



## Vital Signs™ Breathing Circuit Instructions for Use

Products covered by these instructions:

- Vital Signs Adult Anesthesia Breathing Circuit
- Limb-O™ Single Limb Anesthesia Breathing Circuit
- Vital Signs Pediatric Anesthesia Breathing Circuit
- Limb-O™ Ventilator Circuit
- Anesthesia Ventilator Circuit



Please read the "Instructions For Use", "Cautions" and "Warnings" listed below for those products that are included in this kit. Other products contained in this kit may be labeled individually.

Contents: The contents of this kit are packaged in accordance with the specifications of your hospital.

This product is not sterile. It is made of standard medical device materials and is a single-use, disposable product. This product should not be used if physical deterioration, brittleness or discoloration occurs. Good clinical practice requires proper stock rotation to prevent older product from being stored for an excessive period of time.

### For Anesthesia:

1. Ensure that all connections are tight and have not loosened during transit.
2. Attach circuit to equipment to be utilized.
3. Activate oxygen flow and observe that gas is flowing from elbow to insure that there are no occlusions.
4. Occlude elbow, close exhaust valve and pressure test circuit to 30 cmH<sub>2</sub>O pressure for 30 seconds to ensure that there are no leaks.

### For Ventilators:

1. Ensure that all connections are tight and have not loosened during transit.
2. All circuits should be tested for obstructions, occlusions, or leaks in accordance with the ventilator manufacturer's specifications.
3. If any port openings are not utilized, ensure that the attached cover/port caps are secure to prevent leakage.
4. Ventilator monitoring and warning systems should be operational and used as recommended by the ventilator manufacturer.
5. Condensation accumulation within the circuit should be continually monitored during use and evacuated routinely to reduce the hazard of accidental aspiration by the patient.

Please Note: Leakage may be caused by the machine or monitoring equipment and/or breathing circuit.

If corrugated hose is the expandable type:  
Expand circuit prior to connecting to patient. Use two hands to reposition or expand circuit when connected to patient, to prevent pulling on connections.

If anesthesia ventilator hose is included:  
Manufacturer's instructions for the ventilator should be read and the procedures for testing followed.

If there are no testing procedures given, test the breathing circuit as follows:

1. Attach circle breathing circuit to anesthesia machine, and place the breathing bag on the patient port.
2. Close the exhaust valve.
3. Turn the selector valve to ventilator position.
4. Pressurize the circuit to 30 cmH<sub>2</sub>O pressure for 30 seconds to insure that there are no leaks.
5. Open exhaust port valve and return breathing bag to its proper position for use.

Caution: This testing procedure is designed to test the anesthesia ventilator circuit only. Additional steps directed by the mechanical ventilator manufacturer, should be taken to insure proper function of the mechanical ventilator prior to use.

### Warnings: Filter

- The use of Heated Humidification or nebulizers with various drugs or treatments may cause increased resistance to filters;
- Avoid flowing nebulized particles through the bacterial/viral filter or using the filter as a water trap;

- Do not connect the bacterial/viral filter directly to the outlet of a heated humidifier device;
- If gas sampling gas port is included on filter, verify cap is closed tightly.

If face mask with adjustable air cushion is included:

For masks with a tail inflation valve:

1. Insert a luer-tipped syringe into the valve, squeeze valve "O" ring and inflate/deflate.
2. In an emergency Squeeze Valve "O" Ring and inflate by mouth.

For masks with a top valve:

1. Insert a luer-tipped syringe into the valve and inflate/deflate mask cushion.

Placement of mask:

1. Place mask cushion on the patient's chin, roll cushion up the face with a gentle but firm pressure to create an effective mask seal.
2. Refrain from pressing rigid part of the mask against the face, nose or eyes.
3. A head strap can be affixed to the optional prong ring or detached when not needed.

