Kitzbühel - Austria 2017
CORESTA SSPT

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Estimation of e-cigarette aerosol yields based on puff duration

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Context

There is increasing regulatory interest in the quantification and comparison of emission levels of major and minor aerosol constituents from e-cigarettes.

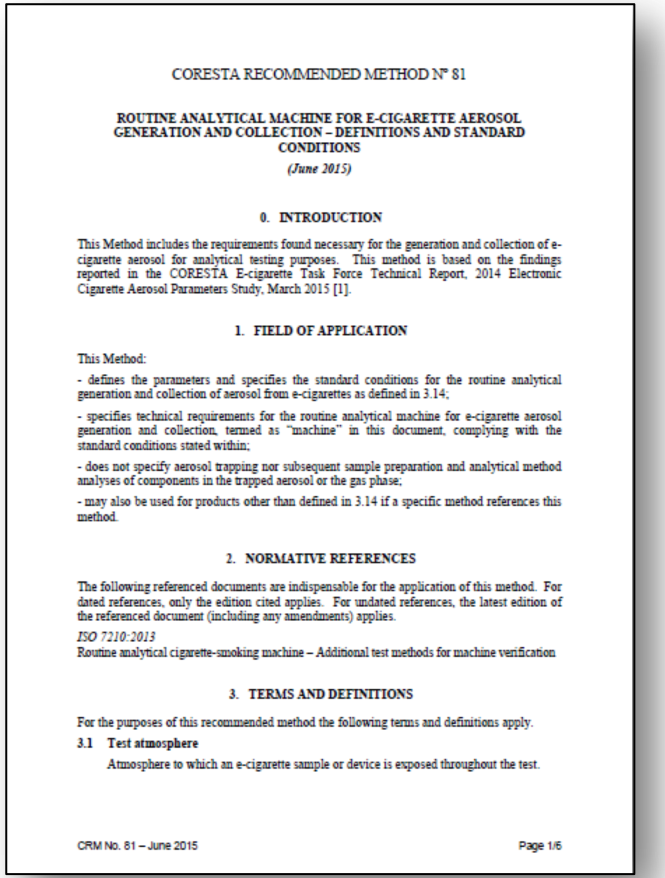
A variety of puffing regimes have been described in the literature.

However, until the recent publication in 2015 of CRM 81[1], no international standard was or still is in place to describe how these products should be tested

[1] *CRM 81 (2015) Routine Analytical Machine for e-Cigarette Aerosol Generation and Collection – Definitions and Standard Conditions*

Please note that the views and arguments presented in this paper have been designed to encourage and stimulate debate and do not necessarily reflect Fontem Ventures' position

CORESTA RECOMMENDED METHOD 81



CORESTA RECOMMENDED METHOD N° 81

ROUTINE ANALYTICAL MACHINE FOR E-CIGARETTE AEROSOL GENERATION AND COLLECTION – DEFINITIONS AND STANDARD CONDITIONS

(June 2015)

0. INTRODUCTION

This Method includes the requirements found necessary for the generation and collection of e-cigarette aerosol for analytical testing purposes. This method is based on the findings reported in the CORESTA E-cigarette Task Force Technical Report, 2014 Electronic Cigarette Aerosol Parameters Study, March 2015 [1].

1. FIELD OF APPLICATION

This Method:

- defines the parameters and specifies the standard conditions for the routine analytical generation and collection of aerosol from e-cigarettes as defined in 3.14;
- specifies technical requirements for the routine analytical machine for e-cigarette aerosol generation and collection, termed as "machine" in this document, complying with the standard conditions stated within;
- does not specify aerosol trapping nor subsequent sample preparation and analytical method analyses of components in the trapped aerosol or the gas phase;
- may also be used for products other than defined in 3.14 if a specific method references this method.

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this method. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7210:2013
Routine analytical cigarette-smoking machine – Additional test methods for machine verification

3. TERMS AND DEFINITIONS

For the purposes of this recommended method the following terms and definitions apply.

3.1 Test atmosphere

Atmosphere to which an e-cigarette sample or device is exposed throughout the test.

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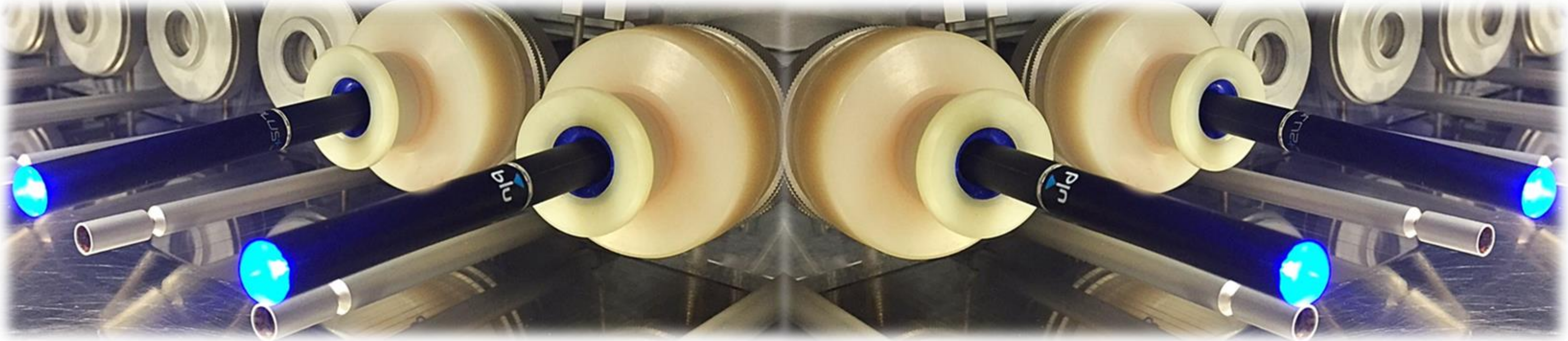

