Notices

Revised

Transcend Sleep Apnea Therapy Starter System User Manual 103084 Rev T
Published May 2018 and supersedes all previous versions.

Notice
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Rx Only
About this user manual

Note  Training is required for the use of this device. All of the information required to operate and maintain this device is found within this manual. It is expected that users will use this manual for their training.

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 Sleep Apnea Therapy Starter System

- The following precautions are cited for the safety of the patient and/or the person operating 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 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.
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Introduction

The Transcend® Sleep Apnea Therapy Starter System (Transcend) provides positive airway pressure to users in the range of 4 to 20 cmH₂O as prescribed by the clinician. Buttons and LED lights facilitate control and provide operational feedback. A DC power jack and a USB port are also incorporated into Transcend.

Indications for use

The Transcend Sleep Apnea Therapy Starter System provides positive airway pressure for treatment of obstructive sleep apnea (OSA) in adults weighing over 66 pounds (30 kg). The device is intended for home and hospital/institutional use.

Contraindications

Transcend 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 PAP.
- Caution should be used when prescribing PAP 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. The following guidelines apply to this document:

<table>
<thead>
<tr>
<th>Warning</th>
<th>Indicates the possibility of serious injury or death to yourself or others.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caution</td>
<td>Indicates the possibility of minor injury or damage to the equipment.</td>
</tr>
<tr>
<td>Note</td>
<td>Indicates a tip, explanation or feature to aid in understanding, or efficient operation of the device.</td>
</tr>
</tbody>
</table>
Warnings

- Do not allow water to enter this device. Transcend should not be exposed to environmental conditions where the system may get wet.

- This device is not intended for life support.

- Transcend must be set up and adjusted by a trained provider before being used for therapy ramp and pressure.

- The air temperature produced by this device can be as much as 10°F higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90°F (32°C).

- Do not block or otherwise obstruct the exhalation ports of the interface. Follow the manufacturer’s instructions included with 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.

- The Transcend is only to be used with the supplied or recommended accessories. Use of accessories not recommended may result in increased electromagnetic emissions or decreased electromagnetic immunity of the PAP system and may be potentially unsafe.

- The Transcend is not defibrillation proof.

- Do not attempt to sterilize Transcend.

- The system is intended for single patient use.

- The device should be used only with masks and connectors recommended by Somnetics or a health care professional. A mask should not be used unless the device is turned on and is properly delivering ramp or therapy pressure. The exhalation port(s) associated with the mask should never be blocked. Explanation of the Warning: The device is intended to be used with masks or connectors specifically designed to have exhalation ports to allow continuous flow of air out of the mask. When the device is turned on and functioning properly air flow from the device flushes the exhaled air out through the mask exhalation port. When the device is not operating, however, 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.

- Strangulation hazard from power cord and air tube. These can become wrapped around a neck and STRANGLE. Keep power cord and air tube more than 3 feet from a baby’s crib and out of baby’s reach. Keep cord and tube out of children’s reach.
• Small parts are unlikely to be expelled from the Transcend enclosure, but in case of severe damage internal components may fragment and create a swallowing or choking hazard if they get out of the enclosure.

Cautions

• Federal law (United States) restricts this device to sale by, or on the order of, a physician.

• Power the Transcend only with the Somnetics-supplied power supplies, mobile power adaptor, or batteries. See Appendix: Part Numbers.

• Discontinue use of the Transcend and contact your physician if respiratory or skin irritations occur.

• Do not introduce objects into the Transcend air inlet or air outlet.

• Inspect the power supply for signs of wear or damage before each use. Replace the power cord if necessary.

• Somnetics recommends replacing the air delivery tubing (hose) after every three months of use.

• To protect the environment, some parts and accessories of the Transcend, including optional batteries, must be disposed of in accordance with local regulations.

Device contains DEHP (a phthalate). Testing has demonstrated that DEHP exposure levels are well below established exposure limits.
Symbols

Attention: Consult accompanying documents

Type BF Applied Part

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

Upper and lower temperature limits


Consult instructions for use

Upper and lower humidity limits

Non-Condensing

Rx Only

Prescription only. U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Precedes reference or item number
Components of the Transcend

Begin by unpacking all items from the Transcend 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 Transcend to you.

