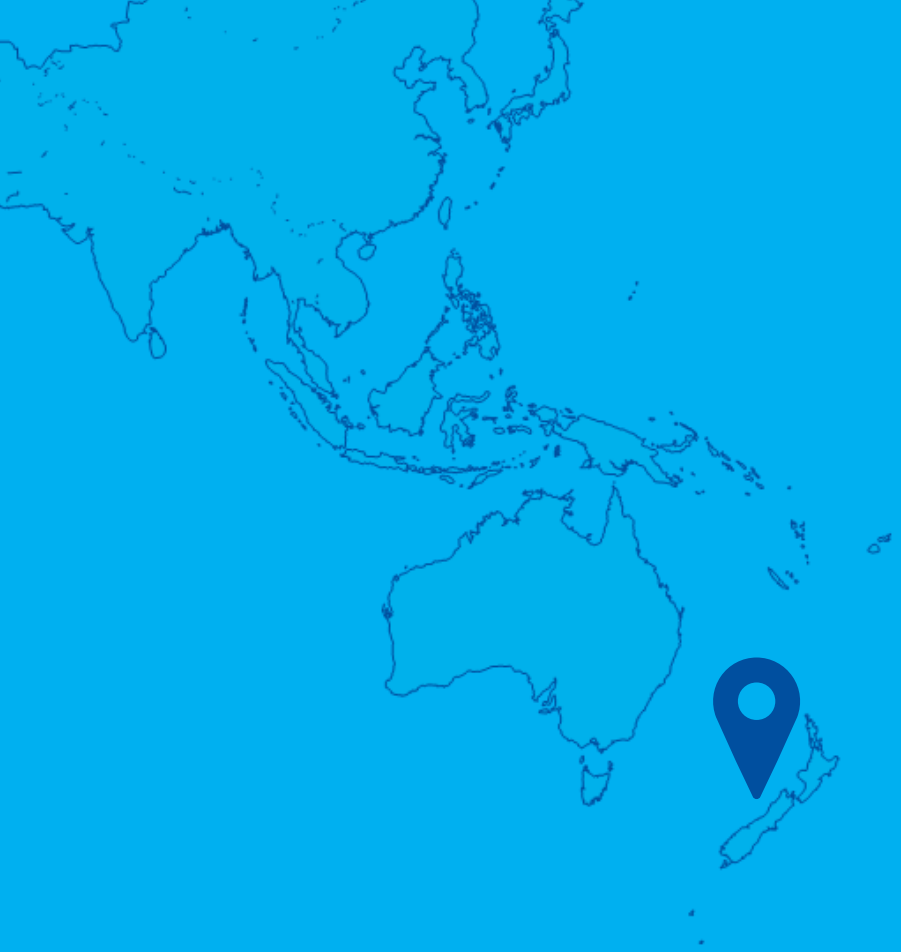

CORESTA 2024

Presentation no. ST16

Influence of nicotine concentration and flavours on mouth level exposure and puffing topography among regular e-cigarette consumers in New Zealand

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Contents

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Background

Vapour product aerosols have a reduced toxicant profile relative to cigarette smoke [1-3]

Consumer's actual exposure is influenced by how they use the product (e.g., puff duration and use frequency)

Use behaviour may be influenced by device characteristics (e.g., power, open pressure drop, e-liquid flavour and nicotine concentration)

Many studies on the impact of nicotine concentration on product use have been small scale, low participant numbers and few conditions (high vs low nicotine)

[1] Shah, N.H., et al., Non-targeted analysis using gas chromatography-mass spectrometry for evaluation of chemical composition of E-vapor products. Front Chem, 2021. 9:742854. DOI: 10.3389/fchem.2021.742854
[2] Wagner, K.A., et al., An evaluation of electronic cigarette formulations and aerosols for harmful and potentially harmful constituents (HPHCs) typically derived from combustion. Regul Toxicol Pharmacol, 2018. 95: p. 153-160. DOI: 10.1016/j.yrtph.2018.03.012
[2] Rudd, K., et al., Chemical composition and in vitro toxicity profile of a pod-based e-cigarette aerosol compared to cigarette smoke. Appl In Vitro Toxicol, 2020. 6(1): p. 11-41. DOI: 10.1089/aivt.2019.0015

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Objectives

Primary Objective

Measure the puffing topography, mouth level exposure (MLE) to aerosol and nicotine, and average daily consumption (ADC) among vapour product consumers when using a closed rechargeable system with e-liquids of five nicotine concentrations (6 – 47 mg/mL) and four flavours

Secondary Objective

Measure the puffing topography & MLE of smokers when using a cigarette for comparison

Vuse ePod 2

Vapour products					
Vuse ePod 2	E-liquid nicotine level (mg/mL)				
	6	12	18	34	47
Crisp Mint	X	X	X	X	X
Golden Tobacco			X		
Tropical Mango			X		
Peppermint Tobacco			X		

Cigarette	
Rothmans Royal	15 mg ISO tar

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Study Design

Central Location Test (Christchurch, New Zealand): Puffing topography & MLE via desktop puffing analyser; sensory perception via questionnaire

Home Use Test: Puffing topography via connected product use behaviour (PUB) device; ADC and sensory perception via questionnaire

	E-CIGARETTE USERS n = 90 (49 male, 41 female)			CIGARETTE SMOKERS n = 35 (14 male, 21 female)
User Group	**18 mg/mL users** n = 19	**34 mg/mL users** n = 35	**47 mg/mL users** n = 36	
Central Location Test (CLT)	• All eight ENDS products • Two 15-min sessions	• All eight ENDS products • Two 15-min sessions	• All eight ENDS products • Two 15-min sessions	• 15 mg cigarette • Two sessions • One cigarette/session
Home Use Test (HUT)	• 18 mg/mL nicotine • All four flavours • Seven days/product	• 34 mg/mL nicotine • Crisp Mint flavour • Seven days	• 47 mg/mL nicotine • Crisp Mint flavour • Seven days	

