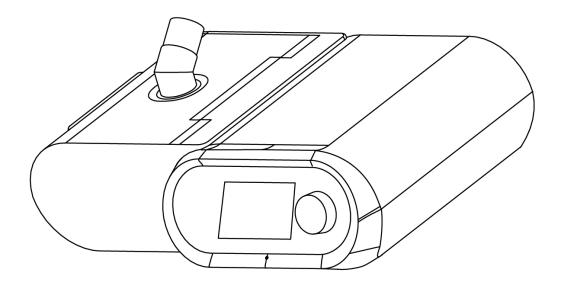
9H∈althG∈ar

SleepZone

User Manual

Sleep Apnea Therapy Devices

Models: C2 & C5



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Contents

| PREFACE | <u>6</u> |
|---|----------|
| CHAPTER 1 PRODUCT OVERVIEW | 7 |
| 1.1 INTENDED PURPOSE, PRODUCT USAGE AND APPLICATION | 7 |
| 1.2 WORKING PRINCIPLE | 8 |
| 1.3 SAFETY TIPS | 8 |
| 1.3.1 WARNING | 8 |
| 1.3.2 Cautions | 10 |
| 1.3.3 CONTRAINDICATIONS | 11 |
| 1.3.4 POTENTIAL SIDE EFFECTS AND SOLUTIONS | 12 |
| CHAPTER 2 APPEARANCE AND ACCESSORIES | 13 |
| 2.1 ABOUT THE MODEL | 13 |
| 2.2 COMPONENT SUMMARY | 13 |
| 2.3 COMPONENTS AND PARTS | 14 |
| 2.4 NOTES ABOUT TERMINOLOGIES AND ACRONYMS | 16 |
| 2.5 ABOUT THE SIGNS | 16 |
| CHAPTER 3 INSTALLATION AND OPERATION | 18 |
| 3.1 PLACEMENT LOCATION | 18 |
| 3.2 SET UP | 18 |
| 3.2.1 Pre-assembly preparation | 18 |
| 3.2.2 CONNECT POWER TO THE MACHINE | 18 |
| 3.2.3 CONNECT THE HOSE TO THE MASK | 19 |
| 3.2.4 FILL THE WATER TANK | 19 |
| 3.2.5 CONNECT THE HOSE TO THE MACHINE | 21 |

| CHAPTER 4 EQUIPMENT USE22 |
|--|
| 4.1 Pre-start inspection - Machine22 |
| 4.2 PRE-START INSPECTION - MASK |
| |
| 4.3 STARTING TREATMENT |
| 4.4 STOPPING TREATMENT23 |
| 4.5 PATIENT AND CLINICIAN MODES24 |
| 4.6 PATIENT MODE24 |
| 4.6.1 ENTER PATIENT MODE24 |
| 4.6.2 PATIENT MENU |
| 4.7 CLINICIAN MODE |
| 4.7.1 ENTER CLINICIAN MODE |
| 4.7.2 RETURN TO PATIENT MODE |
| 4.7.3 CLINICIAN MENU29 |
| 4.8 TREATMENT SETTING PARAMETERS |
| 4.9 Data output |
| CHAPTER 5 HEATING HUMIDIFIER35 |
| |
| 5.1 INTENDED USE |
| 5.2 SPECIFICATIONS35 |
| CHAPTER 6 WIFI37 |
| 6.1 EXPECTED USAGE |
| CHAPTER 7 ALERTS38 |
| 7.1 VISUAL AND AUDIBLE ALERTS38 |
| 7.2 ALERT MESSAGES |
| 7.3 ALERT SUSPENSION40 |
| CHAPTER 8 EQUIPMENT CLEANING AND MAINTENANCE41 |

| 8.1 REPAIR AND MAINTENANCE | 41 |
|---|----|
| 8.2 FREQUENCY | 41 |
| 8.3 CLEANING METHOD | 41 |
| 8.3.1 CLEANING OF CPAP MACHINE AND HOSE | 41 |
| 8.3.2 WATER TANK CLEANING | 42 |
| 8.3.3 AIR FILTER CLEANING AND REPLACEMENT | 42 |
| CHAPTER 9 STORAGE AND TRANSPORTATION | 45 |
| CHAPTER 10 TROUBLESHOOTING | 46 |
| CHAPTER 11 TECHNICAL INFORMATION | 49 |
| 11.1 PARAMETERS | 49 |
| 11.1.1 DEFAULT C2 MACHINE SETTINGS | 49 |
| 11.1.2 DEFAULT C5 MACHINE SETTINGS | 49 |
| 11.1.3 AC ADAPTER PARAMETERS | 50 |
| 11.1.4 MACHINE AMBIENT PARAMETERS | 50 |
| 11.1.5 PHYSICAL AND ELECTRICAL PARAMETERS | 50 |
| 11.1.6 ELECTRIC SAFETY CLASS | 51 |
| 11.2 PNEUMATIC SCHEMATIC DIAGRAM | 52 |
| 11.3 EMC INFORMATION | 52 |
| 11.3.1 Instructions for use | 52 |
| 11.3.2 TECHNICAL DESCRIPTION | 53 |
| 11.3.3 RF INFORMATION | 57 |
| APPENDIX 1: MODEL COMPARISON TABLE | 58 |
| APPENDIX 2: WARRANTY AND DOWNLOADS | 59 |

Preface

5 HealthGear is a registered trademark of CPAP Sales Pty Ltd (hereinafter CPAP Sales)

Models C2 and C5 are Sleep Apnea Therapy Devices (Non-invasive ventilators) have been independently developed by Micomme Medical Technology Development Co., Ltd (hereinafter referred to as Micomme Medical) exclusively for CPAP Sales.

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No additional notice shall be provided in case of any change in the information contained in this document. Micomme Medical reserves the right to change equipment design, performance, components and processes including any other circumstances to continually improve product and quality assurance.

Chapter 1 Product overview

1.1 Intended purpose, product usage and application

This Class IIa Medical Device has been registered and approved by the Australian Therapeutic Goods Administration (TGA) for supply by CPAP Sales Pty Ltd.

It is a portable, mains electricity (AC-powered) device, which may include rechargeable batteries, intended to assist noninvasive ventilation (i.e., without use of an artificial airway) using continuous positive airway pressure (CPAP) during spontaneous respiration, primarily to treat adult patients affected by obstructive sleep apnea (OSA); it may also be intended to treat snoring. It is a small desktop unit with controls, and may include a built-in humidifier; the airway pressure may be automatically adjusted to help provide optimal CPAP through use of a sensor (auto CPAP). The device is intended for use in the home but may also be used in healthcare facilities.

Models C2 and C5 are Obstructive Sleep Apnea Therapy Devices (hereinafter referred to as a "CPAP Machine") providing non-invasive ventilation treatment for patients with obstructive sleep apnea syndrome (OSAS). These CPAP Machines are for use by pediatric patients aged over 7 (with a weight being over 18.1kg or 40lbs) and adult patients (with a weight being over 30kg and 66lbs) only.

This CPAP Machine should be used by patients under the guidance of professionally trained medical staff, with patient as the intended end user/operator. Patients with severe respiratory failure but spontaneous breath should not use a CPAP Machine unless instructed to do so by a medically trained professional.

CPAP Machines need to be used together with a breathing hose and a nasal/face mask suitable to the patient.

To download this User Manual, please visit: cpapsales.com.au/manuals

1.2 Working principle

This CPAP Machine includes a power cord, ac adaptor, hose and Machine (including main control panel, motor, display, control dial, buzzer, enclosure, humidifier, water tank and ozone generator). Room air passes through a filter, and is sent out at a preset pressure and flow rate through the controlled motor and heated humidifier, before reaching the respiratory tract and finally the patient's lungs. The CPAP Machine's system can collect information about the patient's compliance use and Machine operating performance.

1.3 Safety tips

Warnings, cautions and notes apply to the whole User Manual.

