NEFES

Mechanical Ventilator

User Manual

VENTISENSE

Ventisense 40 | Ventisense 60 | Ventisense PRO

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Copyright Information

NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. ŞTİ.

It is recommended to read the information marked with warning symbols carefully, because this information contains important information about safety and cleaning warnings that should be followed while using VENTISENSE.

CE 2696

In terms of traceability, each device of NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. ŞTİ is delivered with a serial number.

UDI-DI	MODEL NAME
08684190120087	Ventisense PRO
08684190120094	Ventisense 40
08684190120100	Ventisense 60

This Instructions for Use applies to Ventisense devices with software version V1.32 and higher.

CONTENTS

INTRODUCTION

General information about **VENTISENSE**.

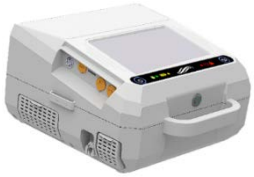
The models of our Mechanical Ventilator are as follows:

- **Ventisense 40**
  This model is intended for pediatric patients.

- **Ventisense 60**
  This model is intended for adult patients.

- **Ventisense PRO**
  This model is intended for both adult and pediatric patients. The patient type is selected on the device.

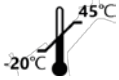
DELIVERY CONTENTS

Picture	Description
	VENTISENSE Ventilator
	Power Supply
	Power Cord
	Oxygen Connection Port
	VENTISENSE Carry Case
	SD Card
	Filter Set (Inspiration and Expiration Filter)
	Documents - User Manual - Undertaking - Warranty Certificate

SYMBOLS

SYMBOLS ON PACKAGE LABEL AND THEIR MEANINGS

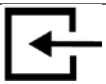
Symbol	Description
	Manufacturer, Place of Production
	Manufacture Date
	Serial Number
	Reference Number
	Refer to the user manual.
	Warning / Caution • Observe the warnings and safety instructions in the operating instructions.
IP22	IP22 Protection Class: • Provides protection against solid foreign objects with a diameter of 12.5 mm or greater, and against vertically falling water drops when the enclosure is tilted up to 15°.
CE 2696	CE – Conformity European • It indicates compliance with Regulation (EU) 2017/745 — MDR (Medical Devices Regulation).

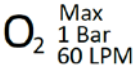
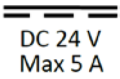
	Read the user manual before using the device.
	Fragile, handle with care.
	Do not use if the package is damaged.
	Keep in a dry place.
	Keep away from sunlight.
	Humidity range in storage and working conditions.
	Temperature range for storage conditions.
	Temperature range for operating conditions.
	Pressure range in storage and operating conditions.

SYMBOLS AND MEANING ON DEVICE LABEL

Symbol	Description
	Serial Number
	Reference Number
	Medical Device
	Manufacturer
	CE – Conformity European • It indicates compliance with Regulation (EU) 2017/745 — MDR (Medical Devices Regulation).
	Type BF Applied Part
	Protection Class II (Protection Isolated)
	Warning / Caution • Observe the warnings and safety instructions in the operating instructions.
	Read the user manual before using the device.
	Do not dispose of the device in the garbage. Contact an authorized customer service center for proper disposal of the device.
IP22	IP22 Protection Class: • Provides protection against solid foreign objects with a diameter of 12.5 mm or greater, and against vertically falling water drops when the enclosure is tilted up to 15°.

SYMBOLS ON THE DEVICE

Symbol	Description
	Inspiration Outlet
	Expiration Inlet
	Valve Control Hose Connection
	Do not block the air inlet / outlet.
	USB Port
	These ports are not in use. Do not connect anything to them.

Symbols Warnings	Description
	Read the user manual before using the device.
	If the label is removed, the device will be out of warranty.
	Use an oxygen source with a maximum flow rate of 60 l/min and a pressure of 1 bar.
	Use only the 24V, 5A adapter supplied with the device.

SYMBOLS IN USER MANUAL

It is represented by three symbols to indicate special warnings and critical information in this user manual.

⚠CAUTION

This symbol indicates situations that may lead to minor injury. Observe all caution notices provided to prevent accidents, injuries, or material damage. This level indicates hazards with a moderate risk of injury.

⚠WARNING

This symbol indicates potentially hazardous situations that could result in serious injury or death. These warnings should be strictly followed for the safe operation of the device. Risks specified at the warning level may lead to severe consequences if realized.

NOTE

This symbol indicates important operating information for the correct, effective, and smooth operation of the device. Notes do not involve safety risks; however, they include tips to be considered for the proper use and maintenance of the device's performance.

INTENDED USE

WARNING

If the device is not used for its intended purpose, it may expose patients to health hazards.

VENTISENSE is a device intended to artificially support respiratory function in cases where the lungs cannot fulfill the vital function of breathing for any reason. The device is intended for use on pediatric and adult patients with a tidal volume of 50 ml or greater. It is designed for use in home healthcare environment applications and is manufactured to provide continuous or intermittent ventilation support to patients.

The device supports pressure-controlled and volume-controlled ventilation operating modes. Ventilation support can be administered through invasive (e.g., via tracheostomy or endotracheal tube) or non-invasive (using a ventilation mask) methods.

VENTISENSE is designed to operate with a dual-limb patient circuit equipped with an expiratory valve. The device can be connected to a low-pressure oxygen source for high-concentration oxygen ventilation and can be used in conjunction with an external humidifier.

USER INFORMATION

The mechanical ventilator device should be used in healthcare facilities by physicians, nurses, electrophysiology technicians, and/or clinical support personnel who have been trained in this field. In home healthcare environments, the device should be used by patients and/or patients' relatives who have been trained in the use of the device.

- Mechanical ventilator device usage training is provided by our sales dealer.

SCOPE OF USE

- Ventisense is intended for use in patients with a minimum tidal volume of 50 ml (patients weighing more than 5 kg).
- Ventisense should be used with an adult patient circuit for adult patients and with a pediatric patient circuit for pediatric patients.

INDICATIONS

VENTISENSE is designed for the treatment and management of the following clinical conditions:

- Acute and Chronic Respiratory Failure
- Chronic Obstructive Pulmonary Disease (COPD)
- Asthma
- Cystic Fibrosis (CF)
- Restrictive Lung Disease
- Obesity-Related Hypoventilation
- Neuromuscular Diseases
- Airway inflammation
- Post-Operative Respiratory Support

CONTRAINDICATIONS

WARNING

Ventilation may be contraindicated in certain existing disease states.

VENTISENSE is contraindicated for patients with the following conditions:

- Arrhythmia (Cardiac Rhythm Disorder)
- Severe Hypotension
- Severe epistaxis or a history of severe epistaxis (risk of recurrence)
- Pneumothorax
- Pneumomediastinum (PM) (presence of air or gas within the mediastinal connective tissue)
- Pneumocephalus (current trauma or surgical conditions that may create a nasopharyngeal fistula)
- Risk of aspiration
- Conditions such as acute sinusitis, otitis media, or tympanic membrane perforation may cause temporary complications in the patient.
- High-Risk Ventilator-Associated Infections

WARNING

Treatment in individual cases should be decided by the attending physician.

SIDE EFFECTS

Potential side effects associated with non-invasive (mask) ventilation:

- Pressure sores and skin disorders on the face
- Eye irritation, redness, or dryness due to mask leaks
- Excessive gastric bloating (aerophagia)
- Aspiration
- Sinusitis
- Nosebleed (epistaxis)

Potential side effects associated with invasive ventilation:

- Ventilator-associated pneumonia (VAP)
- Airway trauma due to endotracheal tube or tracheostomy
- Pulmonary barotrauma (e.g., pneumothorax, pneumomediastinum)
- Volutrauma and atelectrauma
- Airway obstruction due to secretion accumulation
- Ventilator-induced diaphragmatic dysfunction (VIDD) and difficulty weaning due to long-term ventilation

SAFETY WARNINGS

VENTISENSE Device Warnings;

SECTION 1: GENERAL SAFETY WARNINGS

SECTION 2: ELECTRICAL SAFETY WARNINGS

SECTION 3: INSTALLATION CONDITIONS AND TRANSPORTATION WARNINGS

SECTION 4: PRE-USE WARNINGS

SECTION 5: WARNINGS FOR USE WITH EXTERNAL OXYGEN

WARNING

Read and understand all warnings before using the VENTISENSE device.

SECTION 1: GENERAL SAFETY WARNINGS

- Only authorized medical personnel under the supervision of a physician may set the operating mode and parameters on VENTISENSE. The device should not be used by persons who have not fully read and understood this user manual and who are not familiar with the device. Failure to observe these warnings may result in life-threatening situations for the patient.
- Patients connected to life-support devices should be continuously visually monitored. For emergency situations, an alternative ventilation device such as a second ventilator or an emergency ventilation bag should always be kept ready and should be usable by the caregiver personnel or the patient's relative.
- In patients without spontaneous ventilation or who are fully dependent on ventilation, it should be checked whether airway obstruction persists.
- VENTISENSE should be used in accordance with the instructions given by authorized and responsible clinical personnel for treatment.
- VENTISENSE should only be used on patients with diseases identified by responsible clinical personnel.
- Care must be taken to ensure that the patient is not separated from the hose system during ventilation.
- Should not be used with ambient air containing flammable anesthetic or explosive gases. This may cause fires or explosions.
- For VENTISENSE, a hose system tested and approved by the manufacturer is recommended. Using other hose systems may lead to different results.
- For VENTISENSE, it is recommended to use accessories tested and approved by the manufacturer. Using different accessories may result in secondary illnesses due to inadequate ventilation or the use of materials that are harmful to health.
- If a nasal or face mask is used for non-invasive ventilation, this mask should never contain an expiratory hole.
- To ensure patient safety, it is recommended to operate VENTISENSE with all necessary adjustable alarms activated and adapted to the patients.
- Alarm signals should not be ignored. Alarm signals indicate conditions that require immediate intervention.
- VENTISENSE should be serviced periodically, taking into account the "time remaining for service" in the settings menu.
- The device should not be steam-sterilized in an autoclave.
- Filters and other accessories connected to patients in VENTISENSE should be replaced at regular intervals. (See Section: Consumables and Replacement Intervals)
- Regulations regarding used medical materials or local environmental conditions apply to the proper disposal of spare parts.
- It should be ensured that the total resistance of the ventilation system is not higher than 6 hPa at 60 l/min flow in adults and 30 l/min flow in children.
- Any modification to VENTISENSE compromises its operating characteristics. No modifications should be made to the device.
- Use masks approved by your physician for your treatment.

- Use the mask only in accordance with the instructions of the responsible clinical personnel and particularly consider possible contraindications and side effects associated with medication intake and mask use.
- Observe the operating, transportation, and storage conditions.
- Storage of the device at temperatures outside the range of -20 °C and above +45 °C may lead to functional impairment or permanent damage to the device.
- Check the settings of the ventilation and alarm parameters after the service procedure.
- The VENTISENSE device does not contain any medical substance (commercially available or new) or animal tissue or blood components.
- The respiratory device should not be used in a hyperbaric chamber. Such use may cause the respiratory device to malfunction. This situation may lead to the death of the patient or serious deterioration of health.
- Use the external humidification unit strictly in accordance with the arameters prescribed by the attending physician and in compliance with the instructions in the humidifier manufacturer's Instructions for Use (IFU).
- Use only medically suitable external humidification devices that have been tested and certified by authorized bodies (e.g., CE, FDA).
- Always position the external humidification unit at a level lower than both the ventilator and the patient.
- Adding a humidifier or a Water Trap to the breathing circuit may increase the compressible volume of the system and may result in a reduction of the Tidal Volume delivered to the patient. Always verify the delivered volume after any change in the circuit configuration.
- **I**f condensation (water accumulation) is observed inside the breathing circuit during use of the external humidifier, replace the existing circuit with a heated breathing circuit. A heated circuit prevents condensation within the line and protects both the patient and the sensitive components of the device.
- Do not use an external humidifier without bacterial filters on the inspiratory and expiratory ports of the device. Dense humid air within the circuit may enter the flow/pressure sensors and the motor block, causing permanent damage to the device.
- Standard Connection Configuration: Device Inspiratory Port → Bacterial/Viral Filter → Inspiratory Limb → External Humidifier Device → Y-Piece (Patient Connection) → Expiratory Limb → Bacterial/Viral Filter → Exhalation Valve → Device Expiratory Port. Do not add any accessory to the system other than in the sequence shown in the standard connection configuration.
- During use of the external humidifier, regularly inspect the bacterial filters and the expiratory valve for moisture accumulation. Blocked filters increase breathing resistance and may compromise ventilation safety.
- Do not use an HME filter in the breathing circuit system or at the patient connection point during use of an external humidifier. This combination may cause the filter to become excessively saturated with moisture, leading to blockage, increased breathing resistance, and a dangerous reduction in delivered Tidal Volume.

