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ANALYTICAL STUDY SUMMARY

IQOS 3 DATA PACKAGE

PROGRAM NAME(S):	Platform 1 (ZRH, THS)
WORK TYPE:	Exploratory ☐ Developmental ☐ Regulatory submission ☒
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DATE OF ISSUE:	See EDMS reference

1. EXECUTIVE SUMMARY

The integrate assessment plan of the *IQOS* 3 System is conducted according to PMI standard THS comparability protocol and following additional internal and external requirements. Overall the completed aerosol chemistry and physics data package demonstrates that the emissions of the *IQOS* 3 System under both extreme regimes of operation (Forced Warm Aerosol (WA) and Forced no-Warm Aerosol (no-WA)) are comparable to the emissions of the Authorized *IQOS* System. Furthermore, the HPHCs emissions levels of *IQOS* 3 device assessed with the commercially available *HeatSticks* show similar reductions pattern as the HPHCs emissions levels of the Authorized *IQOS* System, when compared to the HPHCs levels in the cigarette smoke (3R4F or 1R6F Reference Cigarette).

2. OBJECTIVE & SCOPE

This document summarizes the aerosol chemistry and physics studies conducted for assessing and characterizing the *IQOS* 3 System, comparatively to the Authorized *IQOS* System. The *IQOS* 3 System is assessed under two extremes firmware settings, Forced Warm WA and Forced no-WA, according to PMI comparability model across the PMI-58 list of constituents and aerosol generated under Health Canada Intense regime (HCI).

Moreover, *IQOS* 3 System performance characterization are conducted by

1) Performing Droplet Size Distribution (DSD) analysis with Forced WA and Forced no-WA vs the Authorized IQOS System
2) Determining the additional 4 HPHCs, Glycidol, furfural, 2-furanmethanol, 3-chloro-1,2-propondiol with Forced WA and Forced no-WA vs the Authorized *IQOS* System
3) Deriving the recommended FDA-18 list of constituents using *IQOS* 3 US commercial configuration and the 3 currently marketed US *HeatStick* variants, under ISO and HCI aerosol generation regimes. Data generated in parallel to the 1R6F reference cigarette

3. DATA SOURCE

All samples identification and description are reported in Section 10. PMI-58 and FDA-18 assays were conducted by Labstat ULC[1], according to their procedures and methods. DSD were performed by Enthalpy Analytical[2]. All methods (chemistry and physics) were accredited according to ISO 17025. The studies for the determination of the 4 additional HPHCs were conducted at PMI R&D laboratories in Neuchâtel, Switzerland.

[1] *Labstat International ULC, 262 Manitou Drive, Kitchener, Ontario, N2C 1L3*
[2] *Enthalpy Analytical, 1 Park Plaza, Suite 1000 Irvine, CA 92614*

4. *IQOS* 3 FORCED WARM AEROSOL (WA) VERSUS THE AUTHORIZED *IQOS* SYSTEM

Table 1: Summary of IQOS 3 System yields with Forced WA firmware setting, the Authorized IQOS System yields, and the yields of the 3R4F[3] reference cigarette. SD – standard deviation; n – sample size