Puff Duration	Puff Volume	Puff Frequency	Puff Profile
3 s ± 0.1 s	55 mL ± 0,3 mL	30 s ± 0.5 s	Rectangular

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Context

In May 2016, the U.S Food and Drug Administration published draft guidance for Industry entitled 'Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems'. Lines 1021 – 1024 of the guidance states:

*"Evaluating new tobacco products under a range of conditions, including both **non-intense** (e.g., lower levels of exposure and lower volumes of aerosol generated) and **intense** (e.g., higher levels of exposure and higher volumes of aerosol generated), enables FDA to understand the likely range of delivery of emissions"*

▼Why asking for two vaping regimes?

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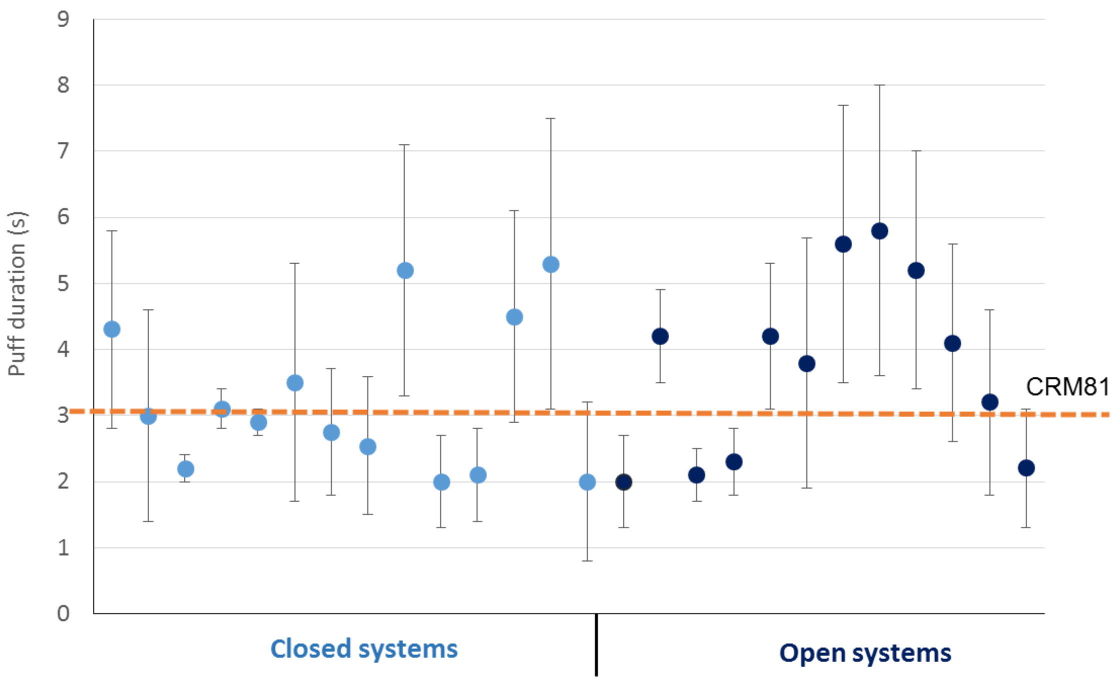
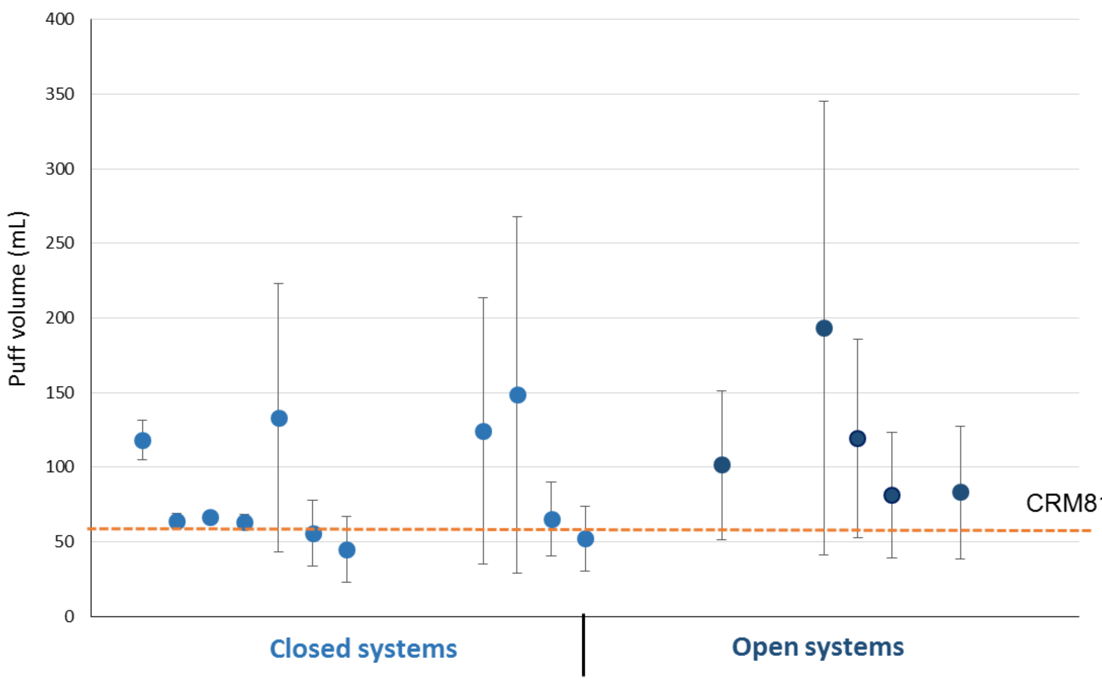
Human vaping topography*

