F&P SleepStyle™

Product Technical Guide

F&P SleepStyle Auto
F&P SleepStyle CPAP

USA

Fisher & Paykel HEALTHCARE

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BEFORE YOU START

This Technical Guide is intended for the healthcare provider and technical personnel only. It includes specifications, spare parts, device checks and troubleshooting for the F&P SleepStyle Auto and CPAP devices.

1. INTRODUCTION

The F&P SleepStyle Auto is an auto-adjusting positive airway pressure device. The F&P SleepStyle CPAP is a continuous positive airway pressure device (CPAP).

This guide refers to the F&P SleepStyle Auto and F&P SleepStyle CPAP as the "device".

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

The healthcare provider is responsible for ensuring that:

- All components used with the device are compatible
- The device is correctly configured with the patient's therapeutic settings
- The effectiveness of the patient's therapy is periodically reassessed

Refer to the *Use and Care Guide* in Appendix C and the *Clinician Guide* in Appendix D for additional information regarding the setup and use of the device.

1.1 APPLICABLE MODELS

This Technical Guide is applicable to the following F&P SleepStyle devices:

SleepStyle Auto	SleepStyle CPAP
SPSAAA	SPSCAA
SPSABA	SPSCBA
SPSAAB	SPSCAB
SPSABB	SPSCBB
SPSABC	SPSCBC
SPSAFC	SPSCFC
SPSAAE	SPSCAE
SPSABE	SPSCBE
SPSAAJ	-
SPSABJ	SPSCBJ
SPSAAK	SPSCAK
SPSABK	SPSCBK
SPSAAN	SPSCAN
SPSABN	SPSCBN
SPSAAS	SPSCAS
SPSABS	SPSCBS
SPSAAU	-
SPSABU	-
SPSAAW	SPSCAW
SPSABW	SPSCBW

Note: *Not all models are available in all countries.*

1.2 WARNINGS/CAUTIONS

For a comprehensive list of warnings and cautions, please refer to the *Use and Care Guide* in Appendix C.

WARNING

To avoid incorrect therapy:
Do not use the device with other medical devices not recommended by Fisher & Paykel Healthcare e.g. breathing system filters or breathing tubes.

1.3 ELECTRICAL SPECIFICATIONS

1.3.1 Means of isolating the device from the supply mains

Mains plug of the detachable power supply cord.

1.3.2 Fuse rating

4 A, Time-lag, breaking capacity: 1500A

Note: *Fuses are not replaceable.*

1.3.3 Battery life

2 years shelf life, 5 years useful life

Note: *Battery is not replaceable or rechargeable.*

1.3.4 Modem

Refer to Appendix B

1.4 MECHANICAL SPECIFICATIONS

1.4.1 Filter specification

Material: High performance non-woven fleece filter medium, progressively structured.

Average efficiency: 83%

Particle size: ~7 micron dust

1.5 ACCURACY OF CONTROLS AND INDICATIONS

1.5.1 Set pressure

Range: 4-20 cmH_2O, 0.5 cmH_2O increments

Device display: 0.1 cmH_2O

The maximum error for displayed and delivered pressures at altitudes up to 3,000 m: ± 1 cmH_2O

2. GENERAL INFORMATION ABOUT THE DEVICE

2.1 THE PNEUMATIC FLOW PATH AND SENSORS

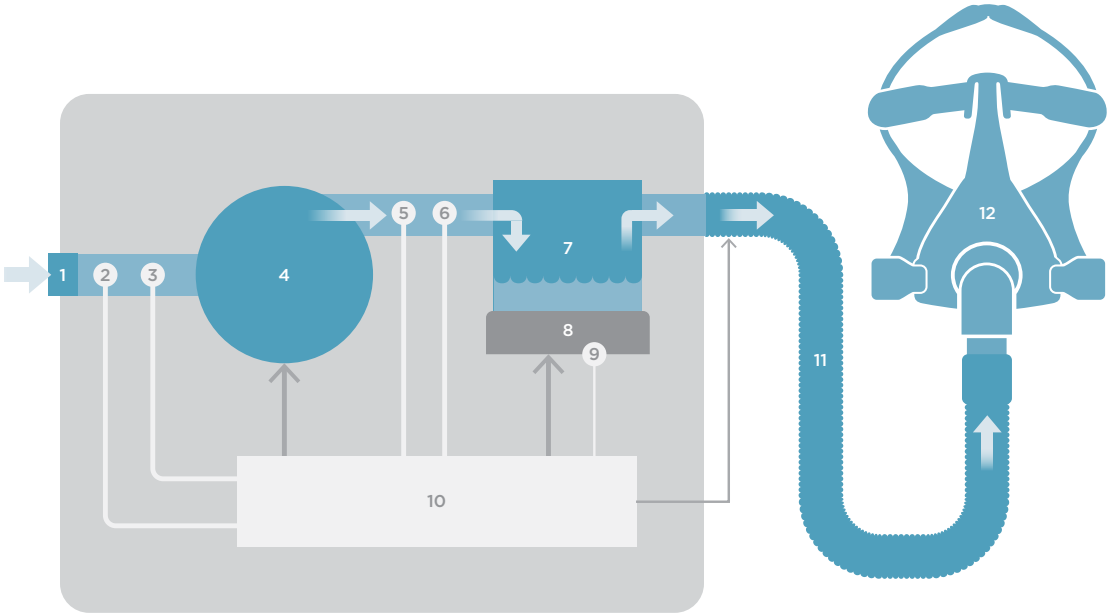

Figure 1: *Air flow from rear of device to patient (refer to table below)*

Number	Description	Range
1	Air inlet filter	-
2	Ambient temperature sensor	0 – 40 °C
3	Flow sensor	-95 – 199 L/min
4	Blower	-
5	Relative humidity sensor	15 – 93 % RH
6	Pressure sensor	0 – 30 cmH_2O
7	Water chamber	-
8	Heater plate	-
9	Heater plate temperature sensor	-10 – 110 °C
10	Control system	-
11	Breathing tube	-
12	Mask	-

3. OPERATION

3.1 IMPORTANT INFORMATION

3.1.1 Function of the device after interruption and restoration of the power supply:

All device settings are permanently retained during power interruption or when the device is disconnected from the wall socket.

After power is restored, the device will restart in the same mode that it was in prior to the power interruption or disconnection.

Note: *Power interruptions in Auto mode will reset the auto algorithm to minimum pressure.*

3.1.2 Error codes:

In the event of an error, a code will be displayed; refer to the *Use and Care Guide* in Appendix C (section 9.2) for a description of the error codes and corrective actions.

4. SUPPORT INFORMATION

4.1 SERVICING NOTES

- This device is not repairable and does not contain any repairable parts.
- The device does not require preventative maintenance.
- Only the replacement parts stated in section 5.9 are designated as replaceable by service personnel.

4.2 CLEANING AND HIGH-LEVEL DISINFECTION

- For cleaning, refer to the cleaning instructions in the *Use and Care Guide* in Appendix C (section 6.2).
- For reprocessing between patients, refer to the cleaning and high level disinfection instructions in the *Clinician Guide* in Appendix D (section 10.2).

5. DEVICE CHECKS

5.1 INTRODUCTION

The device checks in this section may be performed to confirm that the device/accessories are safe and functioning correctly; there is no requirement to perform these checks on a routine basis.

Note: *If any of the device checks fail, please contact your Fisher & Paykel Healthcare representative.*

5.1.1 Recording settings prior to device checks

During the device checks, it is necessary to change many of the device settings; if the device is likely to be returned directly to the patient after conducting device checks, all settings should be recorded and re-entered when the checks have been completed. Refer to the *Use and Care Guide* in Appendix C and *Clinician Guide* in Appendix D for additional information on viewing/changing settings.

5.1.2 Test conditions:

The performance checks should be conducted under the following ambient conditions:

- Temperature: 23 ± 2 °C (73 ± 4 °F)
- Humidity: 50 ± 5 % RH

Note: *Ambient conditions outside the ranges shown above will affect the performance check results.*

5.1.3 Display check

There is not a specific display check process but it is recommended to observe the display throughout the following tests to confirm that it is fully functional and easy to read.

5.2 FAULT LOG CHECK

1. Power up the device and enter the Clinician menu by pressing and holding **Start/Stop** then one of the other device buttons. together until the menu is displayed.
2. Use **Down** to select “Fault log” under “SERVICE INFO” then press **OK** ✓.
3. Use **Down** or **Up** to scroll through the fault log (if applicable).
4. Note any error codes (including the date) so that additional error codes that may occur during the checks will be obvious. Refer to the *Use and Care Guide* in Appendix C (section 9.2) for additional information regarding error codes.

5.3 PRESSURE PERFORMANCE CHECK

5.3.1 Equipment required:

- The device to be tested with a breathing tube fitted - ThermoSmart™ breathing tube or a standard breathing tube with an elbow
- A calibrated manometer with a pressure range to 30cmH_2O and an adaptor with a pressure port for the manometer to fit into the breathing tube (22mm)
- An adaptor (22mm) with a 4mm (maximum) bias flow opening

Note: *The 2 adaptors can be replaced with a single 22mm adaptor having a pressure port for the manometer and a 4mm (maximum) bias flow opening.*

5.3.2 Procedure:

1. Power up the device and enter the Clinician Menu by pressing and holding **Start/Stop** then one of the other device buttons together until the menu is displayed.
2. Using the menu options, set the following parameters:
   - Therapy Mode = CPAP (***Note:*** *Therapy Mode only available on Auto models*)
   - Set Pressure = 10cmH_2O
   - Expiratory Relief = off
   - SensAwake™ = off
3. Exit the Clinician Menu.
4. Connect the manometer adaptor (with manometer attached) and bias adaptor to the end of the breathing tube such that the only opening is the 4mm bias flow opening.
5. Ensure that the breathing tube is fully uncoiled and lying on a flat surface with nothing obscuring the bias flow opening.
6. Press **Start/Stop** to start the pressure delivery.
7. Allow the pressure to stabilise for at least 15 seconds then confirm that the manometer reads 9.5 – 10.5 cmH_2O (add manometer error).
8. Press **Start/Stop** to stop the pressure delivery and leave the system set up in the current configuration.
9. Check the fault log for any new error codes (refer to section 5.2).

5.4 HUMIDIFICATION SYSTEM PERFORMANCE CHECK

5.4.1 Equipment list:

- Refer to the equipment list in the Pressure Performance Check in section 5.3.1.

5.4.2 Procedure:

1. Ensure that the device is still set up as it was during the pressure performance check in section 5.3.
2. Take the water chamber out of the device, fill the water chamber with water up to the maximum water line marked on the side of the chamber then close the chamber.
3. Place the water chamber back into the device and close the device lid.
4. Change the humidity setting to 5.
5. Press **Start/Stop** to start the pressure delivery.
6. Let the device run for 30 minutes to stabilise.
7. Press **Start/Stop** to stop the pressure delivery.
8. Remove the water chamber from the device and empty the chamber.
9. Place the water chamber back into the device and close the device lid.
10. Check the fault log for any new error codes (refer to section 5.2).

ThermoSmart Detection Check (perform only if using a ThermoSmart breathing tube)

11. Press **Menu** to display the home screen.
12. Disconnect the breathing tube from the CPAP outlet.
13. The ThermoSmart icon displayed on the device screen should go off within 5 seconds.
14. Connect the breathing tube back into the CPAP outlet. The ThermoSmart icon should turn on within 5 seconds.

5.5 COMPLIANCE UPLOAD HARDWARE CHECKS

5.5.1 Bluetooth®

1. Confirm that the Bluetooth icon is displayed on the device screen (***Note:*** *Press Menu if icons are not currently displayed).*

   If the icon has a line through it, the Bluetooth function is disabled. Refer to the *Use and Care Guide* in Appendix C (section 4.2) to enable the Bluetooth function.
2. Power cycle the device to make it discoverable if you have not just enabled the Bluetooth function (***Note:*** *The device only remains discoverable for a period of 15 minutes after being powered on or after the Bluetooth function is enabled*).
3. On a Bluetooth capable mobile device (smartphone, tablet, etc.), confirm that the Bluetooth function is enabled and perform a Bluetooth scan ensuring you are within approximately 1m of the device.
4. The mobile device should discover the device and display the following: "SleepStyle_xxxx" (where xxxx are the last 4 digits of the device serial number).
5. On the mobile device, select the device.
6. The mobile device will provide a 6-digit passkey which should also be displayed on the device screen. After confirming that the passkeys match, pair with the device.

5.5.2 Modem

(***Note:*** *Only on applicable models indicated by the modem icon on the front of the device).*

1. Refer to the *Clinician Guide* in Appendix D (section 8.6) to perform a manual data upload.
2. If the data upload is successful, the modem is working and the following steps can be skipped.
3. *If the upload is unsuccessful, record the result code displayed (**Note:** the device will attempt to upload for up to 3 minutes). There are 3 result codes which could indicate a modem problem:*
   - 012 and 073: these codes indicate a lack of signal strength but this could be due to proximity to the nearest cell site/ tower or if the cellular network is down/experiencing problems. If they occur, check with a known good device before determining that the device under test is faulty
   - 055: this code indicates that there is a problem powering the modem module within the device and is most likely due to hardware failure

All other result codes indicate that the device has successfully attempted the upload but is not currently registered on the cellular network. Under these circumstances, the device is considered to be operating correctly unless it has been returned specifically due to an inability to upload data.

5.5.3 InfoUSB

1. Remove the InfoUSB from the device and plug it into the USB port on a PC.
2. Delete the "FPHCARE" folder (if present) from the InfoUSB.
3. Plug the InfoUSB into the device then press **Menu** and confirm that the InfoUSB icon is displayed (***Note:*** *InfoUSB icon may flash, this is normal*).
4. Wait approx. 2 minutes then remove the InfoUSB and plug it back into the PC USB port.
5. Confirm that the "FPHCARE" folder has been created and that it contains a sub-folder "ICON" in which is another sub-folder "xxxxxxxx" (where xxxxxxxx are the last 8 digits of the device serial number).
6. Check the fault log for any new error codes (refer to section 5.2).

5.6 DEVICE INSPECTION

The following inspections should be performed to ensure that the device/accessories are in a safe condition and suitable for use:

5.6.1 Power cord

Check the power cord for cuts, stretching, bent pins or excessive wear; replace cord if necessary. Refer to section 5.9 for replacement power cords.

5.6.2 Enclosure

Check the enclosure for damage or any signs of deliberate alteration; contact your Fisher & Paykel Healthcare representative if these are observed.

5.6.3 Airpath replaceable parts

Check the condition of the chamber, chamber seal, outlet seal, lid, standard breathing tube/elbow or ThermoSmart breathing tube and filter; replace where necessary. Refer to section 5.9 for replacement parts.

5.7 ELECTRICAL SAFETY TEST

To test for electrical safety, perform the Insulation Resistance test as described below and any other tests required by local regulations.

Note: *If any electrical safety tests fail, please contact your Fisher & Paykel Healthcare representative.*

5.7.1 Insulation resistance test:

Use a 500 VDC insulation tester to measure the resistance between the mains plug phase and neutral pins (joined together) and the heater plate - it should be greater than 10 MΩ

5.8 ADDITIONAL INFORMATION

5.8.1 5.8.1 Factory reset:

The factory reset clears all settings and patient data from the device and InfoUSB (***Note:*** *If the InfoUSB is not fitted at the time of factory reset, it will be cleared next time it is put back into the device*).

If the device is to be returned directly to the patient, be sure to record all settings as described in section 5.1.1 and upload the patient data (if required) prior to performing the reset.

To clear the fault log, delete all patient data and restore the device settings back to the factory default values:

1. Power up the device and enter the Clinician Menu by pressing and holding **Start/Stop** then one of the other device buttons together until the menu is displayed.
2. Use **Down** to select "Factory reset" under "SERVICE INFO" then press **OK**
3. Use **Down** or **Up** to select yes [✓] and press **OK**
4. The device will perform a power reset and restart with a language screen prompt – power the device down without changing any settings

5.8.2 Troubleshooting

For troubleshooting information, refer to the *Use and Care Guide* in Appendix C (section 9) and the *Clinician Guide* in Appendix D (section 13).

