

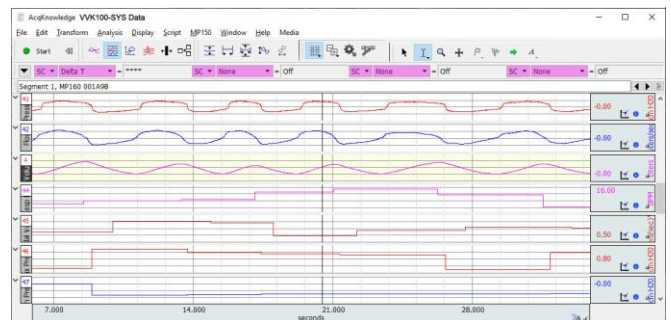
VVK100-SYS VENTILATOR VALIDATION KIT SYSTEM



The **Ventilator Validation Kit** provides ventilator manufacturers and prototype developers with a complete solution for validating new medical/hospital-grade ventilator products intended for human use. The VVK100-SYS includes a pulmonary airflow transducer, airway pressure transducer, differential amplifiers, calibration syringe, and a data acquisition system with automated pulmonary function analysis software to assist in the validation of ventilators. Multiple systems can operate, in concert, to increase productivity and maximize efficiency.

The VVK100-SYS includes:

- [MP160WS/W](#) 16-channel Data Acquisition and Analysis system for Windows or Macintosh. The MP160 system can monitor eight ventilators (pressure, volume), simultaneously.
- [TSD117B](#) Airflow (Pneumotach) Transducer, designed for human use. Can be inserted, in-line, to typical hospital ventilator systems.
 - To aid in interfacing, BIOPAC offers a wide range of tubing, adapters, bacterial filters, valves, and related accessories. Airflow transducer calibration and verification is straightforward.
- [AFT27](#) 3-liter calibration syringe is included for calibration and validation and is certified to meet or exceed an accuracy of 0.5% (3 liters $\pm 0.5\%$).
- [TSD160D](#) differential pressure transducer that can interface with any pneumatic circuit to monitor airway pressure. When combined with the TSD117B, it is possible to monitor airflow and airway pressure to provide the user with real-time validation data of pump volume and pump pressure ranges.
- [AcqKnowledge](#) software controls the hardware, displays the data, and analyzes the signals in real time.
 - The data is also available in real time for further third-party analysis by using the optional [Network Data Transfer](#) licensed feature, providing your systems with immediate network access to the data while the validation process is taking place.
 - Use optional BIOPAC [Basic Scripting](#) to standardize and automate routines to reduce the potential for error and improve data quality.



Optional Add-ons

- [TSD301](#) Galvanic Oxygen Transducer for measuring 0-100% Oxygen levels—synchronized with flow cycling.
- [TSD302](#) Wide Air Range Temperature Transducer + [TSD303](#) Barometric Pressure Transducer for Humidity and Temperature Measurement—synchronized with flow cycling.
 - TSD302 and TSD303 may be used with the Ventilator Validation System to convert volumes from ATPD (ambient temperature pressure, dry) to STPD (standard temperature pressure, dry).
- [TSD127](#) Low Flow Transducer 90 L/min (includes RX127 airflow head coupled to TSD160A precision, highly sensitive, differential pressure transducer) for very low flow and unidirectional measurements (less than 50 L/min), for CPAP mode validation.
 - [Contact BIOPAC](#) to review specific testing requirements and recommended physical configurations for flow testing over multiple dynamic ranges.
- To aid in interfacing, BIOPAC offers a wide range of tubing, adapters, bacterial filters, valves, and related accessories. For example, [AFT17](#) tubing will interface between the TSD160D transducer and the ventilator breathing circuit.
- [AFTCAL-160](#) Differential Pressure Manometer with NIST Calibration is recommended for calibration of TSD160 Series Differential Pressure Transducers.

SETUP

1. Snap the BIOPAC modules together: MP160 – AMI100D – DA100C (for TSD117B) – DA1000C (for TSD160D) – optional DA100C (for TSD301)
2. Connect the TSD117B Airflow (Pneumotach) Transducer to a DA100C Amplifier.
3. Connect the TSD160D Differential Pressure Transducer to a DA100C Amplifier.
4. *Optional:* Connect the TSD301 Galvanic Oxygen Transducer to a DA100C Amplifier.
5. Connect the Transducers to the ventilator circuit (add tubing, filters, etc. as required).



VENTILATOR VALIDATION KIT (VVK100-SYS) TECHNICAL APPLICATION REFERENCE

The Ventilator Validation & Testing [Technical Application Reference](#) covers how to connect the ventilator validation kit (VVK100-SYS) to a standard, typical ventilator to allow for its verification, ventilator test calibration, and measurements for ventilator validation: Pressure and Timing; Cough Pressure Release (obstruction valve); Positive End-Expiratory Pressure (PEEP); Pressure; Oxygen Concentration; Air Flow & Volume.

