SECTION E. Source Group Plan Approval Restrictions.

they demonstrate performance and compliance.

(9) Other information as specified in paragraph (b)(3)(ii) of this section and Sec. 63.5(d)(3) of subpart A of this part.

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) Application for approval of construction. Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) Approval of construction or reconstruction based on prior State preconstruction review. (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and Sec. 63.5(d)(3) and (4) of subpart A of this part if the owner or operator of a new or reconstructed source who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in Sec. 63.5(e)(1) of subpart A of this part.

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in Sec. 63.5 of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) Notification requirements. The owner or operator of each source subject to the emissions standards in Sec. 63.362 shall fulfill all notification requirements in Sec. 63.9 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this paragraph.

(1) Initial notifications.

(i)(A) If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month period after December 6, 1996, such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of Sec. 63.9 of subpart A of this part.

(B) Sources subject to these emissions standards may use the application for approval of construction or reconstruction under paragraph (b)(3)(ii) of this section and Sec. 63.5(d) (3) of subpart A of this part, respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed source subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required

SECTION E. Source Group Plan Approval Restrictions.

under paragraph (b)(3) of this section and Sec. 63.5(d) (3) and (4) of subpart A of this part shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (b)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (b)(3) of this section and Sec. 63.5(d)(3) and (4) of subpart A of this part. For sources subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of Sec. 63.9 of subpart A of this part.

(2) If an owner or operator of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (b)(3)(ii) of this section and Sec. 63.5(d)(3) of subpart A of this part, respectively, in place of the actual emissions data or control efficiencies required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) The owner or operator of any existing sterilization facility subject to this subpart shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by Sec. 63.9(b)(2) and (3) of subpart A of this part. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

VI. WORK PRACTICE REQUIREMENTS.

 # 014 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The facility shall be:

a. Operated in such a manner as not to cause air pollution as that term is defined in 25 Pa. Code § 121.1;

b. Operated and maintained in a manner consistent with good operating and maintenance practices;

c. Operated and maintained in accordance with practices based on the "manufacturer's specifications;" and

APPENDIX II

Example Field Sheets

Analyzer Calibration Data Sheet

Company	
Location	
Source	
Date	
Time	

DIRECT CALIBRATIONS													
Analyzer Type	Zero	Gas 1 Value ____	Gas 2 Value ____	Gas 3 Value ____	Gas 4 Value ____	Gas 5 Value ____	Gas 6 Value ____	Gas 7 Value ____	Gas 8 Value ____	Gas 9 Value ____	Gas 10 Value ____	Gas 11 Value ____	Gas 12 Value ____
Time													

Initial Bias													
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	Bias 7 Value ____	Bias 8 Value ____	Bias 9 Value ____	Bias 10 Value ____	Bias 11 Value ____	Bias 12 Value ____
Time													

RUN _____								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

Channel Inputs	
A	_____
B	_____
C	_____
D	_____
E	_____
F	_____
G	_____
H	_____
I	_____
J	_____
K	_____
L	_____
M	

RUN _____								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

RUN _____								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

RUN _____								
Start:				Stop:				
Bias								
Analyzer Type	Zero	Bias 1 Value ____	Bias 2 Value ____	Bias 3 Value ____	Bias 4 Value ____	Bias 5 Value ____	Bias 6 Value ____	
								HL
								HL
								HL
								HL
								HL
								HL
								HL
Time								HL

Analyzer Response Test

Analyzer Make
Analyzer Model
Analyzer Serial #

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time

System Response Time [ ]

Method 2 FLOW DATA SHEET

Project No. _____
Proj. Name _____

Site Location _____
Unit/Location _____
Stack ID _____

MB / Manometer # _____
Pitot Tube / Probe ID # _____
(cirkc one)

Operator(s) _____
Baro. Pressure _____

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Method 4 MOISTURE DATA SHEET

Project # _____
Proj. Name _____
Date _____
Site Loc. _____
Unit/Loc. _____

Meter Box # _____
Delta Y @ _____
Delta H @ _____
MB Pump # _____
Stack ID _____

Operator(s) _____
Run ___ Baro. Press. _____
Run ___ Baro. Press. _____
Run ___ Baro. Press. _____

RUN #	MOISTURE TRAIN				Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)	Train Leak Check		
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)			PRE		POST
								CFM@	VAC	CFM@ VAC
								@		@
								Imp. #	Initial	Final Diff.
								1		
								2		
								3		
								4		
								5		
								6		
								7		
								8		
								9		
								T		

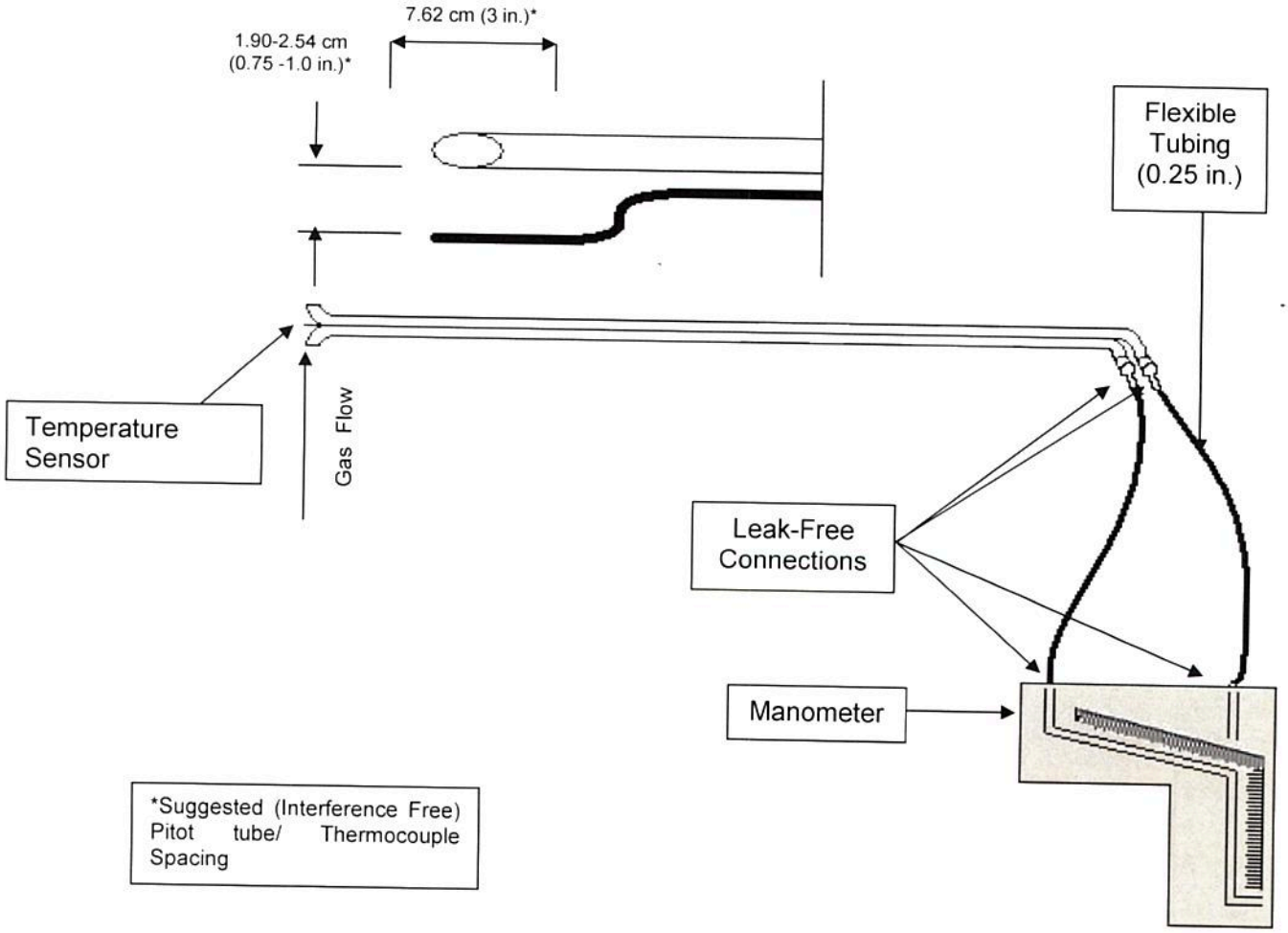
RUN #	MOISTURE TRAIN				Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)	Train Leak Check		
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)			PRE		POST
								CFM@	VAC	CFM@ VAC
								@		@
								Imp. #	Initial	Final Diff.
								1		
								2		
								3		
								4		
								5		
								6		
								7		
								8		
								9		
								T		

RUN #	MOISTURE TRAIN				Start Time		Stop Time		Impingers ICED ?	
	Sampling Time	Dry Gas Meter				EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)	Train Leak Check		
Real Time		VOLUME (ft^3)	Delta H	In.Temp. (°F)	Out Temp.(°F)			PRE		POST
								CFM@	VAC	CFM@ VAC
								@		@
								Imp. #	Initial	Final Diff.
								1		
								2		
								3		
								4		
								5		
								6		
								7		
								8		
								9		
								T		

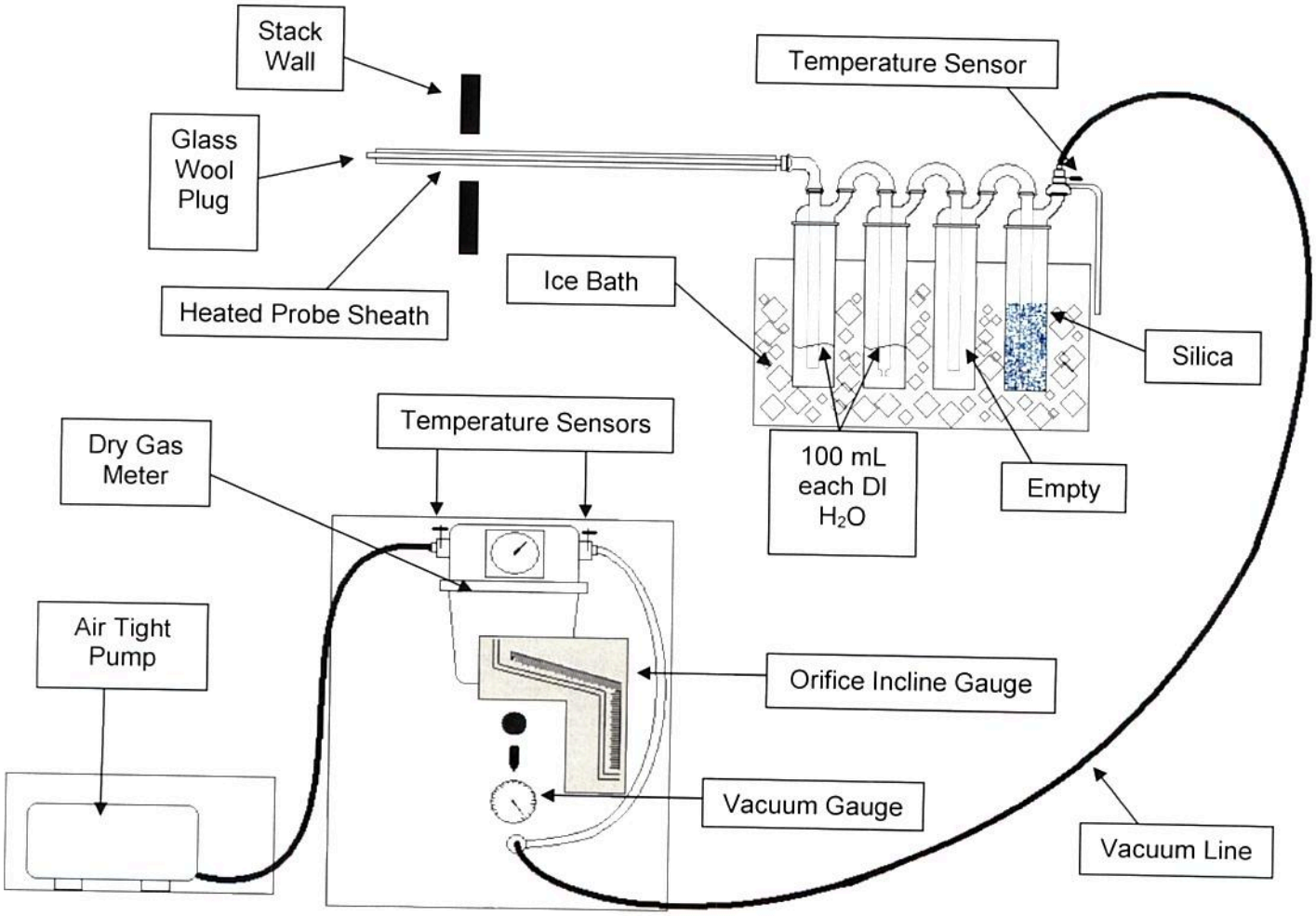
APPENDIX III

Sampling Train Diagrams

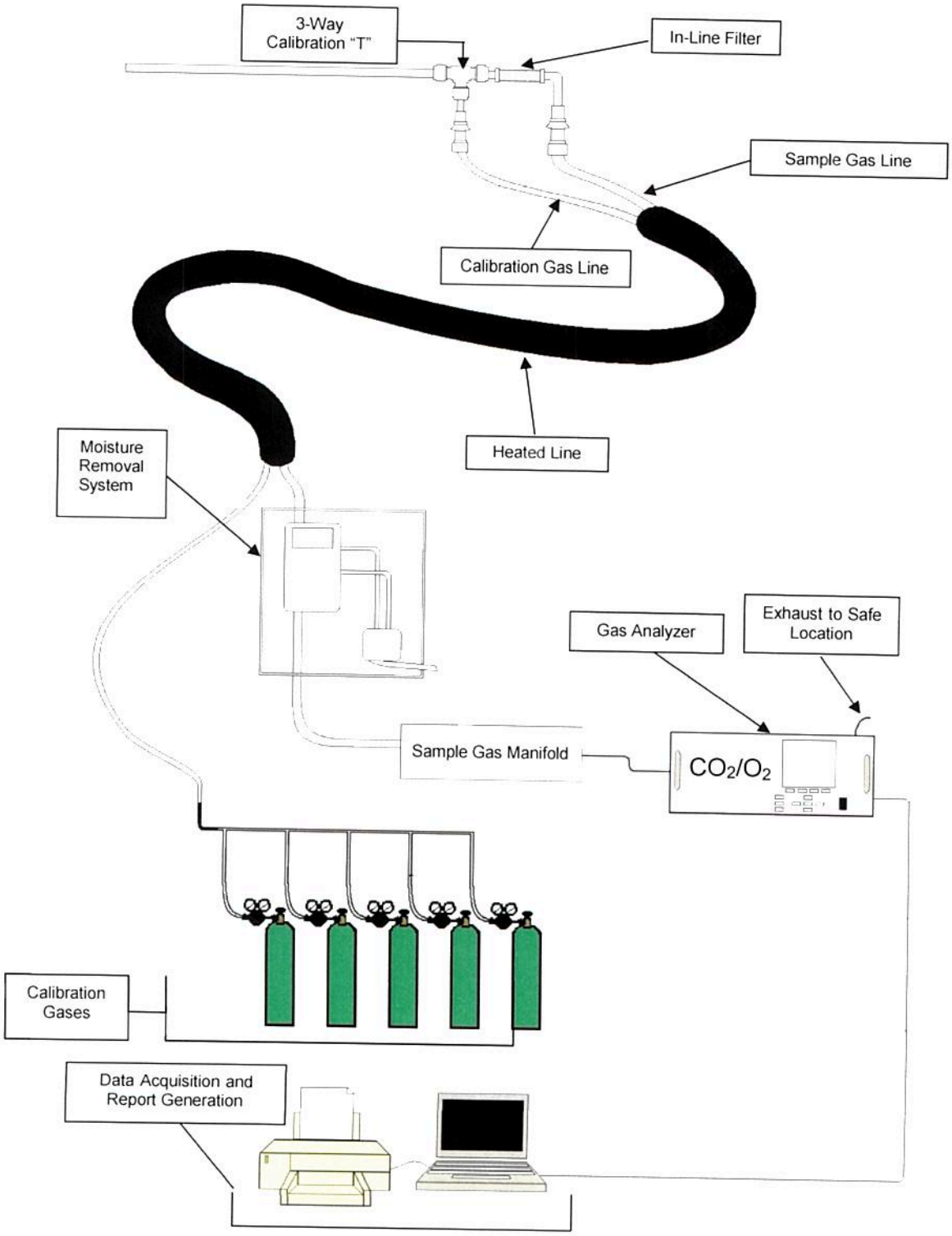
U.S. EPA Method 2- Type S Pitot Tube Manometer Assembly



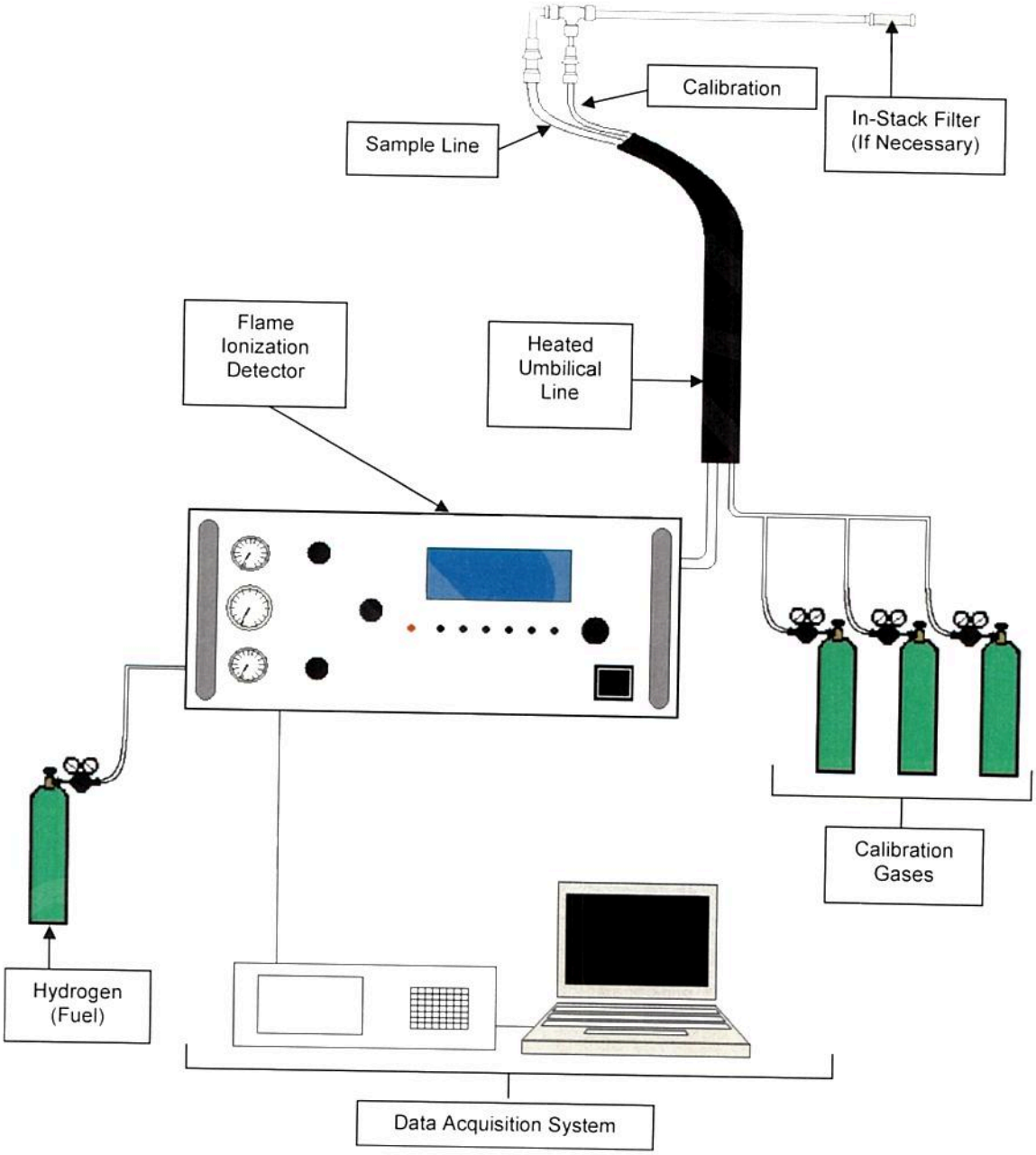
U.S. EPA Method 4- Moisture Content Sample Train Diagram



