

TRANSCEND[®]

Transcend Heated Humidifier™ User Manual



Notices



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Introduction

Thank you for choosing the Transcend Heated Humidifier™ ('Humidifier'), designed to be used with Transcend positive airway pressure (PAP) therapy devices to humidify the air delivered during therapy. Dry air may cause nasal congestion or dryness of the nose, mouth, or throat during sleep apnea therapy, especially in dry or cold climates and in cases of air leakage through the mouth. Humidifying the air may help relieve these symptoms and make therapy more comfortable. Please read all instructions prior to use.

Intended use

The Transcend Heated Humidifier is indicated for the humidification of the air delivered from a compatible Transcend PAP therapy device. The Humidifier is intended for single patient re-use in the home and hospital/institutional environment. The Humidifier is for use only as recommended by a physician.

Contraindications

Please refer to the Transcend User Manual provided with your PAP device for contraindications associated with positive airway pressure therapy.

General warnings

Note: Specific warnings and cautions appear throughout the manual within relevant sections.

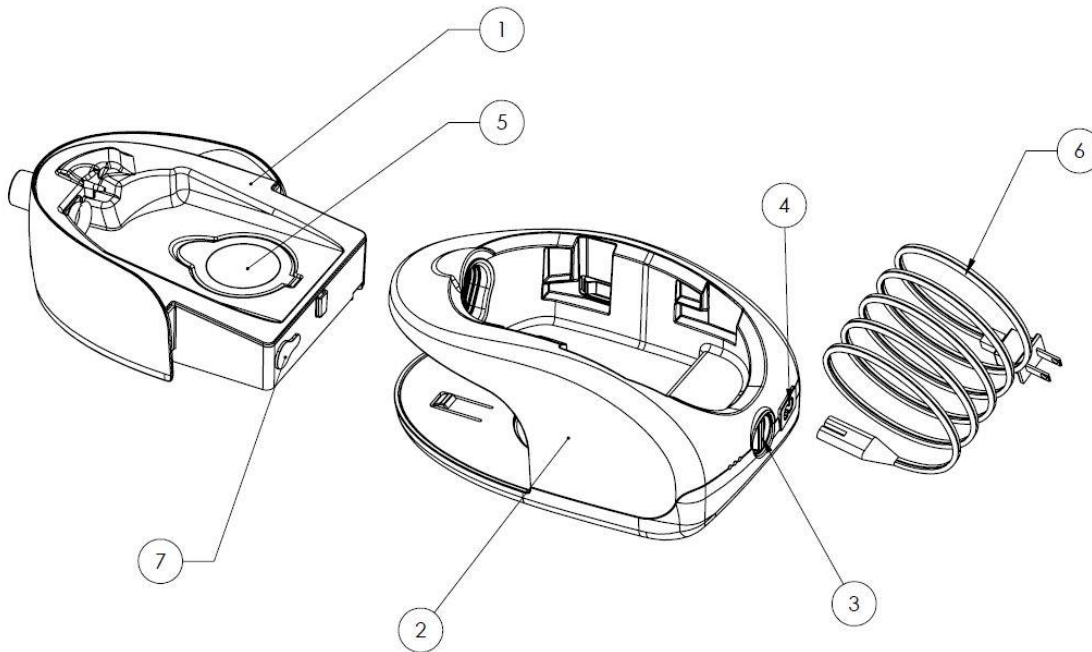
- Use the Humidifier only for its intended use as defined in this User Manual.
- Only use Transcend positive airway pressure devices and a 6 foot air supply tube with the Humidifier.
- The Humidifier is for single patient re-use and must not be re-used on another person. This is to avoid the risk of cross-infection.
- Always place the Humidifier lower than the level of the patient. If it is placed at or above the level of the patient, heated water may flow down the air tubing and into the mask.
- Take care when handling the Humidifier. The water in the reservoir may be hot.
- If liquids are spilled on the Humidifier disconnect the power cord immediately, discontinue use, and contact your service provider.
- Do not modify this equipment without authorization of the manufacturer.
- The Humidifier Water Reservoir must be completely drained of water prior to transport. Water remaining in the Water Reservoir may leak during transport, damage the electrical circuitry of the device, and create a potential electrical shock hazard.

