Estimation of Second Hand Exposure Levels from ENDS and Conventional Cigarette Use, Using Computational Modeling

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Ali A. Rostami*, Jeffery S. Edmiston, George D. Karles

Altria Client Services LLC, Research, Development and Sciences, Richmond, VA 23219, USA

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ABSTRACT

The pre-market tobacco product application (PMTA) draft guidance for an electronic nicotine delivery system (ENDS) recommends providing data that adequately characterize the likely impact of the new product on the health of both users and non-users of the tobacco product. Further, during the public seminar on PMTA for ENDS (November 2016), FDA suggested that when discussing the impact on nonusers, second-hand, and third-hand exposures should be considered.

A computational model to estimate room air levels of selected aerosol constituents has been developed based on well-established physical laws of mass transfer, air flow, and thermodynamic relationships. The model has been verified and validated with experimental data and can be used to estimate the concentrations of selected constituents over time in pre-defined spaces based on the presence of selected constituents in the exhaled breath of ENDS users, or side stream smoke of burning cigarette. The amount of selected constituents in exhaled breath, when using an e-vapor device, was determined experimentally in controlled clinical trials. The side stream smoke data were identified from the published literature.

The model was applied to various space settings such as a car, a private office and a restaurant. Equivalent product use conditions (number of users, product consumption, length of use) for ENDS and conventional cigarettes were used in order to compare the estimated levels of nicotine, formaldehyde, propylene glycol, glycerin and other constituents in each space.

Results indicate that the estimated concentration of nicotine in each space setting due to exhaled aerosol from a cig-a-like ENDS product was approximately 20 times less than a conventional cigarette and two orders of magnitude less than the OSHA permissible limit. The estimated value for formaldehyde during ENDS use was three orders of magnitude less than during cigarette use and between four and five orders of magnitude less than the OSHA limit. The concentrations of propylene glycol and glycerin in each space were also estimated to be orders of magnitude less than the NIOSH and OSHA limits. More data are needed before extending our findings to open tank, modifiable systems.

INTRODUCTION

Development of methodologies that advance our scientific understanding and ability to estimate exposure of users and non-users to ENDS aerosol is critical for characterizing the health impact of ENDS products on the population as a whole.

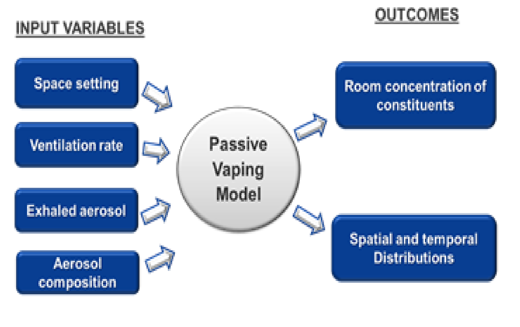
Computational models have a long history of use for estimating and predicting air quality and the level of chemicals in indoor environments (NRC 2007). Models of both indoor and outdoor air quality assessment have been referenced by the US Environmental Protection Agency (EPA) as predictive tools for scientific and educational purposes (EPA 2014, EPA 2015, EPA 2016)

OBJECTIVE

Use computational modeling, validated by experimental data, as a tool to estimate concentrations of aerosol constituents in several confined spaces where ENDS or combustible cigarettes are used.

MODEL DEVELOPMENT

Non-user Exposure Characterization Models



Physics-based models that include fluid flow, mass and heat transfers along with thermodynamic and kinetic interactions

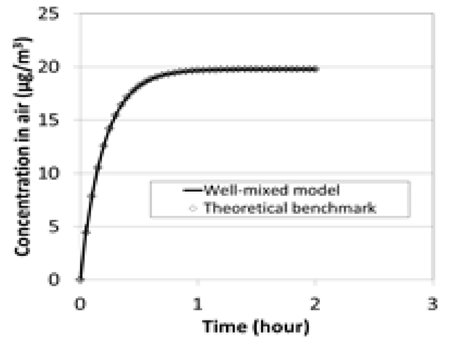
Two Types of Computational Models [7]

Models based on principles similar to those used in the indoor air quality assessment models, referred to by the EPA

Well-mixed Model	Distributed CFD Model
- Total, vapor and particulate concentrations of each constituent in air	- Total, vapor and particulate concentrations of each constituent in air
- Average values for the entire space as a function of time	- Spatial and temporal distribution inside the space