1.3.1 Warning

- The User Manual is for reference only. The description in it can't substitute the guidance of professional medical staff.
- Before using the equipment, please read through and understand the User Manual.
- The equipment is not designed to meet your complete ventilation demand or to be used as life support system.
- Since there is no circuit of expiration in the Ventilator, the user should be provided with a face mask with at least 30LPM air-leaking holes to avoid repeated inhalation of the carbon dioxide resulting from the breath.
- The treatment parameters must be adjusted by trained professional medical staff.
- In case of any discomfort in the equipment use, please immediately contact your professional medical staff.
- Use only the expiration circuit provided by your professional medical staff instead of any anti-static or conductive hose or conduit.
- Winding due to cables and breathing hoses, particularly due to excessive length.
- Do not bend or wrap the breathing line during use.
- When using the breath circuit integrated with expiration holes mask or circuit with independent outlet device, do not bind or seal the air leaking holes, or block the fresh air inlet with adhesive tape, seal or other substances, for it may stop the inspiration of fresh air and even lead to suffocation.
- When the equipment is working, do not cover it with any article, or else the fresh air

inlet may be blocked so that the user may get suffocated.

- Do not try to wear the face mask before the equipment is turned on and works normally; or repeated inspiration of carbon dioxide may be caused. In some case, inspiration of exhaled gas for a few minutes can lead to suffocation.
- In order to ensure normal use, the power supply must be inserted into the socket in a vertical way.
- Do not use this equipment alone for pediatric patients over 7 years old.
- Please keep the equipment away from children and pets.
- Against servicing and maintenance while the equipment is in use.
- Regularly check if there is any damage or wearing sign in the electric wire, cable or power supply device; if there is any, please stop using the device and arrange a replacement.
- The plug is used as disconnect device to the mains supply, do not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.
- To avoid electric shock, please disconnect the plug before cleaning the equipment.
- The equipment maintenance and repair can only be done by the professional repairman authorized by Micomme Medical.
- No modification of this equipment is allowed.
- Do not use the equipment when the room temperature is above 35°C, for the temperature of the air flow in such case may exceed 43°C, and stimulus or damage may be caused to your air passage.
- Keep the equipment from sunshine or heating device when using it, for the air discharged from the equipment in such case may have an elevated temperature.
- Before using the equipment, please check if the present warning SET is suitable for the patient. Improper warning preset in different areas may bring damage to the patient.
- When using the equipment, please prepare simple respirator or other Machine that
 can substitute the equipment for the time being so that the normal treatment of patient
 will not be interrupted and no damage is caused to the patient in case of sudden
 failure with the equipment.
- When noticing an unexplainable change or abnormal or annoying noise with the working equipment,
- If necessary, our company (Micomme Medical) may provide the technical files (e.g. circuit diagram, list of elements, legends, and detailed rules and regulations about calibration) required for the purpose of repair for the qualified technical maintenance and repair staff either designed by us or of other types.

- The product must be used as specified in IEC 60601-1:2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- Additional equipment connected to medical electrical equipment through the
 network/data coupling must comply with the respective IEC or ISO standards (e.g. IEC
 60950 for data processing equipment). Furthermore all configurations shall comply
 with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16
 of the 3Ed. of IEC 60601-1, respectively).
- Anybody connecting additional equipment to medical electrical equipment
 configurations a medical system and is therefore responsible that the system complies
 with the requirements for medical electrical systems. Attention is drawn to the fact that
 local laws take priority over the above mentioned requirements. If in doubt, consult
 your local representative or the technical service department.
- Sources of oxygen must be located more than 1 m from the equipment to avoid the risk of fire and burns.

1.3.2 Cautions

- The equipment can only be operated in the ambient environment of 5°C-35°C.
- To assure normal working, an undamaged reusable sponge filter should be properly fixed at the air inlet.
- The equipment should not be immersed in any liquid, and no liquid is allowed to enter into its enclosure or inlet filter.
- Condensation may damage the equipment. Please raise the equipment temperature to the room temperature before using it.
- Do not cover the equipment with such objects as blanket; or the fresh air intake may be blocked so that the Machine become overheated to affect the treatment or damage the equipment.
- The equipment isn't provided with power-off alert or power-off-resistant design. Within it, there is no battery supply. Therefore, during the use, please ensure the adapter power plug and equipment are properly connected, the power line is reasonably placed in order to prevent the power plug from falling off from the equipment under external force and consequent patient suffocation with harder respiration.
- In case of recovery of power supply after an interruption, the equipment should be restarted in treatment in order to assure normal working.
- The waste and residue generated by the equipment as well as the expiry equipment and its accessories should be classified before treatment so as to prevent environmental pollution or other hazards.
- The pressure sensor of the equipment remains as a key pressure test device, so it

should be sent to the maintenance staff passing the training organized by Micomme Medical for maintenance every half a year; or the accuracy of the equipment's pressure output may be affected.

- All the parameters of the ventilator are stored in non-volatile memory, so disconnection
 of equipment with mains will not affect the SET of all such parameters.
- Replacement of parts shall be made by the parts specified by the manufacturer of the equipment and by the maintenance personnel designated by the manufacturer.

1.3.3 Contraindications

When having severe respiratory failure and no spontaneous breath, please do not use the equipment.

When any of following situations applies to you, please consult professional medical staff before using the equipment;

- Insufficient respiratory drive to tolerate the intermittence of non-invasive ventilation treatment;
- · Acute sinusitis and otitis media;
- Some diseases that may cause intake of stomach contents;
- Inability to clear the secretion;
- Hypotension or apparent hypovolemia within blood vessel;
- Pneumothorax or mediastinal emphysema;
- Craniocerebral trauma or surgery;
- · receiving airway neostomy in the past;
- Pulmonary bulla.

1.3.4 Potential side effects and solutions

The non-invasive PAP (positive airway pressure) may have following potential side effects:

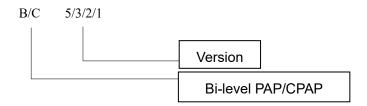
- Dry mouth, nose or throat;
- Abdominal distension;
- Discomfort with ear or sinus;
- Eye irritation;
- Skin irritation caused by face mask;
- Chest discomfort.

When having any discomfort during the use, please immediately seek medical advice from professional medical staff or consult with the supplier.

Chapter 2 Appearance and accessories

2.1 About the model

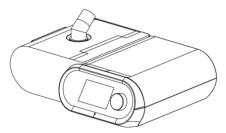
The CPAP Machine product is coded as follows:



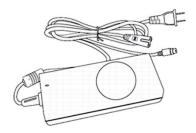
2.2 Component summary

In the unlikely event that any of the following major components or parts are missing, please contact your equipment supplier. It is recommended to use matching parts and materials recommended by the equipment manufacturer. Please consult your equipment supplier or manufacturer when planning to use other alternative products; or the safety performance of the equipment may be affected.

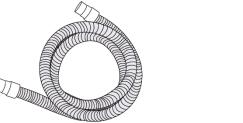
1. Machine with Humidifier



2. Power adapter with Australian Power Cord



3. Hose

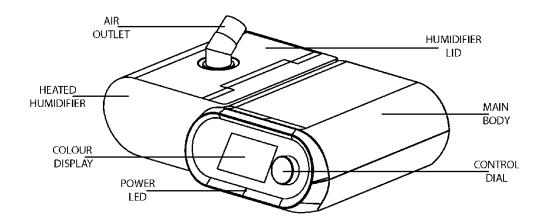


4. Ozone circulation joint connector

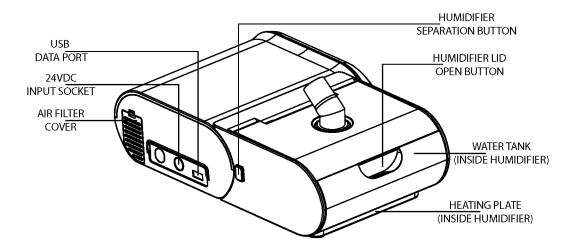


5. Accompanying documents: Quick Start Guide and Packing List.

2.3 Components and parts



| Air outlet | Connection with CPAP Machine hose; 360°rotation; outlet dimensions: Outside Diameter 22mm, Inside Diameter 15mm. | | |
|----------------------------|--|--|--|
| Heated Humidifier | Including water tank, heating plate and air outlet; can be separated from main body of the Machine. | | |
| Control Dial | Rotate the dial clockwise or counterclockwise to scroll through the screen display; increase the value of selected parameter by rotating the dial clockwise and decrease it by rotating the dial counterclockwise. | | |
| Colour Display | Displays settings, and real-time data including working pressure and air leakage. | | |
| Power LED | Green light indicates the Machine is powered. When not lit, it indicated the Machine is disconnected from the power supply. | | |
| Humidifier Lid Open Button | Press the humidifier lid open button to lift up the humidifier lid and pull out the water tank. | | |



