TRANSCEND®
365 mini cpap™

Auto User Manual

Notices

Somnetics®

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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   Some images displayed may differ from the current product presentation

Contents—

Introduction

The 365 miniCPAP™ Auto by Transcend® is a medical device that provides positive airway pressure to users in the range of 4 to 20 cmH$_2$O as prescribed by your clinician.

- The 365 miniCPAP Auto may be used every day on a bedside table and can be packed with you when you travel.
- An interactive LCD interface makes the 365 miniCPAP easy to operate.
- The 365 miniCPAP Auto™ 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 365 miniCPAP Auto™.

*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 Auto 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto™. 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ is not defibrillation proof.

- Do not attempt to sterilize 365 miniCPAP Auto™.

- 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 365 miniCPAP Auto™ 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 Auto 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 Auto 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 365 miniCPAP Auto™ only with the Somnetics-supplied power supplies, or batteries. See Appendix: Part Numbers.

- Discontinue use of the 365 miniCPAP Auto™ and contact your physician if respiratory or skin irritations occur.

- Do not introduce objects into the 365 miniCPAP Auto™ 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. <u>The use of distilled water is required for proper function of the heated humidifier</u>.** 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 365 miniCPAP Auto™, 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:
  - o The equipment must not be positioned in a bed

- o The equipment should not be placed anywhere other than on a firm, flat surface

- o Do not position in a location where pets or children can access equipment

- o Do not position in an open window or other location where dust, sunlight, or pests (insects) can affect equipment safety and/or performance

- o Magnets used to secure the humidifier reservoir to the CPAP may interfere with other medical devices. Do not place the 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:

  - o Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat

  - o Do not block the air intake port, thereby interfering with therapy

PHT

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

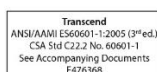# Symbols <small>(the following symbols may appear on the product or packaging)</small>

Caution

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

Temperature limit

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

Consult instructions for use

Humidity limitation

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.
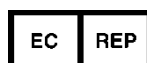
LOT   Batch code

Date of Manufacture

REF   Precedes reference or item number

EC | REP   Authorized Representative in the European Community

Manufacturer

Fragile, handle with care

Keep dry

Serial Number

Use distilled water only. <u>The use of distilled water is required for proper function of the heated humidifier</u>. 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 Auto™

Begin by unpacking all items from the 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ to you.

Included with 365 miniCPAP Auto

- 365 miniCPAP Auto™ device and integrated humidifier

- Universal power supply (PSA3) and power cords

- Travel bag

- Transcend® 365 miniCPAP Auto™ Quick Guide

- USB cable

Accessories (Sold Separately)

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

- P_{10} Battery™

- Patient Mask

The 365 miniCPAP Auto™

Your 365 miniCPAP Auto™ 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 365 miniCPAP Auto™.

Assembling the 365 miniCPAP Auto

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

Follow these steps to assemble the Transcend 365 miniCPAP Auto™:

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 365 miniCPAP Auto™ device, making sure it is fully seated.
3. Plug the power supply into the 365 miniCPAP Auto™. 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 365 miniCPAP Auto

Allow the 365 miniCPAP Auto to adjust to ambient temperature after removing from storage. To begin therapy, plug in the power supply to your 365 miniCPAP Auto and press the Center button to begin therapy. Press the down button to activate Ramp, if desired.

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.

Press Center button to begin therapy.

Then press down button to begin ramp.

Note: If the miniCPAP™ device loses power while delivering therapy, the CPAP will power on as soon as power is restored. The user must hit the Center button to resume therapy.

Home screen and Control Panel
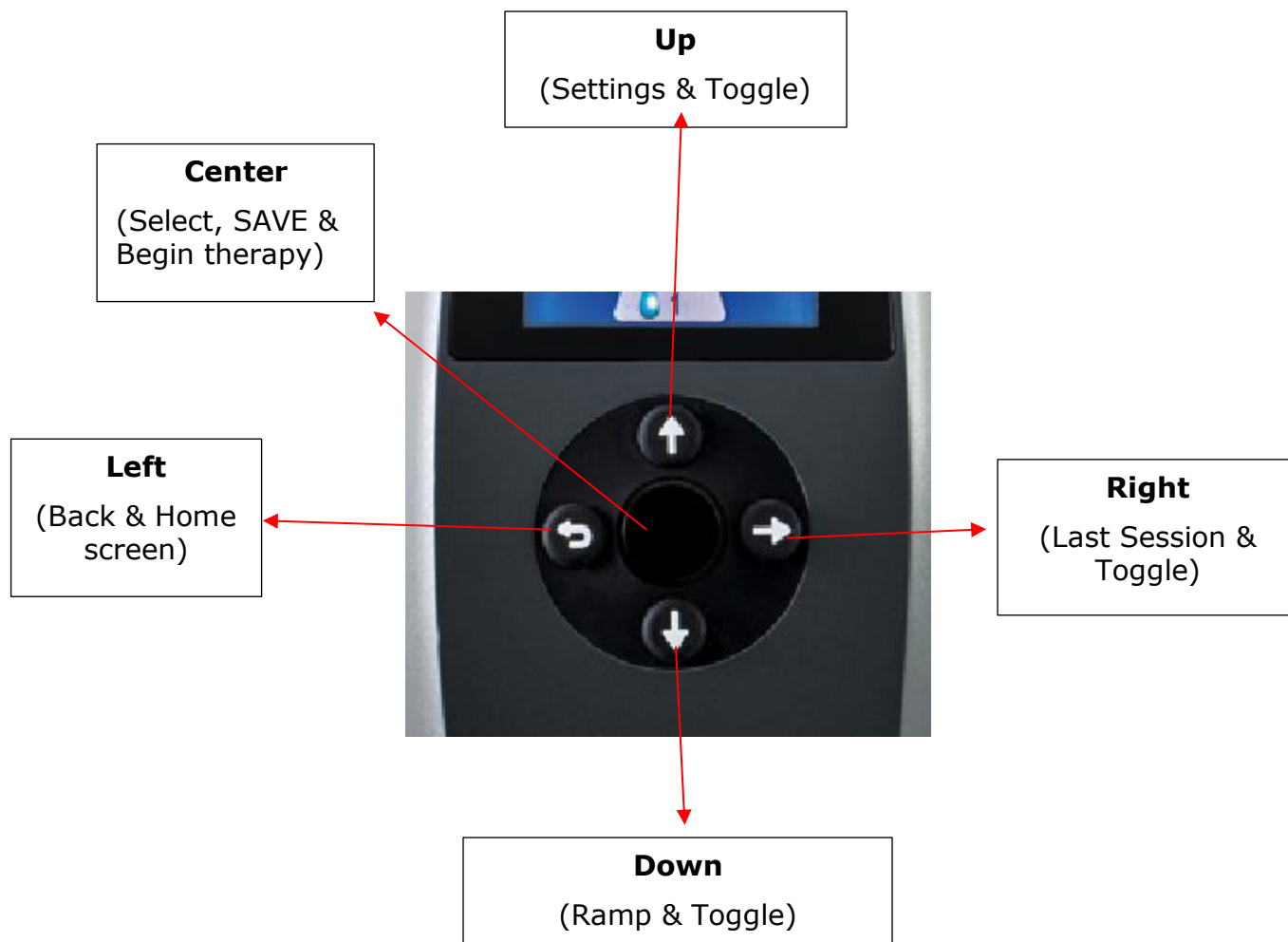
Home Screen

