

TRANSCEND[®]
365 mini **cpap**[™]
User Manual



Notices



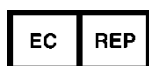
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Rx Only

About This User Manual

NOTE: All 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: Some images displayed may differ from the current product presentation.

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Introduction

The Transcend 365 miniCPAP™ by Transcend® is a medical device that provides positive airway pressure to users in the range of 4 to 20 cmH₂O as prescribed by your clinician. The Transcend 365 miniCPAP product family includes the Transcend 365 miniCPAP and the Transcend 365 miniCPAP Auto.

- The Transcend 365 miniCPAP may be used every day on a bedside table and can be packed with you when you travel.
- An interactive LCD interface makes the Transcend 365 miniCPAP easy to operate.
- The Transcend 365 miniCPAP is the only continuous positive airway pressure (CPAP) device licensed to use integrated Capillary Force Vaporization™ (CFV) humidification technology.* CFV instantaneously combines humidified vapor with the airstream when you inhale, providing a warm, moist, comfortable airflow. This humidification method requires less water than other humidification systems, which reduces the size of the humidifier.
- A DC power jack and USB port are also incorporated into the Transcend 365 miniCPAP.

*Capillary Force Vaporization™ (CFV) humidification technology may be covered by one or more U.S. or foreign patents (patent 6,634,864, patent 7,431,570, patent 7,920,777, patent 8,201,752, patent 7,942,644, patent 5,008,207) and other U.S. or foreign patents pending.

Indications for Use

The 'Transcend 365 miniCPAP System' provides positive airway pressure to support treatment of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The device is intended for home and hospital/institutional use. The integrated humidifier provides humidification of air delivered from the Transcend 365 devices. The use of the humidifier is optional.

Contraindications

The Transcend 365 miniCPAP 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 waking
- 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 365 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 other than as specified in the humidifier reservoir. The Transcend 365 miniCPAP should not be exposed to environmental conditions where the system may get wet. If liquids are spilled onto the machine, unplug the machine and let the parts dry before plugging it back in.
- This device is not intended for life support.
- The Transcend 365 miniCPAP must be set up and adjusted by a trained provider before being used.

- 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 m from the equipment to avoid the risk of fire and burns.
- The Transcend 365 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 365 miniCPAP is not defibrillation proof.
- Do not attempt to sterilize Transcend 365 miniCPAP.
- The device is only compatible with appropriately marketed FDA cleared masks and hoses. A mask should not be used unless the device is turned on and is properly delivering Ramp or therapy pressure. The proper placement and positioning of the mask on the face is critical to the consistent operation of this equipment. 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.
- Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- 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 a baby's reach. Keep cord and tube out of children's reach.
- Small parts are unlikely to be expelled from the Transcend 365 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.
- 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.
- Do not use the Transcend 365 miniCPAP at an altitude above 8000 ft. (2438 m) unless in an airplane, or outside a temperature of 41-95F (5-35 C). Using the device outside of this temperature range or above this altitude can affect the quality of the therapy or injure the user.
- Do not add any attachments or accessories to the humidifier or CPAP that are not approved for use by this instruction. Unapproved accessories may lead to improper functioning of the device and affect the quality of the therapy or injure the user.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Transcend 365 miniCPAP including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

Cautions

- Federal law (United States) restricts this device to sale by, or on the order of, a physician.
- Power the Transcend 365 miniCPAP only with the Somnetics-supplied power supplies, or batteries. See [Appendix: Part Numbers](#).
- Discontinue use of the Transcend 365 miniCPAP and contact your physician if respiratory or skin irritations occur.
- Do not introduce objects into the Transcend 365 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.
- **Use distilled water only. The use of distilled water is required for proper function of the heated humidifier.** Failure to use distilled water will damage the humidifier and require repair or replacement. Alternatively, water may be filtered with the **Transcend Portable Water Filter** for use with your Transcend 365 miniCPAP humidifier. The ZeroWater™ Portable Filter Replacement Cartridge can be purchased directly from your Transcend dealer, or at most major retailers.
- Do not use a nebulizer with the device.
- To protect the environment, some parts and accessories of the Transcend 365 miniCPAP, including optional batteries, must be disposed of in accordance with local regulations.
- The equipment must not be positioned in an environment that can unacceptably affect the basic safety and performance of the equipment. 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 in an open window or other location where dust, sunlight, or pests (insects) can affect equipment safety and/or performance

- Magnets used to secure the humidifier reservoir to the CPAP may interfere with other medical devices. Do not place the Transcend 365 miniCPAP within 6 inches (15 cm) of medical devices such as cardiac pacemakers, ICDs, and implantable neurostimulators.
- The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected. Examples of this would include:
 - 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



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 below established limits. Women who are pregnant or nursing may wish to discuss the benefits and risks of this device with a physician.

Symbols (The following symbols may appear on the product or packaging)



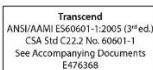
Caution

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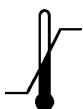
Protected against finger-sized objects and against dripping water when tilted 15 degrees from specified orientation



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



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.



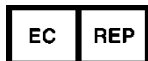
Batch code



Date of Manufacture



Precedes reference or item number



Authorized Representative in the European Community



Manufacturer



Fragile, handle with care



Keep dry



Serial Number



Use distilled water only. The use of distilled water is required for proper function of the heated humidifier. Failure to use distilled water will damage the humidifier and require repair or replacement. Alternatively, water may be filtered with the **Transcend Portable Water Filter** for use with your Transcend 365 miniCPAP humidifier.

Components of the Transcend 365 miniCPAP

Begin by unpacking all items from the Transcend 365 miniCPAP travel bag and inspecting them to ensure they were not damaged during shipment. Report any missing or damaged items to the home healthcare provider that sold the Transcend 365 miniCPAP to you.



Included with Transcend 365 miniCPAP

- Transcend 365 miniCPAP device and integrated humidifier
- Universal power supply (PSA3) and power cords
- Travel bag
- Transcend 365 miniCPAP Quick Guide
- USB cable

Accessories (Sold Separately)

- Air Supply Tube (Compatible with standard 22 mm connector)
- P10 Battery™
- Transcend Portable Water Filter
- TranSync Bluetooth Module
- Patient Mask

The Transcend 365 miniCPAP

Your Transcend 365 miniCPAP comes ready to generate and regulate continuous, positive airway pressure therapy when powered with the included AC power supply or optional battery.

No allergic reactions to materials used in the equipment have been identified with the Transcend 365 miniCPAP.

Assembling the Transcend 365 miniCPAP

Your mask connects directly to the Transcend 365 miniCPAP via the air supply tube.

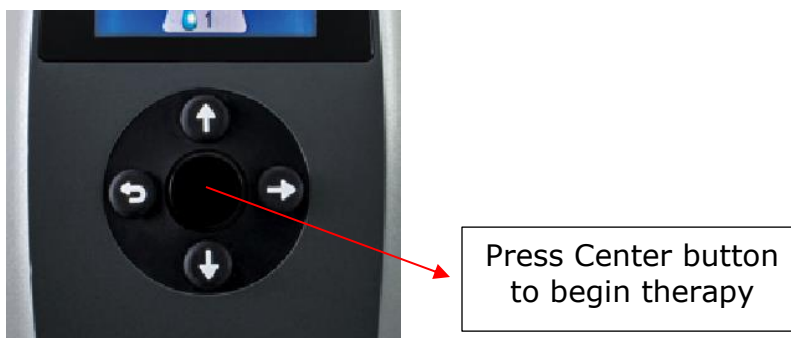
Follow these steps to assemble the Transcend 365 miniCPAP:

1. Connect your mask (sold separately) to an air supply tube with a standard 22mm connector (sold separately).
2. Connect the air supply tube directly to the Transcend 365 miniCPAP device, making sure it is fully seated.
3. Plug the power supply into the Transcend 365 miniCPAP. Place device on a flat, stable surface.
4. Connect the appropriate power cord to the power supply and connect the power cord to a wall outlet.

Getting Started with the Transcend 365 miniCPAP

Allow the Transcend 365 miniCPAP to adjust to ambient temperature after removing from storage. To begin therapy, plug in the power supply to your Transcend 365 miniCPAP and press the Center button to begin therapy.

NOTE: To begin therapy from the home screen, first ensure that no icons are highlighted, then press the Center button. You may also start therapy from any screen by holding the Center power button for three seconds.



NOTE: If the miniCPAP device loses power while delivering therapy, the CPAP will power on and resume therapy as soon as power is restored.

Home Screen and Control Panel



Home Screen

Once power is supplied to the device, the LCD display lights up with the home screen. The top right white numbers on the home screen show the set pressure (large number) and the minimum and maximum pressures (small, lighter numbers - 6 and 10 in this image). The home screen display quick menu options: Compliance Report (left), Settings (top), Last Session Report (right) and Humidification (bottom).

These functions are described in more detail in upcoming sections of the manual.

