

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

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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.

Two Types of Computational Models

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

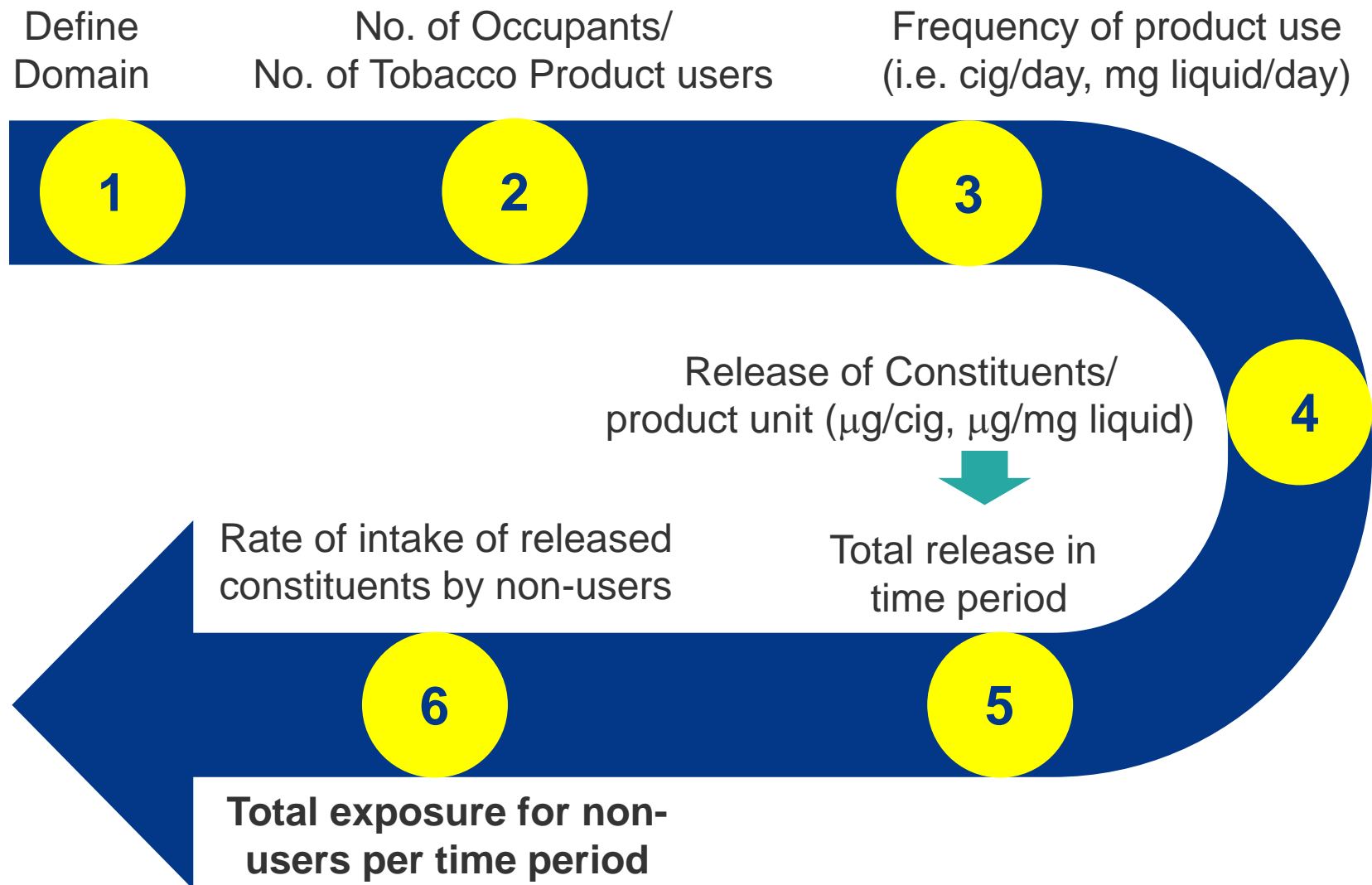
Well-mixed Model

- Total, vapor and particulate concentrations of each constituent in air
- Average values for the entire space as a function of time

