Technical Note – TN0109
Viota® Software Upgrade to Version 9

Proveris Viota Software has had a major update, introduced at Version 9.0.1, which includes the ability to provide automated Plume Front Velocity (PFV) and Spray Duration measurements for pMDI and Soft Mist Inhalers on the SprayVIEW® Measurement System.

Why Velocity and Spray Duration?

In May 2019, the FDA released a Product Specific Guidance for Beclomethasone Dipropionate encouraging alternative *in vitro* testing approaches as a waiver for *in vivo* clinical endpoint studies. Included in the list of proposed *in vitro* tests was the characterization of velocity profiles of the spray. In November 2020, they released another guidance for Tiotropium Bromide expanding on this idea and introducing the measurements of plume front velocity as well as spray duration. The results from these measurements are additional parameters that can be used to help demonstrate bioequivalence for your products.

How Do I Take Advantage of These New Tools on the SprayVIEW Measurement System?

Proveris has updated our flagship Viota Software platform to include new functionality to measure Plume Front Velocity and Spray Duration using a standard Plume Geometry measurement setup for both the SFpMDI (traditional pMDIs) and OSP (soft mist inhalers actuated with the Vereo® NSx actuator) configurations available on a SprayVIEW Measurement System.

Unlocking this new capability is as simple as upgrading your current version of Viota software for your SprayVIEW Measurement System! Please reach out to **support@proveris.com** for more information on your customized upgrade path and allow our team to help answer any questions you may have about the upgrade process and re-validation process.

How Does it Work?

The Plume Front Velocity measurement is achieved by using an image processing algorithm to track the leading edge of the plume as it is emitted from the mouthpiece of an inhaler device using image intensity data. For each image that is taken with the camera, the system will produce a data point consisting of a distance and time components until the plume has left the field of view. Therefore, to maximize the amount of data collected per spray, it is important to adjust your method to maximize the field of view. Once the raw data is collected, the software will apply a curve fit to the data which allows the user to interpolate and solve for velocity at any distance or time they wish.

Spray Duration is calculated using the average image intensity data for each spray. The system uses an automatic algorithm to detect the start and stop times for the spray based on the image intensity. Alternatively, the user can switch to a manual mode and drag the cursors to set the duration before saving the measurement.

When defining methods, users can select Plume Front Velocity as a measurement type for any Plume Geometry task. The spray duration calculation will be included as part of the PFV measurement. When configuring the method, the following options are able to be customized to your specific needs:

- Ability to select Distance or Time mode to calculate the plume front velocity at a particular distance from the mouthpiece, or at a particular time
- Ability to manually set the origin for the measurements at the edge of the mouthpiece for data consistency
- Ability to toggle between an automatic algorithm for spray duration or a manual mode where the duration can be set by dragging cursors to define the start and end times of the spray based on image intensity data
- Ability to export detailed pdf reports for you PFV and spray duration measurements just as with spray pattern or plume geometry.
- Ability to remeasure data with different parameters applied, as well as existing plume geometry data for PFV

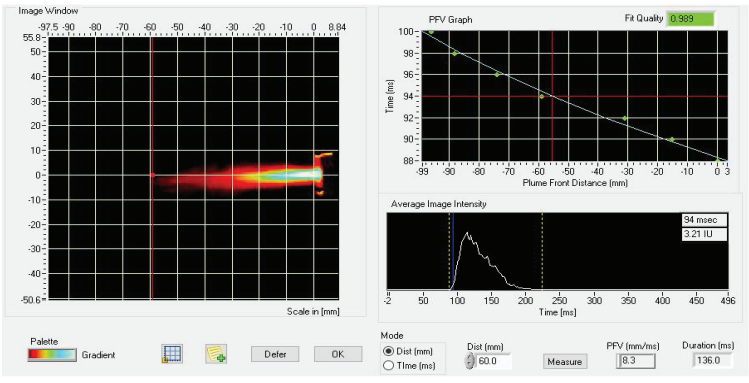

Figure 1: Pending measurements view of a PFV measurement for a pMDI device.

Proveris Scientific Corporation
Two Cabot Road, Hudson, MA 01749 USA
+1 508 460-8822 • sales@proveris.com

Indizo®, Proveris®, Proveris Scientific®, Proveris Scientific and Design®, SnapLock®, Solo®, SprayVIEW®, Vereo® and Viota®. are registered trademarks of Proveris Scientific Corporation. INVIDA™, Kinaero™, Kinaero Cx™, Ergo™ and Proveris by Design™ are trademarks of Proveris Scientific Corporation. Other product and company names mentioned herein are trademarks or trade names of their respective companies.