- Use the nebulizer in accordance with the drug dosage and administration duration prescribed by the physician and according to the nebulizer manufacturer's Instructions for Use (IFU).
- Use only medically suitable nebulizer devices that have been tested and certified by authorized bodies (e.g., CE, FDA).
- Operate the nebulizer only while the ventilator device is actively running. If ventilator operation is stopped, nebulizer use must be discontinued immediately.
- Use of an externally gas-powered nebulizer may affect the ventilator's flow and volume measurement accuracy. Closely monitor the patient and make any necessary parameter adjustments to compensate for the effects of the added gas volume.
- Do not use the nebulizer without bacterial filters installed on the inspiratory and expiratory ports of the device. Drug particles may penetrate into the sensor group and motor block, causing hardware malfunction and permanent damage.
- Standard Connection Configuration: Device Inspiratory Port → Bacterial/Viral Filter → Inspiratory Limb → Nebulizer Inlet → Y-Piece (Patient Connection) → Expiratory Limb → Bacterial/Viral Filter → Exhalation Valve → Device Expiratory Port.
  Do not add any accessory to the system other than in the sequence shown in the standard connection configuration.
- During nebulization, regularly inspect the bacterial filters and the exhalation valve for moisture or drug residue. Blocked filters increase breathing resistance and may compromise ventilation safety.
- Do not use an HME filter in the breathing circuit system or at the patient connection point during nebulizer use. Drug particles may rapidly block the pores of the filter, creating a risk of high airway resistance and sudden loss of Tidal Volume.
- During nebulization or humidification, filters and the exhalation valve may become rapidly blocked by moisture and/or drug residues. This may increase breathing resistance and may cause errors in the ventilator's flow/pressure measurements. Check the filters frequently and replace them immediately if increased resistance is noticed. (BS EN ISO 80601-2-72:2023, 201.7.9.2.2.101 e)
- HMEFs and bacterial / viral filters are single-use devices and must be replaced at least every 24–48 hours (or in accordance with the manufacturer's instructions). Filters that are wet, contaminated with secretions, or saturated with medication must be replaced immediately. Use of contaminated filters may damage the ventilator sensors and cause measurement errors.
- In the case of nebulizer or humidifier use, breathing system filters should be replaced more frequently as there will be more clogging caused by heat and humidity.
- The respiratory device is not used with nitric oxide. Such use may cause the respiratory device to malfunction. It may lead to death or serious health problems for the patient.
- It should not be used with inlet gases (helium or helium mixtures) not specified for ventilator use. Such use may cause the respiratory device to malfunction. It may lead to death or serious health problems for the patient.
- It is the responsibility of the user to ensure that the external oxygen supply pressure and flow are within the range specified in the ventilator instructions to provide the nominal oxygen concentration. Failure to do so may result to the death of the patient or serious deterioration of health.

- The responsible organization should ensure the compatibility of the ventilator and all parts and accessories intended to be connected to the patient before use. A BSF (Breathing System Filter) exposed to moisture from nebulization or humidification results in a VBS (Ventilator Breathing System). In this case:
    - The device filter should be replaced more frequently to prevent obstruction of the breathing system when nebulization or humidification is used.
- The ventilator should be transported and stored using the carrying bag specified in the delivery contents.
- Antistatic or electrically conductive breathing circuits should not be used with the device.
- In cases where the tidal volume is above 50 ml, the accuracy of the inspiratory volume monitoring equipment is within ± (4.0 + (15% of actual inspiratory volume)) ml.
- The accuracy value of the pressure monitoring equipment is ± (3.0 + (5% of set pressure)) hPa.
- The airway pressure tolerance value is ± (2 + (4% of actual reading)) hPa.
- Verify the accuracy of the set volumes and pressures by monitoring them on the device monitor screen.
- Do not cover the ventilator with any object or place it in a position that could cause it to malfunction.
- To reduce the possibility of patient death or serious deterioration in health, you should always have immediate access to a ready-to-use alternative means of ventilation.
- This device is a high-flow device and may affect the oxygen line operation of other devices.
- When necessary, mechanical ventilation can be used with a leak-free, non-invasive mask.
- To prevent death or serious injury, monitor the patient and the ventilator regularly to determine the need to provide emergency ventilation when an alarm sounds or a malfunction occurs in the ventilator.
- Do not attach any apparatus or accessory to the ventilator that is contrary to the instructions for use of the ventilator or the accessory. Otherwise, the ventilator may not function properly, resulting in the loss of the patient's life.
- Do not use the ventilator at temperatures outside the range of 0°C to 40°C or outside the environmental limits specified by the manufacturer. Use outside the specified operating range may lead to degraded ventilator performance, reduced treatment effectiveness, or serious harm to the patient.
- Gas added by the use of a pneumatic nebulizer may adversely affect the accuracy of the ventilator.
- Unintended leaks cause the specified volume values to differ from actual patient values.
- High airway pressure alarm condition occurs within 200 ms.

- Do not connect the ventilator directly to the battery of a battery-powered wheelchair unless such a connection is specifically described in this Instructions for Use or in the wheelchair manufacturer's documentation. An improper power connection may affect ventilator performance and could result in ineffective therapy, serious injury, or death.
- The accuracy of delivered ventilation parameters and monitoring values may be adversely affected by gas added through the use of a pneumatic nebulizer. Carefully monitor the patient and verify ventilator settings during nebulizer therapy.
- Unintentional leaks may cause displayed volume values to differ from the patient's actual values. Verify patient condition and circuit connections regularly, especially when significant leaks are indicated.
- As this Ventisense Mechanical Ventilator uses a Luer connector for other than intravascular or hypodermic access, there is a possibility that an inadvertent connection can occur between this Ventisense Mechanical Ventilator and another medical device or accessory using a Luer connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks.

SECTION 2: ELECTRICAL SAFETY WARNINGS

To reduce the risk of fire, electric shock, or device malfunction, please observe the following warnings.

- For safe operation of the device, only the supplied power supply should be used.
- Electrically conductive or electrostatically charged patient hoses should not be used.
- The Ventilator is not intended to be used in MR environment.
- To disconnect VENTISENSE from the electrical power supply, the power plug should be unplugged from the socket.
- The power plug should be unplugged before cleaning the VENTISENSE.
- The use of accessories or power supplies not approved by us may cause increased electromagnetic beam emissions, reduced durability, or increased leakage current transmitted to the patient.
- During certain diagnostic or therapeutic procedures, mutual interactions may occur between the ventilator and other medical devices. Pay attention to electromagnetic compatibility data and use the devices in a fault-free manner and in accordance with their intended purpose.
- Do not touch the device if it has fallen into water.
- Do not attempt to open the device or the adapter. Maintenance and repair procedures should be performed only by personnel authorized by NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. ŞTİ.

SECTION 3: INSTALLATION CONDITIONS AND TRANSPORTATION WARNINGS

To ensure safe operation of the device, prevent overheating, and reduce the risk of mechanical damage, strictly follow the installation and transportation instructions below.

- The device should be placed on a flat surface in order to be operated.
- Ensure that the air inlet on the side panel of the device and all ventilation openings are not blocked.
- Ensure that the device is operated in environments with sufficient and clean ambient air.
- The device screen and alarm LEDs should not be covered and should always remain visible.
- No objects should be placed on the device.
- Storage and transportation should not be carried out under conditions where the ambient temperature falls below –20°C or exceeds +45°C.
- The device should not be exposed to direct sunlight.
- Do not place the device near containers filled with water (e.g., bathtubs).

SECTION 4: PRE-USE WARNINGS

To ensure the safe operation of the device, guarantee correct ventilation performance, and prevent patient injury, always perform the following checks before connecting the patient to the device.

- The VENTISENSE device is not used in newborns.
- A Physician Interface Access password is given to the authorized person during product delivery.
- A device that does not function properly may pose a danger to the patient or the user. If the device is not functioning correctly, it should not be operated. The service department must be notified of this situation.
- Install the device so that the power plug is easily accessible and can be quickly unplugged in case of danger.
- Do not operate the device if the body or cable of the device or power supply is damaged.
- There is no SPO_2 input on the device. SPO_2 connection is not made to the device. The device cannot be used with SPO_2.
- Before operating the ventilation system (ventilator, hose, humidifier, etc.), check all connections for leakage and the durability of the connected accessory.
- Only use original filters supplied by NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. ŞTİ.
- If the device has previously remained in an environment where the air temperature is very different from the place of use, you should wait at least 1 hour before starting the device until temperature balancing is achieved.

SECTION 5: WARNINGS FOR USE WITH EXTERNAL OXYGEN

The use of oxygen significantly increases the risk of fire. Strictly comply with the following warnings for the safety of the patient, the user, and the environment.

- The warnings of the manufacturer or seller regarding the use of oxygen must be strictly followed.
- The connection between the External Oxygen Source and the Oxygen connection port must be strictly sealed. Otherwise, leaks may occur during ventilation.
- During the use of oxygen, it should be noted that the oxygen interconnection hose connected to the oxygen connection port included in the scope of delivery of VENTISENSE is standard.
- If an oxygen leak occurs, the oxygen supply should be shut off immediately. The room should be ventilated immediately. In the meantime, nearby sparks, any fire and potential sources of fire should be eliminated.
- Oxygen facilitates fires. Therefore, observe the fire protection regulations applicable to the use of oxygen. Degrease the oxygen fittings, connections and surfaces near the oxygen lines. Do not smoke and do not light an open fire. If oxygen is used, an increased concentration of oxygen in the ambient air may occur.
- Do not obstruct the gas intake port.
- Verify that the oxygen flow rate applied to the device does not exceed 60 L/min and 1 Bar.

DEVICE OVERVIEW

VENTISENSE Usage, Control and Fasteners

CONNECTIONS ON RIGHT AND LEFT PANEL

Figure 1 Connections on Right Panel

1. **Expiration Hose Connection Inlet**
   The exhalation valve should be connected to this inlet. The expiration limb of the dual-limb circuit should be connected to the exhalation valve.
2. **Exhalation Valve Control Hose Inlet**
   The control hose of the exhalation valve should be connected to this inlet.
3. **Inspiration Hose Connection Outlet**
   The inspiration limb of the dual-limb circuit should be connected to this outlet.

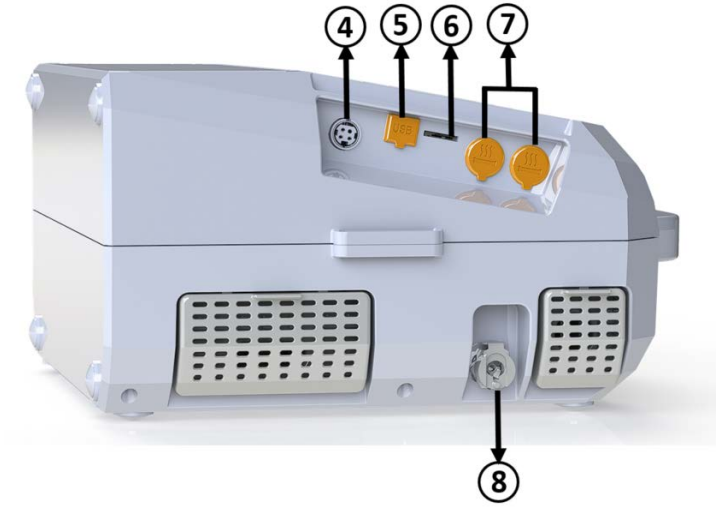


Figure 2 Connections on Left Panel

4. **DC Power Connection**
   The power supply connector is connected here.
5. **USB (Interface)**
   PC connection takes place here using USB interface connection.
6. **SD Card**
   SD card included in the scope of delivery is inserted here.
7. **Ports Not in Use**
   These ports are not in use; no connections should be made.
8. **Oxygen Connection Inlet**
   The external oxygen source is connected here during the use of oxygen. During the use of oxygen, the O_2 connection port given in the scope of delivery should be used.

NOTE

The port inputs with the symbol shown on the side are not used. Do not plug anything in.

CONTROL ELEMENTS

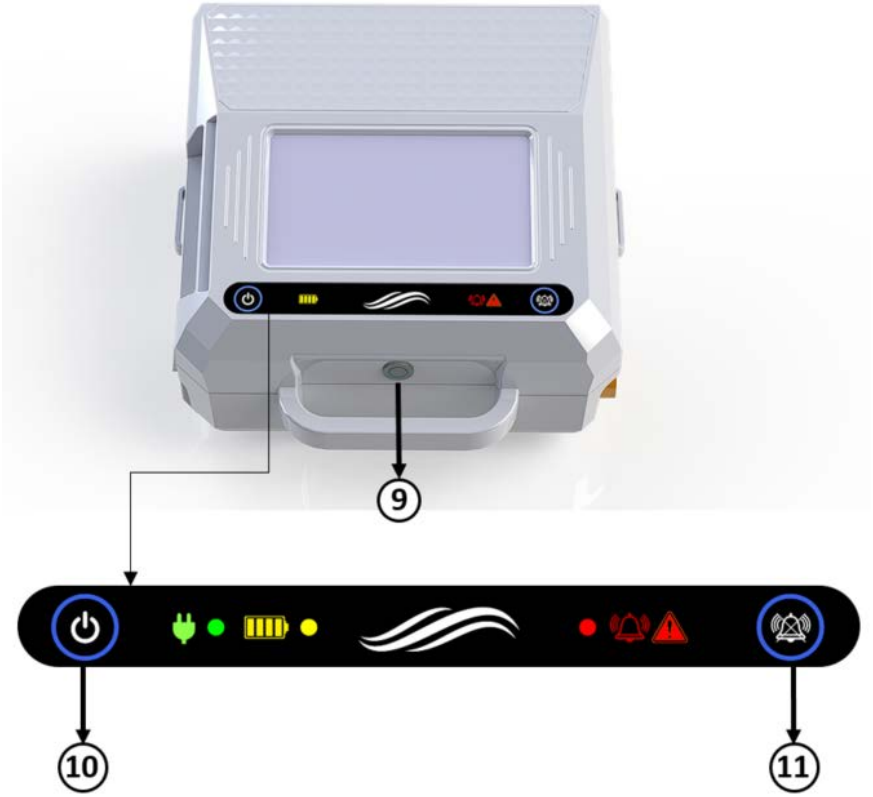


Figure 3 Control Elements

9. **Power On / Off Button**
   The device is turned on and off using this button. The power button is inactive while ventilation operating mode is active. To switch off the device, ventilation operating mode must first be stopped using the Start/Stop key.

10. **Start / Stop Key**
    Ventilation is started and stopped using this key.

Function	Process
Start ventilation	Ventilation is started when the key is pressed briefly.
Stop ventilation	Ventilation is terminated when the key is pressed and held for 3 seconds.

11. Alarm Control Key

The alarm control key has two functions.