5.9 REPLACEMENT PARTS

Product code	Description
900SPS100	Water chamber
900SPS101	Chamber seal
900SPS111	Air filter (single)
900SPS110	Air filters (2-pack)
900SPS120	ThermoSmart breathing tube*
900SPS121	Standard breathing tube with elbow*
900SPS122	Elbow (for use with a standard breathing tube)
900SPS140	Device lid
900SPS141	Outlet seal
900SPS142	Carry bag
900SW101	F&P InfoUSB
* Applied Parts – to fit 22 mm (0.86 in.) Conical Connector	

Product code	Description	Applicable models
900SPS160	Power cord - North America	SPSAAN, SPSCAN, SPSABN, SPSCBN, SPSAAU, SPSABU
900SPS161	Power cord - Australasia	SPSAAA, SPSCAA, SPSABA, SPSCBA
900SPS162	Power cord - Europe	SPSAAE, SPSCAE, SPSABE, SPSCBE, SPSAAW, SPSCAW, SPSABW, SPSCBW
900SPS163	Power cord - Brazil	SPSAAB, SPSCAB, SPSABB, SPSCBB
900SPS164	Power cord - Japan	SPSAAJ, SPSABJ, SPSCBJ
900SPS165	Power cord – United Kingdom	SPSAAK, SPSCAK, SPSABK, SPSCBK
900SPS166	Power cord - China	SPSABC, SPSCBC, SPSAFC, SPSCFC
900SPS167	Power cord – South Korea	SPSAAS, SPSCAS, SPSABS, SPSCBS

Note: *Not all replacement parts are available in all countries.*

APPENDIX A: IEC60601-1-2 EMC TABLES

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The F&P SleepStyle Series is intended for use in the electromagnetic environment specified below. The customer or the user of the F&P SleepStyle Series should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The F&P SleepStyle Series is intended for use in the electromagnetic environment specified below. The customer or the user of F&P SleepStyle Series should ensure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	± 2 kV for power supply lines	± 2 kV	Mains power quality should be that of a typical residential, commercial or professional healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV line to line	± 1 kV	Mains power quality should be that of a typical residential, commercial or professional healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical residential, commercial or professional healthcare facility environment.
Power frequency (50/60 Hz)/ magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical residential, commercial or professional healthcare facility environment.
NOTE: UT is the a.c. mains voltage prior to the application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The F&P SleepStyle Series is intended for use in the electromagnetic environment specified below. The customer or the user of F&P SleepStyle Series should ensure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0.58 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE F&P SLEEPSTYLE SERIES

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

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter W	150 kHz to 80 MHz d = 0.58 √P	80 MHz to 800MHz d = 0.35 √P	800MHz to 2.7 GHz d = 0.70 √P
0.01	0.058	0.035	0.070
0.1	0.18	0.11	0.22
1	0.58	0.35	0.70
10	1.8	1.1	2.2
100	5.8	3.5	7.0
For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

APPENDIX B: MODEM AND BLUETOOTH WIRELESS TECHNOLOGY SPECIFICATIONS

MODEM (APPLICABLE MODELS: SPSAAN, SPSCAN, SPSAAU)

Frequency band of reception	Channel Bandwidth	Frequency band of transmission	Channel Bandwidth	Modulation	Maximum output power during transmission
869 to 894 MHz	200kHz	824 to 849 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	33 dBm ± 2 dB GSM, GPRS
1930 to 1990 MHz	200kHz	1850 to 1910 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	30 dBm ± 2 dB GSM, GPRS
1930 to 1990 MHz	5MHz	1850 to 1910 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	22.5 dBm (± 1.5 dB)
869 to 894 MHz	5MHz	824 to 849 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	22.5 dBm (± 1.5 dB)

MODEM (APPLICABLE MODELS: SPSAAA, SPSAAB, SPSAAE, SPSAAJ, SPSAAK, SPSAAS, SPSAAW, SPSCAA, SPSCAB, SPSCAE, SPSCAK, SPSCAS, SPSCAW)

Frequency band of reception	Channel Bandwidth	Frequency band of transmission	Channel Bandwidth	Modulation	Maximum output power during transmission
869 to 894 MHz	200kHz	824 to 849 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	2 Watts - GSM, GPRS and EDGE
925 to 960 MHz	200kHz	880 to 915 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	2 Watts - GSM, GPRS and EDGE
1805 to 1880 MHz	200kHz	1710 to 1785 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	1 Watt - GSM, GPRS and EDGE
1930 to 1990 MHz	200kHz	1850 to 1910 MHz	200kHz	GSM – GMSK, GPRS – GMSK, EDGE – GMSK, 8PSK	1 Watt - GSM, GPRS and EDGE
2110 to 2170 MHz	5MHz	1920 to 1980 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis
1930 to 1990 MHz	5MHz	1850 to 1910 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis
869 to 894 MHz	5MHz	824 to 849 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis
875 to 885 MHz	5MHz	830 to 840 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis
925 to 960 MHz	5MHz	880 to 915 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis
875 to 890 MHz	5MHz	830 to 845 MHz	5MHz	WCDMA – QPSK, HSDPA – 16-QAM, HSUPA – QPSK, HSPA+ – 16-QAM, 64QAM	23 dBm (+/- 2dBm) Class 3bis

BLUETOOTH WIRELESS TECHNOLOGY (ALL MODELS)

Frequency band of reception	Channel Bandwidth	Frequency band of transmission	Channel Bandwidth	Modulation	Maximum output power
2402 to 2480 MHz	1MHz	2402 to 2480 MHz	1MHz	GFSK, π/4-DQPSK, 8DPSK	6dBm

APPENDIX C: USE AND CARE GUIDE

Use and Care Guide – Front cover

F&P SleepStyle™

Use and Care Guide

F&P SleepStyle Auto
F&P SleepStyle CPAP

English

Fisher & Paykel HEALTHCARE

BEFORE YOU START

Caution: USA Federal Law restricts this device to sale by or on the order of a physician.
Before the device is used for the first time, it must be set up by a healthcare provider.
If your device or any accessories are not operating correctly, please contact your healthcare provider.
Healthcare providers: please contact your Fisher & Paykel Healthcare representative for a copy of the F&P SleepStyle Clinician Guide.

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1. OVERVIEW

WELCOME

Thank you for choosing your F&P SleepStyle device.

The F&P SleepStyle Auto is an auto-adjusting positive airway pressure device.

The F&P SleepStyle CPAP is a continuous positive airway pressure device (CPAP).

This guide refers to the F&P SleepStyle Auto and F&P SleepStyle CPAP as the "device". The device is intended to treat Obstructive Sleep Apnea (OSA) by delivering a flow of positive airway pressure at a level prescribed by the physician, to splint open the airway and prevent airway collapse.

Please read this guide carefully before you use your device. Keep this guide in a safe place so you can refer to it later if you need to.

1.1 INTENDED USE / INDICATIONS FOR 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.

1.2 CONTRAINDICATIONS

⚠ **Warnings**

Do not use this device if you have the following pre-existing conditions as they may contraindicate the use of positive airway pressure:

- Pneumothorax
- Bullous lung disease
- Pneumocephalus
- Cerebrospinal fluid leak
- Recent cranial surgery or head trauma
- Abnormalities of the cribriform plate
- Pathologically low blood pressure
- Bypassed upper airways.

If you are unsure about what pre-existing conditions you have, check with your physician or healthcare provider.

1.3 WARNINGS

To avoid the risk of fire:
Do not use this device with patients requiring supplemental oxygen.

Connecting supplemental oxygen to any part of this system, either at the mask or at the device air outlet, may cause oxygen to build up in the device, and could result in a fire.

1.3.1 To avoid death or serious injury:

- The device must only be used on adult patients.
- The device must only be used for the treatment of OSA.
- The device must only be used on prescription of a physician.
- The device must not be used for life-support applications.

1.3.2 To avoid electric shock:

- Do not use if the device, power cord or accessories are damaged, deformed, or cracked.
- Do not pull on the power cord as it may become damaged.
- Do not use bleach, alcohol, or cleaners with citrus or other natural oils. These substances may degrade the device and accessories.
- Do not immerse the device in water or any other liquid.
- Do not modify the device or accessories.
- Do not take apart the device. Taking the device apart, for example by unscrewing the underside of the device, will damage pressure seals and electrical components.

1.3.3 To avoid burns:

- Do not lie on, and avoid prolonged skin contact with, the ThermoSmart™ breathing tube.
- Do not fill the water chamber with hot water as this may lead to airway burns.
- Do not introduce into or operate the device or accessories in a magnetic resonance (MR) environment as there is a risk of burns due to electromagnetic effects.

1.3.4 To avoid the risk of fire:

- Do not cover the ThermoSmart breathing tube as this may overheat the tube.
- Do not connect electrical accessories not approved for use with the device.
- Do not use this device with patients requiring supplemental oxygen. Connecting supplemental oxygen to any part of this system, either at the mask or at the device air outlet, may cause oxygen to build up in the device, and could result in a fire.
- Sources of oxygen must be located more than 1 m (40 in.) from the device.

1.3.5 To avoid carbon dioxide re-breathing or asphyxiation:

- Do not use masks that do not contain a vent suitable for CPAP therapy, or are not recommended by Fisher & Paykel Healthcare or your healthcare provider.

  Failure to use a mask or accessory that permits spontaneous breathing can cause asphyxiation.
- Remove the mask immediately if the device is powered off (including in the event of a power failure or device malfunction). The flow through the mask may be insufficient to clear all exhaled gas.

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

- Ensure the breathing tube and power cord, including any extension cords, are correctly positioned so they will not become entangled with the body or furniture during sleep.
- Do not use the device without the recommended air filter fitted. This will reduce dust or particles entering the device and breathing tube.
- Do not place the device above head height to prevent water from entering the breathing tube.
- Do not use the device with water in the water chamber if the device is being used in a moving vehicle or ship.

1.3.7 To avoid injury:

- Do not place the device above head height as the device may fall.
- Do not use breathing tubes, parts, and accessories that are not distributed for use with this device or recommended by Fisher & Paykel Healthcare.
- Do not use the breathing tubes or accessories with any other device.

1.3.8 To avoid incorrect therapy:

- Do not cover the device or place it where the air inlet could be obstructed (such as next to curtains).
- Do not use the device adjacent to electrical equipment.
- Do not adjust the pressure. Pressure adjustments should only be made by a qualified healthcare provider.
- Refer to the mask's Use and Care Guide prior to use to ensure correct fit of the mask. Incorrect fit of the mask may affect consistent operation of this device.
- Only clean the device and accessories according to the cleaning instructions set out in section *6 – Caring for Your Device*.
- Do not clean or disinfect the ThermoSmart breathing tube with hot water. This may cause deformation of the tube and reduce therapeutic pressure.
- Use the elbow when rotating the ThermoSmart breathing tube. Incorrect handling may damage the tube.
- Do not remove the InfoUSB, or power off the device, before you see this screen when updating your prescription using InfoUSB:

Press any button to acknowledge and clear this message.

1.3.9 General:

- Only use the device within the operating ranges specified, otherwise the performance of the device could be compromised. See section *8.5 – Operating Ranges*.
- Do not place any part of the device or accessories within 30 cm (12 in.) of any portable mobile radio frequency communication equipment. The device complies with the electromagnetic compatibility requirements of IEC 60601-1-2. In rare occasions where electromagnetic interference is experienced you may notice the device restarting, pressure fluctuations or the humidify being temporarily reduced which may temporarily interrupt the therapy. If such interference should occur, try moving your device or the equipment causing the interference further away. Alternatively, consult your healthcare provider.
- Interference caused by common RF emitters such as diathermy, electrocautery, RFID and security systems may impact the SleepStyle device. This should be taken into consideration before placing the device in the presence of any RF emitters. The SleepStyle device has not been tested in such environments.
- Refer to the Product Technical Guide (613471) for compliance information related to EMC.
- Do not use accessories or power cables which are not provided, or recommended, by Fisher & Paykel Healthcare. This could result in increased electromagnetic emissions or decreased electromagnetic immunity.
- California residents please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit: www.fphcare.com/prop65.
- This device is not repairable and does not contain any repairable parts. Please refer queries relating to the device or accessories to your healthcare provider.
- Do not administer drugs or medications into the device or breathing tube.

1.4 CAUTIONS

1.4.1 To prevent water damage to the device:

- Do not use if the water chamber is damaged.
- Do not fill the chamber housing with water. Only place water in the water chamber.
- Do not fill the water chamber above the maximum water-level line.
- Replace water before each use.
- Do not use the device without the chamber seal fitted to the water chamber.
- Do not fill the water chamber while it is in the device.
- Empty the water chamber before transporting or packing the device.
- Do not use the device with an empty water chamber unless the humidity level is set to 0.
- Do not add aromatic-based or scented oils to the water chamber as these oils can cause damage to the device.

1.4.2 General:

- Changes or modifications not expressly approved by Fisher & Paykel Healthcare voids the user's authority to operate the device.
- Position the device so the power cord connection to the power supply is easily accessible and able to be disconnected.
- Do not use USB drives with the device which are not provided by Fisher & Paykel Healthcare. Use of USB drives other than the InfoUSB may cause data corruption. Do not attempt to change the directories or view the data without software distributed or designed for use with the device.
- Replace the device and accessories if there is any sign of cracking, deformation, discoloration or leaking. It is recommended that you inspect the device, breathing tube, water chamber, chamber seal, outlet seal, air filter and elbow, on a regular basis after cleaning. See section *6.4 – Replacement Parts*.
- Use distilled water to reduce residue build-up on the chamber base. This will extend the life of your water chamber.

1.5 PRECAUTIONS

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

1.6 ADVERSE EFFECTS

- Nosebleeds, perforated ear drum, dryness of the nasopharynx, sinus infection, and middle ear infection may occur from the use of positive airway pressure therapy.

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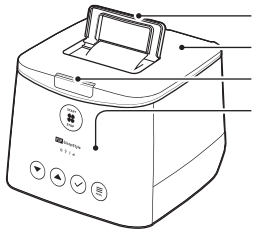
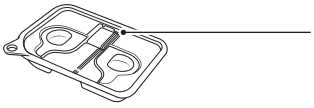
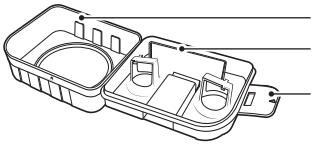
2. GETTING STARTED

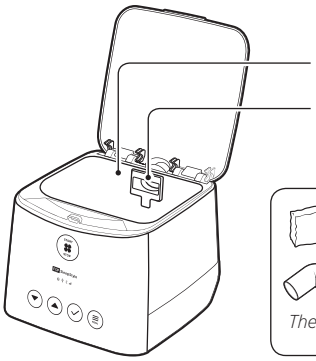
2.1 DEVICE AND ACCESSORIES

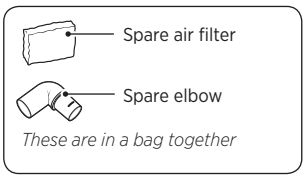
1 x Carry bag
1 x SleepStyle device
1 x Breathing tube
1 x Power cord
1 x F&P SleepStyle Use and Care Guide
1 x F&P SleepStyle Quick Reference Guide
1 x Water chamber
1 x Chamber seal
1 x Outlet seal
1 x F&P InfoUSB (already in InfoUSB port)
1 x Air filter (already in the device)
1 x Spare air filter
1 x Spare elbow (for use with a standard breathing tube)

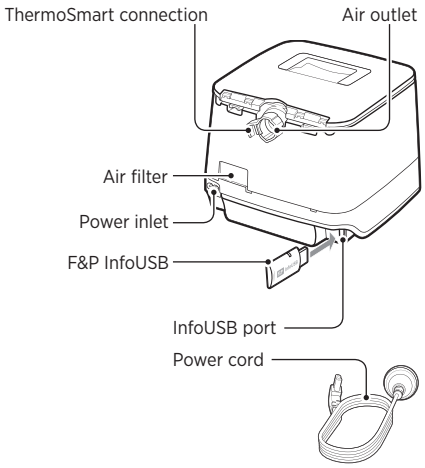


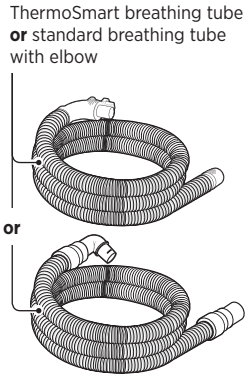






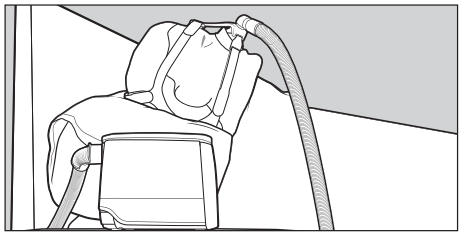






2.2 SETTING UP YOUR DEVICE

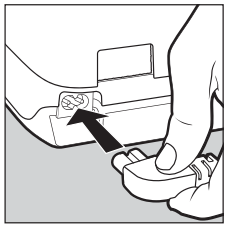
1. Place the device below head height on a stable and level surface, like a bedside table.

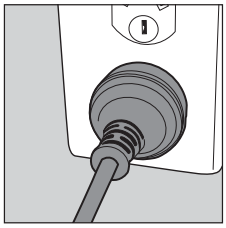


⚠ **Warnings**
To avoid injury, choking, or inhalation of a foreign object:
Do not place the device above head height to prevent water from entering the breathing tube.

2. Connect the power cord and the breathing tube.

Connect the power cord into the power inlet of the device. Connect the other end of the power cord into a power outlet.



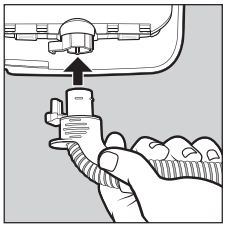


⚠ **Warnings**
To avoid electric shock:
Do not use if the device, power cord, or accessories are damaged, deformed or cracked.

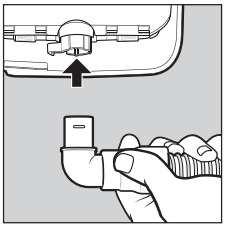
To avoid choking, or inhalation of a foreign object:
Ensure the breathing tube and power cord, including any extension cords, are correctly positioned so they will not become entangled with the body or furniture during sleep.

Breathing tube

Connect your breathing tube into the air outlet.



ThermoSmart breathing tube



Standard breathing tube

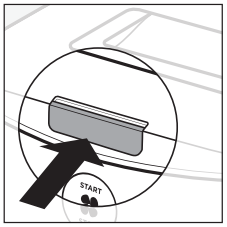
Note: *Make sure the connectors on the ThermoSmart breathing tube click into position with the ThermoSmart connection.*

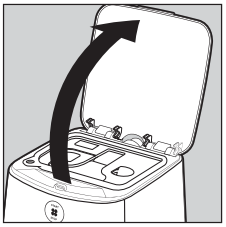
If you have connected the ThermoSmart breathing tube correctly, the ThermoSmart icon will appear on your home screen.

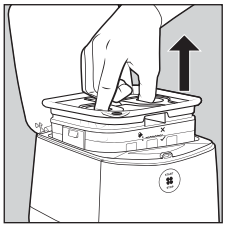
⚠ **Warnings**
To avoid incorrect therapy:
Use the elbow when rotating the ThermoSmart breathing tube. Incorrect handling may damage the tube.

3. Remove the water chamber from the device.

Press the lid latch and open the device lid. Take the water chamber out of the device.







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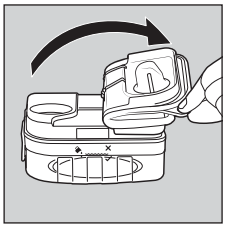
4. Fill the water chamber with water.

Peel back the chamber seal on the left-hand side of the water chamber. Fill the water chamber with water up to the maximum water-level line, as indicated on the side and inside of the water chamber.



⚠ **Warnings**

To avoid burns:

Do not fill the water chamber with hot water as this may lead to airway burns.