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 - 4 and 20 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 immediately bring up the section you highlight on the Home screen. 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.

Up

(Settings & Toggle)

Center

(Select, SAVE & Begin therapy)

Left

(Back & Home screen)

Right

(Last Session & Toggle)

Down

(Ramp & Toggle)

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 365 miniCPAP Auto™.

An optional P_{10} battery pack is also available to power the 365 miniCPAP Auto™.

USB Port

A mini-AB USB port is provided for direct data exchange between the 365 miniCPAP Auto™ and a computer. The 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ for prescription pressure, Ramp settings and Auto settings and also access therapy compliance information with the Transcend desktop software (password protected).

USB port

Power port
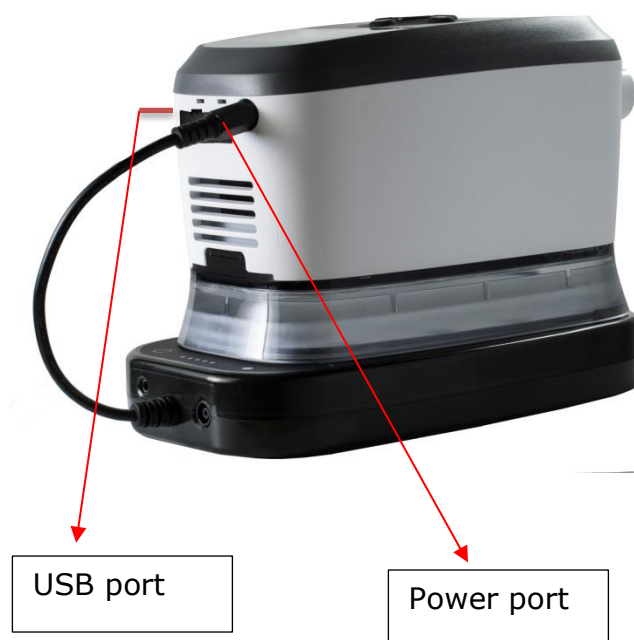
Using the 365 miniCPAP Auto™

## 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 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 LCD lights remain 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 and Down buttons at the same time for three seconds to start Drying Mode. This mode will last 30 minutes unless you interrupt it by pressing any button. 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. Press the down button to activate Ramp, 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).

Press the Left/Back button to return to the Home screen.
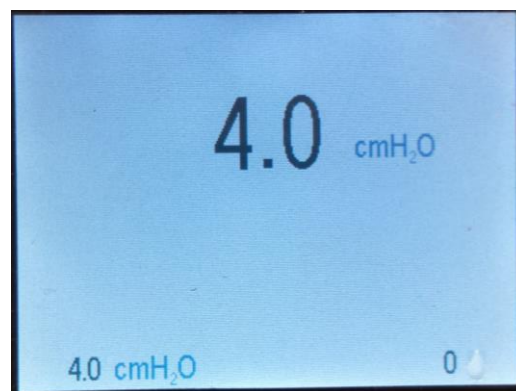
Ending therapy and entering Drying Mode

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 and Down buttons 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 left from a therapy session.

Push and hold the Up and Down buttons to enter Drying Mode.

The 365 miniCPAP Auto Humidifier

Filling the Reservoir

Caution! Use distilled water only. <u>The use of distilled water is required for proper function of the heated humidifier</u>. 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<u> distilled water only</u>. 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.

- Unpackage the Water Filter Kit and follow instruction 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).

Reservoir should be filled to the 'Max Fill' line.

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.

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

Should your heater wick need to be replaced,
here is a look at the heater parts and instructions for replacement.

Wick cover	
Heater Cartridge Wick	

Replacing the Heater 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 counter clockwise 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

Therapy Settings

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 365 miniCPAP Auto is set to a fixed-pressure setting or auto-adjusting therapy pressure.

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 using the password.

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. To activate Ramp during therapy, press 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.
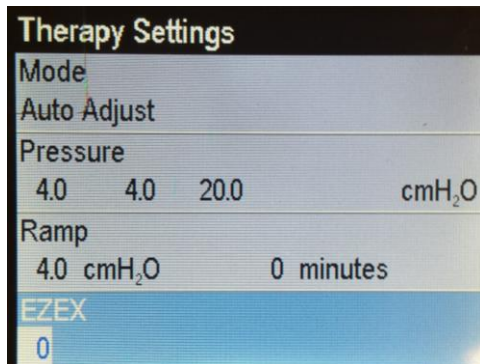

Push the Up or Down button to move the value from 0 to 3. A setting of 0 provides no exhalation relief, 3 provides the greatest exhalation relief. Press the Center button to save your selection.