Condition	Process
Active alarms	When the alarm control key is pressed, the alarm tone is silenced and the active alarm warning is cleared from the screen. A silenced alarm symbol and a caution symbol are displayed in the upper section. 
Muted active alarms	When the alarm control key is pressed, active alarms are redisplayed on the screen and the alarm tone is activated.

When multiple alarm conditions occur simultaneously, alarms are displayed on the screen at intervals of 3 seconds according to their priority order. Active alarms that are silenced using the alarm control key are displayed again on the screen after 120 seconds (except for alarms whose alarm conditions have been resolved). Alarms with ongoing conditions continue to be displayed on the screen according to their priority order.

INDICATOR LEDS AND DISPLAY NOTIFICATIONS

Figure 4 Indicator Leds

12. Power LED

Provides information about the electrical connection status of the device.

Color	Status	Description
Green	LED On	The device is operating while connected to the power supply.
—	LED Off	The device is operating on the internal battery.

13. Battery LED

It gives information about the battery charge status of the device.

Color	Status	Description
Yellow	LED On	The device is operating on the internal battery.
Yellow	LED Flashing	The internal battery of the device is charging.

14. Alarm LED and Display Notification

The alarm LED flashes in case of alarm. It also provides information about the priority of the alarm.

Color	Status	Description
Red	LED Flashing	When a high-priority condition occurs, the alarm condition and the recommended solution are displayed on the screen within a red rectangle.
		When a medium-priority condition occurs, the alarm condition and the recommended solution are displayed on the screen within a yellow rectangle.

FILTERS AND USAGE

Figure 5 Filters

15. Inspiration (Inlet) Filter

The inlet filter filters the air entering the device. It should be replaced in cases of heavy contamination or at least every 2 months (whichever occurs first).

16. Expiration (Outlet) Filter

The outlet filter filters the air exiting the device. It should be replaced in cases of heavy contamination or at least every 2 months (whichever occurs first).

DEVICE INSTALLATION AND ACCESSORY CONNECTIONS

VENTISENSE installation and accessory connections

DEVICE INSTALLATION

The device must be placed on a flat and stable surface to maintain unobstructed airflow through the air inlet and outlet filters; a minimum clearance of 10 cm must be maintained on the left side of the device where the air inlet and outlet filters are located.

Figure 6 Device Installation

VERTICAL AND HORIZONTAL USE

The device can be used in either vertical or horizontal orientation thanks to the automatic screen rotation feature. The screen orientation is automatically adjusted according to the position in which the device is placed.

Figure 7 Vertical and Horizontal Use

DIFFERENT MOUNTING AND USAGE CONFIGURATIONS OF THE DEVICE

1. Mounting to the Operating Environment

The device can be mounted to a sheet metal plate or a suitable surface using 4 units of M5 bolts via the nuts embedded in the body located on the bottom panel.

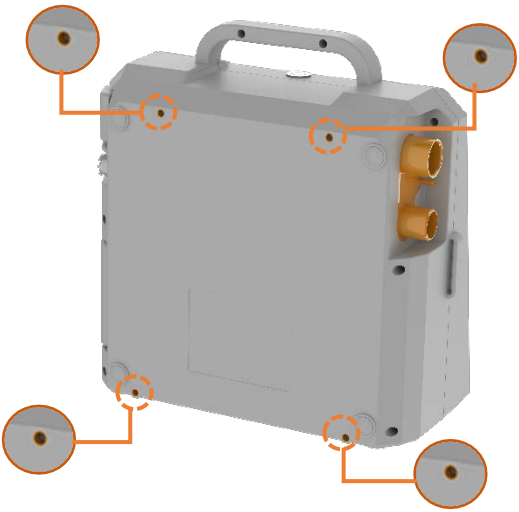


Figure 8 Mounting to the Operating Environment

2. Securing to the Operating Environment

The device can be secured to structural elements such as poles or stands by tensioning with a strap and the lugs located on its sides.

Figure 9 Securing to the Operating Environment

⚠CAUTIONS

During the securing process, care should be taken to ensure that the air inlets and outlets of the device are not obstructed.

POWER SUPPLY

The ventilator can be powered by two different power sources:

1. Mains power via the power supply
2. Internal battery

When the device is operating on mains power, the power LED illuminates green. When the device is operating on the internal battery, the battery LED illuminates yellow. When an external power source is connected, mains power is used as the primary source; in the event of a mains power interruption, the device automatically switches to operation on the internal battery.

MAINS VOLTAGE

INSERTING THE POWER SUPPLY

1. Insert the power supply connector into the DC power input with the flat side of the connector facing downward.
2. Connect the power cable to the power supply.
3. Plug the power cable into a mains outlet (100 - 240 V, 50/60 Hz).

REMOVING THE POWER SUPPLY

1. Unplug the power cable from the mains outlet.
2. Press the lock on the power supply connector to release it and pull it outward
3. Remove the power supply connector from the device.

WARNING

The device must be used only with the power supply provided by the manufacturer.

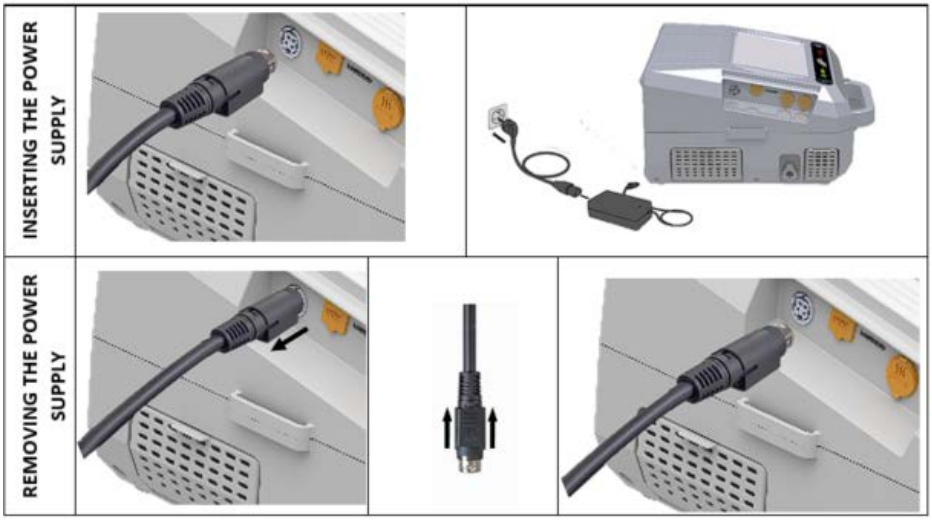


Figure 10 Power Supply Inserting and Removing

INTERNAL BATTERY

The internal battery automatically charges when the device is connected to an external power source. With a fully charged battery, the device can operate for up to 8 hours, depending on usage conditions.

The current charge status of the battery can be monitored via the battery icon in the upper right corner of the screen. While the device battery is charging, the LED next to the power symbol on the keypad will glow green.

POWER FAILURE

In the event of a power outage, the device automatically continues to operate using its internal battery.

WARNING

To eliminate the risk of patient suffocation, the tubing and cable should be positioned so that they do not become entangled around the patient's neck or any limb.

CONNECTING THE DUAL-LIMB BREATHING CIRCUIT

Connect one end of the dual-limb patient circuit coming from the patient to the inspiration limb. Before connecting the other end of the patient circuit to the expiration limb, attach the exhalation valve to the device's expiration limb with the flow direction facing the device. Connect the thin silicone control hose of the exhalation valve to the device's valve control hose connection. Connect the expiration limb of the dual circuit to the end of the exhalation valve. The connection of the patient hose circuit is shown below.

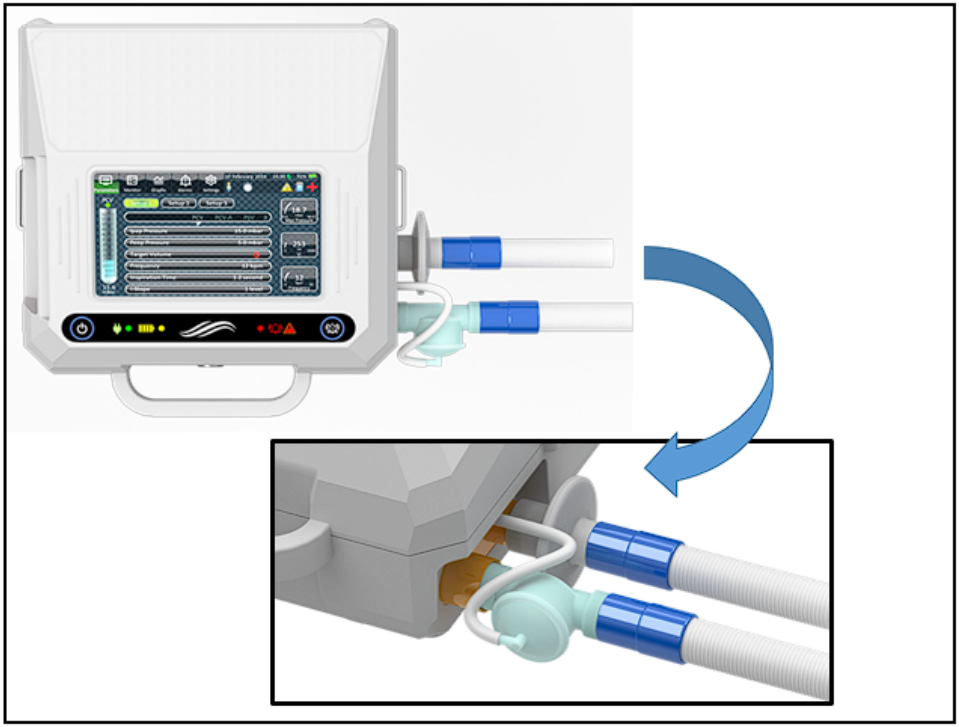


Figure 11 Connecting The Dual-Limb Breathing Circuit (Disposable)

INSERTING SD CARD

Insert the SD card into the SD card slot as shown in Figure 10 and push it in until a “click” sound is heard. When the SD card is inserted correctly, the SD card icon appears on the device screen toolbar. A micro SD card with a minimum capacity of 4 GB is required.

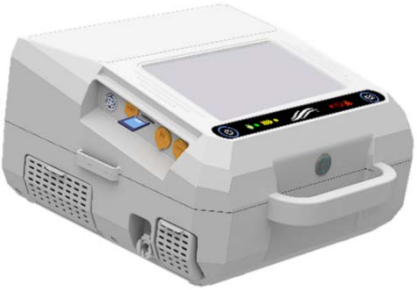


Figure 12 Inserting SD Card

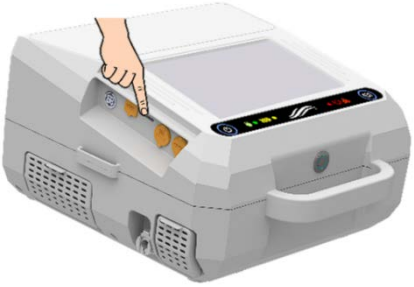


Figure 13 Removing SD Card

REMOVING SD CARD

Press the SD card in the SD card slot once with your finger. The SD card will pop out of the SD card slot.

⚠CAUTION

Do not insert or remove the SD card while the device's motor is running.

USE OF OXYGEN

⚠CAUTION

Before starting to use oxygen, be sure to read the safety warnings on page 18.

⚠WARNING

A water humidifier is not used with the oxygen source. Humidified oxygen causes damage to the device.

The device can be used with an external oxygen source. When using oxygen, the oxygen source must be connected to the oxygen inlet port on the device. When connecting the oxygen, the oxygen connection port provided with the device must be used. The oxygen flow rate is adjusted via the external oxygen source.
The device measures the FiO_2 (oxygen percentage of the inhaled air) value provided to the patient, and this value is displayed on the device screen. The measured FiO_2 value may vary depending on the oxygen flow rate, ventilation settings, and the patient's respiratory conditions. External oxygen supply can be used in all ventilation operating modes.

NOTE

The device measures the oxygen concentration (FiO_2) given to the patient and displays it on the screen; it does not control or adjust the oxygen concentration.

NOTE

The device measures the oxygen concentration (FiO_2) value in the range of 0%–100% via the oxygen sensor. In clinical use, the FiO_2 value depends on the applied oxygen source.

CONNECTING AN EXTERNAL OXYGEN SOURCE

Figure 14 Connecting an External Oxygen Source

The oxygen connection port provided with the device is attached to the end of the oxygen hose connected to the external oxygen source and is used by inserting it into the oxygen inlet connection located on the device.

⚠ CAUTION

Use only the provided oxygen connection port to connect the external oxygen source. Otherwise, you may damage the oxygen port inlet.

EXTERNAL OXYGEN SOURCE CONNECTION

WARNING

Use only clean, medical-grade oxygen sources suitable for medical use.

1. Turn on and operate the device.
2. Connect the external oxygen source to the oxygen inlet connection on the device using the oxygen connection port provided with the device.
3. Start the oxygen flow from the external oxygen source.
4. Adjust the oxygen flow as needed by checking the FiO_2 value displayed on the screen.

DISCONNECTING THE EXTERNAL OXYGEN SOURCE

1. Stop the oxygen flow from the external oxygen source.
2. Disconnect the oxygen hose by pressing the locking latch located on the oxygen inlet port.

Oxygen Monitoring: The FiO_2 section on the monitor screen displays the oxygen concentration administered to the patient as a percentage (%). The displayed FiO_2 value may vary depending on the flow rate set at the oxygen source, ventilation settings, and the patient's respiratory conditions. After changes are made to the oxygen flow, it may take a short time for the FiO_2 value displayed on the screen to update. The device measures and displays the FiO_2 value; it does not control or adjust the oxygen concentration.

USE WITH EXTERNAL HUMIDIFIER

If deemed necessary by a physician, the device may be used with an external humidifier. The use of an external humidifier must be carried out strictly in accordance with the instructions below. Do not use an external humidifier outside of the described method.

