SAFER

TECHRES LAB
POLITECNICO DI MILANO 1863

Device for CPAP therapy

Ver. 1.0 – March 2023

BEFORE YOU START

- This user manual is intended for healthcare professionals.
- Read this user manual before using the device. In addition, you can watch the online videos.
- For further assistance, please contact: techres@polimi.it

Contents

1. Introduction

1.1 Indications for use

The CPAP therapy provided by the device is indicated for the non-invasive respiratory support of spontaneously breathing neonatal patients with respiratory distress who need help to support breathing due to different respiratory problems, including neonatal respiratory distress syndrome, transient tachypnea of the newborn (TTN), apneas of prematurity, meconium aspiration syndrome, sepsis, pneumonia or bronchiolitis. The device is indicated for use in a hospital setting. The device is not indicated for use with patients whose upper airways have been bypassed.

1.2 How does the SAFER CPAP works?

SAFER delivers a pressurized, oxygen-enriched, heated and humidified gas mixture. CPAP is generated using a turbine. Therefore, SAFER does not need a source of compressed medical air. SAFER also has an integrated portable oxygen concentrator and, therefore, does not need an external oxygen source to deliver an oxygen-enriched gas mixture. The SAFER device does not deliver precisely blended gas. A continuous flow of highly concentrated oxygen is injected at the airways opening, and the displayed fraction of inspired oxygen is an estimate. Finally, SAFER has an integrated heated humidifier.

1.3 Abbreviations and units of measure

ABBREVIATIONS

- CPAP = continuous positive airway pressure.
- FiO_2 = Fraction of inspired oxygen

UNITS OF MEASURE

- CPAP is expressed in cmH_2O
- Flow is expressed in L/min
- FiO_2 is expressed in %

2. Warnings

- The SAFER CPAP is to be operated by qualified personnel only. This manual should be read before use.
- Explosion hazard. Do not operate the device in the presence of flammable anaesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- Electrical shock hazard. Do not open or modify the device without the authorization of the manufacturer.
- Do not operate the device if any of the components appear to be damaged or broken.
- Do not block any of the air vents on the sides of the device.
- Before its first use and before the use with a new patient, the device must be cleaned and disinfected according to the Cleaning and disinfection section of this manual.
- Using the humidifier or breathing circuit without cleaning or disinfection between patients can result in infections.
- The device should only be used with the interfaces and breathing circuit specified in this user manual. The use of components not specified in this user manual can result in serious injury to the patient.
- Using the device outside of the following ambient conditions can compromise performance.
    - Recommended temperature: 19 – 37°C
    - Recommended relative humidity: 30 – 90%
    - Recommended barometric pressure: 86kPa – 106kPa

