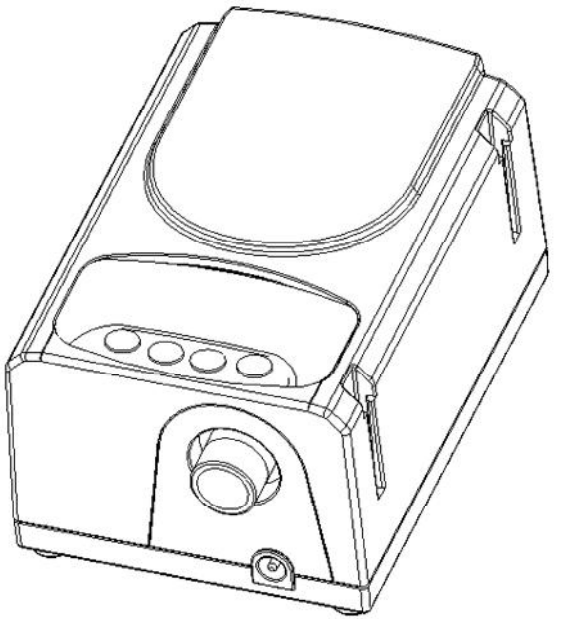
CURASA Basic CPAP

English USER MANUAL



CE
0123

SYMBOL KEY

Attention! Consult accompanying documents	Manufacturer	Date of manufacture	Serial number	Type B applied part	Class II Double insulated	The device, accessories and the packaging have to be disposed correctly at the end of the usage. Please follow Local Laws and Ordinances for disposal	DC Power	Standby	CE marked product

CAUTIONS AND WARNINGS

CAUTIONS!

- This device is restricted to sale by or on the order of a physician.
- Do not use the device before the recommended therapeutic pressure is prescribed by a physician.

- The device should be used with the external AC/DC adapter provided by manufacturer. Use of other AC/DC adapters may damage the device or cause fire and electric shock hazards.
- To prevent water entering the breathing circuit connection on the mask, the device must always be positioned below the head.
- Do not use the device at room temperatures above 35°C. If the device is used when temperature is above 35°C then the temperature of the airflow may exceed 41°C, which could cause thermal irritation or injury to the patient's airway.
- Do not place the device near any items (curtains, bedding, couch) or heating devices (air conditioners, radiators, vents) that may disrupt the airflow around the device.
- Before carrying or packing the device you must empty the humidifier of water
- The device should only be used with CE marked parts provided or recommended by your authorized dealer.
- Check the alarm function regularly and if the device has not been used for a long time please check the power failure alarm before use. If the Power failure alarm is invalid the device must be left in stand-by mode or left running for at least 12 hours before checking the alarm again to make sure it is functioning normally.
- If the device has recently been placed in a very hot or very cold environment, wait for 2 hours to allow temperature to normalize before switching the device on.
- The device can only be operated at temperatures between 5°C and 35°C.

WARNINGS!

- The device cannot be used while mobile.
- This device is for adult use only and not for use by children or persons with certain disabilities who would require supervision in order to use the device safely.

- The device cannot be used for life support.
- Do not use the device in the presence of nitrous oxide or flammable anesthetic mixtures in combination with oxygen or air.
- In the event that the device noise level becomes higher than normal, the devices output of air becomes too hot, the device has an abnormal smell or if any part of the device becomes broken, stop using it immediately contact an authorized dealer.
- The device can only be switched off completely when the power supply is disconnected from the wall socket.
- Make sure the exhalation opening in the mask or swivel is open so that the exhaled air containing CO_2 can escape.
- To avoid rebreathing do not wear the mask for more than 3 minutes when the device is not switched on. (Note. At low pressures the airflow may not be sufficient to remove all exhaled gas (CO_2) therefore some rebreathing may occur.)
- The air inlet of the device should never be covered.
- To avoid electric shock:
    - Do not use the device if the device if the casing or cables are damaged.
    - Do not use the device of it has been dropped in water.
    - Keep device away from water.
    - Before cleaning the device pull the power plug out of the socket.
- This device is for single patient use only and should not be shared with other patients.
- If the patient experiences mucous membrane dryness in the nose and pharynx, frontal sinus trouble, earache, a running nose or skin sensitivity etc. you should consult your physician immediately.
- Operation of the device 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 (e.g., X-ray, CT)
- Magnetic fields (e.g., MRI).
- Do not sterilize the device with high pressured steam

LIABILTY

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

- Tampering, modifying, adding expansion features or repair by persons who have not been authorized by the manufacturer.
- Using accessory or spare parts that are not recommended by us, or not officially registered.
- Using the device in a way that was not instructed in the manual.

