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Use and Care Manual



Fisher & Paykel
HEALTHCARE

BEFORE YOU START



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

Please read this guide before use and save instructions for future reference. Section 2 contains important safety information about the use of this device. The device is suitable for continuous operation.

If you feel that your device or any accessories are not operating correctly, please contact your healthcare provider.

NOTE: This device contains no serviceable parts. Refer all therapy and equipment queries to your healthcare provider.

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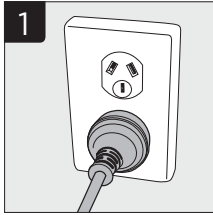
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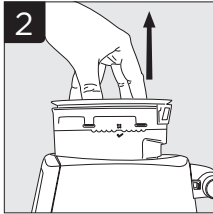
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SECTION 1 - QUICK START INFORMATION

1. GETTING STARTED

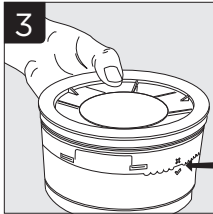


Place the device on a level surface, level with or below head height, to prevent water entering the tubing and the device enclosure. Plug the power cord into the power supply.



Remove the Chamber Lid and reach inside the Water Chamber with your fingers to take hold of the circular chamber grip. Pull the Water Chamber up and out of the device.

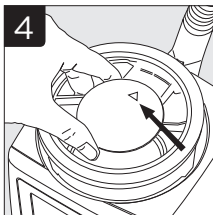
CAUTION: Do not fill the Water Chamber while it is in the device; the Water Chamber should always be removed before filling.



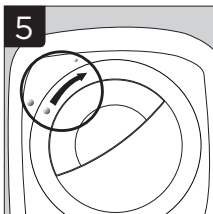
Fill the Water Chamber with distilled water up to the maximum water line, which is marked on the side of the Water Chamber.

CAUTION: Do not use the device without a Water Chamber. Do not use hot water, and water should be replaced before each use.

IMPORTANT: The Water Chamber cannot be disassembled.

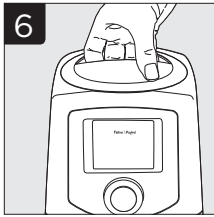


To replace the Water Chamber, the arrow on the circular chamber grip should face toward the Elbow.

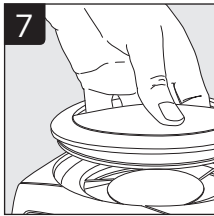


Fit the Chamber Lid by lining up the large dot on the lid ● with the large dot on the top of the device ●. When the two symbols are aligned, apply downward force and turn clockwise to align the large dot with the small dot on the top of the device.

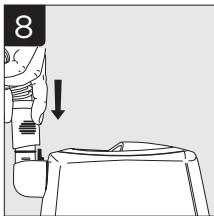
NOTE: The Chamber Lid must be correctly fitted for optimal pressure delivery.



When the Chamber Lid is locked into place, it should be flush, with no gaps for air to leak. It can now be used as a handle for lifting and carrying.

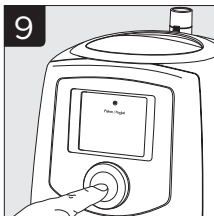



The Chamber Lid can be unlocked by twisting in an anti-clockwise direction, then removed by lifting away from the device.



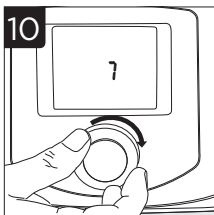
Attach the breathing tube to the Elbow and connect to your mask.

NOTE: Make sure the electrical connectors on the ThermoSmart™ Breathing Tube come together with the electrical connectors on the Elbow. Please refer to Oxygen Elbow user instructions if attaching an Oxygen Elbow.



From the Home Screen, a quick press to the SmartDial™ will start therapy. The Home Screen will light up and the clock-face of the Menu System will rotate to indicate therapy is starting. If Ramp is required, press the SmartDial again and hold for 3 seconds to activate. The Ramp symbol  will display.

Your device is now ready for use.



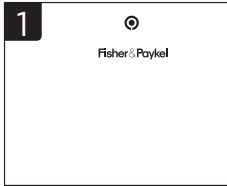
Turn the SmartDial to select and adjust settings. Refer to Section 1, Part 2 for a description of the Menu System.

