COMPLIANCE TEST REPORT
ETHYLENE OXIDE
STERILIZATION CHAMBER EXHAUSTS
AT
CHEMENCE MEDICAL
PROJECT ID: KR-10590

PREPARED FOR:

CHEMENCE MEDICAL
200 TECHNOLOGY DRIVE
ALPHARETTA, GEORGIA 30005

PREPARED BY:

ADVANCED INDUSTRIAL RESOURCES, INC.
3407 NOVIS POINTE
ACWORTH, GEORGIA 30101

OCTOBER 14, 2020

REPORT CERTIFICATION SHEET

Having conducted the Technical Review of this report, I hereby certify the data, information, results, and calculations in this report to be accurate and true according to the methods and procedures used.

Novmeber 16, 2020
Date

Ross Winne
Technical Director
Advanced Industrial Resources

Having written and prepared this report, I hereby certify that the data, information and results in this report to be correct and all inclusive of the necessary information required for a complete third-party review of the testing event.

November 16, 2020
Date

Steven Haigh
Report Preparation Director
Advanced Industrial Resources

Having supervised all aspects of the field testing, I hereby certify the equipment preparation, field sample collection procedures, and all equipment calibrations were conducted in accordance to the applicable methodologies.

November 16, 2020
Date

Scott Gunnell
Field Project Supervisor
Advanced Industrial Resources

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1.0 INTRODUCTION

1.1 SUMMARY OF TEST PROGRAM

The Chemence Medical facility is located at 200 Technology Drive, Alpharetta, GA 30005. Chemence manufactures and distributes adhesive-based medical devices used by many of the largest medical centers around the globe. Chemence also operates medical product and device sterilization chambers using ethylene oxide (EO). Source emissions testing was conducted on one each of the two sets of ethylene oxide sterilization chamber exhausts: EOA and EOE. Similar chambers to EOA are EOB and EOC. EOD is a similar chamber to EOE but is not currently operating. This testing was conducted in response to an EPD letter of August 10, 2020 from Sean Taylor and follow-up conversations with Stephen Damaske and Daniel McCain of EPD regarding the ethylene oxide emissions from this source. Note that weekly batch production is between zero and 3 batches.

Testing was conducted on October 14, 2020, in accordance with the generally approved test protocol developed for projects of this type modified for the small duct diameters. All testing was conducted by Advanced Industrial Resources, Inc. (*AIR*) in accordance with approved USEPA Methods (i.e., 40 CFR 60 Appendix A, Methods 1, 2, 3, 4, and Modified TO-15).

1.2 KEY PERSONNEL

The key personnel who coordinated and this Test Report and their telephone numbers are:

Hugo Escobar, *Chemence Medical*	770-664-7078
Ross Winne, *AIR*	404-843-2100
Scott Wilson, *AIR*	800-224-5007

2.0 PLANT AND SAMPLING LOCATION DESCRIPTIONS

2.1 PROCESS & CONTROL EQUIPMENT DESCRIPTION

The Chemence Medical facility is located at 200 Technology Drive, Alpharetta, GA 30005. Plastic sealed tote baskets are used to hold products and devices for EO sterilization in batch processes after loading to the chambers. Batches typically run for 19 hours, followed by a purge cycle lasting 1 hour for EOA, EOB, and EOC, or 4 hours for EOE. During this purge cycle the gases are vented to the outside.

2.2 SAMPLING LOCATION

The exhaust sampling location for EOA was a 3-inch id section of PVC pipe modified to house a calibrated propeller vane anemometer for measuring the flow in ft/min. The A distance was 3 inches and the B distance was 6 inches to disturbances.

The exhaust sampling location for EOE was a 1.625-inch id section of PVC pipe modified to house a calibrated hot wire anemometer for measuring the flow in ft/min. The A distance was 6 inches and the B distance was 12 inches to disturbances.

3.0 SUMMARY AND DISCUSSION OF TEST RESULTS

3.1 OBJECTIVES

The purpose of the test program was to verify source emissions of ethylene oxide (EO) both in ppm and in lb/hr. The molecular weight (Mw) of EO is 44.05.

3.2 FIELD TEST CHANGES AND PROBLEMS

The testing was conducted in accordance with the general test protocol developed for projects of this type scaled to the smaller exhaust sizes. At the request of EPD, a duplicate sample was taken for each chamber utilizing 2 Summa cannisters simultaneously. No problems were encountered during testing that required deviation from the planned test protocol.

3.3 PRESENTATION OF TEST RESULTS

Emission concentrations and mass rates are summarized in Table 3-1. Reduced and tabulated data from the field-testing is included in Appendix A. The calculations and nomenclature used to reduce the data are presented in Appendix B. Actual raw field data sheets are presented in Appendix C.

Table 3-1

Source	Average Measured ppm (EO)	Average Measured lb/hr (EO)
EOA	52 ppm	0.02602589 lb/hr for the 1-hour cycle
EOE	405 ppm	0.06795603 lb/hr for the 4-hour cycle

EOA average emission concentration was determined to be **52 ppm (0.02603 lb/hr.)** EOE average emission concentration was determined to be **405 ppm (0.06796 lb/hr.)**

3.4 PROCESS MONITORING

All essential process monitoring equipment was operating and data was recorded throughout the test period so as to allow necessary monitoring parameters and limits to be established, where applicable. Data, as made available, is presented in Appendix F.

4.0 SAMPLING AND ANALYTICAL PROCEDURES

Each of the two (2) ethylene oxide (EO) emissions performance tests was comprised of one (1) **duplicate** sampling repetition of four (4) hours for EOE and of one (1) **duplicate** 1-hour for EOA during the purge of each chamber, which followed a nineteen (19) hour sterilization cycle. All testing was according to the methodologies detailed in EPA Methods 1, 2, 3, 4, and Modified TO-15.

Performance testing for this source will be conducted according to the methodology in 40 *CFR* 60, Appendix A. Specifically:

X Method 1 or 1A was used for the qualification of the location of sampling ports and for the determination of the number and positions of stack traverse points, as applicable to sample traverses.

X Method 2 or 2A was employed for the determination of the stack gas velocity and volumetric flow rate during stack sampling using the Type "S" pitot tube or a calibrated anemometer.

X Method 3 was used for the calculation of the density and dry molecular weight of the effluent stack gas.

X Method 4 was used for the determination of moisture (or wet-bulb/dry-bulb).

X Method TO-15 Modified SIM (Selective Ion Monitoring) – VOCs by GCMS in SIM Mode (reporting limit 0.5 ppbv). 6-liter summa cannisters to sample for 240-minute batch sample time using 4-hour flow controllers and for 60-minute batch using 1-hour flow controllers. Sample location will be in the centroid of the small diameter exhaust pipes, which are 1.625 inches for EOE and 3.0 inches for EOA.

Summa cannister samples were recovered on site by sealing and tagging them. All samples were stored upright in a closed shipping box until final laboratory analysis. All samples were ground transported via the *AIR* equipment resource vehicle and shipped for analysis to Eurofins Air Toxics, LLC, Folsom, CA. In order to limit the chain of custody, only essential *AIR* personnel were permitted access to these samples.

5.0 DATA QUALITY OBJECTIVES

The data quality objectives (DQOs) process is generally a seven-step iterative planning approach to ensure development of sampling designs for data collection activities that support decision making. The seven steps are as follows: (1) defining the problem; (2) stating decisions and alternative actions; (3) identifying inputs into the decision; (4) defining the study boundaries; (5) defining statistical parameters, specifying action levels, and developing action logic; (6) specifying acceptable error limits; and (7) selecting resource-effective sampling and analysis plan to meet the performance criteria. The first five steps are primarily focused on identifying qualitative criteria such as the type of data needed and defining how the data will be used. The sixth step defines quantitative criteria and the seventh step is used to develop a data collection design. In regards to emissions sampling, these steps have already been identified for typical monitoring parameters.

Monitoring methods presented in 40 *CFR* 60 Appendix A indicate the following regarding DQOs: Adherence to the requirements of this method will enhance the quality of the data obtained from air pollutant sampling methods. At a minimum, each method provides the following types of information: summary of method; equipment and supplies; reagents and standards; sample collection, preservation, storage, and transportation; quality control; calibration and standardization; analytical procedures, data analysis and calculations; and alternative procedures. These test methods have been designed and tested according to DQOs for emissions testing and analysis. These test methods have been specified and were followed to testing to ensure that DQOs were met for this project.

APPENDIX A

TEST RESULTS

Advanced Industrial Resources, Inc.

Test Results

Chemance Medical

Alpharetta, Georgia

		Units	EOA	EOA - Duplicate	EOE	EOE - Duplicate
Test Date			14-Oct-20	14-Oct-20	14-Oct-20	14-Oct-20
Start Time			10:33	10:33	10:22	10:22
End Time			11:33	11:33	14:22	14:22
P_{bar}	**Barometric pressure**	inches Hg	29.12	29.12	29.12	29.12
p_g	**Gauge pressure of stack gas**	inches H_2O	0.00	0.00	0.00	0.00
P_s	**Pressure of stack gases**	inches Hg	29.12	29.12	29.12	29.12
$B_{ws,act}$	**Actual moisture**	%	0.0175	0.0175	0.0181	0.0181
v_s	**Velocity of stack gas**	ft./min	1,664	1,664	1,915	1,915
v_s	**Velocity of stack gas**	ft./sec	28	28	32	32
D_s	**Diameter of stack**	in	3.00	3.00	1.625	1.625
A_s	**Area of stack**	ft^2	0.0491	0.0491	0.0144	0.0144
T_s	**Temperature of stack gas**	°R	565	565	569	569
Gas Stream Flow Rates						
Q_a	**Vol. Flow rate of actual gas**	cfm	82	82	28	28
Q_w	**Vol. Flow rate of wet gas**	scfm	74	74	25	25
Q_{sd}	**Vol. Flow rate of dry gas**	dscfm	73	73	24	24
Gas Stream Ethylene Oxide Concentrations - TO-15 SIM						
c_{EtO}	**Conc. Of PM in dry stack gas**	ppm	58.0	46.0	360.0	450.0
c_{EtO}	**Conc. Of PM in dry stack gas**	mg/dscm	106.2	84.3	659.4	824.2
c_{PM}	**Conc. Of PM in dry stack gas**	gr/dscf	0.0464	0.0368	0.2880	0.3600
Ethylene Oxide Mass Rates TO-15 SIM						
E_{EtO}	**Emission rate of EtO**	lb/hour	0.029	0.023	0.060	0.076

	ppm	ppm	lb/hr	lb/hr	Averages
EOA	58	58	0.02900615	0.02900615	0.02600551
EOA Dup	46	46	0.02300487	0.02300487	
EOE	360	360	0.06035624	0.06035624	0.06790077
EOE Dup	450	450	0.0754453	0.0754453	

APPENDIX B

EXAMPLE CALCULATIONS

AND

NOMENCLATURE

EXAMPLE CALCULATIONS

$A_n = D_n^2 \pi / 4$

$A_s = D_s^2 \pi / 4$

$B_{ws} = V_{w(std)} / (V_{m(std)} + V_{w(std)})$

$c_{analyte} = (m_{analyte} / V_{m(std)})\ (35.31466\ ft^3/m^3)$

$'c_{analyte} = (m_{analyte} / V_{m(std)})\ (0.015432\ gr/mg)$

$c_{analyte} = 'c_{analyte}\ MW_{analyte} / 24.04\ l/mol$

$CC = t_{0.975}\ (S_d / n^{1/2})$

$d = 1/n\ (\Sigma d_i)$

$DE = (E_{Inlet} - E_{Outlet}) / E_{,Inlet}\ x\ 100\%$

$E_{analyte} = (m_{analyte} / V_{m(std)})\ Q_{sd}\ (60\ min/hr)\ (2.2046x10^{-6}\ lb./mg)$

$E_{analyte} = c_{analyte}\ Q_{sd}\ (60\ min/hr)\ (2.2046x10^{-6}\ lb./mg)$

$I = 100\ T_s\ (K_3\ V_{lc} + Y_m\ V_m\ P_m / T_m) / (60\ \theta\ v_s\ P_s\ A_n)$

where $K_3 = 0.002669\ (in.\ Hg\ ft^3) / (mL\ °R)$

$K_I = [(2.0084x10^7\ \Delta H_@)\ A_n\ (1 - B_{ws})]^2\ (M_d / M_s)\ (T_m / T_s)\ (P_s / P_m)$

$M_d = 0.44\ (\%\ CO_2) + 0.32\ (\%\ O_2) + 0.28\ (\%\ N_2 + \%\ CO)$

$M_s = M_d\ (1 - B_{ws}) + M_w\ B_{ws}$

$P = Qsd / F\text{-}Factor\ x\ 60\ x\ (20.9\text{-}O_2) / 20.9$

$P_m = P_{bar} + \Delta H / 13.6$

$P_s = P_{bar} + p_g / 13.6$

$Q_a = (60\ s/min)\ v_s\ A_s$

$Q_{sd} = (60\ s/min)\ (1 - B_{ws})\ v_s\ A_s\ (T_{std} / T_s)\ (P_s / P_{std})$

$RA = [Abs(d) + Abs(CC)]/RM$

$S_d = [(\Sigma d_i^2 - (\Sigma di)^2/n)/(n\text{-}1)]^{1/2}$

$T_m = t_m + 460°$

$T_s = t_s + 460°$

$V_{m(std)} = V_m\ Y_m\ (T_{std} / T_m)\ (P_m / P_{std})$

$V_{w(std)} = (V_{lc}\ \rho_w\ R\ T_{std}) / (M_w\ P_{std})$

$v_s = K_p\ C_p\ [\Delta p]^{1/2}\ [T_s / (P_s\ M_s)]^{1/2}$

NOMENCLATURE

Symbol	Units	Description
Abs(x)	dimensionless	Absolute value of parameter x
A_n	ft^2	Area of the nozzle
A_s	ft^2	Area of the stack
B_{ws}	dimensionless	Volume proportion of water in the stack gas stream
C_p	dimensionless	Type S pitot tube coefficient
$c_{analyte}$	mg/dscm	Concentration of analyte in dry stack gas, standardized
$'c_{analyte}$	gr./dscf	Concentration of analyte in dry stack gas, standardized
$'c_{analyte}$	ppm	Concentration of analyte in dry stack gas, standardized
CC	dimensionless	One-tailed 2.5% error confidence coefficient
d	ppm	Arithmetic mean of differences
d_i	ppm	Difference between individual CEM and reference method concentration value
D_n	inches	Internal diameter of the nozzle at the entrance orifice
D_s	inches	Internal diameter of the stack at sampling location
DE	percent	Destruction efficiency
DH	inches H_2O	Average pressure differential across the meter orifice
DH@	inches H_2O	Orifice pressure differential that corresponds to 0.75 cfm of air at 68 °F and 29.92 inches of Hg
Dp	inches H_2O	Velocity head of stack gas
$E_{analyte}$	lb./hour	Emission rate of analyte, time basis
I	percent	Isokinetic sampling ratio expressed as percentage
K_I	dimensionless	K-factor, ratio of DH to DP, ideal
K_p	$ft[(lb/lb\text{-}mol)(in.\ Hg)]^{1/2}$	Type S pitot tube constant,
	$s[(°R)(in.\ H_2O)]^{1/2}$	= 85.49
L_p	cfm	Measured post-test leakage rate of the sampling train
M_d	lb./lb.-mole	Molecular weight of gas at the DGM
M_s	lb./lb.-mole	Molecular weight of gas at the stack

NOMENCLATURE

Symbol	Units	Description
M_w	lb./lb.-mole	Molecular weight of water,
		= 18.0
$m_{analyte}$	mg	Mass of analyte in the sample
n	dimensionless	Number of data points
P	MMBtu	Fuel firing rate
P_{bar}	inches Hg	Barometric pressure at measurement site
P_{input}	tons/hour	Process dry mass input rate
p_g	inches H_2O	Gauge (static) pressure of stack gas
P_m	inches Hg	Absolute pressure of meter gases
P_s	inches Hg	Absolute pressure of stack gases
P_{std}	inches Hg	Standard absolute pressure
		= 29.92
Q_a	cfm	Volumetric flow rate of actual stack gas
Q_{sd}	dscfm	Volumetric flow rate of dry stack gas, standardized
R	(in. Hg)(ft^3)	Ideal gas constant,
	(lb-mole)(°R)	= 21.85
RA	percent	Relative accuracy
RE	percent	Removal efficiency
RM	ppm	Average reference method concentration
r_w	lb/mL	Density of water,
		= 0.002201
r_a	g/mL	Density of acetone,
		= 0.7899
S_d	dimensionless	Standard deviation
T_m	°R	Absolute temperature of dry gas meter
T_s	°R	Absolute temperature of stack gas
T_{std}	°R	Standard absolute temperature,
		= 528
$t_{0.975}$	dimensionless	2.5 percent error t-value
t_m	°F	Temperature of DGM
t_s	°F	Temperature of stack gas
q	minutes	Total sampling time

NOMENCLATURE

Symbol	Units	Description
V_{lc}	mL	Total volume of liquid collected
V_m	dcf	Volume of gas sample as measured by the DGM
$V_{m(std)}$	dscf	Volume of gas sample as measured by the DGM, standardized
$V_{w(std)}$	scf	Volume of water vapor in the gas sample, standardized
v_s	ft./sec	Velocity of stack gas
Y_m	dimensionless	DGM calibration coefficient
Y_c	dimensionless	DGM calibration check value
Y_w	dimensionless	Reference (wet) gas meter calibration coefficient
% CO_2	percent	Percent CO_2 by volume, dry basis
% O_2	percent	Percent O_2 by volume, dry basis
% N_2	percent	Percent N_2 by volume, dry basis

APPENDIX C

FIELD DATA

Advanced Industrial Resources, Inc.

