TRANSCEND®

Sleep Apnea Therapy SYSTEM

Transcend 3 miniCPAP™

User Manual

Notices

Revised	Transcend 3 miniCPAP User Manual 103940 Rev C Published August 2019 and supersedes all previous versions.
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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 3 miniCPAP

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 3 miniCPAP USB port other than a computer that is compliant with 60950-1 safety standards. Attaching any other device to the Transcend 3 miniCPAP 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 3 miniCPAP 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 3 miniCPAP or on Transcend 3 miniCPAP 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 3 miniCPAP provides positive airway pressure to users in the range of 4 to 20 cmH_2O as prescribed by the clinician. The Transcend 3 miniCPAP product family includes the Transcend 3 miniCPAP and the Transcend 3 miniCPAP Auto. Buttons and LED lights facilitate control and provide operational feedback. A DC power jack and a USB port are also incorporated into the Transcend 3 miniCPAP.

Indications for use

The Transcend 3 miniCPAP 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

The Transcend 3 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

Adverse effects

You should report unusual chest pain, severe headache or increased breathlessness to your prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

The following side effects have been reported by users of airway delivery devices during CPAP therapy.

- congestion or mucus in the throat
- sneezing or cough
- bloating
- nocturnal wakening
- feelings of claustrophobia
- burn
- Irritation/dryness of the mouth, nose or throat

Precautions for use

This section describes the warnings and cautions associated with use of the Transcend 3 miniCPAP. 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

- Do not allow water to enter this device. Transcend 3 miniCPAP should not be exposed to environmental conditions where the system may get wet.
- This device is not intended for life support.
- The Transcend 3 miniCPAP 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 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 mask. Follow the manufacturer's instructions included with your mask.
- 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. Sources of oxygen must be located more than 1 meter from the equipment to avoid the risk of fire and burns.
- The Transcend 3 miniCPAP 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 3 miniCPAP is not defibrillation proof.
- Do not attempt to sterilize Transcend 3 miniCPAP.
- If the device is to be used by multiple patients a main flow bacteria filter should be installed in-line between the device and the breathing circuit tubing to prevent contamination.
- 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 in operation, air flow from the device flushes 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.
- Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- Do not position the equipment in bed. Covering breathing tubes with a blanket or heating them can affect the quality of therapy or injure the user.
- To prevent disconnection of the tubing during use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- 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 3 miniCPAP 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 3 miniCPAP only with the Somnetics-supplied power supplies, mobile power adapter, or batteries. See **Appendix: Part Numbers**.
- Discontinue use of the Transcend 3 miniCPAP and contact your physician if respiratory or skin irritations occur.
- Do not introduce objects into the Transcend 3 miniCPAP 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 3 miniCPAP, including optional batteries, must be disposed of in accordance with local regulations.
- The equipment must not be covered or positioned in such a way that adversely affects the performance of the equipment, as it may also create a safety issue. Examples of this would include:
    - The equipment must not be positioned in a bed.
    - The equipment should not be placed anywhere other than on a firm, flat surface.
    - Do not position in a location where pets or children can access equipment.
    - Do not position near an open window or other location where dust, or pests (insects) can affect equipment safety and/or performance.
    - Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.
    - Do not block the air intake port, thereby interfering with therapy.

DBP

Device contains DBP (a phthalate). Significant exposure to DBP may interfere with the normal development of the male reproductive tract. Testing has demonstrated that DBP exposure levels are well below established limits. Women who are pregnant or nursing may wish to discuss the benefits and risks of this device with a physician.

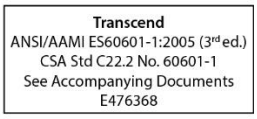
Symbols

Attention: Consult accompanying documents

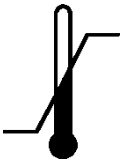
IP22

Protected against finger-sized objects and against dripping water when tilted 15 degrees from specified orientation

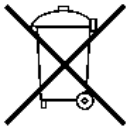
Type BF Applied Part



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



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

Non-Condensing

Upper and lower humidity limits

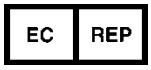
Rx Only

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

Batch code

Date of Manufacture



Authorized Representative in the European Community

Manufacturer

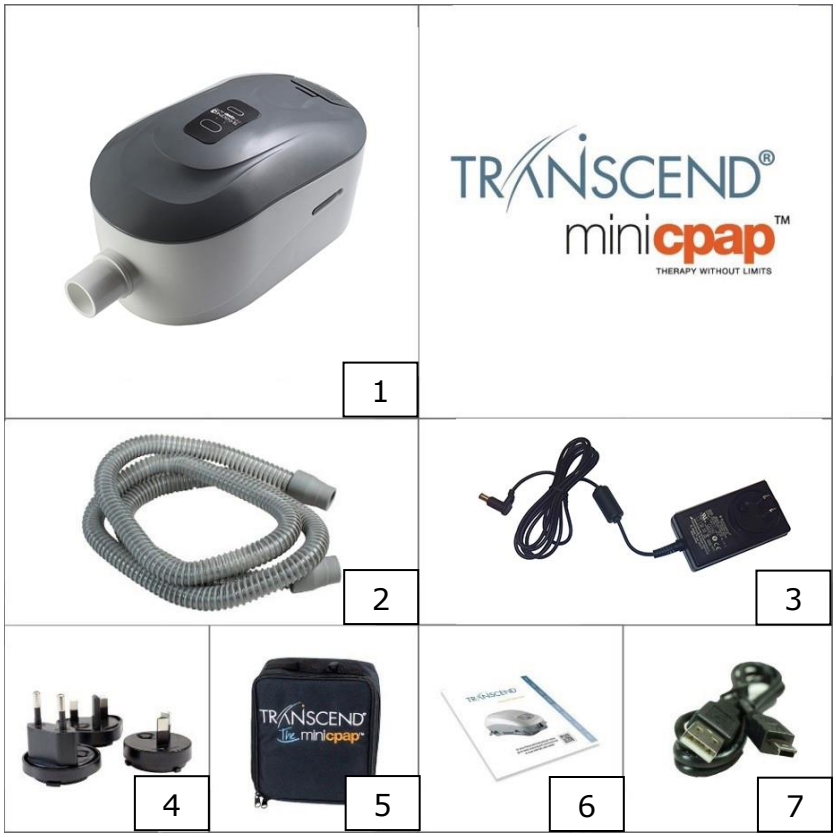
Fragile, handle with care

Keep dry

Serial Number

Components of the Transcend 3 miniCPAP

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 product to you.



