SUNNYGRAND

Sleep Apnoea Breathing Therapy Device

User Manual BiPAP

Before using the device, please read this manual carefully.

Preface

CE 0598

We would like to thank you for purchasing SunnyGrand's Sleep Apnoea Breathing Therapy Device.
Before using the device, please read this Manual carefully. Store this Manual properly for future reference.
Product Name: Sleep Apnoea Breathing Therapy Device
Model: NatrSleep 20S, NatrSleep 20S_Auto, NatrSleep 25S, NatrSleep 25S_Auto, NatrRes 25ST, NatrRes 25ST+, NatrRes 25V, NatrRes 25Vp, NatrRes 30ST, NatrRes 30ST+, NatrRes SVAP, NatrRes SVAP Pro, NatrRes 30V, NatrRes 30Vp, NatrRes 30 Premium
Safety Classification: Class II and type BF protection against electric shocks

Contact Information

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Date of manufacture: see the product label for details
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Website: http://www.sunnygrand.com

Quality Guarantee

Thank you for choosing our device. This device is under warranty from the date of sale.
It is necessary for the user to fill out a device warranty card when purchasing the device. Warranty service is available to the user only after this warranty card is provided.
In the device warranty period, where the device is installed and used in accordance with this Manual, under normal environment and conditions of use, the user can enjoy a free warranty service due to the failure of raw materials or processing. The warranty period is described below.

- Host: 2-year warranty available
- Humidifier (water chamber & humidifier cover): 1-year warranty available

The following conditions are not covered by the warranty.

- Device failure caused by users not operating in accordance with the requirements for use. For example, water, dust, and foreign objects in the host.
- Torn or damaged label on the device.
- Damage caused by non-compliance of device installation with the requirements, standards and related specifications of the device.
- Damage caused by non-compliance of related accessories with the requirements, standards and related specifications of the device in the environment where the device is installed.
- Damage caused by improper use and storage, or unauthorized disassembly and maintenance of the device.
- Damage caused by natural disasters (such as earthquake, flood, and lightning strike), external disasters (such as fire, and house collapse), etc.
- Failure or damage caused by improper storage.

For special needs (such as maintenance or connection to other devices), please contact us directly if you request us to provide circuit diagrams and a list of elements and components of the device. We will provide technical information such as circuit diagrams in part or in full upon your request.

Copyright

All information in this Manual does not constitute a warranty of any kind, express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Every effort has been made in the preparation of this Manual to ensure the accuracy of its contents. However, SunnyGrand assumes no liability or responsibility for any errors or omissions in the contents of this document and reserves the right to improve any devices to enhance device reliability, functionality, or design.

Declaration

The version of this Manual is 1.0. The date of preparation/revision is 2023-11-10. This Manual is subject to appropriate modifications without notice, and SunnyGrand reserves the right of its final interpretation. The images provided in this Manual are for reference only, and shall prevail in kind. Do not use them for other purposes.

The Company is only responsible for the normal operation of the device, and does not make any commitment to the diagnosis of the user's condition. Please consult your clinician and read this Manual thoroughly before using this device.

SunnyGrand shall be responsible for the safety, reliability, and performance of the device only when all the following conditions are met:

- The assembly, re-commissioning, extension, modification, and repair of the device are performed by the authorized personnel of SunnyGrand.
- The device is operated based on this Manual.
- The electrical devices comply with applicable standards.

The Company is not responsible for any personal injuries or other damages caused by the user's violation of the above requirements in the course of use.

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Terms

AHI	Apnoea–Hypopnoea Index
AI	Number of apnoea per hour during sleep.
Apnoea	The loss of respiratory airflow that occurs for more than 10 seconds while the patient is asleep is called apnoea.
APAP	Automatic Continuous Positive Airway Pressure
ASV	Adaptive Support Ventilation
ASV Pro	Adaptive Support Ventilation Pro
CPAP	Continuous Positive Airway Pressure
CSA	Central Sleep Apnoea
EPAP	Expiratory pressure
MSA	Mixed Sleep Apnoea
IPAP	Inspiratory pressure
OSA	Obstructive Sleep Apnoea
OSAS	Obstructive Sleep Apnoea Syndrome
P95	When a user is treated with the device, its pressure value is below a certain pressure value for 95% of the operating time. This pressure value is known as P95, which is usually considered to be the appropriate therapeutic pressure.
PS	Pressure Support
RR	Respiratory Rate
S	Spontaneous

Terms

S-Auto	Spontaneous-Auto
SPC	Smart Pressure Control
S/T	Spontaneous/ Timed
SVAPS	Smart Volume-assured Pressure Support
T	Timed

1 Overview

This chapter focuses on the intended purpose, contraindications, working principle, and safety information of Sleep Apnoea Breathing Therapy Device. Before use, please read this chapter carefully and follow the precautions and safety information described below to ensure proper use of this device.

1.1 Intended Purpose

This product is indicated for the treatment and titration of patients with obstructive sleep apnoea (OSA), respiratory insufficiency, central sleep apnoea (CSA), mixed sleep apnoea (MSA), or periodic breathing, but not for life support. S, S/T, T and SPC modes are indicated for patients weighing over 30 lbs (13 kg); And the other modes are indicated for patients weighing over 66 lbs (30 kg).

NOTE

- In this Manual, "user" refers to the operator who operates this device, and "patient" refers to the person receiving treatment.
- This device is portable and can be used by patients at home. However, patients must complete the setting of therapeutic parameters under the guidance of a clinician before using this device at home.
- The clinical manifestations of obstructive sleep apnoea syndrome (OSAS) mainly include snoring, daytime somnolence, apnoea during sleep, increased nocturia, headache, and other systemic complications.

1.1.1 Intended Environment

This device is used in professional healthcare facility and home environment.

1.1.2 Intended Population

Adult.

1.2 Contraindications and Side Effects

1.2.1 Contraindications

- Patients with chronic heart failure (NYHA 2-4) and patients with moderate to severe central sleep apnoea who have reduced left ventricular ejection fraction (LVEF ≤ 45%) cannot be treated in ASV mode.

- Patients with acute decompensated heart failure (ADHF) and patients with moderate to severe central sleep apnoea who have reduced left ventricular ejection fraction (LVEF ≤ 45%) cannot be treated in ASV mode.

Positive airway pressure therapy is contraindicated in patients with the following conditions.

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

1.2.2 Side Effects

If the patient feels abnormal chest pain, severe headache or dyspnea, report it immediately to the clinician. Acute upper airway infections may require temporary discontinuation of therapy.

The following side effects may occur during treatment with this device.

- Drying and irritation of the nose, mouth or throat
- Nosebleed
- Bloating
- Ear or sinus discomfort
- Eye irritation
- Skin rashes
- Insomnia
- Claustrophobia
- Discomfort breathing

1.3 Device Description

1.3.1 Model Information

NOTE

- Considering that the device interface cannot display the complete names for all modes, the interface is not displayed with BPAP, but only abbreviated with T, S, S/T, and S-Auto.
- All pressure is tested under STPD (standard temperature and pressure dry, pressure of 101.325 kPa at an oper-

ating temperature of 20℃) conditions.

The information for each model of Sleep Apnoea Breathing Therapy Device is shown in Table 1-1.

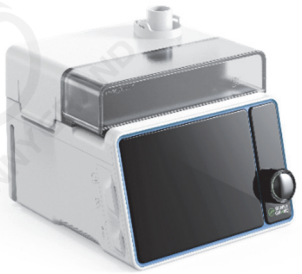
Table 1-1 Model Information

Model	Treatment Mode	Pressure Range (cmH2O)
NatrSleep 20S	CPAP,S	(2~20) cmH_2O
NatrSleep 20S_Auto	CPAP,S, S-Auto	(2~20) cmH_2O
NatrSleep 25S	CPAP,S	(2~25) cmH_2O
NatrSleep 25S_Auto	CPAP,S, S-Auto	(2~25) cmH_2O
NatrRes 25ST	CPAP,S, S/T	(2~25) cmH_2O
NatrRes 25ST+	CPAP,S, S/T, T	(2~25) cmH_2O
NatrRes 25V	CPAP, ASV	(2~25) cmH_2O
NatrRes 25Vp	CPAP, ASV, ASV Pro	(2~25) cmH_2O
NatrRes 30ST	CPAP,S, S/T	(2~30) cmH_2O
NatrRes 30ST+	CPAP,S, S/T, T	(2~30) cmH_2O
NatrRes SVAP	CPAP, S, S/T, T, SPC, SVAPS	(2~25) cmH_2O
NatrRes SVAP Pro	CPAP, S, S/T, T, SPC, SVAPS	(2~30) cmH_2O
NatrRes 30V	CPAP, ASV	(2~30) cmH_2O
NatrRes 30Vp	CPAP, ASV, ASV Pro	(2~30) cmH_2O
NatrRes 30 Premium	CPAP, APAP, S, S/T, T, S-Auto, ASV, ASV Pro, SPC, SVAPS	(2~30) cmH_2O

1.3.2 Model Differences

The differences in models of Sleep Apnoea Breathing Therapy Device are shown in Table 1-2.

Table 1-2 Model Differences

Model	Color of Front Shell Decorative Frame	Illustration
• NatrSleep 20S • NatrSleep 20S_Auto • NatrSleep 25S • NatrSleep 25S_Auto	Blue	
• NatrRes 25ST • NatrRes 25ST+ • NatrRes 25V • NatrRes 25Vp • NatrRes SVAP • NatrRes SVAP Pro • NatrRes 30ST • NatrRes 30ST+ • NatrRes 30V • NatrRes 30Vp • NatrRes 30 Premium	Gold	

1.3.3 Mode Description

The treatment modes of Sleep Apnoea Breathing Therapy Device are described in Table 1-3.

Table 1-3 Mode Description

Treatment Mode	Instruction
CPAP	The device delivers air at a fixed pressure.

1 Overview

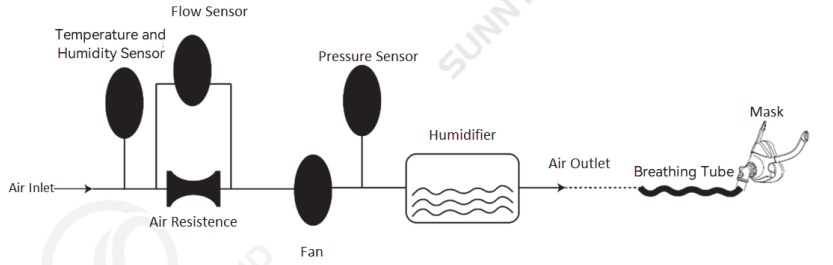
Treatment Mode	Instruction
APAP	The device outputs at the set minimum pressure. Throughout the sleep interval, the device makes smart pressure adjustments between the minimum and maximum pressures based on the patient's respiratory events (such as snoring, obstructive apnoea, restricted airflow, and other common sleep syndromes).
S	Bi-level continuous positive airway pressure with self-triggering. The device provides constant inspiratory and expiratory pressures, and the operating frequency is controlled by the patient's breathing.
S-Auto	Fully automated bi-level continuous positive airway pressure. Throughout the sleep interval, the device makes automatic adjustments to inspiratory and expiratory pressures based on the patient's respiratory events (such as snoring, obstructive apnoea, restricted airflow, and other common sleep syndromes).
T	Bi-level continuous positive airway pressure with timed triggering. The device can provide constant inspiratory and expiratory pressures, and the operating frequency is controlled by the respiratory rate set on the device.
S/T	Bi-level continuous positive airway pressure with self-triggering/time control. When the patient's spontaneous respiratory rate is higher than the set value of the device, the device operates in S mode; And when the patient's spontaneous respiratory rate is lower than the set value of the device, the device operates in T mode.
ASV	Used for the treatment of central sleep apnoea and/or mixed apnoea, and periodic breathing. In ASV mode, the clinician adjusts expiratory positive airway pressure to maintain an unobstructed upper airway. And the minimum and maximum pressures limit the support range of automatically adjusted pressures.
ASV Pro	Used for the treatment of central sleep apnoea and/or mixed apnoea, and periodic breathing. In ASV Pro mode, the device automatically adjusts expiratory pressure (EPAP). This allows the device to maintain an unobstructed upper airway within the range of minimum and maximum expiratory pressure settings. And the minimum and maximum support pressures limit the support range of automatically adjusted pressures.

Treatment Mode	Instruction
SPC	Inspiratory time is preset in SPC mode. There is no spontaneous/flow circulation. When the respiratory rate is higher than the preset value, the patient can trigger inspiration, or time-triggered inspiration at an alternate respiratory rate.
SVAPS	Ventilates with a fixed tidal volume. The device automatically adjusts pressure, and provides a smart alternate respiratory rate. This allows for maintaining the target tidal volume preset, which meets the value of the target tidal volume.

