Instructions for use of positive pressure ventilation treatment

About this manual

The manual mainly introduces the installation and application method of postive airway pressure device .Users should read carefully before application (include warnings, contraindications and notes).

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Version Information

This manual may upgrade due to software upgrading. User will not be notified further.

- Version: A/0
- Issue date: Feb. 2023

Software version:V1

Note: This is a generic version of the manual, which contains the positive pressure ventilation machine and oximeter
A certified wireless module is built into the positive pressure ventilator, which has a label artwork that shows "contains FCC ID: 2AHMR-ESP32-S".

Table of Content

1 Safety

1.1 Purpose

Suitable for patients weighing above 30kg. Suitable for patients with obstructive sleep apnea hypopnea syndrome; double level positive pressure therapy is also used for the treatment of sleep apnea with chronic obstructive pulmonary disease (COPD) and obesity hypoventilation syndrome (OHS). None of these equipment is available for life support. Could not be used for the treatment of central sleep apnea. But it needs to be used under the guidance of a professional doctor.

This product can not be used in a magnetic resonance (MRI) environment.

1.2 Safety information

This manual always uses the following safety symbols that the user should be familiar with and their meaning before operating the instrument.

⚠ warn:

Warning signs indicate potentially dangerous or unsafe operations. Failure to properly execute or comply may result in death, serious personal injury, or property damage. The warning sign shall not be crossed until the conditions specified are not fully understood and satisfied.

⚠ pay attention to:

Attention signs emphasize precautions, provide operational information that the user should know or additional guidance for better use of the product.

⚠ warn:

Need to be used under the guidance of a professional doctor.

Must be performed according to the IFU.

The use guidelines in this manual do not replace the existing medical regimen.

This equipment is only used by trained personnel.

This equipment is intended for adult use only.

This equipment is a non-life support equipment.

Who connects the additional devices to the input / output signal port and is responsible for the system compliance with GB9706.1 standards.

The two TYPE C interfaces of this machine are not USB interfaces and cannot be connected to USB devices. They are only used to connect to the special accessories provided by the company.

Do not wear a mask when the positive pressure ventilator is not opened, otherwise there is a risk of suffocation.

Do not wear the mask when the positive pressure ventilator is not opened and is not working properly to avoid the risk of suffocation.

The exhaust port of the mask should not be blocked. This positive pressure ventilation machine requires a specially designed mask with a vent or connector to exhaust the mask. When the equipment is turned on normally, fresh air from the positive pressure ventilation therapy machine blows the exhaled gas from the mask through the exhaust hole. But when positive pressure ventilation does not work, enough fresh air cannot be provided through the mask.

In order to minimize the possibility of repeated carbon dioxide (CO2) inhalation, patients should pay attention to the following: use the heating line and mask provided by the positive pressure ventilation machine; do not wear a mask for a long time when the equipment stops working; must use a vent mask with vent, do not block or try to block the vent on the mask.

Do not plug the air intake, which will prevent treatment

If you use a full face mask (which covers your mouth and nose), the mask must have a safety (clip) valve.

When using oxygen, the distance between the equipment and the oxygen source should be more than 1 meter, to avoid causing fire and burns.

Do not use the machine close to the toxic gas or harmful gas source accessories.

Humidifier humidification increases the resistance of respiratory filters, and the user must frequently monitor the increased resistance and blockage of respiratory filters to ensure normal pressure delivery.

Do not use the device at room temperature exceeds 35 C (95 F). At room temperature exceeding 35 C (95 F), the pipe air temperature may exceed 43 C (109 F), causing irritation or injury to the respiratory tract.

The humidifier can only add distilled water at room temperature.

When the humidification function is enabled, make sure that there is water in the water tank.

Do not touch the heating plate when the humidifier is heated.

The temperature of the heating disk reaches 90 ± 10℃. The temperature protection switch disconnects the heating power supply, the temperature of the heating plate drops to 60 ± 10℃, and the temperature protection switch is restored.

To avoid condensation of the pipeline gas into water, the heating line provided by the

treatment machine must be used.

The use of supporting heating lines and humidifiers and accessories provided by the Company creates unpredictable risks.

At low pressure, with most double-level positive pressure ventilation therapy devices, some exhaled gas (CO2) remains in the mask and is being repeatedly inhaled.

This device is not suitable for use in the case of combustible anesthetic gas mixed with oxygen, air or nitrogen oxides.

Do not use the equipment in the polluted environment;

Use the specified detergent / disinfectant when cleaning / disinfecting the machine or parts.

To prevent electric shock, always disconnect the power supply before cleaning the equipment. Do not soak the equipment in any liquid.

If sleep apnea reappears, contact the attending physician.

In case of accident during normal use, the equipment shall be stopped immediately and appropriate emergency and corrective measures shall be taken.

The pressure sensor fault prompt, must be repaired before use.

The equipment fails and must be repaired before use.

If there is any abnormal operation of the machine, such as: abnormal sound, drop, abnormal handling, machine water intake, machine shell rupture, please disconnect the power supply, stop using the machine, and contact your supplier.

Repair, service and maintenance shall be performed by the manufacturer or technicians specifically authorized by the manufacturer. Unauthorized maintenance of the machine may lead to personal injury, failure of warranty clauses, or damage to valuable parts.

The equipment shall not be used close or stacked with other equipment with the same or similar working frequency. If it must be used close or stacked, it shall be observed to verify that it can operate normally under the configuration used.

Please use the accessories and power cables specified by the Company, other accessories and power cables may cause the increased radiation or decreased immunity of the equipment.

The power plug of the device cannot be touched after 30 seconds without plugging the power cord.

Even if the other equipment meets the launch requirements of the corresponding national standards, the equipment may still be disturbed by the other equipment.

Do not place the device and its accessories in the MR environment because it may

pose an unacceptable risk to the patient, causing damage to the device or the MR equipment. The equipment and its accessories have not been safely tested in the MR environment.

Never use the equipment and its accessories in the environment with electromagnetic equipment, including: computer tomography (CT scanner), electrotherthermia machine, RFID equipment and electromagnetic safety system (metal detector), because this may cause unacceptable risk to patients or cause damage to the equipment. Some electromagnetic sources may not be obvious, if you notice any unexplained changes in the performance of the device, if the device makes special or harsh sounds, immediately disconnect the power and stop using it. Please contact your home care service provider.

Portable and mobile RF communication equipment may affect the use of this equipment. When using this equipment normally, it is recommended to stay away from portable and mobile RF communication equipment.

The Health Industry Manufacturers Association recommends that the distance between a mobile device and the pacemaker be at least 16 cm to avoid possible interference to the pacemaker.

Do not operate and use the positive pressure machine to avoid personal injury and electric shock risk;

Do not place the positive pressure ventilator directly on the carpet, fabric or other flammable items;

Do not immerse the host equipment in water or let any liquid into the machine;

Keep away from any heating or cooling device, such as radiator, air conditioning, indoor vent, etc., so as not to increase the temperature of gas produced by the equipment;

Do not carry out any maintenance and disassembly when the equipment is running;

Do not place the equipment inside or above any container that can cause vapor condensation.

Equipment shall not be covered or placed where operation or performance will be adversely affected.

The type-c interface provided by this equipment is only applicable to the corresponding accessories provided by the supplier and can not be connected to other equipment.

Failure to use a mask or accessory that reduces repeated carbon dioxide inhalation or allows spontaneous breathing may cause suffocation.

Ensure that the lines are properly connected before use and avoid neck circling risks resulting from the use of breathing lines and hoses.

Do not stretch the tube breathing tube, which may cause an air leak.

If the machine has multiple users, use a low resistance, bacterial filter between the mask and the line to prevent contamination.

The equipment has no alarm function, not applicable for alarm.

If the user needs a TF card, please contact the company to purchase, otherwise it may cause the device can not operate normally.

When handling the equipment, please empty the water in the water tank.

⚠ pay attention to:

Tobacco smoke can accumulate in the device, causing work abnormalities.

The device must maintain a safe distance from the high frequency radiation source (e. g., mobile phone), otherwise it will cause device dysfunction.

If using a TF card, make sure that the TF card is properly inserted into the device before the device is powered on.

To avoid damaging the TF card or causing the loss of record data, ensure to remove or load the TF card.

Prevent pipe twisting or knotting to facilitate smooth air output.

Prevent power cord damage during use.

To ensure safe use, remove the socket of the power cord from the home power outlet before removing the power adapter.

Check whether the power adapter, power cord and each interface are in good condition regularly. If signs of damage are found, replace it immediately to ensure your safe use of the equipment.

Use in combination with other medical devices may alter the performance of the device (e. g., use in combination with humidifiers, filters, respiratory system filters, or exhaust ends).

Line head, dust, light (including sunlight, but not exposed to the sun), etc., will not affect the equipment.

Avoid contact with equipment and pets, pests, or children.

Condensation can damage the equipment. If the device is exposed to an extremely hot or cold temperature, the device should be adjusted to room temperature (operating temperature) before starting treatment. Do not use this device in a temperature environment outside the operating temperature range indicated in the parameters.

Confirm that the equipment filter is not blocked by bed sheets, curtains or other objects, and the air must be able to flow in and out from the equipment freely to ensure the normal operation of the equipment.

When the equipment output gas is abnormal, please check whether the inlet is blocked.

Do not place the equipment directly on carpets, fabrics, or other flammable materials.

Do not place the equipment in or on the container containing the water.

The filter must be kept in good condition and installed in place.

Cigarette smoke can cause smoke accumulation in the machine, which causes the machine to work properly.

The dirty filters may increase the operating temperature and thus affect the equipment performance. Check the filters regularly to ensure their complete cleaning as required.

Before use, ensure that the power cord is firmly installed to your treatment device. Please confirm with your supplier or our company that your power cord matches your equipment.

If the DC comes from the car battery, do not use the device when the car engine is working. Otherwise, the equipment will be damaged.

This equipment can only be placed in a plane with a tilt angle less than 20°.

The user should not pull the power cord when using, put the power cord well, and be careful to trip.

Only the DC power cord and power adapter can be used, and other system accessories will damage the equipment.

To ensure that the treatment pressure setting is set according to the combination of equipment and accessories and according to the individual patient.

Proper placement and fixation of patient interfaces is essential for the continuous operation of the device.

Ensure the compatibility of the equipment and components and all accessories used to connect to the patient before use.

Ensure that treatment pressure settings are based on a combination of equipment and accessories for the individual patient.

The effectiveness of the treatment setting was evaluated regularly.

Respiratory gas channels, confirming that their components and accessories can be used with positive pressure ventilation therapy machines

Please consider changing the treatment pressure.

If you is discarded, follow local environmental regulations.

The correct wearing and position of the mask on the face is critical to the consistency of the device.

Check all the components, accessories connected to the equipment and the equipment for compatibility before using the equipment.

Ensure the patient is set separately for the patient based on the configuration of the device used.

When the device is used by multiple patients, each patient should be equipped with a separate mask that cannot be used otherwise.

If you feel uncomfortable when touching the equipment, please stop using the equipment and contact your equipment supplier immediately. Because it can cause allergies.

To make the effect of the treatment more effective, please periodically reevaluate the treatment setting.

Do not use a wet filter cotton pad.

Refer to the oximetry operating manual when blood oxygen measurement is required.

When the natural environment accident occurs wind and rain, lightning, earthquake, fire, resulting in the failure of network transmission data, the manual TF card is used to save the data.

When the physical media accidental damage causes system failure, power failure, hardware failure and software failure, the protection of the physical environment should be strengthened and the use of equipment should be controlled.

In the case of accidental loss of backup data, the network management countermeasures should be carefully improved, and the effective management of network key should be strengthened to prevent misoperation.

When the user's personal information is unintentionally leaked, the user identification and authentication mechanism should be adopted, and the password should be long enough; the password should be frequently changed, and the password should be properly kept in the confidential place; at the same time, the security awareness of personnel should be strengthened, the transmission range of confidential information should be controlled, and the information transmitted in the network should be encrypted.

If the environment or power supply exceeds the specification range, the machine

may be automatically shut down or the ventilation control cannot meet the specification.

When the gas flow rate and setting exceed the recommended working range, the insufficient humidification system output and the output gas relative humidity is less than 70%.

After the power outage is restored, the user's last parameter setting data can be saved on the device

contraindication

If you have severe respiratory failure and do not have any spontaneous breathing.

This product is not applicable to the following contraindications:

Absolute contraindications

Respiratory drive is not enough to tolerate the intermittent use of noninvasive ventilation therapy;

Acute sinusitis, otitis media;

Epistaxis, which may lead to pulmonary aspiration;

Some conditions that may lead to the inhalation of gastric contents;

Failure to remove secretions;

Hypotension or significant intravascular blood volume insufficiency;

Pneumothorax or a pneumomediastinum;

Recent brain trauma, cerebrospinal fluid leakage or surgery;

Obviously non-cooperative or extremely nervous;

Shock caused by various causes and is not corrected;

nosebleed active period;

Upper gastrointestinal bleeding that is not effectively controlled;

Coma or with a disturbance of consciousness can not cooperate or receive a mask treatment;

Huge vocal cords, polyps, etc.

Relative contraindications

Severe coronary heart disease combined with left heart failure;

The acute phase of otitis media;

Respiratory tract secretions and cough weakness;

Weak spontaneous breathing (except for T mode);

Tracheal intubation (transnasal or oral) and tracheotomy;

Severe nasal congestion caused by various reasons;

- bullae of lung;

Respiratory mask allergy, etc.

Note: In either case, it is only up to the clinician to use the positive pressure ventilation machine.

1.3 Terms and definitions

term	description
CPAP	Continuous positive airway pressure ventilation. That is, the patient is continuously ventilated according to the set pressure. CPAP is characterized by the inspiratory and expiratory phase maintaining the same set constant treatment pressure during sleep, providing a stable supply of pressure. Autonomous breathing mode
APAP	Automatic continuous positive airway pressure ventilation. In each respiratory cycle of the patient, the treatment pressure of the inspiratory and expiratory phase is the same. The ventilator automatically detects the apnea and the airflow decrease due to the airway changes of the patient, and then output the appropriate pressure according to the calculation of the internal software, so that the ventilator can achieve the optimal treatment effect with the minimum output pressure. APAP comfort for patients with pressure requirements above the 10 cm water column outperformed CPAP. Autonomous breathing mode
S	Double horizontal positive pressure ventilation, with higher suction pressure and lower breath pressure, the machine provides higher inspiratory pressure to keep the airway open to support or improve the patient's inspiratory process. It provides a low expiratory pressure, while ensuring the opening of the airway, so that the patient can easily discharge the exhaled gas, while maintaining the normal opening of the patient's airway. S ventilation mode is to with two levels of ventilation pressures, which are constant. Autonomous breathing mode
Auto-s	Automatic double horizontal positive pressure ventilation. The suction pressure and breath pressure of the Auto-s ventilation mode will automatically boost and decrease the pressure based on the upper airway resistance. Autonomic breathing mode.
ASV	Unique automatic double-level positive-pressure ventilation. ASV can automatically control the suction and breath pressure to keep the patient in a comfortable breathing state. Air suction control: automatically track the patient's each breath, calculate the minute ventilation, and then monitor the user's breathing airflow. If the respiratory flow is below the target ventilation and the respiratory airflow decreases, the ventilator increases the inspiratory pressure and allowing the user to inhale enough gas. Until the breathing airflow is normal, the ventilator inspiratory pressure drops again. If the respiratory flow is higher than the target ventilation amount, the strong respiratory airflow will reduce the carbon dioxide in the body to below the threshold. According to the principle of

	central apnea, low CO2 levels can trigger central apnea. In order to eliminate the central apnea that may be triggered, the machine will reduce the inspiratory pressure and allow the patient to absorb less air to avoid triggering the central apnea. Call pressure control: obstructive apnea will lead to the pressure reduction. At this time, the machine will automatically increase the breath pressure, keep the upper airway unobstructed, and control the suction pressure to maintain the stability of ventilation.
T	Time control mode, forced ventilation, the machine controls the patient's inspiratory time and breathing rate according to the set parameters, the patient can only passively follow the machine ventilation. This mode is mainly applicable to patients with weak respiratory trigger ability. It is mainly suitable for patients with no spontaneous breathing or weak spontaneous breathing.
ST	Autonomous breathing and time control automatic switching mode, when the patient breathing rate is higher than the set value of the machine (backup ventilation frequency), the machine operates in the S mode; when the patient breathing rate is lower than the set value of the machine (backup ventilation frequency), the machine operates in the T mode. This pattern works for spontaneous breathing, but may have apnea or arrest. This mode is based on the patient's spontaneous trigger breathing, supplemented by backup time control, to avoid the occurrence of danger, thus ensuring the patient's ventilation needs and reducing the risk of carbon dioxide retention.
Auto-ST	Automatic double level ventilation and standby frequency of ventilation mode, the mode machine is also suitable for central apnea, when patients after central suspension at night, breathing with fixed breathing rate, this mode can also set automatic backup frequency, the machine can according to the patient's spontaneous breathing rate and relative breathing ventilation to intelligent adjustment.
APCV	Complex pressure-controlled ventilation mode. When the patient's breathing rate is greater than the period corresponding to the backup ventilation rate, the ventilator controls the inspiratory time but not the inspiratory time; when the patient's breathing rate is less than the backup ventilation rate. There was an inspiratory trigger, and no expiratory trigger. It is suitable for patients with fast respiratory rate, low tidal volume and hypoxemia.
VA	The capacity is guaranteed. When the patient's breathing effort can meet the normal ventilation standard, the machine will not increase the pressure very high, and the comfort level is higher than the normal ST mode ventilator. When the patient is underventilated, the machine automatically raises the pressure to ensure the patient ventilation. This mode will set a maximum pressure value, even if the patient is underventilated, the pressure will not exceed the set value to avoid

	hyperventilation. Will set a minimum pressure value, even if the patient's ventilation has standard, but the pressure is not below the minimum, so the VA mode can guarantee the effective ventilation within a certain range, also can by set the pressure range, set the pressure in a certain range, let the machine as the patient autonomous breathing ability is different, free fluctuations in the pressure range.

1.4 Graphs and symbols

ID	marking instruction
	date of manufacture
	pay attention to! Review random documents (this manual)
	The humidifier has been heated, do not touch the heating piece
IP 22	Preventing solid foreign matter of 12.5mm from entering the device and til15 degrees can prevent dripping from entering the device (waterproof grade)
	The BF-type application part
	Collect electrical and electronic devices according to EC directive 2012 / 19 / EU
	Electric shock protection protection level: class of equipment protection

	Mandatory reading of this instruction manual
CE 0123	This equipment complies with the EU Medical Equipment Directive 93 / 43 / EEC and meets the basic requirements of Appendix I of this directive, and therefore bears the CE mark
SN	serial number
	Start / stop treatment ventilation button
	TF block
IOIOI	gorge line
CO_2	CO dioxide interface
	Humidifier to unlock the key
	Gas output

	direct current
	Intake cover lock
	Inlet cover unlock
	alternating current (AC
	manufacturer
	nonionizing radiation
	upward
	Afraid of rain
	Afraid of drying

	fragile
	Recyclable material
	No roll
	Batch code

2 Equipment brief introduction

2.1 Equipment list

- main engine

Admito humidifier

Admito heating pipeline

- visor

Power supply adapter

- gripesack

TF card (already inserted).

Filter: hypoallergenic filter, standard filter

SD card reader

Oximetry (optional)

Cuation CO2 monitor (optional)

2.2 Equipment introduction

Positive pressure ventilation treatment machine is composed of fan, control circuit, sensor, airflow output catheter and nasal hood. According to the pre-setting, the machine continuously output a certain horizontal positive pressure and flow

airflow, which is applied to the patient's upper respiratory tract through the pipeline and nasal mask, keeping the upper airway open and unobstructed, eliminating sleep snoring, hypopnea and sleep apnea.

