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Preamble

This manual contains information on the BIYOVENT mechanical ventilator produced by BIOSYS Biyomedikal. Biyovent series ventilators consist of electronic, pneumatic and software sections. Although all possible measures against risks are taken in the design and production of the BIYOVENT ventilator, the patients to which it is connected shall be kept under constant surveillance against an unforeseen malfunction. Biyovent series ventilators are manufactured for use in the Intensive Care Units of the hospitals. It is not suitable for use outside of Intensive Care Units and Hospitals. If you encounter an unexpected effect, contact BİOSYS BİYOMEDİKALimmediately.

BIYOVENT ventilator is produced with advanced technology and entirely with domestic means as a result of the collaboration between Turkish Engineers and Turkish Medical Doctors. BİOSYS Biyomedikal continues its R&D studies for all kinds of new devices containing advanced technology required by the hospitals.

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The expectations of symbols that user manual is include

 Attention: The states that are cause physical injuries and life threats are explained under this title.

 Warning: The states that are cause a failure of Biyovent.

 Note: Extra information about suggestions of Biyovent usage, necessities and alternative methods are given under Note titles.

Part 1
INTRODUCTION

1.1. Introduction

This user manual contains information on the operation of the Biyovent series ventilators. Always read the manual before operating the ventilator system.

1.1.1. Area of Use and Purpose

Figure 1.1. Mechanic Ventilator Images

Biyovent, Intensive Care Mechanical Ventilator (breathing apparatus) is used to perform artificial respiration of the lungs of adult and pediatric patients during intensive care treatment.
Usage areas: surgery, intensive care units, laboratories, pediatrics.

1.1.2. Product Overview

Intensive Care Mechanical Ventilator is a device with pneumatic transmission, progressive respiratory system and automatic fresh air flow with volumetric ventilation option, color screen and wide monitor. The breathing apparatus provides mechanical ventilation to the patient's lungs and reflects various parameters of the patient's condition and helps to monitor the patient's condition.

Gas supply with the ventilator takes place as follows: Pressurized air and oxygen pass through the filter and valves that provide continuous pressure for both gases. Pure pressure sensors measure and control the pressure in the system. Air and oxygen passing through the pressure regulators go to the electromagnetic valve that supplies air for pneumatic control or gas through the valve system.

Mechanical ventilators allow breathing of patients in different ways. Biyovent mechanical ventilator supports patients' breathing in different modes. Differences in respiratory patterns or modes are caused by the difference between breathing being mandatory or spontaneous. In mandatory modes of breathing, the patient's breathing is under the control of the mechanical ventilator as a whole or partially. And in spontaneous modes, the patient's breathing is entirely by their own will or they get some support from mechanical ventilators.

Gas transfer begins with the connection of the ventilator to the wall-type air and oxygen source. The gas moves into the mixing module where gas pressures are arranged according to their respective valves. The valves measure the gases according to the ventilator settings entered, then the gases move to the mixing manifold and accumulator to be mixed by separate air and oxygen flow sensors. Gas pressures are constantly monitored in the manifold and in the accumulator equipment. Then, the mixed gases flow to the inspiratory pneumatic system where they shall be delivered to the patient via the breath delivery flow sensor and the inspiratory valve.

Before the gas reaches the patient, it passes through a bacteria filter and then through an external bacteria filter to which the respiratory circuit is connected. When the gas returns from the patient, it passes through the expiratory extension of the respiratory circuit, and then passes through the expiratory valve flow sensor and expiratory valve. The gas discharge path allows the delivered gas to flow out of the ventilator and into the room.

The ventilator defines the patient's respiratory effort by using pressure triggering or flow triggering method. During pressure triggering, airway pressure decreases as the patient breathes and the inspiratory pressure transducer monitors this drop. Respiratory effort is triggered when the pressure drop exceeds the threshold value. The current difference between inspiration and expiration line is measured during the current triggering. Respiration is triggered when the current difference between the two lines exceeds the threshold value as a result of the patient's effort. In both triggering systems, threshold values are determined by the user. Threshold values shall be set by the user so that they shall be specific to each patient.

1.1.3. Customer Services

For subjects that you want to obtain more information, you may visit www.biosys.com.tr or contact the company by e-mail with the following address:bilgi@biosys.com.tr.

1.1.4. User Profile

The intended use of the device is to provide lung support to be applied to people who cannot meet their respiratory requirements. Device users who shall apply ventilation to a patient are specialist operators trained in respiratory physiology, and persons experienced in mechanical ventilation. The user manual shall be read before operating the device. Users shall participate in the company's User Trainings, and shall always follow the rules for assurance and traceability. Professional judgment shall be applied on the information provided, and support shall be obtained from the user training unit for the device by contacting the company at the following address: bilgi@biosys.com.tr.

The operator shall perform the ventilation operation settings as per the patient's clinical condition and keep the patient under application under constant surveillance.

When applying the device to a patient, the patient and the device shall not be left unattended. Compatibility of the device with the patient shall be judged by the user during the application, and in case of an unexpected complication caused by the device or patient, there shall be a staff member present, who may respond the patient using an ambu bag by interrupting the interaction of the device and patient.

1.1.5. Applicability

This user manual has been prepared for the operation of Biyovent brand intensive care type medical ventilatorsmanufactured by Biosys Biyomedikal Mühendislik. Visit www.biosys.com.tr to access the latest version of the document or notify and request information by e-mailing to the bilgi@biosys.com.tr address.

1.1.6. Copyright Information

Intensive care type medical ventilators with Biyovent logo are internationally registered trademarks of Biosys Biyomedikal Mühendislik A.Ş.. This booklet contains information on the operation of the Biyovent device as a user manual for the product called Biyovent. This information is the exclusive property of Biosys and cannot be reproduced without permission. This manual can be reviewed and changed without notice, when required, by Biosys. You shall ensure that you have the latest version of this manual. For information on this subject, you can visit www.biosys.com.tr, send an e-mail to bilgi@biosys.com.tr or contact Biosys Technical Support Team. While the accuracy of the information provided in this handbook has been tested with some research and tests, it cannot be prioritized against the decisions made by professional users using their judgment. The limited warranty is valid and Biosys A.Ş. performs its responsibilities under the limited warranty as long as the limitations and conditions specified in the warranty of the device are met. The device shall only be used by users with the professional user profile and with the qualifications specified in the manual. No technical intervention shall be made on the device by persons other than the members of the technical service of Biosys. No manual, including the provided information in this manual, shall restrict or prevent the revision or modification of software, hardware, or mechanics of any equipment of the device, performed by Biosys Biyomedikal A.Ş. without prior notice.

1.1.7. Technical Services

To obtain technical assistance, or to order a user manual or service manual, please contact the BİOSYS technical service team using the following number: 0312 472 54 63.

Contact the Biosys technical service team in case of a problem that is not included in the user's manual or that you cannot correct while using the ventilator. Service manual contains information on the operation or repair of the ventilator when it is used by the authorized personnel.

1.1.8. Warranty Information

For information on the warranty conditions of the device, please contact BİOSYS technical service team from the following e-mail address: teknikservis@biosys.com.tr.

1.1.9. Manufacturer

Biosys Biyomedikal A.Ş.

Üniversiteler Mahallesi, İhsan Doğramacı Bulvarı SATGEB Ortak Binaları, ODTÜ Teknokent D:No:23/C, Çankaya ANKARA, TÜRKİYE

1.1.10. Electromagnetic Compatibility

Ventilator system complies with the requirements of TS EN 60601-1-2: 2016, EN 60601-1-2: 2015, IEC 60601-1-2: 2014 standards with its electronic field sensitivity at the level of 3 volts per meter and in the 80 MHz-2.7 GHz frequency range. However, in terms of device immunity, certain devices (mobile phones, radios, pagers, RFID devices, etc.) emit radio frequencies that may disrupt the operation of the ventilator when they are used close to the ventilator. Operators shall be aware against the radio frequency interference when a portable device is used near the ventilator.

1.1.11. Technical Specifications of the Device

Ergonomic Design

- Sleek design with modern features,
- 180° rotatable full touch screen with high resolution
- Touch type quick access keys,
- Upper body detachable from the feet,
- Easy-to-use expiratory valve,
- Protective and securing carrying handles,
- Castors with improved impact absorption

Intelligent Safety System

- Intelligent Alarm Definition,
- Gradual Alarm Levels,
- Adjustable Apnea Duration and Apnea Backup Mode,
- Leakage Compensation,
- Tube Compensation,
- Comparative Sensor Measurement,
- Paramagnetic Oxygen Sensor,

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- Monitoring of the patient trend for a period of 1 week,
- System Logging for 1 Month,
- Internal Battery 2hours,
- 5ms Valve Response time,
- 100mbar Emergency Valve,
- 50mbar Automatic Expiratory Discharge,
- IP21 Sealing
- Expiratory Valve suitable for autoclaving or sterilization with Ethylene Oxide
- 2-Year Warranty (provided by the manufacturer)
- Biyovent makes 16bit measurements at 1KHz rate from 28 sensor channels to increase the compatibility of the device with the patient.

Pressure Controlled Modes

- P-ACV
- P-SIMV+PS
- P-CMV
- P-PSV
- P-Bilevel
- APRV

Volume Controlled Modes

- V-ACV
- V-ACV (PRVC)
- V-CMV
- V-SIMV+PS
- V-SIMV (PRVC)+PS

Spontaneous Modes

- SPN-PS
- SPN-VS

Patient Compatibility and Performance Compliance Pediatric

- Number of Breaths: 1-150/minute
- T inspiration: 0.1-10 seconds
- Tidal Volume: 0.02-0.3 Litres
- Flow: 2-30 Litres/Minute

Adult

- Number of Breaths: 1-100/minute
- T inspiration: 0.1-10 seconds
- Tidal Volume: 0.1-3 Litres
- Flow: 2-120Litres/Minute

Operating Specifications

- Inspiration Pressure: 2-100 mBar
- Inspiration period: 0.1-10 s
- Peep Pressure: 0-50 mbar
- Breathing Speed: (p) 1-150/min.
  (a) 1-100/min.
- Tidal Volume: (p) 2-40 lt/dk
  (a) 2-120 lt/dk
- O2 Mixture: 21-100%
- Spontaneous Pressure Support: 0-100 mbar
- I/E Ratio: 1:10 (x60*)-10:1

(p): Pediatric, (a): Adult

Specifications of Pressure Source

- O2 Pressure: 2-7 Bar Central System/Tube

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- Air Pressure: 2-7 Bar Central System/Tube
- Automatic replacement and alarm indication in case of expiration of the resource
- Ability to Operate with Medical Compressor / Regulator

Electrical Specifications

- Battery Period: 2 hours
  + 8 hours (Optional)
- Mains Voltage: 180 - 264 VAC
- Power Consumption: 47 - 63 Hz 100W

Size and Weight

- Length: 150 cm
- Depth: 58 cm
- Width: 58 cm
- Weight: 55 Kg
- Display Movement: Left and right: 150˚
  Up and down: 15˚
- Display: Full touchscreen

Digital Interfaces

- USB: 4x
- COM: 2x
- LAN: 2x
- HDMI: 1x
- Display Port: 1x
- Mic. In: 1x

1.1.12. Symbol Descriptions

Table 1-1. Symbols on the Packaging and the Product and Their Descriptions

Symbol	Description	Symbol	Description
	CE 93/42/EEC Directive.		Air filter.
	Manufacturer.		Fan inlet.
	Part number.		USB port.

	Attention! Fragile.		Handling direction.
	Keep in a dry environment.		Max. 2 stacks
	Refer to the user manual.		Max. 4 stacks
	BF-type applied part.		Packaging shall be dissambled from the top.
	IEC Material Ingress protection class - Protected against condensation and ingress of fingers and similar objects		Carry by holding from the handling areas only.
	Protective Earthing.		Do not lean on your knee.
	WEEE - Proper waste disposal. Follow the local administrative regulations on disposal of waste with the WEEE symbol.		Do not drop anything on it.
	Do not push - Do not push from the GUI side.		Weighs 55 Kg

	System on/off button.		Do not drop or tip over.
	AC power inlet.		Do not handle with attachment.
	Humidifier power inlet.		

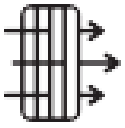
1.1.13. **Abbreviations**

GUI	Graphical User Interface is the general name used to identify software products that aim to facilitate operation of the device by symbolizing commands executed on a computer with various formal and colorful designs.

1.2. Safety Warnings

1.2.1. **Safety Symbols and Descriptions**

Table 1-2. Safety Symbols and Descriptions

Symbol	Description
 ATTENTION!	Warnings.
 WARNINGS!	Indicates possible failures on the device.
 NOTE	Provides additional information.

1.2.2. General Warnings

	This product complies with 2011/65/EU: Directive on the restriction of the use of certain dangerous substances in electrical, electronic home and office equipment.
 ATTENTION!	Only authorized medical personnel shall attempt to set up the ventilator and manage the therapy through the ventilator to ensure proper use and prevent the risk of a physical injury.
	Failure to access suitable alternative ventilation tools immediately in case of a malfunction of the ventilator may result in the death of the patient. An alternative source of ventilation (with mask, as specified in ISO 10651-4) shall also be available when using the ventilator, such as a self-inflating, manually operated respirator.

	Patients using mechanical ventilation shall be supervised by trained personnel to ensure the use of the appropriate ventilation mode.
	The ventilator system is not intended as a comprehensive monitoring device and does not trigger an alarm for all conditions. Read this manual before using the ventilator to understand the ventilator's operating system in more detail.
 ATTENTION!	Topreventinjurytothepatient,donotusetheventilatorif thereisavisiblefailure. Replace the ventilator and have the defective part repaired by BİOSYS BİYOMEDİKAL service personnel.
	To prevent injury to the patient, do not modify the ventilator.
	Do not insert tools or other objects into the ventilation openings to prevent injuries and intervention with the operation of the ventilator.
	The volume of the audible alarm may be adjusted. The user shall adjust the volume of the audible alarm toa level that he/she may recognize the alarm against the noise on the background.

	Do not turn off and turn down the volume of the ventilator's audible alarm system when patient safety may be at risk.
	If a pressure increase is observed during ventilation, check if the airway is open and check for the occlusion of the circuit.
	Do not intervene with bare hands when the LCD screen is broken. Collect the parts of the broken LCD panel with appropriate protective gloves to ensure that it is disposed of as hazardous waste in accordance with local laws.
 **ATTENTION!**	"Although the Biyovent Series ventilators meet the standards specified in their manual, the Lithium Ion battery contained in the device is specified within the cover of the Dangerous Goods according to the European Agreements on the Transport of Dangerous Goods and it is classified as Class 9 - Miscellaneous Dangerous Goods and Objects. Within the scope of commercial activities, together with the relevant lithium ion battery included in the content of the ventilator, it is subject to the relevant specified conditions of the (AITA-ICAO) regulations for airway transport, (IMDG Code) regulations for maritime transport, (RID) regulations for railway transport and (ADR) regulations for road transport, in the national or international transport activities. Transport operations performed by the users of the device within the scope of personal use that are not considered as commercial activities are not subject to these regulations. "
	This device is classified as II B according to Annex IX to the EU Directive 93/42/EEC.
	Dispose of your product's packaging waste separately from other waste, as per the instructions of the local authorities, for environmentally safe recycling.
	Do not dispose of the product with domestic waste when it has reached the end of its service life. Take it to the recycling center to ensure recycling of electrical and electronic equipment.
 Pb	Dispose of used batteries as per local laws and regulations. The symbol on the battery and packaging indicates that the battery delivered with the product shall not be treated as domestic waste. On some batteries, the symbol may have been used in combination with a chemical symbol. If the batteries contain more than 0.0005% mercury or more than 0.004% lead, the chemical symbol Hg is added for mercury and Pb is added for lead. By ensuring that the batteries are disposed of correctly, you shall contribute to the prevention of potential damage to the environment and human health as a result of improper disposal of the batteries.

1.2.3. Warnings on the Operation Environment

 ATTENTION!	Biyovent considers standard temperature as 20 °C and dry pressure as 101,3 kPa.
	Biyovent considers the body temperature of the patient as 37 °C and saturated humidity of air as 100% relative humidity.
	Do not completely or partially cover the ventilator's air inlet and the openings of cooling fan and the alarm speaker. Covering them may cause irreparable results.
	To ensure proper operation of the ventilator, do not position the power input cable in an area that is difficult to access.
	Do not apply different pressures that may change atmospheric pressure in the operating environment of the ventilator. This device is not suitable for use in environments where the atmospheric pressure changes.
	Do not use the ventilator in highly magnetic environments. Using in environments with high magnetic fields may cause the ventilator to malfunction.
	Do not use the ventilator during radiotherapy.
	Do not use the ventilator as a portable ventilator.
	Check for leaks before operating the device.
	Contact the biomedical engineering department of your institution if your Biyovent device is not working or before repositioning any life support equipment. Check the peripheral connections of the device and avoid operations such as hanging, pulling, or applying pressure.

1.2.4. **Warnings Against the Risk of Fire**

 ATTENTION!	Explosion Hazard Do not operate in environments with flammable gases. It becomes more flammable in an oxygen-rich environment.
	To prevent the risk of fire, keep the components of the device away from flammable materials.
	In case of a fire or smoke, immediately disconnect the patient from the ventilators and the ventilator's oxygen supply if it is safe to do so. Disconnect the power of the device.
	The battery of the ventilator shall not be changed by anyone other than the technical service team authorized by BİOSYS BİYOMEDİKAL and the device shall not be intervened for repairs for any reason.
	To minimize the risk of fire, inspect, clean and replace the ventilator's damaged parts that come into contact with oxygen as required.
	To avoid the risk of electrostatic discharge (ESD) and fire, do not use antistatic or electrically powered hoses or tubes in or near the ventilated breathing system.

1.2.5. **Electrical Warnings**

 ATTENTION!	To prevent the risk of electric shock:
	Use genuine Biosys batteries and cables only.
	Do not disassemble the device and do not touch the parts inside the device.

	There is a backup battery system available in the ventilator, against the failure of the mains power or voltage drops below 90 volts approximately. A fully charged battery ensures that the ventilator operates for a minimum of 2 hours at the factory default ventilator settings.
	The ventilator is recharged whenever it is plugged into the mains voltage. If the ventilator is running on battery power, the charge level of the battery is indicated instantly on the status screen.

1.2.6. Warnings on Ventilator Settings

	The operator who shall use the ventilation device shall be a healthcare professional experienced and trained on mechanical ventilators. The operator shall perform the ventilation operation settings as per the patient's clinical condition and keep the patient under application under constant surveillance.
	Use proper alarm limits.
 **ATTENTION!**	Selecting the accessories that shall interact with the patient improperly, failure to maintain them or applying them to the patients may result in incorrect ventilation. Proper accessories shall be applied and inspected by a trained healthcare professional.
	As the internal volumes of the extra accessories to be attached to the device are not defined, these accessories may cause incorrect results in ventilation calculations. Do not use accessories that are not recommended by BİOSYS BİYOMEDİKAL.
	Setting improper alarm limits prevents the device from issuing alarms in conditions that require intervention. Alarm limits shall be adjusted according to the physiological condition of the patient. Do not tamper with alarm limits to mute alarm conditions that may occur.
	Choose the right patient set before starting ventilation of the patient.

1.2.7. **Warnings on gases**

 ATTENTION!	Equipment that can be contaminated by body fluids or used gases in the Gas Path are as follows. - External inspiratory filter - Internal inspiratory filter - inspiration valve - Expiratory valve -
	Do not use antistatic or electrically operated hoses or tubes near the ventilator system.
	Use gas hoses that are recommended by BİOSYS only.
	Lock the castors before installing or lifting the ventilator.
	Patients who are ventilated may be vulnerable to infection. Do not perform non-sterile applications. Always refer to infection control guides of the hospital for accessories under risk of infection. Follow the instructions provided in this manual and hospital protocols for cleaning and sterilization of the ventilator and its components.
	Attach a bacterial filter to the inspiratory and expiratory connections of the device against the risk of infection that may occur within the ventilation device. Replace the patient set, filters, and the expiratory valve before each ventilation procedure.

1.2.8. **Warnings on Accessories**

 ATTENTION!	Do not use electrically operated hoses or tubes.
	Adding accessories to the ventilator may affect the performance of the ventilator. Adding accessories that are not recommended by BİOSYS BİYOMEDİKAL maycause incorrect ventilation operations.
	Frequently inspect the filters connected to the ventilation device and the patient set.
	Using non-recommended connectors may cause disconnection of the patient set connections.

	Carefully plan the paths of the cables and connectors that shall be connected to the ventilator device and the peripheral cables and connectors to reduce the risk of injury to the patient.
	Always use filters designed for use with the Biyovent series ventilators. For the relevant filters, see Biyovent accessories.
	Empty the water trap reservoir on the expiratory valve to prevent fluid contact with the ventilator.

1.2.9. Warnings on Accessories and Their Standards

 ATTENTION!	Installed to the device; patient circuit connectors shall conform with ISO 5356-1: standard, Patient circuit shall conform with: ISO 5367 standard, Humidifying equipment shall conform with: ISO 8185 standard, Power cable shall conform with: IEC 60601-1 standard, The device shall be approved for compliance with IEC 60601 - 1- 11:2015 with all accessories and equipment. For relevant information, contact the technical support from the following address: bilgi@biosys.com.tr.

1.2.10. Warnings on Ventilator Maintenance

 ATTENTION!	In order to ensure proper operation of the ventilator, the maintenance of the ventilator shall be carried out by authorized service technicians trained by BİOSYS BİYOMEDİKAL. Nobody other than the technical service team authorized by BİOSYS BİYOMEDİKAL shall intervene the device.
	Biyovent requires preventive maintenance once every six months. Spare parts or kits are not recommended for preventive maintenance.

1.2.11. Manufacturer's Declaration

 WARNINGS!	Portable and mobile RF communications equipment may affect the performance of the ventilator system. Install and use this device as per the information provided in this manual.
	Unless otherwise stated elsewhere in this manual, the ventilator system shall not be used as adjacent to or stacked with other devices. If it shall be used as adjacent to or stacked with other devices, the ventilator system shall be observed to verify normal operation in the configurations with combined use.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall not be used closer than 30 cm (12 inches) to any part of the ventilator, including cables specified by the manufacturer. Otherwise, the performance of this equipment may be affected adversely.

 ATTENTION!	This device is not intended for residential use and may not provide adequate protection against radio communications in such environments.

 NOTE	The emission characteristics of this equipment are suitable for use in industrial areas and hospitals (CISPR 11 class A). When used in households (this normally requires CISPR 11 class B), this equipment may not provide adequate protection against radio frequency communication services. The user may need to take mitigating measures, such as repositioning or rerouting the equipment.

1.2.12. Electromagnetic Emissions

Table 1-3. Electromagnetic Fields of Study

This ventilator is intended to operate in the electromagnetic environments specified below. The user or customer of the ventilator shall ensure that the ventilator shall be used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions emitted CISPR 11	Group 1 Class A	Ventilator uses RF energy for internal functions only. Ventilator is intended to be used in hospitals only and it shall not be connected to the mains supply.
Harmonic emissions IEC 61000-3-2	Class A	Ventilator is intended to be used in hospitals only and it shall not be connected to the mains supply.
Voltage fluctuations / flickering IEC 61000-3-3	Compatible	

	Compliance with WEEE Directive and Disposal of Waste Product This product does not contain harmful and prohibited substances specified in the "Regulation on Control of Waste Electrical and Electronic Equipment" published by the Ministry of Environment and Urbanization of Turkish Republic. Complies with WEEE Regulation. This product is made of high quality parts and materials that are recyclable and reusable. Therefore, do not dispose of the product with domestic or other waste at the end of its service life. Deliver it to a collection point for the recycling of electrical and electronic equipment. Ask these collection points to the local administration in your area. Help protecting the environment and natural resources by recycling used products. For the safety of children, cut off the power plug before disposing of the product.

1.2.13. **Points To Be Considered**

 **WARNINGS!**	To prevent damage to the device, ensure that the castors are locked during maintenance operations or on inclined surfaces to prevent the movement of the ventilator.
	To ensure full performance, keep the touch screen clean and away from materials that may cause damage.
	Do not use unapproved cleaning agents.
	Do not block the fan vents.
	Install the expiratory and inspiratory filters as specified in the Installation Manual.
	Follow the steps in the Biyovent series installation manual for proper installation of the display.
	Remove the spare batteries of the ventilator before taking it out of the hospital. Failure to remove the batteries may cause damage.

1.2.14. **Notes**

 NOTES	The use of this device by persons who have not received training on mechanical ventilation is prohibited by law.
	During non-invasive (masked) ventilation, there may be a leakage from the edges of the mask worn by the patient. This leakage may cause deviations in ventilation calculations.
	There may be information that are not defined or unavailable in this manual. For detailed information, please contact BİOSYS BİYOMEDİKAL. All applications that not specified in this manual are the responsibility of the operator using the device.
	The user of the device shall be solely responsible for the adverse consequences of technical interventions by those who have not received the user training offered by Biosys, or who have not adopted the user manual and safety system.
	To eliminate the risk of electric shock during the service of the ventilator: If the device is on, turn it off, unplug it from the mains supply, turn the switch on the back cover off, open the back cover, and disconnect the battery connections. Make sure that the power is cut off completely.

1.2.15. **Screen Controls and Indicators**

Following symbols and descriptions are available on the user screen.

