# iCH Auto with Bluetooth

CPAP System

Instruction Manual

Care for a Healthy Life

APEX

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English

EC REP

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676038-0000 V1.1



Model No.: 9S-007301
Please read the instruction manual before use.

# IMPORTANT SAFEGUARDS
# SAVE THESE INSTRUCTIONS
## READ ALL INSTRUCTIONS BEFORE USING

**WARNING –**

1. THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT. It may stop operating due to power interruption without hazard to patient.
2. If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use. **Explanation of the Warning:** When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device and create a risk of fire.
3. Oxygen is inflammable. Oxygen **should not** be used while smoking or in the presence of an open flame.
4. Always ensure the device is generating airflow before the oxygen supply is turned on. Always turn off the oxygen supply before stopping the airflow from the device.
5. This device should not be used in the vicinity of a flammable anaesthetic mixture in combination with oxygen or air and nitrous oxide.
6. The airflow for breathing generated by this device may be as much as 7°C (12.6°F) higher than the room temperature. This device **should not** be used if the room temperature is warmer than 35°C (95°F) to prevent the airflow temperature from exceeding 40°C (104°F) and causing irritation to your airway.
7. If this device overheats, it will stop operating and show message “Error 002” on the display. After cooling down to the proper temperature, the device can be restarted.
8. This machine should be used only with masks (and connectors) recommended by the manufacturer, or by your doctor or respiratory therapist. A mask should not be used unless the CPAP machine is turned on and operating properly. The vent holes for the mask should never be blocked, to allow for proper exhaling. If the vent hole is blocked, the CPAP machine will stop and show message “**Error 002**”. After the machine cools down, please re-connect the power cord to reset the machine.
9. At low CPAP pressure, some exhaled gas may remain in the mask and be breathed in again.

**CAUTION –**

**1.** Make sure the area around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet on the back of the machine clear to prevent overheating and damage of the device. Do not place the machine near a source of hot or cold air. An extremely cold or hot environment may damage the user's respiratory airway.
**2.** If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance between devices or turn off the mobile phone.
**3.** Do not connect the device to the personal computer for data downloading during the treatment. This may cause a failure in the CPAP system.
**4.** To prevent from potential allergic reactions to mask used in the device, This machine shall be used only with masks (and connectors) recommended by the manufacturer.

**5.** U.S. Federal law restricts this device to sale by or on the order of a licensed doctor.

**DANGER** -To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.
6. If product falls into water or other liquids do not reach into the water or other liquids. Unplug immediately.

**WARNING** -To reduce the risk of burns, electrocution, fire or injury to persons:

1. This product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used with or near children or invalids. Choking resulting from a child swallowing a small part that has become detached from the device or its accessories.
3. Use this product only for its intended use as described in this manual, do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service centre for examination and repair.
5. Keep the cord away from heated surfaces.
6. Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
7. Never drop or insert any object into any opening or hose.
8. Follow the national requirementfor disposing of the unit.
9. Do not operate the device before the mask and water chamber have been installed.
10. Disconnect the water chamber from the device when not in use, water entering the device may result in electric shock hazard or damage.
11. Do not use if water comes in contact with the device or enters the tubing.
12. This device is not for use with patients whose supraglottic airways have been bypassed.
13. Do not cover the device with blankets or clothes .
14. Do not remove water chamber while humidifier is heating. Do not touch the heater plate for 30 minutes after the device is disconnected from the mains.
15. No modification of this equipment is allowed.
16. Do not modify this equipment without authorization of the manufacturer.
17. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
18. Do not leave long lengths of air tubing around the top of your bed. It could twist around your head or neck while you are sleeping and lead to strangulation.



## Recommended separation distances between portable and mobile RF communications equipment and this device

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

| **Rated maximum output power of transmitter** W | **Separation distance according to frequency of transmitter** m | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** $d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz** $d = 1.2\sqrt{P}$ | **800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For 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.

## Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Immunity Test | IEC60601 test level | Compliance | Electromagnetic Environment-Guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1.2\sqrt{P}$ 150kHz to 80MHz |
| Conducted RF<br>IEC 61000-4-6 | 3Vrms150 kHz to 80 MHz outside ISM bands[a] | 3Vrms | $d = 1.2\sqrt{P}$ 80MHz to 800MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5G MHz |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3V/m | 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).[b]<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d].<br><br>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) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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



# 1. Introduction

This manual should be used for initial set up of the system and saved for reference purpose.