INTRODUCTION

INTENDED USE

The Curasa CPAP System is for the treatment of adult Obstructive Sleep Apnea (OSA) only. The Curasa CPAP delivers CPAP (Continuous Positive Airway Pressure) therapy. Your home care provider will make the correct pressure settings.

When prescribed by your physician, the ramp function allows you to lower the pressure when you are trying to fall asleep. The air pressure will gradually increase until your prescription pressure is reached. You also have the option of not using the ramp feature at all.

Several accessories are available to make your OSA treatment with the Curasa CPAP System as convenient and comfortable as possible and to ensure that you receive the safe, effective therapy prescribed for you.

CONTRAINDICATIONS

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

- Bullous Lung Disease
- Pneumocephalus
- Pneumothorax
- Pathologically Low Blood Pressure

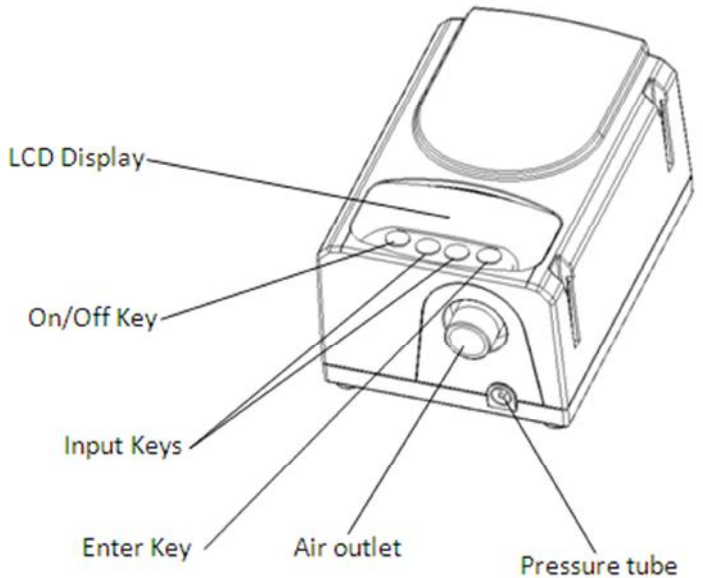
Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when

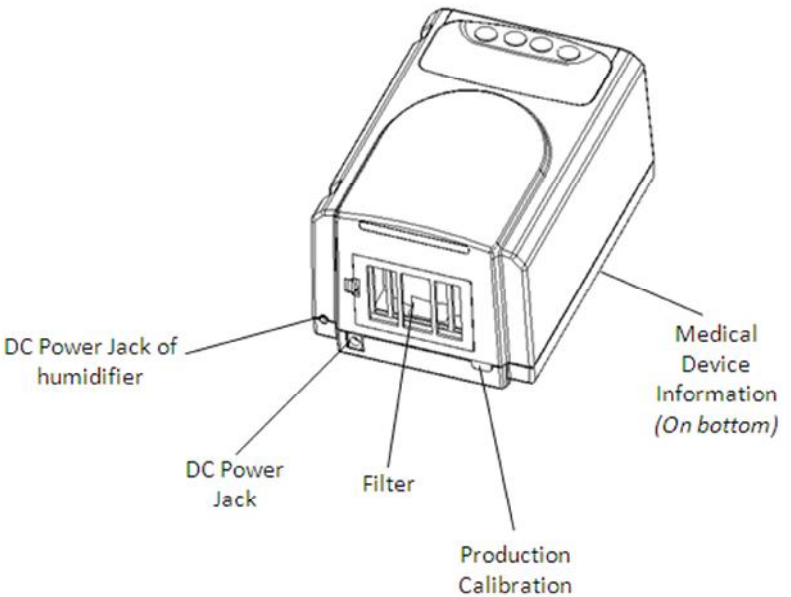
prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)

The use of positive airway pressure therapy may be temporarilycontraindicated if you exhibit signs of a sinus or middle ear infection.Contact your physician if you have any questions concerning your therapy.

