

Efficient, Ergonomic Waste-Shot Collection Station

AB FIA now offers bench-top modules for waste-shot collection of orally inhaled multi-dose drug products. These modules automate the tasks of firing and trapping doses between actual delivered dose uniformity (DDU) determinations as described in the European [R1] and U.S. pharmaceutical compendia [R2]. The waste dosing is thought to be a fast and efficient way of reaching the next dosing period in the typical dosing test regime. The station substantially removes operator

error and potential ergonomic stress. With the FIA TriggerBox II or III (TrB), these modules can regulate and actuate a vacuum-generated airflow for a user-defined time through the device and collect the dose on a high-capacity filter for later disposal.

The Equipment must be connected to a vacuum pump similar to when using a particle-sizing impactor or delivered-dose collector.

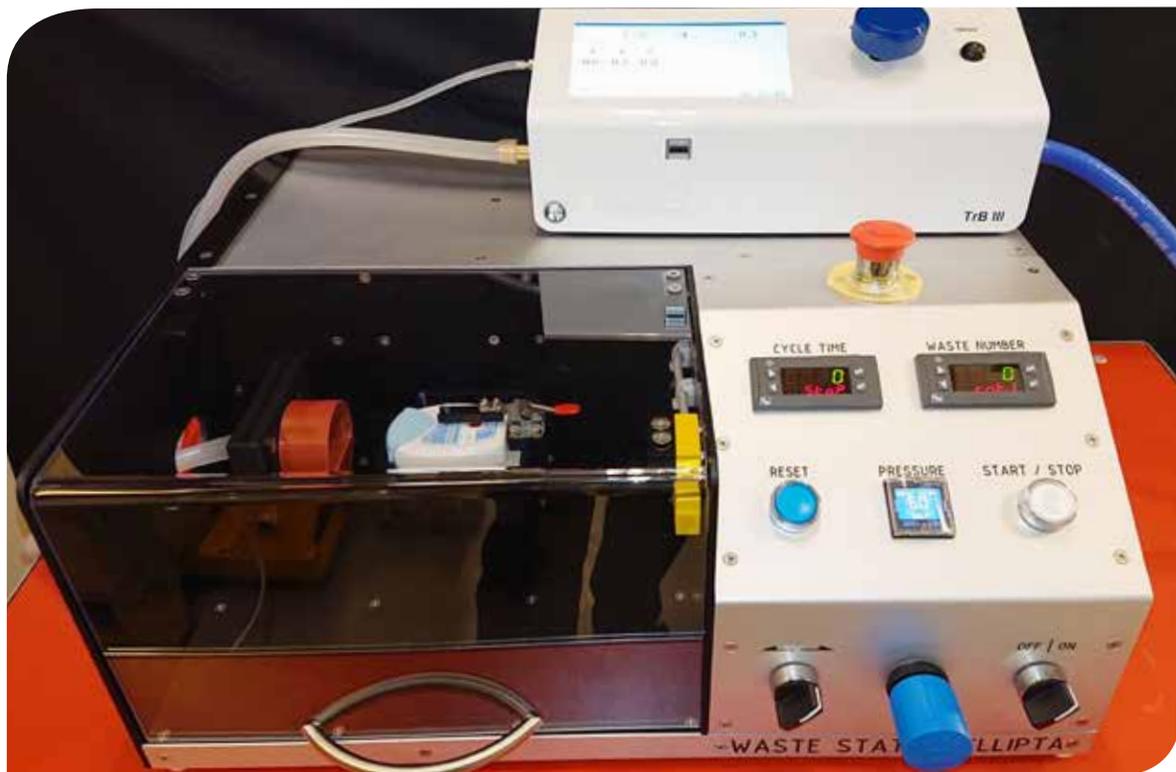


Figure 1. A Waste Station for the Ellipta Device
Intuitive displays of timers and counters allow the user to define the method parameters. Note the TriggerBox on top.



