Somnus® DM18 APAP

CPAP Ventilator

User Manual

Preface

Thank you for purchasing the ventilator manufactured by Dymind Biotech.

Read and understand the entire user manual before operating this device. Store this user manual properly for future reference.

Product name: CPAP Ventilator

Model: DM18 APAP

Safety classification: class II, type BF protection against electric shock

Contact Info for After-Sales Services

Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.

Address: 2/F, Nanfeng Building B, Nanshan Yungu Innovation Industrial Park, No.1183, Liuxian Blvd, Taoyuan Street, Nanshan District, Shenzhen 518055, P.R.China

European Representative: 5 Bankside, Hanborough Business Park, Witney Ox29 8LJ UK

Service Tel: 400-998-7276

Tel: (86-755)26989825

Fax: (86-755)26746162

Email: dymind@dymind.com.cn

Website: http://www.dymind.com.cn/english/

CE 0197

Copyright

Declaration

This user manual may be modified without notice.

Dymind Biotech reserves the right of final interpretation of this user manual.

The pictures in this user manual are indicative only. If there is inconsistency between the pictures and the actual product, the actual product shall govern. Do not use the pictures for other than intended use.

The continuous positive airway pressure (CPAP) ventilator manufactured Dymind Biotech has passed strict clinical test and obtained the national medical equipment registration certificate. The manufacturer is only responsible for the normal working of the device and will not give any commitment to patient illness condition. Please consult your doctor before use and obey the user instructions.

Dymind Biotech shall be responsible for the safety, security, and performance of the product only when all of the following conditions are met:

- The assembly, re-commissioning, extension, modification, and repair of the product are performed by the authorized personnel of Dymind Biotech.
- The product is operated based on this user manual.

The manufacturer will not be responsible if the user violate the requirements, which leads to malaise on body or any other injury.

Content

1 Overview

1.1 Intended Use

The CPAP Ventilator is intended for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing over 30kg (66 lbs). It may be used in the home or hospital.

The CPAP Ventilator has two treatment modes: CPAP and APAP.

- CPAP is suitable for the treatment of mild obstructive sleep apnea syndrome (OSAS).
- APAP is suitable for the treatment of severe OSAS. In this mode, the device can automatically adjust the pressure.

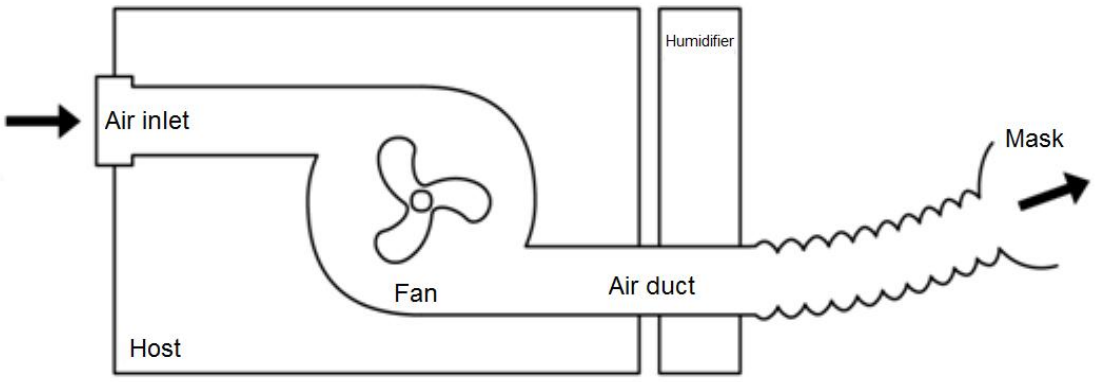
CAUTION

- This device is a portable device for home use. It can be used only after completion of treatment parameter settings under the instruction of a licensed physician.
- The clinical manifestations of obstructive sleep apnea syndrome (OSAS) are mainly: snoring, somnolent at day, sleep apneas, excessive urination at night, headache as well as other complications.

1.2 Operation Theory

OSAS usually performs as airway obstruction, disturbance in respiration, which may cause respective complications. The CPAP Ventilator uses dedicated air compressor to compress filtered air from the surrounding environment to produce continuous positive pressure. The positive pressure is transported to the patient through a breathing tube. The upper airway of the patient is kept open under the positive pressure so that the patient can breathe normally. The working principle of the CPAP Ventilator is illustrated by Figure 1-1.

Figure 1-1 Operation Theory



If the positive pressure is set to an excessively low value, the effect of treatment will be affected; if the positive pressure is set to an excessively high value, the patient will feel uncomfortable.

Therefore, the patient must undergo pressure titration in hospital before using the CPAP Ventilator. A licensed physician will present a report on usage pressure and perform pressure titration for the patient.

The CPAP Ventilator is operated by using the display screen and control buttons on top of the ventilator. The device functions are adjustable. The CPAP Ventilator is fitted with a heated humidifier, which is used to increase the temperature and humidity of the breathed air so as to prevent mucosa drying in nasal cavity and ensure comfort of the patient.

1.3 Warnings, Cautions and Contraindications

1.3.1 Warnings

- Read and understand the entire user manual before operating this device.
- This device is not intended for life support.
- This device can be used only after completion of treatment parameter settings under the instruction of a licensed physician.
- The instructions in this manual are not intended to supersede established medical protocols.
- This device must be used together with the accessories (such as the mask, tube, and power adapter) recommended and provided by Dymind Biotech. The use of accessories other than those specified may have an adverse effect on device functions.
- When connecting the power adapter, check whether the plug is connected to the device's power interface properly.
- This device is not suitable for use in the presence of a flammable anaesthetic mixture in combination with oxygen or air.
- Take off the mask in the case of power failure or in the unlikely event of fault conditions.
- Do not block the vent holes of the mask. If the vent holes are blocked, the patient will repeatedly breathe in exhaled air, which may cause suffocation.
- To avoid scald, do not touch the warm-up plate of the heated humidifier when it is operating.
- Discontinue use if you notice any exceptions of the device, such as significant external damage, liquid ingress, excessively hot output air, or unusual sounds.
- Do not perform repair or maintenance when the device is operating.
- Power supply is specified as a part of this equipment, be sure to use this power supply, or would result in electric shock and other hazards.
- It can be unsafe to interconnect the device with other equipment not described in this manual.
- Bundle or place the cables and hose properly to advoid strangulation due to excessive length.
- Device and system should not be close to other devices or stack. Or it should be observed and verified that it can work normally under his setting, if it has to be closed to other device or stack.
- It's possible to lead to the increasing of electromagnetic radiation of the device and system , or the decreasing of noise immunity if accessory and electric cable which are out of stipulation are used, except for the electric cable which are sold as spare parts of internal components by the manufacturer of the device and system.

