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Puffing topography, mouth level exposure, average daily consumption and machine emissions of two closed-system disposable vapour products

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Contents

Background

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

Consumers' toxicant 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)

A new generation of closed-system disposable vapour products have grown in popularity; however, little is known about consumers' use behaviour and exposure when using these products.

[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

Objectives & Rationale

Objective

Measure the consumer puffing topography, mouth level exposure (MLE) to aerosol and nicotine, and average daily consumption (ADC), and machine-generated emissions of two closed disposable vapour products ("Vuse Go 700" & "Vuse Go 800") and a closed rechargeable system ("Vuse Pro")

Puffing topography studies

- ❑ Informs whether standardised machine puffing regimes for collection of emissions data are reflective of actual use
- ❑ Helps evaluate the risk profile of our products

Puffing topography was measured using a desktop puffing analyser (PA1) [1-2]

Puffing topography:

- ❑ Puff count
- ❑ Flow rate & puff volume
- ❑ Puff duration
- ❑ Inter-puff interval (IPI)
- ❑ Session length
- ❑ Pressure drop (PD) & effort expended

Vuse Go 700 *Vuse Go 800* *Vuse Pro*

Abbreviations: MLE = mouth level exposure; ADC = average daily consumption

[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

Study Design

Parallel design study among users of closed disposable vapour products and users of closed rechargeable vapour products, in the UK

Study Arm 1 – Vuse Pro
Closed rechargeable users (n=59)
"Mint Ice" e-liquid
18 mg/mL nicotine

Study Arm 2 – Vuse Go 700
Cylindrical disposable users (n=59)
"Mint Ice" e-liquid
20 mg/mL nicotine

Study Arm 3 – Vuse Go 800
Box shape disposable users (n=59)
"Mint Ice" e-liquid
20 mg/mL nicotine

Recruitment (n=177)

- ❑ Adult vapers aged 21-65 years
- ❑ ≥1 cartridge per week for ≥6 months
- ❑ Non-rejectors of mint flavours
- ❑ Informed consent via ICF
- ❑ Study participants placed into 1 of 3 study arms according to the self-reported usual product

Central location (CLT)

- ❑ Puffing topography via PA1 (2 x 15-min *ad lib* sessions)
- ❑ 20-min break between each session
- ❑ Estimated MLE via DML by machine calibration
- ❑ Sensory perception via questionnaire
- ❑ Demographics and tobacco & nicotine use history via questionnaire

Home use testing (HUT)

- ❑ 5-day supply of consumables/devices
- ❑ ADC
  - Measured: via count of used devices
  - Self-reported: via daily diary

Abbreviations: ICF = informed consent form; PA1 = puffing analyser 1; MLE = mouth level exposure; DML = device mass loss; ADC = average daily consumption

Results

Demographics + Tobacco & Nicotine Use History

Sex

76 (43%) 101 (57%)

