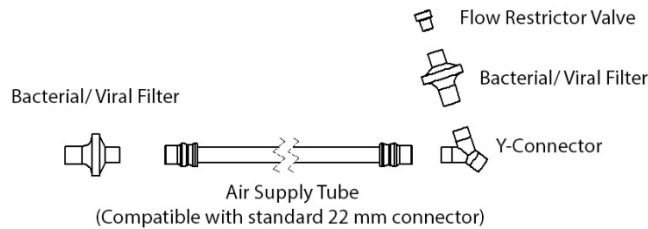


Transcend 3 BiPAP Respiratory Circuit Instructions For Use



Included Items:

- 1- Air supply tube (with standard 22mm connector)
- 2- bacterial/ viral filters
- 1- Y-Connector
- 1- Flow restrictor valve

Not Included:

- Transcend 3 BiPAP
- Non-vented mask with anti-asphyxia valve

INTENDED 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 is authorized by FDA under Emergency Use Authorization during the COVID-19 pandemic.

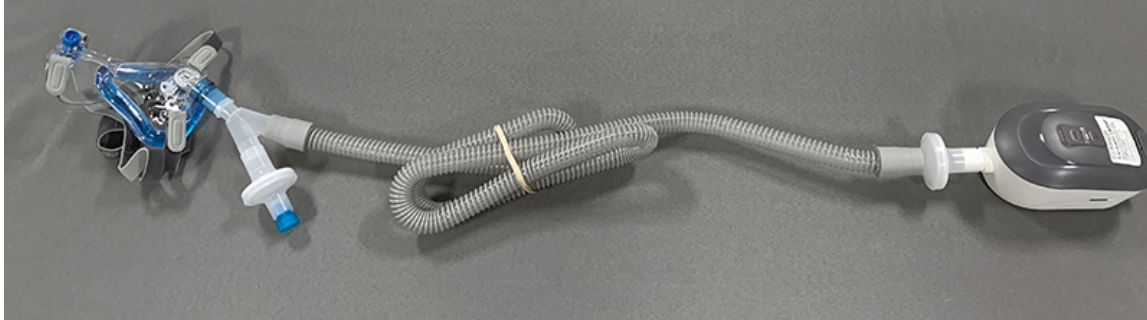
WARNINGS:

- The Transcend 3 BiPAP Respiratory Circuit is for single patient use only. Reuse on multiple patients may result in cross-contamination. Do not attempt to sterilize any components of the Respiratory Circuit. Use of sterilization or cleaning solutions may leave this product nonfunctional.
- Do not block or otherwise obstruct the exhalation ports of the breathing circuit.
- To prevent contamination of the surrounding environment, use only non-vented masks with anti-asphyxia valve and the Transcend 3 BiPAP Respiratory Circuit fitted with a bacterial/viral filter at the exhalation port.
- The Transcend 3 BiPAP 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 BiPAP 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.
- Do not add any attachments or accessories to the respiratory circuit other than as stated in these instructions for use, as the device might not function correctly leading to the risk of degradation of health of the patient.
- 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 coupled to the breathing circuit near the mask rather than adjacent to the Transcend 3 BiPAP outlet port.

CAUTIONS:

- The calibration step should be performed each time a new respiratory circuit is attached to the Transcend 3 BiPAP to ensure accurate therapy (see instructions below).
- Rx Only – Federal law restricts this device to sale by, or on the order of, a physician.

Assembling the Respiratory Circuit



(Mask is not included in the Transcend 3 BiPAP Respiratory Circuit. Included in the image for placement reference.)

1. Begin by attaching a 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.
If using an optional oxygen pressure line adaptor, connect this to the other end of the air supply tube, then connect the adaptor to one of the Y-connector branches. If no adaptor is used, simply connect the air supply tube to one of the Y-connector branches. **WARNING: The only place an optional adaptor should be placed in line with the respiratory circuit is directly between the connection of air supply tube and the Y-connector.**



Placement for optional oxygen pressure line adaptor.

WARNING: This is the only place an optional adaptor should be inserted into the breathing circuit.

(Mask is not included in the Transcend 3 BiPAP Respiratory Circuit. Included in the image for placement reference.)

3. Connect a Bacterial/ Viral Filter to the open branch of the Y-connector, then plug the filter with the Flow Restrictor Valve.
4. The Transcend 3 BiPAP must be calibrated with the respiratory circuit before use. Refer to the Transcend 3 BiPAP User Manual (PN 104052), which can be accessed at the link below. **NOTE: The BiPAP must be calibrated with the respiratory circuit before use. The calibration is performed before a mask is attached to the respiratory circuit.**
5. Once calibration is complete, attach the patient mask to the Y-connector.
6. Initiate air delivery, by pressing the top Power button on the Transcend 3 BiPAP control panel after power is supplied to the device.
7. Properly fit the mask to the patient and ensure the exhalation port is positioned to prevent obstruction to the port. **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 or a reduction in delivered air pressure.**

Storage: The Respiratory Circuit should be stored in a cool dry place.

Disposal: The entire respiratory circuit should be handled in accordance with biohazard disposal procedures.

For more information and user guides, visit www.MyTranscend.com/clinical-guides. For assistance, contact Somnetics: 855-420-7525 or info@somnetics.com.

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