



## PMI RESEARCH &amp; DEVELOPMENT

# Clinical Study Report Corrigendum

## ZRHR-REXC-03-EU

<b>Study Title:</b>	A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement
<b>Short Title:</b>	Reduced exposure study in smokers using Tobacco Heating System 2.2 (THS 2.2) with 5 days in a confinement setting
<b>Study Number:</b>	ZRHR-REXC-03-EU
<b>Product Name:</b>	Tobacco Heating System 2.2 (THS 2.2)
<b>Study Initiated (first subject screened):</b>	29 June 2013
<b>Study Completed (last subject last visit):</b>	26 September 2013
<b>Principal Investigator and Affiliation:</b>	Katarzyna Jarus-Dziedzic, MD, PhD BioVirtus Research Site Sp. z o.o., Mokra 7 05-830 Kajetany, Poland
<b>Sponsor:</b>	Philip Morris Products S.A., PMI Research & Development Quai Jeanrenaud 5, 2000 Neuchâtel, Switzerland
<b>Sponsor Signatories:</b>	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Andrea Donelli, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Patrick Picavet, MD, Medical Safety Officer
<b>Version, Date:</b>	Clinical Study Report v2.0, 08 March 2016 Clinical Study Report Corrigendum v1.0, 26 April 2016

This study was conducted in accordance with Good Clinical Practice.

### Confidentiality Statement

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.



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## **1 LIST OF IN TEXT FIGURES**

N.A.

## **2 LIST OF IN TEXT TABLES**

N.A.



### **3 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS**

Abbreviations used in this document are consistent with those reported in the Clinical Study Report (CSR) version 2.0 dated the 08 March 2016.

### **4 DEFINITION OF TERMS**

Special terms used in this document are consistent with those reported in the CSR.

### **5 RATIONALE**

Due to an omission of the arithmetic mean values and confidence intervals of exhaled CO biomarker, the results are reported in this Corrigendum to the CSR.

### **6 CORRIGENDUM TO THE CLINICAL STUDY REPORT**

#### **6.1 Biomarker of Exposure CO**

##### **6.1.1 Exhaled CO**

Descriptive statistics of the exhaled CO during the course of the study were provided in Appendix 15, [Table 15.2.4.7](#) as geometric means. This Corrigendum provides a new version of [Table 15.2.4.7](#) which includes the arithmetic means and corresponding confidence intervals

#### **6.2 Discussion and Conclusions**

The arithmetic means and confidence intervals reported in the table do not change the interpretation of the exhaled CO results. The table with program run of 21 April 2016 supersedes that of 27 October 2014.



## **7 REFERENCE LIST**

N.A.



## 8 APPROVAL



## 8 APPROVAL

### PRINCIPAL INVESTIGATOR'S SIGNATURE

#### PRINCIPAL INVESTIGATOR'S SIGNATURE

**Study Title:** A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement

**Study Number:** ZRHR-REXC-03-EU

I have read the Corrigendum to Clinical Study Report version 2.0 dated 08 March 2016 referenced above and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Signed:   
Katarzyna Jarus-Dziedzic, MD, PhD

Date: 08 June 2016



## 9 SIGNATURES OF SPONSORS RESPONSIBLE PERSONNEL



### SIGNATURES OF SPONSORS RESPONSIBLE PERSONNEL

This Clinical Study Report was subject to critical review and has been approved by the Sponsor.

#### SPONSOR SIGNATORIES

Study Title:


A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement

Study Number:

ZRHR-REXC-03-EU

We, the undersigned, confirm that to the best of our knowledge this Corrigendum to Clinical Study Report version 2.0 dated 08 March 2016 accurately describes the experimental methods and results of the study.