1.4 Working Principle

It consists of a fan, control circuits, sensors, an airflow output duct, and a mask. According to the presetting, the device continuously outputs airflow with a certain level of positive pressure flow, and applies airflow to the patient's upper airway through the tube and mask. This keeps the patient's upper airway open and unobstructed by positive pressure airflow, eliminating sleep snoring, hypopnoea and sleep apnoea. Figure 1-1.

Figure 1-1 Working Principle Diagram



Too low a pressure set can affect the effectiveness of the treatment. However, too high a pressure can make the patient feel uncomfortable. Therefore, before using the device, the patient needs to undergo a pressure titration in the hospital, where a clinician provides a report on the pressure used and adjusts the pressure for the patient.

The Sleep Apnoea Breathing Therapy Device is integrated with a humidifier. This increases the temperature and humidity of the breathed air, thus preventing the nasal mucosa from drying out and ensuring patient comfort.

The Sleep Apnoea Breathing Therapy Device can be operated through the display screen or control buttons with touch functionality. This allows users to adjust a range of functions of the device.

1.5 Safety Information

1.5.1 Warning

A warning indicates that users shall follow the instructions below the symbol. Otherwise, it may cause injury to the user or operator. Please read all the contents of this guide before using the device.

WARNING

- This device is not suitable for patient's requiring continuous ventilator support.
- Do not add any attachments or accessories to the humidifier that are not listed in the manual of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.
- The humidifier shall not be used with nitric oxide. Such use might cause the humidifier to not function correctly causing serious deterioration of health.
- Use of the humidifier with a gas source that heats the gas provided to the humidifier above a temperature of 41°C can result in impaired humidification output with the potential to cause severe deterioration of health.
- Do not use this device in environments with flammable gases or in oxygen-enriched environments. The device shall be operated at least 1 m from the oxygen source.
- Humidification increases the resistance of the respiratory system filters, so the operator must frequently monitor the respiratory system filters for increased resistance and blockage. This ensures the delivery of therapeutic pressure.
- Incorrect use of masks or accessories may increase the concentration of carbon dioxide to a critical value, resulting in asphyxiation in patients who are not breathing spontaneously.
- If you feel uncomfortable when in contact with the device, stop using the device and contact your supplier immediately. Since the discomfort may cause allergies.
- Do not open or modify the device as there are no user-serviceable parts in the device. The device shall be repaired and serviced only by a service provider authorized by SunnyGrand.
- It is recommended to use this device in conjunction with the breathing tube and mask from SunnyGrand. The use of different types of breathing tubes may affect the actual therapeutic pressure you receive, and change the device.
- Make sure the power cord and plug are in good condition and the device is not damaged.

- Keep the power cord away from hot surfaces.
- Tidy up the breathing tube, and make sure it cannot get tangled around the head or neck of patient.
- If the device has obvious external defects or abnormal performance, do not use it and contact the agent or manufacturer immediately.
- Non-use of SunnyGrand's water chamber may change the performance of the device.
- Do not use the humidifier at altitudes above 2000 meters or at temperatures other than 15℃ ~ 35℃. Since the use of the humidifier outside of this temperature range or above this altitude may affect the quality of treatment or harm the patient.
- To prevent disconnection of tube or tube system during use, especially during gas flow service, only tubes conforming to ISO 5367 or ISO 80601-2-74 can be used.
- Do not place the device in a position inaccessible for operation. Place the device near a power socket and out of the way of any objects. This allows you to easily unplug the device when you need it.
- Do not cover the breathing tube with a blanket. Covering the breathing tube with a blanket may prevent the breathing tube from dissipating heat and increase the temperature of the breathing tube. This may eventually cause the gas to overheat, and harm the patient or affect the effectiveness of the treatment.
- Only use the accessories showed in Appendix D.
- Be careful of electric shock. Do not immerse this device, power supply or power cord in water.
- If any liquid gets onto the surface or inside of the device, unplug the device immediately and dry the water-soaked parts of the device.
- Always unplug the device before cleaning; Make sure all parts are dry before finishing cleaning and plugging the device back in.
- Do not use supplemental oxygen supply while smoking or in the presence of an open flame.
- Always make sure this device is turned on and generating airflow before turning on the oxygen supply.
- Exposure to electrocautery, electrosurgery, defibrillation, X-rays (γ-rays), infrared radiation, and transient electromagnetic fields (including magnetic resonance imaging (MRI) and radio interference) may adversely affect the overall system performance of the device.
- The Health Industry Manufacturers Association (HIMA) recommends a distance of at least 16 cm between the mobile device and the pacemaker. This avoids possible interference with the pacemaker.
- This device uses magnets for its humidifier. To avoid possible effects of localized magnetic fields, the humidifier must be kept at least 6 inches (15 centimeters) away from implanted medical devices, and the magnetic field strength of the active medical implant must be less than 400 mT.

1.5.2 Caution

Caution indicates that the user should follow the instructions below the symbol to avoid possible damage to the device.

CAUTION

- Do not obstruct the gas flow area of the device. This avoids adverse effects on its operation or performance.
  Example 1: do not place the device next to curtains that block the flow of cooling air, which may cause the device to overheat.
  Example 2: do not block the gas inlet, which may interfere with the treatment.
- Make sure the system settings are correct. Since incorrect system settings may result in incorrect pressure readings.
- Do not place the device where it can be easily bumped or tripped over by the power cord.
- Do not place the device higher than the patient's lying height when using the device. If the device is above the patient's lying height, vapor condensation from the device may enter the patient's nose or mouth, posing a risk of asphyxiation.
- The equipment must not be covered or-positioned in such a way that the operation or performance of the equipment is adversely affected.
  Example 1: the air outlet of the device should be positioned lower than the height of the tube and mask to prevent water from entering the tube.
  Example 2: the air inlet and outlet of the device should not be blocked by sheets, curtains, or other objects.
- Before connecting the device, make sure that the power supply is stable and meets the requirements of the device.
- Keep a certain distance from this device when using communication devices, electromechanical devices or MRI devices. Otherwise, it may cause interference with this device.
- Do not dissemble or repair the device without authorization. Contact your device supplier if the device is damaged.
- Do not expose the host to water or to high temperature and high humidity.
- Disconnect the power cord when the device is not in use.

- To avoid unacceptable compromise of the basic safety and performance of the device in a home healthcare environment, keep cords, dust, smoke, and light (sunlight) away from this device, as well as keep the device out of the reach of children, pets, or pests.
- Irregular sleeping habits, alcohol consumption, obesity, and use of hypnotics or sedatives may exacerbate the patient's symptoms.
- The humidifier shall be emptied of water during handling and storage. Otherwise, the water in the humidifier may flow backward into the host of the device, which may damage the motor.
- For proper and safe use, the air inlet of the device shall not be covered, blocked or contaminated.
- Do not use cleaning supplies such as bleach, chlorine, alcohol with a concentration of 80% or more, aromatic solution, antibacterial soap or scented oil to clean the host, humidifier or breathing tube. These cleaning supplies may damage the device and shorten its service life.
- Make sure that the device is waterproofed and transported in a carrying case if used outdoors.
- Be careful not to exceed the maximum water level when adding water. This prevents too much water from getting inside the device and thus damaging the motor.
- Only connect or separate the humidifier when there is no water in the humidifier. When separating the humidifier, pay attention to the humidifier temperature for overheating. It is recommended that cooling the heating plate for 15 minutes before separating the humidifier.
- Do not operate the device in an aircraft. Otherwise, water may enter the host and breathing tube during turbulence.
- If liquid is spilled inside parts other than the humidifier, unplug the device and separate the humidifier. Leave the device to dry before using it again.
- If the power supply of the device is suddenly interrupted during treatment, the device automatically enables the power failure alarm, and the internal speaker emits a "clang- clang- clang" warning for more than 10 seconds. The device stops alerting when power supply is restored.
- The breathing tube shall be a standard 22 mm/15 mm tube.
- The device must be unplugged when not in use.

1.5.3 Note

Note indicates to follow the instructions below the symbol. The symbol highlights important information about an operating procedure that requires special attention.

1 Overview

NOTE

- Before the patient uses the device, the responsible healthcare provider shall check the compatibility of the device and all parts and accessories to be connected to the patient. In addition, the responsible healthcare provider shall ensure that therapeutic pressure settings are individually determined for the patient based on the configuration of the device used, including the accessories.
- Place the mask properly. Proper placement of the mask is critical to the continued operation of this device.
- Regularly reassess the effectiveness of the treatment settings.
- The device can work immediately after taken out of an environment with lower/higher operating temperature.
- Under normal or single fault conditions, accessories may be contaminated and need to be cleaned before use.
- The gas temperature measured at the patient connection port is the reference for displaying the measured temperature of the delivered gas.
- This device does not require battery replacement.
- The following parameters are estimates provided by Sleep Apnoea Breathing Therapy Device, and are not diagnostic parameters
  - Device apnoea (A_{flow}):
  - Device hypopnoea (H_{flow}); and
  - Device apnoea hypopnoea index (AHI_{flow}).

  Apnoea and hypopnoea measured hourly during the day. Apnoea is defined as a reduction in respiratory flow of 75% or more for at least 10 seconds. Hypopnoea is defined as a reduction in respiratory flow to 50% for at least 10 seconds. Apnoea index (AI) and apnoea-hypopnoea index (AHI) are calculated by dividing the total number of events occurring by the total treatment time with the mask enabled (in hours).
- Under the specified operating conditions, the expected operating time for humidifier refills is 12 hours.
- The information about wavelength range and maximum optical output power of the sensor is useful to the clinician for some therapy, for example, photodynamic therapy.
- The maximum optical output power of the sensor is lower than 15mW.
- Make sure you have a good understanding of all aspects of the product and get the maximum benefit during using this product.
- If you experience any physical abnormality, such as chest discomfort, shortness of breath, or severe headache, during the use of the device, stop using it immediately and inform your clinician.
- If skin irritation or breakage occurs as a result of using the mask, please refer to the mask instructions for appro-

priate action.

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and your competent authority.

1.6 Symbol

The following symbols are used in this Manual to indicate danger or information requiring special attention.

Symbol	Meaning
 WARNING	General warning sign Follow the instructions below the symbol to avoid injury to the user or operator.
	Caution Follow the instructions below the symbol to avoid possible damage to the device.
NOTE	NOTE Follow the instructions below the symbol, which highlights the important information of operating procedures that call for special attention.

The device may contain the following symbols:

Symbol	Meaning
	General warning sign
	Caution
	Manufacturer
EC REP	Authorized representative in the European Community/ European Union
SN	Serial number
	Country of manufacture and date of manufacture

1 Overview

Symbol	Meaning
	Non-sterile
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	This is the correct upright position of the distribution packages for transport and/or storage.
UDI	Unique device identifier
MD	Medical device
CE 0598	CE marking, indicates that the device conforms to general safety and performance requirements of the Regulation (EU) 2017/745.
#	Model number
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment).
IP22	IP protection class.
	The humidifier is heated. Do not touch.
	Refer to instruction manual/ booklet
	Consult instructions for use or consult electronic instructions for use

Symbol	Meaning
	Use-by date
	Type BF applied part
	Non-ionizing electromagnetic radiation
	CLASS II equipment
	Batch code
	Single patient multiple use
	Indicates the entity importing the medical device into the locale

2 Installation and Configuration

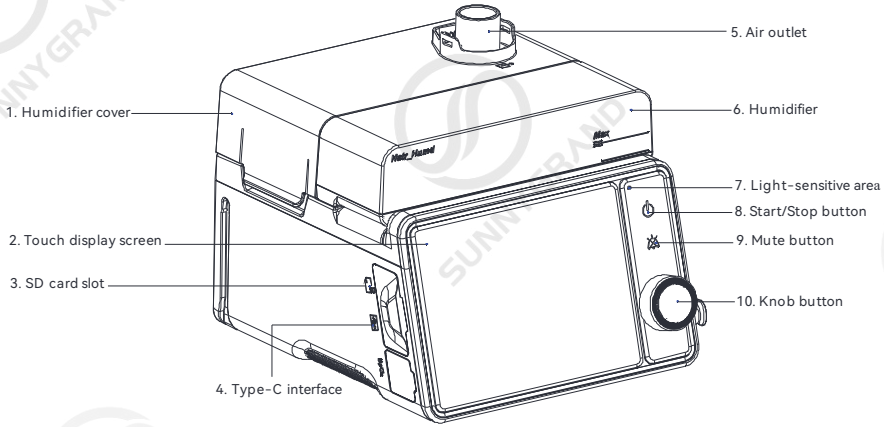
This chapter focuses on the installation and configuration of Sleep Apnoea Breathing Therapy Device. This helps users to understand this device, and to complete its installation.

