TRANSCEND®

Sleep Apnea Therapy SYSTEM

EZEX™ User Manual

Notices

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About this user manual

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.

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Introduction

The Transcend EZEX™ provides positive airway pressure to users in the range of 4 to 20 cmH_2O as prescribed by the clinician. Buttons and LED lights facilitate control and provide operational feedback. A DC power jack and a USB port are also incorporated into the Transcend EZEX.

Indications for use

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

Contraindications

The Transcend EZEX is contraindicated in patients with the following conditions:

- Bullous lung disease
- Pathologically low blood pressure
- Pneumothorax or pneumomediastinum.
- Pneumocephalus has been reported in some users using nasal PAP.

Caution should be used when prescribing PAP for susceptible users such as those with any of these conditions:

- Cerebral spinal fluid (CSF) leaks
- Abnormalities of the cribriform plate
- A prior history of head trauma
- Pneumocephalus

Precautions for use

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

Warning	Indicates the possibility of serious injury or death to yourself or others.
Caution	Indicates the possibility of minor injury or damage to the equipment.

Note Indicates a tip, explanation or feature to aid in understanding, or efficient operation of the device.

Warnings

- Do not allow water to enter this device. Transcend EZEX should not be exposed to environmental conditions where the system may get wet.
- This device is not intended for life support.
- The Transcend EZEX must be set up and adjusted by a trained provider before being used for therapy ramp and pressure.
- The air temperature produced by this device can be as much as 10ºF higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90ºF (32ºC).
- Do not block or otherwise obstruct the exhalation ports of the interface. Follow the manufacturer's instructions included with your interface.
- This equipment is not suitable for use with oxygen or in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.
- The Transcend EZEX 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 EZEX is not defibrillation proof.
- Do not attempt to sterilize Transcend EZEX.
- If the device is to be used by multiple patients a main flow bacteria filter should be installed in-line between the device and the breathing circuit tubing to prevent contamination.
- The device should be used only with masks and connectors recommended by Somnetics or a health care professional. A mask should not be used unless the device is turned on and is properly delivering ramp or therapy pressure. The exhalation port(s) associated with the mask should never be blocked. Explanation of the Warning: The device is intended to be used with masks or connectors specifically designed to have exhalation ports to allow continuous flow of air out of the mask. When the device is turned on and functioning properly air flow from the device flushes the exhaled air out through the mask exhalation port. When the device is not operating, however, fresh air will not be provided through the mask and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

Cautions

- Federal law (United States) restricts this device to sale by, or on the order of, a physician.
- Power the Transcend EZEX only with the Somnetics-supplied power supplies, mobile power adaptor, or batteries. See **Appendix: Part Numbers**.
- Discontinue use of the Transcend EZEX and contact your physician if respiratory or skin irritations occur.
- Do not introduce objects into the Transcend EZEX air inlet or air outlet.
- Inspect the power supplu for signs of wear or damage before each use. Replace the power cord if necessary.
- Somnetics recommends replacing the air delivery tubing (hose) after every three months of use.
- To protect the environment, some parts and accessories of the Transcend EZEX, including optional batteries, must be disposed of in accordance with local regulations.

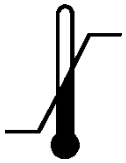
Symbols

Attention: Consult accompanying documents

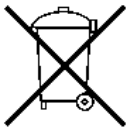
Type BF Applied Part

ETL Classified

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



Upper and lower temperature limits



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

Consult instructions for use

Non-Condensing

Upper and lower humidity limits

Rx Only

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

Precedes reference or item number

Components of the Transcend EZEX

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

- Transcend EZEX
- Standard 6-foot hose (Note: not compatible with optional H_6B or H_9M Waterless Humidification Systems)
- Universal hose adaptor
- Multi-plug universal power supply (PSA2)
- Changeable plug pack
- Transcend Travel bag
- Software CD
- User information CD
- Transcend EZEX Quick Guide
- USB Cable

What's not included (all sold separately)

- H_6B Waterless Humidification System
- H_9M Waterless Humidification System
- Nasal seal (mask cushion for use with H_6B or H_9M Waterless Humidification Systems)
- Transcend Heated Humidifier
- Transcend Mobile Power Adaptor
- Transcend P_4 Battery
- Transcend P_8 Battery
- Battery pouch and chest or arm strap system
- Transcend Base Station
- Transcend LCD Programming Base Station
- Transcend Portable Solar Battery Charger (to be used as an alternative charging source for Transcend P_4 and P_8 batteries)

