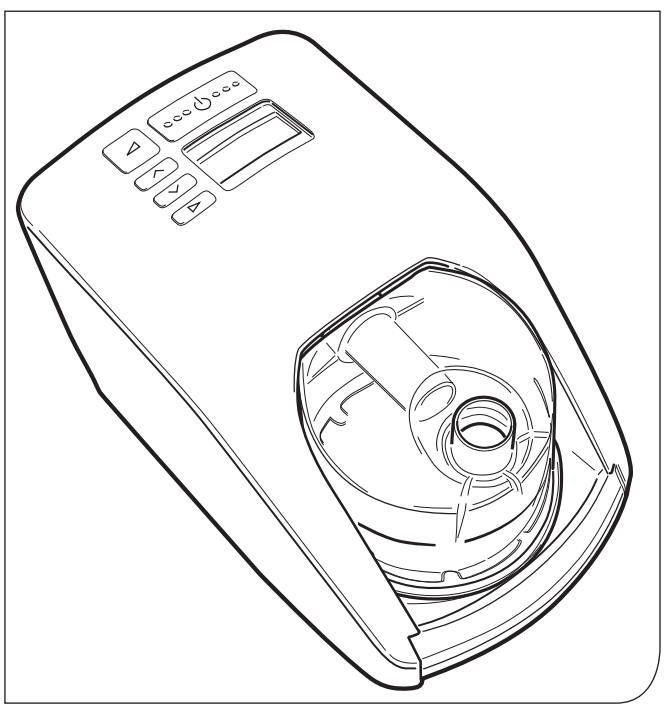
SleepStyle™200

CPAP SERIES

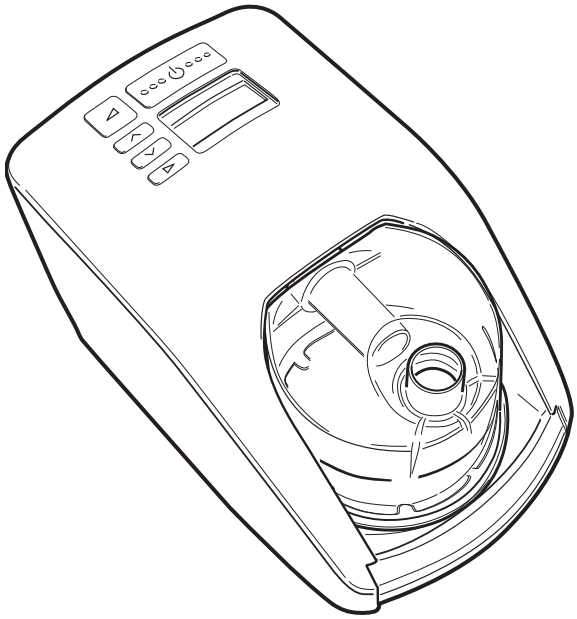
Ambient Tracking™ Plus

Operating Manual

Model HC244, HC242



Fisher & Paykel HEALTHCARE



SleepStyle™ 200 Series
HUMIDIFIED CPAP SYSTEMS

English

The SleepStyle™ 200 Series is a range of CPAP systems designed for use in the home for the treatment of OSA. This manual is specific to the operation of CPAP models HC244 and HC242*.

For further assistance, please contact your local Fisher & Paykel Healthcare office – see reverse for addresses. Please keep this manual for future reference.

*** SleepStyle™ 242 is not available in all countries.**

TABLE OF CONTENTS

PLEASE READ ALL INSTRUCTIONS BEFORE INITIAL USE

Caution: USA Federal Law restricts this device for sale by or on the order of a physician.

1. Symbol Definitions


Type BF
Applied Part


ATTENTION
Consult accompanying documents


Do not throw away


IPX1
Drip-proof

Alternating Current


Class II
Double-insulated


Standby

CE 0123
93/42/EEC
Class IIb

2. Intended Use

The SleepStyle™ 200 Series CPAP Humidifier (HC244/HC242) is for use on adult patients for the treatment of Obstructive Sleep Apnea. The device is for use in the home or sleep laboratory.

3. Warnings, Cautions, Contraindications

NOTES

- This manual refers to the SleepStyle™ 200 CPAP Series unit as "the device".
- If required to use CPAP by a referring physician, you should use your device every time you sleep. Should your device stop working for any reason, contact your healthcare provider immediately.
- The user of this system shall have sole responsibility and liability for any injury to persons or damage to property resulting from operation of the device which is not in accordance with the operating instructions supplied.
- The device should only be used with ISO 17510-2 compliant masks, connectors and delivery tubes recommended by Fisher & Paykel Healthcare, or your healthcare provider.
- We recommend use of Fisher & Paykel Healthcare masks to ensure true data accuracy.
- Under normal operating conditions, the air supplied by the device will not exceed 105.8 °F (41 °C).
- Refer all repairs and maintenance to Fisher & Paykel Healthcare.
- Only insert or remove the SmartStick™ when the device is in standby mode or not connected to mains power.
- The SmartStick™ should only be removed when downloadable data is required by your healthcare provider.
- To avoid data loss, do not remove the SmartStick™ from the device while the light is flashing.
- Use only Fisher & Paykel Healthcare-supplied SmartSticks™.
- Do not operate the device without the SmartStick™ cap secured over the SmartStick™ port.
- Do not operate the device without the cover over the serial port adapter.