2.1 Device Composition

The device consists of host, humidifier, air filter, power cord, power adapter, SD card, breathing tube (AT01, optional), heated breathing tube (AT01W, AT02W, optional), mask (AF01, AN01, AP01, optional), and trolly (AY01, optional).

2.2 Device Introduction

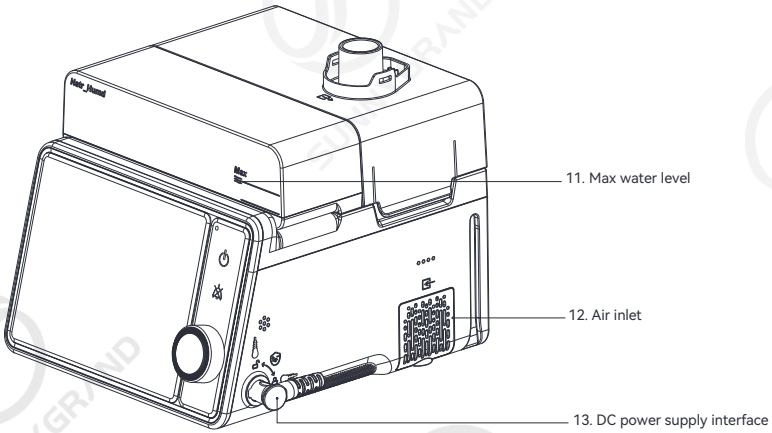
Figure 2-1 Front View of Device



S/N	Button/Module	Instruction
1	Humidifier cover	Used to secure the humidifier to avoid water or air leaks.
2	Touch display screen	Used to select and display menus, treatment information, and prompt messages. There are three kinds of operations on the display screen: tap, slide left and right, and slide up and down. ● Tap: used to select a parameter or option. ● Slide left and right: used to switch between different pages. ● Slide up and down: used to slide to select different option values, or

S/N	Button/Module	Instruction
		to increase or decrease parameter values.
3	SD card slot	Used to insert an SD card to save treatment data. The treatment data can be saved for about one year.
4	Type-C interface	For commissioning by engineers only.
5	Air outlet	Used to connect the breathing tube.
6	Humidifier	Used to store pure water and to heat and humidify the output gas.
7	Light-sensitive area	Used to monitor the light intensity in the environment. This allows the display screen to automatically adjust its brightness.
8	Start/Stop button	Used to start/stop treatment. Short press **Start Button** to start the device; Long press **Start Button** for 3s to stop the device.
9	**Mute** button	Used to temporarily mute the alarm tone.
10	**Knob** button	Used to check menu options and to confirm the option. There are two kinds of operations for **Knob** button: ● OK (press) In the parameter setting interface, press this button to select the current function. ● Rotate In the menu interface, rotate **Knob** button to select items up/down; In the parameter options, rotate **Knob** button to select different option values, or to increase or decrease the parameter values.

Figure 2-2 Right Side of Device



S/N	Interface Name	Instruction
11	Max water level	Maximum water level
12	Air inlet	Gas inlet, with a built-in air filter.
13	DC power supply interface	Used to connect the DC power adapter.

2.3 Installation

NOTE

- Only pure water can be added to the humidifier. The addition of tap or mineral water creates scale, which affects the service life of the humidifier.
- Do not add water through the air outlet of the humidifier. Since the addition of water to the air outlet of the humidifier may damage the motor of this device.
- The device enters the power-on standby state as soon as it is connected to the power supply.
- It is normal for both sides of the DC power adapter to heat up during operation.
- Place the device on a sturdy and flat surface and away from heating or cooling device (such as exhaust fans, radiators, or air conditioners). Be careful not to allow any objects to block the vent. This ensures proper air circulation through the device.

2 Installation and Configuration

- For the installation of the trolly, please refer to the corresponding manual.

Please follow the steps below to install Sleep Apnoea Breathing Therapy Device.

1. Take out the host, water chamber, humidifier cover and other related accessories from the carrying case.
2. Place the water chamber back on top of the device.
3. Pour an appropriate amount of pure water into the water chamber. Be careful not to exceed the maximum water level.
4. Place the humidifier cover, and lightly press to close the humidifier cover, which makes a "click" sound on both sides.

   NOTE

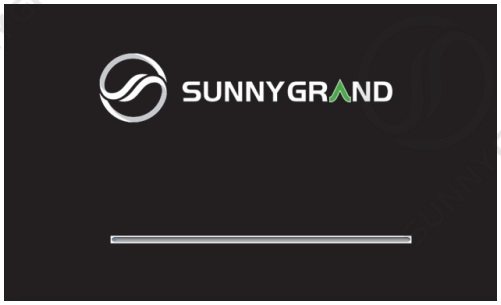
   When the water volume is insufficient, the user shall pull the concealed buckles on both sides of the top cover of the humidifier outward to take out the humidifier cover. Then, the user shall add an appropriate volume of pure water into the humidifier.

5. Install the air filter (factory-installed).
   Follow the steps below to replace the air filter.
   a. Open the air inlet.
   b. Remove the old air filter.
   c. Place the air filter into the filter cartridge cover.
   d. Insert the upper side of the filter cartridge cover into the locating hole.
   e. Lightly press the lower end, making the filter cartridge cover snap completely into place.
6. Install the SD card (factory-installed).
   Follow the steps below to replace the SD card.
   a. Open the dust cover of the SD card on the left side of the device.
   b. Lightly press the SD card to eject it from the memory card port. At this time, the SD card icon disappears from the upper right of the screen.
   c. Place the SD card with the metal sheet side facing the front of the device. Then insert it into the memory card port.
      When the SD card is inserted correctly, the SD card icon at the upper right of the screen lights up.
7. Connect the tube, and try on the mask.

a. Connect one end of the tube to the air outlet of the device, and connect the other end to the mask with the air leakage outlet.
b. Lightly fasten the mask over the nose, adjust for fit, and lightly tighten the four elastic straps until the tightness is appropriate.

8. Connect the power supply.
   a. Plug the DC power connector of the power adapter into the DC power port on the right side of the device, and rotate the DC power connector backward to lock it. Then plug the AC power connector into the AC outlet.
   b. The device performs startup initialization and startup self-test.
      After startup, the display screen is shown in Figure 2-3.

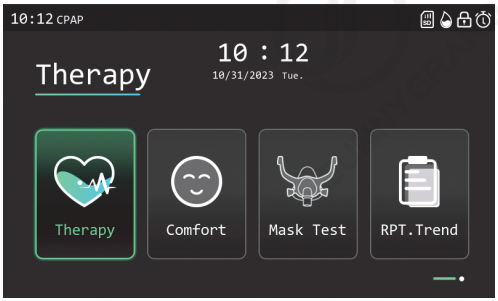
Figure 2-3 Startup Interface

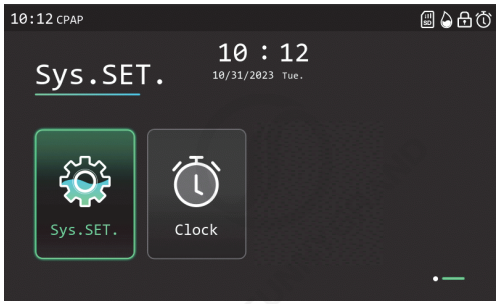


2.4 Main Interface of Device

Take model NatrRes 30 Premium for example, if the power supply is connected successfully and the device is in a normal state, the device automatically enters the main interface, as shown in Figure 2-4.

Figure 2-4 Main Interface





The interface parameters are described in the table below.

No.	Icon	Icon Meaning	Instruction
1		Therapy Interface	Displays real-time pressure and flow.
2		Comfort interface	Used to set Humidity Level, Preheating, Heated Tube (optional), Ramp Time, EPR Levels, Smart Start, Mask Type, and Tube Type.
3		Mask Test interface	Used to test mask wearing.
4		RRT. Trend interface	View historical treatment data.
5		Sys. SET. Interface	Used to set various auxiliary functions of the device.
6		Clock interface	Used to set various parameters of the clock to wake up the patient.

2.5 Description of the Icons in the Upper Right Corner of the Device

No.	Icon	Icon Meaning	Instruction
1		SD card insertion	The status of the SD card insertion. If the icon appears, it indicates that the SD card has been inserted successfully. If the icon does not appear, it indicates that no SD card has been inserted.

No.	Icon	Icon Meaning	Instruction
2		Prompt mute	The device alarm is muted. If the icon appears, it indicates that the device alarm has been muted. If the icon does not appear, it indicates that the device alarm has not been muted.
3		Clinical Settings lock/unlock	The lock status of the **Clinical Settings** interface. If the interface displays the lock icon, it indicates that the **Clinical Settings** interface is locked, and cannot be accessed for operation. If the interface displays the unlock icon, it indicates that the **Clinical Settings** interface is unlocked, and can be accessed for operation. **NOTE:** This function can only be performed by a clinician.
4		Cooling	The cooling status of the device. If the icon appears, it indicates that the device is in cooling. If the icon does not appear, it indicates that the device does not perform cooling.
5		Clock	If the clock is enabled, the clock wakes up the patient at the set time. If the icon appears, it indicates that the clock is enabled. If the icon does not appear, it indicates that the clock is disabled.
6		Humidity Levels	The installation status of the humidifier. The number in the upper right corner represents the current humidity level. If the icon appears, it indicates that the humidifier has been installed successfully. If the icon does not appear, it indicates that the humidifier has not been installed.

No.	Icon	Icon Meaning	Instruction
7		Ramp Time	Used to set the time to perform therapeutic pressure. After the ramp time has been set, the device outputs a start pressure, and then slowly ramps up the pressure to therapeutic pressure at the preset ramp time. This helps the patient to fall asleep. If the icon appears, it indicates that the ramp time function is enabled. If the icon does not appear, it indicates that the ramp time function is disabled. **NOTE:** The value to the right of the icon represents the remaining ramp time, which changes automatically during treatment.
8		Preheating	Used to set the humidifier preheating. If the icon appears, it indicates that the preheating function is enabled. If the icon does not appear, it indicates that the preheating function is disabled. **NOTE:** If the device is connected to a heated breathing tube, the system also preheats the tube according to the current preset tube temperature.
9		Heated Tube	The connection status of the heated breathing tube. If the icon appears, it indicates that the heated breathing tube is connected successfully. If the icon does not appear, it indicates that the heated breathing tube is not connected.

3 Parameter Settings

This chapter focuses on how to set the parameters of the software interface.

NOTE

- The parameters in the **Comfort** settings interface can be set by users. While the advanced settings (that is, **Clinical Set**) must be set by or under the supervision of a clinician.
- This Manual recommends the method of operating the device by touching the display screen. Users can choose the appropriate operation method according to the actual situation and personal habits.
- The following parameter settings are for the **Touch Display Screen** operation. Users can also use **OK** (by pressing **Knob** button) + **Rotate Clockwise** or **Select Counterclockwise** + **OK** (by pressing **Knob** button). This enables the same operation.

3.1 Comfort

3.1.1 Ramp Time Setting

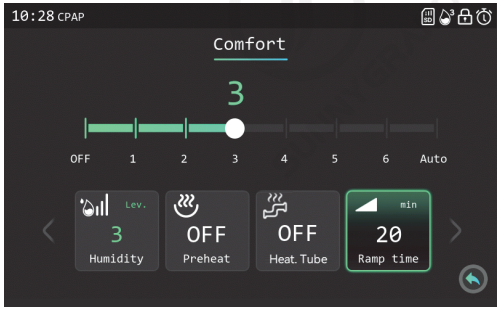
To increase treatment comfort, users can set **Ramp Time**. After the ramp time is enabled, the device outputs a start pressure, and then slowly ramps up the pressure to therapeutic pressure at the preset ramp time. This helps the patient to fall asleep.

NOTE

If the user set **Ramp Time** to **Auto**, the device automatically recognizes the patient's sleep state based on the patient's sleep condition, and performs a ramp automatically after the patient falls asleep. This improves the patient's comfort.

1. Tap **Comfort** > **Ramp Time** to enter **Ramp Time** setting interface. As shown in Figure 3-1.

Figure 3-1 Ramp Time Setting Interface



2. At the upper part of the interface, slide **Adjust Slider** left and right to set **Ramp Time**.

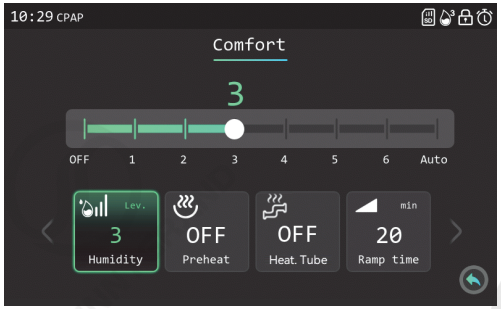
3.1.2 Humidity Levels Setting

3.1.2.1 Setting Humidity Levels

To increase treatment comfort, users can set **Humidity Levels**.