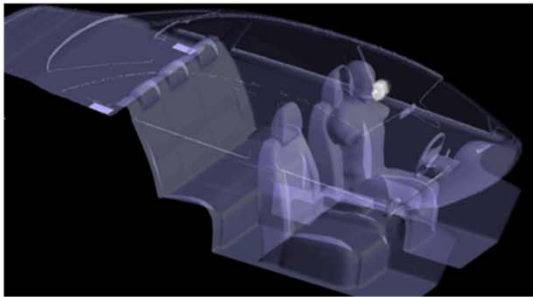
Distributed CFD Model

- Total, vapor and particulate concentrations of each constituent in air
- Spatial and temporal distribution inside the space

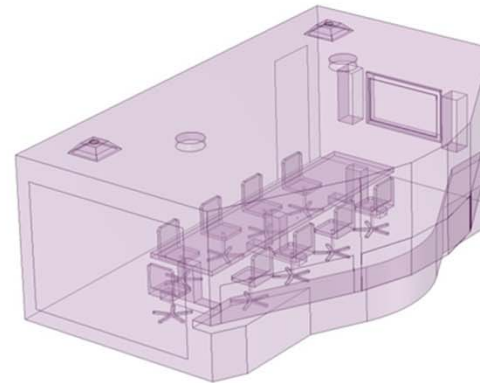
Exhaled Aerosol (ENDS) vs. Cigarette: Model Comparisons



(1) Space Settings



Sedan car (3.17m^3)*



Meeting room (81m^3)



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

Restaurant (270 m^3)

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MARKTEN[®]: 902 mg per day (daily cartridge weight change [in-clinic 16hrs ad libitum use, ALCS, unpublished data])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

* Side stream deliveries for Kentucky Reference 1R4F

Constituent	ug per cigarette consumed * (side stream)*	ug exhaled /mg consumed**
Nicotine	5,600	4.22
Formaldehyde	700	0.0083
Glycerin	NA	162.11
PG	NA	83.86
Acetaldehyde	4,200	BDL
Acrolein	1,300	BDL
Menthol	NA	0.53

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

*Guerin et. al., The Chemistry of Environmental Tobacco Smoke: Composition and Measurement, 1992, p56 .

**Edmiston et al. (2018), Exhaled Breath Levels of Selected Constituents From Controlled Use of MARKTEN® e-Vapor Products in Adult e-Vapor Users, Poster 191, February 24, SRNT 2018, Baltimore, MD.

(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	16,800	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

96% reduction

99.9% reduction

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

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 96% reduction

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

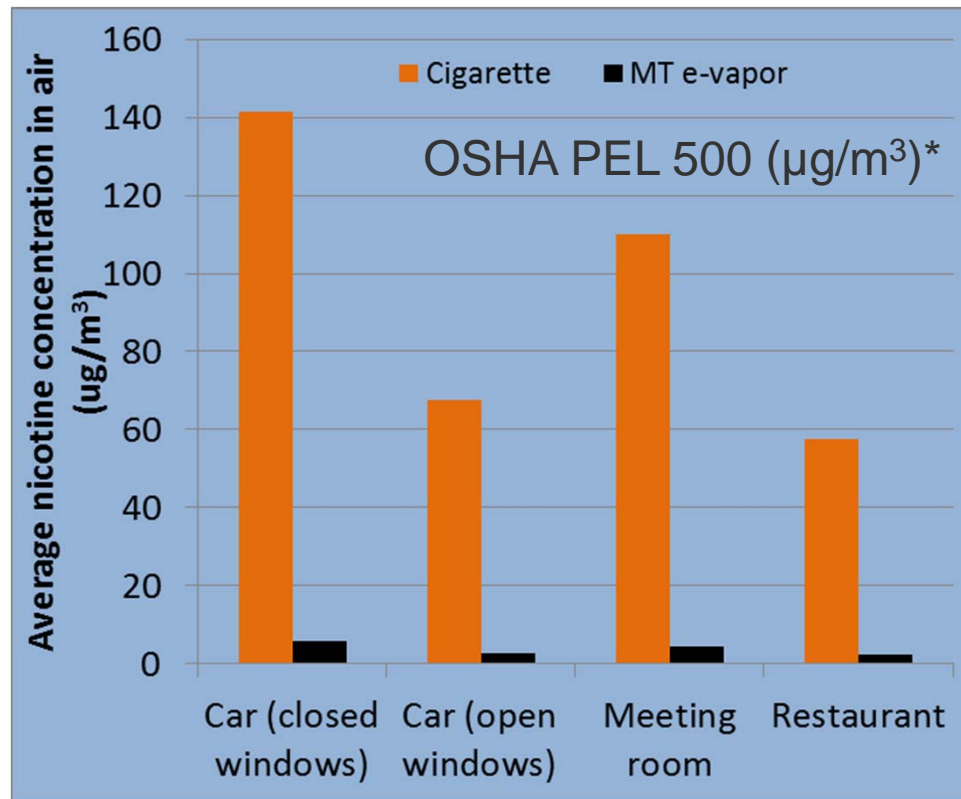
	Duration (hour)	Intake (µg) (Cigarette)	Intake (µg) (MARKTEN [®] e-vapor)
Car (closed windows)	1	6.36	0.00408
Car (open windows)	1	3.04	0.00199
Meeting room	4	19.83	0.01291
Restaurant	2	5.17	0.00345 99.9% reduction

