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Consistency of blu™ e-cigarette nicotine delivery according to the AFNOR standard

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SCIENCE FONTEM VENTURES

1. Introduction

- Demonstrating the consistency of nicotine delivery from an e-cigarette is a requirement of EUTPD2, Article 20, 3(f) (The European Council and the Council of the European Union, 2014) [1]. The Directive states that e-cigarettes placed on the European Union (EU) market should "…*deliver the nicotine doses at consistent levels under normal conditions of use*."
- This means that the dose of nicotine should be within a specified acceptable range around a predefined target value (this can either be the mean average of the nicotine levels, or the labelled claim for nicotine delivery per puff). However, the EUTPD2 does not provide definitions of a "consistent level", "dose" or "normal conditions of use". Therefore defining consistency of nicotine delivery is open to interpretation.
- In 2016, the French national organization for standardization (AFNOR) published the experimental standard "Electronic cigarettes and e-liquids — Part 3" [2] which may form the basis of future European standards. This experimental standard requires the nicotine concentration for the first, third and fifth series of 20 puffs to be within ±25% of the mean value.
- The objective of this study was to assess whether the AFNOR acceptance criteria was achievable using blu™ e-cigarettes marketed in the EU.

2. Experimental Set Up

- Products tested were blu GO, PLUS, FILL and PRO (***Table 1***) with two e-liquids (***Table 2***).
- All device-liquid combinations were vaped on a linear smoking machine (SM450R, Cerulean) under CRM81 vaping regime described in ***Table 3***.
- Aerosol was collected for the first 100 puffs in five blocks of 20 puffs (n = 3).
- For each smoking run (each block of 20 puffs), aerosol was trapped on a 44 mm CFP (Cambridge Filter Pad). Nicotine was analysed using a GC/FID method (ISO 17025 accredited).
- All tests were performed using a square shaped puff profile. During vaping, the blu PRO (push button device) was automatically activated using an electronic thumb (customized in-house system).

Device	Types
GO	Closed-system
PLUS+	Closed-system
FILL	Open-system
PRO	Open-system

Table 1: e-cigarettes tested in this study

	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%

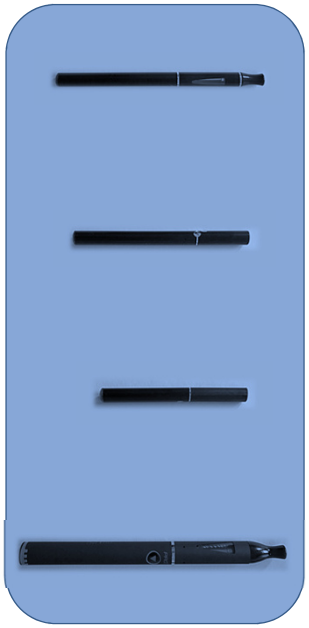
Table 2: e-liquids tested in this study

Puff duration (s)	Puff Volume (mL)	Puff Interval (s)	Puff Block 1	Puff Block 2	Puff Block 3	Puff Block 4	Puff Block 5
3	55	30	1 - 20	21 - 40	41 - 60	61 - 80	81 - 100

Table 3: Vaping regimes used for this study: *CRM 81 [3]*

3. Assessing consistent nicotine delivery

According to the AFNOR experimental standard, the consistent delivery of nicotine is assessed by measuring the quantity of nicotine emitted during the **first**, **third** and **fifth** series of 20 puffs.
The nicotine concentration measured for each of the three puff series should be within a range of ± **25% of the mean value of the three series.**
Figure 1 represents the relative differences from the mean of the puff series for each combinations (Product * E-Liquid * Puff block * Replicate). All product-liquid combinations were found to be within the limits of ± 25% defined by the AFNOR thereby complying with the standard for consistent nicotine delivery.



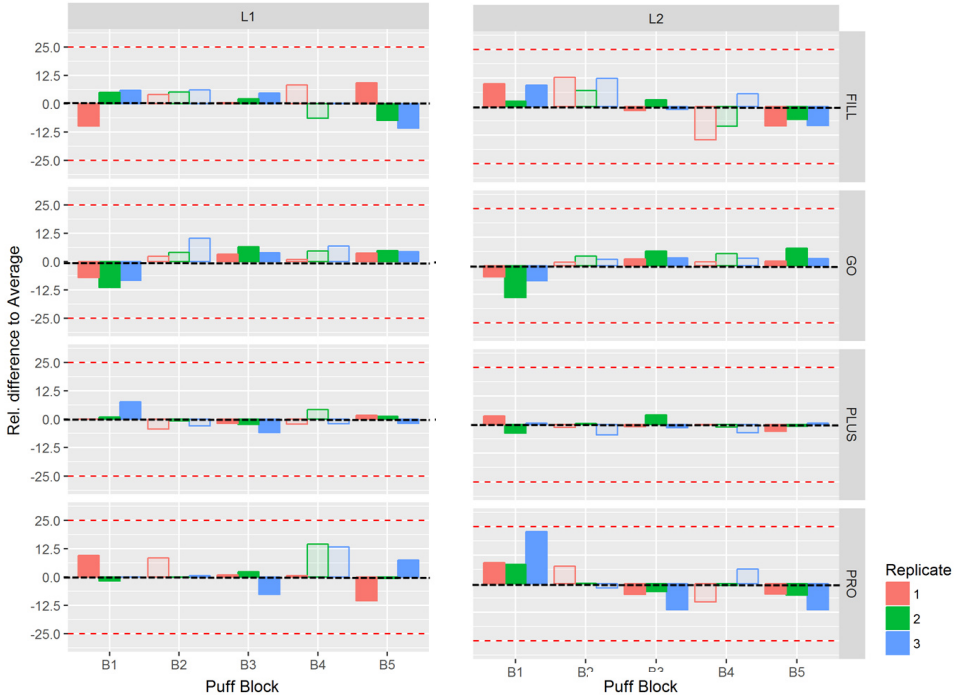


Figure 1: Characterization of nicotine emissions of nicotine for the blu products per puff block for the 2 e-liquids tested
The dashed black lines (y = 0.0) are the positions of each puff series mean.
The dashed red lines are the +/-25% limits for the puff mean series.
Bars that are in bold correspond to the AFNOR selection.

5. Conclusions

- Under the conditions of the test, the blu e-cigarette devices assessed deliver nicotine at consistent levels as defined by the AFNOR experimental standard XP D90-300-3.

References

[1] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC
[2] AFNOR - Association Française de Normalisation - XP D90-300-3: Requirements and test methods for emissions (July 2016)
[3] CORESTA Recommended Method CRM No. 81 "Routine Analytical Machine for E-Cigarette Aerosol Generation and Collection - Definitions and Standard Conditions". June 2015.

Disclosure

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Fontem Ventures B.V. is the manufacturer of the e-cig products used in this study.

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