Field Data

Chemance Medical

Alpharetta, Georgia

EOA			EOE		
Time	ft/min	T_s C^o	Time	ft/min	T_s F^o
10:33	1660	40.6	10:22	3250	109
10:38	1671	40.6	10:32	2270	
10:43	1665	40.7	10:42	1220	
10:48	1671	40.8	10:53	2100	
10:53	1660	40.8	11:03	2246	
10:58	1665	40.8	11:13	1526	
11:03	1655	40.7	11:22	2647	
11:08	1665	40.8	11:32	1200	
11:13	1665	40.7	11:42	2691	
11:18	1671	40.8	11:53	2660	
11:23	1670	40.8	12:04	2240	
11:28	1655	40.8	12:13	1240	
11:33	1660	40.8	12:22	2280	
Average:	**1664.1**	**40.7**	12:32	2150	
			12:42	2330	
			12:52	1040	
			13:02	2300	
			13:12	1155	
			13:22	1145	
			13:32	2220	
			13:42	1029	
			13:52	2365	
		14:02	1125		
	14:12	2315			
	14:22	1128			
	Average:	**1914.9**	**109**		

Input values:		Run Number	
		EOA	EOE
T_{db}	F	103.8	106.1
T_{wb}	F	73.7	74.8
P_g	in H_20	0.00	0.00
P_{bar}	in Hg	29.12	29.12
O_2	%	21.0	21.0
CO_2	%	0.0	0.0
Calculated values:			
P	in Hg	29.12	29.12
MW_{air}	lb/mol	28.84	28.84
p_{sat}	in Hg	0.84	0.87
p	in Hg	0.51	0.53
H	lb H_2O/lb air	0.0111	0.0115
B_{ws}		**0.0175**	**0.0181**

Note: % O_2 and % CO_2 are not important variables. Use 21% and 0% if values have not been measured.

Corn ID

1 hour - 6L1822 - EOA P_{bar} = 29.12

1 hour - 6L2491 - EOA

4 hours - 6L0682 - EOE

4 hours - 6L1011 - EOE

EOE	EOA
start - 1022	start - 1033
stop - 1422	stop - 1133

EOE

- 6L0682 - Initial Vacuum - 29.0" Hg
  Final Vacuum - 9.5" Hg
- 6L1011 - Initial Vacuum - 29.0" Hg
  Final Vacuum - 10" Hg

EOA

- 6L2491 - Initial Vacuum - ~~29.8~~ 28 xon" Hg
  Final Vacuum - 9.5" Hg
- 6L1822 - Initial Vacuum - ~~29.9~~ 28 Hg" Hg
  Final Vacuum - 9.0" Hg

EOE D_s = 1 5/8"

EOA D_s = 3"

EDE

$P_{bar} = 29.12$

Time	Flow (ft./min.)	Vacuum
~~1020~~	~~3250~~ ~~3225~~ ~~125~~	29" Hg
1022		
1032	2270	
1042	1220	
1053	~~34.37~~ 2100	
1103	~~25.59~~ 2246	
1113	~~19.67~~ 1526	
1122	2647	
1132	1200	28" Hg
1142	2691	
1153	2660	
1204	2240	
1213	1240	
1222	2280	
1232	2150	
1242	2330	
1252	1040	
1302	2300	
1312	1155	
1322	1145	
1332	2220	
1342	1029	
1352	2365	
1402	1125	
1412	2315	
1422	1128	

$w_b = 74.8$ °F

$D_b =$ ~~106.7~~ °F
106.1 sum

Fan turns on and off

103.2

$t_s = 109.$

D_s 1.625

EOA

P_{bar} = 29.12

Time	Flow (ft./min.)	t_s (C)		
1033	1660	40.6	28"Hg	40.1 °C
1038	1671	40.6		W_b = 73.7°F
1043	1665	40.7		
1048	1671	40.8		D_b = 103.8 °F
1053	1660	40.8		
1058	1665	40.8	19.5"Hg	
1103	1655	40.7		
1108	1665	40.8		
1113	1665	40.7	15 Hg	
1118	1671	40.8		
1123	1670	40.8	12.5	
1128	1655	40.8		
1133	1660	40.8		

D_s 3.0"

APPENDIX D

LABORATORY REPORT

eurofins | Air Toxics

10/29/2020
Mr. Derek Stephens
Advanced Industrial Resources
3407 Novis Pointe

Acworth GA 30101

Project Name:
Project #: KR10590
Workorder #: 2010412

Dear Mr. Derek Stephens

The following report includes the data for the above referenced project for sample(s) received on 10/16/2020 at Eurofins Air Toxics LLC.

The data and associated QC analyzed by Modified TO-15 SIM are compliant with the project requirements or laboratory criteria with the exception of the deviations noted in the attached case narrative.

Thank you for choosing Eurofins Air Toxics LLC. for your air analysis needs. Eurofins Air Toxics Inc. is committed to providing accurate data of the highest quality. Please feel free to contact the Project Manager: Brian Whittaker at 916-985-1000 if you have any questions regarding the data in this report.

Regards,

Brian Whittaker

Project Manager

eurofins | Air Toxics

WORK ORDER #: 2010412

Work Order Summary

CLIENT:	Mr. Derek Stephens Advanced Industrial Resources 3407 Novis Pointe Acworth, GA 30101	**BILL TO:**	Mr. Derek Stephens Advanced Industrial Resources 3407 Novis Pointe Acworth, GA 30101
PHONE:	404-843-2100	**P.O. #**	
FAX:	404-845-0020	**PROJECT #**	KR10590
DATE RECEIVED:	10/16/2020	**CONTACT:**	Brian Whittaker
DATE COMPLETED:	10/29/2020		

FRACTION #	NAME	TEST	RECEIPT VAC./PRES.	FINAL PRESSURE
01A	KR10590-1 (EOE)	Modified TO-15 SIM	10.5 "Hg	5 psi
02A	KR10590-2 (EOE) DUP	Modified TO-15 SIM	9.5 "Hg	5 psi
03A	KR10590-3 (EOA)	Modified TO-15 SIM	8.5 "Hg	5 psi
04A	KR10590-4 (EOA) DUP	Modified TO-15 SIM	9.0 "Hg	5 psi
05A	Lab Blank	Modified TO-15 SIM	NA	NA
06A	CCV	Modified TO-15 SIM	NA	NA
07A	LCS	Modified TO-15 SIM	NA	NA
07AA	LCSD	Modified TO-15 SIM	NA	NA

CERTIFIED BY: Heidi Hayes DATE: 10/29/20

Technical Director

Certification numbers: AZ Licensure AZ0775, FL NELAP – E87680, LA NELAP – 02089, NH NELAP - 209220, NJ NELAP - CA016, NY NELAP - 11291, TX NELAP - T104704434-20-16, UT NELAP – CA009332020-12, VA NELAP - 10615, WA NELAP - C935
Name of Accreditation Body: NELAP/ORELAP (Oregon Environmental Laboratory Accreditation Program)
Accreditation number: CA300005-014, Effective date: 10/18/2020, Expiration date: 10/17/2021.
Eurofins Air Toxics, LLC certifies that the test results contained in this report meet all requirements of the NELAC standards

180 BLUE RAVINE ROAD, SUITE B FOLSOM, CA - 95630
(916) 985-1000 . (800) 985-5955 . FAX (916) 351-8279

LABORATORY NARRATIVE
EPA TO-15 Ethylene oxide (SIM)
Advanced Industrial Resources
Workorder# 2010412

Four 6 Liter Summa Canister (100% Certified) samples were received on October 16, 2020. The laboratory performed analysis via EPA Method TO-15 using GC/MS in the SIM acquisition mode for the measurement of Ethylene oxide in ambient air.

Receiving Notes

The Chain of Custody (COC) information for samples KR10590-1 (EOE), KR10590-2 (EOE) DUP, KR10590-3 (EOA) and KR10590-4 (EOA) DUP did not match the entries on the sample tags with regard to sample identification. Therefore the information on the COC was used to process and report the samples.

Analytical Notes

Ethylene Oxide is not included on the laboratory's NELAP scope of accreditation for TO-15 SIM. However, TO-15 method and NELAP quality requirements were met.

Dilution was performed on samples KR10590-1 (EOE), KR10590-2 (EOE) DUP, KR10590-3 (EOA) and KR10590-4 (EOA) DUP due to the presence of high level target species.

Samples KR10590-1 (EOE), KR10590-2 (EOE) DUP, KR10590-3 (EOA) and KR10590-4 (EOA) DUP were analyzed 15 days after sample collection which was past the laboratory's SOP specified 14-day hold time, but within the method recommended 30-day hold time.

Definition of Data Qualifying Flags

Nine qualifiers may have been used on the data analysis sheets and indicates as follows:

B - Compound present in laboratory blank greater than reporting limit (background subtraction not performed).

J - Estimated value.

S - Saturated peak.

Q - Exceeds quality control limits.

U - Compound analyzed for but not detected above the reporting limit, LOD, or MDL value. See data page for project specific U-flag definition.

UJ- Non-detected compound associated with low bias in the CCV

N - The identification is based on presumptive evidence.

CN - See Case Narrative

File extensions may have been used on the data analysis sheets and indicates as follows:

a-File was requantified

b-File was quantified by a second column and detector

r1-File was requantified for the purpose of reissue

eurofins | Air Toxics

Summary of Detected Compounds
MODIFIED EPA METHOD TO-15 GC/MS SIM

Client Sample ID: KR10590-1 (EOE)

Lab ID#: 2010412-01A

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1600	360000	3000	660000

Client Sample ID: KR10590-2 (EOE) DUP

Lab ID#: 2010412-02A

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1600	450000	2800	810000

Client Sample ID: KR10590-3 (EOA)

Lab ID#: 2010412-03A

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1500	58000	2700	100000

Client Sample ID: KR10590-4 (EOA) DUP

Lab ID#: 2010412-04A

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1500	46000	2800	83000

eurofins | Air Toxics

Client Sample ID: KR10590-1 (EOE)

Lab ID#: 2010412-01A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102822sim**	**Date of Collection: 10/14/20 2:22:00 PM**	
Dil. Factor:	**33000**	**Date of Analysis: 10/28/20 11:51 PM**	

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1600	360000	3000	660000

Container Type: 6 Liter Summa Canister (100% Certified)

eurofins | Air Toxics

Client Sample ID: KR10590-2 (EOE) DUP

Lab ID#: 2010412-02A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102823sim**	**Date of Collection: 10/14/20 2:22:00 PM**	
Dil. Factor:	**31400**	**Date of Analysis: 10/29/20 12:22 AM**	

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1600	450000	2800	810000

Container Type: 6 Liter Summa Canister (100% Certified)

eurofins | Air Toxics

Client Sample ID: KR10590-3 (EOA)

Lab ID#: 2010412-03A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102824sim**	**Date of Collection:**	**10/14/20 11:33:00 A**
Dil. Factor:	**29900**	**Date of Analysis:**	**10/29/20 12:52 AM**

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1500	58000	2700	100000

Container Type: 6 Liter Summa Canister (100% Certified)

eurofins | Air Toxics

Client Sample ID: KR10590-4 (EOA) DUP

Lab ID#: 2010412-04A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102825sim**	**Date of Collection:**	**10/14/20 11:33:00 A**
Dil. Factor:	**30600**	**Date of Analysis:**	**10/29/20 01:24 AM**

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	1500	46000	2800	83000

Container Type: 6 Liter Summa Canister (100% Certified)

eurofins | Air Toxics

Client Sample ID: Lab Blank

Lab ID#: 2010412-05A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102805sim**	**Date of Collection: NA**	
Dil. Factor:	**1.00**	**Date of Analysis: 10/28/20 11:47 AM**	

Compound	Rpt. Limit (ppbv)	Amount (ppbv)	Rpt. Limit (ug/m3)	Amount (ug/m3)
Ethylene Oxide	0.050	Not Detected	0.090	Not Detected

Container Type: NA - Not Applicable

eurofins | Air Toxics

Client Sample ID: CCV

Lab ID#: 2010412-06A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102802sim**	**Date of Collection: NA**
Dil. Factor:	**1.00**	**Date of Analysis: 10/28/20 10:08 AM**

Compound	%Recovery
Ethylene Oxide	118

Container Type: NA - Not Applicable

eurofins | Air Toxics

Client Sample ID: LCS

Lab ID#: 2010412-07A

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102803sim**	**Date of Collection: NA**	
Dil. Factor:	**1.00**	**Date of Analysis: 10/28/20 10:40 AM**	

Compound	%Recovery	Method Limits
Ethylene Oxide	111	70-130

Container Type: NA - Not Applicable

eurofins | Air Toxics

Client Sample ID: LCSD

Lab ID#: 2010412-07AA

MODIFIED EPA METHOD TO-15 GC/MS SIM

File Name:	**30102804sim**	**Date of Collection: NA**	
Dil. Factor:	**1.00**	**Date of Analysis: 10/28/20 11:12 AM**	

Compound	%Recovery	Method Limits
Ethylene Oxide	105	70-130

Container Type: NA - Not Applicable

APPENDIX E

CALIBRATION DATA

Accurate Solutions Atlanta
ISO/IEC 17025:2005 Accredited

Calibration Certificate

Issue Date: 4/27/2018
Certificate No: 344684

PJLA Calibration
Accreditation# 89897

Calibration Performed By:

Accurate Solutions - Atlanta, Inc.
825 Chance Rd, Suite 10
Marietta, GA 30066

Phone: (770) 428-9400
Performed By: GALEN EVANS

For:

CHEMENCE MEDICAL
200 TECHNOLOGY DRIVE
ALPHARETTA, GA 30005

Contact: HETAL PATEL
770-664-6732

Equipment Information:

Description: HOT WIRE ANEMOMETER

I.D.:	15100075	Serial Number:	15100075
Manufacturer:	AMPROBE	Temp./RH:	20°C / 49%RH
Model Number:	TMA-20HW	Cal. Procedure:	COMPARATIVE
Cal Date:	4/27/2018	As Found:	IN TOLERANCE
Cal. Due Date:	4/30/2019	Calibration Result:	PASS

Calibration Notes

Seq.	Description	Standard	Tol. -	Tol. +	As Found	As Left	Unit
1	Applied Standard	70.0	52.0	88.0	68.0	68.0	FPM
2		150.0	132.0	168.0	151.2	151.2	FPM
3		806.0	788.0	824.0	799.8	799.8	FPM

Standards Used To Calibrate Equipment:

Company	I.D.	Description	Last Cal.	Cal. Due Date
ACCURATE SOLUTIONS	40-06-03532	AIR FLOW STANDARD	4/10/2018	4/30/2023

Accurate Solutions - Atlanta, Inc. maintains a quality system that is accredited by Perry Johnson Laboratory Accreditation, Inc. to meet or exceed the requirements set forth in ISO/IEC 17025:2005. The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI). Calibrations meet or exceed a 4:1 TUR ratio unless otherwise noted.The uncertainty of measurement associated with the measurement result reported in this certificate is available upon request and was accounted for in making the decision of compliance or noncompliance with the relevant specification above. This certificate generated under digital signature by the below indicated technician certified competent in the company quality documents for the test(s) performed. The work was performed at the Accurate Solutions - Atlanta facility above.