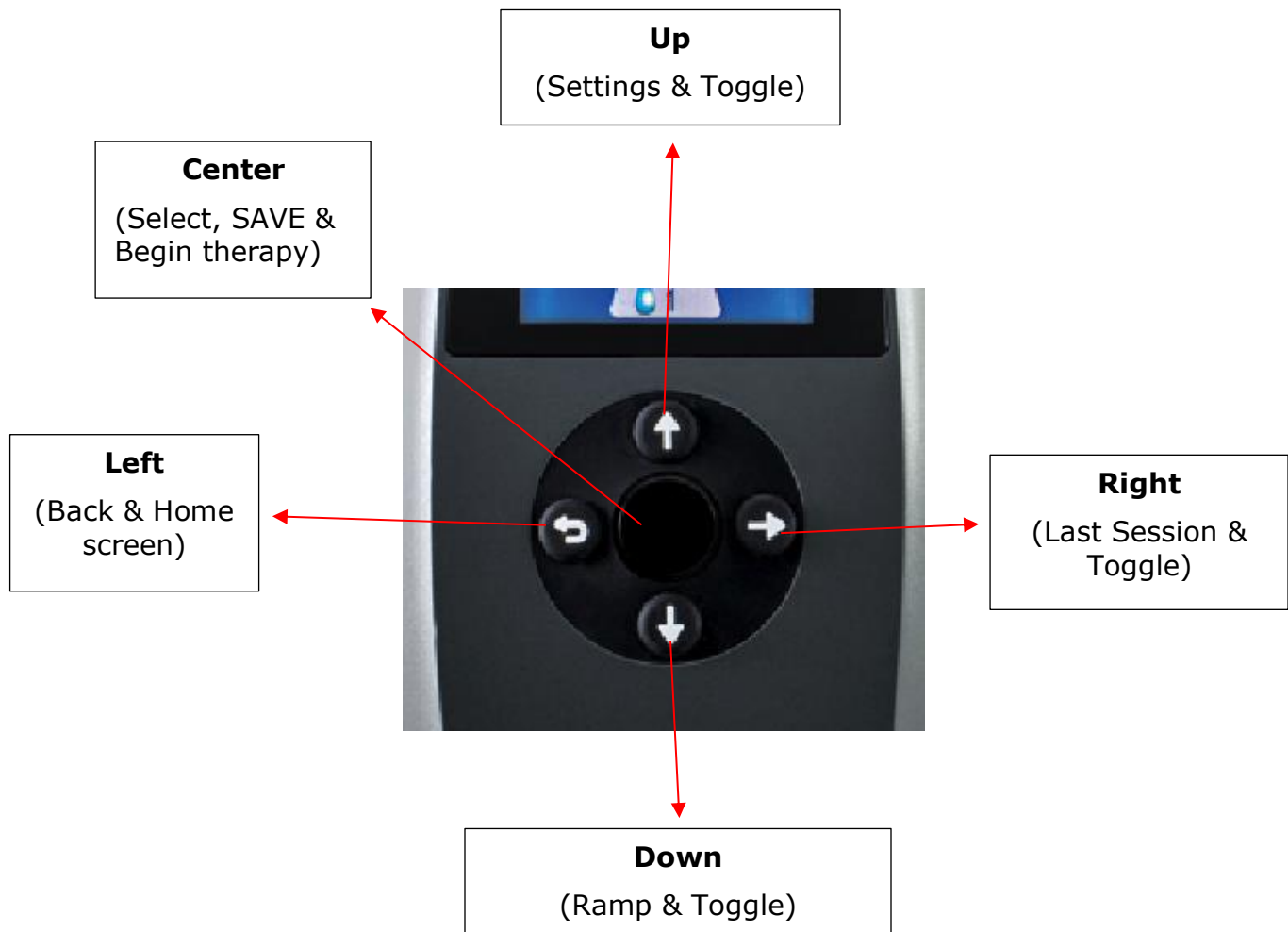
Control Panel

Use the buttons on the Control Panel below it to navigate through your options on the LCD screen. Pressing one of the four directional buttons (Up, Down, Left or Right) on the Control Panel will highlight the corresponding section on the home screen. Pressing the Center button will then immediately bring up the highlighted section. When in a section, these buttons help you navigate to highlight areas and make choices.

- The **Center** button on the Control Panel starts the PAP blower and takes you to the Therapy Mode screen from the home screen. The Center button is used to 'Select', 'Save Settings' and begin CPAP therapy.

NOTE: When changing settings, be sure to press the Center button to save your choice.

- The **Down** button takes you to the Humidifier section from the home screen. The Down button is used to toggle to various selections and also activates Ramp once the CPAP is delivering therapy.
- The **Right** button takes you to the Last Session Report section. It is also used to toggle to various selections.
- The **Left** button navigates you to your Compliance Report. It also acts as the 'Back' button while navigating through screens and will take you to the home screen.
- The **Up** button brings you to the Settings screen from the home screen. It is also used to toggle to various selections.



Power Connection Jack and USB Port

Power Connection Jack

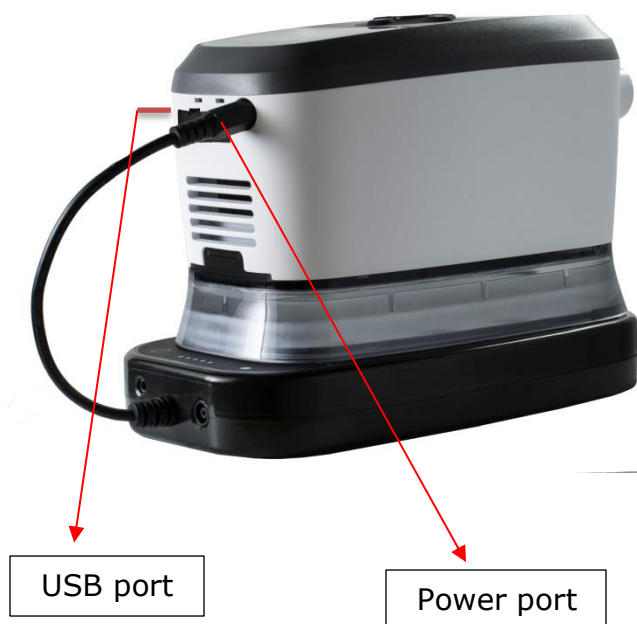
The power jack accepts the barrel plug of the output cable from the AC power source to operate the Transcend 365 miniCPAP.

An optional P10 battery pack is also available to power the Transcend 365 miniCPAP.

USB Port

A mini-AB USB port is provided for direct data exchange between the Transcend 365 miniCPAP and a computer. The Transcend 365 miniCPAP LCD screen interface allows for basic settings adjustment and data viewing necessary for the patient. A key sequence allows clinicians to change therapy settings via the LCD interface.

The USB connection allows the clinician to configure the Transcend 365 miniCPAP for prescription pressure, Ramp settings, and also access therapy compliance information with the Transcend desktop software (password protected).



Using the Transcend 365 miniCPAP

Standard User Modes

Normal operation consists of four modes:

- Off** When the device is not connected to a power source, the device is off.
- Standby** When power is applied to the device the LCD screen lights up and the CPAP enters Standby Mode. Standby Mode is also initiated by pressing the Center 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 LCD switches to its Therapy Mode screen, showing the current pressure (after 30 seconds the LCD will turn off). On Mode is initiated by pressing the Center button when the device is in Standby Mode and the mask is worn by the patient.
- Drying Mode** This mode is accessed from Standby mode. Press and hold the Up button for three seconds to start Drying Mode. This mode will last 30 minutes unless you interrupt it by pressing the Center button to switch to On mode or by pressing and holding the Up button for 3 seconds. Drying mode flushes your CPAP device, tubing and mask of residual moisture left from a therapy session.

Starting Therapy

Press the Center button on the Control Panel to start the CPAP blower and go to the Therapy Mode screen. If Ramp is configured, it will begin automatically. (Note: Once the therapy pressure is reached, Ramp can be reactivated by pressing the Down button, if desired.)

The average pressure readout will be visible. On the bottom of the screen you will see the set pressure (bottom left) and the set humidification level (bottom right).

After 30 seconds of button inactivity, the screen will turn off. It can be reactivated by pressing any button.



Ending Therapy and Entering Drying Mode

When you are finished with your therapy session, press the Center button to return your CPAP to Standby mode.

Drying Mode

Press and hold the Up button for three seconds to start Drying Mode. This mode will last 30 minutes unless you interrupt it by pressing the Center button to begin therapy or by pressing and holding the Up button for 3 seconds.



Push and hold the Up button to enter/exit Dry Mode.

Dry Mode Active



After the 30-minute drying cycle, the blower will turn off and the device will automatically enter Standby Mode. Dry mode flushes your CPAP device, tubing and mask of any residual moisture left from a therapy session.

The Transcend 365 miniCPAP Humidifier

Filling the Reservoir

Caution! Use distilled water only. The use of distilled water is required for proper function of the heated humidifier. Failure to use distilled water will damage the humidifier and require repair or replacement. Alternatively, water may be filtered with the **Transcend Portable Water Filter** for use with your Transcend 365 miniCPAP humidifier. The ZeroWater™ Portable Filter Replacement Cartridge can be purchased directly from your Transcend dealer, or at most major retailers.

Caution! Do not perform this operation near electronic equipment. Always unplug the power source to your CPAP before attempting to remove the reservoir.

1. To remove the reservoir from the CPAP, first disconnect the power source to your CPAP, then set the device on a flat, stable surface and secure the reservoir with one hand while you lift and remove the CPAP with your other hand. **The pieces are simply joined by magnets- there is not a button or latch that releases the humidifier from the CPAP device.**
2. Hold the reservoir at a slight angle and fill it with distilled water only. This step is best performed over a sink in case you spill water while filling the reservoir.

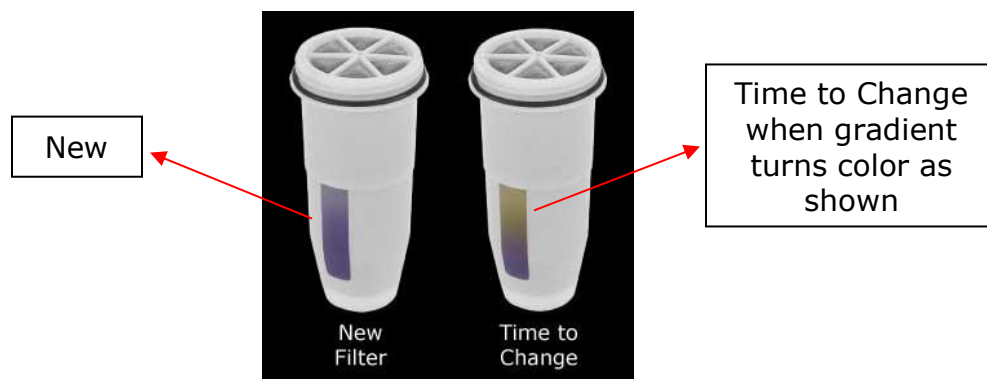


3. You can also use the Transcend 365 Water Filter Kit to fill your reservoir.

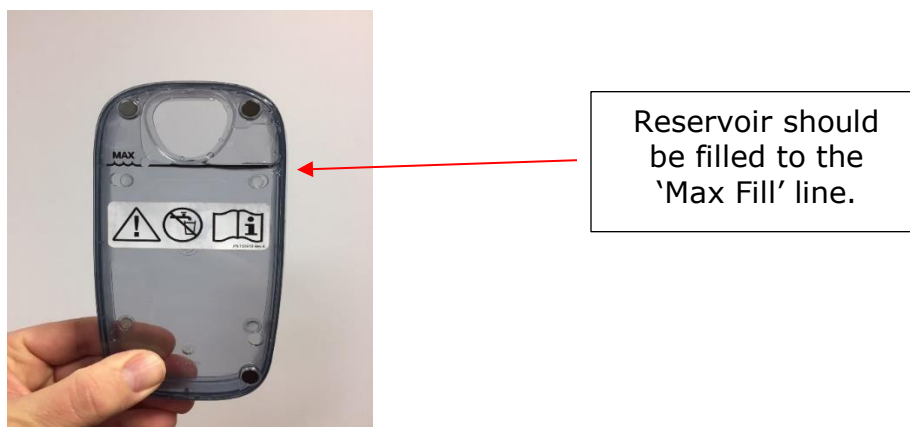


- Unpack the Water Filter Kit and follow instructions contained in the packaging to assemble the kit.
- Place the assembled kit on the Transcend 365 reservoir sitting on a flat surface.
- Add water to the fill line. Do not overfill the water filter as this will overflow the reservoir.
- Allow time for water to flow through the filter and fill the reservoir.

NOTE: It is essential to change the filter when indicated by the color change filter window (as shown below).



4. Check the reservoir is at its full capacity by holding it vertically and viewing the water level. The water should be level with the max fill line (bottom of the reservoir seal).



Repeat steps 2 to 4 as needed to fill and check the distilled water level in the reservoir. The reservoir should be completely filled before each use.

NOTE: The humidifier reservoir must be emptied completely before transporting to avoid damage to the CPAP.



Line up the heater cartridge with the opening in the reservoir.

5. Once the reservoir is filled completely, set it on a secure, flat surface and line up the CPAP heater cartridge with the opening in the reservoir. Hold the reservoir in place and set the CPAP onto it so that the magnets snap the pieces together securely.