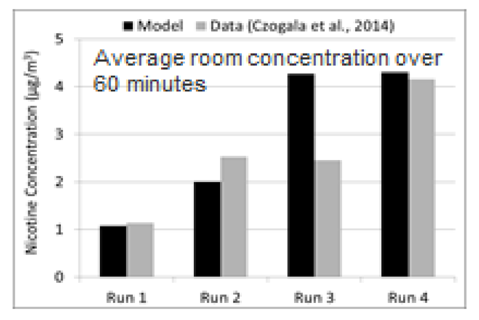
VERIFICATION AND VALIDATION

Verification



Conditions
Space volume : 100 m³
Air change rate : 5 ACH
Number of occupants in room : 15
Duration: 2 hours
Rate of release of constituent : 10 mg/hr

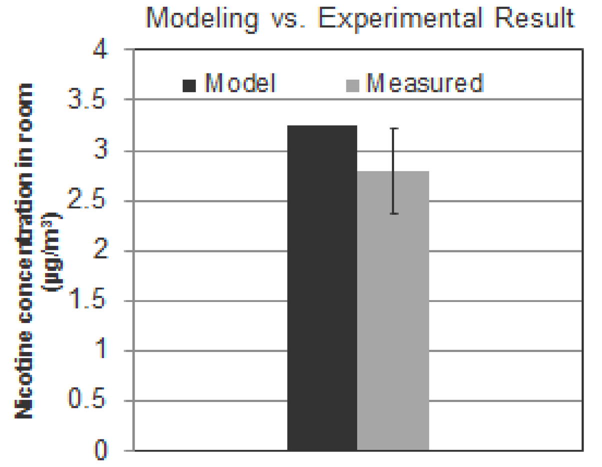
Validation (1)



Conditions
Space volume : 39 m³
Air change rate (ACH) : 6.8 (runs 2-4), 9.8 (run 1)
Smoking machine generated aerosol
Duration: 1 hour
Rate of release of constituent : 7 puffs (runs 1, 2) and 15 puffs (runs 3, 4)

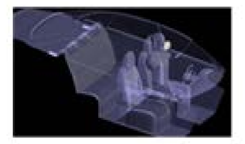
Validation (2)

Controlled Clinical Study [8]:
- 9 individuals took 10 puffs every 30 min for 4 hours on a cig-a-like e-vapor product
- 5s puff duration
- Measured room air levels of selected constituents over 4 hours

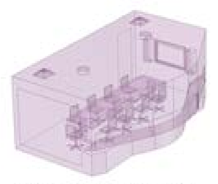


INPUT DATA: Exhaled Aerosol (ENDS) vs. Cigarette

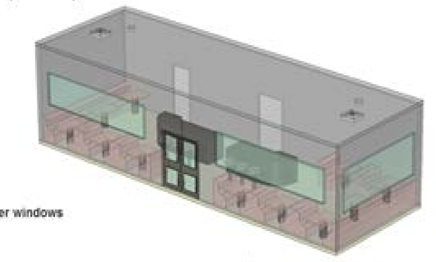
(1) Space Settings



Sedan car (3.17m³)*



Meeting room (81m³)



* Two cases:
(1) Closed windows
(2) Driver and passenger windows open 3 inches

Restaurant (270 m³)

INPUT DATA (cont.)

(2) Number of users and duration of use

	Number of occupants	Number of users	Duration of use (hr)
Car (closed windows)	4	2	1
Car (open windows)	4	2	1
Meeting room	15[a]	3[b]	4
Restaurant	100[a]	15[b]	2

[a] Maximum capacity: ANSI/ASHRAE Standard 62.1-2004, Ventilation for Acceptable Indoor Air Quality
[b] 15.1% of adult population (CDC, 2016)- rounded up for the meeting room.

(3) Product consumption

Cigarette: 14.1 cigarettes per day per user (CDC 2016)

MARKTEN ®: 902 mg per day (daily cartridge weight change [in-clinic 16hrs ad libitum use, ALCS, unpublished data])

(4) Constituents released per unit base

Constituent	ug per cigarette consumed * (side stream) [9]	ug exhaled /mg consumed [6]
Nicotine	5600	4.2207
Formaldehyde	700	0.0083
Glycerin	NA	162.1175
PG	NA	83.8625
Acetaldehyde	4200	BDL
Acrolein	1300	BDL
Menthol	NA	0.53

* Side stream deliveries for Kentucky Reference 1R4F

Side stream smoke is the primary source of second hand exposure. Contributions from the exhaled smoke are not included here.