## 1.1 General Information

Obstructive Sleep Apnea (OSA) is a condition that an intermitted and repetitive obstruction of the upper respiratory tract causes a complete (apnea) or partial (hypopnea) block of breathing airflow during sleep. The syndrome varies depending on the degree of relaxation of the tongue and soft palate.

The most common treatment for OSA is Continuous Positive Airway Pressure (CPAP). CPAP devices can deliver a constant air pressure into your upper airway via a nasal mask. This constant air pressure can keep your airway open during sleep, therefore prevents the OSA.

This device is a micro-processor controlled continuous positive airway pressure device. It features the illuminated, menu-driven LCD display, universal power supply and ramp time adjustment. The ramp time adjustment and ultra quiet operation ensure you to fall asleep comfortably while air pressure slowly builds up to treatment level. The user compliance meter records the total system's operating time for physician's reference.

The system has been tested and successfully approved to the following standards:

| | |
|---|---|
| CE 0197 | IEC/EN 60601-1<br>IEC/EN 60601-1-2<br>IEC/EN 61000-3-2 Class A<br>IEC/EN 61000-3-3<br>CISPR 11 Group 1, Class B |

## ⚠ For US and CANADA only

E348970
53DG

CLASSIFIED C UL US

**Medical Equipment- CPAP**
**WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY**
**IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005,3rd ed.) and CAN / CSA C22.2 No. 60601-1 (2008)**

**The below description for is for Canada only**

Le produit à été testé avec des équipements médicaux et respecte les normes ANSI/AAMI ES60601-1 (2005,3rd ed.) and CAN / CSA C22.2 No. 60601-1 (2008). prévenant les choc électrique, le feu et les risques de blessures physiques.

## Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:
. Reorient or relocate the receiving antenna.
. Increase the separation between the equipment and receiver.
. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
. Consult the dealer or an experienced radio/TV technician for help.

**FCC Caution:** To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. (Example - use only shielded interface cables when connecting to computer or peripheral devices).

## FCC Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 0.5 centimeters between the radiator and your body.

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



| | | | |
|---|---|---|---|
| Power frequency (50/60Hz) magnetic field IEC61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the a.c. mains voltage prior to the application of the test level | | | |

# Appendix A: EMC Information

## Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment-Guidance |
|---|---|---|
| RF emissions CISPR 11 | Group1 | The device 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 emissions CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network. |
| Harmonic emissions IEC61000-3-2 | Class A | |
| Voltage fluctuations / Flicker emissions IEC61000-3-3 | Complies | |

## Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Immunity Test | IEC60601 test level | Compliance | Electromagnetic Environment-Guidance |
|---|---|---|---|
| Electrostatic Discharge(ESD) IEC61000-4-2 | ±6kV contact<br>±8kV air | ±6kV contact<br>±8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/ burst IEC61000-4-4 | ±2kV for power supply line<br>±1kV for input/out line | ±2kV for power supply line<br>±1kV for input/out line | Mains power quality should be that of a typical commercial or hospital environment |
| Surge IEC61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) | 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 IEC61000-4-11 | <5 % UT(>95 % dip in UT)for 0,5 cycle<br>40 % UT(60 % dip in UT)for 5 cycles<br>70 % UT(30 % dip in UT)for 25 cycles<br><5 % UT(>95 % dip in UT)for 5 sec | <5 % UT(>95 % dip in UT) for 0,5 cycle<br>40 % UT(60 % dip in UT) for 5 cycles<br>70 % UT(30 % dip in UT) for 25 cycles<br><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 this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |



## EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

## 1.2 Intended Use

This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated heated humidifier is designed to increase the humidity of the air from the CPAP thereby relieving the symptoms of a dry nose and throat that some people may experience.

⚠ **Cautions: Some patients might have pre-existing contraindications for CPAP therapy, or might experience some potential side effects of using a CPAP device. Please consult your doctor if you have any questions concerning your therapy.**

⚠ **NOTE: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.**

## 1.3 Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients. Should you have any of these conditions, your physician will determine if CPAP therapy is appropriate for you.