WARNINGS

To avoid electric shock from your device, do not:

- Operate the device if the power cord or plug is damaged.
- Operate the device if it has been dropped in water.
- Plug the device into the power socket if it is wet.
- Clean the device while connected to the power socket.
- Store or use the device where it can tilt, fall or be pulled into water. If water has entered the unit enclosure, disconnect the power cord and discontinue use. Seek advice from Fisher & Paykel Healthcare.

To avoid choking or inhalation of a foreign body:

- Never place any object into any opening of the tube.
- Ensure the air filter is fitted during device use.

To ensure optimal therapy, do not:

- Insert the SmartStick™ into any PC that does not have PerformanceMaximizer™ software installed. Changing the directories on the SmartStick™ or attempting to view the data collected without the correct software will result in all data stored on the SmartStick™ being lost. If that were to happen, follow-up therapy would not be possible.
- Operate the device if dropped or damaged.
- Operate the device if not working properly.
- Adjust the pressure. Pressure must only be adjusted by a healthcare professional.
- Operate the device if the tube has been damaged with holes, tears or kinks.
- Block the exhaust flow on the interface.
- Use the mask if the unit is not turned on or not operating properly.

To avoid burns, do not:

- Fill the chamber with boiling water.
- Touch the exposed heater plate or chamber base.

To avoid the risk of fire while using oxygen, do not:

- Turn oxygen flow on when the device is not operating; this can lead to accumulation of oxygen within the device.
- Locate the device in a position where ventilation around the device is restricted.
- Use oxygen while smoking or in the presence of an open flame.
- Use any materials which will burn in air or ignite easily at high oxygen concentration.
- Keep any source of ignition near the product. To avoid ignition, it is preferable to keep all sources of ignition out of the room where supplemental oxygen is being used.
- Keep oxygen regulators, cylinder valves, tubing, connections and all other oxygen equipment near oil, grease or greasy substances. Spontaneous and violent ignition may occur if these substances come into contact with oxygen under pressure.

Other:

- Place the device on a level surface lower than head height to prevent water entering the tubing. If water does enter the tubing, drain excess condensate. Water in the tubing may result in aspiration.
- The device is intended to be used with CPAP masks and connectors that have exhaust flow holes to allow continuous flow of air out of the mask. When the device is turned on and operating properly new air flushes exhaled air out of the mask through the exhaust flow holes. At low CPAP pressures and in the event of power failure or machine malfunction, remove the mask immediately, as flow through the mask may be insufficient to clear all exhaled gas and CO_2 re-breathing may occur which can be hazardous.
- Failure to select the correct altitude level (for any given location) will have an adverse effect on delivered pressure.
- This device is not intended for life support.

CAUTIONS

To prevent water damage to your device:

- Remove the humidification chamber from the device before filling.
- Empty water from the chamber before transporting the device. If the device is required to be handled with water in the chamber, avoid tilting the device to prevent water entering its enclosure.

Other:

- To prevent damage to your PC, only operate the device if it is connected to a PC via an isolated serial port adapter (900HC236).
- To prevent airway irritation, do not use the device when room temperature exceeds 95 °F (35 °C).

CONTRAINDICATIONS

- Research indicates the following pre-existing conditions may contraindicate the use of positive pressure for some patients: pneumothorax, bullous lung disease, pneumocephalus, cerebrospinal fluid leak, recent cranial surgery or trauma, abnormalities of the cribriform plate, pathologically low blood pressure or in patients whose upper airways are bypassed.

PRECAUTIONS

- The safety and effectiveness of positive pressure has not been established in patients with respiratory failure or COPD.