U.S. EPA Method 3A Extractive Gaseous Sampling Diagram



U.S. EPA Method 25A – Total Gaseous Organic Compound Sample Train



APPENDIX B

EMISSION CALCULATIONS

STERILIZATION CHAMBER

STERILIZATION RUN 1
CHAMBER 7 CYCLE 1
15-Dec-20
0836-0858

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	=	13.1	psia	=	90324.5	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	126.86	deg F	=	325.85	deg K	(52.7C)
			n	=	3398.61	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	=	147	lbs ETO charged
	=	0.9999	volume fraction EtO in gas cylinder
W_C	=	66671.4	g ETO charged
W_C	=	1513.47	mol ETO charged

Chamber 7 During Exposure

	3398.61	mol pre-charge gas in chamber
+	1513.47	mol ETO charged
	4912.08	total mol ETO solution in chamber

0.69189 mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	=	1.6	psia	=	11032	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.31446	m3 Pa/mol k				
T	=	120.2	deg F	=	322.15	deg K	(49.0C)
			n	=	419.865	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

	419.865	mol ETO solution remaining in chamber
x	0.69189	mol pre-charge gas / mol ETO solution in chamber
	290.499	mol pre-charge gas remaining in chamber

		419.865	mol ETO solution remaining in chamber
	-	290.499	mol pre-charge gas remaining in chamber
W_R	=	129.365	mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		1513.47	mol ETO charged, W_c
	-	129.365	mol ETO remaining in chamber, W_R
W_I	=	1384.11	mol ETO delivered to inlet
W_I	=	60972.6	g ETO delivered to inlet
W_I	=	134.422	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

$$C = C_{wet} / ((100 - B_{ws}) / 100)$$

C_{wet}	=	0.73	ppmv, wet
B_{ws}	=	1.25971	%
C	=	0.73558	ppmv, dry

$$EtO_{lb/hr} = C * Flowrate * MW * 60 \text{ min/hr} / 385.3 \text{ scf/lb-mol} * 10^{-6}$$

C	=	0.73558	ppmv, dry
Flowrate	=	15727	dscfm
MW	=	44.052	g/mol
$EtO_{lb/hr}$	=	0.07936	lb/hr

$$W_O = C \times V \times (MW/SV) \times (1/10^6)$$

C	=	0.735581	ppmv, dry		
V	=	350364	std. cubic feet	=	9921201 liters
MW	=	44.052	g/mol		
SV	=	24.05	l/mol		
W_O	=	13.3673	g ETO outlet		

Cat Ox Efficiency

$$\%EFF = ((W_I - W_O)/W_I) * 100$$

W_I	=	60972.6	g ETO delivered to inlet
W_O	=	13.3673	g ETO outlet

%EFF = 99.97808

STERILIZATION RUN 2
CHAMBER 7 CYCLE 1
15-Dec-20
1310-1332

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	=	12.9	psia	=	88945.5	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.314462	m3 Pa/mol k				
T	=	126.86	deg F	=	325.85	deg K	(52.7C)
			n	=	3346.72	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	=	155	lbs ETO charged
	=	0.9999	volume fraction EtO in gas cylinder
W_C	=	70299.79132	g ETO charged
W_C	=	1595.836541	mol ETO charged

Chamber 7 During Exposure

	3346.720556	mol pre-charge gas in chamber
+	1595.836541	mol ETO charged
	4942.557097	total mol ETO solution in chamber
	0.677123297	mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	=	1.5	psia	=	10342.5	Pa	
V	=	3600	ft^3	=	101.941	m^3	
R	=	8.314462	m3 Pa/mol k				
T	=	120.56	deg F	=	322.35	deg K	(49.2C)
			n	=	393.379	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

	393.3788901	mol ETO solution remaining in chamber
x	0.677123297	mol pre-charge gas / mol ETO solution in chamber
	266.3660109	mol pre-charge gas remaining in chamber

		393.3788901	mol ETO solution remaining in chamber
	-	266.3660109	mol pre-charge gas remaining in chamber
W_R	=	127.0128792	mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		1595.836541	mol ETO charged, W_c
	-	127.0128792	mol ETO remaining in chamber, W_R
W_I	=	1468.823662	mol ETO delivered to inlet
W_I	=	64704.61996	g ETO delivered to inlet
W_I	=	142.6492595	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

$C = C_{wet} / ((100 - B_{ws}) / 100)$

C_{wet}	=	0.79	ppmv, wet
B_{ws}	=	2.152261056	%
C	=	0.80550	ppmv, dry

$EtO_{lb/hr}$ = C * Flowrate * MW * 60 min/hr / 385.3 scf/lb-mol * 10^-6

C	=	0.80550	ppmv, dry
Flowrate	=	15663	dscfm
MW	=	44.052	g/mol
$EtO_{lb/hr}$	=	0.086549767	lb/hr

W_O = C x V x (MW/SV) x (1/10^6)

C	=	0.8055	ppmv, dry		
V	=	352188.43	std. cubic feet	=	9972867 liters
MW	=	44.052	g/mol		
SV	=	24.05	l/mol		
W_O	=	14.7141823	g ETO outlet		

Cat Ox Efficiency

$\%EFF = ((W_I - W_O)/W_I)*100$

W_I	=	64704.61996	g ETO delivered to inlet
W_O	=	14.7141823	g ETO outlet

%EFF = 99.97726

STERILIZATION RUN 3
CHAMBER 7 CYCLE 1
15-Dec-20
1709-1730

Chamber 7 Conditions @ First Evacuation Cycle

PV=nRT >>> n=PV/RT

P	= 13.0	psia	= 89635	Pa	
V	= 3600	ft^3	= 101.941	m^3	
R	= 8.31446	m3 Pa/mol k			
T	= 126.86	deg F	= 325.85	deg K	(52.7C)
		n	= 3372.66	mol pre-charge gas in chamber	

ETO Delivered to Chamber 7

W_C	= 152	lbs ETO charged
	= 0.9999	volume fraction EtO in gas cylinder
W_C	= 68939.2	g ETO charged
W_C	= 1564.95	mol ETO charged

Chamber 7 During Exposure

	3372.66	mol pre-charge gas in chamber
+	1564.95	mol ETO charged
	4937.61	total mol ETO solution in chamber
	0.68306	mol pre-charge gas / mol ETO solution in chamber

Chamber 7 Conditions After First Evacuation

PV=nRT >>> n=PV/RT

P	= 1.8	psia	= 12411	Pa	
V	= 3600	ft^3	= 101.941	m^3	
R	= 8.31446	m3 Pa/mol k			
T	= 119.48	deg F	= 321.75	deg K	(48.6C)
		n	= 472.935	mol ETO solution remaining in chamber	

ETO Remaining in Chamber 7 After First Evacuation

	472.935	mol ETO solution remaining in chamber
x	0.68306	mol pre-charge gas / mol ETO solution in chamber
	323.041	mol pre-charge gas remaining in chamber

		472.935	mol ETO solution remaining in chamber
	-	323.041	mol pre-charge gas remaining in chamber
W_R	=	149.894	mol ETO remaining in chamber

Chamber 7 ETO Delivered to Peak Shave/Cat Ox Inlet

		1564.95	mol ETO charged, W_c
		- 149.894	mol ETO remaining in chamber, W_R
W_I	=	1415.06	mol ETO delivered to inlet
W_I	=	62336	g ETO delivered to inlet
W_I	=	137.427	lbs ETO delivered to inlet

ETO at Cat Ox Outlet

$C = C_{wet} / ((100 - B_{ws}) / 100)$

C_{wet}	=	0.77	ppmv, wet
B_{ws}	=	2.0345	%
C	=	0.7836	ppmv, dry

$EtO_{lb/hr}$ = C * Flowrate * MW * 60 min/hr / 385.3 scf/lb-mol * 10^-6

C	=	0.7836	ppmv, dry
Flowrate	=	18129.3	dscfm
MW	=	44.052	g/mol
$EtO_{lb/hr}$	=	0.09745	lb/hr

W_O = C x V x (MW/SV) x (1/10^6)

C	=	0.7836	ppmv, dry		
V	=	388643	std. cubic feet	=	1.1E+07 liters
MW	=	44.052	g/mol		
SV	=	24.05	l/mol		
W_O	=	15.7959	g ETO outlet		

Cat Ox Efficiency

$\%EFF = ((W_I - W_O)/W_I)*100$

W_I	=	62336	g ETO delivered to inlet
W_O	=	15.7959	g ETO outlet

%EFF = 99.97466

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	**Allentown, PA**	Moisture Time	0836-0906
Source:	**CatOx Outlet**	**Run No.**	**1**

INPUT DATA	
Beginning Meter Setting (cubic feet):	38.785
Ending Meter Setting (cubic feet):	62.520
Total Metered Volume (cubic feet) [Vm]:	23.735
Water Caught (grams) [Wc]	6.5
Stack Pressure ("H2O) [Ps]	**-2.7**
Barometric Pressure ("HG) [Pb]	**30.31**
Carbon Dioxide (%) [CO2]	**0.49**
Oxygen (%) [O2]	**20.31**
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

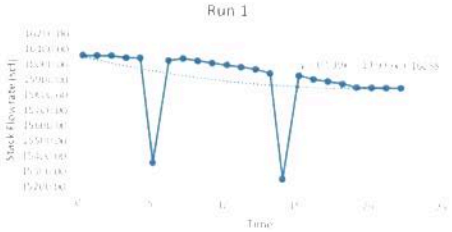
OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	**24.033**
Moisture Volume (cubic feet) [Vws]	0.307
Moisture (% @ stp) [Bws]	**1.26**
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.89
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.75
Absolute Stack Pressure ("Hg) [Pa]	30.11
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	67.41
Standard, Average (SFS) [Vss]:	55.93
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	19196
Standard Average (SCFM):	15928
Dry, Standard Avg (DSCFM):	**15727**

Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
771.1	734.0	37.1
691.2	726.0	-34.8
658.1	657.3	0.8
963.1	959.7	3.4
Water Caught (gms)		**6.5**

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	0836	1.2	174	1.095	73	73	67.32	56.42	19170.68	16067.65
1	0837	1.2	174	1.095	76	73	67.32	56.42	19170.68	16067.65
2	0838	1.2	174	1.095	81	73	67.32	56.42	19170.68	16067.65
3	0839	1.2	175	1.095	85	74	67.37	56.38	19185.79	16055.00
4	0840	1.2	175	1.095	89	75	67.37	56.38	19185.79	16055.00
5	0841	1.1	175	1.049	91	76	64.50	53.98	18368.99	15371.49
6	0842	1.2	176	1.095			67.42	56.33	19200.89	16042.37
7	0843	1.2	175	1.095			67.37	56.38	19185.79	16055.00
8	0844	1.2	176	1.095			67.42	56.33	19200.89	16042.37
9	0845	1.2	177	1.095			67.47	56.29	19215.98	16029.77
10	0846	1.2	178	1.095			67.53	56.24	19231.06	16017.21
11	0847	1.2	179	1.095			67.58	56.20	19246.12	16004.67
12	0848	1.2	180	1.095			67.63	56.15	19261.18	15992.16
13	0849	1.2	182	1.095			67.74	56.07	19291.25	15967.23
14	0850	1.1	183	1.049			64.91	53.64	18484.34	15275.57
15	0851	1.2	183	1.095			67.79	56.02	19306.27	15954.81
16	0852	1.2	185	1.095			67.90	55.94	19336.27	15930.05
17	0853	1.2	186	1.095			67.95	55.89	19351.25	15917.72
18	0854	1.2	187	1.095			68.00	55.85	19366.22	15905.41
19	0855	1.2	189	1.095			68.11	55.76	19396.13	15880.89
20	0856	1.2	189	1.095			68.11	55.76	19396.13	15880.89
21	0857	1.2	189	1.095			68.11	55.76	19396.13	15880.89
22	0858	1.2	189	1.095			68.11	55.76	19396.13	15880.89
23										
24										
Averages:		1.191	180 [Ts]	1.091 [dP]		78.3 [Tm]	67.41	55.93	19196.29	15927.93



y = 0.539x^2 - 19.939x + 16058
F(x) = (0.539/3)x^3 - (19.939/2)x^2 + 16058x +c

x	F(x)		
0	=(0.539/3)*0^3 - (19.939/2)*0^2 + 16058*0 + c	=	0.00
22	=(0.539/3)*22^3 - (19.939/2)*22^2 + 16058*22 + c	=	350,363.85
Area	= F(22) - F(0)	=	**350,363.85** **V (scf)***

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	**Allentown, PA**	Moisture Time	1310-1340
Source:	**CatOx Outlet**	**Run No.**	**2**

INPUT DATA	
Beginning Meter Setting (cubic feet):	131.155
Ending Meter Setting (cubic feet):	155.020
Total Metered Volume (cubic feet) [Vm]:	23.9
Water Caught (grams) [Wc]	10.80
Stack Pressure ("H2O) [Ps]	**-2.8**
Barometric Pressure ("HG) [Pb]	**30.31**
Carbon Dioxide (%) [CO2]	**0.39**
Oxygen (%) [O2]	**20.33**
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

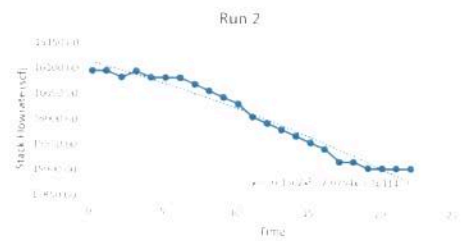
OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	**23.160**
Moisture Volume (cubic feet) [Vws]	0.509
Moisture (% @ stp) [Bws]	**2.15**
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.88
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.64
Absolute Stack Pressure ("Hg) [Pa]	30.10
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	67.83
Standard, Average (SFS) [Vss]:	56.21
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	19317
Standard Average (SCFM):	16008
Dry, Standard Avg (DSCFM):	**15663**

Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
776.7	773.6	3.1
692.2	690.6	1.6
658.5	657.3	1.2
970.9	966.0	4.9
Water Caught (gms)		**10.8**

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	1310	1.2	174	1.095	97	96	67.45	56.52	19210.41	16097.02
1	1311	1.2	174	1.095	103	96	67.45	56.52	19210.41	16097.02
2	1312	1.2	175	1.095	107	96	67.51	56.48	19225.55	16084.34
3	1313	1.2	174	1.095	110	96	67.45	56.52	19210.41	16097.02
4	1314	1.2	175	1.095	111	97	67.51	56.48	19225.55	16084.34
5	1315	1.2	175	1.095	112	98	67.51	56.48	19225.55	16084.34
6	1316	1.2	175	1.095			67.51	56.48	19225.55	16084.34
7	1317	1.2	176	1.095			67.56	56.43	19240.68	16071.69
8	1318	1.2	177	1.095			67.61	56.39	19255.80	16059.07
9	1319	1.2	178	1.095			67.67	56.35	19270.91	16046.48
10	1320	1.2	179	1.095			67.72	56.30	19286.01	16033.92
11	1321	1.2	181	1.095			67.83	56.21	19316.17	16008.89
12	1322	1.2	182	1.095			67.88	56.17	19331.23	15996.41
13	1323	1.2	183	1.095			67.93	56.13	19346.28	15983.97
14	1324	1.2	184	1.095			67.98	56.08	19361.31	15971.56
15	1325	1.2	185	1.095			68.04	56.04	19376.34	15959.17
16	1326	1.2	186	1.095			68.09	56.00	19391.36	15946.81
17	1327	1.2	188	1.095			68.20	55.91	19421.35	15922.18
18	1328	1.2	188	1.095			68.20	55.91	19421.35	15922.18
19	1329	1.2	189	1.095			68.25	55.87	19436.33	15909.91
20	1330	1.2	189	1.095			68.25	55.87	19436.33	15909.91
21	1331	1.2	189	1.095			68.25	55.87	19436.33	15909.91
22	1332	1.2	189	1.095			68.25	55.87	19436.33	15909.91
23										
24										
Averages:		1.200	181 [Ts]	1.095 [dP]		101.6 [Tm]	67.83	56.21	19317.28	16008.28



y = -0.1302x^2 - 7.6754x + 16114
F(x) = -(0.1302/3)x^3 - (7.6754/2)x^2 + 16114x +c

x	F(x)		
0	= -(0.1302/3)*0^3 - (7.6754/2)*0^2 + 16114*0 + c	=	0.00
22	= -(0.1302/3)*22^3 - (7.6754/2)*22^2 + 16114*22 + c	=	352,188.43
Area	= F(22) - F(0)	=	**352,188.43** **V (scf)***

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time.

