Transcend 3 BiPAP

User Manual

Notices

Notice	The information contained in this document is subject to change without notice.
Trademark	Somnetics® and Transcend® are registered trademarks of Somnetics International, Inc.; all rights reserved.
Copyright	

Contact Somnetics International, Inc.

Corporate headquarters	Somnetics International, Inc.
Email	info@somnetics.com
Web	http://www.MyTranscend.com/
Telephone	651.621.1800
Toll-free telephone	877.621.9626
Fax	651.204.0064

Somnetics International, Inc.
103 Osborne Road NE
Fridley, Minnesota 55432 USA

Rx Only

About this User Manual

NOTE: Training is required for the use of this device. 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: For purposes of this manual, some software screen images may differ from the actual screen display. This is only for clear printing and on-screen display of this manual.

Contents

Introduction

The Transcend 3 BiPAP provides ventilation assistance and breathing support to patients suffering from respiratory distress. Buttons and LED lights facilitate control and provide operational feedback. A DC power jack and a USB port are also incorporated into the Transcend 3 BiPAP.

Indications for Use

The Transcend 3 BiPAP is intended for the therapy of adults weighing over 66 pounds (30 kg) with mild to moderate respiratory distress. The device delivers positive airway pressure (PAP), specifically positive end-expiratory pressure (PEEP) with ventilatory support, to provide ventilation assistance and breathing support. The device is intended for use in healthcare settings.

This device does not have traditional FDA clearance or approval. It is authorized by the FDA under an Emergency Use Authorization (EUA) of ventilators, ventilator tubing connectors, and ventilator accessories to treat patients during the COVID-19 pandemic. The EAU applies only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The Transcend 3 BiPAP is not intended for life support, and does not provide mechanical ventilation or flow-controlled ventilation.

Precautions for Use

This section describes the warnings and cautions associated with use of the Transcend 3 BiPAP. The following guidelines apply to this document:

Warning! Indicates the possibility of serious injury or death to patients 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

- There are no audible alarms on this device.
- Therapy status is indicated by illuminated LEDs on the device. Therapy may be interrupted by loss of power to the device or certain fault conditions, which will be indicated by non-illuminated or flashing LEDs on the device. Loss of therapy could result in carbon dioxide rebreathing.
- The Transcend 3 BiPAP is not supported by remote monitoring. Routine visual monitoring of the device and continuous monitoring of patient oxygen saturation level should be performed to ensure proper therapy is maintained.
- Do not allow water to enter this device. Transcend 3 BiPAP should not be exposed to environmental conditions where the system may get wet.
- The Transcend 3 BiPAP is not intended for life support, and does not provide mechanical ventilation or flow-controlled ventilation.
- The Transcend 3 BiPAP must be set up and adjusted by a trained provider.
- The air temperature produced by this device can be as much as 10ºF higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90ºF (32ºC).
- Do not block or otherwise obstruct the exhalation ports of the breathing circuit.
- The Transcend 3 BiPAP is only to be used with the supplied or recommended accessories. Use of accessories not recommended may result in increased electromagnetic emissions or decreased electromagnetic immunity of the PAP system and may be potentially unsafe.
- The Transcend 3 BiPAP is not defibrillation proof.
- Do not attempt to sterilize Transcend 3 BiPAP.
- If the device is to be used by multiple patients, a main flow bacteria filter must be installed in-line between the device and the breathing circuit tubing to prevent contamination. The bacteria filter and complete breathing circuit must be replaced for each patient.
- A new respiratory circuit, patient interface and BiPAP air inlet filter must be applied between patient uses.
- To prevent contamination of the surrounding environment, use only non-vented masks with anti-asphyxia valve and the Transcend 3 BiPAP Respiratory Circuit or other breathing circuits fitted with appropriate filtration for the exhalation port.

- The device should be used only with masks and connectors recommended by Somnetics or a health care professional. A mask should not be placed on a patient unless the device is turned on and is properly delivering pressure. Explanation of the Warning: When the device is in operation, air flow from the device flushes exhaled air out through the vent leak. When the device is not operating, however, fresh air will not be provided through the mask and exhaled air may be rebreathed.
- Use the Transcend 3 BiPAP only with non-vented masks with an anti-asphyxia valve. Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- To prevent disconnection of breathing circuit components and masks, only use items with 22 mm connectors in compliance with ISO 5367 or ISO 5356-1.
- The Transcend 3 BiPAP respiratory circuit can become contaminated with body fluids or microbial material.
- The power cord and air tube present a strangulation hazard. These can become wrapped around a neck and strangle the user. Keep breathing circuit out of children's reach.
- Small parts are unlikely to be expelled from the Transcend 3 BiPAP enclosure, but in the case of severe damage to the device, internal components may fragment and create a swallowing or choking hazard if they get out of the enclosure.
- Do not cover the Transcend 3 BiPAP or place it in a position that affects the proper operation of the device, as it may also create a safety issue. Examples of this include:
    - Do not place the device in a bed.
    - The device should not be placed anywhere other than on a firm, flat surface.
    - Do not position in a location where pets or children can access equipment.
    - Do not position near an open window or other location where dust, or pests (insects) can affect equipment safety and/or performance.
    - Do not position near a curtain or other material that blocks the flow of cooling air, thereby causing the equipment to overheat.
    - Do not block the air intake port, thereby interfering with pressure delivery.
- Do not add any attachments or accessories to the device that are not intended for use in combination with the device, as stated in the instructions for use of the device or accessory as the device might not function correctly leading to the risk of degradation of health of the patient.
- Do not use the device at an altitude above 8,000 ft. or outside a temperature of 41 to 95°F. Using the device outside of this temperature range or above this altitude

can compromise the device performance which consequently can result in degradation of the health of the patient.

- Make sure all components of the breathing circuit are securely attached. Any leak in the connections could result in the aerosolization of virus particles. It could also reduce the delivered air pressure to the patient.

- To reduce the likelihood of disconnection and to prevent adverse device performance, use only accessories compatible with the device. Compatibility is determined by reviewing the instructions for use of either the device or the accessories.

- The respiratory circuit components and bacterial/viral filters should be discarded after each patient use using standard institutional biohazard procedures. Failure to do so could result in cross contamination. No attempt should be made to clean, disinfect, or sterilize these components for multiple users. These components are for single patient use only.

- Only use bacterial/viral filters that are commercially available and designed for use with CPAP machines. Follow the manufacturer's instructions for use of the filter.

- This device is not suitable for ventilator-dependent patients.

- The ventilation supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebulizer.

- Keep the Transcend 3 BiPAP at least 1 meter from oxygen sources. If oxygen will be provided to the patient along with BiPAP therapy, use an oxygen line adaptor. Oxygen should be coupled to the breathing circuit near the mask rather than adjacent to the Transcend 3 BiPAP outlet port.

Cautions

- Federal law (United States) restricts this device to sale by, or on the order of, a physician.
- Power the Transcend 3 BiPAP only with the Somnetics-supplied power supplies or batteries. See **Appendix: Part Numbers**.
- If skin or respiratory irritation occurs, use the Transcend 3 BiPAP at the physician's discretion.
- Do not introduce objects into the Transcend 3 BiPAP air inlet or air outlet.
- Inspect the power supply for signs of wear or damage before each use. Contact your distributor to replace damaged parts if necessary.