1. Place bacterial/viral filters at the inspiratory port outlet and before the exhalation valve on the expiratory port.
2. Connect the inspiratory tubing (hose) to the outlet of the bacterial filter attached to the inspiratory port.
3. Connect the other end of the inspiratory tubing to the gas inlet port of the external humidifier.
4. Connect one end of the tubing used with the humidifier to the gas outlet port of the external humidifier.
5. Connect the other end of this tubing to the Y-piece (patient connection).
6. Connect the expiratory tubing from the Y-piece to the expiratory port.
7.
8. Set the external humidifier to the level prescribed by the physician.
9. Ensure that all connections are correct, leak-free, and securely fitted.

Figure 15 External Humidifier Connection

WARNING

Keep the external humidifier on a flat surface and positioned below the level of the device and the patient.

USE WITH NEBULIZER

If deemed necessary by a physician, the device may be used with a nebulizer. The use of a nebulizer must be carried out strictly in accordance with the instructions below. Do not use a nebulizer outside of the described method.

1. Place bacterial/viral filters at the inspiratory port outlet and before the exhalation valve on the expiratory port.
2. Connect the inspiratory tubing (hose) to the outlet of the bacterial filter attached to the inspiratory port.
3. Connect the other end of the inspiratory tubing to the nebulizer inlet port.
4. Connect one end of the tubing used for patient connection to the nebulizer outlet port.
5. Connect the other end of this tubing to the Y-piece (patient connection).
6. Connect the expiratory tubing from the Y-piece to the expiratory port.
7. Ensure that all connections are correct, leak-free, and securely fitted.

Figure 16: Nebulizer Connection

WARNING

Do not use an HME filter when using an external humidifier or nebulizer.

OPERATING THE DEVICE

Follow the steps below to operate the device:

1. Turn on the device by pressing the on / off button.
2. When the device turns on, the on / off button LED lights up in blue and the device screen turns on.
3. Ensure that the device is connected to a power source or that its internal battery is at an adequate level.
4. Select the operating mode and adjust the parameter settings. (This should be performed by authorized healthcare personnel.)
5. Press the start / stop key located on the keypad of the device.
6. Provide confirmation after verifying the selected operating mode and parameters on the activation screen.

Figure 1716 Operating the Device

TURNING OFF THE DEVICE

1. Terminate the ventilation by pressing and holding the start / stop key for 3 seconds.
2. Ensure that ventilation has completely stopped.
3. Turn off the device by pressing the on / off button located on the front panel.
4. When the device is turned off, the on / off button LED turns off.

Figure 18 Turning Off the Device

VENTILATION OPERATING MODES

Operation Modes

VENTISENSE is categorized into four groups based on the respiratory support mechanism and offers a total of 10 ventilation operating modes:

- Mandatory ventilation modes; the device fully controls the work of respiration.
    - PCV
    - VCV
- Assisted ventilation modes; the device delivers mandatory breaths when the patient has no spontaneous effort. When the patient initiates a breath, the device provides support, allowing the patient to breathe spontaneously.
    - PCV - A
    - VCV - A
- Synchronized Intermittent Mandatory Ventilation Modes; these modes combine both mandatory and spontaneous breathing. The ventilator delivers mandatory breaths at set intervals but also allows the patient to breathe spontaneously when triggered by their own effort.
    - SIMV - P
    - SIMV - V
- Spontaneous Ventilation Modes with/without Device Support; in these modes, the patient has spontaneous breathing. The ventilator only provides supportive pressure or maintains airway patency. The respiratory rate is determined by the patient.
    - CPAP
    - BILEVEL
    - PSV
    - HFO

VENTILATION GROUP	OPERATING MODE	DESCRIPTION
Mandatory Ventilation Modes	PCV	Pressure-Controlled Ventilation
	VCV	Volume-Controlled Ventilation
Supported Ventilation Modes	PCV-A	Supported Pressure-Controlled Ventilation
	VCV-A	Supported Volume-Controlled Ventilation
Synchronized Intermittent Mandatory Ventilation Modes	SIMV-P	Pressure-Controlled Synchronized Intermittent Mandatory Ventilation
	SIMV-V	Volume-Controlled Synchronized Intermittent Mandatory Ventilation
Device-Assisted / Unassisted Spontaneous Ventilation Modes	CPAP	Continuous Positive Airway Pressure
	PSV	Pressure Support Ventilation
	BiLEVEL	Pressure Support Ventilation – Spontaneous
	HFO	High-Flow Oxygen

VENTILATION OPERATING MODE DESCRIPTIONS

OPERATING MODE NAME	DESCRIPTION
(PCV) Pressure Controlled Ventilation	• Ventilation is controlled only by the device. The patient's spontaneous breaths are not supported by the device. • The essence of the breathing cycle is the set frequency and a fixed inspiratory time. • The applied inspiratory volume varies according to lung compliance and resistance. • PCV is used especially in patients with Acute Respiratory Distress Syndrome (ARDS) to avoid high peak pressures.
(VCV) Volume Controlled Ventilation	• The "tidal volume" defined in the device parameters is applied to the patient in each inspiratory cycle. • Ventilation is controlled only by the device. • The essence of the breathing cycle is the set frequency and a fixed inspiratory time. • The applied inspiratory pressure varies according to lung compliance and resistance.
(PCV-A) Assisted Pressure Controlled Ventilation	• It is a PCV mode with adjustable ventilation parameters that enables the patient to breathe spontaneously. • The patient can breathe spontaneously. • The inspiratory time is precisely defined. • The patient can shorten the expiratory time only through their own ventilation and thus increase the set frequency.
(VCV-A) Assisted Volume Controlled Ventilation	• It is a VCV mode with adjustable ventilation parameters that enables the patient to breathe spontaneously. • The patient can breathe spontaneously. • The essence of the breathing cycle is the set frequency and a fixed inspiratory time. • The applied inspiratory pressure varies according to lung compliance and resistance.

(SIMV-P) Pressure Controlled Synchronized Intermittent Mandatory Ventilation	• SIMV-P supports the patient's spontaneous triggers according to the triggering window. • It aims to synchronize the breathing cycles of the patient and the device by detecting spontaneous breaths within the predefined triggering window. • In 40% of the expiratory cycle, spontaneous breathing triggers are detected and supported with the adjusted pressure support parameter. The patient returns to expiration by using expiratory effort. • In 60% of the expiratory cycle, spontaneous breathing triggers are detected and supported with mandatory breaths. The predefined IPAP pressure is applied and continues until the predefined inspiratory time is completed.
(SIMV-V) Volume Controlled Synchronized Intermittent Mandatory Ventilation	• SIMV-V supports the patient's spontaneous triggering according to the triggering window. • It aims to synchronize the breathing cycles of the patient and the device by detecting spontaneous breaths within the predefined triggering window. • In 40% of the expiratory cycle, spontaneous breathing triggers are detected and supported with the adjusted pressure support parameter. The patient returns to expiration by using expiratory effort. • In 60% of the expiratory cycle, spontaneous breathing detection is triggered and supported with mandatory breaths. The predefined tidal volume is applied, and inspiration continues until the predefined inspiratory time is completed.

(PSV) Pressure Support Ventilation	• It is used for partial ventilation support. • If no spontaneous breathing trigger is detected from the patient for the duration set in the apnea time parameter, ventilation is performed by the device at the predefined frequency. • It is the closest and most comprehensive breathing mode to spontaneous breathing for patients. • Since the patient can control the respiratory rate and tidal volume, less sedation is required.
(BiLEVEL) Pressure Supported Ventilation – Spontaneous	• The device responds to the patient's spontaneous breathing. There is no mandatory ventilation. • Since there is no adjustable frequency, inspiration is triggered only by the patient's spontaneous breathing. • In this ventilation mode, Ventisense responds only to the patient's momentary ventilation.
(CPAP) Continuous Positive Airway Pressure	• In CPAP mode, the device applies continuous positive pressure. • In this mode, the patient breathes using their own effort, and no additional support is provided by the device.
(HFO) High Flow Oxygen	• HFO is a flow-controlled mode. • It provides a constant, predefined flow of oxygen mixture to the patient. • It is used together with an external oxygen source, humidifier, and HFNC.

USING THE DEVICE

USER INTERFACES

The device features two different levels of user access: Physician Interface and Home Interface.

1. **Physician Interface:**
   This interface is intended for use by authorized healthcare personnel who have been trained in device setup and ventilation settings. In the Physician Interface, the user can access all device settings, including ventilation operating modes, ventilation parameters, and alarm settings, to perform the appropriate configuration for the patient. While the Physician

   Interface is active, an icon  is displayed in the upper right corner of the screen.

2. **Home Interface:**
   The Home Interface is designed to ensure the safe use of the device in uncontrolled environments, such as the home. In the Home Interface, ventilation and alarm parameters cannot be modified. Patients and caregivers can only monitor the operation of the device; unauthorized changes to settings are prevented. While Home Interface access is active, switching between Setup 1, Setup 2, and Setup 3 is possible. These settings contain ventilation operating modes and parameters previously configured by authorized healthcare personnel. Switching between setups should be performed with the knowledge and approval of authorized healthcare personnel.

   Home Interface is active, an icon  is displayed in the upper right corner of the screen.

MENU STRUCTURE

Main Screen		
Icon	**Name**	**Description**
	**Parameters (Setup 1 / Setup 2 / Setup 3)**	This screen is used to set and save ventilation operating modes and related parameters when Physician Interface is active. Setup 1, Setup 2, and Setup 3 allow the user to save different ventilation operating modes and parameter settings that have been preconfigured. A different ventilation operating mode and the parameters associated with that mode can be defined for each setting field.
	**Monitor**	This screen displays the patient's respiratory parameters and system status in real time during ventilation. This screen monitors 39 different patient parameters, including pressure, volume, frequency, minute ventilation, leakage rate, FiO_2, and spontaneous breathing.
	**Graphs**	This screen provides a visual representation of the patient's ventilation parameters over time and throughout the respiratory cycle. On this screen, Pressure (mbar), Flow (LPM), and Tidal Volume (ml) values are displayed as waveform graphs against the time axis. Additionally, the Tidal Volume – Pressure cycle graph (loop) allows for the evaluation of respiratory mechanics and patient–device compatibility.
	**Alarms**	This screen displays a total of 25 alarm notifications generated by the device, sorted by date and time in reverse chronological order.
	**Settings**	This screen is where the device's general system settings are configured. On this screen, you can manage basic settings related to the device's operation and use, such as language and date/time settings, counter and system controls, user interface, patient type settings, and device software information.

BASIC DISPLAY STRUCTURE

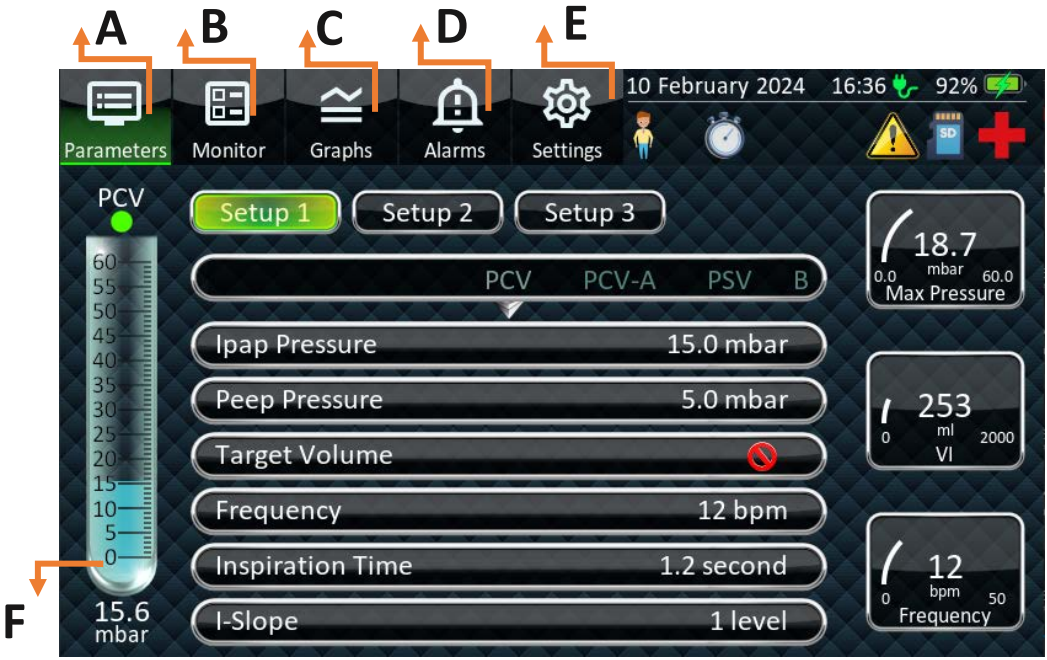


Figure 19 Basic Screen Structure

A. **Parameters**: The parameters of the operating modes are set.

B. **Monitor**: The values resulting from the operating mode operation are observed.

C. **Graphs**:

- Pressure, flow, and tidal volume waveform graphs are observed.
- Tidal volume – pressure cycle graph is observed.

D. **Alarms**: Alarm history is observed.

E. **Settings**: Includes language, time, counters, general and about.

F. **Pressure bar graph**: When the motor is running, the pressure change is observed at the pressure bar.

OPERATING BY TOUCH-CONTROL

The device is controlled via a touchscreen interface. By touching the screen, the user can access the basic functions of the device and perform the following operations:

- Selecting and changing ventilation operating modes,
- Adjusting ventilation parameters,
- Starting and stopping ventilation,
- Switching between the monitoring screen and graphical screens,
- Viewing alarm conditions and acknowledging alarms,
- Configuring system, user, and device settings by accessing the settings menu.

All operations on the touchscreen are supported by visual feedback. Selections and changes made are displayed instantaneously on the screen.

