TRANSCEND®

Sleep Apnea Therapy
User Manual

Somnetics®

Notices

Revised	Sleep Apnea Therapy User Manual 103084 Rev F
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About this user manual

Note This user manual is designed to be duplex-printed (printed on both sides of each sheet). If not printed in this manner, you will find blank pages in your printout.

Note For purposes of this manual, some software screen images may differ from the actual screen display. This is only for clear printing and on-screen display of this manual.

Precautions when using a computer with Transcend

The following precautions are cited for the safety of the patient and operator of the computer as required to meet IEC 60601-1-1 safety regulations.

Definitions A computer compliant with 60950-1 safety standards is one that complies with UL 60950-1 or IEC 60950-1 safety standards.

- Do not plug any devices into the Transcend USB port other than a computer that is compliant with 60950-1 safety standards. Attaching any other device to the Transcend USB port may damage Transcend and may not be safe for the user.
- In order to reduce the risk of leakage currents, use an isolation transformer which is IEC 60601-1 approved to power your computer.
- Do not plug your computer compliant with 60950-1 safety standards or your Transcend into a multiple portable socket outlet (i.e. power strip).
- When using your computer compliant with 60950-1 safety standards, follow the manufacturer’s cleaning instructions.
- When using your computer compliant with 60950-1 safety standards, follow the manufacturer’s instructions for conducting preventative maintenance.
- Do not attach Transcend USB port to your computer compliant with 60950-1 safety standards during preventative maintenance of your computer.
- Do not touch your computer compliant with 60950-1 safety standards and any exposed metal on Transcend or on Transcend cables at the same time.
- Do not touch any exposed metal on your computer compliant with 60950-1 safety standards or exposed metal on connectors or cables.
- For clinicians, do not simultaneously touch the computer compliant with 60950-1 safety standards and the patient.
- Do not use computers that have internal voltages that are accessible without the use of tools in order to gain access to such voltages.

Contents

Introduction

The Transcend Sleep Apnea Therapy System delivers positive pressure from 4 to 20 cm H_2O to the patient as prescribed by the clinician. The therapeutic pressure is continuous. Buttons and LED lights facilitate control and provide operational feedback. A DC power jack, a USB port, and a data card receptacle are also incorporated into the CPAP. The CPAP device is attached to a removable headgear assembly for head-mounting and an interface for therapy delivery.

- Battery-operated – no wires
- Self-contained
- Short breathing tube

Indications for use

The Transcend Sleep Apnea Therapy System is intended for the therapy of adults over 66 pounds (30 kg) with obstructive sleep apnea (OSA). The device delivers continuous positive airway pressure (CPAP), which prevents the collapse of the upper airway, thereby preventing obstructions that can interfere with spontaneous breathing.

Contraindications

The Transcend Sleep Apnea Therapy System is contraindicated in patients with the following conditions:

- Bullous lung disease
- Pathologically low blood pressure
- Pneumothorax or pneumomediastinum.
- Pneumocephalus has been reported in some users using nasal CPAP.

Caution should be used when prescribing CPAP for susceptible users such as those with any of these conditions:

- cerebral spinal fluid (CSF) leaks
- abnormalities of the cribriform plate
- a prior history of head trauma
- pneumocephalus

Precautions for use

This section describes the warnings and cautions associated with use of the Transcend Sleep Apnea Therapy System. The following guidelines apply to this document:

Warning	Indicates the possibility of serious injury or death to yourself or others.
Caution	Indicates the possibility of minor injury or damage to the equipment.
Note	Indicates a tip, explanation or feature to aid in understanding or efficient operation of the device.

Warnings

- This device is not intended for water intake and therefore should not be exposed to environmental conditions where the system may get wet.
- This device is not intended for life support.
- The Transcend Sleep Apnea Therapy System must be set up and adjusted by a trained CPAP provider before being used for therapy ramp and pressure.
- The air temperature produced by this device can be as much as 10ºF higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90ºF (32ºC).
- Do not block or otherwise obstruct the exhalation ports of the interface. Follow the instructions for your interface.
- This equipment is not suitable for use with oxygen or in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.
- Use of accessories other than defined in this manual is potentially unsafe.
- The CPAP system is only to be used with the supplied and recommended accessories. Use of accessories not recommended may result in increased electromagnetic emissions or decreased electromagnetic immunity of the CPAP system.
- The CPAP system is not defibrillation proof.
- This Transcend Sleep Apnea Therapy System is intended for single patient use.

- The device should be used only with masks and connectors recommended by Somnetics or with those recommended by the health care professional or respiratory therapist. A mask should not be used unless the device is turned on and operating properly. The exhalation port(s) associated with the mask should never be blocked. Explanation of the Warning: The device is intended to be used with special masks or connectors that have exhalation ports to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask exhalation port. However, when the device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.

Cautions

- Federal law (United States) restricts this device to sale by or on the order of a physician.
- Power the CPAP system only from the Somnetics-supplied power supply, mobile power adaptor, or batteries. See **Appendix: Part numbers**.
- Use only interface devices approved by Somnetics for use with the Transcend Sleep Apnea Therapy System to be assured of proper leak flow rates. You may find a list at http://www.mytranscend.com/.
- Discontinue use of the CPAP device and contact your physician if respiratory or skin irritations occur.
- Do not introduce liquids or objects into the CPAP device's air inlet/outlet connector.
- Inspect the power cord for signs of wear or damage before each use. Replace the power cord if necessary.
- Somnetics recommends replacing the output hose every three months of use.
- To protect the environment, some parts and accessories of the CPAP system must be disposed of in accordance with local regulations.
- Use only those accessories provided or recommended by Somnetics
- Dispose of batteries properly.

Symbols

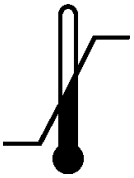
Attention: consult accompanying documents

Type BF Applied Part

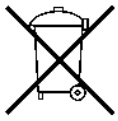
Classified

ETL Seal of Approval demonstrating quality, safety and professional manufacturing of medical product

Intertek



Upper and lower temperature limits



Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC. – Waste Electrical and Electronic Equipment (WEEE)

Consult instructions for use

Upper and lower humidity limits

Non-condensing

Components of the Transcend Sleep Apnea Therapy System

When you receive the Transcend Sleep Apnea Therapy System package, unpack all items from the travel bag and inspect them to ensure they were not damaged during shipment. Report any missing or damaged items to the home healthcare provider that provided the CPAP device to you.