1.3.2 Cautions

- Before turning on the device, make sure the power supply is steady and meets the requirements.
- The use of communications equipment, electromechanical equipment, or MRI equipment near this device may cause interference to this device and should be kept at a distance.
- Do not dissemble or repair the device without authorization. Contact your device supplier if the device is damaged.
- Do not immerse the host in any fluids or place the host in an excessively hot and humid environment.
- Disconnect the power cord when the device is not in use.
- In the home healthcare environment that can unacceptably affect the basic safety and essential performance of the device, please make sure to keep the device away from:
  - lint, dust, light (including sunlight), etc.
  - pet, pest and children.
- Irregular sleep, drinking, fat, obesity, hypnotic or sedatives may aggravate the symptoms

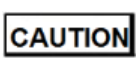
1.3.3 Contraindications

The device is prohibit to use, if patient is among any case below:

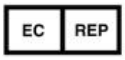
- Pulmonary bulla indicated by a chest CT scan or X-ray
- Pneumothorax, pleural effussion or pneumomediastinum
- Hypotension, such as when shock is not treated immediately
- Severe coronary heart disease (CHD)
- Cerebral spinal fluid leak, traumatic brain injury (TBI), or intracranial pneumatocele
- Acute otitis media
- Facial trauma, postoperation, deformity
- Tacheal secretions excess, sputum excretion
- Afer abdominal operation

1.4 Symbols

The symbols that may be found in this document are defined as follows.

Symbol	Description
 **WARNING**	Alerts you to injury if not operating based on the description under this symbol.
	Alerts you to device damage if not operating based on the description under this symbol.

You may find the following symbols of the ventilator system:

Symbol	Description
	Alerts you to injury if not operating based on the description under this symbol.
	Serial Number of the product
	Date of manufacture
	Manufacturer
IP21	Ingress protection
	Type BF applied part
	Refer to instruction manual
	European CE declaration of conformity
	Authorized Representative in the European Community

1.5 Quality Guarantee

For failures caused by material and manufacturing, Dymind Biotech offers a 2-year warranty on the host, a one-year warranty on the heated humidifier and a three-month warranty on accessories suc h as the tubing, mask, and water tub. The warranty period starts from the date of shipment to the cu stomer. Within the warranty period, Dymind Biotech offers repair service without charge in accordance with warranty obligations.

If you require the electrical diagram or component list of the CPAP Ventilator in special situations (such as maintenance or connection to other devices), contact Dymind Biotech. We will provide you with part of or the entire electrical diagram of the CPAP Ventilator based on your requirements.

You can get repair service without charge only after producing the warranty card filled in upon purchase of the CPAP Ventilator.

1.6 Disposal

The user of the CPAP Ventilator is required to dispose of the device and related packing materials based on applicable national laws and regulations when the device reaches the end of service life. Observe the following disposal instructions unless otherwise specified:

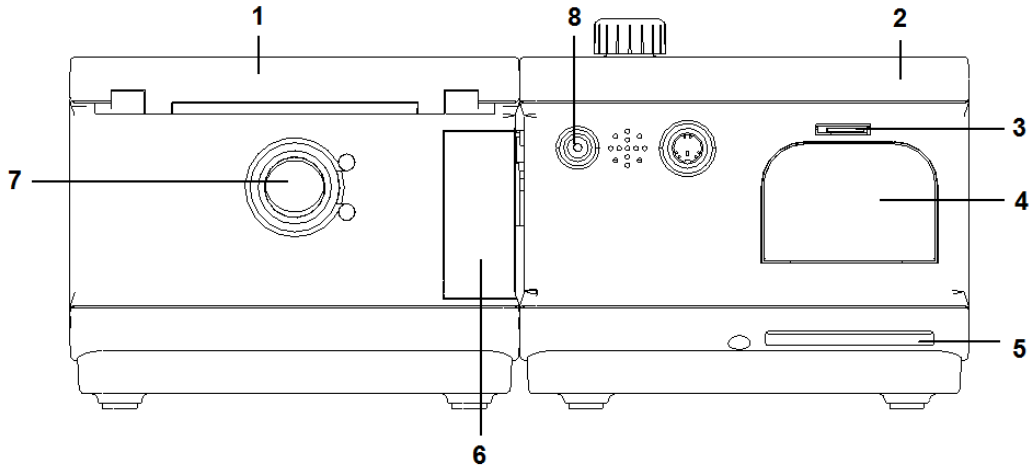
- Send the device that has reached the end of service life to a recycle center. The recycle center enables the user to dispose of the plastic, glass, metal components, printed tube board (PCB), cable, battery, warm-up plate of the heated humidifier, and motor of the device.
- Send the hardboard package and protective plastic package to the recycle center.

2 Installation and Configuration

2.1 Device Composition

The CPAP Ventilator consists of a host, humidifier, air tubing, mask, and power adapter (100–240 V AC, 50/60 Hz, 24 V DC).

2.2 Interfaces



1 - Host

2 - Humidifier

3 - SD card: storing treatment data for up to a year

4 – Air filter and air filter cover: air filter which is used for filtering the dust in the air within device can be installed after filter cover is opened.