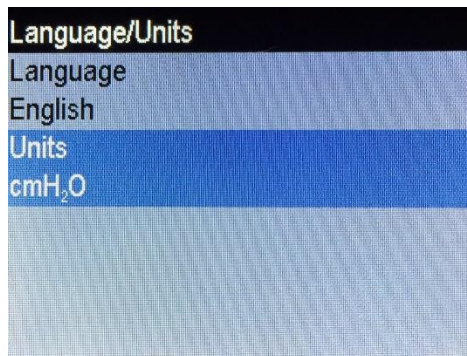Use the Left/Back button to toggle back through screen options or return to the Home screen.

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.**
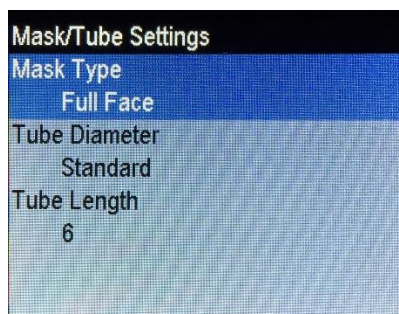
Language Settings

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.

- 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 watthours
- WH◇- Heater watthours 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.

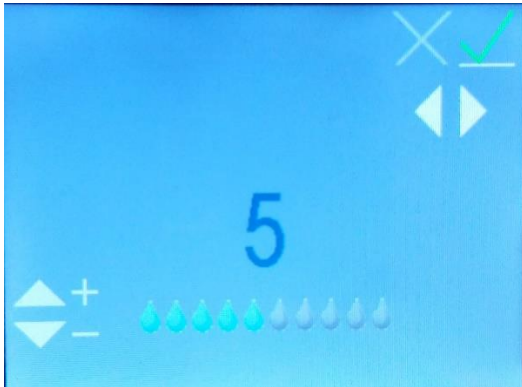| Last Session		
Duration	00:00	
AHI	0.00	
Avg. Leak	0.0	LPM
Avg. Pressure	0.0	cmH₂O
Min. Pressure	0.0	cmH₂O
Max. Pressure	0.0	cmH₂O

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

Push the Left/Back button to return to the Home screen and you will see your new setting displayed on the Humidification icon.

# Compliance Report (Press the Left Button on the Control Panel)

Compliance Report

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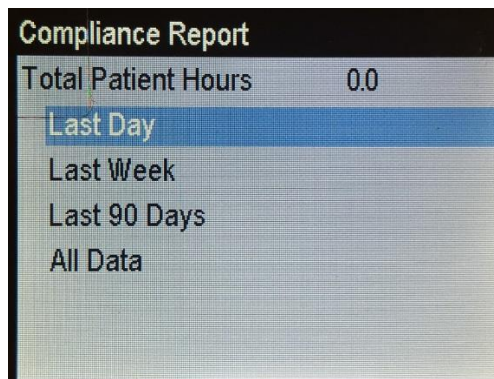
You can choose the time range of Total Patient Hours you would like to view over the Last Day, Last Week, Last 90 days or All Data.

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.

In All Data you will see data for all the days you've been using the device. This screen shows a time stamp in the bottom left of how long the device has been in use.

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 Exclamation (!) – Heater Over-Temperature Detected

Indicated by a flashing red exclamation point.

- During the last therapy session, the heater reached a heat cutoff condition and turned off for the remainder of the session. The status will be reset when the next therapy session is started and humidification will be enabled. If the status persists after subsequent therapy sessions, 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 X – No Heater Detected

Indicated by a flashing red X. The humidifier will be disabled. Caused by:

- 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.

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)
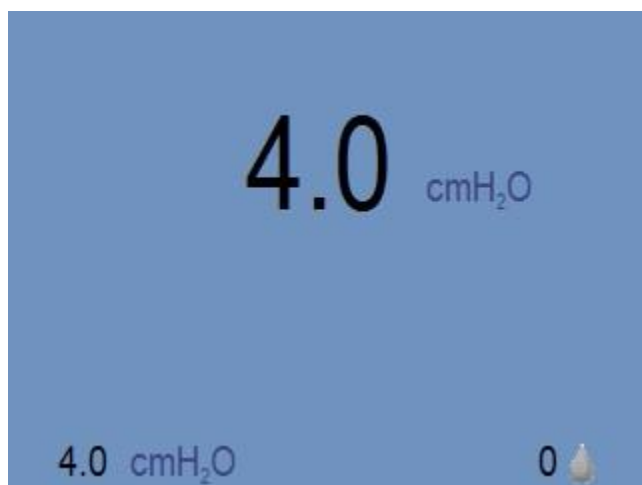
The gray droplet indicates that the humidifier is not active.

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 365 miniCPAP Auto

There are two choices for powering the 365 miniCPAP Auto™ device:

- Use the AC Power Supply (PSA3)

- Use the optional P_{10} 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 P$_{10}$ Battery (Optional Accessory)

The Transcend P$_{10}$ Battery is an optional power source for the 365 miniCPAP Auto™. To use, connect the battery outlet cable to the 365 miniCPAP Auto™ 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.

