



Overview

Understanding the temperature characteristics of aerosols generated by electronic nicotine delivery systems (ENDS) and heated tobacco products (HTPs) are critical factors in product development and regulatory requirements. While FDA-CTP has not established delivered aerosol temperature standards for ENDS and HTP, the NIOSH (National Institute for Occupational Safety and Health) and CEN (European Committee for Standardization) medical device standards can be used, as they outline acceptable inhalation wet-bulb temperatures for aerosols used in heated inhalation medical devices. Both NIOSH and CEN have established a wet-bulb temperature upper limit of 50°C wet-bulb. Previous research and existing standards indicate that safety thresholds for inhaled air temperatures can exceed normal body temperature, with wet-bulb temperature being the most relevant thermal metric for inhaled air. Wet-bulb temperature combines dry-bulb temperature and relative humidity of air to thermodynamically represent the total energy content of air.

This study presents a method for measuring aerosol temperature at multiple points using miniature thermocouples, with conversion to wet-bulb temperature achieved through the Improved Magnus Equation. A variety of commercially available ENDS devices and 1R6F cigarettes were evaluated for aerosol temperature. This approach offers a comprehensive framework for evaluating aerosol temperature profiles, enhancing our understanding of the thermal characteristics of vaped products. Research is currently ongoing for HTP products and will be presented separately.

Wet-Bulb Conversion

The conversion to wet-bulb temperature was done by using the recorded dry-bulb temperatures from thermocouples and humidity levels of puffed air (room air) using Improved Magnus Equation:

$$T_w = T_d \cdot \arctan\left[0.151977 \cdot (rh\% + 8.313659)^{(1/2)}\right] + \arctan(T_d + rh\%) - \arctan\left(\frac{rh\% - 1.676331}{T_d} + 0.00391838 \cdot (rh\%)^{(3/2)}\right) \cdot \arctan(0.023101 \cdot rh\%) - 4.686035$$

T_w - calculated wet-bulb temperature of aerosol;
 T_d - recorded aerosol dry-bulb temperature from TC;
 $rh\%$ - calculated relative humidity of aerosol at test point

It was assumed that emitted aerosol stream contains the same concentration of water as inhaled puffed room air. Two methods were used to calculate rh% of aerosol based on recorded temperature and relative humidity of inhaled room air, assuming that the aerosolized e-liquid formulation does not contain water.

1. By calculating dew point of puffed air using the August-Roche-Magnus approximation:

$$T_s = (b \times \alpha(T, RH)) / (a - \alpha(T, RH)) \text{ with Revised Magnus Coefficients: } a = 17.625, b = 243.04.$$

2. By using Antoine equation to approximate the saturation curve on a psychrometric chart.

$$\log_{10}(P) = a - (b/c+T) \text{ with Antoine Coefficients for Air: } a=4.6543, b=1435.264, c=-64.848.$$

Methods

Fifteen (15) ENDS devices from eight commercially available brands, and combustible reference cigarette 1R6F were tested for a duration of 10 puffs. Generated aerosol temperature was measured with 18 unshielded miniature E-type thermocouples (TC). TC probes were distributed inside testing chamber at four distances from device mouthpiece on axial "x"; 20 mm representing mouth level, 100 mm representing the trachea level, 1 mm and 10 mm representing distance used by commercially available apparatus for aerosol temperature testing. Up to 5 TC probes were placed at every 2 mm from center of testing chamber on axials "y" and "z"; (Figure 1). Temperature (T), relative humidity (RH%) of air stream entering the device, device weight loss (DWL), and aerosol collected mass (ACM) were measured. Cerulean SM450 was used to puff aerosol under CRM81 for ENDS devices and under Health Canada Intense for 1R6F.