STACK FLOWRATE CALCULATOR

Customer Name:	B Braun	Date	12/15/20
Location:	**Allentown, PA**	Moisture Time	1709-1739
Source:	**CatOx Outlet**	**Run No.**	**3**

INPUT DATA	
Beginning Meter Setting (cubic feet):	189.380
Ending Meter Setting (cubic feet):	213.212
Total Metered Volume (cubic feet) [Vm]:	23.8
Water Caught (grams) [Wc]	10.30
Stack Pressure ("H2O) [Ps]	**-3.0**
Barometric Pressure ("HG) [Pb]	**30.35**
Carbon Dioxide (%) [CO2]	**0.38**
Oxygen (%) [O2]	**20.32**
Delta H ("H2O) [H]	2.00
Pitot Tube Factor [Cp]	0.84
Meter Correction Factor [Y]	1.014
Stack Inside Diameter (in) [ID]	29.5
Stack Cross-Section (square feet) [CSA]	4.746

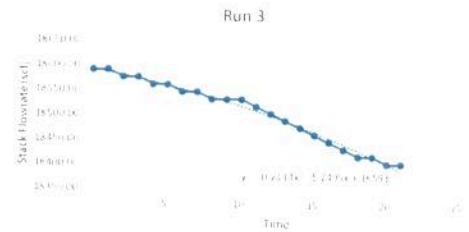
OUTPUT DATA	
Meter Volume (Dry cubic feet @stp) [Vms]	**23.395**
Moisture Volume (cubic feet) [Vws]	0.486
Moisture (% @ stp) [Bws]	**2.03**
Dry Molecular Weight (lb/lb-Mol) [MWd]	28.87
Wet Molecular Weight (lb/lb-Mol) [MWw]	28.65
Absolute Stack Pressure ("Hg) [Pa]	30.13
Stack Gas Velocities (feet/second)	
Actual (ft/sec) [Vsa]:	78.21
Standard, Average (SFS) [Vss]:	64.98
Stack Flowrate (cubic feet/minute)	
Average Actual (ACFM):	22272
Standard Average (SCFM):	18506
Dry, Standard Avg (DSCFM):	**18129**

Impinger Weights		
Final Wt	**Initial Wt**	**Gain**
779.6	776.7	2.9
693.7	692.2	1.5
659.7	658.5	1.2
975.6	970.9	4.7
Water Caught (gms)		**10.3**

STP = Standard Conditions = 68 Deg F (A)
29.92 "Hg (B)

Equations
CSA = ID^2 / 183.3465
Vms = (17.71)(Y)(Vm)(((H / 13.6) + Pb) / (Tm + 460))
Vws = Wc / 21.2
Bws = (100)(Vws) / (Vms + Vws)
MWd = (CO2)(0.44) + (O2)(0.32) + (100 - (CO2 + O2))(.28)
MWw = (Bws)(0.18) + ((MWd)(100 - Bws) / 100)
Pa = Pb + (Ps1 / 13.6)
Vsa = (((Ts + 460) / (((Ps / 13.6) + Pb)(MWw)))^0.5)(Cp)(dP)(85.49)
Vss = (((Vsa)(((Ps / 13.6) + Pb) / (Ts + 460)))(17.71 / 2)
ACFM = (Vsa)(CSA)(60 sec/min)
SCFM = (Vss)(CSA)(60 sec/min)
DSCFM = ((100 - Bws)/ 100)(SCFM)

Minute	Flow Time	Delta P ("H2O)	Stack Temp (Deg F)	Square Root Delta P	Gas Meter Temps (deg F) In	Gas Meter Temps (deg F) Out	Stack Velocities (feet/sec) Ave. Actual (Vsa)	Stack Velocities (feet/sec) Std. Actual (Vss)	Stack Flow Rate Ave. Actual (acfm)	Stack Flow Rate Std. Ave. (scfm)
0	1709	1.6	174	1.265	90	91	77.84	65.28	22169.10	18591.82
1	1710	1.6	174	1.265	95	90	77.84	65.28	22169.10	18591.82
2	1711	1.6	175	1.265	98	91	77.91	65.23	22186.58	18577.17
3	1712	1.6	175	1.265	102	91	77.91	65.23	22186.58	18577.17
4	1713	1.6	176	1.265	108	92	77.97	65.18	22204.04	18562.56
5	1714	1.6	176	1.265	110	93	77.97	65.18	22204.04	18562.56
6	1715	1.6	177	1.265			78.03	65.13	22221.49	18547.98
7	1716	1.6	177	1.265			78.03	65.13	22221.49	18547.98
8	1717	1.6	178	1.265			78.09	65.08	22238.93	18533.44
9	1718	1.6	178	1.265			78.09	65.08	22238.93	18533.44
10	1719	1.6	178	1.265			78.09	65.08	22238.93	18533.44
11	1720	1.6	179	1.265			78.15	65.03	22256.35	18518.94
12	1721	1.6	180	1.265			78.21	64.98	22273.76	18504.46
13	1722	1.6	181	1.265			78.27	64.93	22291.15	18490.02
14	1723	1.6	182	1.265			78.33	64.87	22308.53	18475.62
15	1724	1.6	183	1.265			78.39	64.82	22325.90	18461.24
16	1725	1.6	184	1.265			78.46	64.77	22343.25	18446.90
17	1726	1.6	185	1.265			78.52	64.72	22360.59	18432.60
18	1727	1.6	186	1.265			78.58	64.67	22377.92	18418.33
19	1728	1.6	186	1.265			78.58	64.67	22377.92	18418.33
20	1729	1.6	187	1.265			78.64	64.62	22395.23	18404.09
21	1730	1.6	187	1.265			78.64	64.62	22395.23	18404.09
22										
23										
24										
Averages:		1.600	180 [Ts]	1.265 [dP]		95.9 [Tm]	78.21	64.98	22272.05	18506.09



y = -0.2114x^2 - 5.2495x + 18593
F(x) = -(0.2114/3)x^3 - (5.2495/2)x^2 + 18593x +c

x	F(x)		
0	= -(0.2114/3)*0^3 - (5.2495/2)*0^2 + 18593*0 + c	=	0.00
21	= -(0.2114/3)*21^3 - (5.2495/2)*21^2 + 18593*21 + c	=	388,642.89
Area	= F(21) - F(0)	=	**388,642.89 V (scf)***

*Calculated in accordance with Subpart O by integrating area under curve plotted using volumetric flowrate vs time.

CatOx Outlet Diluent Concentrations of O_2 & CO_2 during Sterilization

Customer Name: B Braun

Location: Allentown,PA

Source: CatOx Outlet

Run No.	1	2	3
Date	12/15/20	12/15/20	12/15/20
Time	0836-0858	1310-1332	1709-1730

Outlet- Oxygen (O_2)

	1	2	3	Average
Average Zero Response (%) (F)	-0.020	0.050	0.035	
Average Upscale Response (%) (G)	11.945	12.000	12.015	
Bias Gas Value (%) (H)	11.92	11.92	11.92	
Run Average, dry, uncorrected (%) (I)	20.36	20.43	20.46	
Run Average, dry, corrected (%) (J)	**20.31**	**20.33**	**20.32**	**20.32**

Outlet- Carbon Dioxide (CO_2)

	1	2	3	Average
Average Zero Response (%) (F)	0.225	0.230	0.255	
Average Upscale Response (%) (G)	9.385	9.325	9.395	
Bias Gas Value (%) (H)	9.229	9.229	9.229	
Run Average, dry, uncorrected (%) (I)	0.71	0.62	0.63	
Run Average, dry, corrected (%) (J)	**0.49**	**0.39**	**0.38**	**0.42**

Equations:

(J)=(I-F)(H)/(G-F)

Definitions:

(F) = Analyzer response to zero gas

(G) = Analyzer response to span gas

(H) = Calibration gas concentration

(I) = Analyzer response to stack gas, measured dry.

AERATION ROOM

EtO Emissions during Aeration Room Test

Customer Name: B Braun
Location: Allentown, PA
Source: Catalytic Oxidizer Outlet

Run No.	1	2	3	
Date	12/15/20	12/15/20	12/15/20	
Time	1042-1142	1155-1255	1535-1635	
				Averages
Stack Moisture (%) (A)	0.56	1.49	0.77	0.94

Ethylene Oxide (EtO)

	1	2	3	Averages	Emission Limit
Run Average, wet (ppmv) (B)	0.71	0.65	0.73		
Run Average, dry (ppmv) (C)	**0.71307**	**0.65774**	**0.73126**	**0.70069**	**1.0**

Equations:

(C) = (B) / ((100 - A) / 100)

Definitions:

(A) = In-stack moisture as measured by U.S. EPA Method 4.
(B) = Analyzer response to stack gas; EtO is measured wet.

STACK MOISTURE CALCULATOR DURING AERATION

Customer:	B Braun
Location:	Allentown, PA
Source:	Catalytic Oxidizer Outlet
Date:	12/15/20

Run Times:

Run 1		Run 2		Run 3	
1042-1142		1155-1255		1535-1635	
IN	OUT	IN	OUT	IN	OUT
Meter Temperatures in Degrees F					
80	78	92	91	86	87
82	79	96	90	86	86
84	79	99	90	89	85
88	80	101	90	92	85
90	80	102	91	94	86
93	81	104	92	96	86
95	82	105	92	98	87
97	84	106	93	100	88
98	85	106	94	101	89
99	85	107	94	102	90
100	87	107	94	103	90
102	88	108	95	104	91
Average Meter Temps.:	87.3 (A)		97.5 (A)		91.7 (A)

Run 1

Impinger Weights		
Final Wt	Initial Wt	Gain
773.6	771.1	2.5
690.6	691.2	-0.6
657.3	658.1	-0.8
966.0	963.1	2.9
Water Caught (gms)		4.0

Run 2

Impinger Weights		
Final Wt	Initial Wt	Gain
720.7	716.3	4.4
720.0	719.2	0.8
639.8	639.1	0.7
965.9	961.1	4.8
Water Caught (gms)		10.7

Run 3

Impinger Weights		
Final Wt	Initial Wt	Gain
722.4	720.7	1.7
719.9	720.0	-0.1
639.8	639.8	0.0
969.8	965.9	3.9
Water Caught (gms)		5.5

INPUT DATA	Run 1	Run 2	Run 3
Beginning Meter Setting (cubic feet) (A):	62.770	96.715	155.275
Ending Meter Setting (cubic feet) (A1):	96.540	130.925	189.100
Meter Volume. (cubic feet) (C):	33.770	34.210	33.825
Water Caught (grams) (D):	4.0	10.7	5.5
Barometric Pressure ("Hg) (B):	30.31	30.31	30.35
Meter Correction Factor (E):	1.014	1.014	1.014
Average Delta H ("H2O) (F):	1.00	1.00	1.00

OUTPUT DATA	Run 1	Run 2	Run 3
Metered Volume (Std.cu.ft.) (G):	33.545	33.365	33.377
Moisture Volume (cubic feet) (H):	0.19	0.50	0.26
Percent Moisture (J):	**0.56**	**1.49**	**0.77**

Calculations

G = ((F /13.6)+ B)/(A +460 deg R))*((L +460)/M)* C * E

H = D / 21.2 grams H2O/cubic foot of saturated air at 68 deg F and 29.92" Hg

J = 100 * H / (H + G)

Standard Conditions = 68 deg F (L)
29.92 "Hg (M)

APPENDIX C

RUN DATA

STERILIZATION CHAMBER

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	8:36:26	20.57	0.56	0.62
12/15/20	8:37:26	20.43	0.59	0.59
12/15/20	8:38:27	20.30	0.66	0.64
12/15/20	8:39:26	20.25	0.70	0.65
12/15/20	8:40:27	20.24	0.71	0.71
12/15/20	8:41:26	20.26	0.70	0.73
12/15/20	8:42:27	20.25	0.73	0.73
12/15/20	8:43:26	20.26	0.74	0.72
12/15/20	8:44:26	20.25	0.76	0.72
12/15/20	8:45:27	20.26	0.75	0.76
12/15/20	8:46:26	20.29	0.74	0.78
12/15/20	8:47:26	20.32	0.74	0.75
12/15/20	8:48:26	20.34	0.74	0.79
12/15/20	8:49:27	20.35	0.74	0.74
12/15/20	8:50:26	20.39	0.74	0.76
12/15/20	8:51:26	20.41	0.73	0.73
12/15/20	8:52:26	20.43	0.73	0.73
12/15/20	8:53:27	20.44	0.73	0.76
12/15/20	8:54:27	20.48	0.73	0.72
12/15/20	8:55:26	20.49	0.73	0.78
12/15/20	8:56:27	20.49	0.73	0.79
12/15/20	8:57:27	20.49	0.73	0.79
Averages		**20.36**	**0.71**	**0.73**
Minimum		**20.24**	**0.56**	**0.59**
Maximum		**20.57**	**0.76**	**0.79**

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	13:10:27	20.65	0.52	0.63
12/15/20	13:11:27	20.60	0.53	0.64
12/15/20	13:12:27	20.44	0.55	0.70
12/15/20	13:13:27	20.35	0.61	0.72
12/15/20	13:14:27	20.33	0.64	0.74
12/15/20	13:15:27	20.31	0.65	0.74
12/15/20	13:16:27	20.30	0.67	0.77
12/15/20	13:17:27	20.36	0.64	0.79
12/15/20	13:18:27	20.35	0.65	0.79
12/15/20	13:19:27	20.34	0.67	0.80
12/15/20	13:20:27	20.37	0.64	0.81
12/15/20	13:21:27	20.37	0.64	0.82
12/15/20	13:22:27	20.36	0.65	0.83
12/15/20	13:23:26	20.40	0.64	0.83
12/15/20	13:24:27	20.41	0.63	0.84
12/15/20	13:25:27	20.45	0.61	0.84
12/15/20	13:26:27	20.45	0.64	0.83
12/15/20	13:27:27	20.48	0.61	0.84
12/15/20	13:28:27	20.50	0.60	0.85
12/15/20	13:29:27	20.53	0.61	0.85
12/15/20	13:30:27	20.54	0.61	0.85
12/15/20	13:31:27	20.56	0.60	0.84
Averages		**20.43**	**0.62**	**0.79**
Minimum		**20.30**	**0.52**	**0.63**
Maximum		**20.65**	**0.67**	**0.85**

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)
12/15/20	17:09:27	20.69	0.49	0.65
12/15/20	17:10:27	20.60	0.51	0.64
12/15/20	17:11:27	20.46	0.54	0.68
12/15/20	17:12:27	20.38	0.60	0.71
12/15/20	17:13:27	20.34	0.63	0.72
12/15/20	17:14:27	20.34	0.65	0.73
12/15/20	17:15:27	20.32	0.66	0.73
12/15/20	17:16:27	20.31	0.69	0.73
12/15/20	17:17:27	20.35	0.67	0.78
12/15/20	17:18:27	20.38	0.65	0.78
12/15/20	17:19:27	20.38	0.66	0.79
12/15/20	17:20:27	20.41	0.65	0.81
12/15/20	17:21:27	20.44	0.65	0.80
12/15/20	17:22:27	20.45	0.65	0.80
12/15/20	17:23:27	20.48	0.65	0.83
12/15/20	17:24:27	20.51	0.65	0.82
12/15/20	17:25:27	20.53	0.64	0.83
12/15/20	17:26:27	20.56	0.63	0.83
12/15/20	17:27:27	20.56	0.66	0.82
12/15/20	17:28:27	20.57	0.66	0.82
12/15/20	17:29:27	20.60	0.63	0.84
Averages		**20.46**	**0.63**	**0.77**
Minimum		**20.31**	**0.49**	**0.64**
Maximum		**20.69**	**0.69**	**0.84**

AERATION ROOM

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	10:42:26	0.73
12/15/20	10:43:27	0.72
12/15/20	10:44:27	0.75
12/15/20	10:45:27	0.76
12/15/20	10:46:27	0.71
12/15/20	10:47:26	0.71
12/15/20	10:48:27	0.72
12/15/20	10:49:26	0.72
12/15/20	10:50:27	0.72
12/15/20	10:51:26	0.72
12/15/20	10:52:26	0.73
12/15/20	10:53:27	0.73
12/15/20	10:54:26	0.73
12/15/20	10:55:27	0.72
12/15/20	10:56:26	0.72
12/15/20	10:57:27	0.72
12/15/20	10:58:26	0.70
12/15/20	10:59:26	0.69
12/15/20	11:00:27	0.69
12/15/20	11:01:26	0.69
12/15/20	11:02:26	0.75
12/15/20	11:03:26	0.74
12/15/20	11:04:27	0.68
12/15/20	11:05:26	0.68
12/15/20	11:06:26	0.74
12/15/20	11:07:26	0.73
12/15/20	11:08:26	0.73
12/15/20	11:09:27	0.68
12/15/20	11:10:26	0.67
12/15/20	11:11:27	0.70
12/15/20	11:12:27	0.71
12/15/20	11:13:26	0.70
12/15/20	11:14:26	0.70
12/15/20	11:15:27	0.70
12/15/20	11:16:27	0.70
12/15/20	11:17:26	0.70
12/15/20	11:18:27	0.70
12/15/20	11:19:27	0.71
12/15/20	11:20:26	0.70
12/15/20	11:21:26	0.70
12/15/20	11:22:26	0.70
12/15/20	11:23:27	0.67

Aeration Room- EtO Run 001

Date	Time	EtO (ppm)
12/15/20	11:24:26	0.65
12/15/20	11:25:27	0.67
12/15/20	11:26:27	0.68
12/15/20	11:27:26	0.68
12/15/20	11:28:27	0.68
12/15/20	11:29:26	0.69
12/15/20	11:30:26	0.69
12/15/20	11:31:27	0.70
12/15/20	11:32:26	0.70
12/15/20	11:33:27	0.71
12/15/20	11:34:26	0.71
12/15/20	11:35:27	0.71
12/15/20	11:36:26	0.72
12/15/20	11:37:26	0.72
12/15/20	11:38:27	0.75
12/15/20	11:39:26	0.76
12/15/20	11:40:27	0.71
12/15/20	11:41:26	0.72
Averages		**0.71**
Minimum		**0.65**
Maximum		**0.76**

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	11:55:27	0.69
12/15/20	11:56:27	0.69
12/15/20	11:57:27	0.69
12/15/20	11:58:26	0.68
12/15/20	11:59:26	0.68
12/15/20	12:00:27	0.68
12/15/20	12:01:27	0.68
12/15/20	12:02:26	0.67
12/15/20	12:03:27	0.67
12/15/20	12:04:27	0.67
12/15/20	12:05:26	0.67
12/15/20	12:06:26	0.67
12/15/20	12:07:26	0.67
12/15/20	12:08:27	0.67
12/15/20	12:09:26	0.66
12/15/20	12:10:27	0.67
12/15/20	12:11:27	0.67
12/15/20	12:12:26	0.66
12/15/20	12:13:27	0.66
12/15/20	12:14:26	0.66
12/15/20	12:15:26	0.65
12/15/20	12:16:27	0.62
12/15/20	12:17:27	0.62
12/15/20	12:18:27	0.62
12/15/20	12:19:26	0.62
12/15/20	12:20:27	0.67
12/15/20	12:21:26	0.68
12/15/20	12:22:26	0.65
12/15/20	12:23:27	0.61
12/15/20	12:24:26	0.66
12/15/20	12:25:27	0.67
12/15/20	12:26:26	0.67
12/15/20	12:27:27	0.61
12/15/20	12:28:27	0.60
12/15/20	12:29:26	0.65
12/15/20	12:30:27	0.66
12/15/20	12:31:26	0.64
12/15/20	12:32:27	0.64
12/15/20	12:33:26	0.63
12/15/20	12:34:27	0.63
12/15/20	12:35:26	0.63
12/15/20	12:36:26	0.63

Aeration Room- EtO Run 002

Date	Time	EtO (ppm)
12/15/20	12:37:26	0.63
12/15/20	12:38:26	0.63
12/15/20	12:39:27	0.64
12/15/20	12:40:27	0.64
12/15/20	12:41:27	0.63
12/15/20	12:42:27	0.63
12/15/20	12:43:26	0.63
12/15/20	12:44:26	0.63
12/15/20	12:45:27	0.63
12/15/20	12:46:27	0.62
12/15/20	12:47:27	0.62
12/15/20	12:48:27	0.63
12/15/20	12:49:27	0.63
12/15/20	12:50:27	0.63
12/15/20	12:51:27	0.66
12/15/20	12:52:27	0.66
12/15/20	12:53:27	0.60
12/15/20	12:54:26	0.61