1. Tap **Comfort** > **Humidity** to enter **Humidity** setting interface. As shown in Figure 3-2.

   Figure 3-2 Humidity Setting Interface



2. At the upper part of the interface, slide **Adjust Slider** left and right to set **Humidity Levels**.

   The **Humidity Levels** can be set before or during treatment. The options include **OFF**, Levels **1** to **6**, and **AUTO**.

   The default is Level **3**.

   The temperature ranges of the humidity levels corresponding to the heated base plate is as follows.

   ➢ Level 1: 30℃ ± 5℃

- Level 2: 37℃ ± 5℃
- Level 3: 44℃ ± 5℃
- Level 4: 49℃ ± 5℃
- Level 5: 56℃ ± 5℃
- Level 6: 60℃ ± 5℃
- Auto: the device automatically calculates and outputs the most appropriate end humidity control (70%~75%) based on the current ambient temperature and humidity, while minimizing the generation of condensation.

3.1.2.2 Stopping Heating or Cooling

Slide the **Adjust Slider** of the **Humidity Levels** to **OFF** to stop heating.

NOTE

- Do not add tap water to the humidifier as it can lead to the accumulation of scale at the bottom, reducing heating efficiency and compromising comfort. Instead, follow the operation instructions provided above the upper cover of the humidifier and use pure water for optimal performance.
- In the morning, check the groove of the tube for condensed water droplets. A small quantity of droplets indicates the set humidity is appropriate. If there are numerous water droplets in the tube and mask, it suggests the humidity is too high and should be reduced. Conversely, if the patient's nose feels dry, it indicates the humidity is too low and should be increased.
- Ensure to empty the humidifier and wipe it clean to maintain a dry and hygienic condition when the device is not in use.
- For daily usage of the device, it is advised to replace the water in the humidifier every day and maintain its cleanliness.

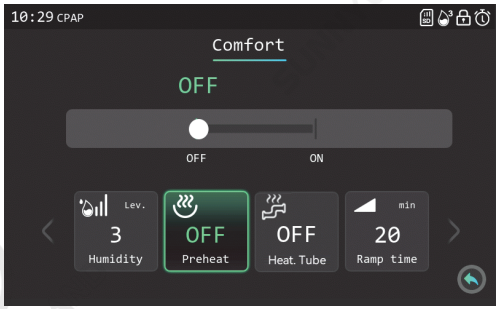
3.1.3 Preheating Setting

The user can set the preheating status.

1. Before setting, make sure that the water chamber is placed correctly. Otherwise, you will be unable to adjust the humidity level or access the preheating function.

2. Tap **Comfort** > **Preheat** to enter the setting interface of **Preheating**. See Figure 3-3. This function is **OFF** by default.

Figure 3-3 Preheating Setting Interface



3. To activate the preheating function, simply Tap **ON** option located in the upper part.

NOTE

- The **Preheating** function can only be activated when the **Humidity Levels** is not set to **OFF**. If the user does not initiate preheating, the device automatically heats and humidifies based on the **Humidity Levels** throughout the treatment process.
- The target temperature of preheating aligns with the currently set humidity level.
- Once the preheating is activated, if the treatment is not initiated within 30 minutes, the device automatically stops the preheating process and enters the cooling state. However, if the treatment is started during preheating, the preheating function automatically switches off, and the display appears gray and non-adjustable.
- When the preheating is active, tapping this button disables the preheating function. If the preheating duration exceeds 2 minutes, a cooling prompt box appears, and the cooling period is restricted to 15 minutes. If the preheating duration is less than 2 minutes, the device automatically enters the standby state.

3.1.4 Expiratory Pressure Release Levels Setting

NOTE

The **EPR Lev.** setting is only supported in CAPA and APAP modes.

The user can set the **Expiratory Pressure Release Levels.**

1. Tap **Comfort** > > **EPR Lev.** to enter the **Expiratory Pressure Release Levels** interface. See Figure 3-4.

Figure 3-4 EPR Levels Setting Interface

1. At the upper part of the interface, slide **Adjust Slider** left and right to set **Expiratory Pressure Release Levels.** This function is **OFF** by default.
   The device automatically detects the patient's respiratory rate and decreases the pressure in the mask during expiration to enhance patient comfort. The larger the value, the greater the pressure release intensity.

NOTE

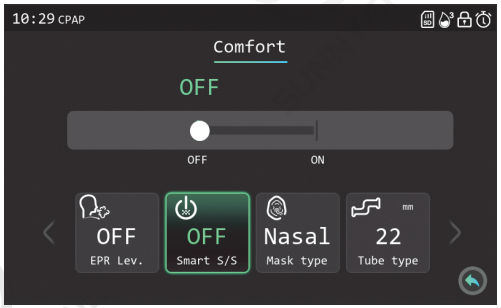
- With the **Expiratory Pressure Release Levels** is activated, the minimum pressure value of **Expiratory Pressure Release Levels** intensity can only reach 4 cmH_2O/hPa. When the set pressure is 4 cmH_2O/hPa and the **Expiratory Pressure Release Levels** is set to 1/2/3, the expiratory pressure release intensity remains at 4 cmH_2O/hPa. However, if the set pressure is 6 cmH_2O/hPa and the **Expiratory Pressure Release Levels** is set to 1/2/3, the expiratory pressure release intensity is 5/4/4 cmH_2O/hPa respectively, and so forth.
- The activation of **Expiratory Pressure Release Levels** may have a slight impact on the efficacy of ventilation therapy, such as potentially causing higher AHI values. If the patient encounters difficulty or extreme discomfort during exhalation while using the device, or if there is resistance towards the expiratory pressure release function, it is advised to deactivate the **Expiratory Pressure Release Levels** and switch to continuous positive airway pressure (CPAP) therapy.

3.1.5 Smart Start Setting

The user can set the **Smart Start** status. Once the **Smart Start** function is enabled, the device automatically enters the treatment state once the patient wears the mask for several cycles of moderate breathing. Additionally, the device can recognize when the mask detaches and automatically stops the treatment. Once the **Smart Start** function is deactivated, you can only control the treatment by pressing the manual start/stop button to turn it on or off.

1. Tap **Comfort** > > **Smart S/S** to enter the **Smart S/S** setting interface. See Figure 3-5.

Figure 3-5 Smart Start Setting Interface



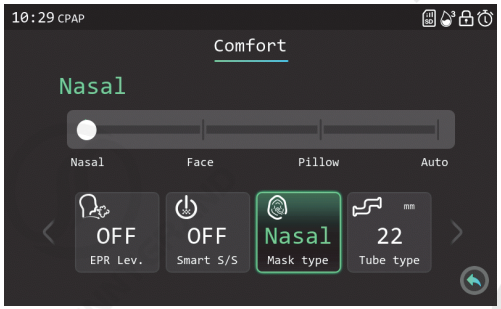
2. To activate/deactivate the **Smart Start** function, tap **ON/OFF**.

3.1.6 Mask Type Setting

The user can set the mask type.

1. Tap **Comfort** > > **Mask Type** to enter the **Mask Type** setting interface. See Figure 3-6.

Figure 3-6 Mask Type Setting Interface



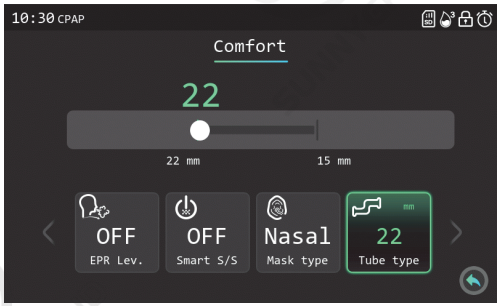
2. At the upper part of the interface, slide **Adjust Slider** left and right to set **Mask Type**.
   Choose the mask type based on the type of the mask actually used, with the default set to **Nasal**.

3.1.7 Tube Type Setting

The user can set the tube type.

1. Tap **Comfort** > > **Tube Type** to enter the **Tube Type** setting interface. See Figure 3-7.

Figure 3-7 Tube Type Setting Interface



2. At the upper part of the interface, slide **Adjust Slider** left and right to switch the **Tube Type**. The default setting is **22 mm**.

3.1.8 Heated Tube Setting

NOTE

The **Heated Tube** in the interface refers to the heated breathing tube.

After the heated breathing tube is connected, the user can set the temperature of the heated breathing tube.

1. Tap **Comfort** > > **Heat. Tube** to enter the setting interface of **Heated Tube**. See Figure 3-8.

Figure 3-8 Heated Tube Setting Interface

2. At the upper part of the interface, slide **Adjust Slider** left and right to set the type of heated breathing tube.

The options for the heated breathing tube are:

- ✧ **OFF** (default)
- ✧ 16℃-34℃
- ✧ **AUTO**

3.2 Mask Test

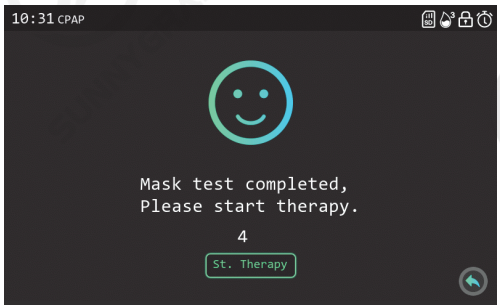
The mask fitting test primarily assesses the user's mask fit, wearing posture and recording the tightness of the mask straps. This helps to ensure that the mask can be easily worn without the need to readjust the straps for subsequent use. The user can perform the mask fitting test.

1. To access the **Mask Test** interface, tap **Mask Test** option in the main interface. See Figure 3-9.

Figure 3-9 Mask Test Interface

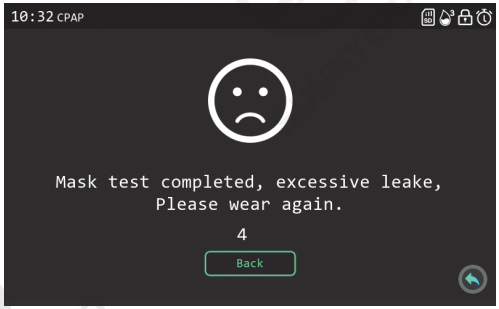
2. To carry out the mask fitting test, tap **St. Mask Tst.** in the **Mask Test** interface.
   - ➢ Upon successful completion of the mask test, the interface is displayed as shown in Figure 3-10.

Figure 3-10 Mask Test Success Interface



➢ When the mask test fails, the interface is displayed as shown in Figure 3-11.

Figure 3-11 Mask Test Failure Interface



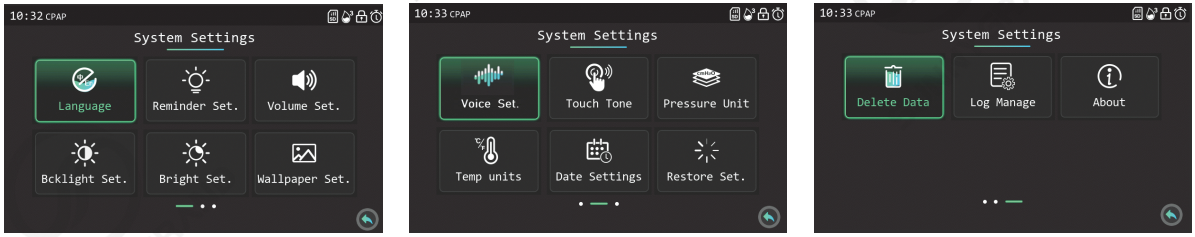
3.3 System Settings

3.3.1 Setting Description

The user can configure relevant options in the **System Settings** based on the patient's usage habits.