⚠ **Cautions**

To prevent water damage to the device:

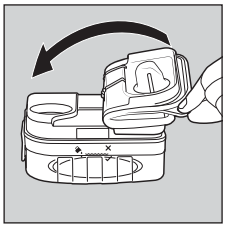
- Do not use if the water chamber is damaged.
- Do not fill the chamber housing with water. Only place water in the water chamber.
- Do not fill the water chamber above the maximum water-level line.
- Replace water before each use.
- Do not fill the water chamber while it is in the device.
- Do not use the device with an empty water chamber unless the humidity level is set to 0.
- Do not add aromatic-based or scented oils to the water chamber as these oils can cause damage to the device.

General:

Use distilled water to reduce residue build-up on the chamber base. This will extend the life of your water chamber.

5. Secure the chamber seal.

Unfold the chamber seal back onto the water chamber. Push down in the finger holds to secure it in place.



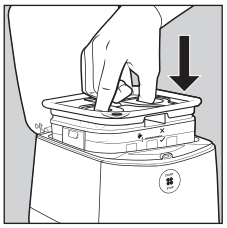
⚠ Cautions

To prevent water damage to the device:

Do not use the device without the chamber seal fitted to the water chamber.

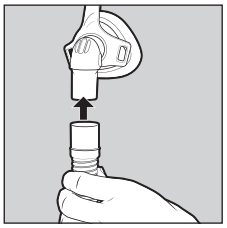
6. Put the water chamber back into the device.

Place the water chamber back into the device. Push the device lid down until the lid latch clicks into position.



7. Connect the mask to the breathing tube.

Holding the mask and the other end of the breathing tube, connect the mask swivel firmly into the breathing tube.



3. USING YOUR DEVICE

3.1 SCREEN ICONS

When your device is plugged in and switched on, you will see the home screen appear with up to four icons. These icons indicate the status of a setting or accessory, as follows:

ThermoSmart Icon*
Indicates that the ThermoSmart breathing tube is connected and working correctly

InfoUSB Icon
Indicates that the F&P InfoUSB is connected and working correctly

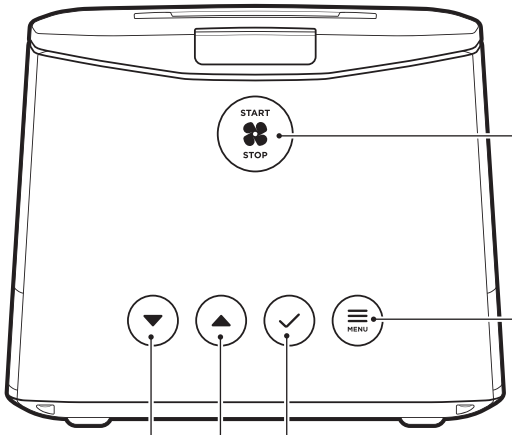
Bluetooth® Icon
Indicates that Bluetooth technology is turned "On" on your device and is working correctly

Modem Icon*
Indicates that modem is turned "On" on your device and is working correctly

Note: *If there is a line through one of these icons, or if there is a gap where an icon usually appears, refer to section* 9.1 – Device troubleshooting *for more information.*

** Not available in all models.*

3.2 DEVICE CONTROLS



Start/Stop
- Press to start and stop therapy.
- Press and hold for 3 seconds to start Ramp.

Menu
- Press to enter the Menu at any time.
- Press to scroll between settings or data screens.

Down and Up
- Press to decrease or increase a comfort setting.
- Press to move between options in a setting.
- Press to show the "Humidity" setting at any time.

OK
- Press to make a selection.
- Press to accept an instruction on the display screen.

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3.3 STARTING THERAPY

1. Fit your mask.

Note: *Refer to your mask's user instructions for more information on how to fit and remove your mask.*

2. Press Start/Stop to begin therapy.

The screen below will appear:

3.4 STOPPING THERAPY

1. Press Start/Stop to stop therapy.

Note: *To reduce condensation, please keep the device plugged in and switched on at the power supply after stopping therapy.*

The screen below will appear:

Your device will then scroll through your therapy data screens. See section *4.1.1 – Therapy Data* for more information on these screens.

2. Remove your mask.

3.5 STAND-BY MODE

The device will enter stand-by mode after 30 seconds if no button has been pressed on the device.

The display screen light will dim but will still be visible to show that your device is still powered on.

Press **Down**, **Up**, **OK**, or **Menu** to wake up the device.

3.6 COMFORT SETTINGS

3.6.1 Ramp

Ramp works by gradually increasing to your prescribed pressure over a 20-minute period.

To start Ramp:

Press and hold **Start/Stop** for 3 seconds until the Ramp symbol appears on the display screen:

If you need to restart Ramp, press and hold **Start/Stop** for 3 seconds.

3.6.2 Humidity

Humidification is the process by which moisture is added to the air you breathe.

You can set the humidity level from 0 (all droplets are transparent) to 7 (all droplets are shaded).

To use humidity, you will need to fill your water chamber with water and ensure the humidity level is at least 1 (one droplet shaded).

To adjust humidity at any time:

1. Press **Down**, **Up** or **Menu**.
2. Press **Down** or **Up** to change the level of humidity.
   The device will save your changes and time out after a period of no interaction. Alternatively, you can exit this setting by pressing **Menu** until you reach the previous screen.

Note: *The default humidity level is 5. If using without a water chamber, or where low power consumption is required, set the humidity level to 0.*

3.6.3 Expiratory relief

Expiratory relief reduces the pressure when you breathe out, and returns to your prescribed pressure when you breathe in.

How to set the expiratory relief level:

1. Press **Menu** to scroll to the "Expiratory relief"' setting.
2. Press **Down** or **Up** to change the level of expiratory relief:
   - Off (no circles shaded)
   - Low (1 circle shaded)
   - Medium (2 circles shaded)
   - High (3 circles shaded).

Note: *Expiratory relief may be restricted by your healthcare provider.*

3.6.4 SensAwake™

We all experience subconscious waking during the night. When this happens, SensAwake will provide pressure relief to help ease your return to sleep.

How to turn SensAwake on or off:

1. Press **Menu** to scroll to the "SensAwake" setting.
2. Press **Down** or **Up** to move between "ON" and "OFF".

Note: *SensAwake may be restricted by your healthcare provider.*

4. VIEWING YOUR THERAPY DATA

4.1 VIEW YOUR THERAPY DATA ON YOUR DEVICE

Your device records your therapy data for the last night, last 7 days, and last 30 days, which you can view at any time.

How to view your therapy data on your device:

1. Press **Menu** to scroll to "My Data".
2. Press **Down** or **Up** to move between the following options:
   - "**D**" – Day (last night's therapy data)
   - "**W**" – Week (average over the last 7 days of therapy data)
   - "**M**" – Month (average over the last 30 days of therapy data).
3. Press **OK** to view the range of therapy data you would like see.

The device will automatically scroll through the following therapy data:

Note: *If you would like to bypass this automated scrolling, press* ***Menu*** *to scroll through the data screens manually.*

4.1.1 Therapy Data:

THERAPY HOURS

Day View: Displays the number of hours that you used your device last night.

Week View: Displays the average number of hours that you used your device over the last 7 days.

Month View: Displays the average number of hours that you used your device over the last 30 days.

MASK LEAK

Day View: Indicates whether the leak from your mask last night was "Normal" or "High".

Week View: Indicates whether, on average, the leak from your mask was "Normal" or "High" over the last 7 days.

Month View: Indicates whether, on average, the leak from your mask was "Normal" or "High" over the last 30 days.

Apnea Hypopnea Index - (AHI)

Day View: Displays the average number of airway breathing events you had per hour last night.

Week View: Displays the average number of airway breathing events you had over the last 7 days.

Month View: Displays the average number of airway breathing events you had over the last 30 days.

Note:

- *The AHI screen may be restricted by your healthcare provider.*
- *The device reported AHI is not equivalent to an AASM (American Academy of Sleep Medicine) AHI and therefore should not be used for diagnosis of OSA or in isolation for titration or clinical management.*

4.2 VIEW YOUR THERAPY DATA ON THE SLEEPSTYLE APP OR WEBSITE

Your SleepStyle device allows you to view your therapy data on the SleepStyle App* or website*. The SleepStyle App uses Bluetooth wireless technology to communicate with your device.

You can download the SleepStyle App, available on the Apple App Store or on Google Play™ for Android™.

You can install the SleepStyle App on iPhone 7 Plus, iPhone 7, iPhone SE, iPhone 6s Plus, iPhone 6s, iPhone 6 Plus, iPhone 6, iPhone 5s, iPhone 5c, iPhone 5, or any leading smartphone with Android.

To pair your SleepStyle device to your mobile device, follow these steps:

1. Turn on your SleepStyle device. The device will remain discoverable for a period of 15 minutes. Make sure your mobile device is within range.

   Note: *Changing the SleepStyle device's Bluetooth setting to "On" will also make it discoverable for 15 minutes. See below for instructions on how to change your Bluetooth setting.*
2. Open your mobile device's Settings menu and turn on the Bluetooth setting.

   Note: *You might need to refer to your mobile phone's user manual for specific instructions on how to turn on the Bluetooth setting.*
3. Open the SleepStyle App and follow the instructions on how to register an account.
4. Follow the instructions in the app on how to pair your mobile device with your SleepStyle device.

Your devices should now be paired. The SleepStyle App will stay up to date with daily therapy data from your SleepStyle device as long as the Bluetooth setting is turned on for both devices.

You only need to do the pairing once. After you have paired your SleepStyle device to your mobile device, it will stay paired and will re-connect automatically until you choose to unpair them.

Should you have any problems pairing your SleepStyle device to your mobile device, try turning your Bluetooth setting off and on again on your mobile device. If the problem continues, try turning your Bluetooth setting off and on again on your SleepStyle device (see below). For more information, visit fpsleepstyle.com.

How to change your Bluetooth setting:

If the Bluetooth setting is "Off" on your device, there will be a line through the Bluetooth icon on your home screen.

To change your Bluetooth setting, follow these steps:

1. From the home screen, hold **Menu** for 5 seconds.
2. Press **Menu** to scroll to the 'Bluetooth' setting.

3. Press **Down** or **Up** to change the setting. Your selection will flash to confirm your selection.

** Not available in all countries.*

5. UPLOADING YOUR THERAPY DATA

5.1 MODEM

If your SleepStyle device has a cellular modem, therapy data will automatically upload to your healthcare provider. This will occur as long as your SleepStyle device is plugged in and switched on at the wall. Only your healthcare provider has access to this data.

Note: *The modem is not available in all models. To identify whether your SleepStyle device has a modem, look for the modem icon on the front of your device. If your device has a modem, and modem is turned on, ensure that the device is placed at least 20 cm (8 in.) away from your body while in use.*

How to change the modem setting:

Your modem should remain "On" so that your therapy data will upload to your healthcare provider.

If you need to change your modem setting, follow these steps:

1. From the home screen, hold **Menu** for 5 seconds.
2. Press **Menu** to scroll through the screens until you reach the "Cellular Modem" setting.

3. Press **Down** or **Up** to change the setting. Your selection will flash to confirm your selection.

If you have turned the modem "Off", it will turn back on automatically after 3 days.

5.2 F&P INFOUSB™

The InfoUSB automatically stores your therapy data. To ensure your therapy data is recorded to the InfoUSB, you will need to make sure that the InfoUSB is in the InfoUSB port.

If the InfoUSB is connected correctly, the InfoUSB icon will appear on the device home screen.

You can remove the InfoUSB from the InfoUSB port if requested by your healthcare provider. You can then upload

your therapy data, or take your InfoUSB with you when you visit them next, or post the InfoUSB to them.

If your healthcare provider updates your prescription or device settings on the InfoUSB, these changes will automatically transfer to your device when the InfoUSB is next inserted into the InfoUSB port.

Note: *The InfoUSB icon will not appear on the display screen while it is in stand-by mode. To check that the InfoUSB is connected correctly, press any button to wake up the device. You should see the InfoUSB icon on screen.*

⚠ Cautions

General:

Only use the 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 device.

5.2.1 SleepStyle website

You can easily upload your therapy data for viewing on the SleepStyle website. This information will also be accessible by your healthcare provider.

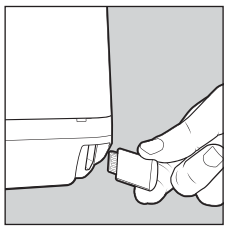
1. Visit fpsleepstyle.com

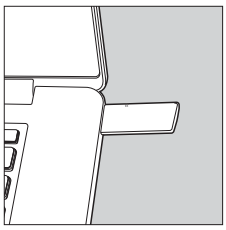
On the registration page, enter your name, email address and date of birth, then click "Register". You will be required to validate your email address and create a password before entering the website. If you have already registered in the SleepStyle App on your mobile device, you can use your email and password to log into the SleepStyle website.

Select the option to link your device. You may be asked to download a plug-in. This allows the SleepStyle website to upload data from your InfoUSB stick.

2. Insert the InfoUSB into a computer's USB port

Remove the InfoUSB from your device and insert it into the USB port of a computer. A small light illuminates when connected to your computer. If the light does not illuminate, please turn the InfoUSB around or make sure that it is inserted fully into the USB port.





Note: *To avoid getting computer viruses on the InfoUSB, keep your computer's anti-virus software up-to-date and do not use the InfoUSB to transfer and store files from your computer.*

3. Follow the on-screen steps to complete linking your device

Your therapy data on your InfoUSB will be uploaded to the SleepStyle website and can be viewed in the "My Data" page. Your healthcare provider will also be able to view this data, if they require it.

5.2.2 InfoUSB application

The InfoUSB application allows you to upload your therapy data to your healthcare provider in 5 easy steps.

1. Insert the InfoUSB into a computer's USB port, as above

2. Install InfoUSB application

From the Mac App Store

Launch the Mac App Store and search for the InfoUSB app. Install this free application. Upon successful installation, open Launchpad and then open the InfoUSB app.

Note: *A Mac running OS X 10.8 or later with a USB port and an internet connection are required.*

From the Windows® Store

Launch the Windows Store and search for the InfoUSB app. Install this free application. Upon successful installation, open the app.

A PC or tablet running Windows 8 or later with a USB port and an Internet connection are required.

From the InfoUSB

If you cannot access the Windows Store, click on the Start button and open "My Computer". Navigate to the drive called "FPHCARE". Open this folder and double-click on the Setup.exe file. Follow the on-screen instructions.

Note: *A PC running a Windows operating system with a USB port and an internet connection are required.*

3. Data transfer

Upon detection of an InfoUSB in your computer, you will be asked to enter your Date of Birth. Enter your Date of Birth and select the Upload button. Ensure that your computer is connected to the internet for successful data transfer to your healthcare provider.

4. Confirmation

After the data has been sent successfully, a confirmation message will appear. If your prescription is updated, you will also see the message "Your healthcare provider has updated your prescription."

5. Future data transfer

Remove the InfoUSB from your computer and place it back into the InfoUSB port of your device. You can now use your device.

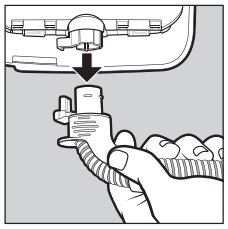
The next time you need to upload your therapy data to your healthcare provider, simply insert the InfoUSB into your computer. The message in Step 3 above will automatically appear.

6. CARING FOR YOUR DEVICE

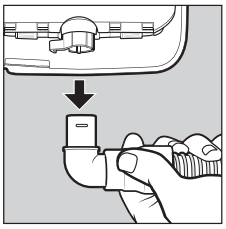
6.1 DISASSEMBLY FOR CLEANING

BREATHING TUBE

1. Hold the elbow of your breathing tube and gently pull it away from the device.

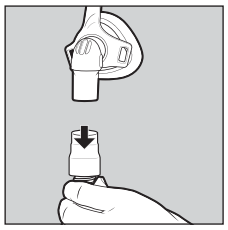


ThermoSmart breathing tube



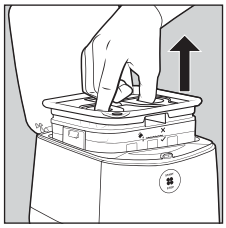
Standard breathing tube

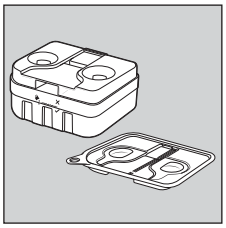
2. Hold both the mask end of the tube and the mask swivel and gently pull them apart.

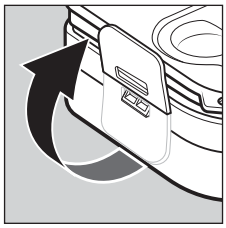


WATER CHAMBER AND CHAMBER SEAL

1. Press the lid latch and open the device lid.
2. Take the water chamber out of the device.
3. Remove the chamber seal from the top of the water chamber and put aside.
4. Lift the tab on the side of the water chamber and lift the chamber lid to open.

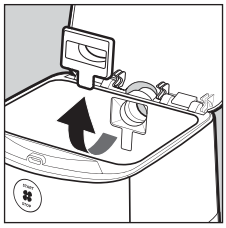






OUTLET SEAL

1. Grip the outlet seal tab.
2. Gently pull the outlet seal out of the device.



6.2 CLEANING YOUR DEVICE AND ACCESSORIES AT HOME

Cleaning your device and accessories can help extend their life and ensure that you continue to receive effective therapy. Below is information on when and how to clean the device and accessories. Refer to your mask's user instructions on how to clean your mask.

⚠ Warnings

To avoid electric shock:
Do not use bleach, alcohol, or cleaners with citrus or other natural oils. These substances may degrade the device and accessories.

To avoid incorrect therapy:
Only clean the device and accessories according to the cleaning instructions below.

⚠ Cautions
General:
Replace the device and accessories if there is any sign of cracking, deformation, discoloration or leaking. It is recommended that you inspect the device, breathing tube, water chamber, chamber seal, outlet seal, air filter and elbow, on a regular basis after cleaning. See section *6.4 – Replacement Parts*.

6.2.1 Wash after each use

The following accessories should be cleaned after each use:
- Breathing tube
- Water chamber
- Chamber seal.

⚠ Warnings
To avoid incorrect therapy:
Do not clean or disinfect the ThermoSmart breathing tube with hot water. This may cause deformation of the tube and reduce therapeutic pressure.