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



MARKTEN[®] e-vapor vs Cigarette (average concentrations)

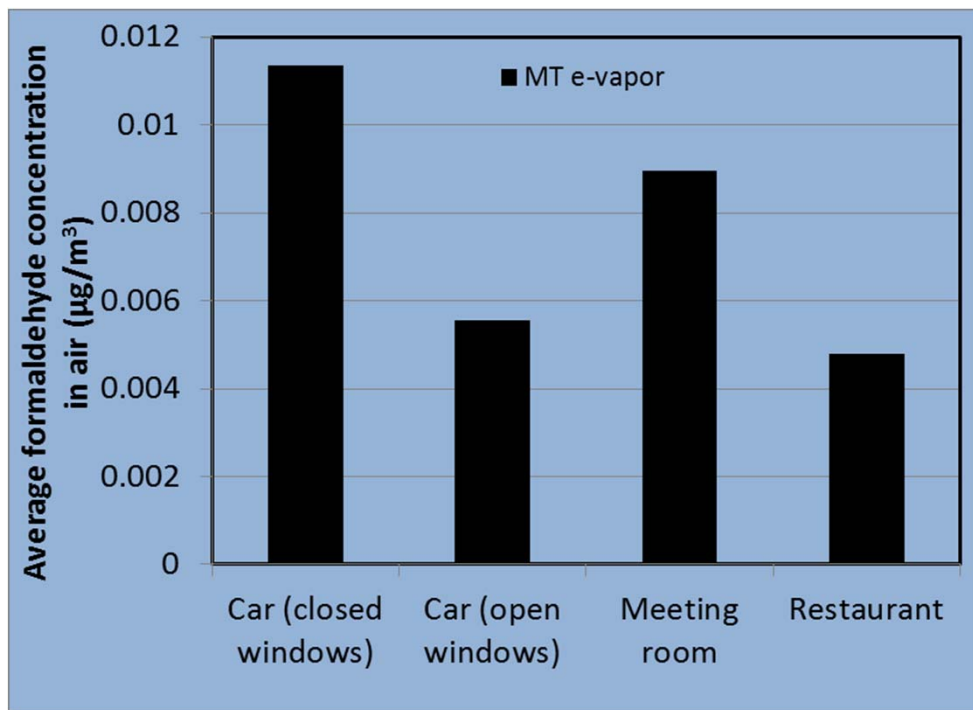
Nicotine



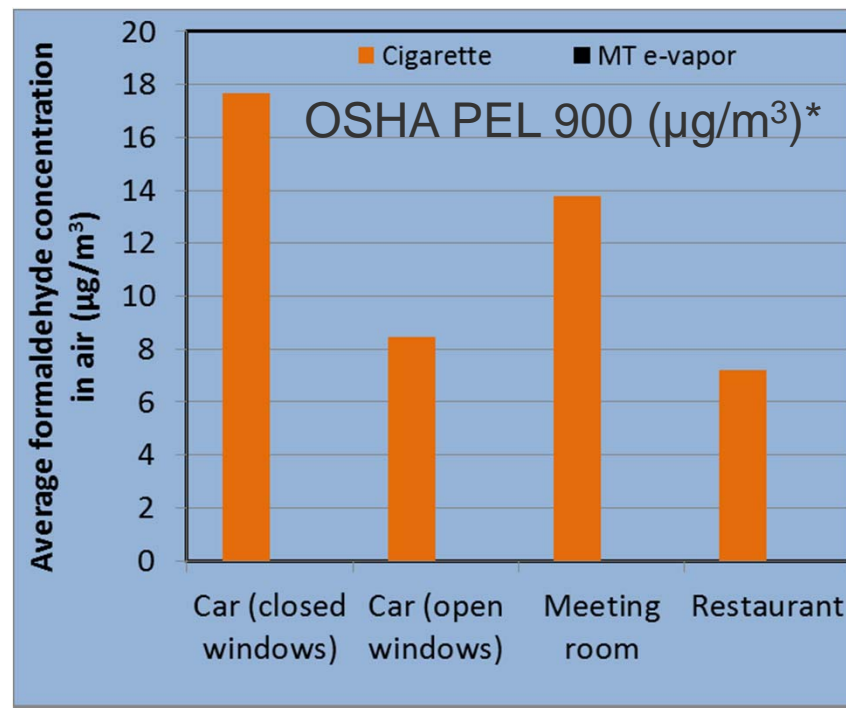
Nicotine concentration in air from **MARKTEN[®]** e-vapor use is significantly less than cigarette use

