Method Optimization for the Measurement of Aerosol Particle Size Characterization from Heated Tobacco Products

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Abstract

Heated Tobacco Products (HTP) contain a tobacco substrate which is designed to be heated to temperatures below 350°C, resulting in an inhalable nicotine-containing aerosol with significant reduction in Harmful and Potentially Harmful Constituents (HPHC) compared to cigarette smoke. Previously a new pressure-feedback loop sampling interface was developed to measure particle size distribution (PSD) of HTP aerosols using a low-flow rate cascade impactor which was presented at AAAR 2023. The objective of this study is to use the interface to systematically investigate the influence of experimental conditions such as the shape of puff profiles, humidity level of the dilution air, and dilution air ratio on the HTP aerosol particle size distribution.
The results demonstrated no significant difference in the particle size distribution and aerosol mass collected on the impactor between bell-shape and square-shape puffing profiles. The results also showed that using humid air for aerosol dilution can minimize aerosol evaporation compared to dry air and result in more accurate HTP PSD measurements. A minimal dilution ratio with humid air of 1.21:1 was established for measuring the mass median aerodynamic diameter of HTP aerosols. Additionally, another methodology was developed to measure emission-based $PM_{2.5}$ of HTP aerosols. Both of these are aerosol-based design parameters required for HTP-related regulatory submissions as per the Premarket Tobacco Product Applications (PMTAs) and Recordkeeping Requirements Final Rule issued by the Food and Drug Administration (FDA) in 2021. Potential transportation loss and sampling artifacts were evaluated to understand the measurement uncertainty associated with $PM_{2.5}$ measurements. Minimal transportation loss was observed in the interface. As previously mentioned, the humidity of dilution air significantly impacted downstream aerosol mass collection, and using humidified air during sampling can minimize aerosol sampling loss. The measured $PM_{2.5}$ concentrations across three HTP products were within the same order of magnitude.

Objective

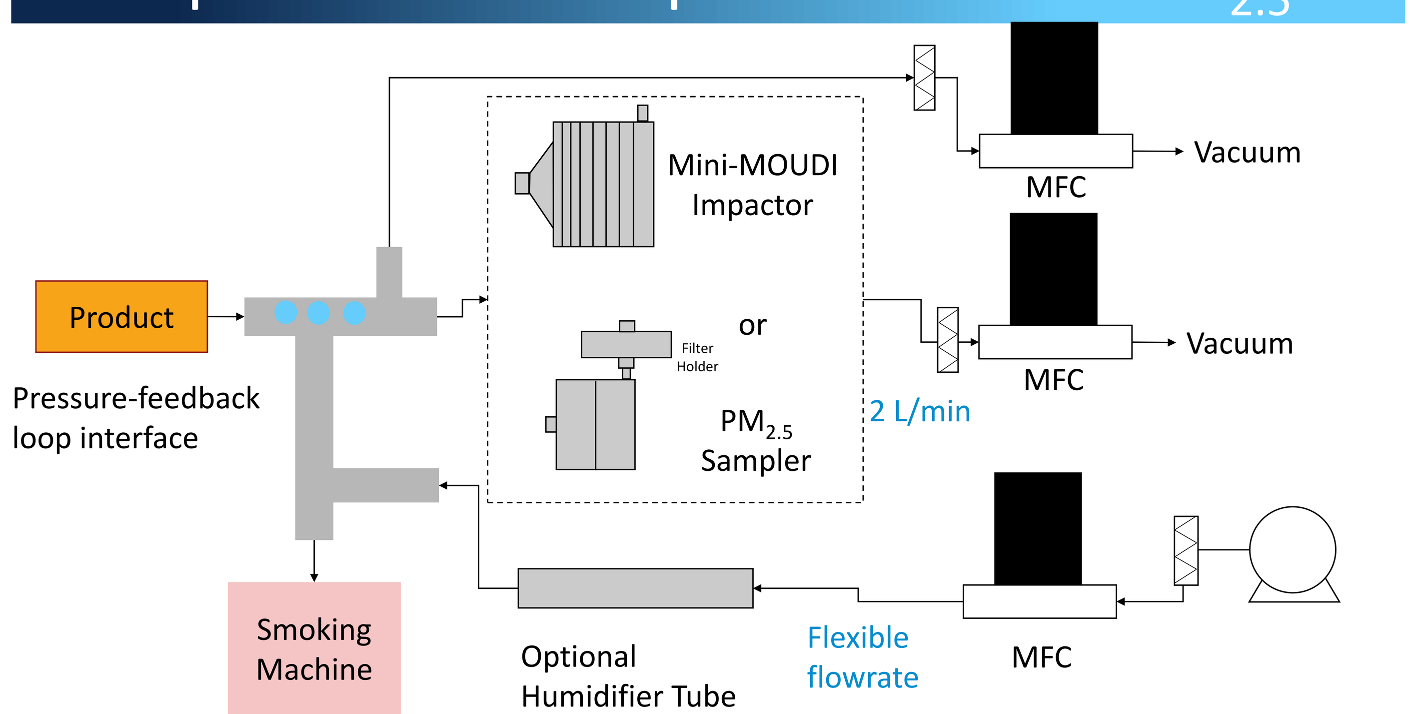
- Optimize methodologies to determine aerosol count median diameter (CMD) and $PM_{2.5}$ in aerosol emissions generated from HTPs using a novel heated tobacco capsule (HTC) prototype and comparator HTPs that use heated tobacco sticks (HTS).
- Use a flexible experimental setup to investigate impacts of puffing profile, mixing air relative humidity (RH), and dilution ratio on PSD.
- Optimize these experimental conditions for cigarette smoke and HTC aerosol measurements.