2.2.1 Equipment model and differences

number	model	pressure cmH2O	Ventilation mode / function										
			CPAP	APAP	S		Auto-S		T	ST		Auto-ST	Vt set up
					S	ASV	Auto-S	Auto-ASV		ST	ASV		
1	HM-C20	4~20	✓										
2	HM-CA20	4~20	✓	✓									
3	HM-B25	4~25	✓		✓								
4	HM-B25A		✓		✓	✓							
5	HM-BA25		✓		✓		✓						
6	HM-BA25A		✓		✓	✓	✓	✓					
7	HM-B30	4~30	✓		✓								
8	HM-B30A		✓		✓	✓							
9	HM-BA30		✓		✓		✓						
10	HM-BA30A		✓		✓	✓	✓	✓					
11	HM-B25C	4~25	✓		✓								✓
12	HM-BA25C		✓		✓		✓						✓
13	HM-ST25		✓		✓		✓		✓	✓			✓
14	HM-STA25		✓		✓		✓		✓	✓		✓	✓
15	HM-B30C	4~30	✓		✓								✓
16	HM-BA30C		✓		✓		✓						✓
17	HM-ST30		✓		✓		✓		✓	✓			✓
18	HM-STA30		✓		✓		✓		✓	✓		✓	✓
19	HM-ST30Pro		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

2.2.2 The applicable applicable for each model / ventilation mode are as follows:

CPAP applicable conditions: upper airway obstruction; constant pressure requirement. Central suspension.

APAP conditions: upper airway obstruction; OSA for different stress needs (obstructive sleep apnea) of sleep; fixed, or multiple pressure changes depending on

sleep stage and sleep position; and inability to tolerate CPAP treatment. APAP is more favorable for patients who do not do the pressure titration.

S Suitable conditions: This mode is mainly suitable for patients with obstructive sleep apnea with good respiratory triggering ability and stable spontaneous breathing.

Auto-S applicable conditions: Double-level automatic ventilators can only be used in patients with snoring, airflow limitation and obstructive sleep apnea syndrome, not for patients with COPD and neuromuscular diseases. In home use, the vast majority of patients actually use a double-level ventilator in S mode. For patients with severe disease requiring T mode, it is recommended to treat them in the hospital.

ASV applicable conditions: This mode is mainly suitable for patients with central suspension.

T applicable conditions: This mode is mainly suitable for patients without spontaneous breathing.

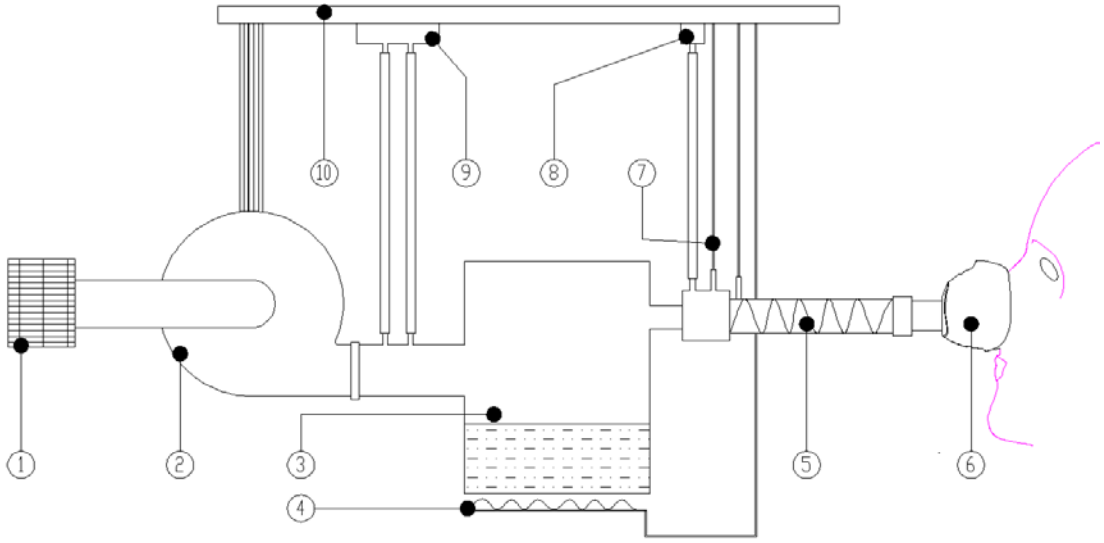
The condition of ST is applicable: pulmonary disease; neuromuscular disease, obesity and hypoventilation, central nervous disease, etc.; such as neuromuscular disease, due to the degeneration of muscle function, leading to weak respiratory muscle, which will lead to the problem of difficult inhalation, double level constant pressure ventilator can actively deliver gas when the patient aspirates, reducing the patient's breathing and work. Suitable for patients with severe OSA with titration pressure over 15cmH2O or above, patients with overlap syndrome or COPD, and neuromuscular diseases.

Auto-ST is suitable for diseases: mainly used for acacerosis, COPD, ALS, cardiopulmonary dysfunction, central suspension and other patients.

APCV applicable symptoms: mainly used for patients with fast respiratory rate, low tidal volume, and hypoxemia

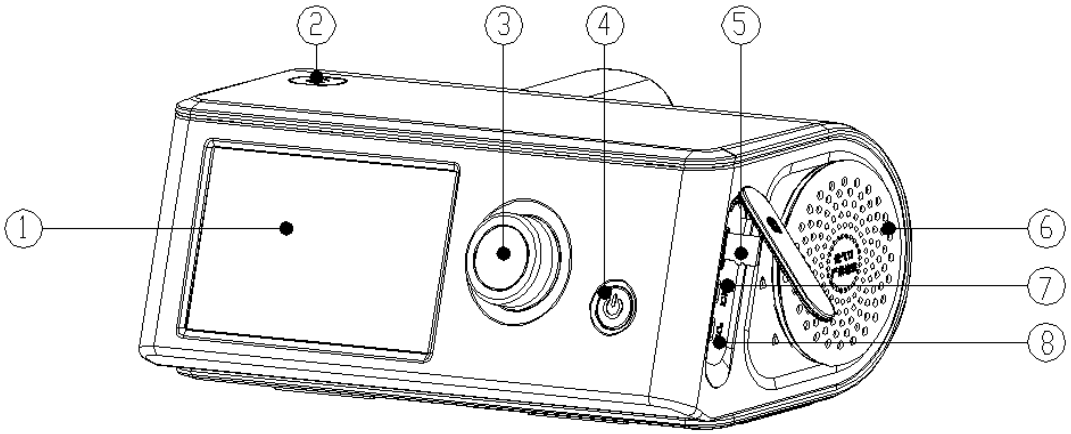
Conditions for VA: obstructive sleep apnea syndrome, COPD, obese hypoventilation, restrictive patients (e. g. ALS, myasthenia gravis), neuromuscular patients; any patient who already uses stress support requiring improved safety.

2.2.3 Schematic diagram of the gas path:



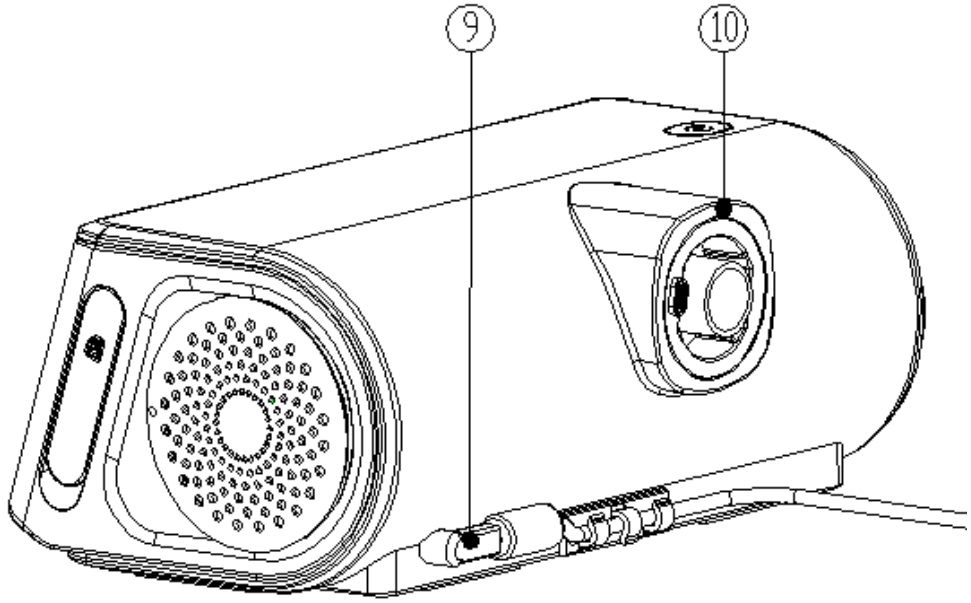
1	Air filter element	4	Humidifier heating plate with a temperature sensor	7	Humidifier temperature sensor	10	main control panel
2	Turbine fan	5	Respiratory line with heating wire temperature sensor	8	pressure pickup		
3	The humidifier	6	nasal mask	9	flow sensor		

3. Equipment installation



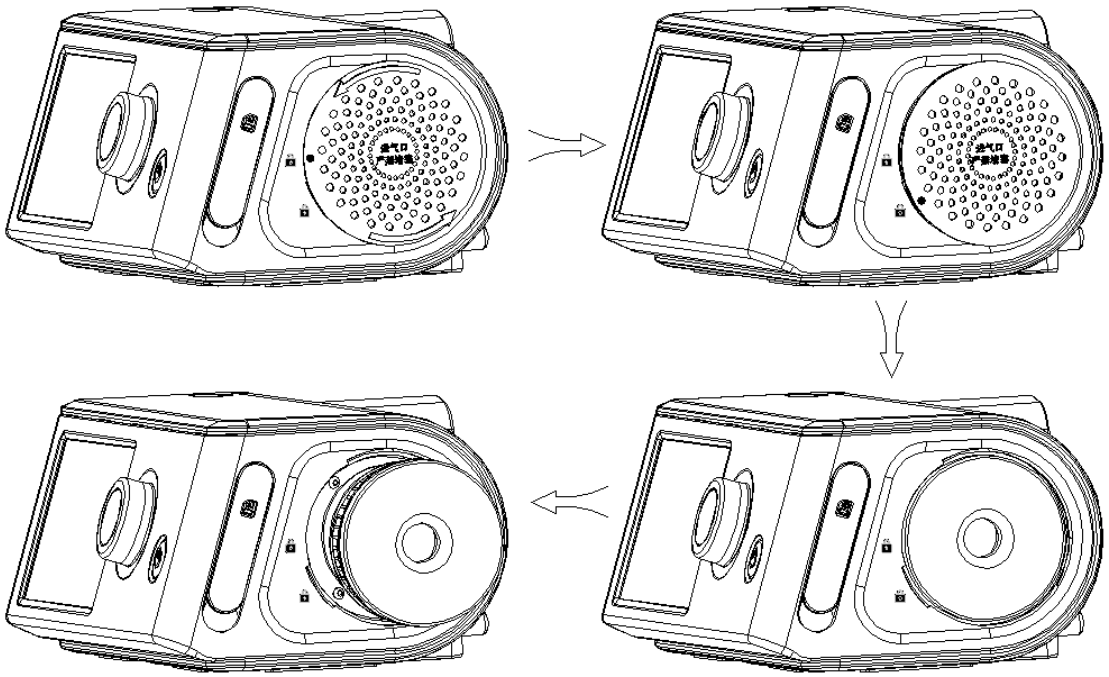
1. Display screen
2, the water tank unlock button
3. Rotate the encoder
4. Start / stop the key
5. TF card interface

6. Air intake cover
7. Debug interface (can not connect the data line, only for internal debugging)
8. Carbon dioxide interface (only connected equipment)



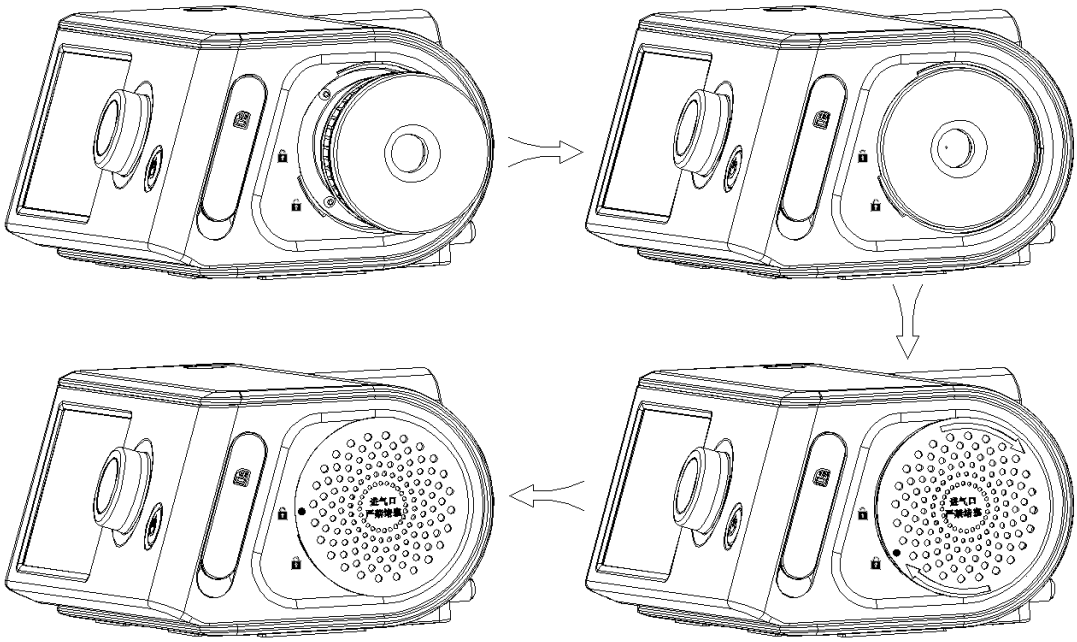
9、Power interface
10. Pipe connection interface

3.1. Change of the air inlet filter element with it



Step 1: Rotate the intake cap counterclockwise to rotate the hollow concave of the intake cap from the locked icon to the unlocked icon position
Step 2: Remove the air intake cap
Step 3: hook the hole in the middle of the filter element with your finger and pull out the filter element outward

Step 4: Remove the filter element



Step 1: Find a new filter element

Step 2: Push the filter element inward into the air inlet

Step 3: Install the intake cap, and the unhollow concave points of the intake cap point to the lock icon

Step 4: Rotate the intake cap clockwise until the concave point points to the position of the lock icon

3.2, and the humidifier

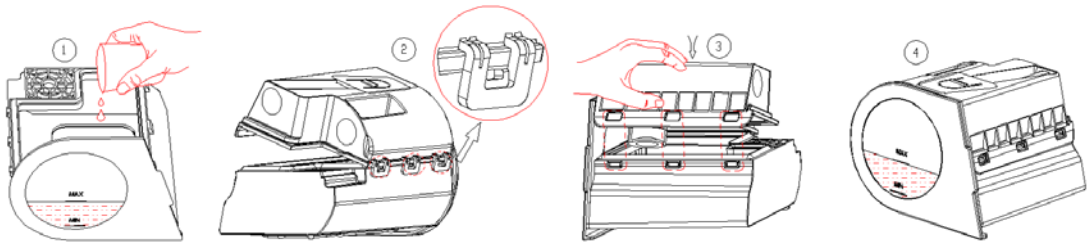
Humidifier water loading:

Step 1: Add no more than 300 ml of distilled water or pure water to the water tank

Step 2: hang the corresponding hook behind the water tank

Step 3: Start to press the water tank cover

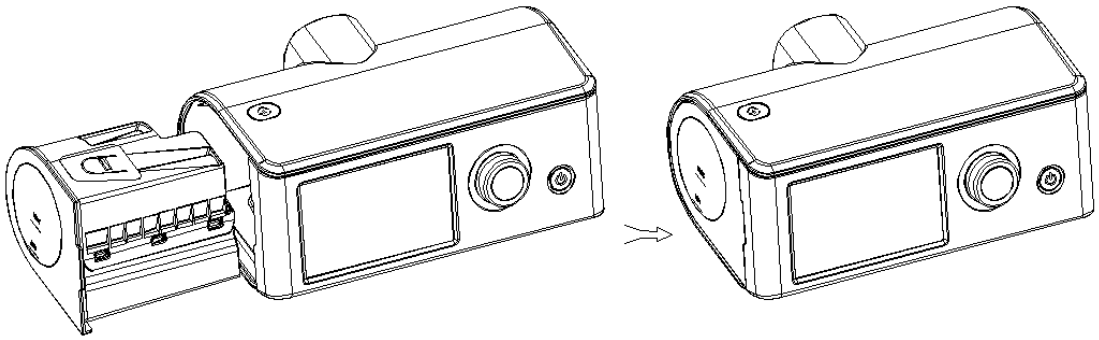
Step 4: Until you hear a "click" sound, indicating that the water tank is locked



Install humidifiers:

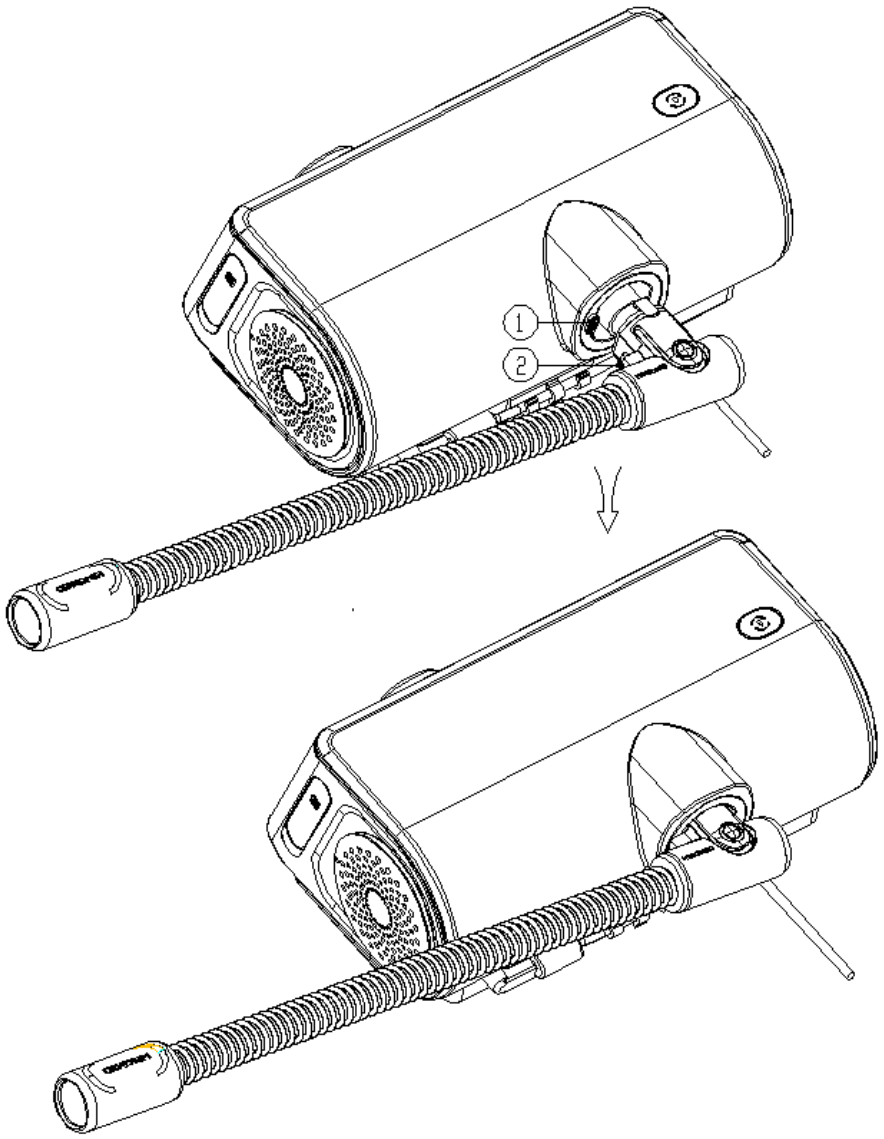
Step 1: Push the water tank into the tank tank of the equipment