HPHCs	Unit	3R4F			*IQOS* 3 System Forced WA			The Authorized *IQOS* System		
		Mean	SD	n	Mean	SD	n	Mean	SD	n
1,3-Butadiene	µg/cig	100	6.87	4	0.115	NA[4]	9	0.169	0.0375	9
1-Aminonaphthalene	ng/cig	29.1	2.56	4	0.033	NA	9	0.0351	NA	9
2-Aminonaphthalene	ng/cig	18.1	2.32	4	0.0161	NA	9	0.019	0.00469	9
3-Aminobiphenyl	ng/cig	5.44	0.226	4	0.00651	0.000942	9	0.00679	0.00102	9
4-(Methyl-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	ng/cig	295	32.5	4	7.52	0.365	9	7.6	0.336	9
4-Aminobiphenyl	ng/cig	3.91	0.293	4	0.00884	0.00157	9	0.00947	0.00193	9
Acetaldehyde	µg/cig	1838	105	4	221	5.83	9	218	7.57	9
Acetamide	µg/cig	12.2	1.86	4	3.55	0.135	9	3.68	0.297	9
Acetone	µg/cig	749	44.4	4	38.3	1.56	9	36.6	2.13	9
Acrolein	µg/cig	180	12.6	4	8.71	0.461	9	8.75	0.748	9
Acrylamide	µg/cig	3.92	0.522	4	1.55	0.0994	9	1.6	0.14	9
Acrylonitrile	µg/cig	20.5	1.81	4	<0.107	NA	9	<0.107	NA	9
Ammonia	µg/cig	34	0.497	4	9.9	1.05	9	11	0.343	9
Arsenic	ng/cig	<7.49	NA	4	<1.2	NA	9	<1.2	NA	9
Benz[a]anthracene	ng/cig	28.9	1.96	4	1.94	0.0756	9	1.91	0.108	9
Benzene	µg/cig	88.8	6.31	4	0.513	0.126	9	0.551	0.147	9
Benzo[a]pyrene	ng/cig	15.1	0.63	4	0.747	0.0422	9	0.741	0.0659	9
Butyraldehyde	µg/cig	93	4.35	4	20.4	0.569	9	20.2	0.617	9
Cadmium	ng/cig	93.2	7.42	4	<0.09	NA	9	<0.09	NA	9
Carbon monoxide (CO)	mg/cig	30.5	1.81	4	0.345	0.028	9	0.364	0.042	9
Catechol	µg/cig	86.9	5.42	4	17.4	0.749	9	18.6	0.736	9
Chromium	ng/cig	<11.9	NA	4	<11	NA	9	<11	NA	9
Crotonaldehyde	µg/cig	59.5	4.41	4	<3.29	NA	9	<3.29	NA	9
Dibenz[a,h]anthracene	ng/cig	1.34	0.0918	4	<0.124	NA	9	<0.124	NA	9
Ethylene oxide	µg/cig	19.2	1.81	4	0.189	0.00597	9	0.205	0.0218	9
Formaldehyde	µg/cig	87.1	7.37	4	9.7	0.819	9	9.88	0.645	9
Glycerol	mg/cig	2.25	0.072	4	4.22	0.311	9	4.56	0.211	9

(table continues)

[3] 3R4F reference cigarette values from a research study conducted in 2018 at Labstat International ULC

[4] « NA » in place of standard deviation indicates the emissions levels for some or all replicates were below the limit of quantification (LOQ) of the analytical method. In these cases instead of the mean, the median is reported for endpoints classified as being generally quantifiable, and the maximum value is reported for endpoints classified as being generally below the limit of quantification.

HPHCs	Unit	3R4F			*IQOS* 3 System Forced WA			The Authorized *IQOS* System		
		Mean	SD	n	Mean	SD	n	Mean	SD	n
Hydrogen cyanide	µg/cig	390	22.8	4	2.61	0.206	9	2.87	0.23	9
Hydroquinone	µg/cig	78.1	6.52	4	8.11	0.425	9	9.2	0.429	9
Isoprene	µg/cig	799	61	4	1.27	0.271	9	1.5	0.189	9
Lead	ng/cig	<25.7	NA	4	<0.49	NA	9	<1.62	NA	9
m-Cresol	µg/cig	2.77	0.194	4	0.0321	0.00297	9	0.0369	0.00577	9
Mercury	ng/cig	4.92	0.0635	4	2.27	0.102	9	2.17	0.15	9
Methyl-ethyl-ketone (MEK)	µg/cig	199	13.1	4	7.76	0.389	9	7.55	0.541	9
Nickel	ng/cig	<12.9	NA	4	<53.1	NA	9	<15.9	NA	9
Nicotine	mg/cig	1.99	0.131	4	1.31	0.0315	9	1.34	0.06	9
Nitric oxide (NO)	µg/cig	471	16.5	4	10.8	0.471	9	10.6	0.446	9
Nitro benzene	µg/cig	<0.027	NA	4	<0.011	NA	9	<0.011	NA	9
Nitrogen oxides (NOx)	µg/cig	524	17.2	4	12	0.464	9	11.9	0.491	9
N-nitrosoanabasine (NAB)	ng/cig	31.8	1.02	4	2.2	0.0975	9	2.17	0.126	9
N-nitrosoanatabine (NAT)	ng/cig	334	12.3	4	16	0.544	9	16.1	0.837	9
N-Nitrosonornicotine (NNN)	ng/cig	336	28.4	4	12.6	0.461	9	12.5	0.533	9
o-Cresol	µg/cig	3.22	0.265	4	0.0734	0.00828	9	0.0856	0.0106	9
o-Toluidine	ng/cig	121	1.04	4	1.02	0.0728	9	1.13	0.246	9
p-Cresol	µg/cig	6.83	0.53	4	0.0665	0.00538	9	0.0786	0.0108	9
Phenol	µg/cig	11.1	0.896	4	1.48	0.168	9	1.69	0.142	9
Propionaldehyde	µg/cig	135	8.15	4	12.7	0.467	9	12.5	0.704	9
Propylene oxide	ng/cig	1000	78.8	4	118	10.7	9	130	15	9
Pyrene	ng/cig	91.9	7.5	4	8.19	0.49	9	8.13	0.597	9
Pyridine	µg/cig	35.2	6.4	4	5.58	0.175	9	5.65	0.356	9
Quinoline	µg/cig	0.315	0.0333	4	<0.003	NA	9	<0.003	NA	9
Resorcinol	µg/cig	<1.32	NA	4	<0.016	NA	9	<0.016	NA	9
Selenium	ng/cig	<4.42	NA	4	<0.83	NA	9	<0.83	NA	9
Styrene	µg/cig	21.7	2.4	4	0.445	0.0185	9	0.491	0.0575	9
Toluene	µg/cig	153	11.5	4	1.54	0.405	9	1.7	0.428	9
Total Particulate Matter (TPM)	mg/cig	47	2.62	4	51	0.701	9	51.9	1.63	9
Vinyl chloride	ng/cig	94.6	7.44	4	<2.19	NA	9	<2.19	NA	9