- Do not use a modified sine wave power inverter to power the humidifier.
- Do not use the Humidifier in the presence of flammable or explosive materials.
- Medical electrical equipment including this device require special precautions regarding electromagnetic compatibility (EMC) and needs to be installed, placed, and used according to EMC information.
- Radiofrequency (RF) communications equipment can effect medical electrical equipment, including this device.
- Other cables and accessories may affect EMC performance.
- Be careful when placing or stacking this humidifier close to or on top of other equipment.

Symbols

	Attention: consult accompanying documents
	Type BF Applied Part
TYPE BF ETL Classified	ETL Seal of Approval demonstrating quality, safety and professional manufacturing of medical product
Intertek	
	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	
	Class II medical electrical equipment
	Caution: Federal Law (United States) restricts this device to sale by or on the order of a Physician.
	Precedes reference or item number

Transcend Heated Humidifier Components



ITEM NUMBER	DESCRIPTION
1	WATER RESERVOIR
2	HUMIDIFIER BODY
3	SETTINGS KNOB
4	POWER INPUT
5	FILL CAP
6	2-PRONG POWER CORD
7	RESERVOIR DRAIN PLUG

Using the Transcend Heated Humidifier

Please follow the sections below to set up, use, and clean your Humidifier.

Setting up your Humidifier

Place the Humidifier on a firm, level surface near your bed. It is recommended that the Humidifier not be placed on a surface that could be damaged by water. Place the Humidifier at a level that is lower than your sleeping position.

Caution: Do not position the Humidifier where it may be stepped on or accidentally overturned.

Filling the Water Reservoir

1. Remove the Water Reservoir by pulling it forward and out of the Humidifier Body (Image 1).
2. Pull up on the Fill Cap to open the Water Reservoir (Image 2).
3. Carefully fill the Water Reservoir with distilled water to the MAX fill line (Image 3).
4. Replace the Fill Cap ensuring it is tightly sealed.

Note: When carrying a filled Water Reservoir, ensure that the Fill Cap is sealed and the air outlet is tilted slightly upward. Take precaution not to tilt the air outlet at a downward angle as water may spill out of the reservoir.

5. Carefully re-insert the Water Reservoir into the Humidifier Body.



Note: The base of the Humidifier Body has guides to help position the Humidifier Reservoir during reinsertion.

Caution: If the Water Reservoir is not fully inserted the heater will not activate and the rightmost LED will turn red.

Warning: Disconnect power from the Humidifier prior to removing, filling, and replacing the Water Reservoir.

Warning: After use, take care when removing the Water Reservoir from the Humidifier as the water and the Water Reservoir may be hot.

Warning: Do not overfill the reservoir. Overfilling may allow water to enter the air supply tubing. Do not fill the reservoir above the indicated maximum fill level.

Warning: Re-insert the Water Reservoir slowly as water may spill into the air supply tubing if the Water Reservoir is not handled carefully.

Powering the Humidifier

The Humidifier is supplied with a power supply that connects to a wall outlet. This power source is for the Humidifier only.

The PAP device must be powered separately using any of the available Transcend power options described in the PAP device User Manual.

To power the Humidifier, plug the power supply cord into the back of the device, then connect the power supply to a wall (main) power outlet (Image 4).



Note: When looking at the back of the device, the leftmost LED will turn solid green indicating that the Humidifier has power.

Note: The Humidifier may only be powered by the AC power supply.

Caution: Do not use a power converter or voltage transformer with Transcend products, as it may damage them. Do not use a modified sine wave power inverter to power the humidifier.

Caution: Transcend automatically converts voltage, but may require a plug adaptor for use in another country. It is recommended you use the interchangeable plug adaptors supplied with the Transcend power supply. Use only the Somnetics-supplied Universal Power Supplies and accessories.

Starting therapy

1. Connect one end of the air supply tubing onto the air outlet of the Humidifier. Connect the other end of the tubing to your user interface (Image 5).

