

DSI Buxco®

E-cigarette, Vapor, & Tobacco (EVT) Smoke Generator User Application Guide



OVERVIEW

This manual provides information on the setup and operation of the Buxco® E-cig Vape Tobacco (EVT) Smoke Generator. This document will provide an overview of the system components, proper assembly, and basic operation.

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WELCOME

Congratulations on joining the community of users worldwide who rely on DSI's products to perform preclinical physiologic research. Thank you for your interest in DSI products. We are committed to providing you with quality products and services.

This manual will help you get to know your E-Cig Vape Tobacco Smoke Generator (EVT). The structure of the manual was designed to guide you through setting up your DSI system.

WHAT YOU WILL BE LEARNING

1. Information on the EVT Smoke Generator System Components
2. Quick Start Guide - How to Set Up an Experiment
3. Configuring the EVT Smoke Generator System for Button Activated E-Cig Test Articles
4. Configuring the EVT Smoke Generator System for 1st Generation E-cig Test Articles
5. Configuring the EVT Smoke Generator System for Tobacco Cigarettes
6. How to use the EVT Software
7. Information on Auxiliary Products offered with the EVT Smoke Generator
8. How to set up the EVT Smoke Generator with other Respiratory Products including the Buxco Inhalation Tower and the Buxco Mass Dosing Chamber

SCIENTIFIC BACKGROUND

Research is being conducted to determine the risk of E-cigarettes and their potential relationship with chronic or acute lung disease. These studies are investigating if the use of e-cigarettes and vaping devices significantly increases the risk of developing lung diseases like asthma, bronchitis, emphysema, and chronic obstructive pulmonary disease (COPD). To better understand the effect of tobacco, E-cigarettes, E-cig pens, and vaping, the International Organization of Standards (ISO) has developed standards around cigarettes, E-cigarettes, and vaping machines; ISO 3308:2012 for tobacco and ISO 20768:2018 for vaping machines. These standards define what is considered a typical puff from a tobacco or vape device.

These standards describe the conditions where a test device (vaping device, 1st Generation E-Cig, or tobacco cigarette) can be “smoked” in a consistent manner. These conditions include but are not limited to puff duration, puff volume, and puff frequency. Below is an example of the “Bell Shaped Puff Profile” used for tobacco cigarettes and the “Trapezoidal Puff Profile” used for vape devices (**Figure 1**).

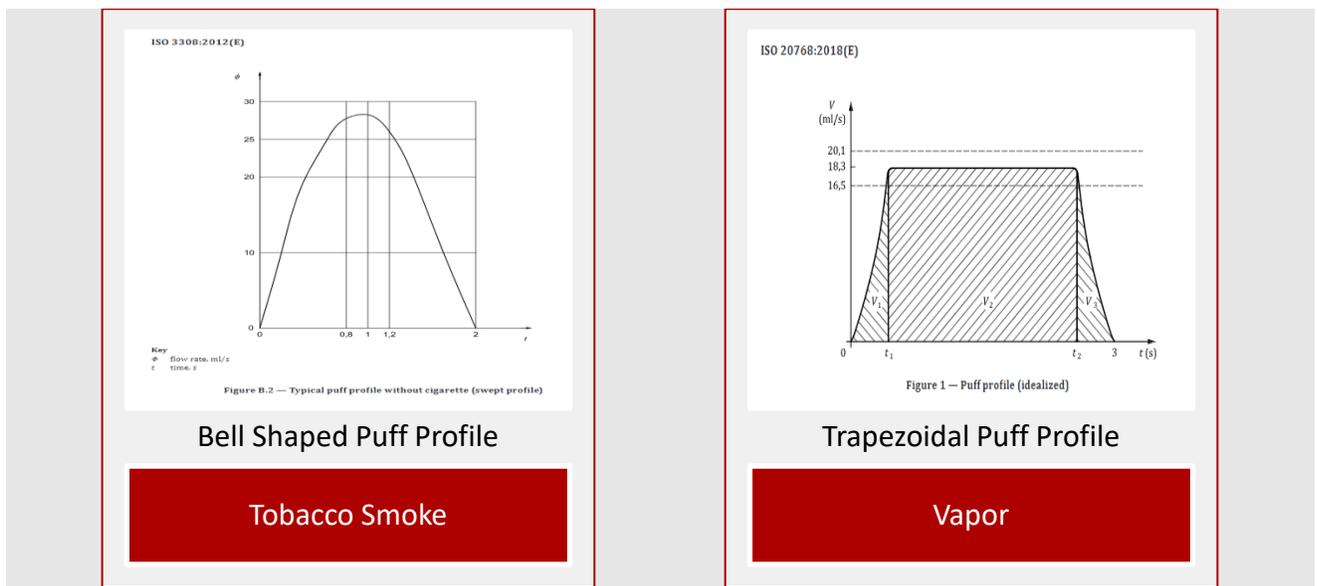


Figure 1 - Tobacco Smoke and Vapor Puff Profile

ISO 3308 also defines the design of a standard cigarette holder and labyrinth seals. Per ISO 20768, this same holder may also be used for electronic vapor products. Below is an image of the “EVT Labyrinth Seal Assembly” used by the EVT Generator with tobacco cigarettes or non-actuated electronic vapor products.



Figure 2 Labyrinth Seal Holder

The EVT Smoke Generator is designed to generate aerosolized particulates from a cigarette, a 1st Generation E-Cig, a Pen, or a Mod device by creating “Standard Puffs”, following the standard puff profiles.

TERMINOLOGY

E-cigarettes, sometimes called E-cigs, vapes, or handheld electronic nicotine delivery systems (ENDS), are devices that create vapor by heating an element that atomizes a liquid solution. This vapor, called Vape, consists of fine and ultrafine particles of particulate matter, usually nicotine and flavors. There are several different devices available on the market today that are used for vaping. E-cigarettes come in many shapes and sizes. Most have a battery, a heating element, and a place to hold a liquid. Some of these devices are activated simply by drawing air through the device, and some devices are activated by a push-button.

1. **Cigarette** – This is a traditional tobacco cigarette. DSI uses the Kentucky Research Cigarette 34F, but any traditional cigarette that is between 7.5mm and 9mm in diameter will fit into the labyrinth seal.



Figure 3 - Cigarette (Traditional)

2. **1st Generation E-Cig** – Also known as E-Cigarette or E-Cig or Cig-a-Like. It is a Cigarette shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution. Some of them are rechargeable and refillable. Others are intended to be disposed of after use. 1st Generation E-Cig users inhale the way they would with a regular cigarette. This inhalation activates the atomizer to heat the liquid in the cartridge and convert the liquid to a vapor. They are designed to mimic the look and feel of combustible cigarettes.

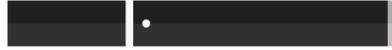


Figure 4 - 1st Generation E-cig

3. **Pens** – Advanced Personal Vaporizers (AVP). Larger than a cigarette, Pens often have a higher capacity battery, may contain a prefilled cartridge or refillable cartridge. These devices come with a manual switch for activating the vape solution.

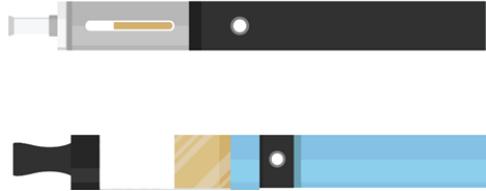


Figure 5 – Pens

4. **Mod Device** - Mod Vape Devices are much larger than a cigarette with a higher capacity battery and typically contains a large refillable cartridge. Like a Pen, Mods have a manual activation button.

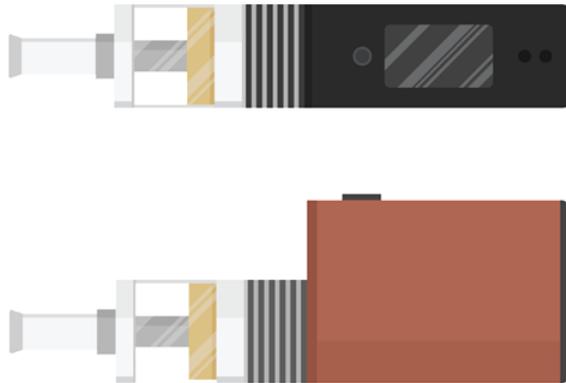


Figure 6 – Mods

SYSTEM OVERVIEW

Data Sciences International has developed the Buxco® EVT Smoke Generator. The EVT Smoke Generator is designed to generate aerosolized particulates from a cigarette, 1st Generation E-Cig, Pen, or Mod devices. The EVT Smoke Generator is designed to meet both traditional cigarette and e-cig ISO standards for puff profiles, as well as provide the user the ability to customize puff parameters. The system can be utilized with both button actuated, as well as non-actuated e-cig devices.

The EVT Smoke Generator is designed for both routine analytical in-vitro testing as well as deliver smoke/vape to various exposure applications, including Inhalation Tower Exposure, and Mass Dosing Chambers.

Puff inhalation and exhalation are accomplished with the use of a patent-pending bellows design. With this design, the bellows are set into motion by a precision stepper motor driven piston. Moving the bellows draws smoke or vapor from the test article into the EVT and finally out to the intended in-vitro or whole animal exposure apparatus. The smoke or vape is contained in a controlled path from the test article to the exposure apparatus, preventing contaminants from fouling sensitive components of the EVT generator, or contaminating the aerosol stream. The bellows assembly components that come in direct contact with smoke or vape product are disposable, making maintenance simple and inexpensive.

The EVT Smoke Generator can be used with tobacco cigarettes and 1st generation E-cigs. It can also be used with button activated Pen or Mod devices. To use any button activated device with the EVT Smoke Generator, you will need a Button Activated Device Holder Accessory Kit (optional).

The EVT Generator can be used as a stand-alone system or in conjunction with several available accessories including: In-Line Photometer Adapter, Button Activation Kit, In-line Reservoir Kit, and the Buxco Supplemental Flow Unit. The In-Line Photometer Adapter can be used to measure the concentration of smoke or vape generated by the EVT. The Supplemental Flow Unit can be used to dilute the output flow to help establish target concentration levels. The In-line Reservoir can aid in mixing and reduce the pulsatile nature of the concentration output if desired.

The EVT Smoke Generator supports use of up to three stations. Each station can be used to sample a single test article. With the use of multiple stations, the EVT Smoke Generator can be configured independently, where one station can be sampling from a tobacco cigarette and another station from an electronic test article. Also, multiple test articles can be operated simultaneously, and exhalation outputs combined, providing an increased puff volume and overall total test material. All three stations can be combined into one smoke or vaping output.

SYSTEM COMPONENTS

This section will provide information on the components of the EVT Smoke Generator. Additional accessory items may be necessary depending on the type of device being sampled or study design.

The following components can be part of an EVT Generator system. Some of these items are optional and are not necessary, depending on the exposure system configuration.



Figure 7 - EVT Generator Components

1. Buxco EVT Smoke Generator Controller

The Buxco EVT Smoke Generator Controller is the base unit used in the EVT Smoke Generator. The Controller contains all the electronic and mechanical hardware required to operate an EVT Smoke Station and generate a standard or customizable “puff”. The EVT Controller also interfaces with the EVT Puff Volume Measurement Kit for calibration and or post-calibration puff volume assessment. The optional In-Line Photometer Adapter is used to measure particulate concentration levels of the resultant flow. The Buxco Supplemental Flow Unit can be used to generate a bias flow for fresh air delivery or to be used to dilute the output concentration stream. The EVT Smoke Generator Controller communicates with the EVT Software via USB connection. The EVT Smoke Generator Controller accepts a regulated, external air supply, 100 psi (6.8 bar) max, for use with button actuated devices. *For more information on setting up external air supply, see: **Setting the Air Pressure for the EVT Button Activation Device Holder Kit.***

2. Buxco EVT Station

The EVT Station is a module that connects to the Controller and houses the hardware mechanisms necessary to create the “puff”. A high precision stepper motor generates a puff cycle. The motor controls the displacement of a piston-cylinder, which in turn produces pressure that actuates the bellows assembly. During inhalation, a vacuum is created at the Inhalation Port. This vacuum draws air through the test article into the bellows assembly. During exhalation, the piston moves back to its home position, in turn, generating a positive pressure on the bellows, causing the smoke or vape to be pushed out through the Exhalation Port.

The Buxco EVT Smoke Generator Controller can control up to three Buxco EVT Stations. Each station can be operated independently from each other, allowing for a sampling of different test articles at the same time. Multiple stations can, alternatively, be operated synchronously, enabling the outputs to be combined for increased puff volume and aerosol mass.

3. Buxco Bellows Assembly

Each Buxco EVT Station comes with a patent-pending bellows assembly. The bellows assembly provides two essential features:

- a. The bellows, including check valve lid, contains the smoke or vape and isolates it from the outside environment and any EVT components that may otherwise be fouled over time.
- b. The bellows assembly provides easy maintenance, necessary as cigarette or vape builds up from use. The bellows assembly is simple to replace for easy maintenance.

4. EVT Puff Volume Measurement Kit

The mass flow meter provided within the EVT Puff Volume Measurement Kit must be used to calibrate the EVT Station any time a bellows assembly is installed and or when switching from bell-shaped (traditional) to trapezoid (e-cig) puff profiles. It may also be used to characterize the puff volume any time before or after an experiment. Puff volume is determined by integrating the flow rate throughout the puff cycle. The pre- and post-puff volume measurement indicates how much the puff volume may have changed during the experiment. The user can then decide if they want to make any adjustments in their experiment data based on this change. The pre- and post-puff volume measurement is stored in the experiment datafile. It is good practice to verify puff volumes using the measurement kit at the beginning and close of a study.



CAUTION. Test article smoke or vape should never be passed through the mass flow sensor directly. Failure to keep smoke or vape out of the sensor could invalidate calibrations or damage the sensor.

5. Buxco Supplemental Flow Unit (optional)

The EVT Controller can power and regulate up to three Buxco Supplemental Flow Units. The flow set point of a given unit is established within the EVT Software. The in-line Photometer Adapter can be used in conjunction with the Supplemental Flow Unit to provide additional control over aerosol concentration levels. With the use of a Supplemental Flow Unit, concentration levels below that which can be established with the use of the EVT alone can be achieved.

6. In-Line Photometer Kit (optional)

The Buxco In-Line Photometer can be used to measure the concentration levels of smoke or vape being delivered to an in-vitro or in-vivo exposure system. The In-Line Photometer measures aerosol concentration levels being delivered to the exposure system and provides that information to the Controller and reported out by the EVT software.

EVT SMOKE GENERATOR CONTROLLER

The EVT Smoke Generator Controller is designed to be the interface between the EVT Smoke Generator Stations, EVT Puff Volume Measurement Kit, the EVT In-Line Photometer Adapter, and the computer with EVT Software. The Controller houses the pneumatic, electrical, and mechanical connections for the station, as well as various accessories. It communicates via USB with the EVT software. The EVT Smoke Generator Controller can control up to three EVT Stations.

The EVT Controller Left Side Panel allows for connecting three auxiliary items; the Buxco Supplemental Flow Unit used to control dilution rates or provide supplemental fresh airflow, the In-line Photometer Adapter for measuring smoke/vape aerosol concentration levels and accumulated mass, and the EVT Puff Volume Measurement Kit used during calibration or when validating puff volumes.

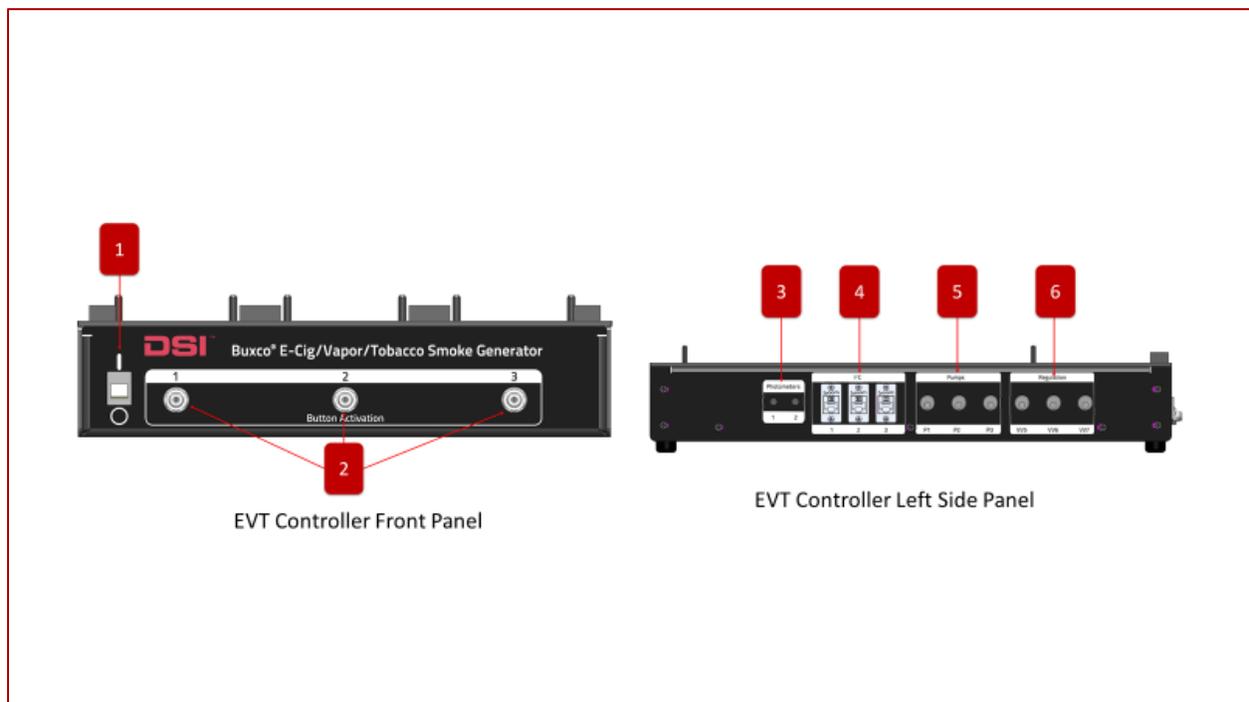


Figure 8 - EVT Smoke Generator Controller

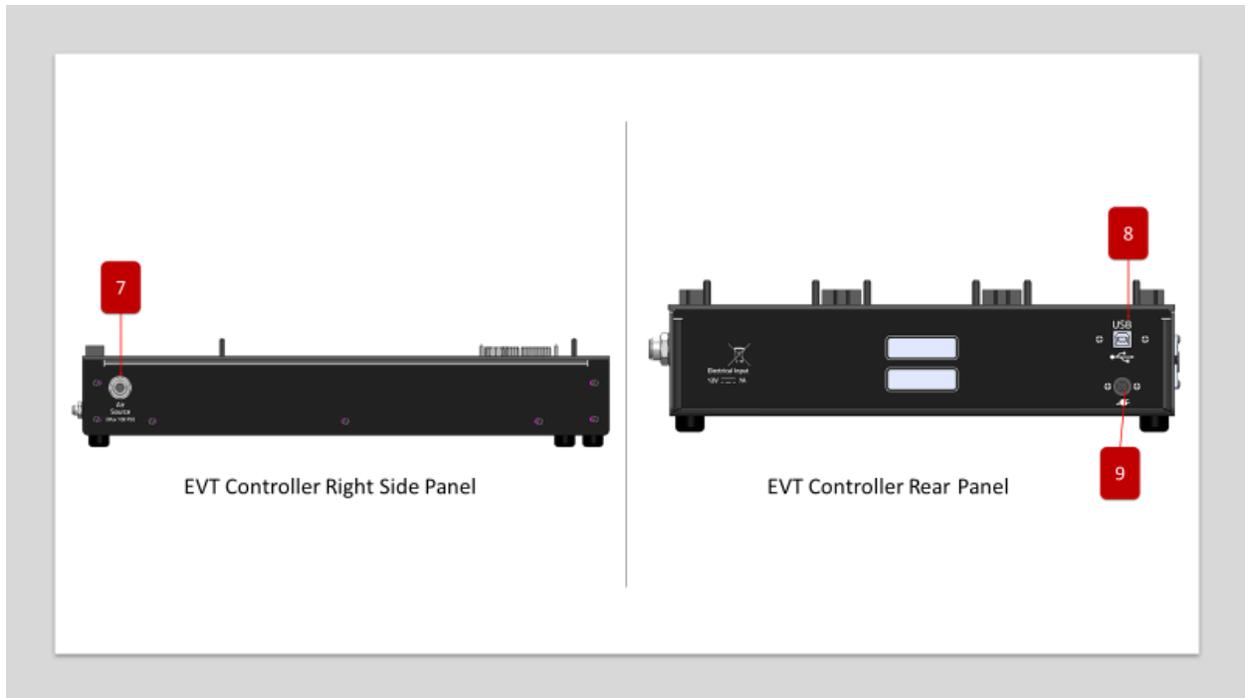


Figure 9 - EVT Smoke Generator Controller

1. On/Off Switch

It is used to turn the power to the EVT Controlled on and off.

2. Button Activation Ports

These three pneumatic ports are for use with optional Button-Activated Device Holder Kit(s). With the use of the kit(s), Pen and or Mod-type actuated devices can be triggered synchronously with puff generation (See EVT Button-Activation Kit under Auxiliary Attachments for more details).

3. Photometer Inputs

The EVT Controller left side panel has two 3.5mm phone jacks designed to accept analog signals from the EVT In-line Photometer. Signals from the photometer are connected to the EVT Front Panel to be read by the EVT Software.

4. I²C Connectors

The I²C Connectors are used to connect the EVT Puff Volume Measurement Kit or Supplemental Flow Units to the EVT Smoke Generator Controller. The first I²C connection can be used with either an EVT Puff Volume Measurement Sensor, or a Supplemental Flow Unit. The 2nd and 3rd I²C connections are to be used only with Supplemental Flow Unit(s).

5. Pumps Connectors

The EVT Controller can connect to up to three Supplemental Flow Units, providing individual control for each. The **Pump** connectors work in conjunction with the **Regulation** connectors to control the flow rate of the Supplemental Flow Unit. One I²C, one Pump Connector, and one Regulation Connector is needed for each Supplemental Flow Unit.

6. Regulation Connectors

The EVT Regulation Connectors are used in conjunction with the Pump Connectors to operate Supplemental Flow Unit(s). One I²C, one Pump Connector, and one Regulation Connector is needed for each Supplemental Flow Unit.

7. External Air Source

The EVT Smoke Generator Controller requires an external air supply when used with the EVT Button-Activated Device Holder Kit. It is not necessary for non-button activated products.

8. USB Connector

The EVT Smoke Generator Controller communicates with the EVT Software via standard USB connection.

9. Power Supply Connector

The EVT Generator is powered via an external power supply.



CAUTION. *Only an approved DSI Power Supply should be used with the EVT Smoke Generator Controller.*

EVT SMOKE GENERATOR STATION

The EVT Smoke Station generates the desired puff profiles by pulling smoke/vapor into and out of the bellows assembly using a precision stepper motor. Each station contains a stepper motor, piston cylinder, and bellows assembly such that each station can function independently. Puffing with multiple stations can also be synchronized through the EVT Controller if desired, allowing the exhale ports to be combined. This provides a larger puff volume than can be delivered by each station independently.

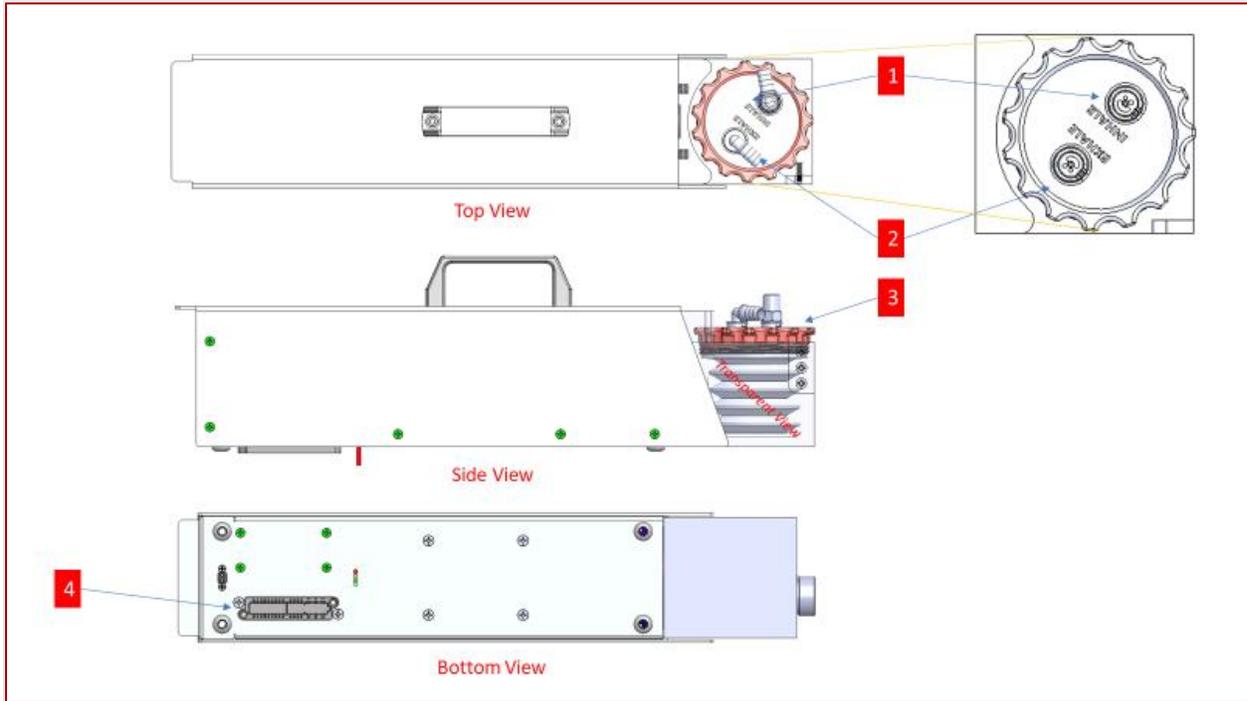


Figure 10 - EVT Station

1. EVT Station Inhale Port

The Inhalation Port is where the Tobacco, 1st Generation E-Cig, or Vape device will be connected. Smoke/vape is drawn into the bellows assembly from the tobacco/vape source at the Inhalation Port.

2. EVT Station Exhale Port

The Exhalation Port is where the puff sample exits the bellows assembly. From here, it can be plumbed directly to an exposure assembly or diluted with additional air supplied by a Supplemental Flow Unit measured for concentration levels with an In-line Photometer.

3. **EVT Bellows Assembly**

Generating tobacco smoke or vape samples creates a harsh environment for sensitive electronic and mechanical components. Residue can cause early failure, particularly on moving parts and electronic components. The Buxco EVT Station is designed to capture and control tobacco and vape samples isolating the aerosol from the external environment and minimizing exposure to any sensitive EVT components. The bellows assembly is intended to be easily removed and made disposable, making maintenance effortless and inexpensive.

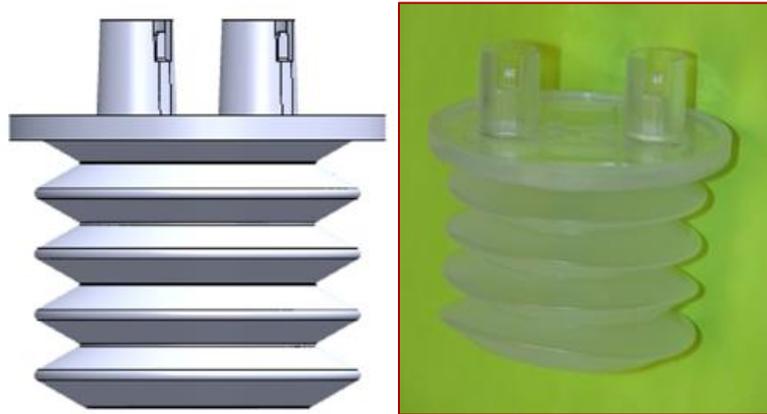


Figure 11 - Bellows Assembly

4. **EVT Station Panel Connector**

The EVT Station is connected to the EVT Smoke Generator Controller through a blind-mate connector allowing for quick, easy connect and disconnect. All power and communication between the Controller and the station are done through this connector.

STEPS TO CONNECT AND REMOVE AN EVT STATION FROM AN EVT SMOKE GENERATOR CONTROLLER

It is easy to connect and remove an EVT Station from an EVT Smoke Generator Controller

1. Place the EVT Smoke Generator Controller on a flat, stable surface.
2. With EVT power switch in the off position, attach the provided power supply between Controller and power outlet. See Figure 9, item 9, for power connector on Controller.
3. Lift the EVT Station by the handle and tilt the bellows side slightly downwards.
4. Insert the bellows side of the station into the alignment tabs located on the top right side of the Controller.
5. Once the bellows side of the station is seated in the alignment tabs, make sure the alignment pins and guides are aligned and push the back of the station onto the Controller.

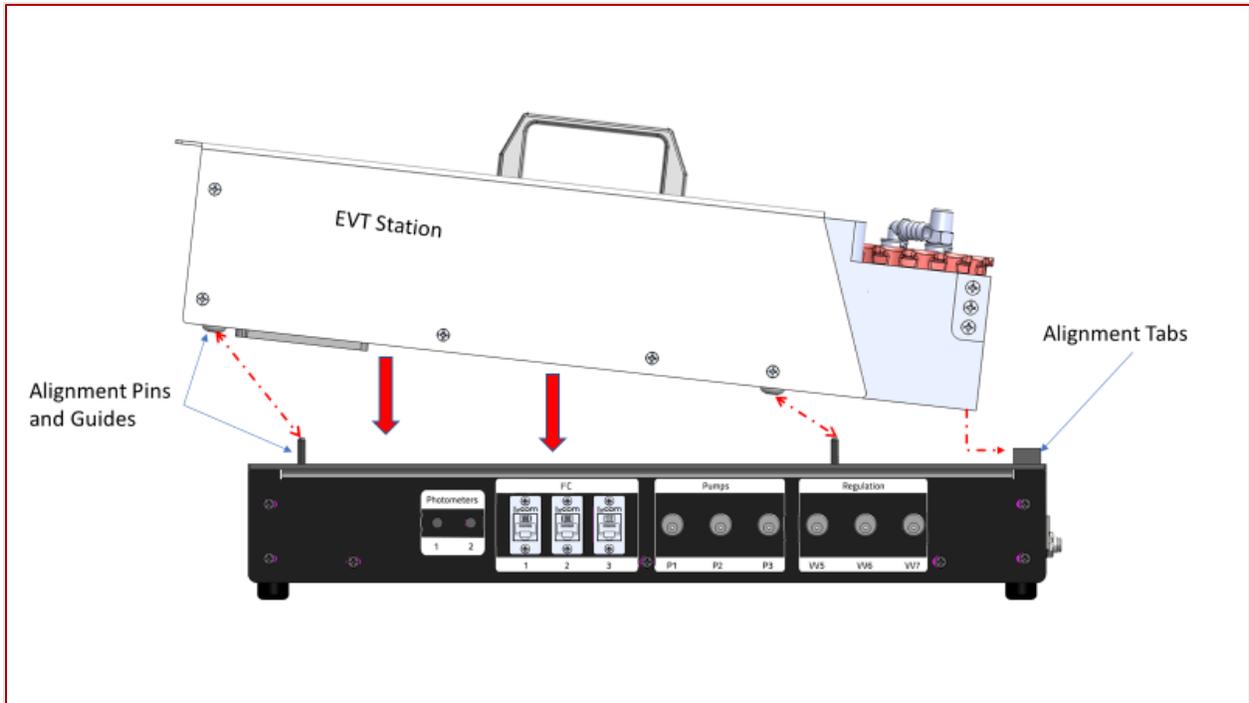


Figure 12 - Attaching the Station to the Controller

Turn on the EVT Controller. Verify that power is being applied to the EVT Station by checking that the blue LED is illuminated, as shown by the picture in Figure 13. *Note, LED may take a few seconds before lighting as the motor driver initiates, and the system verifies the station piston is at the “home” position.*



Figure 13



CAUTION. Always make sure the Controller Power is off before attaching or detaching the station. Failure to do so could damage the Controller or station. This is particularly critical if the station is under power and actively puffing. The system does contain fail-safe spring contacts to minimize such risks, but it is still good practice.

Also, make sure that the light in the station comes on when the Controller is powered up. If the light does not come on, press down on the back of the station to make sure it is fully seated into the Controller connector.

PHYSICAL SETUP (INHALE PORT)

The EVT Station can be configured to capture “Puffs” from different devices, including tobacco cigarettes, 1st Generation E-Cigs, Pens, and Mods. More information on these different configurations is available in the appropriate sections to follow.

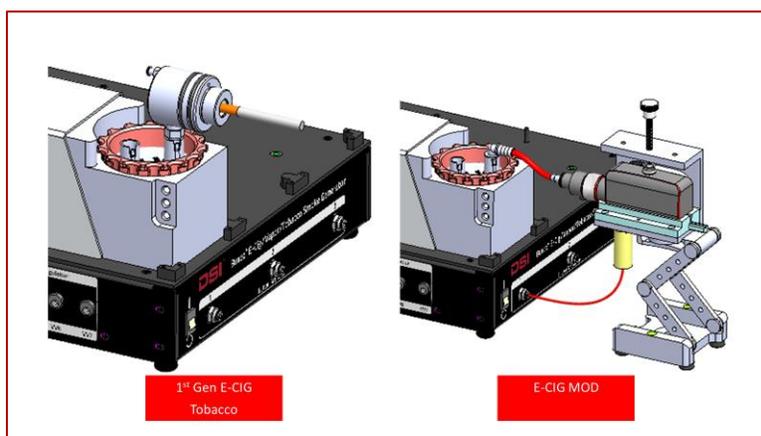


Figure 14 - 1st Generation E-Cig and Mod Example

BELLOWS ASSEMBLY

DSI has developed a unique approach to simulating a “puff” from tobacco or vape devices. A puff is achieved by drawing air through the cigarette or vaping device into the bellows assembly through the Inhale Port and back out through the Exhale Port. The volume and speed of the puff are established by the precise control of the stepper motor and piston. This control allows the system to produce ISO Standard Puffs with a high degree of accuracy (see **Figure 15**) but also enables users to specify custom puff parameters.

As the stepper motor actuates the piston, the pressure generated first expands the bellows, a vacuum is created, drawing air through the cigarette or vaping device. During exhale, the stepper motor returns the piston to the home position, in turn generating a positive pressure that collapses the bellows, pushing the sample of smoke or vape collected in the bellows out through the Exhale Port.

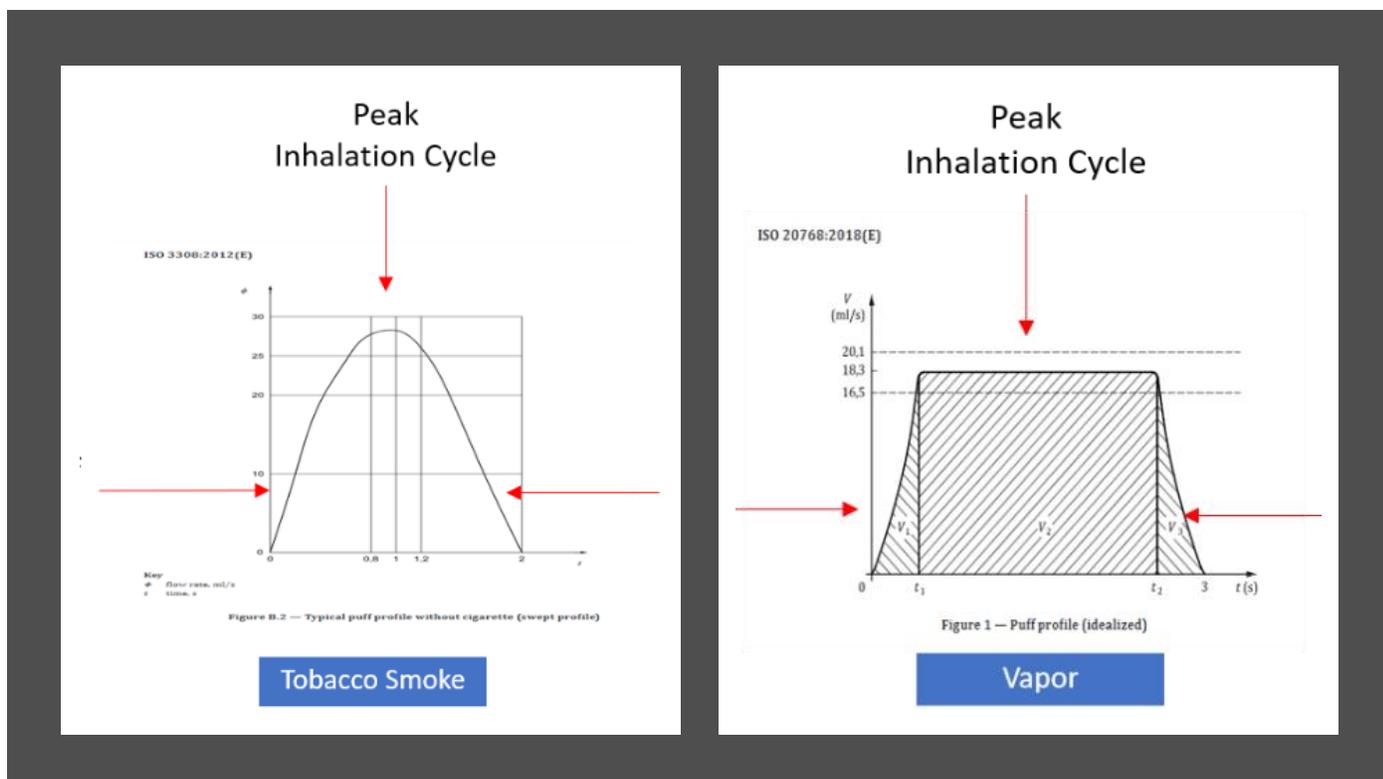


Figure 15 – ISO Standard Puffs for Tobacco and Vape

The bellows, and the valves contained within the bellows lid, are the only moving parts exposed to the harsh environment of smoke or vape aerosol. The aerosol is contained within the bellows assembly, making them the only parts that require regular cleaning and or change out.

CHANGING AND CLEANING THE BELLOWS ASSEMBLY

The bellows assembly, which contains the bellows and the bellows lid with inhale and exhale valves, are exposed to contaminants from the tobacco smoke and vape. This may cause the bellows and valves to become sticky over time. The bellows assembly is designed to be disposable and should be replaced with a new bellows assembly when excessive contamination is visible that cannot be easily cleaned. Depending on how much it has been used, it is possible to clean the bellows and the bellows lid valves periodically.

For more information on how to change and clean the bellows assembly, please see "**Replacing and Cleaning the Bellows Assembly**" in the "**Lifespan, Maintenance, & Troubleshooting, Misc**" section of the manual.

QUICKSTART GUIDE - EXAMPLE EXPERIMENT

The following is an example of how the EVT Smoke Generator and the EVT Software would be used in an experiment. This example will walk you through each step needed to set up and run an experiment and show you how easy it is to begin using the EVT.

For this example, we will use an 1st Generation E-Cig. The cigarette will be attached to the EVT using the Labyrinth Seal Assembly. We will not be using the sidestream containment tube, so this test should be done in a fume hood or area where any sidestream smoke can be removed.



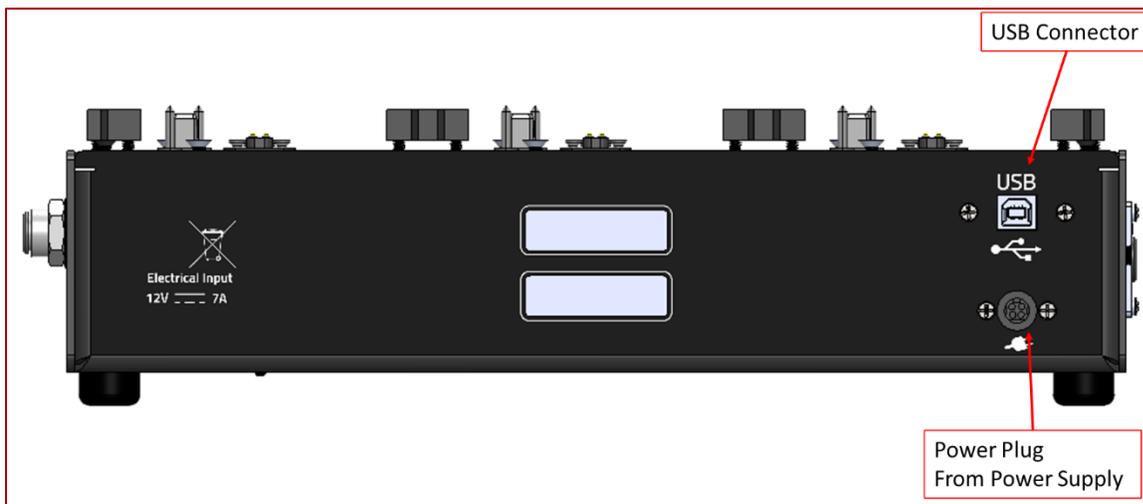
CAUTION. Please consult your institution's guidelines for proper containment and PPE when working with smoke and or vape aerosol.

Before proceeding through this section, please install the EVT Software on the PC you plan to use with your EVT system. The EVT software is located on the USB drive provided.

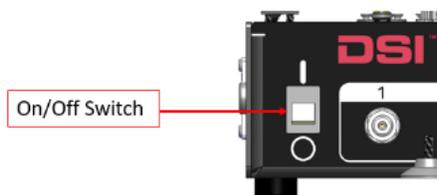
To install, simply locate the EVTSetup application on the USB drive, double click, and follow the instructions in the installation wizard.

STEP 1 – CONNECTING THE EVT CONTROLLER TO A COMPUTER AND POWER SUPPLY

The EVT is powered by a power supply brick plugged into the back of the controller. The Controller communicates with the EVT Software on a PC via a USB cable. Both power supply and USB cable are provided with the EVT system.

