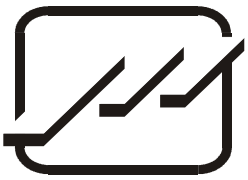
RESPINA.P2

User Manual

Pooyandegan Rah
Saadat Co.



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Manual Purpose

This manual provides the instructions necessary to operate ventilator system based on its intended use. It also describes all adjustable and measurable parameters by the system, defined maneuvers, alarms and briefly all capabilities of the Respina P2 ventilator.

Observance of this manual is a prerequisite for proper operation and assures patient and operator safety. If you have any question about the ventilator, please contact our customer service department. This manual is an essential part of and should always be kept close to the ventilator system, so that it can be obtained conveniently when necessary.

Intended Audience

This manual is provided for healthcare professionals. The healthcare professionals are expected to have working knowledge of medical terminology and procedures as required for operating the ventilator.

Version Information

This manual has a version number. The version number changes whenever the manual is revised due to software or technical specification changes. The version information of this manual is as follows:

Version number	Software version	Release date
O50-L01-V3	P2 VER2.0 R64	September. 2024

Tabel of Contents

1- Introduction

1-1 Device description and indication for use

Respina-P2 is an ICU Ventilator as a medical device for monitoring and treatment of a patient that ventilate patient mechanically who is not able to breathe completely or sufficiently The ventilator system is intended to be used with adult and pediatric patients weighing more than 5 Kg in the ICU. This system is designed in such a way that can provide invasive and non-invasive mechanical ventilation for patients. The ventilator is a high-risk medical device (class III according to Health Ministry of Iran and class II b according to European Union) intended for use by qualified, trained personnel at the discretion of a physician.

1-2 Contraindications

The Respina P2 ventilator is not designed for neonatal patients, it is not equipped with an internal compressor or turbofan. This ventilator is not a portable device and does not meet specific design requirements for emergency department use. In some specific diseases, special measures must be taken to prevent possible injury to the patient. Additionally, Non- invasive ventilation (NIV) should not be used in the following cases:

- Inability to trigger breath
- Intolerance of interface
- Facial or brain injury
- Partial or complete airway obstruction
- Haemodynamic instability

It is strongly NOT recommended to use the ventilator in the following situations:

- Starting and operating the ventilator in the absence of competent medical professionals supervising the procedure.
- If there is no alternative ventilation method and equipment that can be used as a backup.
- Connected the device to an inadequate electric mains power (e.g. without earth connection).
- With gas supply which do not meet medical grade specifications.

It is NOT possible to use the ventilator when any of the following events occurs:

- Never use it in the presence of flammable anesthetic gases.
- Do not use nitric oxide, helium or mixtures containing helium as input gas supply.
- The ventilator is located in the vicinity of MRI equipment or significant sources of electromagnetic radiation.
- During the inter hospital transfer of patients (mobilization outside the assigned institution).

- Failure to strictly comply with the instructions for use, user and intended use environment for this ventilator.
- If the ventilator is located in a hyperbaric chamber.

It is the responsibility of the user to select the appropriate ventilation mode for the underlying disease of the patient. For all ventilator settings, the user needs to consider the respiratory status and the general state of health of the patient in order to optimally adapt the ventilation settings to the patient's condition.

1-3 Side effects

The instructions for use do not discuss about risks that are obvious to users, consequences of obvious improper use of the ventilator and potentially negative effects on patients with one or more illnesses.
Generally, mechanical ventilation may lead to negative effects, such as barotrauma or strain on the circulatory system. Proper selection of ventilation mode and suitable adjustment of setting parameters could decrease potential occurrence of such effects.
Side effects of NIV ventilation includes: ear discomfort, conjunctivitis, skin abrasions due to mask/patient interface, and gastric distention (aerophagia).

1-4 Warnings and safety information

Warning


Read User manual carefully before operating the ventilator system.


The system function can be affected by using unapproved accessories.


The ventilator should only be operated and maintained by trained personnel. In addition, all patients requiring ventilation must be monitored appropriately by qualified medical personnel.


The guidelines for the use of approved accessories, checking the device function and the use of the device in appropriate environmental conditions should be followed by healthcare center.


When the device is turned on, audible and visual alarms will be enabled for a few seconds to check the alarm system. Do not use the device if integrity of the alarm system is in doubt and contact the Customer Service department.


Use only sterilized tracheal tube.


Prolonged use of tracheal tube may harm to patient.


Due to leaks around the mask, the patient expiratory volume may be different from the measured expiratory volume in NIV mode.


Before using the device, prepare necessary equipment to monitor expiratory CO2 in NIV mode.


The NIV mask should be non-vented and have no PEEP control valve.


The patient's respiratory set should be dual-limb.

- There could be hazard of electrical shock by opening the ventilator casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by manufacturer.
- Only medically pure oxygen which is oil-free should be used for ventilation. Do not use anesthetics and explosive gases.
- To prevent fire hazard, keep all ignition sources away from the system.
- Ensure that an alternate source of ventilation is always available.
- In case of uncertainty of device performance, replace the respina ventilator with another ventilator or ventilation device.
- If the ventilator is damaged and ventilation fails, stop using the ventilator because it may lead to the patient death.
- To avoid risk of electric shock, the device must be connected to a mains supply with proper grounding.
- When the ventilator is connected to an external device, the power cable should be used to ensure proper grounding.
- If the ventilator and other devices are connected to the patient at the same time, if necessary, use the equipotentializing jack on the back of the device.
- To prevent EMC effect on the ventilator, the device should not be used adjacent to or in conjunction with other equipment and if adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the ventilator performance.
- Do not replace any accessories or other parts of the device during the patient ventilation.
- Adding attachments to breathing system may decrease pressure and affect the ventilator function.
- Before using the ventilator ensure that a healthy battery with minimum charge is installed.
- If the ventilator has been stored for a long time, recharge the battery before use and make sure it’s healthy.
- If you’re going to store the device for an extended time, charge the battery and remove it from the device.
- Do not use the device in case of the battery failure.
- If the oxygen sensor is faulty or uncalibrated, measurement values will not be reliable.
- The maximum time taken to increase the oxygen concentration in the delivered gas to the patient from 21% to 90% is 12 seconds (in the volumes 30, 150 and 300 ml).
- The device maintenance should always be accomplished in conformity with safety regulations.
- The ventilator must be repaired, assembled, and used by trained personnel. The ventilator must be inspected by trained personnel annually.

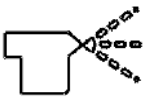
- To prevent cross contamination, a bacteria filter can be placed between the ventilator to patient outlet and the patient breathing circuit.
  Do not reuse disposable filters and check them regularly for blockages, because occlusion of these filters can cause high resistance of breathing circuit.
- There will be some risks of the environment pollution associated with the disposal of the device accessories and parts (e.g. battery, defective accessories). The device and accessories shall be disposed of in compliance with relevant regulations. Contact your municipality to check where you can safely dispose of old batteries.
- Do not sterilize the ventilator.
- If the ventilator is damaged, its life-supporting function will no longer be guaranteed. In this condition do not use the ventilator and use other source of ventilation.
- Do not use the ventilator placed next to a curtain, this could block cooling air thereby causing the equipment to overheat.
- To prevent electric shock while servicing the ventilator, ensure that it is disconnected from all power sources.
- Do not use the ventilator in magnetic resonance imaging (MRI) environment.
- Do not use the ventilator in high- pressure enclosure.
- Do not use the ventilator with nitric oxide.
- Do not use the ventilator with helium or gas mixture containing helium.
- If a gas other than oxygen is mistakenly used in the oxygen inlet of the device, the measurement of oxygen parameters is not done correctly and there is a possibility of an error in the function of the device.
- Maintenanceand cleaning of the device should be conducted according to the manufacturer recommendations in the user manual.
- Use humidifier or HME to prevent delivery of dry and low temperature air to the patient. Do not use the HME and the humidifier at the same time, because it increases resistance of the airway.
- Humidifier failure can cause delivery of low moisture and temperature air to the patient.
- Nebulizer or humidifier could increase resistance of breathing circuit filters. User must check airway filters regularly.
- To prevent possible damages, always turn off the humidifier when the ventilator is off or in standby mode.
- Nebulizer can add gas to the breathing circuit and affect the device measurement accuracy.
- In case of unavailability of the oxygen source, Nebulizer will not function.
- To ensure that last settings and data are saved, shutdown the device by shutdown icon in standby menu.
- Useful life of the device is 10 years. It is recommended to calibrate the device once a year.

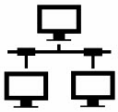
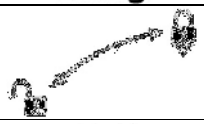
Note:

1- The ventilator is equipped with a safety valve that functions mechanically to keep the pressure below 110 cmH2O.

2- The required time for oxygen concentration to reach from 21 to 90%, in volumes of 30, 150 and 300 ml, in the worst case, is less than 2 minutes.

1-5 Device Labels and Symbols

⊙	On key
	Nebulizer connector
	Gas flow to patient from ventilator
	Gas flow from patient to ventilator
Exhaust	Gas outlet from ventilator
	Refer to manual
O_2 Sensor	O2 Sensor location
SN: xxxxxx	Device serial number
O_2 2.4-6 bar (35 - 87 psi) max. 180 L/min	O2 inlet port
Air 2.4-6 bar (35 - 87 psi) max. 180 L/min	Air inlet port
AC –Input: 100 -240VAC 1.0 - 0.5 A 50/60 Hz	AC input connector
	Battery indicator
	Waste equipment is disposed of in compliance with environmental requirements
CE	Compliance with CE standard requirements
IP21	Degree of protection against dust, rain, etc (drip-proof)
	Manufacturer

 20XX	Manufacturer year
	B-type applied parts
	Equipotential jack
	LAN connection
RS232	Serial connection
	Parts of the device that have high temperature
EC REP	Authorized representative of Europe
	Warning! Refer to the device manual
 11 Kg	Device weight
	Lock and unlock the exhalation valve
	Battery location
Main	Indicates that the ventilator is On
	Alarm active indicator
	Indicates the ventilator running on the battery and the battery charge status
	Indicates the ventilator connection to the mains power and the battery charging
LOCK	Lock/Unlock key of touch screen

1-6 Guarantee and responsibilities

The manufacturer will not take any responsibility if operator:

- misuses the device

- fails to follow operating instructions
- disregards any warning or technical information
- modifies the device in any way
- uses accessories that are not approved or recommended by manufacturer

1-7 Contents list of Technical Manual

The Technical manual includes the following chapter headings. For more information about the device maintenance and servicing, please refer to the Technical manual.

- About this manual
- Theory of operation
- Test and service
- Test equipment and functional tests
- Error codes
- Technical drawings and part list

2- Overview of Respina P2 Ventilator

2-1 Front View

The ventilator system can be controlled by rotary and touch screen. Take the following actions to change parameter and alarm settings:

- Select your desired parameter by touch screen or rotary knob
- Change parameter value by touching + and - options on the screen or turning the knob (turn it clockwise to increase value and counter clockwise to decrease value).
- Then touch Save or push the knob to apply new setting.

The ventilator is equipped with air and oxygen inlets that are connected to compressor or hospital main gas supply. Respina P2 ventilator is composed of the following parts (See figure 2-1).

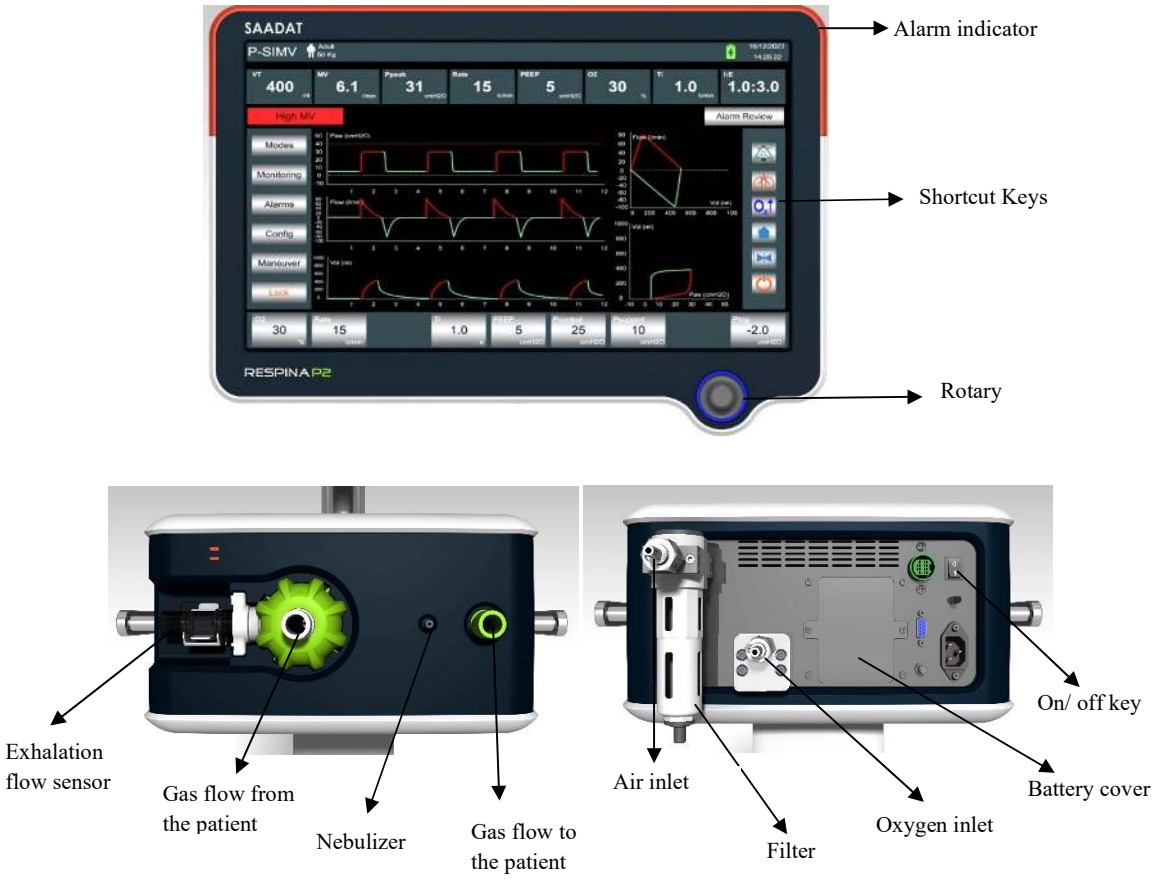


Figure 2-1 Different parts of ventilator

2-2 User interface

The parts of the device that user or patient can interact with are:

- Touch screen and enclosure

- Respiratory set and water traps
- Flow sensor and exhalation valve
- Input filter
- Nebulizer
- Humidifier / HME

2-3 Accessories

Use only manufacturer recommended accessories. These accessories are listed in the below table.

Accessory	Part Number	Singel use
Standard list		
Battery	P26612	--
Exhalation flow sensor	P26395	--
O2 sensor- Galvanic	P26613	--
O2 sensor- Permanent	P26506	--
Exhalation valve	P26371	--
Exhalation valve membrabe	P26349	✓
Exhalation valve- flow sensor interface	P26407	--
Adult respiration set	P26614	✓
HME	P26615	✓
Exhalation filter	P26616	✓
Complete Antistatic Hoses AIR (hospital Air to compressor)	P26516	--
Complete Antistatic Hoses AIR (compressor to ventilator)	P26516	--
Complete Antistatic Hoses O2 (Hospital to ventilator)	P26517	--
Optional list 1		
Pediatric respiration set	P26617	✓
Trolley	P26324	--
Holder of respiratory tubes	P28129	--
Optional list2		
Air compressor	F01451	--
Humidifier	F01492	--
Humidifier Chamber	P26618	✓
Humidifier temperature probe	P26619	--
Heater wire adaptor	P26623	--
Adult respiration set, heated wire	P26620	✓
NIV mask	P26621	--
Nebulizer	P26622	✓

Warning

To prevent possible cross contamination, single-use accessories should not be reused.

Pay attention to expiry date of the accessories and avoid using outdated accessories.

If you see any damage to the packaging of the accessories, do not use them.

The manufacturer approved exhalation filter and HME have a pressure drop lower than 2.9 cmH2O in flow of 30 l/min and dead space of less than 76 ml.

2-4 Note

During ventilation, an active screen will remain for 60 seconds after the user last interaction and then will revert back to the Main Screen.

To prevent accidental change and for more safety if any change is made in the setting and the change is not saved or accepted, the previous setting will be reverted after a specific period of time.

If user selects another menu or parameter before saving a change, the parameter value will return to the previous value.

2-5 Touch Screen

- The touch screen is sensitive against mechanical scratches.
- Do not use pencil or fingernails to touch the screen.
- Scratches on the touch screen surface may affect its functionality.

3- Ventilator preparation for use

3-1 AC Mains Supply

The ventilator operates on 100-240 VAC power supply and frequency of 50- 60 Hz.

Use a grounded cable as the mains power cable.

3-2 Battery

The ventilator is equipped with an internal battery and if it has a proper charge (a new and fully charged battery) it can run up to 2 hours under normal ventilation conditions (you can get a battery with higher capacity from the company).

When the ventilator runs on the battery, "AC Unplug" and the battery symbol as well as its charge status appear on the screen. When the mains power cable is plugged, the battery is charged and the battery symbol indicates the mains power connection.

The battery indicators LEDs on the device will turn green if they are fully charged and orange if they are charging. If the device is unplugged, the LEDs will turn off. If the device has only one battery, no battery, or a battery error, the LEDs will flash red.

Before using the ventilator ensure that a healthy battery with minimum charge is installed.

If the ventilator has been stored for a long time, recharge the battery before use and make sure it's healthy.

Do not use the device in case of the battery failure.

3-3 Air and Oxygen Supply

The device required air and oxygen is supplied by compressor or hospital main gas supply.

Note:

1- The maximum input flowrate required by the ventilator for each gas at a pressure of 280 kPa averaged over 10 s, is 59 L/min.

2- the maximum transient input flowrate averaged for 3 s required by the ventilator for each gas at a pressure of 280 kPa, is 180 L/min.

Warning

Use only medically pure oxygen.

Oxygen supply and tubes carrying oxygen should be oil free, because combination of pure oxygen and oil is explosive.

Permissible pressure range of oxygen supply is 35-87 psi (2.4-6 bar), but minimum pressure range of O2 tubing is 147 psi (10 bar).

Before disconnecting the air and oxygen supply hoses, make sure that the air and oxygen sources are off.

For a proper hose connection, tighten the connection nuts with hand without using a wrench.

Since the ventilator is a high-flow device, if it is connected to a hospital air or oxygen source, make sure that the source is suitable to supply the required flow of the device.

If the input oxygen concentration is less than 92%, the device performance may malfunction.

3-4 Patient Breathing Circuit

Warning

Do not use antistatic or electrically conductive tubing.

Tubing containing oil is highly explosive.