Step 2: until the tank is completely not into the tank tank means that the tank has been installed in the equipment



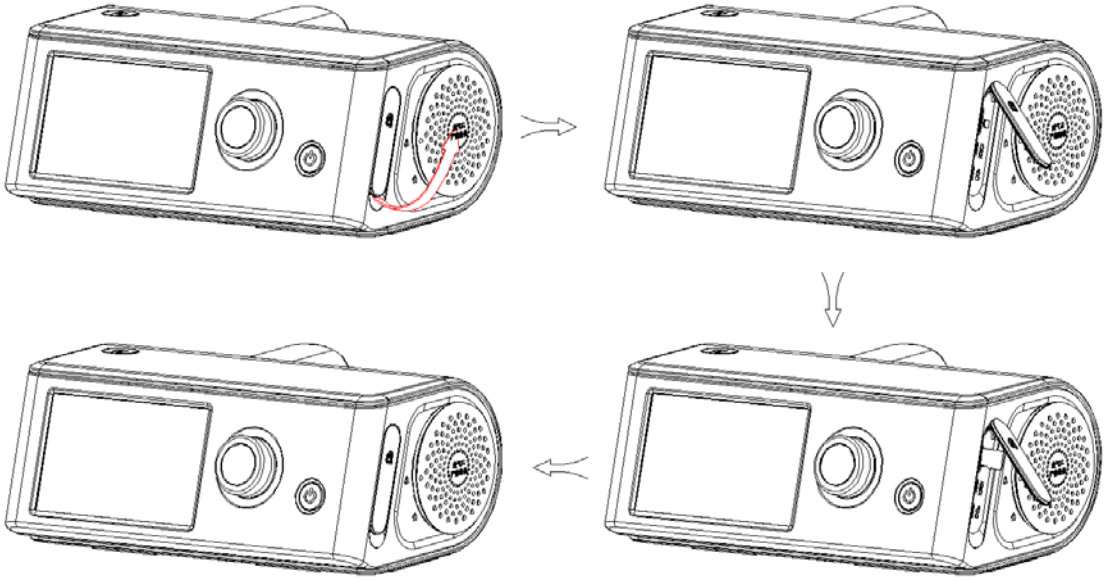
3.3 Respiratory line

Step: 1. align 2 of the pipeline (type-c head) at 1 (type-c hub) of the air outlet;
2. After the alignment, insert the pipeline into the air outlet
Note: The type-c header and the master seat here are corresponding to each other, and other data lines or device lines cannot be connected



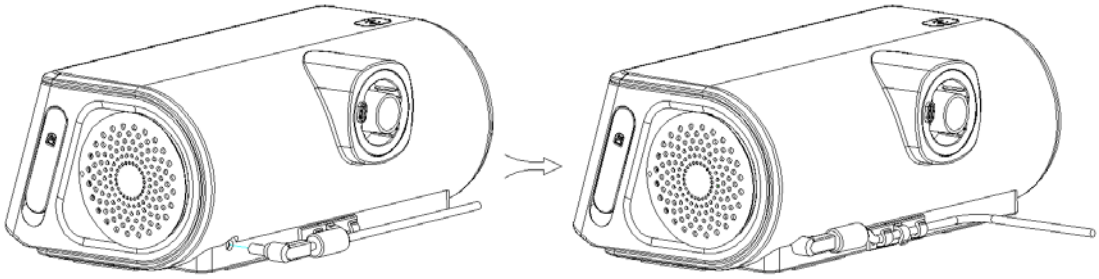
3.4 TF card

Step 1: Turn the waterproof interface cover out
Step 2: Open the waterproof interface cover
Step 3: insert the TF card at the top interface
Step 4: Cover the waterproof interface cover down until it is flush with the equipment shell
Note: Do not unplug the TF card when the device is powered on



3.5 Power supply

Power plug: Step 1: insert the power cord into the power interface of the device
Step 2: Put the plugged-in power cord into the solid wire buckle to prevent the power cord from falling off



3.6 Blood Oxygen module

In the image on the left is the PO2 of Lepu Medical, which meets the standard of GB9706.1; the Bluetooth function and the data of the oximetry test will be sent to the treatment display interface of the device.

3.7 The carbon dioxide module

The CO 2 is connected to the interface of the device, and the data detected by the CO 2 is fed back to the treatment display interface of the device.

3.8 Preparation before use

Before each use, please read this chapter in detail and install the equipment, connect and check according to the instructions in this chapter.

Check the accessories used with the equipment according to their respective operating instructions. Do not use the equipment for any abnormality.

4 Equipment operation

4.1 Start the machine

With the power supply, the equipment enters the main interface, and the white box at the top is the alarm display area to enter the treatment, sleep report, ventilation setting, comfort setting, accessory setting and system setting interface. The screen displays as shown in Figure 1:

Figure 1. Main interface

4.2 Setting-up

Rotate the knob at the main interface to bring the cursor to the ventilation, system, accessory and comfort setting icon, and press the confirmation piece to enter the interface, as shown in Figure 2:

Figure 2 Settings interface

4.3 Sleep report interface

Rotate the knob at the main interface to bring the cursor to the sleep report icon, press the confirmation key and enter the sleep report interface within 24 hours, as shown in Figure 3:

Figure Figure 3 24-hour sleep report

The rotation knob selects the arrow on the top left and then presses the confirmation key to return to the main interface. Select the arrow on the top right, press the confirmation key and enter the annual sleep report, as shown in Figure 4:

Figure 4-year Sleep Report

4.4 Treatment Interface

Rotate the knob at the main interface to bring the cursor to the treatment icon, and press the confirmation key to enter the treatment interface, as shown in Figure 5:

Figure Figure 5 The Treatment Interface

The upper left part of the treatment interface is the waveform display area, the

upper right part is the respiratory monitoring parameters, and the bottom part is the setting parameters. Select the icon in the upper left corner and press the confirmation button, three icons will appear from the right side of the icon to enter the "main interface", "setting interface" and "sleep report interface", and the icon in the upper right corner enters the dynamic lung interface, as shown in Figure 6:

Figure Figure 66-The Dynamic lung interface

4.5 Set up options and description

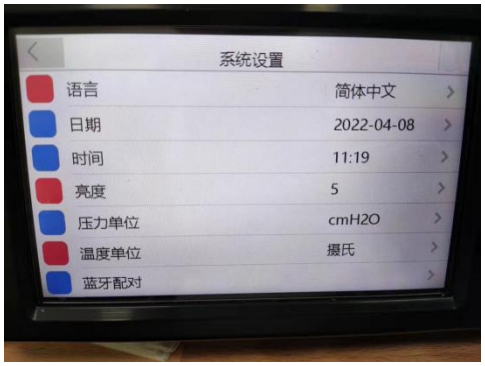
4.5.1 Attachment setting

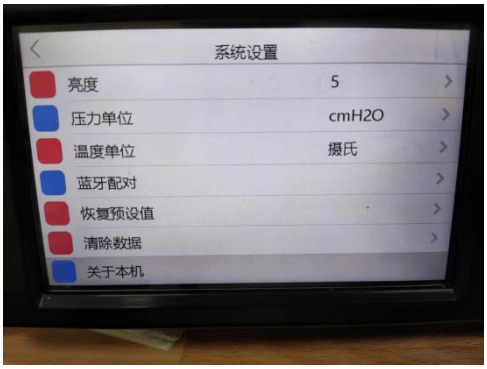
Return to the left bar	Select the uppermost arrow
Pipe type	Inner diameter is 15mm / 22mm
Mask type	nose mask / nose pillow / full face mask
bacteria proof filter	Turn on / off
Oximeter	Turn on / off
Pooling carbon dioxide	Turn on / off

4.5.2 System Settings

Return to the left bar	Select the uppermost arrow
language	All interface languages: simplified / Chinese /

	English
date	The system date can be set
time	The system time can be set up
luminance	The screen brightness can be set
pressure unit	cmH2O / hPa
degree-day	Photo / Fahrenheit
Bluetooth pairing	Search for external Bluetooth devices
Restore preset value	Cancel / confirm
clear data	Clear storage data
About the native	Factory information of equipment

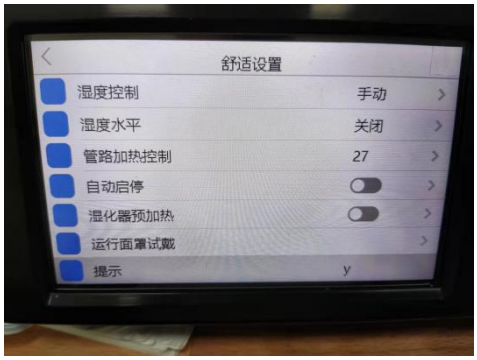




4.5.3 Comfort setting

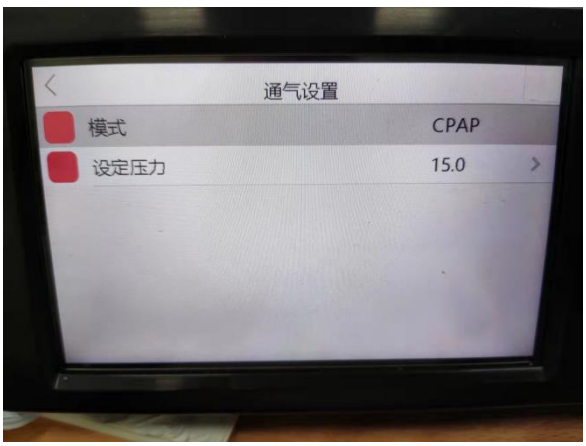
Return to the left bar	Select the uppermost arrow
Time-lapse boost	Time from the starting pressure to the set pressure, Adjustable range 5~45 (optionally off)
Start pressure	Can be set, At 4cmH2O and set up of the minimum The pressure interval is adjustable
Start the breath pressure	Setable in dual horizontal mode, From 0 to 20 cm, the H2O is adjustable
Delayed antihypertensive	After the ventilation mode was stopped, the pressure was slow Slow down, optional: on / off

Temperature level	Humidifier temperature control, 0~8 gear adjustable
Pipe heating	Pipeline temperature control, 0~5 gear is adjustable
temperature control	Turn on / off
Exhale release pressure	End-expiratory pressure release, 0 to 4 cm H2O adjustable
automatic start-stop	Turn on / off



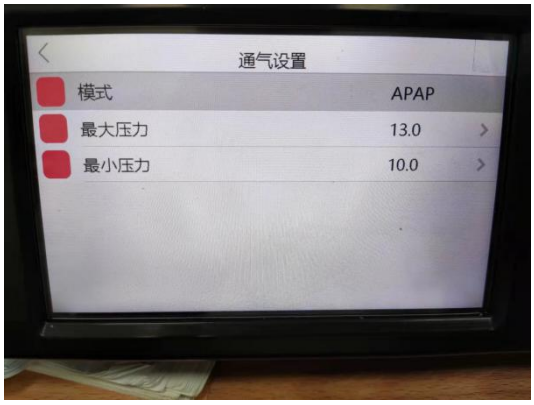
4.5.4 Ventilation Settings (CPAP mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the CPAP mode as an example
setting pressure	From 0 to 30 cm, the H2O is adjustable



4.5.5 Ventilation Settings (APAP mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the APAP mode as an example
maximum pressure	From 0 to 30 cm, the H2O is adjustable
minimum pressure	From 0 to 30 cm, the H2O is adjustable



4.5.6 Ventilation Settings (S mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the S mode as an example
Inhale pressure	From 0 to 30 cm, the H2O is adjustable
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable

Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable

4.5.7 Ventilation Settings (T-mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the T mode as an example
Inhale pressure	From 0 to 30 cm, the H2O is adjustable
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
breathing rate	Set the number of breaths per minute, 5~55 Adjustable (currently unlimited)
inspiratory duration	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable

4.5.8 Ventilation Settings (ST mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the ST mode as an example
Inhale pressure	From 0 to 30 cm, the H2O is adjustable
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
Spare breathing frequency	Set the number of breaths per minute, 5~55 Adjustable (currently unlimited)
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable

4.5.9 Ventilation Settings (Auto-S mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the Auto-S mode as an example
maximum inspiratory pressure	From 0 to 30 cm, the H2O is adjustable
Minimum expiratory pressure	From 0 to 30 cm, the H2O is adjustable
maximal expiratory pressure	From 0 to 30 cm, the H2O is adjustable
pressure support	From 0 to 30 cm, the H2O is adjustable
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable

4.5.10 Gas Settings (Auto-ST mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the Auto-ST mode as an example
maximum inspiratory pressure	From 0 to 30 cm, the H2O is adjustable
Minimum expiratory pressure	From 0 to 30 cm, the H2O is adjustable
maximal expiratory pressure	From 0 to 30 cm, the H2O is adjustable
pressure support	From 0 to 30 cm, the H2O is adjustable
breathing rate	Set the number of breaths per minute, 5~55 Adjustable (currently unlimited)
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable

4.5.11 Ventilation Settings (ASV mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the Auto-ST mode as an example
voluntarily EPAP	Exiratory phase pressure, on / off
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
Minimum pressure support	From 0 to 30 cm, the H2O is adjustable
Maximum pressure support	From 0 to 30 cm, the H2O is adjustable
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable
tidal volume	From 0 to 1,000 ml is adjustable

4.5.12 Ventilation Settings (VA mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the VA model as an example
stature	Set the height required for dead chamber determination, 110-250cm can be set up
breathing rate	Set the number of breaths per minute, 5~55 Adjustable (currently unlimited)
Target pulmonary alveolar ventilation volume	The algorithm determines how many liters to pass per minute
voluntarily EPAP	Exiratory phase pressure, on / off
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
Minimum pressure support	From 0 to 30 cm, the H2O is adjustable
Maximum pressure support	From 0 to 30 cm, the H2O is adjustable
Maximum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Minimum inspiratory time	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 ms adjustable
Inspiratory trigger sensitivity	1~5 File adjustable
Expiratory Trigger Sensitvity	1~5 File adjustable

4.5.13 Ventilation Settings (APCV Mode)

Return to the left bar	Select the uppermost arrow
Ventilation mode	Depending on the ventilator model, this is available Set up the different ventilation modes
	In different ventilation modes, it can be set up The parameters are different
	This interface takes the APCV mode as an example
Inhale pressure	From 0 to 30 cm, the H2O is adjustable
Exhale pressure	From 0 to 30 cm, the H2O is adjustable
breathing rate	Set the number of breaths per minute, 5~55 Adjustable (currently unlimited)
inspiratory duration	From 0.1 to 3.3 seconds are adjustable
Pressure rise time	0~900 Adjustable
Inspiratory trigger sensitivity	1~5 File adjustable

5. Equipment maintenance and cleaning

5.1 Equipment disassembly

After the positive pressure ventilation treatment machine is stopped, the pipeline

of the positive pressure ventilation treatment machine should be removed and washed in time. Before removing the pipe of the positive pressure ventilation treatment machine, the structure should be understood and be removed slowly according to the steps and requirements described below, and not blindly to avoid damage to the pipe and parts.

Pull out the power cord from the wall socket and the back panel of the host;

Press the separation key on the host, gently remove the humidifier from the positive pressure ventilation machine from the left in the horizontal straight direction;

Open the humidifier water tank, pour the water in the water tank and pour the water clean;

Grasp the edge of the air pipe and the equipment connection, and gently pull away from the host machine;

Grab the end of the air tube and the mask and gently separate the mask.

5.2 Maintenance of the equipment

In order to ensure the long-term normal operation of positive pressure ventilation treatment function, it is very necessary to do daily maintenance and preventive maintenance of positive pressure ventilation treatment machine.

Do not place the spare air filter element in the sun exposure, wet and cold environment to avoid damage to the material.

Positive pressure ventilation treatment machine should be regularly repaired, powered, and functional test to ensure effective functional use;

The pipe of the positive pressure ventilation treatment machine should be firmly fixed to avoid rough action, excessive pulling and rupture and air leakage;

Face masks and pipes should be picked and worn every day, and regularly check whether there is any damage;

The positive pressure ventilation treatment machine should be maintained and consumables for 1000 hours;

The duration of the positive pressure ventilation treatment machine is 5 years

When the positive pressure ventilation ventilator is not used for a long time, please remove the power adapter from the household socket, clean it, and keep it in a dry and ventilated environment.

The attached proposed service period is as follows:

component	It is recommended to change the time
filter element	Six months
pipeline	In 1 year

water box	2.5 Years
visor	In 1 year

⚠ Note: the replacement cycle can be shortened depending on the local air quality. If there is damage or cracking, please replace it in time; please use the air filter element provided by the manufacturer.

5.3 Cleaning of the equipment

This equipment does not belong to sterile products, belong to special personnel, so there is no bacterial virus infection problem. But it may breed bacteria or viruses after use. Therefore, the equipment needs to be cleaned and disinfected in the following steps:

Clean the outer surface of the equipment: gently wipe it with a soft wet towel, and then wipe it clean with a dry soft cloth. If necessary, 75% of the medical alcohol can be used to clean the outer surface of the equipment, but the liquid is not allowed to enter the inside of the positive pressure ventilation treatment machine;

Clean line: clean the line before the first use and clean it at least once a week; remove the line from the positive pressure ventilation machine, clean with warm water or neutral washing liquid, rinse thoroughly and dry. If necessary, 75% medical alcohol can be cleaned and disinfected.

Mask / nose mask / nose mask: Clean the mask / nose mask / mouth mask at least weekly before the first use; remove the mask with warm water or neutral detergent, rinse thoroughly, and then dry. If necessary, 75% medical alcohol can be cleaned and disinfected.

Clean the humidifier: remove the humidifier, clean the humidifier with warm water and neutral washing liquid, rinse thoroughly and dry. If necessary, 75% medical alcohol can be cleaned and disinfected.

External disinfection of the whole machine: disinfect the outside of the positive pressure ventilation treatment machine with ultraviolet light or other air disinfection methods. Tubing and mask disinfection: refer to the cleaning manual for the mask and pipe

⚠ warn:

Power supply must be disconnected during cleaning or routine maintenance.

Note: The materials and surfaces used in this product can be resistant to alcohol wiping.

5.4 Equipment handover

⚠ warn:

If the equipment needs to be handed over to another user, parts in close contact with the human body, such as mask, head band, humidifier tank, pipes and air filter elements must be cleaned and disinfected to avoid cross-infection.

⚠ pay attention to:

Equipment does not require a calibration.

5.5. Carry

⚠ pay attention to:

Before traveling with this equipment, thoroughly empty and wipe the humidifier tank to prevent water from entering the device.

The Backpack is used for loading the equipment and accessories. When traveling, please take it with you, please do not check it.

The user can use the device in any one country, without making any changes to it, because the power components will automatically detect the voltage and frequency of the alternating current.

Before departure, the user shall identify the style of the national standard of the destination. Users may need a power outlet converter, which can be bought at an electronics supplier.

