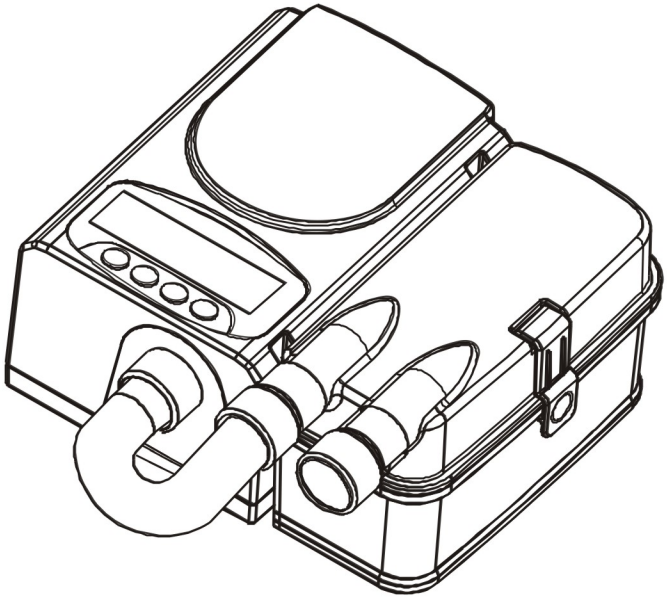
Curasa™

CPAP USER MANUAL

Positive airway pressure device
English

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.

TABLE OF CONTENTS

Chapter 1: Introduction

1.1 Symbol Description

Symbol	Description	Symbol	Description
	Attention, consult accompanying documents		Class II for Protection against Electric Shock
	Manufacturer		DC POWER
	Date of Manufacture		The switch that brings the device to stand-by condition
	Serial Number		European Declaration of Conformity
	Type BF Applied Part		Separate collection for the electrical and electronic equipment per EC Directive2002/96/EC
IPX1	Protected against dripping water		

1.2 Glossary

OSA	Obstructive Sleep Apnea
CPAP	Continuous Positive Airway Pressure
EUT	Expiratory Unloading Technology
Stand By Mode	Power is connected to the system, display is active, blower is not running
Locked Mode	A mode contains a set of features accessible and used by the patients at all time
Unlocked Mode	A mode contains a set of features accessible and used by a medical professional
RAMP	A mechanism of time-delayed pressure rise to the therapeutic pressure to improve patient comfort. RAMP is defined by RAMP starting pressure and RAMP duration time.
AUTOON	When AUTO ON is selected, the device will automatically begin the CPAP therapy as soon as an inhaled breath is detected, instead of manually selecting Therapy.

1.3 Indication / Contraindications

Indication

Curasa CPAP is designed for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment. Heated humidifier is an accessory for Curasa CPAP, which is intended to reduce nasal dryness and irritation by adding moisture to the airflow.

Contraindications

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)
- May be temporarily contraindicated if you exhibit signs of sinus or middle ear infection.

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 the external AC/DC power supply provided by Curative Medical. Use of other AC/DC power supplies 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.
- The device should be used only with patient air circuit provided by Curative Medical. Use of other patient air circuits may cause improper operation of the device.
- 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, disconnect 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.