Signed:

  
Christelle Haziza, PhD  
Manager P1 Clinical Program, Clinical Scientist

Date:

20/05/2016

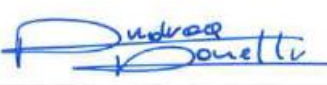
Signed:

  
Guillaume de La Bourdonnaye, MEng, MSc  
Biostatistician

Date:

20 MAY 2016

Signed:

  
Andrea Donelli  
Clinical Scientist

Date:

20 May 2016

Signed:

  
Patrick Picavet, MD  
Medical Safety Officer

Date:

23 MAY 2016



## **10 ADDITIONAL SUMMARIES NOT INCLUDED IN THE TEXT**

### **10.1 Figures**

N.A.

### **10.2 Tables**

Table 15.2.4.7      Descriptive statistics of exhaled CO (ppm) – FAS



**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day -2	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	15.9 (46.3%)	14.6 (66.9%)	17.6 (49.2%)
	95% CI	14.4, 17.6	12.0, 17.8	15.1, 20.5
	Mean (SD)	17.4 (6.76)	17.3 (9.99)	19.2 (7.28)
	95% CI	15.8, 18.9	14.1, 20.5	16.8, 21.6
	Median	17.5	15.0	19.0
	Q25, Q75	12.0, 22.0	8.0, 23.0	14.0, 23.0
	Min, Max	4, 37	4, 44	3, 33

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day -1, 15 min < T <sub>0</sub>	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	10.0 (50.6%)	9.8 (55.2%)	10.9 (39.0%)
	95% CI	8.9, 11.1	8.2, 11.5	9.6, 12.4
	Mean (SD)	11.0 (4.77)	11.0 (5.23)	11.6 (4.13)
	95% CI	9.9, 12.1	9.3, 12.7	10.3, 13.0
	Median	10.0	10.0	11.0
	Q25, Q75	7.0, 15.0	7.0, 13.0	9.0, 14.0
	Min, Max	2, 23	3, 22	4, 22

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day -1, 12:00-02:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	14.2 (58.9%)	12.6 (64.6%)	14.0 (40.0%)
	95% CI	12.6, 16.1	10.4, 15.2	12.3, 15.9
	Mean (SD)	16.2 (7.77)	14.5 (6.79)	14.9 (5.30)
	95% CI	14.4, 18.0	12.3, 16.7	13.2, 16.7
	Median	16.0	14.0	14.0
	Q25, Q75	10.0, 21.0	9.0, 19.0	11.0, 18.0
	Min, Max	2, 45	2, 28	4, 26

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

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Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day -1, 04:00-06:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	15.9 (41.9%)	15.2 (41.8%)	15.5 (35.9%)
	95% CI	14.5, 17.5	13.3, 17.3	13.8, 17.4
	Mean (SD)	17.2 (6.73)	16.3 (6.28)	16.4 (5.91)
	95% CI	15.7, 18.8	14.3, 18.4	14.4, 18.4
	Median	16.0	16.0	16.0
	Q25, Q75	12.0, 21.5	11.0, 20.0	12.0, 19.0
	Min, Max	5, 38	6, 35	7, 34

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day -1, 08:00-10:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	14.4 (59.4%)	13.5 (44.9%)	15.1 (35.7%)
	95% CI	12.7, 16.3	11.7, 15.5	13.5, 16.9
	Mean (SD)	16.3 (7.33)	14.6 (5.29)	16.0 (5.48)
	95% CI	14.6, 17.9	12.8, 16.3	14.2, 17.8
	Median	16.0	15.0	14.0
	Q25, Q75	11.0, 21.0	11.0, 18.0	11.0, 21.0
	Min, Max	3, 41	4, 28	7, 27

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

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Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 0, 15 min < T <sub>0</sub>	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	7.9 (47.0%)	7.6 (55.4%)	8.6 (37.8%)
	95% CI	7.1, 8.8	6.4, 9.0	7.6, 9.7
	Mean (SD)	8.7 (3.58)	8.5 (3.88)	9.2 (3.30)
	95% CI	7.8, 9.5	7.2, 9.8	8.0, 10.3
	Median	8.0	9.0	8.0
	Q25, Q75	6.0, 11.0	5.0, 11.0	7.0, 12.0
	Min, Max	2, 19	3, 18	4, 16