1. Hand-wash the water chamber, chamber seal and breathing tube in a tub of warm, soapy water with a mild dishwashing detergent. Ensure that all visible soil is removed.
2. Rinse the water chamber, chamber seal and breathing tube thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
3. Repeat the rinsing process again, using clean water.
4. Hang the breathing tube, with both ends pointing to the floor, to dry away from direct sunlight or heat e.g. heated towel rails.
5. Leave the water chamber and chamber seal to dry out of direct sunlight or heat.

Note: *The elbow on the standard breathing tube can remain attached when washing after each use. If dirt remains inside the breathing tube after rinsing, use a soft, non-metallic brush to remove it. Rinse the tube again. If the dirt cannot be removed, the breathing tube should be replaced.*

The use of distilled water is recommended during therapy to reduce mineral deposits and stains. Should mineral deposits occur, you can reduce these by soaking the water chamber for 10 minutes in a solution of 1 part white vinegar to 2 parts water. Empty the solution and rinse thoroughly with clean water. Repeat the rinsing process again, using clean water. Leave to dry out of direct sunlight or heat before reassembling.

6.2.2 After 7 days' use

The device and accessories below should be washed after 7 days' use:
- Outlet seal
- Elbow
- Device.

Outlet seal and elbow
1. Disconnect the elbow from the standard breathing tube.
2. Hand-wash the outlet seal and elbow in a tub of warm, soapy water with a mild dishwashing detergent. Ensure that all visible soil is removed.
3. Rinse the outlet seal and elbow thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
4. Repeat the rinsing process again, using clean water.
5. Leave to dry out of direct sunlight or heat.
6. Reconnect the elbow to the standard breathing tube.

Device
1. Turn the device off at the power supply, then remove the power cord from the rear of the device.
2. Wipe the exterior and chamber housing of the device with a clean, damp (not dripping wet) cloth and warm, soapy water using a mild dishwashing detergent.
3. Leave to dry out of direct sunlight or heat.

⚠ Warnings
To avoid electric shock:
- Do not pull on the power cord as it may become damaged.
- Do not immerse the device in water or any other liquid.

Dishwashing
Once every 7 days, you can clean the water chamber, chamber seal, and outlet seal in a domestic dishwasher. Place the water chamber on the top shelf of the dishwasher and ensure the chamber seal and outlet seal are placed in a secure location.

6.3 REASSEMBLY OF THE DEVICE

Once the parts you have cleaned are dry, you can reassemble the parts.

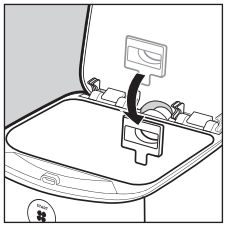
BREATHING TUBE

1. Hold the elbow end of the breathing tube and push it into the air outlet of the device.

   Note: *If you have a ThermoSmart breathing tube, make sure the electrical connectors on the elbow click into position with the ThermoSmart connection.*
2. Holding the mask and the other end of the breathing tube, push the mask swivel firmly into the breathing tube.

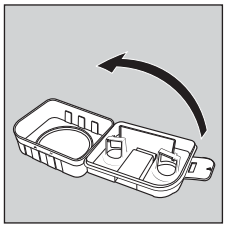
OUTLET SEAL

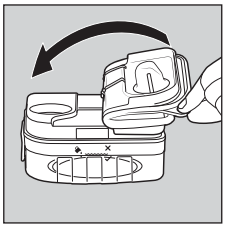
Hold the tab on the outlet seal and push it into the chamber housing inlet. Ensure the tab is sitting flat against the wall of the chamber.

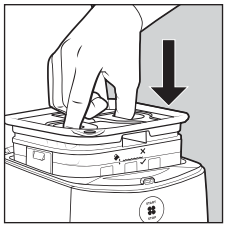


WATER CHAMBER AND CHAMBER SEAL

1. Close the chamber lid. Press the water chamber tab down until it clicks into place.
2. Fill the water chamber with water through either of the filling holes in the top.
3. Secure the chamber seal back onto the water chamber. Ensure it is sitting flat and seals the holes on the chamber lid.
4. Place the water chamber back into the device.







6.4 REPLACEMENT PARTS

Below is a list of replacement parts that are available. Contact your healthcare provider to order these.

900SPS100	Water chamber
900SPS101	Chamber seal
900SPS111	Air filter (single)
900SPS110	Air filters (2-pack)
900SPS120	ThermoSmart breathing tube*
900SPS121	Standard breathing tube with elbow*
900SPS122	Elbow (for use with a standard breathing tube)
900SPS140	Device lid
900SPS141	Outlet seal
900SPS142	Carry bag
900SW101	F&P InfoUSB
900SPS160	North American power cord
900SPS161	Australasian power cord

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

⚠ Warnings

To avoid injury:
Do not use breathing tubes, parts, and accessories that are not distributed for use with this device or recommended by Fisher & Paykel Healthcare.

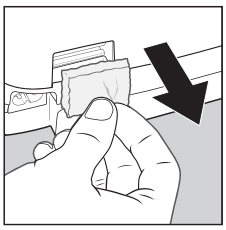
General:
Do not use accessories or power cables which are not provided, or recommended, by Fisher & Paykel Healthcare. This could result in increased electromagnetic emissions or decreased electromagnetic immunity.

6.4.1 Air filter

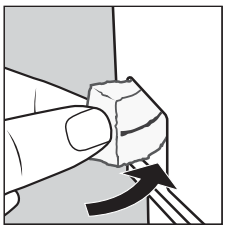
The air filter is located at the rear of the device. Replace the air filter at least once every 3 months, or more frequently if it becomes blocked with dirt or dust. To replace the air filter, please follow the instructions below.

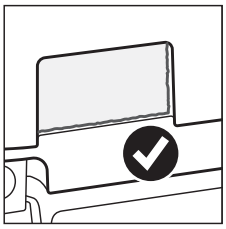
⚠ Warnings
To avoid choking, or inhalation of a foreign object:
Do not use the device without the recommended air filter fitted. This will reduce dust or particles entering the device and breathing tube.

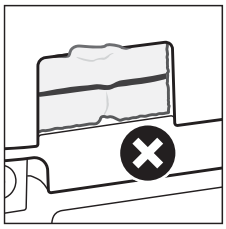
1. To remove, pinch the air filter with your fingers and pull it out of the device.



2. Hold onto the short side of the new air filter. Push into the device so there are no gaps.







7. TRAVELING WITH YOUR DEVICE

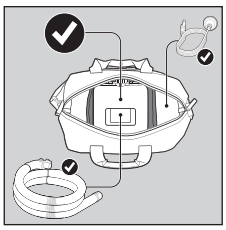
The device has a universal voltage feature that allows it to operate on any domestic AC mains voltage. With the use of the appropriate pin/plug adapter the device can operate in most countries.

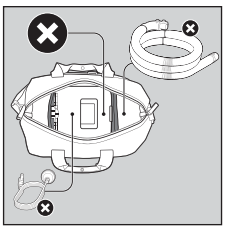
Below is a checklist of what to take with you when you travel:

- Carry bag
- SleepStyle device
- Water chamber (empty)
- Chamber seal
- ThermoSmart breathing tube or standard breathing tube with elbow
- F&P InfoUSB
- Power cord
- Air filter
- Outlet seal
- F&P SleepStyle Use and Care Guide
- Mask

You may also need:

- Extension cord
- Plug adapter





⚠ Cautions
To prevent water damage to the device:
Empty the water chamber before transporting or packing.

Note: *The device is not certified for use on an aircraft. Confirm with your airline whether you can take the device with you as carry-on luggage.*

8. SPECIFICATIONS

8.1 SLEEPSTYLE DEVICE MODELS AND FEATURES

Device model	**SleepStyle Auto**	**SleepStyle CPAP**
Australasia	SPSAAA/SPSABA	SPSCAA/SPSCBA
USA	SPSAAU/SPSABU	
Latin America	SPSAAN/SPSABN	SPSCAN/SPSCBN

Performance features	
Fully integrated humidifier*	Leak compensation
ThermoSmart technology**	Efficacy reporting
Auto-adjusting pressure†	Compliance reporting
SensAwake	F&P InfoUSB
Expiratory relief	Bluetooth wireless technology
Ramp	Cellular modem*
Auto-altitude adjustment	

Compatible with
F&P SleepStyle App and Web‡

** Not available in all models.*
*** The ThermoSmart Breathing Tube is required to activate ThermoSmart.*
† SleepStyle Auto only.
‡ Not available in all countries.

8.2 SYMBOL DEFINITIONS

	For safety reasons, refer to the instructions for use	REF	Catalogue number
	Caution	SN	Serial number
	Consult instructions for use	LOT	Batch code
	Do not use this device with patients requiring supplemental oxygen	90 15	Humidity range
	Fill with water here	60 °C -10 °C	Temperature range
	Maximum water level (do not fill above the water line)	IP22	Protected against ingress of small objects and water drops
	Manufacturer		Do not use if package is damaged
	Date of manufacture		Regulatory Compliance Mark

	Date of shelf life expiry	Rx only	Prescription only
	Type BF applied part		UL Classified mark symbol
	Non-ionizing electromagnetic radiation		Do not discard as regular waste
	Class II equipment		MR unsafe

8.3 PRODUCT SPECIFICATIONS

Dimensions	144 H x 177 W x 183 D mm (5.7 H x 7.0 W x 7.2 D in.)
Weight	1.7 kg (3.7 lb) Packed Weight (max.): 2.7 kg (5.9 lb)
Performance	Pressure Range: 4 to 20 cmH_2O/hPa (in the unlikely event of fault conditions, pressure limited to < 30 cmH_2O)

Maximum flow rates					
CPAP pressure setting (cmH_2O)	4	8	12	16	20
Measured flow at patient connection port (L/min)	>145	>150	>150	>135	>120

Dynamic pressure stability*						
	BPM[1]	**Test pressure**				
		4.0 cmH_2O	8.0 cmH_2O	12.0 cmH_2O	16.0 cmH_2O	20.0 cmH_2O
Dynamic pressure stability (cmH_2O)	10	± 0.5		± 0.8		
	15					
	20					

[1] *BPM – Breaths Per Minute*

Static pressure stability*	
	Auto-adjusting and fixed pressure
Pressure change (cmH_2O) at connection port at a pressure setting of 10 cmH_2O	± 0.5

**Pressure measurement including uncertainty: ± (0.04 cmH_2O + 0.026% of reading)*

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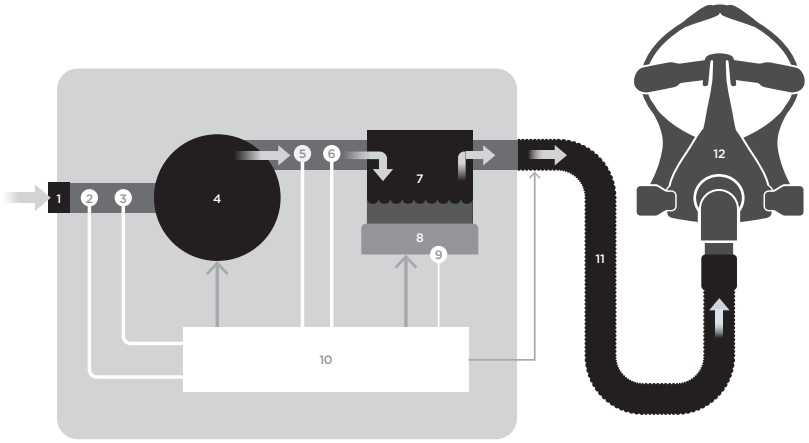
A-20 **ENGLISH**

The pneumatic flow path:



1. Air inlet filter
2. Ambient temperature sensor
3. Flow sensor
4. Blower
5. Relative humidity sensor
6. Pressure sensor
7. Water chamber
8. Heater plate
9. Heater plate temperature sensor
10. Control system
11. Breathing tube
12. Mask

Humidity output	**AH[2] (mgH_2O/L BTPS[3])**	
Tested at 23 °C (73 °F) ambient temperature	**With ThermoSmart breathing tube**	**With Standard breathing tube[4]**
Humidity level 7	>23	>20
Humidity level 6	>21	>18
Humidity level 5 (Default)	>18	>15
Humidity level 4	>17	>14
Humidity level 3	>15	>13
Humidity level 2	>13	>10
Humidity Level 1	>10	>10

[2] AH – Absolute Humidity
[3] BTPS – Body Temperature Pressure Saturated
[4] ISO 8185 – Minimum ambient temperature to achieve the ISO 8185 recommended humidity >10 mgH_2O/L BTPS is 12 °C (54 °F)

Expiratory Relief	
Expiratory relief level	**Pressure reduced during expiration (cmH_2O)**
Off	0 cmH_2O
Low	1 cmH_2O
Medium	2 cmH_2O

High	3 cmH_2O

Electrical ratings		
Rated supply voltage	**Rated current input**	**Rated supply frequency**
100–115 V	1.2 A (2.5 A max.)	50–60 Hz
220–240 V	1.1 A (2.3 A max.)	50–60 Hz

Outlet air temperature	Maximum = 38 °C (100 °F)	
Noise level	Sound pressure level 28 ±1.5 dBA; average sound power level <35 dBA.	
Water chamber volume	380 mL up to the maximum water-level line	
Standards compliance	IEC 60601-1:2012; IEC 60601-1-2:2014; IEC 60601-1-2:2007; IEC 60601-1-11:2015; ISO 80601-2-70:2015; ISO 5356-1:2004; ISO 17510-1:2007; ISO 8185:2007	
Cellular modem (Country and carrier dependent)	UMTS 3G: B1, B2, B5, B6, B8, B19; Maximum power +23 dBm GSM 2G: 850 MHz /900 MHz /1800 MHz /1900 MHz; Maximum power +33 dBm	
Bluetooth technology	2402 - 2480MHz; Maximum power +6 dBm, GFSK, π/4-DQPSK, 8DPSK	
FCC compliance	This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reposition or relocate the receiving antenna. • Increase the separation between the device and receiver. • Connect the device into an outlet on a circuit different from that to which the receiver is connected. • Consult your healthcare provider or your Fisher & Paykel Healthcare representative for help.	
Data recording	The InfoUSB will store up to 5 years of summary efficacy data, 365 days of detailed efficacy data, and 140 hours of high-resolution pressure, leak and flow data. Without an InfoUSB, the device's internal memory is capable of storing up to 1 year of summary efficacy data, 30 days of detailed efficacy data, and 20 hours of high-resolution pressure, leak, and flow data.	
Service life	Device	5 years
	Breathing tubes	12 months
	Water chamber	12 months
	Air filter	3 months
General	The patient is an intended operator.	

8.4 CLASSIFICATIONS

Mode of operation	Continuous operation
Electric shock protection	Type BF
Ingress protection	IP22

8.5 OPERATING RANGES

Ambient temperature (operating range)	12 to 35 °C (54 to 95 °F)
Ambient temperature (extended operating range)[1]	5 to 35 °C (41 to 95 °F)
Ambient Humidity	15 to 90% RH
Altitude	0 to 3,000 m (0 to 9,000 ft.)

[1]Maximum humidity output specification may not be maintained across the extended operating range for the standard breathing tube.

⚠ Cautions
General:
Only use the device within the operating ranges specified, otherwise the performance of the device could be compromised.

Note: *Above 1,500 m (4,500 ft.) the maximum operating pressure will be reduced at high flow rates.*

8.6 STORAGE AND TRANSPORT CONDITIONS

The device should always be stored and transported within the following temperatures and humidity ranges.

Temperature	-10 °C to 60 °C (14 to 140 °F)
Humidity	15 to 90% RH

Note: *The device is immediately suitable for use if transported and stored according to the specified storage and transport conditions.*

8.7 DISPOSAL INSTRUCTIONS

	**Device disposal instructions** This device contains electronics and a lithium battery. Please do not discard as regular waste. Dispose of electronics and lithium battery according to local guidelines.
	**Accessory and spare part disposal instructions** Dispose of breathing tube, water chamber, and other spare parts according to local guidelines. Place the breathing tube, and water chamber in a waste bag at the end of use and discard with normal waste.

8.8 SERVICING

⚠ Warnings
General:
This device is not repairable and does not contain any repairable parts. Please refer queries relating to the device or accessories to your healthcare provider.

The device does not require preventative maintenance.

8.9 WARRANTY STATEMENT

Fisher & Paykel Healthcare warrants that the device (excluding consumable items forming part of the CPAP delivery system), when used in accordance with the 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 here: **www.fphcare.com/sleep-apnea/cpap-devices/warranty-cpap/**

9. 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.

⚠ Warnings
To avoid electric shock:
- Do not modify the device or accessories.
- Do not take apart the device. Taking the device apart, for example by unscrewing the underside of the device, will damage pressure seals and electrical components.

9.1 DEVICE TROUBLESHOOTING*

Problem	Solution
My therapy won't start, and there is no display on the display screen.	The power cord may not be plugged in correctly. **Solution:** Push the power cord connector firmly to confirm it is inserted correctly into the power supply and into the rear of the device.
	Has there been a storm, power outage, or power surge? **Solution:** Check your circuit breaker or fuse, and reset as required. If the display screen does not turn on, return the device to your healthcare provider.
My therapy won't start, but there is a display on the display screen.	There may be water in the blower, preventing it from starting. **Solution:** Turn off at the power supply and unplug the device. Remove the water chamber. Keep the device lid open and tip the device upside down to clear the water from the device. Place the water chamber back in the device. Restart the device.
	Is there an error message on the display? **Solution:** Refer to section *9.2 – Error messages on SleepStyle screen*.
The pressure is fluctuating or insufficient air is being delivered from the device	Your mask may not be fitted correctly, causing leaks. **Solution:** Ensure your mask is correctly fitted. Refer to your mask's user instructions for fitting instructions, or contact your healthcare provider.
	Solution: The delivered pressure may fluctuate due to Electromagnetic Interference (EMI). If fluctuations continue to occur, ensure there is sufficient space between the SleepStyle device and other electrical devices that may cause interference.
	There may be water in the breathing tube. **Solution:** Disconnect the breathing tube and hang with both ends pointing to the floor until all water in the breathing tube has been cleared.
	The device lid may not be closed correctly, the chamber seal may not be fitted to the water chamber correctly, or the outlet seal is missing. **Solution:** Ensure the outlet seal and water chamber with the chamber seal are in the device. Refer to section *6.3 – Reassembly of the device* for detailed instructions on reassembly of these parts.
The device restarts.	**Solution:** It is possible that the device could restart due to Electromagnetic Interference (EMI). No actions are necessary as the device will restart and resume therapy. If restarts continue to occur, ensure there is sufficient space between the SleepStyle device and other electrical devices that may cause interference.
The device is noisy.	Air may be leaking out of the device or breathing tube. **Solution:** Make sure the device lid has been closed properly, the breathing tube and mask are connected correctly, and there are no air leaks or condensation in the breathing tube.
	If the noise is changing while you breathe, this is because the device adjusts the motor speed to maintain the correct pressure as you breathe in and out. This is normal behavior.
The base of the device is warm to the touch even though the device isn't being used.	This is normal and should not cause concern. In stand-by mode, the device consumes approximately 5 W of power. This may cause the feeling of warmth.
There is a build-up of water on the heater-plate.	When therapy has stopped, the device will cool, which may cause condensation to form on the heater-plate. **Solution:** To reduce condensation, please keep the device plugged in and switched on at the power supply after stopping therapy. Before each use, remove the water chamber and dry the chamber housing of the device with a cloth. If the water build-up becomes excessive, please contact your healthcare provider.