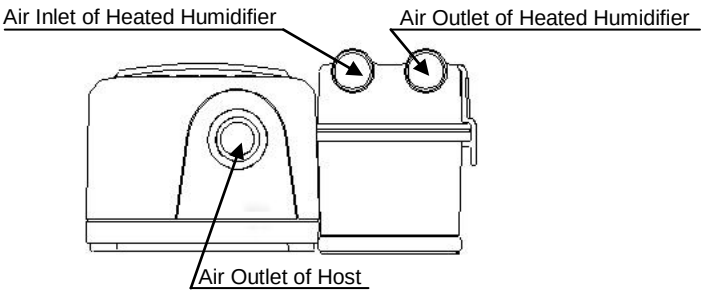
Chapter 2: Device Operation

2.1 Device Description

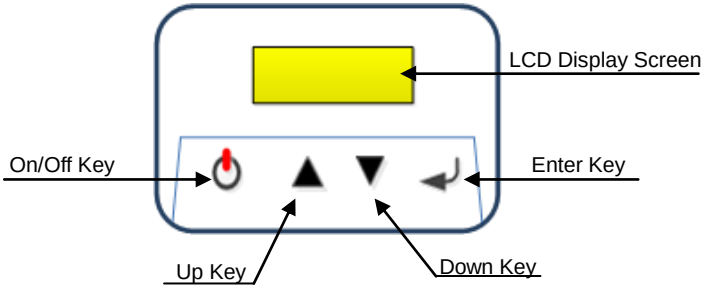
Curasa CPAP device consists of a CPAP device (on the left) and the following accessories. The heated humidifier is as an optional accessory (on the right).

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

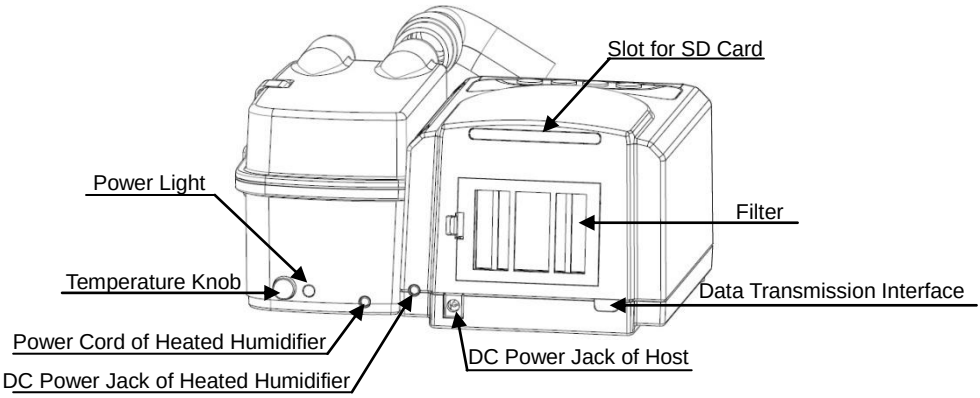
Front Views



Control Panel



Rear View

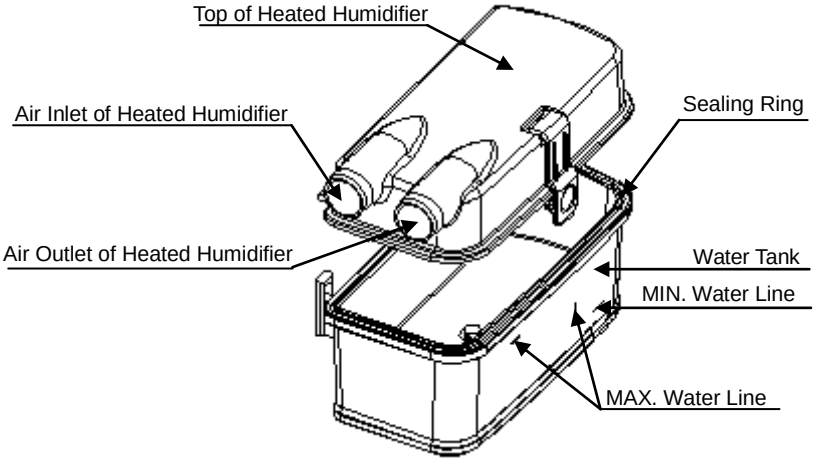


Warning: The device should be used only with external AC/DC adapter provided by manufacturer. Use of other AC/DC adapter may cause damage to the device or cause fire and electric shock hazards.

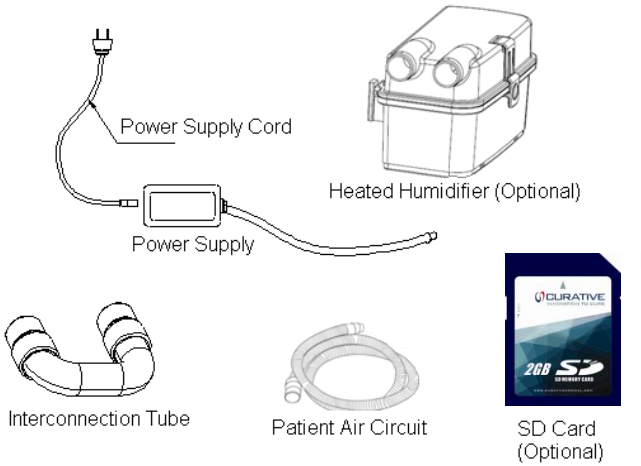
Attention: DC power jack of humidifier is only used for connecting to the host with provided humidifier power cable. Please do not connect it with the other devices.