NOTE: Be careful while inserting the heater cartridge into the reservoir so that the reservoir seal does not get folded over, as this will generate water leaks.



NOTE: In the case that the reservoir seal becomes dislodged from the reservoir, call your Transcend miniCPAP dealer for a replacement.

Humidifier Parts

The Transcend 365 will have either a ceramic wick or a replaceable wick included with the humidifier. The ceramic wick does not need to be replaced if distilled water is used. Should your replaceable heater wick need to be changed, here is a look at the heater parts and instructions for replacement.

Wick cover	
Replaceable Soft Wick	
Ceramic Wick	

Replacing the Soft Wick

To maintain optimal performance of your Transcend 365 miniCPAP, replace your heater wick periodically if humidification performance declines. Call Somnetics customer service at 877 621 9626 for replacements.

1. Disconnect the power source, remove the humidifier reservoir, then turn the CPAP device over and you will see the wick cover. Turn it a half turn counterclockwise and pull to remove it.



2. Pull out the old wick to remove it and discard.
3. Place the new wick into the wick cover, then insert the wick into the humidifier. Minimize handling of the new wick media to avoid contamination.
4. Lock the wick cover into place by giving it a half turn clockwise.

Heater Cartridge Replacement

If your heater cartridge should fail, you will see an alert notice on the LCD screen. See Humidifier LCD Indicators sections below.

NOTE: To replace the heater cartridge, contact your CPAP dealer or Somnetics 877-621-9626 for repair of your device.

Using the LCD Screen

NOTE: If the device is displaying the home screen, the LCD will turn off after 30 seconds of no button activity. If the device is displaying one of the sub-menus/screens, it will shut off after 5 minutes of no button activity. The LCD can be reactivated by pressing any button. If the device is in Standby mode, after 45 minutes of no button activity it will go into low-power sleep state. This is done to reduce power consumption and component wear. Pressing any button will awaken the device.

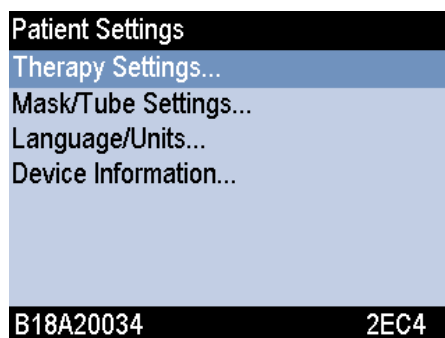
Therapy Settings



Enter the Settings screen by pushing the Up button to highlight the icon, then press the Center button to select it.

In the **Settings** section you will see four subsections:

- **Therapy Settings**
- Mask/Tube Settings
- Language/Units
- Device Information



Press the Center button to enter the **Therapy Settings**.

Therapy Mode

Here you will see the Therapy Mode, which indicates whether your Transcend 365 miniCPAP is set to a fixed-pressure setting or auto-adjusting therapy pressure (Auto mode only available on the Transcend 365 miniCPAP Auto device).

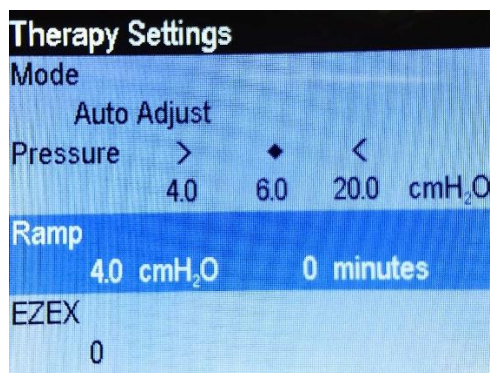
Pressure Settings

You'll also see the Pressure settings.

- If your device is set to **Fixed-Pressure Mode**, you will see one pressure setting.
- If your device is set to **Auto Mode**, the far-left number is the **minimum pressure**, the middle number is **starting pressure** and the right number shows **maximum pressure**.

The **starting pressure** is set to begin CPAP therapy somewhere between the min and max pressure settings. This allows you to begin therapy at your average starting pressure to reduce apneic events while falling asleep. The CPAP will still be able to adjust therapy pressure between the min and max pressure settings as needed.

NOTE: Mode and Pressure settings can only be adjusted by a clinician (requires password-protected access).

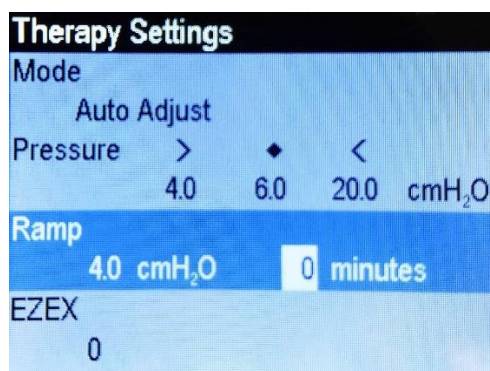


Ramp Settings

The **Ramp** setting starts therapy pressure at a lower setting and gradually increases pressure until it reaches the prescribed therapy pressure, so you can fall asleep comfortably. If the ramp feature is enabled, it will begin automatically when therapy is initiated. Ramp can also be reactivated, if necessary, by pressing the Down button.

Toggle Down to highlight Ramp and press Center button to make comfort adjustments.

Use the Up or Down button to change the Ramp pressure (you cannot go past your starting pressure). **Remember to press the Center button to save your selection.**

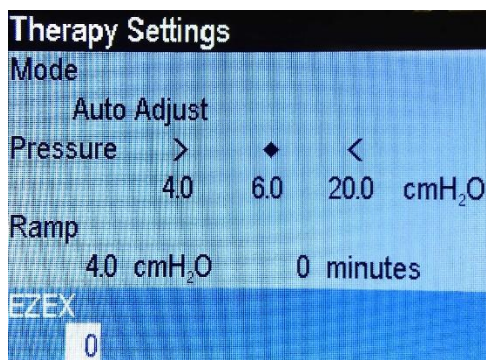


Use the Right button to highlight and the Center button to select Ramp Duration in minutes. Press the Up or Down buttons to change the duration from 0 to 45 minutes, moving through increments of five minutes. **Press the Center button to save your selection.**

EZEX Pressure Relief Settings

The EZEX feature allows you to reduce pressure when you exhale for more comfortable therapy.

Use the Up/ Down buttons to highlight EZEX, then press the Center button to adjust settings. The EZEX settings adjust the amount of pressure drop on exhalation, so that you can comfortably exhale while using your CPAP.

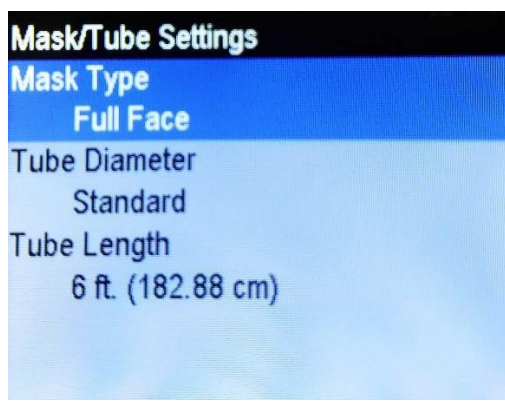


Push the Up or Down button to move the value from 0 to 3. A setting of 0 provides no exhalation relief, 3 provides the greatest exhalation relief. Press the Center button to save your selection.

Use the Left/Back button to toggle back through screen options or return to the home screen.

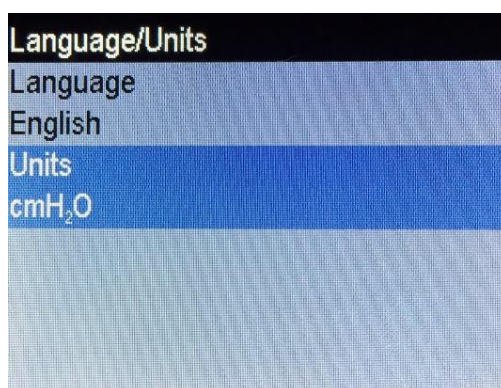
Mask/Tube Settings

These settings help you select the appropriate mask and tube for optimal CPAP performance. Select the settings that apply for you. Use the Up/ Down buttons to highlight the setting, then press the Center button to adjust settings. Use the Up/ Down buttons to toggle through the setting options, then **press the Center button to save your selection.**




Language Settings

These settings help you select your native language and regional settings. Select the language and units that apply for you. Use the Up/ Down buttons to highlight the setting, then press the Center button to adjust settings. Use the Up/ Down buttons to toggle through the setting options, then **press the Center button to save your selection.**



Device Information

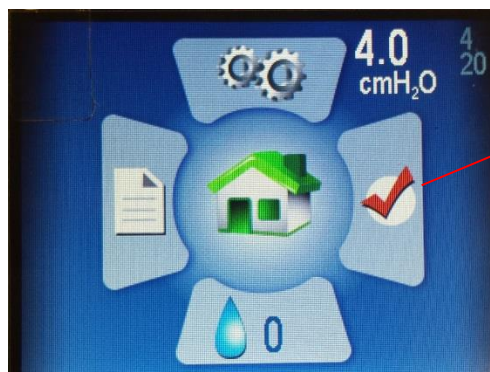
This screen shows the following information.

Device Information			
SN	B18A20034	FW	2EC4
NE	1234	VN	2.0.0
BH	432.6	TH	405.8
HT	335.3	WH	687.8
HT◆	0.0	WH◆	0.0
FLT	0		
	000 000 000 000 000		
DT	2018/10/31 20:48:09		

- SN- Device Serial Number
- NE- Number of events in the compliance log
- BH- Blower hours
- HT- Heater hours
- HT◆- Heater hours w/ detected water issue
- FLT- Fault code summary. See Fault and Alert Code section for more information.
- DT- Date & time
- FW- Firmware checksum
- VN- Version of firmware

- TH- Therapy hours
- WH- Heater wathours
- WH◇- Heater wathours w/ detected water issue
- QR Barcode- link to current manuals and use resources

Last Session Report (Push the Right button on the Control Panel)



Last Session Report

From the home screen, push the Right button to highlight the Last Session Report section. Push the Center button to select it.

Here you'll find a quick look at some of the information that will help you assess your sleep session.

Last Session		
Duration	00 : 00	
AHI	0.00	
Avg. Leak	0.0	LPM
Avg. Pressure	0.0	cmH ₂ O
Min. Pressure	0.0	cmH ₂ O
Max. Pressure	0.0	cmH ₂ O

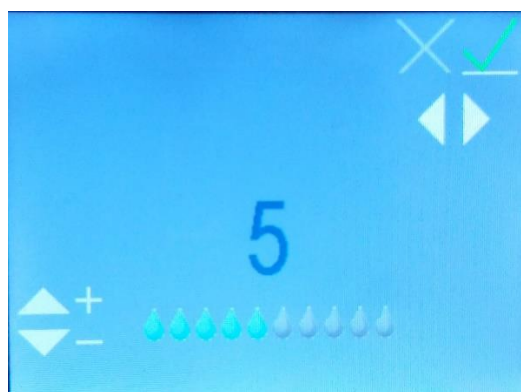
Push the Left/Back button to return to the home screen.