Figure 20 Operation By Touch-Control

⚠ CAUTION

The touchscreen should not be used with wet hands or while there is contact with liquid, and the screen should not be tampered with using sharp, pointed, or hard objects. The touch surface should only be operated with fingertips.

PARAMETERS | ADJUSTING VENTILATION SETTINGS

Click on the “Parameters” option.

Ventilation is activated by the user after selecting the operating mode and adjusting the parameters belonging to that mode.

Ventilation Operating Mode Selection and Parameter Settings:

1. Enter the “Parameters” menu from the main screen.
2. Switch between saved setup (Setup 1, Setup 2, Setup 3) or select one of them.
3. To change the ventilation operating mode, swipe the operating mode selection area with your finger and select the desired operating mode.
4. Adjust the ventilation parameters (e.g., pressure, volume, frequency, etc.) for the selected operating mode.

Figure 21 Ventilation Operating Mode Selection and Parameter Settings

NOTE

While the device is operating in the mode of the selected setup page, the ventilation operating mode cannot be changed via that specific setup page. To change the operating mode, it is necessary to switch to other setup pages.

Activating Ventilation:

1. Press the motor start / stop key on the keypad once.
2. The name of the ventilation operating mode and its parameters will appear on the screen for final check and confirmation, as shown in Figure 20.
3. After checking the settings one last time and ensuring their accuracy, start the ventilation by pressing the "Activate" button.

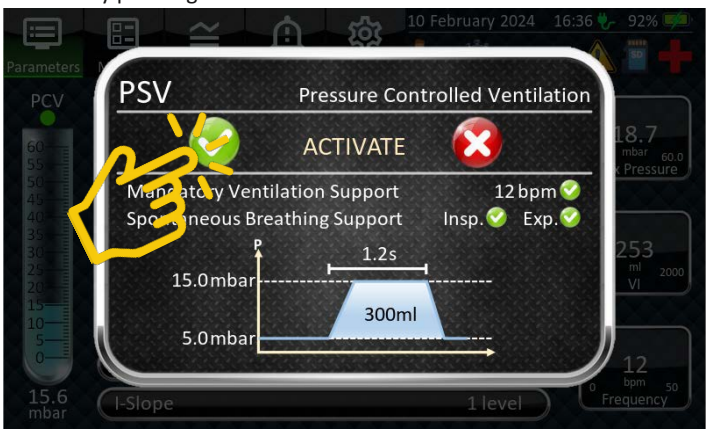


Figure 22 Activating Ventilation

MONITOR | DISPLAYING MEASUREMENT VALUES

Click on the “Monitor” option.

When ventilation is active, the patient's measurement values are displayed in real time on the parameter screen. The displayed measurement values include parameters related to pressure, volume, frequency, oxygen concentration, and respiratory timing. The main parameters monitored include the following (a total of 39 parameters are monitored, not limited to these): Maximum Pressure,

- Inspiratory Volume (VI),
- Expiratory Volume (VE),
- Minute Ventilation Volume (MV),
- Respiratory Rate,
- Inspiratory/Expiratory Ratio (I:E),
- Oxygen Concentration (FiO_2).

The device can also monitor and display additional measurement parameters depending on the selected ventilation operating mode and configured settings.

MONITOR SCREEN CUSTOMIZATION FEATURE

The measurement parameter boxes on the monitor screen can be customized by the user according to their needs. By pressing and holding any measurement parameter, the Monitor Layout Edit Screen opens. On this screen, the measurement parameters desired to be displayed can be selected and assigned to the relevant boxes. As a result of this feature:

- A personalized monitor layout can be created based on clinical requirements,
- Measurement values that require priority monitoring can be highlighted,
- The monitor screen can be dynamically configured according to user preferences and the patient's condition.

Figure 23 Monitor Screen Customization Feature

PARAMETERS ON THE MONITOR SCREEN

Figure 24 Monitor Screen - 1

A. **Maximum Pressure (mbar):** The highest pressure value reached in the airway during ventilation.
B. **IPP (mbar):** The plateau pressure value measured in the airway during the inspiration phase.
C. **PEEP (mbar):** The positive pressure level maintained in the airway at the end of expiration.
D. **Inspiration Volume – VI (ml):** The volume of air delivered to the patient during inspiration in one respiratory cycle.
E. **Expiration Volume – VE (ml):** The volume of air exiting the patient during expiration in one respiratory cycle.
F. **Minute Ventilation Volume – MV (ml):** The total volume of respiratory gas delivered to the patient within one minute.
G. **Frequency (bpm):** The number of breaths per minute.
H. **I:E Ratio:** The ratio of inspiration time to expiration time.
İ. **FiO_2 Concentration (%):** The percentage of oxygen in the respiratory gas delivered to the patient.

Figure 25 Monitor Screen - 2

- **J. Inspiration Flow (LPM):** The instantaneous gas flow passing through the airway during the inspiration phase.
- **K. Maximum Inspiration Flow (LPM):** The highest gas flow value reached during the inspiration phase.
- **L. Average Inspiration Flow (LPM):** The average gas flow value measured during the inspiration phase.
- **M. Expiration Flow (LPM):** The instantaneous gas flow passing through the airway during the expiration phase.
- **N. Maximum Expiration Flow (LPM):** The highest gas flow value reached during the expiration phase.
- **O. Average Expiration Flow (LPM):** The average gas flow value measured during the expiration phase.
- **P. Leakage (LPM):** The gas loss calculated in liters/minute (LPM) due to leaks in the breathing circuit.
- **Q. Leakage Percentage (%):** The ratio of the leak in the breathing circuit to the total gas flow delivered, as a percentage (%).
- **R. Spontaneous Breath (%):** The percentage (%) of total breaths initiated by the patient's own respiratory effort.

Figure 26 Monitor Screen - 3

S. **Compliance (ml/mbar):** The change in volume of the lungs in response to a unit change in pressure.
T. **Resistance (mbar/(L/s)):** The resistance of the airways to airflow.
U. **PEEP Minimum (mbar):** Displays the lowest PEEP pressure value measured during the relevant respiratory cycle.
V. **Inspiration Time (s):** The duration of the inspiration phase in one respiratory cycle.
W. **Expiration Time (s):** The duration of the expiration phase in one respiratory cycle.
X. **Inspiration Flow (s):** The duration during which airflow is applied in the inspiration phase.
Y. **Expiration Flow (s):** The duration during which airflow occurs in the expiration phase.

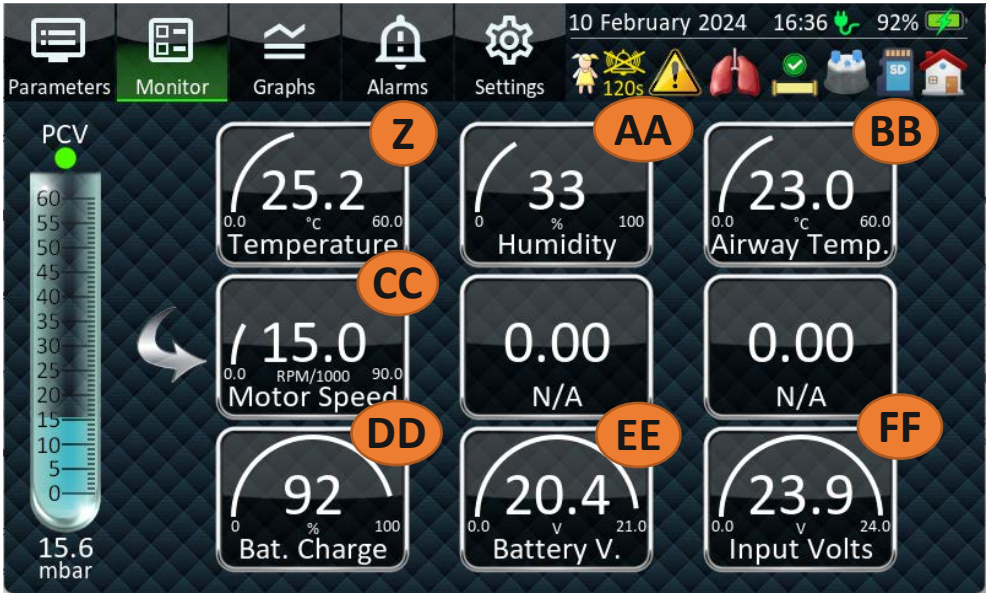


Figure 27 Monitor Screen - 4

Z. Temperature (°C): The air temperature inside the device.

AA. Humidity (%): The amount of humidity inside the device.

BB. Airway Temperature (°C): The air temperature measured in the airway.

CC. Motor Speed (RPM/1000): The revolutions per minute of the device motor (in thousands of RPM).

DD. Battery Charge (%): The current charge level of the device battery as a percentage (%).

EE. Battery Voltage (V): The instantaneous electrical voltage value of the device battery.

FF. Input Voltage (V): The input voltage supplied to the device from an external power source.

SHOWING CURVES

Click on the “Monitor” option.

1. **Waveform Graphics:**
2. During ventilation, the time-dependent changes in airway pressure, flow, and tidal volume are displayed as waveform graphics on the Graphics screen. These graphs allow for real-time monitoring of the ventilation applied by the ventilator and the patient's respiratory curves.

Depending on the selected ventilation operating mode and the set treatment parameters, the following waveform graphics are displayed on the Graphics screen:

- **Pressure (mbar):** The pressure waveform showing the change in pressure over time for the selected ventilation operating mode.
- **Flow (LPM):** The airflow waveform showing the change in airflow over time during the inspiration and expiration phases.
- **Tidal Volume (ml):** The volume waveform showing the change in the volume delivered during each respiratory cycle over time.

Figure 28 Waveform Graphics Screen

3. Loop Graph:

While the waveform graphics are displayed on the Graphics screen, a single touch on the screen switches to the Loop Graph screen. The loop graph shows the relationship between pressure and tidal volume during ventilation, independent of time. In this graph, the inspiration and expiration phases of a respiratory cycle are monitored as a closed loop.

In the graph:

- **Horizontal axis:** Displayed as Pressure (mbar).
- **Vertical axis:** Displayed as Tidal Volume (ml).

The Pressure–Tidal Volume loop graph assists in evaluating lung compliance, observing the appropriateness of ventilation settings, and analyzing the general characteristics of the respiratory cycle. The shape and width of the loop provide clinically significant information regarding the patient's respiratory mechanics, airway resistance, and patient–ventilator interaction.

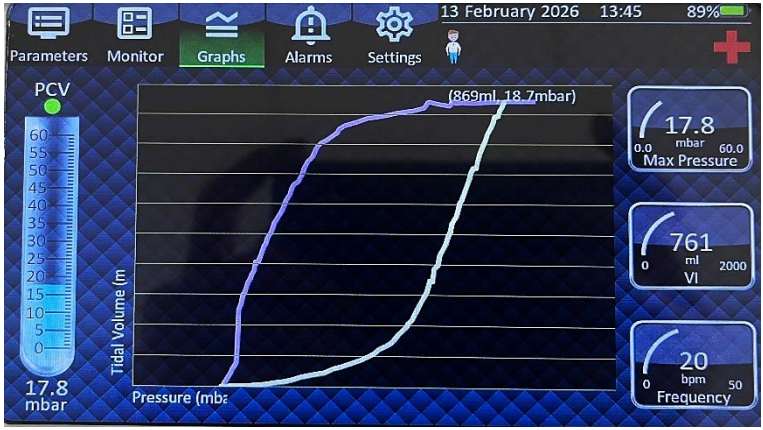


Figure 29 Loop Graph Screen

➔ These graphics assist in the evaluation of patient-ventilator synchrony, the respiratory cycle, and ventilation efficacy.

NOTE

No filtering or smoothing is applied to the monitored graphics.

ALARMS

1. Tap the “Alarms” tab on the main screen.
2. On the Alarms screen, navigate through the alarm logs using the touchscreen.

The Alarms page allows for the retrospective viewing of alarm logs generated by the device. On this screen, occurring alarms are listed with date and time information, with the most recent alarm at the top. The alarm history is used for monitoring the device's operation process, performing clinical evaluations, and retrospectively examining potential issues. The system stores the last 25 alarm logs in its memory and displays them on this page.

SETTINGS

Accessing Settings:

1. Tap the “Settings” option.
2. Switch between settings using the screen.

1. LANGUAGE

The device offers multi-language support for the user interface. By selecting the preferred language from the Settings menu, the device interface can be displayed accordingly.

Figure 30 Language Options

The languages available for the device interface are as follows:

- Turkish
- English
- German
- Spanish
- French
- Chinese
- Russian
- Arabic

2. DATE AND CLOCK SETTING

The date and time information of the device is adjusted using the selection fields on the screen. After the adjustment process is complete, press the “Update” button to save the changes.

Figure 31 Time-Date Setting

3. COUNTERS

The Counters screen is used to display duration information regarding the device's usage and maintenance requirements. On this screen, the operation of the device and the usage periods of connected components can be monitored.

On the left section of the screen, the elapsed time since the device's first activation or the last replacement of the relevant component is shown in hours. The right section contains the limit values defined for each counter. The indicator bars in the middle represent the status of the current usage time relative to the limits. Additionally, the colors of the indicator bars change respectively from **green → yellow → red**, indicating that the limits are nearly reached:

- **Green:** Indicates that the usage period has recently started,
- **Yellow:** Indicates that the occupancy rate of the counter has increased and is at the middle levels of the usage period,
- **Red:** Indicates that the usage time is very close to or has reached the limit specified on the right of the counters. If the counter is full, it indicates a need for maintenance / replacement.