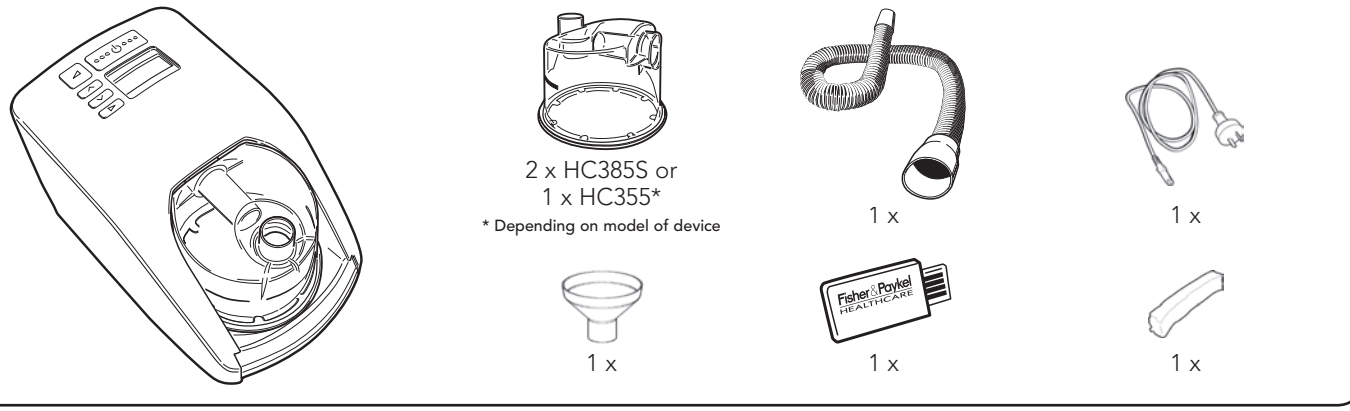
ADVERSE EFFECTS

- Nosebleeds, ear and sinus discomfort may occur from the use of positive pressure therapy.

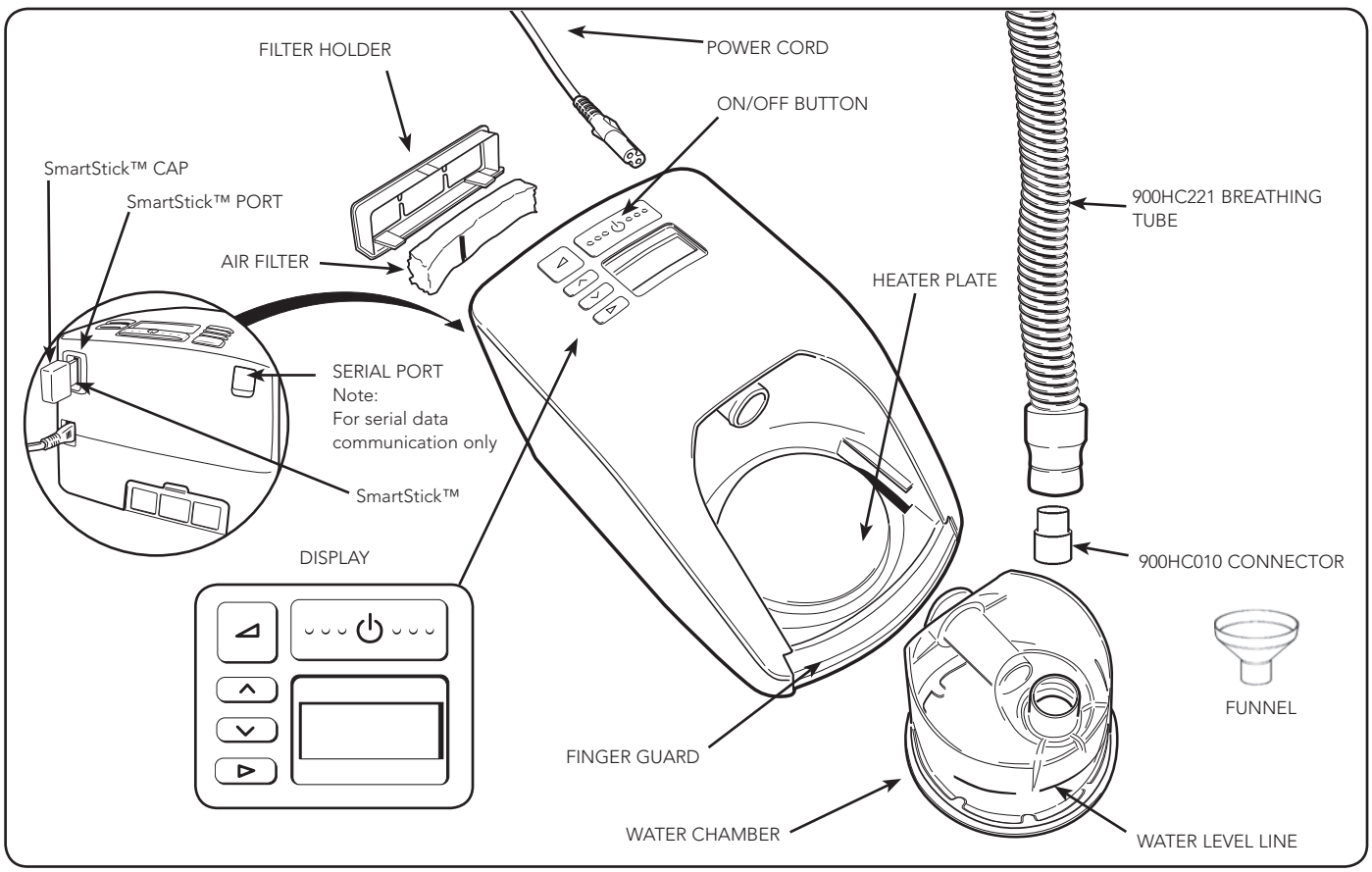
Please contact your physician if you have any questions concerning your therapy.