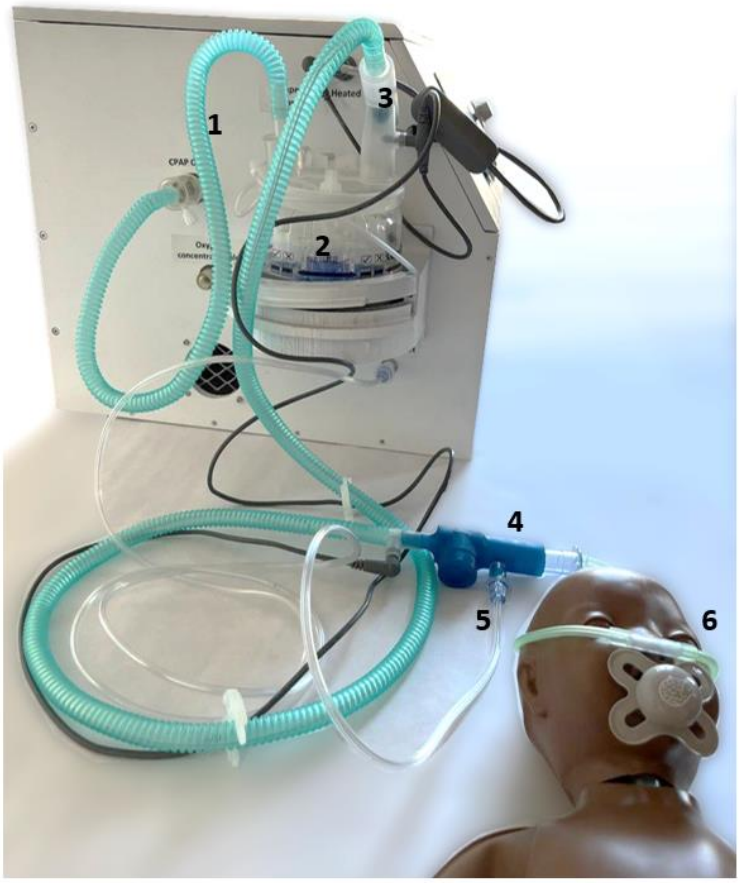
3. Device description

3.1 Device components

1. Touch-screen display
2. Knob to navigate the user interface
3. Turbine inlet
4. Oxygen concentrator inlet
5. CPAP outlet
6. Oxygen outlet
7. Power switch
8. AC power inlet

3.2 Breathing circuit components

1. Humidifier connection tube
2. Humidifier chamber
3. Breathing tube
4. SAFER connector, including the intentional leak and the inlet oxygen port
5. Oxygen tube



4. Device operation

4.1 Starting and stopping the respiratory support

BEFORE YOU START

- Set-up the water chamber
  - Slide the water chamber into the device
  - Use distilled or sterile water to fill the humidifier until the fill line.
- Install the breathing circuit
  - Attach the humidifier connection tube to the CPAP outlet and the humidifier water chamber
  - Attach the breathing tube to the humidifier water chamber
  - Attach the SAFER connector to the free hand of the breathing tube
  - Attach the oxygen tube to the oxygen outlet of the ventilator and the oxygen port

- Select the patient interface

Select the nasal cannula of the correct size based on the patient body weight. Check that the selected size provides a good fit by placing them in the nares. The nasal cannula should fill each nostril completely to ensure adequate pressure transmission, but if the nares appear stretched, a smaller size should be selected.

Immediately remove the prongs from the nares once the correct size is identified and put them aside until they are connected to the CPAP system and a proper gas flow is running through the breathing circuit.

SWITCH ON THE DEVICE

- Plug the power cord into the mains power supply.
- Switch on the device by pressing the On/Off button at the rear of the unit.

- Wait about 5 minutes for the device to warm up. In this way, the patient will receive warm and humidified gas.

CONFIGURE THE DESIRED SETTINGS

- When you turn on the device, it automatically starts delivering CPAP at the default values of 5 cmH_2O of CPAP and 21 % of FiO_2
- You can change the CPAP level and FiO2 using the user interface (See below)