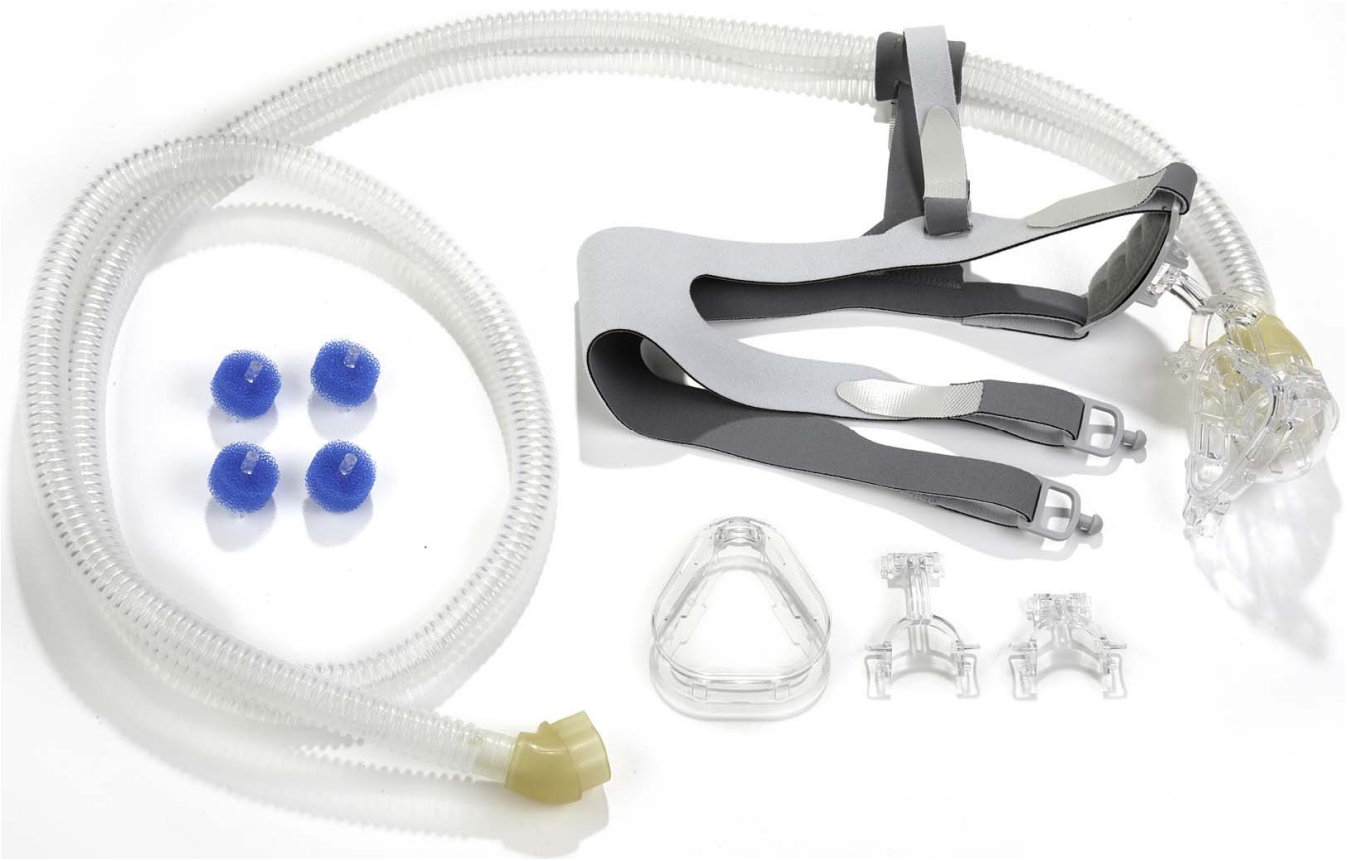
Begin by inspecting all items listed below. Report any damaged or missing items to the home healthcare provider that provided the device to you.

Note Components of the Transcend Sleep Apnea Therapy Starter System, Transcend H_6B Waterless Humidification System, and H_9M Waterless Humidification System are not backwards-compatible with the old Transcend Sleep Apnea Therapy system (PN: 503001).

Transcend Sleep Apnea Therapy System Starter Package

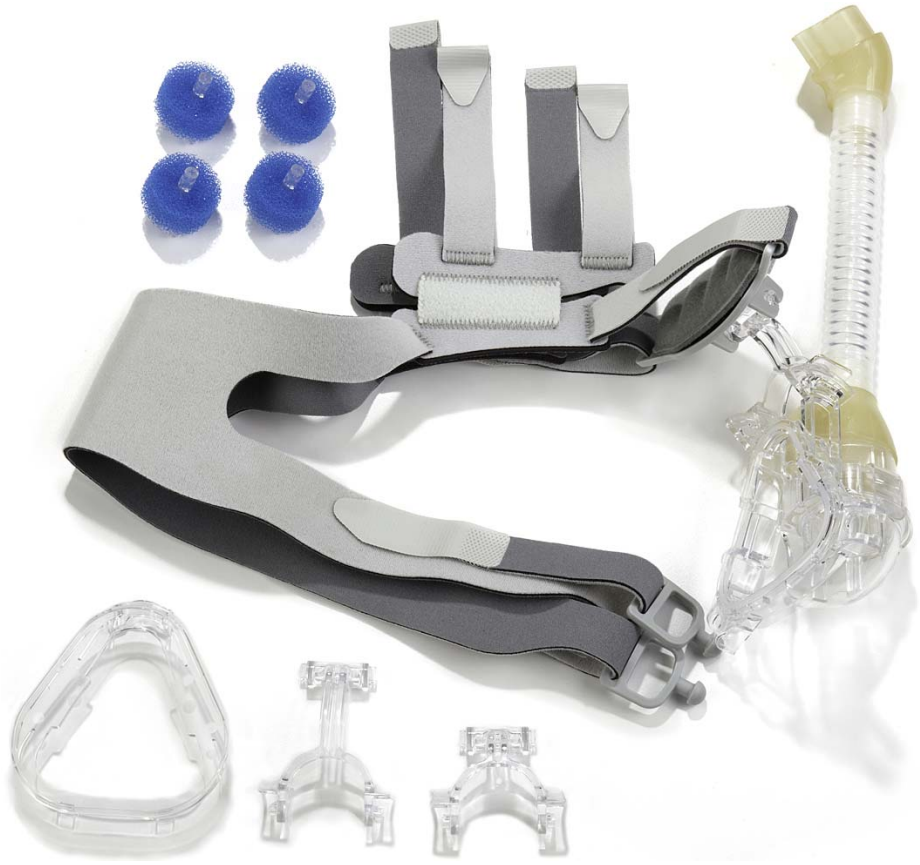
- Transcend CPAP
- Standard 6-foot hose- not HME compatible
- Universal hose adaptor
- Universal AC power supply
- Travel bag
- CD, DVD
- Quick start guide

Transcend H_6B Waterless Humidification System



- Mask shell assembly
- Adjustable arm bars (S,M,L)
- Forehead pad & holder
- Adaptor ring
- Headgear
- Transcend H_6B hose
- 4 HMEs

Transcend H_9M Waterless Humidification System



- Mask shell assembly
- Adjustable arm bars (S,M,L)
- Forehead pad and holder
- Adaptor ring
- Headgear
- Transcend H_9M hose
- 4 HMEs

What's not included (all sold separately)

- A nasal seal
- Transcend mobile power adaptor
- Transcend P_4 Overnight Battery System
- Transcend P_8 Multi-night Battery System
- Docking station
- USB cord

Description of CPAP system components

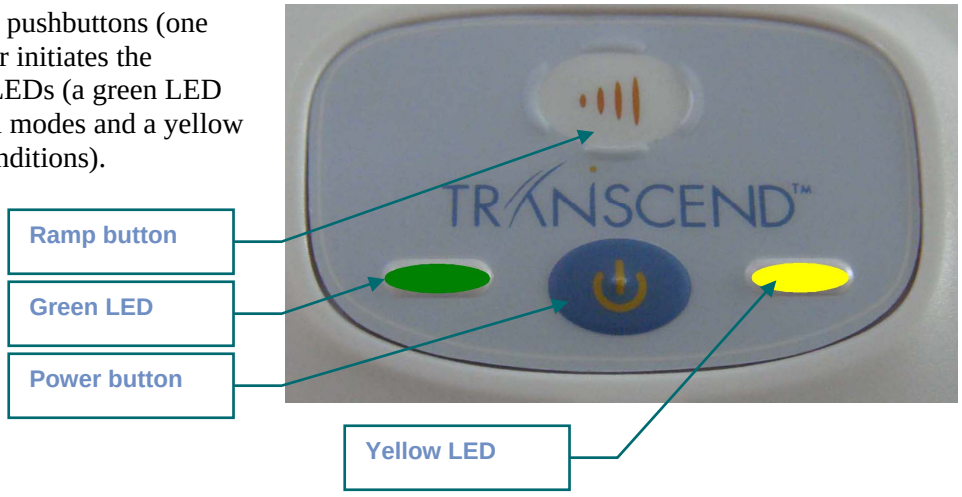
This section presents the following topics::

CPAP device

The CPAP device contains all of the electromechanical hardware necessary to generate and regulate CPAP therapy for delivery to the interface. An external power source connects to the CPAP.