Use only manufacturer approved breathing circuit or tubing. To prevent any leakage resulting from inappropriate connection of tubes, make tubing connections securely. The breathing circuit is composed of the following parts:

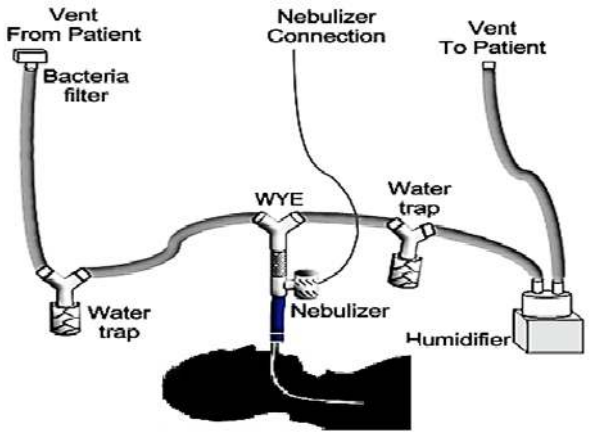


Figure 3-1 Patient breathing circuit

As you can see in above figure one part of the breathing circuit is water trap that removes moisture from the breathing circuit. The water traps need frequent evacuation.

Warning

Breathing circuit filters, respiratory tubes (including water traps), humidifier chamber, HME and in specific condition, exhalation flow sensor and exhalation valve could be contaminated through lung secretions and expiratory gases. For more information about cleaning or disinfection of different parts, please refer to section 7-2 of this manual.

4- Operation

4-1 Use of the Ventilator

Warning

⚠ **The ventilator must be operated only by qualified clinicians.**

Note:

Perform the system test before connecting the ventilator to the patient.

Turn the ventilator on or off using On/Off key placed on the rear panel.

Check that all cable and tubes are connected correctly and the ventilator is connected to an appropriate power source.

4-2 Standby Icon

By pressing Standby icon, you can access the following menu with four options.

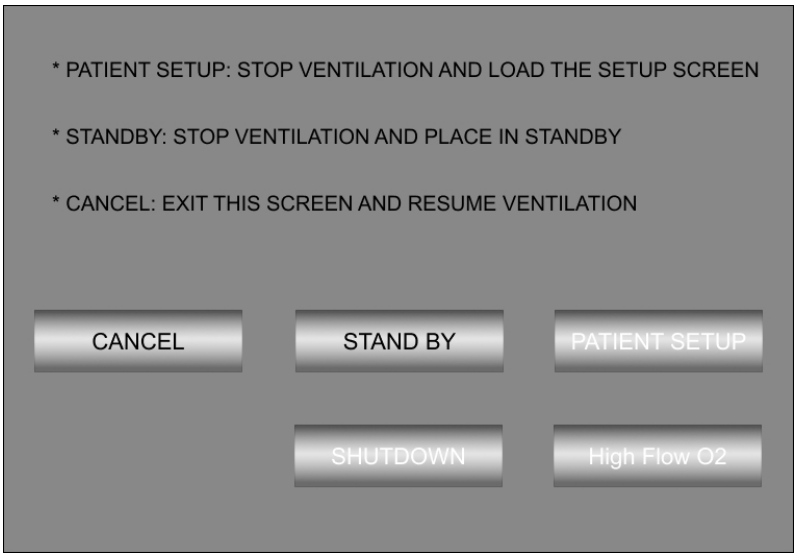


Figure 4-1 Standby menu

Patient Setup : select this option to stop ventilation and load Patient Setup menu. This option is disable until the ventilator is in ventilation mode.

Standby: select this option to stop ventilation, place the device in standby mode and load the main screen. Standby is displayed above the screen.

Cancel: select this option to close the menu and access the previous menu. In this condition ventilation will continue uninterrupted.

Shut down: select this option to shut down the ventilator. This option is disable until the ventilator is in ventilation mode.

High Flow O2: By selecting this option, the window related to the HFO maneuver will be opened. Note that this option is disabled until the device is in Standby mode.

In the HFO maneuver, the user is able to provide a constant flow with the desired percentage of oxygen to the patient. Also, the maximum allowable pressure during this maneuver is determined by the user. If for some reason such as occlussion the pressure increases and reaches the maximum allowable pressure, the device will open the valve. When the pressure drops to a certain value below the maximum allowable pressure defined by the user, the safety valve closes again. The screen image of HFO can be seen in the figure below.

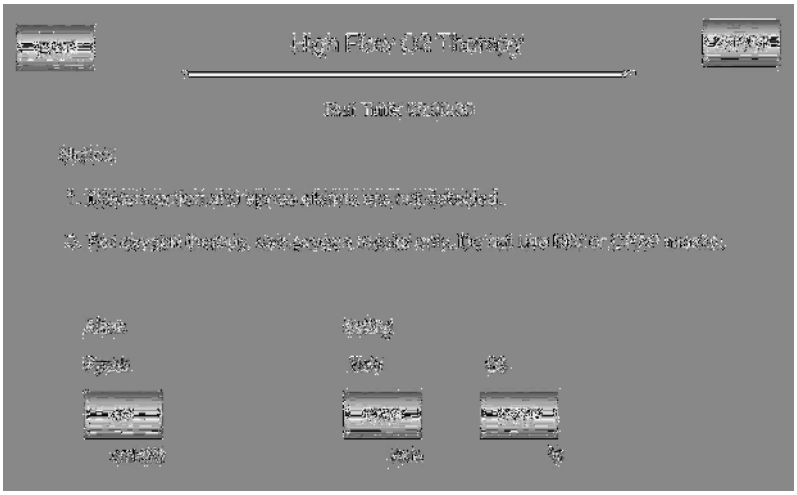


Figure 4-2 HFO window

By pressing the START key, the text of the key changes to STOP, and the Exit key is disabled. The maneuver is activated and continues until the STOP key is pressed. The duration of HFO activation is shown on the screen as RunTime. This time is stopped when the HFO maneuver is finished and is reset with Start. On the HFO screen, the measured values of flow, oxygen and input oxygen (Input O2) parameters are displayed.

Warning

⚠ **The HFO maneuver can only be used for patients who breth spontaneously.**

⚠ **During the HFO maneuver, all device alarms are activated if conditions are met, except for Disconnection, Occlusion, and Apnea alarms.**

⚠ **During the HFO maneuver, an appropriate oxygen therapy mask should be used. Note that you should not use NIV or CPAP masks.**

4-3 100% O2 Icon

Pressing 100% O2 icon on the right-side menu of ventilator (if the oxygen source is available with proper pressure) will deliver a mandatory or assisted breath (like applied pattern in Manual inspiration) depending on ventilation mode and time of icon pressing and 100% oxygen will be delivered for 2 minutes in the current ventilation mode. After 2 minutes the delivered oxygen will return to its original setting.

"100% O2" is shown on the screen throughout the oxygen delivery.

If you press O2 100% icon while the oxygen source is not available or disconnected, “100% O2 Not Available” alarm will be activated and after supplying the oxygen, the maneuver will resume.

If you press the Standby icon, the maneuver will stop. The maneuver will resume if you exit the system from the standby mode. This maneuver cannot be enabled in the standby mode.

If mode, setting parameters and other maneuvers are changed, O2 100% maneuver will be disabled.

4-4 Manual Icon

Press this icon on the right-side menu of the ventilator to deliver one breath to patient in the current setting. In this condition “Manual” is displayed on the screen. In A/C and APRV modes the manual inspiration is mandatory and in PSV and VSV modes the manual inspiration is an assisted breath. In SIMV modes the manual inspiration could be mandatory or assisted breath depending on maneuver. The manual maneuver is active in all ventilation modes.

It should be noted that if the device is set so that the exhalation time is less than 750 milliseconds, Manual breath will not apply.

When the Manual icon is pressed one breath is delivered during the specified interval, for the next breaths the icon should be pressed again (i.e., every icon pressing will deliver one manual breath).

You cannot enable or disable this maneuver in the Standby mode.

4-5 Alarm Silence Icon

Press this icon to silence audible alarms for 120 sec. Pressing the icon again before end of this period will enable sound of all currently active alarms.

If the alarm condition is not removed after 120 sec, the alarm will sound and visual alarm will also be activated. If a new alarm occurs during this period, the silence mode will be deactivated and audible and visual alarms will be enabled.

4-6 Home Icon

Press this icon to return the previous menu.

4-7 Freez Icon

Freezing the screen:
It is possible to freeze the curves and loops simultaneously by touching the “Freeze” icon. In this situation, it is changed to unfreeze. User can resume by touching “freeze” icon.

5- The Ventilator Setting

Warning

⚠ **Only trained users should change the ventilator setting.**

5-1 Turning on the Ventilator

When the ventilator is turned on, self test page will appear. The device automatically checks different mechanical and electronic parts during this test. If there is a failure detect in any part, “NOT OK” will be shown in red. If even one part except parts which are related to the memory of the device detected as “Fail”, “FATAL ERROR” wil be shown. In this case after checking all parts, the menu whould not closed until the problem solve and user turn on and off the device.

Figure 5-1 FATAL ERROR

The skip icon will be activated if it fails in the sections related to checking the memory. The user can enter the patient page by clicking Skip or shutting down the device with the Shut down icon. It is recommended not to use the device in this situation.

Figure 5-2 memory failure

If test of all above items is carried out successfully, the patient option page of the device will appear.

Figure 5-3 Self test Page

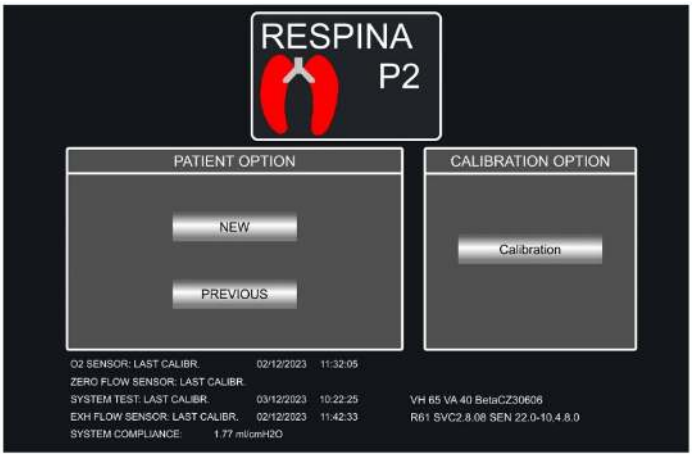


Figure 5-4 Ventilator Welcome Page

5-2 Patient Option

Two options are available in this window: New and Previous

Select “New Patient” and enter specification of new patient, default settings will be set based on input data to the ventilator. Select “Previous Patient”, the ventilation parameters will be set based on previously saved settings. If “New Patient” is selected, the following window will appear to enter data of new patient.

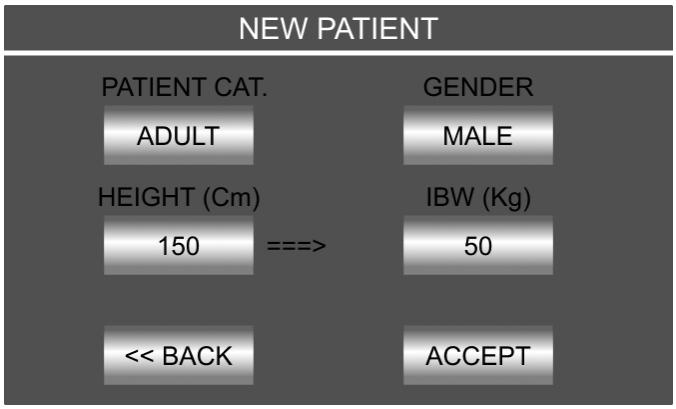


Figure 5-5 New Patient Data Input

The following parameters could be set in above window:

- Patient Category
- Gender
- Height
- IBW

Note:

The Respina P2 ventilator is able to calculate Ideal Body Weight (IBW) automatically based on entered patient height. If calculated IBW value by the device is not approved by the clinician, you can enter IBW value manually.

5-3 Calibration

Select this item to access calibration menu. For more information about this menu, please refer to section 7 of this manual.

5-4 Settings

After entering patient data, the device will load default settings automatically. Then user should select ventilation mode and other parameters settings and confirm the selected mode. After confirming the settings, the patient ventilation will start.

Select a mode from Modes menu and press Accept button. After selecting mode, set relevant parameters to the selected mode and press ACTIVATE. Available ventilation modes are:

PCV, VCV, PRVC-CMV

P-SIMV, V-SIMV, PRVC-SIMV

PSV/CPAP, VSV, APRV

The below parameters could be set by the ventilator:

Parameter	Description
O_2	Percent of delivered oxygen to patient
Rate	Number of mandatory breaths in the minute.
Vt	Tidal volume delivered to patient during each inspiration
T_i	Inspiration time
PEEP	Positive end expiratory pressure
$P_{control}$	Pressure more than PEEP that applies to mandatory breaths in pressure modes
$P_{support}$	Pressure more than PEEP that applies to spontaneous breaths.
P_{high}	High pressure level in APRV mode
P_{low}	Low pressure level in APRV mode
T_{high}	Time at high pressure level in APRV mode
T_{low}	Time at low pressure level in APRV mode
% Esens	This parameter sets percentage of peak inspiratory flow in spontaneous breath and pressure-based mode necessary to terminate inhalationand initiate exhalation. When patient inspiratory flow falls below adjusted Esens by user, exhalation begins. The maximum inspiration time in assisted mode is 2 secs for adults and 1.5 sec for pediatrics.
Rise Time	This parameter determines the time required to rise to $P_{control}$ in pressure breaths. Available options for this parameter are Slow, Med and Fast.
Breath Trigger	Selecting the pattern of patient inspiratory effort in terms of flow or pressure.
Pressure Triggering	The patient breathing effort will result in pressure drop and this reduction is detected by pressure sensor. The user specifies a threshold based on the patient condition to evaluate pressure variations relative to the threshold. If pressure violates the specified threshold, the ventilator will detect patient respiratory effort.
Flow Triggering	In this method of breath triggering the user specifies a threshold based on the patient condition to evaluate flow variations relative to the threshold. If flow violates the specified threshold, the ventilator will detect patient respiratory effort.
Pause	It is a percentage of inhalation time and sets the time that inspiration is paused after set tidal volume has been delivered. During this time no air is inhaled or exhaled by the patient. This parameter is available inVCV and V-SIMV modes.
Flow Pat.	the pattern of applied flow to the patient. Square or Decel. are selectable for this parameter.
Leak Comp.	If “Leak Compensation” is enabled, the ventilator will compensate leaks automatically.

NIV	Ability to use the device non-invasively (NIV) and using a mask. This feature is defined in P-SIMV and PSV/CPAP modes.
Dual control	In volume modes, if patient tries to breathe during inhalation, the device responds to this request by switching on the pressure control. This feature can be selected in square flow pattern.
Auto Tlow	The exhalation phase continues until the expiratory flow reaches a certain percentage of the expiratory flow peak, which is equal to the Auto Tlow adjustment value. This feature is selectable in APRV mode.

5-5 Main Screen

The ventilator main screen consists of different parts (See the figure below).

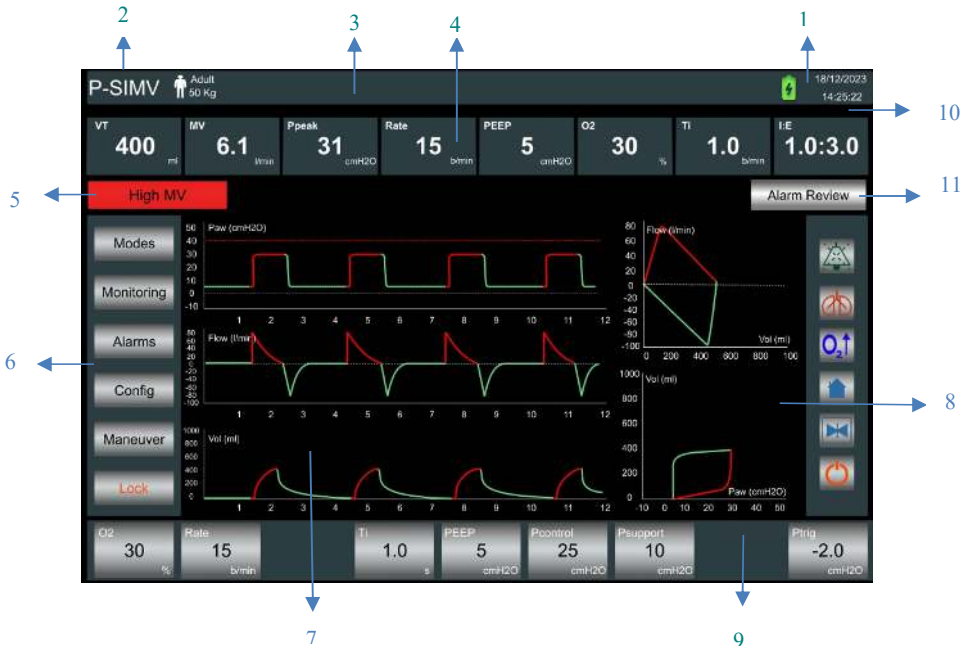


Figure 5-6 Main screen

1. Date, time and battery icon
2. Active ventilation mode
3. Functional alarms (e.g. messages related to activation of maneuvers and apnea mode inactivity)
4. Measured parameters (user can choose which measured parameters are displayed in what configuration)
5. Active alarms
6. The following items are displayed in the left side of the screen. Selecting each item will load a menu in which you can perform relevant settings.

   Modes, Monitoring, Alarms, Config, Maneuver, Activate

7. Respiratory curves (Volume-Time, Flow-Time, Pressure-Time)
8. Respiratory loops (Flow-Volume, Volume-Pressure)
9. Basic parameter settings of current mode
10. Alarms of power supply
11. Alarm review key for quick access to the Event log menu and disabled alarms level 1 and 2

5-6 Monitoring

The user is able to view all the monitoring parameters at once on this page. There is also a Trend option on this page.

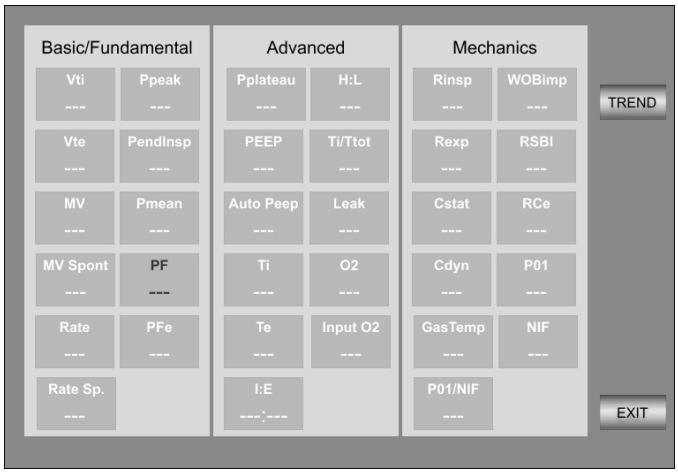


Figure 5-7 Monitoring menue

Trend

You can view stored parameters during 72 hours. The Respina P2 ventilator is able to display trend of three parameters at once. Clicking on label positioned beside each curve will open a menu in which you can select a parameter to be displayed in the trend.

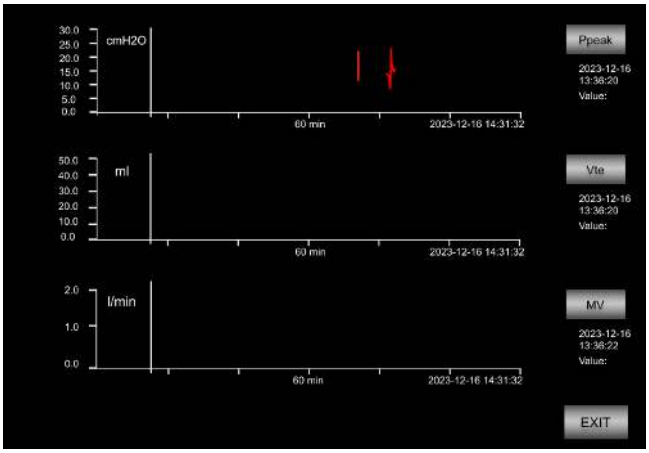


Figure 5-8 Trend

In each curve, the vertical axis represents the numerical value of the parameter and the horizontal axis of the time. it is possible to change time frame by clicking on the written time in the middle of horizontal axis area. These time frames are as follows 60 min, 6 h, 12 h, 24 h, 36 h and 72 h. It should be noted that the changing of the time frame applied on a curve is also applied simultaneously on two other curves. it is also possible to change the scale of parameter by clicking on the vertical axis.