Method Principle

A flexible experimental setup was designed to optimize the experimental conditions for measuring cigarette smoke and HTP aerosol. PSD and $PM_{2.5}$ were measured using a Mini-MOUDI Impactor and a $PM_{2.5}$ Personal Impactor, respectively.

- HTPs aerosols were generated under an intense puffing regime (ISO 20778) which employs a bell-shaped puff profile with 2 sec puff duration and 55 ml puff volume and a standard puff frequency of one puff every 30 secs. The PSD was compared with PSD generated under a square-wave puff profile with the same puff duration, puff volume, and puff frequency.
- Cigarette smoke and HTC aerosol were mixed with dry or wet air to investigate the impact of mixing air RH.
- The dilution air flowrate was adjusted to enable different dilution ratios, allowing for investigating the impact of dilution ratio on PSD. Furthermore, transport loss and $PM_{2.5}$ sampling artifact were evaluated. Finally, the CMD and $PM_{2.5}$ for cigarette smoke and HTP aerosol were measured under the optimized experimental conditions.

Experimental setup for PSD and PM 2.5



Data Reduction

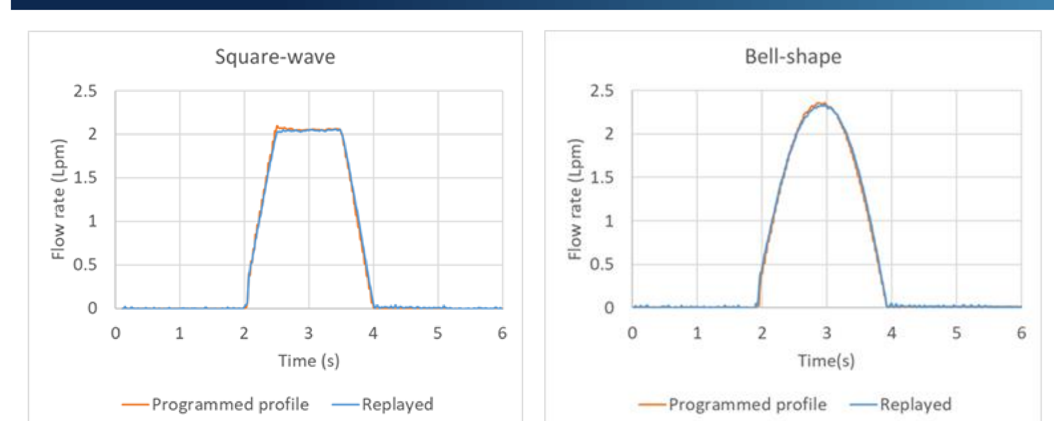
- CMD (µm) was estimated from MMAD using the Hatch-Choate equation.