1 Transcend 3 miniCPAP Auto or Transcend 3 miniCPAP

2 Air Supply Tube (Compatible with standard 22 mm connector)

3 Multi-plug universal power supply (PSA2)

4 Changeable plug pack

5 Transcend Travel bag

6 Transcend 3 miniCPAP Quick Guide

7 USB Cable

What's not included (all sold separately)

- Transcend Mobile Power Adapter
- Transcend P_4 Battery
- Transcend P_8 Battery
- Transcend Portable Solar Battery Charger (to be used as an alternative charging source for Transcend P_4 and P_8 batteries)
- Patient Mask

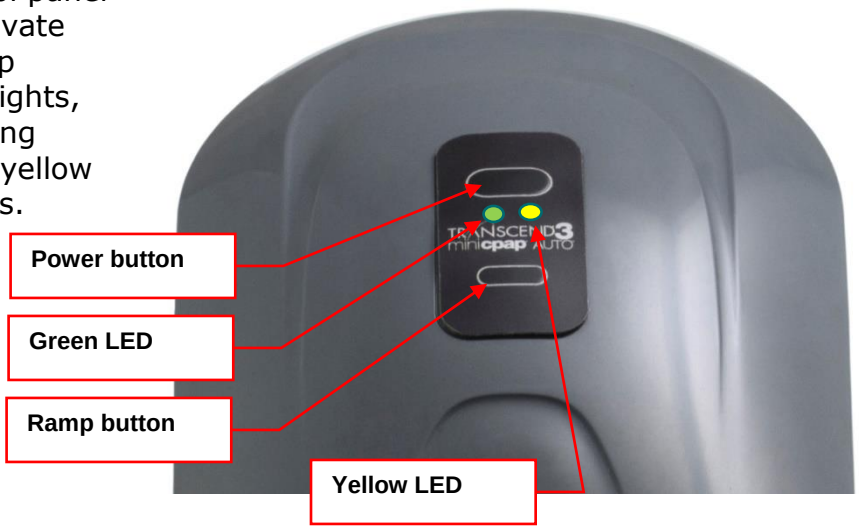
Description of Transcend 3 miniCPAP components

Transcend 3 miniCPAP Device

The Transcend 3 miniCPAP comes ready to generate and regulate continuous positive airway pressure therapy for delivery to the interface (mask). An external power source connects to the Transcend 3 miniCPAP to supply power to the device.

Control panel

The Transcend 3 miniCPAP 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 3 miniCPAP.

A variety of power sources may be used to power the Transcend 3 miniCPAP. 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 adapter 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 3 miniCPAP.

USB port

A mini-AB USB port is provided for direct data exchange between the Transcend 3 miniCPAP and a computer via a USB data cable. This interface allows the clinician to configure the Transcend 3 miniCPAP for prescription pressure, ramp settings and Auto 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 3 miniCPAP through an Air Inlet Filter. The Filter Assembly should be replaced minimally after 6 months of use. Replace more frequently as desired.

Assembling the Transcend 3 miniCPAP

1. Attach the air supply tube to the air outlet on the Transcend 3 miniCPAP device.
2. Connect the mask to the opposite end of the air supply tube.
3. Plug the power supply barrel connector into the Transcend 3 miniCPAP power jack on the rear of the device.
4. Connect power supply to a wall outlet.

Powering the Transcend 3 miniCPAP

There are three choices for powering your Transcend 3 miniCPAP device:

- **Using the Multi-Plug Universal Power Supply (PSA2)**
- **Using the optional Transcend (P_4 or P_8) Battery**
- **Using the optional Transcend Mobile Power Adapter (MPA1)**

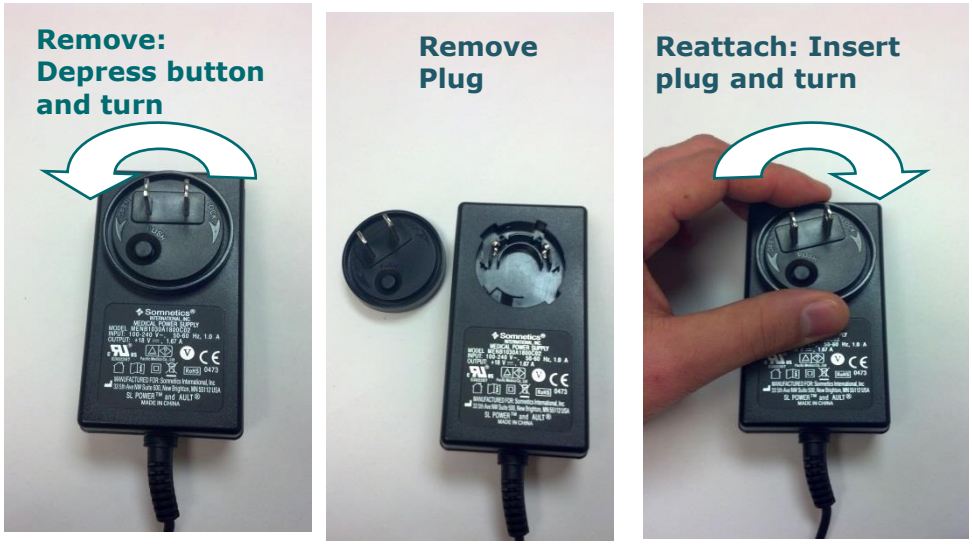
Using the Multi-plug Universal Power Supply (PSA2)

The Multi-plug Universal Power Supply (PSA2) and Changeable Plug Pack containing three (3) exchangeable plugs are contained with each Transcend 3 miniCPAP. 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 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 3 miniCPAP device.
5. Insert the other end of the power supply into an AC line power outlet.
6. The Transcend 3 miniCPAP 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 3 miniCPAP 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 P_4 or P_8 Battery

The Transcend P_4 and P_8 Batteries are optional power sources for Transcend 3 miniCPAP. To use, connect the P_4 or P_8 battery outlet cable to the Transcend 3 miniCPAP by inserting the barrel connector into the power jack on the Transcend 3 miniCPAP. Be sure the power-up LED flash sequence completes indicating that power is being supplied to the Transcend 3 miniCPAP 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 3 miniCPAP 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 P_4 or P_8 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 3 miniCPAP 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 3 miniCPAP 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 3 miniCPAP and that it has successfully entered Standby Mode.

Using the Transcend P_4 or P_8 Battery in conjunction with the Transcend Mobile Power Adapter

Note Use the battery in-line with the Mobile Power Adapter when possible. Connecting the battery in-line with the Mobile Power Adapter 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 plug of the Mobile Power Adapter into the battery.
2. Insert the barrel connector of the battery into the Transcend 3 miniCPAP power jack so that the plug and cord face upward.
3. Plug the Mobile Power Adapter into the mobile power receptacle.
4. The Transcend 3 miniCPAP 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 3 miniCPAP and that it has successfully entered Standby Mode.

Explanation of the Transcend P_4 and P_8 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 Adapter 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 3 miniCPAP.

Charging the Transcend P_4 or P_8 Battery

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

Average Battery Life for P4 Battery (hours)						
		Therapy Pressure (cm H_2O)				
		4	**8**	**12**	**16**	**20**
Breaths per minute	**10**	25	13	9	6	4
	15	19	12	7	5	4
	20	11	8	6	4	4

Average Battery Life for P8 Battery (hours)						
		Therapy Pressure (cm H_2O)				
		4	**8**	**12**	**16**	**20**
Breaths per minute	**10**	50	27	18	13	9
	15	36	25	15	12	9
	20	24	17	13	10	8

Note Charge the battery fully before the first use. Do not connect the Battery to Transcend 3 miniCPAP 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 Adapter during therapy even if the battery is fully charged.

