

Use and Care Guide

F&P SleepStyle Auto F&P SleepStyle CPAP





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 professional.

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

Clinicians: 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 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.

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

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



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

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

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.

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 supplemental oxygen.
- Sources of oxygen must be located more than 1 m (40 in.) from the device.

1.3.5 To avoid carbon dioxide rebreathing 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.
- 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.

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:

Prescription updated

Press any button to acknowledge and clear this message.

1.3.9 General:

- Only use the device within the operating conditions specified, otherwise the performance of the device could be compromised. See section 8.5 - Operating Conditions.
- 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 and the device may affect or be affected due to the effects of electromagnetic interference, in certain circumstances. If interference should occur, try moving your device or the equipment causing interference. Alternatively, consult your healthcare provider.
- 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.

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.

142 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 CPAP device has not been established in patients with respiratory failure or chronic obstructive pulmonary disease (COPD).
- The safety and effectiveness of the autoadjusting 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

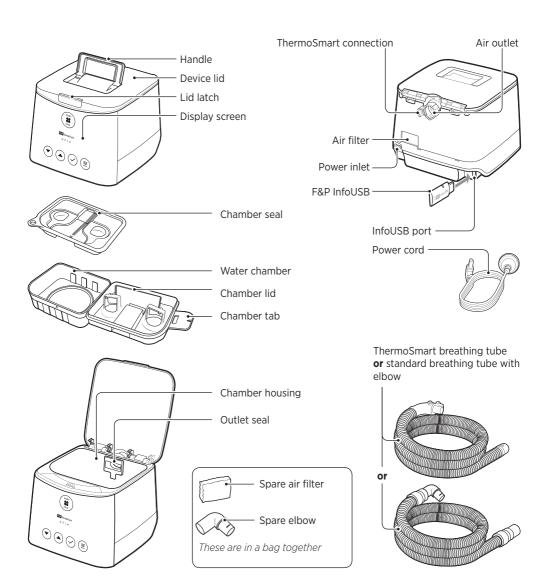
 Nosebleeds, perforated ear drum, dryness of the nasopharynx, sinus infection, and middle ear infection may occur from the use of positive airway pressure therapy.

2. GETTING STARTED

2.1 DEVICE AND ACCESSORIES

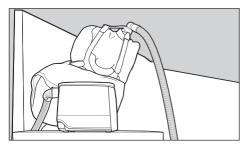
- 1x Carry-bag
- 1 x SleepStyle device
- 1 x Breathing tube
- 1x Power cord
- 1 x F&P SleepStyle Use and Care Guide
- 1 x F&P SleepStyle Quick Reference Guide
- 1x Water chamber

- 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
- $1\,\mathrm{x}$ 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

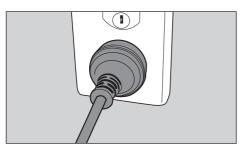
To avoid injury, choking, or inhalation of a foreign object:

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 the power supply.





⚠ Warnings

To avoid electric shock:

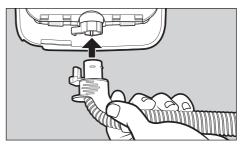
Do not use if the device, power cord, or accessories are damaged, deformed or cracked.

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.

ThermoSmart breathing tube

Connect the ThermoSmart breathing tube into the air outlet.



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:



Note: Screen may differ, depending on the model of the device.

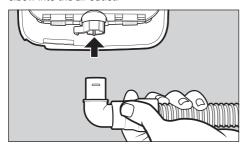
⚠ Warnings

To avoid incorrect therapy:

Use the elbow when rotating the ThermoSmart breathing tube. Incorrect handling may damage the tube

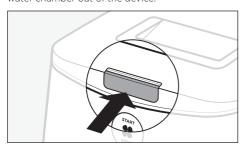
Standard breathing tube

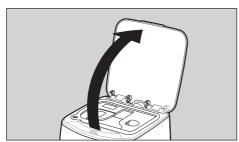
Connect the standard breathing tube with the elbow into the air outlet.