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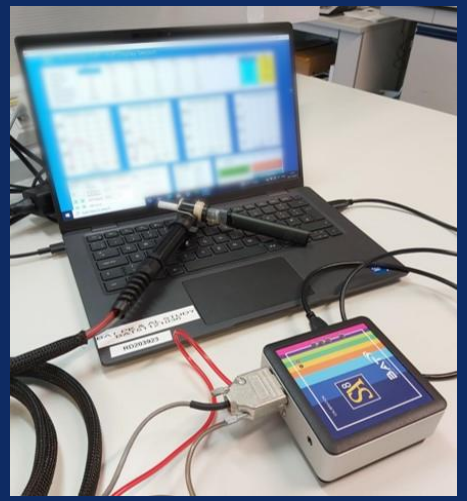
Methodology

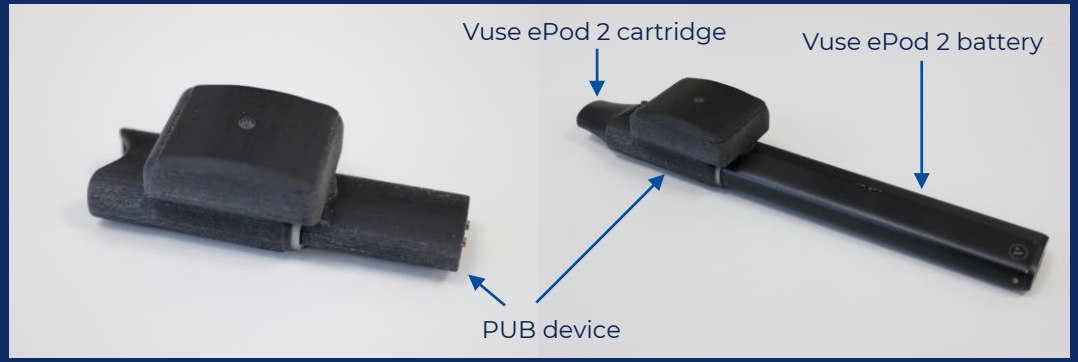


Central Location Testing

- Desktop puffing analyser (PA1) – puff volume, duration, interpuff interval (IPI), flow rate, optical obscuration of aerosol, number of puffs measured in real-time [1-2]
- Participants used the product through the PA1 holder
- MLE to aerosol and nicotine for vapour product estimated from DML by vaping machine calibration [2]
- MLE to NFDPM and nicotine for cigarette estimated from per-puff optical obscuration by machine calibration [1]

Home Use Testing

- Connected *product use behaviour* (PUB) device - duration, IPI, angle held, date, time and number of puffs [3]
- Connects between battery section and e-liquid pod
- MLE to aerosol and nicotine estimated from puff duration by vaping machine calibration



Abbreviations: MLE = mouth level exposure; NFDPM = nicotine-free dry particulate matter

1-Slayford S, Frost B. A device to measure a smokers' puffing topography and real-time puff by puff "tar" delivery. Beit Tab Int. 2014;26(18):74-84
2-Jones J et al., A cross-category puffing topography, mouth level exposure and consumption study among Italian users of tobacco and nicotine products. Sci Rep. 2020;10(1):12
3-Underly RG et al., Dull GM, Nudi E, Pionk T, Prevette K, Smith J (2023). Using a Novel Connected Device for the Collection of Puffing Topography Data for the Vuse Solo Electronic Nicotine Delivery System in a Real-World Setting: Prospective Ambulatory Clinical Study. JMIR Form Res. 7: e49876. doi: 10.2196/49876

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RESULTS

Effect of nicotine concentration

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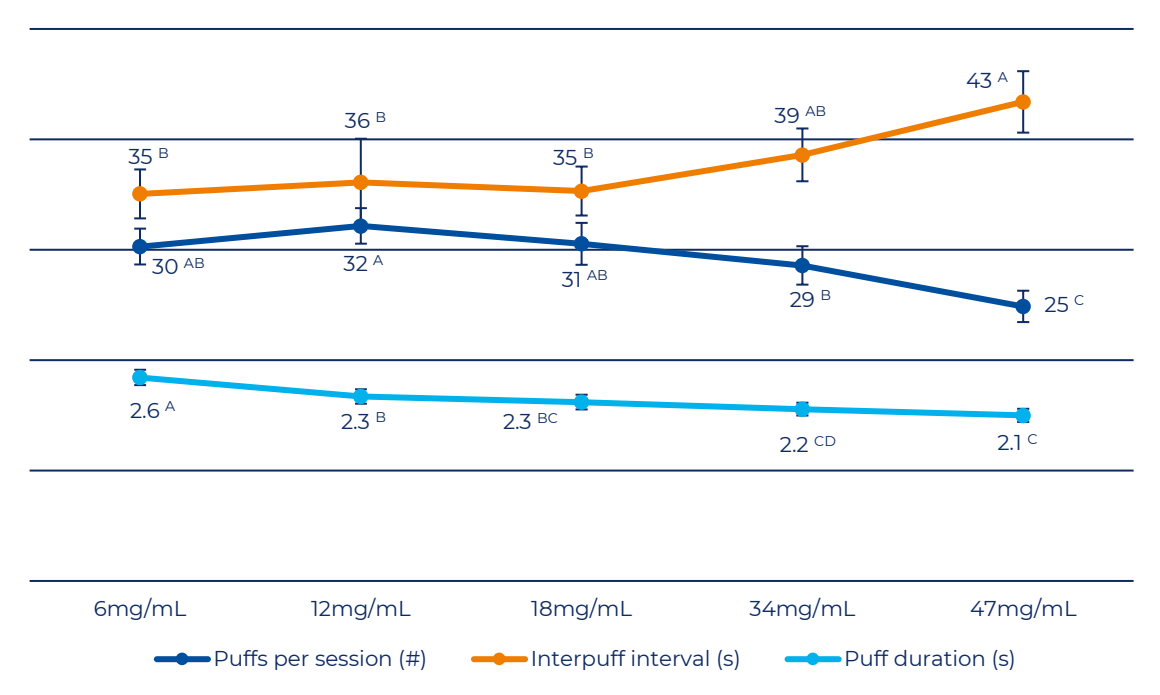
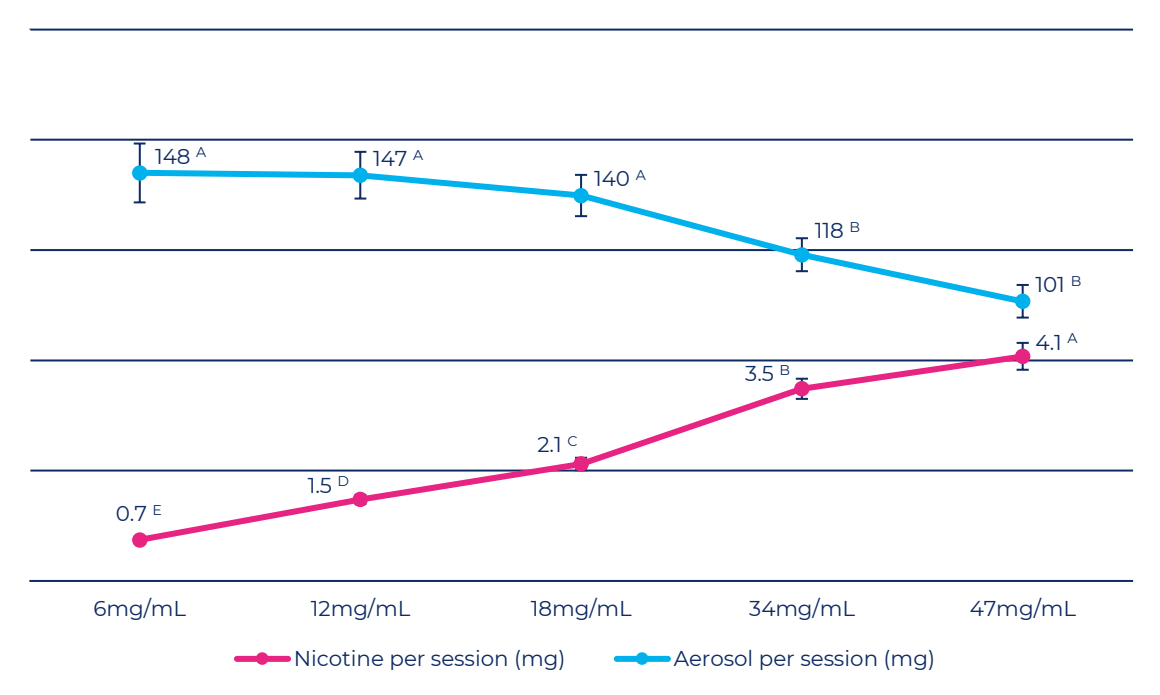
Central Location Testing*