5. *IQOS* 3 FORCED NO-WARM AEROSOL (NO-WA) VERSUS THE AUTHORIZED *IQOS* SYSTEM

Table 2: Summary results of IQOS 3 System yields with Forced no-WA firmware setting, the Authorized IQOS System yields, and the yields of the historical 3R4F reference cigarette. SD – standard deviation; n – sample size

HPHCs	Unit	3R4F			IQOS 3 System Forced no-WA			The Authorized IQOS System		
		Mean	SD	n	Mean	SD	n	Mean	SD	n
1,3-Butadiene	µg/cig	100	6.87	4	0.218	0.0252	9	0.213	0.0196	9
1-Aminonaphthalene	ng/cig	29.1	2.56	4	0.0276	NA	9	0.0321	NA	9
2-Aminonaphthalene	ng/cig	18.1	2.32	4	<0.012	NA	9	<0.012	NA	9
3-Aminobiphenyl	ng/cig	5.44	0.226	4	0.007	0.0023	9	0.007	0.0019	9
4-(Methyl-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	ng/cig	295	32.5	4	6.43	0.334	9	6.58	0 33	9
4-Aminobiphenyl	ng/cig	3 91	0.293	4	0.0082	NA	9	0.009	0.0021	9
Acetaldehyde	µg/cig	1838	105	4	201	13.6	9	197	15.8	9
Acetamide	µg/cig	12.2	1.86	4	3.25	0.268	9	3.38	0.0814	9
Acetone	µg/cig	749	44.4	4	35.3	2.86	9	35.4	3 25	9
Acrolein	µg/cig	180	12.6	4	8.34	0.846	9	8.52	1 11	9
Acrylamide	µg/cig	3 92	0.522	4	1.5	0.118	9	1.56	0.0777	9
Acrylonitrile	µg/cig	20.5	1.81	4	0.127	NA	9	0.116	NA	9
Ammonia	µg/cig	34	0.497	4	10.2	0.986	9	10.5	0.841	9
Arsenic	ng/cig	<7.49	NA	4	<1.2	NA	9	<1.2	NA	9
Benz[a]anthracene	ng/cig	28.9	1.96	4	1.65	0.0639	9	1.59	0.0504	9
Benzene	µg/cig	88.8	6.31	4	0.563	0.0383	9	0.557	0.0278	9
Benzo[a]pyrene	ng/cig	15.1	0.63	4	0.635	0.0425	9	0.617	0.0332	9
Butyraldehyde	µg/cig	93	4.35	4	20.8	1.49	9	20	1 3	9
Cadmium	ng/cig	93.2	7.42	4	<0.09	NA	9	<0.09	NA	9
Carbon monoxide (CO)	mg/cig	30.5	1.81	4	0.438	0.0533	9	0.42	0	9
Catechol	µg/cig	86.9	5.42	4	15	0.904	9	15.7	0.628	9
Chromium	ng/cig	<11.9	NA	4	<11	NA	9	<3.31	NA	9
Crotonaldehyde	µg/cig	59.5	4.41	4	<3.29	NA	9	<3.29	NA	9
Dibenz[a,h]anthracene	ng/cig	1 34	0.0918	4	<0.124	NA	9	<0.124	NA	9
Ethylene oxide	µg/cig	19.2	1.81	4	<0.119	NA	9	0.119	NA	9
Formaldehyde	µg/cig	87.1	7.37	4	7.87	1.05	9	7.51	0.66	9
Glycerol	mg/cig	2 25	0.072	4	4.55	0.287	9	5.07	0.261	9
Hydrogen cyanide	µg/cig	390	22.8	4	2.77	0.432	9	2.57	0.507	9