1. Tap **Sys. SET** option on the main interface to access the **System Settings** interface, as shown in Figure 3-12.

Figure 3-12 System Settings Interface



2. Refer to Table 3-1 for setting of relevant parameters.

Table 3-1 Details of Parameter Setting on System Settings Interface

S/N	Option	Definition	Setting Description
1	Language	Set the language of the system.	Options: English, Chinese, Turkish Default: English
2	Reminder Set.	In the upper right corner of the interface, you can select **Clinical**	Options: Clinical Reminder and Consumable Reminder

S/N	Option	Definition	Setting Description
		Reminder and **Consumable Reminder**.	Default: Clinical Reminder **NOTE:** Please refer to ***3.3.2 Clinical Reminder*** and ***3.3.3 Consumable Reminder*** for detailed operations of Clinical and Accessory
3	Volume Set.	Adjust the device volume.	Options: high, medium, and low Default: Medium
4	Backlitght Set.	Screen off switch: when set to **Auto**, the device automatically enters a black screen state after 30 seconds of inactivity.	Options: automatic and normally open Default: Auto
5	Bright Set.	Adjust the brightness of the display screen. When set to **Auto**, the screen brightness is automatically adjusted based on the current ambient brightness.	Options: auto, high, medium, and low Default: Medium
6	Wallpaper Set.	When the wallpaper switch is set to **ON**, the device automatically enters the wallpaper interface after 30 seconds of inactivity.	Options: ON/OFF Default: ON
7	Voice Set. (optional)	Voice function switch: when set to **ON**, voice interaction can be enabled with the device.	Options: ON/OFF Default: ON
8	Touch Tone	Touch Tone Switch: when set to **ON**, the device provides sound feedback as the user slides the option on the touch screen up and down.	Options: ON/OFF Default: ON

S/N	Option	Definition	Setting Description
9	Pressure Unit	Different pressure units are available for selection.	Options: cmH_2O and hPa Default: cmH_2O
10	Temp Units	Different temperature units are available for selection.	Options: ℃ and ℉ Default: ℃
11	Date Settings	Set the current date and time of the device. Format: YYYY-MM-DD hh-mm. For example, 2017-01-01 10:30.	YYYY: year, such as 2017 MM: month, e.g. 01 DD: date, e.g. 01 hh: hour, e.g. 10 mm: minute, e.g. 30
12	Restore Set.	Restore the device to factory settings.	Options: Yes/No Default: No
13	Delete Data	Delete the patient's sleep quality and sleep report data.	Options: Yes/No Default: No **NOTE:** When the memory card is inserted in the device, exercise caution while deleting data, as this action will result in the removal of all data stored on the memory card.
14	Log Manage	The log stores relevant records of various error prompts that occur during device operation. ● Operating data Show the running time and power-on time of the device. ● System log (number of logs) It is utilized to record the log related to clinical re-	Not configurable. **NOTE:** The maximum capacity of the log is 50 logs. When the logs reache the maximum capacity, the oldest log will be deleted.

S/N	Option	Definition	Setting Description
		minders when the device is in use.	
15	About	Display relevant information of the device.	You can view the device model, serial number, software version and other relevant information.

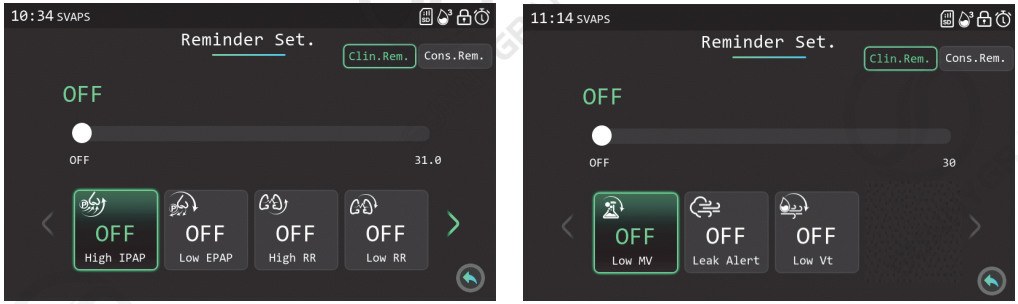
3.3.2 Clinical Reminder

NOTE

CPAP and **APAP** modes only support the setting of **Leak**.

1. Tap **Sys. SET** > **Reminder Set.** to enter the setting interface of **Clinical Reminder** See Figure 3-13.

Figure 3-13 Clinical Reminder Setting Interface



2. Refer to Table 3-2for setting of relevant parameters.

Table 3-2 Details of Parameter Setting on Clinical Reminder Interface

S/N	Option	Definition	Setting Description
1	High IPAP	The actual IPAP is higher than the set value during normal operation.	Options: OFF and 5.0 cmH_2O~31.0 cmH_2O Interval: 0.2 cmH_2O Default: OFF
2	Low EPAP	The actual EPAP is lower than the set value during normal operation.	Options: OFF and 1.0 cmH_2O~26.0 cmH_2O Interval: 0.2 cmH_2O Default: OFF

S/N	Option	Definition	Setting Description
3	High RR	The actual respiratory rate is greater than the set value.	Options: OFF and 5 times/min~60 times/min Interval: 1 time/min Default: OFF
4	Low RR	The actual respiratory rate is lower than the set value.	Options: OFF and 5 times/min~50 times/min Interval: 1 time/min Default: OFF
5	Low MV	The actual minute ventilation is lower than the set value.	Options: OFF and 1 L/min~30 L/min Interval: 1 L/min Default: OFF
6	Leak Alert	During normal operation, a significant amount of air leakage may occur due to reasons such as mask detachment and other factors.	Options: ● ON: the corresponding prompt box pops up on the screen. ● OFF: no prompt. Default: OFF **NOTE:** When both the Smart Start and Leak features are activated simultaneously, if there is a significant amount of air leakage in the device, the device will automatically stop, and the system will not display a Leak pop-up window. However, when only the Smart Start is disabled, and there is substantial air leakage in the device, the system will display a Leak pop-up window.
7	Low VT	The actual tidal volume is lower than the set value.	Options: OFF and 20 mL~4000 mL Interval: 10 mL Default: OFF

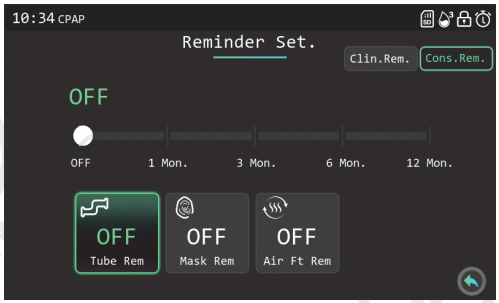
3. Once the configuration is completed, the system will give a reminder or alarm based on the user's settings.

For more information about alarms, see ***9 Alarms and Solutions***

3.3.3 Consumable Reminder

1. To enter the setting interface of **Consumable Reminder**, tap **Sys. SET** > **Reminder Set.** > **Cons. Rem**. See Figure 3-14.

Figure 3-14 Consumable Reminder Setting Interface



2. Refer to Table 3-3 for setting of relevant parameters.

Table 3-3 Details of Parameter Setting on Consumable Reminder Interface

Parameter	Setting Description	Remind Pop-up Window
Tube	The user receives a reminder to contact the device supplier for the time of tube replacement Options: OFF/1 month/3 months/6 months/12 months Default: OFF **NOTE:** ● The tube has a shelf life of 2 years. ● It is recommended to replace the tube every 6 months from the date of first use. ● Refer to this Manual for the shelf life of tube.	

3 Parameter Settings

Parameter	Setting Description	Remind Pop-up Window
Mask	The user receives a reminder to contact the device supplier for the time of mask replacement Options: OFF/1 month/3 months/6 months/12 months Default: OFF **NOTE:** ● The mask has a shelf life of 2 years. ● It is recommended to replace the mask every 6 months from the date of first use. ● Refer to this Manual for the shelf life of mask.	
AirFilter	The user receives a reminder to contact the device supplier for the time of air filter replacement Options: OFF/1 month/3 months/6 months/12 months Default: OFF **NOTE:** The air filter of the device cannot be washed and should be replaced every 3~6 months. Please contact the device supplier to purchase a replacement after use.	

When the **Consumable** pop-up window appears, tapping **Close** button in the upper right corner of the pop-up window indicates that the reminder is ignored. The **Consumable** pop-up window will continue to appear the next time the device is used. If the accessory has been replaced, tap **OK**, and the device will provide a reminder in the next set cycle.

3.4 Clock

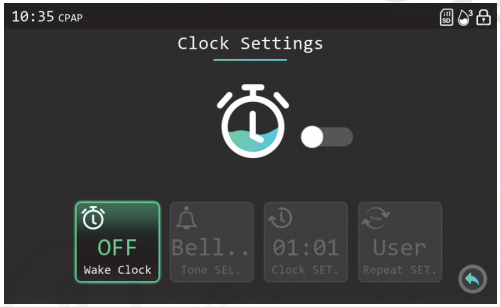
NOTE

- When the user does not set the clock's schedule and only sets the alarm within the valid time of the day, the clock will respond once, and the **Wake Clock** feature will be automatically deactivated after the clock is turned off.
- Once the clock rings, tap **Close** to close it. Tap **Rem in 5min** The clock is closed and will ring again in 5 minutes.
- If no option is selected when the clock rings, it will automatically turn off after 3 minutes of ringing and then ring again after 5 minutes. It will not repeat the above schedule more than 3 times.
- When the user sets the schedule of the clock, it will cycle based on the corresponding date schedule that has been set.

The user can make relevant settings in the clock selection according to the patient's timetable.

1. Tap **Clock** on the main interface to enter the **Clock** interface. See Figure 3-15.

Figure 3-15 Clock Setting Interface



2. Refer to Table 3-4 for setting of relevant parameters.

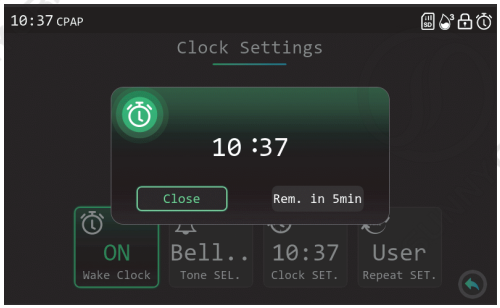
Table 3-4 Details of Parameter Setting on Clock Setting Interface

Option	Definition	Setting Description
Wake Clock	You can activate or deactivate the clock here. When it is set to **ON**, other clock settings can be adjusted.	Options: ON/OFF Default: OFF

Option	Definition	Setting Description
Tone SEL.	You can set the bell sound here.	Options: Bell Sound 1/Bell Sound 2 Default: Bell Sound 1
Clock SET.	You can configure the time for the clock alarms here.	Options: 00:00~23:59
Repeat SET.	You can set the schedule of the clock based on a weekly schedule.	Options: Monday to Sunday

3. After setting, once the **Clock** is activated and the set time is reached, the bell sound will go off and display a **Remind**, as depicted in Figure 3-16.

Figure 3-16 Clock Reminder Pop-up Window



4 Daily Use

This chapter mainly introduces the daily use of the device. Users can utilize the methods presented here for treatment or access information on the patient's sleep quality, sleep report, and device details after using the device.

4.1 Treatment Steps

WARNING

Do not repair or maintain the device in use.

CAUTION

- Always ensure that the air outlet of the device is positioned lower than the height of the tube and mask to prevent water from entering the tube.
- Ensure that the air inlet and outlet of the device are not blocked by sheets, curtains, or other objects.
- Ensure that the tube is not covered by sheets or affected by heating sources (such as electric blankets) for fear of hazards caused by tube deformation.

NOTE

- Check whether the tube is damaged or has any foreign matters before each use. If any, clean or replace the tube.
- The device can only be used after the therapeutic parameters, including detailed treatment settings, Ramp Time, and Hum. Lev., are set by or under the guidance of a clinician.
- In the event of a power outage or device failure, please remove the mask to avoid re-inhaling the exhaled gas.
- In the event of a power outage, the device will automatically shut down. Once the power is restored, the device will automatically start and return to the startup interface (Figure 2-3).
- When the ambient temperature is 20℃, it takes 24 hours for this device to reach its intended operating condition from the maximum or minimum storage temperature after use.

1. Connect the device following the instructions in ***2.3 Installation***.
2. Have the patient lie on the bed and adjust the tube. Ensure that the tube remains unrestricted and can move freely even when the patient is asleep and turning over.
3. Once the patient wears the mask, adjust its tightness until it fits properly, and there is no air leakage during breathing.
4. Press **Start/Stop** button to start treatment.

If the **Smart Start** feature is enabled, the patient can take 3~4 deep breaths after wearing the mask, and the device will automatically start the treatment process. See ***3.1.5 Smart Start Setting*** for details.

5. To enhance the patient's comfort during breathing, adjust the Hum. Lev. accordingly.
   For instructions on how to adjust the Hum. Lev., please refer to "3.1.2 Humidity Levels Setting".
6. Press **Start/Stop** button to stop the treatment after use.
   After stopping the treatment, the device ceases heating and initiates the cooling process. The cooling process ends in about 15 minutes.
7. Remove the mask, unplug the power cord and power off the device.

4.2 Report Viewing

4.2.1 Data Report Viewing

1. Tap **RPT. Trend,** the system enters the **Data Report** interface by default. Users can view the sleep report within a certain period on the **Data Report** interface. See Figure 4-1.