Averages	**0.65**
Minimum	**0.60**
Maximum	**0.69**

PACE Environmental
Minute Average

Date	Time	EtO (ppm)
12/15/20	15:35:27	0.75
12/15/20	15:36:27	0.77
12/15/20	15:37:27	0.72
12/15/20	15:38:27	0.71
12/15/20	15:39:27	0.77
12/15/20	15:40:27	0.76
12/15/20	15:41:27	0.76
12/15/20	15:42:27	0.73
12/15/20	15:43:27	0.71
12/15/20	15:44:27	0.71
12/15/20	15:45:27	0.71
12/15/20	15:46:27	0.75
12/15/20	15:47:27	0.76
12/15/20	15:48:27	0.76
12/15/20	15:49:27	0.71
12/15/20	15:50:27	0.71
12/15/20	15:51:27	0.73
12/15/20	15:52:27	0.78
12/15/20	15:53:27	0.76
12/15/20	15:54:27	0.71
12/15/20	15:55:27	0.71
12/15/20	15:56:27	0.71
12/15/20	16:10:36	0.73
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:50	0.73
12/15/20	16:11:50	0.72
12/15/20	16:11:51	0.72
12/15/20	16:12:27	0.72
12/15/20	16:13:27	0.72
12/15/20	16:14:27	0.72
12/15/20	16:15:27	0.73

Aeration Room- EtO Run 003

Date	Time	EtO (ppm)
12/15/20	16:16:27	0.73
12/15/20	16:17:27	0.73
12/15/20	16:18:27	0.72
12/15/20	16:19:27	0.69
12/15/20	16:20:27	0.69
12/15/20	16:21:27	0.69
12/15/20	16:22:27	0.69
12/15/20	16:23:27	0.74
12/15/20	16:24:27	0.75
12/15/20	16:25:27	0.74
12/15/20	16:26:27	0.73
12/15/20	16:27:27	0.68
12/15/20	16:28:27	0.69
12/15/20	16:29:27	0.72
12/15/20	16:30:27	0.72
12/15/20	16:31:27	0.72
12/15/20	16:32:27	0.72
12/15/20	16:33:27	0.72
12/15/20	16:34:27	0.72
Averages		**0.73**
Minimum		**0.68**
Maximum		**0.78**

APPENDIX D

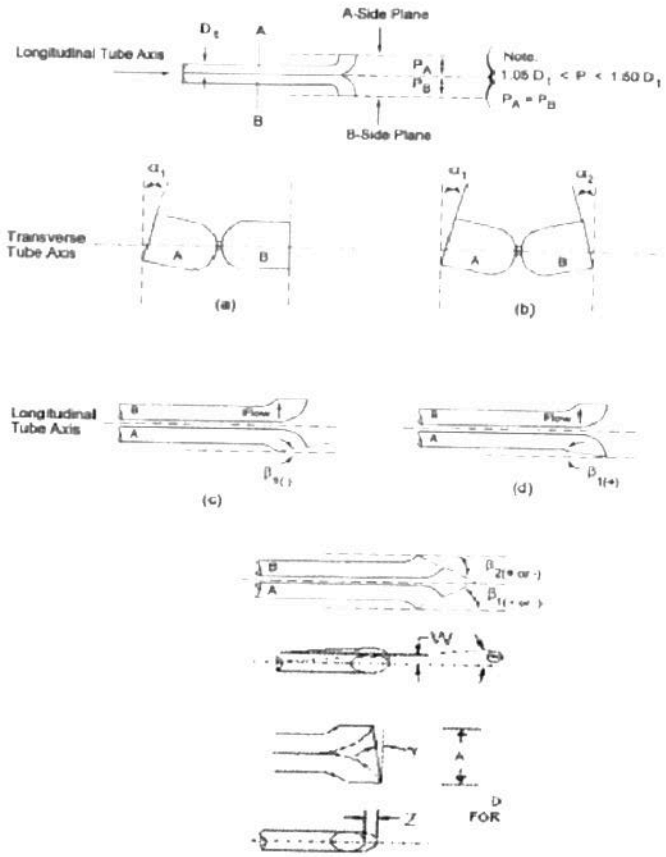
CALIBRATION DATA

Equipment Calibration Documentation

Pitot Tube Inspection Form

Date: 05/06/20
Checked By: CW
Pitot ID: 6-1

Parameter	Allowable Range	Value	Passed
Ports Damaged	No	No	PASS
D_t	$0.188'' \le D_T \le 0.375''$	0.25	PASS
P_A	$P_A = P_B$	0.35	PASS
P_B		0.35	
P	$1.05D_T \le P \le 1.50D_T$	$0.263 \le 0.350 \le 0.375$	PASS
α_1	$\pm 10°$	0	PASS
α_2	$\pm 10°$	0	PASS
β_1	$\pm 5°$	2.1	PASS
β_2	$\pm 5°$	3.5	PASS
A	N/A	0.7	N/A
γ	N/A	1.5	N/A
θ	N/A	0.4	N/A
$Z = A \tan \gamma$	$\pm 0.125''$	0.018	PASS
$W = A \tan \theta$	$\pm 0.031''$	0.005	PASS



This pitot meets all applicable specifications, criteria, and design features and has been assigned a pitot tube factor of 0.84.

METHOD 5 DRY GAS METER CALIBRATION USING CRITICAL ORIFICES

1) Select three critical orifices to calibrate the dry gas meter which bracket the expected operating range.
2) Record barometric pressure before and after calibration procedure.
3) Run at tested vacuum (from Orifice Calibration Report), for a period of time necessary to achieve a minimum total volume of 5 cubic feet.
4) Record data and information in the **GREEN** cells, YELLOW cells are calculated.

PACE ENVIRONMENTAL

DATE: 12/10/2020 METER SERIAL #:

METER PART #: MB04 CRITICAL ORIFICE SET SERIAL #: 1764

BAROMETRIC PRESSURE (in Hg): INITIAL 30.12 FINAL 30.13 AVG (P_{bar}) 30.125

ORIFICE #	RUN #	K' FACTOR (AVG)	TESTED VACUUM (in Hg)	DGM READINGS (FT^3) INITIAL	DGM READINGS (FT^3) FINAL	DGM READINGS (FT^3) NET (V_m)	TEMPERATURES °F AMBIENT	DGM INLET INITIAL	DGM INLET FINAL	DGM OUTLET INITIAL	DGM OUTLET FINAL	DGM AVG	ELAPSED TIME (MIN) θ	DGM ΔH (in H_2O)	(1) V_m (STD)	(2) V_{cr} (STD)	(3) Y	Y % Diff to Average Y	Y % Diff with other orifices	$\Delta H_@$
32	1	0.8316	16	950.065	955.945	5.880	63	68	72	68	68	69	5.50	3.7	5.9636	6.0267	1.011			1.76
	2	0.8316	16	955.945	962.640	6.695	63	72	74	68	68	70.5	6.25	3.7	6.7709	6.8486	1.011			1.75
	3	0.8316	16	962.640	968.525	5.885	63	74	77	68	68	71.75	5.50	3.7	5.9378	6.0267	1.015			1.75
																AVG =	1.012		-0.31	
26	1	0.6825	16	968.525	973.835	5.310	63	72	77	69	69	71.75	6.00	2.5	5.3420	5.3958	1.010			1.75
	2	0.6825	16	973.835	979.140	5.305	63	77	81	69	70	74.25	6.00	2.5	5.3120	5.3958	1.016			1.74
	3	0.6825	16	979.140	984.440	5.30	63	81	83	70	71	76.25	6.00	2.5	5.2872	5.3958	1.021			1.73
																AVG =	1.015	0.17	0.31	
20	1	0.5358	16	999.875	1,005.480	5.605	63	84	86	74	74	79.5	8.00	1.5	5.5443	5.6480	1.019			1.67
	2	0.5358	16	1,005.480	1,012.670	7.190	63	86	87	74	76	80.75	10.25	1.5	7.0957	7.2365	1.020			1.67
	3	0.5358	16	1,012.670	1,021.465	8.795	63	87	89	76	77	82.25	12.50	1.5	8.6556	8.8251	1.020			1.67
																AVG =	1.019	0.55	0.39	
17	1	0.4499	16	984.440	989.580	5.140	63	83	82	71	72	77	8.75	1.1	5.1030	5.1872	1.016			1.75
	2	0.4499	16	989.580	994.730	5.150	63	82	83	72	73	77.5	8.75	1.1	5.1082	5.1872	1.015			1.75
	3	0.4499	16	994.730	999.875	5.145	63	83	84	73	74	78.5	8.75	1.1	5.0938	5.1872	1.018			1.74
																AVG =	1.017	0.30	1.19	
12	1	0.3195	16	1,021.465	1,026.70	5.235	63	84	83	74	77	79.5	12.50	0.56	5.1665	5.2624	1.019			1.75
	2	0.3195	16	1,026.80	1,032.050	5.250	63	83	83	77	77	80	12.50	0.56	5.1765	5.2624	1.017			1.75
	3	0.3195	16	1,032.050	1,037.50	5.450	63	83	83	77	77	80	12.50	0.56	5.3737	5.2624	0.979			1.75
																AVG =	1.005	-0.88	-1.17	

USING THE CRITICAL ORIFICES AS CALIBRATION STANDARDS:
The following equations are used to calculate the standard volumes of air passed through the DGM, V_m (std), and the critical orifice, V_{cr} (std), and the DGM calibration factor, Y. These equations are automatically calculated in the spreadsheet above.

AVERAGE DRY GAS METER CALIBRATION FACTOR, Y = 1.014

AVERAGE $\Delta H_@$ = 1.73

(1) $$Vm_{std} = K_1 * Vm * \frac{Pbar + (\Delta H / 13.6)}{Tm}$$

-0.14

= Net volume of gas sample passed through DGM, corrected to standard conditions

K_1 = 17.64 °R/in. Hg (English), 0.3858 °K/mm Hg (Metric)

T_m = Absolute DGM avg. temperature (°R - English, °K - Metric)

(2) $$Vcr_{std} = K' * \frac{Pbar * \theta}{\sqrt{Tamb}}$$

= Volume of gas sample passed through the critical orifice, corrected to standard conditions

T_{amb} = Absolute ambient temperature (°R - English, °K - Metric)

K' = Average K' factor from Critical Orifice Calibration

(3) $$Y = \frac{Vcr_{std}}{Vm_{std}}$$

= DGM calibration factor

$$\Delta H_@ = \left(\frac{0.75\,\theta}{V_{cr}(std)}\right)^2 \Delta H \left(\frac{V_m(std)}{V_m}\right)$$

METHOD 5 DRY GAS METER CALIBRATION USING CRITICAL ORIFICES

1) Select three critical orifices to calibrate the dry gas meter which bracket the expected operating range.
2) Record barometric pressure before and after calibration procedure.
3) Run at tested vacuum (from Orifice Calibration Report), for a period of time necessary to achieve a minimum total volume of 5 cubic feet.
4) Record data and information in the **GREEN** cells, YELLOW cells are calculated.

DATE: 2/9/2021

METER PART #: MB04

METER SERIAL #:

CRITICAL ORIFICE SET SERIAL #: CO-1764s

BAROMETRIC PRESSURE (in Hg):	INITIAL	FINAL	AVG (P_{bar})
	30.02	30	30.01

ORIFICE #	RUN #	K' FACTOR (AVG)	TESTED VACUUM (in Hg)	DGM READINGS (FT^3) INITIAL	DGM READINGS (FT^3) FINAL	DGM READINGS (FT^3) NET (V_m)	TEMPERATURES °F AMBIENT	DGM INLET INITIAL	DGM INLET FINAL	DGM OUTLET INITIAL	DGM OUTLET FINAL	DGM AVG	ELAPSED TIME (MIN) θ	DGM ΔH (in H_2O)	(1) V_m (STD)	(2) V_{cr} (STD)	(3) Y	Y % Diff to Average Y	Y % Diff with other orifices	$\Delta H_@$
32	1	0.8316	15	289.005	294.015	5.010	65	68	69	68	68	68.25	4.75	3.7	5.0692	5.1751	1.021			1.77
	2	0.8316	15	294.015	299.015	5.0	65	69	71	68	68	69	4.75	3.7	5.0519	5.1751	1.024			1.77
	3	0.8316	15	299.015	304.015	5.0	65	17	74	69	69	57.25	4.75	3.7	5.1667	5.1751	1.002			1.81
																AVG =	1.016	-0.51	-0.50	
20	1	0.5358	16	304.015	309.015	5.0	63	74	77	69	70	72.5	7.25	1.5	4.9918	5.0990	1.021			1.70
	2	0.5358	16	309.015	314.015	5.0	63	77	80	70	71	74.5	7.25	1.5	4.9732	5.0990	1.025			1.70
	3	0.5358	16	314.015	319.110	5.095	63	80	80	71	72	75.75	7.30	1.5	5.0558	5.1342	1.015			1.69
																AVG =	1.021	-0.01	0.50	
12	1	0.3195	16	319.110	324.310	5.20	63	80	82	72	72	76.5	12.50	0.56	5.1410	5.2423	1.020			1.77
	2	0.3195	16	324.310	329.310	5.0	61	82	86	72	77	79.25	12.00	0.56	4.9180	5.0423	1.025			1.75
	3	0.3195	16	329.310	334.310	5.0	59	86	88	77	79	82.5	12.00	0.56	4.8885	5.0520	1.033			1.74
																AVG =	1.026	0.52	1.03	

USING THE CRITICAL ORIFICES AS CALIBRATION STANDARDS:

The following equations are used to calculate the standard volumes of air passed through the DGM, V_m (std), and the critical orifice, V_{cr} (std), and the DGM calibration factor, Y. These equations are automatically calculated in the spreadsheet above.

AVERAGE DRY GAS METER CALIBRATION FACTOR, Y = **1.021**

AVERAGE $\Delta H_@$ = **1.75**

(1) $$Vm_{std} = K_1 * Vm * \frac{Pbar + (\Delta H / 13.6)}{Tm}$$

= Net volume of gas sample passed through DGM, corrected to standard conditions

K_1 = 17.64 °R/in. Hg (English), 0.3858 °K/mm Hg (Metric)

T_m = Absolute DGM avg. temperature (°R - English, °K - Metric)

(2) $$Vcr_{std} = K' * \frac{Pbar * \Theta}{\sqrt{Tamb}}$$

= Volume of gas sample passed through the critical orifice, corrected to standard conditions

T_{amb} = Absolute ambient temperature (°R - English, °K - Metric)

K' = Average K' factor from Critical Orifice Calibration

(3) $$Y = \frac{Vcr_{std}}{Vm_{std}}$$

= DGM calibration factor

$$\Delta H_@ = \left(\frac{0.75\,\theta}{V_{cr}(std)}\right)^2 \Delta H \left(\frac{V_m(std)}{V_m}\right)$$

Thermocouple Calibration Certification

Annual Calibration

Annual Calibration Date: 02/02/20

NIST Reference Thermometer ID No. Omega 1

Calibrated On: 02/02/20

Calibration Due: 02/02/21

Thermocouple ID No.	Ice Water Bath			Ambient			Boiling Water		
	TC readout (°F)	Reference (°F)	Difference (%)	TC readout (°F)	Reference (°F)	Difference (%)	TC readout (°F)	Reference (°F)	Difference (%)
Probe 6-1	28	28.1	-0.02	64	64.5	-0.10	212	212.7	-0.10

Thermocouple temperature readouts are considered acceptable if the thermocouple and reference thermometer absolute temperatures agree within ± 1.5% (Section 10.3 of Method 2)

Post-Test Calibration

Post-Test Calibration Date: 12/16/20

Calibration Completed By: BG

	Thermocouple ID No.:	Probe 6-1					MB-04 Gas Meter (In)	MB-04 Gas Meter (Out)	Gooseneck 2
Ambient Temperature Check	TC Readout (°F):	60					60	60	60
	Reference (°F):	60					60	60	60
	Difference (°F):	0.0					0.0	0.0	0.0

Thermocouple temperature readouts are considered acceptable if the thermocouple and reference thermometer temperatures agree within ± 2°F (alternate calibration procedure of Section 10.5 of Method 5)

Analyzer Calibration Documentation

FM0006 Compliance Test Field Data Sheet

Company	BBRAUN
Location	BETHLEHEM PA
Source	ETO CONTROL
Date	12/15/20
Time	

DIRECT CALIBRATIONS

Analyzer Type	Zero	Gas 1 Value 24.02 O2	Gas 2 Value 18.59 CO2	Gas 3 Value 11.92 O2	Gas 4 Value 9.229 CO2	Gas 5 Value	Gas 6 Value	Gas 7 Value	Gas 8 Value	Gas 9 Value	Gas 10 Value	Gas 11 Value	Gas 12 Value
O2	-0.07	24.06		12.00									
CO2	0.04		18.76		9.28								
Time	723	726	726	729	729								

Initial Bias

Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 8.952 ETO	Bias 4 Value 5.298 ETO	Bias 5 Value 3.140 ETO	Bias 6 Value	Bias 7 Value	Bias 8 Value	Bias 9 Value	Bias 10 Value	Bias 11 Value	Bias 12 Value
O2	-0.01	11.95											
CO2	0.08		9.24										
THC ETO	0.01			8.87	5.23	3.13							
Time	738	740	740	822	819	815							

RUN 1 STERILIZATION

Start: 836 Stop: ~~0857~~ 0858

Bias

Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.229 CO2	Bias 3 Value 3.140 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value
O2	-0.03	11.94					
CO2	0.37		9.53				
THC ETO	0.00			3.09			
Time	905	908	908	902			

HL 270 270
HL 270 270
HL 270 270
HL 270 270
HL 270 270
HL
HL
HL
HL

Channel Inputs

A	
B	
C	
D	
E	
F	
G	
H	
I	
J	
K	
L	
M	

START 839 - 852

RUN 1 AERATION

Start: 1042 Stop: 1142

Bias

Analyzer Type	Zero	Bias 1 Value 11.9202	Bias 2 Value 9.229602	Bias 3 Value 3.140ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value
O2	0.03	12.01					
CO2	0.36		9.45				
THCETO	0.00			3.17			
Time	1150	1147	1147	1144			

HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL		
HL		
HL		

RUN 2 AERATION

Start: 1155 Stop: 1255

Bias

Analyzer Type	Zero	Bias 1 Value 11.9202	Bias 2 Value 9.229602	Bias 3 Value 3.140ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value
O2	0.04	11.98					
CO2	0.25		9.34				
THCETO	0.02			3.17			
Time	1300	1302	1302	1257			

HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL		
HL		
HL		

RUN 2 STERILIZATION

Start: 1310 Stop: ~~1331~~ 1332

Bias

Analyzer Type	Zero	Bias 1 Value 11.9202	Bias 2 Value 9.229602	Bias 3 Value 3.140ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value
O2	0.06	12.02					
CO2	0.21		9.31				
THCETO	0.02			3.12			
Time	1353	1355	1355	1351			

HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL	270	270
HL		
HL		
HL		

RUN 3 AERATION									
Start: 1535				Stop: 1635					
Bias									
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.22 CO2	Bias 3 Value 3.10 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value		
O2	0.04	12.01							
CO2	0.22		9.36						
THC ETO	0.00			3.11					
								HL 270	270
								HL 270	270
								HL 270	270
								HL 270	270
								HL 270	270
Time	1642	1645	1645	1640				HL	
								HL	