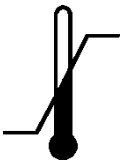
- To protect the environment, some parts and accessories of the Transcend 3 BiPAP, including optional batteries, must be disposed of in accordance with local regulations.
- The BiPAP must be calibrated with the respiratory circuit *before* a mask is attached.
- The BiPAP must be calibrated with the respiratory circuit each time a new respiratory circuit is used with the BiPAP device to ensure accurate therapy.
- Do not attempt to clean or sterilize the Air Inlet Filter for reuse.

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

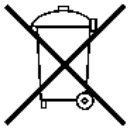
Caution

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

Type BF Applied Part



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.
REF	Precedes reference or item number
LOT	Batch code
	Date of Manufacture
EC REP	Authorized Representative in the European Community
	Manufacturer
	Fragile, handle with care
	Keep dry
SN	Serial Number

Components of the Transcend 3 BiPAP

Begin by unpacking all items from the Transcend travel bag and inspect them to ensure they were not damaged during shipment. Report any missing or damaged items to the distributor that provided the product to you.

Included with the Transcend 3 BiPAP

- Transcend 3 BiPAP
- Transcend Travel bag
- Air Supply Tube (Compatible with standard 22 mm connector)
- Transcend 3 BiPAP User Manual
- Fact Sheet for Healthcare Providers: Emergency Use of Ventilators During the COVID-19 Pandemic
- Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic
- AC power supply (PSA2)
- USB Cable

Accessories (Sold Separately)

- Patient Mask (Non-Vented with anti-asphyxia valve)
- Transcend 3 BiPAP Respiratory Circuit
- Oxygen Line Adaptor
- Transcend P_8 Battery

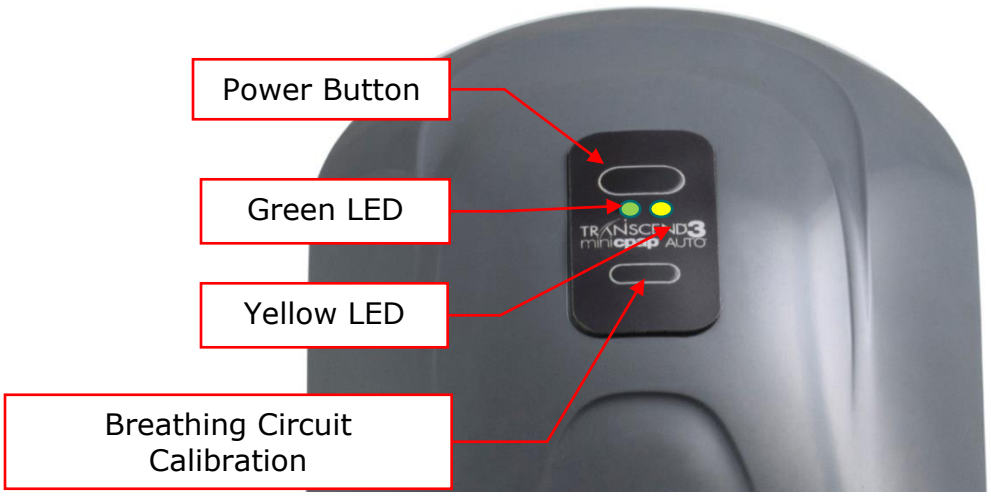
Description of Transcend 3 BiPAP Components

Transcend 3 BiPAP Device

The Transcend 3 BiPAP delivers bi-level pressure. An external power source connects to the Transcend 3 BiPAP to supply power to the device.

Control Panel

The Transcend 3 BiPAP control panel has two push buttons; the top button activates the BiPAP therapy and the bottom button is used to calibrate air pressure with the breathing circuit. There are also two LED lights, including a green LED for indicating normal operational modes and a yellow LED that indicates fault conditions.



Power Connection Jack and USB Port

Power Jack

The power jack accepts the barrel plug of the output cable from a DC power source to operate the Transcend 3 BiPAP.

A variety of power sources may be used to power the Transcend 3 BiPAP. An AC to DC converting power supply is provided with your device and should be used when powering the device by line (wall outlet) power.

Optional Transcend battery packs are also available to power the Transcend 3 BiPAP.

USB port

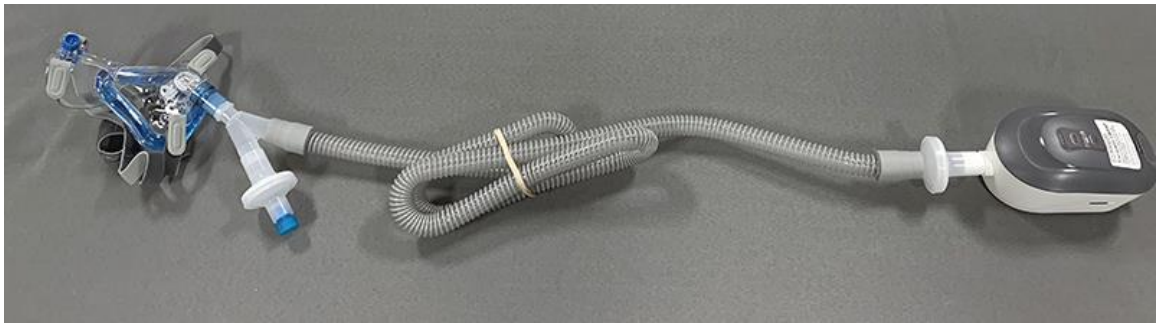
A mini-AB USB port is provided for direct data exchange between the Transcend 3 BiPAP and a computer via a USB data cable. This interface allows the clinician to configure the Transcend 3 BiPAP device with the appropriate therapy settings.

Air Inlet Filter

During therapy operation ambient air is drawn into the Transcend 3 BiPAP through an Air Inlet Filter. The Filter Assembly must be replaced between patients for multi-patient use.

Caution! Do not attempt to clean or sterilize the Air Inlet Filter for reuse.

