NEFES

Respiratory Therapy Device

User Manual

AIRPAP

CPAP | AUTOCPAP | BiLEVEL | BiLEVEL-ST | AUTOBiLEVEL | BiLEVEL-VT | ASV

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Copyright Information

NEFES MEDİKAL TEKNOLOJİ SAN. TİC. LTD. ŞTİ.

AirPAP User Manual rights reserved.

Nefes Medikal Teknoloji San. Tic. Ltd. Şti. products are covered by a 2-year manufacturer's warranty, excluding malfunctions caused by user error.

CE 2696

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

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

UDI-DI	MODEL NAME
08684190120018	CPAP
08684190120025	AUTOCPAP
08684190120032	BiLEVEL
08684190120049	BiLEVEL-ST
08684190120056	AUTOBiLEVEL
08684190120063	BiLEVEL-VT
08684190120070	ASV

This Instructions for Use applies to AirPAP devices with software version V1.06 and higher.

CONTENTS

INTRODUCTION

General information about **AIRPAP**.

AIRPAP is used in the treatment of sleep-disordered breathing; it regulates respiration and sleep quality by keeping the upper airways open during sleep.

AIRPAP draws in ambient air through a filter containing a blower; it regulates the pressure based on feedback from sensors and delivers it to the device outlet as pressurized air. This pressurized air is humidified with heated water in the humidifier and reaches the patient through the tubing system and mask.

The control unit in the therapy device monitors the operation of the blower for the next breath cycle by receiving feedback through sensors during inspiration and expiration. Thus, the patient receives the optimal treatment via the algorithm created according to the operating mode.

While constant pressure is delivered in devices belonging to the **CPAP** group, two-level pressure support is provided in devices belonging to the **BiLEVEL** and **ASV** groups.
AIRPAP features a soft start ramp, an automatic start-stop function, and an adjustable alarm clock for comfortable use.

The built-in accessory of **AIRPAP** is the humidifier. The heating level of the humidifier can be easily adjusted from the device screen.

The models of the AIRPAP Respiratory Therapy Device are as follows:

- **CPAP**
  - Applies constant and continuous positive airway pressure.
  - The patient initiates all respiration; no extra pressure support is provided by the device.
- **AUTOCPAP**
  - Automatically adjusts the pressure according to respiratory limits and obstructions.
  - Operates dynamically between the determined lower and upper limits; gradually decreases the pressure if no pathology is present.
- **BiLEVEL**
  - Applies high pressure during inhalation (IPAP) and low pressure during exhalation (EPAP).
  - Transitions depend entirely on the patient's own respiratory effort and rate, or the set frequency.
- **BiLEVEL-ST**
  - It is a hybrid mode that both tracks the patient and operates on a time-set basis.
  - If the patient does not breathe on their own, the device steps in at the set frequency after the determined period to provide the transition.

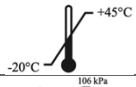
- **AUTOBiLEVEL**
  - It is an intelligent bilevel mode that detects respiratory events such as apnea and snoring.
  - Automatically determines IPAP and EPAP pressures, but leaves the breath transition frequency entirely to the patient's own effort.
- **BiLEVEL-VT**
  - It is average volume-assured pressure support.
  - EPAP is constant; the device automatically adjusts IPAP to achieve a constant target volume (tidal volume) according to the patient's needs.
- **ASV**
  - It is an adaptive servo-ventilator that instantaneously adapts to the respiratory pattern.
  - Steps in during sudden respiratory changes and offers dynamic IPAP/EPAP support to maintain 90% of the patient's normal respiration.

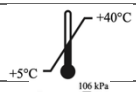
DELIVERY CONTENTS

Picture	Description
	Respiratory Therapy Device
	Power Supply Unit
	Power Cable
	SD Card
	User Manual
	Carrying Bag

SYMBOLS

SYMBOLS ON PACKAGE LABEL AND THEIR MEANINGS

Symbol	Description
	Manufacturer, Manufacturing Site
	Date of Manufacture
	Serial Number
	Reference Number
IP22	IP Protection Level • Provides protection against solid foreign objects of 12.5 mm diameter or greater and vertically falling water drops when tilted up to 15°.
CE 2696	CE – European Conformity • Indicates compliance with Regulation (EU) 2017/745 — MDR (Medical Device Regulation).
	Read the instructions for use before using the device.
	Fragile, handle with care.
	Do not use if package is damaged.
	Keep dry.
	Keep away from sunlight.
	Temperature limit for storage conditions.
	Atmospheric pressure limit for storage conditions.
	Humidity limit for storage and operating conditions.

	Temperature limit for operating conditions.
	Atmospheric pressure limit for operating conditions.

SYMBOLS AND MEANING ON DEVICE LABEL

Symbol	Description
SN	Serial Number
REF	Reference Number
MD	Medical Device
	Manufacturer
CE 2696	CE – European Conformity • Indicates compliance with Regulation (EU) 2017/745 — MDR (Medical Device Regulation).
	Type BF Applied Part
	Protection Class II (Double Insulated Protection)
	Warning / Caution Observe the warnings and safety instructions in the instructions for use.
	Read the instructions for use before using the device.
	Do not dispose of the device in municipal waste. Contact an authorized customer service center for proper disposal of the device
IP22	IP Protection Level • Provides protection against solid foreign objects of 12.5 mm diameter or greater and vertically falling water drops when tilted up to 15°.

SYMBOLS ON THE DEVICE

Symbol	Description
	These ports are not in use. Do not connect anything to them.
	USB Inlet

Symbols Warnings	Description
	Read the user manual before using the device.
	If the label is removed, the device will be void of warranty.

ON-DISPLAY SYMBOLS AND MEANINGS

Symbols	Description
	Main menu
	Warning
	Spontaneous breathing detected.
	SD Card inserted
	Timed Triggering
	Mask Test Performing.
	Ramp
	Apnea detected.
	Hypopnea detected.
	Central Apne detected.
	Snoring detected.

SYMBOLS IN USER MANUAL

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

CAUTION

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

WARNING

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

NOTE

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

INTENDED USE

AIRPAP Respiratory Therapy Devices are used in the treatment of obstructive sleep apnea. The device is used for therapeutic purposes in patients with sleep-related hypoventilation/hypoxemic syndrome (restrictive lung disease, chronic obstructive pulmonary disease, obesity-hypoventilation syndrome, hypoventilation/hypoxemia due to pulmonary parenchymal or vascular pathologies, etc.) whose spontaneous breathing and induction force is insufficient. Often referred to as BIPAP for Bi-Level Positive Airway Pressure, it is a device that delivers a constant flow of air to the patient and ensures maximum and minimum airway pressure during spontaneous breathing.

WARNING

AIRPAP cannot be used in patients who require artificial ventilation. This device is not a life-support system.

USER INFORMATION

Respiratory therapy device can be used in healthcare facilities by doctors, nurses, electro-neurophysiology technicians and/or clinical support personnel trained in this field, in home by patients and/or their relatives who have been trained in the use of the device.

- User training is provided by the authorized distributor.

SCOPE OF USE

AirPAP is suitable for use by adults and children weighing more than 30 kg/12 years.

INDICATIONS

Model Name / Indications	CPAP	AutoCPAP	BILEVEL	BILEVEL - ST	AUTO BILEVEL	BILEVEL – VT	ASV
Obstructive Sleep Apnea Syndrome (OSAS)	X	X	X	X	X	X	X
Mixed or Complex Sleep Apnea			X		X		
Central Apnea							X
Obesity Hypoventilation Syndrome (OHS)	X	X	X	X	X	X	X
Positional OSAS		X					
REM-related OSAS		X					
Chronic Obstructive Pulmonary Disease (COPD)			X	X	X		
Restrictive Pulmonary Disease			X		X	X	
Sleep-Related Hypoventilation/ Hypoxemia Symptoms	X			X		X	
Cheyne Stokes							X

CONTRAINDICATIONS

The following specific conditions may be a contraindication for CPAP, AutoCPAP, BILEVEL, BILEVEL – ST, AUTOBILEVEL, BILEVEL – VT therapy devices:

- Acute decompensated heart failure
- Severe cardiac arrhythmias
- Severe hypotension associated with intravascular volume reduction
- Severe chronic/decompensated pulmonary diseases
- Pneumothorax
- Pneumo Medinum (PM)
- Pneumocephalus (existing trauma or surgery that could produce a nasopharyngeal fistula)
- Severe nosebleeds
- High risk of barotrauma
- Head trauma
- Acute sinus inflammation (sinusitis)
- Otitis media
- Perforation of the eardrum
- Dehydration

WARNING

The following specific conditions may be a contraindication for ASV therapy devices:

- Symptomatic - chronic, systolic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%)
- Moderate to severe predominant central sleep apnea (AHI 15/h, CAHI/AHI 50%, and CAI 10/h).

CAUTION

If device is used with a humidifier, do not mix any additives such as drugs or aromatic oils into humidifier water.

SIDE EFFECTS

Possible side effects include:

- Face respirator and forehead pad scars
- Rashes on the skin of the face
- Nasal congestion
- Dry nose
- Nose bleeding
- dry mouth in the morning
- Sensation of pressure in the nasal cavities
- Irritation of the conjunctival tissue in the eyes
- Gastrointestinal gas

⚠CAUTION

In the presence of paranasal sinus, otitis media, or acute upper respiratory tract infection, it may be necessary to discontinue treatment. Please consult your physician.

SAFETY WARNINGS

AirPAP Device Warnings;

1. GENERAL SAFETY AND CLINICAL USE
2. OXYGEN AND FIRE HAZARDS
3. POWER AND ELECTRICAL SAFETY
4. ENVIRONMENTAL AND OPERATIONAL
5. HUMIDIFICATION AND TUBING SAFETY
6. MAINTENANCE AND CLEANING

WARNING

Read and understand all warnings before using the AirPAP device.

Nefes Medikal Teknoloji San. Tic. Ltd. Şti. Respiratory therapy devices: It has an external, switched, 100 – 240V AC, 50–60Hz input power supply unit. This unit allows connection with all energy grids in world.

It is possible to operate device with 24V DC direct voltage. When connecting the DC power supply to device, please use only Nefes Medikal Teknoloji San. Tic. Ltd. Şti. Use power cable supplied by.

Nefes Medikal Teknoloji San.Tic Ltd.Şti., in following cases; is not responsible for any damage to the device or conditions affecting safety, reliability and performance:

- Operation, modification, expansion, adjustments, repair and maintenance measurements made by persons not authorized by us.
- Use of accessories and spare parts from other manufacturers that are not approved by us for use with NEFES Medikal Teknoloji A.Ş. Respiratory Therapy Device.
- Using the device in a different way than specified in device user manual.
- Failure to comply with hygiene and cleaning instructions in the user manual.