▼ Puff duration



▼ Puff volume



▼ Impact of vaping parameters on emission deliveries?

▼ *19 publications from 2013 to 2016

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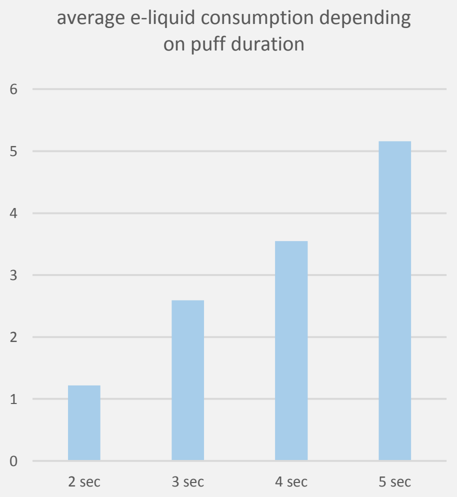
Vaping parameters

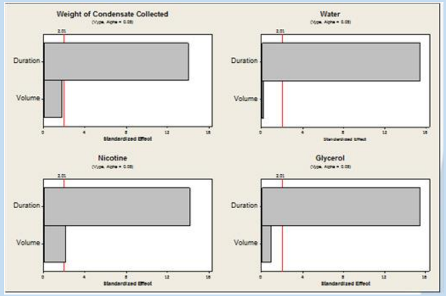
Puff Duration

Most influential parameter!



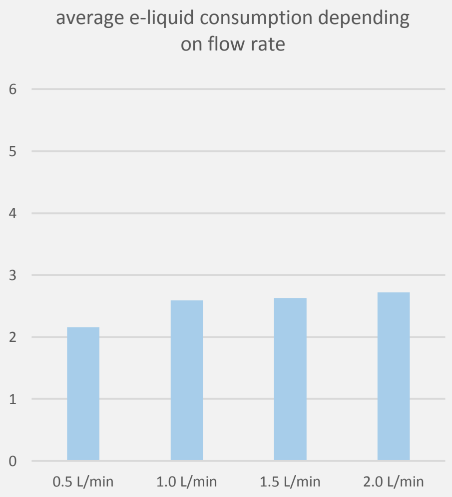
increasing puff duration → strong increase in liquid consumption
(Zhao, Shu, Guo, & Zhu, 2016)

Puff Volume



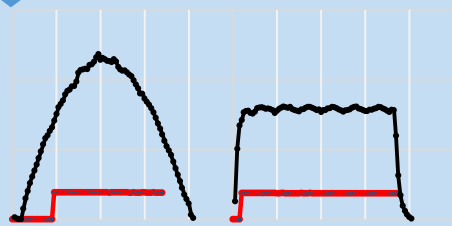
The Pareto charts show duration has a significant effect on the yields of major aerosol constituents, but puff volume does not.
(Davis et al., poster “Influence of machine-based puffing parameters on aerosol yields from e-cigarettes”)

Flow Rate



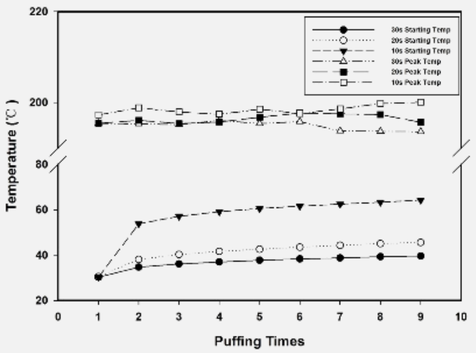
increasing flow rate → liquid consumption only increased slightly
(Zhao, Shu, Guo, & Zhu, 2016)

