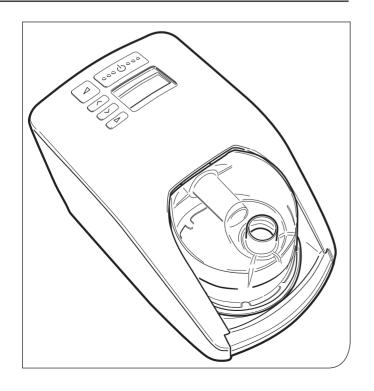


# **Operating Manual**

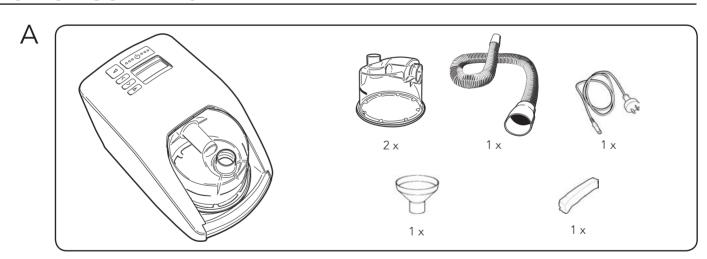


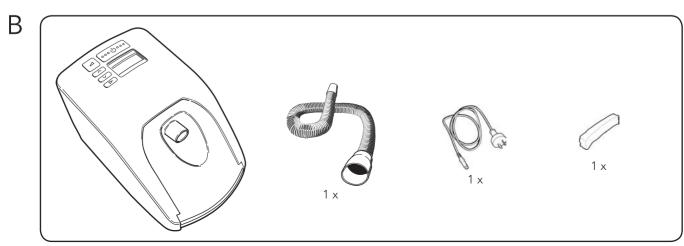


# **SECTION**

English	А
Français	В
Español	С

# PACKAGE CONTENTS







# **Sleep**Style<sup>™</sup> 200 Series HUMIDIFIED CPAP SYSTEMS

The **Sleep**Style<sup>TM</sup> 200 Series are a range of CPAP systems designed for use in the home for the treatment of OSA.

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

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#### 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



Applied Part



ATTENTION accompanying documents



Alternating Current





**C** € 0123 93/42/FEC Class IIb

### 2. Warnings

**PLEASE NOTE:- This manual refers to the Sleep**Style™ 200 Series CPAP unit as "the device".

- 1. The device should only be used with masks, connectors and delivery tubes recommended by Fisher & Paykel Healthcare, or by your physician or respiratory therapist.
- 2. Never operate the device if: a) it has a damaged power cord or plug, b) the tube has been damaged with holes, tears or kinks, c) it has been dropped or damaged, d) it has been dropped into water, e) it is not working properly, f) it is connected to a PC during CPAP treatment.
  - Return the device to an authorised service center for examination and repair.
- 3. Do not use the device when the room temperature exceeds 35°C (95°F) as this may lead to an elevated airflow temperature which may give rise to an irritation of the airways.
- 4. Ensure an air filter is fitted when operating your device.
- \*5. Remove the humidification chamber before filling.
- \*6. Do not fill the chamber with boiling water.
- \*7. When handling the device with chamber and water avoid tilting the device to prevent any chance of water entering the device enclosure.
- \*8. Place your device on a level surface lower than your head height to prevent water entering the respiratory tubing should the device be knocked over.
- 9. Do not store or use your device where it can fall or be pulled into water. If water has entered the device enclosure, disconnect the power cord and discontinue use. Seek advice from your homecare provider.