The parameters that could be trended are listed in below table:

Basic/ Fundamental	Advanced	Mechanics
Vti	Pplateau	R insp
Vte	PEEP	R exp
MV	Auto PEEP	C stat
MV Spont	Ti	C dyn
Rate	Te	WOBimp
Rate Spont	Ti/T tot	RSBI
P peak	Leak	RCe
PendInsp	O_2	Gas Temp
P mean	Input O_2	
Flow HFO		
PFe		

5-7 Alarms

Selecting Alarms will load Alarms Menu in which you can set alarm limits. There is also an Event log option on this page, which is described following. Set alarm limits in two ways:

1. Click on alarm limits (high and low) and set your desired value.
2. Select AutoSet key to set alarm limits of all parameters except Ppeak, Leak, Apnea time, Vt lim automatically based on setting values which are listed below:

Alarm limit	**Equation**
PEEP high	$PEEP_{monitoring} + 5$
PEEP low	$PEEP_{monitoring} - 5$
Rate high	$1.5 * Rate_{monitoring}$
Rate low	$0.5 * Rate_{monitoring}$
MV high	$2 * MV_{monitoring}$
MV low	$0.5 * MV_{monitoring}$
Vte high	$2 * Vte_{monitoring}$
Vte low	$0.5 * Vte_{monitoring}$

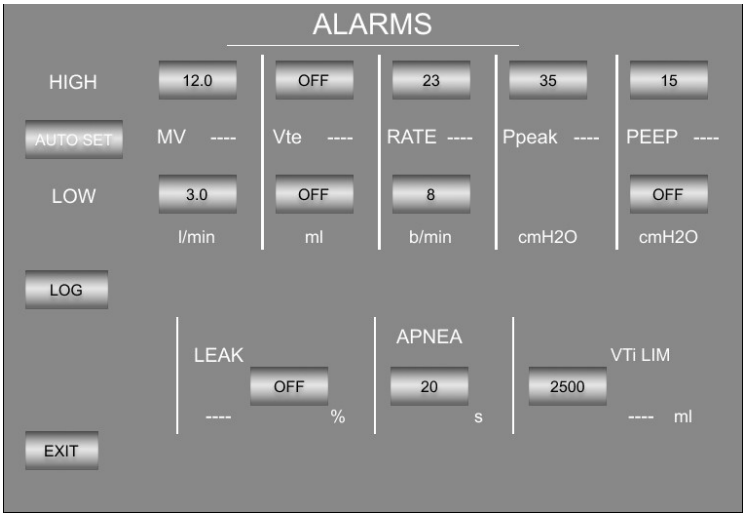


Figure 5-9 Alarms Menu

Warning

Incorrect setting of alarm limits (manually) could affect functionality of the alarm system.

Alarm setting of different parameters is provided in below table:

Parameter	Alarm limits	Unit
MV High	[0.2- 50]	l/min
MV Low	[0.1- 49.5] or Off	l/min
Vte High	[10- 3000]or Off	ml
Vte Low	[5 - 2995] or Off	ml
Rate High	[3-180]	b/min
Rate Low	[2-179]	b/min
P_{peak} High	[10-100]	cmH_2O
PEEP High	[3-60]	cmH_2O
PEEP Low	[2-59]or Off	cmH_2O
Leak	[20-100]or Off	%
Apnea Time	[15-60]	Sec
Vti Limit	[20-3000]or Off	ml

The default values of alarm limits are listed below:

Alarm limit	Default	Alarm limit	Default
MV Low	((Rate*VT)/1000 - (Rate*VT)/2000)	MV High	2*(Rate*VT)/1000
Vte Low	Off	Vte High	Off
Rate Low	Rate-Rate/2	Rate High	Rate+Rate/2
PEEP Low	Off	PEEP High	PEEP +5
Leak	Off	Ppeak High	Pcontrol + 15
Vti Limit	2500	Apnea time	20

Note:

1 . Setting the minimum of Ppeak alarm parameter depends on setting.
2 . High Ppeak alarm limit is set manualy only.
3 . In case of power failure and unavailability of the battery, alarm settings will be saved.
4 . The lower limit of MV alarm can be set to Off only in NIV ventilation. If the user sets the alarm limit to Off, this value changes to 0.1 when exiting non-invasive breathing.
5 . The default of upper and lower lomits of Vte alarm and the lower limit of PEEP alarm are Off.
6 . Alarm limits which are set to Off by the user, will not change by pressing Autoset key.

Event Log

By selecting Event Log from Monitoring menu, you can view the latest alarm events and settings in order of occurrence (up to 2000 events). when the event log list is filling, to record new event, the oldest one is omitted from the list, and new event is record as the 2000th event. If New from Patient Setup menu is selected, the event log will be cleared and after IBW setting subsequent events will be stored. If Previous is selected from Setup menu, new events will be added to the current log.

By clicking on each event, you can view current settings of time of alarm occurrence below the Event Log.

The adjusted value is shown in Set column and the measurement value triggered alarm is shown in Monitor column.

The date and time of each event are specified in the Event Log table.

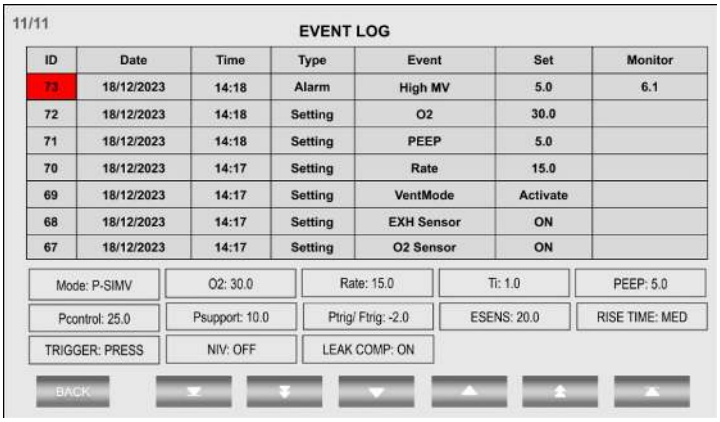


Figure 5-10 Event log

All events in the Event Log include the following data:

- Settings
- Alarm event as well as setting and monitoring values of relevant parameter
- Adjusted high and low alarm limits (using AutoSet key or manually)
- Config settings of the device including:

  Nebulizer, Humidification Type, Compliance Compensation

- Placing the ventilator in standby mode and reactivating ventilation mode
- Turning off (software or hardware) and turning on the device
- Possible faults with the memory of the device reported in self-test

Note:

Power supply interruption would have no effect on Event Log content.

5-8 Config.

The following configurations could be performed in this menu:

- General Setup
- Graphic Settings
- Clinical Setup
- Technical

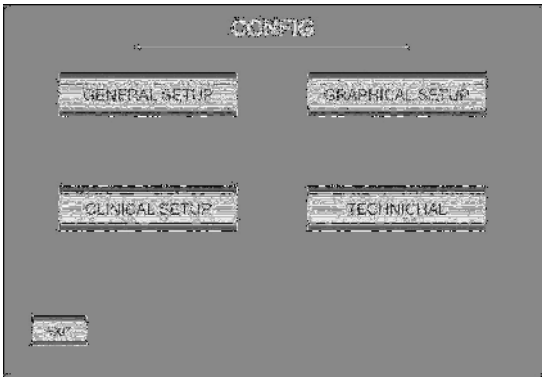


Figure 5-11 Config menu

5-9 General Setup

You can set the below items in the General Setup menu (See the figure 5-8).

- Alarm volume
- Bed number
- Touch sound
- Back light
- Battery status

Warning

The alarm volume should be adjusted according to the ambient noise so that the operator dose not have difficulties recognizing the alarm condition.

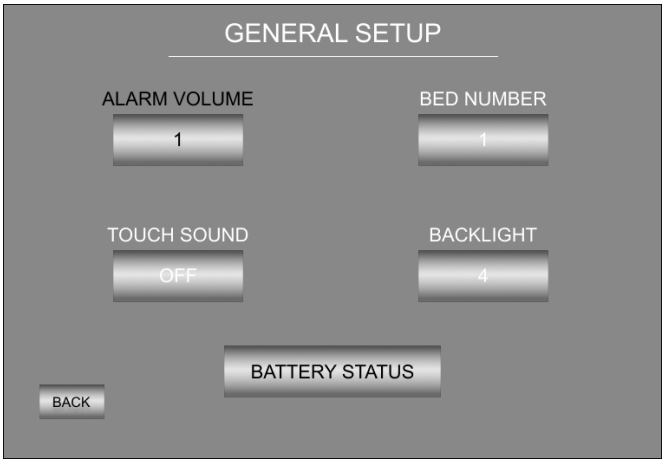


Figure 5-12 General Setup menu

It should be noted that **Back light**, **Touch Sound** and **Bed Number** items are inactive.

5-10 Graphic Settings

This page is currently inactive.

5-11 Clinical Setup

The following items could be set in this menu:

- Smart nebulizer
- Humidification type
- Compliance compensation
- O2 Sensor
- EXH Flow Sensor

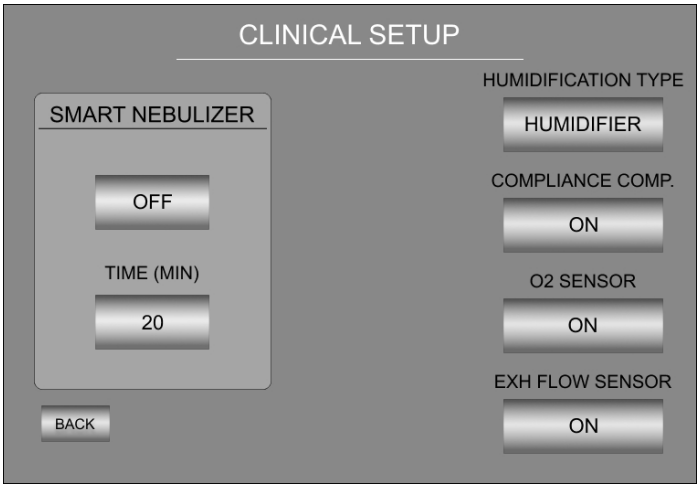


Figure 5-13 Clinical Setup

- **Smart nebulizer**

Activation, deactivation and duration of nebulizer operation can be specified in this section.

By activating the nebulizer from this menu, the nebulizer activates for the time specified by the user and the related message is displayed on the screen. After this period, it will be deactivated automatically.

Available options for the duration of nebulizer activity are: 1 min to 480 min. Default setting is 20 min. Any change in the nebulization time setting will be saved until the next change.

Nebulizer is not activated in inspiratory flow (air and oxygen) less than 11L/min and “Neb. Not Usable” alarm message will be displayed.

The nebulizer will also be disabled in the below conditions and “Neb. Not Usable” alarm message will be displayed (to avoid deviations in flow delivery by the nebulizer):

- If high pressure oxygen source is not available

- If the oxygen pressure is out of the allowed range.

When the nebulizer is enabled, flow and volume waveforms and parameters will be compensated.

If the nebulizer is activated but the conditions for activating the nebulizer are not provided, the system immidiately stops the drug nebulization and after the nebulizer limit is removed, the device continues the remaining time of drug nebulization.

Note:

Since 100% O2 is administered for drug nebulization, the oxygen concentration of delivered gas to patient may exceed the user setting during the nebulization.

If you press the Standby icon, the maneuver will stop. The maneuver will resume if you exit the system from the standby mode (The nebulization message is displayed during this time). If user selects “New Patient” the maneuver will be ended.

This maneuver cannot be enabled in the standby mode.

- **Humidification type**

Three options are available for Humidification including:

- ✓ Humidifier
- ✓ HME
- ✓ None

Warning

HME is disposable and should be exchanged for each patient.

- **Compliance Compensation**

Set **Compliance Compensation** to On/Off in this menu.

- **O2 Sensor**

Select this item to set On/Off the oxygen sensor.

Note:

If you set the O2 sensor to off, “High Oxygen” and “Low Oxygen” alarms will be disabled and the measured value of O2 parameter will not be displayed.

- **EXH Flow Sensor**

Select this item to set On/Off the exhalation flow sensor.

Note:

If you set the EXH flow sensor to off, “High Vte”, “Low Vte”, “Low MV”, “High MV” and “High Leak” alarms will be disabled and measured value of following parameters will not be displayed: Vte, MV, MV spont, PFe, Leak, Rexp, RCe

5-12 Technical settings

Select **Technical** from **Config** menu and enter password in the below page. A menu will appear to perform special settings of the device by the manufacturer authorized experts. One of the settings that the user can make in this menu is to set the time and date of the device. Also, the working time and the active time of the device can be seen on this page.

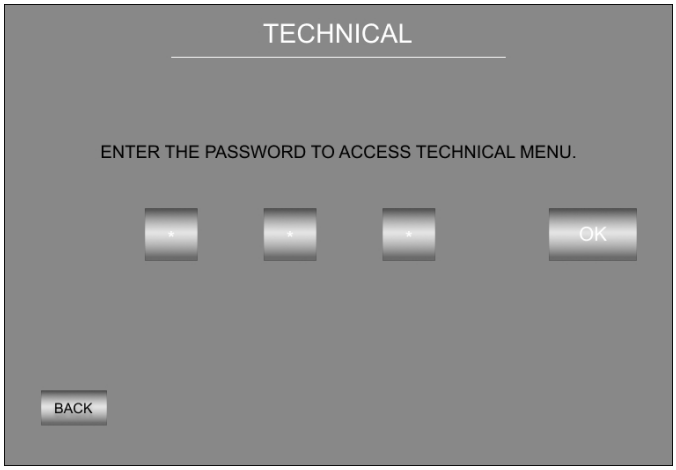


Figure 5-14 Technical menu

It is possible to enter the password by touch screen and rotary knob.

5-13 Maneuver

Select this item to set maneuver of the device. Maneuver options of the Respina P2 ventilator are: **Insp. Hold, Exp. Hold, P0.1, NIF, Suction Support**

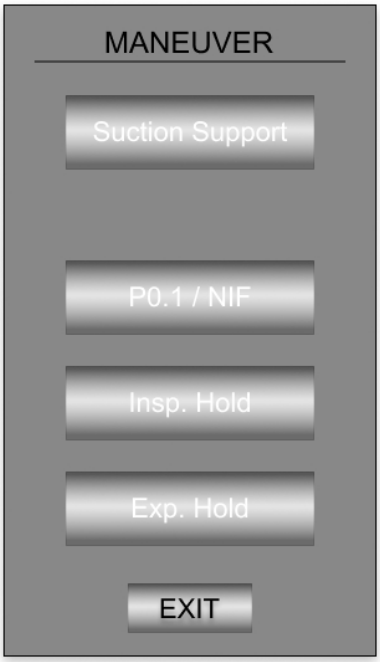


Figure 5-15 Maneuver

- **Expiratory Hold**

Press this button to keep expiration phase in respiratory cycle. **Expiratory Hold** is displayed on the screen as long as the button is pushed. It is possible to perform this maneuver in all modes and will not cause Apnea.

The duration of of the maneuver can be adjusted bey the user (4-20 sec). The Exp-Hold operation ends when the maneuver time ends or when the Stop button is pressed. If the device is triggered before intiating the maneuver, the expiratory hold maneuver will not perform at that respiratory cycle. Additionaly patient is not allowed to trigger the device during the maneuver is performed.

When this button is pressed, some mechanical parameters are calculated more accurately.

It is not possible to change the ventilation mode, setting parameters and using the shortcut keys during expiratory hold maneuver.

- **Inspiratory Hold**

This maneuver can be enabled in all ventilation modes. By pressing this button, neither air is delivered to the patient's lungs nor air is expelled from the lungs through the patient's airway. In other words, the air is trapped in the lung and the ventilation is held in the inspiration phase.

The duration of the maneuver can be adjusted by the user (4-20 seconds). The Insp-Hold operation ends when the maneuver time ends or when the Stop button is pressed.

When this button is pressed, some mechanical parameters are calculated more accurately.

During Inspiratory Hold maneuver if the pressure or volume of delivered air exceeds the alarm limits, Inspiratory Hold procedure will be stopped and relevant alarm (pressure or volume) will be activated. Inspiratory Hold maneuver will not cause Apnea.

Before the end of inspiration and initiation of Inspiratory Hold if the pressure or volume of delivered air exceeds the alarm limits, the inspiration phase will be completed and Inspiratory Hold will not be performed. "Inspiratory Hold" is displayed on the screen during this maneuver.

It is not possible to change the ventilation mode, setting parameters and using the shortcut keys during inspiratory hold maneuver.

- **P0.1**

This parameter is used to determine patient ability to be weaned from mechanical ventilation. It measures the negative airway pressure generated during 100 msec of inspiration occlusion.

The maximum duration of this maneuver is 10 seconds.

Wait until the pressure of 0.5 cm water falls below base pressure (pressure after occlusion). This pressure is considered as P1 and the pressure of 100ms after P1 is considered as P2. The maneuver terminates in P2 and the inspiration resumes. If P1 is not detected after 10 s inspiration begins immediately. The pressure difference between these two points is displayed as the measured parameter P0.1.

If user press Stop button during the maneuver, the maneuver will terminate and normal ventilation will resume. In this condition P0.1 value is not calculated. The maneuver will not be performed if the device is set to an exhalation time of less than 350 ms.

The system leakage may lead to inaccurate measurement.

In A/C, SIMV, PRVC and APRV modes a mandatory breath will be delivered to the patient after this maneuver. In PSV/CPAP, VSV modes the maneuver will be followed by an assist-control breath. Since Apnea Backup is only available in PSV/CPAP and VSV modes and respiratory effort by the patient may terminate P0.1 maneuver, this maneuver will not enable Apnea alarm. If user intends not to switch to the apnea backup during the maneuver, he/she should disable the apnea backup.

If user presses the STOP key during the maneuver, the maneuver terminates and ventilation will resume immediately. In this case, the value of P0.1 is not calculated.

It is not possible to change the ventilation mode, setting parameters and using the shortcut keys during P0.1 maneuver.

- **Negative Inspiratory Force (NIF)**

This parameter measures maximum negative pressure generated during inspiration occlusion. It also indicates maximum strength of the inspiratory muscles especially diaphragm. To measure this parameter, a maneuver with the same name (NIF) is defined.

The NIF maneuver begins after the minimum time has elapsed of exhalation, by clicking the Start key.

During the maneuver (duration is selected by user and ranges from 4 to 20 sec), the pressure drops resulted from the patient respiratory effort are monitored and the lowest pressure value is reported.

The patient will not be able to trigger a breath during the maneuver. The NIF maneuver will not cause Apnea.

A mandatory breath (in A/C, SIMV, PRVC and APRV modes) or an assist-control breath (in PSV/CPAP, VSV modes) will be delivered to the patient after the maneuver. If user intends not to switch to the apnea backup during the maneuver, he/she should disable the apnea backup. If user press Stop button during the maneuver, the maneuver will terminate and immediately a breath will be delivered to the patient. In this condition NIF value is not calculated. If NIF parameter it has a value of NIF before performing this maneuver, it retains the same value as before. The maneuver will not be performed if the device is set to an exhalation time of less than 350 ms.