1. Transcend
2. Standard 6-foot hose (Note: not compatible with optional H6B or H9M Waterless Humidification Systems)
3. Universal hose adaptor
4. Multi-plug universal power supply (PSA2)
5. Changeable plug pack
6. Transcend Travel bag
7. Transcend Quick Guide
8. USB Cable
What’s not included (all sold separately)

- Transcend Heated Humidifier
- Transcend Mobile Power Adaptor
- Transcend P4 Battery
- Transcend P8 Battery
- Transcend Base Station
- Transcend LCD Programming Base Station
- Transcend Portable Solar Battery Charger (to be used as an alternative charging source for Transcend P4 and P8 batteries)
Description of Transcend components

Transcend Device

Transcend comes ready to generate and regulate continuous positive airway pressure therapy for delivery to the interface. An external power source connects to the Transcend to supply power to the device.

Control panel

The Transcend control panel has two pushbuttons used to activate the blower and the pressure ramp feature. There are also two LED lights, including a green LED for indicating normal operational modes and a yellow LED that indicates fault conditions.
**Power connection jack and USB port**

The power jack accepts the barrel plug of the output cable from a DC power source to operate the Transcend.

A variety of power sources may be used to power the Transcend. An AC to DC converting power supply is provided with your device and should be used when powering the device by line (wall outlet) power.

An optional mobile power adaptor connects to a DC power outlet, such as that found in an automobile, truck, RV, boat, or similar vehicle.

Optional Transcend battery packs are also available to power the Transcend.

**USB port**

A mini-AB USB port is provided for direct data exchange between the Transcend and a computer via a USB data cable. This interface allows the clinician to configure the Transcend for prescription pressure, ramp settings and provides access to therapy compliance information that can be viewed by the user and emailed to the clinician.
Air Inlet Filter

During therapy operation ambient air is drawn into the Transcend through an Air Inlet Filter. The Filter Media should be cleaned at least weekly according to the instructions provided in this User Manual and replaced minimally after 6 months of use. Replace more frequently as desired.
Assembling the Transcend

The mask interface connects to Transcend via the air supply tube. One end of the air supply tube attaches to the outlet port of Transcend via the Universal Hose Adaptor. The opposite end of the tube attaches to the user interface.

Follow these steps to assemble the Transcend:

1. Attach the Universal Hose Adaptor to the 6-foot air supply tube (Figure 1).
2. Connect the user interface to the opposite end of the air supply tube.
3. Connect the Universal Hose Adaptor to Transcend making sure it is fully seated into the CPAP (Figure 2).
4. Plug the power supply barrel connector into Transcend as shown in Figure 3.
5. Connect power supply to a wall outlet.
Powering the Transcend

There are three choices for powering your Transcend device:

- Using the Multi-plug Universal Power Supply (PSA2)
- Using the optional Transcend (P4 or P8) Battery
- Using the optional Transcend Mobile Power Adapter (MPA1)
Using the Multi-plug Universal Power Supply (PSA2)

The Multi-plug Universal Power Supply (PSA2) and Changeable Plug Pack containing three (3) exchangeable plugs are contained with each transcend. The changeable plug packs are suitable for use in most countries around the world.

1. Determine which plug is required to power the device based upon the outlet style.

2. If the correct plug is not already attached to the Power Supply remove the attached plug by depressing the button on the detachable plug and turning the plug in a counterclockwise motion until it releases from the power supply.

3. Attach the desired plug by lining up the protruding tabs on the back of the plug blade with the gaps on the Power Supply and gently pushing the plug into the slot. Turn the plug clockwise until it clicks into place. You should hear an audible click.

4. Insert the barrel connector of power supply into power jack on the back of the Transcend device.

5. Insert the other end of the power supply into an AC line power outlet.

6. The Transcend power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend and that it has successfully entered Standby Mode.

**Note** Use only the Somnetics-supplied Universal Power Supplies. Do not use a power converter or voltage transformer with the PSA2 Universal Power Supply.

**Note** Make certain that the plug attachment is fully secured to the Power Supply before inserting the power supply into the wall outlet.
Using the Transcend P₄ or P₈ Battery

The Transcend P₄ and P₈ Batteries are optional power sources for Transcend. To use, connect the P₄ or P₈ battery outlet cable to the Transcend by inserting the barrel connector into the power jack on the Transcend. Be sure the power-up LED flash sequence completes indicating that power is being supplied to the Transcend and that it has successfully entered Standby Mode.

**Note** Fully charge the battery before the first use. Follow the battery charging instructions provided in this User Manual. Do not connect the battery to the Transcend during initial charge.

**Note** Use the battery in-line with the AC power supply when possible. Connecting the battery in-line with the AC power supply allows the battery to charge during therapy and provides backup power to provide uninterrupted therapy in the case of a power outage.

Using the Transcend P₄ or P₈ Battery in conjunction with AC line power

1. Insert the barrel connector from the Universal AC Power Supply into the battery.
2. Insert the barrel connector of the battery into the Transcend power jack so that the plug and cord face upward.
3. Plug the Universal AC Power Supply plug into AC line power.
4. The Transcend power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend and that it has successfully entered Standby Mode.