1. GENERAL SAFETY AND CLINICAL USE

- **WARNING:** The user manual must be read completely before the device is operated.
- **WARNING:** AIRPAP is not a life protection (support) system and cannot be used in patients who need artificial respiration or continuous ventilator support.
- **WARNING:** The device is indicated for use only by adults and children weighing more than 30 kg / 12 years of age.
- **WARNING:** Pregnant and lactating mothers must consult their doctor before using the product.
- **WARNING:** Clinical settings of the device should only be made by the physician, nurse, electroneurophysiology technician, and/or trained clinical support personnel based on the patient's clinical data. Do not change the set pressure yourself.
- **WARNING:** Use the device only for your own therapy, taking into account diseases identified by responsible clinical personnel, and exactly as directed by your doctor. Advice contained in this manual should not supersede instructions given by the prescribing physician.
- **WARNING:** Positive airway pressure therapy may be contraindicated in patients with severe bullous lung disease, pneumothorax, pathologically low blood pressure, dehydration, or cerebrospinal fluid leak.
- **WARNING:** Only use vented (leakage) masks recommended by your physician or the manufacturer. To ensure the disconnection of the tubing system is prevented, only tubes complying with ISO 5367 or ISO 80601-2-74 should be used. Fitting the mask without the device blowing air can result in rebreathing of exhaled air and cause asphyxiation.
- **WARNING:** For therapy safety, the device should be operated in such a way that all adjustable alarms are activated and adapted to patients, and alarm signals must not be ignored.
- **WARNING:** If you experience unusual chest pain, severe headache, increased breathlessness, dryness of the mucous membrane, ear or sinus discomfort, skin rashes, or extreme numbness, stop using the device and contact your doctor immediately.
- **WARNING:** If you notice any unexplained changes in the performance of the device, if it is making unusual sounds, if the device is dropped or mishandled, or if the enclosure is broken, discontinue use immediately and contact the authorized company.
- **WARNING:** Do not open or modify the device. There are no user-repairable parts inside the device. Maintenance and repair should only be done by personnel authorized by Nefes Medikal.
- **WARNING:** Incorrect system setup may result in incorrect mask pressure reading. Check the device and patient connections before switching on the patient-connected device.
- **WARNING:** Efficacy monitoring parameters (Aflow, Hflow, and AHIflow) are approximate measurements provided by sleep apnoea respiratory therapy equipment and are not diagnostic parameters for making a clinical diagnosis.

- **WARNING:** The device does not have an SPO2 input. An SPO2 connection has not been made to the device. The device cannot be used with SPO2.
- **WARNING:** The accuracy of displayed airway pressure values under steady-state conditions shall not exceed ±(2% of the full-scale reading + 4% of the actual reading) in accordance with EN ISO 80601-2-70:2020.
- **WARNING:** The device is a non-sterile product.
- **WARNING:** While carrying the device, hold it with both hands and carry it in its dedicated bag.
- **WARNING:** Only accessories supplied or recommended by Nefes Medikal shall be used with AIRPAP devices. The humidifier, therapy tube, inlet filter and power supply supplied with the device are compatible with CPAP, AUTOCPAP, BiLEVEL, BiLEVEL-ST, AUTOBiLEVEL, BiLEVEL-VT and ASV models. The use of incompatible accessories may result in degraded device performance and ineffective therapy.
- **WARNING:** Reuse of masks, filters, tubing or other accessories beyond the manufacturer's recommended replacement interval may result in reduced performance, contamination, infection risk or ineffective therapy.

2. OXYGEN AND FIRE HAZARDS

- **WARNING:** The device must not be used with ambient air containing flammable anesthetics or explosive gases. This may cause fires or explosions.
- **WARNING:** Sources of oxygen must be located more than 1 meter from the equipment to avoid the risk of fire and burns.
- **WARNING:** Oxygen supports combustion. Supplemental oxygen must not be used while smoking or in the presence of an open flame.
- **WARNING:** Always make sure that the device is turned on and airflow is generated before the oxygen supply is turned on.
- **WARNING:** Always turn the oxygen supply off before the device is turned off, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.

3. POWER AND ELECTRICAL SAFETY

- **WARNING:** The device must be installed so that the mains power plug remains easily accessible in case of emergency. To disconnect AIRPAP completely from power, the power plug must be unplugged.
- **WARNING:** Safe operation of the device is guaranteed only when used with the original power supply (adapter) provided by the manufacturer. The use of accessories or power supplies not approved by the manufacturer may result in increased electromagnetic beam emission, decreased robustness, or increased patient discharge current.
- **WARNING:** The device must not be operated if the housing, power cable, or power supply is damaged. Regularly inspect power cords, cables, and the power supply for damage or signs of wear, and discontinue use and replace if damaged.
- **WARNING:** Keep the power cord away from hot surfaces.
- **WARNING:** Beware of electrocution; do not immerse the device, power supply, or power cord in water. If the device or power supply is dropped into water, do not try to hold it or touch it; unplug it immediately.
- **WARNING:** If liquids are spilled into or onto the device, unplug the device and let the parts dry before plugging it back in.
- **WARNING:** Do not use the appliance near water, such as a bathtub, bathroom sink, kitchen sink, laundry tub, a wet floor.
- **WARNING:** In the event of a power failure, the device does not need to be reprogrammed. When power is restored, the device will operate with the program settings active prior to the power failure.
- **WARNING:** The device does not contain a battery; it operates only via a mains power connection.
- **WARNING:** To prevent electric shock, disconnect the power plug and switch off the device before cleaning the housing. Always ensure that all parts are dry before plugging it back in.

4. ENVIRONMENTAL AND OPERATIONAL

- **WARNING:** Place the device on a firm, flat, and stable surface near your bed. Do not place the device on its side, as water from the humidifier might get into the device.
- **WARNING:** Do not place the device where it can be easily bumped or where someone is likely to trip over the power cord.
- **WARNING:** Never place the device in a closed cabinet, under a bed, or right against a wall. Ensure that the air around the device can circulate easily.
- **WARNING:** Keep the area around the device dry, clean, and clear of anything (e.g., bedding, clothes, curtains) that could block the air inlet filter or cover the power supply unit. Blocking the air tubing or air inlet while in operation could lead to overheating and adversely affect the therapy.
- **WARNING:** Do not expose the device to direct sunlight or place it near any heat sources (e.g., radiators).
- **WARNING:** The device is MR Unsafe. It has not been tested for use in the vicinity of MRI (Magnetic Resonance Imaging), CT, or X-ray equipment. Never bring the device into an MR environment.
- **WARNING:** The device must not be used in hyperbaric oxygen therapy chambers (pressure chambers).
- **WARNING:** To prevent electromagnetic interference, the device should not be used adjacent to or stacked with other equipment. It should be kept at least 30 cm away from portable RF communication equipment (such as mobile phones, radios, and antenna cables).
- **WARNING:** The use of the humidifier with a gas source (e.g., a blower/turbine-based ventilator) that raises the gas supplied to the humidifier above its nominal temperature may result in impaired humidification output, which has the potential to lead to serious health problems.
- **CAUTION:** Operating the device outside the approved temperature range (5°C to 40°C) or altitude (up to 3000 m) may reduce the effectiveness of the treatment and damage the device.
- **CAUTION:** If the device has been stored or transported at extreme temperatures, allow it to acclimate to room temperature for at least 1 hour before operating to prevent internal condensation and ensure safe operation.
- **CAUTION:** The device must not be covered with bedding, clothing, curtains or other materials, and must not be positioned in a manner that could adversely affect its operation or performance.

5. HUMIDIFICATION AND TUBING SAFETY

- **WARNING:** The internal humidifier is designed to hold a maximum of 350 ml of water. Do not overfill the water tub as water may enter the device and air tubing.
- **WARNING**: Use distilled water (pure water) for the humidifier. Do not mix any additives, such as medications, aromatic oils, or scented oils into the humidifier water. These can damage the device, affect humidification performance, and harm the patient's respiratory tract.
- **WARNING:** Humidification can increase the resistance of breathing system filters. The operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.
- **WARNING:** If you use the humidifier, always place the device on a level surface lower than your head to prevent the mask and air tubing from filling with water.
- **WARNING:** Leave the water tub to cool for ten minutes before handling to allow the water to cool and to make sure that the humidifier is not too hot to touch.
- **WARNING:** Make sure that the humidifier water tub is empty before transporting the device.
- **WARNING:** Electrically conductive or electrostatically charged patient therapy tubes should not be used.
- **WARNING:** Covering breathing tubes with a blanket or heating them can affect the quality of the therapy or injure the patient.
- **WARNING:** The humidifier shall not be used with nitric oxide. Such use might cause the humidifier to not function correctly causing serious deterioration of health.
- **WARNING:** Do not add any attachments or accessories to the humidifier that contravene the instructions for use of the humidifier or accessory as the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.

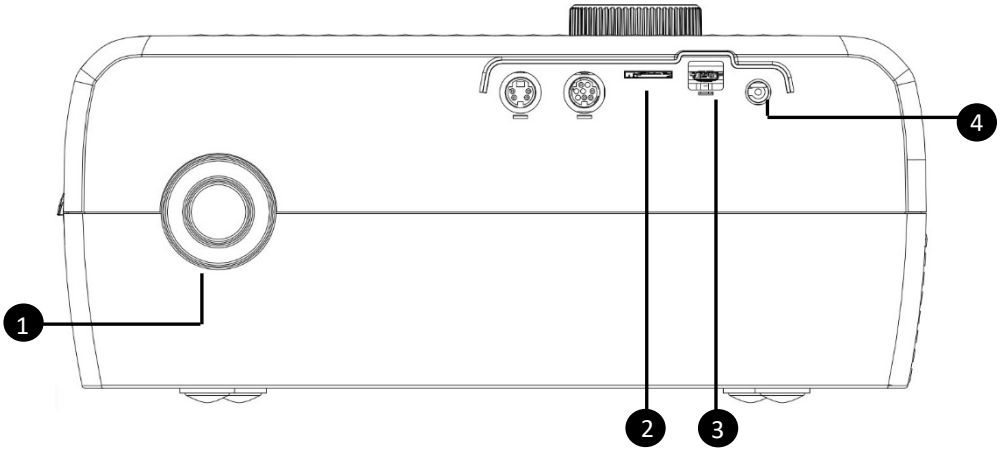
6. MAINTENANCE AND CLEANING

- **WARNING:** Always disconnect the power plug before cleaning the device. Never immerse the device, humidifier, power supply, or power cord in water. Make sure that all parts are completely dry before plugging the device back in.
- **WARNING:** Do not perform any maintenance or cleaning tasks while the device is in operation.
- **WARNING:** Do not open or modify the device. There are no user-repairable parts inside the device. Maintenance and repair should only be done by personnel authorized by NEFES MEDİKAL.
- **WARNING:** The device and its components must not be steam sterilized in autoclaves. High temperature and pressure may cause permanent damage to device components. There is no need for chemical or thermal disinfection of the main device.
- **WARNING:** Do not clean the device with abrasive, solvent-based (acetone, benzene), highly chlorinated substances, bleach, alcohol, aromatic-based solutions, or antibacterial soaps. These agents may damage the display panel and plastic housing, affect humidifier performance, and reduce the life of the products.
- **CAUTION:** Check the air filter regularly. Never use the device without an air filter. The filter must be changed once a month or when the "Filter Change" message appears on the display. Reusing a filter for more than one month is not recommended as it cannot fulfill its protective function.
- **CAUTION:** The service interval indicator (time remaining for service) displayed in the settings menu should be observed, and periodic maintenance must be performed. Failure to perform scheduled maintenance may reduce ventilation performance and jeopardize patient safety.
- **CAUTION:** Disposal of replaced filters, components, and accessories must comply with applicable medical waste regulations and local environmental legislation.

