3. Message on the screen with the name of the alarm.

Depending on the risk for the patient alarms are classified into three groups:

1. Low priority alarm (blue message on the screen);
2. Medium priority alarm (sound alarm, “Alarm” indicator and yellow message on the screen);
3. High priority alarm (sound alarm of the higher frequency and intensity, “Alarm” indicator and red message on the screen).

Depending on the cause of the occurrence and further consequences, the alarms are divided into 2 groups:

1. Physiological alarms -alarms that occur due to patient condition one or more physiological parameters monitoring the patient exceed the predefined alarm limit;
2. Technical alarms - alarms that that occur due to the device or alarm system conditions;

If the alarm is triggered check the patient condition to identify and eliminate the cause of the alarm situation. After removing the cause of the alarm, the device automatically disables the alarm. If several alarm conditions exist, the device switches to the next alarm situation in order of their priority.

In the situation of several alarm conditions at the same time alarm with the highest priority is activated. Messages about other alarms (up to 6 messages) are displayed in the "Alarm List". The alarm log stores information about all current and previous alarms. The lists of alarm messages are stated in *Tables 4.14 – 4.16*, where the text of the alarm message, the short message in brackets which is displayed in the "Alarm List" and the alarm log, as well as the response of the device and operator actions are mentioned. The list of informational messages is stated in *Table 4.17.*

For convenience of the personnel audible alarm can be temporarily disable for 120 s by pressing of the button  or sound mute icon  . The LED above the button informs the personnel about temporarily disabling of the audible alarm. Disabling of the sound alarms does not result in disabling of visual alarms.

Before starting the ventilation make sure that alarm system works properly by checking disconnection or occlusion alarm. To check the disconnection alarm, assemble the breathing circuit in accordance with Figure 3.6 and disconnect the breathing bag from the tee of the patient. The alarm should appear in 30 seconds.

To check the occlusion alarm, assemble the breathing circuit according to the Figure 3.6 and block the output port of expiration valve (Figure 2.1 position 20). The alarm should appear no later than two breath cycles or 5 seconds, whichever is greater.

The ventilator makes self-test after switching on and within the whole operation process. If the critical failures occurred during initial test the ventilator switches to emergency mode. In this case normal ventilation does not start and the ventilator’s replacement is required. If the critical failures occurred during operation the emergency alarm issues but the ventilator continues ventilation process with partial loss of functionality. In case of fatal failure the ventilator could switch to full emergency mode (FEM) and stop the ventilation. The urgent replacement of

ventilator or application of alternative ventilation method is required. For further information refer to it. 4.17.6.

Informational messages

Informational messages are intended to inform the operator about events that have occurred in the device and do not require immediate action from the operator. In the interface the informational messages are displayed in grey color.

For the user convenience, some informational messages are displayed only in the alarm list indication zone (see Figure 4.4position 15) and the message indication zone if there are no active alarms (see Figure 4.4 position 6), some messages are recorded only in the alarm log and events.

The list of informational messages with the indication of the full and abbreviated text of the message, indication place and comments is presented in Table. 4.17.

Please note that informational messages about the the metabolism module functioning are displayed only in the status bar “Metabolism” and are not displayed either in the "Alarm List" or in the alarm log. The list of metabolism status messages is presented in Table. 5.1 section 5.5 Metabolism module.

4.17.1 High priority alarms

Table 4.14. High priority alarms

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
Physiological alarms			
1.	Disconnection (Disconnection)	Disconnection Pressure drop in the patient's breathing circuit	Check the tightness of the breathing circuit connections. Check the tightness of the breathing circuit and expiration valve of the device. Check humidifier. If necessary replace the breathing circuit. Alarm is disabled at the restoring pressure in the first normal breathing cycle.
2.	Apnea Press encoder (Apnea)	Apnea No spontaneous breathing of the patient at the period of the set apnea time Tapnea	This alarm may occur in the SIMV, CPAP+PS and BiSTEP, NIV modes. Check the patient. Turn on the mandatory mode or increase the frequency of mandatory breaths in SIMV modes. The alarm is automatically disabled when the patient makes two sequential unassisted breathing cycles.
3.	Occlusion (Occlusion)	Occlusion Achieving of maximum permissible inspiratory pressure at the volume of inspiration less than 50 %	Check for breathing circuit occlusion or clamping. Check inspiration/expiration filters for contamination, if necessary clean. Alarm is disabled after 2 consecutive normal breathing cycles.
4.	High minute volume (High MV)	High minute volume Minute expiratory volume is above the set top threshold.	Check the condition of the patient in for the hyperventilation. If necessary reinstall the alarm limit of high minute volume. Increase inspiratory trigger threshold if there is suspicion of auto triggering. Alarm is disabled when minute volume is below the threshold.
5.	Low minute volume (Low MV)	Low minute volume Minute expiratory volume is below the set bottom threshold.	Check the patient for adequate ventilation and circuit for hermiticity. If necessary increase the frequency, tidal volume, support pressure or trigger sensitivity.
6.	Pmax is reached (Pmax reached)	Pmax is reached Pmax set by user is achieved.	Check the patient. Check breathing cir-cuit and flow sensor tubes for the in-flection and occlusion. Alarm disappears at the first normal breathing cycle with the real value of PIP below Pmax specified by the user.
7.	High $EtCO_2$ (High $EtCO_2$)	High $EtCO_2$ The measured value of the CO_2 concentration is above the set top threshold.	Check the patient for adequate ventilation and circuit for hermiticity. If necessary adjust the top alarm limit. Alarm is disabled at decreasing of the exhalation volume below the top threshold alarm.
8.	Low $EtCO_2$ (Low EtCO2)	Low $EtCO_2$ The measured value of the CO_2 concentration is below the set bottom threshold.	Check the patient for adequate ventilation and circuit for hermiticity. If necessary adjust the bottom alarm limit. Alarm is disabled when expiratory volume exceeds the bottom threshold alarm.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
9.	Low inspiration pressure (Low pressure)	Low inspiration pressure The measured maximum inspiratory pressure is less than the set threshold.	Check the patient for adequate ventilation and circuit for hermiticity. If necessary adjust the alarm limit. Alarm is disabled at the first breath with the pressure above the set threshold.
10.	Target MV is unreachable (Trg.MV unreach)	Target MV cannot be achieved.	Special alarms of iSV mode, see the description in it. 4.17.5. Check the patient condition. Check the alarm limits, adjust them if necessary.
11.	Vtmin reached (Vtmin reached)	Tidal volume V_t reached minimal level Vtmin.	Special alarms of iSV mode, see the description in it. 4.17.5. Check the patient condition. Check the alarm limits, adjust them if necessary.
Technical alarms			
12.	TRANSITION TO FEM (TRANSITION TO FEM)	The critical malfunction in the device occurred. The device operation is failed.	Use alternative ventilator. Remove the device from operation, see it. 4.17.6. Contact service department.
13.	Tech. Failure (Tech. Failure)	The technical malfunction occurred during switching on. . The device operation is failed.	Further operation of the device is not possible, see it. 4.17.6. Contact service department.
14.	Technical malfunction x (from 1 to 7) (Tech. malf. x)	The technical malfunction occurred in a one unit of the device.	Ventilation continues with the partial loss of functionality. Replace the device. Contact service department. A detailed description of the malfunction and an indication of the unit in which the malfunction occurred are given in *Table App.5.1*, Appendix 5.1.
15.	Technical malfunction CIND (Tech. malf. CIND)	The technical malfunction occurred in CIND.	Ventilation continues with the partial loss of functionality. Replace the device. Contact service department.
16.	Technical malfunction CIVL (Tech. malf. CIVL)	The technical malfunction occurred in CEIVL.	Ventilation continues with the partial loss of functionality. Replace the device. Contact service department.
17.	Technical malfunction Gas Mix. (Tech. malf. GM)	The technical malfunction occurred in GM.	Ventilation continues with the partial loss of functionality. Replace the device. Contact service department.
18.	Less than 10 minutes left (< 10 min left)	The accumulator is fully discharged. Accumulator's charge is insufficient to continue the normal operation of the device. Prior to the full discharge is less than 10 minutes.	Alarm disappears in the accumulator charging mode (mains power). Immediately connect the device to the mains power to charge the accumulator. The alarm message will be removed after beginning of the charging. Contact service department in case of failure.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
19.	Accumulator malfunction (Acc. malfunct.)	The accumulator malfunction occurred.	When the device is switched on, the operator will be offered to switch to the technical failure mode or continue operation with the risk of a sudden shutdown, see it. 3.4.
20.	Low O_2 concentration (Low O2)	The measured value of the oxygen concentration FiO_2 is below set by the operator deviation (1 - 50 %).	Check the connection and the supply of oxygen to the device. If necessary change the limit of O_2 tolerance. Alarm automatically disappears when the oxygen concentration is returned to the normal range.
21.	High O_2 concentration (High O2)	The measured value of the oxygen concentration exceeds the set value on the specified value.	Alarm disappears when the oxygen concentration returns to the normal range.
22.	Fan malfunction (Fan malfunct.)	The electronic unit fan malfunction occurred.	Contact service department. The device may shortly continue normal operation. Alarm disappears after restoring of the normal operation of the fan.
23.	Sound malfunction (Sound malfunc.)	Faulty dynamic transducer (breakage).	Further operation of the device is impossible. Contact service department.
24.	FiO_2 sensor mulfanction (FiO_2 s. malf.)	The ventilation controller FiO_2 sensor malfunction occurred.	The function of FiO_2 level monitoring is not available. There is no change in FiO_2 level control. The device can operate for a short period of time. Contact service department.

4.17.2 Medium priority alarms

Table 4.15. Medium priority alarms

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
Physiological alarms			
1.	High Vexp (High Vexp)	High Vexp Expiratory volume is above the set top threshold. Without leakage this alarm is equal to high inspiration volume alarm	Check the patient for adequate ventilation and circuit for hermiticity. If necessary adjust the top alarm threshold. Alarm is disabled when expiratory volume is below the top alarm threshold.
2.	Low Vexp (Low Vexp)	Low Vexp Expiratory volume is below the set bottom threshold	Check the patient for adequate ventilation and circuit for hermiticity. If necessary adjust the bottom alarm threshold. Alarm is disabled when expiratory volume exceeds the bottom alarm threshold.
3.	High RB (High RB)	Controlled respiratory rate is above than the specified top threshold.	The alarm is automatically disabled when the respiratory rate is equal or less than alarm threshold. If necessary, reduce the respiration rate, or adjust the alarm threshold. If autotriggering is suspected, increase the trigger threshold of the inspiratory trigger.
4.	Low RB (Low RB)	Controlled respiratory rate is below the specified bottom threshold.	The alarm is automatically disabled when the respiratory rate is equal or higher than alarm threshold.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
5.	High PEEP (High PEEP)	PEEP value is above the specified top alarm threshold.	Check the ventilation adequate and tightness of patient circuit. If necessary adjust the alarm limit. Alarm is disabled at the first breath with the pressure below the set threshold
6.	Low PEEP (Low PEEP)	PEEP value is below the specified bottom threshold.	Check the ventilation adequate and tightness of patient circuit. If necessary adjust the alarm limit. Alarm is disabled at the first breath with the pressure above the set threshold
7.	High SpO_2 (High SPO_2)	Measured SpO_2 value is above the specified top alarm threshold.	The alarm is disabled when the SpO_2 value returns to the permissible range.
8.	Low SpO_2 (Low SpO_2)	Measured SpO_2 value is below the specified bottom alarm threshold.	The alarm is disabled when the SpO_2 value returns to the allowable range.
9.	High PR (High PR)	Measured pulse rate is above the specified top alarm threshold.	The alarm is disabled when the measured frequency value returns to the allowable range.
10.	Low PR (Low PR)	Measured pulse rate is below the specified bottom alarm threshold.	The alarm is disabled when the measured frequency value returns to the allowable range.
11.	SpO_2 sensor taken off (SpO_2sens.t-off)	The pulse oximetry sensor is disconnected from the patient.	Connect the sensor to the patient.
12.	Low pulse signal (Low pulse)	The relative level of blood pulsation at measuring point is 0.3 % or less	Provide the required level of perfusion at the location of the SpO2 sensor application. Change the location of the SpO2 sensor application. The alarm is disabled when the pulse filling value becomes higher than 0.3%.
Technical alarms			
13.	Calibrate FiO_2 sensor (Cal.FiO_2 sens.)	Oxygen sensor calibration is required	The alarm is disabled after the FiO_2 sensor calibration [Menu] [Service menu] [Calibration] [CIVL] [FiO_2 sensor calibration];
14.	High O_2 pressure (High O_2 press.)	Input pressure in the oxygen line exceeds 2.5 bar	Contact service department. It is necessary to replace the filter regulator.
15.	Low O_2 pressure (Low O_2 press.)	Input pressure in oxygen line is below the set bottom threshold	The alarm is disabled, when normal pressure is restored.
16.	Low battery (Low battery)	The accumulator is fully discharged. Accumulator's charge is insufficient to continue the normal operation of the device	Connect the device to the mains power to charge the accumulator. The alarm message will be removed after beginning of the charging. Contact service department in case of failure.
17.	Maintenance counter error (Maint.count er)	The maintenance counter malfunction occurred. Maintenance counter keeps a count of time passed from last maintenance.	The device can operate for a short period of time. Contact service department.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
18.	Touch screen is jammed (TS jammed)	Detection of long pressing on the touch screen	Operating with the touch screen is locked. The alarm is disabled, when you stop pressing the touch screen. If it occurs for no apparent reason, contact service department. Ventilation continues without the possibility of changing the ventilation parameters.
19.	Check capno adapt. and calibr. (Check CO_2 adap)	Adapter of the mainstream capnograph is contaminated	The alarm is disabled after cleaning the adapter and performing calibration, see it. 5.1.
20.	SpO_2 sensor error (SpO_2 sens. err)	The pulse oximetry sensor error	Replace the pulse oximetry sensor. Contact service department in case of failure.
21.	Nebulizer failure (Nebul. failure)	The nebulizer control unit malfunction occurred.	Further operation of the device is possible without the nebulizer. The further operation of the nebulizer is not possible. Contact service department.
22.	Paux sensor failure (Paux sens.fail)	The external pressure sensor malfunction occurred.	Further operation of the device is possible without external pressure monitoring Paux. Contact service department.

4.17.3 Low priority alarms

Table 4.16. Low priority alarms

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
Physiological alarms			
1.	Plimit reached (Plimit reached)	The pressure in the circuit reached a value of Pmax - 10 cm H_2O.	Special alarms of iSV mode, see the description in it. 4.17.5. Check the patient condition. Check the alarm limits, adjust them if necessary.
Technical alarms			
2.	No mains voltage (No mains)	No mains voltage. The device automatically switched to battery operation.	If there is a risk of power supply failure for a considerable time, ensure of the back-up methods of mechanical ventilation, which will be necessary when the battery discharge. The alarm is disabled, when connected to the power supply.
3.	O_2 pres < 1bar (O_2 pressure < 1 bar)	Pressure in the oxygen line is less than 1 bar	The message appears even when the alarm "O_2 pressure (min)" is disabled. Recover the input pressure in the oxygen line or use alternative oxygen sources.
4.	FiO_2 sens. Off (FiO_2 sensor turned off)	Operator turned off the FiO_2 sensor.	Further operation of the device is possible without FiO_2 monitoring. Turn on the FiO_2 sensor to continue the monitoring.
5.	Calibr. error (Calibr. error)	Calibration error during calibration process.	Calibration is not performed. Repeat the calibration, following the instructions on the screen of the device; see also the relevant it. 4.16.2 - 4.16.5.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
6.	Protocol Converter error (Prot.Conv. err)	The protocol converter module malfunction occurred.	Further operation of the device is possible without the mainstream capnometer. Contact service department.
7.	Capnometer off (Capnometer off)	No connection with the capnometer	Turn on the capnometer through the menu. After restoring of communication message disappears. If capnometer does not operate, contact service department. Further operation of the device is possible without the mainstream capnometer.
8.	Capnometer error (Capno error)	The capnometer error occurred.	Further operation of the device is possible without the capnometer. Contact service department.
9.	No CAN-Eth module (No CAN-Eth mod)	No connection with CAN-Eth module	Further operation of the device is possible without the CAN-Eth. Contact service department.
10.	No SpO_2 module (No SpO_2 module)	No connection with pulse oximetry module	Further operation of the device is possible without the pulse oximetry sensor. Contact service department.
11.	SpO_2 module not initialized (SpO_2 not init)	The pulse oximetry module is not initialized during the device switching on	The module is missing. Contact service department.
12.	Capnometer not initialized (Capno not init)	The capnometer is not initialized during the device switching on.	The module is missing Contact service department.
13.	Metabolism module not init. (Metab.not init)	The metabolism module is not initialized during the device switching on.	The module is missing. Contact service department.
14.	CAN-Eth not initialized(CAN-Eth no ini)	The CAN-Eth is not initialized during the device switching on.	The module is missing Contact service department.
15.	No Metabolism module (No Metabol.mod)	No connection with metabolism module.	The module is missing Contact service department.
16.	Trends failure (Trends failure)	The trends access malfunction occurred.	The memory card error occurred. It is not possible to view and save trends, does not affect on the device operation. Contact service department.
17.	USB: data media is full (USB: no space)	The USB data storage is full	Replace the USB Mass Storage with a new one with enough free space.
18.	Update $PaCO_2$/$PvCO_2$ (Update CO data)	The $PvCO_2$ and / or $PaCO_2$ values were not updated for more than 4 hours or the $EtCO_2$ value changed for more than 30% from $EtCO_2$ measured during the calculation of cardiac output	Check the patient condition. Update the $PvCO_2$ and / or $PaCO_2$ values.

4.17.4 Informational messages

Table 4.17. Informational messages

No	Message	Alarm log	Indication zone	Comment
1.	Power-up (Power-up)	x		
2.	Shutdown (Shutdown)	x		
3.	SpO_2 sensor disconnected (SpO_2 sens.disc)		x	To continue monitoring, connect the pulse oximetry sensor to the device.
4.	Capnometer warming (Capno warming)		x	Capnometer warming. At the end of warming up the message will automatically disappear.
5.	Capnometer turned off by user (Capno turn off)		x	To continue monitoring, turn on the capnometer in the device menu.
6.	FiO_2 sensor replacement (FiO_2 sens.repl)	x		FiO_2 sensor is being replaced.
7.	Calibr. done (Calibr. done)	x		Calibration is finished successfully
8.	FiO_2 cal. done (FiO_2 cal. done)	x		FiO_2 calibration is finished successfully
9.	Calibr. cancel. (Calibr.cancel.)	x		Calibration is canceled by operator.
10.	FiO_2 sensor calibration (FiO_2 s.calib.)	x		FiO_2 sensor is being calibrated
11.	FiO_2 sensor autocalibration (FiO_2 s.autocal)	x		FiO_2 sensor is being autocalibrated
12.	Capnometer calibration (Capno calibr.)	x		Zero calibration of capnometer
13.	Breathing circuit calibration (Circuit calibr)	x		Breathing circuit calibration
14.	Check delayed alarms (Chk.delay.alrm)		x	Message about the delayed alarms. Check them in the alarm log.
15.	New time is set (New time set)	x		The new clock time is set by the operator
16.	Maintenance (Maintenance)	x		Message after maintenance procedures.
17.	TS calibration (TS calibration)	x		Touchscreen calibration
18.	Ch. net params (Ch. net params)	x		The network settings for connecting the device to the central monitoring have been changed.
19.	Nebulizer is on (Nebulizer on)	x		Nebulizer is on
20.	Suction (Suction)	x		Activation of Sanation function
21.	Oxygenation (Oxygenation)	x		Activation of Oxygenation function
22.	Alv.recr.man. (Alv.recr.man.)	x		Activation of Recruitment maneuver function

No	Message	Alarm log	Indication zone	Comment
23.	Standby mode (Standby mode)	x		Activation of Standby mode
24.	Manual breath (Manual breath)	x		Activation of Manual breath function
25.	Technical Message x (1 or 2) (Tech. msg. x)	x		Service messages. A detailed description of the malfunction and an indication of the unit in which the malfunction occurred are given in Table App.5.2, Appendix 5.2.

4.17.5 Special alarms of iSV mode

Special alarms and messages of iSV mode are formed in addition to the standard alarms of all modes.

High priority alarms:

1. "Target MV is unreachable"
2. "Vt less 4.4 ml/kg" ("Vtmin reached"). This alarm doesn't depend on the standard tidal volume alarm and it can not be corrected or disabled (except standard disabling of sound for 2 minutes).

Low priority alarms:

1. "Plimit reached!"

Conditions of special alarms and messages formation

"Target MV is unreachable" alarm can be generated in two cases:

In the first case the alarm is generated immediately when the change of mode settings is not compatible with the actual values of existing parameters of respiratory mechanics of the patient.

In the second case the alarm is generated with the delay when it is detected that the real minute ventilation does not reach the target value. The delay is necessary to achieve the set minute ventilation, for example in the case of changing the target value from 25 % to 300 % with the maximum pressure increase in step of 2 cmH_2O.

To identify situations when the target minute ventilation can not be achieved, the identification of the expiratory minute volume stabilization is performed, and if the minute volume actually does not reach the target value - the alarm is generated. This eliminates false triggering of the alarm.

Alarm "Vt less 4.4 ml/kg!". This alarm is displayed if Vt is less than Vt min on 3 %, but with delay at least 20 seconds with the retained alarm condition.

"Plimit reached!" message is formed when the circuit pressure is Pmax - 10 cmH_2O. The increase of inspiratory pressure stops - inspiration continues at the pressure Plimit.

4.17.6 Emergency and technical failure modes

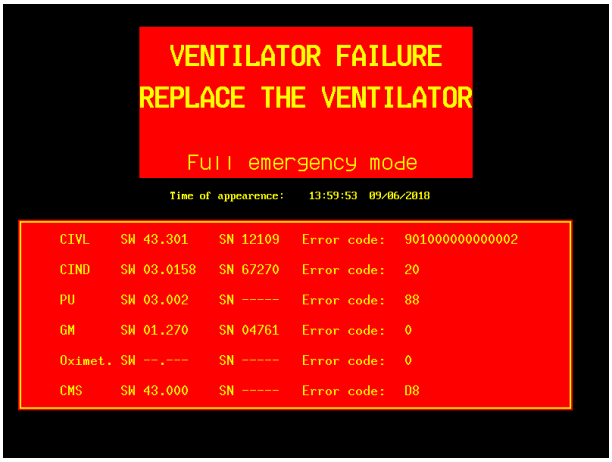
Full emergency mode

The full emergency mode (FEM) is switched on automatically in case of ventilator's module malfunction during the operation. FEM cannot be enabled by the user.

Emergency mode of device is intended only to rescue the patient at the technical failures of the device and to give reserve time to transfer the patient to another type of ventilation. Alarm modes cannot be used longer than their specified time, because this may cause harm to the patient or even fatal consequences.

In FEM emergency valve is opened, expiration valve is opened, only spontaneous breathing of the patient through the device is possible. At the emergency mode high priority alarm signal sounds, following information appears on the screen:

- A message about the switching to FEM and necessity to replace the device;
- Time and date of switching to FEM;
- Table of the major units of the device with indication of the software versions and error codes intended for technical diagnostics of ventilator's malfunction (see interpretation of error codes in the Appendix 5).



When you turn the ventilator turned off in FEM the ventilator switches to technical failure mode.

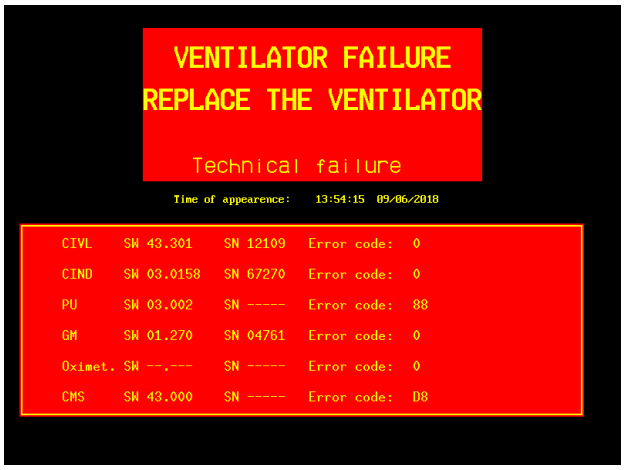
It is not possible to use the ventilator in FEM, please contact the customer service in that case.

Technical failure mode

The technical failure mode is switched on automatically in case of ventilator's module malfunction during the turning on. The ventilator switches to technical failure mode when you turn it on again in FEM or turn it on for the first time when it was switched to FEM in off mode (e.g. due to improper storing conditions).

There is no ventilation in technical failure mode. At the technical failure mode high priority alarm signal sounds, following information appears on the screen:

- A message about the switching to technical failure mode and necessity to replace the device;
- Time and date of switching to technical failure mode;
- Table of the major units of the device with indication of the software versions and error codes intended for technical diagnostics of ventilator's malfunction (see interpretation of error codes in the Appendix 5).



It is not possible to use the ventilator in technical failure mode, please contact the customer service in that case.

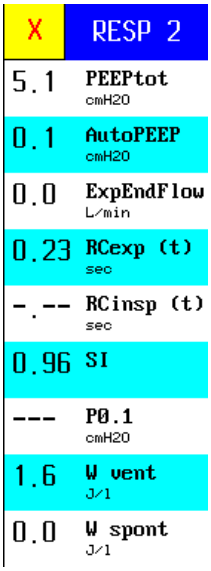
4.18 Extended respiratory monitoring

Devices equipped with this feature have an interactive button "Monitoring" at the left bottom part of the screen, which allows to change the appearance of the monitored parameters window in the left side of the screen (see Figure 4.4, position 14).

When you press the "Monitoring" the following window appears:

When selecting "RESP 1" or "Monitoring" rows, device will return to the main monitoring screen. When selecting "RESP 2" or "RESP 3" windows with their own set of monitoring parameters are displayed. "Metabolism" window displays parameters of metabolism (see it. 5.6).

RESP2 window:



RESP 3 window:

Table 4.18. Description of extended respiratory monitoring parameters, RESP 2 window

Name of parameter	Designation	Additional description
True pressure level in lungs at the end of expiration	PEEPtot	Pressure in the lungs at the end of expiration, taking into account the incomplete expiration PEEPtot=PEEP+AutoPEEP. Displayed if both parameters are measured correctly.
Residual pressure level in lungs	AutoPEEP	Residual pressure in lungs that occurs due to the incompleteness of expiration. It is not measured in the CPAP+PS mode.
Flow at the end of expiration	ExpEndFlow	Residual gas flow from lungs caused by the incompleteness of expiration
Expiratory time constant	RCexp (t)	Time constant determining the potential rate of pressure change in the lungs during expiratory

Name of parameter	Designation	Additional description
		phase RCexp (τexp) = Rexp×Cexp
Inspiratory time constant	RCinsp (t)	Time constant determining the potential rate of pressure change in the lungs during inspiratory phase RCinsp (τinsp) = Rinsp×Cinsp
Stress index	SI	Index characterizes the correctness of PEEP and V_T selection. It is determined in the CMV/VCV and SIMV/VC modes for hardware breaths at the rectangular shape of the flow waveform
Respiratory effort index	P0.1	Index characterizes the strength of the patient's breathing attempts. It is measured in cmH_2O
Work of the ventilator breathing	Wvent	Breathing work performed by the ventilator, it is calculated only by the hardware breaths. Work is 0 for spontaneous breaths
Work of the patient breathing	Wspont	Work of patient's spontaneous breath-ing. It is calculated only by the spontaneous breaths. Work is 0 for hardware (ventilator's) breaths

Table 4.19. Description of extended respiratory monitoring parameters, RESP 3 window

Name of parameter	Designation	Additional description
Inspiratory time, including spontaneous breath	Tinsp	Time of the last inspiration, made by ventilator or patient
Factor of breathing cycle filling	Tinsp/Ttot	The ratio of inspiratory time to total duration of the respiratory cycle.
Factor of spontaneous breathing	MVe_sp/MVe	The ratio of spontaneous breathing minute volume to the total breathing volume.
Resistance to the exhalation	Rexp	Total respiratory resistance during expiratory phase.
Elasticity of respiratory ways (elastance)	E	Reverse value of static compliance. Measured in mmHg in CMV, SIMV, PCV-VG modes.
Resistance of the breathing circuit	Rcirc	The resistance of the breathing circuit, measured at breathing circuit calibration
Compliance of the breathing circuit	Ccirc	The compliance of the breathing circuit, measured at breathing circuit calibration
Dynamic compliance	C (Cdyn)	The indicator of compiance of the lungs, chest and respiratory tract. Dynamic characteristic, calculated during the respiratory cycle.
Rapid shallow breathing index	RSBI	The dimensionless quantity characterizing the depth of patient's breathing. Measured in CPAP+PS, BiSTEP, APRV modes. Only spontaneous breaths are taken into account when calculating the index.

If the parameter is not measured, dashes are displayed instead of its value. Also dashes appear before the first measurement of parameter. If the parameter is measured, but the last measurement was incorrect, flashed dashes are displayed.

By clicking on the icon ✖ in the top part of the window, user returns to the "RESP 1" window.

ATTENTION!

At opening of the extended respiratory monitoring windows the alarm list becomes unavailable. To access the alarm list, go to the RESP 1 window.

4.19 Features of using virus-bacterial and heat and moisture exchange filters

When **virus-bacterial filter** is in the expiration line the undesirable increase in breathing resistance can occur, especially if the filter is used together with the nebulizer and humidifier. This can lead to the hard work of the patient's breathing and increased pressure in the respiratory system (autoPEEP phenomenon). Unwanted pressure increase in the respiratory system of the patient can be identified by the fact that the flow of exhaled gas by the end of exhalation does not fall to zero.

Check the virus-bacterial filter and replace it, if it is suspected that is causes autoPEEP increasing.

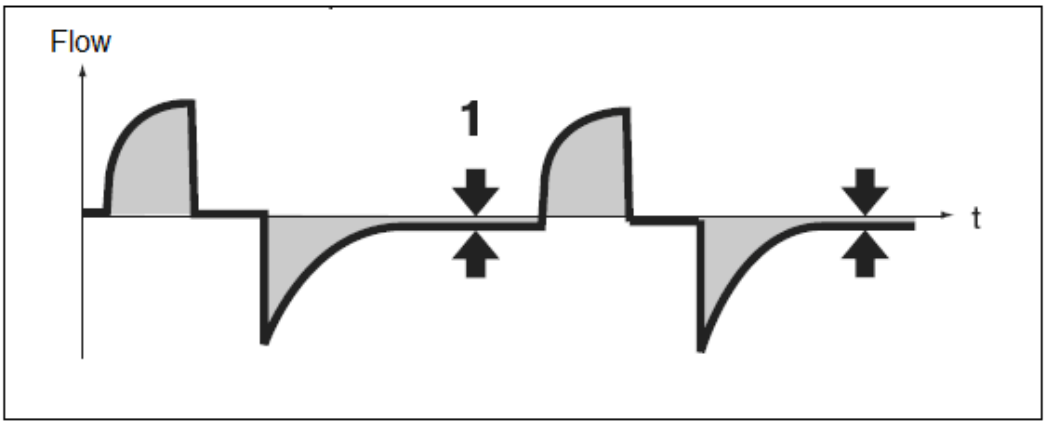


Figure 4.12 – The effect of extending of the expiraiton flow due to the increased filter resistance

The heat and moisture exchange filter in the breathing circuit can significantly increase resistance to the inspiration and expiration.

