A Device to Add Connectivity to a pMDIs Without Impacting Aerosol Performance

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Key Message

The HeroTracker Sense digital adherence and compliance add-on device adds connectivity the Fostair pMDI without impacting the aerodynamic particle size distribution, plume characteristics and dynamic

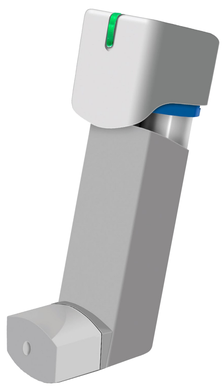

Figure 1: HeroTracker Sense Attached to a Fostair pMDI

Experimental Methods

Three HeroTracker Sense add-on devices were paired up with three Fostair pMDI inhalers. The HeroTracker Sense add-on device attaches to the top of the canister and consists of sensor electronics in the top and a small plastic tube which extends just inside the actuator. A photograph of the assembled pMDI is shown in Figure 1. The aerodynamic particle size distribution (APSD) of the aerosols emitted from the devices with and without the HeroTracker Sense in place were measured using the Next Generation Impactor (NGI) with a United States Pharmacopeia (USP) induction port. The spray pattern and plume geometry of a device with and without the HeroTracker Sense present was measured using an Oxford Lasers FireFly 300W and a Photron Fastcam MC2.1. The dynamic resistance of the devices with and without the HeroTracker Sense present were measured using an apparatus similar to that reported by Bischofberger et al. [4] The resistance was recorded at flow rates of 20, 30 and 40 L/min.

Results and Discussion

The APSDs of the Fostair pMDIs with and without the HeroTracker Sense for BDP and FFD are shown in Figure 2. There is very close agreement between the mass deposited on all impactor stages and the induction port with and without the HeroTracker Sense for both BDP and FFD. Both active pharmaceutical ingredients (APIs) and add-on configurations show large losses in the induction port and peak deposition at stage 5 which has an upper cut off of 1.36 µm at 30 L/min. The mass median aerodynamic diameter (MMAD), geometric standard deviation (GSD) and fine particle mass less than 5 µm (FPM<5µm) were equivalent for both APIs with and without the HeroTracker Sense in place.

