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Client: AYR Labs
Report: SR24227 V2 Evaluation of the Refilla ENDS

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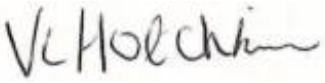

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1. INTRODUCTION

AYR Labs have developed a refillable Electronic Nicotine Delivery System (ENDS) comprising of a handheld aerosolising device and a desktop miniature refilling/recharging device. The collective name for the product is 'Refilla'. The design of Refilla addresses several regulatory and consumer aspects associated with ENDS in the UK/EU:

- Capable of complying with TPD/TRPR
- Capable of reducing toxicant exposure to the user of several common toxicants
- Capable of producing a consistent emission output over a prolonged duration

To evaluate the design, use and safety aspects of Refilla, the product was subjected to several analyses, including a comparative evaluation against market-leading ENDS available on the UK market.

The Refilla "dock" holds the vaporizer device and a bespoke 10ml pre-filled bottle of e-liquid. Once the device is docked into the station, a miniature peristaltic pump fills it with E-liquid and charges it to a pre-determined capacity in a 30-minute cycle time.

Analysis of Refilla included:

- Nicotine Delivery Consistency
- Flavour Delivery
- Aerosol Collected Mass
- Metals in Aerosol
- Toxicants (carbonyls) in Aerosol
- Labelled Puff Count

The device subject of this report is presented in Image 1 below.

1.1 SCOPE

The scope of this report is limited to the evaluation of the Refilla ENDS inclusive of the hand-held ENDS and refilling station. This report consolidates the findings over several individual studies where Refilla was analysed and includes analysis from both pre- (v01) and post-modification (v02) of the Refilla software intended to improve product safety and performance.

The data in this report has been selected for comparison based on the related results and the apparent importance for comparison including internal knowledge of the global regulatory landscape.

2. E-LIQUID VAPOURISED MASS

The e-liquid vapourised mass, or EVM, is a measurement of the output of a device following a period of use under standardised conditions. The purpose of measuring EVM is to provide an initial assessment of a device's performance consistency and to identify any major issues, e.g., a significant decline prior to exhaustion or significant variability.

2.1. Methodology

All ENDS was subject to aerosol generation conditions in accordance with BS EN ISO 20768, comprising the following parameters:

- Puff volume: 50mL
- Puff duration: 3 seconds
- Inter-puff duration: 30 seconds
- Puff profile: Square

Each device was weighed before and after use in blocks of 100 inhalations until the end of the device life was determined using Cerulean End Point Detection. The end of device life was determined when the amount of aerosol gendered was reduced by 60% based on light impedance. For refillable devices, these were recharged and used to the point of exhaustion based on the same criteria as for non-rechargeable devices.

The number of puffs obtained to the end point was recorded in addition to the total e-Liquid Vapourised Mass across the device life. The average EVM was determined by dividing the total ACM by the number of puffs achieved. The % RSD was established based on measured EVM across device life.

Note: Actual Collected Mass (ACM) is different to the EVM as with the ACM, the actual vapour condensate is collected onto a filter pad and the weight is taken of this residue. EVM considers the weight of the devices and therefore the liquid present and is used to back calculate the volume and "weight" of e-liquid used during operation.

2.2. Results

Table 2.2.1: Results of EVM analysis and puff count

Sample Details	Average Number of Puffs[1]	Average EVM per Puff[2]	Standard Deviation[3]	% RSD[4]
Logic Device	300	3.64mg	0.10	2.61
Refilla (v01)	2,765	6.32mg	0.64	10.14
VUSEGO	302	5.98mg	0.78	13.05
Lost Mary BM600	231	5.82mg	0.84	14.45
Lost Mary BM6000	221	8.63mg	1.50	17.33
Veev One	300	4.78mg	0.87	18.21
Njoy ACE	300	6.81mg	1.86	27.38
VUSE Pro	228	4.95mg	1.46	29.48
SMOK Novo	300	8.47mg	4.90	57.87
Blu Bar	300	4.10mg	3.09	75.43

% RSD (% Relative Standard Deviation)

Note:

1. **Average Number of Puffs** represents combined total number of puffs across all devices (different devices used for carbonyls and metals and at failure points) - eg Lost Mary 6000 samples ran to 172 puffs for A then 292 for sample B and 200 for sample C - Total 3 devices @ 664 puffs
2. **Average EVM per Puff** = Number of Puffs / Total Mass
3. **SD** is the Standard Deviation of the puff blocks
4. **%RSD** is based on the individual puff block differences collated across all measurements.