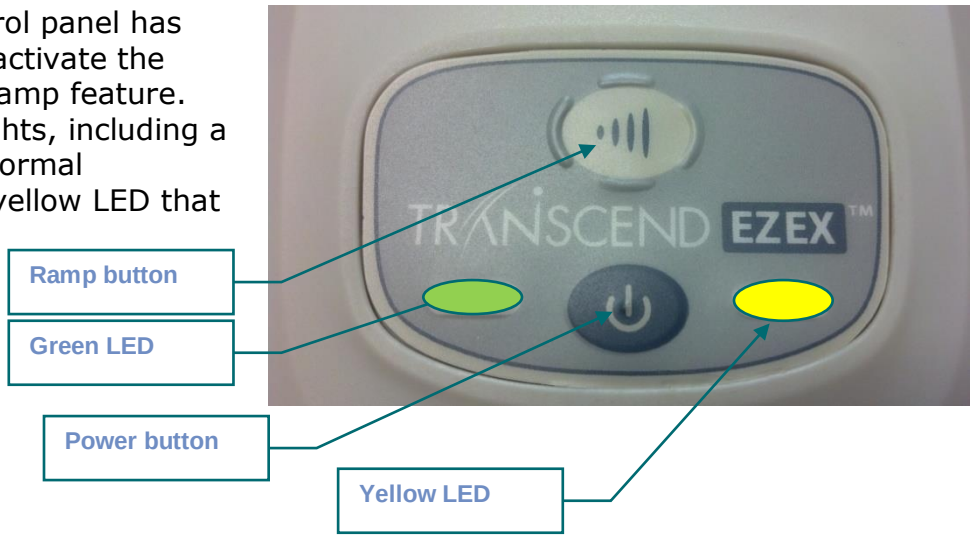
Description of Transcend EZEX components

Transcend EZEX Device

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

Control panel

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



Power connection jack and USB port

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

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

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

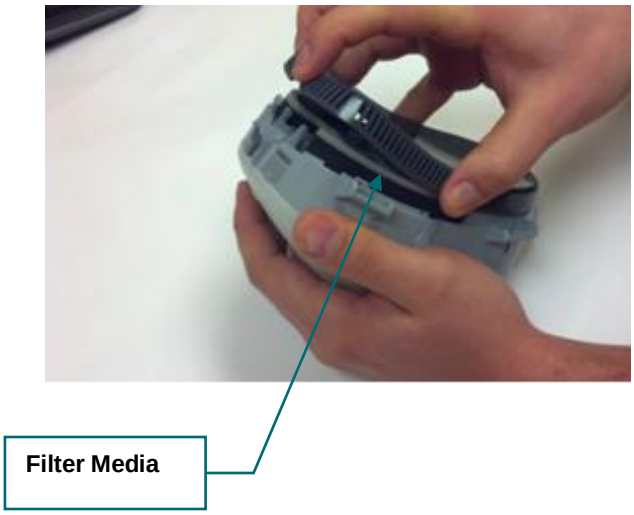
Optional Transcend battery packs are also available to power the Transcend EZEX.

USB port

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

Air Inlet Filter

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

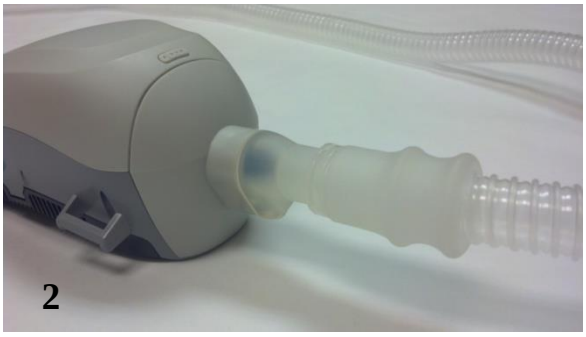


Assembling the Transcend EZEX

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

Follow these steps to assemble the Transcend EZEX System:

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



Powering the Transcend EZEX

There are three choices for powering your Transcend EZEX device:

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

Using the Multi-plug Universal Power Supply (PSA2)

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

1. Determine which plug is required to power the device based upon the outlet style.
2. If the correct plug is not already attached to the Power Supply remove the attached plug by depressing the button on the detachable plug and turning the plug in a counterclockwise motion until it releases from the power supply.
3. Attach the desired plug by lining up the protruding tabs on the back of the plugwith the gaps on the Power Supply and gently pushing the plug into the slot. Turn the plug clockwise until it clicks into place. You should hear an audible click.
4. Insert the barrel connector of power supply into power jack on the back of the Transcend EZEX device.
5. Insert the other end of the power supply into an AC line power outlet.
6. The Transcend EZEX power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend EZEX and that it has successfully entered Standby Mode.