COUNTERS		
Name	**Description**	**Counter Duration**
Operation	Shows the duration the device has remained on since it was turned on.	-
Therapy	Shows the total duration that ventilation is active and the device is providing treatment to the patient.	-
Blower	Shows the total operating time of the device motor.	20000 hours
Filter	Usage time of the filters since the device first started operating or since the last replacement.	1500 hours
Tubing	Usage time of the patient circuit since the device first started operating or since the last replacement.	1500 hours
Battery	Usage time of the battery since the device first started operating or since the last replacement.	15000 hours
Service	The usage time elapsed relative to the period determined for service maintenance.	8000 hours

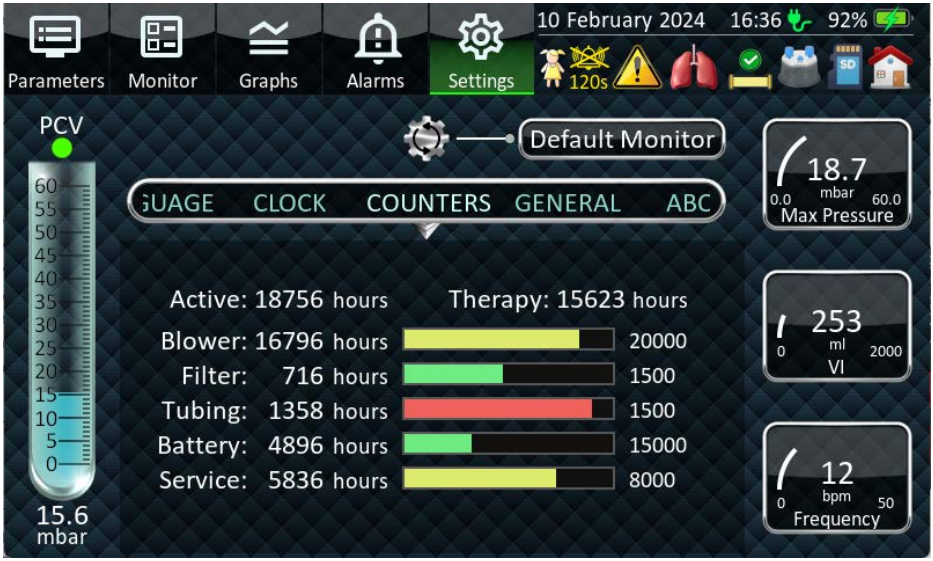


Figure 32 Counters Screen

4. GENERAL

This section contains settings regarding the general operating characteristics of the device and user preferences.

4.1. Factory Settings 

When this option is selected, the device's ventilation operating modes and parameter settings are restored to the system defaults as set at the factory. Additionally, the alarm history recorded on the device is cleared.

NOTE

To restore the device to factory settings, the device motor must be turned off.

NOTE

When the device is restored to factory settings, the counters are not reset.

4.2. Default Monitor 

When this option is selected, the display and layout settings for the monitor screen are restored to system defaults. Monitor customizations made by the user are reset, and the standard screen layout is re-established.

4.3. Physician Interface

The Physician Interface is designed for use only by trained and authorized healthcare personnel. This menu provides access to advanced device settings, including ventilation and alarm parameters.

Access to the Physician Interface is password protected. The password is provided by authorized personnel during device setup.

- Follow the path: **Settings → General → Physician Menu Access**.
- Enter the password provided by authorized personnel to activate the Physician Interface.
- Once the password is verified, access to all ventilation and alarm settings is granted.
- The icon "  " appears in the upper right corner of the screen.
- **Returning to Home Interface:**
- To return to the home interface, turn off "Physician Menu Access" and press the confirmation button.
- When switched to the home interface, the "  " icon appears in the upper right corner of the screen.

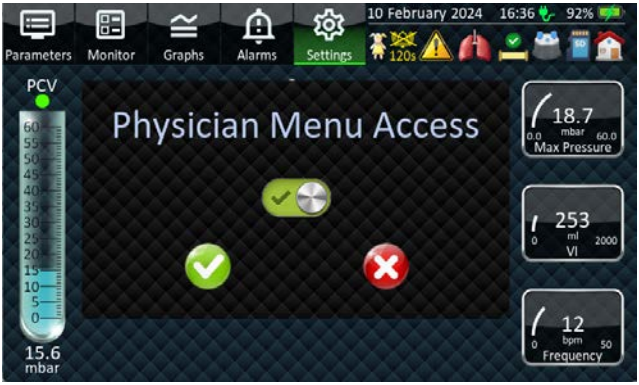


Figure 33 Physician Interface Access Screen

WARNING

The Physician Menu must be used only by trained and authorized healthcare personnel. Unauthorized access may lead to incorrect ventilation settings and compromise patient safety.

4.4. Pediatric Mode

Pediatric Mode allows ventilation parameters to be configured within appropriate ranges for pediatric patients. Pediatric Mode must be disabled for adult patients.

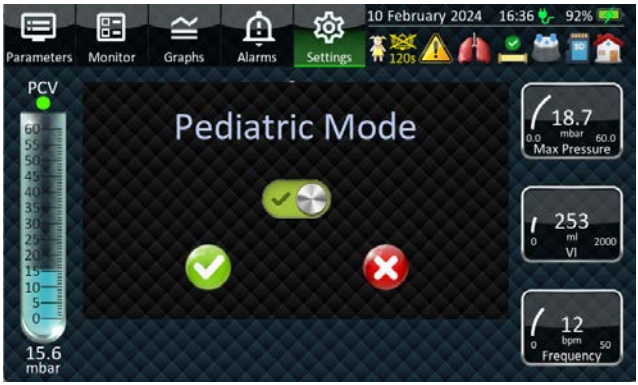


Figure 34 Pediatric Mode Screen

4.5. Automatic Setup Switching

The Automatic Setup Switching feature is designed to support the continuity of ventilation for patients deemed necessary by authorized healthcare personnel in a home environment. Under this feature, appropriate ventilation operating modes and parameters are defined in the Setup 1, Setup 2, and Setup 3 fields previously configured by authorized healthcare personnel. In the event of certain alarm conditions during home use, the device can automatically switch between these settings to prevent interruption of treatment.

Automatic Setup switching is activated if any of the following conditions occur:

- Total alarm duration exceeds 60 seconds, or
- Total number of alarms exceeds 10

When these conditions are met, the device automatically switches through the predefined ventilation settings in the order of **Setup 1 → Setup 2 → Setup 3**. To enable the Automatic Setup Switching feature, follow the menu path **Settings → General → Automatic Setup Switching** and set the relevant option to the "on" position.

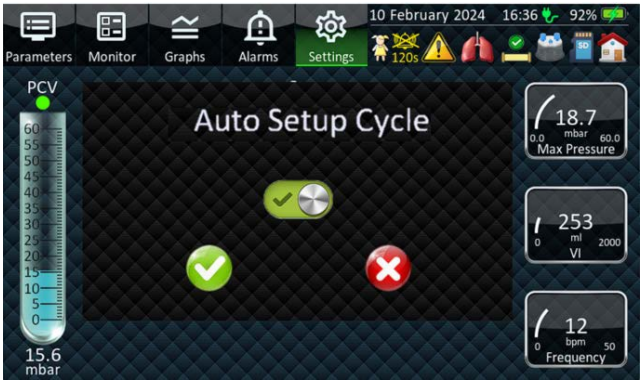


Figure 35 Automatic Setup Switching

WARNING

In high-priority (red) alarm conditions, the Automatic Setup Switching feature does not activate, and the device does not change the current ventilation settings. Necessary intervention must be performed by the user in such alarm situations.

4.6. External Humidifier

When an external humidifier is connected to the patient circuit, it is recommended to enable the “External Humidifier” parameter from the Settings screen. When enabled, the additional volume created by the external humidifier in the patient circuit is included in the ventilator's volume calculations. This ensures that tidal volume measurements are performed more accurately and reliably.

When the “External Humidifier” parameter is activated, the relevant information “ ” icon is displayed on the screen.

Figure 36 External Humidifier

4.7. Leakage Compensation

The Leakage Compensation feature is designed to maintain the efficacy and stability of treatment, especially in non-invasive ventilation (NIV) applications. When leakage compensation is activated, the device automatically corrects ventilation calculations using the amount of leakage detected. Thanks to this feature:

- Tidal volume calculations are adjusted according to detected leaks.
- Inspiration trigger sensitivity is not adversely affected by the presence of leaks.
- Continuity of ventilation and patient-ventilator synchrony are maintained.

When the "Leakage Compensation" parameter is activated, the icon on the right appears if the device does not detect a leakage.

The icon on the right appears when the device detects a leakage during treatment and activates the leakage compensation feature.

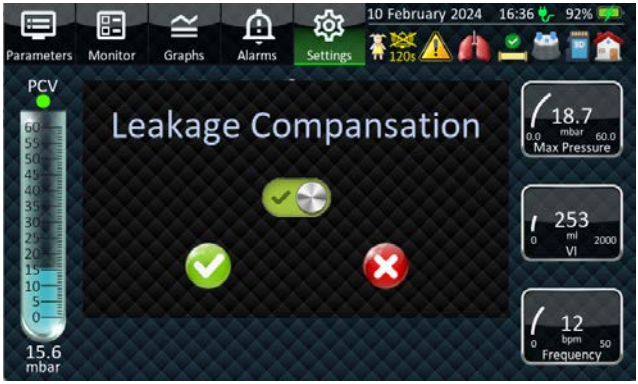


Figure 37 Leakage Compensation

4.8. LCD Brightness

The brightness level of the device screen can be adjusted between levels 3 and 10. As the level increases, the screen brightness increases gradually. The brightness setting can be configured to suit the lighting conditions of the operating environment.

4.9. Volume

The level of the device's alarm and system sounds can be adjusted between levels 1 and 10. As the level increases, the volume increases gradually. The volume setting should be configured according to the ambient conditions of the user.

4.10. Software Update

The update of the device software is performed via an SD card. The **Settings → General → Software Update** option is available to start the software update.

In order to start the update, all of the following conditions must be met:

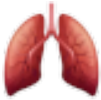
- The VENT2.hex software file must be located in the root directory of the SD card.
- The device's battery charge level must be above 50%.
- The motor must not be running during the update.

Once these conditions are met, the “Software Update” parameter is selected. The update process starts when user confirmation is given. The software update process takes approximately 4–5 minutes. When the update is complete, the device restarts automatically.

⚠ CAUTION

No intervention should be made to the device until the software update is completed. Turning off the device, disconnecting the power supply, or removing the SD card during the update may cause the device to malfunction.

SYMBOLS ON TOOLBAR AND THEIR MEANINGS

Symbol	Description
	Physician Interface
	Home Interface
	Adult
	Pediatric
	Alarms
	Timed Triggering
	Spontaneous Breathing Triggering
	SD card is inserted in device
	Internal Battery Level And Charging Status

DATA RECORDING VIA SD CARD

The device detects the insertion of an SD card only once while it is powered on. If the SD card is repeatedly inserted and removed, the device will not re-detect the card. In this case, for the SD card to be recognized again, the device must be completely turned off and then turned back on using the on/off button.

To start recording, the SD card must be inserted into the device before starting ventilation therapy. After the required ventilation operating mode and parameter settings are made, the motor is started, and the recording process begins automatically. From this moment on, all changes made to ventilation settings and all occurring alarms are recorded.

To review the records at the end of treatment, the motor must first be stopped, and then the SD card should be safely removed.

The system uses 12:00 (noon) as the start of the day and creates a new log file at this time by ending the current record. Each recording is stored in two different file formats:

- Files with the .nef extension; include readable treatment and event logs in XML format, along with all ventilation setting changes made.
- Files with the .nwf extension; record the waveforms (pressure, flow, volume, leak) generated during treatment in a binary system.

All these recorded data can be visualized and examined using the NefesReporter.exe application.

ALARMS AND MESSAGES

⚠ CAUTION

No intervention should be made to the device until the software update is completed. Turning off the device, disconnecting the power supply, or removing the SD card during the update may cause the device to malfunction.

ALARM PRIORITY AND REQUIRED ACTIONS

HIGH PRIORITY ALARM

Requires immediate intervention for patient safety. Check the patient immediately and eliminate the cause of the alarm as soon as possible.

- The alarm message is displayed in a red rectangle on the screen.
- The alarm LED flashes red twice per second.

MEDIUM PRIORITY ALARM

Requires rapid intervention. Identify the cause of the alarm and apply the necessary corrective actions.

- The alarm message is displayed in a yellow rectangle on the screen.
- The alarm LED flashes red once per second.

NOTE

In the event that multiple alarms are triggered simultaneously or consecutively, the alarm with the highest priority is displayed on the screen and reported to the user as a priority.

NOTE

Alarms are detected based on measurement data obtained from pressure and flow sensors.

OVERVIEW OF ALARMS

ADJUSTABLE ALARMS

Adjustable alarms consist of conditional alarms. Alarm limits can only be adjusted by the responsible medical personnel on the parameter screen.

Alarm	Priority	Alarm Status	Reason
High Inspiratory Volume	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	Inspiratory volume is higher than "High Inspiratory Volume".
Low Inspiration Volume	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The inspiration volume is lower than the "Low Inspiration Volume".
High Expiration Volume	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The expiration volume is higher than the "High Expiration Volume".
Low Expiration Volume	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The expiration volume is lower than the "Low Expiration Volume".
High Ventilation Volume per Minute	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The measured ventilation volume per minute is greater than the "High Minute Ventilation Volume".
Low Ventilation Volume per Minute	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The measured ventilation volume per minute is lower than the "Low Minute Ventilation Volume".
Leakage	Medium	The red LED flashes and the alarm message is displayed in a red rectangle on the screen.	The measured Leak amount has exceeded the set Leak alarm limit.
High FiO_2	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The measured FiO_2 is greater than the set "High FiO_2" value
Low FiO_2	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The measured FiO2 is smaller than the set "Low FiO_2" value.

Apnea Alarm	Medium	The red LED flashes and a red rectangle appears on the monitor screen	The adjustable time ("Apnea Alarm") has been exceeded
High Frequency	Medium	The red LED flashes and a red rectangle appears on the monitor screen	The measured frequency is greater than “High Frequency”.
Low Frequency	Medium	The red LED flashes and a red rectangle appears on the monitor screen.	The measured frequency is smaller than “Low Frequency”.

