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Indoor Air Quality Assessment of the Tobacco Heating System THS 2.2, Electronic Cigarettes and Cigarette using a dedicated Exposure Room

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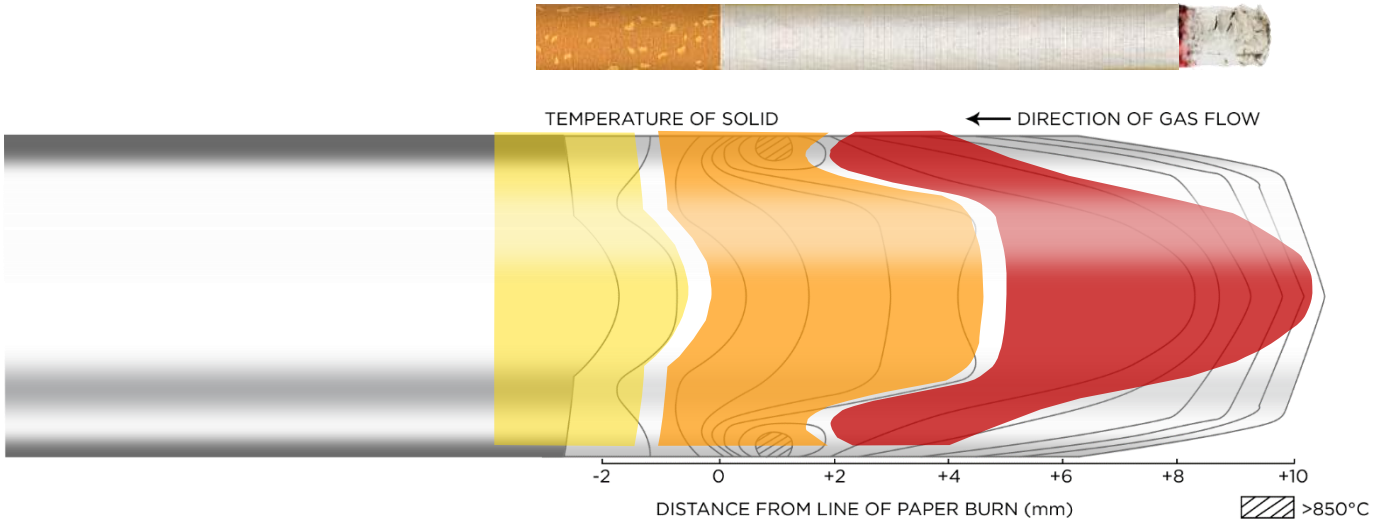
What is happening in a combustible cigarette?

- Combustion, pyrolysis and distillation are the three phenomena occurring in a combustible cigarette
- Formation of toxicants is temperature dependent: great majority of Harmful and Potentially Harmful Constituents are formed during Pyrolysis and Combustion processes



Distillation <300°C	Pyrolysis ~300-700°C	Combustion >750°C
Transfer from tobacco into smoke (e.g. nicotine, aromas)	Chemical decomposition (e.g. biopolymers degradation, PAHs & phenols formation)	Exothermic degradation process (e.g. CO, CO_2, NO/NOx, H_2O)

Heat-not-Burn Principle

- If the tobacco is heated at a temperature below that required to initiate combustion, the principal cause of the formation of HPHCs would be removed
- The resulting aerosol would be of a different composition compared to cigarette smoke

Combustion	Distillation	
Smoke	Aerosol (Vapor)	
Cigarette	Tobacco Heated Products	Nicotine Containing Products
		

- Smoke is a visible suspension of carbon and other solid particles in air, typically one emitted from a burning substance
- An aerosol is a mixture made up of liquid droplets suspended within a gas

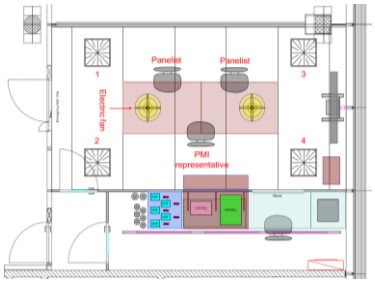
Is there any second hand exposure when using RRPs*?