Remember, bring a spare air filter and a respiratory treatment emergency document (completed and signed by the user's physician). When traveling by plane, the user should present the multilingual respiratory therapy emergency documents to the baggage control and customs personnel to prove that this device is a medical treatment device

5.6 Common fault analysis

If the following problem occurs to the equipment, please refer to the following table for the solution. If you cannot resolve the problem yourself, please contact the equipment supplier or our company

Tip name	type	Possible cause	measure
Input voltage exception		Ininsert adapter, resulting in	The special adapter configured for this equipment shall be used

		voltage too high or too low	
In TF card data synchronization, do not unplug the TF card, do not power		1. Data synchronization when inserting TF card; 2. Import the configuration in TF card	no-operation
TF cards were pulled out		1. No TF card in the equipment	Insert a write-readable TF card
The TF card is full, please replace the TF card		In the standby state, the TF card storage space is only 200M	Empty the TF card after replacing the TF card or exporting the data
The TF card cannot be written. Remove it and insert it again		The TF card is read only, not written	Pull out the TF card, unlock and insert again
For the TF card fault, please pull it out and insert it again		A TF card failure, it may be: 1. TF card cannot be read and write; 2. TF card reading and writing data errors, etc.	Pull out the TF card, insert it again, or replace a new TF card
The humidifier fier has insufficient water		1, the humidifier has no water; 2. The pure water in the humidifier evaporates after evaporation	Remove the humidifier and add the appropriate amount of water
No heating line was detected		1. No heating line is connected 2. Heating line type-c interface is not well connected	Check the connection status of heating line, type-c interface when inserted, contact the supplier if repeated

system mistake		1, the RTC clock is abnormal 2、	Try to restart and contact the supplier if repeated
A lot of leakage		1. The face mask and the heated breathing line are not well connected 2. The water tank is not connected	Check the connection status of the mask and the heated breathing line, and that of the humidifier
Pipe blockage		Mask, heated breathing lines, or air intake are blocked	Check the mask and heating breathing tube, and the air inlet
The fan temperature is abnormal		The fan temperature is too high	Please wait for the equipment to cool before starting the equipment, please contact the supplier if repeated
The idifier temperature is abnormal		The heating chassis temperature is too high	Please wait for the equipment to cool before starting the equipment, please contact the supplier if repeated
Heating heating tube has abnormal temperature		The heating breathing line is too high	Please wait for the equipment to cool before starting the equipment, please contact the supplier if repeated
Asphyxia / apnea			
hyperpiesia			
The heating breathing line is expired, please replace it		In the standby state, the time exceeds the use time of the heated breathing tube setting	Click OK, and replace the heated breathing line
Humiditer is expired, please replace		In the standby state, the time exceeds the use time set by the humidifier	Click "OK" and replace the humidifier

Filter service life is expired, please be replaced		In the standby state, the time exceeds the usage time set by the filter	Click "OK" and replace the filter
Change the mask when it has expired		The standby state exceeds the usage time of the mask setting	Click "OK" and replace the face mask

5.6.1 Troubleshooting

If your device is problems during use, try the measures listed in the following table, and if it still fails, contact your equipment maintenance provider.

question	Possible cause	measure
After the device is not responsive, the display screen is not bright or the backlight on the button is not bright	The power supply of the device is not connected or the power socket is dead	Check the power supply interface and confirm that the device is properly connected to the power supply. Make sure the power outlet is charged. Ensure that the AC power cord is properly connected to the power supply and device interface. If the fault still occurs, contact your supplier and repair the equipment together with the power supply so that they can determine whether the equipment fails or the power supply fails.
inward mask leakage	The mask is not tight or inappropriate in size	Make sure your mask is appropriate and worn correctly, refer to the mask manual for details, or use the mask matching test function to check the mask for air leakage
The nose is dry or blocked	The humidity level is set as too low	Adjust the humidity level gear
Water in the mask and hose	The humidity level is set too high, and the temperature of the heating and breathing tube is set too low	Adjust the temperature of the humidity level gear and the heated breathing tube
xerostomia	Oral air leakage	Raise the humidity level Wear a headband to fix the chin

Too much pressure in the mask (feeling Feel too much air)	The delayed step-up function is turned off close	Turn on the delay boost function
Low pressure in the mask (feel insufficient air)	The delayed boost function is in come into force.	Wait for pressure to adjust to appropriate level or close delay boost time
Treatment was stopped, but the device remained ventilated	The equipment is cooling	The device is cooling the line and will automatically stop ventilation after a few minutes
Abscreen display (blank or blue screen)	Device drop or collision	Disconnect the equipment power supply, and then reconnect the power supply. If the problem remains, please contact your supplier
The humidifier is leaking	The humidifier is not installed correctly. The humidifier is damaged	Check that the humidifier is being installed correctly. Check the humidifier for damage. Contact your supplier to replace a new humidifier.
The button is not responsive	Program exception or key button failure	Disconnect the equipment power supply, and then reconnect the power supply. If the problem remains, please contact your supplier
The knob has no response	Knob failure	Disconnect the equipment power supply, and then reconnect the power supply. If the problem remains, please contact your supplier
There is no response to the display	The display fault	Disconnect the equipment power supply, and then reconnect the power supply. If the problem remains, please contact your supplier

5.7 Service

⚠ pay attention to:

Maintenance and maintenance of the equipment is the responsibility of the patient. Please check the following items to make sure it works properly:

Are the vent tubes and mask systems sealed?

Does the treatment pressure develop? Is it displayed by the display yet?

Is the water in the humidifier being heated?

If any fault occurs, please contact the equipment supplier for repair.

⚠ pay attention to:

Disposal of ventilators and packaging materials out of service life according to the relevant national laws and regulations, which will cause harm to the environment. Generally, the ventilators, cardboard and protective plastics for packaging shall be sent to a recycling mechanism, which shall be capable of disposing of plastic, glass, metal parts, printed circuit boards, wires and cables, heating boards and motors.

⚠ pay attention to:

Only authorized engineers can repair, dismantle, operate and other actions. The equipment will be maintained free only by following safety instructions and cleaning and maintenance instructions. In addition to regular cleaning and maintenance, we recommend that you send the equipment to the company's customer service department for technical maintenance. If the user requests to provide the technical information such as the circuit diagram of the equipment and the list of components due to special needs, please contact the company directly, and the company will provide the corresponding technical data according to the user's requirements.

National after-sales Service Department Telephone number:

6 Appendix List

appendix

A technical specifications

project		
work environment	temperature	5°C~35℃
	relative humidity	10%~95% (non-condensing)
	atmospheric pressure	70kPa~106kPa
	above sea level	0m ～2600m

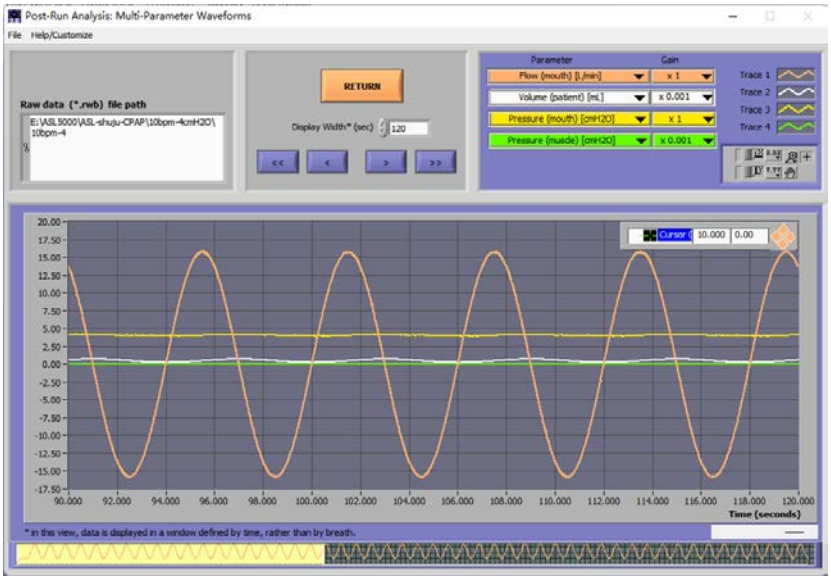
Storage environment	temperature	-25℃ ~ 70℃
	relative humidity	10%~95% (non-condensing)
	atmospheric pressure	70kPa~106kPa
Safety features	Type of shock protection	Adventitia equipment
	Electric shock protection grade	BF mould
	work pattern	continuous work
	Protection grade of fluid intake	IP22
	The safety of the flammable anesthetic gas level	Should not be used in the presence of a flammable anesthetic gas mixed with air or a flammable anesthetic gas mixed with oxygen or nitrous oxide
	Installation and use classification	portable set
	Power connection mode	Adapter has a removable power supply cord
Electrical specifications	AC input	Shenzhen Longxc Power Supply Co., LTD. Adapter model: LXCP90 () -0240416 AC Input: 100～240Vac ， 50/60Hz ， 1.8A max
	DC output	24VDC,4.16A
Run noise	A discharge discharge sound pressure level	30dB(A)±2dB(A)@10cmH2O
	A meter weight sound power level	38dB(A)±2dB(A)@10cmH2O
Physical specifications	Size length * width * height) mm	254.5 mm×159mm×103.5 mm
	weight	About 1.6 kg
	display screen	5-inch TFT, display screen of 640 * 480
	buzzer	Send a prompt sound
	SD card interface	Store the parameters during operation to provide clinical data for engineering analysis and improvement
	SPO2 interface	Connect the SPO 2 module with Bluetooth,

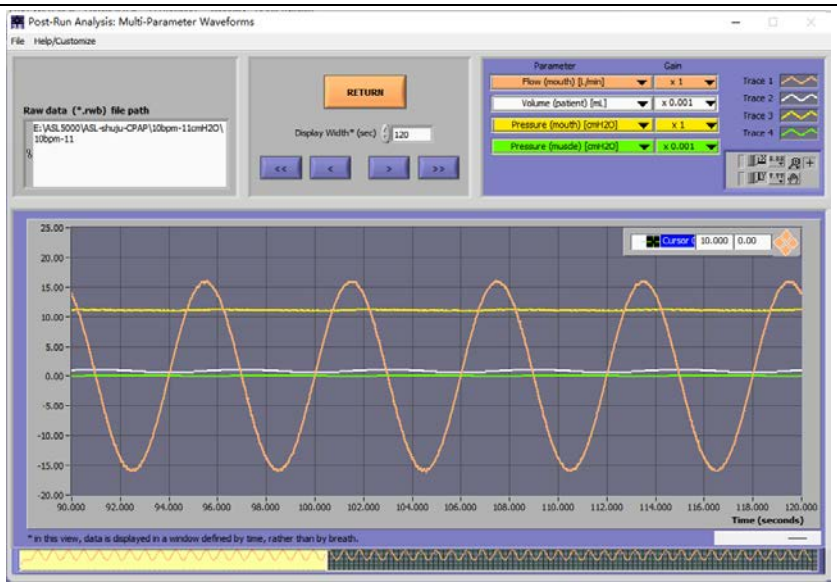
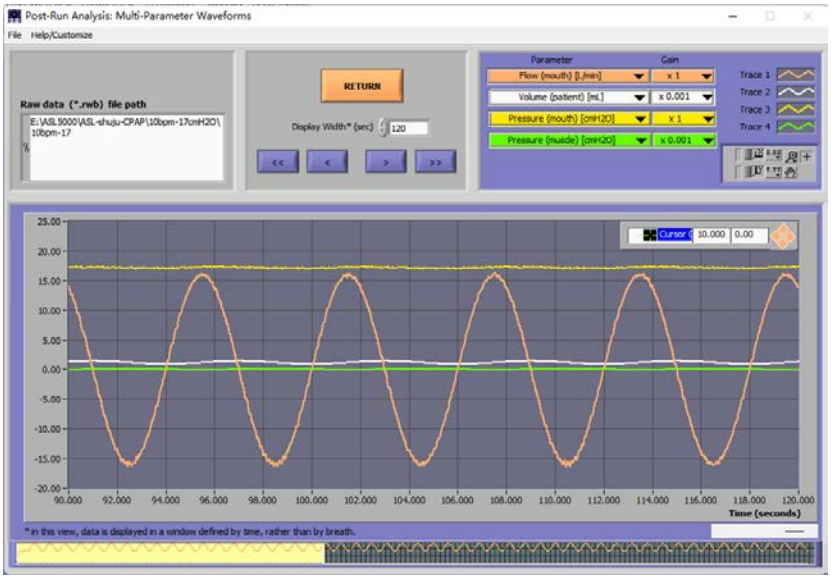
	CO2 interface	Used to connect the external CO2 module, the signal isolation processing
	Pipe heating interface	22mm, conical joint
electromagnetic compatibility	RF emission grade	Group 1, Grade B
pressure (BTPS)	Set the range	4.0-20cmHzO (CPAP)
	Maximum limit pressure	30cmHzO
	Static pressure control accuracy	± 0.5 cmH 20 (worst condition)
	Dynamic pressure control accuracy	.5± 1 cmH 2O (worst condition)
The humidifier	The maximum pressure drop	At 60 LPM flow, 0.3 cmH 2 O
	Minimum humidity output	10mgH2O / L (measured at maximum flow rate, 35℃, 15% relative humidity
	Slot capacity	Up to 285ml ± 15ml
	Maximum temperature of the heating plate	95℃
	Heating protection switch temperature	90℃±10℃
	Maximum gas temperature	≤41℃
	Heating air line disconnection temperature	≤41℃
	maximum working pressure	40cmH2O
	preheating time	1H
Heating pipeline	adaptability	
	air-resistor	2.04cmH2O (at rated flow of 80 LPM)
	maximum pressure	40cmH2O
	bore	15mm
	Tube length	1.83m±0.17m
	heating temperature	16 ~ 30℃

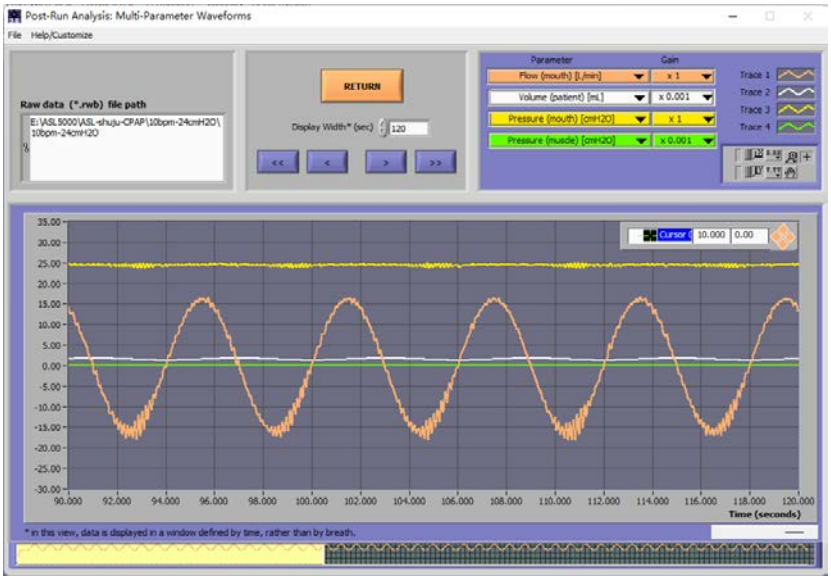
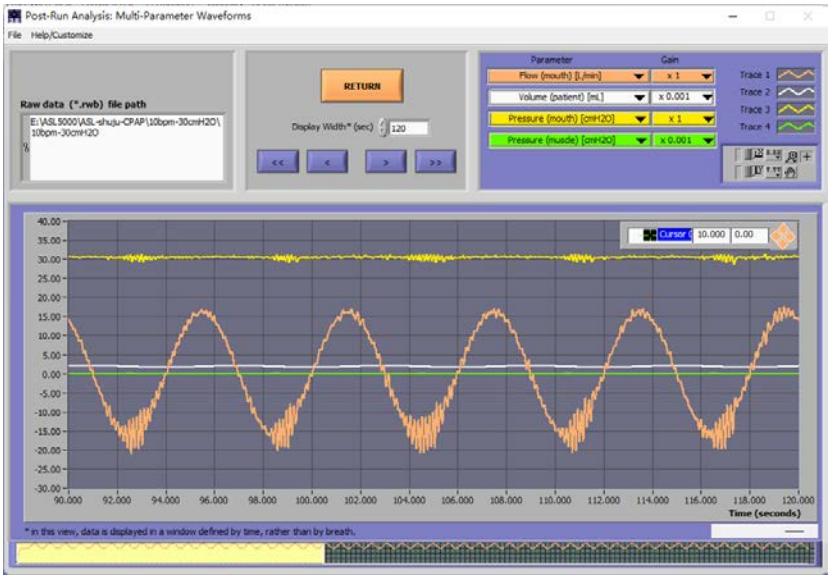
	Air outlet temperature	≤41℃
	matter	Soft plastic tube with heating
rate of flow	Maximum flow rate (maximum adjustable Pressure 1 / 3,2 / 3 and minimum, max)	Model with a maximum pressure of 20cmH2O: 4cmH2O:≥130L/min ; 9cmH2O:≥120L/min 15cmH2O:≥110L/min ; 20cmH2O:≥100L/min Model with a maximum pressure of 25cmH2O: 4cmH2O:≥130L/min ; 11cmH2O:≥120L/min 18cmH2O:≥110L/min ; 25cmH2O:≥100L/min Model with a maximum pressure of 30cmH2O: 4cmH2O:≥130L/min ; 13cmH2O:≥120L/min 21cmH2O:≥100L/min ; 30cmH2O:≥100L/min
tidal volume	Set the range	200-2000 ml, 10 ml step, control error ± 20% set point, capacity guarantee (VA) advanced option available
	Monitoring scope	From 0-2000 ml, at 1 ml resolution, the error is ± 20% of the monitored value, and the double-level mode applies
minute ventilation	Set the range	2-30 L/min, step length 0.5 L / min, precision ± 20% of set value, adaptive support ventilation (ASV) advanced option available when on
	Monitoring scope	0-30 L/min, with a resolution of 0.1L / min, with an accuracy of ± 20% of the monitored value, and the double-level mode applies
bacteria proof filter	Rated flow rate is 30 L/min	Upper limit of low resistance pressure is 1cmH2O
		Upper limit of high efficiency pressure is 1.5cmH2O