Humidifier (Press the Down button on the Control Panel)

Humidity Level



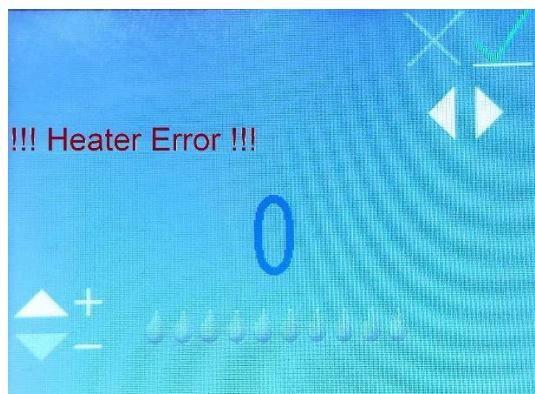
From the home screen, push the Down button to highlight the Humidifier section. Push the Center button to select it.



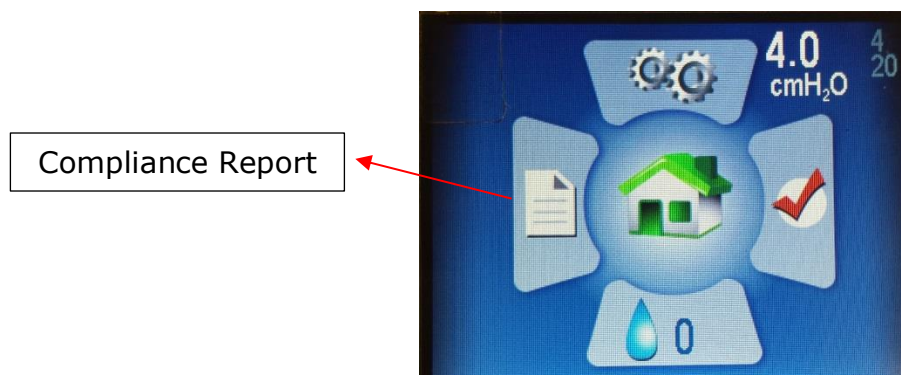
Use the Up or Down buttons to move the humidification level from 0 to 10 (0 = no humidification, 10 = maximum humidification). You will see the water droplet icons move to a higher or lower value. **Once you reach the desired setting, use the Left and Right buttons to toggle to the green checkmark, if it's not already highlighted, then press the Center button to save your settings.**

To exit out of the humidifier settings without saving any changes, select the red X by using the Left and Right buttons to highlight it, then press the Center button

If the device detects a detached or damaged humidifier it will display an error message in the Humidifier screen, indicating that the humidifier is not operational.



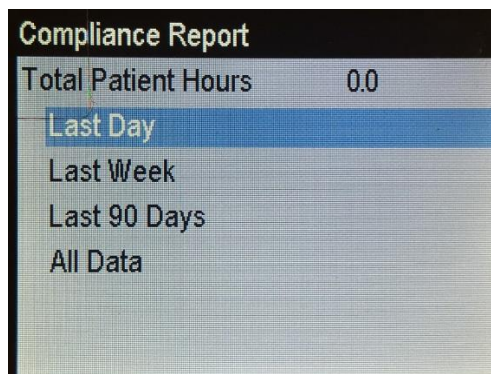
Compliance Report (Press Left button on the Control Panel)



From the home screen, push the Left button to highlight Compliance Report. Push the Center button to select it.

This section shows the data you may need to send to your doctor to demonstrate that you are using the device enough to stay compliant for insurance purposes.

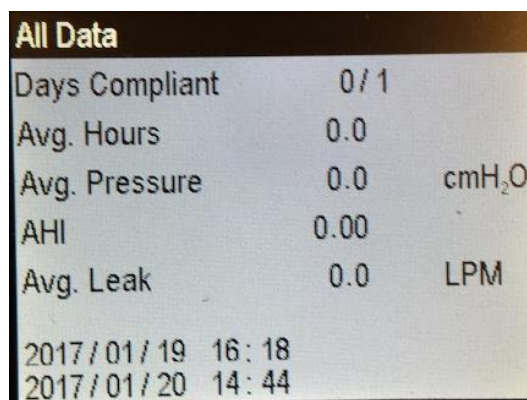
You can view the information here, however, you or your clinician will need to use a computer and the Transcend desktop software to view, print or send the Compliance Report to your doctor.



You can choose the time range of Total Patient Hours you would like to view over the Last Day, Last Week, Last 90 days or All Data.

Use the Up or Down buttons to highlight the time range you would like to view, then press the Center button to select it.

In Last Day, Last Week or Last 90 days, you will see the Days Compliant, Average Hours, Average Pressure, AHI (Apnea-Hypopnea Index) and Leak rates.



All Data		
Days Compliant	0 / 1	
Avg. Hours	0.0	
Avg. Pressure	0.0	cmH ₂ O
AHI	0.00	
Avg. Leak	0.0	LPM
2017/01/19 16:18		
2017/01/20 14:44		

In All Data you will see data for all the days you've been using the device. This screen shows two time stamps in the bottom indicating the oldest and most recent entries in the compliance log (Note: Time stamps are in UTC).

When you are finished, use the Left/Back button to return to the home screen.

Humidifier LCD indicators in Standby Mode

Water Status Indicators

These indicators will only be displayed if humidifier is set to a level > 0. They will appear in lower right portion of the home screen

Flashing Blue Droplet - Out of Water



Indicated by a flashing blue droplet. Humidifier will be disabled during therapy. Can be caused by:

- No water in the reservoir – only displayed if heater/humidifier is set to level > 0.
- If this status appears but there is water in the reservoir, it indicates an error likely due to moisture in the CPAP. Allowing the system to dry out may correct the issue. To do this, run the CPAP in Dry Mode.

NOTE: After drying the system, disconnect and reconnect the power source to ensure the status is reset.

Flashing Yellow Droplet and Diamond – Tap Water Detected



Only distilled water should be used with this humidifier. A flashing yellow droplet and yellow diamond indicate that water other than distilled water is detected in the reservoir. The humidifier can still be used, although doing so with any type of water other than distilled will shorten heater life and may void the warranty on the heater. This indicator may be caused by:

- Using water that is less pure than distilled water in the reservoir.
- Using distilled water in a reservoir that previously had tap water and wasn't sufficiently rinsed. If this is the case, it is recommended to dump out the reservoir

water and rinse with distilled water. Replace water in reservoir with distilled water for use.

- Or, the water signal is corrupt and reporting an incorrect value. This is most likely caused by moisture in the CPAP. Allowing the system to dry out may correct the issue. To do this, run the CPAP in Dry Mode.

NOTE: After drying the system, disconnect and reconnect the power source to ensure the status is reset.

Flashing Red Droplet and X – Bad Water Signal Detected



Indicated by a flashing red droplet and red 'X'. The humidifier will be disabled during therapy.

This indicates a corruption, most likely caused by moisture in the CPAP. Allowing the system to dry out may correct the issue. To do this, run the CPAP in Dry Mode.

NOTE: After drying the system, disconnect and reconnect the power source to ensure the status is reset.

Heater Status Indicators

These appear in lower right portion of the home screen (next to the humidification icon)

Flashing Red X – Heater Detached or Damaged



Contact your supplier for repair or replacement.

If assistance is needed to reset an indicator, contact your medical equipment provider or Somnetics customer service 877-621-9626.

Combination Indicators

The Water and Heater status symbols are not mutually exclusive. It is possible that both issues may occur and will be shown in combination in the lower right portion of the LCD screen.

Example:



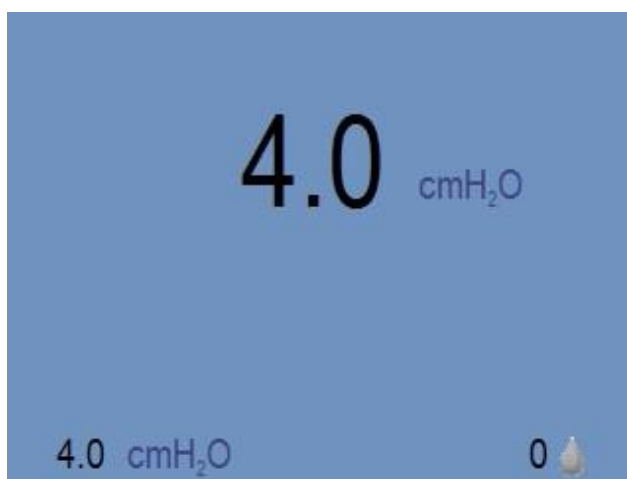
Humidifier LCD Indicators in Therapy Mode

During therapy, the water/heater status and the humidifier setting is displayed in the lower right corner of the screen. The status consists of a water droplet that can have one of three colors:

- Gray droplet – Humidifier is disabled because humidifier setting is 0 (off).
- Blue droplet – Humidifier is enabled and operating.
- Red droplet – Humidifier is disabled because a condition was detected that does not permit humidifier operation.

Most users will be asleep and unaware if the status condition changes during the night. Additional status information is displayed on the home screen in Standby (see section above) after therapy.

Therapy with Humidifier Turned Off (setting 0)



The gray droplet indicates that the humidifier is not active.

Therapy with Humidifier ON (setting > 0) - Normal Operation, No Errors, Heater Enabled.



The blue droplet indicates that the humidifier is active.

NOTE: This includes cases where decreased water quality (tap water) was detected.

Error Condition Detected, Humidifier Disabled.



The red droplet indicates that the humidifier is not active. Normal CPAP therapy is not affected. This can be caused by any one of the following:

- Out of water condition detected.
- Bad water signal detected.
- Bad heater signal detected.
- Heater over-temperature detected.

More details about which error disabled the heater will be displayed on the standby screen (see LCD indicators in Standby Mode section) after therapy completes.

Powering the Transcend 365 miniCPAP

There are two choices for powering the Transcend 365 miniCPAP device:

- Use the AC Power Supply (PSA3)
- Use the optional P10 Battery

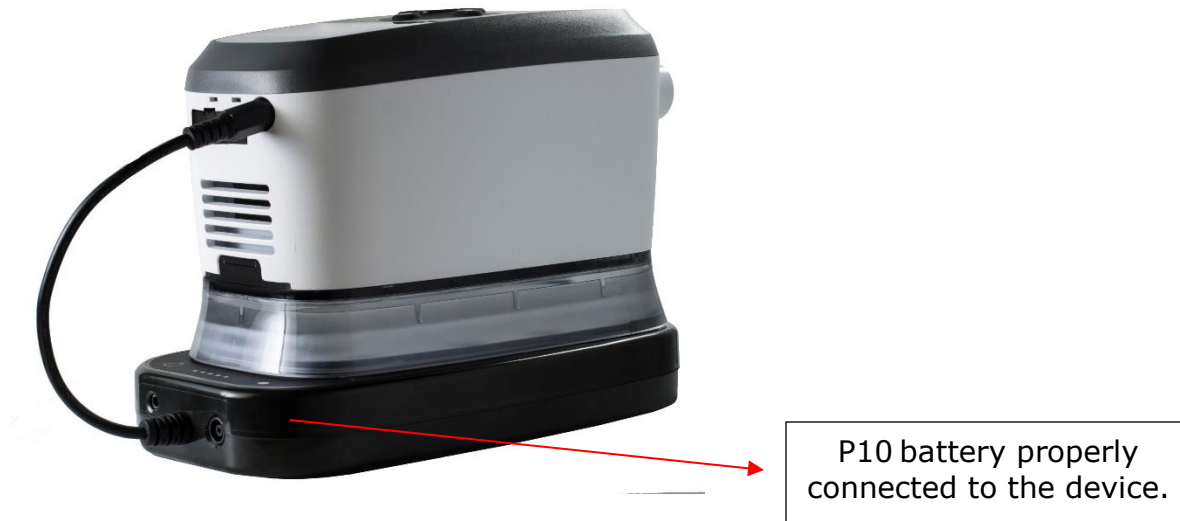
Using AC Power Supply (PSA3)

The AC power supply included with your CPAP device can power your CPAP from any standard AC outlet. Simply plug the power supply into the wall and insert the barrel connector into the power inlet on the back of your CPAP device.