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

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Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 0, 12:00-02:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	16.0 (54.0%)	15.1 (52.1%)	15.9 (49.9%)
	95% CI	14.2, 18.0	12.9, 17.7	13.6, 18.6
	Mean (SD)	17.8 (8.08)	16.9 (8.12)	17.6 (7.75)
	95% CI	16.0, 19.7	14.2, 19.5	15.1, 20.2
	Median	16.5	16.0	15.0
	Q25, Q75	12.5, 22.0	12.0, 21.0	12.0, 23.0
	Min, Max	2, 51	4, 50	5, 36

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 0, 04:00-06:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	14.6 (48.6%)	15.1 (47.1%)	15.6 (38.3%)
	95% CI	13.1, 16.2	13.0, 17.4	13.8, 17.7
	Mean (SD)	16.2 (7.71)	16.6 (7.95)	16.7 (6.27)
	95% CI	14.4, 18.0	14.1, 19.2	14.6, 18.8
	Median	14.0	15.0	16.0
	Q25, Q75	10.5, 20.5	12.0, 20.0	12.0, 21.0
	Min, Max	6, 41	5, 48	7, 33

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 0, 08:00-10:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	15.4 (54.8%)	15.6 (36.5%)	16.9 (42.1%)
	95% CI	13.7, 17.3	13.9, 17.5	14.8, 19.3
	Mean (SD)	17.1 (7.71)	16.7 (6.83)	18.2 (6.56)
	95% CI	15.4, 18.9	14.5, 18.9	16.0, 20.3
	Median	16.0	14.0	18.0
	Q25, Q75	11.5, 20.0	13.0, 18.0	13.0, 23.0
	Min, Max	1, 42	7, 43	5, 34

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 1, 15 min < T <sub>0</sub>	n	80	41	0
	BLOQ - n (%)	0	0	
	Geometric Mean (CV%)	8.5 (40.1%)	8.2 (46.0%)	
	95% CI	7.8, 9.3	7.1, 9.5	
	Mean (SD)	9.1 (3.32)	9.0 (3.76)	
	95% CI	8.3, 9.9	7.7, 10.2	
	Median	8.0	8.0	
	Q25, Q75	7.0, 12.0	6.0, 12.0	
	Min, Max	2, 18	3, 17	

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 1, 08:00-10:00 AM	n	0	0	39
	BLOQ - n (%)			0
	Geometric Mean (CV%)			7.7 (37.3%)
	95% CI			6.8, 8.7
	Mean (SD)			8.2 (2.94)
	95% CI			7.2, 9.2
	Median			8.0
	Q25, Q75			6.0, 10.0
	Min, Max			4, 15

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 1, 12:00-02:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	5.3 (49.2%)	13.4 (39.1%)	5.5 (52.7%)
	95% CI	4.8, 6.0	11.9, 15.2	4.6, 6.5
	Mean (SD)	5.9 (2.29)	14.4 (5.91)	5.9 (2.72)
	95% CI	5.3, 6.4	12.5, 16.4	5.0, 6.8
	Median	6.0	14.0	6.0
	Q25, Q75	4.0, 7.0	10.0, 17.0	4.0, 7.0
	Min, Max	1, 12	7, 34	0, 12

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 1, 04:00-06:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	3.7 (59.5%)	13.5 (43.4%)	4.1 (48.6%)
	95% CI	3.3, 4.3	11.8, 15.4	3.5, 4.9
	Mean (SD)	4.2 (2.10)	14.7 (6.53)	4.5 (1.74)
	95% CI	3.7, 4.7	12.6, 16.8	3.9, 5.1
	Median	4.0	14.0	4.0
	Q25, Q75	3.0, 6.0	10.0, 17.0	3.0, 5.0
	Min, Max	0, 10	5, 32	1, 9

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 1, 08:00-10:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	3.2 (57.7%)	11.9 (47.8%)	3.1 (53.5%)
	95% CI	2.8, 3.6	10.2, 13.7	2.6, 3.7
	Mean (SD)	3.8 (3.74)	13.2 (6.78)	3.3 (1.82)
	95% CI	2.9, 4.7	11.0, 15.4	2.7, 4.0
	Median	3.0	11.0	3.0
	Q25, Q75	2.0, 4.5	9.0, 16.0	2.0, 5.0
	Min, Max	1, 34	5, 42	0, 8

