TF.01.125 | Rev: 00

2026

VENTISENSE

MECHANICAL VENTILATOR

Technical Reference Manual

Ventisense 40 | Ventisense 60 | Ventisense PRO

A. Gökhan Gültekin

Nefes Medikal Teknoloji

TABLE OF CONTENTS

1. INTRODUCTION

1.1 What Is Mechanical Ventilation?

Mechanical ventilation is the process of artificially supporting or fully replacing alveolar gas exchange by applying positive pressure to the airway through a device when the lungs are unable to maintain adequate respiratory function. The respiratory system has two primary functions: oxygen (O_2) delivery and carbon dioxide (CO_2) elimination. Failure of either or both of these functions—regardless of the underlying cause—results in life-threatening respiratory failure.

From a physiological perspective, respiratory failure is classified into two main types. Type 1 (hypoxemic) respiratory failure is characterized by insufficient oxygenation, defined as PaO_2 <60 mmHg; ventilation/perfusion (V/Q) mismatch, intrapulmonary shunt, diffusion impairment, and alveolar hypoventilation are the primary pathological mechanisms involved. Type 2 (hypercapnic / ventilatory) respiratory failure is defined by $PaCO_2$ >45 mmHg and results from inadequate alveolar minute ventilation; respiratory muscle weakness, suppression of central respiratory drive, or air trapping associated with obstructive lung diseases are among the most common causes. [2, 3]

The primary goals of mechanical ventilation may be summarized as follows: providing and maintaining adequate alveolar ventilation, preserving arterial oxygenation, reducing the workload of respiratory muscles, allowing time for recovery of the underlying pathology, and minimizing ventilator-induced lung injury (VILI). [1, 3] To achieve these goals, the selected ventilation mode, pressure/volume parameters, and alarm limits must be carefully configured according to each patient's individual clinical profile.

1.2 Home Mechanical Ventilation

Home Mechanical Ventilation (HMV) is an established treatment strategy that enables patients with chronic respiratory failure to receive mechanical ventilatory support outside the hospital environment, within their own homes. Historically, HMV began during the poliomyelitis epidemics of the 1950s with negative-pressure "iron lung" devices, evolved into invasive positive-pressure ventilation via tracheostomy during the 1980s, and subsequently transitioned toward mask-based noninvasive ventilation (NIV) beginning in the 1990s. Today, NIV has become the predominant form of HMV.

The Eurovent study [4] reported the prevalence of HMV in Europe as 6.6 per 100,000 population; however, this rate has increased substantially over subsequent years due to technological advancements, increased awareness, and expanding clinical indications. Current evidence demonstrates that HMV improves quality of life, reduces hospital admission rates, and positively affects survival in many patient populations—particularly those with neuromuscular disorders—when appropriate patient selection criteria are applied. [5, 14]

The principal determinants of successful HMV include: appropriate patient and indication selection, optimal device and ventilation mode configuration, comprehensive training for patients and caregivers, regular clinical follow-up with blood gas and sleep monitoring, and effective caregiver burden management. HMV is a high-risk therapy that requires medical prescription and specialist supervision; inappropriate use may result in both medical and legal consequences.

i NOTE

VENTISENSE is a home-use mechanical ventilator designed in accordance with ISO 80601-2-72 and certified as a Class IIb medical device under MDR (EU) 2017/745.

The device requires physician prescription, adequate patient/caregiver training, and regular clinical follow-up.

Figure 1 — VENTISENSE Mechanical Ventilator

1.3 Intended Use

VENTISENSE is designed to artificially support or maintain respiratory function in patients whose lungs are unable to perform vital respiratory functions for any reason. The device is intended for pediatric and adult patients weighing more than 5 kg and requiring tidal volumes of at least 50 mL, and is designed specifically for home healthcare applications.

Ventilation may be delivered invasively (tracheostomy or endotracheal tube) or noninvasively (ventilation mask; HFNC in HFO mode). The device is capable of providing continuous or intermittent ventilatory support and is suitable for both ventilator-dependent (life-support-dependent) and non-dependent patients.

1.4 Indications for Use

VENTISENSE is indicated for the treatment and management of the following clinical conditions. The clinical context and role of mechanical ventilation for each indication are described below.

Acute and Chronic Respiratory Failure

Respiratory failure represents the broadest and most fundamental indication for mechanical ventilation. In acute conditions (e.g., ARDS, severe pneumonia, sepsis-related acute respiratory failure), ventilation serves as a life-saving emergency intervention. In chronic conditions—particularly neuromuscular diseases, COPD, and obesity hypoventilation syndrome—mechanical ventilation is used as a long-term supportive strategy; it corrects alveolar hypoventilation, relieves respiratory muscle workload, and reverses hypercapnia. In home settings, nocturnal ventilation is generally preferred initially; as disease progresses, support may be extended to 24-hour ventilation.

Chronic Obstructive Pulmonary Disease (COPD)

COPD is characterized by chronic airflow limitation, air trapping (auto-PEEP), and mechanical disadvantage of the respiratory muscles. In advanced COPD, respiratory muscles become insufficient against hyperinflated lungs, resulting in hypercapnic chronic respiratory failure due to load-capacity imbalance. Noninvasive ventilation (particularly BiLEVEL) is strongly recommended in ATS/ERS guidelines because it reduces intubation rates and shortens hospital stay during COPD exacerbations. Long-term home NIV may also positively affect survival in chronic hypercapnic COPD patients ($PaCO_2$ >45 mmHg).

Asthma

In respiratory failure developing after severe asthma attacks or acute exacerbations, noninvasive mechanical ventilation may provide supportive care during the post-intensive-care recovery phase prior to discharge or in the home environment. Air trapping caused by bronchospasm-related increased airway resistance predisposes asthma patients to auto-PEEP development; therefore, selecting ventilation modes with low respiratory rates and prolonged expiratory times is critically important.

Cystic Fibrosis (CF)

Cystic fibrosis causes thick mucus accumulation within the lungs and airway obstruction, eventually leading to ventilation-perfusion mismatch and hypercapnic respiratory failure. Noninvasive mechanical ventilation reduces respiratory muscle workload, supports secretion mobilization, and improves exercise tolerance in CF patients. It may also be used as bridge therapy while awaiting lung transplantation. High-flow oxygen therapy (HFO) may additionally provide supplemental oxygen support in CF patients.

Restrictive Lung Disease

Restrictive disorders—including interstitial lung diseases, kyphoscoliosis, thoracoplasty, and pleural diseases—mechanically limit lung expansion and progressively increase the workload on respiratory muscles. Particularly in chest wall deformities, nocturnal noninvasive ventilation significantly improves sleep quality, relieves morning headaches and daytime somnolence, and contributes to normalization of daytime $PaCO_2$ levels.

Obesity-Related Hypoventilation

Obesity hypoventilation syndrome (OHS) is defined as daytime hypercapnia ($PaCO_2$ >45 mmHg) and hypoventilation in patients with BMI >30 kg/m². In severe OHS cases where CPAP alone is insufficient, BiLEVEL therapy is preferred. Clinical studies demonstrate that noninvasive ventilation significantly reduces nocturnal CO_2 retention, relieves daytime somnolence, and improves PaO_2 in OHS patients. [11, 32] Long-term management should be combined with bariatric intervention or lifestyle modification whenever appropriate.

Neuromuscular Disorders

Neuromuscular disorders represent one of the patient populations with the strongest evidence base for mechanical ventilation. Conditions including ALS (Amyotrophic Lateral Sclerosis), Duchenne Muscular Dystrophy (DMD), Spinal Muscular Atrophy (SMA), myasthenia gravis, and phrenic nerve paralysis progressively weaken the respiratory muscles. Nocturnal hypoventilation typically develops initially, while advanced disease stages may require continuous invasive ventilation via tracheostomy. The combination of noninvasive ventilation and cough-assist devices has significantly reduced tracheostomy requirements and prolonged survival in diseases such as Duchenne muscular dystrophy and SMA. [12, 13, 34] In this patient population, HMV reduces hospital admission rates, improves quality of life, and helps maintain caregiver burden at manageable levels.

Airway Inflammation

Airway inflammation associated with asthma, chronic bronchitis, and allergic reactions increases airway resistance, elevates the work of breathing, and reduces exercise tolerance. During acute episodes, noninvasive mechanical ventilation supports respiratory muscles, while intermittent ventilatory support during recovery helps restore the functional reserve of the overloaded respiratory system.

Postoperative Respiratory Support

Patients with pre-existing pulmonary impairment (e.g., COPD, chronic respiratory failure, obesity) are at significantly increased risk of postoperative respiratory failure following major surgical procedures. In the postoperative period, prophylactic noninvasive ventilation—particularly BiLEVEL or CPAP—reduces atelectasis formation, improves oxygenation, and lowers the risk of reintubation. Short-term CPAP is also supported by strong clinical evidence in cases of pulmonary edema following cardiothoracic surgery.

1.5 Contraindications

VENTISENSE is contraindicated under the following conditions. The clinical rationale and explanation for each contraindication are provided below.

⚠ WARNING

The presence of contraindications may significantly increase clinical risk.
In cases of uncertainty, the responsible physician must be consulted before using the device.

Neonates (Patients Weighing Less Than 5 kg)

VENTISENSE is not intended for neonatal patients weighing less than 5 kg. The device has a minimum technical tidal volume limit of 50 mL, corresponding to approximately 10 mL/kg for a 5 kg infant—equivalent

to the upper safety threshold defined in international pediatric ventilation guidelines (PALICC, PEMVECC). Due to the highly sensitive and variable respiratory mechanics of neonates, the proportionally greater losses associated with circuit compliance, and the requirement for specialized neonatal ventilation protocols, this patient population falls outside the intended scope of VENTISENSE.

Magnetic Resonance (MR) Environment

VENTISENSE is not classified as MR Safe and must not be brought into MRI environments. Strong magnetic fields may attract ferromagnetic components, resulting in uncontrolled device movement, damage to electronic systems, or sudden ventilator failure. In addition, the device may interfere with MRI image quality. When MRI is required, the patient must be transitioned to an MR-compatible backup ventilation system prior to examination, and VENTISENSE must remain outside the MRI suite.

Hazardous Gases (Flammable, Anesthetic, Nitric Oxide, Helium)

In environments containing flammable or explosive anesthetic gas mixtures (e.g., halothane, enflurane), the device's electrical system may act as an ignition source, creating fire or explosion hazards. Nitric oxide (NO) may cause permanent damage to sensor hardware and lead to measurement inaccuracies. Helium or helium-containing gas mixtures may disrupt the device's flow and volume measurement algorithms due to their low density, potentially resulting in inaccurate tidal volume delivery and unsafe ventilation parameters. None of these substances may be used with VENTISENSE.

Hyperbaric Oxygen Therapy Chambers

Environmental pressure within hyperbaric chambers is significantly elevated (typically 2–3 atmospheres). This high-pressure environment adversely affects the accuracy of VENTISENSE pressure and flow sensors, which are calibrated for standard atmospheric conditions. Sensor inaccuracies may result in incorrect tidal volume delivery and pressure transmission, potentially leading to life-threatening uncontrolled ventilation. In hyperbaric therapy settings, only ventilators specifically certified for pressurized environments should be used.

Untreated Pneumothorax or Pneumomediastinum

Pneumothorax refers to the accumulation of free air within the pleural space. Applying positive-pressure mechanical ventilation in untreated pneumothorax may rapidly increase pleural air accumulation and lead to tension pneumothorax—a medical emergency associated with risk of cardiac arrest. A similar mechanism may increase mediastinal pressure in pneumomediastinum. These conditions must first be treated appropriately (e.g., tube thoracostomy), after which mechanical ventilation may be reconsidered cautiously under clinician supervision once stabilization is achieved.

Severe Hypotension

Positive-pressure mechanical ventilation increases intrathoracic pressure and reduces venous return; this effect may further compromise already impaired cardiac filling pressures. In hypovolemic shock and severe hypotension—particularly when associated with intravascular volume depletion—positive-pressure ventilation may dangerously reduce cardiac output. Severe hypotension must first be stabilized with appropriate fluid resuscitation and vasopressor therapy before ventilation is initiated with caution.

Cerebrospinal Fluid Leak, Recent Head Trauma, or Pneumocephalus

In the presence of skull base fractures, cranial surgery, or nasopharyngeal fistulas, noninvasive positive-pressure ventilation delivered via mask may force air through cranial defects into the intracranial cavity. This may result in dangerously elevated intracranial pressure (ICP), pneumocephalus, and permanent central nervous system injury. This contraindication primarily applies to mask-based NIV; when ventilation is required, invasive airway access (e.g., tracheostomy) should be considered in collaboration with neurology and intensive care specialists.

Severe Bullous Lung Disease

Bullous emphysema is characterized by large, thin-walled air spaces (bullae) within the lungs. Positive-pressure ventilation may preferentially overdistend these weakened regions instead of uniformly expanding healthy lung tissue. Bullae rupture may lead to massive pneumothorax and rapidly developing tension pneumothorax. If ventilation is unavoidable in such patients, the lowest feasible tidal volume and airway pressure should be used, and close patient monitoring is mandatory.

Inability to Protect the Airway or Loss of Swallow Reflex

In patients with impaired or absent swallowing reflexes, mask-based noninvasive ventilation significantly increases the risk of aspiration of gastric contents into the lungs. Aspiration pneumonia and pneumonitis are serious complications associated with mechanical ventilation. In these patients, invasive airway management should be preferred; tracheostomy or endotracheal intubation provides a sealed airway and helps prevent aspiration.

Facial Deformities Preventing Proper Mask Fit

The effectiveness of mask-based noninvasive ventilation depends on achieving an adequate seal between the patient's face and the mask. Severe facial trauma, congenital facial deformities, extensive surgical defects, or severe burns may prevent proper mask fitting, resulting in excessive leakage, inability to deliver target tidal volume and pressure support, false alarms, and unsafe ventilation. In such cases, invasive ventilation via tracheostomy should be considered.

1.6 Intended Users

User	Interface	Authorization
Physician, Nurse, Authorized Healthcare Personnel	Clinician Interface (password protected)	Ventilation mode, parameter, and alarm configuration
Patient, Family Member, Caregiver	Home Interface	Basic operation (following comprehensive training)

2. PRODUCT INFORMATION AND TECHNICAL SPECS

2.1 Models and Comparison

VENTISENSE is available in three different models. Although all models share the same fundamental operating principle, they differ in terms of supported patient population and ventilation parameter ranges.

Feature	Ventisense 40	Ventisense 60	Ventisense PRO
Target Patient Population	Pediatric	Adult	Adult + Pediatric
Respiratory Rate	4–60 bpm	4–30 bpm	4–60 bpm
Pressure Range	3–40 mbar	3–60 mbar	3–60 mbar
Tidal Volume	50–200 ml	200–2000 ml	50–2000 ml

Figure 2 — Ventisense

2.2 Technical Specifications

2.2.1 Physical and Mechanical Specifications

Parameter	Value
Dimensions (W × L × H)	275 × 275 × 145 mm
Weight	2,8 kg
Sound Pressure Level	60,5 dB(A) ort. (ISO 80601-2-72)
Sound Power Level	61,3 dB(A)
Gas Outlet Port	22 mm OD (male conical, ISO 5356-1)
Protection Class IP22	IP22
Housing Material	Flame retardant ABS/PC plastic (UL94-V0)
Display	7″ Color TFT-LCD Capacitive Touchscreen

2.2.2 Electrical Properties

Parameter	Value
Mains Voltage	100–240 VAC, 50/60 Hz
DC Voltage	24 V DC / 5 A
Power Consumption	120 W
Internal Battery	18.5 V, 5000 mAh, 92 Wh Li-Ion
Battery Operating Time	~8 hours
Electrical Safety	Class II, BF Type Applied Part

2.2.3 Pneumatic Performance

Parameter	Value / Range
Maximum Operating Pressure	60 hPa (mbar)
Minimum Operating Pressure	3 hPa (mbar)
Maximum Flow	200 L/min
Triggering	Flow triggered
Pressure Accuracy	±(3.0 + 5% × set pressure) hPa
Volume Accuracy	±(4.0 + 15% × set volume) ml
High Pressure Alarm Time	≤ 200 ms

2.2.4 Measurement Ranges and Accuracy

Parameter	Patient Group	Adjustment Range	Accuracy
Pressure (P)	Adult	3–60 mbar	±(3,0 + %5 × target)
Pressure (P)	Pediatric	3–40 mbar	±(3,0 + %5 × target)
Frequency (F)	Adult	4–30 bpm	±0,1 sn
Frequency (F)	Pediatric	4–60 bpm	±0,1 sn
Insp. Volume (VI)	Adult	200–2000 ml	±(5 + %10 × target)
Insp. Volume (VI)	Pediatric	50–200 ml	±(5 + %10 × target)
Minute Volume (MV)	Adult /Ped.	0–25 L	—
FiO_2	Adult /Ped.	0–%100	±%1,5

2.2.5 Environmental Conditions

Condition	Operation	Storage / Transportation
Temperature	0°C – +40°C	-20°C – +45°C
Humidity	%15–95 (non-condensing)	%15–95 (non-condensing)
Atmospheric pressure	50–106 kPa	50–106 kPa
Altitude	0–3000 m	—

2.2.6 Expected Service Life

The expected service life of the device is 20,000 operating hours. This value is based on the life specification of the critical pneumatic component, the motor/turbine, and has been verified through real-time performance testing. Periodic maintenance is mandatory to ensure continued safe operation.

2.3 Conformity and Certification

Standard / Regulation	Scope
EN ISO 80601-2-72:2023	Basic requirements for home ventilators
IEC 60601-1 / EN 60601-1-2	Electrical safety and EMC
IEC 60601-1-8	Alarm systems
IEC 60601-1-6 / IEC 62366	Usability engineering
EN ISO 60601-1-11	Suitability for home healthcare services
EN ISO 18562-1/2/3	Respiratory gas biocompatibility
IEC 62304	Medical device software lifecycle
MDR (EU) 2017/745	EU Medical Device Regulation — Class IIb
ISO 13485	Medical Devices Quality Management System

i NOTE

VENTISENSE is one of the world's first and only CE-marked household mechanical ventilators certified under MDR (EU) 2017/745. NB No: 2696 — UDEM Adriatic d.o.o. (Zagreb, Croatia)

3. PHYSICAL COMPONENTS AND CONNECTIONS

3.1 Connection Ports

All external connections of the VENTISENSE device are located on the right and left side panels.

3.1.1 Right Panel Connections

Figure 3 — Right Panel Connections

Port	Definition
Expiration Hose Connector	The exhalation valve is connected to this inlet; the expiration hose of the double-legged circuit is connected to the exhalation valve.
Exhalation Valve Control Hose Inlet	The control hose of the exhalation valve is attached to this inlet.
Inspiration Hose Connector	The inspiration hose of the dual-legged circuit is connected to this outlet.
Oxygen Inlet Port	An external oxygen supply is connected via this port (Max. 60 L/min, 1 bar).

3.1.2 Left Panel Connections

Figure 4 — Left Panel Connections

Port	Definition
DC Power Input	The power supply (adapter) is connected to this input.
USB (Interface)	USB interface port for PC connection.
SD Card	SD card slot for saving therapy data.
Unused Ports	These ports are out of service; connections should not be made.

3.2 Control Elements

Element	Location	Function
On/Off Switch	Front panel	Turns the device on/off
Engine Start/Stop	Front panel	Starts/stops ventilation (press and hold for 3 seconds to stop)
7″ Touchscreen	Front panel	Full parameter setting and monitoring interface
LED Status Indicators	Front panel	Alarm and operating status visual notification.

3.3 Installation Options

Figure 5 — Mounting Points

VENTISENSE can be mounted to sheet metal with 4 M5 bolts thanks to the nuts embedded in the body. It can be secured to posts or legs by tightening it with the help of the tabs on the body and a strap.

VENTISENSE can be used with special mounting support for wheelchair users. The device is mounted to the rear bag of the wheelchair, to a holder compatible with the side panel, or to a carrier fixed to the chair frame, preserving the patient's mobility and daily living activities. During installation, care should be taken to ensure that the air inlet and outlet openings are not obstructed, the hoses are not kinked, and the connections are not loosened by patient movement.

Figure 6 — Wheelchair Mounting (rear)

Figure 7 — Wheelchair Mounting

⚠ During wheelchair assembly, the air intake and exhaust vents of the device must not be blocked.
⚠ Patient circuit hoses should be routed so that they do not come into contact with chair moving parts.

4. INSTALLATION AND CONNECTION

4.1 Power Connection and Turning On the Device

Figure 8 — Power Connection

The adapter's power input is plugged into the power port on the left panel with the arrows pointing downwards. The device is switched on by pressing the On/Off button on the front panel. During startup, the sensors, valves, and alarm equipment are checked with an automatic power-on self-test.

4.2 Accessing the Physician Menu

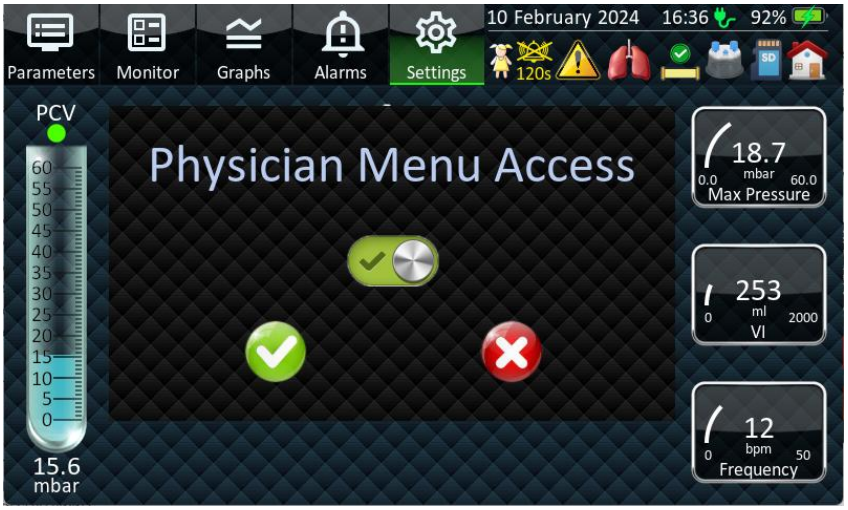


Figure 9 — Accessing the Physician Menu

To adjust modes and parameters, the Physician Menu must be activated. While the device is operating in Home mode, follow these steps:

- Go to Settings → General → Access to the Physician Menu.
- Physician Mode is activated by entering the password 2904.
- The icons on the top panel of the device indicate the active mode (Home icon / Red Plus).

NOTE

The Physician's Menu password is given to authorized personnel upon product delivery. Unauthorized modification of parameters can jeopardize patient safety.

4.3 Mode and Parameter Adjustment

Figure 10 — Parameter Adjustment Screen

The modes and parameters determined by the physician are adjusted and then activated by selecting one of the Setting 1, Setting 2, or Setting 3 screens from the Parameters page. The ability to define three independent setting profiles allows the clinician to be prepared for different clinical scenarios in advance.

4.4 Exhalation Valve Connection

Figure 11 — Exhalation Valve Connection

- The exhalation valve is placed on the exhalation inlet of the device — with the arrow pointing towards the device.
- The valve tubing is attached to the valve inlet between the inspiration and expiration ports.

4.5 Bacterial Filter and Patient Circuit Connection

Figure 12 — Bacterial Filter and Patient Circuit

- A bacterial filter is installed in the inspiration port.
- The patient circuit tubing is connected sequentially: to the exhalation line via the exhalation valve, and to the inspiration line via the bacterial filter.

⚠ WARNING

When using an external humidifier, do not operate the device without installing bacterial filters in the inspiration and expiration ports.

Standard connection sequence: Device Inspiration Port → Bacterial/Viral Filter → Inspiration Line → Humidifier → Y-Piece → Exhaust Line → Bacterial/Viral Filter → Exhaust Valve → Device Exhaust Port

4.6 HMEF — Humidifier Filter Connection

Figure 13a — HMEF Connector

Figure 13b — Catheter Connection

- An HMEF (humidifying filter) is placed at the end of the patient circuit.
- A catheter is attached to the end of the HMEF filter to establish a connection with the patient.

4.7 Use with External Humidifier

If deemed necessary by the doctor, the device can be used with an external humidifier. The use of an external humidifier should be carried out according to the parameters determined by the attending physician and the humidifier's user manual.

Connection Steps

- Install a bacterial/viral filter in the inspiration port and in front of the exhalation valve in the expiration port.
- Connect the inspiration hose to the outlet of the bacterial filter attached to the inspiration port.
- Connect the other end of the inspiration hose to the gas inlet port of the external humidifier.
- Attach one end of the hose, which will connect to the humidifier's gas outlet port, to the humidifier.
- Connect the other end of this hose to the Y-piece (patient connector).
- Connect the expiration hose coming from the Y-piece to the expiration port.
- Adjust the external humidifier setting to the level determined by your doctor.
- Check that all connections are correctly, leak-proof, and securely installed.

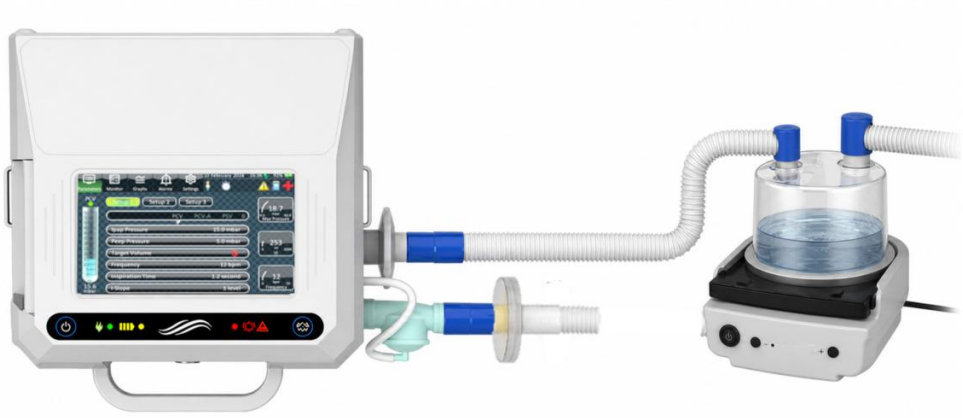


Figure 14 — External Humidifier Connection

⚠ WARNING

When using an external humidifier, be sure to install bacterial/viral filters on both the inspiration and expiration ports of the device.

Standard connection sequence: Device Inspiration Port → Bacterial/Viral Filter → Inspiration Line → External Humidifier → Y-Piece → Exhaust Line → Bacterial/Viral Filter → Exhaust Valve →

Device Exhaust Port.
When using an external humidifier, do not use an HMEF filter at the patient port or within the circuit; this combination can lead to excessive circuit resistance.
Ensure the external humidifier is positioned on a flat, stable surface, lower than the device and the patient.
During use, regularly check the bacterial filters and exhalation valve for moisture accumulation; clogged filters increase respiratory resistance.

4.8 Use with a Nebulizer

If deemed necessary by the doctor, the device can be used with a nebulizer. Nebulizer use should be carried out according to the medication dosage and administration duration determined by the physician, and in accordance with the nebulizer manufacturer's instructions.

Connection Steps

- Install a bacterial/viral filter in the inspiration port and in front of the exhalation valve in the expiration port.
- Connect the inspiration hose to the outlet of the bacterial filter attached to the inspiration port.
- Connect the other end of the inspiration tube to the nebulizer's inlet port.
- Connect one end of the tubing to be used for patient connection to the nebulizer's output port.
- Connect the other end of this hose to the Y-piece (patient connector).
- Connect the expiration hose coming from the Y-piece to the expiration port.
- Check that all connections are correctly, leak-proof, and securely installed.

Figure 15 — Nebulizer Connection

⚠ WARNING

Use the nebulizer only while the ventilator is actively operating. If the ventilator is stopped, nebulizer use must also be stopped immediately.
Do not use an HMEF filter at the patient connection point or in the circuit when using a nebulizer; drug particles can quickly clog the filter.
During nebulizer use, regularly check the bacterial filters and exhalation valve for moisture or medication residue.
The use of a pneumatic nebulizer may affect the accuracy of the ventilator's flow and volume measurements; closely monitor the patient and readjust parameters if necessary.
During nebulization or humidification, circuit filters and the exhalation valve can quickly become clogged due to moisture and/or drug residue. HMEF and bacterial/viral filters are single-use; they should be replaced at least every 24–48 hours or as directed by the manufacturer.

4.9 Oxygen Connection

Figure 16 — Oxygen Connection

- The oxygen port inside the bag is attached to the end of the hose coming from the oxygen source.
- This port connects to the oxygen inlet on the right panel of the device.

⚠ WARNING

The oxygen flow rate to be applied to the device should not exceed 60 L/min and the pressure should not exceed 1 bar.

Oxygen use significantly increases the risk of fire. Do not allow any ignition source near the device.

4.10 Starting and Stopping Therapy

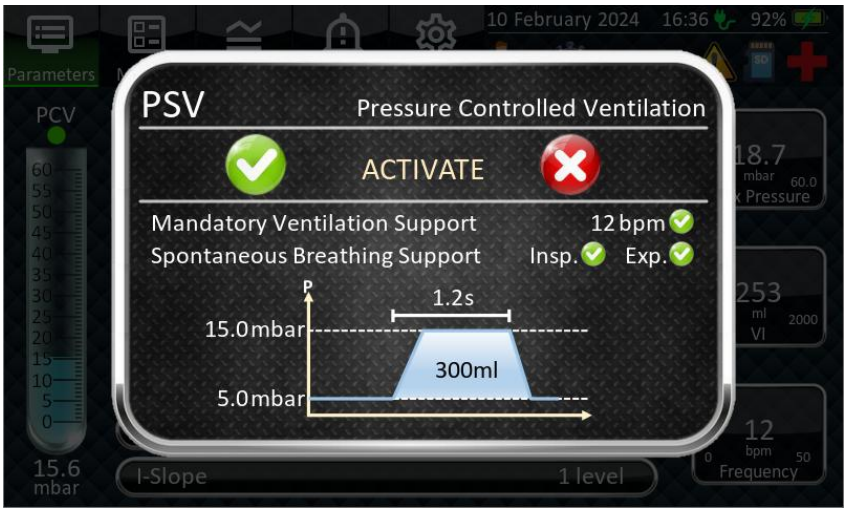


Figure 17 — Initiating/Stopping Therapy

After all connections are completed:

- The motor start/stop button is pressed.
- The confirmation screen opens; the configured mode and parameter information are checked one last time.
- Ventilation is started by pressing the confirmation button.
- In volume-targeted modes, compliance is calculated after the first breath; the device applies the closest volume value on the second breath.
- To end the therapy, the motor is stopped by pressing and holding the motor start/stop button for 3 seconds.

4.11 Top Panel Icons

The top panel of the VENTISENSE display features a series of icons indicating the device's current status. These icons provide real-time visual information about patient type, operating mode, power supply, trigger type, and active features. All icons and their meanings are explained individually below.

PATIENT TYPE ICONS — Indicate the age group of the active patient.		
	**Newborn / Infant Pediatric**	This device is not suitable for newborns or premature patients. However, when the tidal volume is measured below 30 ml in pediatric mode, this icon is displayed to indicate this.
	**Pediatric Patient**	The device operates with a pediatric patient profile. Pediatric mode is active; the parameter ranges are suitable for child patients.
	**Adult Patient**	The device operates with an adult patient profile. Pediatric mode is disabled; only full adult parameter ranges apply.
WORKING INTERFACE ICONS — Indicate the user interface level.		
	**Home Mode**	The device is in the patient/caregiver interface. In this mode, parameter and alarm settings cannot be changed; only basic operations (start/stop, brightness, volume) can be performed.
	**Physician Mode**	Physician Mode is active. Accessed via password, this mode allows you to change the ventilation mode, all parameters, and alarm limits. It is for authorized healthcare personnel only.
TRIGGER-TYPE ICONS — Updated with every breath while therapy is active.		
	**Spontaneous Triggering**	The final breath was triggered by the patient's spontaneous effort. The patient's own respiratory effort enables the device to initiate inspiration. This indicates good patient-device synchronization.
	**Timed Trigger**	The last breath was triggered by the device's timer. The patient did not exert spontaneous effort, or no effort was detected; the device automatically initiated the breath. If this icon appears continuously, the trigger sensitivity or patient condition should be reviewed.
POWER SUPPLY ICONS — Indicates the active power supply.		
	**AC Power — Mains**	The device operates connected to mains electricity (AC). This is the primary and recommended power source.
	**Battery Operated / Charged**	The device is operating on its internal battery or the battery is charging. This is displayed when AC power is lost or during charging.
	**Battery Level**	Displays the current charge level of the internal battery. When operating on battery power, the battery icon's charge level should be monitored; pay attention to the 30% and 10% battery alarms.
DATA / STORAGE ICONS		
	**SD Card Inserted**	An SD card is inserted into the device's SD card slot. Therapy data may be saved to the SD card, or a software update file may be present. The SD card does not need to remain inserted during therapy; it is recommended to remove it after the update process is complete.

STATUS AND WARNING ICONS

	**Alarm / Warning**	An active alarm or warning is present. Audible and visual notifications accompany the alarm, depending on its priority. The cause of the alarm should be determined and addressed accordingly.

FEATURE STATUS ICONS — Displayed when active

	**External Moisturizing Active**	The External Humidifier feature has been enabled in the settings menu. Volume calculations provide more accurate results by including the humidifier space. It is especially recommended for pediatric patients.
	**Leakage Compensation — Normal**	Leakage compensation is active and the circuit leakage is within normal limits; the algorithm corrects according to the leakage.
	**Leakage Compensation — Being Fixed**	Leakage compensation is active and a significant leakage has been detected; the algorithm is correcting volume calculations and trigger sensitivity in real time according to the leakage. The source of the leakage should be investigated.

