Technical Note – TN0108
Spray Pattern: Manual versus Automatic

Characterization of Spray Pattern and Plume Geometry are important for evaluating the performance of the device pump. Various factors can affect the Spray Pattern and Plume Geometry, including the size and shape of the nozzle, the design of the pump, the size of the metering chamber, and the characteristics of the formulation[1]. When performed using a non-impaction method like the SprayVIEW®, Spray Pattern is calculated using a time-averaged sequence of images of the spray event. The Viota® application uses image processing algorithms to identify the pattern and calculate its true shape and perimeter, as well as all of the secondary measurements such as area and ellipticity, etc.

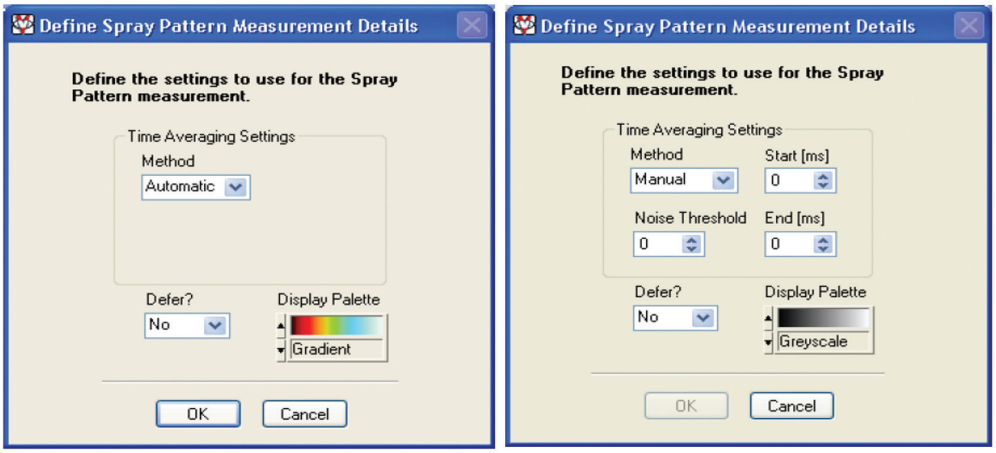


Figure 1. Defining the measurement for a Spray Pattern measurement in Viota. Note the additional parameters needed for manual mode.

The default setting in Viota is for the Automatic algorithm. In this mode, the spray start time, spray end time, and noise threshold are calculated automatically. Viota automatically selects the most appropriate value for each of these variables as calculated from the Average Intensity vs. Time data. A filter is used to remove any noise and help sharpen the gradients when the spray starts and stops. The threshold value is essentially the level of baseline signal left after the filtering.

When reviewing the Spray Pattern data, you will find the noise threshold value that was selected for your automatic measurement. Also note that a noise threshold value of zero is entirely possible and valid for the algorithm. A zero value simply means that the background intensity level of the image sequence is actually zero (which is ideal from a processing perspective because this level will maximize the dynamic range of the processed images).

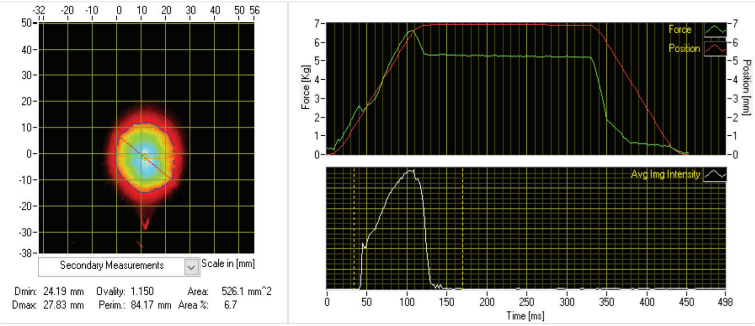
Threshold	Time Avg. Mode	Start Time [ms]	End Time [ms]
0	Automatic	34	170
15	Manual	25	175
5	Manual	25	175

Figure 2. Screenshot of the Task Data for several Spray Pattern measurements showing where to find the threshold value that was used. Notice in this case, the automatic algorithm produced a threshold value of 0 which is still valid.

