

Pump delivery and spray content uniformity
collection testing for vertically-actuated and
side-actuated nasal sprays



It's all about confidence in your data

Confidence in your data is critical in making the right decisions. Whether developing a new product, generating submission data, or conducting QC release or stability testing, it's important to test the product's true performance. The Indizo® Automated Nasal Spray Collection System completely automates the arduous and error-prone tasks of spraying, weighing, and sample collection of nasal spray products. Variability and limitations introduced by technique, fatigue, or lack of experimental design are eliminated, delivering consistent and reliable results.

The Indizo system is part of a complete Nasal Spray Solution for Development, Release, and Stability Testing. The system is based on the gold standard Vereo® automated actuator and Viota® software unifying your testing parameters across spray content uniformity, pump delivery, droplet size distribution (DSD), spray pattern, and plume geometry. Capable of generating over 1,000 measurements per day unattended, Indizo can easily be adopted into Quality by Design or release testing with limited operator intervention.

Typical applications

Release and Stability Testing

- Spray Content Uniformity
- Through Life Testing
- Pump Delivery
- Fire Down
- Pump QC (incoming)

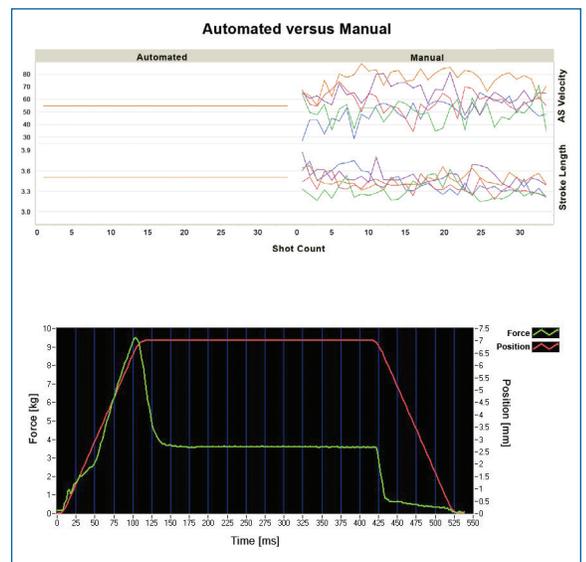
Product Characterization Studies

- Device Selection via Shot Weight
- Priming Studies
- Overfill / Tail-off Determination
- Device Robustness
- Shaking Studies

Reduce out-of-specifications and inconsistent results

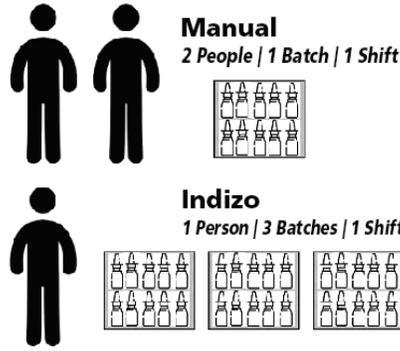
- Mechanical actuation based on human usage parameters eliminates variability due to technique and fatigue
- Precise actuation, control, and force feedback provide insight into product performance, and help resolve out-of-specification (OOS)
- Integrated balance for accurate weighing
- Precision fit sample collectors eliminate variation and inconsistent results due to "spray and flip" manual method
- All critical parameters and results are recorded for process control and root cause analysis on any variations

An example graph of data from a hand study that shows the variation in actuation velocity (mm/s) and stroke length (mm) of a commercial nasal spray from three analysts compared with the reproducibility of automated actuation.

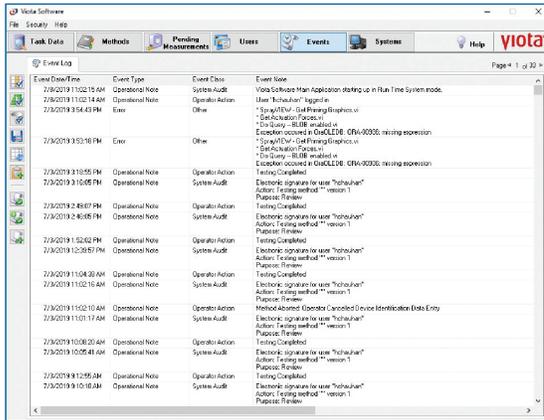


Do more with less

- 1 person can release up to 3 batches per day of spray content uniformity or pump delivery through life testing.
- Less than 20 minutes of setup time
- Frees up additional resource(s) for more technique dependent analyses
- Generate up to 1,000 measurements for Quality by Design (QbD) studies with limited operator intervention



Audit defense with full traceability



- Built-in reports allow review of all key parameters
- All critical parameters including methods, samples, and operators are recorded for complete traceability
- Data can be used to quickly identify and assign root cause for OOS investigations
- Compliant to regulatory requirements such as 21 CFR part 11

Intuitive software walks the user through method setup and execution with step-by-step prompts. Develop and release your method, then set and forget the Indizo while you focus on more critical tasks.

Easy to use

- Can be configured for vertical or side actuated nasal sprays
- Step-by-step guide to develop and run methods
- Pre-run operational checks ensure error free setup and execution.
- Uninterruptible power supply (UPS) backup runs system in case of power failures



The complete nasal solution



- Integrates with the Viota database for method and data sharing
- Share actuation parameters across your testing requirements – spray content, pump delivery, droplet size distribution (DSD), spray pattern, and plume geometry
- Consolidate data

Let us do the work - Proveris Laboratories

- **Method Development**
Develop, optimize, and validate methods using human realistic actuation parameters for Release, Stability, or QbD Studies
- **Cross Over Studies**
Manual to automated verification study to demonstrate performance and support method validation
- **SOP Development Assistance**
Help with establishing and updating current SOPs to include Indizo system into your workflow
- **Training**
Operation, method development, troubleshooting, QbD best practices



System Overview

- System**
- Vereo NSx Actuator for vertical actuation or SSx Actuator for side actuation
 - Viota Software
 - Mettler Toledo Analytical Balance
 - Uninterrupted Power Supply (UPS)

- Tray Configuration**
- Spray content uniformity / pump delivery: 10 device capacity with 20 dose content collectors and 10 sample collectors
 - Pump delivery only: 20 device capacity and 20 sample collectors

- Size**
- Floor-standing system / self-contained
 - Height: 74.3 in (189 cm) Width: 46 in (117 cm) Depth: 31 in (80 cm)

- Electrical Requirements** – 100-120VAC 50/60Hz 10A or 220-240VAC 50/60Hz 5A

The Proveris advantage

Complete Solution

Proveris offers a complete suite of testing solutions that covers the lifetime of your OINDP product from early development to manufacturing release.

Scientific Focus

Our line of instruments and lab service offerings help you uncover the true performance of your combination drug product and get to market faster!

Industry Leader

Our experts collectively bring more than 25 years of experience in the field of OINDPs and have helped to shape the regulatory landscape for bioequivalence studies.

Unmatched Customer Support

Global service organization offering world-class support and additional value-add services to help you maximize the benefits from your instruments.



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