- Bullous lung disease
- Pneumothorax
- Pathologically low blood pressure due to or associated with intravascular volume depletion
- Severe cardiac arrhythmias or coronary artery disease
- Stroke
- Seizures
- Penumocephalus has been reported in a patient using nasal Continuous Airway pressure

# 2. Product Description

## 2.1 Unpacking the Contents

Components include:

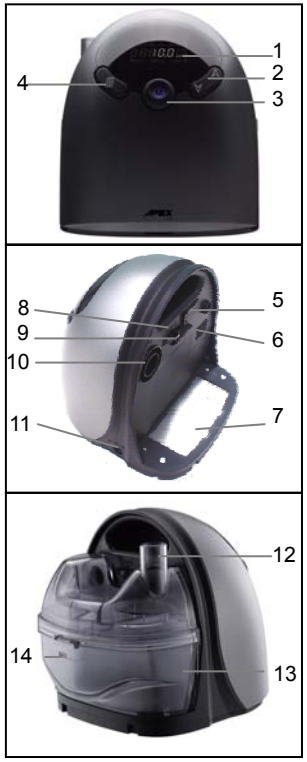
(1) Main CPAP device with integrated heated humidifier
(2) Power supply adapter and AC power cord
(3) User manual
(4) Flexible air tubing, 1.8 m length
(5) Carrying bag
(6) Bluetooth module

⚠ **CAUTION:** Patient should not connect the device to a personal computer for data downloading. This may cause the CPAP system failure.

To secure contents inside, the device and accessories are bundled in a paper packaged box. Unpack this box by removing the device and accessories and check for any damage, which may have occurred during shipping. If there are damages, please contact your dealer immediately.

## 2.2 System Overview

1. LCD Display
2. Up & Down Button
3. Start/Standby Button
4. Menu Button
5. Bluetooth module Connector
6. Air Filter
7. Heater Platform
8. Heater Indicator
9. Heater Control knob
10. Air Outlet
11. Power Socket
12. Air Outlet of the Water Chamber
13. Fill Line
14. Water Chamber






# 10. Servicing

The iCH series systems are intended to provide safe and reliable operation according to the instructions provided by Apex Medical. Apex Medical recommends that the iCH system be inspected and serviced by authorized technicians if there is any sign of wear or concern with device function. Otherwise, service and inspection of the devices generally should not be required during the five year design life of the device.

# 11. Limited Warranty

Apex Medical Corp. (hereafter 'Apex') gives the customer a limited manufacturer warranty on new original Apex products and any replacement part fitted by Apex in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship. To exercise your rights under this warranty, please contact your local, authorized Apex dealer.

**NOTE: Warranty is only valid in the country of purchase.**

| Product | Warranty period |
|---|---|
| CPAP devices (including external power supply units) | 2 years |
| Water chamber | 6 months |
| Mask systems | 6 months |
| Disposable products | None |

## Symbols

BF symbol, which indicated this product is according to the degree of protecting against electric shock for type BF equipment.

Attention, should read the instructions.

Refer to instruction manual

Attention, should read the instructions.

Class II

IP21 Protected against solid foreign objects of 12.5 mm and greater; Protected against vertically falling water drops.

Disposal of Electrical & Electronic Equipment (WEEE):
This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

Fill line

Air flow direction

EC REP Authorized representative in the European community

Manufacturer

# 9. NOTE, CAUTION, AND WARNING STATEMENTS

**NOTE:** Indicates information that you should pay special attention to.

**CAUTION:** Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

**WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.



# 3. Installation

## 3.1 Disassembling the Water Chamber

1. Turn the device off and allow the heater and water to cool. If necessary, disconnect the flexible tubing from the water chamber.
2. Place thumb on the top of the water chamber and tip it upward as shown in Figure 3-1. Remove the water chamber from the system.
3. Unlock the water chamber by pulling the tab as shown in Figure 3-2. Remove the chamber lid from the base.

**Figure 3-1**

**Figure 3-2**

## 3.2 Filling the Water Chamber

1. Fill the chamber to the fill line with distilled water (approx. 300 ml), as shown in Figure 3-3.
2. If the silicon gasket has been removed, replace it securely on the top edge of the water chamber base. Otherwise, the device will not deliver air properly.
3. Position the water chamber on the heater plate and push the bottom forward to lock it in place, as shown in Figure 3-4. Make sure the silicon connector on the inlet connector fits securely over the CPAP device air outlet.