- 10. Never block the air openings of the device or place it on a soft surface such as a bed or couch, where the filter area may be blocked. Keep the air openings free of lint, hair or the like.
- 11. Ensure the device is dry before plugging into the power socket.
- 12. A mask should not be used unless the device is switched on, and operating properly. The vent hole(s) associated with the mask should never be blocked.
- 13. Due to the operating temperature of the heater plate, avoid making contact to the exposed heater plate or
- 14. At low CPAP pressures, the flow through the mask may be insufficient to clear all exhaled gas from the tubing, and consequently some re-breathing may occur.
- 15. Adjusting the pressure control can result in ineffective therapy. The pressure control must only be adjusted by a healthcare professional.
- 16. Never drop or insert any object into any opening or tube.
- 17. Always switch off the device and unplug the power cord from the power socket before cleaning.
- \*18. Empty all the water from the chamber before transporting your device.
- 19. Refer all maintenance to qualified service personnel except as outlined in this manual.
- \* Only applicable to integrated CPAP devices

# 3. Oxygen Use Warnings

If supplemental oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. This ensures that oxygen will not flow through the tube and accumulate in the device enclosure.

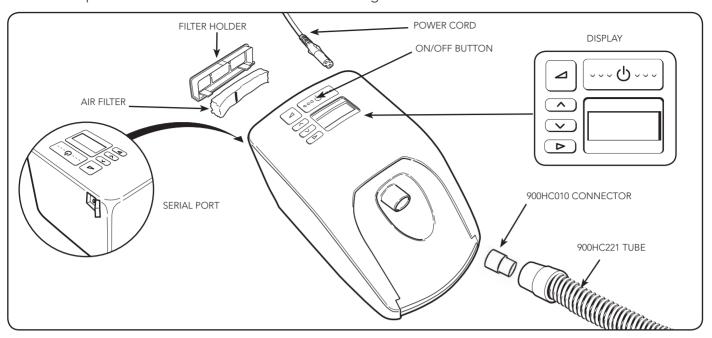
- The device should be located in a position where ventilation around the device is not restricted.
- It is recommended that supplemental oxygen be administered at the mask.
- Oxygen should not be used while smoking or in the presence of an open flame.
- The use of oxygen in therapy requires that special care be taken to reduce the risk of fire. Any materials which will burn in air and some that will not are easily ignited and burn rapidly in high concentrations of oxygen. Accordingly, for safety it is necessary that all sources of ignition be kept away from the product and preferably out of the room in which it is being used.
- A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen equipment.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection and leak rate.

# 4. Intended Use

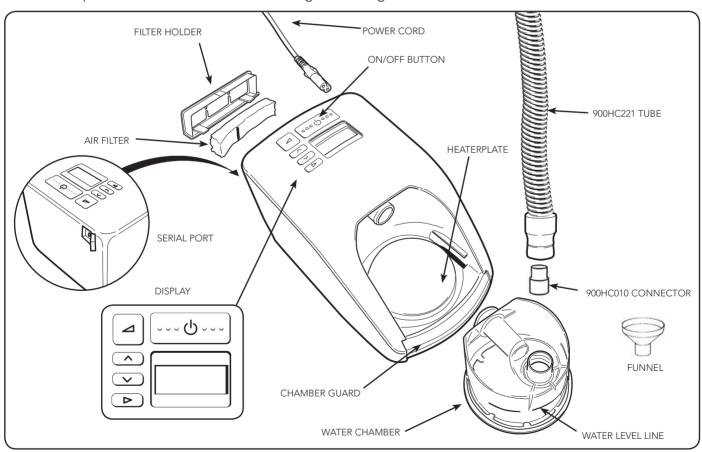
The device is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is done by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to the device relieves the drying and irritating effects on the patient airways which usually arises from use of a CPAP system. The CPAP device is for use on adult patients at home or in the sleep lab. Please refer to the HC230-Series Product range listed in the Appendix section of this manual.

# 5. DESCRIPTION OF THE DEVICE

### 5.1 Important Parts of Your Device - Standard Range



### 5.2 Important Parts of Your Device - Integrated Range



### 5.3 Accessories

HC013	Conversion Kit – Cold Humidification	900HC230	Compliance Maximizer Software
HC014	Conversion Kit – Heated Humidification	900HC232	Compliance Download Serial Cable
HC385S	Standard Humidification Chamber	900HC607	Titration Maximizer Software
HC355*	Extended Life Humidification Chamber	900HC236	Isolated Serial Adaptor
900HC010	Connector	900HC226	Lead Extension Kit
900HC221	Tube		
900HC240	Filter	*Not availab	ole in all countries

### 6. Cleaning & Maintenance

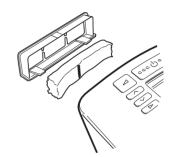
- 1. Switch off the device and unplug from the power socket.
- 2. Wipe the exterior of the device with a clean, damp (not wet) cloth and mild dishwashing detergent. Do not use harsh abrasives or solvents, as these may damage the device.
- DAILY

Clean chamber and tube.