Cert. #: 344684 Authorized Signature/Technician: GALEN EVANS Date: 4/27/2018

Calibration Certificate

Accurate Solutions Atlanta
ISO/IEC 17025:2005 Accredited

Issue Date: 11/10/2020
Certificate No: 368950

PJLA Calibration
Accreditation# 89897

Calibration Performed By:
Accurate Solutions - Atlanta, Inc.
825 Chance Rd, Suite 10
Marietta, GA 30066

Phone: (770) 428-9400
Performed By: GALEN EVANS

For: CHEMENCE MEDICAL
200 TECHNOLOGY DRIVE
ALPHARETTA, GA 30005

Contact: RICHARD NARDINI
470-359-2896 X208

Equipment Information:

Description: **HOT WIRE ANEMOMETER**

I.D.:	15100075	Serial Number:	15100075
Manufacturer:	AMPROBE	Temp./RH:	23°C / 52%RH
Model Number:	TMA-20HW	Cal. Procedure:	COMPARATIVE
Cal Date:	11/10/2020	As Found:	IN TOLERANCE
Cal. Due Date:	11/30/2021	Calibration Result:	PASS

Calibration Notes: Tolerance is ±18 up to 600 FPM, then 3% of reading.

Seq.	Description	Standard	Tol. -	Tol. +	As Found	As Left	Unit
1	Applied Standard	120.0	102.0	138.0	114.0	114.0	FPM
2		497.0	479.0	515.0	494.0	494.0	FPM
3		1996.0	1936.0	1956.0	1941.0	1941.0	FPM

Standards Used To Calibrate Equipment:

Company	I.D.	Description	Last Cal.	Cal. Due Date
ACCURATE SOLUTIONS	40-06-03532	AIR FLOW STANDARD	11/5/2020	11/30/2022

Accurate Solutions - Atlanta, Inc. maintains a quality system that is accredited by Perry Johnson Laboratory Accreditation, Inc. to meet or exceed the requirements set forth in ISO/IEC 17025:2017. The calibration results published in this certificate were obtained using equipment capable of producing resuts that are traceable through NIST to the International System of Units (SI). Calibrations meet or exceed a 4:1 TUR ratio unless otherwise noted or uncertainties are provided; Any uncertainty of measurement or TUR reported in this certificate is expressed as expanded uncertainty value at approximately the 95% confidence level using a coverage factor of k=2; Uncertainty computation does not include instrument under test resolution or repeatability; Any statement of conformity was made using a simple limit criteria not accounting for any uncertainties; or as determined by the contract review on file. This certificate generated under digital signature by the below indicated technician certified competent in the company quality documents for the test(s) performed. The work was performed at the Accurate Solutions - Atlanta facility indicated above.

Cert. #: 368950 Authorized Signature/Technician: GALEN EVANS Date: 11/10/2020

Calibration Certificate

Accurate Solutions Atlanta
ISO/IEC 17025:2005 Accredited

Issue Date: 11/10/2020
Certificate No: 368954

PJLA Calibration
Accreditation# 89897

Calibration Performed By:
Accurate Solutions - Atlanta, Inc.
825 Chance Rd, Suite 10
Marietta, GA 30066

Phone: (770) 428-9400
Performed By: GALEN EVANS

For: CHEMENCE MEDICAL
200 TECHNOLOGY DRIVE
ALPHARETTA, GA 30005

Contact: RICHARD NARDINI
470-359-2896 X208

Equipment Information:

Description: **VANE ANEMOMETER WITH IR THERMOMETER**

I.D.:	160602500	Serial Number:	160602500
Manufacturer:	EXTECH	Temp./RH:	23 °C / 52%RH
Model Number:	AN200	Cal. Procedure:	OEM PROC
Cal Date:	11/10/2020	As Found:	IN TOLERANCE
Cal. Due Date:	11/30/2021	Calibration Result:	PASS

Calibration Notes

Seq.	Description	Standard	Tol. -	Tol. +	As Found	As Left	Unit
1	Air Flow, Observed Standard	120	76	164	118	118	FPM
2		875	809	941	882	882	FPM
3		1724	1632	1816	1663	1663	FPM
4	IR Temperature	25	23	27	25	25	°C
5		270	265	275	269	269	°C

Standards Used To Calibrate Equipment:

Company	I.D.	Description	Last Cal.	Cal. Due Date
ACCURATE SOLUTIONS	160122045	CALIBRATOR, IR	10/30/2020	10/31/2021
ACCURATE SOLUTIONS	40-06-03532	AIR FLOW STANDARD	11/5/2020	11/30/2022

Accurate Solutions - Atlanta, Inc. maintains a quality system that is accredited by Perry Johnson Laboratory Accreditation, Inc. to meet or exceed the requirements set forth in ISO/IEC 17025:2017. The calibration results published in this certificate were obtained using equipment capable of producing resuts that are traceable through NIST to the International System of Units (SI). Calibrations meet or exceed a 4:1 TUR ratio unless otherwise noted or uncertainties are provided; Any uncertainty of measurement or TUR reported in this certificate is expressed as expanded uncertainty value at approximately the 95% confidence level using a coverage factor of k=2; Uncertainty computation does not include instrument under test resolution or repeatability; Any statement of conformity was made using a simple limit criteria not accounting for any uncertainties; or as determined by the contract review on file. This certificate generated under digital signature by the below indicated technician certified competent in the company quality documents for the test(s) performed. The work was performed at the Accurate Solutions - Atlanta facility indicated above.

Cert. #: 368954 Authorized Signature/Technician: GALEN EVANS Date: 11/10/2020

Calibration Certificate

Accurate Solutions Atlanta
ISO/IEC 17025:2005 Accredited

Issue Date: 5/3/2018
Certificate No: 344740

PJLA Calibration
Accreditation# 89897

Calibration Performed By:
Accurate Solutions - Atlanta, Inc.
825 Chance Rd, Suite 10
Marietta, GA 30066

Phone: (770) 428-9400
Performed By: GALEN EVANS

For: CHEMENCE MEDICAL
200 TECHNOLOGY DRIVE
ALPHARETTA, GA 30005

Contact: HETAL PATEL
770-664-6732

Equipment Information:

Description: **VANE ANEMOMETER WITH IR THERMOMETER**

I.D.:	160602500	Serial Number:	160602500
Manufacturer:	EXTECH	Temp./RH:	20 °C / 49%RH
Model Number:	AN200	Cal. Procedure:	OEM PROC
Cal Date:	4/27/2018	As Found:	IN TOLERANCE
Cal. Due Date:	4/30/2019	Calibration Result:	PASS

Calibration Notes

Seq.	Description	Standard	Tol. -	Tol. +	As Found	As Left	Unit
1	Air Flow, Observed Standard	75	32	118	83	83	FPM
2		806	751	861	813	813	FPM
3		2008	1933	2083	2051	2051	FPM
4	IR Temperature	25	23	27	25	25	°C
5		250	245	255	247	247	°C

Standards Used To Calibrate Equipment:

Company	I.D.	Description	Last Cal.	Cal. Due Date
ACCURATE SOLUTIONS	160122045	CALIBRATOR, IR	8/17/2017	8/31/2018
ACCURATE SOLUTIONS	40-06-03532	AIR FLOW STANDARD	4/10/2018	4/30/2023

Accurate Solutions - Atlanta, Inc. maintains a quality system that is accredited by Perry Johnson Laboratory Accreditation, Inc. to meet or exceed the requirements set forth in ISO/IEC 17025:2005. The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI). Calibrations meet or exceed a 4:1 TUR ratio unless otherwise noted.The uncertainty of measurement associated with the measurement result reported in this certificate is available upon request and was accounted for in making the decision of compliance or noncompliance with the relevant specification above. This certificate generated under digital signature by the below indicated technician certified competent in the company quality documents for the test(s) performed. The work was performed at the Accurate Solutions - Atlanta facility above.

Cert. #: 344740 Authorized Signature/Technician: GALEN EVANS Date: 4/27/2018

APPENDIX F

PROCESS OPERATION DATA

Glue
LOT: 040482-R5 **RUN #** 100A94

Operation	Description	Date Completed
4a	Operation 1 – Staging and Preconditioning *(Minimum 12 hours)	AA 19 Oct 2020
	Operation 2– EO Gas Consumable Preparation	AA 19 Oct 2020
4b	Operation 3 – Tote Preperation and Bag Sealing	AA 19 Oct 2020
	Operation 4 – Transfer and Load Time	AA 19 Oct 2020
4c	Operation 5 – Sterilization/Aeration	AA 19 Oct 2020
	Operation 6- Dosimeter Check	AA 19 Oct 2020
PRODUCTION REVIEW COMPLETED BY/DATE:	Dmitri Dmitrovic 19 Oct 2020	

Acceptance Criteria & Final Release			
The sterilization load/bag/tote contains appropriate QTY of devices.	☑ Yes ☐ No	The environment within the EO sterilization bag is ≥30% (absolute minimum at the start of the cycle during the warm-up phase is 24%RH	☑ Yes ☐ No
The average preconditioning environment is ≥12hours at ≥68°F and ≥30%RH.	☑ Yes ☐ No	Devices are aerated within the sterilizer set to 50°C for ≥1 hour.	☑ Yes ☐ No
The average sterilizer cabinet temperature is 50ºC± 3°.	☑ Yes ☐ No	All Dosimeters (for all bags) pass the calibration triangle.	☑ Yes ☐ No
The net EO delivered to each sterilization bag is 9.98g-12.00g	☑ Yes ☐ No	The BIs are negative (remain orange).	☑ Yes ☐ No
Two (2) Humdichips were placed into every sterilization bag.	☑ Yes ☐ No	The positive control turns positive (turbid and yellow).	☑ Yes ☐ No
The transfer time from 'white room' to final cartridge activation is ≤17 minutes.	☑ Yes ☐ No	The incubation time/temperature for the BIs is 7 days at 35-39°C.	☑ Yes ☐ No
The average environment within the EO sterilization bag is 50ºC± 3°	☑ Yes ☐ No		
Comments:	☑ N/A		
QA Release:	26 Oct 2020		

Operation 1 - Staging for EO Sterilization

Minimum Quantity and Maximum Quantity Are Both 600 Pouches/Blisters per Tote
Exofin XL min/ max is 99 pouches in each tote
Exofin® Fusion min/max is 18 pouches in each tote and/or 45 pouches in each liner bag
Ampoule boxes (Mastic/Glugone) min/max is 15 boxes per tote

Lot#:	040482-R5	Tote#:	1-10	Qty:	6,000	Dunnage Qty/ Tote#:	N/A ☒
Lot#:	N/A ☒	Tote#:	N/A ☒	Qty:	N/A ☒	Dunnage Qty/ Tote#:	N/A ☒
Lot#:	N/A ☒	Tote#:	N/A ☒	Qty:	N/A ☒	Dunnage Qty/ Tote#:	N/A ☒

Operation 1 - Preconditioning *(Minimum 12 hours)

Data Logger ID:	R17771			Calibration Due Date:	DEC 2020		
Data Logger Prepared as outlined in WI-MED-0018							
Start Time:	2:55am	Start Date:	13OCT2020	End Time:	2:55pm ~~13OCT2020~~ ER 13OCT2020	End Date:	13OCT2020
Avg. Temperature (≥68ºF):	76.26 ºF			Avg. Relative Humidity (≥ 30%):	57.16 %		
Operator Signature/Date:	Elizabeth Rosales 13OCT2020			**Checked By/Date:**	Manuela Beltran 13OCT2020		
QA Signature/Date:	Zahra Mcclemore 13 OCT 2020				☒ Pass ☐ Fail*		

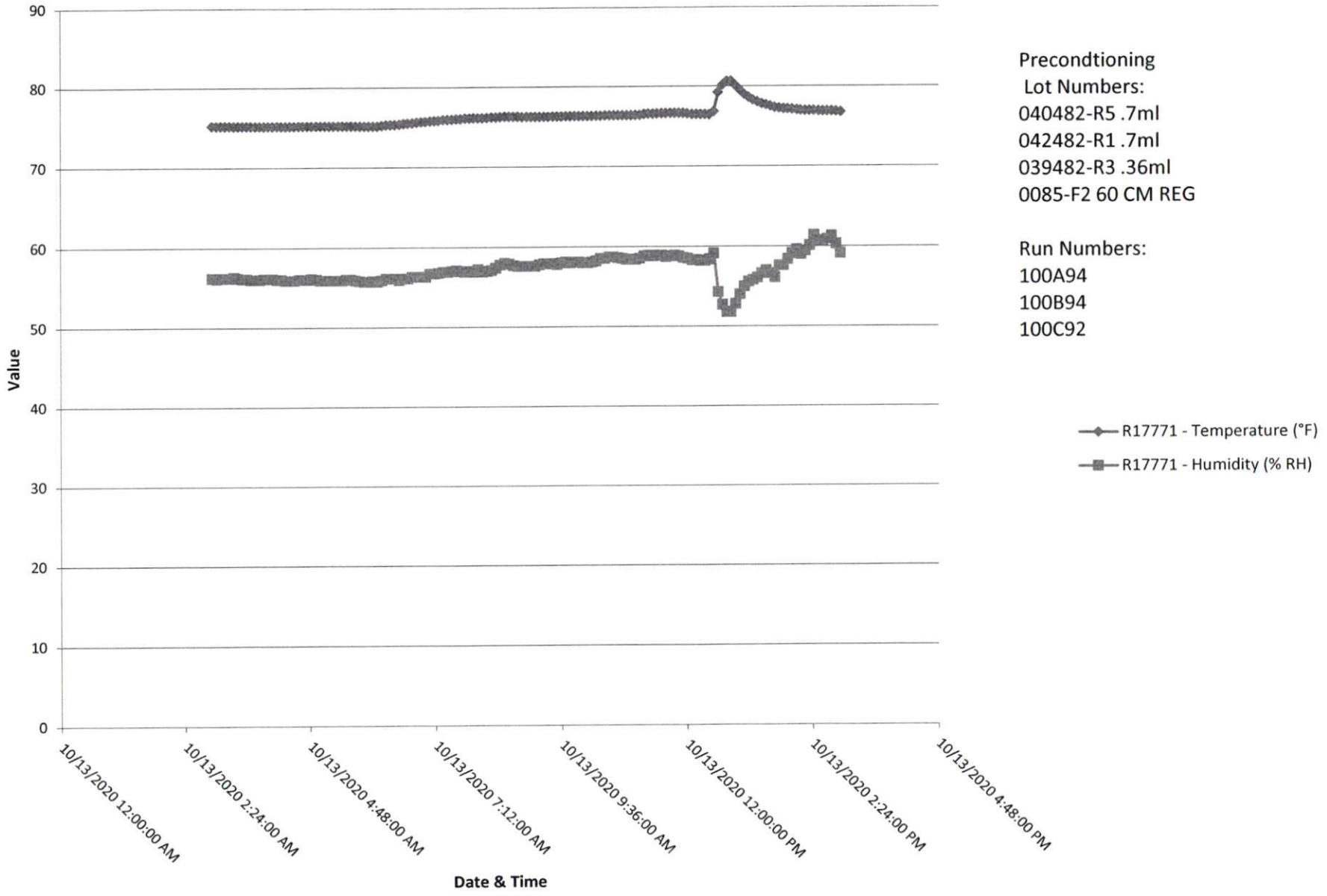
Operation 2 - Data Logger Setup (see WI-MED-0018)

Data Logger ID:	P70074	Calibration Due Date:	Apr 2021	Programmed Start Date/Time (include Quickstart):	13OCT2020 1:05pm
Data Logger ID:	Q37941	Calibration Due Date:	Jul 2021	Programmed Start Date/Time (include Quickstart):	13OCT2020 1:05pm

****Verify that totes are arranged as outlined in WI-MED-0018**

Printed by/date: ER 13Oct2020 Lot: 040482-R5 Run #: 100A94

R17771 MultiChannel Preconditioning



Device Name:		**RHTemp1000IS**	**RHTemp1000IS**
Device Description:		**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:		**R17771**	**R17771**
Device ID:	**R17771**	**MultiChannel**	**MultiChannel**