5 - Air inlet

6 - Humidifier separation button: press this button and pull in 2 opposite directions simultaneously, then the host and humidifier will be separated.

7 - Air outlet: connected to the tubing

8 - DC power: connected to the DC power adapter

2.3 Installation

Take the following steps to install the CPAP Ventilator:

1. Connect the host to the heated humidifier.

In alignment with the air channel and electrical connection of the humidifier, gently push the host so that the connecting clip of the host and that of the humidifier are locked to each other.

2. Inject water into the water tub.
   a. Press the OPEN button of the humidifier. When the cap pops up, lift the cap and take out the water tub.
   b. Pour a proper amount of purified water into the water tub. Be sure not to exceed the highest water level.
   c. Insert the water tub into the humidifier and gently press on the cap.

CAUTION

Only purified water can be added to the water tub. If running water or mineral water is added, incrustation will occur, affecting the service life of the water tub.

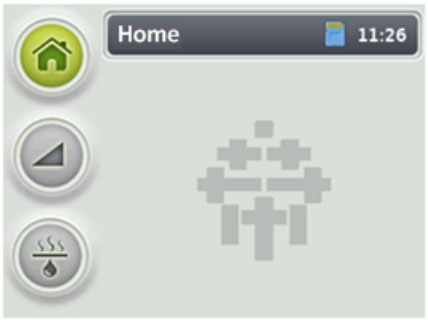
3. Install the air filter.

   Gently pinch on both sides in the lower part of the air filter cover, take off the cover, insert the air filter into the cover, insert the upper part of the cover into the pilot hole, and press the lower part of the cover so that the cover is locked.
4. Install the microSD card.
5. Connect to the tubing and put on the mask.
   a. Connect one end of the tubing to the air outlet of the humidifier and the other end to the mask with the exhalation port.
   b. Gently fit the mask onto your nose, adjust the mask, and gently tighten the four elastic bands until you have a comfortable fit.
6. Connect to a power supply.

   Connect the DC power plug of the power adapter to the DC power interface on the back of the ventilator and connect the AC power plug to the AC power socket.

   After power-on, the **Home** screen of the ventilator appears on the display screen (Figure 2-1).

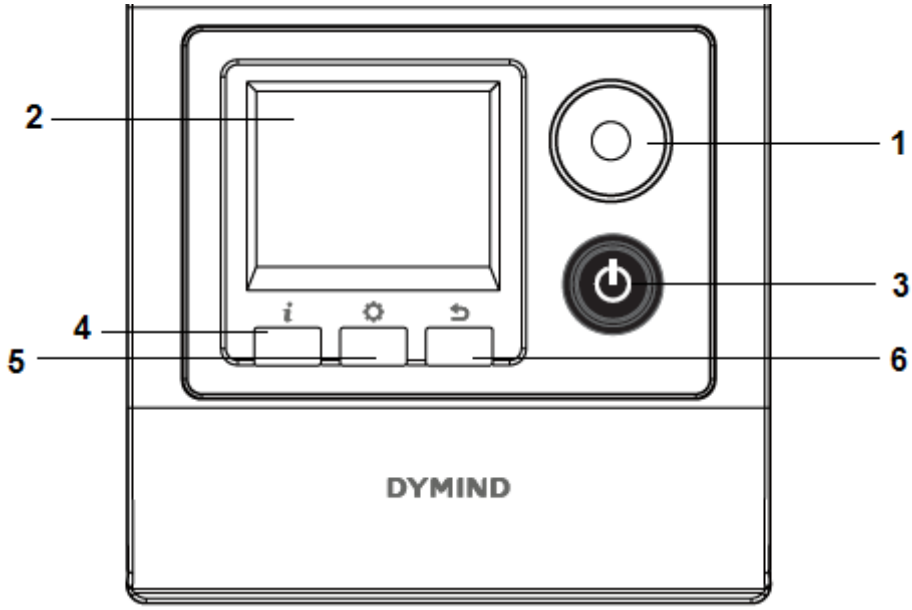
Figure 2-1 Home screen



CAUTION

- The ventilator enters the power-on standby state after being connected to a power supply. The  button is used to start or stop pressure output.
- The temperatures on both sides of the DC power adapter increase when the ventilator is operating. It is a normal phenomenon.
- Place the ventilator on a firm and flat surface away from any heating or cooling equipment (such as fans, radiators, or air-conditioners). Do not block the vent holes with objects and ensure normal air circulation inside the ventilator.

2.4 Operation Panel



1 - Control Wheel/Push Button: Use this button to select a menu option and confirm the selection.

- The **control wheel** button supports three operations: pressing (for confirming the selection), rotating clockwise, and rotating counterclockwise.
- Pressing: When the control wheel is pressed on the parameter setup screen, the specified function is selected.
- Rotating clockwise/counterclockwise: When the control wheel is rotated in the menu column, the previous/next menu option is selected. When the control wheel is rotated in parameter options, different values are selected or the value of the specified parameter is increased or decreased.
- When the control wheel is pressed and held for 3s on the **Humidity Level** screen, the temperature and humidity levels of the humidifier are increased if the ventilator is not in **Warming Up** or **Cooling Down** state. If the ventilator is in **Warming Up** state, the temperature and humidity levels of the humidifier are reduced.

2 - Display screen: A menu, treatment information, and alarm information appear here.

3 - : Use this button to start or stop treatment.

4 - : Use this button to view the patient's sleep quality report and the ventilator's service information.

5 - : Use this button to set parameters.

- Press the button to enter the user setup screen. Basic parameters such as **Mask Fit**, **Tube**, and **Mask** can be set. See section 2.5.3 "User Setup".
- Press and held the button and control wheel at the same time for 3s to enter the detailed setup screen. Detailed treatment parameters such as **Work Mode**, **Humidity Level**, and **Xlief** can be set. See section 2.5.4 "Detailed Setup".

6 - : Use this button to cancel the current operation or return to the previous screen.

2.5 Batch Parameter Settings

The user can set the treatment parameters quickly though Micro SD.