4. Description of the Device

4.1 Package Contents



4.2 Important Parts of Your Device



4.3 Accessories

HC385S	Standard Humidification Chamber	**900HC611**	SmartStick™ (5-Pack)
HC355*	Extended Life Humidification Chamber	**900HC225**	Water Funnel (10-Pack)
900HC010	Connector	**900HC630**	SmartStick™ Mailer (25 pack)
900HC221	Breathing Tube		
900HC240	Air Filter	***Not available in all countries**	

5. Device Technology

5.1 Ambient Tracking™ Plus

Ambient Tracking™ Plus provides effective humidification under changing conditions by automatically adjusting the heater plate in response to changes in room temperature and leaks caused by the mouth and/or mask leak. This humidification technology maximizes humidity under ambient conditions and minimizes condensation to reduce mask pressure fluctuations, ensuring the most effective performance of the device.

6. Setup Instructions

6.1 System Setup

1. Remove the device from its packaging.
2. Place the device on a low shelf or on the floor beside your bed, so the device is positioned below head height.
3. Chamber Setup
   a. Remove one water chamber from the packaging.
   b. Remove the blue caps and discard them (Fig.1).
   c. Fill the chamber up to the water-filling line with distilled water only; an optional funnel is supplied for easy filling (Fig.2).
   Never fill the chamber while it is attached to the device.
   When moving your device, ensure the water chamber is empty.
   Machine failure due to water damage is not covered by warranty.
   d. To attach the water chamber to the device, press down the finger guard, line up the rear chamber hole to the CPAP outlet and slide the chamber on (Fig.3, Fig.4).
   e. When the chamber is fitted correctly, the finger guard will click into place.
4. One end of the tube has a white plastic connector. Push this onto the outlet on top of the chamber (Fig.5).
5. Connect the other end of the tube to the mask.
6. Plug the device power cord into the rear of the device and into your household power socket.
7. When connected to mains power the device will be in standby mode.
8. The SmartStick™ is located at the rear of the device. Detach the cap and ensure the SmartStick™ is inserted in the correct orientation. The "Fisher & Paykel Healthcare" logo should be the right way up. If the label is upside down remove the SmartStick™ and reinsert the SmartStick™ in the correct orientation. When the SmartStick™ is inserted into the device a small light at the end of the SmartStick™ will flash. The light will remain illuminated indicating that data is being logged to the SmartStick™ (Fig.6).

   NOTES:
   - To download or update settings, only insert or remove the SmartStick™ when the device is in standby mode or disconnected from mains power. Do not insert or remove the SmartStick™ while the pressure is on.
   - Only SmartSticks™ supplied by Fisher & Paykel Healthcare can be used in the device.

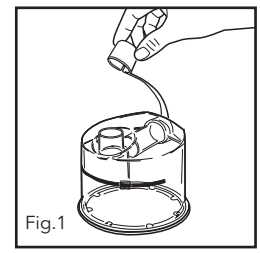


Fig.1

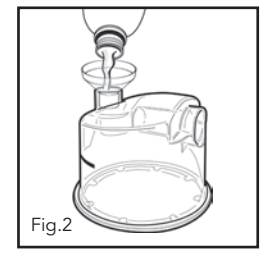


Fig.2

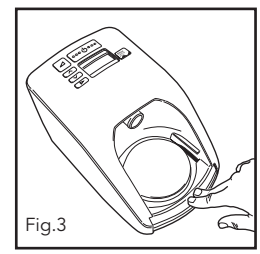


Fig.3

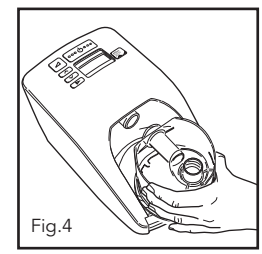


Fig.4

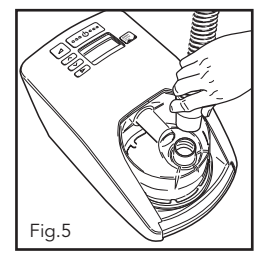


Fig.5

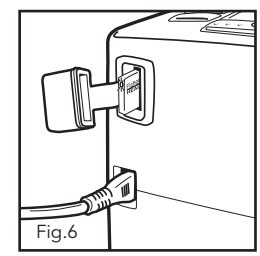


Fig.6

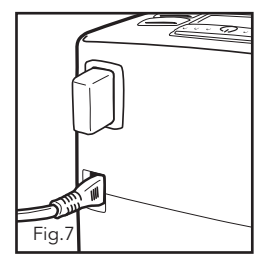


Fig.7

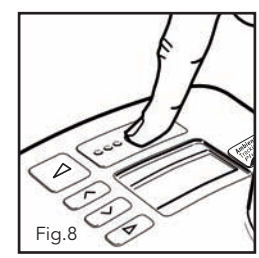


Fig.8

9. Once the SmartStick™ is correctly inserted, secure the SmartStick™ cap over the SmartStick™. If the SmartStick™ is not being used, the cap must still be secured in place (Fig.7).
10. Activate the device by pressing the on/off button (Fig.8). Upon activation, "ON" will flash three times on the LCD display followed by a humidity setting (factory default setting - see Section 8.1).
11. For changing settings refer to Section 8: Controls and Display.

