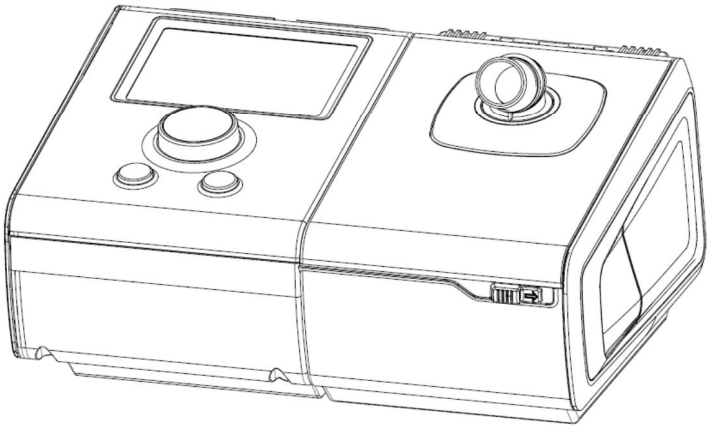
Lotus™

Bi-level Positive Airway Pressure Device

ST30/25/20 USER MANUAL

CE 0123



CURATIVE

Attention: Before first using the device, it is necessary to read the user manual carefully. Keep the manual in a safe place so that you can refer to it whenever necessary.

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Chapter 1: Introduction

1.1 Symbol Description

Symbol	Description	Symbol	Description
	Manufacturer		Date of Manufacture
	Attention, consult accompanying documents		DC POWER
SN	Serial Number		Alarm mute
	Type BF Applied Part		Ramp of CPAP therapy
IP21	Protected against dripping water		Caution, hot surface
	Class II for Protection against Electric Shock	CE 0123	European Declaration of Conformity
EC REP	Authorised representative in the European community	REF	Catalogue Number
LOT	BATCH CODE		Separate collection for the electrical and electronic equipment per EC Directive 2002/96/EC.

1.2 Glossary

IPAP	Inspiratory Positive Air Pressure
EPAP	Expiratory Positive Air Pressure
CPAP	Continuous Positive Air Pressure
VT	Tidal Volume
ml	Milliliters, a unit of measure for volume in Lotus device
MV	Minute Ventilation
BPM	Breaths per minute
LK	Leakage Volume per minute
Lpm	Liters per minute, a unit of measure for leak in Lotus device
ISLP	Inspiratory Slope, speed of rising pressure
ESNS	Expiration Sensitivity, the sensitivity of expiration triggering
MODE	Mode of Operation

IE	Inspiratory Time % of Respiratory Cycle, this shows the percentage of inspiration time in a respiration cycle, applicable with T, ST, APCV modes
RAMP	A mechanism of time - delayed pressure rise to therapeutic Pressure, to improve patient comfort. RAMP Delay shall be defined by RAMP duration time and gradually increase from 4.0cmH_2O. The user shall be able to adjust the ramp duration time.
AUTO ON	When the AUTOON feature is selected, the device shall begin to deliver CPAP therapy as soon as the system detects an inhaled breathe in the air pathway.
Locked Mode	Locked Mode is a state where the features and parameters of the Lotus device cannot be changed unless the device is unlocked. This prevents accidental changes to be made while the device is functioning.
Unlocked Mode	Unlocked Mode is a state where the features and parameters of the Lotus device can be changed freely
LowMV	Low minute ventilation alarm
LowVT	Low tidal volume alarm
Power Fail	System Alarm indicating a Power Failure Condition
MaskOff	System Alarm indicating a mask - removed condition
HiPRES	High pressure alarm, for airway pressure that is 3 cm H2O higher than the IPAP setting for a time period longer than 1 second
APNEA	Apnea alarm
Standby Mode	Power is connected to the system, display is active, motor is not running
SD Card	Secure Digital data storage card for data transfer. SD Card should be formatted as FAT32 file system before use.

1.3 Indication / Contraindications

Indication

Lotus ST30/25/20 is designed for the treatment of sleep apnea and/or hypopnea syndrome. It reduces the frequencies of sleep apnea/hypopnea and increases nocturnal SaO2. It is intended to be used in the home or hospital/institutional environment.

Heated humidifier is an accessory for Lotus ST30/25/20, which is intended to reduce nasal dryness and irritation by adding moisture to the airflow.

Contraindications

- Pneumothorax
- Air in mediastinum
- Cerebrospinal fluid leakage, air in skull
- Extremely low blood pressure or shock
- Confusion or coma, not able to cooperate or accept mask
- Excessive secretions in the airway as well as not coughing effectively, weak voluntary breathing

Contact your medical professional if you have any question.

1.4 Warnings

- The device is not used for life support and not suitable for emergency use.
- The device must be used under the instructions of medical professionals.
- The device must be used with a regulatory approved mask. To prevent re-breathing, the device must be turned on within 3 minutes after putting on the mask; and you must take off the mask immediately when the device is turned off.
- During use, do not cover the air inlet of the CPAP device.
- Operation of the therapy may be adversely affected by
  - Electromagnetic fields exceeding the level of 3V/m in the test conditions of EN 60601-1-2
  - The operation of high frequency (diathermy) equipment
  - Defibrillators, or short wave therapy equipment
  - Radiation sources(e.g. x-ray, CT)
  - Magnetic fields(e.g. MRI)
- Do not use the device in a place filled with inflammable gases, anesthetics or Nitrous Oxide (NO) gas.
- If any part of the device is broken, please stop using the device.
- If the device noise level is suddenly higher than normal, and/or if the output air is too hot or has abnormal smell, stop using immediately and contact your medical professional.
- The device must be repaired or checked by personnel qualified by Curative Medical. Do not open the device and change any part yourself.
- The device should be used only with external AC/DC adapter provided by Curative Medical. Use of other AC/DC adapter may damage the device or cause fire and electric shock hazards.
- For safe operation, the humidifier must always be positioned below the breathing circuit connection at the mask.
- Under normal use, the max pressure of the outlet should not exceed 3 kpa (≈30cmH2O), under single fault condition it should not be more than 4 kpa (≈40cmH2O).
- Do not use the device at room temperatures above 95 degrees F.