(**Note**: Users can set all parameters of device , for details, see ***3 Parameter Settings***.)

The procedure is as below :

1. Abtain the configuration file from your local agent.
2. Finish the customization of configuration file with the help of your local agent.
3. Copy the configuration file to Micro SD.
4. Insert the Micro SD into the host, Press button 3 seconds under stand-by condition.

   The system will input the configuration file , and finish the parameter setting.

   13 parameters can be set in the configuration file. See Table 2-1.

Table 2-1 Parameter settings in configuration file

No.	Parameter	Value
1	Mode	CPAP, APAP
2	Treat Pressure (for CPAP only)	4~20 hPa
3	Max Pressure (for APAP only)	4~20 hPa
4	Min Pressure (for APAP only)	4~20 hPa
5	Start Pressure for CPAP only (the initial pressure output when the ramp feature is enabled.)	4~20 hPa
6	Start Pressure for APAP only (the initial pressure output when the ramp feature is enabled.)	4~20 hPa
7	Max Ramp	0~60 min
8	Xlief	1~3
9	I-sensitivity	1~5
10	E-sensitivity	1~5
11	I-rate	1~3
12	Smart Start	On, Off
13	Humidity Level	1~6

3 Parameter Settings

CAUTION

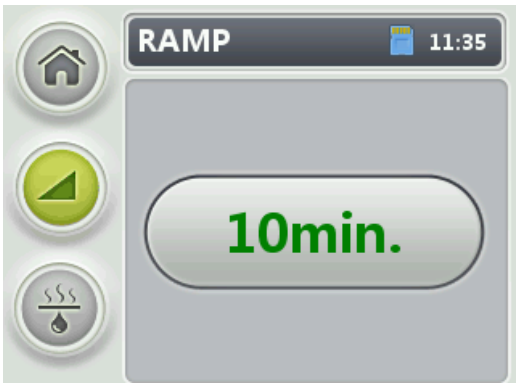
The parameters on the user setup screen (press the button to enter the screen) can be set by the patient. Other parameters must be set by a licensed physician or under the instruction of a licensed physician.

3.1 Ramp Time

You can set ramp on the **Home** screen to increase the treatment comfort degree. (The ramp feature is disabled by default.)

1. On the **Home** screen, rotate the control wheel to the **RAMP** menu and press the control wheel to enter the **RAMP** screen (see Figure 3-1).

Figure 3-1 Setting the ramp time



2. Rotate the control wheel to select the ramp time and press the control wheel to confirm the selection.

   When the ramp feature is enabled, the ventilator outputs an initial pressure and slowly increases the initial pressure to the therapeutic pressure during the predefined ramp time to help the patient fall asleep. When the ramp time ends, the ventilator automatically detects the patient's respiration conditions and adjusts pressure accordingly.

   For details about the setting of the ramp time, see section ***3.4.1 Detailed Treatment Settings.***

3.2 Humidity Level

When the host is connected to the heated humidifier, you can set the humidity level for the warm-up of the humidifier to ensure that the air output by the ventilator has a proper temperature when being humidified.

Rotate the control wheel to the **Humidity Level** menu and press the button to enter the **Humidity**

Level screen.

- Setting the humidity level

  Rotate the control wheel to select a humidity level for the humidifier and press the button to confirm the selection (see Figure 3-2).

Figure 3-2 Setting the humidity level

The level of humidity can be set before or after cure. The value of **Humidity Level** ranges from **1** to **6**, or it can be set to **Off**.

- (When **Humidity Level** is not set to **Off**) Warming up or cooling down

  Before starting treatment, press and held the control wheel for 3s. If the ventilator is not in **Warming Up** or **Cooling Down** state, the temperature and humidity levels of the humidifier are increased (see Figure 3-3). If the ventilator is in **Warming Up** state, the temperature and humidity levels of the humidifier are reduced (see Figure 3-4).

Figure 3-3 Warming up

Figure 3-4 Cooling down

CAUTION

During treatment, the ventilator will stop warming when the treatment is stopped.

- Stop warming or cooling

  Rotate the control wheel to **Off** to stop warming or cooling.

Figure 3-5 Stop warming or cooling

CAUTION

- Humidity Level is set to a proper value if small drops of condensed water exist inside the groove of the tubing in the next morning. Humidity Level is set to an excessively large value if many water droplets exist inside the tubing and mask; Humidity Level is set to an excessively low value if you feel nose dryness; in these cases, reduce or increase the value of Humidity Level.
- When you lie down, keep the ventilator slightly lower than your head so that drops of condensed water flow back to the water tub of the humidifier to prevent respiratory impairment.
- Empty water in the water tub of the humidifier when it is not used.

3.3 User Setup (Button)

Press the button to enter the user setup screen (see Figure 3-6).

Figure 3-6 User setup screen

The following parameters can be set by the patient.

CAUTION

Rotate the control wheel clockwise or counterclockwise to switch to other menus or options. Press the control wheel button to confirm the settings, or press the button to cancel the settings.

Parameter	Setting Description
Tube	This parameter specifies the tubing type: Standard (diameter: 22 mm)

