Matching Impactor Rise-Time Profiles with a Volume and Resistance Compensator

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Introduction

Abbreviated Impactor Measurement (AIM) has several perceived benefits for both R&D and QC applications. However, AIM has been found to result in differences in flow rate rise-time profiles compared to measurements with full resolution impactors. Differences in flow rate rise time profile are a recognised issue for DPI testing because of the dependence on rise-time for the actuation of DPI devices and subsequent dispersion and aerolisation of the dose. The difference in rise-time is due to the difference in volume and flow resistance between the full resolution impactors and abbreviated impactors.

Objective

Investigate whether flow rate rise-time profiles can be matched between full and abbreviated impactors, using a novel Volume and Flow Resistance Compensator, to ensure comparable test conditions can be achieved.

Volume and Resistance Compensator (VRC)

The VRC inserts additional volume and flow resistance between the abbreviated impactor and the flow controller. The volume and resistance can be adjusted to account for different impactor configurations:

- **Choke plates with varying orifice sizes can be interchanged to alter the flow resistance**
- **The piston can be moved up and down a graduated scale to change the volume**

Method

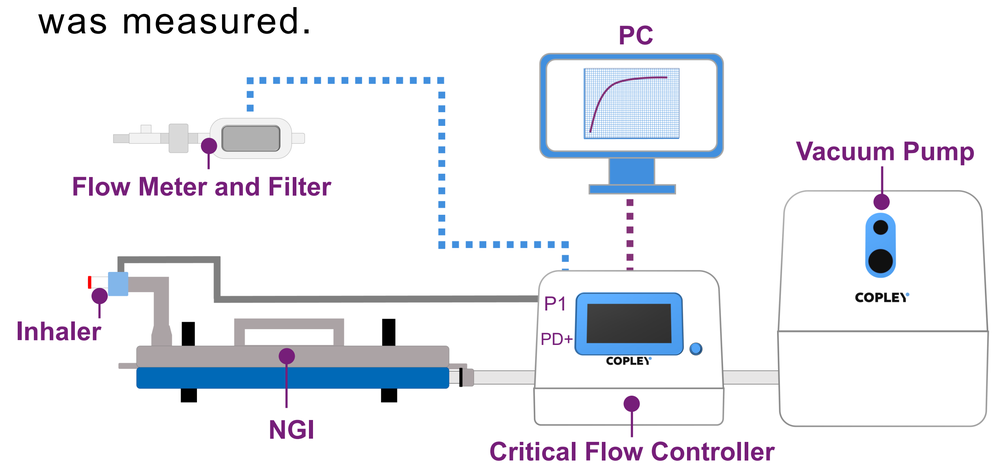
Step 1: Flow Resistance

1. The flow resistance of both the NGI and ACI (60 L/min configuration) were measured at 60 L/min.
2. The flow resistance of the **FSI + VRC** and the **FSA + VRC** were adjusted to match the flow resistance of the respective full resolution impactor as follows:

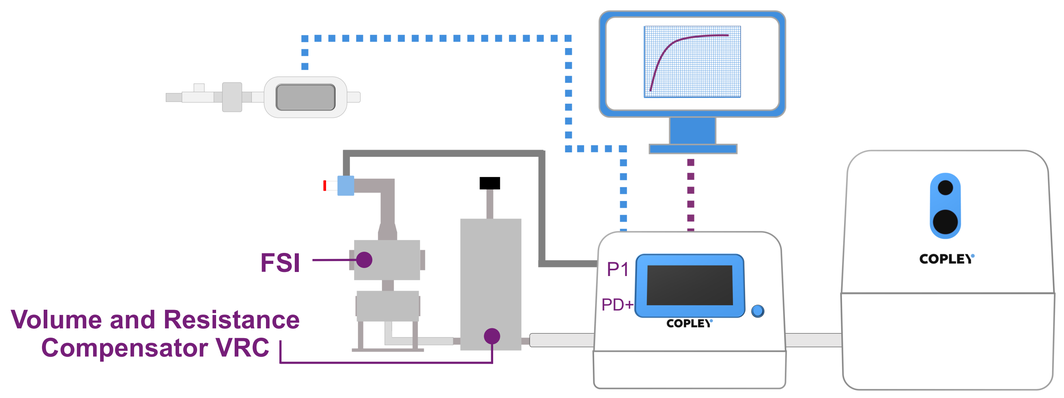
Full Resolution Impactors		Abbreviated Impactors		
Configuration	Flow Resistance at 60 L/min ($kPa^{0.5}minL^{-1}$)	Configuration	Choke Plates	Flow Resistance at 60 L/min ($kPa^{0.5}minL^{-1}$)
NGI with Preseparator and Induction Port	0.055	FSI with 5 micron @ 60 L/min insert	4 mm and 4.5 mm	0.055
60 L/min ACI with Preseparator and Induction Port	0.044	FSA (stages -1, 1, F) with 60 L/min Preseparator and Induction Port	5 mm and 5 mm	0.043