Precondtioning
Lot Numbers:
040482-R5 .7ml
042482-R1 .7ml
039482-R3 .36ml
0085-F2 60 CM REG
Run Numbers:
100A94
100B94
100C92

Date	Time	Channel 1 Temperature (°F)	Channel 2 Humidity (% RH)
10/13/2020	2:55:49 AM	75.186	56.2
10/13/2020	3:00:49 AM	75.186	56.1
10/13/2020	3:05:49 AM	75.186	56.2
10/13/2020	3:10:49 AM	75.186	56.2
10/13/2020	3:15:49 AM	75.186	56.2
10/13/2020	3:20:49 AM	75.204	56.3
10/13/2020	3:25:49 AM	75.204	56.2
10/13/2020	3:30:49 AM	75.186	56.1
10/13/2020	3:35:49 AM	75.186	56.1
10/13/2020	3:40:49 AM	75.186	56
10/13/2020	3:45:49 AM	75.186	56
10/13/2020	3:50:49 AM	75.186	56
10/13/2020	3:55:49 AM	75.168	56.1
10/13/2020	4:00:49 AM	75.186	56.1
10/13/2020	4:05:49 AM	75.186	56.1
10/13/2020	4:10:49 AM	75.186	56
10/13/2020	4:15:49 AM	75.168	56
10/13/2020	4:20:49 AM	75.168	55.9
10/13/2020	4:25:49 AM	75.168	55.9
10/13/2020	4:30:49 AM	75.168	55.9
10/13/2020	4:35:49 AM	75.168	56
10/13/2020	4:40:49 AM	75.168	56
10/13/2020	4:45:49 AM	75.168	56
10/13/2020	4:50:49 AM	75.168	56.1
10/13/2020	4:55:49 AM	75.168	56
10/13/2020	5:00:49 AM	75.168	55.9
10/13/2020	5:05:49 AM	75.15	55.9
10/13/2020	5:10:49 AM	75.15	55.9
10/13/2020	5:15:49 AM	75.168	55.9
10/13/2020	5:20:49 AM	75.15	55.9
10/13/2020	5:25:49 AM	75.15	55.9
10/13/2020	5:30:49 AM	75.168	56
10/13/2020	5:35:49 AM	75.168	56
10/13/2020	5:40:49 AM	75.15	55.9
10/13/2020	5:45:49 AM	75.15	55.8
10/13/2020	5:50:49 AM	75.15	55.7
10/13/2020	5:55:49 AM	75.132	55.7
10/13/2020	6:00:49 AM	75.15	55.8
10/13/2020	6:05:49 AM	75.168	55.7
10/13/2020	6:10:49 AM	75.222	55.9
10/13/2020	6:15:49 AM	75.276	56.1
10/13/2020	6:20:49 AM	75.312	56.1
10/13/2020	6:25:49 AM	75.348	56.1
10/13/2020	6:30:49 AM	75.384	55.9
10/13/2020	6:35:49 AM	75.456	56.1
10/13/2020	6:40:49 AM	75.51	56.1
10/13/2020	6:45:49 AM	75.564	56.3
10/13/2020	6:50:49 AM	75.618	56.3
10/13/2020	6:55:49 AM	75.672	56.3
10/13/2020	7:00:49 AM	75.708	56.3
10/13/2020	7:05:49 AM	75.78	56.7
10/13/2020	7:10:49 AM	75.834	56.7
10/13/2020	7:15:49 AM	75.87	56.8
10/13/2020	7:20:49 AM	75.906	56.9

10/13/2020	7:25:49 AM	75.96	56.9
10/13/2020	7:30:49 AM	75.996	57
10/13/2020	7:35:49 AM	76.032	57.1
10/13/2020	7:40:49 AM	76.05	57
10/13/2020	7:45:49 AM	76.086	56.9
10/13/2020	7:50:49 AM	76.104	57
10/13/2020	7:55:49 AM	76.122	56.9
10/13/2020	8:00:49 AM	76.122	57.2
10/13/2020	8:05:49 AM	76.14	56.9
10/13/2020	8:10:49 AM	76.158	57
10/13/2020	8:15:49 AM	76.212	57.1
10/13/2020	8:20:49 AM	76.23	57.4
10/13/2020	8:25:49 AM	76.284	57.8
10/13/2020	8:30:49 AM	76.302	58
10/13/2020	8:35:49 AM	76.302	57.9
10/13/2020	8:40:49 AM	76.302	57.7
10/13/2020	8:45:49 AM	76.302	57.6
10/13/2020	8:50:49 AM	76.284	57.6
10/13/2020	8:55:49 AM	76.284	57.6
10/13/2020	9:00:49 AM	76.284	57.6
10/13/2020	9:05:49 AM	76.284	57.6
10/13/2020	9:10:49 AM	76.266	57.8
10/13/2020	9:15:49 AM	76.266	57.9
10/13/2020	9:20:49 AM	76.248	57.9
10/13/2020	9:25:49 AM	76.266	57.9
10/13/2020	9:30:49 AM	76.266	57.8
10/13/2020	9:35:49 AM	76.284	58
10/13/2020	9:40:49 AM	76.302	58.1
10/13/2020	9:45:49 AM	76.32	58
10/13/2020	9:50:49 AM	76.338	58.1
10/13/2020	9:55:49 AM	76.338	58.1
10/13/2020	10:00:49 AM	76.338	58
10/13/2020	10:05:49 AM	76.338	58
10/13/2020	10:10:49 AM	76.338	58.1
10/13/2020	10:15:49 AM	76.374	58.2
10/13/2020	10:20:49 AM	76.356	58.5
10/13/2020	10:25:49 AM	76.392	58.5
10/13/2020	10:30:49 AM	76.392	58.7
10/13/2020	10:35:49 AM	76.41	58.7
10/13/2020	10:40:49 AM	76.41	58.6
10/13/2020	10:45:49 AM	76.41	58.5
10/13/2020	10:50:49 AM	76.41	58.4
10/13/2020	10:55:49 AM	76.428	58.4
10/13/2020	11:00:49 AM	76.428	58.4
10/13/2020	11:05:49 AM	76.464	58.5
10/13/2020	11:10:49 AM	76.518	58.8
10/13/2020	11:15:49 AM	76.536	58.9
10/13/2020	11:20:49 AM	76.536	58.8
10/13/2020	11:25:49 AM	76.59	58.9
10/13/2020	11:30:49 AM	76.626	58.9
10/13/2020	11:35:49 AM	76.644	58.7
10/13/2020	11:40:49 AM	76.626	58.8
10/13/2020	11:45:49 AM	76.644	58.9
10/13/2020	11:50:49 AM	76.644	58.8
10/13/2020	11:55:49 AM	76.626	58.6
10/13/2020	12:00:49 PM	76.572	58.5
10/13/2020	12:05:49 PM	76.518	58.3
10/13/2020	12:10:49 PM	76.482	58.3
10/13/2020	12:15:49 PM	76.464	58.2
10/13/2020	12:20:49 PM	76.446	58.2
10/13/2020	12:25:49 PM	76.428	58.4
10/13/2020	12:30:49 PM	76.824	59.1
10/13/2020	12:35:49 PM	79.236	54.3
10/13/2020	12:40:49 PM	80.208	52.7
10/13/2020	12:45:49 PM	80.622	51.8
10/13/2020	12:50:49 PM	80.658	51.8
10/13/2020	12:55:49 PM	80.01	52.8
10/13/2020	1:00:49 PM	79.47	54
10/13/2020	1:05:49 PM	79.02	55
10/13/2020	1:10:49 PM	78.642	55.6
10/13/2020	1:15:49 PM	78.3	55.8
10/13/2020	1:20:49 PM	78.012	56.1
10/13/2020	1:25:49 PM	77.796	56.6
10/13/2020	1:30:49 PM	77.634	57
10/13/2020	1:35:49 PM	77.472	56.6
10/13/2020	1:40:49 PM	77.328	56.1
10/13/2020	1:45:49 PM	77.238	57.6
10/13/2020	1:50:49 PM	77.184	57.6
10/13/2020	1:55:49 PM	77.148	58.4
10/13/2020	2:00:49 PM	77.094	59.1
10/13/2020	2:05:49 PM	77.04	59.6
10/13/2020	2:10:49 PM	76.968	59
10/13/2020	2:15:49 PM	76.95	59.4
10/13/2020	2:20:49 PM	76.932	60.1
10/13/2020	2:25:49 PM	76.932	61.4
10/13/2020	2:30:49 PM	76.914	60.7
10/13/2020	2:35:49 PM	76.878	60.7
10/13/2020	2:40:49 PM	76.86	60.9
10/13/2020	2:45:49 PM	76.842	61.3
10/13/2020	2:50:49 PM	76.824	60.3
10/13/2020	2:55:49 PM	76.77	59.1
		76.26252414	57.15655172

Operation 2 – EO Gas Consumable Preparation							
EO Gas Canister Pre-Weight Information Recorded on Pg. 5				Box labels are printed and match each tote.			
EO Bag Information Recorded on Pg. 4				PCDs are placed in the center of the load.			
EO Gas Canister Labeled and mounted to tote (s) with product.				Positive Control same Lot number as PCDs in totes			
EZ Test BIs not damaged, Labeled, inside PCD and sealed.				Dosimeter is labeled and placed in the center of the load.			
Humidichips (2) placed inside Humiditube inside the tote.				Equipment Logbooks filled out.			
2 Data loggers placed into the front of the tote (hotest and coolest locations):							
Control Number (Location):	050A94	Serial Number:	P70074	Control Number (Location):	090A94	Serial Number:	Q37941
Operator Signature/date:	Elizabeth Roxales 13Oct2020			**Checked By/date:**	Manuela Beltran 13Oct2020		

Operation 3 - Tote Preparation and Bag Sealing			
EO Bag Sealer Asset ID:	54774	EO Bag Sealer Calibration Due Date:	Feb 2021

QA Line Clearance – Proceed to Bag Sealing	
All steps in Operation 2 are complete and all consumables are loaded into each tote	
QA Signature/Date:	Zahra McLemore 13 OCT 2020

Operation 4 - Transfer & Load Time					
Time left "white room" area (b):	4:10pm	Sterilizer Temp (50ºC± 3º):	49.5 ºC	Printer Paper/Ink Checked:	☑
Check to ensure each tote remains vacuum sealed prior to loading into the chamber:					
Time Last Cartridge Activated (a):	4:13pm	Total Transfer Time (c) **(a-b) Not to exceed 17 minutes:**	3 min		
Time/Date that cycle started (countdown completed/doors locked):	4:14pm 13Oct2020				
Operator Signature/Date:	Manuela Beltran 13Oct2020	**Checked By/Date:**	Elizabeth Roxales 13Oct2020		

Printed by/date: ER 13Oct2020 Lot: 040482-R5 Run #: 100A94

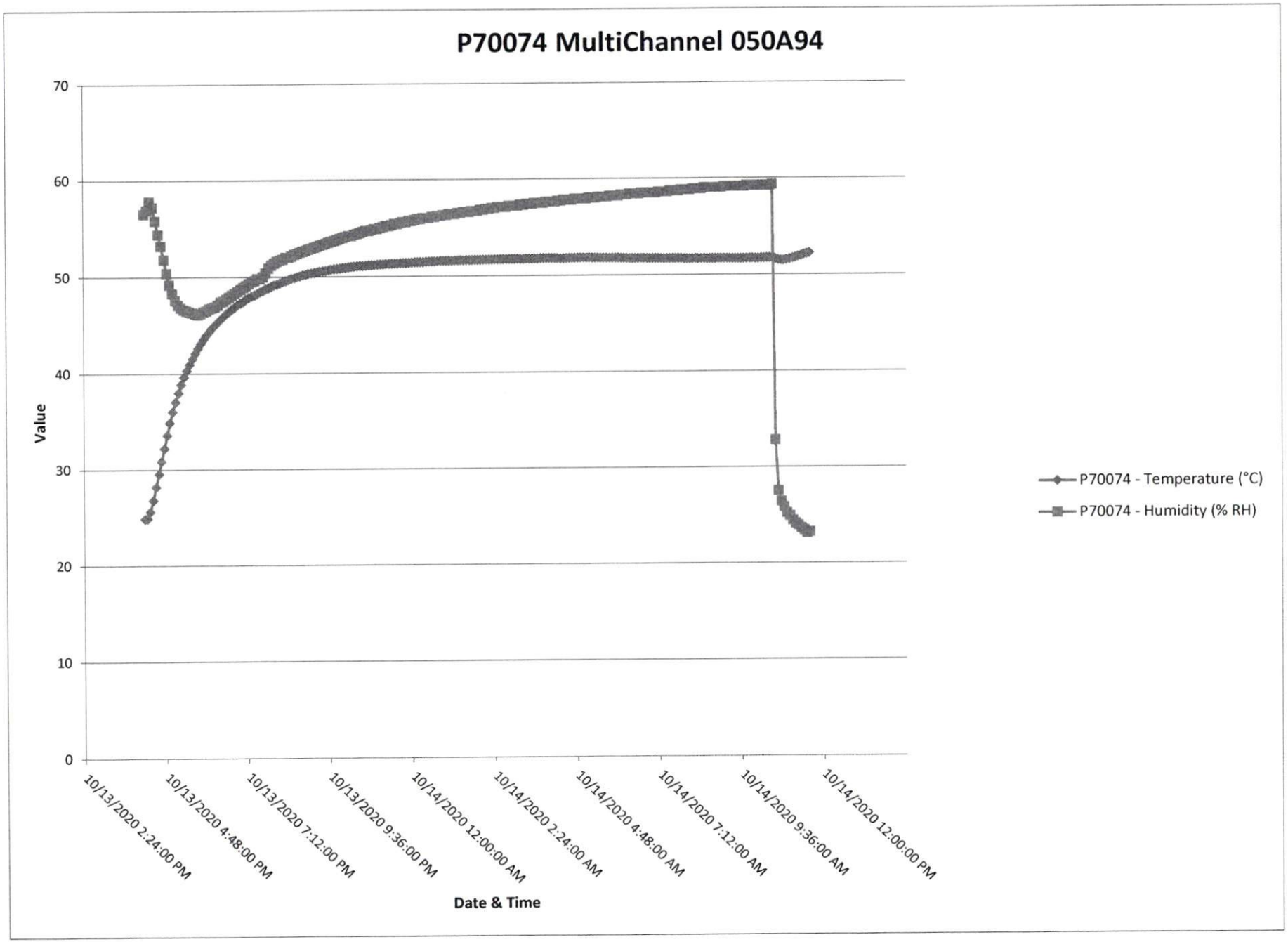
Operation 5 - Sterilization / Aeration					
Time sterilizer "UNLOAD" pressed (Minimum 16 hours from "Cycle Start"):	10:25am	**Sterilize end time (After countdown/doors unlocked):**	10:30am		
Aeration start time (after countdown completed/doors locked):	10:33am				
Aeration End Time (when countdown is completed/doors unlocked):	11:33am	**Date:**	14OCt2020		

Operation 5 - EO Data Logger Downloading					
Data Logger Offloaded as outlined in WI 09-014 – **Record Batch Number and Control Number on Printouts**					
Data Logger ID:	P70074	**Control Number:**	050A94		
Start Date/Time on Datalogger Printout:	13OCt2020 4:10pm	Sterilizer Temp (50ºC± 3°):	49.45	°C	
End Date/Time on Datalogger Printout:	14OCt 2020 11:35am	Avg. Relative Humidity Must Be ≥ 30% (for totes with product):	53.55	%	
Data Logger ID:	Q37941	**Control Number:**	090A94		
Start Date/Time on Datalogger Printout:	13OCt2020 4:10pm	Sterilizer Temp (50ºC± 3°):	49.96	°C	
End Date/Time on Datalogger Printout:	14OCt2020 11:35am	Avg. Relative Humidity Must Be ≥ 30%(for totes with product):	55.72	%	

BI Incubation					
BIs/Dosimeters submitted to QC (submit P.2 with TR if multiple lots:			**TR #:**	**BI:**	20-2856
Attach EO Chamber Printout 50ºC± 3°	**MIN:**	49.9 °C	**MAX:**	50.2 °C	**Attached:** ☑