Table 1-4. Screen Controls and Indicators

Symbol	Description	Symbol	Description
	Battery Full		Battery Low (Connect to Power Supply)
	Batteries Are Being Recharged		Turn Off Alarm For 2 Minutes
	Confirm Selection		Cancel Selection

	Scroll Right		Scroll Left
	Male		Female
	Child		Turn the System Off
	Previous Patient Information		Humidifier Active
	Screen Lock On		Restore Settings
	New Patient Information		Lock Screen
	Slider Increase		Dynamic Lung Indication
	Settings		O2 level

Part 2
GENERAL INFORMATIONS

2.1. Product Views

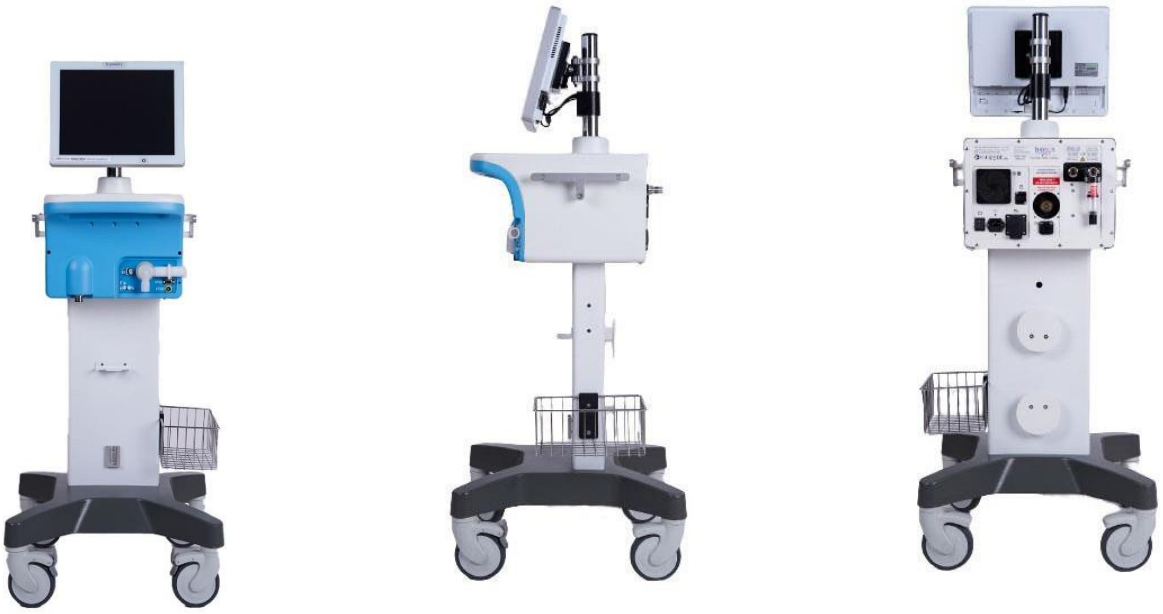


Figure2.1 Biosys Product View

2.2. Technical Speciation's of the Product Hardware and Software

2.2.1. **Full Touchscreen User Screen**

The device receives the commands from the user via this full touch screen, commands are executed thanks to the GUI software running on the screen, and the results are also displayed to the user through this screen.

In the lower half of the screen, there is a cover that may only be intervened by the Biosys Technical Support Team to close the screen and electrical connections. On the upper middle surface of the screen, thereare no other operators than the alarm, such as a keypad etc.

Figure 2.2. Full Touchscreen Display

You may turn on the device by pressing and holding the ON button of the device on the bottom right of the screen for 3 seconds.

ATTENTION!	Do not intervene the back cover of the display, and prevent any intervention.
	The user of the device is responsible for any interventions to the back cover of the display by persons other than the authorized department.
	Except for the interventions by Biosys Technical Support Team, the warranty of the product shall be void if it is determined that the security strip on the back cover of the display is broken, it the back cover is found to be tampered with a sharp or pointed tool.

ATTENTION!	If the display has been intervened by the Biosys Technical Team, the security tape on the cover is delivered as renewed.
	Display shall be cleaned by wiping with a sterile cloth and solution if the device is off.

2. Mounting Configurations

The ventilator system may be mounted independently at the patient's bedside. The screen and body may be mounted on a wheeled base and there is a handle for moving the system.

3. Battery Support

The ventilator system is equipped with a battery system in order to provide backup power in case of a power failure from the mains supply. The instantaneous charge status is displayed on the status screen while running on battery power. The device sounds an alarm and warns the operator when the battery charge level reaches a critical level.

4. Screen Symbols and Abbreviations

The following table contains the symbols and abbreviations used on the ventilator.

Table 2-1. Screen Symbols and Abbreviations

Symbol	Description	Symbol	Description
T_A	Apnea Period	C_{DYN}	Dynamic compliance
R_{DYN}	Dynamic Resistance	**EEF**	Expiration end flow.
P_{LEND}	Inspiration end pressure.	**LEAK**	Expiration leak.
LEAK$_Y$	Expiration leak on PEEP as measured by the proximal flow sensor.	V_{ET} **MNT**	Mandatory tidal volume expirated.
$V_{E\ TOT}$	Expiration minute volume.	$V_{E\ SPONT}$	Spontaneous minute volume expirated.
$V_{TE\ SPONT}$	Expiration spontaneous tidal volume.	V_{TE}	Expiration tidal volume.
E_{SENS}	Expiration sensitivity	T_E	Expiration period.
V_{SENE}	Flow sensitivity.	**V-**$_{TRIG}$	Flow triggering.
P_H	High pressure setting.	T_H	High pressure period.
T_H**:** T_L	Ratio of high pressure period to low pressure period.	**I:E**	Inspiration period/Expiration period.
C_{20}**/C**	Ratio of high pressure period to low pressure period.	V_{LEAK}	Inspiratory leak.
T_I	Inspiration period.	P_I	Inspiration pressure.
V_{TI}	Inspiration tidal volume.	P_L	Low pressure setting.
T_L	Low pressure period.	P_{MEAN}	Mean circuit pressure.
NIF	Negative inspiration force.	**%**O_2	Oxygen percentage.

$P_{0,1}$	Airway occlusion pressure 100 ms.	**C_{PAV}**	PAV-based lung compliance.
E_{PAV}	PAV-based lung elastance.	**% Support**	Percentage support setting for whole compensation and PAV+.
R_{PAV}	PAV-based patient resistance.	**R_{TOT}**	PAV-based total airway resistance.
WOB_{TOT}	PAV-based respiration operation of the patient and the ventilator during inspiration.	**P_{PEAK}**	Peak circuit pressure.
PEF	Peak expiratory flow.	**V_{MAX}**	Peak inspiratory flow.

PSF	Peak spontaneous flow.	**PEEP**	Set or monitored positive expiration end pressure.
%LEAK	Leak percentage.	**P_{PL}**	Plateau pressure.
T_{PL}	Plateau period.	**P_{COMP}**	Compensation pressure.
P_{SENS}	Pressure sensitivity.	**P_{SUPP}**	Pressure support level.
P_{-TRIG}	Pressure triggering.	**V_{TIY}**	Proximal inspiration tidal volume.
V_{TEY}	Proximal expiration tidal volume.	**$V_{TI\ MND}$**	Proximal mandatory inspiration tidal volume.
$V_{TI\ SPNT}$	Proximal spontaneous inspiration tidal volume.	**V_{TLY}**	Proximal inspiration tidal volume when VLTY leak is activated.
Rr	Respiration speed and number of apnea respirations.	**RR/ V_T**	Spontaneous rapid/shallow respiration index.
$T_{I\ SPONT}$	Spontaneous inspiration period.	**T_I / T_{TOT}**	Spontaneous inspration period ratio.
C_{STAT}	Static compliance.	**R_{STAT}**	Static resistance.
V_T	Tidal volume.	**$PEEP_{TOT}$**	Total PEEP.
Rr_{TOT}	Total respiration speed (observed).	**VC**	Vital capacity.
VS	Volume Support.		

2.2.5.Audible Indicators

The alarm limits set on the user screen are issued in various tones. (Varies by model).

NOTES	Alarms are muted for 2 minutes when mute alarms button is pressed.

Table 2-2. Audible Indicators

Alarm Type	Description
High priority alarm tone	Three tones are repeated continuously. Sounds when a high priority alarm occurs

2.2.6.Connectors

Connectors specified below are available in the ventilator:

- Ventilator outlet port (Port to the patient): Coaxial conical connection with the size of 22mm where the external inspiratory bacteria filter is attached.
- Expiratory port (Port from the patient): The expiration extension of the patient circuit is connected to the inlet of the expiratory bacteria filter. This port is compatible with the 22mm conical connection.
- Proximal Flow Sensor: To prevent inadvertent disconnections, a keyed pneumatic connector with locking feature is provided for the proximal flow sensor.
- Standard interface connectors: USB, HDMI and Ethernet connectors are provided.

3. Installation of Product

1. Installation of the Components of the Ventilator

Installation of the ventilator shall be performed by service personnel who are trained and authorized by BİOSYS BİYOMEDİKAL. Nobody other than the technical service team authorized by BİOSYS BİYOMEDİKAL shall intervene the device. Installation instructions for the ventilator are not included in this manual. For the installation instructions, (See Biyovent Installation Manual).

2. Use of Mains Power

The ventilator operates with the mains power under normal conditions. To connect the ventilator to mains power, (See Connecting the Ventilator to the Mains Power)

3. Battery Usage

While the device connected to the mains power is on, it also recharges its batteries. Fully charged batteries support ventilator operation up to 2 hours in case of a power failure.

4. Installation of the Ventilator

Installation of the Biyovent Ventilator and its initial operation is described here. Be sure to read and understand the user manual to avoid any problems.

 NOTES	No part of the ventilator contain latex.

 ATTENTION!	Always use the ventilator on a flat surface to avoid interruption of operation or damage to the ventilator.

1. Connect the ventilator to power sources and hospital sources.
2. Connect the patient circuit to the ventilator.
3. Turn on the ventilator using the power switch

2.3.5. Packages of Device

Device is delivered as 2 different boxes by Biosys. The first box containing the body (Box 1 Body-Device Serial Number) and the second box (Box 1 Leg-Device Serial Number) are distinguished by their names.

 NOTES	Make sure that the Device IDs on Box 1 and Box 2 are the same.

Table 2-3. On the Box or Packaging:

Name	Intensive Care Type Mechanical Ventilator
Model	BİYOVENT
Serial number	xxxxxx
Box: Contents	Box 1 Body (or) Box 2 Leg

Table 2-4. Contents of Box 1: (Box 1 Body-Device Serial Number)

Quantity	Equipment
1	Instructions for Installation
1	User Manual
1	User Interface Screen GUI
1	Device Body

Table 2-5. Contents of Box 2: (Box 2 Leg-Device Serial Number)

Quantity	Equipment
1	Patient Connection Tube
1	Gas Hose
1	Wheeled Base of the Device
1	Power Cable

A Biyovent Ventilator installed with equipment and accessories weigh approx. 55 kg. While lifting the device, it shall be lifted by gripping the gray handles on both sides of the body in a balanced manner.

 WARNINGS!	The weight of the device may be more than one or more people may carry (judge the weight you can lift before lifting the device against the risk of crushing, pinching or injuries of your foot, and avoid lifting the device).
 ATTENTION!	Dropping the device you have lifted in the air suddenly, quickly and harshly may damage the device and harm you.

2.4.Positioning of the Product

 WARNINGS!	Carry the ventilator with proper orientation by holding with both hands from the side grips on a flat, smooth floor, to avoid adverse effects or damage to the operation of the ventilator.

Ventilator shall be positioned so that it shall stand by the bedside of the patient on its castors.

PART 3

BIOSYS PRODUCT CONNECTIONS

3.1. Connecting the Ventilator to the Mains Voltage

 NOTES	Access to the power outlet and location of the power cable: Make sure that the power outlet used for the ventilator is easily accessible, and that the only way to disconnect it from the outlet is to completely remove the power from the ventilator.
 WARNINGS!	Connect the ventilator to a grounded electrical outlet to ensure proper ventilator operation and to prevent the risk of electric shock.
 ATTENTION!	Make sure that the device is plugged into an outlet known to be grounded well and that supports 220V, 5 Amps.

Figure 3.1. Connecting the Ventilator to the Mains Voltage

NOTES	The ventilator shall be connected to the mains from the inlet shown by1 in the figure above.
	The button indicated by 2 in the figure above is the machine's on/off switch.

3.2. Connecting to Gas Sources

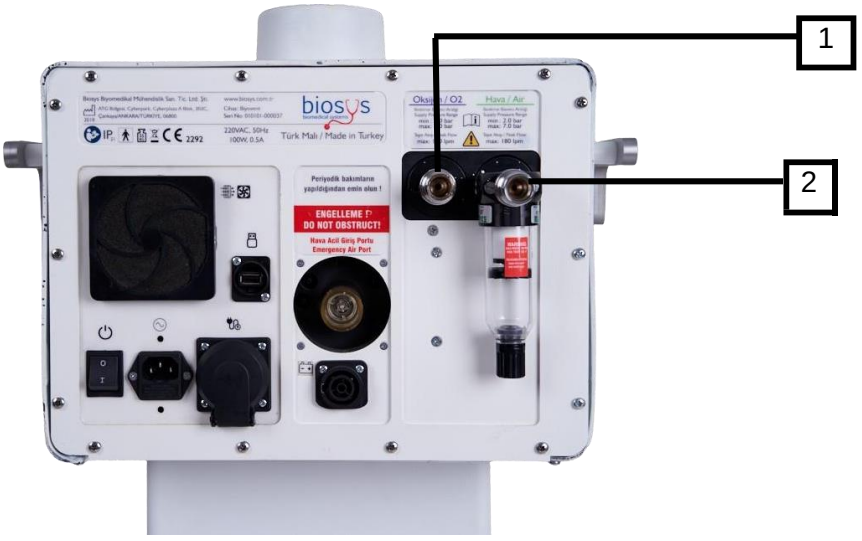


Figure 3.2. Connecting to Gas Sources

NOTES	Pressurized oxygen supply is properly installed at the machine inlet, indicated by 1 in the figure above, with the help of a Jack + Suitable pipe.
	Compressed air source is properly installed at the machine inlet, indicated by 2 in the above figure, with the help of a Jack + Suitable pipe.

3.3. Installation of a Filter

Ventilator are delivered with external and internal inspiratory filters. Inspiration and expiration filters shall be used in ventilators to prevent the risk of infection.

ATTENTION!	To minimize the risk of infection, always use the ventilator with inspiratory and expiratory bacteria filters.
	Do not use filters designed for use with ventilators other than the BİYOVENT ventilator.
	Do not re-use disposable inspiratory and expiratory bacteria filters and ensure that they are disposed of as medical waste as per the local legislation.

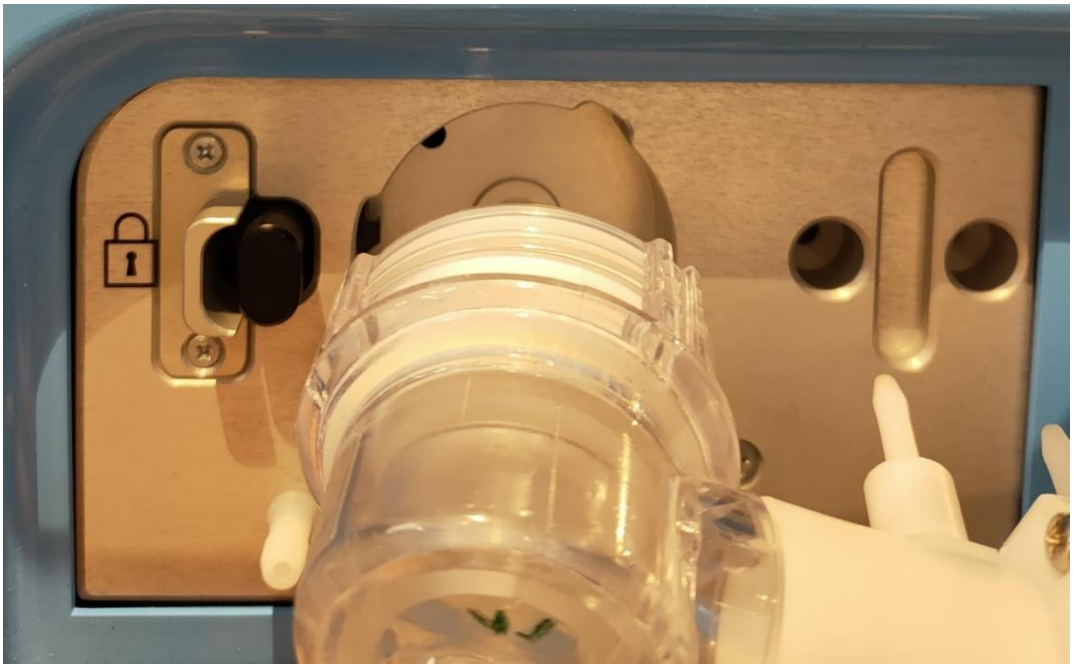


Figure 3.3. Installation of a Filter

NOTES	Filter shown with A on the figure above is properly connected to the machine inlet shown with 1 from the end shown with 2.

3.4. Connection of the Patient Circuit

Figure 3.4. Connection of the Patient Circuit

NOTES	The part of the patient tube that allows delivery of air to the patient shall be properly connected to the machine inlet shown with 1 on the figure above.
	The part of the patient tube that allows return of air from the patient shall be properly connected to the machine inlet shown with 2 on the figure above.

3.5. Connection of the Flex Arm

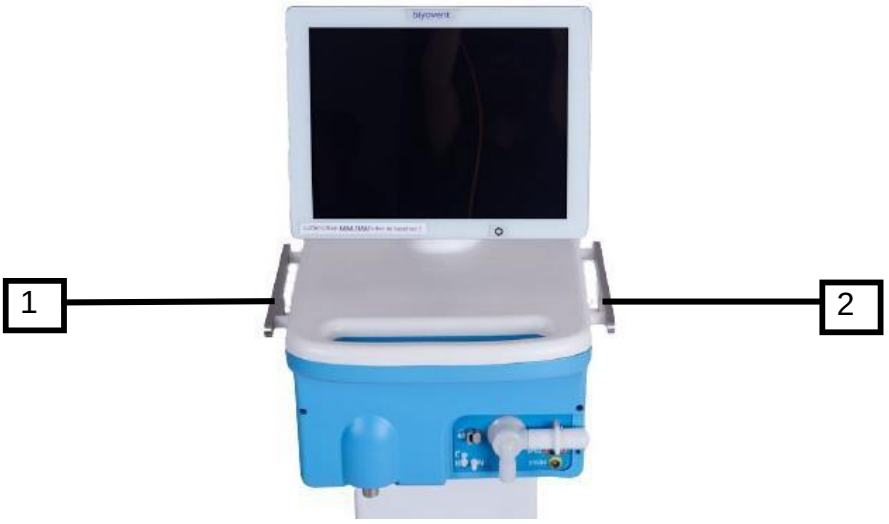


Figure 3.5. Connection of the Flex Arm

NOTES	Flex arm shall be connected to the one that is with the proper angle of the holding arms shown with 1 and 2 on the figure above.

3.6. Draining of the Condensation Collected in the Machine Inlet

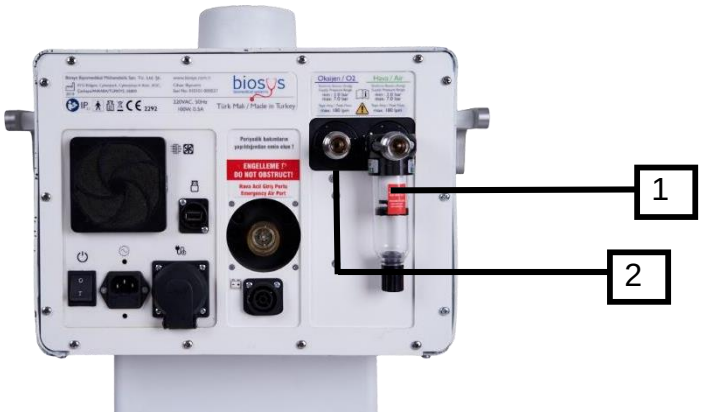


Figure 3.6. Draining of the Condensation Collected in the Machine Inlet

NOTES	When collection of condensation is observed in the water retainers on the filter + regulator shown with 1 and 2 on the figure above, remove the transparent capsule at the bottom by rotating it and re-attach it after cleaning the capsule by rotating it again.

3.7. Removal/Installation of the Expiratory Valve

ATTENTION!	In order to minimize the risk of infection, the expiratory valve shall be removed and sterilized with autoclave or ethylene oxide every time a patient is connected to the machine.

3.7.1. Installation of the Expiratory Valve

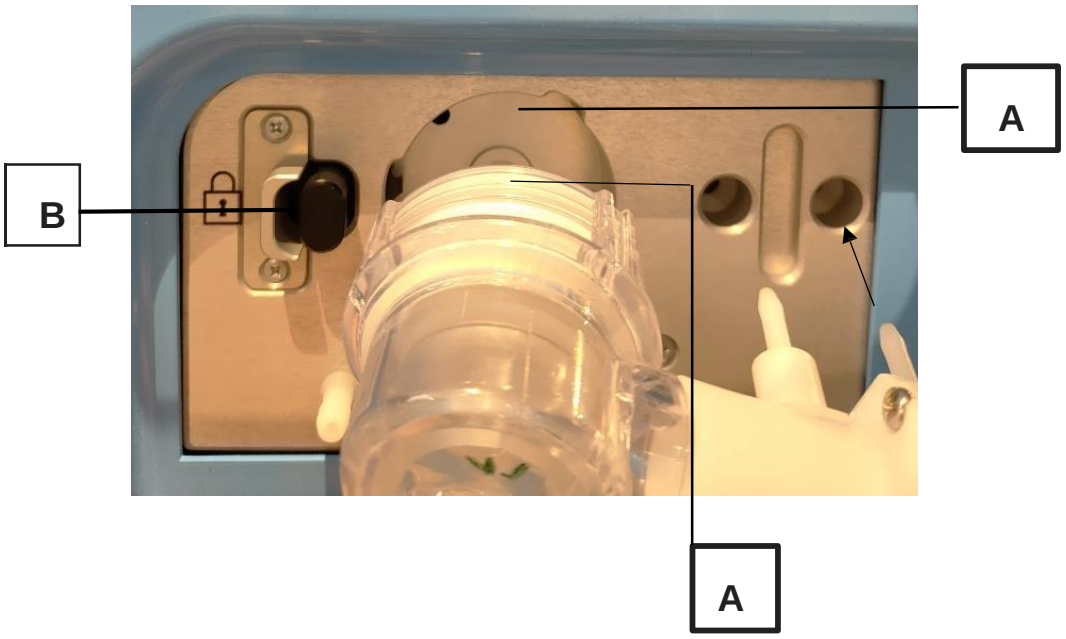


Figure 3.7. Installation of the Expiratory Valve

NOTES	Installation of the expiratory valve shown with 1 on the figure above; Press the button shown with B on the figure above first (Continue to press on the button until the installation of the Expiratory Valve is completed.) Place the expiratory valve to the machine so that the surfaces shown with A on the figure above are aligned with each other. The nipples on the Expiratory Valve shown with the black arrows on the figure above are snapped on with the holes on the machine.

3.7.2Removal of the Expiratory Valve

Figure 3.8. Removal of the Expiratory Valve

NOTES	Removal of the expiratory valve shown with 1 on the figure above from the machine; Press the button shown with A on the figure above first (Continue to press on the button until the removal of the Expiratory Valve is completed.) While holding the button pressed, pull the Expiratory Valve back carefully.

3.8. Preparing the Ventilator for Use

ATTENTION!	Do not lean against the screen and use it to carry the ventilator. Otherwise, the Screen and locking mechanism may break or the ventilator may overturn.

Before ventilating the patient, configure it to display all of the parameters, information and patient data from the BIYOVENT user interface on the Display.

3.8.1.Patient Kit Connection

The patient kit is prepared as provided below.

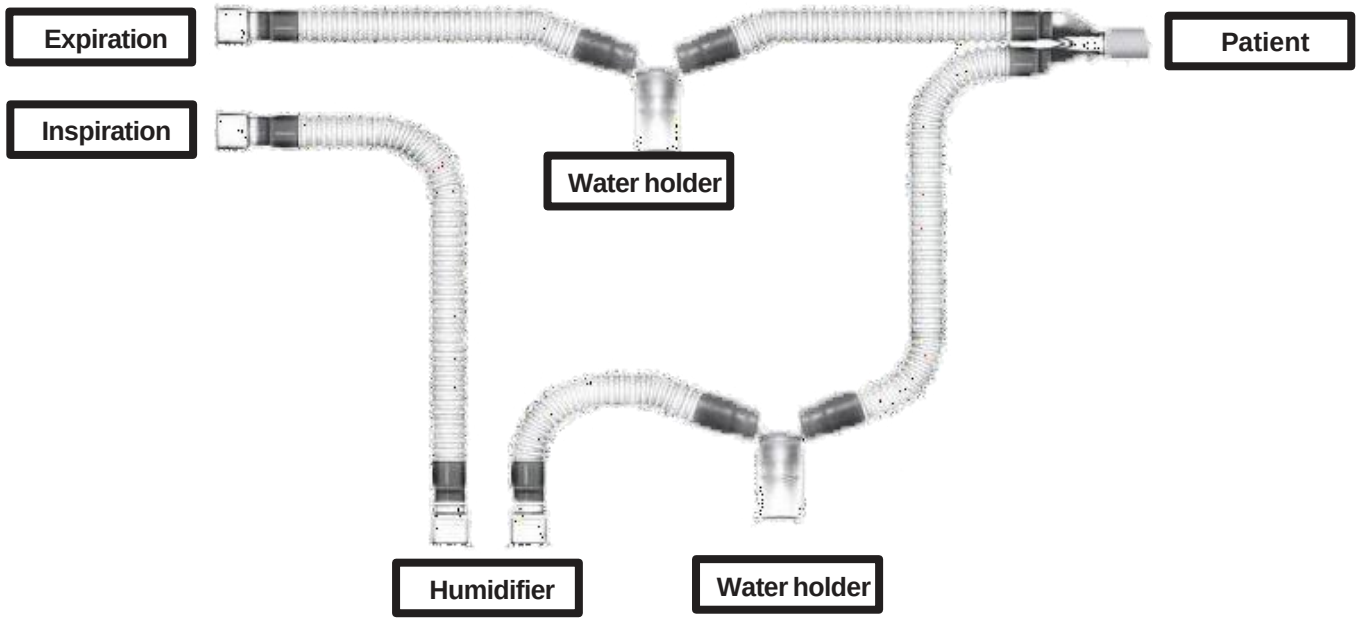


Figure3.9. Preparing the Ventilator for Use

The prepared patient kit inspiration connection is connected to point A as shown in the figure below. The part that says expiration is connected to the point B of the device.