2.3. Conclusion

It can be seen in the data presented that the Logic Device produced the best relative standard deviation for the number of inhalations completed (300); the Refilla device was the second-best performing device even though the device conducted approximately nine times (900%) more inhalations than all the other devices tested. It was also noted that the Logic device although producing the best relative standard deviation the average EVM per puff was nearly half that of the Refilla device.

3. NICOTINE DELIVERY DOSE

The Refilla ENDS was subject to analysis to determine the dose of nicotine at a mid-life point (300 puff seconds) of a device over 10 inhalations. The dose of nicotine delivery is a core aspect of the consumer experience when using ENDS. It is common for ENDS to decrease in nicotine delivery as the output of the device decreases with decreasing battery voltage.

3.1. Methodology

The Refilla ENDS was subject to aerosol generation conditions in accordance with BS EN ISO 20768, comprising the following parameters:

- Puff volume: 50mL
- Puff duration: 3 seconds
- Inter-puff duration: 30 seconds
- Puff profile: Square

Samples were inhaled to waste for 160 inhalations and then 10 inhalations of aerosol were collected onto 44mm Cambridge Filter Pads (CFPs). The CFPs were extracted using an appropriate extraction solution and subject to analysis by GC-FID. Analysis was performed using a validated method in accordance with ISO 17025 under Inter Scientific's scope of accreditation.

3.2. Results

Table 3.2.1: Summary of nicotine dose **(Nicotine presented in mg/10 inhalations)**

Sample Details	Block 1 (0-50 inhalations) Average EVM per inhalation mg	Block 2 (50-100 inhalations) Average EVM per inhalation mg	Block 3 (100-160 inhalations) Average EVM per inhalation mg	Block 4 (160-170) inhalations) Average EVM per inhalation mg	Block 4 (160-170) inhalations) Nicotine mg/10 inhalations
Lost Mary BM6000 Menthol 20mg/ml	10.13	10.34	8.07	11.20	1.72
Refilla 10k Puffs Green (2437)	6.94	6.75	6.80	7.04	1.37
Vuse Go Edition 01 Mint Ice 20mg/ml	6.82	6.82	6.62	6.25	1.06
Veev One Blue Mint 1.8%	5.87	5.91	5.77	4.94	0.99
Vuse Mint Ice 2000 puffs 20mg/ml	5.80	5.81	5.73	5.52	0.98
Lost Mary Menthol 2%	7.56	6.33	5.96	5.54	0.86

3.3. Conclusion

It can be seen from the above results that the Refilla device achieved the second highest Nicotine dose of the products tested with the higher “volume” Lost Mary BM6000 achieving the highest Nicotine dose.

4. FLAVOUR DELIVERY

Assessment of the consistency of flavour (non-nicotine) components was performed in order to evaluate the consistency of aromatic or volatile compounds across several devices. Whilst nicotine consistency has been established, the consistency of aromatic or volatile compounds in aerosol in not necessarily intrinsically linked. Both formulation properties and device functionality, including temperature of coil, may result in variability of favour delivery.

4.1. Methodology

For the purpose of this assessment, menthol was used as a surrogate flavour, common across several products. Four of the five products used in the assessment of nicotine consistency contained menthol.
Samples of aerosol were collected onto 44mm Cambridge Filter Pads (CFPs). The CFPs were extracted using an appropriate extraction solution and subject to analysis by GC-FID. Analysis was performed using a validated method in accordance with ISO 17025 under Inter Scientific's scope of accreditation.

4.2. Results

Table 4.2.1: Summary of flavour consistency (Menthol presented in mg/10 inhalations)

Sample Details	Block 1 (10-20 inhalations)	Block 2 (20-30 inhalations)	Block 3 (30-40 inhalations)	Average	SD	%RSD
VUSE Pro – Mint Ice	0.48	0.47	0.45	0.47	0.02	3.27
Lost Mary BM6000 - Menthol	0.46	0.45	0.48	0.46	0.02	3.30
Refilla(v01) – Menthol	0.47	0.48	0.51	0.49	0.02	4.28
VUSEGO – Mint Ice	0.53	0.59	0.64	0.59	0.06	9.39

4.3. Conclusion

It can be seen from the data presented that the menthol delivery is comparable in the tested products with the VUSE GO being the least consistent in flavour delivery (concentration of menthol in the aerosol).

5. METALS IN AEROSOL

Assessment of the content of metals in the aerosol component was performed to evaluate the potential degradation of the vaporiser components. Whilst metal content has been can be established to be at or below detection levels for e-liquids the process of creating aerosol can thorough the applied heating of a metal coil can cause degradation of the metal components which can be presented in the aerosol.