Assembling the Accessory Respiratory Circuit



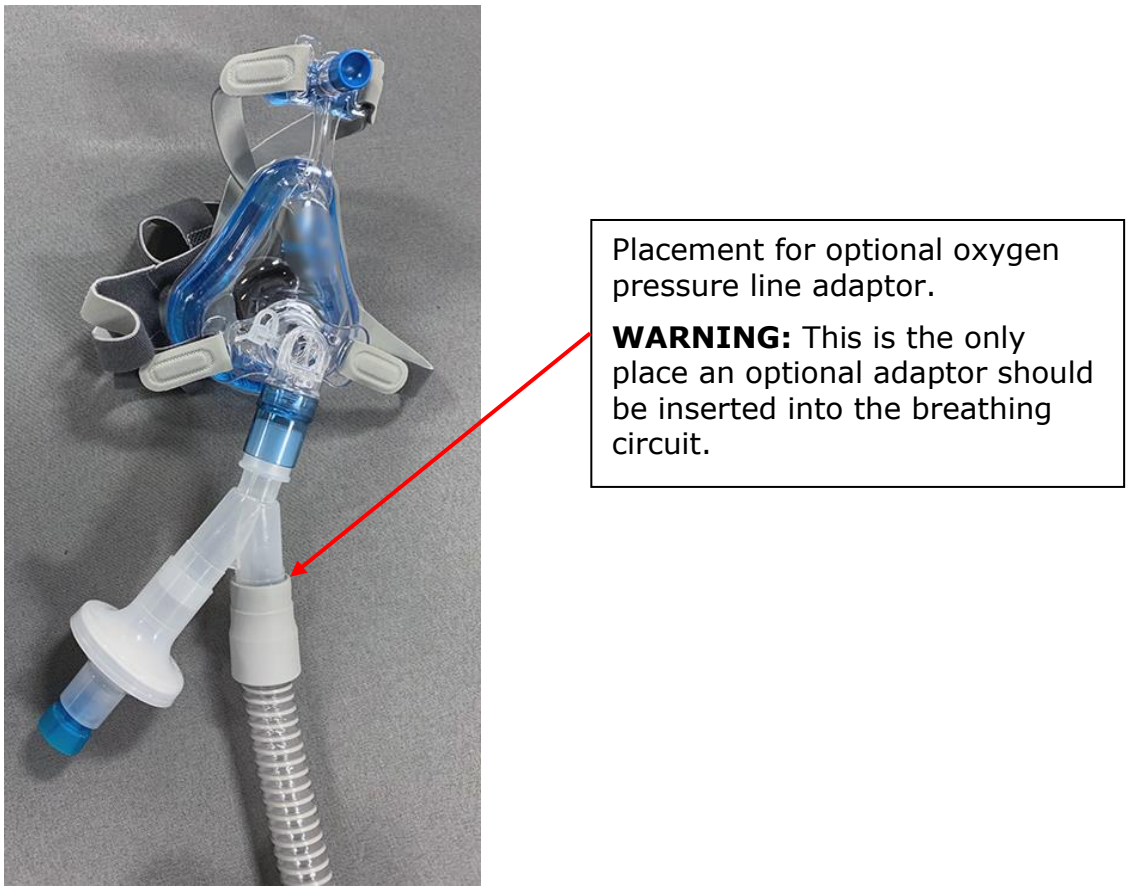
(Mask is not included in the Transcend 3 BiPAP Respiratory Circuit.)

1. Begin by attaching the bacterial/ viral filter to the air outlet of the BiPAP device.
2. Connect the air supply tube with standard 22mm connector to the bacterial/ viral filter.

3. If using an optional oxygen pressure line adaptor, connect this to the other end of the air delivery tube, then connect the adaptor to one of the Y-connector branches. If no adaptor is used, simply connect the air delivery tube to one of the Y-connector branches.

Warning! Do not add any attachments or accessories to the device that are not intended for use in combination with the device, as stated in the instructions for use of the device or accessory as the device might not function correctly, leading to the risk of degradation of health of the patient.

Warning! Keep the Transcend 3 BiPAP at least 1 meter from oxygen sources. If oxygen will be provided to the patient along with BiPAP therapy, use an oxygen line adaptor. Oxygen should be coupled to the breathing circuit near the mask rather than adjacent to the Transcend 3 BiPAP outlet port.



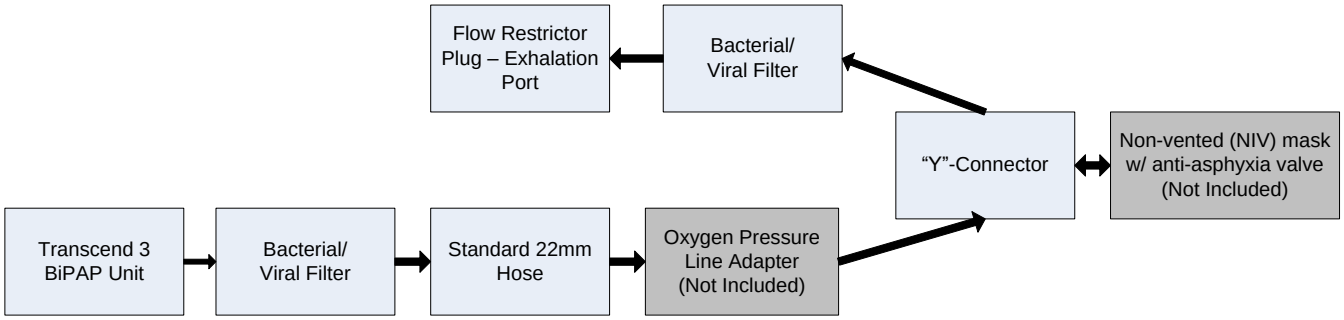
(Mask is not included in the Transcend 3 BiPAP Respiratory Circuit.)

4. Connect the Bacterial/ Filter to the open branch of the Y-connector, then plug the filter with the Flow Restrictor Valve.

NOTE: The BiPAP must be calibrated with the respiratory circuit before use. The calibration is done *before* a mask is attached.

Warning! Make sure all components of the breathing circuit are securely attached. Any leak in the connections could result in the aerosolization of virus particles. It could also reduce the delivered air pressure to the patient.

The following diagram shows the flow of flow-direction-sensitive components.



Warning! The Transcend 3 BiPAP respiratory circuit can become contaminated with body fluids or microbial material.

Calibrating the Transcend 3 BiPAP with Respiratory Circuit

1. Begin with the assembled respiratory circuit attached to the BiPAP device.

   Caution! The BiPAP must be calibrated with the respiratory circuit *before* a mask is attached.

   Caution! The BiPAP must be calibrated with the respiratory circuit each time a new respiratory circuit is used with the BiPAP device to ensure accurate therapy.

2. Connect the BiPAP to a power source, then press the bottom button on the control panel (below the logo) to initiate the calibration process.

   NOTE: Do not block or plug the open end of the Y-connector during calibration, as this could affect the calibration settings.

3. The blower will begin and will continue for 15-20 seconds until the calibration process is complete.

4. Once the calibration is complete, the blower will disengage, and the green LED light will blink to indicate the device has returned to Standby Mode.

5. It is now ready to connect with a patient mask for use.

Warning! Use the Transcend 3 BiPAP only with non-vented masks with an anti-asphyxia valve. Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.

Assembling the Transcend 3 BiPAP

1. After assembling the respiratory circuit and calibrating the BiPAP device with it, attach the mask. See the "Assembling the Accessory Respiratory Circuit" and "Calibrating the Transcend 3 BiPAP with Respiratory Circuit" sections for details.
2. **Caution! The BiPAP must be calibrated with the respiratory circuit each time a new respiratory circuit is used with the BiPAP device to ensure accurate therapy.**
3. Plug the power supply barrel connector into the Transcend 3 BiPAP power jack on the rear of the device.
4. Connect the power supply to a wall outlet.

Using the Transcend 3 BiPAP

When a power source is connected to the device, the Transcend 3 BiPAP power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is supplied to the Transcend 3 BiPAP, then a green LED light will flash to show the device has successfully entered Standby Mode. During therapy delivery, a solid green LED light will illuminate to indicate the device is delivery BiPAP therapy.

NOTE: If the Transcend 3 BiPAP loses power while delivering therapy, it will resume delivering therapy as soon as power is restored and the power button is pressed. The device will repeat the power-up LED flash sequence and a flashing green LED light will indicate the BiPAP has entered Standby Mode prior to the blower restarting.

Warning! There are no audible alarms on this device.