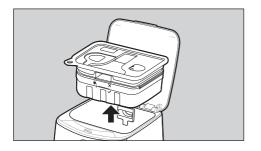


3. Remove the water chamber from the device.

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

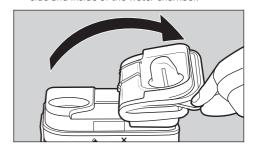






4. Fill the water chamber with water

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





Marnings

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:

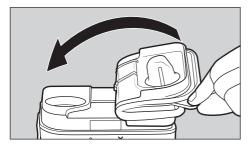
- Do not use if the water chamber is damaged.
- Do not fill the chamber housing with water.
 Only place water in the water chamber.
- Do not fill the water chamber above the maximum water-level line.
- · Replace water before each use.
- Do not fill the water chamber while it is in the device.
- Do not 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.

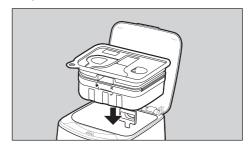


⚠ Cautions

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

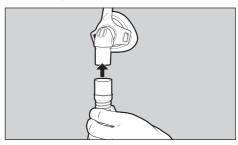
6. Put the water chamber back into the device.

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

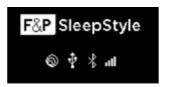
When your device is plugged in and switched on, you will see the home screen appear with up to four icons. These icons indicate the status of a setting or accessory, as follows:

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

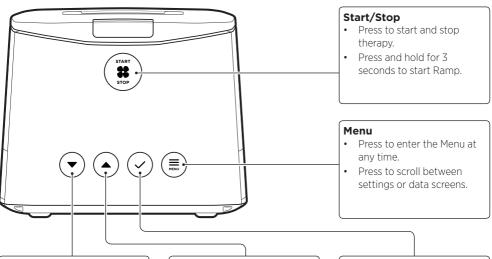
Modem Icon*

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 9.2 - Screen Icons Troubleshooting for more information.

* Not available in all models.

3.2 DEVICE CONTROLS



Down

- Press to decrease a comfort setting.
- Press to move between options in a setting.
- Press to show the "Humidity" setting at any time

υр

- Press to increase a comfort setting.
- Press to move between options in a setting.
- Press to show the "Humidity" setting at any time

ОК

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

3.3 STARTING THERAPY

1. Fit your mask.

Note: Refer to your mask's Use and Care Guide for more information on how to fit and remove your mask

2. Press Start/Stop **\$2** to begin therapy.

The screen below will appear:



3.4 STOPPING THERAPY

1. Remove your mask.

2. Press Start/Stop **\$2** 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:

Therapy Hours: The number of hours that you used your device last night.



Mask Leak: If your mask leak was "Normal" or "High" last night.



AHI (Apnea Hypopnea Index): The average number of airway breathing events (apneas and/or hypopneas) you had per hour last night.



For more information on viewing your therapy data, see section 4.1 – View Your Therapy Data on Your Device.

Note: The AHI screen may be restricted by your healthcare provider.

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.



Note: If SensAwake is "On" (see section 3.6.4 - SensAwake) then you don't need to start Ramp. The device will automatically reach your prescribed pressure when you fall asleep. However, if you feel the SensAwake pressure is too high, you can use Ramp.

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:

- Press Down ▼, Up ▲ or Menu ≡.
- 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:



- Press Menu = to scroll to the "Expiratory relief" setting.
- 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:



- Press Menu = to scroll to the "SensAwake" setting.
- 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).
- 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.

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.

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 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:

- 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 Bluetooth.
 - **Note**: You might need to refer to your mobile phone's user manual for specific instructions on how to turn on Bluetooth.
- 3. Open the SleepStyle App and follow the instructions on how to register an account.
- 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 Bluetooth 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.