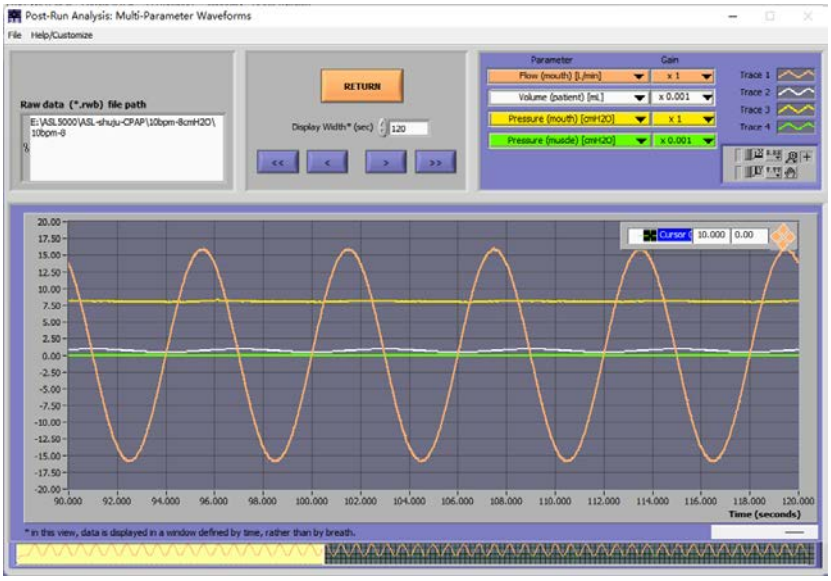
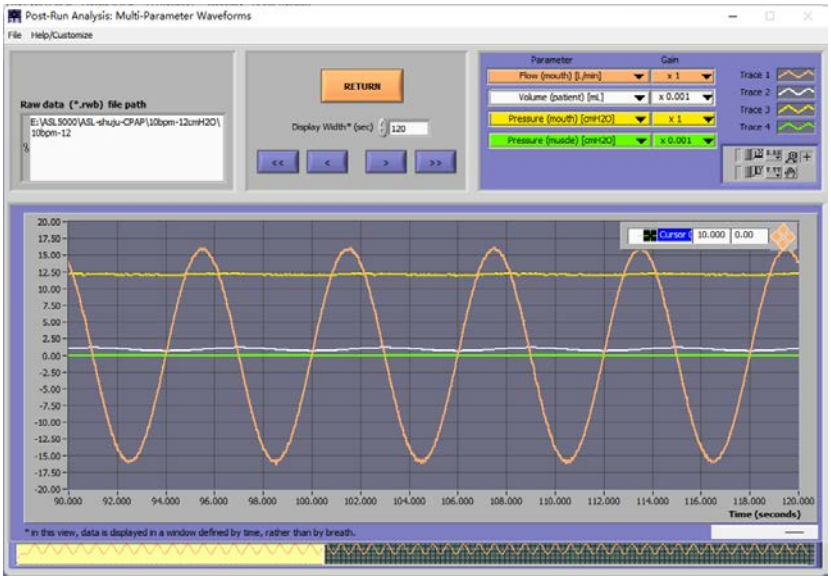
B Pressure capacity curve:

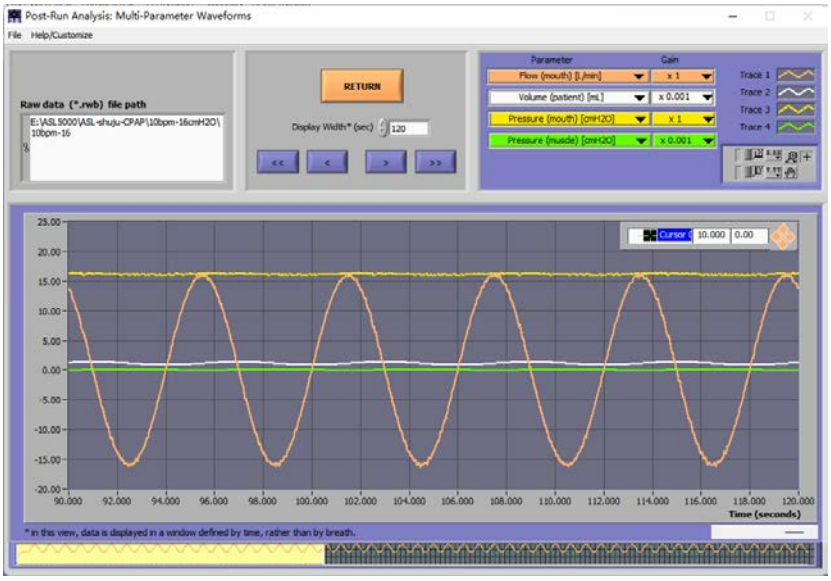
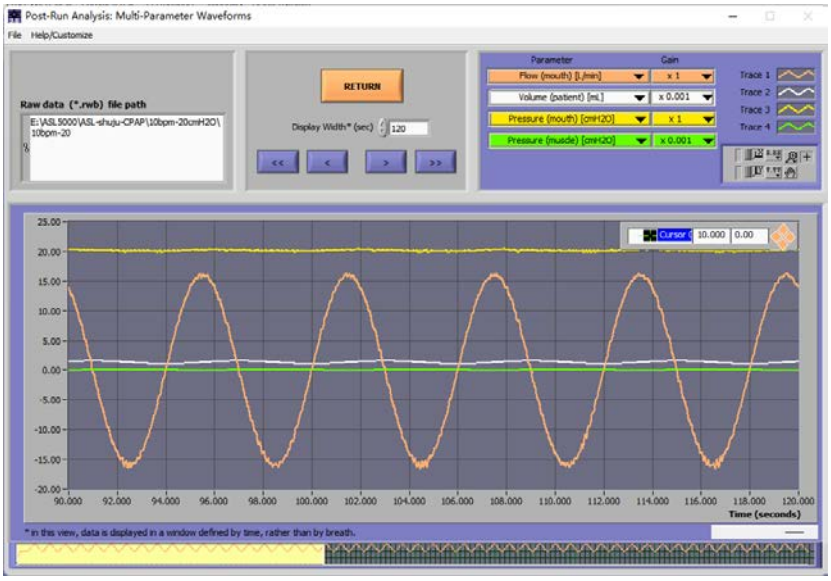
CPAP pattern:

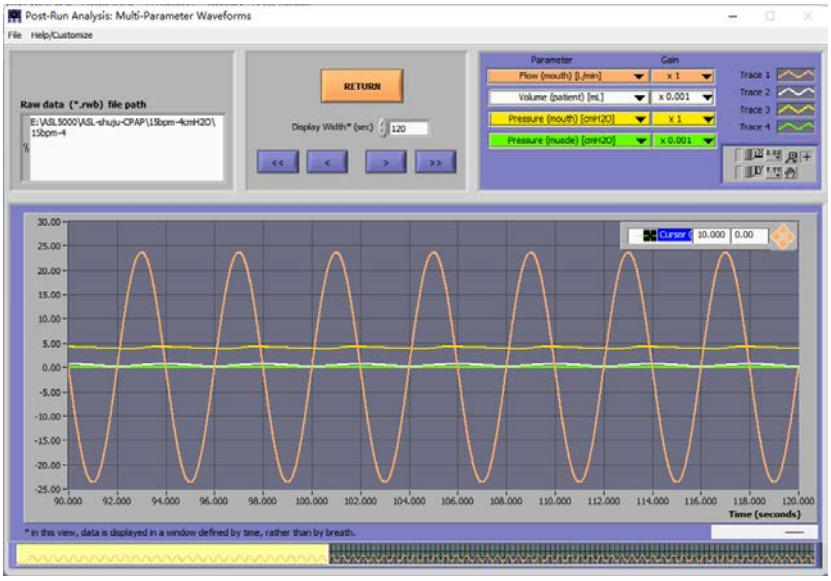
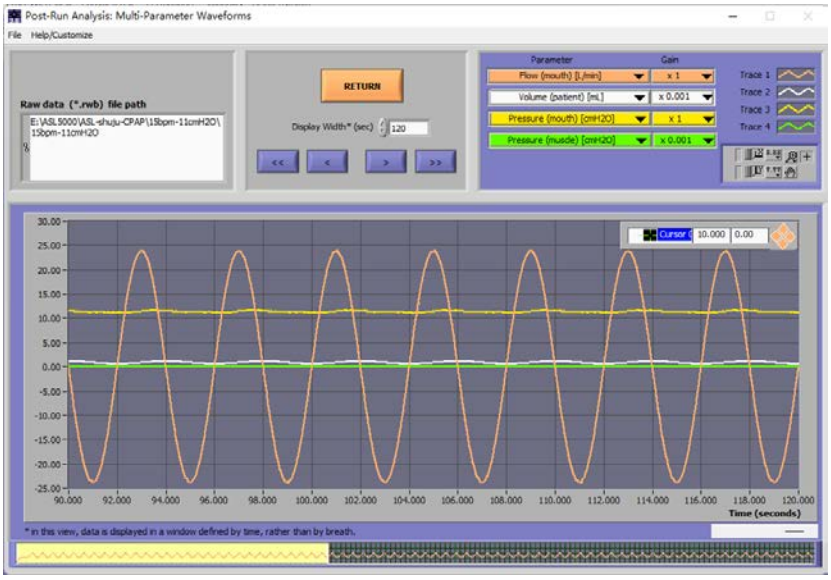
Suitable for all the models	Fractional ratio of the maximum adjustable pressure
	4cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	11cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500

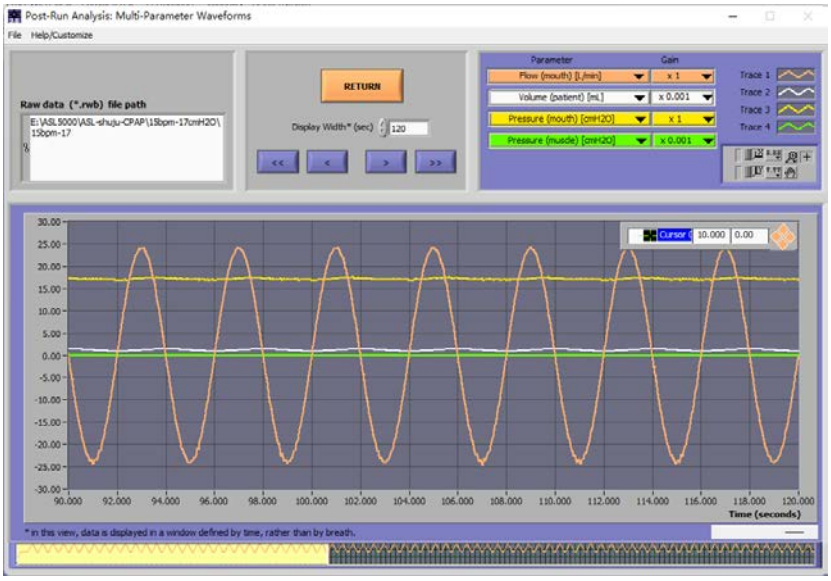
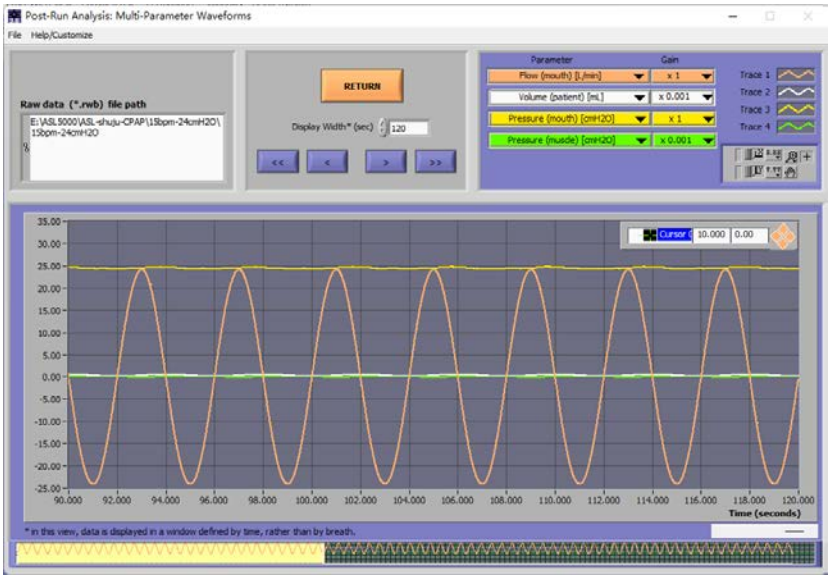
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	17cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	24cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500

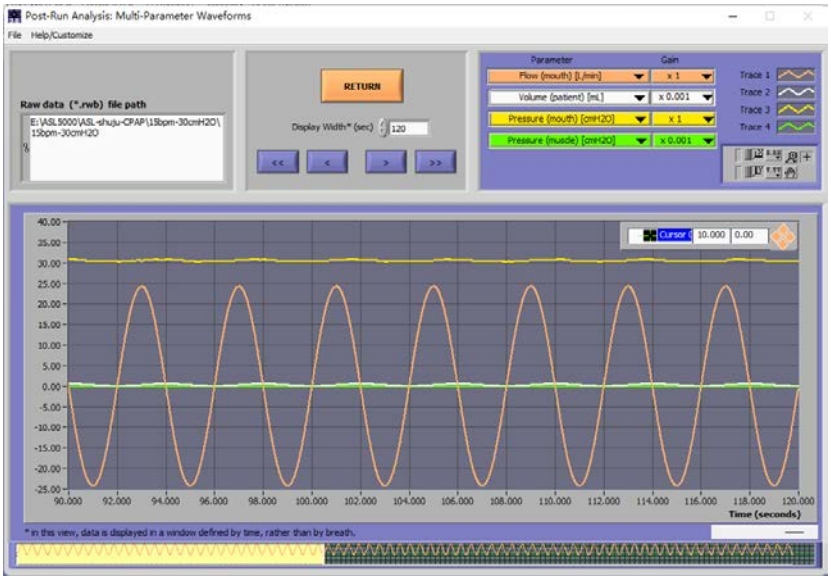
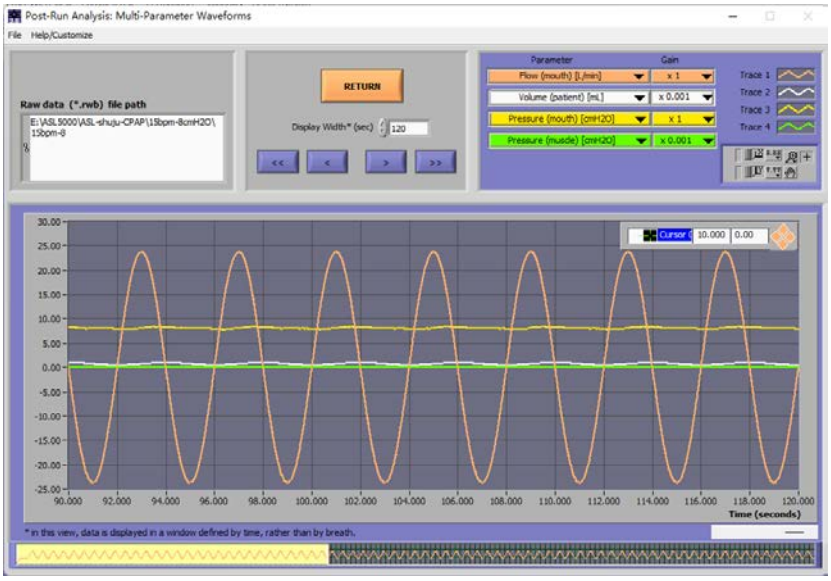
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	30cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	8cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500

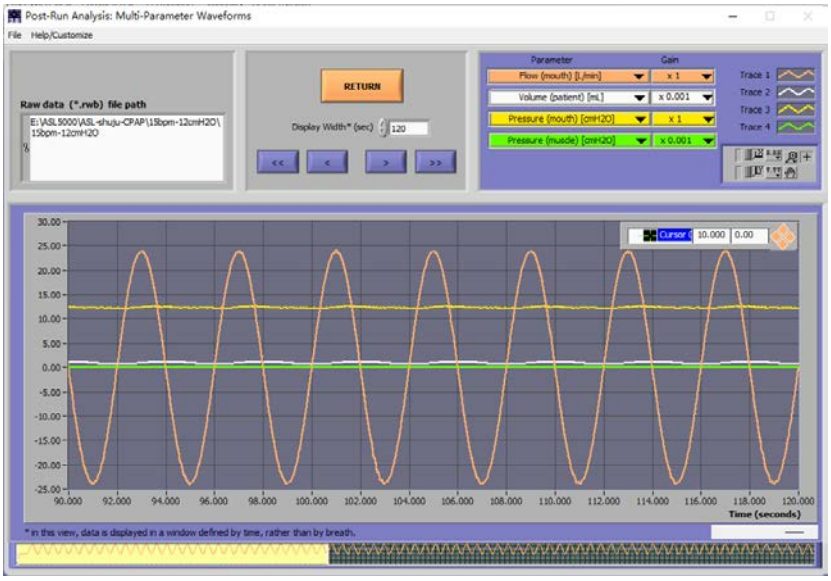
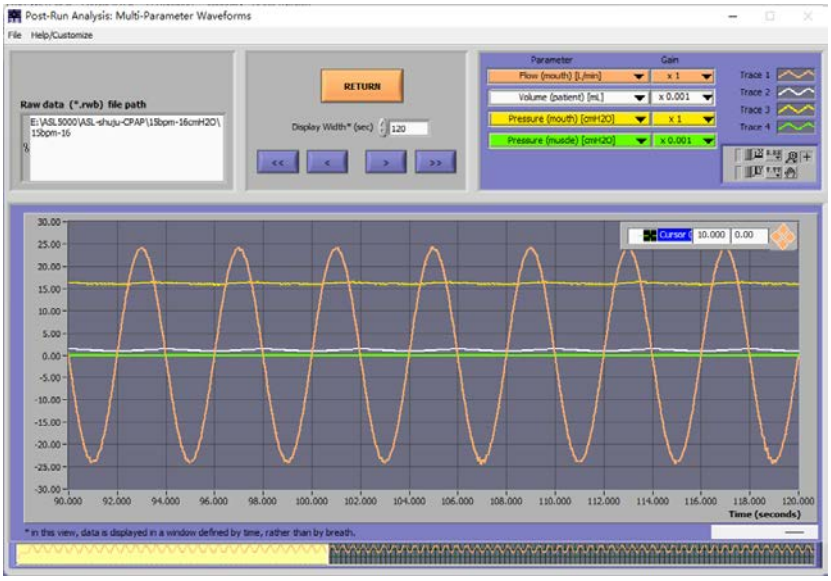
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	12cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	16cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500

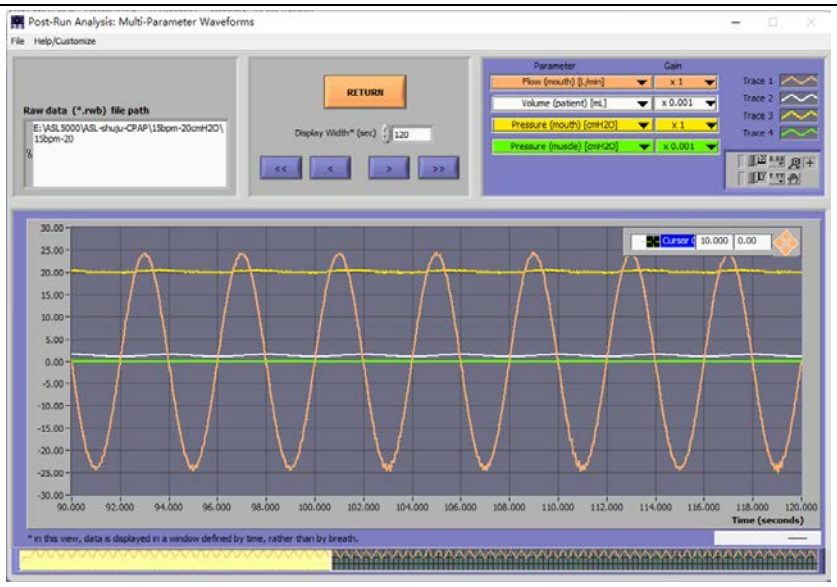
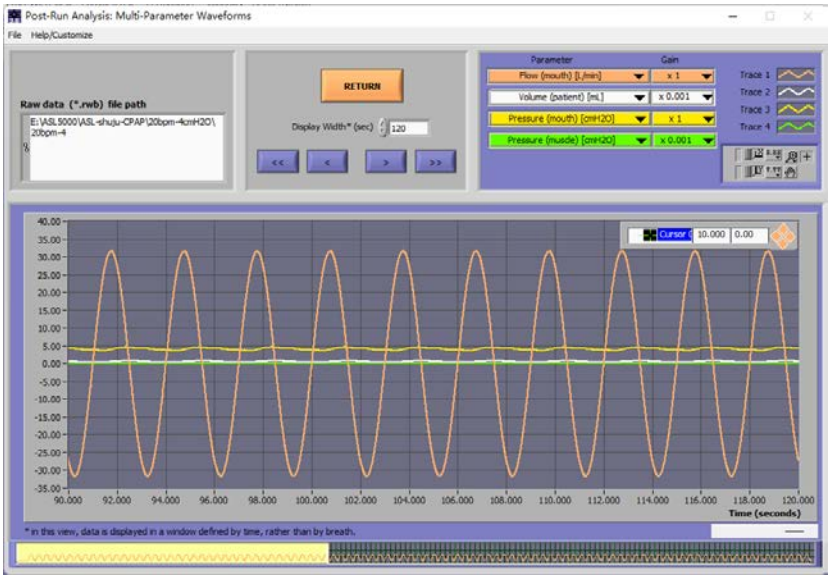
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	20cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for all the models	Fractional ratio of the maximum adjustable pressure
	4cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