ℹ NOTE

The icons on the top panel are updated in real time during therapy.

The trigger type icon (lung/stopwatch) may change with each breath; a continuous stopwatch icon may indicate that the patient's condition needs to be assessed.

Icon order and position may have changed depending on the software version; please review the latest release notes.

5. VENTILATION MODES

VENTISENSE supports 10 ventilation modes. These modes are selected based on the patient's clinical condition, spontaneous breathing capacity, treatment goals and patient-ventilator synchronization requirements.

Category	Modes	Key Features
Mandatory Ventilation	PCV, VCV	Ventilation is completely controlled by the device; spontaneous breathing is not supported
Assisted Ventilation	PCV-A, VCV-A	Device delivers mandatory breaths at set rate while also detecting patient trigger effort
Synchronized Intermittent Mandatory Ventilation	SIMV-P, SIMV-V	Mandatory breaths synchronized with patient effort at set frequency; spontaneous breaths allowed in between
Spontaneous / Support Ventilation	PSV, BiLEVEL, CPAP, HFO	All or most breaths initiated by patient; device provides pressure support

5.1 PCV — Pressure Controlled Ventilation

PCV Pressure Controlled Ventilation

Ventilation is completely controlled by the device. In each breathing cycle, the set inspiratory pressure (IPAP) is held constant for the set duration. Spontaneous breathing is not supported by the device. Delivered tidal volume varies depending on the patient's lung compliance and airway resistance.

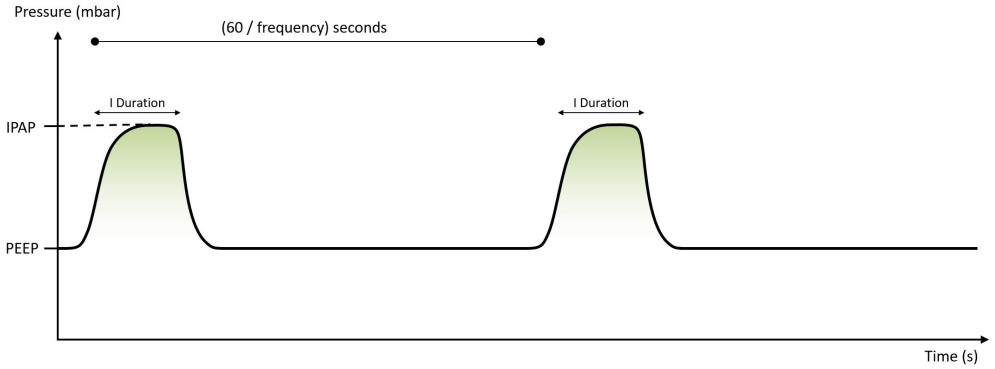


Figure 18 — PCV Mode: Pressure Waveform

5.1.1 Physiological Basis and Operating Mechanism

In PCV mode, the device rapidly reaches the set inspiratory pressure and maintains it steadily throughout the inspiratory time. This "square pressure waveform" pattern allows high initial flow at the start of inspiration enabling early alveolar opening; then flow decreases exponentially (decelerating flow pattern).

This decelerating flow profile is one of the most notable pneumatic advantages of PCV over VCV [17, 18]: gas distributes more homogeneously among lung regions; compartments with different time constants can reach pressure within the inspiratory time, improving ventilation-perfusion matching.

Tidal volume is variable in pressure-controlled modes. The following equation summarizes this relationship: Vt = ΔP × Crs (ΔP = IPAP − PEEP; Crs = Respiratory System Compliance). When lung compliance decreases (eg atelectasis, pneumonia) or airway resistance increases, less tidal volume is delivered at the

same pressure setting. Therefore, continuous monitoring of tidal volume and minute ventilation is mandatory.

5.1.2 Clinical Indications

PCV is the preferred mode in clinical situations where pressure must be precisely limited. Primary indications include:

- Acute Lung Injury (ALI) / ARDS: Lung-protective ventilation with tidal volume 6 ml/kg IBW, plateau pressure ≤30 cmH_2O [20]
- Patients with reduced compliance (pulmonary edema, pneumonia, fibrosis): PCV limits peak airway pressure
- Patients at risk of barotrauma: PCV prevents unexpected pressure spikes
- Neonatal and pediatric patients: Low tidal volumes and pressure limits are more easily maintained
- Post-operative respiratory support: Stable pressure delivery in the early post-operative period
- Initial setting for new ventilator patients: Simple and rapid titration

5.1.3 Clinical Advantages

Advantage	Description
Pressure Limitation	Maximum airway pressure never exceeds the set IPAP value; the risk of barotrauma is reduced.
Reduced Flow Profile	Gas distribution is more homogeneous; V/Q matching and oxygenation are improved.
Alveolar Recruitment	Atelectatic regions are forced open with high early flow + constant pressure duration.
Leak Tolerance	The pressure target is maintained despite circuit leaks.
Low Sedation Requirement	The adaptive flow profile provides patient comfort; less neuromuscular blockade may be required.

5.1.4 Clinical Disadvantages and Considerations

Disadvantage	Description
Variable Tidal Volume	Tidal volume changes unpredictably when compliance or resistance changes; this creates a risk of hypoventilation or volutrauma.
CO_2 Control is Difficult	Minute ventilation is not constant; Frequent pressure adjustments are necessary in cases of hypercapnia.
Continuous Monitoring is Necessary	Tidal volume, minute ventilation, and SpO_2 should be continuously monitored.

i NOTE

If the tidal volume target is exceeded in PCV, decrease the inspiratory pressure; if it is insufficient, increase it. If PaO_2 is low, increase PEEP; if $PaCO_2$ is high, increase the frequency or IPAP value.

5.1.5 PCV Parameter Summary

Parameter	Clinical Description
IPAP	Target inspiratory pressure. Indirectly determines tidal volume magnitude.
PEEP	End-expiratory pressure; Affects alveolar collapse and oxygenation.
Tidal Volume	Monitoring reference; actual delivered volume varies depending on compliance.
Frequency	Affects minute ventilation and CO_2 removal.

Parameter	Clinical Description
Insp. Time	Determines the I:E ratio; longer inspiration duration increases mean airway pressure.
I-Slope	Rate of pressure rise; Affects patient comfort and inspiratory synchronization. 1.5x IPAP every 20 breaths; atelectasis prevention strategy.
Sigh	Target inspiratory pressure. Indirectly determines tidal volume magnitude.

5.2 VCV — Volume Controlled Ventilation

VCV Volume Controlled Ventilation

The set tidal volume is precisely delivered to the patient in each inspiration cycle. Ventilation is controlled by the device; Spontaneous breathing is not supported. The inspiratory pressure varies depending on the patient's lung compliance and airway resistance; pressure increases as compliance decreases or resistance increases.

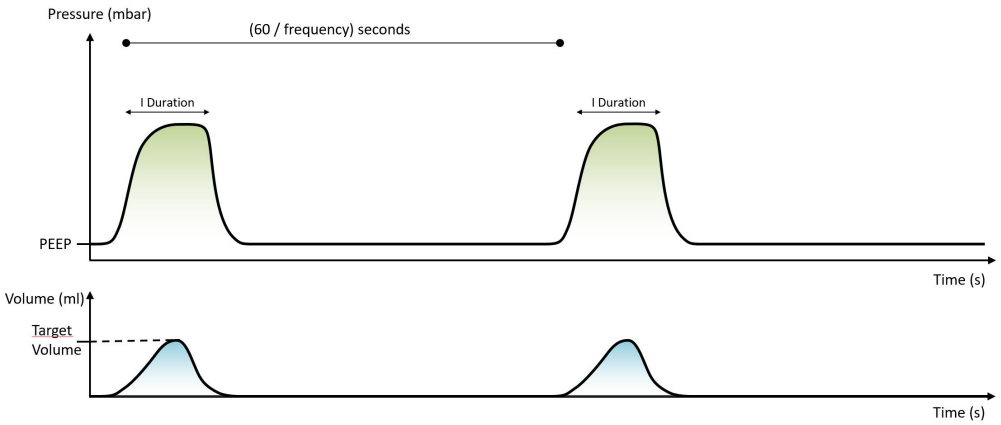


Figure 19 — VCV Mode: Pressure and Volume Waveforms

5.2.1 Physiological Basis and Operating Mechanism

In VCV mode, the device dynamically adjusts the pressure required to deliver the set tidal volume. Classic VCV uses a constant (square) flow wave: a constant flow is delivered throughout inspiration, and inspiration ends when the volume target is reached. This model provides predictable minute ventilation and CO_2 control, but since peak airway pressure is not controlled, barotrauma risk may arise from compliance changes.

VCV is the most widely used ventilation mode in the world clinically; global epidemiological studies show that VCV is preferred in approximately 60% of total mechanical ventilation time. [19] The main reason for this prevalence is the predictable control of minute ventilation and CO_2 removal.

5.2.2 Clinical Indications

- ARDS and Lung Protective Ventilation: Within the ARDSNet protocol, VCV is the mode that can most clearly implement the target of 6 ml/kg tidal volume and plateau pressure ≤30 cmH_2O. Since the tidal volume can be precisely adjusted, the control of the risk of volutrauma is direct. [20]
- Neuromuscular Diseases (ALS, Duchenne Muscular Atrophy): In patients with complete or significant loss of respiratory muscle strength, ensuring the reliable delivery of adequate tidal volume is crucial. VCV provides this assurance.
- Metabolic Acidosis and Brain Damage: In situations requiring precise control of CO_2 levels (e.g., hyperventilation strategy for increased intracranial pressure), predictable minute ventilation is critically important.
- Post-operative ventilation: Provides reliable and manageable ventilation in patients with standard respiratory mechanics.
- Patients under sedation or with neuromuscular blockade: In situations where spontaneous respiratory effort is absent, VCV provides complete control.

5.2.3 Clinical Advantages and Disadvantages

Advantage	Disadvantage
Tidal volume and minute ventilation are constant and predictable.	As pulmonary compliance decreases, pressure increases; risk of barotrauma.
CO_2 control is direct and reliable.	Patient-device asynchrony is more frequent; comfort may be lower.

Advantage	Disadvantage
Precise adherence to lung-protective tidal volume target.	Constant flow wave; gas distribution is less homogeneous compared to PCV.
Weaning parameters are easy to monitor.	Active exhalation or muscle contraction can dangerously increase peak pressure.

⚠ WARNING

Be sure to set the maximum pressure (Max. Pressure) parameter in the VCV.
When compliance drops suddenly (e.g., pneumothorax, secretory plug), pressure can rise to dangerously high levels.
Aim to keep the plateau pressure below 30 cmH_2O.

5.2.4 VCV Parameter Summary

Parameter	Clinical Description
PEEP	It affects oxygenation; it prevents alveolar collapse.
Target Volume	Precise tidal volume to be delivered with each breath. Target 6–8 ml/kg IBW.
Frequency	It directly determines CO_2 emission and minute ventilation rate.
Inspiratory Period	Constant tidal volume delivery time affects the I:E ratio.
Maximum pressure	The safety limit against barotrauma; an alarm is generated if this value is exceeded.
Minimum Pressure	Lower limit for detecting circuit leakage or abnormally low compliance.
Sigh	1.5x volume delivery per 20 breaths; atelectasis prevention.

5.3 PCV-A — Assisted Pressure Controlled Ventilation

PCV-A Assisted Pressure Controlled Ventilation — Supported Pressure Controlled Ventilation

This is a pressure-controlled mode that allows the patient to breathe spontaneously with device assistance. The device delivers forced breaths at a set frequency while also sensing the patient's triggering effort. The set IPAP pressure is applied with each triggered or timed breath. The inspiration time is fixed. The cycle can be brought forward by triggering; this can increase the total respiratory rate. The tidal volume delivered is compliance-dependent.

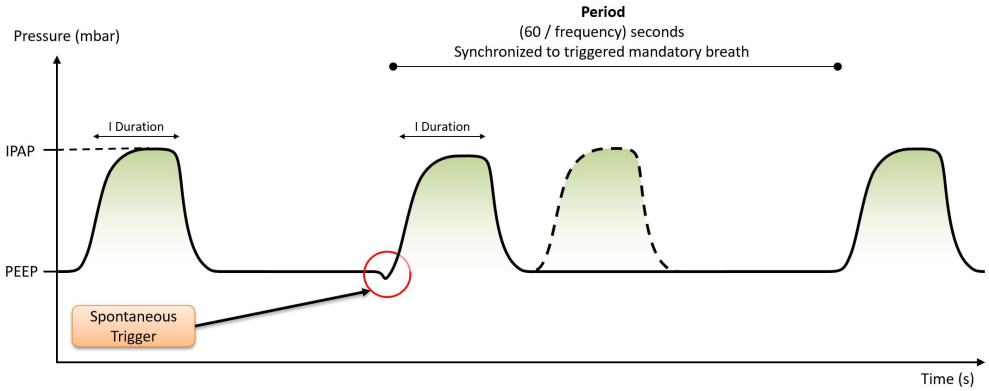


Figure 20 — PCV-A Mode: Triggered and Timed Breath Waveforms

5.3.1 Physiological Basis

PCV-A is PCV with the addition of a spontaneous breathing component. Unlike mandatory PCV, the patient can advance the inspiration cycle (trigger); this ensures synchronization between the patient's neural breathing rhythm and the device. In this approach, also called Assist-Control (AC) mode, every patient effort is met with full pressure support. This feature reduces patient workload and increases comfort; however, in patients with high respiratory drive, there is a risk of entering a cycle of air hunger (tachypnea) because pressure is applied with each triggered breath.

5.3.2 Clinical Indications

- Acute Respiratory Failure Requiring Partial Respiratory Support: If the patient has spontaneous breathing but it is insufficient, PCV-A ensures both a safe forced breathing rate and a response to spontaneous effort.
- Early Post-operative Period: Provides full support as the effects of anesthesia wear off and the patient regains their respiratory reflexes.
- Neuromuscular Disorders: Combines full pressure support for spontaneous effort with mandatory background frequency in patients with residual respiratory muscle strength.
- Transition in Sedation Reduction Process: Used as an intermediate step when transitioning from full control mode (PCV) to more spontaneous modes (PSV, BiLEVEL).

5.3.3 Clinical Advantages

- Full pressure support with every breath: Whether triggered or timed, IPAP is applied for every inspiration.
- It protects respiratory muscles: By providing a full response to spontaneous effort, it delays diaphragmatic atrophy.
- Safe backup frequency: In case of apnea, the device maintains the necessary breaths.
- It can reduce sedation: Less sedation may be needed thanks to spontaneous breathing synchronization.

i NOTE

Prevent premature re-triggering by appropriately adjusting the Trigger Lock parameter in PCV-A.
The risk of tachypnea and air entrapment should be considered in patients with high respiratory drive.
Continue monitoring tidal volume; changes in compliance can affect volume.

5.3.4 PCV-A Parameter Summary

Parameter	Clinical Description
IPAP	Pressure applied with each breath (triggered or timed).
PEEP	End-expiratory pressure is important for both oxygenation and trigger sensitivity.
Frequency	Mandatory backup frequency; the patient can bypass this.
Inspiratory Period	Fixed inspiration time for each breath.
Maximum pressure	Security limit.
I-Slope	The rate at which pressure rises affects patient synchronization.
Inspir. Trigger	The patient's threshold for perceiving their effort.
Trigger Lock	The waiting time at the beginning of expiration to prevent premature re-triggering.
Sigh	Preventing atelectasis: Periodic deep breathing.

5.4 VCV-A — Assisted Volume Controlled Ventilation

VCV-A Assisted Volume Controlled Ventilation — Supported Volume Controlled Ventilation

This is a volume-controlled mode that allows the patient to breathe spontaneously with device assistance. A set tidal volume is delivered with each triggered or timed breath. Inspiratory pressure varies depending on compliance and resistance. The cycle can be brought forward with patient triggering; this can increase the total respiratory rate.

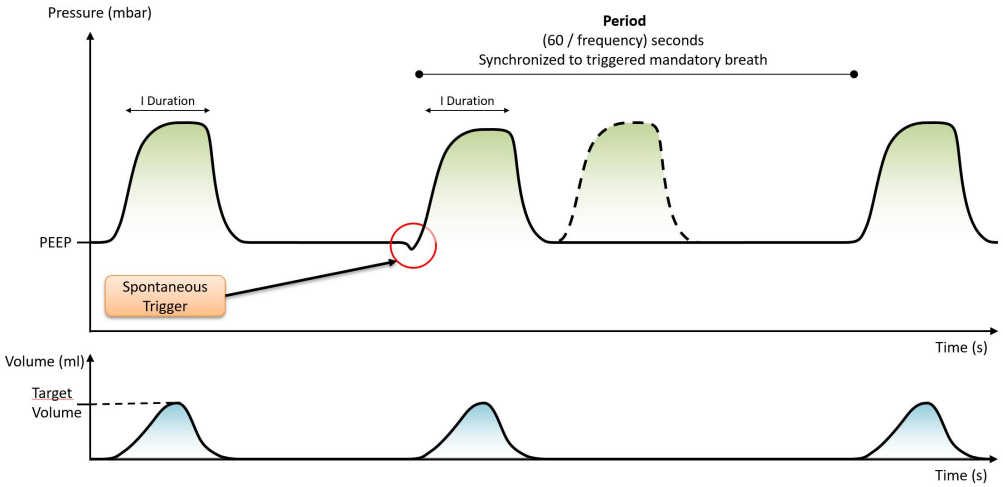


Figure 21 — VCV-A Mode Waveforms

5.4.1 Physiological Basis

VCV-A uses the same assist-control logic as PCV-A; the key difference is that the control variable is volume, not pressure. The device delivers the set tidal volume precisely with every effort the patient makes. This guaranteed volume delivery is a significant advantage, especially in situations where CO_2 control is critical. However, since pressure changes when compliance changes, and mismatches can occur between patient effort and device flow, patient-device asynchrony (especially flow starvation) is more common.

5.4.2 VCV-A vs. PCV-A: Selection Guide

Criterion	VCV-A Preference	PCV-A Preference
Minute ventilation control	✓ Certain, predictable	Variable
Tidal volume control	✓ Fixed warranty	Compliance dependent
Pressure limitation	Caution: Pressure is variable.	✓ IPAP is never breached
Gas distribution / Comfort	Less homogeneous	✓ Decreasing flow profile
CO_2 control is required.	✓ Complete control	Difficult
Leakage tolerance	Annoyed	✓ Pressure is maintained

5.4.3 Clinical Indications

- Metabolic Acidosis or Cranial Hypertension: In situations requiring tight CO_2 control, VCV-A ensures tidal volume and minute ventilation.
- ARDS — Lung Protective Strategy: Supports spontaneous breathing effort while maintaining a target tidal volume of 6 ml/kg IBW.
- Weaning Initiation: Full control is exercised during the transition from VCV to assisted mode.

5.4.4 VCV-A Parameter Summary

Parameter	Clinical Description
PEEP	End-expiratory pressure; for alveolar patency and triggering.
Target Volume	The precise tidal volume to be delivered with each breath.
Frequency	Minimum required respiratory rate; the patient may exceed it.
Inspiratory Period	Tidal volume delivery time.
Maximum pressure	Barotrauma protection against compliance changes.
Minimum Pressure	Lower limit for low compliance or leakage warning.
Inspir. Trigger	Spontaneous effort detection threshold.
Trigger Lock	Early re-triggering prevention period.
Sigh	Preventing atelectasis: Periodic deep breathing.

5.5 SIMV — Synchronized Intermittent Mandatory Ventilation

SIMV (Synchronized Intermittent Mandatory Ventilation) is a well-established ventilation strategy developed in the early 1970s and has been the most common weaning mode for the next two decades. The basic principle of SIMV is to deliver mandatory breaths at a set frequency while simultaneously allowing the patient spontaneous breathing during the expiration phase. The synchronization mechanism aims to align the spontaneous breathing effort with the mandatory breathing cycle.

5.5.1 SIMV Algorithm and Trigger Window

In VENTISENSE, the SIMV algorithm divides the EPAP duration into two parts:

- The first 40% section — Spontaneous breathing window: If the patient exerts spontaneous effort within this interval, the device applies PS (Pressure Support); exhalation occurs through the patient's own effort. This is spontaneous assisted breathing.
- The final 60% section — Mandatory breathing window: If spontaneous exertion occurs during this interval, the device recognizes it as mandatory breathing and supports it with IPAP (SIMV-P) or target tidal volume (SIMV-V); exhalation occurs after the inspiration period.
- If there is no spontaneous effort: The device delivers fully forced breaths according to the frequency setting.

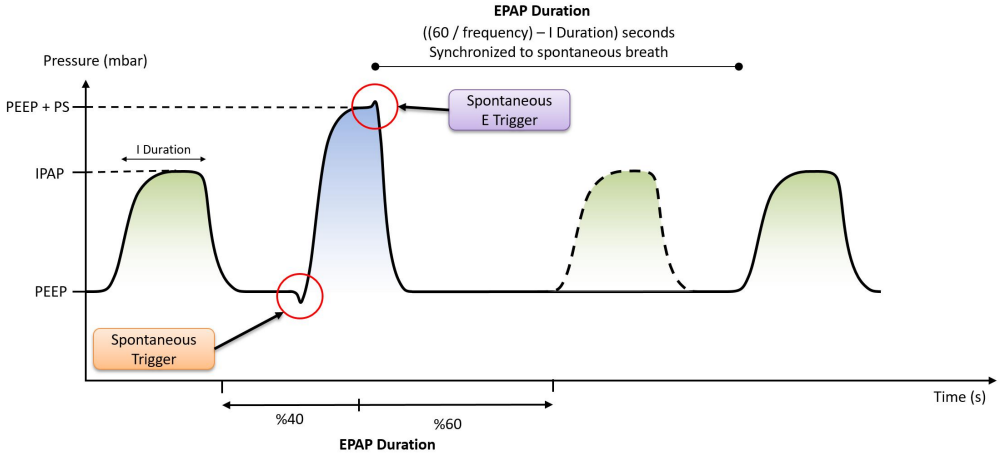


Figure 22 — SIMV: Spontaneous Breathing Triggering (40% Window)

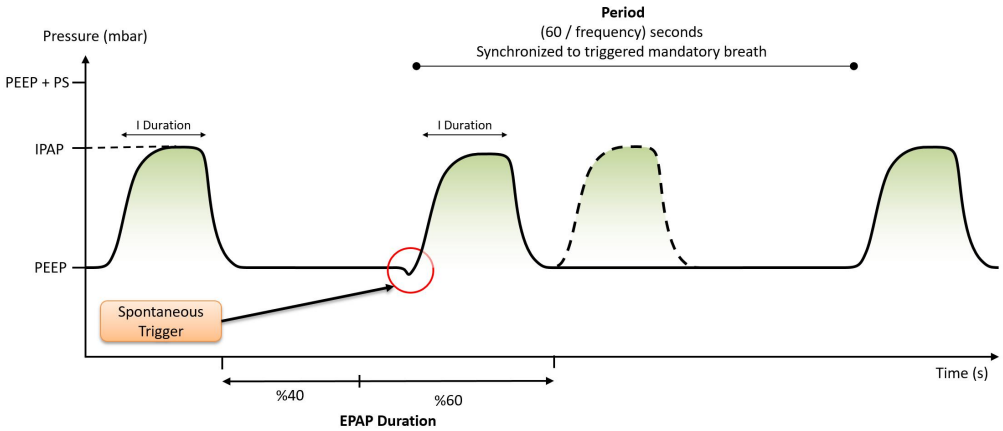


Figure 23 — SIMV: Mandatory Breathing Trigger (60% Window)

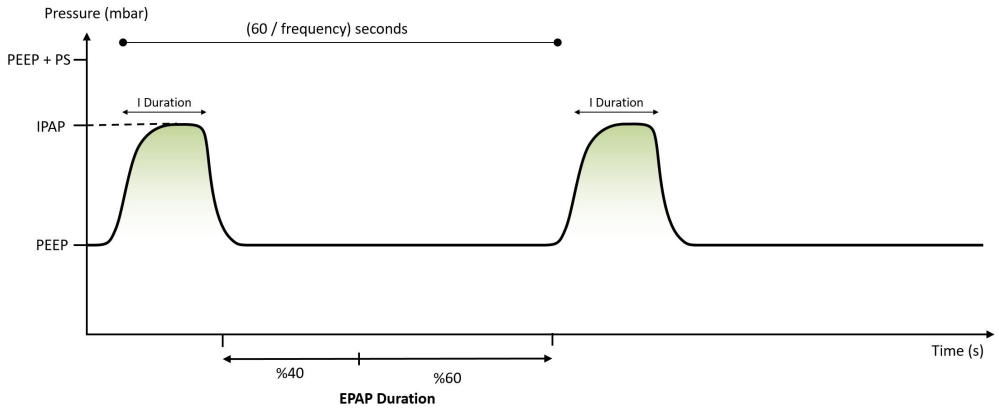


Figure 24 — SIMV: Absent Spontaneous Breathing — Mandatory Breathing

5.5.2 Clinical Indications

- Patient-Device Synchronization: In patients with spontaneous breathing, asynchrony is reduced by aligning mandatory breaths with patient effort.
- Ventilation Dependence Risk Management: Compared to full control modes, respiratory muscles continue to function partially; this can delay muscle atrophy.
- Reducing the Risk of Barotrauma: Synchronizing mandatory and spontaneous breathing prevents breath stacking, reducing the risk of air entrapment and pressure increase.
- Long-Term Home Ventilation: Especially in advanced stages of neuromuscular diseases, a combination of mandatory backup ventilation and spontaneous respiratory support creates an ideal profile.

5.5.3 Evaluation of Clinical Evidence

SIMV was the preferred mode of weaning in over 90% of hospitals in the US in the 1980s. [24] However, subsequent randomized trials have revealed significant limitations:

- Weaning Efficiency: Studies show that SIMV prolongs weaning time compared to T-piece trials or gradual PSV reduction. The body cannot increase respiratory work proportionally to the reduced number of forced breaths; this "failure of adaptation" can lead to fatigue. [26, 28]
- Spontaneous Breathing Workload: When full support is not provided during spontaneous breaths (without a power source), the patient has to work against circuit and valve resistance; this increases the respiratory workload.
- Patient Comfort: The difference between required and spontaneous breath sizes can lead to a feeling of disharmony.

i NOTE

When SIMV is used in combination with PSV (SIMV+PS), supporting spontaneous breaths reduces the work of breathing.

For patients aiming for weaning, switching to PSV may be a more efficient alternative.

SIMV is particularly valuable in cases involving neuromuscular disease, chronic ventilation dependence, and the goal of preserving respiratory muscles.

5.5.4 SIMV-P — Pressure Controlled SIMV

Mandatory breaths are delivered under pressure control (with IPAP pressure). Spontaneous breaths are supported by adjustable PS support.

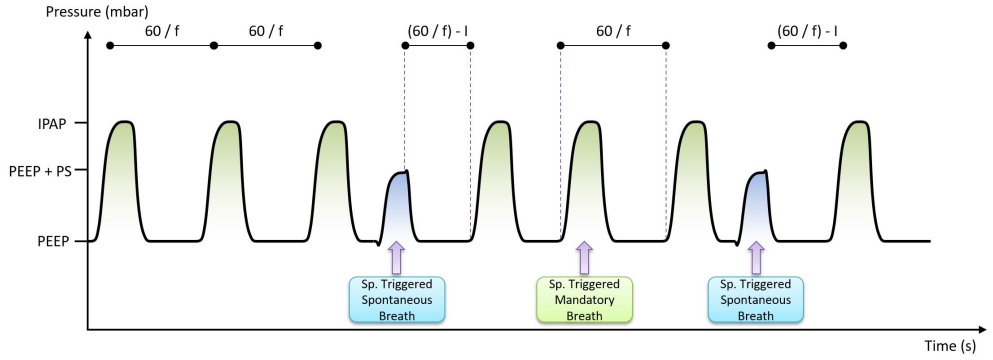


Figure 25 — SIMV-P: All Event Types (Spontaneous / Mandatory / None)

Parameter	Clinical Description
IPAP	Inspiratory pressure for forced breaths.
PEEP	Positive end-expiratory pressure.
Frequency	The number of required breaths per minute.
Inspiratory Period	The mandatory breathing inspiration period.
Pressure Support (PS)	The support pressure added to spontaneous breaths is added on top of PEEP.
I-Slope	Rate of pressure increase.
Inspir. Trigger	Spontaneous effort detection threshold.
Exp. Trigger	The criterion for starting expiration in spontaneous breaths is 5%–100%.
Trigger Lock	Early re-triggering prevention.
Max./Min. Inspiration Time	Inspiration time limits in spontaneous breathing.
Sigh	Preventing atelectasis: periodic deep breathing.

5.5.5 SIMV-V — Volume Controlled SIMV

Mandatory breaths are delivered with a controlled tidal volume. Spontaneous breaths may receive pressure support.

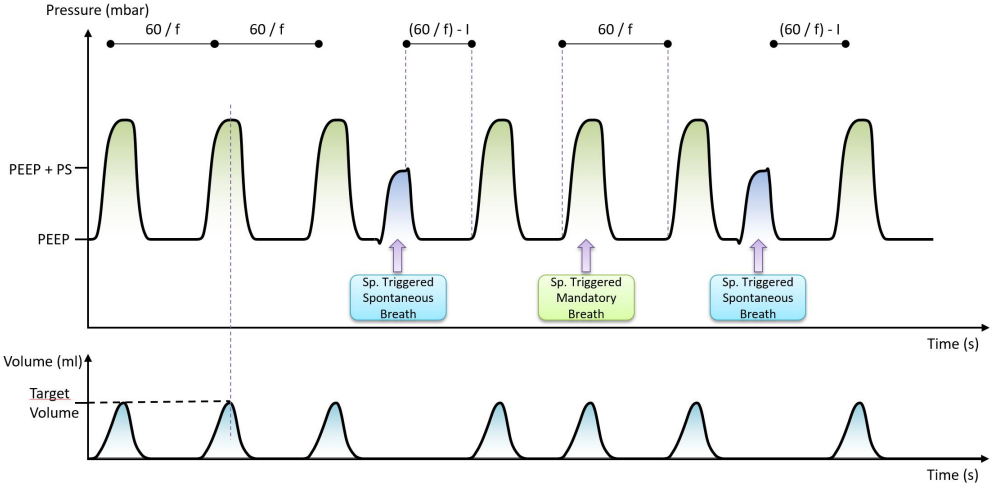


Figure 26 — SIMV-V: All Event Types

Parameter	Clinical Description

Parameter	Clinical Description
PEEP	Positive end-expiratory pressure.
Target Volume	Precise tidal volume for forced breaths.
Frequency	The number of required breaths per minute.
Inspiratory Period	The mandatory breathing inspiration period.
Pressure Support (PS)	Additional pressure support for spontaneous breathing.
Maximum pressure	The maximum allowable pressure in tidal volume transfer.
Minimum pressure	Lower limit for low compliance/leakage warning.
I-Slope	Rate of pressure increase.
Inspir. Trigger	Spontaneous effort detection threshold.
Exp. Trigger	The criterion for starting expiration in spontaneous breathing.
Trigger Lock	Early re-triggering prevention.
Max./Min. Inspiration Time	Inspiration time limits in spontaneous breathing.
Sigh	Preventing atelectasis: periodic deep breathing.

5.6 PSV — Pressure Support Ventilation

PSV (Pressure Support Ventilation)

PSV applies the appropriate support pressure by detecting each spontaneous inspiratory effort of the patient. The device does not initiate breathing on its own; it is entirely dependent on patient triggering. If spontaneous breathing is not detected during the apnea period, mandatory ventilation is initiated with an automatic backup frequency. PSV is the most physiological mode in which the patient controls both the timing of inspiration and the expiratory transition.

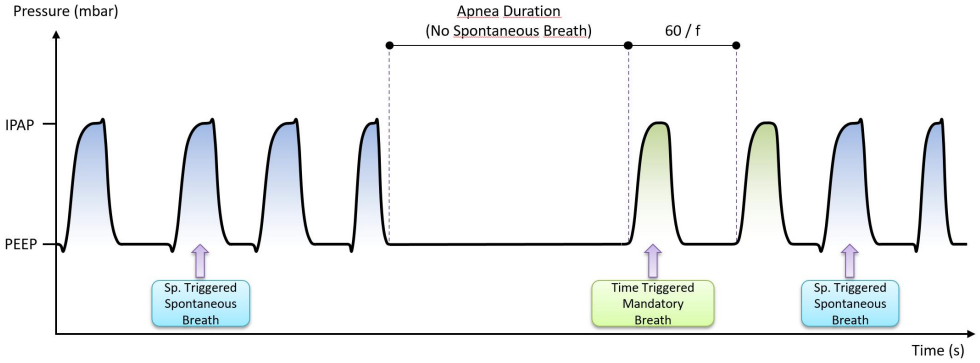


Figure 27 — PSV Mode: Patient-Triggered Pressure-Supported Breathing

5.6.1 Physiological Basis

In PSV, each inspiration involves three phases. The first phase is triggering: the patient creates a change in circuit flow with a small effort; the device detects this and initiates pressure support. The second phase is limiting: the device quickly reaches the IPAP value and the flow begins to decrease; this decelerating flow profile optimizes gas distribution. The third phase is cycling: when the inspiratory flow decreases by a percentage of the set expiratory trigger from the peak value, the device switches to PEEP and the patient performs passive exhalation.

The key feature of PSV is that the patient's respiratory drive, muscle strength, and lung mechanics directly affect tidal volume. High respiratory drive + high PS = excessively large tidal volume and risk of increased transpulmonary pressure. Low respiratory drive + low muscle strength = insufficient tidal volume; in case of apnea, backup takes over.