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Problem	Solution
I don't think my humidifier is working.	The humidity level may be incorrect. **Solution:** Check if the humidity level is above 0. See section *3.6 – Comfort Settings* for more information on changing the humidity setting.
	The water chamber may be empty. **Solution:** Check if there is water in the water chamber. See section *2.2 – Setting Up Your Device* for instructions on filling your water chamber.
	The ThermoSmart breathing tube is not connected to the device correctly. **Solution:** Remove the ThermoSmart breathing tube from the device and re-connect. Make sure that the electrical connectors click together with the ThermoSmart connection. When connected correctly, the ThermoSmart icon will appear on your home screen.
	Solution: The humidity may be temporarily reduced due to Electromagnetic Interference (EMI). Stop and then restart therapy again using the Start / Stop button and full humidity will be enabled.
The ThermoSmart icon has a line through it or there is a gap where this icon should appear.	The tube may not be connected correctly or there may be an error with the ThermoSmart breathing tube. You will still be treated and get humidity, but it may not be optimal. **Solution:** Remove the ThermoSmart breathing tube from the device and re-connect. Make sure that the electrical connectors click together with the ThermoSmart connection. When connected correctly, the ThermoSmart icon will appear on your home screen.
	You may be using a standard breathing tube. Consult your healthcare provider for more information.
The InfoUSB icon has a line through it or there is a gap where this icon should appear.	The InfoUSB may not be connected correctly or there may be an error with the InfoUSB. You will still be treated, but your therapy data may not be recorded to the InfoUSB. **Solution:** Remove the InfoUSB from the InfoUSB port and reinsert. When connected correctly, the InfoUSB icon will appear on your home screen.
The Bluetooth icon has a line through it.	The Bluetooth setting is turned "Off" on your device or there may be an error with the Bluetooth setting. You will still be treated, but your therapy data may not be available on your SleepStyle app. **Solution:** Turning the Bluetooth setting off and on again on your mobile device may resolve connectivity issues. Refer to section *4.2 – View your therapy data on the SleepStyle App or website* for instructions on changing your Bluetooth setting.
The modem icon has a line through it.	Modem is turned "Off" on your device or the modem has failed to connect. You will still be treated, but your therapy data may not be uploaded to your healthcare provider. **Solution:** Turning modem off and on again on your SleepStyle device may resolve connectivity issues. Refer to section *5.1 – Modem* for instructions on changing your modem setting.

⚠ Warnings
*If your problem persists please contact your healthcare provider.

9.2 ERROR MESSAGES ON SLEEPSTYLE SCREEN

If a fault is detected with your device or its accessories, an error message will appear on the display screen. Identify the error code in the ranges specified below and follow the appropriate corrective action. If the error persists or reoccurs, please consult your healthcare provider. Do not attempt to repair the device yourself.

Error codes between	**Solution**
100–199	Your device may not be able to provide effective therapy. Your device may have shut down or may not be able to provide your prescribed pressure. **Solution:** Turn the power off and on at the power supply to restart the device.
400–499	Humidity may have been disabled. Your device is still safe to use without humidity. You will still be treated at your prescribed pressure. **Solution:** Turn the power off and on at the power supply to restart the device.
510 or 512	There may be a problem with your ThermoSmart breathing tube. Your device is still safe to use. You will still be treated and get humidity, but it may not be optimal. **Solution:** Try reconnecting your ThermoSmart breathing tube. When connected correctly, the ThermoSmart icon will appear on the home screen. Alternatively, turn the power off and on at the power supply to restart the device.
500–599 (excluding 510 or 512)	The ThermoSmart breathing tube may have been disabled. Your device is still safe to use. You will still be treated and get humidity, but it may not be optimal. **Solution:** Turn the power off and on at the power supply to restart the device.

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 (Sponsor)
Fisher & Paykel Healthcare Pty Ltd,
19-31 King Street, Nunawading,
Melbourne, Victoria 3131.

Tel: +61 3 9871 4900
Fax: +61 3 9871 4998

Austria
Tel: 0800 29 31 23
Fax: 0800 29 31 22

Benelux
Tel: +31 40 216 3555
Fax: +31 40 216 3554

Brazil
Fisher & Paykel do Brasil,
Rua Sampaio Viana, 277 cj 21,
Paraíso, 04004-000,
São Paulo – SP, Brazil

Tel: +55 11 2548 7002

China
代理人/售后服务机构:
费雪派克医疗保健 (广州) 有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号

电话: +86 20 32053486
传真: +86 20 32052132

Denmark
Tel: +45 70 26 37 70
Fax: +46 83 66 310

Finland
Tel: +358 94 1590 355
Fax: +46 83 66 310

France
Tel: +33 1 6446 5201
Fax: +33 1 6446 5221

Germany
Tel: +49 7181 98599 0
Fax: +49 7181 98599 66

Hong Kong
Tel: +852 2116 0032
Fax: +852 2116 0085

India
Tel: +91 80 2309 6400
Fax: +91 80 2972 0853

Irish Republic
Tel: 1800 409 011
Fax: +44 1628 626 146

Italy
Tel: +39 06 7839 2939
Fax: +39 06 7814 7709

Japan
Tel: +81 3 5117 7110
Fax: +81 3 5117 7115

Korea
Tel: +82 2 6205 6900
Fax: +82 2 6309 6901

Northern Ireland
Tel: 0800 132 189
Fax: +44 1628 626 146

Norway
Tel: +47 21 60 13 53
Fax: +47 22 99 60 10

Russia
Tel and Fax: +7 495 782 21 50

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
İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi,
İletişim Bilgileri: Ostim Mahallesi 1249.
Cadde No:6, Yenimahalle,
Ankara, Türkiye 06374,

Tel: +90 312 354 34 12
Fax: +90 312 354 31 01

UK EC REP
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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Fisher & Paykel HEALTHCARE

APPENDIX D: CLINICIAN GUIDE

Clinician Guide – Front cover

F&P SleepStyle™

Clinician Guide

F&P SleepStyle Auto
F&P SleepStyle CPAP

USA

Fisher & Paykel HEALTHCARE

CLINICIAN GUIDE

To be retained by the clinician.

This guide refers to the F&P SleepStyle Auto and F&P SleepStyle CPAP as the “device”.

The device is intended to treat Obstructive Sleep Apnea (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.

For queries relating to the device or accessories please refer to your Fisher & Paykel Healthcare representative.

***Note**: This guide is for the clinician only. To prevent patients altering their therapeutic pressure, please ensure they do not have access to this guide.*

INTENDED USE / INDICATIONS FOR 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.

TABLE OF CONTENTS

1. WARNINGS

To avoid the risk of fire:
Do not use this device with patients requiring supplemental oxygen.
Connecting supplemental oxygen to any part of this system, either at the mask or at the device air outlet, may cause oxygen to build up in the device, and could result in a fire.

Refer to the F&P SleepStyle Use and Care Guide for contraindications, warnings, cautions, and information essential for safe operation, transport, storage and set up of the device.

Refer to section *10 – Multi-Patient Use* for cleaning and high-level disinfection of the device.

2. GETTING STARTED

Before using this Clinician Guide, please ensure you have read and understood the F&P SleepStyle Use and Care Guide.

You must be familiar with the contraindications, warnings, cautions, symbols, definitions and operating instructions which apply to the device.

Refer to the Product Technical Guide (613471) for compliance information related to EMC

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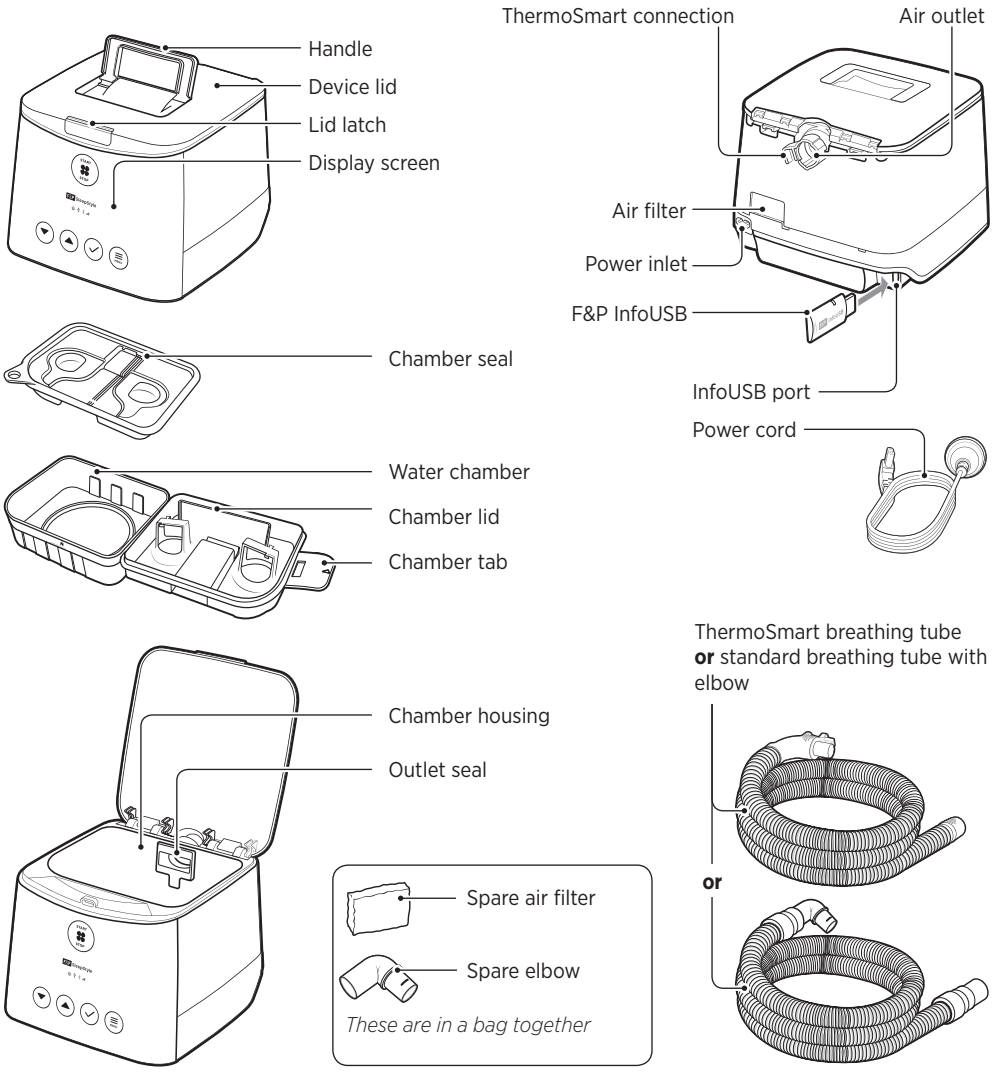
2.1 F&P SleepStyle and Accessories

1 x Carry-bag
1 x SleepStyle device
1 x Breathing tube
1 x Power cord
1 x F&P SleepStyle Use and Care Guide
1 x F&P SleepStyle Quick Reference Guide
1 x Water chamber
1 x Chamber seal
1 x Outlet seal
1 x F&P InfoUSB (already in InfoUSB port)
1 x Air filter (already in the device)
1 x Spare air filter
1 x Spare elbow (for use with a standard breathing tube)



2.2 F&P SleepStyle Models and Features

Device model	SleepStyle Auto
USA	SPSAAU/SPSABU

Performance features	
Fully integrated humidifier*	Leak compensation
ThermoSmart technology**	Efficacy reporting
Auto-adjusting pressure†	Compliance reporting
SensAwake	F&P InfoUSB
Expiratory relief	Bluetooth wireless technology
Ramp	Cellular modem*
Auto-altitude adjustment	

Compatible with	
F&P InfoSmart™	F&P SleepStyle App and Web‡

** Not available in all models.*
*** The ThermoSmart Breathing Tube is required to activate ThermoSmart.*
† SleepStyle Auto only.
‡ Not available in all countries.

2.3 First Start-up

When the device is powered up for the first time, or after a factory reset, you will be asked to select the language used in the device menus. The default language may vary.

1. Press **Down** ▼ or **Up** ▲ to scroll through the languages if necessary.
2. Press **OK** ✓ to confirm your selection.

You will be greeted in the selected language and taken to the device's home screen.

3. USING THE CLINICIAN MENU

3.1 How to Enter the Clinician Menu

1. Press and hold **Start/Stop**.

2. With your other hand, press and hold any one of the four buttons on the bottom row (**Down**, **Up**, **OK**, or **Menu**) for 3 seconds until "CLINICIAN MENU" appears on the screen.

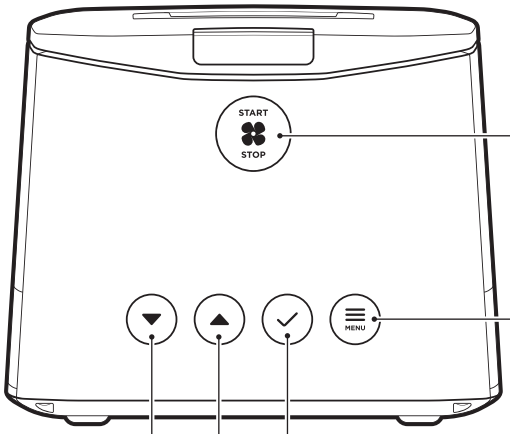
3.2 How to Exit the Clinician Menu

1. On the main Clinician Menu screen, press **Menu**.
   Alternatively, press **Down** or **Up** to scroll to "**Exit clinician menu**", located at the top and bottom of the main Clinician Menu screen.

2. You will be asked if you would like to "**Exit clinician menu?**".
   Press **Down** or **Up** to select Yes.
3. Press **OK** to confirm your selection.

***Note**: The Clinician Menu will default back to the Patient Menu after 15 minutes of no interaction, or if Start/Stop is pressed. Pressing Start/Stop will exit the Clinician Menu and start, or stop, therapy.*

3.3 F&P SleepStyle Controls for Clinician Menu



Start/Stop
- Press and hold, along with **Down** ▼, **Up** ▲, **OK** ✓, or **Menu** ☰, to enter the Clinician Menu.

Menu
- Press to go back one level.
- Press to exit to the Patient Menu from the main Clinician Menu screen.

Down and Up
- Press to navigate the device menu.
- Press to adjust a comfort setting.
- Press to move between options in a setting.

OK
- Press to select a setting.
- Press to make a selection.
- Press to accept an instruction on the display screen.

3.4 Clinician Sub-menus

The Clinician Menu has four sub-menus: Therapy, Comfort, Device, and Service Info.

Below is a guide to the settings in each sub-menu that you can Activate/Deactivate, or, choose to show/hide information that appears in the Patient Menu. For more detailed information, please refer to the relevant section in this Clinician Guide.

Sub-menu	Settings
Therapy Options Auto Mode  CPAP Mode 	**Therapy Mode** **Auto:** Selects auto-adjusting mode and the minimum and maximum pressure range. **CPAP:** Selects fixed pressure mode and allows you to set the prescribed pressure.
	Auto Mode **Min and Max pressure:** Sets minimum and maximum pressure. These can also be adjusted independently if Auto Mode has been selected.
	CPAP Mode **Set pressure:** Allows you to set the prescribed pressure.
Comfort Options 	**SensAwake** **Activate SensAwake:** Activates or Deactivates the SensAwake feature. If **No** ☒ is selected, SensAwake will be Deactivated, you will be taken back to the main Clinician Menu screen, and the SensAwake Patient Menu item will be removed from the Patient Menu. **SensAwake pressure:** When SensAwake is Activated, the next automatic menu screen will allow you to adjust the SensAwake pressure value. **Allow patient to deactivate:** If **Yes** ☑ is selected, SensAwake will be visible in the Patient Menu and the patient will be able to turn SensAwake On or Off. Patients cannot adjust the SensAwake pressure. If **No** ☒ is selected, SensAwake will disappear from the Patient Menu so that the patient cannot choose to switch SensAwake On or Off. SensAwake will still run in the background as set up by the clinician.

Sub-menu	Settings
	Expiratory relief **Activate Expiratory relief:** Activates or Deactivates the expiratory relief feature. If **No** ☒ is selected, expiratory relief will be Deactivated, you will be taken back to the main Clinician Menu screen, and the "Expiratory Relief" Patient Menu item will be removed from the Patient Menu. **Expiratory relief (level):** When expiratory relief is Activated, the next automatic menu screen will allow you to adjust the expiratory relief level from 0 – 3 pressure units (cmH_2O). **Allow patient to adjust:** If **Yes** ☑ is selected, expiratory relief will be visible in the Patient Menu and the patient will be able to adjust the expiratory relief level from Off (0 shaded circles) to On, and up to 3 (3 shaded circles). If **No** ☒ is selected, expiratory relief will disappear from the Patient Menu so that the patient cannot choose to adjust the expiratory relief level. Expiratory relief will still run in the background as set up by the clinician.
	Humidity Adjust the level of humidity; the default setting is 5.
Device Options 	**Display pressure** Option to show or hide pressure whilst therapy is on. Also set the pressure units of the device. **Display AHI** Option to show or hide AHI when a patient views their therapy data. **Time** Set the time of the device's internal clock to ensure therapy data is reported accurately (24 hour format). **Language** Set the language that you would like the device to display.
Service Options 	**Information** View software version and total runtime hours of the device.
	Fault log A list of fault codes and the dates on which they occurred since last factory reset.
	Clear patient data Clears all therapy data from the device and the InfoUSB linked to the device.
	Factory reset A factory reset removes all data and prescription settings from the device and InfoUSB. It will restart the device with the default factory settings. To avoid data corruption, please do not turn off the device while the factory reset is in progress. After a factory reset, the device will restart as if it is being started for the first time. Refer to section *2.3 – First Start-up*.