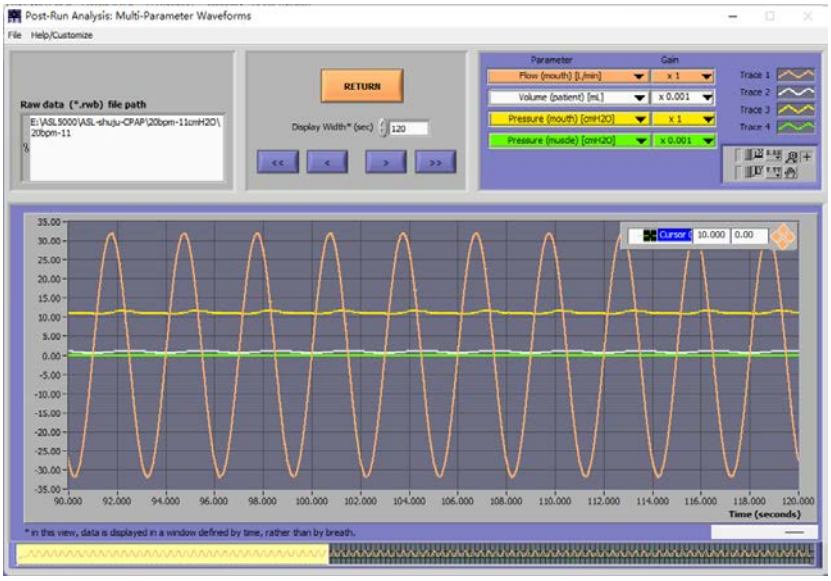
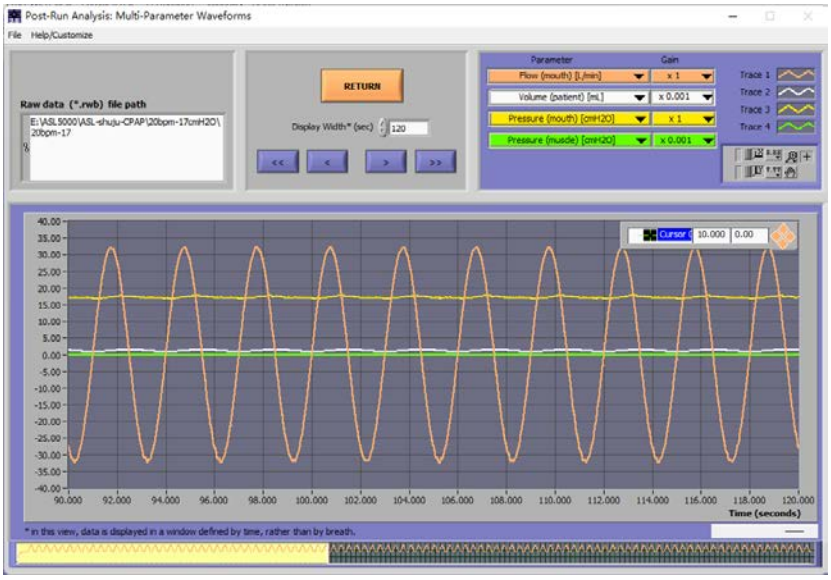
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	11cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	17cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

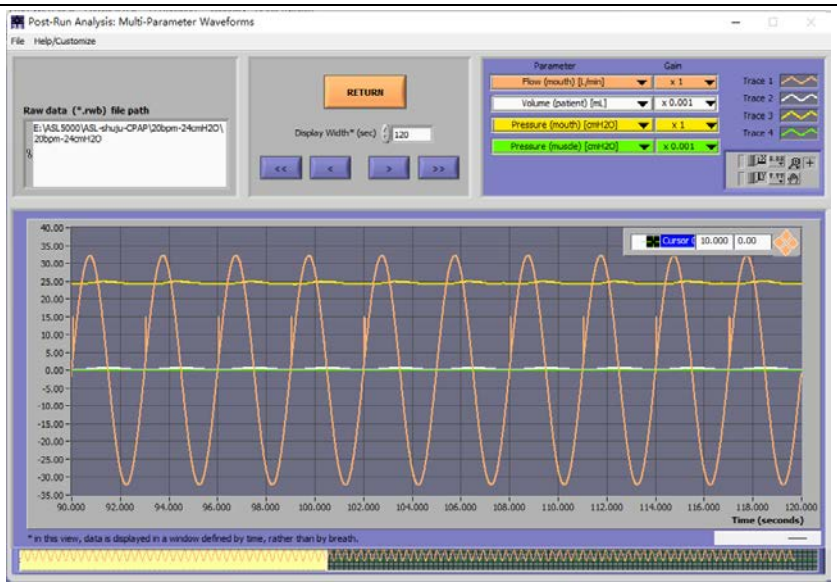
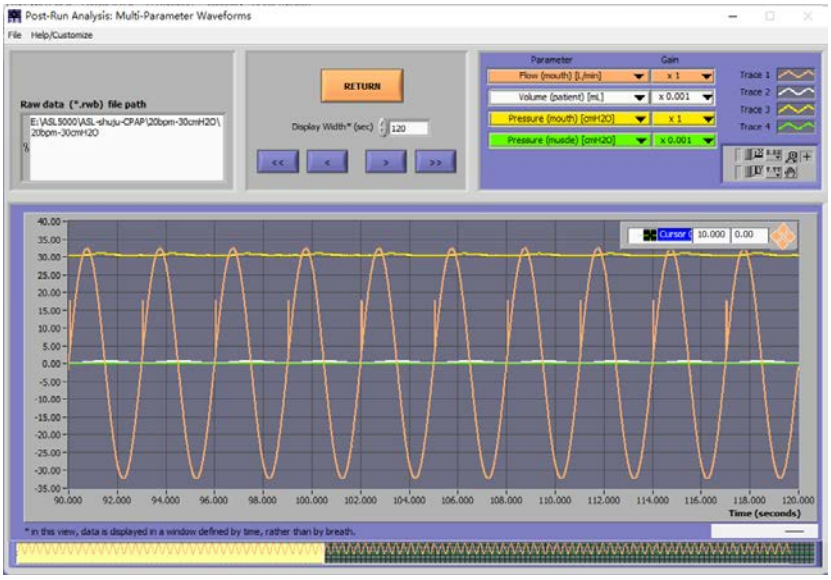
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	24cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	30cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

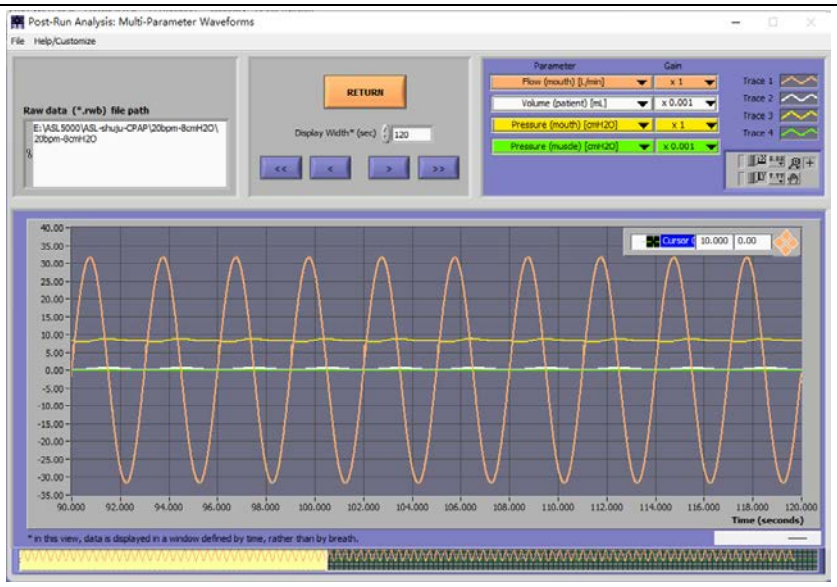
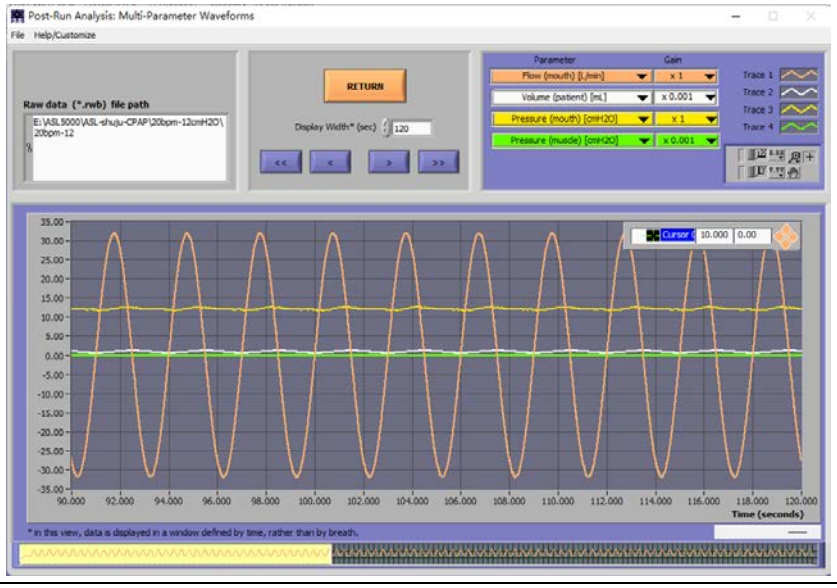
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	8cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	12cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

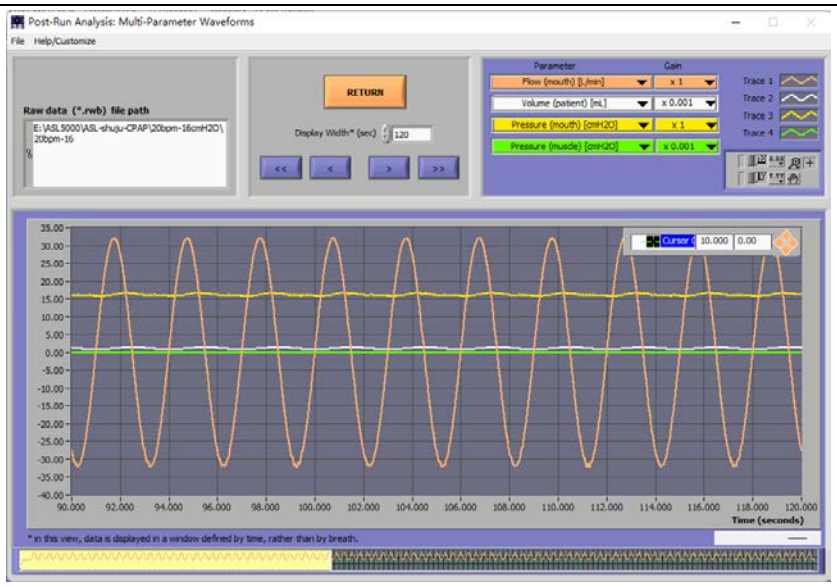
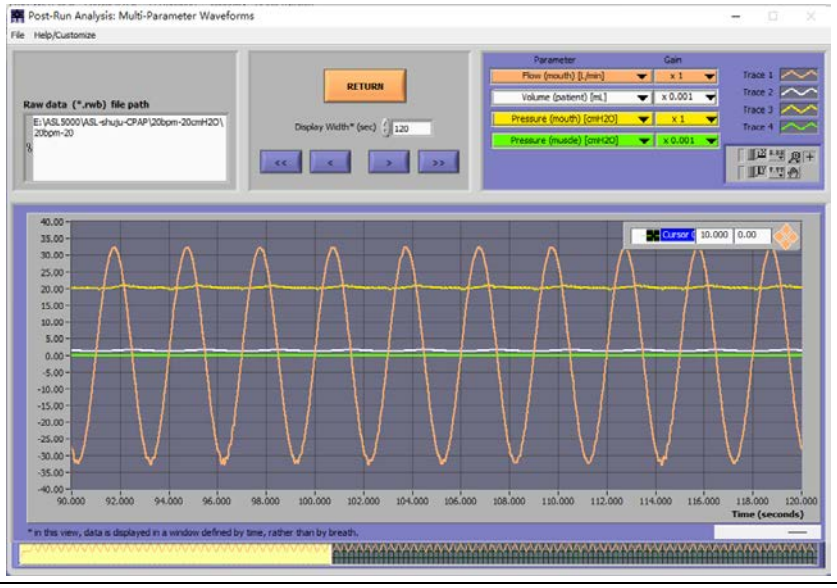
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	16cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	20cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Suitable for all the models	Fractional ratio of the maximum adjustable pressure
	4cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	11cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	17cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	24cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Suitable for HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	30cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	8cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

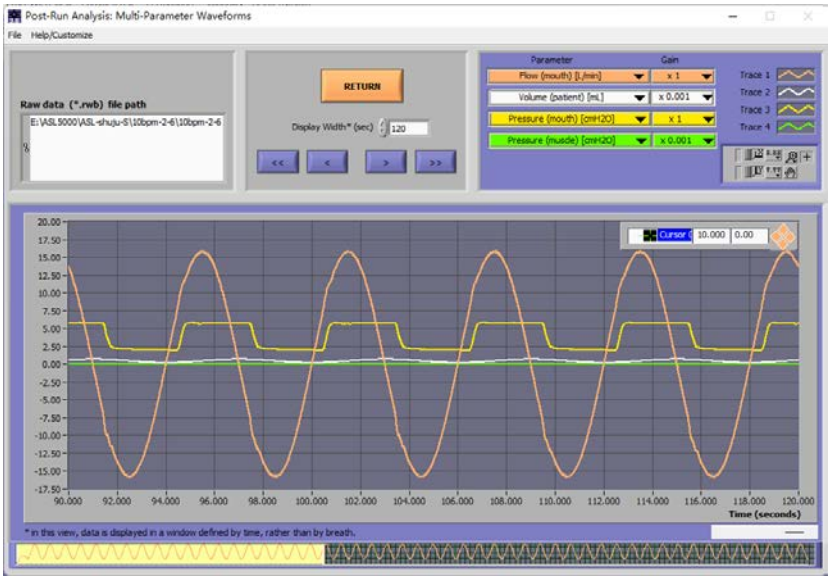
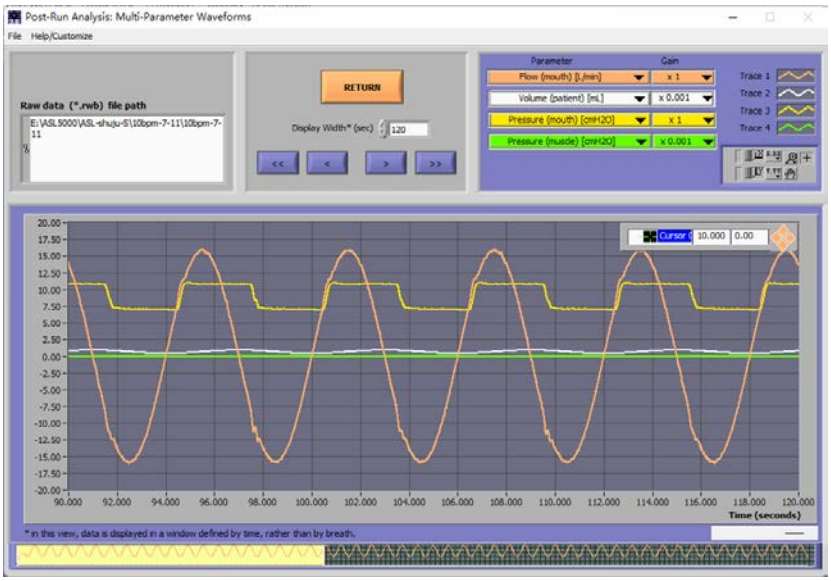
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	12cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	16cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

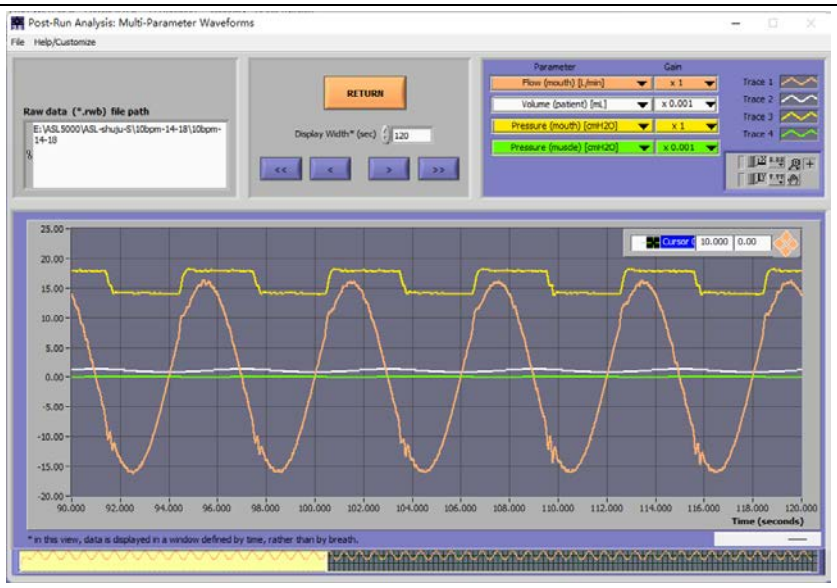
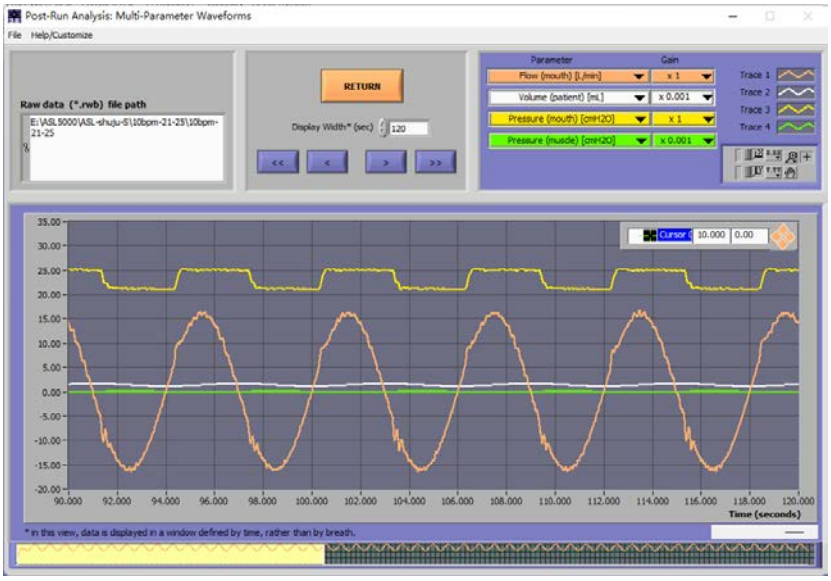
Pressure / volume curves and respiratory pressure change plots	
For all models except the HM-ST30Pro	Fractional ratio of the maximum adjustable pressure
	20cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	