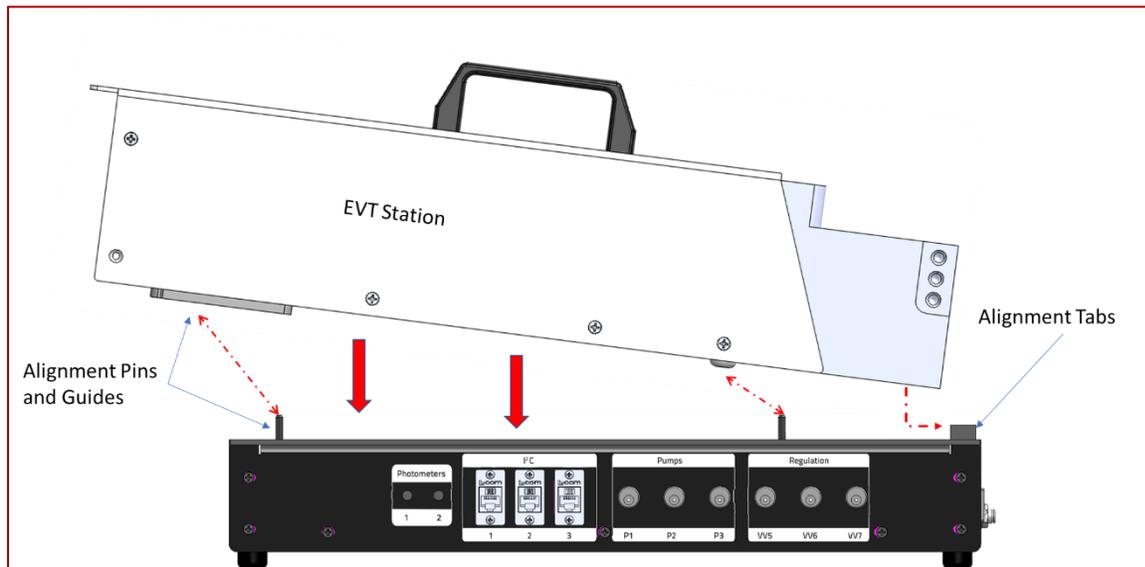


Once the power supply and USB cable have been connected, make sure EVT Controller is powered off before attaching station.

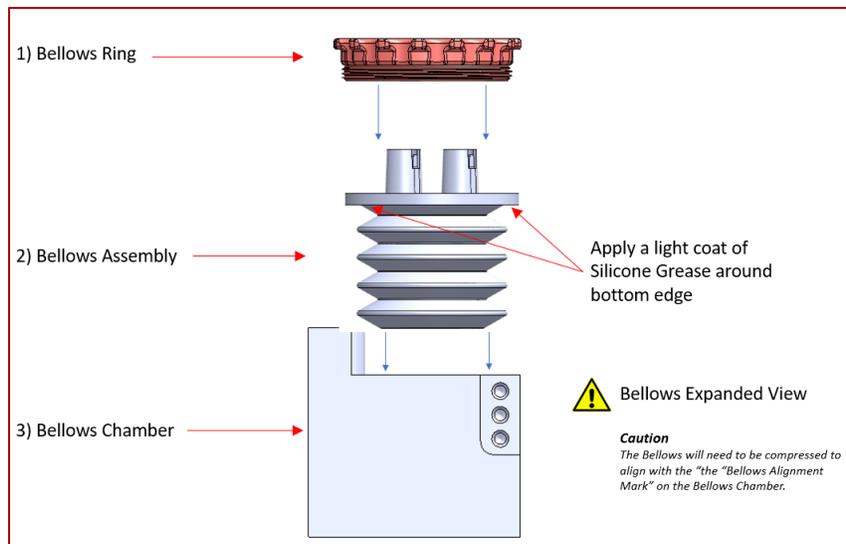


STEP 2 - CONNECTING AN EVT STATION TO THE CONTROLLER

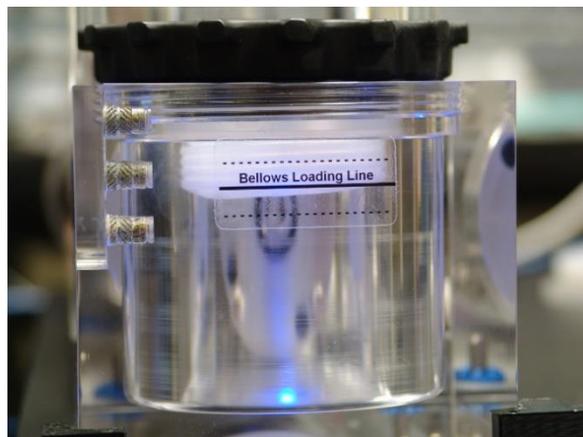
1. Place the Controller on a flat, stable surface.
2. Lift the EVT Station by the handle and tilt the bellows side slightly downwards.
3. Insert the bellows side of the station into the alignment tabs located on the top right side of the Controller, as shown in the figure below.
4. Once the bellows side of the station is seated in the alignment tabs, make sure the alignment pins and guides are aligned and push the back of the station onto the Controller.
5. You should now switch on your controller and verify the station LED comes on.



Install a Bellows assembly into the Bellows assembly housing of the EVT Smoke Generator Station. Please be sure to add a little grease around the lower edge of the bellows assembly to prevent a leak. Grease and a small applicator swab are part of the EVT Station Accessory kit.



CAUTION: Before beginning any experiment, make sure to install/replace the Bellows Assembly only after the station has been powered up and in "home" position (LED light is on). Also make sure Bellows is in a compressed state and such that it is aligned with the bellows loading line. If not, remove the bellows and adjust accordingly. The bellows should be as close to the loading line as possible. Failure to do so could cause bellows to "bottom out" to the bellows

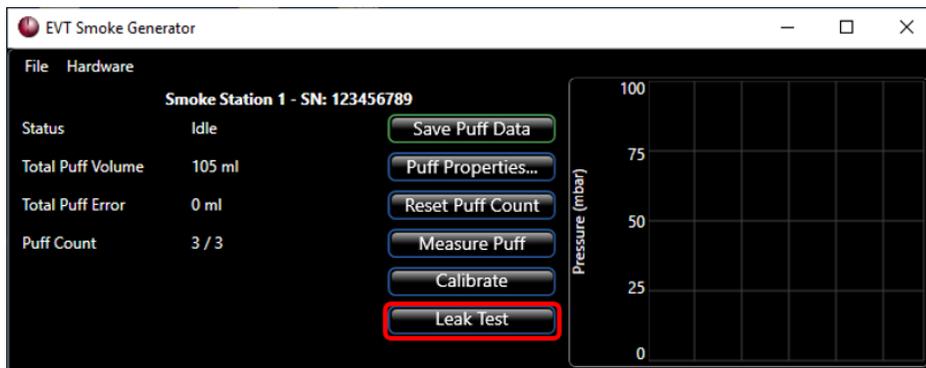


- Before running an experiment, two tests need to be performed. The bellows assembly should be checked to verify there are no leaks
- The bellows assembly needs to be calibrated, and it is recommended puff volume be measured both prior and post-study.

STEP 3 – PERFORMING A LEAK TEST

The leak test assures that the system is sealed correctly.

- 1) Launch the EVT Software by double-clicking on the EVT Application Icon.
- 2) Click on **Leak Test**



The Leak Test window will open.

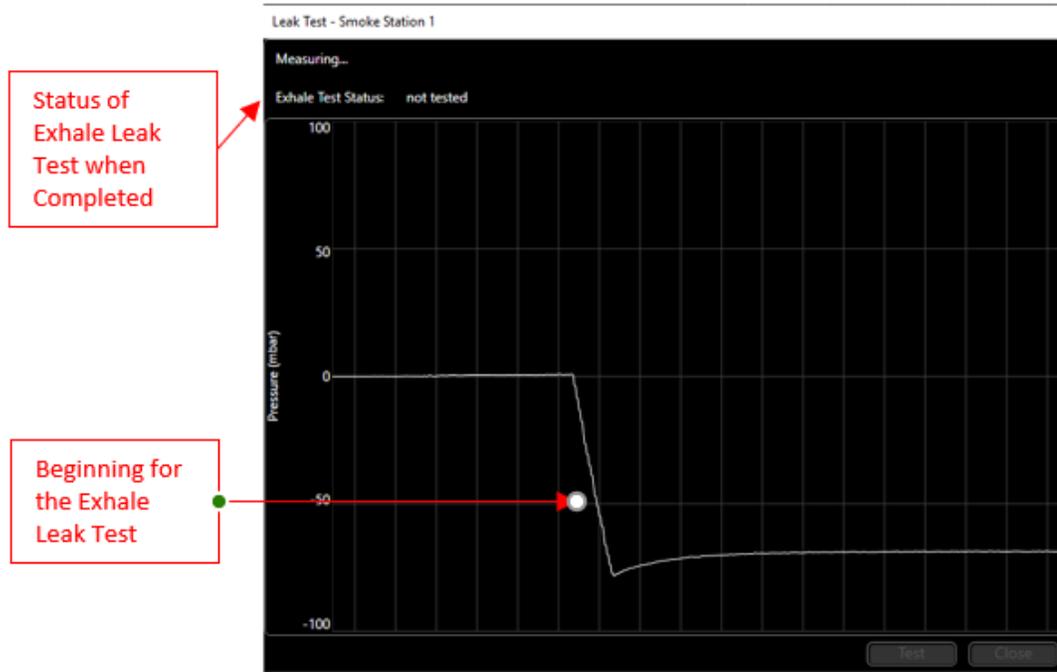
Instructions can be found on the top of the Leak Test screen. The status of the leak test can also be seen at the top of the screen.



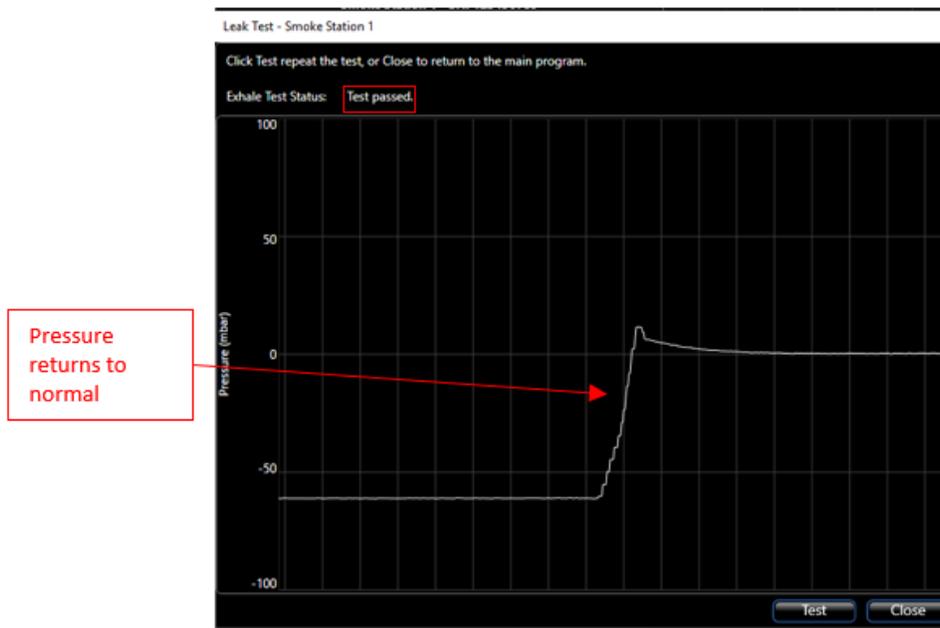
- 3) Start by inserting a leak test plug into the Inhale Port of the bellows lid (a leak test plug as shown is provided in the Station Accessory kit).



- 4) Click on the **Test** button. The Exhale leak test will begin. The pressure measurement should drop sharply negative, then decay for a time in a positive direction, and finally, stabilize to a flat line at negative pressure. After roughly 30 seconds, the Exhale Test Status should indicate that the test passed.



- 5) At the end of the test, the Exhale Test Status should indicate Test Passed, and the pressure reading should return to normal. If leak test should fail, check to make sure bellows ring is secure, and grease is present between bellows and the bellows chamber mating surfaces. Subsequent failures may indicate bellows assembly should be changed.



STEP 4 – PERFORM A CALIBRATION AND PUFF VOLUME MEASUREMENT TEST

The bellows assembly calibration is necessary to achieve accurate puff volumes. The calibration routine makes adjustments to the system to account for flow resistance and measured puff volume.

Before beginning an experiment, it is recommended that you calibrate each station and capture a puff volume measurement.

The EVT Puff Volume Measurement Kit, see EVT Puff Volume Measurement Kit – Parts List section for more information on the parts, will be used to calibrate the bellows assembly and measure the volume of the puff during a puff cycle. For more information on measuring the puff volume, see the Measuring the Puff Volume section of the manual.

PERFORMING A CALIBRATION

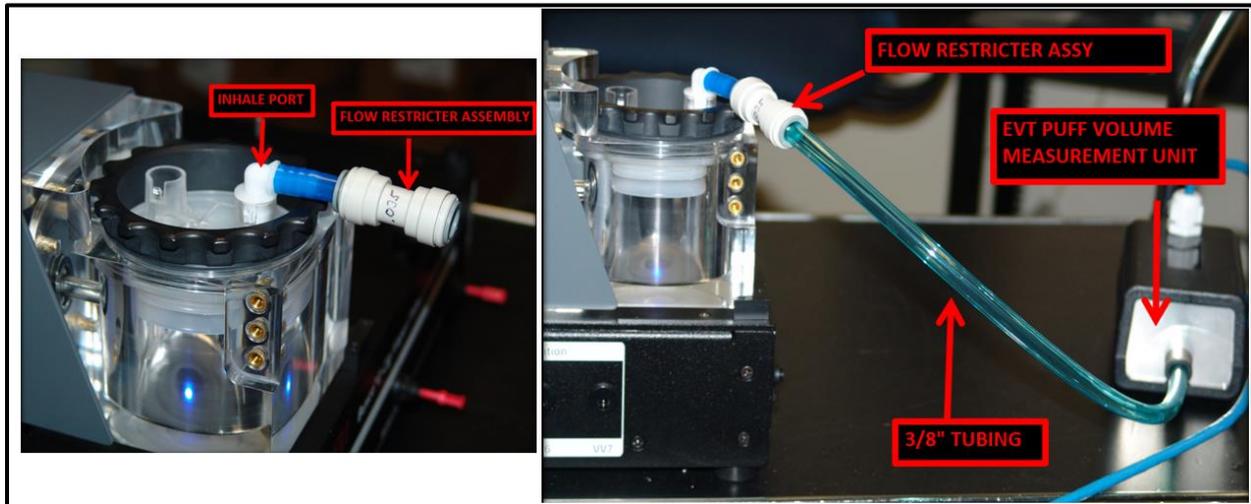
Different type of cigarette/e-cigarette will have different resistant values. The calibration process is used to determine the resistant value in order to ensure the puff properties specified in are achieved.

- 1) Connect the Flow Restrictor Assembly that came with your EVT system to the bellows assembly lid at the Inhalation Port, as shown below.
- 2) Connect a 3/8" tube from the inlet of the Flow Restrictor assembly to the Mass Flow Meter.



Take note which side tubing is connected to mass flow sensor, the direction of flow should agree with the arrow label on top of the mass flow sensor.

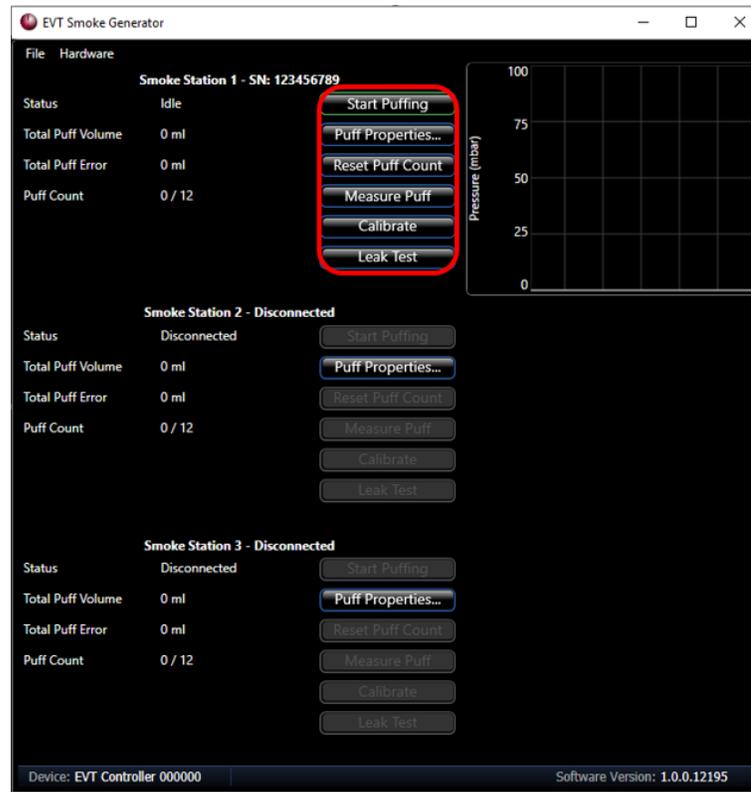
- 3) Connect the cable from the Mass Flow Meter to position “1” of the I²C connections on the EVT Smoke Machine Controller. Make sure that the flow direction is aligned correctly with the direction indicated by the arrow on the top of the flow meter. Also, make note of the Slope and Offset values listed on the calibration label on the Mass Flow Meter.



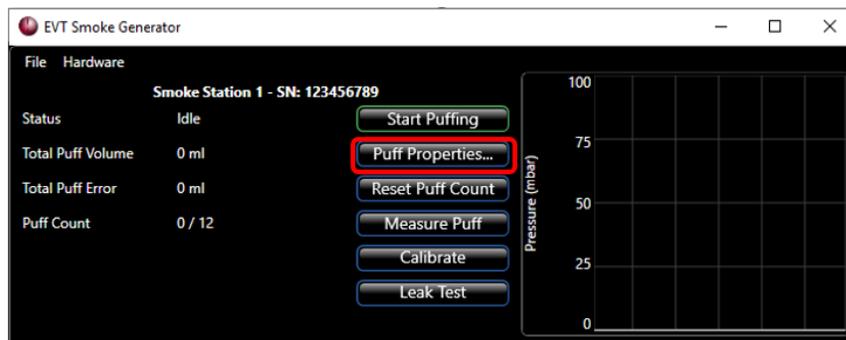
- 4) Launch the EVT Smoke Machine Software by double-clicking on the EVT Software Icon.



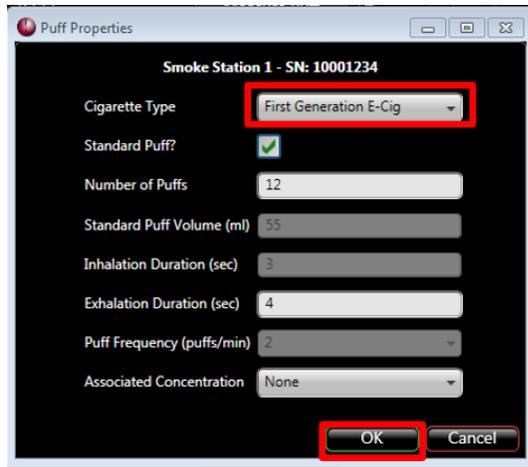
The EVT Software Main Window should open. Make sure that the setting selections highlighted below are enabled (not grayed out), and the Pressure graph is scrolling.



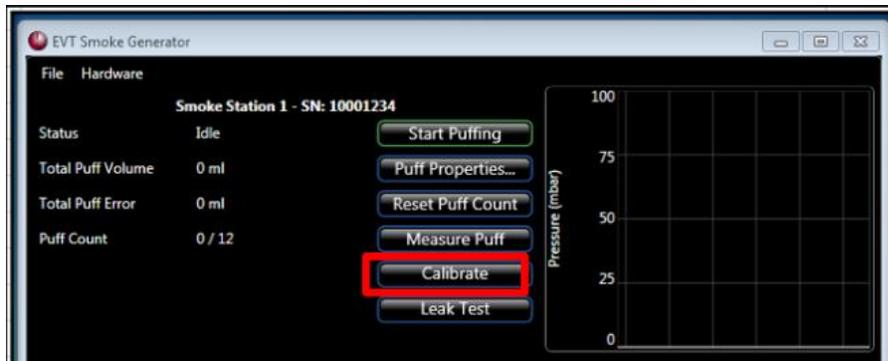
- 5) Click on the “Puff Properties” button.



- 6) Select “First Generation E-Cig for the Cigarette Type, or Traditional Cigarette if using a Bell-shaped puff profile.
- 7) Make sure the “Standard Puff” checkbox is checked.
- 8) Click OK

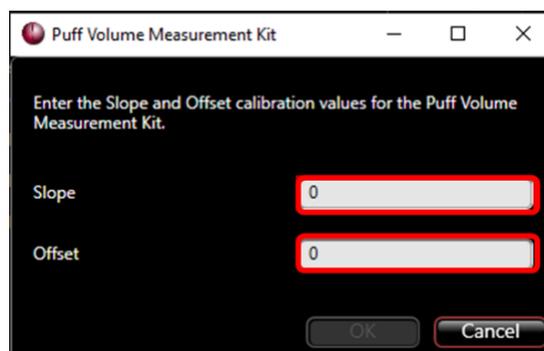


9) Click the “Calibrate” button.



10) The Calibration window will open.

If this is the first time that you have calibrated using the Mass Flow Meter, a secondary window will open, allowing you to enter the Slope and Offset calibration values for a specific Mass Flow Meter. The Slope and Offset values are found on a label on the Mass Flow Meter.



11) Click OK, and the Calibration window will open.

Click the calibrate button, and the calibration process will begin. Information on the status of the calibration process is indicated on the top left portion of the Calibration window.



First, the zero-flow baseline pressure is measured. This is quickly followed by puff cycles. During this time, the response time of the puff pressure is measured. This process is repeated five times, and the average response time is calculated. The status of the calibration process is indicated in the top left part of the window. Example: “Measurement 2 of 5 complete, preparing for the next measurement”. The response time of the system is indicated at the bottom of the screen. The example shows a rising edge response time of 0.171 seconds and a falling edge response time of 0.185 seconds. These time constants are indicative of the flow resistance and are used by the system to adjust the acceleration and deceleration phases of the puff profile accordingly.



- 12) When the calibration process is complete, the software will display “Measurement Complete” and the system will be ready to measure a puff volume.

The Calibration window will indicate the current puff volume setting and the measured puff volume. The initial puff volume is 0.00 ml since we have not yet run the puff volume measurement process.

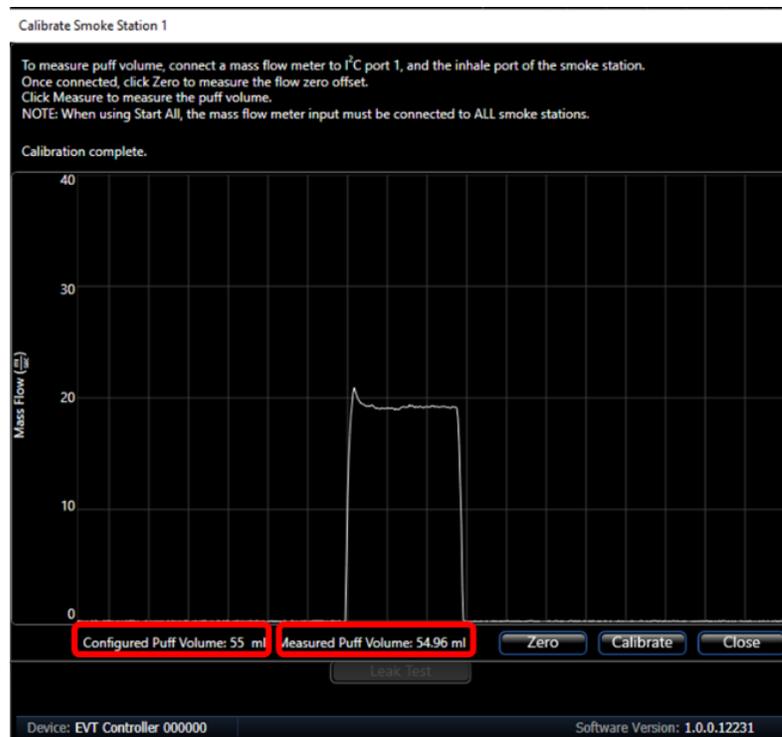


- 13) Start the Puff Volume Measurement process by clicking the “Zero” button. The EVT system will quickly measure the flow offset. Once completed, click the “Calibrate” button.

Take note -- make sure when zeroing that the mass flow sensor is connected to the inhalation side of bellows assembly. If unconnected, ambient airflow from a hood or similar could otherwise impact accuracy.

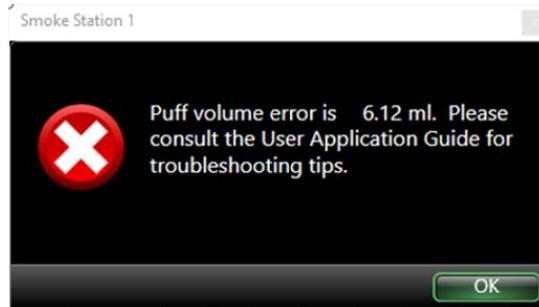


- 14) The EVT system will begin measuring a puff volume. First, it will measure the baseline flow. Then it will measure a puff volume. It will repeat this process three times. When completed, the configured volume and the measured volume will be displayed at the bottom of the window.



- 15) Once the calibration process is complete, click "Close."

The maximum allowable calibration error is ± 4.0 ml around the expected volume. If the measured volume error is greater than 4.0 ml, the EVT software will indicate an error (see example error message below). If this occurs, repeat leak test to make sure you have a leak-tight system and check that your mass flow sensor is attached correctly as outlined in Step 4 – Perform a Calibration and Puff Volume Measurement Test.



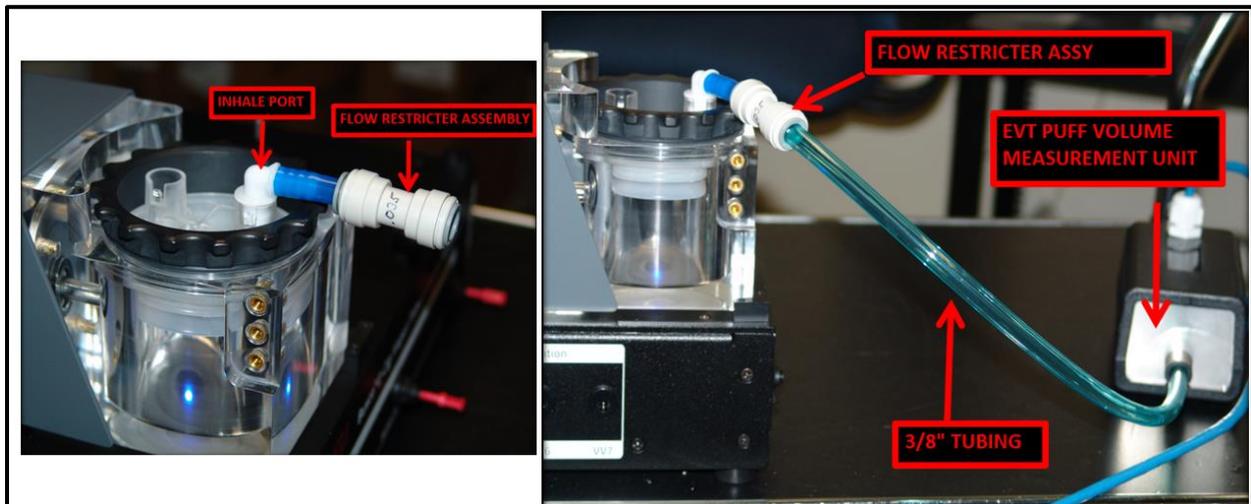
MEASURING THE PUFF VOLUME

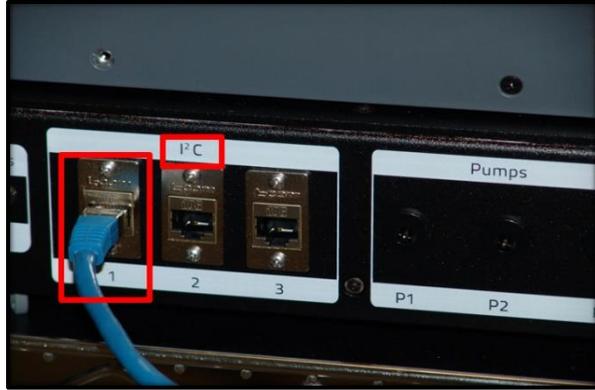
It is possible to measure the puff volume anytime, without performing a full calibration. This is not a required step. The value of running the puff volume prior to and post puff delivery is that you can confirm that the puff volume is the same both times. This will confirm to the researcher that nothing has changed during the course of the experiment and the system is running as expected.

To measure the puff volume, you will need to connect the Puff Volume Measurement Kit.

Follow the same setup procedure as used in the calibration process:

- 1) Connect the Flow Restrictor Assembly to the Bellows assembly lid, as shown below.
- 2) Connect a 3/8" tube from the inlet of the Flow Restrictor assembly to the Mass Flow Meter.
- 3) Connect the cable from the Mass Flow Meter to position "1" of the I²C connections on the EVT Smoke Machine Controller.

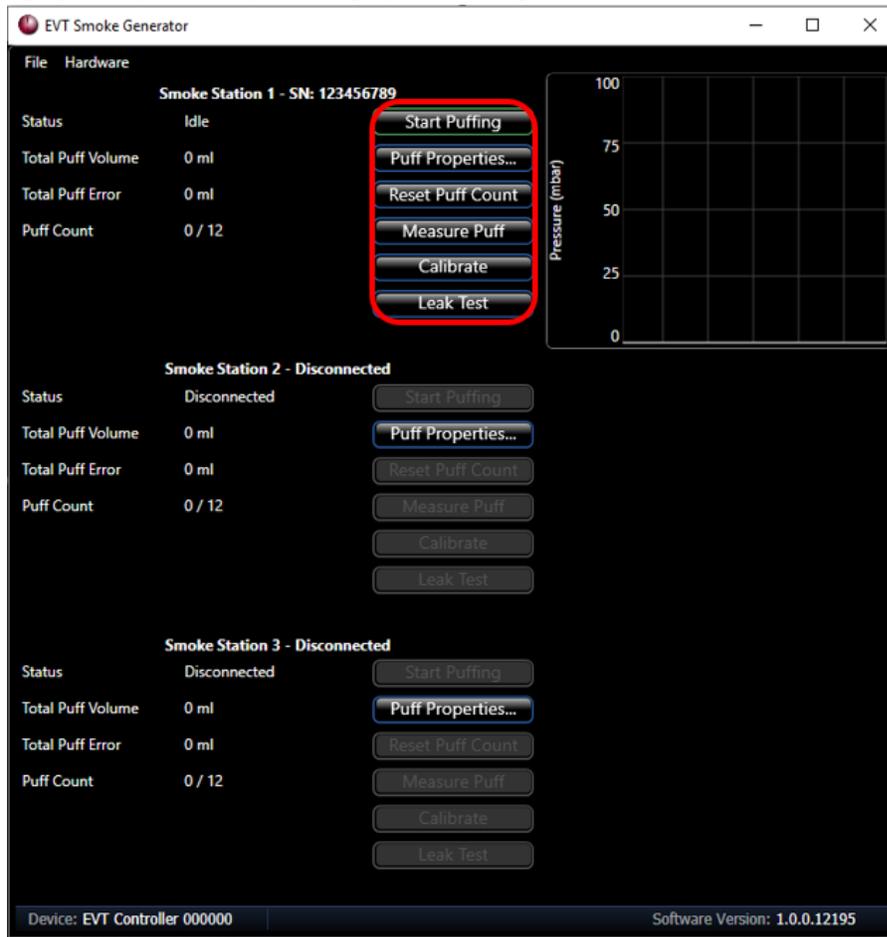




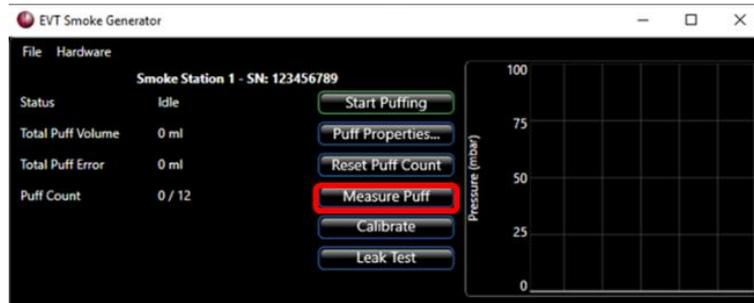
- 4) Launch the EVT Smoke Machine Software by double-clicking on the EVT Software Icon.



The EVT Software Main Window should open. Make sure that the setting selections highlighted below are enabled (not grayed out), and the pressure graph is scrolling.



- 5) Click on the “Measure Puff” button



- 6) This will open the Measure Puff window. The puff measurement window will indicate the current puff volume setting and the measured puff volume. The current measured puff volume is 0.00 ml since we have not yet run the puff volume measurement process.



- 7) Start the Puff Volume Measurement process by clicking the “Zero” button. The EVT system will quickly measure the flow offset. *Make sure before zeroing that the mass flow sensor is connected to the Inhalation Port to avoid ambient flow, causing a poor zero offset.*
- 8) Once completed, click the “Measure” button.



- 9) The EVT system will begin measuring a Puff Volume. When completed, the configured volume and the measured volume will be displayed at the bottom of the window.

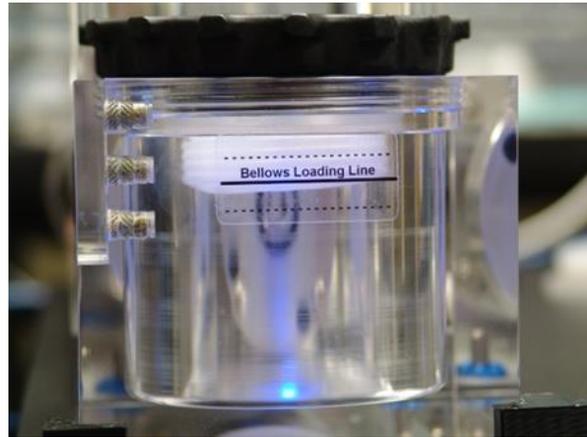


- 10) Once the Puff Measurement process is complete, click "Close."

STEP 5 – CONFIGURE THE EXPERIMENT IN THE SOFTWARE



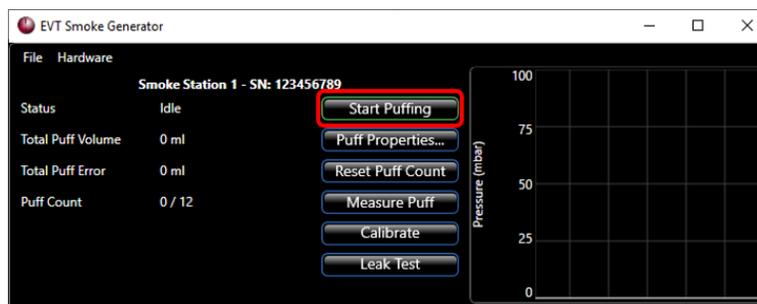
CAUTION: Before beginning any experiment, make sure to install/replace the Bellows Assembly only after the station has been powered up and in “home” position (LED light is on). Also make sure Bellows is in a compressed state and such that it is aligned with the bellows loading line. If not, remove the bellows and adjust accordingly. The bellows should be as close to the loading line as possible. Failure to do so could cause bellows to “bottom out” to the bellows chamber during use and achieve lower than indicated puff volumes.



At this point, you are ready to start your experiment.

Note: if custom parameters were desired outside of standard defaults, those would need to be set before starting an experiment under the Puff Properties window. For now, we'll proceed assuming the puff parameters are left per the standard First Generation E-cig, and station was calibrated under those conditions.

To begin the Experiment, click on the Start Puffing button in the Main Window



Note: If you were alternatively running a tobacco cigarette, you should be ready to light the cigarette at the beginning of the first puff before clicking start. In a tobacco cigarette study, however, traditional ISO bell shape profile would also be selected under Puff Properties before running the Calibration and Measure Puff routines and before starting the study.

For this example, we will continue with the selected 1st Gen e-cig standard profile. Click the Start Puffing button. The Experiment Information window will open. *If the Experiment Information window does not open, check to see if “Enable prompts for Experiment Information and Puff Measurement” was not enabled in the Program Settings window.*

- 1) Enter the name of the Experiment.
- 2) Enter the Experiment Description.
- 3) Set the Criteria to Automatically Stop Puffing to 3.

Experiment Information

Experiment Name Experiment 1

Experiment Description Test Experiment 3 Puffs

NOTE: Using an existing experiment name will result in puffs being appended in the output files.

Criteria to Automatically Stop Puffing

Maximum number of puffs 3

Stop when maximum number of puffs is completed.

Stop automatically when concentration falls below 0 mg/m³ for 3 consecutive puffs.

Stop automatically when Total Exposed Material is 0 mg.

Pre-Experiment Puff Measurement

Time 1/1/0001 12:00:00 AM

Volume 0.00 ml Measure

Post-Experiment Puff Measurement

Time 1/1/0001 12:00:00 AM

Volume 0.00 ml Measure

Start Cancel

STEP 6 - PRE-EXPERIMENT PUFF MEASUREMENT

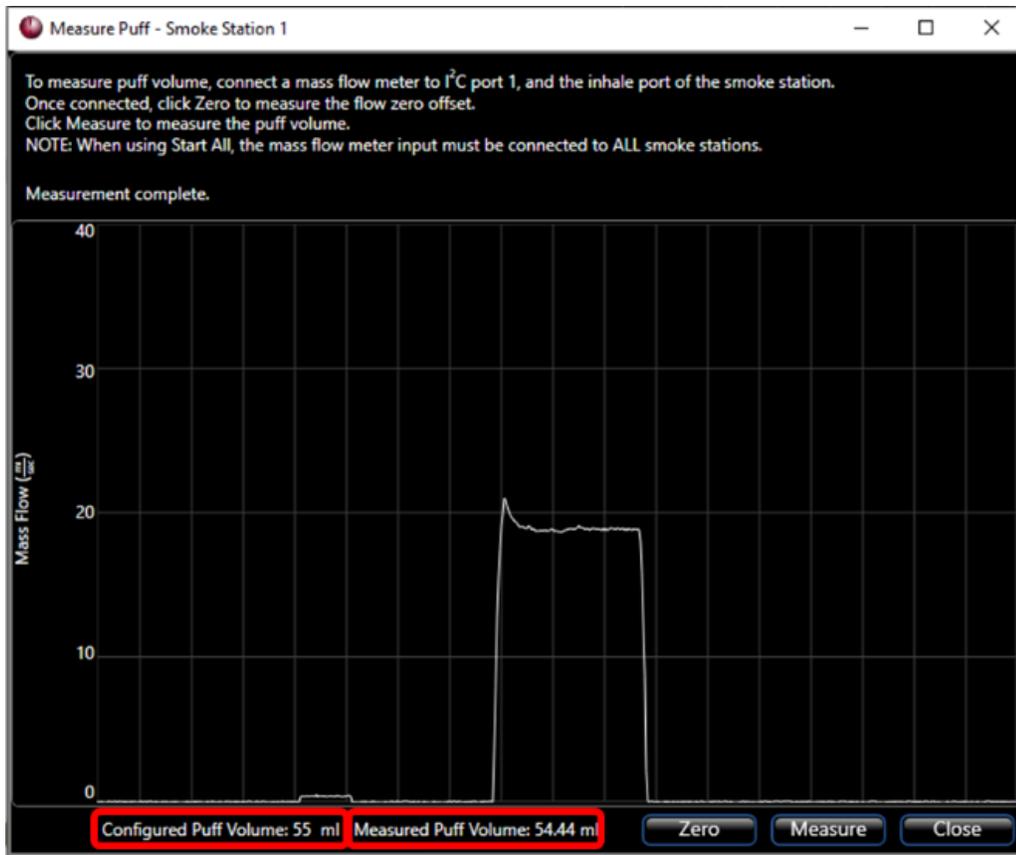
- 4) Click the “Measure” button for the Pre-Experiment Puff Measurement. This will open the Measure Puff Window. Follow the same procedure outlined in Performing a Calibration of Step 4 – Perform a Calibration and Puff Volume Measurement Test to attach Mass Flow Sensor with a flow resistor: I²C at the position 1, mass flow connected to Inhalation Port. The puff measurement window will indicate the current puff volume setting and the measured puff volume. The current measured puff volume is 0.00 ml since we have not yet run the puff volume measurement process.



- 5) Start the Puff Volume Measurement process by clicking the “Zero” button. The EVT system will quickly measure the flow offset.
- 6) Once completed, click the “Measure” button.



- 7) The EVT system will begin measuring a Puff Volume. When completed, the configured volume and the measured volume will be displayed at the bottom of the window.



8) Once the Puff Measurement process is complete, click “Close.”