Puff Profile



Bell shaped puff profiles switch devices on later than square shaped profile (takes longer until minimum flow rate to activate puff sensor is reached). This leads to a delay in heating.
(internal study)

Puff Interval



Starting temperature increases with shorter interval, but no effect on peak temperature
(Zhao, Shu, Guo, & Zhu, 2016)

To evaluate the effect of vaping parameters on emission deliveries for blu™ e-cigarette products

GO
PLUS
} Closed systems

FILL
PRO
} Open systems

Study protocol

Vaping regimes:

	Puff Duration [s]	Flow Rate [mL/s]	Puff Volume [mL]
1	2	13.75	27.5
2	3	18.33	55
3	4	13.75	55
4	6	13.75	82.5

- Aerosol was collected for the first 100 puffs in five blocks of 20 puffs (n = 3).
- All tests were performed using rectangular puff profile.
- Weight loss, ACM, PG, VG, Water and Nicotine were analysed using 17025 accredited methods.

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Liquid composition:

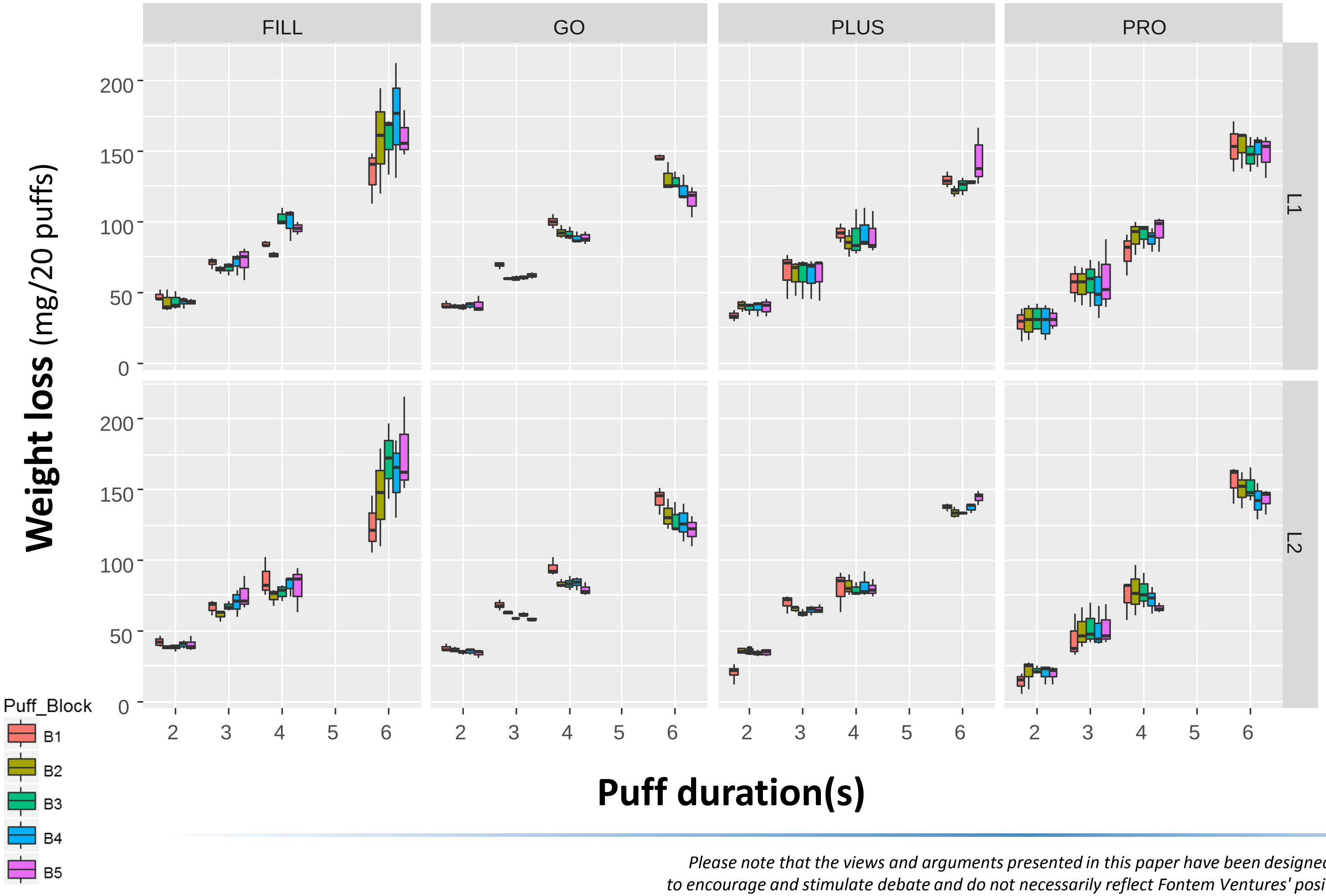
	PG (w/w)	VG (w/w)	Nicotine (w/w)
Liquid 1 (L1):	68.8 %	30 %	1.2%
Liquid 2 (L2):	48.8 %	50 %	1.2%