2. F&P ICON MENU SYSTEM


Simple Mode

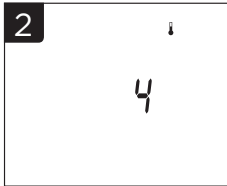
The **Simple Mode** is the default Menu System of the F&P ICON.*

* Not in all models



1. On/Off and Ramp

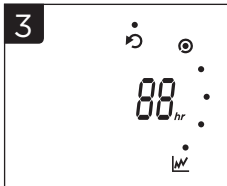
- A quick press to the SmartDial will start therapy.
- To activate Ramp, press the SmartDial again and hold for 3 seconds. The Ramp symbol will appear .



2. Humidity





- To control the level of humidity delivered to the mask, turn the SmartDial to select the desired humidity level from 0 (off) to 7 (maximum). Press again to accept the change. For example, if the air is feeling too cold, increase the Humidity setting in increments of 1 or 2 over 2 to 3 nights until you find the level that is comfortable.


NOTE: The default setting is Humidity level 4. If using without water, or where low power consumption is required (e.g. for aircraft and trucking use), set the humidity level to 0.



3. Sleep Data

Press and hold the SmartDial for 7 seconds to access the Sleep Data setting. Turn the SmartDial to scroll through each of the following statistics:

- Total Compliant Hours *hr*.
- Average Compliant Hours over the last 30 nights *hr* . Press the SmartDial to access the average for the last 7 nights and again for the last night.
- Percentage of nights used greater than 4 hours over the last 30 nights  *>4hr*. Press the SmartDial to access the percentage for the last 7 nights.
- The number of nights elapsed since therapy commenced .
- Check Sum .
- Exit the Sleep Data setting.


NOTE: A  symbol will appear on the Home Screen once the compliance requirements have been achieved for the North America models only.

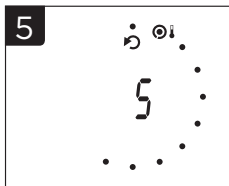
Advanced Mode

The **Advanced Mode** is a menu system for users that provides additional features that are not available in Simple Mode. (**Note: This Mode may be restricted by your healthcare provider.**)




4. On/Off and Ramp



- A quick press to the SmartDial will start therapy.
- To activate Ramp, press the SmartDial again and hold for 3 seconds. The Ramp symbol will appear .



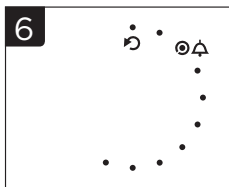
5. Humidity

- To control the level of humidity delivered to the mask, turn the SmartDial to the Humidity setting . Press to enter and turn the SmartDial again to select the desired humidity level from 0 (off) to 7 (maximum). Press again to accept the change. For example, if the air is feeling too cold increase the Humidity setting in increments of 1 or 2 over 2 to 3 nights until you find the level that is comfortable.







NOTE: The default setting is Humidity level 4. If using without water, set the humidity level to 0. The humidity level cannot be adjusted if Flight Mode is set to ON.

- The Boost control offers three additional levels (1, 2, 3) to optimize the Humidity setting. Press and hold the SmartDial for 3 seconds while in the Humidity setting  and the Boost symbols  will appear. Turn to select low (1), medium (2) or high (3) and press again to accept the change.

CAUTION: The Boost control should only be used in extreme situations when experiencing symptoms from your CPAP therapy. The default Boost setting (medium) will be suitable for most patients.

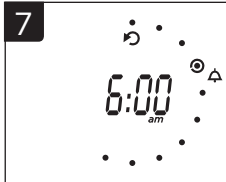


6. Alarm On/Off


- Turn the SmartDial to the Alarm setting , press to enter, then turn to select either On  or Off . Press again to accept the change.
- If Alarm On  is chosen, turn the SmartDial to select either the default bell  or the music symbol for AlarmTunes™ , and press again to accept the change.
- Press the SmartDial once to snooze the Alarm for 10 minutes, twice to turn the Alarm off and a third time to discontinue therapy.

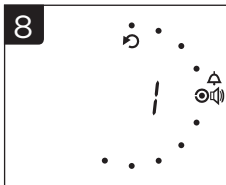
NOTE: The AlarmTunes symbol is only visible when the InfoUSB™ is inserted. F&P Studio™ software is required to utilize the AlarmTunes feature.

- If AlarmTunes is selected, turn the SmartDial to select the desired music track (from 1 to 5, depending on how many songs are loaded onto the InfoUSB), or if there are two or more songs loaded select Auto for shuffle and press again to accept the change. Refer to the F&P Studio CD for instructions to install and transfer music to your InfoUSB.