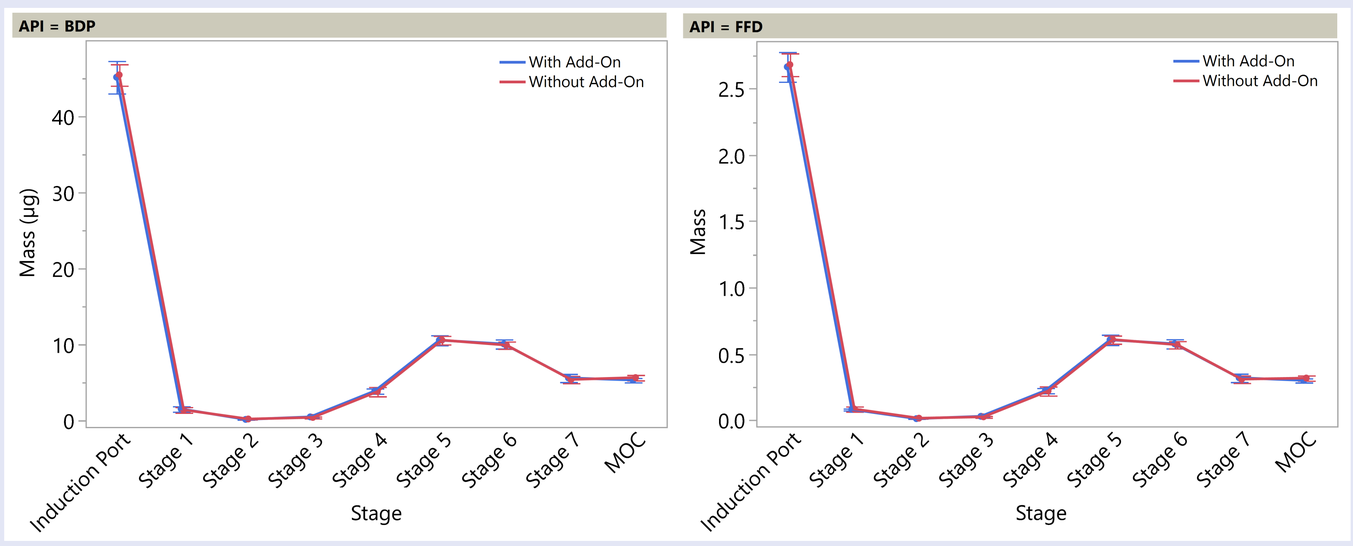

Figure 2: Mass deposited on NGI stages for BDP (left) and FFD (right) emitted from Fostair pMDI with (blue) and without (red) the HeroTracker Sense add-on. Points show means and bars show standard deviations

The resistances of three pMDIs with and without the HeroTracker Sense at 20, 30 and 40 L/min are shown in Figure 4. The same decrease in resistance with increasing flow rate was observed for the Fostair pMDI with and without the HeroTracker Sense present. The airflow through the pMDI device is therefore not materially impacted by the HeroTracker Sense.

The shape of the plume emitted from a pMDI influences the oropharyngeal and hence the thoracic deposition. The spray pattern at 3 and 6 cm from a single pMDI device with and without the HeroTracker Sense were measured. The ovality ratios showed that at 3 cm there are small and insignificant differences with and without the HeroTracker Sense and at 6 cm there are no differences with and without the add-on device.

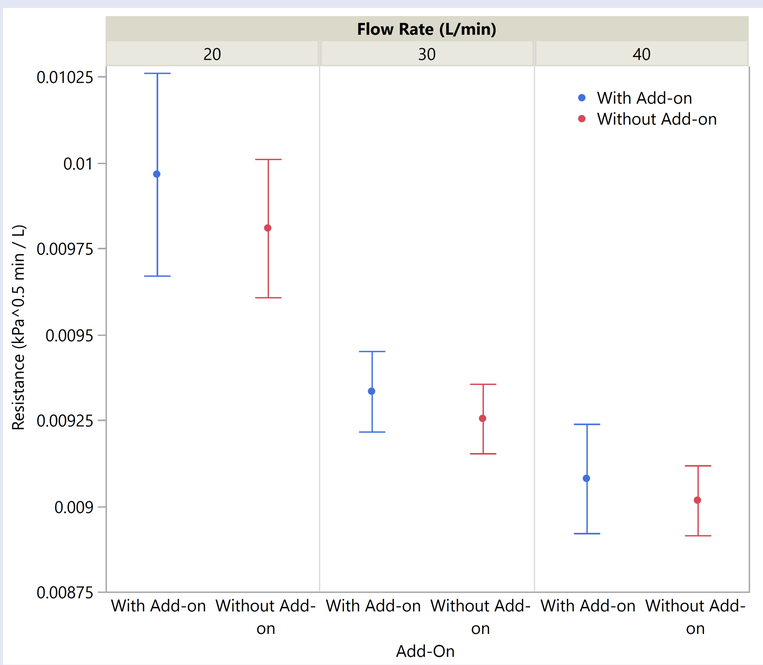

Figure 3: Device resistance at 3 flow rates for Fostair pMDI with (blue) and without (red) the HeroTracker Sense add-on. Points show means and bars show standard deviations

Conclusion

It is important to ensure that when adding connectivity to a medical device, the performance of the device is maintained. This study demonstrated that the HeroTracker Sense add-on device, which attaches to the top of a pMDI actuator and has a tube which extends inside the actuator body, maintained the performance of the inhaler. The HeroTracker Sense can therefore facilitate recording of coordination of inspiration with actuation, flow rate and inhalation duration leaving the aerodynamic particle size of the emitted particles, the emitted fine particle mass, the spray pattern, plume geometry or the dynamic resistance of the pMDI unchanged.

References

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