

### VVK100-SYS VENTILATOR VALIDATION SYSTEM

#### VENTILATOR REFERENCE SCHEMATIC

This simplified ventilator schematic indicates how to connect the [VVK100-SYS](#) to a standard, typical ventilator to allow for its verification and assumes that

- air, properly humidified (100%) and oxygen titrated (21-95% oxygen) will be provided at the INFLOW for delivery to the patient
- INFLOW is controlled to provide the proper timing and values of the required high and low ventilator patient circuit pressures

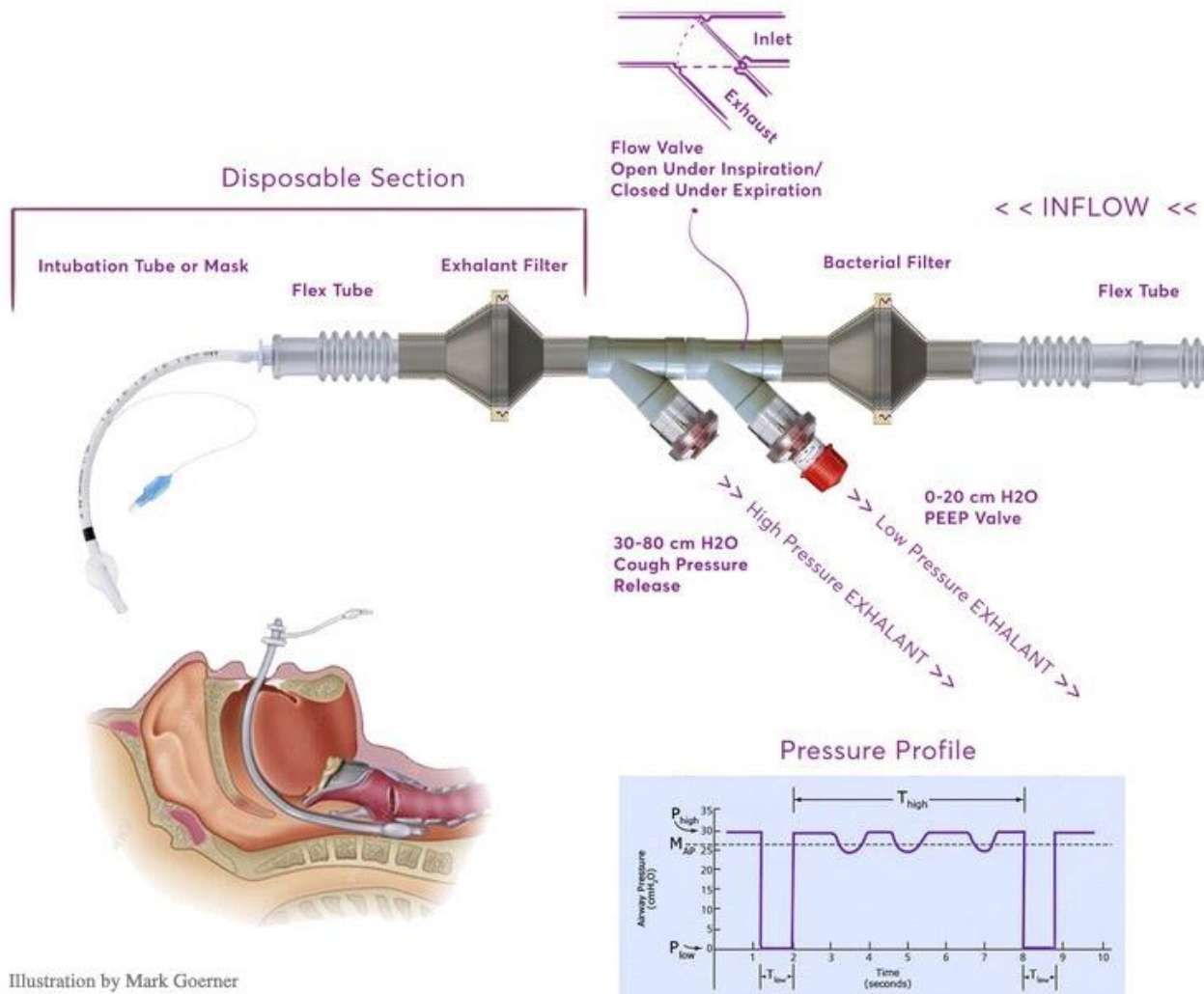


Figure 1. Ventilator reference schematic

#### MEASUREMENTS FOR VALIDATION

- **Pressure and Timing** The primary measurement will be the pressure and timing profile shown in the light purple graph titled “Pressure Profile” (Fig. 1). All these recorded pressure and timing values are critical for ventilator validation. The pressure and timing measures can be performed at the point (volume) that connects between the Cough Pressure Release valve and Exhalant Filter. However, these measurements can be performed anywhere in the patient breathing circuit.

- **Cough Pressure Release** There will be a need to measure how the Cough Pressure Release valve opens when there is a patient cough or another overpressure event like a clogged (with mucus) patient airway tube. This valve will be typically be set to open somewhere between 30-60 cm H<sub>2</sub>O. The MP160 with TSD160D is used to verify this overpressure release level and the quickness of valve opening.
- **Positive End-Expiratory Pressure (PEEP)** There will be a need to measure how the Positive End-Expiratory Pressure (PEEP) valve behaves when the patient exhales. This valve will be set to slowly release expired air down to the PEEP set pressure (0-20 cm H<sub>2</sub>O), during patient exhalation. The MP160 with TSD160D is used verify the pressure drop curve of this release.
- **Pressure** All pressure measurements can be performed at the volume point between the Exhalant Filter and the Cough Pressure Release valve. This measurement is accomplished by employing a 1/4" sampling port at the point of this volume and running a 1/4" silicone tube to the TSD160D positive input port. The negative input port of TSD160D remains open to the atmosphere. In this regard, all pressure measurements are directly compared to ambient pressure levels.
- **Oxygen Concentration** There will be a need to measure the oxygen concentration at the volume point between the Exhalant Filter and the Cough Pressure Release valve, or at another appropriate point in the patient breathing circuit. This can be at the same volume location where the above pressure measurements are made. Use an [O2100C](#) Oxygen Measurement Amplifier set to 0-100% oxygen scaling and then measure how the oxygen concentration varies during the cycling observed in the "Pressure Profile" light purple graph.
- **Air Flow & Volume** There will be a requirement for patient circuit air flow and volume measurements. For these measurements, the TSD117 is placed in-line at the desired point in the patient air flow circuit. Typically, this air flow measurement is performed at the point of the Exhalant Filter. The TSD117 will provide measures of bidirectional air flow. To obtain volume over any given flow cycle, *AcqKnowledge* software is employed to integrate the flow signal to obtain the indicated volume.

#### VVK100-SYS CALIBRATION

- All pressure, flow and volume measures can be calibrated using external water columns (manometers) and the AFT27 3-liter Calibration Syringe—certified to meet or exceed an accuracy of 0.5% (3 liters ±0.5%).
- Oxygen calibration can be performed by exposing the [O2100C](#) air sampling input alternately to the 20.93% oxygen in ambient air and the 100% oxygen provided at oxygen distribution points in the medical facility.