P$_{10}$ battery properly connected to the device.
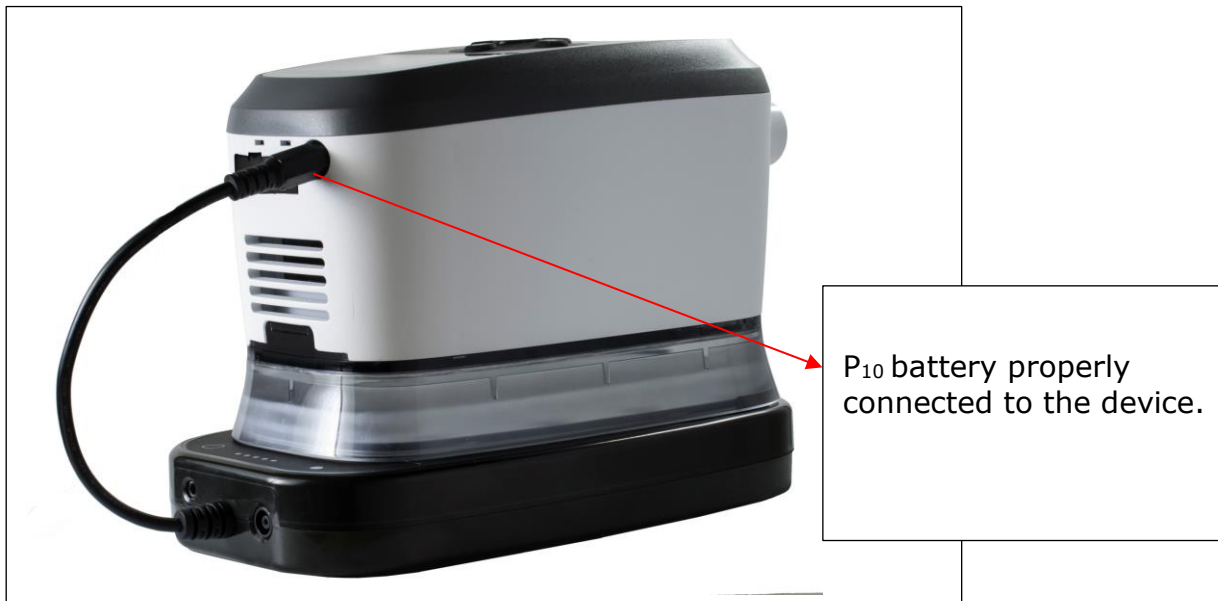
Note   Fully charge the battery before the first use. Follow the battery charging instructions provided in this User Manual. **Do not connect the battery to the 365 miniCPAP Auto™ during the battery's initial charge.**

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 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 P$_{10}$ 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto

The 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ before cleaning.

- Do not submerge the 365 miniCPAP Auto™ 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 365 miniCPAP Auto™.

- 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 365 miniCPAP Auto™.

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
365 miniCPAP Auto™	Weekly	5-Year

Warning: Do not submerge the Transcend 365 miniCPAP Auto™, 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 and Down buttons 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 365 miniCPAP Auto™ 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.

Flip open door

Remove filter
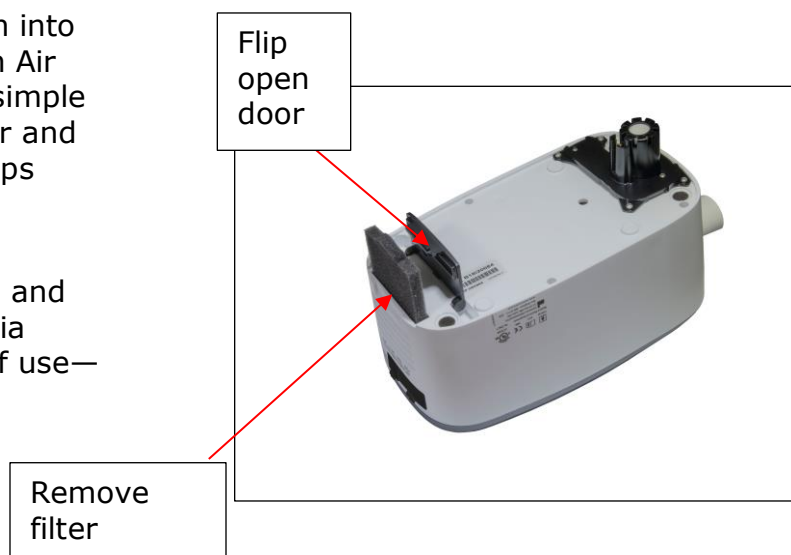
Environmental Information

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® 365 miniCPAP Auto 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.

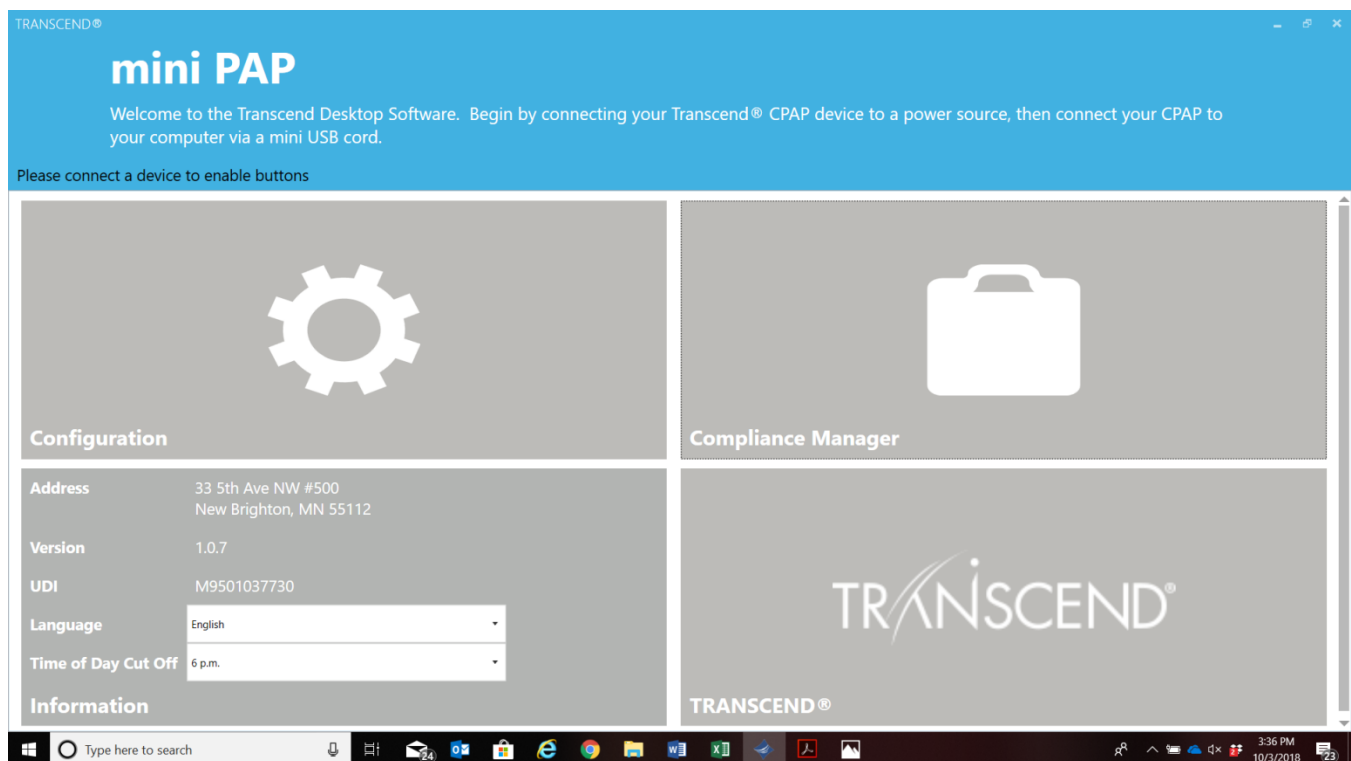3 **Simple Steps** and you're ready to use your software.