Increased resistance causes the increased patient’s work during spontaneous breathing or initialization trigger effort at trigger support ventilation. Under unfavorable circumstances, increasing of the expiration resistance can lead to an undesirable increasing of the pressure in the respiratory system of the patient (autoPEEP phenomenon).

The resistance connected with the heat and moisture exchange filter, the device cannot control directly. Therefore, when using the heat and moisture exchange filter user should:

- frequently monitor the patient's condition;
- carefully follow to the guidance on the proper use of heat and moisture exchange filter.

ATTENTION!

It is prohibited to use heat and moisture exchange filter with nebulizer or with the respiratory gas humidifier!

4.20 Nebulizer

The device provides the use of pneumo spray-type nebulizers (inhalation solutions sprayers), for example, CIRRUS 2505 made by INTERSURGICAL. These nebulizers are intended for operation with one patient and cannot be sterilized and reused.

ATTENTION!

While working with the nebulizer, do not use heat and moisture exchange filter. Inhalation of different medicines can cause blockage of the filter with increasing resistance to exhalation of the breathing circuit.

For preparing the nebulizer for operation:

- Connect the connecting tube supplied with the nebulizer to the "Nebulizer" fitting on the front panel of ventilator and to the inlet fitting of the nebulizer (see Figure 4.13).

Figure 4.13 – Connection of the connecting tube of the nebulizer to the nipple on the front panel of the ventilator

- Connect the nebulizer to the breathing circuit as shown in Figure 4.14. Operating position of the nebulizer is below the breathing circuit.
- Make sure that device is working properly in the appropriate ventilation mode.
- Set the desired time of nebulizer's operation in [Menu] → [Additional functions] → [Nebul. work time] (0 - 60 min).
- Turn on the nebulizer by pressing the encoder.

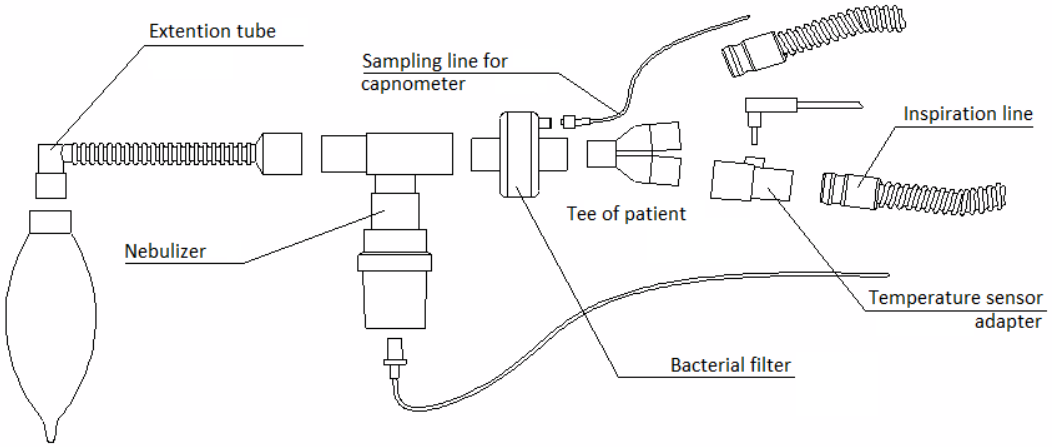


Figure 4.14 – One of the variants of connection of the nebulizer

It is possible to turn the nebulizer on only if the device operates in one of the ventilation modes. If you turn the nebulizer immediately at the power supply, nothing will happen.

During inhalation in the indication area gray information message "Nebulizer is on" is displayed. After the set time interval inhalation stops automatically, and the message disappear.

For early termination of the inhalation select "Nebul. work time 0 min" in [Menu] → [Additional functions].

When user turns the nebulizer on again, countdown will start working.

The device can be provided with blocking of nebulizer in pediatric mode. In addition operation of the nebulizer is blocked in ventilation mode with the volume control with set V_T of less than 100 ml.

For the operation in the pediatric mode, the nebulizer with vibrating mesh without introducing additional flow is recommended (AeroNeb PRO), which can be supplied on request in the delivery kit of the device. Such nebulizer does not require synchronization with the device and operates independently. All controls are located on the nebulizer.

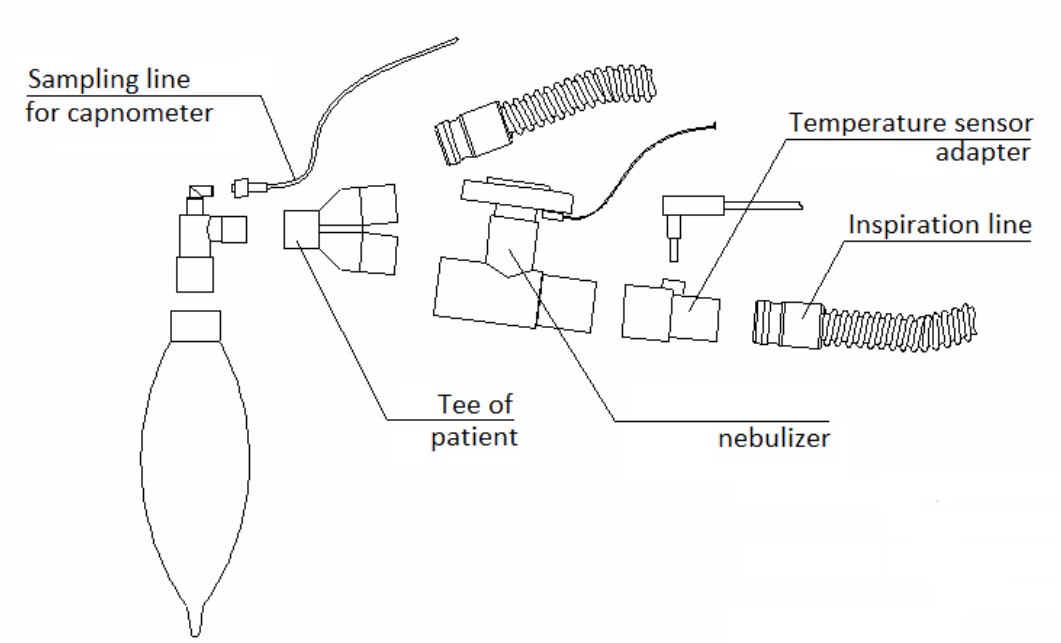


Figure 4.15 – Connecting of the nebulizer AeroNeb Pro

During the operation in every breathing cycle the device delivers pressure of 1.8 bar into the spray chamber of nebulizer. Pure oxygen is used to create the pressure.

At every inspiration medicines are sprayed from the inhaler container. Since spraying is carried out with oxygen, FiO_2 value of the inspired gas mixture slightly increases. Therefore during inhalation, it is necessary to consider an increase in oxygen concentration in air mixture.

Due to its principle of operation the nebulizer creates additional inspiratory flow. In the modes with volume control the device software takes into account this additional flow.

The software of the ventilator blocks the nebulizer if set tidal volume is less than the additional flow generated by the nebulizer. In this case it is necessary to transfer the ventilator to operation with the pressure control.

In the absence of pressure in oxygen line and if the nebulizer is turned on, the display will show that the nebulizer is on, however, compressed oxygen will not enter the chamber because of its absence. So spraying of the medicines by the nebulizer will not occur.

Operation of the nebulizer is prohibited in the following situations:

1. Abnormal alarm conditions such as "disconnection", "occlusion". To re-enable the nebulizer use menu of device.
2. For the volumetric mode of ventilation such inspiratory volume and time are set, that the performance of the nebulizer plus the breathing gas minimum flow produced by the flow generator will result in exceeding the inspiration volume specified by the user.
3. At selection of any calibration operations in the service menu.

Features of the pneumatic spray-type nebulizer operation:

- The inaccuracies of the displayed and set tidal volume (volume of inspiration), inspiratory pressure, minute ventilation will exceed the values specified in the current Manual, because that additional flow cause by the nebulizer can vary from instance to instance. Use measured values of expiratory volume and respiratory rate indicated correctly to control the adequacy of ventilation with the nebulizer.
- Displayed value of the oxygen concentration in the breathing mix (blue EtO_2) may differ from that set on the device one (FiO_2). This happens because the device measures and regulates the oxygen concentration directly on the outlet of the device, and at low flow of breathing gas from the device and additional large flow from the nebulizer, significant increasing of the set for the normal conditions EtO_2 indication inaccuracy can occur.
- When using the nebulizer it is recommended to disable of the metabolism module, because the ingress of the medicine into the monitoring line can cause its occlusion.
- CIRRUS 2505 nebulizer provides 74 % of particles less than 5 microns in diameter (median of diameter is 2.75 microns) at the gas mixture flow of 8 lpm. Maximum gas mixture flow is 10 lpm.

Operation of nebulizer is possible only if the device is connected to the high pressure oxygen line.

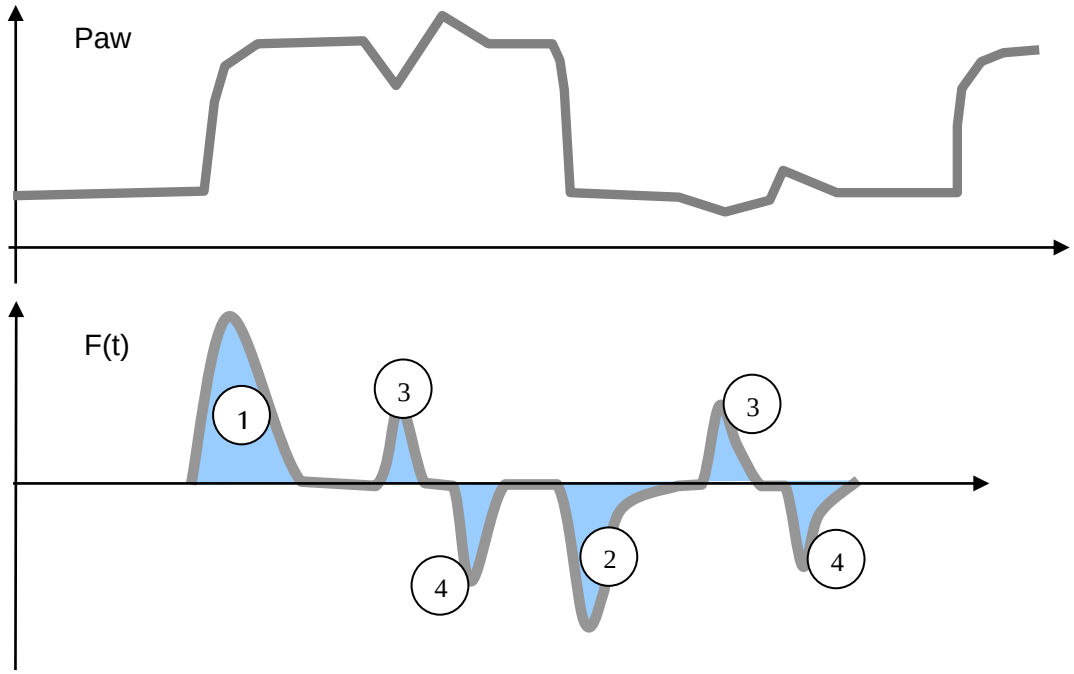
4.21 "Open valve" function

The "Open valve" function reflects the current trend of maintenance and support of spontaneous breathing at all stages of the ventilation.

The "Open valve" allows the patient to breathe freely during any phase of the hardware respiratory cycle.

The "Open valve" function operates in all ventilation modes. In ventilation modes with volume control (CMV/VCV, SIMV/VC), the "Open valve" function operates in the inspiratory phase.

The “Open valve” function does not operate during static compliance measurement.



1 – hardware inspiration
2 – hardware expiration
3 – spontaneous inspiration
4 – spontaneous expiration

Figure 4.16 – Spontaneous inspirations and expiration at any phase of ventilator’s breathing cycle

“Open valve” function increases flow of the inspired mixture in the presence of spontaneous patient’s effort, allowing him to breathe (3) regardless of the hardware respiratory cycle phase (1, 2) and opens the expiration valve at the patient’s attempt of exhalation (4) independently the phase of the hardware respiratory cycle (1, 2). The device will maintain the pressure corresponding to the phase of the ventilator’s breathing cycle.

Note:

The sensitivity threshold of the function is 0.2 mbar

5 OPTIONAL FEATURES OF THE DEVICE

5.1 Mainstream CO_2 sensor (capnometer)

External module of breathing gas analysis without sampling (hereinafter – mainstream capnometer) is optionally delivered with the device and allows to monitor:

- CO_2 concentration at the end ($EtCO_2$) and at the beginning ($FiCO_2$) of the exhalation;
- capnogram (PCO_2).

Capnometer operating principle is based on the method of measuring the infrared light absorbtion in the absorption spectrum of carbon dioxide.

ATTENTION!

Only mainstream CO_2 sensors supplied by Triton Electronic Systems Ltd. are compatible with ventilator.

The module includes the mainstream CO_2 sensor and airway adapters for different types of patients:

1. *Enclosure of the sensor;*
2. *Airway adapter (adult and neonate);*
3. *Socket for the connection to the ventilator;*
4. *Cable of the sensor.*

Figure 5.1 - Mainstream capnometer

ATTENTION!

It is not recommended to connect an mainstream capnometer when the device is switched on.

Connection of the mainstream capnometer:

- Check the sensor window and airway adapter. They must be dry and clean. Clean or replace the adapter if necessary.
- Connect the adapter with CO_2 sensor - combine labels on the adapter and sensor and connect till latching (see Figure 5.2).

Figure 5.2 – Connection of CO_2 sensor and airway adapter

- Connect the CO_2 sensor to the connector "CO_2" port on the front panel (see Figure 5.3).

Figure 5.3 – Connecting the CO_2 sensor to the CO_2 connector of the ventilator

- Turn on the device. The mainstream capnometer will switch on.
- In the graph setting menu (it. 4.12.1) select units of the displayed graphs: PCO_2 (%) or PCO_2 (mmHg).
- Wait for warm-up interval of mainstram capnometer (message on the display will disappear).

ATTENTION! **The interval of capnometer warming is about 2 minutes. Herewith a "Capno warming" message appears in the capnogram field.**

- Make zero calibration of capnometer if necessary (the first use of the module, or change of the airway adapter type).
- Insert the airway adapter between the elbow and tee of the ventilator circuit according to the scheme in Figure 5.4. It is recommended to connect the airway adapter directly or as close to the endotracheal tube as possible to reduce dead space.

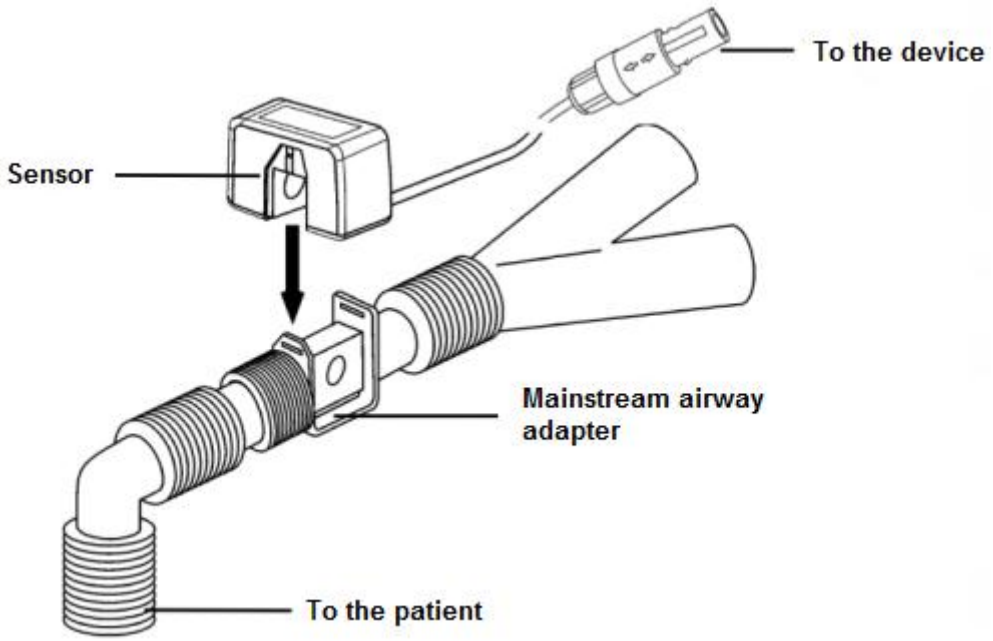


Figure 5.4 – Connection of the mainstream capnometer to breathing circuit

ATTENTION! **Windows of the airway adapter should be arranged vertically with respect to ground. This reduces or completely prevents contamination of adapter windows by the patient's discharge.**

ATTENTION!

Do not use CO_2 measurement results as the only basis for measuring ventilation parameters without taking into account clinical data and independent indicators, such as blood gases. CO_2 measurements may be inaccurate if there is a leak in the circuit or the sensor is fault.

ATTENTION!

Place the CO_2 sensor and cable in a such way to avoid entanglement, suffocation, or accidental rupture of the cable

Mainstream capnometer functioning

During operation mainstream capnometer displays the measured $EtCO_2$ value and capnogram (if selected in the graph window).

The CO_2 concentration can be displayed on the screen as partial pressure (mmHg) and (or) as the percentage concentration (%) depending on the settings of monitored parameter and graphics in the menu.

During operation capnometer continuously analyzes the state of its technical parameters and units. Together with capnometer device also has protocol converter.

In case of situations that prevent normal operation, capnometer is disabled with the failure message: "Capnometer error" or "Protocol Converter error".

There is no influence on measuring accuracy of the mainstream capnometer in case of high respiration rate and I:E ration.

The cyclic pressure below 10 kPa does not significantly influence on measuring accuracy of the mainstream capnometer.

There is no drift in CO_2 concentration measuring accuracy: within 6 hours the measuring accuracy complies with stated one.

Measurement accuracy:

- CO_2 concentration: $\pm(0,2+0,06K_{meas})$ %

- CO_2 partial pressure $\pm(1,52+0,06P_{meas})$ mmHg

Total system response time and rise time: not more than 180 ms

Zero calibration of the mainstream capnometer

Zero calibration of the mainstream capnometer allows to compensate the optical differences between the various types of airway adapters. These differences are caused by differences in the material of the window of disposable and reusable adapters and differences in the size of the adapter window.

Calibration should be carried out with the replacement of the airway adapter, as well as after its disinfection / sterilization.

ATTENTION!

The zero calibration procedure of the module is available only upon completion of the warm interval of capnometer, which is about 2 minutes. At the warm-up the appropriate message is displayed.

ATTENTION!

During the calibration procedure, the airway adapter shall be installed in the mainstream CO_2 sensor and disconnected from the breathing circuit.

When the airway adapter is changed with the adapter of the same type, generally calibration is not required.

To calibrate:

- Wait for completion of warm-up interval of the capnometer (message of the warming up on the display will disappear).
- Enter [Menu] → [Service menu] → [Calibration] → [CAPNO].

- Select and click on the line "Zero calibration for MS capno".

For correct calibration it is necessary to ensure absence of CO_2 in the measuring cell of the adapter used in the calibration during the whole calibration interval which takes up to 30 seconds.

Checking the alarm limits of CO_2 sensor

Before using the mainstream CO_2 sensor ensure that alarm system works properly. Follow the instructions below:

1. Connect the CO_2 sensor with airway adapter to ventilator and display the PCO_2 graph.
2. Take a breath to the airway adapter, ensure that $EtCO_2$ measurement and PCO_2 graph are displayed on the screen.
3. Set the upper alarm limit of $EtCO_2$ parameter lower then measured value.
4. Ensure that alarm “High $EtCO_2$” is activated.
5. Set the lower alarm limit of $EtCO_2$ parameter higher then measured value.
6. Ensure that alarm “Low $EtCO_2$” is activated.

Before using on the patient, the mainstream CO2 sensor must be cleaned and disinfected, and the airway adapter must be reprocessed.

Disinfection of mainstream CO_2 sensor and reprocessing of airway adapters

Please, follow the recommendation stated in it. 3.5.1 for cleaning and disinfection procedure of mainstream CO_2 sensor. For information regarding to reprocessing of airway adapters refer to it. 3.5.2.

5.2 Volume capnometry

Optionally the device may be equipped with the function of volume capnometry, which operates only together with mainstream capnometer. Volume capnometer (sometimes the “volumetric capnometer” term is used) allows to define the following parameters:

- elimination of CO_2 per minute (VCO_2), which characterizes the metabolism rate (e.g., high value indicates sepsis etc.), and reflects the effectiveness of applied respiratory therapy in dynamics;
- functional dead space (Vd);
- minute alveolar ventilation (MValv).

The calculation method of the CO_2 amount per expiration is the combined integration of patient flow curve and the capnogram from the mainstream capnometer (see Figure 5.5).

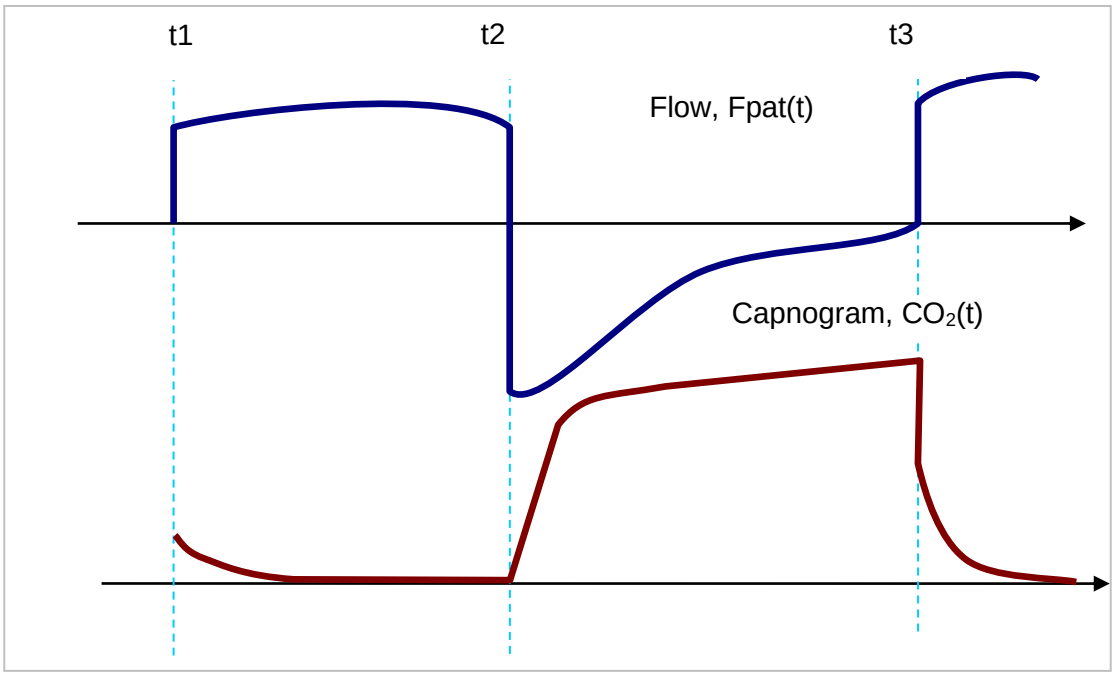


Figure 5.5 – Synchronization of the capnogram with the flow curve

CO_2 elimination per breathing cycle is:

$$VCO2_i = \int_{t2}^{t3} F_{\text{pat}}(t) \cdot CO2(t) \cdot dt - \int_{t1}^{t2} F_{\text{pat}}(t) \cdot CO2(t) \cdot dt \qquad (1)$$

where: *VCO2i – CO_2 elimination per i-breathing cycle, units, ml,*

CO2(t) – the relative concentration of CO_2,

F_{pat}(t) – the patient's flow rate, lpm.

Measuring units of VCO_2 are milliliters given to the patient’s condition (BTPS). Such reduction is necessary for the correct application of the formulas for calculating other parameters.

Elimination of CO_2 per minute is:

$$VCO2_m = \sum_{i=1}^{n} VCO2i \qquad (2)$$

where: *VCO_2m – CO_2 elimination per minute,*

n – number of breaths during the last minute.

Method of calculation of the functional dead space that effectively allows to assess the volume of gas lost in the respiratory tract, or gas that doesn't take part in the gas exchange is modified Bohr equation:

$$Vd_i = \frac{EtCO2_i - \frac{1}{t3-t2}\int_{t2}^{t3} CO2(t)\cdot dt}{EtCO2_i}\cdot Vt_i \qquad (3)$$

where: Vd_i *– functional dead space, ml,*

Vt_i *– expiration volume,*

$\int_{t2}^{t3} CO2(t)\cdot dt$ *– average concentration of carbon dioxide in the exhalation*

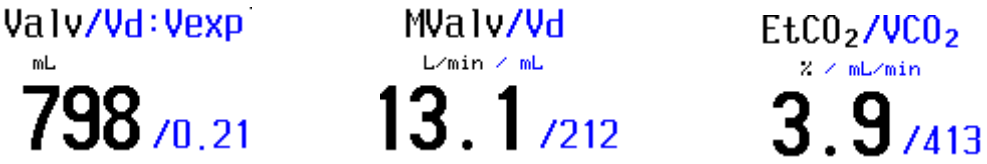
t3-t2 – expiratory time

Alveolar ventilation per minute is equal to the difference between the minute respiratory volume and the amount of dead space ventilation.

$$MValv_m = \sum_{i=1}^{n} VTi - VDi \qquad (4)$$

Minute ventilation contains not only gas that participates in the gas exchange, but ventilation is wasted in the airways. Thus the high minute ventilation does not always indicate the actual achievement of the alveolar area. Some part of the tidal volume falls into non-perfused or poorly perfused lung areas. MValv/Vd ratio characterizes the ratio of alveolar ventilation and dead space ventilation, and allows to evaluate the severity of disease.

To display the volume capnometry parameters select "$EtCO_2/VCO_2$" and "MValv/Vd" in the menu of settings of measuring parameter blocks (it.4.12.2) or by pressing of the touch button on the corresponding measurement parameter field:



The device also displays the graph of the instantaneous amount of carbon dioxide CO_2 exhaled by the patient

$$VCO2(t) = F_{pat}(t)\cdot CO2(t) \qquad (5)$$

5.3 Cardiac output by Fick

The function for cardiac output calculation by Fick works in conjunction with the volume capnometry because it is necessary to know the elimination of carbon dioxide VCO_2 and alveolar concentration of CO_2 for calculation of cardiac output CO.

Monitoring of cardiac output is recommended for all patients subjected to ventilation, as the artificial ventilation itself leads to induced inhibition of cardiac output.

The accuracy of the cardiac output calculation by Fick is strongly influenced by the following conditions - the presence of pulmonary shunts, the non-ventilated areas of the lung and other abnormalities of ventilation-perfusion ratios.

The calculation of cardiac output (CO) is performed by Fick equation:

$$CO = \frac{VCO_2 \cdot P_{vCO_2}}{(P_{vCO_2} - P_{aCO2}) \cdot k_r} \quad , \qquad (6)$$

where: *CO – cardiac output, ml/min,*

VCO_2 – minute CO_2 elimination, ml/min,

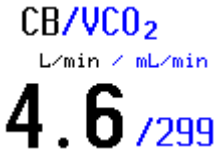
$PvCO_2$ – CO_2 partial pressure in the venous blood, mmHg,

$PaCO_2$ – CO_2 partial pressure in the arterial blood, mmHg,

($PvCO_2$ - $PaCO_2$) – delta of blood or arterial-venous difference, mmHg,

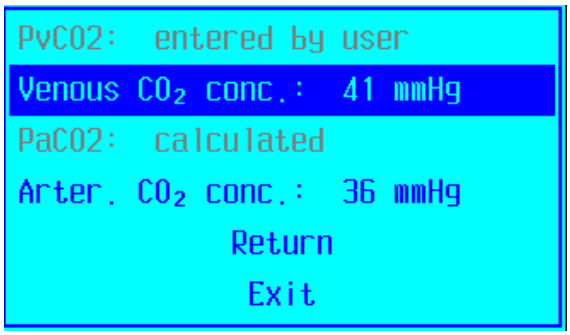
K_r – solubility of CO_2 in the blood plasma in the blood plasma (equal 0.53 at T=38 °C).

For displaying of the digital values of cardiac output and minute CO_2 elimination select CO/VCO_2 for the one of the modules of the measurement parameters [Menu] → [Display settings] → [Choose measured par. blocks]:



Enter the menu of venous and arterial CO_2 concentration parameters by pressing on the digital values of "CO/VCO_2", which is touch button, or through the menu of additional functions:

Button or [Menu] → [Additional functions] → [Cardiac output (by Fick)]:



In this menu enter the value of the venous ($PvCO_2$) and/or arterial ($PaCO_2$) CO_2 concentration obtained using one of the laboratory techniques. There are three possible ways to enter parameters:

1. Enter only $PvCO_2$ value, $PaCO_2$ value is calculated automatically as $PvCO_2$–5 mmHg.
2. Enter only $PaCO_2$ value, $PvCO_2$ value is calculated automatically as $PaCO_2$+5 mmHg.
3. Enter both values $PvCO_2$ and $PaCO_2$.

Explanatory inscriptions "entered by the user" and "calculated" show the way of entering of parameter.

At the entering of venous concentration parameters $PvCO_2$ and $PaCO_2$ they are checked for correctness:

- permitted range 10 - 150 mm Hg,
- venous CO_2 concentration is always higher than arterial,
- delta of blood from 3 to 12 mmHg; if the values are outside the allowable limits, boundary values are taken.

If $PaCO_2$ and/or $PvCO_2$ values were not updated for more than 4 hours or $EtCO_2$ value changed for more than 30% since last CO measurement, the ventilator displays the warning message: "Update $PaCO_2$/$PvCO_2$".

5.4 Pulse oximetry module

Optionally the device can be equipped with built-in pulse oximetry module which allows to monitor:

- oxygen saturation of arterial blood hemoglobin SpO_2;
- peripheral pulse rate PR;
- photoplethysmogram.

The delivery kit of the device contains the pulse oximetry sensor, usually finger clip-type one. On special request other types of pulse oximetry sensors are available.

To connect the sensor to the ventilator hold the connector housing, firmly insert it into "SpO_2" connector of the ventilator (yellow) ensuring their mutual orientation in which the two halves will join. The connector contains the special fastener that makes impossible accidental disconnection, for example by pulling for the sensor cable.