RUN 3 STERILIZATION									
Start: ~~1215~~ 1709				Stop: 1730					
Bias									
Analyzer Type	Zero	Bias 1 Value 11.92 O2	Bias 2 Value 9.22 CO2	Bias 3 Value 3.10 ETO	Bias 4 Value	Bias 5 Value	Bias 6 Value		
O2	0.03	12.02							
CO2	0.29		9.43						
THC ETO	0.00			3.09					
								HL 270	270
								HL 270	270
								HL 270	270
								HL 270	270
								HL 270	270
Time	1734	1737	1737	1732				HL	
								HL	

RUN							
Start:				Stop:			
Bias							
Analyzer Type	Zero	Bias 1 Value	Bias 2 Value	Bias 3 Value	Bias 4 Value	Bias 5 Value	Bias 6 Value
Time							

HL
HL
HL
HL
HL
HL
HL

QA/QC Bias/Drift Calculator

Oxygen

Calibration Gas Standard Concentrations (%) (C_v)		
Zero	Mid	High/Span (CS)
0.00	11.92	24.02

Analyzer Calibration Error (ACE ≤ 2% of range)			
Actual Analyzer Response (C_{Dir}):	-0.07	12.00	24.06
Analyzer Cal Error (%)	-0.29	0.33	0.17

Initial System Bias (SB ≤ 5% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	11.92
Actual Analyzer Response (C_s):	-0.01	11.95
Initial System Bias (%)	0.25	-0.21
Sterilization Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	-0.03	11.94
System Bias (%)	0.17	-0.25
Drift (%):	0.08	0.04
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.03	12.01
System Bias (%)	0.42	0.04
Drift (%):	0.25	0.29
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.04	11.98
System Bias (%)	0.46	-0.08
Drift (%):	0.04	0.12
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.06	12.02
System Bias (%)	0.54	0.08
Drift (%):	0.50	0.04
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.04	12.01
System Bias (%)	0.46	0.04
Drift (%):	0.08	0.04
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.03	12.02
System Bias (%)	0.42	0.08
Drift (%):	0.04	0.04

Carbon Dioxide

Calibration Gas Standard Concentrations (%) (C_v)		
Zero	Mid	High/Span (CS)
0.00	9.229	18.59

Analyzer Calibration Error (ACE ≤ 2% of range)			
Actual Analyzer Response (C_{Dir}):	0.04	9.28	18.76
Analyzer Cal Error (%)	0.22	0.27	0.91

Initial System Bias (SB ≤ 5% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	9.229
Actual Analyzer Response (C_s):	0.08	9.24
Initial System Bias (%)	0.22	-0.22
Sterilization Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.37	9.53
System Bias (%)	1.78	1.34
Drift (%):	1.56	1.56
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.36	9.45
System Bias (%)	1.72	0.91
Drift (%):	0.05	0.43
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.25	9.34
System Bias (%)	1.13	0.32
Drift (%):	0.59	0.59
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.21	9.31
System Bias (%)	0.91	0.16
Drift (%):	0.32	0.43
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.22	9.36
System Bias (%)	0.97	0.43
Drift (%):	0.05	0.27
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.29	9.43
System Bias (%)	1.34	0.81
Drift (%):	0.38	0.38

Definitions:

ACE = Analyzer Calibration Error, percent of calibration span

C_{Dir} = Measured concentration of a calibration gas (low, mid, or high) when introduced in direct calibration mode, ppmv or %

C_v = Manufacturer certified concentration of a calibration gas (low, mid, or high), ppmv or %

C_s = Measured concentration of a calibration gas (low, mid, or high) when introduced in system calibration mode, ppmv or %

CS = Calibration span, ppmv or %

D = Drift assessment, percent of calibration span

SB = System bias, percent of calibration span.

SB_i = Pre-run system bias, percent of calibration span.

SB_{final} = Post-run system bias, percent of calibration span.

Equations:

ACE = $((C_{Dir} - C_v) / CS) * 100\%$

SB = $((C_s - C_{Dir}) / CS) * 100\%$

D = $|SB_{final} - SB_i|$

M25A QA/QC CE/Drift Calculator

Ethylene Oxide

Analyzer Range (CS)	Calibration Gas Standard Concentrations (ppm) (C_v)			
	Zero	Low	Mid	High
10	0.00	3.140	5.298	8.952

Analyzer Calibration Error (ACE ≤ 5% of cal std)				
Actual Analyzer Response (C_s):	0.01	3.13	5.23	8.87
Analyzer Cal Error (%)	0.10	-0.32	-1.28	-0.92

Sterilization Post Run 1 Drift (D ≤ 3% of range)		
	Zero	Bias Gas
Cal Gas Standard Concentration:	0.00	3.140
Actual Analyzer Response:	0.00	3.09
Drift (%):	0.10	0.40
Aeration Post Run 1 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.17
Drift (%):	0.00	0.80
Aeration Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.02	3.17
Drift (%):	0.20	0.00
Sterilization Post Run 2 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.02	3.12
Drift (%):	0.00	0.50
Aeration Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.11
Drift (%):	0.20	0.10
Sterilization Post Run 3 Drift (D ≤ 3% of range)		
Actual Analyzer Response:	0.00	3.09
Drift (%):	0.00	0.20

Definitions:

ACE = Analyzer Calibration Error, percent of calibration span

C_s = Measured concentration of a calibration gas (low, mid, or high) when introduced in system calibration mode, ppmv

C_v = Manufacturer certified concentration of a calibration gas (low, mid, or high), ppmv

CS = Calibration span, ppmv

D = Drift assessment, percent of calibration span

Equations:

ACE = $((C_s - C_v) / CS) * 100\%$

D = ((pre analyzer response - post analyzer response) / CS) * 100%

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	7:23:28	-0.07	0.04	0.09	DIRECT ZERO
12/15/20	7:24:27	13.79	10.62	0.06	
12/15/20	7:25:27	24.14	18.85	0.07	
12/15/20	7:26:27	24.06	18.76	0.06	DIRECT HIGH CO2 O2
12/15/20	7:27:27	23.78	18.29	0.06	
12/15/20	7:28:26	13.05	9.01	0.03	
12/15/20	7:29:26	12.00	9.28	0.02	DIRECT MID CO2 O2
12/15/20	7:30:27	14.56	5.88	0.05	
12/15/20	7:31:27	20.97	0.15	0.04	
12/15/20	7:32:27	13.14	0.13	0.07	
12/15/20	7:33:27	0.04	0.07	0.04	
12/15/20	7:34:27	12.11	0.10	0.05	
12/15/20	7:35:26	4.40	0.10	0.02	
12/15/20	7:36:26	0.01	0.08	0.08	
12/15/20	7:37:26	-0.01	0.08	0.06	
12/15/20	7:38:27	-0.01	0.08	0.01	INITIAL BIAS ZERO
12/15/20	7:39:27	2.62	2.51	0.08	
12/15/20	7:40:27	11.95	9.24	0.03	INITIAL BIAS CO2 O2
12/15/20	7:41:27	13.79	7.01	0.05	
12/15/20	7:42:26	8.21	0.51	0.05	
12/15/20	7:43:27	0.01	0.12	0.05	
12/15/20	7:44:26	-0.01	0.12	0.03	
12/15/20	7:45:26	-0.01	0.12	0.02	
12/15/20	7:46:27	-0.01	0.12	0.03	
12/15/20	7:47:26	-0.02	0.12	0.08	
12/15/20	7:48:27	-0.02	0.12	0.03	
12/15/20	7:49:26	-0.02	0.12	0.07	
12/15/20	7:50:27	-0.02	0.12	0.03	
12/15/20	7:51:26	-0.01	0.12	0.05	
12/15/20	7:52:26	-0.02	0.12	0.06	
12/15/20	7:53:27	-0.01	0.14	0.03	
12/15/20	7:54:26	-0.02	0.15	0.19	
12/15/20	7:55:27	-0.02	0.15	3.18	
12/15/20	7:56:26	-0.02	0.16	3.32	
12/15/20	7:57:27	-0.02	0.16	3.16	
12/15/20	7:58:26	-0.02	0.15	3.15	
12/15/20	7:59:26	-0.02	0.15	3.15	
12/15/20	8:00:27	-0.02	0.16	3.24	
12/15/20	8:01:26	-0.02	0.15	3.33	
12/15/20	8:02:26	-0.02	0.15	3.39	
12/15/20	8:03:26	-0.02	0.16	3.47	

Pre Calibrations

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	8:04:27	-0.02	0.16	3.17	
12/15/20	8:05:26	-0.02	0.15	3.17	
12/15/20	8:06:26	-0.02	0.15	3.20	
12/15/20	8:07:26	-0.02	0.15	3.22	
12/15/20	8:08:26	-0.02	0.15	3.19	
12/15/20	8:09:27	-0.02	0.18	3.24	
12/15/20	8:10:26	-0.03	0.19	3.26	
12/15/20	8:11:27	-0.03	0.20	3.29	
12/15/20	8:12:27	-0.02	0.20	3.34	
12/15/20	8:13:26	-0.03	0.20	3.34	
12/15/20	8:14:26	-0.03	0.20	3.11	
12/15/20	8:15:27	-0.03	0.20	3.13	INITIAL BIAS LOW THC
12/15/20	8:16:27	-0.03	0.20	3.10	
12/15/20	8:17:26	8.10	0.32	8.33	
12/15/20	8:18:27	0.31	0.19	5.13	
12/15/20	8:19:27	-0.03	0.21	5.23	INITIAL BIAS MID THC
12/15/20	8:20:26	-0.03	0.23	5.19	
12/15/20	8:21:26	7.02	0.32	9.36	
12/15/20	8:22:27	-0.02	0.23	8.87	INITIAL BIAS HIGH THC
12/15/20	8:23:27	-0.03	0.23	7.09	
12/15/20	8:24:26	13.20	0.43	1.81	
12/15/20	8:25:27	20.53	0.52	0.70	
12/15/20	8:26:27	20.53	0.52	0.67	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	9:00:27	13.00	0.56	1.60	
12/15/20	9:01:27	0.02	0.37	3.09	
12/15/20	9:02:27	-0.01	0.37	3.09	BIAS 1 LOW THC
12/15/20	9:03:27	-0.01	0.38	1.34	
12/15/20	9:04:27	-0.02	0.38	0.06	
12/15/20	9:05:27	-0.03	0.37	0.00	BIAS 1 ZERO
12/15/20	9:06:27	3.32	3.28	0.07	
12/15/20	9:07:26	11.91	9.49	0.00	
12/15/20	9:08:27	11.94	9.53	0.00	BIAS 1 CO2 O2
12/15/20	9:09:26	12.19	9.09	0.12	
12/15/20	9:10:27	19.16	1.46	0.29	
12/15/20	9:11:27	20.56	0.73	0.26	

Post Cal Aeration Run 001

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	11:43:26	0.06	0.36	1.74	
12/15/20	11:44:27	0.04	0.36	3.17	BIAS 2 THC
12/15/20	11:45:27	0.18	0.57	2.36	
12/15/20	11:46:27	11.15	8.92	0.10	
12/15/20	11:47:26	12.01	9.45	0.05	BIAS 2 CO2 O2
12/15/20	11:48:26	8.77	6.62	0.05	
12/15/20	11:49:27	0.06	0.40	0.00	
12/15/20	11:50:26	0.03	0.36	0.00	BIAS 2 ZERO
12/15/20	11:51:26	0.03	0.36	0.00	
12/15/20	11:52:26	9.12	0.50	0.55	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	12:55:27	13.10	0.48	1.98	
12/15/20	12:56:27	0.09	0.24	3.11	
12/15/20	12:57:27	0.06	0.24	3.17	BIAS 3 THC
12/15/20	12:58:27	0.10	0.31	2.51	
12/15/20	12:59:26	0.25	0.36	0.10	
12/15/20	13:00:26	0.04	0.25	0.02	BIAS 3 ZERO
12/15/20	13:01:27	2.97	2.75	0.07	
12/15/20	13:02:27	11.98	9.34	0.08	BIAS 3 CO2 O2
12/15/20	13:03:27	13.35	7.67	0.30	
12/15/20	13:04:27	20.57	0.59	0.66	
12/15/20	13:05:27	20.61	0.55	0.64	

Post Cal Sterilization Run 002

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	13:49:27	1.75	0.38	1.32	
12/15/20	13:50:27	0.08	0.21	3.08	
12/15/20	13:51:27	0.07	0.21	3.12	BIAS 4 THC
12/15/20	13:52:27	0.07	0.21	1.74	
12/15/20	13:53:27	0.06	0.21	0.02	BIAS 4 ZERO
12/15/20	13:54:27	5.53	4.63	0.09	
12/15/20	13:55:27	12.02	9.31	0.04	BIAS 4 CO2 O2
12/15/20	13:56:27	13.99	7.05	0.15	
12/15/20	13:57:27	21.04	0.29	0.21	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	16:38:27	0.09	0.21	0.76	
12/15/20	16:39:27	0.06	0.21	2.83	
12/15/20	16:40:27	0.05	0.22	3.11	BIAS 5 THC
12/15/20	16:41:27	0.05	0.22	0.44	
12/15/20	16:42:27	0.04	0.22	0.00	BIAS 5 ZERO
12/15/20	16:43:27	0.04	0.22	0.00	
12/15/20	16:44:27	5.98	4.98	0.06	
12/15/20	16:45:27	12.01	9.36	0.00	BIAS 5 CO2 O2
12/15/20	16:46:27	12.24	9.02	0.27	
12/15/20	16:47:27	20.22	0.81	0.69	

PACE Environmental
Minute Average

Date	Time	O_2 (%)	CO_2 (%)	THC (ppm)	
12/15/20	17:30:27	20.61	0.62	0.98	
12/15/20	17:31:27	5.66	0.62	1.04	
12/15/20	17:32:27	0.06	0.29	3.09	BIAS 6 THC
12/15/20	17:33:27	0.04	0.29	2.20	
12/15/20	17:34:27	0.03	0.29	0.00	BIAS 6 ZERO
12/15/20	17:35:27	0.35	0.68	0.03	
12/15/20	17:36:27	11.46	9.10	0.01	
12/15/20	17:37:27	12.02	9.43	0.00	BIAS 6 CO2 O2
12/15/20	17:38:27	12.03	9.45	0.00	
12/15/20	17:39:27	15.82	5.62	0.04	
12/15/20	17:40:14	20.10	6.93	0.02	

Analyzer Response Time Documentation

Analyzer Response Test

Analyzer Make
Analyzer Model CM ~~ZRE~~
Analyzer Serial # NSF0123

O2

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time
1	N2	25
1	24-02 O2	35
2		35
2		40

System Response Time [ ]

Analyzer Response Test

Analyzer Make CAI ~~ZRE~~ CO2
Analyzer Model
Analyzer Serial # N5F4123

Methods 7E, 3A, 10
Use Low and High Gases and perform during initial system bias

Perform 2 runs as follows: Run the Low gas. Record the time it takes the Low gas to reach 95% of the value. Repeat the process for the High gas. The response time is dictated by the longest run seen to achieve 95% of the gas value used.

Run #	Gas Type	Response Time
1	N2	35
1	18.59 CO2	35
2		35
2		35

System Response Time [ ]

Analyzer Response Test

Analyzer Make VIG
Analyzer Model 200
Analyzer Serial # 5150712

THC

Methods 25A & B
Use Zero and High Gases and perform during initial system bias

Perform 3 runs as follows: Run Zero (N2) gas until the analyzer stabilizes, then quickly switch to high gas. Record the time it takes the high gas to reach 95% of the value.

Run #	Gas Type	Response Time
1	8.952 ETO	20
2		20
3		20

Avg Response Time [ ]

Analyzer Interference Check Documentation

Method 7E-Interfernce Response

Applies to Models: 600 Series NDIR/PMD, 100/200/300 Series NDIR/PMD, ZRE w/PMD
Date of Test: 1/26/2011
Analyzer Type: PMD
Model: 602-P
Serial Numer: U09018-M
Calibration Span: 20.7% O2, balance N2

Test Gas	Interfernt Concentration	Zero Response	Span Response	Interferent Response
SO2	513 ppm	0.000%	0.020%	0.020%
H2O	0.82%	0.015%	0.020%	0.020%
N2O	10.00 ppm	0.000%	0.000%	0.000%
NO	94.9 ppm	0.000%	0.000%	0.000%
NO2	99.8 ppm	0.000%	0.000%	0.000%
CO	900 ppm	0.000%	0.000%	0.000%
CH4	90.9 ppm	0.000%	0.000%	0.000%
HCl	27.99ppm	0.000%	0.000%	0.000%
Sum of Responses				0.004%
% of Calibration Span				0.019%

Method 7E-Interfernce Response

Applies to Models: 600 Series NDIR, 100/200/300 Series NDIR, ZRE
Date of Test: 1/26/2011
Analyzer Type: NDIR
Model: 602-P
Serial Numer: U09018-M
Calibration Span: 20.2% CO2/Balance N2

Test Gas	Interfernt Concentration	Zero Response	Span Response	Interferent Response
SO2	102.6 ppm	0.000%	0.000%	0.000%
H2O	0.82%	0.055%	0.055%	0.055%
N2O	10.00 ppm	0.005%	0.010%	0.010%
NO	94.9 ppm	0.005%	0.025%	0.025%
NO2	99.8 ppm	0.010%	0.010%	0.010%
CO	100.0 ppm	0.010%	0.010%	0.010%
CH4	101.0 ppm	0.010%	0.010%	0.010%
HCl	27.99ppm	0.010%	0.010%	0.010%
Sum of Responses				0.013%
% of Calibration Span				0.064%

Calibration Gas Certificates

Bottle Manifest & Range Confirmation

Range	25% - 35%	45% - 55%	80%	90%
0 - 1%	0.25 - 0.35	0.45 - 0.55	0.80	0.90
0 - 2%	0.50 - 0.70	0.90 - 1.10	1.60	1.80
0 - 5%	1.25 - 1.75	2.25 - 2.75	4.00	4.50
0 - 20%	5.00 - 7.00	9.00 - 11.00	16.00	18.00
0 - 60%	14.98 - 20.97	26.96 - 32.95	47.92	53.91

Range	25% - 35%	45% - 55%	80% - 90%
0 - 50 ppm	12.5 - 17.5	22.5 - 27.5	40 - 45
0 - 300 ppm	75 - 105	135 - 165	240 - 270
0 - 600 ppm	150 - 210	270 - 330	480 - 540
0 - 800 ppm	200 - 280	360 - 440	640 - 720
0 - 2000 ppm	500 - 700	900 - 1100	1600 - 1800
0 - 5000 ppm	1250 - 1750	2250 - 2750	4000 - 4500
0 - 10000 ppm	2500 - 3500	4500 - 5500	8000 - 9000

CO2 / O2 / NOX / SO2 / CO				
	RATA/Stack Test	CGA Pollutant	CGA O2	CGA CO2
High bottle	sets range	n/a	n/a	n/a
Mid bottle	40-60% high bottle	50-60% range	8-12%	10-14%
Low bottle	zero gas	20-30% range	4-6%	5-8%

Customer: B. Braun

Date: 12/11/2020

	Bottle #	Gas Value	UN #	Class	Expiration Date	Start PSI	End PSI	Regulator #
1	EB0091033	N2	1066	2		800	500	
2	CC113434	18.59 CO2 / 24.02 O2	1956	2		1600	1500	
3	CC215297	11.92 O2 / 9.229 CO2	1956	2		1500	1300	
4	CC733138	3.140 ETHOX%	1956	2		2000	1400	
5	CC734295	5.298 ETHOX	1956	2		2000	1900	
6	CC734294	8.952 ETHOX	1956	2		2000	1900	
7	CC00855B	Air	1002	2		1000	MT	
8	ALM049313	H2	1049	2		1200	1100	
9	XC015461B	N2	1066	2		1800	1700	
10								
11								
12								
13								
14								
15								
16								

Airgas - Chemtrec - 1 800 424 9300
Praxair - Chemtrec - 1 800 424 9300
Liquid Tech - Chemtel - 1 800 255 3924

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF BATCH ANALYSIS

Grade of Product: CEM-CAL ZERO

Part Number:	NI CZ15A	Reference Number:	160-401871681-1
Cylinder Analyzed:	CC715535	Cylinder Volume:	142.0 CF
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2000 PSIG
Analysis Date:	Aug 05, 2020	Valve Outlet:	580
Lot Number:	160-401871681-1		

Expiration Date: Aug 05, 2028

ANALYTICAL RESULTS

Component	Requested Purity	Certified Concentration
NITROGEN	99.9995 %	99.9995 %
CARBON DIOXIDE	< 1.0 PPM	<LDL 0.03 PPM
NOx	< 0.1 PPM	<LDL 0.02 PPM
SO2	< 0.1 PPM	<LDL 0.02 PPM
THC	< 0.1 PPM	<LDL 0.03 PPM
CARBON MONOXIDE	< 0.5 PPM	0.165 PPM

Permanent Notes: Airgas certifies that the contents of this cylinder meet the requirements of 40 CFR 72.2

Cylinders in Batch:

ALM018038, ALM025957, ALM045320, ALM046684, ALM054065, ALM057380, CC114910, CC138957, CC17355, CC193212, CC401985, CC412860, CC482572, CC501937, CC503602, CC709870, CC715535, CC75111, CC80842, EB0091033, EB0113053, SG9101576, SG9159620BAL, XC033769B

Impurities verified against analytical standards traceable to NIST by weight and/or analysis.