Note: Standard 6 foot air tubing is supplied with the Transcend PAP device. If you have been using the PAP device without the Humidifier, the universal hose adaptor must be removed from the 6 foot air tubing prior to use. Air tubing is not included with the Humidifier.

2. Place the PAP device into the corresponding slots located at the top of the Humidifier; then slide the device forward until the nose cone is inside the humidifier body (Image 6).

Note: The Transcend PAP device has arm bars which help to guide it into the Humidifier port.

3. Power the Transcend PAP device as described in the corresponding User Manual. The PAP device may be powered via wall (main) power, Transcend battery, or Transcend Mobile Power Adaptor as appropriate.

Note: Be sure that the user interface is fit firmly in place before initiating therapy.

4. Initiate therapy by pressing the power button (⏻) on the PAP device. Air flow from the PAP device will turn on the Humidifier automatically and it will begin warming the Water Reservoir. The middle LED on the back of the humidifier will turn solid green to indicate that the Humidifier is heating the Water Reservoir and is delivering humidification (Image 7).

Note: The Humidifier temperature setting must be in the range of 1 to 5 to initiate warming. A temperature setting of 0 will turn off the heating function of the Humidifier.



Note: The Humidifier will not begin warming the Water Reservoir until the PAP device power button has been pressed and the PAP device is in Therapy Mode. It may take up to 60 minutes to reach the set Humidifier temperature depending upon the selected heat setting.

Note: If a fault has occurred with the humidifier all three LEDs will begin to flash. Please refer to the troubleshooting section of this user manual for more information.

5. Adjust the heat setting by using the dial located on the back of the Humidifier (Image 8).

Note: Heated humidification can be adjusted to a level of 0 to 5. The 0 setting will turn the heating function to 'off.' A setting of 5 provides the highest level of humidification. If a

heat setting has been recommended by your physician, begin at that setting and then adjust the dial up or down to reach your humidification comfort level.

Warning: Place the Humidifier at a level that is lower than your sleeping position to prevent condensation from collecting in air supply tubing and patient interface. Avoid using a heat setting that may result in the collection of condensation in the air tubing.

Ending therapy

1. To stop therapy at any time, press the power button (⏻) on the Transcend PAP device (Image 9).

Note: It may take up to 60 seconds for the middle green LED to turn off.



Image 8



Image 9

Cleaning and maintenance

1. Unplug the Humidifier from the wall outlet and allow it to cool to the touch.
2. Remove the PAP device by pulling it backward, sliding it out of the guide slots of the Humidifier (Image 10).

a. Periodic Cleaning: Clean the exterior of the Humidifier as needed. Use a mix of 5% mild liquid detergent in distilled water (1.6 fl oz. liquid detergent per quart of distilled water). This will clean away surface residue.

- Submerge a lint-free cotton cloth into the detergent solution.
- Wipe the exterior of the Humidifier using a gentle, back and forth wiping motion from the front to back of the device.
- Rinse the cloth in clear water to remove residual cleaning solution.
- Wring excess water from the cloth then wipe the Humidifier using a gentle front to back wiping motion to remove any detergent solution remaining on its surface.
- Wipe the device with a dry, lint-free cotton cloth until the device is fully dry



Image 10

b. Daily Cleaning: Follow the instructions below to clean the Water Reservoir.

- Remove Water Reservoir from the Humidifier Body and open the Fill Cap (Image 11).
- Fill the Reservoir to the maximum water mark with a solution of 5% mild liquid detergent in distilled water. (1.6 fl oz. liquid detergent per quart of distilled water) (Image 12).
- Replace Fill Cap.
- Cover the output port with your hand and gently shake the Reservoir back and forth for 10 seconds.



Image 11



Image 12

- Remove the Drain Plug and drain the solution (Image 13).
- Replace the Drain Plug.
- Open the Fill Cap and rinse the inside of the Reservoir thoroughly with clean water.
- Remove the Drain Plug to empty the Reservoir.

Note: Repeat steps as needed to remove excess solution.

- Return the reservoir to the Humidifier Body (Image 14).
- To fully dry the Reservoir, turn on “Drying mode” by pressing and holding the ramp button then the power button on the Transcend PAP device. Drying mode will last for 30 minutes and turn off automatically (Image 15).