(table continues)

HPHCs	Unit	3R4F			IQOS 3 System Forced no-WA			The Authorized IQOS System		
		Mean	SD	n	Mean	SD	n	Mean	SD	n
Hydroquinone	µg/cig	78.1	6.52	4	7.5	0.557	9	8.11	0.424	9
Isoprene	µg/cig	799	61	4	1.59	0.17	9	1.6	0.177	9
Lead	ng/cig	<25.7	NA	4	<1.62	NA	9	<0.49	NA	9
m-Cresol	µg/cig	2.77	0.194	4	0.025	NA	9	0.029	0.0031	9
Mercury	ng/cig	4 92	0.0635	4	2.52	0.0759	9	2.35	0.0928	9
Methyl-ethyl-ketone (MEK)	µg/cig	199	13.1	4	8.6	0.855	9	8.87	0.722	9
Nickel	ng/cig	<12.9	NA	4	<15.9	NA	9	<15 9	NA	9
Nicotine	mg/cig	1 99	0.131	4	1.19	0.0444	9	1.25	0.0445	9
Nitric oxide (NO)	µg/cig	471	16.5	4	11.1	0.79	9	10.4	1 12	9
Nitro benzene	µg/cig	<0.027	NA	4	<0.011	NA	9	<0.011	NA	9
Nitrogen oxides (NOx)	µg/cig	524	17.2	4	12.9	0.903	9	12.1	1 14	9
N-nitrosoanabasine (NAB)	ng/cig	31.8	1.02	4	2.07	0.111	9	2.12	0.162	9
N-nitrosoanatabine (NAT)	ng/cig	334	12.3	4	13.6	0.458	9	14	0.958	9
N-Nitrosonornicotine (NNN)	ng/cig	336	28.4	4	6.31	0.216	9	6.47	0.495	9
o-Cresol	µg/cig	3 22	0.265	4	0.058	0.0095	9	0.068	0.0033	9
o-Toluidine	ng/cig	121	1.04	4	0.957	0.0673	9	0.965	0.0526	9
p-Cresol	µg/cig	6.83	0.53	4	0.051	0.007	9	0.06	0.0041	9
Phenol	µg/cig	11.1	0.896	4	1.24	0.165	9	1.44	0 11	9
Propionaldehyde	µg/cig	135	8.15	4	12.5	1.07	9	12.4	1 23	9
Propylene oxide	ng/cig	1000	78.8	4	117	6.51	9	115	5 14	9
Pyrene	ng/cig	91.9	7.5	4	5.62	0.224	9	5.42	0.188	9
Pyridine	µg/cig	35.2	6.4	4	5.52	0.276	9	5.53	0.321	9
Quinoline	µg/cig	0 315	0.0333	4	<0.011	NA	9	<0.011	NA	9
Resorcinol	µg/cig	<1.32	NA	4	<0.055	NA	9	<0.055	NA	9
Selenium	ng/cig	<4.42	NA	4	<0.83	NA	9	<0.83	NA	9
Styrene	µg/cig	21.7	2.4	4	0.416	0.0253	9	0.418	0.0313	9
Toluene	µg/cig	153	11.5	4	1.84	0.146	9	1.91	0.0784	9
Total Particulate Matter (TPM)	mg/cig	47	2.62	4	51.5	1.09	9	52.6	1 13	9
Vinyl chloride	ng/cig	94.6	7.44	4	<2.19	NA	9	<2.19	NA	9

6. REDUCED FORMATION ASSESSMENT

Table 3: Percent reductions in yields of IQOS 3 System with both extreme firmware regimes (Forced WA and Forced no-WA) and The Authorized IQOS System yields in comparison to the yields of the 3R4F reference cigarette. When the HPHCs yields for both IQOS products and the reference 3R4F reference cigarette are below LOD or LOQ, % reductions are not calculated and ND (Not defined) are reported. For HPHCs below LOD or LOQ in IQOS products, but not in the 3R4F reference cigarette, the % reductions are calculated using the LOD or LOQ values.