**CAUTION:** Do not overfill the water chamber. Damage to the device may occur.

**CAUTION:** Use only room temperature water; do not fill the chamber with hot or chilled water.

**CAUTION:** Do not turn the heater on without the water chamber installed

**CAUTION:** When installing the water chamber, do not allow water to spill into the device.

**CAUTION:** Do not move the device when the chamber has water in it.


**Figure 3-3**

**Figure 3-4**

## 3.3 Setting Up

1. Place the device on a flat surface and at a lower level than your sleeping position.
2. Connect one end of the air tubing firmly to the air outlet on the back of the device, as shown in Figure 3-5.
3. Connect the other end of the air tubing to the mask system. Put on the mask and headgear according to the mask instruction manual.
4. Plug the socket end of the AC power cord into the power supply adapter. Plug the pronged end of the AC power cord into a main electrical outlet.
5. Plug the power supply cord's adapter connector into the power inlet on the right side of the device, as shown in Figure 3-6.
6. Once the power supply cord's adapter connector is plugged into the power inlet, the CPAP system is in ready to operate position ("**STANDBY**" sign appears in LCD display)

⚠ **NOTE: The AC power cord also serves to disconnect the device.**

⚠ **NOTE: Do not position the equipment so that it is difficult to operate the disconnecting device.**

**Figure 3-5**

**Figure 3-6**



# 8. Technical Specifications

| Item | | Specifications |
|---|---|---|
| Power Supply | | 60W, DC 24V, 2.5A |
| Power Adapter | | DELTA ELECTRONICS, Model No.: MDS-060BAS24 A<br>Input: AC 100~240VAC, 50/60Hz |
| Pressure Range | | 4 –6.5 cm$H_2O$ (adjustable in 0.5 cm$H_2O$ increments) |
| Operating Altitude | | up to 8,000 ft (2,438 m) |
| Dimensions (W x D x H) | | 16.5 x 19.7 x 17.6 cm |
| Weight | | 1.14 kg |
| Sound Level | | < 28 dBA at 10 cm$H_2O$, 1 meter distance |
| Water Capacity | | 300ml |
| Heater Settings | | 1 to 6 from 40°C-70°C |
| Pressure Drop | | 0.2cm$H_2O$ @ 60LPM |
| Humidity Output: | | ≥ 10 mg$H_2O$/L<br>(Ambient temperature: 23°C ± 2°C & Relative humidity: 60% ± 15%) |
| Environment | Temperature | Operating: +5°C to +35°C (+41°F to +95°F)<br>Storage: -15°C to 50°C (+5°F to +122°F)<br>Shipping: -15°C to 70°C (+5°F to +158°F) |
| | Humidity | Operating: 15%RH to 95%RH non-condensing<br>Storage: 10%RH to 90%RH non-condensing<br>Shipping: 10%RH to 90%RH non-condensing |
| Classification | | Class II<br>Type BF, Applied Parts: Mask<br>Not suitable for use in the presence of a flammable anaesthetic mixture<br>IP21: Protected against solid foreign objects of 12.5 mm and greater;<br>Protected against vertically falling water drops.<br>Continuous operation. |

⚠ **Note:** the manufacturer reserves the right to modify the specifications without notice.

| | | |
|---|---|---|
| | right.<br>3. Flexible tube is blocked. | correctly.<br>3. Unblock the flexible tube. |
| Condensation in mask or flexible tube | 1. The heater plate setting is too high.<br>2. The operating environment or position of heated humidifier is not correct. The temperature close to mask or flexible tube is low. | 1. Adjust the control knob to low temperature setting.<br>2. Remove any air conditioner which may nearby the heated humidifier. Or keep room temperature up near 25°C |
| Water Leakage | 1. Water chamber is not properly assembled.<br>2. Water chamber worn out. | 1. Remove the water chamber from the heated humidifier, pour out the water and reassemble the water chamber again, making sure water chamber closes securely, and fill the water till it reaches fill line and check if it still leaks or not.<br>2. Replace with a new water chamber. |

### Error / Warning Messages shown on LCD

| Message type | Definition | Message in LCD |
|---|---|---|
| Error:<br>Primary function can't execute. | Error for abnormal system settings | **Error 001** |
| | Error for flow generator failure | **Error 002** |
| | Error for abnormal timer setting or timer failure | **Error 003** |
| | Error for flow sensor failure | **Error 004** |
| | Error for heater failure (thermal fuse blows off) | **Error 005** |
| Warning: | Out of system memory | **Warn 001** |
| | System memory is nearly full | **Warn 002** |

⚠**NOTE:** When the warning message appears, contact your doctor or equipment provider to download the memory data and reset the meter.



