Ambulatory Use of Electronic Nicotine Delivery Systems - Redefining Topography Endpoints

Robert Underly, Evan Nudi, Tim Pionk, and Jeffrey Smith

Current Topography Assessments

Rochester Institute of Technology

In Clinic Use

- Confinement (with some combination of the below):
  - Fixed puff count
  - Fixed puff session length
  - Fixed time in clinic
  - Variable methods of quantification

Natural Environment

- Ambulatory Use
- “Sessions” of use
- Portable data capture device

The Landscape of Topography Endpoints

Current Endpoints
Puff Duration
Puff Volume
Time Between Puffs
Flow Rate
Puffs Count

- Each endpoint is contingent on the test condition (natural environment vs confinement).
- Puffs counts are currently difficult to understand broadly as some studies hold this variable constant or limit subjects' time with the product.
- No study has currently reported cumulative data for endpoints over a day of use.

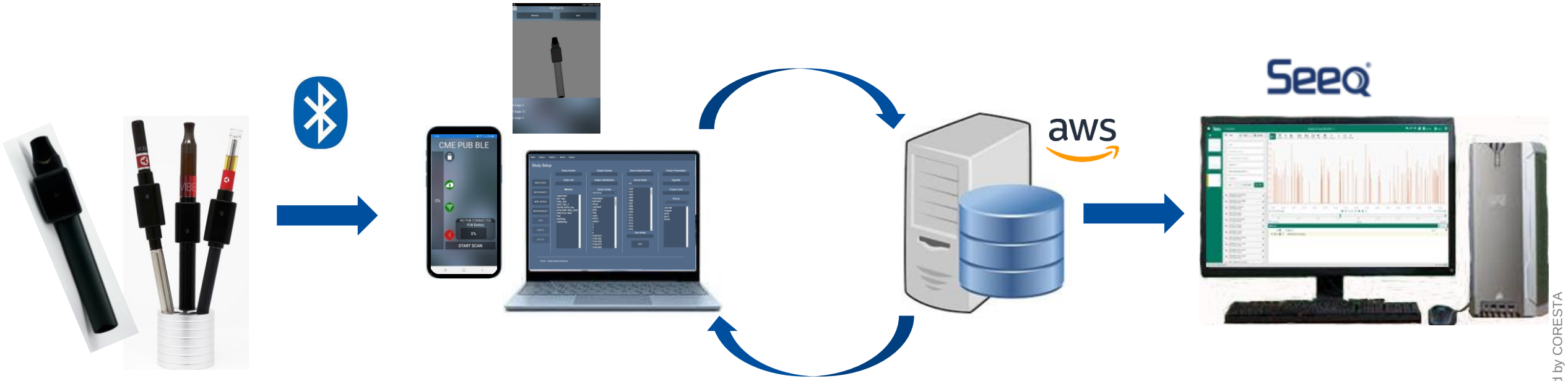
Product Use and Behavior (PUB) Instrument

Parameter	Unit
Puff Duration	Seconds (s) (battery active)
Number of Puffs	Count (# of battery activations)
Sessions of Use	Count
Inter Puff Interval (IPI)	Seconds (s) (Latency between activations)
Angle of Use	Puff initiation and conclusion (XYZ planes)
Battery Characteristics	Voltage and Current
…with the addition of every data point collected is time/date stamped	