DESCRIPTION OF THE DEVICE

CURASA CPAP



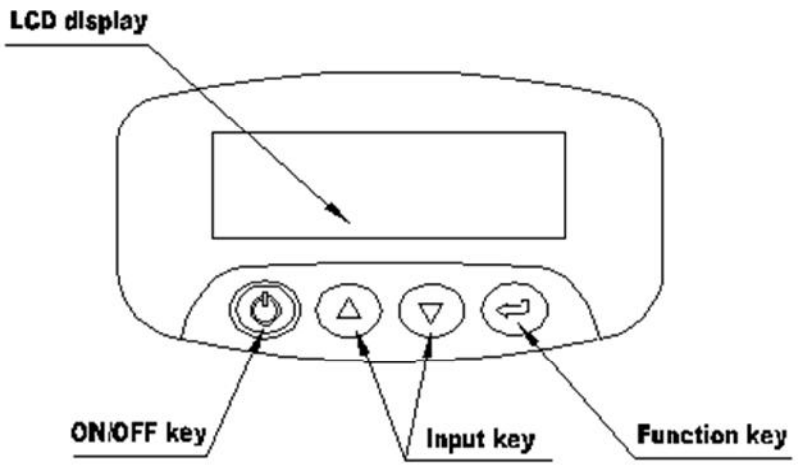


DATA TRANSMISSION

Attention! The data transmission interface is only used during production or service when transmitting data to RS232 or the USB of a PC.

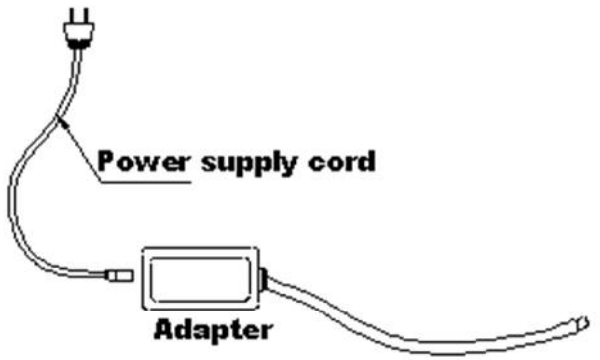
Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). All configurations shall comply with the current version of the standard for SYSTEMS IEC 601-1-1. If you are in doubt consult the technical service department or your local representative. RS232 and the USB port are only for technical use.

CONTROL PANEL



ACCESSORIES

Power supply cord and power supply adapter



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

ACCESSORIES AND PARTS

- Curasa CPAP device (including one fine filter)
- Power supply (including one power supply cord for AC input)
- Hose

CONNECTING THE SYSTEM

- Check whether the device is damaged and if any accessories or parts are missing.
- Put the device on a stable and even surface. Make sure the air inlet in the back of the device is not blocked.
- Connect the power supply adapter with the power supply cord and then connect the DC output of adapter with DC power jack on the back of the device.
- Connect the two ends of the hose to the device's air outlet and mask separately. (Mask not included)
- Connect to the power supply. Power supply adapter: AC input voltage range: AC 100-240V (50/60Hz); DC output: 24VDC2.5A Max. When the device is on the power indicator light will illuminate and the display will show the preset parameters.

PARAMETERS, KEYS AND DISPLAY

PARAMETERS

Function	Introduction	Range
PRESS	CPAP Pressure	4-20cmH_2O(~0.4-~2.0kPa) 0.5 cmH_2O(0.05kPa) per step
AUTOON	Automatic operation mode (ON/OFF)	N/A
RAMP	Ramp time. When using the ramp function the pressure starts at 4cmH_2O and rises until the device reaches the prescribed setting for CPAP therapy.	0-60min increasing pressure 1 step per minute.
START	Start pressure in Ramp time	4-20cmH_2O(~0.4-~2.0kPa) 0.5 cmH_2O(0.05kPa) per step
OPERATE	Display the operation time	0-99999hr
THERAPY	Display the therapy time	0-99999hr
CLEAR THERAPY?	Clear the therapy time	Choose between YES or NO
DD-MM-YYYY	Displays the date	N/A
HH-MM-SS	Displays the time	N/A
VERSION	Displays the software version of the device	N/A
PASSWD	Password for changing pressure (password can only be accessed in edit mode)	4 digits

KEYS

ON/OFF KEY

 Press the key down gently for about 1-2 seconds to turn on the device.

When the device is turned on the background light of LCD display will be illuminated. It will be turned off if no any action is performed within 5 seconds. When the Power supply is plugged in the device is in stand-by mode. The power indicator will be continuously on when the device is in stand-by mode.

Device On/Off means that motor is On or Off.

Power On/Off means that power supply is On or Off.