- Remove the breathing tube from the chamber.
- Rinse the tube with soapy water. Hang up hose with hose ends pointing to floor to dry.
- Remove the chamber by pushing down the finger guard and pulling out the chamber.
- Pour out & discard the remaining water.
- Clean the chamber with soapy water, rinse and dry.
- 4 WEEKIY

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.
- 5. Replace the air filter when it becomes significantly discoloured, at least once every 3 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.



## 7. SETUP INSTRUCTIONS

How to set up your system

- 1. Remove your device from its packaging.
- Place the device on a low shelf or on the floor beside your bed, so that the device is positioned below head height.
- 3. Chamber Setup (only applicable to integrated CPAP devices)
  - 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 (Fig.2).

Never fill the chamber while it is attached to the device. When moving your device, ensure that the water chamber is empty. Device failure due to water damage is not covered by warranty.

- d. To attach the water chamber to the device, press down the finger guard and slide the chamber on (Fig.3) (Fig. 4).
- e. When the chamber is fitted correctly, the finger guard will click into place.
- One end of the tube has a white plastic connector.
   Push this onto the outlet on top of the chamber (Fig.5) or CPAP outlet (Fig.5a).
- 5. Connect the other end of the tube to the mask.
- Plug the device power cord into your household power socket and into the rear of the device.
- 7. Switch on the device by pressing the on/off button (See Fig.6). The current humidity setting is displayed.
- 8. For changing the setting refer to section 8 "Controls and Display".









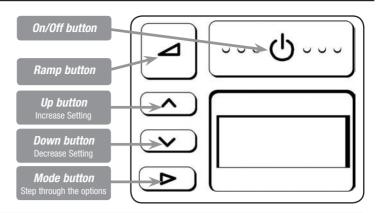






# 8. Controls and Display - Integrated CPAP Range

## 8.1 DISPLAY DESCRIPTION AND FUNCTIONS



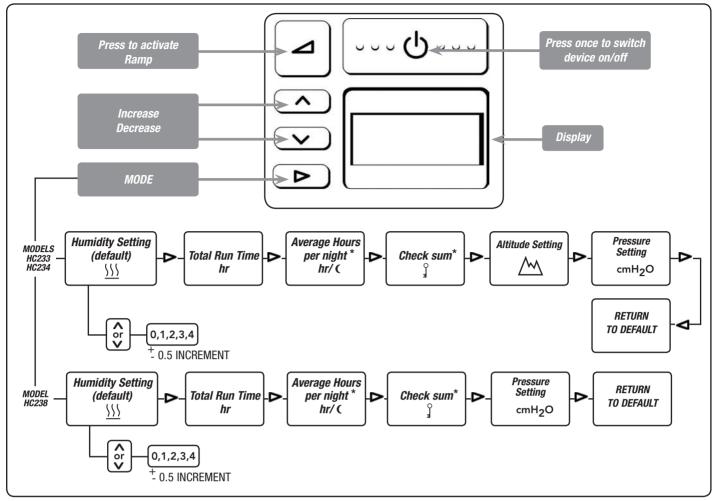
KEY	FUNCTION & DESCRIPTION	OPERATION
Ф	ON/OFF Switches the device ON & OFF	TO SWITCH "ON"  ● Press ① button briefly  ■ The device will default to display the humidity setting.
		TO SWITCH "OFF"  ● Remove your mask  ● Press 🖰 button briefly
V	RAMP Reduces pressure to a lower level to help you fall asleep. The pressure will gradually return to full operating pressure over 20 minutes	TO START THE RAMP  • Press the   button  NB: to reset ramp during a cycle the device must be switched off first  TO SWITCH "OFF"  • Press the   button
<b>^</b>	INCREASE/DECREASE Adjusts settings up or down	<ul> <li>◆ Press the</li></ul>
<b>D</b>	<b>MODE</b> To step through options	Press sequentially to step through and view options available