Results – Statistics (ANOVA)

	Device	Liquid	Puff Duration	Puff Volume	Puff Block
Weight loss	NS	NS	S	NS	NS
ACM	NS	NS	S	NS	NS
Nicotine	NS	NS	S	NS	NS
PG	NS	S	S	NS	NS
VG	NS	S	S	NS	NS

S = $P_{value} < 0.001$

Weight loss versus puff duration



Stability among the puff blocks

WL "comparable" between devices and liquids investigated, which indicates that both base liquid composition and device design had no significant impact on the aerosol delivery in this study

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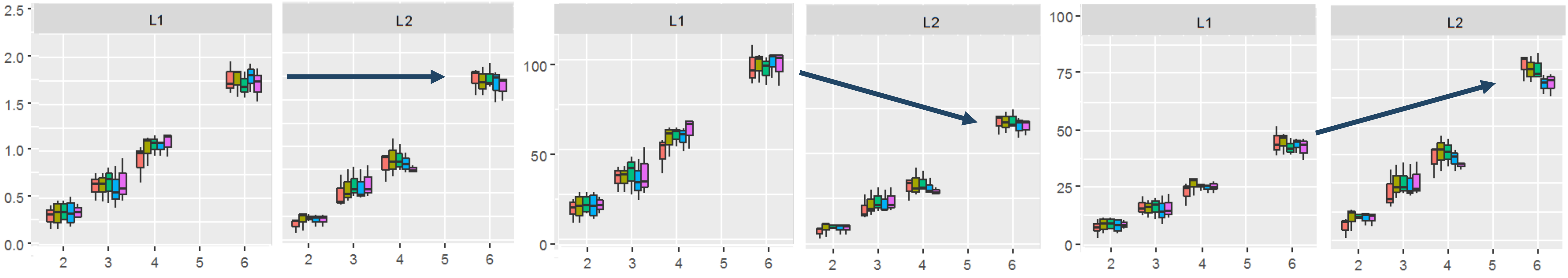
Nicotine – PG – VG vs puff duration vs e-liquids (PRO)

Nicotine PG VG



- Stability among the puff blocks for nicotine PG and VG
- base liquid composition have no significant impact on the nicotine delivery
- PG and VG yields are correlated with base liquid composition

	PG (w/w)	VG (w/w)	Nicotine (w/w)
Liquid 1 (L1):	68.8 %	30 %	1.2%
Liquid 2 (L2):	48.8 %	50 %	1.2%

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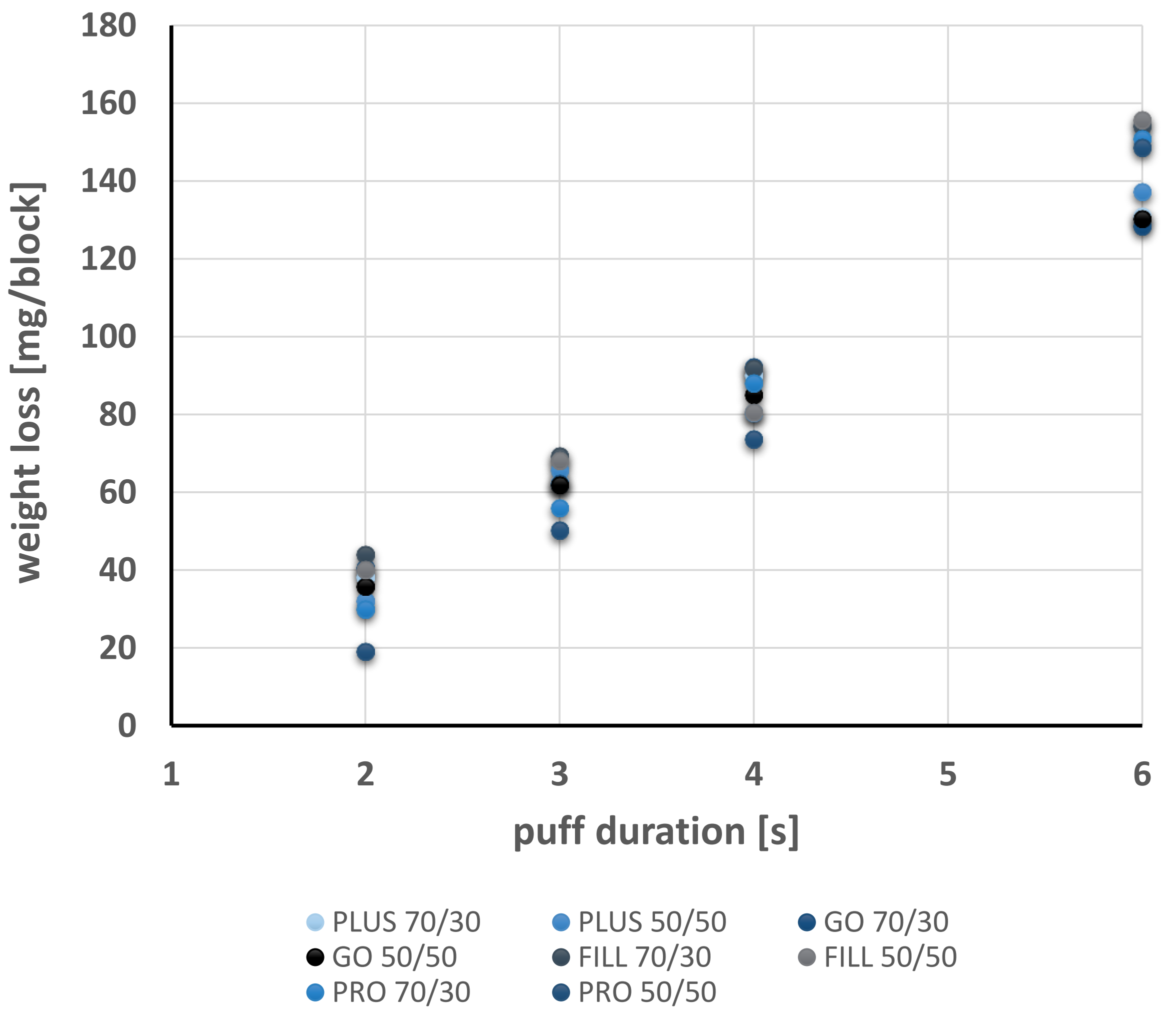
Impact of puff duration on weight loss