Using the Transcend P₄ or P₈ Battery in conjunction with the Transcend Mobile Power Adaptor

**Note** Use the battery in-line with the Mobile Power Adaptor when possible. Connecting the battery in-line with the Mobile Power Adaptor allows the battery to charge during therapy and provides backup power to provide uninterrupted therapy in the case of a power outage.

1. Insert the barrel connector of 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. Plug the Mobile Power Adaptor into the mobile power receptacle.
4. The Transcend power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend and that it has successfully entered Standby Mode.
Explanation of the optional Transcend P₄ and P₈ Battery LED lights

- Red LED light: A steady red light signifies a fault with the battery. Do not use or charge the battery when the red LED light is showing. Contact the home healthcare provider that provided the battery to you for a replacement.

- Yellow LED light: Indicates the battery is charging.

- Green LED light: Indicates the battery is fully charged.

**Note** The battery will show a red LED light for two seconds when it is first plugged in.

**Note** The battery will show a yellow or green LED light when it is used in-line with the Universal AC Power Supply or Mobile Power Adaptor indicating its charge level.

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

### Charging the Transcend P₄ or P₈ Battery

**Note** Battery life may vary based on device settings, leak, patient breath pattern, environmental conditions, or battery age.

<table>
<thead>
<tr>
<th>Breaths per minute</th>
<th>Therapy Pressure (cm H₂O)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>15</td>
<td>19</td>
</tr>
<tr>
<td>20</td>
<td>11</td>
</tr>
</tbody>
</table>

### Average Battery Life for P₄ Battery (hours)

<table>
<thead>
<tr>
<th>Breaths per minute</th>
<th>Therapy Pressure (cm H₂O)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>15</td>
<td>36</td>
</tr>
<tr>
<td>20</td>
<td>24</td>
</tr>
</tbody>
</table>

**Note** Charge the battery fully before the first use. Do not connect the Battery to Transcend during the initial charge.

**Note** To maintain maximum battery performance Somnetics recommends using the Battery in-line with the AC Power Supply or Mobile Power Adaptor during therapy even if the battery is fully charged.
• Connect the power outlet barrel connector from the Universal Power Supply or Mobile Power Adaptor to the power connection jack on the P₄ or P₈ Battery.

• Connect the Universal Power Supply or Mobile Power Adaptor to a power source.

• A full battery charge is indicated when the LED light on the Battery turns from yellow to green.

• It may take up to five (5) hours to charge the P4 battery and up to eight (8) hours to charge the P8 battery.
Using the Transcend Mobile Power Adaptor (MPA1)

Transcend may be powered with an optional Mobile Power Adaptor. The Mobile Power Adaptor is supplied with two cables: one to connect the MPA1 to the Transcend device, and the other to connect the MPA1 to a mobile power receptacle.

**Note** Use only the Somnetics-supplied Transcend Mobile Power Adaptor.

1. Connect both cables to the base of the Mobile Power Adaptor.
2. Insert the barrel connector of the MPA1 output cable to the power jack of the Transcend.
3. Insert the plug connector into the mobile power receptacle (e.g. cigarette lighter outlet).
4. The Transcend power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend and that it has successfully entered Standby Mode.

**Note** Make certain that the cables are securely connected to the Mobile Power Adaptor and to the power jack on the back of the Transcend. It may be necessary to unplug the cables and reconnect to ensure a good connection.
Using the Transcend

The control panel of the Transcend has two pushbuttons that activate the blower and initiate the pressure ramp feature. There are also two LED lights, including a green LED for indicating normal operational modes and a yellow LED for indicating fault conditions. The Transcend operational status is displayed by LED illumination states.

When a power source is connected to the device the Transcend power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend and that it has successfully entered Standby Mode. During therapy delivery, the LED lights remain off to avoid disturbing the patient and/or bed partner.

Note  If the Transcend loses power while delivering therapy it will resume delivering therapy as soon as power is restored and you press the power button. The device 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 applied to the device it completes the power-up LED sequence and enters Standby Mode. Standby Mode is also initiated by pressing the power button when the device is in On Mode or if the mask is removed while in On Mode. As long as power is supplied to the device it will remain in Standby Mode until On or Drying Mode is initiated.
- **On**: When in On Mode the blower is working and regulated device therapy pressure is being generated. The LED lights remain off. On Mode is initiated by pressing the power button when the device is in Standby Mode and the mask is worn by the patient.
- **Drying**: To initiate Drying Mode depress the Ramp button and press the Power button simultaneously. When in Drying Mode the blower runs at a low speed for 30 minutes. During Drying Mode the LED lights remain off and blower pressure is not regulated to provide therapy.
Starting therapy

The Transcend control panel has two pushbuttons to activate the blower and the pressure ramp feature. There are also two LED lights, including a green LED for indicating normal operational modes and a yellow LED that indicates fault conditions.