- Connect the power outlet barrel connector from the Universal Power Supply or Mobile Power Adapter to the power connection jack on the P_4 or P_8 Battery.
- Connect the Universal Power Supply or Mobile Power Adapter 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 Adapter (MPA1)

Transcend 3 miniCPAP may be powered with an optional Mobile Power Adapter. The Mobile Power Adapter is supplied with two cables: one to connect the MPA1 to the Transcend 3 miniCPAP device, and the other to connect the MPA1 to a mobile power receptacle.

Note Use only the Somnetics-supplied Transcend Mobile Power Adapter.

1. Connect both cables to the base of the Mobile Power Adapter.
2. Insert the barrel connector of the MPA1 output cable to the power jack of the Transcend 3 miniCPAP.
3. Insert the plug connector into the mobile power receptacle (e.g. cigarette lighter outlet).
4. The Transcend 3 miniCPAP 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 3 miniCPAP and that it has successfully entered Standby Mode.

Note Make certain that the cables are securely connected to the Mobile Power Adapter and to the power jack on the back of the Transcend 3 miniCPAP. It may be necessary to unplug the cables and reconnect to ensure a good connection.

Using the Transcend 3 miniCPAP

The control panel of the Transcend 3 miniCPAP 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 3 miniCPAP operational status is displayed by LED illumination states.

When a power source is connected to the device the Transcend 3 miniCPAP 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 3 miniCPAP 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 3 miniCPAP 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.

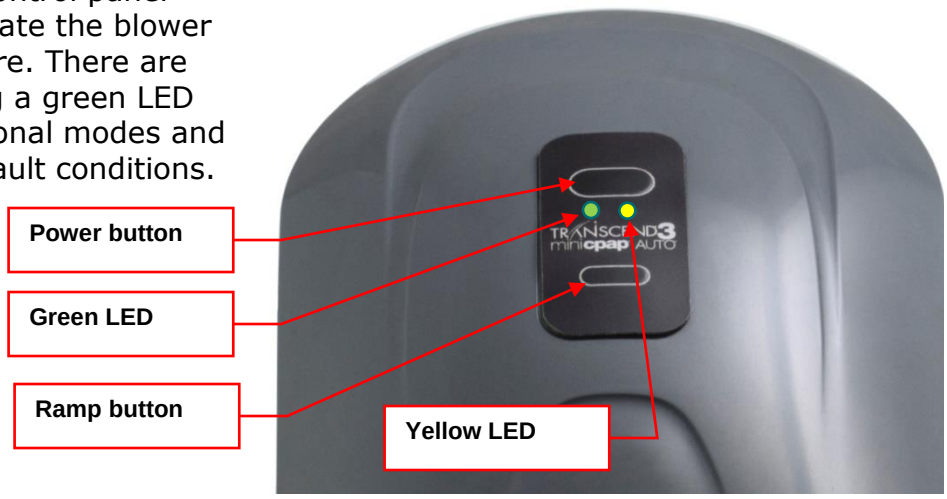
Standard user modes

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 3 miniCPAP 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 3 miniCPAP 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 3 miniCPAP 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 software section of this manual displays how to modify ramp settings on your device.

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 3 miniCPAP is in On Mode. If not, press the power button.
2. Adjust your mask to eliminate mask leaks.
3. Press the Ramp button. The pressure will drop to the Ramp starting pressure 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 3 miniCPAP will resume at the full prescribed pressure as soon as power is restored.

Using the EZEX function

The EZEX function is a special feature that decreases therapy pressure on exhalation. This feature is designed to provide additional comfort to the patient by reducing the amount of resistance they experience as they exhale.

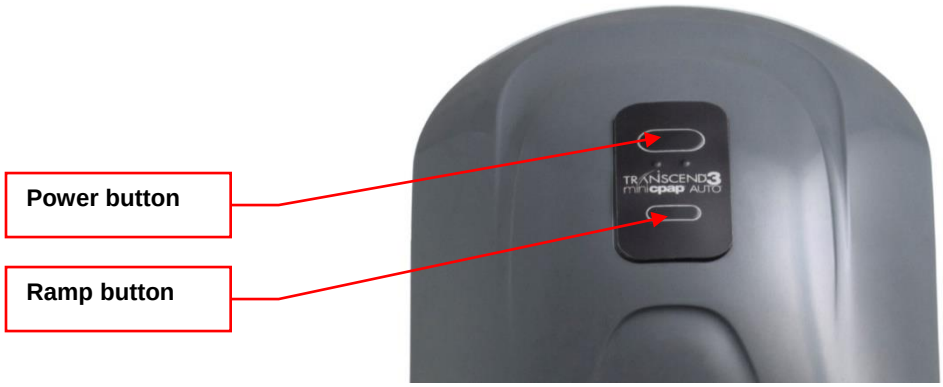
There are four EZEX settings: OFF, 1, 2 or 3; progressively increasing the amount of pressure relief from none to maximum. The software section of this manual displays how to modify EZEX settings.

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 3 miniCPAP Filter Media should be replaced every six months at minimum.

1. Remove the filter assembly by pulling the tab on the back of the device to release it. Then pull the filter assembly away from the device.

2. Discard the entire filter assembly and replace with a new one.

Caring for your Transcend 3 miniCPAP and its components

Transcend 3 miniCPAP is a maintenance free device. This section presents the following topics:

- **Cleaning the exterior**
- **Cleaning of accessories**
- **Cleaning for multiple users**

Warning:

- Unplug the Transcend 3 miniCPAP before cleaning.
- Do not submerge the Transcend 3 miniCPAP 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 3 miniCPAP.
- 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 3 miniCPAP.

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 3 miniCPAP 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 3 miniCPAP 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:

Product	Periodic Cleaning Cycle	Product Service Life
Transcend 3 miniCPAP	2x/Month	5-Year

Cleaning of Accessories

The following accessory 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.

Accessory	Periodic Cleaning Cycle	Product Service Life
Air Supply Tube	Daily	3-Month

1. Fully immerse the air supply tube 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 air supply tube by immersing in distilled water. Move the air supply tube in a back and forth motion for approximately10 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 outside of the air supply 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.

Cleaning for Multiple Users

If using the device on multiple users, perform the following steps to clean the device before each new user:

1. Unplug the power supply prior to cleaning.
2. Remove and discard the bacterial/viral filter.
3. Remove and discard the used air supply tube.
4. Follow instructions for cleaning the exterior of the device as noted in Cleaning the Exterior (above).

5. Apply a new bacterial/viral filter to the air outlet of the Transcend 3 miniCPAP and attach a new air supply tube before providing the device to a new user.

Warning: The air supply tubing, mask assembly and bacterial/viral filters should be discarded after each patient use using standard institutional biohazard procedures. No attempt should be made to clean, disinfect, or sterilize these components for multiple users. These components are for single patient use. No attempt should be made to clean, disinfect or sterilize these components. Manufacturer's instructions must be followed with regard to cleaning, disinfecting, and re-use of patient interfaces (masks).