How to change your Bluetooth setting:

If Bluetooth is "Off" on your device, there will be a line through the Bluetooth \$\frac{1}{2}\$ on your home screen:



To change your Bluetooth setting, follow these steps:

- From the home screen, hold Menu for 5 seconds
- Press Menu = to scroll to the 'Bluetooth' setting.



 Press Down ▼ or Up ▲ to change the setting. Your selection will flash to confirm your selection.

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 turned on at the power supply. Only your healthcare provider has access to this data.

Note: The cellular modem is not available in all models. To identify whether your SleepStyle device has a cellular modem, look for the modem icon on the front of your device. If your device has a cellular 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:

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

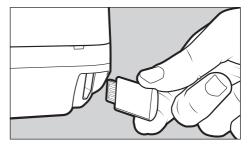


 Press **Down** or **Up** to change the setting. Your selection will flash to confirm your selection.

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 $\hat{\Psi}$ 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 Ψ 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 Ψ on screen.

⚠ Cautions

General:

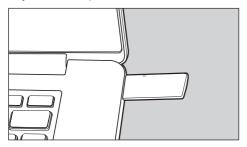
Only use the InfoUSB with the device. Use of any other USB drives may cause data corruption. Do not attempt to change the directories or view the data without software distributed or designed for use with the device.

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

When requested by your healthcare provider, 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.

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

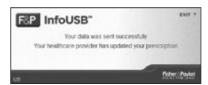
Upon detection of an InfoUSB in your computer, the message below will appear:



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, the confirmation message below 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.

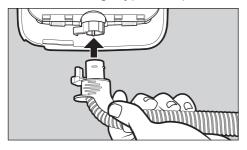
6. CARING FOR YOUR DEVICE

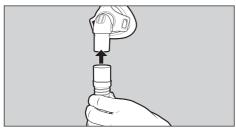
6.1 DISASSEMBLY FOR CLEANING

Breathing tube

ThermoSmart breathing tube

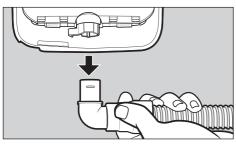
- 1. Hold the plastic connector and gently pull it away from the device.
- 2. Hold both the mask end of the tube and the mask swivel and gently pull them apart.

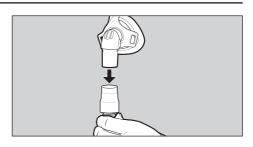




Standard breathing tube with elbow

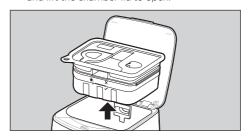
- Hold the elbow and gently pull it away from the device.
- 2. Hold both the mask end of the tube and the mask swivel and gently pull them apart.

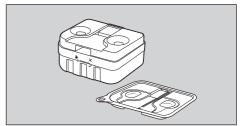


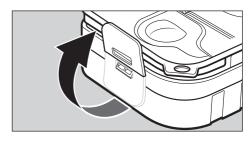


Water chamber and chamber seal

- 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.

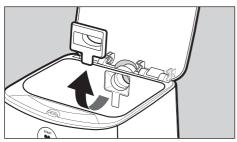






Outlet seal

- 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 Use and Care Guide 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.

Breathing tube

Note: The elbow on the standard breathing tube can remain attached when washing after each use.

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

Note: 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.

/ 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.

Water chamber and chamber seal

- Hand-wash the water chamber and chamber seal in a tub of warm, soapy water with a mild dishwashing detergent. Ensure that all visible soil is removed.
- Rinse the water chamber and chamber seal thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
- Repeat the rinsing process again, using clean water.
- Leave the parts to dry out of direct sunlight or heat before reassembling.

Note: 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.

Note: 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.

Outlet seal and elbow

- 1. Disconnect the elbow from the standard breathing tube.
- 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.
- Rinse the outlet seal and elbow thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
- Repeat the rinsing process again, using clean water.
- 5. Leave out of direct sunlight or heat before reassembling.
- Reconnect the elbow to the standard breathing tube.