It is not possible to change the ventilation mode, setting parameters and using the shortcut keys during NIF maneuver.

- **Suction Support**

The suction maneuver includes the below phases:

- Premier 100% O2
- Suction
- Final 100% O2

After selecting and starting each phase, the next phase will be enabled. Each phase is carried out for maximum 2 minutes and then relevant button will be disabled and a progress bar is filled up.

You can cancel the maneuver by pressing **Stop** button and you can exit from the Suction Support page by pressing **Back** button. In the below conditions the suction support maneuver will not be enabled and the message "SUCTION NOT Usable" will appear:

- When NIV is set On
- During 100% O2 maneuver
- When high pressure oxygen source is not available.

Premier 100% O2

At this stage, after pressing the Premier O2 100% key, the device delivers breaths with 100% oxygen for a maximum of 2 minutes. At this time, the user has 2 minutes to press the suction key and disconnect the device from the patient for suction. If after 2 minutes of 100% oxygen delivery time, the user does not press the suction button, the maneuver will end and the system will automatically enter its previous breathing phase. In this case, the user must exit the menu by pressing the Back key to activate the device menues.

The message "**Disconnect Within 120 Seconds to Suction the Patient**" appears above the page during this phase.

Suction

After selecting suction, you must perform suctioning, connect the patient to the device and press **Final 100% O2** within maximum 2 minutes. If you press **Final 100% O2** button during this time, the device will enter final ventilation phase; otherwise, the device will start ventilation in the previous mode.

Note:

During the suction phase, flow value will be zero and the below alarms will be disabled for 2 minutes: Low PEEP, Low MV, Low VTe, Low Rate, APNEA, Disconnection

The message "Perform Suction and Reconnect within 120s" appears above the page during the suction phase.

Final 100% O2

In this phase 100% O2 is delivered to the patient for maximum 2 minutes. Then the device automatically returns to the previous settings and exits from the maneuver page.
If you press Stop button during this phase (2 minutes), the device will exit from this maneuver and start working in the previous mode.

Note:

1- If the suction is carried out during the nebulization, the nebulizer will stop working.
2- Setting parameters or ventilation mode could not be changed during this maneuver.
3- Other menus and shortcut keys are inactive during the Suction Support maneuver.

5-14 Shuting down the ventilator

To turn off the ventilator, standby the device and select the shut down key. The message "Please wait…" will be displayed about 6 seconds. Then the ventilator will be shut down.

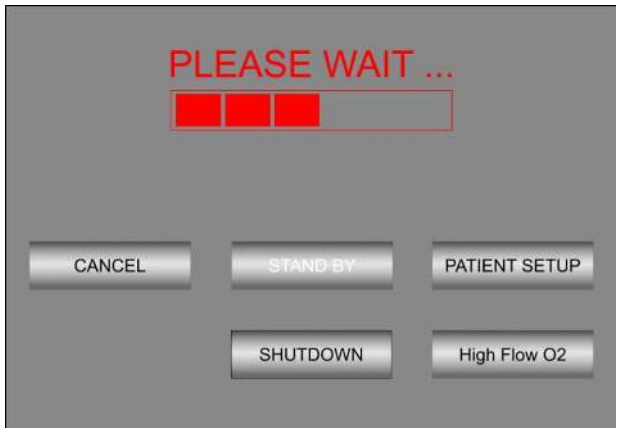


Figure 5-16 shuting down the ventilator

If it is not possible to shut down the device for any reason, you can turn off (hardware) the ventilator by holding the On/Off button on the back of the device for about 10 seconds.

Warning

Pay attention that turning off (hardware) the ventilator is not recommended in normal situation because it may cause problems with to save the latest data and settings.

6- Alarms

Warning

Always verify the audible and visual alarms when the ventilator is powered on.

When the system is powered on, the indicators light up. If all indicators light up, it will show proper functioning of the indicators. At the same time as the indicators light up, a beeping sound is heard, which indicates the accuracy of the sound of the device.

Note:

- Alarm volume can be set by selecting General Setup from Config menu. It ranges from 1 to 7. Alarm sound pressure ranges from 48 db(A) to 62 db(A) according to the selected volume (1 to 7).
- If the device turns off in a non-software way during ventilation, a continuous beep is activated for a few minutes.
- Note that during Standby mode active alarm sounds are turned off and only visual alarms (alarm message and LED) are displayed.

6-1 Alarm Priority

All audible and visual alarms comply with IEC 60601-1-8 and ISO 80601-2-12 requirements.

Audible and visual alarms are classified based on priority as:

High, Medium, Low (Information)

Alarm priority	Visual alarm	Audible alarm	Remarks
High	Message on the red background, indicator flashes with frequency of 2 Hz.	5 repeated signals sound "DO-DO-DO—DO-DO" every 10 seconds.	User can not cancel alarm or delete the alarm message from the screen until alarm condition is removed. When the alarm cause is removed, the relevant message in the Alarm bar is deleted and the user can check the alarm message in the Event Log page.
Medium	Message on the yellow background, indicator flashes with frequency of 0.5 Hz.	3 repeated signals sound "DO-DO-DO" every 20 seconds.	User can not cancel alarm or delete the alarm message from the screen until alarm condition is removed. When the alarm cause is removed, the relevant message in the Alarm bar is deleted and the user can check the alarm message in the Event Log page.
Low/ Information	Message on the cyan background, indicator flashes with frequency of 0.25 Hz.	1 signal sounds "DO" every 30 seconds.	User can not cancel alarm or delete the alarm message from the screen until alarm condition is removed. When the alarm cause is removed, the relevant message in the Alarm bar is deleted and the user can check the alarm message in the Event Log page.

Alarms are always displayed in order of priority from the left to the right in the alarm bar.

Up to 3 alarms can be displayed in the alarm bar. Priority of the alarms is defined as below:

- Priority order among active alarms is that level 1 alarm has the highest priority and level 2 and 3 alarms have lower priority respectively. In all three levels, new alarms have higher priority.
- Among level 1 alarms, **Apnea**, **High Pressure** and **Low MV** have the highest priority (irrespective of their occurrence time)

6-2 Alarm sound

Each alarm priority has unique tone and pattern. Audible alarms of the ventilator in terms of priority are as below:

- High alarm level sounds "DO-DO-DO--DO-DO" every 10 seconds;
- Medium level alarm sounds "DO- DO-DO" every 20 seconds;
- Low level alarm sounds "DO-" every 30 seconds.

6-3 Alarm Silence icon

To silence alarm sound for 120 seconds, press Alarm Silence icon positioned on the membrane. If a new alarm occurs during this time, the silence condition will be cancelled.

If the Alarm Silence icon is pressed again during 120 secs, the device will exit from the silence mode and the alarm sound will be enabled.

Figure 6-1 Alarm Silence icon

During the Silence mode, active alarm messages blink in the alarm bar.

6-4 Alarms

High Priority Alarm	Alarm Definition	Ventilator reaction to alarm
High Inh. Pressure	The maximum pressure has been exceeded from its limit during inhalation. The airway has been occluded partially.	The inhalation terminates and expiration begins.
Apnea	No breath has been delivered in PSV/CPAP, VSV or APRV mode during the specified time	If current mode is one of VSV, PSV/CPAP or APRV modes and apnea backup is active, apnea backup ventilation starts and apnea alarm is enabled.

High Priority Alarm	Alarm Definition	Ventilator reaction to alarm
		If apnea bachup is not active, only apnea alarm will be enabled.
Occlusion	The breathing circuit from the ventilator to patient (or vice versa) or expiration valve has been occluded. This alarm is activated during expiratory.	In the exhalation: 1-Occlusion alarm is activated. 2-Inhalation valve closes and exhalation valve opens. 3-Trigger is inactivated. 4-Safety valve opens.
Disconnection	The breathing circuit is disconnected from the patient.	Ventilation continues.
Low PEEP	PEEP pressure has violated low PEEP alarm setting in two consecutive respiratory cycles.	Ventilation continues.
High MV	Exhaled minute volume has exceeded high MValarm limit in three respiratory cycles.	Ventilation continues.
Low MV	Exhaled minute volume has been below the limit set in the three respiratory cycles.	Ventilation continues.
Plim Reached	In volume-based modes and during inhalation if the airway pressure exceeds “high Ppeak alarm -5” in five consecutive respiratory cycles.	The exhalation valve opens during inhalation.
High Oxygen	The oxygen concentration is too high compared with high alarm setting (more than 6%) for about 30 seconds. Since the maximum amount of oxygen percentage measurement is 100, so in cases where the user's adjustment value is 94 to 100, with the oxygen percentage exceeding that value, the High Oxygen alarm device will not work.	Ventilation continues.
Low Oxygen	The oxygen concentration is too low compared with low alarm setting (more than 6%) for about 30 seconds. Or the oxygen concentration is less than 18%.	Ventilation continues.
High O2 Pressure	The oxygen inlet pressure is more than the specified level.	Ventilation continues.
Low O2 Pressure	The oxygen inlet pressure is lower than the specified level. This alarm will not be enabled if the oxygen concentration is set to 21%.	If the Air source is available, ventilation continues with Air only. The safety valve opens if the pressure of both Air and Oxygen sources drops or disconnects.
High Air Pressure	The air inlet pressure is more than the specified level.	Ventilation continues.

High Priority Alarm	Alarm Definition	Ventilator reaction to alarm
Low Air Pressure	The air inlet pressure is lower than the specified level. This alarm will not be enabled if the oxygen concentration is set to 100%.	If the Oxygen source is available, ventilation continues with Oxygen only. The safety valve opens if the pressure of both Air and Oxygen sources drops or disconnects.
High Gas Temperature	If the measured gas temperature parameter (gas temp) exceeds the allowed limit (45 ° C).	Ventilation continues.
Error code 17	--	Ventilation continues.
Error code 2	--	Ventilation continues.
Fatal Error 5	--	Ventilation continues with the following settings: Mode: PCV, Rate: 15, Ti: 1, PEEP: 2, Pcontrol: 20, Trigger: Pressure, Ptrig: -3, O2: 100
Fatal Error 6	--	Ventilation continues with the following setting: Mode: PCV, Rate: 15, Ti: 1, PEEP: 2, Pcontrol: 15, Trigger: Pressure, Ptrig: -3, O2: 100

Medium Priority Alarm	Alarm Definition	Ventilator reaction to alarm
High Rate	Respiratory rate (including spontaneous and mandatory breaths) has exceeded high alarm setting in three respiratory cycles.	Ventilation continues.
Low Rate	Respiratory rate (including spontaneous and mandatory breaths) has violated low alarm setting in three respiratory cycles.	Ventilation continues.
Vti Limit Reached	Inspired tidal volume has exceeded high alarm setting in three consecutive respiratory cycles.	The inhalation phase will switch to the exhalation phase (whether alarm is activated or not) once Vti has exceeded alarm limit.
High Vte	Exhaled tidal volume has exceeded high Vt_e alarm setting in three consecutive respiratory cycles.	Ventilation continues.
Low Vte	Exhaled tidal volume has been below the limit set in three consecutive respiratory cycles.	Ventilation continues.
High PEEP	PEEP pressure has exceeded high PEEP alarm setting in two consecutive respiratory cycles.	Ventilation continues.
Volume Not Delivered	In PRVC-CMV, PRVC-SIMV and VSV modes (that pressure set by device), if in 3 consecutive respiratory cycle reaching to the maximum allowable pressure prevents deliver the set volume which is set by user, this alarm is activated.	Ventilation continues.

Medium Priority Alarm	Alarm Definition	Ventilator reaction to alarm
	The maximum pressure limit is equal to the upper limit of high-pressure alarms minus 5 cmH2O Assisted breaths in the PRVC-SIMV mode do not affect this alarm.	
High Leak	Leak value has exceeded alarm limit in three consecutive respiratory cycles.	Ventilation continues.
High Gas Temperature	If the measured gas temperature parameter (gas temp) exceeds the allowed limit (44 ° C).	Ventilation continues.
Error code 4	--	Ventilation continues.

Low Priority Alarm (information)	Alarm Definition	Ventilator reaction to alarm
Exh Sensor Error	The expiratory flow sensor function is impaired. Possible causes: exhalation flow sensor failure or disconnection.	Ventilation continues. If flow trigger mode is active, the device will switch to a pressure trigger mode. In this condition you cannot select flow trigger mode. Some parameters such as Vte that are measured by this sensor will be displayed blank.
Exh Not Fitted	Exhalation flow sensor is not placed correctly.	Ventilation continues. If flow trigger mode is active, the device will switch to a pressure trigger mode. In this condition you cannot select flow trigger mode. Some parameters such as Vte that are measured by this sensor will be displayed blank.
O2 Sensor Error	O2 sensor failure	Ventilation continues. O2 parameter is displayed blank.
Inverse Ratio	Exhalation time is more than inhalation time.	Ventilation continues.
Neb. Not Usable	The nebulizer does not function.	The nebulizer is disabled. When the nebulization condition is provided (flow is higher than 11L/min and pressure of the oxygen source is 1,2 bar), the nebulizer will be activated.
100% O2 Not Usable	100% O2 key does not function.	100% O2 maneuver is disabled. When the oxygen source is available, 100% O2 is delivered.
High Gas Temperature	If the measured gas temperature parameter (gas temp) exceeds the allowed limit (42 ° C).	Ventilation continues.

Low Priority Alarm (information)	Alarm Definition	Ventilator reaction to alarm
Suction Not Available	The suction maneuver could not be performed.	The maneuver is disabled.
Error code 1	--	Ventilation continues.
Error code 3	--	Ventilation continues.
Error code 7	--	Ventilation continues.
Error code 8	--	Ventilation continues.
Low Input Oxygen	The inlet oxygen concentration is less than 75%. If the input oxygen sensor is inactive, this alarm will not be activated.	Ventilation continues.
Input O2 Sensor Error	The function of the input oxygen sensor is disrupted. If the input oxygen sensor is inactivate, this alarm will not be activated.	Ventilation continues.

The power supply alarms include:

High Priority Alarm	Alarm Definition	Ventilator reaction to alarm
Battery Low	Internal battery voltage is lower than 20%.	Ventilation continues.
No Battery	Atleast one of two batteries is not available during plugging the device to the power.	If the device is connected to the mains power, ventilation continues.
Battery Deffect	The battery failure.	If the device is connected to the mains power, ventilation continues.

Medium Priority Alarm	Alarm Definition	Ventilator reaction to alarm
Battery Low	Internal battery voltage is lower than 20- 40%.	Ventilation continues.
AC Unplug	The device is unplugged.	Ventilation continues by using internal battery.

Low Priority Alarm (information)	Alarm Definition	Ventilator reaction to alarm
Battery check	The device has not been run on battery for a long time.	Ventilation continues.

Note:

1. Low battery alarm is activated with medium priority, with a minimum sound alarm volume of 5.
2. Low battery warning is activated with high priority, with a alarm volume of 7.

Technical messages	Definition
Insp.Hold	Inspiratory Hold maneuver has been enabled.
Exp.Hold	Expiratory Hold maneuver has been enabled.
Manual Insp.	Manual Ispiratory maneuver has been enabled.
O2 100%	100% O2 is delivered to the patient.
Nebulizer	Nebulizer has been enabled.
Suction	The suction maneuver has been enabled.
Apnea off	Apnea backup has been disabled in PSV/CPAP, VSV and APRV modes.

Warning

⚠ **Announcing Oxygen related alarms have a delay about 40 seconds.**

⚠ **The disconnection alarm may not be activated if the endotracheal tube is disconnected from the patient.**

In certain situations, or in the presence of some alarms, a series of alarms are deactivated which are listed in the table below.

Situation	Deactivated alarm
Until 60 seconds after the start of inspiration and after 3 respiratory cycles	High PEEP
	Low PEEP
	High MV
	Low MV
	High Vte
	Low Vte
	High Rate
	Low Rate
	High Oxygen
	Low Oxygen
	High Leak
Until 45 secods after Inh/ Exh hold and suction maneuvers	Low PEEP
	Low MV
	Low Vte
	Low Rate
Until 15 seconds after increasing PEEP value by the user	Disconnection
During suction maneuver	Low PEEP
	Low MV

	Low Vte
	Low Rate
	Disconnection
	Apnea
During O2 100% maneuver and 60 seconds after that	High Oxygen
In case of failure, absence or inactivity of the exhalation flow sensor	High MV
	Low MV
	High Vte
	Low Vte
	High Leak
During disconnection alarm	Low PEEP
	Low MV
	Low Vte
	High Rate
	Low Rate
	High Leak
During occlusion alarm	Disconnection
During No battery and Battery defect alarms	Battery check
During HFO maneuver	Disconnection
	Occlusion
During CPAP mod with P_s=0	Disconnection

6-5 Alarms test

Select the following settings.

Alarm test setting			
Mode:	VCV	Apnea time:	20 s
Trigger Type:	Flow	High Rate:	100 b/min
Rate:	10 b/min	Low Rate:	2 b/min
Vt:	500 ml	High Ppeak:	40 cmH_2O
Pause:	0 %	High MV:	50 l/min
Oxygen:	21 %	Low MV:	2 l/min
Ti:	1.4 s	High Vte:	1000 ml
Ftrig:	3 l/min	Low Vte:	200 ml
Flow pat.:	Decel.	High PEEP:	8 cmH_2O
		Low PEEP:	3 cmH_2O
		Leak:	100 %

Test the alarms according to the following instructions.

High pressure alarm test: Allow the ventilator to operate at the above settings with a test lung. Press the test lung during inhalation to activate the High-pressure alarm. Check that high pressure alarm is activated on the same breath and inhalation terminates.

Low Vte and Low MV alarms test: Change MV low alarm limit to 12 l/min. Check that after a while, first the Low MV alarm and then the Low Vte should be activated. Change MV low alarm limit back to 2 l/min.

Low O2 Pressure and Low Oxygen alarms test: Change O2 to 100% and disconnect the oxygen supply. Check that Low O2 Pressure alarm is activated immediately and Low Oxygen alarm is activated after a few breaths. Change the oxygen setting back to 21%.

Low Air pressure alarm test: Disconnect the air supply. Check that Low Air Pressure alarm is activated immediately. Connect the air supply line.

Occlusion alarm test: Occlude the expiratory path completely during the exhalation phase. Verify that occlusion alarm is activated after two breaths.

Disconnection alarm test: Disconnect the patient breathing circuit from the ventilator outlet port during the exhalation phase. Check that Disconnection alarm is activated after a while breath cycles. Then connect the breathing circuit to the port.

Power source transition test: Disconnect the power cable. Check that the ventilator continues operating on the battery power. In this condition the battery icon and "AC Unplug" message are displayed on the screen. Connect the power cable to the ventilator. Verify that the battery icon and "AC Unplug" message are removed from the screen.

Battery low alarm test: To test the internal battery, ensure that the battery is fully charged (more than 95%). Disconnect AC mains power and operate the ventilator on 21% oxygen. Ensure that medium priority low battery alarm is activated when the battery charge decreases. The ventilator should continue operation. Then a high priority alarm will be activated.

Apnea alarm test and Apnea backup active mode: Change the ventilation mode to VSV and activate Apnea backup. Do not trigger the device. Check that apnea alarm is activated and apnea backup ventilation begins within 20 s. Change the ventilation mode back to VCV.