To disconnect and undock of the connector it is necessary to take up his enclosure and pull it. The outer part of the movable connector housing unlocks the fastener while moving. Therefore unlocking the connector is possible only by pulling by the hand of his enclosure.

ATTENTION!

To avoid damage of the sensor never try to pull on the cable to unlock the connector!

Figure 5.7 - Connecting the pulse oximetry sensor to the ventilator

Application of the pulse oximetry sensor to the patient:

Clip-type pulse oximetry sensor

- Use a finger without pressure cuff or arterial catheter.
- Select the finger with good pulse volume and the most close to the size of the sensor (if the nail polish is applied, remove it prior the application of the sensor). Make sure the finger completely covers the area of the sensor. Place the sensor so that the cable is along the back surface of the hand:

Figure 5.8 – Application of the clip-type pulse oximetry sensor

- At impossibility of proper placement of the sensor on the selected finger choose another finger.

ATTENTION!

To obtain the necessary accuracy and stability of measurement results finger and hand must be immovable.

Universal pulse oximetry sensor

CAUTION!

Avoid tissue compression during application of the pulse oximetry sensor.

The universal pulse oximetry sensor can be applied for all patient groups.

- If you use the universal pulse oximetry sensor on neonates or infant, apply the sensor on palm or foot (see Figure 5.9). There is no difference from which side an emitter located. Fix the sensor by strap.

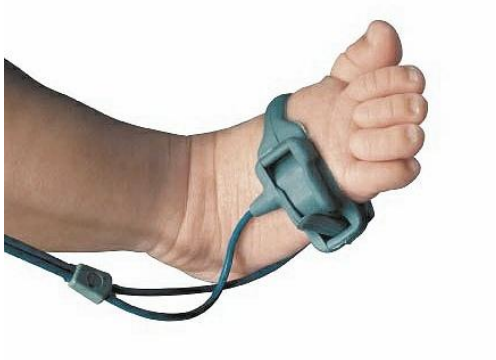


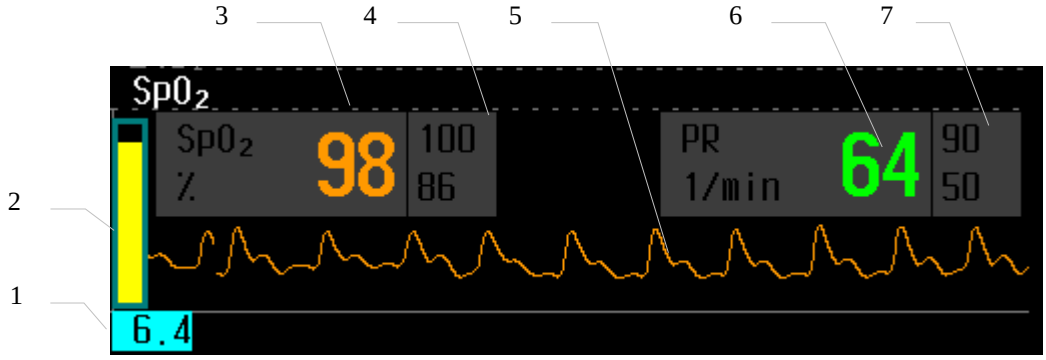
Figure 5.9 – Application of universal pulse oximetry sensor to neonate or infant

- If you use the universal pulse oximetry sensor on child or adult, apply the sensor on finger and fix it by the strap, as shown in Figure 5.10.

Figure 5.10 – Application of universal pulse oximetry sensor to child or adult

SpO_2 monitroring:

- Select the SpO_2 graph in the [Menu] → [Display settings] → [Graphs]:
- After installing of the sensor to the patient over some time (period of adaptation) photoplethysmogram appears on the screen. It is visual indication of the pulse (Fgure. 5.11, position 5). To the left from it is a column showing the pulse volume level (position 2). In saturation window measured numeric value of SpO_2 is displayed (position 3). If four graphics on the screen are set, the only PPG curve will be shown.



1 the numerical value of pulse volume in percent;

2 pulse volume bar in the logarithmic scale;

3 the numerical value of SpO_2;

4 the numerical values of SpO_2 alarm thresholds;

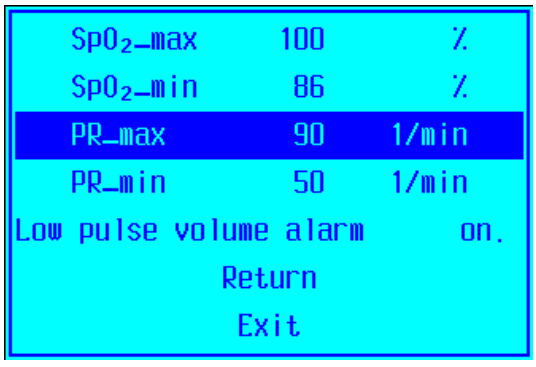
5 photoplethysmogram (PPG curve):

6 numerical value of the pulse rate;

7 the numerical values of pulse rate alarm.

Figure 5.11 – Window of the pulse oximetry channel

- By clicking on the SpO_2 graph field with numeric values (which are graphical buttons) menu of thresholds settings becomes available:

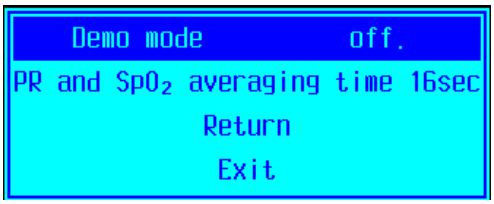


In this menu user can set the required SpO_2 and PR alarm thresholds and disable the low pulse volume alarm.

ATTENTION!

Because automatic control of the alarm signal triggering in the device is not provided, it is necessary to check the activation of the alarm by changing the value of the upper or lower threshold of one of the parameters.

- By clicking on other areas of SpO_2 graph without numerical values control menu of the SpO_2 module becomes available:



The "PR and SpO_2 averaging time" parameter is set depending on the patient's mobility and regulates the averaging time of the displayed SpO_2 and PR (standard default value is 16 s, that is most suitable for restless patients).

The device does not allow to adjust the delay of alarm signal triggering, but allows to adjust averaging time that influences to the delay.

At the minimum averaging time (4 s), the alarm signal triggering will occur earlier with respect to the parameter change and its crossing the alarm thresholds than at the maximum averaging time (16 s).

- Pulse volume is the numerical value of the pulsating component of the measured signal caused by the pulsation of arterial blood flow. As pulse oximetry is based on the ripple signal, the pulse volume parameter can be used as the quality indicator for the SpO_2 measurement. The entire scope of the volume pulse bar corresponds to 10 %. If the pulse volume is 0.3 % or lower, the bar will turn red, the frame surrounding the bar will blink red, and the display will show the message "Low pulse signal".
- Small signal amplitudes are automatically enhanced, so photoplethysmogram always has approximately the same size, so follow the physiological view of the curve (non-physiological curves can be recognized by the angular or the toothed form or by the increased noise).

ATTENTION! **General or local hypothermia, or labored blood circulation in the hand can lead to instable operation of device and unreliable result of measurement.**

CAUTION! **To eliminate the violations of local circulation till the press necrosis and to obtain reliable measurement results reinstall the pulse oximetry sensor at least every 4 hours (for children up to one year - every 30 ... 60 minutes).**

CAUTION! **The sensor wetted by the liquid or with damaged insulation can cause burns during the use of electrosurgical instruments. Use only dry and faultless sensors.**

CAUTION! **Sensor wire should never lie under the patient to avoid bedsores.**

ATTENTION! **Avoid the falling of the sensor or its cable under the wheels of carts and other heavy objects to prevent them from damage and failure.**

ATTENTION! **Only pulse oximetry sensors listed in the "Delivery set" section of the current Manual can be used with the device. The wavelength of the sensor's emitters in the radiation maximum in the red range is 660 nm, in the infrared range of 905 nm.**

The SpO_2 measurement accuracy

- SpO_2 Measuring accuracy in a range 70 - 100 %: ±2 %
- Data update period: 1 s

The SpO_2 measurement accuracy comply with international standard ISO 80601-2-61. Compliance tests were made by using pulse oximetry sensor, reusable, clip, adult RM.501.00.124-01 and pulse oximetry sensor, reusable, wrap, neonatal RM.501.00.004-01. The measurement accuracy was defined as a result of clinical tests on 64 patients from ICU

(adult at the age from 20 to 81 years and neonates/infants at the age 10 days to 7 month, male and female, white skin color) using CO-oximeter.

The SpO_2 measurement accuracy in the condition of low perfusion (from 0.04 to 0.4) was confirmed by the tests performed on simulator Biotek Index 2 for pulse volume higher that 0.04%.

The measurements carried out by the pulse oximetry module are probabilistic and it can be expected that only two thirds of these measurements can fall within the limits of the standard deviation in comparison with the measurements performed with the CO-oximeter.

Intravascular administration of dyes such as methylene blue, indigo carmine, or any substances containing dyes that alter the usual absorption of light by blood can lead to erroneous SpO_2 measurement results.

Cleaning and disinfection of pulse oximetry sensors

Please, follow the recommendation stated in it. 3.5.1 for cleaning and disinfection procedure of sensor.

5.5 Metabolism module

The device can be equipped with the module of metabolic parameters measuring by indirect calorimetry method that allows to measure:

- oxygen consumption VO_2, ml/min;
- elimination of CO_2 per minute VCO_2, ml/min;

according to the measured values module calculates:

- respiratory quotient RQ, relative units;
- resting energy expenditure REE, kcal/day.

The measurement of oxygen consumption VO_2 is produced by co-processing of instantaneous values of oxygen concentration and flow rate.

The measurement of carbon dioxide exhaled by the patient VCO_2 is produced by co-processing of instantaneous values of capnogram and flow rate.

Respiratory quotient RQ is calculated using equation:

$$RQ = VCO_2 / VO_2 \qquad (7)$$

Modified Weir equation for the indirect calorimetry is used to calculate the resting energy expenditure:

$$REE\ (kcal/day) = (3.941 \times VO_2 + 1.106 \times VCO_2) \times N \qquad (8)$$

where: *REE – total energy consumption (resting energy expenditure) at rest,*

VCO_2 – minute volume of the exhaled CO_2, lpm,

VO_2 – minute volume of the consumed O_2, lpm,

N - the number of minutes in the day.

Pneumatic system of the metabolism module has two ports. Input “REE” pneumo connector is located directly on the water trap of the device and is used for the sampling line connection. Output port (see Figure.2.1, position 22) is also located on the front panel and is used for elimination of the test sample to the atmosphere or ventilation system of medical facilities.

Water trap is designed for protection of the pneumatic system of device from liquid.

1 - Clamps for securing;
2 - Bacterial filter;
3 - Pneumo connector for the sampling line;
4 - Removable tank - water trap.

Figure 5.12 – Water trap

Preparing for operation

- Install the water trap in the appropriate ports on the front panel of the ventilator.
- Install a heat and moisture exchanging (bacterial) respiratory filter to the patient's tee of the breathing circuit
- Connect mainstream CO_2 sensor to the ventilator (see Figure.2.1, position 26). Operation of mainstream capnometer is described in Section 5.1.

- Join the airway adapter with mainstream capnometer and connect it to the patient's tee in the breathing circuit.
- Connect the monitoring line adapter to the airway adapter of the mainstream capnometer.
- Connect the monitoring line to the adapter on the breathing circuit and to the water trap on the ventilator*.

** - use the monitoring line from the delivery set or similar (internal diameter 1.2 mm, length 1.8 ... 2 m with two connectors of the Luer-Lock type at the end).*

During preparing for the operation observe the following guidelines:

ATTENTION

Make sure that all elements of measurement scheme are securely connected to each other. The measurement results are not valid If the leakage occurred.

- Use only clean and dry sampling lines, without drops of liquid inside.
- For dripping of the condensate produced in connecting device middle part of it should be hung higher that its ends. Port of the adapter connected to the sampling line should be faced up to eliminate the accumulation of moisture in the adapter (see Figure 5.13).

Figure 5.13 – Connecting of the sampling line

Turning on the metabolism module

- Before switching on the metabolism module connect and warm up the mainstream capnometer (see it.5.1).
- Select row “Metabolism” in the “Monitoring” window to turn on the metabolism module (see Figure 4.4, position 14):

- Check the appearance of the metabolic parameters display window and the status message "Measurement" in the bottom line of the window:

** - FiO2 readings may appear with a delay of a few seconds.*

- During using the metabolism module, it is recommended to display PCO_2, PO_2 [%] window, where capnogram and oxigram of the respiratory cycle (FiO2(t) - EtO2(t)) are displayed simultaneously.

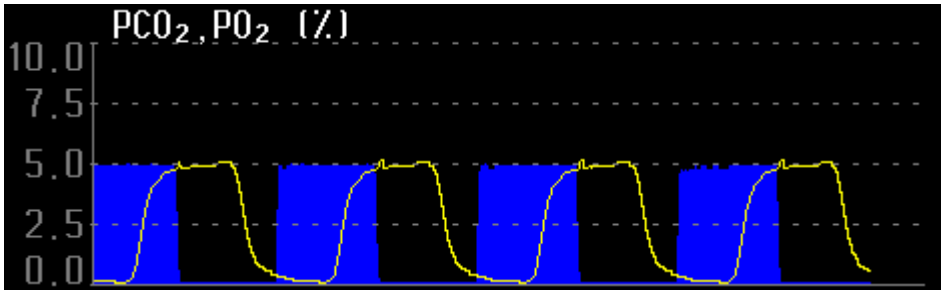


Figure 5.14 - Combined graph of capnogram and oxigram

- At displaying of metabolic parameters VCO_2, VO_2, RQ, REE averaging is performed in the interval of 1 min.
- VO_2, VCO_2, RQ, REE parameters are stored in the trend and can be viewed later (see it. 4.13).

Metabolism status messages

ATTENTION!

Metabolism status messages are displayed only in the bottom line of the "Metabolism" window. These messages are not displayed neither in the area of alarm list indication nor 'Alarm log' section.

Table 5.1. Metabolism status messages

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
1.	Measuring	Measurement	Metabolism module is working properly.
2.	Zero calibr.	Zero calibration	The message disappeared automatically after calibration finishing.
3.	Warming	Warming	The message disappeared automatically after warming finishing.
4.	Occlusion	Occlusion	Check the sampling line and water trap for occlusion. If it is necessary replace the sampling line with a new one.

No	Alarm message	Alarm conditions	Reaction of ventilator, operator's actions
5.	Drying	Drying of the line	The message disappeared automatically after calibration finishing.
6.	User turn off	Turned off by user	The message disappeared automatically after turning on the metabolism module.
7.	Off. Occlusion	Turned off due to occlusion	The message disappeared automatically after removing the occlusion and turning on the metabolism module.
8.	Emitter malfun	Emitter malfununction	The ventilator continue operation without metabolism module. Contact service department.
9.	Receiver malf.	Receiver malfununction.	
10.	Compress malf.	Compress malfununction.	
11.	Press.sens err	Pressure sensor error	
12.	Off. Overheat	Off. Overheat	
13.	Poured chamber	Emitter malfununction	
14.	Not used	Metabolism module is not used	Metabolism module is not used. The message disappeared automatically after starting operation.
15.	Blowing failed	Blowing failed	The message disappeared automatically after finishing of the blowing.

ATTENTION!

Correct measuring of metabolic parameters is provided at the FiO_2 values not exceeding 60 %. This is caused by the features of the current method of measurement.

ATTENTION!

For the more accurate measurement of metabolic parameters it is recommended before the start of patient's ventilation to calibrate the O_2 sensor of metabolism module through [Menu] → [Service Menu] → [Calibration] → [CAPNO] in accordance with it. 4.16.2.

- Calculation of metabolic parameters is blocked in the absence of fixing of respiration, during zero calibration and occlusion of sampling line.
- When operating with metabolism module remember that explosion of liquid through sampling line in its measuring path can affect normal operation, so the device has number of measures for protection against moisture.
- The main barrier protecting the measuring path from the liquids is water trap for the separation and condensation of the moisture in the sample and for its accumulation in the special removable water trap reservoir, which periodically has to be emptied. It takes about 40 hours for water trap to become full under condition of operating temperature 23°C, patient respiration gas 37° and 100% RH.

CAUTION!

Handle the contents of water trap as you would handle any bodily fluid. Failure to follow this instruction causes infection.

- During long-term operation of metabolism module under high humidity of the sample gas sampling line can accumulate a significant amount of condensate, which leads to the formation of liquid droplets. Large number of droplets can cause occlusion of the measuring path and metabolism module malfunction. In the case of frequent messages about tract occlusion it is usually sufficient to replace the sampling line for a new dry one.
- After every finishing of operation with metabolism module it is recommended to disconnect the sampling line from it and run for 5 ... 10 minutes to dry its internal pneumatic system, and to extend the service life of the oxygen sensor.

Timely empty the water trap, never allow its limit filling. Remember that the liquid in the measuring path of metabolism module may cause undesired operation! In case of ingress of liquid in the measuring path of metabolism module WARRANTY REPAIR IS NOT PERFORMED.

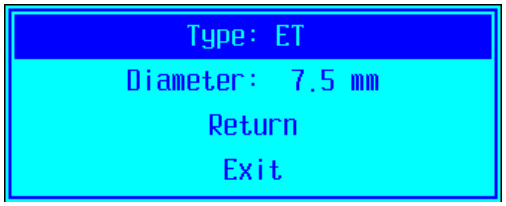
Test of pneumatic system hermiticity

- Test of the pneumatic system hermiticity is recommended after each emptying of water trap and in cases of any doubts in the correct operation, for example, in accuracy of measurement.
- The test can be performed by short time closing of the sampling line inlet connected to the inlet port of water trap. It should lead to displaying of message "Occlusion" in the status bar in the "Metabolism" window.
- During test of the pneumatic system hermiticity the pneumatic system should be closed for the short time, or after two failed attempts to block it the metabolism module will automatically be turned off with the status message “Occlusion”.
- If test was not successful, disconnect of the sampling line from water trap and directly close the inlet port of water trap. If message about occlusion appears, the reason is in the tube or its loose connection with inlet port, and if not, the reason is inside pneumatic system of the device.
- Firstly ensure that there are no leaks in the water trap reservoir, especially if the malfunction has appeared after it`s discharge. Carefully check the installation of the removable reservoir paying particular attention to its integrity and hermiticity. If necessary, replace the water trap with the new one.
- Also the cause of poor hermiticity may be outworn or damaged sealing rings (O-rings) of counterpart port of water trap. In this and other cases call customer service to find the reasons of leakage and their elimination.
- To return to the normal operation of the metabolism module close the "Metabolism" window and enter the window again through the "Monitoring" menu.

5.6 Compensation of endotracheal tube resistance

Before the beginning of the ventilation, check the parameters of the used endotracheal tube in [Menu] → [Ventilation parameters] → [Patient's parameters] → [Tube parameters]:

- Tube type – endotracheal (ET), tracheostomy (TST);
- The diameter of the tube.



Selection of the tube diameter is made depending on the patient's ideal weight IBW in the permitted range of the weight (for the protection from errors):

Table 5.2. Application of the endotracheal tube

IBW, kg	Default diameter of ET and TST, mm	Permitted range of the diameters of ET and TST, mm
7 - 10	4.5	4.5
10 - 19	4.5	4.5 - 5.5
19 - 25	5.0	5.0 - 6.0
25 - 32	5.5	5.5 - 7.0
32 - 37	6.0	6.0 - 7.5
37 - 50	6.5	6.5 - 8.0
50 - 61	7.0	7.0 - 9.0
61 - 71	7.5	7.5 - 9.5
71 - 101	8.0	8.0 - 10
101 - 130	8.5	8.5 - 10
130 - 150	9.0	9.0 - 10

The average value of the ET diameter for the current ideal body weight of the patient is set by default.

The function of the endotracheal tube compensation is available in CPAP+PS mode by adjusting of ETC parameter in the line of ventilation parameters setting (top row).

The user can select the desired level of the tube resistance compensation from 0 to 100 %. A value of 0 corresponds to the OFF state (the initial state of the device at power up).

Optionally the function of the endotracheal tube compensation may be available in other modes of the ventilation.

At the activation of the tube resistance compensation, the instantaneous pressure after the tube is calculated as follows:

$$Paw1 = Paw - \Delta P \qquad (9)$$

where: *Paw1 – pressure after (below) the tube, cmH_2O,*

Paw – measured pressure, cmH_2O,

ΔP – pressure drop on the tube calculated according to the data about the type and diameter of the tube and the set degree of compensation, cmH_2O

Also at the activation of the function pressure curve changes its form on the device's display. Not only the pressure in the circuit, but also calculated pressure below the tube is displayed

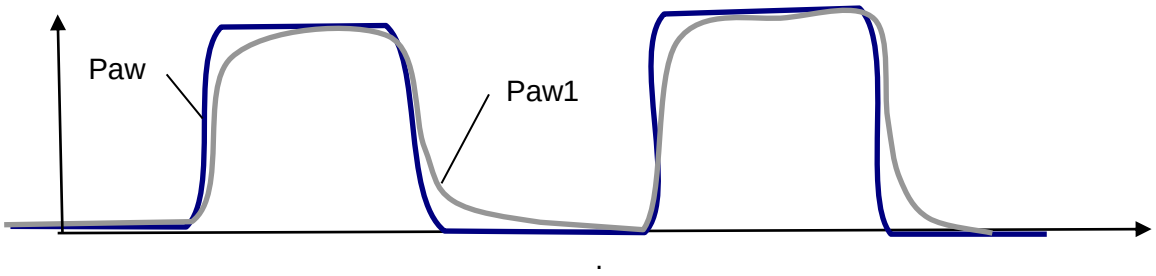


Figure 5.15 – Calculated pressure curve

5.7 “Auxiliary external pressure” function

If the external pressure monitoring function is available, the device has “Paux” fitting (see Figure 2.1, position 15) for auxiliary pressure monitoring with the catheter. In dependence of measuring site there are two major types of the catheters:

1**) tracheal catheter**; Tracheal catheter is intended for the monitoring of the actual pressure in the trachea and the actual PEEP regardless of the ventilation parameters.

2) **esophageal balloon catheter** for measuring pressure in esophagus or **multifunction nasogastric catheter** for measuring in esophagus or stomach.

The esophageal and multifunction nasogastric balloon catheters are intended mainly for the monitoring of esophageal pressure to calculate transpulmonary pressure on the inspiration and expiration phase. In addition, multifunction nasogastric catheter allows to monitor pressure in the stomach and feed the patient.

ATTENTION!

Before switching on the device make sure that monitoring line for pressure measurement disconnected from the “Paux” fitting (see Figure 2.1, position 15). Connect the monitoring line when the device is switched on.

Auxiliary external pressure displaying

To display the window of digital values of maximum, medium and minimum auxiliary external pressure select Paux for one of the blocks of measurement parameters in [Menu] → [Display settings] → [Choose measured par. blocks]:

Monitoring of external auxiliary pressure waveform is made on any graph field by selecting of the Paux curve for displaying in [Menu] → [Display settings] → [Graphs].

On Paux curve following data are displayed:

- Paux scale (coincides with the Paw graph, is set by the parameter Pmax);
- external pressure curve on a blue screen;
- yellow Paw-Paux curve:

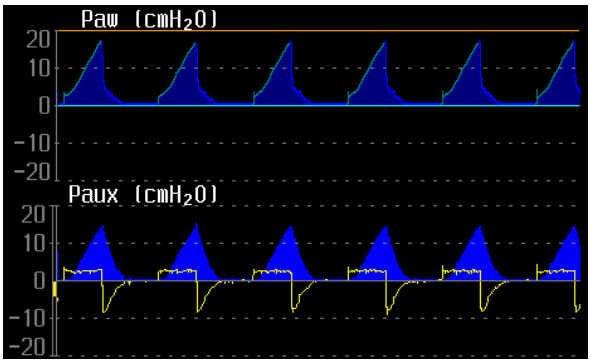


Figure 5.16 – Additional external pressure curve

At selection of the "Loop" type of graphs the spirometric loop V/Paux becomes available:

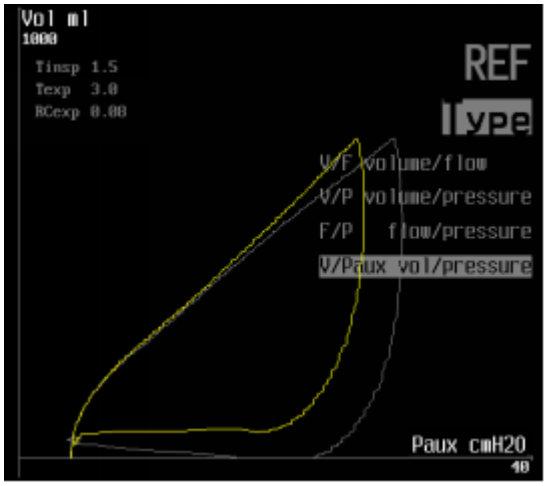


Figure 5.17 – Additional external pressure curve

Assembly of the circuit of external auxiliary pressure measurement in trachea

Assembly scheme for pressure measurement in trachea is shown in Figure 5.18.

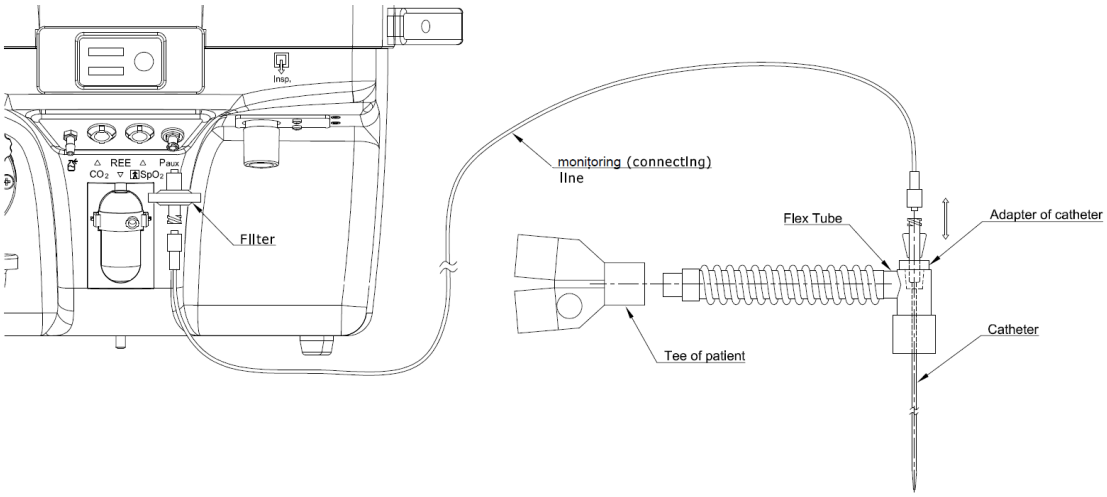
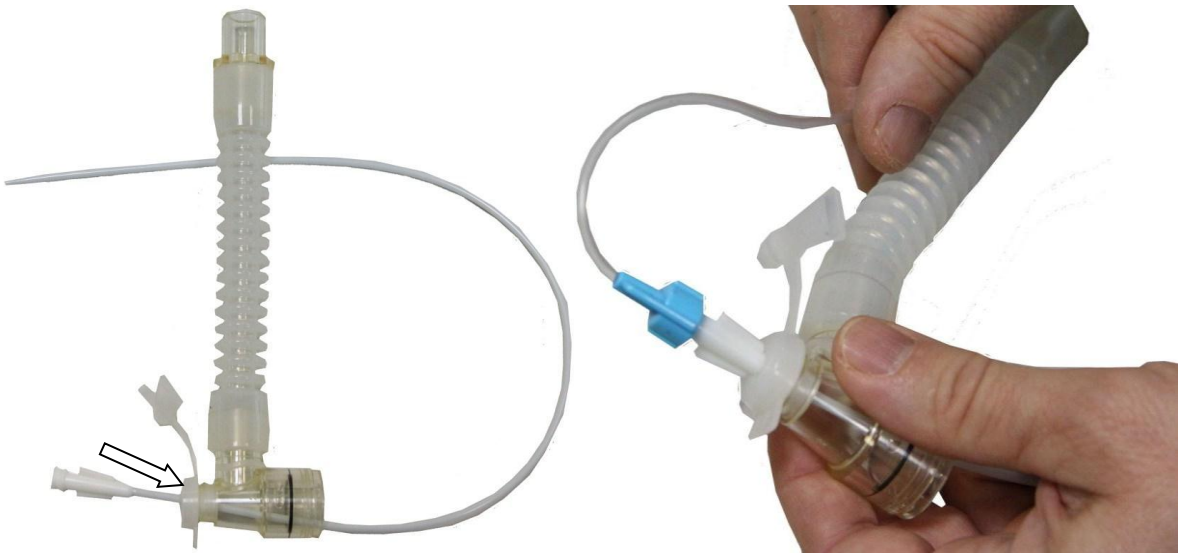


Figure 5.18 – Connection scheme of the tracheal catheter

- Connect a respiratory (virus-bacterial) filter with the Luer connector and an monitoring line to the Paux pressure port.

CAUTION! **Measurement of external auxiliary pressure without respiratory (virus-bacterial filter) is not allowed.**

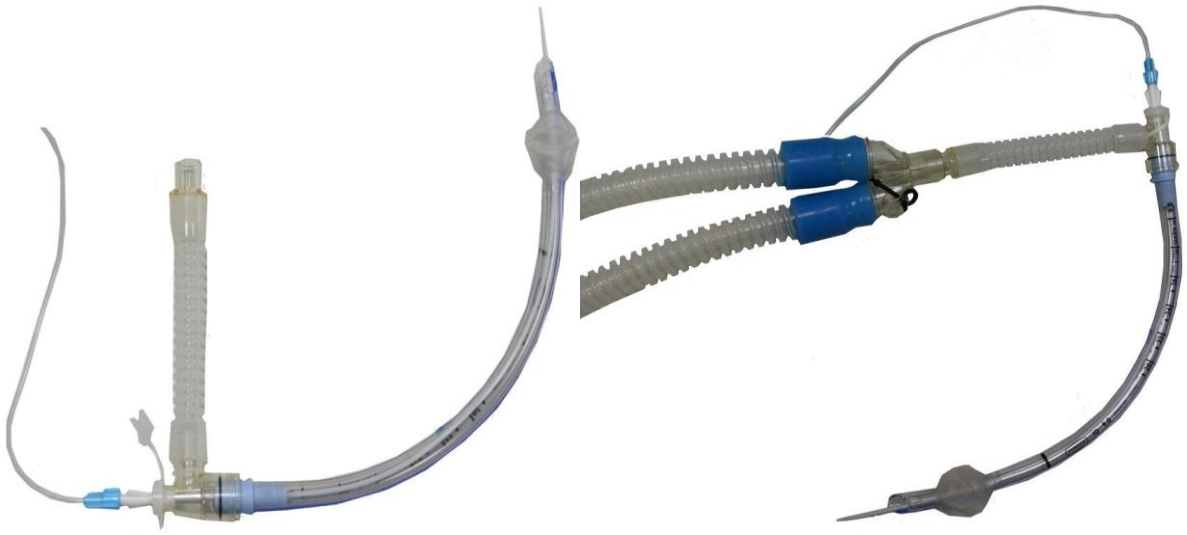
- Pass the catheter from the delivery set of the device through the adapter of the catheter into the flex tube connector. Cut the catheter tube according to the length of the endotracheal tube (see Figure 5.19a). Connect the monitoring line to the catheter (see Figure 5.19b).



a) *b)*

Figure 5.19 – Connecting of the catheter (a) and monitoring line (b)

- Connect the endotracheal or tracheostomy tube to the flex tube connector (Figure 5.20a). Then the assembly should be connected to the tee of the breathing circuit (Figure 5.20b).



a) *b)*

Figure 5.20 – Connection of the endotracheal tube (a) and the tee of the breathing circuit (b)

Assembly of the circuit of external auxiliary pressure measurement in esophagus or stomach

- Follow the procedure operation instructions supplied with the catheters.
- Connect a hydrophobic (virus-bacterial) filter with the Luer connector and monitoring line to the Paux pressure port (see Figure 5.21).