Your device is now ready for use.

6.2 Updating Settings

1. The SmartStick™ can be used by your healthcare provider, to remotely view your compliance or efficacy data and make adjustments to the settings.
2. Once the device is in standby mode or disconnected from mains power, the SmartStick™ can be safely removed and sent to your healthcare provider.
3. When the SmartStick™ is returned, follow instructions above to ensure the SmartStick™ is reinserted correctly. A blue light will illuminate on the end of the SmartStick™ when it is inserted correctly and « USB » will flash on the device LCD.
4. When the blue light has stopped flashing, press any button on the device to acknowledge data download. The settings will now be updated on the device.

7. Oxygen Use

If oxygen is required, it is recommended that supplemental oxygen be administered at the mask. Please see instructions specific to your mask type.

NOTE:

- At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary, depending on the pressure settings, patient's breathing pattern, mask selection and leak rate.

Before using oxygen with the device, please see oxygen warnings in Section 3.

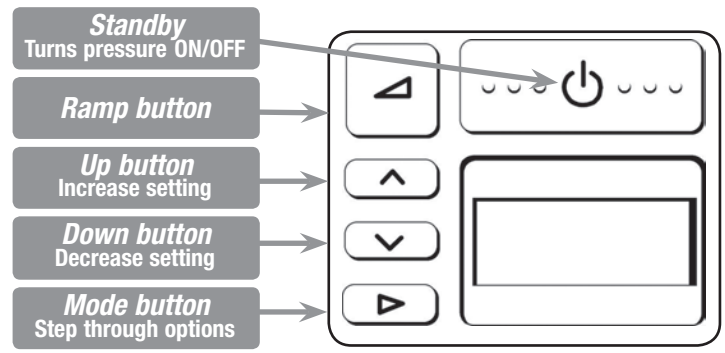
8. Controls and Display

8.1 Display Descriptions and Functions

NOTES:

Default Display

- For initial use the device will default to display humidity (≋) as per factory settings.
- When humidity is displayed, the level of humidity can be changed using ∧ and ∨ buttons: increase if experiencing airway dryness; decrease if experiencing excessive condensation.



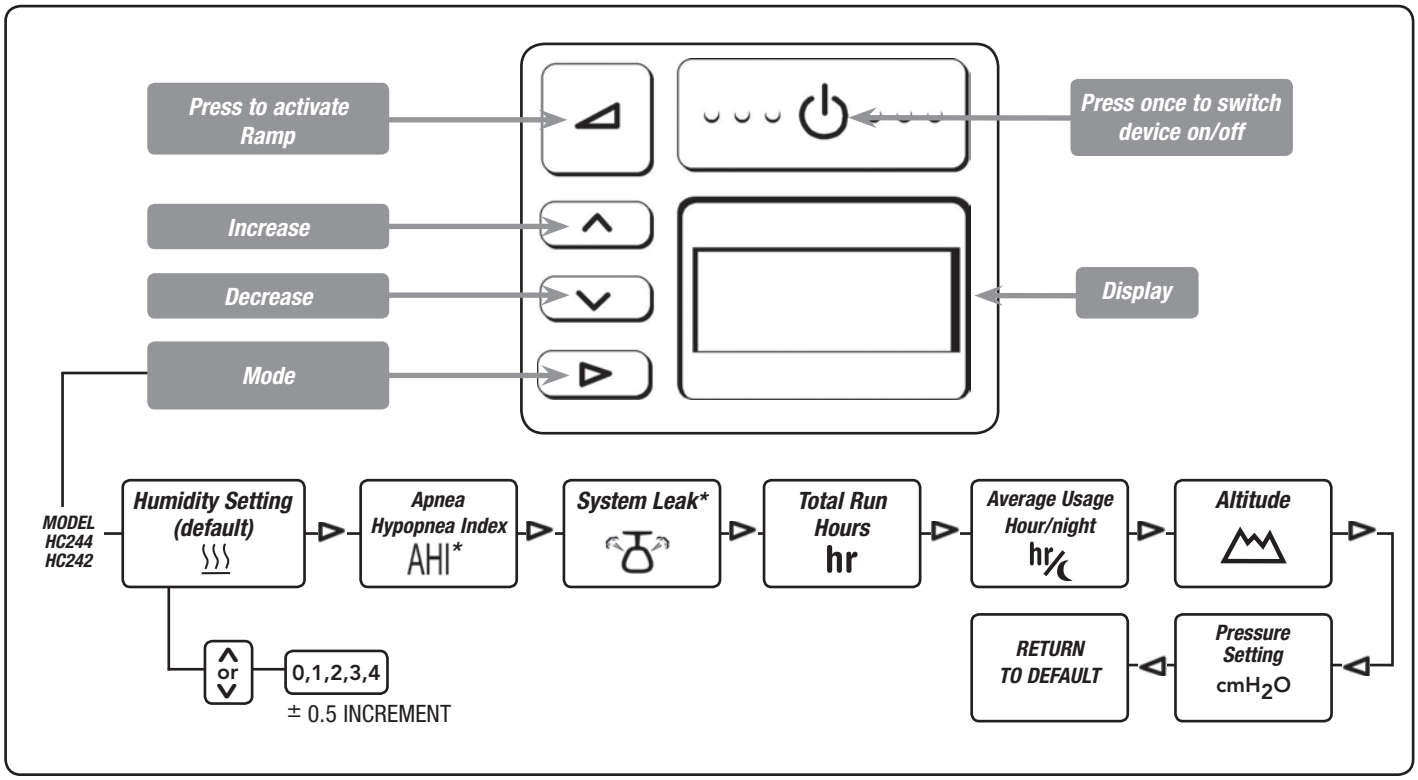
KEY	FUNCTION AND DESCRIPTION	OPERATION
⏻	***STANDBY*** Switches the pressure ON and OFF	***TO START PRESSURE (pressure on)*** ● Press ⏻ button briefly. "ON" will flash three times on the LCD, then the default will display ***TO STOP PRESSURE (pressure off)*** ● Remove your mask ● Press ⏻ button briefly. "OFF" will flash three times on the LCD, then the device will return to standby mode and the default will display
◿	***RAMP*** Reduces pressure to a lower level to help you fall asleep. The pressure will gradually return to full operating pressure over 20 minutes	***TO START PRESSURE (pressure on)*** ● Press the ◿ button Note: To reset ramp during a cycle, the device must be switched off first ***TO SWITCH "OFF"*** ● Press the ⏻ button
∧ ∨	***INCREASE/DECREASE*** Adjusts settings up or down	● Press ∧ and ∨ buttons to raise or lower settings
▷	***MODE*** To step through options	● Press sequentially to step through and view options available