Device

- Turn the device off at the power supply, then remove the power cord from the rear of the device.
- 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.

6.3 REASSEMBLY OF THE DEVICE

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

Breathing tube

ThermoSmart breathing tube

 Hold the end of the breathing tube with the electrical connectors and push it into the air outlet of the device

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

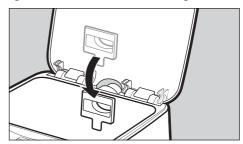
Holding the mask and the other end of the breathing tube, push the mask swivel firmly into the breathing tube.

Standard breathing tube with elbow

- 1. Hold the elbow end of the breathing tube and push it into the air outlet of the device.
- 2. Hold both the mask end of the breathing tube and the mask swivel, and push them together.

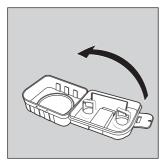
Outlet seal

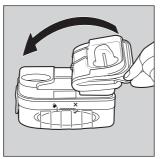
Hold the tab on the outlet seal and push it into the chamber housing inlet. Ensure the tab is sitting flat against the wall of the chamber housing.

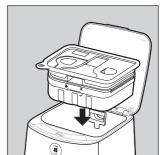


Water chamber and chamber seal

- 1. Close the chamber lid. Press the chamber tab down until it clicks into place.
- 2. 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 by pressing down in the finger holds. 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.

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.

6.4.1 Air filter

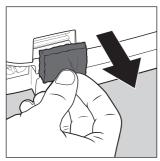
The air filter is located at the rear of the device. Replace the air filter at least once every 3 months, or more frequently if it becomes blocked with dirt or dust. To replace the air filter, please follow the instructions below.

⚠ Warnings

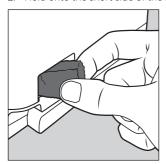
To avoid choking, or inhalation of a foreign object:

Do not use the device without the recommended air filter fitted. This will reduce dust or particles entering the device and breathing tube.

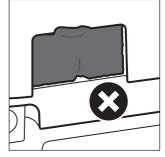
1. To remove, pinch the air filter with your fingers and pull it out of the device.



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

7.1 THINGS TO REMEMBER BEFORE YOU TRAVEL

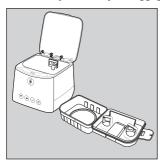
The device has a universal voltage feature that allows it to operate on any domestic AC mains voltage (between 100 and 240V AC). With the use of the appropriate pin/plug adapter the device can operate in most countries.

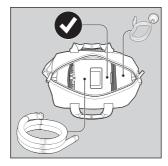
Below is a checklist of what to take with you when you travel:				
Power cord				
Air filter				
Outlet seal				
F&P SleepStyle Use and Care Guide				
Mask				
☐ Plug adapter				

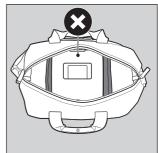
⚠ Cautions

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 MATRIX

Performance features	SleepStyle Auto	SleepStyle CPAP
Fully integrated humidifier*	•	•
Auto-Adjusting Pressure	•	
ThermoSmart Technology**	•	•
SensAwake	•	•
Expiratory relief	•	•
Central Sleep Apnea detection	•	•
Ramp	•	•
Auto-Altitude Adjustment	•	•
Leak Compensation	•	•
Efficacy reporting	•	•
Compliance reporting	•	•
F&P InfoUSB	•	•
Bluetooth wireless technology	•	•
Cellular modem*	•	•

^{*} Not available in all models.

^{**} In some countries, the ThermoSmart breathing tube needs to be purchased as an accessory to activate ThermoSmart.