INPUT KEYS

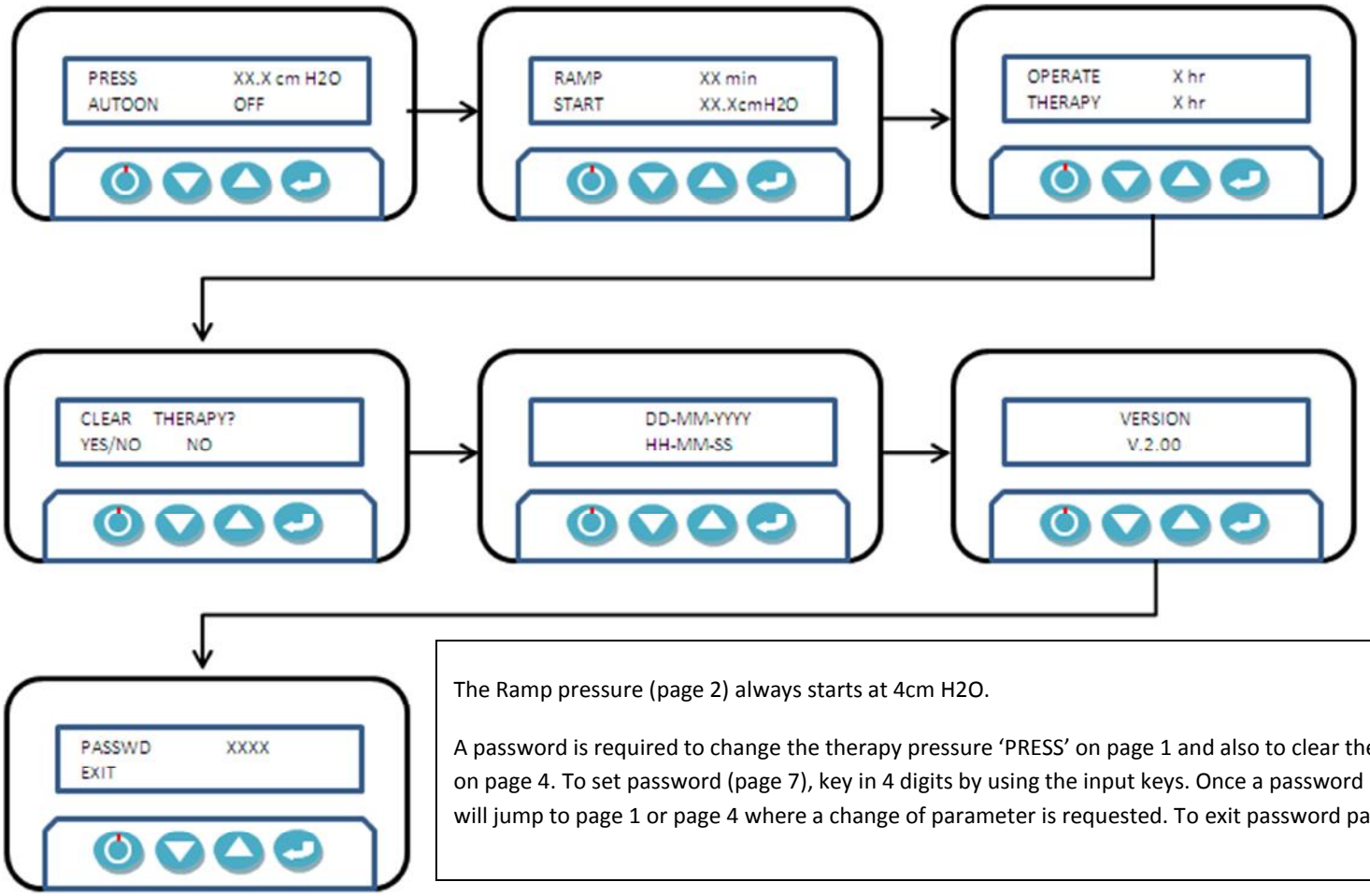
 Input keys are used for selecting functions and adjusting the parameters of a given function.

RETURN KEY

 Return key is used for accessing edit mode and confirming changes of parameters.

- To access edit mode to adjust parameters press the  key once so that the editing function field blinks.
- With the input keys  change the value of the selected parameter.
- Press  key again to confirm and move to next parameter automatically.

DISPLAY



The Ramp pressure (page 2) always starts at 4cm H2O.