Figure 4-1 Data Report Interface

2. For details on the parameters displayed on the **Data Report** interface, please refer to Table 4-1.

Table 4-1 Details of Parameters on Data Report Interface

Parameter	Description
Period	You can view the sleep reports of a specific period. The options are **Today**, **This Week**, **1 Month**, **3 Months**, **6 Months**, and **1 Year**.
Days of use	The total number of days treated with the device during the sleep reporting period is recorded here.

Parameter	Description
Day > 4hrs	The number of days with the device used for more than 4 hours during the sleep reporting period is recorded here.
Avg. Use Time	The average number of hours of device usage for treatment of patient per day during the sleep reporting period is recorded here.
Avg. Leak	The average air leakage of treatment with the device per day during the sleep reporting period is recorded here.
AI	Today's apnoea index during the sleep reporting period is recorded here.
AHI	Today's apnoea index + hypopnoea index during the sleep reporting period is recorded here.
Avg. AI	The average value of the apnoea index per day during the sleep reporting period is recorded here. **NOTE:** This information is only displayed in the **This Week**, **1 Month**, **3 Months**, **6 Months**, and **1 Year** interfaces.
Avg. AHI	The average of apnoea index + hypopnoea index per day of the patient during the sleep reporting period is recorded here. **NOTE:** This information is only displayed in the **This Week**, **1 Month**, **3 Months**, **6 Months**, and **1 Year** interfaces.
Avg. Press.	The average IPAP during the sleep reporting period is recorded here.
IPAP P95	The P95 pressure value during the sleep reporting period is recorded here. The 95th percentile with the treatment pressure of the device sorted from small to large after usage of the device. **NOTE:** This parameter is valid only when the device has been used for more than 4 hours.

4.2.2 Viewing AHI Trend Chart

NOTE

The **AHI Trend Chart** can only be viewed under **This Week**, **1 Month**, **3 Months**, **6 Months** or **1 Year**.

Tap **RPT. Trend** > **AHI Trn.** to view the **AHI Trend Chart**. See Figure 4-2.

Figure 4-2 AHI Trn. Interface

4.2.3 Viewing P95 Trend Chart

NOTE

- The **P95 Tre.** can be viewed only under APAP, ASV, ASV Pro, S-Auto, and SVAPS.
- The **P95 Tre.** can only be viewed when the period is **This Week**, **1 Month**, **3 Months**, **6 Months** or **1 Year**.

Tap **RPT. Trend** > **P95 Tre.** to view the **P95 Trend Chart**. See Figure 4-3.

Figure 4-3 P95 Trend Interface

5 Cleaning and Maintenance

Clean the device and its accessories regularly during their daily use to prevent respiratory infection. Clean and maintain the device according to the instructions in this chapter.

WARNING

- Before cleaning, make sure to disconnect the power plug.
- Follow the manufacturer's instructions to clean the mask and tubes, and determine the cleaning cycle.
- Do not repair or maintain the device in use.

CAUTION

- Do not use abrasive cleaners, alcohol with a concentration of more than 80%, chlorine-containing substances, acetone, or other solvents to clean the device and its accessories.
- Do not wipe with hot boiled water. Excessive heating of the material may lead to premature aging of the material.
- After cleaning with detergent, thoroughly rinse all accessories and components of the humidified part in clean water; then dry all parts with a lint-free cloth to prevent any calcareous deposits from accumulating.

5.1 Device Cleaning

CAUTION

- When cleaning the host, only wipe the periphery of the connecting socket, avoiding its inside.
- After cleaning, the detergent should be removed and should not remain on the surface.
- When cleaning the display screen and enclosure of host, noncorrosive detergent should be used.
- Most detergents must be diluted before use.
- Do not use abrasive materials for cleaning.

Device Components/Accessories	Detergent	Frequency	Process
Host	Neutral detergent	Before and after use, at least 2 times per day	1. Before cleaning the device, the host power must be turned off and the AC power must be disconnected. 2. Soak a soft and clean lint-free cloth in warm water or neutral detergent. 3. Wipe the front panel and enclosure of the host. 4. After cleaning the host, dry it with a piece of clean and dry soft cloth. 5. After wiping, place it in a ventilated and clean environment for air drying, but do not expose it to the sun.
Water chamber	Neutral detergent	● Once every 7 days ● Before and after replacing patients.	1. Remove the water chamber from the host every 7 days or before and after patient replacement. 2. Soak the water chamber in warm water or neutral detergent, and clean it with a soft and clean lint-free cloth. After cleaning with detergent, rinse at least three times with clean water for 5 minutes to ensure no residual detergent. 3. After cleaning, wipe it with a piece of clean and dry soft cloth. 4. After wiping, dry it in a ventilated environment, but avoid exposure to the sun.

5.2 Device Transfer

For hygiene reasons, if the device is handed over to another patient for use, parts in contact with this patient, such as the mask, water chamber, tubes, and air filter cartridges, should be replaced with new ones.

After the transfer, please complete the setting of therapeutic parameters under the guidance of a clinician before use.

6 Travelling with the Device

NOTE

- Ensure that the area you are traveling to is equipped with a power cord suitable for your device.
- Before traveling, make sure to check the type of power socket available in your travel area. If necessary, please carry the socket converter.

To carry this device while traveling, please follow the steps below for packing.

1. Remove the water chamber and empty all the water from it.
2. Use a lint-free cloth to dry the device and let it air dry.
3. After confirming that the device has been dried, pack the device and accessories into a carrying case.

7 Service and Maintenance

NOTE

The patient is responsible for maintaining and servicing the Sleep Apnoea Breathing Therapy Device.

Please perform the following checks each time you use the device to ensure it operates normally:

- Are the tube and mask properly sealed?
- Does therapeutic pressure develop? Is the display functioning normally?
- Is the water in the humidifier heated?

If the Sleep Apnoea Breathing Therapy Device malfunctions or if unexpected operations or events occur, please contact SunnyGrand or the device supplier for assistance. Repairs can only be performed by authorized engineers.

By correctly following the instructions for installation, cleaning, and maintenance of the Sleep Apnoea Breathing Therapy Device, you can extend the device's service life and receive free maintenance during the warranty period.

8 Disposal

8 Disposal

Do not dispose of the product in the household waste. Consult an authorized, certified electronic waste recycling company for proper disposal. You can find out their address from your environmental officer or from your local council.

The device packaging (cardboard box and inserts) can be disposed of as waste paper.

9 Alarms and Solutions

This chapter mainly describes the potential alarm messages and their corresponding solutions.

9.1 Alarm Classification and Description

9.1.1 Alarm Classification

The alarm classification and description of the device are listed in Table 9-1.

Table 9-1 Alarm Classification

Alarm Priority	Classification Symbol	Description
High	! ! !	The user should promptly address the issue that triggered the alarm.
Medium	! !	The user can address the issue that triggered the alarm after completing simple operations.
Low	!	The user should remain vigilant as the device status changes.

9.1.2 Details of Alarm Messages

Alarms are triggered when the device malfunctions during operation.

The table below lists the possible alarm messages of the device along with their corresponding causes and solutions. If the problem still exists after using the method provided in Table 9-2, please contact the clinician or device supplier for further assistance.

CAUTION

Against setting alarm limits to extreme values that can render the ALARM SYSTEM useless

9 Alarms and Solutions

NOTE

- If the problem triggering the alarm is not solved, the high-priority alarm pop-up window will reappear after 2 seconds of being cleared, and the low-priority alarm pop-up window will reappear after 6 seconds of being cleared.
- Only the **Pressure Sensor Fault**, **Power Outage**, and **Air Leakage** alarms are triggered in CPAP mode and APAP mode.
- On average, the alarm signal is generated with a delay of 5 breathing cycles.

Table 9-2 Details of Alarm Messages

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
/	Pressure sensor fault	High	Within 10s	The alarm sound of "Beep-Beep ... Beep-Beep" sounds, accompanied by the red pop-up indicator flashing, and the alarm lasts for at least 30s.	The pressure sensor fault may occur if the air pressure port is blocked or the sensor connecting line is disconnected.	Please contact the device supplier.

9 Alarms and Solutions

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
	Hot heating plate	High	Within 10s	The alarm sound of "Beep-Beep ... Beep-Beep" sounds, accompanied by the red pop-up indicator flashing, and the alarm lasts for at least 30s.	The heating plate fails.	Please contact the device supplier.

9 Alarms and Solutions

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
/	Power outage	Medium	Immediately	The alarm sound of a simple "Beep" sound without a pop-up indicator, and the alarm lasts for at least 10s	There is a power outage during the treatment process.	The alarm is not operable, and only the device emits a prompt tone. **NOTE:** ● This feature is enabled by default and cannot be edited by the user. ● The log is maintained when the ALARM SYSTEM is powered down and the time of powering down is captured in the log.

9 Alarms and Solutions

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
	Air leakage	Low	Within 10s	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	Air leakage occurs due to mask detachment during the normal operating process.	Check the connection status of mask or breathing tube.
	High IPAP	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	The actual IPAP is higher than the set value.	Check the breathing tube or contact the clinician to adjust parameters.
	Low RR	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	The actual respiratory rate is lower than the set value.	Check the breathing tube or contact the clinician to adjust parameters.

9 Alarms and Solutions

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
	Low EPAP	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s. **NOTE:** With the Ramp Time activated, no alarm is triggered in the process.	The actual EPAP is lower than the set value.	Check the breathing tube or contact the clinician to adjust parameters.
	High RR	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	The actual respiratory rate is greater than the set value.	Check the breathing tube or contact the clinician to adjust parameters.

Alarm Icon	Description	Alarm Priority	Delay	Prompt	Possible Cause	Solution
	Low VT	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	The actual tidal volume is lower than the set value.	Check the breathing tube or contact the clinician to adjust parameters.
	Low MV	Low	15 breathing cycles at most	The alarm sound of "Beep", accompanied by the yellow pop-up indicator lit steadily, and the alarm lasting for at least 30s.	The actual minute ventilation is lower than the set value.	Check the breathing tube or contact the clinician to adjust parameters.

9.2 Details of Alarm Sound

9.2.1 Alarm Mute

When the device triggers an alarm, you can press **Mute** button to silence the device, and it will remain muted for at least 120 seconds. If the cause of alarm has not been eliminated after the mute time expires, the alarm sound will resume ringing. If the **Mute** button is tapped again during the mute, the alarm sound will resume ringing.

9.2.2 Alarm Sound Pressure Level

9 Alarms and Solutions

The device has undergone testing in accordance with relevant standards, and the test results indicate that the volume of the audible alarm signal meets the requirements. The sound pressure range of the measured audible alarm signal is shown in Table 9-3.

Table 9-3 Alarm Sound Pressure Level

Alarm Priority	Measured Sound Pressure Level (dB)	Background Sound Pressure Level (dB)	Remarks
High	67.1	38.5	Maximum volume
Medium	63.9	38.2	Maximum volume
Low	63.9	38.2	Maximum volume

9.3 Verifying Alarms

After the device is started, the user can check whether the alarm system functions normally at any time.

9.3.1 Power Failure Alarm Test

1. Disconnect the power plug while the device is in use for treatment.
2. Check whether the device immediately triggers a power failure alarm.

9.3.2 Air Leakage Alarm Test

1. Remove the mask while the device is in use for treatment.
2. Check whether the device prompts air leakage within 10s.
3. Press **Mute** button to verify if the device is in the mute state and maintains this state for at least 120s. If the cause of alarm has not been eliminated after the mute time expires, the alarm sound will resume ringing.

Press **Knob** button to dismiss the prompt box.

10 Troubleshooting

The table below lists the possible causes and solutions of some symptoms. If these solutions do not work as expected, please contact the clinician or device supplier.

Device Failure

Symptom	Possible Cause	Solution
The area of the face in contact with the mask becomes red	● The mask pad (soft part inside the mask) becomes rigid. ● The mask is too tight ● The distance between the forehead frame of the mask and the patient's forehead is incorrect. ● The mask size does not fit properly. ● The patient is experiencing an allergic reaction to the mask material.	● Replace the mask or mask pad. ● Adjust the tightness of the mask. ● Adjust the distance. ● Contact the device supplier to choose alternative masks. ● Place some padding material between the patient's skin and the mask, and consult the clinician and device supplier. Alternatively, use a rubber-free mask.
Water enters the mask	If the humidification function is enabled, moisture condensation may occur due to the temperature difference between the tube and the ambient air.	● Reduce the humidity level of the device, or increase the ambient temperature. ● Always ensure that the air outlet of the device is positioned lower than the height of the tube and mask to prevent water from entering the tube.
The device is making excessive noise	The tubes are connected improperly	● Connect the tubes to the correct interfaces. ● Reinstall the water chamber.