Warning: Only use bacterial/viral filters that are commercially available and designed for use with CPAP machines. Follow the manufacturer's instructions for use of the filter. Only use those commercially available filters that do not require recalibration of the PAP device.

Warning: Do not submerge the Transcend 3 miniCPAP or power supply in liquid. Do not allow liquid or cleaning solution to enter the device.

Environmental Information

This Machine should be disposed of separately, not as unsorted municipal waste. To dispose of your machine, you should use appropriate collection and recycling systems available in your region. If information on these disposal systems in needed, please contact your local waste administration.

Software User Guide

Your Transcend 3 miniCPAP device comes with easy-to-use software that helps you adjust settings, observe, print and send reports and store all your data so you can access it any time.

3 **Simple Steps** and you're ready to use your software.

STEP 1

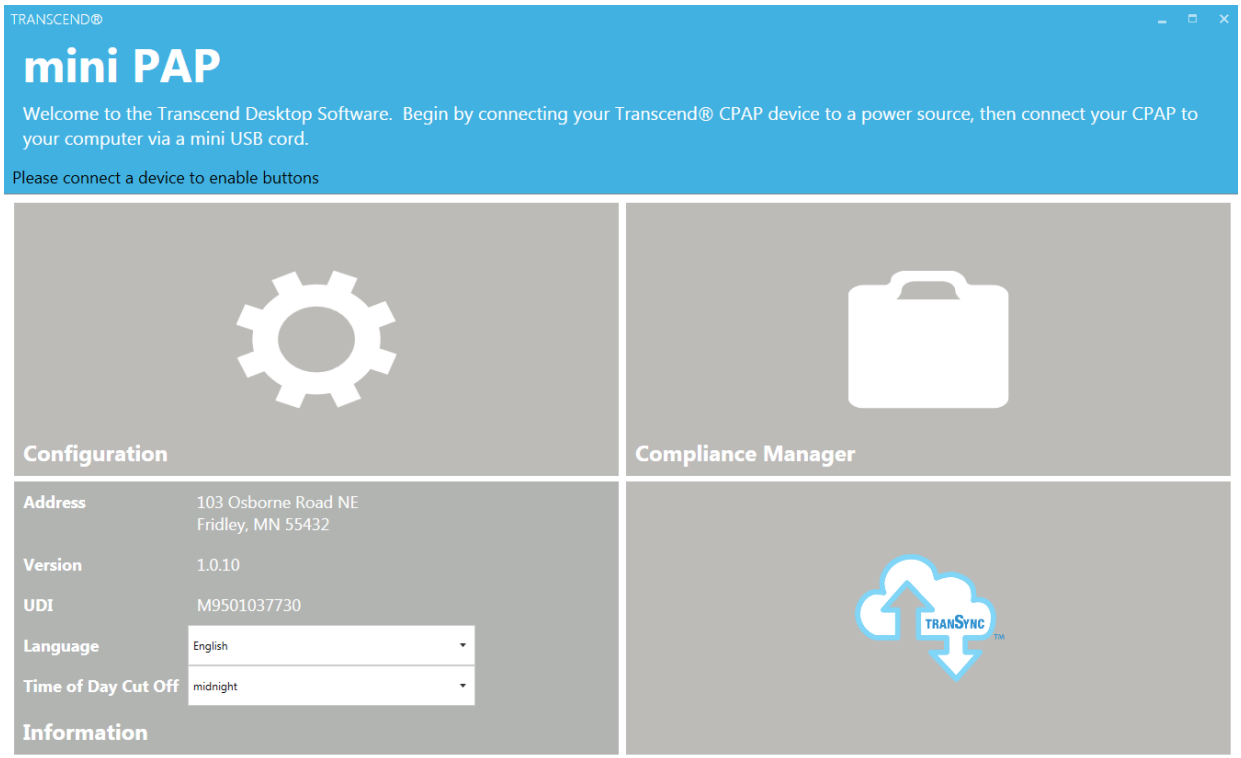
Start by downloading the device software onto your computer using this link:

NOTE: You must install the driver before downloading the software.

https://transcend.miniCPAPsoftware.com

Once you download the software, it will automatically update as we make changes and improvements.

When you open the software, the home screen will appear.

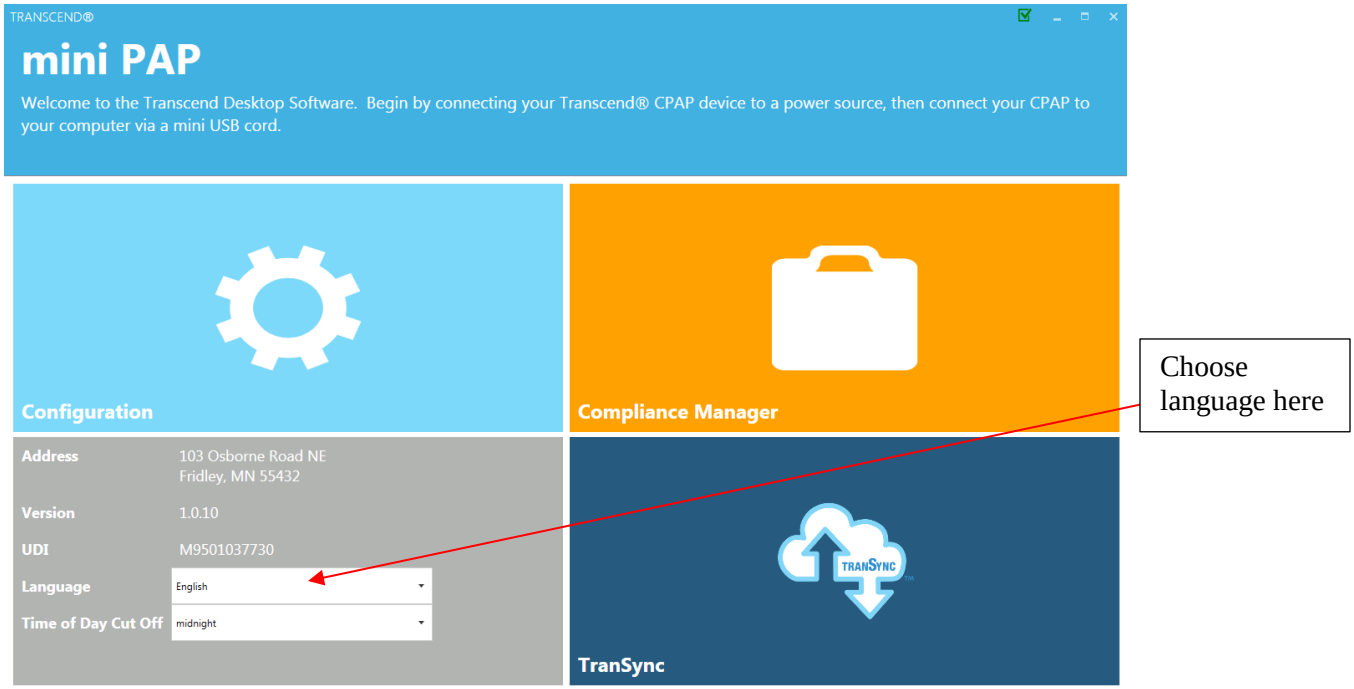


STEP 2

Connect your Transcend 3 miniCPAP device to a power source, then connect it to your computer using the supplied mini-USB cord. The mini end of the USB cord goes into the opening next to the power cord on the device; open the rubber cover to access the opening. The larger side goes into a USB portal on your computer.

