kinaero cx™

PMDI COLLECTION SYSTEM

Automated shaking, actuation, and sample collection for delivered dose uniformity (DDU) and aerodynamic particle size distribution (APSD).

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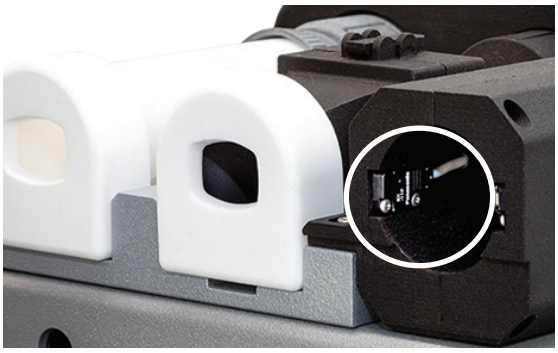
Introduction

Delivered dose uniformity (DDU) and aerodynamic particle size distribution (APSD) are critical quality attributes (CQAs) for pressurized metered dose inhalers (pMDIs) making the tests a primary focus for *in vitro* characterization. Traditional methods for performing these tests involves manual shaking, mating of the device with the collection vessel, and actuation. These methods do not always provide consistent results and inconsistencies can negatively impact testing outcomes. For example, improper shaking and shake-to-fire intervals can cause variations in the delivered dose from 75% to 320% of label claim per actuation. In addition, out-of-specification results for the delivered dose during a single actuation can change the total drug concentration, introducing variability that will impact final results. The Kinaero Cx provides a reliable automated solution built around the gold standard Vereo® Automated Actuator where shaking parameters, shake-to-fire timing, actuation velocity/acceleration, and flow rate can all be tightly controlled for repeatable results. With the ability to work with most pMDI devices, and the flexibility to run DDU and APSD measurements on the same platform, the Kinaero Cx reduces risks, such as human variability and operator fatigue that can lead to development project delays or hold ups with product release to the market.

Kinaero Cx pMDI Collection System

The Kinaero Cx easily integrates into DDU and APSD test workflows to automate shaking, actuation, and dose/sample collection in a reliable, repeatable manner. Using the intuitive and powerful software platform, users can set up methods to specify shots into all 3 collector locations (cascade impactor throat, DUSA, and waste), each with their own independent automatic flow rate control. In addition, an on-board mate sensor means teaching is not required to work with inhalers of different geometries.



The on-board mate sensor allows the Kinaero Cx to confirm the positioning of the inhaler – no teaching involved.

Based on Proveris's proven Vereo® Actuator technology

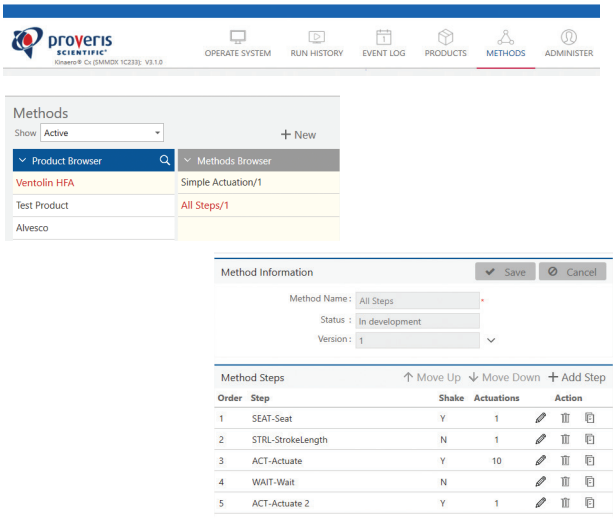
The Kinaero Cx provides an automated enhancement to our industry leading Vereo SFMDx Actuator for pMDI devices. The SFMDx ensures precise, reproducible control of stroke length, contact and end-of-stroke limits, actuation velocity/acceleration, hold time, and return velocity/acceleration for actuating pMDI devices. In addition, an integrated shake axis with shake angle, duration, and frequency control offers rapid shake-to-fire timing for suspension formulations. Rapid, consistent shake-to-fire timing is critical to achieve highly reproducible results. The Kinaero Cx maintains a fast and uniform shake-to-fire timing, resulting in highly reproducible DDU and APSD results.

Force-position actuation data collected by Vereo Actuator as displayed in the software.

Powerful software platform supports data storage and regulatory compliance

The Kinaero Cx is the first solution for DDU and APSD testing that employs a powerful software platform for easy instrument control, data storage, and report generation, while offering the tools to comply with FDA 21 CFR Part 11 requirements.

- Create and manage users with definable permissions (i.e., Administrators, Developers, and Operators).
- Develop and store specific methods to test products that include all necessary actuation parameters and flow conditions for sample collection.
- Open and run saved methods and store data in a local database for easy review of information
- Create and evaluate products using advanced features such as force/position vs time plots for all actuations to aid in OOS investigations



Easy to use software allows for complete control of critical testing parameters.

Achieve total workflow efficiency

Utilizing a unique snap-fit design, DUSA tubes and waste collector cartridges can be easily swapped in and out. This makes method set-up fast and efficient. Custom DUSA back end fitting and lip ensures that the sample integrity is maintained after an inhaler is fired into the DUSA tube for downstream processing.

- Easily set up a method calling for multiple DUSAs to match your current workflow (e.g., 3 beginning, 4 middle, 3 end of life).
- Fire all waste shots into the provided waste collector, or use alongside the Kinaero Fire-Down System for increased throughput.
- Swappable device holder inserts can be used to match the unique geometry of any inhaler design.
- Cascade impactor kit for both NGI and ACI allows for easy switching between DDU and APSD workflows with minimal manual intervention.

Kinaero High-Throughput Fire-Down System can be used alongside the Kinaero Cx for increased throughput.

Achieve accurate flow rates with precise control

Using an in-line micro-electromechanical systems (MEMS) based flow meter and independent stepper controlled valves for each collector location, the system allows for automated and precise setting of the desired flow rate which will vary depending on the type of test performed.

- Requires only a vacuum source, eliminating the need for other utilities such as compressed air.
- Proveris-designed external flow verification tool available to perform verifications at regular intervals.
- Set your desired flow rate and total volume of air for the method in the software and let the system do the work.

Cascade impactor throat collector, DUSA, and waste locations, each with their own independent and automatic flow control rate.

The complete pMDI solution

- The Kinaero Cx pMDI Collection System can be used independently or in conjunction with the Kinaero Fire-Down System for increased throughput.
- The Break and Resume functions in the software allows for samples to be transferred in between systems easily with full data tracking.
- The Vereo SFMDx Actuator can be employed for other *in vitro* tests, such as spray pattern (SP), plume geometry (PG), and droplet size distribution (DSD) testing to ensure consistency and repeatability of the device actuation.

System overview

System	– Kinaero Cx Automated pMDI Collection	Part Number: 8600
	– Vereo SFMDx Actuator for Kinaero Cx	Part Number: 8650
	– Kinaero Cx Configured Windows 10 Workstation (ask about requirements if providing your own workstation)	Part Number: 010300-00
	– Kinaero Cx Cascade Impactor Kit	Part Number: 010145-00
Size	– Benchtop Operation – Height: 23.4 in (59.5 cm); Width: 21.9 in (55.6 cm); Depth: 24.6 in (62.4 cm) – Weight: 80 lbs (36 kg). Weight with Actuator: 95 lbs (43.1 kg)	
Electrical	– 100-240 VAC, 50/60Hz, 3 A (480 W)	
Regulatory	– FDA 21 CFR part 11 compliant	

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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