With increasing concentration of nicotine in e-liquid:

Overall trends

- Mean puff duration decreased
- IPI increased (reduced puff frequency, i.e. fewer puffs per 15-min)
- Estimated MLE to nicotine (per 15-min session & per puff) increased
- MLE to aerosol per session decreased





Abbreviations: MLE = mouth level exposure; IPI = inter-puff interval

* Data are mean from 90 participants who used each product twice. Error bars indicate standard error. Data were analysed by mixed-effects ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); those not sharing the same alphabet letter were significantly different ($p<0.05$). Participants were given a maximum of 15-min in which to use the product.

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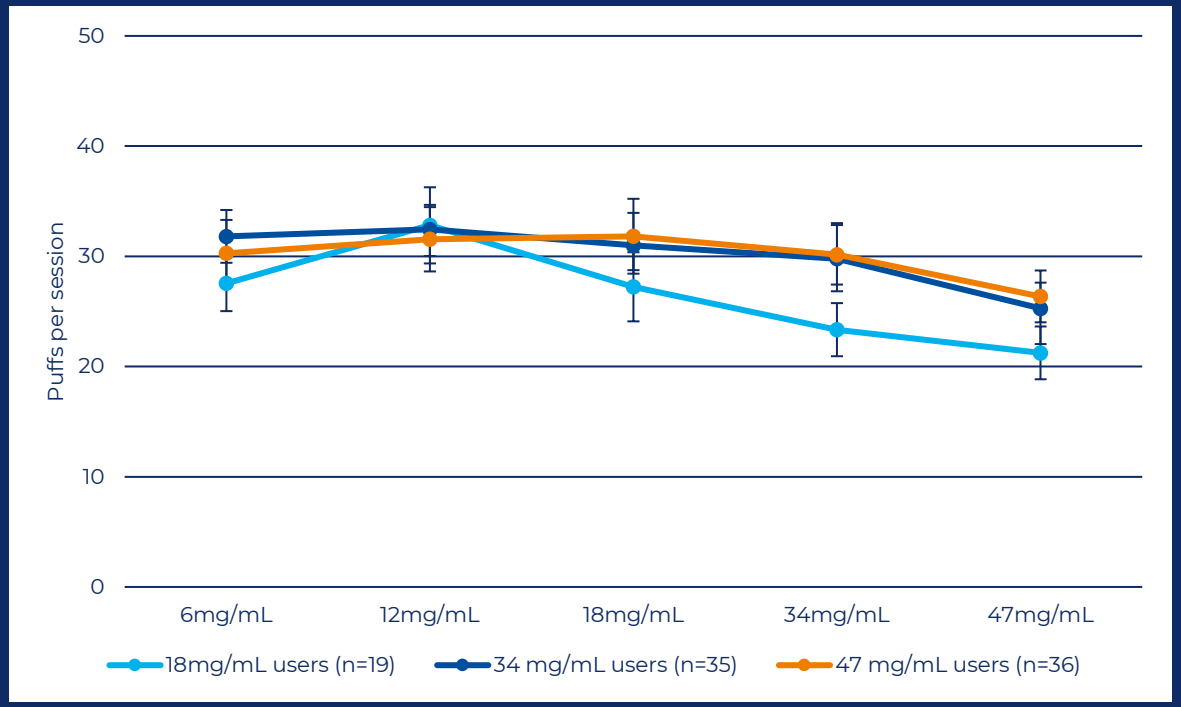
Central Location Testing*