Control panel

The CPAP control panel has two pushbuttons (one activates the blower and the other initiates the pressure ramp feature) and two LEDs (a green LED for indicating normal operational modes and a yellow LED used for indicating fault conditions).



Power jack and USB port

The power jack accepts the barrel plug of the output cable from a DC power source to operate the CPAP. The range of DC input voltage acceptable to the CPAP is 14VDC to 19VDC.

A variety of power sources may power the CPAP. When using a wall outlet, the AC power supply connects to the CPAP.

An optional mobile power adaptor connects to a DC power outlet when auto, marine, or other sources of power are accessible.

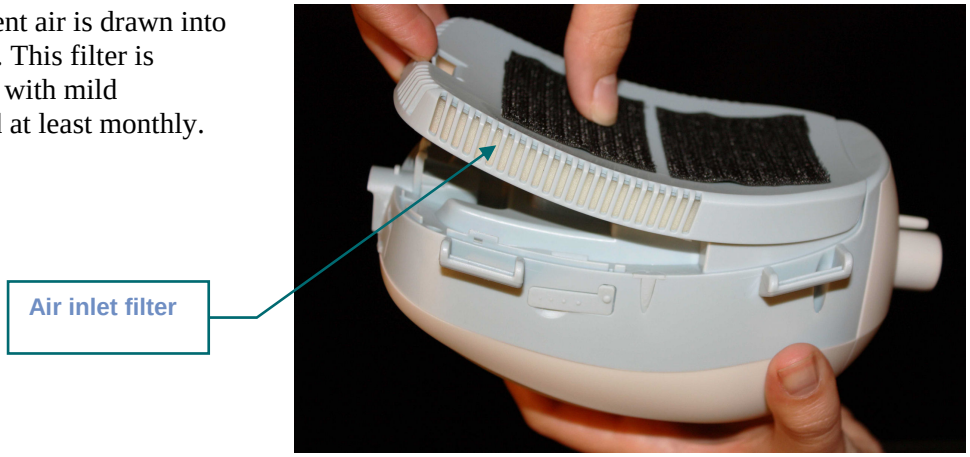
Optional battery packs are available to power the CPAP.

USB port

A mini-AB USB port is provided for direct data exchange between the CPAP and a computer via a USB data cable. This interface allows the clinician to configure the CPAP for the patient's prescription and allows the patient to view and email therapy data to the clinician.

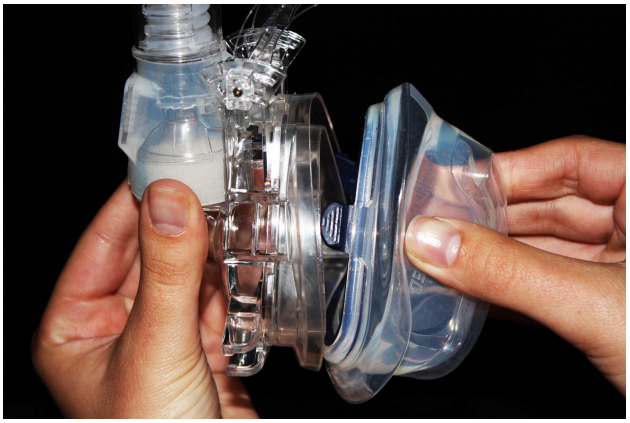
Data card receptacle and air inlet filter

During therapy operation, ambient air is drawn into the CPAP through an inlet filter. This filter is washable and should be washed with mild dishwashing detergent and dried at least monthly.



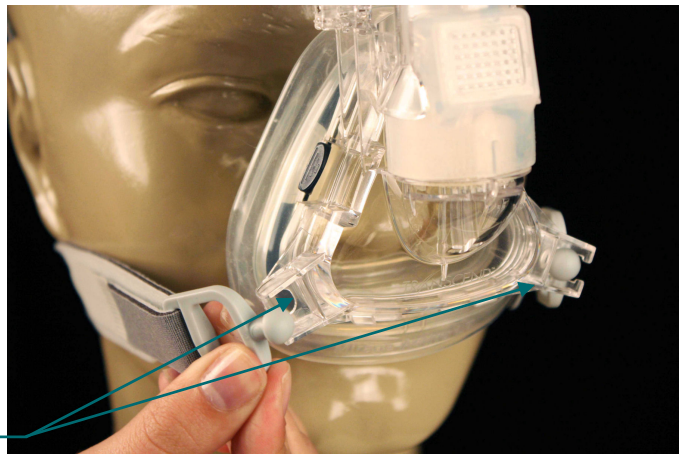
Interface for Transcend H_6B and H_9M Waterless Humidification Systems

The interface connects the therapy pressure delivered by the CPAP device to the patient. The interface includes a hard plastic shell and a nasal seal (purchased separately from your homecare provider) that seals the pressurized interface against the face. The shell accepts the air supply tube from the CPAP device and has a port that the CPAP's pressure sensing tube attaches to; this tubing connection permits the sensing of air pressure within the interface shell when it is sealed against the patient's face. The interface also has a vent for discharge of exhaled air.



The plastic notches on the air supply tube must line up with the slots on the HME housing and the pressure sensing tube must fit properly over the pressure sensor port on the HME housing.

Headgear for Transcend H_6B and H_9M Waterless Humidification Systems



Transcend H_6B Humidification System headgear

The Transcend H_6B humidification system headgear holds the Transcend interface and H_6B hose in place with a set of straps and ball clips. The interface headgear should be adjusted so that the forehead pad rests just above the brow line and the mask fits snugly against the face. A fold-over hook and loop strap secures the H6B hose on top of the head once the interface headgear is properly fitted.

Transcend H_9M Humidification System headgear

The Transcend H_9M humidification system headgear allows the CPAP to be worn on the head. It holds the CPAP and interface in place with a series of straps and ball clips. The interface headgear should be adjusted so that the forehead pad rests just above the brow line and the mask fits snugly against the face. Once lying down, the headgear should be readjusted, so that the CPAP is allowed to move slightly without breaking the mask seal.

Assembling the Transcend CPAP System

The interface connects to the CPAP via the air supply tube. The CPAP has a port that the air supply tube attaches to; the other end of the tube attaches to a mating fitting on the interface. It is important that the pressure sensor line is connected properly to the pressure sensor ports on the CPAP and the interface. The procedures for connecting the Transcend CPAP system depend on which package you purchase. This section presents the following topics:

Assembling the Transcend Sleep Apnea Therapy Starter System

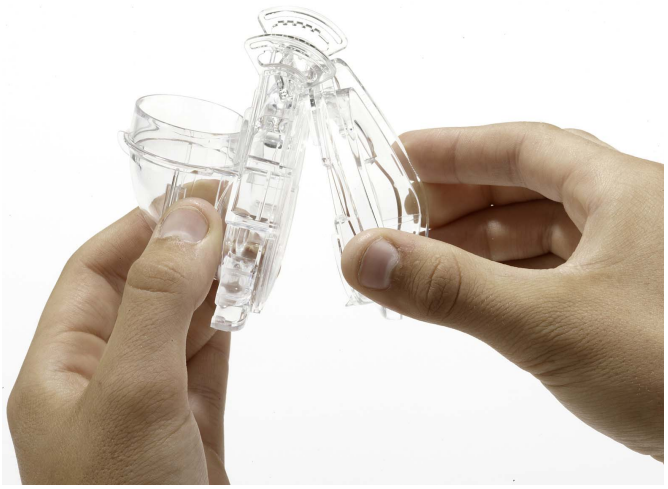
Follow these steps to assemble the Transcend Sleep Apnea Therapy Starter System:

1. Attach the universal hose adaptor to the 6-foot hose.
2. Then attach the universal hose adaptor to the CPAP.
3. Attach the interface to the other end of the hose.
4. Plug the power supply into the CPAP.
5. Connect power supply to a power source.