PATIENT MENU	DISPLAY	OPERATION
For viewing of CPAP settings, humidity, compliance data, altitude and pressure settings		<b>TO VIEW ITEMS</b> Press the "▷" button to sequentially view:
	<u> </u>	<ul> <li>Humidity Setting (default display)</li> <li>For adjusting humidity levels to minimize upper airway side effects from CPAP use. Press  A and  ➤ buttons to raise or lower settings</li> </ul>
	hr	Total run hours     Displays the total number of hours the device has been switched on (includes hours without mask use)
	hr/C	Average compliance hours per night*     Displays average number of hours the device has been used at night with the mask on
	j j	Checksum*     Displays information for medical practitioner or dealer use to check compliance
	M	Altitude setting     Displays altitude setting
	cmH <sub>2</sub> O	Pressure setting     Displays pressure setting

PATIENT MENU - ADDITIONAL SETTINGS	DISPLAY	OPERATION			
<ul> <li>To access additional settings:         From the Default setting "HUMIDITY"</li></ul>	M	<ul> <li>Altitude         Select "m" for metres of "ft" for feet using the</li></ul>			
	3000/\/	● Altitude level  - Set the altitude level by pressing the    and    keys  - Press    to exit menu  NOTE: Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.			
	cmH <sub>2</sub> O	• Actual Pressure Displays actual pressure NOTE: Only available on devices with Automatic Altitude Adjustment/Leak Compensation feature			

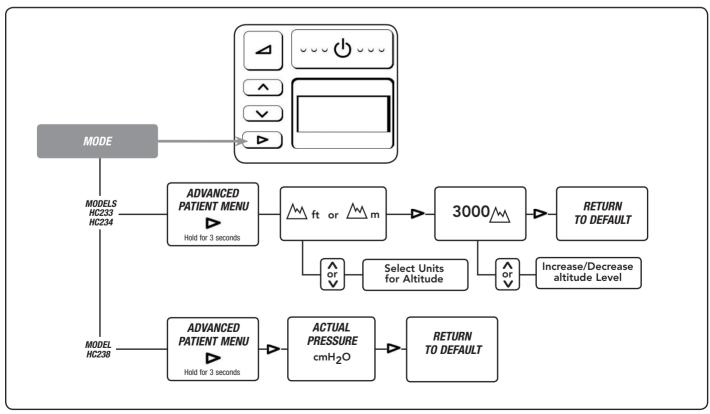
NOTE: Manual adjustment of altitude is not featured on units where there is the Automatic Altitude Adjustment/Leak Compensation feature
 \* Only available on devices with Compliance Monitoring.

### 8.2 PATIENT MENU SUMMARY - INTEGRATED CPAP RANGE



<sup>\*</sup> Only available on devices with Compliance Monitoring.

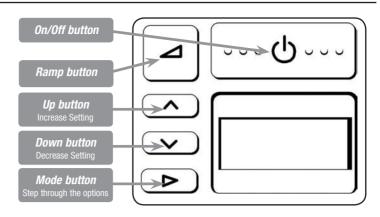
### 8.3 Patient Menu - Additional Settings Summary - Integrated CPAP Range



• Warning: Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.