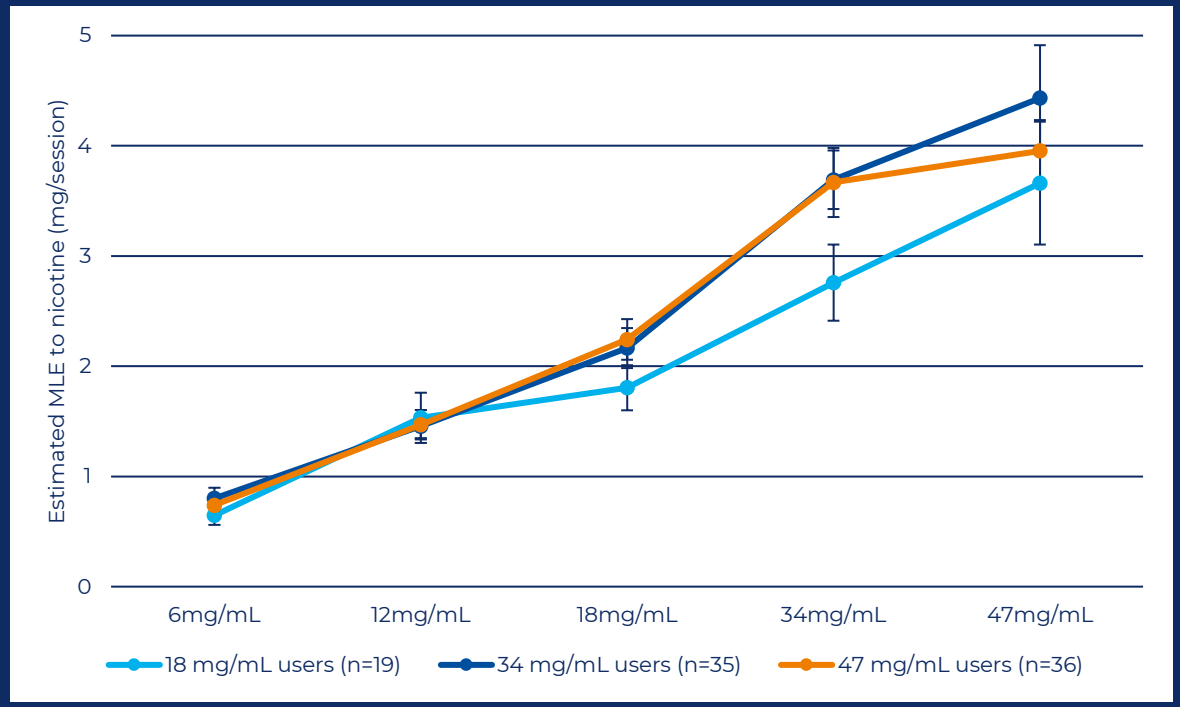
With increasing concentration of nicotine in e-liquid:

Trends across nicotine user groups

- 18 mg/mL users took fewer puffs than 34 & 47 mg/mL users
- No differences in other topography attributes among user groups



- At higher nicotine concentrations – lower estimated MLE to nicotine for regular 18 mg/mL users compared with 34 & 47 mg/mL users



Abbreviations: MLE = mouth level exposure
* Participants used each product twice. Error bars indicate standard error. Participants were given a maximum of 15-min in which to use the product.

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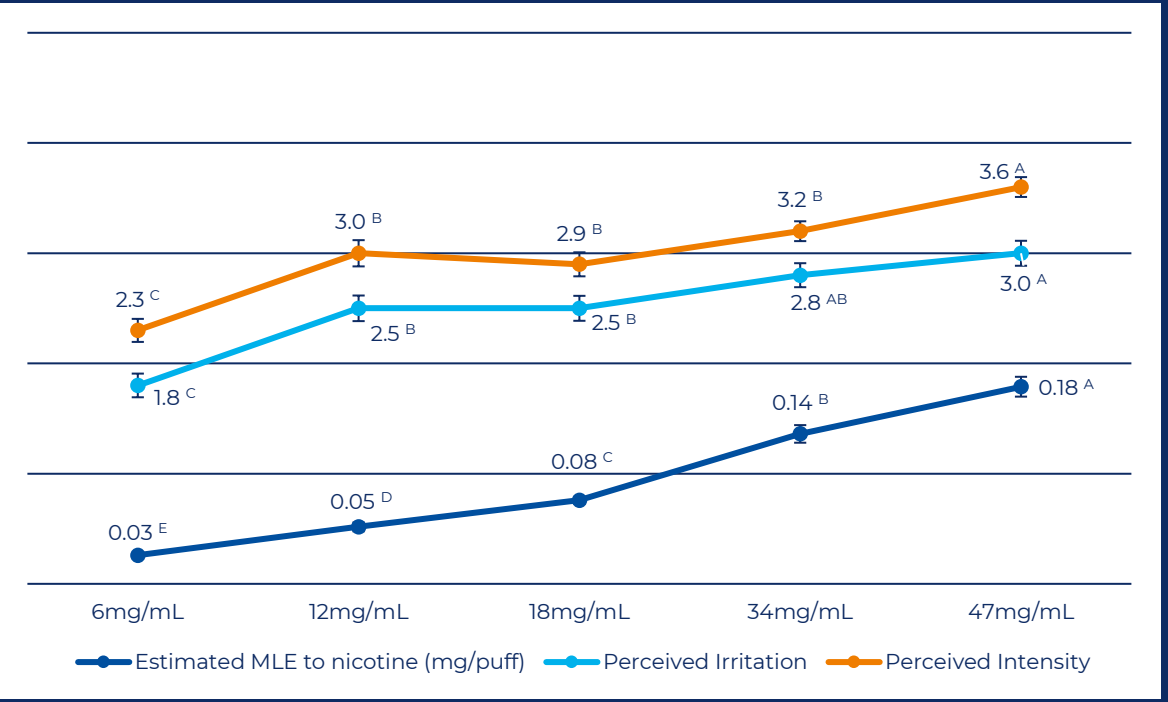
Central Location Testing*

With increasing concentration of nicotine in e-liquid:

Overall trends

- Perceived intensity and irritation increased
- No differences in overall liking or other sensory perception attributes



Abbreviations: MLE = mouth level exposure

* Data are mean from 90 participants who used each product twice. Error bars indicate standard error. Data were analysed by mixed-effects ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); those not sharing the same alphabet letter were significantly different ($p<0.05$). Participants were given a maximum of 15-min in which to use the product.