Approved for Release

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an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: EPA Protocol

Part Number:	E03NI79E15A00E4	Reference Number:	160-401903519-1
Cylinder Number:	CC215297	Cylinder Volume:	150.5 CF
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
PGVP Number:	A12020	Valve Outlet:	590
Gas Code:	CO2,O2,BALN	Certification Date:	Sep 15, 2020

Expiration Date: Sep 15, 2028

Certification performed in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (May 2012)" document EPA 600/R-12/531, using the assay procedures listed. Analytical Methodology does not require correction for analytical interference. This cylinder has a total analytical uncertainty as stated below with a confidence level of 95%. There are no significant impurities which affect the use of this calibration mixture. All concentrations are on a mole/mole basis unless otherwise noted.

Do Not Use This Cylinder below 100 psig, i.e. 0.7 megapascals.

ANALYTICAL RESULTS

Component	Requested Concentration	Actual Concentration	Protocol Method	Total Relative Uncertainty	Assay Dates
CARBON DIOXIDE	9.000 %	9.229 %	G1	+/- 0.5% NIST Traceable	09/15/2020
OXYGEN	12.00 %	11.92 %	G1	+/- 0.3% NIST Traceable	09/15/2020
NITROGEN	Balance				

CALIBRATION STANDARDS

Type	Lot ID	Cylinder No	Concentration	Uncertainty	Expiration Date
NTRM	102505	K025852	7.016 % CARBON DIOXIDE/NITROGEN	+/- 0.5%	Jan 13, 2022
NTRM	10010602	1D38055	9.967 % OXYGEN/NITROGEN	+/- 0.3%	Apr 19, 2022

ANALYTICAL EQUIPMENT

Instrument/Make/Model	Analytical Principle	Last Multipoint Calibration
HORIBA VA5011 T5V6VU9P NDIR CO2	NDIR	Sep 09, 2020
SIEMENS OXYMAT 6 - N1-W5-951 - O2	PARAMAGNETIC	Sep 01, 2020

Triad Data Available Upon Request

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
600 Union Landing Road
Cinnaminson, NJ 08077-0000
Airgas.com

CERTIFICATE OF ANALYSIS
Grade of Product: EPA Protocol

Part Number:	E03NI57E15A37E3	Reference Number:	82-401390363-1
Cylinder Number:	CC113434	Cylinder Volume:	159.3 CF
Laboratory:	124 - Riverton (SAP) - NJ	Cylinder Pressure:	2015 PSIG
PGVP Number:	B52019	Valve Outlet:	296
Gas Code:	CO2,O2,BALN	Certification Date:	Jan 10, 2019

Expiration Date: Jan 10, 2027

Certification performed in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (May 2012)" document EPA 600/R-12/531, using the assay procedures listed. Analytical Methodology does not require correction for analytical interference. This cylinder has a total analytical uncertainty as stated below with a confidence level of 95%. There are no significant impurities which affect the use of this calibration mixture. All concentrations are on a volume/volume basis unless otherwise noted.

Do Not Use This Cylinder below 100 psig, i.e. 0.7 megapascals.

ANALYTICAL RESULTS

Component	Requested Concentration	Actual Concentration	Protocol Method	Total Relative Uncertainty	Assay Dates
CARBON DIOXIDE	19.00 %	18.59 %	G1	+/- 0.8% NIST Traceable	01/09/2019
OXYGEN	24.00 %	24.02 %	G2	+/- 0.5% NIST Traceable	01/10/2019
NITROGEN	Balance				

CALIBRATION STANDARDS

Type	Lot ID	Cylinder No	Concentration	Uncertainty	Expiration Date
NTRM	13060731	CC413777	16.939 % CARBON DIOXIDE/NITROGEN	+/- 0.6%	May 08, 2019
NTRM	09061420	CC273671	22.53 % OXYGEN/NITROGEN	+/- 0.4%	Mar 08, 2019

ANALYTICAL EQUIPMENT

Instrument/Make/Model	Analytical Principle	Last Multipoint Calibration
Horiba VIA 510-CO2-19GYCXEG	NDIR	Jan 04, 2019
Horiba MPA 510-O2-7TWMJ041	Paramagnetic	Jan 04, 2019

Triad Data Available Upon Request

C. Mindy Clinch
Approved for Release

Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: CERTIFIED STANDARD-SPEC

Customer:	PACE ENVIRONMENTAL PRODUCTS		
Part Number:	X02NI99C15AJ846		
Cylinder Number:	CC733138	Reference Number:	160-401938392-1
Laboratory:	124 - Plumsteadville - PA	Cylinder Volume:	144.3 Cubic Feet
Analysis Date:	Oct 29, 2020	Cylinder Pressure:	2015 PSIG
Lot Number:	160-401938392-1	Valve Outlet:	350

Expiration Date: Oct 29, 2021

Product composition verified by direct comparison to calibration standards traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	3.000 PPM	3.140 PPM	+/- 5%
NITROGEN	Balance		

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Airgas
an Air Liquide company

Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
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Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: CERTIFIED STANDARD-SPEC

Customer:	PACE ENVIRONMENTAL PRODUCTS		
Part Number:	X02NI99C15A0047	Reference Number:	160-401938393-1
Cylinder Number:	CC734295	Cylinder Volume:	144.3 Cubic Feet
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
Analysis Date:	Oct 29, 2020	Valve Outlet:	350SS
Lot Number:	160-401938393-1		

Expiration Date: Oct 29, 2021

Product composition verified by direct comparison to calibration standards traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	5.000 PPM	5.298 PPM	+/- 5%
NITROGEN	Balance		

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Airgas Specialty Gases
Airgas USA, LLC
6141 Easton Road
Bldg 1
Plumsteadville, PA 18949
Airgas.com

CERTIFICATE OF ANALYSIS

Grade of Product: PRIMARY STANDARD

Customer:	PACE RNVIRONMENTAL PRODUCTS		
Part Number:	X02NI99P15A0619	Reference Number:	160-401938394-1
Cylinder Number:	CC734294	Cylinder Volume:	144.3 Cubic Feet
Laboratory:	124 - Plumsteadville - PA	Cylinder Pressure:	2015 PSIG
Analysis Date:	Oct 29, 2020	Valve Outlet:	350SS
Lot Number:	160-401938394-1		

Expiration Date: Oct 29, 2021

Primary Standard Gas Mixtures are traceable to N.I.S.T. weights and/or N.I.S.T. Gas Mixture reference materials.

ANALYTICAL RESULTS

Component	Req Conc	Actual Concentration (Mole %)	Analytical Uncertainty
ETHYLENE OXIDE	8.500 PPM	8.952 PPM	+/- 1%
NITROGEN	Balance		

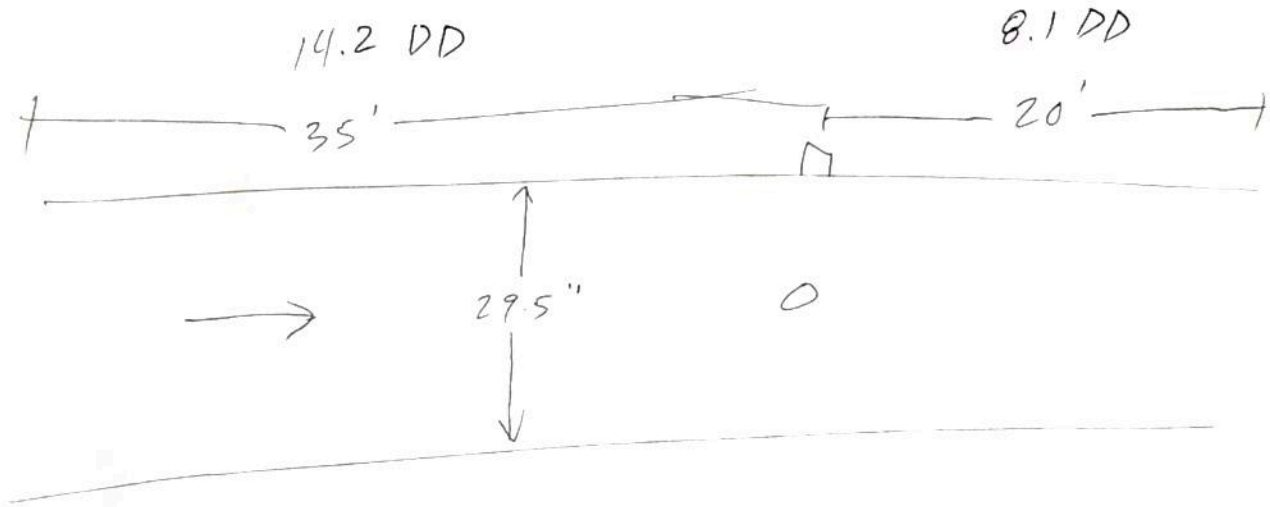
Approved for Release

APPENDIX E

FIELD SHEETS

BBRAUN 12/15/20

CAT OX OUTLET



Traverse Point Calculator

Project:	B. Braun Outlet Sampling Location

Stack Diameter:			29.5
Number of Points Needed in Each Port:			8
Sample Train:			Flow

Port Extention =

Distance from Stack Wall (inches):	Calculated Points			Points with Port Extension			Stratification Check
Point 1			0.9			0.9	4.9
2			3.1			3.1	14.8
3			5.7			5.7	24.6
4			9.5			9.5	
5			20.0			20.0	
6			23.8			23.8	
7			26.4			26.4	
8			28.6			28.6	
9							
10							
11							
12							

Stack Cross Sectional Area

4.746

U.S. EPA Method 1 Traverse Point Percentages

# of Points	4	6	8	10	12
	0.067	0.044	0.032	0.026	0.021
	0.25	0.146	0.105	0.082	0.067
	0.75	0.296	0.194	0.146	0.118
	0.933	0.704	0.323	0.226	0.177
		0.854	0.677	0.342	0.25
		0.956	0.806	0.658	0.356
			0.895	0.774	0.644
			0.968	0.854	0.75
				0.918	0.823
				0.974	0.882
					0.933
					0.979

RUN # _____

Location: _____

Date: _____

Start Time: _____

End Time: _____

BBRAUN

CATOX OUTLET

12/14/20

RUN DATA

R_{ADO}: _____ degrees

R_{SLO}: _____ degrees

Carbon Dioxide (%) [CO2] _____

Oxygen (%) [O2] _____

Methane (%) [CH4] _____

Moisture (%) [Bws] _____

Stack Static Pressure ("H2O) [Ps] _____

Barometric Pressure ("Hg) [Pb] _____

Cyclonic Flow Check

TRAVERSE DATA

Port/Point	{Reading} Yaw Angle (deg)	P1-P2 (in H_20)	P4-P5 (in H_20)	Stack Temp (deg F)
A1	2			
2	2			
3	0			
4	0			
5	0			
6	0			
7	0			
8	0			
B1	4			
2	3			
3	1			
4	0			
5	0			
6	0			
7	1			
8	1			

Method 2 FLOW DATA SHEET

Project No. PBRAUN
Proj. Name

Site Location BETHLEHEM, PA
Unit/Location STERILIZATION
Stack ID 29.5

MB / Manometer # M1304
Pitot Tube / Probe ID # 6-1
(circe one)

Operator(s) BG
Baro. Pressure 30.31

Start Time		Stop Time
Date 12/15/20	Leak Check PRE ✓ POST ✓	WB
RUN # PRELIM	STATIC -2.7	DB
		Stack
Real Time	Traverse Pt.	Delta P / Temp. (°F)
	A1	1.0
	2	1.1
	3	1.3
	4	1.3
	5	1.3
	6	1.2
	7	1.2
	8	1.1
	B1	0.76
	2	1.1
	3	1.2
	4	1.2
	5	1.2
	6	1.2
	7	1.2
	8	1.0

AVERAGE 1.148

Start Time		Stop Time
Date	Leak Check PRE POST	WB
RUN #	STATIC	DB
		Stack
Real Time	Traverse Pt.	Delta P / Temp. (°F)

USED POINT A7

Start Time		Stop Time
Date	Leak Check PRE POST	WB
RUN #	STATIC	DB
		Stack
Real Time	Traverse Pt.	Delta P / Temp. (°F)

Start Time		Stop Time
Date	Leak Check PRE POST	WB
RUN #	STATIC	DB
		Stack
Real Time	Traverse Pt.	Delta P / Temp. (°F)

Method 2 FLOW DATA SHEET

Project No. B. Braun
Proj. Name

Site Location Bethlehem, PA
Unit/Location Sterilization
Stack ID 24.5

MB / Manometer # MB04
Pitot Tube / Probe ID # C-1
(cirice one)

Operator(s) LR
Baro. Pressure 30.31

Start Time		Stop Time	
Date	Leak Check	WB	
12/15/20	PRE ✓		
RUN #	POST ✓	DB	
1	STATIC		
	-2.7	Stack	
Real Time	Traverse Pt. (Min.)	Delta P	Temp. (°F)
0836	0	1.2	174
	1	1.2	174
	2	1.2	174
	3	1.2	175
	4	1.2	175
	5	1.1	175
	6	1.2	176
	7	1.2	175
	8	1.2	176
	9	1.2	177
	10	1.2	178
	11	1.2	179
	12	1.2	180
	13	1.2	182
	14	1.1	183
	15	1.2	183
	16	1.2	185
	17	1.2	186
	18	1.2	187
	19	1.2	189
	20	1.2	189
	21	1.2	189
0858	22	1.2	189
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE ✓		
RUN #	POST ✓	DB	
2	STATIC		
	-2.8	Stack	
Real Time	Traverse Pt. (Min.)	Delta P	Temp. (°F)
1310	0	1.2	174
	1	1.2	174
	2	1.2	175
	3	1.2	174
	4	1.2	175
	5	1.2	175
	6	1.2	175
	7	1.2	176
	8	1.2	177
	9	1.2	178
	10	1.2	179
	11	1.2	181
	12	1.2	182
	13	1.2	183
	14	1.2	184
	15	1.2	185
	16	1.2	186
	17	1.2	188
	18	1.2	188
	19	1.2	189
	20	1.2	189
	21	1.2	189
1332	22	1.2	189
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE ✓		
RUN #	POST ✓	DB	
3	STATIC		
	-3.0	Stack	
Real Time	Traverse Pt. (Min.)	Delta P	Temp. (°F)
1709	0	1.6	174
	1	1.6	174
	2	1.6	175
	3	1.6	175
	4	1.6	176
	5	1.6	176
	6	1.6	177
	7	1.6	177
	8	1.6	178
	9	1.6	178
	10	1.6	178
	11	1.6	179
	12	1.6	180
	13	1.6	181
	14	1.6	182
	15	1.6	183
	16	1.6	184
	17	1.6	185
	18	1.6	186
	19	1.6	186
	20	1.6	187
1730	21	1.6	187
	22		
	23		
	24		
	25		

Start Time		Stop Time	
Date	Leak Check	WB	
	PRE		
RUN #	POST	DB	
	STATIC		
		Stack	
Real Time	Traverse Pt.	Delta P	Temp. (°F)

Method 4 MOISTURE DATA SHEET

Project # B. Braun
Proj. Name
Date 12/15/2020
Site Loc. Bethlehem, PA
Unit/Loc. Sterilization

Meter Box # MB04
Delta Y @ 1.014
Delta H @ 1.73
MB Pump # MB P04
Stack ID 29.5

Operator(s) LR
Run 1 Baro. Press. 30.31
Run 2 Baro. Press. 30.31
Run 3 Baro. Press. 30.35

RUN # 1 — MOISTURE TRAIN — Start Time 835 — Stop Time 906 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
836	0	38.785	2.0	73	73	36	-1
	5	42.7	2.0	76	73	36	-1
	10	46.7	2.0	81	73	36	-1
	15	50.7	2.0	85	74	37	-2
	20	54.6	2.0	89	75	38	-2
	25	58.55	2.0	91	76	38	-2
906	30	62.520	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	734.0	771.1	
2	726.0	691.2	
3	657.3	658.1	
4	959.7	963.1	
5			
6			
7			
8			
9			
T			

RUN # 2 — MOISTURE TRAIN — Start Time 1310 — Stop Time 1340 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1310	0	131.155	2.0	97	96	46	-1
	5	135.0	2.0	103	96	42	-1
	10	139.1	2.0	107	96	41	-1
	15	143.0	2.0	110	96	42	-2
	20	147.1	2.0	111	97	43	-2
	25	151.1	2.0	112	98	43	-2
1340	30	155.020	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	773.6	776.7	
2	690.6	692.2	
3	657.3	658.5	
4	966.0	970.9	
5			
6			
7			
8			
9			
T			

RUN # 3 — MOISTURE TRAIN — Start Time 1709 — Stop Time 1739 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1709	0	189.380	2.0	90	91	40	-1
	5	193.35	2.0	95	90	39	-1
	10	197.3	2.0	98	91	38	-2
	15	201.25	2.0	102	91	36	-2
	20	205.2	2.0	108	92	36	-2
	25	209.2	2.0	110	93	36	-2
1739	30	213.212	–	–	–	–	–

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 5"

Imp. #	Initial	Final	Diff.
1	776.7	779.6	
2	692.2	693.7	
3	658.5	659.7	
4	970.9	975.6	
5			
6			
7			
8			
9			
T			

Method 4 MOISTURE DATA SHEET

Project # B. Braun
Proj. Name
Date 12/15/2020
Site Loc. Bethlehem, PA
Unit/Loc. Aeration