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

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

Using the Transcend P_4 or P_8 Battery

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

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

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

Using the Transcend P_4 or P_8 Battery in conjunction with AC line power

1. Insert the barrel connector from the Universal AC Power Supply into the battery.
2. Insert the barrel connector of the battery into the Transcend EZEX 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 EZEX power-up LED flash sequence should initiate. Once the power-up LED flash sequence is complete the LED lights will turn off. This sequence indicates that power is being supplied to the Transcend EZEX and that it has successfully entered Standby Mode.

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

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

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

Explanation of the optional Transcend P_4 and P_8 Battery LED lights

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

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

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

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

Charging the Transcend P_4 or P_8 Battery

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

Average Battery Life for P4 Battery (hours)

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

Average Battery Life for P8 Battery (hours)

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

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

Note To maintain maximum battery performance Somnetics recommends using the Battery in-line with the AC Power Supply or Mobile Power Adaptor during therapy even if the battery is fully charged.

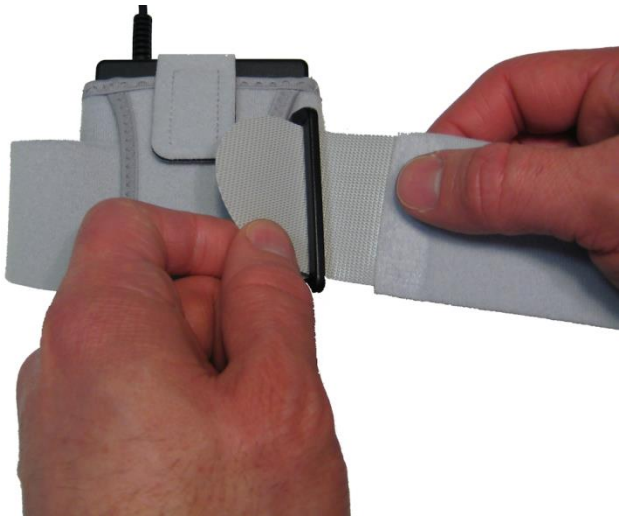
- Connect the power outlet barrel connector from the Universal Power Supply or Mobile Power Adaptor to the power connection jack on the P_4 or P_8 Battery.
- Connect the Universal Power Supply or Mobile Power Adaptor to a power source.
- A full battery charge is indicated when the LED light on the Battery turns from yellow to green.
- It may take up to five (5) hours to charge the P4 battery and up to eight (8) hours to charge the P8 battery.

Using the optional chest or arm strap with a Transcend P_4 or P_8 Battery

Slide battery into the battery pouch and attach the Velcro strap to secure.

Insert the buckle through the loop of the battery pouch with the Velcro facing towards the battery pouch.

With the pouch loop facing outward, wrap the strap around the chest or arm and thread the end of the strap through the buckle.



Continue to pull the strap through the buckle and secure the Velcro to the strap. Place pouch on arm and adjust strap as needed for a comfortable fit.

Using the Transcend Mobile Power Adaptor (MPA1)

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

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

1. Connect both cables to the base of the Mobile Power Adaptor.
2. Insert the barrel connector of the MPA1 output cable to the power jack of the Transcend EZEX.
3. Insert the plug connector into the mobile power receptacle (e.g. cigarette lighter outlet).

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

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

Using the Transcend EZEX

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

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

Note If the Transcend EZEX loses power while delivering therapy it will resume delivering therapy as soon as power is restored and you press the power button. The device will repeat the power-up LED flash sequence prior to the blower restarting.

Standard user modes

Normal operation consists of four modes:

Off — When the device is not connected to a power source the device is off. Control panel LEDs are both off.