STEP 3

Select your preferred language by choosing one from the dropdown menu.



Now You're Ready to Use the Transcend 3 miniCPAP Software

You can see on the Home screen interface that there are two primary areas to choose from: Configuration or Compliance Manager. Let's explore each one.

***NOTE: If you disconnect your CPAP from a power source while in the software program, the software will return to the home screen until power is resupplied. Any unsaved settings will be lost.**

CONFIGURATION

Select the Configuration box to open the configuration settings application.

Notice that when you are on any screen, in the right upper corner you will see icons for the available applications in the software. Simply click on any of them and you will go directly to that section.

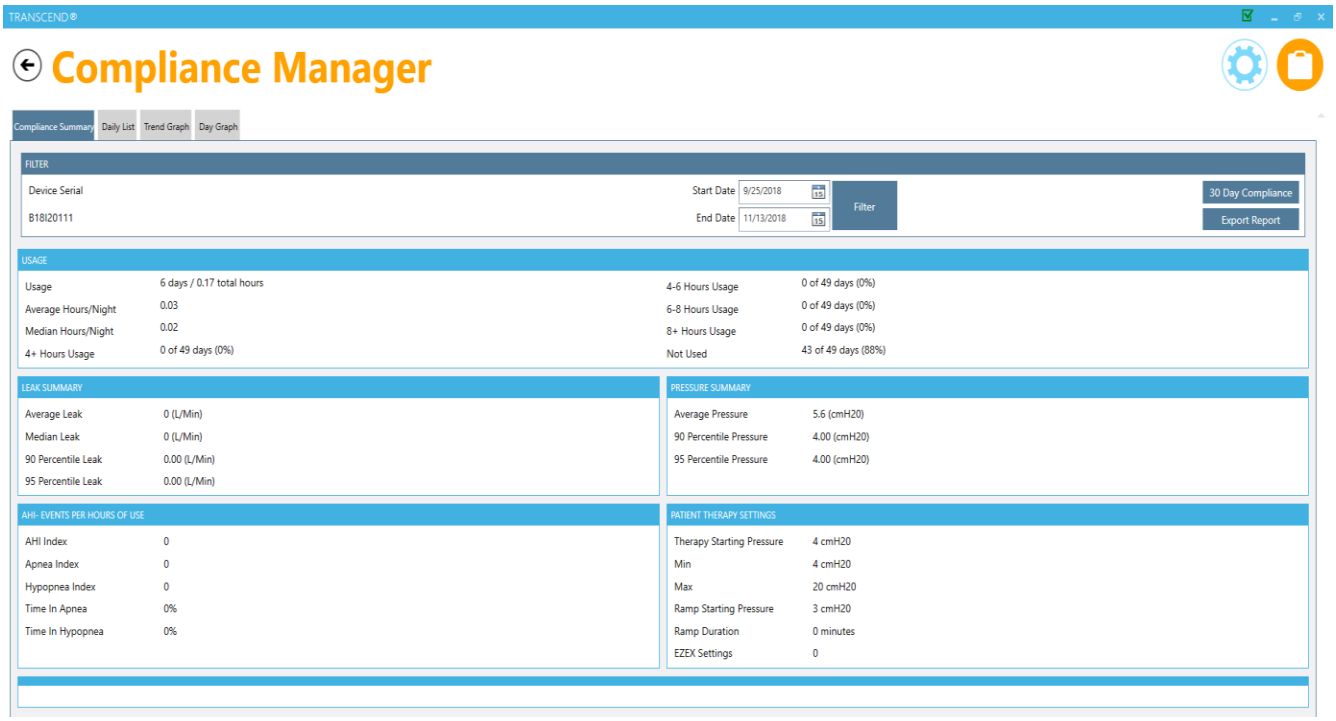
The Configuration area is used to adjust various settings on the device. Some features, such as the Therapy Pressure and Calibration are clinician settings and are only available with a password. You can, however, adjust the Starting Ramp Pressure, Ramp Duration and EZEX pressure relief settings if these options have been set by your clinician to be adjustable. To change them, simply slide on the red oval across the line to the right or left.

- The **Therapy Pressure is a clinician setting** that can only be accessed with a password. This setting will show either Fixed or Auto setting, depending on which device you have (Auto mode only available on Transcend 3 miniCPAP Auto device). If you have a fixed pressure device, one therapy pressure is available for adjustment. If setting an Auto device, the 'Auto' tab will show as such and you may adjust the therapy pressure range by sliding the left and right cursors along the metric line to the prescribed setting range.
- The **Starting Ramp Pressure** controls the pressure at which your CPAP therapy starts when you engage the Ramp feature. This selection can be adjusted up to 1cmH20 below your Therapy Pressure.
- The **Ramp Duration** controls how long it takes for your CPAP to reach your prescribed therapy pressure when the Ramp feature is engaged. The Ramp feature provides you with a lower therapy pressure to help you fall asleep more comfortably as it slowly Ramps the CPAP pressure up to your prescribed therapy level. This setting can be adjusted between 5 and 45 minutes, or toggle the switch to OFF to deactivate this feature.
- The **EZEX Setting** drops the pressure as you breathe out to make exhalation while using your miniCPAP more comfortable for you. This can be set to OFF, or pressure relief settings between 1 and 3 (3 being the greatest amount of pressure relief).
- The **Calibrate feature is a clinician setting** that can only be accessed with a password. To calibrate the device, first make the appropriate adjustments to the other CPAP settings and click the update button. *You will not be able to calibrate the device while you are adjusting the other CPAP settings until you click* update. Connect the mask tubing and a manometer to the CPAP and power on the machine. If calibration is needed, select the calibrate button and slide the setting to the appropriate level. Click the calibrate complete button when finished.

***NOTE: To SAVE your adjustments to your CPAP settings, click the update button (next to the calibrate button on your screen) before navigating to another screen.**

COMPLIANCE MANAGER

Because both you and your clinician have an interest in the quality of your sessions, the **Compliance Manager** generates summary data and reports so you can review your sessions by day, week, month or longer.