Note: Ensure that power is supplied to the Transcend PAP device and Humidifier.

- Refill the Reservoir with distilled water before the next use.



Image 13



Image 14



Image 15

c. Weekly Maintenance: Inspect the Water Reservoir and Fill Cap for wear or deterioration. If the Water Reservoir begins to leak, replace it immediately with a new Reservoir. Contact your home medical equipment provider or call Somnetics customer service at 1-877-621-9626 for assistance.

Warning: To avoid the potential for electric shock unplug the Humidifier from the power source and remove the Transcend PAP device before cleaning the humidifier. Allow the Humidifier to dry completely before plugging it back into a power source.

Warning: The Water Reservoir is the only part of the Heated Humidifier that should be submerged in water. Never submerge any other part of the Humidifier in water. Do not allow water to enter the interior of the Humidifier Body. In the event water enters the interior of the Humidifier Body, wipe the surfaces dry of water using a lint-free cotton cloth and allow to fully air dry before plugging it back in to a power source.

Servicing

No further maintenance is required. Do not open the Humidifier Body. There are no serviceable parts inside. Repairs and servicing should only be performed by a service agent authorized by the manufacturer. It is recommended the water reservoir (P/N 503080) be replaced every 6 months.

Replacement Parts and Accessories

Item	Part Number		Item	Part Number
Water Reservoir Assembly	503080		US 2-Prong Power Cord	503074
Transcend Heated Humidifier	503064		UK 2-Prong Power Cord	503076
EU 2-Prong Power Cord	503075		AU 2-Prong Power Cord	503077
Water Reservoir Drain Plug	503083		Transcend Heated Humidifier Travel Bag	503085

Technical Specifications

Dimensions (LxWxH)	9 in x 5.5 in x 4.7 in
Weight	2.2 lbs (998g) empty; 3.1 lbs (1406g) with water to the max fill line.

AC Supply Input	100-240V, 50-60Hz
Water Reservoir Volume up to maximum fill level	325 mL
Working Pressure Range	4 to 20 cm H ₂ O
Warm up time	Up to 1 hour depending on heat setting
Inspiratory/Expiratory Pressure Drop:	0.375 cmH ₂ O @ 50 LPM (Liters per Minute)
Gas Leakage of the Humidification System at max operating pressure:	4.85 LPM
Maximum Gas Temperature:	77°F (25°C)
Sound power level (@10 cmH ₂ O pressure, static)	37.0 dB
Sound pressure level (@10 cmH ₂ O pressure, static)	29.0 dB
Maximum heater plate temperature	131°F (55°C)

Humidifier Performance			
(Testing Completed at 20°C, Elevation 800 ft)			
CPAP Pressure	Heater Setting	Relative Humidity %	Nominal System Output (mg/L)
4 cmH ₂ O	1	80%	12
	2	82%	
	3	>90%	
	4	>95%	
	5	>95%	21
12 cmH ₂ O	1	65%	14
	2	67%	
	3	70%	
	4	>75%	
	5	>75%	14

20 cmH ₂ O	1	55%	10
	2	59%	
	3	60%	
	4	>65%	
	5	>65%	15

This device was not evaluated up to 8000 feet of elevation.

Storage and Transport

Temperature Range (-4)-140°F (-20-60°C)

Humidity Range 10-90% RH

Caution: Empty the water reservoir before traveling with the heated humidifier.

Operating Conditions

Ambient Temperature Range 41-95°F (5-35°C)

Gas Inlet Temperature Range 41-95°F (5-35°C)

Humidity Range 10-80% RH

Caution: Humidity performance may be compromised if used outside the defined ambient temperature range and humidity range.

Troubleshooting

Problem	Probable Cause	Solution
Humidifier does not turn on	Incorrect setup	<ol style="list-style-type: none"> 1. Ensure that you have the fully seated the PAP device into the Heated Humidifier and that you have pressed the PAP power button. 2. Be sure the PAP device and Heated Humidifier are connected to power.
Humidifier does not heat the Water Reservoir	Incorrect setup	<ol style="list-style-type: none"> 1. Ensure that you have followed the correct setup. The middle green LED will indicate that the Heated Humidifier is warming the Water Reservoir. It may take up to 45 seconds to reach the desired temperature.

