A Novel Approach to the Assessment of Electronic Cigarette Topography Characteristics

Jeffrey S. Smith[1] and Steven Alderman[2]

RAI Services Company[1] and RAI Innovations Company[2], Winston Salem, NC, USA

Abstract

The use of electronic nicotine delivery systems (ENDS) has increased dramatically over the last decade. However, during this same period of time, there has been very little empirical evidence to describe how consumers use these new products. One reason for this scarcity of data is that techniques and approaches used to collect topography (puff) characteristics have yet to catch up with the changes in format and function of new ENDS products. We have developed a new approach that will assess ENDS topography use characteristics in both controlled (in-clinic) and naturalistic (ambulatory) environments. The Product Use and Behavior (PUB) instrument is positioned between the power unit and cartridge of an ENDS product and acts as a sentinel, recording the periods of product activation over a continuous period of use without impacting how the subject interacts with the ENDS product. This new approach provides data on puff duration, inter-puff interval, total number of puffs, battery characteristics (voltage/current), as well as how these characteristics vary across use sessions in the form of cumulative use patterns over time. Additionally, data captured by the PUB instrument can also be used to estimate mouth level exposure (eMLE) per puff and over product use periods. The PUB instrument produces data that will provide insights into how consumers interact with and use ENDS products.

Introduction

Electronic nicotine delivery system (ENDS) products have been marketed in the United States for more than a decade. Developing the tools needed to understand how consumers use these products has been an ongoing challenge. Scientists have explored and used several approaches to measure ENDS use. Some have attempted to use traditional topography instrumentation, which evaluate changes in air flow / air pressure to identify puffing patterns. Other groups have implemented techniques that evaluate recorded-use sessions. A third approach used by some labs is to develop new instruments that allow for some ambulatory evaluation of ENDS product use.

We have developed a new approach to ENDS product use measurement which resolves many of the existing challenges associated with evaluating ENDS use. The Product Use and Behavior (PUB) instrument for ENDS products can effectively measure actual use patterns of ENDS products in near real-time and produce data that may improve the understanding of how consumers use ENDS products. The overarching goal of this effort was to produce a simple and durable tool that would not impair normal use experience for the end-user, be easy to implement in either clinical or ambulatory studies, and provide data on multiple aspects of product usage. An additional driving priority was that the PUB instrument would minimally impact the normal functioning of the ENDS product as the PUB acquires data.

The Product Use and Behavior Instrument

Product Use Measurements

Parameter	Unit
Puff Duration	Seconds (s) (battery active)
Number of Puffs	Count (# of battery activations)
Number of Sub-Puffs	Count
Inter Puff Interval (IPI)	Seconds (s) (latency between activations)
Angle of Use	Puff initiation and conclusion (XYZ planes)
Battery Characteristics	Voltage and current
Every data point collected is time/date stamped	

Data Management

- At the completion of a segment of data acquisition, the PUB instrument will sync with a Bluetooth-compatible device and begin the upload process (near real-time)
- Data are uploaded to an Amazon Web Services Redshift Database
- All aspects of data transfer and storage processes are US FDA compliant (per 21 CFR Part 11)
- Data are accessible for additional analytics (direct or via export)

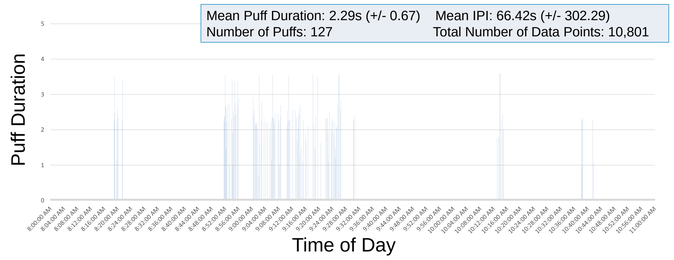
Assessment of PUB Accuracy

Smoking Regimen	Mean Duration (Sec)	Mean IPI (Sec)	Mean Voltage at Battery	Mean Voltage at Cartridge	Mean Current (mA)	Mean PUB Resistance
55/2/30	1.928 (+/- .02)	28.515 (+/- .02)	3.205 (+/- .03)	3.057 (+/- .03)	1467 (+/- 21)	0.216 Ω
55/3/30	2.915 (+/- .07)	27.177 (+/- .07)	3.185 (+/- .06)	3.031 (+/- .06)	1538 (+/- 79)	
55/4/30	3.892 (+/- .11)	26.607 (+/- .11)	3.264 (+/- .09)	3.116 (+/- .10)	1483 (+/- 29)	
55/5/30	4.812 (+/- .08)	25.690 (+/- .08)	3.188 (+/-.12)	3.025 (+/- .12)	1629 (+/- 39)	

- Several versions of the PUB instrument (across several ENDS products) were evaluated to determine accuracy of puff measurement
- ENDS products with PUB instruments installed were evaluated on a Cerulean SM450 across several puffing regimens
- Duration and IPI measures were within an acceptable margin of error and were consistent across all trials (a total duration of 30 seconds for each puff trial [puff duration + IPI] was captured by the PUB instrument)
- There was a minimal loss of voltage through the PUB instrument
- The installation of the PUB minimally impacts resistance between the ENDS battery and e-liquid cartridge

Internal Pilot Evaluation

	Product A (N=8)	Product B (N=10)
Mean Puff Duration	3.01s (+/- 1.38)	2.47s (+/- 1.29)
Mean Number of Puffs	176.11 (+/- 133.05)	173.80 (+/- 63.43)
Mean IPI	6892.82s (+/- 73981.88)	5943.68s (+/- 72091.46)
Mean Voltage	3.18 (+/- 0.20)	3.60 (+/- 0.16)
Mean Current	1569.48 (+/- 207.78)	1222.43 (+/- 217.57)



With ENDS products the IPI now represents multiple different measures that will need to be quantified in a manner that is different from previous topographical approaches (e.g., within bout IPI, between bout IPI, and overnight). We are currently developing non-biased approaches to define what an IPI is and how it needs to be quantified and how inter-session intervals (ISI) should be operationalized.

Estimate of Mouth Level Exposure

Several investigators have shown that total particulate matter (TPM) production rates are “constant” within a battery / e-liquid system. Since the PUB captures the length of puff and battery characteristics during individual puffs, these values can be used to generate an estimate of TPM production per puff, if the TPM production rate is known. These data, generated over a period of use, can be used as an estimate of mouth level exposure (eMLE) for either the total TPM, or (assuming the composition of the e-liquid is known) eMLE of each constituent of the e-liquid. We are currently generating constants for several battery / e-liquid product combinations to determine if this approach produces useful eMLE insights.

Conclusions

The initial R&D bench testing and data from our internal pilot study suggest that the Product Use and Behavior instrument for ENDS products can effectively measure actual use patterns in near real-time and produce data that may improve our understanding of how consumers use ENDS products. Additional efforts are ongoing that will increase the ease of interpreting use patterns and to generate values for a wide variety of products and flavors for evaluation of this tool for MLE estimation.

Acknowledgements

The authors would like to acknowledge Bradley Brown from Carolina Medical Electronics for his efforts supporting the design and development of the PUB, Geraldine Neal and Christine Campbell for their support performing the internal pilot study, and Megan Whelen and Robert Underly for their editorial support in the development of this poster. Additional thanks to the many RAIS/RAII team members that provided guidance throughout the development of this instrument.