DEVICE OVERWIEW

AirPAP Use, Control, and Connection Components

CONNECTIONS ON THE BACK PANEL



Picture 1: Connections on Back Panel

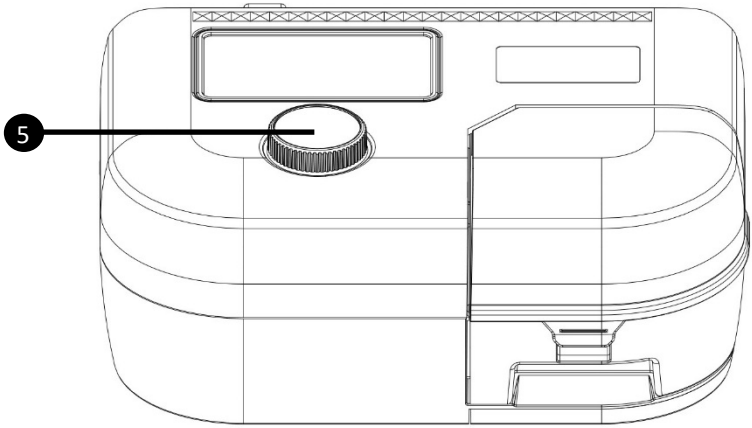
1. **Therapy Tubing Inlet**
   It is where the therapy hose circuit is connected
2. **SD Card Inlet**
   SD card included in the scope of delivery is inserted here
3. **USB Inlet**
   PC connection takes place here using USB (Interface) Connection.
4. **Power Supply Inlet**
   The power supply connector is connected here.

NOTE

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

CONTROL ELEMENTS

In **Nefes Medikal Teknoloji** respiratory therapy devices; User interaction is done via LCD touch display and knob.

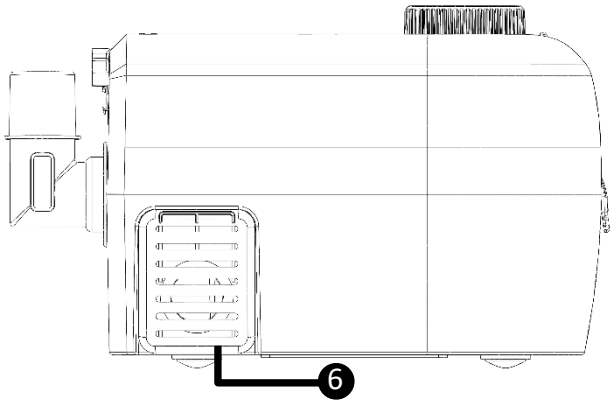


Picture 2: Control Elements

5. **Knob/Multi-Function Button:**
   - Modifying and confirming parameter values
   - Performing the function of starting and stopping therapy

➢ **All adjustments that can be made on device are made with touch LCD display and knob.**

FILTERS AND USAGE



Picture 3: Filter

6. Inlet Filter

- The inlet filter can be removed to be changed at certain intervals.

BEFORE USING

1. A malfunctioning device presents a danger to patient or user. If device is not working properly, do not continue to operate device. In this case, inform service.

2. The device only works in conjunction with the power supply. There is no external battery. Position the device so that it is easily accessible to the socket and can be quickly removed in case of danger.

3. Never operate device in very cold environments. Wait approximately 1 hour for temperature to stabilize. (Device should be operated at temperatures between 5 °C and 40 °C.)

4. Check air filter regularly. Clean filter at regular intervals. **Never use device without an air filter.**

5. Clean your mask system and constantly check all its parts, especially the therapy hose, mask and headgear. We recommend cleansing your face before going to bed to remove skin oils and cosmetics. This process extends life of mask and reduces possibility of skin irritation.

6. Do not operate device if device or its power supply or power cable is damaged.

WARNING

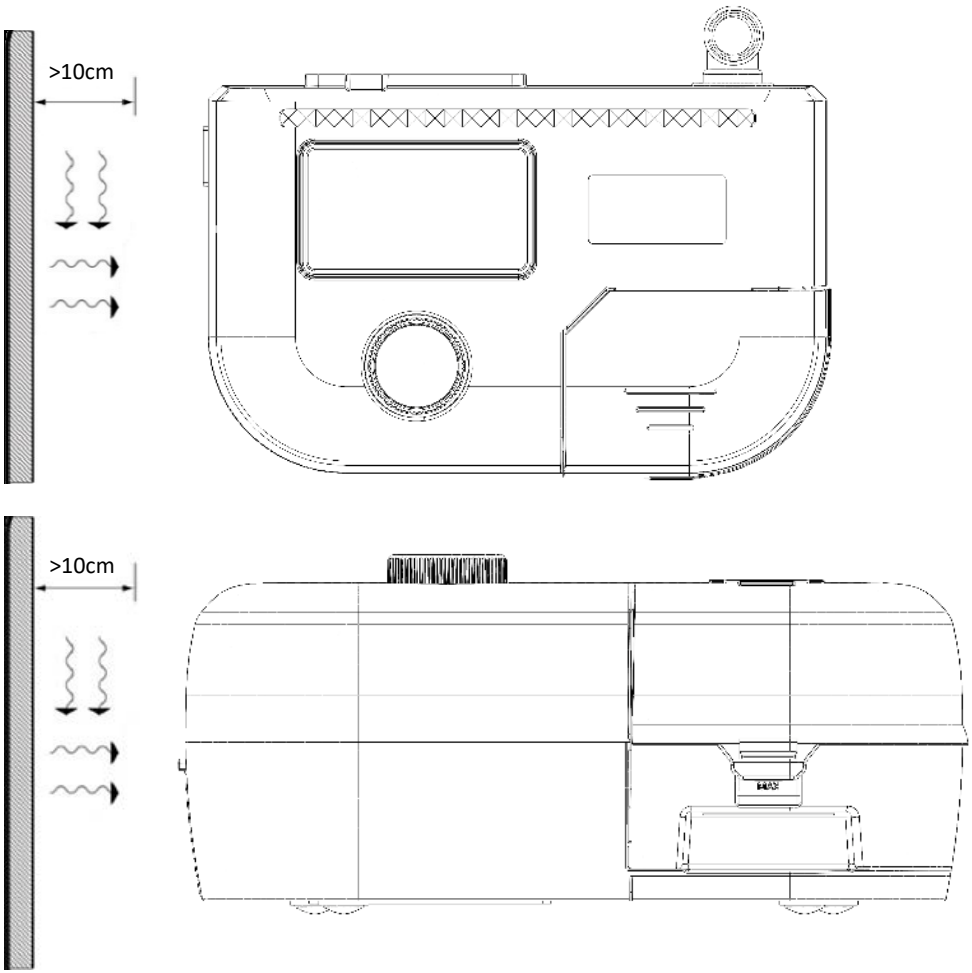
Pre-Start Warnings

- Place device on a hard, flat surface near your bed place it.
- Do not place any container filled with liquid on device.
- Protect device from high temperatures, humidity and liquids protect.
- No objects should be placed on the device.
- Device should not be exposed to direct sunlight.
- Do not place the device near containers filled with water.
- Device, air inlet on side panel and all
- Do not block ventilation slots

DEVICE INSTALLATION AND ACCESSORY CONNECTIONS

DEVICE INSTALLATION

The device must be placed on a level and stable surface without restricting the use of the air intake filter.



Picture 4: Air Inlet Filter

- Place the device on a flat surface.
- Ensure that the device is level lower than the user's sleeping position.
- Ensure that the inlet filter on the side panel of the device is not in contact with any other object or surface.
- Connect the device to the power supply.
- Ensure that there is sufficient water in the humidifier chamber.
- The water capacity of the AIRPAP humidifier is sufficient for continuous use throughout the night (averaging 8 hours).
- Connect the therapy tubing to the air outlet.
- Connect the mask to the other end of the therapy tubing, place the mask on your face, and follow the mask instructions for use.
- Press the "start/stop" button on the device screen to start the therapy.

POWER SUPPLY

AIRPAP must be connected to the mains via the power supply for operation.

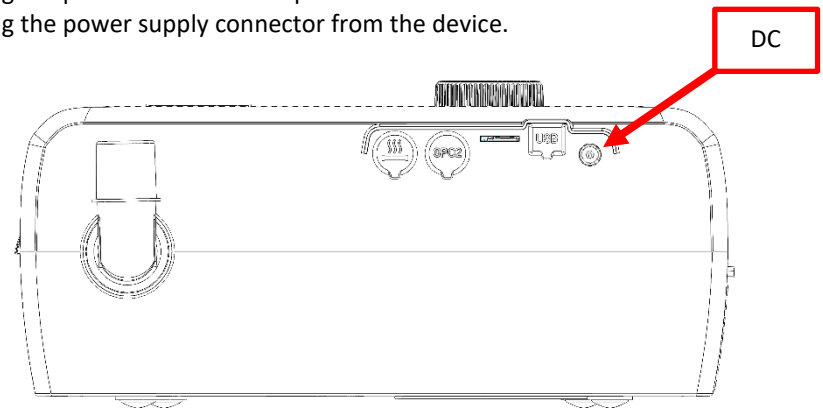
MAINS VOLTAGE

INSERTING THE POWER SUPPLY

1. Connect the power supply connector to the DC connector on the rear panel of the device.
2. Connect the power cable to the power supply.
3. Plug the power cord into an outlet (100 - 240 V, 50/60 Hz).