Standard User Modes

Normal operation consists of the following modes:

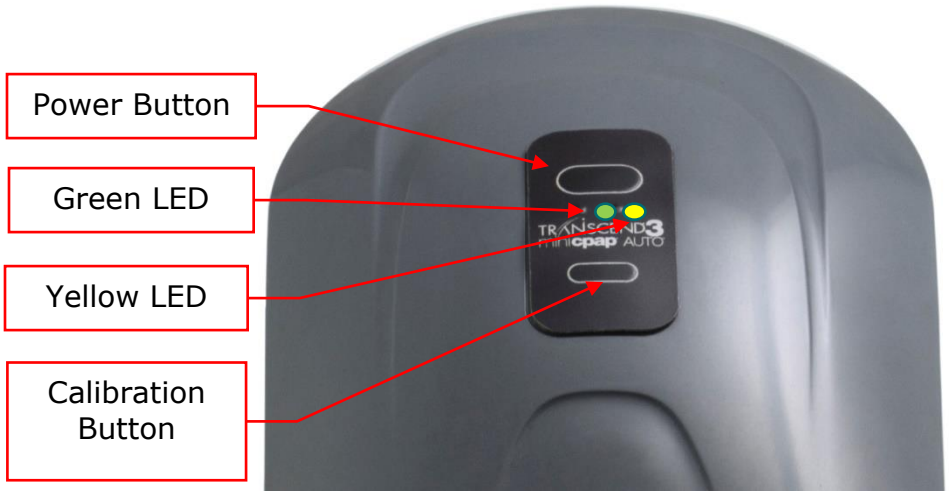
Off	When the device is not connected to a power source the device is off. Control panel LEDs are both off.
Standby	When power is applied to the device it completes the power-up LED sequence and then the green LED will flash as the device enters Standby Mode. Standby Mode is also initiated by pressing the power button when the device is in Therapy Mode or if the mask is removed while in Therapy Mode. As long as power is supplied to the device, it will remain in Standby Mode until Therapy Mode is initiated.
Therapy	When in Therapy Mode the blower is working and air pressure is being generated. The green LED light remains on. Therapy Mode is initiated by pressing the power button when the device is in Standby Mode and the mask is worn by the patient.
Calibration	Calibration of the BiPAP device, with attached breathing circuit, is initiated by pressing the bottom button on the control panel (below the logo). Solid yellow and green LED lights will show during calibration.

LED Light Indicators:

- Flashing Green – Standby Mode
- Solid Green – Therapy Mode
- Solid Green/Yellow – Calibration is in process
- Yellow Flashing – Mode Failure, call Somnetics customer support 855-420-7525
- Combination Flash Sequence – When power is applied to the BiPAP device

Starting Therapy

The Transcend 3 BiPAP control panel has two pushbuttons to activate the blower and calibrate the device with the respiratory circuit.



Before starting therapy, make sure the device has been properly cleaned since the last patient use. Follow instructions in the "Cleaning for Multiple Users" section.

1. Connect the Transcend 3 BiPAP to a power source and allow it to enter Standby Mode. Flashing green LED light will appear when the device enters Standby.
2. If a new respiratory circuit is used with the BiPAP, you must calibrate the device before use. See "Calibrating the Transcend 3 BiPAP" section for details on this process.

   Caution! The BiPAP must be calibrated with the respiratory circuit each time a new respiratory circuit is used with the BiPAP device to ensure accurate therapy.

   Warning! A new respiratory circuit, patient interface and BiPAP air inlet filter must be applied between patient uses.
3. Be sure the patient interface is properly fitted before initiating therapy. Ensure that the exhalation port is positioned to prevent obstruction.

   Warning! Only use a non-vented mask with anti-asphyxia valve.

   Warning! Make sure all components of the breathing circuit are securely attached. Any leak in the connections could result in the aerosolization of virus particles. It could also reduce the delivered air pressure to the patient.
4. To initiate air delivery, press the top Power button.

   Warning! There are no audible alarms on this device.

Warning! The Transcend 3 BiPAP is not supported by remote monitoring. Routine visual monitoring of the device and continuous monitoring of patient oxygen saturation level should be performed to ensure proper therapy is maintained.

Ending Air Delivery

To end air delivery, press the Power button to deactivate the blower and return the device to Standby Mode.

Ventilation modes

The Transcend 3 BiPAP provides pressure-controlled ventilatory support. The device uses flow to monitor the patient waveform and adjust for inspiratory and expiratory pressure therapy.

Mandatory Only	This is the mandatory oscillation mode. The BiPAP delivers air pressure based upon the set inspiratory/ expiratory ratio (I:E ratio) and the programmed breath rate (BPM).
Spontaneous Only	BiPAP only mode. Delivers IPAP/ EPAP pressure based upon the patient's breath waveform.
Mixed	(**Default mode**) BiPAP operates in "Spontaneous" mode until it cannot detect the patient's breath, then it automatically switches to a "Mandatory" mode. Once patient breath is detected again, it automatically switches back to "Spontaneous" mode.

Warning! The Transcend 3 BiPAP is not intended for life support and does not provide mechanical ventilation or flow-controlled ventilation.

Warning! There are no audible alarms on this device.

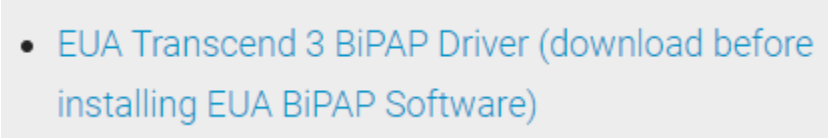
Warning! The Transcend 3 BiPAP is not supported by remote monitoring. Routine visual monitoring of the device and continuous monitoring of patient oxygen saturation level should be performed to ensure proper therapy is maintained.

NOTE: The Transcend 3 BiPAP does not save past system performance or patient data.

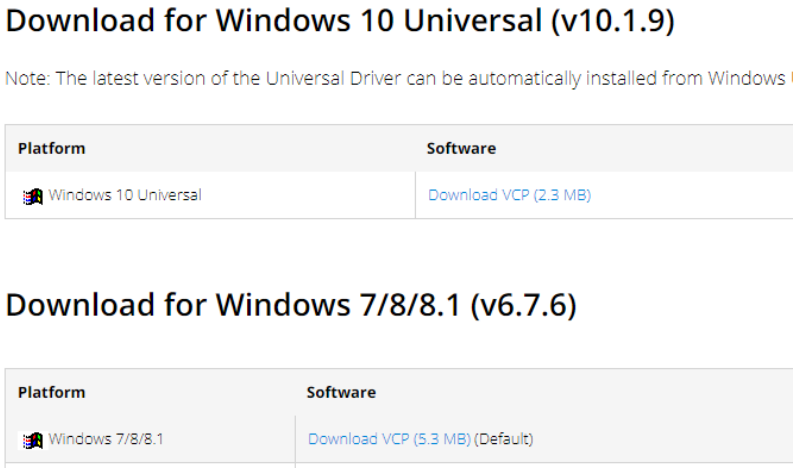
Transcend BiPAP Software Guide

Start by downloading the device software onto your computer using this link: **https://mytranscend.com/clinical-guides**.

1. Begin by downloading the BiPAP software driver,
   a. Click on the link for the BiPAP driver:

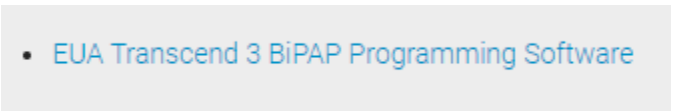
   

   b. This will take you to the VCP Driver download page. Choose the "Download VCP" link appropriate for your operating system.

