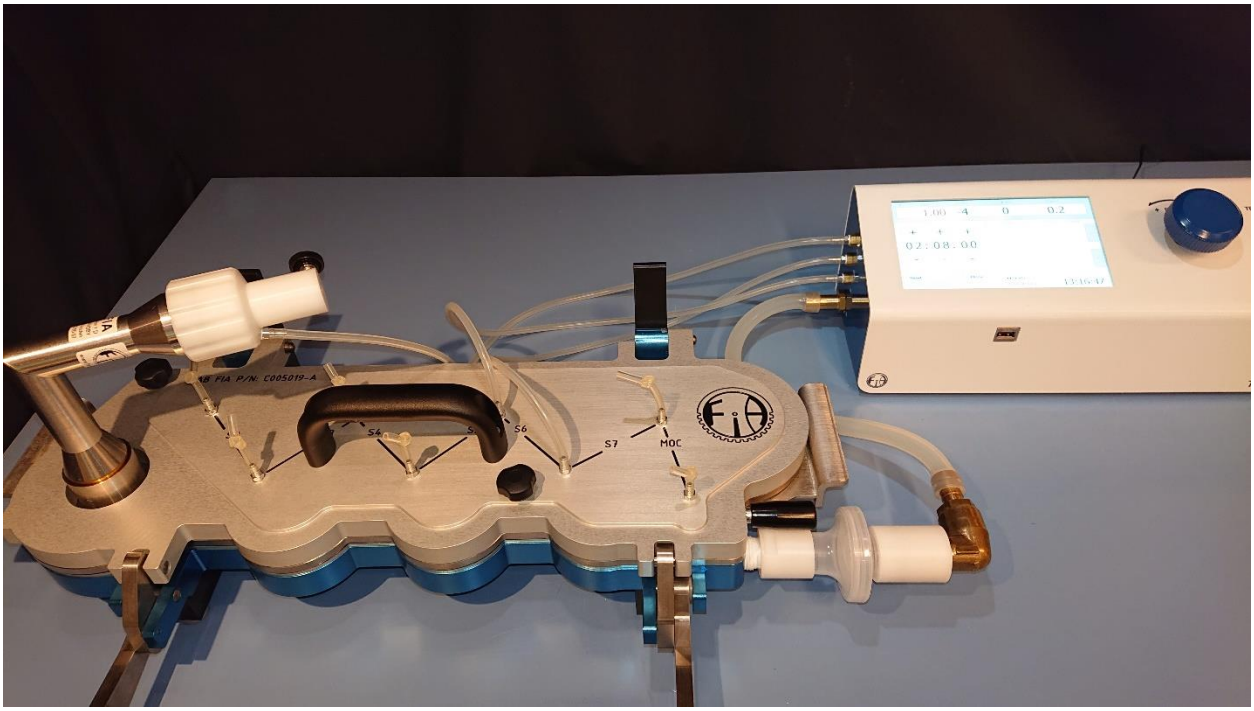
Management of Impactor Quality

Estimating Nozzle Diameter via Pressure Drop Measurement

The ability to self-manage impactor nozzle quality is an important benefit for FIA customers who already own the FIA TrB III trigger box (ref. 1 https://shop.fia.se/all-products/triggerbox-model-iii/) in combination with a speciality lid (https://shop.fia.se/all-products/ngi-stage-pressure-drop-lid/) . FIA is now offering these measurements to customers who send their impactors -- either NGI or ACI -- to FIA for the same nozzle testing!

Impactor Quality -- Optical Inspection versus Pressure Drop Measurement

Pharm. Eur. 2.9.18 and USP 601 recommend optical inspection of impactor nozzles to ensure proper size fractionation performance of the impactor. Periodic pressure drop measurements can then tell the user if there have been any meaningful changes to the nozzles since the previous optical inspection. The user can thereby assess whether the nozzles are still within pharmacopeial specifications and decide when and if a fresh optical inspection will be beneficial.



Why Pressure Drop Measurement?

Because of limited availability of costly optical inspection equipment, “stage mensuration” of an impactor means it is out of service for four to six weeks or more. With pressure drop measurements, the testing is much faster.

Why is Pressure Drop Technically Accurate for Nozzle Quality?

Pressure drop and the area-mean nozzle diameter of any impactor stage are quantitatively related by way of the Bernoulli principle and as applied to practical impactor nozzles (ref 2). Ideally, pressure drop measurements are taken directly after an optical inspection so that any changes can be tracked. As an interim measure, generally applicable discharge coefficients are available for NGI and ACI stages (ref 3) and can be applied to estimate the area-mean nozzle diameter solely from pressure drop measurements.

Why FIA?

FIA now guarantees impactors sent to FIA for pressure drop measurement will be at FIA's lab no more than five days! For the upper stages, we have rated pin gages by which we can measure if the stage nozzles are within specification. Pressure drop and dimensional checks will come with a certificate. In our machine shop we can also repair impactors and individual stages after agreement with the customer. The new FIA service, available to all impactor users, is MUCH FASTER and LESS expensive than optical inspection!! TRY IT NOW; you'll be glad you did!!!

References

1. Roberts, D. L., M. Svensson, K. Sandell, D. Sandell, "Experimental and Theoretical Investigation of a New Approach to In-Use Impactor Quality Specifications," Drug Delivery to the Lung 2018, Edinburgh, UK, The Aerosol Society, December 12-14, 2018, pg. 213-6.
2. Roberts, D. L., N. Maidment, M. A. Copley, "Improved Protocol for Relating Impactor Stage Pressure Drop to the Suitability for Routine Use," Drug Delivery to the Lung 2017, Edinburgh, UK, The Aerosol Society, December 6 to 8, 2017, pg. 94-7.
3. Versteeg, H. K., D. L. Roberts, F. Chambers, A. Cooper, M. Copley, J. P. Mitchell, "A Cross-Industry Assessment of the Flow Rate-Elapsed Time Profiles of Test Equipment Typically Used for Dry-Powder Inhaler (DPI) Testing: Part 2 – Analysis of Transient Air Flow in the Testing of DPIs with Compendial Cascade Impactors," Aerosol Sci. Tech., 54(12), 1448-70 (2020).