Sterilization Consumable Lot Information							
EOGas lot number(s):	191956	**Exp. Date:**	09Jul2024	**Dosimeter lot number(s):**	204517	**Exp. Date:**	12 Feb2023
EOGas bag lot number(s):	EOKCM031090419	**Exp. Date:**	N/A ER13OCt2020	**Humidichip lot number(s):**	204610	**Exp. Date:**	19 Feb2023
***BI lot number(s) :**	G-214	**Exp. Date:**	13Jun2021	***If multiple lots used, 1 PC from each lot must be present**			
Scale/Balance ID:	00358051163			**CAL Due:**	OCt 2020		

Printed by/date: ER 13 Oct2020 Lot: 040482-R5 Run #: 100A94


P70074 MultiChannel 050A94
70
60
50
40
30
20
10
0
Value
10/13/2020 2:24:00 PM
10/13/2020 4:48:00 PM
10/13/2020 7:12:00 PM
10/13/2020 9:36:00 PM
10/14/2020 12:00:00 AM
10/14/2020 2:24:00 AM
10/14/2020 4:48:00 AM
10/14/2020 7:12:00 AM
10/14/2020 9:36:00 AM
10/14/2020 12:00:00 PM
Date & Time
P70074 - Temperature (°C)
P70074 - Humidity (% RH)

Device Name:		**RHTemp1000IS**	**RHTemp1000IS**
Device Description:		**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:		**P70074**	**P70074**
Device ID:	**050A94**	**MultiChannel**	**MultiChannel**

Date	Time	Channel 1 Temperature (°C)	Channel 2 Humidity (% RH)
10/13/2020	4:10:41 PM	24.85	56.5
10/13/2020	4:15:41 PM	24.88	56.9
10/13/2020	4:20:41 PM	25.59	57.8
10/13/2020	4:25:41 PM	26.81	57.2
10/13/2020	4:30:41 PM	28.17	55.8
10/13/2020	4:35:41 PM	29.54	54.4
10/13/2020	4:40:41 PM	30.87	53.2
10/13/2020	4:45:41 PM	32.19	51.8
10/13/2020	4:50:41 PM	33.57	50.4
10/13/2020	4:55:41 PM	34.85	49.2
10/13/2020	5:00:41 PM	36.01	48.3
10/13/2020	5:05:41 PM	37.04	47.6
10/13/2020	5:10:41 PM	37.98	47.1
10/13/2020	5:15:41 PM	38.84	46.8
10/13/2020	5:20:41 PM	39.6	46.6
10/13/2020	5:25:41 PM	40.3	46.5
10/13/2020	5:30:41 PM	40.94	46.4
10/13/2020	5:35:41 PM	41.53	46.3
10/13/2020	5:40:41 PM	42.09	46.2
10/13/2020	5:45:41 PM	42.61	46.1
10/13/2020	5:50:41 PM	43.09	46.2
10/13/2020	5:55:41 PM	43.54	46.4
10/13/2020	6:00:41 PM	43.95	46.5
10/13/2020	6:05:41 PM	44.33	46.7
10/13/2020	6:10:41 PM	44.68	46.8
10/13/2020	6:15:41 PM	45.02	46.9
10/13/2020	6:20:41 PM	45.34	47.1
10/13/2020	6:25:41 PM	45.64	47.4
10/13/2020	6:30:41 PM	45.92	47.5
10/13/2020	6:35:41 PM	46.18	47.7
10/13/2020	6:40:41 PM	46.41	47.9
10/13/2020	6:45:41 PM	46.66	48.1
10/13/2020	6:50:41 PM	46.87	48.3
10/13/2020	6:55:41 PM	47.08	48.5
10/13/2020	7:00:41 PM	47.29	48.7
10/13/2020	7:05:41 PM	47.47	48.9
10/13/2020	7:10:41 PM	47.65	49.1
10/13/2020	7:15:41 PM	47.82	49.3
10/13/2020	7:20:41 PM	47.98	49.5
10/13/2020	7:25:41 PM	48.13	49.6
10/13/2020	7:30:41 PM	48.28	49.8
10/13/2020	7:35:41 PM	48.43	49.8
10/13/2020	7:40:41 PM	48.58	50
10/13/2020	7:45:41 PM	48.73	50.4
10/13/2020	7:50:41 PM	48.86	50.9
10/13/2020	7:55:41 PM	48.99	51.2
10/13/2020	8:00:41 PM	49.13	51.4
10/13/2020	8:05:41 PM	49.24	51.6
10/13/2020	8:10:41 PM	49.37	51.7
10/13/2020	8:15:41 PM	49.49	51.8
10/13/2020	8:20:41 PM	49.59	52
10/13/2020	8:25:41 PM	49.7	52
10/13/2020	8:30:41 PM	49.8	52.1
10/13/2020	8:35:41 PM	49.89	52.3
10/13/2020	8:40:41 PM	49.98	52.4
10/13/2020	8:45:41 PM	50.07	52.5
10/13/2020	8:50:41 PM	50.15	52.6
10/13/2020	8:55:41 PM	50.23	52.7
10/13/2020	9:00:41 PM	50.31	52.8
10/13/2020	9:05:41 PM	50.35	52.9
10/13/2020	9:10:41 PM	50.42	53
10/13/2020	9:15:41 PM	50.47	53.1
10/13/2020	9:20:41 PM	50.53	53.2
10/13/2020	9:25:41 PM	50.58	53.3
10/13/2020	9:30:41 PM	50.63	53.4
10/13/2020	9:35:41 PM	50.68	53.5
10/13/2020	9:40:41 PM	50.72	53.6

10/13/2020	9:45:41 PM	50.77	53.7
10/13/2020	9:50:41 PM	50.81	53.8
10/13/2020	9:55:41 PM	50.85	53.9
10/13/2020	10:00:41 PM	50.89	54
10/13/2020	10:05:41 PM	50.92	54.1
10/13/2020	10:10:41 PM	50.95	54.2
10/13/2020	10:15:41 PM	50.99	54.2
10/13/2020	10:20:41 PM	51.02	54.3
10/13/2020	10:25:41 PM	51.05	54.4
10/13/2020	10:30:41 PM	51.07	54.5
10/13/2020	10:35:41 PM	51.1	54.6
10/13/2020	10:40:41 PM	51.13	54.7
10/13/2020	10:45:41 PM	51.15	54.7
10/13/2020	10:50:41 PM	51.16	54.8
10/13/2020	10:55:41 PM	51.19	54.9
10/13/2020	11:00:41 PM	51.21	54.9
10/13/2020	11:05:41 PM	51.23	55
10/13/2020	11:10:41 PM	51.26	55.1
10/13/2020	11:15:41 PM	51.28	55.2
10/13/2020	11:20:41 PM	51.29	55.2
10/13/2020	11:25:41 PM	51.31	55.3
10/13/2020	11:30:41 PM	51.33	55.4
10/13/2020	11:35:41 PM	51.33	55.4
10/13/2020	11:40:41 PM	51.35	55.5
10/13/2020	11:45:41 PM	51.36	55.6
10/13/2020	11:50:41 PM	51.38	55.6
10/13/2020	11:55:41 PM	51.41	55.7
10/14/2020	12:00:41 AM	51.41	55.7
10/14/2020	12:05:41 AM	51.42	55.8
10/14/2020	12:10:41 AM	51.43	55.9
10/14/2020	12:15:41 AM	51.45	55.9
10/14/2020	12:20:41 AM	51.46	56
10/14/2020	12:25:41 AM	51.47	56
10/14/2020	12:30:41 AM	51.49	56
10/14/2020	12:35:41 AM	51.5	56.1
10/14/2020	12:40:41 AM	51.53	56.1
10/14/2020	12:45:41 AM	51.53	56.2
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10/14/2020	1:00:41 AM	51.57	56.3
10/14/2020	1:05:41 AM	51.57	56.4
10/14/2020	1:10:41 AM	51.57	56.4
10/14/2020	1:15:41 AM	51.59	56.4
10/14/2020	1:20:41 AM	51.59	56.5
10/14/2020	1:25:41 AM	51.61	56.5
10/14/2020	1:30:41 AM	51.62	56.6
10/14/2020	1:35:41 AM	51.64	56.6
10/14/2020	1:40:41 AM	51.64	56.6
10/14/2020	1:45:41 AM	51.65	56.7
10/14/2020	1:50:41 AM	51.66	56.7
10/14/2020	1:55:41 AM	51.66	56.7
10/14/2020	2:00:41 AM	51.66	56.8
10/14/2020	2:05:41 AM	51.66	56.8
10/14/2020	2:10:41 AM	51.66	56.9
10/14/2020	2:15:41 AM	51.66	56.9
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10/14/2020	2:45:41 AM	51.71	57.1
10/14/2020	2:50:41 AM	51.72	57.2
10/14/2020	2:55:41 AM	51.72	57.2
10/14/2020	3:00:41 AM	51.72	57.2
10/14/2020	3:05:41 AM	51.73	57.2
10/14/2020	3:10:41 AM	51.72	57.3
10/14/2020	3:15:41 AM	51.72	57.3
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10/14/2020	3:25:41 AM	51.73	57.4
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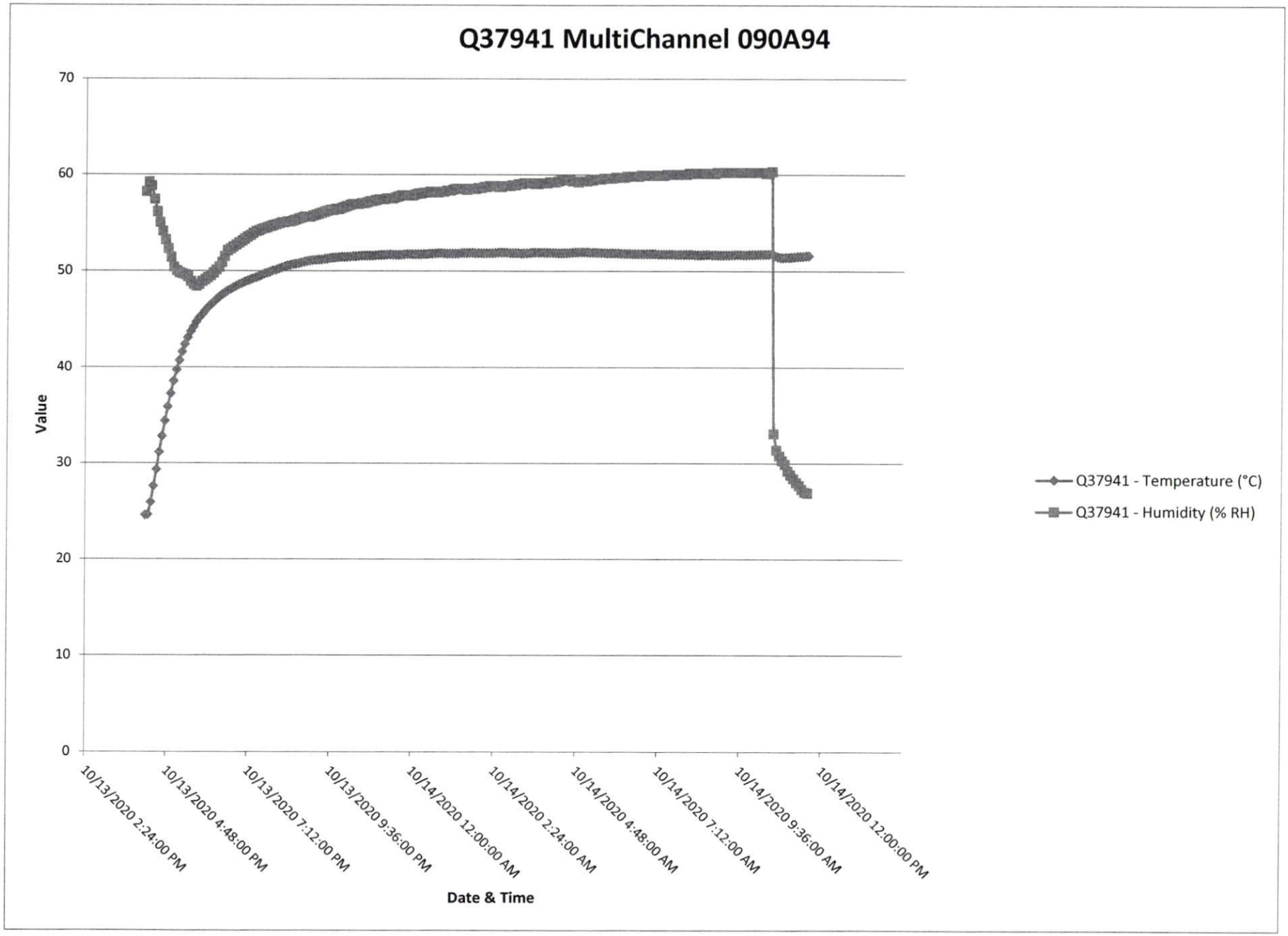
10/14/2020	3:50:41 AM	51.78	57.5

10/14/2020	3:55:41 AM	51.77	57.6
10/14/2020	4:00:41 AM	51.77	57.6
10/14/2020	4:05:41 AM	51.77	57.6
10/14/2020	4:10:41 AM	51.77	57.6
10/14/2020	4:15:41 AM	51.77	57.7
10/14/2020	4:20:41 AM	51.76	57.7
10/14/2020	4:25:41 AM	51.76	57.8
10/14/2020	4:30:41 AM	51.76	57.8
10/14/2020	4:35:41 AM	51.77	57.8
10/14/2020	4:40:41 AM	51.78	57.8
10/14/2020	4:45:41 AM	51.8	57.9
10/14/2020	4:50:41 AM	51.8	57.9
10/14/2020	4:55:41 AM	51.8	57.9
10/14/2020	5:00:41 AM	51.81	57.9
10/14/2020	5:05:41 AM	51.8	57.9
10/14/2020	5:10:41 AM	51.8	58
10/14/2020	5:15:41 AM	51.81	58
10/14/2020	5:20:41 AM	51.8	58
10/14/2020	5:25:41 AM	51.8	58.1
10/14/2020	5:30:41 AM	51.79	58.1
10/14/2020	5:35:41 AM	51.78	58.1
10/14/2020	5:40:41 AM	51.78	58.1
10/14/2020	5:45:41 AM	51.78	58.2
10/14/2020	5:50:41 AM	51.77	58.2
10/14/2020	5:55:41 AM	51.77	58.2
10/14/2020	6:00:41 AM	51.77	58.2
10/14/2020	6:05:41 AM	51.76	58.3
10/14/2020	6:10:41 AM	51.75	58.3
10/14/2020	6:15:41 AM	51.75	58.3
10/14/2020	6:20:41 AM	51.75	58.4
10/14/2020	6:25:41 AM	51.73	58.4
10/14/2020	6:30:41 AM	51.73	58.4
10/14/2020	6:35:41 AM	51.73	58.4
10/14/2020	6:40:41 AM	51.73	58.5
10/14/2020	6:45:41 AM	51.73	58.5
10/14/2020	6:50:41 AM	51.73	58.5
10/14/2020	6:55:41 AM	51.72	58.5
10/14/2020	7:00:41 AM	51.73	58.5
10/14/2020	7:05:41 AM	51.72	58.5