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 2, 15 min < T <sub>0</sub>	n	80	41	0
	BLOQ - n (%)	0	0	
	Geometric Mean (CV%)	3.1 (40.1%)	8.1 (44.8%)	
	95% CI	2.8, 3.4	7.1, 9.4	
	Mean (SD)	3.4 (1.26)	8.9 (3.79)	
	95% CI	3.0, 3.7	7.6, 10.1	
	Median	3.0	8.0	
	Q25, Q75	2.0, 4.0	6.0, 11.0	
	Min, Max	1, 6	3, 21	

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 2, 08:00-10:00 AM	n	0	0	39
	BLOQ - n (%)			0
	Geometric Mean (CV%)			2.9 (42.7%)
	95% CI			2.5, 3.3
	Mean (SD)			3.1 (1.17)
	95% CI			2.7, 3.5
	Median			3.0
	Q25, Q75			2.0, 4.0
	Min, Max			1, 6

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 2, 12:00-02:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.7 (49.2%)	11.6 (56.1%)	2.5 (47.6%)
	95% CI	2.4, 3.1	9.8, 13.7	2.1, 3.0
	Mean (SD)	3.0 (1.33)	13.1 (6.60)	2.6 (1.29)
	95% CI	2.6, 3.3	11.0, 15.3	2.2, 3.1
	Median	3.0	12.0	3.0
	Q25, Q75	2.0, 4.0	9.0, 15.0	2.0, 4.0
	Min, Max	0, 7	2, 34	0, 6

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 2, 04:00-06:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.7 (53.5%)	13.0 (45.5%)	2.4 (50.8%)
	95% CI	2.4, 3.1	11.3, 14.9	2.0, 2.8
	Mean (SD)	3.0 (1.54)	14.2 (6.35)	2.4 (1.40)
	95% CI	2.6, 3.4	12.1, 16.2	1.9, 2.9
	Median	3.0	14.0	2.0
	Q25, Q75	2.0, 4.0	10.0, 18.0	2.0, 3.0
	Min, Max	1, 9	5, 37	0, 6

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 2, 08:00-10:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.3 (57.4%)	13.2 (44.7%)	2.5 (60.0%)
	95% CI	2.0, 2.7	11.5, 15.2	2.0, 3.1
	Mean (SD)	2.5 (1.45)	14.5 (6.47)	2.6 (1.73)
	95% CI	2.2, 2.9	12.4, 16.6	2.0, 3.2
	Median	2.0	13.0	2.0
	Q25, Q75	1.5, 3.0	10.0, 18.0	1.0, 4.0
	Min, Max	0, 8	6, 34	0, 8

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 3, 15 min < T <sub>0</sub>	n	80	41	0
	BLOQ - n (%)	0	0	
	Geometric Mean (CV%)	2.9 (49.6%)	7.6 (45.5%)	
	95% CI	2.5, 3.2	6.6, 8.7	
	Mean (SD)	3.2 (1.37)	8.3 (3.77)	
	95% CI	2.8, 3.5	7.1, 9.6	
	Median	3.0	7.0	
	Q25, Q75	2.0, 4.0	6.0, 9.0	
	Min, Max	1, 7	3, 18	

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 3, 08:00-10:00 AM	n	0	0	39
	BLOQ - n (%)			0
	Geometric Mean (CV%)			2.8 (46.5%)
	95% CI			2.4, 3.3
	Mean (SD)			3.0 (1.19)
	95% CI			2.6, 3.5
	Median			3.0
	Q25, Q75			2.0, 4.0
	Min, Max			1, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 3, 12:00-02:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.9 (50.2%)	12.1 (44.3%)	2.6 (51.7%)
	95% CI	2.5, 3.2	10.6, 13.9	2.2, 3.1
	Mean (SD)	3.0 (1.46)	13.3 (6.04)	2.7 (1.40)
	95% CI	2.7, 3.4	11.3, 15.2	2.2, 3.2
	Median	3.0	12.0	3.0
	Q25, Q75	2.0, 4.0	8.0, 16.0	2.0, 4.0
	Min, Max	0, 6	6, 31	0, 7