5.1. Methodology

The Refilla ENDS was subject to aerosol generation conditions in accordance with BS EN ISO 20768, comprising the following parameters:

- Puff volume: 50mL
- Puff duration: 3 seconds
- Inter-puff duration: 30 seconds
- Puff profile: Square

Samples of aerosol were collected into a solvent of 5% Nitric Acid and 10% Methanol utilising an impinger aerosol capture device. The solutions were subject to analysis by ICP-MS. Analysis was performed using a validated method in accordance with ISO 17025.

5.2. Results

Table 5.2.1: Aerosolised nickel in devices

Puff Block	**0-100 puffs**	**100-200 puffs**	**Average for 100 puffs µg**	**2000 - 10 days @200 puffs - µg**
Sample Details	**µg/100**			**µg/2000**
Lost Mary BM6000	ND	ND	ND	0.5^
VUSEGO	ND	ND	ND	0.5^
Lost Mary BM600	0.1	0.19	0.145	1.45
VUSE Pro	0.07	0.32	0.195	1.95
Refilla (v01)	ND	ND	ND	0.5^

Note:
ND – None Detected
^ - 10-day consumption values have been calculated at the LOD value of 0.05ug/100 inhalations for none detected values.

Table 5.2.2: End of life test for Aerosol Nickel

Study	Sample Details	µg/50 Tested at end of life of the product
PN24128.3	Refilla (v02)	<0.06

Note:
*Refilla v01 is the original supplied device
**Refilla v02 is data from latest samples and tested at 3300-3450 inhalations
Nickel (LOD = 0.05µg/100 Inhalations and LOQ = 0.06 µg/100 Inhalations)
All other additional analytes were below the limit of detection.

5.3. Conclusion

It can be seen from the data provided that the Refilla device would deliver 4 times less Nickel over its operational life than the worst performing device, with it releasing half of the nickel content than the average of the devices tested for a longer duration. The Refilla device was also tested after "end of life" would be considered to show the devices worst case emittance and this was lower than two of the devices at just 200 inhalations.

6. CARBONYLS IN AEROSOL

The excessive heating of e-liquid may result in the terminal degradation of the formulation, leading to an increase in detectable levels of several carbonyls, including formaldehyde. Excessive heating may result from due to several causes including: excessive heating of the coil/excessive energy to coil, inconsistent coil resistance resulting in 'hot spots',

6.1. Methodology

The Refilla ENDS was subject to aerosol generation conditions in accordance with BS EN ISO 20768, comprising the following parameters:

- Puff volume: 50mL
- Puff duration: 3 seconds
- Inter-puff duration: 30 seconds
- Puff profile: Square

Samples of aerosol were collected into a solvent of DNPH utilising an impinger aerosol capture device. The solutions were subject to analysis by HPLC. Analysis was performed using a validated method in accordance with ISO 17025 under Inter Scientific's scope of accreditation.

6.2 Results

Table 6.2.1: Aerosolised Formaldehyde in modified Refilla device and comparable ENDS.

Puff Block	0-100 puffs	100-200 puffs	400-500 puffs	900-1,000 puffs	1,900-2,000 puffs	2,900-3,000 puffs	Average for 100 puffs µg	2,000 - 10 days @ 200 puffs - µg
Device	**µg/100**							**µg/2000**
Refilla (v02)	ND	ND	ND	ND	ND	ND	ND	9.0^
Lost Mary BM600	ND	ND	-	-	-	-	ND	9.0^
Veev One	ND	ND	-	-	-	-	ND	9.0^
Logic Device	ND	ND	-	-	-	-	ND	9.0^
Njoy Ace	ND	ND	-	-	-	-	ND	9.0^
Lost Mary BM6000	0.45	1204.17	-	-	-	-	602.31	12046.2
VUSEGO	1.27	ND	-	-	-	-	0.86	17.2^
Blu Bar	1.27	ND	-	-	-	-	0.86	17.2^
VUSE Pro	2.24	1.27	-	-	-	-	1.76	35.2
SMOK Novo	549.2	35.7	-	-	-	-	292.45	5849

Note:
Cells in grey indicate device was not tested due to device life.
Formaldehyde (LOD = 1.27µg/100 Inhalations and LOQ = 0.45 µg/100 Inhalations)
ND – None Detected
^ 10-day consumption values have been calculated at the LOD value of 0.05ug/100 inhalations for none detected values.

Table 6.2.2: Aerosolised Acetaldehyde in modified Refilla device and comparable ENDS.