STEP 1

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

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 Auto 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.

Open rubber cover to access mini USB

Power cord

Mini USB cord
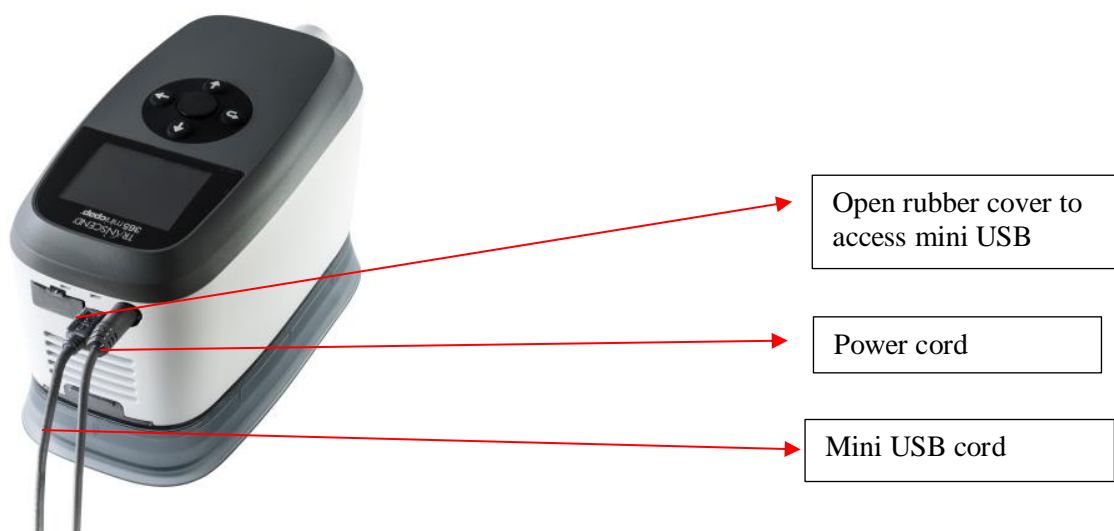
STEP 3

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

Choose language here
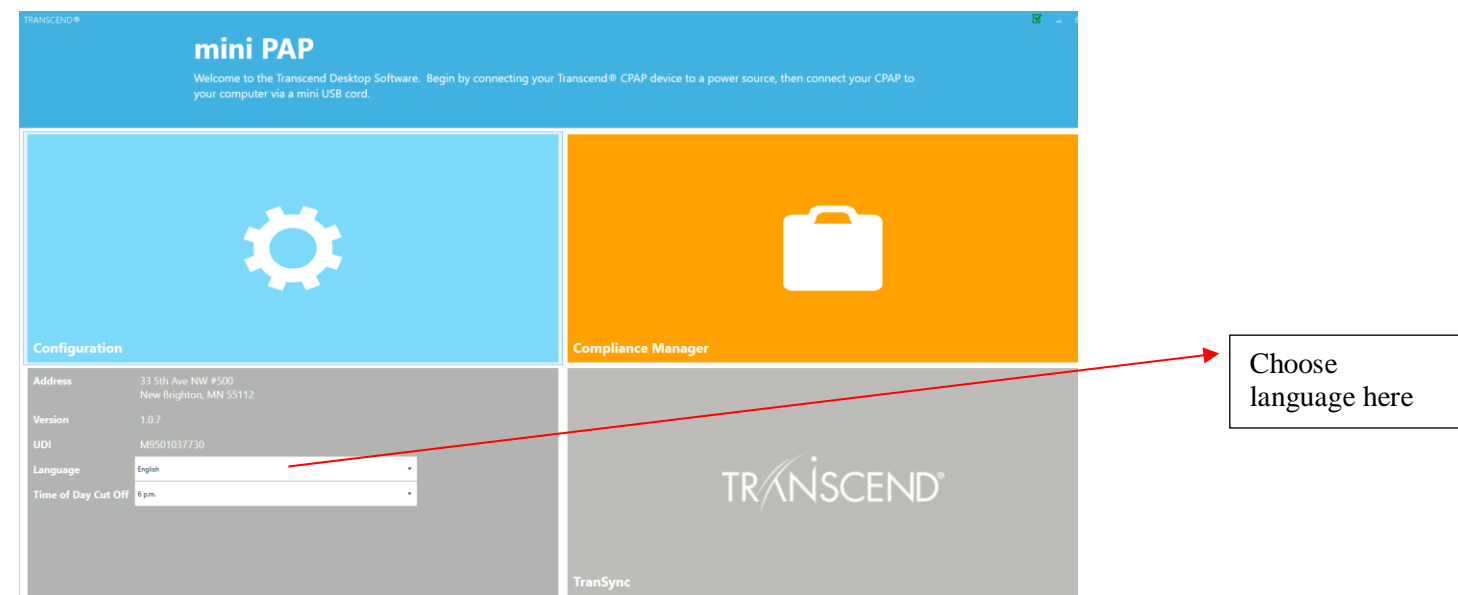
**Now You're Ready to Use the Transcend® 365 miniCPAP Auto Software**