* 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.

Formaldehyde due to exhaled aerosol



Formaldehyde



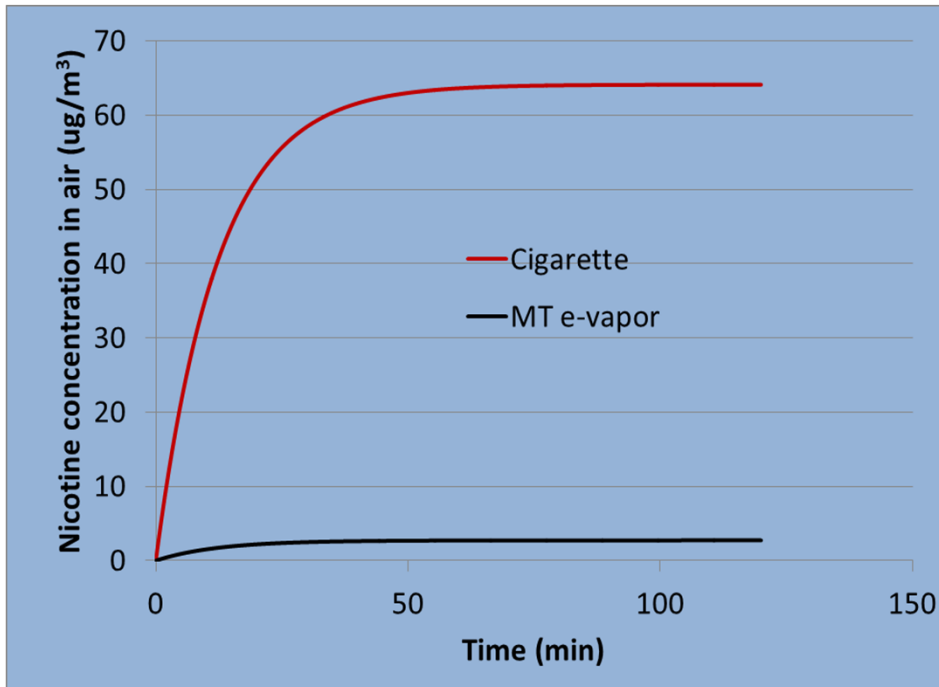
Formaldehyde concentration in air from MARKTEN[®] e-vapor use is substantially less than cigarette use

* 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.