| Humidifier | Press the button in order to remove the humidifier portion from the |
|-----------------------|--|
| Separation button | Machine. |
| USB Data Port | For use with USB memory stick to save sleep therapy usage data. |
| 24VDC Input Socket | Connection with power adapter. |
| | The foam filter screens out normal household dust and pollen, the |
| Air Filter cover | filter cover is designed to keep the filter in place and should not be |
| | blocked at any time. |
| Humidifier Lid | Press the button to allow the humidifier lid to be opened upwards |
| Release button | and allow the removal of the water tank. |
| Water tank (Inside | The water tank can be removed and filled with distilled water for |
| Humidifier) | later use. The amount of water should be less than the max |
| , | indicator line. |
| Heating plate (Inside | There is a heater plate within the base of the humidifier for heating |
| Humidifier) | the water tank. |

2.4 Notes about terminologies and acronyms

You may encounter the following terminologies and acronyms when using the device. Please read carefully before use.

| Terminology/acronym | Definition | |
|---------------------|---|--|
| cmH ₂ O | Pressure unit, cmH2O. | |
| AHI | Apnea and hypopnea index: the frequency of apnea and hypopnea incidence in each hour. | |
| 95% pressure | This is a value of pressure. In a period of treatment the treatment pressure of the Machine is lower than this value for 95% of the treatment time. | |
| LEAK | Air leakage: the air flow leaking from the hose or face mask during the treatment. | |

2.5 About the signs

You may find following signs on the equipment or when using the device.

Please read carefully before use.

| Sign | Definition | | |
|-------------|---------------------------------|--|--|
| \triangle | Attention | | |
| 浓 | BF application component | | |
| | Category II (double insulation) | | |
| IP21 | Dustproof waterproof level | | |

| \otimes | Component beyond repair by user. | |
|-----------|--|--|
| | It is in line with the rules about recycling and reusing of waste electrical and electronic Machines/limited use of toxic substances in Waste Electrical and Electronic Equipment/Restriction of the Use of Certain Hazardous Substances (WEEE/RoHS) | |
| | Ramp function. | |
| COMF | Comfort level function. | |
| 2 | Icon indicating startup of heating and humidifying Machine. | |
| | WIFI on (Feature not currently available in Australia) | |
| | Hot surface | |
| === | Direct current | |
| | Refer to instruction manual/booklet | |

Chapter 3 Installation and operation

3.1 Placement location

The CPAP Machine should be placed on a solid and flat table or fixed on support. The user should operate the equipment in a position where it is easy to access the equipment and see clearly the information displayed on it. A distance of at least 5cm should be kept between the equipment and wall to ensure the equipment's air inlet is not covered by curtains, quilts or other objects. The air around the equipment should keep moving smoothly and away from any heating or cooling device (such as forced vent, radiator, and air conditioning) to ensure the system can work normally.

3.2 Set up

Your Machine will already have been pre-set by your equipment provider and should be ready to use without any adjustments. A Quick Start Guide was supplied with this Machine to help you get started.

3.2.1 Pre-assembly preparation

The Machine with humidifier are already assembled. No pre-assembly is required.

3.2.2 Connect power to the Machine

Fit the power cord and power supply together. Connect the mains plug to the AC wall socket and the 24VDC plug into the back of the Machine.

Caution: please ensure the power line is inserted firmly to prevent the power supply becoming loose in case of equipment movement.

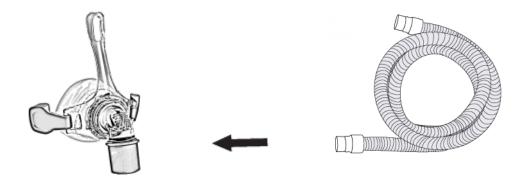
Attention! Do not connect the device to any unauthorised devices unless recommended by the manufacturer or your health care provider.

3.2.3 Connect the hose to the mask

Connect either end of the hose tubing supplied with your equipment to your mask.

The mask may have been included as part of a package, or can be purchase separately.

Any brand of mask will fit on this hose.

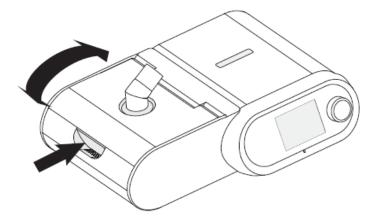


3.2.4 Fill the water tank

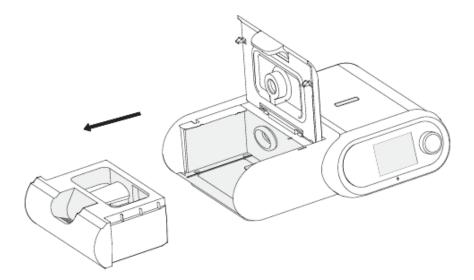
Before use, please ensure the water within the tank is <u>below</u> the max indicator line.

Warning: Do not activate the humidification function when there is no water tank or no water within the water tank.

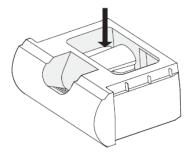
Remove the water tank by pressing the lid release button on the upper cover of the humidifier and gently lift the cover upwards.



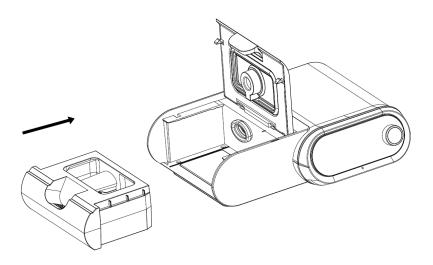
Fully open the humidifier cover lid and slide the water tank out of the main unit.



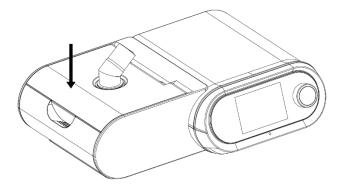
Carefully add <u>distilled</u> water into the water tank. Do not over-fill and do not operate without water, unless the humidifier heating is set to OFF.



Slide the water tank back into the humidifier.

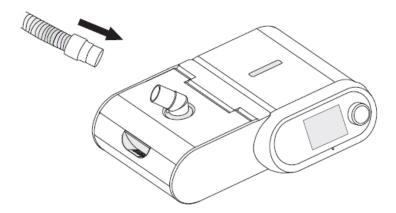


Close the upper cover of the water tank firmly until the lid clicks into place.



3.2.5 Connect the hose to the Machine

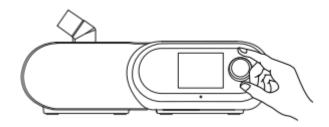
Finally, connect the other end of the hose to the swivel connector on top of the humidifier.



If required, before use, adjust the humidifier temperature to your personal preference in the [Set] > [Param] menu.

In this case, select the desired setting between 1 and 5 based on personal comfort and environmental conditions. The higher the number, the more moisture is added to the airflow treatment. Too much moisture will cause water droplets in the hose or mask.

The humidifier can also be turned off in the [Set] > [Param] menu.



Page 21 of 60 © 2020 All Rights Reserved

Chapter 4 Equipment use

Before starting treatment, please check the equipment and accessories to ensure they are intact and free from any damage.

4.1 Pre-start inspection - Machine

After the CPAP Machine is properly connected with the power supply, its LCD will show the main startup menu, where treatment parameters can be checked and set. In the event that the CPAP Machine fails to display this menu after 2 seconds, please check all power connections points. After the main menu appears, the [Treat] option should be highlighted, indicating the CPAP Machine is ready for use.

4.2 Pre-start inspection - Mask

The CPAP Machine is designed to be used together with a CPAP mask. For further information regarding the mask, please use the manual provided with the mask.