STEP 7 - ATTACHING THE CIGARETTE, E-CIG, MOD, OR PEN DEVICE & CHAMBERS

Remove the Mass Flow Meter and attach the appropriate nicotine delivering device to the system, by referring to the following sections

- Setting up a 1st Generation E-Cig or Traditional Tobacco Cigarettes

Setting Up a Mod or Pen Device

- In-line Photometer Adapter
- Adding the Supplemental Flow Unit to An EVT Smoke Machine Station

Attach the appropriate chamber type to the system by referring to the sections:

Using the Mass Dosing Chamber with the EVT Smoke Generator

APPLICATION OVERVIEW

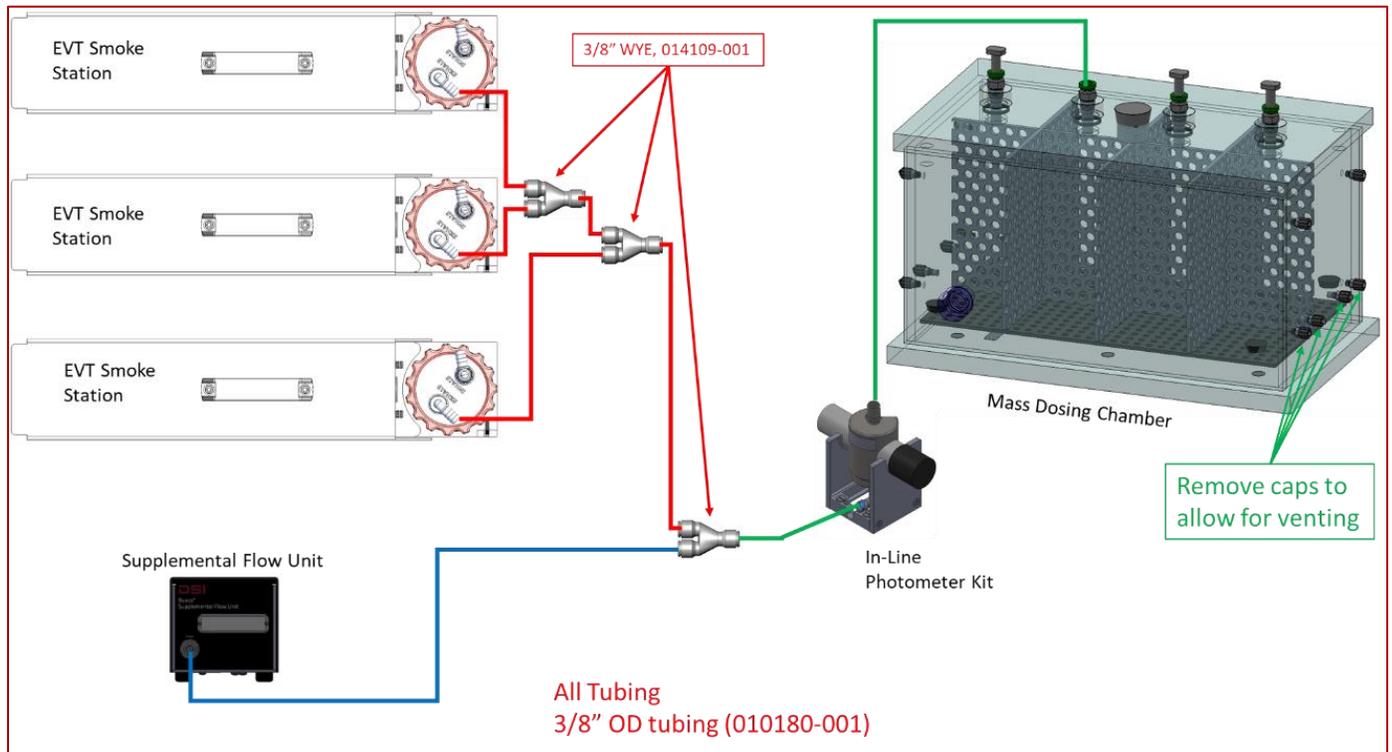
The exposure of subjects with smoke or vape is conveniently done using DSI's Mass Dosing system. Subjects are placed in a chamber and are exposed to smoke or vape for a desired time. The Mass Dosing system is particularly useful for exposures to tobacco.

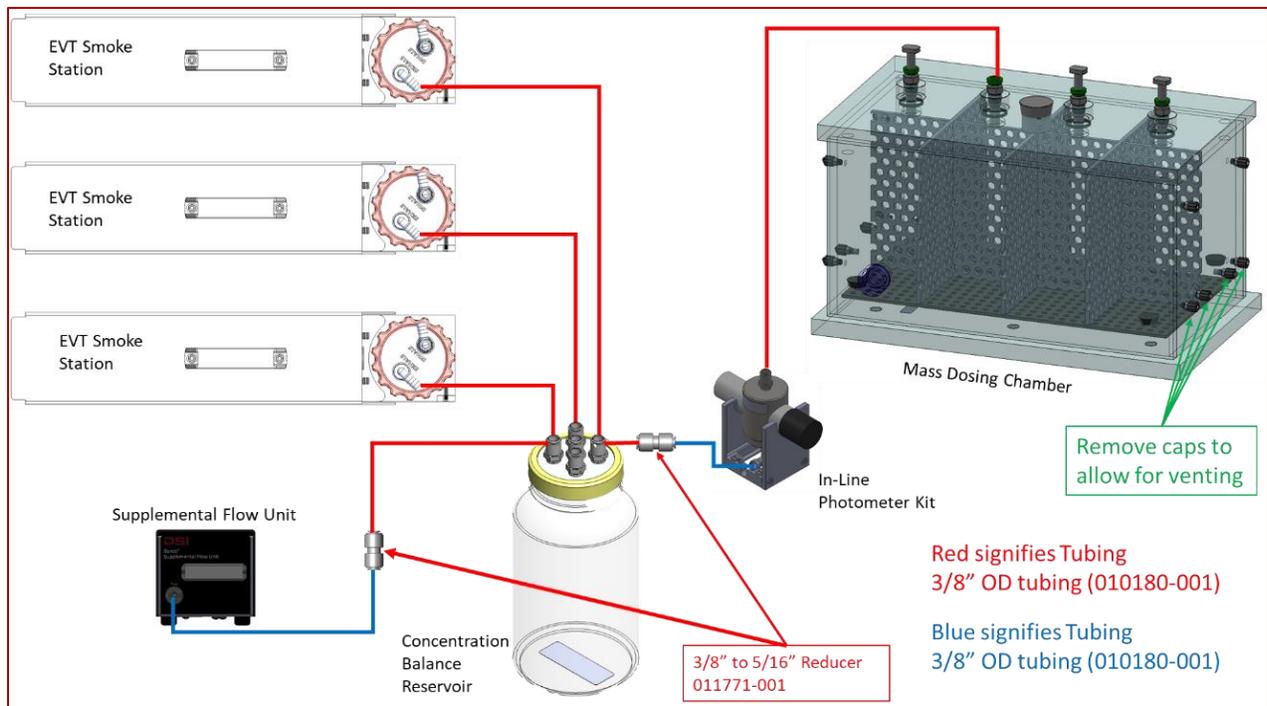
A Mass Dosing chamber is a rectangular acrylic box with a flexible design that accommodates various types of aerosol and bias flow sources. A port on the lid is designed for an Aerogen Aeroneb® nebulizer.

For more information on the Mass Dosing Chamber, see the Mass Dosing System Application Manual.

⚠ Note: A gasket is included in the accessory kit and can be used to further contain smoke/vapor inside the chamber. See the Mass Dosing System Application Manual for more information.

The EVT Smoke Machine can be configured to work with the Mass Dosing Chamber.



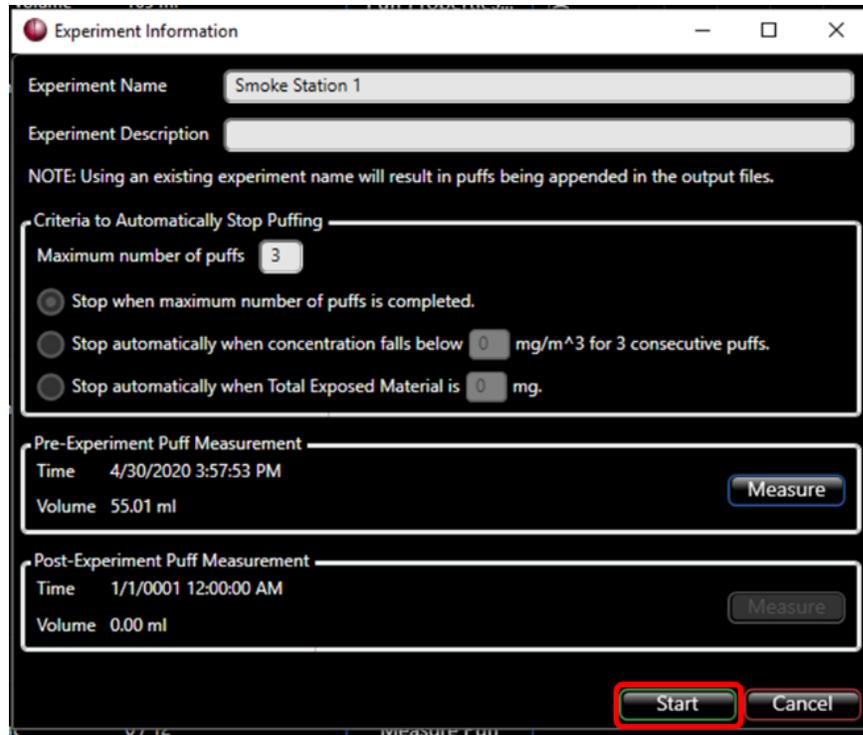


Using the Buxco Inhalation Tower with the EVT Smoke Generator

- Using the Mass Dosing Chamber with the EVT Smoke Generator

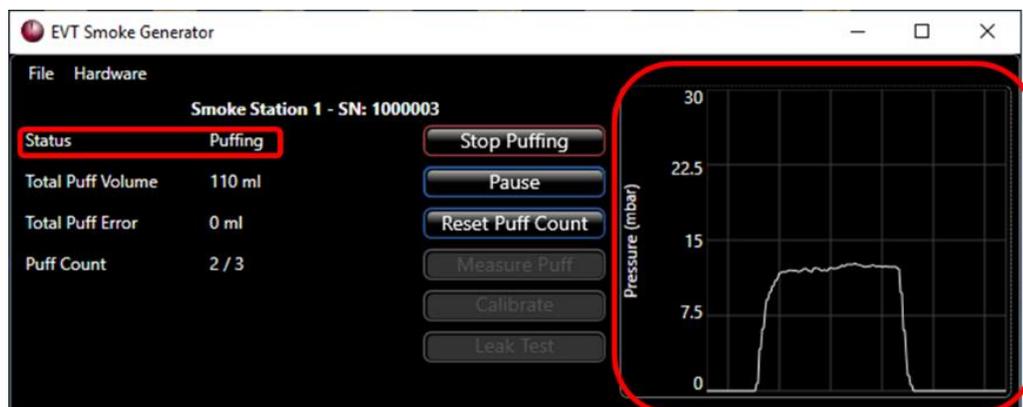
STEP 8 - RUNNING THE EXPERIMENT

When the device is attached and you are all ready to begin the experiment, click Start. Refer to Start Puffing – Running an Experiment for more information.

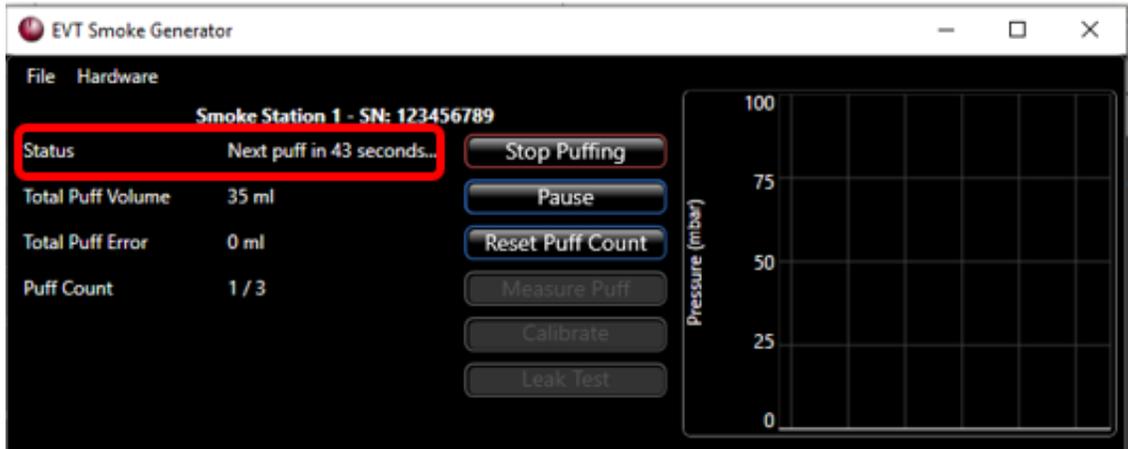


The EVT Smoke Generator will begin puffing. The following sequence should occur

- 1) The status field in the main window will display “Initializing Puff” at the beginning of the puff cycle.
- 2) The station will start to draw air through the device.
- 3) The status field will display “Puffing” during the puff cycle.
- 4) The Pressure Signal graph will display puff pressure as it is being measured by the EVT Smoke Machine Station. Puff pressure shows the appropriate puff characteristic for the type of device being measured. In the graph below, the trapezoidal-shape of a E-cig is displayed.



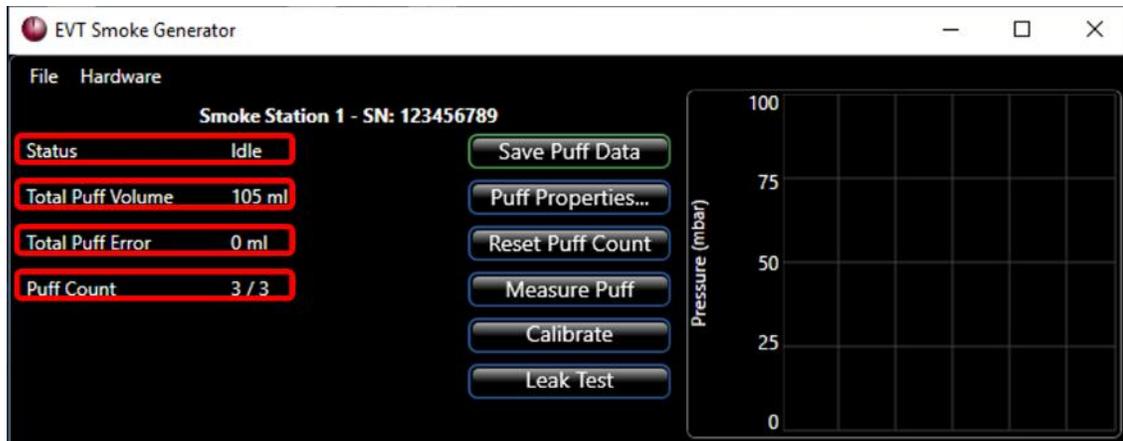
- 5) Once the first puff is completed, the Status should display “Next puff in XX seconds” and start counting down.
Note: For Tobacco Cigarettes, this time allows the user to discard exhausted cigarettes, and be ready to light the next one before the start of the next puff.



- 6) The next Puff will start, and the process will be repeated until the total number of puffs has been completed.

At this point, the system will go back into idle mode, and the main window will display the Total Puff Volume, the Total Puff Error, and the Puff Count.

Note: You do have the ability to stop puffing anytime during this process by clicking the Stop Puffing button. Pressing the Stop Puffing button during a puff cycle will cause the system to complete the puff cycle before stopping.



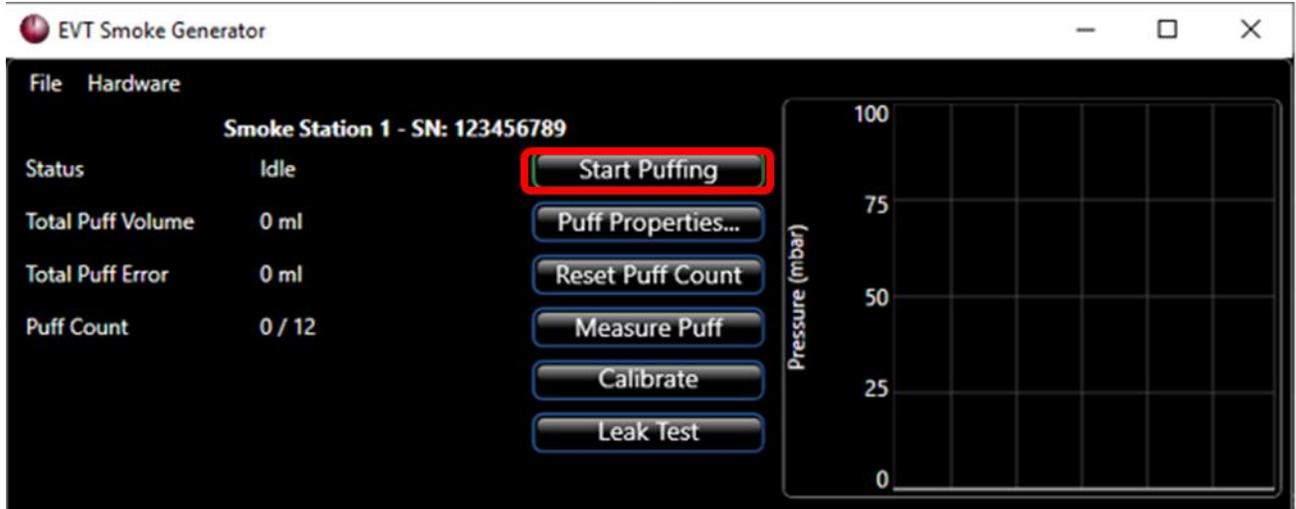
You have completed an experiment. However, you still need to take a Post-Experiment Puff Measurement and save the experiment data.

STEP 9 - SAVING PUFF VOLUME DATA

You can capture a post-experiment puff measurement and, at the same time, save information about the puff volume and concentration measurements in a comma-delimited file. The data file is stored at the location called out in the Experiment Information window.

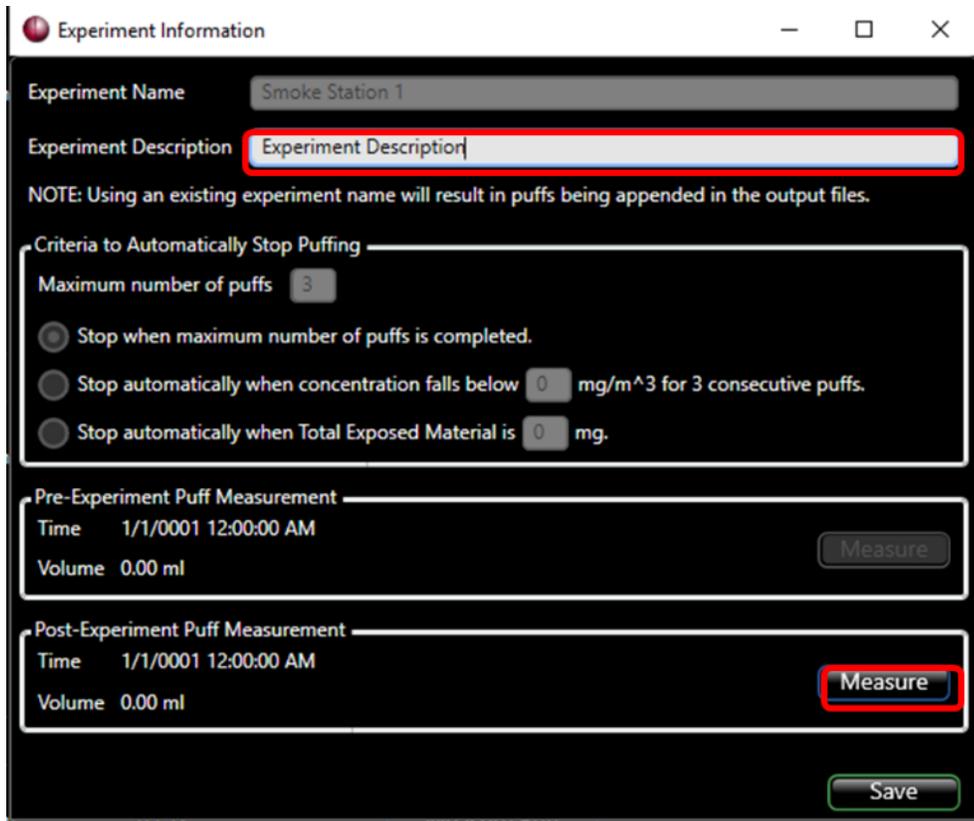
If mass flow meter was removed, re-attach the mass flow meter/Puff Volume Measurement Kit. Information on this is found in **Step 4 – Perform a Calibration and Puff Volume Measurement Test**. Once the kit is attached and ready for use:

- 1) Click the Save Puff Data button on the Main Window.

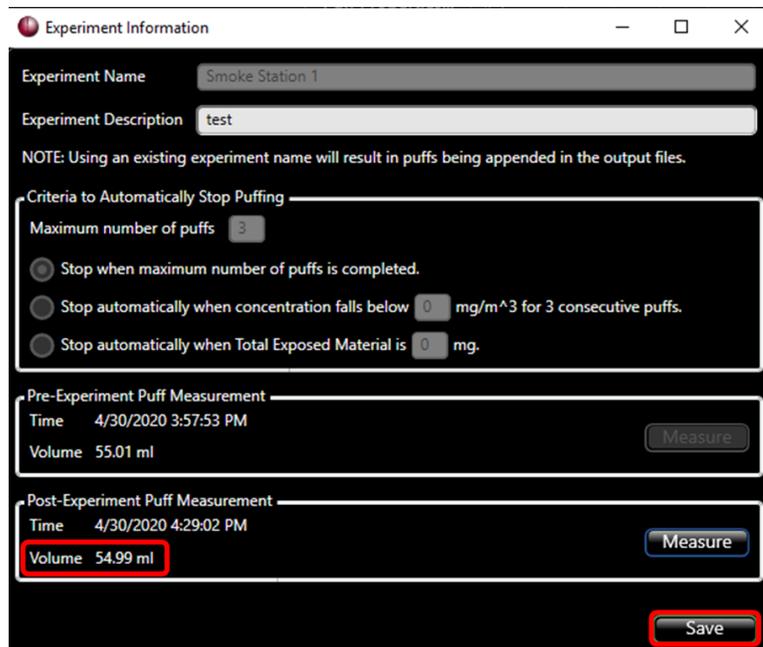


The Experiment Information window will open.

- 2) Enter any information you would like in the Experiment Description Field.

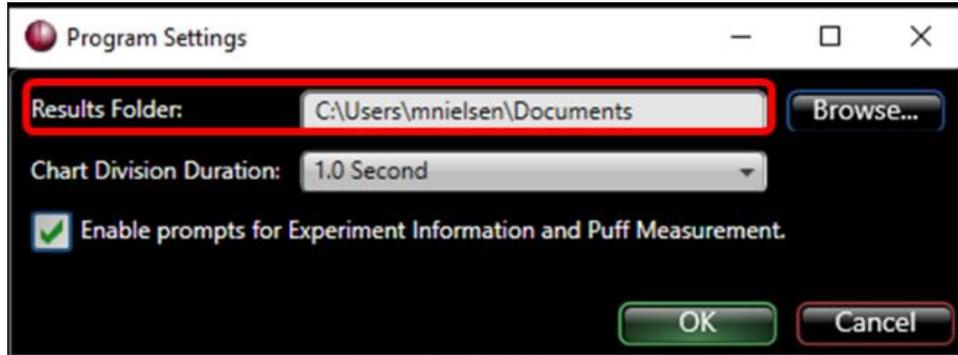


- 3) Click on the “Measure” button in the Post-Experiment Puff Measurement to capture a post-experiment Puff Volume measurement. Follow the same process as in **Step 6 - Pre-Experiment Puff Measurement** and connection of the mass flow meter in Performing a Calibration section (I²C at the position 1, mass flow connected to Inhalation Port).
- 4) Click close. The Post-Experiment Puff Measurement will now indicate the actual puff volume measurement.



5) Click Save.

This will save data for the experiment into a CSV file. This data file is stored at the location called out in the Experiment Information window.



For more information on the format of the dataset, see *Information on Data Files* in section *EVT Software User's Manual* in this manual.

EVT SOFTWARE USER'S MANUAL

The EVT Software package, used in conjunction with the EVT Smoke Generator, will generate consistent aerosolized particles representative of what would be found in a “Standard Puff” from a tobacco cigarette, 1st Generation E-Cig, Pen, or Mod vape device. The EVT Software package allows the user to set the parameters of the sampling process, including the puff profile type, the puffing frequency, the inhalation and exhalation duration, the puff volume, and more.

EVT SMOKE GENERATOR - THE MAIN WINDOW

When the EVT Smoke Generator Software application is launched, the main window is displayed. The main window provides information about any EVT Smoke Station connected to the EVT Controller, as well as identifying any disconnected station bays. Pressure information for each connected station is also displayed next to the station's information. Note that in Figure 16 (the example screenshot) the information displayed in the main window will adjust depending on the hardware connected and the experiment/puff properties. For example, additional hardware such as the supplemental flow unit and photometer will also display appropriate values.

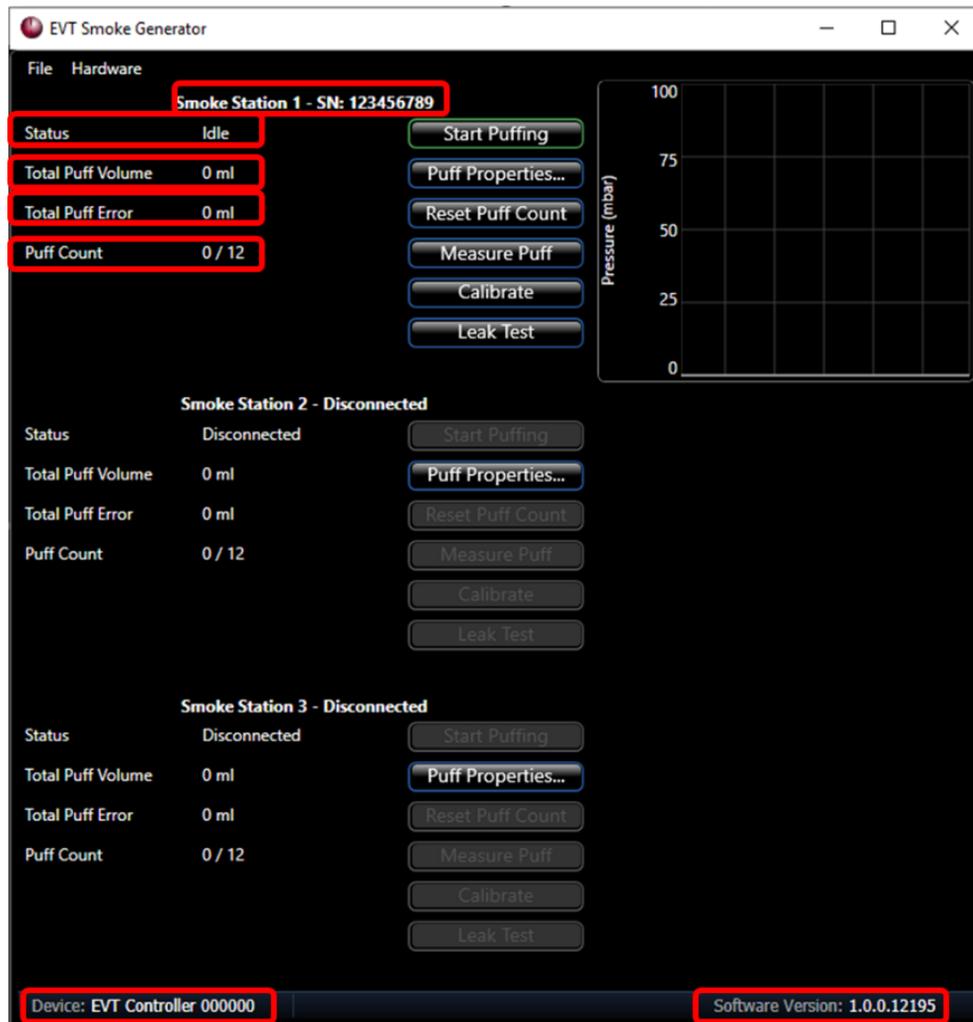


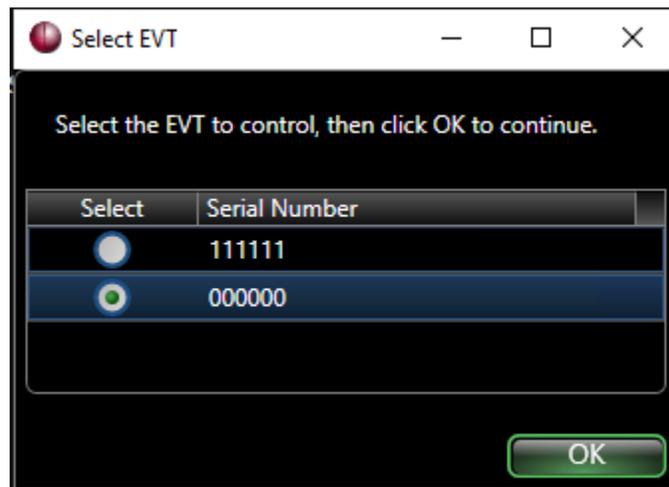
Figure 16 – EVT Smoke Generator Main Software Window

Main Software Window Information	
Smoke Station Number and Serial Number	This indicates the serial number of a Smoke Station and which slot it is attached to in the EVT controller
Status	The current status of the Station. This will indicate the following: <ul style="list-style-type: none"> • Idle when the station is not running an experiment • Initializing Puff at the beginning of a puff cycle • Puffing during the entire puff cycle • Number of seconds until the next puff will occur. This is important when traditional cigarettes need to be replaced.
Total Puff Volume	This value indicates the total volume accumulated by all the puffs in the current experiment.
Total Puff Error	The Total Puff Error is determined by the difference between the number of intended vs. actual steps traveled by the stepper motor.
Puff Count	The total number of puffs completed since the beginning of the experiment
Device: EVT Controller XXXXXX	Displays the serial number of the controller
Software Version XXX.XXXXX	Displays the version of the EVT Software currently running

USING MULTIPLE EVT CONTROLLERS

Multiple EVT Controllers may be used simultaneously on a single computer. This can be achieved by opening an instance of the EVT software for each EVT controller. For example, 2 instances of the EVT software will need to be open in the event that 2 EVT controllers are being used.

If the software detects multiple EVT controllers, the EVT software will prompt the user to specify which device the given instance of the software will control.



In the Main Window, The Device EVT Controller field (in the bottom left corner) will reflect the assigned EVT Controller.

EVT Smoke Generator

File Hardware

Smoke Station 1 - SN: 100008

Status	Idle	Start Puffing
Total Puff Volume	0 ml	Puff Properties...
Total Puff Error	0 ml	Reset Puff Count
Puff Count	0 / 12	Measure Puff
		Calibrate
		Leak Test

Smoke Station 2 - SN: 100007

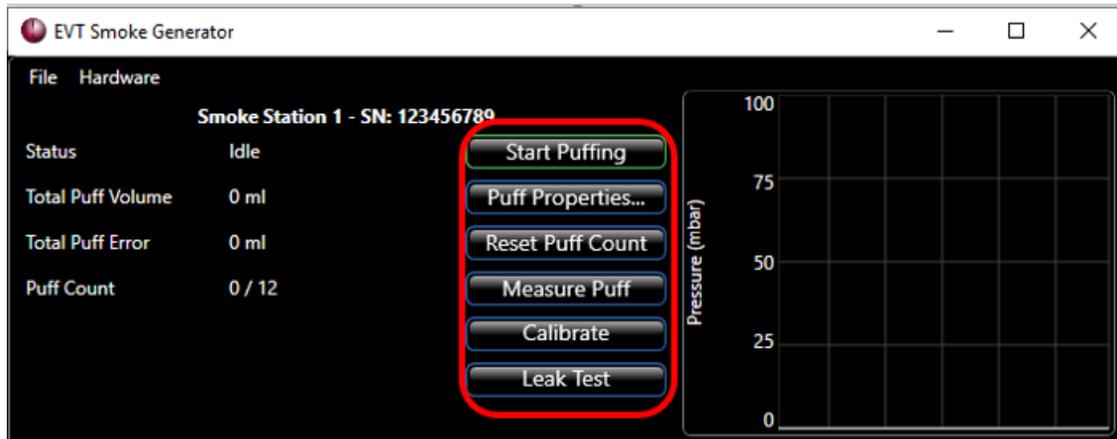
Status	Idle	Start Puffing
Total Puff Volume	0 ml	Puff Properties...
Total Puff Error	0 ml	Reset Puff Count
Puff Count	0 / 12	Measure Puff
		Calibrate
		Leak Test

Smoke Station 3 - SN: 100010

Status	Idle	Start Puffing
Total Puff Volume	0 ml	Puff Properties...
Total Puff Error	0 ml	Reset Puff Count
Puff Count	0 / 12	Measure Puff
		Calibrate
		Leak Test

Device: **EVT Controller 000000** Software Version: 1.1.0.12581

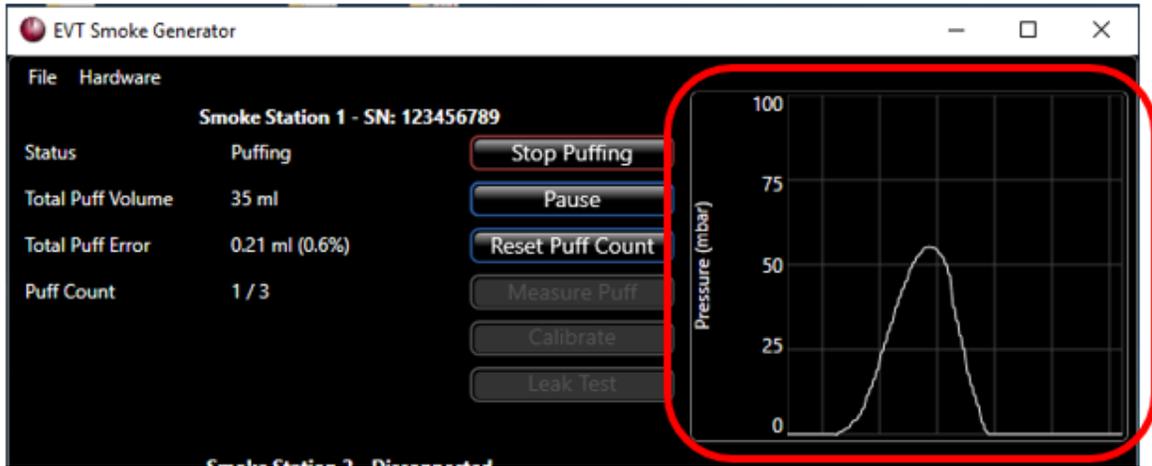
EVT STATION BUTTONS



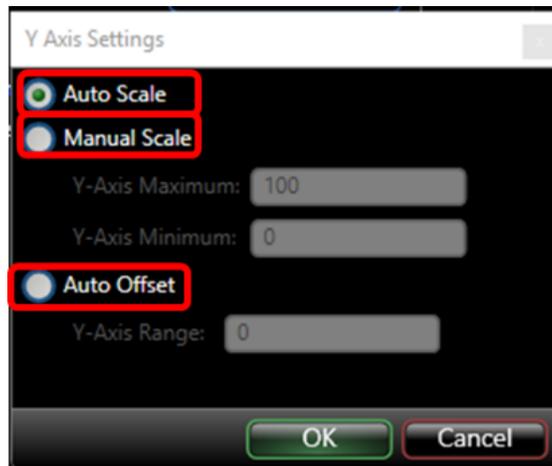
Station Buttons	
Start Puffing Stop Puffing Pause/Resume Puffing Save Puff Data	<p>This feature Controls Puffing Actions.</p> <ul style="list-style-type: none"> • Start Puffing - Begins the experiment by starting the first puff cycle. Puffing will continue until the total puff count is reached or if Stop Puffing is selected. <i>Note: If “Enable prompts for Experiment Information and Puff Measurement” is selected in the Program setting window, the Experiment Information window will open.</i> • Stop Puffing - Stops the puffing cycles. The Puff Count shows the current number of completed puffs and will not be reset until the start of the next experiment (selecting Start Puffing again). • Pause - Temporarily stops the puffing cycles. When ready, click the Resume Puffing button to continue the experiment. • Save Puff Data - This selection will only be displayed if “Enable prompts for Experiment Information and Puff Measurement” is selected in the Program Settings window. Selecting Save Puff Data opens the Experiment Information window and allows experiment data to be saved.
Puff Properties	<p>Determines the attributes of a puff that will be used for the experiment. Puff Properties include:</p> <ul style="list-style-type: none"> • The number of puffs in the experiment • The Puff Volume • The Inhalation Duration • The Exhalation Duration • The Puff Frequency in puffs per minute • Associate a photometer to measure concentration.
Reset Puff Count	Resets both the Puff Count as well as the Total Puff Volume
Measure Puff	It opens the Measure Puff window, which allows the user to measure the puff volume using the mass flow sensor.
Calibrate	Opens the calibration window, which allows the user to calibrate the EVT Smoke Generator station.
Leak Test	Opens window to perform a Bellows Assembly leak test.

EVT STATION GRAPH

This graph displays the pressure being measured by the EVT station in real-time. When puffing is occurring, the graph should show the pressure curve representing the puff. The X-axis and Y-axis of the pressure graph can be changed.



To change the Y-axis, double click anywhere on the Y-axis, and the Y-Axis Settings window should open.



Graph Axis Setting	
Auto Scale	Selecting the Auto Scale allows the EVT Software to maximize the Y-Axis based on data being currently displayed on the graph
Manual Scale	Selecting Manual Scale allows the user to input the maximum and minimum values for the Y-Axis
Auto Offset	This option allows the user to set the Y-axis height without specifying the Y max and Y min.

The pressure X-axis scale can be adjusted by navigating to the Program Settings Window. See Program Settings section in the EVT Software User’s Manual in this manual.

PUFF PROPERTIES

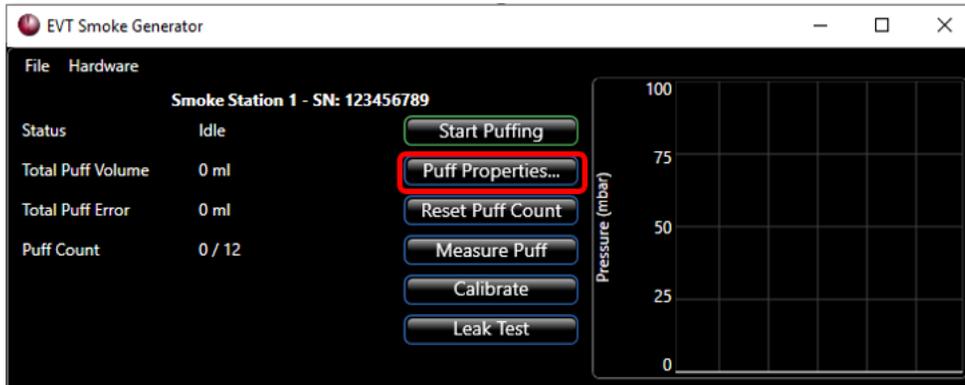
The versatile EVT Smoke Generator allows users to pick “Standard Puffs” or use custom parameters for a large variety of experiments. Cigarette types include Mod Vaporizer Devices, Mid-Size “Pen” E-cigarettes, 1st Generation

E-cigarettes, and Tobacco Cigarettes. By selecting a Tobacco Cigarette, the bell-shaped puff profile is utilized. The e-cig trapezoid puff-profile is utilized for all other selections.

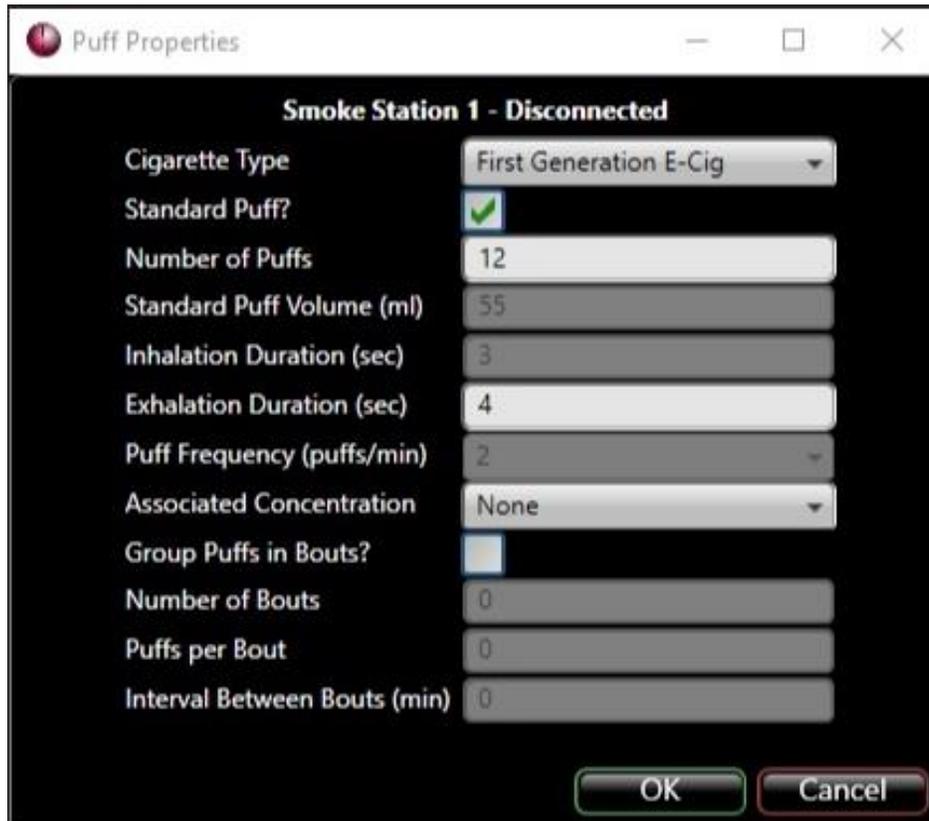
To customize puff parameters, the user can un-check the “Standard Puff” box and set the Puff Volume, the Inhalation Duration (sec), the Exhalation Duration (sec), and the Puff Frequency in puffs per minute.

The user can also set the Number of Puffs for the experiment and associate a photometer (optional) to a station for concentration measurements

To access the Puff Properties, click on the Puff Properties button on the main window.



This will open the Puff Properties Window.