1.5 Cautions

- Do not turn over or tilt the device to avoid water in the humidifier getting into the device.
- Do not carry the device around with water in the humidifier. Please empty the humidifier before carrying the device.
- Do not sterilize the device with high pressured steam.
- Do not clean the filter with water. Change the filter every month.
- If the device has recently been placed in a very hot or very cold environment, wait for about 2 hours for temperature compensation before switching on the device.
- The device may only be operated at temperatures between 41 degrees F and 95 degrees F.(5° to 35°C)
- To switch the device off completely is by disconnecting the power cord from the wall socket.
- Avoid getting water into the SD card slot.

1.6 How to Use Safely

Before using the device, read this part carefully. If your device doesn't work properly, contact your medical professional immediately.

- The device must be used under the instructions of your medical professional.
- The device should only be used with Curative Medical approved accessories.
- When using a mask or patient interface accessory, check the manufacturer's instructions for proper use and care.
- Do not place the device in the cabinet or under the bed.

- Do not place the device near any heating source such as a heater.
- Do not add any drug in the humidifier.
- Check the alarm function regularly. If the device has not been used for a long time, please check the power failure alarm before use. Contact your dealer if it does not work.
- If mucous membrane dryness in nose and pharynx, fontal sinus trouble, earache, a running nose or skin sensitivity etc occurs, you should consult your medical professional immediately.
- For electric safety:
  a) Do not switch on the device if device or cable is damaged.
  b) Keep the device dry at all times.
  c) Do not place container or glasses filled with liquid on the device
  d) Do not use the device in a damp room, such as a bathroom, near a bath tub or sink.
  e) Do not place the device near loose bedding or drapery.
  f) Before cleaning the device, unplug the power cord from the wall socket.

Before carrying or packing the device, make sure to empty the water from the humidifier

1.7 Disclaimers

The manufacturer shall not be held liable for any damage in case of:

- Tampering, modifying, adding expansion features, repair by person who has not been authorized by the manufacturer.
- Using accessory and spare parts which are not recommended by Curative Medical.
- Using the device in a different way from what has been described in the manual.

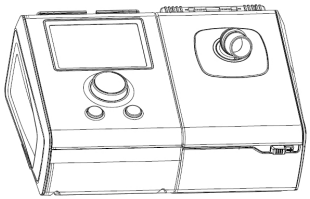
Chapter 2: Device Operation

2.1 Device Description

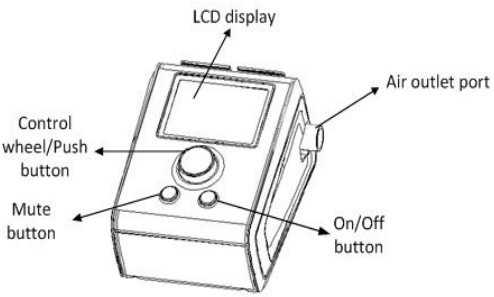
Lotus ST30/25/20 device consists of a CPAP device (on the left) and the following accessories. The heated humidifier is as an optional accessory (on the right).

The Bluetooth is as an optional accessory.

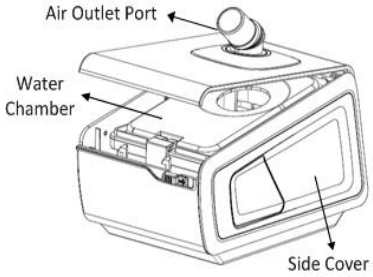
- 1 of SD card
- 1 of patient air circuit (hose)
- 1 of power supply adapter and its cord
- 1 of user manual
- 1 of carrying case
- 1 of heated humidifier(optional)



Front Views

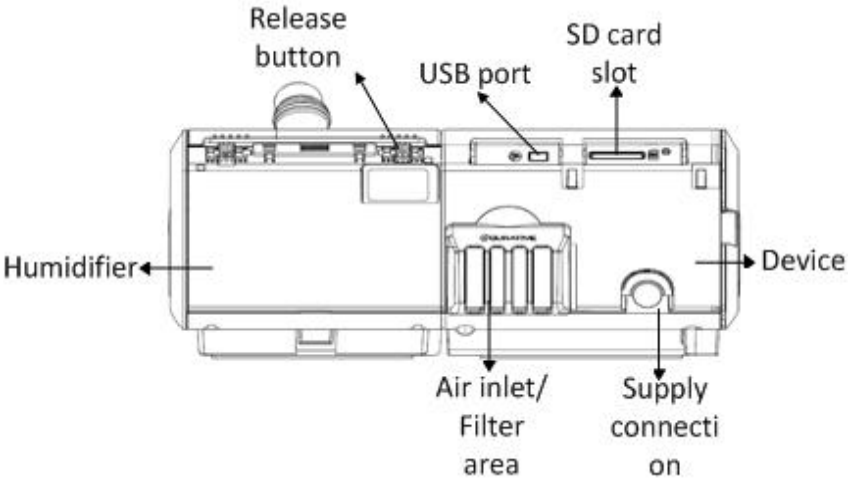


BiPAP device



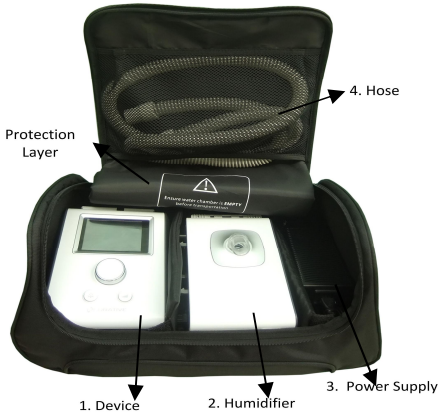
Humidifier

Rear View



Warnings: Data transmission interface is used for transmitting data with connecting to USB of PC. Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). All configurations shall comply with the current version of the standard for SYSTEMS IEC 601-1-1.