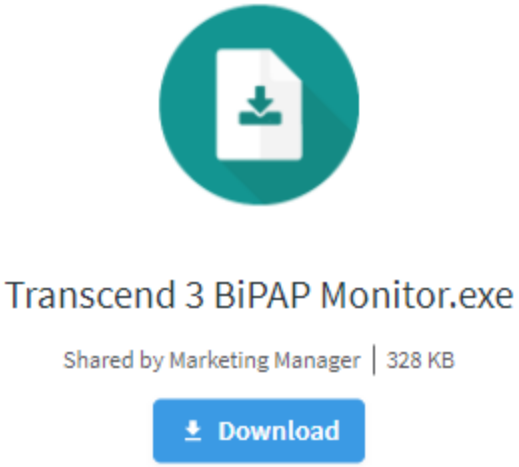
   

   c. This will download an archive (.zip) file containing the driver files. This file will be downloaded to the default download location for your browser (usually "Downloads").
   d. Browse to the download location and extract the archived file into a sub-folder. Note the location of the sub-folder.
   e. The first time you connect a Transcend BiPAP to the computer, the computer may prompt you for drivers. If it does, choose the "Browse my computer for driver software" option and supply the sub-folder noted in the previous step. Note: You may need Administrator privileges for this.

2. Next, download the Transcend 3 BiPAP Programming Software.
   a. Click on the link to download the software:

   b. This will take you to a download page. Select the "Download" button:



c. This will download the software program to the Downloads location used by your browser (usually "Downloads").
d. Browse to the downloads folder and locate the downloaded file, "Transcend 3 BiPAP Monitor.exe". Use the mouse to drag this file to your Desktop.

NOTE: The Transcend 3 BiPAP Programming Software is only compatible with Windows operating systems.

3. Look for the Transcend 3 BiPAP software icon on your desktop and click on it to open the program.

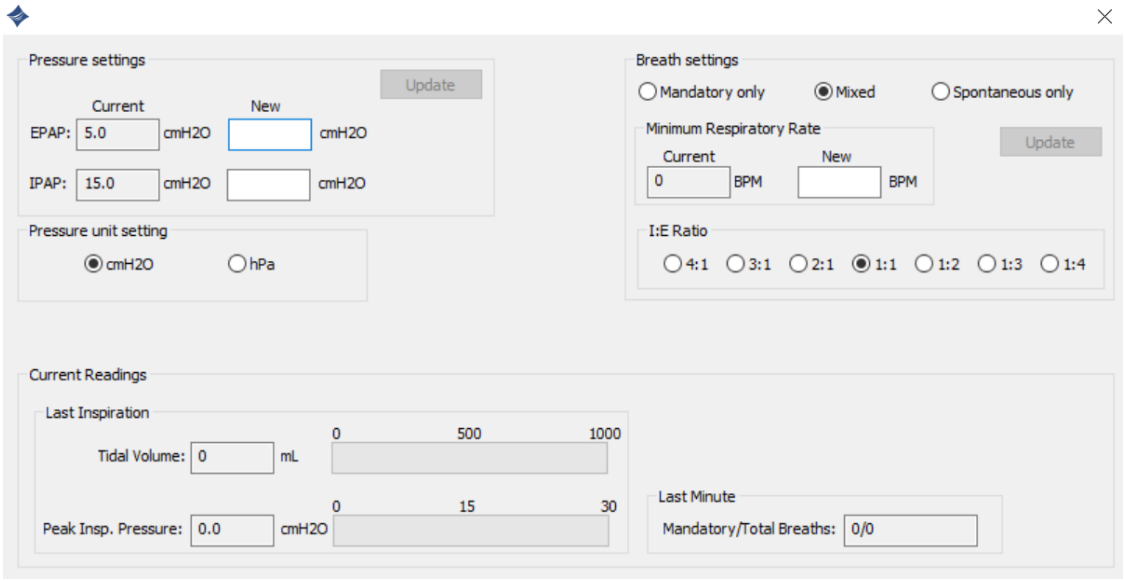
Note: The first time you run the software, you may get a warning message from Microsoft Defender. If this happens, click the "More Info" link in the message and then choose the "Run anyway" button.

BiPAP Settings Configuration

1. Connect your Transcend 3 BiPAP 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 of the USB cord goes into a USB portal on your computer.

NOTE: If you disconnect your BiPAP from a power source while in the software program, any unsaved settings will be lost.

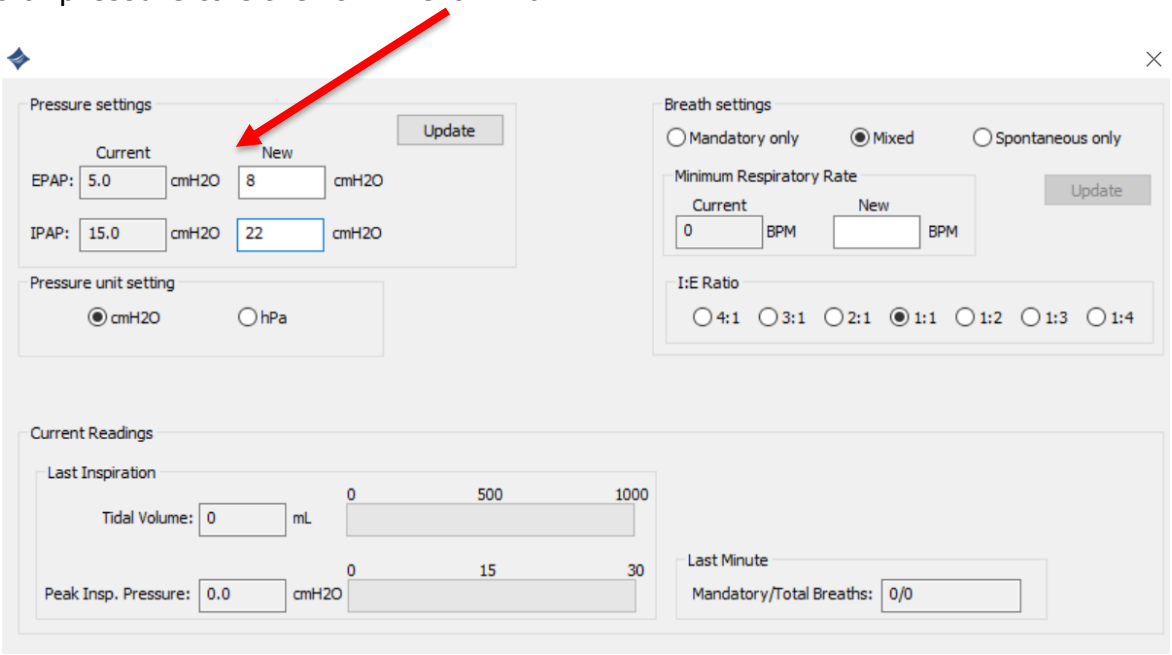
2. Open the Transcend 3 BiPAP Programming Software. You will see the following screen.



3. The BiPAP is programmed with **Default Settings** set to "Mixed" Mode, IPAP: 15 cmH2O, EPAP: 5 cmH2O, and minimum Respiratory Rate: 0.