Please wear the face mask by following the steps below:

- 1. Connect the headband with the face mask (ensuring the headgear is correctly orientated);
- 2. Position the mask on the face;
- 3. Adjust the tightness of the headgear so that face mask is slightly pressing on the face without causing any indentations;
- 4. The mask should be worn firmly but not uncomfortably to avoid leaks.

Attention! If the Machine is not in proper working condition, sufficient fresh air cannot be provided. In this case carbon dioxide can build within the mask and cause discomfort. When applying the mask prior to sleep, please ensure the air flow starts correctly on the Machine.

4.3 Starting treatment

When [Treat] is showing on the display, press the control dial button to start the CPAP therapy treatment. The airflow pressure will be displayed on the screen. In the unlikely event of an error occurring, an alert tone will be sound, and a corresponding red alert message will be display at the top left of the screen.

When the equipment is connected correctly, the screen display will light up and then automatically turn off after 15 seconds. The backlight timing can be changed in the [System] > [Backlight] menu. Options are 15, 30, 45, 60 seconds, and ON full time. You can illuminate the screen back at any time by pressing or turning the control dial.

If "Auto On" has been enabled, airflow will start automatically once breathing has been detected through the face mask.

Tip: Leave the Machine with [Treat] showing on the screen so that the device is ready to begin the next therapy session.

The Machine contains an internal memory. This ensures that all settings applied to the Machine, including treatment mode, treatment pressure, humidifier level, ramp time, and COMF remain the same as before the last shutdown or power disconnection. On the initial startup, the settings applied will be those set by your service provider, or the default settings.

4.4 Stopping treatment

To cease the airflow, press the control dial once to wake up the screen, then press and hold the control dial for 3 seconds until the airflow stops.

If "Auto OFF" has been enabled, airflow should stop 10 seconds after mask removal.

Depending on the brand and type of mask, accurate detection may not always be possible.

4.5 Patient and clinician modes

The equipment can be adjusted in two modes: namely Patient and Clinician.

Patient Mode: in this mode, users can adjust a limited number of parameters which relate to comfort, convenience and day to day device usage.

Clinicians Mode: in this mode, professional technicians and medical staff can adjust all parameters, including treatment pressure and CPAP/Auto mode selection (for C5 Machine only).

Warning: non-professional staff are forbidden to access the Clinicians Mode.

4.6 Patient mode

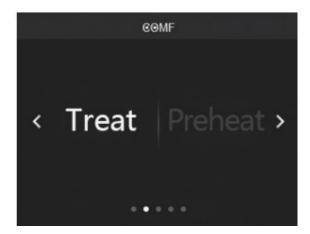
4.6.1 Enter patient mode

Power on the equipment and wait for 2s or so, the equipment will automatically enter the Patient Mode and display the idle menu.

4.6.2 Patient menu

(1) Main menu

After the equipment is connected correctly, the following idle menu will appear.



Page 24 of 60 © 2020 All Rights Reserved

(2) Status Bar

The grey status bar in the upper part of the display is used to show symbols of features that have been enabled and any alert messages.

The symbols in status bar have following meanings:

Comfort. This icon will appear when exhalation pressure relief comfort setting between 1 and 3 has been enabled and set. With this setting enabled, it will be easier to breath out against the airflow coming in. This can be helpful for some patients, especially those using nasal pillow masks.

Heated Humidifier: This icon will appear when the heated humidifier has been enabled. The number relates to the level of humidification that has been set, from 1 (minimum moisture) to 5 (maximum moisture). The factory default setting is 2. Select the desired setting based on personal comfort and environmental conditions.

The higher the number, the more moisture is added to the airflow treatment. Too much moisture will cause water droplets in the hose or mask.

Tip: If the Machine is to be used without the humidifier, the humidifier setting must be set to OFF in the [Set] > [Param] menu.

WIFI: This icon will be displayed when the Machine has been successfully connected to a home WiFi network (2.4GHz only) in the [System] > [Network] menu.

When this function is set up and activated, the equipment will be automatically connected with WIFI to upload the treatment data to a remote server so that the medical staff can learn about the Machine use state.

Tip: This feature is not currently available in Australia.

(3) Operation menu

[Treat]: used to start and stop the therapy (airflow) treatment.

[Preheat]: the humidifier can be turned on in advance of treatment to pre-heat the distilled water, ready to provide the soonest humidification.

[Set]: used to set the device;

Param: Parameters such as Comfort, Humidifier, Auto ON, Auto OFF and;

Time: Date settings including Year, Month, Date, Hour and Minutes.

[System]: used to;

Output: Save historical therapy data to the USB stick;

Network: Set up and check device connection to a 2.4GHz home WiFi

Update: only use if instructed by your service provider to download new operating software;

Diagnose: used to display simple percentage feedback of therapy use;

Clean: used to start ozone cleaning cycle;

Backlight: used to set time for display to stay lit;

Language: English or Chinese options;

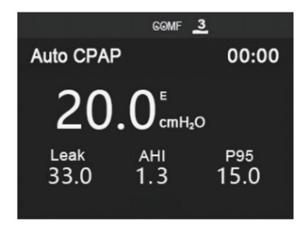
Reset: used to reset Machine settings back to factory default settings. Usage and compliance data cannot be reset.

Version: used to display current software version of the device;

[Info]: used to show key information relating to the CPAP therapy treatment including AHI, P95, Leakage, Treatment Time and Treatment Days over the following time periods; 1 Day: 7 Days: 30 Days. Total Work Time (Run Time) can also be viewed here. At 9am each morning, this information updates. Eg. The 1 day info resets to zero.

(4) Treatment Screen

During treatment, the screen will display information similar to the one shown below.



Auto CPAP or CPAP: Depending on the model (C2 = CPAP, C5 = Auto-CPAP)

Time: Time in use since treatment therapy last started.

Pressure: The real-time therapy pressure the device is delivering. Typically, a number between 4 and 20cmH20. The IPAP/EPAP state is also displayed. I = Inspiration (breathing in), and E = Expiration (breathing out)

Leak: The leak value (typically hose, mask or mouth leak) will vary during use and is displayed in the bottom left corner of the display. This value will turn red if the leak is excessive, exceeding 60litres/minute.

All masks have an intentional leak to prevent inhalation of your own breath which contains carbon dioxide. The intentional leak value varies depending on the type and brand of mask, but is typically around 20~30l/m.

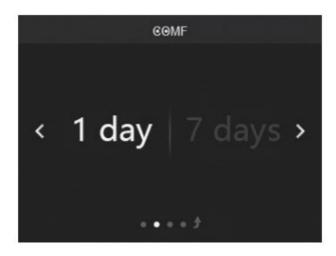
AHI; Apnea Hypopnea Index. Shows the number of events per hour, where no breathing or shallow breathing has occurred for 10 seconds or more. The target AHI is under 5/hour, and the lower the number the better.

P95: The pressure or less at which the Machine has been running at for 95% of the time.

The AHI and P95 displayed during therapy are the results of the last treatment session.

(5) Info Menu

After [Info] has been selected on the menu, a treatment summary can be displayed on the screen for the last 1 day, 7 days or 30 days.



"1-day", "7-day" and "30-day" displays a basic treatment summary report for the period selected.

Tip: At 9am each morning, this information updates. Eg. The 1 day info resets to zero.

(6) Menu Navigation:

- Step 1: Rotate the control dial left or right to wake up the screen.
- Step 2: Rotate the control dial to move the cursor to the setting requiring adjustment.
- Step 3: Press the control dial and move the cursor to adjust the setting.
- Step 4: Rotate the control dial left or right to choose the parameter to be set.
- Step 5: Repeat step 2-4 to continue with the setting of other parameters.
- Step 6: Rotate the control dial to show [Exit], and press to return to the home screen.

Tip: Leave the Machine with [Treat] showing on the screen so that the device is ready to begin the next therapy session.

4.7 Clinician mode

Warning: non-professional staff are forbidden to access the Clinicians Mode.