10/14/2020	7:10:41 AM	51.72	58.6
10/14/2020	7:15:41 AM	51.71	58.6
10/14/2020	7:20:41 AM	51.71	58.6
10/14/2020	7:25:41 AM	51.72	58.6
10/14/2020	7:30:41 AM	51.71	58.7
10/14/2020	7:35:41 AM	51.7	58.7
10/14/2020	7:40:41 AM	51.7	58.7
10/14/2020	7:45:41 AM	51.7	58.7
10/14/2020	7:50:41 AM	51.7	58.8
10/14/2020	7:55:41 AM	51.69	58.8
10/14/2020	8:00:41 AM	51.69	58.8
10/14/2020	8:05:41 AM	51.68	58.8
10/14/2020	8:10:41 AM	51.68	58.9
10/14/2020	8:15:41 AM	51.68	58.9
10/14/2020	8:20:41 AM	51.67	58.9
10/14/2020	8:25:41 AM	51.67	58.9
10/14/2020	8:30:41 AM	51.67	59
10/14/2020	8:35:41 AM	51.67	59
10/14/2020	8:40:41 AM	51.67	59
10/14/2020	8:45:41 AM	51.67	59
10/14/2020	8:50:41 AM	51.67	59
10/14/2020	8:55:41 AM	51.67	59
10/14/2020	9:00:41 AM	51.66	59
10/14/2020	9:05:41 AM	51.66	59.1
10/14/2020	9:10:41 AM	51.66	59.1
10/14/2020	9:15:41 AM	51.66	59.1
10/14/2020	9:20:41 AM	51.66	59.1
10/14/2020	9:25:41 AM	51.67	59.1
10/14/2020	9:30:41 AM	51.67	59.1
10/14/2020	9:35:41 AM	51.66	59.1
10/14/2020	9:40:41 AM	51.67	59.1
10/14/2020	9:45:41 AM	51.67	59.2
10/14/2020	9:50:41 AM	51.68	59.2
10/14/2020	9:55:41 AM	51.69	59.2
10/14/2020	10:00:41 AM	51.68	59.2
10/14/2020	10:05:41 AM	51.69	59.2
10/14/2020	10:10:41 AM	51.7	59.2
10/14/2020	10:15:41 AM	51.71	59.2
10/14/2020	10:20:41 AM	51.72	59.2
10/14/2020	10:25:41 AM	51.72	59.2
10/14/2020	10:30:41 AM	51.73	59.3
10/14/2020	10:35:41 AM	51.62	32.8
10/14/2020	10:40:41 AM	51.49	27.5
10/14/2020	10:45:41 AM	51.46	26.4
10/14/2020	10:50:41 AM	51.46	25.8
10/14/2020	10:55:41 AM	51.5	25.2
10/14/2020	11:00:41 AM	51.58	24.9
10/14/2020	11:05:41 AM	51.67	24.4
10/14/2020	11:10:41 AM	51.75	24.1
10/14/2020	11:15:41 AM	51.85	23.9
10/14/2020	11:20:41 AM	51.94	23.6
10/14/2020	11:25:41 AM	52.03	23.4
10/14/2020	11:30:41 AM	52.12	23.1
10/14/2020	11:35:41 AM	52.2	23.2
		49.44683761	53.5482906


Q37941 MultiChannel 090A94
70
60
50
40
30
20
10
0
Value
10/13/2020 2:24:00 PM
10/13/2020 4:48:00 PM
10/13/2020 7:12:00 PM
10/13/2020 9:36:00 PM
10/14/2020 12:00:00 AM
10/14/2020 2:24:00 AM
10/14/2020 4:48:00 AM
10/14/2020 7:12:00 AM
10/14/2020 9:36:00 AM
10/14/2020 12:00:00 PM
Date & Time
Q37941 - Temperature (°C)
Q37941 - Humidity (% RH)

Device Name:		**RHTemp1000IS**	**RHTemp1000IS**
Device Description:		**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:		**Q37941**	**Q37941**
Device ID:	**090A94**	**MultiChannel**	**MultiChannel**

Date	Time	Channel 1 Temperature (°C)	Channel 2 Humidity (% RH)
10/13/2020	4:10:40 PM	24.57	58.2
10/13/2020	4:15:40 PM	24.62	59.2
10/13/2020	4:20:40 PM	25.91	58.8
10/13/2020	4:25:40 PM	27.59	57.4
10/13/2020	4:30:40 PM	29.37	56.1
10/13/2020	4:35:40 PM	31.12	55
10/13/2020	4:40:40 PM	32.8	54.1
10/13/2020	4:45:40 PM	34.4	53.2
10/13/2020	4:50:40 PM	35.88	52.3
10/13/2020	4:55:40 PM	37.28	51.4
10/13/2020	5:00:40 PM	38.56	50.4
10/13/2020	5:05:40 PM	39.7	50
10/13/2020	5:10:40 PM	40.71	49.8
10/13/2020	5:15:40 PM	41.59	49.7
10/13/2020	5:20:40 PM	42.37	49.6
10/13/2020	5:25:40 PM	43.06	49.4
10/13/2020	5:30:40 PM	43.68	48.9
10/13/2020	5:35:40 PM	44.2	48.6
10/13/2020	5:40:40 PM	44.68	48.4
10/13/2020	5:45:40 PM	45.11	48.6
10/13/2020	5:50:40 PM	45.48	48.9
10/13/2020	5:55:40 PM	45.83	49.1
10/13/2020	6:00:40 PM	46.15	49.3
10/13/2020	6:05:40 PM	46.44	49.5
10/13/2020	6:10:40 PM	46.73	49.8
10/13/2020	6:15:40 PM	47.01	50.1
10/13/2020	6:20:40 PM	47.28	50.4
10/13/2020	6:25:40 PM	47.52	50.9
10/13/2020	6:30:40 PM	47.72	51.5
10/13/2020	6:35:40 PM	47.91	52.1
10/13/2020	6:40:40 PM	48.08	52.3
10/13/2020	6:45:40 PM	48.24	52.5
10/13/2020	6:50:40 PM	48.4	52.7
10/13/2020	6:55:40 PM	48.57	52.9
10/13/2020	7:00:40 PM	48.72	53.1
10/13/2020	7:05:40 PM	48.86	53.3
10/13/2020	7:10:40 PM	48.99	53.5
10/13/2020	7:15:40 PM	49.1	53.7
10/13/2020	7:20:40 PM	49.21	53.9
10/13/2020	7:25:40 PM	49.32	54.1
10/13/2020	7:30:40 PM	49.45	54.2
10/13/2020	7:35:40 PM	49.58	54.3
10/13/2020	7:40:40 PM	49.71	54.4
10/13/2020	7:45:40 PM	49.82	54.5
10/13/2020	7:50:40 PM	49.92	54.6
10/13/2020	7:55:40 PM	50.02	54.7
10/13/2020	8:00:40 PM	50.11	54.8
10/13/2020	8:05:40 PM	50.22	54.9
10/13/2020	8:10:40 PM	50.33	55
10/13/2020	8:15:40 PM	50.44	55
10/13/2020	8:20:40 PM	50.53	55.1
10/13/2020	8:25:40 PM	50.6	55.1
10/13/2020	8:30:40 PM	50.67	55.2
10/13/2020	8:35:40 PM	50.73	55.3
10/13/2020	8:40:40 PM	50.8	55.4
10/13/2020	8:45:40 PM	50.87	55.5
10/13/2020	8:50:40 PM	50.95	55.6
10/13/2020	8:55:40 PM	51.01	55.6
10/13/2020	9:00:40 PM	51.06	55.6
10/13/2020	9:05:40 PM	51.1	55.7
10/13/2020	9:10:40 PM	51.13	55.8
10/13/2020	9:15:40 PM	51.16	55.9
10/13/2020	9:20:40 PM	51.18	56
10/13/2020	9:25:40 PM	51.21	56.1
10/13/2020	9:30:40 PM	51.26	56.2
10/13/2020	9:35:40 PM	51.31	56.3
10/13/2020	9:40:40 PM	51.35	56.3

10/13/2020	9:45:40 PM	51.38	56.4
10/13/2020	9:50:40 PM	51.4	56.4
10/13/2020	9:55:40 PM	51.42	56.5
10/13/2020	10:00:40 PM	51.43	56.6
10/13/2020	10:05:40 PM	51.44	56.7
10/13/2020	10:10:40 PM	51.46	56.8
10/13/2020	10:15:40 PM	51.5	56.9
10/13/2020	10:20:40 PM	51.53	56.9
10/13/2020	10:25:40 PM	51.55	56.9
10/13/2020	10:30:40 PM	51.56	57
10/13/2020	10:35:40 PM	51.57	57
10/13/2020	10:40:40 PM	51.57	57.1
10/13/2020	10:45:40 PM	51.57	57.2
10/13/2020	10:50:40 PM	51.58	57.2
10/13/2020	10:55:40 PM	51.59	57.3
10/13/2020	11:00:40 PM	51.62	57.4
10/13/2020	11:05:40 PM	51.65	57.4
10/13/2020	11:10:40 PM	51.66	57.4
10/13/2020	11:15:40 PM	51.67	57.5
10/13/2020	11:20:40 PM	51.68	57.5
10/13/2020	11:25:40 PM	51.67	57.5
10/13/2020	11:30:40 PM	51.67	57.6
10/13/2020	11:35:40 PM	51.67	57.7
10/13/2020	11:40:40 PM	51.69	57.8
10/13/2020	11:45:40 PM	51.71	57.8
10/13/2020	11:50:40 PM	51.73	57.8
10/13/2020	11:55:40 PM	51.74	57.8
10/14/2020	12:00:40 AM	51.74	57.8
10/14/2020	12:05:40 AM	51.73	57.9
10/14/2020	12:10:40 AM	51.73	58
10/14/2020	12:15:40 AM	51.73	58
10/14/2020	12:20:40 AM	51.73	58.1
10/14/2020	12:25:40 AM	51.74	58.1
10/14/2020	12:30:40 AM	51.76	58.2
10/14/2020	12:35:40 AM	51.79	58.2
10/14/2020	12:40:40 AM	51.81	58.1
10/14/2020	12:45:40 AM	51.82	58.1
10/14/2020	12:50:40 AM	51.82	58.2
10/14/2020	12:55:40 AM	51.81	58.2
10/14/2020	1:00:40 AM	51.81	58.3
10/14/2020	1:05:40 AM	51.8	58.3
10/14/2020	1:10:40 AM	51.79	58.4
10/14/2020	1:15:40 AM	51.8	58.5
10/14/2020	1:20:40 AM	51.81	58.5
10/14/2020	1:25:40 AM	51.84	58.5
10/14/2020	1:30:40 AM	51.87	58.5
10/14/2020	1:35:40 AM	51.88	58.4
10/14/2020	1:40:40 AM	51.88	58.5
10/14/2020	1:45:40 AM	51.87	58.5
10/14/2020	1:50:40 AM	51.86	58.5
10/14/2020	1:55:40 AM	51.85	58.6
10/14/2020	2:00:40 AM	51.84	58.6
10/14/2020	2:05:40 AM	51.82	58.7
10/14/2020	2:10:40 AM	51.82	58.7
10/14/2020	2:15:40 AM	51.82	58.8
10/14/2020	2:20:40 AM	51.85	58.8
10/14/2020	2:25:40 AM	51.87	58.8
10/14/2020	2:30:40 AM	51.89	58.7
10/14/2020	2:35:40 AM	51.9	58.7
10/14/2020	2:40:40 AM	51.89	58.8
10/14/2020	2:45:40 AM	51.89	58.8
10/14/2020	2:50:40 AM	51.88	58.8
10/14/2020	2:55:40 AM	51.87	58.9
10/14/2020	3:00:40 AM	51.86	58.9
10/14/2020	3:05:40 AM	51.84	59
10/14/2020	3:10:40 AM	51.83	59
10/14/2020	3:15:40 AM	51.84	59.1
10/14/2020	3:20:40 AM	51.85	59.1
10/14/2020	3:25:40 AM	51.88	59.1
10/14/2020	3:30:40 AM	51.9	59.1
10/14/2020	3:35:40 AM	51.92	59
10/14/2020	3:40:40 AM	51.93	59
10/14/2020	3:45:40 AM	51.92	59.1
10/14/2020	3:50:40 AM	51.91	59.1

10/14/2020	3:55:40 AM	51.9	59.1
10/14/2020	4:00:40 AM	51.89	59.2
10/14/2020	4:05:40 AM	51.88	59.2
10/14/2020	4:10:40 AM	51.87	59.2
10/14/2020	4:15:40 AM	51.86	59.3
10/14/2020	4:20:40 AM	51.85	59.4
10/14/2020	4:25:40 AM	51.86	59.4
10/14/2020	4:30:40 AM	51.87	59.4
10/14/2020	4:35:40 AM	51.9	59.4
10/14/2020	4:40:40 AM	51.93	59.3
10/14/2020	4:45:40 AM	51.95	59.3
10/14/2020	4:50:40 AM	51.96	59.2
10/14/2020	4:55:40 AM	51.96	59.3
10/14/2020	5:00:40 AM	51.95	59.3
10/14/2020	5:05:40 AM	51.94	59.3
10/14/2020	5:10:40 AM	51.92	59.4
10/14/2020	5:15:40 AM	51.91	59.4
10/14/2020	5:20:40 AM	51.9	59.5
10/14/2020	5:25:40 AM	51.89	59.5
10/14/2020	5:30:40 AM	51.88	59.5
10/14/2020	5:35:40 AM	51.87	59.6
10/14/2020	5:40:40 AM	51.86	59.6
10/14/2020	5:45:40 AM	51.85	59.6
10/14/2020	5:50:40 AM	51.84	59.6
10/14/2020	5:55:40 AM	51.83	59.7
10/14/2020	6:00:40 AM	51.83	59.7
10/14/2020	6:05:40 AM	51.82	59.7
10/14/2020	6:10:40 AM	51.82	59.7
10/14/2020	6:15:40 AM	51.81	59.8
10/14/2020	6:20:40 AM	51.8	59.8
10/14/2020	6:25:40 AM	51.79	59.8
10/14/2020	6:30:40 AM	51.78	59.8
10/14/2020	6:35:40 AM	51.78	59.8
10/14/2020	6:40:40 AM	51.78	59.9
10/14/2020	6:45:40 AM	51.78	59.9
10/14/2020	6:50:40 AM	51.78	59.9
10/14/2020	6:55:40 AM	51.78	59.9
10/14/2020	7:00:40 AM	51.77	59.9
10/14/2020	7:05:40 AM	51.77	59.9

10/14/2020	7:10:40 AM	51.76	59.9
10/14/2020	7:15:40 AM	51.75	59.9
10/14/2020	7:20:40 AM	51.75	59.9
10/14/2020	7:25:40 AM	51.74	60
10/14/2020	7:30:40 AM	51.73	60
10/14/2020	7:35:40 AM	51.73	60
10/14/2020	7:40:40 AM	51.72	60
10/14/2020	7:45:40 AM	51.72	60
10/14/2020	7:50:40 AM	51.71	60
10/14/2020	7:55:40 AM	51.71	60
10/14/2020	8:00:40 AM	51.7	60
10/14/2020	8:05:40 AM	51.7	60.1
10/14/2020	8:10:40 AM	51.7	60.1
10/14/2020	8:15:40 AM	51.69	60.1
10/14/2020	8:20:40 AM	51.69	60.1
10/14/2020	8:25:40 AM	51.69	60.1
10/14/2020	8:30:40 AM	51.68	60.1
10/14/2020	8:35:40 AM	51.68	60.1
10/14/2020	8:40:40 AM	51.68	60.1
10/14/2020	8:45:40 AM	51.67	60.1
10/14/2020	8:50:40 AM	51.67	60.1
10/14/2020	8:55:40 AM	51.67	60.2
10/14/2020	9:00:40 AM	51.67	60.2
10/14/2020	9:05:40 AM	51.67	60.2
10/14/2020	9:10:40 AM	51.67	60.2
10/14/2020	9:15:40 AM	51.67	60.2
10/14/2020	9:20:40 AM	51.67	60.2
10/14/2020	9:25:40 AM	51.68	60.2
10/14/2020	9:30:40 AM	51.68	60.2
10/14/2020	9:35:40 AM	51.69	60.2
10/14/2020	9:40:40 AM	51.69	60.2
10/14/2020	9:45:40 AM	51.69	60.2
10/14/2020	9:50:40 AM	51.7	60.2
10/14/2020	9:55:40 AM	51.71	60.2
10/14/2020	10:00:40 AM	51.72	60.2
10/14/2020	10:05:40 AM	51.72	60.2
10/14/2020	10:10:40 AM	51.73	60.2
10/14/2020	10:15:40 AM	51.74	60.2
10/14/2020	10:20:40 AM	51.74	60.1
10/14/2020	10:25:40 AM	51.74	60.1
10/14/2020	10:30:40 AM	51.75	60.3
10/14/2020	10:35:40 AM	51.6	33.1
10/14/2020	10:40:40 AM	51.47	31.4
10/14/2020	10:45:40 AM	51.41	30.8
10/14/2020	10:50:40 AM	51.39	30.3
10/14/2020	10:55:40 AM	51.4	29.9
10/14/2020	11:00:40 AM	51.41	29.2
10/14/2020	11:05:40 AM	51.44	28.8
10/14/2020	11:10:40 AM	51.47	28.4
10/14/2020	11:15:40 AM	51.49	28
10/14/2020	11:20:40 AM	51.52	27.7
10/14/2020	11:25:40 AM	51.54	27.3
10/14/2020	11:30:40 AM	51.56	27
10/14/2020	11:35:40 AM	51.6	26.9
		49.95666667	55.72008547