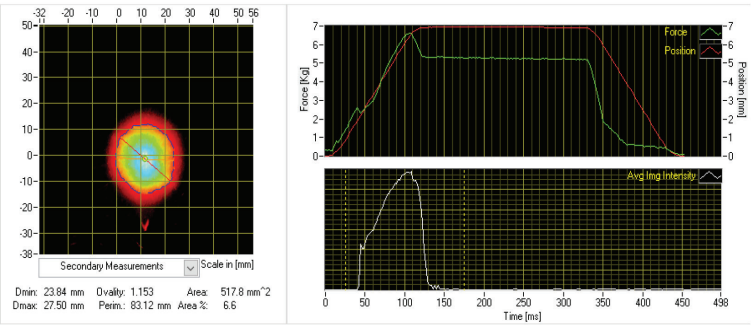
When should you use the manual option? When using Automatic mode, you should always take a look at the Intensity versus time graph to see if the algorithm has selected an appropriate start, and particularly, an appropriate end time. From our experience, for certain devices, the end time value can be very difficult to determine with high repeatability when the Average Intensity vs Time data exhibits a gradual transition back down to the base level as the spray ends. If you notice it is not consistently picking a suitable end time, we recommend trying manual mode and using previously generated data to pick the proper end time. Also, if you still see noise in your time-averaged image or other artifacts, it might be a good idea to try re-measuring with manual mode.

When you select the manual option, you will have to enter the start and end times of the spray in milliseconds as well as the noise threshold. We generally recommend a noise threshold level of 5 or less. Just keep in mind that the scale for the threshold value is from 0-255. The physical units of intensity are non-dimensional (i.e., it doesn't have typical units like kg, Pa, mm, etc.) so we don't report any units. However, the range of the reported values is 0 to 255 since the raw images are 8-bits deep/pixel. A good idea would be to remeasure any measurement created using the automatic algorithm, and vary the threshold value in order to see how it affects the results.

Threshold Value =0



Threshold Value = 5



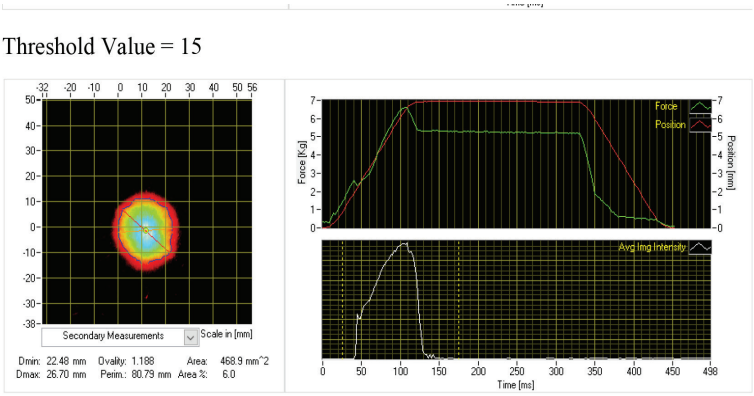


Figure 3. Shown here are 3 different measurements of the same Spray Pattern image. You can see that the jump from a threshold of 0 to 5 actually reduces noise artifacts and only a negligible affect on the measurements (i.e., Spray Pattern area). The measurement with a threshold of 15 shows a much smaller Spray Pattern area, indicating that the algorithm actually eliminated good signal as a result of the higher threshold value. Proveris recommends that you generally stay below a value of 10 in order to not eliminate signal from the calculations.

If you have additional questions regarding Spray Pattern measurements or need more information, please don't hesitate to contact a Proveris engineer at support@proveris.com.

References

1. https://www.fda.gov/media/70867/download Guidance for Industry Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Biopharmaceutics. April 2003.

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