# 9. Controls and Display - Standard CPAP Range

## 9.1 DISPLAY DESCRIPTION AND FUNCTIONS



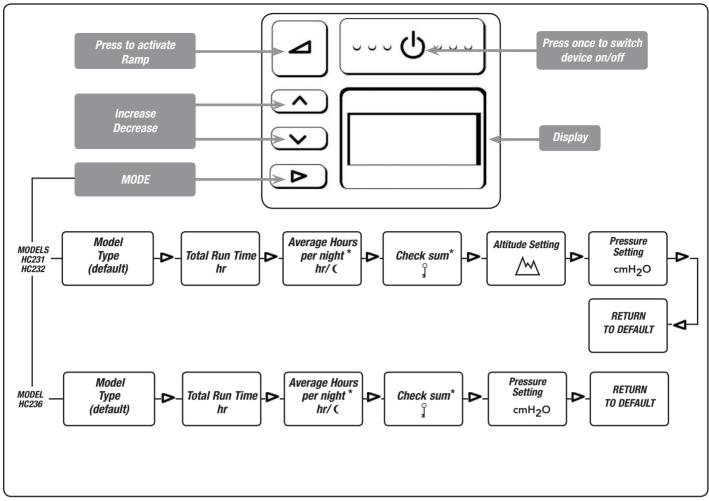
KEY	FUNCTION & DESCRIPTION	OPERATION
Ф	ON/OFF Switches the device ON & OFF	TO SWITCH "ON"  • Press
		TO SWITCH "OFF"  • Remove your mask • Press ♥ button briefly
Ρ	RAMP Reduces pressure to a lower level to help you fall asleep. The pressure will gradually return to full operating pressure over 20 minutes	TO START THE RAMP  • Press the ✓ button NB: to reset ramp during a cycle the device must be switched off first  TO SWITCH "OFF"  • Press the 🖒 button
^ V	INCREASE/DECREASE Adjusts settings up or down	● Press the   and   button to raise or lower settings
٥	<b>MODE</b> To step through options	Press sequentially to step through and view options available

PATIENT MENU	DISPLAY	OPERATION
For viewing of CPAP settings, humidity, compliance data, altitude and pressure settings		<b>TO VIEW ITEMS</b> Press the "▶" button to sequentially view:
	<b>23</b> <i>x</i>	Model Type (default display)     Displays model type as default setting
	hr	Total run hours     Displays the total number of hours the device has been switched on (includes hours without mask use)
	hr/C	Average compliance hours per night*     Displays average number of hours the device has been used at night with the mask on
	) I	Checksum*     Displays information for medical practitioner or dealer use to check compliance
	M	Altitude setting     Displays altitude setting
	cmH <sub>2</sub> O	Pressure setting     Displays pressure setting

PATIENT MENU - ADDITIONAL SETTINGS	DISPLAY	OPERATION		
To access additional settings:  From the Default setting	M	<ul> <li>Altitude         Select "m" for metres of "ft" for feet using the</li></ul>		
Press the "▶" key for 3 seconds  • To view subsequent items: Press the "▶" key.	3000/\/	Altitude level     - Set the altitude level by pressing the		
	cmH <sub>2</sub> O	Actual Pressure     Displays actual pressure     NOTE: Only available on devices with Automatic Altitude Adjustment/ Leak Compensation feature		

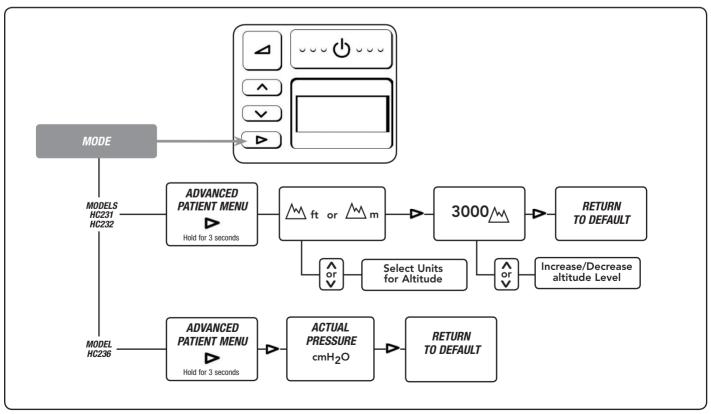
NOTE: Manual adjustment of altitude is not featured on units where there is the Automatic Altitude Adjustment/Leak Compensation feature
 \* Only available on devices with Compliance Monitoring.

### 9.2 Patient Menu Summary - Standard CPAP Range



<sup>\*</sup> Only available on devices with Compliance Monitoring.

### 9.3 Patient Menu - Additional Settings Summary - Standard CPAP Range



• Warning: Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.

#### • For integrated CPAP devices:

### a. 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 clinician for advice.

#### b. 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 (183cm) 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' (183 cm) of tubing will increase condensation.