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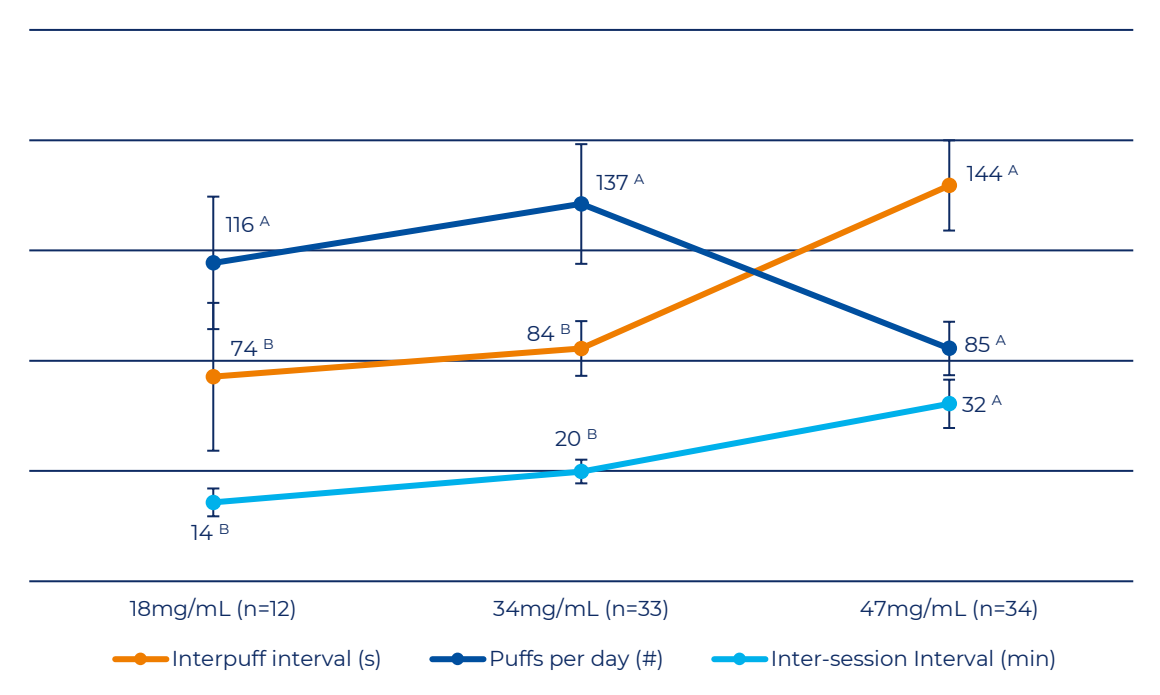
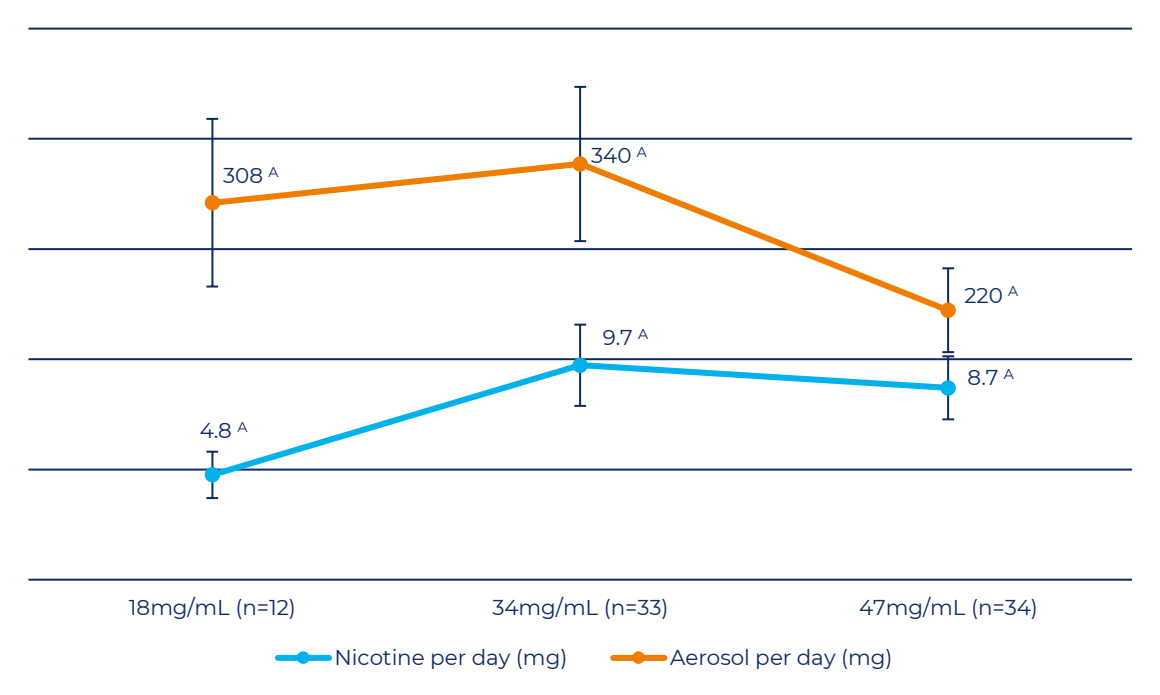
Home Use Testing*

When participants used their usual nicotine concentration:

- 47 mg/mL users puffed less frequently than 18 and 34 mg/mL users
- No differences in puff duration (1.58-1.67 s) or ADC (0.6-0.75 pods/day)



- No significant differences in estimated MLE per day
- However, MLE to nicotine per day was lowest for 18 mg/mL users



Abbreviations: ADC = average daily consumption (self-reported via daily consumption diary); MLE = mouth level exposure.
* Participants used only their usual nicotine concentration (either 18, 34 or 47 mg/mL). Only participants with valid data are included. Error bars indicate standard error. Data were analysed by one-way ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); those not sharing the same alphabet letter were significantly different ($p<0.05$). Participants were given a maximum of 15-min in which to use the product.