4. THERAPY OPTIONS

4.1 Therapy Mode

In this menu, you can select the pressure mode.

This can be changed from CPAP (fixed pressure), to Auto (auto-adjusting pressure) in device models with this feature (F&P SleepStyle Auto only).

1. Press **Down** ▼ or **Up** ▲ to scroll to the "Therapy mode" menu.
2. Press **OK** ✓ to select "Therapy mode".

3. Press **Down** ▼ or **Up** ▲ to change the selection.
4. Press **OK** ✓ to confirm your selection.

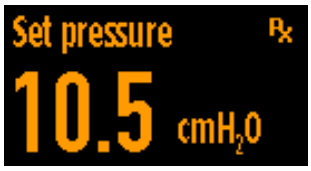
***Note**: Pressing* **OK** ✓ *will automatically take you to set the therapy pressure. Pressing Menu* ☰ *will take you back to the main Clinician Menu.*

4.2 Setting the Therapy Pressure

4.2.1 CPAP mode

This setting allows the prescribed fixed pressure to be set.

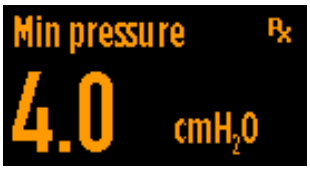
The device has a default fixed pressure setting of 10 cmH_2O, which can be adjusted in increments of 0.5 cmH_2O within the range of 4 to 20 cmH_2O.



1. Press **Down** ▼ or **Up** ▲ to change the prescribed pressure.
2. Press **OK** ✓ to confirm and exit to the main Clinician Menu.

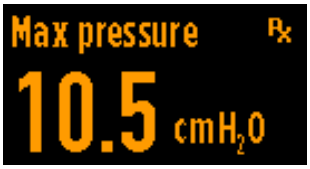
4.2.2 Auto mode (Auto models only)

Minimum pressure: Adjust the minimum starting pressure in 0.5 cmH_2O increments from 4 cmH_2O to the maximum pressure setting. The default setting is 4 cmH_2O.



1. Press **Down** ▼ or **Up** ▲ to change the minimum pressure.
2. Press **OK** ✓ to confirm and move on to maximum pressure.

Maximum pressure: Adjust the maximum pressure in 0.5 cmH_2O increments from the minimum pressure setting to 20 cmH_2O. The default setting is 18 cmH_2O.



1. Press **Down** ▼ or **Up** ▲ to change the maximum pressure.
2. Press **OK** ✓ to confirm and exit to the main Clinician Menu.

***Note**: Minimum and maximum pressure can be accessed independently from the main Clinician Menu, under Therapy.*

5. COMFORT OPTIONS

5.1 Humidity

The humidity level can be set to 0 (Off) or between 1 and 7 (On). The default humidity setting is 5.

1. Press **Down** ▼ or **Up** ▲ to scroll to the "Humidity" setting.
2. Press **OK** ✓ to select "Humidity".

3. Press **Down** ▼ or **Up** ▲ to change the level of humidity.
4. Press **OK** ✓ to accept the change.

If a ThermoSmart breathing tube is connected to the device, the ThermoSmart icon will appear on the Patient Menu home screen.

5.2 Expiratory Relief

In this menu, expiratory relief can be Activated or Deactivated.

If Activated, the expiratory relief level can be set to Off (3 transparent circles), Low (1), Medium (2), or High (3). The default setting is Activated and the default expiratory relief level is Low (1).

You can also select whether the patient is able to adjust expiratory relief.

1. Press **Down** ▼ or **Up** ▲ to scroll to the "Expiratory relief" setting.
2. Press **OK** ✓ to select "Expiratory relief".

3. You will be asked if you would like to "Activate Expiratory relief." Press **Down** ▼ or **Up** ▲ to change the setting.
4. Press **OK** ✓ to accept the change.

If you have activated expiratory relief:

5. Press **Down** ▼ or **Up** ▲ to change the expiratory relief level.
6. Press **OK** ✓ to confirm and exit to the main Clinician Menu.

You will be asked if you would like to "Allow patient to adjust?". This allows you to set whether the patient can turn expiratory relief On or Off and adjust the expiratory relief level:

7. Press **Down** ▼ or **Up** ▲ to change the setting.

   Yes ☑ will allow the patient to turn expiratory relief On or Off and adjust the expiratory relief level. **No** ☒ will remove expiratory relief from the Patient Menu. Expiratory relief will still run in the background as set up by the clinician.
8. Press **OK** ✓ to accept the change and exit to the main Clinician Menu.

5.3 SensAwake™

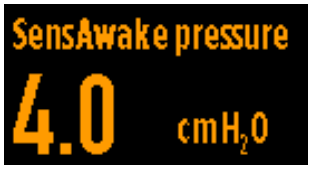
In this menu, SensAwake can be Activated or Deactivated.

If Activated, the SensAwake pressure can be set between 4 and 20 cmH_2O, in 0.5 cmH_2O increments. The default setting is Activated and the default SensAwake pressure is 4 cmH_2O.

You can also select whether the patient is able to turn SensAwake On or Off. Patients cannot adjust the SensAwake pressure.

1. Press **Down** ▼ or **Up** ▲ to scroll to the "SensAwake" setting.
2. Press **OK** ✓ to select "SensAwake".

3. You will be asked if you would like to "Activate SensAwake". Press **Down** ▼ or **Up** ▲ to change the setting.
4. Press **OK** ✓ to accept the change.



If you have Activated SensAwake:

5. Press **Down** ▼ or **Up** ▲ to change the SensAwake pressure.
6. Press **OK** ✓ to confirm your selection.

You will be asked if you would like to "Allow patient to deactivate?". This allows you to set whether the patient can turn SensAwake On or Off.

7. Press **Down** ▼ or **Up** ▲ to change the setting.

   Yes ☑ will allow the patient to turn SensAwake On or Off. **No** ☒ will remove SensAwake from the Patient Menu. SensAwake will still run in the background as set up by the clinician.
8. Press **OK** ✓ to accept the change and exit to the main Clinician Menu.

***Note**: In Auto mode, SensAwake pressure cannot be set above the minimum pressure. In CPAP mode, SensAwake pressure cannot be set above the prescribed fixed pressure. This is the pressure the patient will receive when they start therapy until a sleep-disordered breathing event occurs.*

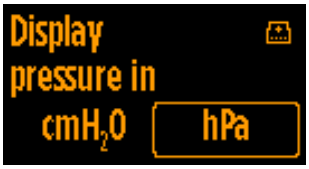
6. DEVICE OPTIONS

6.1 Display pressure

Display pressure allows you to show or hide the pressure level during therapy. The default setting is pressure hidden during therapy. This option also allows you to set the pressure units of the device in cmH_2O or hPa.

1. Press **Down** ▼ or **Up** ▲ to scroll to the "Display pressure" setting.
2. Press **OK** ✓ to select "Display pressure".

3. Press **Down** ▼ or **Up** ▲ to change the setting. If you select **No** [✗], the patient will not see their pressure during therapy. If you select **Yes** [✓], the patient will see their pressure during therapy.
4. Press **OK** ✓ to accept the change. You will now see the pressure unit selection screen.



5. Press **Down** ▼ or **Up** ▲ to change the setting. The units you select will be displayed during therapy (if this has been enabled in the previous screen) and when selecting therapy pressure.
6. Press **OK** ✓ to confirm your selection.

6.2 Display (Patient) AHI

Display AHI allows you to show or hide AHI when a patient views their therapy data. The default setting is AHI shown in the Patient Menu.

1. Press **Down** ▼ or **Up** ▲ to scroll to the "Display AHI" setting.
2. Press **OK** ✓ to select "Display AHI".

3. Press **Down** ▼ or **Up** ▲ to change the setting.

   If you select **No** [✗], the patient will not see their AHI when viewing "My Data" in the Patient Menu or in any of the data screens displayed when they stop therapy. If you select **Yes** [✓], the patient will see their AHI when viewing 'My Data and in the data screens displayed when they stop therapy.
4. Press **OK** ✓ to accept the change and exit to the main Clinician Menu.

6.3 Time

To ensure accurate therapy data reporting, the time on the device's internal clock needs to be set.

The time must be set in 24 hour format.

To set the device time:

1. Press **Down** ▼ or **Up** ▲ to scroll to "Time" and press **OK** ✓ to select.

2. Press **Down** ▼ or **Up** ▲ to select the correct Hour and press **OK** ✓. Press and hold **Down** ▼ or **Up** ▲ to fast-scroll.

3. Press **Down** ▼ or **Up** ▲ to select the correct Minutes and press **OK** ✓. Press and hold **Down** ▼ or **Up** ▲ to fast-scroll.

6.4 Language

The language screen allows you to select the language that appears on the device for the Patient and Clinician Menus.

1. Press **Down** ▼ or **Up** ▲ to scroll to "Language".
2. Press **OK** ✓ to select.

3. Press **Down** ▼ or **Up** ▲ to select the language.
4. Press **OK** ✓ to accept the change and exit to the main Clinician Menu.

7. SERVICE OPTIONS

7.1 Information

The Information screen shows the software version the device is running and the total number of runtime hours of the device.

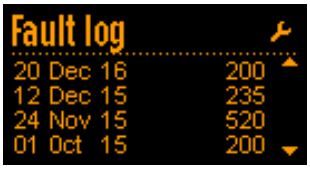
1. Press **Down** ▼ or **Up** ▲ to scroll to "Information".
2. Press **OK** ✓ to select.

3. Once you are ready to exit, press **OK** ✓ or **Menu** ☰ to exit to the main Clinician Menu.

7.2 Fault Log

This is a list of fault codes and the dates on which they occurred since the last factory reset.

1. Press **Down** ▼ or **Up** ▲ to scroll to "Fault log".
2. Press **OK** ✓ to select.



3. Press **Down** ▼ or **Up** ▲ to scroll through the list of recorded faults.
4. Once you are ready to exit, press **OK** ✓ or **Menu** ☰ to exit to the main Clinician Menu.

7.3 Clear Patient Data

"Clear patient data" allows you to delete all of the therapy data from the device and the associated InfoUSB.

1. Make sure the InfoUSB is plugged into the device.
2. Press **Down** ▼ or **Up** ▲ to scroll to "Clear patient data".
3. Press **OK** ✓ to select.

4. You will be asked "Are you sure?". If you select **No** [✗], you will be taken to the main Clinician Menu and therapy data will not be cleared. If you select **Yes** [✓], a clearing sequence will start.

5. Press **OK** ✓ to exit to the main Clinician Menu once the clearing sequence is complete. Alternatively, the device will automatically exit after 3 seconds.

7.4 Factory Reset

A factory reset will delete all data and prescription settings from the device and the InfoUSB. Please do not turn off the device while the factory reset is in progress. The device will restart with the default factory settings.

1. Make sure the InfoUSB is plugged into the device if you would like it to be cleared.
2. Press **Down** ▼ or **Up** ▲ to scroll to "Factory reset".
3. Press **OK** ✓ to select.

4. You will be asked "Are you sure?". If you select **No** [✗], you will be taken to the main Clinician Menu and data will not be cleared. If you select **Yes** [✓], a clearing sequence will start.

5. Once the clearing sequence is complete, the device will restart and you will be taken through the First-Start up sequence. See section *2.3 – First Start-Up*.

***Note**: If the InfoUSB is not in the device at the time of the factory reset, it will not be cleared. The next time it is inserted into the device, compliance data on the InfoUSB will be overwritten. If there is data from other devices on the InfoUSB, that data will not be deleted at the time of the factory reset. You can manually clear all data from the InfoUSB using a computer.*

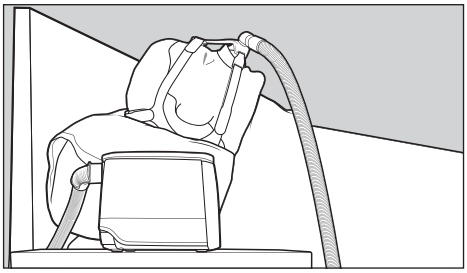
8. PATIENT SETUP

8.1 Device Setup

Below is a guide for taking a patient through the device setup. You may wish to refer the patient to the F&P SleepStyle Quick Reference Guide.

***Note**: Please ensure the patient has read and understood all Warnings, Cautions, and setup instructions in the F&P SleepStyle Use and Care Guide.*

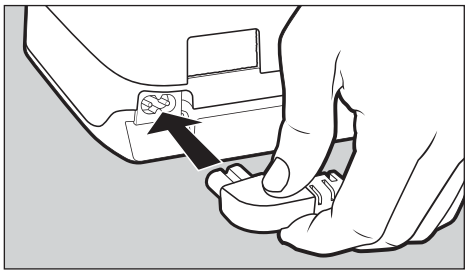
1. Place the device on a stable and level surface (like a bedside table).

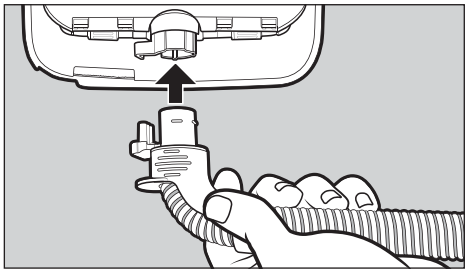


⚠ Warnings

To avoid injury, choking, or inhalation of a foreign object:
Do not place the device above head height to prevent water from entering the breathing tube.

2. Connect the power cord and ThermoSmart breathing tube (or the standard breathing tube and elbow).



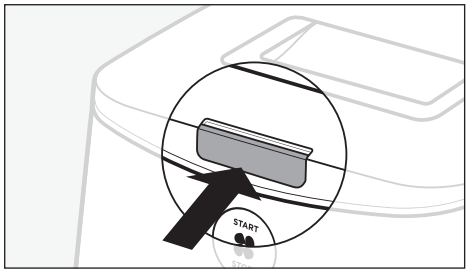


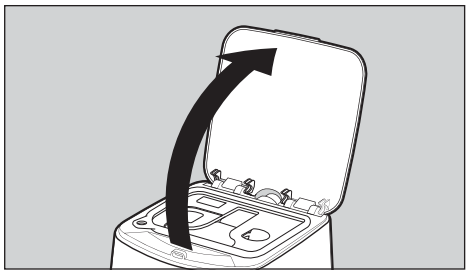
⚠ Warnings

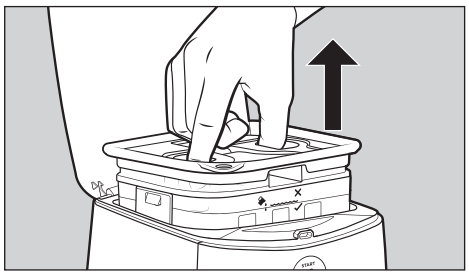
To avoid electric shock:
Do not use if the device, power cord, or accessories are damaged, deformed or cracked.

To avoid choking, or inhalation of a foreign object:
Ensure the breathing tube and power cord, including any extension cords, are correctly positioned so they will not become entangled with the body or furniture during sleep.

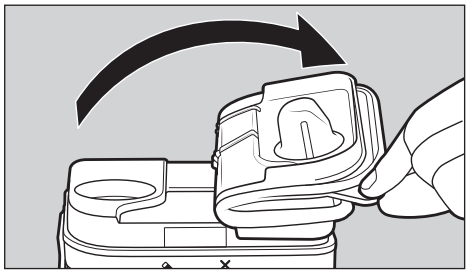
3. Open the device lid and remove the water chamber.

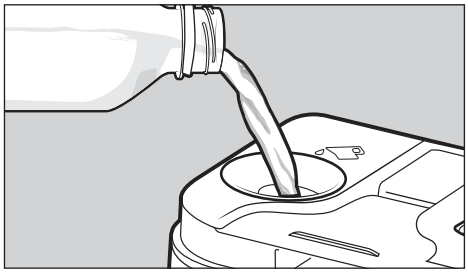






4. Fold back the chamber seal using the corner tab. Fill the water chamber up to the maximum water-level line.





⚠ Warnings

To avoid burns:
Do not fill the water chamber with hot water as this may lead to airway burns.

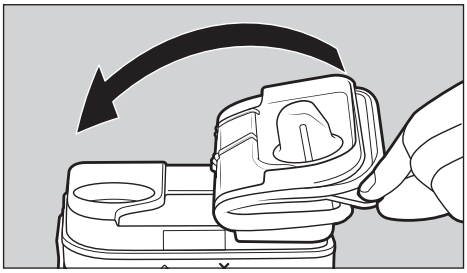
⚠ Cautions

To prevent water damage to the device:

- Do not use if the water chamber is damaged.
- Do not fill the chamber housing with water. Only place water in the water chamber.
- Do not fill the water chamber above the maximum water-level line.
- Replace water before each use.
- Do not fill the water chamber while it is in the device.
- Do not use the device with an empty water chamber unless the humidity level is set to 0.
- Do not add aromatic-based or scented oils to the water chamber as these oils can cause damage to the device.

General:
Use distilled water to reduce residue build-up on the chamber base. This will extend the life of the water chamber.

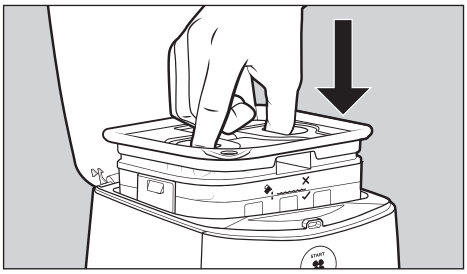
5. Unfold the chamber seal and push down in the finger holds to secure it in place.