PATIENT MENU	DISPLAY	OPERATION
For viewing settings: **Humidity and Usage Data.** Starting from the default display, press ▷ sequentially to view ***NOTE: To exit menu, wait six seconds for LCD to revert to default display***	≋	● **Displays humidity setting** Adjust humidity to minimize upper airway side effects from treatment. Press ∧ and ∨ to adjust humidity setting
	AHI	● **Apnea Hypopnea Index (AHI)*** Displays the average AHI for the last treatment session
		● **System leak*** Displays system leak history for the last treatment session in liters per minute (LPM). System leak is comprised of exhaust flow, mask leak and mouth leak. Exhaust flow is the expected leak at the interface exhalation port required to flush CO_2 from the mask. A reading of 60 or below indicates an acceptable level of leak
	hr	● **Total run hours** Displays the total hours the device has been run with the pressure on
	hr/☾	● **Average usage hours per night** Displays the average number of hours per night the device has been used

PATIENT MENU - ADDITIONAL SETTINGS	DISPLAY	OPERATION
● To access additional settings: From the default display Press the ▷ button for three seconds ● To view subsequent items: Press the ▷ button ***NOTE: To exit menu, wait six seconds for LCD to revert to default display***	m ft	● **Altitude units** Displays altitude units Select "m" for meters or "ft" for feet using ∧ and ∨ buttons
		● **Altitude level** Displays altitude level Press ∧ and ∨ buttons to alter altitude