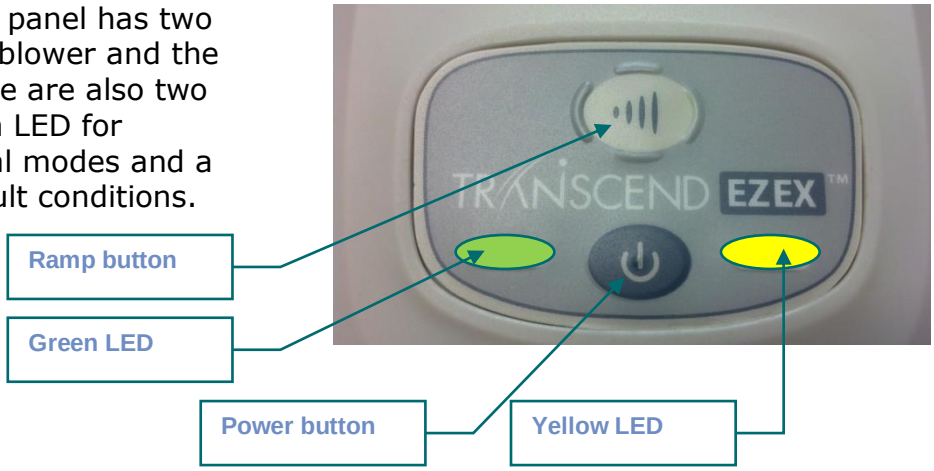
Standby — When power is applied to the device it completes the power-up LED sequence and enters Standby Mode. Standby Mode is also initiated by pressing the power button when the device is in On Mode or if the mask is removed while in On Mode. As long as power is supplied to the device it will remain in Standby Mode until On or Drying Mode is initiated.

On — When in On Mode the blower is working and regulated device therapy pressure is being generated. The LED lights remain off. On Mode is initiated by pressing the power button when the device is in Standby Mode and the mask is worn by the patient.

Drying — To initiate Drying Mode depress the Ramp button and press the Power button simultaneously. When in Drying Mode the blower runs at a low speed for 30 minutes. During Drying Mode the LED lights remain off and blower pressure is not regulated to provide therapy.

Starting therapy

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



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

Using the ramp function

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

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

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

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

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

Using the EZEX function

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

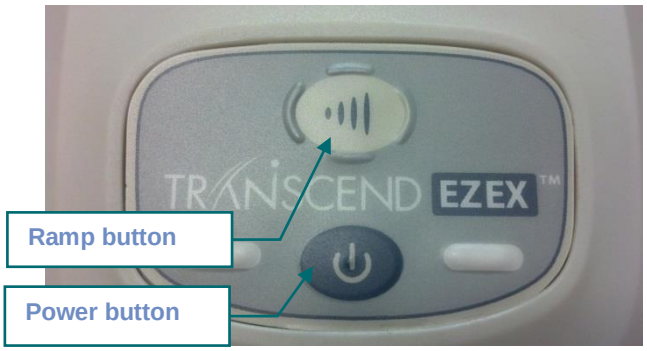
There are four EZEX settings: OFF, 1, 2 or 3; progressively increasing the amount of pressure relief from none to maximum.

Ending therapy

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

Drying mode

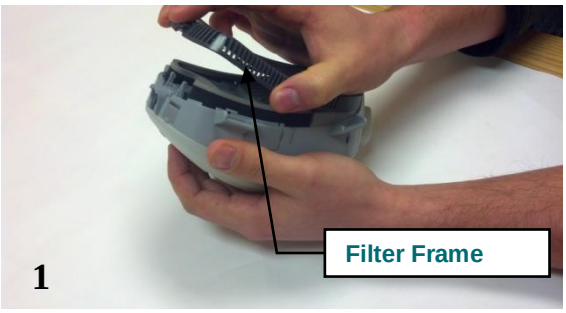
At the end of each therapy session it is recommended the user initiates the Drying Mode. To initiate Drying Mode depress the Ramp button and press the Power button simultaneously. When in Drying Mode the blower runs at a low speed for 30 minutes. During Drying Mode the LED lights remain off and blower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