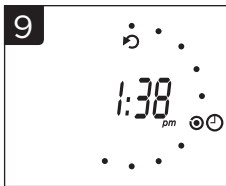
7. Alarm Time

- Turn the SmartDial to the Alarm Time setting  and press to enter. Turn the SmartDial to select the hour, press to accept. Turn to select the minutes and press again to accept the change.




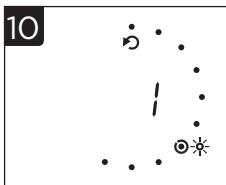
8. Alarm Volume

- To adjust the volume of the alarm, turn the SmartDial to the Alarm Volume setting  and press to enter. Turn the SmartDial to adjust the volume from quiet to loud and press again to accept the change.
- To adjust the “click” volume of the SmartDial, press and hold for 3 seconds while in the Alarm Volume setting. The volume symbol  will be present, turn to select the desired volume and press again to accept the change.





9. Clock Time

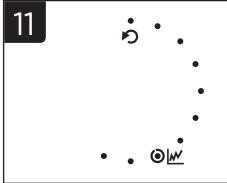
- Turn the SmartDial to the Clock Time setting  and press to enter. Turn the SmartDial to select the hour, minutes, 12-hr or 24-hr time. After each selection, press again to accept the change.






10. Brightness

- Turn the SmartDial to the Brightness setting  and press to enter. Turn the SmartDial to select the desired *Home Screen Brightness* and press to accept the change.
- To adjust the *Active Screen Brightness*, press and hold the SmartDial for 3 seconds and the device symbol will appear .




NOTE: The Home Screen Brightness controls the level of light emitted by the LCD when the device is in “stand-by” or “pressure on” mode, and the Active Screen Brightness controls the level of light emitted by the LCD whilst navigating the Menu System.




11. Sleep Data

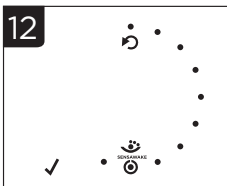
Turn the SmartDial to the Sleep Data setting  and press to enter. Alternatively, press and hold the SmartDial for 7 seconds. Turn the SmartDial to either the Centers for Medicare and Medicaid (CMS) report  (US specific) or Patient report  and press to enter.

Turn the SmartDial to scroll through each of the following statistics:




- Total Compliant Hours *hr*.
- Average Compliant Hours over the last 30 nights *hr*. Press the SmartDial to access the average for the last 7 nights and again for the last night.
- Percentage of nights used greater than 4 hours over the last 30 nights  *>4hr*. Press the SmartDial to access the percentage for the last 7 nights.
- The number of nights elapsed since therapy commenced .
- Check Sum .
- AHI for last 30, 7, and 1 nights.
- Leak for last 30, 7, and 1 nights.
- 90th percentile pressure for last 30, 7, and 1 nights.
- SensAwake for last 30, 7, and 1 nights.
- Exit the Sleep Data setting.

NOTE: A  symbol will appear on the Home Screen when the Sleep Data is within the compliance requirements. Once CMS requirements are met, the data within the CMS sub-menu will stop logging.

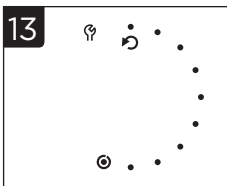
- Exit the Sleep Data setting.



12. SensAwake On/Off

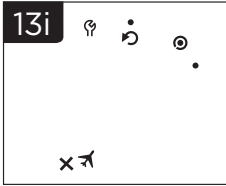
The SensAwake setting is available on both Auto and Premo models, but may be restricted by your healthcare provider. To adjust, turn the SmartDial to the SensAwake setting  and press to enter. Turn the SmartDial to select On  or Off  and press again to accept the change.

NOTE: This setting is not available with the Novo model.



13. User Preferences

Turn the SmartDial to the User Preferences  setting and press to enter.



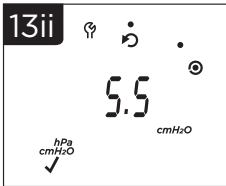
13i. Flight Mode

Flight Mode allows for the device to operate on a reduced power (75 W). Situations for use in this mode might include long-haul air flights and camping.

NOTE: Humidity output will be significantly reduced in this mode and is not recommended for long-term use.

- Turn the SmartDial to the Flight Mode setting and press to enter. Turn to select On or Off and press again to accept the change.
- The Flight Mode symbol will be displayed continuously on the Home Screen while the Flight Mode is activated.

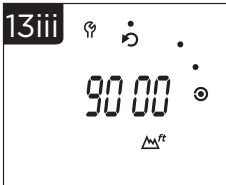
NOTE: If you are intending to use your CPAP during flight, confirm with your airline for F&P ICON approval prior to travel.