Using the P10 Battery (Optional Accessory)

The Transcend P10 Battery is an optional power source for the Transcend 365 miniCPAP. To use, connect the battery outlet cable to the Transcend 365 miniCPAP by inserting the barrel connector into the power jack on the device. The LCD will show the home screen when power is supplied to the CPAP.



- NOTE:** Fully charge the battery before the first use. Follow the battery charging instructions provided in the User Manual. Do not connect the battery to the Transcend 365 miniCPAP during the battery's initial charge.
- NOTE:** The CPAP draws power from the battery while connected. If the battery is not used in line with the AC power supply, unplug the battery from the CPAP when not in use.
- NOTE:** Allow up to 20 seconds for the CPAP to complete the battery status check and power up after connecting to the battery.
- NOTE:** Using the battery in-line with the AC power supply charges the battery during therapy and provides backup power for uninterrupted therapy in the case of a power outage.

Charging the P10 Battery

- Connect the power outlet barrel connector from the Universal Power Supply to the power connection jack on the P10 Battery.
- Connect the Universal Power Supply to a power source.
- A full battery charge is indicated when the LED light gauge is lit to 100%.
- It may take up to 7 hours to charge the P10 battery.



- When charging, the far-right LED charging indicator will blink.
- Bi color for charging:
 - When charging, LED is Green and flashing
 - When fully charged, LED is solid Green
 - When not charged or there is a fault, LED is Red.

Push and hold this button for at least one second to check battery status.

This “fuel gauge” of five LED lights shows how much power is left in the battery. The first light indicates the battery is 1-20% charged, the second light means 21-40% charged, the third light indicates 41-60% charged, the fourth light means 61-80% charged and light five shows 81-99% charged.

Using the P10 Battery in-line with the AC Power

1. Insert the barrel connector from the Universal AC Power Supply into the circular opening in the battery.
2. Insert the barrel connector of the battery into the Transcend 365 miniCPAP power jack.
3. Plug the Universal AC Power Supply plug into a power outlet.
4. When power is supplied, the LCD screen will light up and the CPAP enters Standby Mode. The LCD screen enters sleep mode (light turns off) after 30 seconds.

Caring for Your Transcend 365 miniCPAP

The Transcend 365 miniCPAP device is a maintenance-free device. However, it's important to keep it clean to ensure maximum efficiency and durability. Cleaning cycle frequencies identified below are checked against product service life.

Warning:

- Unplug the Transcend 365 miniCPAP before cleaning.
- Do not submerge the Transcend 365 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 365 miniCPAP.
- Do not place cleaning materials, such as a cloth or liquid, into the device air inlet or air outlet connector.

Cleaning the Unit

Follow these instructions to clean the exterior of the Transcend 365 miniCPAP:

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

Product	Periodic Cleaning Cycle	Product Service Life
Transcend 365 miniCPAP	Weekly	5-Year

Warning: Do not submerge the Transcend 365 miniCPAP, power supply or power accessory (battery) in liquid. Do not allow liquid or cleaning solution to enter the device.

Caring for the Humidifier Reservoir

Follow these instructions to care for the humidifier reservoir.

1. Rinse the reservoir with distilled water weekly.
2. Reattach the humidifier reservoir to the PAP device.
3. Press and hold the Up button for three seconds to start Drying Mode. This mode will last 30 minutes unless you interrupt it by pressing any button. After the 30-minute drying cycle, the blower will turn off and the device will automatically enter Standby Mode. Dry mode flushes your CPAP device, tubing and mask of any residual moisture.
4. Refill the reservoir with water prior to next use.

NOTE: The humidifier reservoir should be replaced every 6 months or when any leaking or physical damage is noted.

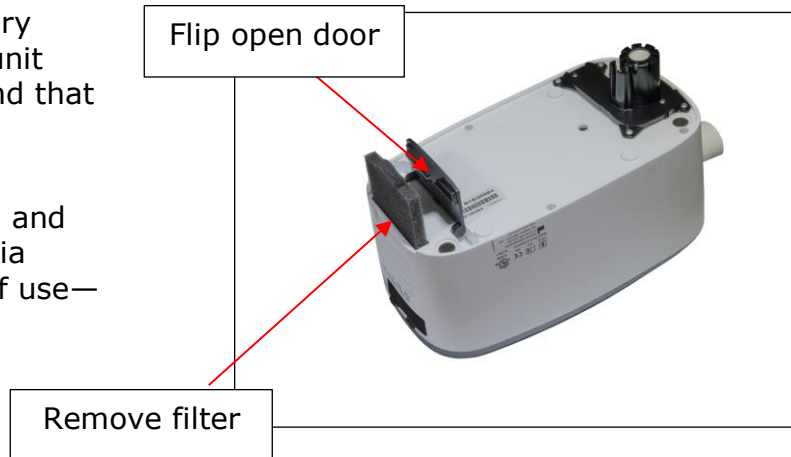
Cleaning Your Mask and Air Hose

Follow the manufacturer's instructions on cleaning your mask and air hose, including appropriate detergents and frequency of cleaning.

Replacing the Filter Media

During therapy, ambient air is drawn into the Transcend 365 miniCPAP through an Air Inlet Filter. The Filter Media is very simple to replace. Simply turn the unit over and look for the door on one end that pops open easily.

Open door to remove the used filter media, replace with new filter media and secure the filter door. The filter media should be replaced after 6 months of use—or sooner if it is dirty.



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 is needed, please contact your local waste administration.

Transcend Software User Guide

Your Transcend 365 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

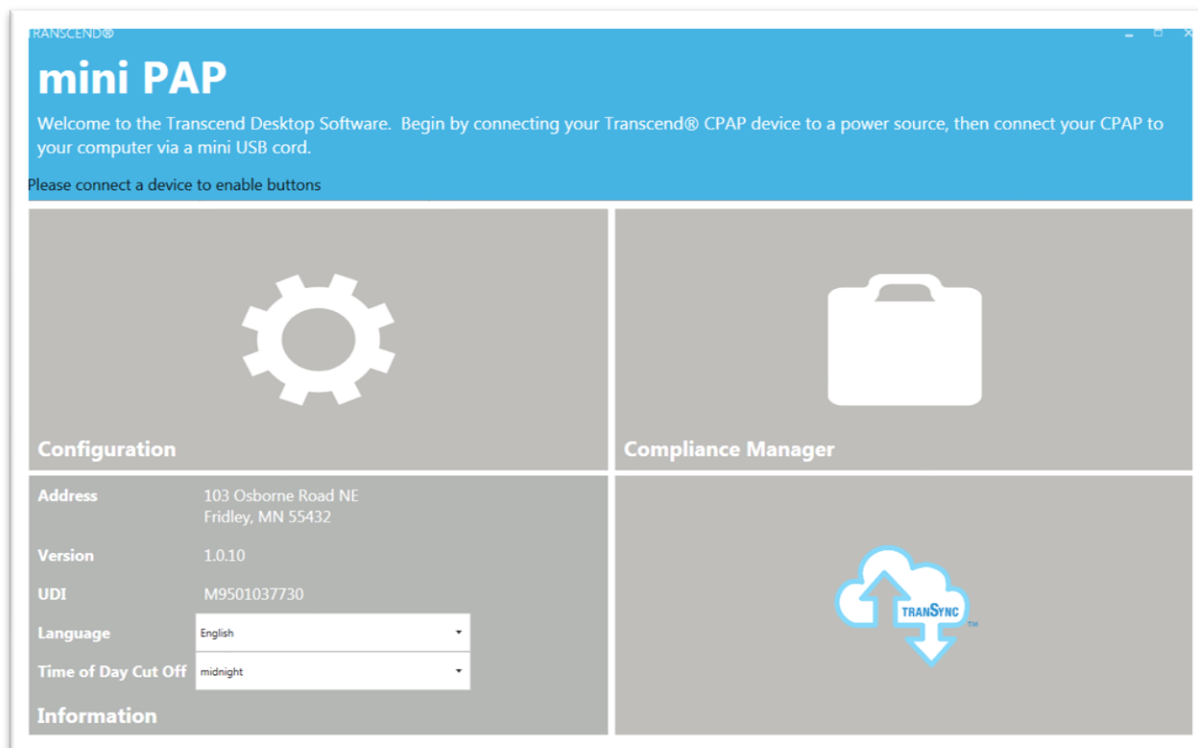
Start by downloading the device software onto your computer using this link:

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

<https://transcend.miniCPAPsoftware.com>

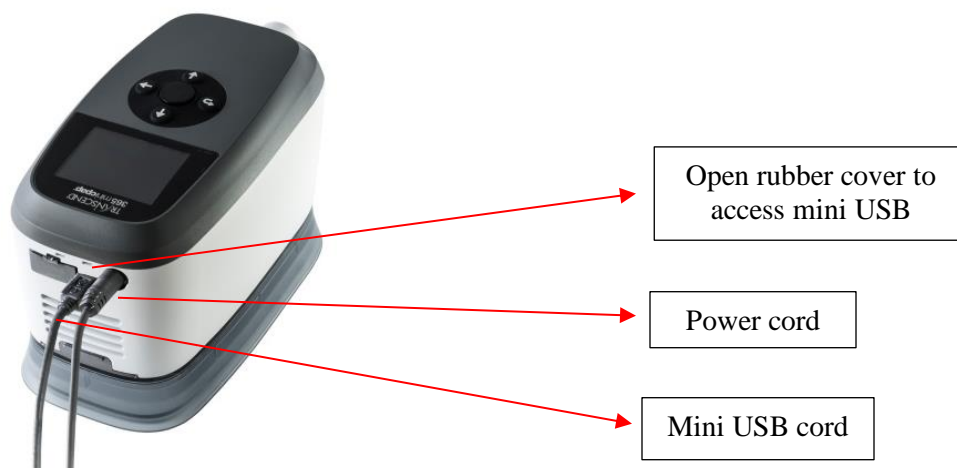
Once you download the software, it will automatically update as we make changes and improvements.