If Vital Signs HCH is included:

1. Pressure check system to ensure leak-free connections.
2. When ready for patient use, connect HCH securely to endotracheal tube, tracheostomy tube or face mask.
3. Ventilatory compensation for the internal dead space of the HCH may be necessary.
4. When using the HCH, the ventilation parameters and arterial blood gases should be monitored closely.
5. Replace every 24 hours as needed to prevent accumulation of secretions.

### Warnings: HCH

This device cannot be used:

- In patients who cannot tolerate the additional mechanical dead space of this device;
- In patients who cannot tolerate the additional airway resistance of this device;
- In patients who produce voluminous secretions;
- When this device is used instead of a heated humidifier, the patient should be monitored closely. If complications are observed, such as mucous plugging, proper airway care must be instituted.
- Always utilize appropriate alarms and visually monitor patients on life support equipment.

If pressure port is included:

1. Attach manometer tubing to pressure port.
2. Tighten all connections with a push-twist motion. Ensure that all connections are secure.
3. Test interface and manometer during the initial circuit testing.

If temperature monitoring port is included:

1. Attach temperature sensing probe to monitoring unit and patient breathing circuit.
2. Tighten all connections with a push-twist motion. Ensure that all connections are secure.
3. Test interface before using according to the equipment manufacturers' recommendations and verify on monitor.

If oral airway is included:

1. Check for clear airflow prior to use.

If gas sampling interface is included:

1. Attach gas sampling line to monitoring unit and patient breathing circuit, if required.
2. Tighten all connections to luer adapters with a push-twist motion. Ensure that all connections are secure.
3. Check for proper capillary connections and function prior to use.
4. Test interface before using according to monitoring equipment manufacturer's recommendations and verify.
5. Replace sampling line if blockage or leakage is found when tested.

If blood pressure cuff is included:

1. Select the cuff which covers at least 2/3 of the upper arm or thigh.
2. For Cuff-Able™, place cuff with "artery line" over patient's artery.

Warnings: blood pressure cuffs

- The cuff should never be applied to a limb being used to administer intravenous solutions.
- The cuff complies with American Heart Association recommendations of cuff width to arm circumference ratios if the end of the cuff overlaps the blue printed line. Accuracy may be minimally affected by placement beyond the line.

If VitalTemp™ esophageal stethoscope is included:

- The temperature sensing thermistor in our 400 series probes follow the YSI-400 series published temperature to resistances curve with an accuracy of  $\pm 2^\circ$  over the range of  $25^\circ$  to  $45^\circ\text{C}$ . The temperature sensing thermistor in our 700 series probes follow the YSI-700 series published temperature to resistance curve with an accuracy of  $\pm 2^\circ$  over the range of  $25^\circ$  to  $45^\circ\text{C}$ .
1. Attach and secure all connections between esophageal

stethoscope, patient monitoring cable, and patient monitor.

2. Test esophageal stethoscope before using according to equipment manufacturer's recommendations and verify results on monitor.

### Warnings

- Do not rinse, soak, wash or sterilize circuit or components.
- Patient, ventilator, and circuit must be monitored on a regular basis as per established hospital standards of care.
- Severe mask pressure can lead to facial and/or optic nerve damage.

**Some of the devices covered by these Instructions For Use may contain phthalates, please refer to additional packaging for phthalate contents.**

### Risks and Precautionary Measures related to Phthalates:

This instruction pertains to the phthalate symbol marked on the device or its packaging. If this device is used for the treatment of children, or treatment of pregnant or nursing women; please note that the following types of procedures may increase the risk of exposure to phthalates: Exchange transfusion in neonates, total parenteral nutrition in neonates, multiple procedures in sick neonates, hemodialysis in peripubertal males, male foetus and male infant of pregnant women, and lactating women; and massive blood infusion into trauma patients. Although these procedures have the potential for increased risk of exposure, conclusive evidence of human health risks has not been established. As a precautionary measure, to reduce the potential for unnecessary exposures to phthalates, the product must be used in accordance with the instructions for use, and practitioners should refrain from using this product beyond the period of time the product is medically necessary or needed.



This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse.



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