HPHCs	*IQOS* 3 System Forced WA	*IQOS* 3 System Forced no-WA	The Authorized *IQOS* System (with *IQOS* 3 Forced WA)	The Authorized *IQOS* System (with *IQOS* 3 Forced no-WA)
1,3-Butadiene	>99.9%	99.8%	99.8%	99.8%
1-Aminonaphthalene	>99.9%	>99.9%	>99.9%	>99.9%
2-Aminonaphthalene	>99.9%	>99.9%	99.9%	>99.9%
3-Aminobiphenyl	99.9%	99.9%	99.9%	99.9%
4-(Methyl-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	97.5%	97.8%	97.4%	97.8%
4-Aminobiphenyl	99.8%	>99.8%	99.8%	99.8%
Acetaldehyde	88.0%	89.1%	88.1%	89.3%
Acetamide	70.9%	73.4%	69.8%	72.3%
Acetone	94.9%	95.3%	95.1%	95.3%
Acrolein	95.2%	95.4%	95.1%	95.3%
Acrylamide	60.5%	61.7%	59.2%	60.2%
Acrylonitrile	>99.5%	>99.4%	>99.5%	>99.4%
Ammonia	70.9%	70.0%	67.6%	69.1%
Arsenic	ND	ND	ND	ND
Benz[a]anthracene	93.3%	94.3%	93.4%	94.5%
Benzene	99.4%	99.4%	99.4%	99.4%
Benzo[a]pyrene	95.1%	95.8%	95.1%	95.9%
Butyraldehyde	78.1%	77.6%	78.3%	78.5%
Cadmium	>99.9%	>99.9%	>99.9%	>99.9%
Carbon monoxide (CO)	98.9%	98.6%	98.8%	>98.6%
Catechol	80.0%	82.7%	78.6%	81.9%
Chromium	ND	ND	ND	ND
Crotonaldehyde	>94.5%	>94.5%	>94.5%	>94.5%
Dibenz[a,h]anthracene	>90.7%	>90.7%	>90.7%	>90.7%
Ethylene oxide	99.0%	>99.4%	98.9%	>99.4%
Formaldehyde	88.9%	91.0%	88.7%	91.4%
Hydrogen cyanide	99.3%	99.3%	99.3%	99.3%
Hydroquinone	89.6%	90.4%	88.2%	89.6%
Isoprene	99.8%	99.8%	99.8%	99.8%

(table continues)

HPHCs	*IQOS* 3 System Forced WA	*IQOS* 3 System Forced no-WA	The Authorized *IQOS* System (with *IQOS* 3 Forced WA)	The Authorized *IQOS* System (with *IQOS* 3 Forced no-WA)
Lead	ND	ND	ND	ND
m-Cresol	98.8%	>99.1%	98.7%	99.0%
Mercury	53.9%	48.8%	55.9%	52.2%
Methyl-ethyl-ketone (MEK)	96.1%	95.7%	96.2%	95.5%
Nickel	ND	ND	ND	ND
Nitric oxide (NO)	97.7%	97.6%	97.7%	97.8%
Nitro benzene	ND	ND	ND	ND
Nitrogen oxides (NOx)	97.7%	97.5%	97.7%	97.7%
N-nitrosoanabasine (NAB)	93.1%	93.5%	93.2%	93.3%
N-nitrosoanatabine (NAT)	95.2%	95.9%	95.2%	95.8%
N-Nitrosonornicotine (NNN)	96.2%	98.1%	96.3%	98.1%
o-Cresol	97.7%	98.2%	97.3%	97.9%
o-Toluidine	99.2%	99.2%	99.1%	99.2%
p-Cresol	99.0%	99.3%	98.8%	99.1%
Phenol	86.7%	88.8%	84.8%	87.0%
Propionaldehyde	90.6%	90.7%	90.7%	90.8%
Propylene oxide	88.2%	88.3%	87.0%	88.5%
Pyrene	91.1%	93.9%	91.2%	94.1%
Pyridine	84.1%	84.3%	83.9%	84.3%
Quinoline	>99%	>96.5%	>99%	>96.5%
Resorcinol	ND	ND	ND	ND
Selenium	ND	ND	ND	ND
Styrene	97.9%	98.1%	97.7%	98.1%
Toluene	99.0%	98.8%	98.9%	98.8%
Vinyl chloride	>97.7%	>97.7%	>97.7%	>97.7%

7. *IQOS* 3 SYSTEM WITH COMMERCIAL FIRMWARE – FDA 18

Table 4: Summary results of the FDA-18 HPHCs measured under the Health Canada Intense regime in IQOS 3 device aerosol with the commercial firmware and each of the three HeatStick variants currently commercially available in the U.S., in comparison to their levels in the smoke of the 1R6F reference cigarette. SD – standard deviation; n – sample size.