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RESULTS

Effect of flavour liking

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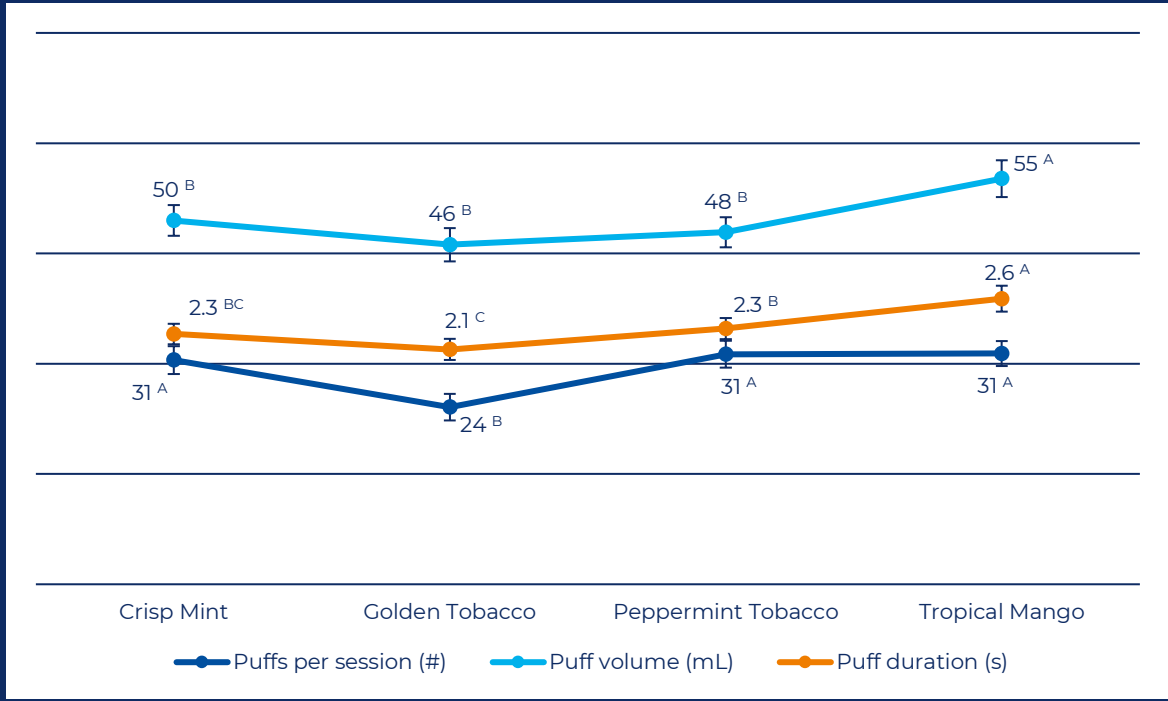
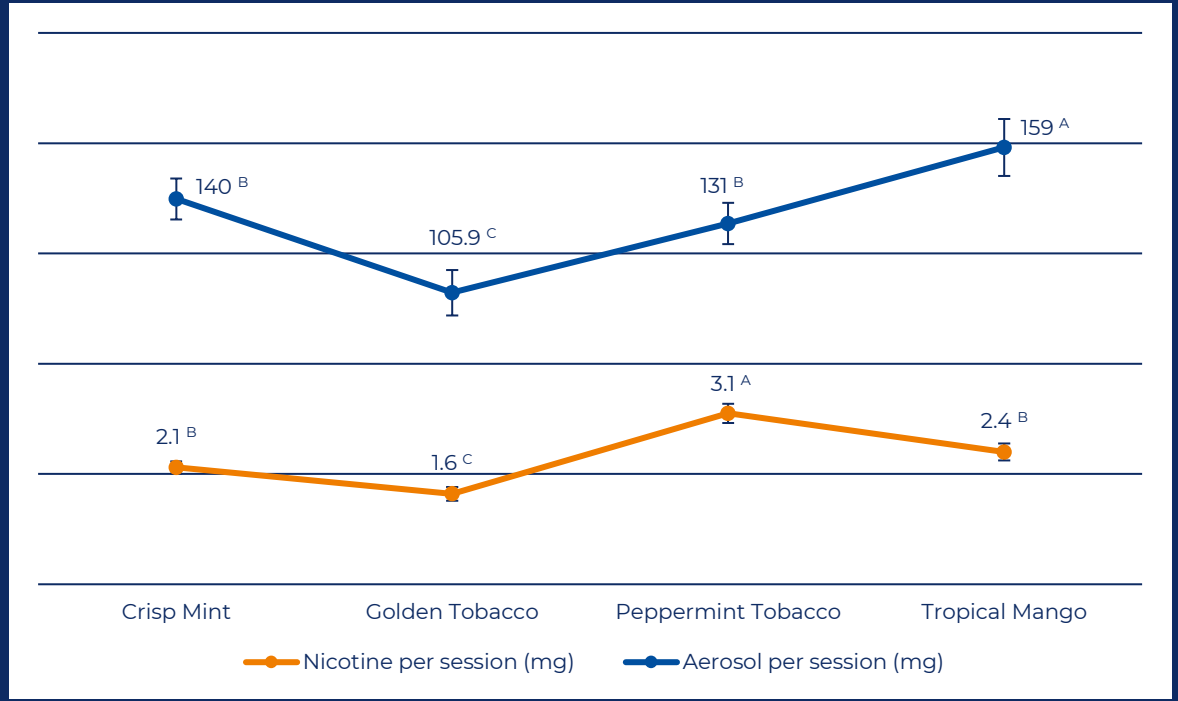
Central Location Testing*

Across flavours at 18 mg/mL nicotine:

- Shorter puff duration, fewer puffs, and lower MLE for Golden Tobacco flavour, consistent with lower taste liking rating (1.8 vs 3.2 -3.8**) and lower overall liking rating (2.0 vs 3.3 – 3.7**)
- Slightly larger puffs of longer duration when using Mango flavour (55 vs 46 – 50 mL puff volume; 2.6 vs 2.1 – 2,3 s puff duration)





Abbreviations: MLE, = mouth level exposure

* Data are mean from 90 participants who used each product twice. Error bars indicate standard error. Data were analysed by mixed-effects ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); those not sharing the same alphabet letter were significantly different ($p<0.05$). Participants were given a maximum of 15-min in which to use the product.