# 4. Operation

⚠**NOTE:** Always read the operating instructions before use.

## 4.1 Control Panel Description

**Buttons on control panel and main use of the buttons:**


**START/STANDBY**

To start the treatment, simply press the ***"START/STANDBY"*** button. To stop the treatment, press the ***"START/STANDBY"*** button again. The display will switch between ***[STANDBY]*** and Therapy Pressure ***[ XX.X cmH$_2$O]*** or ***[ XX.X hPa]*** in cmH$_2$O or hPa unit.

**MENU**

Press the ***"MENU"*** button to enter the setting mode when device is in standby mode. The adjustment setting includes alarm ON/OFF, clock alarm setting, compliance meter, and total operating meter. When each setting's value has been changed, press ***"MENU"*** for confirmation and press ***"MENU"*** again for next setting selection. Please refer to 4.3 Function Description section for detailed information.

**UP**

Press the ***"UP"*** button to increase the selected value.

**DOWN**

Press the ***"DOWN"*** button to decrease the selected value.

## 4.2 Function Description

Getting Started – First time use.
For first-time use, follow the steps below:

1. Make sure that your package contains a face or nasal mask with headgear. If not, your care provider can recommend the type of mask and headgear you must obtain
2. Attach tubing and mask (see Setup section).
3. Attach power cord to the unit and an electrical outlet (see Setup section). Unit will power-on automatically.
4. Press the ***"START/STANDBY"*** button – Airflow to the mask will begin.
5. You can now place the Headgear and Mask over your head and face and begin treatment.

## 4.3 Menu Button - Option Description

**(1) Pressure Unit**

The first selection of pressing ***"MENU"*** button is to set Pressure Unit ***[cm$H_2O$ / hPa]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the preferred pressure unit and press ***"MENU"*** for confirmation. There are two pressure unit, cm$H_2O$ and hPa.

**(2) Compliance Meter**

Press ***"MENU"*** button to select the ***[CM XXXX.X hr]*** menu. The compliance meter records the total therapy hours for the device. The compliance meter should be re-set only by the provider, a respiratory therapist or by a doctor.

**(3) Alarm**

Press ***"MENU"*** button to select the ***[Alarm on/off]*** menu, and press ***"UP"*** or ***"DOWN"*** button to set the alarm on or off. When the alarm is turned on, the audible alarm will activate with warning messages shown on the LCD display. Set alarm off to mute the audible alarm.

**(4) Clock Alarm**

Press ***"MENU"*** button to select the ***[Clock Alarm on/off]*** menu and press ***"UP"*** or ***"DOWN"*** button to set the clock alarm on or off. When the clock alarm is set on, the display will show the time on the left side. Press ***"UP"*** or ***"DOWN"*** button to set the time to wake you up. Once the clock alarm is activated, press the start/standby button to mute the audible alarm.

**(5) Clock**

Press ***"MENU"*** button to select the ***[Clock XX:XX]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the current time.

⚠**NOTE:** If you set a new time that occurs in the past then the "Invalid Data" which does not exist for this new period would be erased.

**(6) Turning off the Device**

Remove the power cord from the electrical outlet, and disconnect power cord from the power socket on the right side of the device.

⚠**NOTE:** Once the setting is confirmed, press the ***"MENU"*** button. Otherwise, the device will automatically go back to standby without saving the modification if no action is taken in 20 seconds.



**NOTE:** Please follow national requirements to dispose of the unit properly.

## 6.4 Water Chamber

1. Turn the heater off and allow the heater and water to cool.
2. Disconnect the flexible tubing from the water chamber. Place thumb on the top of the water chamber and lift it to separate it from the system. Open the chamber and empty the remaining water.
3. Use a mild detergent to wash all the chamber parts. Rinse all the parts with clear water and allow them to air dry.
4. All items of the chamber are subject to normal wear and tear and may eventually be replaced. Replace the chamber parts if any damage is present.