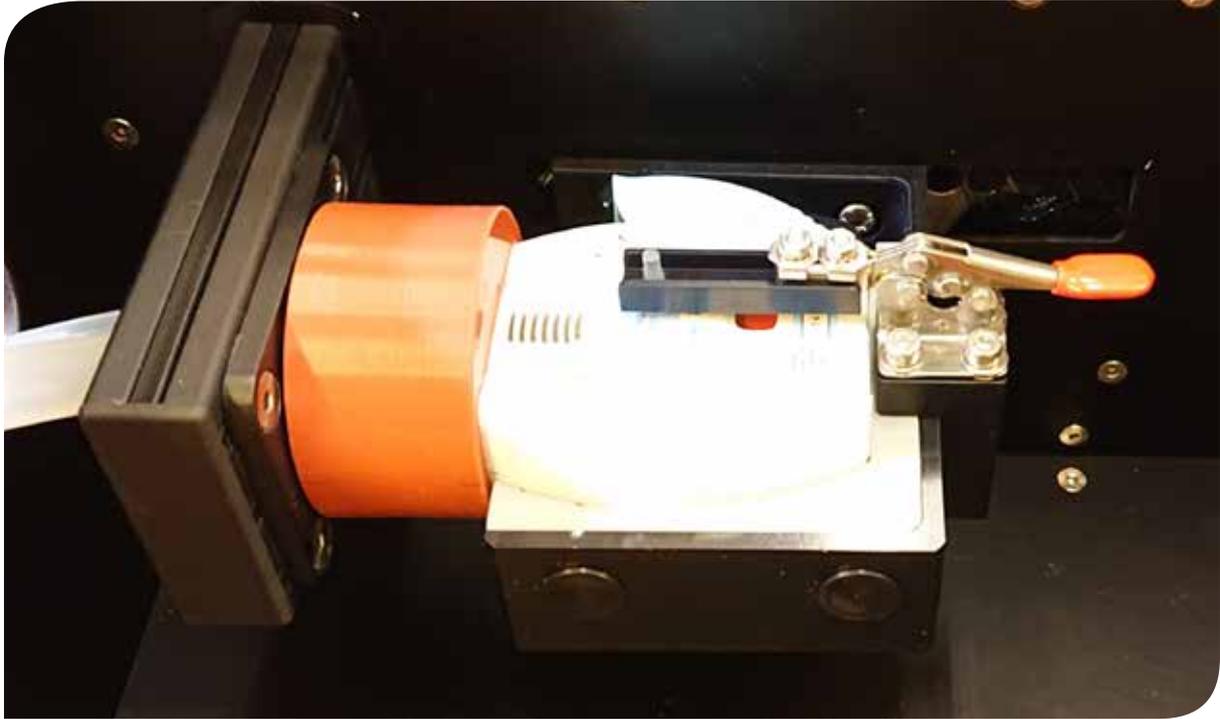


Figure 2. The Ellipta Device
*The Ellipta Device mated with the inlet for dose withdrawal.
The lever to the right clamps the device in the nest.*

Customized Waste Station

Each type of Waste Station is customized according to the specific device to be tested. The station types described here are for the Ellipta® and Turbuhaler® devices and are readily available from FIA. Also stations for generics of Ellipta, or those based on the ICores® device are available. These devices are loaded by a twisting motion and there is no need for agitation or similar. Waste stations for other devices, such as DPIs needing agitation or other types of manipulation, or pMDIs, are also available from FIA.

In Figure 1 the Ellipta station is shown. The operator lifts the lid and positions and locks the device in the customized nest. After the lid has been closed, the device mates with the mouthpiece adapter at the inlet and the station actuates the airflow, as seen in Figure 2. The forward motion simultaneously opens the inhaler cover which loads the device, and the backward motion closes it after dose withdrawal. The process is repeated as many times as previously entered on the display by the operator. The option to set an extended cycle-time allows the device to rest between dosing to avoid, e.g., build-up of static forces. Otherwise, the whole operation takes around 10 s per dose. An anti-static device can be positioned near the inlet without disturbing the process or hinder operator access.

The wasted doses are captured on a high-capacity filter (as seen in Figure 3), typically with a capacity of 10 g before replacement is needed. Other containers and filters can be accommodated upon customer request. All surfaces inside the containment area are black to aid spotting of powder spillage. The compartment also provides a safe containment of the device during operation.

As mentioned, other bench-top modules have conveniently been customized for other inhaler devices. Successful applications have been made for the Turbuhaler and generics thereof, such as the ICores. Figure 3 shows the station for the Turbuhaler. Due to the characteristics of the device the inhaler is twisted in an upright position and then rotated into a horizontal position when withdrawing the dose. Other orientations when loading or withdrawing the dose can be realized through further customizations. Also depending on the method, partial rotation of the mouthpiece to simulate the cap-off/cap-on patient manoeuvre can be accounted for. To avoid “memory” effects of the device after intense periods of dose withdrawals, the recommended configuration is to rotate the device into two different orientations between each dose, as seen in Figure 4. This way the risk of powder aggregating internally in a biased way, is reduced.



Figure 3.
A Waste Station for the Turbuhaler Device
The TrB on top is connected to the waste filter and a pressure tap to measure the P1 value, enabling real-time measurement of the pressure drop across the inhaler device during the dosing event.



Figure 4. Two orientations of the dose withdrawal of the Turbuhaler, the mouthpiece facing in two different orientations.

The airflow and valve control are managed by the FIA TrB flow controller, and the readings are presented on the screen, on a regular lab printer, or as an electronic file.

The filter inside the station captures the dose very efficiently with low pressure drop. A pressure port (P1)

is positioned close to the inlet and the pressure is presented together with the flow by the TrB for each dose.

The station provides not only substantial speed and repeatability improvements but can also reduce work-related limb disorders caused by persistent manual activation of the inhaler.

Order Information

The listed items here are readily available. Other devices can be accommodated with proper configuration changes.

Station Type	Article Number	Characteristics
Waste Station Ellipta	C011397	A custom bracket to press the Ellipta device against the inlet of the dose collector.
Dose Station Turbuhaler/ICores	C009866	Dose loading and withdrawal in different orientations. Optionally with cap-on/off simulation.

References

- [R1] European Pharmacopoeia (Ph. Eur.) 10th Edition *Preparations for inhalation* (0671)
- [R2] United States Pharmacopoeia General Chapter <601>
Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders, official as of May 1, 2021
- [R3] S. Hugosson, J. Lindberg, T. Lööf, B. Olsson, *Proposals for Standardized Testing of Powder Preparations for Inhalation*, Pharm Forum, Vol 19, 3:5458-5466, 1993.



*Figure 5.
The TriggerBox III*

The TriggerBox – Important Module of the Dose Stations

The dose stations rely on the well-established Triggerbox from FIA, acting as a module on the station. The user can thus be confident that the station and the TriggerBox are reliable and with long-term support, just as any other of FIA's equipment since the early 90's.

Critical Flow Controller

The TrB II and TrB III ensure compliance with standard pharmacopeial methods, both recording and storing key system parameters. These include run duration and pressure drop (P1), as well as the actual flow rate (TrB III). Many inhaler test methods rely on critical flow conditions across the flow control valve, aiming to ensure the same flow rate on each test. The TrB does clearly displays that in-real time and in the presented data, so there are no assumptions.



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