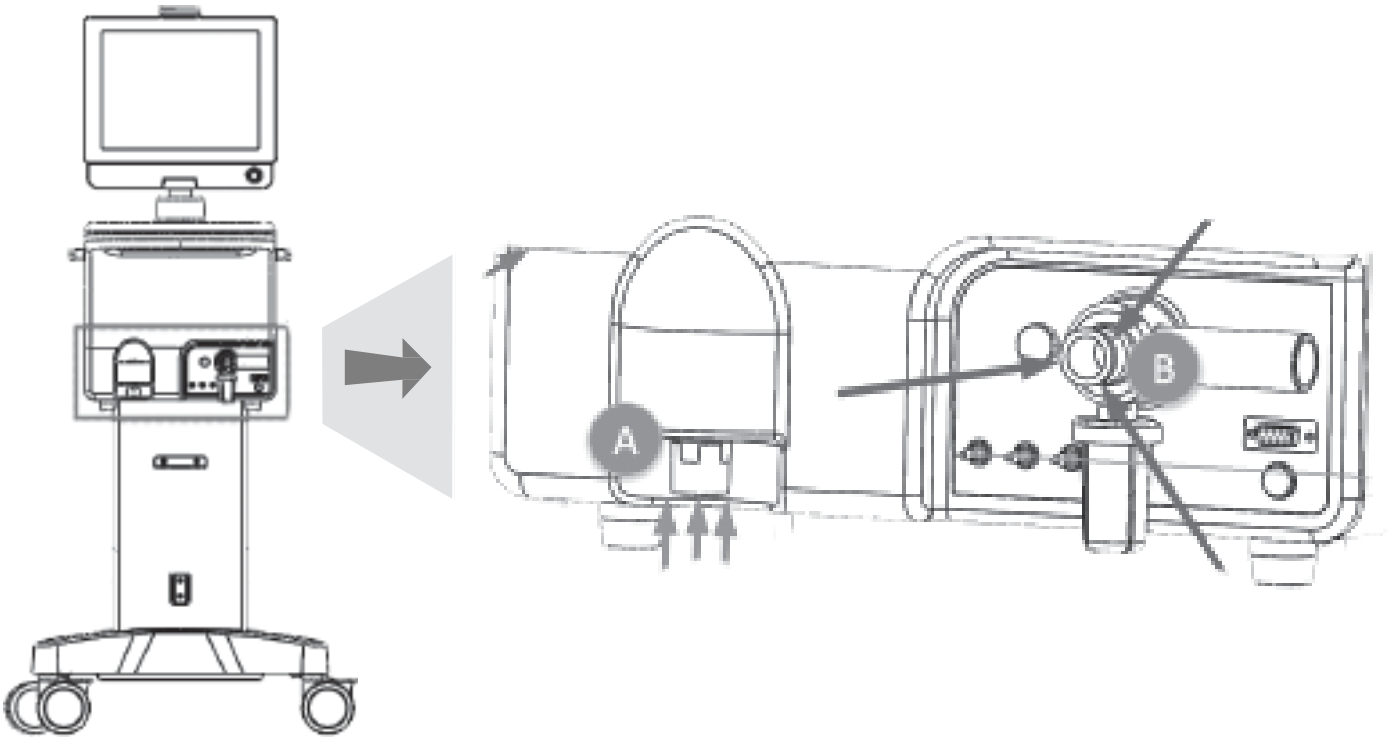


Figure3.10. Preparing the Ventilator for Use

3.8.2.Date and Time Format

The date and time cannot be configured as desired by the institute. The date format is as follows;

1. DD.MM.YYYY

3.8.3.New Patient Installation Defaults

1. Press the button corresponding to Male, Female, Kid, new patient defaults.

Figure 3.11. New Patient Installation

2. Press the Mode and Trigger type settings button corresponding to the required parameters.
3. Configure O2 per PBW and ml/kg rate.
4. Repeat the same process according to each patient type.
5. After the settings are completed, press apply button.

3.8.4.Alarm Sound Level

1. By pressing alarm limits button, configure the settings from the displayed menu.
2. Touch the alarm limits button again to disappear the alarm menu.

3.8.5. Oxygen and Air Source Connection

The medical air source (black and white intermittent patterned hose) is connected to the location indicated by H as shown below, and the oxygen source (white hose) is connected to the location indicated by O.

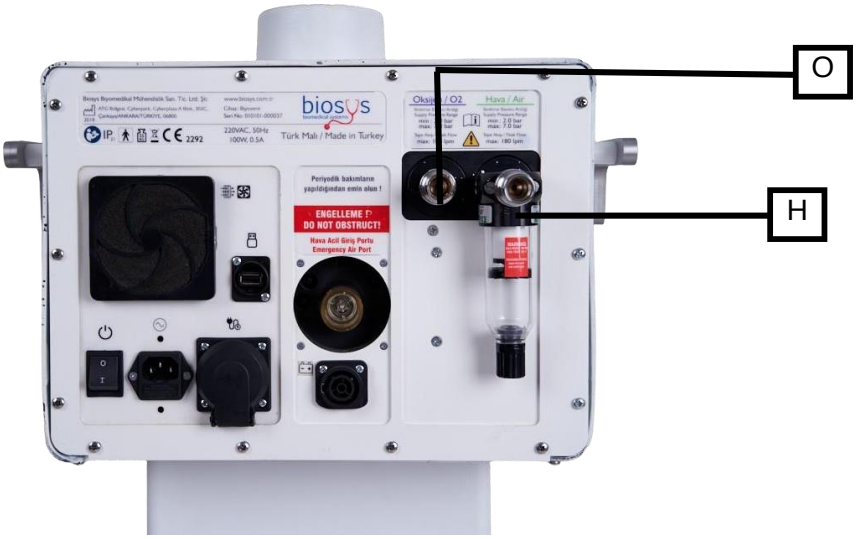


Figure 3.12. Oxygen and Air Source Connection

3.9. Gases and Units of Measurement

Operating Environment:

Temperature	: 10°C - 40°C
Atmospheric Pressure	: 0.8 Bar- 1.1 Bar
Humidity	: 5%-90% Non-Condensing

Transportation and Storage Conditions:

Temperature	: -30°C - 60°C
Atmospheric Pressure	: 0.5 Bar- 1.1 Bar
Humidity	: 5%-95% Non-Condensing

The settings are:

Ventilation Frequency (RR)	: 100 Breaths/Minute, Adult 100 Breaths/Minute, Pediatric
Tidal Volume (Vt)	: 0.1 Litres – 3 Litres, Adult 0.01 Litres – 0.3 Litres, Pediatric
Inspiration Time (Ti)	: 0.1 Seconds – 10 Seconds
Inspiration Flow (F):	: 1 Litre/Minute– 120 Litres/Minute, Adult 1 Litre/Minute – 30 Litres/Minute, Pediatric
Maximum Flow	: 1 Litre/Minute – 240 Litres/Minute, Adult
Inspiration Pressure (Pins)	: 0 mbar – 100 mbar
Inspiration Limit (Pmax)	: 1 mbar – 100 mbar
Peep Pressure (PEEP)	: 1 mbar – 50 mbar
Support Pressure (Psupp)	: 0 mbar – 100 mbar
Ramp Inclination (Ramp)	: 0 Seconds - 2 Seconds
O2 Concentration (FiO2)	: 21%- 100%
Trigger Accuracy (Ftrigger)	: 0.1 Litres/Minute – 20 Litres/Minute
Flow Termination (Frat)	: 1% - 80%

Graphical Screens

Pressure (P)	: mbar
Flow (F)	: Litre/Minute
Volume (V)	: mLitre

Supply Pressure:

Air	: 2.5 bar – 7 bar
Oxygen	: 2.5 bar – 7 bar

Tube Compensation:

Adult	: 5mm – 12mm Diameter

Biyovent

Pediatric	: 2mm – 8mm Diameter
Neonates	: 2mm – 5mm Diameter

Measured Values:

Compliance	: 0 mLitre/mbar – 1000 mLitre/mbar
Resistance	: 0 mbar/(Litre/Minute) - 20 mbar/(Litre/Minute)
Leakage	: 0 Litre/Minute– 100 Litres/Minute
Leak Compensation	: 0% - 80%

PART 4
VENTILATOR OPERATING MODES

4.1. Starting of the Inspiration

Inspiration (breathing) may be initiated by the patient or the mechanical ventilator.

Triggering by the patient shall be selected as current triggering or pressure triggering. When the desired threshold value is reached, the inspiration process is supported by the mechanical ventilator. In order to trigger the inspiratory effort of the patient within the breathing cycle, there are periods called as the "trigger window". Respiratory effort of the patient is supported only during this trigger window period, when the trigger value is reached.

Triggering of the mechanical ventilator starts the inspiration process without the patient's effort for inspiration. All forced mechanical ventilator triggers are time dependent. Inspiration is started by calculating the number of breaths targeted by the user.

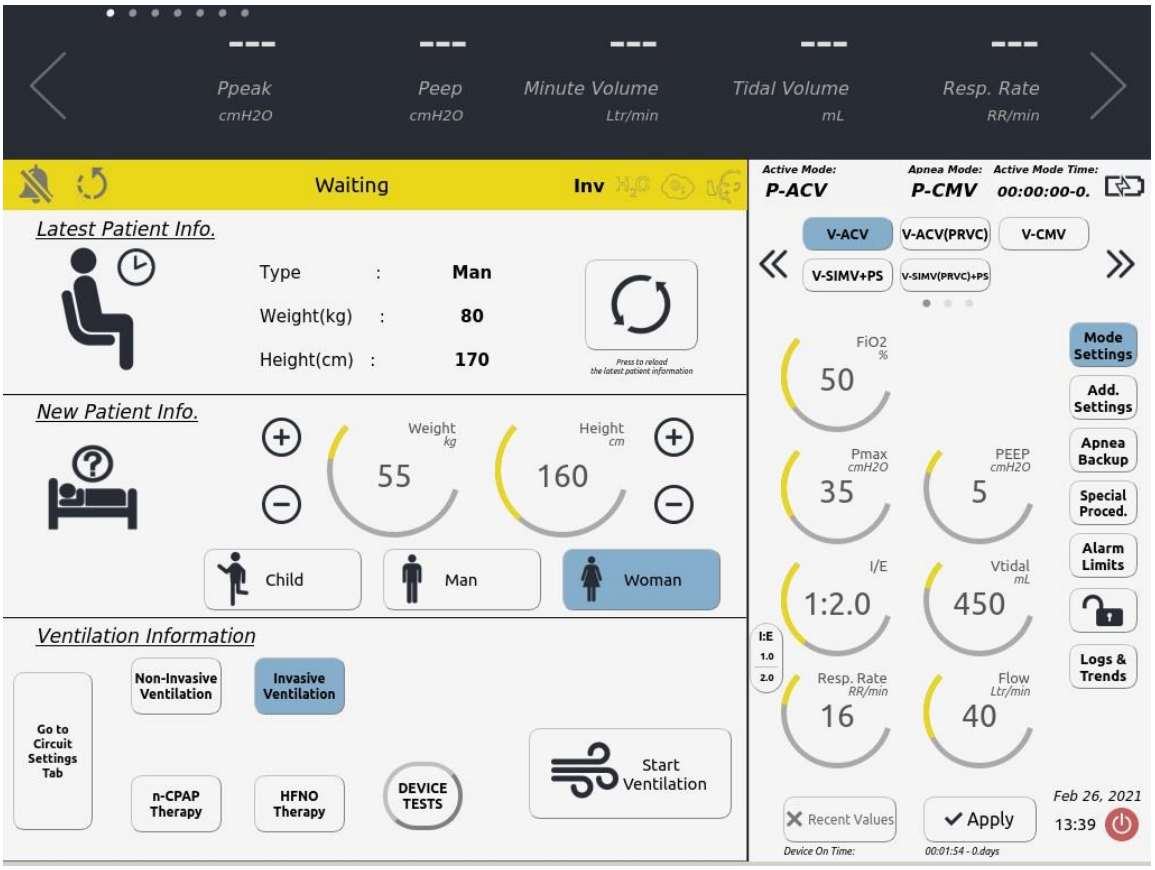


Figure 4.1. Starting of the Inspiration

1. Enter the Inspiration settings as per the Clinical evaluation of the patient.
2. Press "Start Ventilation".

4.2. Starting of the Expiration

Starting of expiration (exhalation) is based on current or time cycle.

Expiration triggering by current cycle is performed in two ways. The first and frequently used method is to start expiration when the maximum air flow rate achieved during inspiration is dropped by the rate set in advance. This method is closely related to the patient effort and lung mechanics in inspiration. The second method starts the expiration when the patient's inspiratory air flow rate decreases to the expiration rate set in advance. Here, the air flow rate that shall be reached for the start of the expiration is fixed.

Expiration triggering by time cycle starts when the inspiration period previously set by the user expires. There is little or no contribution from the patient in the starting of this expiration.

ATTENTION!	BİYOVENT adjusts the expiration period automatically as per the parameters entered.

4.3. n-CPAP Therapy (Nasal Continuous Positive Airway Pressure)

As the name suggests, this therapy provides continuous positive pressure support to the patients with a special mask. Moreover, it provides the opportunity to provide oxygen support.

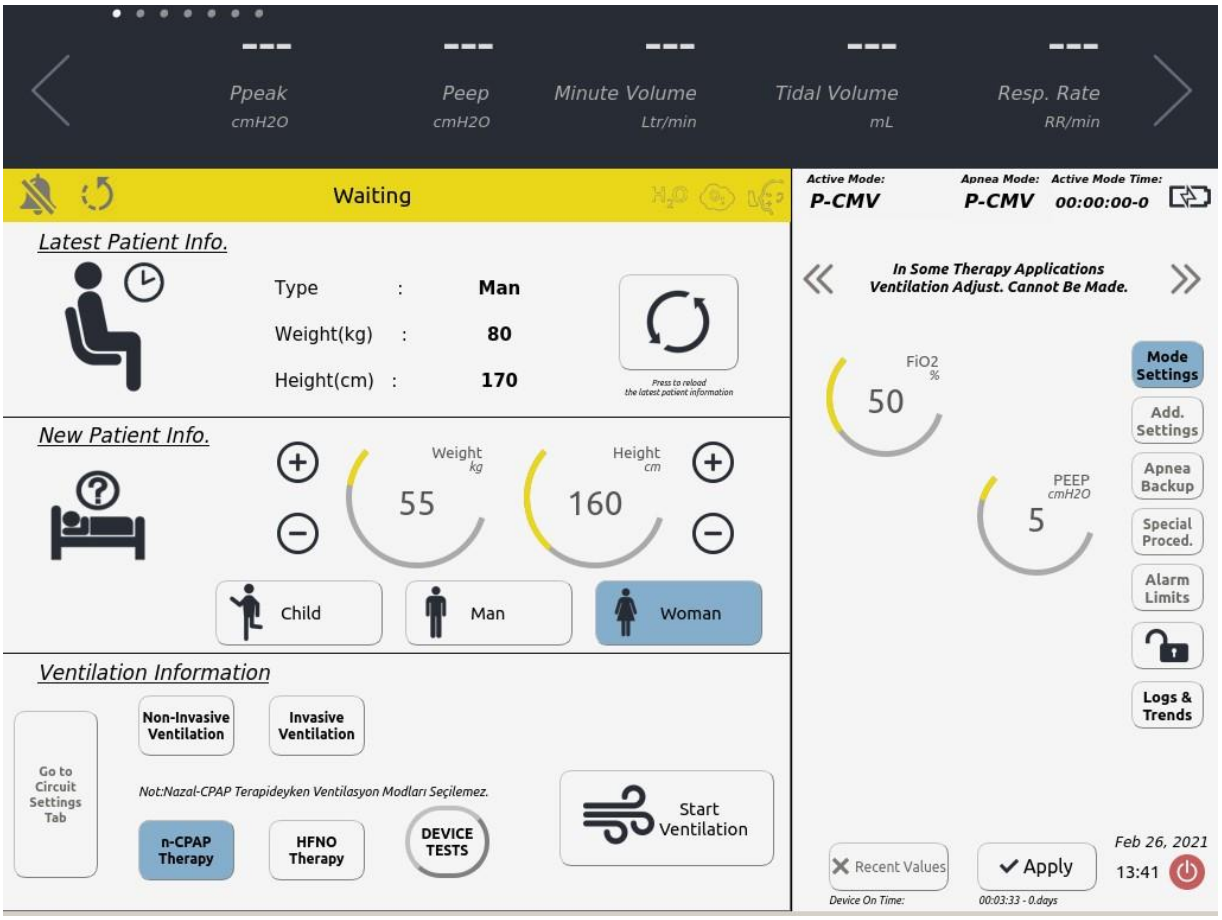


Figure 4.2. n-CPAP Therapy (Nasal Continuous Positive Airway Pressure)

4.4.HFO Therapy (High Flow Oxygen Therapy)

Allows provision of high flow oxygen support to the patients. It is recommended to be used with the active humidifier that shall be added to the device (see the active humidifier section in the following pages).

ATTENTION!	Pressure applied to the patient varies according to flow rate, airway resistance and lung compliance. Airway pressure alarm values shall be carefully examined.

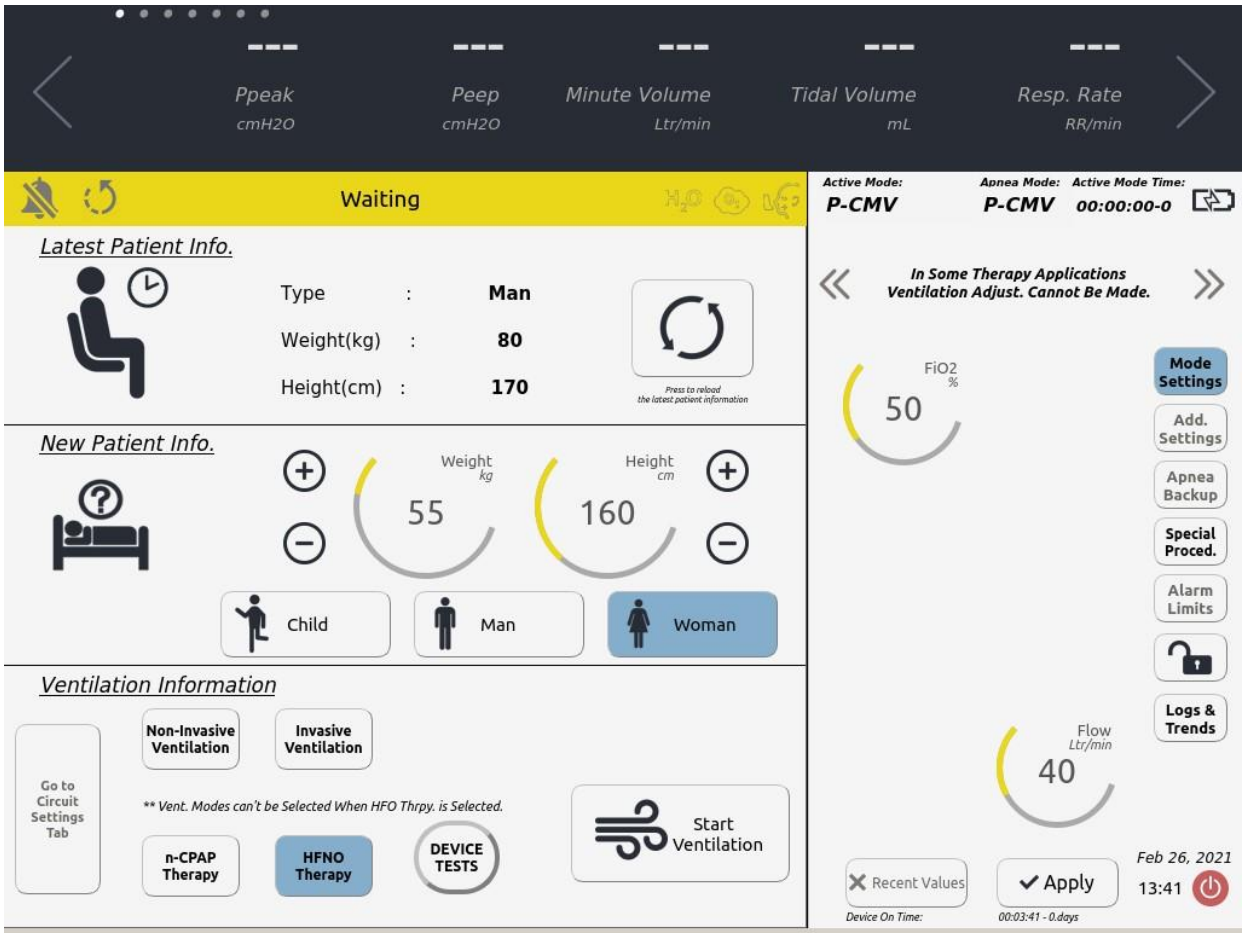


Figure 4.3. HFO Therapy (High Flow Oxygen Therapy)

4.5.Ventilator Settings

The ventilator offers various breath delivery options. During the treatment of the patient, the operator should carefully select the ventilation mode and settings to be used for the patient per the Clinical assessment, the condition and requirement of the patient, and in accordance with the benefits and limitations of the breath delivery Options and operating conditions. As the condition of the patient changes over time, it should be periodically assessed whether the selected Modes and settings are best for the current requirements of the patient or not.

The following ventilator settings are displayed on the new patient installation screen.

- Estimated Body Weight: Select gender and length of the patient.
- Ventilation Type: Determine the ventilation type to be delivered. (Invasive or Non-Invasive)
  - o Invasive: The ventilation performed by using endotracheal or tracheostomy tubes.
  - o Non-Invasive: Non-perforated full face masks, nasal masks, or ventilation

performed by using cuffless endotracheal tubes.

- Mode: Select respiration mode.

4.6.Volume-Targeted Modes

In the volume-targeted modes, airway pressure depends on the tidal volume, inspiration period, airway resistance as well as the compliance of the respiratory system. The set tidal volume shall always be given (tried to be given) to the patient. Increased resistance or decreased compliance leads to an increase in pressure. To protect the respiratory system from damage caused by high pressure, the upper pressure limit shall be set correctly. During the inspiration period, when the upper pressure limit is reached, the inspiration shall be continued at this pressure level for the time specified. In such a case, the targeted tidal volume may not be achieved.

In volume-controlled modes, the ventilation per minute is the multiplication of the tidal volume (VT) and the number of breaths (RR).

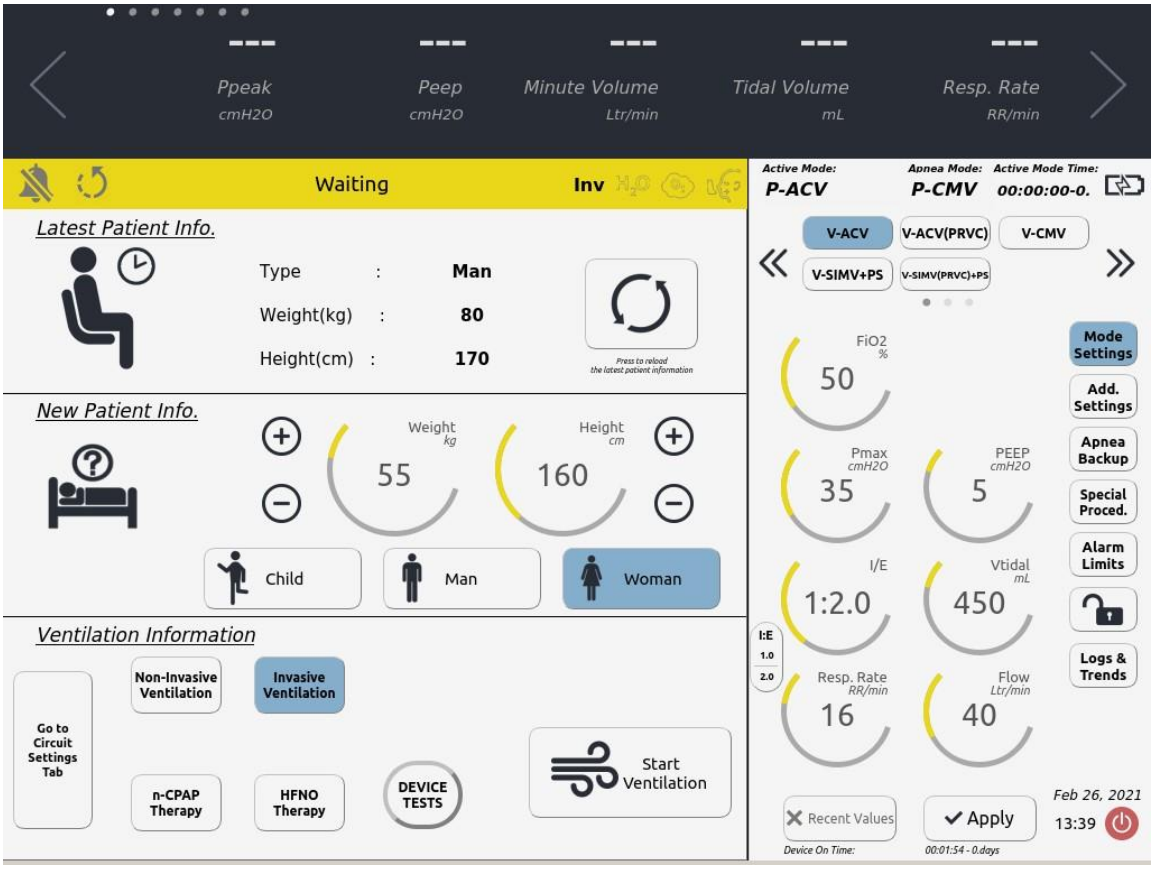


Figure 4.4. Volume-Targeted Modes

1. Enter the parameters to the Clinical Evaluation of the patient.
2. Click to confirm the parameters entered.
3. Click to exit without confirming the parameters entered.

4.6.1. V-CMV (VOLUME TARGET - CONTINUOUS MANDATORY VENTILATION)

This is the volume-targeted ventilation type with a conventional time cycle. It provides forced ventilation per minute. Targeted forced ventilation per minute is determined by the tidal volume and the number of breaths. Inspiration, expiration rate and the inspiration period determine the pressure and current curve. The ventilator automatically performs an inspiration pause. This pause time depends on tidal volume, inspiratory flow rate and period.

Table 4-1. Mechanical Ventilator Settings

Mechanical Ventilator Settings						
Pmax	**fiO2**	**VT**	**Ti**	**RR**	**PEEP**	**Flow**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.6.2. V-ACV (VOLUME TARGET - ASSIST CONTROL VENTILATION)

This is the volume-targeted ventilation type with a conventional time cycle. It provides forced ventilation per minute.Targeted forced ventilation per minute is determined by the tidal volume and the number of breaths. Inspiration, expiration rate and the inspiration period determine the pressure and current curve. The ventilator automatically performs an inspiration pause. This pause time depends on tidal volume, inspiratory flow rate and period. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths. If the patient's spontaneous breaths exceed the targeted number of breaths, this increases the ventilation volume per minute.

Table 4-2. Mechanical Ventilator Settings

Mechanical Ventilator Settings						
fiO2	**Pmax**	**VT**	**Ti**	**RR**	**PEEP**	**Flow**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.6.3. V-SIMV+PS (VOLUME TARGET - SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION)

It is a combination of pressure-targeted time-looped ventilation type and the mode that gives pressure support to spontaneous breaths between these mandatory breaths. Targeted forced ventilation per minute is determined by the tidal volume and the number of breaths. Inspiration, expiration rate and the inspiration period determine the pressure and current curve. The ventilator automatically performs an inspiration pause. This pause time depends on tidal volume, inspiratory flow rate and period. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths.

If the patient triggers a new breath between the mandatory breaths, this breath is supported as pressure- supported and current-cycled.If the spontaneous breath process corresponds to the triggering window period of the next mandatory breath, the spontaneous breath is continued at the targeted pressure and flow values, then postponed to the following mandatory breath period. This adaptation may lead to a change in the number of mandatory breaths.