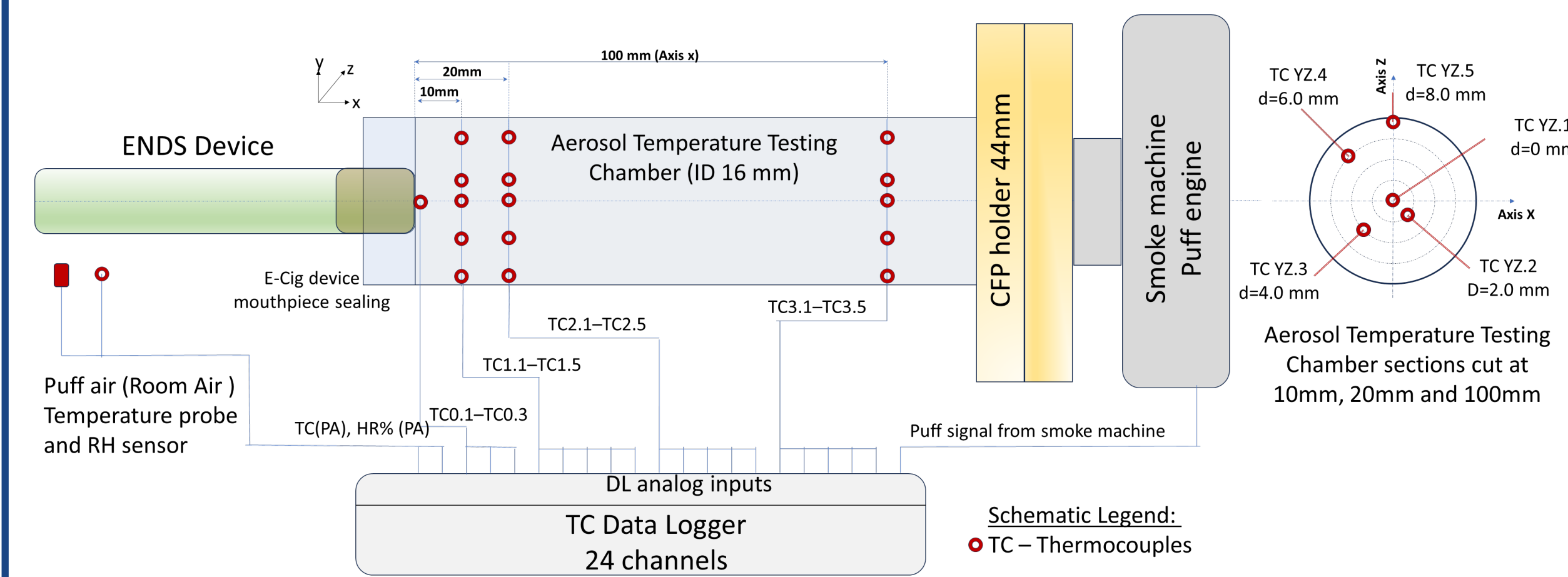


Figure 1. Aerosol Temperature Testing Chamber Schematic.

Conclusions

- Temperature distribution along the axial (x) direction is highest at 1 mm from the mouthpiece and drops significantly within the next 10 mm of the aerosol stream.
- All converted average peaks of dry-bulb temperatures to wet-bulb meet the NIOSH temperature upper limit of 50°C wet-bulb for heated inhalation devices.
- No correlation was found between aerosol temperature and device yield per puff.
- Temperature distribution along the axial (y, z) directions does not always peak at the center of the testing chamber and varies depending on the mouthpiece diffuser configuration.
- HTP product testing is ongoing to further evaluate aerosol temperature distribution and confirm current findings.