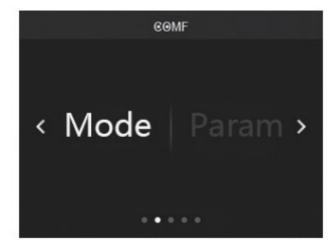
4.7.1 Enter clinician mode

- (1) Power up the equipment, then move the cursor to display [Set] on the screen
- (2) Press and hold the control dial for 5 seconds until [Mode] is displayed
- (3) The clinician can now make setting adjustments

4.7.2 Return to patient mode

(1) Rotate the control dial until [Exit] shows on the screen, then press the control dial. Repeat this process until "Exit" can no longer be seen when rotating the control dial.

4.7.3 Clinician menu



Select "Mode" to adjust treatment mode and treatment pressure.

Select "Param" to adjust additional including Ramp time and Ramp starting pressure.

The range of available setting options will depend on the device model. C2 is for CPAP Machines, C5 is for Auto-CPAP Machines.

4.8 Treatment setting parameters

| Parameter | Setting range | Description | Mode |
|-------------|---------------|-----------------------------------|-----------------|
| Exit | | Return to the previous menu | Patient Mode |
| LAIL | | Tretain to the previous menu | Clinician Mode |
| | | CPAP Mode: provides | |
| | CPAP | continuous positive airway | |
| | OI AI | pressure ventilation. | |
| | | Auto-CPAP Mode (C5 only): | Clinician Mode |
| Treatment | | provides automatic adjustment | |
| Mode | Auto CPAP | varying the positive airway | |
| selection | Auto CFAF | pressure as per the airway | |
| | | obstruction state. | |
| | | Select the Treatment Pressure | |
| | | based on the patient's | |
| CPAP | 4~20cmH20 | prescription. This will be one | Clinician Mode |
| CPAP | 4~20CIIIH20 | value between 4cmH20 and | Clinician Mode |
| | | 20cmH20 in 0.5cmH20 | |
| | | increments. | |
| Max CPAP | 4~20cmH20 | Set the upper pressure limit for | Clinician Mode |
| IVIAX OI AI | 4~20CHH20 | automatic CPAP ventilation | Cililician Wode |
| Min CPAP | 4~20cmH20 | Set the lower pressure limit for | Clinician Mode |
| WIIII CPAP | 4 200111120 | automatic CPAP ventilation. | Olimodii Wode |
| | | Switch exhalation pressure relief | |
| COMF | OFF, 1, 2, 3 | comfort technology OFF, or | Patient Mode |
| COIVII | OI 1, 1, 2, 3 | choose a setting of 1, 2 and 3. | Clinician Mode |
| | | The higher the number, the | |

| | | easier it will be to breathe out | |
|------------|----------------|----------------------------------|----------------|
| | | against the airflow. | |
| | | agamot the annow. | |
| | | Typically used in CPAP Mode, | |
| | | the Ramp feature allows the | |
| Domn time | OFF or 5~45 | Machine to start at a lower | Patient Mode |
| Ramp time | minutes | pressure and slowly ramp up to | Clinician Mode |
| | | the treatment pressure over the | |
| | | Ramp time selected. | |
| | | When a Ramp time has been | |
| | | selected, choose the starting | |
| | | pressure. Over the Ramp time | |
| | | selected, the Machine pressure | |
| | | will slowly rise until; | |
| | | a) The CPAP Treatment | |
| | 4cmH2O ~ CPAP | Pressure has been reached | Patient Mode |
| Ramp start | Pressure | (CPAP Mode only) | Clinician Mode |
| | | or | |
| | 4cmH20 ~ min | b) The min CPAP pressure has | |
| | CPAP pressure | been reached (Auto CPAP Mode | |
| | | only) | |
| | | Stop and restart the Machine to | |
| | | begin the Ramp time again. | |
| | | Select the desired setting based | |
| 11 | 055 400 45 | on personal comfort and | Patient Mode |
| Humidifier | OFF. 1,2,3,4,5 | environmental conditions. | Clinician Mode |
| | | The higher the number, the more | |

| | | moisture is added to the airflow | |
|----------|-----------|--------------------------------------|----------------|
| | | treatment. Too much moisture will | |
| | | cause water droplets in the hose | |
| | | or mask. If the Machine is to be | |
| | | used without the humidifier, the | |
| | | humidifier setting must be set to | |
| | | OFF. | |
| | | Select ON to preheat the | Patient Mode |
| Preheat | ON or OFF | humidifier to level 1 in advance of | |
| | | starting the treatment. | Clinician Mode |
| | | If "Auto on" function is turned on: | |
| | | In idle state with [Treat] showing | |
| | | on the display, the Machine will | |
| | | detect and automatically start | |
| | | the airflow when breathing | Patient Mode |
| Auto on | ON or OFF | through the connected mask is | Clinician Mode |
| | | detected. | Cirilcian Mode |
| | | If "Auto on" function is turned off: | |
| | | The Machine will not | |
| | | automatically start. | |
| | | If "Auto off" function is turned on: | |
| | | | |
| | ON or OFF | During use, the Machine will | Patient Mode |
| Auto off | | detect if the mask has been | |
| | | removed and stop the airflow. | Clinician Mode |
| | | Detecting mask removal and | |
| | | stopping the airflow will take | |

| | | around 10 seconds. Depending | |
|--------------|----------------|---------------------------------------|----------------|
| | | on the type of mask, accurate | |
| | | detection of the mask being | |
| | | removed may not always be | |
| | | possible. | |
| | | If "Auto off" function is turned off: | |
| | | During use, the Machine will not | |
| | | automatically stop the airflow | |
| | | when the mask has been | |
| | | removed. | |
| | | If "Backlight" ON is selected, the | |
| | | screen will stay on all the time. | |
| | | Alternatively, the backlight can be | |
| | | set to automatically turn off after | Patient Mode |
| Backlight | ON,15,30,45,60 | 15, 30, 45 or 60 seconds. | |
| | | Note: Regardless of the backlight | Clinician Mode |
| | | setting, the green power LED is | |
| | | always illuminated, as long as | |
| | | power is applied to the Machine. | |
| | | This feature is not currently used. | |
| | | When this function is set up and | |
| WIFI setting | Off/on | connected, the device can | |
| | | automatically connect via WIFI to | Patient Mode |
| | | upload treatment data to a | Clinician Mode |
| | | remote server, so that medical | |
| | | staff can learn about treatment | |
| | | therapy use. | |
| | | | |

| Language | Chinese/English | Choose the language you prefer. | Patient Mode |
|----------|-----------------|-----------------------------------|--------------------------------|
| | | | Clinician Mode |
| Reset | ON | To reset the Machine back to the | |
| | | factory default settings, select | Patient Mode |
| | | ON. | Clinician Mode |
| | | Compliance Use is not reset. | |
| Version | | Display the software version of | Patient Mode |
| | | the equipment. | Clinician Mode |
| Clean | Yes or No | Select Yes, to start the cleaning | |
| | | cycle. Before running the clean | Patient Mode Clinician Mode |
| | | cycle, please refer to section | |
| | | 8.3.4 of this User Manual for | |
| | | detailed instructions. | |

4.9 Data output

- 1. Ensure that the supplied USB memory flash drive is inserted into the rear of the Machine.
- 2. In the "System" menu, press the control dial to select "Output".
- 3. After the copy process has been completed, the CPAP Machine prompts "Copy completed, exit". Press the control dial button to complete this process.

The daily usage data files will be saved to the "HEALDATA" folder of the USB memory flash drive. Note: Do not remove the USB memory flash drive during the data output process.

Chapter 5 Heating humidifier

5.1 Intended use

The heated humidifier uses a sprung metal plate to transfer heat to distilled water in the water tank. This provides heated and humidified air to ensure a more comfortable therapy experience for the user. It is not intended for use with patients whose upper airways have been bypassed.