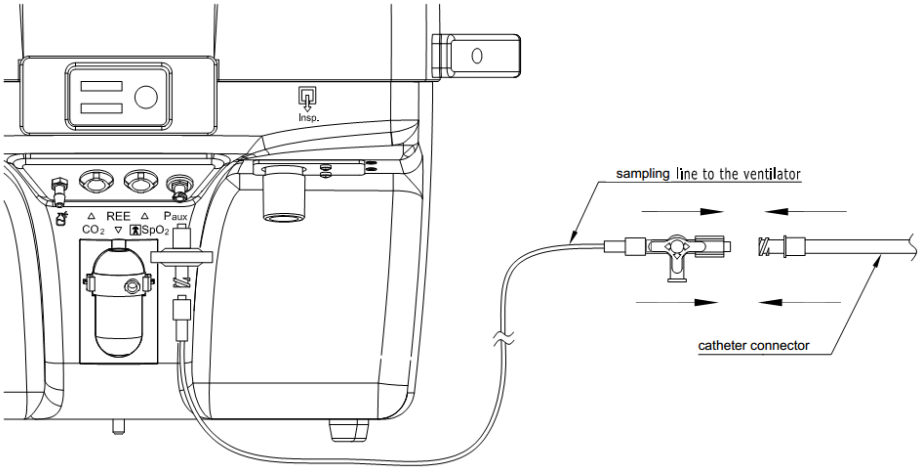
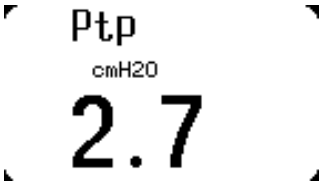


Figure 5.21 - Connection of the esophageal balloon catheter or multifunction nasogastric catheter to the ventilator

Indication of transpulmonary pressure

To display the calculated transpulmonary pressure select the Ptp value for one of the measurement parameter blocks through [Menu] → [Display settings] → [Choose measured par.blocks]:



Transpulmonary pressure is calculated in the ventilator on each respiratory cycle according to the following algorithm:

Ptp = (Paw end of inspiration - Paw end of expiraiton) - (Pes end of inspiration - Pes end of expiraiton),

where: *Pes – pressure in the esophagus, (Paux=Pes),*

Paw – airway pressure.

Transpulmonary pressure shall be within: 0 < Ptp < 25 cmH_2O.

Shifting of the Ptp graph into negative area (Ptp < 0) means that esophageal pressure Pes is higher than PEEP, the PEEP adjustment - increasing is required.

5.8 Operating with low pressure oxygen source

Optionally the device can be equipped with an additional inlet oxygen nipple for connection to the low-pressure oxygen source.

Low-pressure oxygen sources include all types of concentrators with a pressure up to 0.5 kgf/cm^2 (bar). It is recommended to use oxygen concentrators with a capacity of at least 5 lpm.

- Connect the device to the low-pressure source using oxygen hose and quick-release connector from the delivery kit of the device.

ATTENTION!

It is prohibited to connect pressure sources with operating pressure more than 0.5 kgf/cm^2 (bar) to the low-pressure connection because it can lead to device failure.

ATTENTION!

It is forbidden to supply humidified oxygen to the device to prevent its failure.

- By the flow regulator on the low-pressure oxygen source set the oxygen flow approximately corresponding to the minute respiration volume. If the minute volume is greater than the capacity of the oxygen concentrator, set the maximum flow value. It is allowed to set the maximum flow value on the oxygen concentrator even at the required minute respiration volume < 5 lpm. In this case there will be only a certain oxygen overcharge, and the device will provide the set oxygen concentration.
- Disable the low oxygen pressure alarm in the device's menu, see it. 4.14
- Disable the FiO_2 deviation alarm, see it. 4.14.

When operating with a low-pressure oxygen source, it is necessary to take into account certain features of the ventilator design:

- The mixer of device tries to create the desired flow of oxygen at any inlet pressure. If the oxygen flow is less than required, oxygen deficit is replaced by air and the measured FiO_2 value will be differ from the set value.
- When using oxygen concentrator, in the moment of maximum inspiratory flow oxygen pressure can vary greatly, but there are no significant changes in FiO_2 due to the oxygen line capacity.

Table 5.3. Approximate limits of maintaining of the oxygen concentration in the inspired gas during operation from the oxygen concentrator with performance of 5 lpm

Minute volume of breathing (MV), lpm	Peak inspiratory flow, lpm, maximum value	Achievable FiO_2, with error < 10%
5	15	55
10	30	45
15	45	37

ATTENTION!

The functions of the oxygenation and nebulizer are not available during operation from the low pressure oxygen source.

5.9 Data exchange with computer

Communication interface for connection to a personal computer (PC)

The devices equipped with the IEEE 802.3 Ethernet communication interface can operate within information system. The device can be connected directly to the computer or to the Ethernet router - in this case several ventilators can be connected to the PC. If the ventilator is connected to the router, the computer can be remote.

In the simplest case it is necessary to connect the ventilator and PC using a standard UTP cable with RJ45 connectors. For connection use the "Ethernet" connector on the back of the device.

The ventilator transmits graphical curves, measured parameters of the ventilator, monitored parameters of respiratory mechanics.

Window screenshot

The device can be equipped with the function of saving the current screen image (screenshot) to the external device USB-flash memory.

Before working with the device connect the standard device USB-flash memory to the USB-connector on the rear panel.

To save the image on the screen of the device, press the button 

on the main screen of device (see Figure 4.4, position 8), or press the button  (Figure 2.1b, position 27), located on the front panel of the electronic unit (only for MV300).

Image is saved in the file scr0000.bmp (number changes with the increasing of the number of files) in the SCREEN directory (file system FAT).

During screenshot (up to 40 sec), the work with the interface (touch screen, buttons and encoder) is blocked; the content of the screen is not updated. This condition is indicated by symbol 

. Ventilation is not interrupted, and the rest of the algorithms of the device are normally carried out.

Saving trends to USB-flash

Devices equipped with a USB connector have the function of saving the selected trend fragment to external USB flash memory device. The trend file is saved in the text format .csv and can be viewed in EXCEL, CALC OpenOffice programs or in a similar spreadsheet program. The file records all 34 parameters at a rate of 1 per minute, stored in the trend. The text encoding in the file is 866 Cyrillic, separator is semicolon (;).

Example for Excel 2003:

Select the "Data" tab in the "Import external data" item (select "Receive external data" in other versions of Excel), select the "Import data" item (in other versions of Excel choose "From text" instead). In the new "Select data source" window, open the current file from USB-flash. In the appeared text editor, follow the steps and set the following parameters:

1 step: data format - with delimiters, file format - under the number 866 (Cyrillic (DOS));

2 step: delimiter character - semicolon;

3 step: data format - in “more detail” select split the integer and fractional part "." (point).

After setting all the parameters, select "Done" and in the new window select the import of data into a new sheet, then click OK.

In the upper line contains the parameter names, the leftmost columns have the time of the trend recording in the format day / month / year / hour / minute. The line records the parameter values for the current moment. The bottom line shows the serial number of the ventilator.

To avoid malfunctions, before turning on the device connect standard USB flash memory device (USB-flash) to the USB connector on the rear panel.

To record a trend fragment, enter the trend view function, select the necessary fragment (i.e., the beginning and end of the trend). The record scale of a trend fragment can be changed via [Menu] - [Trends] - [Edit] on 156; 312 or 104 minutes. If USB flash drive is inserted into the slot, the RECORD button will be available in the lower right corner of the trend screen. Active button is bright yellow, non-active is gray. At clicking button the selected trend fragment is saved to a file. The file name is trend0000.csv (the number is changed when the number of files is increased)

For your notes

6 MAINTENANCE OF THE DEVICE

Before performing any maintenance, ensure that the device and its accessories are properly disinfected.

To ensure the proper functioning of the device during its service life make regular maintenance in accordance with it. 6.1

Maintenance of device is the responsibility of the user of the device and is not included in the warranty obligations of the manufacturer or supplier.

Maintenance routines do not involve disassembly / assembly of the electronic unit and does not require specialized skills and knowledge.

If any defects that require disassembly of the electronic unit are found, the device must be transferred to the repair organizations authorized by Triton Electronic Systems Ltd. that have the proper qualifications and the necessary equipment.

Maintenance should be carried out with the frequency recommended in it.6.1. Even if the device is taken out of service and is temporarily stored, at least every 6 months check the operation of the device and the FiO_2 sensor, perform the training of the built-in rechargeable battery.

6.1 Maintenance schedule

№	Routine	Periodicity	Description
1.	Visual inspection and test of controls	monthly	it.6.2
2.	Cleaning of fan filters	monthly	it.6.3
3.	Check of sealing gaskets of oxygen hose and water trap	1 time in 3 months	it.6.4
4.	Check of the filter-regulator	1 time in 3 months	it.6.5
5.	Check of the expiration valve	monthly	it.6.6
6.	Check and calibration of the FiO_2 oxygen sensors and the metabolism module	monthly	it.6.7
7.	Check of built-in accumulator	1 time in 3 months	it.6.8
8.	Calibration of the exhalation flow sensor	monthly	it.4.16.3
9.	Check of the compliance of the set and displayed volume of inspiration and expiration	monthly	it.6.9
10.	Check of PEEP	monthly	it.6.10
11.	Check and calibration of mainstream CO_2 sensor	monthly*	it.6.11
12.	Breathing circuit calibration	monthly**	it.4.16.5

* - Calibration of mainstream CO_2 sensor is performed with every replacement of the airway adapter or breathing circuit

** - Calibration of the breathing circuit is intended to adapt the device to the breathing circuit. It is recommended to perform it at the device turning on and especially at changing of breathing circuit type.

6.2 Visual inspection and test of controls

The device shall not have mechanical damages and signs of liquid ingress. The shell of the power cord shall not have any damage or sharp bends.

Buttons and encoder shall clearly respond calling the appropriate action. There shall be no false responses. If the control touch button area you press is offset relative to its graphical designation calibrate the touch panel through [Menu] → [Service menu] → [Calibration] → [CIVL] → [Touch screen calibration].

6.3 Cleaning and replacement of fan filters

Remove the plastic grid of the cooling fan and fresh air fan on the rear panel of the device (see Figure 2.2, positions 2, 8), easily pulling them toward to you. Remove the dust filters and clean them by washing in soap solution, rinse in clean water and dry. In the case of their substantial deterioration use the new dust filters supplied (2 pcs.) or order them through the service organization.

Make sure that filters are completely dry, set them back in their place and snap the plastic grids of the fans.

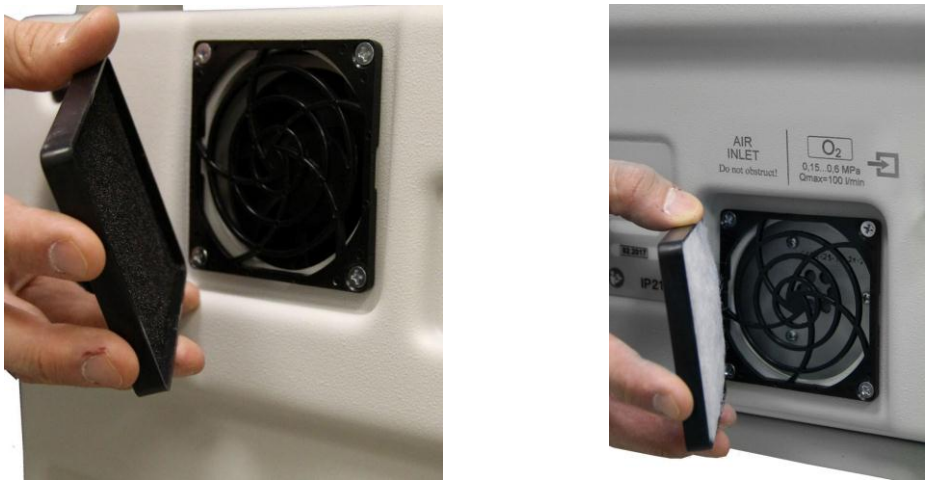


Figure 6.1 – Cleaning and replacing of the dust filter

6.4 Check of sealing gaskets

Check the condition of the sealing gaskets of the:

- oxygen hose;
- water trap fittings of metabolism module.

The sealing gaskets should not have any visible damage or undue strain.

If necessary replace the gasket ordering them at the manufacturer.

6.5 Check of the filter-regulator

ATTENTION!

Always disconnect the oxygen hose during filter-regulator maintenance.

Check the O-ring of the water trap reservoir of the reducer. The ring should not have visible damage or undue strain.

Check the O-ring in the cap nut of the filter-regulator for connection to the O_2 port. The ring should not have visible damage or undue strain. If necessary replace with supplied spare one.

Check the microfilter, in the case of severe contamination replace by supplied spare filter. For this purpose unscrew the filter housing and then the filter itself from the housing (see Figure 6.2). Insert the new filter (never try to clean old!) and repeat the steps in reverse order.

Figure 6.2 – Disconnection of filter-regulator housing

6.6 Check of the expiration valve

Detach removable part of the expiration valve, check the condition of the membrane (see Figure 6.3).

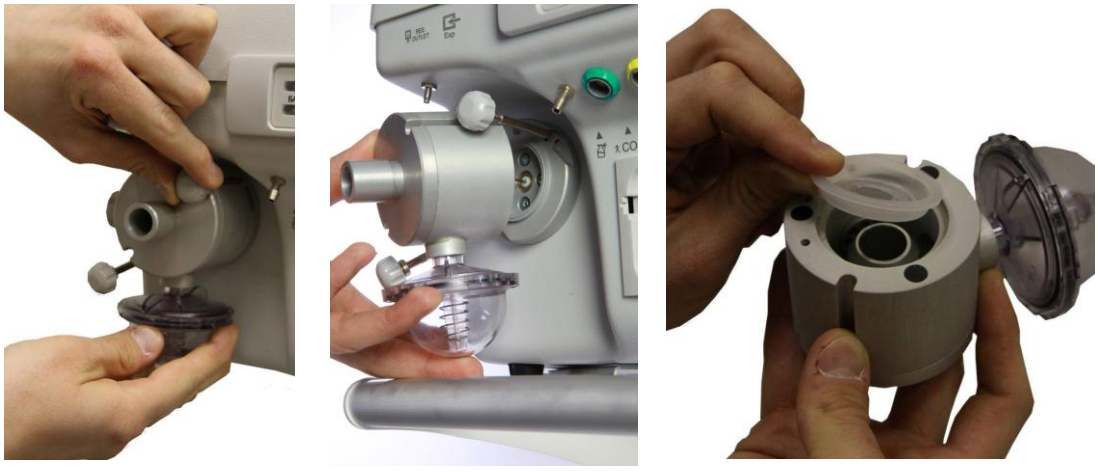


Figure 6.3 – Disconnection of expiration valve housing

The membrane should have no visible damage or undue strain. If necessary replace by the supplied spare membrane.

Check the condition of three silicone sleeves on the device enclosure. If necessary replace the sleeves ordering them at the manufacturer.

After each disassembly / assembly of the expiration valve, it is recommended to calibrate flow sensor at the expiration (it. 4.16.3).

6.7 Check and calibration of the FiO_2 oxygen sensors and the metabolism module

The device contains two oxygen sensors - the FiO2 oxygen sensor and the oxygen sensor of the metabolism module.

To verify the accuracy of measuring oxygen sensors make the following:

- Connect the device to the oxygen source.
- Assemble breathing circuit. Connect patient tee to the respiratory bag through intubation tube.
- Connect water trap of ventilator with patient tee port by the sampling line.
- Switch on the device in any mandatory ventilation mode, set the tidal volume V_T of 400 ml.
- Monitor the FiO_2 oxygen sensor readings in one of the measurement parameter blocks (by selecting the value "FiO_2"). The readings of the metabolism module's oxygen sensor can be monitored in the respiratory monitoring window "Metabolism" (can be selected using the graphic button "Monitoring").
- By setting different FiO_2 values in the range 21 - 100%, check that the absolute error of the measured values of FiO_2 does not exceed ± 3%.

If the measurement error exceeds ± 3%, disconnect the device from the oxygen source and calibrate the oxygen sensors (it. 4.16.2).

If calibration fails, replace oxygen sensors.

ATTENTION! **Replacement of the oxygen sensor of metabolism module requires disassembly of the device and can only be performed by qualified personnel authorized by Triton Electronic Systems Ltd.**

Replacement of the FiO_2 oxygen sensor can be performed independently. For this purpose unscrew the two screws of the oxygen sensor cover. Carefully take the inspiratory connector assembly, so as not to break off the wires of the connector. Disconnect the sensor power cable. By counterclockwise rotating unscrew the faulty sensor (see Figure 6.4). Install a new sensor (in some cases, a spare sensor can be included in the delivery kit). Assemble the inspiratory connector in the reverse order. Calibrate the oxygen sensor (item 4.16.2).

Figure 6.4 – FiO_2 sensor replacement

Disposal of electrochemical oxygen sensors shall be performed similarly to batteries and accumulators by collection in specialized containers for further reprocessing according national rules.

6.8 Check of built-in accumulator

Fully discharge the accumulator. Connect the device to the mains ("Battery" and "Power" indicators should be green). Fully charge the accumulator ("Battery" indicator will be off). Check the operation time of the device from the fully charged accumulator. Recharge the accumulator.

To maintain the capacity and extend the lifetime of the accumulators, train them least 1 time in 3 months.

If necessary replace the accumulator. For this purpose:

- Disconnect device from mains power.
- Remove the expiration valve, tilt the device to the front of the housing, providing access to the battery compartment cover.
- Remove the 4 screws of battery compartment cover. Pull out the cover and take it out of the slots in the housing of the device (see Figure 6.5)
- Successively take out the accumulators from the housing. If necessary use a flat screwdriver.
- Disconnect the accumulator cable and the jumper between the accumulators.

Figure 6.5 – Replacement of accumulator

- Connect new accumulators observing polarity.
- Install the accumulators in the reverse order. At installation observe that the wires are not pinched, but evenly located inside the compartment.

Dispose accumulators according to the manufacturer's instructions, for example, by collection in specialized containers for further processing.

It is allowed to use accumulators with the characteristics specified in this Manual for replacement.

6.9 Check of the set tidal volume

To make the test:

- Assemble the scheme shown in Figure 6.6.

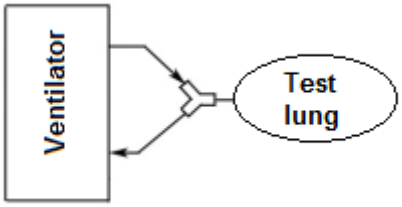


Figure 6.6 – Check of the set tidal volume

- Connect the ventilator to the oxygen source and switch on the device.
- Set the following ventilation modes and parameters:

Mode CMV/VCV;	Patient: child;
FormFlow = rectangular;	Ttrig = 93 %;
FiO_2 = 21 %;	P_{max} = 60 cmH_2O;
RB = 15 ^{1}/min;	PEEP = 3 cmH_2O;
V_T = 200 ml;	Tinsp = 1.2 sec;
Ftrig = 10 lpm.	

- In the service menu of the device turn off the H_2O correction (choose correction by ATP condition on inspiration).
- In one of the measurement parameter blocks select the indication of Vexp / Vinsp (the inspiration and expiration volumes).
- Consistently set the values of the tidal volume V_T = 400 ml, 600 ml, 800 ml, and make sure that the measuring error of the expiratory volume Vexp and the inspiratory volume Vinsp does not exceed ± 15%.

If the measurement error exceeds ± 15% calibrate flow sensor on expiration (it. 4.16.3). If it doesn't help, device shall be sent for repair.

6.10 Check of PEEP

- Assemble the scheme in Figure 6.6. Connect the breathing circuit to the device. Connect the endotracheal tube (ETT) to the patient tee. Install the breathing bag on the patient tee, previously ETT shall be placed in the breathing bag (3L).
- Turn on the device, set any mandatory ventilation mode with respiratory rate RB = 15-20 1/min.
- Consistently set the parameter PEEP = 0, 5, 10, 20 cmH_2O. After 3 - 5 respiratory cycles monitor the corresponding values of the PEEP being displayed. Deviation from the set value shall not exceed ± 2 cmH_2O.

6.11 Check and calibration of mainstream CO_2 sensor

Check the cleanliness of the mainstream CO_2 sensor and the reusable airway adapter surfaces, especially their optical elements. Contamination and moisture can cause decreasing of the CO_2 concentration measuring accuracy.

If necessary clean and disinfect the mainstream CO_2 sensor and the airway adapter in accordance with it. 5.1, to make surfaces are dry and clean.

Calibrate mainstream CO_2 sensor:

- Connect the mainstream CO_2 sensor to the device in accordance with it. 5.1. During the calibration procedure, the airway adapter shall be installed in the mainstream CO_2 sensor and disconnected from the breathing circuit.
- Turn on the ventilator, and the mainstream CO2 sensor will also be turned on.
- Wait for sensor warming up (the message about warming on the display disappears).
- Enter [Menu] → [Service menu] → [Calibration] → [CAPNO].
- Select “Zero calibration for MS capno”. During calibration (approximately 30 sec) ensure absence of CO_2 in the measuring chamber of adapter.
- If calibration is successful, the required CO2 measuring accuracy is ensured.

For your notes

7 TROUBLESHOOTING

Name of the fault, external demonstrations and additional signs	Probable cause	Remedies and recommendations for further actions
The device does not work from the mains power supply, "Power" LED is not illuminated. When operated from the accumulator the alarm message about the absence of mains voltage is displayed.	No mains voltage or voltage is low	Check the mains voltage in outlet
	Fuses have burned out	Check or replace the mains fuses
The device does not operate from the accumulator; the alarm message about accumulator discharge is displayed.	Accumulator is discharged	Charge the accumulator (see it. 4.2)
"Battery" indicator is red	Accumulator or charger is faulty	Call for Triton Electronic Systems Ltd. service or your local representative
Alarm message about disconnection is displayed	Disconnection of the circuit has happened	Check the tightness of the breathing circuit connections; if necessary replace the breathing circuit
Alarm message about occlusion is displayed	Breathing circuit, inspiration or expiration filter is occluded.	Check breathing circuit for occlusion or compression, check the inspiration / expiration filters, if necessary clean
	Faulty expiration valve	Call for Triton Electronic Systems Ltd. service or your local representative
Alarm message about high oxygen pressure is displayed	The device is connected to the compressed oxygen source without the filter-regulator (or filter-regulator is defective), and safety valve was triggered (0.25 - 0.35 MPa)	Connect or replace the filter-regulator
Alarm message about low oxygen pressure is displayed	Input pressure of oxygen line is lower than 0.2 MPa	Ensure the normal operating pressure on the device input.
The device has switched into the emergency mode. Alarm message about ventilator replacement and error codes are displayed	Technical failure of one or more modules of the device.	Call for Triton Electronic Systems Ltd. service or your local representative
"Fan malfunction" alarm message is displayed	Fan malfunction (blades don't rotate)	Call for Triton Electronic Systems Ltd. service or your local representative

If the problem can not be solved by the proposed measures, contact your service representative, or customer service of the manufacturer Triton Electronic Systems Ltd.

For your notes

8 TRANSPORTATION

The device shall be transported in manufacturer packing in a fixed condition by all types of covered transport without limitation of distance, according to the transportation regulations on the current type of transport.

Before device transportation under negative temperatures it is necessary to connect the device to a high pressure air source (4 - 6 kgf/cm^2 (bar)), to turn on the device, and leave it for 3 - 5 minutes operating (CMV/VCV mode, RB = 20 ^{1}/min, MV = 30 lpm) for blowing of condensate and drying of internal lines and the expiration valve.

The device shall be transported at air temperature from -50 to +50 °C.

After transportation under negative temperatures, device should be sustained before unpacking in normal climatic conditions within 12 hours.

9 STORAGE

The device in manufacturer packing shall be stored in the closed warmed and ventilated room at air temperature from +5 to +40 °C and relative humidity that not exceed 80 % at temperature 25 °C.

In case of temporary withdrawal, the device shall be stored without manufacturer's packaging in storehouse at a temperature from +5 °C to +40 °C and relative humidity not more than 80 % (at a temperature of +25 °C). Devices should be placed on a rack shelf in single line. Do not store the device in places containing acid-base vapors and vapors of other deleterious substances.

In case of long-term storage after use the device should be placed in polyethylene case and if possible packaged in manufacturer's packaging way to protect against possible mechanical damage.

In case of long-term storage of device to maintain its operability carry out tests according Section 6 at least every six months. If necessary, accessories with a limited service life should be replaced. At malfunction the device shall be sent for repair.

When the device is put into storage, the battery shall be charged. Storage of the device with a discharged accumulator and absense of accumulator training during storage will lead to premature accumulator failure.

10 DISPOSAL

After end of service life the device should be utilized.

The device shall be disposed in accordance with the local rules for collection, storage and disposal of waste from medical facilities in the country of using the device.

For countries covered by Directive 2012/19/EU (WEEE)
The device is not intended for household use and is not subject to disposal with standard electrical and electronic equipment.

For detailed information contact your local sanitation and environmental authorities or waste disposal companies.

Before disposal the device shall be cleaned and disinfected in accordance with the requirements of section 3.6 of current Manual.

Accumulators and O_2 sensors shall be disposed as hazardous waste in accordance with the requirements of applicable laws and regulations. Their extraction for recycling shall be made by organizations authorized by Triton Electronic Systems Ltd. for the maintenance of the device.

For your notes

11 WARRANTY

11.1 Warranty

These warranty obligations are common and apply to equipment made by Triton Electronic Systems Ltd. sold and used outside the Russian Federation. Specific obligations for warranty service are stipulated in the particular equipment delivery contract and are performed by authorized service centers of Triton Electronic Systems Ltd. at providing relevant documents.

The warranty for new equipment is provided if the detected malfunction caused by the use of low-quality materials or violation of the manufacturing technology is properly registered (recognized) by the authorized service center "Triton Electronic Systems" and includes:

- free repair of equipment or its replacement with a similar one in case of impossibility of repair;
- free delivery to an authorized service center.

Terms of warranty repair shall not exceed 20 working days from the receipt of the failed equipment in an authorized service center. The warranty period is extended for the period of time during that the equipment was under repair (on the basis of repair data entered in the current Manual).

The warranty operation period of the new equipment is 12 months and is calculated from the equipment commissioning date by the authorized service center "Triton Electronic Systems". In the absence of a note on commissioning in current Manual, the warranty period is calculated from the date of sale of the equipment under the supply contract, but not more than 18 months from the date of sale, or, in the absence of the contract, from the date of manufacturing of the equipment specified on the equipment and in the current Manual. In any case, the warranty operation period can not exceed 18 months from the date of manufacture of the equipment.

For the equipment repaired in the authorized service center there is an additional warranty of 6 months and it is calculated from the date of completion of the repair specified in the current Manual. The warranty covers only the repaired modules and units of the device.

Warranty obligations do not apply to disposables supplied with equipment. Complaints on them shall be sent to the respective manufacturer. Also the warranty does not apply to the expiration of disposables from delivery kit.

Warranty service is not provided for:

- not following the operating instructions stated in user manual;
- absence of user manual or serial number on the equipment, as well as incomplete delivery kit equipment;
- equipment malfunctions caused by impacts (falls), violation of the rules of packaging, storage and transportation, ingress of foreign objects or liquids, voltage drops or inconsistency with power supply standards and other similar external factors;
- faults caused by the use of non-recommended or low-quality spare parts and consumables;
- absence of mandatory periodic maintenance;
- detection of attempted repairs by persons and organizations not authorized by the manufacturer;
- normal wear and tear of accessories, spare parts and consumables.

Keep the current user manual for the entire warranty period. Make sure that the commissioning and maintenance repair data are made timely and correct.

For free consultations about operation and maintenance please contact the manufacturer by phone. +7 (343) 304-60-57, e-mail to info@treat-on.com, or local distributor in your region.

11.2 Guarantee procedure

In order to use the guarantee service you need:

1. Note the following information:

- equipment name, serial number and date of manufacture (on the back of the equipment);
- commissioning date by a representative of an authorized service center (in current manual or the commissioning act);
- the nature of the malfunction.

2. To specify with a representative of authorized service center nature of the manifestation of the malfunction. When confirming the malfunction, agree on procedure and terms of delivery of the equipment to service center or terms of service engineer's departure to the place of operation.
3. To deliver the equipment to service center assemble a complete delivery set of equipment and pack it in order to avoid damage to the equipment during transportation. It is preferable to use the equipment original package.
4. After delivery of the equipment to service center, you will be informed about the results of technical examination and the timing of receipt of the repaired equipment in case of recognition of the case as a guarantee.

In case of event that the service center receives warranty equipment that does not contain defects declared by the buyer, company reserves the right to charge payment for delivery, testing and after-sales service of the equipment.

11.3 Address for notes and complaints

Production site	12/5 Sibirskiy Trakt str. 620100 Ekaterinburg, Russia
Service	phone: +7 (343) 304-60-57
Post address	p/b 522, 620063 Ekaterinburg, Russia
E-mail	info@treat-on.com
Web-site	www.treat-on.com

12 CERTIFICATE OF ACCEPTANCE

Intensive Care Ventilator MV___ serial No _____, software kit No_____complies with the technical specifications TESM.941144.001 TU and considered suitable for operation.

Date of manufacturing_____

QC stamp

QC representative_____/_____/

signature name

13 COMMISSION DATE MARK

Commission date _____

day, month, year

Operating company (customer):

_____

company name

_____

responsible representative, position, signature, name

stamp

Service company (provider):

_____

company name

_____

responsible representative, position, signature, name

stamp

For your notes

14 MAINTENANCE AND REPAIR DATA

14.1 Device maintenance (MA)

This section is filled by a representative of the service personnel or service organization. The frequency and order of maintenance are specified in Section 6 of current Manual.