Results

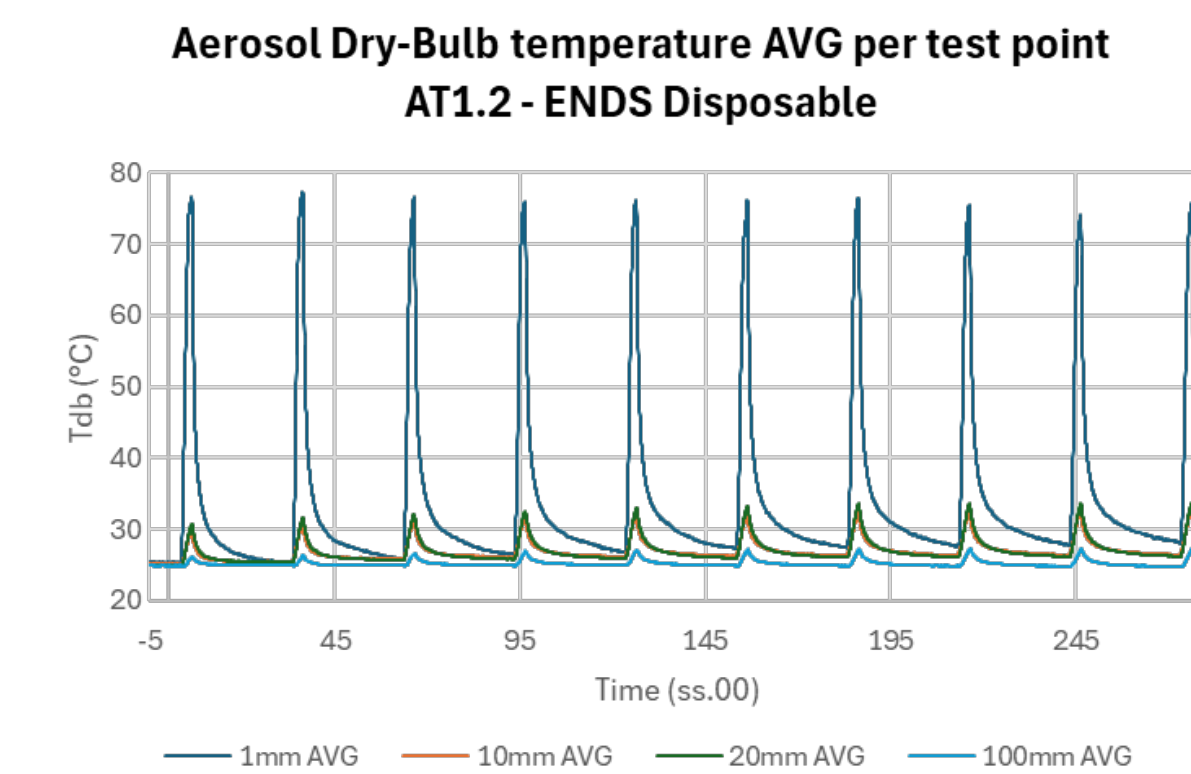


Figure 2. Aerosol Dry-Bulb Plot AT1.2 Representative plot of aerosol temperature for ENDS devices.