13ii. Display Pressure

The Display Pressure setting provides two display options for the Home Screen. Time is the default setting, however this can be changed to show pressure (cmH₂O or hPa) if required.

- Turn the SmartDial to the Display Pressure setting and press to enter. Turn to select On or Off and press again to accept the change.
- If a different unit of measure is required, press the SmartDial and hold for 3 seconds. Turn the SmartDial to select either cmH₂O or hPa and press again to accept the change.



13iii. Altitude Adjustment

- For models without automatic Altitude Adjustment, turn the SmartDial to the Altitude setting and press to enter. Turn the SmartDial to select the Altitude level from 0 to 9,000 ft and press to accept the change.
- To choose meters, press the SmartDial and hold for 3 seconds while at the Altitude Adjustment setting. When the symbol starts to flash, turn to select meters and press to accept the change. Press the SmartDial again to enter the menu and turn to adjust to the desired Altitude level. Press again to accept the change.

3. COMMUNICATING SLEEP DATA

- The USB Port houses the InfoUSB 2 which records patient compliance, efficacy and flow data. The InfoUSB 2 must be pushed completely into the USB Port until it clicks into place. To remove, push the end of the InfoUSB 2 for a spring-release retrieval.
- The InfoUSB 2 is used to record sleep data from the device memory when it is inserted into the USB Port of the device and to store music for use with AlarmTunes. The InfoUSB 2 can be removed and sent to your healthcare provider to view and adjust settings. Changes will be automatically transferred when the InfoUSB 2 is next inserted into the USB port of the device.

InfoUSB 2 Application*

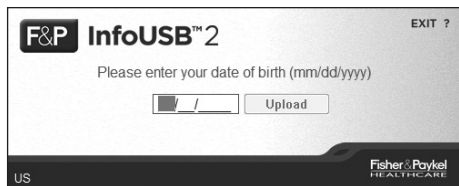
The InfoUSB 2 application is intended for home and clinical use as an accessory with the InfoUSB 2.

How to install and use

When requested by your healthcare provider, remove the InfoUSB 2 from your CPAP device and insert it into the USB port of a computer connected to the internet.

The first time you insert the InfoUSB 2 into your computer, open Windows Explorer and navigate to the drive called FPHCARE.

1. To install an InfoUSB detector on your computer, open this folder and double-click on the Setup.exe file. Follow the on-screen instructions. Upon successful installation of the InfoUSB 2 application, and upon detection of an InfoUSB 2 in your computer, InfoUSB 2 will automatically launch and the message below will appear.
2. To run InfoUSB 2 application once, click on the InfoUSB application. InfoUSB 2 will automatically launch and the message below will appear.



Enter your date of birth and click the Upload button.

After the data has been uploaded successfully, a confirmation message will appear. Remove the InfoUSB 2 from your computer and place it back into your CPAP device. The CPAP device is now ready to be used for future logging. The InfoUSB detector only needs to be installed once. The next time you place the InfoUSB 2 into you computer, the start screen (image above) will appear automatically.

* Not available in all countries.

4. CLEANING AND MAINTENANCE

The device should be cleaned as follows:

- Ensure the wall power outlet is turned off before unplugging the device from the power supply where appropriate.
- Wipe the exterior and basin of the device (when the Water Chamber has been removed) with a clean, damp (not wet) cloth and mild dishwashing detergent. Do not use harsh abrasives, solvents or alcohol as these may damage the device.

Daily

Clean the Water Chamber, Chamber Lid and the Breathing Tube:

- Unlock the Chamber Lid by twisting in the anti-clockwise direction and lift away from the device.
- Wash the Chamber Lid in a mild dishwashing detergent, rinse thoroughly and dry.
- Disconnect the Breathing Tube from the mask and the device Elbow.
- Clean Breathing Tube with warm, soapy water, rinse thoroughly and hang with both ends pointing to the floor to dry.
- Remove the Water Chamber and discard any remaining water. Do not remove the rubber seal on the chamber.
- The one-piece Water Chamber should not be disassembled.
- The Water Chamber can be washed in a domestic dishwashing machine, or cleaned and washed with mild dishwashing detergent, then rinsed and dried.