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



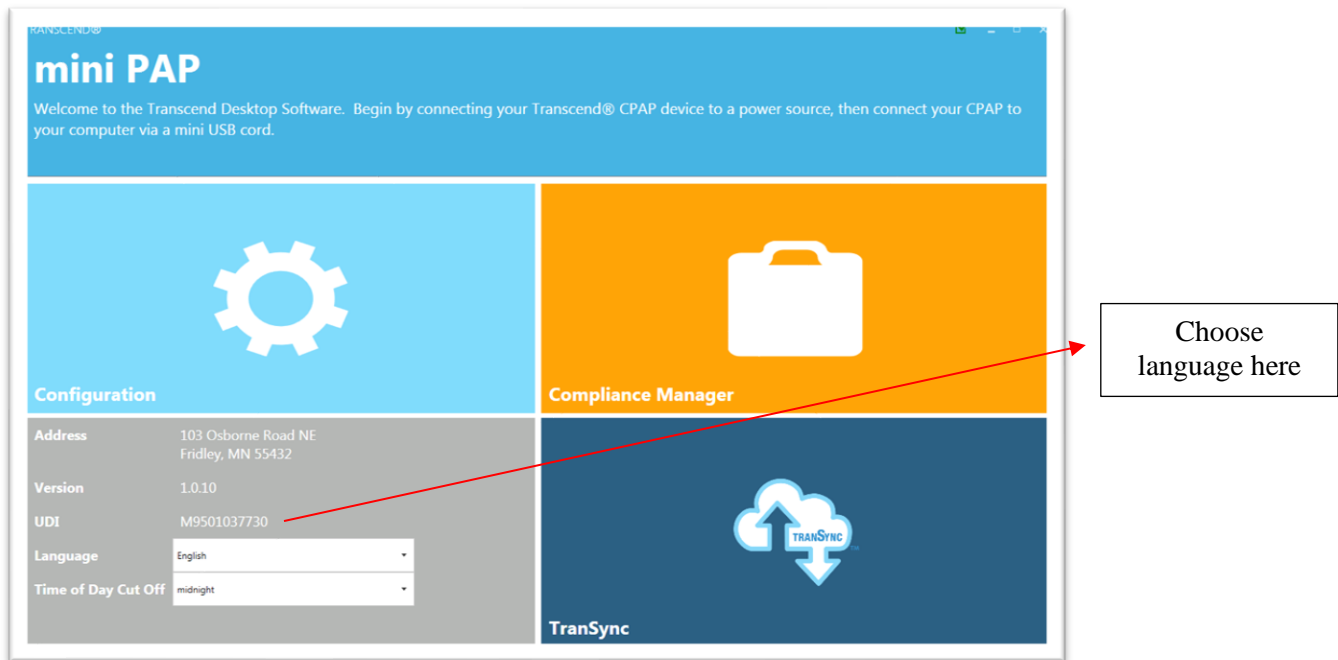
STEP 2

Connect your Transcend 365 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 end goes into a USB portal on your computer.



STEP 3

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



Next, select the Time of Day Cut Off from the four choices in the dropdown menu (midnight, 6 a.m., noon, 6 p.m.). This value will be used to group sleep usage into 24-hour days. You should pick the cut off that represents a time when you are least likely to be sleeping. For example, if you typically sleep overnight and take occasional afternoon naps, "noon" would be a good choice. Conversely, if you work overnight and sleep during the day, "midnight" would be a better option.

Now You're Ready to Use the Transcend 365 miniCPAP Software

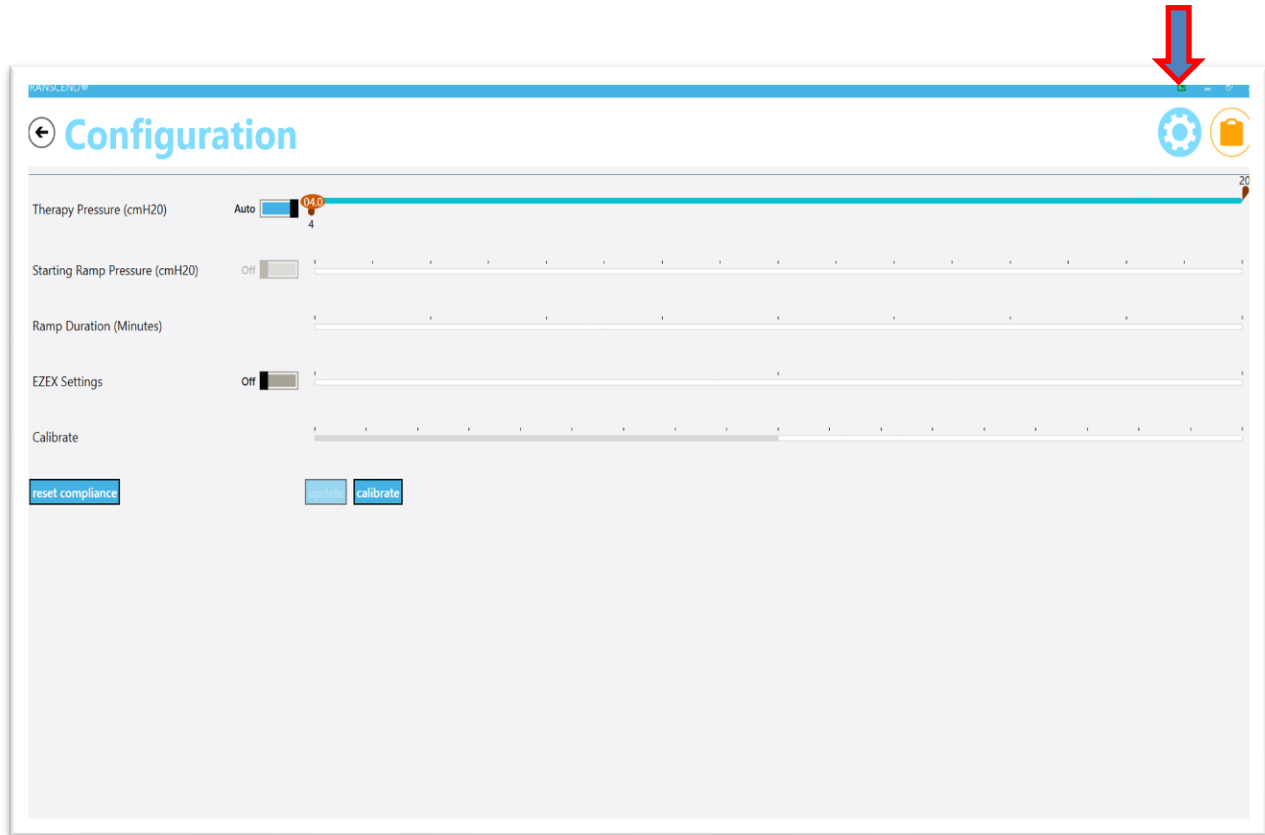
You can see on the home screen interface that there are two primary areas to choose from: Configuration or Compliance Manager. Let's explore each one.

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 on an Auto setting, depending upon which device you have (Auto mode only available on Transcend 365 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. The CPAP will gradually increase the pressure across the ramp duration until the Therapy Pressure is reached.
- 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.

Compliance Manager

Compliance Summary | Daily List | Trend Graph | Day Graph

FILTER

Device Serial: B18I20111 | Start Date: 9/25/2018 | End Date: 11/13/2018 | Filter | 30 Day Compliance | Export Report

USAGE

Usage	6 days / 0.17 total hours	4-6 Hours Usage	0 of 49 days (0%)
Average Hours/Night	0.03	6-8 Hours Usage	0 of 49 days (0%)
Median Hours/Night	0.02	8+ Hours Usage	0 of 49 days (0%)
4+ Hours Usage	0 of 49 days (0%)	Not Used	43 of 49 days (88%)

LEAK SUMMARY

Average Leak	0 (L/Min)
Median Leak	0 (L/Min)
90 Percentile Leak	0.00 (L/Min)
95 Percentile Leak	0.00 (L/Min)

PRESSURE SUMMARY

Average Pressure	5.6 (cmH2O)
90 Percentile Pressure	4.00 (cmH2O)
95 Percentile Pressure	4.00 (cmH2O)

AHI EVENTS PER HOURS OF USE

AHI Index	0
Apnea Index	0
Hypopnea Index	0
Time In Apnea	0%
Time In Hypopnea	0%

PATIENT THERAPY SETTINGS

Therapy Starting Pressure	4 cmH2O
Min	4 cmH2O
Max	20 cmH2O
Ramp Starting Pressure	3 cmH2O
Ramp Duration	0 minutes
EZEX Settings	0

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.

Start Date 9/25/2018

End Date September 2018

Su	Mo	Tu	We	Th	Fr	Sa
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

4-6 Hours Usage (%)

6-8 Hours Usage (%)

8+ Hours Usage (%)

Not Used 43 of 49 days (88%)

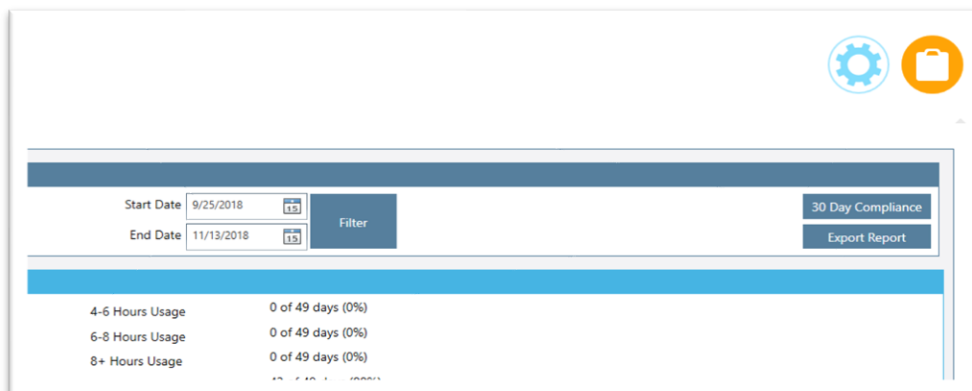
PRESSURE SUMMARY

Average Pressure 5.6 (cmH2O)

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).



Start Date: 9/25/2018 15

End Date: 11/13/2018 15

Filter

30 Day Compliance

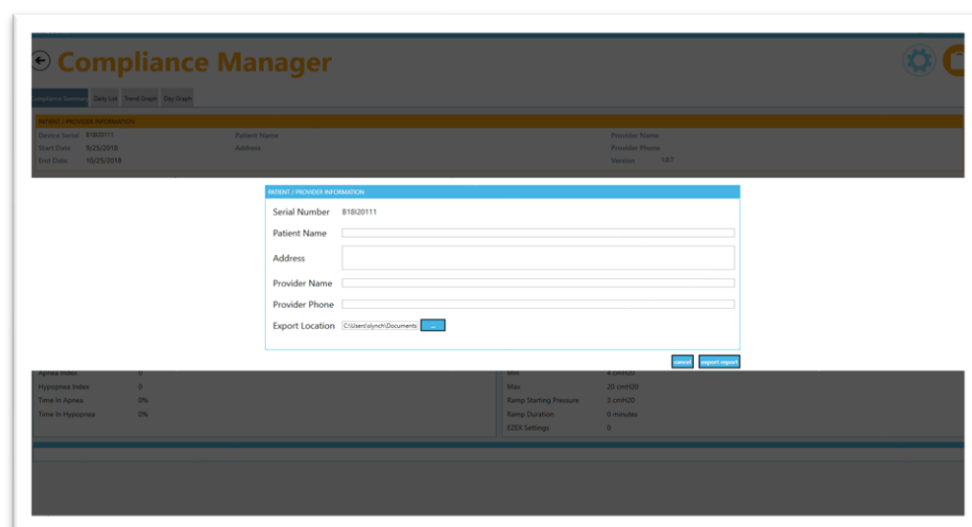
Export Report

4-6 Hours Usage	0 of 49 days (0%)
6-8 Hours Usage	0 of 49 days (0%)
8+ Hours Usage	0 of 49 days (0%)

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.