5.6.2 Clinical Indications

- Weaning — Ventilation Decompression: PSV is considered the gold standard for mechanical ventilation decompression. Randomized studies have shown that gradual reduction with PSV increases the successful extubation rate and shortens weaning time compared to T-piece trials and SIMV. Gradual reduction of PSV allows for the gradual re-strengthening of respiratory muscles. [28]
- Chronic Respiratory Failure — Long-Term Home Ventilation: In patients with COPD, neuromuscular disease, and restrictive lung disease, long-term PSV reduces dyspnea, increases exercise tolerance, and improves quality of life. According to StatPearls data, patients with small artificial airways, chronic muscle weakness, and COPD particularly benefit from PSV. [27]
- ARDS Recovery Phase: As the patient regains spontaneous breathing capacity during the acute phase while controlled ventilation is applied, switching to PSV helps protect respiratory muscles.
- Non-invasive ventilation (NIV): PSV is one of the basic modes of NIV delivered via mask; its effectiveness has been proven in COPD exacerbation, cardiogenic pulmonary edema, and post-extubation support.
- Comfort-Oriented Support: This is considered the most comfortable mode for patients who have strong spontaneous breathing but require additional support.

5.6.3 Clinical Advantages and Disadvantages

Advantage	Disadvantage
The most physiological mode is when the patient controls their breathing.	There is no guarantee against apnea — apnea backup must be set up.

Advantage	Disadvantage
Patient comfort is maximized; sedation is reduced.	Tidal volume is variable; risk of excessively large breaths.
It protects and strengthens the respiratory muscles.	Risk of P-SILI (self-inflicted lung injury) in high respiratory drive
The most proven mode for weaning	Managing asynchronous situations can be complex.
It can be used in both invasive and non-invasive procedures.	If leaks occur, the cycle criterion may be violated.

⚠ WARNING

Be sure to set the Apnea Duration parameter. If there is no spontaneous breathing during the apnea period, backup ventilation will be activated.

High PS levels can lead to high tidal volume and a risk of P-SILI; do not exceed the target of 8–10 ml/kg IBW.

Before initiating PSV, assess whether the patient has adequate respiratory drive.

5.6.4 PSV Parameter Summary

Parameter	Clinical Description
IPAP	The level of pressure support indirectly determines tidal volume.
PEEP	Positive end-expiratory pressure; for oxygenation and triggering.
Target Volume	Monitoring reference (it is recommended not to exceed 8–10 ml/kg).
Frequency (Backup)	The mandatory breathing rate that will be activated in case of apnea.
Inspir. Period (Backup)	The inspiration period during apneic backup breaths.
Maximum pressure	Security limit.
I-Slope	The rate at which the pressure rises affects comfort and trigger quality.
Inspir. Trigger	Spontaneous effort threshold; too sensitive → auto-triggering, too coarse → delayed triggering.
Exp. Trigger	End-inspiratory flow percentage can be increased in obstructive disease.
Trigger Lock	Early re-triggering prevention.
Max./Min. Inspiration Time	Safety limits against loop disruption.
Apnea Duration	The spontaneous breathing waiting threshold; if exceeded, the backup system kicks in.
Sigh	Preventing atelectasis: periodic deep breathing.

5.7 BiLEVEL

BiLEVEL Bilevel Positive Airway Pressure

BiLEVEL (also known as BiPAP) is a spontaneous breathing mode that applies two separate pressure levels. High pressure (IPAP) is applied during inspiration, and low pressure (EPAP/PEEP) is applied during expiration. All breaths are triggered by the patient; the device does not initiate forced breaths. The respiratory rate, timing, and expiratory transition are controlled by the patient.

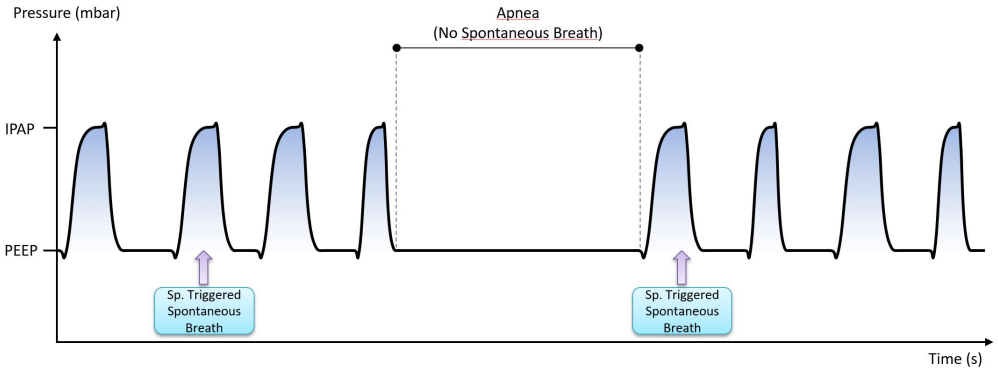


Figure 28 — BiLEVEL Mode: Two Pressure Level Waveform

5.7.1 Physiological Basis

The basic physiological principle of BiLEVEL mode is to increase CO_2 removal and alveolar ventilation by applying a higher pressure during the inspiration phase, and to maintain airway patency with a lower pressure (EPAP) during the expiration phase. The difference between IPAP and EPAP (delta pressure or driver pressure) determines the magnitude of effective ventilation support provided with each breath. Higher delta pressure → larger tidal volume and better CO_2 removal; EPAP prevents airway collapse and obstructive sleep apnea.

5.7.2 BiLEVEL and PSV Comparison

BiLEVEL and PSV are based on similar pneumatic principles but have some important differences:

Feature	BiLEVEL	PSV
Parameter naming	IPAP / EPAP	IPAP / PEEP (same physical size)
Mandatory backup frequency	None (no trigger in case of apnea)	Var (apnea backup frequency)
Main area of use	Non-invasive ventilation (NIV); home therapy	Invasive and non-invasive; weaning
Typical patient profile	COPD, OHS, neuromuscular disease, OSA	Intensive care weaning; acute respiratory failure

5.7.3 Clinical Indications

- COPD Type 2 Respiratory Failure (Hypercapnic): BiLEVEL is the NIV strategy with the best level of evidence in COPD. In patients with pH <7.35 and $PaCO_2$ >45 mmHg, BiLEVEL treatment reduces the need for intubation, lowers mortality, and shortens hospital stay. ATS/ERS guidelines strongly recommend BiLEVEL in COPD exacerbations. [10, 31]
- Obesity Hypoventilation Syndrome (OHS): In obese patients, the tone of the upper airway muscles decreases during sleep, leading to alveolar hypoventilation. BiLEVEL significantly reduces nocturnal CO_2 retention, eliminates daytime somnolence, and improves PaO_2 . BiLEVEL is preferred in OHS patients who do not respond well to CPAP.
- Neuromuscular Diseases (ALS, Duchenne Muscular Dystrophy, Spinal Muscular Atrophy, Phrenic Nerve Palsy): In these patients, progressive weakening of the respiratory muscles leads first to nocturnal hypoventilation and, in later stages, to chronic respiratory failure. BiLEVEL is initially started as nocturnal ventilation; as the disease progresses, it can be switched to 24-hour support.

- Restrictive Chest Wall Disorders (Kyphoscoliosis, Thoracoplasty): Mechanical restriction of the rib cage makes breathing difficult. Nighttime BiLEVEL support improves sleep quality and rests the respiratory muscles.
- Obstructive Sleep Apnea + Hypoventilation: In combined conditions where CPAP alone is insufficient, BiLEVEL provides both apnea treatment and ventilation support.

5.7.4 Clinical Advantages

- Effective control of CO_2 excretion: The IPAP-EPAP difference (driving pressure) directly affects CO_2 excretion; hypercapnia can be treated by increasing IPAP.
- Patient comfort: Full compliance with spontaneous breathing rhythm provides advantages in terms of comfort and long-term adaptation.
- Non-invasive application: Since it can be applied through a mask, the risks of invasive ventilation can be avoided.
- Home environment suitability: This is the most commonly used mode for long-term home ventilation and can be easily managed with patient and caregiver training.

i NOTE

BiLEVEL initial setting: EPAP 4–8 cmH_2O, IPAP 10–20 cmH_2O; titrate according to patient response and blood gas values.
If $PaCO_2$ is high, increase IPAP (widen the delta pressure). If SpO_2 is low, increase EPAP.
Consider alternative treatment options for patients with severe dyspnea or low consciousness.

5.7.5 BiLEVEL Parameter Summary

Parameter	Clinical Description
IPAP	Inspiratory pressure. The difference (ΔP) between this and EPAP determines tidal volume and CO_2 elimination.
PEEP (EPAP)	Positive expiratory pressure. For airway patency and oxygenation.
Target Volume	Monitoring reference.
Maximum pressure	Security limit.
I-Slope	The rate of pressure rise provides slow adjustment comfort for a high resistance profile.
Inspir. Trigger	Sensitivity to spontaneous effort detection.
Exp. Trigger	The expiratory transit criterion is of critical importance in obstructive pulmonary disease.
Trigger Lock	Early re-triggering prevention.
Max./Min. Inspiration Time	Safety limits against loop disruption.
Sigh	Preventing atelectasis: Periodic deep breathing.

5.8 CPAP — Continuous Positive Airway Pressure

CPAP stands for Continuous Positive Airway Pressure.

CPAP applies constant positive airway pressure throughout the entire respiratory cycle (both inspiration and expiration). The patient breathes using their own respiratory effort; the device does not provide additional inspiratory pressure support, it only maintains the determined pressure level stably. Maintaining airway patency and improving oxygenation are the primary goals.

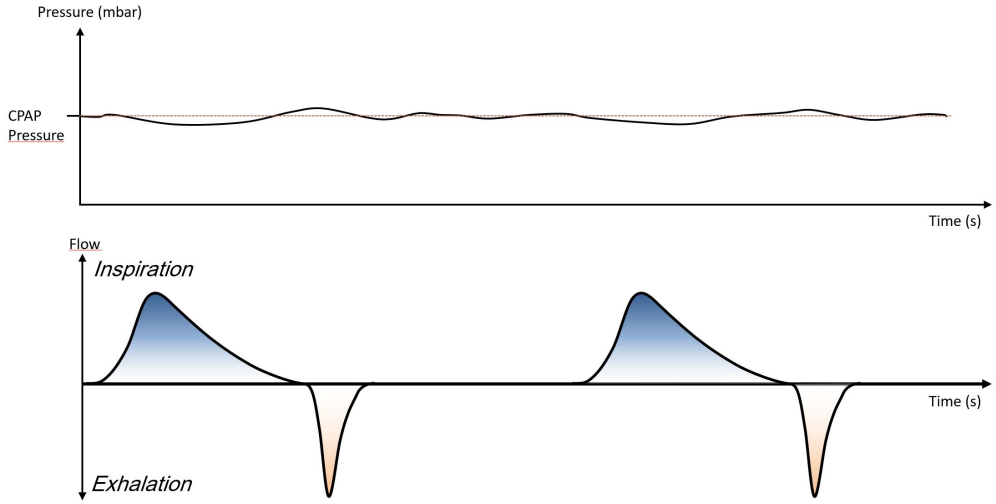


Figure 29 — CPAP Mode: Steady Pressure Waveform

5.8.1 Physiological Basis

The physiological effects of CPAP occur through several mechanisms. First, it maintains airway patency: positive pressure prevents soft tissue collapse in the upper airway, and the alveoli remain open at the end of expiration (prevention of atelectasis). Second, it increases FRC (Functional Residual Capacity): CPAP increases gas volume in the lungs, reducing intrapulmonary shunting and improving ventilation-perfusion matching. Third, it has cardiac effects: positive intrathoracic pressure reduces left ventricular afterload; this effect is particularly valuable in cardiogenic pulmonary edema. Fourth, it balances auto-PEEP: in COPD, external CPAP application lowers the trigger threshold against accumulated intrinsic PEEP and reduces the work of breathing.

5.8.2 Clinical Indications

- Obstructive Sleep Apnea (OSA): CPAP is the primary standard of OSA treatment. Positive pressure at night prevents upper airway closure; it significantly reduces the apnea-hypopnea index (AHI). Long-term CPAP use has been shown to reduce hypertension, lower the risk of heart failure, and reduce the recurrence of atrial fibrillation by 40%. [35, 36]
- Cardiogenic Pulmonary Edema: In acute cardiogenic pulmonary edema, CPAP application significantly reduces the need for intubation and lowers short-term mortality. A meta-analysis of all studies shows that CPAP statistically significantly reduces the need for intubation in cardiogenic pulmonary edema. [37, 38]
- Neonatal and Preterm Infant Support: In the NICU setting, CPAP, along with surfactant therapy, is a primary support modality in the management of premature lung disease (RDS).
- Post-Extubation Support: Short-term CPAP application may be performed to prevent respiratory failure that may develop after weaning from invasive ventilation.
- Final Weaning Phase: In the final phase of invasive ventilation weaning, CPAP is used to test the patient's spontaneous breathing with minimal support.

5.8.3 Comparison of CPAP and BiLEVEL

Feature	CPAP	BiLEVEL
Pressure	Single constant pressure	Two pressure systems: IPAP (inspiratory) + EPAP (expected)
CO_2 emission	Not supported	Active support with IPAP-EPAP difference
Ventilation support	No; only pressure.	Yes; tidal volume is increased.
Primary indication	OSA, cardiogenic edema, oxygenation disorder	Type 2 respiratory failure, hypercapnia
Complex management	Simple, single parameter.	More complex; two pressure settings, delta adjustment.

i NOTE

A 5–12 cmH_2O range is recommended for initiating CPAP; titrate according to SpO_2 and patient tolerance.

If the patient is still dyspneic or hypercapnic despite adequate oxygenation, consider switching to BiLEVEL.

CPAP contraindications: Severe hypotension, facial anomaly/trauma, risk of loss of consciousness.

5.8.4 CPAP Parameters

Parameter	Clinical Description
CPAP Pressure	Constant pressure level applied throughout the entire cycle (mbar). Typical range: 5–12 cmH_2O. 6–14 cmH_2O in OSA treatment; 5–10 cmH_2O in cardiogenic edema; 5 cmH_2O in the final stage of weaning.

5.9 HFO — High-Flow Oxygen Therapy

HFO High Flow Oxygen — High Flow Oxygen Therapy (HFNC)

HFO is a flow-controlled support mode that delivers a constant, high-flow heated and humidified oxygen mixture. Unlike classic mechanical ventilation modes, it does not control the respiratory cycle; instead, it supports oxygenation, dead space washout effect, and patient comfort by delivering a high-flow conditioned gas to the airway. An external oxygen source, heated humidifier, and HFNC (high-flow nasal cannula) are mandatory.

5.9.1 Physiological Mechanisms of Action

Four key mechanisms explaining the clinical benefits of HFNC have been identified:

- Anatomical Dead Space Washout: High-flow continuously cleanses CO_2 from the anatomical dead space in the upper airways and proximal tracheobronchial tree. This effect reduces CO_2 rebreathing, increasing gas exchange efficiency and improving effective alveolar ventilation.
- Increased FRC and Weak PEEP Effect: When HFNC is applied at a flow rate of 20–60 L/min, a portion of the flow creates a slight positive pressure in the airway. While not as strong as PEEP, this effect supports alveolar patency; studies show it increases FRC by approximately 25%.
- Reducing the Work of Respiratory Work: The high flow rate matches or exceeds the patient's inspiratory flow demand, significantly reducing the patient's own respiratory effort. The heated and humidified gas prevents airway dehydration, preserves mucociliary clearance, and reduces dyspnea.
- Stable FiO_2 Delivery: Conventional oxygen methods (nasal cannula: max 5–6 L/min, mask: max ~10 L/min) reduce FiO_2 by mixing with room air. HFNC provides a stable FiO_2 delivery of 21%–100% at a flow rate of 20–70 L/min; this reliability is critical in acute hypoxemic respiratory failure.

5.9.2 Clinical Indications

- Acute Hypoxemic Respiratory Failure (Type 1): The 2015 FLORALI study demonstrated that HFNC significantly reduced 90-day mortality in acute hypoxemic respiratory failure compared to standard oxygen therapy and NIV. The ESICM's 2023 ARDS management guidelines recommend its preference over conventional oxygen therapy in non-mechanically ventilated patients except in cases of cardiogenic pulmonary edema and COPD exacerbation. [42]
- Post-Extubation Support: In patients successfully weaned from invasive ventilation, HFNC reduces the risk of re-intubation; its superiority over standard oxygen has been demonstrated in randomized studies.
- Palliative Care and Comfort: HFNC offers a comfortable alternative for dyspnea control in end-stage disease.
- Mild-to-Moderate Hypoxemia — Patients with Poor Mask Tolerance: HFNC provides an effective alternative for patients who cannot tolerate NIV masks.
- Sleep Environment: For patients who cannot tolerate NIV masks at night but require oxygen support, HFNC may be preferred due to its comfort.

5.9.3 Physiological Profile According to Flow Rate

Flow Range	Dominant Physiological Effect
20–45 L/min	Reduction in respiratory work, improvement in mucociliary clearance, washing of dead spaces.
45–60 L/min	The PEEP effect becomes more pronounced, FRC increases, and oxygenation improves.
60–70 L/min	Maximum pressure effect; patient comfort limits may be pushed.

5.9.4 Comparison of HFNC and NIV (BiLEVEL/CPAP)

Feature	HFNC	NIV (BiLEVEL / CPAP)
FiO_2 control	✓ Stable and reliable	Can be affected by mask leaks.

Feature	HFNC	NIV (BiLEVEL / CPAP)
Patient comfort	✓ Very high; no masks.	Mask printing, leakage discomfort.
CO_2 emission	Dead space washout indirectly	✓ With direct pressure support
PEEP effect	Weak, flow-dependent	✓ Precise and adjustable
Talking / eating	✓ Possible	Limited
Indication	Type 1 hypoxemic insufficiency	Type 2 hypercapnic insufficiency

⚠ WARNING

In HFO mode, an external oxygen source, heated humidifier, and HFNC are mandatory. Do not use with missing components.

HFNC is not a replacement for NIV in the primary treatment of hypercapnic conditions such as COPD exacerbation and cardiogenic pulmonary edema.

Monitor the patient's condition closely; if an adequate response is not obtained within 1 hour, do not delay switching to more invasive support.

5.9.5 HFO Parameters

Parameter	Clinical Description
Flow Rate (L/min)	Start at 20–30 L/min; increase according to patient tolerance and SpO_2 target. Typical target for adult patients is 40–60 L/min, and for pediatric patients 2 L/kg/min.

i NOTE

In VENTISENSE HFO mode, FiO_2 is determined by the flow rate of the external oxygen source and the device's mixing ratio.

Monitor the actual delivered FiO_2 with the O_2 sensor and adjust the external oxygen flow according to the target SpO_2 value.

6. PARAMETERS — DETAILED EXPLANATIONS

This section describes all ventilation parameters used in the VENTISENSE device in a detailed clinical context. The physiological basis, clinical significance, and adjustment principles of each parameter are presented below.

6.1 Parameter Summary Table (All Modes)

The table below shows a comparative overview of the parameters for all modes.

Parameter	PCV	VCV	PCV-A	VCV-A	SIMV-P	SIMV-V	PSV	BiLEVEL	CPAP	HFO
IPAP	✓		✓		✓		✓	✓		
PEEP	✓	✓	✓	✓	✓	✓	✓	✓		
CPAP Pressure									✓	
Flow Rate										✓
Target Volume	✓	✓	✓	✓		✓	✓	✓		
Frequency	✓	✓	✓	✓	✓	✓	✓			
Inspiratory Period	✓	✓	✓	✓	✓	✓	✓			
Maximum pressure		✓	✓	✓		✓	✓	✓		
Minimum Pressure		✓		✓		✓				
Pressure Support (PS)					✓	✓				
I-Slope	✓		✓		✓	✓	✓	✓		
Sigh	✓	✓	✓	✓	✓	✓	✓	✓		
Inspir. Trigger			✓	✓	✓	✓	✓	✓		
Exp. Trigger					✓	✓	✓	✓		
Trigger Lock			✓	✓	✓	✓	✓	✓		
Maximum Inspiration Time					✓	✓	✓	✓		
Minimum Inspiration Time					✓	✓	✓	✓		
Apnea Duration							✓			

6.2 Pressure Parameters

6.2.1 IPAP — Inspiratory Positive Airway Pressure

IPAP (Inspiratory Positive Airway Pressure) is the level of positive pressure the device applies to the airway during the inspiration phase. It acts as a driving pressure that facilitates gas entry into the lungs and is a key parameter determining the magnitude of tidal volume. Physiologically, the difference between IPAP and PEEP (delta pressure or "driving pressure") refers to the magnitude of pressure support delivered to the patient: a larger delta pressure means a larger tidal volume and better CO_2 elimination.

In clinical practice, IPAP is usually initiated between 10–25 cmH_2O. High IPAP values are used to correct hypercapnia in patients with CO_2 retention (e.g., COPD, neuromuscular disease), while low IPAP values limit the risk of pressure injury (barotrauma). In a lung-protective ventilation strategy, it is recommended that the difference (ΔP) between IPAP and PEEP should not exceed 15 cmH_2O.

i NOTE

The relationship between IPAP = PEEP + Pressure Support (PS): IPAP is higher than PEEP.
If $PaCO_2$ is high, increasing IPAP widens the delta pressure and increases CO_2 removal.
Tidal volume should be monitored; in lung-protective ventilation, the target is 6–8 ml/kg ideal body

weight.

6.2.2 PEEP — Positive End-Expiratory Pressure

PEEP (Positive End-Expiratory Pressure) is the positive pressure maintained in the airway at the end of expiration. Physiologically, PEEP prevents alveolar collapse at the end of expiration, increases functional residual capacity (FRC), and improves oxygenation by reducing intrapulmonary shunt. In non-invasive ventilation, the equivalent of PEEP is called EPAP (Expiratory Positive Airway Pressure); both terms are clinically equivalent.

Typical baseline PEEP levels are 4–8 cmH_2O, but higher levels (10–18 cmH_2O) may be required in patients with severe oxygenation impairment such as ARDS. PEEP also reduces respiratory work by offsetting intrinsic PEEP (auto-PEEP) accumulated in obstructive lung diseases such as COPD and asthma, and lowers left ventricular afterload in cardiogenic pulmonary edema.

⚠ WARNING

Excessive PEEP can reduce cardiac output, lead to barotrauma, and increase cerebral venous pressure.

PEEP titration decisions should be made by the clinician based on the patient's clinical condition.

6.2.3 CPAP Pressure

This parameter, specific to CPAP mode, defines the positive airway pressure maintained throughout the entire respiratory cycle (both in the inspiration and expiration phases). CPAP does not provide additional inspiratory pressure support; it only maintains the airway open with continuous positive pressure. The patient breathes with their own respiratory effort; the device's role is to maintain this pressure level stably. The typical clinical range is 5–12 cmH_2O.

6.2.4 Maximum Pressure (Max. Pressure)

The maximum pressure parameter limits the highest airway pressure the device is allowed to apply during inspiration. In volume-controlled modes (VCV, VCV-A, SIMV-V), it acts as a safety limit against pressure increases that may occur when lung compliance changes. When this limit is exceeded, the device generates an alarm and terminates inspiration if necessary. This is critical for preventing the risk of barotrauma (pneumothorax, pneumomediastinum, alveolar rupture).

In clinical practice, maintaining a plateau pressure below 30 cmH_2O is one of the primary goals of lung-protective ventilation. The maximum pressure setting should be configured to meet this goal.

6.2.5 Minimum Pressure

Minimum pressure, in volume-controlled modes, defines the minimum pressure threshold that the device must apply during inspiration. In situations where airway resistance is very low or lung compliance is very high, a drop in pressure below the expected value to reach the target tidal volume may indicate a possible circuit leak or measurement error. Minimum pressure is used to detect these situations and alert the clinician.

6.2.6 Pressure Support (PS)

In SIMV modes, this is supplemental pressure support applied to spontaneous breaths. This added pressure, above the PEEP level, supports the patient's spontaneous breathing effort, reducing the work of breathing. When PS = 0, the patient breathes entirely under their own power against circuit resistance; higher PS values relax the respiratory muscles further, but excessive support can lead to patient-device asynchrony. During the weaning process, PS is gradually reduced to encourage strengthening of the respiratory muscles.

6.3 Volume and Time Parameters

6.3.1 Target Volume (Tidal Volume)

Tidal volume is the amount of air that enters and leaves the lungs in each respiratory cycle. In volume-controlled modes (VCV, VCV-A, SIMV-V), this value is precisely transmitted by the device; in pressure-controlled and spontaneous modes, it is used as a target reference for monitoring purposes. In adult

patients, the physiological tidal volume is approximately 400–600 ml (average 500 ml), and in mechanical ventilation, the target is 6–8 ml/kg ideal body weight as part of a lung-protective strategy.

The use of large tidal volumes (>10 ml/kg) increases the risk of volutraum and lung injury (VILI). In particular, a target of 6 ml/kg and keeping the plateau pressure below 30 cmH_2O is strongly recommended in international guidelines, especially in ARDS patients. [20] In pediatric patients, the range of 5–8 ml/kg is considered the physiological norm; it is recommended not to exceed 10 ml/kg as the upper safety limit. [22, 23]

i NOTE

In VENTISENSE's volume-targeted modes, compliance is calculated after the first breath;
The device applies the closest delivered volume value starting from the second breath.

6.3.2 Respiratory Frequency (Frequency — bpm)

Respiratory rate determines how many forced breaths the device delivers per minute and is one of the fundamental components of minute ventilation (MV = Frequency × Tidal Volume). Minute ventilation is the main determinant of CO_2 removal: adjustment is made by increasing the frequency in case of hypercapnia and decreasing it when maintaining hypoxic vasoconstriction is desired.

In adult patients, the normal respiratory rate is 12–20 bpm, and the initial setting for mechanical ventilation is usually 12–16 bpm. In obstructive diseases such as COPD and asthma, a slow frequency (8–12 bpm) and a long expiration time are preferred; otherwise, a new breath begins before expiration is complete, and auto-PEEP (air entrapment) develops. In pediatric patients, the normal frequency varies between 20–60 bpm depending on age.

6.3.3 Inspiration Time (Insp. Duration)

Inspiration time defines how many seconds the inspiration phase lasts in each breath cycle. Together with the total cycle time (60 / Frequency), it determines the I:E ratio (inspiration:expiration ratio). The normal physiological I:E ratio is 1:2, meaning that for every unit of inspiration time, there are two units of expiration time. This ratio allows the lungs to fully empty through passive recoil (elastic retraction).

In obstructive pulmonary diseases (COPD, asthma), a short inspiration time (I:E 1:3 or 1:4) is preferred to prolong the expiration time. Conversely, in severe ARDS, the I:E ratio can be set to 1:1 or even inverse (2:1) to increase mean airway pressure and improve oxygenation; however, this strategy requires deep sedation. The typical adult baseline value is 0.8–1.2 seconds.

6.3.4 Maximum and Minimum Inspiration Time

In spontaneous breathing support modes (PSV, BiLEVEL, SIMV), the inspiration time is variable, not fixed; it can differ with each breath depending on patient effort and when the expiration trigger criterion is met. The maximum inspiration time is the upper limit at which the inspiration phase will end: when this time is reached, the device interrupts inspiration and switches to expiration, regardless of whether the expiration trigger criterion is met or not. This feature prevents pressure build-up that can be caused by prolonged inspiration in patients with high lung compliance or in cases of leakage.

The minimum inspiration time determines how long after inspiration the inspiration phase can be terminated. It is used to prevent short and inadequate inspirations when premature expiration is triggered (especially with high expiration trigger sensitivity).

6.3.5 Apnea Duration

This parameter, specific to PSV mode, defines the maximum time that passes without detecting spontaneous breathing. When this time is exceeded, the device switches to apnea backup mode and begins delivering forced breaths at the set backup frequency. This mechanism protects patient safety in situations where spontaneous breathing is weakened or temporarily stopped (sleep apnea, sedative effect, fatigue). The typical apnea duration is set to 15–30 seconds depending on the clinical situation.

i NOTE

In PSV mode, an alarm is generated when apnea backup is activated.
Backup frequency and inspiration duration parameters must be predefined.

6.3.6 Flow Rate (Specific to HFO Mode)

In HFO (High Flow Oxygen) mode, this parameter defines the constant and continuous flow of oxygen mixture delivered to the patient in liters per minute (L/min). In high-flow oxygen therapy (HFNC — High Flow Nasal Cannula), the flow rate is typically set between 20–60 L/min; the high flow clears respiratory dead space, creates a small amount of positive pressure (flushing effect), and increases patient comfort. This mode should be used with an external oxygen source and a heated humidifier.

6.4 Triggering and Synchronization Parameters

6.4.1 Inspiration Trigger Sensitivity (Inspiratory Triggering)

Inspiration triggering is the mechanism by which the device initiates assisted inspiration by detecting the patient's spontaneous breathing effort. VENTISENSE uses a flow-triggered system: when the patient creates a negative flow change in the circuit with a small inspiratory effort, the device detects this change and initiates assisted breathing. Trigger sensitivity refers to the minimum flow threshold (L/min) required for the device to trigger breathing.

When the trigger sensitivity is set too high (low threshold), artifacts such as heartbeats or circuit vibrations can cause involuntary triggering (auto-triggering). Too low sensitivity (high threshold), on the other hand, causes the patient to exert excessive effort to trigger breathing, leading to delayed triggering asynchrony and increased respiratory work. The optimal trigger threshold should be adjusted according to individual patient characteristics to minimize asynchrony.

6.4.2 Expiratory Trigger Sensitivity (Exp. Trigger)

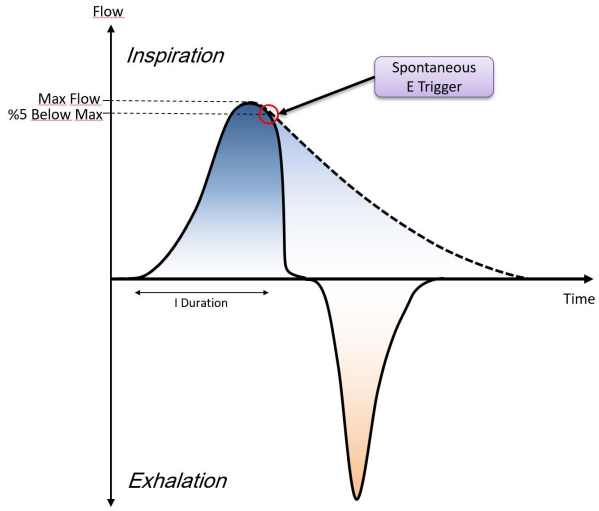


Figure 30a — Exposure Trigger 5% (Most Sensitive)

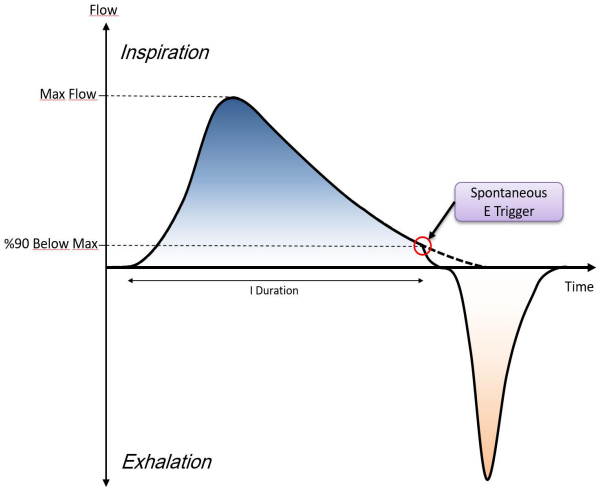


Figure 30b — Exponential Triggering 100% (Roughest)

Expiration triggering (cycling-off criterion) determines when the inspiration phase ends in modes including PSV and spontaneous breathing. The device uses the peak inspiratory flow (PIF) reached during

inspiration as a reference; expiration triggering occurs when the flow drops by a set percentage from this peak value. In VENTISENSE, this sensitivity can be adjusted between 5% and 100%.

5% (most sensitive): Expiration is triggered by a slight drop in flow from peak value; a short and rapid inspiration cycle occurs. Preferred in restrictive lung disease and low compliance situations. [46, 47] There is a risk of premature cycling and double triggering at the very sensitive setting. 100% (coarsest): Triggering occurs at the point where peak flow approaches zero; allows for a long and slow inspiration cycle. Used to reduce the risk of delayed triggering and intrinsic PEEP in obstructive diseases with high airway resistance such as COPD.

6.4.3 Trigger Lock

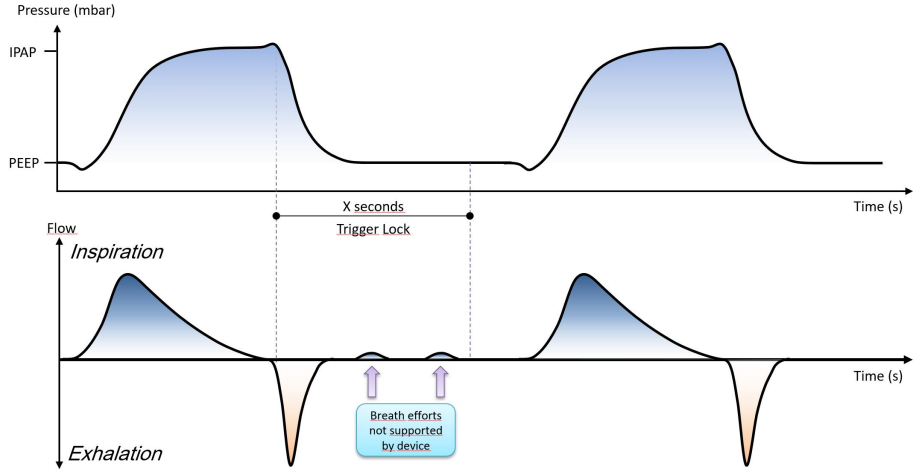


Figure 31 — Trigger Lock Mechanism

The trigger lock disables spontaneous breath triggering for a set duration from the beginning of the expiration phase. This mechanism is primarily used to prevent patient-device asynchrony (especially unintentional premature triggering and double triggering). Preventing the trigger window from opening as soon as expiration begins allows the lungs to empty sufficiently and PEEP to remain stable. If the trigger lock duration is kept too long, it can increase the patient's waiting time for triggering and increase the work of breathing; therefore, it should be adjusted in a balanced manner.