Strong and linear effect of Puff Duration on weight loss

The yields are "comparable" between devices and liquids investigated, which indicates that both base liquid composition and device design had no significant impact on the aerosol delivery in this study

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Global Modelisation – Weight loss vs puff duration

Weight Loss ~ Vaping parameters + Devices features + Liquid + 2^{nd} order interactions

Vaping parameters	Devices features	Liquid	2nd order interactions
Puff Duration	Power	Liquid	Power * Puff Duration
Flow Rate	$Power^2$		Power * Flow Rate
$Puff\ Duration^2$	Sqrt (Power)		Power * Liquid
Sqrt (Puff Duration)	Log (Power)		Puff Duration * Flow Rate
Log (Puff Duration)			Puff Duration * Liquid
			Flow Rate * Liquid

More than 26.000 combinations of models were assessed.

#Param	Vaping parameters			Devices features			Liquid	2nd order		R^2
	Puff Duration	Flow Rate	…	Power	$Power^2$	…	Liquid	Puff Duration * Power	…	
#1	✘									**89.1%**
#2	✘							✘		90.0%
#3	✘						✘	✘		90.3%
#4	✘			✘	✘			✘		90.5%
…										

- **89% of the weight loss changes is explained by puff duration**
- Using all significant parameters, the model has improved from 89.1% to 90.5%.