A password is required to change the therapy pressure 'PRESS' on page 1 and also to clear the Therapy Time on page 4. To set password (page 7), key in 4 digits by using the input keys. Once a password is accepted it will jump to page 1 or page 4 where a change of parameter is requested. To exit password page select EXIT.

FUNCTIONS OF THE DEVICE

AUTOON

If AutoOn feature is selected, the first breath will activate the device when the patient is wearing the mask.

- The device will switch to standby mode if:
  - The mask is off for 3 seconds or more,
  - The patient hose is disconnected, or
  - The humidifier is switched off.

CPAP MODE

In CPAP mode the device will output the set pressure constantly.

RAMP FUNCTION

When this function is selected the device will start delivering the minimum air pressure first before increasing the pressure steadily to the set pressure within the set time. This function is to allow the patient to fall asleep more comfortably. This soft start function is particularly helpful for patients who are not accustomed to continuous positive airway pressure therapy. The pressure delay time range is between 0 - 60 minutes with pressure steps every minute.

SKIPPING RAMP FUNCTION

When using Ramp function pressing the On/Off key will activate the Ramp. If the On/Off key is pressed again the Ramp function will be skipped and the air pressure will rise to the set pressure.

ALARMS

POWER FAILURE

WARNING! During use if a power failure occurs patients may inhale expired air.

- In case of a power failure or if the power cord is disconnected the alarm will sound to inform the patient that they should remove the mask.
- The alarm can be switched off by pressing the on/off key or will switch off automatically if power resumes.

CHECKING THE POWER FAILURE ALARM

Switch the device on and keep running for at least 10 seconds. If the power cord is unplugged or the power is switched off at the socket the alarm should sound. Check whether the alarm lasts long enough (around 30sec). When the device is switched on the alarm should stop automatically. Please check the alarm at least once a month.

LEAKAGE

WARNING! To minimize leakage ensure that the headgear is adjusted and fits appropriately

- If the AUTO ON function is disabled and the device detects that a patient's mask has been taken off, or if there is an air leak, the motor will run at a lower speed automatically and the pressure will reduce to below the set pressure.
- When the excessive air leakage is stopped the device will work normally again and return to the set pressure.

CLEANING AND MAINTENANCE

CLEANING THE CURASA CPAP

WARNING! To avoid electrical shock unplug the Curasa CPAP power cord before cleaning the device

WARNING! Do not immerse the device in liquid or allow any liquid to enter the enclosure, inlet filter, or any other openings

1. To clean the exterior of the device use a dampened cloth and a mild detergent. Allow the device to dry completely before plugging in the power cord.
2. The mask and tubing should be cleaned daily. For details on cleaning your mask and accessories refer to the cleaning instructions packaged with the accessories.

CHANGING FILTER

The fine filter is in the filter cassette at the back of the device. Take it out and change it with a new one every week. Never use the device without a filter.

Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters for cleanliness. If there is a lot of dust or smoke in the environment change the filter more frequently.

TROUBLESHOOTING

- Different problems that may be encountered, their causes and solutions are detailed below.

Problem	Cause	Solution
Dryness in mouth and pharynx	Breathing through mouth	Use chin strap or full face mask
		Low therapeutic pressure (notify your dealer or physician)
Irritated or dry eyes	Leakage between mask and skin	Adjust the mask's position and headgear.
		If the mask is worn out, request a replacement from your dealer or physician.
		Try another type of mask.
Redness or inflammation of skin under the mask	Headgear is too tight	Loose the headgear
	Wrong mask size	Ask your physician
	Allergic reaction	Ask your physician

- If your dealer cannot resolve the problems, please consult your physician or contact our service center.

MACHINE RELATED PROBLEMS

Problem	Cause	Solution
Low output pressure	Air leak is detected by the device.	Dry thoroughly or clean the pressure tube.
		Check all connections to reduce leakage. Re-seat mask and adjust headgear to reduce leakage around mask.
Discomfort due to high pressure.	When pressure is over 13cmH_2O(~1.3kPa), some patients will feel discomfort. However, this pressure may be needed for effective therapy.	You may take up to 4 weeks to be accustomed to higher pressures. When using the device, breathe through nose with mouth closed and keep calm. If you continue to experience discomfort consult your physician.
Symptoms of sleep apnea syndrome appears again. (like day time sleepiness)	When your weight is increased, your nose is blocked or you drink etc, you need higher pressures.	Consult your physician.
Air is too warm	Dirty filter	Change filter
	Air inlet blocked	Check air inlet
	The device is too close to wall, curtains or other objects, which hinders air circulation	Take away the device to keep it over 20cm from wall, curtains or other objects
No air flow	Defective device	Contact our service center
	Water in the pressure tube	Dry the pressure tube thoroughly