HPHCs	Unit	1R6F			*IQOS* 3 Commercial Firmware[8]								
					Marlboro HeatSticks			Marlboro Smooth Menthol HeatSticks			Marlboro Fresh Menthol HeatSticks		
		Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n
1,3-butadiene	µg/cig	104	11	7	0.236	0.037	7	0.264	0.035	7	0.258	0.038	7
1-aminonaphthalene	ng/cig	21.4	0.8	7	0.034	0.001	7	0.042	0.004	7	0.051	0.011	7
2-aminonaphthalene	ng/cig	13.5	0.9	7	< 0.012	NA	7	< 0.012	NA	7	< 0.012	NA	7
4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK)	ng/cig	193	11	7	9.73	1.07	7	8.21	0.65	7	9.38	0.90	7
4-aminobiphenyl	ng/cig	2 96	0.13	7	0.0093	NA	7	0.012	0.003	7	0.010	0.002	7
Acetaldehyde	µg/cig	1539	122	7	190	12	7	216	28	7	192	8	7
Acrolein	µg/cig	172	14	7	9.16	0.88	7	10.1	1.8	7	8.64	0.99	7
Acrylonitrile	µg/cig	22.4	1.7	7	0.141	0.012	7	0.143	0.012	7	0.150	0.012	7
Ammonia	µg/cig	28.7	1.7	7	11.4	1.0	7	12.3	0.4	7	11.7	0.3	7
Benzene	µg/cig	78.3	6.3	7	0.538	0.053	7	0.575	0.060	7	0.586	0.046	7
Benzo(a)pyrene	ng/cig	15.9	0.5	7	0.491	0.038	7	0.718	0.016	7	0.573	0.019	7
Carbon monoxide (CO)	mg/cig	28.7	1.5	20	0.423	0.063	20	0.420	0.071	20	0.429	0.056	20
Crotonaldehyde	µg/cig	46.7	3.9	7	3.378	NA	7	< 3.29	NA	7	< 3.29	NA	7
Formaldehyde	µg/cig	92.8	13.4	7	7.8	0.5	7	8.4	0.6	7	7.5	0.4	7
Isoprene	µg/cig	835	70	7	1.68	0.22	7	1.80	0.20	7	1.73	0.10	7
Nicotine	mg/cig	2.02	0.10	20	1.31	0.07	20	1.25	0.07	20	1.28	0.05	20
Nitrosonornicotine (NNN)	ng/cig	215	10	7	13.9	1.0	7	9.36	1.30	7	9.64	0.72	7
Toluene	µg/cig	115	9	7	1.67	0.16	7	1.64	0.18	7	1.69	0.17	7

Table 5: Summary of results of the FDA-18 HPHCs measured under the ISO Standard regime in IQOS 3 System aerosol with the commercial firmware and each of the three HeatStick variants currently commercially available in the U.S., in comparison to their levels in the smoke of the 1R6F reference cigarette. SD – standard deviation; n – sample size.

HPHCs	Unit	1R6F			*IQOS* 3 Commercial Firmware[5]								
					Marlboro HeatSticks			Marlboro Smooth Menthol HeatSticks			Marlboro Fresh Menthol HeatSticks		
		Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n
1,3-butadiene	µg/cig	34	3	7	< 0.095	NA	7	< 0.095	NA	7	< 0.095	NA	7
1-aminonaphthalene	ng/cig	12.7	0.7	7	< 0.027	NA	7	< 0.027	NA	7	< 0.027	NA	7
2-aminonaphthalene	ng/cig	8.7	1.0	7	< 0.012	NA	7	< 0.012	NA	7	< 0.012	NA	7
4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK)	ng/cig	78	7	7	4.24	0.29	7	4.16	0.47	7	4.53	0.45	7

(table continues)

HPHCs	Unit	1R6F			*IQOS* 3 Commercial Firmware[5]								
					Marlboro HeatSticks			Marlboro Smooth Menthol HeatSticks			Marlboro Fresh Menthol HeatSticks		
		Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n
4-aminobiphenyl	ng/cig	1.47	0.06	7	0.006	NA	7	0.007	NA	7	0.005	NA	7
Acetaldehyde	µg/cig	520	37	7	132	7	7	152	6	7	133	14	7
Acrolein	µg/cig	51	5	7	3.98	0.39	7	4.7	0.5	7	3.81	0.61	7
Acrylonitrile	µg/cig	4.8	0.9	7	< 0.107	NA	7	< 0.107	NA	7	< 0 107	NA	7
Ammonia	µg/cig	8.1	0.6	7	1.8	0.2	7	2.0	0.1	7	2.2	0.3	7
Benzene	µg/cig	25.1	4.1	7	0.248	0.018	7	0.283	0.022	7	0.284	0.021	7
Benzo(a)pyrene	ng/cig	6.8	0.2	7	< 0.354	NA	7	0.407	0.075	7	< 0 354	NA	7
Carbon monoxide (CO)	mg/cig	9.8	0.8	20	0.232	NA	20	0.240	NA	20	0.270	NA	20
Crotonaldehyde	µg/cig	9.3	1.2	7	< 3 29	NA	7	< 3.29	NA	7	< 3.29	NA	7
Formaldehyde	µg/cig	28.7	2.7	7	4 5	0.3	7	4.9	0.2	7	4.6	0.4	7
Isoprene	µg/cig	261	24	7	0.83	0.06	7	0.96	0.08	7	0.97	0.06	7
Nicotine	mg/cig	0.68	0.04	20	0.47	0.04	20	0.52	0.05	20	0.53	0.04	20
Nitrosonornicotine (NNN)	ng/cig	82	5	7	6.4	0.4	7	4.69	0.46	7	5.33	0.69	7
Toluene	µg/cig	31	6	7	0.72	0.07	7	0.77	0.08	7	0.78	0.06	7