Testing of Adjustable Alarms

Adjustable alarm conditions can be verified by setting the corresponding alarm limit and intentionally causing the monitored parameter to exceed or fall below the set threshold value. The ventilator generates the relevant alarm when the configured limit is reached.

MANDATORY ALARMS

Mandatory alarms comprise alarms with technical conditions. Alarm conditions are fixed in the device and cannot be changed by the user

Alarm Name	Priority	Visual Warning	Alarm Condition (Reason)	Recommended Intervention
Low PEEP Pressure	High	The red led flashes and the alarm message is displayed in a red rectangle on the screen.	The measured PEEP value decreased 3 mbar below the set PEEP value, which persisted for 5 consecutive respiratory cycles.	The inspiration hose may be leaking; Check the hose and/or check the patient's health status.
High PEEP Pressure	High	The red led flashes and the alarm message is displayed in a red rectangle on the screen.	The measured PEEP value increased by 3 mbar above the set PEEP value, and this persisted for 5 consecutive respiratory cycles.	There may be a blockage in the expiratory tube; Check the hose and/or check the patient's health status.
Obstruction	High	The red led flashes and the alarm message is displayed in a red rectangle on the screen.	An obstruction alarm is generated when airway obstruction is detected that persists for 5 seconds and 2 breathing cycles, whichever is longer. Conditions: - Max. expiratory flow < 0.8 LPM → Expiratory line blocked - Max. inspiration flow < 1.5 LPM → Inspiration line blocked - Adult: Maximum flow < (Max. Pressure / 10) → Patient cannula or circuit blocked Pediatric: Maximum flow < (Max. Pressure / 8)	Check the flow values specified in the alarm conditions. Once you have determined the condition from which the alarm originates, check the patient circuit, patient cannula, and inspiration/expiration lines for occlusion accordingly.

Disconnection	High	The red led flashes and the alarm message is displayed in a red rectangle on the screen.	The device detects connection interruptions at 4 different connection points: - Exhalation valve hose - Expiratory line - Inspiration line - Patient side (cannula/tube) The Disconnection Alarm activates if at least one of the following conditions persists for 5 seconds: - If the maximum inspiration flow exceeds the threshold value • Threshold Values; Adult: 60 LPM, Pediatric: 46 LPM - If the measured leakage value exceeds 20 LPM - If the conditions of 8 LPM > inspiration flow and 8 LPM > expiration flow are met simultaneously	Check all ports on the patient circuit. Ensure that the exhalation valve control tubing, inspiration line, expiration line, and patient-side connections are correctly and securely connected to the device and the patient. If necessary, reconnect the connections and verify that the alarm has disappeared.
High Pressure	High	The red LED flashes and a red rectangle appears on the monitor screen.	For 3 breath cycles; - In pressure-targeted ventilation operating modes: The measured airway pressure exceeds the set IPAP value by 5 mbar, - In volume-targeted ventilation operating modes: The measured airway pressure exceeds the set maximum pressure (Pmax) value by 5 mbar. This may occur as a result of patient-induced reactions such as the patient coughing, sighing, active respiratory effort, or temporary increase in airway resistance.	Check the patient and the respiratory circuit immediately. If there is a temporary pressure increase caused by the patient, intervention may not be required; However, if the alarm persists, airway resistance, patient-ventilator compliance, and ventilation settings should be evaluated by authorized medical personnel.

Max. Pressure limit reached	Medium	The red LED flashes and a yellow rectangle appears on the monitor screen.	In volume-targeted ventilation operating modes, the device detects this situation if the targeted tidal volume cannot be reached despite staying within the set maximum pressure limit. If this condition persists for 3 consecutive breathing cycles, the "Max. Pressure Limit Reached" alarm is triggered.	Ventilation settings should be evaluated by authorized health personnel. If necessary, maximum pressure and/or tidal volume settings should be reconfigured to be appropriate for the patient's clinical condition. In addition, the patient circuit, airway resistance and possible obstructions should be checked
Min. Pressure Limit Reached	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	In volume-targeted ventilation operating modes, the device detects this situation if the targeted tidal volume is not reached despite staying within the set minimum pressure limit. If this condition persists for 3 consecutive breathing cycles, the "Min. Pressure Limit Reached" alarm is triggered.	Ventilation settings should be evaluated by authorized health personnel. If necessary, the minimum pressure and/or tidal volume settings should be reconfigured to be appropriate for the patient's clinical condition. In addition, patient-ventilator compatibility and possible leakage situations should be checked.
Battery Operation	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The mains connection is disabled, the device runs on battery power.	Reconnect the power supply.

Battery 30%	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The usable capacity of the battery has decreased to 30%.	To ensure uninterrupted operation of the device, charge the battery as soon as possible by connecting it to an external power source.
Battery 10%	High	The red led flashes and a red rectangle appears on the monitor screen.	The usable capacity of the battery has decreased to 10%.	To prevent the device from shutting down and ventilation from being interrupted, immediately charge the battery by connecting it to the external power source.
High Temperature	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	When the device internal temperature reaches 60 °C, the "High Temperature" alarm is triggered one-time (one-shot). When the alarm is muted by the user, the visual and audible warning ends.	Make sure that the ambient temperature at which the appliance is operated is within the nominal values. If the alarm persists, there may be a malfunction in the device's fan; Switch off the appliance and contact an authorised technical service.

VE Unreadable	Medium	The red LED flashes and a yellow rectangle appears on the monitor screen.	In treatments using external humidifiers, in-device moisture may occur as a result of improper use of the humidifier filter. In this case, expiratory volume (VE) measurement cannot be performed temporarily and the device cannot read the VE value.	Ensure that the appropriate humidifier filter is used when using an external humidifier and replace the filter at recommended intervals. If necessary, allow the internal environment of the appliance to dry. This alarm is displayed once on the screen when the condition occurs. Once the alarm is muted, the alarm will not be triggered again unless the same condition occurs again.
Service	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The service usage period defined for the device (8000 hours) has expired.	In order to maintain the safe and correct operation of the device, an authorized service should be consulted and necessary maintenance procedures should be performed.
Fan Usage Time Exceeded	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The total operating time of the appliance fan has reached the limit of 20,000 hours.	The device should be referred to an authorized service center for evaluation of fan performance and safe operation of the device.

Filter Expiration Exceeded	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The usage time of its filters has reached the limit of 1500 hours.	Device filters should be replaced with new ones and the relevant meter should be reset after replacement.
Circuit Usage Time Exceeded	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The usage time of the patient circuit has reached the limit of 1500 hours.	The patient circuit should be replaced with a new one. After the replacement, the relevant meter should be reset.
Battery Usage Time Exceeded	Medium	The red led flashes and a yellow rectangle appears on the monitor screen.	The total usage time of the internal battery has reached the limit of 15,000 hours.	The device should be sent to an authorized service for the evaluation of battery performance, and if necessary, the battery should be replaced.

TESTING ALARM CONDITIONS

- **Obstruction Alarm:** The outlet of the breathing circuit is briefly closed to block the airflow. If the airway obstruction continues for 5 seconds or 2 respiratory cycles (whichever is longer), it is verified that the obstruction alarm is activated.
- **Disconnection Alarm:** A disconnection state is created by controlled detachment of the patient circuit or breathing line. If this situation continues for 5 seconds, the activation of the disconnection alarm is observed.
- **Low PEEP Alarms:** A low PEEP condition is created by forming a controlled leak in the breathing circuit or by leaving the circuit outlet open. If this condition continues for 5 consecutive respiratory cycles, it is verified that the relevant alarm is activated.
- **High PEEP Alarms:** A high PEEP condition is created by closing the end of the expiration hose. If this condition continues for 5 consecutive respiratory cycles, it is verified that the high PEEP alarm is activated.
- **Battery Alarms:** The device is disconnected from the external power source and operated with the internal battery. It is checked that the relevant battery alarm occurs when the battery level drops.
- **Power Failure Alarm:** It is verified that the alarm is activated when the power connection cable is removed and the mains supply is cut off.

WARNING

The patient must absolutely not be connected to the device during alarm tests. If any abnormality is detected in the alarm functions, the device must not be used, and an authorized service must be contacted.

TIME-LIMITED SILENCING OF ALARMS

Alarms can be temporarily silenced for two minutes by pressing the alarm button on the keypad. When the alarm sound is silenced, the alarm LED continues to flash, indicating that the alarm condition is still active. If the cause of the alarm is not eliminated within this period, the alarm will reactivate both audibly and visually after 2 minutes. Even if the alarm message has been cleared from the screen by pressing the alarm control button, if the alarm condition persists, it will be displayed again and give an audible warning at the end of the period.

RECORDING ALARMS

The device automatically records the last 25 alarms occurred. When a new alarm occurs, the oldest alarm record is deleted from the alarm history and the new alarm is recorded. If an SD card is inserted into the device, alarm records can also be saved to the SD card. There is no upper limit for the number of alarms recorded on the SD card.
Recorded alarms can be viewed with date and time information via the Alarm History menu.

CLEANING AND MAINTENANCE

1. OVERVIEW

This section describes the general principles for the cleaning, replacement, and maintenance of the VENTISENSE ventilator device and accessories provided by Nefes Medikal Teknoloji San. Tic. Ltd. Sti. In order to maintain the safe, effective, and long-lasting use of the device, cleaning and maintenance procedures must be performed in accordance with the specified intervals and methods.

For accessories and consumables belonging to other manufacturers used with VENTISENSE, the respective manufacturer's own instructions for use, cleaning, and replacement should be taken as a basis.

Nefes Medikal Teknoloji San. Tic. Ltd. Sti. is not responsible for problems arising from the improper use of third-party products or cleaning practices contrary to the instructions.
Improper or inadequate cleaning practices may:

- Adversely affect device performance,
- Shorten the service life of consumables,
- Risk patient safety.

2. CLEANING

Home Use

To clean the outer surfaces of the device, use a soft cloth moistened with the chemicals specified in the table below. After cleaning, the surfaces should be wiped with a cloth moistened with clean water to remove chemical residues. Ensure the device is completely dry before restarting. Do not allow liquids to enter the device.

Clinical / Physician Use

In clinical environments or cases where bacterial contamination is suspected, the outer surfaces of the device are wiped using a surface chemical suitable for the table below. After the cleaning process, the device must be completely dried before operation.

SURFACE CLEANING CHEMICALS
70% isopropyl alcohol (30% tap water)
15% Ammonia (85% tap water)
10% chlorinated bleach (90% tap water)
Hydrogen Peroxide
Dish soap
Hospital disinfectant cleaners
Ammonia-based household cleaners

3. CONSUMABLES AND REPLACEMENT INTERVALS

Product	Exchange Period
Inspiration Filter (Inlet Filter)	Every 2 months
Expiration Filter (Outlet Filter)	Every 2 months
Patient Circuit	Every 2 months
Bacteria Filter	Every 2 days
Humidifier Filter	Every 2 days
Catheter	1 per week
Mask	Every 6 months or according to manufacturer recommendations

NOTE

In case of excessive contamination, moisture, or damage, replacement must be performed immediately without waiting for the specified intervals.

3.1. PATIENT CIRCUIT

The patient circuit used with the device is designed for single-patient use. The hose circuit should not be cleaned, disinfected, or used on other patients. For the hose circuit used with the device, the use and replacement instructions provided by the hose circuit manufacturer must be followed. Hose systems that are not suitable for reuse must be disposed of in accordance with the applicable legislation.

⚠ CAUTION

Patient circuits that are excessively worn, damaged, or where leaks are detected must be immediately taken out of use and replaced with a new one.

3.2. REPLACING THE FILTERS

To maintain the correct and safe operation of the device, the inlet and outlet filters must be replaced at specified intervals or in case of contamination.

1. Replacing the Inlet (Inspiration) Filter

- Remove the inlet filter from the device by pushing it downwards from the protrusion located at the top of the filter.
- Install the new inlet filter by pressing it into its place on the device. Ensure that the tab on the filter snaps into its place on the device.

2. Replacing the Outlet (Expiration) Filter

- Remove the outlet filter from the device by pushing it downwards from the protrusion located at the top of the filter.
- Install the new outlet filter by pressing it into its place on the device. Ensure that the tab on the filter snaps into its place on the device.

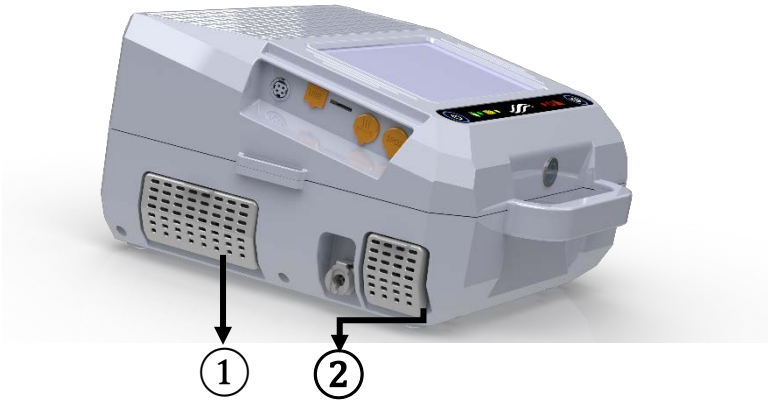


Figure 38 Replacing The Filters

⚠ CAUTION

Make sure that the filters are placed correctly. The device must not be operated without the filters installed.

4. ROUTINE CHECKS AND MAINTENANCE WORK

This section describes the routine checks and maintenance procedures that must be performed to maintain the safe operation of the device.

WARNING

Inspection or maintenance work must not be performed while the patient is connected to the ventilator. An alternative ventilation method must be provided to the patient during these procedures.