Device model	SleepStyle Auto	SleepStyle CPAP
Australasia	SPSAAA/SPSABA	SPSCAA/SPSCBA
North America	SPSAAN	SPSCAN

8.2 SYMBOL DEFINITIONS

③	For safety reasons, refer to the instructions for use	REF	Catalogue number
<u> </u>	Caution	SN	Serial number
[]i	Consult instructions for use	LOT	Batch code
②	Do not use this device with supplemental oxygen	15_250	Humidity range
A	Fill with water here	2007	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
M	Date of manufacture	&	Regulatory Compliance Mark
\square	Date of shelf life expiry	Rx only	Prescription only
济	Type BF applied part	c us	UL Classified mark symbol
((*))	Non-ionizing electromagnetic radiation	X	Do not discard as regular waste
	Class II equipment		

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 ₂ O/hPa (in the unlikely event of fault conditions, pressure limited to < 30 cmH ₂ O)

Maximum flow rates					
CPAP pressure setting (cmH ₂ O)	4	8	12	16	20
Measured flow at patient connection port (L/min)	97	150	175	159	137

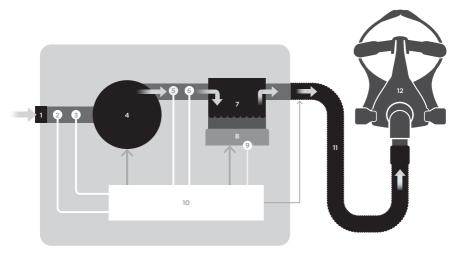
Dynamic pressure stability*							
	BPM ¹		Test pressure				
		4.0 cmH ₂ O	8.0 cmH ₂ O	12.0 cmH ₂ O	16.0 cmH ₂ O	20.0 cmH ₂ O	
Dynamic pressure stability	10						
(cmH ₂ O)	15	± 0.5		± 0.8			
	20						

¹ BPM - Breaths Per Minute

Static pressure stability*	
	Auto-adjusting and fixed pressure
Pressure change (cmH ₂ O) at connection port at a pressure setting of 10 cmH ₂ O	± 0.5

^{*}Pressure measurement including uncertainty: \pm (0.04cmH₂O + 0.026% of reading)

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		
Tested at 23 °C (73.4 °F) ambient temperature AH² (mgH₂O/L B¹		
With ThermoSmart breathing tube		
Humidity level 7	> 23	
Humidity level 5 > 18		
With standard breathing tube		
Humidity level 7	> 15	
Humidity level 5	> 10	

² AH - Absolute Humidity

³ BTPS - Body Temperature Pressure Saturated

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

Gas temperatures	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 {Ed 3.1}: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:	UMTS 3G: B1, B2, B5, B6, B8, B19	; Maximum power +23 dBm	
	GSM 2G: 850MHz/900MHz/1800	DMHz/1900MHz; Maximum power +33 dBm	
Bluetooth technology:	2402 - 2480 MHz; Maximum pov	wer +6 dBm, GFSK, σ/4-DQPSK, 8DPSK	
FCC compliance	digital device, pursuant to part 1st to provide reasonable protection installation. This device generate energy and, if not installed and use harmful interference to raguarantee that interference will a device does cause harmful interference be determined by turning that to try to correct the interference. Reposition or relocate the receiver increase the separation between the device into an orange of the receiver is connected.	 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 	
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 CONDITIONS

Ambient temperature	5 to 35 °C (41 to 95 °F)
Humidity	15 to 90% RH
Altitude	0 to 3,000 m (0 to 9,000 ft)

/ Cautions

General:

Only use the device within the operating conditions 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. Refer to section 8.6 - 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 mask, breathing tube, water chamber, and other spare parts according to local guidelines. Place the mask, breathing tube, and water chamber in a waste bag at the end of use and discard with normal waste.

8.8 SERVICING



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.