Table 4-3. Mechanical Ventilator Settings

Mechanical Ventilator Settings							
fiO2	**VT**	**Ti**	**RR**	**PEEP**	**Psupp**	**Ramp time**	**Flow**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.6.4. V-ACV(PRVC)

This is the time-cycled, volume-targeted, pressure-controlled ventilation type. It provides forced ventilation per minute. Targeted tidal volume is provided to the patient as pressure-controlled during the desired inspiration process.

Targeted forced ventilation per minute is determined by the tidal volume and the number of breaths. Inspiration, expiration rate, inspiration period and volume that shall be delivered to the patient determine the current curve. The ventilator automatically performs an inspiration pause. This pause time depends on tidal volume, inspiratory flow rate and period. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths. If the patient's spontaneous breaths exceed the targeted number of breaths, this increases the ventilation volume per minute.

Table 4-4. Mechanical Ventilator Settings

Mechanical Ventilator Settings					
fiO2	**VT**	**Ti**	**RR**	**PEEP**	**Flow**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.6.5. V-SIMV (PRVC) +PS

This is the combination of the time-cycled, volume-targeted, pressure-controlled ventilation type and the mode where pressure support is provided to the spontaneous breaths between these mandatory breaths. Targeted forced ventilation per minute is determined by the tidal volume and the number of breaths. Inspiration, expiration rate, inspiration period and volume that shall be delivered to the patient determine the current curve. The ventilator automatically performs an inspiration pause. This pause time depends on tidal volume, inspiratory flow rate and period. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths. If the patient triggers a new breath between the mandatory breaths, this breath is supported as pressure-supported and current-cycled.

If the spontaneous breath process corresponds to the triggering window period of the next mandatory breath, the spontaneous breath is continued at the targeted pressure and flow values, then postponed to the following mandatory breath period. This adaptation may lead to a change in the number of mandatory breaths.

Table 4-5. Mechanical Ventilator Settings

Mechanical Ventilator Settings						
fiO2	**VT**	**Ti**	**RR**	**PEEP**	**Psupp**	**Pmax**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.7. Pressure-Targeted Modes

Pressure-controlled modes have two fixed pressure values. The lower one of these is PEEP, and the higher one is Pinsp. Tidal volume depends on the difference between these pressure values, the compliance and resistance of lungs. And ventilation volume per minute is equal to the multiplication of the tidal volume caused by this pressure difference and the number of breaths. As lung compliance and resistance may differ from breath to breath, tidal volume from breath to breath may also change. And this may cause differences in the ventilation volume per minute. Alarm limits shall be carefully set to prevent the patient both from improper changes in the tidal volume and the improper changes in the volume per minute. Tidal volume high (VThigh), tidal volume low (VTlow), volume per minute high (MVhigh), volume per minute low (MVlow) alarms shall be set carefully in pressure-controlled modes. Target pressure values are tried to be resumed in case of a leak,too.

The time for reaching the targeted pressure value (ramp time) is set by the user.

4.7.1. P-CMV (PRESSURE TARGET - CONTINUOUS MANDATORY VENTILATION)

This is the pressure-targeted ventilation type with a conventional time cycle. Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance.

The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the number of targeted breaths and pressure differences.

Table 4-6. Mechanical Ventilator Settings

Mechanical Ventilator Settings				
fiO2	**Pinsp**	**Tinsp**	**RR**	**PEEP**

ATTENTION!	VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.7.2. P-ACV (PRESSURE TARGET - ASSIST CONTROL VENTILATION)

This is the pressure-targeted ventilation type with a conventional time cycle. Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths. In this mode, triggering more breaths than the determined number of breaths is supported by the determined pressure value and inspiration period.

The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the number of breaths and pressure differences.

Table 4-7. Mechanical Ventilator Settings

Mechanical Ventilator Settings				
fiO2	**Pinsp**	**Tinsp**	**RR**	**PEEP**

ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.7.3. P-SIMV + PS (PRESSURE TARGET - SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION + PRESSURE SUPPORT VENTILATION):

It is a combination of pressure-targeted time-looped ventilation type and the mode that gives pressure support to spontaneous breaths between these mandatory breaths. Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance. If the breathing effort of the patient exceeds the trigger value, it may trigger the mandatory breaths. In this mode; triggering the breaths in an amount that is more than the determined number of breaths is supported by pressure targeted, flow-looped mode. The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the number of breaths and pressure differences.

If the spontaneous breath process corresponds to the triggering window period of the next mandatory breath, the spontaneous breath is continued at the targeted pressure and flow values, then postponed to the following mandatory breath period. This adaptation may lead to a change in the number of mandatory breaths.

 ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

Table 4-8. Mechanical Ventilator Settings

Mechanical Ventilator Settings					
fiO2	**Tinsp**	**Psupp**	**Pinsp**	**RR**	**PEEP**

4.7.4. PC-APRV (PRESSURE CONTROL-AIRWAY PRESSURE RELEASE VENTILATION):

It is the mode triggered by the pressure-targeted, time-looped mechanical ventilator. In this mode, the low pressure (Plow, PEEP), high pressure (Phigh) values and the period of these pressure values (Tlow, Thigh) are determined. The mechanical ventilator passes to the determined pressure values at the determined periods. The transition between these pressure values is time-looped and mechanical ventilator triggered. The spontaneous breaths of the patient are allowed by means of high pressure (Phigh). Spontaneous breathing of the patient at both pressure levels is allowed.

CO2 shotis ensured through passingtolow pressure level (Plow, PEEP) to high pressure level (Phigh). Tidal volume occurs as a result of the difference between two pressure values (Plow and Phigh), at the same time connected to the lung resistance and elastance. The ventilation volume per minute may differ according to this.

Table 4-9. Mechanical Ventilator Settings

Mechanical Ventilator Settings				
fiO2	**Pinsp**	**Plow**	**Thigh**	**Tlow**

 ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.7.5. P-PSV (PRESSURE TARGET - PRESSURE SUPPORT VENTILATION):

It is a pressure-targeted, flow-looped mode. It can be triggered by the patient or machine. All spontaneous breaths of the patient is supported by the targeted pressure value (Pinsp). This support is flow-looped. The inspiration number and period are determined by the patient. If the number of the triggered breaths is under the number of adjusted breaths, the breath that is triggered by the flow-looped, pressure-targeted mechanical ventilator is started.

Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance. The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the number of breaths and pressure differences.

Table 4-10. Mechanical Ventilator Settings

Mechanical Ventilator Settings			
fiO2	**Psupp**	**RR**	**PEEP**

 ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.7.6. BiLevel:

It is the combination of the synchronized, time-looped, pressure-targeted mandatory ventilation mode and the mode that allows the spontaneous breathing at both pressure levels. Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance. Pressure support may be provided to spontaneous breaths. The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the total of breaths (spontaneous and mandatory) and pressure differences.

Table 4-11. Mechanical Ventilator Settings

Mechanical Ventilator Settings					
fiO2	**Pinsp**	**Tinsp**	**RR**	**PEEP**	**Psupp**

 ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.8 Spontaneous (Assisted) Modes

The contribution of the patient to the work-load of breathing during the use of spontaneous modes is more than the mechanical ventilator. In all spontaneous modes, the breathing effort of the patient is supported by the mechanical ventilator at different rates.

In order to facilitate the compliance of the patient with the ventilation support, the air flow in PS (Pressure Support) and VS (Volume Support) modes is arranged, in sequence, with the period of achieving target pressure (ramp time) and flow settings. In both settings, the period to achieve the target pressure is determined.

4.8.1. SPN-PS (SPONTANEOUS - PRESSURE SUPPORTVENTILATION):

The spontaneous breaths in the patient's PEEP level are supported by the targeted pressure support. The breaths triggered by the patient are supported as pressure-targeted and flow-looped. Tidal volume occurs as a result of the difference between two pressure values (PEEP and Pinsp), at the same time connected to the lung resistance and elastance. The ventilation volume per minute is ensured by the amount of the tidal volume occuring as a result of the number of supported breaths and pressure differences.

Table 4-12. Mechanical Ventilator Settings

Mechanical Ventilator Settings		
fiO2	**PEEP**	**Psupp**

ATTENTION!	The trigger value may be adjusted. VThigh, Vtlow, MVhigh, MVlow alarms should be adjusted carefully.

4.8.2. SPN-VS (SPONTANEOUS - VOLUME SUPPORTVENTILATION):

The spontaneous breaths in the patient's PEEP level are supported at the amount of desired volume. The breaths triggered by the patient to give the desired volume are supported as volume-targeted, pressure-controlled, and flow-looped. The pressure support may also vary depending on the changes in lung resistance and elastance to deliver the desired volume to the patient. The ventilation volume per minute is ensured by the number of supported breaths and the amount of supported tidal volume.

Table 4-13. Mechanical Ventilator Settings

Mechanical Ventilator Settings			
fiO2	**VT**	**Pmax**	**PEEP**

ATTENTION!	The trigger value may be adjusted. Phigh value should be adjusted carefully.

4.9. Detail Modes

Detail mode settings allow us to adjust the ventilator system further. In this way, the area of intervention to the patient's breath is expanded. For a more accurate treatment, the interventions should be performed by the users who are experts in the area of ventilator.

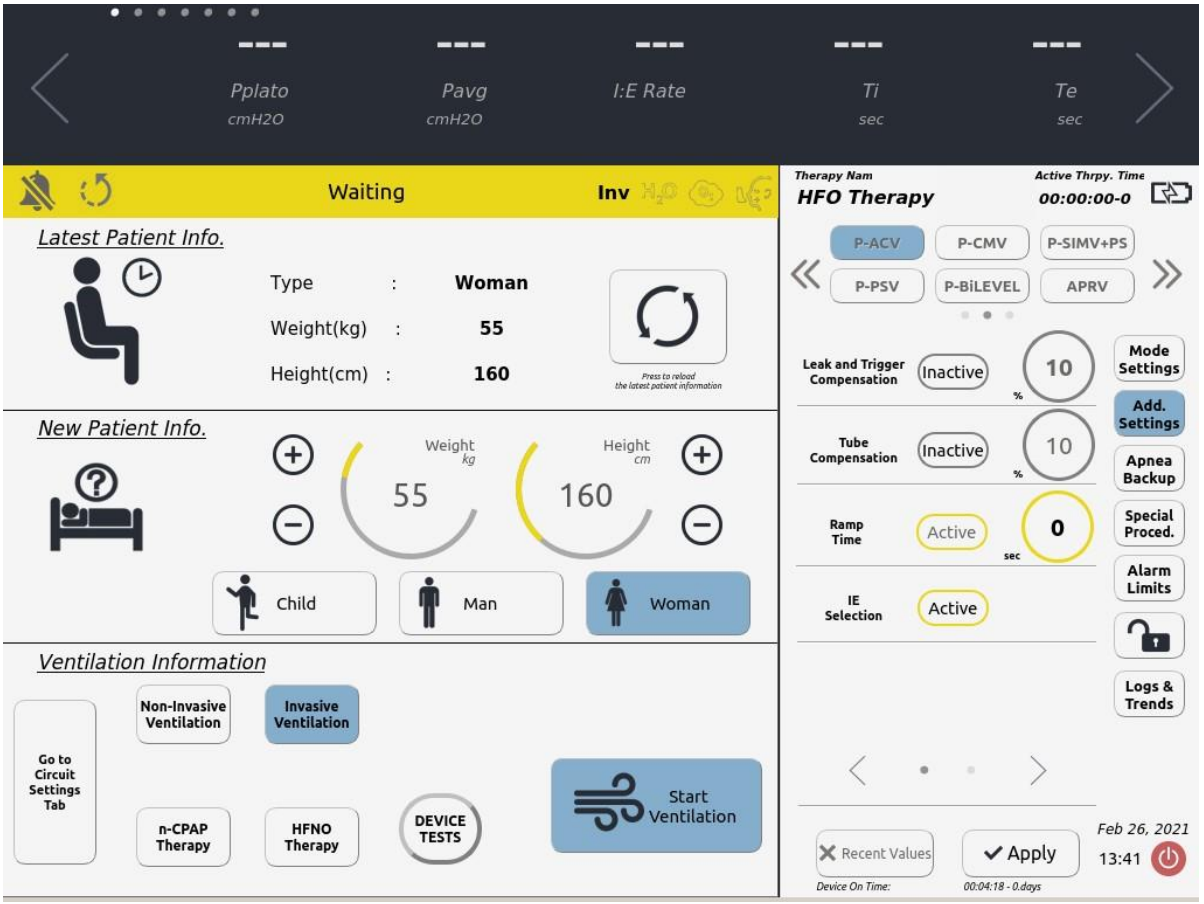


Figure 4.5. Detail Modes

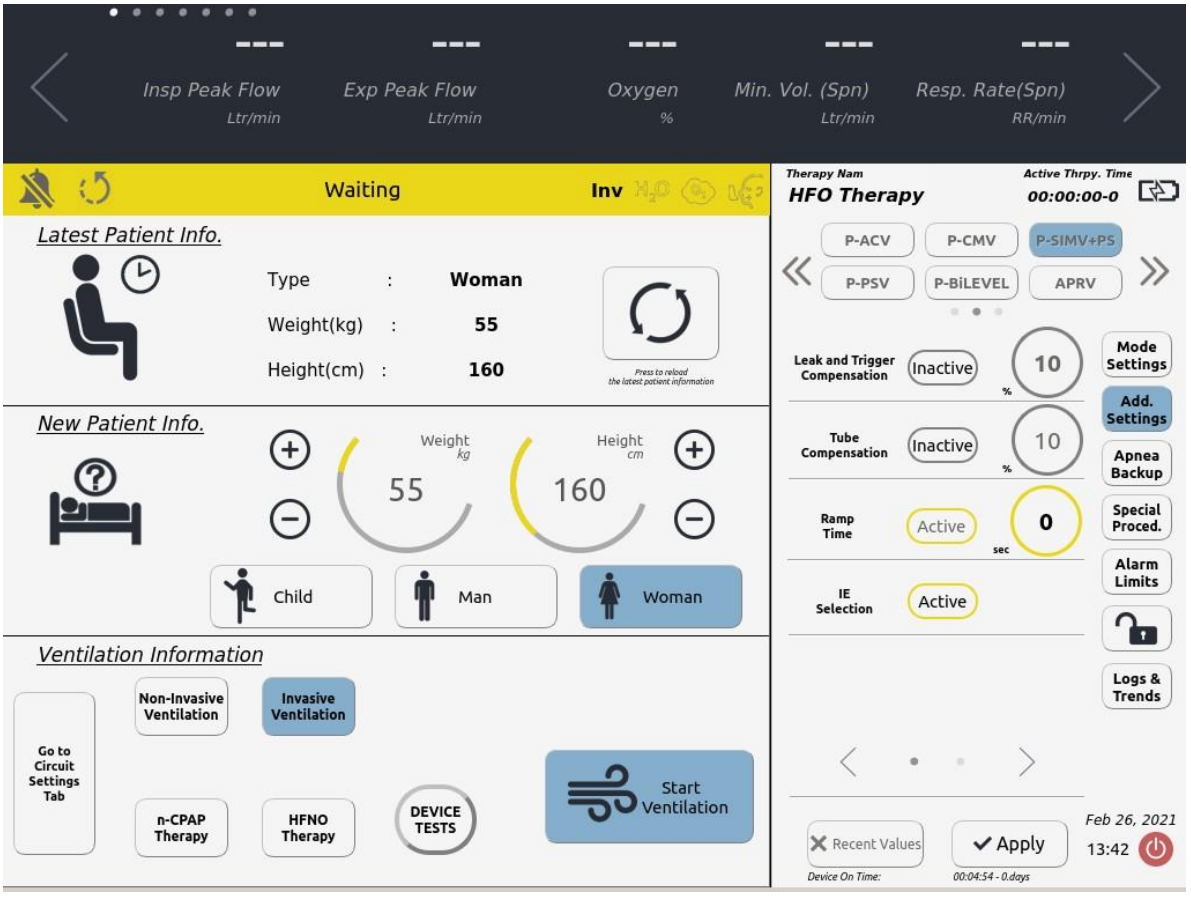


Figure 4.6. Detail Modes

1. Leak and Trigger Compensation

When the ventilator is connected to the patient, the system turns into a closed circuit. It is used in case of leak in closed circuit and particularly in non-invasive mechanical ventilation modes. The leak in the closed circuit is tried to be compensated in terms of percentage. The device will automatically trigger itself in case of leak. With the trigger compensation, the trigger value will be increased at the value of leak, and thus, “auto-triggering” will tried to be prevented.

2. Tube Compensation

Endotracheal tube causes airway resistance. This causes an increase in the work-load of the respiratory system. And tube compensation is also used to overcome the endotracheal tube resistance of patients who are breathing in the mechanical ventilation. The tube compensation is easily adjusted and precisely compensates the tube-induced resistance, and contributes to the patient's respiratory process. As long as controlled ventilation is applied to patients, the ventilator does not cause problems, as it can overcome artificial airway resistance. But in cases such as separation from ventilation, artificial resistance caused by the tube at the moment when the patient needs to breathe spontaneously makes breathing much more difficult.

3. Ramp Time

It is used in pressure-targeted modes (for both flow and time-looped breaths). It determines the time that the mechanical ventilator rises to the target pressure value during inspiration. Keeping the Ramp Time short allows the inspiration to start with a higher flow rate, while keeping it longer allows it to start with a lower flow rate.

4. Inspiration Termination Rate

The inspiration is flow-looped in modes using pressure support in the mechanical ventilator. The inspiration is terminated when the flow speed in the respiratory tracts fall to a certain percentage of the peak flow rate with an inspiration termination rate.

5. Inspiration Termination Time

The inspiration is flow-looped in modes using pressure support in the mechanical ventilator. In some cases, the inspiration termination time may be prolonged more than the user's request or the time not suitable for the patient. With the inspiration termination time setting, the maximum time of the pressure support time applied to the patient can be adjusted.

6. Triggering

Triggering is the variable starting the inspiration. It can be adjusted as flow or pressure trigger. The trigger sensitivity should be carefully adjusted. If the trigger sensitivity is set to high, the patient spends more effort to trigger the machine and the breathing work-load increases. If the trigger sensitivity is set low, the initiation of the inspiration in every small effort disrupts the patient-ventilator compliance.

PART 5
PREPARING THE VENTILATOR FOR USE

5.1.Operation

This section explains the operation of Biyovent Series Ventilator and forms of the following parts.

- Using Ventilator
- Using User Interface of Ventilator
- Making main settings, alarm settings or apnea settings
- Testing alarms

1. Ventilator Function

The air and oxygen taken from the hospital sources enter into the ventilator and flow separately from the oxygen and air flow sensors. Then these gases are mixed in the chamber of the mixing module. Furthermore in the mixing module, there is an oxygen sensor that monitors the air-oxygen mixture according to the O2 setting set by the user.
After the gas is mixed, the breath delivery flow sensor measures the gas flow and flows through the valve to the inspiration pneumatic system for proper breath delivery tidal volumes and pressures. In the inspiration pneumatic system, there is a safety valve that prevents excessive pressure cases before it is delivered to the patient through the gas bacteria filters and passes through the inspiration extension of the patient circuit. After the exhalation, the gas flows through the patient circuit expiratory extension, through the expiratory bacteria filter, and through the exhalation port where the exhalation valve flow sensor is located.

2. Using User Interface Screen

The user interface screen is used to interact with the ventilator when ventilating or in anyoperating mode.

ATTENTION!	Do not lean against the screen and use it to carry the ventilator. Otherwise, the Screen and locking mechanism may break or the ventilator may overturn**.**

Biyovent welcome screen is as follows. The user can quickly apply ventilation to the patient by selecting the modes on this screen and pressing the "Start Ventilation" button.

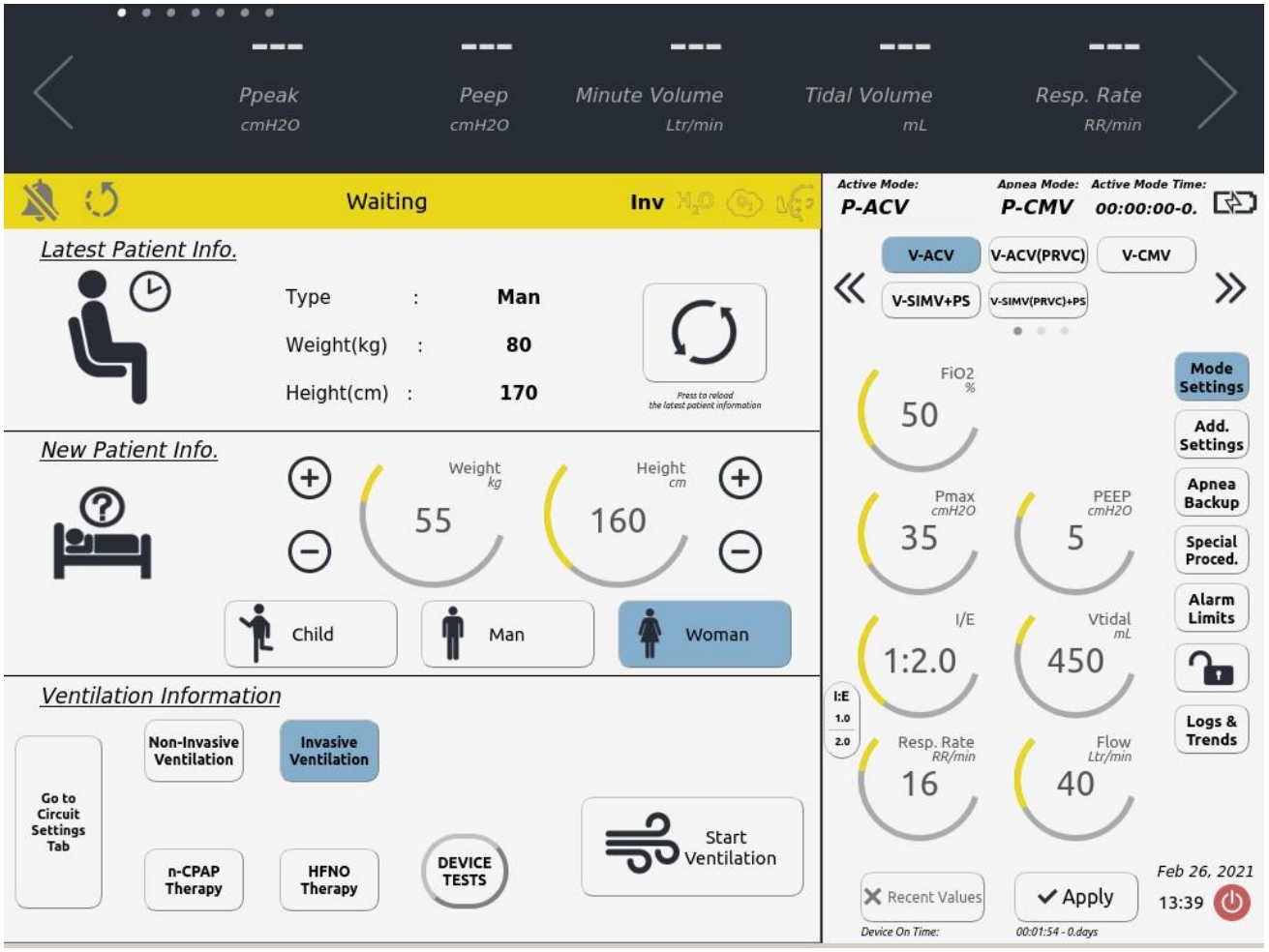


Figure 5.1. Using the User Interface Screen

1. **Menu Tag:** It is located in the right part of User Interface Screen. Apnea, Humidifier, Alarm Sound Mute, Grid, Screen Capture, Alarm Limits, Screen Lock and Log menus can be accessed here. The user makes the settings from this menu.
2. **Graphic Display Field:** It is located in the middle of the User Interface screen. It shows various breath waveforms.
3. **Vital Patient Data Band:** It is located at the top of the User Interface Screen. Patient data band shows the monitored patient data and can be configured to show the desired patient data.
4. **Apnea Setting Field:** It is located in the right part of User Interface Screen. The user can configure the Apnea settings in this menu.
5. **Humidifier Settings Field:** It is located in the right part of User Interface Screen. The user can configure the Humidifier settings in this menu.
6. **Alarm Mute Field:** It is located in the right part of User Interface Screen. The user can mute the alarm for 2 minutes by pressing this button.
7. **Alarm Limits Field:** It is located in the right part of user interface screen. The user can set the alarm limits from the menu to be opened by pressing this button.

8. **Screen Lock:** It is located in the right part of user interface screen. The user locks the screen by pressing this button and no change can take effect on the screen.
9. **Log Field:** It is located in the right part of user interface screen. The user can access to the patient data and system info from the menu to be opened by pressing this button.