Parameter	Setting Description
Mask	This parameter specifies the mask type. Values: Nasal, Full Face
Xlief	The ventilator automatically detects respiratory rhythm when it is operating and reduces the pressure inside the mask during exhalation to increase the patient comfort level. The higher the parameter value, the higher the pressure release level. The default value is 3. Values: 3, 2, 1, Off **NOTE** The **Xlief** parameter appears on the user setup screen only when the **Xlief** parameter on the detailed setup screen is set to **Patient** by a licensed physician.
I-sensitivity	The inspiratory trigger sensitivity (ITS) of the device. The range is between 1 and 5, and the default value is 3. The higher the value, the higher the sensitivity. **NOTE** The **I-sensitivity** appears on the user setup screen only when the **I-sensitivity** parameter on the detailed setup screen is set to **Patient** by a licensed physician.
E-sensitivity	The expiratory trigger sensitivity (ETS) of the device. The range is between 1 and 5, and the default value is 3. The higher the value, the higher the sensitivity. **NOTE** The **E-sensitivity** appears on the user setup screen only when the **E-sensitivity** parameter on the detailed setup screen is set to **Patient** by a licensed physician.
I-rate	The inspiratory flow rate (IFR) of the device. The range is between 1 and 3, and the default value is 2. The higher the value, the greater the flow rate. **NOTE** The **I-rate** appears on the user setup screen only when the **I-rate** parameter on the detailed setup screen is set to **Patient** by a licensed physician.
Mask Fit	Press the control wheel to start the mask fit function; or press the  button to stop. • When the mask does not have air leaks, a prompt is displayed indicating that the mask is worn properly. • When the mask has air leaks, a prompt is displayed indicating that the mask needs to be adjusted. If the patient does not stop the mask fit function halfway, the ventilator will automatically start treatment 3 minutes after the mask is put on.
Smart Start	When the ventilator is in standby state and the patient puts on the mask and takes deep breathing 2~3 times, the ventilator is started automatically and outputs the predefined pressure. Once the mash is taken off, the therapy will be stopped. Values: On, Off **NOTE** The **Smart Start** parameter appears on the user setup screen only when the **Smart Start** parameter on the detailed setup screen is set to **Patient** by a licensed physician.

3.4 Detailed Setup (Button + Shuttle Button)

CAUTION

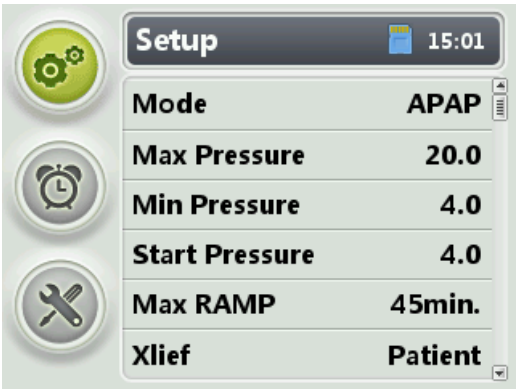
The parameters on the detailed setup screen must be set by a licensed physician or under the instruction of a licensed physician.

Press and held the button and control wheel at the same time for 3s to enter the detailed setup screen (see Figure 3-7). The treatment parameters, reminder parameters, and system configurations can be set.

3.4.1 Detailed Treatment Settings

Rotate the control wheel clockwise or counterclockwise on the **Setup** screen to switch to other menus or options. Press the control wheel to confirm the settings, or press the button to cancel the settings.

Figure 3-7 Detailed setup screen



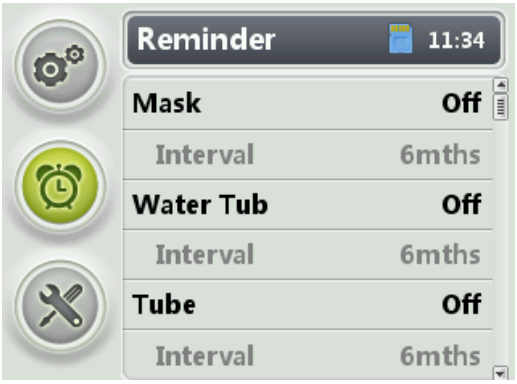
Parameter		Setting Description
Mode		This parameter specifies the work mode of the ventilator. Please set it according to the actual situation. • CPAP: short for Continuous Positive Airway Pressure. The device can provide continuous CPAP according to the different condition of patient. • APAP: short for Automatic Continuous Positive Airway Pressure. The device can adjust and find the best curing pressure automatically according to the sleep condition of patient.
CPAP	Treat Pressure	This parameter specifies the maximum therapeutic pressure in CPAP mode. Value range: 4.0~20.0. The default value is 5.0.
APAP	Max Pressure	This parameter specifies the maximum therapeutic pressure in APAP mode. The default value is 20.0.
	Min Pressure	This parameter specifies the minimum therapeutic pressure in APAP mode. The default value is 4.0.
Start Pressure		This parameter specifies the initial pressure output by the ventilator when the ramp feature is enabled. **NOTE** The parameter is displayed only when **Max RAMP** is not set to **Off**.

Parameter	Setting Description
Max RAMP	This parameter specifies the maximum ramp time. Values: • Off: to disable the ramp feature. • 5 minutes/10 minutes/…/55 minutes/60 minutes: user-defined maximum ramp time. If Max RAMP is set to 10 minutes, Ramp Time on the Home screen can be set to OFF, 5 minutes, or 10 minutes. **NOTE** The ramp feature enables slow increase of the therapeutic pressure from the minimum pressure to the maximum pressure during the maximum ramp time, so that the patient can fall asleep more comfortably.
Xlief	The ventilator automatically detects respiratory rhythm when it is operating and reduces the pressure inside the mask during exhalation to increase the patient comfort level. The higher the parameter value, the higher the pressure release level. The default value is **3**. Values: 3, 2, 1, Off, Patient. **NOTE** When the parameter is set to **Patient**, the **Xlief** parameter appears on the user setup screen and can be set.
I-sensitivity	The inspiratory trigger sensitivity (ITS) of the device. The higher the value, the higher the sensitivity. The default value is **3**. Values: 1, 2, 3, 4, 5, Patient. **NOTE** When the parameter is set to **Patient**, the parameter appears on the user setup screen and can be set.
E-sensitivity	The expiratory trigger sensitivity (ETS) of the device, including: 1~5, Patient. The default value is 3. The higher the value, the higher the sensitivity. **NOTE** When the parameter is set to **Patient**, the parameter appears on the user setup screen and can be set.
I-rate	The inspiratory flow rate (IFR) of the device. The default value is 2. The higher the value, the higher the flow rate. Values: 1, 2, 3, Patient. **NOTE** When the parameter is set to **Patient**, the parameter appears on the user setup screen and can be set.
Mask	This parameter specifies the mask type. Values: Nasal, Full Face
Tube	This parameter specifies the tube type: Standard (diameter: 22 mm)
Smart Start	When the ventilator is in standby state and the patient puts on the mask and takes deep breathing 2~3 times, the ventilator is started automatically and outputs the predefined pressure. Once the mash is taken off, the therapy will be stopped. Values: On, Off, Patient. **NOTE** When the parameter is set to **Patient**, the **Smart Start** parameter appears on the user setup screen. To enter the user setup screen and enable/disable the Smart Start function, press the ⚙ button.