Attention: Data transmission interface is used for transmitting data with connecting to PC.

Heated Humidifier



Accessory



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 checked 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 then 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 to see if anything is missing or damaged. Contact your medical professional if needed.

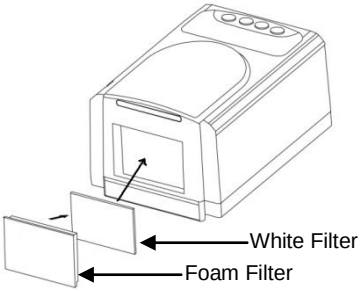
Step 2: Installing the Filter

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

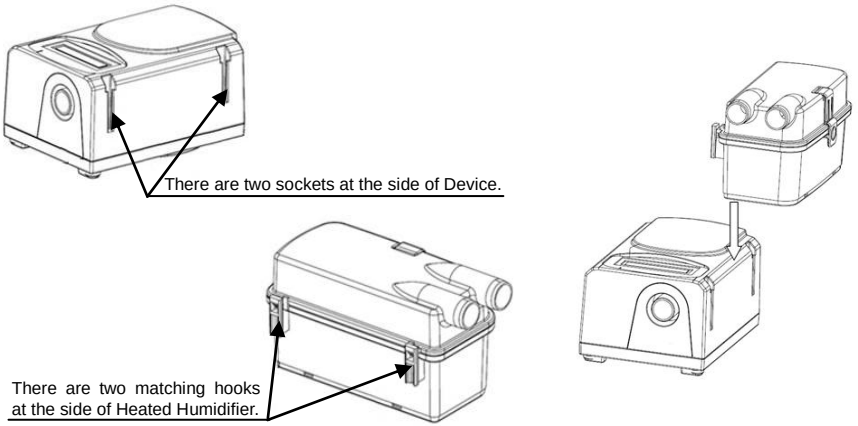
The Curasa CPAP comes with a filter cassette to hold the grey foam filtrate material. The white filter is optional and can be used in addition to the foam filter. The white filter is recommended for people who are sensitive to tobacco smoke or exposed to other fine particulate matter. This filter has to be changed and not cleaned at all.

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

1. Remove the filter cassette by lifting the lid.
2. Insert the filters to the filter cassette as shown in the illustration on the right.
3. Place the filter cassette back.



Step 3: Connecting the Heated Humidifier (Optional)

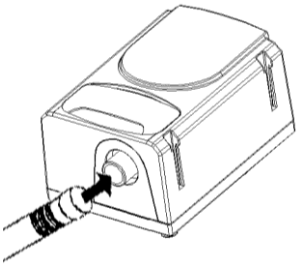


1. Slide the two pieces together by aligning the hook parts into the socket grooves. Now the two parts are connected and ready for use.
2. Open the humidifier latch and lift the humidifier cover up.

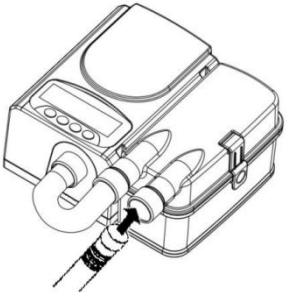
3. Rinse the chamber with water. Place the chamber on a flat surface, and fill it with drinking water (approximately 243ml) below the maximum line located on the right side of chamber.
   CAUTION! Before the water chamber been filled and placed into the humidifier, do not connect the power to the device.
   CAUTION! Fill the humidifier with drinking water below the maximum water line. Do not add any additives into the water.
4. Snap the latch back to close the heated humidifier.