- Tobacco Heating Systems or Nicotine Containing Products apply fast-acting electronic temperature control to heat tobacco or e-liquid
- The aerosols generated from RRPs consists mainly of water, glycerin and nicotine (+ propylene glycol & flavoring agents for NCPs)
- As RRPs do not generate sidestream, the aerosol exhaled by the user will be the only source of polluting substances
- How do THS 2.2 and NCPs impact Indoor Air Quality? What are the possible polluting substances presenting an exposure source to potential bystanders?

Product type	Combustible Cigarette	Reduced Risk Products		Background
Test Item	Marlboro Gold	Tobacco Heated System THS 2.2 	E-Cigarette refillable / rechargeable 	People present in the room not using any product
Matrix	Environmental Tobacco Smoke (ETS)	Environmental Aerosol (EA)		Other source of indoor air pollution (BKG)

*: Reduced-Risk Products (“RRPs”) is the term the company uses to refer to products with the potential to reduce individual risk and population harm in comparison to smoking combustible cigarettes.

How to simulate an environment and assess the impact of a product on Indoor Air Quality?

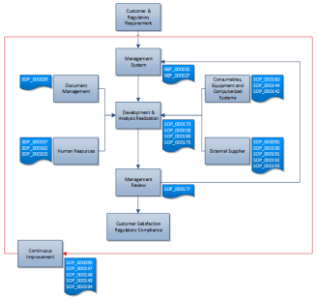


Environmentally Controlled Room (IAQ room)

Model environment

Model Environment	Room conditions defined by CEN Standard EN 15251:2007				
Category used for specification	Ventilation m^3/h	Air change 1/h	# of smokers	Cig/pers/h	Cig/h
Office	156	2.16	2	2	4
Hospitality	555	7.68	4	2	8
Residential I/II	121 / 87	1.68 / 1.20	2	1.5	3

Adult Volunteer Panelists

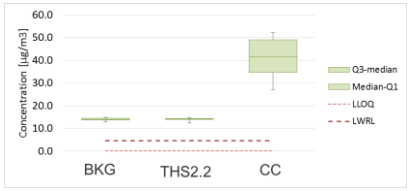


Quality Management System (ISO17025)

Assessing the impact of a product use on indoor air quality requires strict control over many elements

Category	Compounds
ISO measurement standards for ETS (ISO Norms 15593, 2001; 18144, 2003; 18145, 2003; 11454, 1997)	RSP gravimetric [µg/m³]
	UVPM-THBP [µg/m³]
	FPM-scopoletin [µg/m³]
	Solanesol [µg/m³]
	3-Ethenylpyridine [µg/m³]
	Nicotine [µg/m³]
ISO measurement standard for TVOCs (ISO 16000-6, 2011)	TVOC (Total Volatile Organic Compounds)
Carbonyls	Acetaldehyde [µg/m³]
	Acrolein [µg/m³]
	Crotonaldehyde [µg/m³]
	Formaldehyde [µg/m³]
VOCs	Acrylonitrile [µg/m³]
	Benzene [µg/m³]
	1,3-Butadiene [µg/m³]
	Isoprene [µg/m³]
	Toluene [µg/m³]
Inorganics	Carbon monoxide [ppm]
	Nitrogen oxide (NO) [ppb]
	Nitrogen oxides (NOx) [ppb]