Age

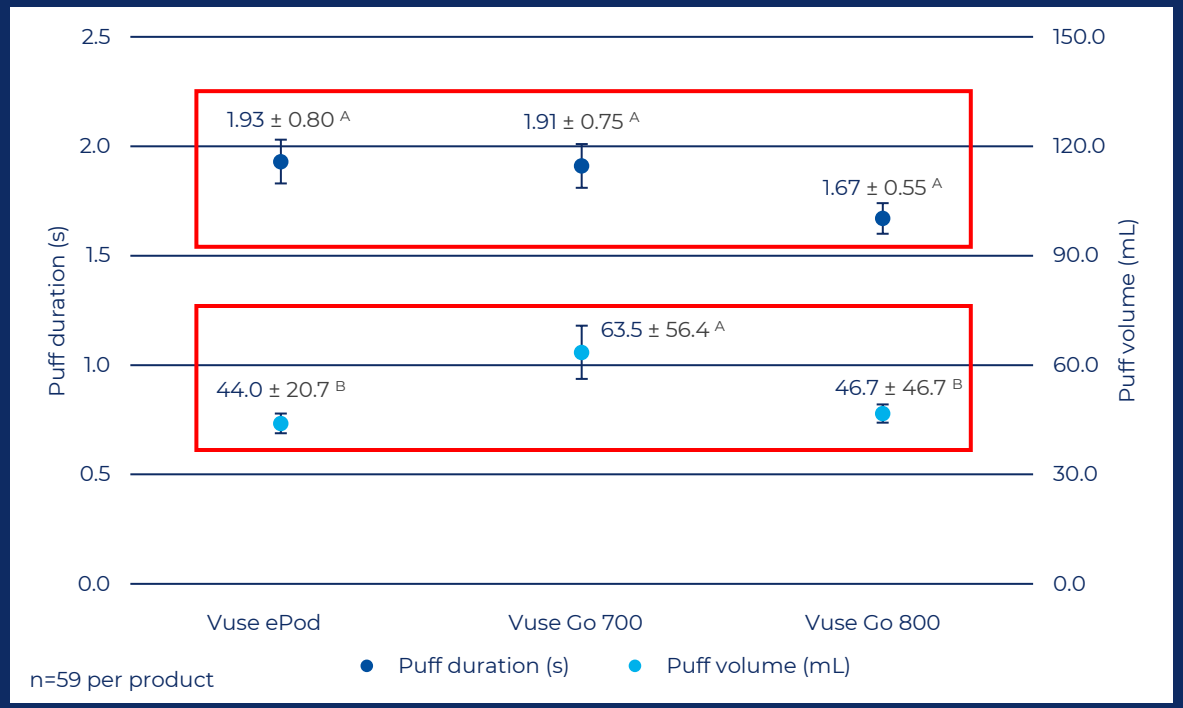
Age Group	Number (%)
21-25	33 (19%)
26-30	37 (21%)
31-35	28 (16%)
36-45	45 (26%)
46-55	25 (14%)
56-65	9 (5%)

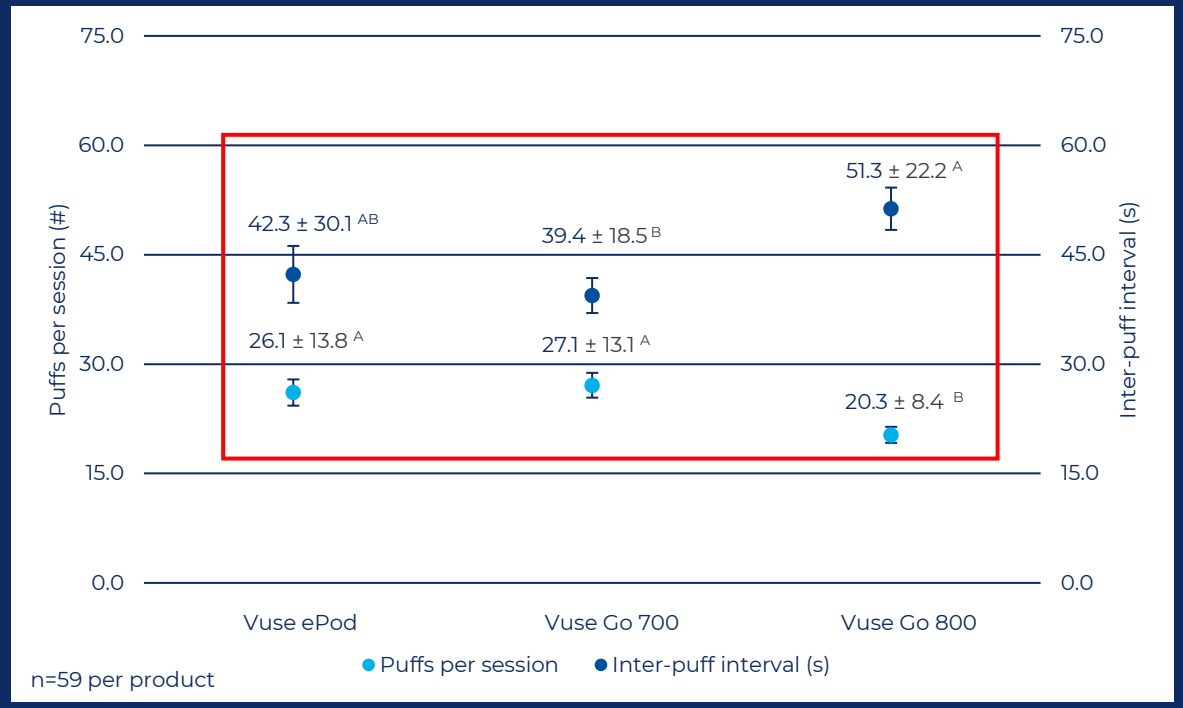
- **Demographics were balanced across the study arms**
- **Fruit-flavoured e-liquids were most popular across all groups**
  - mint flavours slightly more popular among the users of closed rechargeable systems than closed disposable systems