$$Weight\ Loss = 26.70 \times Puff\ Duration - 19.14 \quad (R^2 = 0.891)$$

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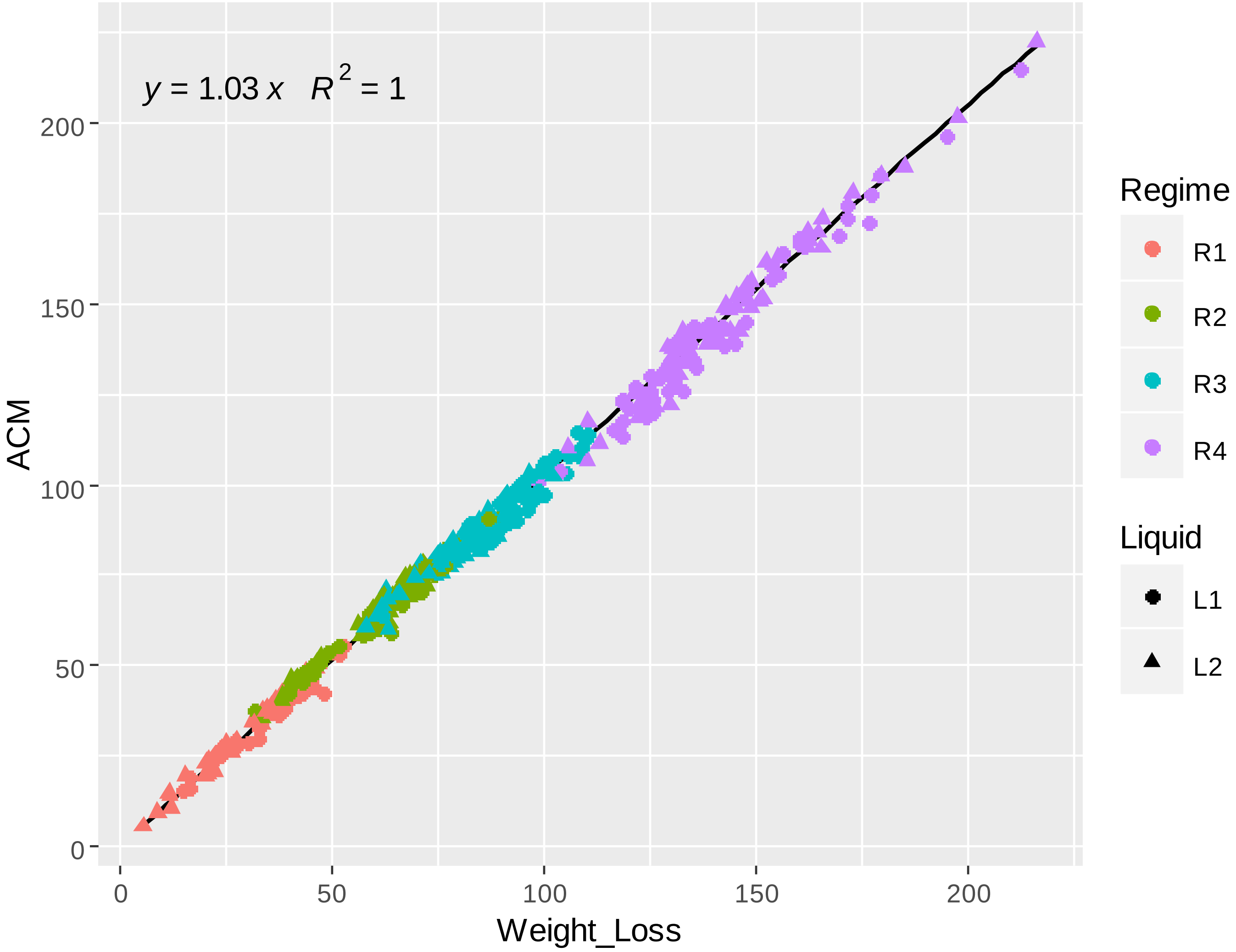
ACM and Weight Loss Correlation



Aerosol Collected Mass well correlated to Weight Loss

Method of trapping is efficient whatever the devices, liquids and vaping parameters

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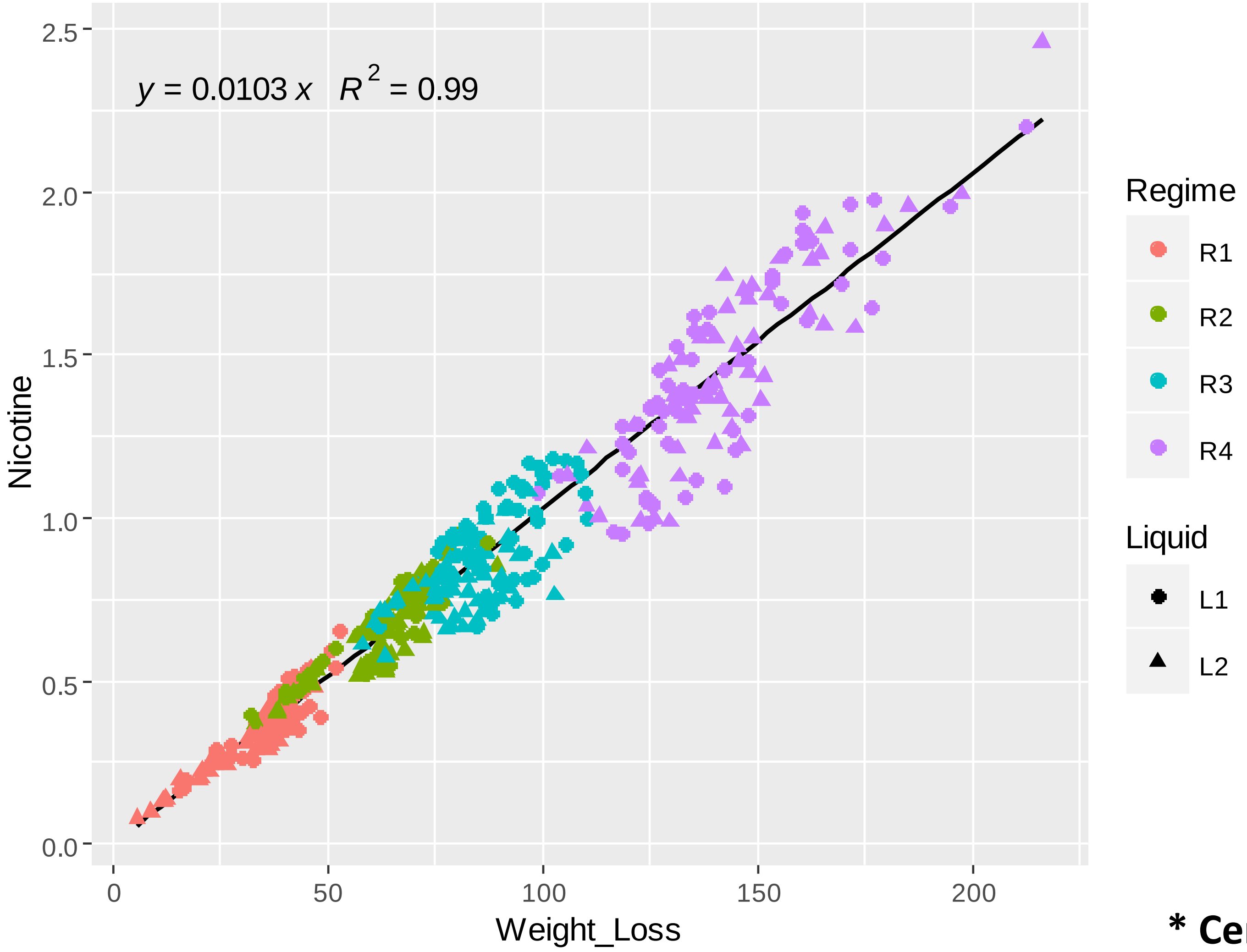
Nicotine and Weight Loss Correlation