6.5 Specific Respiratory Support Parameters

6.5.1 Inspiratory Slope (Rise Time)

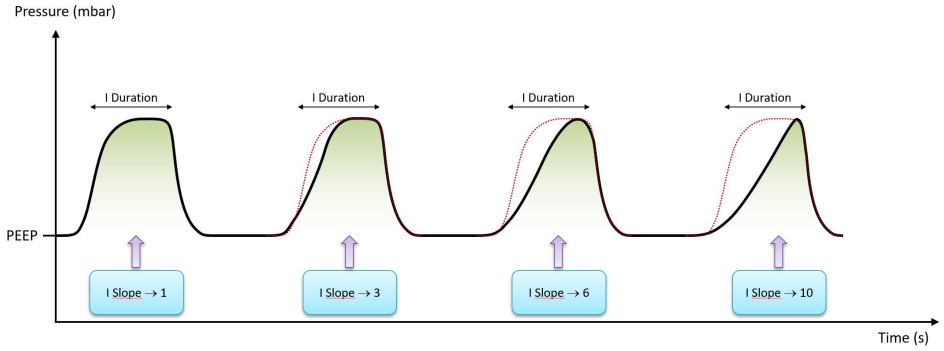


Figure 32 — Effects of Inspiration Slope (Rise Time)

Inspiratory rise time/pressure ramp is a critical parameter for patient comfort and respiratory synchronization, defining the time it takes for the device to reach the target inspiratory pressure (IPAP) from the PEEP level. [66] In VENTISENSE, it is adjustable between 1 and 10: Level 1 represents the steepest (fastest) rise ramp, and Level 10 represents the slowest rise ramp.

A rapid rise time (low range) alleviates flow starvation in patients with high respiratory effort and improves patient-device synchronization; however, excessively rapid rise can lead to uncomfortable pressure and flow peaks at the beginning of inspiration. A slow rise time (high range) allows for more gradual adaptation of the patient to the pressure; however, very slow rise can result in delayed target pressure attainment and increased inspiratory work. For optimal adjustment, patient respiratory effort, circuit flow curves, and patient comfort should be evaluated together.

6.5.2 Sigh

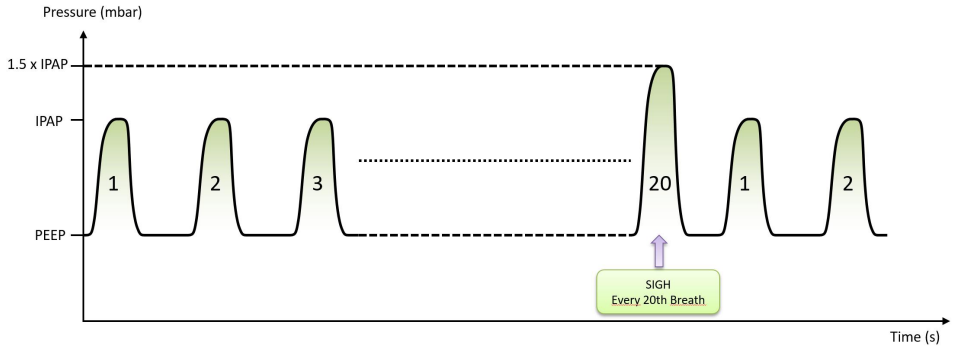


Figure 33 — Sighing Activity

Sighing is a periodic deep breath that a human spontaneously performs about 12 times an hour in nature, with a volume 1.5–2 times larger than the normal tidal volume. [48] Its physiological function is to prevent atelectasis and reopen closed alveoli. In mechanical ventilation, the application of constant tidal volume leads to a lack of spontaneous sighing and may predispose to alveolar closure and atelectasis over time.

In VENTISENSE, a breath of 1.5 times the inspiratory pressure is applied every 20 breaths. Clinical studies [48, 49] have shown that when used in conjunction with PSV, sigh increases end-expiratory lung volume (EELV), improves compliance, raises PaO_2 , and reduces inspiratory respiratory process (P0.1). It is particularly recommended to reduce atelectrauma in patients requiring long-term mechanical ventilation.

7. ALARMS — FULL ALARM REFERENCE

VENTISENSE is equipped with a priority alarm system compliant with the IEC 60601-1-8 standard. Alarms are categorized as High, Medium, and Low priority and are transmitted simultaneously as audible (acoustic) and visual (LED + screen notification). This section describes all 36 alarms of the device in detail under three classes, including their algorithmic operating principle, clinical significance, possible causes, and intervention methods.

⚠ WARNING

Never ignore alarm signals. Every alarm is a critical warning about the patient's or device's condition.

When the alarm is activated, FIRST assess the patient. If in doubt, switch to manual ventilation with an Ambu bag.

Avoid setting alarm limits too broadly; this can lead to dangerous situations being detected too late.

7.1 General Alarm Management Principles

The universal response sequence to follow when any alarm is activated:

- First, assess the patient: Consciousness, color, respiratory effort, chest movement, SpO_2 , hemodynamic findings.
- Switch to manual ventilation if necessary: Initiate manual ventilation with an Ambu bag, connect to an independent oxygen source. The principle of "patient first, device second" applies in all alarm situations. [70]
- Systematically check the circuit: Visually and manually inspect all connection points from the patient to the device.
- Identify and resolve the cause of the alarm: Systematically evaluate possible causes.
- Restart ventilation and continue monitoring: Verify parameters after the problem is resolved.

ℹ NOTE

It is mandatory to have a ready and functioning ambu bag at each patient's bedside.

Alarm silencing only provides temporary acceptance intervention; it will reactivate until the cause of the alarm is resolved.

To avoid unnecessary alarm fatigue: Set alarm limits appropriate to the clinical situation, not wide limits. [60, 70]

7.2 CLASS 1: MANDATORY ALARMS

Mandatory alarms are a class of alarms that directly threaten patient safety and cannot be disabled. According to IEC 60601-1-8, these alarms remain active in all ventilation modes, cannot be switched off by the user, and always produce audible and visual notifications. Nine mandatory alarms are defined in VENTISENSE.

Alarm Name	Priority
Disconnection	High
Blockage	High
High PEEP Pressure	High
Low PEEP Pressure	High
High Pressure	High
Battery Alarm 10%	High
Fall Alarm	High
High pressure limit reached.	Middle
Low pressure limit reached.	Middle
AND Unreadable	Middle

7.2.1 Disconnection Alarm

The disconnection alarm is activated when a significant air leak or complete disconnection occurs in the ventilation circuit. This alarm is of high priority because loss of ventilation support is life-threatening; hypoxia can develop within minutes, especially in patients who have no or very weak spontaneous breathing.

Alarm Triggering Criteria

The alarm is triggered if at least one of the following conditions is met for 5 seconds:

Condition	Threshold	Clinical Significance
Average Inspiratory Flow > Threshold	Adult: 60 LPM / Pediatric: 46 LPM	The circuit is open; air is not reaching the patient.
Leakage Value > Threshold	20 LPM	The Insp-Exp spread exceeds the normal limit.
(Inspiratory Flow > 8 LPM) AND (Expected Flow > 8 LPM)	—	Ventilation continues despite partial rupture.

The device independently monitors the following four connection points: exhalation valve hose connection, expiration line, inspiration line, and patient-side connection (cannula/tube/mask).

Possible Causes

From where	Explanation	Risk Factors
Complete disconnection from patient contact	Complete disconnection of the cannula, tube, or mask from the circuit. Complete loss of ventilation in a patient without spontaneous breathing.	Patient movement, coughing, caregiver intervention, mask slipping during sleep.
Loose circuit connection	A connection that is not fully locked in any component (Y-piece, adapter, filter).	Points that were not compressed sufficiently during installation.
Exhalation valve rupture	If the exhalation valve protrudes from the expiratory inlet, the inspiratory pressure cannot be maintained.	Inadequate restraint, patient movement.
Hose rupture or hole	Continuous leakage due to physical damage to the circuit tubing.	Prolonged use, mechanical stress, bites (pediatric)
Major mask leak (NIV)	Breakdown of the seal between the face mask and the skin. In one study, clinically significant leakage was detected in 76% of NIV patients. [57]	Ill-fitting mask, excessive/insufficient head strap, beard, sleeping with mouth open.
cerebrovascular leakage (invasive)	Insufficient inflation or deflation of the endotracheal/tracheostomy tube cuff. The target cuff pressure should be 20–30 cmH_2O.	Skipping routine cuff pressure check can lead to cuff puncture.
Mouth leak (nasal mask)	If the mouth is left open during nasal mask use, there will be significant leakage throughout the entire circuit.	REM sleep, sedative medications, decreased jaw tone.

Clinical Outcomes

- Complete rupture — patient without spontaneous breathing: Life-threatening hypoxia and hypercapnia within minutes; risk of sudden cardiac arrest. This is the most urgent alarm scenario.
- Partial leakage — patient with spontaneous breathing: Sufficient tidal volume cannot be delivered; SpO_2 decrease and $PaCO_2$ increase develop gradually; compensatory mechanisms may lead to delayed detection of the alarm.

- Chronic large leak (NIV): Treatment efficacy is severely reduced; nocturnal hypoventilation, morning headache and somnolence develop. [57, 58]

Intervention Algorithm

My name	Action
1	SpO_2 , consciousness, respiratory effort — is there spontaneous breathing?
2	In case of suspicion, maintain ventilation with an Ambu bag and connect an independent oxygen source.
3	Visually and manually check all connections from the patient to the device.
4	Check patient connection: cannula/tube position, mask fit, cuff pressure (20–30 cmH_2O)
5	Tighten all T-piece, adapter, filter, and valve connections.
6	Is the exhalation valve correctly positioned and properly seated? Is the control hose attached?
7	Replace any torn/damaged circuit board components with new ones.
8	Restart ventilation; monitor leakage levels.

i NOTE

At NIV, try alternative mask types (full face, nasal, nasal pad) to reduce mask leakage.
Consider switching to a chin strap or full face mask to prevent mouth leakage.
In invasive ventilation, measure cuff pressure every 8 hours using a manometer.

7.2.2 Obstruction Alarm

The obstruction alarm is activated when it detects a significant flow obstruction in the inspiratory or expiratory line or in the patient cannula. The obstruction prevents the device from delivering air to the patient or restricts the patient's expiration; in both cases, ventilation is compromised. [59, 60]

Alarm Triggering Criteria

The alarm is activated if one of the following conditions is met within 5 seconds and 2 breath cycles:

Condition	Diagnosis	Mechanism
Maximum expansive flow < 0.8 LPM	Expiration line is blocked.	The patient is unable to expel → air entrapment, increased pressure.
Maximum Inspiratory Flow < 1.5 LPM	Inspiration pathway is blocked.	Air cannot reach the patient → insufficient tidal volume.
Avg. Inspiratory Flow < Max. Pressure/10 (Ped: /8)	Patient cannula/tube is blocked	Pressure is being applied but the flow is very low → severe obstruction.

When the alarm is activated, VENTISENSE attempts to temporarily resolve the blockage: it tries to overcome the obstruction by increasing the pressure by a maximum of 2 mbar. If this automatic response fails, the alarm continues.

Possible Causes

From where	Explanation	Risk Factors
Secretion accumulation / Mucus plug	The most common cause of obstruction. Secretions accumulating in the airway cause partial or complete obstruction; the mucus plug inside the tube obstructs both inspiratory and expiratory flow. [59]	Insufficient hydration, inadequate humidification, neuromuscular disease (reduced cough strength)
Endotracheal/tracheostomy tube kinking	Tube kinking due to neck position. Permanent deformation may occur in spirally reinforced tubes with excessive neck flexion.	Excessive neck flexion or extension
Endobronchial advancement of the tube	If the tube goes too far in → single-lung ventilation; inspiratory flow decreases.	Skipping the fixation depth check causes neck movement.
Bronchospasm	Contraction of airway smooth muscles → airway resistance significantly increases.	Asthma, COPD, allergen or irritant exposure
Circuit bending	The inspiration/expiration hose is kinked, obstructing the flow.	Long circuit, inadequate fixation, patient movement.
Water accumulation (condensation)	Water droplets accumulating in the circuit severely restrict flow.	Unheated circuit + humidifier use, cold environment.
Clogged filter (bacteria/HMEF)	Filter resistance increases dramatically when the filter becomes clogged due to secretions or moisture.	Exceeding the recommended replacement interval (24–48 hours)
Exhalation valve malfunction	Failure of the valve to close → air escapes during the expiration phase; failure of the valve to open → air entrapment.	Foreign body, secretion contamination, mechanical failure

Clinical Outcomes

- Inspiratory line obstruction: Insufficient tidal volume is delivered; hypoventilation, increased $PaCO_2$, decreased SpO_2 .

- Expiratory line obstruction: Patient unable to expel → air entrapment, increased auto-PEEP → decreased cardiac output, risk of barotrauma.
- Complete cannula obstruction: Progressively increasing pressure buildup in the lungs → the most critical scenario.

Intervention Algorithm

My name	Action
1	SpO_2 , respiratory effort, chest movement symmetry, breath sounds (auscultation)
2	Initiate ventilation with an Ambu bag. Manual ventilation: if difficult → patient obstruction; if easy → circuit obstruction.
3	Straighten circuit bends; empty water traps.
4	Check the HMEF and bacterial filters; replace them immediately if clogged or wet.
5	Auscultate respiratory sounds (rhonchi → secretions; wheezing → bronchospasm)
6	If secretions are suspected, perform aspiration using sterile technique.
7	If the catheter doesn't pass: deflate the cuff, remove the tube, and ventilate with an Ambu bag (complete blockage).
8	Check the endotracheal tube depth (typically 21–23 cm at tooth level in adults).
9	Nebulized bronchodilator (salbutamol / ipratropium) in suspected bronchospasm.
10	Check the exhalation valve; clean or replace it if it is contaminated with secretions.

⚠ WARNING

If the aspiration catheter cannot pass through the tube, there is a COMPLETE OBSTRUCTION.
In this situation, the cuff should be deflated, the tube removed, and the patient ventilated with an Ambu bag.
It is essential that the necessary equipment for re-tubation is always readily available.

7.2.3 High PEEP Pressure

The high PEEP alarm is activated when the measured end-expiratory pressure (PEEP) exceeds the set PEEP value by 3 mbar and persists for 5 consecutive breaths. This alarm usually indicates the presence of intrinsic PEEP (auto-PEEP). Auto-PEEP is a serious complication of mechanical ventilation; if not diagnosed early, it can lead to hemodynamic collapse, barotrauma, and life-threatening conditions. [53, 55]

Alarm Triggering Criteria

Condition	Duration
Measured PEEP > Set PEEP + 3 mbar	5 consecutive breaths

Intrinsic PEEP (Auto-PEEP) — Clinical Description

Intrinsic PEEP (Auto-PEEP) is the residual pressure remaining in the lungs when the next inspiration begins before the expiration phase is complete. In normal physiology, passive expiration is completed by elastic retraction and the end-respiratory pressure drops to PEEP. When auto-PEEP develops, this balance cannot be achieved; residual air accumulates in the lungs in each cycle and dynamic hyperinflation develops. [53, 54, 55]

Auto-PEEP Formation Mechanisms

Mechanism	Typical Scenario
Insufficient expiration time	High frequency or long inspiration time → breath stacking
Increased airway resistance	COPD: airway collapse; Asthma: bronchospasm; Secretion plug; Circuit kinking. COPD is the most common cause of auto-PEEP mechanical ventilation. [53]
Decreased lung compliance	ARDS, pulmonary edema — increases the risk in combination with high resistance.
Excessive minute ventilation	Very high tidal volume + frequency combination
Active expiration	Forceful expiration in an agitated patient → paradoxical auto-PEEP

Clinical Outcomes

- Barotrauma: Excessive hyperinflation raises alveolar wall tension above a critical threshold → pneumothorax, pneumomediastinum.
- Hemodynamic impairment: Increased intrathoracic pressure reduces venous return → cardiac output decreases. Auto-PEEP is the most common cause of sudden hypotension after invasive ventilation in COPD/asthma. [55]
- Triggering difficulty: The patient must first overcome auto-PEEP with each effort → respiratory work increases dramatically, "missed trigger" develops. [53]
- CO_2 retention: Hyperinflated dead space increases → effective alveolar ventilation decreases → $PaCO_2$ increases.

Other Possible Causes

From where	Explanation
Exhalation valve malfunction — it won't close.	If the valve does not close during inspiration, pressure builds up.
Incorrect PEEP setting	Entering too high PEEP by mistake
Water accumulation in the expiration line	Increases expiratory resistance → auto-PEEP-like picture

Intervention Algorithm

My name	Action
1	Assess SpO_2 , blood pressure, pulse, respiratory effort, and breath sounds (wheezing?).
2	Reduce respiratory rate (2–4 bpm) → lengthen expiration time
3	Adjust the I:E ratio: extend the expiration time (e.g., 1:2 → 1:3)
4	Check circuits and water traps; remove kinks and blockages.
5	Check exhalation valve
6	Administer a nebulized bronchodilator if bronchospasm is suspected.
7	Question whether the PEEP setting is consistent with clinical rationale.
8 (Auto-PEEP)	Set external PEEP to 70–85% of auto-PEEP value → lower the triggering threshold (under expert supervision)
9 (Severe hypotension)	Temporarily interrupt the circuit for 15–30 seconds → spontaneous expiration → cardiac output recovers; rule out pneumothorax first.

⚠ WARNING

Sudden hypotension after invasive ventilation in a patient with COPD or asthma → consider hemodynamic deterioration due to auto-PEEP.
Do not perform the circuit removal maneuver without ruling out pneumothorax.

7.2.4 Low PEEP Pressure

The low PEEP alarm is activated when the measured end-expiratory pressure falls 3 mbar below the set PEEP value and this condition persists for 5 consecutive breaths. PEEP is a critical determinant of alveolar patency and oxygenation; PEEP loss can rapidly lead to atelectasis and impaired oxygenation in the lungs.

Alarm Trigger Criteria

Condition	Duration
Measured PEEP < Set PEEP − 3 mbar	5 consecutive breaths

Possible Causes

From where	Explanation	Risk Factors
Circuit leakage	Loose connection or torn hose → pressure cannot be maintained during the expiration phase.	Assembly error, prolonged use.
The exhalation valve remains open.	Failure of the valve to close during the expiration phase → PEEP cannot be generated.	Foreign body, mechanical failure
cerebrovascular leakage (invasive)	Insufficient cuff pressure → PEEP loss + tidal volume loss	Skipping routine cuff pressure check
Major mask leak (NIV)	In NIV, mask seal failure → expiratory pressure decreases.	Improper mask, head strap misalignment.
Patient active expiration	Very forceful expiration → transient PEEP drop; seen in patient-device asynchrony.	Patient agitation, inadequate sedoanalgesia

Clinical Outcomes

- Alveolar collapse and atelectasis: With PEEP loss, alveolar closure begins at the end of expiration.
- Oxygenation impairment: Continued perfusion of atelectatic alveoli increases intrapulmonary shunt; PaO_2 decreases.
- Atelectrauma: Repetitive opening-closing damage is a key component of VILI. [1]
- Cardiogenic complication: A decrease in PEEP may increase left ventricular afterload.

Intervention Algorithm

My name	Action
1	Monitor SpO_2 and oxygenation — is hypoxia developing?
2	Systematically check all circuit connections.
3	Measure cuff pressure during invasive procedures (target: 20–30 cmH_2O)
4	Identify the source of the leak in the NIV; adjust the headband tension.
5	Check the exhalation valve — is it closing?
6	Restart ventilation; monitor measured PEEP after 5–10 breaths.

7.2.5 High Pressure

The High Pressure alarm is a safety mechanism designed for sudden and dangerous pressure increases caused by patient-device asynchrony. This alarm is activated especially when the patient actively exhales during the inspiratory phase of ventilation (active exhalation), resulting in airway pressure exceeding normal limits. It is active in all pressure-controlled and volume-controlled modes.

Alarm Triggering and Device Response

When the airway pressure exceeds +5 mbar or the maximum pressure setting (IPAP), the device will interrupt inspiration for safety and return to PEEP (expiratory pressure). If this happens 3 times, the device will activate a High Pressure alarm.

Primary Cause: Patient-Device Asynchrony

Patient-ventilator dyssynchrony (PVD) is one of the most common complications of mechanical ventilation. Literature reports that the incidence of asynchrony in patients undergoing mechanical ventilation varies between 5–50% depending on the study. [32, 33] Asynchrony predisposes to muscle fatigue, increased need for sedation, VILI, and poor clinical outcomes. [64]

Asynchronous Mechanisms and Their Relationship with High Pressure

Asynchronous Type	Mechanism	Its Relationship with High Pressure
Double Triggering / Breath Stacking	When a patient receives inadequate inspiratory support or the inspiration time is set too short, a second breath is triggered before expiration begins. The two breaths can stack, doubling the tidal volume. This occurs in approximately 5–10% of patients with ARDS and those receiving protective ventilation. [33, 37]	Two stacked breath volumes + the patient's active inspiratory effort raise blood pressure to pathogenic levels.
Expiratory Fighting	While the patient actively attempts to exhale during the inspiration phase, the device simultaneously delivers inspiratory gas. The resulting pressure reaches a pathological peak value: IPAP + the patient's expiratory muscle pressure.	Pathological peak pressure directly triggers this alarm.
Reverse Triggering	In a patient being ventilated from a controlled environment, the device breath initiates diaphragmatic contraction; if the timing of the contraction coincides with the device cycle, the pressure increases. [33, 38]	Pressure increase is typical at the end of the inspiration phase.
Delayed Cycling	The inspiration phase is prolonged because the expiration trigger threshold is set too low; the device is still sending inspiration while the patient actively begins to exhale.	Muscle pressure plus increased inspiratory gas pressure in a patient unable to expirate.

Other Possible Causes

From where	Explanation
Acute obstruction	Sudden secretion blockage or bronchospasm suddenly increases airway resistance → peak pressure rise. This may coincide with an obstruction alarm.
Cough	Strong contraction of the expiratory muscles → temporary peak pressure increase. The alarm usually

From where	Explanation
	resolves spontaneously when the cough is complete.
Patient agitation	An agitated or crying patient can produce strong muscle tension.
Pneumothorax	Sudden drop in compliance and increased airway resistance → peak pressure rise. If accompanied by unilateral loss of breath sounds, it indicates an emergency.
Pulmonary edema	Decreased compliance → higher pressure is required for the same volume.
Entering a maximum pressure setting that is too low.	If the setting is below the patient's actual need, the alarm becomes excessively frequent. The alarm limit should be consistent with clinical values.

Intervention Algorithm

My name	Action
1	Assess the patient: is there consciousness, respiratory effort, cyanosis, or agitation?
2	Auscultate the breath sounds: are they bilateral, is there wheezing?
3	Is it asynchrony? Observe the patient's respiratory timing and examine the circuit pressure curve.
4	Suspected obstruction → aspiration and circuit inspection
5	Suspected bronchospasm → bronchodilator
6	Suspected pneumothorax → urgent assessment, needle decompression if necessary.
7 (Asynchrony)	Re-evaluate inspiration time, expiration trigger sensitivity, and I:E ratio.
8 (Asynchrony)	Optimize trigger lock; adjust trigger sensitivity.
9 (Asynchrony)	Consider mode change (e.g., controlled → assisted); evaluate sedoanalgesia.
10	Verify that the maximum pressure limit is within the safe value determined by the clinician.

i NOTE

Temporary high blood pressure alarms caused by coughing are an expected physiological response; they are not a service alarm.

Repeated asynchrony → review mode settings; optimize ventilation parameters before frequent sedation increases. [32]

7.2.6 Battery Alarm 10%

This is a high-priority mandatory alarm that activates when the battery capacity drops to 10% (or approximately 45–50 minutes of operation time). This alarm is designed to alert the clinician well in advance of ventilation interruption and allow sufficient time for emergency power connection.

Clinical Significance and Intervention

In the event of a power outage, cable disconnection, or adapter malfunction in a home environment, the VENTISENSE's 18.5V Li-ion internal battery (~8 hours capacity) activates to maintain ventilation. There is still sufficient time for action when the battery drops to 10%; however, this alarm should absolutely not be ignored.

My name	Action
1	Connect the device to the AC power source immediately.
2	Why did the AC power cut out? (Was the cable disconnected? Is the adapter faulty? Was there a power outage?)
3	Plan for an alternative power source (UPS, generator) if the power outage lasts for a long time.
4	Provide a full battery charge soon.

⚠ WARNING

The internal battery is for emergency backup and short-term transport only; it cannot be used as a continuous primary power source.

Planning for a UPS (uninterruptible power supply) or generator in a home environment is recommended.

7.2.7 Drop Alarm

VENTISENSE is equipped with a built-in acceleration sensor that detects when the device is dropped during therapy. When the device encounters a high acceleration value exceeding a certain threshold while therapy is active — a fall, tipping over, or hard impact — the Fall Alarm is triggered.

Alarm Trigger Mechanism

The accelerometer continuously monitors sudden changes in speed (acceleration) in three axes. When a sudden change in acceleration exceeding normal movement limits (fall signature) is detected during therapy, the alarm is activated immediately. This mechanism covers scenarios such as hose pulling, tripping and falling, or falling out of bed.

Possible Clinical Consequences of Falls

A fall during therapy can lead to many different dangers:

- Patient disconnection: During a fall, a hose, mask, or cannula may detach; the patient's ventilation support is suddenly interrupted.
- Exhalation valve dislodgement: A fall or impact can strain the valve connection; if the valve dislodges, pressure control is lost during the exhalation phase.
- Disconnection of circuit connection points: Y-pieces, filter adapters, or hose connections may loosen; this can create hidden leaks, even if they seem clinically insignificant.
- Device mechanical damage: Screen breakage, port damage, or stress fractures in internal components may occur; even if there are no visible problems, the integrity of internal components may be compromised.
- Disconnected battery or power outage: A severe impact may affect the battery compartment or adapter connection.

Intervention Algorithm

My name	Action
1	FIRST, assess the patient: Consciousness, SpO_2 , respiratory effort — is ventilation ongoing?
2	Is the patient's connection secure? Check the mask/cannula/tube position.
3	Check that the exhalation valve is in place, in the correct direction, and fully seated.
4	Tighten all circuit connection points (Y-piece, filter, hose ends) by hand.
5	Visually inspect the device's exterior: screen, ports, power input, battery cover.
6	Check the power supply connection; is the AC cable and adapter damaged?
7	Restart ventilation and monitor tidal volume, pressure, and leakage values over several breaths.
8	Contact service if there is apparent mechanical damage or if ventilation values deviate from normal.
9	Even if the device functions properly after a fall, it is recommended to report the incident to technical service.

NOTE

Even if the device appears to function without problems after being dropped, it may still have internal component damage.

Inform the service team at the next scheduled maintenance check following the fall.

Position the device on stable surfaces, in easily accessible locations, and ensure the circuit hoses are not strained.

7.2.8 High Pressure Limit Reached

This alarm is specific to volume-targeted modes (VCV, VCV-A, SIMV-V). In volume-controlled ventilation, the device dynamically increases the pressure required to reach the target tidal volume. However, if this increase reaches the device's safety pressure limit — before the target volume is reached — the "High Pressure Limit Reached" alarm is activated.

The Difference Between 7.2.8 and 7.2.5 (High Pressure)

Feature	High Pressure (7.2.5)	High Pressure Limit Reached (7.2.8)
Mod	All modes	Volume-targeted modes only (VCV, VCV-A, SIMV-V)
Mechanism	Sudden pathological pressure increase (asynchrony, obstruction)	The pressure required to reach the volume target has reached its limit.
Device response	Inspiratory mode is interrupted, switching to PEEP; alarm after 3x.	Volume is insufficient; an alarm is triggered.
Clinical meaning	Asynchrony, obstruction, pneumothorax	Sudden drop in compliance or increase in resistance

Possible Causes

From where	Explanation
Sudden drop in lung compliance	Atelectasis, pneumonia, pulmonary edema, ARDS — higher pressure is needed for a stiffening lung; the limit is exceeded, volume becomes insufficient.
Increased airway resistance	Bronchospasm, secretion plug, tube kinking — increased resistance increases pressure requirements.
Setting the maximum pressure limit too low	If the safety limit is not high enough, the limit will be reached before the desired volume is achieved.
Endobronchial advancement of the tube	Single-lung ventilation → effective compliance decreases.
Pneumothorax	Sudden loss of compliance → additional pressure requirement → limit overshoot

Intervention Algorithm

My name	Action
1	Assess the patient: breath sounds, chest movement symmetry, SpO_2
2	Listen to the lungs: are they bilateral? Are there signs of atelectasis or pneumothorax?
3	Increased airway resistance → aspiration, bronchodilator, tortuosity control
4	Decreased compliance → evaluate underlying clinical conditions (pneumonia, edema, ARDS)
5	Check if the maximum pressure limit has been set correctly.
6	The goal is to treat the underlying cause, not just increase IPAP as a temporary solution.
7	A switch from volume-targeted mode to pressure-targeted mode (PCV) could be considered.

7.2.9 Low Pressure Limit Reached

This alarm is specific to volume-targeted modes. If the pressure required to reach the target tidal volume falls below the device's minimum pressure setting — meaning the device reaches the target volume with significantly less pressure than expected — the "Low Pressure Limit Reached" alarm is activated.

The Difference Between 7.2.9 and Low PEEP Alarm

Feature	Low PEEP Pressure (7.2.4)	Low Pressure Limit Reached (7.2.9)
Measurement time	End of expiration	During the inspiration phase
Mod	All modes	Volume-targeted modes only
Meaning	PEEP is not adequately protected (leaked)	The pressure required to reach tidal volume is much lower than expected (overcompliance or large leakage).

Possible Causes

From where	Explanation
Large circuit leakage	In the presence of a large leak, the pressure required to reach the volume decreases; however, the actual tidal volume may not be reaching the patient.
A sudden increase in lung compliance.	For example, complete muscle relaxation with over-sedation or after pleural effusion drainage → transition from stiffness to a large and soft lung.
Setting the minimum pressure too high	A false alarm is generated if the safety limit is higher than the actual pressure.
cuff deflation (invasive)	If the cuff is fully lowered or near the outlet, tidal volume escapes the circuit; the pressure remains low.

Intervention Algorithm

My name	Action
1	Check if tidal volume is actually being delivered to the patient (is there chest movement?)
2	Check for circuit leaks: connection points, cuff pressure, mask seal.
3	Was there a sudden change in the patient's clinical condition? (Muscle relaxation, pleural effusion?)
4	Verify that the minimum pressure setting is appropriate for the clinical situation.
5	If the leakage is large → Apply the Disconnection algorithm.

7.2.10 VE Unreadable

The "VE Unreadable" alarm is activated if the expiratory flow sensor is unable to measure. In this case, the expiratory flow cannot be measured, and therefore the expiratory volume (VE — Volume Expired) cannot be calculated. The alarm does not mean the device has stopped ventilation; ventilation continues, but the expiratory volume becomes unmonitorable.

Physiological Basis

VENTISENSE measures expiratory flow using a flow sensor on the device side of the exhalation valve. For this sensor to function correctly, the exhalation valve must be securely seated in the device port, and the sensor surface must be clean and dry. If the sensor cannot read, the VE volume cannot be calculated, meaning that one of the key criteria for an obstruction alarm cannot be assessed.

Possible Causes

From where	Explanation	Solution
Exhalation valve coming out of the port	The most common reason. When the valve is disconnected from the device, the sensor is deactivated; airflow cannot be detected.	Ensure the valve is correctly positioned and fully seated; check the locking mechanism.
Moisture — condensation	Respiratory moisture can cause moisture to accumulate on the sensor surface; condensed water droplets impair flow detection.	Leave the device without ventilation for a few minutes; the moisture may evaporate. If necessary, adjust the circuit routing to keep the valve clean.
mucus or secretion discharge	Patient secretions or mucus may splash onto the sensor side of the valve; this is a temporary contamination.	Carefully clean the sensor side of the valve; install a new valve if necessary.
Sensor temporary malfunction	The sensor may temporarily become unresponsive due to high humidity or contamination; it should recover spontaneously once the source is removed.	Addressing the cause and waiting a few minutes is usually enough.

Intervention Algorithm

My name	Action
1	Assess the patient: Is ventilation ongoing? Chest movement, SpO_2
2	Check that the exhalation valve is securely seated in the device port.
3	Is there any moisture or secretion on the valve sensor surface? Visually inspect.
4	If there is moisture: remove the valve, wait for the sensor surface to dry (a few minutes).
5	If there is secretion: carefully clean the valve; install a clean valve if necessary.
6	Reinstall the valve; did the alarm go off?
7	If the alarm persists, contact customer service.

i NOTE

During a VE Unreadable alarm, ventilation continues but expiratory volume cannot be monitored. During this period, closely monitor the patient; continue monitoring chest movement and SpO_2 . Repeated and unreadable VE alarms may require exhalation valve or sensor replacement.

7.3 CLASS 2: ADJUSTABLE ALARMS

Adjustable alarms are a class of alarms that can be customized by the clinician according to the patient's clinical condition and individual ventilation profile. Setting the limits of these alarms too wide can lead to delayed detection of dangerous situations, while setting them too narrow can lead to unnecessary alarm fatigue and cause the clinician to ignore critical warnings. [60, 70] For each patient, the limits should be individualized according to the target parameters, clinical condition, and ventilation mode.