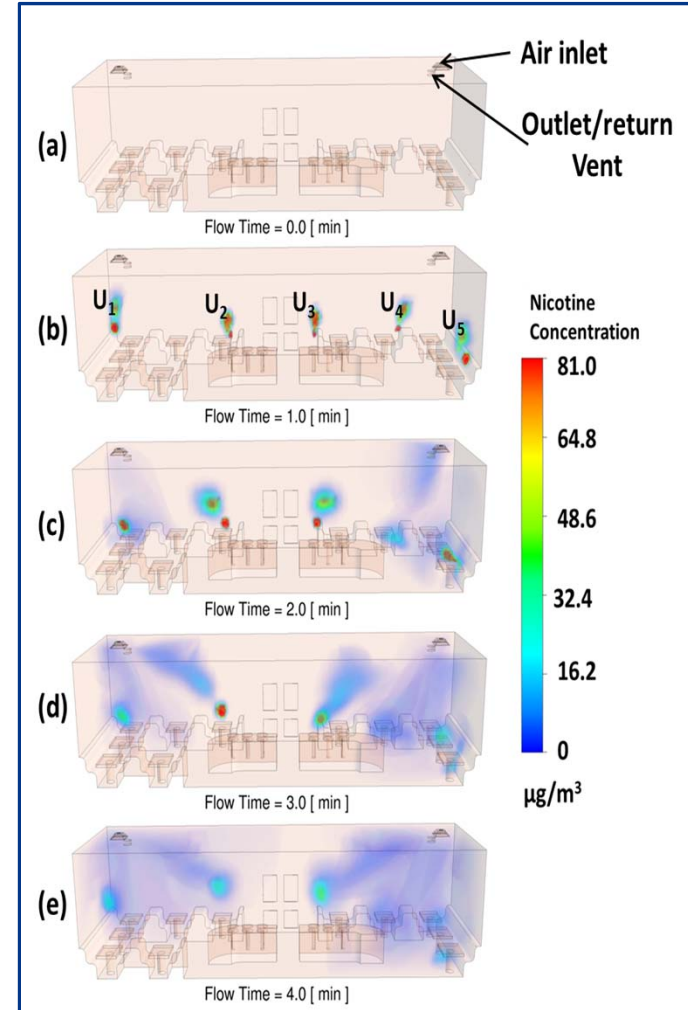
Nicotine Concentration Distributions

Restaurant Example

Average nicotine concentration over time



Nicotine concentration distribution



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

- 5 individuals use MARKTEN[®] e-vapor 13

Other Constituents

Average propylene glycol concentration in air ($\mu\text{g}/\text{m}^3$)

	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 ($\mu\text{g}/\text{m}^3$)

	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

Conclusions

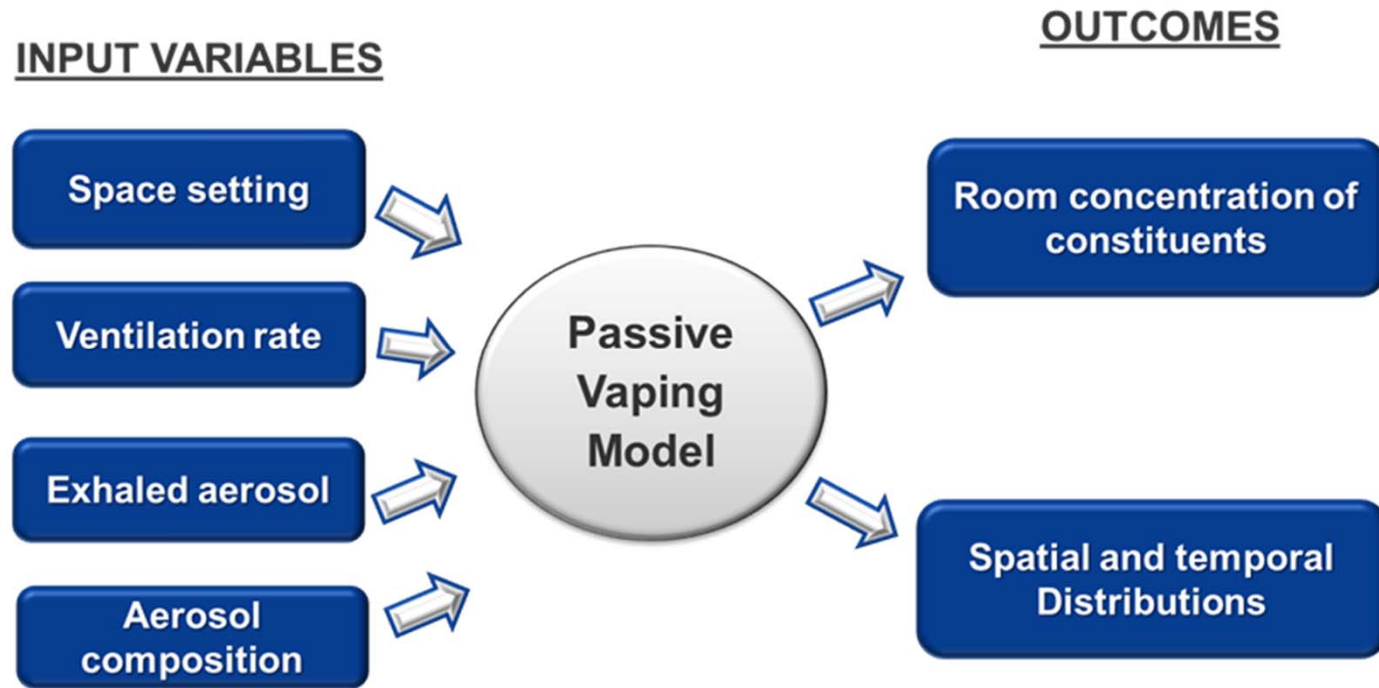
- We have estimated the concentration of constituents in air due to exhaled aerosol from use of the MARKTEN® e-vapor and compared with that of using conventional cigarettes and with the permissible limits of OSHA* and AIHA
- Three space settings were used as examples in the study: (1) A car (open and 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.