** Via self-reported questionnaire, scored on a scale of 1-5 where 1 = "dislike a lot" and 5 = "like a lot"

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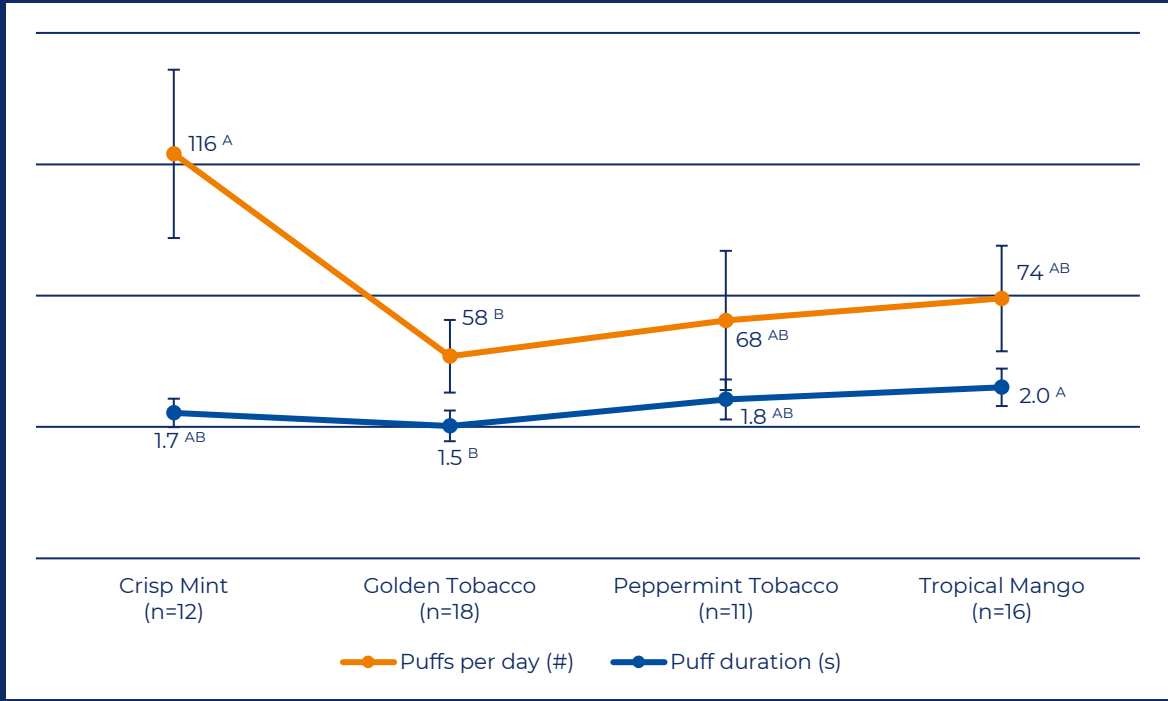
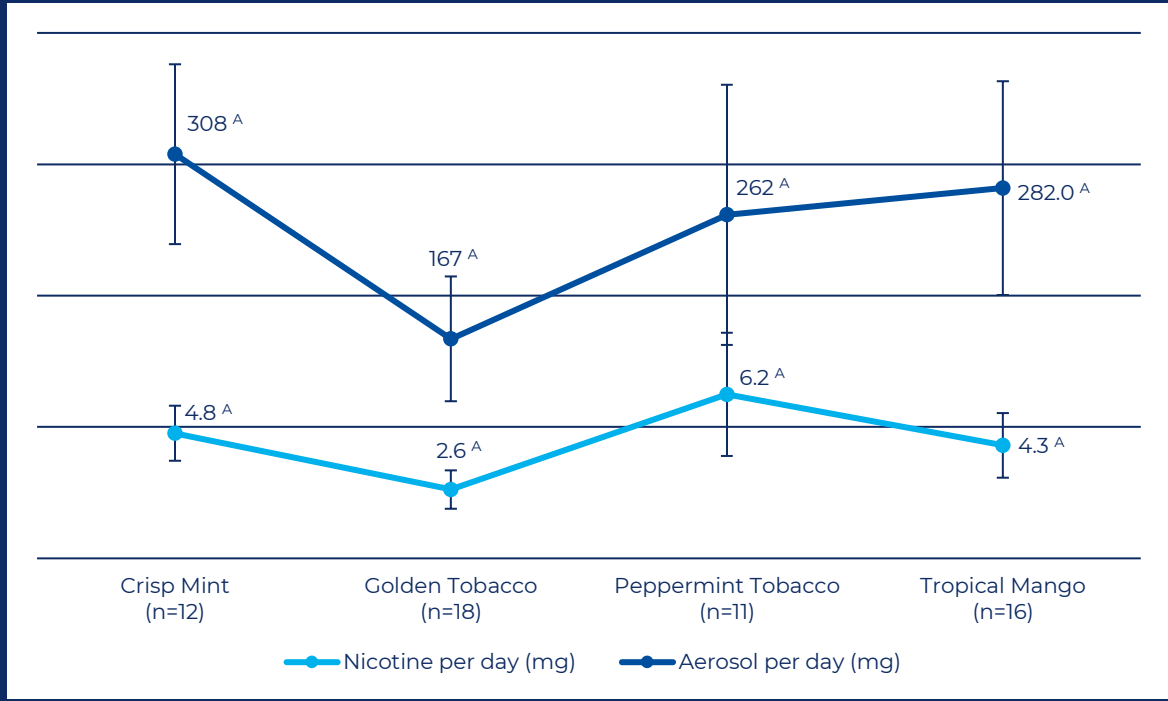
Home Use Testing*

Across flavours at 18 mg/mL nicotine:

- Fewer puffs and shorter puff duration for Golden Tobacco flavour consistent with findings in CLT
- Higher number of puffs for Crisp Mint flavour (not statistically significant) may be attributable to accessibility of this flavour in New Zealand
- No significant differences in MLE to aerosol or nicotine





Abbreviations: MLE = mouth level exposure; CLT = central location test

* Only participants with valid data are included. Error bars indicate standard error. Data were analysed by mixed-effects ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); those not sharing the same alphabet letter were significantly different ($p<0.05$). Participants were given a maximum of 15-min in which to use the product.