Alarm Name	Typical Adjustment Guide
Apnea Alarm	Target: 15–30 seconds (in PSV/BiLEVEL/CPAP modes)
High frequency	Approximately 150% of the set frequency
Low Frequency	Approximately 60% of the set frequency
High Inspiratory Volume	Target TV 150% (not exceeding 8 ml/kg IBW)
Low Inspiratory Volume	60-70% of Hedef TV
High Expiratory Volume	150% of Hedef TV
Low Expiratory Volume	60-70% of Hedef TV
High Minute Ventilation Volume	Target MV 120–150%
Low Minute Ventilation Volume	Target MV is 60–80%
Leakage Alert	According to clinical tolerance guidelines (1–20 LPM)
High FiO_2	10–15% above target FiO_2
Low FiO_2	5–10% below target FiO_2 .
High SpO_2	With external pulse oximeter connection (not yet available)
Low SpO_2	With external pulse oximeter connection (not yet available)
High Heart Rate	With external pulse oximeter connection (not yet available)
Low Heart Rate	With external pulse oximeter connection (not yet available)

7.3.1 Apnea Alarm

The apnea alarm is activated when no respiratory effort is detected by the patient for a specified period in spontaneous breathing support modes (PSV, BiLEVEL, CPAP). This alarm is a critical safety mechanism that prevents complete cessation of ventilation in spontaneous breathing-dependent modes. [41, 42]

Working Mechanism

When the apnea period ends, VENTISENSE automatically switches to backup mode: it begins delivering forced breaths with the set backup frequency and inspiration duration. This backup ventilation is activated simultaneously with the apnea alarm and continues until the patient's spontaneous breathing resumes.

Possible Causes

From where	Clinical Description	Risk Factors
Excessive sedation / Opioid effect	Central respiratory drive suppression is the most common cause. Sedative or opioid drugs reduce or completely suppress the respiratory drive.	New sedation change, opioid initiation, drug accumulation.
Disease progression	In advanced stages of neuromuscular diseases, the respiratory center may weaken; spontaneous breathing may become insufficient.	ALS, Duchenne, SMA advanced stage
Central sleep apnea	The temporary interruption of respiratory impulses by the central nervous system during sleep.	Brainstem-affected neurological disease, heart failure
False apnea diagnosis due to circuit leakage.	In the presence of a large leak, the trigger flow threshold cannot be met; the device may not be able to detect true spontaneous breathing.	Mask leak, head leak
The trigger sensitivity is very low.	Very high trigger threshold → weak patient effort undetectable → false apnea alarm.	Especially in patients with weak respiratory muscles
Deep sleep (REM)	Temporary respiratory irregularities during REM sleep are normal in some patients; however, prolonged periods of apnea are pathological.	OHS, OSA

Clinical Outcomes

- If apnea's backup mechanism fails or is insufficient: Hypoxia, hypercapnia, loss of consciousness, cardiac arrest.
- False apnea alarm: Unnecessary backup ventilation → patient-device asynchrony, sleep disruption, comfort disturbance. [39]
- Recurrent nocturnal apneas: Morning headache, daytime somnolence, hypercapnic awakening — require nocturnal monitoring.

Intervention Algorithm

My name	Action
1	Has backup ventilation been activated? Is it working? → Is SpO_2 stable?
2	Assess the patient: consciousness, color, respiratory effort.
3	When was the sedation dose last changed? Does it have opioid or sedative effects?
4	Check for circuit leakage → large leakage can cause

My name	Action
	false apnea detection.
5	Is the trigger sensitivity too high (threshold too high)? → Lower the Insp. trigger value.
6	Are there any neurological changes? Is consciousness suppressed? Inform your doctor.
7	Is sedation reduction necessary? → Physician's decision
8 (Night alarm)	Recurrent apnea throughout the night → perform transcutaneous CO_2 or oximetry monitoring; assess PSV → BiLEVEL transition.

i NOTE

In PSV mode, be sure to define the apnea backup frequency and inspiration duration beforehand.

If the apnea alarm duration is set too short, it can cause false alarms; if it is set too long, it can cause a delay in intervention.

Recurrent apnea alarms are a sign of nocturnal hypoventilation; nocturnal oximetry or capnography should be planned.

7.3.2 High Frequency / Low Frequency Alarms

Frequency alarms are activated when the total measured respiratory rate (spontaneous + device-induced breaths) exceeds the set limits. Respiratory rate is a key indicator of CO_2 clearance, patient-device synchronization, and the patient's overall respiratory load.

High Frequency Alarm

It gives an alarm when the respiratory rate increases significantly (tachypnea). In adult patients, the normal respiratory rate is 12–20 bpm, and the typical upper limit of alarm in mechanical ventilation is determined as ~150% of the set frequency or according to the clinical situation. [3]

From where	Explanation
Inadequate ventilation support.	PS or IPAP is too low → the patient tries to equalize CO_2 by breathing more without adequate support.
Pain or agitation	Increases respiratory drive; physiological stress response.
Hypercapnia / metabolic acidosis	Increased $PaCO_2$ → increased central respiratory drive → tachypnea
Hypoxia	Decrease in SpO_2 → peripheral chemoreceptor stimulation → increased respiratory rate
Fever / infection	With every 1°C increase in fever, O_2 consumption and CO_2 production increase → respiratory rate rises.
Auto-PEEP	Due to difficulty triggering, the patient makes numerous efforts; some cannot trigger the trigger but the frequency increases.
Patient-device asynchrony	Insufficient or inappropriate support → the patient increases their own breathing.

Low Frequency Alarm

The system triggers an alarm when the respiratory rate drops to a critical level (bradypnea). In modes involving spontaneous breathing (PSV, BiLEVEL), if the respiratory rate falls below the reserve frequency, it is evaluated together with an apnea alarm.

From where	Explanation
Excessive sedation / opioid suppression	Suppression of the central respiratory drive → bradypnea or apnea
Disease progression	Neuromuscular progression → respiratory muscles failed
Extensive ventilation support	High PS or IPAP → excessive CO_2 is excreted → respiratory drive is reduced (hypocapnic suppression)
Hypothermia	Metabolism slows down → CO_2 production decreases → respiratory rate decreases.
Circuit leakage (false alarm)	The frequency measured during a major leak may not reflect reality.

Intervention

High frequency	Low Frequency
Hypoxia/hypercapnia? → Blood gas analysis or capnography	Sedation control → reduce if necessary
Is ventilation support adequate? → Increase PS/IPAP	Neurological changes? → Inform your doctor.
Pain/agitation → Sedoanalgesia management	Excessive PS → reduce FiO_2 /PS; Track CO_2
Suspected infection → Fever, inflammation parameters	Trigger the apnea alarm → Apply the apnea episode algorithm.

7.3.3 Inspiration/Expiration Volume Alarms

VENTISENSE independently monitors both inspiratory (VI) and expiratory (VE) volumes, and separate high/low alarm limits can be defined for each. Inspiratory volume refers to the gas the device delivers to the patient, while expiratory volume refers to the gas the patient exhales. The difference between these two values reflects the leakage volume in the system.

High Inspiratory/Expiratory Volume

The alarm is activated when the measured tidal volume exceeds the upper limit. High tidal volume is critical for volutrauma and lung injury (VILI). The ARDSNet study [20] demonstrated that limiting tidal volume to 6 ml/kg IBW significantly reduced ARDS mortality; above 8 ml/kg, the risk of mortality increased. [46]

From where	Explanation
High PS/IPAP — extreme support	High support in pressure-controlled modes → larger-than-expected tidal volume when patient compliance is good.
Patient-device asynchrony — breath stacking	Double trigger/breath stacking → two breaths in a single cycle → double volume [33, 37]
Increased lung compliance	Edema resolution, bronchospasm subsidence → larger volume at the same pressure
Increased respiratory drive	Pain, agitation, hypercapnia → patient takes deep breaths
Setting the alarm limit too low	Strict limits that do not reflect clinical reality → unnecessary alarms

Low Inspiratory/Expiratory Volume

The alarm is activated when tidal volume falls below the lower limit. Low tidal volume indicates a risk of hypoventilation and hypercapnia.

From where	Explanation
Circuit leakage	The transmitted volume is lost through leakage; the measured volume is low.
Blockage	Airway or circuit obstruction → reduced delivered volume
Compliance decline	Stiffening lungs → less volume at the same pressure (in pressure-controlled modes)
Respiratory drive reduction	Sedation, neuromuscular disease progression → weak spontaneous exertion → low volume
PS/IPAP inadequacy	Insufficient support → patient unable to produce sufficient volume

Intervention

High Volume	Low Volume
Breath stacking? → Asynchrony assessment	Leak? → Connection drop algorithm
Is PS/IPAP too high? → Reduce; monitor tidal volume.	Blockage? → Blockage algorithm
Lung protective limit: 6–8 ml/kg IBW [20]	Change in compliance? → Underlying clinical assessment

7.3.4 Minute Ventilation Volume Alarms

Minute ventilation (MV = Frequency × Tidal Volume) is the most direct indicator of alveolar CO_2 clearance. MV monitoring alarms detect hypoventilation (low MV → hypercapnia) and hyperventilation (high MV → hypocapnia/alkalosis) early. [47]

High Minute Ventilation

Both an increase in frequency and an increase in tidal volume can increase MV.

From where	Explanation
Follow-up	Pain, agitation, hypercapnia, hypoxia, fever → respiratory rate increases → mechanical ventilation increases.
Breath stacking	Double triggering → large, stacked breaths disrupt the MV calculation.
Extensive ventilation support	Very high PS/IPAP → large tidal volume + patient triggering → high MV.
High frequency setting	Very high frequency setting by the clinician
Metabolic acidosis	Compensatory hyperventilation → effort to lower $PaCO_2$ → increased mechanical ventilation.

Low Minute Ventilation

Both frequency reduction and tidal volume reduction decrease MV.

From where	Explanation
Large circuit leakage	Losses due to leakage → measured MV does not reflect reality
Blockage	Airway obstruction → decreased tidal volume → decreased mechanical ventilation
Excessive sedation	Suppression of the respiratory drive → both frequency and volume decrease.
Neuromuscular disease progression	Respiratory muscle strength is failing → MV is decreasing
Inadequate ventilation support.	PS/IPAP is too low → patient is not receiving enough support → MV is insufficient.

Intervention

- High mechanical ventilation (MV): Identify the cause (tachypnea, asynchrony, metabolic acidosis) → treat the cause; reduce PS/IPAP if excessive; monitor CO_2 /pH.
- Low mechanical ventilation: Rule out leakage and obstruction; review sedation; assess PS/IPAP increase; inform physician if neurological changes are present.

7.3.5 Leakage Alarm

The leak alarm is activated if the circuit leakage value, calculated from the difference between inspiratory and expiratory volumes, exceeds the threshold set by the clinician. In VENTISENSE, the leak alarm threshold can be set between 1 and 20 LPM; leaks above this value trigger an alarm. This alarm operates independently of the Disconnection alarm — while Disconnection uses a fixed threshold value, the Leak Alarm is customizable by the clinician. Although small leaks are tolerable in NIV, large leaks impede effective ventilation. [57, 58]

The Concept of Escape: Voluntary and Involuntary

There are two types of leaks in non-invasive ventilation:

- Intentional leakage: Continuous release of air through the expiration port designed to prevent rebreathing in single-hose circuits. This leakage is known and accounted for by the device.
- Unintentional leakage: Unintentional leakage from between the mask and skin, from the mouth or from circuit connections. This leakage leads to triggering difficulty, low tidal volume, prolonged inspiration and patient-device asynchrony. [58]

Possible Causes

From where	Explanation	Risk Factors
Mask mismatch	An ill-fitting mask is the most common source of leaks. The mask position may change during sleep, increasing leakage.	Small/large mask, flat or wide face profile, beard
Mouth leak (nasal mask)	When a patient wearing a nasal mask opens their mouth, gas escapes from the entire system.	REM sleep, sedative medications, neuromuscular muscle weakness
Headband insufficient tension	Too loose a head strap → the mask moves, leakage increases.	The patient is moving; the caregiver is incorrectly adjusting the patient.
Circuit connections	Loose adapter, filter, or Y-piece connection.	Prolonged use causes hose tension.
cerebrovascular leakage (invasive)	Insufficient cuff pressure → leakage around the tube.	Skipping routine measurement

Setting the Leakage Alarm Limit

Correctly setting the leakage threshold is critical. Some leakage is inevitable in patients undergoing NIV (non-invasive intravenous injection) (including voluntary leakage). Setting the leakage limit too low will generate unnecessary alarms, while setting it too high will lead to delayed detection of significant leakages. As a general principle, a threshold approximately 1.5–2 times the level of voluntary leakage is an appropriate starting point; then it is individualized.

Intervention

My name	Action
1	Identify the source of the leak: mask, mouth, circuit, head?
2	Mask leak → Adjust head strap tension; try alternative mask type.
3	Mouth leakage → consider switching to a chin strap or full face mask
4	Circuit leakage → compress all connections
5	Head leakage → bringing the pressure to 20–30 cmH_2O
6	Is the leakage limit appropriate? Readjusted by the clinician if necessary.

7.3.6 High FiO_2 / Low FiO_2 Alarms

FiO_2 alarms are activated when the inspiratory oxygen fraction, measured by the device's oxygen sensor, falls outside the upper and lower limits defined by the clinician. Both low and high oxygen concentrations can have serious clinical consequences; therefore, FiO_2 monitoring is an integral component of mechanical ventilation.

High FiO_2 Alarm

Oxygen-induced lung damage (oxygen toxicity) develops with sustained exposure to high FiO_2. PaO_2 > 100 mmHg is defined as hyperoxia; high oxygen leads to the production of reactive oxygen species (free radicals) and causes cell membrane damage. The main target of acute hyperoxia is the lung parenchyma. [58]

From where	Explanation
The oxygen supply flow is very high.	The flow rate of the external oxygen supply is set too high → FiO_2 is rising.
Sensor error	O_2 sensor calibration is faulty or aged → incorrect high reading.
Oxygen line connection problem	Due to the leak, the O_2 concentration changes unintentionally.

Low FiO_2 Alarm

A drop in FiO_2 below the target value increases the risk of hypoxia. Since hypoxia is life-threatening, a low FiO_2 alarm is a high priority. Brain damage develops much faster than with hyperoxia; untreated hypoxia can lead to neuronal damage within 4 minutes. [58]

From where	Explanation
The oxygen supply has run out or been interrupted.	The oxygen tank is empty or the oxygen concentrator is malfunctioning.
The oxygen line connection was cut.	The external oxygen hose was disconnected from the device.
The flow rate is very low.	Oxygen supply flow is insufficient to reach the target FiO_2.
Large circuit leakage	High leakage → mixing with equipment room air → measured FiO_2 decreases.
O_2 sensor malfunction	The sensor is giving an incorrect low reading.

Intervention

High FiO_2	Low FiO_2
Control and reduce the oxygen supply flow rate.	Check the oxygen supply: is the cylinder full? Is the concentrator working?
Check/calibrate the O_2 sensor.	Check the oxygen hose connection.
Target SpO_2: 92–98% (88–92% in COPD) [58]	Connect the hose; increase the flow rate.
Minimize long-term high FiO_2 levels.	Monitor SpO_2 immediately; if hypoxia is present, intervene urgently.

7.3.7 SpO_2 and Heart Rate Alarms

These four alarms — High SpO_2 [12], Low SpO_2 [13], High Heart Rate [14], Low Heart Rate [15] — will be activated by integrating an external pulse oximeter device into VENTISENSE. This integration is not yet available; it is planned in the product development process and will be available when the relevant hardware and software support is completed. Therefore, the following descriptions provide the clinical information infrastructure that will be valid when the feature is activated in the future.

Low SpO_2 Alarm

When pulse oximeter integration is active, this alarm will be activated if the measured arterial oxygen saturation (SpO_2) falls below the defined lower limit. SpO_2 monitoring is clinically invaluable for titrating oxygen therapy and instantaneous assessment of ventilation adequacy. The target SpO_2 range is set at 92–98% for most patients, while 88–92% is targeted for COPD patients. [58, 59]

A low SpO_2 level may indicate hypoxemia, ventilation failure, leakage, secretion obstruction, atelectasis, or pulmonary complications (pneumothorax, atelectasis).

High SpO_2 Alarm

SpO_2 exceeding the upper limit indicates hyperoxia — the presence of excess oxygen. SpO_2 > 98–99% increases the risk of continuous free oxygen radical production; oxygen toxicity may develop, especially in premature infants and with prolonged exposure to high FiO_2. This alarm functions as an early warning that triggers FiO_2 reduction. [57]

High/Low Heart Rate Alarms

Heart rate alarms, thanks to pulse oximeter integration, will combine real-time heart rate monitoring with mechanical ventilation management. Tachycardia (high heart rate) may indicate hypoxia, pain, hypercapnia, fever, or hemodynamic stress; bradycardia (low heart rate) may be due to severe hypoxia, vagal reflex activation, or drug effect and may be a precursor to cardiac arrest.

i NOTE

SpO_2 and heart rate alarms require the integration of an external pulse oximeter.
This integration is not currently available; it is planned during the product development process.
Until this feature is activated, SpO_2 and heart rate should be monitored independently using an external pulse oximeter.

7.4 CLASS 3: SYSTEM ALARMS

System alarms are a class of alarms that report the technical status, maintenance requirements, and operational conditions of a device. These alarms report situations that may affect the safe and accurate operation of the device, but not directly the patient's physiology. System alarms should not be ignored; timely intervention protects both patient safety and device lifespan.

Alarm Name	Trigger Condition
Service Alert	Critical service need (technical failure)
Battery Operated Active	AC power cut off; battery activated.
Battery Alarm 30%	Battery capacity dropped to 30%.
Fan Time Exceeded	The predicted operating hours for the motor/fan component have been exceeded.
Filter Time Exceeded	The intended operating hours for the air filter have been exceeded.
Cycle Time Exceeded	The intended usage time for the patient circuit has been exceeded.
Service Time Exceeded	It's time for periodic maintenance.
Battery life exceeded.	The battery's expected lifespan has been exceeded.
High Device Temperature	The indoor temperature exceeded the 60°C threshold.
Alarms silenced.	All alarms have been silenced.

7.4.1 Service Alarm

The Service Alarm is activated when the device's automated internal system monitoring detects a critical technical malfunction or unexpected system behavior. This alarm may include situations such as sensor failure, software error, hardware communication malfunction, or an undetected anomaly in the pneumatic system. When the service alarm is activated, the clinical safety of the device is questioned; therefore, it should be addressed with the highest priority.

⚠ WARNING

Do not continue using the device when the Service Alarm is activated.
Transfer the patient to an alternative ventilation source (backup device, Ambu bag).
Report the device to a service center; do not attempt to repair it yourself.

My name	Action
1	Place the patient on manual ventilation using an Ambu bag.
2	If there is a backup ventilator, activate it.
3	Turn off the device; call the service team immediately.
4	Note down the alarm code and conditions.

7.4.2 Battery Alarms

Battery Alarm 30%

It activates when the battery capacity drops to 30%; approximately 2–2.5 hours of reserve remain. This alarm is a pre-alert warning before 10% (Mandatory Alarm); it gives the clinician more time to restore the AC power connection.

My name	Action
1	Connect the device to the AC power source.
2	If the AC power has been cut off, investigate the cause (cable, adapter, mains outage).
3	Activate your backup power supply (UPS/generator) plan if there is a possibility of a prolonged power outage.

Battery Power ON

This is an informational alarm activated when the AC power supply is interrupted and the internal battery kicks in. Ventilation continues uninterrupted; however, battery capacity is limited (~8 hours on a full charge). This alarm serves as a notification until the battery level drops to 30%.

My name	Action
1	Determine why the AC power supply was interrupted.
2	Connect to AC power as soon as possible.
3	Increase your monitoring of the battery indicator; be prepared for the upcoming 30% alarm.

7.4.3 Maintenance and Life Cycle Alarms

VENTISENSE monitors the predicted operating times for critical components using counters. These counters can be viewed in the Settings → General → Counters menu. A system notification is activated when the defined limit for the relevant component is exceeded.

Alarm	Component	Clinical Significance	Intervention
Fan Time Exceeded [25]	Engine / Turbine (Blower)	The motor is the pneumatic heart of the device, providing all flow and pressure generation. Motors exceeding the projected 20,000 operating hours may lead to performance degradation, manifesting as reduced flow, pressure fluctuations, and increased noise.	Contact service; a motor replacement should be scheduled.
Filter Time Exceeded [26]	Device Air Filter	A clogged filter restricts the airflow into the device; this increases motor load and can impair tidal volume and pressure accuracy.	Change the filter immediately (use only the original filter). After changing the filter, you can reset this counter by tapping on Filter on the counters screen.
Cycle Time Exceeded [27]	Patient Circuit (Hose Set)	Circuits used for extended periods are at risk of biofilm accumulation on the inner surface, loss of elasticity, and wear at connection points. This increases the risk of infection and leakage.	Change the patient circuit; always use the new circuit when a new patient passes through. After changing the circuit, you can reset this counter by touching the circuit on the counters screen.
Service Time Exceeded [28]	Periodic Technical Maintenance	Comprehensive technical inspection of all device components includes calibration verification and necessary part replacements. Failure to perform maintenance on time can lead to silent performance losses.	Call the service team; schedule a technical maintenance appointment.
Battery Time Exceeded [29]	Internal Li-ion Battery	Battery capacity decreases over time; a battery that has exceeded its expected lifespan can no longer provide full capacity, making emergency power support unreliable.	Contact the service center for battery replacement.

i NOTE

All care time alerts are critical to patient safety; act without delay.

Maintenance interval alarms can be viewed in the alarm list; inform your doctor and technical service when they are activated.

7.4.4 High Device Temperature

The High Device Temperature alarm is activated when the thermal sensor inside the device detects that the temperature has exceeded the 60°C threshold. This threshold measures the internal temperature of the device; the internal temperature can be significantly higher than the ambient temperature due to the motor, electronic components, and pneumatic system. Therefore, even if the ambient temperature is kept within the 40°C operating limit, the internal temperature may exceed the 60°C threshold; this is sufficient to trigger an alarm. If the alarm is activated, the electronic components, sensors, and motor may be at risk of malfunction.

Possible Causes

From where	Explanation	Solution
Blocking air entry	The device's air inlet and outlet vents are blocked by a surface, fabric, or wall → cooling air cannot enter.	Ensure there is at least 10–15 cm of space around the device; avoid placing it on soft surfaces (pillows, blankets).
Extremely high ambient temperature	When the ambient temperature is above 40°C, the device exceeds its cooling capacity.	Move the device to a cool, shaded area; provide air conditioning or ventilation.
Filter clogging	A clogged air filter restricts cooling airflow → the interior temperature rises.	Change the filter immediately (this may be accompanied by a "Filter Time Exceeded" alarm).
Engine overload	The motor may overheat due to prolonged high-flow operation or a blocked circuit.	Circuit and filter inspection; engine maintenance.
Direct sunlight	The device should be placed in a location that receives direct sunlight.	Keep away from sunlight; use a curtain or protective covering.
Engine cooling fan malfunction	If the fan cooling the device's internal motor stops or slows down, the cooling capacity is lost and the internal temperature rises rapidly. Regardless of other reasons, it can exceed the 60°C threshold on its own.	Turn off the device; notify service — fan replacement required.

Intervention Algorithm

My name	Action
1	Assess the patient: is ventilation still ongoing?
2	Check the device's position: is the air intake open?
3	Is the ambient temperature above 40°C? → Move to a cooler environment.
4	Check the air filter → replace it if it's clogged.
5	Turn the device off for a few minutes; let it cool down.
6	Restart the device; if the alarm persists, contact a service technician.

⚠ WARNING

If the high temperature alarm persists, immediately turn off the device and switch the patient to alternative ventilation.
Do not reuse a heat-damaged device without service approval.

7.4.5 Alarms Silenced

This notification alarm is designed to remind you that the device's alarm sounds have been silenced and that active alarms are not being audibly transmitted. According to IEC 60601-1-8, alarm silencing should only be applied temporarily for patient assessment, care intervention, or identification of the alarm source, and should automatically reactivate after a specified period.

⚠ WARNING

Routinely silencing alarm sounds can lead to life-threatening situations going unnoticed.
Muting is only a temporary solution; the audible notification should not be turned off until the cause of the alarm is addressed.
Continuously monitor the patient visually and keep track of screen notifications.

7.5 Alarm Management Summary Table

Alarm	Class	Priority	The Most Common Reason	First Aid
Disconnection	Compulsory	High	Mask/cannula separation, major leak.	Patient → Manual ventilation → Check the circuit
Blockage	Compulsory	High	Secretion, circuit bending, filter clogging	Test manual ventilation → Clear the airway
High PEEP	Compulsory	High	Auto-PEEP (COPD/asthma), high frequency	Reduce frequency → Adjust I:E → Monitor hemodynamics
Low PEEP	Compulsory	High	Mask/head leak, valve malfunction	Leak detection → Measure cuff pressure → Valve check
High Pressure	Compulsory	High	Patient-device asynchrony, blockage.	Assess asynchrony → Rule out obstruction
Battery Alarm 10%	Compulsory	High	AC power cut off.	Connect to AC power immediately → Plan for backup power.
Fall Alarm	Compulsory	High	Physical fall/impact	Patient → Check the entire circuit → Look for mechanical damage
High pressure limit reached.	Compulsory	Middle	Sudden drop in compliance, increase in resistance.	Evaluate breath sounds → Treat obstruction/bronchospasm
Low pressure limit reached.	Compulsory	Middle	Large leakage, sudden increase in compliance.	Check actual volume transmission → Leak detection
AND Unreadable	Compulsory	Middle	Exhalation valve discharge, moisture/secretion	Check the valve → Remove moisture → Wait
Apnea Alarm	Adjustable	High	Excessive sedation can lead to disease progression.	Is backup in operation? → Assess sedation → Leak check
High/Low Frequency	Adjustable	Middle	Asynchrony, sedation, hypoxia/hypercapnia	Monitor SpO_2 /CO_2 → Optimize support level
High/Low Volume	Adjustable	Middle	Asynchrony, leakage, compliance change	Breathing obstruction? Leakage? → Treat the cause.

Alarm	Class	Priority	The Most Common Reason	First Aid
High/Low Minute Volume	Adjustable	Middle	Tachypnea, leakage, sedation, congestion	Frequency, support, leakage assessment.
Leakage Alert	Adjustable	Middle	Mask mismatch, head leak, circuit	Identify the source of the leak → Optimize the mask/cuff/circuit
High/Low FiO_2	Adjustable	Medium-High	Oxygen supply problem, sensor error.	Check O_2 source and connection → Adjust flow rate
High/Low SpO_2	Adjustable	High (planned)	It will be activated by an external pulse oximeter.	Not yet available
High/Low Heart Rate	Adjustable	High (planned)	It will be activated by an external pulse oximeter.	Not yet available
Service Alert	System	High	Critical hardware/software failure	Place the patient on manual ventilation → Call the service
Battery Operated Active	System	Notification	AC power loss	Connect to AC power → Increase battery monitoring.
Battery Alarm 30%	System	Middle	AC power loss	Connect to AC power → Backup power plan
Fan Time Exceeded	System	Middle	Engine life limit exceeded.	Contact service; schedule engine replacement.
Filter Time Exceeded	System	Middle	Air filter life limit	Change the filter immediately.
Cycle Time Exceeded	System	Middle	Patient circuit life limit	Change the circuit
Service Time Exceeded	System	Middle	Periodic maintenance time	Schedule a technical maintenance appointment.
Battery life exceeded.	System	Middle	Battery life limit	Contact service for battery replacement.
High Device Temperature	System	High	Air intake obstruction, fan malfunction, filter blockage	Correct location → Filter check → Cool → Report to service
Alarms silenced.	System	Notification	The alarm sound was turned off.	Do not constantly silence until the cause is resolved.

8. SETTINGS

The VENTISENSE device's Settings menu is designed to regulate clinical usage preferences, device behavior, and system configurations. Some settings in this menu are only accessible when Physician Mode is active. Accessed via Settings → General, this section contains eight separate configuration items.

8.1 Accessing the Physician Menu

VENTISENSE offers two user interface levels: Home Mode and Physician Mode. The Physician Menu is a password-protected access layer that allows only authorized healthcare personnel to change the ventilation mode, all parameters, and alarm limits. Patients and their caregivers operate in Home Mode as standard; in this mode, only basic operations (starting/stopping therapy , alarm sounds, and screen brightness adjustment) can be performed.

To activate the Physician Menu:

- Go to Settings → General → Access to Physician Menu.
- Enter the 4-digit code provided with the device. (Default: 2904)
- Once confirmed, the Physician icon (red plus sign) will become active in the upper panel of the screen.
- When Physician Mode is active, mode, parameter, and alarm settings can be changed from the Parameters page.

⚠ WARNING

Do not share your Physician Mode password with unauthorized persons.
Parameter changes should only be made by healthcare professionals who are knowledgeable about the subject.
Incorrect parameter settings can lead to serious clinical consequences.

8.2 Pediatric Mode

Pediatric Mode configures the device for pediatric patients weighing 5–30 kg. When this setting is activated, parameter ranges, alarm thresholds, and some calculation algorithms automatically switch to values appropriate for pediatric physiology.

The main effects of pediatric mode on ventilation are:

Parameter / Property	Adult Mode	Pediatric Mod
Frequency Range	4–30 bpm	4–60 bpm
Tidal Volume Range	200–2000 ml	50–200 ml
Max. IPAP	60 mbar	40 mbar
Obstruction Flow Threshold	Maximum Pressure / 10	Maximum Pressure / 8
Connection Break Inspir. Flow Threshold	60 LPM	46 LPM

Model-Based Pediatric Mode Configuration

Model	Pediatric Mode Default	Is it changeable?	Explanation
VENTISENSE 60	Closed (Adult)	No — it's fixed.	Designed for adult patients only. Pediatric mode is disabled by default and cannot be changed by any user.
VENTISENSE 40	Open (Pediatric)	No — it's fixed.	Designed exclusively for pediatric patients. Pediatric mode is enabled by default and

Model	Pediatric Mode Default	Is it changeable?	Explanation
			cannot be changed by any user.
VENTISENSE PRO	Configurable	Yes — with Physician Mode	both adult and pediatric use . Only in this model can Pediatric Mode be turned on and off while Physician Mode is active.

⚠ WARNING

In VENTISENSE 60, pediatric mode is permanently off; in 40, it is permanently on.
Attempting to change this setting will be rejected by the device due to model -specific restrictions.
Operating with an incorrect patient group configuration poses a serious clinical risk.

8.3 Automatic Setting Change

profiles when an alarm condition persists for a specific period or frequency . This mechanism is designed to support patient safety, especially during nighttime hours when immediate intervention is difficult in a home environment.

Automatic Setting Switching transition conditions:

- the total alarm duration exceeds 60 seconds , or
- When the total number of alarms exceeds 10

The transition sequence is: Active Setting → Setting 2 → Setting 3. For example, if the alarm condition persists while Setting 1 is active, the device switches to Setting 2; if the alarm persists in Setting 2, it switches to Setting 3. Each profile must be pre-configured by the clinician.

i NOTE

To use this feature, Settings 1, 2, and 3 must be predefined by your physician.
A notification is generated when the automatic transition occurs; the clinician should evaluate the patient as soon as possible.
It can be enabled via Settings → General → Change Automatic Setting → On.

8.4 External Humidifier

The External Humidifier setting should be activated when using an active, heated humidifier connected to the device. This setting makes fine adjustments to the flow and volume measurement algorithms, taking into account the expected humidity and condensation conditions in the circuit. The correct setting increases the reliability of tidal volume and minute ventilation measurements.

In clinical practice:

- If using an active heated humidifier → External Humidifier: On
- If only HMEF (passive moisture-heat exchange filter) is used → External Humidifier: Off
- If a humidifier is used in conjunction with oxygen → External Humidifier: On

i NOTE

When using a humidifier, it is mandatory to install bacterial/viral filters on both the inspiration and expiration ports of the device.
If this setting is left off while an external humidifier is connected, measurement errors may occur.

8.5 Leakage Compensation

In non-invasive ventilation (NIV), some leakage is unavoidable; both from the intentional expiratory port of the single-tube circuit and unintentional leaks occur between the mask and the skin. The Leak Compensation feature allows the device to estimate this leakage in real time and increase the inspiratory

flow accordingly. This ensures that the target pressure or volume is maintained more consistently, even if circuit leakage increases.

Clinical benefits of leakage compensation:

- Even in the case of large mask leaks, the target IPAP and PEEP are more reliably protected.
- Trigger sensitivity is less affected by leakage; patient-device synchronization improves.
- The frequency of unnecessary connection drop alarms may decrease.

Important notes:

- In invasive ventilation (via tracheostomy/intubation tube), leak tolerance is very low; it is recommended to keep this setting closed.
- The compensation algorithm is predictive; very large leakages can still trigger a Disconnection alarm.

ℹ NOTE

Leakage compensation is recommended to be kept open in NIV applications and closed in invasive applications.
This setting can be changed while Physician Mode is active.

8.6 LCD Brightness

This setting allows you to adjust the screen brightness between 1 and 10. This setting directly affects the patient's sleep comfort: lower brightness is preferred for nighttime use, while higher brightness improves readability in well-lit environments during the day.

Clinical recommendations:

- Nighttime use (sleep): Levels 1–3 — patient sleep is not interrupted, caregiver can still see alarm notifications.
- Daytime use or clinician assessment: Level 7–10 — improves readability in sunlight.
- Long-term low-brightness protection preserves screen life.

ℹ NOTE

LCD brightness adjustment is also accessible in Home Mode; Physician Mode is not required.
The screen can automatically switch to high brightness in alarm situations.