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

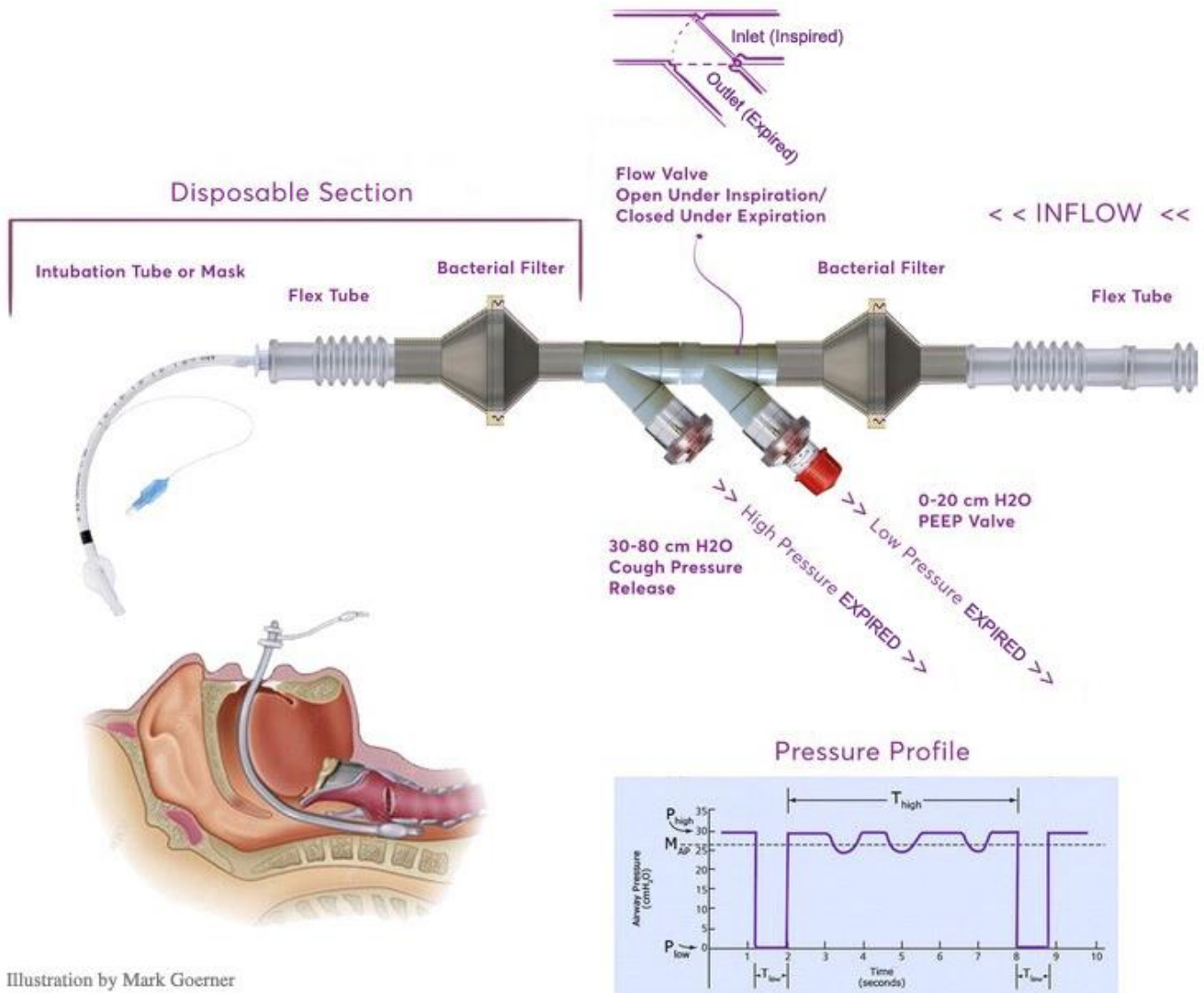


Illustration by Mark Goerner

MEASUREMENTS FOR VALIDATION

- The primary measurement will be the pressure and timing profile shown in the light purple graph titled “Pressure Profile.” 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.
- 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 H₂O. The MP160 with TSD160D is used to verify this overpressure release level and the quickness of valve opening.
- 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 H₂O), during patient exhalation. The MP160 with TSD160D is used verify the pressure drop curve of this release.
- 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.
- 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 OXY100C 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.
- 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 \pm 0.5%).

Oxygen calibration can be performed by exposing the TSD301 to the 20.93% oxygen in ambient air and the 100% oxygen source for the ventilator.