Indoor air contaminants



Study design & report

Technical expertise

Dedicated methods

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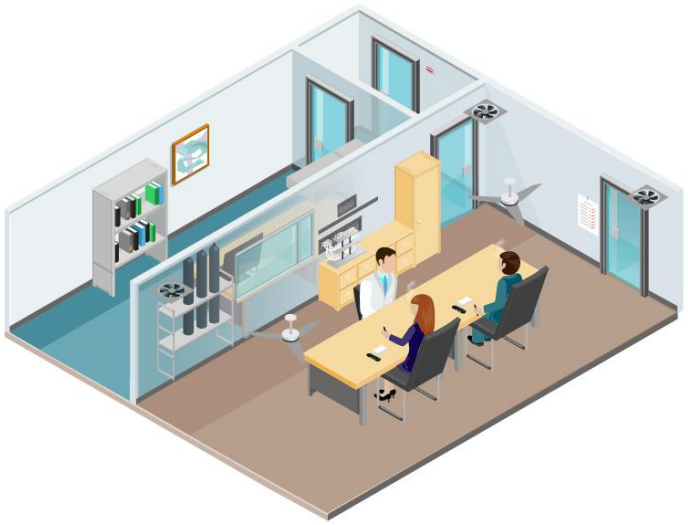
IAQ room & simulated environments



Temperature & pressure controlled. Humidity monitored

Air change: 0.5 to 12.2 per hour, ventilation: 37 to 879 m^3/h

Collection: 26 pumps with mass flow controller

Environmental specifications according to CEN Standard (EN 15251:2007)

Environments	Ventilation Rate [m^3/h]	Air changes [per hour]	Design Occupancy	Test items smoked per hour
Residential	121	1.68	2	3
Residential II	87	1.20	2	3
Residential III	37	0.5	2	3
Office	156	2.16	2	4
Hospitality	555	7.68	4	8

Indoor Air Quality constituents

- All analytical methods & IAQ room accredited under ISO17025 (International Organization for Standardization, 2005) by the Swiss Accreditation Service
- All methods validated for Combustible Cigarette & RRPs (THS 2.2 and e-cigarettes)
- Methods for Tobacco-Specific NitrosAmines, phenols & aerosol formers under development

Category	Compounds
ISO measurement standards for ETS (ISO Norms 15593, 2001; 18144, 2003; 18145, 2003; 11454, 1997)	RSP gravimetric [$\mu g/m^3$]
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Carbonyls	Acetaldehyde [$\mu g/m^3$]
	Acrolein [$\mu g/m^3$]
	Crotonaldehyde [$\mu g/m^3$]
	Formaldehyde [$\mu g/m^3$]
VOCs	Acrylonitrile [$\mu g/m^3$]
	Benzene [$\mu g/m^3$]
	1,3-Butadiene [$\mu g/m^3$]
	Isoprene [$\mu g/m^3$]
	Toluene [$\mu g/m^3$]
Inorganics	Carbon monoxide [ppm]
	Nitrogen oxide (NO) [ppb]
	Nitrogen oxides (NOx) [ppb]