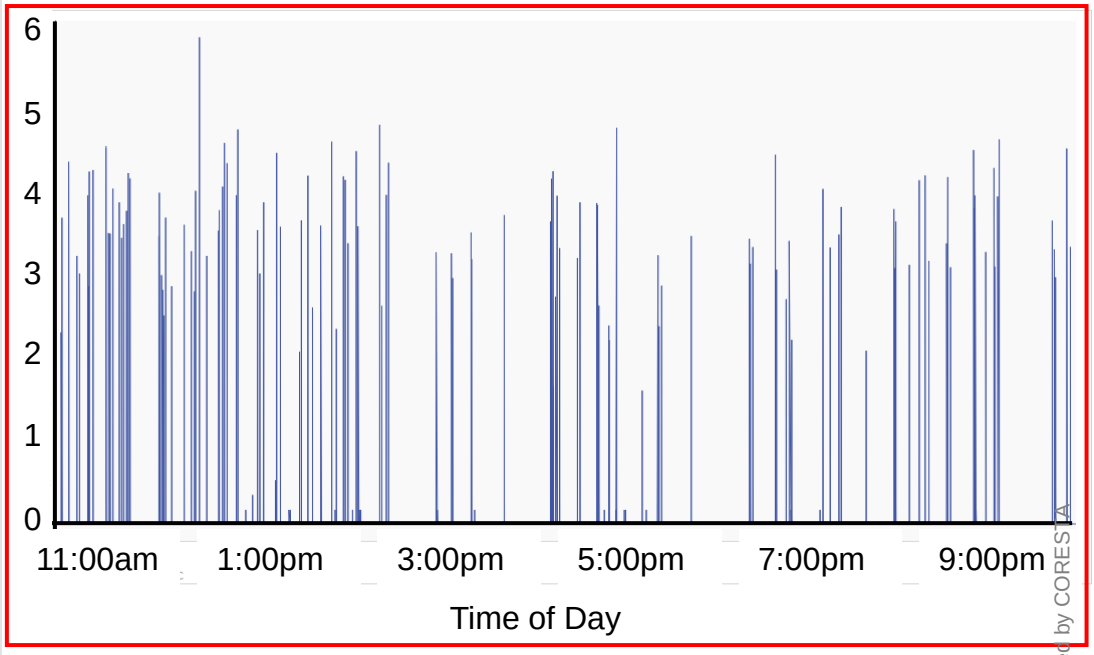
Product Use and Behavior (PUB) Instrument

Product Characteristics with and without the PUB		
	Vuse Alto	Vuse Alto with PUB
Product Battery Life (mean puffs)	209	210
PUB Battery Life (mean puffs)	N/A	2000
Idle Battery Life (hours)	>168	72
Mean Puffs per Cartridge	304	310
Product Charge Time (minutes)	55 ± 7	N/A
PUB Charge Time (minutes)	N/A	15 - 60
Total Particulate Matter (55/30/3)	6.46	6.09
Pressure Drop (mmWg)	105	125
Product Length (mm)	105	145
Product Weight (grams)	22.6	42.8
Activated Product Voltage	3.0	3.0
Product Resistance	1.25	1.35