4.1. MAINTENANCE AND INSPECTION PERIODS

When is it necessary?	What should be done?	By whom?
Before delivery of each new device	Safety and function control	Distributor / Authorized Service
Monthly or earlier in case of heavy contamination	Cleaning / replacing the inlet and outlet filter	Distributor / Authorized Service
Every 6 months without a bacteria filter	Expiratory valve replacement	Distributor / Authorized Service
Every 12 months	Maintenance 1 (general check and tests)	Distributor / Authorized Service
Every 2 years	Maintenance 2 (detailed system check)	Distributor / Authorized Service
Every 20,000 fan operating hours or every 5 years	Maintenance 3 (fan and critical component check/replacement)	Distributor / Authorized Service

4.2. COUNTERS AND MAINTENANCE INDICATORS

The device uses internal counters to monitor the usage periods of critical components. These counters ensure that maintenance and part replacement requirements are detected in a timely manner.

On the **Counters** screen, for each component:

Total usage time,

Defined limit value,

Limit occupancy status is displayed with graphical indicator bars.

The color of the indicator bars changes from **green → yellow → red** depending on how close the usage time is to the limit.

Counter Name	Description	Limit Value	What to Do When the Limit Is Exceeded
Operation	Shows the total power on time of the device.	-	For informational purposes only.
Therapy	It shows the total time the device has been on active ventilation.	-	For informational purposes only.
Fan (Motor)	It shows the total operating time of the fan (motor).	20,000 hours	Engine control and replacement should be done if necessary by an authorized service
Filter	It shows the usage time of the inlet and outlet filters.	1,500 hours.	Filters must be replaced.
Patient Circuit	It shows the usage time of the patient circuit.	1,500 hours.	The patient circuit should be changed.
Battery	It shows the usage time of the internal battery.	15,000 hours	The battery must be replaced by an authorised service centre.
Service	It follows the periodic maintenance period of the device.	8,000 hours	The device should be directed to an authorized service center.

TECHNICIAL SPECIFICATIONS

The manufacturer reserves the right to make technical changes

Power Supply	
Mains Voltage	100-240 VAC 50-60 Hz – 24 VDC 120 W
DC Voltage	24 V DC / 5A
Internal Battery	Lithium ion battery, 92Wh
Electrical Protection	Class II, Type BF
Features and Performance	
Dimensions (W x D x H)	275 x 275 x 145 mm
Weight	2.8 kg
Max. Operating pressure	60 mbar
Min. Operating pressure	3 mbar
Max. Flow	200 l/min
Intended Tidal Volume Range	50-2000 mL
Sound Pressure Level	60.5 dBA (average), tested in accordance with ISO 80601-2-72
Sound Power Level	61.3 dBA (calculated)
Operating Conditions	
Temperature Range	0°C - 40°C
Humidity Range	15% to 95% (non-condensing)
Pressure Range	50 kPa to 106 kPa
Storage Conditions	
Temperature Range	-20°C - 45°C

Humidity Range	15% to 95% (non-condensing)
Pressure Range	50 kPa to 106 kPa

Measurement Values		
Parameters	**Measurement**	**Accuracy**
Pressure (P)	Adult: 3 – 60 mbar Pediatric: 3 – 40 mbar	± (3 mbar + (5% adjusted pressure))
Frequency (F)	Adult: 4 – 30 bpm Pediatric: 4 – 60 bpm	± 0,1 sec
I:E	1:10 – 10:1	-
Inspiration Volume (VI) Expiration Volume (VE)	Adult: 200 – 2000 ml Pediatric: 50 – 200 ml	Monitoring: ±(4+(15% adjusted volume)) Target: ±(5 ml + 10 % of the set volume).
Minute Volume (MV)	0 – 25 L	-
FiO_2	%0 - %100	±%1,5

Internal Battery Life Cycle

The maximum life cycle of the internal battery is indicated below.

Operation mode	**VCV**	**VCV**
Tidal Volume	450 ml	200 ml
Frequency	12	20
Inspiration Time	1 sn	1 sn
PEEP	6	6
Linear Resistance Ra(17)(18) (19)	20 mbar $(l/s)^{-1}$ %10	5 mbar $(l/s)^{-1}$ %10
Isothermal Compliance, Ca	20 ml $(mbar)^{-1}$ %5	20 ml $(mbar)^{-1}$ %5
Operating Time	7 hours 30 min.	9 hours

AFFECTED PARAMETERS

This section summarizes the functional relationships between ventilator setting parameters. Changes made to one parameter may affect the effective values or operating limits of other parameters. Therefore, it is recommended that related parameters be evaluated together when making adjustments.

The table below shows the parameters that are directly related to each parameter and can be affected by setting changes.

PARAMETERS	AFFECTED PARAMETERS
FREQUENCY	INSPIRATION TIME
	I/E
INSPIRATION TIME	TRIGGER LOCK
	FREQUENCY
MAX. PRESSURE	MIN. PRESSURE
	PEEP
MIN. PRESSURE	MAX. PRESSURE
	PEEP
PRESSURE SUPPORT (PS)	IPAP
	PEEP

FLOW RESISTANCE AND COMPLIANCE PERFORMANCE REQUIREMENTS OF BREATHING CIRCUITS

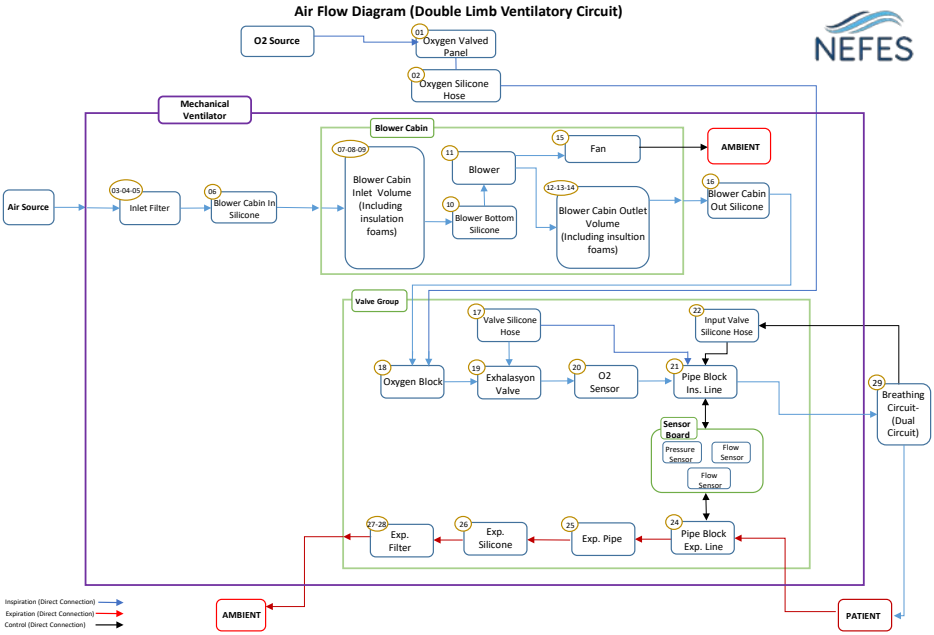
Patient Category	Volume Range	Flow Resistance (breathing circuit set) hPa/l/min (cmH2O/l/min)	Flow Resıstance (per meter) hPa/l/min/m (cmH2O/l/min/m
Adult	200 ml – 2000 ml	0,06	0,03
Pediatric	50 ml – 200 ml	0,12	0,06

TABLE 1: Gas Path Resistance of Breathing Circuits

Patient Category	Volume Range	Compliance Limit (Breathing Circuit Sets) Ml/Hpa (Ml/Cmh2o)	Compliance Limit (Per Unit Meter) Ml/Hpa/M (Ml/Cmh2o/M)	Test Pressure Hpa (Cmh2o)
Adult	200 ml – 2000 ml	5	0,8	60 ± 3
Pediatric	50 ml – 200 ml	4	0,7	60 ± 3

TABLE 2: Compliance of Respiratory Circuits

PNEUMATIC DIAGRAM



COMPLIANCE WITH STANDARDS

The VENTISENSE ventilator device has been designed, developed, and validated in accordance with the harmonized standards listed below.

EN ISO 13485:2016 / A11:2021: Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 14971:2019 / A11:2021: Medical devices – Application of risk management to medical devices

EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN ISO 20417:2021: Medical devices – Information to be supplied by the manufacturer

EN 62366-1:2015 / A1:2020: Medical devices - Part 1: Application of usability engineering to medical devices

EN 60601-1:2006 / AC:2022-12: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015 / A1:2021: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

EN 60601-1-6:2010 / A2:2021: Medical electrical equipment - Part 1-6: General requirements for basic safety andessential performance - Collateral standard: Usability

EN 60601-1-8: 2007/A2:2021: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

EN 60601-1-11: 2015/A1:2021: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

EN ISO 80601-2-72: 2023: Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

EN 62304:2006 / A1:2015: Medical device software – Software life cycle processes

EN 18562-1:2020: Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

EN 18562-2:2020: Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

EN 18562-3:2020: Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)

ELECTROMAGNETIC COMPATIBILITY (EMC)

The electromagnetic compatibility tests and results of VENTISENSE according to the EN 60601-1-2:2016/A1:2021 standard are given in the table below. Users must ensure that the device is used in an environment suitable for the table.

Compliance Checks	IEC 60601 Control Level	Eligibility Level	Electromagnetic Environment Guide
Electrostatic discharge (ESD) according to IEC 61000-4-2 directive	± 8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The floor should be wooden, concrete or ceramic. For synthetic floors, the relative humidity should be at least 30%.
Radiated RF regime according to IEC 61000-4-3 directive	Field strength: 3 V/m Frequency range: 80 MHz - 2.7 GHz Modulation: 80% AM (1 kHz)	80 Mhz - 2700MHz, 3V/m)	For 80 MHz – 800 MHz: d = 1.7 √P For 800 MHz – 2.7 GHz: d = 3.25 √P
Electrical fast transient regimes / burst according to IEC 61000-4-4 directive (EFT/Burst)	Power lines: ±2 kV Input/output lines: ±1 kV Pulse frequency: 100 kHz Application time: ≥ 60 s	Power lines: ±2 kV Input/output lines: ±1 kV	The quality of the supply voltage should be equivalent to a typical commercial or hospital setting.
According to IEC 61000-4-5 directive overvoltage / Surge	Test voltage: 0.5 kV, 1 kV, 2 kV Impact characteristic: 1.2/50 µs (voltage) Phase angle: 0°, 90°, 180°, 270° Repetition time: 60 s	L–N: 0.5 kV-1 kV L–PE: 0.5 kV-1-2 kV N–PE: 0.5 kV-1-2 kV	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
RF regime transmitted according to IEC 61000-4-6 directive	Voltage level: 3 Vrms Frequency range: 150 kHz-80 MHz Frequency step: 1% Standby time: 2 s Modulation: 80% AM (1 kHz)	Power ports: 3 Vrms, 0.15 – 80 MHz ISM and amateur radio bands: 6 Vrms, 0.15 – 80 MHz 80% AM (1 kHz)	Portable and mobile RF communication equipment should be kept away from the device.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8 directive	Field strength: 30 A/m Test frequency: 50 Hz Observation time: 60 s	30 A/m, 50 Hz	Power frequency magnetic fields should be at the levels expected in a typical commercial or hospital setting.
According to IEC 61000-4-11 directive, voltage drops, short interruptions and voltage fluctuations at supply inputs	Phase angle: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° Standby interval: ≥ 10 s Test cycle: 3	0 % UT; 0.5 period 0 % UT; 1 period 70 % UT; 25 periods 0 % UT; 250 periods	The supply voltage quality should be equivalent to a typical commercial or hospital setting. It is recommended to use an external backup power source or battery for uninterrupted operation.

EMISSION TEST (EMISSION EXPERIMENTS)

The VENTISENSE device has been tested for electromagnetic emissions according to the **EN 60601-1-2:2014 + A1:2021** standard and found to be compliant.

Emission Test	Standard	Compliance Level	Electromagnetic Environment Guide
RF Emissions	CISPR 11	Group 1, Class B	The device uses RF energy only for its internal functions. Therefore, RF emissions are low and are not expected to cause interference in nearby electronic equipment.
Harmonic Current Emissions	IEC 61000-3-2:2019	Class A	The device is suitable for use in all establishments, including domestic establishments, directly connected to the low-voltage power supply network.
Voltage Fluctuations / Flicker Emissions	IEC 61000-3-3:2013 + A1:2019	Compliant	The device does not cause voltage fluctuations in the low-voltage power supply network.

DISPOSAL

Proper disposal contributes to the protection of natural resources and prevents harmful substances from reaching the environment.

DEVICE

The device should not be disposed of with household waste. Contact authorized customer service for proper disposal.

BATTERY

Replaced batteries must be recycled according to the law on batteries. Contact authorized customer service for proper disposal.

PACKAGING

The packaging is taken back by the sales partner. But it can also be disposed of with normal household waste.

HOSE SYSTEM

The hose system should not be disposed of with household waste. Contact authorized customer service for proper disposal.

FILTERS

The Filters should not be disposed of with household waste. Contact authorized customer service for proper disposal.

LEGAL NOTICE

NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. STİ; cannot be held responsible for direct or indirect effects that may occur on the safety, reliability, and performance of the product in the following cases:

- Intervention, modification, improvement, adjustment, repair, or maintenance operations on the product performed by persons **other than authorized and trained personnel**,
- The use of **third-party accessories, consumables, or spare parts** whose use with the product has not been approved by the manufacturer,
- The use of the product **outside of the purpose, manner of use, and instructions** specified in the user manual,
- Failure to comply with the **hygiene, cleaning, and maintenance instructions** specified in the user manual.

In such cases, the safe operation and performance of the product cannot be guaranteed. This legal notice does not affect the legal warranty rights of users under the applicable legislation.

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