PM2.5 & tobacco smoke-related particulate matter markers

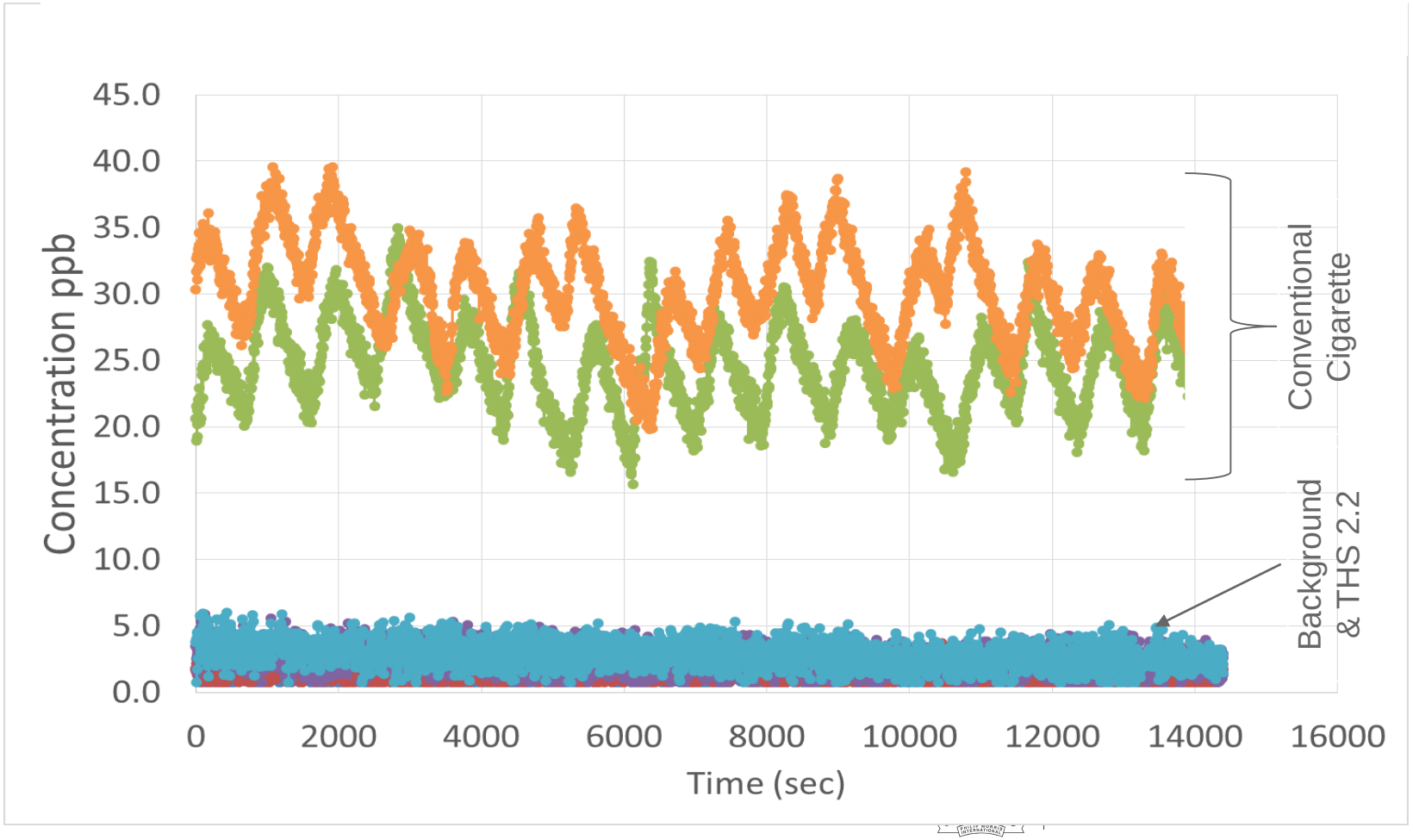
Gas-phase tobacco-specific markers

Air quality marker

Compounds selected based on:
- Relevance for air quality
- Relative abundance in THS2.2 aerosol (i.e. the most abundant)
- Carbonyls & VOCs compounds are part of the FDA list of HPHCs
- Gas-phase tobacco non-specific markers
- Gas-phase combustion marker