CONNECT THE PATIENT

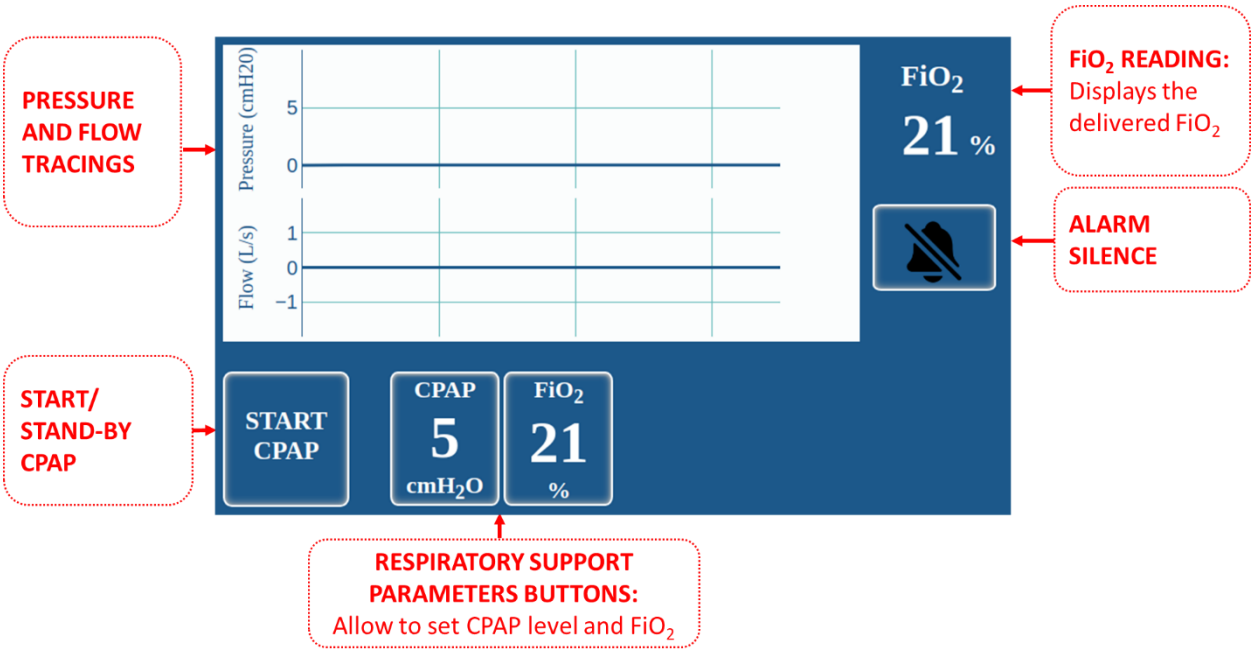
- Place the nasal cannula in the nares and connect them to the SAFER connector and breathing circuit.
- Check that the patient is breathing normally.
- Continuous monitoring of oxygen saturation is highly recommended during respiratory support.
- Check that the measured pressure corresponds to the set pressure.
- Check the pressure and flow tracings on the screen. The pressure should oscillate around the desired CPAP level, and the flow should oscillate around zero.

AFTER USE

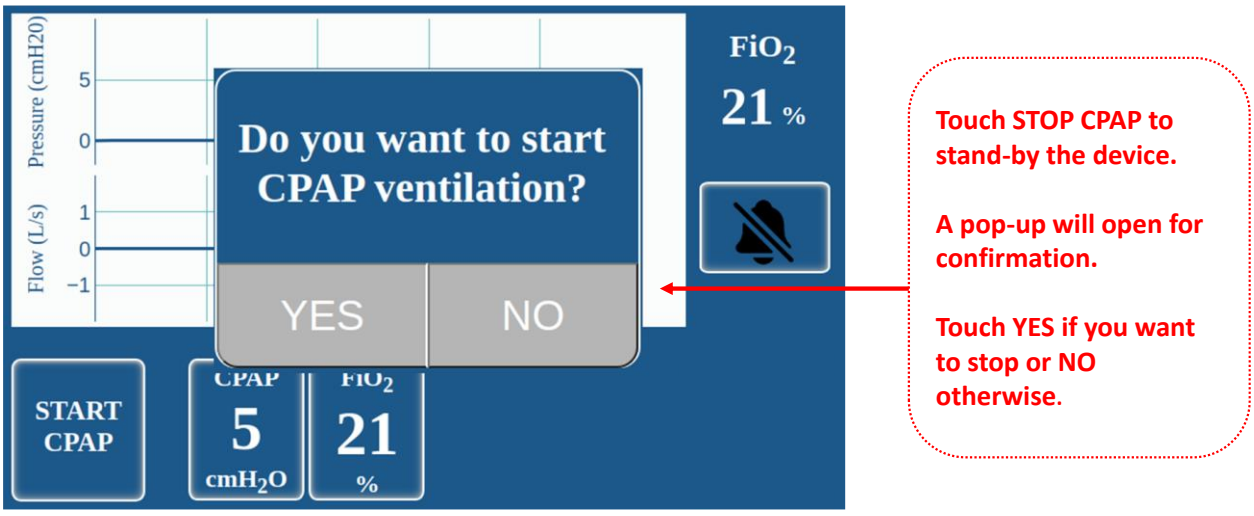
- Touch the STOP button on the screen to put the ventilation on stand-by.
- Switch the On/Off button at the rear of the unit.