8. FOUR ADDITIONAL HPHCS: *IQOS* 3 SYSTEM FORCED WA AND *IQOS* 3 FORCED NO-WA VERSUS THE AUTHORIZED *IQOS* SYSTEM

Table 6: Summary of results of IQOS 3 System yields with both extreme firmware regimes (Forced WA and Forced no-WA), the Authorized IQOS System yields, and the yields of the 1R6F reference cigarette, for the four additional HPHCs. SD – standard deviation; n – sample size.

HPHCs	Unit	1R6F			*IQOS* 3 Forced WA			*IQOS* 3 Forced no-WA			*IQOS* 2.4		
		Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n
2-furanmethanol	µg/stick	4.57	0.351	4	35.7	3.08	4	31.2	2.1	4	31.5	1.66	4
3-chloro-1,2-Propanediol	µg/stick	4.40	0.20	4	10.95	0.79	4	13.67	1.65	4	12.38	1.27	4
Furfural	µg/stick	26.1	3.65	4	33.9	2.13	4	31.7	1.74	4	32.1	3.77	4
Glycidol	µg/stick	2.41	0.278	4	6.07	0.307	4	5.44	0.268	4	5.69	0.333	4

9. DROPLET SIZE DISTRIBUTION

Table 7: MMAD and GSD values for IQOS 3 System assessed with both extremes firmware regimes (Forced WA and Forced no-WA), and the Authorized IQOS System with the same batch of THS Monitor HeatSticks.

Replicate	IQOS 3 Forced WA		IQOS 3 Forced no-WA		IQOS2.4	
	MMAD [µm]	GSD [-]	MMAD [µm]	GSD [-]	MMAD [µm]	GSD [-]
1	0.821	1.44	0.644	1.55	0.859	2.12
2	0.71	1.38	0.756	1.36	0.84	1.74
3	0.775	1.81	0.667	1.5	0.971	1.87
4	0.771	1.34	0.795	1.37	0.662	1.79
5	0.811	1.5	0.795	1.68	0.599	1.78
6	0.704	1.44	0.71	1.46	0.789	1.58
7	0.756	1.41	0.731	1.43	0.719	1.48
8	0.766	1.52	0.773	1.63	0.662	1.52
9	0.742	1.38	0.663	1.52	0.671	1.51
Mean±SD	0.762±0.0397	1.47±0.139	0.726±0.0581	1.5±0.107	0.752±0.12	1.71±0.209

10. SAMPLE IDENTIFICATION

Table 8: Aerosol chemistry and physics assessment studies summary.

Assay	Device	Tobacco sticks	Batch number	Manufactured date	SMP Code	Study number	Study Report Date
PMI-58	*IQOS* 3 System Forced WA[5]	THS Monitor[6]	Device B-72500 Stick IC2911171 SMS Code SMS.007622.RD	Device: 18-Jun-2019 Stick: 23-May-2017	SMP123290	Labstat report NS487-H	26-Jul-2019
	IQOS 3 System Forced no-WA[7]	THS Monitor	Device B-79845 Stick IC2911171 SMS Code	Device: 20-Dec-2019 Stick: 23-May-2017	SMP133179	Labstat report NS530-H	10-Feb-2020
	The Authorized *IQOS* System	THS Monitor	Device B-72348 Stick IC2911171 SMS Code SMS.007622.RD	Device: 17-Jun-2019 Stick: 23-May-2017	SMP123289; SMP133178	Labstat reports NS487-H; NS530-H	26-Jul-2019; 10-Feb-2020

(table continues)

[5] Firmware configured to maintain "warm aerosol" mitigation active continuously
[6] A single batch of HeatStick Regular with Dorado II blend and Flavor system Ron used as reference for product assessment, and control for the analytical testing
[7] Firmware configured to prevent "warm aerosol" mitigation from activating

