

# SleepOneBilevel S

## User Manual
















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Rev.02

**INDEX**

INDEX..... **Error! Bookmark not defined.**  
SYMBOL DEFINITIONS ..... **Error! Bookmark not defined.**  
IMPORTANT SAFEGUARDS ..... **Error! Bookmark not defined.**  
GENERAL INFORMATION..... 4  
PARTS AND ACCESSORIES ..... **Error! Bookmark not defined.**  
SYSTEM CONTENT..... **Error! Bookmark not defined.**  
ACCESSORIES..... **Error! Bookmark not defined.**  
ASSEMBLY OF SLEEPONE DEVICE ..... 6  
INSTRUCTION FOR USE ..... 7  
MAINTENANCE AND CLEANING ..... 12  
POSSIBLE PROBLEMS ..... 13  
SPECIFICATION ..... 16

## SYMBOL DEFINITIONS

	Class II electrical protection– double		Type BF equipment– applied part insulated
	Standby – turns the device on or off		Next Item and adjust the settings on LCD display
	Setting		Previous Item and adjust the settings on LCD display
	Ramp – Starts the ramp function		Heat
	IPX1 Drip-Proof		100 – 240 Volts AC input 50/60 Hz
	Locked		Unlocked
	Read user guide before operating		

## IMPORTANT SAFEGUARDS

When using electrical products basic safety precautions should always be followed. Read all instructions that is mentioned to this guide before using this device. Important information is highlighted by the following items.

Danger	Urgent safety information for hazards that will cause serious injury or death.
Warning	Important safety information for hazards that might cause serious injury.
Caution	Information for preventing damage to the product.
Note	Information to which you should pay special attention.

 **READ THESE INSTRUCTIONS CAREFULLY BEFORE USING THIS DEVICE.  
KEEP THESE INSTRUCTIONS**

### DANGER

Electrical shock hazard, do not use device while bathing.

Electrical shock hazard, do not immerse this device into water or any other liquid.

Electrical shock hazard, do not attempt to open or remove the case. There are no user serviceable internal components.

SleepOne should be used only with masks recommended by Kare Medical.

SleepOne is not a life support device and may stop operating with certain device faults or with a power failure.

To avoid electric shock, always unplug power cord from outlet power source when performing cleaning.

Use only accessories recommended by Kare Medical Ltd Co.

**CAUTION**–Never rinse or place the device in water. Never allow liquids to get into or around any of the ports, switches or air filter; doing so will result in device damage. If this occurs, discontinue use and remove the power cord from the power source. Allow the device to completely dry before use.

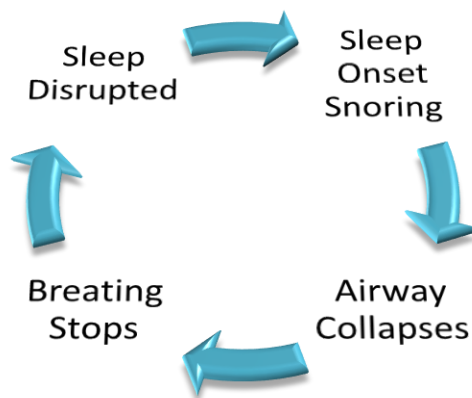
**CAUTION**–Do not place the SleepOne device where it can be fallen down the floor or where the power cord may create a trip hazard.

**CAUTION**–Oxygen is a prescription gas and should only be administered under the supervision of a doctor.

## GENERAL INFORMATION

SleepOne Bilevel is a device which is intended for use in treating Obstructive Sleep Apnea (OSA).

Obstructive sleep apnea (OSA) is the most common category of sleep-disordered breathing. The muscle tone of the body ordinarily relaxes during sleep, and at the level of the throat the human airway is composed of collapsible walls of soft tissue which can obstruct breathing during sleep. It can be seen process of OSA on the following diagram.



***Cycle of Obstructive Sleep Apnea***

Individuals with low muscle tone and soft tissue around the airway (e.g., because of obesity) and structural functions that give rise to a narrowed airway are at high risk for obstructive sleep apnea. The elderly are more likely to have OSA than young people. Men are more typical sleep apnea sufferers than women and children, although it is not uncommon in the latter two.

Bilevel device is intended to provide noninvasive pressure support for patients with

respiratory insufficiency or obstructive sleep apnea. Device 'splints' the patient's airway open during sleep by means of a flow of pressurized air into the throat, Device applies Inspiratory Positive Airway Pressure(IPAP) during inhalation and Expiratory Positive Airway Pressure(EPAP) during exhalation

## **CONTRAINDICATION**

Positive airway pressure may be contraindicated in some patients with the following conditions:

- Pneumothorax or pneumomediastinum
- Pathologically low blood pressure, particularly if associated with intravascular volume depletion
- Cerebrospinal fluid leak, recent cranial surgery or trauma
- Severe bullous lung disease
- Dehydration.