7- Maintenance

In this section maintenance procedure of the ventilator including calibration, cleaning, preventive maintenance and disposal of components and accessories will be described.

7-1 Calibration

Note:

Use compressed air system of hospital to calibrate the ventilator.

There is a calibration option in startup page of the ventilator. Selecting this option will load a window (See figure 7-1) in which you can select different types of calibration.

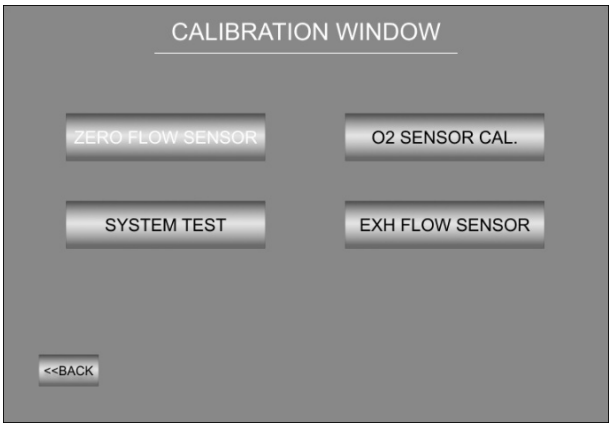


Figure 7-1 Calibration window

- **O2 Sensor Calibration**

O2 sensor calibration is performed to ensure accuracy of the sensor. Inaccuracy of the sensor will result in erroneous measurement and incorrect recognition. Calibrate galvanic O2 sensor before using the ventilator and after replacing the oxygen sensor. Also, the calibration of the permanent oxygen sensor should be done by the company's experts and in case of measurement inaccuracy. Before this test, make sure that air and oxygen sources are available and the patient breathing circuit is disconnected.

Press START button and wait until the calibration process is complete. New and previous sensor calibration results are displayed. Select SAVE to store new calibration results. As shown in the figure, the type of oxygen sensor (Galvannic/ Permanent) is displayed at the top of this screen.

Warning

Note that the oxygen sensor calibration must be performed with 100% oxygen source.

Note:

If there is an input oxygen sensor and if it is active and healthy, the value read by the input oxygen sensor is used in the calibration process. Otherwise, the input oxygen concentration is considered 100%.

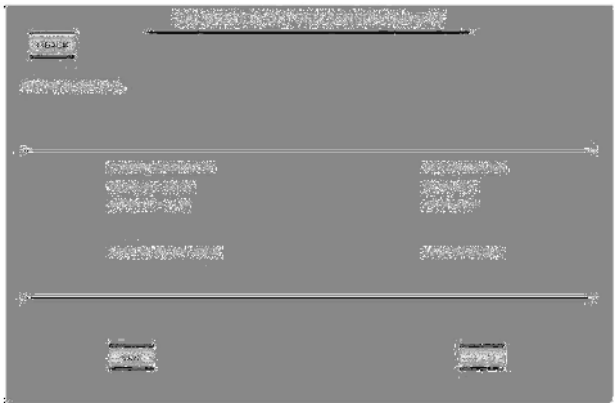


Figure 7-2 O2 Sensor Calibration page

- **System Test**

The system test should always be performed before using the ventilator or after replacing the patient respiration set.

This test is performed to inspect the patient breathing circuit. Any leakage in the patient tubing system could be calculated using this test. In addition to the leakage, this test will also measure total compliance of the patient tubing system.

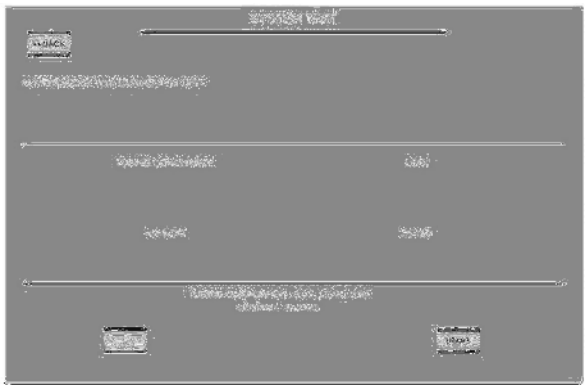


Figure 7-3 System Test page

Press START button to start the system test. It should be noted that the circuit wye is closed during this test. When the test is complete, select save button to store the calibration results.

- **EXH. Flow Sensor Calibration**

This test is used to calibrate exhalation flow sensor. It should be noted that the circuit wye is closed during this test. Press START button and wait until the calibration process is complete. Select SAVE button to store the calibration data.

This test should be performed before using the device, after cleaning or replacing the exhalation flow sensor or if incorrect exhalation volume is measured by the sensor (e.g. when the difference between Vte and Vti values increases significantly. It should be noted that leakage could be cause the reduction of Vte).

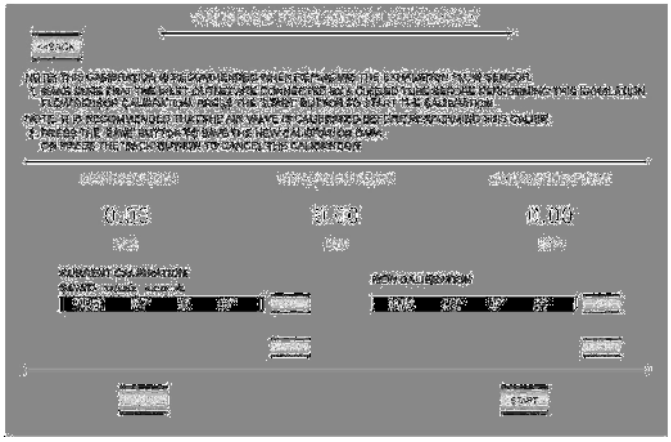


Figure 7-4 Exh Flow Sensor Calibration page

7-2 Cleaning and Disinfection

Follow instructions of this manual to clean and disinfect different parts of the ventilator. In addition, to perform each method follow hospital protocols.

Display screen

The screen should be cleaned and disinfected after each patient or as required. Use a soft cloth damped with water and soap to clean the screen. To disinfect the screen, use a soft cloth damped with ethanol to disinfect the screen.

Exterior surface

Clean exterior surfaces by using a soft cloth damped with water and soap. Disinfect exterior surfaces of the device using isopropyl alcohol.

Clean and disinfect the exterior surfaces of the ventilator after each patient or as required.

Warning

Do not sterilize the ventilator.

Patient tubing system

The patient tubing system components are single-use, dispose of them according to relevant regulations.

Humidifier

Use the single patient use chamber.

Clean and disinfect the humidifier according to manufacturer instructions. For more information, please refer to the humidifier manual.

Warning

The humidifier could cause high resistance of the airway and pressure drop.

Check resistance of the airway regularly.

Reusable Expiratory Flow Sensor

Clean or disinfect the expiratory flow sensor according to manufacturer instructions for each patient or as required.

Singel use Expiratory Flow Sensor

These types of sensors are single use. Dispose of them according to relevant regulations.

Warning

Do not autoclave the expiratory flow sensor.

Clean the expiratory flow sensor immediately after the nebulizer is used.

Nebulizer failure is not detected by a ventilator.

Exhalation Valve

After each patient or as required, clean the exhalation valve by rinsing and drying with soap and water and then disinfect.

Exhalation valve- flow sensor interface

After each patient or as required, clean the exhalation valve by rinsing and drying with soap and water and then disinfect.

Warning

⚠ **Replace faulty exhalation flow sensor.**

⚠ **Replace expiratory filter and HME every 24 hours or as needed. It should be noted that expiratory filter and HME are disposable and must be replaced for each patient.**

⚠ **Replace faulty exhalation membrane. Note that the exhalation membrane is disposable and must be replaced for each patient.**

7-3 Cleaning and disinfecting

- Before disinfecting the ventilator, make sure that the equipment is switched off and disconnected from the power line.
- Exterior surface of the device should be disinfected after each use. Use isopropyl alcohol to disinfect.
- Do not use strong solvents such as acetone or ammonia.
- Do not use rough material, such as steel wool, etc.
- Do not let the cleaning agent enter into the housing of the system.
- Dry out the cleaning agents on any part of the device.

Recommended cleaning and disinfection methods of different parts of the ventilator are provided in the below table.

<table>
<tr><th>Ventilator part</th><th>Single use</th><th>Cleaning</th><th>Disinfection</th></tr>
<tr><td>Display screen</td><td>-</td><td rowspan="3">Using water and soap</td><td>Using ethanol</td></tr>
<tr><td>Exterior surfaces, trolley and tubes holder</td><td rowspan="2">-</td><td rowspan="2">Using isopropyl alcohol</td></tr>
<tr><td>Air compressor</td></tr>
</table>

Ventilator part	Single use	Cleaning	Disinfection
Hoses and the components behind the ventilator	-		-
Exhalation valve	-		Using isopropyl alcohol
Exhalation valve-flow sensor interface			
Exhalation flow sensor	-	According to manufacturer instructions	
Exhalation membrane	✓	-	-
Tubing system	✓	-	-
NIV mask	-	According to manufacturer instructions	
HME	✓	-	-
Nebulizer	✓	-	-
Humidifier	-	According to manufacturer instructions	
Humidifier temperature probe			
Humidifier chamber	✓	-	-
Exhalation filter	✓	-	-

7-4 Preventative Maintenance

7-4-1 Exhalation Flow Sensor

If replacement of the exhalation flow sensor is required, use only recommended exhalation flow sensors by manufacturer (See section 2-3). The exhalation flow sensor should be replaced every 6 months or when the exhalation flow sensor failure message is displayed during exhalation flow sensor calibration. Take the following actions to replace this sensor:

Detach the exhalation flow sensor from exhalation valve.

Carefully remove the exhalation flow sensor and replace it with a correct one.

7-4-2 Exhalation Valve and Membrane

Take the following actions to replace the exhalation valve:

Remove the exhalation flow sensor.

Turn the exhalation valve counterclockwise.

Remove the exhalation valve, exhalation valve- flow sensor interface and the membrane.

When reinstalling the exhalation valve, make sure that the membrane is placed in correct direction. After placing the membrane, check that round steel plate positioned at the back of the membrane is visible.

7-4-3 Battery test and replacement

Connect the device to the power and observe that the LED indicators of the battery are steady green (full charge) or steady red (charging). The flashing of this indicator in orange means the battery failure.

Wait until the device's battery is fully charged. Activate the device in normal settings in ventilation mode (normal power consumption). Unplug the device and observe that the device continues to work with the battery. Wait and see that the device continues to work normally with the battery for at least half an hour (Medical centers may consider a minimum time of more than half an hour according to the results of their risk analysis).

Note:

A new and fully charged battery should keep the device on for 2 hours, but the capacity of energy that can be stored in the battery decreases by passing time (this applies to all batteries). Therefore, it is normal that the operation of the device with the battery will decrease over time. It is strongly recommended to replace the battery whenever this time becomes less than half an hour.

Note:

The battery health test should be performed every 3 months to ensure proper battery performance.

Warning

Before using the ventilator ensure that a healthy battery with minimum charge is installed.

If the ventilator has been stored for a long time, recharge the battery before use and make sure it's healthy.

If you're going to store the device for an extended time, charge the battery and remove it from the device.

Do not use the device in case of the battery failure.

Replace internal battery of the ventilator every two years or as required. Use only manufacturer recommended batteries (see section 2-3). Take the following actions to replace the battery:

Loosen the screw that attaches cover of the battery compartment to the device.

Remove the battery and replace it with a correct one.

Warning

Always perform the tests related to power and battery after the battery replacement.

Do not use the device in case of the battery failure.

7-4-4 Ventilator preventive maintenance table

The following table summarizes the replacement intervals of the ventilator accessories, the intervals of calibrations and the person incharge of performing each operation:

Operation	intervals	Responsible person
Oxygen sensor (galvanic) calibration	Before using the ventilator and after replacing the oxygen sensor	User
Oxygen sensor (permanent) calibration	In case of inaccuracy in measurement	Expert
Exhalation flow sensor calibration	Before using the ventilator, after cleaning or replacing the exhalation flow sensor or if the expiratory volume is incorrectly measured by the sensor	User
System test calibration	Before using the ventilator and after replacing the patient breathing tube	User
Air valve calibraion	Annually	Expert
Oxygen valve calibration	Annually	Expert
Exhalaion valve calibration	Annually	Expert
Input oxygen sensor calibration	Annually	Expert
Periodic calibration	Annually	Expert
Air inlet filter check	Annually or every 5000 hours of ventilator operation (each occurred earlier)	User
Evacuating the water of the air inlet drain (the glass housing of the air filter on the back of the device)	Every 100 working hours of the device (4 days)	User
Oxygen filter check	Annually or every 5000 hours of ventilator operation (each occurred earlier)	Expert
Oxygen sensor replacement	After the expiration date or sensor failure	Expert
Exhalation flow sensor replacement	In case of damage	Expert
Battery replacement	Every two years or during battery failure	Expert
Exhalation valve- flow sensor interface replacement	In case of damage	Expert
Exhalation valve membrane replacement	After each patient or in case of damage	Expert
Respiration set replacement	After each patient	User
HME replcament	After each patient, every 24 hours or as needed	User
Exhalation filter replcament	After each patient, every 24 hours or as needed	User

Operation	intervals	Responsible person
Complete Antistatic Hoses AIR (hospital Air to compressor) replacement	In case of damage	Expert
Complete Antistatic Hoses AIR (compressor to ventilator) replace ment	In case of damage	Expert
Complete Antistatic Hoses O2 (Hospital to ventilator) replacement	In case of damage	Expert
Humidifier chamber replacement	After each patient	User
Humidifier temperature probe replacement	According to manufacturer instructions	Expert
NIV mask replacement	According to manufacturer instructions	User
Nebulizer replacement	After each patient	User

User: trained personnel of medical centers
Expert: After-sales service expert or trained people by the manufacturer

Warning

⚠ **In addition to above mentioned calibration and maintenance procedures that could be performed by the user, it is recommended that the device is calibrated once a year by trained service experts.**

8- Ventilation

8-1 Ventilation modes

The Respina P2 ventilator provides the following ventilation modes:

VCV, V-SIMV, PCV, P-SIMV, PRVC-CMV, PRVC-SIMV, VSV, PSV/CPAP, APRV

- **VCV (Volume Controlled Ventilation)**

During this mode the ventilator delivers the set tidal volume to the patient in inspiration phase. This mode is a volume-controlled mode. The user sets tidal volume, Inspiratory time (Ti) and respiratory rate. Peak flow (Flow), expiratory time (Te) and Ratio of inspiratory time to expiratory time (I:E) are calculated automatically based on the adjusted parameters by user.

A higher inspiratory time will decrease peak flow (at a specific tidal volume) and a lower tidal volume will result in shorter peak flow (at a specific inspiratory time). High values of tidal volume or low Ti could result in excessive pressure in the patient breathing circuit.

Excessive increasing in pressure or volume could terminate inhalation. In this situation set tidal volume may not deliver to the patient and corresponding alarm be activated. As the pressure approaches the pressure alarm (active pressure), the exhalation valve opens and prevents further increase in pressure. If this happens in a few breathing cycles, the alarm for not delivering the user's adjusted volume will be activated (see the alarms chapter).

The flow Pttern sets by the user. Two square and decelerating (Decel.) flow patterns are selectable in this ventilator.

The time which neither air is delivered to the patient nor exhaled from the patient’s lung through the airway defin as a Pause. This parameter is adjustable as a percentage of inspiratory time between 0 and 75%.

In this mode the patient could synchronize a mandatory breath with respiratory effort. In specific times the device indicates sensitivity to the patient effort and allows synchronization of mandatory breath. The device sensitivity to the patient respiratory effort is shown in the trigger window. This window begins from 350 ms after the start of exhalation (Min exhalation) until the start of the next cycle.

The curve of flow versus time is shown in the below figure. The red part of the curve is related to inspiration phase and the blue part is related to the exhalation phase.

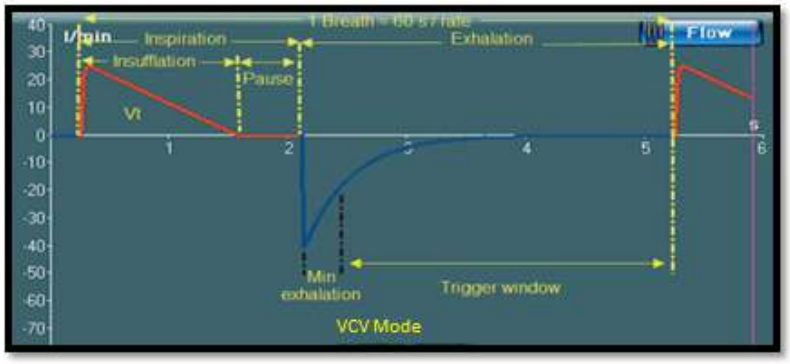


Figure 8-1- Flow versus time curve in VCV mode

The operator encounters some limitations in setting high and low limits of parameters in a ventilation mode, these limitations result from other ventilation parameters setting. these limitations are defined to meet the following conditions:

- Ti should not be less than 100 ms and less than 10% of the respiratory cycle time.
- Pause time is considered a part of Ti. However, the part of the Ti that remains after reducing the pause time should not be less than 100 ms.
- Ti should not be greater than 5s and greatern than 80% of the respiratory cycle time.
- Te should not be less than 200 ms and 20% of the respiratory cycle time.

In volume-based modes with a square flow pattern, the device delivers the user's adjustable volume to the patient with a constant amount of flow during the inhalation time.

Note:

While Vt, Rate, Pause and Ti parameters are changed by the user, Flow and Pause time will be displayed on the screen. It should be noted that if Compliance Compensation and Leak Compensation are desabled, the deliverd flow may be different from the flow displayed on this menue.

Adjustable parameters in VCV mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
V_t	Tidal volume delivered during inspiration
PEEP	Positive end expiratory pressure
Ti	Inspiratory time
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
Pause	Percentage of inhalation time after which the current volume is delivered, respiration remains in the inhalation and then exhalation begins. During this period, no volume is transferred to the patient.
Flow Pat.	the pattern of applied flow to the patient
Dual control	If the patient tries to breathe during inhalation, the device responds to this request by switching on the pressure control

Dual control:

Dual control is a feature in volume modes (VCV, V-SIMV) that allows the patient to receive more volume than the set value if needed, in case of activation. If the patient triggers to breathe during inhalation and causes a drop in pressure, the volume control is temporarily changed to pressure control.

Dual Control increases device compatibility with the patient and reduces work of breathing.

The condition for changing from volume control to pressure in a square flow is a pressure drop of more than 2 cmH2O or a pressure drop below PEEP but in a decelerating flow, only the pressure drop below the PEEP cause the changing into the pressure control.

The condition for returning from pressure control to volume in the same respiration is to reduce the flow to the initial value (flow applied due to device settings).

It should be noted that the start of the inhalation phase in each respiratory cycle, will always be with volume control due to the choice of volume mode.

Example: If Ti = 2.0 s and Vt = 1200 ml are set, the device applies 36 L/min during inhalation. In the first cycle, Dual Control is inactive and it is observed that the volume of about 1200 ml has been transferred and the patient's trigger has not been responded by the device. In the second cycle, with the activation of Dual Control, the patient's trigger, which has led to a drop in pressure of more than 2 cmH2O, is detected by the device and responded by switching to the pressure control. For this reason, a volume of about 1450 ml has been delivered to the patient. In this example, because the flow rate has dropped to 36 liters per minute before the end of inhalation, the device has returned to volume control.