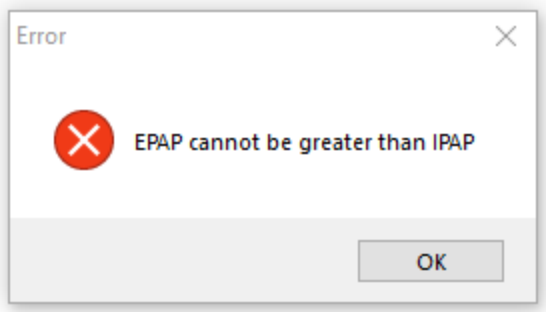
NOTE: IPAP is the delivered pressure to the patient during the inhalation phase and **EPAP** is the delivered pressure during the exhalation phase. These therapy pressures are delivered either in response to the detected patient breath waveform while the device is in the "**Spontaneous**" breathing mode, or they're delivered as defined by the **BPM** and **I:E Ratio** set for therapy in the "**Mandatory**" breathing mode. (The "**Mixed**" breathing mode automatically switches between both of these breathing modes depending upon whether the patient breath is detected or not.) **See the Ventilation Modes section of the manual for more details.**

4. The **Pressure Settings** can be changed by entering a value into the fields in the "New" column. System pressures are settable between 3-25 cmH2O, with a maximum difference of 15 cmH2O between the IPAP and EPAP settings. You may also adjust the units of pressure to either cmH2O or hPa.

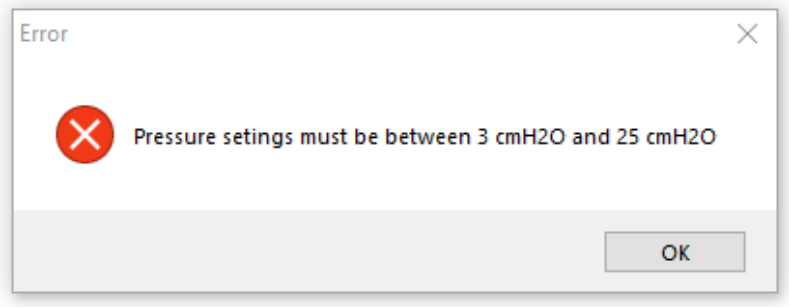


NOTE: The IPAP setting must be greater than the EPAP setting.

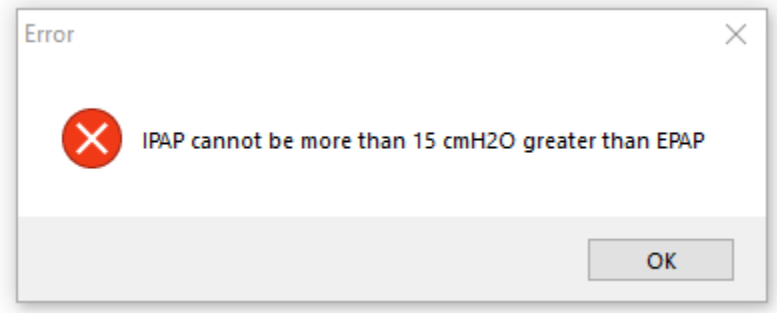
If the entered EPAP setting is greater than the IPAP setting, you will receive the following message. Click "OK" and correct the values for these settings to proceed.



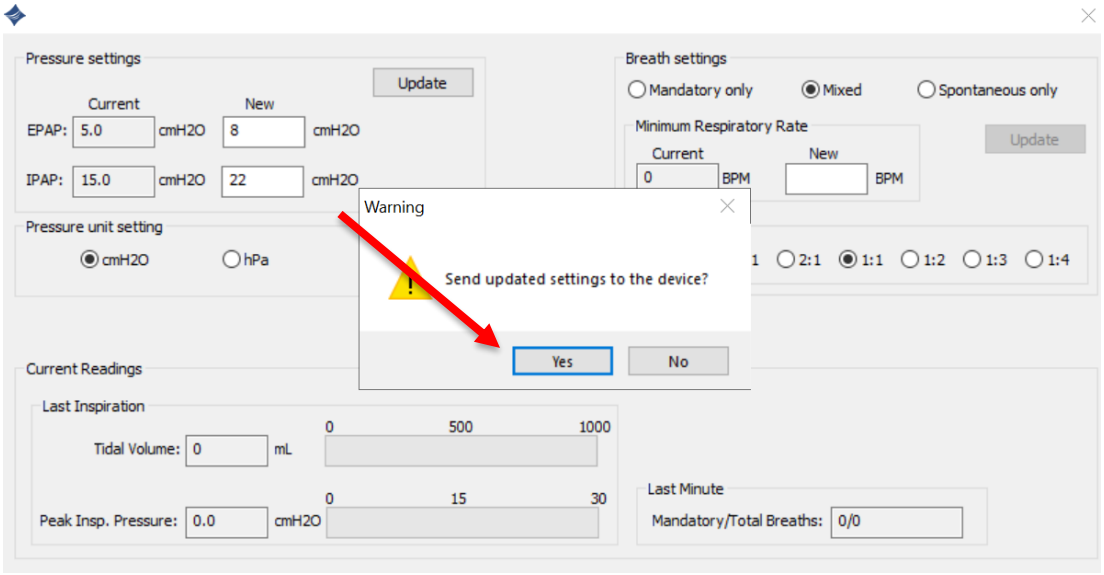
IF the EPAP or IPAP settings are outside of the valid range (3-25 cmH2O), you'll receive the following message. Click "OK" and correct the values for these settings to proceed.



If the difference between the EPAP and IPAP settings exceeds the allowable range (a maximum difference of 15 cmH2O), you'll receive the following message. Click "OK" and correct the values for these settings to proceed.



5. You must click the "Update" button to save any changes. If valid settings are entered, a pop-up window will display to confirm the change to the settings. Select "Yes" to save your new settings.



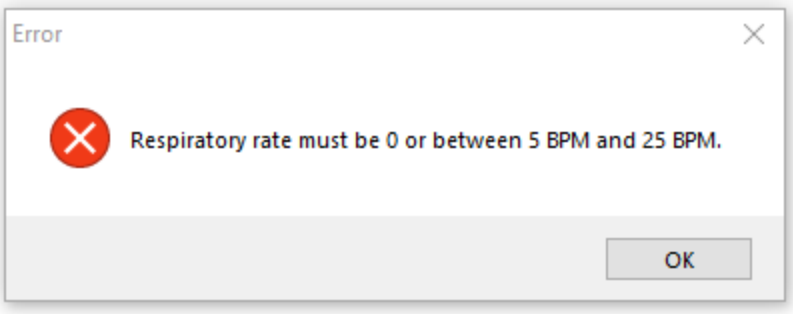
6. The saved settings will then appear in the gray fields under "Current."

7. Next, you can adjust the **Breath Settings**. These control the mode on which the BiPAP Operates:
   - **Mandatory Only**- This is the mandatory oscillation mode. In this mode, the BiPAP doesn't measure the patient's breath to deliver therapy, but instead delivers air pressure based upon the set inspiratory/expiratory ratio (I:E ratio) and the breath rate (BPM).
     NOTE: I:E ratio refers to the ratio of inspiratory time: expiratory time. In normal spontaneous breathing, the expiratory time is about twice as long as the inspiratory time (e.g. 1:2 I:E ratio). An inverse ratio refers to when the **I:E ratio** is 2:1 or higher and is typically used to ventilate non-compliant lungs.
     NOTE: The respiratory rate (BPM) must be set between 5-25 BPM.