10 Troubleshooting

Symptom	Possible Cause	Solution
The inhaled air is too hot	● The air inlet or air filter is blocked. ● The device is too close to the wall, curtain, or other object, causing inadequate air circulation.	● Clean or replace the air filter and clean the air inlet. ● Position the device in a well-ventilated area, maintaining a distance of at least 20 cm from walls, curtains, and other objects.

Somatosensory Issues

Symptom	Possible Cause	Solution
Dry nasal mucosa, cool sensation of nose, runny nose, nasal obstruction, and catching a cold	The nose responds to the airflow or cold. Nasal mucosa becomes dry and expanded due to rapid airflow, leading to a cool sensation in the nose.	● Increase the humidity level of the device. ● Consult a clinician. Do not interrupt the treatment process unless advised by the clinician.
Sensation of dryness in the mouth and throat	The patient experiences open mouth during sleep.	● Attach a strap under the jaw. ● Consult the clinician and consider using an oral-nasal mask.
OSA symptoms recur within the same day		
Eye irritation	● The mask is not properly fixed, leading to air leakage. ● The size or model of the mask is unsuitable.	● Reduce the distance between the forehead frame of the mask and the patient's forehead. ● Please consult the device supplier to select an alternative mask. If necessary, add additional filler to the mask.

10 Troubleshooting

Symptom	Possible Cause	Solution
Pain of nose, sinuses or ear	Nasosinusitis or otitis media	Contact the clinician immediately.
Experiencing discomfort due to the unfamiliarity with the set therapeutic pressure	The patient feels uncomfortable when the therapeutic pressure exceeds 13 cmH_2O. However, in some cases this is necessary to prevent apnoea.	It may take up to 4 weeks for pressure adaptation. Have the patient relaxed while using the device. Ask the patient to breathe through the nose and close the mouth. If the symptoms persist, please contact your clinician.

Appenidx A. Specification

NOTE

The risk class of the device is Class IIa.

A.1 Basic Indicators

Environment Conditions	/	Operating Environment	Transportation or storage Environment
	Ambient temperature	15℃~35℃	-20℃~60℃
	Relative humidity	15%~95% (non-condensing)	15%~95% (non-condensing)
	Atmospheric pressure	86 kPa~106 kPa	50 kPa~106 kPa
Dimensions	• Dimension: 188 mm (length) × 173 mm (width) × 163.5 mm (height) • Weight: approx. 1.9 kg		
AC Input	AC voltage 100~240 V, frequency 50/60 Hz, and rated power 80 W		
Power Adapter Output	DC voltage 24 V, current 3.33 A		
Running Mode	Continuous operation		
Degree of Protection Against Electric Shock	Class II, type BF applied part **NOTE:** The breathing tube, heated breathing tube and mask(s) are applied parts.		
Protection Class	IP22		
Safety Level	Sleep Apnoea Breathing Therapy Device cannot be categorized as an AP/APG device. The device shall not be used under the conditions where air mixes with flammable anaesthetic gas or where oxygen or nitrous oxide mixes with flammable anaesthetic gas.		

Appenidx A. Specification

Maximum Gas Temperature	Not exceeding 43℃
Heated Tube Temperature cutout	106℉ (41℃)
Water Chamber Capacity	300 ± 20 mL (not exceeding the max water level)
Output Humidity	The maximum humidity output is not less than 12 mgH_2O/L under the conditions of an ambient temperature of 15 ℃ to 35℃ and a relative humidity of 15%.
Tube	22 mm/15 mm taper joint, no more than 1.2 m long, with all joints suitable for the 22 mm taper air outlet.
Treatment Mode	• NatrSleep 20S_Auto: CPAP, BPAP-S, BPAP-S-Auto • NatrSleep 25S_Auto: CPAP, BPAP-S, BPAP-S-Auto • NatrSleep 20S: CPAP, BPAP-S • NatrSleep 25S: CPAP, BPAP-S • NatrRes 25ST: CPAP, BPAP-S, BPAP-ST • NatrRes 25ST+: CPAP, BPAP-S, BPAP-ST, BPAP-T • NatrRes 25V: CPAP, ASV • NatrRes 25Vp: CPAP, ASV, ASV Pro • NatrRes SVAP: CPAP, S, S/T, T, SPC, SVAPS • NatrRes 30ST: CPAP, BPAP-S, BPAP-ST • NatrRes 30ST+: CPAP, BPAP-S, BPAP-ST, BPAP-T • NatrRes 30V: CPAP, ASV • NatrRes 30Vp: CPAP, ASV, ASV Pro • NatrRes SVAP Pro: CPAP, BPAP-S, BPAP-ST, BPAP-T, SPC, SVAPS • NatrRes 30 Premium: CPAP, APAP, BPAP-S, BPAP-ST, BPAP-T, BPAP-S-Auto, ASV, ASV Pro, SPC, SVAPS
Trigger Method	Spontaneous trigger, timed trigger

Sound Pressure Level	Noise level ≤30 dB with the output pressure of the device of 10 cmH_2O
Altitude Compensation	Automatic altitude compensation
Pressure compensation	Automatic air leakage pressure compensation
Air Outlet	22 mm conical outlet
Data and Device (System) Interface	SD memory card, wireless transmission module
Data Storage	Stored in .sg data format on the SD card
Expected Service Life	5 years

NOTE

- The device remains operational and safe for the user even under extreme conditions of use, such as AC power supply voltage ranging from -15% to +10%, DC power supply voltage ranging from -15% to +25%, temperature between 35°C to 40°C, relative humidity of 10% to 15%, or atmospheric pressure ranging from 70 kPa to 86 kPa. However, extended or repeated operation of the device under such extreme conditions may lead to premature aging of components, necessitating more frequent maintenance.
- As the device reaches the end of its service life, the treatment effectiveness may decrease. Please ensure timely replacement with a new device.

A.2 Technical Indicators

Maximum Single Failure Steady-state Pressure	• CPAP and APAP modes: In the single failure state, the maximum pressure at one end of the tube connected to the patient should not exceed 30 cmH_2O. • ASV, ASV Pro, S, S/T, T, S-Auto, and SVAPS modes: In the single failure state, the maximum pressure at one end of the tube connected to the patient should not exceed 40 cmH_2O.

Appenidx A. Specification

IPAP and EPAP Difference	IPAP-EPAP ≥ 2 cmH_2O
Pressure Display Precision	± (0.4 cmH_2O + 4% actual reading).
Ramp Time	The options of Ramp Time are OFF, 5 to 45 minutes, or automatic, with an interval of 5 minutes and an error not exceeding ±5%.
Expiratory Tidal Volume	Measuring range: 0~4000 mL.
Minute Ventilation	Measuring range: 0~30 L/min.
Inspiratory/Expiratory Ratio	The inspiratory/expiratory ratio depends on the respiratory rate and inspiratory time. The available range is 1:50~2:1. **NOTE:** Applicable to T and S/T modes

Appenidx A. Specification

Pressure:

Model	Pressure Range (hPa) of CPAP and APAP Modes	Pressure Range (hPa) of S, S/T, T and SPC Modes	Pressure Range (hPa) of ASV and ASV Pro Modes	Pressure Range (hPa) of S-Auto Mode	Pressure Range (hPa) of SVAPS Mode
NatrSleep 20S_Auto	(4.0-20.0) cmH_2O	Inspiratory pressure (IPAP): 4–20 cmH_2O; Expiratory pressure (EPAP): 2–18 cmH_2O	/	PS: 0-10 cmH2O; Minimum expiratory pressure (Min EPAP): 2 cmH2O; Maximum inspiratory pressure (Max IPAP): 20 cmH_2O	/
NatrSleep 25S_Auto		IPAP: 4–25 cmH2O; EPAP: 2–23 cmH_2O	/	PS: 0-10 cmH_2O; Min EPAP: 2 cmH_2O; Max IPAP: 25 cmH_2O	/
NatrSleep 20S		IPAP: 4–20 cmH_2O; EPAP: 2–18 cmH_2O	/	/	/
NatrSleep 25S		IPAP: 4–25 cmH_2O; EPAP: 2–23	/	/	/

Appenidx A. Specification

Model	Pressure Range (hPa) of CPAP and APAP Modes	Pressure Range (hPa) of S, S/T, T and SPC Modes	Pressure Range (hPa) of ASV and ASV Pro Modes	Pressure Range (hPa) of S-Auto Mode	Pressure Range (hPa) of SVAPS Mode
		cmH_2O			
NatrRes 25ST		IPAP: 4–25 cmH2O; EPAP: 2–23 cmH_2O	/	/	/
NatrRes 25ST+		IPAP: 4–25 cmH_2O; EPAP: 2–23 cmH_2O	/	/	/
NatrRes 25V		/	Max PS: 5-20cmH_2O; Min PS: 0-6 cmH_2O; EPAP: 2–15 cmH_2O	/	/
NatrRes 25Vp		/	Max PS: 5-20cmH_2O; Min PS: 0-6 cmH_2O;	/	/
NatrRes SVAP		IPAP: 4–25 cmH_2O; EPAP: 2–23 cmH_2O	/	/	Max PS: 0-23cmH_2O; Min PS: 0-20 cmH_2O; EPAP: 2–23

Appenidx A. Specification

Model	Pressure Range (hPa) of CPAP and APAP Modes	Pressure Range (hPa) of S, S/T, T and SPC Modes	Pressure Range (hPa) of ASV and ASV Pro Modes	Pressure Range (hPa) of S-Auto Mode	Pressure Range (hPa) of SVAPS Mode
					cmH_2O
NatrRes 30ST		IPAP: 4–30 cmH2O; EPAP: 2–25 cmH_2O	/	/	/
NatrRes 30ST+		IPAP: 4–30 cmH2O; EPAP: 2–25 cmH_2O	/	/	/
NatrRes 30V		/	Max PS: 5-20cmH_2O; Min PS: 0-6 cmH_2O; EPAP: 2–15 cmH_2O	/	/
NatrRes 30Vp		/	Max PS: 5-20cmH_2O; Min PS: 0-6 cmH_2O; Max EPAP: 2 -15 cmH_2O; Min EPAP: 2 -15 cmH_2O	/	/

Appenidx A. Specification

Model	Pressure Range (hPa) of CPAP and APAP Modes	Pressure Range (hPa) of S, S/T, T and SPC Modes	Pressure Range (hPa) of ASV and ASV Pro Modes	Pressure Range (hPa) of S-Auto Mode	Pressure Range (hPa) of SVAPS Mode
NatrRes SVAP Pro		IPAP: 4–30 cmH_2O; EPAP: 2–25 cmH_2O	/	/	Max PS: 0–28 cmH_2O; Min PS: 0–20 cmH_2O; EPAP: 2–25 cmH_2O
NatrRes 30 Premium		IPAP: 4–30 cmH_2O; EPAP: 2–25 cmH_2O	Max PS: 5–20cmH_2O; Min PS: 0–6 cmH_2O; EPAP: 2–15 cmH2O	PS: 0–10 cmH_2O; Min EPAP: 2 cmH_2O; Max IPAP: 30 cmH_2O	Max PS: 0–28cmH_2O; Min PS: 0–20 cmH_2O; EPAP: 2–25 cmH_2O

NOTE

All pressure is tested under STPD (standard temperature and pressure dry, pressure of 101.325 kPa at an operating temperature of 20℃) conditions.

Interval Pressure	Pressure Error Range	Static Pressure Stability
0.2 cmH_2O	Not more than ±0.5 cmH_2O	The error range not exceeding ±0.5 cmH_2O

Bi-level positive airway pressure mode, Dynamic AIRWAY PRESSURE ACCURACY-Minimum water lever

Breath Rate	Inspiratory Pressure (cmH_2O [hPa]) (Means, Standard Deviations)				
	6	11	18	25	29
10	-0,16 / 0.24	-0,37 / 0.37	-0,38 / 0.37	-0.29 / 0.26	-0.11 / 0.37

15	-0,34 / 0.32	-0.18 / 0.31	-0.35 / 0.31	-0.26 / 0.37	-0,02 / 0.45
20	0,17 / 0.46	0,13 / 0.41	-0,08 / 0.34	-0.29 / 0.36	-0,28 / 0.36

Breath Rate	Expiratory Pressure (cmH_2O [hPa]) (Means, Standard Deviations)				
	2	7	14	21	25
10	-0.27 / 0.05	-0.04 / 0.12	0.13 / 0.14	-0.05 / 0.29	-0.02 / 0.34
15	-0.22 / 0.09	0.01 / 0.20	-0.22 / 0.16	-0.14 / 0.38	0.11 / 0.39
20	-0.04 / 0.15	-0.05 / 0.25	-0.04 / 0.25	-0.26 / 0.29	-0.29 / 0.31

Bi-level positive airway pressure mode, Dynamic AIRWAY PRESSURE ACCURACY-Maximum water lever

Breath Rate	Inspiratory Pressure (cmH_2O [hPa]) (Means, Standard Deviations)				
	6	11	18	25	29
10	-0.02 / 0.26	-0.33 / 0.38	-0.38 / 0.38	-0.27 / 0.27	-0.06 / 0.38
15	-0.17 / 0.34	-0.15 / 0.34	-0.30 / 0.33	-0.24 / 0.38	-0.02 / 0.42
20	-0.19 / 0.45	-0.12 / 0.42	-0.10 / 0.33	-0.30 / 0.35	-0.26 / 0.35

Breath Rate	Expiratory Pressure (cmH2O [hPa]) (Means, Standard Deviations)				
	2	7	14	21	25
10	-0.13 / 0.05	-0.18 / 0.20	0.14 / 0.16	-0.11 / 0.30	0.03 / 0.30
15	-0.09 / 0.11	-0.03 / 0.26	0.19 / 0.19	-0.18 / 0.37	0.12 / 0.38
20	-0.05 / 0.15	-0.16 / 0.27	-0.13 / 0.29	-0.22 / 0.31	-0.26 / 0.32

NOTE

The table above is based on the data that covers between 50 and 75% of the inspiratory phase and between 50 and 75% of the expiratory phase. The measurement uncertainty of the bi-level pressure accuracy is ≤1cmH_2O. These data time slots start immediately after the initial transient overshoot/undershoot periods and end at the point that flow diminishes to an equivalent absolute value of its starting point, towards the end of the breath phases (this corresponds to the % ranges of values given immediately above).