4.2 Graphical user interface

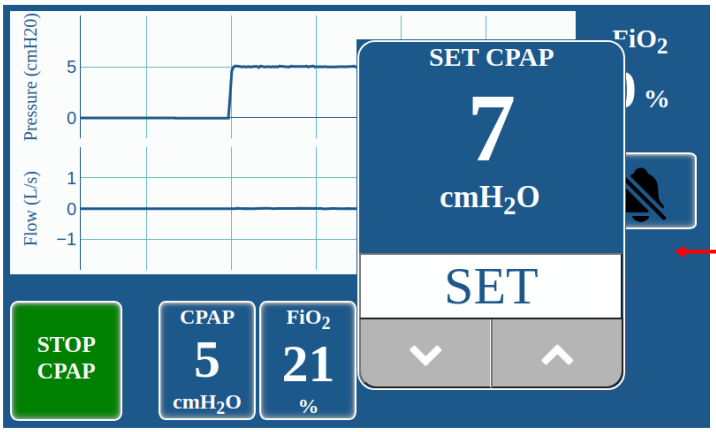
The figure below represents the main elements of the graphical user interface.



Start CPAP



Set the desired CPAP



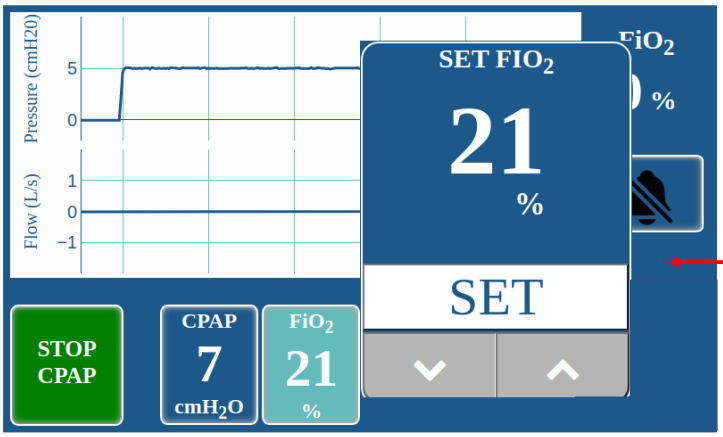
Touch the CPAP button to change the setting.

A pop-up will appear to increase or decrease the value.

Touch SET to confirm the new value.

If you press anywhere else, the pop-up closes and the value will not be updated.

Set the desired FiO_2



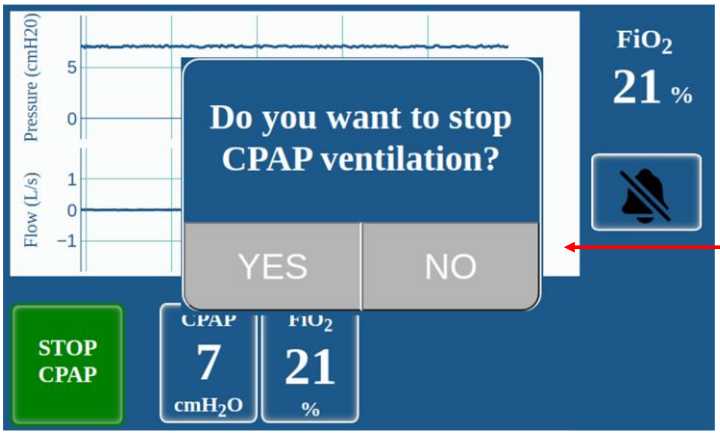
Touch the FiO_2 button to change the setting.

A pop-up will appear to increase or decrease the value.

Touch SET to confirm the new value.

If you press anywhere else, the pop-up closes and the value will not be updated.

Stop CPAP



To stop CPAP ventilation, press the STOP CPAP button.