## **SleepOne Bilevel Devices**

SleepOne Bilevel device was initially used mainly by patients for the treatment of sleep apnea at home. Obstructive sleep apnea occurs when the upper airway becomes narrow as the muscles relax naturally during sleep. This reduces oxygen in the blood and causes arousal from sleep. SleepOne BILEVEL device stops this phenomenon by delivering a stream of compressed air via a hose to a nasal pillow, nose mask or full-face mask, splinting the airway (keeping it open under air pressure) so that unobstructed breathing becomes possible, reducing and/or preventing apneas and hypopneas.

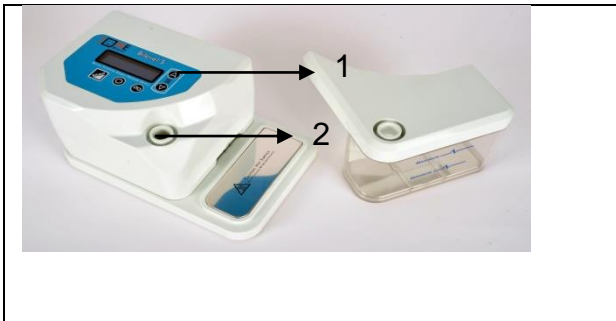
## **PARTS AND ACCESSORIES**

### **SYSTEM CONTENTS**

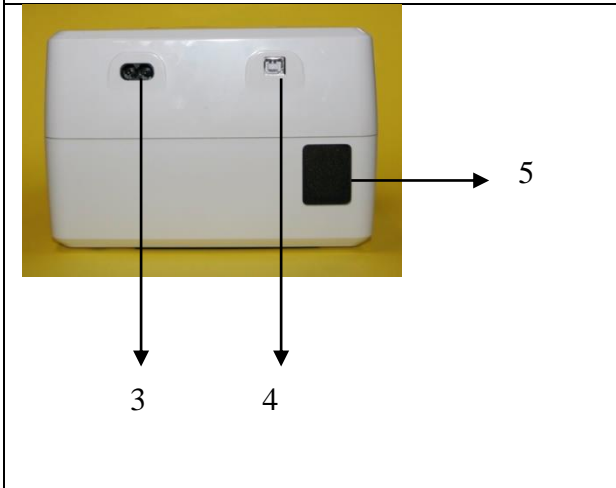
- 1.Sleep One Device
- 2.AC Cord
- 3.Carrying Case
- 4.Air Supply Tube
- 5.Standard filter pack(spare)
- 6.User Manual

### **ACCESSORIES**

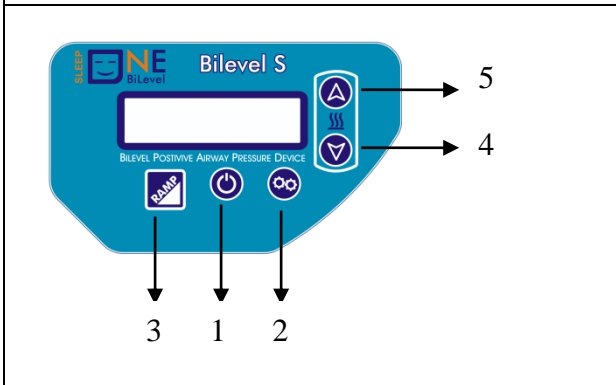
- 1.Heater-Humidifier
- 2.CPAP Masks



- 1. Keypad/LCD Display
- 2. Air Supply Port on Top



- 3. AC Connector
- 4. USB Port
- 5. Air Inlet Filter



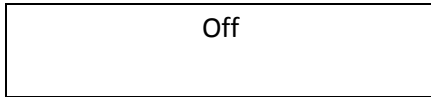
- 1. Standby – turns the device on or off
- 2. Setting
- 3. Ramp – Starts the ramp function
- 4. Previous Item and Adjust the Settings on LCD Display
- 5. Next Item and Adjust the Settings on LCD Display

**ASSEMBLY OF SLEEPONE DEVICE**

1. Place the SleepOne on a stable surface. Ensure that the air inlet in the back of the device is not blocked by anything.  
**NOTE**– *Never place the SleepOne device on a soft surface.*
2. Insert the power cord into the back of the device. Make sure the power cord is fully inserted into the connector. Plug the other end of the power cord into the AC outlet.
3. Attach the air supply tubing to the air supply interface on the top of the device.
4. Prepare the mask by referring to the mask’s instruction guide.
5. Connect the air supply tubing to the mask

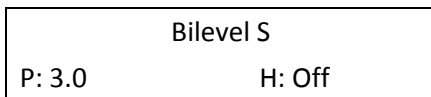
## INSTRUCTION FOR USE

To begin operation, verify that your SleepOne is connected to a power source. When plugged in, the LCD display should appear as noted.