Assay	Device	Tobacco sticks	Batch number	Manufactured date	SMP Code	Study number	Study Report Date
	3R4F Reference Cigarette	NA	NA	NA	NA	Labstat report NS407-GLP	15-Jun-2018
FDA-18*	*IQOS* 3 System Commercial Firmware[8]	Marlboro HeatSticks (PM0000424)	Device B-81234 Stick B-82173/ 41-3694401 SMS Code SMS.008564.RD	Device: 05-Feb-2020 Stick: 16-Jul-2019	SMP136144	Labstat report NS531-H	26-Feb-2020
	IQOS 3 System Commercial Firmware[8]	Marlboro Smooth Menthol HeatSticks (PM0000425)	Device B-81234 Stick B-82172/ 41-3684215 SMS Code SMS.008563.RD	Device: 05-Feb-2020 Stick: 10-Jul-2019	SMP136145	Labstat report NS531-H	26-Feb-2020
	IQOS 3 System Commercial Firmware[8]	Marlboro Fresh Menthol HeatSticks (PM0000426)	Device B-81234 Stick B-82175/41-3790729 SMS Code SMS.008565.RD	Device: 05-Feb-2020 Stick: 11-Nov-2019	SMP136153	Labstat report NS531-H	26-Feb-2020
	1R6F Reference Cigarette	NA	NA	NA	NA	Labstat report NS531-H	26-Feb-2020
4 Additional HPHCs Glycidol, furfural, 2-furanmethanol, 3-chloro-1,2-propondiol	*IQOS* 3 System Forced WA[5]	THS Monitor6	Device B-79852 Stick IC2911171 SMS Code SMS.007622.RD	Device: 18-Dec-2019 Stick: 23-May-2017	SMP134841	RLS-THR-2020-1; RLS-THR-2020-2	14-Feb-2020

(table continues)

[8] Firmware version 1.3.0 and temperature profile C28 corresponding to the commercial BOM in present application

Assay	Device	Tobacco sticks	Batch number	Manufactured date	SMP Code	Study number	Study Report Date
4 Additional HPHCs Glycidol, furfural, 2-furanmethanol, 3-chloro-1,2-propondiol	*IQOS* 3 System Forced no-WA[7]	THS Monitor[6]	Device B-79858 Stick IC2911171 SMS Code SMS.007622.RD	Device: 20-Dec-2019 Stick: 23-May-2017	SMP134840	RLS-THR-2020-1; RLS-THR-2020-2	14-Feb-2020
	The Authorized *IQOS* System	THS Monitor[6]	Device B-72348; Stick IC2911171 SMS Code SMS.008417.RD	Device: 17-Jun-2019 Stick: 23-May-2017	SMP134667	RLS-THR-2020-1; RLS-THR-2020-2	14-Feb-2020
	1R6F Reference Cigarette	NA	NA	NA	NA	RLS-THR-2020-1; RLS-THR-2020-2	14-Feb-2020
DSD	*IQOS* 3 System Forced WA[5]	THS Monitor[6]	Device B-79852 Stick IC2911171 SMS Code SMS.007622.RD	Device: 18-Dec-2019 Stick: 23-May-2017	SMP133239	Q19494	22-Jan-2020
	IQOS 3 System Forced no-WA[7]	THS Monitor[6]	Device B-79858 Stick IC2911171 SMS Code SMS.007622.RD	Device: 20-Dec-2019 Stick: 23-May-2017	SMP133220	Q19494	22-Jan-2020
	The Authorized *IQOS* System	THS Monitor[6]	Device B-79883; Stick IC2911171 SMS Code SMS.007567.RD	Device: 19-Dec-2019 Stick: 23-May-2017	SMP133219	Q19494	22-Jan-2020

11. REFERENCE DOCUMENTS

[1] PMI-RRP-SOP-112377 - Product Comparability Assessment (RDNEU)
[2] PMI-RRP-SOP-113217 - RRP Comparability Assessments - Aerosol Chemistry

Version	Changes
1.1	*Minor updates to correct for table captions and table layout formatting*

12. ACRONYMS

DSD	:	Droplet Size Distribution
FDA	:	Federal Drug Administration
HPHCs	:	Harmful and Potentially Harmful Constituents
ISO	:	International Organization for Standardization
LOQ	:	Limit of Detection
LOQ	:	Limit of Quantification
NA	:	Not Applicable
ND	:	Not Defined
no-WA	:	NO Warm Aerosol
PMI	:	Philip Morris International
SD	:	Standard Deviation
THS	:	Tobacco Heating System
WA	:	Warm Aerosol

13. SIGNATURES

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