MA No	MA date	Company, position, MA resp.person	Remarks, works performed	Signature of MA responsible person

14.2 Device repair

Repair date	Malfunction	Company, position, repair resp.person	Works performed	Signature of repair responsible person

For your notes

APPENDIX 1 DESCRIPTION OF VENTILATION MODES

Appendix 1.1 Description of CMV / VCV mode

In CMV/VCV mode (Controlled Mandatory Ventilation / Volume Control Ventilation) the patient receives the set tidal volume. Flow curve is rectangular or decreasing (as shown below), according to doctor's choice. The device provides the set volume of a respiratory cycle at the set respiratory rate with the set duration of the respiratory cycle.

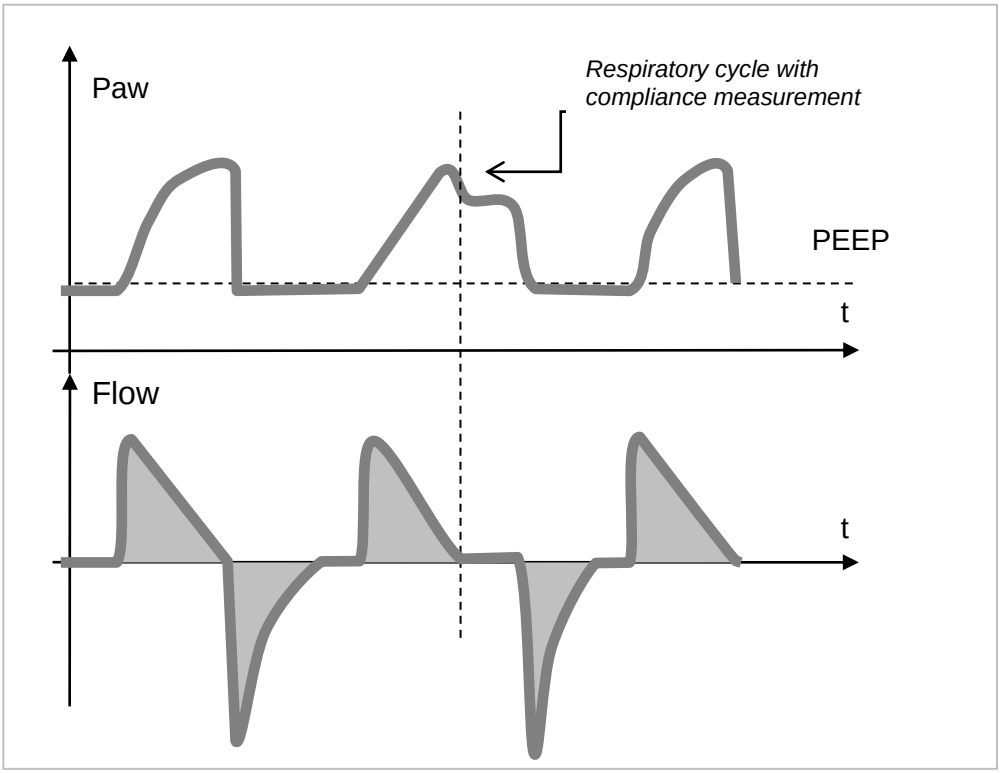


Figure. App. 1.1 – Graphs of pressure (top) and flow (bottom) in CMV / VCV modes with decreasing flow. The shaded area shows volumes of both inspiration and expiration

In the CMV/VCV mode possibility of support of the spontaneous breaths initiated by the patient is provided. This possibility is realized by setting of the trigger sensitivity. Automatic breath is triggered when trigger operates within a trigger window.

In CMV/VCV modes user also can set the inspiration pause by Tplat parameter.

Appendix 1.2 Description of CMV / PCV mode

In CMV/PCV mode (Controlled Mandatory Ventilation / Pressure Control Ventilation) the breath is carried out at the set pressure with the set respiratory rate and duration of the respiratory cycle.

The level of pressure is set by inspiration pressure Pi which is supplied over PEEP and rigidly held during inspiration. The device displays the measured tidal and minute breath volumes.

The minute breath volume is measured on an exhalation by summation of expiratory volumes within a minute.

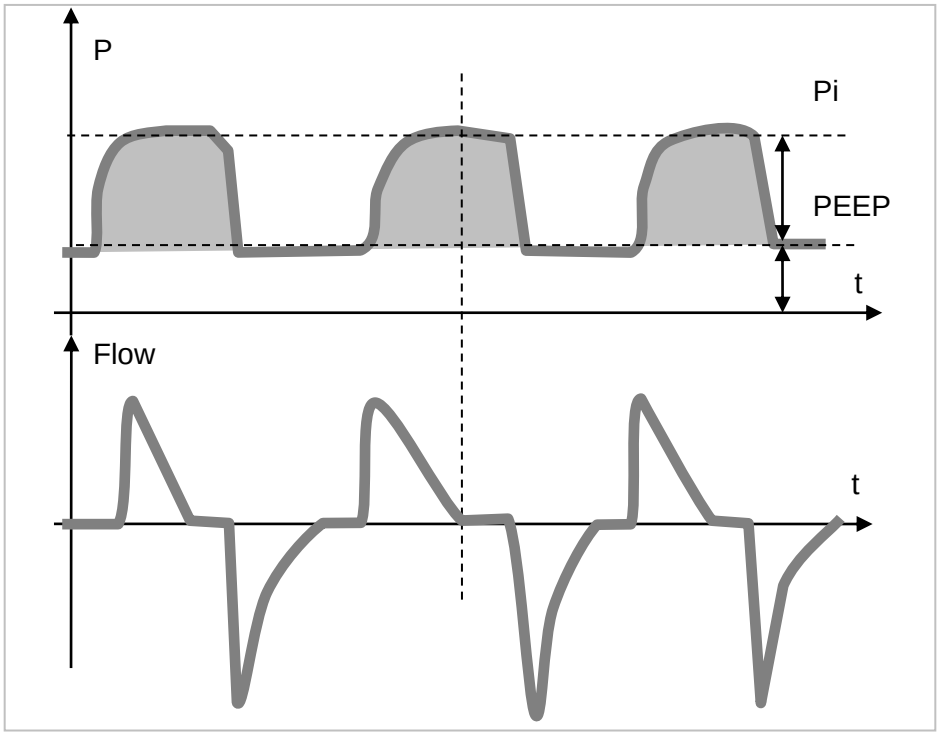


Figure App. 1.2 – Graphs of pressure (top) and flow (bottom) in CMV / PCV modes

In the CMV/PCV mode possibility of support of the spontaneous breaths initiated by the patient is provided. This possibility is realized by setting of the trigger sensitivity. Automatic breath is triggered when trigger operates within a trigger window.

Appendix 1.3 Description of SIMV/VC, SIMV/PC, SIMV/DC modes

SIMV/VC, SIMV/PC, SIMV/DC modes - Synchronized Intermittent Mandatory Ventilation with volume control, pressure control and double control.

In these modes pressure support of spontaneous patient's breath (by PS - Pressure Support) is also realized. If device detects independent respiratory attempts of the patient, these breaths are carried out synchronously with them, in case of absence of attempts - automatically upon the end of the set interval of expectation. In intervals between ventilator's breaths the patient can independently breathe through the circuit.

Independent breaths of the patient are supported by the set level of pressure, invariable throughout all time (support pressure, PS). Criterion of the spontaneous breath termination is flow falling to the set level ETS from the maximum. Reserve criterion is time, if the flow does not manage to decrease to ETS for the maximum allowed inspiratory time.

Decreasing of the mandatory breaths frequency and tidal volume (inspiration pressure) promotes increasing of part of independent breath, and on the contrary.

The SIMV/DC mode is analogue of the SIMV/PC mode, except that the ventilator's breath is carried out according double control (DC) method similarly to the PCV-VG mode.

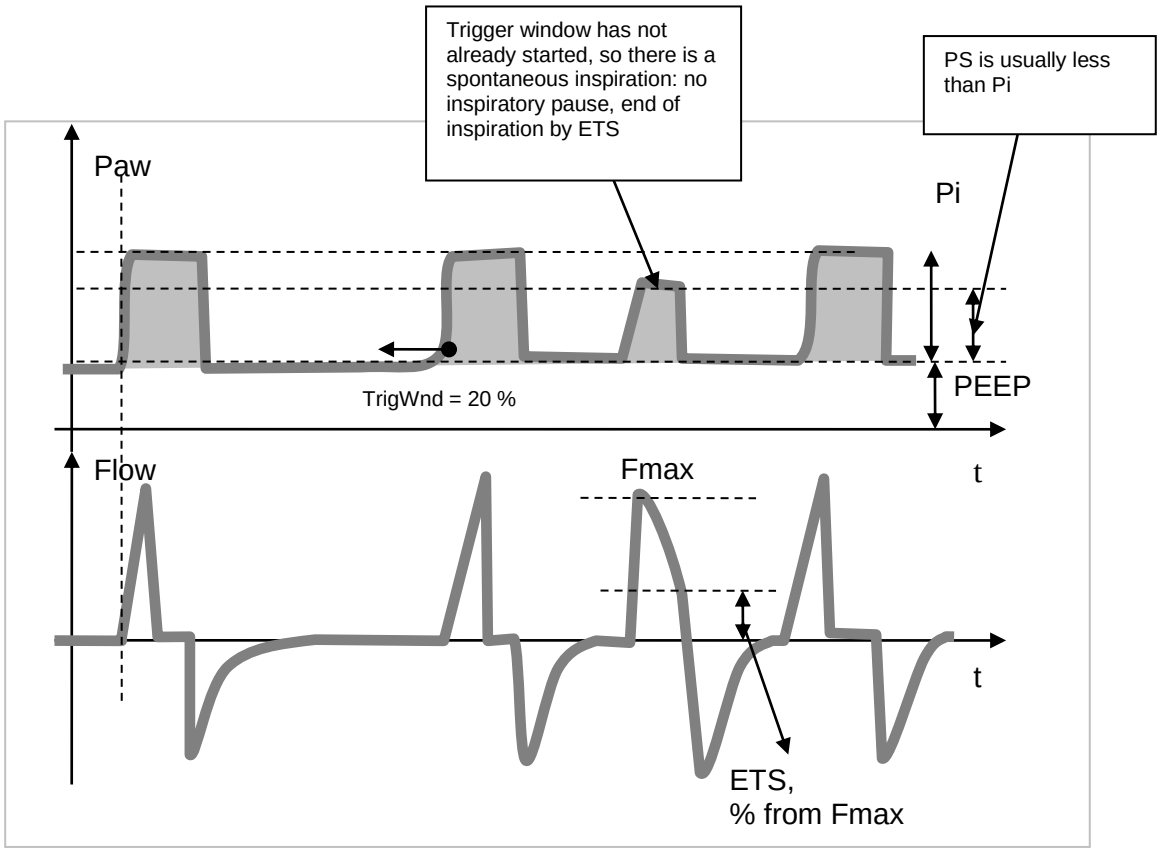


Figure App. 1.3 – SIMV mode

Appendix 1.4 Description of CPAP+PS mode

CPAP+PS (Constant Positive Airway Pressure) is spontaneous breathing with the set positive pressure in the airways. The device supports the spontaneous inspiration attempt with pressure (PS).

Cycle of inspiration support is triggered at the activation of the inspiration trigger (pressure or flow).

The rate of inspiratory pressure rise is set by Pramp parameter.

The pressure at the peak of inspiration equals to PIP = PEEP + PS. Criterion of the end of spontaneous inspiration is flow drop to the set flow ETS value from maximum (expiratory trigger or trigger of the end of inspiration).

Reserve criterion of end of inspiration is time, if the flow does not have time to decrease to ETS for the maximum allowed inspiratory time Tinsp. In CPAP+PS mode the maximum inspiratory time Tinsp is limited to 4 s.

In the CPAP+PS mode the Tinsp parameter defines the inspiratory time if trigger of the end of inspiration was not activated before (for example, because of the leakage in the circuit). If leakage is detected or suspected, activate the leakage compensation function.

At the absence of spontaneous breathing through a pre-set time Tapnea, apnea alarm is triggered and the ventilator switches to the APNEA.

Appendix 1.5 Description of BiSTEP mode

BiSTEP mode (analogue of BiPAP*) is the spontaneous breathing mode with two levels of positive airway pressure with the possibility of pressure support. The patient may breathe through the ventilator in the both phases of circuit pressure. The transition from low to high pressure phase is essentially pressure controlled inspiration; the transition from high pressure phase is expiration. However, unlike the PCV mode inspiration and expiration can be separated with substantial time interval during which the patient breathes spontaneously. The device separately calculates the volumes of hardware and spontaneous breathing.

At the coincidence of spontaneous breathing cycle with the transition between phases, the ventilator goes from low to high phase synchronizing process with the patient's inspiration, and from high to low phase synchronizing the transition to the expiration.

Spontaneous breaths are supported by the device, as well as in other modes.

Criterion for the start of the inspiration cycle is the activation of the inspiration trigger (flow or pressure). The criterion for the end of spontaneous inspiration is a flow drop to the set value ETS from the maximum. Reserve criterion is time, if the flow does not have time to decrease to ETS for the maximum allowed inspiratory time.

In the absence of spontaneous breathing through a preset time Tapnea, apnea alarm is triggered and the device switches to the APNEA mode.

Practically modes similar BiPAP (BiLevel, DuoPAP, etc.) are applied unfairly rare. In particular, this is due to the fact that the processes in these modes are very dependent on the setting of parameters. Therefore the detailed description of the features BiSTEP mode is shown below.

Let's consider two cases, when the operation depends on the pressure setting.

Case 1 - the total pressure Plow + PS is less than pressure of the high phase Phigh. On the low pressure phase spontaneous inspiration will be supported by pressure PS. On the high pressure phase spontaneous inspiration/expiration will be performed on the constant pressure background, similarly to CPAP+PS. The curve of the airway pressure will have the following form (see Figure App. 1.4):

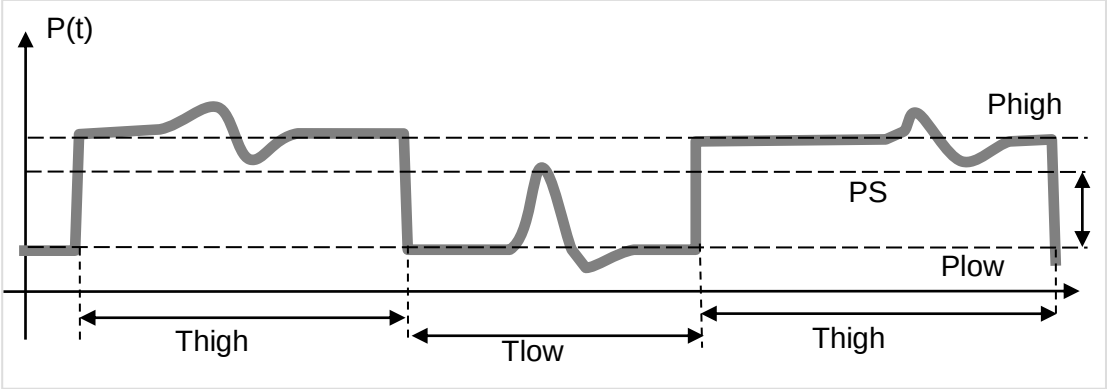


Figure App. 1.4 – Airway pressure curve

** BiPAP® is a registered trademark of "Respironics Inc"*

Case 2 - the total pressure Plow + PS is more than pressure of the high phase Phigh, the pressure curve has the following form (see Figure App. 1.5):

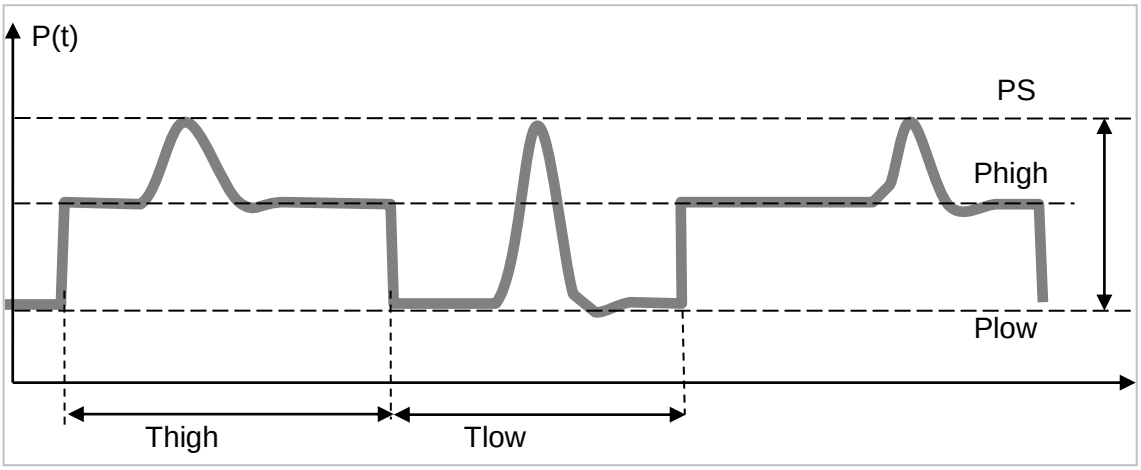


Figure App. 1.5 – Airway pressure curve

At the detection of spontaneous inspiration in any phase, spontaneous inspiration support will be up to the same pressure. Tidal volume receiving by the patient will vary depending on the phase of spontaneous breath.

BiSTEP mode at the appropriate parameter settings can replace CMV/PCV, SIMV/PC modes.

The operation of device is close to the CMV/PCV mode under the following conditions: spontaneous respiratory patient's contribution is small, respiratory rate is quite high (it means time Thigh corresponds to the physiological inspiratory time 0.5 - 1.5 seconds) and Thigh/Tlow ratio is selected in the range of 1 - 3. The difference is that any spontaneous breath will be supported with the pressure.

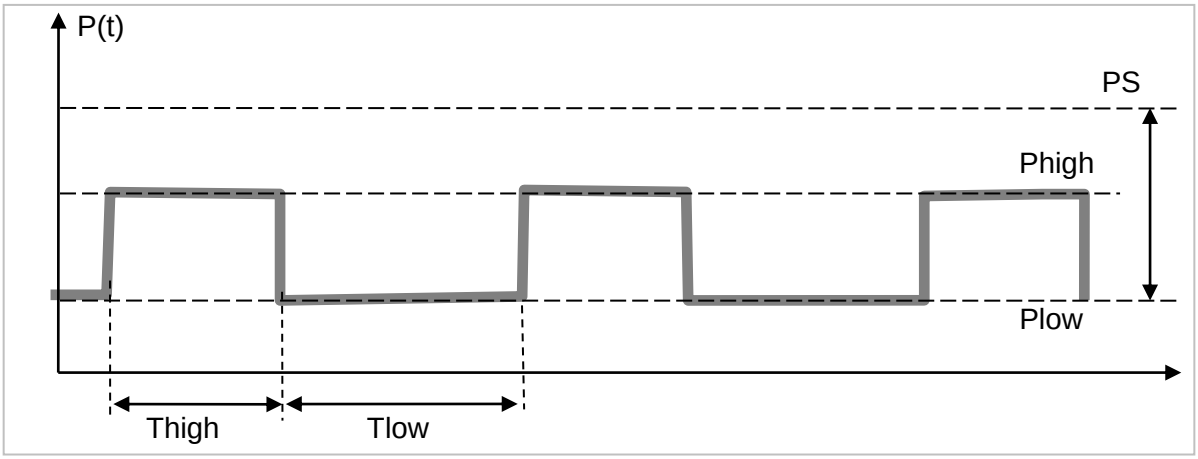


Figure App. 1.6 – Pressure support of spontaneous inspiration

The operation of device is close to the SIMV/PC mode (see Figure App. 1.7) if Thigh time corresponds to the physiological inspiratory time (0.5 - 1.5 seconds), the selected Thigh/Tlow ratio is 3 or more, and respectively the hardware breaths frequency is smaller:

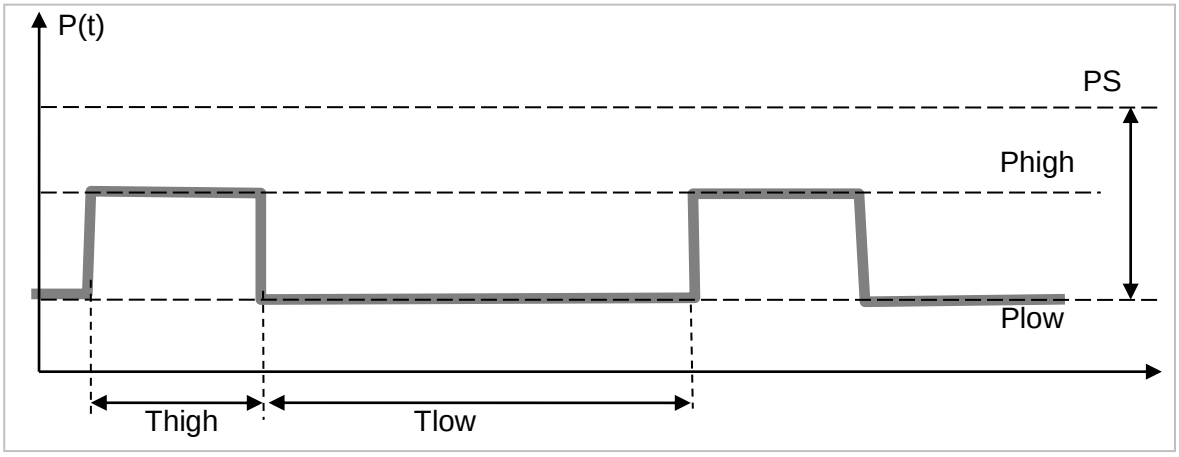


Figure App. 1.7 – Airway pressure curve

The difference is that any spontaneous breath in the low or high pressure phase is supported with the pressure.

At the inverse ratio of high and low pressure phases, Thigh/Tlow<1, the operation of device approximates to the APRV mode:

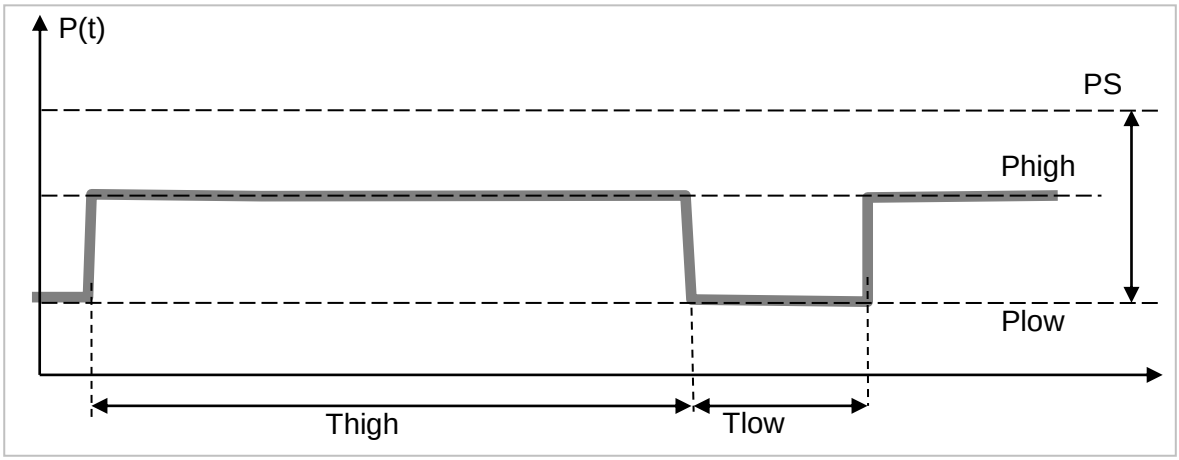


Figure App. 1.8 – The operation of device is approaching to the APRV mode

Appendix 1.6 Description of NIV mode

The NIV mode (NIV - non-invasive ventilation) is spontaneous breathing through a face mask with the predetermined positive pressure in the airways and the predetermined spontaneous breaths support. This mode is very similar to CPAP+PS, but there are minor differences - they are associated with the leakage at non-invasive support:

1. The NIV mode always operates with leakage compensation.
2. FiO_2 is set in the range of 21 - 70 %.
3. The trigger of the spontaneous inspiration is set only by pressure (it is more "rough").
4. Special indicator Facc is used for the mode.
5. In the absence of spontaneous breathing, the ventilator enters APNEA mode. Unlike other ventilation modes when the doctor can choose the APNEA mode either by pressure or by volume, in NIV mode APNEA mode operates only by pressure.

Breathing circuit calibration [Menu] → [Service menu] → [Calibration] → [Breathing circuit calibration], measuring the circuit parameters shall always be carried out after circuit change and autoclaving. This is suitable for any mode, but is especially important for the transition from invasive to non-invasive ventilation and vice versa.

Due to the presence of the leakage model, the ventilator can compensate large leak up to 90 lpm. At the large leakage FiO_2 drop can occur.

To control the size of the leak, the user should turn on its displaying in any of the rectangles of measured parameters block via [Menu] → [Display settings] → [Choose measured par. blocks] → [Leak]. In the LEAK field two leaks will be displayed: peak leakage at the inspiration and averaged leakage during expiration. Leakage will depend upon the pressure in the inspiratory line, the degree of fitting of the mask to the patient and/or the number of open ports on the mask.

Using of the mainstream capnometer at NIV is inappropriate, because the expiration can go through the existing gap in the mask and will not get into the chamber of the mainstream capnometer.

Appendix 1.7 Description of APRV mode

APRV mode (Airway Pressure Release Ventilation) is ventilation with pressure release in the airways; it is an extension of BiSTEP mode. The patient in this mode breathes independenly with a predetermined level of pressure support.

If the patient requires a high-pressure CPAP (or PEEP), a significant reserve of non-exhalted gas is created in the lungs of the patient. This residual gas accumulates a significant amount of carbon dioxide that may hinder its excretion to the environment and contributes to increasing of carbon dioxide level in the arterial blood. It is resulted in the danger and the preconditions for the hypercapnia.

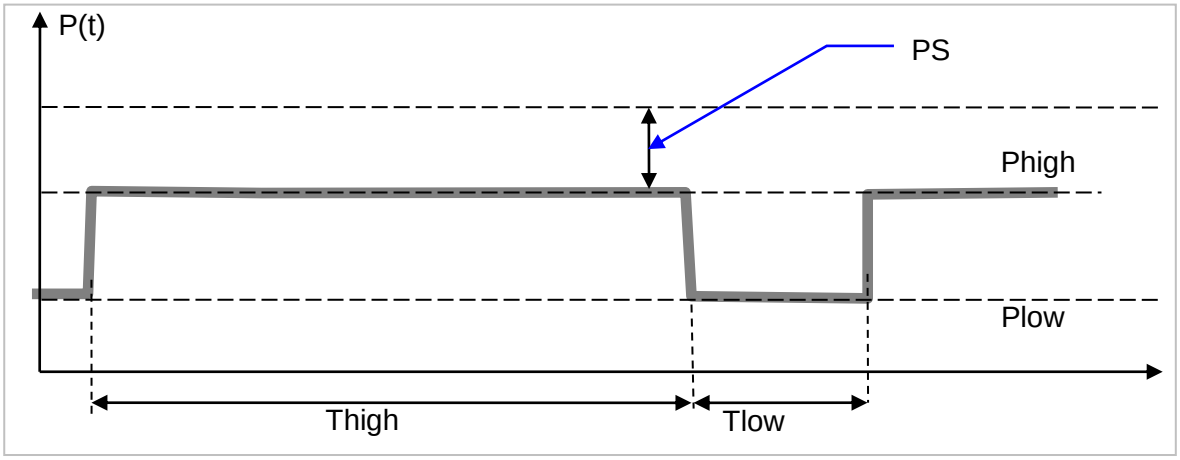


Figure App. 1.9 – Device operation in APRV mode

APRV mode allows to release the lungs from the reserve gas with specified intervals due to the low pressure phase Tlow.

Restoring of the previous level of PEEP in the beginning of Thigh phase is performed by fresh gas without carbon dioxide, thereby eliminating the above premise for hypercapnia.

So APRV mode allows to replace periodically the residual gas in the lungs, improving excretion of carbon dioxide.

APRV mode has an important difference from BiSTEP that lies in two aspects:

- In APRV mode the low pressure phase Tlow should be significantly shorter than the high pressure phase Thigh, but sufficient for the residual gas exhalation from the lungs.
- In the low pressure phase spontaneous breaths support is not performed to ensure a complete elimination of gas from the lungs.

In other aspects APRV mode is similar to CPAP+PS, but the support pressure count is made from pressure Phigh. Limiting of circuit pressure is performed by level (Phigh + PS + 5) cmH_2O.

Appendix 1.8 Description of PCV-VG mode

PCV-VG mode is the mandatory ventilation mode with guaranteed delivery of the target tidal volume at the lowest possible pressure. It is more effective mode of substitute ventilation than VCV and PCV, because it combines the strengths of both without imperfections.

The PCV-VG mode functionally repeats the CMV / PCV mode with one exception: instead of the target inspiratory pressure, the user sets the target inspiratory volume. The inspiration pressure is adjusted by the ventilator with every new inspiration depending from the target volume.

The PCV-VG mode is intended for use in patients practically without independent breathing; the patient is too weak to allow his respiratory activity actually control the ventilation. The clinical efficacy of the mode is associated with the more regular shape of inspiratory pressure curve, more homogeneous mixing of air in the lungs and the precise inspiration volume.

At initial mode settings, select the appropriate value of Pramp. The higher is the target volume, the greater is the value of Pramp. For example, at the high set target volume and low Pramp, situation can occur when the inspiratory target volume will not be achieved.

PCV-VG is the mandatory ventilation mode. To increase the flexibility of the mode, it is combined with the A/C (assisted control) mechanism. It is mechanism of trigger window for the mandatory breaths. The user can allow the inspiration to be initiated by the patient by the TrigWnd parameter (trigger window). The trigger window is the time from the end of expiration to the beginning of the next expiration, the duration of the trigger window can be set from 0 to 100 % of the specified time interval.

- When TrigWnd is set to 0%, patient’s inspiration attempts are ignored by the device, each breath is performed according to the algorithm set by the doctor. Such setting is necessary, first of all, for patients at known condition that excludes attempts of spontaneous breathing.
- If TrigWnd is set to 100%, patient’s inspiration attempt leads to inspiration according to the ventilator’s rules at any time point between the beginning and the end of the expiration. If there were no patient’s attempts, ventilator provides a breath. Such duration of the trigger window is optimal for the patients whose body is able to reflect the inspiration needs, but at the same time it is too weak to breathe on its own.
- Middle TrigWnd values are set when the doctor has "limited trust" in the patient's organism; requests for inspiration are accepted, but not immediately after the end of the previous inspiration.