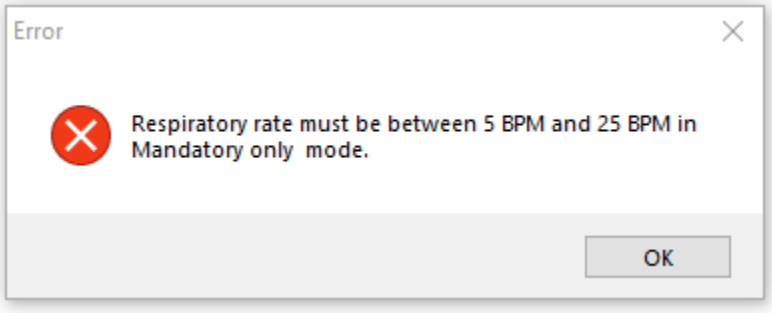
- **Spontaneous Only**- Delivers air pressure based upon the patient's breath. The devices delivers the set inspiratory pressure when patient inhalation is detected and changes to expiratory pressure when patient exhalation is detected.
- **Mixed**- (Default) BiPAP operates in "Spontaneous" mode until it cannot detect the patient's breath, in which case it will automatically switch to "Mandatory" mode. Once patient breath is detected again, it automatically switches back to "Spontaneous" mode.
  NOTE: The respiratory rate (BPM) may be set to 0 or between 5-25 BPM. If the BPM is set to 0, the device will deliver a continuous pressure.

8. Set the BiPAP to the appropriate **Breath Settings** mode, **Minimum Respiratory Rate** and **I:E Ratio**, then click the "Update" button to confirm your changes to these settings.

If an invalid **Respiratory Rate** is set for **Spontaneous Only** or **Mixed** breathing modes, you will receive the following message. Click "OK" and correct the values for these settings to proceed.



If an invalid **Respiratory Rate** is set for the **Mandatory Only** breathing mode, you will receive the following message. Click "OK" and correct the values for these settings to proceed.



Viewing Live Data with the Transcend 3 BiPAP Software

The "Current Readings" section of the software allows the user to view real-time data of the BiPAP therapy delivery. To utilize this function, the BiPAP must be in operation while connected to the computer via USB. Open the BiPAP Programming Software while the BiPAP is in operation to view the Tidal Volume and Peak Inspiratory Pressure.

NOTE: Unintentional leaks in the air circuit can affect tidal volume measurement accuracy.

The "Last Minute" readout displays the total number of breaths detected in the last minute and how many of those breaths were delivered by the mandatory breath setting (mandatory breaths/ total breaths).

Warning! There are no audible alarms on this device.

Warning! The Transcend 3 BiPAP is not supported by remote monitoring. Routine visual monitoring of the device and continuous monitoring of patient oxygen saturation level should be performed to ensure proper therapy is maintained.

Powering the Transcend 3 BiPAP

You may use the following approved accessories to power the Transcend 3 BiPAP device:

- Multi-Plug Universal Power Supply (PSA2)
- Optional Transcend P8 Battery

NOTE: It is recommended that the P8 Battery accessory is only used in-line with the AC power supply as a backup power source.

1. Insert the barrel connector of power supply into power jack on the back of the Transcend 3 BiPAP device.
2. Insert the other end of the power supply into an AC line power outlet.
3. The Transcend 3 BiPAP power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the green LED light will blink to indicate the BiPAP is in Standby Mode.

NOTE: Use only the Somnetics-supplied power supplies. Do not use a power converter or voltage transformer with the PSA2 Universal Power Supply.

NOTE: Make certain that the plug attachment is fully secured to the Power Supply before inserting the power supply into the wall outlet.

Using the Transcend P8 Battery

Using the Transcend P_8 Battery in-line with the AC Power Supply

The Transcend P_8 Battery is an optional power source for Transcend 3 BiPAP.

1. Insert the barrel connector from the Universal AC Power Supply into the battery.
2. Insert the barrel connector of the battery into the Transcend 3 BiPAP power jack so that the plug and cord face upward.
3. Plug the Universal AC Power Supply plug into AC line power.
4. The Transcend 3 BiPAP power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the green LED light will flash to indicate the BiPAP has entered Standby Mode.

NOTE: It is recommended that the P8 Battery accessory is only used in-line with the AC power supply as a backup power source. Connecting the battery in-line with the AC power supply allows the battery to charge during therapy and provides backup power to provide uninterrupted therapy in the case of a power outage.

NOTE: If using the P8 Battery is the sole power source, be sure to fully charge the battery before the first use. Follow the battery charging instructions provided in this User Manual. Do not connect the battery to the Transcend 3 BiPAP during initial charge.

Explanation of the Transcend P_8 Battery LED lights

- Red LED light: A steady red light signifies a fault with the battery. Do not use or charge the battery when the red LED light is showing. Contact the distributor that provided the battery to you for a replacement.
- Yellow LED light: Indicates the battery is charging.
- Green LED light: Indicates the battery is fully charged.

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

NOTE: The battery will show a yellow or green LED light when it is used in-line with the Universal AC Power Supply indicating the battery charge level.

NOTE: The battery will show no LED light when it is used as the sole power source to power the Transcend 3 BiPAP.

Charging the Transcend P_8 Battery

- Connect the power outlet barrel connector from the AC Power Supply to the power connection jack on the P_8 Battery.
- Connect the AC Power Supply to a power source.
- A full battery charge is indicated when the LED light on the Battery turns from yellow to green.
- It may take up to eight hours to charge the P8 battery.

  NOTE: Battery life may vary based on device settings, leak, patient breath pattern, environmental conditions, or battery age.
  NOTE: Charge the battery fully before the first use. Do not connect the Battery to Transcend 3 BiPAP during the initial charge.
  NOTE: To maintain maximum battery performance Somnetics recommends using the Battery in-line with the AC Power Supply during use, even if the battery is fully charged.

Caring for your Transcend 3 BiPAP and its Components

This section presents the following topics:

- **Cleaning for Multiple Users**

Warning!

- Unplug the Transcend 3 BiPAP before cleaning.
- Do not submerge the Transcend 3 BiPAP or power supply in liquid.
- Prevent water from entering any openings of the device.
- Do not use abrasive cleaning agents to clean the device.
- Do not attempt to sterilize the Transcend 3 BiPAP.
- Do not place cleaning materials, such as a cloth or liquid, into the device air inlet or air outlet connector.

Cleaning for Multiple Users

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

1. Unplug the power supply prior to cleaning.
2. Remove and discard the entire breathing circuit (air supply tube, flow restrictor valve, bacterial/viral filters, the Y-connector and the patient interface) in accordance with biohazard disposal procedures.
3. Wipe the entire exterior of the device with a cleaning agent that has at least 70% alcohol concentration.
4. Remove the air inlet filter assembly by pulling the tab on the back of the device to release it. Then discard air inlet filter assembly and replace with a new filter assembly.

Warning! Apply a new respiratory circuit and patient interface before the next patient use.

Warning! The respiratory circuit components and bacterial/viral filters should be discarded after each patient use using standard institutional biohazard procedures. Failure to do so could result in cross contamination. No attempt should be made to clean, disinfect, or sterilize these components for multiple users. These components are for single patient use only.

Warning! Only use bacterial/viral filters that are commercially available and designed for use with CPAP machines. Follow the manufacturer's instructions for use of the filter.

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

Environmental Information

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

Fault codes

Fault codes

When the Transcend 3 BiPAP encounters a fault the processor resets and enters a fault loop. In this loop, the device repeatedly flashes the yellow fault LED to indicate the specific fault encountered. If the device is reset or power cycled while in fault mode, it re-enters fault mode upon power up. To exit fault mode, the fault must be acknowledged by holding the power button down until the fault LED stops flashing. At this point, when the power button is released, the processor resets and the device powers up in standby mode.