Puffing Topography at CLT*

Overall, puffing topography was similar between the two disposable & the rechargeable vapour products

- No significant differences observed in mean puff duration (1.67 – 1.93 s)
- Mean puff durations were less than the 3s duration of ISO 20768:2018#
- Larger puff volumes taken on Vuse Go 700 due to lower open PD†
- Fewer puffs on average taken on Vuse Go 800 (reason unclear)





Abbreviations: ISO = International Organization for Standardization; = PD = pressure drop

* Data are mean from 59 participants per product, who used the product twice. 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 *ad libitum*.

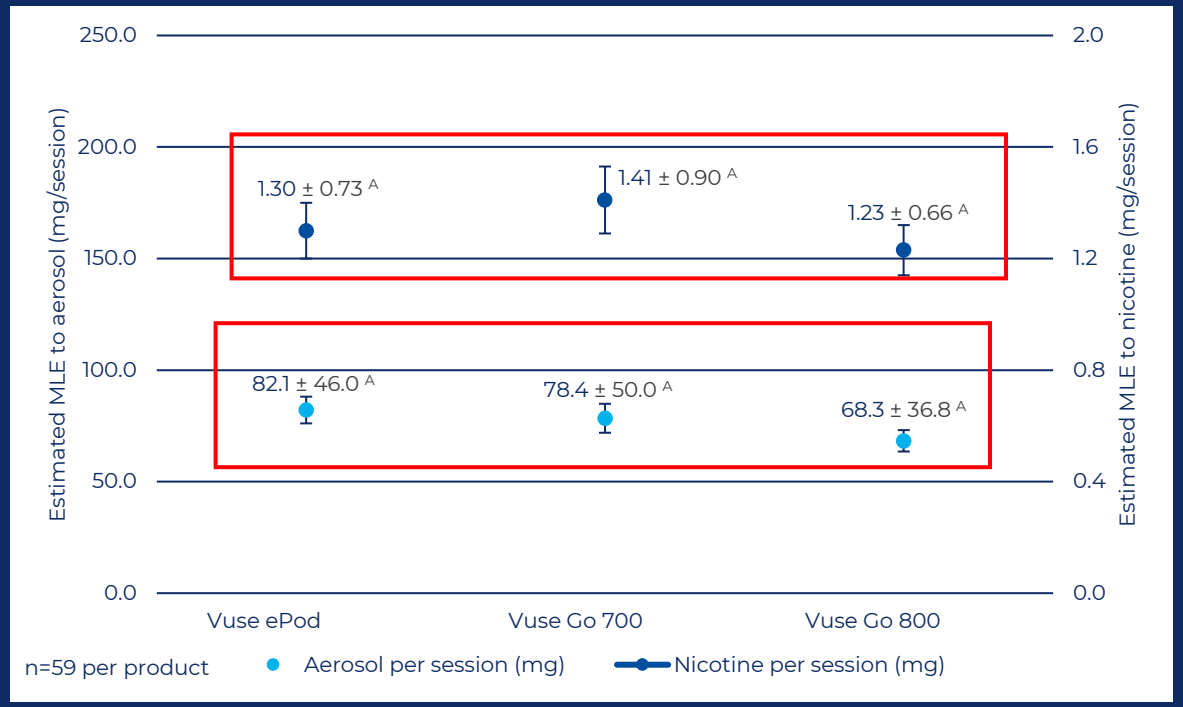
Machine puffing conditions of volume 55mL, duration 3.0s, frequency 30s, with a rectangle profile shape

