

COMPANY PROFILE: NOVI SYSTEMS

NOVI

AUTOMATION SYSTEMS

In December 2015 the inhaler automation specialists Novi Systems launched their latest product, a ten-way shake and fire system for pMDIs called DecaVertus. Novi continues to innovate, bringing efficiency, precision and repeatability to inhalation labs around the world.

INNOVATING FOR MORE THAN TWO DECADES

Novi's long association with the inhaler industry started more than twenty years ago when British multinational Fisons asked it to create a system for automatically shaking an inhaler. Since then, Novi has shaken and fired inhalers in every way you may think of, recovered drug from impactors and DUSAs, collected countless waste shots and detected countless plumes.

ICTUS

Novi's main technology platform is a fully automated Andersen Cascade Impactor (ACI) system called the Ictus. The user loads up to thirty inhalers onto the system and returns later to find rows of vials with drug recovered from ACI stages ready for HPLC analysis. Each Ictus is built according to the specification of the customer and over the years has



Figure 1: The Vertus can be used with a wide range of collection devices including NGI (shown here), ACI, DUSAs and waste filters.

incorporated all elements of inhaler preparation and drug recovery for aerodynamic particle size distribution and dose content uniformity test methods.

Variants of Ictus have included, amongst others, pMDI and DPI versions, force-actuation and breath-actuation, critical flow control, leak testing, waste shots, DUSA automation, weighing, actuator changing (to remove dirty actuators after waste shots), anti-static measures, plate coating and dose detection/verification.

Using the tried-and-trusted Ictus technology base, Novi has created a family of bench-top devices that can be used in more flexible arrangements in smaller scale R&D and production environments.

Novi continues to innovate, both through custom projects and their ever-expanding portfolio of products.

VERTUS

The predecessor to Novi's new ten-inhaler tester DecaVertus is the single-inhaler tester, the Vertus (Figure 1). The Vertus has proven popular since its launch in 2010 and has been delivered across the world. It automates all aspects of dose delivery of pMDIs to ACIs, NGIs, DUSAs and waste. The analyst fits a collection device, fits an inhaler, selects the method to use and presses "Start".

The collection device (ACI, NGI, DUSA or waste) is integrated with the system, which means that no manual intervention is required during the process. This reduces potential variation in the method (especially the critical time between end of shake and actuation) and improves productivity as the analyst does not have to be present

Airflow control is part of the system, which means that no separate pump, airflow meter or pressure meter is required and no measurements need to be recorded – these are all logged by the Vertus.

DECAVERTUS

The DecaVertus, discussed in more detail in Novi's previous article ("A New, Advanced Highthroughput System for Automated Inhaler Testing", *ONdrugDelivery Magazine, Issue 62 (December 2015), pp 14-17*), was designed from the ground up to set a new standard in pMDI dosing to waste. It uses identical technology to the Vertus to shake and fire the inhalers, and to control airflow through waste filters – which are again the same on both systems. This means that methods can be readily transferred from one system to the other with no adjustment required.

The Vertus and DecaVertus can work alongside each other and waste shots conducted on either with the assurance that results will be the same. Issues can be diagnosed and firmware updated remotely.

The primary advantages of the DecaVertus are:

- The entire inhaler is tested as it would be used by a patient (although cans can also be tested on their own)
- A large range of programmable control over shaking, firing & airflow parameters
- Assurance that each inhaler is experiencing the correct shaking, firing and airflow parameters set

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- Greatly reduced cleaning requirement and improved health and safety
- Flexible – any pMDI can be tested, in-actuator or can-only
- Independent airflow control at every channel
- Modern, slick and intuitive touch screen interface
- Fitting inhalers to the system is quick and intuitive.

FLUTUS

Flutus Air is an airflow controller for pMDI testing which takes up no more room on your lab bench than a small laptop.

The Flutus gives you airflow without a pump by generating precisely controlled airflow without use of noisy, high maintenance vacuum pumps – it plugs straight into your lab air supply.

Its intuitive touch screen display is simple and convenient to use. Simply plug in the power and lab air supply, connect your Impactor and you are ready to:

- Perform automatic leak tests on demand
- Precisely set the airflow
- Record how the airflow is affected as the pMDI is fired into the Impactor.

WaSC

WaSC is a bench-top waste shot collector for inhalers. It is considerably smaller and cheaper than a fume cupboard – but it can trap thousands of shots safely and conveniently.

There is no need for a vacuum pump as WaSC plugs straight into your lab air supply. WaSC switches on automatically when you approach it. (Alternatively, if you need precise control over timing, an external switch can be attached.) Bag and remove the filter with just a twist for safe and clean disposal in seconds.

VERY HIGH-THROUGHPUT PLUME DETECTION

Novi has developed a high-speed plume detection system for in-process testing of inhalers on production lines. It can detect a plume up to once a second per channel for over 25,000 shots with no break in operation. The system controls the airflow through the inhaler and can be used for breath-actuated inhalers. The system captures the entire waste drug in a cartridge that can be double-bagged and unclipped for quick and safe disposal.

CUSTOM PROJECTS

Over the years Novi has been involved in automating inhaler testing it has created many bespoke systems to meet test requirements that standard equipment cannot deliver. Examples of such bespoke systems are:

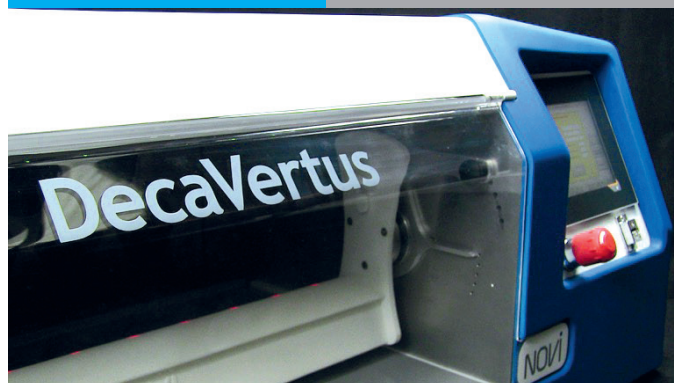
- pMDI shot weight systems
- pMDI arc-shaking systems
- DPI and other inhaler handling systems
- ACI plate-coating systems
- Dose preparation for plume detection systems

Novi has gathered a lot of experience of what works well and what doesn't, what is worth doing, and what is too expensive for the benefit gained. Get in touch with them for your next requirement and find out how they can help you.

NOVI
AUTOMATION SYSTEMS

new
**10-WAY SHAKE
AND FIRE
TO WASTE**

Setting the new
standard in
MDI wasting



Meet Novi
at RDD 2016
Table 81

- In-actuator and can-only wasting
- Control all aspects of the shake and fire cycle
- Less cleaning and no clogging
- Dedicated airflow control and filters on each channel
- Automatic alerts when the filters need changing
- No need for fume cupboard
- No pump required

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