5.2 Specifications

Working voltage: 24VDC

Water tank volume: 270ml

Maximum working pressure: 30cmH₂O

Air supply pressure range: 1-30cmH₂O

Working environment range: 5°C - 35°C

Range of input air temperature: 5°C - 35°C

Transmitted air temperature: no higher than 37°C (as recommended)

Statically humidified water temperature range: 35°C - 45 (±5)°C

Preheat time: 5 minutes from 23°C to 45°C

Heating time: When humidifier is at level 1, it takes 5 minutes to heat from 23°C to 45°C. In level 2, it takes 5 minutes to heat from 23°C to 55°C. In level 3, it takes 7 minutes to heat from 23°C to 65°C. In level 4, it takes 10 minutes to heat from 23°C to 75°C. In level 5, it takes 15 minutes to heat from 23°C to 85°C.

Protection against over-hot heating plate: 125±10°C

 Humidification ability: Under the premise of a flow rate of 20 to 40 L/min, it is more than 10 mg/L. If the flow rate exceeds 40 L/min, the humidification ability cannot be guaranteed for more than 10 mg/L.

Recommended flow rate range: 20-40L/min

Maximum leak: less than 20ml/min (maximum working pressure: 30cmH2O)

5.3 Cautions

- It is advised to <u>only</u> use distilled water to prevent scale and calcification occurring which can result in corrosive holes.
- It is necessary to clean the heating humidifier and change the water in it every day so as to prevent breeding of bacteria.
- When filling the water tank, it should first be removed from the humidifier. After the tank is emptied after use, ensure the tank is dry before re-inserting to the humidifier.
- Do not overfill the water chamber as water may backflow into the Machine, damaging the motor or other components.
- It is necessary to regularly check if there is any sign of damage or wear on the heating humidifier. If damage is detected do not use the humidification function and contact your service provider before using it again.
- When removing the water tank after use, it is important to remember the base plate will be hot and to take precautions to avoid burning yourself.
- Do not use a humidifier or water chamber or humidifier that has not been designed for this unit.
- Certain unpredictable risks may arise when the equipment uses externally connected humidifier or its humidifier is connected to other CPAP Machine.
- The use of humidifier beyond the specified ambient temperature and humidity may affect the humidification performance.
- When the humidifier is exposed to electric cautery, electro surgery, defibrillation, X-ray (γ-ray), infrared radiation, and transient electromagnetic field (such as MRI and radio disturbance), it may affect the normal working of the temperature sensor in it, and eventually the humidification ability of the device.
- The output hose of the heating humidifier should be lower than the user as much as
 possible to prevent the condensate within hose from flowing backward into the face
 mask.
- It is not recommended to use the humidifier if the room temperature exceeds the maximum temperature specifications.

Tip: If the Machine is to be used without the humidifier, the humidifier setting must be set to OFF in the [Set] > [Param] menu, otherwise an alert message will occur after 40 seconds.

Chapter 6 WIFI

6.1 Expected usage

This equipment is provided with an in-built 2.4GHz WIFI module that can connect with the M+ cloud service platform provided by the manufacturer. This platform can collect data including but not limited to the setup parameters, treatment information, and treatment report generated during the user treatment process for analysis of user treatment effect and supply of better subsequent service.

The manufacturer shall strictly keep those collected data confidential and shall not use them for any commercial purpose related to a third party.

Note: This feature is not currently available in Australia.

If this feature becomes available in the future, details will be provided on our website. Purchasers of this equipment and subscribers of our support services will be notified of available options.

Chapter 7 Alerts

7.1 Visual and Audible Alerts

If an unexpected fault event occurs with the Machine during use, an alert message in red text will be displayed in the upper left corner of the screen, accompanied by an audible beeping sound.

If power is disconnected from the Machine during use (Eg. A power cut), 2 beeps will sound, followed by a 15 second pause. This will continue until power has been restored, or until the internal device power has been exhausted.

7.2 Alert messages

| Name | Alert description | Alert principle | Handling measures |
|-----------------------|--|--|--|
| Turbine | The turbine blower / motor stops working | A sensor detects rotation of the turbine rotor. If rotation is not detected within a certain period of | Immediately disconnect from the power and contact your service provider. |
| | | time, an alert will be given. | , |
| Heating humidifier | The temperature in heating humidifier becomes too high | When the temperature of heater element is over 90°C for more than 10 seconds, an alert will be given. | Immediately disconnect from the power and contact your service provider. |
| Humidifier fault | Humidifier is disconnected | If the machine is to be used without the humidifier connected, it | Disconnect the power, wait for 30 seconds. Before trying again, turn the |

| | | must be switched off electronically first, otherwise an alert will be given after 40 seconds. | humidifier off in the [Set] > [Param] menu. If the problem persists, contact your service provider. |
|--------------------|--|---|--|
| Pressure sensor | The pressure sensor fails | If the pressure sensor reads a negative value for 30 seconds or more, an alert will be given. | Disconnect the power supply, wait for 1 minute, then re-apply the power and run the Machine again. If the problem persists, immediately disconnect from the power and contact your service provider. |
| Flow sensor | The flow sensor fails | The flow sensor reads error data for over 30 seconds, an alert will be given. | Disconnect the power supply, wait for 1 minute, then re-apply the power and run the Machine again. If the problem persists, immediately disconnect from the power and contact your service provider. |
| High- pressure | The air flow output pressure exceeds 35cmH20 | If the pressure sensor detects the hose pressure is over 35cmH20 for 6 seconds or more, an alert will be given. | Immediately disconnect from the power and contact your service provider. |

| Disconnecti | The mask or tubing hose is disconnected from the CPAP Machine | The pressure sensor detects a problem for over 30 seconds, an alert will be given. | Check if there is any damage to the hose or face mask; ensure the connection between the air outlet and hose is normal and the face mask is correctly worn; Mask leaks should be under 60l/m if the problem persists, contact your service provider. |
|--------------|--|--|--|
| Tubing block | The flow in the air outlet tubing becomes nearly 0 due to obstruction/blockage | The flow sensor reads an incorrect value for more than 30 seconds, an alert will be given. | Check if the hose or face mask is blocked; ensure the hose is not crushed or bent. If problem persists, contact your service provider. |

7.3 Alert Suspension

If an alert is shown or heard, press the dial button during the alert to suspend it.

If the problem is not rectified within 30 seconds, the alert reminder will reoccur.

If you cannot resolve the alert, please contact your equipment provider for assistance.

Chapter 8 Equipment cleaning and maintenance

8.1 Repair and maintenance

If the equipment or accessories are damaged, or their original functions can't be guaranteed, discontinue use of the equipment.

If you need to have the equipment repaired, cleaned, preventively checked or maintained, please contact your equipment provider or manufacturer (Micomme Medical)

8.2 Frequency

Based on standard hygiene considerations, the manufacturer recommends the following maintenance schedule:

- Clean the equipment, mask and hose before the initial use, then weekly;
- Empty any remaining water in the water tank each morning and clean the tank thoroughly at least once per week to prevent the growth of bacteria;
- Check and clean the air filter once a month and replace it every six months;
- Replace the face mask and hose every 6-12 months or as required.

8.3 Cleaning method

8.3.1 Cleaning of CPAP machine and hose

Disconnect the equipment from the power supply before cleaning it or carrying out regular maintenance.

Clean the front panel and exterior enclosure with soft damp cloth, moistened with warm water or mild disinfectant or CPAP cleaning wipes. Dry the equipment completely before inserting the power connection.

Warnings:

- 1. When the equipment is used by more than one user, the filter should be replaced for each user.
- 2. Clean the respiration hose and face mask by referring to the individual cleaning instructions included with these accessories.

8.3.2 Water tank cleaning

Remove the water tank from the humidifier and wash in warm soapy water with a mild liquid disinfectant. Rinse with clean water, then wipe clean the components, and air dry.

After each clean, check the seal of the water tank is intact.

8.3.3 Air filter cleaning and replacement

The air filter should be cleaned in warm water and mild disinfectant, and the disinfectant residue should be completely washed away. The filter should be completely dried before being returned to the Machine. If the air filter is damaged in any way, please replace it immediately.

- 1. Disconnect the power supply of equipment.
- Remove the filter cover.
- 3. Squeeze the middle part of the filter to remove it.
- 4. Check the cleanliness and completeness of the filter.
- 5. Clean the filter with warm water mixed with neutral disinfectant, wash it with water to remove the disinfectant residue, completely dry the filter and then re-fix it; or change the filter upon finding any damage.