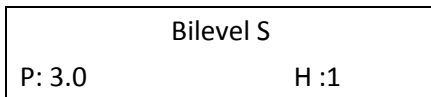


Put on your CPAP mask and press the ON/OFF button on the keypad to turn on airflow or put on your CPAP mask and take a few breaths to turn on airflow automatically. If the device does not automatically start after taking 2-3 breaths, Auto On function may have been disabled. If Auto ON is disabled, you must manually press the ON/OFF button to start and stop the device. The pressure in your mask will rise to the set pressure in a while.

The display shows the actual mask pressure while the device is in use. Because this is the actual pressure, the device pressure reading may vary slightly as you breathe. Your display should appear as noted.



If your SleepOne Bilevel systems include a humidifier, after heater has been enabled from the menu, heater controls and status are displayed as noted in the image.



Press the ON/OFF button to turn the device off. You may also simply remove your mask. After a few seconds the device will display the message "Mask Off" If you do not put the mask on again the device will automatically turn off after a while. If the device does not turn off automatically, the Auto Off function may have been disabled. In this case you must manually turn the device off.

LCD Display	Description				
<table border="1"> <tr> <td>EX -&gt; S</td> <td>bpm: 12</td> </tr> <tr> <td>P:5.0</td> <td>I/E 1:1.0</td> </tr> </table>	EX -> S	bpm: 12	P:5.0	I/E 1:1.0	This is the first real time info screen. In this screen breath state (EX for exhale, IN for inhale), breath for minute(bpm), measured mask pressure and I:E ratio is displayed .
EX -> S	bpm: 12				
P:5.0	I/E 1:1.0				
<table border="1"> <tr> <td>EX -&gt; S</td> <td>leak:30</td> </tr> <tr> <td>EV: **</td> <td>vol:800</td> </tr> </table>	EX -> S	leak:30	EV: **	vol:800	This is the second real time info screen. In this screen breath state(EX for exhale , IN for inhale), leak , event markers(AP for Apnea, HY for Hipoapnea and SN for snore) and tidal volume in mL.
EX -> S	leak:30				
EV: **	vol:800				

<p>EPAP 5.0 cmH2O</p>	<p>This is a pressure setting which controls the pressure during exhale. This setting can not be adjusted by patient. Only clinicians are authorized to adjust this level.</p>
<p>IPAP 10.0 cmH2O</p>	<p>This is a pressure setting which controls the pressure during inhale. This setting can not be adjusted by patient. Only clinicians are authorized to adjust this level.</p>
<p>EPAP Rounding 2</p>	<p>This is a setting which controls the comfort rounding when switching IPAP to EPAP.If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>IPAP Rounding 5.0</p>	<p>This is a setting which controls the comfort rounding when switching EPAP to IPAP. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>Ins. Trigger 5</p>	<p>This is a setting which controls the patient flow during exhalation to trigger inspiration. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>Exp. Trigger %80</p>	<p>This is a setting which controls the patient flow during inhalation to trigger exhalation. If menu is unlocked, press Settings button to activate it. Use the Up and Down button to adjust the settings .</p>
<p>Tubing Length 1.8 m</p>	<p>The standard tubing length is 1.8 meters however customer can adjust tubing length of 3.0 meters. If menu is unlocked, press Settings button to activate it. Use the Up and Down button to adjust the settings .</p>
<p>Delay Time 0 minutes</p>	<p>Selectable delay time setting. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>Delay Pressure 3.0 cmH2O</p>	<p>This is a pressure setting which controls the operating EPAP during the delay time. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>