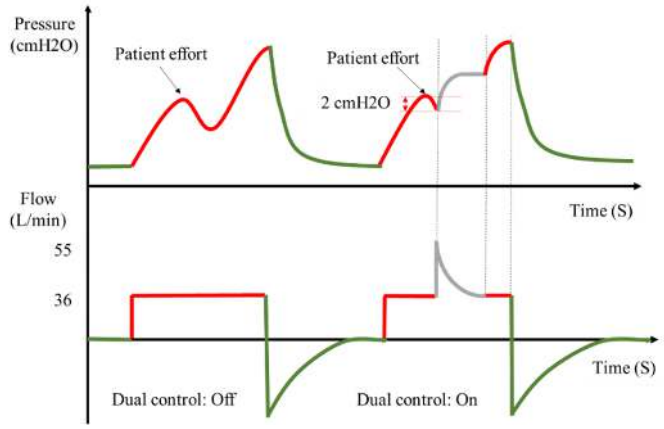


Figure 8-2- Dual control

- **PCV (Pressure Controlled Ventilation)**

In this mode the user sets Pcontrol, Respiratory Rate and Inspiratory time (Ti). The ventilator should maintain the airway pressure on Pcontrol during inspiratory time.

PEEP value is added to Pcontrol, thus the ventilator maintains the airway pressure on PEEP+Pcontrol.

Rise time is a parameter that determines the speed to reach the control pressure (Pcontrol) and has three values, Fast, Med and Slow.

In this mode as VCV mode the patient could synchronize a mandatory breath with respiratory effort.

High values of Pcontrol or Ti will increase tidal volume delivered to the patient. Any change in lung compliance and resistance of the patient airway could affect Vti delivered to the patient.

High limit of Pcontrol is determined in a way that total PEEP plus Pcontrol does not exceed 80 cmH2O.

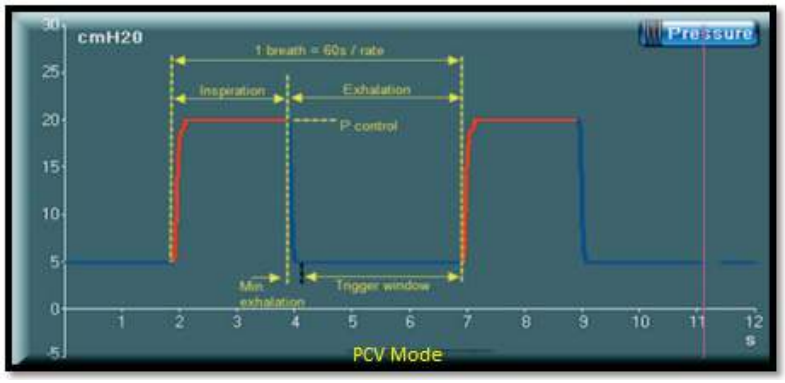


Figure 8-3- Pressure curve in PCV mode

The pressure curve in PCV mode is shown in the above figure. As you can see the pressure has a constant value equal to Pcontrol + PEEP in the inspiratory phase that this value is set by the user.

When the operator adjusts the parameters of a respiratory mode, he/ she is faced with limitations in setting the upper and lower limits of these parameters, which are due to the adjustment of other respiratory parameters.

Excessive increasing in pressure or volume could terminate inhalation. In this condition, the Ti applied by the device may be less than the set value (see the alarms chapter).

Note:

When changing the Rate and Ti parameters, the values of Te and I: E are displayed on the parameter setting menue.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

Adjustable parameters in PCV mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
T_i	Inspiratory time
PEEP	Positive end expiratory pressure
$P_{control}$	Inspiratory pressure above PEEP in mandatory breaths
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **PRVC-CMV (Pressure Regulated Volume Control Continuous Mandatory Ventilation)**

In this mode the ventilator delivers the set tidal volume to the patient while airway pressure is maintained constant during breath. The pressure will remain constant per breath and the ventilation continues for duration of the set Ti. If delivered volume is lower than the set tidal volume, the pressure will be increased in the next breath. If delivered volume is more than the set tidal volume, the pressure will be decreased in the next breath.

The pressure variations to achieve the setting tidal volume will not be more than 3 cmH2O per breath. Low pressure limit is equal to PEEP+3 cmH2O and high-pressure limit is equal to Pmax - 5 cmH2O (Pmax is high limit of pressure alarm). If upper limit of pressure is reached and target volume is not delivered to the patient, the message "Volume not Delivered" will be displayed (see the alarms chapter).

Excessive increasing in pressure or volume could terminate inhalation. In this condition, the Ti applied by the device may be less than the set value (see the alarms chapter).

When the operator adjusts the parameters of a respiratory mode, he/ she is faced with limitations in setting the upper and lower limits of these parameters, which are due to the adjustment of other respiratory parameters.

Note:

When changing the Rate and Ti parameters, the values of Te and I: E are displayed on the parameter setting menue.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

Adjustable parameters in PRVC-CMV mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
T_i	Inspiratory time
PEEP	Positive end expiratory pressure
V_t	Target tidal volume delivered per breath
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **V-SIMV (Volume Controlled Synchronized Intermittent Mandatory Ventilation)**

In this mode mandatory breaths are volume controlled and spontaneous breaths are pressure supported. This mode is a combination of mandatory and spontaneous breaths.

The curve of pressure versus time in V-SIMV mode is shown in the below figure. Inspiration and the exhalation phases of mandatory breath are shown by red and dark green and inspiration and the exhalation phases in spontaneous breath are shown by light green and yellow.

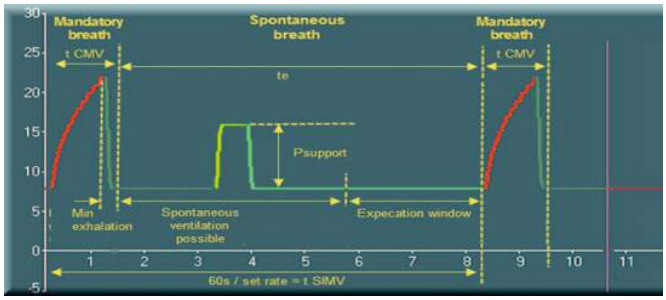


Figure 8-4- Pressure curve in V-SIMV mode

The exhalation consists of two windows:

The patient respiratory effort triggers an assisted breath within Spont window. The patient also can trigger a mandatory breath within Expectation window.

When the operator adjusts the parameters of a respiratory mode, he/ she is faced with limitations in setting the upper and lower limits of these parameters, which are due to the adjustment of other respiratory parameters.

Excessive increasing in pressure or volume could terminate inhalation. In this situation set tidal volume may not deliver to the patient and corresponding alarm be activated. As the pressure approaches the pressure alarm (active pressure), the exhalation valve opens and prevents further increase in pressure. If this happens in a few breathing cycles, the alarm for not delivering the user's adjusted volume will be activated (see the alarms chapter).

The flow Pttern sets by the user. Two square and decelerating (Decel.) flow patterns are selectable in this ventilator.

The time which neither air is delivered to the patient nor exhaled from the patient's lung through the airway defin as a Pause. This parameter is adjustable as a percentage of inspiratory time between 0 and 75%.

Note:

While Vt, Rate, Pause and Ti parameters are changed by the user, Flow and Pause time will be displayed on the screen. It should be noted that if Compliance Compensation and Leak Compensation are desabled, the deliverd flow may be different from the flow displayed on this menue.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

Adjustable parameters in V-SIMV mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
V_t	Target tidal volume delivered per breath
PEEP	Positive end expiratory pressure
$P_{support}$	Pressure more than PEEP that applies to spontaneous breaths.
Ti	Inspiratory time
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalationand initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure
Pause	Percentage of inhalation time after which the current volume is delivered, respiration remains in the inhalation and then exhalation begins. During this period, no volume is transferred to the patient.
Flow pat.	the pattern of applied flow to the patient
Dual control	If the patient tries to breathe during inhalation, the device responds to this request by switching on the pressure control

- **P-SIMV (Pressure Controlled Synchronized Intermittent Mandatory Ventilation)**

This mode is a combination of mandatory and spontaneous breaths. Mandatory breath is pressure controlled and spontaneous breath is pressure supported.

Excessive increase of pressure or deliverd volume could cause terminating the inhalation. In this situation, applied Ti may shorter than set Ti (see the alarms chapter).

Note:

When changing the Rate and Ti parameters, the values of Te and I: E are displayed on the parameter setting menue.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

The pressure curve in P-SIMV mode is shown in the below figure. The patient triggers a mandatory breath in synchronization with respiratory effort within Expectation window and triggers a pressure supported breath within Spontaneous window.

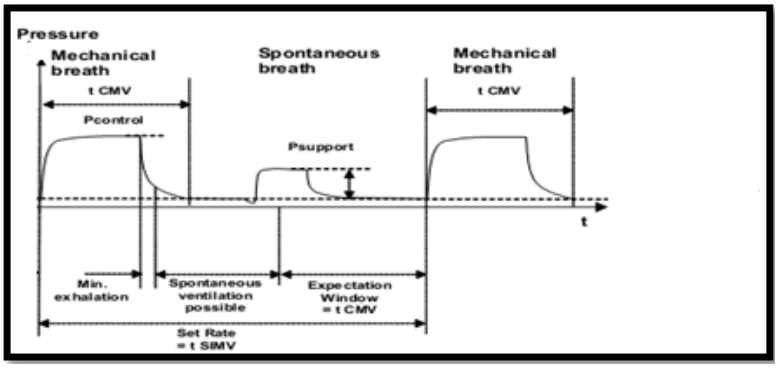


Figure 8-5- Pressure curve in P-SIMV mode

P-SIMV mode is similar to V-SIMV mode except those mandatory breaths in V-SIMV mode are volume controlled, but in P-SIMV mode are pressure controlled.

Adjustable parameters in this mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
T_i	Inspiratory time
PEEP	Positive end expiratory pressure
$P_{control}$	Inspiratory pressure above PEEP in mandatory breaths
$P_{support}$	Pressure more than PEEP that applies to spontaneous breaths.
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalation and initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **PRVC-SIMV (Pressure Regulated Volume Synchronized Intermittent Mandatory Ventilation)**

Mandatory breaths in this mode are similar to PRVC-CMV mode. The ventilator delivers breaths during Ti with pressure values that vary in each inspiration to achieve the target tidal

volume. The pressure values will not vary more than 3 cmH2O per breath. Only difference of this mode with PRVC-CMV is that the ventilator could deliver spontaneous breaths which are pressure supported.

Excessive increase of pressure or deliverd volume could cause terminating the inhalation. In this situation, applied Ti may shorter than set Ti (see the alarms chapter).

Note:

When changing the Rate and Ti parameters, the values of Te and I: E are displayed on the parameter setting menue.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

The below parameters could be set in this mode:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
Rate	Mandatory breaths per minute
V_t	Target tidal volume delivered per breath
T_i	Inspiratory time
PEEP	Positive end expiratory pressure
$P_{support}$	Pressure more than PEEP that applies to spontaneous breaths.
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalationand initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **VSV (Volume Support Ventilation)**

This mode is a spontaneous breath mode and patient effort determines respiratory rate. In this mode the user sets tidal volume. When the patient makes an effort, the ventilator delivers pressure supported breath to achieve the set tidal volume. Low pressure limit is equal to PEEP + 3 cmH2O and high-pressure limit is equal to Pmax –5 cmH2O (Pmax is high pressure limit).

If upper limit of pressure is reached and target volume is not delivered to the patient, the message "Volume not Delivered" will be displayed (see the alarms chapter).

Excessive increase of pressure or deliverd volume could cause terminating the inhalation.

When the operator adjusts the parameters of a respiratory mode, he/ she is faced with limitations in setting the upper and lower limits of these parameters, which are due to the adjustment of other respiratory parameters.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

The below parameters could be set in this mode:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
V_t	Target tidal volume delivered per breath
PEEP	Positive end expiratory pressure
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalationand initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **PSV/CPAP (Pressure Support Ventilation/ Continuous Positive Airway Pressure)**

This mode like VS mode is a spontaneous breath mode, except that the ventilator delivers pressure supported breaths in response to the patient effort.

If the user sets Psupport to 0 cmH2O, a pressure equal to PEEP is maintained during inspiration that in this condition the mode is Continuous Positive Airway Pressure.

Excessive increase of pressure or deliverd volume could cause terminating the inhalation (se the alarms chapter).

When the operator adjusts the parameters of a respiratory mode, he/ she is faced with limitations in setting the upper and lower limits of these parameters, which are due to the adjustment of other respiratory parameters.

Note:

During inhalation, if the airway pressure for any reason (such as the patient's cough) exceeds the value specified for it, the exhalation valve opens and prevents further increase in pressure.

The flow and pressure curve in PSV/CPAP mode is shown in the below figure. As you can see when the patient respiratory effort is detected, the ventilator delivers a pressure supported breath to assist the patient spontaneous breath (in PEEP condition, PEEP+ Psupport).

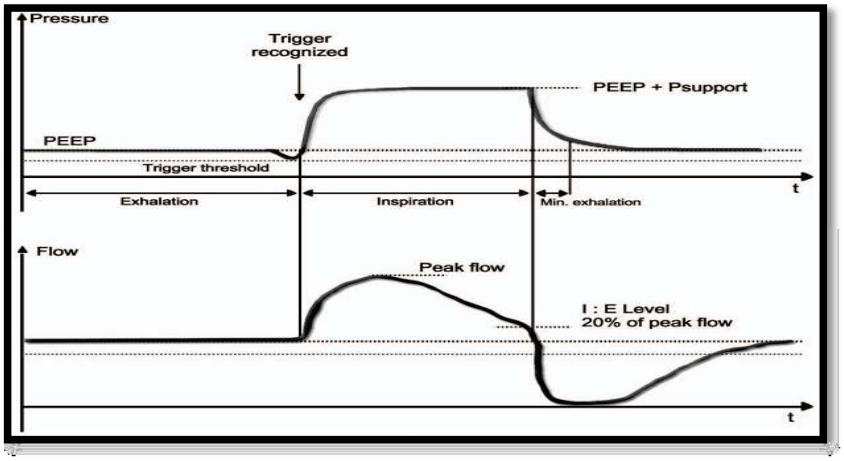


Figure 8-6- Pressure and flow curve in PSV/CPAP mode

Adjustable parameters in this mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
PEEP	Positive end expiratory pressure
$P_{support}$	Pressure more than PEEP that applies to spontaneous breaths.
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalationand initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **APRV (Airway Pressure Release Ventilation)**

APRV is a pressure-based ventilation mode that allows patients to breathe spontaneously at two user-selected pressure levels (Phigh, Plow).

Thigh and Tlow determine the duration of exposure to each pressure levels. The device is in the inhalation phase during Thigh and in the exhalation phase duting Tlow. The minimum possible time for Thigh is one second and the maximum possible time for Tlow is two seconds.

Note:
The patient is not allowed to trigger the device at the low-pressure level.

Auto Tlow parameter:

By setting the Auto Tlow parameter, the duration of stay at low pressure level can be related to changes in expiratory flow. In this case, the low-pressure time continues until the expiratory flow reaches a certain level of the expiratory flow peak.

Example: In the following figure, in the first cycle, Auto Tlow = off and Tlow = 1.2 s are set. It is observed that the exhalation lasts 1.2 s. In the second cycle, Auto Tlow is changed to 75%

by the user, and because the peak expiratory flow rate has been 100 L/min, when the expiratory flow reaches 75 L/min, the low pressure time terminates:

(PFe * Auto Tlow= 100 * 0.75= 75)

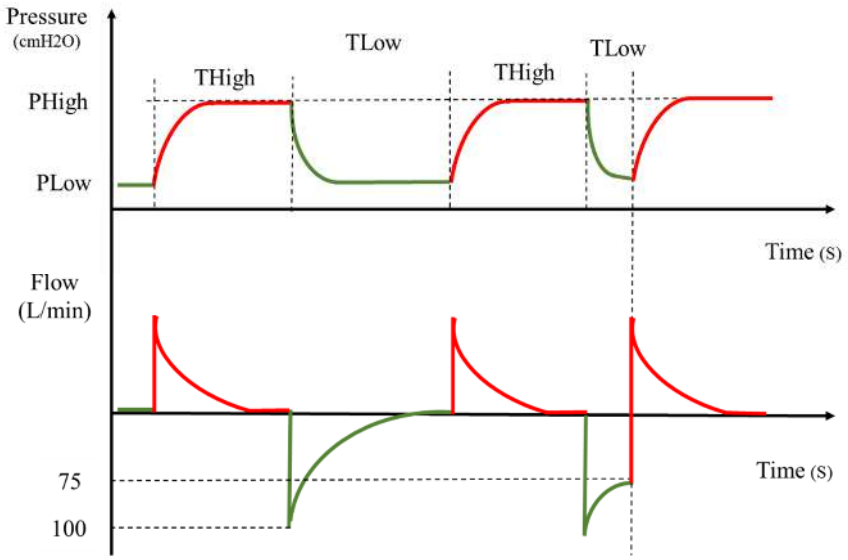


Figure 8-7- Pressure and flow curves in APRV mode with adjustable Auto Tlow

Note:

If the user sets the Auto Tlow value other than off, the set Tlow value is set by the user as the maximum low level presseure time (in this case this parameter is displayed as Tlow Max). This is important when the expiratory flow peak is not detected for any reason or the expiratory flow rate is greatly reduced due to the patient's physiological condition.

In the following conditions, the device is not able to detect expiratory flow peak:

- If the exhalation flow peak is less than 5 L/min
- If the exhalation flow sensor is damaged or disabled by the user

Note:

- The Thigh time may be set by the user to a value greater than the apnea time, in this case it is recommended to disable the apnea mode if necessary.
- If apnea is detected at the high-pressure level due to failure to detect the patient's respiratory effort, the device enters the exhalation as soon as possible and enters the apnea after 200 milliseconds.
- If apnea is detected at the low-pressure level due to failure to detect the patient's respiratory effort, if 200 milliseconds have elapsed from the exhalation phase, the device enters apnea mode.

Adjustable parameters in this mode are:

Parameter	Definition
O_2	Percentage of delivered oxygen to the patient
P_{high}	High PEEP level
P_{low}	Low PEEP level
T_{high}	Time at high PEEP level
T_{low}	Time at low PEEP level
Auto T_{low}	Determines how long the device stays at the low-pressure level (exhalation)
Trigger	The method of detecting the patient's respiratory effort (flow or pressure).
F Trig/ P Trig	Threshold of detecting patient respiratory effort based on flow or pressure
% Esens	Percentage of peak inspiratory flow in spontaneous breath necessary to terminate inhalationand initiate exhalation.
Rise Time	Time required for inspiratory pressure to rise to set pressure

- **Apnea Backup**

If no breath is delivered to the patient within a specific period (Tapnea), backup ventilation will be provided. This function is available in PSV/CPAP, VSV and APRV modes. PCV mode has been considered as backup mode. You can set off Apnea Backup in each ventilation mode.

Backup settings (PCV) include Pcontrol, Rate and Ti and other parameters are according to current settings. It should be noted that PEEP, Pcontrol and Psupport parameters put restrictions on each other in backup mode.

Note:

If the apnea backup activated through APRV mode, the Plow parameter is considered instead of PEEP.

When apnea backup is on if the patient makes no breath effort once the set apnea time has passed, backup ventilation will be provided and apnea alarm will be activated. If apnea backup is off, apnea alarm will be activated and the ventilator will not switch to backup ventilation mode (in this condition if apnea backup is set on, backup ventilation will be provided).