Nicotine correlated to the Weight Loss.

However global modelisation becomes difficult for nicotine due to the high variability, especially for R4

*** Certainly due the nicotine measurement**

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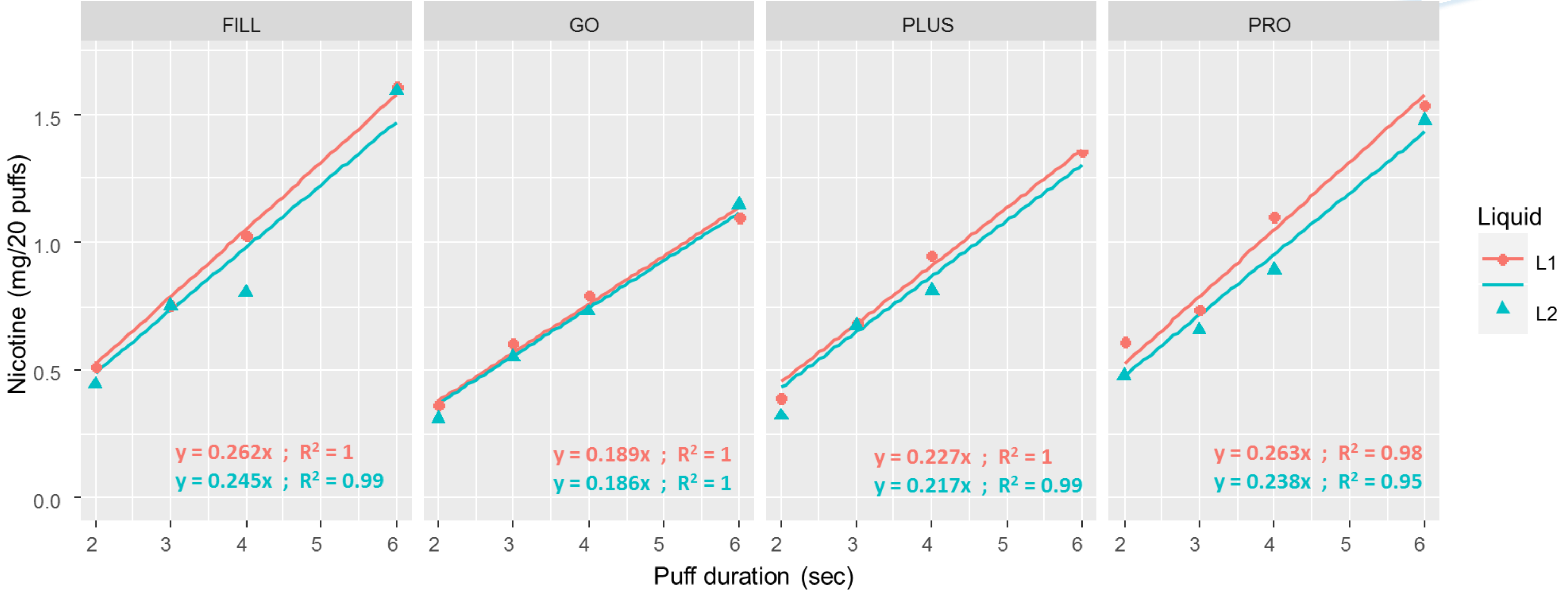
Modelisation – nicotine vs puff duration per device/e-liquid



- Linear correlation between aerosol nicotine yield and puff duration
- Base liquid composition has no significant impact on the aerosol delivery

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Conclusions & Discussions

- The data obtained in this study showed there is a strong linear correlation between the aerosol yields and puff duration.
- Puff volume and air flow showed minor influence on aerosol yields.
- The observed correlations between puff duration and aerosol yields showed that yields changes can be explained mainly by puff duration. An increase in puff duration will increase aerosol yields in a same manner
- A single vaping regime appears to be sufficient for characterizing a product for main compounds aerosol yields

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I would like to thank Laboratories at Imperial Brands PLC for their assistance with sample analyses