Puff Properties Dialog Window	
Cigarette Type	<p>This drop-down menu allows the user to select from four different types of cigarettes. This selection will set the puff attributes to the “Standard Puff” for that type of cigarette. Note: the “Standard Puff” checkbox needs to be checked to prepopulate and lock in standard puff values.</p> <p>Choices include</p> <ul style="list-style-type: none"> • Tobacco Cigarette -- bell-shaped profile, no button activation • First Generation E-cig – e-cig trapezoid-shaped profile, no button activation • Mid-Size “Pen” E-cig – e-cig trapezoid-shaped profile, with button activation • Mod Vaporizer –e-cig trapezoid-shaped profile, with button activation
Standard Puff	If selected, it will set the Puff Attributes to be that of a “Standard Puff” according to traditional or e-cig ISO standards. When this field is unselected, the user has the option to update the puff properties.
Number of Puffs	This is the total number of puffs that will occur over the entire experiment.
Standard Puff Volume (ml)	This value represents the total puff volume, in ml, for each puff. If the Standard Puff is selected, this value will be determined by the Cigarette type and cannot be changed by the user. Uncheck the Standard Puff selection to change this value. If “Standard Puff” is unchecked, the allowable puff volume range is 10-100ml, as long as the maximum system flow rate of 30ml/s is not exceeded.
Inhalation Duration (sec)	This is the total amount of time in seconds for the inhalation period of the puff. If the Standard Puff is selected, this value will be determined by the Cigarette type and cannot be changed by the user. Uncheck the Standard Puff selection to change this value. The allowable range is 1-5 sec, as long as the maximum system flow rate of 30ml/s is not exceeded. Note: If this field has a red box around it, the specified duration is not achievable by the system and should be updated appropriately.
Exhalation Duration (sec)	This is the total amount of time in seconds for the exhalation period of the puff. The allowable range is dictated by puff frequency and inhalation duration. Please note that the system assumes a 1 second overhead to initialize each puff. Note: If this field has a red box around it, the specified duration is not achievable by the system and should be updated appropriately.
Puff Frequency (puffs/min)	This is the puffing rate in puffs per minute. If the Standard Puff is selected, this value will be determined by the Cigarette type and cannot be changed by the user. Uncheck the Standard Puff selection to change this value. The allowable range 1-6 puff/min.
Associated Concentration	An EVT In-Line Photometer Adapter (optional) can be used to measure the concentration levels of smoke or vape generated by the smoke generator. In this field, pick select the photometer you would like associated with the specified station.
Group Puffs in Bouts?	When enabled, the user can create a puff profile based on Puff Bouts. The user can specify the number of puffs should be delivered and the time interval between bouts.

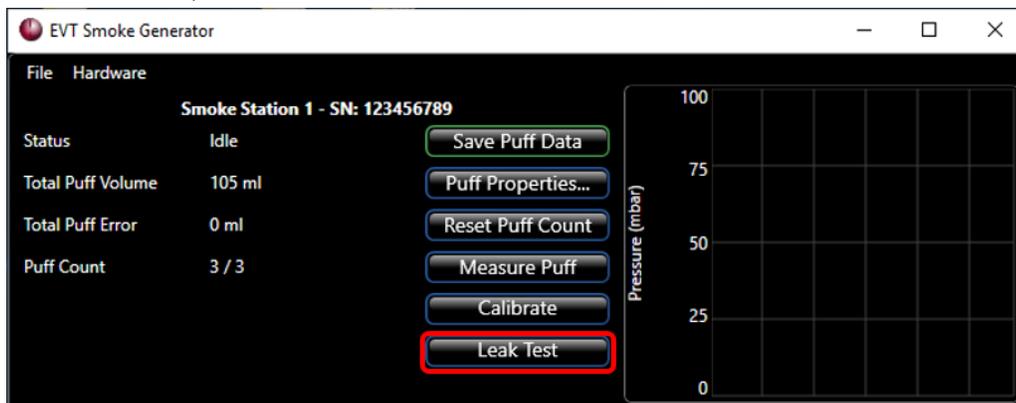
Puff Properties Dialog Window	
Number of Bouts	This is the number of bouts that will occur
Puffs per Bout	This is the number of puffs that are considered a bout.
Interval Between Bouts (min)	This is the time, in minute, from the start of a bout until the start of the subsequent bout.

The graph displays two distinct puff sequences. Each sequence consists of two individual puffs. A red bracket labeled 'Bout' spans the duration of one such sequence. A larger red bracket labeled 'Interval' spans the time from the beginning of the first sequence to the beginning of the second sequence.

LEAK TEST

The Leak Test is used to verify that there are no leaks in the bellows assembly. The leak test has the user plug the inhale port, and attempts to draw air out through the exhale port, looking to see if the pressure level holds as expected.

To access the Leak Test window, click on the Leak Test button on the Main Window.



This will open the Leak Test window.



Instructions	Instructions on the steps for performing a leak test can be found on the top of the window
Inhale Test Status	<p>This indicates the status and results of the Inhalation Leak Test.</p> <ul style="list-style-type: none"> • Not tested – The test has not yet been started • Indicated the results of the test <ul style="list-style-type: none"> ○ Test passed ○ Tested Failed: Initial pressure too low

CALIBRATE

The Calibration Button is used to calibrate the EVT system. Calibration is necessary to achieve accurate puff volumes. Calibration should be performed at minimum when changing out the bellows assembly and when changing to or from the bell and trapezoid-shaped profiles (i.e. if using bell-shaped profiles station should be calibrated using that profile and similar if using e-cig trapezoid profiles). Calibration assesses the flow resistance and adjusts the acceleration and deceleration phases of the puff accordingly. It also measures and applies a correction to the puff volume with the use of the mass flow sensor.

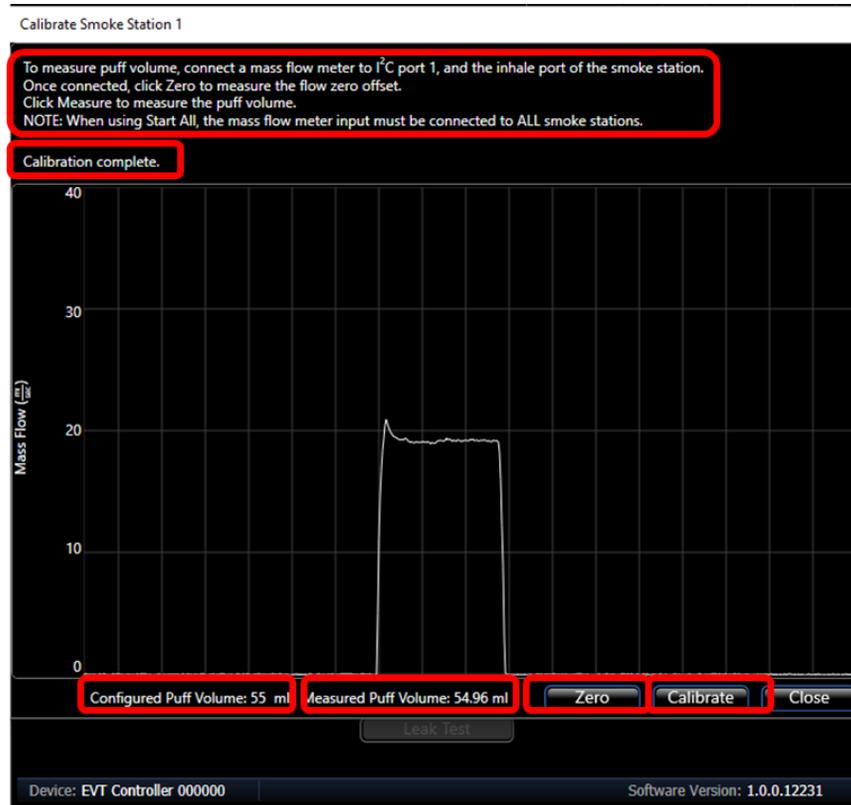
To access that Calibration Window, click on the “Calibrate” button on the EVT Main Window.



This will open the Calibration Window. Click on the “Calibrate” button.



Calibration Status Top Left	Provides information on the status of the calibration process <ul style="list-style-type: none"> • Measuring Pressure Zero Baseline • Starting Puff • Measuring Puff • Measurement 'X' of 5 complete, preparing for the next measurement
Measured Time Constant (example 0.171)	Indication of the EVT Station's response time during the rising edge of inhalation
Measured Time Constant (example 0.185)	Indication of the EVT Station's response time during the falling edge, i.e., start of exhalation.
Abort	This will stop the calibration process at the end of the current puff cycle.

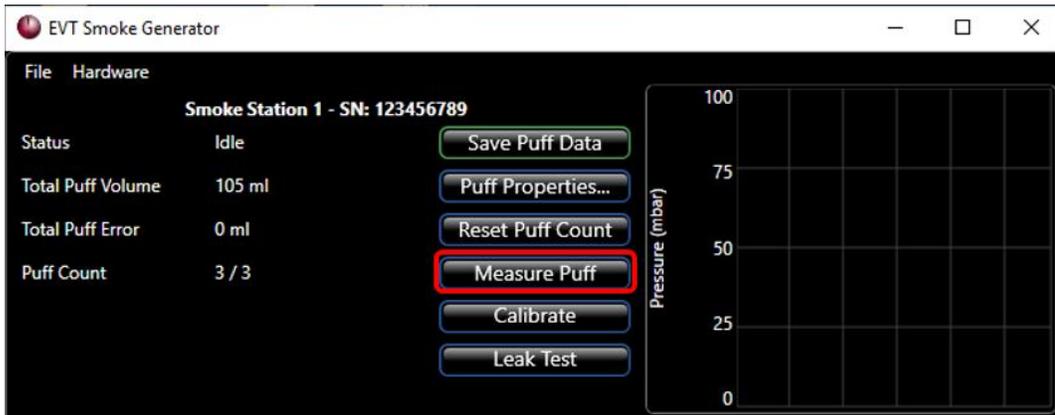


Puff Measurement Instructions Top Left	Instructions on how to perform a calibration are shown on the top of the Calibration Window
Puff Measurement Status	Provides information on the status of the Puff Measurement process <ul style="list-style-type: none"> • When clicking the “Zero” button <ul style="list-style-type: none"> ○ Measuring Flow Offset • When clicking the “Calibrate” Button <ul style="list-style-type: none"> ○ Measuring Base Line ○ Waiting for puff to start ○ Measuring Puff ○ Calibration Complete
Configured Puff Volume (example 55 ml)	Indicates the Puff Volume value set by the EVT software
Measured Puff Volume (example 54.96 ml)	Indicates that actual puff volume measured by the Mass Flow Meter during the calibration process
Zero	Initiates the baseline measurement before performing a puff measurement
Calibrate	This will initiate the calibration process. Once initiated, the puff measurement process will measure three puff cycles. Clicking “Close” will abort the process.

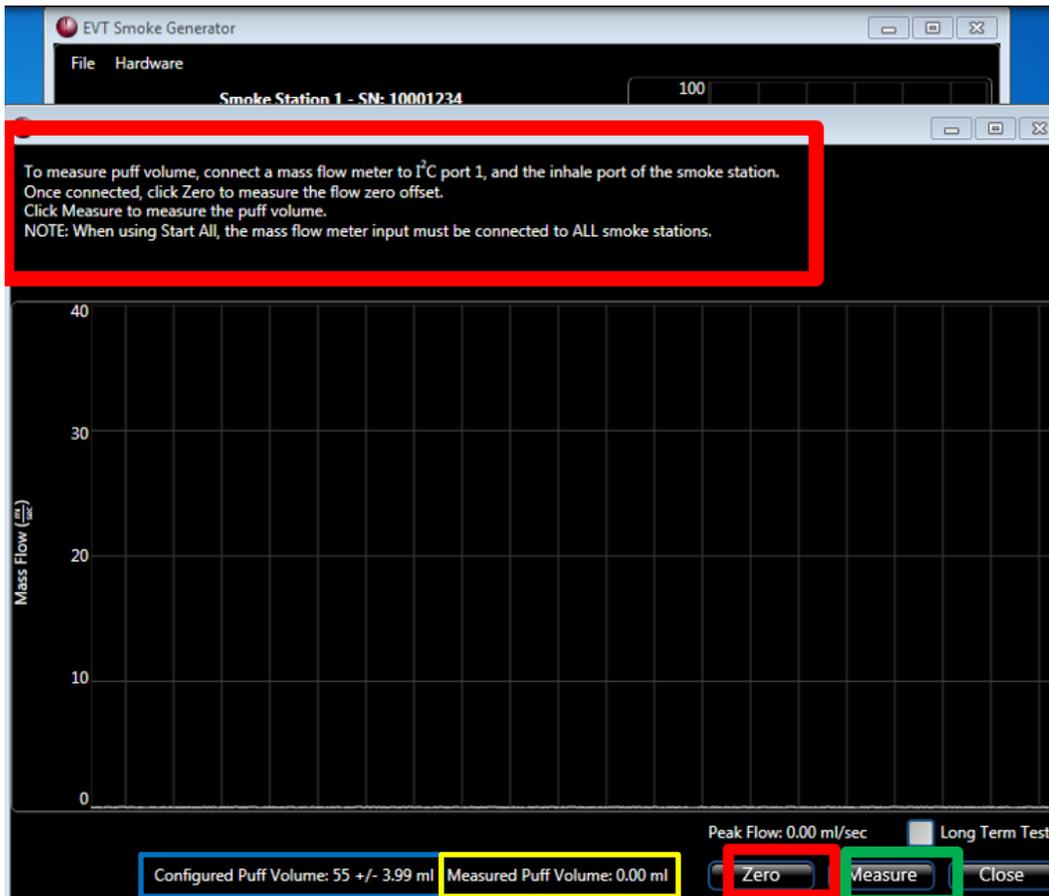
MEASURE PUFF

The Measure Puff button is used to measure and record the 1 puff volume as measured using the EVT Puff Volume Measurement Kit.

To access the Measure Puff window, click Measure Puff on the Main Window.



This will open the Measure Puff window.

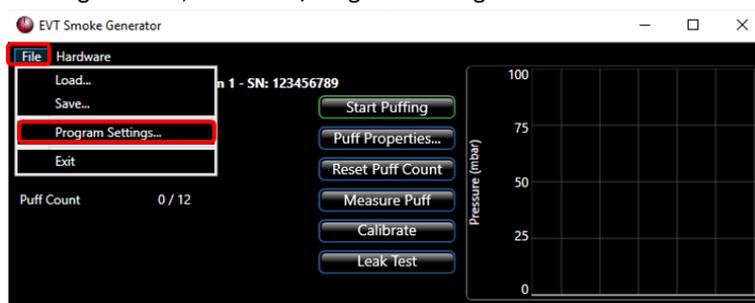


Instructions	Instructions on how to set up the hardware to measure the puff volume using the mass flow sensor.
Zero	When selected, this measures the value of the Mass Flow Meter with no airflow. It is used to capture any offset inherent in the Mass Flow Unit.
Measure	When activated, this starts the puff measurement process
Configured Puff Volume	This is the value of the Puff Volume set in the Puff Properties window
Measured Puff Volume	This is the puff volume measured by integrating the airflow through the Mass Flow Unit over the time of the puff cycle
Peak Air Flow	This is the maximum airflow measured by the Mass Flow Unit during the puff cycle.

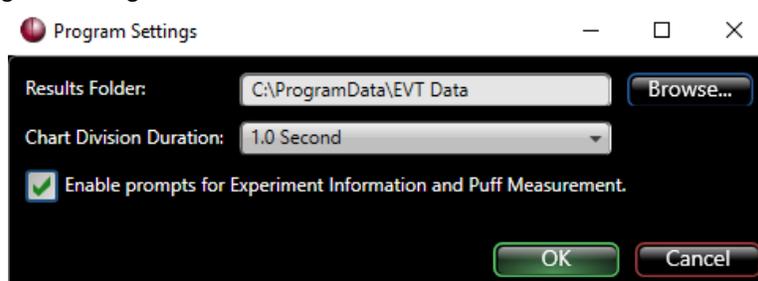
PROGRAM SETTINGS

The program setting window allows the user to determine if the Experiment Information and Puff Measurement prompts are enabled, the Chart Division Duration (Puff Pressure Graph X-axis scaling), and where the results data will be stored at the end of the experiment.

To access the Program Setting window, select File/Program Settings



This will open the Program Settings window.



Program Settings Windows Prompts	
Results Folder	This is the location where the results data for the experiment is stored. You can change the location by clicking Browse and selecting a different location
Chart Division Duration	This sets the limits of the X-axis for the Puff Pressure Graph displayed on the EVT Software's main window. The width of the X-axis can be set between 0.1 to 60 seconds in preset increments through a drop-down selection list.
Enable prompts for Experiment Information and Puff Measurement	The Enable prompts for Experiment Information, and Puff Measurement determines if puff pressure measurements will be stored in an experiment file. If selected:

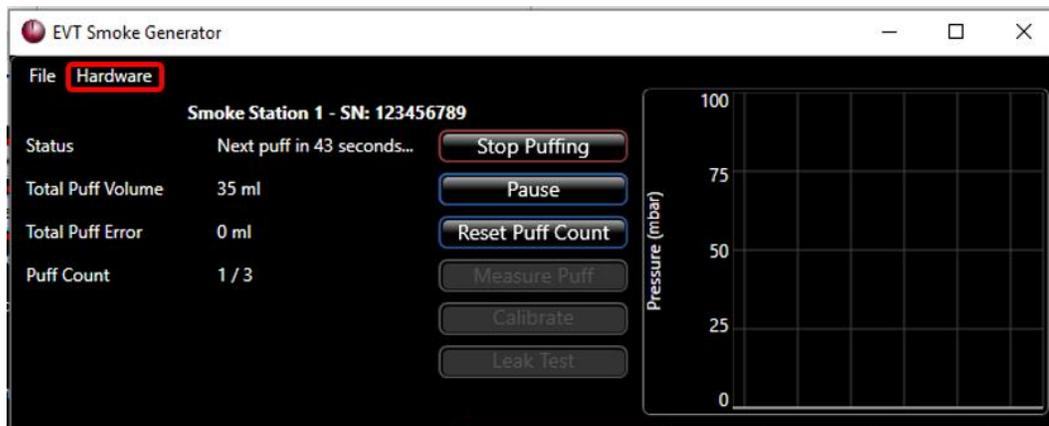
Program Settings Windows Prompts

	<ul style="list-style-type: none">• When the experiment is started, the Experiment Information window will open. Information can be added or modified before starting the experiment.• At the end of the experiment, the Experiment Information window will open, allowing the user to make changes to experiment information and to save the puff pressure measurements to an excel file. <p>If not selected:</p> <ul style="list-style-type: none">• When the experiment is started, the puffs will begin immediately. The Experiment Information window will not open.• The program will automatically save data (with the exception of pre/post experiment puff volumes) when the experiment is done.
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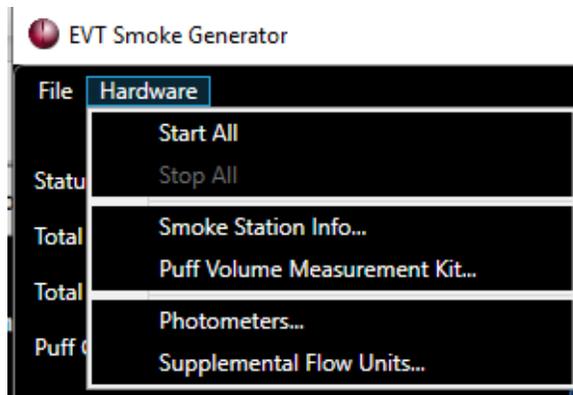
HARDWARE MENU

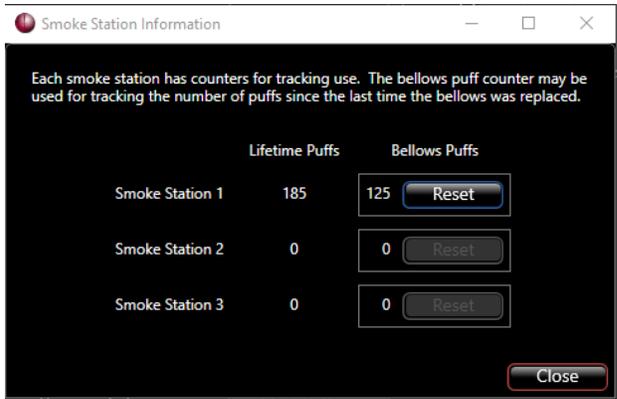
The Hardware Menu provides access to hardware settings used by the EVT Controller, EVT Station, and the EVT Accessory Kits. This includes resetting the number of puffs a bellows assembly has seen when changing bellows, entering slope and offset information for calibrating the Mass Flow Meter of the Puff Volume Kit, setting the maximum concentration levels of the photometer(s), and setting the flow rate for the Supplemental Flow Units.

To access the Hardware Menu, click Hardware on the EVT Main Window.



This will open the Hardware Menu.



Hardware Menu Drop Down													
Start All	This allows the user to start the puffing synchronously across all attached stations on the EVT Smoke Generator.												
Smoke Station Info...	<p>Clicking on the “Smoke Station Info...” button opens the Smoke Station Information window.</p> <p>Lifetime Puffs: Each station has a warranty lifespan of 100,000 puffs. The station is expected to work after 100,000 puffs.</p> <p>Bellows Puffs: Each station tracks the total number of puffs a bellows has performed since it was last replaced. Upon replacing the station with a new bellow, this counter can be reset in this dialog window. Please refer to Replacing and Cleaning the Bellows Assembly section on when to change the bellows.</p>  <table border="1" data-bbox="630 1050 1247 1449"> <thead> <tr> <th></th> <th>Lifetime Puffs</th> <th>Bellows Puffs</th> </tr> </thead> <tbody> <tr> <td>Smoke Station 1</td> <td>185</td> <td>125 <input type="button" value="Reset"/></td> </tr> <tr> <td>Smoke Station 2</td> <td>0</td> <td>0 <input type="button" value="Reset"/></td> </tr> <tr> <td>Smoke Station 3</td> <td>0</td> <td>0 <input type="button" value="Reset"/></td> </tr> </tbody> </table>		Lifetime Puffs	Bellows Puffs	Smoke Station 1	185	125 <input type="button" value="Reset"/>	Smoke Station 2	0	0 <input type="button" value="Reset"/>	Smoke Station 3	0	0 <input type="button" value="Reset"/>
	Lifetime Puffs	Bellows Puffs											
Smoke Station 1	185	125 <input type="button" value="Reset"/>											
Smoke Station 2	0	0 <input type="button" value="Reset"/>											
Smoke Station 3	0	0 <input type="button" value="Reset"/>											
Puff Volume Measurement Kit...	The Puff Volume Measurement Kit measures the volume of a puff. This measurement can be used to calibrate or validate the accuracy of the puff volume before or post an experiment. For more information on the Puff Volume Measurement Kit, see EVT Puff Volume Measurement Kit – Parts List in section Lifespan, Maintenance, & Troubleshooting, Misc of the manual.												
Photometers...	<p>The users should select the same sensitivity setting for both Photometer jacks (Port and Inflow) set in the Casella Handheld Monitor. For more information, please see Photometer Software Setup in the</p> <p>In-line Photometer Adapter section of this manual.</p>												

Hardware Menu Drop Down

Supplemental Flow Units...

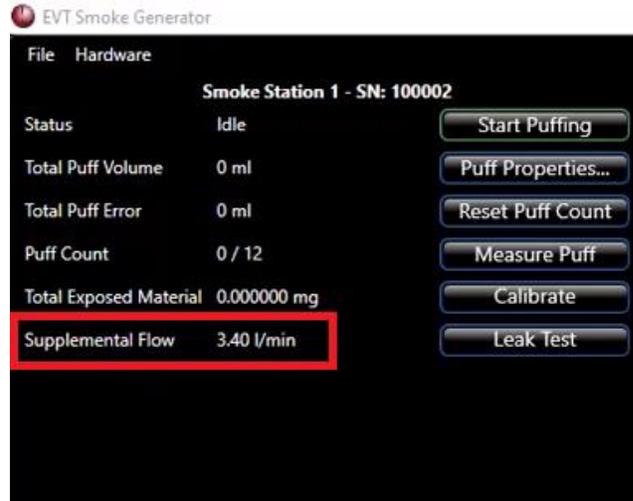
Up to 3 supplemental flow uses can be attached to the system. In this dialog box, the user can set the flow units for each supplemental unit.

Once the user enters a value greater than 0 and clicks OK the supplemental flow unit(s) will turn on. For information on setting up the supplemental flow unit, please refer to the

Supplemental Flow Unit – Setting Flow section of this user manual.

To turn off the supplement flow, go back into **Hardware>Supplemental Flow Units** and change value to zero. *Note: you may need to click on another cell (or hit tab key) in order for the OK button to be enabled.*

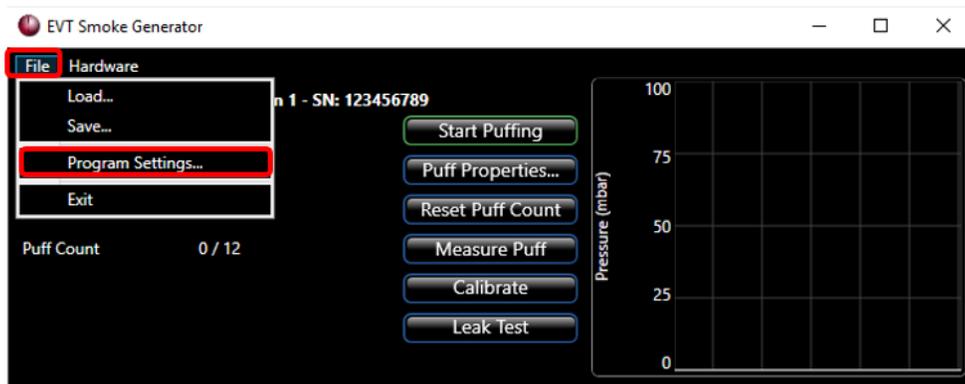
The supplemental flow real-time values can be seen in the main window EVT Smoke Generator window:



EXPERIMENT INFORMATION

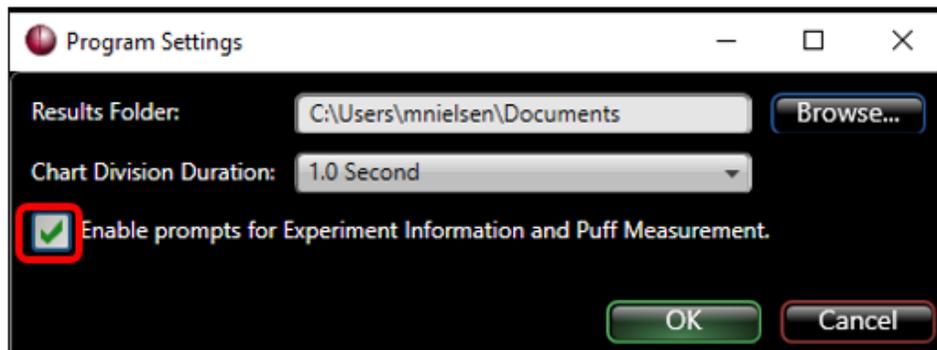
Enabling the Experiment Information and Puff Measurements option allows the user to name the experiment and provide a description of the experiment. It also allows the user to set criteria for automatically stopping puff cycles. By default, the system will stop when the specified number of puffs has been completed. When the system is operated with an In-Line Photometer Kit, there are additional options to automatically stop based upon concentration or Total Exposed Material. Finally, the Experiment Information window, when used in conjunction with EVT Puff Volume Measurement Kit, allows the user to capture Pre and Post Experiment Puff Measurements.

To have the Experiment Information window open, ensure the “Enable Prompts for Experiment Information and Puff Measurements” option is selected in the Program Settings Window. To verify the Enable Prompts for Experiment Information and Puff Measurements is enabled, click on the File button on the Main Window.



The Programs Settings window should open.

Make sure the Enable prompts for Experiment Information and Puff Measurements are enabled. Click OK



EXPERIMENT WINDOW DIALOG

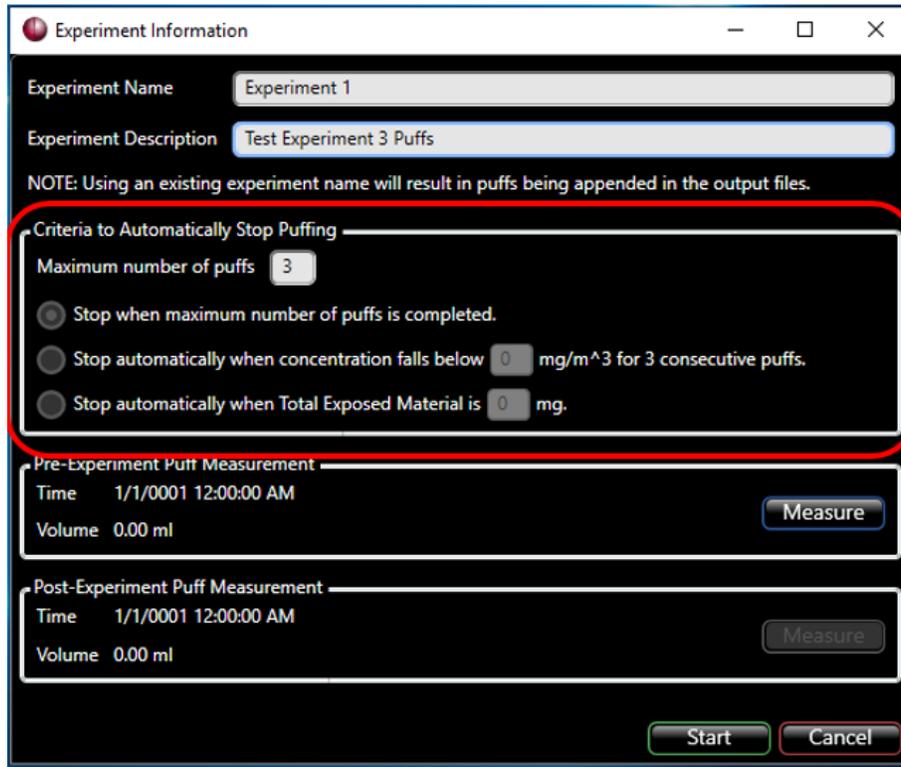
At the beginning and end of the experiment, the Experiment Information Window will open.

Experiment Name	<p>This is the name of the file that is used to store the results of the experiment. The format of the data file is EXPERIMENT 1.csv.</p> <p><i>Note: If the same experiment name is used more than once, each subsequent data set saved will be appended to the end of the previous experiment file.</i></p>
Experiment Description	<p>This allows the user to a description of the Experiment.</p>

CRITERIA TO AUTOMATICALLY STOP PUFFING

There are times when you may want to stop an experiment before it has completed the total number of puffs. For example, if the device, E-Cig Pen or Mod, runs out of fluid, you may want to stop puffing.

The EVT Smoke Machine Controller can monitor the particle concentration levels using the EVT In-Line Photometer Adapter (Optional). From the concentration levels, the total amount of exposed material can be determined. Puffing can be stopped if either the concentration level gets too low or the total exposed material reaches a preset level.



Experiment Information Dialog Window	
Maximum Number of Puffs	This sets the total number of puffs that will be performed during the Experiment.
Stop when the maximum number of puffs is completed	When selected, this determines when the Experiment will end. When the total number of puffs matches this number, the EVT Controller will stop puffing and end the experiment
Stop automatically when concentration falls below X mg/m³ for three consecutive puffs	<p>When selected, the EVT Controller will stop puffing if the concentration levels assessed by the EVT In-Line Photometer Kit (Optional) fall below the set concentration level for three consecutive puffs, <u>prior</u> to reaching the maximum number of puffs. Concentration is measured in mg/m³.</p> <p>This feature is ideal for electronic cigarettes. The system will stop once the liquid runs out if it hasn't reach the maximum number of puffs.</p> <p>This feature requires the use of a photometer and will be greyed out (disabled) when a photometer is not associated with the station in the Puff Properties.</p>

Experiment Information Dialog Window	
Stop automatically when Total Exposed Material is X mg.	<p>When selected, the EVT Controller will stop puffing when the total amount of exposed material reached the set level, <u>prior</u> to reaching the maximum number of puffs. The total amount of exposed material is measured in mg.</p> <p>This feature requires the use of a photometer and will be greyed out (disabled) when a photometer is not associated with the station in the Puff Properties.</p>

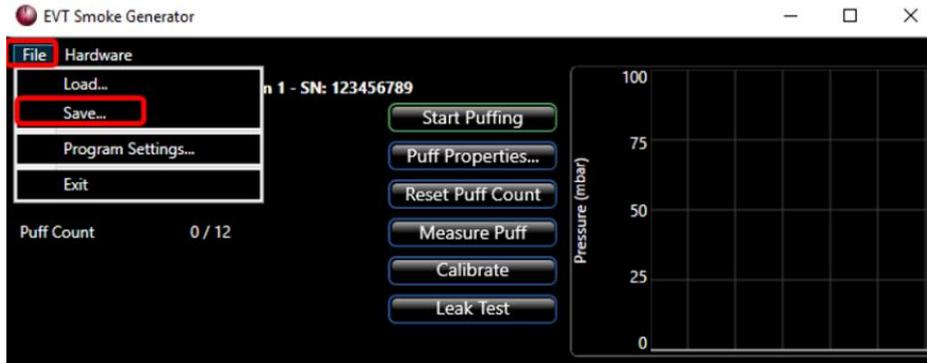
PRE AND POST EXPERIMENT PUFF MEASUREMENTS

The EVT Software has the option of collecting a Pre-Experiment Puff Measurement and a Post-Experiment Puff Measurement. These puff measurements are a way of determining how much the actual puff volume may have changed during the experiment. The user can compare the two puff volumes and, if they believe that the puff volume has changed significantly, they can decide if they want to adjust the volume measurements captured in the Experiment Data File. This is an optional step to take measurements prior and post experiment, but it is encouraged as it can help assess if the puff volume changed during the course of the experiment more than is desirable.

Pre-Experiment Puff Measurement	A Pre-Experiment Puff Volume Measurement can be taken before you begin an experiment. This information is stored in the Experiment Data file.
Post-Experiment Puff Measurement	A Post-Experiment Puff Volume Measurement can be taken after an experiment. This information is stored in the Experiment Data file.

SAVING AND LOADING PROFILES & CALIBRATIONS

The EVT Software allows you to save Experiment Profile Information. By saving the Experiment Profile, it can be loaded later to reproduce the experiment. Experiment information is saved to an XML file. The XML file contains information such as Photometer and Supplemental Flow settings, puff properties settings, graph scaling, the location where results are stored, as well as an indicator if the Experiment Information option was selected. Once you have completed setting up the experiment, you can save the experiment information to be loaded again for potential use in future experiments. To save the experiment, select File and Save.



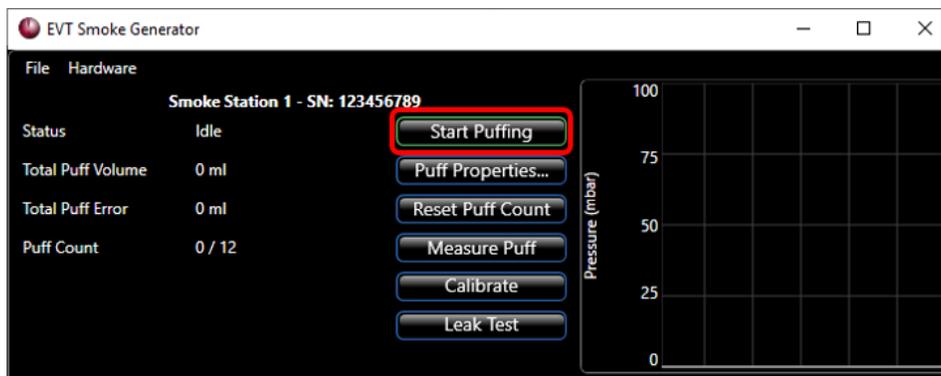
Windows File Manager will open. You can save the experiment information to the default folder or select one of your own.

Once an experiment has been saved, it can be reloaded at any time by selecting File/Load and selecting the appropriate experiment file.

START PUFFING – RUNNING AN EXPERIMENT

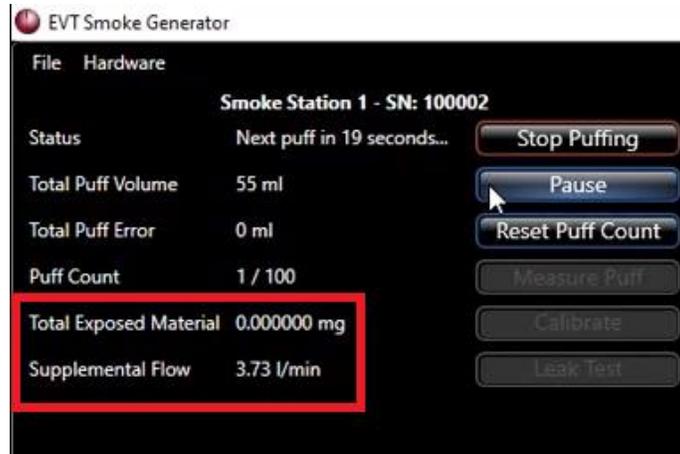
Once all the experiment parameters are set, the experiment can begin.

To begin the Experiment, click on the Start Puffing button in the Main Window.



The Experiment Information dialog will appear and prompt the user to enter the experimental information. See

Experiment Window Dialog for more information on the fields in this dialog. If a supplemental flow unit is associated with the station, the station information will include the the real-time value of the supplemental flow along with the ending criteria specified in the “Criteria to Automatically Stop Puffing” as shown in the screenshot below. In the screenshot below, the criteria specified was “Stop automatically when Total Exposed Material is x mg”.



Note: if at anytime during the experiment the user would like to pause puffing, the user can select “Pause” without stopping the entire experiment (see screenshot above with the option of Pause displayed). When the user would like to commence puffing, the user should select “Resume Puffing”

The main interface/graph display, example shown in Figure 17, will update specific to the user’s setup. In the example below. The user set the maximum number of puffs to 100 and has selected to “Stop automatically when Total Exposed Material is 1 mg”. Therefore, the dialog window for station 1 has Puff Count displayed (see information displayed within the yellow rectangle of Figure 17) and Total Exposed Material (see information displayed within the red rectangle of Figure 17). Also, the user is using a supplemental Flow unit and that flow of the unit is displayed (see information displayed within the blue rectangle of Figure 17). The graphs will displayed the pressure graph (purple rectangle of Figure 17) and photometer concentration, when applicable, (green rectangle of Figure 17).

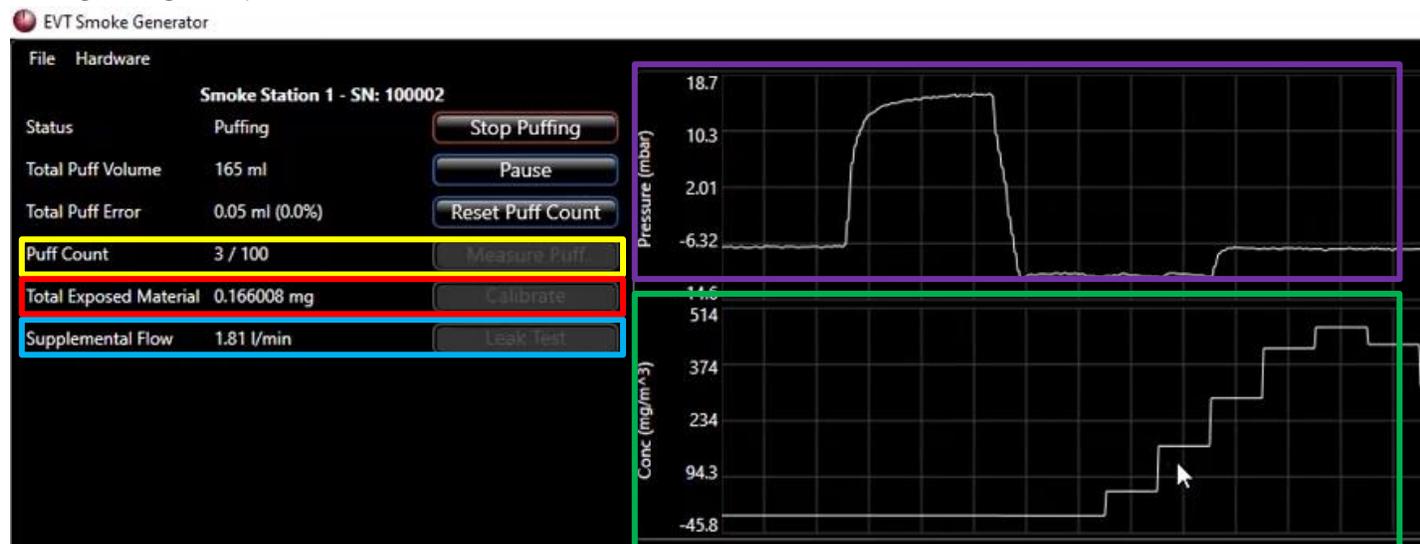


Figure 17

ENDING AN EXPERIMENT AND SAVING DATA

When an experiment is completed, the Experiment Information Window will open.

The user is allowed to enter or modify the Experiment Description, capture a Post-Experiment Puff Volume Measurement, and save the Experiment Data.

Figure 18 – Ending an Experiment within the Experiment Information Dialog

INFORMATION ON DATA FILES

The EVT Software saves data from the experiment into CSV files. The data files are described within this section.

EVT EXPERIMENT LOG.CSV

There is a single file used to store the results from all performed experiments. This file is appended to at the completion of each experiment.