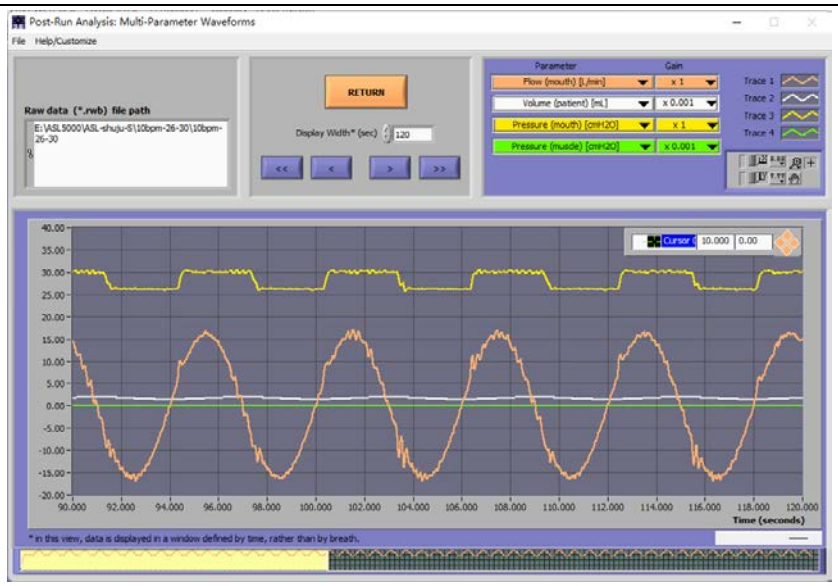
Double-level positive airway pressure pattern:

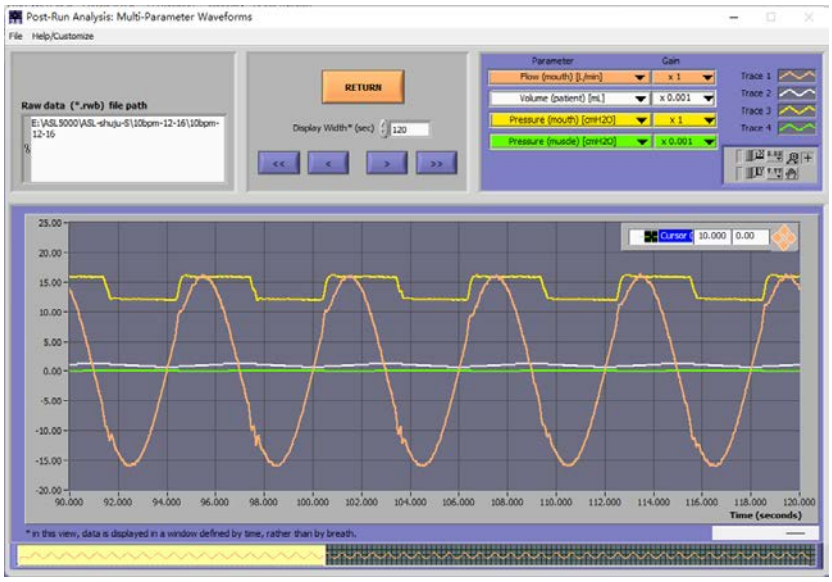
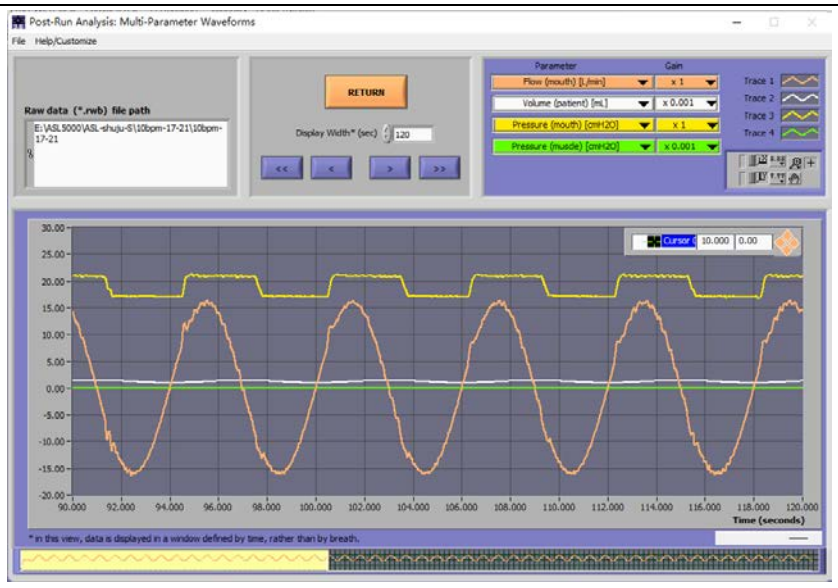
Model Series 1: refers to models with maximum inspiratory pressure of 30cmH2O including HM-B30A, HM-BA30, HM-BA30A, HM-B30C, HM-BA30C, HM-ST30, HM-STA 30, HM-ST30Pro.

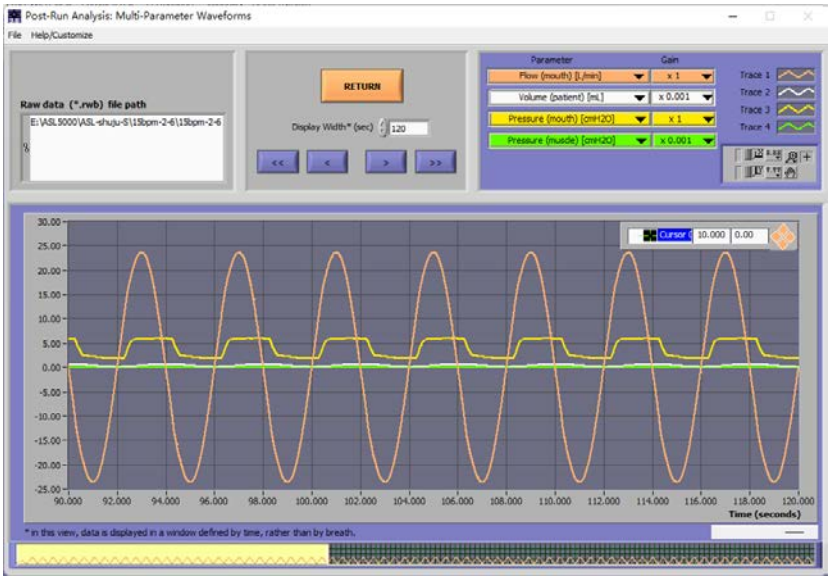
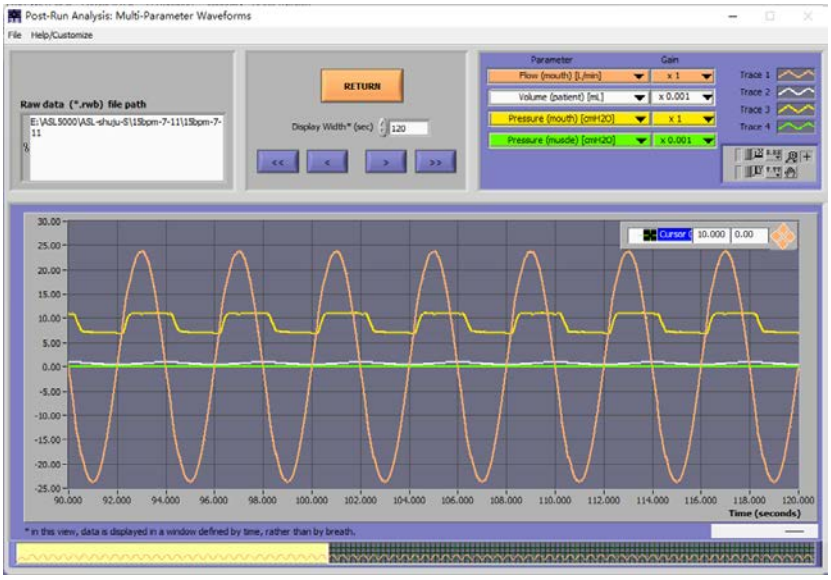
Model Series 2: refers to models with maximum inspiratory pressure of 25cmH2O, including HM-B25, HM-B25A, HM-BA25, HM-BA25A, HM-B25C, HM-BA25C, HM-ST25, HM-STA 25.

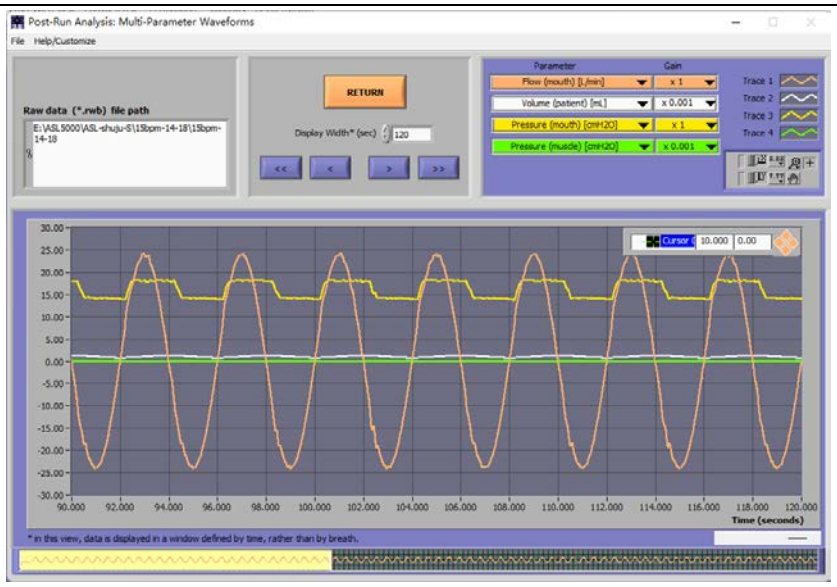
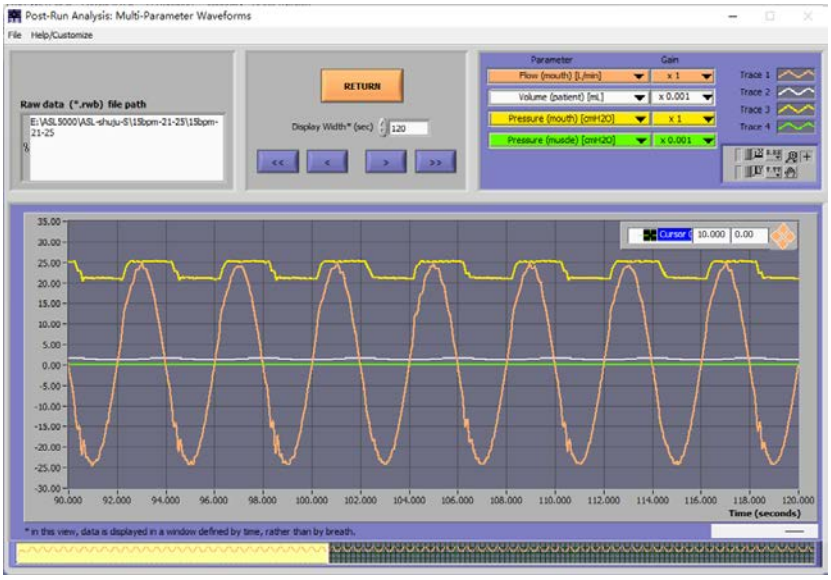
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 6cmH2O; expiratory phase 2cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 11cmH2O; expiratory phase 7cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure

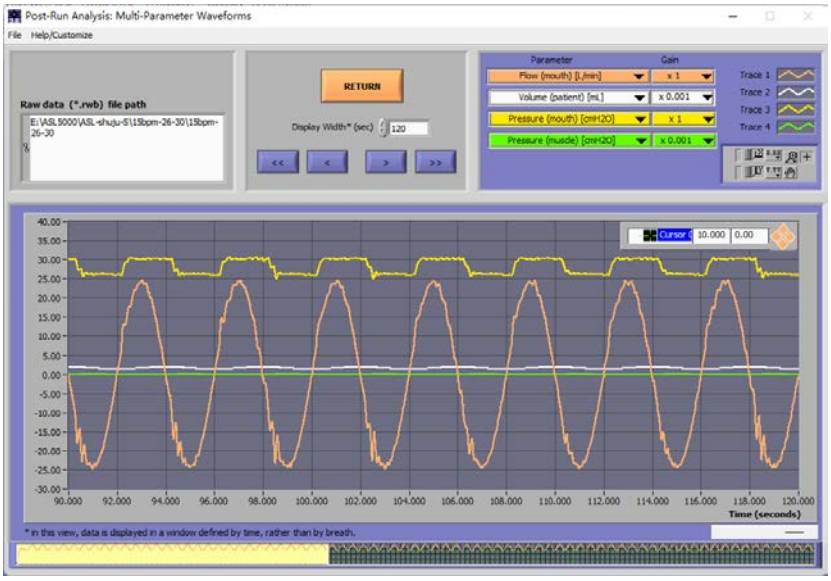
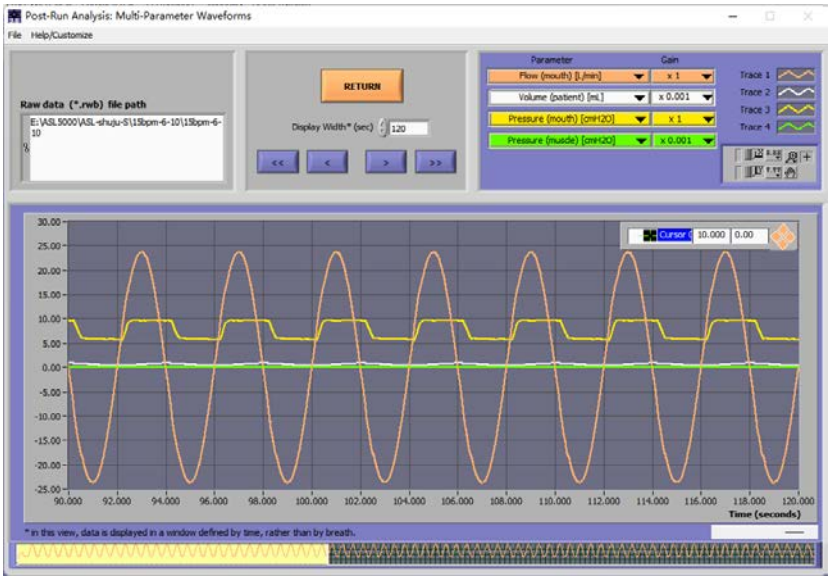
	Inspiratory phase 18cmH2O; expiratory phase 14cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 25cmH2O; expiratory phase 21cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 30cmH2O; expiratory phase 26cmH2O
f breathing rate /	10

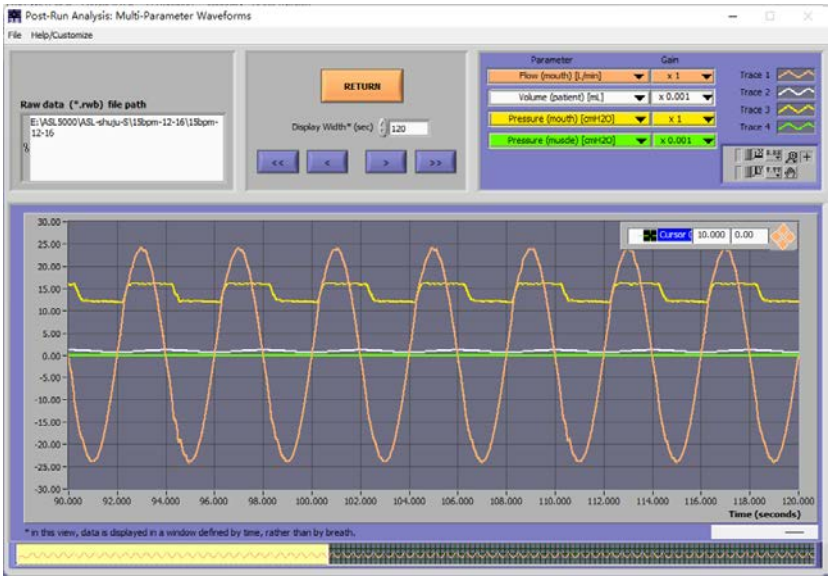
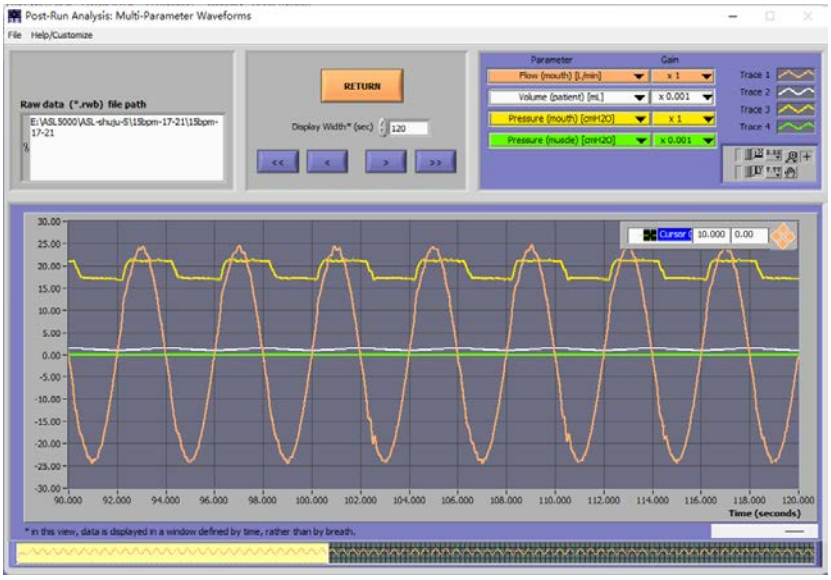
(Number of breaths / min)	
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 10cmH2O; expiratory phase 6cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 16cmH2O; expiratory phase 12cmH2O
f breathing rate / (Number of breaths / min)	10

