

Rise-time Measurement Instrument Stig™

The Importance of Rise-Time

This FIA product addresses the dynamics of testing dry-powder inhalers (DPIs), specifically the rise-time of the air-flow. Compendial methods of testing DPIs call for an abrupt start and abrupt end to the air flow, an attribute aimed at representing the way a patient uses a DPI. The starting and stopping of the air flow introduces time-variant conditions in the test equipment (cascade impactor) and in the device itself. Experimental and computational studies of these conditions are continuing to elucidate the important characteristics of the device and test system that should be known and controlled to establish a sound quality control test for products that are, or are about to be, registered.

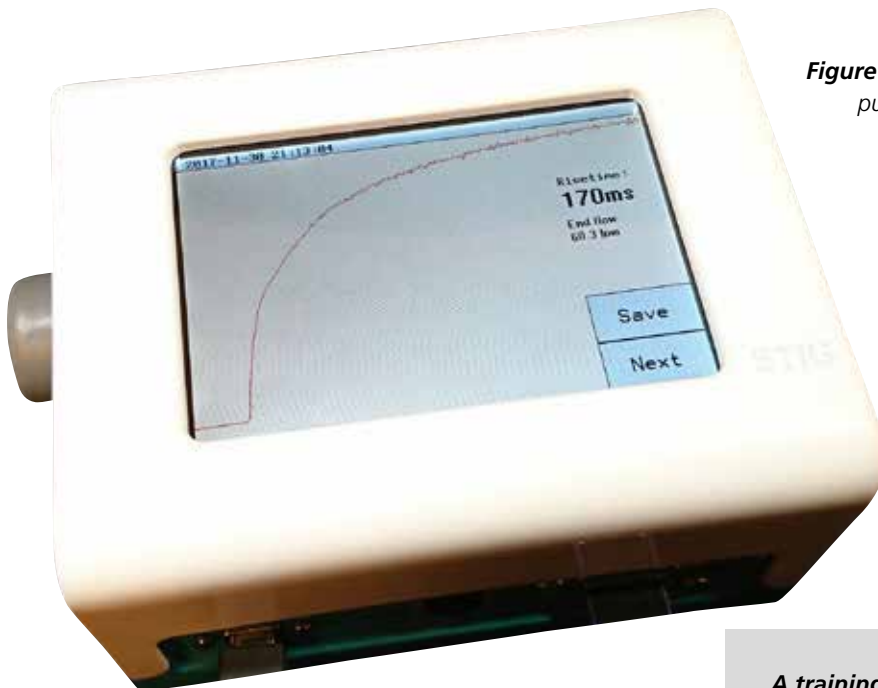


Figure 1. FIA's instrument, known as Stig™, puts in users hands the most important measure of the time-dependent air flow start-up, namely, the rise-time.

A training programme is offered together with the instrument, which helps the user to understand its usage and our experts will help you get started understanding how to setup your measurement.



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It is important that the rise-time is known and under control when testing inhalation devices. Russell-Graham and colleagues¹ showed that the fine particle dose increases as the rise time decreases. Previous and subsequent theoretical analyses point out reasons for this effect.^{2,3} For established products, then, quality control (QC) testing requires knowing that the rise-time remains in a specified range...now possible with Stig™. For GMP QC Stig™ can be locked to acquire and present the rise-time according to a defined and validated method.



Since patients do generate different inhalation air-flow profiles, it is also important during the development of a new drug product to adjust the prototype devices to exhibit a sensible rise-time, close to what will take place in patient use. This mindset is equally important for DPIs and for breath-actuated MDI devices.

Stig™ also makes possible the recording of air-flow profiles so that they can be reproduced on a breathing simulator (such as FIA' equipment F-SIG 6300) for studying nebulizers. Versatile, user-friendly, best-in-class – that is the new Stig™ from FIA.

Key features of Stig™:

- Rise-time measurement 0.1-1 s using a thermal flow meter
- Average rise-time from a series of measurements
- Touch-screen which displays a graph of flow vs. time, rise-time and the final flow
- Printed records of the measurement with optional printer
- Rise-time profile saved to USB-memory
- Date and time
- Battery powered
- IQ/OQ and quality certificate for the regulated industry
- Training program and specialist support available

For contact and more information

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References

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