Assembling the Transcend H_6B Waterless Humidification System

Follow these steps to assemble the Transcend H_6B waterless humidification system:

1. Attach the adaptor ring to the mask shell. Connect the top clip first; then connect the bottom clips. Both must click firmly into place.



2. Clip the nasal seal into the adaptor ring.

3. Connect the adjustment arm bar of the appropriate size to the mask shell by squeezing the sides of the arm until it fits into place, as shown.

4. Slide the arm bar into the forehead piece.

5. Attach the headgear to the interface and connect the forehead pad to the forehead piece.

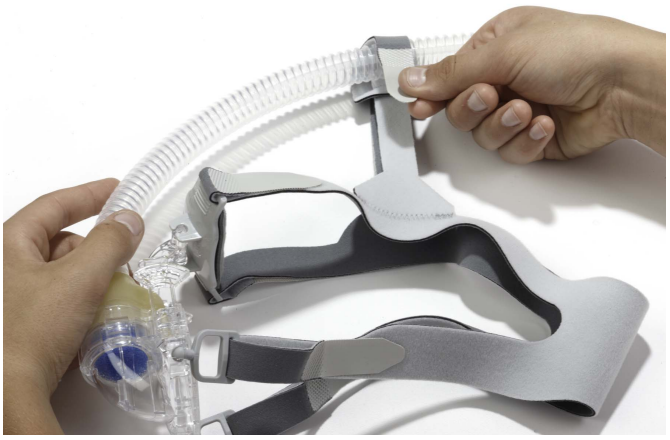
6. Connect top headgear strap through the slot on the side of the headgear.

7. Insert the heat moisture exchanger (HME) in to the HME cartridge, refer to **Replacing the HME**, page 38.

8. Connect the Transcend H_6B hose to the mask shell.

9. Secure the Transcend H_6B hose to the headgear using the fold over hook and loop strap.

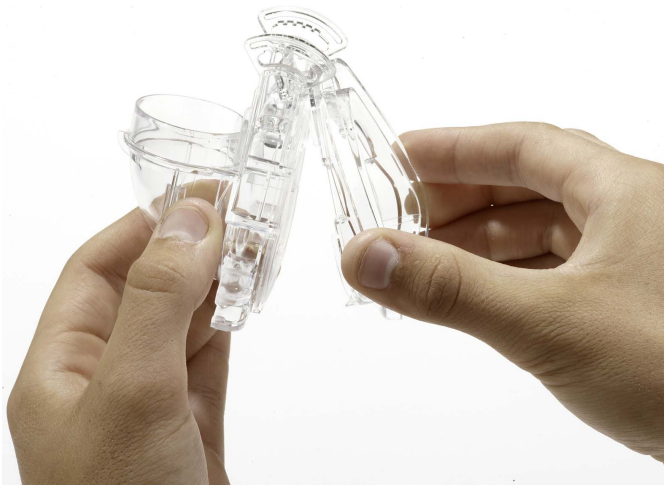
10. Connect the Transcend H_6B hose to the CPAP.



Assembling the Transcend H_9M Waterless Humidification System

Follow these steps to assemble the Transcend H_9M Waterless Humidification System:

1. Attach the adaptor ring to the mask shell. Connect the top clip first; then connect the bottom clips. Both must click firmly into place.

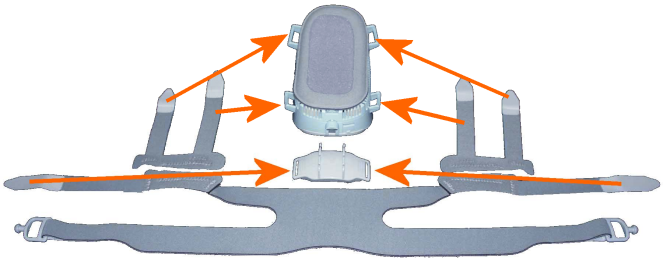


2. Clip the nasal seal into the adaptor ring.

3. Connect the adjustment arm bar of the appropriate size to the mask shell by squeezing the sides of the arm until it fits into place, as shown.

4. Slide the arm bar into the forehead piece.

5. Attach the headgear to the CPAP as shown.



6. Attach the interface to the remaining headgear straps and place the forehead pad on the forehead piece.

7. Insert the heat moisture exchanger (HME) into the HME cartridge, refer to **Replacing the HME**, page 38.

8. Connect the Transcend H_9M hose to the mask shell.
9. Connect the Transcend H_9M hose to the CPAP.

Fitting the Transcend H_6B and Transcend H_9M Waterless Humidification Systems

This section presents the following topics:

Transcend H_6B Waterless Humidification System

1. Put on the interface and headgear without the hose attached. The rear headband sits at the nape of the neck.
2. Fit the mask so the forehead pad rests just above the brow line.
3. If the mask does not fit so the forehead pad rests just above the brow line, change out the arm bar to the appropriate size. Slide the arm bar out of the forehead piece then remove the arm bar by pinching the sides near the mask to release it from the slide adjustment. Select another size arm bar and attach to the slide adjustment and forehead piece.

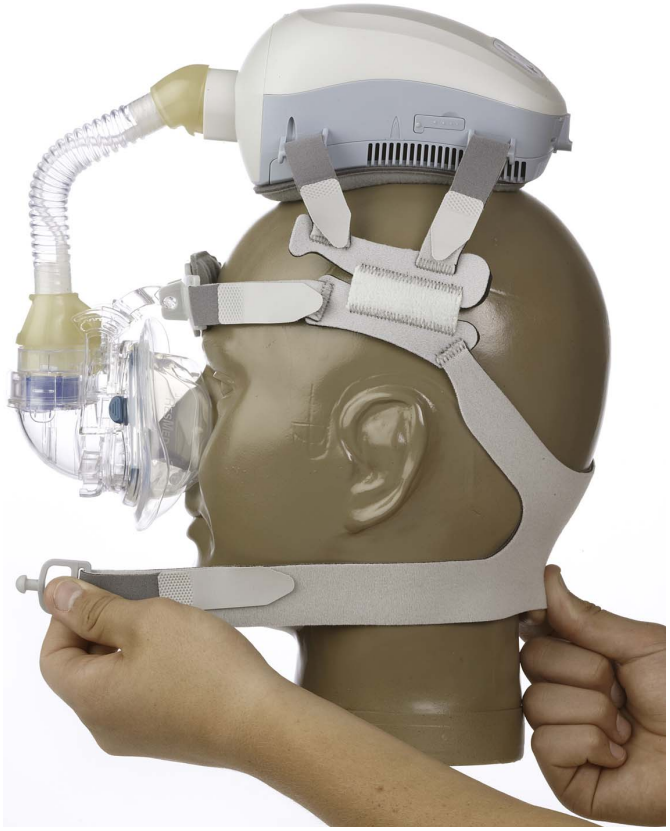
4. Gently squeeze the sides of the arm bar to slide the closer to or mask further away from the face so that it fits comfortably against the nose.

5. Connect the headgear to the interface by inserting the ball clips into the notches on mask shell.
6. Adjust the headgear straps until the interface feels secure.

7. Attach the Transcend H_6B hose to the interface then attach the hose to the headgear with the fold over hook and loop strap.
8. Attach the other end of the hose to the CPAP.