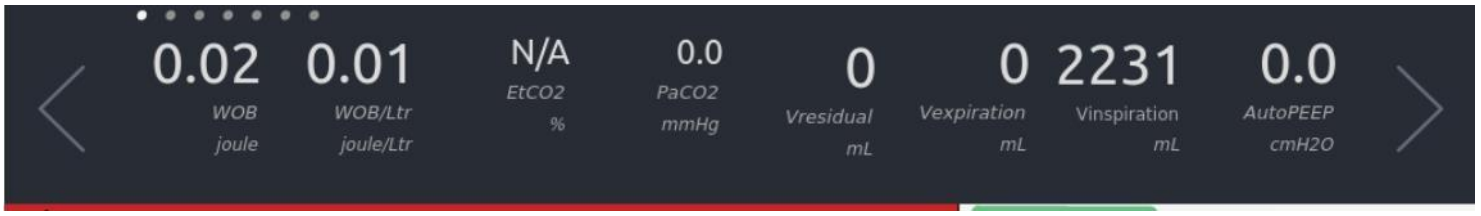


Figure 5.2. Vital Patient Data Band

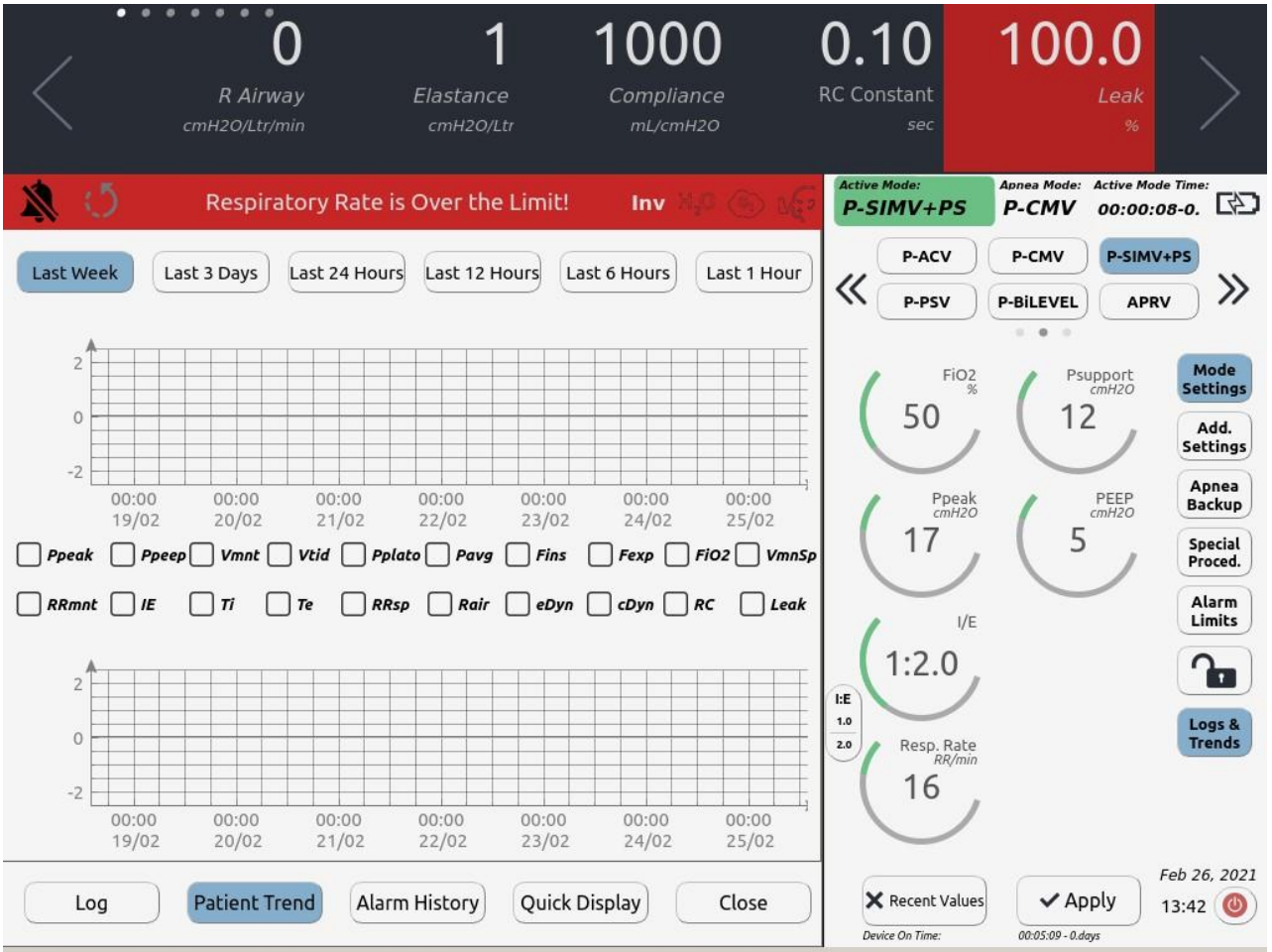


Figure 5.3. Log & Trends – Patient Trend

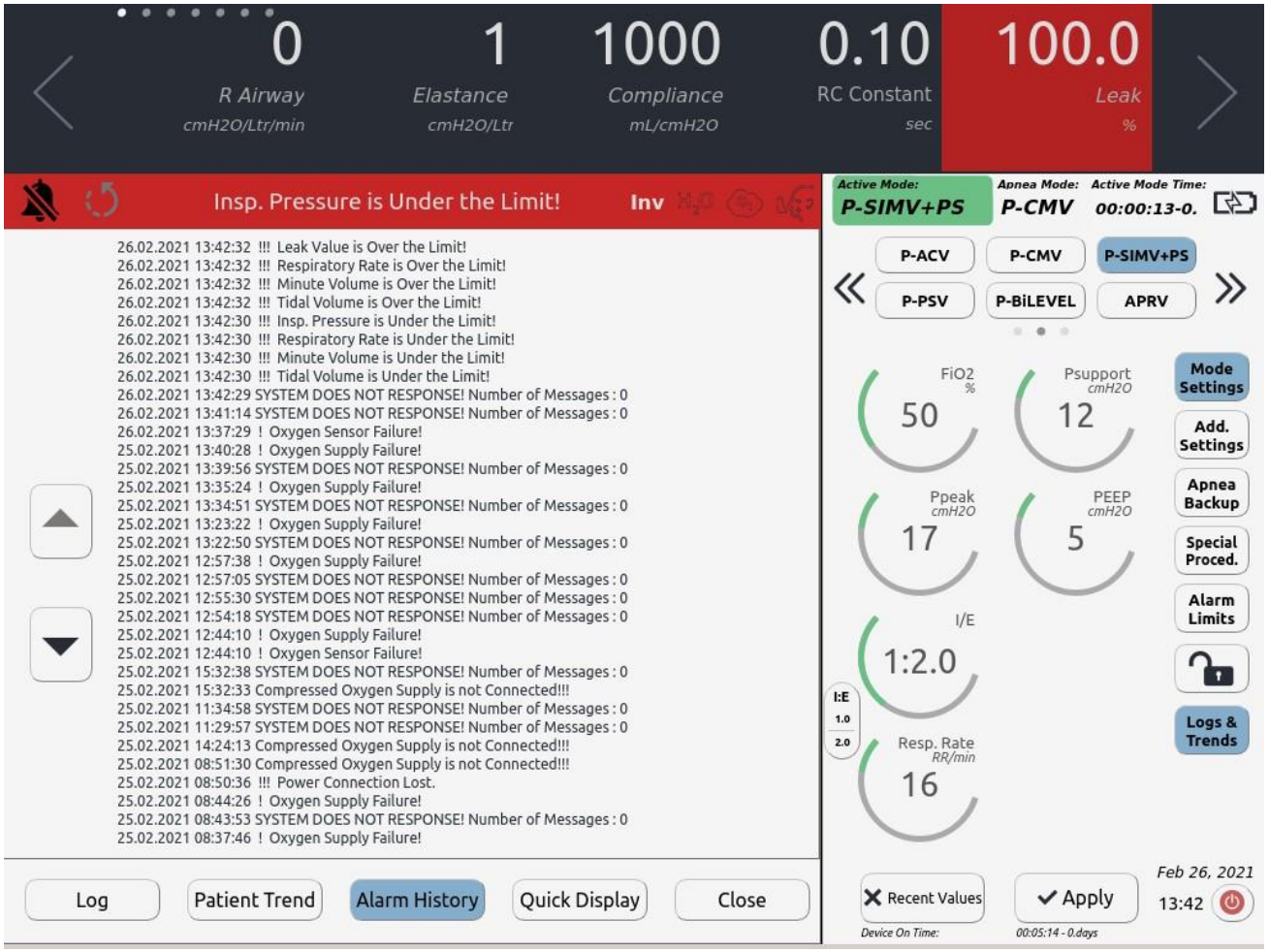


Figure 5.4. Log & Trends - Alarm History

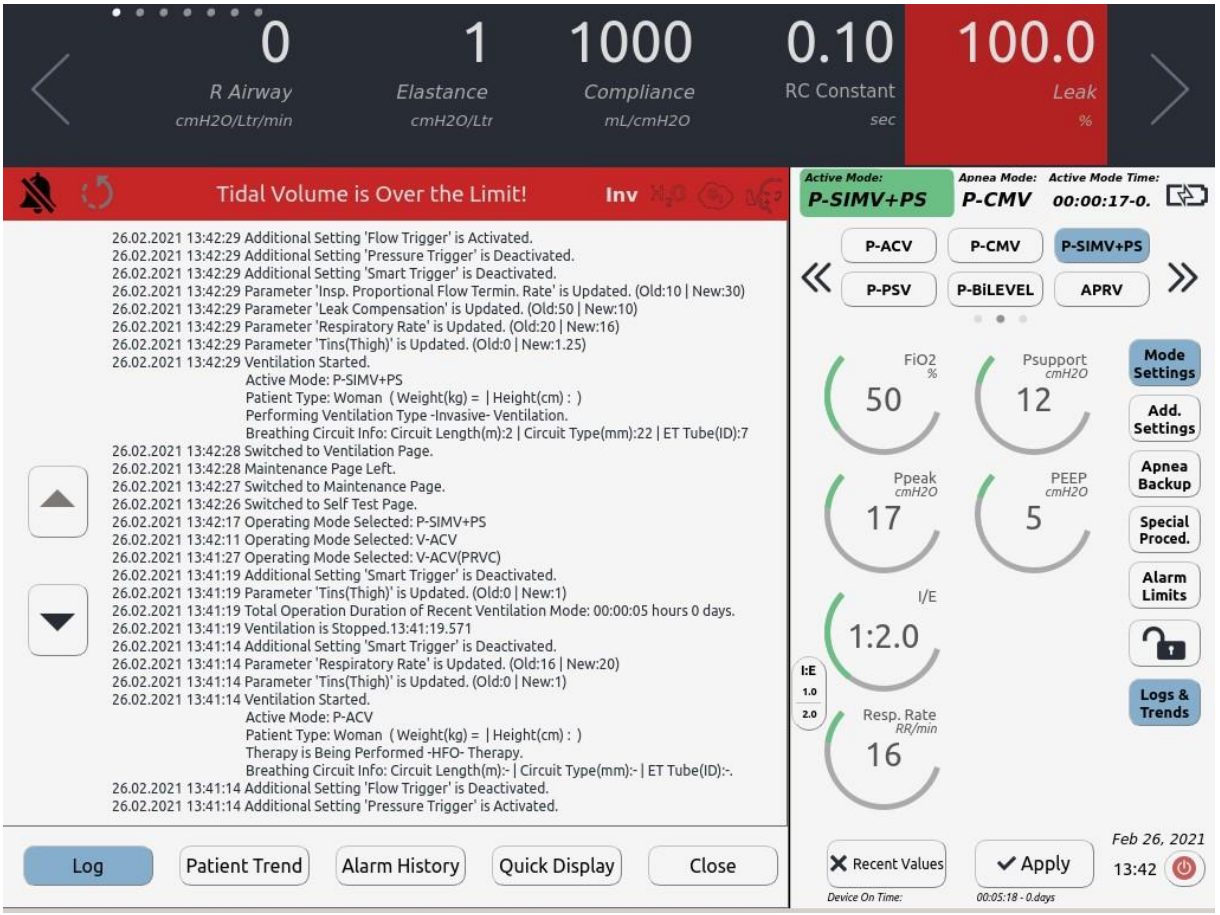


Figure 5.5. Log & Trends – Log

After the user selects the relevant patient type, can make the settings on the screen provided below and apply the desired ventilation to the patient by pressing the Apply button.

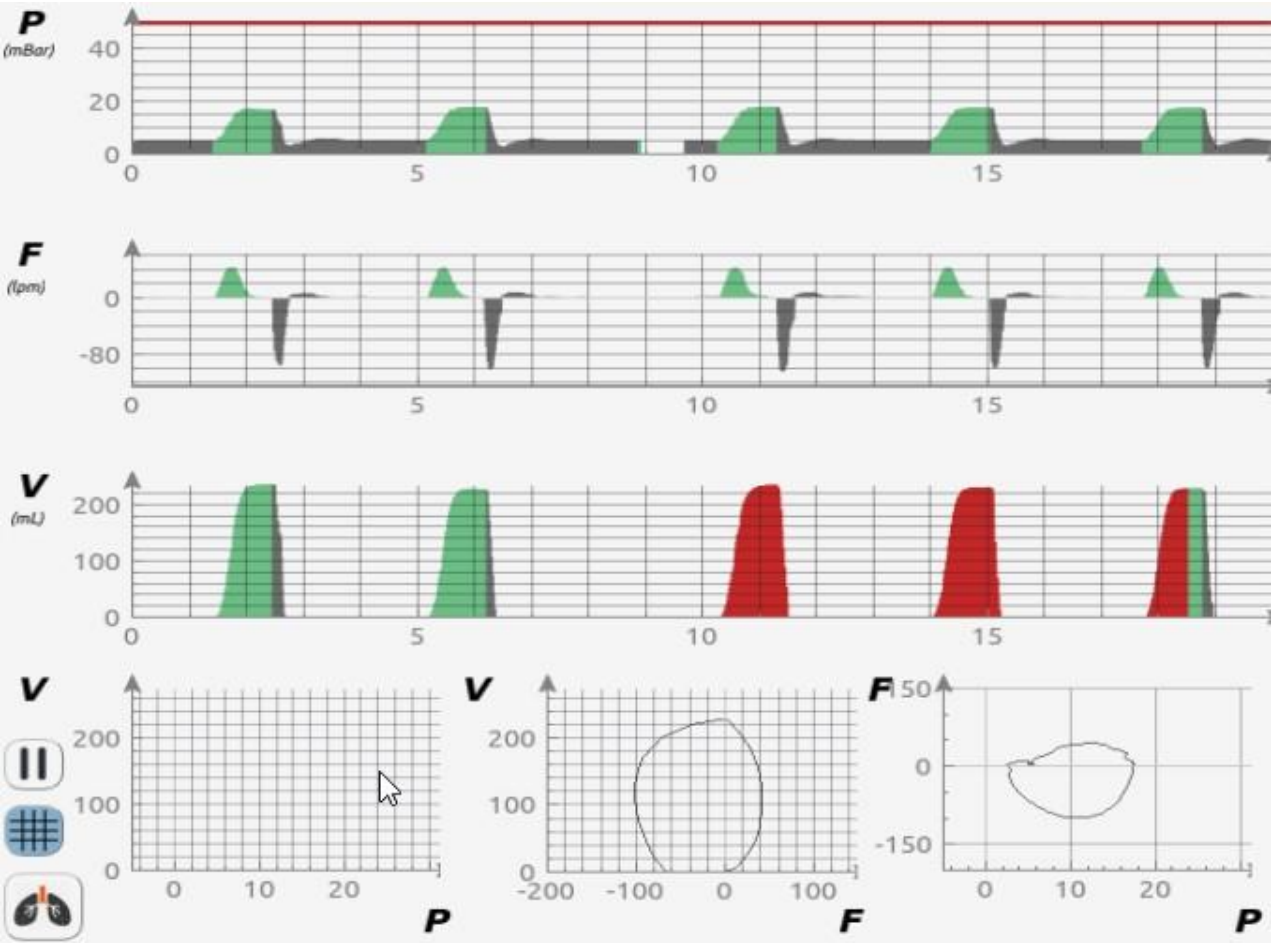


Figure 5.6. Ventilation Screen

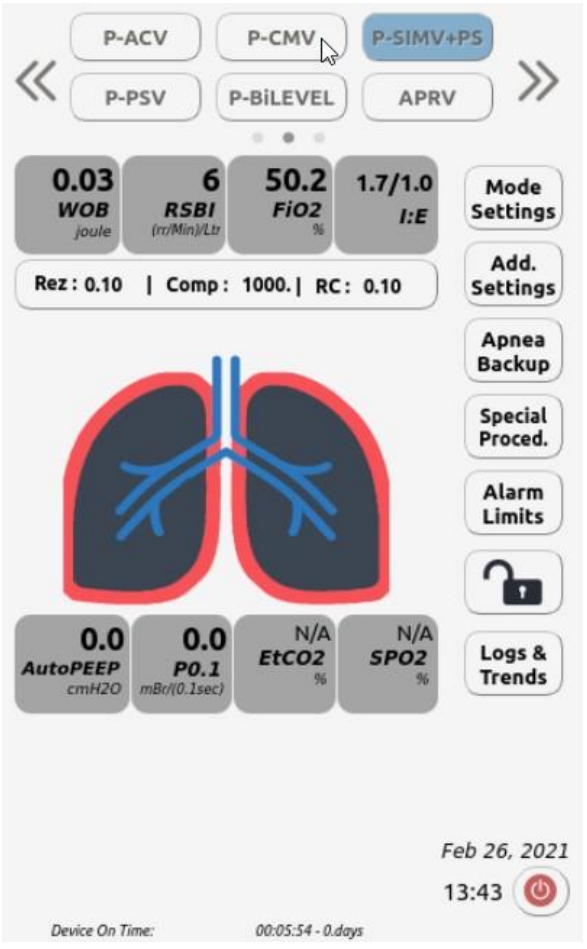


Figure 5.7. View of Lungs

2. Operation of Ventilator

1. General Warnings

 ATTENTION!	Do not place liquid containing containers on the ventilator.
	A "welcome screen" is displayed after the ventilator is turned on And self-testing (a short calibration test) runs during the start up. The ventilator ensures the following options after the welcome screen is displayed: start ventilation with previous patient info or new patient info.
 NOTES	Quick start ensures quick installation and start up of the mechanical ventilation. The respiration target values and alarm values that have been previously set in the quick start option may not be appropriate for every patient. Before using this feature, review the Quick Start parameters and ensure that they are in compliance with the clinical values of the patient.

5.2.2.Screen User Interaction

The ventilation parameters are entered over the user interface by using the following general steps.

1. Tap the settings displayed in the user interface.
2. Pull up the slider to increase the value or down to decrease the value.
3. Press Apply button to apply the setting and ensure that the Apply button is green.
4. Press Start Ventilation button.

5.2.3.Using Quick Start Method

1. Select Patient Type.
2. Press Start Ventilation button.

4. Tube Compensation

Tube Compensation is a spontaneous type selected during the installation of the ventilator. Ensures the additional positive pressure delivery by the ventilator to overcome the resistance imposed by the artificial airway of the patient.

5. Activating TK

1.Select TK from user interface screen.

2.Enter patient info.

ATTENTION!	To prevent inappropriate ventilation with TK, select the appropriate tube type and tube ID according to the clinical assessment of the patient. Setting an ET tube or tracheostomy tube that is greater or smaller than the actual value may result in improper ventilator support leading to over or underventilation.

5.2.6.Apnea Support Mode

The patient can be ventilated while the Bioovent Device is in one of the SPN-VS operating modes.This indicates that the exhalation reflex belongs to the patient and the patient triggers the device.

If the patient has apnea, apnea support mode is applied to the patient (If a ventilated patient cannot re-trigger the device for 10 seconds from the last moment it triggers the device through breathing, the patient is counted in the state of apnea.).

Apnea support mode automatically activates as soon as apnea status is detected. The patient is ventilated in one of the mandatory modes due to a situation that cannot be triggered by the patient.

When the bilateral apnea support feature is activated, the breath mode returns to the last set spontaneous mode after the trigger is activated.

In the system, one of the 2 compulsory modes with pressure control and volume control is applied as apnea support mode. When this option is selected as spontaneous operating mode

ATTENTION!	Apnea support mode is activated only when the operating mode is one of the spontaneous modes.
	Apnea backup mode is not required when applying mandatory mode to the patient. Therefore, this mode is not automatically activated.

5.2.7.Apnea Settings

After the performance of appropriate ventilator settings for the patient, tap the apnea tab on the left side of the ventilator screen. Although it is not necessary to change the apnea settings, set the default settings as appropriate for the patient. The apnea ventilation ensures pressure control or volume controlled breath types.

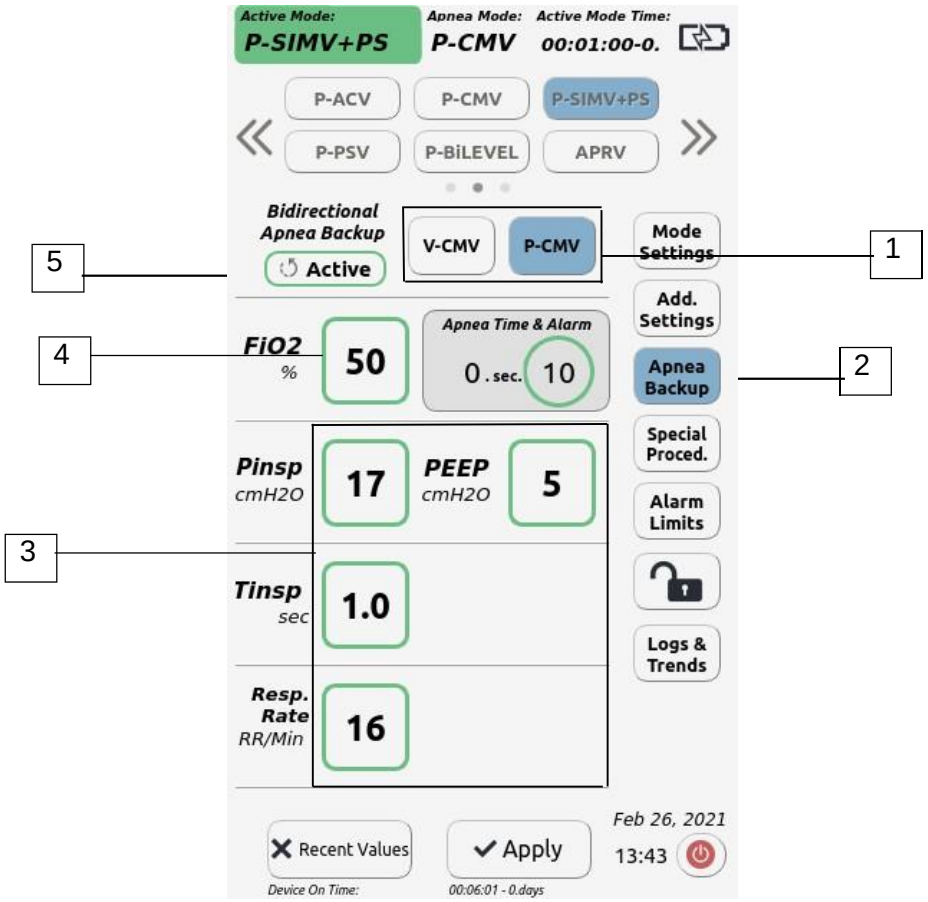


Figure 5.8. Apnea Settings

Table 5-1. Apnea Settings

Entering the Informations of Circuit	
Apnea Support Mode	Selecting the mode to be applied in case of apnea.
Apnea Time	Trigger time of apnea mode.
Apnea Mode Settings	Mode settings to be applied in case of apnea.
FiO2 Settings	FiO2 to be applied in apnea mode.
Bilateral Apnea Support	When bidirectional apnea support is activated, apnea after triggered, the breathing mode returns to the last set spontaneous mode

5.2.8.Maneuver additional gases

Inspiration and Expiration Hold, pure Oxygen delivery to the patient, water vapor and nebulizer activation settings are adjusted from this screen.

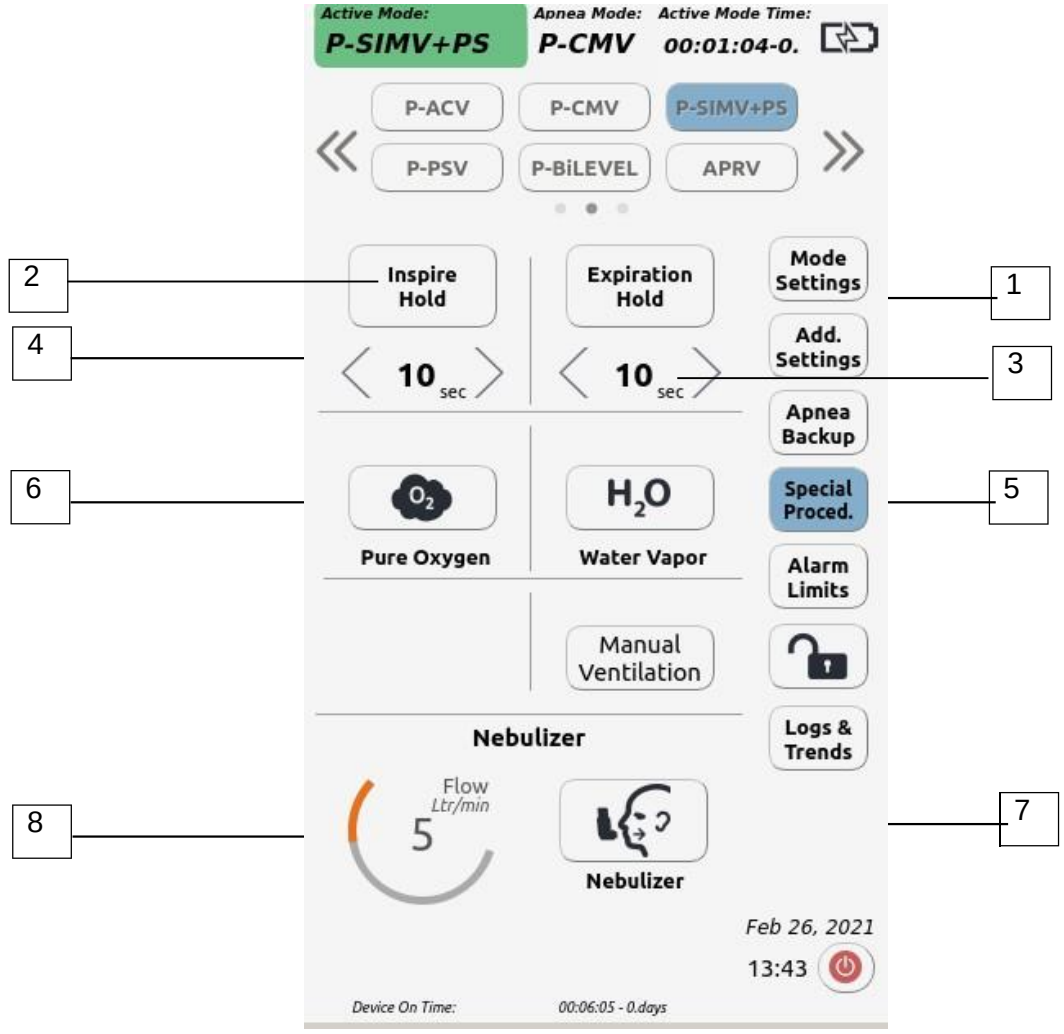


Figure 5.9. Maneuver additional gases

Table 5-2. Maneuver additional gases

Entering Circuit Informations	
1. Expiration Hold	During the set time, it keeps the patient in the expiratory phase.
2. Inspiration Hold	During the set time, it keeps the patient in the Inspiration phase.
3. Expiration Hold Time	Sets the expiration hold time.
4. Inspiration Hold Time	Sets the Inspiration hold time.
5. Damp	Activates the humidifier that connects to the Ventilator.
6. Pure Oxygen	It ensures that the patient is given pure oxygen for 120 seconds.
7. Nebulizer	Activates the nebulizer.
8. Nebulizer Flow	Adjusts the minute flow of the nebulizer on a liter basis.

9. Alarms

The user is informed by vocalizations that depend on the priorities of the alarms.

10. Alarm Settings

The alarm limits are set according to the patient by selecting the alarm limits button located on the left side of the ventilator user interface.

NOTES	If quick ventilation is selected, ventilation operation is initiated with the limits set by the alarm limits.
	The operator can change the settings by reviewing the instructions below

5.2.11.Setting Alarm Limits

1. Touch the alarm limits button on the right side of the Biyovent user screen.
2. Set the appropriate alarm limits according to the patient's clinical assessment.
3. Click the Apply button.