Puff Block	0-100 puffs	100-200 puffs	400-500 puffs	900-1,000 puffs	1,900-2,000 puffs	2,900-3,000 puffs	Average for 100 puffs µg	2,000 - 10 days @ 200 puffs - µg
Device	**µg/100**							**µg/2000**
Refilla (v02)	ND	ND	ND	ND	ND	ND	ND	18.6^
Lost Mary BM600	ND	ND	-	-	-	-	ND	18.6^
Veev One	ND	ND	-	-	-	-	ND	18.6^
Logic Device	ND	ND	-	-	-	-	ND	18.6^
Njoy Ace	ND	ND	-	-	-	-	ND	18.6^
Lost Mary BM6000	ND	2024.53	-	-	-	-	1012.73	20254.6^
VUSEGO	ND	ND	-	-	-	-	ND	18.6^
Blu Bar	ND	ND	-	-	-	-	ND	18.6^
VUSE Pro	10.46	11.05	-	-	-	-	10.76	215.2
SMOK Novo	671.3	37.4	-	-	-	-	354.35	7087

Cells in grey indicate device was not tested due to device life.
Acetaldehyde (LOD = 2.3 µg/100 Inhalations and LOQ = 0.93 µg/100 Inhalations)

Note:
LOQ value used if <LOQ
"–" signifies "Not tested"
ND – None Detected
^ 10-day consumption values have been calculated at the LOD value of 0.05ug/100 inhalations for none detected values.

Refilla consistently contains no Formaldehyde where other devices had seen to "spike" or dry wick.

6.3. Conclusion

It can be seen from the data obtained that the modified Refilla v02 device was able to perform through its life without the production of carbonyls. The software modification from Refilla v01 to v02 removed any small traces of carbonyls from the vapour output. Three of the competitor devices tested did show elevated levels of carbonyls during the testing periods they were active.

7. LABELLED PUFF COUNT

The labelled puff count confirmation is a measurement of the output of a device following a period of used under standardised conditions. The purpose of measurement of total number of puffs is to prove the labelled claim performance of a device and to identify gross issues, such as a significant decline prior to exhaustion or significant variability.

7.1. Methodology

The Refilla ENDS was subject to aerosol generation conditions in accordance with BS EN ISO 20768, comprising the following parameters:

- Puff volume: 50mL
- Puff duration: 3 seconds
- Inter-puff duration: 30 seconds
- Puff profile: Square

The number of inhalations were measured before the aerosol fell by 60% of the total initial aerosol volume at the beginning of testing, the number of inhalations were then recorded over multiple samples.

7.2. Results

Table 7.2.1: Puff Count Totals

Study	Sample Details	Claimed Puff seconds	Puffs (3 seconds)	Achieved Device 1	Achieved Device 2	Achieved Device 3	Average	% of total	Comment for report
PN24128	Lost Mary BM6000	6000	2000	172	292	124	196	9.8	10% of stated
PN24128	VUSEGO	800	266.67	306	298		302	113.25	Achieved assuming reported in 1 seconds
PN24128	Lost Mary BM600	600	200	237	225		231	115.5	Achieved assuming reported in 1 seconds
PN24128	VUSE Pro	1900	633.33	380			380	60	60% of stated
PN24128.3	Refilla v02	10000	3333.33	3500	3500	3500	3500	105	Achieved

7.3. Conclusion

It can be seen from the data obtained that the Refilla device achieved and even exceeded it stated puff count where the comparable device only achieved 10% of its stated capacity and puts this in line with devices with up to a 10% smaller claim.

8. ANNEX

8.1. Annex I: Previous study and report list

- PN24097
- PN24128
- PN24128.2
- PN24128.3
- PN25010

8.2. Annex II: Comparator product images.

Image 8.2.1: Lost Mary BM6000

Image 8.2.2: Lost Mary BM600

Image 8.2.3: VUSE GO

Image 8.2.4: VUSE PRO

Image 8.2.5: Veev One

Image 8.2.6: Logic

Image 8.2.7: Blu Bar

Image 8.2.8: SMOK Novo 2

Image 8.2.9: NJOY Ace

9. CHANGE HISTORY

Document Change History			
A#	**Change Summary**	**Version**	**Date**
-	New DRAFT document	1	December 6th, 2024
-	DRAFT version finalised – draft watermark removed, and document approved.	1	December 16th, 2024
25-025	Updated section 2 – additional note added Updated Section 3 – Updated results from PN25010 Updated Section 5 – Added additional "Note" Updated Section 8 – Addition of new study number	2	February 05th, 2025