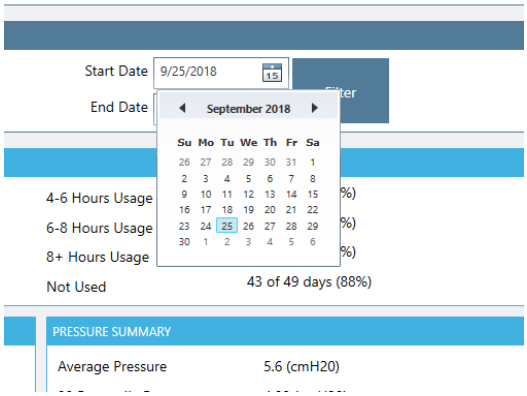
You can see the primary data summaries are:

- Usage
- Leak Summary
- Pressure Summary
- AHI-Events per Hours of Use
- Patient Therapy Settings

General Functions

Filtering by Date

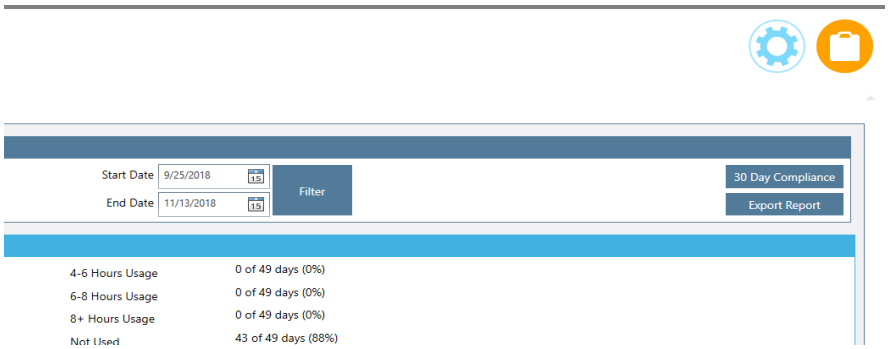
Tailor the date range of information by clicking on the calendar icons next to choose the desired start and end dates.



Then click the Filter button to update the start and end dates you would like to view.

Generate Compliance (Last 30 days of compliance report)

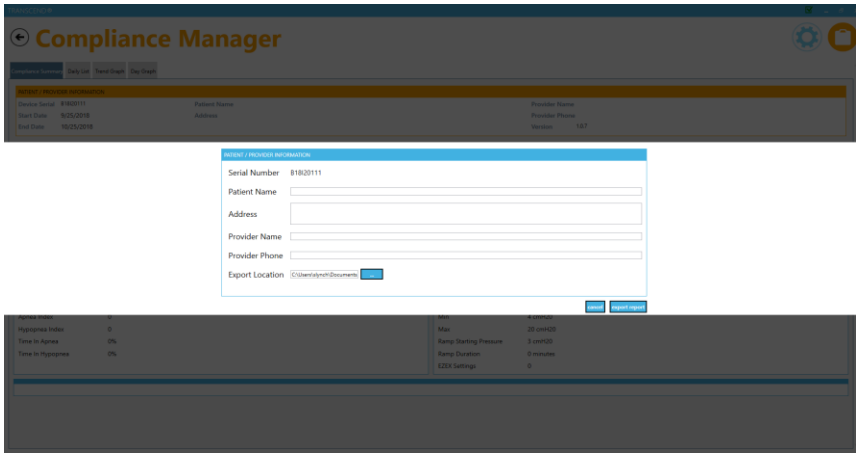
The 30 Day Compliance button will automatically pull the last 30 day window of compliance data that has at least 70% compliance (4+ hours of therapy 70% of the time).



Export Report

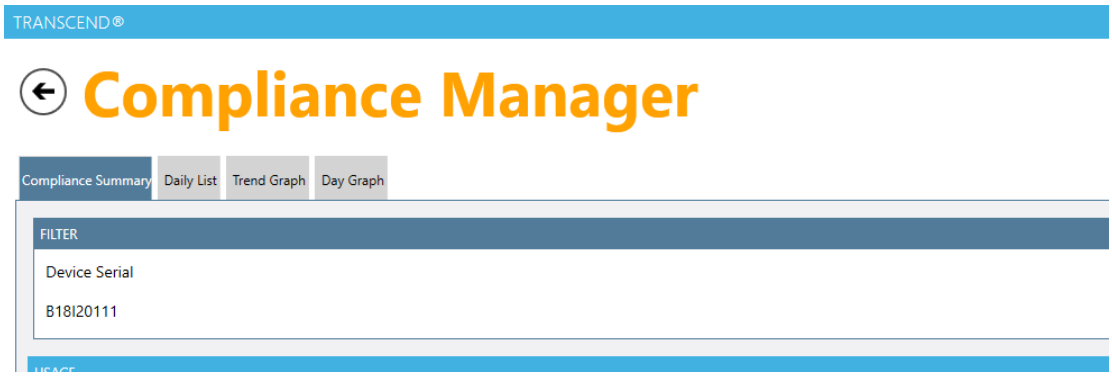
When you choose Export Report, you can save the data you are currently viewing on your screen as a .pdf document on your computer.

You will see the following screen after choosing Export Report. Type in the info you wish to save with your report: your name, address, provider name, provider phone and select a location for the .pdf to be stored on your computer. Desktop is recommended as an export location since the file will be easy to locate. Click export report button to save your report as a pdf. Once it's saved, you can click on the .pdf document to view or print it from your computer.



Choose a View

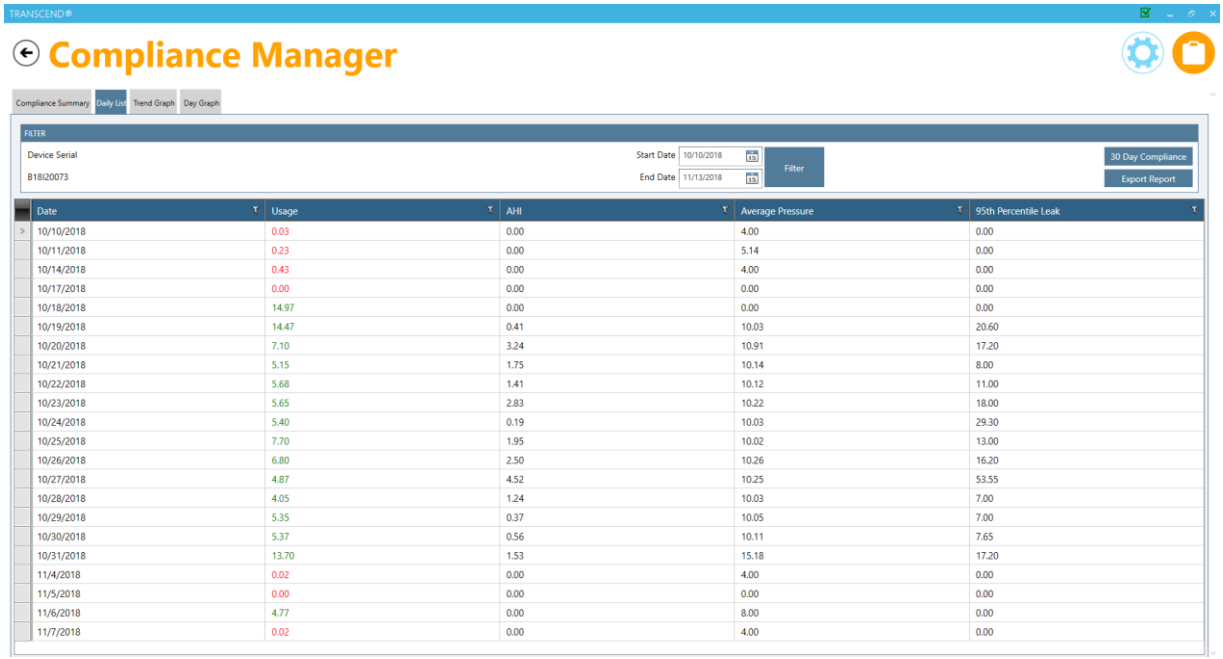
At the top of the page you will also see three grey tabs: Daily List, Trend Graph and Day Graph.