Meter Box # MB04
Delta Y @ 1.014
Delta H @ 1.73
MB Pump # MBP04
Stack ID 29.5

Operator(s) LR
Run 1 Baro. Press. 30.31
Run 2 Baro. Press. 30.31
Run 3 Baro. Press. 30.35

1042 LR

RUN # 1

MOISTURE TRAIN — Start Time ~~1040~~ 1042 LR — Stop Time 1142 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
~~1040~~ 1042 LR	0	62.770	1.0	80	78	37	-1
	5	65.6	1.0	82	79	37	-1
	10	68.5	1.0	84	79	36	-1
	15	71.3	1.0	88	80	36	-1
	20	74.05	1.0	90	86	37	-1
	25	76.8	1.0	93	81	37	-1
	30	79.6	1.0	95	82	38	-1
	35	82.4	1.0	97	84	38	-1
	40	85.25	1.0	98	85	39	-1
	45	88.1	1.0	99	85	40	-1
	50	90.9	1.0	100	87	40	-1
	55	93.7	1.0	102	88	40	-1
1142	60	96.540	—	—	—	—	—

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 4"

Imp. #	Initial	Final	Diff.
1	771.1	773.6	
2	691.2	690.6	
3	658.1	657.3	
4	963.1	966.0	
5			
6			
7			
8			
9			
T			

RUN # 2

MOISTURE TRAIN — Start Time 1155 — Stop Time 1255 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1155	0	96.715	1.0	92	91	44	-1
	5	~~99~~ 98.55	1.0	96	90	43	-1
	10	102.4	1.0	99	90	42	-1
	15	105.3	1.0	101	90	40	-1
	20	108.1	1.0	102	91	40	-1
	25	111.0	1.0	104	92	41	-1
	30	113.85	1.0	105	92	41	-1
	35	116.7	1.0	106	93	41	-1
	40	119.55	1.0	106	94	42	-1
	45	122.4	1.0	107	94	41	-1
	50	125.25	1.0	107	94	42	-1
	55	128.1	1.0	108	95	42	-1
1255	60	130.925	—	—	—	—	—

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15	0.001	@ 4"

Imp. #	Initial	Final	Diff.
1	716.3	720.7	
2	718.2	720.0	
3	639.1	639.8	
4	961.1	965.9	
5			
6			
7			
8			
9			
T			

RUN # 3

MOISTURE TRAIN — Start Time 1535 — Stop Time 1635 — Impingers ICED ? ✓

Real Time	Sampling Time	Dry Gas Meter VOLUME (ft³)	Delta H	In.Temp. (°F)	Out Temp.(°F)	EXIT Impinger Temp.(°F)	Pump Vacuum ("Hg)
1535	0	155.275	1.0	86	87	43	-1
	5	158.1	1.0	86	86	39	-1
	10	160.95	1.0	89	85	38	-1
	15	163.8	1.0	92	85	39	-1
	20	166.6	1.0	94	86	39	-1
	25	169.4	1.0	96	86	40	-1
	30	172.2	1.0	98	87	40	-1
	35	175.0	1.0	100	88	40	-1
	40	177.8	1.0	101	89	40	-1
	45	180.65	1.0	102	90	40	-1
	50	183.45	1.0	103	90	40	-1
	55	186.3	1.0	104	91	40	-1
1635	60	189.100	—	—	—	—	—

Train Leak Check

PRE CFM@	PRE VAC	POST CFM@	POST VAC
0.001	@ 15"	0.001	@ 4"

Imp. #	Initial	Final	Diff.
1	720.7	722.4	
2	720.0	719.9	
3	639.8	639.8	
4	965.9	969.8	
5			
6			
7			
8			
9			
T			

APPENDIX F

STRATIFICATION CHECK

STRATIFICATION CHECK

Customer Name: B Braun
Site Location: Allentown, PA
Source: CatOx Outlet
Date: 12/15/20

Point	O_2 Concentration (%) (A)	Deviation (% of mean) (B)	Deviation (difference from mean) (C)
1	20.25	0.2	0.0
2	20.27	0.2	0.0
3	20.38	0.4	0.1

Average Response (D) = 20.3
Maximum (% of Mean) (B) = 0.4 %
Maximum (diff from Mean) (C) = 0.1 % diff

Equations:
B = A- D/ D*100
C (diluent) = A- D

ALLOWABLE:
(single point sampling)
B ≤ 5% of mean OR
C (diluent) ≤ 0.3% diff

ALLOWABLE:
(3 point sampling)
B ≤ 10% of mean OR
C (diluent) ≤ 0.5% diff

NOTE: If >10% stratification, 12 point sampling must be done; Sampling points selected according to Method 1- Table 1-2.

Strat Check- CatOx Outlet

PACE Environmental
Minute Average

Date	Time	O_2 (%)		
12/15/20	8:36:26	20.57		
12/15/20	8:37:26	20.43		
12/15/20	8:38:27	20.30		
12/15/20	8:39:26	20.25		
12/15/20	8:40:27	20.24		
12/15/20	8:41:26	20.26	**Pt. 1**	**20.25**
12/15/20	8:42:27	20.25		
12/15/20	8:43:26	20.26		
12/15/20	8:44:26	20.25		
12/15/20	8:45:27	20.26		
12/15/20	8:46:26	20.29	**Pt. 2**	**20.27**
12/15/20	8:47:26	20.32		
12/15/20	8:48:26	20.34		
12/15/20	8:49:27	20.35		
12/15/20	8:50:26	20.39		
12/15/20	8:51:26	20.41	**Pt. 3**	**20.38**
12/15/20	8:52:26	20.43		

APPENDIX G

EtO GAS CERTIFICATE & RECORDED PROCESS DATA

balchem

CERTIFICATE OF ANALYSIS

Document Print Date 12-07-2020

ARC Specialty Products Balchem Corporation

Customer: 214100-00 B Braun Medical(PA) Batch No: UTLX930113K20

Product: F1100000 Ethylene Oxide

Manufacturing Site Address:

BALCHEM CORPORATION
95 Balchem Ln
Green Pond, SC 29446 USA

Phone: 1-843-844-8511
Fax:

Quality Contact: Regina C. Loftin
Email: rloftin@balchem.com

Analytical Results

Test Description	Specification				Batch Analysis
	Method	Units	Min	Max	Result
NVR	Non volatile residue, G/100ML	g/100ml	0.000	0.005	0.001
INFRARED ARC	Identity by infrared spec.				Pass
CO2	Carbon Dioxide, PPM	ppm.	0.0	50.0	10.0
COLOR PT-CO	Color, APHA 500, PT-CO	PT-CO	0	10	5
SUSMATTER	Suspended Matter, Substantially Free				Pass
COA STATEMENT	Results below are from supplier COA				
PURITY	Purity, %	%	99.90	100.00	99.99
WATER PPM	Water	ppm.	0.0	25.0	5.0
ACID-ACETIC	Acidity, as Acetic Acid	ppm.	0.0	20.0	10.0
ALDEHYDES	Total Aldehydes	ppm.	0.0	30.0	5.0
Expiration Date	The Expiration Date for this product				
Expiration Date cont	is 120 days from Fill Date.				

Q.A. Reviewed
BVM 12-8-2020

Customer Comments:

This Certificate is computer generated. No signature is required.

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balchem
Solve Today. Shape Tomorrow.

DRUM OUT LIST

52 Sunrise Park Road
New Hampton, NY
10958 USA

ARC Specialty Products Balchem Corporation

Customer name	Customer account	Customer requisition	Order number
B Braun Medical(PA)	214100-00	HLH4500599468	S200002708
Item number	**Product name**	**Packaging**	
F1100000-LXS-400	Ethylene Oxide	UN 1A1	

Batch number:	UTLX930113K20	U/M:	lb			
Serial number		**Gross weight**	**Tare weight**	**Net weight**	**Fill date**	**Expiration date**
E000746 X		673.00	273.00	400.00	11/16/2020	3/16/2021
E001170 X		679.00	279.00	400.00	11/16/2020	3/16/2021
E001676 X		675.00	275.00	400.00	11/16/2020	3/16/2021
E002186 X		660.00	260.00	400.00	11/16/2020	3/16/2021
E004100 X		677.00	277.00	400.00	11/16/2020	3/16/2021
E004179 X		676.00	276.00	400.00	11/16/2020	3/16/2021
E006385 X		692.00	292.00	400.00	11/16/2020	3/16/2021
E006444 X		692.00	292.00	400.00	11/16/2020	3/16/2021
Batch subtotal:		5424.00	2224.00	3200.00		

Total:	5424.00	2224.00	3200.00

RCH 12.8.2020

Q.A. Reviewed
BY RCH 12.8.2020

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Sterilization Run 1

gas charge (147 lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	8:36 AM	52.7	13.1	310	317
12/15/20	8:37 AM	52.7	12.3	308	317
12/15/20	8:38 AM	52.5	11.3	311	317
12/15/20	8:39 AM	52.2	10.5	311	318
12/15/20	8:40 AM	51.8	9.7	312	319
12/15/20	8:41 AM	51.5	8.9	310	321
12/15/20	8:42 AM	51.2	8.2	309	324
12/15/20	8:43 AM	51.0	7.7	310	331
12/15/20	8:44 AM	50.8	7.0	312	338
12/15/20	8:45 AM	50.7	6.4	314	344
12/15/20	8:46 AM	50.4	5.8	316	350
12/15/20	8:47 AM	50.2	5.2	317	355
12/15/20	8:48 AM	50.0	4.6	316	360
12/15/20	8:49 AM	49.8	4.1	316	365
12/15/20	8:50 AM	49.7	3.6	317	369
12/15/20	8:51 AM	49.5	3.2	317	373
12/15/20	8:52 AM	49.4	2.9	316	376
12/15/20	8:53 AM	49.3	2.5	316	378
12/15/20	8:54 AM	49.2	2.2	315	380
12/15/20	8:55 AM	49.1	2.0	314	381
12/15/20	8:56 AM	49.1	1.8	314	382
12/15/20	8:57 AM	49.0	1.6	314	382
Averages		**50.5**	**6.1**	**313.4**	**349.9**

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Sterilization Run 2

gas charge (155 lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	1:10 PM	52.7	12.9	308	321
12/15/20	1:11 PM	52.7	12.9	310	321
12/15/20	1:12 PM	52.5	11.7	310	321
12/15/20	1:13 PM	52.2	10.7	310	321
12/15/20	1:14 PM	51.8	10.0	310	321
12/15/20	1:15 PM	51.5	9.2	311	322
12/15/20	1:16 PM	51.3	8.4	311	325
12/15/20	1:17 PM	51.0	8.0	310	331
12/15/20	1:18 PM	50.8	7.2	311	338
12/15/20	1:19 PM	50.6	6.6	313	346
12/15/20	1:20 PM	50.4	5.9	315	353
12/15/20	1:21 PM	50.2	5.3	316	359
12/15/20	1:22 PM	50.0	4.8	316	364
12/15/20	1:23 PM	49.9	4.4	316	368
12/15/20	1:24 PM	49.8	3.8	317	373
12/15/20	1:25 PM	49.7	3.4	316	377
12/15/20	1:26 PM	49.5	2.9	316	380
12/15/20	1:27 PM	49.4	2.6	317	383
12/15/20	1:28 PM	49.3	2.3	316	384
12/15/20	1:29 PM	49.3	2.0	315	386
12/15/20	1:30 PM	49.2	1.8	314	387
12/15/20	1:31 PM	49.2	1.5	314	388
Averages		**50.6**	**6.3**	**313.3**	**353.1**

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Sterilization Run 3

gas charge (152 lbs)					
Date	Time	Temp	Pressure	TE121 (CatOx Inlet)	TE124 (CatOx Outlet)
		degrees C	psia	degrees F	degrees F
12/15/20	5:09 PM	52.7	13.0	308	323
12/15/20	5:10 PM	52.7	12.4	308	323
12/15/20	5:11 PM	52.5	11.7	309	323
12/15/20	5:12 PM	52.1	10.8	308	323
12/15/20	5:13 PM	51.7	9.9	309	323
12/15/20	5:14 PM	51.4	9.3	309	324
12/15/20	5:15 PM	51.0	8.3	310	327
12/15/20	5:16 PM	50.8	7.8	312	333
12/15/20	5:17 PM	50.5	7.1	314	340
12/15/20	5:18 PM	50.3	6.5	313	347
12/15/20	5:19 PM	50.0	5.9	315	354
12/15/20	5:20 PM	49.8	5.2	316	360
12/15/20	5:21 PM	49.6	4.7	316	365
12/15/20	5:22 PM	49.4	4.3	316	370
12/15/20	5:23 PM	49.3	3.8	317	374
12/15/20	5:24 PM	49.1	3.3	316	378
12/15/20	5:25 PM	49.0	3.0	316	380
12/15/20	5:26 PM	48.9	2.6	315	383
12/15/20	5:27 PM	48.8	2.3	315	384
12/15/20	5:28 PM	48.7	2.0	315	385
12/15/20	5:29 PM	48.6	1.8	314	386
Averages		**50.3**	**6.5**	**312.9**	**352.6**

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Process Data Aeration Run 1

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 10:42 AM	310	338
12/15/20 10:43 AM	310	338
12/15/20 10:44 AM	311	338
12/15/20 10:45 AM	308	338
12/15/20 10:46 AM	307	337
12/15/20 10:47 AM	309	337
12/15/20 10:48 AM	309	336
12/15/20 10:49 AM	310	335
12/15/20 10:50 AM	309	334
12/15/20 10:51 AM	309	334
12/15/20 10:52 AM	309	334
12/15/20 10:53 AM	309	334
12/15/20 10:54 AM	309	334
12/15/20 10:55 AM	309	333
12/15/20 10:56 AM	309	333
12/15/20 10:57 AM	309	333
12/15/20 10:58 AM	308	333
12/15/20 10:59 AM	310	332
12/15/20 11:00 AM	311	332
12/15/20 11:01 AM	312	332
12/15/20 11:02 AM	311	332
12/15/20 11:03 AM	309	332
12/15/20 11:04 AM	308	333
12/15/20 11:05 AM	311	333
12/15/20 11:06 AM	311	333
12/15/20 11:07 AM	309	332
12/15/20 11:08 AM	308	332
12/15/20 11:09 AM	308	332
12/15/20 11:10 AM	310	332
12/15/20 11:11 AM	311	332
12/15/20 11:12 AM	311	331
12/15/20 11:13 AM	310	330
12/15/20 11:14 AM	309	330
12/15/20 11:15 AM	309	331
12/15/20 11:16 AM	309	331
12/15/20 11:17 AM	309	330
12/15/20 11:18 AM	309	330
12/15/20 11:19 AM	309	330
12/15/20 11:20 AM	309	329
12/15/20 11:21 AM	309	329
12/15/20 11:22 AM	309	329
12/15/20 11:23 AM	309	329
12/15/20 11:24 AM	310	328
12/15/20 11:25 AM	312	328

Process Data Aeration Run 1

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 11:26 AM	311	328
12/15/20 11:27 AM	311	328
12/15/20 11:28 AM	311	329
12/15/20 11:29 AM	311	329
12/15/20 11:30 AM	311	329
12/15/20 11:31 AM	311	329
12/15/20 11:32 AM	311	329
12/15/20 11:33 AM	311	329
12/15/20 11:34 AM	311	329
12/15/20 11:35 AM	311	329
12/15/20 11:36 AM	311	329
12/15/20 11:37 AM	311	329
12/15/20 11:38 AM	311	329
12/15/20 11:39 AM	308	329
12/15/20 11:40 AM	308	329
12/15/20 11:41 AM	309	329
Average	**309.7**	**331.6**

Process Data Aeration Run 2

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 11:55 AM	310	326
12/15/20 11:56 AM	310	326
12/15/20 11:57 AM	310	325
12/15/20 11:58 AM	310	325
12/15/20 11:59 AM	310	325
12/15/20 12:00 PM	310	325
12/15/20 12:01 PM	310	325
12/15/20 12:02 PM	310	325
12/15/20 12:03 PM	309	325
12/15/20 12:04 PM	309	325
12/15/20 12:05 PM	309	324
12/15/20 12:06 PM	309	324
12/15/20 12:07 PM	309	324
12/15/20 12:08 PM	309	324
12/15/20 12:09 PM	309	324
12/15/20 12:10 PM	309	324
12/15/20 12:11 PM	309	324
12/15/20 12:12 PM	308	323
12/15/20 12:13 PM	308	323
12/15/20 12:14 PM	308	323
12/15/20 12:15 PM	308	323
12/15/20 12:16 PM	310	323
12/15/20 12:17 PM	312	323
12/15/20 12:18 PM	311	323
12/15/20 12:19 PM	312	323
12/15/20 12:20 PM	312	323
12/15/20 12:21 PM	310	323
12/15/20 12:22 PM	308	324
12/15/20 12:23 PM	310	324
12/15/20 12:24 PM	311	324
12/15/20 12:25 PM	310	324
12/15/20 12:26 PM	308	323
12/15/20 12:27 PM	308	322
12/15/20 12:28 PM	310	323
12/15/20 12:29 PM	311	323
12/15/20 12:30 PM	310	322
12/15/20 12:31 PM	309	322
12/15/20 12:32 PM	309	322
12/15/20 12:33 PM	309	322
12/15/20 12:34 PM	310	323
12/15/20 12:35 PM	310	322
12/15/20 12:36 PM	310	322
12/15/20 12:37 PM	310	322
12/15/20 12:38 PM	310	322

Process Data Aeration Run 2

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 12:39 PM	310	322
12/15/20 12:40 PM	310	322
12/15/20 12:41 PM	310	322
12/15/20 12:42 PM	311	322
12/15/20 12:43 PM	311	322
12/15/20 12:44 PM	311	323
12/15/20 12:45 PM	311	322
12/15/20 12:46 PM	311	322
12/15/20 12:47 PM	311	322
12/15/20 12:48 PM	311	322
12/15/20 12:49 PM	311	323
12/15/20 12:50 PM	310	323
12/15/20 12:51 PM	310	323
12/15/20 12:52 PM	308	323
12/15/20 12:53 PM	308	322
12/15/20 12:54 PM	310	322
Average	**309.8**	**323.2**

Process Data Aeration Run 3

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 3:35 PM	312	334
12/15/20 3:36 PM	310	333
12/15/20 3:37 PM	307	333
12/15/20 3:38 PM	310	333
12/15/20 3:39 PM	311	333
12/15/20 3:40 PM	309	333
12/15/20 3:41 PM	308	333
12/15/20 3:42 PM	308	333
12/15/20 3:43 PM	309	333
12/15/20 3:44 PM	311	333
12/15/20 3:45 PM	312	332
12/15/20 3:46 PM	312	332
12/15/20 3:47 PM	309	332
12/15/20 3:48 PM	308	332
12/15/20 3:49 PM	309	333
12/15/20 3:50 PM	311	333
12/15/20 3:51 PM	312	332
12/15/20 3:52 PM	311	332
12/15/20 3:53 PM	309	331
12/15/20 3:54 PM	308	331
12/15/20 3:55 PM	310	331
12/15/20 3:56 PM	311	331
12/15/20 3:57 PM	311	331
12/15/20 3:58 PM	311	330
12/15/20 3:59 PM	311	330
12/15/20 4:00 PM	310	331
12/15/20 4:01 PM	310	331
12/15/20 4:02 PM	310	331
12/15/20 4:03 PM	310	330
12/15/20 4:04 PM	310	330
12/15/20 4:05 PM	310	330
12/15/20 4:06 PM	310	330
12/15/20 4:07 PM	310	329
12/15/20 4:08 PM	310	329
12/15/20 4:09 PM	310	328
12/15/20 4:10 PM	310	328
12/15/20 4:11 PM	310	328
12/15/20 4:12 PM	309	328
12/15/20 4:13 PM	309	328
12/15/20 4:14 PM	309	328
12/15/20 4:15 PM	308	327
12/15/20 4:16 PM	308	327
12/15/20 4:17 PM	308	327
12/15/20 4:18 PM	308	327

Process Data Aeration Run 3

Date & Time	CatOx Inlet (temp °F) TE121	CatOx Outlet (temp °F) TE124
12/15/20 4:19 PM	310	326
12/15/20 4:20 PM	311	326
12/15/20 4:21 PM	311	326
12/15/20 4:22 PM	312	326
12/15/20 4:23 PM	312	326
12/15/20 4:24 PM	310	327
12/15/20 4:25 PM	308	327
12/15/20 4:26 PM	308	327
12/15/20 4:27 PM	309	327
12/15/20 4:28 PM	311	327
12/15/20 4:29 PM	311	326
12/15/20 4:30 PM	310	326
12/15/20 4:31 PM	310	325
12/15/20 4:32 PM	309	326
12/15/20 4:33 PM	309	326
12/15/20 4:34 PM	309	326
Average	**309.8**	**329.5**

CMS PERFORMANCE EVALUATION REPORT

Anguil Catalytic Oxidizer System

B. Braun Medical, Inc. / Allentown, PA Facility

February 2021

1. Introduction

B. Braun Medical Inc. ("B. Braun") operates a medical device manufacturing facility in Allentown, Pennsylvania. Certain medical devices require sterilization using ethylene oxide and subsequent aeration to ensure product safety and compliance with FDA regulations. The sterilization and aeration processes are subject to the Ethylene Oxide Emission Standards for Sterilization Facilities found at 40 CFR Part 63 Subpart O, and are operated in accordance with the terms and conditions of the facility's State Only Operating Permit (PADEP Permit # 39-00055). Pursuant to PADEP Plan Approval 39-00055B, B. Braun has completed construction and installation of a new catalytic oxidizer system to control ethylene oxide emissions from the facility. The catalytic oxidizer system is equipped with a Continuous Monitoring System ("CMS") used to demonstrate compliance with the pertinent operating limits and permit conditions. According to Table 1 of 40 CFR Part 63 Subpart O, the facility is required to perform a performance evaluation of the CMS during the performance test of the control device. Performance testing of the control device was performed by PACE Environmental on December 15, 2020 pursuant to the protocol approved by PADEP and is described in the accompanying Compliance Emissions Test Report. This report documents the performance of the associated CMS during performance testing of the control device.