Transcend H_9M Waterless Humidification System

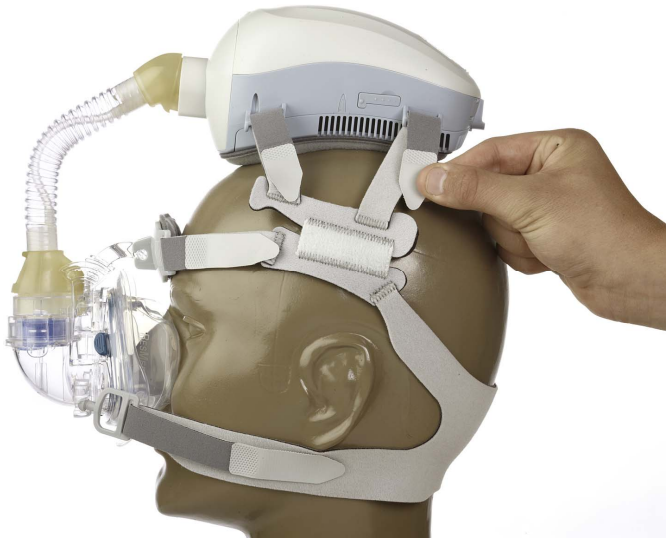
1. Once the Transcend H_9M Waterless Humidification System has been completely assembled , place Transcend on the head so that the rear head band fits at the nape of the neck.
2. Fit the mask so the forehead pad rests just above the brow line.



3. If the mask does not fit so the forehead pad rests just above the brow line, change out the arm bar to the appropriate size. Slide the arm bar out of the forehead piece, then remove the arm bar by pinching the sides near the mask to release it from the slide adjustment. Select another size arm bar and attach to the slide adjustment and forehead piece.
4. Connect the bottom straps of the headgear to the interface by inserting the ball clips into the notches on mask shell.

5. Gently squeeze the sides of the arm bar to slide the mask further from or closer to the face, so that it fits comfortably against the nose.
6. Adjust the headgear straps until the interface feels secure.

7. Once the interface is properly fitted, slightly tighten the top headgear straps that connect to the CPAP so that you may lie down.
8. Make sure that the rear headband is still seated at the nape of the neck.
9. Adjust the interface straps or mask adjustments as necessary so the interface creates a complete seal against the face. The interface should feel secure while lying down, but the CPAP will shift slightly with movement of the head.



Powering the CPAP

The Transcend Sleep Apnea Therapy System offers three choices for powering your CPAP device:

- Using the universal AC power supply (page 27)
- Using the Transcend P4 or P8 battery systems (page 28)
- Using the mobile power adaptor (page 32)

Using the universal AC power supply

The Transcend Sleep Apnea Therapy System includes a universal AC power supply adaptor. It provides 19VDC for powering the CPAP device. A detachable power cord connects to the AC line (100-240VAC, 50/60Hz).

Note Use only the Somnetics-supplied AC power supply. For non-US power systems, use a plug adaptor (not a power-converter).

1. Attach the AC power cord to the power supply.
2. Insert the AC power cord plug into AC line power wall outlet.
3. Insert the barrel connector of power supply into the power jack on the back of the CPAP.
4. Ensure the CPAP power-up LED flash sequence completes and the LEDs remain off afterwards; this indicates that power is being supplied to the CPAP and that the CPAP has successfully entered standby mode.

Note Make certain that the cables are securely connected to the power supply and to the power jack on the back of the CPAP. It may be necessary to unplug the cables and reconnect to ensure a good connection.

Using the Transcend P_4 or P_8 battery systems

The battery is an optional power source for Transcend. Connect the battery to Transcend and ensure the CPAP power-up LED flash sequence completes and the LEDs remain off afterwards. This indicates that power is being supplied to the CPAP and that the CPAP has successfully entered standby mode.

Note For peak performance, Somnetics recommends keeping the power supply or mobile adaptor connected to the battery even after the battery is fully charged (the green LED is illuminated).

Note The P_4 battery system is not recommended for therapy pressures of 15 or greater.

Note The P_8 battery system is not recommended for therapy pressures of 19 or greater.

Using the optional Transcend P_4 Overnight Battery System or P_8 Multi-night Battery System with AC line power

Note Fully charge the battery before first use as indicated by the LED turning from yellow to green. Charge time may take as much as five hours for a P_4 Overnight Battery System or eight hours for a P_8 Multi-night Battery System.

Note If an electrical outlet is available, use it. This will charge the battery and allow for maximum use when AC line power is not available, such as during a power outage. The CPAP device switches automatically to battery power in such events.

Note To charge the battery without the CPAP device attached, connect the power supply to the battery.

1. Insert the barrel plug from the universal AC power supply into the battery.
2. Insert the barrel plug of the battery into the Transcend ™ power jack so that the plug and cord face upward.
3. Plug the AC power supply plug into AC line power.

Using the Transcend P_4 Overnight Battery System or P_8 Multi-night Battery System with the mobile power adaptor

Note If a power receptacle for the mobile power adaptor is available, use it. This will charge the battery and allow for maximum use while traveling.

Note To charge the battery without the CPAP device attached, connect the mobile power adaptor to the battery pack.

1. Insert the barrel plug from the mobile power adaptor into the battery.
2. Insert the barrel plug of the battery into the Transcend power jack so that the plug and cord face upward.
3. Insert the second mobile power adaptor cable into the mobile power receptacle.

Explanation of the Transcend P_4 Overnight Battery System or P_8 Multi-night Battery System LED lights

- Red LED light: Signifies a fault with the battery. Do not use or charge. Contact the home healthcare provider that provided the battery to you for a replacement.
- Yellow LED light: The battery is charging.
- Green LED light: The battery is fully charged.

Note The battery will show a red LED light briefly when it is first plugged in.

Note The battery will show a yellow or green LED light when it is used with an additional power source (AC power supply or mobile power adaptor) to power Transcend.

Note The battery will show no LED light when it is used as the sole power source to power Transcend.

Charging the Transcend P_4 Overnight Battery System or P_8 Multi-night Battery System

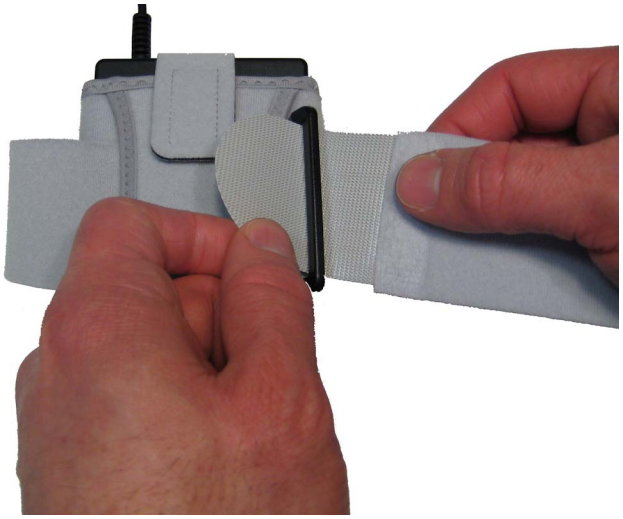
Note Battery life varies depending on the pressure setting and breathing patterns.

- Charge the battery fully before the first use.
- For maximum performance, Somnetics recommends keeping the power supply or mobile power adaptor connected to the battery pack even after it is fully charged.

Using the chest or arm strap with a Transcend P_4 Overnight Battery System or P_8 Multi-night Battery System

Insert the buckle through the strap loop of the battery pouch with the Velcro facing the battery.

With the buckle facing outward, wrap the strap around the chest or arm and thread the end of the strap through the buckle.



Continue to pull the strap through the buckle and secure the Velcro to the strap. Adjust as needed for a comfortable fit.

Using the mobile power adaptor

The Transcend Sleep Apnea Therapy System may be powered with an optional 12VDC mobile power adaptor. The mobile power adaptor is supplied with two cables: one to connect to your CPAP, and the other to connect to a mobile power receptacle (e.g. 12VDC automotive/cigarette lighter).

Note Use only the Somnetics-supplied mobile power adaptor.

1. Connect both of the cables to the base of the mobile power adaptor.
2. Insert the 12VDC connector into the 12VDC mobile power receptacle (e.g. cigarette lighter).
3. Insert the barrel connector of the mobile power adaptor's output cable to the power jack of the CPAP.
4. Ensure the CPAP power-up LED flash sequence completes and the LEDs remain off afterwards; this indicates that power is being supplied to the CPAP and that the CPAP has successfully entered standby mode.