Thus, formally, spontaneous breaths are forbidden in PCV modes, but using of the trigger window allows to cancel the waiting for the end of expiration and start ventilator inspiration earlier.

Appendix 1.9 Description of APNEA mode

The apnea ventilation mode (APNEA) is not independent full mode of ventilation. In fact it is a mechanism to ensure patient's safety at the suddenly stop of breathing in modes with support of patient spontaneous breaths. The ventilator automatically switches to the apnea ventilation mode when it detects the absence of respiratory cycles in the set time interval.

Functionally the apnea ventilation mode is CMV mode with preset parameters, with pressure or volume control.

Type of the apnea ventilation (with volume/pressure control) and time of absence of patient's respiratory activity (Tapnea, in seconds) are defined by the user.

Although the apnea parameters have default values, the doctor does not have the right to ignore the apnea mode setting, because it is one of the steps to ensure patient safety.

In the apnea ventilation mode with volume control respiratory rate RB and tidal volume Vapnea are set automatically but can be adjusted by the user.

In the apnea ventilation mode with pressure control respiratory rate RB is set automatically according to the same rules as the function of the ideal body weight. The target inspiratory pressure in the apnea ventilation mode with the pressure control Piapnea is set by the user.

In the NIV mode only apnea ventilation with the pressure control is available.

Apnea ventilation mode is not intended for the long-term patient ventilation. Therefore the transition of the ventilator to this mode triggers an alarm, attracting the attention of the user, showing the need for making a decision about the future strategy of ventilation. The parameters of this mode most often are not optimal for the particular patient. They are offered by the device on the basis of the ideal body weight of the patient at the transition to any ventilation mode with the possibility of correction of apnea parameters by user.

Exit from the apnea ventilation mode and automatic recovery of the last ventilation mode after synchronization with the breathing cycle can be done by two ways:

- Press the encoder knob. Returning to the previous ventilation mode will be synchronized with the respiratory cycle and realized at the beginning of inspiration.
- If trigger window was set, and the device will generate two consecutive breaths triggered by the patient with the type and value of trigger taken from the previous ventilation mode before the apnea. If before the apnea one of the modes BiSTEP, APRV, NIV was active, then the trigger window at the apnea ventilation will be set to 100 %. Returning to the previous ventilation mode will be synchronized with the respiratory cycle and realized at the beginning of inspiration.

In the APNEA mode settings, PEEP is not available for change, and its value is equal to that set in the current ventilation mode.

Appendix 1.10 Description of the intelligent adaptive ventilation iSV

Appendix 1.10.1 Function of iSV mode. General description

ISV mode is an integral ventilation mode - with the support of patients without spontaneous breathing and with any level of spontaneous respiratory activity.

The mode includes both mandatory (PCV-VG) and assisted ventilation (CPAP+PS). The algorithm of its time cycles reminds SIMV. At the same time the mode is similar to CMV, but all the basic parameters that ensure patient required minute ventilation are automatically set in accordance with data of his respiratory mechanics.

If the patient has no spontaneous breathing, iSV provides hardware breaths with optimal values of V_T and RB. At the appearance of spontaneous breaths the mode provides pressure support the level of pressure depends on the respiratory activity of the patient. The more active is the patient, the lower support level he needs.

Its differences from other modes:

- provides automatic control of the set MV;
- automatically adjusts the proportion of mandatory and assisted ventilation depending on the patient's respiratory activity;
- automatically determines the parameters of control and support pressure;
- automatically in real time determines the optimal respiratory rate and target tidal volume on the basis of the patient's respiratory mechanics, providing the minimum work of breathing;
- automatically adjusts the I: E ratio;
- prevents the situation with the development of perceptible autoPEEP;
- provides ventilation at the minimum possible airway pressure (uses double control);
- automatically calculates static and dynamic (in real-time, taking into account RCexp) limits of the safe ventilation for Vt, RB and I:E, ensures strict compliance of the ventilation parameters for each inspiration with these limits;
- provides the best conditions for both the patient and the physician at the apnea;
- if necessary, provides the MV adaptation depending on the actual needs of the patient;
- it is designed for ventilation from intubation to extubation and was originally designed for separation of patients from ventilator as his spontaneous respiratory activity is recovered;
- has minimum basic control settings: % MV for ventilation and FiO_2 and PEEP - for oxygenation.

The mode provides guaranteed minute volume regardless of the degree of spontaneous respiratory activity of the patient. In the absence of spontaneous breathing it provides hardware inspirations with double control (PCV-VG). In the presence of spontaneous respiratory activity of the patient the mode becomes identical to CPAP+PS, but the support pressure level PS is automatically adjusted to provide the set MV. As the recovery of spontaneous breathing, the level of the support pressure is reduced to the minimum of 5 cmH_2O.

The application of iSV for newborn patients has not been sufficiently studied. Therefore the selection of the iSV mode is blocked for patients with height up to 57 cm or weight up to 5 kg.

Appendix 1.10.2 Assessment of respiratory rate

The respiratory rate RB is calculated by Otis equation in the modification suggested by Y.V. Kofman, engineer of Triton Electronics Systems Ltd. Unlike the commonly used Otis equation, this modification does not require multiple iterations and does not require initial RB value, and therefore is more convenient and fast.

Appendix 1.10.3 Assessment of the tidal volume

Tidal volume is determined by dividing the target minute volume to the target frequency:

Vt = MV / RB.

Appendix 1.10.4 Limits of the safe iSV ventilation. General concepts

Not all versions of tidal volume to the respiratory rate ratio determined by the Otis equation are safe for the patient.

At very low frequency, respectively, large tidal volume is required for the target MV that can cause volumotrauma of the patient's lungs. At the same time at the high respiratory rate, tidal volume approaches the dead space volume. It results only in dead space ventilation, and the absence of alveolar ventilation. Such conditions do not occur at the small deviations of respiratory mechanics parameters (the compliance, resistance) that are transported to the Otis equiation through the expiratory constant. However at the more significant deviations of these parameters from the normal values, the risk volumotrauma or hypoventilation increases dramatically.

The graph connecting tidal volume and inspiration frequency for the current MV, looks approximately as follows:

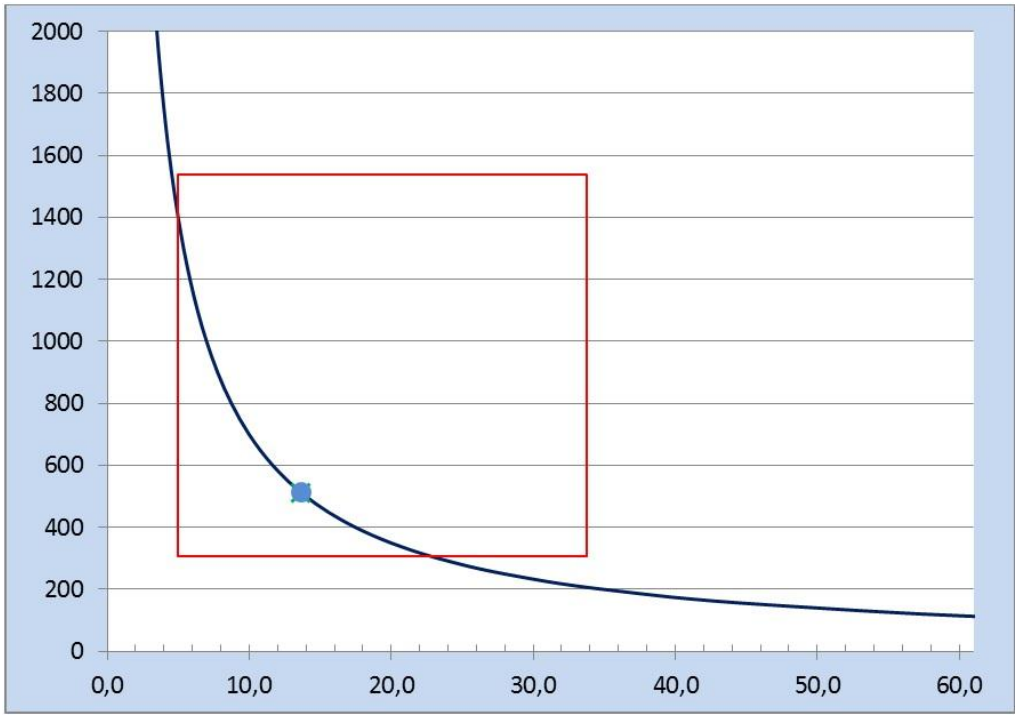


Figure App. 1.10 – Inspiration volume (vertical scale) vs. respiratory rate (horizontal scale) for current MV

The square on the graph represents the limits of safe ventilation. If the calculated RB or Vt are beyond the square, the ventilator limits these parameters. In this case the output frequency and volume control setting are provided with safe ventilation limits. At the restrictive disease (low

compliance) the square takes the form of a horizontal rectangle, and at the obstructive pathology (high resistance, high compliance) the square becomes vertical (without autoscaling).

Appendix 1.10.5 I:E ratio, medical aspects

Inspiration:expiration (I:E) ratio of a healthy person, as well as of mammals is based on the physiology of breathing. Expiratory time is usually 2 – 3 times more than inspiratory time. The natural I:E ratio lies typically in the range of 1:2 – 1:3. This is due to the fact that the breath is always active and caused by work of the inspiration respiratory muscles (diaphragm, the intercostal muscles, straightening ribs).

Expiration at quiet condition is always passive and its implementation requires more time. Full expiration time takes at least 4 expiratory constants.

At the active physical activity the respiratory rate (and further I:E ratio) increases to eliminate the carbon dioxide. At the very heavy work the respiratory rate and tidal volume can be increased significantly, expiratory time may become less than 3RC and even 2RC because of enabling of the expiration muscles. So expiration takes less time than in the quiet state (effect of pseudo decreasing of the expiratory constant).

At the patient's airway pathology, as well as heavy state due to sepsis, inflammation, fever, ketoacidosis at diabetes and so on, significant changes happens in the pattern of breathing.

There is a relationship between the number of expiratory constants in the breathing cycle (T total) defined by the Otis equation and respiratory mechanics of the patient. The more constants are "placed" in the breathing cycle, the harder are the lungs, respectively, the less is compliance, respectively, I:E ratio tends to 2:1. And conversely, the less number of the constants are in the breathing cycle, the higher is the resistance, I:E ratio tends to 1:4 giving priority to expiration.

With the height of the real patient and standard values of compliance and resistance for each patient height (there is a direct correlation), ideal RB for the patient can be calculated according to the Otis equation. Comparing this value with the real RB, that takes into account also the safety limits, operator can get the difference. For example, subtract from RBideal the RBreal, and get a certain value. If the difference is not large, it is recommended to ventilate with I:E = 1:2. If difference is negative (depending on the degree of deviation), ventilate with 2:1. If positive, tend to use 1:4.

Appendix 1.10.6 Calculation of the respiratory cycle phases (I:E)

Range of automatic I:E settings is from 2:1 to 1:4. It is also the boundary for correcting of I:E within the range. The I:E ratios, when the inspiration is longer than expiration are inverse and requires special enabling.

Algorithm of I:E control supports the following rules:

- Minimum expiratory time: Te min ≥ 2RC;
- Minimum inspiratory time: Ti min ≥ 1 RC, but not less than 0.5 seconds for adults and children weighing more than 10 kg IBW; in children less than 10 kg IBW - not less than 0.35 seconds.

In the advanced settings the restriction to the inversion "Allow IRV in iSV" (inverse ventilation - IRV) is provided. IRV is disabled by default. To enable set the range I:E from 2:1 to 1:4, to disable set 1:1 - 1:4. This is caused by the fact that in some medical facilities ventilation in the inversion mode is not performed.

Appendix 1.10.7 Start of iSV mode

After running of the iSV mode the device delivers 3 test breaths in the mode

SIMV/PC+PS. Pi = PS.

Parameters of starting breaths are determined in accordance with the ideal weight of the patient:

IBW, kg	Pi, cmH_2O	Ti, s	RB, 1/min	Minimum target frequency, 1/min
3 - 5	15	0.4	30	15
6 - 8	15	0.6	25	12
9 - 11	15	0.6	20	10
12 - 14	15	0.7	20	10
15 - 20	15	0.8	20	10
21 - 23	15	0.9	15	7
24 - 29	15	1	15	7
30 - 39	15	1	14	7
40 - 59	15	1	12	6
60 - 89	15	1	10	5
90 - 99	18	1.5	10	5
> 100	20	1.5	10	5

Regardless of the type of breath (hardware, synchronized hardware or supporting), the average value of compliance as well as the average RCe value for the Otis equation are calculated after three breaths to correct hardware and supporting breaths with DC.

At the switching from another mode Pi/PS are saved if the initial pressure applied in the previous mode is not greatly deviated from the start value. This allows to make softer and more imperceptible transition for the patient and to reduce fluctuations in both Pi/PS and MV.

Appendix 1.10.8 General description of the iSV pattern mode adjustment algorithm

Throughout the iSV operation Otis equation is solved for each breathing cycle. The findings are limited by the boundaries of the safe ventilation. Calculated data are necessary both for hardware and spontaneous breaths.

Graphically the automatic transition from the mandatory ventilation to supporting one looks as follows:

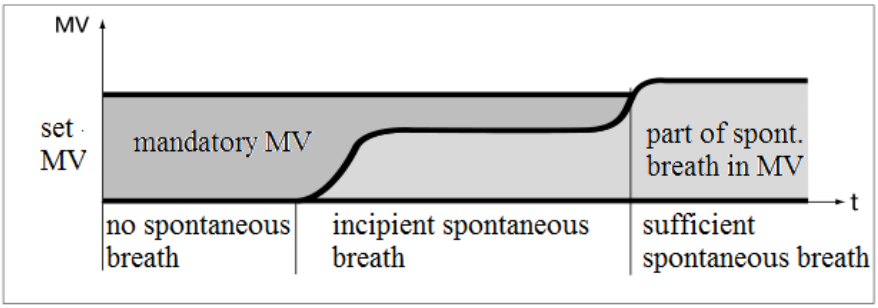


Figure App. 1.11 – Graphical representation of the automatic transition from mandatory ventilation to assisted

If the patient in iSV mode has no spontaneous breathing, the device carries out mandatory ventilation. The parameters of breaths are calculated in real time by the Otis equation. Hardware breaths are performed in the double control mode.

The second part of the mode reminds CPAP+PS, but the volume of supporting breaths is regulated automatically through the pressure. If the spontaneous breath occurs, pressure support PS is provided.

At the moments of spontaneous respiratory activity, spontaneous breaths are notable for their uneven depth and lability of their frequency. Control of the hardware and supporting breaths is made by different algorithms.

The bottom limit for the mandatory breaths is 5 cmH_2O. The bottom limit for the PS breaths is also 5 cmH_2O. This pressure is required to compensate the resistance of the endotracheal tube, breathing circuit and filters.

Appendix 1.10.9 Function of MV adaptation

The function of MV adaptation is a tool that allows the physician to choose the best respiratory minute volume for a particular patient.

Initial respiratory minute volume (%MV = 100) is quite average value calculated for the healthy person in the passive state and having an average metabolism. One can say that the calculated value MV protects the patient, but it does not guarantee the development of hypo- or hyperventilation, although extreme and rough deviations are mostly excluded.

Therefore the function of MV adaptation was introduced in the iSV mode. It is intended to clarify (to increase) the value of target MV at the appearance of the spontaneous breathing.

In all cases function of MV adaptation is activated only manually by pressing "Adapt.MV" button in the edit parameters bar (bottom line of the screen).

The essence of the function of MV adaptation lies in the automatic step-by-step increasing of %MV at the development of tachypnea and automatically returning to its initial value that is set by the physician at the absence of tachypnea.

At the termination of spontaneous breathing at the stage of adaptation, when the percentage of MV is increased, the pattern is supported with hardware breaths calculated for the current (accumulated) %MV. At the further absence of spontaneous breaths the current %MV decreases to the value %MV set by the physician with step of 5 %. Such decrement %MV prevents the subsequent patient’s hyperventilation at the at short-time tachypnea.

When real minute volume is above 200 %, the further adaptation is not carried out. The pressure PS is fixed at the level providing tidal volume calculated according to the Otis equation for MV = 200 %.

Appendix 1.10.10 Pmin parameter

The Pmin parameter in the ISV mode allows the operator to set the minimum pressure for the spontaneous breaths support. Device will not decrease the Psup below this value even if the parameters of the patient's respiratory mechanics allow this. This parameter can be useful in patients with unconfirmed breathing system that are on artificial ventilation due to other reasons (cerebral insufficiency, necessity in sedation, hypercatabolism, etc.), because it allows the operator to regulate the minute ventilation structure (respiratory rate and respiratory volume).

Appendix 1.11 Selection of ventilation modes at the patient's disturbance and cough

In the volume-controlled modes (CMV/VCV, SIMV/VC) and at patient's cougth, the maximum pressure Pmax alarm can be activated at the coincidence of the moments of inspiration and cough:

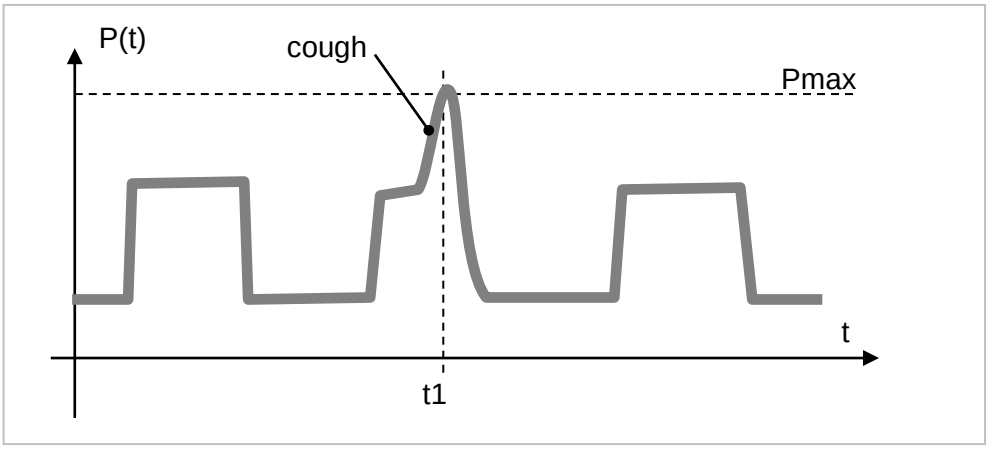


Figure App. 1.12 – Cough

At time t1 cough is superimposed to the inspiration process. The pressure in the circuit sharply increases and reaches Pmax. In response the device limits the pressure in the circuit at Pmax level and stops the inspiration by giving freedom of action to the patient, and triggers the alarm.

Proper installation of Pmax level on 10 - 15 cmH_2O above the inspiratory pressure creates reserve pressure and usually prevents the achievement of Pmax and alarm triggering. However at the intense coughing this measure is not always effective, alarms can be generated frequently. It can distract and annoy the staff and even lead to a reduction in its vigilance.

In such a situation it is recommended to select ventilation modes with pressure control (CMV/PCV, SIMV/PC), that are more resistant to pressure drops. The airway pressure curve will have the form (see Figure App. 1.13):

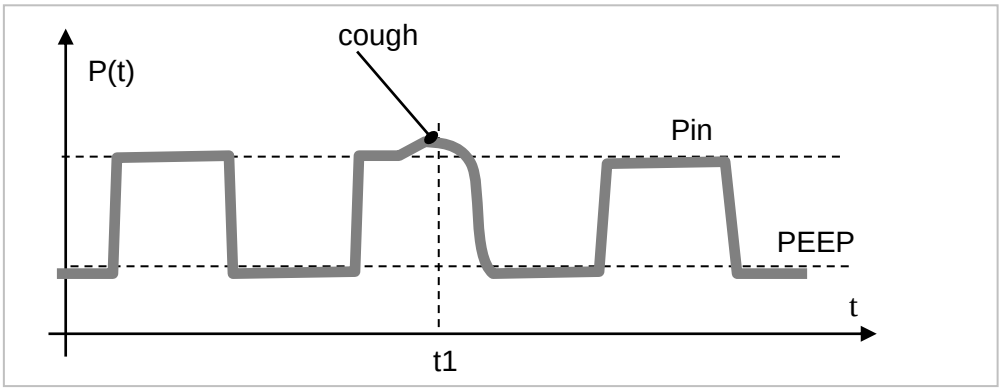


Figure App. 1.13 – Cough in pressure control modes

In these modes, if the cough occurs at the time of inspiration, the device produces a pressure limit by opening the desired degree of the expiration valve, thus giving the patient the possibility to exhale. The device keeps the pressure on the level of Pi and do not generate alarms. If cough occurs in the expiratory phase, device holds pressure at the PEEP level by opening the expiration valve.

APPENDIX 2 METHODS OF DETERMINING PARAMETERS

Appendix 2.1 Compliance and resistance

The compliance is a characteristic of compliance (extensibility) of broncho-pulmonary system of the patient. Resistance parameter is a measure of patient's airway and the endotracheal (tracheostomy) tube resistance.

The static compliance and resistance (Cst and Rst) are measured in all modes of ventilation having hardware breaths by special hardware test breath. The measurement period in the range of 0 - 10 minutes is set by the user in [Menu] → [Ventilation parameters] → [Compl. meas period]. If necessary the user can measure the value of compliance and resistance at any time by pressing the Cst/Rst window in the indication area of monitoring parameters.

Hardware test breath differs from the usual inspiration at operation in any mode of ventilation because of the presence of inspiratory plateau. Test breaths in the CMV/VCV and SIMV/VC modes always have rectangular flow waveform. Test breaths in the modes CMV/PCV and SIMV/PC can have a little pressure dip during the formation of the plateau. For any test breaths inspiratory time will be increased to the 0.5 - 2.0 s (for the formation of the plateau).

The device has also a second method for calculating of the compliance and resistance - dynamic, i.e. at every inspiration without a special test inspiration by solving a system of differential equations connecting the pressure and flow of gas in the breathing circuit. In the device's interface, the parameters obtained by this method are named as C and R and are displayed in separate block of measurement parameters. The values of the parameters C and R vary on every respiratory cycle.

At C and R parameters obtaining, a modern mathematical method for calculating lung mechanics called the LSF (least square fitting) is used. The LSF method is based on the analysis of the mathematical model of the lungs mechanical activity in real time during the whole respiratory cycle.

Leakage in the circuit, depending on its value, can cause significant error in the compliance and resistance measurement.

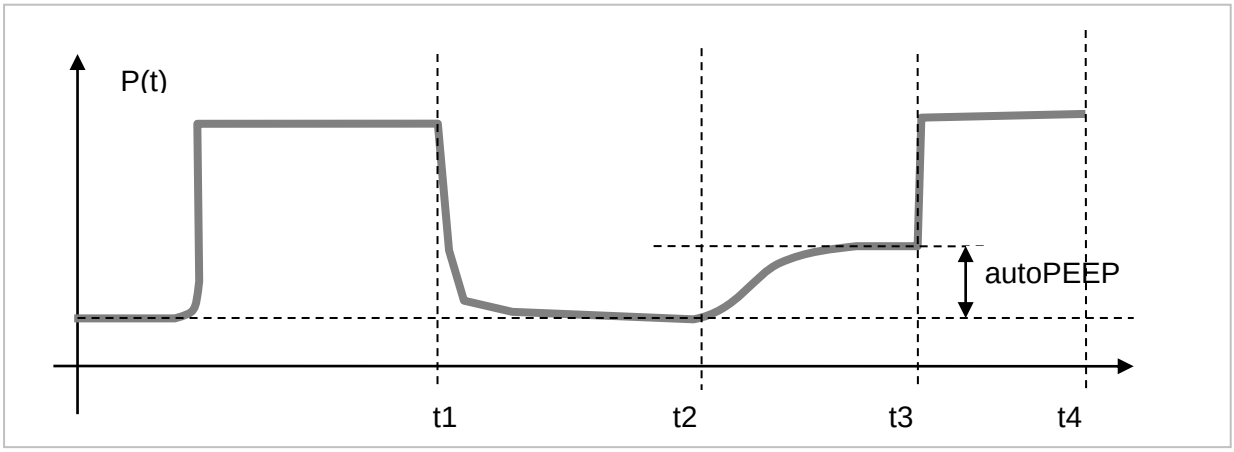
Appendix 2.2 AutoPEEP

AutoPEEP occurs when the ventilator settings (frequency, volume and inspiratory time) does not correspond to the patient's capabilities. In this case the patient before the start of the new inspiration does not have enough time to exhale the air of the previous breath. Accordingly, the end expiratory pressure is higher than the specified by ventilator setting.

AutoPEEP measurement is realized only for inactive patients in the mandatory breath cycles. Measurement is carried out by creating an expiration delay (expiration hold) by the command of operator or periodically (after the time specified in software).

For measurement by the operator's command, select "autoPEEP" in any block through [Menu] [Display settings] [Choose measured par.blocks]. To measure click on the autoPEEP block, then the block will change color from white to blue (indicating the beginning of the measurement), and after the end of inspiration, the measured value will be displayed on it. To re-measure, press the autoPEEP block again.

For periodic measurement using graphical button "Monitoring" select RESP2 window, where measured autoPEEP value will be displayed.



t1-t2 expiraiton time,t2-t3 expiration hold (time of autoPEEP measurement)

Figure App.2.1 – Increasing of pressure in the circuit at the closed expiration valve due to patient's end of expiration

Expiratory phase t1-t2 is carried out normally without deviations. At the time of the end of the exhalation, inspiratory and expiratory flows are stopped, expiration valve is closed and flow generator is also stopped. If there is an excessive pressure in the lungs, the gas flows from the lungs to the breathing circuit. Pressure equalization occurs in the circuit-lungs system. At the moment when the pressure change in the circuit becomes equal or less than 0.5 cmH_2O/s, but no earlier than 0.5 s and not later than 3 seconds, the procedure ends and inspiration begins.

$$autoPEEP = P(t3) – P(t2)$$

Expiration hold in any case can not exceed 3 seconds.

Appendix 2.3 Mean pressure in the circuit for the respiratory cycle (Pmean)

Mean pressure for the respiratory cycle in the breathing circuit is calculated as follows:

$$Pmean = \frac{1}{T} \cdot \int_0^T P(t) \cdot dt,$$

where: *Pmean – mean pressure in the circuit for the respiratory cycle,*
T – period of the respiratory cycle,
P(t) – pressure in the circuit in the moment of time t.

Appendix 2.4 Time constant of the respiratory tract (τexp, τinsp)

Time constant of the respiratory tract is the product of compliance and resistance:

$$t = C \times R.$$

It is necessary to record the time constant on the inspiration and expiration because these values differ in different situations (τ_{insp} in most cases exceeds τ_{exp}). Thre difference is especially expressed at the broncho-obstructive syndrome. Therefore the device calculates both parameters for correct selection of inspiration and expiratory time.

Cst and Rinsp values are measured in the respiratory cycle with inspiration pause. In order to minimize the error in the calculation of PEEP, in cases of significant decrease of compliance and increased aerodynamic resistance (respiratory distress syndrome, edema of lungs, bronchial obstruction and so on) expiration is divided to 2 phases - fast and slow at the calculation of τ_{exp}, because t of different areas of lungs can significantly differ. Fast one is associated mainly with the gas flow from the breathing circuit. The slow one is related mainly with the gas flow from the broncho-pulmonary tract. The ventilator detects τ_{exp} for slow expiratory phase. To eliminate the distortion of the result by the expiration part from the breathing circuit (fast phase), the first 50 ms of expiratory phase are not included in the analysis.

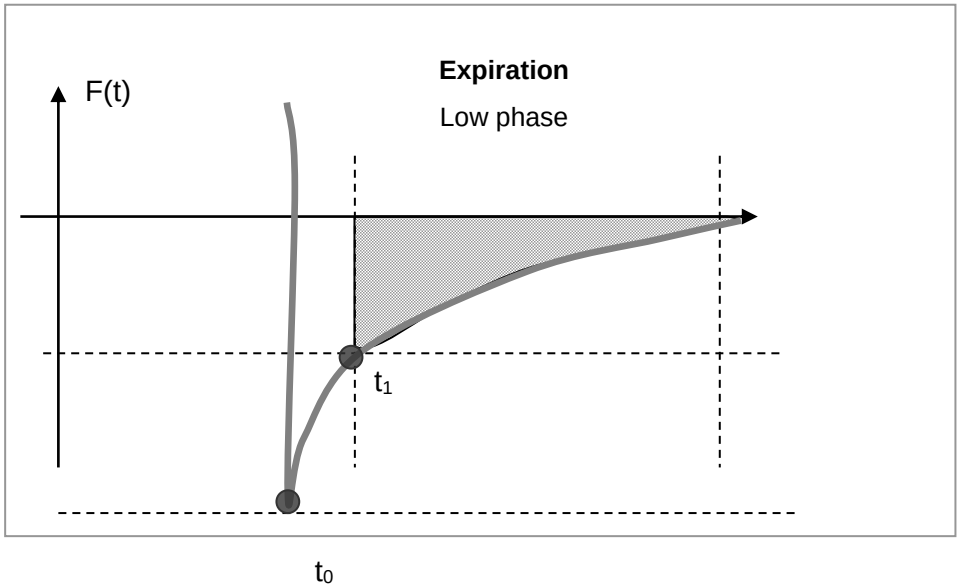


Figure App.2.2 – Time constant on inspiration

Under the conditions of passive expiration, as a first approximation, expiratory flow is described by the exponential law (RC-circuit model):

$$F = F_{max} \exp(-\tau_{exp}/t) \qquad (1),$$

where: F_{max} *– peak expiratory flow,*

τ_{exp} *– time constant.*

Volume during expiration:

$$V(t) = Vexp(1 - \exp(-\tau_{exp} / t)) \qquad (2),$$

where: *V(t) – current expiration volume,*

V_{exp} *– total expiration volume.*

Equation (2) shows that texp is a time during that 63 % of the expiration volume Vexp is removed from the lungs.

Expiration process can be divided into 3 stages:

1) The release of the gas from the circuit.

2) The gas flow from the upper respiratory tract, "fast" areas of lungs.

3) The gas flow from the "slow" areas of the lungs.

Stages 2, 3 relate to the slow phase.

This partition is conditional. The stages can be combined and occur simultaneously for certain values of resistance, compliance and ventilation parameters.

Calculation of τ_{exp} is performed by the formula (1) by the method of least squares based on data about the flow received during passive expiration. This eliminates the step of gas releasing from the circuit, and the calculation is made for the most informative "slow" part of the flow curve. The following figure shows typical expiratory flow curves for different values of resistance (R = 5 $cmH_2O/l/s$ and R = 50 $cmH_2O/l/s$).