	Gas Pre-Weight (g)	Gas Post-Weight (g)	Net Weight Release (g)
Tote #1	88.38	77.73	10.65
Tote #2	88.24	77.75	10.49
Tote #3	88.41	7794	10.47
Tote #4	88.36	77.83	10.53
Tote #5	88.20	77.78	10.42
Tote #6	88.25	77.82	10.43
Tote #7	88.15	77.67	10.48
Tote #8	88.26	77.76	10.50
Tote #9	88.26	77.79	10.47
Tote #10	88.33	77.81	10.52

All EO Gas Post Weights Pass (9.98g-12.00g) ☑ Yes ☐ *No (*If "No" notify Supervisor)

Operator/Date: Manuela Beltran 14Oct2020

Checked By/Date: Ben Kilmer 16 OCT 2020

Attach Pre and Post Weights Below:

Pre A

001:N + 88.380 g
002:N + 88.246 g
003:N + 88.413 g
004:N + 88.360 g
005:N + 88.208 g
006:N + 88.250 g
007:N + 88.155 g
008:N + 88.263 g
009:N + 88.261 g
010:N + 88.338 g

Pre A

001:N + 77.730 g
002:N + 77.754 g
003:N + 77.942 g
004:N + 77.835 g
005:N + 77.783 g
006:N + 77.821 g
007:N + 77.672 g
008:N + 77.760 g
009:N + 77.790 g
010:N + 77.819 g

Dosimeter Check		
1		(P) F
2		(P) F
3		(P) F
4		(P) F
5		(P) F
6		(P) F
7		(P) F
8		(P) F
9		(P) F
10		(P) F

Printed by/date: ER 13Oct2020 Lot: 040482-R5 Run #: 100A94

LOT: 040482-R5/039482-R3/0085-F2 60 cm Reg **RUN #** 360E21

Operation	Description	Date Verified
4a	Operation 1 – Staging and Preconditioning - Minimum 12 hours	AA 21 Oct 2020
	Operation 2– EO Gas Consumable Preparation	AA 21 Oct 2020
4b	Operation 3 – Tote Preperation and Bag Sealing	AA 21 Oct 2020
	Operation 4 – Transfer and Load Time	AA 21 Oct 2020
4c	Operation 5 – Sterilization/Aeration	AA 21 Oct 2020
	Operation 6- Dosimeter Check	AA 21 Oct 2020
PRODUCTION REVIEW COMPLETED BY/DATE:	Ramesh Bhandari 21 Oct 2020	

Acceptance Criteria and Final Release			
The sterilization tote contains appropriate qty of devices between the minimum and maximum specification.	☑ Yes ☐ No	The environment within the EO sterilization bag is ≥30%	☑ Yes ☐ No
The average preconditioning environment is ≥12hours at ≥68°F and ≥30%RH.	☑ Yes ☐ No	Devices are aerated within the sterilizer set to 50°C for ≥4 hours.	☑ Yes ☐ No
Temperature Range is between 33° C to 55° C measured from the dataloggers in the totes.	☑ Yes ☐ No	All Dosimeters (for all bags) pass the calibration triangle.	☑ Yes ☐ No
The minimum sterilization time requirement is ≥ 19 Hours to a maximum sterilization time of ≤ 38 hours and 10 minutes.	☑ Yes ☐ No	The BIs are negative (remain orange).	☑ Yes ☐ No
Two (2) Humdichips were placed into every sterilization bag.	☑ Yes ☐ No	The positive control turns positive (turbid and yellow).	☑ Yes ☐ No
The sterilizer cabinet temperature is set to 50ºC	☑ Yes ☐ No	The incubation time/temperature for the BIs is 7 days at 35-39°C.	☑ Yes ☐ No
EO gas release is ≥22g but ≤45g	☑ Yes ☐ No		
Comments:	☑ N/A		
QA Release:	22 Oct 2020		

Verify that totes are arranged as outlined in WI-MED-0063

Operation 1 - Staging for EO Sterilization

Small Blister Maximum Quantity Is 1,500 Blisters Per Tote
Exofin® Fusion Max Is 56 Pouches In Each Tote
The Minimum Quantity for Both Fusion and Small Blisters are 4 blisters In Each Tote

Lot#: 040482-R5		Tote #: 1-5		Qty: 6,375	
Lot#: 039482-R3	N/A ☐	Tote #: 6-9	N/A ☐	Qty: 5,098	N/A ☐
Lot#: 0085-F2	N/A ☐	Tote #: 10-18	N/A ☐	Qty: 482	N/A ☐
Lot#: Dunnage	N/A ☑	Tote #: 19-27	N/A ☑	Qty: 27,000	N/A ☑*
Lot#:	N/A ☑	Tote #:	N/A ☑	Qty:	N/A ☑

Operation 1 - Preconditioning *(Minimum 12 hours) and Data Logger Setup

Preconditioning Room N/A ☐ **Preconditioning Chamber N/A** ☑

EO Room Data Logger		Data Logger ID	R17771	Calibration Due Date	DEC 2020
Tote #	~~010E21~~ *	Data Logger ID	~~R17757~~ *	Calibration Due Date	~~DEC 2020~~ *
Tote #	110E21 *	Data Logger ID	~~R17768~~ *	Calibration Due Date	~~DEC 2020~~ *

Precondition in Preconditioning Room

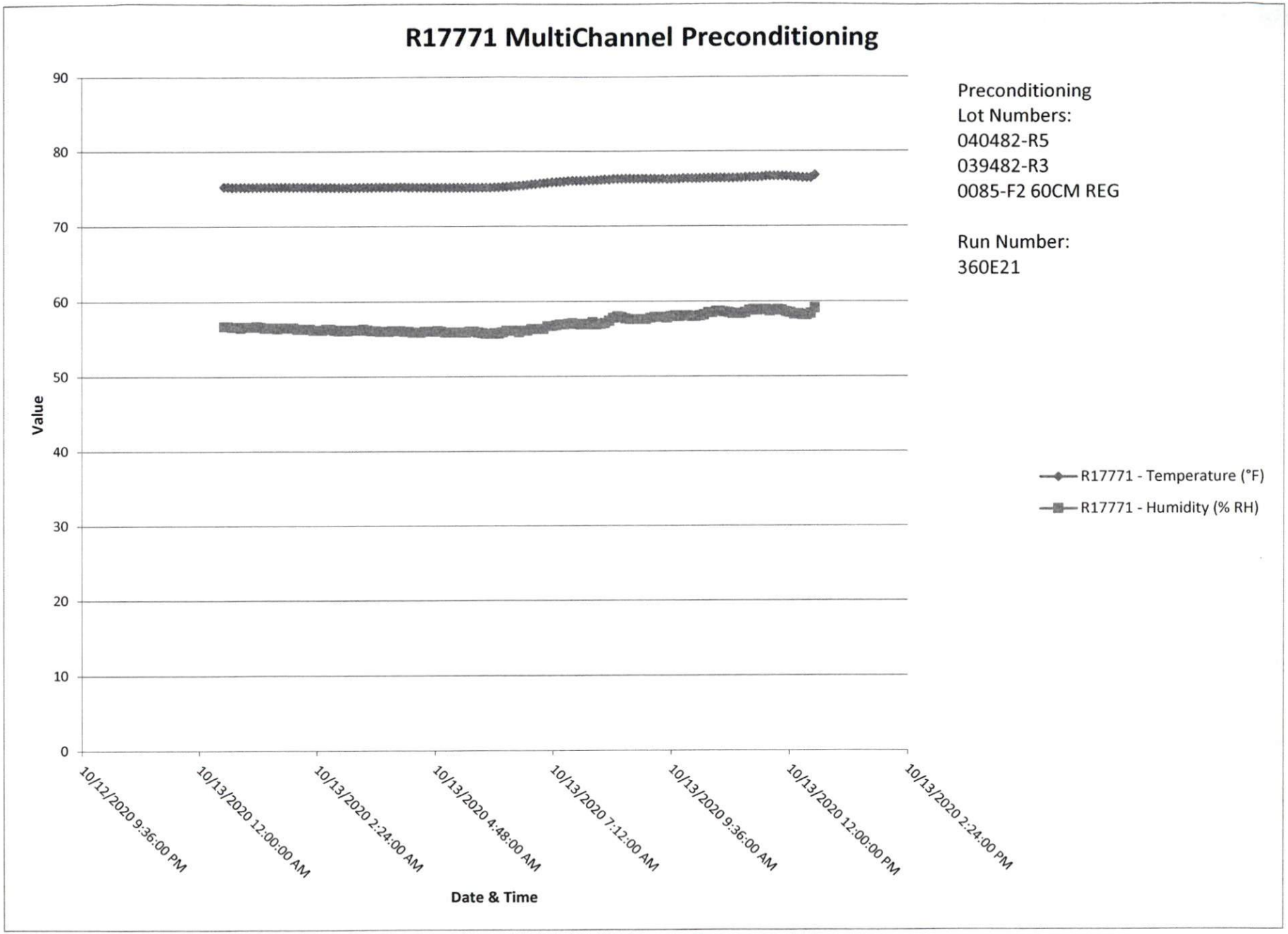
Start Time	12:30am N/A ☐	Start Date	13OCT2020 N/A ☐	End Time	12:30pm N/A ☐	End Date	13OCT2020 N/A ☐
Avg. Temperature (≥68°F)	N/A ☐ 75.73 °F	Avg. Relative Humidity (≥ 30%)	N/A ☐	56.~~70~~ 99 ER 13OCT2020 %			

If preconditioning is performed in the chamber then prepare all totes with consumables and have QA check operation 2 and 3.

Operator Signature/Date	Elizabeth Rosales 13OCT2020	**Checked By/Date**	Manuela Beltran 13OCT2020
QA Signature/Date	Yahra McLemore 13OCT 2020	☑ Pass ☐ Fail*	

* EE: ER 13OCT2020

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60CM Reg Run #: 360E21


R17771 MultiChannel Preconditioning
90
80
70
60
50
40
30
20
10
0
Value
10/12/2020 9:36:00 PM
10/13/2020 12:00:00 AM
10/13/2020 2:24:00 AM
10/13/2020 4:48:00 AM
10/13/2020 7:12:00 AM
10/13/2020 9:36:00 AM
10/13/2020 12:00:00 PM
10/13/2020 2:24:00 PM
Date & Time
Preconditioning
Lot Numbers:
040482-R5
039482-R3
0085-F2 60CM REG
Run Number:
360E21
R17771 - Temperature (°F)
R17771 - Humidity (% RH)

Device Name:		**RHTemp1000IS**	**RHTemp1000IS**
Device Description:		**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:		**R17771**	**R17771**
Device ID:	**R17771**	**MultiChannel**	**MultiChannel**

Preconditioning
Lot Numbers:
040482-R5
039482-R3
0085-F2 60CM REG
Run Number:
360E 21

Date	Time	Channel 1 Temperature (°F)	Channel 2 Humidity (% RH)
10/13/2020	12:30:49 AM	75.258	56.7
10/13/2020	12:35:49 AM	75.258	56.7
10/13/2020	12:40:49 AM	75.24	56.6
10/13/2020	12:45:49 AM	75.24	56.6
10/13/2020	12:50:49 AM	75.24	56.5
10/13/2020	12:55:49 AM	75.24	56.6
10/13/2020	1:00:49 AM	75.24	56.6
10/13/2020	1:05:49 AM	75.24	56.6
10/13/2020	1:10:49 AM	75.24	56.7
10/13/2020	1:15:49 AM	75.24	56.6
10/13/2020	1:20:49 AM	75.24	56.5
10/13/2020	1:25:49 AM	75.222	56.5
10/13/2020	1:30:49 AM	75.24	56.5
10/13/2020	1:35:49 AM	75.222	56.4
10/13/2020	1:40:49 AM	75.222	56.5
10/13/2020	1:45:49 AM	75.222	56.5
10/13/2020	1:50:49 AM	75.24	56.5
10/13/2020	1:55:49 AM	75.222	56.5
10/13/2020	2:00:49 AM	75.222	56.3
10/13/2020	2:05:49 AM	75.204	56.3
10/13/2020	2:10:49 AM	75.204	56.3
10/13/2020	2:15:49 AM	75.204	56.3
10/13/2020	2:20:49 AM	75.204	56.2
10/13/2020	2:25:49 AM	75.204	56.2
10/13/2020	2:30:49 AM	75.204	56.2
10/13/2020	2:35:49 AM	75.204	56.3
10/13/2020	2:40:49 AM	75.204	56.3
10/13/2020	2:45:49 AM	75.186	56.2
10/13/2020	2:50:49 AM	75.186	56.1
10/13/2020	2:55:49 AM	75.186	56.2
10/13/2020	3:00:49 AM	75.186	56.1
10/13/2020	3:05:49 AM	75.186	56.2
10/13/2020	3:10:49 AM	75.186	56.2
10/13/2020	3:15:49 AM	75.186	56.2
10/13/2020	3:20:49 AM	75.204	56.3
10/13/2020	3:25:49 AM	75.204	56.2
10/13/2020	3:30:49 AM	75.186	56.1
10/13/2020	3:35:49 AM	75.186	56.1
10/13/2020	3:40:49 AM	75.186	56
10/13/2020	3:45:49 AM	75.186	56
10/13/2020	3:50:49 AM	75.186	56
10/13/2020	3:55:49 AM	75.168	56.1
10/13/2020	4:00:49 AM	75.186	56.1
10/13/2020	4:05:49 AM	75.186	56.1
10/13/2020	4:10:49 AM	75.186	56
10/13/2020	4:15:49 AM	75.168	56
10/13/2020	4:20:49 AM	75.168	55.9
10/13/2020	4:25:49 AM	75.168	55.9
10/13/2020	4:30:49 AM	75.168	55.9
10/13/2020	4:35:49 AM	75.168	56
10/13/2020	4:40:49 AM	75.168	56
10/13/2020	4:45:49 AM	75.168	56
10/13/2020	4:50:49 AM	75.168	56.1
10/13/2020	4:55:49 AM	75.168	56
10/13/2020	5:00:49 AM	75.168	55.9
10/13/2020	5:05:49 AM	75.15	55.9
10/13/2020	5:10:49 AM	75.15	55.9