Note Make certain that the cables are securely connected to the power adaptor and to the power jack on the back of the CPAP. It may be necessary to unplug the cables and reconnect to ensure a good connection.

Using the CPAP

The control panel of the CPAP has two pushbuttons (one activates the blower and the other initiates the pressure ramp feature) and two LEDs (a green LED for indicating normal operational modes and a yellow LED for indicating fault conditions). CPAP operational status is displayed by LED illumination states.

When a power source is connected to the CPAP, the LEDs on the control panel initially flash the yellow LED once followed by three quick flashes of the green LED. During therapy delivery, the LEDs remain off to avoid disturbing the patient and/or bed partner.

Note If the CPAP loses power while delivering therapy, it will resume delivering therapy as soon as power is restored and you press the power button (the CPAP will repeat the power-up LED flash sequence prior to the blower restarting).

Standard user modes

Normal operation consists of four modes:

Off When the device is not connected to a power source, the device is off. Control panel LEDs are both off.

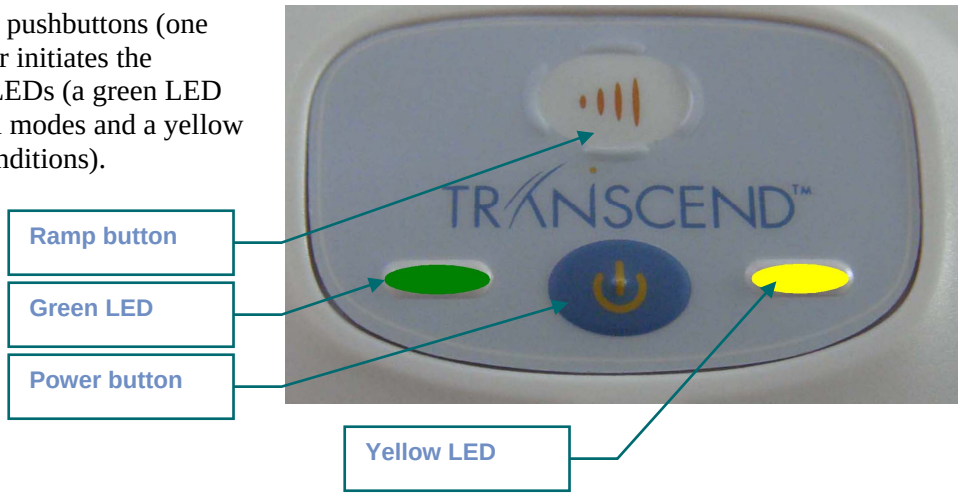
Standby When power is initially applied to the device, the device enters standby mode (after a brief power-up sequence denoted by LED flashes). Standby mode is also initiated by pressing the power button when the device is in on mode or if the device is removed from the head while in on mode.

On The blower is on and regulated CPAP therapy pressure is being generated. The LEDs remain off. The on mode is initiated by pressing the power button when the device is in standby mode and being worn by the patient.

Drying Hold the **Ramp** button down and press the **Power** button to put the device into drying mode, the blower turns on at a relatively low speed that is not pressure-regulated for 30 minutes. The LEDs remain off.

Starting therapy

The CPAP control panel has two pushbuttons (one activates the blower and the other initiates the pressure ramp feature) and two LEDs (a green LED for indicating normal operational modes and a yellow LED used for indicating fault conditions).



1. Ensure that Transcend is completely connected to a power source and is in standby mode (when power is initially applied to the device, it enters Standby mode after a brief LED power-up flash sequence).
2. Press the power button to turn Transcend on. Air flow will begin as the blower delivers your prescribed pressure.

Using the ramp function

The ramp feature acclimates you to air flow by starting at a lower pressure and gradually increasing to your prescribed pressure setting as you fall asleep. The minimum ramp pressure and ramp time are set by your clinician. To accelerate the rate of the gradual pressure increase, hold the ramp button down until you reach a comfortable pressure. The device will continue in ramp mode until it reaches your prescribed therapy pressure.

1. Be sure Transcend is turned on; if not, press the power button.
2. Adjust your mask to ensure there are no leaks.
3. Press the ramp button (top button). The pressure will drop to a reduced level, set by your clinician, and will gradually increase over a preset amount of time until it reaches your prescribed therapy pressure.

Note Momentarily pressing the Ramp button during ramped pressure delivery will not affect the pressure delivered. If you wish to stop the gradual pressure increase of the ramp function you must turn off the device. The next time the blower is turned on it will deliver the prescribed therapy pressure.

Note Pressing and holding the Ramp button during ramped pressure delivery will accelerate the rate of gradual pressure increase. When the ramp button is released, the pressure will start from the pressure attained upon release of the Ramp button and the rate of increase from that pressure will return to its normal increasing pressure rate. This method can be used to quickly increase the initial ramp pressure.

Note In the event of power loss during ramp, the CPAP will resume at the full prescribed pressure as soon as power is restored.

Ending therapy

To end the delivery of CPAP therapy while the blower is on, press the Power button to deactivate the blower.

If the blower is off while the power is applied, the device is in standby mode. It is recommended that you initiate drying mode function to clean the Transcend interior after completing each therapy session.

Drying mode

When your therapy session is complete, put the CPAP device in drying mode by holding the Ramp button down and pressing the Power button.

The blower then operates at a relatively low speed without pressure regulation. This allows the air path through the output hose and the interface to be flushed with fresh air and removes traces of moisture from the CPAP interior. After 30 minutes, the device automatically enters standby mode.

Replacing disposable parts

This section presents the following topics about replacing disposable parts:

Replacing the base pad

Replace the base pad (part number 503009) as needed.

Replacing the forehead pad

Replace the forehead pad (part number 503010) as needed.

Replacing the air inlet filter

Transcend's air inlet filter should be replaced every six months.

1. Remove the pad from the bottom of the CPAP.
2. Remove the filter plate by gently squeezing the tab at the back of the plate towards the front of the CPAP and pulling the plate away from the CPAP.
3. To replace the new filter plate, lay it on the CPAP with the front clips being put into place first. Once the front is in place you can snap in the back clip. Make sure the filter plate is completely connected and discard the used bottom plate.
4. Reattach the pad to the CPAP.

Replacing the HME

The HME should be changed weekly.

1. Disconnect the air supply tube from the mask shell by grasping the HME cartridge and release the lateral clips.

2. To remove HME, pull out of the HME cartridge.

3. Insert the new HME into the HME cartridge and reattach to the mask shell. There will be an audible click once the HME cartridge is in place.

Caring for your Transcend and components

This section presents the following topics:

Cleaning the interior with drying mode

Drying mode should be used daily to clean the Transcend interior.

1. Set Transcend on a dry and stable surface (cloth surface is not recommended as it may get soiled). Do not wear Transcend while it is in drying mode.
2. To use drying mode, Transcend must be plugged in to a power source.
3. To enable drying mode, press and hold the ramp button (top button) then press the power button (bottom button).
4. Low pressure air flow will begin and last for 30 minutes until cleaning session is completed, then it will return to standby mode. To end the drying mode before the 30 minute session is complete, press the power button. Transcend will return to standby mode.

Cleaning the exterior

Clean the exterior of your Transcend as needed. Use a damp soft cloth or paper towel with mild dishwashing soap to wipe clean. Never submerge Transcend in water. Do not get soap or water in the device.

Cleaning components

The headgear, interface, device and forehead pads should be washed weekly. The tubing should be washed daily. This section presents the following topics:

Cleaning components

The CPAP pad, headgear, interface, and forehead pad should be washed weekly. The air supply tube should be washed daily.

1. Completely disconnect the components.
2. Hand wash in warm water with a mild dishwashing soap.
3. Rinse thoroughly.
4. Air dry; components must be completely dry before reconnecting.
5. Reconnect the components.