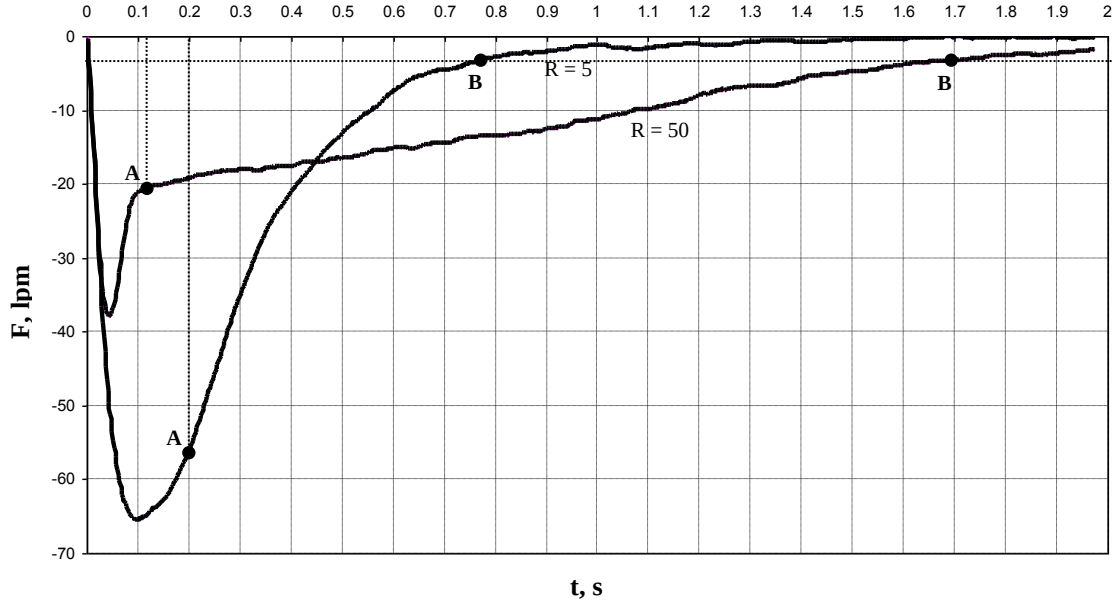


Figure App.2.3 – Graphs of flow on inspiration for patients with different resistance values

Portions of the curve (0-A) are discarded, measurement is carried out in the area A-B. Evaluation of the correctness of τ_{exp} values is carried out by calculating the confidence factor of flow curve approximation that should be at least 0.6. Otherwise the measurement is considered to be misleading and dashes (--) are displayed instead of the R.

Average value of the time constant of the section A-B is calculated using this procedure. It takes into account the resistance of the patient's lungs, the resistance of the endotracheal tube and the resistance of the expiraiton valve.

Measurement of τ_{exp} is performed on the each expiration; the averaging is made over the last 4 cycles.

Appendix 2.5 Work of breathing (WOB)

The device calculates the work of breathing per 1 liter of tidal volume. This parameter can be calculated by the algorithm in 2 versions: the work of spontaneous breathing of the patient attempts Wspont (important indicator in deciding to terminate the ventilation) and the work of breathing of device and patient Wvent (can be used to monitor the adequacy of the device's participation at the auxiliary ventilation).

WOB is calculated according to the formula:

$$W = \frac{1}{V_{insp}} \int_{t1}^{t2} \Delta P(t) \cdot F(t) \cdot dt ,$$

where: *t1 – beginning of the next inspiration,*

t2 – end of the next inspiration,

ΔP(t) – pressure change in the circuit at the inspiration, ΔP(t) = P(t)-PEEP,

F(t) – flow,

Vinsp – inspiration volume.

At the calculation of the work of breathing, the PEEP value is not considered as it does not create extra work. However the high PEEP value may increase the work of breathing, because it may reduce the compliance. Presence of autoPEEP always leads to increased work of breathing.

The work of breathing is calculated in any mode at selecting of this option by the user. Calculation of the WOB is made on each inspiration. The ventilator displays the measured value and the long-term trend of this parameter.

Appendix 2.6 Rapid shallow breathing index (RSBI)

Rapid shallow breathing index is also known as SBI. RSBI index indicates the adequacy of spontaneous ventilation under the spontaneous breathing support (CPAP+PS, BiSTEP, APRV).

The device calculates the RSBI index in accordance with the following formula:

$$RSBI = f_{spont} / \tau_{exp},$$

where *fspont - frequency of spontaneous breaths*,

τ_{exp} *– time constant of the respiratory tract at the expiration*.

Calculation of the RSBI is performed only at spontaneous inspiration in CPAP+PS, BiSTEP, APRV modes. Measurement of texp is made at the each exhalation and is averaged for the last 4 cycles.

Appendix 2.7 Stress index (SI)

The device uses a graphical method for finding the stress index SI.

The idea of the stress index was suggested by Ranieri[2] in 2000. Stress index is an integral indicator of the correct choice of PEEP and inspiratory volume Vt. In accordance with the definition Ranieri, stress index can be measured only for mandatory inspiraitons with a rectangular flow waveform - in CMV/VCV and SIMV/VC modes.

Stress index is calculated as the factor of deviation of P(t) waveform from the triangular curve (at the constant flow).

Range of allowable values of SI is from 0.1 to 2.0 with step of 0.01.

Case I: Correct PEEP and Vt values, SI is in the range from 0.9 to 1.1.

Case II: Low PEEP value, SI < 0.8.

Case III: Excessive PEEP of Vt value, SI > 1.1.

[2] Ranieri, V. M., H. Zhang, L. Mascia, M. Aubin, C. Y. Lin, J. B. Mullen, S. Grasso, M. Binnie, G. A. Volgyesi, P. Eng, and A. S. Slutsky. Pressure-time curve predicts minimally injurious ventilatory strategy in an isolated rat lung model. *Anesthesiology* 2000; 93:1320-1328.

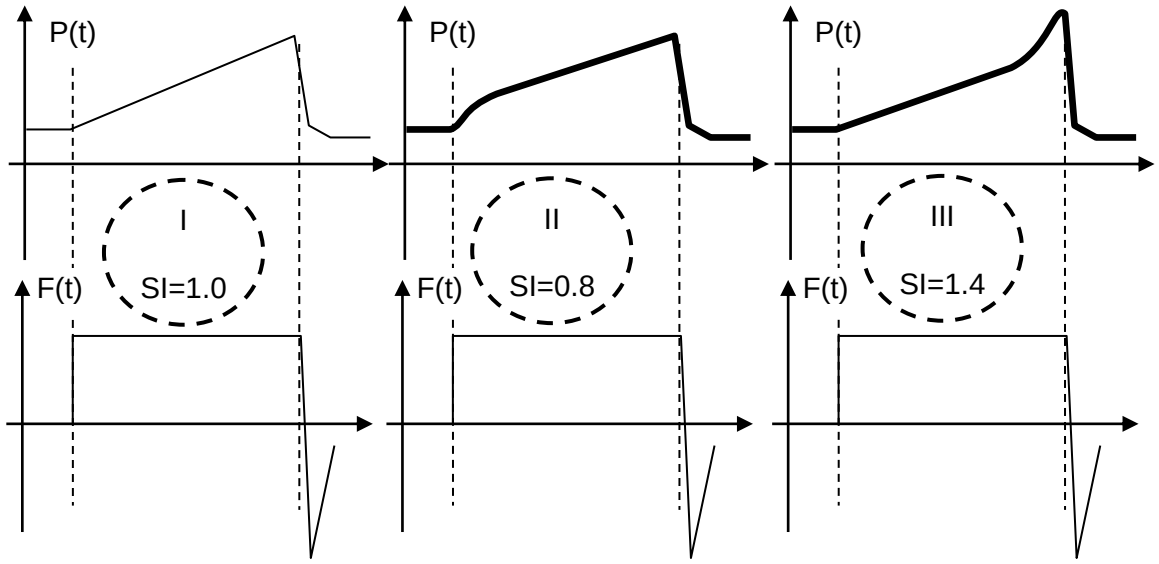


Figure App.2.4 – Volume control: pressure graphs at normal (SI = 1), low (SI < 1) and high (SI>1) stress-index

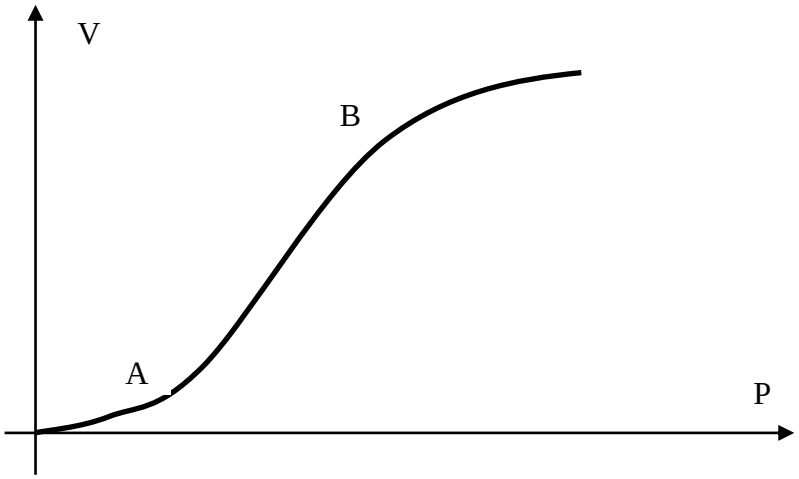


Figure App. 2.5 – at the correctly selected PEEP the pressure increases linearly

If PEEP and Vt values are selected properly, the whole range of the inspiratory pressure values lies on the linear part of the curve V (P), between points A and B (case I).

The idea of Ranieri - under these conditions the pressure in the circuit should increase according to the following law:

$$P(t) = a \times t^b + c,$$

where: *c – corresponds to the pressure at the beginning of the inspiration (point A),*

b – stress index SI.

At b=1 the equation becomes linear.

Appendix 2.8 Patient's respiratory effort P0.1

The value P0.1 characterizes the patient's ability to the independent breathing. P0.1 value is the pressure difference between the moment of start of the inspiration (t = 0) and moment of completion of 100 ms in the occluded circuit. This pressure difference is generated by the inspiratory effort of the patient. P0.1 measurement is valuable for the physician in the specific conditions of patient's ventilation and performed by the device with the current settings of the inspiratory trigger. Change of sensitivity or trigger type will change the moment of activation of the inspiratory trigger and is likely will change the measured value of P0.1.

Running of the function

The P0.1 value is measured by the device P0.1 only for the spontaneous breaths in SIMV, CPAP+PS, BiSTEP, APRV modes. P0.1 measurement is not performed if the leakage compensation is enabled due to the impossibility of occlusal circuit creating. P0.1 measurement is interrupted at the sanitiation support and mandatory breath. Lung recruitment maneuver does not effect to the P0.1 measurement. P0.1 measurement is initiated by activating of the RESP2 window. Measuring of P0.1 is made automatically 1 time in 1 minute.

In the classical method P0.1 value is measured at the closed inspiratory and expiratory branches of the patient's circuit:

$$P0.1 = P(t100) - P(t0)$$

Many studies have shown that the patient feels occlusion of the circuit if the occlusion time exceeds 0.15 seconds. He begins to worry that affects the measurement process. 0.1 seconds is a compromise for both physicians and patients.

The following procedure is used in the device:

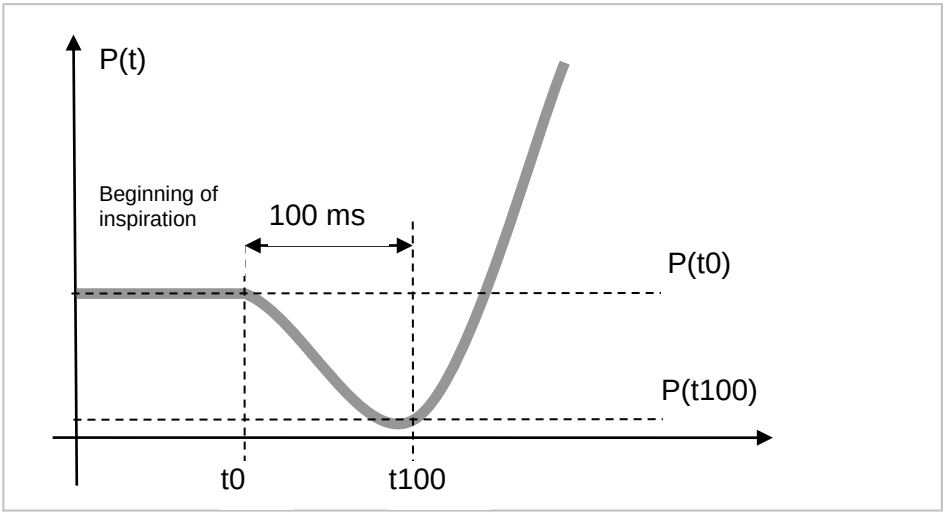


Figure App.2.6 – Measuring of P0.1 parameter

If pressure in the circuit at the time t100 has fallen no lower than 1 cmH_2O as a result of the patient's efforts and there is no inspiratory flow, the P0.1 is calculated as follows:

$$P0.1 = P(t100) - P(t0)$$

If the pressure has dropped below 1 cmH_2O, compliance and correction associated with flow are added to the calculated value.

Appendix 2.9 Ideal body weight of the patient (IBW)

The concept of the ideal body weight

IBW is an average function of the height and sex and does not depend on the actual weight of the patient. It is used to determine the target MV, tidal volume and respiratory rate. The concept of ideal weight has the important physiological significance - people of different weights, but the same height have statistically similar size of lungs. Optimal inspiration volume better correlates with height than with the weight.

Calculation of IBW for the adult patients

IBW in kg for men and women with the height from 130 to 250 cm:

For man: IBW = 0.908×height (cm) – 88.022

For woman: IBW = 0.905×height (cm) – 92.006

Alternative calculation published in the international website ARDS.net:

For man: IBW = 50+2.3×(height (in) – 60);

For woman: IBW = 45.5+2.3×(height (in) – 60);

where *height* – height in inches.

In both cases the results of the ideal body weight calculation are almost identical.

Calculation of IBW for the children

Calculation of IBW for children is a bit more complicated, because there is a nonlinear dependence between the weight and the height. For pediatric mode centile WHO (World Health Organization) tables compiled on the basis of multi-center studies conducted in many countries are used. Brief description of tables is as follows. Measurements of weight and height in children of the same age are performed, and research results are divided into a number of "corridors" or percentiles. The maximum incidence (75 %) corresponds to the average corridor or 50th percentile, which can be considered as the ideal weight. The remaining 4 corridors are distributed according to the degree of deviation. The last match corridors correspond to the incidence of 3 %. Girls and boys have small differences in the height-weight ratio.

Table App. 2.1 – Centile tables for boys and girls under the age of 2 years.

0 - 2 years, average (0-2 years Median th. (WHO))		
Height, cm	Weigth, kg	
	Boys	Girls
45	2.4	2.5
46	2.6	2.6
47	2.8	2.8
48	2.9	3.0
49	3.1	3.2
50	3.3	3.4
51	3.5	3.6
52	3.8	3.8
53	4.0	4.0
54	4.3	4.3
55	4.5	4.5
56	4.8	4.8
57	5.1	5.1
58	5.4	5.4

0 - 2 years, average (0-2 years Median th. (WHO))		
Height, cm	Weigth, kg	
	Boys	Girls
86	11.7	11.5
87	12.0	11.7
88	12.2	12.0
89	12.5	12.2
90	12.7	12.5
91	13.0	12.7
92	13.2	13.0
93	13.4	13.2
94	13.7	13.5
95	13.9	13.7
96	14.1	14.0
97	14.4	14.2
98	14.6	14.5
99	14.9	14.8

59	5.7	5.6
60	6.0	5.9
61	6.3	6.1
62	6.5	6.4
63	6.8	6.6
64	7.0	6.9
65	7.3	7.1
66	7.5	7.3
67	7.7	7.5
68	8.0	7.7
69	8.2	8.0
70	8.4	8.2
71	8.6	8.4
72	8.9	8.6
73	9.1	8.8
74	9.3	9.0
75	9.5	9.1
76	9.7	9.3
77	9.9	9.5
78	10.1	9.7
79	10.3	9.9
80	10.4	10.1
81	10.6	10.3
82	10.8	10.5
83	11.0	10.7
84	11.3	11.0
85	11.5	11.2

100	15.2	15.0
101	15.4	15.3
102	15.7	15.6
103	16.0	15.9
104	16.3	16.2
105	16.6	16.5
106	16.9	16.9
107	17.3	17.2
108	17.6	17.6
109	17.9	18.0
110	18.3	18.3
111	18.9	19.0
112	19.2	19.4
113	19.6	19.8
114	20.0	20.2
115	20.4	20.7
116	20.8	21.1
117	21.2	21.5
118	21.6	22.0
119	22.0	22.4
120	22.4	23.4
122	25.0	23.4
124	26.0	24.0
126	27.0	24.7
128	28.0	25.3
130	30.0	26.0

For the children with height from 130 to 150 cm ideal body weight is calculated as for the adult patients.

For your notes

APPENDIX 3 ELECTROMAGNETIC ENVIRONMENT

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11:2009	Group 1	The ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2009	Class A	The ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2:2009	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3:2008	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 6 kV contact; ± 8 kV air	± 6 kV contact; ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4:2012	± 2 kV for power supply lines; ± 1 kV for input/output lines	± 2 kV for power supply lines; ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2005	± 1 kV line(s) to line(s); ± 2 kV line(s) to earth	± 1 kV line(s) to line(s); ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note. U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6:2008	3 Vrms 150 kHz to 80 MHz Outside industrial, scientific and medical (ISM) bands[1)] 10 Vrms 150 kHz to 80 MHz in ISM bands[1)]	3 V 10 V	Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$
Radiated RF IEC 61000-4-3:2008	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 $\sqrt{P}$ (80 to 800 MHz); d = 2.3 $\sqrt{P}$ (800 MHz to 2.5 GHz), where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1. At 80 MHz and 800 MHz, the higher frequency range applies. *Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ventilator. *[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*			

Recommended separation distances between portable and mobile RF communications equipment and the ventilator

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

Rated maximum output power of transmitter, W	**Separation distance according to frequency of transmitter, m**			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.20	1.20	1.20	2.30
10	3.80	3.80	3.80	7.27
100	12.00	12.00	12.00	23.00

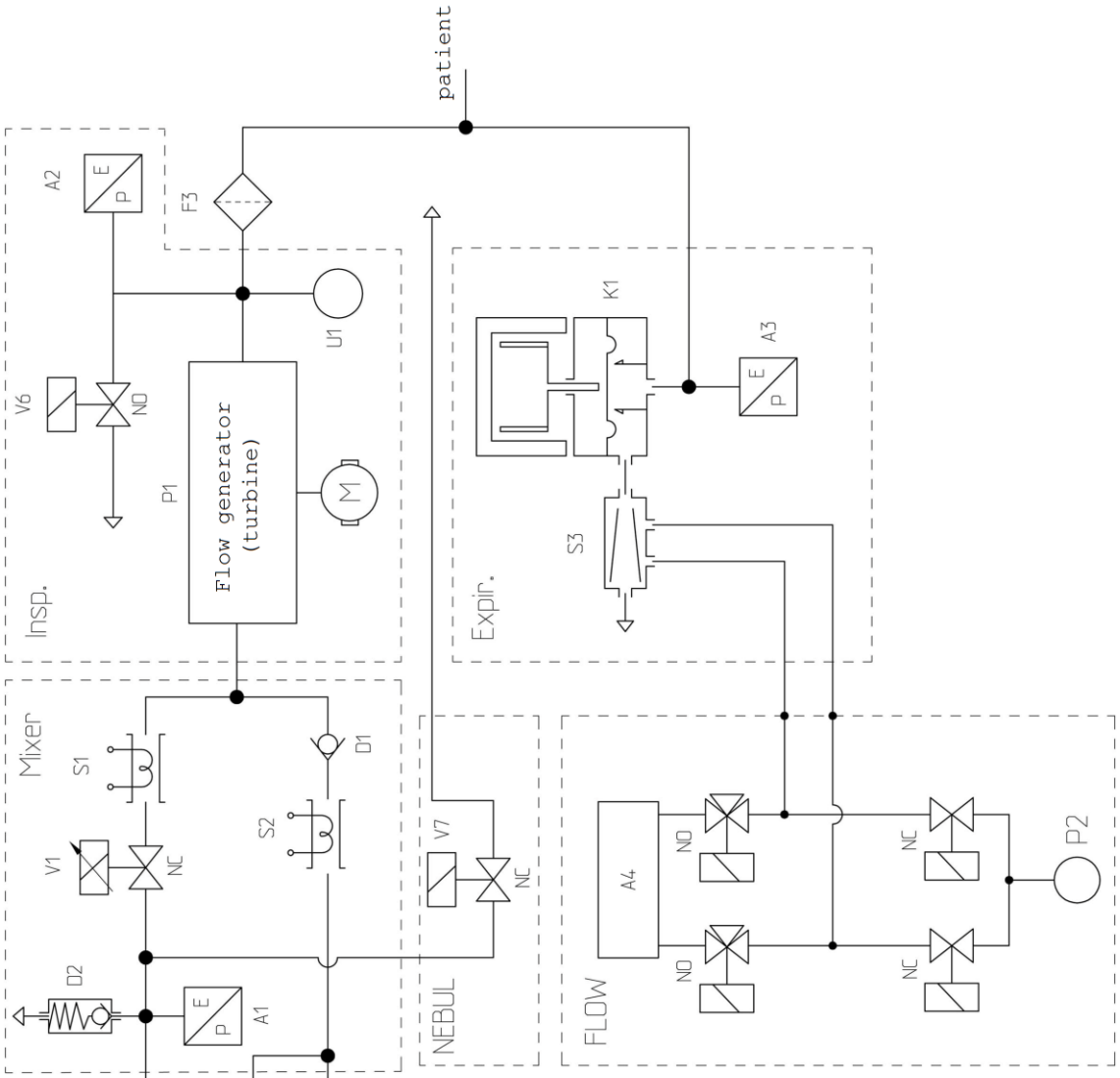
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

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

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

For your notes

APPENDIX 4 PNEUMATIC SCHEME OF VENTILATOR



Pos. design.	Name
A1	Pressure sensor MPX5700DP
A2...A3	Pressure sensor MPX2010DP
A4	Pressure sensor OCXL050S
D1	Return valve
D2	Safety valve
F1	Filter-regulator N104-DS09
F2	Filter FE80 F145
F3	Bactericidal filter 1944
K1	Expiration valve
P1	Blower
P2	Compressor P027C R0-0V 12V
V1	Proportional valve
V2...V5	Valve SY114-6GZ SMC
V6	Emergency valve
V7	Valve A321-1D2-U72 CAMOZZI
S1...S2	Flow sensor AWM720P1
S3	Flow sensor
U1	Oxygen sensor OOM202

For your notes

APPENDIX 5 TECHNICAL MALFUNCTION AND EVENTS

At the unsuccessful starting tests or at the transition into emergency mode of ventilation the device displays error codes for the particular modules:

- CIVL – ventilation controller
- CIND – display controller
- PU – power unit
- GM – gas mixer circuit
- PR.CONV. – protocol converter circuit (mainstream capnometer)
- SpO_2 – pulse oximetry module

Appendix 5.1 Technical malfunction

If a technical malfunction occurs, the ventilation can be temporary continued with the partial loss of functionality. When the device is turned on again, a switching to a technical failure occurs, see it. 4.17.6. Further operation of the device is not possible, see it. 4.17.6. Contact service department.

A detailed description of the malfunction and an indication of the unit in which the malfunction occurred are given in *Table App 5.1.* This information is to be reported to the service department.

Table App. 5.1 Technical malfunction messages

No	Alarm message	Alarm conditions	Module
1.	Technical malfunction 1 (Tech.malf.1)	There is no communication with the gas mixer	CIVL
2.	Technical malfunction 2 (Tech.malf.. 2)	The expiration valve malfunction occurred.	CIVL
3.	Technical malfunction 3 (Tech.malf.. 3)	The purge compressor malfunction occurred.	CIVL
4.	Technical malfunction 4 (Tech.malf.. 4)	The flow generator malfunction occurred	CIVL
5.	Technical malfunction 5 (Tech.malf.. 5)	There is no communication with the ventilation controller	CIND
6.	Technical malfunction 6 (Tech.malf.. 6)	There is no communication with the power unit	CIND
7.	Technical malfunction 7 (Tech.malf.. 7)	Safety valve malfunction occurred.	CIVL

Appendix 5.2 Technical messages

Technical messages are intended to inform the operator about events in the device and do not require immediate action from the operator. Technical messages are intended for service personnel. A detailed description of the technical messages and an indication of the unit in which the malfunction occurred are given in *Table App 5.2.*

Table App. 5.2 Technical malfunction messages

No	Alarm message	Alarm conditions	Module
1	Technical Message 1 (Tech. msg..1)	CIND restart type R	CIND
2	Technical Message 2 (Tech. msg..2)	CIND restart type F	CIND

APPENDIX 6 DELIVERY SET

Name		Part number	Quantity, items
1.	Intensive Care Ventilator	TESM.941144.001-01 Triton Electronic Systems Ltd, Russian	1
	including:		
1.1.	electronic unit		1
	- MV200	TESM.230001 Triton Electronic Systems Ltd, Russian Federation	
	- MV300	TESM.230002 Triton Electronic Systems Ltd, Russian Federation	
1.2.	filter-regulator	TESM.186143 Triton Electronic Systems Ltd, Russian Federation	1
1.3.	mobile trolley	TESM.186307-01 Triton Electronic Systems Ltd, Russian Federation	1
1.4.	high pressure oxygen hose	TESM.046002-01 Triton Electronic Systems Ltd, Russian Federation	1
1.5.	arm for the patient circuit	TESM.189015 Triton Electronic Systems Ltd, Russian Federation	1
1.6.	basket	TESM.189014 Triton Electronic Systems Ltd, Russian Federation	by special order
1.7.	humidifier	VH-2000 VADI Medical Technology Co. Ltd, Taiwan	by special order
		MR810 Fisher & Paykel Healthcare Ltd, New Zealand	
		MR850 Bundle Fisher & Paykel Healthcare Ltd, New Zealand	
1.8.	humidifier chamber	G-314002 VADI Medical Technology Co., Ltd., Taiwan	by special order
		MR370 Fisher & Paykel, New Zealand	
1.9.	patient circuit, disposable, adult	038-01-155B Flexicare Medical Ltd, UK	1
		5009 Intersurgical Ltd, UK	
1.10.	patient circuit, disposable, adult	RT206 Fisher & Paykel Healthcare Ltd, New Zealand	by special order
		038-31-768 Flexicare Medical Ltd, UK	
1.11.	patient circuit, disposable, adult	RT105 Fisher & Paykel Healthcare Ltd, New Zealand	by special order
		038-01-163 Flexicare Medical Ltd, UK	
1.12.	patient circuit, reusable, adult	900MR784 Fisher & Paykel Healthcare Ltd, New Zealand	by special order
1.13.	patient circuit, disposable, pediatric	038-02-155B Flexicare Medical Ltd, UK	1
		5513 Intersurgical Ltd, UK	

Name		Part number	Quantity, items
1.14.	patient circuit, disposable, pediatric	4504810 Intersurgical Ltd, UK 5504810 Intersurgical Ltd, UK	by special order
1.15.	patient circuit, disposable, neonatal	038-03-315 Flexicare Medical Ltd, UK 4510 Intersurgical Ltd, UK	by special order
1.16.	patient circuit, disposable, neonatal	RT225 Fisher & Paykel Healthcare Ltd, New Zealand 038-03-340C Flexicare Medical Ltd, UK	by special order
1.17.	patient circuit, reusable, adult / pediatric	KD-“MS-1” Medsilicon Ltd, Russian Federation	by special order
1.18.	filter bacterial, adult, disposable	1944 Intersurgical Ltd, UK 038-41-365 Flexicare Medical Ltd, UK	1
1.19.	filter bacterial, pediatric, disposable	1644 Intersurgical Ltd, UK 038-42-365 Flexicare Medical Ltd, UK	by special order
1.20.	HME filter, adult, disposable	Filta-Therm 1942 Intersurgical Ltd, UK 038-41-355 Flexicare Medical Ltd, UK	1
1.21.	HME filter, pediatric, disposable	Filta-Therm 1641 Intersurgical Ltd, UK 038-42-355 Flexicare Medical Ltd, UK	by special order
1.22.	hydrophobic filter	010-740 Flexicare Medical Limited, UK REF 2715 Intersurgical Ltd, UK	by special order
1.23.	breathing bag	0.5 L 038-83-805NL Flexicare Medical Limited, UK 0.5 L 2805 Intersurgical Ltd, UK	by special order
1.24.	breathing bag	3 L 2830-00 S Intersurgical Ltd, UK 3 L 038-81-830NL Flexicare Medical Limited, UK	1
1.25.	connector	15M-22M/15 REF2714 Intersurgical Ltd, UK 15M-22M/15 010-641 Flexicare Medical Limited, UK	by special order
1.26.	connector	22F-22F REF1967, Intersurgical Ltd, UK	by special order

Name		Part number	Quantity, items
1.27.	mainstream CO_2 module, including: mainstream CO_2 sensor	TESM.506001 Triton Electronic Systems Ltd, Russian Federation	by special order
	airway adapter, reusable, adult/pediatric	TESM.706020 Triton Electronic Systems Ltd, Russian Federation	
	airway adapter, reusable, pediatric/neonatal	TESM.706021 Triton Electronic Systems Ltd, Russian Federation	
1.28.	nebulizer pneumatic	032-10-005 Flexicare Medical Ltd, UK	1
		Cirrus REF 2605 Intersurgical Ltd, UK	
1.29.	nebulizer	Aeroneb Aerogen Ltd, Ireland	by special order
1.30.	mask	NovaStar, size L Draeger, Germany	by special order
		Full Face, size L BMC Medical, China	
1.31.	mask	NovaStar, size S Draeger, Germany	by special order
		Full Face, size S BMC Medical, China	
1.32.	mask	NovaStar, size M Draeger, Germany	by special order
		Full Face, size M BMC Medical, China	
1.33.	mask for NIV	FaceFit REF2250 Intersurgical Ltd, UK	by special order
		FaceFit REF2255 Intersurgical Ltd, UK	
1.34.	mask for NIV	FaceFit REF2251 Intersurgical Ltd, UK	by special order
1.35.	mask for NIV	FaceFit REF2252 Intersurgical Ltd, UK	by special order
1.36.	mask	NIV431 Fisher & Paykel Healthcare Ltd, New Zealand	by special order
1.37.	flex tube	G-322011 VADI Medical Technology Co., Ltd., Taiwan	by special order
1.38.	gas monitoring line	2 m 010-700 Flexicare Medical Limited, UK	by special order
		2.45 m REF2732 Intersurgical Ltd, UK	
1.39.	nut	M6-6H.5.016 GOST 3032-76	1
1.40.	pulse oximetry sensor, reusable, clip, adult	RM.501.00.124-01 Triton Electronic Systems Ltd, Russian Federation	by special order
1.41.	pulse oximetry sensor, reusable, wrap, neonatal	RM.501.00.004-01 Triton Electronic Systems Ltd, Russian Federation	by special order
1.42.	pulse oximetry sensor, reusable, clip, adult	RM.501.00.124-01 Triton Electronic Systems Ltd, Russian Federation	by special order

