kinaero™

HIGH-THROUGHPUT PMDI FIRE-DOWN SYSTEM

High-precision solution for automated shaking and fire-down of devices or canisters

proveris
SCIENTIFIC

Supports R&D and Production goals for precision, accuracy, and productivity

Eliminate product variability

Proper shaking, shake-to-fire intervals, and consistent dose delivery are vital to the success of pMDI commercial and laboratory operations. Improper shaking and shake-to-fire intervals in testing can vary the delivered dose from 75% to 320% of label claim per actuation. Over- or under-delivery of the delivered dose during a single actuation can change the total drug concentration, introduce variability, and impact final results.

The Kinaero™ High-Throughput Fire-Down System is a testing solution that precisely automates shaking and actuation. Engineered for customer success, accuracy and repeatability are ensured through controlled, consistent shaking and uniform dose delivery of every shot throughout life testing.

System benefits ensure success

Precision control reduces risk	– Precise control of critical parameters allows for uninterrupted laboratory testing by eliminating risks that result from OOS due to inconsistent data
Accuracy delivers quality results	– Accuracy and consistency produces quality results for testing at the beginning, middle, and end of the device life – Automated actuation controlled by force, position, or time ensures that each device or canister is properly actuated every time and in every position, ensuring consistency with every fired shot
Automation increases productivity	– Allows for processing of up to 10 devices with shaking, shake-to-fire intervals, and fire-down – Frees up analysts' time for higher value work – Minimizes downtime that can result from fatigue-induced errors of manual actuation – Lab ergonomics improved by removing risk of injury from repetitive stress of manual actuation
Documentation ensures compliance	– The need for proper documentation is critically important from development to quality control. The Kinaero Fire-Down System provides the ability to track and control methods by product to enable rapid method development and ensure proper revision control.

Universal device and canister cassettes

Engineered for precision, flexibility, reliability

Precision

- Devices or canisters are held securely within the precision-engineered Universal Cassettes allowing for proper actuation every time and in every position
- Programmable shaking parameters are controlled for required duration, frequency, angle, and shake-to-fire delay for optimal patient-formulation-device performance
- Programmable modes of actuation—force limited, velocity driven time- or position-based for achieving patient-user target results
- Each actuation is electro-mechanically controlled eliminating the issues and variability introduced by using a pneumatic approach to actuation.

Flexibility

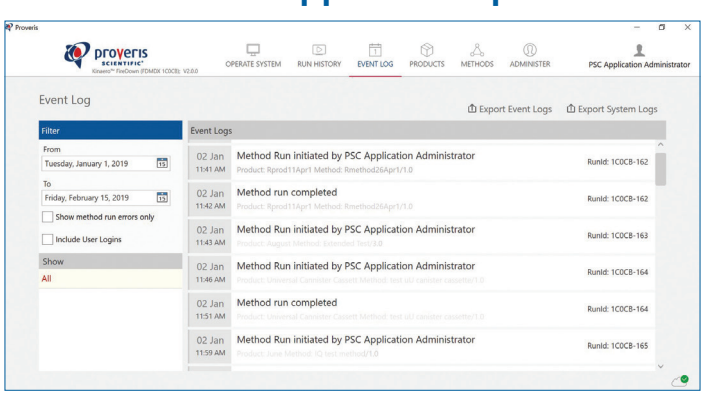
- Set and Forget rapid life testing—10-device capacity for Canister-only or Device-specific cassettes
- Break and Resume function maximizes throughput by allowing multiple users. Users can stop the method, perform another task, and resume the method later.
- Large touchscreen display for user-friendly method entry and operation
- Accellerated method development achieved by automating repetitive steps
- Flexible user permissions (R&D vs. QC vs. Developer vs. Operator)
- Product focused—all data is grouped by product for efficient organization and retrieval
- Universal Cassettes allow use of a wide range of devices or canisters
- Self-contained evacuation system eliminates the need for vacuum or pressurized air connections
- Low-maintenance, long-lasting, multi-filtration system eliminates the need for exhaust

Reliability

- Consistent actuation control ensures high-quality reproducible results
- Stored methods can be shared by syncing multiple systems

User friendly features: large touch screen display, Universal Cassettes, self-contained evacuation system

Easy-to-use software that supports compliance submission



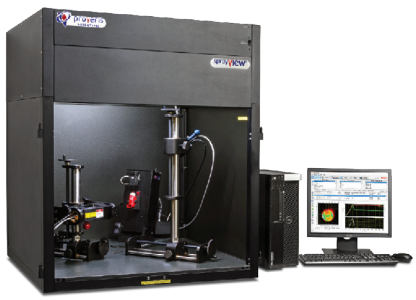
Comprehensive event log supports compliance

- Compliance to regulatory requirements such as 21 CFR Part 11 by providing security options and documenting all aspects of the run
- All critical parameters are recorded for process control and variation cause identification
- Flexibility for R&D needs by allowing programming of all parameters
- Ease-of-use is built in using a guided workflow model that indicates options for efficient screening of shaking and priming as well as operating parameters
- Robustness of methods increases as methods can be shared by multiple systems

Integration with Proveris products

The Kinaero Fire-Down System can work in conjunction with the KinaeroMATE™ pMDI Collection System to automate the entire workflow. The Break and Resume function allows for samples to be moved from one system to the other and returned back without starting new methods or creating different audit reports while sample information is tracked between systems. The Data Hub also allows for method and data "sharing" between Kinaero Systems.

KinaeroMATE and Kinaero Systems



SprayVIEW Measurement System

Proveris product family for pMDI testing

Why choose Proveris?

Based on twenty years of experience, we offer a unique blend of technical knowledge and understanding of global regulatory guidelines, incorporating Quality by Design (QbD) in our protocols, and effectively assisting our customers.

The Proveris advantage

Complete Solution for Orally Inhaled and Nasal Drug Product (OINDP)

Proveris offers analytical instruments and laboratory services that support product development, method optimization, (A)NDA submission for R&D, workflow optimization, and root cause analysis for OOS/OOT for QC.

Scientific Focus

Applying intelligent automation technology, modern data analysis, and proven experimentation techniques leading to superior product knowledge.

Unmatched Customer Support

From R&D through product release, customers benefit from high-quality instrumentation, easy-to-use software, and advanced technical support.

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