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

Device LED	Fault LED	Error	Comments
Off	Flashes 2 times	Stack overflow	Internal software fault.
Off	Flashes 3 times*	Pressure too high	While delivering therapy, the pressure sensor measured a pressure greater than 30 cmH2O. This could be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 4 times*	No Pressure	While delivering therapy, the pressure sensor measured approximately 0 cmH2O. This could be due to an open output hose. This could also be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 6 times	Attempt to set invalid time	An attempt was made to set the device real time clock (RTC) to an invalid value. The device RTC is configured as part of the manufacturing process, thus this error should only occur then.

Device LED	Fault LED	Error	Comments
Off	Flashes 7 times*	Pressure sensor out of range	While in standby, the pressure sensor reads a value outside its expected range. This could be due to a "pinched" or blocked pressure sense tube or fluctuation in ambient temperature This could also be due to faulty pressure sensor or electronics.
Off	Flashes 9 times	Bad firmware checksum	At power up, the device calculates a checksum of the firmware code and compares it against the checksum it calculated when it was initially programmed. This error indicates some part of the firmware has been corrupted. Likely causes would be electrostatic discharge or hardware problem.
Off	Flashes 11 times	Stalled blower	While delivering therapy, the device failed to detect any blower motion for 2 seconds. This is likely due to a faulty blower motor, loose blower connector or faulty electronics.
Off	Flashes 12 times	Low power	While delivering therapy, the device determined that the blower was stalled (see above). However, a check of the voltage indicates there may not be sufficient power to spin the blower. This is likely due to a faulty power supply or battery.
Off	Flashes 13 times*	Processor over-temp	The processor on-chip temperature sensor has reported an excessive temperature.
Off	Flashes 14 times*	Blower over-temp	The blower thermistor has reported an excessive temperature.
* If this fault occurs, check all tubes and hoses to ensure that they are properly connected. If the fault occurred during therapy, make sure the mask is properly fitted and not leaking. Check that all filters are properly installed and not excessively dirty.			

Troubleshooting

Problem	Probable Cause	Solution
Nose or throat irritation.	Dry air.	Add humidity to the room.
	Dirty air inlet filter.	Change the Air Inlet Filter Assembly.
Device control panel LEDs don't illuminate when power supply is connected the device.	Power source is not properly connected.	Check all power connections.
	AC power may not be active.	Use another power outlet. Confirm outlet is not controlled by a wall switch.
No airflow from the device.	Device motor failure; or, electronics failure.	Contact the distributor's technical service department.

Yellow fault LED flashes general fault warning sequence	Device detects an operating error.	Note the number of times the yellow fault LED flashes before the flash sequence repeats. Refer to **Fault and alert codes** for possible correction. If error indication continues after taking corrective action by holding down the power button until the yellow fault led stops flashing, contact your distributor's technical service department.
Device shuts down during air delivery	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 distributor's technical service department.

Appendix: Part numbers

This section presents three topics:

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

Disposable parts

Item	Part number		Item	Part number
Transcend 3 Air Inlet Filter Assembly	503109		Transcend 3 BiPAP Respiratory Circuit	500221
Viral/ Bacterial Filter (50 Pack)	6216			

Accessories

Item	Part number	
Transcend P_8 Battery	503023	
Changeable Plug Pack	503060	

Replacement parts

Item	Part number		Item	Part number
Transcend 3 BiPAP	500220		Transcend Travel Bag	503012

Item	Part number		Item	Part number
Multi-plug Universal Power Supply Set (Contains 503059 & 503060)	503078		Multi-plug Universal Power Supply (PSA2)	503059
			USB cable	503020

Appendix: Specifications

This section presents the following topics:

Transcend 3 BiPAP

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

AC power supply - PSA2

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

Batteries (optional)

Transcend P_8 Battery	14.4 VDC, 5,200 mAH

Transcend 3 BiPAP Performance

Inspiratory Pressure (IPAP) Range	3-25 cm H_2O
Expiratory Pressure (EPAP) Range	3-24 cm H_2O (EPAP pressure must be 1-15 cmH2O lower than IPAP setting)
Calibration Pressure Accuracy	±5% of pressure target
Accuracy of pressure setting:	±1 cm H_2O or ±10%, whichever is greater
Maximum system shutdown pressure:	30 cm H_2O
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

The Transcend 3 BiPAP is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF radiated emissions CISPR 11	Group 1	The Transcend 3 BiPAP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF conducted emissions CISPR 11	Class B	The Transcend 3 BiPAP is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The Transcend 3 BiPAP is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2, 4, 6 kV contact ±8 kV air	N/A. The Transcend Auto does not have conductive surfaces. ±2, 4, 6, 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Line power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±0.5*, 1 kV differential mode ±2 kV common mode	Line power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	Line power quality should be that of a typical commercial or hospital environment. If the user of the Transcend Auto requires continued operation during power line interruptions, it is recommended that the Transcend Auto be powered from the battery. NOTE: U_T is the A.C. line voltage before application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 KHz to 80 MHz	Recommended separation distance: d = $1.17\sqrt{P}$

The Transcend 3 BiPAP is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (compliance level adjusted to meet FDA limits) 80 MHz to 2.5 GHz NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.	Recommended separation distance: d = $0.35\sqrt{P}$ 80 MHz to 800MHz Recommended separation distance: d = $0.70\sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

IEC 60601-1 Compliance

Protection against electric shock:	Class II Type BF
Degree of protection against ingress of water:	IP22. Protected against ingress of solid foreign objects greater than or equal to 12.5 mm in diameter. Vertically falling drops shall have no harmful effects.
Use of flammable gasses:	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.

Performance

Pressure

Testing in accordance with ISO 80601-2-70:2015 and ISO 80601-2-80:2018 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. Dynamic ventilation determined according to noise test instruction given in ISO 80601-2-80:2018, using the basic standards ISO 3744 and ISO 4871.

Sound power level (@ 10cm H_2O pressure, static)	38.4 dB
Sound pressure level (@ 10cm H_2O pressure, static)	30.4 dB
Sound pressure level (@ 10cm H_2O pressure, static)*	26.2 dB
Working pressure range:	3 to 25 cm H_2O
Pressure limit:	30 cm H_2O

*Sound pressure level reported in a typical use environment

Maximum flow rate (typical)		Test Pressures				
		4 cm H_2O	8 cm H_2O	12 cm H_2O	16 cm H_2O	20 cm H_2O
	Measured pressure at the patient connection port (hPa)	3.51	7.53	11.51	15.45	19.53
	Average flow at the patient connection port (l/min)	82.8	94.7	95.5	99.4	102.0

Appendix: Limited Warranty

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

Product	Warranty Period*
Transcend 3 BiPAP	Available only during FDA EUA
Transcend P8 Batteries	9 months

*From date of user purchase.

If the product fails to perform in accordance with the product specifications, Somnetics will replace, at its option, any materials or parts of the product, that are stated to be defective. Customer will receive a new product replacement. 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 replacement, the proof of purchase, including proof of the date of purchase, is required. To exercise your rights under this warranty, contact your local, authorized Somnetics dealer or Somnetics at 103 Osborne Road NE, Fridley, Minnesota 55432 USA, 1.855.420.7525 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: 855.420.7525

Fax: 651.204.0064

Transcend 3 BiPAP User Manual

104052 Rev B 2020-08