1. Connect the Transcend to a power source and allow it to enter Standby Mode.
2. Be sure your user interface is fit firmly in place before initiating therapy.
3. To initiate therapy press the Power button. Pressing the Power button when Transcend is in Standby Mode will initiate On Mode. Air flow will begin as the blower delivers or ramps to prescribed therapy pressure.

Using the ramp function

The Ramp feature lets users acclimate to air flow by starting at a lower pressure and gradually increasing to the prescribed pressure setting as the user falls asleep. The minimum ramp pressure and ramp time are set by the clinician. If the Ramp feature was not set for you by a clinician, this feature will not be available to you.

To accelerate the rate of the pressure increase during Ramp, hold the Ramp button down until the device reaches a comfortable therapy pressure. When the Ramp button is released the device will continue in Ramp Mode until it reaches the prescribed therapy pressure.

1. Be sure the Transcend is in On Mode. If not, press the power button.
2. Adjust your mask to eliminate mask leaks.
3. Depress the Ramp button. The pressure will drop to the Ramp starting pressure as set by the clinician and will gradually increase over a preset length of time until reaching the prescribed therapy pressure.

**Note**  Momentarily pressing the Ramp button during ramped pressure delivery will not affect the pressure delivered. To stop the gradual pressure increase of the ramp function, turn off the device by pressing the Power button. The next time the blower is turned on it will deliver the prescribed therapy pressure.

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

To end the delivery of therapy while the blower is on, press the Power button to deactivate the blower and return the device to Standby Mode. It is recommended the user initiate the Drying Mode function after each therapy session to dry the device interior.

Drying mode

At the end of each therapy session it is recommended the user initiates the Drying Mode. To initiate Drying Mode depress the Ramp button and press the Power button simultaneously. When in Drying Mode the blower runs at a low speed for 30 minutes. During Drying Mode the LED lights remain off and blower pressure is not regulated to provide therapy. Using the Drying Mode flushes air through the system to remove traces of moisture from the interior of the device and airway circuit. After the 30-minute drying cycle, the blower will turn off and the device will automatically enter Standby Mode.
Replacing the Filter Media

The Transcend Filter Media should be replaced every six months at minimum.

1. Remove the Filter Frame by gently pressing the button release at the back of the Filter Frame towards the front of the device. Then pull the filter frame away from the device.

2. To replace the Filter Media remove the used filter and discard. Lay a new Filter in the channel on the base of the Transcend device.

3. Reconnect the Filter Frame to the device by placing the front clip into place first. Once the front clip is in place snap the back clip into place. Make sure the Filter Frame is completely connected before use.

Note: If using an earlier generation of the Air Inlet Filter: Remove the Filter Frame (foam will be attached) and discard. Replace with a new earlier generation Filter Frame.

Note: Earlier generation Air Inlet Filters and Filter Frames are not compatible with later generation Transcend devices.
Caring for your Transcend and components

Transcend is a maintenance free device. This section presents the following topics:

- **Cleaning the exterior**
- **Cleaning of accessories**
- **Cleaning the filter media and filter frame**

**Warning:**

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

**Cleaning the Exterior**

Follow these instructions to clean the exterior of the Transcend device.

1. Unplug the power supply prior to cleaning and disconnect the device from power cords.

2. Mix a solution of 5% mild liquid detergent in distilled water (1.6 fl oz liquid detergent per quart of distilled water). Mild detergent should contain biodegradable anionic surfactants and no phosphate.

3. Submerge a lint-free cotton cloth into the detergent solution.

4. Wring excess water from the cloth then wipe the exterior of the Transcend device for approximately 20 seconds using a gentle, back and forth wiping motion from the front to back of the device. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.

5. Rinse the cloth in clear water to remove residual cleaning solution.

6. Wring excess water from the cloth then wipe the Transcend device using a gentle front to back wiping motion to remove any detergent solution remaining on its surface.

7. Wipe the device with a dry, lint-free cotton cloth until the device is fully dry.
Exterior cleaning of the device should be performed as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Periodic Cleaning Cycle</th>
<th>Product Service Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend CPAP</td>
<td>2x/Month</td>
<td>5-Year</td>
</tr>
</tbody>
</table>

Cleaning of Accessories

The following accessories should be cleaned with a 5% solution of mild liquid detergent in distilled water (1.6 fl oz liquid cleaning detergent per quart of distilled water). Mild detergent should contain biodegradable anionic surfactants and no phosphate. Follow these steps to clean the accessories.