<p>Auto On Disabled</p>	<p>This option controls the Auto-ON function, which automatically starts the flow of air after breathing once or twice into the mask. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>Auto Off Disabled</p>	<p>This option controls the Auto-OFF function, which automatically stops the flow of air after taking off the mask. If menu is unlocked, press Settings button to activate it . Use the Up and Down button to adjust the settings .</p>
<p>Firmware 5.0.0</p>	<p>Shows version of installed firmware.</p>
<p>USB MODE Enabled</p>	<p>To Activate the USB Mode, press Settings button. Use the Up and Down button to adjust the settings.</p>
<p>Heater Disabled</p>	<p>This option controls the Heater functions if the heater. To Activate the Heater Menu, press Settings button. Use the Up and Down button to adjust the settings.</p>
<p>Serial DB10-0000</p>	<p>Shows the serial number of the device</p>
<p>Set Pressure 3.0 cmH2O</p>	<p>This is a pressure setting which controls the operating pressure in CPAP mode.</p>

The following chart shows each Display you will scroll through using the Up or Down buttons after pressing the Settings button on the keypad. Once the final Display is reached, pressing the Next button will return you to the first Display.

Locks are setted by clinicians before patients start therapy. If the menu is unlocked, patient can edit some settings according to their comfort.

## Menu Display

Bilevel S  
P: 3.0 cmH2O      H:OFF

EX -> S              bpm: 12  
P:5.0                  I/E 1:1.0

EX -> S              leak:30  
EV: \*\*                Vol:800

EPAP  
5.0 cmH2O

IPAP  
10 cmH2O

EPAP Rounding  
2

Bilevel  
Mode

IPAP Rounding  
2

Bilevel  
Mode

Ins. Trigger  
5


Bilevel  
Mode


Exp. Trigger  
%80


Bilevel  
Mode


Tubing Length  
1.8 m


## Adjusting Display

EPAP Rounding  
2 

IPAP Rounding  
2 

Ins. Trigger  
5 


Exp. Trigger  
%80 

Tubing Length  
1.8 m 


Delay Time  
0 minutes

Delay Time  
0 minutes 


Delay Pressure  
3.0 cmH2O

Delay Pressure  
3.0 cmH2O 

Auto On  
Disabled

Auto On  
Disabled/Enabled 

Auto Off  
Disabled

Auto Off  
Disabled/Enabled 

Firmware  
1.0 01/02/2010

USB MODE  
Disabled


USB MODE  
Disabled/Enabled

Heater  
Disabled

Heater  
Disabled/Enabled

Serial  
DB10-0000

Set Pressure  
3.0 cmH2O

Set Pressure  
3.0 cmH2O 

## PATIENT MESSAGES

<div style="border: 1px solid black; padding: 5px; width: fit-content;">                 Delay Running 5 Minutes Left             </div>	While Ramp Mode is active, this message is display every 5 minutes to let you know how much time is left in the delay.
<div style="border: 1px solid black; padding: 5px; width: fit-content;">                 Mask Off             </div>	This message appears whenever a high airflow condition occurs. High airflow is normally due to a poor mask fit or a removed mask. If the high airflow condition persists for about 30 seconds, the device will automatically turn off (if AutoOFF function is enabled).
<div style="border: 1px solid black; padding: 5px; width: fit-content;">                 Error E00             </div>	If a device error message is displayed, refer to POSSIBLE PROBLEMS AND HOW TO SOLVE THEM for instructions.
<div style="border: 1px solid black; padding: 5px; width: fit-content;">                 Check Mask Fit             </div>	The leak of your mask is calculated simultaneously and if the amount of leak exceeds 100 liters/minute for more than 3 times , this notification is displayed on the screen unless the mask is properly fitted to your face.

## MAINTENANCE AND CLEANING

### DANGER

Electric shock hazard – Do not attempt to open or remove the case; there are no user-serviceable components inside. If service is required, contact your provider.

### WARNING

If the operation of the device appears to get out of normal operation or begins to be heard unusual sounds, do not continue to use device and contact your provider company.

If the device has been fallen down, verify functionality of the device. If the device does not function or the case is damaged, do not continue to use device and contact your provider company.

If the device does not appear to be functioning properly refer to the possible problems and how to solve them section for instructions.

Standard Air-Inlet Filter–Check the filter every 10 days and clean it if necessary. Replace the filter every 6 months or sooner if it is damaged.

**CAUTION**–Never rinse or place the device in water. Never allow liquids to get into or around any of the ports, switches or air filter. *If this occurs, do not use the device. Contact your provider company for service.*

## Device Case Cleaning

1. Unplug the SleepOne from the power source. Use a clean dry cloth and mild detergents for cleaning the unit.
2. Allow the device to dry completely before plugging it into a power source.

### Filter Cleaning

#### Air-Inlet Filter (Standard)

1. The air-inlet filter should be checked every 10 days and cleaned as necessary. The filter is located in the rear of the device.