3.4.2 Reminder Configuration

Rotate the **control wheel** to the **Reminder** menu on the **Setup** screen and press the button to enter the **Reminder** screen (see Figure 3-8). On the **Reminder** screen, the operator can set the time for notifying the patient of replacing components or the time for device maintenance.

Figure 3-8 Reminder screen



Parameter	Setting Description
Mask	This parameter specifies the time for notifying the user of contacting his/her device supplier to replace the mask. The default value is **Off**, indicating that the user is not notified. **NOTE** • The shelf life of mask is 24 months. • It is suggested to change the mask after every 6 months use.
Water Tub	This parameter specifies the time for notifying the user of contacting his/her device supplier to replace the water tub. The default value is **Off**, indicating that the user is not notified.
Tube	This parameter specifies the time for notifying the user of contacting his/her device supplier to replace the air tubing. The default value is **Off**, indicating that the user is not notified. **NOTE** • The shelf life of air tubing is 3 years. • It is suggested to change the air tubing after every one year use.
Filter	This parameter specifies the time for notifying the user of contacting his/her device supplier to replace the filter. The default value is **Off**, indicating that the user is not notified. **NOTE** The air filter of the device is not washable. It is suggested to be changed after 3~6 months use. Please contact your local agent for purchasing.
Service	This parameter specifies the time for notifying the user of sending the ventilator to his/her device supplier for maintenance. The default value is **Off**, indicating that the user is not notified.

3.4.3 System Configuration

Rotate the control wheel to the **Configuration** menu on the **Setup** screen and press the control wheel to enter the **Configuration** screen (see Figure 3-9). On the **Configuration** screen, the operator can set such parameters as **Language**, **Set Time**, and **LCD Light**.

Figure 3-9 Configuration screen

Parameter	Setting Description
Language	This parameter specifies the language used by the ventilator. Values: English, Chinese, Française, Española, Português, Deutsch, Korean
Restore Def.	This parameter is used to restore the ventilator to factory defaults.
Erase Data	This parameter is used to delete the patient's sleep quality and sleep report data.
Press. Units	This parameter can be set to hPa or cmH2O.
LCD Light	This parameter is used to enable or disable the screen backlight. Values: • Auto: The backlight is turned off some time after no buttons are pressed. The backlight is turned on when a button is pressed. • Always: The backlight is always on.
Set Time	This parameter specifies the current date and time of the ventilator. It is in the format of *YYYY-MM-DD hh-mm*, for example, 2014-01-01 12:30. Values: • YYYY: specifies the year, for example, 2014. • MM: specifies the month, such as 01. • DD: specifies the date, such as 01. • hh: specifies the hours, such as 12. • mm: specifies the minutes, such as 30. During operation, the ventilator records the user's usage information based on this clock. Therefore, it is necessary to check the clock accuracy frequently.

4 Routine Use

WARNING

Do not perform repair or maintenance when the device is operating.

The patient can undergo treatment by using the methods described in this chapter, or view the sleep quality and sleep report the previous day.

4.1 Treatment Steps

CAUTION

- Check whether the tube is damaged or contains foreign bodies each time before using the ventilator. If the tube is damaged or contains foreign bodies, clean or replace the tube.
- The ventilator can be used only after completion of treatment parameter settings (including detailed treatment settings, ramp settings, and humidity level settings) by a licensed physician or under the instruction of a licensed physician.

1. Connect the ventilator based on section ***2.3 Installation***.
2. Lie down on a bed and adjust the tube so that the tube can move freely when you turn over during sleep.
3. Put on the mask and tie the headbands and adjust them until you have a comfortable fit and there are no air leaks when you breathe.
4. Press the button to start treatment.

   If the **Smart Start** function is enabled (see Figure 4-1), you can take two deep breaths and the ventilator will automatically start treatment. See ***3.4.1 Detailed Treatment Settings***.

Figure 4-1 Enabling the Smart Start function

5. Adjusting the humidity level will help to make breathing more comfortable.

   For details, see ***3.2 Humidity Level***.

6. After using the ventilator, press  to stop therapy.
7. Put off the mask and headbands and unplug the power cord to shut down the ventilator.

CAUTION

- In the case of power failure or in the unlikely event of fault conditions, take off the mask to avoid inhaling the air you have exhaled previously.
- In the case of power failure, the device will shut down automatically. After power restoration, the device will automatically start up and return to the initial interface (Figure 2-1).
- Do not block the air inlet and outlet of the ventilator with any bed cover, curtain, or other objects.
- Always keep the air outlet of the humidifier lower than the tube and mask to prevent ingress of water inside the tube.

4.2 Sleep Report

Press the  button to enter the **Sleep Quality** screen, which displays the patient's sleep quality and sleep report.

4.2.1 Sleep Quality

Parameter	Description
Period	This parameter records the patient's sleep quality the previous night.
Usage	This parameter records the time when the patient uses the ventilator the previous night.
AHI	This parameter records the patient's AHI index.

4.2.2 Sleep Report

Parameter	Description
Period	This parameter specifies the period of a sleep report, which may be one day, one week, one month, three months, six months, or one year.
Days>4hrs	This parameter records the number of days when the ventilator is used for more than 4 hours. For example, the value **10/20** indicates that the number of device usage days is 20, with 10 days of device usage exceeding 4 hours per day.
Avg. Usage	This parameter records the average hours of device usage every day.
Used Hrs	This parameter records the total hours of device usage.