Attention: Never install a wet/damp filter into the Machine. We recommend you clean the filter in the morning and alternate with a spare filter to ensure adequate drying time for cleaned filter.

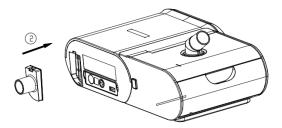
8.3.4 Machine cleaning

This CPAP Machine has a built-in ozone cleaning function. The cleaning cycle takes approximately 30 minutes to complete and will clean the CPAP Machine including motor, humidifier, hose and water tank.

- Make sure that there is no water in the water chamber before cleaning.
- Ensure the CPAP Machine is in a well-ventilated environment during cleaning.
- Do not power off the Machine during cleaning.
- 1. Remove the CPAP Machine inlet cover/filter.

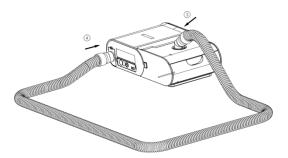


2. Install the ozone circulation joint.

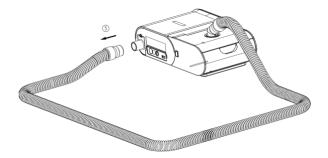


3. Remove, empty and reinsert the water tank.

4. Remove the mask from the hose and connect the hose to the ozone circulation joint forming a loop connection as shown below;



- 5. Move the cursor on to [System] > [Clean] then press the control dial button. Follow the on-screen instructions, then select (Yes) to start the cleaning process. "Cleaning" will be displayed on the screen, together with a progress percentage indication.
- 6. The cleaning cycle will finish once the display shows 100%.



- 7. Remove the hose and ozone circulation joint, then refit the air inlet cover/filter.
- Press the control dial button to blow 10 minutes of fresh room air through the hose and
 Machine to remove any residual ozone odor.
- 9. After 10 minutes, the Machine will stop blowing air.
- 10. Turn the control dial and press to [Exit].
- 11. Re-attach your mask to the hose and wait 2 hours before selecting [Treat] to begin CPAP therapy.

If you find the fresh clean smell unpleasant, run the Machine in Treat Mode to blow more air through the system.

Chapter 9 Storage and transportation

9.1 Storage

The packed CPAP Machine can be stored in a clean and well ventilated room that has an ambient temperature of -10-55°C and relative humidity of 15-95%, and is free from any corrosive gas.

9.2 Transportation

After being packed into the case, the CPAP Machine can be transported in a common way, but should be protected from moisture, sunlight and shock during the process.

Important: When travelling with the Machine, ensure the water tank is completely dry before packing up your Machine.

Chapter 10 Troubleshooting

In the unlikely event of a fault occurring, the please refer to the possible causes and solutions in the following table;

| Fault/error message | Cause | Solution |
|--|--|---|
| The equipment stops working, or; | No AC Power. | Check wall socket is switched on and the AC Power Supply Cord is firmly plugged in. Check the fault is not with the power socket by plugging in a lamp or other device. Check with your electricity service provider in case there is a power outage in your area. |
| There is no display, or; The green LED is not lit on the front of the | Power Supply Adaptor is not inserted into the back of the Machine. Power Supply Adaptor has failed. | Check if green LED is lit on the front of the Machine. Re-insert DC plug firmly in back of Machine. Check if the blue LED is showing on the Power Supply Adaptor. Try in another wall socket. |
| Machine. | Power Supply Adaptor faulty. Power cord damaged or equipment failure. | Discontinue use and contact your equipment provider. |

| The equipment temperature is excessively high | The equipment is close to heater or in bright sunshine or it is a hot day. | Regulate the room temperature and keep the equipment away from direct sunlight and heating devices. If the error persists, contact your equipment provider. |
|--|---|--|
| Screen not displaying correctly | The device is damaged after falling onto the ground or being water affected, or affected by strong electromagnetic interference. | Remove the power supply and move the equipment into an environment with low electromagnetic interference. If the error persists, contact your equipment provider. |
| The contact between the face mask and the skin causes skin irritation or allergy | The face mask is not properly adjusted or incorrect sizing, or skin irritation is caused due to the raw material or cleanliness of the face mask. | Adjust the headgear or consider alternative mask options Ensure appropriate hygiene protocol is adhered to as per cleaning instructions included with the mask. If the problem persists, stop use and contact your equipment provider. |
| It feels uncomfortable when wearing the face mask | The face mask is incorrectly worn or of an incorrect size | Adjust the headgear properly or consider alternative mask options. If you are new to CPAP therapy, practice first. Refer to the included support brochure for advice. If the problem persists, contact your equipment provider. |

| | Air leak with the face mask. | Adjust the headgear to properly wear the face mask and prevent air leaks. When necessary, change the face mask. |
|---|---|--|
| | Damaged face mask. | Replace the damaged face mask. |
| | Machine settings need adjusting. | Contact your equipment provider. |
| The equipment works, | Airflow will not start. | Check the display shows [Treat] on the screen. |
| but does not achieve the desired results. | Airflow will not Auto Start within 15 secs. | Make sure Auto On is set to ON in the setup menu. |
| | Airflow will not Auto Stop after 15 secs. | Make sure the Auto Off is ON in the set up menu. |
| | Too much moisture in the hose or mask. | Reduce the humidifier setting to a lower number in the [Set] > [Param] menu or set humidifier to off. Consider using an optional hose cover or heated hose. |

If the error cannot be resolved immediately, please discontinue use and contact your equipment provider.

Warning: The Machine can only be repaired by qualified professionals.

Chapter 11 Technical information

11.1 Parameters

11.1.1 Default C2 Machine Settings

• CPAP Mode

CPAP: 10cmH20

• Humidifier: 2

Pre-Heat: Off

· Comf: Off

Auto on: On

Auto off: On

Ramp time: 10 minutes

• Ramp start: 4cmH20

Backlight: 15 seconds

Language: English

• Time and Date: Australian Eastern Standard Time (AEST = UTC+10h)

11.1.2 Default C5 Machine Settings

Auto-CPAP Mode

Max: 16cmH20

Min: 6cmH20

Humidifier: 2

Pre-Heat: Off

Comf: Off

Auto on: On

Auto off: On

Ramp time: Off

Ramp start: 4cmH20

Backlight: 15 seconds

Language: English

• Time and Date: Australian Eastern Standard Time (AEST = UTC+10h)

11.1.3 AC Adapter parameters

Specified Adapter Model: HY72-024

Specified Adapter Manufacture: ShenZhen Hongyi Electronic Technology CO. Ltd.

11.1.4 Machine ambient parameters

| Parameter | Working conditions | Storage conditions |
|----------------------|--|---------------------------------|
| Temperature | 5°C ∼ 35°C | -10°C ∼ 55°C |
| Relative humidity | 15% \sim 95% (non-condensate) | 15% \sim 95% (non-condensate) |
| Atmospheric pressure | 83~102kPa (5,600 feet above the sea level) | |

11.1.5 Physical and electrical parameters

| Parameter | Value |
|------------------|---------------------------------------|
| Outer dimensions | 28.8cm L x 20.2cm W x 8.4cm H |
| Weight | 1.9kg |
| AC power supply | 100 ~ 240VAC,50/60 Hz |
| AC | 1.5A (max) |
| DC | 2.5A (max) |
| Fuse rating | T3.15A 250V, interrupting rating:100A |

11.1.6 Electric safety class

| Parameter | Value |
|--|---|
| Safety class against electric shock | Class II |
| Electric shock protection degree | BF application component |
| Waterproof level | IP21 |
| Mode of operation | Continuous operation |
| Safety class when used in combustible | It can't be used in combustible |
| anesthetics mixed with air or oxygen or helium | anesthetics mixed with air or oxygen or |
| oxide | helium oxide |

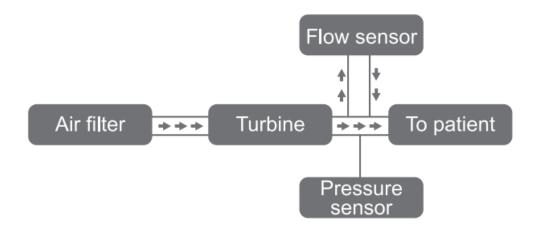
Extreme environment statement:

When the environment and power supply (or gas supply) exceed the extreme values in the following ranges, the change of one parameter and keeping of other parameters within the normal ranges will severely affect the equipment performance, and even cause certain harm to the user.