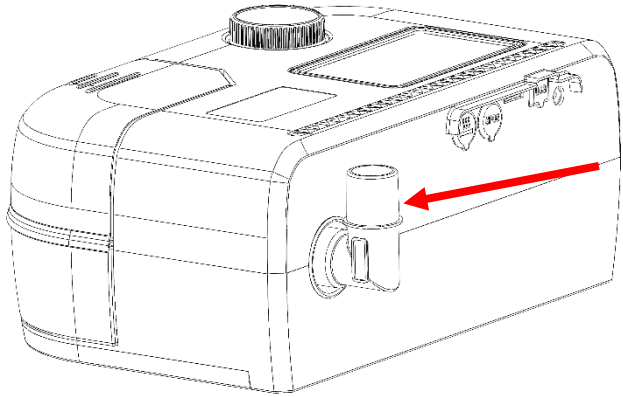
REMOVING THE POWER SUPPLY

1. Unplug the power cord from the power outlet.
2. Unplug the power supply connector from the device.



Picture 5: Power Supply Inserting and Removing

CONNECTING THE THERAPY HOSE CIRCUIT

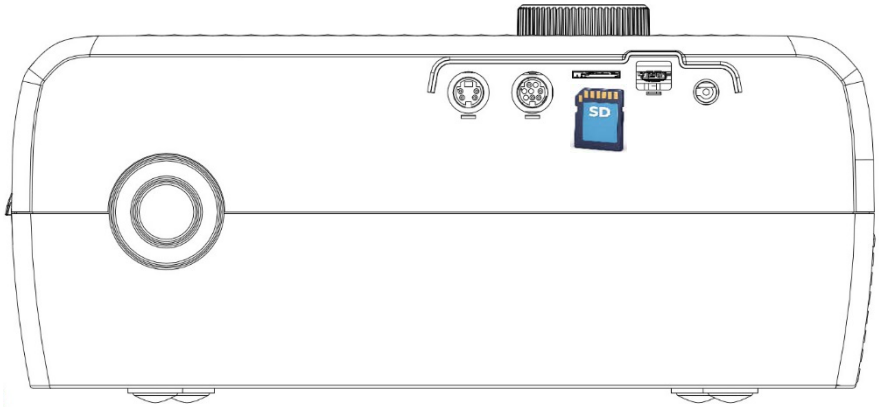


Picture 6: Connecting the Therapy Hose Circuit

Firstly, the 90-degree plastic adapter piece that comes out of the bag is attached to the hose inlet on the rear panel of the device. At the end of the plastic piece, the therapy hose circuit is attached.

INSERTING SD CARD

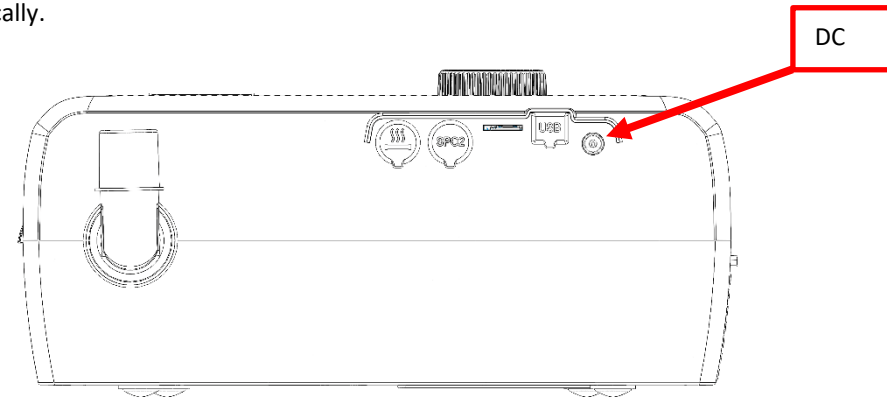
Insert the SD card into the SD card slot in accordance with Picture, pushing it in until you hear a "click" sound. It will then appear in the toolbar. Minimum 4 GB SD card is used. It appears in the toolbar when the SD Card is inserted correctly.



Picture 7: Inserting SD Card

OPERATING THE DEVICE

The device does not work without being connected to the power supply. Connect the device power supply to the DC port on the rear panel of the device. The device will turn on automatically.



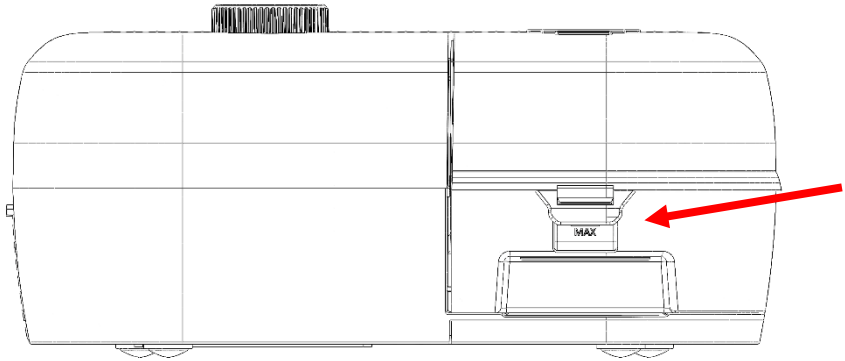
Picture 8: Operating the device

TURNING OFF THE DEVICE

After stopping the therapy on the device with the help of touch or knob, the device is automatically switched off by removing the power supply of the device.

HUMIDIFIER SETTING

Fill the humidifier with distilled water up to the maximum level (350 ml). Place the humidifier into the humidifier reservoir of the respiratory therapy device. To activate the humidifier, turn on the "Heater" mode in the settings and adjust the heating level.



Picture 9: Humidifier

RESPIRATORY THERAPY DEVICE MODES

Operation Modes

AirPAP products are designed for patients to receive the most appropriate treatment with 8 modes.

Mode Name	Description
CPAP – Continuous Positive Airway Pressure	• It is a therapy mode in which a single set positive airway pressure is continuously applied throughout the respiratory cycle. • All respiratory cycles are spontaneously initiated and terminated by the patient. • The set pressure level is maintained throughout both the inspiratory and expiratory phases. • No mandatory breaths or additional inspiratory pressure support are provided by the device. • The applied positive pressure helps keep the upper airway open. **Physiological Basis** It creates a pneumatic splint effect in the upper airway, preventing pharyngeal collapse. It increases functional residual capacity, reduces upper airway resistance, and maintains airway patency during sleep. Alveolar stability is preserved while the work of breathing is reduced. **Clinical Indications** First-line treatment for Obstructive Sleep Apnea (OSA). It may be used for snoring, upper airway resistance syndrome, mild cardiogenic pulmonary edema, and selected hypoxemic patients.
AUTOCPAP – Automatic Positive Airway Pressure	• It is a therapy mode that automatically adjusts positive airway pressure throughout the respiratory cycle between the set minimum and maximum pressure limits. • All respiratory cycles are spontaneously initiated and terminated by the patient. • The therapy pressure is automatically adjusted within the set pressure range according to the patient's respiratory needs. • No mandatory breaths or additional inspiratory pressure support are provided by the device.

	• The device makes pressure adjustments according to its algorithm by monitoring apnea, hypopnea, and snoring events. • The applied positive pressure helps keep the upper airway open. **Physiological Basis** It is based on the same fundamental physiology as CPAP but dynamically adjusts the pressure according to the severity of respiratory events. It aims to maintain airway patency while reducing unnecessary exposure to high pressure. **Clinical Indications** OSA patients whose pressure requirements vary throughout the night, patients experiencing weight changes, and patients with variable obstruction related to body position or REM sleep.
Bilevel - S (Spontaneous)	• It is a therapy mode that delivers two levels of positive airway pressure, in which all respiratory cycles are spontaneously initiated and terminated by the patient. • Inspiratory Pressure (IPAP) is applied during the inspiratory phase, and Expiratory Pressure (EPAP) is applied during the expiratory phase. • The device switches between Inspiratory Pressure (IPAP) and Expiratory Pressure (EPAP) values according to the patient's breathing. • The respiratory rate is determined by the patient; no mandatory breaths are delivered by the device. **Physiological Basis** It provides ventilatory support through the difference between IPAP and EPAP. It increases tidal volume and alveolar ventilation, while the lower pressure during expiration improves patient comfort and reduces the work of breathing. **Clinical Indications** Hypercapnic respiratory failure, COPD, obesity hypoventilation syndrome, neuromuscular diseases, and OSA patients who cannot tolerate CPAP.
Bilevel - T (Timed)	• It is a time-controlled therapy mode that delivers two levels of positive airway pressure according to the set respiratory rate and inspiratory time. • It does not support the patient's spontaneous effort. • The respiratory cycle is generated by the device according to the set respiratory rate and inspiratory time.

	• Inspiratory Pressure (IPAP) is applied during the inspiratory phase, and Expiratory Pressure (EPAP) is applied during the expiratory phase. • When the Assist Mode parameter is activated: o The device detects the patient's spontaneous inspiratory effort. The respiratory rate is determined by the patient. o The patient's spontaneous expiratory effort does not affect the set inspiratory time. **Physiological Basis** Ventilation is provided entirely in a time-controlled manner. Minimum ventilation is intended to be ensured by the specified respiratory rate and inspiratory time. **Clinical Indications** Patients with insufficient or unreliable spontaneous breathing, central hypoventilation conditions, and certain neuromuscular diseases.
Bilevel - ST (Spontaneous – Timed)	• It is a bi-level positive airway pressure therapy mode that supports the patient's spontaneous breathing and provides time-controlled mandatory breaths if no spontaneous inspiratory effort is detected within the set time interval. • Inspiratory Pressure (IPAP) is applied during the inspiratory phase, and Expiratory Pressure (EPAP) is applied during the expiratory phase. • If no spontaneous inspiratory effort is detected within the set respiratory rate interval, the device initiates a mandatory breath according to the set respiratory rate. **Physiological Basis** It supports spontaneous breaths while a backup respiratory rate is activated in cases of insufficient breathing. Thus, both patient comfort and minimum ventilation are ensured. **Clinical Indications** Commonly used in patients with COPD, obesity hypoventilation syndrome, neuromuscular diseases, and nocturnal hypoventilation.
Bilevel - VT (Volume-Targeted)	• It is a bi-level positive airway pressure therapy mode that supports the patient's spontaneous breathing and operates toward a target tidal volume. • If no spontaneous inspiratory effort is detected within the set respiratory rate interval, the device provides a time-controlled mandatory breath.