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



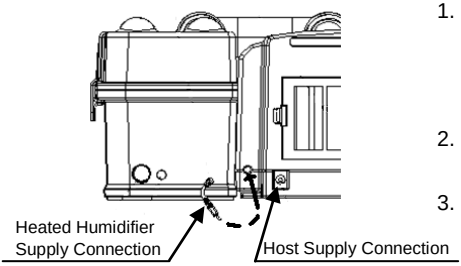
Step 5: Placement of device for use near bed

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.



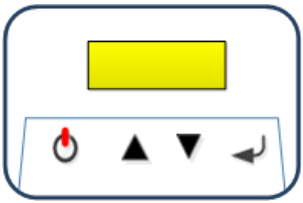
1. Plug the pronged end of power cord to the power inlet on the back of the device, as shown in the illustration on the left.
2. Plug the socket end of the power supply cord to the wall.
3. Now device is ready for use.

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

Device home screen



1. On/Off Key

   When the power supply is connected, the device is at stand-by mode. The On/Off key is to turn the blower of the device on or off. To turn the device on, press the On/Off key down for over 1 second. To turn the device off and switch to stand-by mode, press the on/off key. When the device is turned on, the background light of LCD display will be illuminated. When no action is performed within 1 minute, the display background light is off and the therapy parameters cannot be adjusted.

2. Up and Down Key

   The up (△) and down (▽) Keys are used to select the functions and adjust parameters.

3. Enter Key

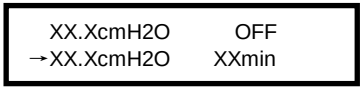
   Enter key has 2 functions:

   i) bring you to the edit mode;

   ii) confirm the editing

   To change the therapy parameters especially for the first time user, press the enter (↵) key for 1 second which brings you to the edit mode. The blinking field can be edited. Press the up (△) and down (▽) key to select the parameter, then press the enter (↵) key again to confirm the setting of each parameter.

4. Status Screen

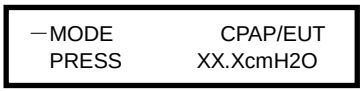


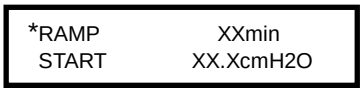
The Status Screen is a summary of all the settings of the current mode.

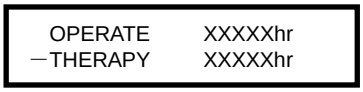
Parameter	Introduction	Range
XX.XcmH2O	First Row: current prescription pressure Second Row: current therapy pressure	4 cmH_2O to 20 cmH_2O, 0.5 cmH_2O / step
ON/OFF	Status of the AUTO ON function	On, off
XXmin	Ramp time	0 to 60, 1min / setp

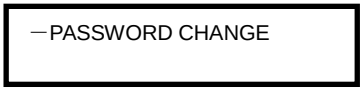
Display screens

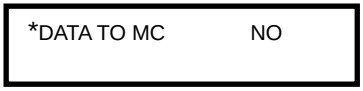
CPAP Mode











SERIAN NUMBER
XXXXXXXXXXXX

Note:

1. Pressure Settings have been preset for you by your provider. The Status screen shows the pressure setting of the device.
2. Without pressing any key, the display will return to the Status Screen in 30 seconds.

Parameter	Introduction	Comment
MODE	Operating mode	CPAP/EUT
PRESS	Set pressure for CPAP mode	4 cmH_2O to 20 cmH_2O, 0.5 cmH_2O / step
RAMP	Ramp time	0 to 60, 1min / setp
START	Start ramp pressure	4 cmH_2O to the smaller between MinP and CPAP, 0.5 cmH_2O / step
AUTOON	Therapy automatically on/off	On, off
OPERATE	Hours that the blower has accumulated since the beginning of its useful life	0 to 99999 hours
THERAPY	Hours that the blower has accumulated over the course of treatment	0 to 99999 hours
DATE	Month Day Year	Eg: JAN 01 2013
TIME	Hour: Minute: Second	Eg: 14: 02: 33
LANGUAGE	Select language	English, German, French
PASSWORD CHANGE	Change password	Default password is 0000.
SERIAL NUMBER	Serial number of the device	Eg: 88654343G660

Power Light of Heated Humidifier

The green indicator LED is on while the humidifier is heating the water.