Name		Part number	Quantity, items
		NEMA 5-15 IEC320 C13 3 m, 125V,10A, 18AWG/3 black StayOnline	
		India IS 1293 16A3 IEC 60320 C13 3m, 250V, 10A, H05VV-F3x1.0 black, StayOnline	
1.43.	Adult esophageal balloon catheter set	REF 47-9005, CooperSurgical, Inc., USA	by special order
1.44.	Multifunction nasogastric catheter	NutriVent REF09031015, SIDAM s.r.l., Italy	by special order
1.45.	Catheter	TESM. 046502 Triton Electronic Systems Ltd, Russian Federation	by special order
2.	**Spare parts:**		
2.1.	fuse	T2.0AL/250V Radiodetal, Russian Federation	2
2.2.	microfilter	TESM.189017 Triton Electronic Systems Ltd, Russian Federation	1
2.3.	membrane	TESM.236501 Triton Electronic Systems Ltd, Russian Federation	1
2.4.	dust filter	TESM.009926 Triton Electronic Systems Ltd, Russian Federation	2
2.5.	water trap	60-13100-00 Dryline Water Trap, Adulit ARTEMA, Sweden	by special order
2.6.	ring	TESM.049124 Triton Electronic Systems Ltd, Russian Federation	2
3.	**Accompanying documents:**		
3.1.	User manual	TESM.941144.001-01 UM	1
4.	**Transport package**	TESM.233003	1

APPENDIX 7 ADDITIONAL PARAMETERS AND CHARACTERISTICS

No	Parameter	Value (description)
1.	**General features**	
1.1.	Type of patients	Adults, children
1.2.	Type of drive	Built-in flow generator “turbine”. Electric, compressorless. The device is independent from the compressed air sources.
1.3.	Input oxygen pressure	It is allowed to use low-pressure oxygen sources with operating pressure range 0.5 - 1.5 kgf / cm^2 (bar) (see p. 3.3.5)
1.4.	Operation from a low pressure oxygen sources (optional)	Low-pressure oxygen sources with a working pressure range up to 0.5 kgf / cm^2 (bar) (see p. 5.8)
1.5.	Position of flow and pressure sensors	All sensors (flow and pressure) are located inside of the device and protected against water condensation effects and mechanical damage.
1.6.	The ability to use accessories, breathing circuits of various types, including coaxial	Available
1.7.	Quick replacing of the oxygen sensor without device disassembling	Available
1.8.	Function of the oxygen sensor calibration: - automatic, without interruption of ventilation - service (manual)	 Available Available
1.9.	Disable O_2 monitoring and alarm triggering at the oxygen sensor failure	Available
1.10.	Ability to ventilate only by air in the absence of oxygen. Ability to disable the alarm in the absence of oxygen and ventilation only by air.	Available Available
1.11.	User interface	Control via the touch screen, quick keys (buttons) for parameters, the regulator of the "Encoder" type for the quick parameter changes.
1.12.	Log of alarms and events (1000 messages)	Available
1.13.	Automatic calculation of start ventilation parameters according to the ideal body weight and patient’s age category	Available
1.14.	Saving last used mode and ventilation parameters settings, opportunity to apply them for the next ventilation session.	Available
1.15.	The automatic self-test before connecting	At the ventilator’s switching testing of all modules is conducted with the displaying of the detected faults.
1.16.	Built-in accumulator charging time	No more than 3 hours with accumulator with charge current not less than 2.9 A
1.17.	Ability to correct delivered tidal volume according to the conditions: temperature, humidity, pressure	ATP, ATPS, ATPD, BTPS
1.18.	Active expiration valve ensures free breathing of the	Available

No	Parameter	Value (description)
	patient during mandatory breaths.	
1.19.	Response delay of the expiration valve	up to 5 ms
1.20.	Maximum (peak) flow on inspiration	180 lpm
1.21.	Nebulizer turning on automatic indication	Available
1.22.	Automatic leakage compensation during invasive ventilation	Available
1.23.	Automatic leakage compensation during noninvasive ventilation	Available
2.	**Built-in functions**	
2.1.	Oxygenation	Enabling 100% FiO_2 for 2 minutes
2.2.	Standby mode	Stop ventilation on personnel demand, the device goes into standby mode
2.3.	Alveolar recruitment maneuver	The transient increasing of PEEP to the specified level
2.4.	Suction	Automatic detection of disconnection and connection of the circuit with oxygenation before disconnecting and after connecting of the circuit
2.5.	Leak compensation	The device automatically compensates leakage in the circuit in all modes of ventilation. If the leakage is too large and can not be compensated, circuit disconnection alarm is triggered.
2.6.	Manual breath (manual ventilation)	Immediate breath by the operator' command, if necessary clinician may perform breaths with the desired frequency
2.7.	"Freezing" / analysis of graphs	Stopping of the graphs for the analysis of instantaneous values
2.8.	Screen lock	Protects the device from unintended modification of the ventilation modes
2.9.	Display brightness control	Changing the brightness of the screen in day and night mode
3.	**Ventilation parameters**	
3.1.	Rate of the pressure rise (inspiration pressure increase phase), Pramp	5 - 200 cmH_2O/s
3.2.	Plateau time, Tplat	0 - 70 % from inspiratory time
3.3.	Trigger window, TrigWnd	0-60 s
3.4.	Criterion of spontaneous inspiration volume exceeding of 25ml	Available
3.5.	Flow acceleration, Facc	10 - 100 %
3.6.	Support flow (base flow), Fsupp	0 - 30 lpm
3.7.	"Open valve" function	Available
3.8.	Factor of increasing/decreasing of target MV in the iSV mode, %MV	25 - 300 %
3.9.	Function of MV adaptation it the iSV mode, Adapt.MV	Available
3.10.	Limiting pressure in the breathing circuit in iSV mode, Plimit	0 - 72 cmH_2O (mbar)
3.11.	Minimum support pressure of spontaneous breaths,Pmin	3 - 50 cmH_2O (mbar)

No	Parameter	Value (description)
3.12.	Endotracheal tube compensation, ETC	0 - 100 %
4.	**Respiratory monitoring parameters**	
4.1.	Mean pressure for the respiratory cycle	Pm
4.2.	Residual pressure level in lungs	AutoPEEP
4.3.	Minute volume of spontaneous breaths	MVspont
4.4.	Frequency of spontaneous breaths	fspont
4.5.	Dynamic compliance/ resistance	C, R (LSF)
4.6.	Peak inspiratory flow	FlowPeak
4.7.	Leakage flow from the breathing circuit	Leak
4.8.	Plateau pressure	Pplat
4.9.	Elimination of CO_2 per minute (option)	VCO_2
4.10.	Minute alveolar ventilation, alveolar ventilation (option)	MValv, Valv
4.11.	Functional dead space (option)	Vd
4.12.	Cardiac output according to Fick (option)	CO
4.13.	Auxiliary external pressure (option) Transpulmonary pressure (option)	Paux Ptp
5.	**Extended respiratory monitoring (RESP2 window)**	
5.1.	True pressure level in lungs at the end of expiration (pressure in the lungs by the end of exhalation taking into account the incomplete expiratory PEEtot = PEEP + AutoPEEP)	PEEPtot
5.2.	Residual pressure level in lungs (that occurs due to the incompleteness of exhalation)	AutoPEEP
5.3.	Flow at the end of expiration (residual gas flow from the lungs arising from incomplete exhalation)	ExpEndFlow
5.4.	Expiratory time constant (time constant that determines the potential rate of pressure change in the lungs during expiration τexp = Rexp × Cexp)	RCexp
5.5.	Inspiratory time constant (time constant that determines the potential rate of pressure change in the lungs during inspiration τinsp = Rinsp × Cinsp)	RCinsp
5.6.	Stress index. The coefficient describes the adequacy of PEEP and Vt selection. Can be defined in the CMV/VCV and SIMV/VC modes for hardware breaths at the rectangular waveform.	SI
5.7.	Respiratory effort index. Parameter characterizes the strength of the patient's breathing attempts. Measured in cmH_2O	P0.1
5.8.	Work of the patient breathing. Parameter characterizes the work of breathing of the patient based on 1 liter of tidal volume	Wspont
5.9.	Work of the ventilator breathing. Parameter characterizes the work of breathing of the ventilator based on 1 liter of tidal volume	Wvent
6.	**Extended respiratory monitoring (RESP 3 window)**	
6.1.	Inspiratory time, including spontaneous (time of the last inspiration, made by ventilator or patient)	Tinsp
6.2.	Factor of breathing cycle filling (ratio of inspiratory time to total respiratory cycle time)	Tinsp/Ttot

No	Parameter	Value (description)
6.3.	Factor of spontaneous breathing (ratio of the minute volume of spontaneous breathing to the total breathing volume)	MVe_sp / MVe
6.4.	Resistance to the exhalation (total airway resistance during exhalation)	Rexp
6.5.	Elasticity of respiratory ways (elastence). Parameter is reverse to the static compliance. Measured in mmH_2O/ml.	E
6.6.	Resistance of the breathing circuit, measured in the circuit test	Rcirc
6.7.	Compliance of the breathing circuit, measured in the circuit test	Ccirc
6.8.	Compliance	Cdyn
6.9.	Rapid shallow breathing index (dimensionless parameter characterizing the depth of patient's breathing)	RSBI
7.	**Graphical monitoring**	
7.1.	Number of curves simultaneously displayed on the screen	1, 2, 3 or 4 selected by the user
7.2.	Displaying of spirometry loops	Simultaneous display of 3 curves and 1 loop at the user's choice. Ability to save ("freeze") the reference loop and to the store the moment of saving. Analysis of the main parameters of the respiratory cycle.
7.3.	Graphs (spirometric curves) with automatic scaling of the amplitude versus time	• Paw (pressure); • Flow (flow); • Vol (volume); • Loops: - volume/flow V-F, - volume/pressure V-P, - flow/pressure F-P, Optional: • PCO_2 (capnogram in mmHg); • PCO_2 (capnogram in%); • PO_2 (oxigram in %); • SpO_2 (photoplethysmogram); • graph of iSV mode; • VCO_2 (volume capnogram); • Paux (external auxiliary pressure) with Paw – Paux curve; V/Paux (volume/auxiliary external pressure curve)
7.4.	Displaying of the respiratory activity of the patient	• Icon at the beginning of the spontaneous breath • Highlighting of the graph contour Paw in phase of spontaneous breaths • Marker at the start of spontaneous inspiration
7.5.	Selection of the type of spirometry loops	Selection of one of three possible loops
7.6.	Scaling curves - pressure waveform in the range -20…120 cmH_2O	The vertical scale of the pressure curve in the airways user chooses using Pmax

No	Parameter	Value (description)
	(mbar) - flow waveform in the range -250…250 lpm	parameter. The other curves are scaled automatically. The horizontal scale of the curve is set automatically when user switch the child / adult mode or manually select scanning speed from "1, 2, 4".
7.7.	Mode of freezing and analysis of the graphical curves	"Freezing" of graphic curves and review with the cursor of the instantaneous values of flow, volume, pressure, time
7.8.	Displaying of the graphic curves in the contour or filling form	According to the user's selection space under the curve can be filled for the better contrast
7.9.	Identification of phases and type of the respiratory cycle	Inspiratory phase is highlighted with blue color for the hardware breath and white color for the spontaneous breaths. In addition, the start of spontaneous inspiration is marked with vertical line.
8.	**Option modules and functions**	
8.1.	Mainstream capnometer (external)	Provides the evaluation of CO_2 concentration (partial pressure) directly in the patient tee (main stream) in the range of 0 - 15 % (0 - 115 mmHg)
8.2.	Function of volume capnometry	Provides the evaluation of: • amount of carbon dioxide exhaled by the patient VCO_2; • functional dead space Vd; alveolar minute ventilation MValv, alveolar ventilation Valv
8.3.	Function of cardiac output calculation (in accordance with A. Fick method)	Provides calculation and displaying of cardiac output by A.Fick
8.4.	Pulse oximetry module	Provides the evaluation of: • oxygen saturation of arterial hemoglobin SpO_2 in the range of 70 - 100 %; • peripheral pulse rate PR in the range of 15 - 320 1/min
8.5.	Metabolism module	Provides the evaluation of: • oxygen consumption VO_2; • carbon dioxide elimination VCO_2; • respiratory quotient RQ; resting energy expenditure of the patient REE
8.6.	Function of the endotracheal tube resistance compensation	• Provides calculation of airway pressure taking into account the resistance of the endotracheal tube
8.7.	"Auxiliary external pressure" function	Provides the measuring of the pressure Paux in the trachea or the esophagus using a catheter with displaying of Paux and Paw-Paux curves and the calculation of the transpulmonary pressure Ptp
8.8.	The interface for connection to the personal computer (Ethernet connector on the rear panel). Interface for connecting USB flash memory device (USB connector on the rear panel).	Transmitted data: graphic curves, ventilation parameters, monitoring parameters. Transmitted data: screenshot (current status of the screen), the alarm log, the service log, selected segment of trend.

Note:

The presence of some characteristics / parameters in the device is determined by the equipment of the device and the terms of the supply agreement.

GLOSSARY

?	Failure of compliance and resistance measurement
%MV	Factor of increasing/decreasing of target MV in the iSV mode.
τexp	Expiratory time constant (RCexp). Time constant determining the potential rate of pressure change in the lungs during expiratory phase. Calculated parameter displayed in RESP2 window. τexp = Rexp × Cexp
τinsp	Inspiratory time constant (RCinsp). Time constant determining the potential rate of pressure change in the lungs during inspiratory phase. Calculated parameter displayed in RESP2 window. τinsp = Rinsp × Cinsp
Acc.charge	The residual capacity of the accumulator (in %).
Adapt.MV	Function of MV adaptation in the iSV mode
APNEA	Automatic backup ventilation mode in cases of pressure and volume apnea. Apnea ventilation mode is not fully independent ventilation mode. It is a mechanism to ensure patient safety in case of cessation of respiration in modes with support of the patient's spontaneous breathing. The device automatically switches to apnea ventilation mode when it detects absence of respiratory cycles during the set time interval. Functionally, the apnea ventilation mode is CMV mode with preset parameters, with control or volume control.
Apnea	Cessation of ventilator's and spontaneous breathing.
APRV	Airway pressure release ventilation mode. It is an extension of the CPAP+PS mode. The patient in this mode breathes independently with the help of a pressure support level.
ATP	Type of flow correction on inspiration and expiration. Ambient Temperature, Pressure – conversion is carried out for the relative humidity of 30% and ambient temperature of 25 °C.
ATPD	Type of flow correction on inspiration and expiration. Ambient Temperature, Pressure, Dried – ambient temperature and pressure with humidity 0 %; this correction is similar to ATP at 0% relative humidity.
ATPS	Type of flow correction on inspiration and expiration. Ambient Temperature, Pressure, Saturated – ambient temperature and pressure with humidity 100 %, this correction is similar to ATP at 100% relative humidity.
AutoPEEP	Residual pressure in lungs that occurs due to the incompleteness of expiration.
BiSTEP	Spontaneous breathing with two levels of continuous positive airway pressure with pressure support of spontaneous breaths. The patient can breathe through the device in both phases of the pressure in the circuit. The transition from the low-pressure phase to the high one is the inspiration with pressure control, the transition from the high-pressure phase is the expiration. However, unlike the PCV mode, inspiration and expiration can be separated by a significant time interval during that the patient breathes spontaneously. The device calculates separately the volumes of ventilator's and spontaneous breathing.
Breathing circuit calibration	Intended to adapt the device to the breathing circuit (see it. 4.16.6).
BTPS	Type of flow correction on inspiration and expiration. Body Temperature, Pressure, Saturated, with 100 % humidity.
CAN-Ethernet	Network card

C (LSF) **Cdyn**	Indicator of lungs compliance. It is measured dynamically by solving a system of equations connecting the pressure and flow of gas in the breathing circuit. The measurement is carried out during the inspiratory phase in the current respiratory cycle.
CAPN MS	Mainstream capnometer (service menu message).
CAPNO	Symbol of CO_2 measurement (capnography)
Capnogram	Graphical representation of the instantaneous carbon dioxide concentration.
Cardiac output according to Fick equation	See CO.
Ccirc	Compliance of the breathing circuit, measured at the short internal test.
CIND	Display controller. Part of the device's hardware and software responsible for displaying and parameterization.
CIVL	Ventilation controller. Part of the device's hardware and software responsible for patient's ventilation.
CMS	Central monitoring system
CMV/PCV	Controlled Mandatory Ventilation / Pressure Control Ventilation. Controlled mandatory ventilation with pressure control. In this mode inspiration is provided at with the set pressure, respiratory rate and inspiratory time. The pressure value is set by Pi parameter delivered above PEEP and firmly guaranteed during inspiration.
CMV/VCV	Controlled Mandatory Ventilation / Volume Control Ventilation. Controlled mandatory ventilation with volume control. In this mode the patient receives the set tidal volume. The shape of the flow curve is rectangular or decreasing, at the physician's choice.
CO	Cardiac output according to Fick equation. Indirect method of assessing cardiac output by oxygen consumption estimation.
Compl. meas.period	Compliance measurement period. Defines the time between the cycles of compliance and resistance measurements.
Compliance	See C
Compliance of the breathing circuit	See Ccirc
CPAP+PS	Constant Positive Airway Pressure. The ventilation mode supporting spontaneous breathing with the set positive airway pressure. The device supports the spontaneous inspiration attempt with pressure (PS). The criterion for starting the inspiration support cycle is the inspiratory trigger (flow or pressure).
Cst	Static compliance. Indicator of lungs compliance. Measured by creating a pause on inspiration (inspiratory pause).
Display controller	See CIND
E	Elastance (elasticity of respiratory ways). Reverse value of static compliance. Measured in mmH_2O, in CMV, SIMV, PCV-VG modes.
Elasticity of respiratory ways (elastance)	See E
Elimination of CO_2 per minute	The difference between the CO_2 concentration of in the exhaled and inhaled mixture.
ETC	Endotracheal tube compensation. Ventilation parameter.
$EtCO_2$	Concentration (partial pressure) of CO_2 in the exhaled mixture.
ETS	Expiration trigger sensitivity. Ventilation parameter.

ExpEndFlow	Flow at the end of expiration (residual gas flow from lungs caused by the incom-pleteness of expiration), lpm. Displayed in RESP 2 window.
Expiration trigger sensitivity (ETS)	Expiration trigger sensitivity - percentage of peak inspiratory flow at which the device switches from inspiration to expiration in the respiratory cycle with pressure support.
Expiratory time constant	See τ_{exp}
Expiratory volume	See Vexp
Facc	Flow acceleration. Ventilation parameter.
Factor of breathing cycle filling	See Tinsp/Ttot
Factor of spontaneous breathing	Ratio of the minute volume of spontaneous breathing to the total breathing volume. Calculated as: MVe_sp / MVe
FEM	Full emergency mode. See it. 4.17.6 Description of emergency mode
$FiCO_2$	Concentration (partial pressure) of CO_2 in the inspired mixture. Displayed in any of the fields of the screen.
FiO_2	Fractional concentration of inspired oxygen. Displayed in any of the fields of the screen.
FiO_2-EtO_2	Oxygen consumption (difference between oxygen concentration in the inhaled and exhaled mixture), for the metabolism module.
Flow	Flow waveform (graph).
Flow at the end of expiration	See ExpEndFlow.
Flow graph	See Flow
FlowPeak	Peak inspiratory flow. Displayed in separate window of measured parameters block.
FormFlow	Flow waveform
Fspont	Frequency of spontaneous breaths
Fsupp	Support flow.
Ftrig	Flow trigger sensitivity (operation threshold)
Functional dead space	See Vd. The default value is calculated as a function of the patient's growth.
Gas mixer	See GM.
Gas mixture	Gas entering the patient: environmental air enriched with oxygen, warmed and moistened. At operation of nebulizer - with medications.
GM	Gas mixer. Part of the hardware responsible for mixing of external air and oxygen inside the ventilator.
Humidifier	Device for increasing the humidity of the respiratory mixture.
I:E	Inspiratory:expiratory ratio
Inspiratory pause	The final interval of inspiratory time when the pressure is fixed and there is no air flow to the patient.
Inspiratory time	See Tinsp.
Inspiratory time constant	See τ_{insp}
Inspiratory volume	See Vinsp
iSV	Intellectual support ventilation
Leak	Leakage, otherwise - the difference between the volume of inhaled and exhaled air, loss of volume of the respiratory mixture in the system "ventilator-patient".
LSF	Least square fitting. Modern mathematical method of computer calculating of

	lung mechanics parameters.
Mainstream capnometry	Measurement of the carbon dioxide concentration directly in the breathing circuit. All breathing gas passes through a special adapter.
Mean pressure for the respiratory cycle	See Pm.
Minute alveolar ventilation	See MValv
Minute volume	See MV
MS	Mainstream CO_2 sensor (service menu message).
MV	Minute volume (the sum of tidal volumes per minute).
MValv	Minute alveolar ventilation.
MVe_sp / MVe	Factor of spontaneous breathing.
MVexp	Expiratory minute volume (volume eliminated from the patient)
MVspont	Minute volume of spontaneous breaths.
NIV	Non-invasive ventilation of lungs. The mode of spontaneous breathing with a set positive pressure in the airways and set support of spontaneous breathing through the face mask. The mode is very similar to CPAP+PS, the differences are due to the inevitability of leakage in non-invasive ventilation.
Occlusion	Blocking of patient's expiration or inspiration. Can be caused by the action of the ventilator or occlusion of the respiratory circuit.
Open Valve	"Open valve" function. Reflects the current trend of maintaining and supporting spontaneous breathing at all stages of ventilation. See it.4.21 "Open valve function"
Oxygen consumption	See VO_2
P0.1	Respiratory effort index. Index characterizes the strength of the patient's breathing attempts. It is measured in cmH_2O.
$PaCO_2$	Arterial CO_2 concentration obtained using one of the laboratory techniques
Paux	Auxiliary external pressure.
Paw	Airway pressure waveform (graph).
PCV-VG	Mandatory ventilation with guaranteed delivery of target respiratory volume at minimum possible pressure. Functionally mode repeats the CMV / PCV mode with one exception: instead of the target pressure, the user sets the target inspiratory volume. The inspiratory pressure is corrected by the device with each new inspiration according to the target volume.
PCO_2	Capnogram (graph).
Peak inspiratory flow	See FlowPeak
Peak inspiratory pressure	See PIP
PEEP	Positive end-expiratory pressure
PEEPtot	True pressure level in lungs at the end of expiration. Pressure in the lungs at the end of expiration, taking into account the incomplete expiration PEEPtot= PEEP + AutoPEEP. Displayed if both parameters are measured correctly.
Phigh	Pressure value in the high pressure phase (in the BiSTEP, APRV modes).
Photoplethysmogram (PPG)	Graph showing the change in tissue transparency in the section of the optical sensor. Transparency of tissues changes due to narrowing and widening of blood vessels because of pulsating arterial blood.
Pi	Inspiratory pressure.

Piapnea	Inspiratory pressure above apnea PEEP level in the apnea mode.
PIP	Peak inspiratory pressure.
Plateau pressure	See Pplat.
Plateau time	Selection the measuring units (% or sec).
Plimit	Value of pressure limitation in the breathing circuit in the iSV mode.
Plow	Pressure value in the low pressure phase (in the BiSTEP, APRV modes).
Pm	Mean pressure for the respiratory cycle.
Pmax	Maximum acceptable inspiratory pressure.
Pmin	Minimum acceptable support pressure of spontaneous breaths.
PMM	Pressure measurement module (service menu message).
Pplat	Plateau pressure. Pressure on the inspiratory pause in volume control modes.
PR	Peripheral pulse rate
PR.CONV.	Protocol converter (service menu message).
Pramp	Rate of the pressure rise. This value determines the time of reaching of the target pressure in the pressure control mode and at spontaneous inspiration support.
Pressure graph	See Paw
PS	Support pressure of spontaneous breath.
Ptp	Transpulmonary pressure
Ptrig	Pressure trigger sensitivity (operation threshold). See trigger.
PU	Power unit (service menu message).
Pulse oximetry module	Optional module that provides monitoring of oxygen saturation of arterial blood hemoglobin SpO2, peripheral pulse rate PR, displaying of photoplethysmogram.
$PvCO_2$	Venous CO_2 concentration obtained using one of the laboratory techniques
PO_2	Oxigram for operation with metabolism module (calculated as the difference FiO_2 - EtO_2) (graph).
Qmax	The maximum oxygen flow passed through the port.
R (LSF)	Resistance (resistance of airways to the respiratory mixture flow). It is measured dynamically by solving a system of equations connecting the pressure and flow of gas in the breathing circuit. The measurement is carried out during the inspiratory phase in the current respiratory cycle.
Rapid shallow breathing index	See RSBI
RB	Rate of breathing, respiratory rate (frequency of mandatory breaths).
RBapnea	Respiratory rate in the apnea mode.
RCexp	See τ_{exp}
RCinsp	See τ_{insp}
Rcirc	Resistance of the breathing circuit measured during breathing circuit calibration.
REE	Resting energy expenditure. Total energy consumption in rest, kkal/day.
REF	Reference loop.
Reference loop	See Ref.

Residual pressure level in lungs	See AutoPEEP.
Resistance	See R, Rst.
Resistance of the breathing circuit	See Rcirc.
Resistance of the endotracheal tube	One of the components of resistance.
Resistance to the expiration	See Rexp.
Respiratory effort index	See P0.1.
Respiratory quotient	See RQ.
Respiratory quotient	See RQ.
Resting energy expenditure	See REE.
Rexp	Resistance to the expiration. The total resistance of the airways during the expiratory phase.
RQ	Respiratory quotient.
RSBI	Rapid shallow breathing index. The dimensionless quantity characterizing the depth of patient's breathing. Measured in CPAP+PS, BiSTEP, APRV modes. See Appendix 2.6.
Rst	Resistance (resistance of airways to the respiratory mixture flow). Measured by creating a pause on inspiration (inspiratory pause).
Safety valve	One of the elements of patient safety. In case of emergency occlusion of the circuit, the device opens the safety valve and provides further ventilation with the discharge of the exhaust air through this valve to the atmosphere until the causes of occlusion are eliminated.
Sampling line	Thin plastic tube for sampling of the respiratory mixture by the metabolism module.
SI	Stress index. Index characterizes the correctness of PEEP and Vt selection. It is determined in the CMV/VCV and SIMV/VC modes for hardware breaths at the rectangular shape of the flow waveform.
Sigh	Mode of the deepen sigh.
SIMV/DC	Synchronized Intermittent Mandatory Ventilation / Double Control. Ventilation mode, the analogue of the SIMV / PC except that the ventilator's breath is performed in a double-check mode similar to the PCV-VG.
SIMV/PC	Synchronized Intermittent Mandatory Ventilation / Pressure Control.
SIMV/VC	Synchronized Intermittent Mandatory Ventilation / Volume Control.
SpO_2	Oxygen saturation of arterial blood hemoglobin.
Stress index	See SI.
Support flow	The respiratory mixture flowing through the circuit at the intervals of absence of gas exchange between the ventilator and the patient, necessary to support spontaneous inspiration.
Tapnea	Time of transition to the apnea mode in case of the absence of ventilator's and spontaneous breathing. Controlled parameter.
Texp	Expiratory time.

Thigh Time of the high pressure phase in the BiSTEP, APRV modes.

Tinsp Inspiratory time. Parameter that specifies the time of the ventilator's inspiration or the maximum time of spontaneous inspiration. Controlled parameter.

Tinsp/Ttot Factor of breathing cycle filling. Ratio of inspiratory time to total respiratory cycle time.

Tlow Time of the low pressure phase in the BiSTEP, APRV modes.

Tplat Plateau time

Trigger Threshold value for the detection of spontaneous inspiration. Trigger can operate by volume and pressure. The lower trigger value means the higher trigger sensitivity to the air fluctuations in the breathing circuit.

Trigger Vinsp 25 ml Additional criterion for the inspiratory trigger activation at exceeding the inspiratory volume of 25 ml, that ensures triggering at slow (prolonged) spontaneous inspirations.

TrigWnd Trigger window. The trigger window or the fraction of the expiratory time when a spontaneous inspiration is expected. The expiration is divided into two parts by the trigger window: 1) the period when ventilator's expiration shall occur, if previously there were no spontaneous inspiration attempts 2) a period when spontaneous inspiration attempts are expected and supported. The value of the trigger window can be set in percent or seconds, depending on the [Menu] [Trig.window] parameter.

V Volume. The volume graph shows the volume of the respiratory mixture consumed by the patient in a single breathing cycle.

Valv Alveolar ventilation is lung ventilation minus ventilation of dead space. Normally the alveolar ventilation is 70 - 75% of MV. Alveolar ventilation is calculated according to the formula: MAV = (V_T - V_d) × RB, where MAV - minute alveolar ventilation, V_T - tidal volume, V_d - dead space volume , RB - respiratory rate.

Vapnea Tidal volume in the apnea mode.

VCO_2 Elimination of CO_2 per minute (difference between CO_2 concentration in the inhaled and exhaled mixture).

Volume capnography waveform.

Vd Functional dead space. The inspiratory air volume that almost does not take part in gas exchange. The default value is calculated as a function of the patient's growth.

Ventilation controller See CIVL.

Vexp Expiratory volume.

Vinsp Inspiratory volume.

VO_2 Oxygen consumption (difference between oxygen concentration in the inhaled and exhaled mixture).

Volume capnometry Measurement of the amount of CO_2 released by the patient. Has a greater diagnostic and prognostic value than a conventional capnogram.

Volume capnometry graph Graphical representation of the instantaneous carbon dioxide released by the patient.

Volume graph See V.

V_T Tidal volume.

Vtmax The level of inspiratory volume limitation in the iSV mode calculated by the formula Vtmax = (Vtmax calc. coeff.) x IBW, where IBW is the ideal weight and the calculation coefficient Vtmax is set by the user in the range 7-30 ml / kg

Water trap Part of the breathing circuit. Water trap is intended for protection of device from the liquid.

Work of the patient breathing See Wspont.

Work of the ventilator breathing	See Wvent.
Wspont	Work of the patient breathing. Energy consumption at respiratory movements. It is calculated only by the spontaneous breaths. Work is 0 for hardware breaths.
Wvent	Work of the ventilator breathing. Energy consumption at respiratory movements. It is calculated only by the hardware breaths. Work is 0 for spontaneous breaths.
T disconn.in NIV	Delay time of disconnection alarm triggering in the NIV mode.