⚠ Cautions

To prevent water damage to the device:
Do not use the device without the chamber seal fitted to the water chamber.

6. Place the water chamber back into the device and close the device lid.



8.2 Starting Therapy

1. Ask the patient to fit their mask.
2. Press **Start/Stop** to start therapy.

The screen below will appear:

8.3 Stopping Therapy

1. Get the patient to remove their mask.
2. Press **Start/Stop** to stop therapy.

The device screen below will appear:

3. The screen will then scroll through the patient's therapy data from the session that has just finished (if the session has lasted 6 minutes or longer).

   Therapy Hours: Number of hours the patient used their device.

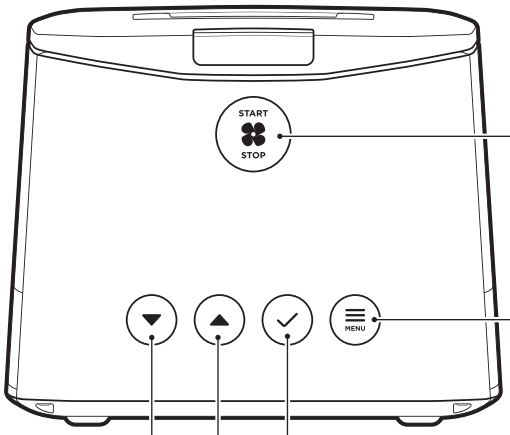
   Mask Leak: If the patient's mask leak was "Normal" or "High".

   AHI: Average number of apneas or hypopneas the patient had per hour.

***Note**: If you would like to bypass this automated scrolling, press Menu to scroll through the data screens manually.*

8.4 User Controls for the Patient Menu

The Patient Menu has different controls to the Clinician Menu. When in the Patient Menu, please use the controls as outlined below.



Start/Stop
- Press to start and stop therapy.
- Press and hold for 3 seconds to start Ramp

Menu
- Press to enter the Menu at any time.
- Press to scroll between settings or data screens.

Down and Up
- Press to decrease or increase a comfort setting.
- Press to move between options in a setting.
- Press to show the “Humidity” setting at any time.

OK
- Press to make a selection.
- Press to accept an instruction on the display screen.

8.5 Patient Menu Settings

The Patient Menu refers to all the settings that the patient can view to access and make adjustments to their therapy. Please refer to the F&P SleepStyle Use and Care Guide for more details.

From the home screen, or during therapy, press **Menu** to access the device menu.

Note: *For more information on the Patient Menu home screen, including the four indicator icons, refer to section* 3.1 – Screen icons *in the F&P SleepStyle Use and Care Guide.*

8.5.1 Ramp

Ramp works by gradually increasing the air pressure to the prescribed pressure over a 20-minute period. Ramp can be activated in both CPAP and Auto mode.

To start ramp, press and hold **Start/Stop** until the Ramp symbol appears on the screen.

Ramp will increase to the prescribed pressure over a 20-minute period, starting from one third of the prescribed pressure, if the device is in CPAP mode, or minimum pressure, if the device is in Auto mode.

Note*: If SensAwake is on, then Ramp is not required if the minimum SensAwake pressure is comfortable for the patient.*

8.5.2 Humidity

The patient can set the humidity level to 0 (Off) or between 1 and 7 (On).

8.5.3 Expiratory relief

Expiratory relief is available with all models, and the following settings are available:

Off, low (1), medium (2), or high (3).

8.5.4 SensAwake

SensAwake is available with all models, and the patient can turn SensAwake On or Off.

Note*: SensAwake is defaulted to Off in CPAP mode.*

8.5.5 My Data

This setting allows the patient to view their basic therapy data (daily, weekly, or monthly) on the device, including:

- Therapy Hours – Last night
- Therapy Hours – Last 7 days
- Therapy Hours – Last 30 days
- Mask Leak – Last night
- Mask Leak – Last 7 days
- Mask Leak – Last 30 days
- AHI – Last night
- AHI – Last 7 days
- AHI – Last 30 days

The AHI screens can be hidden from the Patient Menu. In the Clinician Menu, go to the “Device” sub-menu, scroll to “Display AHI” and then select **No** [X].

8.6 Hidden Data Transfer Menu

This hidden menu is intended for troubleshooting over the phone, between the clinician and the patient. The following are instructions to provide to the patient to guide them in accessing and navigating this hidden menu.

8.6.1 Access the hidden data transfer menu

From the home screen, or during therapy, hold **Menu** ☰ for 5 seconds.

8.6.2 Send my data*

This option allows the patient to manually upload their therapy and compliance data to F&P InfoSmart so you can view the data, instead of waiting for the next scheduled upload, or if an issue has occurred during a scheduled upload.

To manually upload the patient's therapy data to F&P InfoSmart, ask the patient to:

1. Press **Down** ▼ or **Up** ▲ to change the selection to **Yes** ☑. The device will begin the manual upload of the patient's therapy data. The following screens will appear in sequence as the device searches for a signal and transmits the data (this process may take a few minutes):

***Note**: If the modem has been turned off and the user selects Yes ☑, the modem will automatically activate for data transfer.*

2. If the data has uploaded successfully, the following screen will appear:

If the data has not uploaded successfully, the following screen will appear instead:

Instruct the patient to attempt a manual upload again. If the error persists, record the number on the screen and contact your Fisher & Paykel Healthcare representative.

3. Once the upload is complete, press **OK** ✓ or **Menu** ☰ to acknowledge and clear the message and return to the "Send my data" menu.
4. Press **Menu** ☰ to scroll to the next screen in the hidden menu. To exit the hidden menu, continue pressing **Menu** ☰ until the home screen is reached.

8.6.3 Cellular Modem (On/Off)*

This option allows the patient to turn the cellular modem On or Off.

To turn the cellular modem On or Off, ask the patient to:

1. Press **Menu** ☰ until they reach the "Cellular Modem" setting.

2. Press **Down** ▼ or **Up** ▲ to change the selection. The selected option will flash once to indicate the selection has been saved.
3. Press **Menu** ☰ to scroll to the next screen in the hidden menu. To exit the hidden menu, continue pressing **Menu** ☰ until the home screen is reached.

***Note**: If turned Off, the modem will automatically turn back On after 3 days.*

* Only available in models with a cellular modem.

8.6.4 Bluetooth® Technology (On/Off)

This option allows the patient to turn Bluetooth wireless technology On or Off.

To turn Bluetooth On or Off, ask the patient to:

1. Press **Menu** ☰ until they reach the "Bluetooth" setting.

2. Press **Down** ▼ or **Up** ▲ to change the selection. The selected option will flash once to indicate the selection has been saved.
3. Press **Menu** ☰ to scroll to the next screen in the hidden menu. To exit the hidden menu, continue pressing **Menu** ☰ until the home screen is reached.

8.6.5 Clear all paired devices

If the Bluetooth pairing fails, then clearing all paired devices will allow the patient to restart the pairing process. The patient may also wish to do this should they choose to forget the F&P SleepStyle device from their mobile device. Clearing all paired devices should only be done as a last resort.

This feature is also useful if you, or the patient, would like to replace the mobile device that the device is currently paired to. The device can pair with multiple mobile devices; however, only one mobile device with the app can see the patient's therapy data.

***Note**: This option is only available if Bluetooth is On.*

To clear all paired devices, ask the patient to:

1. Press **Menu** ☰ until they reach the "Clear all paired devices?" screen.

2. Press **Down** ▼ or **Up** ▲ to change the selection to **Yes** ☑.
3. Press **OK** ✓ to clear all paired devices. Wait for the following screen to appear:

4. Press **OK** ✓ or **Menu** ☰ to acknowledge and clear the message.
5. Press **Menu** ☰ to return to the Patient Menu home screen.

8.7 Stand-by Mode

The device will enter stand-by mode after 30 seconds if no button has been pressed on the device.

The display screen light will dim but will still be visible to show that the device is still powered on. Press **Down** ▼, **Up** ▲, **OK** ✓, or **Menu** ☰ to wake up the device.

9. SERVICING

⚠ Warnings

General:
This device is not repairable and does not contain any repairable parts. Please refer queries relating to the device or accessories to your Fisher & Paykel Healthcare representative.

The device does not require preventative maintenance.

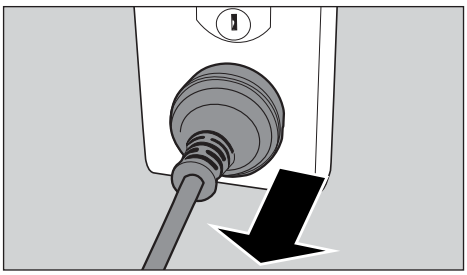
10. MULTI-PATIENT USE

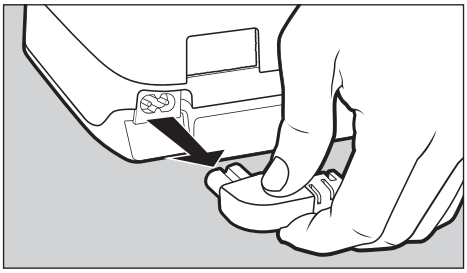
High-level disinfection cleaning is required when the device is intended for multiple-patient use.

10.1 Disassembly for Cleaning and High-Level Disinfection

DEVICE

Disconnect the device from the mains power supply and remove the power cord from the rear of the device.



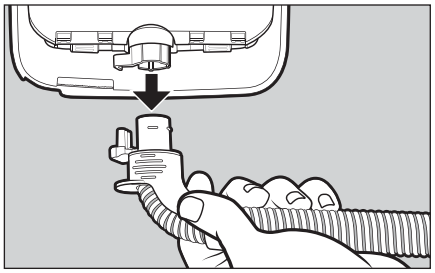


⚠ Warnings

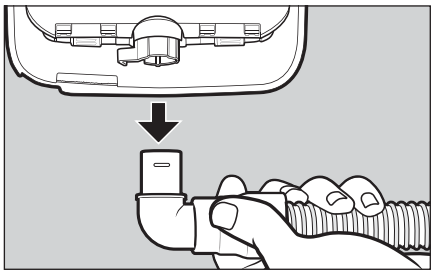
To avoid electric shock:
Do not pull on the power cord as it may become damaged.

BREATHING TUBE

1. Hold the plastic connector and gently pull it away from the device.

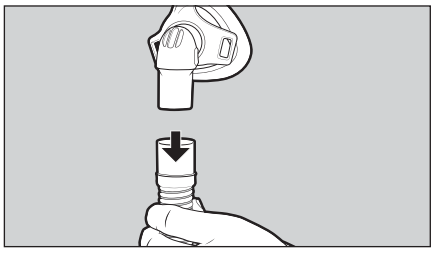


ThermoSmart breathing tube (must be replaced between patients)



Standard breathing tube

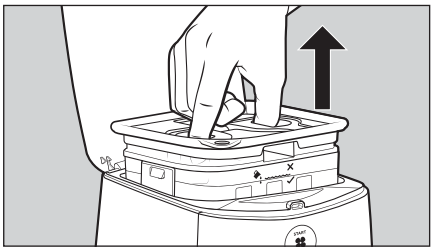
2. Hold both the mask end of the tube and the mask swivel and gently pull them apart.



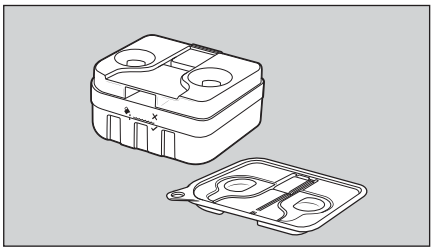
3. Disconnect the elbow from the standard breathing tube.

WATER CHAMBER AND CHAMBER SEAL

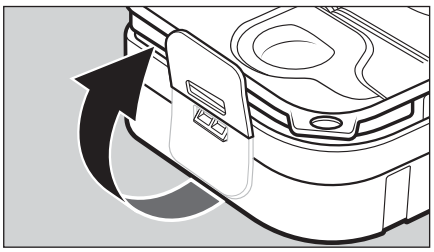
1. Press the lid latch and open the device lid.
2. Take the water chamber out of the device.



3. Remove the chamber seal from the top of the water chamber and put aside.

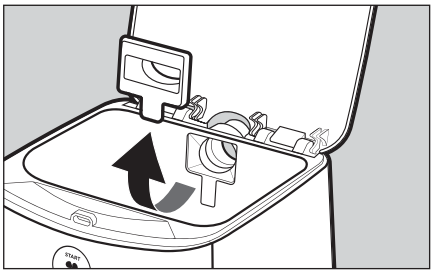


4. Lift the chamber tab and lift the chamber lid to open.



OUTLET SEAL

1. Grip the outlet seal tab.
2. Gently pull the outlet seal out of the device.



10.2 Cleaning and High-Level Disinfection of the Device and Accessories

To maintain optimal therapy and presentation of the device and accessories, regular cleaning is recommended. Refer to the cleaning instructions in section *6 – Caring for Your Device* of the *F&P SleepStyle Use and Care Guide*.

For reprocessing between patients, follow the cleaning and then the high-level disinfection instructions below.

⚠ Warnings

To avoid electric shock:

- Do not use bleach, alcohol, or cleaners with citrus or other natural oils. These substances may degrade the device and accessories.
- Do not immerse the device in water or any other liquid.

To avoid incorrect therapy:

- Only clean the device and accessories according to the cleaning instructions below.
- Do not clean or disinfect the ThermoSmart breathing tube with hot water. This may cause deformation of the tube and reduce therapeutic pressure.

⚠ Cautions

General:
Replace the device and accessories if there is any sign of cracking, deformation, discoloration or leaking. It is recommended that you inspect the device, breathing tube, water chamber, chamber seal, outlet seal, air filter and elbow, on a regular basis after cleaning. See section *12 – Replacement Parts*.

10.2.1 CLEANING

DEVICE

1. Wipe the exterior of the device and the chamber housing with a clean, damp (not dripping) cloth and warm soapy water using a mild dishwashing detergent.
2. Leave to dry out of direct sunlight or heat.

WATER CHAMBER, CHAMBER SEAL, STANDARD BREATHING TUBE, OUTLET SEAL AND ELBOW

1. Hand-wash these accessories in a tub of warm, soapy water with a mild dishwashing detergent. Ensure all visible soil is removed.
2. Rinse thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
3. Repeat the rinsing process again, using clean water.
4. Hang the standard breathing tube, with both ends pointing to the floor, to dry away from direct sunlight or heat.
5. Leave the water chamber, chamber seal, outlet seal and elbow to dry out of direct sunlight or heat.

***Note**: If dirt remains inside the standard breathing tube after rinsing, use a soft, non-metallic brush, to remove it. Rinse the tube again. If the dirt cannot be removed, the standard breathing tube should be replaced.*

10.2.2 HIGH-LEVEL DISINFECTION

***Note**: High-level disinfection may be repeated 20 times per part, then they should be replaced. The air filter and ThermoSmart breathing tube must be replaced between patients. Refer to section 10.4 – Replacing the Air Filter between Patients. The device lid does not require high-level disinfection.*

	Thermal Disinfection		**Chemical Disinfection**
	75 °C (167 °F) for 30 minutes	**90 °C (194°F) for 1 minute**	**CIDEX™ OPA**
Standard breathing tube	✔	⚠ **No**	✔
Elbow	✔	✔	✔
Water chamber	✔	✔	✔
Chamber seal	✔	✔	✔
Outlet seal	✔	✔	✔

THERMAL DISINFECTION

1. Immerse the disassembled parts in a water bath. Ensure that no air bubbles are trapped inside the standard breathing tube.
2. Increase the water bath temperature to 75 °C (167 °F).
3. Soak for 30 minutes.
4. Air-dry out of direct sunlight or heat.

***Note**: Higher temperatures may damage the standard breathing tube. The elbow, water chamber, chamber seal and outlet seal can be thermally disinfected separately from the standard breathing tube in a water bath at 90 °C (194 °F) for 1 minute.*

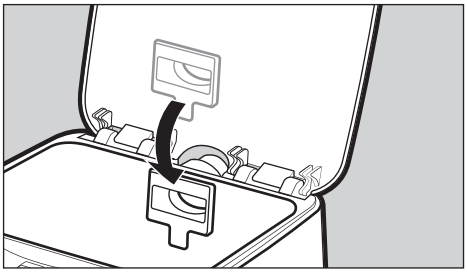
CHEMICAL DISINFECTION

1. Immerse the disassembled parts in a cleaning solution using CIDEX OPA. Follow the manufacturer's instructions for concentration, temperature, and time.
2. Ensure that no air bubbles are trapped inside the standard breathing tube.
3. Thoroughly rinse each part in a tub of water by immersing completely for a minimum of 1 minute.
4. Repeat the rinsing process twice more using fresh water each time for a total of 3 rinses.
5. Air-dry out of direct sunlight or heat.

10.3 Reassembly of the Device and Accessories

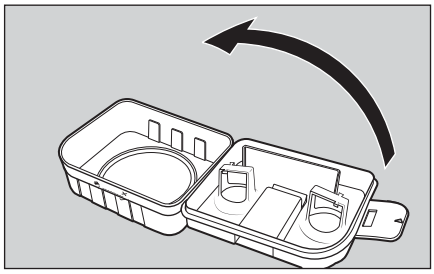
OUTLET SEAL

Hold the tab on the outlet seal and push it into the chamber housing inlet. Ensure the tab is sitting flat against the wall of the chamber housing.

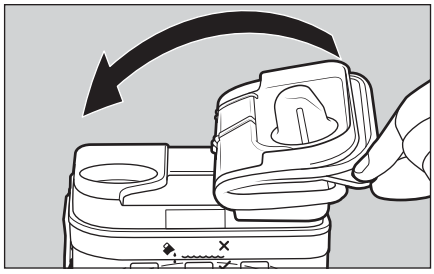


WATER CHAMBER AND CHAMBER SEAL

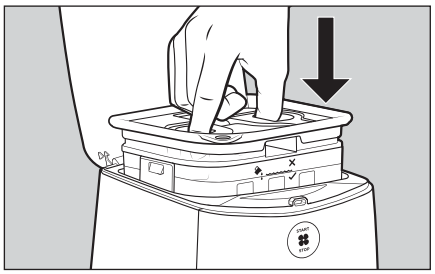
1. Close the chamber lid. Press the chamber tab down until it clicks into place.