Step 9: Heated humidifier adjustment (optional)

The heated humidifier heating level can be adjusted by turning the temperature knob. To increase heat turn clockwise, to decrease heat turn counter clockwise.

2.3 Device Operation

2.3.1 Operating Mode

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

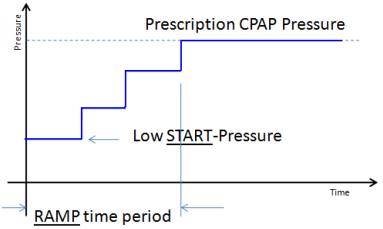
In CPAP mode, the device delivers a continuous pressure at one level.

■ **Expiratory Unloading Technology Mode : EUT Mode**

In EUT mode, the device will lower the output pressure during the beginning of expiration and then gradually returning to the set therapy pressure. You can select 3 comfort levels: “1” the lower level; “2” the middle level; “3” the higher level (larger pressure decrease).

2.3.2 RAMP Set Up

RAMP can be set by RAMP time and START pressure.



START	Start ramp pressure: 4 cmH_2O to CPAP pressure, 0.5 cmH_2O / step
RAMP	Ramp time,0 to 60 minutes, 1 min/step

Rampstart pressure (START) nomally is set up by a medical professional. Ramptime (RAMP) can be changed by pressing the Enter-Key and adjust it by the Up-Key or Down-Key.To disable a pre-set RAMP, set the RAMP time to zero minute.

2.3.3 AUTOON Set Up

When the AUTO ON 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 AUTO ON. When the AUTO ON feature is OFF, you must start device by pressing the On/Off-Key. And AUTO OFF works at pressure 6 cmH_2O to 20 cmH_2O.

2.3.4 Device Alarm

When an audible alarm beeps, one of these 2 system faults occurred: power off and mask off.

- Power off: power shut down or power cord disconnected when device is running.
- Mask off: mask is taken off from the face or a significant mask leak when AUTOON is OFF and mask off works at pressure 6 cmH_2O to 20 cmH_2O.

Pressing the On/Off key can close the power off alarm, and pressing the up (△), down (▽) or return (↩) key can silence the mask off alarm. 1 minute after muting, the audible alarm will beep againif the situation persists.

2.3.5 Data Download

The Curasa CPAP System is equipped with a Secure Digital, SD Card® interface in the rear of the device. This data card is used to download compliance (or device usage) information from the machine. It collects the machine settings and durations of usage for the machine.

Note: SD Card, Secure Digital Card is a *trademark or registered trademark of SD-3C, LLC in the United States, other countries or both*
Note: SD Card formatted as FAT32 file system.

The following diagrams show how to download the compliance information from the machine into the data card. (SD card previously placed in the unit in its dedicated slot located in the top of the rear Curasa CPAP unit).

*DATA TO MC NO

Press the Enter key once and the selection will begin to flash.

*DATA TO MC YES

By selecting the Up arrow key, the selection will change to YES. Press the Enter key to confirm this selection.

*DATA TO MC	YES
WRITING…	*EXIT

As the device is transferring compliance information to the data card, the device will indicate that it is in the process of transferring the information. “WRITING” will appear.

*DATA TO MC	YES
SUCCESS	*EXIT

When it is complete, the display will show the word “SUCCESS”. Press the Enter key and the device will return to home screen.

*DATA TO MC	YES
DATA ERR	*EXIT

If the status shows DATA ERR or ERROR. Try re-inserting the data card or using a new card and repeat the process.

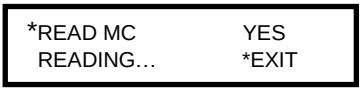
2.3.6 Read Therapy Command

The Curasa CPAP System can set physician commands via SD card. Physician can set therapy command into SD card via data analysis software.
The following diagrams show how to read therapy command from the data card.

The SD card has to be placed after received back from the physician, in its dedicated slot located in the Curasa top rear.

Press the Enter key once and the selection will begin to flash.

By selecting the Up arrow key, the selection will change to YES. Press the Enter key to confirm this selection.



As the device is reading physician command from data card, the device will indicate that it is in the process of reading the information. “READING” will appear.

When it is complete, the display will show the word “SUCCESS”. New physician settings are now available in your unit.