Daily List

When you select the Daily List tab you will see a general summary for the date range you have indicated. Daily List shows the Date, Hours Used, Average AHI (Apnea Hypopnea Index), Average Pressure and Average Leak percentile for each therapy session.

You can reverse the order of the data shown by selecting the column header you wish to reorganize (Date, Usage, AHI, Average Pressure or 95th Percentile Leak).

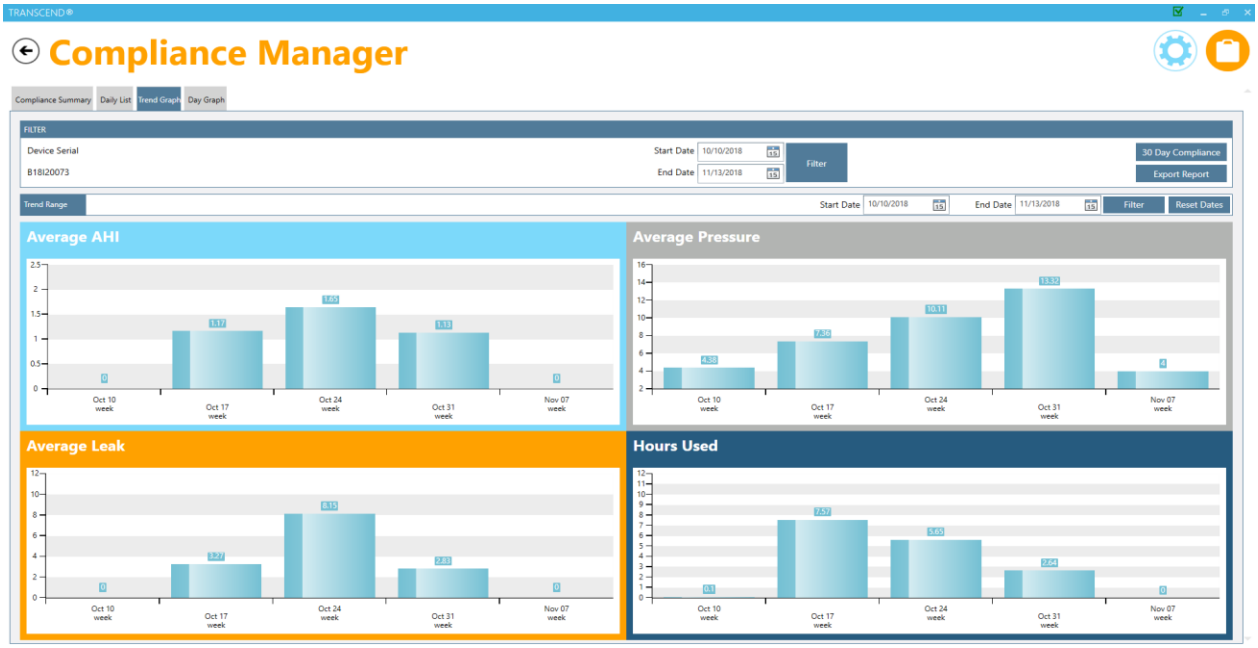


Date	Usage	AHI	Average Pressure	95th Percentile Leak
10/10/2018	0.03	0.00	4.00	0.00
10/11/2018	0.23	0.00	5.14	0.00
10/14/2018	0.43	0.00	4.00	0.00
10/17/2018	0.00	0.00	0.00	0.00
10/18/2018	14.97	0.00	0.00	0.00
10/19/2018	14.47	0.41	10.03	20.60
10/20/2018	7.10	3.24	10.91	17.20
10/21/2018	5.15	1.75	10.14	8.00
10/22/2018	5.68	1.41	10.12	11.00
10/23/2018	5.65	2.83	10.22	18.00
10/24/2018	5.40	0.19	10.03	29.30
10/25/2018	7.70	1.95	10.02	13.00
10/26/2018	6.80	2.50	10.26	16.20
10/27/2018	4.87	4.52	10.25	53.55
10/28/2018	4.05	1.24	10.03	7.00
10/29/2018	5.35	0.37	10.05	7.00
10/30/2018	5.37	0.56	10.11	7.65
10/31/2018	13.70	1.53	15.18	17.20
11/4/2018	0.02	0.00	4.00	0.00
11/5/2018	0.00	0.00	0.00	0.00
11/6/2018	4.77	0.00	8.00	0.00
11/7/2018	0.02	0.00	4.00	0.00

Trend Graph

When you click the Trend Graph tab at the top of the page, you'll see the data in graphic form.

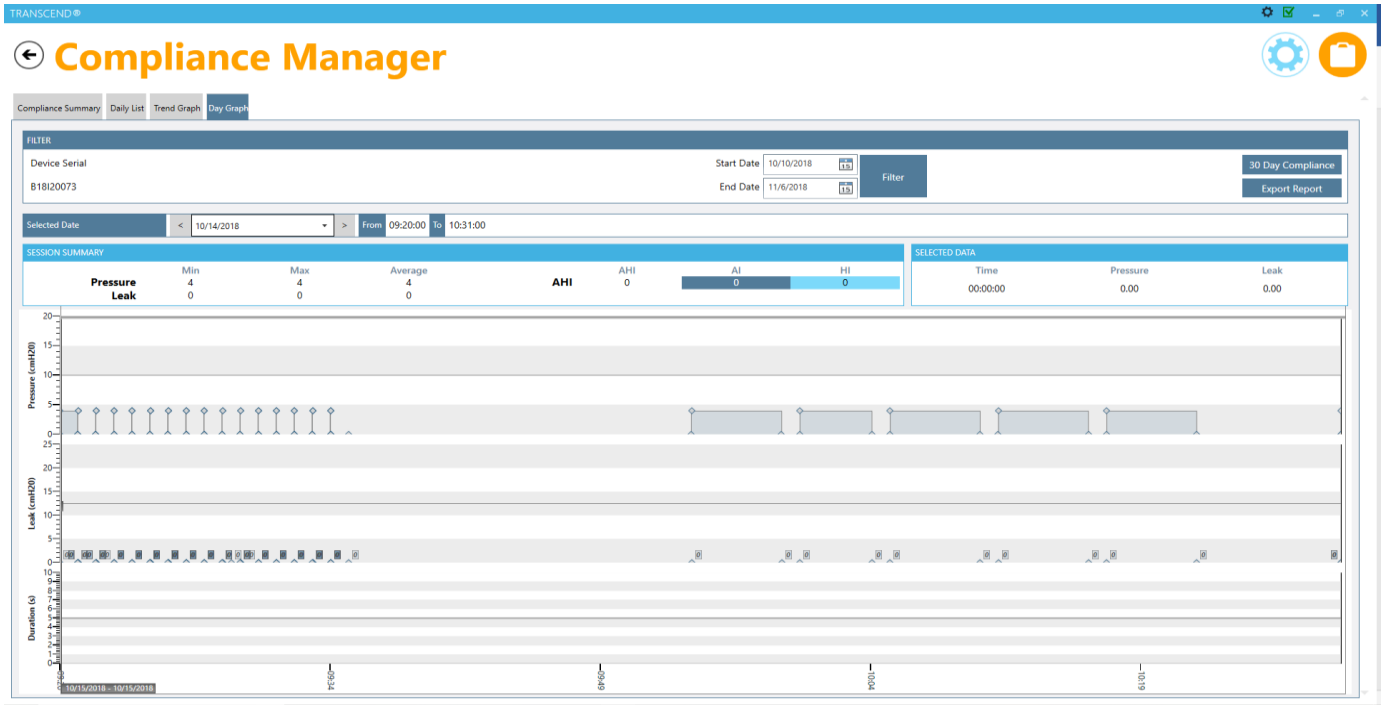
Simply click on any bar graph and you will automatically see trend ranges by month, week or day each time you click (this change in date range is reflected in the Trend Range section).