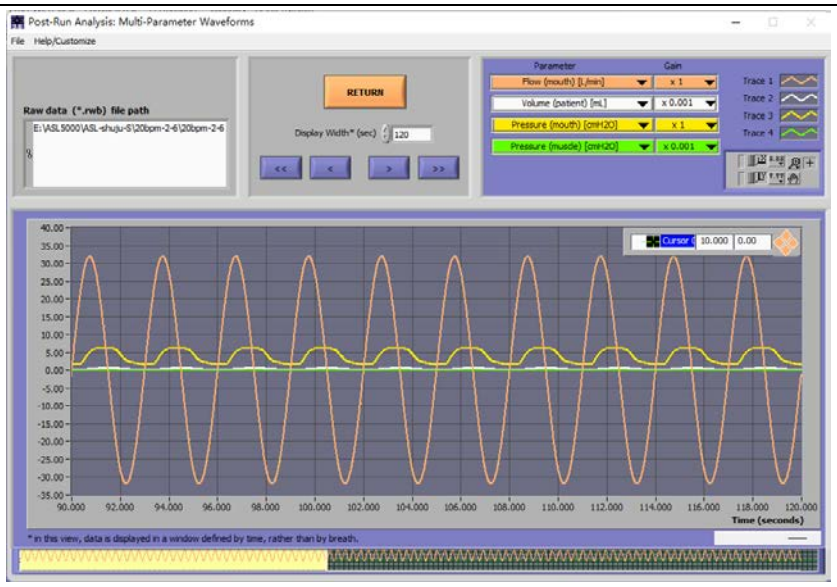
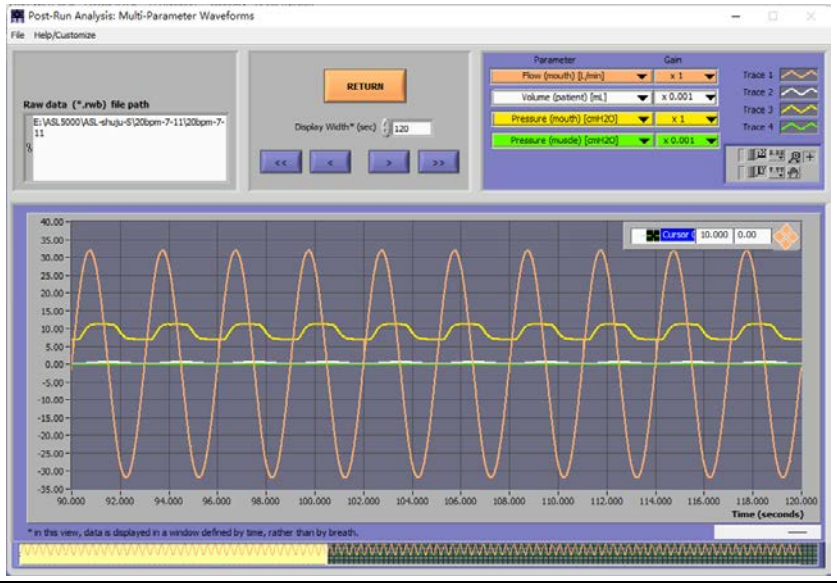
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 21cmH2O; expiratory phase 17cmH2O
f breathing rate / (Number of breaths / min)	10
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 6cmH2O; expiratory phase 2cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

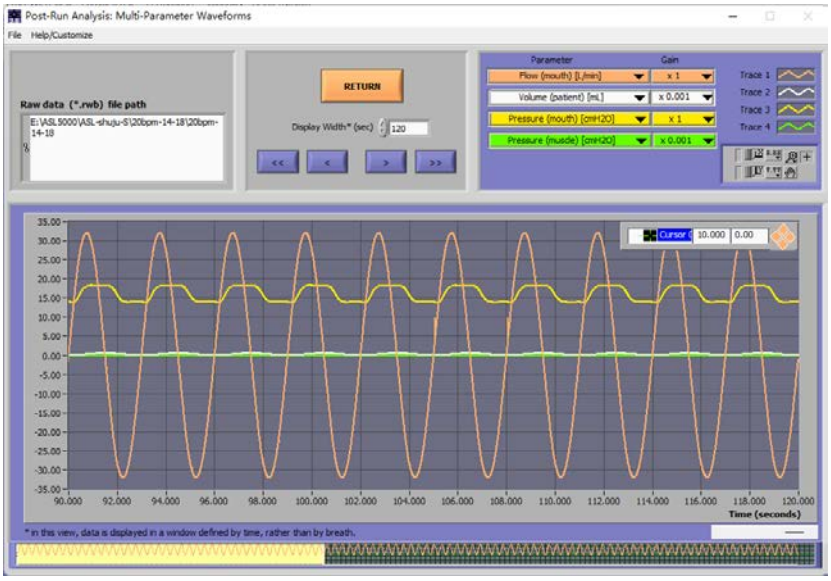
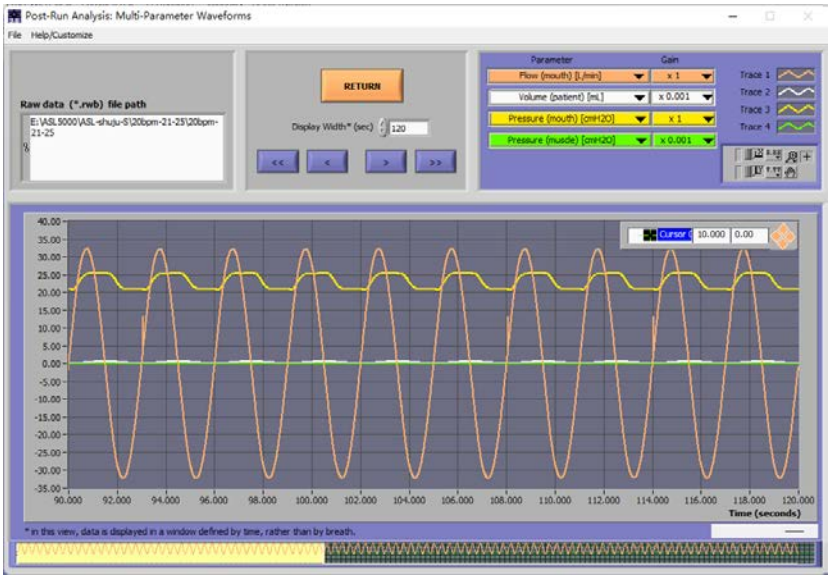
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 11cmH2O; expiratory phase 7cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 18cmH2O; expiratory phase 14cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

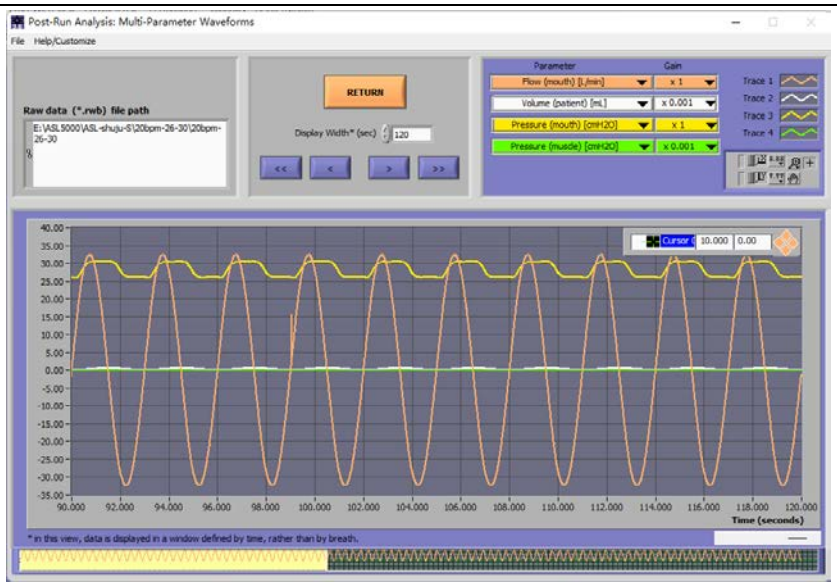
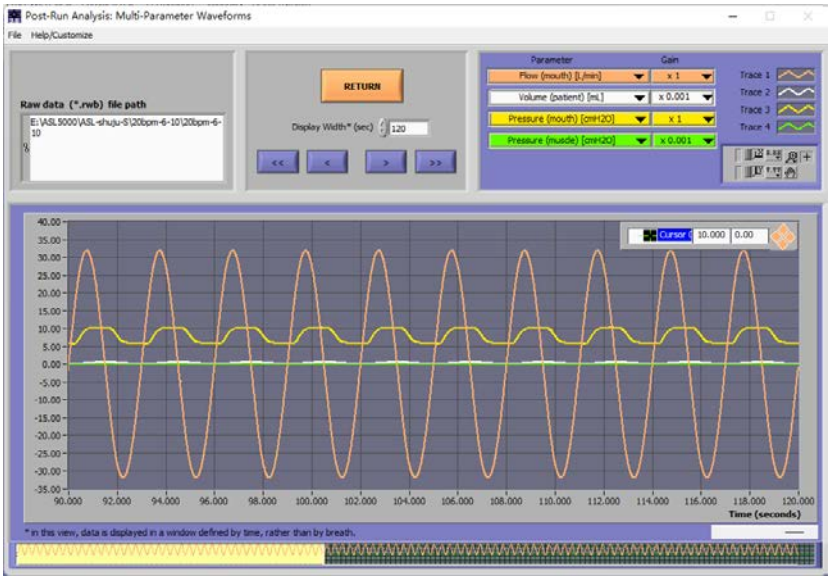
Pressure / volume curves and respiratory pressure change plots	
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 25cmH2O; expiratory phase 21cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 30cmH2O; expiratory phase 26cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

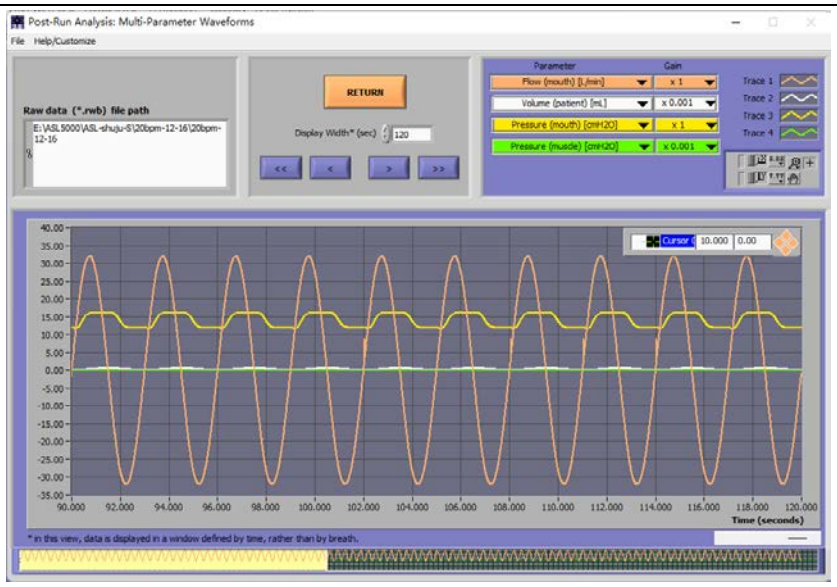
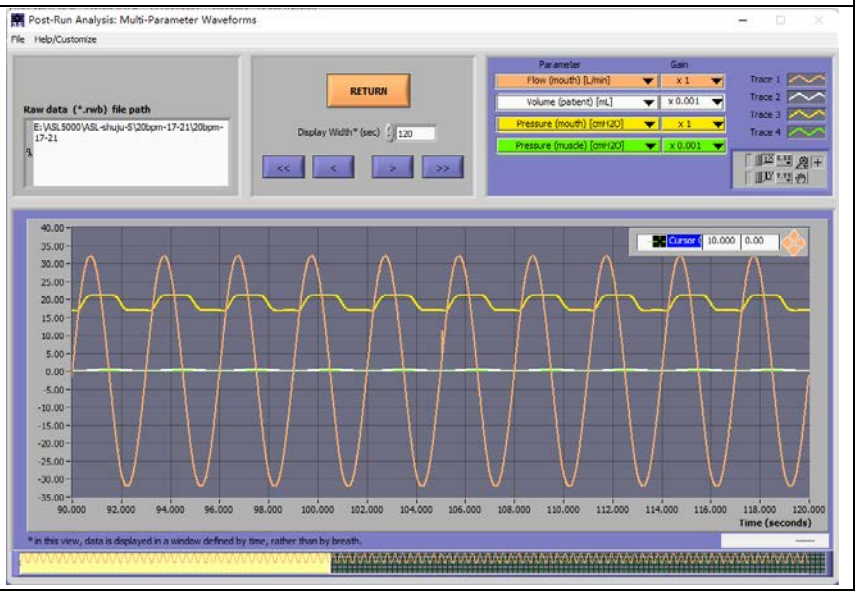
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 10cmH2O; expiratory phase 6cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 16cmH2O; expiratory phase 12cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 21cmH2O; expiratory phase 17cmH2O
f breathing rate / (Number of breaths / min)	15
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 6cmH2O; expiratory phase 2cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 11cmH2O; expiratory phase 7cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 18cmH2O; expiratory phase 14cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
All models	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 25cmH2O; expiratory phase 21cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 1	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 30cmH2O; expiratory phase 26cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 10cmH2O; expiratory phase 6cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 16cmH2O; expiratory phase 12cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500

Pressure / volume curves and respiratory pressure change plots	
Model Series 2	Fractional ratio of the maximum adjustable pressure
	Inspiratory phase 21cmH2O; expiratory phase 17cmH2O
f breathing rate / (Number of breaths / min)	20
Vt tidal volume /ml	500
Pressure / volume curves and respiratory pressure change plots	

C. Electromagnetic compatibility information is in compliance with radio management

C.1 Electromagnetic compatibility

⚠ Note: Positive pressure ventilation treatment machine meets the requirements of YY 9706.102-2021 standard electromagnetic compatibility.

⚠**pay attention to:**This equipmentand so onbasicfunctionFor:

Static pressure error of the patient connector: the static pressure error shall be ± 0.5 cmH_2O

⚠ Note: Users should install and use the EMC information provided in the random documents.

⚠ Note: Portable and mobile RF communication equipment may affect the performance of positive pressure ventilation treatment machine, and avoid strong electromagnetic interference, such as close to mobile phones, microwave oven, etc.;

⚠ Note: Guidelines and manufacturer statements are detailed in the attachment.

⚠ Warning: Positive pressure ventilation machine should not be used near or stacked with other equipment. If it must be used near or stacked, verify normally in the configuration used.

⚠ Warning: The use of unspecified accessories and cables may increase the cables sold by the manufacturer for the internal components.

Guidance and manufacturer's declaration of electromagnetic emission: The positive pressure ventilation treatment machine is intended to be used in the following specified electromagnetic environment. Users of this device shall ensure that the device is used in such an electromagnetic environment.

Launch test	compliance	The Electromagnetic Environment-A Guide to the
The RF emission of GB 4824 CISPR 11	Group 1	The positive pressure ventilator uses RF energy only for its internal function. Thus, its RF emission is low and has little chance of interference with nearby electronics
The RF emission of GB 4824 CISPR 11	B class	The positive pressure ventilation treatment machine is suitable for use in all buildings, including home buildings and buildings directly connected to the public low-voltage power supply grid.
The harmonic emission occurs at GB 17625.1 IEC 61000-3-2	A class	
Voltage fluctuation / flicker emission GB 17625.2 IEC 61000-3-3	accord with	

Guidance and manufacturer's declaration of electromagnetic immunity: Positive

pressure ventilation treatment machine is intended to be used in the following specified electromagnetic environments. Users of this device shall ensure that the device is used in such an electromagnetic environment.

immunity test	IEC 60601 Test level	In line with the level	Guide to the electromagnetic environment
Electrostatic discharge (ESD) GB/T 17626.2 IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The ground shall be wood, concrete or tile, and at least 30% if covered with synthetic material.
Electric fast transient pulse population GB/T 17626.4 IEC 61000-4-4	± 2kV, to the power cord ± 1kV for the input / output lines	± 2kV, to the power cord	Grid supply shall be of quality used in typical commercial or hospital settings.
surge GB/T 17626.5 IEC 61000-4-5	± 1 kV line to line The ± 2 kV line faces the ground	± 1 kV line to line	Grid power shall be of quality used in typical commercial or hospital settings.
Power input line power Pressure temporary drop, short time and medium time Broken and voltage changes GB/T 17626.11 IEC 61000-4-11	<5% UT, for 0.5 cycles (On UT,> 95% down) 40% UT, which was continued for 5 cycles (On UT, 60% down) 70% UT, which was continued for 25 cycles (On UT, 30% down) <5% UT and continued for 5s (On UT,> 95% down)	<5% UT, for 0.5 cycles (On UT,> 95% down) 40% UT, which was continued for 5 cycles (On UT, 60% down) 70% UT, which was continued for 25 cycles (On UT, 30% down) <5% UT and continued for 5s (On UT,> 95% down)	Grid power shall be of quality used in typical commercial or hospital settings. If a user (equipment or system) requires continuous operation during power interruption, recommend (equipment or system).
Power frequency magnetic field （50/60Hz） GB/T 17626.8 IEC 61000-4-8	3A/m	3A/m,50/60Hz	The power frequency magnetic field shall have horizontal characteristics in a typical commercial or hospital setting.
Note: UT is the AC net voltage before the test voltage is applied			

Guidance and manufacturer's declaration of electromagnetic immunity: Positive pressure ventilation treatment machine is intended to be used in the following specified electromagnetic environments. Users of this device shall ensure that the device is used in such an electromagnetic environment.

immunity test	IEC 60601 Test level	In line with the level	Guide to the electromagnetic environment
RF conduction GB/T 17626.6 IEC 61000-4-6 radio-frequency radiation GB/T 17626.3 IEC 61000-4-3	3 V (valid value) 150 kHz ～ 80 MHz 3V/m 80 MHz ～ 2.5 GHz	3V (valid value) 3V/m	Portable and mobile RF communication devices should not exceed the recommended isolation distance Use from any part of the positive pressure machine, including electricity cable. The distance is calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance d =1.2 √ P d =1.2 √ P 80 MHz ～ 800 MHz d =2.3 √ P 800 MHz ～ 2.5 GHz In formula: P-maximum according to the transmitter manufacturer Rated output power, measured in watt (W); D- -The recommended isolation distance is measured i  (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field station A to determine that at each frequency range b should be lower than the coincidence level. Interference may occur near the equipment marking the following symbols

Note 1: Formula at 80 MHz and 800 MHz.

Note 2: These guidelines may not be suitable for all situations, and the electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and human bodies.

A The field strength of stationary transmitters, such as wireless (cellular / cordless) telephone and ground mobile radio base stations, amateur radio, amplitude and FM radio radio and television radio, is not accurately predicted in theory. In order to evaluate the electromagnetic environment of the fixed RF transmitter, the survey of the electromagnetic field should be considered. If the field strength of the PEEP site is higher than the applicable RF compliance level mentioned above, the PEEP should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be required, such as readjust the orientation or position of the positive pressure ventilation ventilator.

B In the entire frequency range of 150 kHz to 80 MHz, the field strength should be lower than 3V / m.

Recommended isolation distance between portable and mobile RF communication equipment and positive pressure ventilation therapy machine: Positive pressure ventilation therapy machine is suitable for controlled electromagnetic environments. Depending on the maximum rated output power of the communication equipment, the buyer or user may prevent electromagnetic interference by maintaining the minimum

distance between the portable and mobile RF communication equipment (transmitter) and the positive pressure ventilation treatment machine as recommended below.

The transmitter is the most rated Large output power / W	Isolation distance / m for the different frequencies of the corresponding transmitter		
	150 kHz ～ 80 MHz d =1.2 √P	80MHz ～ 800 MHz d =1.2 √P	800MHz ～ 2.5GHz d =2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency bar, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).

Note 1: High frequency band 1 formula at 80 MHz and 800 MHz frequency points.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.

Standard compliance
IEC 60601-1 General safety requirements for medical electrical equipment
IEC 60601-1-2 Electromagnetic compatibility
EN ISO 17510-1 Sleep Apnea Respiratory therapy device
ISO 3744
ISO 4871
RTCA / DO-160F Article 21, Class M; emission of RF energy

C.2. Radio management compliance

RF parameter for RED

project	description
	Wireless module
Emission frequency or frequency band (MHZ)	2412~2472MHZ

Modulation type	DSSS;OFDM
Effective radiation power (dBm)	802.11b: 17± 2 dBm (@11Mbps) 802.11g: 14± 2 dBm (@54Mbps) 802.11n: 13± 2 dBm (@MCS7)

The wireless module (model: ESP32-S) used in this equipment complies with the main requirements of Directive 2014 /53/ EU and other relevant clauses.

⚠ Warning: When using the wireless module function of the device, the distance from the human body is greater than 20cm.

FCC Compliance Statements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

RF Exposure Compliance for positive pressure ventilation machine

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This equipment should be installed and operated with minimum distance 20cm between the radiator.

RF Exposure Compliance for oximeter

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.