Apnea mode is disabled if:

- the patient triggers two consecutive breaths.
- the patient triggers four consecutive breaths within the latest 10 breaths.
- the user changes the ventilation mode (for example an apnea occurs in PSV/CPAP mode)
- the user selects a ventilation mode except PSV/CPAP mode.
- the user inactivates the apnea mode.

Other notices

- Ins. Hold, Exp. Hold and Manual maneuvers can be performed in the apnea mode.

- Manual inspiration maneuver will not disable the apnea mode.
- If the apnea backup conditions occurred during one of PSV/CPAP, VSV or APRV modes, selecting another mode will result in disabling the apnea backup. If the new mode is one of the PSV/CPAP or VSV modes, the apnea alarm will remain active until the patient triggers the device.

In addition, these two modes are set separately in Apnea Backup window.

When apnea backup is on, the current backup mode is displayed red instead of ventilation mode.

Note:

- In volume-based modes, if the airway pressure exceeds the upper limit of the pressure alarm – 5 cmH2O, the exhalation valve opens. Also, if the pressure has exceeded the upper limit of the pressure alarm, the inhalation terminates and the exhalation begins.
- In pressure-based modes during inhalation, if the pressure exceeds the set pressure + 4 cmH2O, the exhalation valve opens to maintain pressure. But if the pressure has exceeded the upper limit of the pressure alarm, the inhalation terminates and the exhalation begins.
- In volume-based modes, the exhalation valve opening to maintain pressure may cause that the set volume does not deliver to the patient.

8-2 Limitations of setting parameters

In adjusting the setting parameters in different modes, some respiratory parameters limit each other. These restrictions are divided into several categories:

- Dependence of Rate, Flow and Vti
- Dependence of Rate and Ti
- Dependence of Plow, Phigh, Psupport, Ppeak, PEEP and High-pressure alarm limit that shown in the following table:

Restrictions of parameters	Ventilation mode
$PEEP + P_{control} \leq 80$	PCV/CPAP& P-SIMV, Apnea Backup
$PEEP + P_{support} \leq 80$	P-SIMV, PRVC-SIMV, V-SIMV & PSV/CPAP
$PEEP + 10 \leq HPresAlarm$	VSV, PRVC-CMV, PRVC-SIMV
$PEEP + 7 \leq HPresAlarm$	VCV, PCV, V-SIMV, P-SIMV, PSV/CPAP
$PEEP + P_{control} + 5 \leq HPresAlarm$	PCV & P-SIMV
$PEEP + P_{support} + 5 \leq HPresAlarm$	P-SIMV, PRVC-SIMV, V-SIMV & PSV/CPAP

Restrictions of parameters	Ventilation mode
Plow + 7 ≤ HPresAlarm	APRV
Plow + 3 ≤ Phigh	APRV
PHigh + 5 ≤ HPresAlarm	APRV

Warning

⚠ **Note that while changing the respiratory modes, setting parameters may be limited depending on the circumstances.**

8-3 Leak Compensation

The leak compensation function is used to compensate leakages of flow during the inspiration and expiration. To prevent long inspiration time in the volume modes, the volume will be increased through inspiratory flow. In order to make the delivered volume to the patient equal to the preset volume, the measured flow leakage is added to the set flow as a constant value. The added leakage value to the set flow is calculated according to the below table.

Leakage compensation capability can be selected in all breathing modes.

	Invasive	**NIV**
Pediatric	40%	80%
Adult	50%	90%

The maximum leakage flow value is according to the below table. These limits are used in the measurement of leakage flow.

	Invasive	**NIV**
pediatric	15 l/min	30 l/min
adult	20 l/min	50 l/min

It should be noted that added volume to inspiratory volume could be limited in the above conditions.

In order to display actual flow delivered to the patient, the leakage flow value is used to correct inspiratory flow and volume curves and also VTi parameter.

The parameters of the expiratory flow including MV, PFe, Vte and MV Spont will not be compensated. In addition, the other parameters for which expiratory flow values are used (e.g RCe) could be measured incorrectly in case of leakage.

In the pressure modes, the set pressure is compensated through increasing the delivered flow and then flow and volume curves and parameters are corrected.

Note:

If expiratory flow sensor is faulty or inactive, the leak compensation will not be enabled. If the sensor is disabled or fails to function during the compensation, the leak compensation will not be disabled. In this condition the compensation is not possible and the leakage flow will be zero. The compensation will be resumed when the problem is resolved.

Warning

⚠ **If leakage compensation or compliance compensation is enabled in volume-controlled modes, delivered flow by the device may be different from the set flow.**

8-4 Non-Invasive Ventilation (NIV)

Non-Invasive Ventilation is a function available in P-SIMV and PSV/CPAP modes of the Respina P2 Ventilator. If this function is enabled, (NIV) will be shown next to current mode. The NIV is basically designed for the leak compensation; thus, activation of the leak compensation is a prerequisite for this function. Thus, when the leak compensation is set to Off, the user can not enable the NIV and when the NIV is set to On, the user will not be able to disable the leak compensation.
If the NIV is enabled in PSV/CPAP mode and the Apnea backup mode is enabled, the NIV will remain active in apnea mode.

Note:

- In order to improve NIV function, it is recommended to use flow trigger mode during the NIV activation.
- If expiratory flow sensor is faulty or inactive, the NIV will not be enabled. If the sensor is disabled or fails to function during the NIV, the NIV will not be disabled. In this condition the compensation is not possible and the NIV will be resumed when the problem is resolved.
- When the NIV is set to On, low VTe and MV alarms settings may be needed to change or disable.

To prevent delivery of high volume to the patient, set high pressure alarm setting carefully during the leak compensation and NIV activation.

If the leakage is removed immediately, high volume may be delivered to the lung in the early cycles.

8-5 Input oxygen concentration compensation

If high-pressure oxygen is supplied from a source such as a hospital oxygen generator, the concentration of oxygen is not constant and may increase or decrease in concentration at different hours of the day and night. To manage this event, the input oxygen sensor module has been designed to minimize the effect of fluctuations in the input oxygen concentration by adjusting the oxygen concentration delivered to the patient. The measured value for the input oxygen concentration is displayed and the corresponding alarms are also announced.

If the concentration of the input oxygen supply changes and the input oxygen sensor is active, the amount of oxygen delivered to the patient is corrected to deliver the desired oxygen to the patient, but to reduce possible risks, the amount of corrected oxygen is limited to a maximum of 30%.

8-6 Monitoring Data

Monitored parameters are displayed above the screen during ventilation. To configure monitored parameters, act in this way:

1. Touch a monitored parameter that you want other parameter is displayed in its place.
2. A window will be opened that shows the name of all the measured parameters with their measured values. Select the desired parameter from this window.
3. The following parameters will not be displayed until 30 seconds after the start of ventilation and after 3 breathing cycles: MV, Vte, MV spont, Leak, Rate, Rate spont, O2

All monitored parameters of the Respina P2 ventilator are listed in below table:

Parameter	Description	Measurement unit
P_{peak}	Peak pressure during inhalation. This parameter is calculated and updated in each breath.	cmH_2O
PEEP	Positive end expiratory pressure. This parameter is calculated and updated in each breath.	cmH_2O
P_{mean}	Average airway pressure during a respiratory cycle. This parameter is calculated and updated in each breath.	cmH_2O
$P_{endInsp}$	End inspiratory pressure. This parameter is calculated and updated in each breath.	cmH_2O
V_{te}	Exhaled tidal volume. This parameter is calculated and updated in each breath.	ml
V_{ti}	Inspired tidal volume. This parameter is calculated and updated in each breath.	ml
MV	Volume of air expired in one minute including mandatory and spontaneous breaths. This parameter is calculated in 8 breaths but updated at each breath.	ml
MV_{Spont}	Volume of air expired in one minute during spontaneous breaths. This parameter is calculated in 8 breaths but updated at each breath.	ml

Parameter	Description	Measurement unit
Leak	Percentage of leak flow. This parameter is calculated in 5 breaths but updated at each breath.	%
PF	Peak inspiratory flow. This parameter is calculated and updated in each breath.	l/min
PF_e	Peak expiratory flow. This parameter is calculated and updated in each breath.	l/min
Rate	Number of spontaneous and mandatory breaths in one minute. This parameter is calculated in 8 breaths but updated at each breath.	b/min
Rate Sp.	Number of spontaneous breaths in one minute This parameter is calculated in 8 breaths bat updated at each breath.	b/min
Ti	Inspiratory time. This parameter is calculated and updated in each breath.	Sec
Te	Expiratory time. This parameter is calculated and updated in each breath.	Sec
I:E	Ratio of inspiratory time to expiratory time. This parameter is calculated and updated in each breath.	--
H: L	Ratio of time at high pressure to time at low pressure in APRV mode. This parameter is calculated and updated in each breath.	--
Ti/Ttot	Ratio of inspiratory time to total respiratory cycle time. This parameter is calculated and updated in each breath.	%
C_{stat}	Static compliance of lung Lung compliance measures extent of lung expansion. High compliance indicates the lung flexibility and low compliance indicates the lung stiffness and its resistance against expansion. If the pressure remains unchanged for approximately 150 milliseconds, this parameter is calculated. - If a patient is making respiratory effort during the measurement cycle especially pause time it may cause erroneous measurement of lung compliance. - Fault of pressure and flow sensors may result in erroneous measurement of this parameter. - The system leakage could result in invalid parameter value.	ml/cmH_2O
C_{dyn}	Dynamic compliance of lung This parameter measures compliance of lung tissue as well as alterations in airway resistance, includes all mandatory and supported breaths. The system leakage could result in invalid parameter value. This parameter is calculated and updated in each breath.	ml/cmH_2O

Parameter	Description	Measurement unit
R_{insp}	Inspiratory flow resistance This parameter is measured when the ventilator is in the following conditions: - Volume mode - Square wave pattern - Pause ≥ 200 ms If above conditions are not provided, R_{insp} parameter will not be measured even if Insp. Hold maneuver is applied. The system leakage could result in invalid parameter value. This parameter is calculated and updated in each breath.	$cmH_2O/l/Sec$
R_{exp}	Expiratory flow resistance This parameter is measured in the following conditions: - Volume mode - Pause ≥ 200 ms If above conditions are not provided, R_{exp} parameter will not be measured even if Insp. Hold maneuver is applied. This parameter iscalculated and updated in each breath.	$cmH_2O/l/Sec$
Auto PEEP	Auto PEEP occurs when expiratory time is inadequate. Factors leading to auto PEEP are high respiratory rate, high minute ventilation, airway closure and inverse ratio I:E ventilation. When exhalation time is short, the lungs may not be deflated fully and not reach their normal volume. This parameter is calculated and updated in each breath.	cmH_2O
$P_{plateau}$	This parameter measures the pressure applied to airway during an inspiratory pause. This parameter is calculated and updated in each breath. If the Pause time is less than 50 milliseconds due to setting the Pause% parameter, this parameter will not be measured.	cmH_2O
RSBI	Rapid Shallow Breathing Index. This parameter is calculated in 8 breaths but updated at each breath. This parameter is calculated in PSV/CPAP and VSV modes.	b/min/l
O_2	Percent of inspired oxygen This parameter is updated about every 3 seconds and the displayed value represents the last 12 seconds.	%
Input O_2	Input oxygen concentration To prevent oxygen loss, this parameter is measured approximately every 10 minutes and the time of the last measurement is displayed in front of this parameter. Note: If it is necessary to measure this parameter in real-time, disable and re-enable this sensor. Note that this measurement takes more than 70 seconds.	%

Parameter	Description	Measurement unit
P0.1	Airway occlusion pressure This parameter measures the negative airway pressure generated during 100 msec of inspiration occlusion. This parameter is used to determine patient ablity to be released from mechanical ventilation. A maneuver has been defined for measurement of this parameter.	cmH_2O
NIF	Negative inspiratory force This parameter measures maximum negative pressure generated during inspiration occlusion. It also indicates maximum strength of the inspiratory muscles especially diaphragm. A maneuver has been defined for measurement of this parameter.	cmH_2O
P0.1/NIF	Ratio of P0.1 to NIF	--
WOBimp	This parameter indicates the work required of the patient to trigger the ventilator. The Respina P2 ventilator measures this parameter in all mandatory and supported breaths triggered by the patient except in APRV ventilation mode. If the ventilator delivers a breath while it is not triggered by the patient, WOBimp value will be displayed zero. This parameter is calculated and updated in each breath.	J/L
RCe	Expiratory time constant This parameter indicates time constant of the lung deflation and is measured during 100 to 500 msec of the expiration. This parameter is calculated and updated in each breath.	Sec
Gas Temp	The output gas temperature of the device The output gas temperature from the device, which is calculated by air flow and oxygen sensors. The temperature of each gas, is affected by the calculation of the output gas temperature, if its flow is higher than 0.5 liters per minute.	°C

Note:

All flow and volume measurements, curves and loops are displayed in BTPS units.

Note:

- If the device is unable to calculate a parameter due to reasons such as sensor failure or non-fulfillment of the calculation conditions, the desired parameter will be displayed as --.
- Also, if a sensor is disabled by the user, the parameters that are used in the calculation of that sensor will be displayed as blank spaces.

8-7 Respiratory Curves

Respiratory curves are displayed in the middle of the screen. These curves from top to bottom are: Pressure-time, Flow-time, Volume-time

In the curve inspiration phase of mandatory breaths is displayed in red and the exhalation phase is displayed in green. Inspiration phase of spontaneous breaths is displayed in yellow and the exhalation phase is displayed in green.

The Respina P2 ventilator displays two respiratory loops at the right side of the screen. These loops are: Flow-Volume, Pressure-Volume

- **Changing scale of respiratory curves**

There are some scales for each curve by default. The user can select desired scale by touching axes of the curve.

Available scales for below parameters are:

Time: (0, 12) (0, 30) (0, 120)

Pressure: (-5, 30) (-10, 50) (-20, 80) (-60, 150)

Flow: (-20, 15) (-80, 40) (-100, 80) (-200, 200)

Volume: (0, 50) (0, 200) (0, 900) (0, 1200)

Default setting of time scale in all pressure-time, volume-time and flow-time curves is (0,12). The user can change default setting to one of above ranges. Changing the time scale of one curve makes the same change to the other curves.

Flow, pressure and volume values may exceed the selected scale by some changes in parameters of the current ventilation mode.

When the scale of a curve is changed, the same change is made in corresponding loop. If the numerical value of the curve exceeds the display window, the curve is displayed as a dot.

9- Technical Specifications

Technical Specifications			
Ventilation Modes	Assisted Control Mandatory Ventilation		A/C
	Synchronized Intermittent Mandatory Ventilation		SIMV
	Spontaneous Ventilation		SPONT
Breath Types	Volume–controlled breaths		VCV, V–SIMV (With Dual control in the breath)
	Pressure–controlled breaths		PCV, P–SIMV, PSV/CPAP
	Volume Targeted Pressure–controlled breaths (Pressure Regulated Volume Control) & (Volume Support)		PRVC–CMV, PRVC–SIMV, VSV
	Dual level PEEP breaths		APRV (With Auto Tlow)
Patient Type	Patient Height		42 – 250 cm
	IBW (Ideal Body Weight)		5 – 200 Kg
	Gender		Male, Female
VBS (Ventilator Breathing System)	Compliance		0.5 – 5 ml/cmH2O
	Inspiratory Resistance		0 – 2.5 cmH2O.s/l
	Expiratory Resistance		0 – 2.5 cmH2O.s/l
Apnea Backup	Settings		On (Rate, Pcontrol, Ti); OFF
Breath triggering	Pressure triggering		(-2) – (-20) cmH2O
	Flow triggering		2 – 20 l/min
Additional Setting	Parameter	Uncertainty of measurement	Range
	Respiratory Rate	±1 b/min or 4% wig	2– 150 b/min
	Respiratory Rate apnea	±1 b/min or 4% wig	5 – 150 b/min
	Tidal Volume	For 50–2600 ml: ± (4 ml + 15% Actual reading) For 20–49 ml: ± (7 ml + 15% Actual reading)	20 – 2600 ml (Compliance & BTPS compensated)
	PEEP / CPAP	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 50 cmH2O
	Pcontrol	±12% or ±(2cmH2O +4% Actual reading) wig	2 – 80 cmH2O
	Psupport	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 80 cmH2O
	Peak Flow	±12% or ±(3 l/min +4% Actual reading) wig	0.2 – 250 l/min
	Leak Comp	--	On or Off
	Flow Pattern	--	Square, Decel.
	NIV Non- Invasive Ventilation	--	On or Off; Available in P-SIMV, PSV/CPAP and apnea modes.
	I–Time (Ti)	± 0.02 sec	0.1 – 10.0 sec
	Pause (insp plateau)	±0.02 sec	0 – 75% of Inspiratory time
	Rise time	--	Fast, Med, Slow
	Exhalation sensitivity	±12% or ±(3 l/min +4% Actual reading) wig	5 – 85 % of peak flow
	Oxygen (FiO2)	± (3 %) full scale	21 – 100 %
	Phigh	±12% or ±(2cmH2O +4% Actual reading) wig	5 – 50 cmH2O

	Plow	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 47 cmH2O
	Thigh	±0.02 sec	1.0 –29.8 sec
	Tlow	±0.02 sec	0.2 –2.0 sec
	Auto Tlow	±12% or ±(3 l/min +4% Actual reading) wig	5 – 85 % of peak flow
	Nebulizer	±10 s	On or Off; User selected duration (1– 480 minutes)
	Humidification Type	--	None, HME, Humidifier
	Compliance Compensation	--	On or Off
	Graph Setting	--	Waveforms: flow, pressure, volume Loops: P/V, F/V
	Trend Data	--	all parameters, 72 hours
	Trend resolution	--	6 seconds
	Displayed Measurements	--	6 parameters
	Audio/ Settings	--	Audio Level
Monitored / Displayed Patient Values	**Pressure Values**		
	Ppeak (peak pressure during a breath)	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	PEEP (pressure at end exhalation)	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	Pmean (averaged mean pressure)	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	$P_{endInsp}$	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	Volume / Flow Values		
	Vte (expiratory tidal volume)	For 50- 2600 ml: ±(4 ml + 15% Actual reading) For 20- 49 ml: ±(7 ml + 15% Actual reading)	0 – 3000 ml
	Vti	For 50- 2600 ml: ±(4 ml + 15% Actual reading) For 20- 49 ml: ±(7 ml + 15% Actual	0 – 3000 ml
	MV (exhaled minute volume)	±15 % or ±(0.3 l/min) wig	0 – 99 l/min
	MV Spont (spontaneous exhaled minute volume)	±15 % or ±(0.3 l/min) wig	0 – 99 l/min
	Leak	±12 % or ±(3% + 4% Actual reading) wig	0 – 100%
	PFe (peak expiratory flow)	±12% or ± (3 l/min +4% Actual reading) wig	0 – 250 l/min
	Time Values		
	Rate (measured mandatory and spontaneous breaths per minute)	±1 b/min or 4% wig	0 – 200 b/min
	Rate Sp.	±1 b/min or 4% wig	0 – 200 b/min
	Inspiration Time (Ti)	± 0.2 sec	0.1 – 99.9 sec
	Expiratory Time (Te)	± 0.2 sec	0.1 – 99.9 sec
	I:E, calculated only	--	1: 99 – 99:1
	H:L	--	1:599 – 299:1
	Ti/Ttot	±5% or ±1 wig	1 – 99.9 %

	Respiratory Mechanics		
	Cstat (Static compliance, lung stiffness)	±35% or ±2 ml/cmH2O wig	0 – 250 ml/cmH2O
	Cdyn (Dynamic compliance)	±35% or ±2 ml/cmH2O wig	0 – 250 ml/cmH2O
	Rinsp (Resistance of airways and tubes)	For 0- 20 cmH2O/L/sec: ±10 cmH2O/L/sec For other range: ±50% Actual reading	0 – 1000 cmH2O/l/sec
	R_{exp}(Expiratory resistance)	For 0- 20 cmH2O/L/sec: ±10 cmH2O/L/sec For other range: ±50% Actual reading	0 – 1000 cmH2O/l/sec
	Auto PEEP (Actual PEEP – set PEEP)	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	Pplateau	±12% or ±(2cmH2O +4% Actual reading) wig	0 – 120 cmH2O
	RSBI (Measured breathing rate divided by Insp tidal volume) (RR/Vt = RSBI)	±10% or ±40 b/min/l wig	0 – 3000 b/min/l
	O2 Response time < 30 s	±3 %	15 – 100 %
	Input O2 Measuring interval ~ 10 min	±3 %	15 – 100 %
	P0.1 (The maximal slope of the airway pressure drops during the first 100 ms when the airway is occluded.)	± (2 cmH20 + 4%)	-30 – 0 cmH2O
	NIF (The maximum negative pressure generated during inspiration against an occluded airway)	± (2 cmH20 + 4%)	-60 – 0 cmH2O
	P0.1/NIF	--	0 – 100 %
	WOBimp (Work of breathing)	± 10% Actual reading	0 – 20 j/l
	RCe (Expiratory time constant)	± (0.2 s + 20 % of Actual reading)	0 – 99.9 sec
	Gas Temp Resolution: 0.1	2.5 °C	0-80 °C
	Real Time Curves		
	Pressure - Time, Flow - Time , Volume - Time		Pressure over time, Flow over time, Volume over time
	P–V Loop, F–V Loop		Pressure–volume loop, Flow–volume loop
Performing Procedures	Inspiration-Hold		Pause the ventilator at end inspiration Maximum allowable duration shall be 4-20 sec
	Expiration-Hold		Pause the ventilator in expiration Maximum allowable duration shall be 4-20 sec
	Manual Breathing		Delivery a mandatory breath during the next expiratory breath in all mode
	P0.1		The maximal slope of the airway pressure drops during the first 100 ms when the airway is occluded.