5 Cleaning and Maintenance

WARNING

- Unplug the CPAP Ventilator before cleaning.
- Clean the mask and air tubing based on the instruction of the manufacturer and determine the cleaning period.
- Do not perform repair or maintenance when the device is operating.

CAUTION

- Do not clean the ventilator and accessories with any abrasive cleaner, alcohol, chlorine-bearing compound, acetone, or any other solvents.
- Over-warming of materials may cause material pre-aging.
- Wash all accessories and parts of the humidifier in clean water after cleaning with a detergent. Wipe all parts with a lintless cloth to prevent calcareous sediments accumulation.

The CPAP Ventilator and accessories must be cleaned regularly under normal usage to prevent the user from contracting respiratory tract infection.

5.1 Daily Cleaning

The mask and the water tub of the humidifier must be cleaned daily.

WARNING

Ensure that the ventilator is unplugged and the water tub of the humidifier is cool before cleaning.

5.1.1 Cleaning the Mask

Carefully clean the mask with a mild detergent.

- Carefully clean the silica gel pad that is in close contact with skin during normal usage.
- Check whether the vent holes of the mask are unblocked.
- Rinse the mask in clean water and wipe the mask with a clean cloth to prevent stains.
- Suspend the mask and air dry. Avoid direct sunlight on the mask or place the mask on a radiator.

CAUTION

- The shelf life of mask is 24 months.
- It is suggested to change the mask after every 6 months use.

5.1.2 Cleaning the Water Tub of the Humidifier

It is recommended that water in the water tub be changed and the water tub be washed every day based on the following steps:

1. Switch off the ventilator and keep it off for 15 minutes for cooling down.
2. Open the cap of the humidifier by pressing the [OPEN] button.
3. Take out the water tub and discard any remaining water.
4. Wash all parts in the dishwasher or a solution of warm water (not higher than 50oC) and a mild dishwashing detergent.
5. Rinse the water tub with clean water and allow to air dry.
6. Fill the water tub and close the cover. Inspect the water tub for any leak or damage. Replace the water chamber if any damage is present.

CAUTION

Prevent ingress of water inside the ventilator during washing.

5.2 Weekly Cleaning

5.2.1 Cleaning the Air Filter

The air filter of the device is not washable. It is suggested to be changed after 3~6 months use. Please contact your local agent for purchasing.

CAUTION

The standby air filters should avoid direct sunlight, be away from wet or cold site, otherwise they will be damaged.

5.2.2 Enclosure

Wipe the outside of the CPAP Ventilator with a cloth slightly dampened with water. Use a dishwashing detergent when necessary.

CAUTION

Before using the ventilator, ensure that the enclosure is thoroughly dry and there are no moisture ingress inside the ventilator.

5.2.3 Cleaning the Air Tubing

1. Disconnect the tube from the ventilator and mask.
2. Clean the tube with a detergent and rinse the tube in clean water.

3. Air dry the tube in a shady and cool place until the tube is thoroughly dry.

CAUTION

- The shelf life of air tubing is 3 years.
- It is suggested to change the air tubing after every one year use.

5.2.4 Cleaning the Headbands

1. Remove the headbands from the mask.
2. Wash the bands by hand in water at about 30^{o}C or in a solution of warm water containing mild soap liquids. (Because the headbands may be decolored, wash the bands separately for the first time.)
3. Spin-dry the headbands at low speeds or drain the headbands.

CAUTION

Do not iron the headbands; otherwise, the magic tapes of the bands may be damaged.

5.3 Disinfection

Generally there is unnecessary to sterilize the device if you follow the right cleaning instructions. When the humidifier was contaminated or used in clinical, you can get standard disinfectants from a pharmacist to do the disinfection.

CAUTION

- Disinfectants will damage the device’s surface and shorten its life. Therefore, for the specific disinfectant suitable materials and instructions , you should follow the manufacturer's advise.
- After cleaning with disinfectants, wash all parts of the device in close with the patient in clean water, such as the mask, headbands and tube, to keep skin away from infections

After disinfection, check if there are any parts damaged traces. If so, please replace the defective parts.

5.4 Transfer the Device

When the device is transferred to another patient, for health reason, it is recommended that you replace the parts in contact with the patient, such as the mask, headbands, water tub, tub and air filter.

6 Service and Repair

CAUTION

The CPAP Ventilator should be maintained by the user.

Check the following items before using the ventilator:

- Check whether the air tubing and mask are sealed
- Check whether the treatment pressure is generated and appears on the display screen
- Check whether the water inside the humidifier is warmed up.

If the CPAP Ventilator is faulty, or unexpected operation or events occur, contact Dymind Biotech or your device supplier. Repair can only be done by an authorized engineer.

Long-term usage and free repair service of the CPAP Ventilator are possible only when the user complies with the security and cleaning & maintenance guidelines of the ventilator.

7 Troubleshooting

The table below lists common problems you may have with the CPAP Ventilator and possible solutions to those problems. If none of the corrective actions solve the problem, contact your physician or device supplier.

Problem	Possible Cause	Solution
You feel mucosa drying in nasal cavity, nose coldness or congestion, have a running nose, or catch a cold.	The symptoms are the nose's responses to the airflow from the ventilator or cold symptoms. Nose coldness is caused by the fast-flowing air, stimulating the nasal mucosa and resulting in nose dryness or swelling.	• Increase the humidity level of the heated humidifier. • Consult your physician. Do not stop treatment unless advised by your doctor.
You feel dryness in the oral cavity or throat.	You may sleep with your mouth open.	• Wrap a fixing band around your lower jaw. • Consult your physician and consider the use of a full-face mask.
OSA occurs multiple times during a day.		
You have pricking eyes.	• The mask is not fixed properly, causing air leaks. • The size and model of the mask are incorrect.	• Shorten the distance between the prefrontal frame of the mask and your forehead. • Contact your device supplier and select a mask of a different model. Insert fillers into the mask when necessary.
The skin in the contact position between your face and the mask reddens.	• The mask pad (the soft part inside the mask) hardens. • The mask is too tight. • The distance between the prefrontal frame of the mask and your forehead is incorrect. • The size of the mask is incorrect. • You are allergic to the mask materials.	• Replace the mask or mask pad. • Loosen the mask and headbands. • Try different distances. • Contact your device supplier and select a different mask. • Use a fixing material in the contact position between your face and the mask and consult your physician and device supplier, or use a rubber-free mask.
Ingress of water inside the mask.	If the heated humidifier is used, the temperature difference between the air tubing and surrounding air will cause	• Reduce the temperature level of the heated humidifier or increase the temperature of the surrounding environment.