Additional Supporting Slides

Non-user Exposure Characterization Models

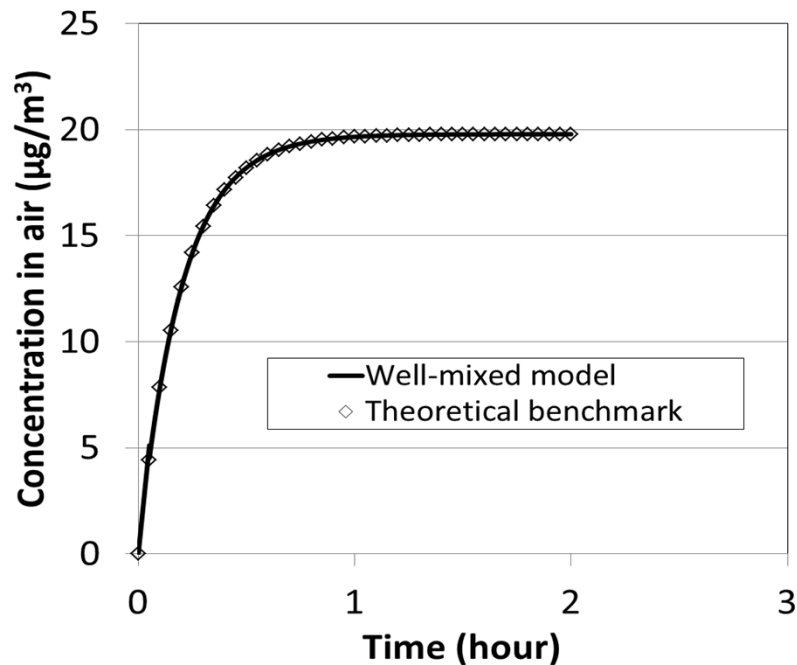


Physics-based models that include fluid flow, mass and heat transfers along with thermodynamic and kinetic interactions