Carrying Case



The carrying case has four compartments. Compartments 1 and 2 are for the device and humidifier respectively. In the case of without using humidifier, the device shall be placed in the compartment 2 to maintain the balance. Compartment 3 is for all the accessories except the hose. The protection layer and patient air circuit (hose) placed in the compartment 4 are designed to protect the device's LCD screen and humidifier's air outlet.

2.2 First Time Setup

Warning! Do not use the device until a medical professional has adjusted the settings. To order any accessories not included with the device, contact your medical professional.

Warning! Do not connect any equipment to the device unless recommended by Curative Medical.

Warning! Power failure alarm needs to be check at least once a month to ensure the alarm is effective. Keep the device running for at least 10 seconds, unplug the cord or switch off the power the alarm should activate. Check whether the alarm lasts long enough (>30sec).

CAUTION! If the device has been exposed to either very hot or very cold temperatures, allow the device to adjust to room temperature (approximately 2 hours) before beginning setup.

Step 1: Checking the Device and its Accessory

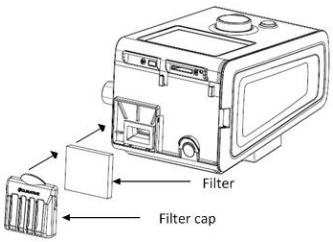
Check the device and its accessories are missing or damaged. Contact your medical professional if needed.

Step 2: Installing the Filter

CAUTION! The filter must be in place at all times when the device is operational.

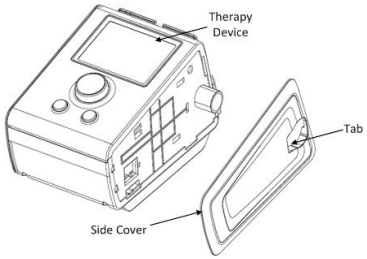
If the filter is not already installed in your device, follow the steps and figure below to install the filter:

1. Remove the filter cap by lifting the lid.
2. Insert the filter to the filter cap, white side facing the cap side.
3. Place the filter cap back.

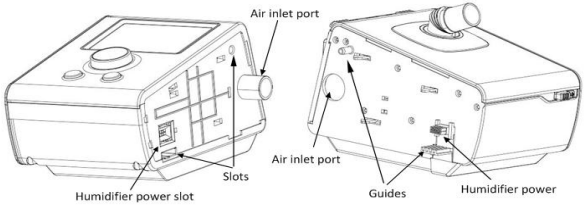


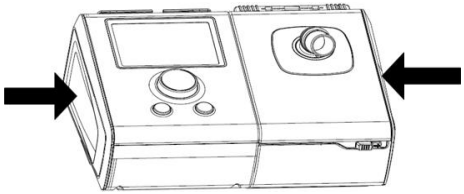
Step 3: Connecting the Heated Humidifier (Optional)

1. To connect the device to the humidifier, first you must remove the side cover on the device by pressing the tab on the side cover and pulling the cover away from the device.

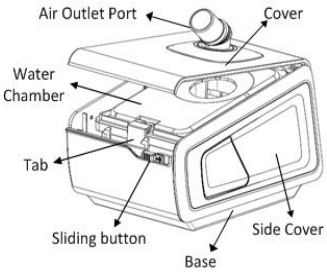


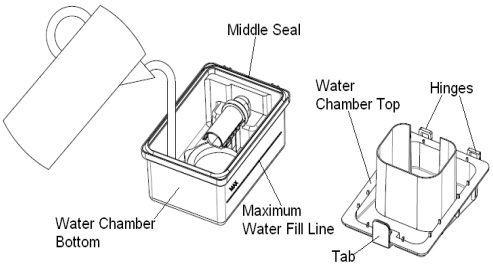
2. Line up the device and humidifier side by side. Make sure the air outlet of the device fits into the air inlet of the humidifier, the guides on the humidifier fit into the slots of the device, and then push the two together.





3. Open the humidifier by sliding the slide button to the right and lifting the humidifier cover up, then simply place your index finger into the hole of the water chamber and take out from the humidifier.



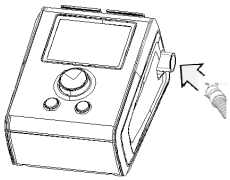


4. Lift the tab on the water chamber to separate its top from the button.

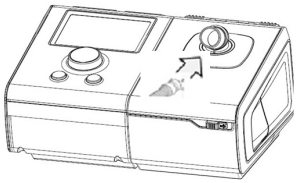
5. Place the chamber on a flat surface, and fill it with drinking water (approximately 300ml) below the maximum line located on the right side of chamber.
   CAUTION! Before the water chamber been filled and placed into the humidifier, do not connect the power to the device.
   CAUTION! Fill the humidifier with drinking water below the maximum water line. Do not add any additives into the water.
   CAUTION! When installing the water chamber, do not allow any water to spill into the humidifier or therapy device.
6. Reassemble the water chamber by inserting the hinges of the water chamber top back to its bottom. Snap the tab back.

Step 4: Connecting patient air circuit (hose)

When use the device alone: Connect the hose to the air outlet of the device



When use the device with heated humidifier: Connect the hose to the air outlet of humidifier



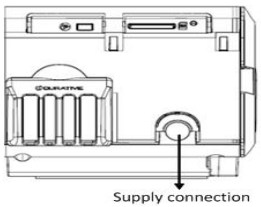
Step 5: Placement of device for use near bed

Place the device on a firm flat surface. Make sure the device is away from any heating or cooling equipment (e.g. air vents, radiant heaters or air conditioners). Also make sure that loose bedding and curtains do not block the air inlet/filter area of the device. Air must flow freely around the device.