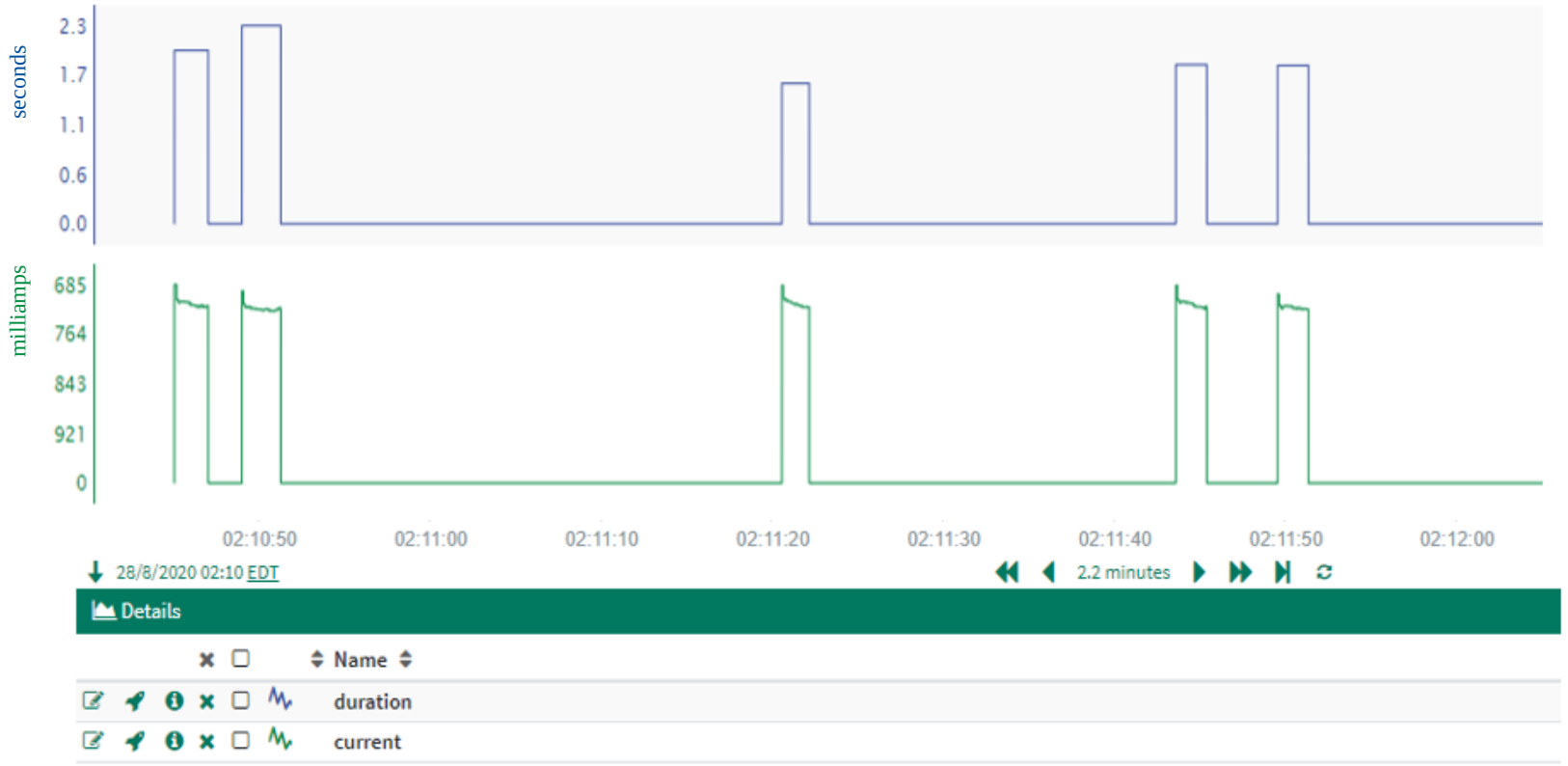
Product Use and Behavior Instrument



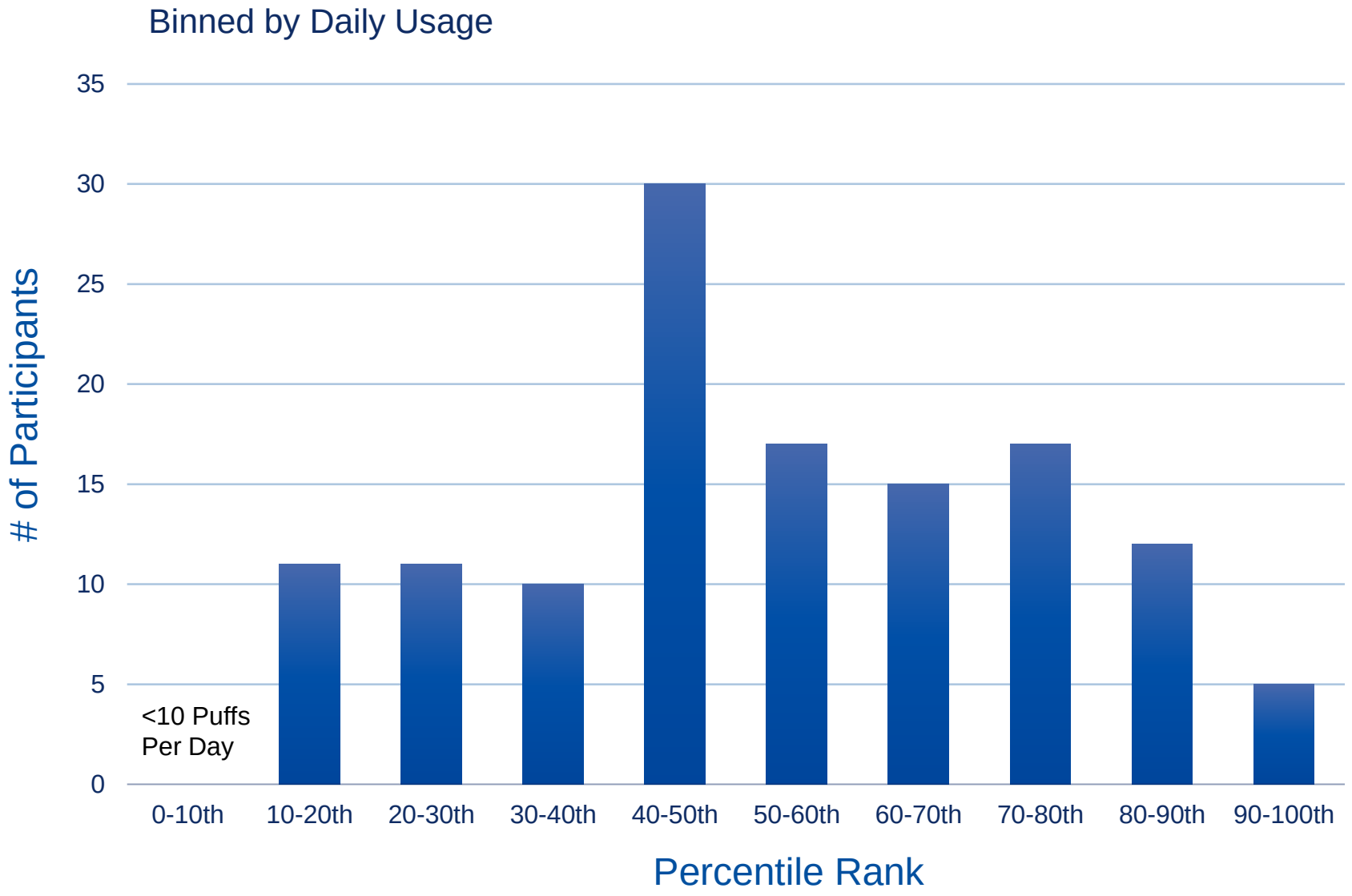
Cumulative Time-series Data