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 3, 04:00-06:00 PM	n	80	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.9 (48.8%)	14.8 (37.1%)	2.5 (51.4%)
	95% CI	2.6, 3.3	13.2, 16.7	2.1, 3.0
	Mean (SD)	3.2 (1.49)	15.9 (6.75)	2.6 (1.51)
	95% CI	2.8, 3.6	13.7, 18.1	2.0, 3.1
	Median	3.0	14.0	2.0
	Q25, Q75	2.0, 4.0	12.0, 18.0	2.0, 4.0
	Min, Max	0, 8	8, 42	0, 7

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 3, 08:00-10:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.6 (52.9%)	13.8 (40.0%)	2.0 (55.8%)
	95% CI	2.2, 2.9	12.2, 15.7	1.7, 2.5
	Mean (SD)	2.7 (1.36)	14.9 (6.48)	2.1 (1.27)
	95% CI	2.4, 3.1	12.8, 17.0	1.6, 2.5
	Median	3.0	13.0	2.0
	Q25, Q75	2.0, 4.0	11.0, 17.0	1.0, 3.0
	Min, Max	0, 6	6, 35	0, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 4, 15 min < T <sub>0</sub>	n	79	41	0
	BLOQ - n (%)	0	0	
	Geometric Mean (CV%)	2.9 (42.2%)	8.6 (35.8%)	
	95% CI	2.6, 3.2	7.7, 9.7	
	Mean (SD)	3.1 (1.19)	9.1 (3.18)	
	95% CI	2.8, 3.4	8.1, 10.2	
	Median	3.0	9.0	
	Q25, Q75	2.0, 4.0	7.0, 11.0	
	Min, Max	1, 6	4, 17	

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 4, 08:00-10:00 AM	n	0	0	39
	BLOQ - n (%)			0
	Geometric Mean (CV%)			2.7 (36.5%)
	95% CI			2.4, 3.1
	Mean (SD)			2.8 (1.08)
	95% CI			2.4, 3.2
	Median			3.0
	Q25, Q75			2.0, 4.0
	Min, Max			0, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 4, 12:00-02:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.9 (43.7%)	12.2 (45.7%)	2.3 (48.3%)
	95% CI	2.6, 3.2	10.6, 14.1	1.9, 2.8
	Mean (SD)	3.2 (1.30)	13.4 (5.78)	2.4 (1.29)
	95% CI	2.8, 3.5	11.5, 15.3	1.9, 2.8
	Median	3.0	13.0	2.0
	Q25, Q75	2.0, 4.0	9.0, 16.0	2.0, 3.0
	Min, Max	1, 8	5, 25	0, 6

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 4, 04:00-06:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.8 (50.4%)	13.3 (51.5%)	2.7 (41.5%)
	95% CI	2.5, 3.2	11.4, 15.6	2.3, 3.1
	Mean (SD)	3.0 (1.47)	14.9 (7.12)	2.6 (1.32)
	95% CI	2.6, 3.4	12.6, 17.2	2.1, 3.0
	Median	3.0	13.0	2.0
	Q25, Q75	2.0, 4.0	9.0, 19.0	2.0, 4.0
	Min, Max	0, 7	3, 33	0, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 4, 08:00-10:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.6 (44.6%)	14.2 (39.1%)	2.5 (46.2%)
	95% CI	2.3, 2.9	12.6, 16.1	2.1, 2.9
	Mean (SD)	2.6 (1.31)	15.3 (6.30)	2.6 (1.24)
	95% CI	2.3, 3.0	13.3, 17.4	2.1, 3.0
	Median	2.0	14.0	2.0
	Q25, Q75	2.0, 3.0	10.0, 18.0	2.0, 3.0
	Min, Max	0, 6	7, 32	0, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 5, 15 min < T <sub>0</sub>	n	79	41	0
	BLOQ - n (%)	0	0	
	Geometric Mean (CV%)	2.3 (48.3%)	7.3 (42.8%)	
	95% CI	2.0, 2.6	6.4, 8.4	
	Mean (SD)	2.5 (1.08)	8.0 (3.34)	
	95% CI	2.2, 2.7	6.8, 9.1	
	Median	2.0	7.0	
	Q25, Q75	2.0, 3.0	6.0, 9.0	
	Min, Max	0, 5	3, 18	