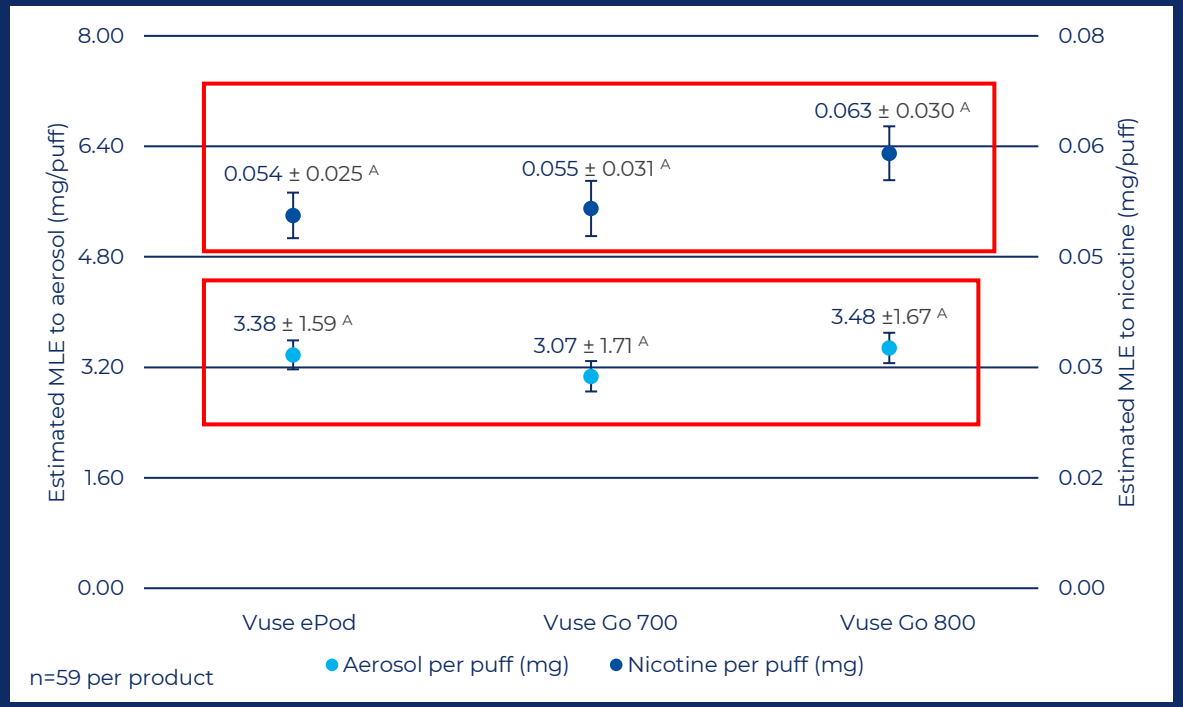
† Open pressure drop at 17.5mL/s. Vuse Pro 70-100mmWG; Vuse Go 700 30-80mmWG; Vuse Go 800 60-80mmWG

Estimated Mouth Level Exposure (MLE) at CLT*

Overall, estimated MLE was similar between the two disposable & the rechargeable vapour products

- MLE was estimated from device mass loss by machine calibration under a range of puffing regimes
- No significant differences observed among products in estimated MLE to aerosol or nicotine (per session or per puff)