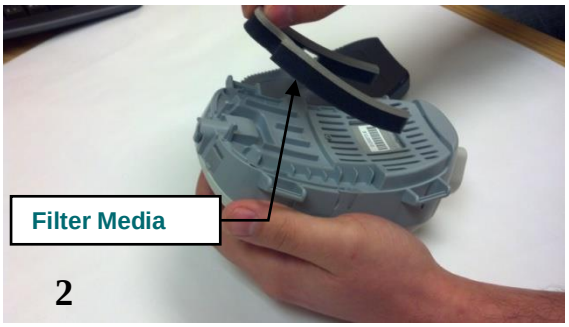


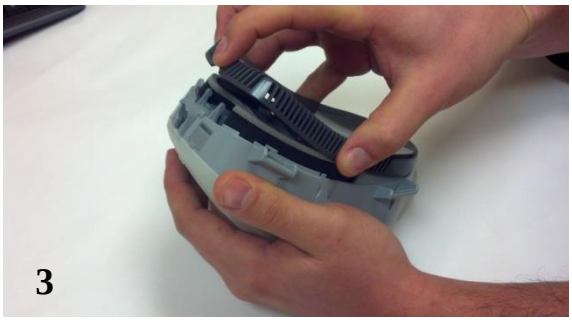
Replacing the Filter Media

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

1. Remove the Filter Frame by gently pressing the button release at the back of the Filter Frame towards the front of the device. Then pull the filter frame away from the device.
2. To replace the Filter Media remove the used filter and discard. Lay a new Filter in the channel on the base of the Transcend EZEX device.
3. Reconnect the Filter Frame to the device by placing the front clip into place first. Once the front clip is in place snap the back clip into place. Make sure the Filter Frame is completely connected before use.







Caring for your Transcend EZEX and components

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

- **Cleaning the exterior**
- **Cleaning of accessories**
- **Cleaning the filter media and filter frame**
- **Cleaning for multiple users**

Warning:

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

Cleaning the Exterior

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

1. Unplug the power supply prior to cleaning and disconnect the device from power cords.
2. Mix a solution of 5% mild liquid detergent in distilled water (1.6 fl oz liquid detergent per quart of distilled water). Mild detergent should contain biodegradable anionic surfactants and no phosphate.
3. Submerge a lint-free cotton cloth into the detergent solution.
4. Wring excess water from the cloth then wipe the exterior of the Transcend EZEX device for approximately 20 seconds using a gentle, back and forth wiping motion from the front to back of the device. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.
5. Rinse the cloth in clear water to remove residual cleaning solution.
6. Wring excess water from the cloth then wipe the Transcend EZEX using a gentle front to back wiping motion to remove any detergent solution remaining on its surface.
7. Wipe the device with a dry, lint-free cotton cloth until the device is fully dry.

Cleaning of Accessories

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

Accessory	Periodic Cleaning Cycle	Product Lifetime
Transcend Base Station	2x/Month	2-Year

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

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

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

Accessory	Periodic Cleaning Cycle	Product Lifetime
Headgear – H_6B and H_9M Systems	1x/Week	6-Month
Forehead Pad	1x/Week	6-Month
CPAP Unit Base Pad	1x/Week	6-Month
Mask Shell Assembly	1x/Week	3-Month
Universal Hose Adapter	Daily	3-Month
Air Supply Tube	Daily	3-Month

1. Fully immerse the accessory in the cleaning solution.
2. While immersed, thoroughly wipe the surface with a lint-free cotton cloth. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.

3. Clean the inside of the air supply tube by lifting, then lowering the ends of the tube while the tube is filled with cleaning solution.
4. Rinse accessories by immersing in distilled water. Move the accessory in a back and forth motion for approximately10 seconds to remove cleaning agent residue.
5. Rinse the air supply tube in distilled water by fully immersing. Lift, then lower, the ends of the tube while the tube is filled with water. Repeat this motion for approximately 10 seconds to remove cleaning agent residue.
6. Dry the accessory by wiping with dry, lint-free cotton cloth. Allow the accessory to air dry as needed.
7. Dry the outside of the air delivery tube with a dry, lint-free cotton cloth. Allow the tube to air dry until the inside of the tube is dry. Length of drying time will depend on ambient conditions.

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

Cleaning the Filter Media and Filter Frame

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

1. Begin by removing the Filter Media and Filter Frame from the device (see **Replacing the Filter Media** for instructions on filter removal and replacement).
2. Mix a solution of 5% mild liquid detergent in distilled water (1.6 fl oz liquid detergent per quart of distilled water). Mild detergent should contain biodegradable anionic surfactants and no phosphate.
3. Fully immerse the **Filter Frame** in the detergent solution.
4. While immersed, thoroughly wipe each surface of the Filter Frame with a lint-free cotton cloth. Apply firm pressure and ensure contact with all accessible contact surfaces to adequately remove soil buildup.
5. Rinse the Filter Frame by immersing in distilled water and gently moving it forwards and backwards for approximately 10 seconds.
6. Use a clean, dry, lint-free cotton cloth to dry all surfaces of the Filter Frame.
7. To clean the **Filter Media**, first submerge a lint-free cotton cloth into the cleaning solution.
8. Wipe the Filter Media with cloth to remove any visible residue. Wipe all surfaces for a minimum of 10 seconds.
9. Rinse the cotton cloth in distilled water to remove residual cleaning solution.