Step 6: Connecting Power to the Device

Warning: The device should be used only with power supply provided by Curative Medical. Use of other power supplies may cause damage to the device or fire and electric shock hazards.

Warning: Inspect the power cord for any signs of damage, replace the damaged cord immediately.



1. Plug the pronged end of power cord to the power inlet on the back of the device.
2. Plug the socket end of the power supply cord to the wall.
3. Now device is ready for use.

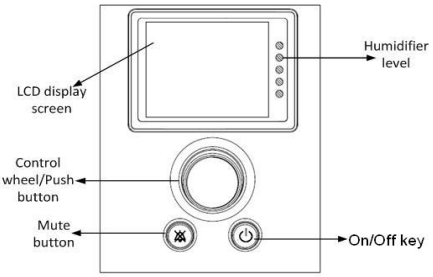
Step 7: Connecting the Mask

1. See medical professional for the mask that best fits your needs.
2. Place the mask on the face and secure the mask using the headgear strap according to the

manufacturer's instructions.

3. Taking the patient end of the hose connect to the end of the mask.
4. Adjust the hose, mask and headgear until the setup is comfortable without large air leak.

Step 8: Device Display and Buttons



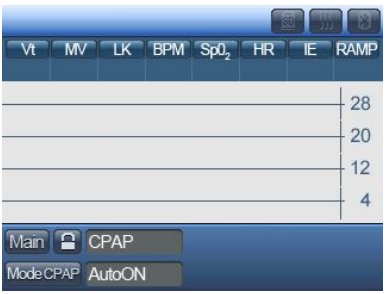
1. Control wheel/push button:
   It has 2 functions:
   i) bring you to the edit mode;
   ii)confirm the editing
   To change the therapy parameters especially for the first time user, turn the control wheel to select different parameters on the monitor screen and main setting screen, press the wheel for 1 second which brings you to the edit mode. The blue highlight field can be edited. Turn the wheel to select the parameter, then press it again to confirm the setting of each parameter.

2. Mute Key:
   Mutes the alarm sound for 1 minute. If the alarm sounds again after 1 minute, it means that the alarm event persists.

3. On/Off Key:
   Press the On/Off key for 1 second to turn on the airflow and begin the therapy; press the wheel for 3 seconds continuously to turn off the device.

   CAUTION: To switch the device off completely, disconnect the power supply cord from the wall socket.
   CAUTION: Do not start therapy until the patient air circuit is properly connected.

Monitor screen



Mode:	Operation mode: CPAP/S/T/ST/APCV
Vt:	Tidal Volume(ml)
MV:	Minute Ventilation(L)
LK:	Leakage volume per minute(L)
BPM:	Patient's respiration frequency(bpm)
SpO_2:	Blood oxygen saturation(Optional)
HR:	Pulse Heart rate(Optional)
IE:	Percentage of Inspiration time in a respiration cycle(%)
RAMP:	Ramp time

There are five operating modes: CPAP, S, T, ST, APCV Mode. The display will differ depending on what operating mode your physician has prescribed for you. Turn the control wheel to select “Mode” and press the wheel to access the mode setting screen.

■ **Continuous Positive Airway Pressure Mode : CPAP Mode**

In the Continuous Positive Airway Pressure (CPAP) mode, the device delivers a continuous pressure at one level.

■ **Spontaneous Mode: S Mode**

Inspiration/Expiration phase switch is based on patient's spontaneous breathing. During the inspiration phase, the device delivers preset IPAP pressure; during expiration, the device delivers preset EPAP pressure.

■ **Timed Mode : T Mode**

The Inspiration/Expiration switch is based on the setting of respiration backup rate with BPM (Respiration frequency) and IE% (percentage of inspiration time over a respiration cycle). The pressure will be switched automatically at a rate determined by BPM and IE%. T Mode only works in manual mode (AUTO OFF).

■ **Spontaneous-Timed Mode: ST Mode**

ST mode includes 2 patterns, when the patient is able to breath spontaneously, the device works as S mode; however, when the patient is unable to breath spontaneously or breath slower than the preset backup rate (BPM), the device will switch to T mode. ST mode works in manual mode (AUTO OFF).

■ **Pressure Control Mode: APCV**

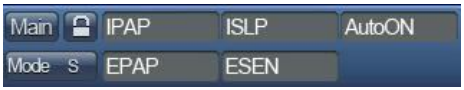
APCV mode is similar to the ST mode, except that all breaths are machine-cycled. The APCV mode is a pressure-limited, machine-or-patient triggered, time-cycled mode. Therefore, the inspiratory pressure may be triggered by the patient or by the therapy device, but IPAP will be pressure-limited with a set cycle time determined by the inspiratory time control. APCV Mode only works in manual mode (AUTO OFF).

CPAP Mode:

CPAP 4.0: Set pressure for CPAP mode, 4 to 20cmH_2O, 0.5 cmH_2O per step

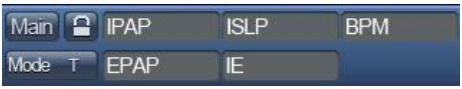
AutoON: Therapy automatically on/off

S Mode:

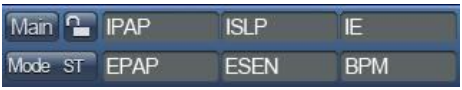


IPAP: Inspiration Pressure,
4 to 20cmH_2O with ST20
4 to 25cmH_2O with ST25
4 to 30cmH_2O with ST30
0.5 cmH_2O per step

T Mode:



ST Mode:



APCV Mode:

EPAP:	Expiration Pressure, 4 to 20cmH_2O, 0.5 cmH_2O per step
	Speed of rising pressure, 1 to 6, 1 per step
ISLP:	Sensitivity of expiration triggering, 1 to 6, 1 per step
ESEN:	Sensitivity of expiration triggering, 1 to 6, 1 per step
IE:	Percentage of Inspiration time in a respiration cycle, 10% to 80%, 1% per step
BPM:	Respiration backup rate, 5 to 50, 1bpm per step

AutoON Feature

When the AutoON Feature is ON, the device can be started automatically by breathing through the air circuit. If the airflow does not start in a few breaths, check the display and the status of the AutoON. When the AutoON feature is OFF, you must start device by pressing the On/Off key.