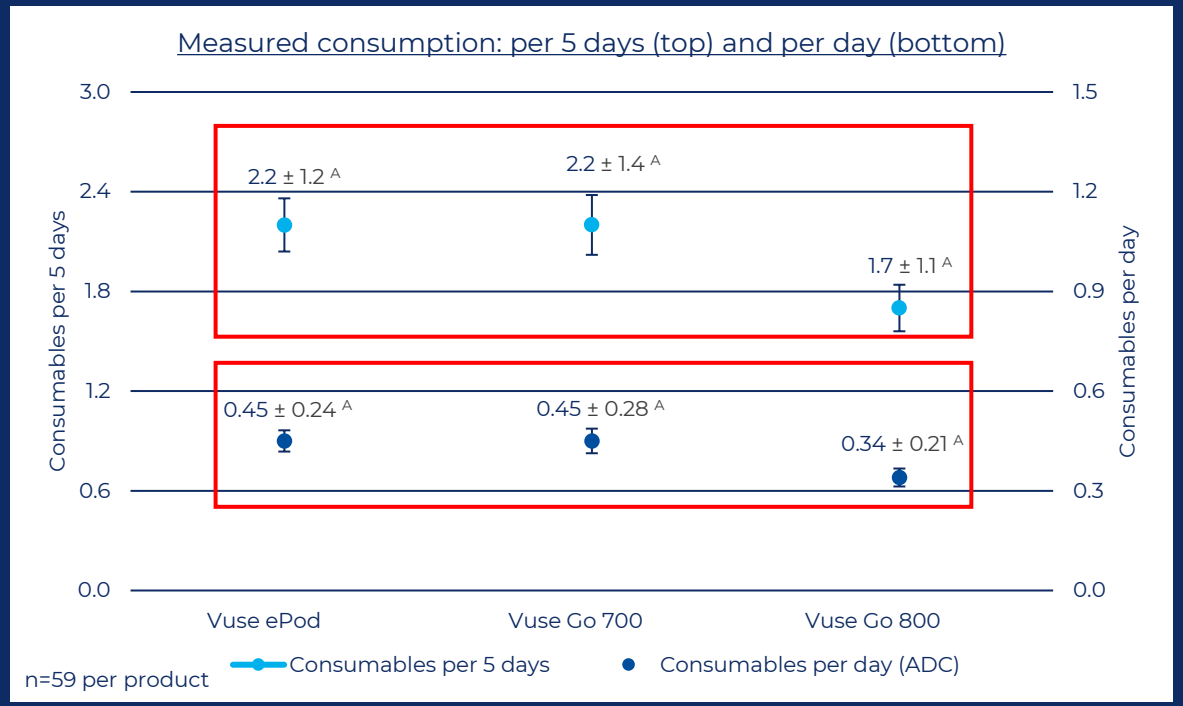
Abbreviations: MLE = mouth level exposure; ACM = aerosol collected mass