	• Expiratory Pressure (EPAP) is applied during the expiratory phase. • The Inspiratory Pressure (IPAP) value varies according to the patient's lung compliance and airway resistance in order to achieve the target tidal volume. • IPAP remains within the set minimum and maximum Inspiratory Pressure limits. **Physiological Basis** It automatically adjusts inspiratory pressure to maintain the target tidal volume. By adapting to changes in lung mechanics, it aims to provide more stable ventilation. **Clinical Indications** Patients with neuromuscular diseases requiring variable ventilatory support, obesity hypoventilation syndrome, and chronic alveolar hypoventilation conditions.
AutoBilevel (Automatic Pressure-Adjusted)	• It is a bi-level positive airway pressure therapy mode that supports the patient's spontaneous breathing and automatically adjusts positive airway pressure within the pressure limits. • All respiratory cycles are spontaneously initiated and terminated by the patient. • Expiratory Pressure (EPAP) is applied according to the set Minimum Expiratory Pressure value. • Inspiratory Pressure (IPAP) is applied without exceeding the set Maximum Inspiratory Pressure value. • The device makes pressure adjustments according to its algorithm by monitoring apnea, hypopnea, and snoring events. • The set Pressure Support value determines the pressure support applied during inspiration and the difference between IPAP and EPAP. • No mandatory breaths are delivered by the device. **Physiological Basis** While maintaining bi-level pressure support, it automatically adjusts pressures according to upper airway events. It aims to provide both obstruction control and ventilatory support. **Clinical Indications** OSA patients with high or variable pressure requirements, patients with CPAP failure or intolerance, and patients with concomitant hypoventilation.

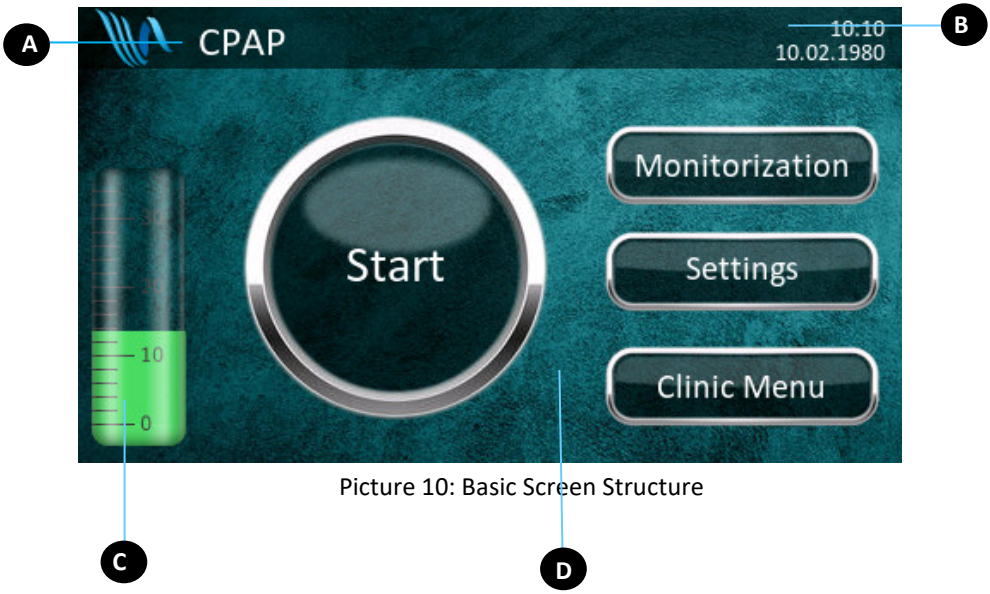
ASV – Adaptive Servo Ventilation	• It is an adaptive bi-level positive airway pressure therapy mode that continuously monitors the patient's breathing pattern and automatically adjusts pressure support to help maintain target ventilation. • If spontaneous breathing becomes insufficient or no spontaneous inspiratory effort is detected, the device provides time-controlled mandatory breaths. • Expiratory Pressure (EPAP) is automatically adjusted within the set Minimum Expiratory Pressure and Maximum Expiratory Pressure limits. • Pressure Support (PS) is automatically adjusted within the set Minimum Pressure Support and Maximum Pressure Support limits to help maintain target ventilation. • The device makes pressure adjustments according to its algorithm by monitoring apnea, hypopnea, and snoring events. • Central apneas are differentiated, and device responses are adjusted accordingly. • Tidal volume is measured during each cycle, and inspiratory pressure is adjusted to achieve the calculated target average tidal volume. **Physiological Basis** By analyzing the patient's minute ventilation, it adjusts pressure support on a breath-by-breath basis. It reduces fluctuations in the breathing pattern and stabilizes ventilation. **Clinical Indications** Central sleep apnea, Cheyne–Stokes respiration, and complex sleep apnea syndrome. The use of this mode in certain patients with symptomatic heart failure and reduced ejection fraction should be carefully evaluated according to current clinical guidelines.

VENTILATION MODE SYSTEMATIC CODES

Modes	Systematic Code	Full Systematic Name
CPAP	CPAP	Continuous positive airway pressure
Auto CPAP	CPAP	Continuous positive airway pressure
Bilevel-S	S/T-PS/PC(q)	Spontaneus/timed ventilation with pressure-support for spontaneous breaths and pressure control with flow termination for ventilator-initiated breaths
Bilevel-T	S/T-PS/PC(q)	Spontaneus/timed ventilation with pressure-support for spontaneous breaths and pressure control with flow termination for ventilator-initiated breaths
Bilevel-ST	S/T-PS/VC(q)	Spontaneus/timed ventilation with pressure-support for spontaneous breaths and volume control for ventilator-initiated breaths
Bilevel-VT	S/T-vtPS/vtPC	Spontaneus/timed ventilation with volume targeted press-support for spontaneous breaths and volume targeted pressure control for ventilator-initiated breaths
Auto Bilevel	S/T-vtPS/vtPC	Spontaneus/timed ventilation with volume targeted press-support for spontaneous breaths and volume targeted pressure control for ventilator-initiated breaths
ASV	CSV-vtPS	Continuous spontaneous ventilation wit volume targeted pressure-support

See BS EN ISO 19223:2021 Annex Table E.1.

BASIC SCREEN STRUCTURE



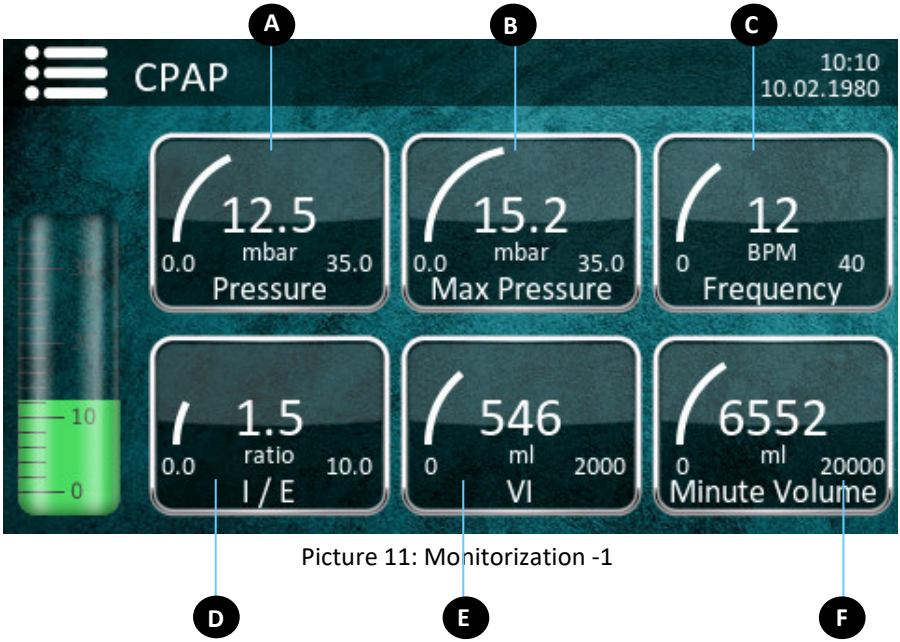
Picture 10: Basic Screen Structure

A. Current Mode
B. Toolbar
C. Pressure Display Bar
D. Display Content Screen

- To start therapy, press the "Start" button that appears on the screen.
- To end therapy, press and hold the "Stop" button that appears on the screen.

DISPLAY SELECTION

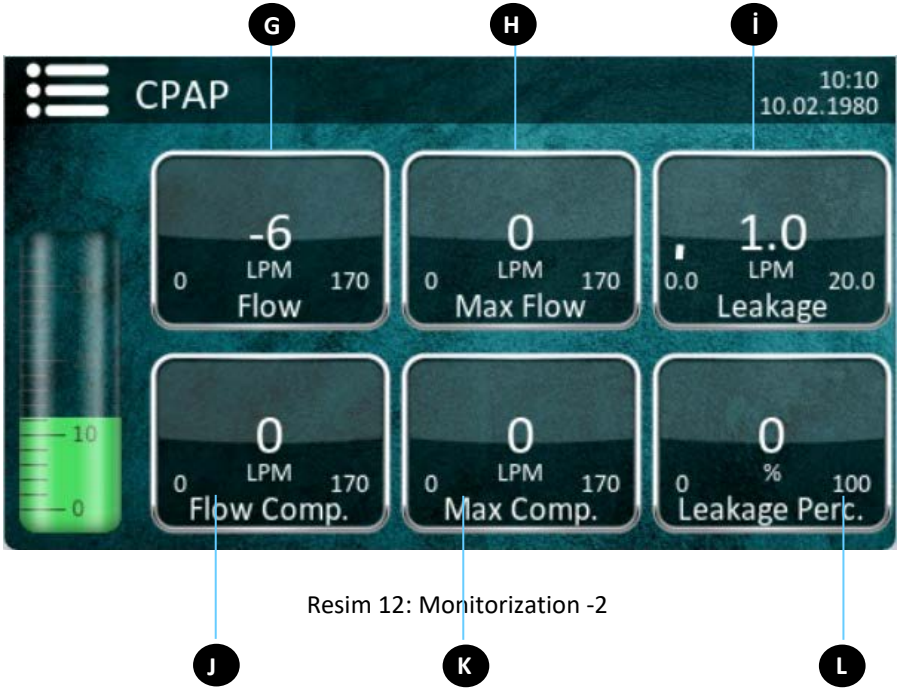
Monitorization
Tap on "Monitorization" option on the main menu.



Picture 11: Monitorization -1

A) **Pressure (mbar):** Displays the instantaneous pressure value measured in the airway during therapy.
B) **Maximum Pressure (mbar):** Displays the highest pressure value reached in the airway during therapy.
C) **Frequency (BPM):** Displays the respiratory rate per minute.
D) **I:E Ratio:** Displays the ratio of inspiratory time to expiratory time.
E) **Inspiratory Volume – VI (ml):** Displays the volume of air delivered to the patient during inspiration within one respiratory cycle.
F) **Minute Volume (ml):** Displays the total volume of respiratory gas delivered to the patient within one minute.

DISPLAY SELECTION



Resim 12: Monitorization -2

G) Flow (LPM): Displays the instantaneous gas flow delivered by the device.

H) Maximum Flow (LPM): Displays the maximum gas flow within a respiratory cycle delivered by the device.