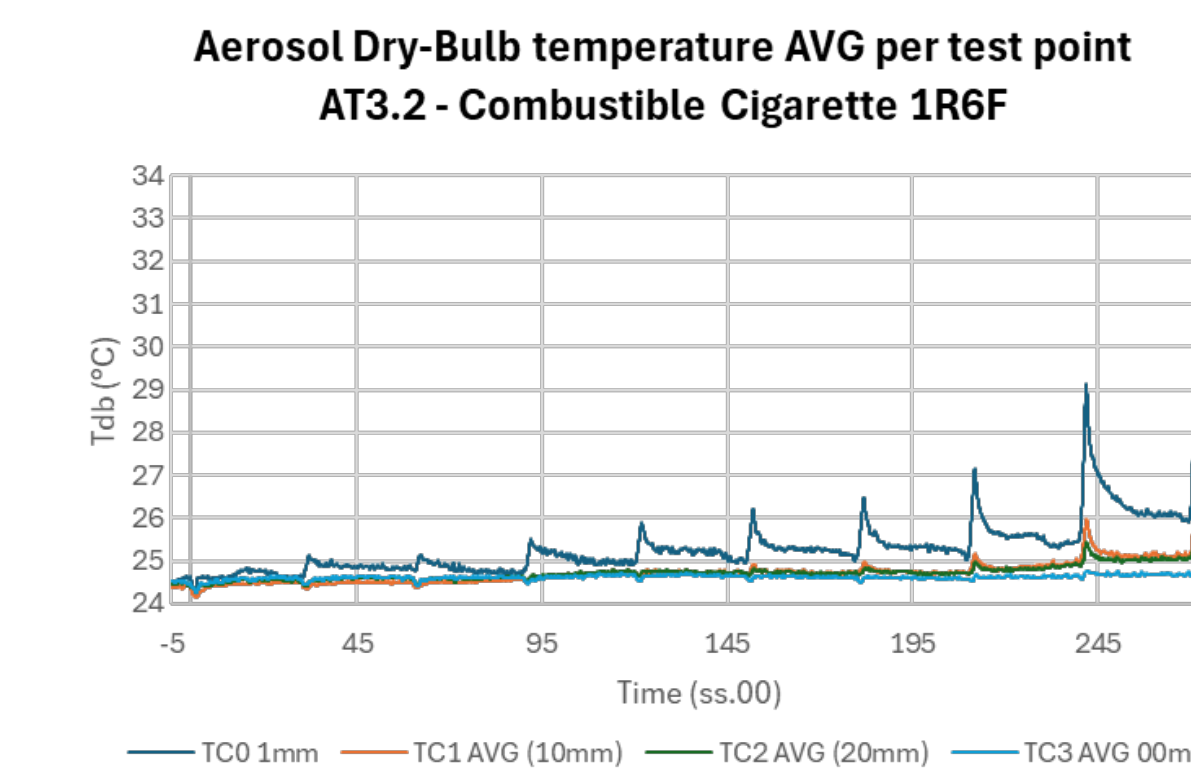


Figure 3. Aerosol Dry-Bulb Plot AT3.2. Representative aerosol temperature plot for 1R6F combustible cigarette.

References

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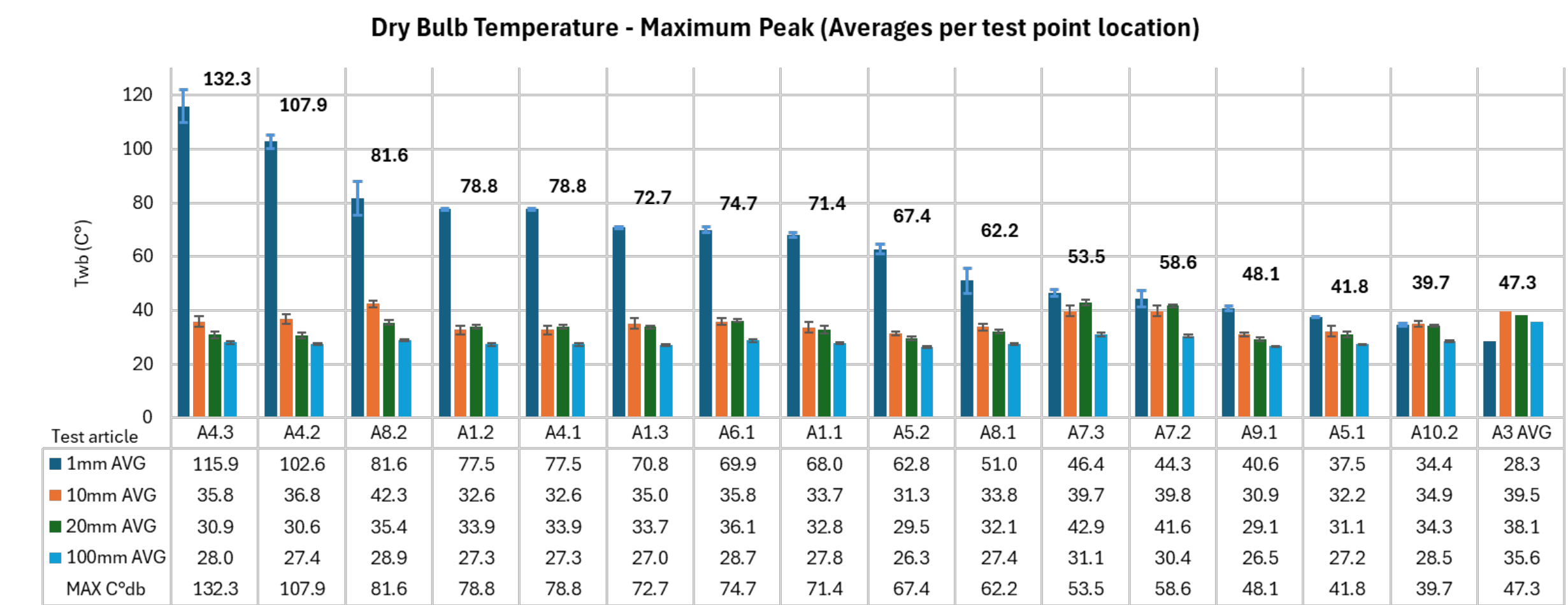


Figure 4. Dry-Bulb Maximum Peak. Averages of maximum peaks from 5 probes along the axial (y) for each test location on axial (x) and maximum temperature recorded for each test article.