There are several ways of reducing condensation in the tube:

- 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
- iii Warm the air in the room.

### c. 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 will often contain minerals which can damage the chamber, causing pitting in the base, even if the water is passed through a filter.

### d. When do I replace my water chamber?

Replace the chamber if the plastic walls of the chamber become cracked or cloudy or the chamber base becomes pitted. (Note: If the chamber leaks at all, it should be replaced immediately).

#### • Can I use my device in other countries?

Yes. Simply use the appropriate electrical socket adaptor 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.

### 11. Specifications

**DIMENSIONS:** 275mm x 170mm x 140mm

 $(10.8" \times 6.7" \times 5.5")$ 

**WEIGHT:** 1.9kg (4.2lbs)

(3.0kg packaged in bag incl. accessories)

**ELECTRICAL RATINGS** 

50-60 Hz Supply Frequency:

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

220-240V~ (0.8A, 1.8A max) Note: These values represent

average current

DC to AC Inverter requirements: 115V - 200W/300W surge

230V - 300W/500W surge

Heater Plate: 85W max 65°C (149°F) max Heater Plate Temperature:

**PERFORMANCE** 

Pressure Range 4 to 20 cmH<sub>2</sub>O

Altitude Range 0 to 3000m, or 0 to 9000 ft STANDARDS COMPLIANCE

Designed to conform to the

EN / IEC 60601-1 requirements of: UL60601-1

CSA C22.2/No.601.1

AS3200.1.0

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 equipment due to the effects of electromagnetic interference. If this should happen, try moving your unit or the location of the device causing interference, or alternatively consult your homecare provider.

### 12. Operating Conditions:

AMBIENT TEMPERATURE: 5 - 35°C

HUMIDITY: 10 - 95% RH

ALTITUDE: 0 - 3000m (9000ft)

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

### 13. Storage and Transport conditions:

The device should be stored and transported in environmental conditions of: -10 to  $60^{\circ}\text{C}$  .

## 14. TROUBLESHOOTING:

If you feel that your device is not operating correctly, consult your homecare dealer. Do not attempt to repair the device yourself.

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

### 15. APPENDIX

The following table lists the main difference in features across the HC230 Product Range.

	Product Code					
Features	HC231	HC232	HC233	HC234	HC236	HC238
Standard CPAP	<b>✓</b>	1			1	
Fully Integrated CPAP with Heated Humidification			1	1		1
Patient Compliance Monitoring (LCD & Full Download)		1		/	1	1
Auto Altitude Adjustment					/	1
Leak Compensation					/	1
Ambient Tracking PLUS			1	1		1
Proportional Ramp	✓	1	1	✓	✓	1

#### Note:

• Some models may not be available for sale in certain countries



USA Tel: +1 800 446 3908 or +1 949 453 4000 Fax:+1 949 453 4001

AUSTRALIA Tel:+61 3 9879 5022 Fax:+61 3 9879 5232 AUSTRIA Tel: 0800 29 31 23 Fax: 0800 29 31 22 BENELUX Tel:+31 78 644 0924 Fax:+31 78 644 0914 CHINA Tel:+86 20 3205 3486 Fax:+86 20 3205 2132 FRANCE Tel:+33 1 6446 5201 Fax:+33 1 6446 5221 GERMANY Tel:+49 7182 93777 0 Fax:+49 7182 93777 99 INDIA Tel:+91 80 4123 6041 Fax:+91-80-4123 6044 IRISH REPUBLIC Tel: 1800 409 011 ITALY Tel:+39 06 7839 2939 Fax:+39 06 7814 7709 JAPAN Tel:+81 3 3661 7205 Fax:+81 3 3661 7206 MIDDLE EAST Tel: +9 71 4 360 0849 Fax: +9 71 4 368 8110 SPAIN Tel:+34 902 013 346 Fax:+34 902 013 379 SWITZERLAND Tel: 0800 83 47 63 Fax: 0800 83 47 54 UK (EU Authorised Representative) Tel: +44 1628 626 136 Fax: +44 1628 626 146 Nthn Ireland Tel: 0800 132 189