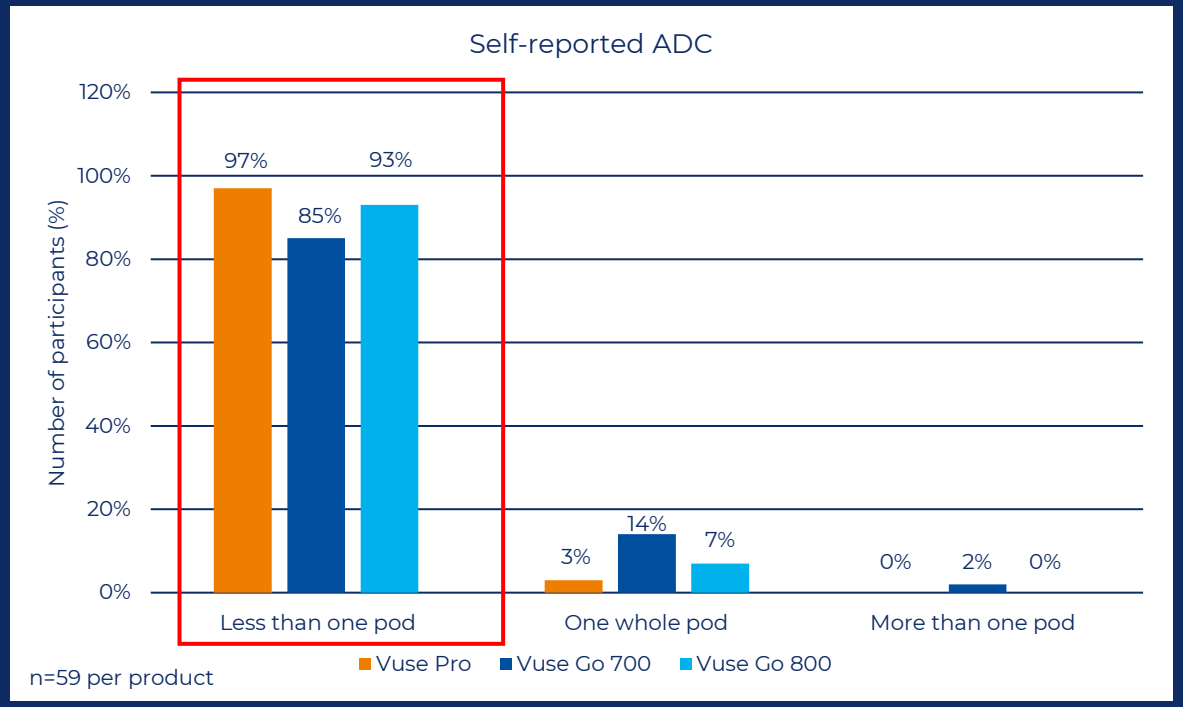
* MLE Data are mean from 59 participants per product, who used the product twice for. Error bars indicate standard error. Data were analysed by one-way ANOVA, followed by Tukey's post-hoc test. For a given parameter, values sharing the same alphabet letter were not significantly different ($p>0.05$); 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 *ad libitum*.

Average Daily Consumption (ADC) in HUT*

ADC was similar between the disposable & the rechargeable vapour products

- No significant differences observed among products in measured consumption (per 5 days or per day)
- Measured ADC is consistent with self-reported ADC





* Measured consumption determined by count of used devices following a 5-day home use test. Self-reported average daily consumption determined using daily consumption diaries – participants using Vuse Pro were asked to estimate the percentage (%) of the e-liquid cartridge used per day by visibly assessing the amount of e-liquid used; users of Vuse Go were asked if they used less than one product, one whole product, or more than one product per day (due to lack of e-liquid visibility). Data are mean from 59 participants per product. 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 ($p<0.05$).