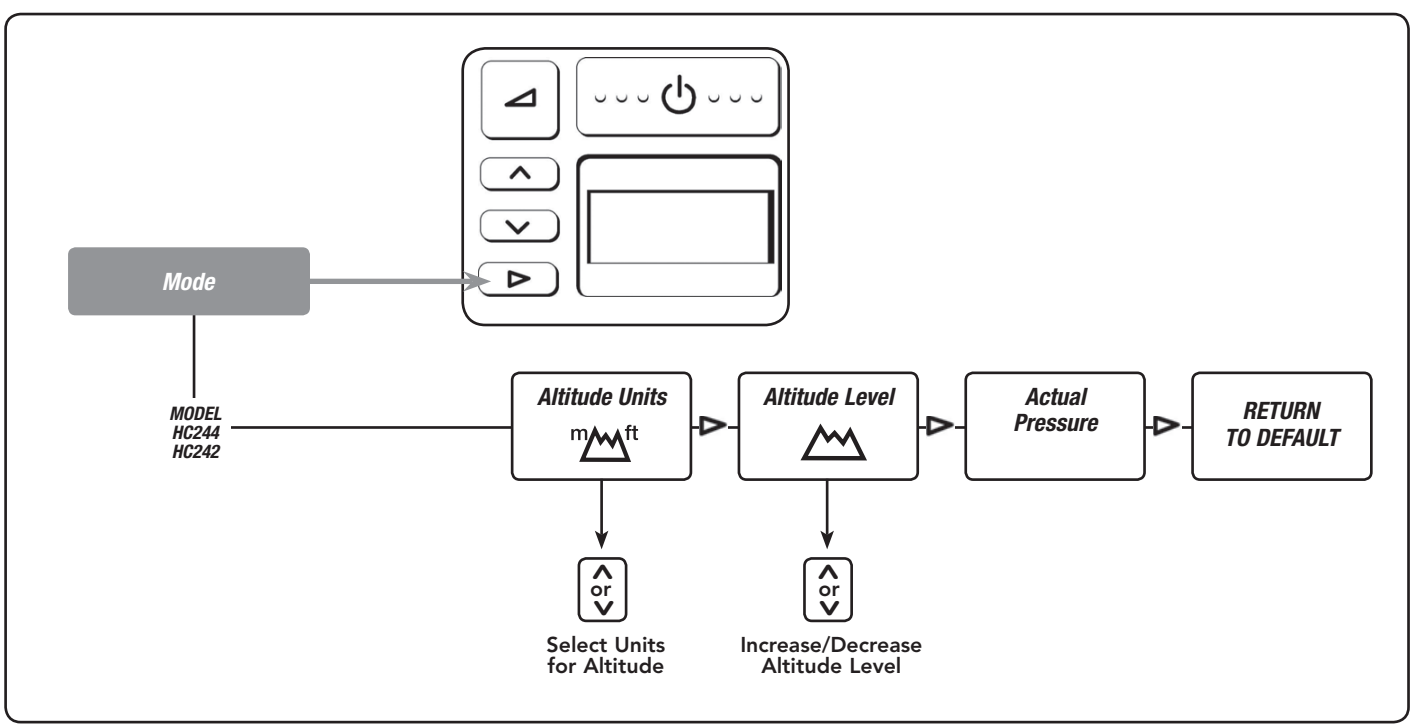
* ***Activated by your healthcare provider; if not activated, will not be displayed. Refer to your interface instructions regarding exhaust flow characteristics.***

8.2 Patient Menu Summary



NOTE: To exit menu, wait six seconds for LCD to revert to default display.
** Only displayed if activated by healthcare provider.*

8.3 Patient Menu - Additional Settings Summary



● ***Warning:*** *Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.*
NOTE: To exit menu, wait six seconds for LCD to revert to default display.

9. Cleaning and Maintenance

PLEASE NOTE: The device should be cleaned as required.

1. Unplug the device from mains power.
2. Wipe the exterior of the device with a clean, damp (not wet) cloth and mild dishwashing detergent. Do not use harsh abrasives or solvents, as these may damage the device.
3. DAILY
   Clean chamber and tube.
   - Remove the breathing tube from the chamber and mask.
   - Clean the tube with warm soapy water. Rinse the tube thoroughly. Hang up the tube with the tube ends pointing to the floor to dry.
   - Remove the chamber by pushing down the finger guard and pulling out the chamber.
   - Pour out and discard the remaining water.
     NOTE: To completely remove water, guide residual water between vanes and shake well (Fig.1).
   - For standard (HC385S) chambers, clean and wash with soapy water, then rinse and dry. Extended life chambers (HC355) can be cleaned in a domestic dishwashing machine.

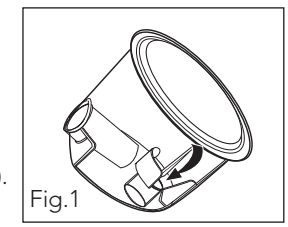


Fig.1

4. WEEKLY
   Thoroughly clean the chamber.
   - Soak the inside of the chamber for 10 minutes in a solution of one part white vinegar to two parts water. Empty the vinegar solution and rinse chamber well with water.
5. Replace the air filter when it becomes significantly discolored, at least once every three months or after 1000 hours' machine running time.
   - Remove the filter holder from the back of the device and take out the filter.
   - Replace the old filter with a new filter: ensure the vertical black line is facing towards the device (Fig.2).

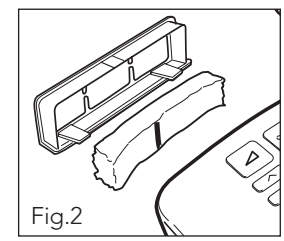


Fig.2

This device does not require routine servicing or calibration.