Weekly

Thoroughly clean the Water Chamber, Outlet Seal, and the Elbow:

- Soak the inside of the Water Chamber for 10 minutes in a solution of one part white vinegar to two parts water.
- Empty the vinegar solution and rinse the Water Chamber thoroughly with water.
- Disconnect the Elbow from the device and the Outlet Seal can be easily removed by lightly pushing it from the back of the device into the Water Chamber housing.
- The Elbow and the Outlet Seal can be cleaned and washed with mild dishwashing detergent, then rinsed and dried.
- Please place the Outlet Seal before the Elbow in seal cavity when re-fitting.

Air Filter

The Air Filter is located on the rear of the device. The Air Filter ensures the air is filtered from particles and dust. To access, first pull out the Filter Grill, then pinch the gauze to remove. The Filter Grill must be pushed back into the cavity to keep the Air Filter in place.

Replace the Air Filter when it becomes significantly discolored, at least once every three months or after 1,000 hours' worth of running time.

NOTE: When replacing the Air Filter the black stripe should be on the inside.

Breathing Tube and Water Chamber

It is recommended that you inspect the device and all parts on a regular basis after cleaning. The equipment should be replaced immediately if there is any sign of cracking, discoloration or leaking.

NOTE: The device is not serviceable and should not be disassembled. Refer all therapy and equipment queries to your healthcare provider.














The device is intended for single or multiple use. Refer to the high level disinfection instructions in the Healthcare Provider Manual for cleaning between users.

SECTION 2 - OTHER PRODUCT INFORMATION

1. INTENDED USE

The device is for use on adult patients for the treatment of Obstructive Sleep Apnea (OSA).
The device is for use in the home or sleep laboratory.

2. SYMBOL DEFINITIONS

	Type BF Applied Part		Alternating Current
	ATTENTION Consult accompanying documents		Class II Medical Electrical Equipment
	Do not discard as regular rubbish		Conforms with medical device directive 93/42/EEC
	Drip-proof		Date of manufacture
	Catalogue number		Serial number
	Prescription only		Authorized representative in the European community
	NZ Radio Interference C-tick mark		
	UL Classified symbol		

3. GENERAL WARNINGS AND CAUTIONS

This manual refers to the **F&P ICON** series model as “the device”.

The device treats OSA by delivering a flow of continuous positive airway pressure (CPAP) at a level prescribed by the physician, to splint open the airway and prevent airway collapse.

3.1 Contraindications

Research indicates that 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.

3.1.1 Precautions:

- The safety and effectiveness of positive pressure has not been established in patients with respiratory failure or chronic obstructive pulmonary disease.
- The safety and effectiveness of the auto-adjusting device has not been established in patients with congestive heart failure, obesity hypoventilation syndrome or central sleep apnea.

3.1.2 Adverse effects:

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

3.2 Warnings

3.2.1 To avoid electric shock from the device:

- Only operate if the device, power cord and plug are dry and in good working order.
- If water damage occurs to your device, disconnect the power cord, discontinue use immediately and seek advice from your healthcare provider.
- Do not store or use the device where it can be pulled into water.

3.2.2 To avoid choking, or inhalation of a foreign object:

- Never place any non-approved objects into any opening of the device, breathing tube or mask.
- Ensure the recommended filter is fitted to the device before use.
- Ensure the breathing tube is positioned so it can not become entangled with the body or furniture during sleep.

3.2.3 To avoid burns:

- Do not fill the Water Chamber with hot water.
- After use, wait for the water to cool before touching, carrying or emptying the Water Chamber.
- Do not touch the heater plate shortly after the device has been operating.
- Do not touch the water in the Water Chamber while the device is operating.
- Position the ThermoSmart Breathing Tube so it is uncovered and free from bedding or other materials.

3.2.4 Other:

- Ensure the device is stored and operated on a surface, level or below head height, to prevent water entering the tubing and the device enclosure.
- The device is not intended to be used as a life-supporting device.
- The device complies with the electromagnetic compatibility requirements of IEC60601-1-2. 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.
- Do not block the flow through the device as this may cause the motor to overheat.
- Do not block the exhaust flow holes of the mask as they are designed to allow a continuous flow of air out of the mask and if blocked CO₂ re-breathing may occur.
- In the event of power failure, machine malfunction or if the device is turned off, remove the mask immediately as the flow through the mask may be insufficient to clear all exhaled gas, which may result in CO₂ re-breathing occurring that can be hazardous.
- The device is not suitable for use in environments with flammable anaesthetic mixtures with air or oxygen or nitrous oxide.