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 5, 08:00-10:00 AM	n	0	0	39
	BLOQ - n (%)			0
	Geometric Mean (CV%)			2.0 (41.2%)
	95% CI			1.7, 2.3
	Mean (SD)			2.1 (0.76)
	95% CI			1.8, 2.4
	Median			2.0
	Q25, Q75			2.0, 3.0
	Min, Max			1, 4

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 5, 12:00-02:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.1 (43.4%)	11.2 (48.3%)	2.1 (52.0%)
	95% CI	1.9, 2.4	9.7, 13.0	1.7, 2.6
	Mean (SD)	2.1 (1.09)	12.5 (6.11)	2.1 (1.41)
	95% CI	1.8, 2.3	10.5, 14.4	1.6, 2.6
	Median	2.0	10.0	2.0
	Q25, Q75	1.0, 3.0	8.0, 15.0	1.0, 3.0
	Min, Max	0, 4	4, 26	0, 7

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 5, 04:00-06:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.2 (51.0%)	11.8 (53.7%)	2.0 (45.9%)
	95% CI	1.9, 2.5	10.1, 13.9	1.7, 2.4
	Mean (SD)	2.3 (1.11)	13.4 (7.36)	2.1 (1.13)
	95% CI	2.0, 2.6	11.0, 15.7	1.6, 2.5
	Median	2.0	11.0	2.0
	Q25, Q75	1.0, 3.0	9.0, 17.0	1.0, 3.0
	Min, Max	0, 4	2, 45	0, 5

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 5, 08:00-10:00 PM	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.0 (46.5%)	12.3 (52.4%)	2.2 (51.5%)
	95% CI	1.8, 2.3	10.5, 14.4	1.8, 2.6
	Mean (SD)	2.0 (1.04)	13.9 (7.77)	2.0 (1.44)
	95% CI	1.7, 2.3	11.4, 16.4	1.5, 2.5
	Median	2.0	11.0	2.0
	Q25, Q75	1.0, 3.0	9.0, 16.0	1.0, 3.0
	Min, Max	0, 5	5, 39	0, 6

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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**Table 15.2.4.7 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THS 2.2 (N=80)	CC (N=41)	SA (N=39)
Day 6/Discharge	n	79	41	39
	BLOQ - n (%)	0	0	0
	Geometric Mean (CV%)	2.3 (38.4%)	6.5 (41.8%)	2.1 (45.8%)
	95% CI	2.1, 2.6	5.6, 7.4	1.8, 2.4
	Mean (SD)	2.5 (0.89)	7.0 (3.05)	2.3 (0.89)
	95% CI	2.2, 2.7	6.0, 8.0	1.9, 2.6
	Median	2.0	7.0	2.0
	Q25, Q75	2.0, 3.0	5.0, 8.0	2.0, 3.0
	Min, Max	0, 4	3, 19	1, 4

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Geometric: mean, CV% and 95% confidence interval (CI) are reported.

Note: T<sub>0</sub> = Time of first product use on study day.

Note: No BLOQ values recorded for this parameter.

Appendix 15.3.3.2

Path: /cvn/projects/prj/development/000000106324/dev/tables/t\_co.sas

Program Run: 21APR16 cvn\_kbooth Program Status: FINAL

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### **10.3 Subject Data**

N.A.

### **10.4 Statistical Output**

N.A.

## **11 CORRIGENDUM APPENDICES**

N.A.