2. Secure the chamber seal back onto the water chamber by pushing down in the finger holds. Ensure it is sitting flat and seals the holes on the chamber lid.



3. Place the water chamber back into the device.



BREATHING TUBE

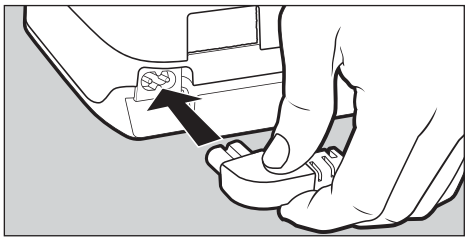
1. Hold the elbow end of the breathing tube and push it into the air outlet of the device.

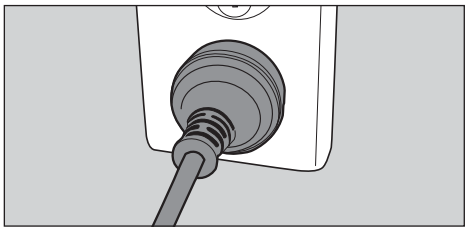
   Note: *If you are connecting a new ThermoSmart breathing tube, make sure the electrical connectors on the elbow click into position with the ThermoSmart connection.*

2. Holding the mask and the other end of the breathing tube, push the mask swivel firmly into the breathing tube.
3. Reconnect the elbow to the standard breathing tube.

DEVICE

Reconnect the power cord to the rear of the device and reconnect the power cord to the mains power supply.





10.4 Replacing the Air Filter between Patients

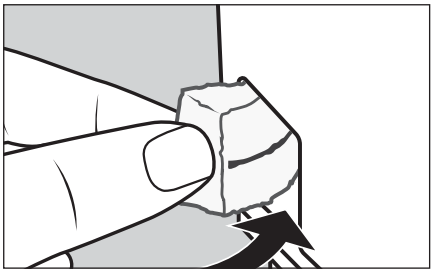
The air filter is located at the rear of the device and ensures the air intake into the device is filtered to remove particles and dust. The air filter is not washable and must be replaced between patients. To replace the air filter, please follow the instructions below.

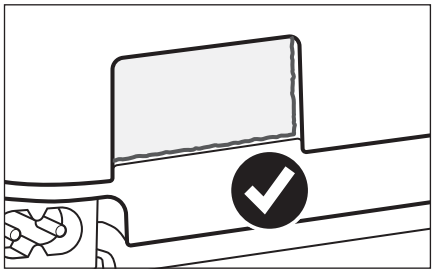
⚠ Warnings

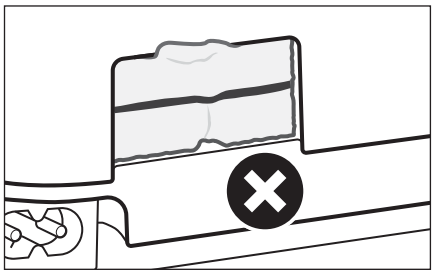
To avoid choking, or inhalation of a foreign object:
Do not use the device without the recommended air filter fitted. This will reduce dust or particles entering the device and breathing tube.

1. To remove, pinch the air filter with your fingers and pull it out of the device.

2. Hold onto the short side of the new air filter. Push into the device so there are no gaps.







10.5 Deleting Therapy Data between Patients

For accurate compliance reports, data must be cleared from the device memory, as well as the InfoUSB, before use by another patient. Follow the instructions in section *7.3 – Clear Patient Data* to delete therapy data from the device's memory.

11. THERAPY AND COMPLIANCE DATA

***Note**: The device reported AHI is not equivalent to an AASM (American Academy of Sleep Medicine) AHI and therefore should not be used for diagnosis of OSA or in isolation for titration or clinical management. In accordance with guidelines for OSA patient management (including the American Academy of Sleep Medicine and American Thoracic Society), a comprehensive patient review should be considered prior to adjusting patient therapy.*

To ensure PAP treatment remains effective when pressure relief options are active, it is recommended to enable pressure relief features during titration. It is also recommended to monitor the patient after initiating treatment to assess the effect of pressure relief.

The retrieval of therapy and compliance data is available in a range of solutions to suit different patient needs.

11.1 Modem

If the device has a cellular modem, therapy and compliance data will automatically upload from the patient's device to your F&P InfoSmart account.

The patient can also use F&P SleepStyle Web or App* if the device has a modem. To use the F&P SleepStyle App via modem, the patient will need

- F&P SleepStyle with Cellular Modem**
- F&P SleepStyle App installed on iPhone 7 Plus, iPhone 7, iPhone SE, iPhone 6s Plus, iPhone 6s, iPhone 6 Plus, iPhone 6, iPhone 5s, iPhone 5c, or iPhone 5 and connected to Wi-Fi or a mobile data network. The app is available on the App Store.

Or

- F&P SleepStyle App installed on any leading smartphone with Android™ connected to Wi-Fi or a mobile data network. The app is available on the Google Play™ store.

***Note**: For the patient to view their latest therapy and compliance data on SleepStyle Web or App via modem, they will need to wait 1 hour after stopping therapy to see the data. To ensure the data is uploaded successfully, the patient must not unplug the device during this time*

If data has not been uploaded, you can contact the patient and ask them to manually send the data from their device. Refer to section *8.6.2 - Send my data* to take the patient through this process.

11.2 Bluetooth Technology

The Bluetooth wireless technology feature allows patients to pair the device with a mobile device so they can use the F&P SleepStyle App*. The app allows them to view their CPAP therapy progress, set goals, and identify and troubleshoot any issues. You can also view their therapy data when it uploads via the app, if their mobile device has connected to Wi-Fi or a mobile data network.

To use the F&P SleepStyle App via Bluetooth, the patient will need:

- F&P SleepStyle with Bluetooth
- F&P SleepStyle App installed on iPhone 7 Plus, iPhone 7, iPhone SE, iPhone 6s Plus, iPhone 6s, iPhone 6 Plus, iPhone 6, iPhone 5s, iPhone 5c, or iPhone 5 and connected to Wi-Fi or a mobile data network. The app is available on the App Store.

Or

- F&P SleepStyle App installed on any leading smartphone with Android connected to Wi-Fi or a mobile data network. The app is available on the Google Play store.

Once the app is installed, the patient will need to open the app and follow the on-screen instructions to pair the device with their mobile device via Bluetooth, and then link to their F&P SleepStyle account so they can view their therapy data.

11.3 F&P InfoUSB™

The InfoUSB (stored in the InfoUSB port) records therapy data from the internal memory of the device, and this data can be transferred to a report format using InfoSmart Web* or the InfoSmart application. The following data is recorded in InfoSmart reports:

- 7 days' detailed efficacy data (including AHI, pressure and leak)
- Customizable summary data of up to 12 months
- Cumulative summary data from first use
- Summary report of up to 12 months of data.

With the InfoUSB and SleepStyle Web*, or the InfoUSB application, patients will have the ability to send their therapy and compliance data, as well as receive remote prescription changes via the internet. InfoSmart Web has built-in customizable automated telephone, email, and text messages that can be set to remind the patient to complete the data transfer in a timely manner.

⚠ Cautions

General:
Only use the 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 device.

The InfoUSB may become full if used to store other files. This may result in the report not downloading from the InfoUSB or the InfoSmart report having missing data. Refer to section *13.1 – Device Troubleshooting* if this problem occurs.

** Not available in all countries.*

*** Not available in all models.*

12. REPLACEMENT PARTS

Below is a list of replacement parts that are available.

Product code	Description
900SPS100	Water chamber
900SPS101	Chamber seal
900SPS111	Air filter (single)
900SPS110	Air filters (2-pack)
900SPS120	ThermoSmart breathing tube*
900SPS121	Standard breathing tube with elbow*
900SPS122	Elbow (for use with a standard breathing tube)
900SPS140	Device lid
900SPS141	Outlet seal
900SPS142	Carry-bag
900SPS160	North American power cord
900SPS161	Australasian power cord
900SW101	F&P InfoUSB

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

⚠ Warnings

To avoid injury:
Do not use breathing tubes, parts, and accessories that are not distributed for use with this device or recommended by Fisher & Paykel Healthcare.

General:
Do not use accessories or power cables which are not provided, or recommended, by Fisher & Paykel Healthcare. This could result in increased electromagnetic emissions or decreased electromagnetic immunity.

13. TROUBLESHOOTING*

If you feel that the device is not operating correctly, please refer to the following suggestions. If the problem continues, please contact your Fisher & Paykel Healthcare representative.

⚠ Warnings

To avoid electric shock:

- Do not modify the device or accessories.
- Do not take apart the device. Taking the device apart, for example by unscrewing the underside of the device, will damage pressure seals and electrical components.

13.1 Device Troubleshooting

Problem	Solution
There is no visible display or power.	The power cord may not be inserted fully into the device or the plug may not be correctly connected to the power supply. **Solution:** Ensure the power cord plug is fully inserted into the device and the mains plug is connected to the power supply.
Therapy won't start, but there is a display on the screen.	There may be water in the blower, preventing it from starting. **Solution:** Turn off at the power supply and unplug the device. Remove the water chamber. Keep the device lid open and tip the device upside down to clear the water from the device. Place the water chamber back in the device. Restart the device.
	Is there an error message on the display? **Solution:** Refer to section *13.2 - Error Messages on SleepStyle Screen*, identify the error code and take the appropriate corrective action.
The pressure is fluctuating or insufficient air is being delivered from the device.	The patient's mask may not be fitted correctly, causing leaks. **Solution:** Ensure the mask is correctly fitted. Refer the patient to their mask's Use and Care Guide for fitting instructions.
	The device lid may not be closed correctly, the chamber seal may not be fitted to the water chamber correctly, or the outlet seal is missing. **Solution:** Ensure the chamber seal is correctly secured to the water chamber. Ensure the outlet seal and water chamber are in the device. Refer to section *10.3 - Reassembly of the Device and Accessories* for detailed instructions on reassembly of these parts.
	There may be water in the breathing tube. **Solution:** Disconnect the breathing tube and hang with both ends pointing to the floor until all water in the breathing tube has been cleared.
	The delivered pressure may fluctuate due to Electromagnetic Interference (EMI). **Solution:** Ensure there is sufficient space between the SleepStyle device and other electrical devices that may cause interference.

*If your problem persists please contact your healthcare provider.

Problem	**Solution**
The device restarts.	It is possible that the device could restart due to Electromagnetic Interference (EMI). No actions are necessary as the device will restart and resume therapy. If restarts continue to occur, ensure there is sufficient space between the SleepStyle device and other electrical devices that may cause interference.
The base of the device is warm to the touch even though the device isn't being used.	This is normal and should not cause concern. In stand-by mode, the device consumes approximately 5 W of power. This may cause the feeling of warmth.
There is a build-up of water on the heater-plate.	When therapy has stopped, humidity in the water chamber can cool, causing condensation to form. **Solution:** To reduce condensation, the device should be plugged in and switched on at the power supply after stopping therapy. Before each use, the water chamber should be removed and the chamber housing dried with a cloth. If the water build-up becomes excessive, please contact your Fisher & Paykel Healthcare representative for further information.
The humidifier doesn't appear to be working.	The humidity level may be incorrect. **Solution:** Check the humidity level is above 0. See section 5 - Comfort Options for detailed information on the humidity setting.
	The water chamber may be empty. **Solution:** Check if there is water in the water chamber. Refer to section *8.1 - Device Setup* for instructions on filling the water chamber.
	The ThermoSmart breathing tube is not connected correctly to the device. **Solution:** Remove the ThermoSmart breathing tube from the device and reconnect, making sure that the electrical connector on the breathing tube is correctly fitted into the device. When connected correctly, the ThermoSmart icon appears on the device home screen. If the ThermoSmart icon does not appear, the ThermoSmart breathing tube is not working and should be replaced.
	Solution: The humidity may be temporarily reduced due to Electromagnetic Interference (EMI). Stop and then restart therapy again using the Start / Stop button and the full humidity will be enabled.
Report not downloading from the InfoUSB or the InfoSmart report is missing data.	The device failed to detect the InfoUSB. **Solution:** Remove the InfoUSB and insert it fully into the InfoUSB port of the device. When inserted correctly, the InfoUSB icon appears on the device home screen.
	The InfoUSB may have been removed whilst data was syncing, used to store other files, or may be full. **Solution:** Use a computer to delete the InfoUSB contents and reinsert for at least 2 minutes.
	The InfoUSB is faulty. **Solution:** Replace the InfoUSB. See section 12 - Replacement Parts.

Problem	**Solution**
The device will not pair to a mobile device using Bluetooth.	The device may not be discoverable or Bluetooth may not be turned on either device. **Solution:** Turning the Bluetooth setting off and on again on the mobile device may resolve connectivity issues. Refer to section *4.2 - View your therapy data on the SleepStyle App or website* in the F&P SleepStyle Use and Care Guide for instructions on changing the Bluetooth setting.

13.2 Error Messages on SleepStyle Screen

If a fault is detected with the device or its accessories, a screen will appear with a notification and an error code. Identify the error code in the ranges specified below and follow the appropriate corrective action. If the error continues or reoccurs, record the number displayed and contact your Fisher & Paykel Healthcare representative for further instructions.

Error codes between	**Solution**
100–199	The device may not be able to provide effective therapy. The device may have shut down or may not be able to provide the prescribed pressure. **Solution:** Turn the power off and on at the power supply to restart the device.
400–499	Humidity may have been disabled. The device is still safe to use without humidity. The patient will still be treated at the prescribed pressure. **Solution:** Turn the power off and on at the power supply to restart the device.
510 or 512	There may be a problem with the ThermoSmart breathing tube. The device is still safe to use. The patient will still be treated and get humidity, but it may not be optimal. **Solution:** Try reconnecting your ThermoSmart breathing tube. When connected correctly, the ThermoSmart icon will appear on the home screen. Alternatively, turn the power off and on at the power supply to restart the device. If the error continues or reoccurs, replace the ThermoSmart breathing tube. See section *12 - Replacement Parts*.
500–599 (excluding 510 or 512)	The ThermoSmart breathing tube may have been disabled. The device is still safe to use. The patient will still be treated and get humidity, but it may not be optimal. **Solution:** Turn the power off and on at the power supply to restart the device. If the error continues or reoccurs, See section *12 - Replacement Parts*.

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 (Sponsor)
Fisher & Paykel Healthcare Pty Limited
19-31 King Street, Nunawading,
Melbourne, Victoria 3131.

Tel: +61 3 9871 4900
Fax: +61 3 9871 4998

Austria
Tel: 0800 29 31 23
Fax: 0800 29 31 22

Benelux
Tel: +31 40 216 3555
Fax: +31 40 216 3554

Brazil
Fisher & Paykel do Brasil
Rua Sampaio Viana, 277 cj 21, Paraíso,
04004-000
São Paulo – SP, Brazil

Tel: +55 11 2548 8002

China
代理人/售后服务机构:
费雪派克医疗保健（广州）有限公司,广州高新技术产业开发区科学城科丰路31号G12栋301号

电话: +86 20 32053486
传真: +86 20 32052132

Finland
Tel: +358 (0)405 406618
Fax: +46 (0)8 36 6310

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 5117 7110
Fax: +81 3 5117 7115

Korea
Tel: +82 2 6205 6900
Fax: +82 2 6309 6901

Northern Ireland
Tel: 0800 132 189

Russia
Tel and Fax: +7 495 782 21 50

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,
Alinteri Bulvari 1161/1 Sokak
No. 12-14, P.O. Box 06371 Ostim,
Ankara, Turkey

Tel: +90 312 354 34 12
Fax: +90 312 354 31 01

UK EC REP
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: +1 800 446 3908
or +1 949 453 4000
Fax: +1 949 453 4001

For patent information, see **www.fphcare.com/ip.**

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Fisher & Paykel HEALTHCARE

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 (Sponsor)
Fisher & Paykel Healthcare Pty Ltd,
19-31 King Street, Nunawading,
Melbourne, Victoria 3131.

Tel: +61 3 9871 4900
Fax: +61 3 9871 4998

Austria
Tel: 0800 29 31 23
Fax: 0800 29 31 22

Benelux
Tel: +31 40 216 3555
Fax: +31 40 216 3554

Brazil
Fisher & Paykel do Brasil,
Rua Sampaio Viana, 277 cj 21,
Paraíso, 04004-000,
São Paulo – SP, Brazil

Tel: +55 11 2548 7002

China
代理人/售后服务机构:
费雪派克医疗保健 (广州) 有限公司,
广州高新技术产业开发区科学城科丰路31号G12栋301号

电话: +86 20 32053486
传真: +86 20 32052132

Denmark
Tel: +45 70 26 37 70
Fax: +46 83 66 310

Finland
Tel: +358 94 1590 355
Fax: +46 83 66 310

France
Tel: +33 1 6446 5201
Fax: +33 1 6446 5221

Germany
Tel: +49 7181 98599 0
Fax: +49 7181 98599 66

Hong Kong
Tel: +852 2116 0032
Fax: +852 2116 0085

India
Tel: +91 80 2309 6400
Fax: +91 80 2972 0853

Irish Republic
Tel: 1800 409 011
Fax: +44 1628 626 146

Italy
Tel: +39 06 7839 2939
Fax: +39 06 7814 7709

Japan
Tel: +81 3 5117 7110
Fax: +81 3 5117 7115

Korea
Tel: +82 2 6205 6900
Fax: +82 2 6309 6901

Northern Ireland
Tel: 0800 132 189
Fax: +44 1628 626 146

Norway
Tel: +47 21 60 13 53
Fax: +47 22 99 60 10

Russia
Tel and Fax: +7 495 782 21 50

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
İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi,
İletişim Bilgileri: Ostim Mahallesi 1249.
Cadde No:6, Yenimahalle,
Ankara, Türkiye 06374,

Tel: +90 312 354 34 12
Fax: +90 312 354 31 01

UK EC REP
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

REF 613471 REV A 2018–10

Fisher & Paykel HEALTHCARE