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Periodic Cleaning Cycle</th>
<th>Product Service Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend Base Station</td>
<td>2x/Month</td>
<td>2-Year</td>
</tr>
</tbody>
</table>

1. Dampen a lint-free cotton cloth with the cleaning solution.
2. Wring excess water from the cloth and thoroughly wipe each surface using a back and forth or circular wiping motion. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.
3. Rinse the cotton cloth in distilled water to remove residual cleaning solution.
4. Wring excess water from the cloth then wipe the accessory to remove any cleaning solution remaining on its surface.
5. Dry surfaces by wiping with a dry, lint-free cotton cloth.
6. Be sure the accessory is fully dry before reassembling or using.

**Warning:** Do not allow water or detergent solution to enter the Base Station.

The following accessories can be fully submerged in the described cleaning solution. Follow the instructions below for proper cleaning.

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Periodic Cleaning Cycle</th>
<th>Product Service Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Hose Adapter</td>
<td>Daily</td>
<td>3-Month</td>
</tr>
<tr>
<td>Air Supply Tube</td>
<td>Daily</td>
<td>3-Month</td>
</tr>
<tr>
<td>Inlet Filter Frame</td>
<td>2x/Month</td>
<td>5-Year</td>
</tr>
</tbody>
</table>

1. Fully immerse the accessory in the cleaning solution.
2. While immersed, thoroughly wipe the surface with a lint-free cotton cloth. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.
3. Clean the inside of the air supply tube by lifting, then lowering the ends of the tube while the tube is filled with cleaning solution.
4. Rinse accessories by immersing in distilled water. Move the accessory in a back and forth motion for approximately 10 seconds to remove cleaning agent residue.
5. Rinse the air supply tube in distilled water by fully immersing. Lift, then lower, the ends of the tube while the tube is filled with water. Repeat this motion for approximately 10 seconds to remove cleaning agent residue.

6. Dry the accessory by wiping with dry, lint-free cotton cloth. Allow the accessory to air dry as needed.

7. Dry the outside of the air delivery tube with a dry, lint-free cotton cloth. Allow the tube to air dry until the inside of the tube is dry. Length of drying time will depend on ambient conditions.

**Note:** It is recommended that fabrics air dry at room temperature for 30-60 minutes prior to reassembly or use.

---

**Cleaning the Filter Media and Filter Frame**

Clean the foam Filter Media and Filter Frame at least once per week. Follow these steps to clean:

1. Begin by removing the Filter Media and Filter Frame from the device (see Replacing the Filter Media for instructions on filter removal and replacement).

2. Mix a solution of 5% mild liquid detergent in distilled water (1.6 fl oz liquid detergent per quart of distilled water). Mild detergent should contain biodegradable anionic surfactants and no phosphate.

3. Fully immerse the Filter Frame in the detergent solution.

4. While immersed, thoroughly wipe each surface of the Filter Frame with a lint-free cotton cloth. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.

5. Rinse the Filter Frame by immersing in distilled water and gently moving it forwards and backwards for approximately 10 seconds.

6. Use a clean, dry, lint-free cotton cloth to dry all surfaces of the Filter Frame.

7. To clean the Filter Media, first submerge a lint-free cotton cloth into the cleaning solution.

8. Wipe the Filter Media with cloth to remove any visible residue. Wipe all surfaces for a minimum of 10 seconds.

9. Rinse the cotton cloth in distilled water to remove residual cleaning solution.

10. Wring excess water from the cloth then wipe all surfaces of the Filter Media to remove any cleaning solution remaining on its surface.

11. Dry surfaces by wiping with a dry, lint-free cotton cloth.

12. Allow the Filter Media to air dry at room temperature for approximately 30-60 minutes before reassembly. Drying time will depend on ambient conditions.
13. Reconnect the Filter Media and filter frame to the Transcend.

**Note:** To clean an earlier generation Air Inlet Filter remove the Filter Frame (foam will be attached) and follow steps 2-6 above. Allow the Filter to air dry for 30-60 minutes. Drying time will depend on ambient conditions. Reattach the Air Inlet Filter to the CPAP.
Fault and Alert Codes

Fault Codes

When Transcend encounters a fault the processor resets and enters a fault loop. In this loop, the device repeatedly flashes the yellow fault LED to indicate the specific fault encountered. If the device 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 device powers up in standby mode.