Appenidx A. Specification

Maximum flow under the set pressure

When the flow at pressures of P_{min}, P_{min}+1/3 (P_{max}-P_{min}), P_{min}+2/3 (P_{max}-P_{min}), and P_{max} is set to the values listed in the table below, the average flow at the patient interface should be greater than 80% of the corresponding flow value in the table.

Model	NatrSleep 20S_Auto, NatrSleep 25S_Auto, NatrSleep 20S, NatrSleep 25S, NatrRes 25V, NatrRes 25Vp, NatrRes30V, NatrRes 30Vp			
Test Mode	CPAP			
Test Pressure	4.0	9.4	14.6	20.0
Patient Interface Pressure (cmH_2O)	3.0	8.4	13.6	19.0
Average Flow of Patient Interface (L/min)	60	60	60	60
Model	NatrRes 25ST, NatrRes 25ST+, NatrRes SVAP			
Test Mode	T or ST mode			
Test Pressure	4.0	11.0	18.0	25.0
Patient Interface Pressure (cmH_2O)	3.0	10.0	17.0	24.0
Average Flow of Patient Interface (L/min)	60	60	60	60
Model	NatrRes 30ST, NatrRes 30ST+, NatrRes SVAP Pro, NatrRes 30 Premium			
Test Mode	T or ST mode			
Test Pressure	4.0	12.6	21.4	30.0

Patient Interface Pressure (cmH_2O)	3.0	11.6	20.4	29.0
Average Flow of Patient Interface (L/min)	60	60	60	60

NOTE

- The above values are measured at the end of the airway.
- CPAP and APAP: P_{max} is the maximum therapeutic pressure and P_{min} is the minimum therapeutic pressure.
- S, S/T, T and S-Auto modes: P_{max} is the maximum EPAP and P_{min} is the minimum EPAP.
- All flow is tested under STPD (standard temperature and pressure dry, pressure of 101.325 kPa at an operating temperature of 20°C) conditions.

Measurement system uncertainties

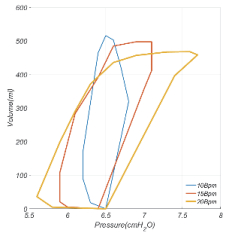
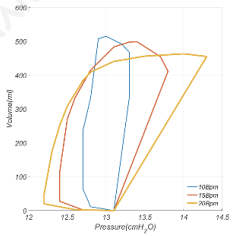
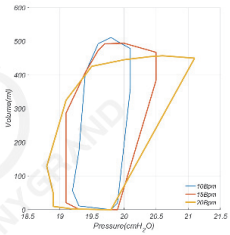
- For measures of flow: ±1.5L/min or ±2.7% of reading (whichever is greater)
- For measures of volume (< 100 mL): ±5mL or 6% of reading (whichever is greater)
- For measures of volume (≥ 100 mL): ±20mL or 3% of reading (whichever is greater)
- For measures of static pressure: ±0.15cmH_2O(hPa)
- For measures of dynamic pressure: ±0.5cmH_2O(hPa)
- For measures of time: ±10ms

Value	Range	Display Resolution	Accuracy
I:E Ratio	1:50–2:1	0.1	/
Tidal Volume	0–4000 mL	1mL	±20%
Minute Ventilation	0–30 L/min	0.1 L/min	±20%
Respiratory Rate	5-50BPM	1 BPM	±1.0 BPM

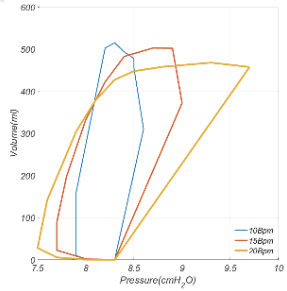
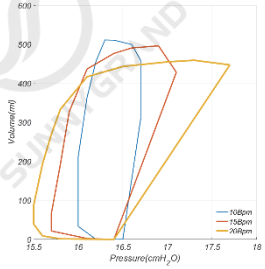
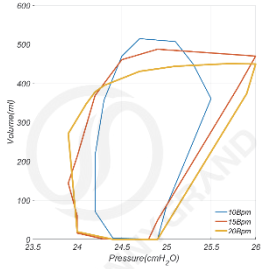
Pressure Capacity Curve

- Model: NatrSleep 20S_Auto and NatrSleep 20S

Appenidx A. Specification

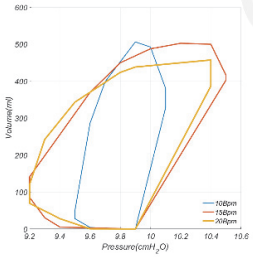
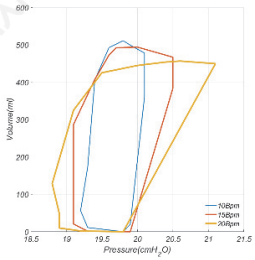
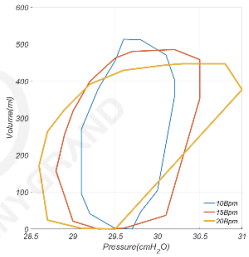
1/3 Maximum Pressure	2/3 Maximum Pressure	Maximum Pressure
		

- Model: NatrSleep 25S_Auto, NatrSleep 25S, NatrRes 25ST, NatrRes 25ST+, NatrRes 25V, NatrRes 25Vp, and NatrRes SVAP

1/3 Maximum Pressure	2/3 Maximum Pressure	Maximum Pressure
		

- Model: NatrRes 30ST, NatrRes 30ST+, NatrRes 30V, NatrRes 30Vp, NatrRes SVAP Pro, and NatrRes 30 Premium

Appenidx A. Specification

1/3 Maximum Pressure	2/3 Maximum Pressure	Maximum Pressure
		

Appenidx B. Packing List

Please refer to the packing list enclosed with the device.

Appenidx C. EMC Requirements

WARNING

- To avoid improper operation, do not use this device adjacent to or stacked with other devices. If you must use this device together with other devices, carefully observe both this device and the others to ensure they are operating properly.
- Using accessories, sensors, and cables not specified or provided by the device manufacturer can lead to increased electromagnetic radiation or reduced electromagnetic immunity of the device, resulting in improper operation.
- Keep portable RF communication devices, including peripheral devices such as antenna cables and external antennas, at a distance of no more than 30 cm (12 inches) from any part of the ME device, including cables specified by the manufacturer. Otherwise, the functionality of the device can be degraded.

Table C-1 Guidance and Manufacture's Declaration – Electromagnetic Emission

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The Sleep Apnoea Breathing Therapy Device (model: NatrSleep 20S_Auto, NatrSleep 25S_Auto, NatrSleep 20S, NatrSleep 25S, NatrRes 25ST, NatrRes 25ST+, NatrRes 25V, NatrRes 25Vp, NatrRes SVAP, NatrRes 30ST, NatrRes 30ST+, NatrRes 30V, NatrRes 30Vp, NatrRes SVAP Pro, NatrRes 30 Premium) is intended for use in the electromagnetic environment specified below. The customer or the user of the Sleep Apnoea Breathing Therapy Device should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Sleep Apnoea Breathing Therapy Device 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 Sleep Apnoea Breathing Therapy Device 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 fluctua-	Complies	

tions/ flicker emis-sions IEC 61000-3-3		

Table C-2 Guidance and manufacture's declaration – electromagnetic immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The Sleep Apnoea Breathing Therapy Device (model: NatrSleep 20S_Auto, NatrSleep 25S_Auto, NatrSleep 20S, NatrSleep 25S, NatrRes 25ST, NatrRes 25ST+, NatrRes 25V, NatrRes 25Vp, NatrRes SVAP, NatrRes 30ST, NatrRes 30ST+, NatrRes 30V, NatrRes 30Vp, NatrRes SVAP Pro, NatrRes 30 Premium) is intended for use in the electromagnetic environment specified below. The customer or the user of Sleep Apnoea Breathing Therapy Device 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sleep Apnoea Breathing Therapy Device requires continued

input lines IEC 61000-4-11	Single phase: at 0° 0 % U_T; 250/300 cycles	Single phase: at 0° 0 % U_T; 250/300 cycles	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	30 A/m	30 A/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.			

Table C-3 Guidance and Manufacture's Declaration – Electromagnetic Immunity- Non-life supporting me equipment and me systems

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 10V/m 80 MHz to 2.7 GHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Sleep Apnoea Breathing Therapy Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ 150 KHz to 80 MHz $d = 1.167\sqrt{P}$ 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 Sleep Apnoea Breathing Therapy Devices used exceeds the applicable RF compliance level above, the Sleep Apnoea Breathing Therapy Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sleep Apnoea Breathing Therapy Device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table C-4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Ventilator

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Ventilator
The Sleep Apnoea Breathing Therapy Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sleep Apnoea Breathing Therapy Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sleep Apnoea Breathing Therapy Device 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 in meters (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.

Appenidx D. Accessory

Appenidx D. Accessory

Description	Model	Type
Mask	AF01/AN01/AP01	Single patient multiple use
Breathing Tube	AT01	Single patient multiple use
Heated Breathing Tube	AT01W / AT02W	Single patient multiple use
Water Chamber	AH020	Reusable
Trolly	AY01	Reusable

Appenidx E. Names and Contents of Toxic and Harmful Substances or Elements

Part Name	Toxic and Harmful Substances or Elements					
	Plumbum (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr(VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Built-in Circuit Board	○	○	○	○	○	○
Enclosure	○	○	○	○	○	○
Display Screen	○	○	○	○	○	○
Internal Electronic Wires	○	○	○	○	○	○
Accessories	○	○	○	○	○	○

○: indicates that the content of the toxic and harmful substance in all homogeneous materials of the part is below the limit specified in the RoHS Directive 2011/65/EU.

×: indicates that the content of the toxic and harmful substance in at least one homogeneous material of the part exceeds the limit specified in the RoHS Directive 2011/65/EU.

WARRANTY STATEMENT

Thank you for choosing our device. This device is under warranty from the date of sale.

The following conditions are not covered by the warranty.

- Device failure caused by users not operating in accordance with the requirements for use. For example, water, dust, and foreign objects in the host.
- Torn or damaged label on the device.
- Damage caused by non-compliance of device installation with the requirements, standards and related specifications of the device.
- Damage caused by non-compliance of related accessories with the requirements, standards and related specifications of the device in the environment where the device is installed.
- Damage caused by improper use and storage, or unauthorized disassembly and maintenance of the device.
- Damage caused by natural disasters (such as earthquake, flood, and lightning strike), external disasters (such as fire, and house collapse), etc.
- Failure or damage caused by improper storage.

SUNNYGRAND

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E-mail: support@sunnygrand.com

Website: http://www.sunnygrand.com

WARRANTY CARD

Subpage

Device Information

Product Model _____

Product SN. _____

Sales Date _____

User Information

Contact _____

Tel. _____

E-mail _____

Address

_____

_____

Fault Description

WARRANTY CARD

Device Information

Product Model _____

Product SN. _____

Sales Date _____

User Information

Contact _____

Tel. _____

E-mail _____

Address

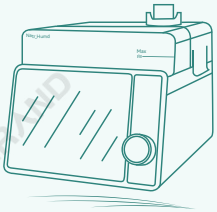
_____

_____

Distributor Information

Company _____

Tel. _____



SUNNYGRAND

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