If the status shows DATA ERR or ERROR. Try writing physician command again and retry and repeat the process.

2.3.7 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 white filter is disposable and should be replaced after 30 nights of use or sooner if it appears dirty. Do not reuse or wash it. The foam filter can be washed regularly and allow it air dry before inserting it to the filter cassette.
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 from the cassette in the back of device.
2. Insert the fine filter to the filter cassette.

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 straighten 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. Hold the heated humidifier and slide it up to disconnect the humidifier from the device.
3. Open the humidifier by pressing its latch and lifting the humidifier cover up.
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 latch 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 lighted up	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 power inlet.
Airflow does not turn on	May be a problem with the blower	Make sure the device is powered correctly, and On/Off key is pressed 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 connecting tube is well connected

		between the heated humidifier and the device.
	Humidifier cover does not close correctly	Open the humidifier latch and lift the humidifier cover up, check for any damage, then press the cover back to make sure the latch is closed correctly
	Middle seal is damaged	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 not connected correctly	Detach the device from the humidifier and reconnect. Make sure connecting tube is well connected between the heated humidifier and 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

When insert the USB cable into the data transmission interface, no reaction on the PC	Data transmission interface damaged, such as by water	Air dry the device and contact your medical professional
Mask is on, but mask off alarm beeps	Significant leak	If the mask is on, check whether all connections are correct and secure. (Check the patient air circuit, the connecting tube 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 Curasa CPAP 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 Curasa CPAP System according to electromagnetic information in list.

The Curasa CPAP System is intended for use in the electromagnetic environment specified below. The user of the Curasa CPAP System should ensure that it is used in such an environment.

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Curasa 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 Curasa series Positive Airway Pressure Devices (with humidifier) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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 Curasa 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) are 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 Curasa 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 Curasa series Positive Airway Pressure Device (with humidifier) is used exceeds the applicable RF compliance level above, the Curasa 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 Curasa 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 Curasa series Positive Airway Pressure Device (with humidifier)

The Curasa 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 Curasa 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 Curasa 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

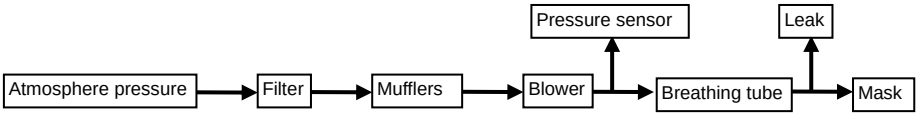
Pressure range..... ..... 4-20 cmH_2O
Pressure variance.....± (2% of the full scale reading+4% of the actual reading)
Ramp time..... 0-60min. adjustable 1min./step
Noise…..<30dB（A）(at 10 cmH_2O/~1.0kPa)
Dimensions..... 180mm L×201mmW × 105mmH
Weight..... 1.6Kg (1.2Kg without humidifier)
Air temperatureathumidifieroutlet…….…….. ... ⩽41°C
DC Voltage…….…….. 24VDC
DC Current.....2.5A Maximum
Humidifier maximum load power.....20W
Protection again electric shock..... Class Ⅱ
Degree of protection against electric shock.....Type BF Applied Part
Degree of protection against harmful ingress of water…IPX1
Disinfect ， sterilize class.....refer to the accessory user manual
The max pressure of humidifier.....2kPa（20cmH_2O）
Fuses…….…….. (T3.15A) there are no user-replaceable fuses
Patient connection port according with 22mm tapered connection port regulated by ISO5367

AC/DC Power Supply
Model: SNP-A069
Input: 100-240V ~, 50-60Hz, 1.8MAX
Output: +24V ⎓, 2.5A

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 schematic diagram：



Maximum Flow Rate:

Pressure(cmH_2O)	Flow(l/min)
7	83

15	103
20	120

Stability Pressure Variation:

Pressure(cmH_2O)	△p
7	≤0.4
15	≤0.5
20	≤0.4

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 Curasa CPAP 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 Medical Inc.
Address: 3327 Kifer Road, Santa Clara, CA 95051, USA
Phone: 1-408-414-2188
Fax: 1-408-413-3000
E-mail: customer_service@curativemedical.com