RAMP Feature

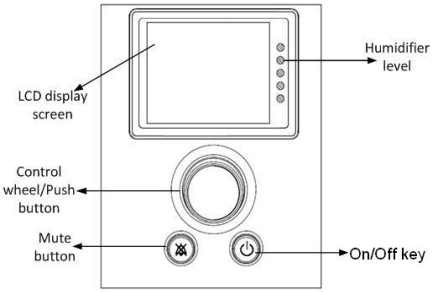
The RAMP feature will reduce the pressure to 4.0cmH_2O and then gradually increase (RAMP) to the set pressure prescribed so that you can fall asleep more comfortably.
Your medical professional will set a RAMP time, if you feel the RAMP time is too long or too short, you can change the setting.

Locking and Unlocking Feature

The Lotus device can be locked to prevent accidental changing of the settings on the device. First, rotate the control wheel to area  of the display in monitor screen. The open padlock icon shows that it is active. By depressing and holding the wheel for 3 seconds, the padlock should appear closed  .
In this state, the device will not allow any settings to be changed except the control wheel is accidentally touched. The closed padlock icon of the monitor screen will remain closed after the device is switched off. As long as power is connected to the Lotus device, the settings in locked mode are retained.
The device can be unlocked by depressing the control wheel again for three seconds. The padlock icon in the monitor screen will appear unlocked.

Step 9: Heated humidifier adjustment

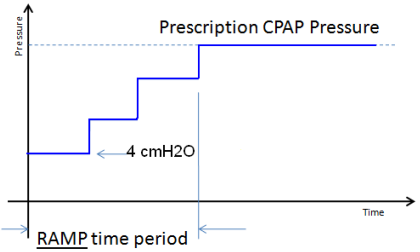
The heated humidifier level can be adjusted in five levels and displayed by the five LED lights on the right side of the display screen. No light on means no heat, more lights on means heat increases. In other words, the relative humidity increases. The humidifier heating level can be adjusted by turning the control wheel. To increase heat turn clockwise, to decrease heat turn counter clockwise.



Note: If condensation persists inside the patient air circuit (hose), try to lower the heat setting of the humidifier. If a high heat setting is required to maintain comfort, try to wrap the patient air circuit in a cloth. Keeping the air circuit warm will reduce condensation inside the circuit.

2.3 Device Operation

2.3.1 Device Setting

RAMP	0 to 60 minutes, 1 min/step  To disable a pre-set RAMP, set the RAMP time (Ramp) to zero minute.
Humidifier	With(ON) / without(OFF) When humidifier is connected to device, will appear on upper right screen
Back Light	For LCD screen's 0 to 5
Auto on	Device automatically turns the airflow on when patient breathes to the mask. Otherwise the airflow turns on by on/off key.

2.3.2 Alarm Settings

The Alarm set menu is an option on the main menu where changes to the settings can be initiated.

If the alarm function of LowMV, LowVT, HiPRES or Apnea is ON, and an alarm condition applies, visual alarm will blink on upper left of monitor page, in addition to the audible alarm. Pressing the mute key can silence the audible alarm, not the content alarm. 1 minute after muting, the audible alarm will beep again if the situation persists.

And if it is OFF, when an alarm condition applies, there will be no sound warning, the visual alarm will blink on the monitor page.

Either setting the alarm ON or OFF, details of the alarm information will be recorded in the device.

2.3.2.1 Leak alarm (MASKOFF)

If the device's AUTO function is disabled (AUTO OFF), the device will be turned on by pressing the On/Off key. When the device detects patient's mask is taken off or the air leak is too much, the motor will run at a lower speed with sound alarm. When the air leakage stops, the device will work normally again and returning to the set pressure. Meanwhile, humidifier shall be kept on.

2.3.2.2 Apnea alarm (APNEA)

The apnea alarm detects the cessation of spontaneous breathing.
Alarm is detected when the time between spontaneous breaths exceeds the Apnea alarm setting. The alarm setting range is from 10 to 40S, 5S per step.
The alarm is terminated when two consecutive spontaneous breaths occur within the apnea alarm time setting or press the mute key.

2.3.2.3 Low minute ventilation alarm (LOWMV)

The low minute ventilation alarm detects when user is not receiving a specified volume of air on a per minute basis.
Alarm is detected when the calculated minute ventilation $\leqslant$ the alarm setting. The alarm setting range is from 1 to 10 L/m, 1 L/m per step.
The alarm is terminated when the calculated minute ventilation > the alarm setting or press the mute key.

2.3.2.4 Low tidal volume alarm (LOWVT)

The low tidal volume alarm is detected when the calculated tide volume $\leqslant$ the alarm setting.
The alarm setting range is from 100 to 500 ml, 50 ml per step.
The alarm is terminated when the calculated tide volume > the alarm setting or press the mute key.

2.3.2.5 High pressure alarm (HiPRES)

The high pressure alarm limits the high pressure to the patient.
Alarm is detected when the pressure $\geqslant$IPAP + 3 cmH_2O.
The alarm is terminated when the pressure$<$IPAP + 3 cmH_2O or press the mute key.

2.3.3 Power Failure

During use, if power failure occurs, patients may inhale the expired air. In case of power failure or power cord is disconnected, the alarm will sound. Patient shall take off the mask in time. Power recovery or pressing the mute key will stop the alarm.