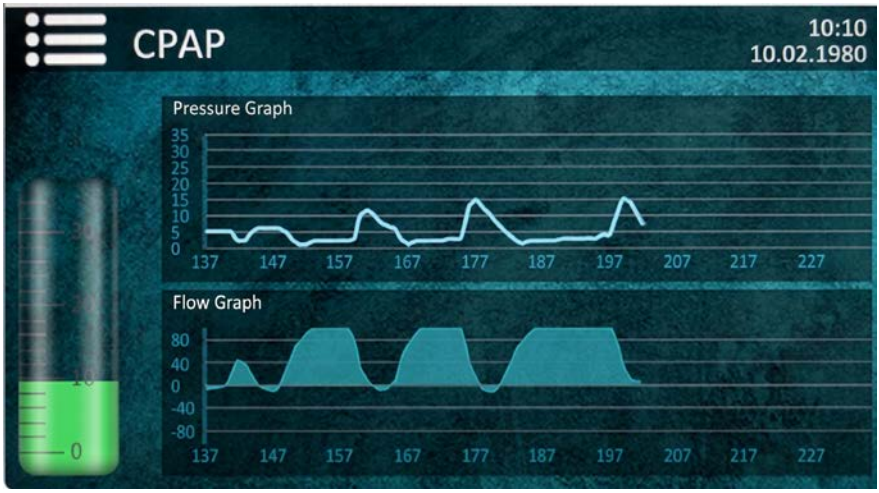
İ) Leakage (LPM): Displays the gas loss in the system by calculating the air leakage occurring in the system or mask in liters per minute (LPM).

J) Flow Compensation (LPM): Displays the instantaneous gas flow with leak compensation applied.

K) Maximum Flow Compensation (LPM): Displays the maximum gas flow within a respiratory cycle with leak compensation applied.

L) Leak Percentage (%): Displays the ratio of the leakage in the breathing circuit to the total delivered gas flow as a percentage (%).

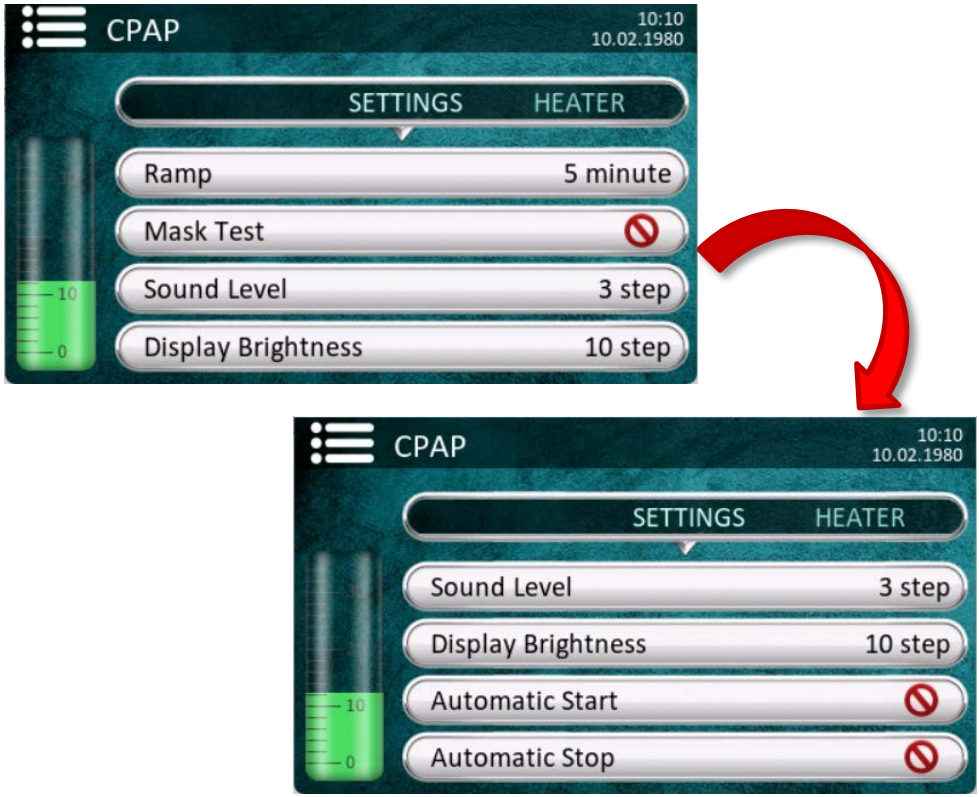
GRAPHICS



Picture 13: Graphics

- You can access the waveforms (graphs) by tapping anywhere on the Monitoring menu.
  - **Pressure Graph**
    Allows you to monitor real-time pressure data.
  - **Flow Graph**
    Allows you to monitor real-time gas flow data with leak compensation applied.

SETTINGS



Picture 14: Settings

Ramp, Mask Test, Sound Level, Display Brightness, Automatic Start and Automatic Stop parameters are set on the Settings page.

- **Sound Level:** Adjusts the level of the warning and alarm sounds generated by the device. The volume level can be adjusted between 1 and 3. To mute the warning and alarm sounds, the volume level must be set to the " " position.
- D**isplay Brightness:** Adjusts brightness level of the screen. Display brightness can be changed between 1-10 levels. In cases where you want to turn off display brightness, it should be set to " " position.
- **Automatic Start:** When you put on the mask and start breathing, the device will automatically start the therapy.
- **Automatic Stop:** When you remove the mask, the device will automatically stop the therapy.

- **Ramp:** It is gradual increase of set therapy pressure, starting from 3 mbar for set time, over set ramp time (5-45 minutes). When the ramp is set, '' '' icon is displayed on toolbar.In therapies where ramp is not used, ramp should be in '' '' position.

Picture 15: Ramp

- **Mask Test:** It is designed to help you evaluate and identify possible air leaks around your mask. During the mask test, " " icon is displayed on toolbar. Mask test is performed between 5-60 seconds. In therapies where you do not want to perform a mask test, mask test should be set to " " position.

Picture 16: Mask Test

When therapy is started after mask test time is set, "Mask Test" indicated in the image is displayed on the main menu. You can cancel your mask test by pressing "Stop" button.

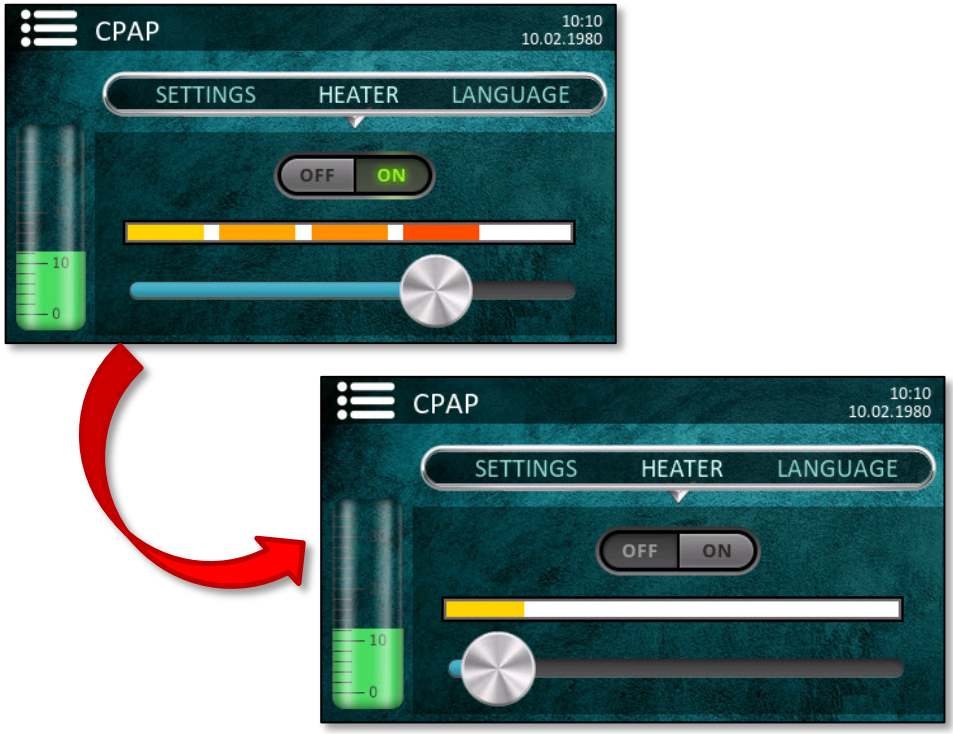
NOTE

Put on your mask before mask test starts. You must not breathe during mask test time.

NOTE

"Mask Test" time can be adjusted by the patient by entering Settings Menu

➢ **HEATER**



Picture 17: Heater

On/Off: Bring the system to the "ON" position by tapping the "OFF/ON" button located on the heater setting screen. When the heater is active, the button will light up with a green light. To turn it off, it is sufficient to tap the button again and bring it to the "OFF" position; in this case, the green light will go out.

Heater Level Adjustment: Select a level between 1-5 by sliding the grey round button on the touchscreen right/left.

➢ **LANGUAGE**

Device offers user two language options, Turkish and English. When you want to change language option; in the settings menu, "LANGUAGE" line should be pressed using touch display.

Picture 18: Language

Language change is made on the device by pressing on the country flag belonging to the language to be used.

➢ **STATISTICS**

User can access last six therapy data from statistics display. Therapy underlined in therapy line is displayed as current end-user therapy. When user wants to reach the statistics; in settings menu, the "Statistics" line should be pressed using touch display.

Picture 19: Statistics

➢ **COUNTERS**

Device is display where it shows device run times to user. To reach this display; should press the "Counters" line using touch display in settings menu.

Picture 20: Counters

Counters on this display:

- **Operation**: Shows total time the device has been turned on while plugged in.
- **Therapy**: Shows total therapy time that device has applied to patient.
- **Fan:** Shows total time device's fan has been running.
- **Filter**: Shows usage time of device's filter.
- **Mask**: Shows usage time of device's mask.
- **Service**: Shows time the device should arrive for service.

❖ These times are shown with bar indicated in image. It is shown in green when used, yellow over time, and red when nearing expiration.