8.7 Sound Level

It adjusts the intensity of alarm and procedure sounds between 1 and 10. According to the IEC 60601-1-8 standard, audible notification of high-priority alarms is mandatory; the sound level does not eliminate this requirement, it only customizes the sound intensity according to the clinical environment.

Clinical recommendations:

- Home environment (sleeping room): Levels 5–7 — a level audible to the caregiver without unnecessarily waking the patient.
- Noisy environment (shared living space, vehicle interior): Level 8–10 — for audibility above ambient noise.
- Setting the volume too low can cause alarm notifications to be noticed late.

⚠ WARNING

Do not set the volume to 0 (completely mute); alarm notifications will become inaudible, compromising patient safety.
Verify that the alarm sound is audible significantly above the ambient noise level.

8.8 Software Update

VENTISENSE's built-in firmware can be updated via an SD card. Software updates may include new features, improved algorithms, bug fixes, and regulatory compliance updates. The update process should only be performed by authorized technical service personnel or under the instructions of Nefes Medikal.

Update Prerequisites

When you enter the update menu, the device automatically checks the following three conditions. If any of these conditions are not met, the update cannot be started:

Condition	Need	Explanation
SD Card File	The VENT2.hex file must be located in the root directory of the SD card.	The file should be located directly in the root directory (/), with its original name, and not in a subfolder.
Battery Level	The device's battery level must be above 50%.	If the power is interrupted during the update, the device may become unstartable; therefore, sufficient battery life is essential.
Engine Status	The engine (turbine) should not be running.	Updates cannot be initiated while therapy is active; stop therapy first.

Update Procedure

- Disconnect the patient from the device; if necessary, activate an alternative ventilation source (backup device or Ambu bag).
- Copy the update file (VENT2.hex) obtained from Nefes Medikal to the root directory of the SD card — not into a folder, but directly there.
- Verify that the device's battery level is above 50%.
- Stop the therapy; make sure the motor is not running.
- Insert the SD card into the SD card slot on the left panel of the device.
- Go to Settings → General → Software Update.
- The device verifies three conditions; if all are met, the update confirmation screen will be displayed.
- Confirm the on-screen confirmation; the update will start automatically.
- The update takes approximately 4-5 minutes. During this time, do not interfere with the device, do not remove the SD card, and do not disconnect the power.
- The device will automatically restart once the update is complete.
- After restarting, verify the new version from Settings → About → Software Version.

⚠ WARNING

Do not turn off the device, disconnect the power, or remove the SD card during the update process.
An incomplete update may prevent the device from starting; in this case, technical service intervention is required.
Use only signed update files provided by Nefes Medikal.
Do not initiate updates while the patient is connected to the device.

Post-Update Checks

Control	Action
Version verification	Confirm the expected version from Settings → About → Software Version.
Parameter and alarm limits	The update parameters are preserved; however, review all patient settings.
Maintenance record	Enter the update date and new version number into the device maintenance log.

Procedure for Resolving Update Issues

Problem	Possible Cause	Solution
The update menu is not opening.	SD card is not inserted or recognized.	Remove and reinsert the SD card; replace the card if it is faulty.
VENT2.hex not found error	The file is in a subfolder or has an incorrect name.	Copy the file to the root directory of the SD card with its original name (VENT2.hex).
Low battery warning	Battery is below 50%.	Charge the device by connecting it to AC power; try again when it reaches above 50%.
Engine running warning	Therapy is still active.	Stop the therapy; wait for the engine to stop completely.
The update was interrupted before it was complete.	Power outage, SD card ejected, or shutdown occurred.	Technical service intervention is required — do not try again on your own.
The version hasn't changed.	Update not complete.	Repeat the procedure from the beginning; if the problem persists, call Nefes Medikal.

i NOTE

Software updates must be documented in accordance with regulatory requirements.
Record the update date, the new version number, and the person who applied it.

9. RECORDING AND REPORTING

VENTISENSE permanently stores all parameters, alarm conditions, and waveforms of each therapy session via its SD card recording feature; the obtained data can be viewed and reported through the NefesReporter computer software .

9.1 Recording with an SD Card

9.1.1 Technical Architecture and Security

Since SD cards are removable storage media, read/write operations may be interrupted by power outages or user actions; this carries the risk of corruption of the card contents or the file system. To minimize this risk, VENTISENSE has defined all SD card read/write operations as separate operating system tasks. Thanks to this architecture, a potential SD card error is prevented from negatively affecting the device's ventilation function under any circumstances.

9.1.2 SD Card Usage Guidelines

Rule	Explanation
File system	The SD card must be formatted in FAT32; the device performs a file system verification upon initial insertion.
Time to put it on	It can be installed when the device is off or on; it is only introduced to a turned-on device once.
Extraction	For security reasons, a card will not be detected when reinserted after being removed from a working device; the device needs to be restarted.
Status indicator	When the card is properly recognized, the SD Card icon appears on the top panel; in case of an error, the icon disappears.
Update card	If the SD card was used for updating, it can also be used for recording therapy sessions.

9.1.3 File Formats

Two separate files are created on the SD card for each therapy session. Both files share the same naming scheme; only their extensions are different.

Extension	Full Name	Format	Contents
.NEF	Nefes Event File	XML (text-based)	Device information, therapy start/end times, all parameter changes, all alarm states.
NWF	Nefes Wave File	Binary data	Pressure, flow, volume, and leakage waveforms — in 32-bit floating-point format with a 100 ms sampling period.

9.1.4 File Naming

Files are named according to the following format scheme:

File Name Format
NEFES -{SERIAL NUMBER}-{UNIX TIMESTAMP}.NEF NEFES -{SERIAL NUMBER}-{UNIX TIMESTAMP}.NWF Example: NEFES-VP26259998-1754066432.NEF NEFES -VP26259998-1754066432.NWF

Unix timestamp: January 1, 1970, 00:00:00 UTC
It represents the number of seconds that have passed since then .

9.1.5 NEF File — XML Structure

The NEF file can be read with any text editor or XML viewer. The root element of the file is <VENTISENSE_root>, and it contains the following sections:

XML Tag	Contents
<name>, <manufacturer>, <serialno>, <model>, < software >	Device identification information
< start >	Therapy start: date/time, timestamp, active mode, active setting set, language, all parameters of 3 setting sets, device settings.
<parameter_change>	Each parameter change includes: date/time, which parameter of which setting set was changed, and the current status of all setting sets.
<alarmUpdate>	Each alarm status change includes: date/time, active alarm list (ID + name), total number of alarms.
<stop>	Therapy end: date/time, mode, reason for termination, last parameter status.

Below is an example event flow taken from a real NEF file:

Example NEF Event Flow

16:40:32 - 01.08.2025 Therapy start date
16:40:45 - 01.08.2025 Parameter Change Setting: 1 IPAP: 14
16:40:50 - 01.08.2025 Parameter Change Setting: 1 MOD: PCV
16:40:57 - 01.08.2025 Parameter Change Setting: 1 Frequency: 15
16:41:00 - 01.08.2025 Parameter Change Active Setting: 1 → 1
16:41:20 - 01.08.2025 Parameter Change Setting: 1 High Inspiration Volume: 50
16:41:32 - 01.08.2025 Alarm HIGH INF. VOLUME
16:41:45 - 01.08.2025 Alarm HIGH INPUT VOLUME + LINK COPY
16:41:50 - 01.08.2025 Alarm HIGH INF. VOLUME
16:41:57 - 01.08.2025 Parameter Change Setting: 1 High Inspiration Volume: 0
16:42:00 - 01.08.2025 Alarm NO ALARM
16:42:21 - 01.08.2025 End of therapy

Example NEF File Content

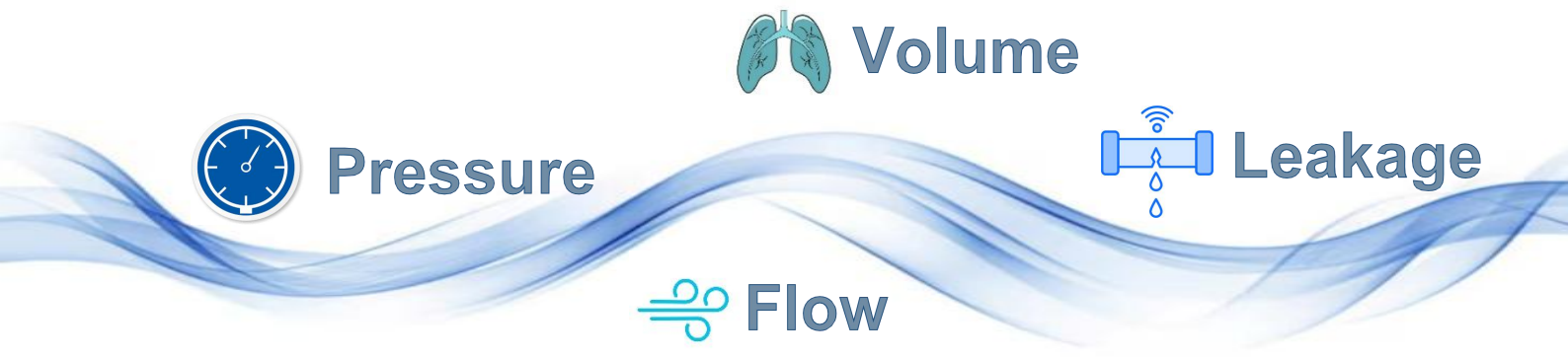
```
<VENTISENSE_root>
<name>Ventisense</name>
<manufacturer>NEFES Medikal Teknoloji LTD. STI.</manufacturer>
<serialno>VP26259998</serialno>
<model>VENTISENSE PRO</model>
<software> 1.19 </software>
< start >
<datetime>16:40:32-1.8.2025</datetime>
<timestamp>1754066432</timestamp>
<mode>PCV</mode>
<setup>2</setup>
<language>1</language>
<parameters>
<setup1>2.0|20.0|5.0|0.0|19.0|1.0|60.0|8.5|2.0|1.0|0.0|10.0|30.0|0.0|10.0|0.3|10.0|10.0|30.0|0.0|0.
0|0.
0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|</set
up1>
<setup2>0.0|15.5|4.0|0.0|14.0|1.1|58.0|7.5|3.0|1.0|0.0|10.0|30.0|0.0|10.0|0.3|10.0|10.0|30.0|0.0|0.
```

```
0|0.
0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|</set
up2>
<setup3>7.0|14.5|5.5|250.0|12.0|1.2|60.0|8.0|2.0|1.0|0.0|10.0|30.0|0.0|10.0|0.3|10.0|10.0|30.0|0.0|
0.0|0 .0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.0|0.
0|</setup3>
</parameters>
<settings>1.0|0.0|0.0|0.0|0.0|10.0|1.0|0.0|0.0|0.0|0.0|0.0|</settings>
</start>
```

9.1.6 NWF File — Waveform Data

An NWF file contains waveform data saved in binary format. Four waveform values are written as 32-bit floating-point values every 100 milliseconds. The saved channels are: Pressure, Flow, Volume, Leakage.

This file can only be meaningfully viewed with the NefesReporter computer software; the program is required to interpret the raw binary data.



9.1.7 Solstice and Registration Limit

No recording can exceed 24 hours. To keep file sizes manageable and to ensure each recording is associated with a single day, the active recording is automatically terminated and a new recording is started at the defined turning point (12:00 PM).

Solstice Example

A therapy session initiated on 01.01.2025 at 22:00.
If the process is stopped at 16:00 on 02.01.2025, two recordings will be created on the SD card:

Record 1: Start: 22:00:00 — 01.01.2025 End : 12:00:00 — 02.01.2025
Record 2: Start: 12:00:01 — 02.01.2025 End : 16:00:00 — 02.01.2025

9.2 NefesReporter — Imaging and Reporting Software

NefesReporter, developed by Nefes Medical Technology, is a Windows desktop application designed to view, analyze, and report therapy data recorded on SD cards from VENTISENSE mechanical ventilators and AirPAP CPAP devices. The program runs on the .NET 10 platform and offers Turkish and English language support.

i NOTE

The program can be downloaded free of charge from Nefes Medikal's website.

9.2.1 Startup

When the program is first launched, the Startup Screen is displayed. This screen is the general introduction to the program and guides the user through the registry loading process. Language selection flags (TR/EN) are located in the upper right corner; clicking on the flags instantly switches the interface to the selected language, and this preference is retained on the next launch. The Nefes Medikal logo and program version information are located in the center of the screen. From this screen, the user can navigate to the registry folder and begin viewing data using the "Select Device/Folder" button.

Figure 34 — Nefes Reporting Program – Login Screen

9.2.2 Device and Registration Selection

When the user selects the folder where the SD card was copied, the program scans all .NEF and .NWF files in that folder. The found records are grouped according to the device serial number and date/time information and transferred to the Record Explorer.

If a folder contains records for more than one different device, the "Device Selection" window opens. This window lists the model name, serial number, number of records found, and the last record date for each device. The user selects the relevant device from the list to continue viewing.

Figure 35 — Nefes Reporting Program – Device Selection Screen

9.2.3 Record Explorer

The Record Explorer is a panel that lists all therapy records for the selected device in a hierarchical tree structure. Records are organized by Year → Month → Day → Session; clicking on each node takes you down to the next level. The most recent record is automatically selected.

You can navigate sequentially between records using the forward/backward navigation buttons located at the top of the explorer. Information about the selected record (record name, folder number, total number of records) is displayed in the explorer header area. All display panels update automatically when the selection changes.

In the Multiple Records view, clicking on the year, month, or day nodes in the explorer will transfer all records within the specified time range to analysis mode together.

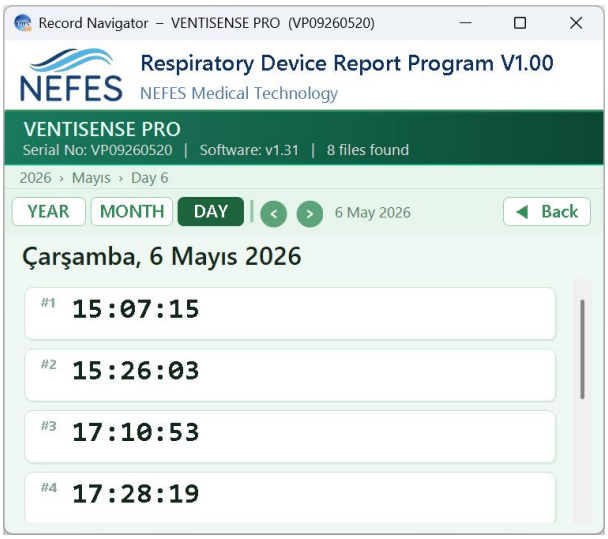


Figure 36 — Nefes Reporting Program – Navigator Screen

9.3 Single Record Viewing Module

When a single session is selected from the Record Explorer, the Ventisense Viewer opens. The left sidebar contains eight navigation buttons: Summary, Therapy Information, Statistics, Settings, Alarms, Waveform, Patient Information, and Reporting. Each button loads the corresponding content panel into the central area.

9.3.1 Summary Screen

The Summary Screen presents the most critical data from the selected therapy session in a way that allows for quick review.

Area	Contents
Session Header	Device model, serial number, software version, therapy date, and total duration.
Session Cards (3 pieces)	Therapy start time · Therapy end time · Total therapy duration (hours:minutes :seconds)
Alarm Cards (4 pieces)	Total number of alarms · Longest alarm duration · Total alarm duration · Total number of parameter changes; red/yellow alarm distinction is shown under each card.
Pressure and Leakage Metrics	Average IPAP, average PEEP, average tidal volume, average minute ventilation, average leakage; each metric is supported by a horizontal indicator bar.
Therapy Time Bar	A colored time bar showing the active therapy duration in proportion to the time of day.

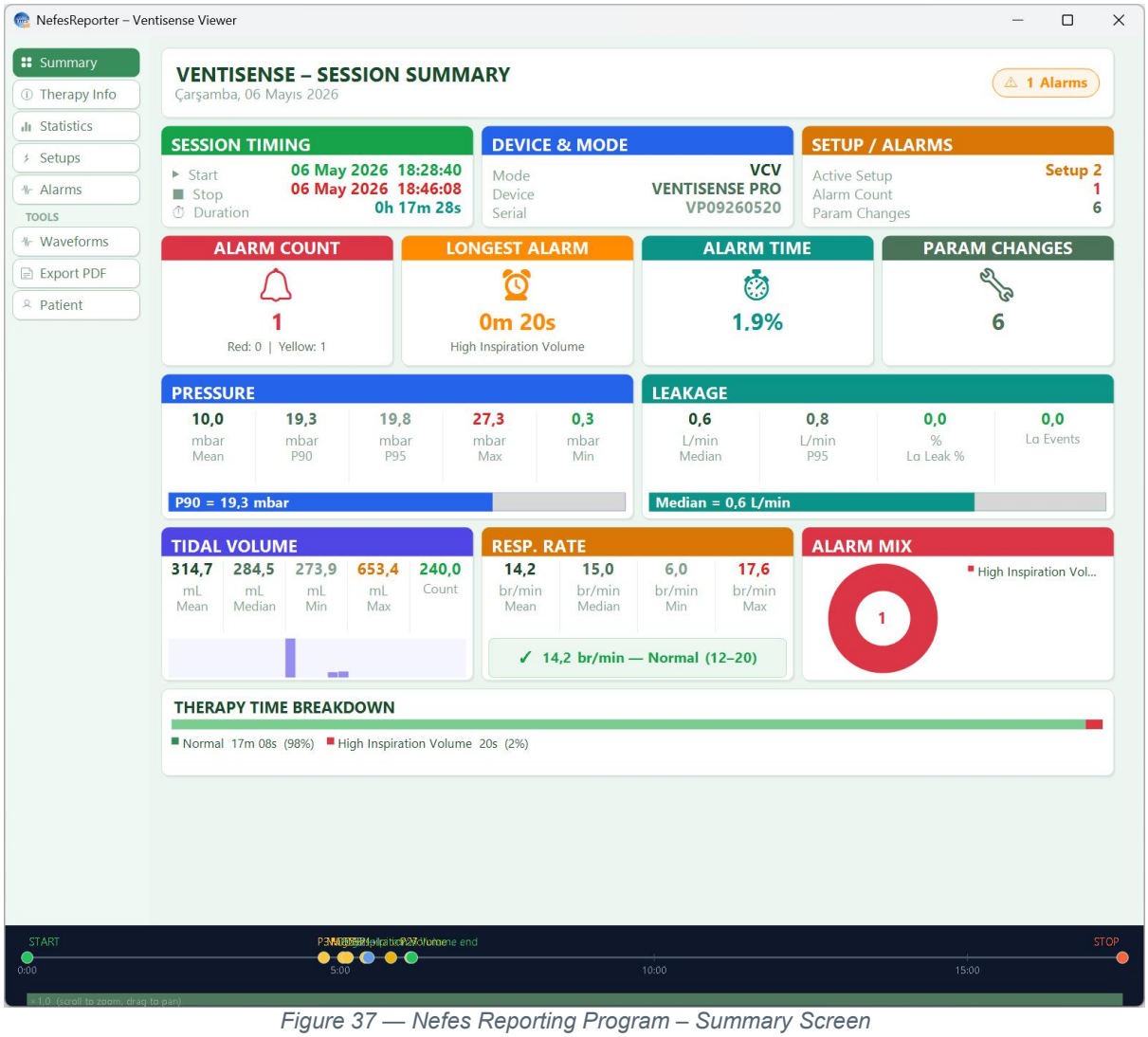


Figure 37 — Nefes Reporting Program – Summary Screen

9.3.2 Therapy Information Screen

The Therapy Information Display provides a comprehensive view of the ventilation parameters applied throughout the session.

Area	Contents
Therapy Information Cards (6 cards)	Active mode · Active setting set number · Patient type (adult/pediatric) · Humidifier status · Leak compensation status · Mean respiratory rate (bpm)
Table of Settings Parameters	All parameters of the 3 active setting sets (Setting 1, Setting 2, Setting 3) during therapy are displayed side-by-side in 3 equal columns; parameters that cannot be applied to the mode are masked in gray for visual separation.
Parameter Change Time Schedule	Every parameter change made during the session is listed chronologically; information on which parameter was changed in which setting set is included.

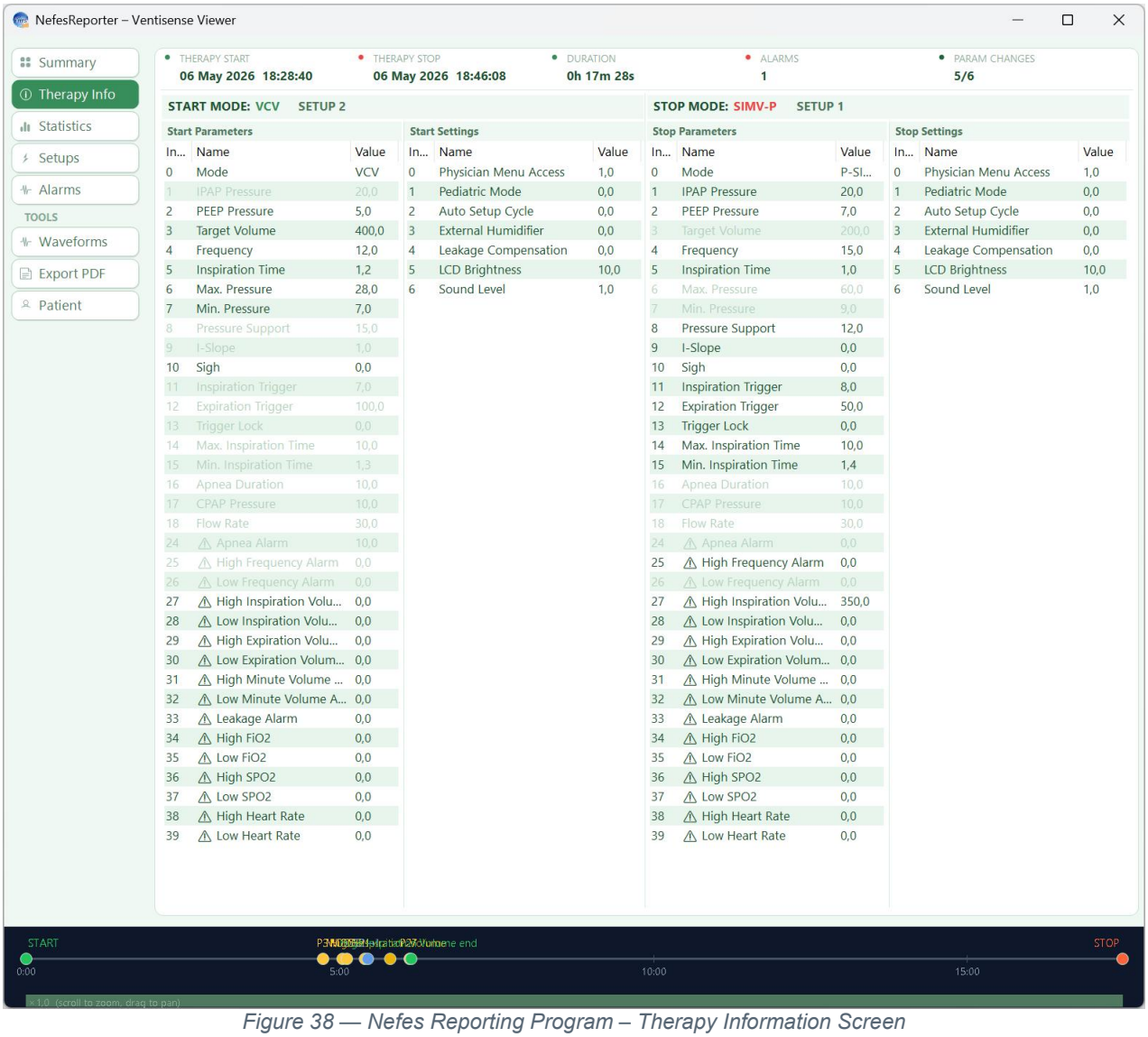


Figure 38 — Nefes Reporting Program – Therapy Information Screen

9.3.3 Statistics Screen

The Statistics Screen provides a numerical statistical analysis of the parameters measured during the session.

Area	Contents
Statistics Table	Minimum, average, and maximum values for each measurement parameter; parameters: IPAP, PEEP, Tidal Volume, Minute Ventilation, Respiratory Rate, Leakage, FiO_2
Histograms	Pressure distribution histogram (frequency plot in mbar); Tidal volume distribution histogram; Respiratory rate band plot — interactive zoom with ScottPlot on all graphs.

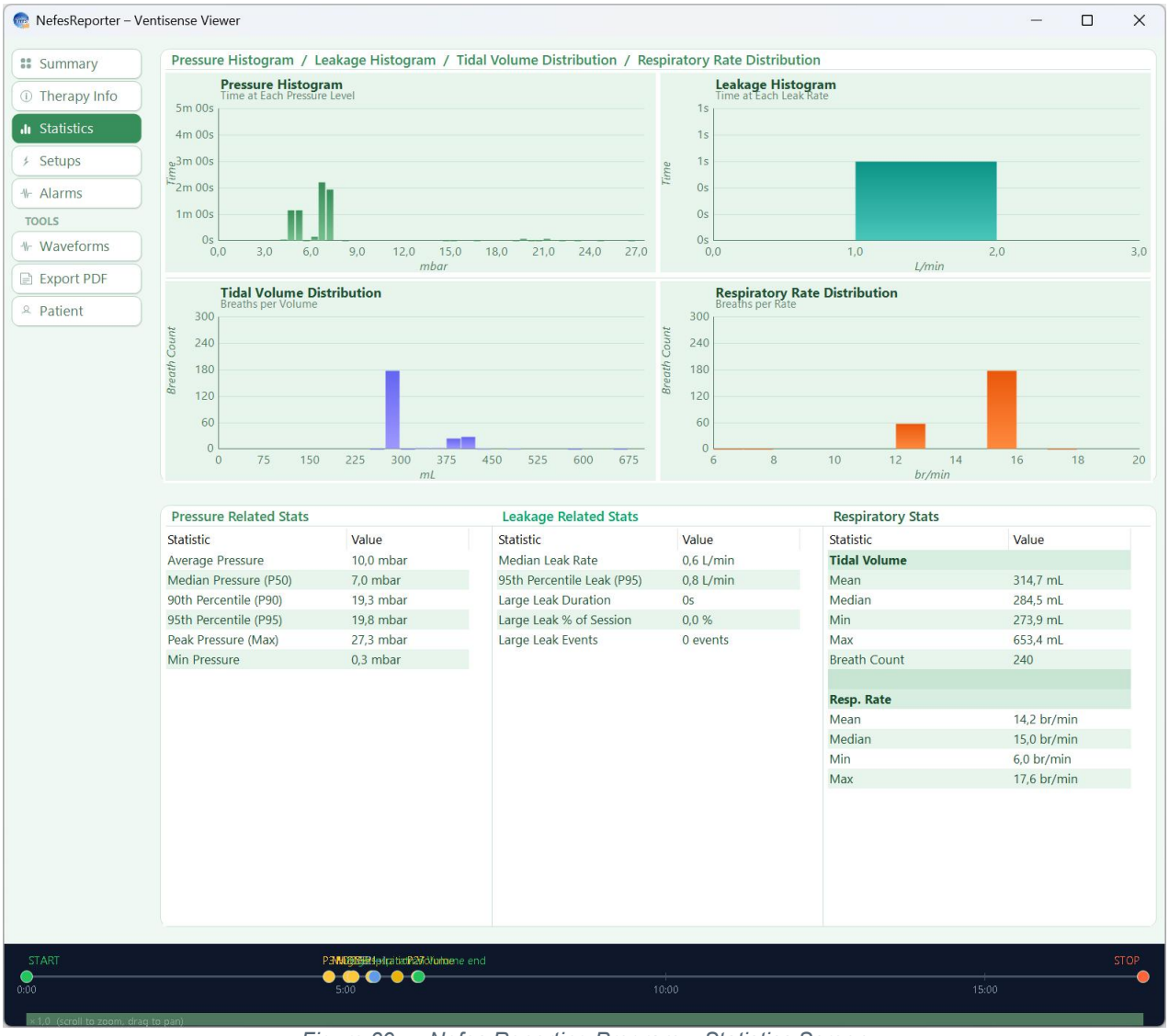


Figure 39 — Nefes Reporting Program – Statistics Screen

9.3.4 Settings Screen

The Settings screen displays a comparative view of the start and end parameter values of three sets of settings stored on the device throughout the session. The parameters active at the beginning and end of the session are presented side-by-side; any changed parameters are highlighted to draw the clinician's attention. Each set of settings includes mode, IPAP, PEEP, tidal volume, frequency, inspiration time, and all other mode parameters. When hovering over parameter changes, the current active setting/mode/parameter values are summarized in a small window that appears on the screen.

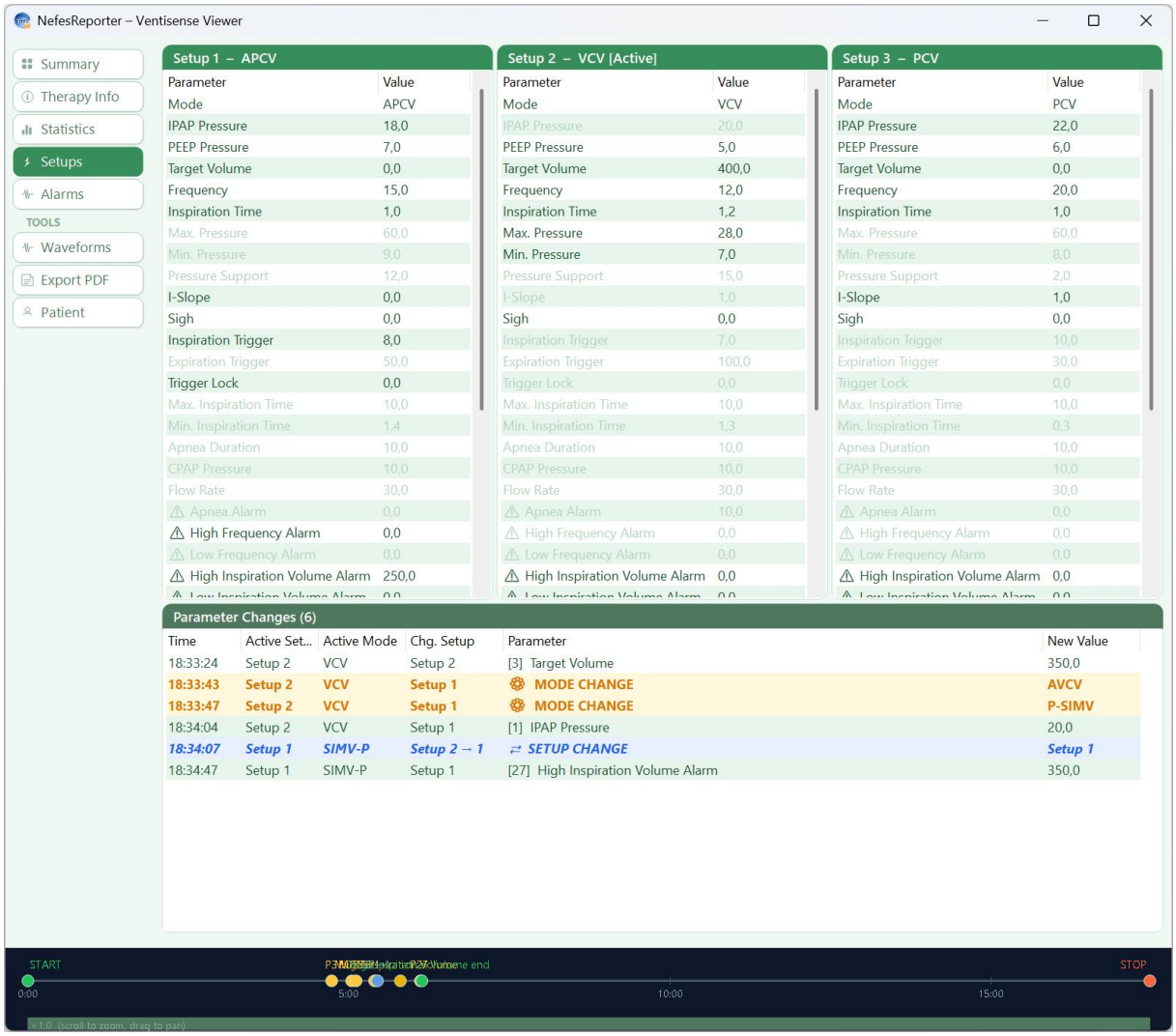


Figure 40 — Nefes Reporting Program – Parameters Screen

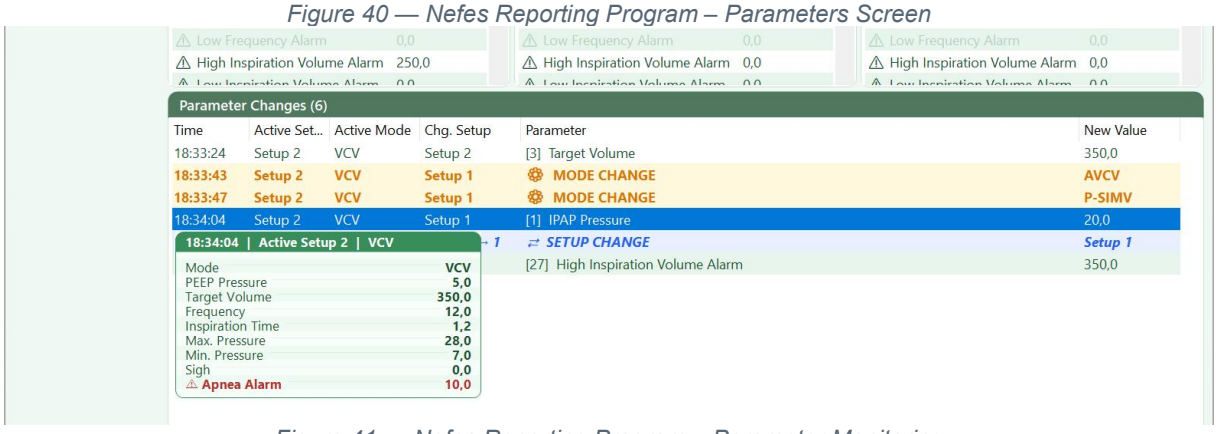


Figure 41 — Nefes Reporting Program – Parameter Monitoring

9.3.5 Alarms Screen

The Alarms screen provides a detailed timeline of all alarm events recorded during the session.