3.2.5 To ensure optimal therapy:

- Do not operate the device, Water Chamber, or breathing tube if it is dropped, damaged or not working as intended.
- Pressure adjustments should only be made by a qualified healthcare provider.
- Only use masks, breathing tubes and accessories compliant with ISO 17510-2, distributed for use with this device, and recommended by Fisher & Paykel Healthcare or your healthcare provider.
- It is recommended to only use the parts that have been specified in this manual.
- On models without automatic altitude adjustment, ensure the altitude level is manually adjusted to ensure optimal pressure delivery.
- Do not use the device without a Water Chamber in place.
- If using the device without water in the Water Chamber it is recommended to set the humidity level to zero.
- It is recommended to use distilled water to extend the life of your Water Chamber. This is likely to prevent residue buildup on the chamber base.

3.2.6 Using supplemental oxygen with your device:

- Supplemental oxygen can be administered at the mask end of the breathing tube or with an Oxygen Elbow.

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

- Ensure there is no obstruction downstream of the Oxygen Port as this can affect the delivered oxygen concentration.
- Oxygen concentration should be measured at the point of delivery to the patient.
- Avoid the risk of fire:
 - Only use oxygen when the device is operating. If the device is turned off it can lead to accumulation of oxygen within the device.
 - Ensure adequate ventilation is provided around the device.
 - Remove any source of ignition: such as cigarettes, an open flame, or materials which burn or ignite easily at high oxygen concentration.
 - Keep oxygen regulators, cylinder valves, tubing, connections and all other oxygen equipment away from oil, grease or greasy substances. Spontaneous and violent ignition may occur if these substances come into contact with oxygen under pressure.

3.3 Cautions

3.3.1 To prevent water damage to the device:

- Remove the Water Chamber from the device before filling.
- Do not fill the Water Chamber above the maximum level.
- Do not move, carry, transport or store the device with water in the Water Chamber.

3.3.2 General:

- Only use the device within the Operating Conditions specified in Section 2, Part 4.
- Position the device so the power cord connection to the power supply is easily accessible.
- Only clean the device in accordance with the cleaning instructions set out in the Cleaning and Maintenance Section (Section 1, Part 4) and only when it is disconnected from the power supply.
- Only use the F&P ICON InfoUSB with the device. Use of any other USB drives may cause data corruption. Do not attempt to change the directories or view the data without software distributed or designed for use with the F&P ICON.

3.4 Replacement Parts

900ICON200	Water Chamber (10 pack)	900HC221	Standard Breathing Tube**
900ICON202	InfoUSB 2 (5 pack)	900ICON214	Silver Gloss Lid
900ICON203	InfoUSB 2* (5 pack)	900ICON216	Matt Gray Lid
900ICON112	F&P Studio CD	900ICON217	Charcoal Lid
900ICON204	Elbow	900ICON218	Filter Grill
900ICON205	Oxygen Elbow	900ICON503	Air Filter (single pack)
900ICON206	Outlet Seal	900ICON213	Air Filter (2 pack)
900ICON208	ThermoSmart Breathing Tube**	900ICON315	Carry-bag

* US and Canada only

** Applied Parts – to fit 0.86 inches (22 mm) Conical Connector

4. PRODUCT SPECIFICATIONS

DIMENSIONS: 6.3 H x 6.7 W x 8.7 D in. (160 H x 170 W x 220 D mm)

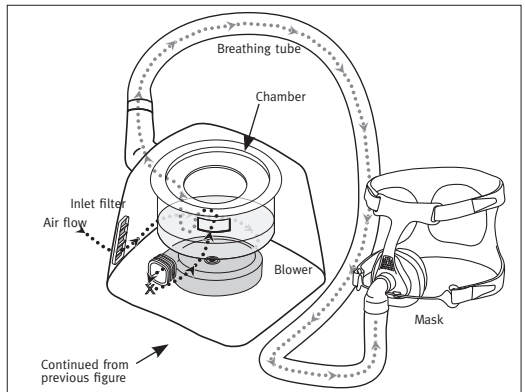
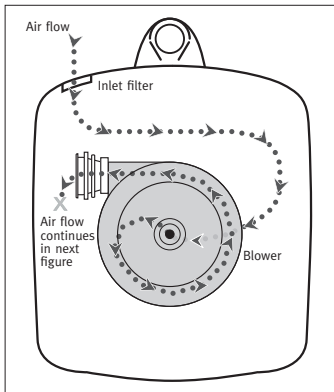
WEIGHT: 4.8 lb (2.2 kg) Packed Weight 8.7 lb (4.0 kg)

PERFORMANCE: Pressure Range: 4 to 20 cmH₂O / hPa (in the unlikely event of fault conditions, pressure may reach up to 29 cmH₂O)