(5a) Rate of release by all users: cigarette

Space	Number of occupants	Number of users	Total (all users) release rate (µg/hr)			
			Nicotine	Formaldehyde	Acetaldehyde	Acrolein
Meeting Room	15[a]	3[b]	27,418	2,100	12,600	3,900
Car (closed windows)	4	2	11,200	1,400	8,400	2,600
Car (open windows)	4	2	11,200	1,400	8,400	2,600
Bar/restaurant	100[a]	15	84,000	10,500	63,000	19,500

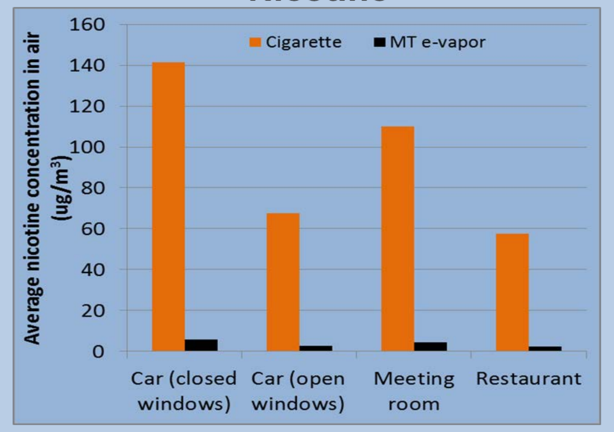
(5b) Rate of release by all users: MARKTEN® e-vapor

Space	Number of occupants	Number of users	Total (all users) exhaled rate (µg/hr)				
			Nicotine	Glycerol	PG	Formaldehyde	Menthol
Meeting Room	15[a]	3[b]	714	27,418	14,183	1.4025	89.634
Car (closed windows)	4	2	476	18,278	9,456	0.925	59.756
Car (open windows)*	4	2	476	18,278	9,456	0.925	59.756
Bar/restaurant	100[a]	15	3,569	137,085	70,915	7.0125	448.17

a. Maximum capacity: ANSI/ASHRAE Standard 62.1-2004, Ventilation for Acceptable Indoor Air Quality.
b. Slightly higher than CDC report cited earlier (15.1 % of adult population)- for both cigarette and e-vapor users

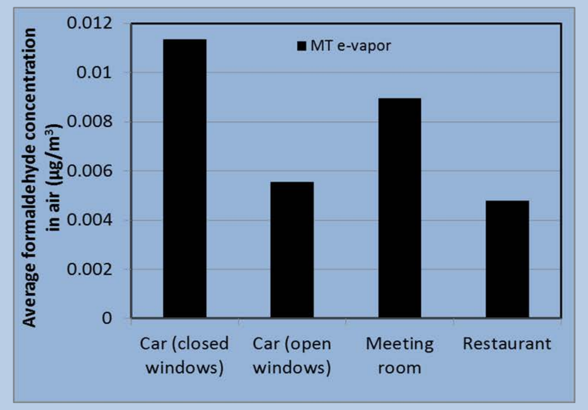
RESULTS for Room Concentrations : Exhaled Aerosol (ENDS) vs. Cigarette

Nicotine

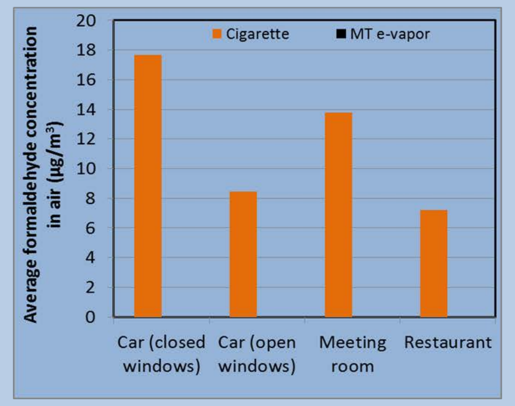


Nicotine concentration in air from MARKTEN ® e-vapor use is significantly less than cigarette use

Formaldehyde due to exhaled aerosol

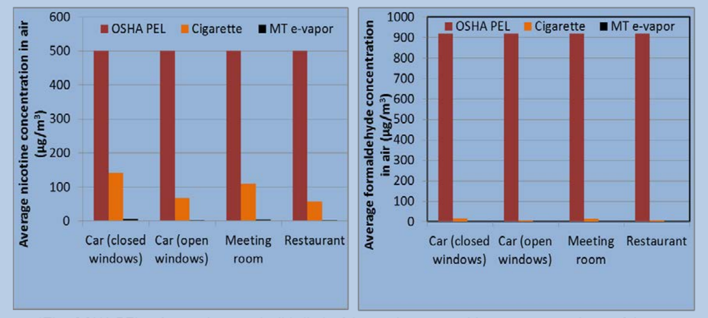


Formaldehyde



Formaldehyde concentration in air from MARKTEN ® e-vapor use is substantially less than cigarette use

Concentrations in Air Compared with OSHA PEL*



*The OSHA PEL refers to the permissible limit of the total average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded.