10. Frequently Asked Questions

- **When I wake up in the morning, my nose and throat feel dry. What can I do?**
  Try increasing your humidity setting. If this does not help, please contact your healthcare provider for advice.
- **How do I prevent condensation in the tubing?**
  The humidity setting enables adjustment of humidity, so that there should be fine misting in the six inches (15 cm) of the breathing tube closest to your face. If the humidity setting is too high for the conditions, condensation may occur in the breathing tube.
  NOTE: Using greater than 6 ft (183 cm) of tubing will increase condensation.
  There are several ways to reduce condensation in the tube:
  i. Ensure the device is not positioned in a cool draft.
  ii. Decrease the humidity setting on your device slightly. Gradually decrease the setting until the condensation no longer occurs.
  iii. Warm the air in the room.
- **Do I have to use distilled water with my device?**
  The use of distilled water will maximize the life of the water chamber. Water from the faucet (even if it is passed through a filter) will often contain minerals which can damage the chamber, causing pitting in the base, corrosion and possibly leaks.
- **When do I replace my water chamber?**
  It is recommended that the chamber is replaced every six months or if the plastic walls of the chamber become cracked or discolored or the chamber base becomes pitted. Regular cleaning will increase the lifespan of your chamber.
  (NOTE: If the chamber leaks at all, it should be replaced immediately.)
- **When do I replace my breathing tube?**
  It is recommended that the breathing tube is replaced every six months or if there are any signs of cracking or deterioration. Regular cleaning will increase the lifespan of your breathing tube.
- **Can I use my device in other countries?**
  Yes. Simply use the appropriate electrical socket adapter and the device will automatically adapt to any voltage supply.
  (NOTE: When moving your device, ensure that the water chamber is empty. Machine failure due to water damage is not covered by warranty.)
- **Can I use supplemental oxygen with my device?**
  Yes, oxygen can be administered at the mask. Turn the device on before turning on the oxygen. Ensure that the oxygen source is turned off before turning off the device to avoid oxygen accumulating in the machine. See Section 7 for more details.
- **Which masks are suitable for use with a SleepStyle™ 200 CPAP Series device?**
  It is recommended that you use a Fisher & Paykel Healthcare mask. Consult your healthcare provider regarding mask selection.
- **What happens to my device during power failure?**
  Upon restoration of the power supply, the device will restart in the same operation mode with the same settings as before the power failure.

11. Product Specifications

DIMENSIONS: 10.8" x 6.7" x 5.5"
(275 mm x 170 mm x 140 mm)

WEIGHT: 4.2 lbs (1.9 kg)
(3.0 kg packaged in bag incl. accessories)

PERFORMANCE:

Pressure Range: 4 to 20 cmH_2O
(In the unlikely event of fault conditions pressure may reach up to 30 cmH_2O)

Altitude Range: 0 to 9000 ft or 0 to 3000 m

Maximum Flow Rates

CPAP Pressure Setting (cmH_2O)	4	8	12	16	20
Measured pressure at the patient connection port (cmH_2O)	3	7	11	15	19
Maximum flow rate (L/Min) at mask connection port	76	85	85	85	86

Static Pressure Stability (long term)
-0.05 to 0.18 cmH_2O pressure difference, measured at the mask connection port, at the pressure setting of 10 cmH_2O

Dynamic Pressure Stability (short term)

CPAP Pressure Setting (cmH_2O)	4	8	12	16	20
Pressure Difference (cmH_2O) at mask connection port	-0.61 to +0.94	-0.66 to +0.90	-0.77 to +0.86	-0.91 to +0.85	-0.98 to -0.86

Humidity: Maximum Humidity = 43.9 mg/L (BTPS), 100% RH at 4 cmH_2O, with humidity setting 4
Typical Humidity = 27.2 mg/L (BTPS), 99.2% RH at 10 cmH_2O, with humidity setting 4

Gas Temperature: Max = 105.8 °F (41 °C)

Noise Level: <30 dBA

STANDARDS COMPLIANCE:

Complies with: EN / IEC 60601-1
AS3200.1.0
UL 60601-1

ELECTRICAL RATINGS:

Supply Frequency: 50-60 Hz

Supply Voltage and Current: 1.2 A, 1.3 A ~ (100-115 V max),
0.8 A, 1.8 A ~ (220-240 V max)

NOTE: These values represent average current.

DC to AC Inverter Requirements: 115 V - 200 W/300 W surge
230 V - 300 W/500 W surge

Heater Plate: 85 W max

Heater Plate Temperature: 149 °F (65 °C) max

The device complies with the electromagnetic compatibility requirements of IEC 60601-1-2. In certain circumstances the device may affect or be affected by nearby portable mobile radio frequency communication equipment, due to the effects of electromagnetic interference. If this should happen, try moving your device or the location of the equipment causing interference, or alternatively consult your healthcare provider.

12. Operating Conditions

AMBIENT TEMPERATURE: 41 - 95 °F (5 - 35 °C)

HUMIDITY: 10 - 95% Relative Humidity

ALTITUDE: 0 - 9000 ft (0 - 3000 m)

NOTE: Above 4500 ft (1500 m), the maximum operating pressure will be reduced.

13. Storage and Transport

The device should be stored and transported in environmental conditions of: 14 to 140 °F (-10 to 60 °C).

14. Troubleshooting

If you feel that your device is not operating correctly, **please contact your local Fisher & Paykel Healthcare office – see back cover for addresses and contact information.**

15. Device and Consumables Disposal Instructions

- Unit Disposal Instructions
  This unit contains electronics. Please do not discard as regular rubbish. Dispose according to local guidelines for disposing of electronics.

- Consumable Disposal Instructions
  Place the mask, breathing tube and water chamber in a rubbish bag at the end of use and discard with normal rubbish.

Fisher & Paykel Healthcare has a policy of continued product improvement and reserves the right to alter specifications without notice.

Fisher & Paykel HEALTHCARE

CE 0123

Fisher & Paykel Healthcare Offices:

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