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.
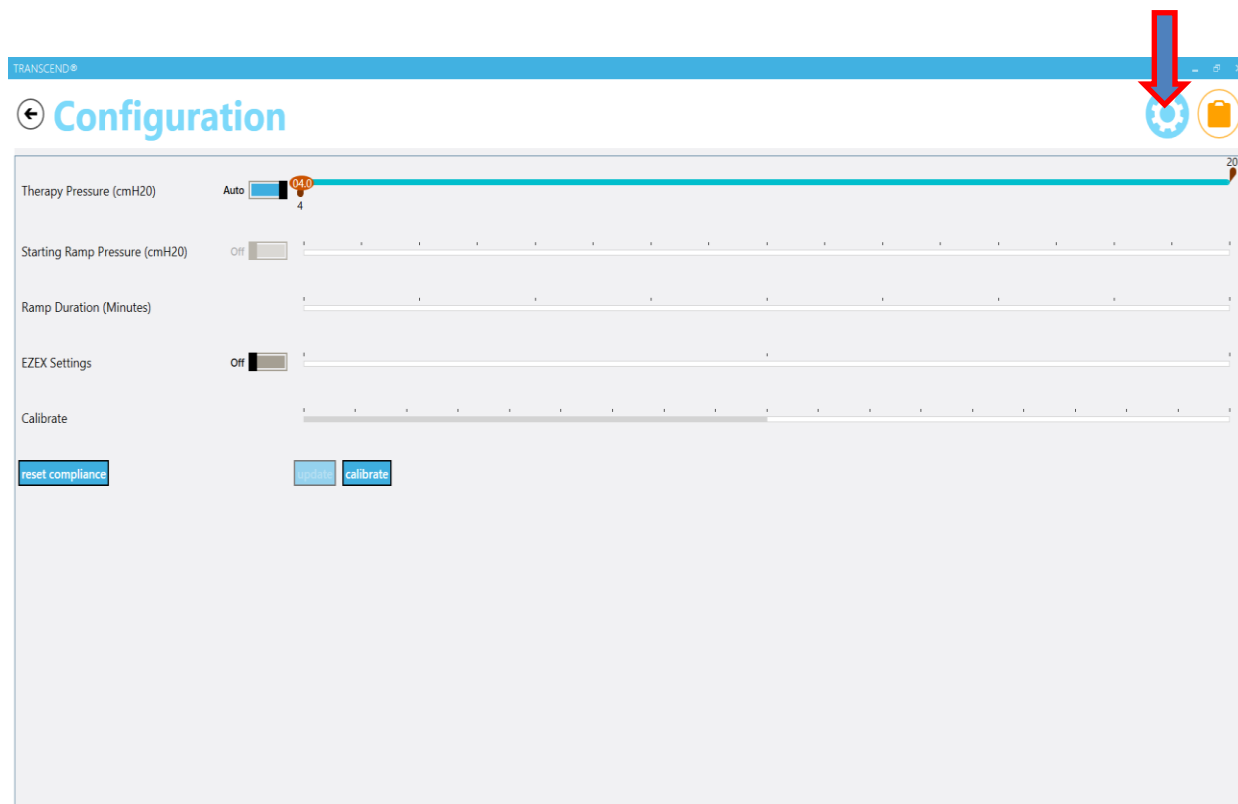
The Configuration area is used to adjust various settings on the device. Some features, such as the Therapy Pressure and Calibration are clinician settings and are only available with a password. You can, however, adjust the Starting Ramp Pressure, Ramp Duration and EZEX pressure relief settings if these 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. 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.
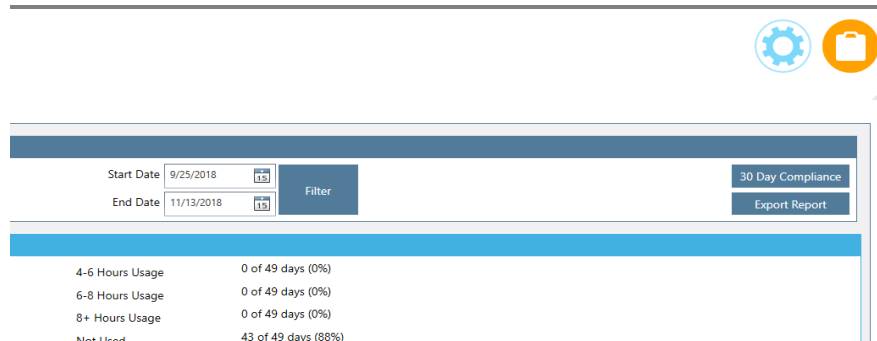
Then click the Filter button to update the start and end dates you would like to view.