N 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	Possible cause	Solution
My therapy won't start, and there is no display on the display screen.	The power cord may not be plugged in correctly.	Push the power cord connector firmly to confirm it is inserted correctly into the power supply and into the rear of the device.
	The power cord may be damaged.	If damaged, stop using your device immediately and contact your healthcare provider for a replacement power cord.
	Has there been a storm?	Check your circuit breaker or fuse, and
	Has there been a power outage/ power surge?	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	There may be water in the blower, preventing it from starting.	Turn off at the power supply and unplug the device.
display screen.		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? If so, there may be a fault with your device or accessories.	Refer to section 9.3 - Error Messages on SleepStyle Screen, identify the error code and take the appropriate corrective action.
	No error message.	Turn the device off at the power supply, wait a few seconds then reconnect to power. If the problem continues, contact your healthcare provider.

Problem	Possible cause	Solution
The pressure is fluctuating or insufficient air is being delivered from the device.	Your mask may not be fitted correctly, causing leaks.	Ensure your mask is correctly fitted. Refer to your mask's Use and Care Guide for fitting instructions, or contact your healthcare provider.
	The air inlet filter is dirty or the air inlet has become blocked.	Replace the air filter. Remove any blockage from the air inlet.
	There may be water in the breathing tube.	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 or the chamber seal may	Ensure the water chamber is in the device.
	not be fitted to the water chamber correctly.	Refer to section 6 - Caring for Your Device for detailed instructions on assembly.
The device is noisy.	Air is leaking out of the device or	Make sure:
	breathing tube.	The device lid has been closed properly;
		The breathing tube and mask are connected correctly;
		There are no air leaks and condensation in the breathing tube.
	Noise changes while you breathe	The device adjusts the motor speed to maintain the correct pressure as you breathe in and out, this is normal behavior.
The heater-plate and/	This is normal and should not cause	concern.
or water chamber base is warm to the touch, even though the device isn't	The power supply is located directly underneath the heater-plate. In stand- by mode, it generates approximately 5 W of power. This may cause the feeling of warmth.	
being used.	The water chamber is also fully insulated by the device, which can cause heat to be retained.	
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.	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.

Problem	Possible cause	Solution
I don't think my humidifier is working.	The humidity level is incorrect.	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.	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 warming up.	The ThermoSmart breathing tube is not connected to the device correctly.	Remove the ThermoSmart breathing tube from the device and reconnect. Make sure that the electrical connectors click together with the ThermoSmart connection.
		When connected correctly, the ThermoSmart icon will appear on your home screen:
		F&P SleepStyle ⊚ † ∜ ₄d
	The humidity level is incorrect.	Check if the humidity level is above 0. See section 3.6 - Comfort Settings
		for more information on changing the humidity setting.

9.2 SCREEN ICONS TROUBLESHOOTING

Problem	Possible cause	Solution
The ThermoSmart icon has a line through it	There may be an error with the ThermoSmart breathing tube.	You will still be treated and get humidity, but it may not be optimal.
There is a gap where the ThermoSmart icon usually appears.	The ThermoSmart breathing tube may not be connected correctly.	Remove the ThermoSmart breathing tube from the device and reconnect. Make sure that the electrical connectors click together with the ThermoSmart connection.
		When connected correctly, the ThermoSmart icon will appear on your home screen:
		F&P SleepStyle
		If the problem persists, please consult your healthcare provider.
	You may be using a standard breathing tube.	Consult your healthcare provider for more information.