	NIF	The maximum negative pressure generated during inspiration against an occluded airway
	Suction	This function allows breaths to be delivered with a 100% O2 concentration, before and after a tracheal suction maneuver. Suction support disconnection time: 20 – 120 s; Resolution: 10
	O2 100%	Delivers O2 100% for 2 minutes
	Standby	Places ventilator in standby mode
	Nebulizer	During the nebulization time, the nebulizer valve opens synchronous to inspiration to provide pressure for an external medication nebulizer
	Input O2 Sensor	On or Off, available in all modes.
Advanced Features	Dual control in the breath	Switching from Volume to Pressure control (and vice versa) during the inspiratory phase of each breath cycle (In square flow pattern). Available in VCV and V-SIMV modes.
	Auto Tlow	Automatically determination of Tlow to terminate expiration at an adjustable percentage of peak expiratory flow. Available in APRV mode.
	Active Exhalation valve (Pressure relief during inhalation)	Available in all modes
Configuration Setting	Nebulizer	Duration: 1-480 min, Resolution:1 Accuracy: ±10 s
	Humidification Type	None, HME, Humidifier
	Compliance Comp	On or Off;
Power and Gas Supply	AC input	100 to 240 VAC (47 – 63 Hz)
	Battery Backup (with fully charged batteries)	2 hours (Upgradable to 4 hours)
	High pressure air inlet supply	Clean oil-free and medical grade 2.4 – 6.0 bar, full performance 1.0 – 2.4 bar, degraded performance 0.0 – 0.8 bar, alarm
	High pressure oxygen inlet supply	Clean dry and oil–free medical grade oxygen 2.4 – 6.0 bar, full performance 1.0 – 2.4 bar, degraded performance 0.0 – 0.8 bar, alarm
Battery specification	Type	Two separate Li- Ion batteries
	Voltage, Energy	11.1 V, Totally> 48 Wh
Alarm System	Auditory alarm	Internal speakers
	Visual alarm	In the TFT display
	Indicator	LED
	Types	Technical, Physiological, Messages
	Priorities	High, Medium, Low

Environmental Data	Operating temperature	Battery operation: 5 – 40 °C Mains operation, battery full charged: 5 – 35 °C Mains operation, battery charging: 5 – 30 °C
	Storage and transport temperature	(-10) – 60 °C
	Operating Humidity	15% – 95% non condensing
	Storage and transport Humidity	5% – 95% non condensing
	Operating altitude	11,000 ft (3,500 m) above sea level
Physical Data	Width x depth x height (main case)	45 x 35 x 29 cm
	Weight	≈10.2 Kg
	Noise Level	TBD
Display	TFT Size	12.1" wide, with Touch screen
Pressure Safety	Maximum limited pressure	110 cmH2O
	Maximum operating pressure	80 cmH2O
Compliance and Approvals	Classifications	Class I, Type B, internally powered, drip–proof equipment for continuous operation EMC related group and classification: I-B
	Meets International Standards	EN 60601-1:2005 + AMD1:2012 + AMD2:2020 EN 60601-1-2: 2014 AMD1:2020 EN 60601-1-8: 2006 + AMD1:2012 + AMD2:2020 CSV ISO 80601-2-12: 2020

EMC Declaration for Respina P2 Ventilator

Guidance and manufacturer's declaration – Ventilator Respina P2 emissions		
The Ventilator Respina P2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ventilator Respina P2, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Ventilator Respina P2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Ventilator Respina P2 is suitable for use in all establishments, including domestic establishments 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	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Ventilator Respina P2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ventilator Respina P2 should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input a.c. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input a.c. power	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input a.c. power	0 % U_T; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	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 test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Ventilator Respina P2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ventilator Respina P2should assures that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	Input a.c. power	3 V 0,15 MHz – 80 MHz	
	PATIENT coupling	6 V in ISM bands between 0,15 MHz and 80 MHz	
	Signal input/output parts	80 % AM at 1 kHz	
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2020)	
Proximity magnetic Fields IEC 61000-4-39	ENCLOSURE	Refer to the following table (table 11 of EN 60601-1-2: 2020)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380- 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430- 470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704- 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]

[a] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] r.m.s., before modulation is applied.

10- Pneumatic Diagram

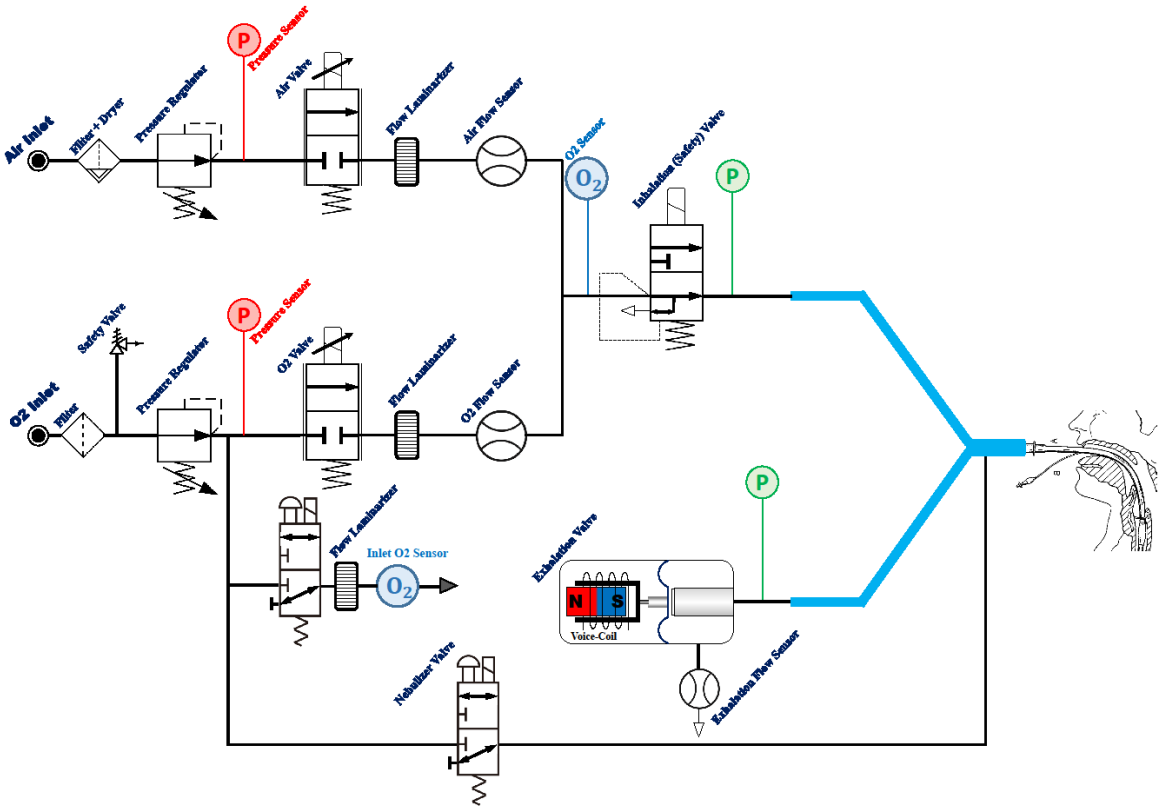


Figure 10-1 Pneumatic diagram

11- Troubleshooting

Alarm Message	Possible Cause	Corrective Action
High Inh Pressure	The maximum pressure during the inhalation exceeds the defined limit for the respiratory cycle. The airway has been occluded partially.	- Check the patient condition. - Check the device settings. - Check the alarm limits. - Check the patient airway.
High PEEP	PEEP pressure has exceeded high PEEP alarm setting.	- Check the device settings. - Check the alarm limits. - Check the patient airway.
Low PEEP	PEEP pressure has violated low PEEP alarm setting.	- Check the device settings. - Check the alarm limits
High MV	Exhaled minute volume has exceeded high MValarm setting.	- Check the patient condition. - Check the device settings. - Check the alarm limits. - Ensure that exhalation flow sensor is faultless and calibrated.
Low MV	Exhaled minute volume has violated low MValarm setting.	- Check the patient condition. - Check the device settings. - Check the alarm limits. - Ensure that exhalation flow sensor is faultless and calibrated.
High Vte	Exhaled tidal volume has exceeded high Vt_e alarm setting.	- Check the device settings. - Check the alarm limits. - Ensure that exhalation flow sensor is faultless and calibrated.
Low Vte	Exhaled tidal volume has violated low Vt_e alarm setting.	- Check the device settings. - Check the alarm limits. - Ensure that exhalation flow sensor is faultless and calibrated.
Vti Limit Reached	Inspired tidal volume has exceeded high alarm setting.	- Check the device settings. - Check the alarm limits.
High Rate	Respiratory rate (including spontaneous and mandatory breaths) has exceeded high alarm setting.	- Check the patient condition. - Check the device settings. - Check the alarm limits. - If Ftrig is used, ensure that exhalation flow sensor is faultless and calibrated.
Low Rate	Respiratory rate (including spontaneous and mandatory breaths) has violated low alarm setting.	- Check the patient condition. - Check the device settings. - Check the alarm limits.

Alarm Message	Possible Cause	Corrective Action
		- If Ftrig is used, ensure that exhalation flow sensor is faultless and calibrated.
Apnea	No breath has been delivered in set mode (no patient triggered breath or delivered breath by the ventilator)	- Check the patient condition. - Check the device settings (especially ventilation mode and trigger value) - Check the alarm limits. - If Ftrig is used, ensure that exhalation flow sensor is faultless and calibrated.
High Leak	Leak value has exceeded alarm limit.	- Check the patient airway. - Check the alarm limits. - Ensure that exhalation flow sensor is faultless and calibrated. - If the alarm persists, contact the Customer Service department.
Plim Reached	In volume based modes and during inhalation if the airway pressure exceeds“ high Ppeak alarm -5”	- Check the patient airway. - Check the device settings. - Check the pewssure alarm range.
High Oxygen	The oxygen concentration is too high compared with high alarm setting.	- Ensure that the oxygen sensor is faultless and calibrated. - Check the air and oxygen sources.
Low Oxygen	The oxygen concentration is lower than the lower with low alarm setting.	- Ensure that the oxygen sensor is faultless and calibrated. - Check the oxygen source. - Check the inlet pressure oxygen source concentration.
Low Input oxygen	The input oxygen concentration is lower than the minimum set limit.	- Ensure that the input oxygen sensor is faultless and calibrated. - Check the inlet pressure oxygen source concentration.
Volume Not Delivered	The set volume has not been delivered to the patient (in one of PRVC-CMV, PRVC-SIMV or VSV modes that the pressure is determined by the device).	- Check the device settings. - Check the alarm limits (high limit of Ppeak).
Disconnection	The breathing circuit from the ventilator to the patient is disconnected.	- Check the patient airway.
Occlusion	The breathing circuit or expiration valve has been occluded.	- Check the patient condition. - Check the patient airway. - Check expiration valve.
High O2 Pressure	The oxygen inlet pressure is more than the specified level.	- Check the oxygen source. - If the alarm persists, contact the Customer Service department.
Low O2 Pressure	The oxygen inlet pressure is lower than the specified level.	- Check the oxygen source. - If the alarm persists, contact the Customer Service department.

Alarm Message	Possible Cause	Corrective Action
	This alarm will not be enabled if the oxygen concentration is set to 21%.	
High Air Pressure	The air inlet pressure is more than the specified level.	- Check the air source. - If the alarm persists, contact the Customer Service department.
Low Air Pressure	The air inlet pressure is lower than the specified level. This alarm will not be enabled if the oxygen concentration is set to 100%.	- Check the air source. - If the alarm persists, contact the Customer Service department.
Exh Sensor Error	Exhalation flow sensor failure	- Ensure that exhalation flow sensor is connected securely. - Replace exhalation flow sensor and calibrate new sensor before use. - If the alarm persists, contact the Customer Service department.
Exh Not Fitted	The exhalation flow sensor is not in place properly.	-Make sure the flow sensor is connected properly.
O2 Sensor Error	O2 sensor failure	- Ensure that O2 sensor is connected to the system securely. - Replace O2 sensor and calibrate new sensor before use. - If the alarm persists, contact Customer Service department.
Input O2 Sensor Error	Input O2 sensor failure	- Ensure that input O2 sensor is connected to the system securely. - Replace input O2 sensor and calibrate new sensor before use. - If the alarm persists, contact Customer Service department.
Inverse Ratio	Inhalation time is more than exhalation time.	- Check the device settings.
High Gas Temperature	The gas output temperature of the device has exceeded the allowed temperature ranges. This is the allowed temperature ranges are: 42, 44 and 45, which activate the alarm from the lowest priority to the highest priority, respectively.	- Ensure that the temperature of delivered air or oxygen is not too high. - If the alarm persists, contact the Customer Service department.
Battery Low	Internal battery voltage is too low.	- Plug in the device to charge the battery. - If the alarm persists, contact the Customer Service department.

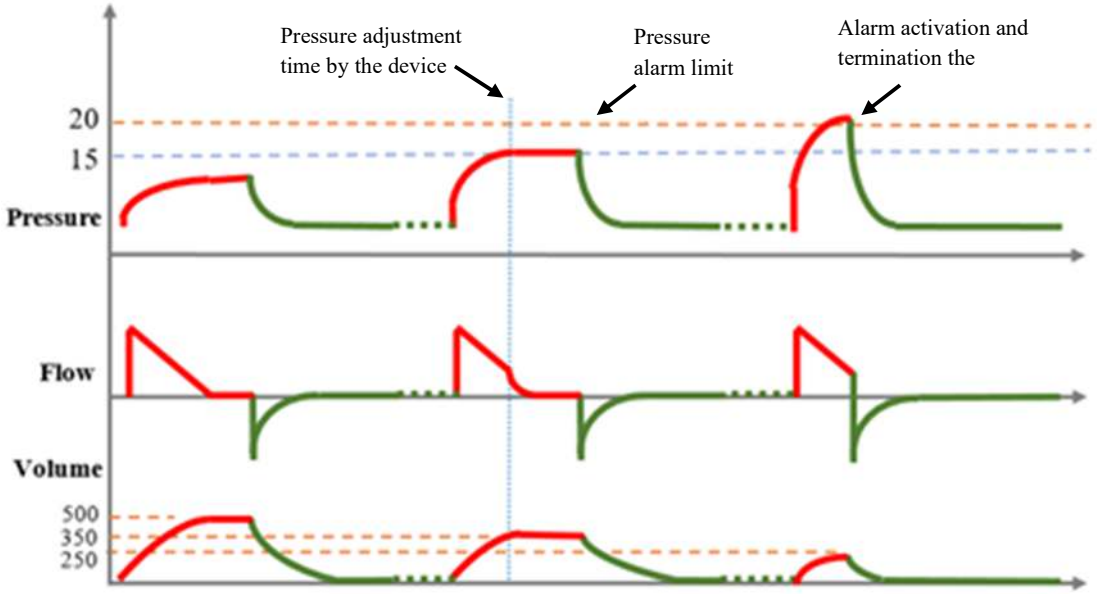
Alarm Message	Possible Cause	Corrective Action
AC Unplug	The device is unplugged.	- Plug in the device.
Battery Defect	The battery failure	Contact the Customer Service department.
No Battery	Both batteries or one of them are not connected to the device.	- Make sure the presence and connection of healthy batteries to the device. - If the alarm persists, contact the Customer Service department.
Battery check	The device has not been run on battery for a long time.	Let the device run continuously on battery for at least 30 minutes.
Error code XX	--	- Contact the Customer Service department.
Fatal Error X	--	- Contact the Customer Service department.
100% O2 Not Usable	High pressure oxygen source (higher than 1,2 bar) is not available.	Check the inlet oxygen source pressure.
Neb. Not Usable	Flow setting is lower than 11L/min. High pressure oxygen source is not available. The oxygen source pressure is out of range and the nebulizer will not activate.	Check that flow is not higher than 11L/min. Check the inlet oxygen source pressure.
Suction Not Usable	-The device is in the NIV mode. - 100% O2 key is pressed before selecting the suction maneuver. - “Low O2 Pressure” alarm is active.	- Disable the NIV mode. - Stop 100% O2 phse. - Check pressure of the oxygen source.

12- Attachments

This section of the manual provides a more complete explanation of some topics.

P_{lim} Reached alarm

In volume modes, if the airway pressure in five consecutive breaths approaches the level of the pressure alarm but does not pass, then a Plim Reached alarm is activated.



Pressure, flow and volume curves in VCV mode

Example: In the figure above, the VCV mode is set to a decelerating flow waveform with an adjustable volume of Vt = 500 mL and a pressure alarm level equal to Palarm = 20 cmH2O. If the airway pressure approaches the alarm limit, the device will prevent the pressure from increasing, but the inhalation phase will continue. However, if for any reason the airway pressure exceeds the alarm limit, the inhalation phase immediately terminates and atarts the exhalation phase.

Warning

⚠ **Note that if this alarm is activated, less volume may be delivered to the patient.**

⚠ **Continuation of the Plim Reached alarm may cause harm to the patient due to reduced delivery volume.**

Note:

Airway pressure depends on factors such as device settings, airway resistance and lung capacity.