10. Wring excess water from the cloth then wipe all surfaces of the Filter Media to remove any cleaning solution remaining on its surface.
11. Dry surfaces by wiping with a dry, lint-free cotton cloth.
12. Allow the Filter Media to air dry at room temperature for approximately 30-60 minutes before reassembly. Drying time will depend on ambient conditions.
13. Reconnect the Filter Media and filter frame to the Transcend EZEX.

Cleaning for Multiple Users

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

1. Unplug the power supply prior to cleaning.
2. Remove and discard the bacterial/viral filter.
3. Remove and discard the used air supply tube.
4. Follow instructions for cleaning the exterior of the device as noted in Cleaning the Exterior (above).
5. Apply a new bacterial/viral filter to the Universal Hose Adaptor of the Transcend EZEX and attach a new air supply tube before providing the device to a new user.

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

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

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

Faultand alert codes

Fault codes

When the Transcend EZEX 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.

Device LED	Fault LED	Error	Comments
Off	Flashes 2 times	Stack overflow	Internal software fault.
Off	Flashes 3 times*	Pressure too high	While delivering therapy, the pressure sensor measured a pressure greater than 30 cmH2O. This could be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 4 times*	No Pressure	While delivering therapy, the pressure sensor measured approximately 0 cmH2O. This could be due to an open output hose. This could also be due to a "pinched" or disconnected pressure sense tube. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 6 times	Attempt to set invalid time	An attempt was made to set the device real time clock (RTC) to an invalid value. The device RTC is configured as part of the manufacturing process, thus this error should only occur then.
Off	Flashes 7 times*	Pressure sensor out of range	While in standby, the pressure sensor reads a value outside its expected range. This could be due to a "pinched" or blocked pressure sense tube or fluctuation in ambient temperature. This could also be due to faulty pressure sensor or electronics.
Off	Flashes 9 times	Bad firmware checksum	At power up, the device calculates a checksum of the firmware code and compares it against the checksum it calculated when it was initially programmed. This error indicates some part of the firmware has been corrupted. Likely causes would be electrostatic discharge or hardware problem.
Off	Flashes 11 times	Stalled blower	While delivering therapy, the device failed to detect any blower motion for 2 seconds. This is likely due to a faulty blower motor, loose blower connector or faulty electronics.
Off	Flashes 12 times	Low power	While delivering therapy, the device determined that the blower was stalled (see above). However, a check of the voltage indicates there may not be sufficient power to spin the blower. This is likely due to a faulty power supply or battery.
Off	Flashes 13 times*	Processor over-temp	The processor on-chip temperature sensor has reported an excessive temperature.
Off	Flashes 14 times*	Blower over-temp	The blower thermistor has reported an excessive temperature.
* If this fault occurs, check all tubes and hoses to ensure that they are properly connected. If the fault occurred during therapy, make sure the mask is properly fitted and not leaking. Check that all filters are properly installed and not excessively dirty.			

Alert codes

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

Device LED	Fault LED	Error	Comments
Off	Flashes 15 times	Cannot regulate	Device repeatedly detected the monitored pressure outside of the therapy target range. The device attempts to continue to deliver therapy. The alert is an indication that filters and the mask should be inspected for cleanliness and proper fit.

Troubleshooting

Problem	Probable Cause	Solution
Discomfort due to a feeling of high pressure.	Transcend EZEX 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. If you are using the Transcend Heated Humidifier, increase the setting. If you are using the H6B or H9M waterless humidification system, replace the HME.
	Dirty air filter.	Change and/or clean the Filter Media.
Transcend EZEX control panel LEDs don't flash or illuminate when power supply connected to DC input jack.	Power source is not properly connected.	Check all power connections.
	AC power may not be active.	Use another power outlet. Confirm outlet is not controlled by a wall switch.
No airflow from the Transcend EZEX.	Device motor failure; or, electronics failure.	Contact the homecare provider's technical service department.
Yellow fault LED flashes general fault warning sequence	Device detects an operating error.	Note the number of times the yellow fault LED flashes before the flash sequence repeats. Refer to **Fault, alert and reminder 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, universal hose adaptor, tubing); or use of external hardware past recommended lifetime.	Secure all equipment to ensure a proper seal. Replace any external hardware exceeding recommended lifetime. If the problem persists, call your homecare provider's technical service department.