Checking the power failure alarm

Keep the device running for at least 10 seconds, unplug the power cord or turn off the power switch, the alarm shall sound. Check whether the alarm lasts long enough. When the device is powered on, the alarm shall stop automatically. Please check the alarm at least once every month.

2.3.4 Device Data

Date(local)	Year-Month-Day Eg: 2014-05-28
Time(local)	Hour: Minute: Second Eg: 14: 02: 33
Blue Tooth	ON( will appear on upper right screen) / OFF
SpO_2 connect	With(on) / Without(off)
Erase Patient Data	Erase all compliance data, therapy time and patient information on the device by password confirmation. Blower run time can not be erased.
Change Password	To change password: 1. Enter the old password(manufacture default is 0000) Note: If password is incorrect, “Invalid Password” will pop up. 2. Enter the new password in both “New” and “Confirm”, then password would be changed sucessfully, and system returns to the Setting screen.
Language	Select language English, Chinese

2.3.5 Report Screen

If you are interested to know your therapy status, you can select the “report” screen by turning the control wheel, and then press the push button to confirm.

There are two reports displayed on the device.

Run time	Date	Current date
	Time	Current local time
	Blower run time	Device running hours (max. 5 digits) and minutes Eg: 105h 50m
	Therapy time	Total therapy time in hours (max. 5 digits) and minutes. Eg: 105h 50m
Alarm	Mask Off	Frequency of each alarm in last week and last month
	Apnea	
	Hi-Pressure	

	Low VT	
	LowMV	

2.3.6 Therapy Data Download

The device is equipped with a compliance data download feature via a SD Card. (Note: SD card must be formatted in FAT32).The data includes therapy settings and therapy time. In order to download data to the SD card and bring it to your medical professional, please follow the steps below. Note:  will appear on upper right screen.

1. Only when you are not using the device, take the SD card out from the SD case. Insert the SD card (facing the labeled side down) into the SD card slot at the back of the device.
2. Observe LCD screen displaying “SD Card Activated”, “Information success” and hear a beep sound. This indicates your data is downloaded to the SD card. If you see the LCD screen displaying “Information failed”, you need to press the SD card to eject it out of the slot. Then reinsert it into the slot until “Information success”. Note: For any question and problem, please contact your medical professional.
3. Take out the SD card from the slot. Place the SD card into the SD case. Bring it to your medical professional.

2.3.7 Therapy Alteration

If the medical professional altered your therapy setting after reviewing the data, you need to do the following before next therapy. Note:  will appear on upper right screen.

1. Insert the SD card into the slot.
2. Observe the LCD screen displaying “SD Card Activated” and “Information success” and hear a beep sound. This indicates your device setting has been changed. If you see the LCD screen displaying “Information failed”, you need to eject the SD card out of the slot. Then reinsert it into the slot until “Information success”. Note: For any question and problem, please contact your medical professional.
3. Take out the SD card from the slot. Place the SD card into the SD case. Now you can start therapy.

2.3.8 Product Information

Turn the control wheel to select “Main” and “About”, detail information of Lotus ST30/25/20 will display on the device which including the software version and the serial number.

2.3.9 Turn off the Device

Simply by pressing the On/Off key for 1 second, the device will be turned off. The Heated Humidifier is controlled directly by the device; it will be turned off as well.

The power to the device can only be turned off by unplugging the socket of the power supply cord from the wall.

Chapter 3: Cleaning

3.1 Cleaning Device

WARNING! To avoid electrical shock, always unplug the device power cord before cleaning the device.
CAUTION! Do not immerse the device in liquid or allow any liquid entering the device, inlet filter, or any openings.

Unplug the device and clean the front panel and exterior of the device using a cloth dampened with water. Allow the device to dry completely before plugging in the power cord.

3.2 Changing Filter

The filter is disposable and should be replaced after 30 nights of use or sooner if it appears dirty. Do not reuse or wash the filter.
CAUTION! Dirty filter may cause device high operating temperature which may affect performance. Regularly examine the inlet filter as needed to ensure integrity and cleanliness.

1. Remove the filter cap by lifting the lid.
2. Insert the fine filter to the filter cap, white side facing the cap side.
3. Place the filter cap back.

3.3 Cleaning Patient Air Circuit

1. Disconnect the patient air circuit (hose) from the device. Gently wash the patient air circuit in a warm water solution. Rinse the patient air circuit thoroughly in the running water, and straight out the patient air circuit for air dry.
2. Inspect the patient air circuit for any damage after cleaning. Replace the damaged part.

For cleaning your mask, refer to the cleaning instructions of mask.

3.4 Cleaning Heated Humidifier

WARNING! Only water chamber can be cleaned by water. DO NOT immerse the humidifier into any fluids/water.
WARNING! To avoid electrical shock, disconnect the power cord before cleaning the water chamber.
WARNING! Empty and clean the water chamber daily to prevent bacteria growth.

Water chamber cleaning:

1. Disconnecting the power cord from the wall socket, and allow the heater plate and water to cool.
2. Press the latch at upper rear of humidifier with your right hand finger, and pull the

device simultaneously with your left hand to disconnect the humidifier from the device.

3. Open the humidifier by sliding the sliding button to the right and lifting the humidifier cover up, then simply place your index finger into the hole of the water chamber and take out from the humidifier.
4. Lift the tab of the water chamber to separate the top from the bottom of the water chamber. Empty any remaining water from the bottom of the water chamber.
5. Wash the parts of the water chamber in a warm water solution with a mild liquid detergent. Gently wash the middle seal. Rinse the parts with clean water. Wipe the parts completely. Allow them to air dry. Inspect the chamber and middle seal for damage. Contact your medical professional if any damage found.
6. Place the middle seal back into the seal slot on the water chamber bottom, and make sure it fits evenly in the slot to prevent potential leakage.
7. Fill the water chamber with drinking water up to the maximum fill line located on the right side of the chamber.
8. Reassemble the water chamber by inserting the hinges of the water chamber top back to its bottom. Snap the tab back. Note: If the top does not easily snap onto the bottom, separate the two parts, check the middle seal and 2 hinges' placement, reassemble again.