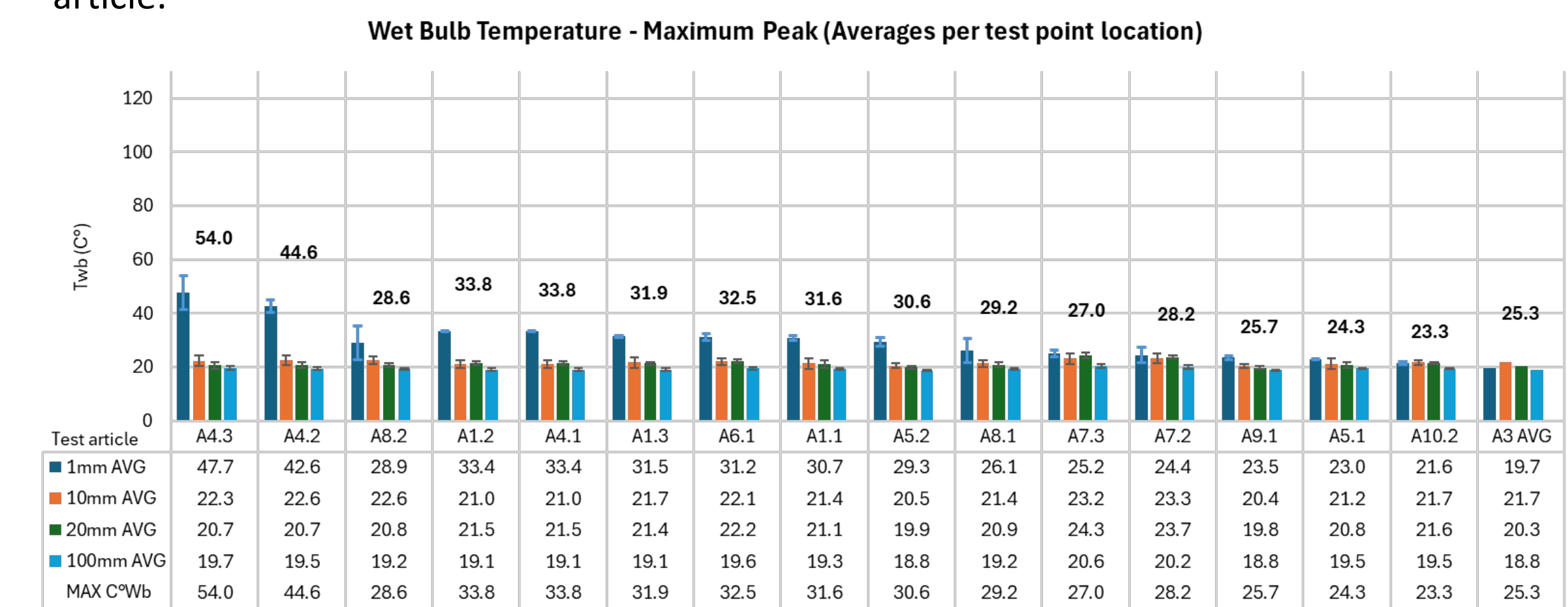


Figure 5. Wet-Bulb Maximum Peak. Converted Wet-Bulb averages of maximum peaks from 5 probes along the axial (y) for each test location on axial (x), along with maximum temperature recorded for each test article.

The maximum standard deviation among five probes at a single location was 23°C. The highest measured dry-bulb temperatures ranged from 132.3–36.4°C at the 1 mm location, 51.4–32.9°C at 10 mm, 47.4–30.7°C at 20 mm, and 33.3–26.8°C at the 100 mm location. Both methods used for calculating aerosol relative humidity (RH%) produced similar wet-bulb temperature conversion results, with a variance of no more than 0.1°C.