NOTE

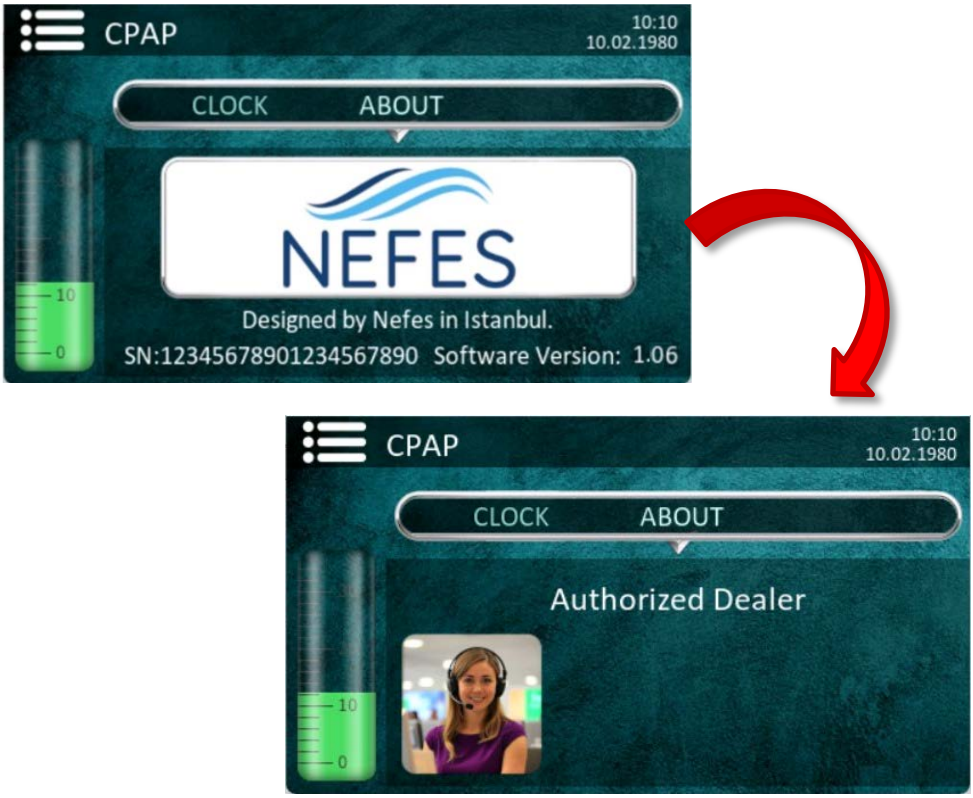
After changing Filter and Mask, counter display should be displayed and press and hold line you have changed. In this case, "Reset Mask Counter? Or Reset Filter Counter?" screen will appear. When you select this operation as "Yes" after change, counters will be reset.

- **CLOCK**

Picture 21: Counters

You can edit the date and time information of the device from this screen. To make the changes valid, it is sufficient to press the Update button.

➢ **ABOUT**



Picture 22: Counters

On the About screen; you can view the manufacturer of the device, the place of manufacture, the serial number, and the software version. Also, when you click on the screen, you can access the authorized dealer information.

DEVICE MESSAGES

Fixed Alarms

- **Leakage Alarm**
  This alarm is active only when the automatic-stop function is turned off. When the therapy tube comes off or is removed, or if the mask slips off your face or is removed, the device automatically gives an audible and visual “Leakage Alarm”.
- **Mask alarm**
  This alarm function is active only when automatic function is turned off. If mask slips from your face or tube comes out of device, device automatically gives an audible and visual alarm.
- **Service and Filter Alarm**
  It is alarm that gives filter change time of device and time to go to service by showing relevant situation on display.

CLEANING AND DISINFECTION

Description	Cleaning	Change
AIRPAP	At periodic intervals	-
Humidifier	Weekly	-
Power Supply	At periodic intervals	-
Power Cable	At periodic intervals	-
Therapy Tube	Weekly	According to manufacturer's data
Mask	Daily	On Patient Change or Based on Manufacturer data
Inlet Filter	-	Every month

DAILY CLEANING OF MASK

- Detach mask at therapy tube.
- Clean mask as described in manufacturer's instructions for use.
- When time specified in Counters menu for mask expires, a "Mask Change" message will be displayed to you. In this case, when you change mask, reset your mask counter from Settings Counters screen.

CHANGING FILTER

- Filter must be changed when “Filter Change” message appears on screen. Remove filter from its place on side panel of device and replace it with a new one. Reset your filter counter from Settings Counters screen.

WARNING

- Never operate device without a filter.
- Only use original **Nefes Medikal Teknoloji San. Tic. Ltd. Şti**. filters. Otherwise, device warranty will be void.

CLEANING DEVICE

- Unplug power cord from electricity.
- Wipe device first with a cloth slightly moistened with soapy water and then with a dry cloth.

CLEANING THERAPY TUBE

- Wash hose thoroughly with mild soapy water and dry it.

HUMIDIFIER CLEANING

- Disconnect humidifier from device after removing therapy tube.
- Open humidifier cover.
- Wash water tank and cover of humidifier under warm water.
- Dry the inside and outside with a dry cloth and reattach humidifier to device.
- There is no need for chemical or thermal disinfection of device and its parts.

WARNING

After disinfection, thoroughly rinse all disinfected components with clean water, especially those in close contact with the patient, such as humidifiers, masks, caps and tubing, to prevent residues from damaging the skin or respiratory tract or causing allergies.

MAINTENANCE AND CALIBRATION

- Device gives a service warning after 2000 hours of use. Device giving service warning should be made by technical service personnel authorized by Nefes Medikal Teknoloji San. Tic. Ltd. Şti.
- Maintenance and calibration of device that comes to technical service is checked and performed.

TROUBESHOOTING

TROUBLESHOOTING

Problem	Possible Cause	Solution
Weather is very warm	The filter is dirty	Change filter
	Air inlet clogged	Make sure air inlet is open
	Nefes AIRPAP too close to a heater	Check location of Nefes AIRPAP.
No airflow	Device is faulty	Call technical service
Low airflow	Ramp function active	Reduce ramp time
	Air inlet clogged	Make sure air inlet is open
Motor is constantly running at maximum speed	There is a leak in device	Call technical service

TECHNICAL INFORMATION

	Parameters	CPAP	AUTOCPAP	BiLEVEL
Modes	CPAP	S	S	S
	AUTOCPAP	-	S	S
	BiLEVEL S	-	-	S
	AUTOBiLEVEL	-	-	-
	BiLEVEL T	-	-	-
	BiLEVEL ST	-	-	-
	BiLEVEL VT	-	-	-
	ASV	-	-	-
Pressure Range	3-20 mbar	S	S	-
	3-25 mbar	-	-	S
	3-35 mbar	-	-	-
Memory	4 GB Micro SD Card	S	S	S
Comfort	Display Light Adjustment	S	S	S
	Sound Level	S	S	S
	Automatic Start/Stop	S	S	S
	Ramp	S	S	S
	Mask Test	S	S	S
Masks	Nasal / Full Face	O/S	O/S	O/S
Power Supply	60 W	S	S	S
Additional Indicators	Pressure	S	S	S
	Tidal Volume	S	S	S
	Frequency	S	S	S
	I/E Ratio	S	S	S
Working Principle	Pressure Targeted	S	S	S
	Volume Targeted	-	-	-
Programs	AP	S	S	S

- Technical specifications are subject to technical modifications.

TECHNICAL INFORMATION

	Parameters	AUTO BiLEVEL	BiLEVEL-ST	BiLEVEL-VT	ASV
Modes	CPAP	S	S	S	S
	AUTOCPAP	S	S	S	S
	BiLEVEL S	S	S	S	S
	AUTOBiLEVEL	S	S	S	S
	BiLEVEL T	-	S	S	S
	BiLEVEL ST	-	S	S	S
	BiLEVEL VT	-	-	S	S
	ASV	-	-	-	S
Pressure Range	3-20 mbar	-	-	-	-
	3-25 mbar	S	-	-	-
	3-35 mbar	-	S	S	S
Memory	4 GB Micro SD Card	S	S	S	S
Comfort	Display Light Adjustment	S	S	S	S
	Sound Level	S	S	S	S
	Automatic Start/Stop	S	S	S	S
	Ramp	S	S	S	S
	Mask Test	S	S	S	S
Masks	Nasal / Full Face	O/S	O/S	O/S	O/S
Power Supply	60 W	S	S	S	S
Additional Indicators	Pressure	S	S	S	S
	Tidal Volume	S	S	S	S
	Frequency	S	S	S	S
	I/E Ratio	S	S	S	S
Working Principle	Pressure Targeted	S	S	S	S
	Volume Targeted	-	-	S	S
Programs	AP	S	S	S	S

- Technical specifications are subject to technical modifications.

TECHNICAL INFORMATION

CPAP and AUTOCPAP for models.

Features	Values
Dimensions(mm) (W X L X H)	270 x 178 x 124
Heavy	About 1.74kg
Sound Pressure Level	30dB
Power Supply	100-240VAC, 50-60Hz external power supply, 24V DC.
External DC Input	24V DC
Pressure Range	3-20 mbar
Pressure Accuracy	±(2% of the full-scale reading + 4% of the actual reading)
Power Consumption	30 VA (mean value)
Power Consumption (in standby mode)	< 2.5 VA
Noise level (without mask)	<29 dB(A) (10 mbar)
Delivered air volume	180 L/dk
Storage temperature	-20° C - +45° C
Storage atmospheric pressure range	50kPa-106kPa (0 – ~5500m)
Air humidity (operating and storage)	%10-95 relative humidity
Operating temperature range	+5°C - +40° C
Operating atmospheric pressure range	70kPa-106kPa (0 - ~3000m)
Heated Humidifier	Humidifier Heater Level: 1 – 5 Water level: Max. 350 ml

- Technical specifications are subject to technical modifications.

TECHNICAL INFORMATION

BiLEVEL and AUTOBiLEVEL for models

Features	Values
Dimensions(mm) (W X L X H)	270 x 178 x 124
Heavy	About 1.74kg
Sound Pressure Level	30dB
Power Supply	100-240VAC, 50-60Hz external power supply, 24V DC.
External DC Input	24V DC
Pressure Range	3-25 mbar
Pressure Accuracy	±(2% of the full-scale reading + 4% of the actual reading)
Power Consumption	30 VA (mean value)
Power Consumption (in standby mode)	< 2.5 VA
Noise level (without mask)	<29 dB(A) (10 mbar)
Delivered air volume	180 L/dk
Storage temperature	-20° C - +45° C
Storage atmospheric pressure range	50kPa-106kPa (0 – ~5500m)
Air humidity (operating and storage)	%10-95 relative humidity
Operating temperature range	+5°C - +40° C
Operating atmospheric pressure range	70kPa-106kPa (0 - ~3000m)
Heated Humidifier	Humidifier Heater Level: 1 – 5 Water level: Max. 350 ml

- Technical specifications are subject to technical modifications.