Area	Contents
Alarm Event List	For each alarm event: date/time, list of active alarm names, number of simultaneously active alarms; events are listed in chronological order.
Alarm Color Coding	High priority (red) alarms are colored red, medium priority (yellow) alarms are colored yellow, and the end of the alarm is colored green.
Alarm Summary	The screen displays a summary of the total number of red alerts, the total number of yellow alerts, and the type of alert that lasted the longest.

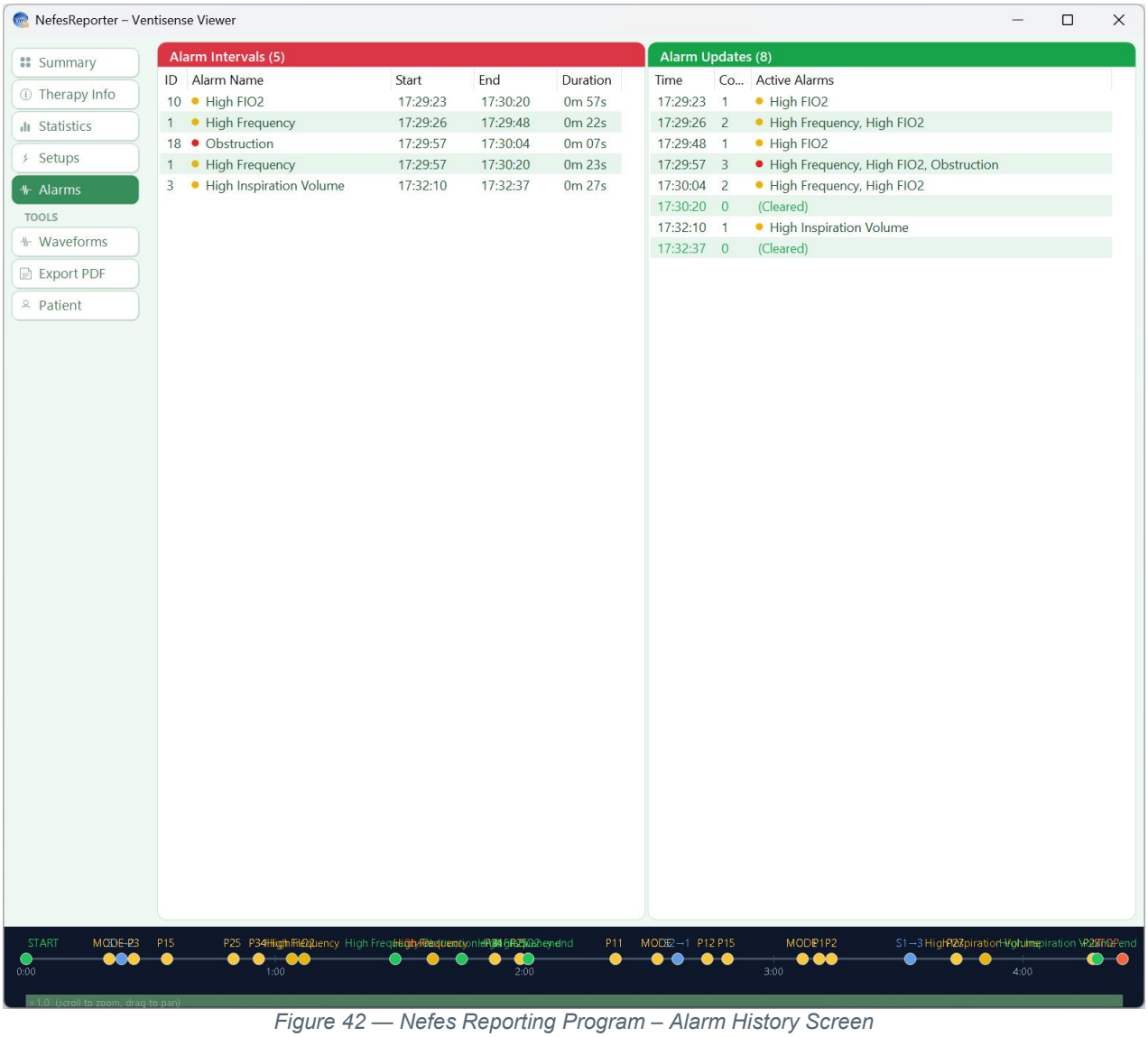


Figure 42 — Nefes Reporting Program – Alarm History Screen

9.3.6 Waveform Display

The Waveform Display visualizes raw pneumatic data read from a .NWF file on a real-time graph. This display is the most technically data-intensive part of the program.

Graphic Channel	Explanation
Pressure (mbar)	Changes in airway pressure over time are monitored at IPAP levels during the inspiration phase and PEEP levels during the expiration phase.
Flow rate (L/min)	The change in airflow velocity over time is shown as positive values for inspiration and negative values for expiration.
Volume (ml)	The cumulative tidal volume curve returns to zero at each respiratory cycle.
Leakage (L/min)	Change in circuit leakage amount over time

All channels are displayed synchronously on the timeline. You can zoom in/out on the desired time interval by rotating the mouse wheel. For the graphs to appear meaningful, the maximum zoom level is set to display 10 minutes on the screen. You can scroll the graphs along the timeline by holding down the left mouse button. At the bottom of the graph is a Timeline showing events (alarms, parameter changes) on the timeline. Hovering over an icon displays the event details in a pop-up window. The waveform view can be opened in a separate window for full-screen viewing.

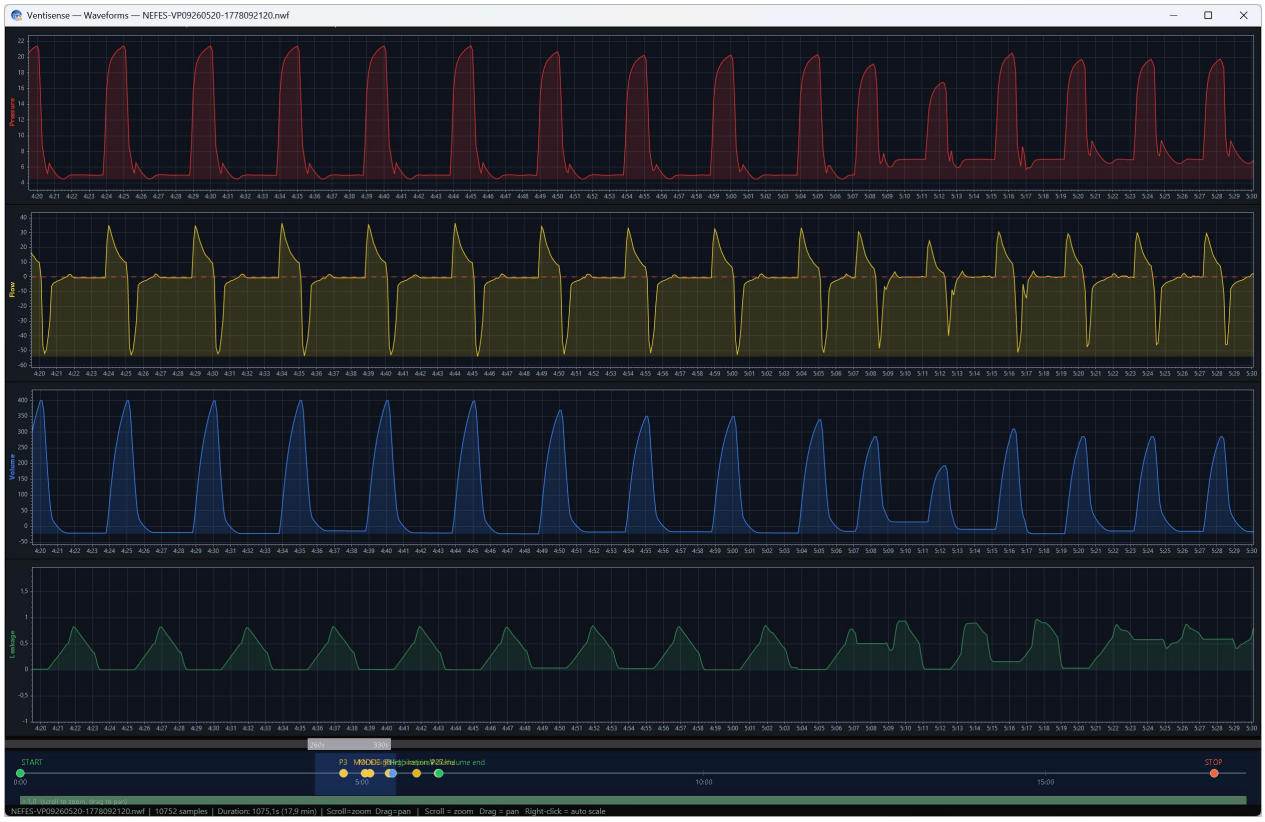


Figure 43 — Nefes Reporting Program – Waveform Display

9.3.7 Timeline

The TimelineVent is a horizontal event strip common to all screens in the single recording viewing module . It represents the entire session on a single timeline; visualizing alarm and parameter change events recorded throughout therapy with color-coded nodes.

Component	Explanation
Therapy Starting Knot	The node positioned on the left edge with the label "START" represents the moment the session begins. The label is drawn to the left.
Therapy Ending Node	The node positioned on the right edge with the label "END" represents the moment the session ends. The label is drawn right-aligned.
Alarm Buttons (Colored Circles)	Each alarm status change is marked as a small circle on the time axis. High-priority (red) alarms are shown as red circles, and medium-priority (yellow) alarms as yellow/amber circles. When the alarm status ends (all alarms are cleared), the node is marked in a different color.
Parameter Change Nodes	Each parameter change made during the session is marked as a circle of a different color on the time axis. These nodes are color-coded to distinguish them from alarm nodes.
Node Tooltip Information	When you hover over any node, an information panel opens in the upper corner of the screen. Alarm nodes display the date/time of the event and the names of the currently active alarms. Parameter change nodes show the date/time of the change and which parameter was changed.
Watch Labels	Hour markers are displayed at specific intervals along the timeline. Hour markers located very close to nodes are hidden to prevent visual clutter.
Waveform Synchronization	In the Waveform view, the timeline works in full sync with the waveform graphs: when you zoom in on a specific time interval by dragging the mouse over the graphs, the timeline updates simultaneously. Right-clicking returns to the original full view.
Scrollbar	A horizontal scroll bar appears in zoomed-in views or on long recordings; it's used to navigate between different time periods within a session.

NOTE

The timeline only shows alarm and parameter change events; it is a Vent-specific component.
Red circle = high priority alarm activated | Yellow/Amber circle = medium priority alarm activated
Numerous nodes can accumulate over long sessions; it is recommended to perform the analysis by synchronizing the waveform and focusing on a specific time period.

9.3.8 Patient Information Screen

The Patient Information Screen is the panel where patient identification information for a record is displayed and edited. This information is saved to a program-specific local database, not a .NEF file; it is associated with the device serial number.

Area	Contents
Identity Information	Patient's full name, date of birth, gender, patient identification number.
Clinical Information	Diagnosis, name of attending physician, institution information.

Area	Contents
Physical Data	Height, weight, and body mass index (BMI) are used to calculate ideal body weight (IBW).
Notes	Free text area — for clinician notes.

When patient information is recorded, the program automatically fills in the information for that patient in subsequent sessions; the patient's identification information appears in the header section of each report.

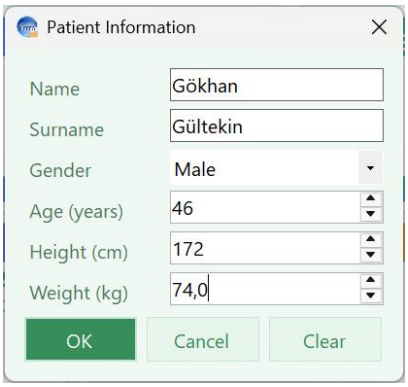


Figure 44 — Nefes Reporting Program – Patient Information Screen

9.3.9 Reporting (PDF Transfer)

The reporting panel is used to generate a comprehensive clinical PDF report of the selected therapy session. The report is prepared according to the Nefes Medikal design template and consists of five sections suitable for clinical and technical use.

Report Page	Contents
Chapter 1 — Summary	Patient information, session summary tape, 3 session cards, 4 alarm cards, pressure and leak metrics, therapy time bar .
Chapter 2 — Therapy Information	6 therapy information cards, parameter tables for 3 setting sets (gray masking applied according to mode)
Chapter 3 — Statistics and Alerts	Pressure/tidal volume/respiratory rate histograms, statistical tables, alarm summary
Chapter 4 — Events	Parameter change timeline, alarm log details.
Chapter 5 — Waveforms	Pressure, flow, volume, leakage graphs and timelines of events.

The report is automatically generated in Turkish or English, depending on the program's active language setting. Each page includes a header with device information, a page number, and Nefes Medikal's corporate identity.

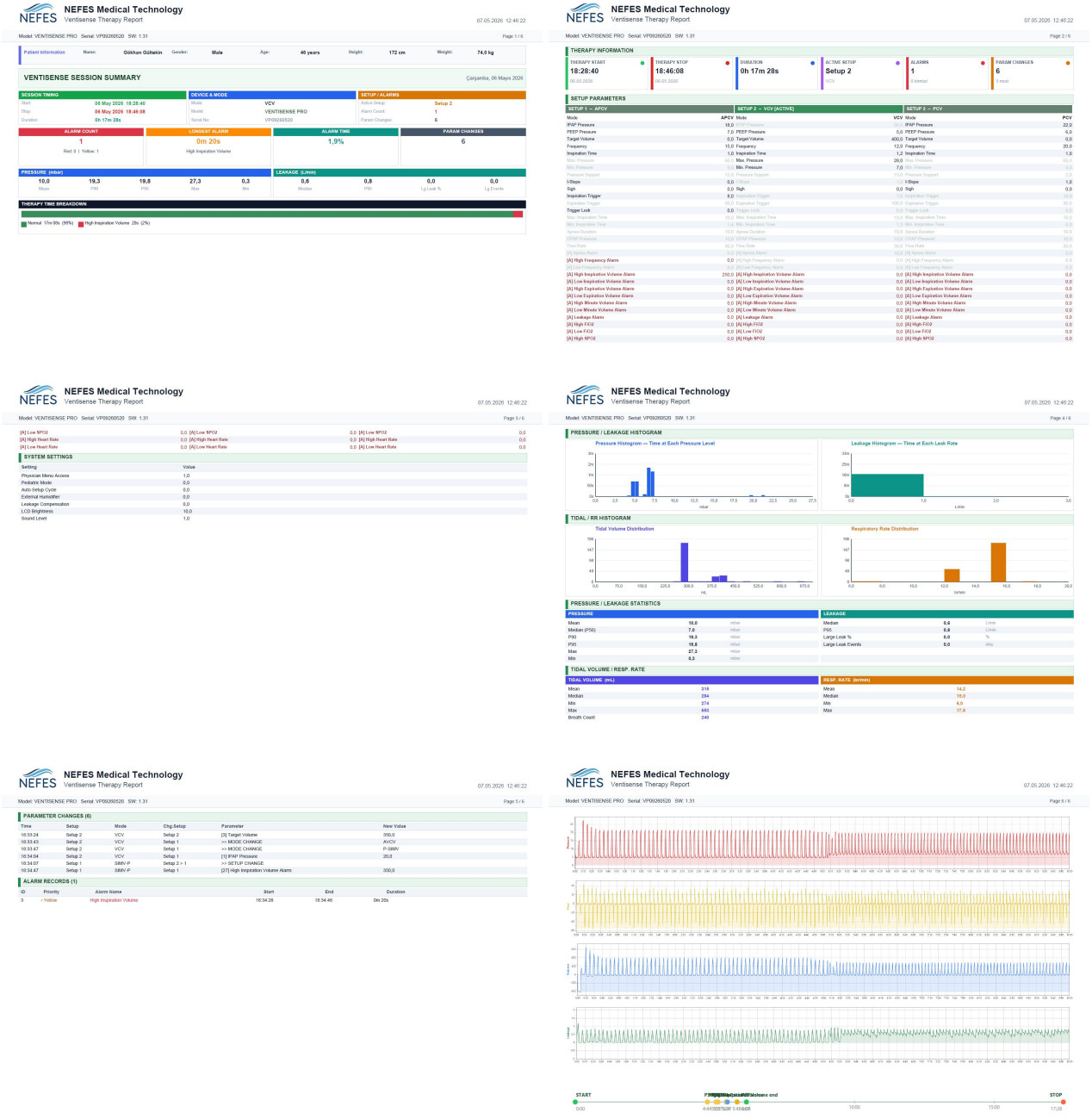


Figure 45 — Nefes Reporting Program – Single Record Report Example

9.4 Multiple Record Module

The Multiple Record Module allows for the collective analysis of multiple therapy sessions from the same device. When a year, month, or day node is selected in the Record Explorer, all records within that time range are transferred to the Multiple Record view. This mode is designed for long-term ventilation parameter monitoring, alarm load analysis, and multi-session clinical reporting.

Multiple Log module, the left sidebar contains four section buttons: Summary, Log Information, Statistics, Alarms, and Reporting.

9.4.1 Multiple Records — Summary Screen

The Summary Screen summarizes ventilation data from all Ventisense sessions within the selected time range on a single screen.

Area	Contents
Period Title Band	Device model, serial number, software version, selected period (start-end date), total number of records, and total therapy duration.
Period Metric Charts (4 pieces)	Registration Start (first session of the term) · Registration End (last session of the term) · Total Duration · Total Number of Sessions
Ventilation Trend Graphs (4 charts)	Four separate line graphs showing the change over time on a session basis: Average IPAP (mbar) · Average PEEP (mbar) · Average Tidal Volume (ml) · Average Leakage (L/min) — each graph visualizes the sessions sequentially on the time axis.
Session Summary Table	For each record, on a line-by-line basis: sequence number, start date/time, end date/time, total duration, start mode, end mode.

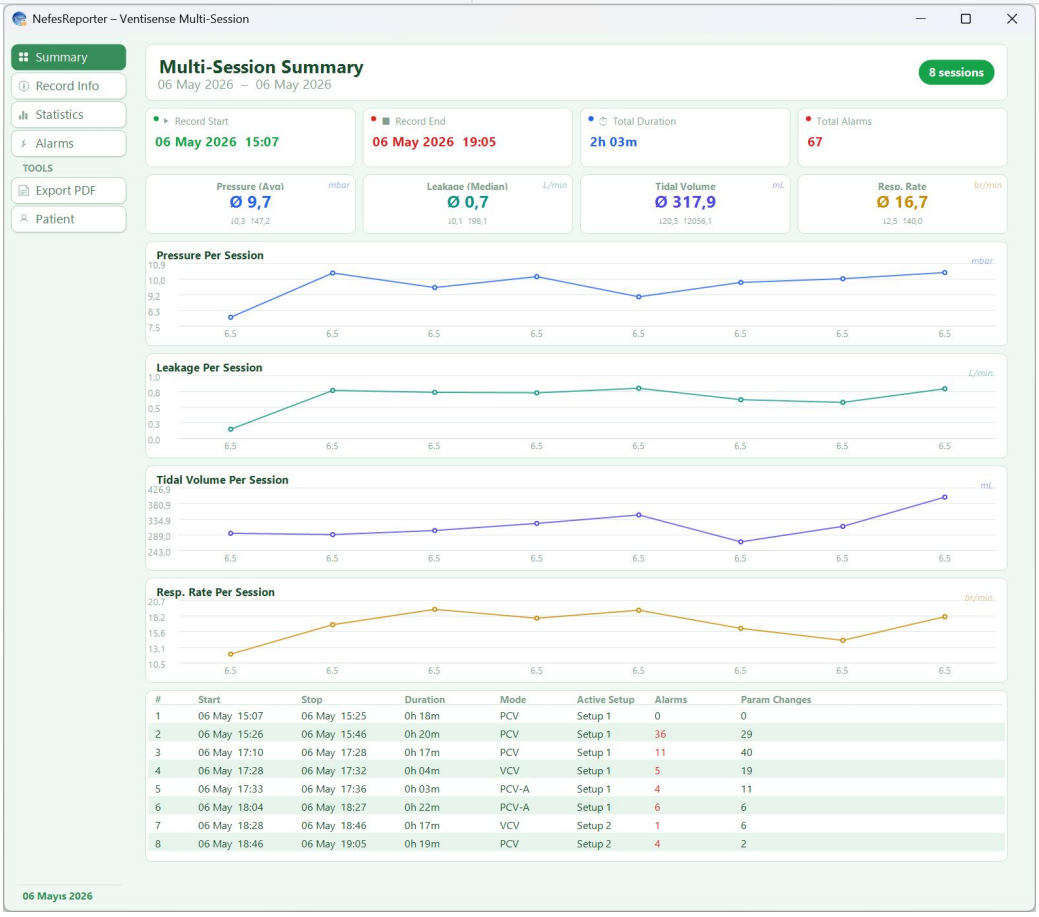


Figure 46 — Nefes Reporting Program – Multiple Record Summary Screen

9.4.2 Multiple Records — Record Information Screen

The Recording Information Screen provides a comparative overview of the ventilation modes and parameters used in all sessions throughout the period.

Area	Contents
Sessions — Start/End Modes	The ventilation mode in which each session started and ended is shown side-by-side; this is used to track mode changes.
Initial Parameters According to Fashion	For each mode used during the period, the parameter values at the beginning of each session are listed in columns on a session-by-session basis. Parameters that change between sessions are highlighted with a special symbol (⇅); unchanging, constant parameters are shown as normal. This table allows the clinician to monitor long-term parameter consistency and the optimization process.
Aggregate Parameter Summary	The minimum, maximum, and most frequently used values encountered for each parameter during the selected period show how much the parameters varied on a session basis.

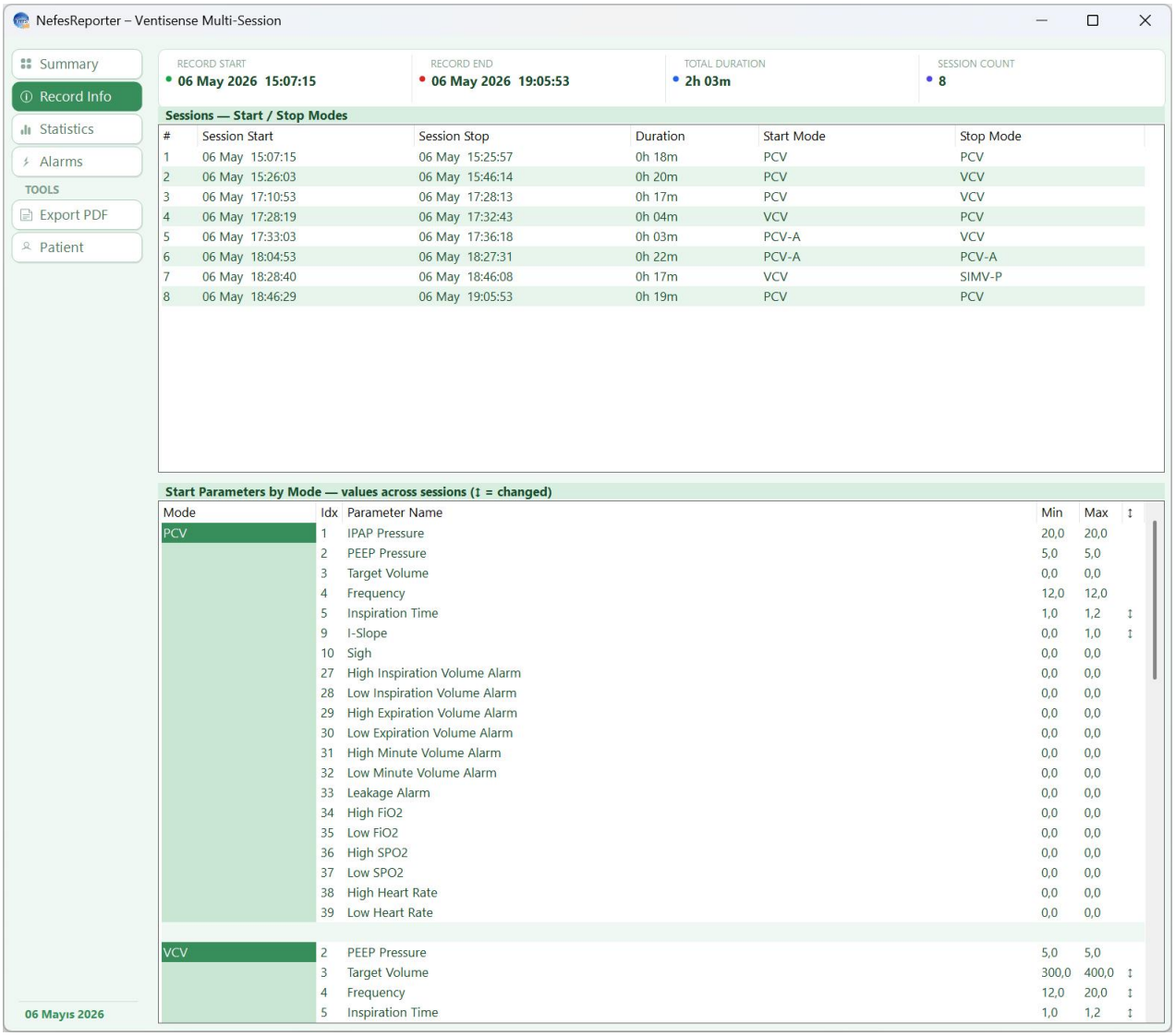
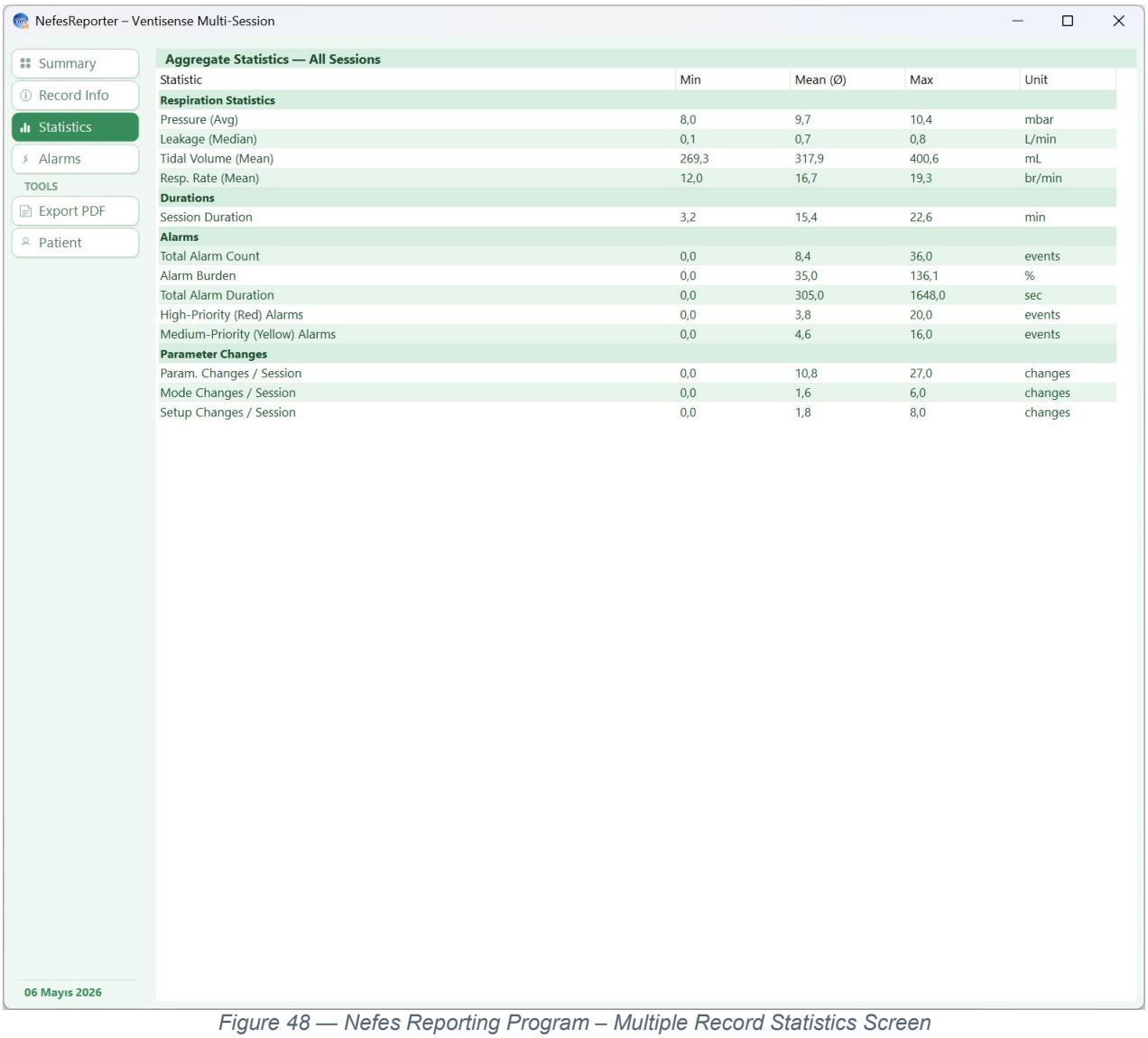


Figure 47 — Nefes Reporting Program – Multiple Record Information Screen

9.4.3 Multiple Records — Statistics Screen

The Statistics Screen presents pneumatic measurement data from all sessions in an aggregated statistical framework.

Area	Contents
Aggregate Statistics Table	Throughout the period, measurements from all sessions are combined to calculate minimum, average, and maximum values for each parameter; parameters include: IPAP, PEEP, Tidal Volume, Minute Ventilation, Respiratory Rate, and Leakage.
Session-Based Comparison	Average values for each session are listed side-by-side; consistency within sessions and differences between sessions can be evaluated.



Aggregate Statistics — All Sessions

Statistic	Min	Mean (Ø)	Max	Unit
Respiration Statistics				
Pressure (Avg)	8,0	9,7	10,4	mbar
Leakage (Median)	0,1	0,7	0,8	L/min
Tidal Volume (Mean)	269,3	317,9	400,6	mL
Resp. Rate (Mean)	12,0	16,7	19,3	br/min
Durations				
Session Duration	3,2	15,4	22,6	min
Alarms				
Total Alarm Count	0,0	8,4	36,0	events
Alarm Burden	0,0	35,0	136,1	%
Total Alarm Duration	0,0	305,0	1648,0	sec
High-Priority (Red) Alarms	0,0	3,8	20,0	events
Medium-Priority (Yellow) Alarms	0,0	4,6	16,0	events
Parameter Changes				
Param. Changes / Session	0,0	10,8	27,0	changes
Mode Changes / Session	0,0	1,6	6,0	changes
Setup Changes / Session	0,0	1,8	8,0	changes

Figure 48 — Nefes Reporting Program – Multiple Record Statistics Screen

9.4.4 Multiple Records — Alarms Screen

The Alarms screen provides an integrated view of alarm events recorded across all sessions throughout the period. Each alarm record is listed with the date and time information indicating which session it belongs to.

Area	Contents
Alarm Log List	Alarm events from all sessions are displayed in a single list in chronological order; each record includes the date/time, the names of the simultaneously active alarms, and the total number of alarms.
Alarm Color Coding	High priority (red) alarms are shown with a red background, medium priority (yellow) alarms with a yellow background; alarm end (NO ALARMS) is indicated in green.
Separation Between Sessions	Alarm logs for different sessions are separated by session header lines; this shows how much alarm load each session carried throughout the period.