Nicotine and formaldehyde concentrations in air from MARKTEN ® e-vapor use are orders of magnitude less than indoor air permissible limits. For a better comparison, the duration of exposure needs to be similar to OSHA definition. It is shorter in these examples.

Other Constituents

Average acetaldehyde concentration in air (µg/m³)

	Cigarette	MARKTEN® e-vapor	OSHA PEL
Car (closed windows)	34.12	0	36,0000
Car (open windows)	16.32	0	36,0000
Meeting room	26.56	0	36,0000
Restaurant	13.86	0	36,0000

Average acrolein concentration in air (µg/m³)

	Cigarette	MARKTEN® e-vapor	OSHA PEL
Car (closed windows)	106.15	0	250
Car (open windows)	50.80	0	250
Meeting room	82.63	0	250
Restaurant	43.12	0	250

Other Constituents

Average propylene glycol concentration in air (µg/m³)

	Cigarette	MARKTEN® e-vapor	AIHA Limit
Car (closed windows)	N/A	114.74	36,0000
Car (open windows)	N/A	56.09	36,0000
Meeting room	N/A	90.66	36,0000
Restaurant	N/A	48.54	36,0000

Average glycerin concentration in air (µg/m³)

	Cigarette	MARKTEN® e-vapor	OSHA PEL
Car (closed windows)	N/A	221.81	5,000
Car (open windows)	N/A	108.44	5,000
Meeting room	N/A	175.27	5,000
Restaurant	N/A	93.84	5,000

N/A = Release rate not reported in side stream smoke [9]

Estimated Non-users Intake

Total intake of nicotine during exposure time by non-users (µg)

	Duration (hour)	Intake (µg) (Cigarette)	Intake (µg) (MARKTEN® e-vapor)
Car (closed windows)	1	50.95	2.07
Car (open windows)	1	24.37	1.01
Meeting room	4	158.6	6.57
Restaurant	2	41.39	1.75

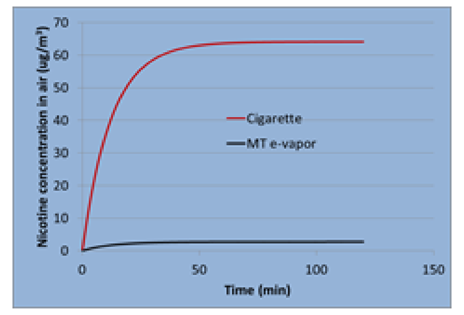
Total intake of formaldehyde during exposure time by non-users (µg)

	Duration (hour)	Intake (µg) (Cigarette)	Intake (µg) (MARKTEN® e-vapor)
Car (closed windows)	1	6.36	0.00408
Car (open windows)	1	3.04	0.00199
Meeting room	4	19.83	0.01291
Restaurant	2	5.17	0.00345

Intake= (average concentration) x (exposure duration) x (breathng volume)x (breathing rate)

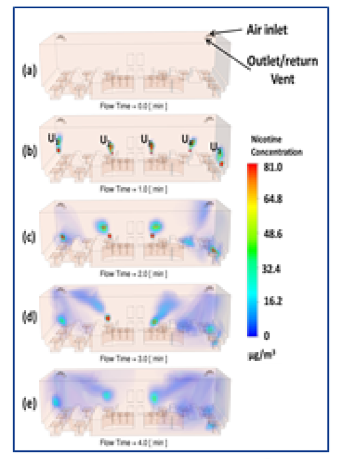
Nicotine Concentration Distributions Restaurant Example

Average nicotine concentration over time



15 individuals use one cigarette per hour for two hours
15 individuals use MARKTEN ® e-vapor at an equivalent rate of use

Nicotine concentration distribution



5 individuals use MARKTEN ® e-vapor

CONCLUSIONS

- We have estimated the concentration of constituents in air due to exhaled aerosol from use of the MARKTEN® e-vapor and compared with that of using conventional cigarettes and with the permissible limits of OSHA* and AIHA
- Three space settings were used as examples in the study: (1) A car (open and closed windows), (2) a meeting room and (3) a restaurant.
- Results from the computational models show that nicotine and formaldehyde concentrations in air from the use of MARKTEN® e-vapor are significantly less than cigarette under equivalent use conditions.
- PG and glycerin levels in air from MARKTEN® e-vapor use were orders of magnitude less than OSHA and AIHA limits in all three spaces that were studied.
- Finally, intake amounts of each constituent by Non-users during the example use of MARKTEN® and cigarettes were calculated.

*The OSHA PEL refers to the permissible limit of the total average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded

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