Model Verification and Validation

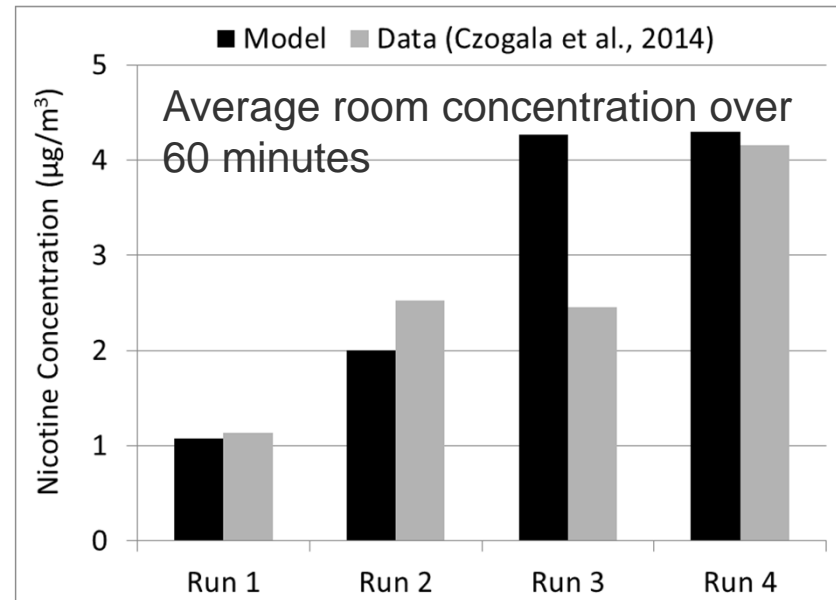
Verification



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)

Room volume 112 m³

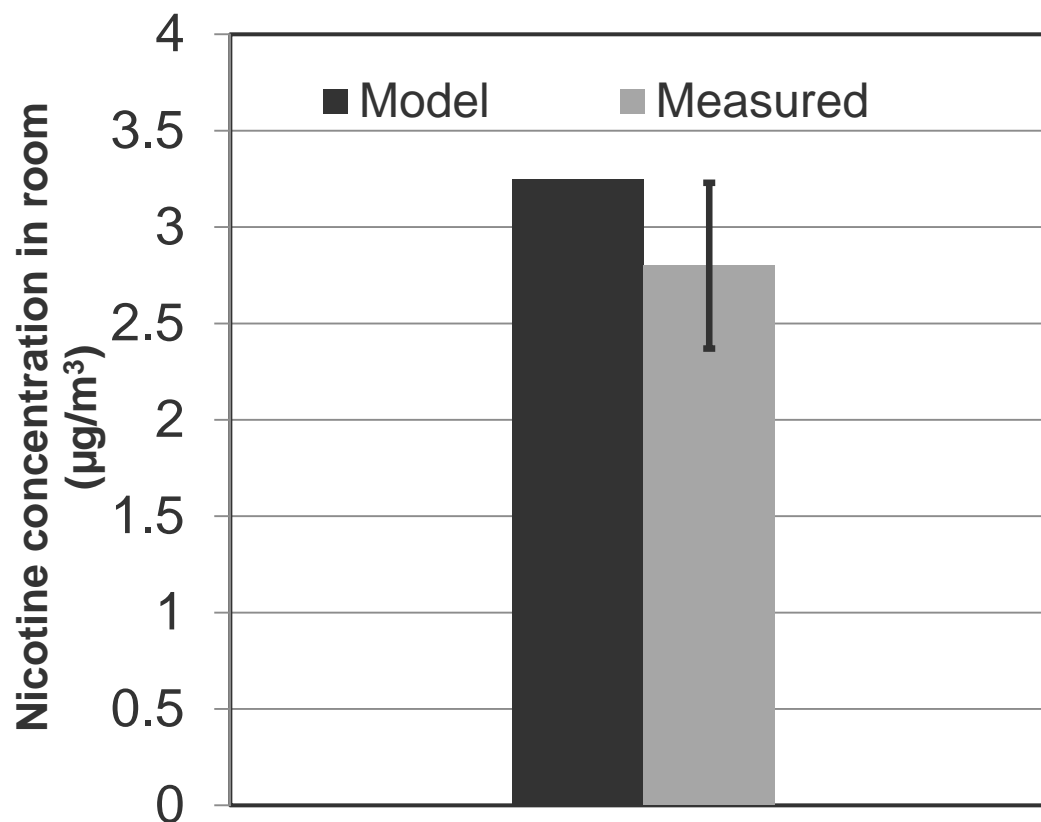


Controlled Clinical Study*:

- 9 individuals-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

Validation (2)

Modeling vs. Experimental Result



Average concentration over 4 hours

*Sarkar Et al. (2017) Determination of Selected Chemical Levels in Room Air, and on Surfaces after the Use of Cartridge- and Tank-Based E-Vapor Products or Conventional Cigarettes, Int. J. Environ. Res. Public Health, 14, 969; doi:10.3390/ijerph14090969

Other Constituents

Average acetaldehyde concentration in air ($\mu\text{g}/\text{m}^3$)

	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 ($\mu\text{g}/\text{m}^3$)

	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