Problem	Probable Cause	Solution
PAP device turns on but then stops working	Massive air leak causing system to shut down	<ol style="list-style-type: none"> 1. Ensure that the air supply hose is fully connected to the Heated Humidifier and to your mask. 2. Securely fit the mask to your face before powering up the PAP device. 3. Be sure the Water Reservoir gasket is in place and the Water Reservoir cover is fully seated. 4. Ensure the PAP device is fully seated in the Heated Humidifier.
The red LED is illuminated on the Humidifier	Water supply is low or water reservoir is detached from the humidifier.	<ol style="list-style-type: none"> 1. Ensure that the water reservoir is properly attached to the humidifier body. The reservoir has guides that will help to secure it in place. 2. Check the water supply inside of the water reservoir. If the water is low then the red LED will illuminate to signal a refill.
Water is splashing on your face	<p>The Water Reservoir is overfilled.</p> <p>The settings knob is set too high causing condensation to form in the air tube and mask.</p>	<ol style="list-style-type: none"> 1. Empty some water from the Water Reservoir. 2. Adjust the setting to a lower setting.
Air does not feel moist	<p>The settings knob is set too low.</p> <p>The heater is not working.</p>	<ol style="list-style-type: none"> 1. Adjust the setting to a higher setting. 2. If the problem persists, contact your home medical equipment provider or Somnetics customer service at 1-877-621-9626.
Air feels too moist	The settings knob is set too high.	<ol style="list-style-type: none"> 1. Adjust the setting to a lower setting.
Leaking Water Reservoir	<p>Water Reservoir may be cracked or damaged.</p> <p>The lid may not be on correctly.</p>	<ol style="list-style-type: none"> 1. Ensure that the reservoir cover is fully attached to the reservoir base. Refer to "reassembling the water reservoir" section. 2. Inspect the Water reservoir for damage or cracks. If there are signs of damage, contact your home medical equipment provider or Somnetics customer service at 1-877-621-

Problem	Probable Cause	Solution
		9626 to order a replacement.
All three LEDs at the back of the Humidifier are flashing.	Humidifier is in a fault state.	<ol style="list-style-type: none"> 1. Unplug the Humidifier power supply. 2. Wait for 10 seconds. 3. Reattach the power supply to the Humidifier. If the problem continues contact your home medical equipment provider or Somnetics customer service at 1-877-621-9626.

Electromagnetic emissions


The Transcend Heated Humidifier is intended for use in the electromagnetic environment specified below. Ensure the Heated Humidifier is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF radiated emissions CISPR11	Group 1	The Heated Humidifier system 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 Heated Humidifier system is suitable for use in all 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 Heated Humidifier is intended for use in the electromagnetic environment specified below. Ensure the Heated Humidifier is used in such an environment.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2, 4, 6 kV contact ±8 kV air	N/A. The HH 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	<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	Line power quality should be that of a typical commercial or hospital environment. If the user of the CPAP system requires continued operation during power line interruptions, it is recommended that the CPAP system be powered from the battery. Note U _T is the A.C. line voltage before application of the test level.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment – guidance
	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 5 sec)	
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 ¹ , should be less than the compliance level in each frequency range ² . Interference may occur in the vicinity of equipment marked with the following symbol: 

1 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the humidifier system is used exceeds the applicable RF compliance level above, the humidifier system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EN 60601-1 compliance

Protection against electric shock:	Class II
Degree of protection against ingress of water:	Type BF IP21

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 Starter System	3 years
Transcend Auto System	3 years
Transcend EZEX System	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 proof of the date of purchase, is required. Any repair, replacement, or refund obligation would not apply if the device has been repaired or otherwise altered in a facility not authorized in writing by Somnetics. To exercise your rights under this warranty, contact your local, authorized Somnetics dealer or Somnetics at 33 5th Avenue, New Brighton, Minnesota 55112 USA, 1.877.621.9626 or 1.651.621.1800.

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