Column Name	Format	Definition
Start Time	Date and Time Example: 2020-04-28 13:34:00	This is the date and time that the experiment started. Format is yyyy-mm-dd hh:mm:ss
Experiment Name	Text User Input Examples: Experiment 1 3 Stations Puffing	This is the Experiment Name entered by the user in the Experiment Information Window. The default is Experiment 1

Column Name	Format	Definition
		<i>Note: If the experiment name is not changed, and an additional experiment is run, the data will be appended to the experimental data set.</i>
Experiment Description	Text User Input Example: E-Cig Vape Test	This is a description of the experiment entered by the user in the Experiment Information Window.
Controller SN	Number Format Example: 1234	This is the serial number of the EVT Smoke Machine Controller used in the experiment
Smoke Station SN	Text Examples: 1001256 1001256, 1001257, 1001258	This is the serial number(s) of the EVT Smoke Station(s) used in the experiment. If multiple stations are used, the serial numbers are separated with a comma. The values are listed in the order of stations starting with station 1.
Total Puffs	Number Example: 1243	This is the total number of puff cycles performed in the experiment.
Total Exposed Material	Number Reported in mg/m ³ Example: 1.2345	This is the total amount of material generated during the experiment, reported in mg/m ³ .
Initial Puff Measurement Time	Date and Time Example: 2020-04-28 13:34:00	This is the time when the Pre-Experiment Puff Volume Measurement was performed as part of the Experiment Information Window.
Initial Puff Volume	Number Reported in m; Examples: 55.22 44.36, 46.81, 46.95	This is the Pre-Experiment Puff Volume recorded when the Pre-Experiment Puff Volume Measurement was performed. It is reported in ml. If there are more than one station, the puff volume for each station will be reported separated by a comma.
Post-Puff Measurement Time	Date and Time Example: 2020-04-28 13:34:00	This is the time when the Post-Experiment Puff Volume Measurement was performed as part of the Experiment Information Window.
Post Puff Volume	Number Reported in m; Examples: 55.22 44.36, 46.81, 46.95	This is the Pre-Experiment Puff Volume recorded when the Pre-Experiment Puff Volume Measurement was performed. It is reported in ml. If there is more than one station, the puff volume for each station will be reported separated by a comma.
Puff Volume	Number Example: 55	This is the value of the pull volume selected in the Puff Properties Window. The number is reported in ml.
Puff Duration	Number Example: 4	This is the Inhalation time duration of the puff set in the Puff Properties Window. The number is reported in msec.
Exhale Duration	Number Example: 3	This is the Exhalation time duration of the puff set in the Puff Properties Window. The number is reported in msec.
Puff Frequency	Number Example: 6	This is the rate of puffing during the experiment set in the Puff Properties Window. It is reported in puffs per minute
Cigarette Type	Text Example: MidSizePenECig	This is the cigarette type selected in the Puff Properties Window. Options are: Traditional Cigarette First Generation E-Cig Mid-Size "Pen" E-Cig

Column Name	Format	Definition
		MOD Vaporizer
Time Constant 1	Number Reported in Seconds Examples: 0.00025 0.00015, 0.000162, 0.000124	This is the rising edge time constant determined during the calibration process. It is measured each time a calibration is performed. The values are reported in seconds. Calibration will fail if the value exceeds 0.001 seconds. If more, then one station is used during the experiment, the value for each station will be separated by a comma. The values are listed in the order of stations starting with station 1.
Time Constant 2	Number Reported in Seconds Examples: 0.00025 0.00015, 0.000162, 0.000124	This is the falling edge time constant determined during the calibration process. It is measured each time a calibration is performed. The values are reported in seconds. Calibration will fail if the value exceeds 0.001 seconds. If more, then one station is used during the experiment, the value for each station will be separated by a comma. The values are listed in the order of stations starting with station 1.
Associated Concentration	Number	This is the value of the concentration of smoke or vape as measured by the photometer. It is measured in mg/m ³

PUFF LOG.CSV

The software generates a log of all puffs performed during the experiment. This log is saved into a file that is named using the smoke station information. For example, an experiment run on station 1 will be named "Smoke Station 1 Puff Log.CSV". If multiple experiments are performed, the results will be appended.

Column Name	Format	Definition
Puff Time	Date and Time Example: 2020-04-28 13:34:00	This is the date and time that the puff started. Format is yyyy-mm-dd hh:mm:ss
Step Error	Number	The difference in the number of steps performed by the stepper motor and the programmed number of steps.
Photometer Average	Number	The average photometer reading during the exhale portion of the puff. This column will be blank if an In-Line Photometer Kit is not enabled for the smoke station.

SIGNALS.CSV

The software generates a log of all signals measured during the experiment. This log is saved into a file that is named using the smoke station information. For example, an experiment run on station 1 will be named "Smoke Station 1 Signals.CSV". If multiple experiments are performed, the results will be appended, following a header indicating the start of the experiment, and sampling rate.

Column Name	Format	Definition
Pressure	Number	The pressure samples measured during the experiment. Units a millibar.
Concentration	Number	The photometer samples measured during the experiment. Units are mg/m ³

SETTING UP A 1ST GENERATION E-CIG OR TRADITIONAL TOBACCO CIGARETTES



The EVT Smoke Generator Controller can be used to collect aerosolized samples from 1st Generation Cigarettes (E-Cigs) and traditional tobacco cigarettes. This is done by drawing air through the E-Cig or cigarette into the Inhale Port of the bellows assembly like the way Mod or Pens are sampled. Air can be drawn in the precise, controlled flow and volume, providing a clean representation of a “Standard Puff,” as called out in ISO Standards.

FITTING OPTIONS/ATTACHMENT POINTS

The 1st Generation E-Cig or traditional Cigarette can be held in place for use with the EVT Smoke Generator Controller using two different methods.

1) **Labyrinth Assembly**

The 1st Generation E-Cig or traditional tobacco cigarette can be inserted into the Labyrinth Assembly and held in place. The labyrinth assembly supports the 1st Generation E-Cig or traditional cigarette while providing an airtight seal. 1st Generation E-Cigs or cigarettes can be quickly replaced by simply pulling out the used article and inserting a new one into the labyrinth assembly. The EVT Software will display the amount of time before the next puff or allows the user to pause the system while replacing the test article. Note - as specified within ISO 20768, the neoprene backer washer may be removed if desired

when using the labyrinth seal assembly with e-cigs to allow additional insertion length and support for the e-cig.

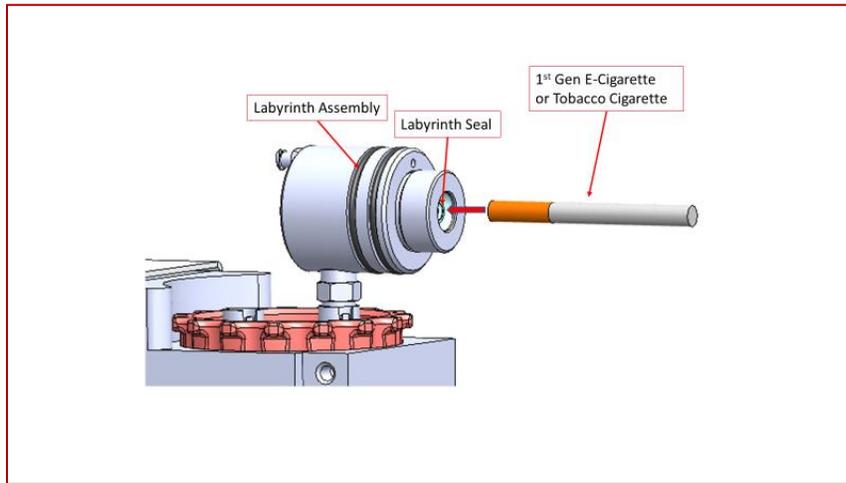


Figure 19 – Labyrinth Assembly

- 2) The 1st Generation E-Cig can alternatively be held in place using the elbow connector (014008-001) and a short piece of tubing. The tubing must be sized appropriately to the e-cig to ensure a good seal. The elbow connector is connected to the Inhale port of the bellows assembly. The small piece of tubing can be connected to the end of the elbow fitting. The E-Cigarette can be inserted into the tubing, as demonstrated in Figure 20



Figure 20 – Placing 1st Gen E-Cigarette in Elbow Connector in the Inhale Port of the Bellows Assembly

LIGHTING

Traditional Tobacco Cigarettes must be lit at the beginning of the experiment, and after each cigarette is exhausted and needs to be replaced with a new cigarette. This must be done at the beginning of a puff, so the action of drawing air into the cigarette will help light the tobacco.

For the first cigarette, the user will insert the cigarette into the Labyrinth Assembly, bring a flame (or heating element) to the end of the cigarette, and click on the “Start Puffing” button in the EVT Software.

The EVT software allows the user time to replace exhausted cigarettes between puffs. The Main Window status display indicates the time to the beginning of the next puff. The user will know when the next puff will begin so they can replace the cigarette and bring a flame (or heating element) to the tip of the cigarette as the puff starts. EVT software interface also allows the study to be paused and restarted to allow for more time between new test articles if required or other study maintenance.

PUFF SETTINGS

PUFF SETTINGS – 1ST GENERATION E-CIG

The EVT software, used in conjunction with the EVT Smoke Generator Controller, can sample the 1st Gen E-Cigarette by drawing air through the device. The sample is called a “puff.” Puff properties are determined by the volume of air drawn during the puff, the inhalation duration of the puff, and the exhalation duration of the puff. The concentration of smoke or vape is determined by the puff properties, the puffing frequency, the total number of puffs performed, and any additional dilution air added by the Supplemental Flow Controller during the experiment.

The EVT Software can be used to tailor the “puff” attributes by allowing the user to set the parameters of the puff. A preset standard “puff” for 1st Gen E-Cigarette devices based on ISO standards can be selected, or the puff attributes can be customized to user-specified parameters. For 1st Generation E-Cigs, just as with Pens and Mods ISO 20768:2018 calls for a puff volume of 55ml with an inhalation duration of 3 seconds and a puff frequency of 2 puffs per minute.

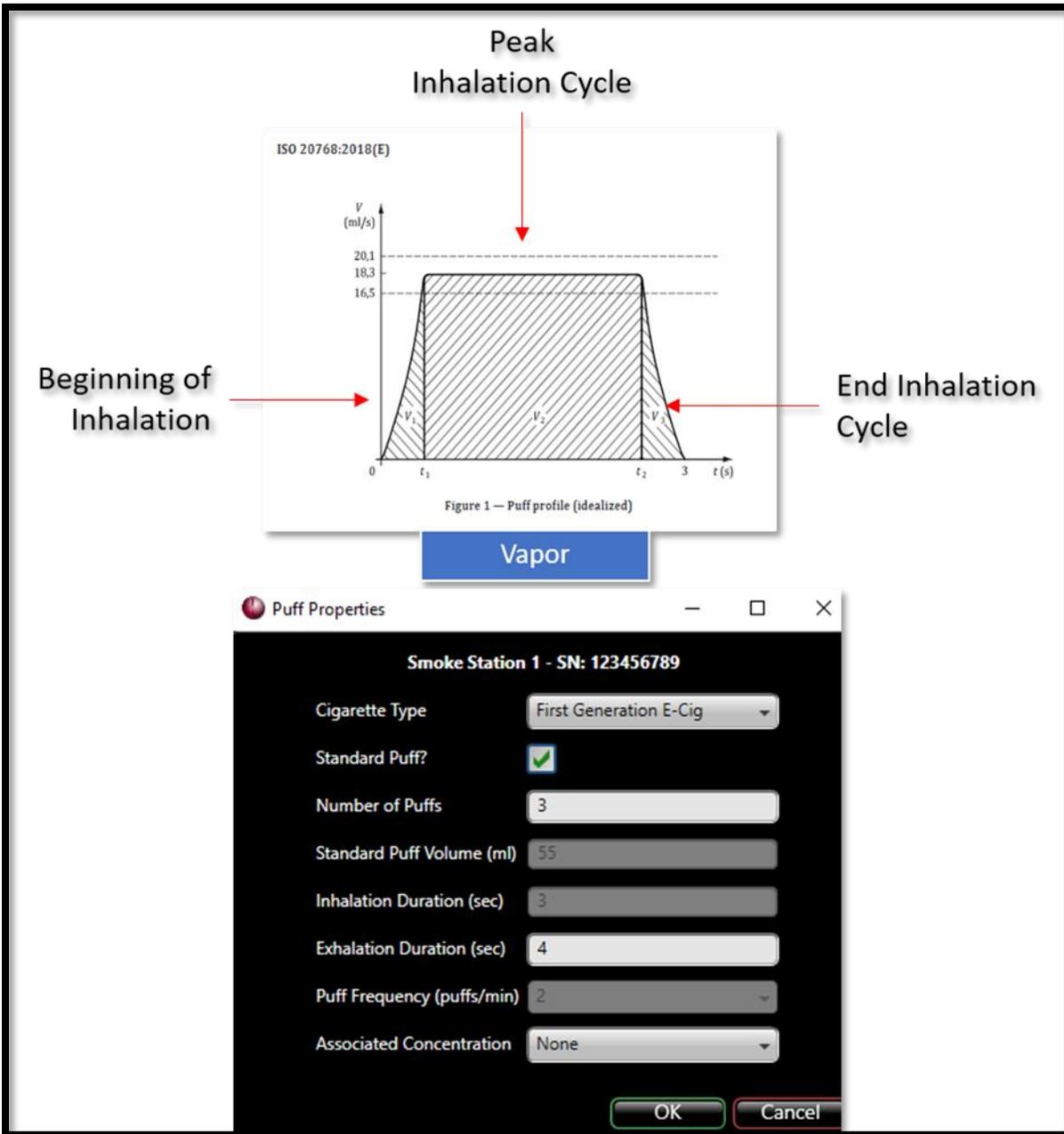


Figure 21

More information on how to set the Puff Properties can be found in the Puff Properties section in the EVT Software User’s Manual part of this manual.

PUFF SETTINGS – TRADITIONAL CIGARETTES

The EVT software, used in conjunction with the EVT Controller, can sample a traditional tobacco cigarette by drawing air through the test cigarette while it is lit. The sample is called a “puff.” Puff properties are determined by the volume of air drawn during the puff, the inhalation duration of the puff, and the exhalation duration of the puff. The concentration of smoke is determined by the puff properties, the puffing frequency, the total number of puffs performed, and any additional dilution air added by the Supplemental Flow Controller during the experiment.

The EVT Software can be used to adjust the “puff” attributes by allowing the user to set the parameters of the puff. A preset standard “Puff” for traditional tobacco cigarettes based on ISO standards can be selected, or the puff attributes can be customized to a variety of requirements. For traditional tobacco cigarettes, ISO 3308:2012 calls for a puff volume of 35ml with an inhalation duration of 2 seconds and a puff frequency of 1 puff per minute.

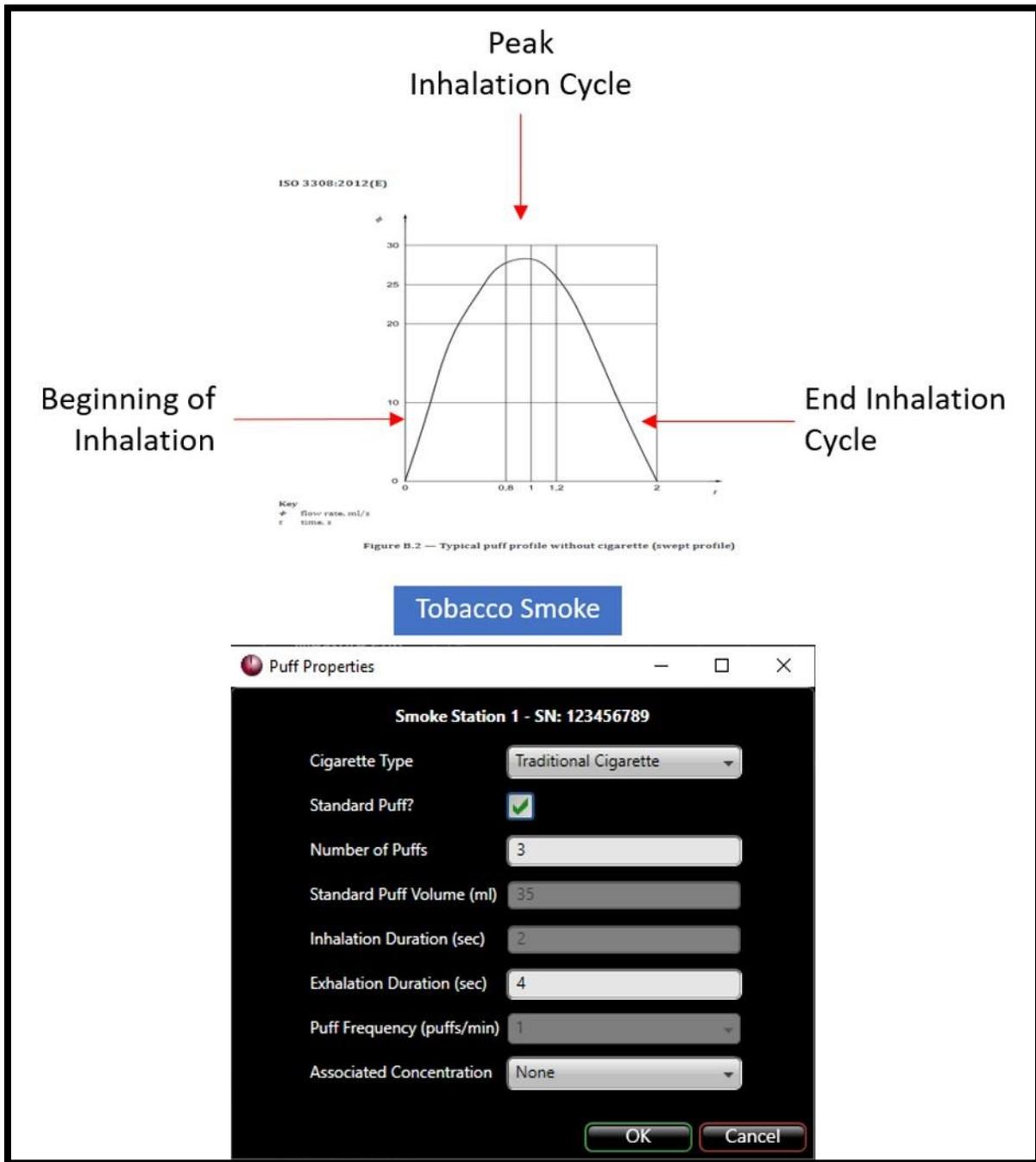


Figure 22

More information on how to set the Puff Properties can be found in the Puff Properties section in the EVT Software User's Manual part of this manual.

SIDESTREAM SMOKE CAPTURE

The Labyrinth Assembly also has a feature that can be used to capture sidestream smoke from the cigarette. It utilizes a containment cover that is attached to the assembly, which will prevent the smoke from escaping from the system. The containment cover captures the smoke from the cigarette and allows it to be diverted. The smoke can be pulled out of the cover through a connector to divert the side stream either back to the main exhalation output or to an alternative desired location.

There are two sidestream connectors, one located on the side of the Labyrinth Assembly and the other on the Labyrinth Assembly End Cap. The connector located on the End Cap, connector 5 shown below, is an exhaust port. A vacuum should be connected to this port to draw air, and sidestream smoke through the tube and either back into the main exhaust port flow, filtered, or another desired target. The connector located on the Labyrinth Assembly, connector 4 shown below, should be left open, allowing air to be drawn into the assembly and out through the exhaust connector.

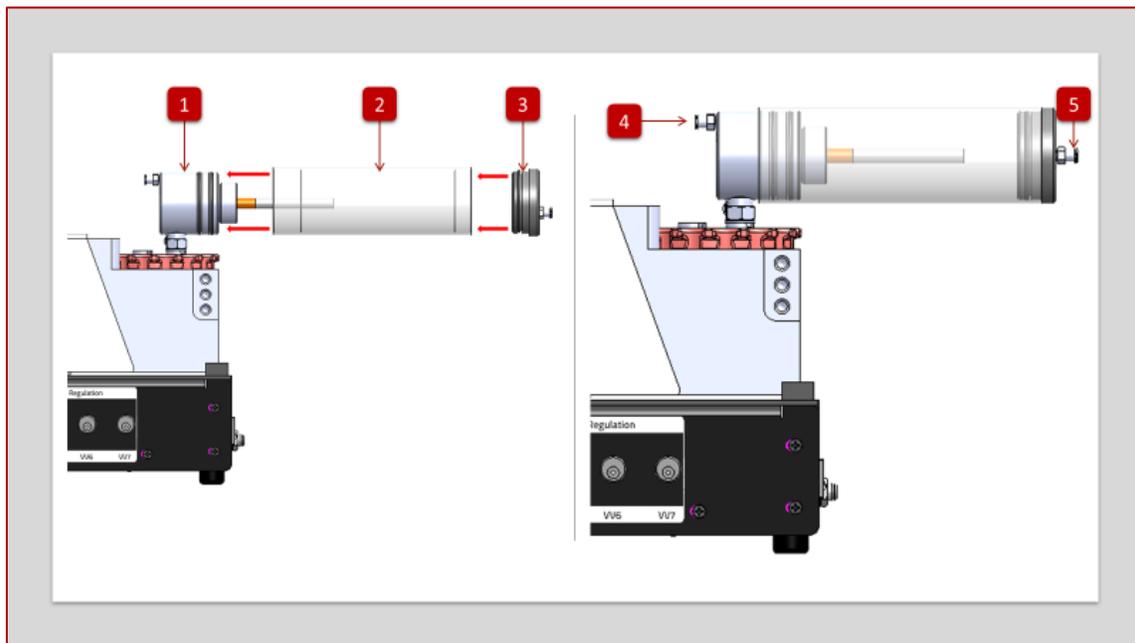


Figure 23

- (1) Labyrinth Assembly
- (2) Labyrinth Assembly Cover
- (3) Labyrinth Assembly End Cap
- (4) Intake Port Connector
- (5) Exhaust Port Connector

To use the sidestream smoke feature

- 1) Make sure that the exhaust tube is connected to the exhaust connector (5), and a vacuum is applied.
- 2) Make sure the Intake Port connector (4) is left open.
- 3) Insert a cigarette into the Labyrinth Assembly.
- 4) Light the cigarette at the beginning of the first puff, or next puff.
- 5) Slide the Labyrinth Assembly Cover and Labyrinth Assembly End Cap over the Labyrinth Assembly.

When it is time to replace the cigarette, slide the cover and end cap off the Labyrinth Assembly and remove the expended cigarette. Repeat steps 1-6 above. *Note: the sidestream cover may be protected from falling cigarette embers by lining tube with aluminum foil or similar.*

SETTING UP A MOD OR PEN DEVICE

The EVT Generator can be used to collect aerosolized samples from devices such as Mods or Pens that are activated with button ignition. The EVT Controller, in conjunction with the Buxco EVT Button-Activated Device Holder Kit, can activate the Mod or Pen Device by pushing the ignition button during the “puff” cycle and acquiring a sample of the aerosolized vape. The push-button timing is designed to be synchronous to within 0.1 sec of start and completion of puff as defined in ISO 20768. It will continue to ignite the device for every puff sample until the total number of puffs has been acquired.

The Mod or Pen is held in place using the Buxco EVT Button-Activated Device Holder Kit. The EVT Smoke Generator Controller provides air to the device holder platform through the Button Activation ports located on the front of the Controller. This air activates a small piston that pushes and holds the ignition button during the Inhale cycle. The EVT Station draws air through the Mod or Pen into the bellows assembly and then is pushed out from Exhale Port, just as when using non-actuated devices.

ATTACHING A MOD DEVICE OR PEN TO THE EVT BUTTON-ACTIVATED DEVICE HOLDER KIT

The EVT Button-Activated Device Holder Kit contains a platform assembly that holds the Mod or Pen device while it is being sampled by the EVT Smoke Machine. The platform holds the device in place and allows for device angle adjustment to ensure the wick remains in contact with the vaping liquid during use.

A Mod or Pen can be installed onto the platform using the steps listed below. The primary components of the EVT Button-Activated Device Holder Kit are shown below (see **Figure 24 – Device Holder Kit**).

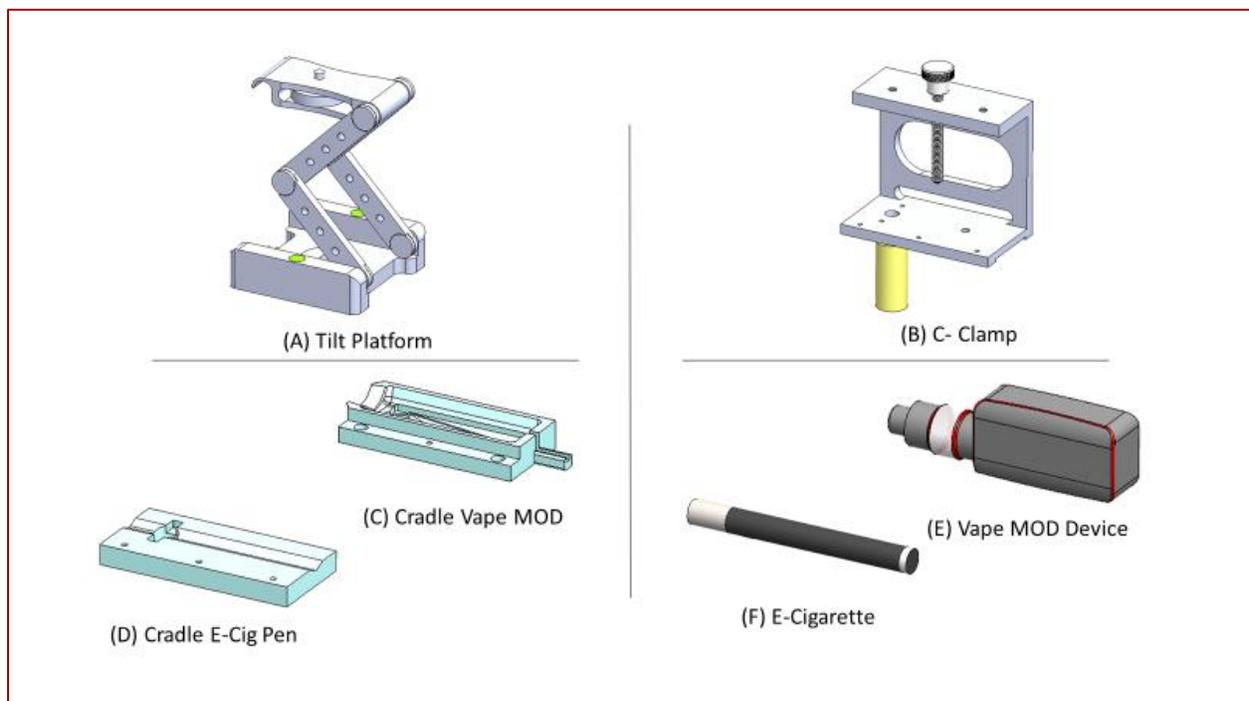


Figure 24 – Device Holder Kit

Directions for installing a Mod or Pen device on to the EVT Button-Activated Device Holder Kit.

- 1) Attach the C-Clamp (B) to the Tilt Platform (A)
 - a. Place the C-Clamp to on top of the Tilt Platform and secure it by tightening the attachment screw located below the top of the platform. Allow clearance for the igniter push button piston.

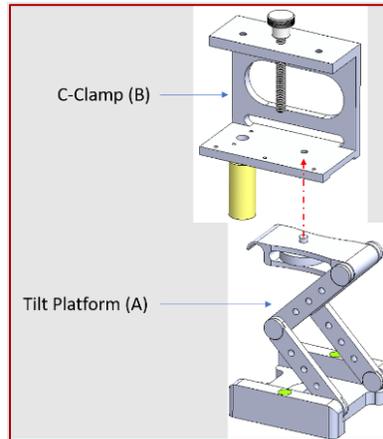


Figure 25

- 2) Insert the Cradle (C for Mod, D for Pen) into the C-Clamp (B) by placing it on the C-Clamp then sliding it into the opening in the side of the clamp.

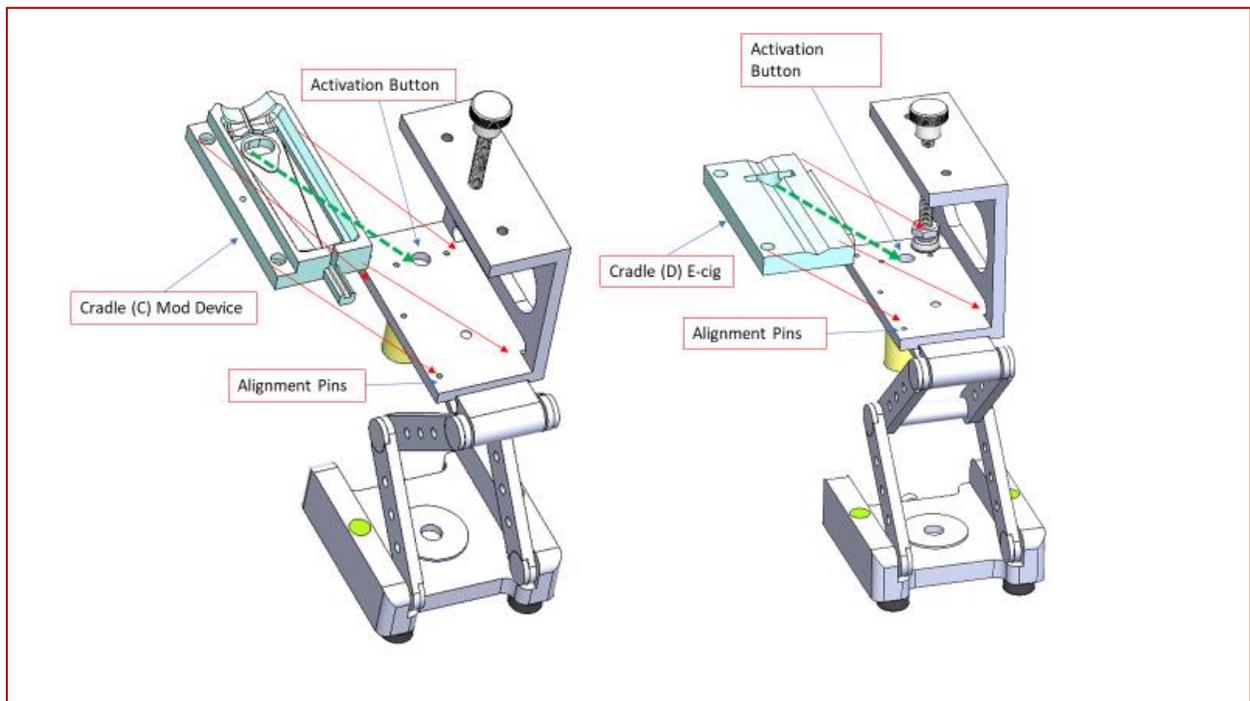


Figure 26

- 3) Place the Mod (E) or the Pen (F) on to the Cradle and clamp it into place with the clamp screw by rotating it counterclockwise until snug.

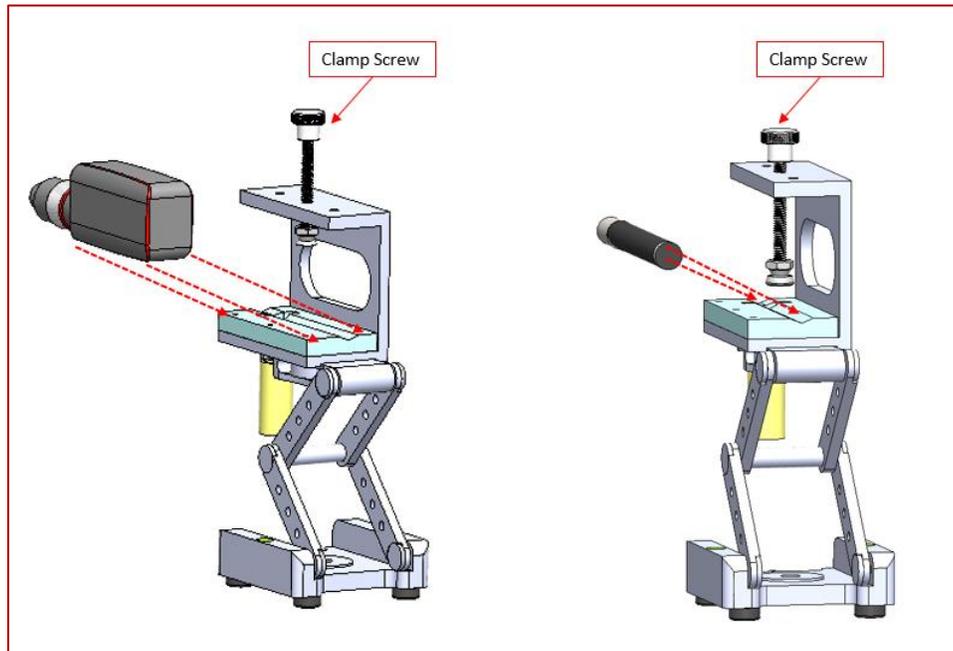


Figure 27

ATTACHING FLOW PATH TUBING FOR THE INHALATION PORT

DSI provides a Barbed Drip Tip Adaptor, which is used to connect the Mod Tank. This Drip Tip Adaptor is then connected with a high-temperature silicone tubing to an elbow connector attached to the Inhale Port of the EVT bellows assembly.

For Pen devices, simply attach the high-temperature silicone tubing to the Pen's mouthpiece. The other end of the tubing is connected to the elbow connector attached to the Inhale Port of the EVT Bellows Assembly.



CAUTION. *High-temperature silicone tubing is recommended. The heat from the Mod could damage or melt lower-temperature tubing, such as urethane tubing.*

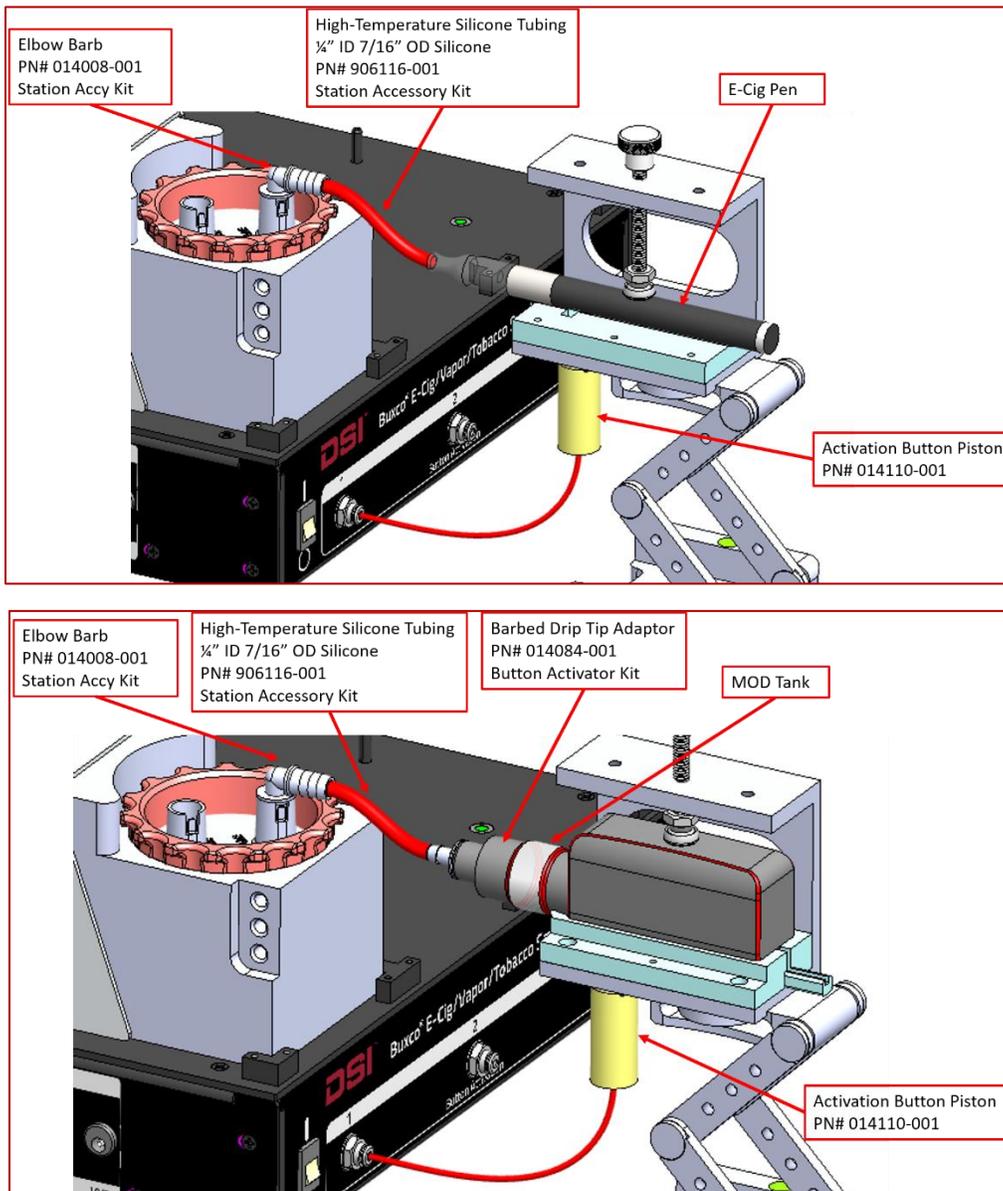


Figure 28 - Mod and Pen Connections

ANGLE/HEIGHT ADJUSTMENT

The Mod or Pen is held in place by the EVT Button Activated Device Holder Kit. The Holder Kit can be raised and lowered as well as tilted backward to hold the Mod or Pen in place properly.

The height of the Mod or Pen should be set, so the device is slightly lower than the connection to the Inhale Port on the bellows assembly. This will prevent any condensation of vape fluid within tubing from running into the bellows assembly. Also, try to minimize the number of bends between the drip tip and the Inhale port connector to minimize the pooling of condensed fluid within the line. To adjust the height of the Mod, simply expand or contract the tilt platform legs.

The Mod should also be tilted backward so the fluid in the Mod tank stays in the tank and will not flow into the barbed drip tip adapter connected to the front of the Mod. It is suggested that the Mod or Pen Device should be tilted backward at roughly a 30° tilt. To tilt the Mod device back, lift the front of the tilt platform while holding the legs of the platform in place. Once the desired angle of the platform is established, re-tighten the platform joints with Allen wrench provided in the kit to ensure the device angle is stable throughout your study (*Note A in Figure 29 – Holder Kit Connections*)

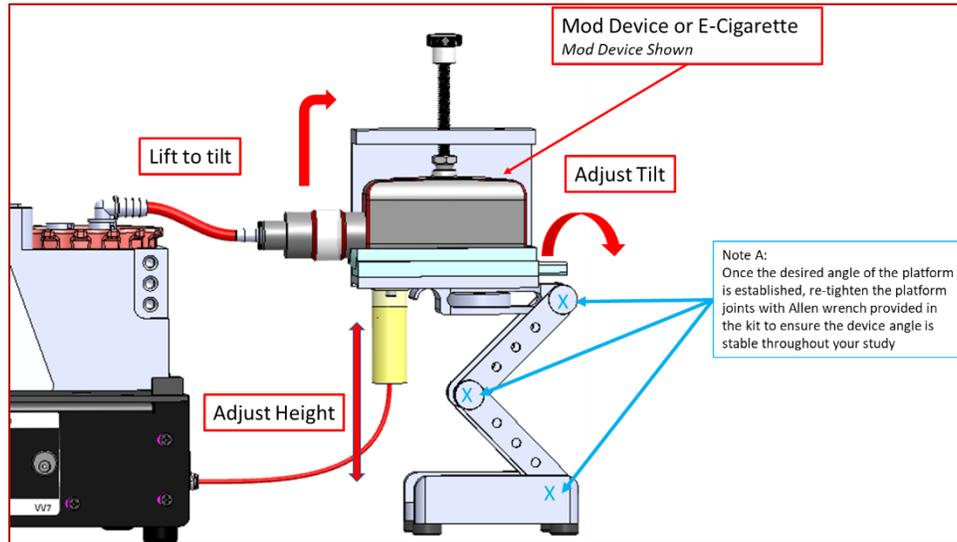


Figure 29 – Holder Kit Connections

EVT BUTTON-ACTIVATED DEVICE HOLDER KIT

The Buxco EVT Button-Activated Device Holder Kit is designed to hold a Pen or Mod device in place, tilt the device to the proper angle to ensure wick stays in contact with vaping liquid, and maximize fluid consumption during use, and activate the device during the inhale portion of puff cycle. The button activation cylinder, located on the platform, is connected to the Controller via a small (1/8" OD) tube attached to the Button Activation connection on the front of the Controller.

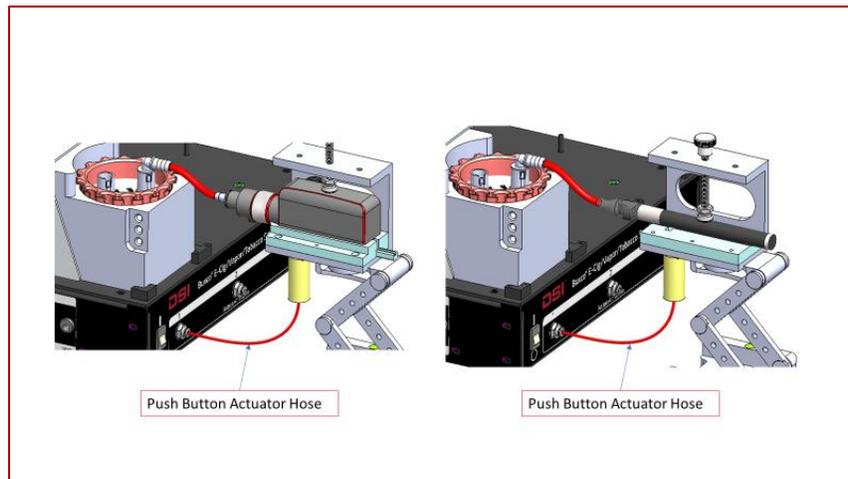


Figure 30 - Button Activation

Button activation is done using a small cylinder located on the tilt platform. This cylinder is activated by air from the EVT Smoke Machine Controller. The cylinder is driven by an external regulated air source attached to the Controller's Air Source Connector.