# 7. Troubleshooting

The table below lists troubleshooting solutions for the problems that may happen. If the problem persists, contact your equipment provider's service agent.

| Problem | Possible Causes | Solutions |
|---|---|---|
| No display | 1. The power cord is not connected to the power socket.<br>2. LCD failure or controlled PCB failure. | 1. Ensure the power cord is connected.<br>2. Contact your equipment provider for repair. |
| Display code incorrect | LCD failure or controlled PCB failure. | Contact your equipment provider for repair. |
| Illuminator under LCD is not on | LED failure | Contact your equipment provider for repair. |
| Buttons do not work | Button failure | Contact your equipment provider for repair. |
| Air delivered is slow | 1. During ramp time.<br>2. Filter is too dirty.<br>3. Flow generator failure. | 1. Check the ramp time setting<br>2. Change or clean the filter regularly.<br>3. Contact your equipment provider for repair. |
| Integrated humidifier power on indicator not lit up | 1. Power cord not plugged into a working AC outlet.<br>2. Power switch is not turned on<br>3. PCB or indicator worn out<br>4. Fuse blown | 1. Plug in the power cord to a working AC outlet.<br>2. See Set up procedure and turn the power on.<br>3. Contact your local agent or EU representative for service.<br>4. Contact your local agent or EU representative for service. |
| Heater on indicator not lit at all | 1. Heater plate over heating<br>2. PCB indicator worn out | 1. Contact your local agent or EU representative for service.<br>2. Contact your local agent or EU representative for service. |
| There is no air flow through the mask | 1. Device is not turned on or working correctly<br>2. Flexible tubing is not connected | 1. Check the power cord is connected properly.<br>2. Reconnect the flexible tubing |

an authorized service agent. Do not drop any object into the air tube or air outlet.

## 6.2 Tubing and Mask

The tubing and mask should be checked and cleaned regularly. Please refer to the cleaning instruction s that come with the accessories.

1. Disconnect the air tubing from the air outlet of the device.
2. Remove the air tubing and headgear straps from the mask.
3. Wash the mask system according to the instructions supplied with it.
4. Wash the air tubing in warm water using mild detergent. Rinse thoroughly, hang and allow to dry.
5. Before next use, assemble the mask and headgear according to the mask user instructions.
6. All items of the mask and air tubing are subject to normal wear and tear and may eventually be replaced. Replace the mask and the air tubing if they are damaged.

⚠**CAUTION:** Do not use bleach, chlorine-, alcohol-, or aromatic-based (including all scented oil moisturizing or antibacterial soaps to clean the cushion, mask or air tubing. These sol may cause hardening and reduce the life of the product.

⚠**CAUTION:** Do not wash or dry the mask or air tubing at a temperature above 70°C (160°F)

⚠**WARNING:** Do not use any cleaner containing fragrance or conditioners as they will leave a residue.

⚠**WARNING:** The mask must not be re-used by another person. This is to avoid the risk of cross-infection.

## 6.3 Air Filter

For an optimum operation of the device, the air filter can be cleaned by the user at least once every two weeks or more often if this device is operated in a dusty environment. It is recommended that the filter be replaced with a new one after 6 months of use; however, depending on the air quality, the replacement time may vary.

⚠**CAUTION:** Dirty air filter may cause high operating temperatures that affect device performance. Ensure the air filter is cleaned and fitted at all times

1. Remove the dirty filter from the enclosure on the rear of the device.
2. Wash the filter in warm water with a mild detergent, and rinse with water. Allow the filter to air dry completely before reinstalling. Do not use a filter that is not completely dry. If the filter is torn, replace it.
3. Reinstall the filter.



**(7) Compliance Information**

Hold ***"UP"*** and ***"DOWN"*** button to read compliance information while in the standby screen. Press ***"START/STANDBY"*** button to go back to standby screen

**i. Period**

When entering the compliance information mode, the LCD screen should start blinking to allow you to select the period. Press ***"UP"*** or ***"DOWN"*** button to select the period from 1 day to 90 days. After selecting the period, press ***"MENU"*** to confirm. Press ***"DOWN"*** button to read more compliance information.

**ii. Usage Hours / Compliance Hours**

The **Usage Hours** ***[XXX hrs]*** records the therapy hours under the set time frame. Press ***"MENU"*** button to reselect the time frame, or press ***"DOWN"*** button to read more compliance information.

**iii. Average Compliance Hours per day**

The **Average Compliance Hours per day** ***[X.X hrs/d]*** records the average compliance hours per day over the different time frame. Press ***"UP"*** or ***"DOWN"*** button to read last or next compliance information.