Appendix: Part numbers

This section presents three topics:

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

Disposable parts

Item	Part number		Item	Part number
Filter Media	503067		Base Pad (optional)	503009
Transcend EZEX Filter Frame	503072		Forehead Pad	503010
Transcend HME (Heat Moisture Exchanger) (optional)	503008		Standard 6-foot hose	503081

Accessories

Item	Part number		Item	Part number
Transcend H_6B Waterless Humidification System	303005		Transcend Battery Arm Band	503027
Transcend H_9M Waterless Humidification System	303006		Transcend Battery Pouch, P_8 Battery	503025
Transcend P_8 Battery	503023		Transcend Battery Pouch, P_4 Battery	503028
Transcend P_4 Battery	503026		Transcend Base Station	503033
Transcend Heated Humidifier	503064		Transcend Heated Humidifier Travel Bag	503085
Mobile Power Adapter (MPA1)	503029		Transcend LCD Programming Base Station	503055
Battery Chest Strap	503024		Transcend Portable Solar Charger	503056

Replacement parts

Item	Part number		Item	Part number
Transcend EZEX	503066		Mask Shell Assembly	503034
Transcend EZEX Unit	503069		Adjustment Arm Bars Set of 3: S, M, L	503036
Transcend H_6B Headgear	503040		Forehead Piece	503037
Transcend H_9M Headgear	503007		Transcend H_9M Hose	503038
Headgear Ball Clips	503011		Transcend H_6B Hose	503039
Transcend Travel Bag	503012		Transcend Universal Hose Adaptor	503043
Mirage Activa Adaptor Ring – S	503018		Multi-plug Universal Power Supply (PSA2)	503059
Mirage Adaptor Ring – M/L	503014		Changeable Plug Pack	503060
Ultra Mirage II Adaptor Ring	503015		ComfortGel Adaptor Ring - L	503017

Item	Part number		Item	Part number
ComfortGel Adaptor Ring – S/M	503016		USB cable	503020
Multi-plug Universal Power Supply Set (Contains 503059 & 503060)	503078			

Appendix: Specifications

This section presents the following topics:

- **Transcend EZEX**
- **AC power supply - PSA2**
- **Mobile power adaptor (optional) - MPA1**
- **Batteries**
- **Transcend EZEX Performance**
- **Manufacturer's declaration**

Transcend EZEX

Transcend EZEX weight:	Less than 1.0 lbs (454 gm)
Transcend EZEX dimensions:	6.1 in x 3.5 in x 2.8 in (15.4 cm x 8.9 cm x 7.0 cm)
Air outlet connector port dimensions:	19-mm diameter proprietary connector
Universal Adaptor port dimensions:	22-mm diameter connector

AC power supply - PSA2

AC supply input:	100-240 VAC, 50-60Hz
AC supply output:	19VDC, 2.6 Amp

Mobile power adaptor (optional) - MPA1

Mobile power adapter input:	13.0 VDC nominal. 10 to 15.5 VDC, 7.5 Amp
Mobile power adapter output:	19.0 VDC, 2.1 Amp

Batteries (optional)

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

Transcend EZEX performance

Working pressure range:	4 to 20 cm H_2O
Accuracy of pressure setting:	±1 cm H_2O or ±10%, whichever is greater
Maximum system shutdown pressure:	30 cm H_2O
Ramp time duration:	0-45 min + 25% time variance
Operating temperature range:	41 to 95°F (5 to 35°C)
Storage/transport temperature range:	-4 to 140ºF (-20 to 60ºC)
Operating humidity range:	10% to 80% relative humidity, non-condensing
Storage/transport humidity range:	10% to 90% relative humidity, non-condensing
Altitude range:	0-8000 feet (automatically adjusted)

Manufacturer's declaration

This section presents the following topics:

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

Electromagnetic emissions

The Transcend EZEX 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 EZEX 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 EZEX 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 EZEX 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	±2, 4, 6 kV contact ±8 kV air	N/A. The Transcend EZEX 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±0.5*, 1 kV differential mode ±2 kV common mode	Line power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5 sec)	Linepower quality should be that of a typical commercial or hospital environment. If the user of the Transcend EZEX requires continued operation during power line interruptions, it is recommended that the Transcend EZEX 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 10 KHz to 100 MHz*	Recommended separation distance: d = $1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (compliance level adjusted to meet FDA limits) 26 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:

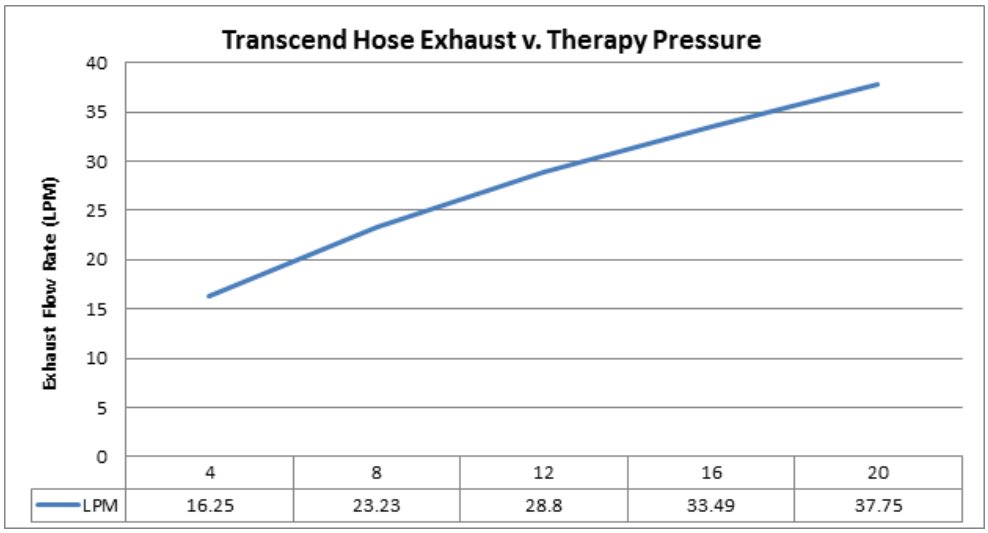
IEC 60601-1 compliance

Protection against electric shock: Degree of protection against ingress of water: Use of flammable gasses:	Class II Type BF IP21 Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen, or with nitrous oxide.

Interface physical characteristics

Interface (shell/seal) weight:	0.14 lbs (62 g)
Seal dead space	Less than 301 cc
9” Transcend hose dimensions:	16-mm diameter, 20 cm long
6’ Transcend hose dimensions:	16-mm diameter, 1.9 m long
6’ Standard hose dimensions:	21-mm diameter, 1.8 m long

Performance

Sound power level (@ 10cm H_2O pressure, static)	34.6 dB
Sound pressure level (@ 10cm H_2O pressure, static)	26.6 dB
Resistance to flow of the mask and application accessories	0.140 hPa (cm H_2O) @ 50 l/min 0.278 hPa (cm H_2O) @ 100 l/min
Working pressure range:	4 to 20 cm H_2O
Pressure limit:	30 cm H_2O
Vent flow rate curve:	

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)	3.1	7.0	11.0	15.0	19.0
	Average flow at the patient connection port (l/min)	71.91	75.45	74.29	73.24	71.49

HME moisture loss	Test condition		
	Tidal volume (ml)	Breath rate (1/min)	Moisture loss (mg/L)
	1000	10	18.5
	750	12	18.6
	500	15	15.6
	250	20	12.2

HME pressure drop v. flow -	Flow rate (L/min)	Insp. pressure drop (hPa)	Exp. pressu

			redrop(hPa)
Initial	30	0.13	0.13
	60	0.43	0.43
	90	1.00	0.93
After 24 hours	30	0.17	0.17
	60	0.50	0.47
	90	1.10	1.07
Internal volume	8.59 cm^3		

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 Sleep Apnea Starter System	3 years
Transcend Auto	3 years
Transcend EZEX	3 years
Transcend Heated Humidifier**	2 years
Transcend P4 and P8 Batteries	9 months
Transcend Portable Solar Charger	1 year
Transcend Mobile Power Adaptor	1 year
Transcend LCD Programming Base Station	2 years

*From date of user purchase

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

If the product fails to perform in accordance with the product specifications, Somnetics will repair or replace, at its option, any materials or parts of the product, which upon Somnetics' examination appear defective. 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 proff 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.

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Transcend EZEX User Manual

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