Cleaning the air inlet filter

Clean the foam air inlet filter at least monthly by removing and rinsing in water with mild dishwashing soap. Make sure the filter is thoroughly rinsed and dried before replacing in the CPAP device. Replace the filter every six months (see **Replacing the air inlet filter**, page 37).

Warning

- Unplug the CPAP device before cleaning it.
- Do not submerge the CPAP device or power supply in liquid.
- Prevent water from entering any of the device's openings.
- Do not use harsh or abrasive cleaning agents to clean any CPAP components.
- Do not sterilize the CPAP device.
- Do not place cleaning materials, such as a cloth or liquid, into the CPAP air inlet or air outlet connector.

Fault, alert and reminder codes

This section describes four types of fault, alert and reminder codes:

- Non-smartcard fault codes
- Smartcard fault codes
- Alert
- Filter change reminder

Non-smartcard fault codes

When the CPAP encounters a non-smartcard fault, the processor resets and enters a fault loop. In this loop, the CPAP repeatedly flashes the yellow fault LED to indicate the specific fault encountered. If the CPAP is reset or power cycled while in fault mode, it re-enters fault mode upon power up. To exit fault mode, the fault must be acknowledged by holding the power button down until the fault LED stops flashing. At this point, when the power button is released, the processor resets and the CPAP powers up in standby mode.

Device LED	Fault LED	Error	Comments
Off	Flashes 2 times	Stack overflow	Internal software fault.
Off	Flashes 3 times*	Pressure too high	While delivering therapy, the pressure sensor measured a pressure greater than 30 cmH2O. This could be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 4 times*	No Pressure	While delivering therapy, the pressure sensor measured approximately 0 cmH2O. This could be due to an open output hose. This could also be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 6 times	Attempt to set invalid time	An attempt was made to set the CPAP real time clock to an invalid value. The CPAP RTC is configured as part of the manufacturing process, thus this error should only occur then.
Off	Flashes 7 times*	Pressure sensor out of range	While in standby, the pressure sensor read a value outside its expected range. This could be due to a "pinched" or blocked pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 9 times	Bad firmware checksum	At power up, the CPAP calculates a checksum of the firmware code and compares it against the checksum it calculated when it was initially programmed. This error indicates some part of the firmware has been corrupted. Likely causes would be electrostatic discharge or hardware problem.
Off	Flashes 11 times	Stalled blower	While delivering therapy, the CPAP failed to detect any blower motion for 2 seconds. This is likely due to a faulty blower motor, loose blower connector or faulty electronics.
Off	Flashes 12 times	Low power	While delivering therapy, the CPAP determined that the blower was stalled (see above). However, a check of the voltage indicates there may not be sufficient power to spin the blower. This is likely due to a faulty power supply or battery.
Off	Flashes 13 times*	Processor over-temp	The processor on-chip temperature sensor has reported an excessive temperature.

Device LED	Fault LED	Error	Comments
Off	Flashes 14 times*	Blower over-temp	The blower thermistor has reported an excessive temperature.
* If this fault occurs, check all tubes and hoses to ensure that they are properly connected. If the fault occured during therapy, make sure the mask is properly fitted and not leaking. Check that all filters are properly installed and not excessively dirty.			

Smartcard fault codes

When the CPAP detects a problem while communicating with the smartcard, it flashes the yellow fault LED to identify the error. The green device LED is also illuminated during this time to differentiate the fault from the non-smartcard faults enumerated above. The fault is acknowledged by removing the card.

Device LED	Fault LED	Error	Comments
On	Flashes 1 times	Communication/ media error	CPAP was unable to establish or maintain communications with the smartcard. This may be due to a card not seated correctly in the slot, a bad/dirty slot connector or a defective card. Retry first with the same card to see if it's a seating issue. Then try a different card to see if it's a problem in the card or the CPAP.
On	Flashes 5 times	Could not erase	Probably a defective card but could be seating issue. Retry, if problem persists, try different card.
On	Flashes 6 times	Bad prescription data	The prescription data on the card is corrupt. Probably caused by defective card but could also indicate problem with software that created the card.
On	Flashes 8 times	Wrong prescription data	The card, with prescription data on it, is intended for a different serial number/patient than the CPAP being used. The card should be sent back to the provider.

Alert codes

Alerts are like faults except they do not reset the processor when they occur (i.e. the CPAP continues as usual).

Device LED	Fault LED	Error	Comments
Off	Flashes 15 times	Cannot regulate	CPAP repeatedly detected the monitored pressure outside of the therapy target range. The CPAP attempts to continue to deliver therapy. The alert is an indication that filters and the mask should be inspected for cleanliness and proper fit.

Filter change reminder

Every six months, the green LED flashes as a reminder that the air inlet filter should be changed. The LED only flashes when the CPAP is in standby mode and the CPAP otherwise still functions as normal. The reminder may be acknowledged in a manner similar to acknowledging a fault (hold down the power button until the green LED stops flashing). Acknowledging the reminder resets the reminder timer (i.e. it will return in six months). The reminder should be acknowledged in conjunction with changing the filter.

Troubleshooting

Problem	Probable Cause	Solution
Discomfort due to a feeling of high pressure.	CPAP device pressure may be set too high.	Breathe slowly through your nose with your mouth closed. Use the ramp pressure, if available. If the pressure remains problematic, contact your homecare provider.
Nose or throat irritation.	Dry air.	Add humidity to the room. Contact your homecare provider.
	Dirty air filter.	Change and/or clean the air inlet filter.
CPAP control panel LEDs don't flash or illuminate when power supply connected to DC input jack.	Power source is not properly connected.	Check all power connections.
	AC power may not be active.	Use another power outlet. Confirm outlet is not controlled by a wall switch.
		Test another device with this outlet.
	Faulty power source (AC power supply, mobile power adaptor or battery)	Check for steady green LED on power source. If power source LED is not lit, contact your homecare provider's technical service department.
No airflow from the CPAP system.	Device motor failure; or, electronics failure.	Contact the homecare provider's technical service department.
Yellow ault LED flashes general fault warning sequence	Device detects an operating error.	Note the number of times the yellow fault LED flashes before the flash sequence repeats. Refer to **Fault, alert and reminder codes** (page 42) for possible correction. If error indication continues after taking corrective action by holding down the power button until the yellow fault led stops flashing, contact your homecare provider's technical service department.
Inconsistent pressure	Ensure you're not using the battery outside of intended pressure ranges.	The P4 battery system is not recommended for therapy pressures of 15 or greater. The P8 battery system is not recommended for therapy pressures of 19 or greater.

Appendix: Part numbers

This section presents three topics:

- Disposable parts
- Accessories
- Replacement parts

Disposable parts

Item	Part number		Item	Part number
Air Inlet filter	503003		CPAP unit base pad	503009
HME	503035		Forehead pad	503037

Accessories

Item	Part number		Item	Part number
P_8 Multi-night Battery System	503023		Battery sleeve, large	503025
Transcend P_4 Overnight Battery System	503026		Battery sleeve, small	503028
Mobile power adaptor-MPA1	503029		Chest Strap	503024
			Arm Strap	503027

Replacement parts

Item	Part number		Item	Part number
Transcend Sleep Apnea Therapy Starter System	503042		Interface shell	503034
Transcend H_6B Waterless Humidification System	303005		Transcend H_6B Hose	503039
Transcend H_9M Waterless Humidification System	303006		Transcend H_9M Hose	503038
CPAP unit	503002		Interface forehead pad holder	503005
Transcend H_6B Headgear	503040		Shell adaptor, Activa – S	503018
Transcend H_9M Headgear	503007		Shell adaptor, Activa – M/L	503014
HME (old)	503008		Shell adaptor, ComfortGel – S/M	503016
HME (new)	503035		Universal Hose Adaptor	503043
Ball clip	503011		Shell adaptor, ComfortGel – L	503017
Power supply, AC-PSA1	503013		Shell adaptor, Ultra Mirage II	503015
CPAP patient travel bag	503012		Compliance software	503019
Card reader	503022		Compliance USB cable	503020
			Compliance card	503021