**iv. Days＞4 Hours**

The **Days＞4 Hours** ***[＞4 X.X d]*** records the cumulative number of days that exceeded 4 hours over the different time frame. Press ***"UP"*** or ***"DOWN"*** button to read last or next compliance information.

**v. AHI**

The ***[AHI XX.X]*** records the average Apnea Hypopnea Index (AHI) over the different time frame. Press ***"UP"*** or ***"DOWN"*** button to read last or next compliance information.

**vi. Average Pressure**

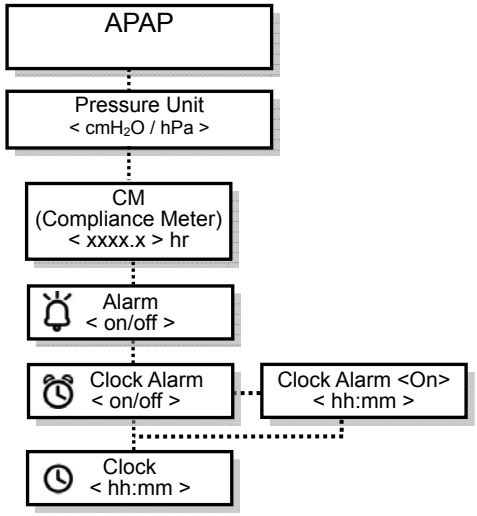
The ***[P XX.XcmH$_2$O]*** or ***[P XX.XhPa]*** records the average pressure over the different time frame. Press ***"UP"*** or ***"DOWN"*** button to read last or next compliance information.

**vii. Average Leak Rate**

The ***[Leak XX.X lpm]*** records the average leak over the different time frame. Press ***"UP"*** button to read last or next compliance information or press ***"MENU***" to come back to the main menu.

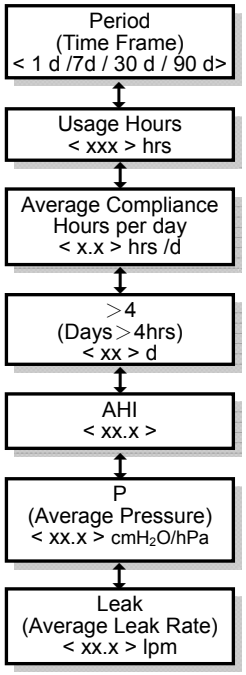
## 4.4 Flowchart of Menu settings

Enter the user's menu mode by pressing the "***MENU***" button.




In each setting, when the preferred value has been selected, press ***"MENU"*** for confirmation and press ***"MENU"*** again to enter next selection.

## 4.5 Flowchart of Compliance Information reading






## 4.6 Using the heated humidifier

1. Turn the control knob on the back of the device to turn on the heater and the heater on indicator above the knob will light up (orange light), as shown in Figure 4-1

**Figure 4-1**

2. Adjust the control knob to increase the humidity in the range of 1 to 6 (see diagram). 1 is minimum humidity, 6 is maximum humidity. The optimum setting is dependent on the ambient temperature and humidity of your room.

⚠**Danger**: In order to avoid the destruction or damage to the device or even the hazard of electric shock, when the water chamber is attached, DO NOT fill water from the outlet port of the water chamber. Users must fill water no more than the maximum mark after the water chamber is removed from the device.

# 5. Bluetooth Function

With Bluetooth module, this device has Bluetooth function. You can pair the therapy device to a mobile device that has the APEX App. APEX App is an App which can help Obstrucitve Sleep Apnea patients enhance their sleep therapy experience.

## 5.1 Pairing with an enabled Mobile Device

Follow the steps to manually pair with your mobile phone

1. Connect your Bluetooth module to the miniUSB port
2. ''BT ON'' will be shown on the screen
3. Open our APEX App and choose the ''APEX'' device on your mobile phone

⚠**NOTE:**Paring works best when your device and mobile device are in the same room

⚠**NOTE:**You can only pair your therapy device to one mobile device at any given time.

# 6. Cleaning & Maintenance

## 6.1 Device

The device should be checked and dusted regularly (at least every 30 days). Wipe with a damp cloth and a mild detergent and keep it free from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case. All parts should be air-dried thoroughly before use. Inspect the device and all circuit parts for any damage after cleaning and replace if necessary.

⚠ **WARNING:** Don't try to open this device. Repairs and internal servicing should only performed by