	If quick ventilation is selected, ventilation operation is initiated with the limits set by the alarm limits.
	The operator can change the settings by reviewing the instructions below
ATTENTION!	The corresponding alarm is not activated during ventilation when the alarm limits are closed or set to excessively high or low values. Thus, the effectiveness of the related alarm is reduced in order to alert the operator when monitoring and intervention is required.
	Before starting ventilation and changing ventilation settings, make sure that the alarm settings are appropriate for the patient.
NOTES	Do not block the patient end connection while the ventilator is waiting for a patient to connect.

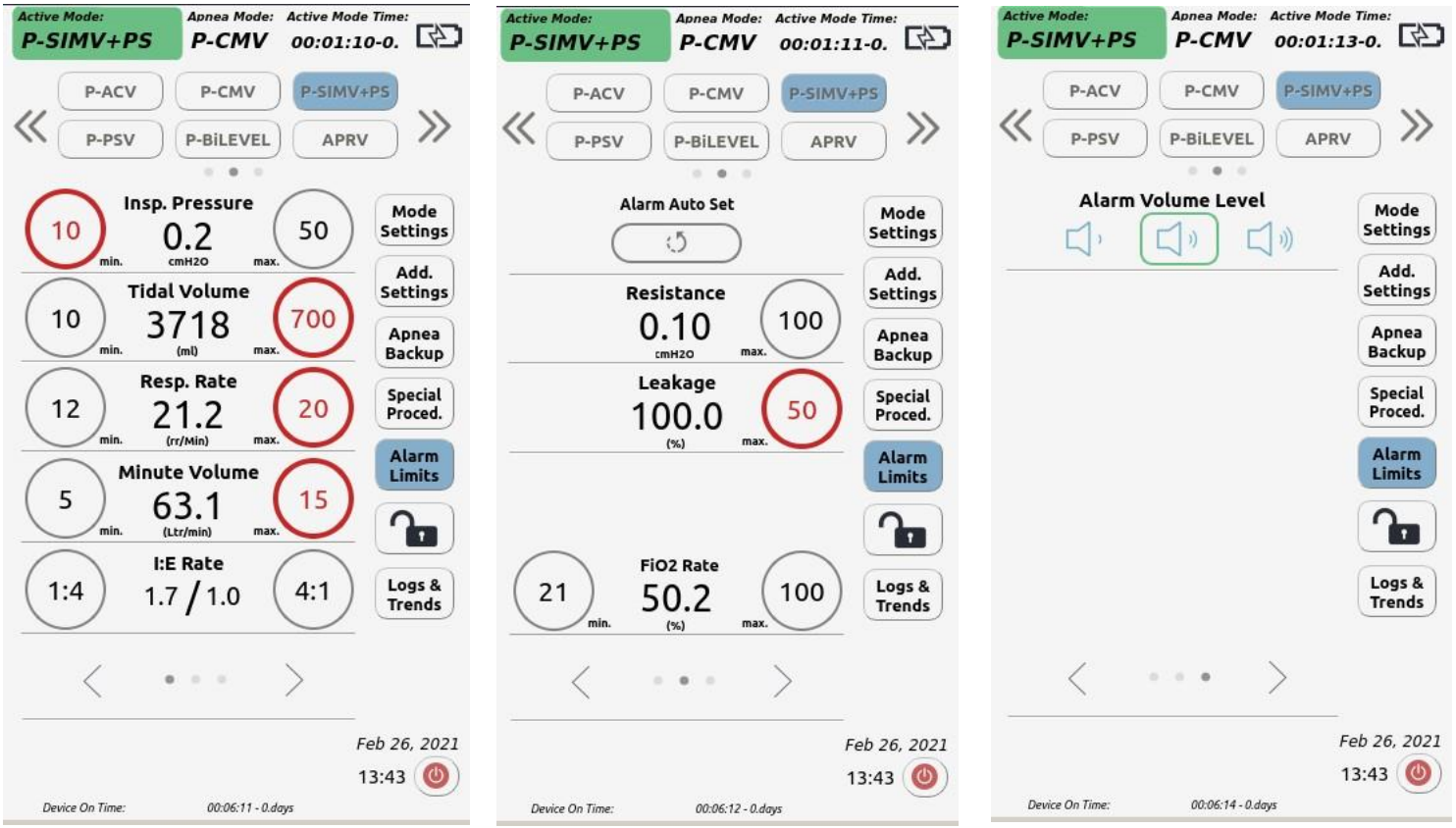


Figure 5.10. Alarm Limits

Alarm limits are set by deciding lower and upper limits in the menu. With the alarm otoset tab, the lower and upper limit of the alarm is set automatically according to the mode settings. On the third alarm page, the alarm volume is set.

5.2.12. Screen Lock

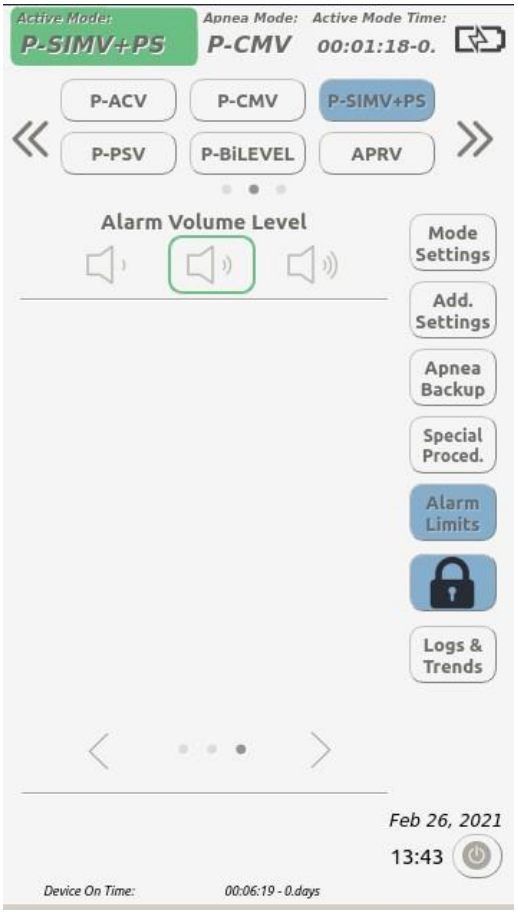


Figure 5.11. Screen Lock

It is located on the right side of the user interface screen. By tapping this tab, the user locks the screen and no changes are made to the screen.

5.2.13.Logs & Trends

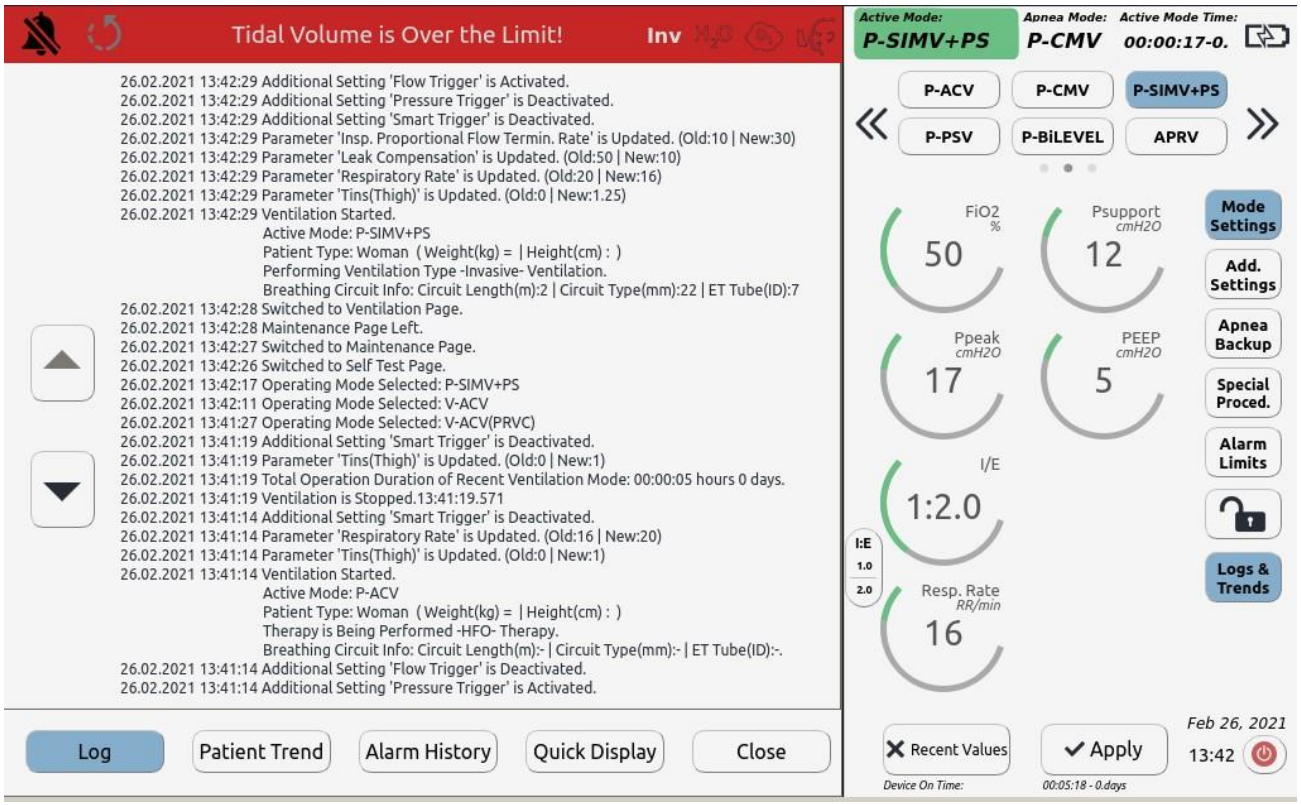


Figure 5.12. Logs & Trends

Patient data and system information can be accessed from the menu that will be opened by clicking on the Log & trends tab.
From the Log & trends screen, all operations applied to the ventilator can be seen in the log section, patient data can be seen in the trend section, and alarm records can be seen in the alarm history section.

5.2.14 Device Status Bar

In this bar, errors occurring in the system until the device is switched on and off, errors due to serial port connection and over limit warnings are displayed to the user.

The status information of the device is displayed here.

Example: Ventilation is in the uninitialized position and waiting for the start ventilation command.

Figure 5.13. When the device waiting for the start ventilation command

Example: When the device is operating under normal conditions (No error has been shown on the status bar)

Figure 5.14. When the device is operating under normal conditions

Example: One of the abnormalities that occur in the device will be seen as follows.

Figure 5.15. The abnormality

5.2.15 Alarm to be displayed on the Status Information Bar, Warnings

NOTES	All the alarm status phrases that inform the user by being displayed on the status information bar are given below.

1) M11_MECHANICAL_RESOURCES_AIR_NONE;
2) M12_MECHANICAL_RESOURCES_AIR_LOW;
3) M13_MECHANICAL_RESOURCES_O2_NONE;
4) M14_MECHANICAL_RESOURCES_O2_LOW;
5) M21_MECHANICAL_QUALITY_AIR_HUMIDITY;
6) M22_MECHANICAL_QUALITY_AIR_HOT;
7) M23_MECHANICAL_QUALITY_O2_HUMIDITY;
8) M24_MECHANICAL_QUALITY_O2_HOT;
9) M25_MECHANICAL_QUALITY_O2_LOW;
10) M31_MECHANICAL_LEAKAGE_PNEUMATIC;
11) M41_MECHANICAL_LEAKAGE_TANK;
12) M51_MECHANICAL_REDUCER_NEBULIZER;
13) M52_MECHANICAL_REDUCER_AUX;
14) M53_MECHANICAL_REDUCER_EXP;
15) M61_MECHANICAL_EMERGENCY_VALVE;
16) R11_REG_COMMUNICATION;
17) R12_REG_COMMUNICATION_INCOMING;
18) R13_REG_COMMUNICATION_SENT;
19) R21_REG_IV_3V;
20) R22_REG_IV_3I;
21) R23_REG_IV_5V;
22) R24_REG_IV_5I;
23) R25_REG_IV_12V;
24) R26_REG_IV_12I;
25) R27_REG_IV_15V;
26) R28_REG_IV_15I;
27) R31_REG_TEMPERATURE_CARD;
28) R32_REG_TEMPERATURE_PNEUMATIC;
29) R33_REG_VALVE_AIR;
30) R34_REG_VALVE_O2;
31) R35_REG_VALVE_NEBULIZER_AIR;
32) R36_REG_VALVE_NEBULIZER_O2;
33) R37_REG_VALVE_PRESSURE_AIR;
34) R38_REG_VALVE_PRESSURE_O2;
35) R39_REG_VALVE_TANK;
36) R3A_REG_VALVE_PEEP_IN;
37) R3B_REG_VALVE_PEEP_OUT;
38) R3C_REG_VALVE_PEEP_DISCHARGE;

39) R41_REG_SENSOR_PRESSURE_AIR;
40) R42_REG_SENSOR_PRESSURE_O2;
41) R43_REG_SENSOR_FLOW_AIR;
42) R44_REG_SENSOR_FLOW_O2;
43) R45_REG_SENSOR_O2;
44) R46_REG_SENSOR_FLOW_NEBULISER;
45) R47_REG_SENSOR_FLOW_EXP;
46) R48_REG_SENSOR_FLOW_AUX;
47) R49_REG_SENSOR_PRESSURE_INSP;
48) R4A_REG_SENSOR_PRESSURE_PRESSURE_AUX;
49) R4B_REG_SENSOR_PRESSURE_PEEP;
50) R4C_REG_SENSOR_PRESSURE_TANK;
51) R51_REG_HOSE_NONE;
52) R52_REG_HOSE_VALVE;
53) R53_REG_HOSE_LEAKAGE;
54) R54_REG_HOSE_AUX_LEAKAGE;
55) R55_REG_HOSE_AUX_FLOW;
56) R61_REG_COMPONENT;
57) P11_POWER_COMMUNICATION;
58) P12_POWER_COMMUNICATION_INCOMING;
59) P13_POWER_COMMUNICATION_SENT;
60) P21_POWER_IV_3V;
61) P22_POWER_IV_3I;
62) P23_POWER_IV_5V;
63) P24_POWER_IV_5I;
64) P25_POWER_IV_12V;
65) P26_POWER_IV_12I;
66) P27_POWER_IV_15V;
67) P28_POWER_IV_15I;
68) P31_POWER_TEMPERATURE_AC;
69) P32_POWER_TEMPERATURE_DC;
70) P33_POWER_TEMPERATURE_DCDC;
71) P41_POWER_AC_CURRENT;
72) P42_POWER_AC_HUMIDIFER;
73) P51_POWER_DC_VOLTAGE_LOW;
74) P52_POWER_DC_VOLTAGE_HIGH;
75) P53_POWER_DC_CURRENT_HIGH;
76) P54_POWER_DC_CURRENT_BLOWER_HIGH;
77) P61_POWER_BAT1_NONE;
78) P62_POWER_BAT1_VOLTAGE;
79) P63_POWER_BAT1_DATE;
80) P64_POWER_BAT1_CURRENT_SENT;
81) P65_POWER_BAT1_CURRENT_INCOMING;
82) P66_POWER_BAT2_VOLTAGE;
83) P67_POWER_BAT2_DATE;

84) P68_POWER_BAT2_CURRENT_SENT;
85) P69_POWER_BAT2_CURRENT_INCOMING;
86) P71_POWER_FAN1;
87) P72_POWER_FAN2;
88) P73_POWER_FAN3;
89) P81_POWER_SCREEN_VOLTAGE_LOW;
90) P82_POWER_SCREEN_VOLTAGE_HIGH;
91) P83_POWER_SCREEN_CURRENT_LOW;
92) P84_POWER_SCREEN_CURRENT_HIGH;
93) "Tidal Volume Below Target Range"
94) "Tidal Volume Above Target Range"
95) "Minute Volume Below Target Range"
96) "Tidal Volume Above Target Range"
97) "The Number of Breaths Below Target Range"
98) "The Number of Breaths Above Target Range"
99) "Maximum Pressure Above Target Value"
100) "Leakage Value Below Target Range"
101) "Leakage Value Above Target Range"
102) "Apnea Status"
103) "Cannot Connect to the System”

5.2.16 Color Warnings

These alarms or systemic alarms are monitored from the device's status bar. Information about the status of the device is displayed to the user in the status bar with red-green-yellow color changes in the order of importance.

 WARNINGS!	The limits of some alarms are determined by the user. These alarms are also displayed on the parameter monitoring screen

Example: In the image below, an alarm occurs in Minute Volume,Tidal Volume, Ppeak, Leak and Respiration Rate.

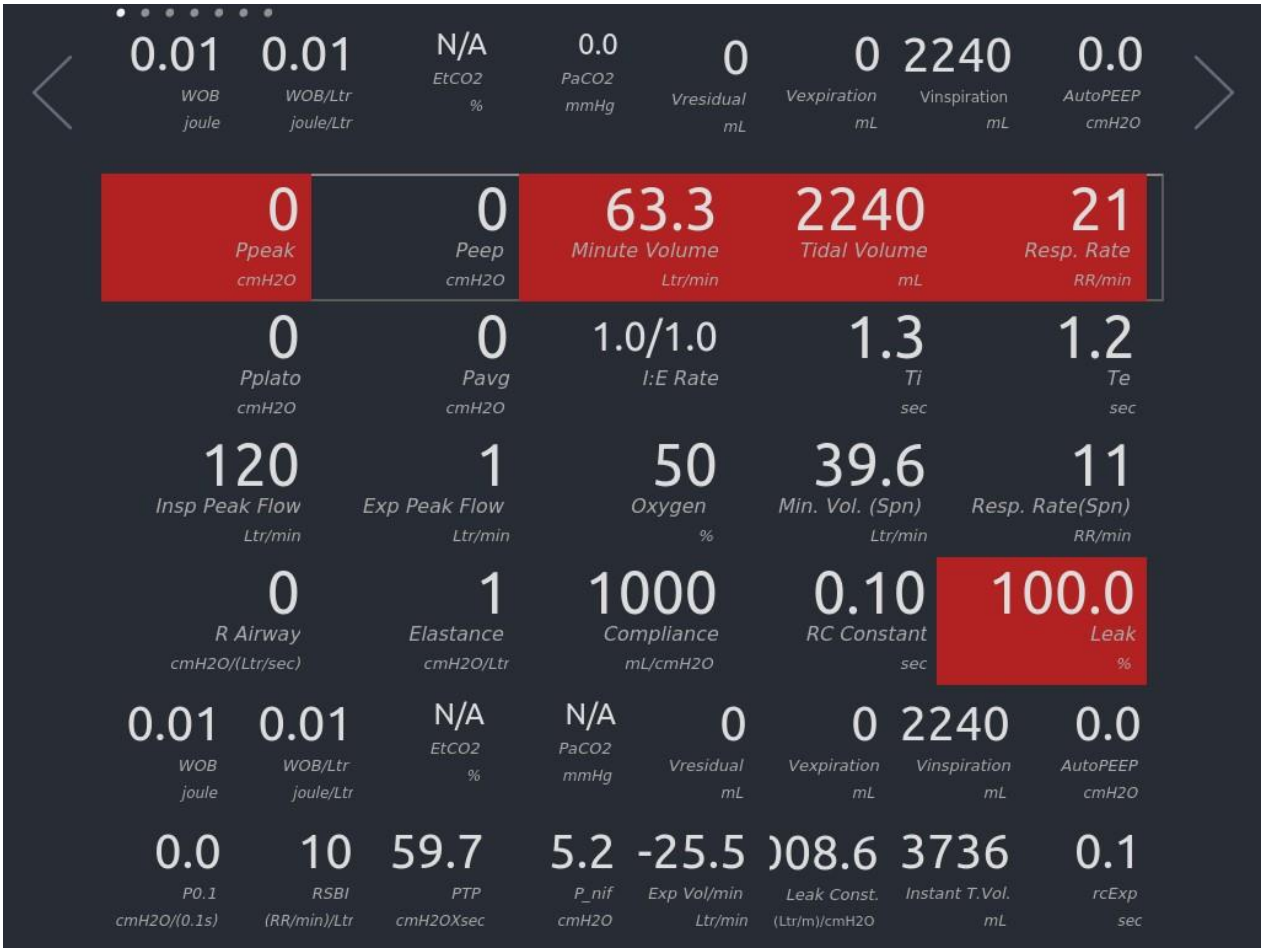


Figure 5.16. Alarm of Minute Volume,Tidal Volume, Ppeak, Leak and Respiration Rate

5.3 Ventilator Gas Supply Error

If there is an interruption or error in a gas supply source, the device continues ventilation using the other gas source.

	When this error occurs, it appears as a priority alarm in the status bar.
 WARNINGS!	**In the status bar, one of the explanations stated below is displayed;** **M11_MECHANICAL_RESOURCES_AIR_NONE;** **M12_MECHANICAL_RESOURCES_AIR_LOW;** **M13_MECHANICAL_RESOURCES_O2_NONE;** **M14_MECHANICAL_RESOURCES_O2_LOW.**

PART 6
DEVICE AND ACCESORIES

There is no mandatory accessory that Biosys states that it should be used with the device. If accessories are required, they must be provided by the hospital. The standards to be complied with are given in the general warnings section. Accessories approved by Biosys are mandatory to use on the device. If these accessories are not used, maintenance and warranty coverage expire.

ATTENTION!	Equipment considered as accessories for the device are: Handle, Battery, Patient Set, Hepa Filter, Nebulizer.

6.1 Hose Settings

The hose settings screen open by pressing the Hose Settings Button that stays in the left side of the screen.

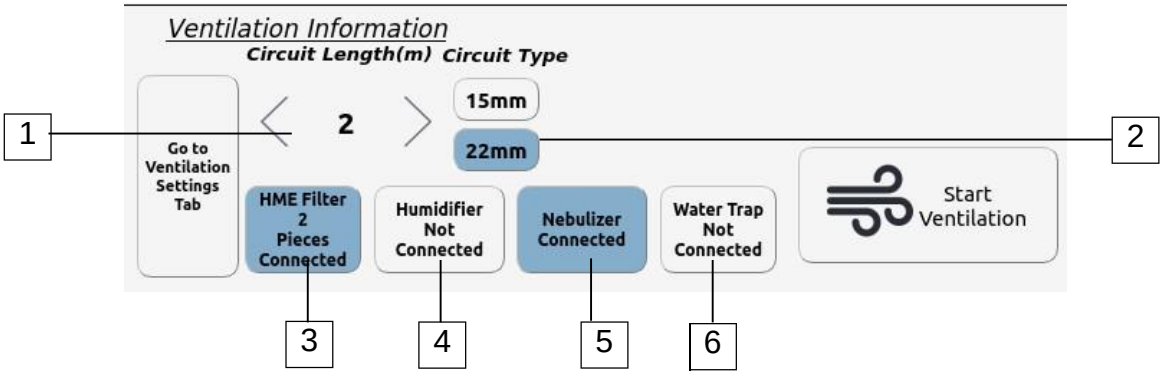


Figure 6.1. Hose Settings Screen

Table 6-1. Hose Settings Screen

Informations of Circuit	
1. The Length of The Circuit	Enter the circuit length connected to the device.
2. Diameter of Circuit	Enter the circuit diameter connected to the device.
3. Bacteria Filter	Enter the number of bacteria filters added to the device.
4. Humidifier	Select if the humidifier is connected to the circuit.
5. Nebulizer	Select if the nebulizer is connected to the circuit.
6. Water Trap	Enter the number of water traps added to the device.

6.2 Patient Sets

Patient sets should be attached and removed as shown in the device assembly guide. Old, worn, forced or ragged patient sets should not be used.

 ATTENTION!	Biosys is not responsible for the use of a patient set that is not recommended by Biosys. Also, Biosys is not responsible for the problems caused by the non compliant use of patient sets.
	The device user is responsible for the problems caused by the inappropriate use of patient sets.
	It is not possible for Biosys to know and accept the patient set standards used in all hospitals or usage areas. When using a sterile patient set, follow the recommendations of the Biosys company.

The user should be aware of the following before ventilating at each different patient change:

1- The user must make sure that he / she has changed the patient set

2 Checking if there is a problem in the new patient set,

3 Biosys company is not responsible for the problems that may arise in case of any failure in any of the ‘steps of the change of filters (transport of the infection caused by the patient set, poor performance of the device, failure of the patient to be properly ventilated, damage to the patient).

6.3. Humidifier

Use the humidifier to add heat and moisture to the breath. The humidifier accessory should be attached when the device is off or when the device is on but ventilation is not started.

ATTENTION!	Do not plug or unplug the humidifier accessory while ventilating
	Make sure that the CIT is made after the humidifier accessory is attached. (See In-Device Tests)
	Follow the humidifier manufacturer's instructions for use.
	Use humidifiers recommended by BIOSYS.
	If the device is powered by a battery, the humidifier will not work.

Figure 6.2. Humidifier Connection

NOTES	Appropriate humidifier is connected to the apparatus on the machine, indicated by 1 in the above figure.
	Humidifier connectors are connected to the machine from the inlet shown by 2 in the figure above.

6.4. Managing the Nebulizer Function

Nebulizer settings are opened by pressing the shortcut button on the right of the screen.