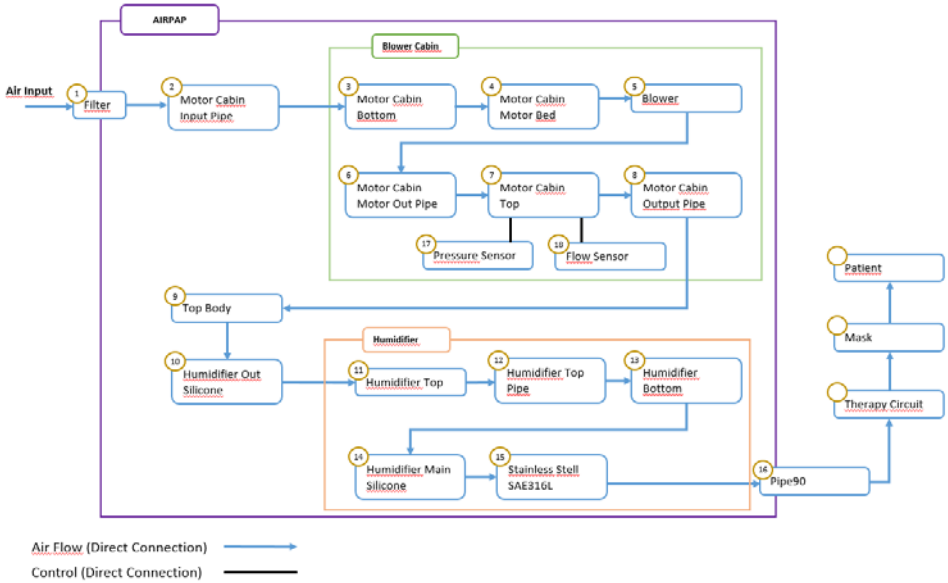
TECHNICAL INFORMATION

BiLEVEL-ST, BiLEVEL-VT and ASV for models.

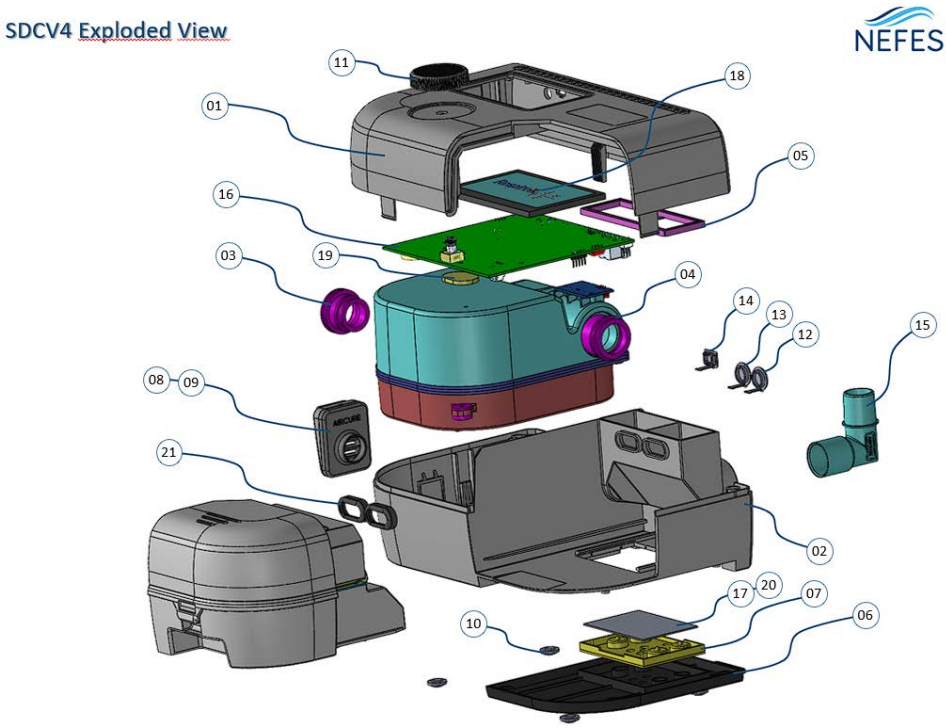
Features	Values
Dimensions(mm) (W X L X H)	270 x 178 x 124
Heavy	About 1.74kg
Sound Pressure Level	30dB
Power Supply	100-240VAC, 50-60Hz external power supply, 24V DC.
External DC Input	24V DC
Pressure Range	3-35 mbar
Pressure Accuracy	±(2% of the full-scale reading + 4% of the actual reading)
Power Consumption	45 VA (mean value)
Power Consumption (in standby mode)	< 2.5 VA
Noise level (without mask)	<29 dB(A) (10 mbar)
Delivered air volume	180 L/dk
Storage temperature	-20° C - +45° C
Storage atmospheric pressure range	50kPa-106kPa (0 – ~5500m)
Air humidity (operating and storage)	%10-95 relative humidity
Operating temperature range	+5°C - +40° C
Operating atmospheric pressure range	70kPa-106kPa (0 - ~3000m)
Heated Humidifier	Humidifier Heater Level: 1 – 5 Water level: Max. 350 ml

- Technical specifications are subject to technical modifications.

PNEUMATIC DIAGRAM



EXPLODED VİEW



NOTE

Humidifier, Filter and 90 Degree Adapter are detachable parts that can be removed by the user.

MAXIMUM FLOWRATE OF AIRPAP EQUIPMENT ON THE SET

201.12.1.103		TABLE: Maximum flowrate				P
BREATHING GAS PATHWAY Configuration ..... :					with 1.8m ±0.15 breathing tube	P
Sleep apnoea breathing therapy equipment mode ..... :					TEST MODE	
Test Pa (hPa or cmH2O)		P_min	P_min + 25% (P_max - P_min)	P_min + 50% (P_max - P_min)	P_min + 75% (P_max - P_min)	P_max
		3 hPa	7.5 hPa	11.5 hPa	16 hPa	20 hPa
Measured pressure at the patient connection port (hPa)		2,90	7,80	11,80	16,09	20,40
Average flow at the patient connection port (l/min)	1st meas	27,00	76,50	104,97	126,25	149,03
	2nd meas	27,80	75,95	105,43	129,88	150,33
	3rd meas	27,20	77,08	106,08	130,30	147,85
	4th meas	26,90	74,46	105,29	131,28	150,14
	5th meas	27,10	77,03	104,39	130,52	149,73
	6th meas	27,20	75,00	105,26	129,00	149,20
	7th meas	27,00	76,26	103,00	129,69	149,96
	8th meas	27,20	76,72	105,77	129,56	149,22
	9th meas	27,70	76,48	106,38	130,00	149,83
	10th meas	28,40	76,50	105,84	128,04	150,39
	Measurement result	27,350	76,198	105,041	129,452	149,568
Supplementary information:						

EN ISO 80601-2-70 PRESSURE ACCURACY

Stability of Static Airway Pressure Accuracy
The average of the most positive pressure deviations: 0.43 mbar
The average of the most negative pressure deviations: 0.32 mbar

Dynamic airway pressure accuracy / BILEVEL
The average of the most positive pressure deviations: 0.43 mbar
The average of the most negative pressure deviations: 0.32 mbar

Dynamic airway pressure accuracy / CPAP
The average of the most positive pressure deviations: 1.176 mbar
The average of the most negative pressure deviations: 1.014 mbar

See TF.02.86 80601-2-70 Test Report.

NOTE

Unless otherwise stated, all gas volume, flow and leakage specifications provided in this manual are expressed at STPD (Standard Temperature and Pressure, Dry) conditions.

COMPLIANCE WITH STANDARDS

AIRPAP Respiratory Therapy Device has been designed to comply with the following standards.

- EN ISO 60601-1:2006/A1:2022 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN ISO 60601-1-2: 2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN ISO 60601-1-6:2010/A2:2021 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN ISO 80601-2-70:2020 Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
- EN ISO 80601-2-74:2021 Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

ELECTROMAGNETIC COMPATIBILITY (EMC)

The electromagnetic compatibility test and results of the AIRPAP according to EN 60601-1-2 standard are given in the table below. Users must ensure that the device is used in an environment according to the table.

Compliance Controls	IEC 60601 Control Level	Suitability Level	Electromagnetic Environment Guide
Electrostatic discharge (ESD) according to IEC 61000-4-2 directive	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic materials, the relative air humidity should be at least 30%.
Electrical Fast Transient Regimes / Burst According to IEC 61000-4-4 directive	±2kV, for mains lines Connection time ≥ 120 sec	± 2kV, for mains lines Connection time ≥ 60 sec	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment.
Surge voltages according to IEC 61000-4-5 directive / Surge	Source impedance: 2Ω, 18 µF: 0,5 kV, 1 kV Number of impulse voltages: 10 impulse voltage / phase angle Phase Angle: 0°, 90°, 180°, 270° Repetition time: 60 sec	±1 kV line to line, ± ±2 kV mains line to ground line	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment.

Voltage drops, short interruptions and surges in the voltage supply according to IEC 61000-4-11 directive	Number of voltages drops: 3 drop levels: 100% in 0.5 periods (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°)	0% UT; 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° at 0.5 period, 70% UT; 25 periods, 0% UT; 1 period, 0% UT; 250 periods	The quality of the supply voltage must be equivalent to that of a typical commercial or hospital environment. If the user wants the device to continue to function even in the event of interruptions in the power supply, it is recommended to use an uninterruptible power supply of the device.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8 directive	30 A/m	30 A/m, 50 Hz	Magnetic fields at mains frequency must be equivalent to that of a typical commercial or hospital environment.
Transmitted RF regime according to IEC 61000-4-6 directive	10 V Effective value 150 kHz - 80 MHz, within ISM bands	150kHz - 80MHz, 3Vrms, 80% AM (1kHz) mains power	Portable and mobile radios and equipment must be kept at a short distance from the device; the recommended protective distance calculated according to the formula applicable to the transmitter frequency: 1,7 m
Radiated RF regime according to IEC 61000-4-3 directive	3 V/m 80 MHz - 2.7 GHz 80% AM at 2 Hz	80 Mhz - 2700MHz, 3V/m, 80% AM (1kHz)	3 m for 80 MHz - 2700 MHz

EMISSIONS TEST

Interference Measurements	Suitability Level	Electromagnetic Environment Guide
Conducted Emission TS EN 55011	Class B	The sample is positioned 0.4 metres from the shielded chamber and fed via LISN.
Radiated Emission TS EN 55011	Class B	The sample is carried out outdoors at a distance of 10 metres on a 0.8-metre-high rotating table. A 360-degree scan is performed across the rotating table to capture the highest field value.
Harmonic Emissions IEC 61000-3-2:2019	Class A	The specimen is placed on a 0.8-metre-high wooden table. Under normal operating conditions, it is tested for the determination of the highest harmonic components.
Voltage Flicker Emissions EN 61000-3-3:2013/A1:2019	Compatible	The specimen is placed on a 0.8-metre-high wooden table. Under normal operating conditions, it is operated to produce the most unfavourable stress variations.

PATIENT INFORMATION

Name.....

Surname.....

Address .....

.....

.....

District / City.....

Postal Code .....

Phone Number .....

Date of Birth.....

Social Security Institution .....

Mask Type .....

Mask Size .....

LEGAL WARNING

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

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

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