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).
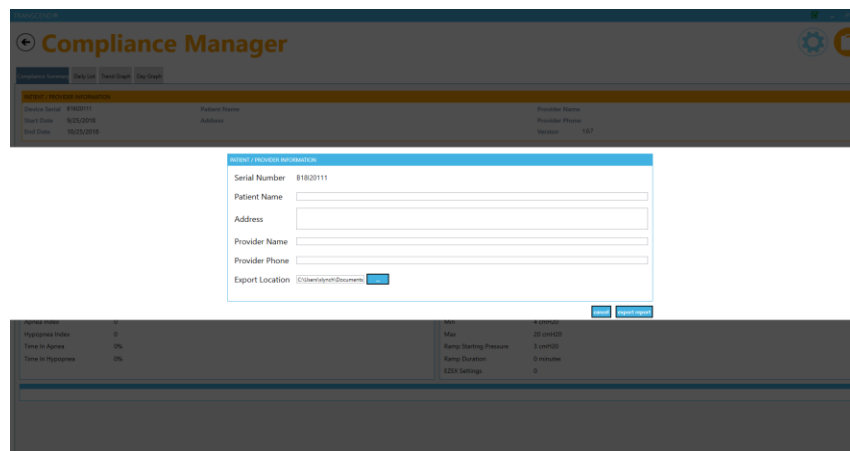
Start Date 9/25/2018	30 Day Compliance
End Date 11/13/2018 Filter	Export Report

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%)
Not Used	43 of 49 days (88%)

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.
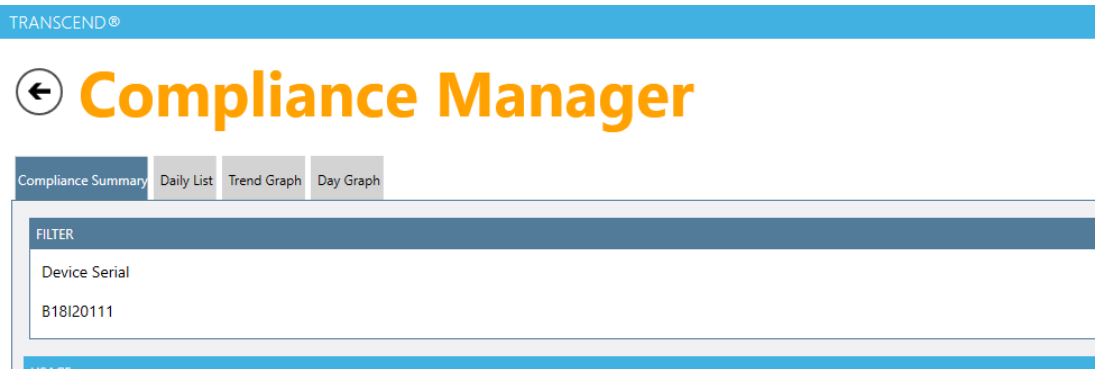
Daily List

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).

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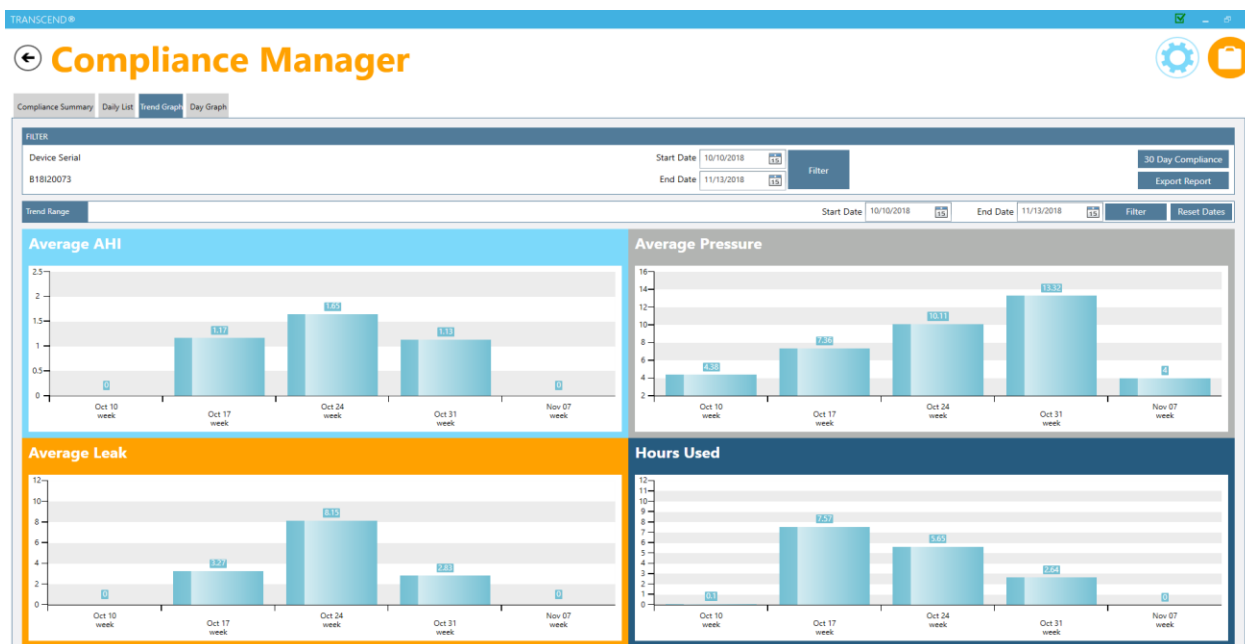
At any time, you can adjust the date range you want to view by changing the date range and clicking the Filter button. You can reset the date range after you've finished drilling down by hitting the Reset Dates button.