$$CMD = \frac{MMAD}{\exp[3(lnGSD)^2]}$$

- Emission-based $PM_{2.5}$ (µg/m³):

$$PM_{2.5} = \frac{Aerosol\ mass}{Puff\ volume \times puff\ number}$$

Results: Impacts of Puff Profiles on Size Distribution



- Both reproduced profiles matched well with profiles programmed with the smoking machine.

Puff- profile	MMAD (µm)	GSD
Bell-shaped	0.69 ± 0.03	1.55 ± 0.03
Square-shaped	0.70 ± 0.01	1.59 ± 0.03

- ***Puff profiles have no significant impact on aerosol size distribution.***

Methods have been optimized to quantitate the count median diameter (CMD) and $PM_{2.5}$ of aerosols generated from HTPs

Results – Impact of RH of mixing air on PSD

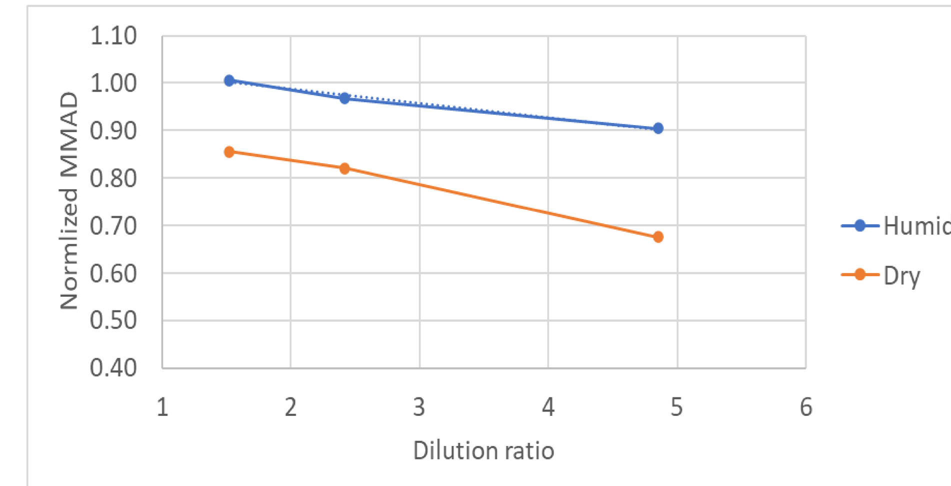
Product	1R6F	HTC Prototype	Comparator HTP1	Comparator HTP2
Puff RH	58 ± 6 %	93 ± 3 %	93 ± 1 %	94 ± 1 %

- The RH of mainstream smoke in 1R6F agrees with previous study [1].
- The RH of mainstream aerosol in HTC prototype and comparator HTPs are higher than that of cigarette smoke.

Product	1R6F		HTC	
Mixing Air	Dry (RH = 14 - 22%)	Wet (RH = 91%)	Dry (RH = 14 - 22%)	Wet (RH = 91%)
MMAD (µm)	0.55	0.59	0.59	0.69