Maximum Flow Rates					
CPAP Pressure Setting (cmH ₂ O)	4	8	12	16	20
Measured flow at patient connection port (Lpm) – Auto/Premo	62.1	101.5	129.4	148.8	143.3
Measured flow at patient connection port (Lpm) – Novo	46.7	52.4	56.5	60.6	64.5

Dynamic Pressure Stability						
	Breath Rate BPM	Test Pressure				
		Pmin	Pmin 1/4 (Pmax-Pmin)	Pmin 1/2 (Pmax-Pmin)	Pmin 3/4 (Pmax-Pmin)	Pmin
		4.0 cmH ₂ O	8.0 cmH ₂ O	12.0 cmH ₂ O	16.0 cmH ₂ O	20.0 cmH ₂ O
Novo Dynamic Pressure Stability (cmH ₂ O)	10	0.76	0.84	0.90	0.99	1.04
	15	0.76	0.84	0.91	0.99	1.04
	20	1.16	1.22	1.28	1.38	1.44
Auto/Premo Dynamic Pressure Stability (cmH ₂ O)	10	0.13	0.16	0.22	0.28	0.33
	15	0.27	0.26	0.31	0.37	0.44
	20	0.52	0.47	0.47	0.52	0.54

THE PNEUMATIC FLOW PATH:



Static Pressure Stability

	Auto/Premo	Novo
Pressure change (cmH ₂ O) at connection port at a pressure setting of 10 cmH ₂ O	0.2	0.4

Humidity

With ThermoSmart Breathing Tube

Maximum Humidity	36 mg/L Body Temperature and Pressure Saturated (BTPS), 82% RH at 10 cmH ₂ O, with Humidity level 7 and Boost level high.
Typical Humidity	24 mg/L (BTPS), 90% RH at 10 cmH ₂ O, with Humidity level 4 and Boost level medium.

With Standard Breathing Tube

Maximum Humidity	32.24 mg/L, 73.21% RH at 10 cmH ₂ O with Humidity level 7 and Boost level high.
Typical Humidity	17.97 mg/L, 85.88% RH at 10 cmH ₂ O with Humidity level 4 and Boost level medium.

Electrical Ratings

Rated Supply Voltage	Rated Current Input	Rated Supply Frequency
100 - 115 V	1.27 A (1.43 A Max)	50 - 60 Hz/400 Hz
220 - 240 V	1.07 A (1.21 A Max)	50 - 60 Hz

GAS TEMPERATURES:

Maximum = 100 °F (38 °C)

NOISE LEVEL:

Sound Pressure Level < 29 dBA
Average Sound Power Level < 37 dBA

WATER CHAMBER VOLUME:

420 ml up to the maximum fill line

STANDARDS COMPLIANCE:

IEC60601-1: 1988 + A1 & A2; AS/NZS 3200.1.0: 1998
EN60601-1: 1990 + A1-A2; UL60601-1: 2003

DATA RECORDING:

The InfoUSB records up to 365 days of summary efficacy data, 7 days of detailed efficacy data (AHI, Leak), Pressure and Leak data (50 Hz), as well as cumulative data from first use. The device memory can also record up to 365 sessions of summary data or up to 200 sessions (400 hours) of detailed efficacy data.

STORAGE AND TRANSPORT:

The device should always be stored and transported within the following temperatures:

Transport: 14 to 140 °F (-10 °C to 60 °C)

Storage: 14 to 140 °F (-10 °C to 60 °C)

CAUTION: Ensure water is emptied from the Water Chamber before traveling.

OPERATING CONDITIONS:

Ambient Temperature: 41 to 95 °F (5 to 35 °C)

Humidity: 15 to 95% Relative Humidity

Altitude: 0 to 9,000 ft (0 to 3,000 m)

NOTE: Above 4,500 ft (1,500 m) the maximum operating pressure will be reduced.

5. F&P ICON MODELS AND FEATURES MATRIX

Performance Features	Auto	Premo	Novo
Fully Integrated	•	•	•
ThermoSmart Technology*	•	•	•
Auto-Adjusting Pressure	•		
Efficacy Reporting	•	•	
Compliance Reporting	•	•	•
InfoUSB	•	•	•
SensAwake	•	•	
Proportional Ramp	•	•	•
Altitude Adjusting	Automatic	Automatic	Manual
Leak Compensation	•	•	
Clock and Alarm Tunes	•	•	•
InfoSmart™ Software	•	•	•
Plug Type	Auto	Premo	Novo
Australasia/China	ICONAAA	ICONPBA	ICONNAA
Europe	ICONAAE/ICONAHE**	ICONPAE**/ICONPBE/ICONPHE**	ICONNAE
United Kingdom/Hong Kong	ICONAAK	ICONPBK	ICONNAK
North America (model numbers with HT include heated breathing tube)	ICONAAN/ICONAAN-HT	ICONPBN/ICONPBN-HT	ICONNAN/ICONNAN-HT
Brazil	ICONAAB	ICONPBB	ICONNAB
Japan/Taiwan	ICONAAJ	ICONPBJ	ICONNAJ