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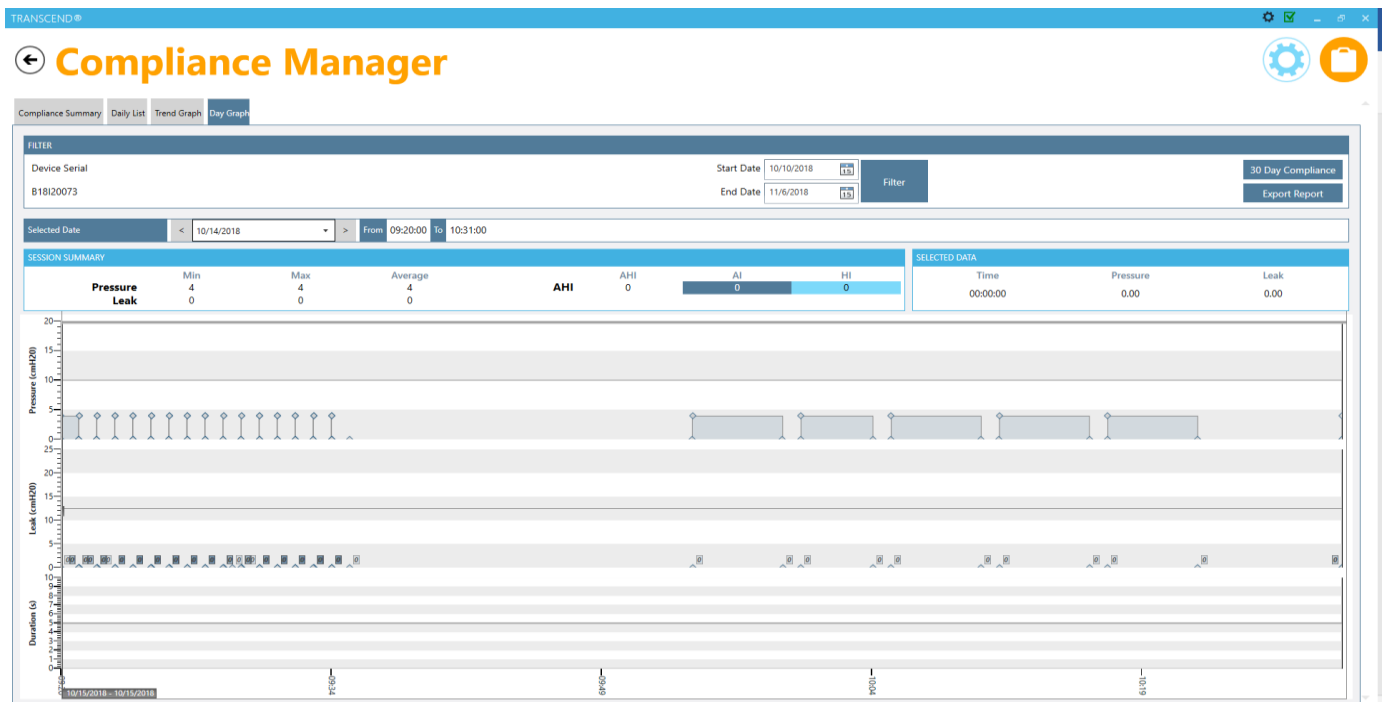
Questions? Call 877-621-9626 or email info@somnetics.com.

Fault and Alert Codes

Fault Codes

When the 365 miniCPAP Auto™ 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 <u>first observed</u> 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
2	Stack overflow	Internal software fault.
3*	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.
4*	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.
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.
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.

Fault Number	Error	Comments
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.	365 miniCPAP Auto™ 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 heater wick if it doesn't appear to be wicking water from the reservoir.
	Dirty air filter.	Change and/or clean the Filter Media.
365 miniCPAP Auto™ 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 365 miniCPAP Auto™.	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 Wick Six Pack	503111
Transcend Heater Cartridge Wick	503097			

Accessories

Item	Part number		Item	Part number
Transcend P_{10} Battery	503098		Transcend 365 Water Filter Kit	503110

Replacement Parts

Item	Part number		Item	Part number
Transcend 365 miniCPAP™ Auto Service Unit	503090		Transcend Travel Bag	503012
USB cable	503020		Transcend 365 miniCPAP™ Water Reservoir	503093
Transcend 365 miniCPAP™ Heater Cartridge (available to CPAP dealer only)	503095		Transcend 365 miniCPAP™ Auto Power Supply PSA3	503100
US 2-Prong Power Cord	503074		UK 2-Prong Power Cord	503076
EU 2-Prong Power Cord	503075		AU 2-Prong Power Cord	503077

Appendix: Specifications

This section presents the following topics:

- **365 miniCPAP Auto™ device**

- **AC power supply – PSA3**

- **Batteries**

- **Transcend 365 miniCPAP Auto™ performance**

- **Manufacturer's declaration**

365 miniCPAP Auto™

Transcend 365 miniCPAP Auto™ weight:	1.7 lbs (770 gm)
Transcend 365 miniCPAP Auto™ 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:	20 VDC, 3.25 Amp

P10 Battery (optional) -

Transcend P_{10} Battery	18.0 VDC, 5,200 mAH (93.6Wh)

365 miniCPAP Auto 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 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 365 miniCPAP Auto™ 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 Auto™ 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 365 miniCPAP Auto™ 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 365 miniCPAP Auto™ 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 1 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 1 cycles 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 Auto™ requires continued operation during power line interruptions, it is recommended that the Transcend 365 miniCPAP 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	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: $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800MHz Recommended separation distance: $d = 0.70\sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

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_2O	+/- 0.5 cm H_2O	Static pressure accuracy has a measurement uncertainty of 0.37 cmH_2O.
Dynamic	+/- 1.0 cm H_2O or 10%, whichever is greater	Dynamic pressure accuracy has a measurement uncertainty of 0.73 cmH_2O.

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_2O pressure, static)	*41.7 dB(A)*	+/- 2 dB(A)
Sound pressure level (@ 10cm H_2O pressure, static)	*33.7 dB(A)*	+/- 2 dB(A)
Sound pressure level (@ 10cm H_2O pressure, static) *	*27.7 dB(A)*	+/- 2 dB(A)
Working pressure range:	4 to 20 cm H_2O	
Pressure limit:	30 cm H_2O	

*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™ Auto**	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 33 5th Avenue, New Brighton, Minnesota 55112 USA, 1.877.621.9626 or 1.651.621.1800.

Contact

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