SEEQ – Real-time Analysis

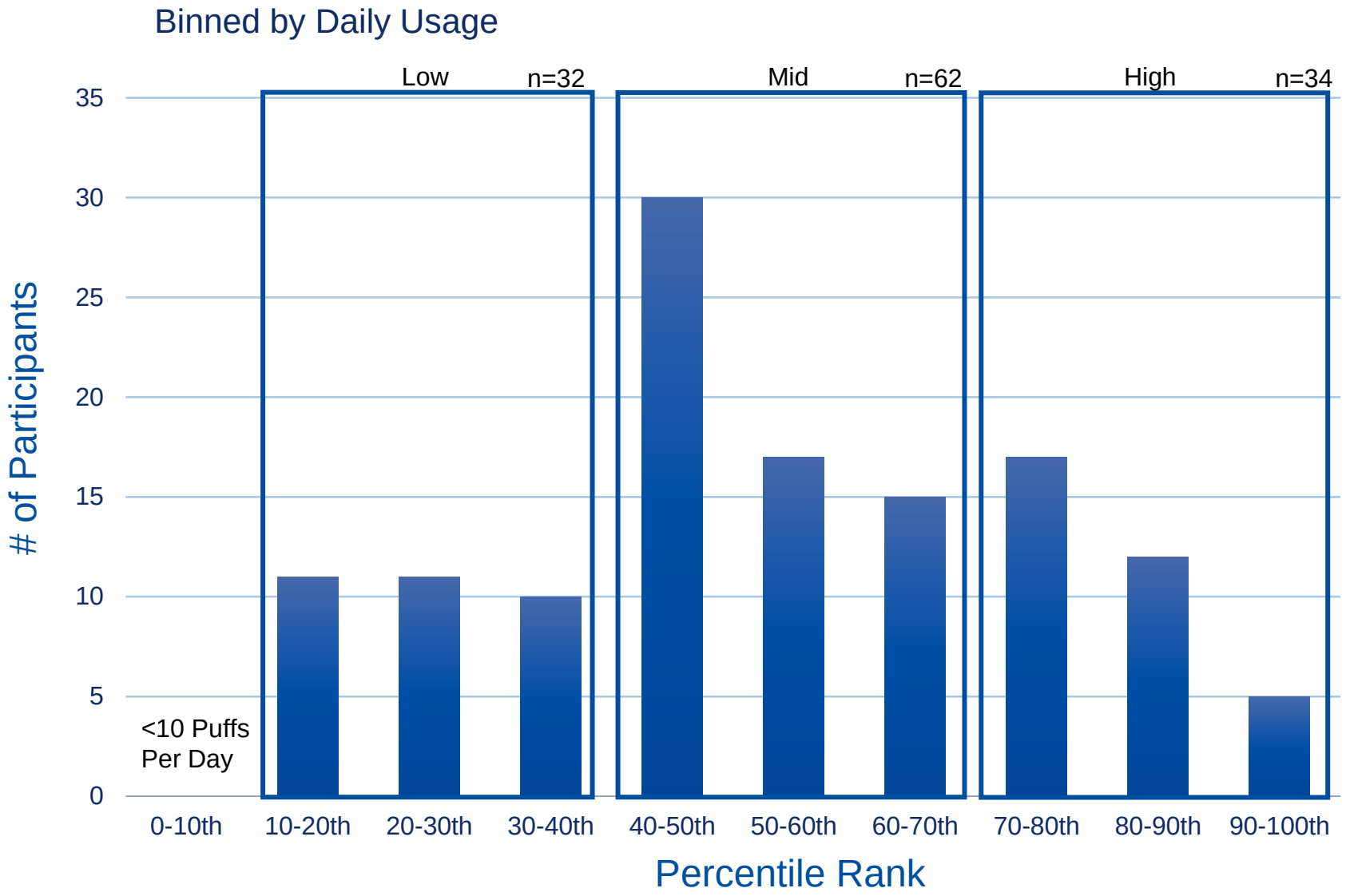


Understanding the Stratification of Use



Percentile	Mean Puffs per Day
0 – 10th	N/A
10th – 20th	18.27
20th – 30th	34.89
30th – 40th	57.92
40th – 50th	82.30
50th – 60th	104.29
60th – 70th	133.82
70th – 80th	162.23
80th – 90th	211.99
90th – 100th	305.04

