When designing a device intended for use in drug delivery, it is important to consider the amount of force needed to actuate the device properly in order to deliver the dose consistently and within specification, according to the drug's label claim. Just like other key actuation parameters such as velocity, stroke length, etc., force to actuate has been studied and indicated to be a critical quality attribute (CQA) according to regulatory bodies. In fact, it was mentioned specifically in the FDA's April 2018 guidance document on metered dose inhalers.

Using Proveris Scientific's Vereo Automated Actuators, the force and position profiles for an actuation event can be recorded automatically and then a measurement can be created using the Pending Measurements tab. In this tech note, we will describe the recommended procedure for measuring the force to actuate using both the SprayVIEW® Measurement System as well as standalone Vereo® Automated Actuators.

Force to Actuate Procedure

Proveris Scientific defines Force to Actuate as the amount of resistive force exhibited by a device when it begins to emit the spray. Thus, ideally, the force measurement should be taken at the time when the spray first starts to exit the nozzle or orifice of the device being measured. You can utilize a Plume Geometry measurement on the SprayVIEW in order to select the point where the spray event begins. When analyzing a Plume Geometry measurement, you can select the playback tool and then advance the video forward until the point where the spray begins (shown in Figure 1 below). Proveris recommends running a sample size of at least 3 replicates across 3 different devices in order to create an average value for the time of the spray event start.
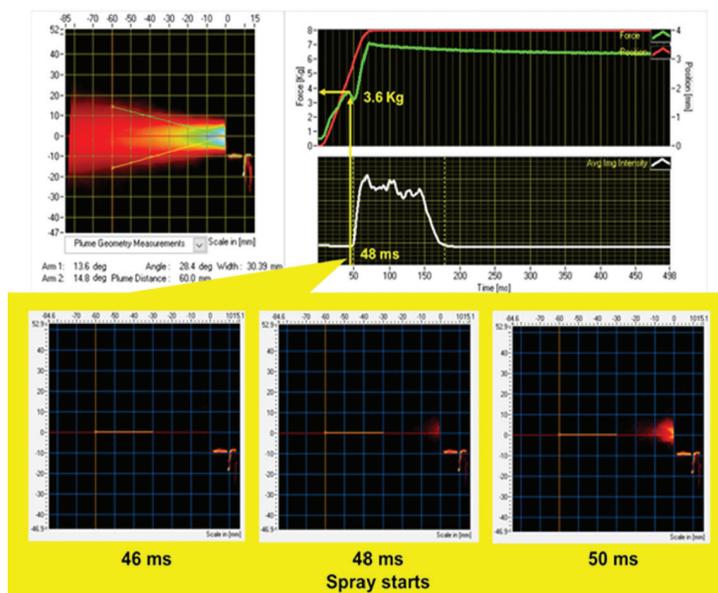

Figure 1. Example Plume Geometry Measurement showing the time when the spray begins to exit the mouthpiece of the inhaler. This point can then be used to calculate Force to Actuate.

From here, you can then define an actuation task and use it to measure the Force to Actuate. After an actuation task completes, you will be able to analyze it in the Pending Measurements tab. Below in Figure 2 shows an example of a Force to Actuate measurement.
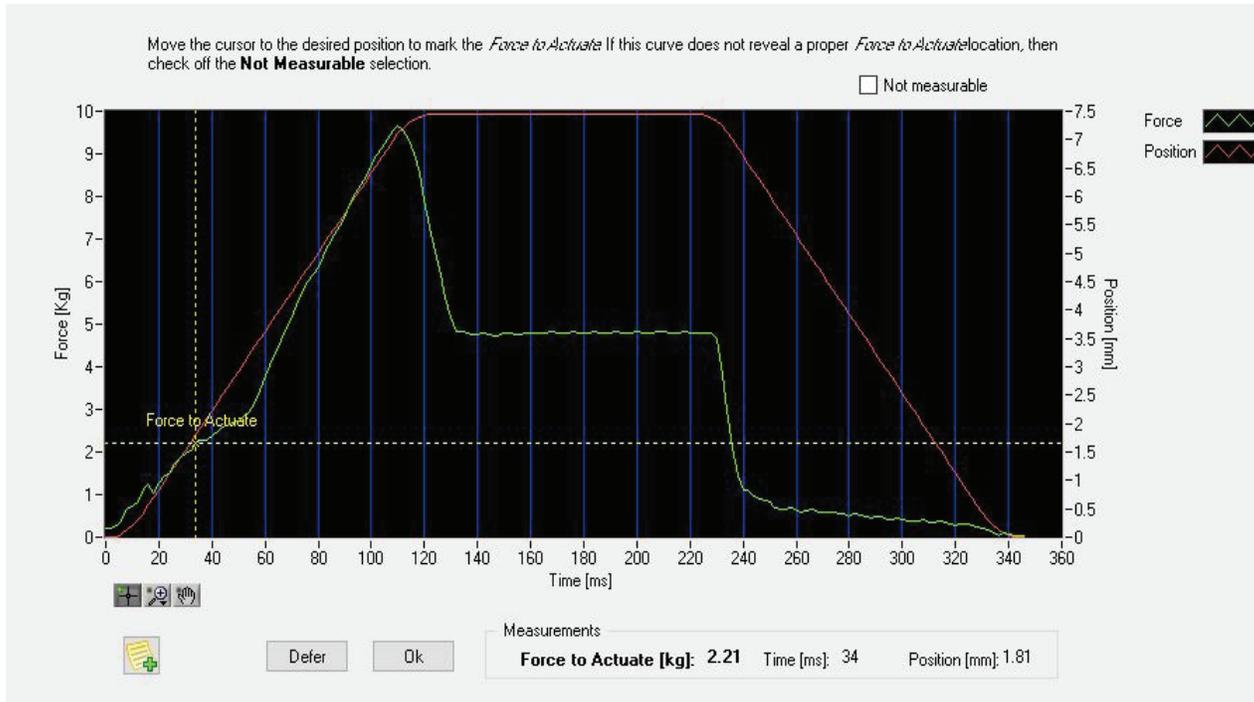

Figure 2. Example of a Force to Actuate Measurement in Viota. The user can drag the Force to Actuate cursor to the desired time point and then click "Ok" in order to save the measurement. After this, a report can be printed by accessing the measurement in the Task Data tab.

The user can drag the Force to Actuate cursor to the desired time (based on the average time found in the Plume Geometry study). Once this is completed, they will press the "Ok" button to save the measurement. Then, the measurement can be accessed at any time in the Task Data and a report can also be printed if desired.

It should be noted that the Force to Actuate Measurement in Viota automatically sets the cursor at the first major inflection point in the course of the actuation event. Generally, this point corresponds with the beginning of the delivery stroke in nasal spray pumps or the point where the valve begins to open in an MDI. Therefore, for users of standalone Vereo Actuators, this inflection point can be used as the Force to Actuate for those who do not have access to a SprayVIEW measurement system. Proveris does recommend, however, that the user perform a small study in order to verify consistency of that inflection point for their device. Proveris Laboratories can assist in providing device characterization services in the form of a contract service should you have any interest. With access to our SprayVIEW Measurement System in our fully cGMP compliant laboratory, our team can perform measurements on your device and help you select the point for the start of the spray event, allowing you to perform Force to Actuate Measurements on your own with a Vereo Actuator.

If you have questions regarding the Force to Actuate or need any additional information, please don't hesitate to contact a Proveris engineer at support@proveris.com.