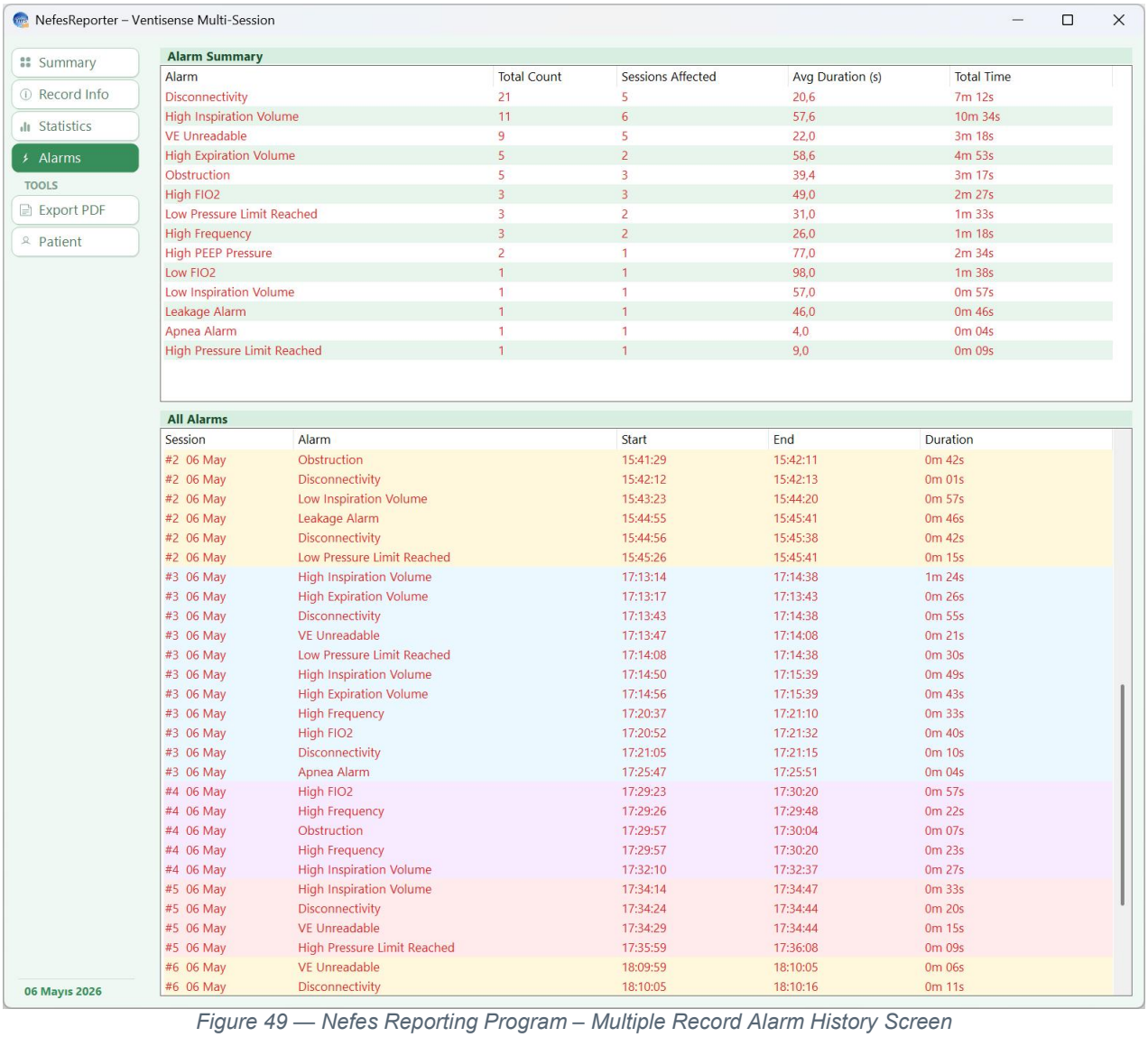


Figure 49 — Nefes Reporting Program – Multiple Record Alarm History Screen

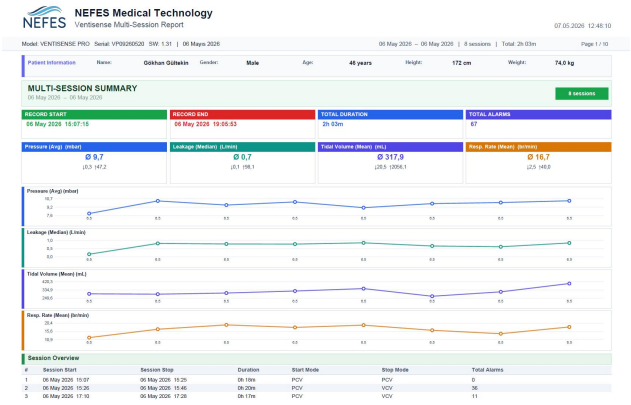
9.4.5 Multiple Records — Reporting (PDF Export)

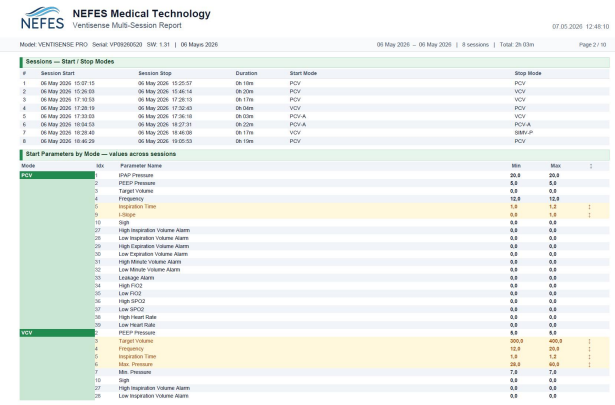
The Multi-Record Reporting panel generates a multi-page clinical PDF report covering all Ventisense sessions during the selected period.

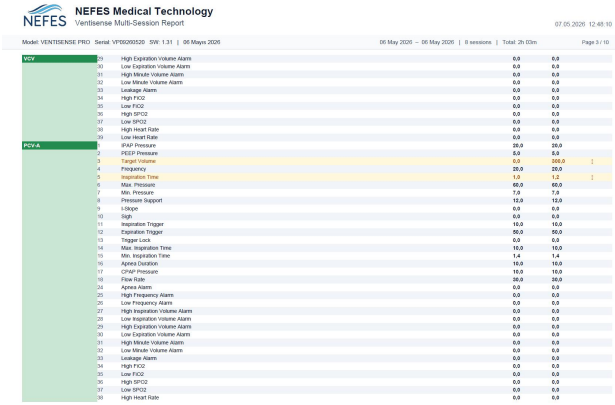
Report Page	Contents
Chapter 1 — Term Summary	Patient information includes: period heading band (device model, serial number, software, date range, number of sessions, total duration); 4 period metric cards; four ventilation trend graphs (IPAP, PEEP, Tidal Volume, Leakage); session summary table.
Section 2 — Log Information, Statistics, and Alarms	Session mode table (start/end mode); starting parameters by mode (parameters that vary by session are highlighted);
Chapter 3 — Statistics	Aggregate statistics table
Chapter 4 — Alarms and Parameter Change Logs	Combined alarm log list for all sessions; parameter change logs for all sessions.

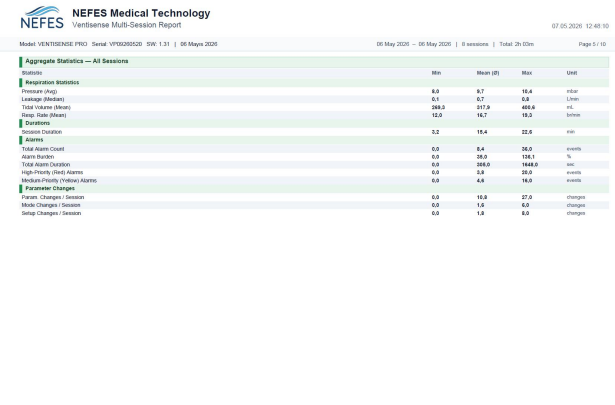
i NOTE

The Multiple Record report uses the same corporate design template as the single session report.
Each page includes information such as model, serial number, software version, date range, number of sessions, total duration, and page number.
The report is generated in Turkish or English, depending on the active language preference.









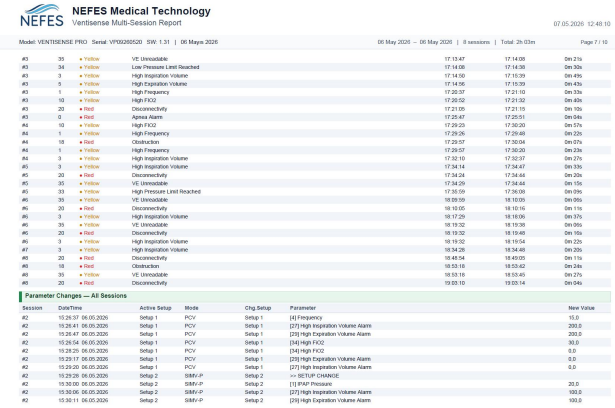


Figure 50 — Nefes Reporting Program – Example of a Multiple Record Report

10. MAINTENANCE AND CLEANING

10.1 Consumables and Replacement Intervals

Component	Replacement Interval	Notes
Patient Circuit (Double-legged Hose)	According to clinical protocol	It must be replaced with a new one when a new patient transfers.
HMEF Filter	At least every 24–48 hours	Replace it immediately if it gets wet or contaminated.
Bacteria/Viral Filter (Device)	According to manufacturer's instructions	More frequent when using a humidifier or nebulizer.
Inspiration Filter (Device)	Regular check-ups	Only original filters should be used.
Expiration Filter (Device)	Regular check-ups	Only original filters should be used.
Battery	20,000 hours or as recommended by the manufacturer.	Avoiding complete discharge prolongs battery life.

10.2 Cleaning

- Turn off the device and unplug the power cord before cleaning.
- Wipe the body with a slightly damp microfiber cloth.
- Do not use acetone, benzene, or abrasive substances; they will damage the screen and plastic housing.
- Do not sterilize the device in an autoclave.

10.3 Periodic Maintenance

The remaining service time should be monitored via the device's Settings → General → Counters menu. Failure to perform maintenance on time can reduce device performance and endanger patient safety.

10.4 Disinfection with Ozone

✓ VENTISENSE MECHANICAL VENTILATOR

SUITABLE FOR OZONE DISINFECTION.

VENTISENSE internal gas paths have been verified and approved for material compatibility with gas-phase ozone disinfection performed with the Mfresh YL-S3500 ozone generator.

Ozone disinfection is an advanced biocidal method applied in VENTISENSE technical service processes to eliminate bacteria, viruses, fungi, and other pathogens from internal pneumatic (gas) pathways. This section describes the scientific background of ozone, the VENTISENSE-specific application protocol, and safety requirements, along with clinical evidence.

10.4.1 Antimicrobial Mechanism of Ozone

Ozone (O_3) is one of the most potent oxidative disinfectants known. Its effect on microorganisms is based on a multidimensional oxidative stress mechanism that occurs through the formation of free radicals; this mechanism leads to irreversible damage to cell membranes, protein structures and nucleic acids (RNA/DNA). [71]

Aim	Mechanism of Action	Conclusion
Cell Membrane	Lipid peroxidation — disruption of membrane integrity	Loss of intracellular fluid → cell death
Protein Structures	Irreversible oxidation and denaturation	Enzyme inactivation → metabolic functions cease

Aim	Mechanism of Action	Conclusion
Nucleic Acids (DNA/RNA)	Chain breakage and base damage.	Replication impossible → death or inactivation
Viral Envelope	Envelope oxidation in enveloped viruses.	Loss of infectivity → virus neutralization
Biofilm	Decomposition of the polysaccharide matrix	Dissolving the biofilm layer

10.4.2 Clinical Evidence Base

The antimicrobial efficacy of ozone disinfection is supported by extensive literature evidence:

- Viruses: Enveloped viruses have been shown to be particularly sensitive to ozone; infectivity is rapidly lost with oxidation of the viral envelope. [72] Of particular note are the studies on SARS-CoV-2: it has been experimentally proven that high levels of viral inactivation are achieved with 10–20 minutes of exposure in controlled ozone applications. [73]
- Bacteria: Inactivation occurs in both gram-positive and gram-negative bacteria as a result of cell wall and membrane damage. It has been reported that ozone can cause significant microbial reduction in short periods of time such as 5–15 minutes. [75]
- Fungi, Spores and Biofilm: Ozone has also been shown to be effective on fungal, spore and biofilm structures; this feature strengthens its broad-spectrum antimicrobial profile . [76]
- Penetration into Closed Spaces: Due to its application in gaseous form, ozone penetrates capillary airways and hard-to-reach surfaces, providing effective disinfection where conventional liquid disinfectants cannot reach. [74]

10.4.3 VENTISENSE — Material Compatibility

The effects of ozone disinfection on the electronic integrity of VENTISENSE have been examined in light of scientific literature , and the device's suitability for ozone disinfection has been confirmed. This assessment is comprehensively documented in the RP.25.01 Ozone Disinfection Scientific Basis and Literature Review Report prepared by Nefes Medikal R&D unit.

Component Category	Risk assessment	Rest
PCB / Motherboard	In modern passivated PCB components, temporary exposure for less than 20 minutes does not lead to structural changes.	[77]
Semiconductors (Sensors)	Ozone is used as a surface cleaning agent in the semiconductor industry; it does not damage the silicon dioxide layer.	[77]
Metallic Surfaces / Circuits	Corrosion only begins with a combination of high concentration (>100 ppm) + prolonged exposure (>24 hours) + liquid phase moisture.	[78]
Plastic / Polymer Components	In short-term (less than 20 minutes) applications, polymer degeneration remains well below the corrosion threshold.	[78]
Pneumatic Airways	Gas-phase application of ozone ensures complete penetration into internal capillary pathways; this is the primary goal of disinfection.	[RP.25.01]

i NOTE

VENTISENSE internal gas passages are suitable for ozone disinfection, and this method has been approved as a technical service protocol.

Application times under 20 minutes remain well below the corrosion threshold, posing no threat to device lifespan or electronic functionality.

10.4.4 Equipment Used

Equipment	Technical Specifications
Mfresh YL-S3500 Ozone Generator	Capacity: 3,500 mg/h (3.5 g/h) | Method: Corona Discharge | Control: Manual timer
Ozone Disinfection Box	Volume: ~31.5 liters (28 × 26.5 × 42.5 cm) | Material: Plastic container with silicone hose inlet
Connection	Silicone ozone tubing + disposable patient circuit.

10.4.5 Disinfection Protocol — Step-by-Step Implementation

Step 1: Preparation and Parameter Setting

- After the exterior cleaning of the VENTISENSE device is completed, it is placed inside the Ozone Disinfection Box.
- A circuit 30cm in length is attached to the device. Circuit is connected to the expiration port with resistance simulator
- Device parameters: PCV Mode, IPAP: 30 mbar, PEEP: 5 mbar, Tidal Volume: Off, Frequency: 15 bpm, Inspiration Time: 1 s.
- The device is switched on and the following disinfection parameters are set:

Parameter	Value
Mod	PCV
IPAP	30 mbar
PEEP	5 mbar
Target Volume	Closed
Frequency	15 bpm
Inspiration Time	1 second

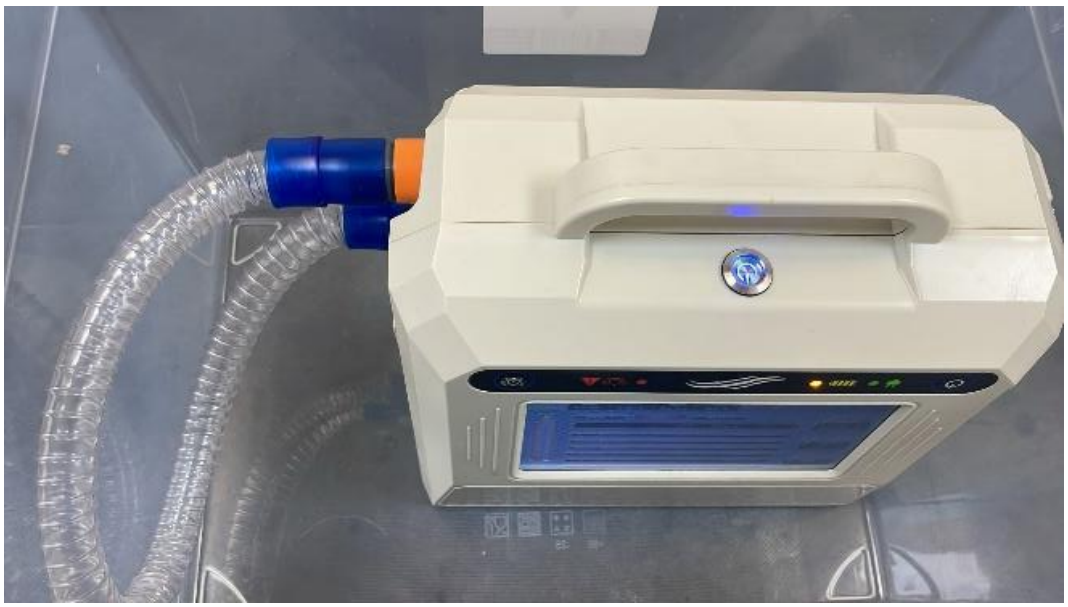


Figure 51—Ozone Generator Connection and Active Shocking

Stage 2: Active Shock Treatment — 5 Minutes

- The silicone hose connected to the outlet port of the Mfresh ozone generator is routed into the disinfection box.
- The box lid is sealed tightly to ensure a leak-proof seal.
- The generator is started by setting the timer to 5 minutes.

During a 5-minute active shock treatment process, the concentration in a 31.5-liter container reaches approximately 9,238 mg/m³. This value is well above the lethal dose threshold (100 mg/m³) defined for bacteria and viruses. Mathematical calculations: A device with a capacity of 3,500 mg/h reaches a concentration of 100 mg/m³ in a 31.5-liter container in just 3.2 seconds. [RP.25.01]

Stage 3: Closed Enforcement Waiting — 15 Minutes

- The generator will automatically shut off after 5 minutes. The box lid MUST NOT BE OPENED.
- VENTISENSE continues to operate inside the enclosure, circulating the trapped ozone gas through the internal gas passages for another 15 minutes.
- This step ensures complete penetration of ozone into the capillary pneumatic pathways and sufficient contact time across all internal surfaces.

Total contact time = 5 min (active shocking) + 15 min (closed recirculation) = 20 minutes. This time was determined by leaving a conservative safety margin above the reported ranges of 10–20 minutes [73] for viruses and 5–15 minutes [75] for bacteria .

Stage 4: Ventilation and Evacuation

- After the total 20-minute process is complete, the box is opened outdoors or in a well-ventilated area.
- After opening the box, wait approximately 30 minutes for the ozone level to drop to a safe level; do not tamper with the device before this time has elapsed.
- Once the process is complete, the device is taken to the technical service desk and the process is recorded on the FR.25.05 Technical Service Control Form.

Figure 52 — Ozone Disinfection: Ventilation Phase

10.4.6 Concentration Calculation and Safety Limits

Engineering calculations based on the Mfresh YL-S3500's 3,500 mg/h production capacity and 31.5-liter disinfection box demonstrate that the protocol is both effective and remains within safe limits: [RP.25.01]

Duration	Concentration per box	Evaluation
3.2 seconds	~100 mg/m³ (50 ppm)	The lethal threshold for microorganisms is being crossed.
5 minutes (active shock treatment)	~9.238 mg/m³	Complete saturation — full penetration into the capillary pathways.
20 minutes (total)	Calculated peak value	The disinfection objective is being successfully completed.
20 minutes OPEN box (forbidden)	~36.952 mg/m³	Occupational health and safety violation — at a level that

Duration	Concentration per box	Evaluation
		threatens human health.

These calculations clearly demonstrate why the generator was not operated for the full 20 minutes and why a closed-loop recirculation strategy was chosen: if the generator had continued to operate for 20 minutes , the concentration would have reached a level that would threaten human health in the event of an indoor toxic leak. The 5-minute active + 15-minute closed-loop recirculation strategy reduces the occupational health and safety risk to zero while maintaining maximum biocidal efficacy.

10.4.7 Security Requirements

⚠ WARNING

Ozone is a strong oxidizing gas at high concentrations ; it should not be inhaled directly.

The procedure should only be performed in a closed, well-ventilated area where no people are present.

Access to the transaction area should be blocked during the application process.

The entire 20-minute protocol must be completed before the box lid is opened.

If a strong chlorine/bleach-like odor is detected, the area should be immediately ventilated and evacuated.

The device should not be tampered with until the ozone level has dropped to a safe level (approximately 30 minutes after opening the lid).

10.4.8 Maintenance of the Ozone Generator

The stainless steel/ceramic plates (Ozone Plates) that enable ozone production with the Mfresh YL-S3500's Corona Discharge technology will have reduced ozone production capacity as they become dirty. These plates should be carefully wiped with alcohol or ammonia-soaked cleaning cloths every 6 months.

11. DEFINITIONS AND ABBREVIATIONS

Abbreviation / Term	Explanation
IPAP	Inspiratory Positive Airway Pressure
EPAP / PEEP	Expiratory Positive Airway Pressure / Positive End-Expiratory Pressure
PCV	Pressure Controlled Ventilation
VCV	Volume Controlled Ventilation
PSV	Pressure Support Ventilation
SIMV	Synchronized Intermittent Mandatory Ventilation
CPAP	Continuous Positive Airway Pressure
HFO	High Flow Oxygen
HFNC	High Flow Nasal Cannula
BiLEVEL	Bilevel Positive Airway Pressure
FiO_2	Fraction of Inspired Oxygen
HMEF	Heat and Moisture Exchanger Filter
TV / Vt	Tidal Volume — Tidal Volume
MV	Minute Volume
bpm	Breaths Per Minute — Number of Respirations per Minute
I:E	Inspiration:Expiration ratio
PS	Pressure Support (SIMV spontaneous breathing support)
NIV	Non-Invasive Ventilation
PESS	Programmable Electronic Safety System
EMC	Electromagnetic Compatibility

12. RELATED DOCUMENTS

Document No.	Document Name
TF.01.123	VENTISENSE User Manual
TF.01.21	VENTISENSE Product Information
TF.01.86	ISO 80601-2-72 Test Report
TF.01.83	Alarm Verification Test Report
TF.01.60	Technical Drawing File
TF.01.70	Critical Supplier/Material Information
TF.03.41	Chemical Declaration (CMR / Phthalate Content)
RP.25.01	Ozone Disinfection Scientific Basis and Literature Review Report
TL 25.04	Ozone Disinfection Instructions

13. REFERENCES

The clinical sources, evidence-based medicine guidelines, randomized controlled trials, systematic reviews, and international consensus documents cited in this technical reference handbook are listed below numbered. Citation numbers are indicated in square brackets [n] within the text.

[1] Slutsky AS, Ranieri VM. Ventilator-Induced Lung Injury. N Engl J Med. 2013;369(22):2126-2136.

[2] Bhatt SP, Bhatt GD, Bhatt M. Respiratory Failure in Adults. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. NCBI Bookshelf NBK526127.

[3] Mora Carpio AL, Mora JI. Ventilator Management. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. NCBI Bookshelf NBK448186.

[4] Lloyd-Owen SJ, Donaldson GC, Ambrosino N, et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. Eur Respir J. 2005;25(6):1025-1031.

[5] Garner DJ, Berlowitz DJ, Douglas J, et al. Home mechanical ventilation in Australia and New Zealand. Eur Respir J. 2013;41(1):39-45.

[6] Ergan B, Oczkowski S, Rochwerg B, et al. European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. Eur Respir J. 2019;54(3):1901003.

[7] Oliveira MG, Garner DJ, Berlowitz DJ, et al. Home mechanical ventilation: a narrative review and a proposal of practical approach. Respir Care. 2024.

[8] Lim WJ, Mohammed Akram R, Carson KV, et al. Update in Noninvasive Home Mechanical Ventilation. Int J Chron Obstruct Pulmonary Dis. 2024.

[9] Kato J, Hayashi T. Home mechanical ventilation in children with chronic respiratory failure: a narrative review. J Young Med Sci. 2022.

[10] Rochwerg B, Brochard L, Elliott MW, et al. Official ERS/ATS clinical practice guidelines: noninvasive ventilation for acute respiratory failure. Eur Respir J. 2017;50(2):1602426.

[11] Masa JF, Pérez de Llano L, De Lucas Ramos P, et al. Efficacy of different treatment alternatives for obesity hypoventilation syndrome. Pickwick Study. Am J Respir Crit Care Med. 2015;192(1):86-95.

[12] Finder JD, Birnkrant D, Carl J, et al. Respiratory care of the patient with Duchenne muscular dystrophy: ATS consensus statement. Am J Respir Crit Care Med. 2004;170(4):456-465.

[13] Bach JR, Ishikawa Y, Kim H. Prevention of pulmonary morbidity for patients with Duchenne muscular dystrophy. Chest. 1997;112(4):1024-1028.

[14] Povitz M, Jones SF, Pendharkar SR, et al. Clinical Outcomes Associated with Home Mechanical Ventilation: A Systematic Review. J Clin Sleep Med. 2016.

[15] Esteban A, Alía I. Clinical management of weaning from mechanical ventilation. Intensive Care Med. 1998;24(10):999-1008.

[16] Nichols D, Haranath S. Pressure control ventilation. Crit Care Clin. 2007;23(2):183-199.

[17] Deranged Physiology. Practical differences between pressure and volume controlled ventilation. derangedphysiology.com. 2022.

[18] Chacko B, Peter JV, Tharyan P, et al. Pressure-controlled versus volume-controlled ventilation for acute respiratory failure due to acute lung injury or ARDS. Cochrane Database Syst Rev. 2015.

[19] Esteban A, Ferguson ND, Meade MO, et al. Evolution of mechanical ventilation in response to clinical research. Am J Respir Crit Care Med. 2008;177(2):170-177.

[20] Acute Respiratory Distress Syndrome Network. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. N Engl J Med. 2000;342(18):1301-1308. [ARDSNet protocol]

[21] Hamahata NT, Sato R, Doklestić K, et al. Physiology, Tidal Volume. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. NCBI Bookshelf NBK482502.

[22] Rimensberger PC, Cheifetz IM; Pediatric Acute Lung Injury Consensus Conference Group (PALICC). Ventilatory support in children with pediatric acute respiratory distress syndrome. Pediatr Crit Care Med. 2015;16(5 Suppl 1):S51-60.

[23] Kneyber MCJ, de Luca D, Calderini E, et al. Recommendations for mechanical ventilation of critically ill children from the Paediatric Mechanical Ventilation Consensus Conference (PEMVECC). Intensive Care Med. 2017;43(12):1764-1780.

[24] Esteban A, Anzueto A, Alía I, et al. How is mechanical ventilation employed in the intensive care unit? Am J Respir Crit Care Med. 2000;161(5):1450-1458.

[25] Gupta P, Giehler K, Walters RW, Meyerink K. Synchronized Intermittent Mandatory Ventilation. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. NCBI Bookshelf NBK549846.

[26] Brochard L, Rauss A, Benito S, et al. Comparison of three methods of gradual withdrawal from ventilatory support during weaning from mechanical ventilation. Am J Respir Crit Care Med. 1994;150(4):896-903.

[27] Hinkelbein J, Spelten O, Wetsch WA. Pressure Support. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. NCBI Bookshelf NBK482391.

[28] Esteban A, Frutos F, Tobin MJ, et al. A comparison of four methods of weaning patients from mechanical ventilation. N Engl J Med. 1995;332(6):345-350.

[29] OpenAnesthesia. Pressure Support Ventilation. openanesthesia.org. 2025.

[30] Mehta S, Hill NS. Noninvasive ventilation. Am J Respir Crit Care Med. 2001;163(2):540-577.

[31] Plant PK, Owen JL, Elliott MW. Early use of non-invasive ventilation for acute exacerbations of chronic obstructive pulmonary disease on general respiratory wards: a multicentre randomized controlled trial. Lancet. 2000;355(9219):1931-1935.

[32] Mokhlesi B, Masa JF, Brozek JL, et al. Evaluation and Management of Obesity Hypoventilation Syndrome. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2019;200(3):e6-e24.

[33] Simonds AK. Home ventilation. Eur Respir J Suppl. 2003;47:38s-46s.

[34] Bourke SC, Tomlinson M, Williams TL, et al. Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomized controlled trial. Lancet Neurol. 2006;5(2):140-147.

[35] Patel SR, White DP, Malhotra A, et al. Continuous positive airway pressure therapy for treating sleepiness in a diverse population with obstructive sleep apnea. Arch Intern Med. 2003;163(5):565-571.

[36] Giannopoulos G, Deftereos S, Kossyvakis C, et al. Clinical aspects of obstructive sleep apnea and cardiovascular consequences. Front Physiol. 2022.

[37] Gray A, Goodacre S, Newby DE, et al. Noninvasive ventilation in acute cardiogenic pulmonary edema. N Engl J Med. 2008;359(2):142-151.

[38] Fraser J, Gould TH, Tucker O, et al. Continuous Positive Airway Pressure. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025. NCBI Bookshelf NBK482178.

[39] Frat JP, Thille AW, Mercat A, et al. High-flow oxygen through nasal cannula in acute hypoxemic respiratory failure. N Engl J Med. 2015;372(23):2185-2196. [FLORALI Study]

[40] Mauri T, Turrini C, Eronia N, et al. Physiologic Effects of High-Flow Nasal Cannula in Acute Hypoxemic Respiratory Failure. Am J Respir Crit Care Med. 2017;195(9):1207-1215.

[41] Ischaki E, Pantazopoulos I, Zakynthinos S. Nasal high flow therapy: a novel treatment rather than a more expensive oxygen device. Eur Respir Rev. 2017;26(145):170028.

[42] Fan E, Del Sorbo L, Goligher EC, et al. An Official ATS/ESICM/SCCM Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med. 2017;195(9):1253-1263.

[43] Parke RL, McGuinness SP, Eccleston ML. A preliminary randomized controlled trial to assess effectiveness of nasal high-flow oxygen in intensive care patients. Respir Care. 2011;56(3):265-270.

[44] Cortegiani A, Longhini F, Carlucci A, et al. High-flow nasal oxygen therapy: physiological mechanisms and clinical implications. Minerva Anestesiol. 2019;85(10):1111-1119.

[45] Harboe S, Hjalmarsson S, Soreide E. Flow trigger setting in mechanically ventilated patients: a scoping review. Intensive Care Med Paediatr Neonatal. 2024.

[46] Tassaux D, Gainnier M, Battisti A, Jolliet P. Impact of expiratory trigger setting on delayed cycling and inspiratory muscle workload. Am J Respir Crit Care Med. 2005;172(10):1283-1289.

[47] Liu L, Yu Y, Xu X, et al. Automatic Adjustment of the Inspiratory Trigger and Cycling-Off Criteria Improved Patient-Ventilator Asynchrony During Pressure Support Ventilation. Front Med (Lausanne). 2021.

[48] Pelosi P, Cadringher P, Bottino N, et al. Sigh in acute respiratory distress syndrome. Am J Respir Crit Care Med. 1999;159(3):872-880.

[49] Mauri T, Eronia N, Turrini C, et al. Sigh in Patients With Acute Hypoxemic Respiratory Failure and ARDS. Chest. 2021;159(1):440-455. [PROTECTION Study]

[50] Chiumello D, Quintel M. Positive End-Expiratory Pressure. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025. NCBI Bookshelf NBK441904.

[51] Amboss. Mechanical Ventilation — NIPPV Settings. amboss.com. 2023.

[52] Deranged Physiology. Inspiratory pause, I:E ratio and inspiratory rise time. derangedphysiology.com. 2023.

[53] Nickson C. Intrinsic PEEP. Life in the Fast Lane—Critical Care Compendium. litfl.com. 2024.

[54] Respiratory Therapy Zone. Auto-PEEP: Complication of Mechanical Ventilation. respiratorytherapyzone.com. 2026.

[55] NCBI Bookshelf. Positive End-Expiratory Pressure (PEEP). NBK441904. StatPearls Publishing; 2025.

[56] CN Meditech. How to Troubleshoot Ventilator Alarms and Failures in Clinical Settings. cnmeditech.com. 2026.

[57] Fanfulla F, Tognella S, Simovici C, et al. Leak Monitoring in Noninvasive Ventilation. Arch Bronconeumol. 2004.

[58] Luján M, Sogo A, Grimau C, et al. Influence of leak detection and compensation in non-invasive ventilation. Eur Respir J. 2019.

[59] Respiratory Therapy Zone. Ventilator Problems and Troubleshooting: An Overview. respiratorytherapyzone.com. 2025.

[60] Respiratory Therapy Zone. Ventilator Alarms: Types, Causes, and Troubleshooting. respiratorytherapyzone.com. 2026.

[61] ESICM PACT Course. Airway Management. pact.esicm.org . 2024.

[62] FP Notebook. Ventilator Troubleshooting. fpnotebook.com. 2025.

[63] Appendini L, Patessio A, Zanaboni S, et al. Physiologic effects of positive end-expiratory pressure and mask pressure support during exacerbations of COPD. Am J Respir Crit Care Med. 1994;149(5):1069-1076.

[64] Brochard L, Slutsky A, Pesenti A. Mechanical Ventilation to Minimize Progression of Lung Injury in Acute Respiratory Failure. Am J Respir Crit Care Med. 2017;195(4):438-442.

[65] eCampus Ontario. Initiation and Titration of NIV/BiPAP Settings. Basic Principles of Mechanical Ventilation. pressbooks.pub . 2023.

[66] Chatburn RL, Mireles-Cabodevila E. Closed-loop control of mechanical ventilation: description and classification of targeting schemes. Respir Care. 2011;56(1):85-102.

[67] Vrijlandt RLJE, Ketelaar ME, Stelma FF, et al. Indications for home mechanical ventilation in children: changes over four decades. Pediatr Pulmonol. 2024.

[70] Bhatt GD, Bhatt M. Ventilator Safety. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. NCBI Bookshelf NBK526044.

[71] Khadre MA, Yousef AE, Kim JG. Microbiological Aspects of Ozone Applications in Food: A Review. Journal of Food Science. 2001;66(9):1242-1252. DOI: 10.1111/j.1365-2621.2001.tb15196.x.

[72] Hudson JB, Sharma M, Petric M. Inactivation of Norovirus by ozone gas in conditions relevant to healthcare. Journal of Hospital Infection. 2007;66(1):40-45.

[73] Yano H, Nakano R, Suzuki Y, et al. Inactivation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by gaseous ozone treatment. Journal of Hospital Infection. 2020;106(4):837-838. DOI: 10.1016/j.jhin.2020.10.004.

[74] Sharma M, Hudson JB. Ozone gas is an effective and practical antibacterial agent. American Journal of Infection Control. 2008;36(8):559-563. DOI: 10.1016/j.ajic.2007.10.021.

[75] Tseng CC, Li CS. Ozone for Inactivation of Aerosolized Bacteriophages. Aerosol Science and Technology. 2006;40(9):683-689.

[76] Tiwari BK, Brennan CS, Curran T, et al. Ozone in Food Processing and Preservation. Wiley-Blackwell; 2010.

[77] Oizumi et al. Ozone-Based Cleaning Technology for Advanced Semiconductor Device Manufacturing. Journal of The Electrochemical Society. 1998.

[78] Lee SC, et al. Materials Compatibility and Disinfection Efficacy of Gaseous Ozone. Clinical Microbiology and Infection. 2002.