Problem	Possible cause	Solution
The InfoUSB icon has a line through it 🕻	There may be an error with the InfoUSB.	You will still be treated, but your therapy data may not be recorded to the InfoUSB.
There is a gap where the InfoUSB icon usually appears.	The InfoUSB may not be connected correctly.	Remove the InfoUSB from the InfoUSB port and reinsert. When connected correctly, the InfoUSB icon will appear on your home screen: Fap SleepStyle
The Bluetooth icon has a line through it	Bluetooth is turned "Off" on your device.	You will still be treated, but your therapy data may not be available on
mile throughter,	There may be an error with the Bluetooth setting.	your SleepStyle app. Refer to section 4.2 - View your therapy data on the SleepStyle App or website for instructions on changing your Bluetooth setting. Turning Bluetooth off and on again on your mobile device may resolve connectivity issues. If the problem persists, please consult your healthcare provider.
The modem icon has a line through it	Modem is turned "Off" on your device.	You will still be treated, but your therapy data may not be uploaded to
	The modem has failed to connect.	your healthcare provider. Refer to section 5.1 – Modem for instructions on changing your modem setting. Turning modem off and on again on
		your SleepStyle device may resolve connectivity issues.
		If the problem persists, please consult your healthcare provider.
There is a gap where the modem icon usually appears.	Modem is not available on your device model.	Consult your healthcare provider for more information.

9.3 ERROR MESSAGES ON SLEEPSTYLE SCREEN

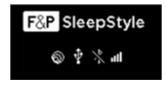
If a fault is detected with your device or its accessories, an error message will appear on the display screen. Identify the error code in the ranges specified below and follow the appropriate corrective action. If the error persists or reoccurs, please consult your healthcare provider. Do not attempt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

Error codes between	Description	Corrective action
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.	Turn the device off at the power supply. Wait 15 seconds, and then turn the device back 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.
		Turn the device off at the power supply. Wait 15 seconds, and then turn the device back on at the power supply to restart the device.
510 or 512	There may be a problem with your ThermoSmart breathing tube.	You will still be treated and get humidity, but it may not be optimal.
		Try reconnecting your ThermoSmart breathing tube.
		When connected correctly, the ThermoSmart icon will appear on the home screen:
		F&P SleepStyle
		⊕ † ½ ad
		Turn the device off at the power supply. Wait 15 seconds, and then turn the device back on at the power supply to restart the device.
500-599 (excluding 510	The ThermoSmart breathing tube may have been disabled.	You will still be treated and get humidity, but it may not be optimal.
or 512)		Turn the device off at the power supply. Wait 15 seconds, and then turn the device back on at the power supply to restart the device.

9.4 SLEEPSTYLE APP TROUBLESHOOTING

Try the following steps if you have trouble connecting to, or receiving data from, your SleepStyle device:

- 1. Ensure that your mobile device has Bluetooth turned on and is close to your SleepStyle device.
- 2. Check that Bluetooth is "On" on your SleepStyle device. If Bluetooth is "Off", there will be a line through the Bluetooth icon on your home screen:



If Bluetooth is "Off", see section 4.2 - View your therapy data on the SleepStyle App or website for instructions on changing your Bluetooth setting.

- 3. Open the Bluetooth settings page on your mobile device. Try turning Bluetooth off and then back on again, then check that your SleepStyle device appears in the paired devices list. If it is not currently connected, try tapping on it to connect.
- 4. Turn the power to your SleepStyle device off for 10 seconds and then turn it back on. Re-launch the app, ensuring that your mobile device is near your SleepStyle device*.

If you have a case or cover on your mobile device, try removing this and repeating the above steps. Ensure that other potential sources of radio interference are minimized or removed.

If you have tried the above steps and still cannot connect, try deleting the pairing on your SleepStyle device and starting again:

- 5. Open the Bluetooth settings page on your mobile device. Find your SleepStyle device in the paired devices list. Delete the pairing.
- 6. On your SleepStyle device, hold **Menu** = for 5 seconds.
- 7. Press Menu = to scroll through the screens until you reach the "Clear all paired devices?" setting.



8. Press **Down ▼** or **Up** ▲ to select Yes



9. Press **OK** \checkmark to confirm the selection. Wait for the following screen to appear:



 Open the Bluetooth settings page on your mobile device and search for new devices. Your SleepStyle should be shown in the list of discovered devices. Select "SleepStyle" and follow the instructions on your mobile device.

If the problem continues, please contact your healthcare provider.

*Approximately 30 cm (1 ft).

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