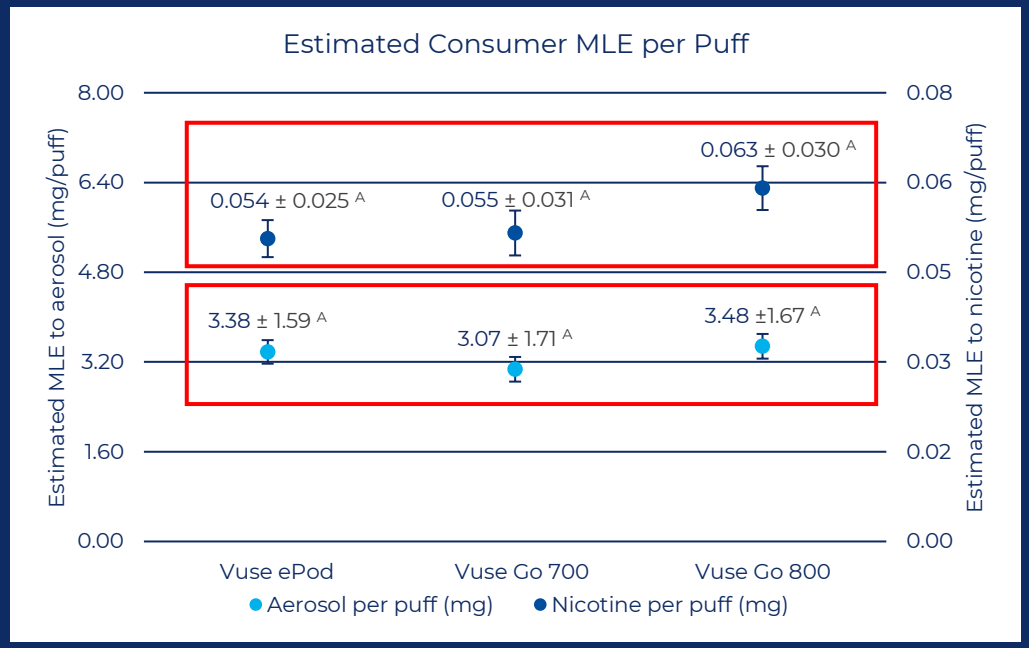
Machine Emissions*

Overall, machine emissions were similar between the disposable and the rechargeable vapour products

- Machine ACM and nicotine yields were greater than the estimated consumer MLE (per puff & per session)

Aerosol constituent	Unit	1R6F Reference Cigarette	Vuse Pro	Vuse Go 700	Vuse Go 800
Main aerosol constituents per puffs					
TPM/ACM#	mg/puff	6.01 ± 0.34	6.48 ± 0.57	6.92 ± 0.26	6.81 ± 0.19
Nicotine	mg/puff	0.23 ± 0.01	0.08 ± 0.01†	0.11 ± 0.00	0.11 ± 0.00
Menthol	mg/puff	-	0.057 ± 0.009†	0.066 ± 0.003	0.057 ± 0.002
Water	mg/puff	2.12 ± 0.11	0.41 ± 0.04†	0.48 ± 0.03	0.57 ± 0.02
Glycerol	mg/puff	0.19 ± 0.00	2.95 ± 0.43†	2.51 ± 0.09	2.36 ± 0.11
Propylene glycol	mg/puff	0.04 ± 0.00	1.54 ± 0.27†	2.43 ± 0.10	2.49 ± 0.06

- Levels of TobReg9 analytes were significantly lower in the emissions of all three Vuse products compared to the 1R6F reference cigarette
- Eight of the nine TobReg9 analytes were below either the LOD or the LOQ



Abbreviations: LOD, = limit of detection; LOQ, = limit of quantification; ACM = aerosol collected mass; TSNA = tobacco-specific nitrosamine; VOC = volatile organic compound; CO = carbon monoxide; NNK = 4-[methyl(nitroso)amino]-1-(3-pyridinyl)-1-butanone; NAB, = N-nitrosoanabasine; NAT = N-nitrosoanatabine; NNN = N-nitrosonornicotine.

* Smoke (TPM) from the 1R6F reference cigarette was generated using the Health Canada Intense (HCI) ISO/TR19478-1:2014 machine puffing regime of volume 55mL, duration 2.0s, frequency 30s, with a bell profile shape and 100% blocking of the perforations; vapour product aerosol (ACM) was generated using ISO 20768:2018 machine puffing regime of volume 55mL, duration 3.0s, frequency 30s with a rectangle profile shape with five replicates, twenty-five puffs per replicate.

Mean of 25 replicates across all analytical tests.

† 3-Mean of 4 replicates as one replicate reported anomalous ACM and was therefore excluded.

Conclusions

Participant puffing behaviour was broadly consistent with ISO 20768:2018 machine puffing parameters

- Mean puff durations (1.7 -1.9s) and mean estimated MLE to aerosol (3.1-3.5mg/puff) were less than those of the ISO 20768:2018* machine puffing regime, indicating that emissions collected using this regime (6.5-6.9mg/puff) are likely an overestimation of average consumer exposure

Overall, the consumer use behaviour, MLE and emissions were similar between the two disposable vapour products and the rechargeable vapour product

- Suggesting that the overall aerosol composition and therefore the risk profile of these two types of vapour products are likely to be comparable

It is essential to measure consumer use behaviour of new products in addition to emissions to ensure that standardised machine puffing regimes used to generate emissions data remain broadly reflective of actual consumer use.

* Machine puffing conditions of volume 55mL, duration 3.0s, frequency 30s with a rectangle profile shape

Thank you for listening

Any questions?

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