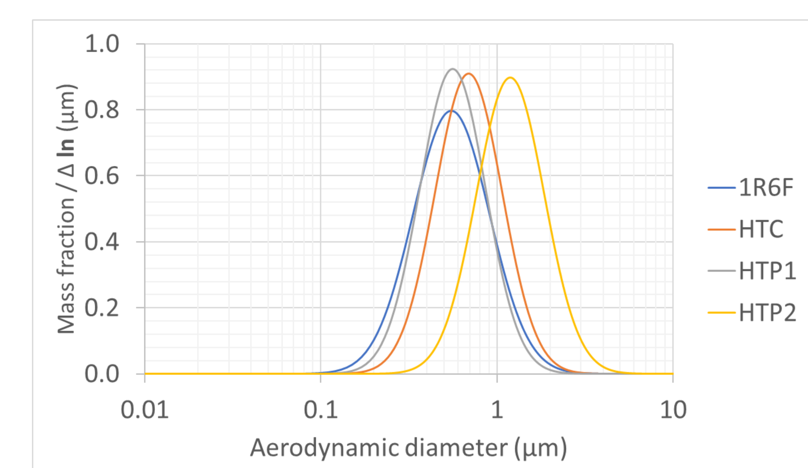
- Selecting a RH in the mixing air that approximates the RH of the puff is important to preserve the initial aerosol size.
- As the cigarette smoke size growth was less than 10% when RH is below 90% [2, 3], mixing with dry air was selected. Mixing with wet air might result in 1R6F smoke size growth, which agrees with previous study[3].
- As the RH in HTC aerosol is high, mixing air with high humidity was selected.

Results – Impact of dilution air on PSD of HTC



- Higher dilution ratios can lead to underestimating particle size for HTPs.
- Dilution ratio of 1.52 was applied for all HTP and cigarette PSD measurements to minimize evaporation.

Results – PSD across different products



Product	1R6F	HTC	HTP1	HTP2
MMAD (µm)	0.55	0.69	0.56	1.19
CMD (µm)	0.26	0.39	0.32	0.66

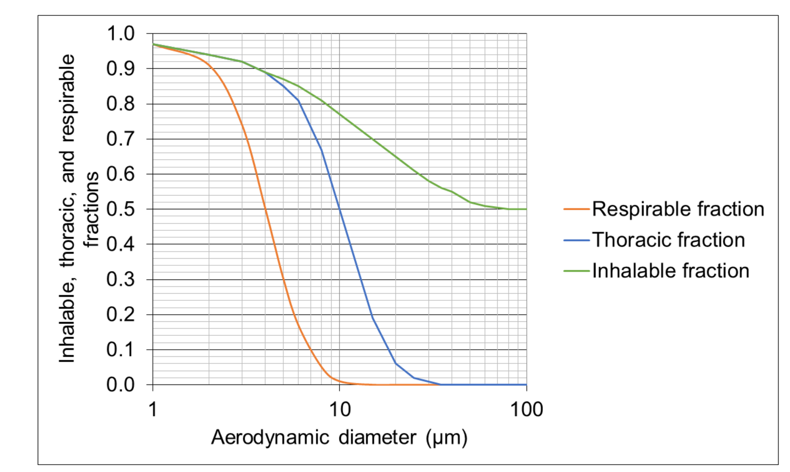
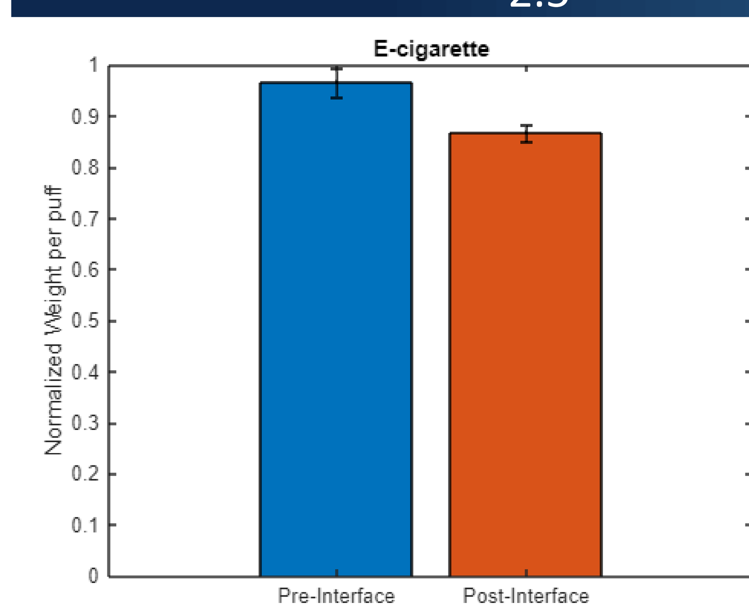