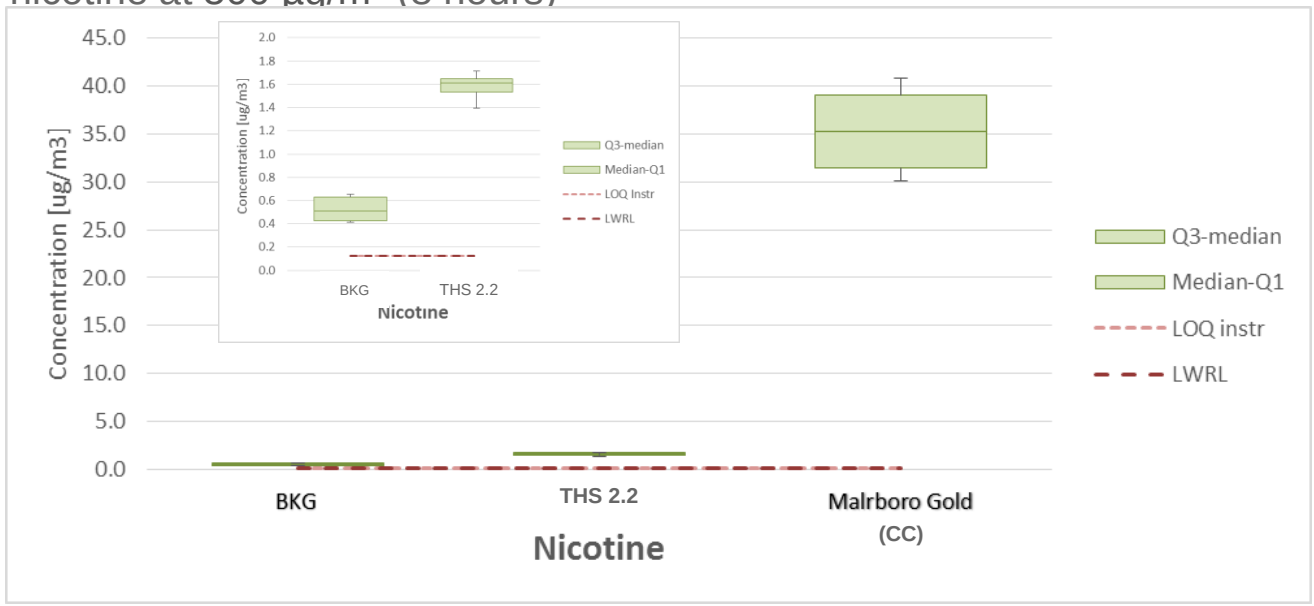
Example of comparison: Nitrogen Oxide (office conditions)

- ETS of CC: several maxima reflecting the smoking pattern of the panelist
- EA of THS2.2: not different than background and below the LOQ (2.5 ppb)



Example of comparison – nicotine (office conditions)

- Nicotine was measured in the working range of the method for the three matrices.
- Concentrations in ETS are significantly higher than in EA of THS 2.2.
- The indoor impact of the product is the difference between BKG and THS 2.2 concentrations (*e.g* 34.7 µg/m^3 for CC and 1.1 µg/m^3 for THS 2.2 in office conditions for nicotine)
- The European Agency for Safety and Health at Work[1] has established an exposure limit for nicotine at 500 µg/m^3 (8 hours)



Q1-Q3: quartiles; LOQ: Limit of Quantification, LWRL: Lowest Working Range Limit

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1) *Directive 2006/15/EC - indicative occupational exposure limit values*

Contribution of THS 2.2 & CC on Indoor Air Quality

	Analyte	THS 2.2$_{adjusted}$ (THS 2.2 – BKG) (-): THS 2.2 equivalent to BKG				CC$_{adjusted}$ (CC – BKG) (*): BKG not subtracted (<LWRL)			
		Residential	Residential 2	Office	Hospitality	Residential	Residential 2	Office	Hospitality
ETS markers	RSP gravimetric [µg/m^3]					236*	268*	204*	147*
	UVPM-THBP [µg/m^3]					39.6*	40.8*	38.5*	18.4*
	FPM-scopoletin [µg/m^3]					8.05*	8.50*	7.88*	4.04*
	Solanesol [µg/m^3]					10.2*	9.84*	10.2*	4.68*
	3-Ethenylpyridine [µg/m^3]	-	-	-	-	6.02*	7.61*	6.39*	3.94*
	Nicotine [µg/m^3]	0.69	1.81	1.10	0.66	29.7	29.1	34.7	34.6
Carbonyls	Acetaldehyde [µg/m^3]	2.66	5.09	3.65	1.40	70.2	83.8	58.8	33.1
	Acrolein [µg/m^3]	-	-	-	-	6.94*	5.65*	6.42*	3.03*
	Crotonaldehyde [µg/m^3]	-	-	-	-	2.19*	2.11*	2.04*	0.99*
	Formaldehyde [µg/m^3]					27.1	35.5	28.9	17.5
VOCs	Acrylonitrile [µg/m^3]					2.53*	3.61*	2.61*	1.36*
	Benzene [µg/m^3]	-	-	-	-	7.09	9.24	6.58	3.50
	1,3-Butadiene [µg/m^3]	-	-	-	-	13.0*	16.8*	12.6*	5.79*
	Isoprene [µg/m^3]	-	-	-	-	71.5	99.4	75.9	37.0
	Toluene [µg/m^3]	-	-	-	-	11.1	26.1	14.9	8.76
Gases	Carbon monoxide [ppm]	-	-	-	-	1.63*	2.17*	1.59*	<0.92*
	Nitrogen oxide (NO) [ppb]	-	-	-	-	26.2	35.6	27.0*	14.8*
	Nitrogen oxides (NOx) [ppb]	-	-	-	0.52	29.4	39.7	29.4	15.0