Problem	Possible Cause	Solution
	condensation.	• Always keep the air outlet of the humidifier lower than the tube and mask to prevent ingress of water inside the tube.
You feel pain in the nose, paranasal sinuses, or eyes.	Nasosinusitis or otitis media	Contact your physician immediately.
You feel uncomfortable because the treatment pressure is not suitable.	The user will feel uncomfortable when the treatment pressure is higher than 13 hPa. In some situations, however, it is necessary to set the treatment pressure over 13 hPa to prevent OSA.	It may take up to four weeks to adapt to the treatment pressure. Try to relax yourself when using the ventilator. Breathe through your nose and keep your month closed. If the problem persists, contact your physician.
The noise level of the Ventilator is too high.	• The air tubing is connected incorrectly. • The humidifier and host are not connected tightly.	• Connect the air tubing to the correct interface of the host. • Reconnect the humidifier to the host.
The inhaled air is too hot.	• The air inlet or air filter is blocked. • The ventilator is too close to a wall, curtain, or other objects, obstructing air circulation.	• Clean or replace the air filter (see section 4.2 "Weekly Cleaning") and clean the air inlet. • Place the ventilator in a place with good air flow and in a distance of at least 20 cm away from a wall, curtain, or other objects.

Appendix A Specifications

A.1 Basic Specification

Dimensions	270 mm × 162 mm × 106 mm		
Weight	1.6 kg		
Power supply	100–240 V AC, 50/60 Hz; 24 V DC		
Air outlet	22 mm conical air outlet		
Data storage	microSD card, data management software		
Degree of protection against electric shock	Class II, type BF Applied Part, the mask is applied part		
Ingress protection	IP21 – Drip-Proof, Vertical		
Work Mode	CPAP, APAP		
Sound Pressure Level	< 30 dB, when the ventilator is working at the pressure of 10 hPa (According to ISO 17510-1:2002)		
Environmental conditions	-	During usage	During transportation or storage
	Ambient temperature	5°C to 35°C	–20°C to +60°C
	Relative humidity	15%~80% (non-condensing)	10%~93% (non-condensing)
	Atmospheric pressure	86~106 kPa	50~106 kPa
Altitude compensation	Automatic altitude compensation		
Pressure compensation	Automatic air-leak pressure compensation		
Expected service life	More than 5 years		

A.2 Technical Specification

Pressure and Flow Rate

Pressure Range	4~20hPa (display resolution 0.1hPa, interval 0.2 hPa)
Pressure Measurement Tolerance	±0.5hPa or ±4% of measured value
Flow Measurement Tolerance	±5 L/min or 10% of measured value, whichever is greater
Ramp Time	0~60min, ±10%

Maximum Single Fault Steady Pressure

The pressure between the patient and the tubing is no more than 30hPa under single failure state.

Maximum Flow at Set Pressures

When the **Pressure** is set as below, the average flow from the patient connection port should be no more than the respective **Maximum Flow** as below. (The patient connection port is connected to a standard resistance with 4 mm internal diameter, 40 mm length and outlet angle of 45°.)

Pressure (hPa)	Maximum Flow (L/Min)
4	30
8	35
12	40
16	45
20	55

Maximum Dynamic Pressure Variation

CAUTION

It will increase the range of pressure if you open the **Xlief** function.

Pressure (hPa)	Maximum dynamic pressure variation (hPa)		
	10 bpm	15 bpm	20 bpm
4	≤1.2	≤1.2	≤1.3
8	≤1.3	≤1.5	≤1.7
12	≤1.3	≤1.5	≤1.7
16	≤1.3	≤1.5	≤1.7
20	≤1.3	≤1.5	≤1.7

Appendix B Terms

A	
AHI	Apnea Hypoventilation Index
APAP	Automatic Continuous Positive Airway Pressure
C	
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
E	
ETS/E-sensitivity	Expiratory Trigger Sensitivity
I	
IFR/ I-rate	Inspiratory Flow Rate
ITS/I-sensitivity	Inspiratory Trigger Sensitivity
O	
OSA	Obstructive Sleep Apnea
OSAS	Obstructive Sleep Apnea Syndrome

Appendix C EMC Requirements

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

CAUTION

- This unit has been thoroughly tested and inspected to assure proper performance and operation!
- This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

WARNING

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the Ventilator as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The CPAP Ventilator *is* intended for use in the electromagnetic environment specified below. The customer of the user of the CPAP Ventilator should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CPAP Ventilator use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The CPAP Ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The CPAP Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of CPAP Ventilator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ventilator requires continued operation during power mains interruptions, it is recommended that the Ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The CPAP Ventilator *is* intended for use in the electromagnetic environment specified below. The customer or the user of CPAP Ventilator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CPAP Ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE** 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CPAP Ventilator is used exceeds the applicable RF compliance level above, the CPAP Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CPAP Ventilator. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between

portable and mobile RF communications equipment and the Ventilator .

The CPAP Ventilator *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CPAP Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CPAP Ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D Packing List

No.	Name	Quantity
1	Host	1
2	Humidifier	1
3	Air tubing	1
4	Nasal mask	1
5	Air Filter	2
6	Power adapter	1
7	MicroSD card	1
8	Ventilator User Manual	1
9	Carrying case	1
10	Power cable	1
11	Ventilator Quick Start Guide	1
12	Ventilator Packing List	1