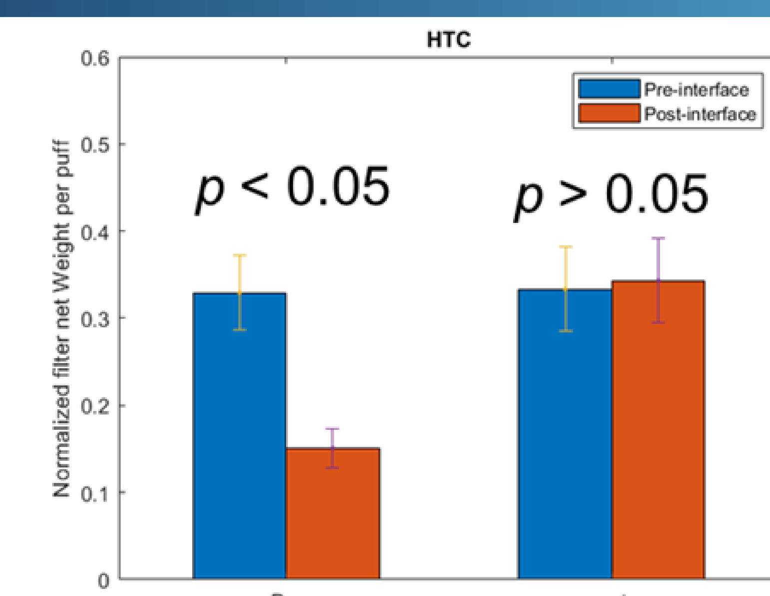
Figure above source from American Conference of Governmental Industrial Hygienists (ACGIH) sample criteria [4]

- Based on ACGIH sample criteria, most aerosols are all respirable.

Results – $PM_{2.5}$ Measurement



- E-cigarette aerosol was applied to evaluate transport loss because e-cigarette aerosol is less volatile than HTP.
- Insignificant transport loss is 10%



- Mixing with dry air can cause negative sampling artifact .

Emission–based $PM_{2.5}$ across different products

	1R6F	HTC Prototype	Comparator HTP1	Comparator HTP2
$PM_{2.5}$ (µg/m³)	3.53×10^7 ± 2.56×10^6	5.58×10^7 ± 1.12×10^6	3.32×10^7 ± 4.16×10^6	2.79×10^7 ± 6.21×10^6

- The measured $PM_{2.5}$ concentrations across three HTPs were comparable and within the same order of magnitude as those measured for cigarette smoke.

*All HTP Comparator products tested use heated tobacco sticks (HTS).

References

1. Borgerding, M. and H. Klus. 2005. Analysis of complex mixtures--cigarette smoke. Exp Toxicol Pathol 57 Suppl 1:43-73.
2. Ishizu, Y., K. Ohta, T. Okada. 1980. The effect of moisture on the growth of cigarette smoke particles. Contributions to Tobacco & Nicotine Research 10:161-168.
3. Johnson, T. J., J. S. Olfert, C. U. Yurteri, R. Cabot, J. McAughey. 2015. Hygroscopic effects on the mobility and mass of cigarette smoke particles. Journal of Aerosol Science 86:69-78
4. Hinds, W. C., & Zhu, Y. (2022). Aerosol technology: properties, behavior, and measurement of airborne particles: John Wiley & Sons.

Conclusions

- An experimental setup has been optimized to measure the CMD and emission-based $PM_{2.5}$ of cigarette smoke and aerosols generated from HTPs.
- Optimization recommendations:
  - Mixing with wet air for HTP measurements
  - Applying a low dilution ratio (1.52X) for both HTP and cigarette measurements

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