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RESULTS

Nicotine delivery - comparison with a tobacco cigarette

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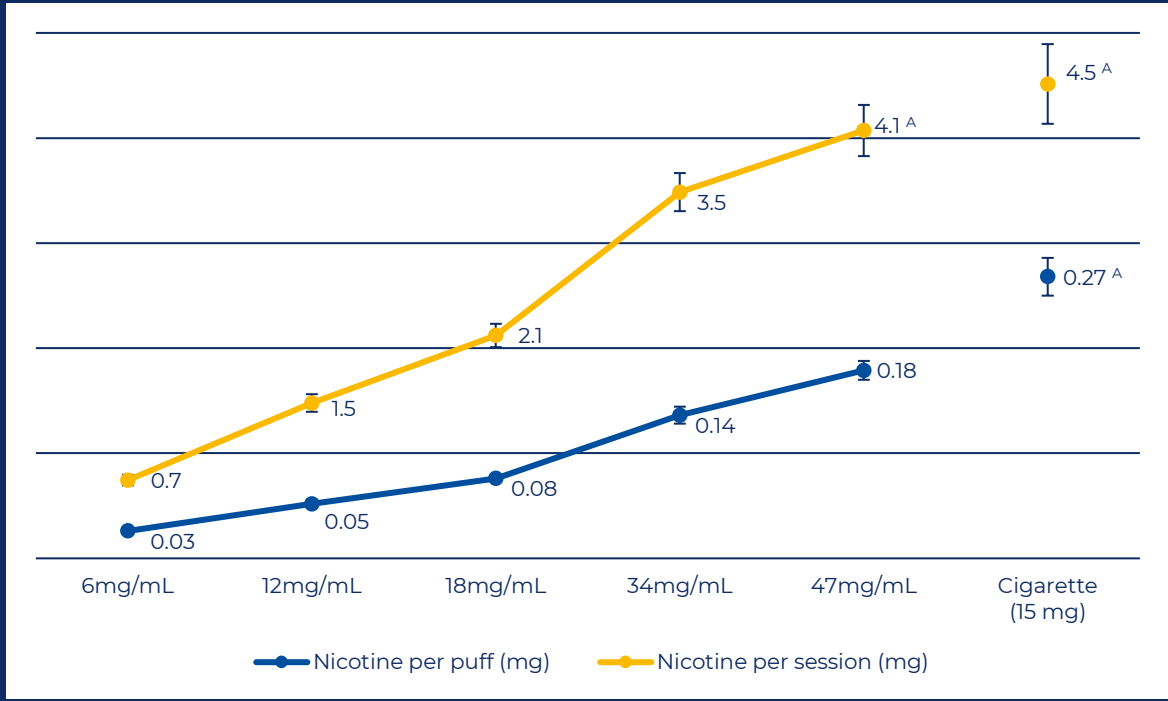
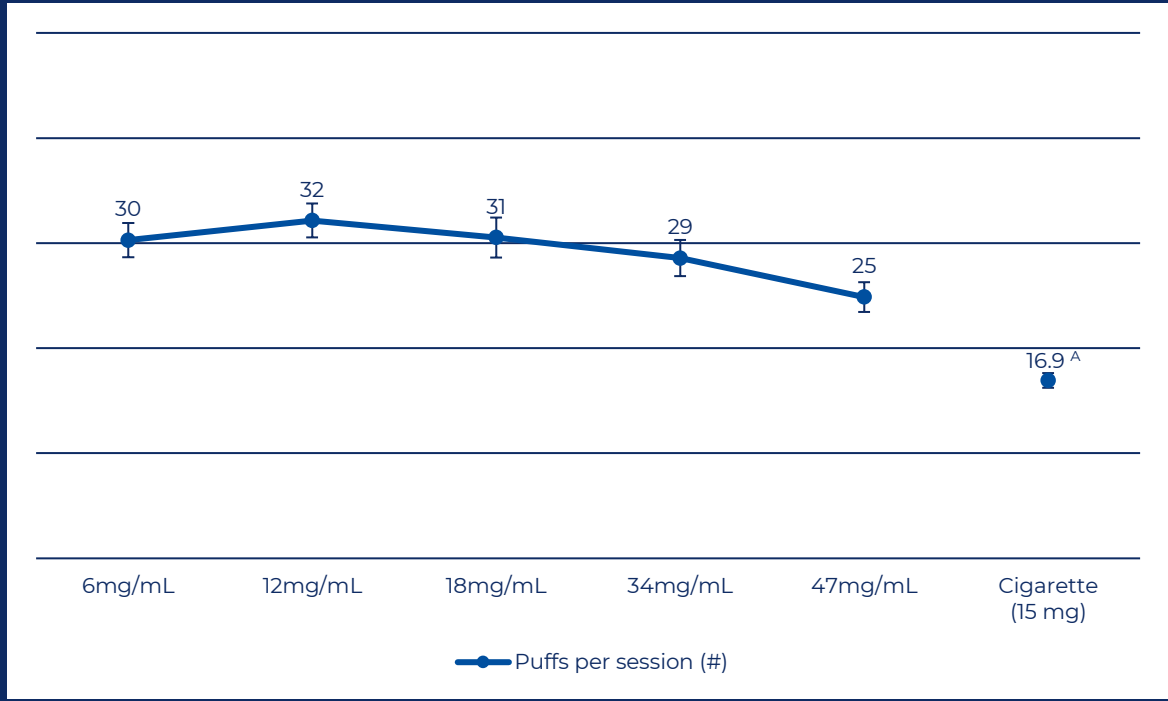
Nicotine delivery: vapour vs cigarette*

Central location testing - estimated MLE to nicotine: vapour product vs cigarette

- Estimated MLE to nicotine per puff for 47 mg/mL vapour product was significantly lower than 15 mg cigarette
- Vapers took significantly more puffs per 15-min vaping session than cigarette smokers took per cigarette
- Thus, total estimated MLE to nicotine for 47 mg/mL vapour product was similar to the cigarette





Abbreviations: MLE = mouth level exposure

* Data are mean from 90 e-cigarette users (using only the e-cigarette) and 35 cigarette smokers (using only the cigarette) who used each product twice. Error bars indicate standard error. Data were analysed by mixed-effects ANOVA, followed by Dunnett's post-hoc test. For a given parameter, values that do not share the letter A are significantly different from the cigarette ($p<0.05$).

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Conclusions

Puffing behaviour was broadly consistent with ISO20768:2018 machine puffing regime

- Average puff durations (1.5 -2.6s) were less than the 3s recommended by CORESTA
- Puff volumes (46 – 55mL) and IPI (35 – 143s) were broadly consistent with the recommended 55mL volume and 30s frequency

Both nicotine level and flavour influence consumers' puffing behaviour

- Puff duration and puff frequency tended to decrease with increasing nicotine concentration and this may be associated with self-titration or higher perceived irritation
- Flavours with a lower overall liking score tended to result in reduced use behaviour

Nicotine concentration and e-liquid flavour play an important role in helping adult smokers who would otherwise continue to smoke to instead switch to Vapour Products

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Thank you for listening

Any questions?

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