Understanding the Stratification of Use



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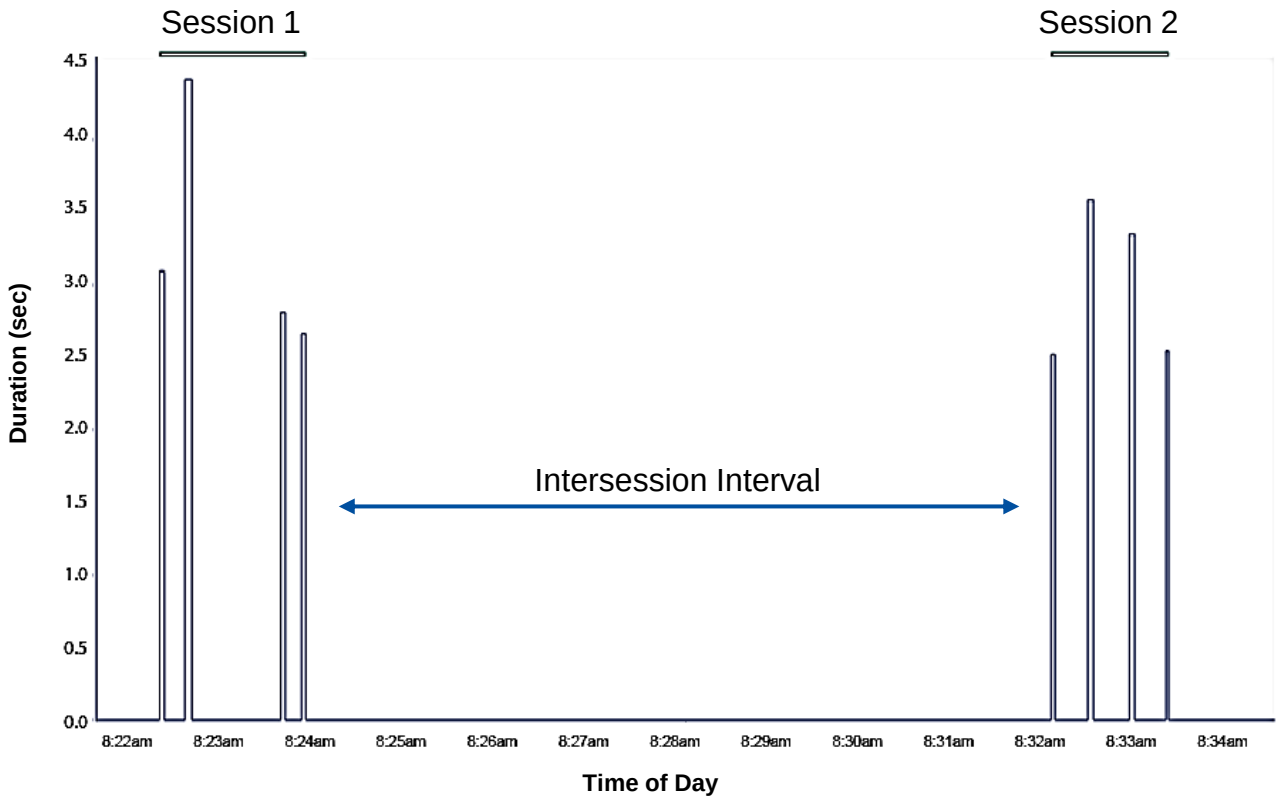
Defining Sessions of Use

Operational Definition for Session:

A period of use in which consecutive puffs occur without exceeding the mean Inter-puff interval (IPI). Gaps between puffs that exceed the mean IPI are identified as Intersession Intervals.

An initial data “cleansing” step was performed in which the 95th-99th percentile of IPIs were removed (12 – 16 hour gaps in use) from each subject.

Intersession Interval



Intersession Interval		
Group	Mean (sec)	St. Dev.
Low	177.09	± 451.52
Mid	57.67	± 215.28
High	22.09	± 99.68

Topography Endpoints

Variable	Mean	St. Dev.
Mean Puffs Per Day	111.25	± 68.31
IPI (sec)	3671.66	± 6541.64
Mean Puff Duration (sec)	2.60	± 1.18

n=128

Using only the traditional topography endpoints for cumulative time-series data, the data provide limited insight into use behavior.

Topography Endpoints in the Context of Sessions

REYNOLDS
A BETTER TOMORROW

Variable	Low Users		Mid Users		High Users	
	Mean	St. Dev.	Mean	St. Dev.	Mean	St. Dev.
Mean Daily Puffs	36.37	± 17.40	100.79	± 22.17	200.80	± 53.51
Mean Daily Sessions	6.83	± 6.51	22.05	± 13.09	58.75	± 31.29
Session Length (sec)	158.92	± 301.11	146.27	± 277.10	90.75	± 185.37
IPI with Sessions (sec)	51.00	± 72.22	45.67	± 48.68	35.06	± 38.03
Puffs within Sessions	5.02	± 7.30	4.44	± 6.08	3.40	± 4.30
Mean Puff Duration (sec)	2.36	± 1.43	2.80	± 1.27	2.49	± 1.07
Intersession Interval (min)	177.09	± 451.52	57.67	± 215.28	22.09	± 99.68