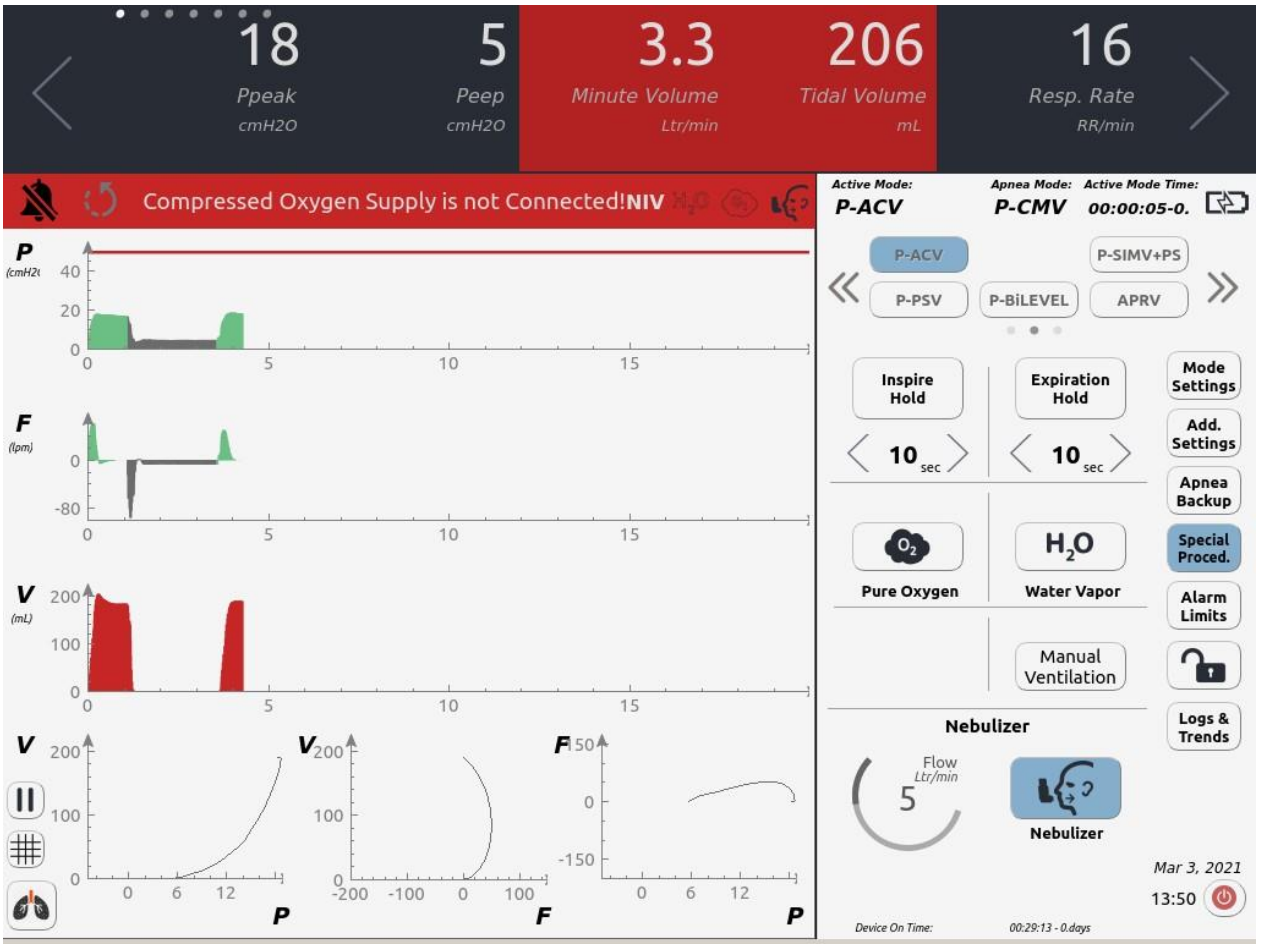


Figure 6.3. Managing the Nebulizer Function

Indicator values are clicked to adjust Flow and Oxygen parameters. With the slider opened on the side, change of value is provided. While making these settings, the color of the indicators turns orange.

WARNINGS!	If the indicators are orange, it indicates that the parameters have been changed. However, it also indicates that it has not been applied to the patient yet.
ATTENTION!	A started nebulization process does not end spontaneously. To stop nebulization, the user should press the same button again and the button color should be changed to pale gray.
	Make sure that the appropriate nebulizer is used for the patient. The user is responsible for the negativities that may arise in terms of the contribution of the used Nebulizer to the treatment process, the device and Biosys are not held responsible.
WARNINGS!	If the nebulizer button is pale gray, the patient is not nebulized.
	If you want to apply nebulization to the patient, make sure the color of this button is blue.

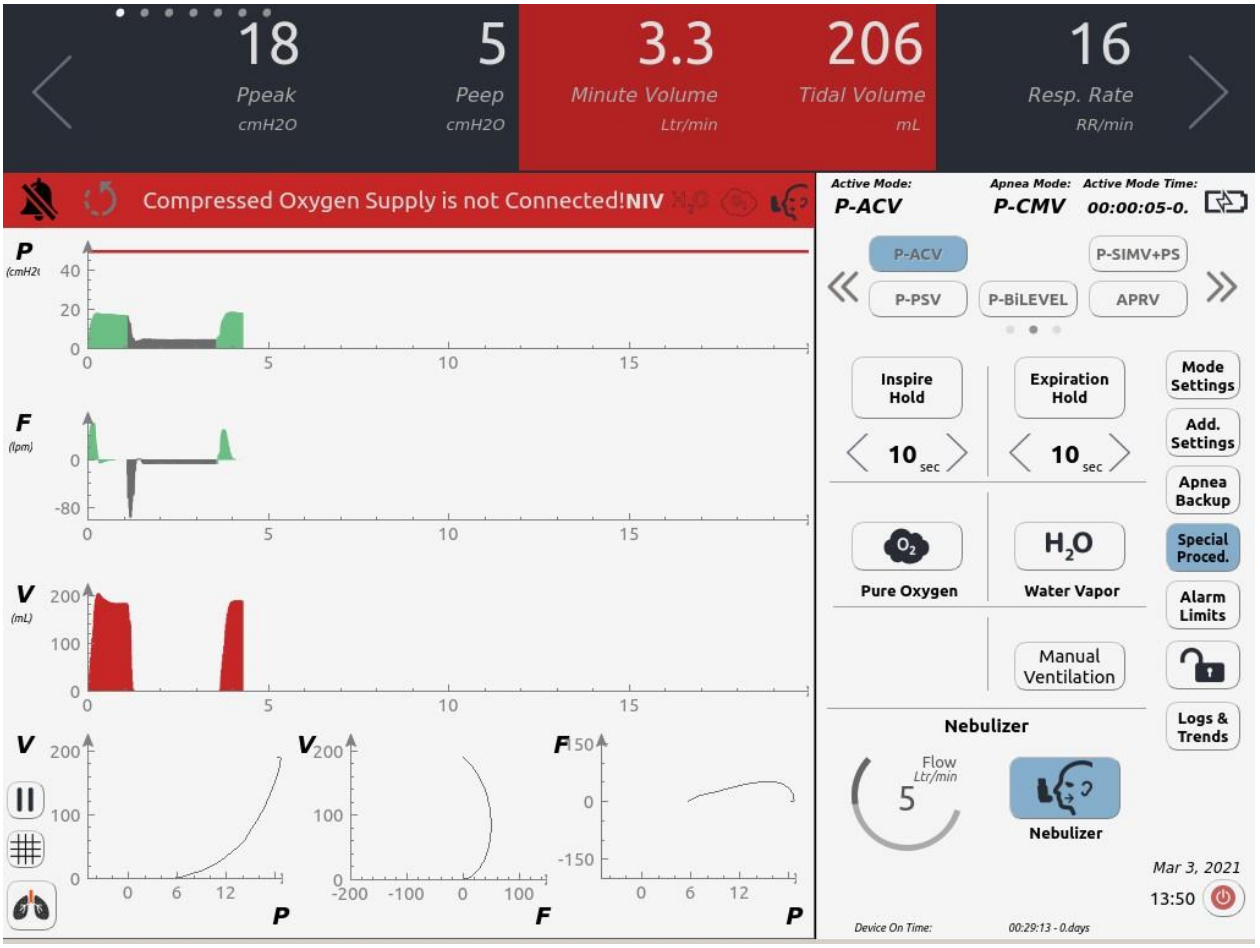


Figure 6.4. Managing the Function of the Nebulizer

The process of applying the nebulizer to the patient is started by pressing the 

' button. If the nebulizer is applied to the patient, the color of the button turns blue.

Figure 6.5. Managing the Function of the Nebulizer

5. Device Cleaning

1. Screen Cleaning

If the device is off, its screen should be cleaned in accordance with the hospital cleaning standards. If the device is working, the screen lock is activated by pressing the screen lock button and the screen is cleaned in accordance with the cleaning standards.

WARNINGS!	It is not possible for Biosys to know the sterilization and cleaning standards of all hospitals and usage areas. Clean only as recommended.

Screen lock passive: 

Screen lock is active: 

6.5.2. Flow Sensor Cleaning

 ATTENTION!	After the expiratory valve comes from sterilization, the metal leaf part inside the flow sensor part must be closed. If the metal sheet part is not closed, the values obtained will not be correct. Therefore, the metal leaf part should be checked.

6.5.3. Device Body Cleaning

The body of the device should be cleaned using micro fiber cloth and non-alcohol medical device disinfectants.

 WARNINGS!	The pipe inlets and outlets are checked after cleaning the device body. Do not start ventilation without confirming that CIT tests have been completed and the results are OK.
 ATTENTION!	Oxygen transition areas in the device body are not cleaned with oil-containing cleaners. (Otherwise, explosion or combustion may occur.)
	Do not clean the device body while the device is on and ventilating.
 WARNINGS!	The user of the device is responsible for possible rule violations regarding the cleaning process.

4. Screen Foot Cleaning

The foot of the device should be cleaned using micro fiber cloth and non-alcohol medical device disinfectants.

5. Emergency Evacuation Filter Replacement

The bacteria filter in the emergency evacuation outlet of the device should be changed in every patient.

6. Sterilization of Expiration Valve

Sterilization of the expiratory Valve: after cleaning of the Expiratory Valve, steam sterilization(autoclave), other low temperature sterilization or high level disinfection should be applied.

 ATTENTION!	Disinfection, antisepsis, sterilization (DAS) prepared by the Association ” Disinfection Antisepsis Sterilization Guide 2019 " Page 23 table.2

 WARNINGS!	The expiratory valve consists of 4 parts. Cleaning of the membrane part inside the expiratory valve must be performed with precision. After cleaning the membrane, it should be checked for tears and holes

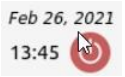
PART 7
STOPPING VENTILATION AND TURNING OFF THE VENTILATOR

7.1. Turning Off the Device While the Ventilation Process is Active

While the device is performing ventilation operation, the button to turn off the device is inactive.

WARNINGS!	You cannot turn off the device without stopping the ventilation procedure.
ATTENTION!	In case of a power failure, the internal batteries of the device will be activated and will allow ventilation for 2 (two) more hours if it is fully charged.

7.2. Stopping Ventilation

When you want to stop the ventilation process, press 

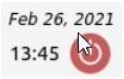
the in the lower left corner of the screen. Then the user is expected to make the final decision on the screen on the right.

ATTENTION!	The decision to stop ventilation is a very important decision for the patient. The process is based entirely on the user's judgment.
WARNINGS!	The recordings of the device on and off time are recorded in the recorder.

7.3. Turning Off the Device While Ventilation Is Not Applied

The device off button is active when ventilation is not applied.

WARNINGS!	While ventilation is not applied, "Waiting" is displayed on the status information bar of the device, ventilation graphics are not seen and gas inlet and outlet are not observed in the patient tubes.

The system is turned off by touching the 

button located in the lower right corner of the screen.

7.4. Turning Off The Ventilator in an Emergency Situations

It may be necessary to turn off the ventilator in an emergency situation. Disconnect the patient from the ventilator and provide the patient's respiratory support before turning off the device. It is possible to stop the entire system with the emergency shutdown button indicated by X below. According to the 'CE' standards, stop ventilation from the user screen before stopping the entire system.

Figure 7.1. Turning of the Ventilator in an Emergency Situations

5. Independence of Ventilator Control Function and Related Risk Control Precautions

1. Traceable Data

All parameters applied to the patient are monitored by clicking on the area in the figure or using the right and left arrow keys.

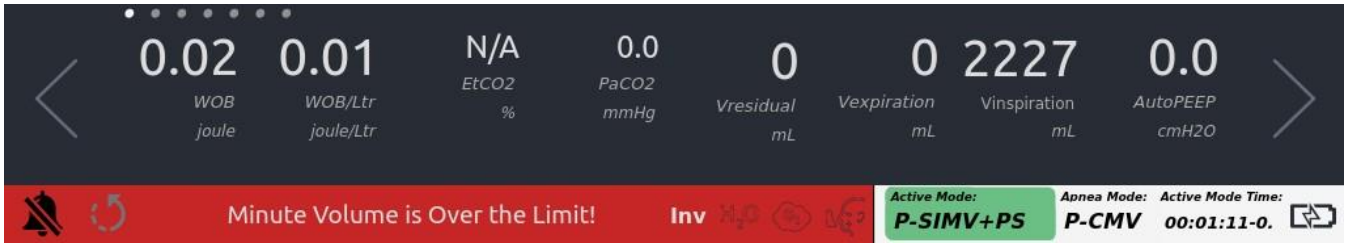


Figure 7.2. Traceable Data

The upper band section is clicked to minimize the informative screen that covers the entire screen. This way, the full screen view is exited.

WARNINGS!	The traceable values appear as “---“ when ventilation is not applied.

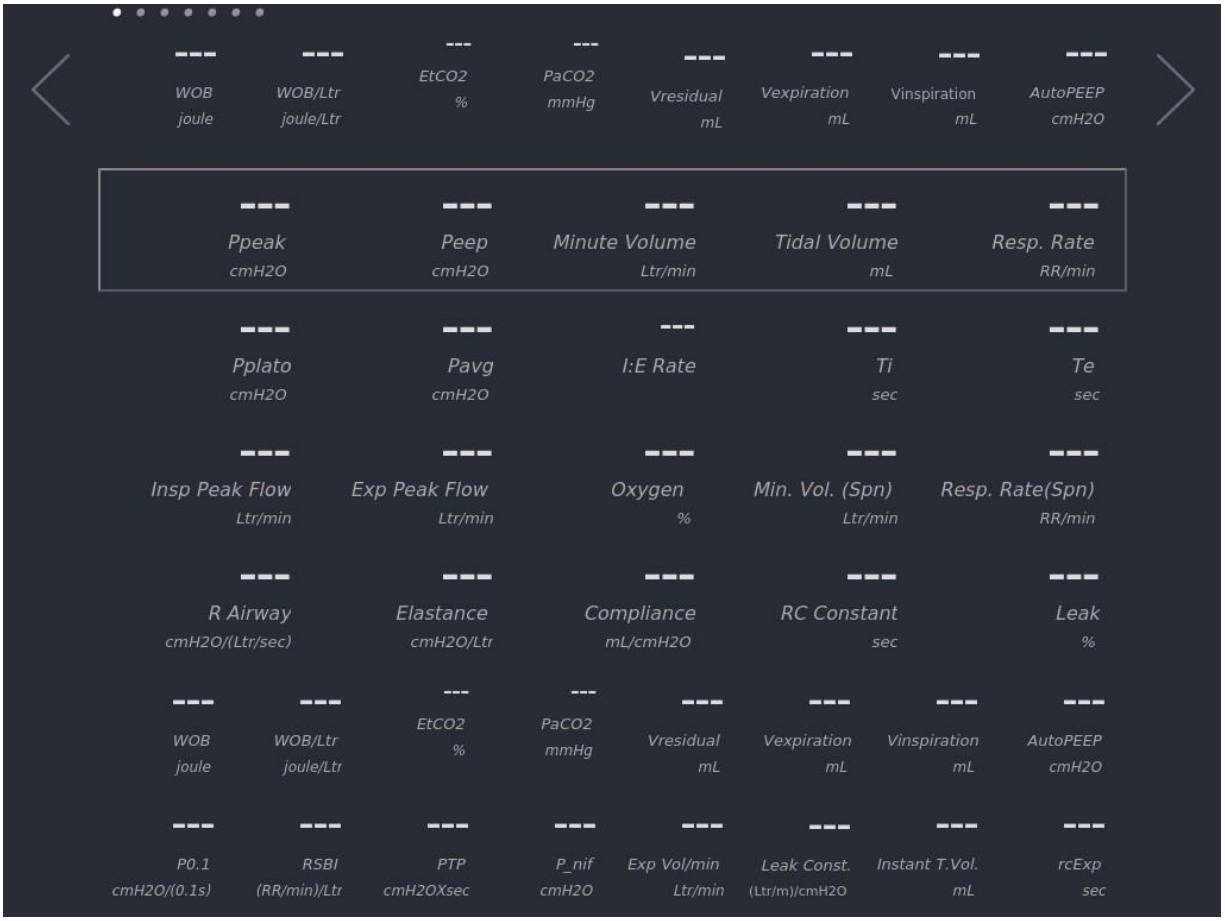


Figure 7.3. Traceable Data

When the ventilation application process is started, the values of the traceable data are readable.

Figure 7.4. Traceable Data

7.5.2. Monitoring and Control Screen of Electronic Equipment Operation

Operational monitoring of the electronic cards that belong to the device is done on the screen below,

 WARNINGS!	Values are readable when ventilation begins to be applied.

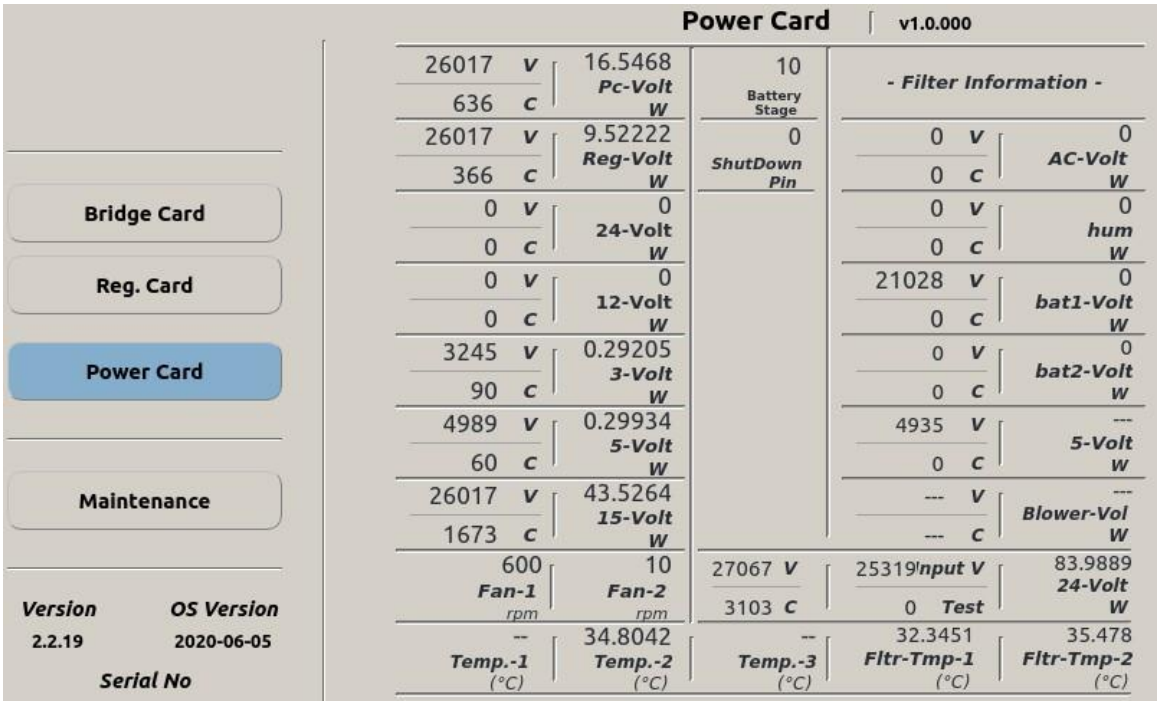


Figure 7.5. Monitoring and Control Screen of Electronic Equipment Operation

7.5.3. Ventilation Application Control Function

After switching on the device, parameter change settings are checked with the "Apply" or "Last Values" buttons (the decision to apply the changes to the patient or the decision indicating that the changes are abandoned is expected from the user.)

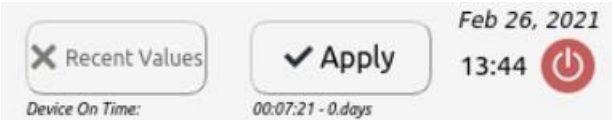


Figure 7.6. Ventilation Application Control Function

 WARNINGS!	Make sure all ventilation settings are suitable for the related patient. This decision is based entirely on the ventilation training the user receives and the user's judgment.
	When the device is running for the first time; If the "Last Values" button is pressed for a command directory that has never been applied before, values from the average will be loaded on the system. The user should check these values and consciously consider pressing the start ventilation button, which is the next step.

7.5.4. Ventilation Application Start/Stop

To start ventilation; The "Start Ventilation" button is pressed.

 WARNINGS!	The traceable values appear as “---“ when ventilation is not applied.

PART 8
SAFETY PRECAUTIONS FOR CONNECTION TO MEDICAL GAS PIPING SYSTEM

8.1.Safety Precautions

 ATTENTION!	Do not use the ventilator with anesthetic gases.
	When applying ventilation to the patient, use clean, dry gases suitable for medical use.
	The use of a single gas source can cause incorrect ventilation and hypoxemia if the source is depleted. Connect two gas sources to the ventilator to ensure that a gas source can be supplied to the patient if the gas supply is interrupted.
 WARNINGS!	The ventilator has two connection ways for gas supply. Air inlet and Oxygen inlet.
 ATTENTION!	Connect the ventilator to a gas pipe source that is in compliance with ISO 7396-1: 2007.

	To prevent the risk of fire, there should be no spark, igniting tools (cigarettes, matches, heaters, flammable chemicals) in the environment where the device is located. Attention should be paid to the hose inlets and outlets and gas lines of the device. (It should be remembered that the Biovent Ventilator contains oxygen from combustible gases!)
	It should be ensured that the accessories (hoses, valves) in the ventilator's gas supply sources are not worn. The accessories should not contain any residual chemicals and any kind of oil. (When the oil, petroleum, solvents or tar-contaminated fabric or surfaces in the environment come into contact with oxygen, they easily ignite and burn massively. Oxygen is oxidizing.)
 ATTENTION!	When the possibility of fire is noticed in the environment where the device is located (smell, temperature, etc.) 1)The device should be quickly disconnected from the hospitaloxygen pressure gas source. 2)All feeds to the device must be closed. (The switch on the back should be closed and disconnected from the mains voltage.)
	After the device is received the infection, isolation guide of the hospital must be read and its rules must be acknowledged before making any intervention to any part of the device.
	The Biovent Ventilator device is designed as a monitoring and support device for patients who are treated in the intensive care units of hospitals. It is not possible to create alarms (colored and verbal warnings, records, behaviors) for every imaginable complication in device-user-patient relationship. The situations in which the device will show an alarm are as specified in the Alarms & Warnings item in this manual.
	The ventilator is not used with gases containing helium or helium mixtures.
	The device is designed for use with oxygen and air only. It should not be connected to any gas other than oxygen and air.

 ATTENTION!	Please make sure to read this user guide before operating the device. Before proceeding to practice, interpret the situations correctly stated in this manual with your educational knowledge, experience and judgment, and make sure you absorb the information received.
	Do not use hard, sharp, piercing objects when using the user screen GUI. The touch screen is only suitable for use with bare hands or thin examination gloves, it is not possible to know and test the properties of all types of gloves used in hospitals by Biosys. Please follow the recommended GUI usage method.
	Do not approach any part of the device with hard, cutting, piercing tools.
	The device is designed to be used in intensive care units only, considering hospitals' intensive care unit standards.
	An alternative source of ventilation should be available during the application of the biovent device to the patient.
	The biovent device is a device that supports breathing exchange related to the upper respiratory tract. It provides inputs based on various patient types, breathing modes that the clinician can choose, and various combination data. Regarding this application, the judgment and decision of the quantity and quantity settings of the parameters such as model, time, amount, pressure, flow, time and density belong to the user and this is based on the clinical knowledge of the clinician.
	The device is designed for use only in the intensive care units of hospitals. (It cannot be used in hyperbaric, normal, etc. room conditions).
	The operating time of the device is recorded. It can run 2 hours with fully charged batteries.

8.2. In-Device Test

In-device tests are the tests that are performed automatically when the device is turned on, checking the system features and compliance that should be performed before the ventilation begins, in case of patient change, changing patient set, changing filter and starting ventilation.

Opening Test: These are automatic tests at device startup. Test steps:

- Valves Test: Carries out functional tests of the valves.
- Expiratory Valve Test: Tests the functionality of the expiratory valve.
- Checking the pressure sensors: Controls the functionality of pressure sensors. Calibrates according to the atmospheric pressure.

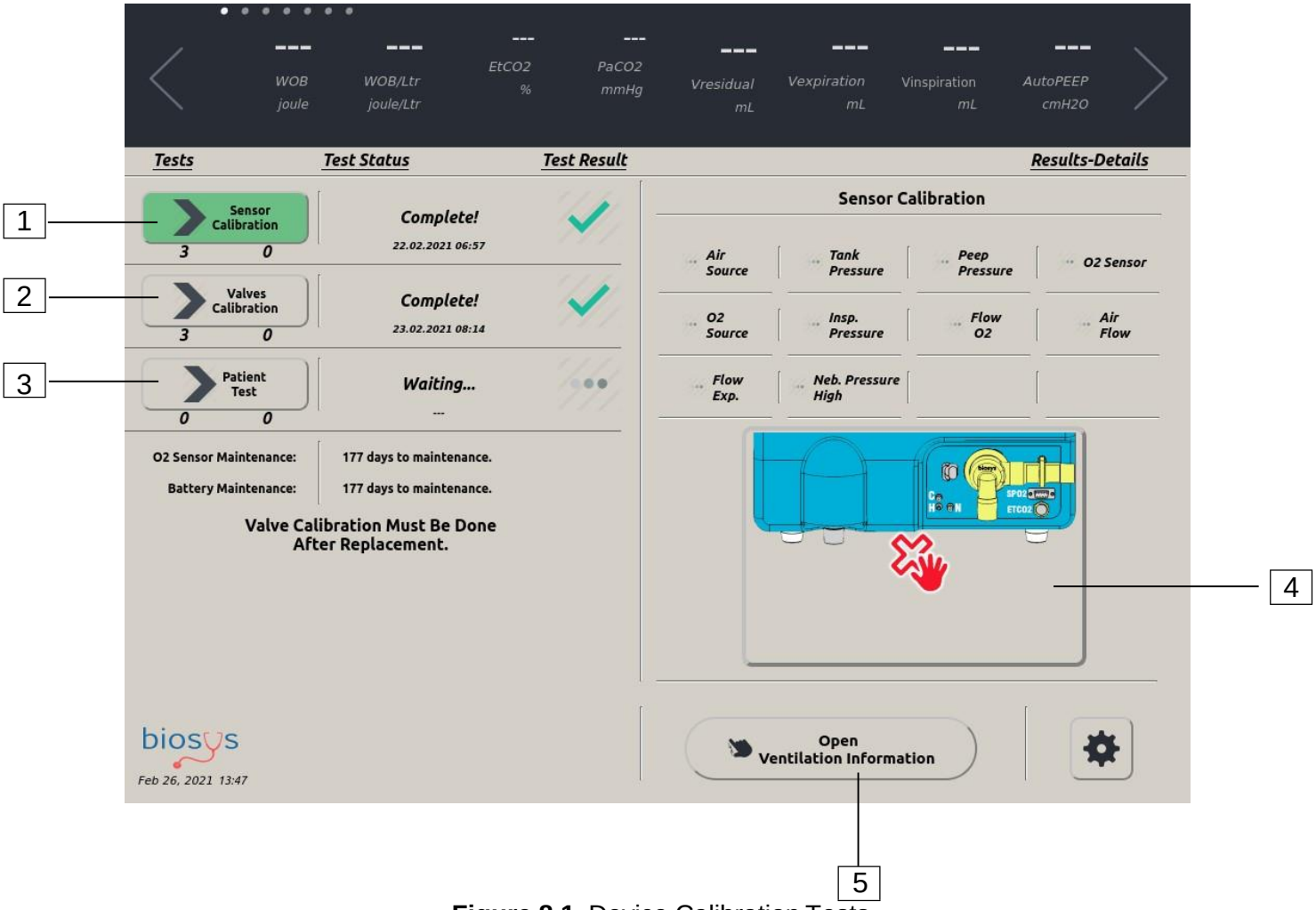


Figure 8.1. Device Calibration Tests

Table 8-1. Calibration Screen

Calibration Screen	
1. Sensor Calibration	Calibrates the sensors contained in the device.
2. Valve Calibration	Calibrates the valves contained in the device.
3. Circuit Calibration	Calibrates the patient circuit used in the device.
4. Starting the Calibration	Used to initiate the selected calibration.
5. Main Menu Button	to return to the main menu after calibration.