**Note:** It is recommended that the user attempt to reset any failure when it is first observed on the device, as transient issues may cause the device to enter a failure mode without any actual device malfunction or failure. If the fault code reoccurs after device reset, the below table summarizes likely unit response, potential device issue(s) and troubleshoot suggestions associated with the Transcend unit.

<table>
<thead>
<tr>
<th>Device LED</th>
<th>Fault LED</th>
<th>Error</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off</td>
<td>Flashes 2 times</td>
<td>Stack overflow</td>
<td>Internal software fault.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 3 times*</td>
<td>Pressure too high</td>
<td>While delivering therapy, the pressure sensor measured a pressure greater than 30 cmH2O. This could be due to a &quot;pinched&quot; or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 4 times*</td>
<td>No Pressure</td>
<td>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 &quot;pinched&quot; or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 6 times</td>
<td>Attempt to set invalid time</td>
<td>An attempt was made to set the device real time clock (RTC) to an invalid value. The device RTC is configured as part of the manufacturing process, thus this error should only occur then.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 7 times*</td>
<td>Pressure sensor out of range</td>
<td>While in standby, the pressure sensor reads a value outside its expected range. This could be due to a &quot;pinched&quot; or blocked pressure sense tube or fluctuation in ambient temperature. This could also be due to faulty pressure sensor or electronics.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 9 times</td>
<td>Bad firmware checksum</td>
<td>At power up, the device 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.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 11 times</td>
<td>Stalled blower</td>
<td>While delivering therapy, the device failed to detect any blower motion for 2 seconds. This is likely due to a faulty blower motor, loose blower connector or faulty electronics.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 12 times</td>
<td>Low power</td>
<td>While delivering therapy, the device 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.</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 13 times*</td>
<td>Processor over-temp</td>
<td>The processor on-chip temperature sensor has reported an excessive temperature.</td>
</tr>
<tr>
<td>Device LED</td>
<td>Fault LED</td>
<td>Error</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-----------</td>
<td>---------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Off</td>
<td>Flashes 14 times*</td>
<td>Blower over-temp</td>
<td>The blower thermistor has reported an excessive temperature.</td>
</tr>
</tbody>
</table>

* If this fault occurs, check all tubes and hoses to ensure that they are properly connected. If the fault occurred during therapy, make sure the mask is properly fitted and not leaking. Check that all filters are properly installed and not excessively dirty.

## Alert codes

Alerts are similar to faults but they do not reset the processor when they occur (i.e., the device continues to deliver therapy pressure).

<table>
<thead>
<tr>
<th>Device LED</th>
<th>Fault LED</th>
<th>Error</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off</td>
<td>Flashes 15 times</td>
<td>Cannot regulate</td>
<td>Device repeatedly detected the monitored pressure outside of the therapy target range. The device attempts to continue to deliver therapy. The alert is an indication that filters and the mask should be inspected for cleanliness and proper fit.</td>
</tr>
</tbody>
</table>
## Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Probable Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort due to a feeling of high pressure.</td>
<td>Transcend device pressure may be set too high.</td>
<td>Breathe slowly through your nose with your mouth closed. Use the ramp pressure, if available. If the pressure remains problematic, contact your homecare provider.</td>
</tr>
<tr>
<td>Nose or throat irritation.</td>
<td>Dry air.</td>
<td>Add humidity to the room. Contact your homecare provider. If you are using the Transcend Heated Humidifier, increase the setting. If you are using the H6B or H9M waterless humidification system, replace the HME.</td>
</tr>
<tr>
<td>Transcend control panel LEDs don’t flash or illuminate when power supply connected to DC input jack.</td>
<td>Power source is not properly connected.</td>
<td>Check all power connections.</td>
</tr>
<tr>
<td>No airflow from the Transcend.</td>
<td>Device motor failure; or, electronics failure.</td>
<td>Contact the homecare provider’s technical service department.</td>
</tr>
<tr>
<td>Yellow fault LED flashes general fault warning sequence</td>
<td>Device detects an operating error.</td>
<td>Note the number of times the yellow fault LED flashes before the flash sequence repeats. Refer to <a href="#">Fault and alert codes</a> 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.</td>
</tr>
<tr>
<td>Device shuts down during therapy</td>
<td>Improper seal of external hardware (mask, universal hose adaptor, tubing); or use of external hardware past recommended service life.</td>
<td>Secure all equipment to ensure a proper seal. Replace any external hardware exceeding recommended service life. If the problem persists, call your homecare provider’s technical service department.</td>
</tr>
</tbody>
</table>
Appendix: Part numbers

This section presents three topics:

- **Disposable parts**
- **Accessories**
- **Replacement parts**

## Disposable parts

<table>
<thead>
<tr>
<th>Item</th>
<th>Part number</th>
<th>Item</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Media</td>
<td>503067</td>
<td>Standard 6-foot hose</td>
<td>503081</td>
</tr>
<tr>
<td>Transcend Filter Frame</td>
<td>503071</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Accessories

<table>
<thead>
<tr>
<th>Item</th>
<th>Part number</th>
<th>Item</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend P₈ Battery</td>
<td>503023</td>
<td>Transcend Base Station</td>
<td>503033</td>
</tr>
<tr>
<td>Transcend P₄ Battery</td>
<td>503026</td>
<td>Transcend Heated Humidifier Travel Bag</td>
<td>503085</td>
</tr>
<tr>
<td>Transcend Heated Humidifier</td>
<td>503064</td>
<td>Transcend LCD Programming Base Station</td>
<td>503055</td>
</tr>
<tr>
<td>Transcend Mobile Power Adapter (MPA1)</td>
<td>503029</td>
<td>Transcend Portable Solar Battery Charger</td>
<td>503056</td>
</tr>
</tbody>
</table>

## Replacement parts

<table>
<thead>
<tr>
<th>Item</th>
<th>Part number</th>
<th>Item</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend</td>
<td>503042</td>
<td>Transcend Universal Hose Adapter</td>
<td>503043</td>
</tr>
<tr>
<td>Transcend CPAP Unit</td>
<td>503002</td>
<td>Multi-plug Universal Power Supply (PSA2)</td>
<td>503059</td>
</tr>
<tr>
<td>Transcend Travel Bag</td>
<td>503012</td>
<td>Changeable Plug Pack</td>
<td>503060</td>
</tr>
<tr>
<td>Multi-plug Universal Power Supply Set (Contains 503059 &amp; 503060)</td>
<td>503078</td>
<td>USB cable</td>
<td>503020</td>
</tr>
</tbody>
</table>
Appendix: Specifications

This section presents the following topics:

- **Transcend**
- **AC power supply - PSA2**
- **Mobile power adaptor (optional) - MPA1**
- **Batteries**
- **Transcend performance**
- **Manufacturer’s declaration**

### Transcend

<table>
<thead>
<tr>
<th>Transcend weight:</th>
<th>Less than 1.0 lbs (454 gm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend dimensions:</td>
<td>6.1 in x 3.5 in x 2.8 in (15.4 cm x 8.9 cm x 7.0 cm)</td>
</tr>
<tr>
<td>Air outlet connector port dimensions:</td>
<td>19-mm diameter proprietary connector</td>
</tr>
<tr>
<td>Universal Adaptor port dimensions:</td>
<td>22-mm diameter connector</td>
</tr>
</tbody>
</table>

### AC power supply - PSA2

<table>
<thead>
<tr>
<th>AC supply input:</th>
<th>100-240 VAC, 50-60Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC supply output:</td>
<td>18 VDC, 1.67 Amp</td>
</tr>
</tbody>
</table>

### Mobile power adaptor (optional) - MPA1

<table>
<thead>
<tr>
<th>Mobile power adaptor input:</th>
<th>13.0 VDC nominal. 10 to 15.5 VDC, 7.5 Amp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile power adaptor output:</td>
<td>19.2 VDC, 2.6 Amp</td>
</tr>
</tbody>
</table>

### Batteries (optional)

<table>
<thead>
<tr>
<th>Transcend P₈ Battery:</th>
<th>14.4 VDC, 5,200 mAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend P₄ t Battery:</td>
<td>14.4 VDC, 2,600 mAH</td>
</tr>
</tbody>
</table>
Transcend performance

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working pressure range:</td>
<td>4 to 20 cm H₂O</td>
</tr>
<tr>
<td>Accuracy of pressure setting:</td>
<td>±1 cm H₂O or ±10%, whichever is greater</td>
</tr>
<tr>
<td>Maximum system shutdown pressure:</td>
<td>30 cm H₂O</td>
</tr>
<tr>
<td>Ramp time duration:</td>
<td>0-45 min + 25% time variance</td>
</tr>
<tr>
<td>Operating temperature range:</td>
<td>41 to 95°F (5 to 35°C)</td>
</tr>
<tr>
<td>Storage/transport temperature range:</td>
<td>-4 to 140°F (-20 to 60°C)</td>
</tr>
<tr>
<td>Operating humidity range:</td>
<td>10% to 80% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Storage/transport humidity range:</td>
<td>10% to 90% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Altitude range:</td>
<td>0-8000 feet (automatically adjusted)</td>
</tr>
</tbody>
</table>
Manufacturer’s declaration

This section presents the following topics:

- **Electromagnetic emissions**
- **Electromagnetic immunity**
- **IEC 60601-1 Compliance**

## Electromagnetic emissions

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

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF radiated emissions</td>
<td>Group 1</td>
<td>The Transcend 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.</td>
</tr>
<tr>
<td>RF conducted emissions</td>
<td>Class B</td>
<td>The Transcend 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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td>IEC 61000-3-2</td>
<td></td>
</tr>
</tbody>
</table>

## Electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±2, 4, 6 kV contact, ±8 kV air</td>
<td>N/A. The Transcend does not have conductive surfaces. ±2, 4, 6, 8 kV air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines, ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines, ±1 kV for input/output lines</td>
<td>Line power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode, ±2 kV common mode</td>
<td>±0.5*, 1 kV differential mode, ±2 kV common mode</td>
<td>Line power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Immunity test</td>
<td>IEC 60601 test level</td>
<td>Compliance level</td>
<td>Electromagnetic environment—guidance</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Voltage dips, short interruptions, and voltage variations on power supply input lines | <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 Transcend requires continued operation during power line interruptions, it is recommended that the Transcend 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                                      | 3 A/m                                                                                | 3 A/m                                                                           | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |
| Conducted RF                                                                  | 3 Vrms 150 kHz to 80 MHz                                                             | 3 Vrms 150 KHz to 80 MHz                                                        | Recommended separation distance: $d = 1.17 \sqrt{P}$                                                  |
| Radiated RF                                                                   | 3 V/m 80 MHz to 2.5 GHz                                                              | 10 V/m (compliance level adjusted to meet FDA limits) 80 MHz to 2.5 GHz          | 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, should be less than the compliance level in each frequency range.  
Interference may occur in the vicinity of equipment marked with the following symbol: |

$P$
IEC 60601-1 compliance

| Protection against electric shock:                  | Class II |
| Degree of protection against ingress of water:     | Type BF  |
| Use of flammable gasses:                           | IP21. Protected against ingress of solid foreign objects greater than or equal to 12.5 mm in diameter. Vertically falling drops shall have no harmful effects. |
|                                                     | Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide. |

**Interface physical characteristics**

| 6’ Standard hose dimensions:                        | 21-mm diameter, 1.8 m long |

**Performance**

| Sound power level (@ 10cm H₂O pressure, static)      | 37.0 dB                  |
| Sound pressure level (@ 10cm H₂O pressure, static)   | 29.0 dB                  |
| Working pressure range:                              | 4 to 20 cm H₂O           |
| Pressure limit:                                      | 30 cm H₂O                |

| Maximum flow rate (typical)                          | Test Pressures           |
|                                                     | 4 cm H₂O | 8 cm H₂O | 12 cm H₂O | 16 cm H₂O | 20 cm H₂O |
| 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)  | 71.91 | 75.45 | 74.29 | 73.2 | 71.49 |
Appendix: Limited warranty

Somnetics warrants its products to be free of defects in materials and workmanship and will perform in accordance with the product specifications for a period specified in the following table:

<table>
<thead>
<tr>
<th>Product</th>
<th>Warranty Period*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcend Sleep Apnea Therapy Starter System</td>
<td>3 years</td>
</tr>
<tr>
<td>Transcend Auto</td>
<td>3 years</td>
</tr>
<tr>
<td>Transcend EZEX</td>
<td>3 years</td>
</tr>
<tr>
<td>Transcend Heated Humidifier**</td>
<td>2 years</td>
</tr>
<tr>
<td>Transcend P4 and P8 Batteries</td>
<td>9 months</td>
</tr>
<tr>
<td>Transcend Portable Solar Charger</td>
<td>1 year</td>
</tr>
<tr>
<td>Transcend Mobile Power Adaptor</td>
<td>1 year</td>
</tr>
<tr>
<td>Transcend LCD Programming Base Station</td>
<td>2 years</td>
</tr>
</tbody>
</table>

*From date of user purchase

** Except water reservoir, which is warranted for 6 months.

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 product, which upon Somnetics’ examination appear defective. Customer will receive a manufacturer-refurbished or new product replacement, solely at the company’s discretion if the product is not repairable. This warranty 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 its products. 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 the period noted in the table above for the individual 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 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. Proof of purchase, including proof of the date of purchase, is required. 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.

Somnetics International, Inc.
33 5th Avenue NW, Suite 500
New Brighton, Minnesota 55112 USA

http://www.mytranscend.com/

Phone: 651.621.1800
Toll-free: 877.621.9626
Fax: 651.204.0064

Transcend Sleep Apnea Therapy Starter System User Manual

[REF] 103084 Rev T