Problem	Cause	Solution
Low air flow	Ramp function is active	Decrease soft start time
	Air inlet blocked	Check air inlet
Motor always operates at maximum speed	The pressure tube is not connected or it is blocked	Check the pressure tube
	Leakage in the device	Contact our service center
When turned on, the device doesn't work	The device is in automatic operation (AUTO ON)	Set the device to manual operation (AUTO OFF)
	Power is not plugged in	Check whether power cable is connected with the device
	No electric supply	Check main electricity supply,
	Fuse is blown (Note: before checking, unplug power cable)	Change fuse Contact our service center
Motor works normally but the output pressure is lower than the set pressure	Patient hose or pressure tube is not correctly connected with the device	Check whether connection is correct and firm
	Air leakage through mask or patient tube	Contact our service center
Only low output pressure	Dirty filter or air outlet blocked	Change filter, check air outlet
	Therapeutic pressure readjusted	Consult your physician
	Soft start function active	If necessary, cancel soft start function or set soft start function time again
Too noisy	Patient hose is not connected or connected incorrectly	Check connection
	Leakage through mask or patient hose	Check patient hose
	Not air tight between humidifier and device	Check humidifier and device
Power failure alarm invalid	The device not used for long time (at least three months)	Put the device on stand-by mode for 12 hours.

SERVICE

- Service of the Curasa CPAP should only be performed by persons authorized by the company.
- To ensure the device is properly maintained, the user must read the Curasa CPAP sleep apnea breathing therapy device's safety instructions and cleaning instructions.

SPECIFICATIONS

Curasa CPAP	
Pressure range	4cm H_2O (~0.4kPa) -20 cm H_2O (~2.0kPa)
Pressure variance	±0.4 cm H_2O (~0.04kPa)
Ramp time	0-60min. adjustable in min/step
Noise: (10 cm H_2O/~1.0kPa)	<29dB (A)
Dimensions	170 mm L* 117 mmW * 93 mmH
Weight	1.4Kg (1.0Kg without humidifier)
Water temperature	44°C Maximum
DC Voltage	24VDC
DC Current	2.5A Maximum
Protection again electric shock	Class II
Degree of protection against electric shock	Type B Applied Part
Degree of protection against harmful ingress of water	Ordinary Equipment, IPX0
Electromagnetic Compatibility	Curasa CPAP sleep apnea breathing therapy device meets the requirements of EN 60601-1-2.
Fuses	There are no user-replaceable fuses.

AC/DC adapter	
Model	SNP- A069
Output	+24V ⎓, 2.5A
Input	100-240V ~, 50/60Hz, 2-1A

Operation	
Temperature	+5°C ～ +35°C
Relative humidity	10%％～ 93%(non-condensing)
Atmosphere pressure	700hPa ～ 1060hPa

Transport or storage	
Temperature	-20°C ～ +55°C
Relative humidity	10% ～ 93%(non-condensing)
Atmosphere pressure	500hPa ～ 1060hPa

DISPOSAL

This device, its accessories and its packaging have to be disposed correctly at the end of the usage. Please follow Local Laws or Regulations for disposal.

ELECTRIC MAGNETIC INFORMATION

GUIDANCE AND MANUFACTURERS DECLARATION OF ELECTROMAGNETIC IMMUNITY FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE SUPPORTING

Attention! Please use Curasa CPAPSleep apnea breathing therapy device according to electric magnetic information in list.

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

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Curasa CPAP uses 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 CPAPis 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 ±4 kV air ±8 kV air	±6 KV contact ±4 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	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% 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 CPAPrequires continued operation during power mains interruptions, it is recommended that the Curasa CPAPbe 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	Power frequency magnetic fields should be at normal levels typical of a location in a commercial or hospital environment.
NOTE: UT is the A/C mains voltage prior to application of the test level.			

<table>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment including cables should not be used close to any part of the Curasa CPAPother than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 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 metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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 CPAPis used exceeds the applicable RF compliance level above, the Curasa CPAPshould be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as, re-adjusting or relocating the Floton Auto CPAP.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE FLOTON AUTO CPAP

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

Rated maximum output power of transmitter (W)	Separation distance according to the 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	0.39	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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

CONTACT DETAILS

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