- —— Ambient temperature range: 5°C-35°C;
- ---- Relative humidity range: 15% 95%;
- —— Atmospheric pressure range: 83 $\,\sim\,$ 102kPa;
- —— AC power voltage: -15% +10% of rated voltage;
- —— DC power voltage: -15% +25% of rated voltage.

11.2 Pneumatic schematic diagram

The pneumatic schematic diagram of the equipment is as follows:



11.3 EMC information

11.3.1 Instructions for use

The Sleep Apnea Therapy Devices referred to in this User Manual are are suitable for home healthcare environments.

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment including cables specified by the manufacturer, otherwise, degradation of the performance of this equipment could result.

The performance of these Sleep Apnea Therapy Devices that was determined to be "The display works normally, device runs without trouble, and the pressure output is normal" and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or

degraded due to EM DISTURBANCES. (For details, see Chapter 9 Fault Analysis and Troubleshooting)

11.3.2 Technical description

Table 1

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|----------------|--|
| Emissions test | Compliance | |
| RF emissions | Group 1 | |
| CISPR 11 | | |
| RF emissions | Class [B] | |
| CISPR 11 | | |
| Harmonic emissions | Not Applicable | |
| IEC 61000-3-2 | | |
| Voltage fluctuations/ flicker | Not Applicable | |
| emissions | | |
| IEC 61000-3-3 | | |

Table 2

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | |
|--|---------------------------------|---|--|--|
| Immunity Test | IEC 60601-1-2 | Compliance level | | |
| | Test level | | | |
| Electrostatic discharge | ±8 kV contact | ±8 kV contact | | |
| (ESD) | ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±2 kV, ±4 kV, ±8 kV, ±15 kV air | | |
| IEC 61000-4-2 | | | | |
| Electrical fast | ±2 kV for power supply lines | ±2 kV for power supply lines | | |
| transient/burst | ±1 kV signal input/output | Not Applicable | | |
| IEC 61000-4-4 | 100 kHz repetition frequency | 100 kHz repetition frequency | | |
| Surge | ±0.5 kV, ±1 kV differential | ±0.5 kV, ±1 kV differential mode | | |
| IEC 61000-4-5 | mode | Not Applicable | | |
| | ±0.5 kV, ±1 kV, ±2 kV common | | | |
| | mode | | | |
| Voltage dips, short | 0 % UT; 0,5 cycle. At 0°, 45°, | 0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, | | |
| interruptions and voltage | 90°, 135°, 180°, 225°, 270° | 180°, 225°, 270° and 315°. | | |
| variations on power supply | and 315°. | 0 % UT; 1 cycle and 70 % UT; 25/30 | | |
| input lines | 0 % UT; 1 cycle and 70 % UT; | cycles; Single phase: at 0°. | | |
| IEC 61000-4-11 | 25/30 cycles; Single phase: at | 0 % UT; 250/300 cycle | | |
| | 0°. | • | | |
| | 0 % UT; 250/300 cycle | | | |
| Power frequency magnetic | 30 A/m | 30 A/m | | |
| field | 50Hz/60Hz | 50Hz/60Hz | | |
| IEC 61000-4-8 | | | | |

| Conduced RF | 3 V | 3 V | |
|---|------------------------------|------------------------------------|--|
| IEC61000-4-6 | 0,15 MHz – 80 MHz | 0,15 MHz – 80 MHz | |
| | 6 V in ISM and amateur radio | 6 V in ISM and amateur radio bands | |
| | bands between 0,15 MHz and | between 0,15 MHz and 80 MHz | |
| | 80 MHz | 80 % AM at 1 kHz | |
| | 80 % AM at 1 kHz | | |
| Radiated RF | 10 V/m | 10 V/m | |
| IEC61000-4-3 | 80 MHz – 2,7 GHz | 80 MHz – 2,7 GHz | |
| | 80 % AM at 1 kHz | 80 % AM at 1 kHz | |
| NOTE U _T is the A.C. mains voltage prior to application of the test level. | | | |

Table 3

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | | |
|--|-----------|--------------|-------------------------|---------------------------------|------------|----------|----------|
| Radiated RF | Test | Band | Service | Modulation | Modulation | Distance | IMMUNITY |
| IEC61000-4-3 | Frequency | (MHz) | | | (W) | (m) | TEST |
| (Test | (MHz) | | | | | | LEVEL |
| specifications | | | | | | | (V/m) |
| for ENCLOSURE PORT IMMUNITY to | 385 | 380 – 390 | TETRA 400 | Pulse modulation 18 Hz | 1,8 | 0.3 | 27 |
| RF wireless communicatio ns equipment) | 450 | 380 – 390 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |

| 710 | 704 – | LTE | Pulse | 0,2 | 0.3 | 9 |
|------|-------|----------------------|------------|-----|-----|----|
| 745 | 787 | Band 13, | modulation | | | |
| 780 | | 17 | 217 Hz | | | |
| 810 | 800 – | GSM | Pulse | 2 | 0.3 | 28 |
| 870 | 960 | 800/900, | modulation | | | |
| 930 | | TETRA 800, | 18 Hz | | | |
| | | iDEN 820, | | | | |
| | | CDMA 850, | | | | |
| | | LTE Band 5 | | | | |
| 1720 | 1 700 | GSM | Pulse | 2 | 0.3 | 28 |
| 1845 | _ | 1800; | modulation | | | |
| 1970 | 1 990 | CDMA 1900; | 217 Hz | | | |
| | | GSM 1900; | | | | |
| | | DECT; | | | | |
| | | LTE Band 1, 3, | | | | |
| | | 4, 25; UMTS | | | | |

| 2450 | 2 400 | Bluetooth | Pulse | 2 | 0.3 | 28 |
|------|-------|-----------|------------|-----|-----|----|
| | _ | , | modulation | | | |
| | 2 570 | WLAN, | 217 Hz | | | |
| | | 802.11 | | | | |
| | | b/g/n, | | | | |
| | | RFID | | | | |
| | | 2450, | | | | |
| | | LTE | | | | |
| | | Band 7 | | | | |
| 5240 | 5 100 | WLAN | Pulse | 0,2 | 0.3 | 9 |
| 5240 | _ | 802.11 | modulation | | | |
| 5785 | 5 800 | a/n | 217 Hz | | | |
| 0/00 | | | 211112 | | | |

11.3.3 RF information

| For WIFI | For BLE |
|-------------------------------------|-------------------------------------|
| Operating Frequency: 2400~2483.5MHz | Operating Frequency: 2400~2483.5MHz |
| Max. Transmitter Power: 17.66dBm | Max. Transmitter Power: 0.18dBm |
| | |

Appendix 1: Model comparison table

| Note | e: •Standard | C2 | C5 |
|----------------------|--------------------------|--------|---------|
| ○ Option | al - Not Available | 02 | Co |
| Mode | CPAP | • | • |
| | AUTOCPAP | - | • |
| | BPAP | - | - |
| | Minimum Pressure | 4cmH₂O | 4cmH₂O |
| | Maximum Pressure 20cmH₂O | | 20cmH₂O |
| Therapeutic | Comfort Level • | | • |
| Effects | 45 Minute Ramp | • | • |
| | Heated Humidifier | • | • |
| | Pre-Heat | • | • |
| | Auto airflow Start | • | • |
| Extended Features | Auto Airflow Stop | • | • |
| | Wi-Fi | • | • |
| | Ozone Cleaning | • | • |

Appendix 2: Warranty and Downloads

Review and download latest content as shown below;

Warranty Policy

www.cpapsales.com.au/refunds-warranty-and-returns

Quick Start Guide

www.cpapsales.com.au/manuals

User Manual

www.cpapsales.com.au/manuals

WiFi Setup

www.cpapsales.com.au/wifi-setup

• FAQ (Frequently Asked Questions)

https://cpapsales.freshdesk.com/support/home

6HealthGear

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