THS 2.2 is not a source of Environmental Tobacco Smoke (ETS)

2 compounds attributable to the use of THS 2.2

Analytes median levels obtained after background subtraction. “-”: the value is equivalent to background value

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Nicotine-containing Product (e-cig)– impact on IAQ

- Exploratory study on eight markers and on three products (rechargeable / refillable)

Model Environment	Ventilation [m^3/h]	Air change [L/h]	# of vapers	E-cig/pers/h	E-cig/h
Residential II	87	1.20	2	1.5	3

- Large differences between the consumed e-liquids during the sessions were measured and were explained by the different vaping behavior of panelists. These are ~~is~~ reflected in analytes measured above background levels

Analyte	Solaris KS $_{adjusted}$ *	Nicolites $_{adjusted}$ *	Vivid $_{adjusted}$ *
RSP gravimetric [µg/m^3]	-	-	-
3-Ethenylpyridine [µg/m^3]	-	-	-
Nicotine [µg/m^3]	0.221 (0.0761-0.411)	0.791 (0.305-5.57)	1.28 (0.444-3.67)
Glycerin [µg/m^3]	26.5 (21.2-52.1)	15.6 (9.78-90.3)	25.7 (22.0-99.8)
Propylene glycol [µg/m^3]	20.7 (13.0-24.0)	204 (90.1-1381)	143 (34.7-503)
Acetaldehyde [µg/m^3]	-	-	-
Formaldehyde [µg/m^3]	-	-	-
TVOC[µg/m^3](toluene equivalent)	-	-	-

- Nicotine, glycerin and propylene glycol levels were higher in indoor air compared to background levels in all studied e-cig brands.

Conclusion

- Our indoor air quality studies performed with THS 2.2 and e-cigs, simulating real life situations in a controlled environment show that:
  - Markers of combustion are absent in Environmental Aerosols of all measured Reduced-Risk Products
  - THS 2.2 does not emit Environmental Tobacco Smoke (ETS)
  - Of the measured compounds only two, nicotine and acetaldehyde, were found in air following the use of THS 2.2. The measured levels, however, are much lower than those following the use of CC, and orders of magnitude below the maximum exposure levels as defined in existing air quality guidelines in the EU and Japan for example
- Using THS 2.2 indoors does not have a negative impact on the overall air quality
- Environmental Aerosols of NCPs are composed of nicotine & aerosol formers. Levels are influenced by the vaping behavior but are at least 50 times lower than the guideline values that exist for these compounds.

References

- PMI SCIENCE - https://www.pmiscience.com/
- ARTICLES
  - Validation of selected analytical methods using accuracy profiles to assess the impact of a Tobacco Heating System on indoor air quality. Talanta (2016) **158**, 165-178. doi:10.1016/j.talanta.2016.05.022.
  - Comparison of the impact of the Tobacco Heating System 2.2 and a cigarette on indoor air quality, Regulatory Toxicology and Pharmacology (2016), **80**, 91-101. doi:10.1016/j.yrtph.2016.06.005

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