Humidifier cleaning:

1. Clean the humidifier base by wiping with a damped cloth. Clean the humidifier air outlet port by using a damped bottle brush or a damped cloth.
2. Inspect the humidifier for any damage. Allow it to air dry before reconnecting to the device.

3.5 Routine Check

- Check the device and accessories for damage.
- Before each use, check patient air circuit (hose). Make sure it is free of tears and punctures.
- Inspect the power supply for any damage.
- Examine the filter to ensure integrity and cleanliness.
- Inspect the water chamber and middle seal for any damage.

Contact your medical professional for replacement of any damaged part.

Chapter 4: Troubleshooting and Service

4.1 Troubleshooting

Problems which may be encountered, their causes and resolving methods are listed below. Please consult your medical professional or contact Curative Medical approved service center for any problems you have.

Problem	Why it happened	What to do
When you apply power to the device the LCD display screen does not	No power at the outlet or the device is unplugged	Check the outlet and verify that the device is properly plugged in. Make sure the power supply cord is securely connected to the device's

lighted up		power inlet.
Airflow does not turn on	May be a problem with the blower	Make sure the device is powered correctly, and “Therapy” is selected and confirmed by pressing the control wheel/button to start the blower.
Ramp feature does not work when you press the Ramp button	Your medical professional did not prescribe Ramp for you	Discuss this feature with your medical professional
	CPAP pressure is set to the minimum ramp pressure	Check the setting on your device screen. If the ramp starting pressure is the same as the therapy pressure, the Ramp feature will not work. Make sure that the ramp time setting is >0.
Airflow is much warmer than usual	Filter may be dirty	Replace the filter
	Device may be placed in direct sunlight or near a heater	Make sure that the device is properly ventilated. Keep the device away from direct sunlight, heating equipment, bedding or curtains.
	Humidifier level maybe too high	Check the humidifier settings. Refer to the user manual to make sure the humidifier is working properly
High Leak	Patient air circuit is not connected correctly or doesn’t seal properly	Remove your mask and patient air circuit to check for kinks, tears or any damage, reconnect correctly
	Device and humidifier are not connected correctly	Detach the device from the humidifier and reconnect. Make sure the air inlet port on the humidifier align well to the air outlet port on the device
	Humidifier cover does not close correctly	Slide the sliding button to the right and lift the humidifier cover up, check for any damage, then press the cover back to make sure the sliding button is closed correctly
	Water chamber in the humidifier does not close correctly or middle seal is damaged	Separate and reassemble the water chamber. Check the seal for any tears or other damage
Heated humidifier not work	Loose humidifier power connection	Check humidifier power connection to the device
Device is operating but the humidifier’s airflow is low or none	Humidifier has an airflow obstruction	Contact your medical professional
	Device and humidifier are	Detach the device from the humidifier

	not connected correctly	and reconnect. Make sure the air inlet port on the humidifier align well to the air outlet port on the device.
Excessive condensation in the patient air circuit	Humidifier level setting is too high	Reduce the humidifier level setting.
	Humidifier may be operating in direct sunlight or near a heater	Make sure that the humidifier is properly ventilated. Keep the humidifier away from direct sunlight, heating equipment, bedding or curtains.
Dryness and irritation of nose and throat	Dry air	If using humidifier, make sure it is on. If do not use humidifier, contact your medical professional
Cold nose	Low room temperature	Raise room temperature
	Low temperature airflow	Adjust humidifier to high level
Dryness in mouth and pharynx	Breathing through mouth	Use chin strap or full face mask Ask your medical professional to lower therapy pressure
Irritated or dry eyes	Leakage between mask and skin	Adjust the mask's position and headgear. If the mask is worn out, change it or try another type of mask.
Water in the mask	When room temperature is low and the humidifier is on, it may cause water condensation	Lower the humidifier's heating level or increase the room temperature. Wrap the patient air circuit (hose) in a towel or soft cloth to keep warm.
	Device is located higher than the mask	Make sure the CPAP is positioned lower than the mask.
Pain in nose, sinuses or ears	Irritation or inflammation	Stop therapy and see your medical professional immediately
Display screen or parameters cannot be scrolled through	Control wheel/Push button may be broken	Verify the Power Supply is fully connected. Contact your medical professional.
Data downloading screen shows Information failed	Problem with inserting the SD card	Press the SD card to eject it out of the slot. Remove it and re-insert the SD card into its slot.
	Damaged SD card	Alter the SD card
	SD card slot damaged	Contact your medical professional
When insert SD card into SD Card slot, no message display on LCD screen display	SD card slot damaged, such as by water	Air dry the device and contact your medical professional
Mask is on, but mask	Significant leak	If the mask is on, check whether all

off alarm beeps		connections are correct and secure. (Check the patient air circuit, the connection between device and humidifier, the water chamber and the middle seal)
Power failure alarm	Power shut down or power cord disconnected when device is running.	Check the power connection.
The device's output pressure is lower than the set pressure	Air leakage	Check whether all connections are correct and secure.
	Patient air circuit is kinked or damaged	Check the tube and ensure it is free of kinks.
	Dirty filter or air outlet blocked	Change filter, check air outlet for obstruction.
Ramp is on, but air flow is low	Ramp time may be too long	Decrease ramp start time

4.2 Service

In case of any deficiency, contact your Provider or the Curative Medical Service Center. Service is only executed by persons authorized by Curative.

For proper maintenance, please read the Lotus ST30/25/20 User Manual for instructions.