8.2.1. Applying Calibration Tests

Three process of calibration that must be completed. The steps that are seen on the calibration screen must be compeleted respectively. A figure is seen on the right side of the screen for every step of calibrations and these figures show what will applied to the patient circuit. A green teak appear when the calibration test finish successfully.

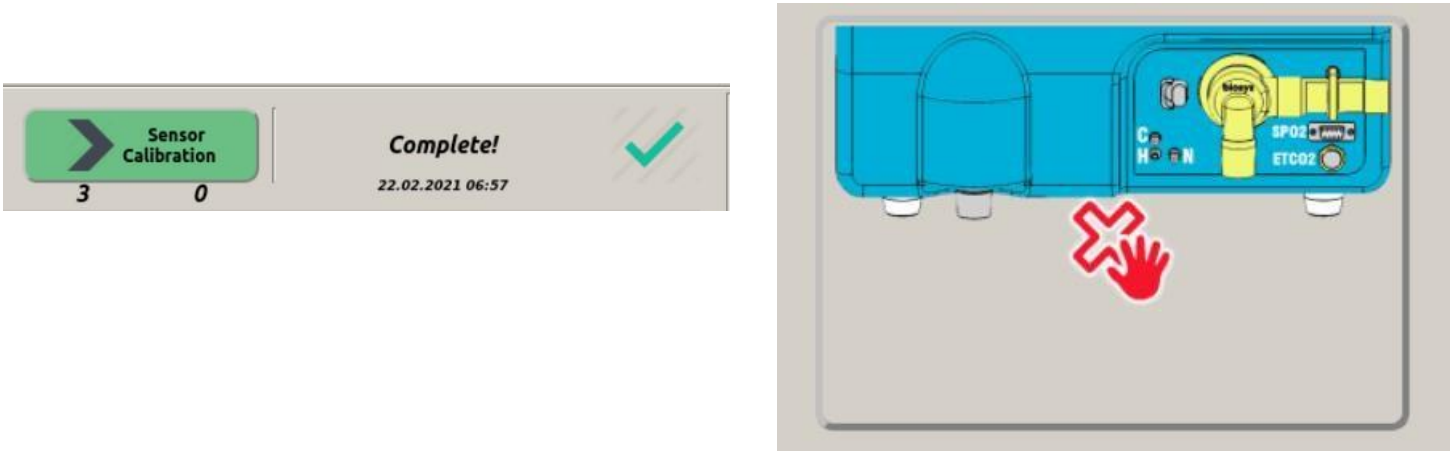


Figure 8.2. Sensor calibration

Patient circuit is ejected from the device and clicked the figure after the sensor calibration is selected.

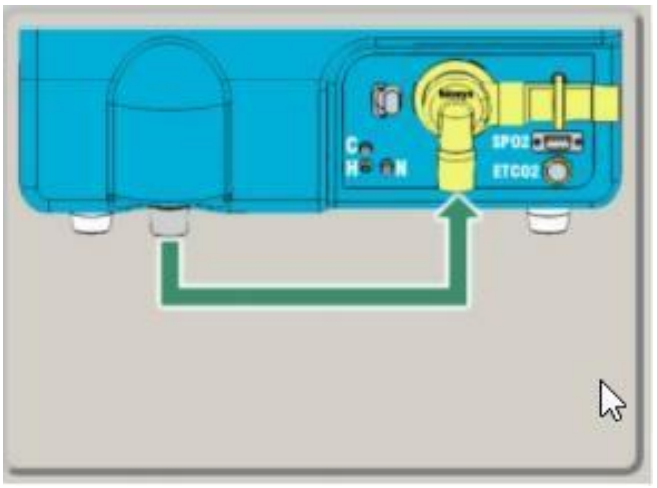


Figure 8.3. Valve Calibration

After Sensor Calibration test finish, the Valve Calibration should be selected. Inspiration and Expiration should be connected to each other as it seen in the figure. Start the valve calibration test by touching the figure.

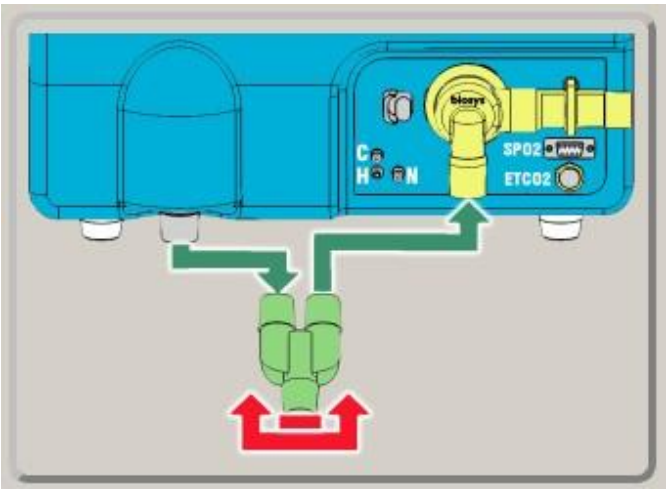


Figure 8.4. Patient Circuit Test

After Valve Calibration test finish, the Patient Circuit Test should be selected. Patient Circuit should be connected to the device as it seen in the figure. The tip of the circuit is closed by a finger and start the calibration test by touching the figure.

PART 9
INDICATIONS, NASAL MASK USAGE

1. Indications

Mechanical ventilation (MV) is one of the most commonly used treatment methods in modern intensive care units. It is aimed to ventilate the lung and oxygenate the blood adequately until the pathology causing respiratory failure disappears with mechanical ventilation. It is also aimed to remove carbon dioxide from the body. For this purpose; air, oxygen mixtures are provided through devices in different volumes, pressures, flows and concentrations. Positive pressure ventilation has a beneficial effect as well as many side effects. Patients undergoing mechanical ventilation should be evaluated individually. Potential benefits should be maximized and side effects should be minimized. Positive pressure ventilation has physiological effects on body systems.

Positive pressure ventilation corrects blood gas with arterial PO2 and PCO2, but in some cases it can increase shunt and dead space.
Atelectasis, barotrauma, acute lung injury, pneumonia, hypoventilation / hyperventilation and oxygen toxicity are pulmonary complications caused by positive pressure ventilation.

1. Main Respiratory Support Indications

Respiratory acidosis/hypercapnia (arterial pH ≤7.35 and/or PaCO2≥6.0 kPa, 45 mmHg) Hypoxia
Clinical signs of severe shortness of breath suggesting respiratory failure and/or increased respiratory work (use of assistive respiratory muscles, abdominal paradoxical movement or intercostal retraction)
Respiratory alert deficiency/abundance
Reducing the use of oxygen in shock

9.1.2.Main Invasive Mechanical Ventilation Indications

Cardiac and/or respiratory arrest
Unstable hemodynamics and/or cardiac arrhythmia
Upper airway obstruction
Non-respiratory organ failure;
Severe encephalopathy (Glasgow coma scale <8-10)
Respiratory secretions cannot be eliminated
Severe upper gastrointestinal bleeding

Aspiration risk is high
Facial surgery, trauma (head/face/respiratory tract) or deformity
Not cooperative/unable to protect the airway

9.1.3. Mechanical Ventilation Complications

volutrauma, atelectrauma, biotrauma Auto-PEEP
Ventilator-associated pneumonia
Cardiovascular Arrhythmia
Myocardial ischemia
Acute kidney failure
Gastrointestinal bleeding
Pneumoperitoneum
Stress ulcer formation and gastrointestinal bleeding
Gastrointestinal motility changes
impaired liver function, cholecystitis without stones.
Anemia, thrombocytopenia, venous thromboembolism)
Thyroid-adrenal disorders, stress hyperglycemia
Intracranial Pressure Increase

 ATTENTION!	The device should not be exposed to any effects against malfunctions such as material breaking, material breaking, material breaking, device integrity, or disintegration. If such cases occur, separate the device and the patient safely. Notify the biomedical department of the hospital.
	If the device operates differently than expected, disconnect the device from the patient and notify the biomedical department of the hospital.

9.2Nasal Mask Usage

WARNINGS!	There is a high probability of leakage during ventilation with a breathing mask. For this reason, there are measurement differences between the inhaled air and the exhaled air**.**

The following steps are applied in order to wear the mask.

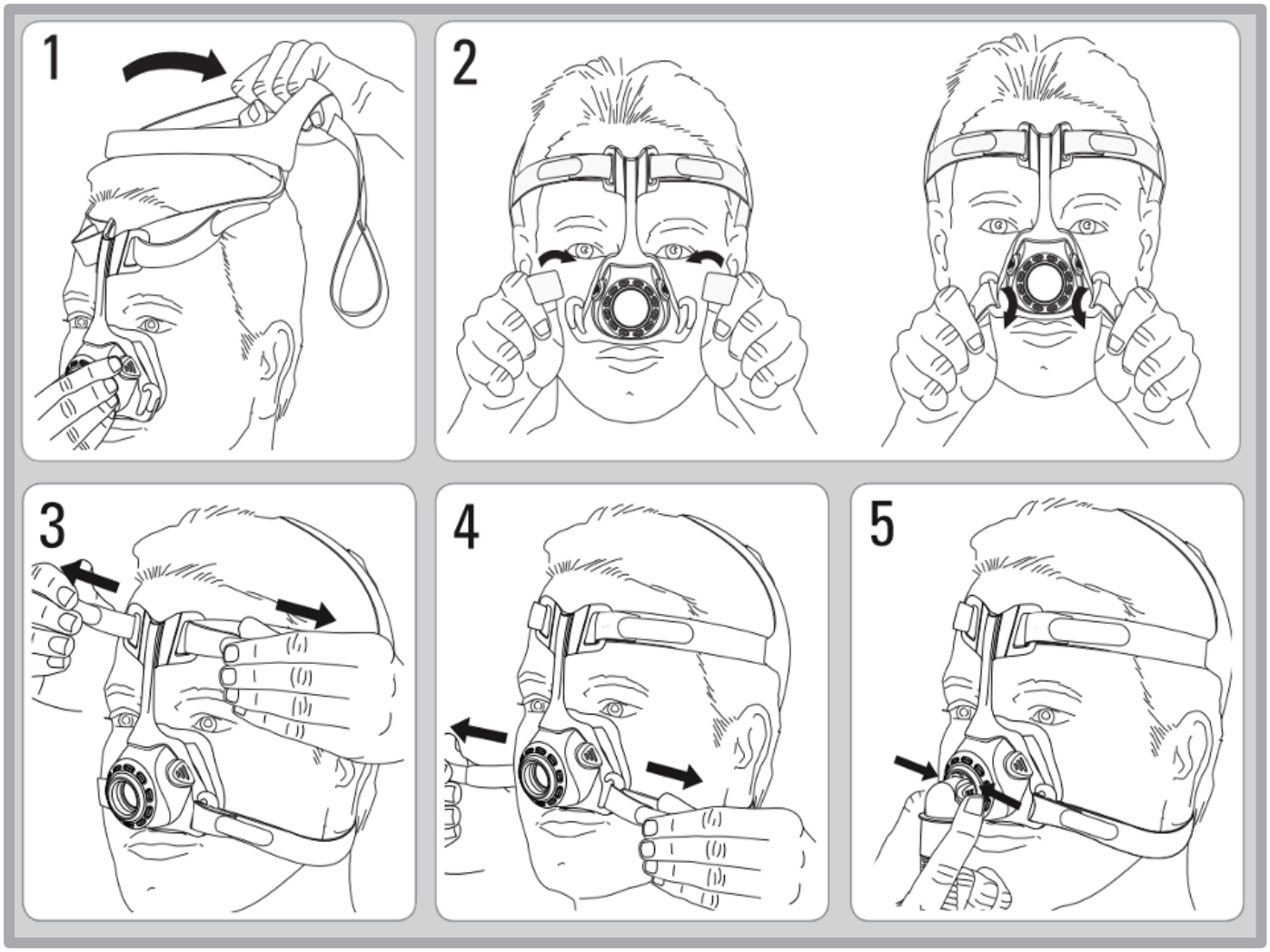


Figure 9.1. Nasal Mask Usage

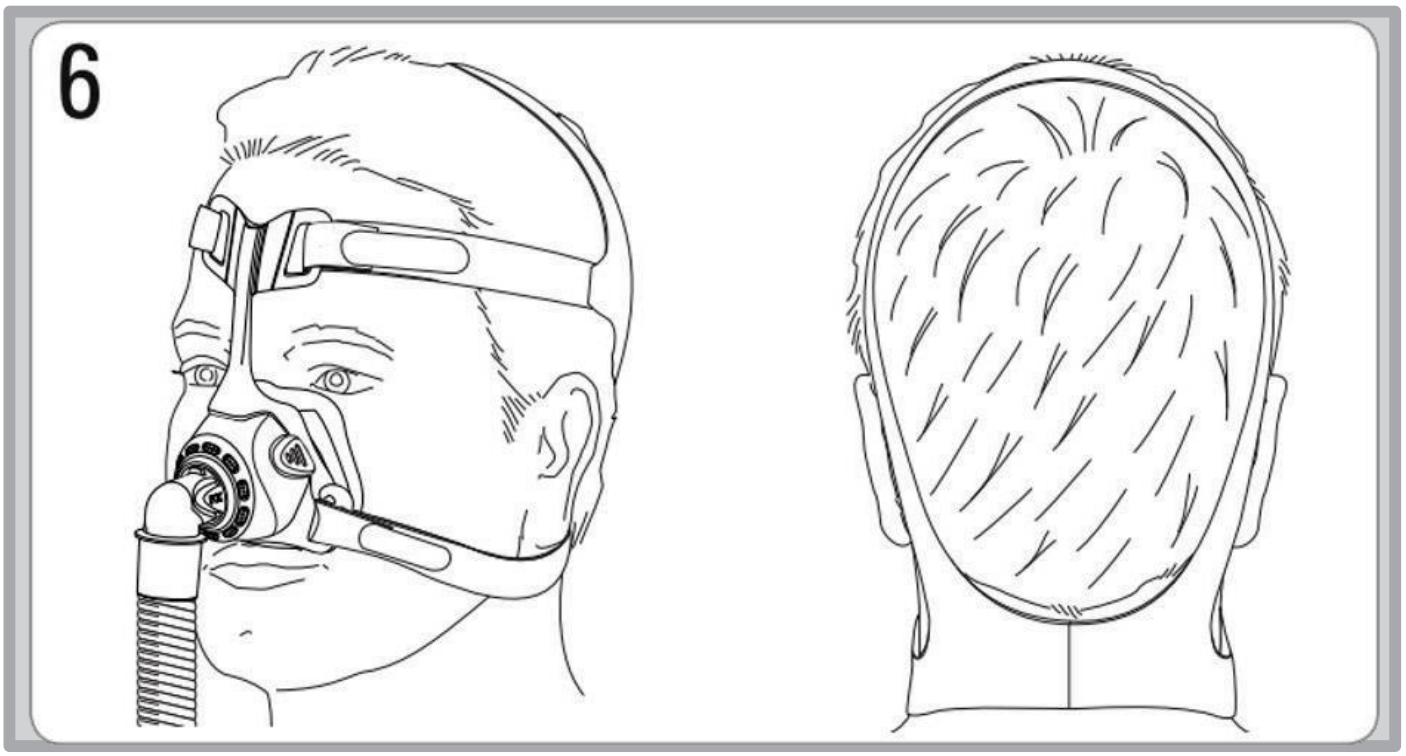


Figure 9.2 Nasal Mask Usage

The following steps are applied in order to wear the mask.

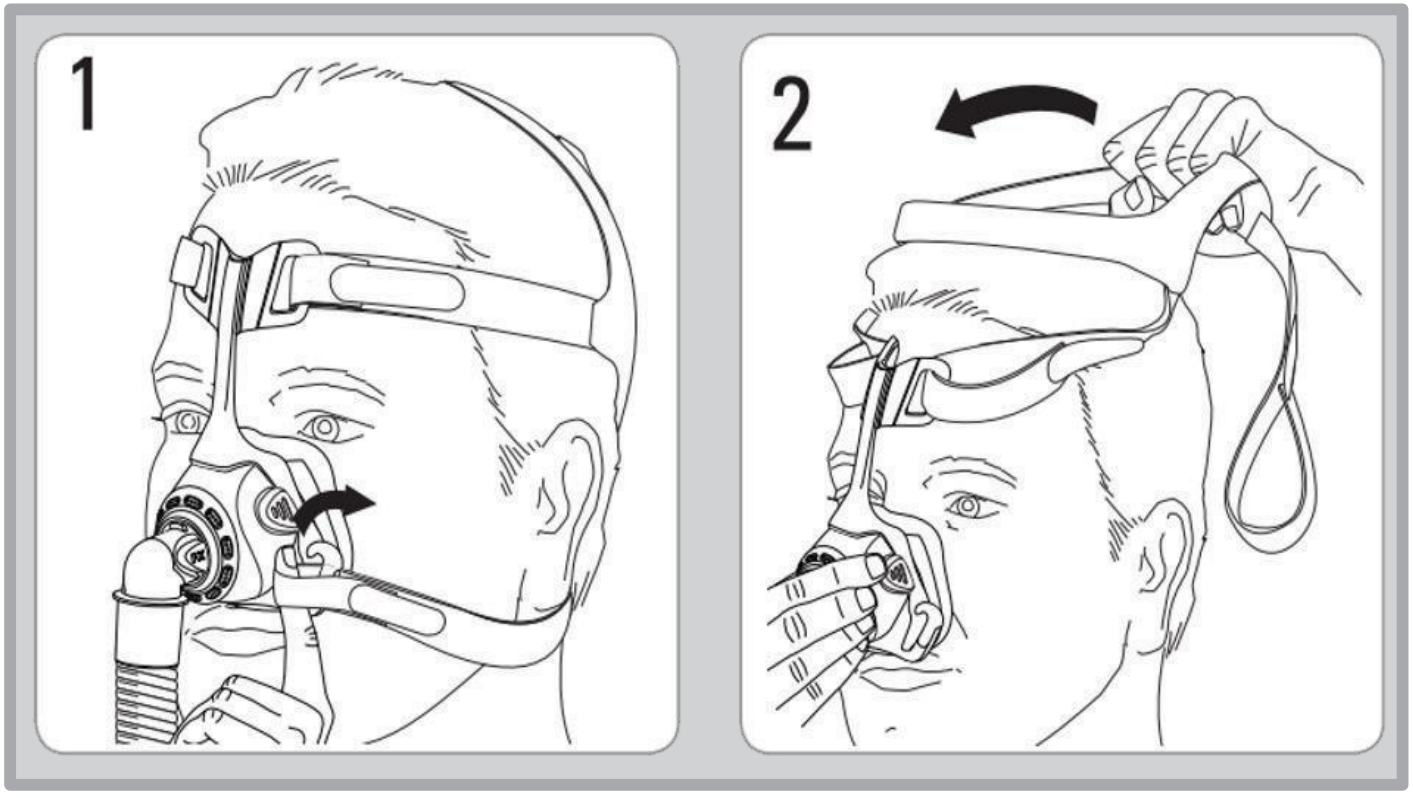


Figure 9.3 Nasal Mask Usage

9.3 If the ventilator does not open properly;

If the device does not turn on as expected after pressing the bioovent device's on button, follow the procedures described in this section:

Table9-1 If the ventilator does not open properly

Problem	Possible Trouble	Prevention
Biyovent is connected to the AC power supply and there is no power.	There is no power in the AC power supply or the voltage value is wrong.	Connect to a power source that is known to work properly. Check that the mains power is 220V. If the ventilator still does not work, check the input fuses. If it still does not work, contact the authorized service.
Biyovent is connected to the DC power supply and the device does not turn on.	If the DC power source is the battery, the batteries may be dead.	Try to operate the device with full batteries. If the ventilator still does not work, check the input fuses. If it still does not work, contact the authorized service.

4. Customer Services

1. Usage Errors and Considerations Regarding Warranty

The following issues are fixed for payment. The warranty terms do not apply to these situations;

Damages and malfunctions caused by usage errors,

Damages and malfunctions during loading, unloading and transportation after delivery of the goods to the consumer,

Damages and malfunctions caused by the electricity (socket, voltage, grounding etc.) network and/or infrastructure (drain, ground, environment, etc.) of the place where the goods are used,

Damages and malfunctions caused by natural events and fire, flood, etc.

Damages and malfunctions arising from the use of the goods contrary to the items that are stated in the introduction and usage manuals,

In case of maintenance, repair or any other intervention by unauthorized people, the warranty given to the property will cease.

The warranty period of the goods replaced during the warranty application is limited to the remaining warranty period of the purchased goods.

We kindly ask you to follow the recommendations below.

When you receive your product, please make sure that the Warranty certificate is approved by your Authorized Dealer.

Use your product according to the user manual principles.

When you have a service request regarding your product, please contact our Call Center from the phone numbers above.

Ask the technician who comes for service about the “technician ID card”.

When you are done, do not forget to ask for a "Service Voucher" from the Authorized service technician. The “Service Receipt” you will receive will benefit you in case of any problems that may arise in your product in the future.

Product lifetime: 10 years. (Time needed to keep spare parts necessary for the product to perform its function)

Manufactured by Arçelik and Aselsan A.Ş.
Country of Origin: Turkey

Figure 9.4. Labels

Figure 9.5. Labels

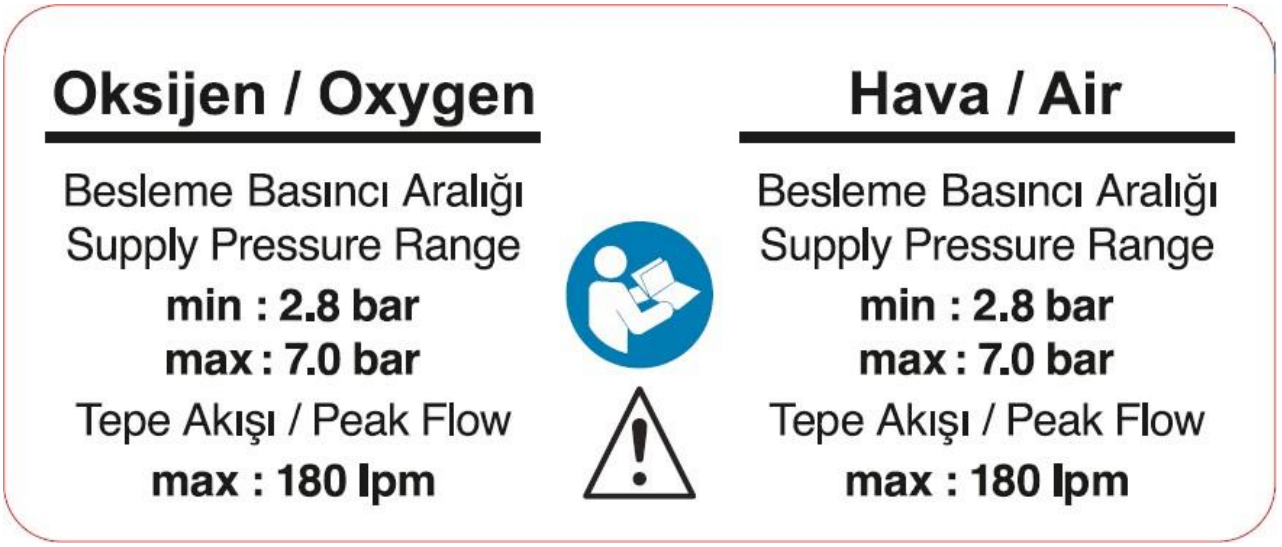


Figure 9.6. Labels

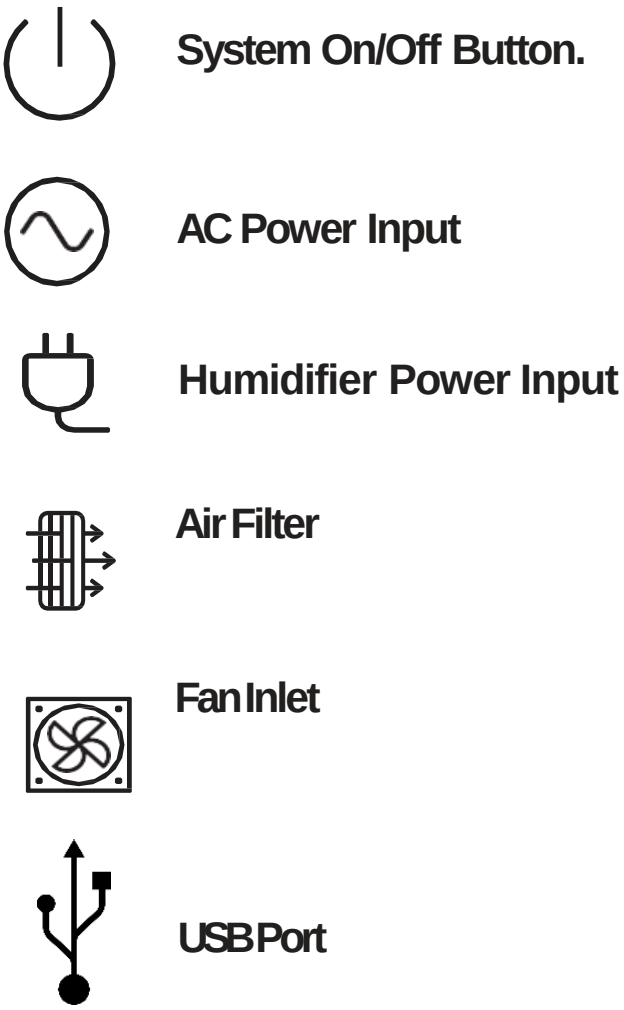


Figure 9.9. Labels

Oxygen Hose Color Code: White