**CAUTION**—*Proper filter function is important for the operation of the device and to protect the device from damage.*

2. To clean, remove filter from the frame.
3. Wash the filter in a solution of warm water and mild detergent, and rinse with water. Allow the filter to dry completely. If the filter is damaged, contact your provider company for a replacement.
4. Ensure the filter is completely dry before installation and use.

### Tubing

The air supply tubing should be cleaned daily. Remove the tubing from the device and mask. Use a mild detergent and water to clean the inside of the tubing. Rinse the tubing and allow to air dry.

## POSSIBLE PROBLEMS AND HOW TO SOLVE THEM

If you are having problem with the operation of your SleepOne , please refer to the table below for a list of problems with possible reasons and solutions. If you are unable to resolve the problem by following, contact your provider.

Possible Problem	Reason	Solution
Display shows nothing.	<ol style="list-style-type: none"> <li>1. Device is not plugged in or the power cord is not firmly fitted to outlet power.</li> <li>2. There is no outlet power.</li> </ol>	<ol style="list-style-type: none"> <li>1. Ensure that power cord is firmly fitted to the SleepOne and the power outlet.</li> <li>2. Ensure outlet power is live</li> </ol>
SleepOne does not start when breathing into the mask.	<ol style="list-style-type: none"> <li>1. The Auto-ON function has been disabled.</li> <li>2. There is no power to the device.</li> <li>3. Breath is not deep enough for the Auto-ON function to detect.</li> </ol>	<ol style="list-style-type: none"> <li>1. Use the ON/OFF button to start and stop the device.</li> <li>2. Ensure that power cord is firmly fitted to the SleepOne and the power outlet.</li> <li>3. Breathe deeper to start the SleepOne.</li> <li>4. Make sure the air supply port plug is firmly fitted into the unit.</li> </ol>

	<p>4. The air supply port plug is missing or not firmly fitted.</p> <p>5. The humidifier chamber is not fully engaged into the cradle or is missing.</p>	<p>5. Slide the humidifier chamber fully into the slot.</p>
<p>The airflow has stopped suddenly during use.</p>	<p>1. The Auto-OFF function has detected large airflow because of wrong placed mask.</p> <p>2. During use you may breathe by mouth.</p>	<p>1. Ensure you have a good mask fit; adjust the mask and headgear as needed.</p> <p>2. Contact your provider company for a chin strap or different mask which will help prevent mouth breathing.</p> <p>If problem is not resolved with above solutions, disable Auto-OFF function.</p>
<p>The display shows an error.</p>	<p>An error has occurred in the device and requires servicing.</p>	<p>Contact your provider company for service.</p>
<p>Symptoms of OSA have recurred.</p>	<p>1. Air filter may be obstructed.</p> <p>2. Sleep apnea condition has changed.</p>	<p>1. Clean or replace the air filter and change the location of device against drapes and other dusty surfaces.</p> <p>2. Contact your doctor.</p>
<p>Dryness of throat or nose.</p>	<p>Inadequate humidity.</p>	<p>1. Add Heated Humidifier.</p> <p>2. Increase the heater setting on the humidifier.</p>
<p>Condensation of water is collecting in the hose causing a gurgling noise.</p>	<p>1. Your humidification setting is too high.</p> <p>2. The room temperature fluctuates from higher to lower levels through the night.</p>	<p>Reduce the humidifier heater setting and/or increase the temperature of the room.</p>
<p>Air from flow generator seems to be too warm.</p>	<p>1. The air filter(s) is/are dirty.</p> <p>2. The air inlet port is blocked.</p> <p>3. The room</p>	<p>1. Refer to the filter cleaning section for instructions on filter maintenance.</p> <p>2. Unblock the air inlet.</p> <p>3. Decrease the room temperature.</p> <p>4. Locate the device away from the heat</p>

	<p>temperature is too high.</p> <p>4. The SleepOne is located near a heat source.</p>	<p>source so the air being drawn into the device is at room temperature.</p> <p>If the problem persists contact your provider company.</p>
<p>Nasal, sinus or ear pain, possibly with runny nose.</p>	<p>You may have a reaction to air flow pressure.</p>	<p>Do not continue to use and contact your doctor.</p>

## SPECIFICATIONS

Size.....	18.1 x 15.5 x 11.7 cm
Weight.....	1.25kg
Electrical Requirements.....	100-230 V AC
Maximum Power Consumption.....	50W
Pressure Range.....	3-35 cm H2O
Operating Temperature Range.....	5°C to 40°C
Operating Humidity Range.....	0% to 95% RH
Sound Level (tested per ISO 17510).....	<30dB

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