* In some countries the ThermoSmart Breathing Tube needs to be purchased as an accessory to activate ThermoSmart Technology

** Part may vary depending on country

6. DEVICE AND CONSUMABLES DISPOSAL INSTRUCTIONS



Device Disposal Instructions

This device contains electronics. Please do not discard as regular rubbish. Dispose of electronics according to local guidelines.



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.

7. WARRANTY STATEMENT

Fisher & Paykel Healthcare warrants that the CPAP (excluding consumable items forming part of the CPAP delivery system), when used in accordance with its instructions for use, shall be free from defects in workmanship and materials and will perform in accordance with Fisher & Paykel Healthcare's official published product specifications for a period of 2 years from the date of purchase by the end user. This warranty is subject to the limitations and exceptions set out in detail in <http://www.fphcare.com/osa/cpap-solutions/cpap-warranty.html>.

8. TROUBLESHOOTING

If you feel that your device is not operating correctly, please refer to the following suggestions. If the problem persists, please consult your healthcare provider. Do not attempt to repair the device yourself.

Problem	Possible Cause	Solution
I cannot turn the pressure on or off	The device is likely to be in the Advance Mode of the Menu System and the selection may not be at the 12 o'clock position.	Turn the selection circle to the 12 o'clock position and press the SmartDial to turn the pressure on or off.
Insufficient air is delivered from the device	The Chamber Lid may not be correctly fitted to the device. Ensure the Water Chamber is in the device.	Refer to Section 1, Part 1.
"Error" is displayed on the Home Screen of the device	An error may have been detected with the device.	Disconnect from power, then connect and re-start device. If error persists, record the number displayed and contact your healthcare provider for further instructions.
AlarmTunes does not work	The Alarm may be set to "off". The Alarm may be set to "buzzer". F&P Studio software may not have been installed. The Alarm volume may not be set loud enough. The InfoUSB may not be inserted all the way into the USB port.	Refer to Section 1, Part 2 for instructions on the Alarm Setting. Once F&P Studio software has been installed onto your computer and your favorite songs selected, download onto your InfoUSB and then ensure the InfoUSB is inserted into the USB Port of the device.
The Heater-Plate and/or Water Chamber base is warm to the touch even though the device isn't being used	The power supply is located directly underneath the Heater-Plate and in standby mode generates approximately 5 W of power, which causes the feeling of warmth. The Water Chamber is also fully insulated by the device which can cause heat to be retained. This is perfectly normal and should not cause concern.	If concerned about overheating, unplug the device from the power supply when it is not being used.
I think my Water Chamber is leaking because there is a build-up of water on the Heater-Plate	After therapy the device will cool, which may result in condensation forming inside the Water Chamber and pooling on the heater plate.	Before each use remove the Water Chamber and dry the basin of the device with a cloth. If the water build-up becomes excessive, please contact your healthcare provider.
I don't think my Humidifier is working	Check the Humidity setting is above 1. Check your Water Chamber as it may be empty.	Refer to Section 1, Part 2 for more information on the humidity controls.
The InfoUSB symbol  is constantly flashing on the Home Screen	The InfoUSB may not be inserted correctly.	Take the InfoUSB completely out of the USB port, then insert again until it clicks.
The device seems noisy; there is a hissing noise coming from the device	The Chamber Lid may not be properly fitted, causing air to leak.	Remove the Chamber Lid and replace again so that it is completely flush with the device, by following the instructions set out in Section 1.

Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348, Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com
Australia Fisher & Paykel Healthcare Pty Limited, 36-40 New Street, PO Box 167, Ringwood, Melbourne, Victoria 3134, 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 40 216 3555 Fax: +31 40 216 3554 **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 7181 98599 0 Fax: +49 7181 98599 66 **India** Tel: +91 80 4284 4000 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 **Northern Ireland** Tel: 0800 132 189 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, P.O. Box 06371 Ostim, Alinteri Bulvari 1161/1 Sokak No. 12-14, Ankara, Turkey Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK**  Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: +44 1628 626 136 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

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