At any time, you can adjust the date range you want to view by changing the date range and clicking the Filter button. You can reset the date range after you've finished drilling down by hitting the Reset Dates button.

Day Graph

Select the Day Graph tab is used to show data that has been drilled down to the day in the Trend Graph tab or you can simply go to this tab to select a particular day's worth of data. You can choose the day you would like to view by selecting the date in the Selected Date field.



Questions? Call 877-621-9626 or email info@somnetics.com.

Fault and alert codes

Fault codes

When the Transcend 3 miniCPAP 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.

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 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.
Off	Flashes 7 times*	Pressure sensor out of range	While in standby, the pressure sensor reads a value outside its expected range. This could be due to a "pinched" or blocked pressure sense tube or fluctuation in ambient temperature This could also be due to faulty pressure sensor or electronics.
Off	Flashes 9 times	Bad firmware checksum	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.
Off	Flashes 11 times	Stalled blower	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.
Off	Flashes 12 times	Low power	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.

Device LED	Fault LED	Error	Comments
Off	Flashes 13 times*	Processor over-temp	The processor on-chip temperature sensor has reported an excessive temperature.
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 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).

Device LED	Fault LED	Error	Comments
Off	Flashes 15 times	Cannot regulate	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.

Troubleshooting

Problem	Probable Cause	Solution
Discomfort due to a feeling of high pressure.	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 the Filter Media.
Device 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.
No airflow from the device.	Device motor failure; or, electronics failure.	Contact the homecare provider's technical service department.
Yellow fault 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 and alert codes** 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.
Device shuts down during therapy	Improper seal of external hardware (mask, tubing); or use of external hardware past recommended service life.	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.

Appendix: Part numbers

This section presents three topics:

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

Disposable parts

Item	Part number		Item	Part number
Transcend 3 Filter Assembly	503109		Standard 6-foot hose	503081

Accessories

Item	Part number		Item	Part number
Transcend P_8 Battery	503023		Transcend Mobile Power Adapter (MPA1)	503029
Transcend P_4 Battery	503026		Transcend Portable Solar Battery Charger	503056

Replacement parts

Item	Part number		Item	Part number
Transcend 3 miniCPAP Auto	503104		Transcend Travel Bag	503012
Transcend 3 miniCPAP Auto Service Unit	503105		Multi-plug Universal Power Supply (PSA2)	503059
Transcend 3 miniCPAP	503106			
Transcend 3 miniCPAP Service Unit	503107		Changeable Plug Pack	503060
Multi-plug Universal Power Supply Set (Contains 503059 & 503060)	503078		USB cable	503020

Appendix: Specifications

This section presents the following topics:

- **Transcend 3 miniCPAP**
- **AC power supply - PSA2**
- **Mobile power adapter (optional) - MPA1**
- **Batteries**
- **Transcend 3 miniCPAP performance**
- **Manufacturer's declaration**

Transcend 3 miniCPAP

Transcend 3 miniCPAP weight:	1.09 lbs (494 gm)
Transcend 3 miniCPAP dimensions:	7.48 in x 3.74 in X 3.7 in (19 cm x 9.5 cm X 9.4 cm)
Air outlet connector port dimensions:	22-mm diameter standard connection

AC power supply - PSA2

AC supply input:	100-240 VAC, 50-60Hz
AC supply output:	18 VDC, 1.67 Amp

Mobile power adaptor (optional) - MPA1

Mobile power adapter input:	13.0 VDC nominal. 10 to 15.5 VDC, 7.5 Amp
Mobile power adapter output:	19.2 VDC, 2.6 Amp

Batteries (optional) -

Transcend P_8 Battery	14.4 VDC, 5,200 mAH
Transcend P_4 Battery	14.4 VDC, 2,600 mAH

Transcend 3 miniCPAP 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 95°F (5 to 35°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 90% relative humidity, non-condensing
Altitude range:	0-8000 feet (Automatically adjusted)

Manufacturer's declaration

This section presents the following topics:

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

Electromagnetic emissions

The Transcend 3 miniCPAP 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.

Emissions test	Compliance	Electromagnetic environment—guidance
RF radiated emissions CISPR 11	Group 1	The Transcend 3 miniCPAP 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 Transcend 3 miniCPAP 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 Transcend 3 miniCPAP 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.	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 Transcend Auto 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.

The Transcend 3 miniCPAP 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.	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
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.
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 Transcend Auto requires continued operation during power line interruptions, it is recommended that the Transcend Auto 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 150 KHz to 80 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) 80 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

IEC 60601-1 compliance

Protection against electric shock:	Class II Type BF
Degree of protection against ingress of water:	IP22. 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.
Use of flammable gasses:	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:	22-mm diameter, 1.8 m long

Performance

Sound power level (@ 10cm H_2O pressure, static)	38.4 dB					
Sound pressure level (@ 10cm H_2O pressure, static)	30.4 dB					
Sound pressure level (@ 10cm H_2O pressure, static)*	26.2 dB					
Working pressure range:	4 to 20 cm H_2O					
Pressure limit:	30 cm H_2O					
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)	3.73	7.27	10.86	14.97	18.87
	Average flow at the patient connection port (l/min)	94.8	139.8	135.3	128.4	121.3

*Sound pressure level reported in a typical use environment

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:

Product	**Warranty Period***
Transcend 3 miniCPAP Auto and Transcend 3 miniCPAP	3 years
Transcend P4 and P8 Batteries	9 months
Transcend Portable Solar Charger	1 year
Transcend Mobile Power Adaptor	1 year

*From date of user purchase.

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 103 Osborne Road NE, Fridley, Minnesota 55432 USA, 1.877.621.9626 or 1.651.621.1800.

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