Compliance Manager

Serial Number: 81820111

Patient Name:

Address:

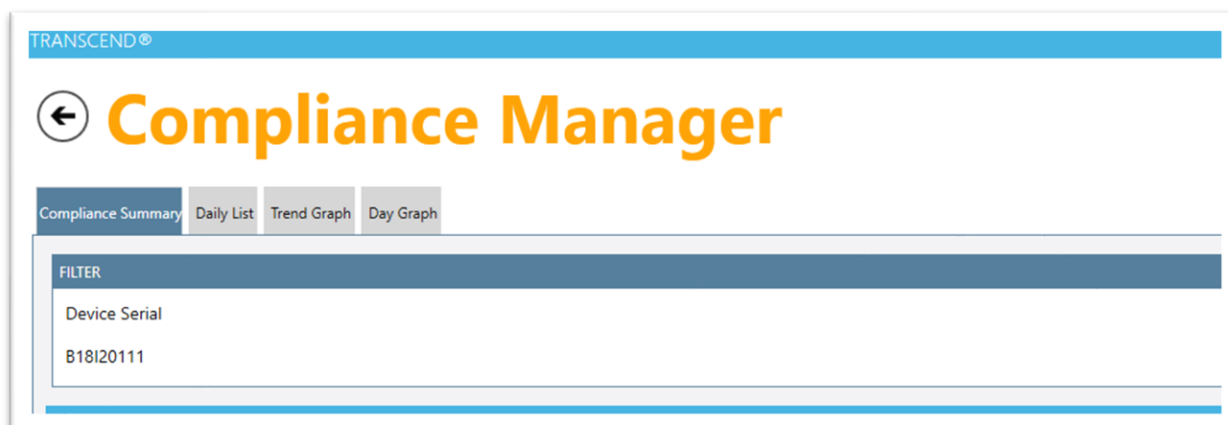
Provider Name:

Provider Phone:

Export Location: C:\Users\johnd\Documents

Print Export Report

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.

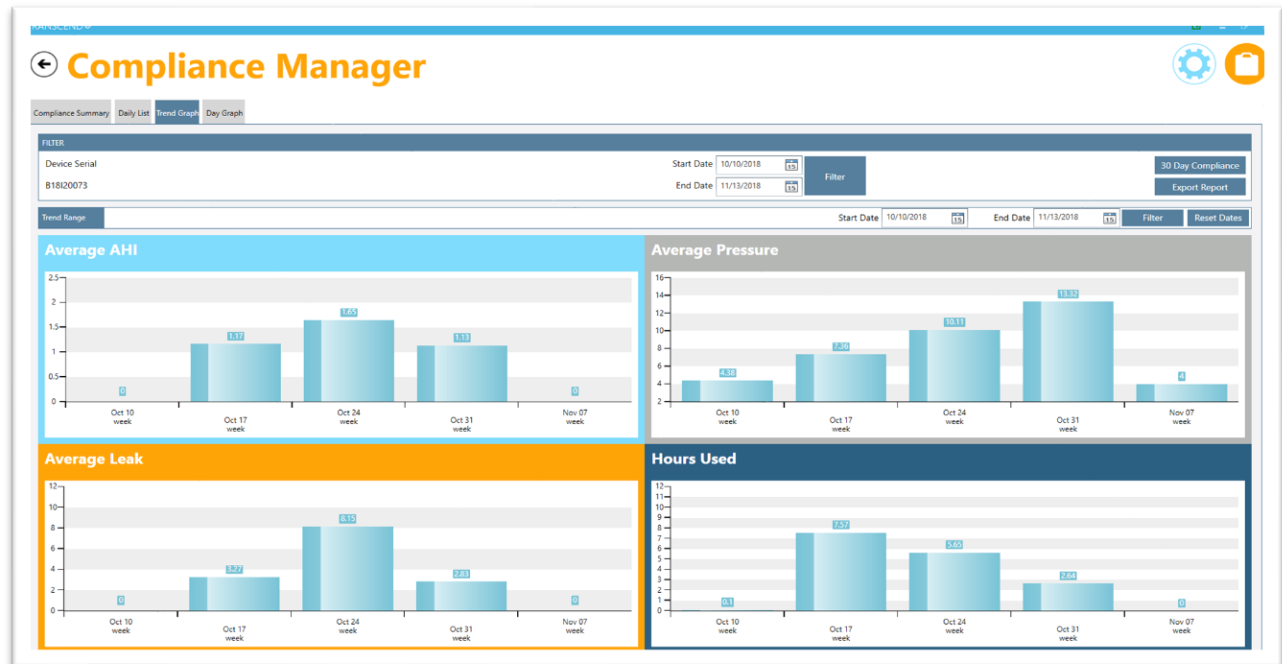
You can reverse the order of the data shown by selecting the column header you wish to reorganize (Date, Usage, AHI, Average Pressure or 95th Percentile Leak).

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.

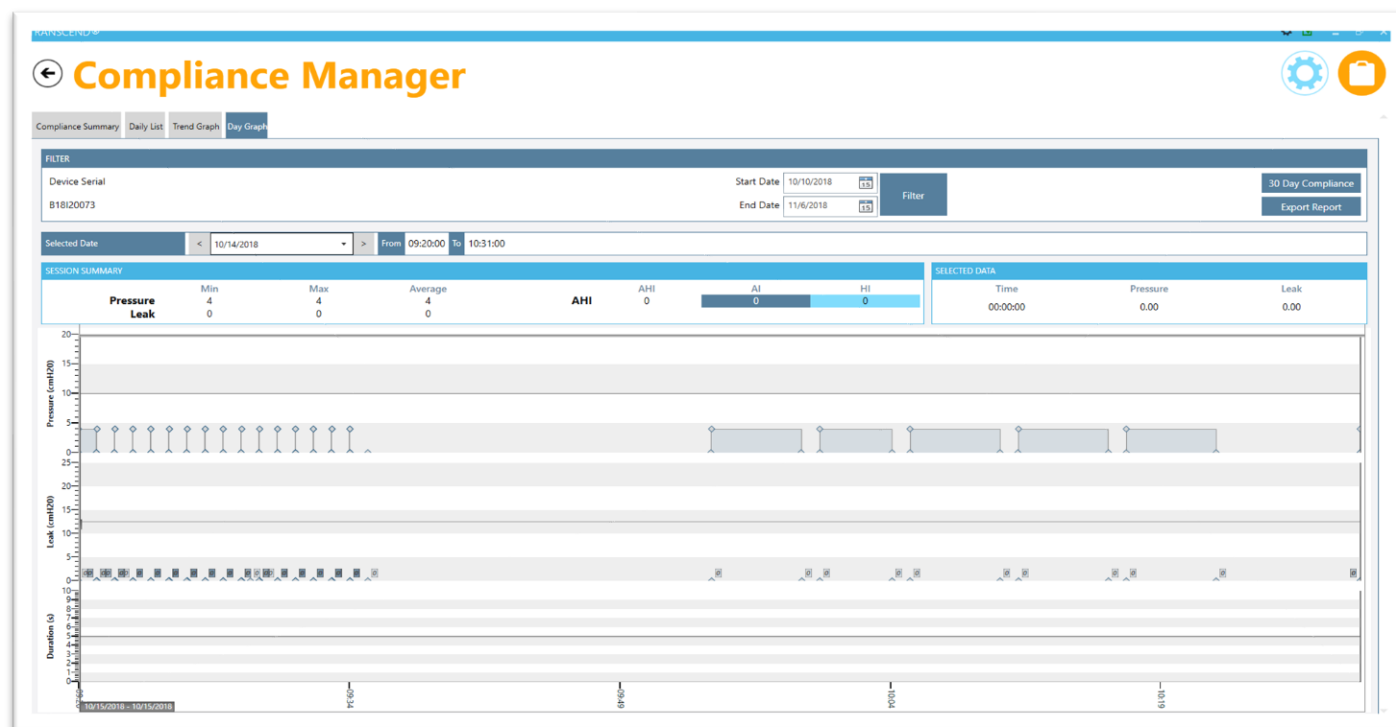
Simply click on any bar graph and you will automatically see trend ranges by month, week or day each time you click (this change in date range is reflected in the Trend Range section).



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.

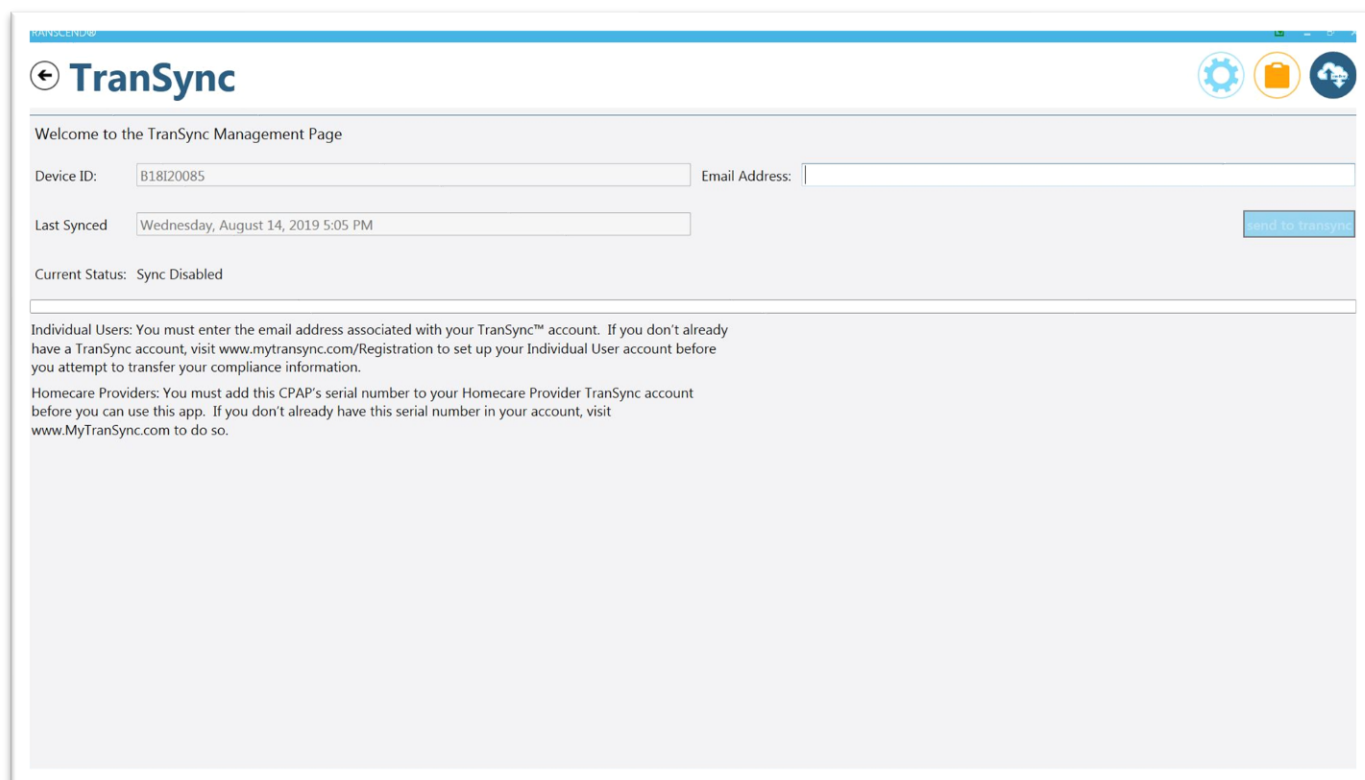


TranSync

The TranSync Compliance Monitoring System is designed to provide patients with a secure and convenient way to view compliance data and transmit it to homecare providers and clinicians via the secure, cloud-based TranSync website (www.MyTranSync.com).