Step 2: Rise-Time

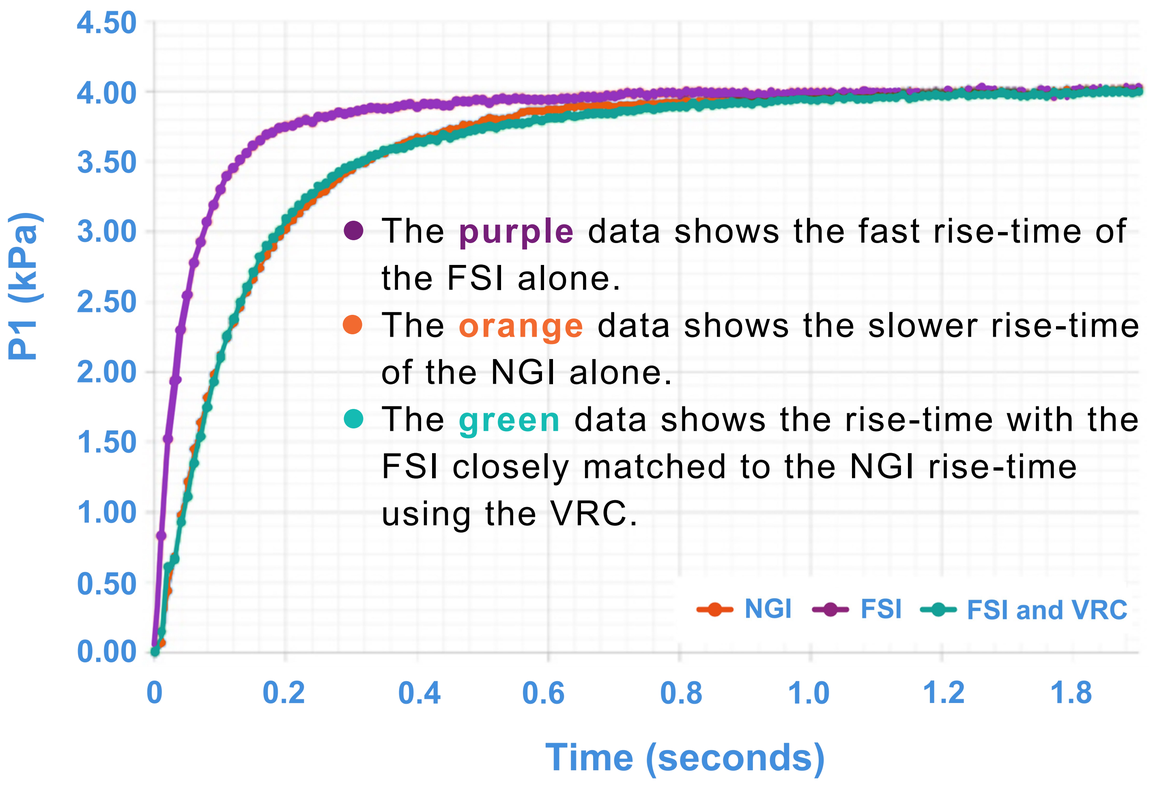
1. A P1 pressure of 4kPa was set.
2. The rise-time of the NGI and ACI with a Symbicort® DPI was measured.



3. A P1 pressure of 4kPa was set.
4. The rise-time of the **FSI + VRC** and the **FSA + VRC** with a Symbicort® DPI was then measured.



Results: FSI/NGI only



- The **purple** data shows the fast rise-time of the FSI alone.
- The **orange** data shows the slower rise-time of the NGI alone.
- The **green** data shows the rise-time with the FSI closely matched to the NGI rise-time using the VRC.

Conclusion

The flow resistance and flow rate rise-time were closely matched between:

- **FSI + VRC and NGI**
- **FSA + VRC and ACI**

The VRC volume required to achieve a matched rise-time was less than the calculated difference in theoretical volume between the impactors. Further work would be required to fully understand the reasons for this outcome.

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