SETTING THE AIR PRESSURE FOR THE EVT BUTTON ACTIVATION DEVICE HOLDER KIT

The amount of pressure needed to trigger the ignition button on electronic nicotine delivery devices can vary from device-to-device. It is essential to set the pressure level high enough to push the ignition button reliably but not too high to damage the device. We have the following to hold true on some devices we have evaluated

- A pressure of 50 psi generally used for Mod Devices, example SMOK X-Priv
- A pressure of 30 psi generally is used for Pen Devices, example NJOY Standard Research Cigarette (SREC)



CAUTION. *Using excess pressure to operate the activation cylinder on the EVT Button Activation Device Holder Platform can damage the Mod or Pen device. As a general rule -- to establish required pressure slowly increase input air pressure supply to Controller until the activation is just achieved and add ~10psi (.75bar) to ensure activation.*

CONSIDERATIONS FOR MOD COIL LIFE

When using a Mod device, it is important to take into consideration the life of the ignition coil or wick. Coils or wicks will burn out or leak with time and need to be replaced. Higher frequency, puff volumes, and MOD wattage will tend to decrease life requiring replacement more frequently.

When mounting the Mod or Pen on the EVT Holder Kit, check that your device does not leak fluid.



CAUTION. Vaping devices vary considerably from manufacturer to manufacture and can generate significant heat, primarily when utilized at higher puff frequencies than would otherwise typically be utilized. Care should be taken when establishing settings for MOD and puff parameters such as to avoid overheat device and or when handling this device during use.

TIMING/MECHANICAL LIMITATIONS

There are limitations to how the puff parameters can be set.

- The maximum number of puffs per minute is determined by the puff parameters. The maximum number of puffs is the sum of the inhalation duration time, the exhalation duration time, and 1 second of "Set Up" Time. For example, if the inhalation duration and the exhalation duration are both set to 5 seconds, considering a 1 second set up time, the total time for a single puff would be 11 seconds. In this example, the maximum number of puffs per minute would be limited to 5.
- The maximum flow rates the EVT Smoke Machine can generate during a puff is 30ml/sec. This is simply a limitation of the travel speed of the stepper motor and the bellows assembly.

PUFF SETTINGS

The EVT software, used in conjunction with the EVT Controller, can sample the Mod device by drawing air through the Mod while the EVT Holder Kit activates the ignition button. The sample of vape is acquired by pulling air through the Mod in what is called a “puff.” Puff characteristics are determined by the volume of air drawn during the puff, the inhalation duration of the puff, and the exhalation duration of the puff. The concentration of smoke or vape, the amount of fine and ultrafine particles, are affected by the puff properties, the puffing frequency, and the total number of puffs performed during the experiment.

The EVT Software can be used to adjust the “puff” attributes by allowing the user to set the parameters of the puff. A preset “Standard Puff” for Mod or Pen devices, based on ISO standards, can be selected, or the puff can be customized with a variety of settings. For Mod or Pen devices, ISO 20768:2018 specifies for a puff volume of 55ml with an inhalation duration of 3 seconds and a puff frequency of 2 puffs per minute. The flow profile is characterized by a trapezoidal shape like what is shown in the figure below.

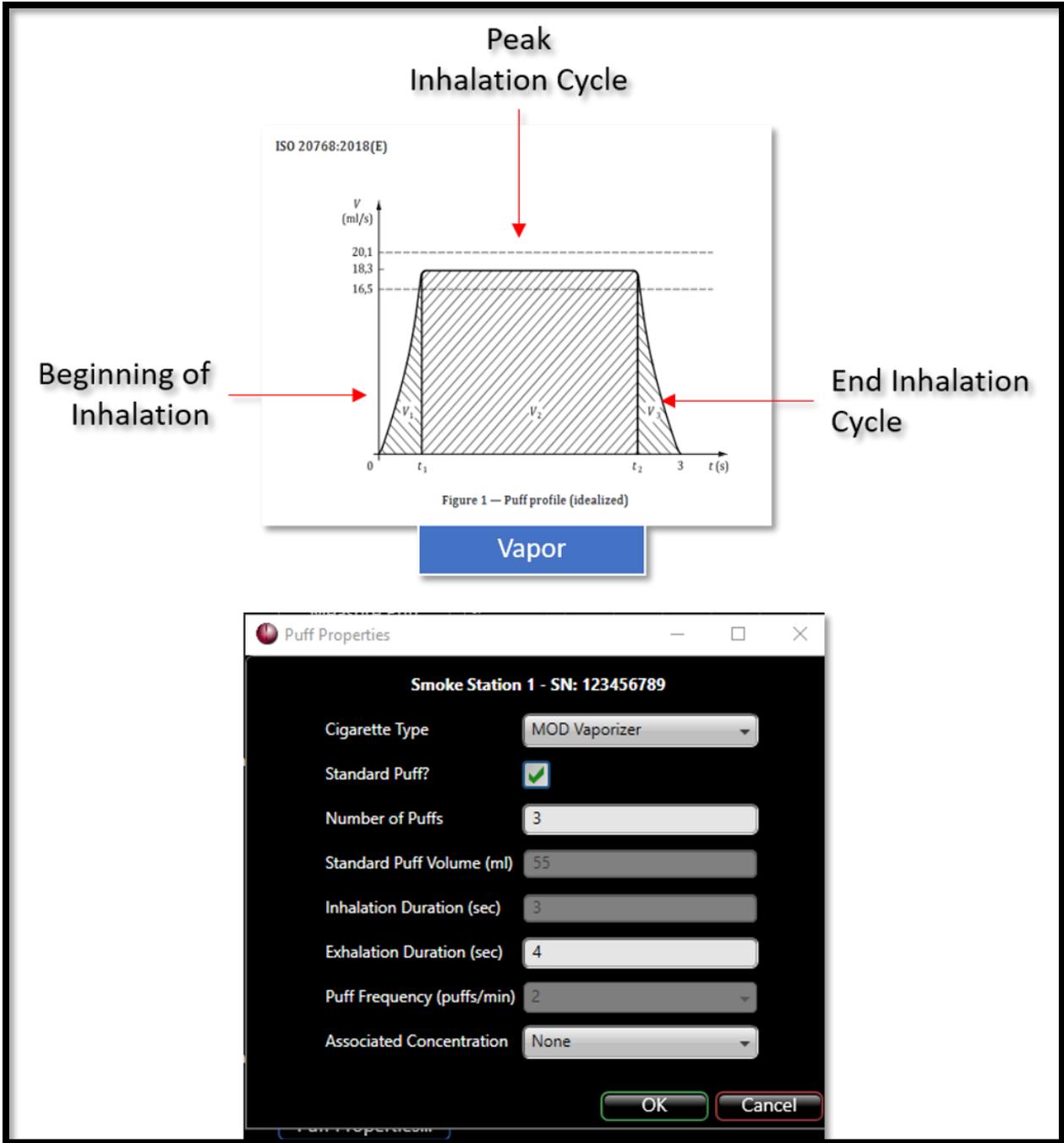


Figure 31 - The flow profile is characterized by a trapezoidal shape for the MOD vaporizer and the Mid-Size “Pen” E-Cig

More information on setting Puff Properties can be found in the *Puff Properties* sections of this manual.

EVT SMOKE MACHINE KITS:

EVT PUFF VOLUME MEASUREMENT KIT (MASS FLOW SENSOR)

The EVT Puff Volume Measurement Kit is used to calibrate or validate the puff volume generated by the EVT Station. The puff volume is measured as a part of the calibration process, where it is used to adjust the station piston displacement to achieve the target volume. A measured pre-experiment and post-experiment puff volume can be captured and stored in the experiment data file for review when the experiment is done.

The Puff Volume Measurement Kit consists of a Mass Flow Meter and all the tubing and connections necessary to perform a puff volume measurement.

- 1) Connect the Inhale inlet on the Smoke Machine Station to the flow restrictor tubing assembly that was provided with your Measure Puff Kit. The Flow Restrictor Assembly consists of an elbow connection that is inserted into the Inhale Port on the bellows assembly, a Flow Restrictor, and a small piece of tubing connecting them. **Note: It is essential to connect tubing to mass flow sensor such that anticipated flow is in the direction of the arrow label indicated on top of the mass flow sensor.**
- 2) Plug the Mass Flow Meter into the number 1 I²C port of the EVT Controller.

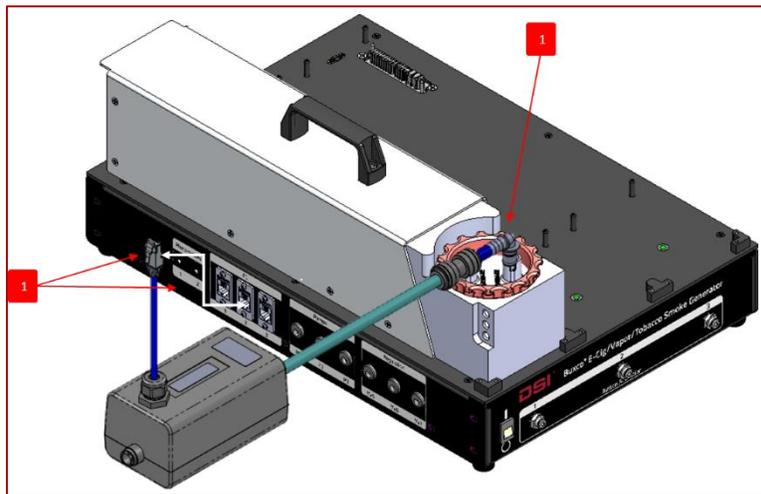


Figure 32 - Connecting the Mass Flow Meter (Puff Measurement Kit) to the EVT Controller

For more information on how to capture a puff volume measurement, see the Measuring the Puff Volume section in this manual.

IN-LINE PHOTOMETER ADAPTER

Real-time smoke or vape concentration levels can be measured using the EVT In-line Photometer Adapter. The photometer probe can be located on the “Exhalation” line from the EVT Station, as shown in Figure 33 - EVT with Photometer Kit, and or post-dilution and or mixing with the use of the Buxco Supplemental Flow Unit(s) or EVT Reservoir Kit mixing vessel. Signals from the In-line Photometer are connected to the EVT Controller Panel and can be configured for use using the EVT Software.



CAUTION. Placing the Casella CEL-712 Photometer directly in-line with a concentrated vape or smoke output may reduce the time required between probe cleanings. Please consult the Casella manual for additional information on proper cleaning methods and or if required, how to have your probe serviced by Casella. DSI has found that when using MOD devices with a heavy aerosol mass that adding dilution is the preferred approach.

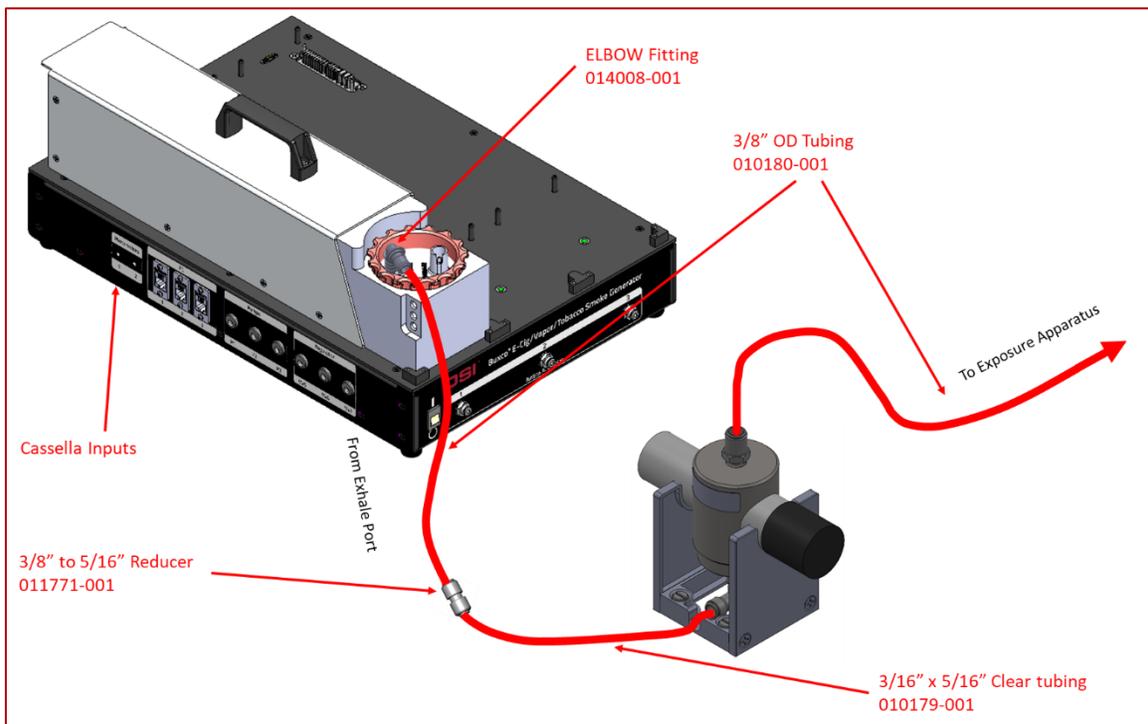


Figure 33 - EVT with Photometer Kit

The monitoring of aerosol concentration from the EVT Generator allows users to assess the level of smoke or vape concentration that subjects are being exposed to.

The section that follows describes how to connect and use the Casella CEL-712 Photometer (EVT In-line Photometer Adapter) with the Buxco EVT Station for exhalation flow concentration measurements. For further details on the CEL-712 Photometer, please see the Casella user manual.



CAUTION. Always use the power supply provided with the photometer.

Failure to use the power supply could result in data loss as the handheld device will go into sleep mode and stop transmitting data to the Controller.

PHYSICAL SETUP (PORT)

The following section outlines the physical connections to attach the photometer to a Buxco In-Line Photometer Adapter for measuring smoke/vape concentration levels from the EVT Generator.



Figure 34 - Photometer Kit

To attach the photometer to the EVT Generator:

1. Insert photometer wand into Adaptor A. Line up the Photometer Wand, so the opening is aligned with that of the adaptor.
2. Insert Adaptor B into the base of adaptor A making sure the screw holes on the base of adaptor B align with the screw holes for Adaptor A



Figure 35

3. Place the assembly on to the In-Line Photometer Stand.
4. Connect tubing from the EVT Generator Exhale port (and optional Supplemental Flow Unit) to the bottom connector of the photometer probe. This is the inflow from the EVT Generator. Connect tubing from the top of the In-line Photometer Assembly to the exposure source (Inhalation Tower, Mass Dosing Chamber, WBP Chambers). This is the outflow from the EVT Generator.

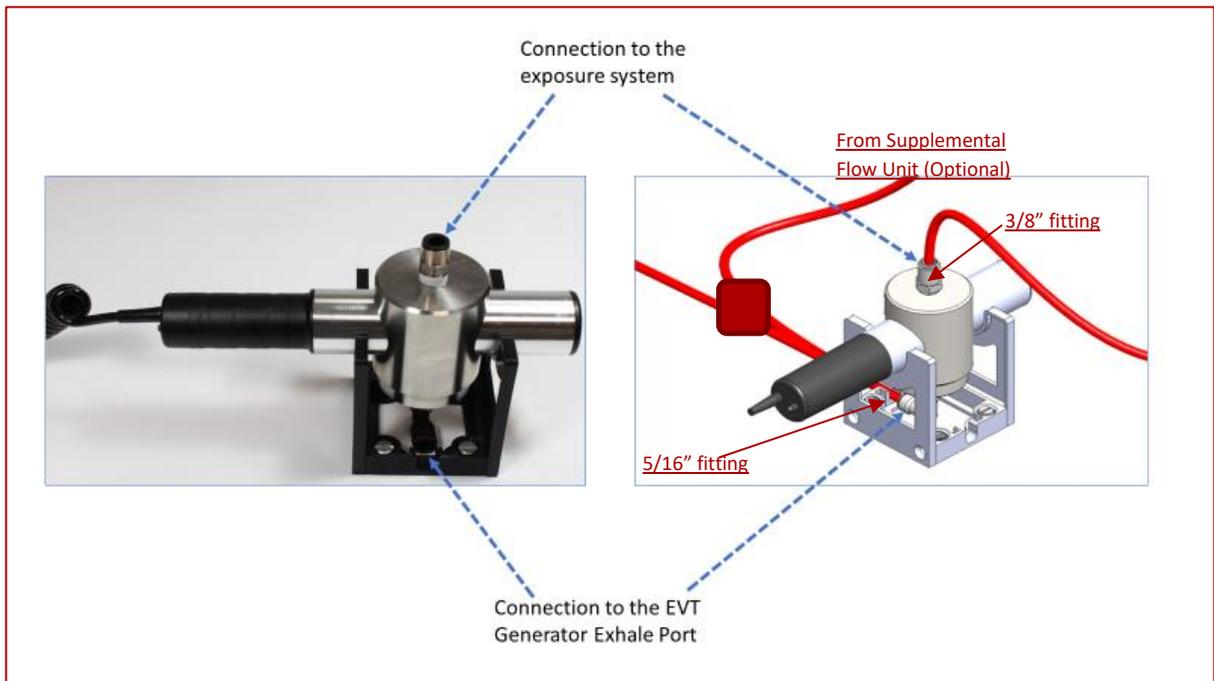


Figure 36 – Photometer Tubing Connection

5. Attach the power cable from the power input port on the bottom of the Casella digital handheld component to a wall outlet.
6. Attach the photometer cable from the 2.5mm output port on the bottom of the Casella digital handheld component to the jack on the EVT Generator labeled **Photometer Inputs**.



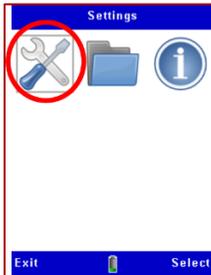
1. Power input port
2. Mini B USB port
3. 2.5mm output port

CASELLA HANDHELD MONITOR SETUP

The Casella Monitor needs to be set up to scale the output voltage for a fixed specified concentration range. The EVT software is required to be configured to match this setting, which is covered in the next section.

To set up the handheld monitor:

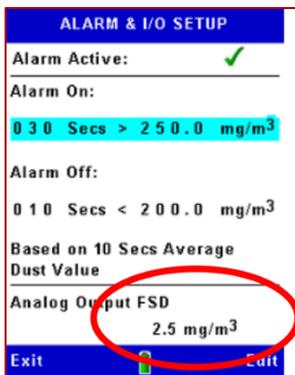
1. On the Casella handheld monitor, located the **Settings** screen and select the **Wrench** to access **Setup**.



2. Select the **Bell** icon to set up the I/O.



Adjust the **Analog Output FSD** to the closest range, but not below what you expect to read. *Please note the screenshot below is an example and does not representative suggested values for this application as typical value should be at $\sim 2500 \text{ mg/m}^3$ or greater.*

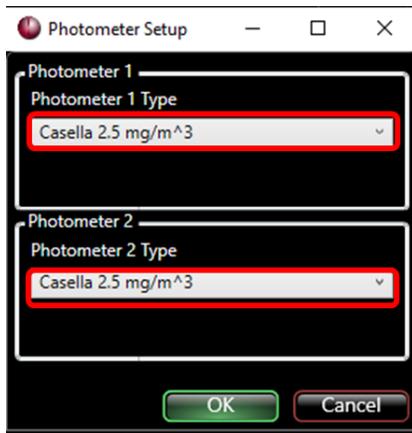


CAUTION. Always use the power supply provided with the photometer.

Failure to use the power supply could result in data loss as the handheld device will go into sleep mode and stop transmitting data to the Controller.

PHOTOMETER SOFTWARE SETUP

When launching the EVT Software, select Photometer from the Hardware menu. The Photometer Setup window will appear and allow users to adjust the software to match the photometer settings. Use the drop-down menu to select the **same** sensitivity setting for both Photometer jacks (Port and Inflow) set in the Casella Handheld Monitor.



PHOTOMETER CALIBRATION

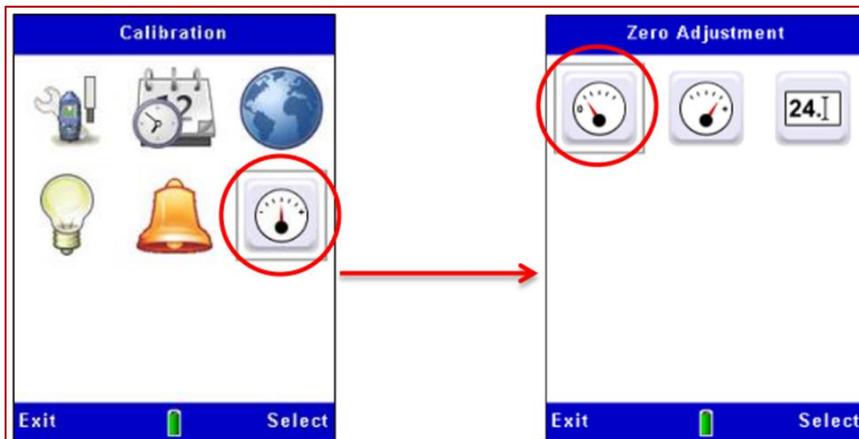
The Casella CEL-712 Photometer is a sensitive measuring instrument. Before making measurements, it is recommended that the user performs a 'Zero' and 'Span' check. The Zero adjustment sets the instrument to zero when there is no particulate contamination present. The Span calibration restores the instrument to the factory standard settings for sensitivity.

PURGING THE PROBE AND SETTING THE ZERO ADJUSTMENT

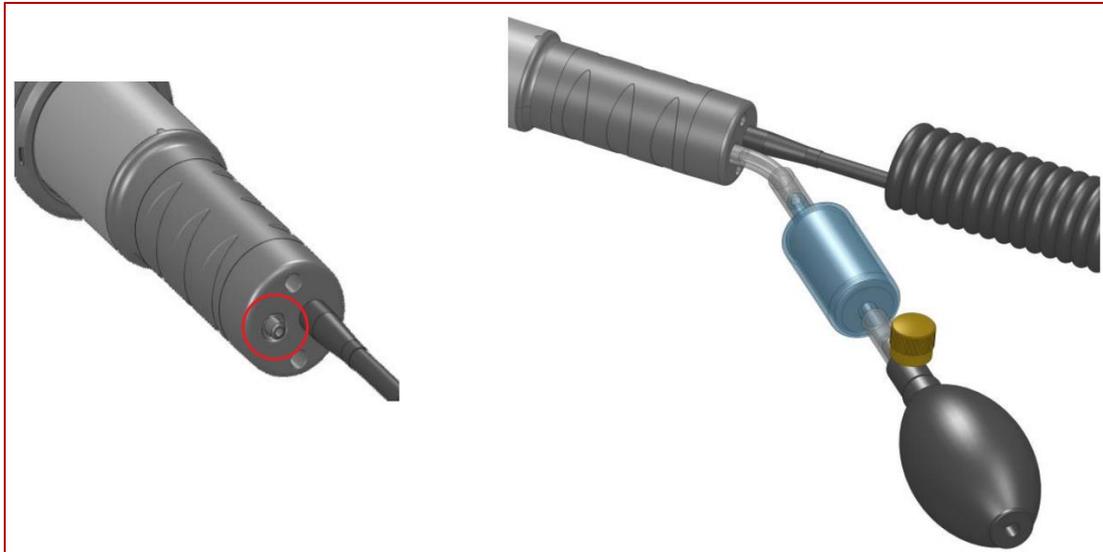
Before making measurements, it is essential to purge the probe with clean air and perform a 'Zero' adjustment.

To purge the probe and perform the zero adjustment:

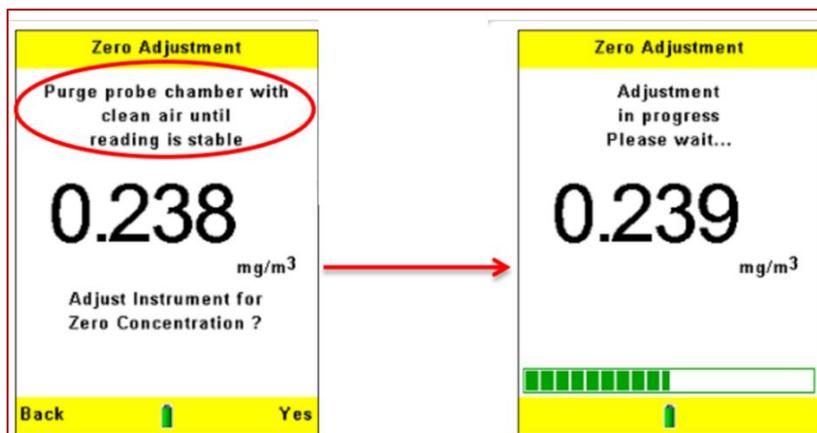
1. Display the instrument's **Setup** screen, select the **Calibration** option, and press the **Select** soft key.
2. Choose the **Zero Adjustment** option and press the **Select** soft key.



3. Slide the collar over the probe inlet, leaving a small gap (1-3mm) to restrict the entry of particulates into the sample chamber and from which the purge air can escape.
4. Attach the purge bellows to the probe's purge inlet at the location (remove the protective rubber cap, ensure you retain it safely and refit once the purging and Zero settings are complete)



5. Squeeze and release the purge bellows 5 or 6 times over a 10 second period to inject clean air into the chamber and removes possible contamination of particulates that might have settled on the optical components inside the probe.
6. Allow a few seconds for automatic ranging and for the reading to stabilize. If the reading does not stabilize, squeeze the bulb five or six times and try again.
7. When the measurements stabilize during the clean-air purge, press the **Yes** soft key to start the zero adjustment. A progress bar is displayed during the zero adjustment, and the screen will indicate whether the calibration is successful.



8. Press the **OK** soft key to return to the main **Calibration** screen.
9. After the instrument zero has been set, **ensure the rubber cap is placed back on the probe's purge inlet.**

Note: If the calibration fails, purge the probe with clean air for a more extended period and then repeat the calibration procedure.

SETTING THE SPAN

The Microdust Pro is supplied with an optical 'Calibration Insert,' which is used to establish a known instrument sensitivity or 'Span.' When inserted into the probe, the Calibration Insert creates a stable and fixed scattered effect and signal level.



CAUTION. *It is essential to use the optical Calibration Insert, which matches a specific probe.*

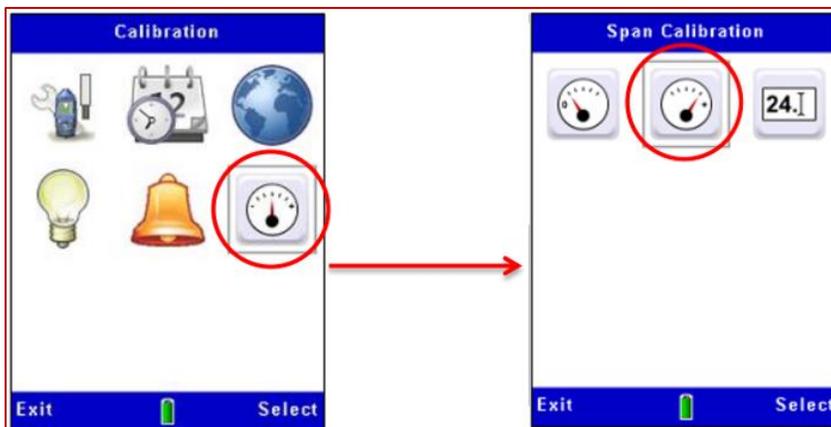
Calibration Inserts and probes are supplied as matched pairs, always ensure the correct Insert is used for a given probe. The reference value for the Calibration Insert provided for the probe is shown on the label. This value should be entered within the Microdust using the 'Span Ref.' icon within the Calibration menu.

To set the span:

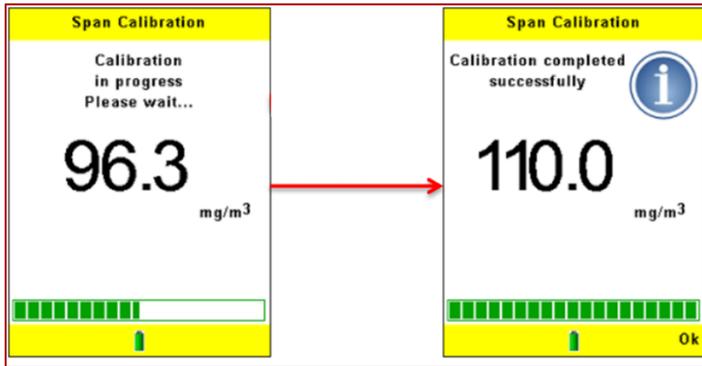
1. Fit the Calibration Insert into the probe's measurement chamber with the arrow pointing towards the probe's handle.



2. Display the instrument's **Setup** screen, select the **Calibration** option, and press the **Select** soft key.
3. Choose the **Span Calibration** option and press the **Select** soft key.



4. Press the **Yes** soft key to start the calibration. An automatic delay occurs after pressing the Yes soft key to allow the reading to stabilize. A progress bar is displayed during the calibration.



5. After successful calibration, the display should show a reading within \pm two digits of the value shown on the Calibration Insert. This confirms that the default factory-set sensitivity of the instrument has been achieved. Press the **OK** soft key.

CONNECTING THE EVT IN-LINE PHOTOMETER KIT

The EVT In-line Photometer Kit can be placed anywhere along the smoke or vape path to measure concentration levels. Below are two examples.

Figure 37 - Photometer Kit is a simple configuration that connects the Exhale Port from the EVT Station directly into the photometer Kit. The flow from the photometer can be routed to the exposure apparatus for dosing animals.



CAUTION. Placing the Casella CEL-712 Photometer directly in-line with a concentrated vape or smoke output may reduce the time required between probe cleanings. Please consult the Casella manual for additional information on proper cleaning methods and or if required, how to have your probe serviced by Casella. DSI has found that when using MOD devices with a heavy aerosol mass that adding dilution is the preferred approach.

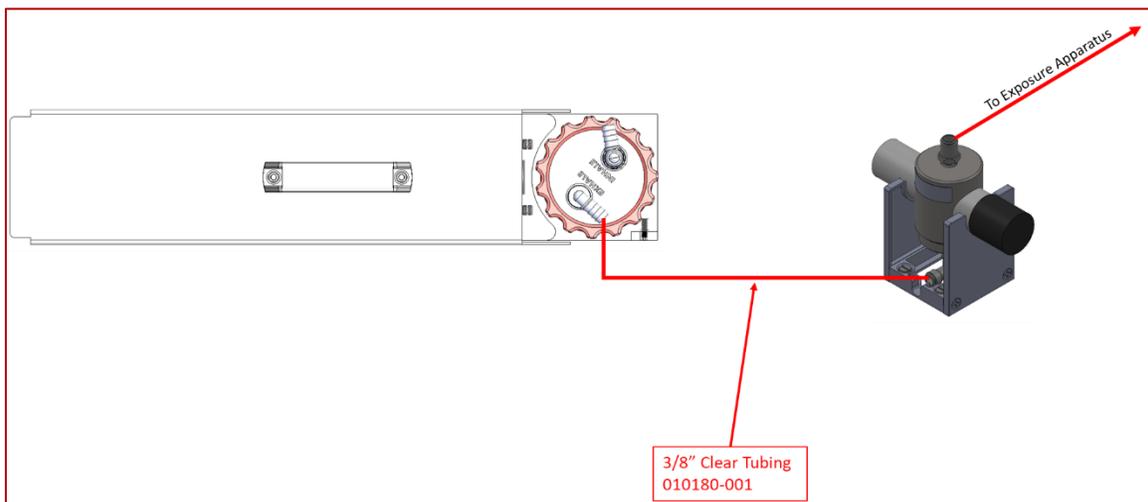


Figure 37 - Photometer Kit

Figure 38 - Photometer Kit with Supplemental Flow Unit is a configuration that allows the EVT system to vary the flow rate of the supplemental flow and, in turn, the aerosol concentration levels.

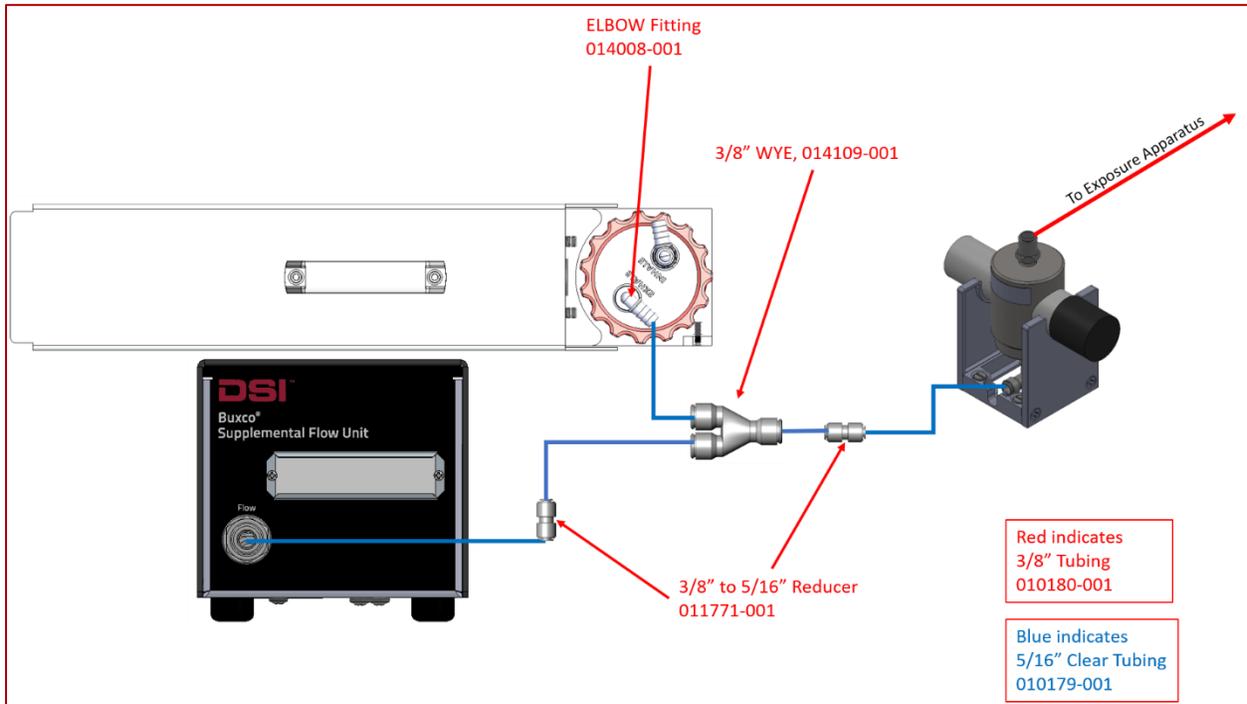


Figure 38 - Photometer Kit with Supplemental Flow Unit

As shown in Figure 39 - Photometer Kit with Supplemental Flow Unit and 3 Stations, for the maximum particle concentration levels, the output of up to three EVT Smoke Stations can be connected through a manifold. This, in conjunction with a Supplemental Flow Unit, provides the greatest control on flow rates and concentration levels.

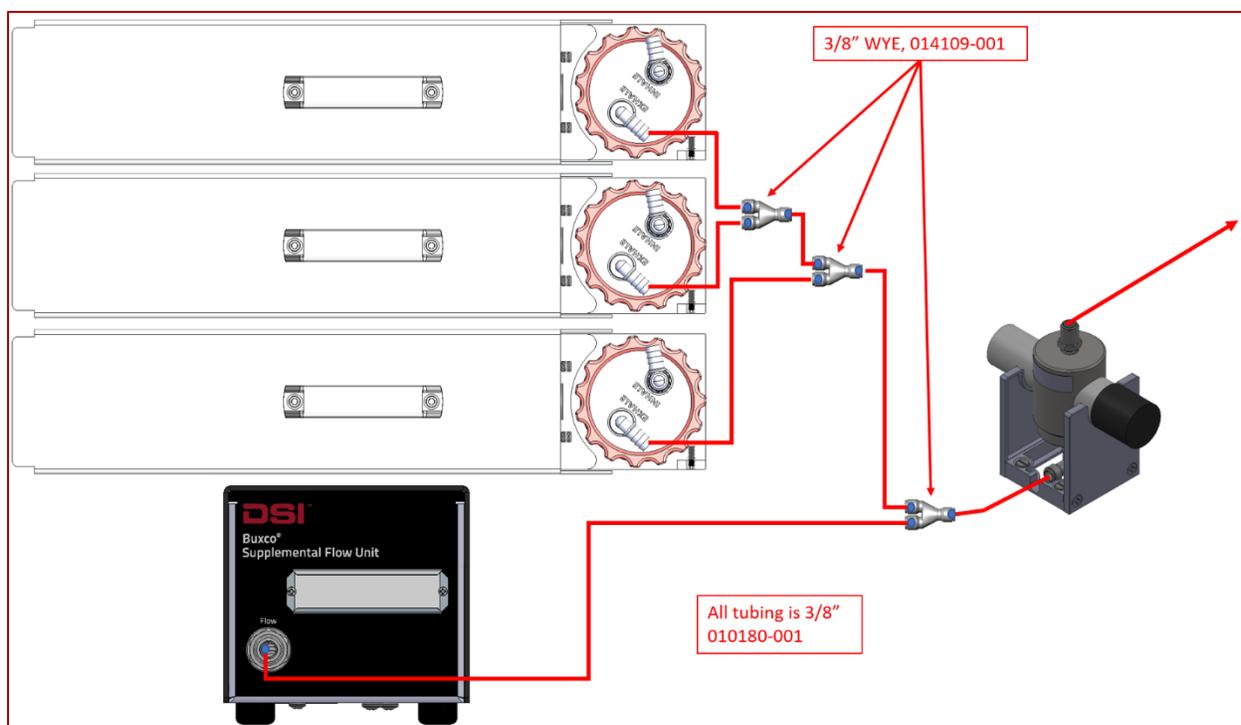


Figure 39 - Photometer Kit with Supplemental Flow Unit and 3 Stations

GRAVIMETRIC CALIBRATION

Items Required:

- EVT Generator
- EVT Station
- Casella CEL-712 Photometer
- Inline Photometer Kit
- Supplemental Flow Unit
- Test article (E-cig, Mod, etc.)
- 22 μm , \varnothing 50 mm, PTFE filter (Recommend [Tisch Brand DF15274 filter](#) or similar)



Warning: When using the photometer, care should be taken not to saturate the sensor. Concentrated aerosols will quickly foul the sensor, resulting in a frequent need for cleaning. Please consult the Casella manual for additional information on proper cleaning methods and if required, how to have your probe serviced by Casella.

The photometer relies on a light emitter, a reflector, and a photoelectric transducer. Aerosol that passes between the emitter and the reflector scatters light and reduces the reflected intensity measured at a photoelectric transducer. A gravimetric calibration is used correlate the intensity of light reflected with aerosol concentration.

Calibration utilizes a filter downstream of the photometer to capture all generated aerosol. A metered source of flow is used to pull aerosol through the photometer, into the filter trap. After running aerosol through the photometer and the filter, a comparison of filter weight prior to a gravimetric test to filter weight after the test will

reveal the mass of aerosol accumulated in the filter. A second measure of mass is calculated from photometer readings, using the photometer's recorded average concentration multiplied by volumetric flow and test duration. The gravimetric calibration factor is simply the ratio between the measured mass accumulated in the filter, and the mass registered by the photometer.

The following calculation should be used to determine the gravimetric calibration factor, N:

$$N = \frac{M_a}{\bar{C}_p Q T}$$

Where:

M_a = Mass of aerosol accumulated in the filter (mg)

\bar{C}_p = Average aerosol concentration recorded by the photometer (mg/m³)

Q = Volumetric Flow through the photometer (m³/s)

T = Duration of gravimetric calibration(s)

Because light scattering is dependent on aerosol properties including size and composition, parameters that affect these properties must be conserved between gravimetric calibration and the subsequent experimental run. These conditions include:

- Puff volume
- Puff duration
- Puff frequency
- Exhalation duration
- E-cigarette type or Mod Power Settings
- Supplemental flow *

*Supplemental flow should be equivalent in magnitude to flow that will be used during the experiment, but the direction should be reversed for gravimetric calibration to pull aerosol through the photometer and into the filter.