Appendix: Specifications

This section presents the following topics:

CPAP

CPAP device weight:	0.94 lbs (425.5 gm)
CPAP device dimensions:	6.1 in x 3.5 in x 2.8 in (15.4 cm x 8.9 cm x 7.0 cm)
Air outlet connector port dimensions:	19-mm diameter proprietary connector
Universal Adaptor port dimensions:	22-mm diameter connector

AC power supply — PSA1

AC supply input: AC supply output:	100-240 VAC, 50-60Hz 19VDC, 2.6 Amp

Mobile power adaptor — MPA1

Mobile power adaptor input:	13.5 VDC nominal. 12 to 15.5 VDC

Batteries

P_8 Multi-night Battery System	14.4 VDC, 5,200 mAH (for therapy pressures of 4 to 18 cm H_2O)
Transcend P_4 Overnight Battery System	14.4 VDC, 2,600 mAH (for therapy pressures of 4 to 14 cm H_2O)

CPAP performance

Working pressure range:	4 to 20 cm H_2O
Accuracy of pressure setting:	±1 cm H_2O or ±10%, whichever is greater
Maximum system shutdown pressure:	30 cm H_2O
Ramp time duration:	0-45 min + 25% time variance
Operating temperature range:	41 to 104°F (5 to 40°C)
Storage/transport temperature range:	-4 to 140ºF (-20 to 60ºC)
Operating humidity range:	10% to 80% relative humidity, non-condensing
Storage/transport humidity range:	10% to 95% relative humidity, non-condensing
Altitude range:	0-8000 feet

Manufacturer's declaration

This section presents the following topics:

Electromagnetic emissions

The CPAP system is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP system should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF radiated emissions CISPR 11	Group 1	The CPAP system 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 conducted emissions CISPR 11	Class B	The CPAP system 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	

Electromagnetic immunity

The CPAP system is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2, 4, 6 kV contact ±8 kV air	N/A. The CPAP system does not have conductive surfaces. ±2, 4, 6, 8 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Line power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±0.5*, 1 kV differential mode ±2 kV common mode	Line power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	Linepower quality should be that of a typical commercial or hospital environment. If the user of the CPAP system requires continued operation during power line interruptions, it is recommended that the CPAP system be powered from the battery. Note U_T is the A.C. line voltage before application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 10 KHz to 100 MHz*	Recommended separation distance: $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (compliance level adjusted to meet FDA limits) 26 MHz to 2.5 GHz Note At 80 MHz and 800 MHz, the higher frequency range applies.	Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800MHz Recommended separation distance: $d = 0.70\sqrt{P}$ 800MHz to 2.5 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[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 

[1] 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 CPAP system is used exceeds the applicable RF compliance level above, the CPAP system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CPAP system.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

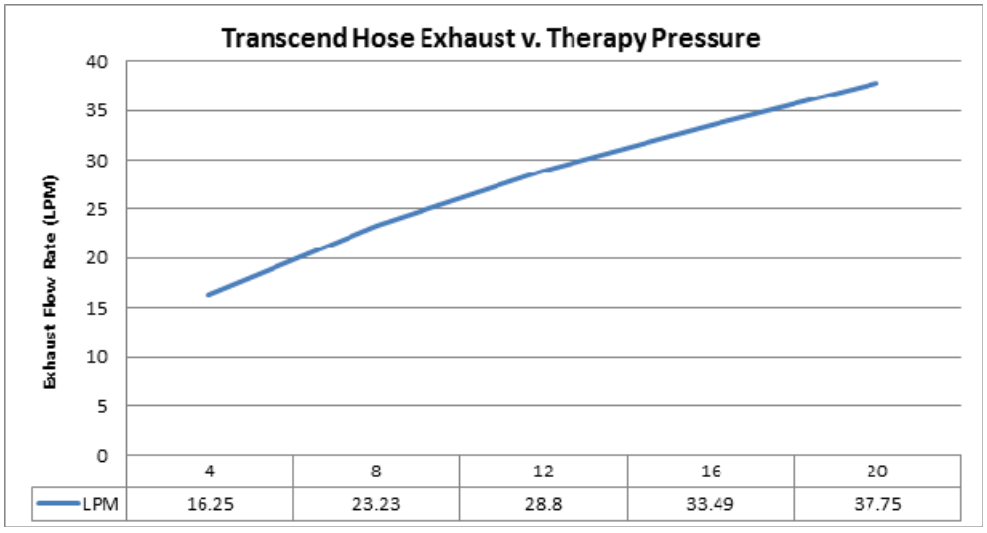
EN 60601-1 compliance

Protection against electric shock: Degree of protection against ingress of water: Use of flammable gasses:	Class II Type BF IPX0 Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.

Interface physical characteristics

Interface (shell/seal) weight:	0.14 lbs (62 g)
Seal dead space	Less than 301 cc
9" CPAP hose dimensions:	16-mm diameter, 20 cm long
6' CPAP hose dimensions:	16-mm diameter, 1.9 m long
6' Standard hose dimensions:	21-mm diameter, 1.8 m long

Performance

Sound power level (@ 10cm H_2O pressure, static)	37.0 dB
Sound pressure level (@ 10cm H_2O pressure, static)	29.0 dB
Resistance to flow of the mask and application accessories	0.140 hPa (cm H_2O) @ 50 l/min 0.278 hPa (cm H_2O) @ 100 l/min
Working pressure range:	4 to 20 cm H_2O
Pressure limit:	30 cm H_2O
Vent flow rate curve:	

Maximum flow rate (typical)		**Test Pressures**				
		4 cm H_2O	**8 cm H_2O**	**12 cm H_2O**	**16 cm H_2O**	**20 cm H_2O**
	Measured pressure at the patient connection port (hPa)	3.1	7.0	11.0	15.0	19.0
	Average flow at the patient connection port (l/min)	74.13	76.34	79.92	80.13	80.38

HME moisture loss	**Test condition**		
	Tidal volume (ml)	**Breath rate (1/min)**	**Moisture loss (mg/L)**
	1000	10	18.5
	750	12	18.6
	500	15	15.6
	250	20	12.2
HME pressure drop v. flow -	**Flow rate (L/min)**	**Insp. pressure drop (hPa)**	**Exp. pressure drop (hPa)**
Initial	30	0.13	0.13
	60	0.43	0.43
	90	1.00	0.93
After 24 hours	30	0.17	0.17
	60	0.50	0.47
	90	1.10	1.07
Internal volume	8.59 cm^3		

Appendix: Limited warranty

Somnetics warrants the Transcend Sleep Apnea Therapy System units to be free of defects in materials and workmanship and will perform in accordance with the product specifications for a period of 2 years from the date of sales by Somnetics to the dealer. The battery packs are similarly warranted for a period of 9 months from the date of sale by Somnetics to the dealer.

If the product fails to perform in accordance with the product specifications, Somnetics will repair or replace, at its option, any materials or parts of the Transcend Sleep Apnea Therapy System, which, upon Somnetics's examination appear defective. This does not cover damages caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship. Somnetics will pay customary freight charges from Somnetics to dealer location only.

Somnetics disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties, including warranty of merchantability or fitness for the particular purpose are limited to two years. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights, and you may also have rights which vary from state to state.

To qualify for repair, replacement, or refund, the defective device must be returned to Somnetics within 30 days after the discovery of the defect. Any repair, replacement, or refund obligation would not apply if the device has been repaired or otherwise altered in a facility not authorized in writing by Somnetics To exercise your rights under this warranty, contact your local, authorized Somnetics dealer or Somnetics at 33 5th Avenue, New Brighton, Minnesota 55112 USA, 1.877.621.9626 or 1.651.621.1800.

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