Data can be uploaded to the TranSync website with the use of either the Transcend Desktop Software or the TranSync Bluetooth Module and mobile app.

Users must use the email address associated with their TranSync account. If you don't already have a TranSync account, or have a profile set up by your homecare provider, visit www.mytransync.com/Registration to set up your individual account before you attempt to transfer compliance information.



The screenshot shows the TranSync Management Page. At the top, there is a header with the TranSync logo and three icons: a gear, a shopping bag, and a group of people. Below the header, a welcome message reads "Welcome to the TranSync Management Page". The main form area contains three input fields: "Device ID" with the value "B18120085", "Email Address" (empty), and "Last Synced" with the value "Wednesday, August 14, 2019 5:05 PM". To the right of the "Last Synced" field is a blue button labeled "Send to TranSync". Below the form, the "Current Status" is "Sync Disabled". At the bottom, there are two paragraphs of text: "Individual Users: You must enter the email address associated with your TranSync™ account. If you don't already have a TranSync account, visit www.mytransync.com/Registration to set up your Individual User account before you attempt to transfer your compliance information." and "Homecare Providers: You must add this CPAP's serial number to your Homecare Provider TranSync account before you can use this app. If you don't already have this serial number in your account, visit www.MyTranSync.com to do so."


Enter the email address associated with the registered device serial number. Press the Send to TranSync button to transfer your compliance information to the cloud. Once complete, your compliance information can be viewed on the web and mobile applications.

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

TranSync Mobile App

The TranSync mobile app (available for IOS and Android) can be downloaded from the Apple® and Google® app stores. The app user guides can be downloaded at www.MyTranscend.com/support. The app can be used to view compliance data uploaded to the TranSync cloud database (www.MyTranSync.com) via the desktop software or the TranSync Bluetooth Module.

TranSync Bluetooth Module

TranSync Mobile System Compatibility	
iOS	Version 11.1 or later
Android	Version 5.0 (API level 21) or later
Regulatory	FCC Part 15 Compliant 

NOTE: The patient is the intended operator of the TranSync System, including use of the TranSync wireless Module.

TranSync data transmission functions will be disabled during therapy use. All TranSync related functions can be safely used with the device in standby mode.

To use your Bluetooth Module, insert with logo facing up.



No servicing or maintenance of the Module is allowed during use. To download the TranSync Mobile App or the TranSync Mobile App User Guide go to <https://MyTranscend.com/support>. No maintenance is required for this component.

Fault Codes

Fault Codes

When the Transcend 365 miniCPAP device encounters a fault, the processor resets and enters a fault loop. In this loop, the device shows the home icon as red to indicate that a fault has been 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, while on the home screen and highlighting the home icon, press the center button. Then the device will go to a new screen and show the specific fault number. To clear the fault, move down to the check mark and press the center button. 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 troubleshooting suggestions associated with the Transcend unit.

Fault Number	Error	Comments
1	Date/time reset	The CPAP clock was reset. This could be due to a discharged backup clock battery or transient power spike or electrostatic discharge.
2	Stack overflow	Internal software fault.
3*	Pressure too high	While delivering therapy, the pressure sensor measured a pressure greater than 30 cmH ₂ O. This could be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
4*	No Pressure	While delivering therapy, the pressure sensor measured approximately 0 cmH ₂ O. 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.
5	Self-test fault	Appears when CPAP system fails power-on fault test.
6	Attempt to set invalid time	An attempt was made to set the device real time clock (RTC) to an invalid value.
7*	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.
8	Unable to reconcile compliance log	During powerup/boot, the device was unable to build/update the metadata associated with the compliance log.

Fault Number	Error	Comments
9	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.
11	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.
12	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.
13*	Processor over-temp	The processor on-chip temperature sensor has reported an excessive temperature.
14*	Blower over-temp	The blower thermistor has reported an excessive temperature.
* If this fault occurs, check hose to ensure that it is properly connected. If the fault occurred during therapy, make sure the mask is properly fitted and not leaking. Check the filter is properly installed and not dirty.		

Troubleshooting

Problem	Probable Cause	Solution
Discomfort due to a feeling of high pressure.	Transcend 365 miniCPAP 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. Increase the setting on the humidifier. Check to make sure there is water in the reservoir. Replace soft heater wick if it doesn't appear to be wicking water from the reservoir. For ceramic wick replacement please contact your dealer for support.
	Dirty air filter.	Change and/or clean the Filter Media.
Transcend 365 miniCPAP LCD doesn't 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 Transcend 365 miniCPAP.	Device motor failure; or, electronics failure.	Contact the homecare provider's technical service department.
LCD shows red home icon	Device detects an operating error.	Note the number that shows when entering the fault screen. 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**

NOTE: All disposable parts, accessories and replacement parts are single patient reusable and are not for multi-patient use.

Disposable Parts

Item	Part number	Item	Part number
Transcend 365 miniCPAP Air Inlet Filter	503096	Transcend 365 miniCPAP Heater (Soft) Wick Six Pack	503111
Transcend Heater Cartridge (Soft) Wick	503097		

Accessories

Item	Part number	Item	Part number
Transcend P10 Battery	503098	Transcend 365 Water Filter Kit	503110
Transcend 365 Bluetooth Module	503112		

Replacement Parts

Item	Part number	Item	Part number
Transcend 365 miniCPAP™ Service Unit	503090	Transcend 365 miniCPAP™ Water Reservoir	503093
USB cable	503020	Transcend 365 miniCPAP™ Power Supply PSA3	503100
Transcend Travel Bag	503012	UK 2-Prong Power Cord	503076
US 2-Prong Power Cord	503074	AU 2-Prong Power Cord	503077
EU 2-Prong Power Cord	503075		

Appendix: Specifications

This section presents the following topics:

- [Transcend 365 miniCPAP device](#)
- [AC power supply – PSA3](#)
- [Batteries](#)
- [Transcend 365 miniCPAP performance](#)
- [Manufacturer’s declaration](#)

Transcend 365 miniCPAP

Transcend 365 miniCPAP weight:	1.7 lbs (770 gm)
Transcend 365 miniCPAP dimensions:	7.8 in x 3.8 in x 4.5 in (19.9 cm x 9.7 cm x 11.5 cm)
Air outlet connector port dimensions:	22-mm diameter connector

AC Power Supply (PSA3)

AC supply input:	100-240 VAC, 50-60Hz
AC supply output:	22 VDC, 2.9 Amp

P10 Battery (Optional)

Transcend P10 Battery	18.0 VDC, 5,200 mAH (93.6Wh)
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Transcend 365 miniCPAP Performance

All gas volume, flow, and leakage specifications shall be expressed at STPD (standard temperature and pressure, dry)	
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 140°F (-20 to 60°C)
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 365 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 365 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The Transcend 365 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±2, 4, 8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst 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 signal input/output lines	Line power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±0.5*, 1 kV differential 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 1 cycle 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 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	Line power quality should be that of a typical commercial or hospital environment. If the user of the Transcend 365 miniCPAP requires continued operation during power line interruptions, it is recommended that the Transcend 365 miniCPAP 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	30 A/m	30 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: $d = 1.17\sqrt{P}$

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	<p>Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800MHz</p> <p>Recommended separation distance: $d = 0.70\sqrt{P}$ 800MHz to 2.5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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. Falling drops (15 degrees tilted) 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.

Performance

Pressure

Testing in accordance with ISO 80601-2-70:2015 for pressure accuracy and measurement uncertainty of manufacturer's test equipment

Pressure type	Accuracy	Measurement uncertainty
Static at 10 cm H ₂ O	+/- 0.5 cm H ₂ O	Static pressure accuracy has a measurement uncertainty of 0.37 cmH ₂ O.
Dynamic	+/- 1.0 cm H ₂ O or 10%, whichever is greater	Dynamic pressure accuracy has a measurement uncertainty of 0.73 cmH ₂ O.

Acoustics

Values determined according to noise test code given in ISO 80601-2-70:2015, using the basic standards ISO 3744 and ISO 4871.

Sound Type	Measurement	Uncertainty
Sound power level (@ 10cm H ₂ O pressure, static)	41.7 dB(A)	+/- 2 dB(A)
Sound pressure level (@ 10cm H ₂ O pressure, static)	33.7 dB(A)	+/- 2 dB(A)
Sound pressure level (@ 10cm H ₂ O pressure, static) *	27.7 dB(A)	+/- 2 dB(A)
Working pressure range:	4 to 20 cm H ₂ O	
Pressure limit:	30 cm H ₂ O	

*Sound pressure level reported in a typical use environment.

Flow

Maximum flow rate (typical)		Test Pressures				
		4 cm H ₂ O	8 cm H ₂ O	12 cm H ₂ O	16 cm H ₂ O	20 cm H ₂ O
	Measured pressure at the patient connection port (hPa)	3.42	6.88	10.85	14.85	18.84
	Average flow at the patient connection port (l/min)	81.75	107.4	109.12	107.16	104.19

Humidifier Specifications

Humidity Output	≥ 12 mg H ₂ O/L	Uncertainty: 2.5 mg/L
Maximum Gas Temperature	42.3 °C	
Maximum Specific Enthalpy	176.36 kJ/m ³	Uncertainty: 20 kJ/m ³
Water Capacity	195 mL, up to fill line 240 mL, maximum reservoir capacity	
Gas Leakage (Reservoir)	0.145 LPM	

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 365 miniCPAP**	2 years
Transcend P10 Battery	9 months

*From date of user purchase.

** Except water reservoir and heating element, which are 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 103 Osborne Road NE, Fridley, Minnesota 55432 USA, 1.877.621.9626 or 1.651.621.1800.

Contact

Somnetics International, Inc.
103 Osborne Road NE
Fridley, Minnesota 55432 USA
<http://www.MyTranscend.com/>

Phone: 651.621.1800

Toll-free: 877.621.9626

Fax: 651.204.0064

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