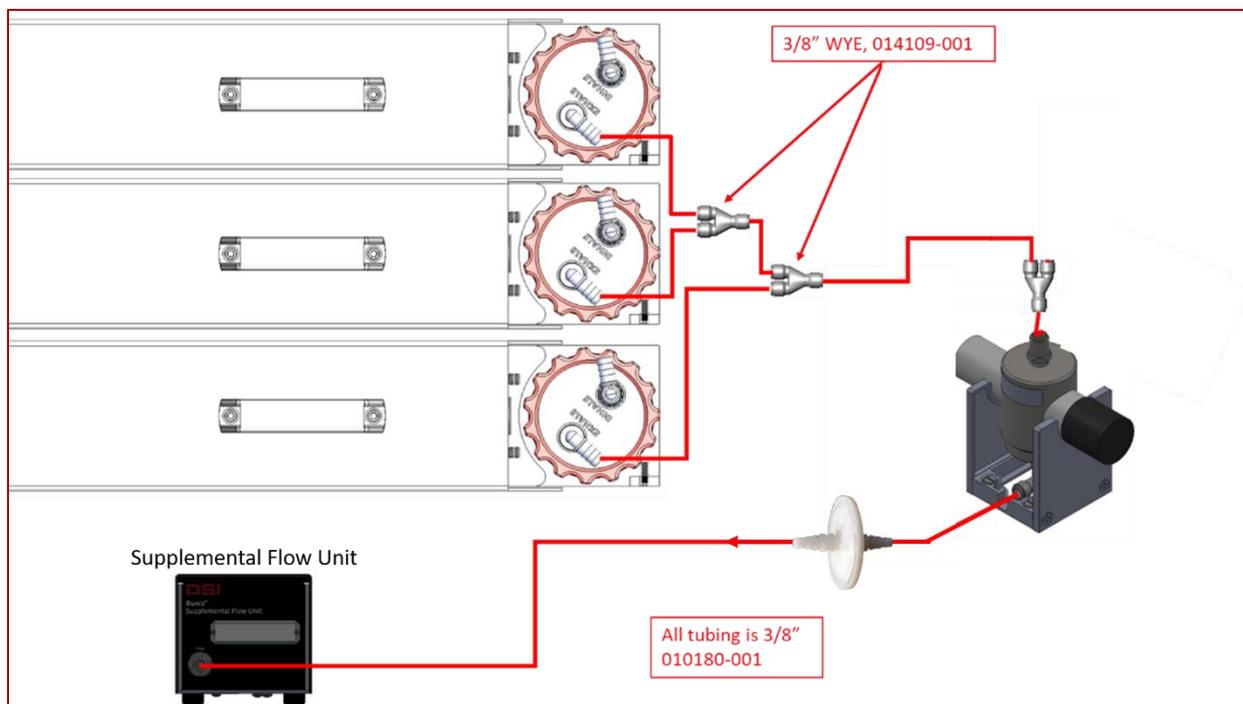


Figure 40 - Photometer Kit with Supplemental Flow Unit and 3 Stations for Gravimetric Calibration to Pull Aerosol

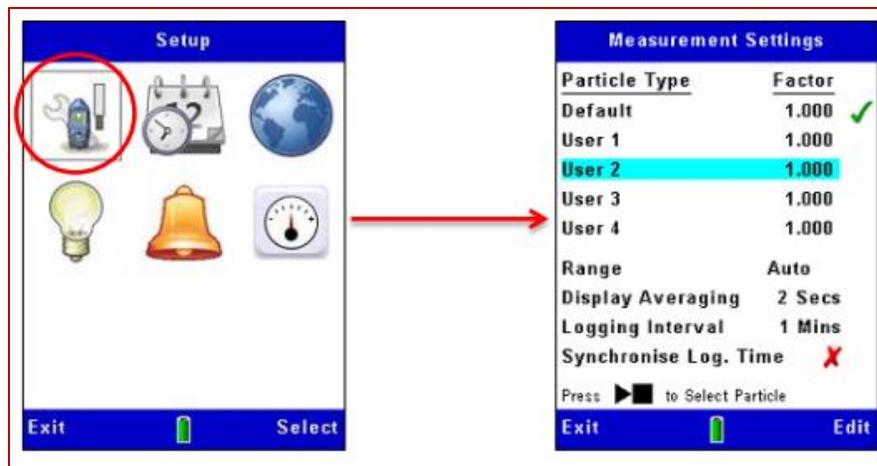
Test Setup Instructions:

1. Set up the photometer:
 - a. Make sure that “Factor” is set to 1. The photometer does not need to be attached to the EVT station
 - b. Set “Zero” and “Range” as described in **Photometer Calibration**.
 - c. Set range to “Auto”

Measurement Settings	
Particle Type	Factor
Default	1.000 ✓
User 1	1.000
User 2	1.000
User 3	1.000
User 4	1.000
Range	Auto
Display Averaging	2 Secs
Logging Interval	1 Mins
Synchronise Log. Time	✗
Press ▶ to Select Particle	
Exit	Edit

- d. Insert Photometer wand into Inline adapter kit.
2. Attach test articles to the inhale ports as described in **Setting up a Mod or Pen Device**.

3. Route tubing from exhale ports to the inline photometer adapter, making sure there is an inlet open to ambient air between the station and the photometer (for dilution.)
4. Attach the 22 nm filter to the bottom of the Inline photometer via tubing.
5. Attach Supplemental flow to the other opposite end of the filter via tubing.
6. Configure Supplemental Flow for negative flow, and attach electrical connections as described in **Supplemental Flow Unit – Setting Flow.**
7. Set up software:
 - a. Set puff parameters as they will be used in subsequent experiments.
 - b. Set bias flow to the desired magnitude.
8. Commence puffing and start recording Photometer readings simultaneously (± 3 seconds)
9. Allow puffing to continue for about 15 minutes (longer for small puffs, shorter for larger puffs.)
10. End puffing and stop photometer data logging simultaneously (± 3 seconds)
11. Use equation 1 to compute N.
12. Enter the computed value for N into the photometer under the field, "Factor."



SUPPLEMENTAL FLOW UNIT – SETTING FLOW

The Supplemental Flow Unit is used to provide additional, regulated flow into the system. It contains a mass flow sensor, a pump, and a variable valve used to regulate flow to the user-defined target flow settings specified within the EVT software. Additional flow may be necessary to dilute the concentration levels of the smoke or vape generated.

The Supplemental Flow Unit is powered and regulated via the EVT Controller. Up to three Supplemental Flow Units may be connected to the Controller. The maximum flow specification for each Supplemental Flow Unit is 5 L/min free flow.

Units may be configured to either push or pull flow directions by connecting tubing jumpers on the rear panel. Depending on the purpose, the user would define each supplement unit's flow rate in the EVT software, make the proper polarity connections in the back, and label the unit in the front panel; e.g., Unit A, Push.

Note: The most common configuration for Supplemental Flow Units is the Push mode. This will add room air to the flow from the EVT Smoke Generator, thus diluting concentration levels. In pull mode, care must be taken to not contaminate the Supplemental Flow Unit with smoke or vape.

Additionally, when using in Push Mode, to prevent contamination from room air particulates, a filter (HEPA-VENT Filter 50mm Diameter Item# 012268-001) should be attached to the Pump-In port.

PUSH/PULL TUBING CONFIGURATIONS

The following outlines the tubing jumper positions of the Supplemental Flow Unit for **PUSH** or **PULL** flow directions:

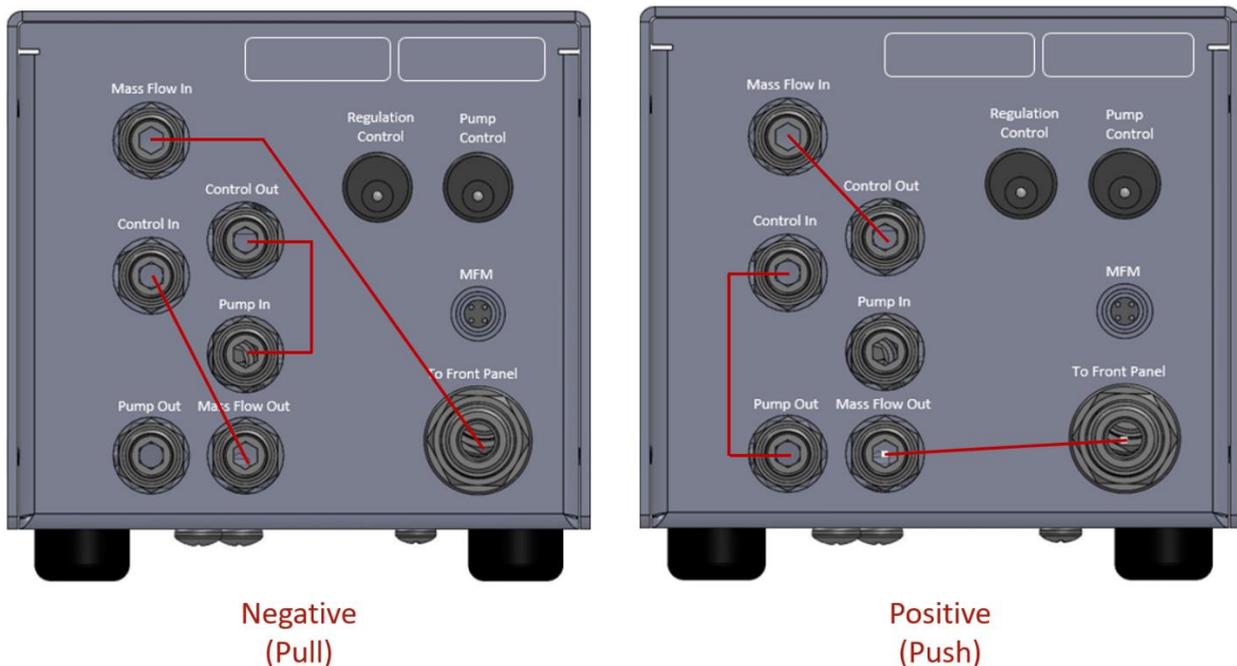


Figure 41 – Supplemental Flow Unit Tubing Jumper Positions for Pull or Push

ADDING THE SUPPLEMENTAL FLOW UNIT TO AN EVT SMOKE MACHINE STATION

To add the supplemental Flow Unit to an EVT Smoke Station, connect the Supplemental Flow Unit to one side of a “T” connector (supplied in the Supplemental Flow Unit Kit). Connect the other side of the “T” connector to the exhale port of the Smoke Machine Station. The output of the “T” connector will consist of the smoke or vape being generated from the Smoke Machine added into the flow from the Supplemental Flow Unit.

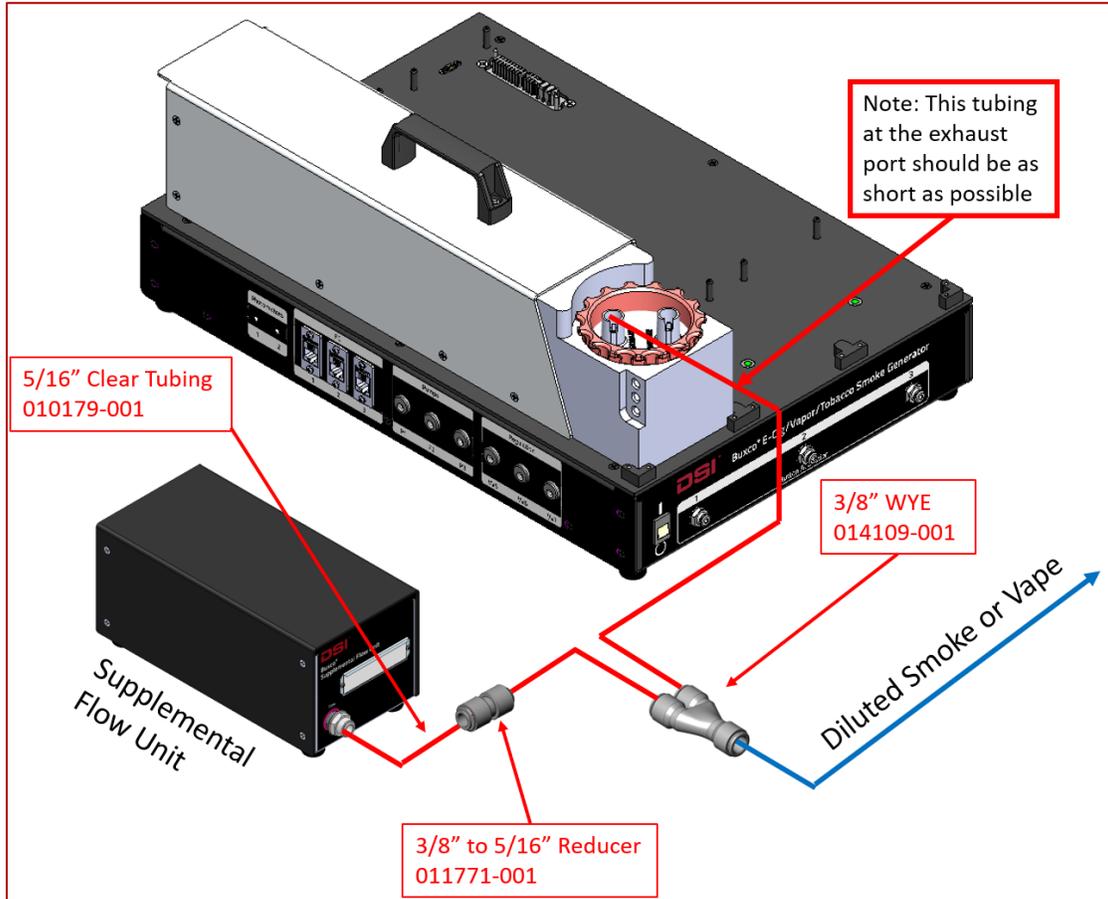


Figure 42 – EVT with Supplemental Flow Unit Tubing Configuration

The Supplemental Flow Unit is connected to the EVT Smoke Machine Controller, as shown in Figure 43 - Electrical Connections for the Supplemental Flow Unit. Multiple Supplemental Flow Units can be used if required.

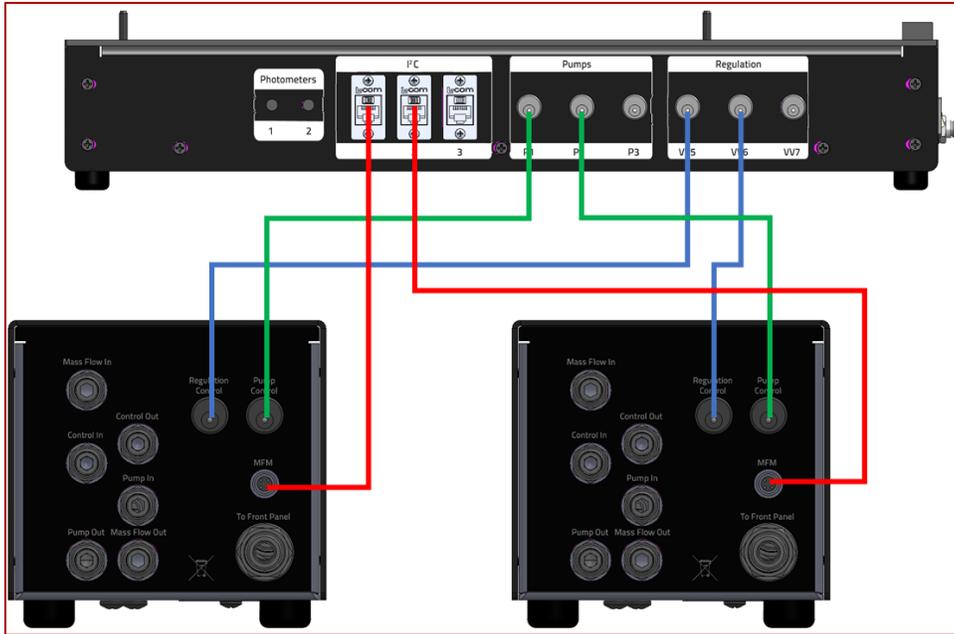


Figure 43 - Electrical Connections for the Supplemental Flow Unit

EVT INLINE SMOKE RESERVOIR KIT

The reservoir Kit is an optional accessory that can be used to either aid in supplemental flow mix and or combine several EVT Stations exhaust flows for increased particle concentration levels. Up to four devices can be connected to the reservoir, including EVT Stations, Multiple EVT Stations, and Supplemental Flow Units. Any unused connections should be plugged with a connector plug.

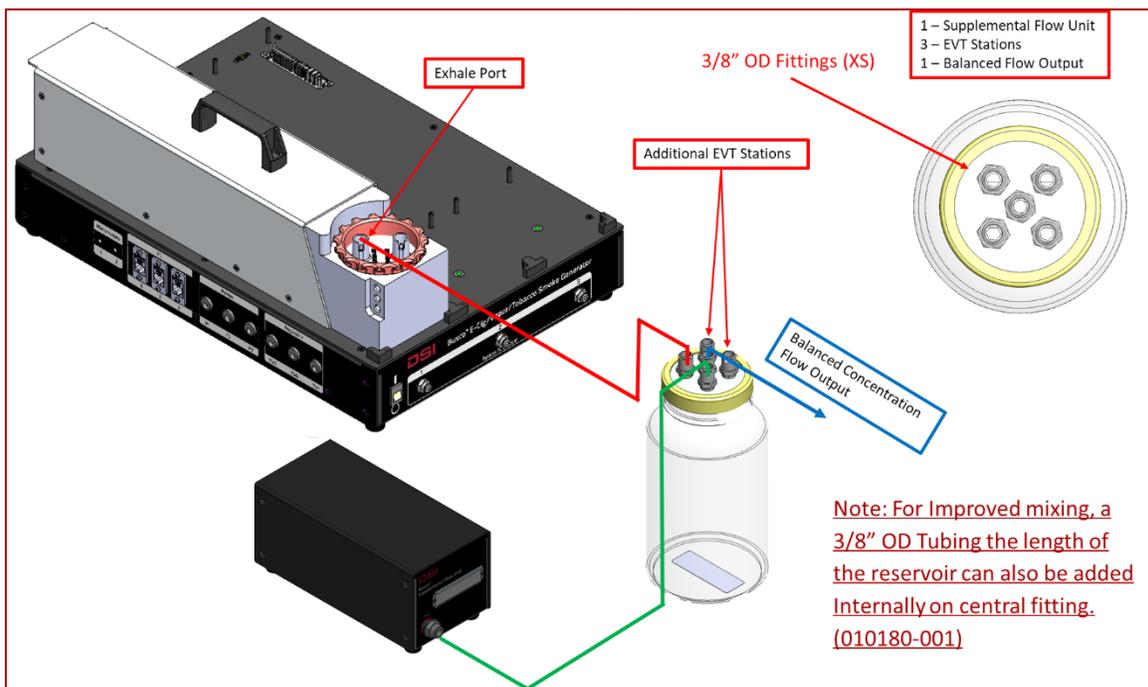


Figure 44 - Connecting the INLINE SMOKE RESERVOIR KIT

USING THE MASS DOSING CHAMBER WITH THE EVT SMOKE GENERATOR

APPLICATION OVERVIEW

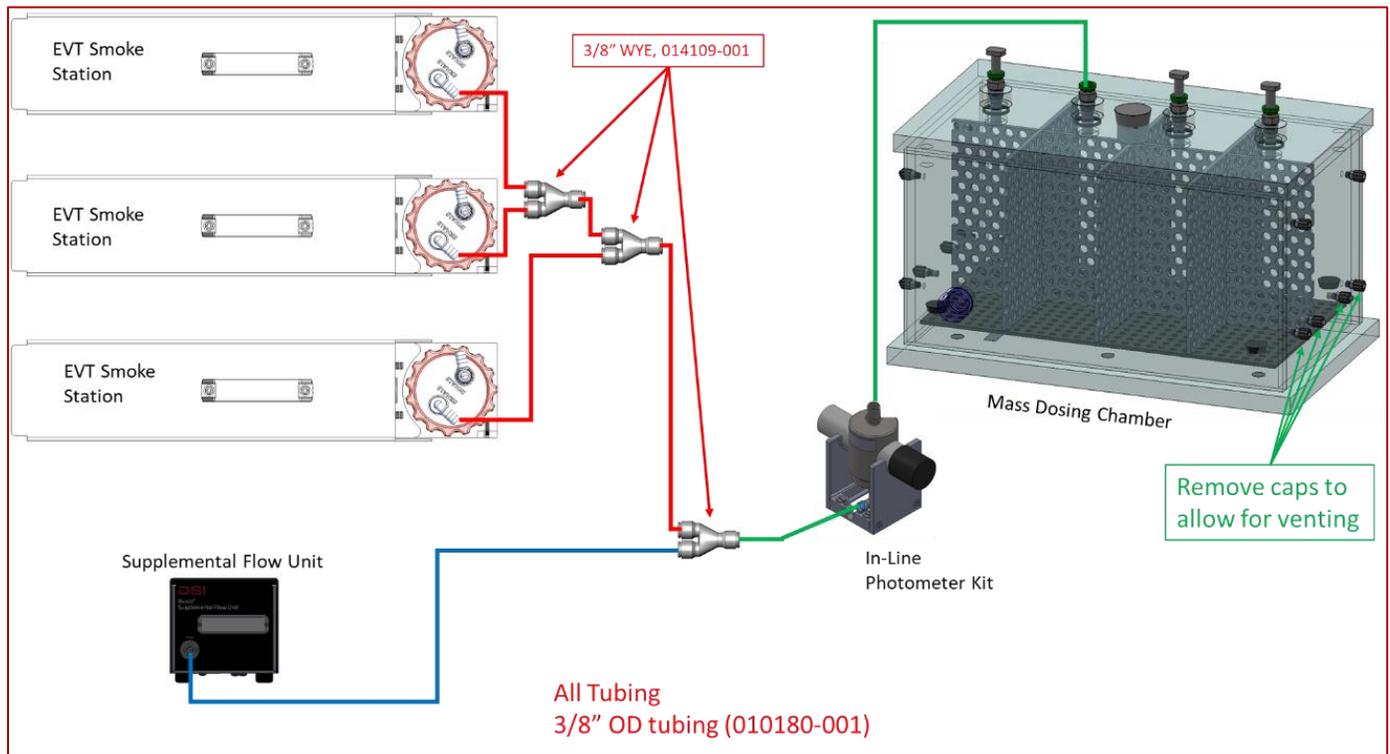
The exposure of subjects with smoke or vape is conveniently done using DSI's Mass Dosing system. Subjects are placed in a chamber and are exposed to smoke or vape for a desired time. The Mass Dosing system is particularly useful for exposures to tobacco.

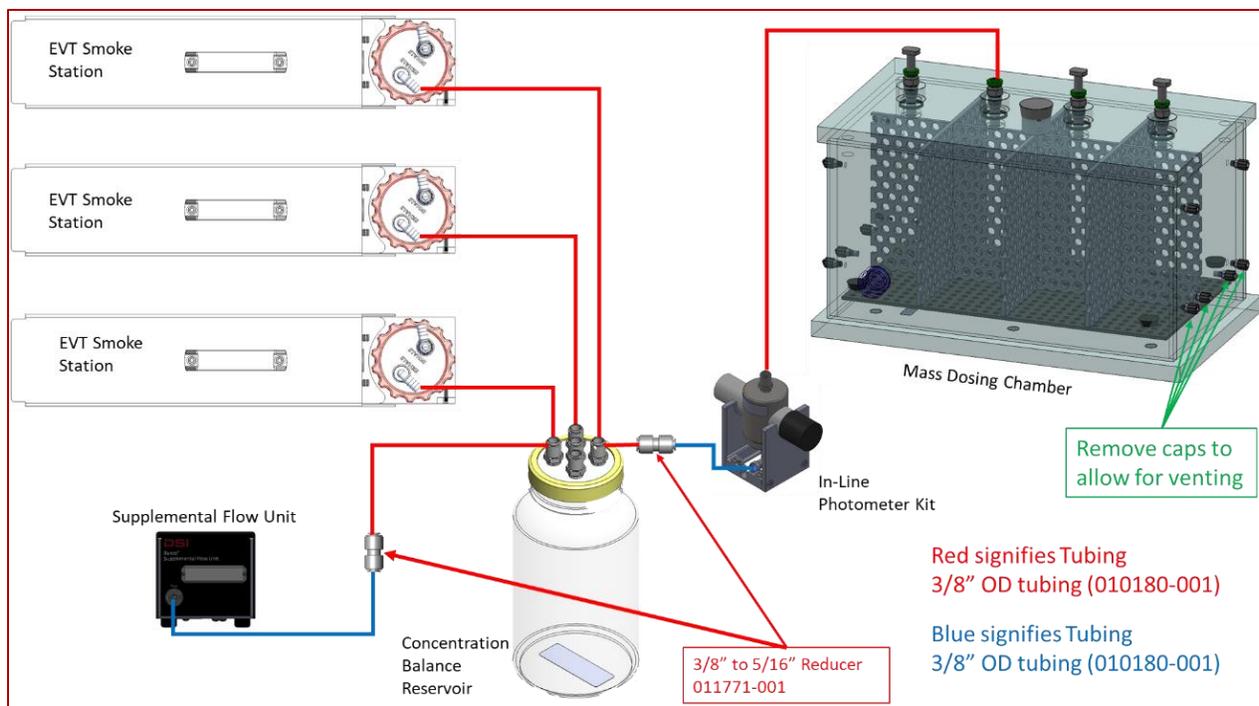
A Mass Dosing chamber is a rectangular acrylic box with a flexible design that accommodates various types of aerosol and bias flow sources. A port on the lid is designed for an Aerogen Aeroneb® nebulizer.

For more information on the Mass Dosing Chamber, see the Mass Dosing System Application Manual.

⚠ Note: A gasket is included in the accessory kit and can be used to further contain smoke/vapor inside the chamber. See the Mass Dosing System Application Manual for more information.

The EVT Smoke Machine can be configured to work with the Mass Dosing Chamber.





USING THE BUXCO INHALATION TOWER WITH THE EVT SMOKE GENERATOR

APPLICATION OVERVIEW

Since the pulmonary system is considered a vital organ, it is essential to have instruments allowing researchers to study the effects of environmental toxins and chemical entities when inhalation is the primary route of exposure. Inhalation research often presents the challenge of greater variability in toxin delivery as compared to other administration methods such as intravenous injection or an oral dose.

Inhalation Towers ensure that simultaneous exposure of compounds or gases to the lungs of rodents is controlled, consistent, and defined. Researchers must calculate an accurate measurement of the inhaled aerosol, which is derived by knowing the concentration of the aerosol delivered as well as the animal's minute volume. Most systems use an assumed minute volume value based on animal species and mass; DSI's Inhalation Tower provides the ability to integrate plethysmography, allowing for direct minute volume measurement and eliminating the need to make assumptions.

The stackable inhalation tower uses a flow-past design in which there is an inner and outer column. The smoke or vape from the EVT Smoke Generator is introduced into the inner column and drawn out from the outer column. The subjects are typically arranged as spokes around the tower where they receive air to breathe from the inner column, while the outer column draws away excess air and the air expired by the subjects. Each subject has its port, and care is taken to ensure that each port is identical in every way. The symmetry of design is critical.

Controlling the exposure is the job of the FinePointe Tower Controller. The tower controller uses two mass flow sensors to monitor and regulate two flows. One flow provides air into the tower, and the other flow draws air out

of the tower. The unit regulates the pressure in the outer column to achieve a target pressure, which is either slightly above or below zero, as selected by the user. This pressure is monitored in real-time, providing instant feedback and uses rapid response valves to allow the excess pressure to vent as needed

For more information on the configuration and use of the Buxco Inhalation Tower, please reference the Buxco Inhalation Tower Application Guide.

SETTING UP THE EVT SMOKE GENERATOR TO THE INHALATION TOWER

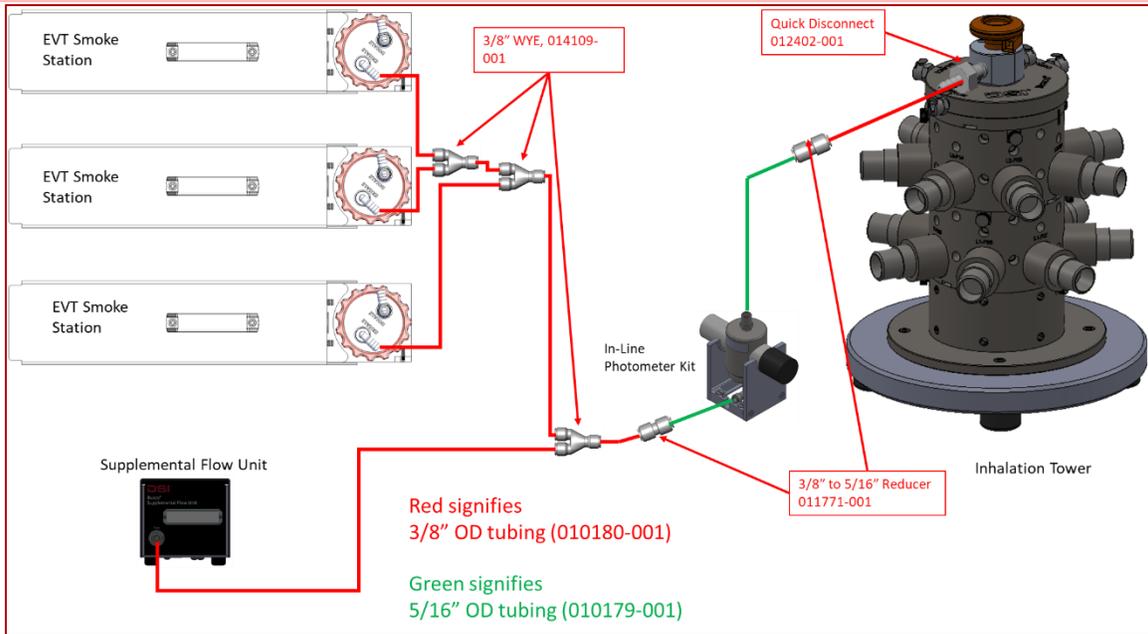


Figure 45 - EVT Generator with the Inhalation Tower

The electrical connections for the Supplemental Flow Unit and the In-Line Photometer Kit are shown in Figure 46.

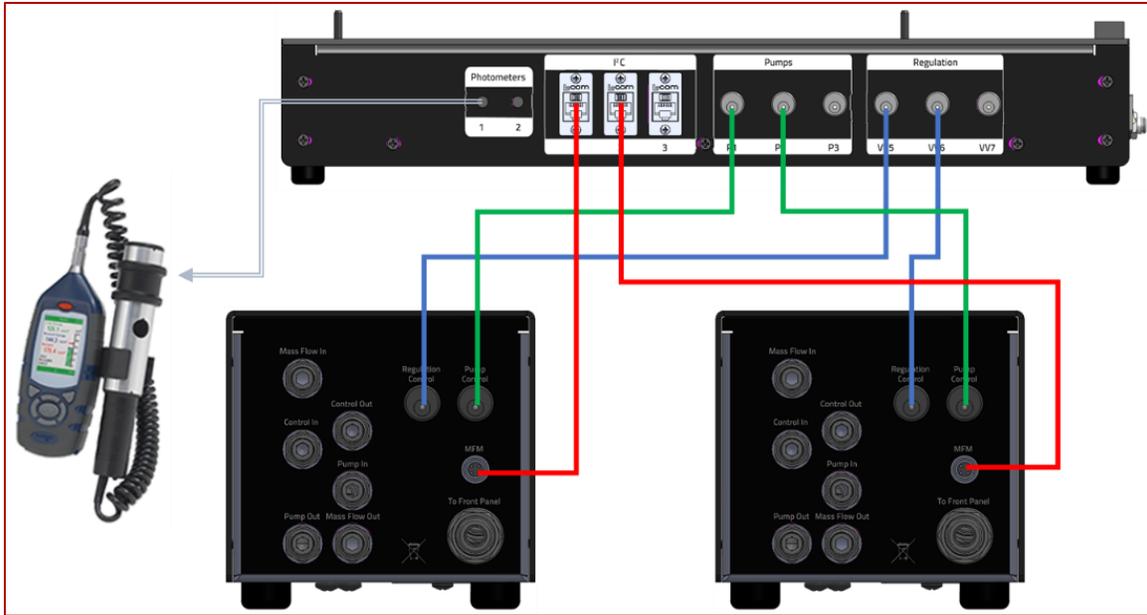


Figure 46, Electrical Connections Supplemental Flow Unit and In-Line Photometer Kit

LIFESPAN, MAINTENANCE, & TROUBLESHOOTING, MISC

REPLACING AND CLEANING THE BELLOWS ASSEMBLY

The bellows assembly, which contains the bellows and the bellows lid with inhale and exhale check valves, are exposed to contaminants from the tobacco smoke and vape. This will cause the bellows and valves to become sticky over time. The bellows assembly is designed to be disposable and should be replaced at approximately 10,000 cycle intervals and or when unable to clean adequately. Depending on the test medium, how much it has been used, and the degree of acceptable residues for studies, it is possible to clean the bellows and the bellows lid valves periodically.

CLEANING THE BELLOWS

The bellows may be cleaned with warm, soapy water using dish soap. This cleaning procedure only applies when E-Cig or Pen devices are used. When traditional cigarettes are used, the bellows must be replaced and cannot be successfully cleaned because of the excessive tar that is produced.

REPLACING THE BELLOWS

The bellows assembly may be replaced by simply following these steps:

- a) With station attached, turn on the power to the EVT Smoke Generator Controller



It is critical that the EVT Smoke Generator Controller be powered on before installing the bellows. Turning on the EVT Smoke Generator Controller will position the stepper motor in the "Home" position, which is the default position of the bellows when it is lined up with the "Bellows Alignment Mark" on the Bellows Chamber.

- b) Unscrew the Bellows Ring (1) from the Bellows Chamber (3) by rotation counterclockwise and remove from the chamber assembly.
- c) Lift the bellows assembly from the Bellows Chamber and discard.
- d) Place a light coat of grease around the bottom edge of the new bellows assembly.

- e) With the bellows in a fully compressed state, insert a new bellows assembly into the Bellows Chamber.
- f) When installed into the bellows chamber, the bottom of the bellows must line up within the Bellows Alignment Marks on the bellows chamber. This is considered the home position for the bellows.
- g) Place the Bellows Ring (1) on top of the bellows assembly and screw the assembly together by rotating the ring clockwise until hand tightened. Then turn roughly $\frac{1}{4}$ turn further.

A small amount of grease should be applied to the underside of the bellows assembly, as shown in **Figure 47 - Bellows Assembly**. Grease and a small applicator swab will be part of the EVT Station Accessory kit.

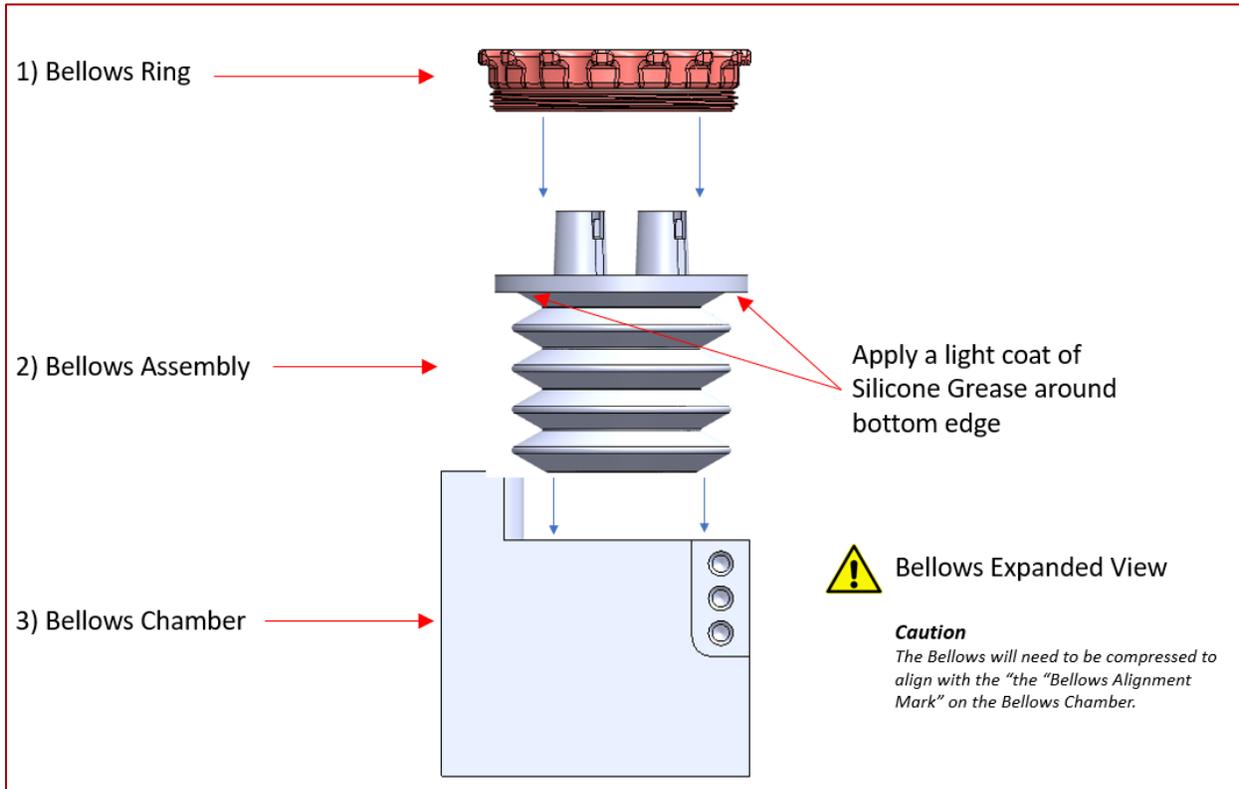


Figure 47 - Bellows Assembly

How often the bellows and valves will need to be cleaned or replaced varies depending on the amount of exposure to contaminants over time. There is not a standard rule for when to change the bellows, but here are some guidelines to follow.

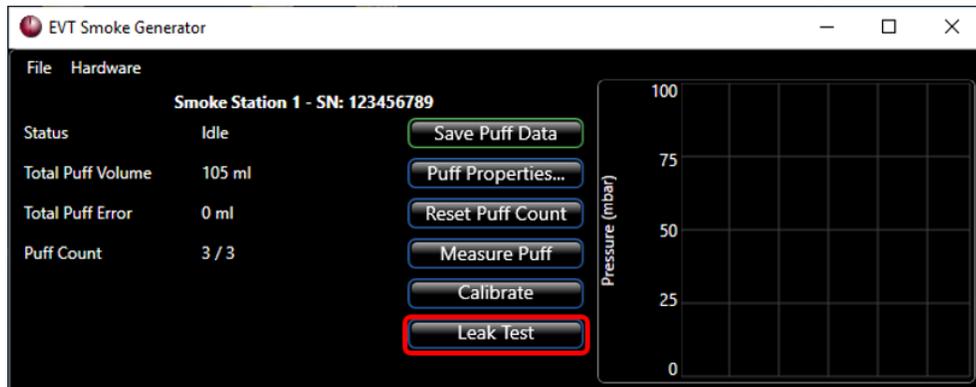
If the bellows assembly fails the leak test, then it should be replaced. If the test article is being changed, it would be best to replace the bellows and bellows lid to eliminate any possible cross-contamination. The bellows assembly should be replaced at least every 10,000 cycles.

PERFORMING AN INTERNAL LEAK TEST

Whenever the bellows are replaced, and periodically during use, it is essential to perform a leak check on the station to make sure the bellows assembly is adequately sealed. To perform a leak check, do the following.

- 1) Launch the EVT Software by double-clicking on the EVT Application Icon.

2) Click on **Leak Test**



The Leak Test window will open.

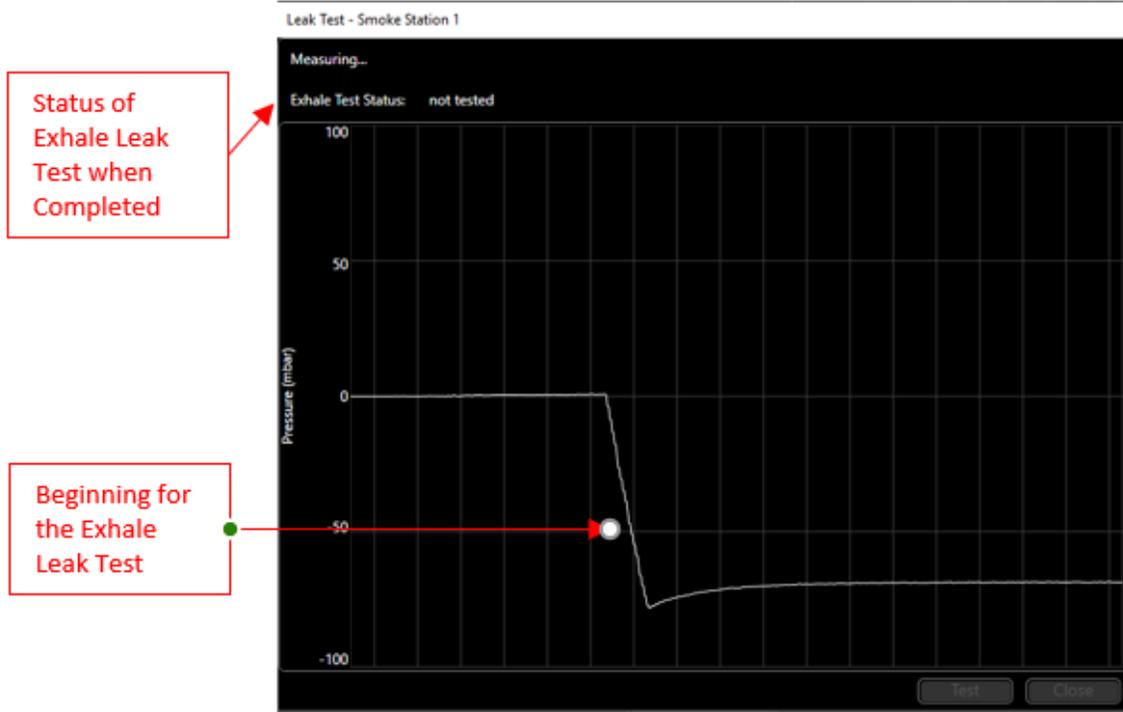
Instructions can be found on the top of the Leak Test screen. The status of the leak test can also be seen at the top of the screen.



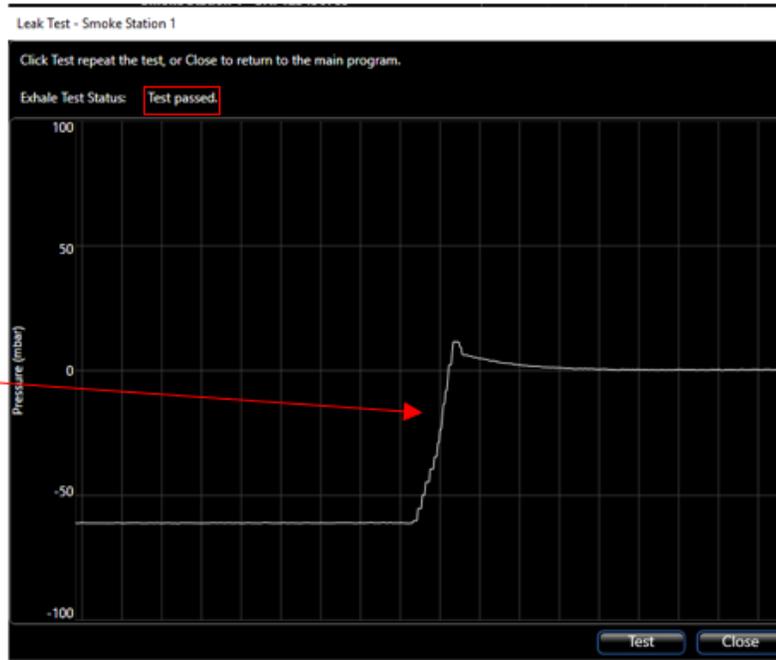
3) Start by inserting a leak test plug into the Inhale port of the bellows cap (leak test plugs are provided in the station Accessory kit).



- 4) Click on the **Test** button. The “Exhale” leak test will begin. The pressure measurement should drop sharply negative, then decay for a time in a positive direction. Then the pressure should stabilize to a flat line at a negative level. After roughly 30 seconds, the Exhale Test Status should indicate that the test passed.