2. Facility Identification Information

Owner/Operator:	B. Braun Medical, Inc.
Mailing and Physical Address:	901 Marcon Blvd Allentown, PA 18109
FRS Number:	110000334745
PADEP eFacts Facility ID:	514477

3. Continuous Monitoring System

The catalytic oxidizer system is equipped with temperature monitoring and control. The CMS required by the Subpart O regulations and the Plan Approval consists of a Type K thermocouple installed at the inlet of the catalyst bed and used to monitor and control the temperature of the gas stream entering oxidation chamber. Initial operational compliance of the control device has been demonstrated by ensuring that the temperature in the oxidation chamber is maintained at a temperature above the minimum oxidation temperature recommended by the catalyst manufacturer while the catalytic oxidizer system is operating and controlling ethylene oxide emissions. During the stack test, the oxidizer inlet temperature was operated at a set point of 154.4°C / 310°F, in order to ensure sufficient margin above the minimum inlet temperature recommended by the catalyst manufacturer (150°C / 302°F). According to Plan Approval condition E.III.6.c, ongoing compliance will be demonstrated by maintaining an inlet temperature above the minimum oxidation temperature achieved during the successful performance test (152.8°C / 307°F). The output of the thermocouple is monitored continuously and recorded by a Data Acquisition System ("DAS") at approximately 10-second intervals. The temperature monitor comprising the CMS is identified as follows:

Description	CatOx Bed Temperature - Inlet
Tag Name	Anguil_TE121
Asset ID	211907
Manufacturer	Pyromation

4. Performance Evaluation Objectives

The objectives of the Performance Evaluation are:

- Demonstrate that the CMS temperature monitor is accurate and precise
- Demonstrate proper functioning of the CMS and DAS

5. Data Quality Objectives

The following Data Quality Objectives have been developed to meet the objectives of the CMS Performance Evaluation:

- 3-point calibration certificates for the temperature monitor showing that the CMS meets the required level of accuracy (±5.6°C) before and after the performance test
- A comparison of the before and after calibration checks showing that the calibration drift is maintained within the required level of accuracy (±5.6°C) throughout the performance test
- Continuous records from the DAS showing that the CMS and DAS functioned correctly throughout the performance test
- Daily average oxidation temperatures generated by the DAS showing that the DAS is capable of generating the CMS summary data required by 40 CFR 63.364(c)

6. Performance Evaluation Results

A performance evaluation of the CMS was performed during the scheduled performance test of the catalytic oxidizer system. As discussed below, all performance evaluation and data quality objectives were achieved, indicating proper functioning of the CMS and the ability to demonstrate compliance with the minimum oxidation temperature limit.

6.1. Demonstrate that the CMS temperature monitor is accurate and precise

Prior to the performance test, accuracy of the CMS temperature monitor was assessed by performing a calibration check according to B. Braun's calibration procedure (SOP-MD-2000203) and metrology program (SOP-MD-2005713). A 3-point calibration check was performed using NIST-traceable standards and equipment covering the temperature range necessary to demonstrate compliance with the minimum oxidation temperature operating limit.

The temperature monitor is required to meet the minimum accuracy specified in the Subpart O regulations and in the PADEP Plan Approval:

> 40 CFR 63.364(c)(4): *The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).*

Following the performance test, the accuracy of the CMS temperature monitor was again verified using a 3-point calibration check. Precision of the CMS temperature monitor was assessed by comparing the

before and after calibrations, which are included as Attachment 1 to this report. The table below summarizes the temperature deviation from the standard value during each calibration, as well as the deviation or "drift" across the before and after calibrations. The deviation within each calibration and across the calibrations are within approximately 1°C and confirm that the CMS temperature monitor has acceptable accuracy and precision for demonstrating compliance with the minimum oxidation temperature limit.

		Before Performance Test (12/12/2020)			After Performance Test (12/22/2020)			
Setpoint	Units	Standard Value	Instrument Value	Deviation	Standard Value	Instrument Value	Deviation	Drift
140	°C	139.212	139.6	0.39	139.121	139.5	0.38	-0.1
160	°C	158.895	159.3	0.41	158.615	159.1	0.48	-0.2
180	°C	178.903	179.2	0.30	178.399	178.8	0.40	-0.4

6.2. Demonstrate proper functioning of the CMS and DAS

The functionality of the CMS was assessed during the performance test by ensuring that the temperature monitor provided continuous and expected measurement data to the DAS. The oxidation temperature setpoint was adjusted and the output of the inlet temperature monitor TE-121 was recorded to show that the adjustment was measured.

The functionality of the DAS was assessed during the performance test by ensuring that the DAS recorded complete temperature data from the CMS temperature monitor throughout the performance test. Data from the catalyst outlet temperature monitor TE-124 was also recorded to show measurement of the temperature adjustment as well as the characteristic temperature rise across the oxidation chamber as ethylene oxide is exothermically destroyed during sterilization chamber venting. This data is included to further demonstrate the correct and expected function of the DAS but TE-124 is not considered to be part of the control device CMS. Although TE-124 is not part of the control device CMS, the accuracy/precision of the temperature probe was similarly assessed and was found to be acceptable. The before and after calibration check sheets for TE-124 are also included in Attachment 1.

The temperature data recorded by the DAS on the day of the performance test is included as Attachment 2 and demonstrates proper function of the CMS and DAS throughout the performance test as well as the ability to generate CMS summary information including the daily average oxidation temperature.

7. Quality Assurance/Quality Control ("QA/QC")

As required by 40 CFR 63.8(e)(3)(i), the CMS performance evaluation is required to include both an internal and external QA program. The facility is also required to have a written QC program for the CMS.

7.1. QC Program

Quality control of the CMS will be achieved largely through B. Braun's existing metrology and preventative maintenance programs. As a manufacturer of medical devices, B. Braun adheres to strict quality standards and Good Manufacturing Practices required by FDA regulations at 21 CFR, and is required to have robust systems in place to ensure instrumentation is calibrated and that records are

maintained. The CMS temperature monitor has been entered into B. Braun's asset management system to ensure that the required semiannual calibration will be performed by instrument technicians on a timely basis. The calibrations are performed according to B. Braun's calibration procedure (SOP-MD-2000203) and metrology program (SOP-MD-2005713) to ensure that they are maintained within the required range of accuracy. Spare temperature monitors are maintained at the facility in a calibrated state, so they will be on-hand in the event of a CMS malfunction or failing calibration. CMS malfunctions will trigger and record alarm conditions to the DAS.

7.2. Internal QA Program

Internal quality assurance of the CMS will likewise be achieved largely through B. Braun's existing metrology and preventative maintenance programs. Through a criticality assessment, the CMS temperature probes have been identified in B. Braun's asset management system as 'EH&S Critical' to ensure that the required semiannual calibrations will be reviewed by metrology and EH&S staff on a timely basis. EH&S staff also reviews CMS data and alarms to ensure compliance with environmental requirements.

7.3. External QA Program

Similarly, B. Braun has robust auditing processes to ensure that all instrumentation is calibrated and functioning correctly, as required by environmental, safety, and product quality regulations. The CMS data generated through the performance evaluation will be reviewed for accuracy and completeness by a third party. CMS data and alarms are recorded by the DAS and are maintained and available for inspection by PADEP as well as third-party auditors. B. Braun's environmental management systems, including CMS data and alarms, are routinely audited by external consultants and auditors as part of the facility's ISO14001 recertification process and according to company policies.

Attachment 1 – Temperature Monitor Calibrations

Calibration Certification

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
610-266-0500

Asset ID:	211907	Owner Cost Center:	329005358 - Sterilization Operations	Cal Completed Date:	12/12/2020
Work Order #:	**WRK_CAL-0075282**	Recall Cost Center:	329005358 - Sterilization Operations	Next Due Date:	06/30/2021
Description:	Catalyst Inlet Temp Control Thermocouple Type K (TE-121)	Serviced By:	B.Braun (Lab)	Interval:	6
Location:	Sterilization - Anguil CatOx 16294	Temperature:	N/A N/AV	Initial Cal Interval:	
Criticality:	EH & S Critical	Humidity(%RH):	N/A	Cal SOP 1:	SOP-MD-2000203
Manufacturer:	Pyromation	As Found Condition:	In Tolerance	Cal SOP 2:	
Model:	K68U-048-00-8HN31 540-02	As Left Condition:	Meets All Specifications	Results Comments:	N/A
Serial Number:	N/A	Calibration Status:	Calibrated		

Measurement Information

Reading Num	Setpt	Standard Units	Inst Units	Lower Cal. Limit	Upper Cal. Limit	As Found			As Left		
						Standard	Instrument	Deviation	Standard	Instrument	Deviation
1	140.0	°C	°C	137.80	142.20	139.212	139.6	0.39	139.212	139.6	0.39
1	160.0	°C	°C	157.80	162.20	158.895	159.3	0.41	158.895	159.3	0.41
1	180.0	°C	°C	177.80	182.20	178.903	179.2	0.30	178.903	179.2	0.30

Standards Used

Standard ID	Date Due	Description	Manufacturer	Model	Serial Number
209425- Temperature Display Fluke 1524	04/30/2021	Temperature Display	Fluke	1524	3354102
209426- PRT 5616	04/30/2021	Platinum Resistance Thermometer	Measurment Specialties	5616-12	68361
211176- Dry Block Calibrator	04/30/2021	Dry Block Calibrator	Hart Scientific	9140 -C	B93680

Electronic Signatures

Reason	Display Name	Date/Time
Completed By	Nelson Perez	12/12/2020 7:59:04 AM
Review	Danis Botrus	12/14/2020 6:41:52 AM

B|BRAUN

Calibration Certification

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
610-266-0500

Asset ID:	211907	Owner Cost Center:	329005358 - Sterilization Operations	Cal Completed Date:	12/22/2020
Work Order #:	**WRK_CAL-0075421**	Recall Cost Center:	329005358 - Sterilization Operations	Next Due Date:	06/30/2021
Description:	Catalyst Inlet Temp Control Thermocouple Type K (TE-121)	Serviced By:	B.Braun (Lab)	Interval:	6
Location:	Sterilization - Anguil CatOx 16294	Temperature:	N/A N/AV	Initial Cal Interval:	
Criticality:	EH & S Critical	Humidity(%RH):	N/A	Cal SOP 1:	SOP-MD-2000203
Manufacturer:	Pyromation	As Found Condition:	In Tolerance	Cal SOP 2:	
Model:	K68U-048-00-8HN31 540-02	As Left Condition:	Meets All Specifications	Results Comments:	N/A
Serial Number:	N/A	Calibration Status:	Calibrated		

Measurement Information

Reading Num	Setpt	Standard Units	Inst Units	Lower Cal. Limit	Upper Cal. Limit	As Found			As Left		
						Standard	Instrument	Deviation	Standard	Instrument	Deviation
1	140.0	°C	°C	137.80	142.20	139.121	139.5	0.38	139.121	139.5	0.38
1	160.0	°C	°C	157.80	162.20	158.615	159.1	0.49	158.615	159.1	0.49
1	180.0	°C	°C	177.80	182.20	178.399	178.8	0.40	178.399	178.8	0.40

Standards Used

Standard ID	Date Due	Description	Manufacturer	Model	Serial Number
209425- Temperature Display Fluke 1524	04/30/2021	Temperature Display	Fluke	1524	3354102
209426- PRT 5616	04/30/2021	Platinum Resistance Thermometer	Measurment Specialties	5616-12	68361
211176- Dry Block Calibrator	04/30/2021	Dry Block Calibrator	Hart Scientific	9140 -C	B93680

Electronic Signatures

Reason	Display Name	Date/Time
Completed By	Nelson Perez	12/22/2020 9:34:49 AM
Review	Danis Botrus	12/22/2020 11:35:27 AM

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Calibration Certification

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
610-266-0500

Asset ID:	211912	Owner Cost Center:	329005358 - Sterilization Operations	Cal Completed Date:	12/12/2020
Work Order #:	**WRK_CAL-0075281**	Recall Cost Center:	329005358 - Sterilization Operations	Next Due Date:	06/30/2020
Description:	Catalyst Outlet Temp Thermocouple Type K (TE-124)	Serviced By:	B.Braun (Lab)	Interval:	6
Location:	Sterilization - Anguil CatOx 16294	Temperature:	N/A N/AV	Initial Cal Interval:	
Criticality:	EH & S Critical	Humidity(%RH):	N/A	Cal SOP 1:	SOP-MD-2000203
Manufacturer:	Pyromation	As Found Condition:	In Tolerance	Cal SOP 2:	
Model:	K68U-048-00-8HN31 540-02	As Left Condition:	Meets All Specifications	Results Comments:	Drywell is calibrated to 300C.
Serial Number:	N/A	Calibration Status:	Calibrated		

Measurement Information

Reading Num	Setpt	Standard Units	Inst Units	Lower Cal. Limit	Upper Cal. Limit	As Found			As Left		
						Standard	Instrument	Deviation	Standard	Instrument	Deviation
1	150.0	°C	°C	147.80	152.20	149.808	149.5	-0.31	149.808	149.5	-0.31
1	275.0	°C	°C	272.80	277.20	274.018	273.3	-0.72	274.018	273.3	-0.72
1	300.0	°C	°C	297.00	303.00	298.925	297.9	-1.03	298.925	297.9	-1.03

Standards Used

Standard ID	Date Due	Description	Manufacturer	Model	Serial Number
201580 - Hart Scientific 9140 Dry-well Calibrator	04/30/2021	Hart Scientific 9140 Dry-well Calibrator	Hart Scientific	9140	A55669
211183 - Handheld Thermometer	05/31/2021	Temperature Display	Fluke	1523	3491990
211184 - PRT	05/31/2021	Platinum Resistance Thermometer	Burns Engineering	5627A-12	991744

Electronic Signatures

Reason	Display Name	Date/Time
Completed By	Nelson Perez	12/12/2020 8:06:43 AM
Review	Danis Botrus	12/14/2020 6:40:43 AM

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Calibration Certification

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109
610-266-0500

Asset ID:	211912	Owner Cost Center:	329005358 - Sterilization Operations	Cal Completed Date:	12/22/2020
Work Order #:	**WRK_CAL-0075423**	Recall Cost Center:	329005358 - Sterilization Operations	Next Due Date:	06/30/2021
Description:	Catalyst Outlet Temp Thermocouple Type K (TE-124)	Serviced By:	B.Braun (Lab)	Interval:	6
Location:	Sterilization - Anguil CatOx 16294	Temperature:	N/A N/AV	Initial Cal Interval:	
Criticality:	EH & S Critical	Humidity(%RH):	N/A	Cal SOP 1:	SOP-MD-2000203
Manufacturer:	Pyromation	As Found Condition:	In Tolerance	Cal SOP 2:	
Model:	K68U-048-00-8HN31 540-02	As Left Condition:	Meets All Specifications	Results Comments:	N/A
Serial Number:	N/A	Calibration Status:	Calibrated		

Measurement Information

Reading Num	Setpt	Standard Units	Inst Units	Lower Cal. Limit	Upper Cal. Limit	As Found			As Left		
						Standard	Instrument	Deviation	Standard	Instrument	Deviation
1	150.0	°C	°C	147.80	152.20	149.818	149.6	-0.22	149.818	149.6	-0.22
1	275.0	°C	°C	272.80	277.20	274.254	273.3	-0.95	274.254	273.3	-0.95
1	300.0	°C	°C	297.00	303.00	299.139	298.1	-1.04	299.139	298.1	-1.04

Standards Used

Standard ID	Date Due	Description	Manufacturer	Model	Serial Number
201580 - Hart Scientific 9140 Dry-well Calibrator	04/30/2021	Hart Scientific 9140 Dry-well Calibrator	Hart Scientific	9140	A55669
209428- Temp Display Fluke 1524	04/30/2021	Temperature Display	Fluke	1524	3354103
211889- PRT 5627A	06/30/2021	Platinum Resistance Thermometer	Fluke	5627A	996834

Electronic Signatures

Reason	Display Name	Date/Time
Completed By	Nelson Perez	12/22/2020 9:58:40 AM
Review	Danis Botrus	12/22/2020 11:37:02 AM

Trend - [Anguil.aaTrend*]
Temperature setpoint adjustment
Exotherm (sterilizer evacuation)
Temperature setpoint adjustment
Statistics
Daily averages
Tag Name
Angul_TE121
Angul_TE124
Description
CatOx Bed Temperature - inlet
CatOx Bed Temperature - outlet
Ready
3:31 PM
2/8/2021