Low users: n=32; Mid Users: n=62; High Users: n=34

Topography Endpoints in the Context of Sessions

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Topography Endpoints in the Context of Sessions

Variable	Vuse Solo		Vuse Ciro		Vuse Vibe		Vuse Alto	
	Mean	St. Dev.	Mean	St. Dev.	Mean	St. Dev.	Mean	St. Dev.
Mean Daily Puffs	184.41	± 97.99	205.05	± 161.02	247.66	± 154.49	200.80	± 53.51
Mean Daily Sessions	32.26	± 19.56	43.48	± 37.30	71.55	± 63.66	58.75	± 31.29
Session Length (sec)	156.98	± 313.12	99.46	± 222.86	60.33	± 144.29	90.75	± 185.37
IPI within Sessions (sec)	26.89	± 60.40	23.51	± 26.72	20.25	± 22.63	35.06	± 38.03
Puffs within Sessions	6.04	± 6.74	5.19	± 7.94	3.71	± 5.53	3.40	± 4.30
Mean Puff Duration (sec)	2.11	± 0.84	2.69	± 1.25	1.95	± 1.13	2.49	± 1.07
Intersession Interval (min)	57.66	± 260.97	33.55	± 157.17	20.59	± 121.70	22.09	± 99.68

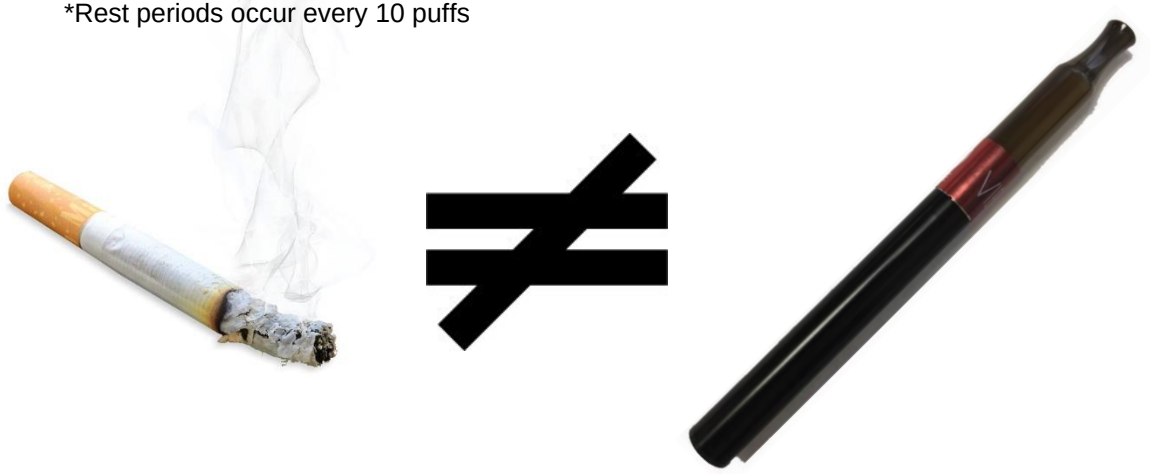
Data from the 70th percentile of use. Solo: n=19; Ciro: n=16; Vibe: n=15; Alto: n=34

Advancing Topography

- Ambulatory data collection, along with appropriate data analytics, allows for a more expansive scope of consumer use behavior.
- Understanding patterns of use may allow for the improvement of products to be more acceptable to smokers wanting to transition to products lower on the risk continuum
- Using these data to drive analytic testing (puff regimen) parameters can provide more accurate estimates of consumer exposure.

	Regimen	Volume	IPI	Duration	Rest Period
Current	Non-Intense	55	30	3	N/A
Current	Intense	80	15	5	N/A
New	Non-Intense	55	30	3	60 sec*
New	Intense	80	15	5	60 sec*

*Rest periods occur every 10 puffs



Acknowledgements

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