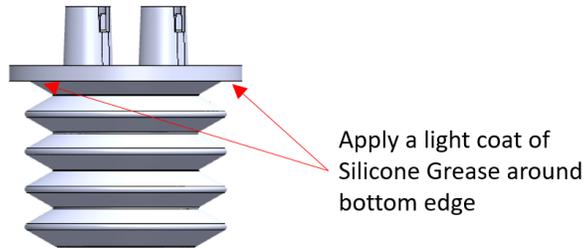
- 5) At the end of the test, the Exhale Test Status should indicate Test Passed, and the pressure reading should return to normal.



Pressure returns to normal

If the leak test fails, try the following:

- 1) Most likely, the issue would be a seal between the bellows and the chamber. Apply a light coat of grease to the bottom of the bellows assembly, reinsert into the bellows chamber, and try the leak test again.



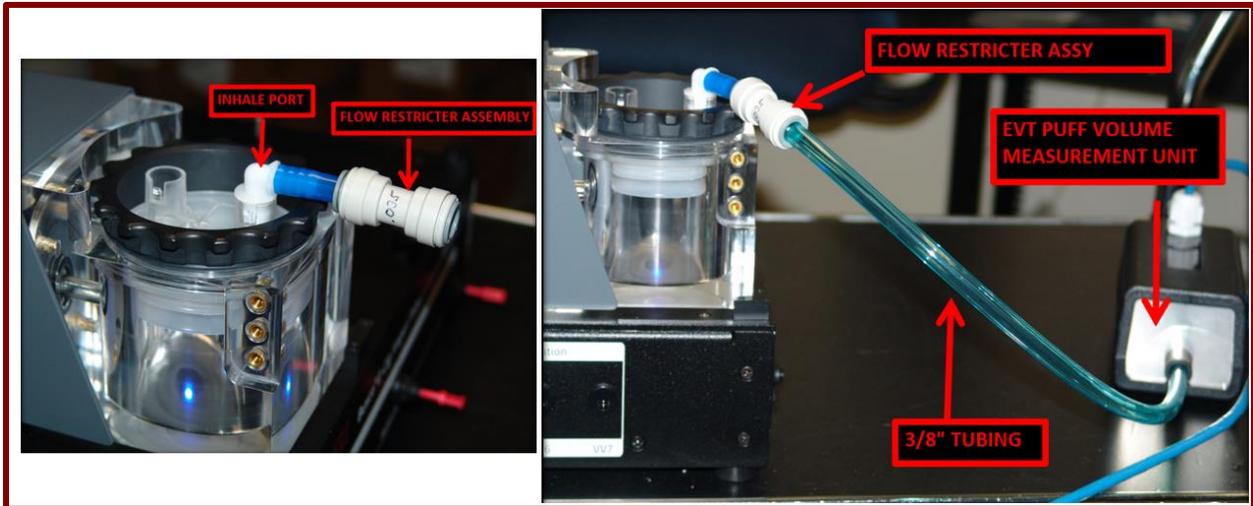
- 2) Look for small cracks in the Bellows Lid.
- 3) Look for small pinholes in the bellows.
- 4) Try a different bellows assembly.

PERFORMING A CALIBRATION

- 1) Connect the Flow Restrictor Assembly that came with your EVT system to the bellows assembly lid at the Inhalation Port, as shown below.
- 2) Connect a 3/8" tube from the inlet of the Flow Restrictor assembly to the Mass Flow Meter.

⚠ Note: which side tubing is connected to mass flow sensor, the direction of flow should agree with Arrow label on top of the mass flow sensor.

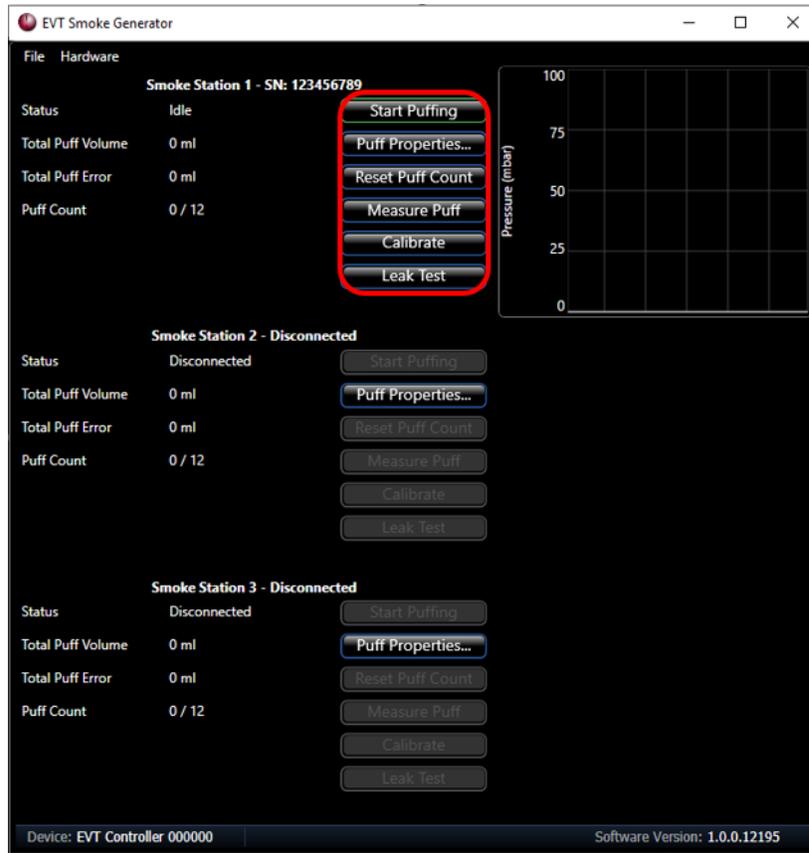
- 3) Connect the cable from the Mass Flow Meter to position "1" of the I²C connections on the EVT Smoke Machine Controller. Make sure that the flow direction is aligned correctly with the direction indicated by the arrow on the top of the flow meter. Also, make note of the Slope and Offset values listed on the calibration lable on the Mass Flow Meter.



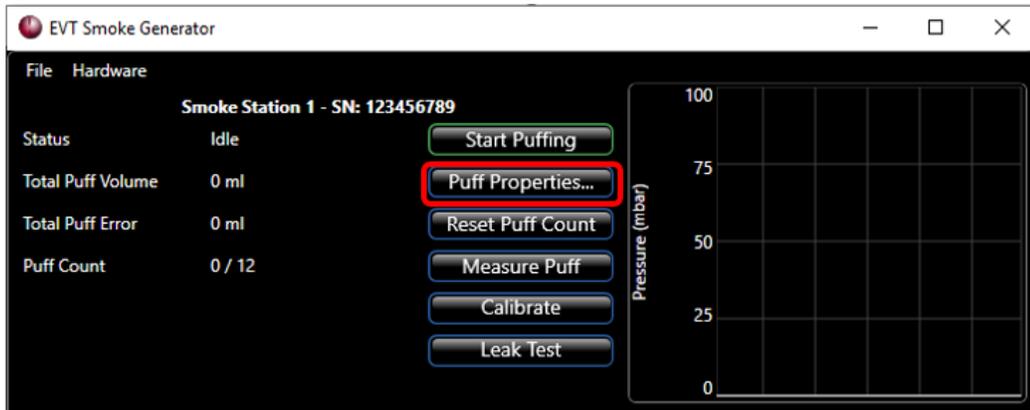
- 4) Launch the EVT Smoke Machine Software by double-clicking on the EVT Software Icon.



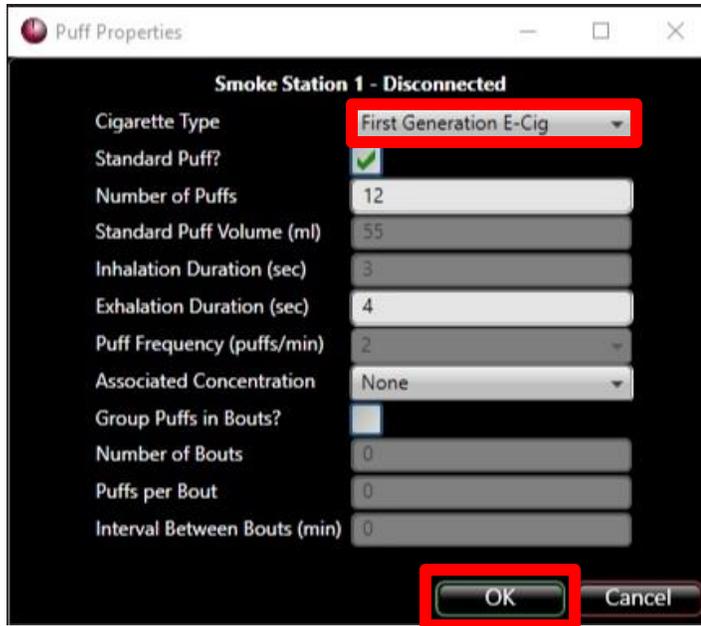
The EVT Software Main Window should open. Make sure that the setting selections highlighted below are enabled (not grayed out), and the Pressure graph is scrolling.



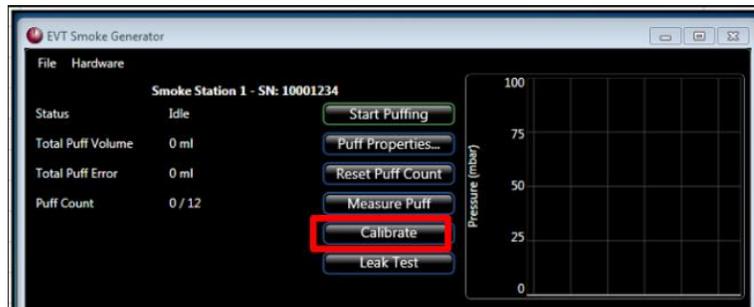
5) Click on the “Puff Properties” button.



- 6) Select “First Generation E-Cig for the Cigarette Type, or Traditional Cigarette if using a Bell-shaped puff profile.
- 7) Make sure the “Standard Puff” checkbox is checked.
- 8) Click OK

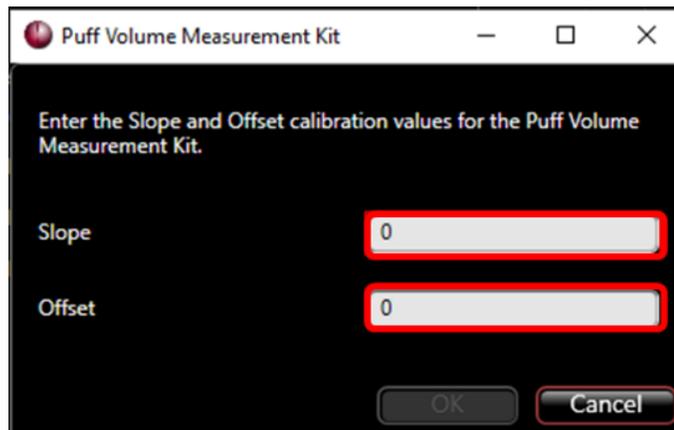


9) Click the “Calibrate” button.



10) The Calibration Window will open.

If this is the first time that you have calibrated using a particular Mass Flow Meter, a secondary window will open, allowing you to enter the Slope and Offset calibration values for the Mass Flow Meter. The Slope and Offset values are found on a label on the Mass Flow Meter.



11) Click OK, and the Calibration Window will open.

Click the calibrate button, and the calibration process will begin. Information on the status of the calibration process is indicated on the top left portion of the Calibration Window.



First, the zero-flow baseline pressure is measured. This is quickly followed by a puff cycle. During this time, the response time of the puff pressure is measured. This process is repeated five times, and the average response time is calculated. The status of the calibration process is indicated in the top left part of the window. Example: "Measurement 2 of 5 complete, preparing for the next measurement". The response time of the system is indicated at the bottom of the screen. The example shows a rising edge response time of 0.171 seconds and a falling edge response time of 0.185 seconds. These time constants are indicative of the flow resistance and are used by the system to adjust the acceleration and deceleration phases of the puff profile accordingly.



- 12) When the calibration process is complete, the software will display “Measurement Complete” and the system will be ready to measure a puff volume.

The Calibration window will indicate the current puff volume setting and the measured puff volume. The initial puff volume is 0.00 ml since we have not yet run the puff volume measurement process.



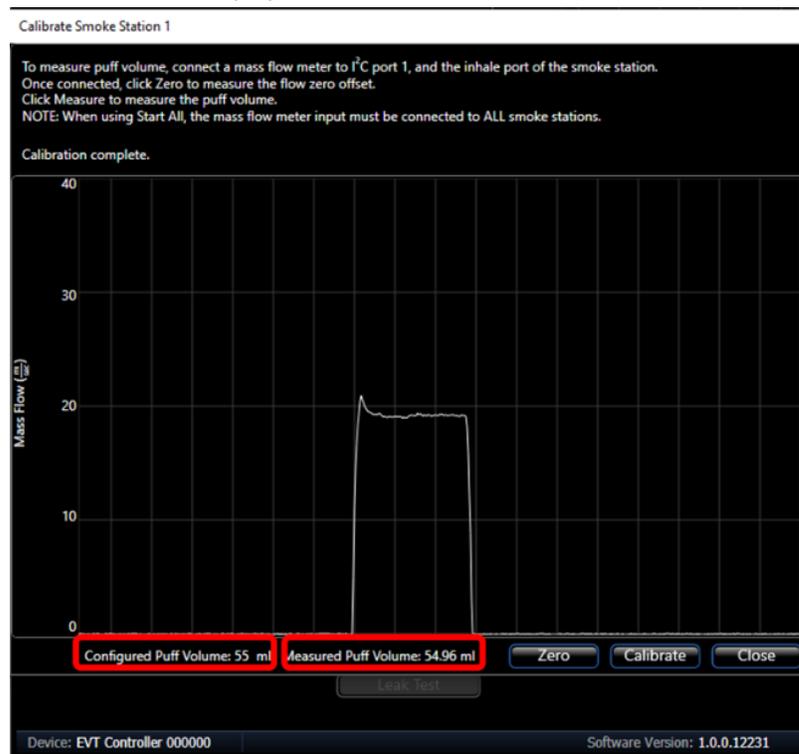
- 13) Start the Puff Volume Measurement process by clicking the “Zero” button. The EVT system will quickly measure the flow offset. Once completed, click the “Calibrate” button.



Note: Ensure the mass flow sensor is connected to the inhalation side of bellows assembly when zeroing. If it is unconnected, ambient airflow from a hood or similar could otherwise impact accuracy.

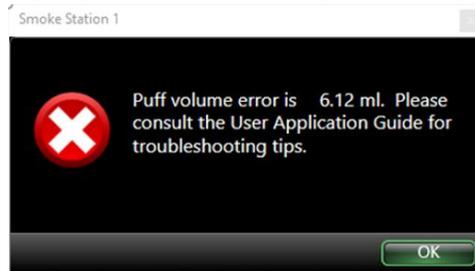


- 14) The EVT system will begin measuring a puff volume. First, it will measure the baseline flow. Then it will measure a puff volume. It will repeat this process three times. When completed, the configured volume and the measured volume will be displayed at the bottom of the window.



- 15) Once the calibration process is complete, click "Close."

The maximum allowable calibration error is ± 4.0 ml around the expected volume. If the measured volume is greater than 4.0 ml, the EVT software will indicate an error. If this occurs, repeat leak test to make sure you have a leak-tight system and check that your mass flow sensor is attached correctly.



CUSTOM CRADLE – CUSTOMER ACCESS TO BASIC CRADLE GEOMETRY (STEP FILE)

Electronic nicotine delivery device types and form-factors continue to evolve. Although the two 3D printed cradle types for MOD and PEN in the EVT Button-Act Device Holder Kit may accommodate alternative devices, they were designed with certain models in mind – SMOK X-Priv MOD and NJOY Standard Electronic Research Cigarette (SREC) - PEN. If you require the use of an alternative device(s) that does not fit within the provided holders, custom cradle geometries may be produced. To facilitate modifications, a 3D mechanical STEP FILE can be found here (insert link here?). These files may be used to design and produce your device holder cradle but still interface with the provided C-Clamp and pneumatic piston of the EVT Device Holder Kit. For any further assistance, please consult DSI technical support.

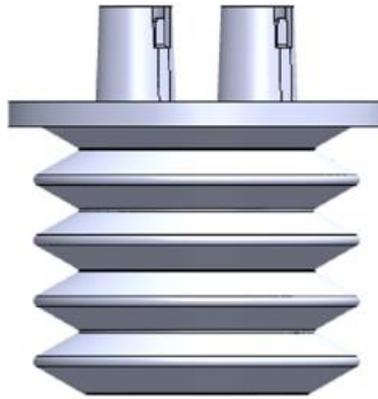
KITS, CONTENTS & USES

REPLACEMENT EVT BELLOWS ASSEMBLIES

The Bellows Assemblies are a consumable part that will need to be cleaned or replaced frequently. How often the bellows and valves will need to be cleaned or replaced varies depending on the amount of exposure to contaminants over time. There is not a standard rule for when to change the bellows, but here are some guidelines to follow.

If the bellows assembly fails the leak test, then it should be replaced. If the test article is being changed, it would be best to replace the bellows and bellows lid to eliminate any possible cross-contamination. The bellows assembly should be replaced at least every 10,000 cycles.

Replacement Bellows Assemblies are sold in kits with quantities of 10 or 50. Part numbers are shown below.

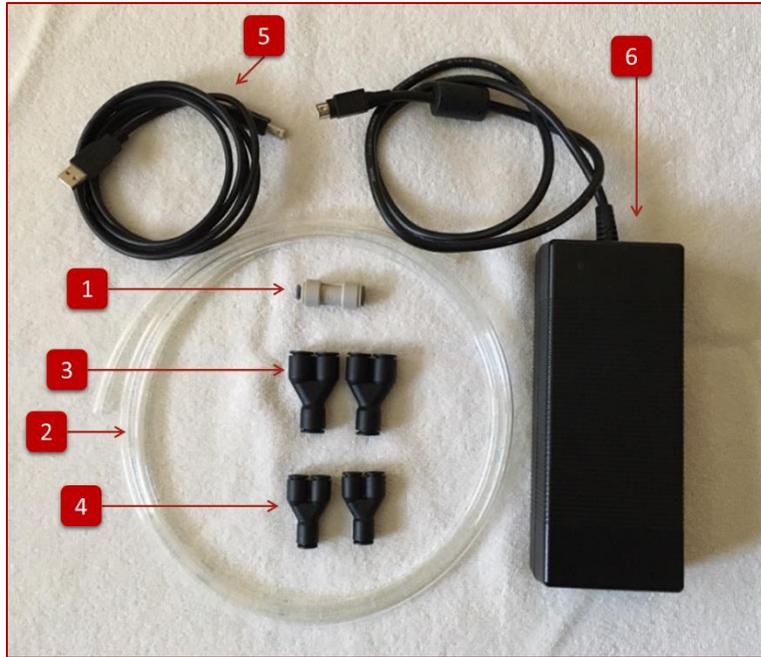


EVT Bellows Assemblies Replacements	Quantity	DSI Part Number
EVT Bellows Assemblies	10	601-2068-001
EVT Bellows Assemblies	50	601-2069-001

EVT SMOKE MACHINE CONTROLLER ACCESSORY KIT – PARTS LIST

The following outlines the components available in the EVT Smoke Machine Controller Accessory Kit.

Replacement Kit Part Number: **601-2261-001**

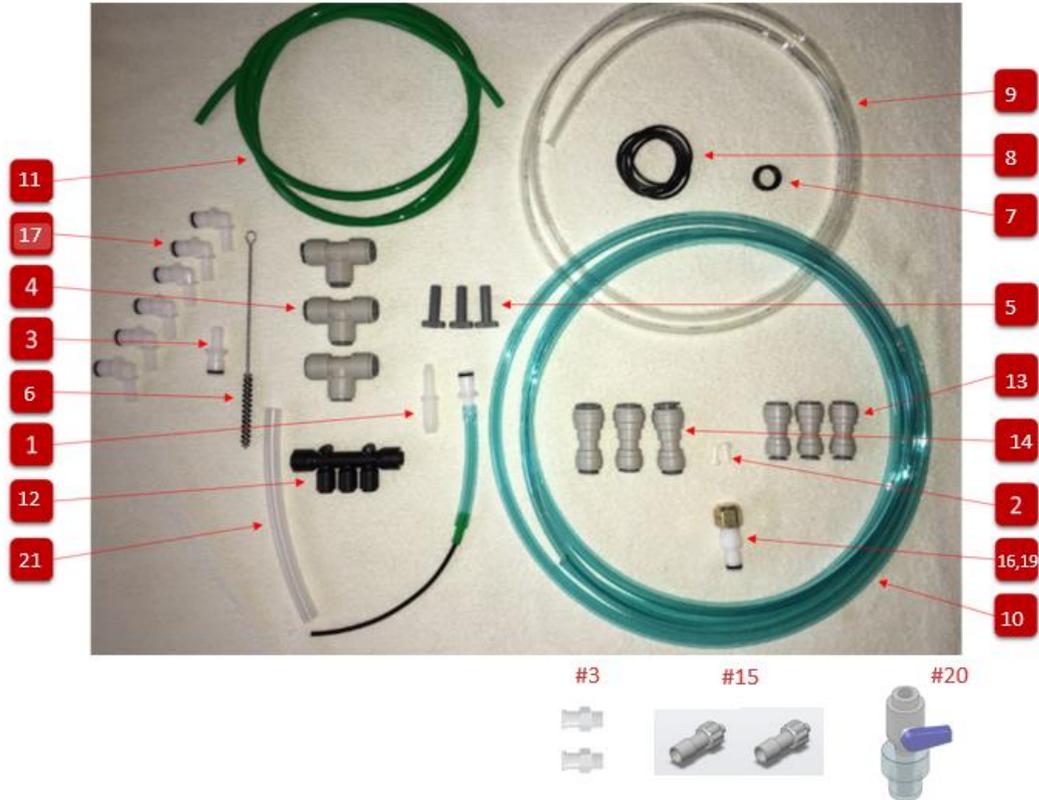


Find Number	Description	Quantity	DSI Part Number
1	FIT, PC, 1/4" – 5/16" ACETAL	1	008750-001
2	TUBE, CLEAR, POLYUR, 3/16"x5/16"	6FT	010179-001
3	FIT, PC, WYE, 5/16 TUBE, NYLON	2	014108-001
4	FIT, PC, WYE, 3/8 TUBE, NYLON	2	014109-001
5	CBL 10' BLACK, USB-A	1	601-2551-001
6	POW EXTERNAL POWER SUPPLY	1	601-2552-001

EVT SMOKE STATION ACCESSORY KIT – PARTS LIST

The following outlines the components available in the EVT Smoke Station Accuracy Kit.

Replacement Kit Part Number: **601-2262-001**

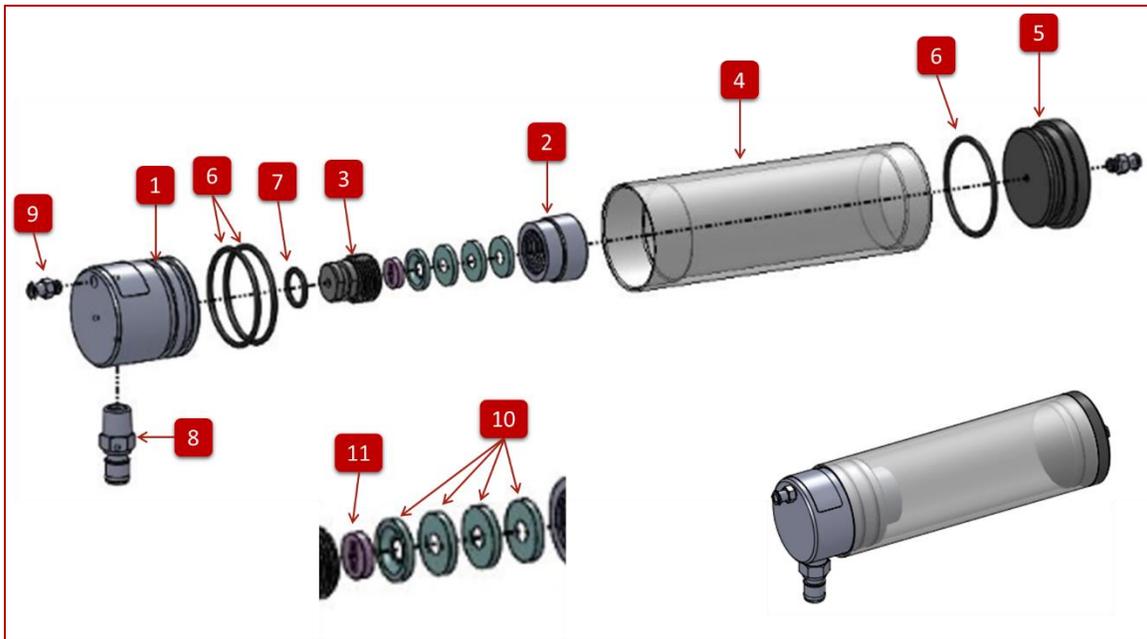


Find Number	Description	Quantity	DSI Part Number
1	TUBING REDUCER 1/4" TO 3/8"	1	006169-003
2	FIT, LUER, MALE, PLUG, WHITE	2	008667-001
3	FIT,LUER,FEMALE,1/4-28,WHT,NYL	2	008689-001
4	FIT T FIT-3/8INOD TUBING	3	008726-001
5	FIT 1/4IN PLUG	3	008737-001
6	NYON LOOP HANDLE BRUSH	1	008850-001
7	O-RING, #113, BUNA-N	2	009446-001
8	O-RING, #131, BUNA-N	6	009470-001
9	TUBE, CLEAR,POLYUR,3/16"X5/16"	6	010179-001
10	TUBE, BLUE, POLYUR, .245"X3/8"	10	010180-001
11	TUBE, GREEN, POLYUR, 1/8"X1/4"	6	010199-001
12	FIT, MANIFOLD-1/4IN OD 5 TUBES	1	011102-001
13	FIT REDUCING CPLNG 3/8 TO 5/16	3	011771-001
14	FIT, REDUCER, 1/2" TO 3/8"	3	012305-001
15	FIT M LUER 1/4" BARB TUBE ID	2	014167-001
16	FITTING, Q/C, 1/4 NPT, ACETAL	1	014007-001
17	FITTING, QC, EL, 1/4 HOSE BARB	6	014008-001
18	FITTING, QC, 1/4 HOSE BARB	6	014082-001
19	FITTING, CAP, BRASS, 1/4 NPT	1	014101-001
20	WBP BALL VALVE W/NEB PRT ADPTR	1	601-1538-002
21	TUBE, HI-TEMP 1/4 ID, 7/16 OD	.5	906116-001

EVT CIGARETTE HOLDER AND CONTAINMENT TUBE – PARTS LIST

The following outlines the components that are available in the EVT Cigarette Holder and Containment Tube kit.

Replacement Kit Part Number: **601-2064-001**

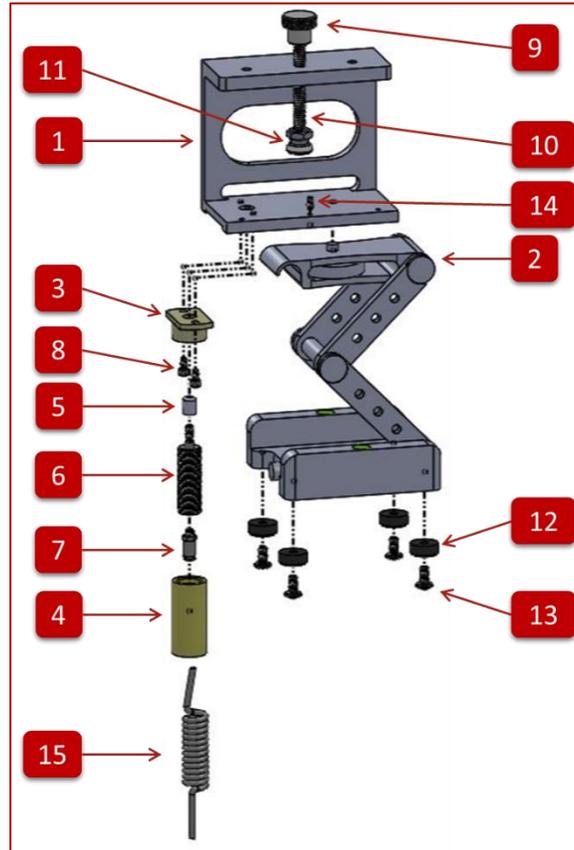


Find Number	Description	Quantity	DSI Part Number
1	ADAPTER, LABYRINTH SEAL, EVG	1	013901-001
2	CAP, LABYRINTH SEAL, EVG	1	013902-001
3	SUPPORT, LABYRINTH WASHER SEAL	1	013903-001
4	TUBE, SMOKE ISOLATOR, EVG	1	013935-001
5	CAP, ISOLATOR TUBE, EVG	1	013936-001
6	O-RING, #131, BUNA-N	3	009470-001
7	O-RING, #113, BUNA-N	1	009446-001
8	FITTING, Q/C, 1/4 NPT, ACETAL	1	014007-001
9	FIT, LUER, FEMALE, 1/4-28, WHT, NYL	2	008689-001
10	SEAL, LABYRINTH, CIG/E-CIG	4	013773-001
11	WASHER, LABYRINTH, CIG/E-CIG	1	013774-001
0	SILICONE GREASE, 5.3 OZ		

EVT BUTTON-ACTIVATION DEVICE HOLDER KIT – PARTS LIST

The following outlines the components available in the EVT Button-Act Device Holder Kit.

Replacement Kit Part Number: **601-2070-001**



Find Number	Description	Quantity	DSI Part Number
1	CLAMP ECIG BUTTON ACTIVATOR	1	014066-001
2	CAMERA MOUNT, TILT ACCESS	1	014047-001
3	FLANGE BIMBA CYL ACTIVATOR	1	014067-001
4	SLEEVE, BIMBA CYL ACTIVATOR	1	014068-001
5	BUTTON, BIMBA, CYL ACTIVATOR	1	014069-001
6	BIMBA CYLINDER, 1/2" STROKE	3	014072-001
7	FIT, 10-32, 1/16" ID TUBE BARB	1	014073-001
8	SCREW, SHCS, 6-32 x 1/4", BO	2	008992-001
9	KNOB, 184-20, 3/4" DIA BO	1	905798-001
10	ROD, 1/4-20, 2-3/4" LG, STL	2	014075-001
11	SWIVEL, 1/4-20, 5/8" DIA	2	014075-001
12	BUMPER, RUBBER, 5/8" DIA	2	014081-001
13	SCREW, PHMP, 10-32 x 3/8", SS	4	008892-001
14	SET SCREW, CUP, 6-32 x 1/4", SS	1	906124-001
15	TUBE, COILED, 1/8 OD, 85A PUR	1	014110-001

EVT PUFF VOLUME MEASUREMENT KIT – PARTS LIST

The following outlines the components available in the EVT Puff Volume Measurement Kit.

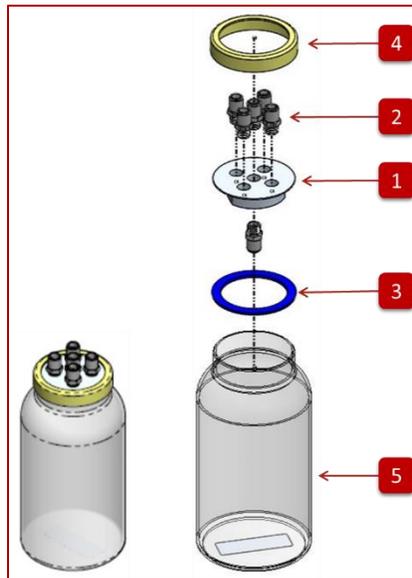
Replacement Kit Part Number: **601-2065-001**

Find Number	Description	Quantity	DSI Part Number
1	CLAMP ECIG BUTTON ACTIVATOR	1	014066-001
2	CAMERA MOUNT, TILT ACCESS	1	014047-001
3	FLANGE BIMBA CYL ACTIVATOR	1	014067-001
4	SLEEVE, BIMBA CYL ACTIVATOR	1	014068-001
5	BUTTON, BIMBA, CYL ACTIVATOR	1	014069-001
6	BIMBA CYLINDER, 1/2" STROKE	3	014072-001
7	FIT, 10-32, 1/16" ID TUBE BARB	1	014073-001
8	SCREW, SHCS, 6-32 x 1/4", BO	2	008992-001
9	KNOB, 184-20, 3/4" DIA BO	1	905798-001
10	ROD, 1/4-20, 2-3/4" LG, STL	2	014075-001
11	SWIVEL, 1/4-20, 5/8" DIA	2	014075-001
12	BUMPER, RUBBER, 5/8" DIA	2	014081-001
13	SCREW, PHMP, 10-32 x 3/8", SS	4	008892-001
14	SET SCREW, CUP, 6-32 x 1/4", SS	1	906124-001
15	TUBE, COILED, 1/8 OD, 85A PUR	1	014110-001

EVT IN-LINE SMOKE RESERVOIR – PARTS LIST

The following outlines the components available in the EVT In-Line Smoke Reservoir kit.

Replacement Kit Part Number: **601-2066-001**

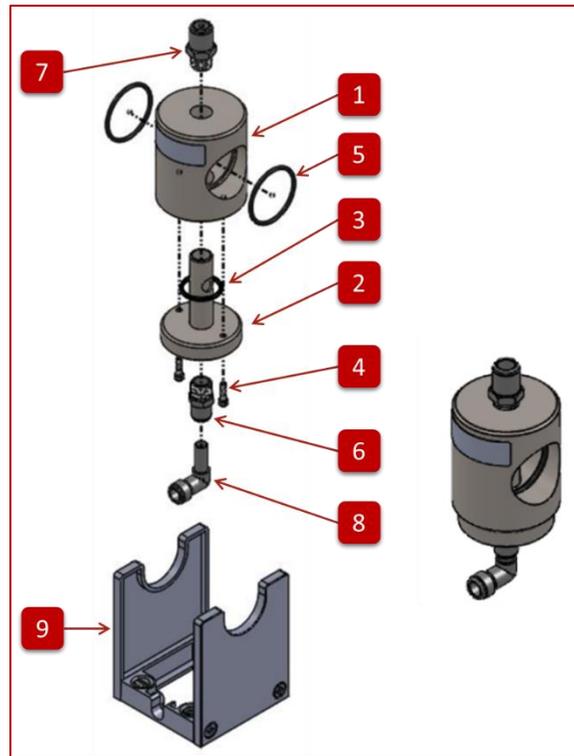


Find Number	Description	Quantity	DSI Part Number
1	LID, AREOSOL CONCENTRATION BAL	1	104077-001
2	FIT, PC, 1/4NPT-3/8", NICKEL	6	007873-001
3	GASKET, SILICONE, WIDE MOUTH	3	014079-001
4	RING, WIDE MOUTH, SSSL	1	014078-001
5	JAR, MASON, 64 OUNCE WIDEMOUTH	1	014080-001

IN-LINE PHOTOMETER KIT – PARTS LIST

The following outlines the components available in the In-Line Photometer kit.

Replacement Kit Part Number: **601-3192-001**



Find Number	Description	Quantity	DSI Part Number
1	ADAPTER, CENTER, IN-LINE PHOTO	1	012157-001
2	ADAPTER, TOP, IN-LINE PHOTOMTR	1	012166-001
3	O-RING, #118, BUNA-N	2	009443-001
4	CAP SCREW, 6/32 X 1/2" SS	4	904633-001
5	O-RING #126	4	009484-001
6	FIT, PC, 1/4"NPT-5/16", NICKEL	1	007601-001
7	FIT, PC, 1/4"NPT-3/8", NICKEL	1	007873-001
8	FIT, PC,EL,5/16STEM-5/16,NYLON	1	008754-001
9	SUBASSY, IN-LINE PHOTMTR STAND	1	014104-001

SPECIFICATIONS

SPECIFICATION

Station Longevity: 100,000 cycles min

Station Connect/Disconnect 1,000 min

Bellows Longevity 10,000 puffs, min

E-Cig Standard Puff, as per ISO 20768

- a. Puff Volume: 55ml \pm 0.6ml as calibrated and measured with provided 1kPa flow restrictor, or \pm 3.7 ml with pressure drop from 0 to 3kPa*
- b. Puff Duration: 3 \pm 0.1s
- c. Puff Frequency: 2 per min \pm 0.5s
- d. Puff Shape: Rising and Falling edge of trapezoid shall not exceed 10% of volume as measured with pressure drop 1kPa to 3kPa
- e. Puff Max Flow Rate: 18.5 \pm 1.8ml/s

Traditional Standard Puff, as per ISO 3308

- a. Puff Volume: 35ml \pm 0.3ml as calibrated with a provided 1kPa flow restrictor, \pm 3.0 with pressure drop from up to 3kPa*
- b. Puff Duration: 2 \pm 0.1s
- c. Puff Frequency: 1 per min \pm 0.5s
- d. Puff Shape: Maximum flow rate between 25-30ml/s at 0.8s \leq tm \leq 1.2s for a 1Kpa pressure drop device.

Customizable Puff Limits

- a. Puff Duration: 1-5 \pm 0.1 seconds
- b. Puff Frequency 1-6 puff/min \pm 0.5 seconds
- c. Puff Volume: 10-100ml \pm 3.0 ml* for a 1Kpa flow restriction
- d. Max Flow Rate: 30ml/sec

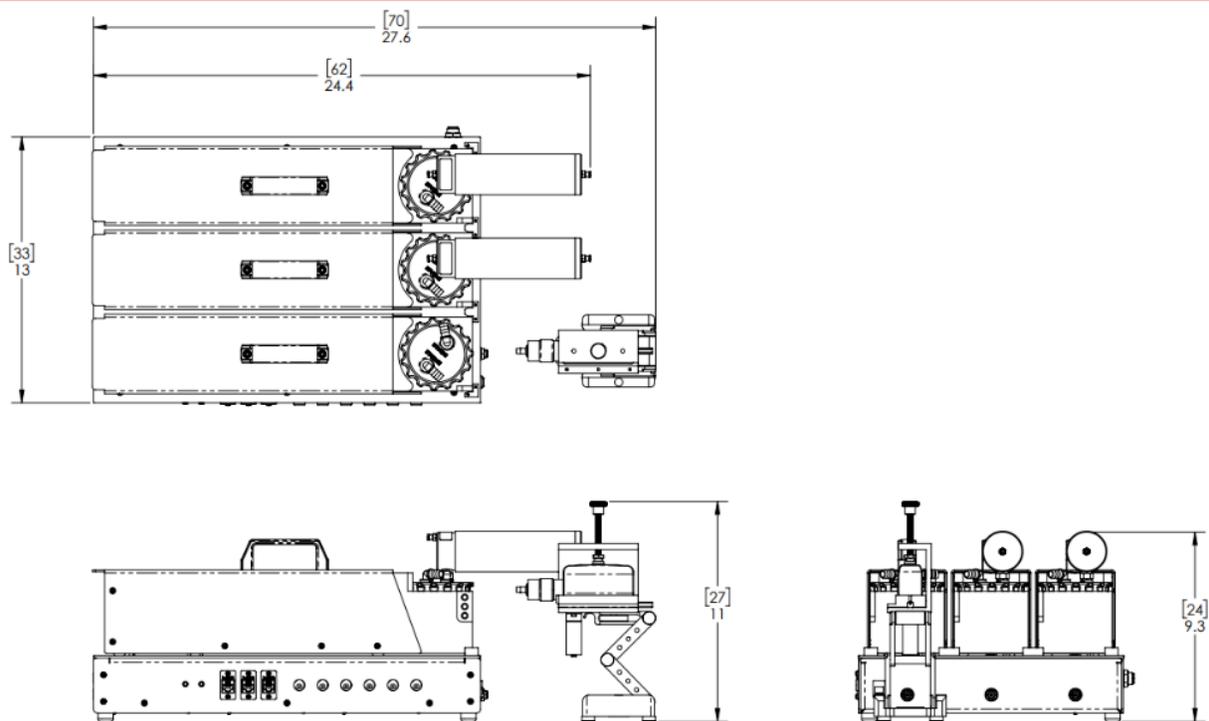
Accuracy of Measure Puff Sensor Calibration within \pm 0.15 ml

Button Actuator Timing, within 0.1 seconds of start and stop of puff

* Volume accuracy when calibrated using Measure Puff Mass Flow Sensor and standard 1kPa flow restrictor. Volume accuracy may be improved to within Measure Puff Mass Flow Sensor accuracy if calibrating with specific test article resistance and actual puff parameters used.

As noted in the calibration section, the calibration procedure should, at minimum, be performed each time the bellows assembly is changed out and or when switching from one profile type to the next, i.e., E-Cig to Traditional puff profiles or vice versa.

DIMENSIONS



WEIGHT

EVT Smoke Machine Controller – 11.5 lbs.

ECT Smoke Machine Station – 9.0 lbs.

OPERATING ENVIRONMENTAL CONDITIONS

- Indoor use
- Altitude up to 2000 m;
- Ambient temperature 4°C to 40°C
- 4°C to 40°C; 10% - 80% Rh, Non-condensing
- Mains supply voltage fluctuations not to exceed $\pm 10\%$ of the nominal voltage;
- Supply voltage, voltage range: 100-240VAC, 50/60Hz, 4.0A, 180W Max.
- Overvoltage Category 2
- Pollution degree 2

DSI cannot guarantee the safety of this device if used other than intended or used by any procedures other than those described in this manual.

The AC/DC adapter requires a connection to protective earthing (ground), only use with a power supply outlet and power supply cord that provides protective earthing.

Only use a detachable power cord (AC/DC adapter) that allows for protective earthing and is a minimum of 18 AWG. This cord will need to have appropriate agency approvals, such as UL, CSA.

TECHNICAL SUPPORT

DSI™ is available to help you with your questions and concerns. Should you hit a roadblock or need some additional training, please feel free to contact us. We are happy to help!

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