Chapter 5: Electromagnetic Compliance

Guidance and manufacturer's Declaration of Electromagnetic Immunity for Non-Life Supporting Equipment and Systems

Attention! Please use Lotus ST30/25/20 System according to electromagnetic information in list.

The Lotus ST30/25/20 System is intended for use in the electromagnetic environment specified below. The user of the Lotus ST30/25/20 System should ensure that it is used in such an environment.

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Lotus series Positive Airway Pressure Devices (with humidifier) use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Lotus series Positive Airway Pressure Devices (with humidifier) is suitable for use in all

Harmonic emissions IEC 61000-3-2	Class A	establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 KV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode +/-2kV common mode	±1 kV differential mode +/-2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Lotus series Positive Airway Pressure Devices(with humidifier) requires continued operation during power mains dips & interruptions, it is recommended that the series Positive Airway Pressure Devices(with humidifier) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	3 A/m	3 A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE： UT is the A/C mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should not be used no closer to any part of the Lotus series Positive Airway Pressure Devices(with humidifier),including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	80 MHz to 800 MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1：At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2：These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV			

broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Lotus series Positive Airway Pressure Device (with humidifier) is used exceeds the applicable RF compliance level above, the Lotus series Positive Airway Pressure Device (with humidifier) should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as, re-adjusting or relocating the Lotus series Positive Airway Pressure Device (with humidifier).

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

Recommended separation distances between portable and mobile RF communications equipment and the Lotus series Positive Airway Pressure Device (with humidifier)

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 6: Specifications

IPAP range..... 4–20cmH2O with ST20 (392Pa-1960Pa)
4–25cmH2O with ST25 (392Pa-2450Pa)
4–30cmH2O with ST30 (392Pa-2942Pa)
EPAP range……..... 4–20cmH2O (392Pa-1960Pa)
CPAP range……..... 4–20cmH2O (392Pa-1960Pa)
Pressure variance..... ± (2% of the full scale reading + 4% of the actual reading)
Plim max ……..3kPa (30 cmH_2O) (normal use)
3.5kPa (35 cmH_2O) (single fault)
Ramp time..... 0-60min. adjustable 1min./step
BPM……5-50bpm
IE%.....10%-80%
Noise (1m from unit in patient position)……..< 33dB(A) (at 10 cmH_2O/~1.0kPa)
(Corresponds to an acoustic power level of 41 dB (A))
Dimensions:
Device..... 212 mm L×160 mmW × 124 mmH
Weight..... 2Kg (with humidifier)
Patient connection port .....22 mm size (complying with ISO 5356-1)
Air temperature at humidifier outlet……≤41°C
DC Voltage……..... 24VDC
DC Current..... 3.3A Maximum
Humidifier maximum load power..... 38.4W
Protection again electric shock..... Class Ⅱ
Degree of protection against electric shock..... Type BF Applied Part
Degree of protection against harmful ingress of water…..... IP21
Disinfect ，sterilize class.....refer to the accessory user manual
The max permitted operating pressure of humidifier.....3kPa (30cmH_2O)
Fuses……..... (T3.15A) there are no user-replaceable fuses
Means of triggering ……..PID control

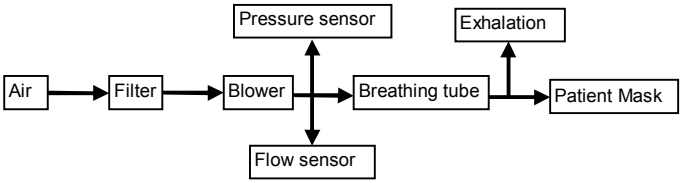
Patient connection port according with 22mm tapered connection port regulated by ISO5367

AC/DC Power Supply
Model: BJE1M-0080-N600
Input: 100-240V, 50-60Hz, 1.8MAX
Output: 24V ⎓, 3.3A

Operation:
Temperature..... +5℃～+35℃
Relative humidity..... 10％～95％ (non-condensing)
Atmosphere pressure…… 700hPa～1060hPa

Transport or storage:
Temperature..... -20℃～+55℃
Relative humidity..... 10％～95％ (non-condensing)
Atmosphere pressure…… 500hPa～1060hPa

Pneumatic diagram:



Pressure Accuracy:

Pressure Increments: 4.0 to 30.0 cmH_2O (in 0.5 cmH_2O increments)
Pressure Stability:

	Static	Dynamic < 10 cmH_2O	Dynamic ≥10.0 to 30.0 cmH_2O
Device	±0.5 cmH_2O	≤0.6cmH_2O	≤1.0 cmH_2O
Device with humidifier	±0.5 cmH_2O	≤0.6cmH_2O	≤1.0 cmH_2O

Maximum Flow Rate:

		Test pressure (cmH_2O)				
		4.0	10.5	17.0	23.5	30.0
With humidifier	Measured pressure (hPa)	3.9	10.3	16.7	23.1	29.6
	Average flow at the patient connection port (l/min)	95	140	156	139	119
Without humidifier	Measured pressure (hPa)	3.8	10.3	16.8	23.3	29.8
	Average flow at the patient connection port (l/min)	95	140	147	131	111

Chapter 7: Disposal

Except for used parts and packing items particularly specified, please dispose according to your country's law or return to our company.

Chapter 8: Limited warranty

Curative Medical warrants that Lotus ST30/25/20 device and humidifier shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by Curative Medical to the dealer. If the product fails to perform in accordance with the product specifications, Curative Medical will repair or replace, at its option, the defective material or part. Curative Medical will pay customary

freight charges from Curative Medical to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

Curative Medical disclaims all liability for economic loss, loss of profits, overhead or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties, in addition, any implied warranties including any warranty of merchantability or fitness for the particular purpose are limited to two years, some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Curative Medical dealer or Curative Medical.

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CURATIVE

Protected by patents
US patent 7,717,112
7,717,112 B2
201210570391.1

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