A pop-up opens to ask for confirmation.

Press YES if you want to start ventilation, otherwise press NO.

When you stop CPAP, the button turns blue again.

Rotary push knob

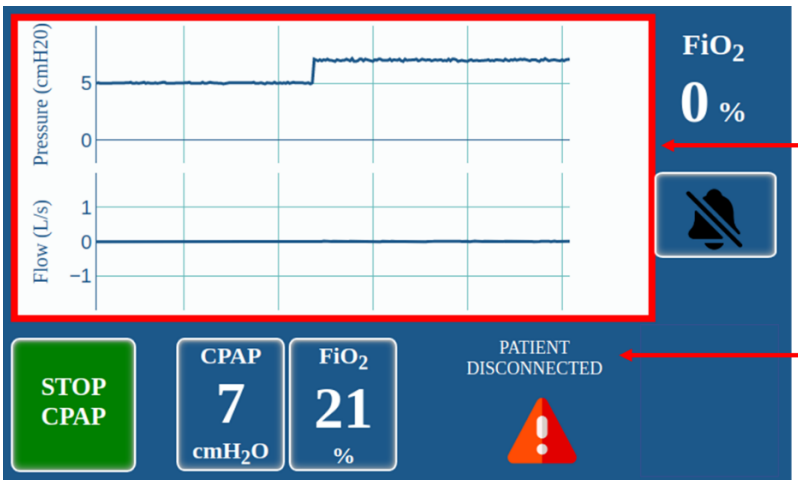
It is possible to navigate the user interface using the rotary push knob. Turn the rotary knob to select the key of interest. The selected key will turn light blue.

Push the knob to confirm. When you select the respiratory parameters buttons, a pop-up window will appear, as described before. Use the rotary knob to increase or decrease the parameter value and push the knob to confirm.

4.3 Alarm System

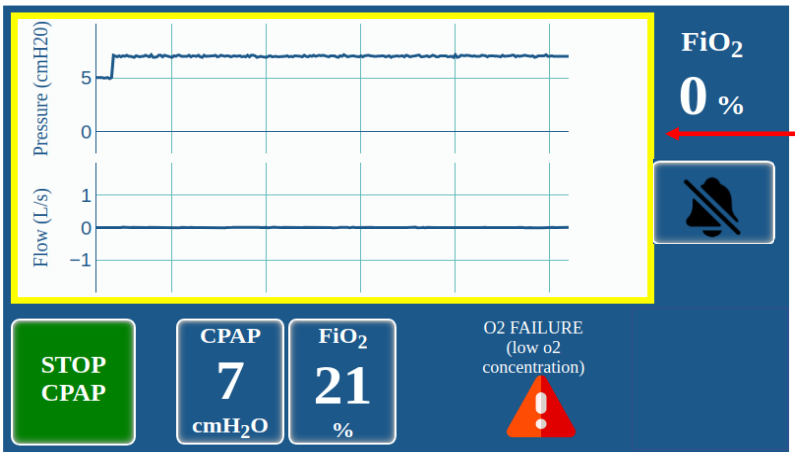
An alarm condition is indicated by:

- Audible alarm tone
- Visual alarm indicator:



For HIGH PRIORITY alarms the frame turns red

The name of the alarm and the alarm icon will appear



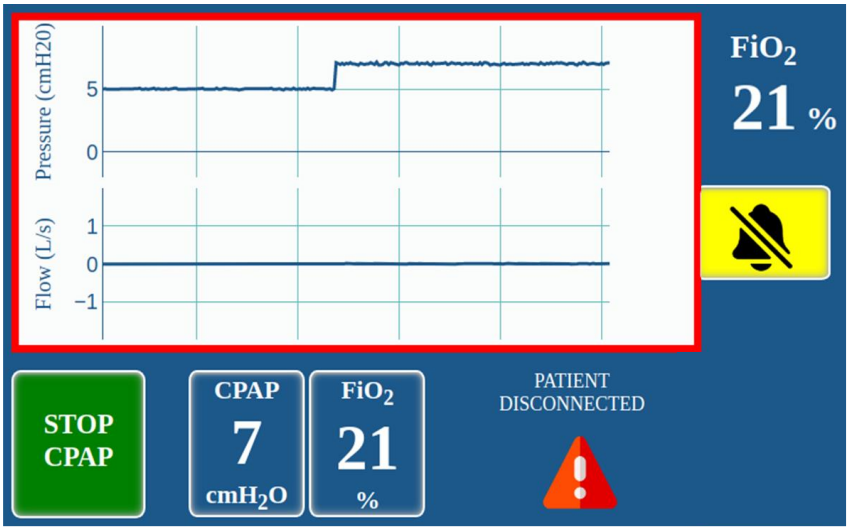
For LOW PRIORITY alarms the frame turns yellow

List of alarms

ALARM	**PRIORITY**	**SOLUTION**
Patient disconnected	High	Check that the breathing circuit, SAFER connector, oxygen tube and nasal cannulae are connected properly. Check that the nasal cannulae are placed correctly in the patients' nares.
Low pressure	High	The device is not able to pressurize the patient circuit. Contact the assistance.
High pressure	High	The turbine is not working properly. Contact assistance.
Tube occlusion	High	Check for breathing tube occlusions. Check that the intentional leak is in place and not occluded.
Low FiO_2	Low	Contact the assistance.
High temperature in the humidifier chamber	High	Check that there is enough water in the water chamber.
Low temperature in humidifier chamber	Low	The most likely cause for this is that the device is operating in low temperature ambient conditions. You are prompted for acknowledgment.
Low water level	Low	Check that there is enough water in the chamber.

Alarms silence

Audible alarms may be suspended, while visual alarms cannot not.



Touch the alarm silence button to silence the alarm.

When the action is executed the background will turn yellow

When a HIGH PRIORITY alarm is recognized, it automatically reactivates after 60 seconds; LOW PRIORITY alarms stay silenced.

4.3 Cleaning and disinfection

The SAFER CPAP must be reprocessed between uses with different patients. The reprocessing steps should be carried out as soon as possible after using the device.

Humidifier chamber	Fill a sink or large bucket with clean water and add a mild detergent to form a detergent solution. Submerge each part in the solution and wipe down with a cloth until clean. Use the small end of the brush to clean the small tube in the humidifier. Use the big end of the brush to clean inside the breathing tubes, PEEP column, and the gas input and output on the humidifier. After cleaning, rinse all of the parts in a large amount of distilled water to remove any residue from the cleaning process. Make sure that all surfaces are thoroughly rinsed, including the inside of the tubes and humidifier. After rinsing, leave all of the parts to dry completely before proceeding to the next step. Submerge the humidifier chamber in
Display and outer surface	Use a clean cloth moistened with a mild detergent solution to gently wipe the target surfaces

4.4 Maintenance

The SAFER CPAP includes several parts that must be replaced or serviced during the lifetime of the device.

COMPONENT	Duration/maintenance information
Breathing circuit Humidifier water chamber	Disposable breathing circuits should be disposed of, and re-usable breathing circuits should be cleaned and disinfected between patients according to the manufacturer's recommendations in case of prolonged respiratory support of the same patient. The lifetime of re-usable breathing circuits is 2 years or 150 uses.
Air filters	Replace/clean every 6 months

5. Specifications

PHYSICAL SPECIFICATIONS	
Dimensions	40 cm x 34 cm x 40 cm (depth x height x width)
Weight	11 kg

ELECTRICAL SPECIFICATIONS	
Supply frequency	50 – 60 Hz
Supply voltage/current	220 – 240 V
	110 – 115 V
Average power consumption	60 W

PERFORMANCE SPECIFICATIONS	
CPAP	Default: 5 cmH_2O
	Range: 3 – 10 cmH_2O
FiO2	Default: 21 %
	Range: 21 % - 70 %
Air flow range	3 – 10 L/min
Maximum oxygen flow	2 L/min