10/13/2020	5:15:49 AM	75.168	55.9
10/13/2020	5:20:49 AM	75.15	55.9
10/13/2020	5:25:49 AM	75.15	55.9
10/13/2020	5:30:49 AM	75.168	56
10/13/2020	5:35:49 AM	75.168	56
10/13/2020	5:40:49 AM	75.15	55.9
10/13/2020	5:45:49 AM	75.15	55.8
10/13/2020	5:50:49 AM	75.15	55.7
10/13/2020	5:55:49 AM	75.132	55.7
10/13/2020	6:00:49 AM	75.15	55.8
10/13/2020	6:05:49 AM	75.168	55.7
10/13/2020	6:10:49 AM	75.222	55.9
10/13/2020	6:15:49 AM	75.276	56.1
10/13/2020	6:20:49 AM	75.312	56.1
10/13/2020	6:25:49 AM	75.348	56.1
10/13/2020	6:30:49 AM	75.384	55.9
10/13/2020	6:35:49 AM	75.456	56.1
10/13/2020	6:40:49 AM	75.51	56.1
10/13/2020	6:45:49 AM	75.564	56.3
10/13/2020	6:50:49 AM	75.618	56.3
10/13/2020	6:55:49 AM	75.672	56.3
10/13/2020	7:00:49 AM	75.708	56.3
10/13/2020	7:05:49 AM	75.78	56.7
10/13/2020	7:10:49 AM	75.834	56.7
10/13/2020	7:15:49 AM	75.87	56.8
10/13/2020	7:20:49 AM	75.906	56.9
10/13/2020	7:25:49 AM	75.96	56.9
10/13/2020	7:30:49 AM	75.996	57
10/13/2020	7:35:49 AM	76.032	57.1
10/13/2020	7:40:49 AM	76.05	57
10/13/2020	7:45:49 AM	76.086	56.9
10/13/2020	7:50:49 AM	76.104	57
10/13/2020	7:55:49 AM	76.122	56.9
10/13/2020	8:00:49 AM	76.122	57.2
10/13/2020	8:05:49 AM	76.14	56.9
10/13/2020	8:10:49 AM	76.158	57
10/13/2020	8:15:49 AM	76.212	57.1
10/13/2020	8:20:49 AM	76.23	57.4
10/13/2020	8:25:49 AM	76.284	57.8
10/13/2020	8:30:49 AM	76.302	58
10/13/2020	8:35:49 AM	76.302	57.9
10/13/2020	8:40:49 AM	76.302	57.7
10/13/2020	8:45:49 AM	76.302	57.6
10/13/2020	8:50:49 AM	76.284	57.6
10/13/2020	8:55:49 AM	76.284	57.6
10/13/2020	9:00:49 AM	76.284	57.6
10/13/2020	9:05:49 AM	76.284	57.6
10/13/2020	9:10:49 AM	76.266	57.8
10/13/2020	9:15:49 AM	76.266	57.9
10/13/2020	9:20:49 AM	76.248	57.9
10/13/2020	9:25:49 AM	76.266	57.9
10/13/2020	9:30:49 AM	76.266	57.8
10/13/2020	9:35:49 AM	76.284	58
10/13/2020	9:40:49 AM	76.302	58.1
10/13/2020	9:45:49 AM	76.32	58
10/13/2020	9:50:49 AM	76.338	58.1
10/13/2020	9:55:49 AM	76.338	58.1
10/13/2020	10:00:49 AM	76.338	58
10/13/2020	10:05:49 AM	76.338	58
10/13/2020	10:10:49 AM	76.338	58.1
10/13/2020	10:15:49 AM	76.374	58.2
10/13/2020	10:20:49 AM	76.356	58.5
10/13/2020	10:25:49 AM	76.392	58.5
10/13/2020	10:30:49 AM	76.392	58.7
10/13/2020	10:35:49 AM	76.41	58.7
10/13/2020	10:40:49 AM	76.41	58.6
10/13/2020	10:45:49 AM	76.41	58.5
10/13/2020	10:50:49 AM	76.41	58.4
10/13/2020	10:55:49 AM	76.428	58.4
10/13/2020	11:00:49 AM	76.428	58.4
10/13/2020	11:05:49 AM	76.464	58.5
10/13/2020	11:10:49 AM	76.518	58.8
10/13/2020	11:15:49 AM	76.536	58.9
10/13/2020	11:20:49 AM	76.536	58.8
10/13/2020	11:25:49 AM	76.59	58.9
10/13/2020	11:30:49 AM	76.626	58.9
10/13/2020	11:35:49 AM	76.644	58.7
10/13/2020	11:40:49 AM	76.626	58.8
10/13/2020	11:45:49 AM	76.644	58.9
10/13/2020	11:50:49 AM	76.644	58.8
10/13/2020	11:55:49 AM	76.626	58.6
10/13/2020	12:00:49 PM	76.572	58.5
10/13/2020	12:05:49 PM	76.518	58.3
10/13/2020	12:10:49 PM	76.482	58.3
10/13/2020	12:15:49 PM	76.464	58.2
10/13/2020	12:20:49 PM	76.446	58.2
10/13/2020	12:25:49 PM	76.428	58.4
10/13/2020	12:30:49 PM	76.824	59.1
		75.72811034	56.98689655

Operation 2 - Data Logger Setup for Sterilization

Preconditioning Room N/A ☐ **Preconditioning Chamber N/A** ☒

Location #	010E21	Data Logger ID	R17757	Calibration Due Date	Dec 2020	Programmed Start Date/Time (include Quickstart)	13 Oct 2020 12:~~30~~ 29 pm EE: ER 13 Oct 20
Location #	170E21	Data Logger ID	R17768	Calibration Due Date	Dec 2020	Programmed Start Date/Time (include Quickstart)	13 Oct 2020 12:29 pm

Operation 2 – EO Gas Consumable Preparation

EO Gas Canister Pre-Weight Information	☒ Yes ☐ No	Box labels are printed and match each tote:	☒ Yes ☐ No
EO Bag Information Recorded	☒ Yes ☐ No	PCDs are placed in the center of the load:	☒ Yes ☐ No
EO Gas Canister Labeled and mounted to tote (s) with product	☒ Yes ☐ No	Positive Control is the same Lot number as PCDs in totes	☒ Yes ☐ No
EZ Test BIs not damaged, Labeled, inside PCD	☒ Yes ☐ No	Dosimeter is labeled and placed in the center of the load	☒ Yes ☐ No
Humidichips (2) placed inside Humiditube inside the tote	☒ Yes ☐ No	Equipment Logbooks filled out	☒ Yes ☐ No
2 Data loggers placed into the front of the tote (hottest and coolest locations)	☒ Yes ☐ No		
Operator Signature/date:	Elizabeth Rosales 13 Oct 2020	**Checked By/date:**	Amanda Beltran 13 Oct 2020

Sterilization Consumable Lot Information

EO Gas lot number(s)	10072	**Exp. Date**	31 Jan 2023	**Dosimeter lot number(s)**	204517	**Exp. Date**	12 Feb 2023
EOG bag lot number(s)	N/A ER 13 Oct 2020	**Exp. Date**	ER N/A 13 Oct 2020	**Humidichip lot number(s)**	204610	**Exp. Date**	19 Feb 2023
***BI lot number(s)**	G-214	**Exp. Date**	13 Jun 2021	***If multiple lots used, 1 PC from each lot must be present**			
Scale/Balance ID:	0035805163			**CAL Due:**	Oct 2020		

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60CM Reg Run #: 360E21

Operation 3 - Tote Preparation and Bag Sealing			
EO Bag Sealer Asset ID	I-28434	EO Bag Sealer Calibration Due Date	OCt 2020

QA Line Clearance – Proceed to bag sealing once QA gives approval	
All steps in Operation 2 are complete and all consumables are loaded into each tote	
QA Signature/Date:	Yahra Melendez 13 OCT 2020

Operation 4 - Transfer & Load Time

Preconditioning in Chamber N/A ☒ n/a MB 14Oct2020

Chamber Temperature is Set at 30°C	☐ Yes ☐ No			Printer Paper/Ink Checked	☑ Yes ☐ No
Start Time		Start Date		Operator Signature/Date	
				Checked By/Date	
End Time		End Date		Operator Signature/Date	
				Checked By/Date	

Sterilization In Chamber

Time left "white room" area (b)	2:48pm N/A ☐	Sterilizer EOE Temp set to 50°C	☑ Yes ☐ No	Printer Paper/Ink Checked:	☑ Yes ☐ No

Activate all EO Cartridges

Time Last Cartridge Activated (a):	2:53pm	Total Transfer Time (a-b) should be ≤ 17 minutes:	8 (5) min
Time/Date that cycle started (doors Shut):	2:54pm 13Oct2020	Operator Signature/Date	Manuela Beltran 13Oct2020
		Checked By/Date	Elizabeth Rosales 20Oct2020 for 13Oct2020

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60CM Reg Run #: 360E21

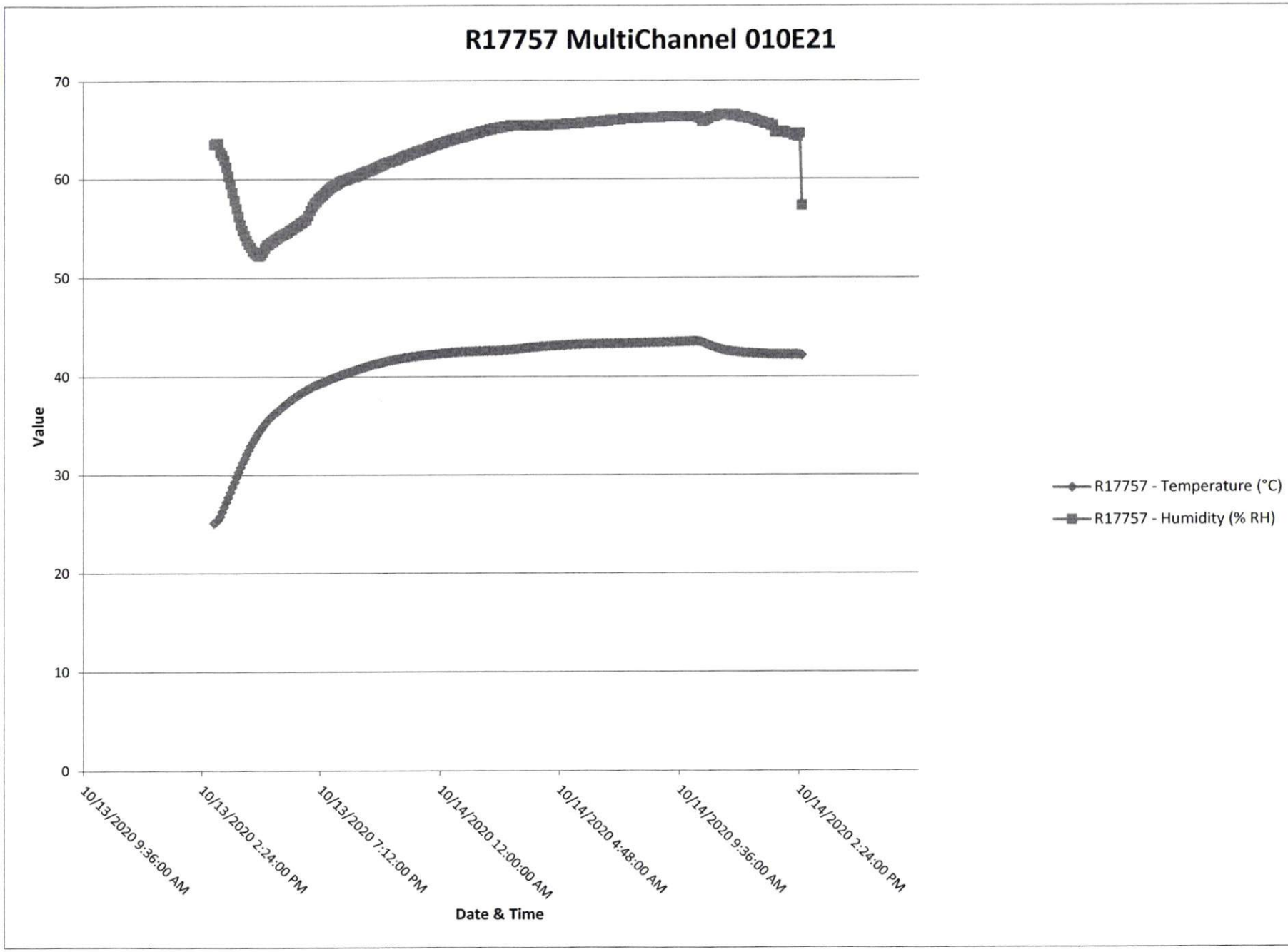
Operation 5 - Sterilization / Aeration			
Time sterilizer "UNLOAD" pressed (Minimum 19 hours from "Cycle Start"):	10:19 am	**Sterilize end time (After countdown/doors unlocked):**	10:25am
Minimum Areation time is ≥ 4 hours			
Aeration start time (after countdown completed/doors locked)	10:27am		
Aeration End Time (when countdown is completed/doors unlocked)	2:27 pm		
Operator Signature/Date	Marisela Beltran 14OCT2020	Checked By/Date	14 OCT 2020

Operation 6 - EO Data Logger Downloading							
Data Logger Offloaded as outlined in WI-MED-0018 – Record Lot Number and location # (Control Number) on Printouts **Include the start date and time on data logger printout.** **Include the end time on the data logger printout.** **Average Relative Humidity Must Be > 30% (for totes with product)**							
Location #	010E21	**Data Logger ID**	R17757	Start Date/Time	13OCT2020 2:54 pm	Avg. Relative Humidity	[2]* ~~40.93~~ 62.92 %
				End Date/Time	14OCT2020 2:29 pm	Sterilizer Temp	[2]* ~~to~~ 40.93 °C
Location #	170E21	**Data Logger ID**	R17768	Start Date/Time	13OCT2020 2:54 pm	Avg. Relative Humidity	55.78 %
				End Date/Time	14OCT2020 2:29 pm	Sterilizer Temp	50.95 °C

BI Incubation							
Bis submitted to QC	☒ Yes ☐ No			**TR #**	20-2859	**BI Lot #**	G-214
Attach EO Chamber Printout (Preconditioning)	**MIN**	n/a ER15OCT2020 °C		**MAX**	n/a ER15OCT2020 °C	**Printout Attached**	☐ Yes ☒ No
Attach EO Chamber Printout (Sterilization)	**MIN**	*~~50~~ 45 °C		**MAX**	50 °C	**Printout Attached**	☒ Yes ☐ No

*EE: ER15OCT2020
[2]*EE: ER16OCT2020

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60 CM Reg Run #: 360E21


R17757 MultiChannel 010E21
70
60
50
40
30
20
10
0
Value
10/13/2020 9:36:00 AM
10/13/2020 2:24:00 PM
10/13/2020 7:12:00 PM
10/14/2020 12:00:00 AM
10/14/2020 4:48:00 AM
10/14/2020 9:36:00 AM
10/14/2020 2:24:00 PM
Date & Time
R17757 - Temperature (°C)
R17757 - Humidity (% RH)

Device Name:		**RHTemp1000IS**	**RHTemp1000IS**
Device Description:		**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:		**R17757**	**R17757**
Device ID:	**010E21**	**MultiChannel**	**MultiChannel**

Date	Time	Channel 1 Temperature (°C)	Channel 2 Humidity (% RH)
10/13/2020	2:54:44 PM	25.08	63.5
10/13/2020	2:59:44 PM	25.22	63.6
10/13/2020	3:04:44 PM	25.46	63.6
10/13/2020	3:09:44 PM	25.78	62.7
10/13/2020	3:14:44 PM	26.22	62.4
10/13/2020	3:19:44 PM	26.71	61.9
10/13/2020	3:24:44 PM	27.2	61.2
10/13/2020	3:29:44 PM	27.72	60.3
10/13/2020	3:34:44 PM	28.24	59.5
10/13/2020	3:39:44 PM	28.76	58.6
10/13/2020	3:44:44 PM	29.27	57.8
10/13/2020	3:49:44 PM	29.78	57
10/13/2020	3:54:44 PM	30.28	56.2
10/13/2020	3:59:44 PM	30.77	55.4
10/13/2020	4:04:44 PM	31.24	54.8
10/13/2020	4:09:44 PM	31.7	54.3
10/13/2020	4:14:44 PM	32.14	53.8
10/13/2020	4:19:44 PM	32.56	53.4
10/13/2020	4:24:44 PM	32.96	53.1
10/13/2020	4:29:44 PM	33.33	52.7
10/13/2020	4:34:44 PM	33.69	52.5
10/13/2020	4:39:44 PM	34.03	52.3
10/13/2020	4:44:44 PM	34.35	52.2
10/13/2020	4:49:44 PM	34.66	52.3
10/13/2020	4:54:44 PM	34.95	52.6
10/13/2020	4:59:44 PM	35.22	53
10/13/2020	5:04:44 PM	35.46	53.3
10/13/2020	5:09:44 PM	35.68	53.4
10/13/2020	5:14:44 PM	35.89	53.6
10/13/2020	5:19:44 PM	36.09	53.7
10/13/2020	5:24:44 PM	36.29	53.9
10/13/2020	5:29:44 PM	36.48	54
10/13/2020	5:34:44 PM	36.66	54.2
10/13/2020	5:39:44 PM	36.84	54.3
10/13/2020	5:44:44 PM	37.02	54.4
10/13/2020	5:49:44 PM	37.19	54.5
10/13/2020	5:54:44 PM	37.36	54.6
10/13/2020	5:59:44 PM	37.53	54.8
10/13/2020	6:04:44 PM	37.69	54.9
10/13/2020	6:09:44 PM	37.84	55.1
10/13/2020	6:14:44 PM	37.99	55.2
10/13/2020	6:19:44 PM	38.13	55.3
10/13/2020	6:24:44 PM	38.27	55.5
10/13/2020	6:29:44 PM	38.39	55.6
10/13/2020	6:34:44 PM	38.52	55.8
10/13/2020	6:39:44 PM	38.64	55.9
10/13/2020	6:44:44 PM	38.77	56.3
10/13/2020	6:49:44 PM	38.87	56.8
10/13/2020	6:54:44 PM	38.98	57.2
10/13/2020	6:59:44 PM	39.07	57.5
10/13/2020	7:04:44 PM	39.17	57.7
10/13/2020	7:09:44 PM	39.26	58
10/13/2020	7:14:44 PM	39.36	58.2
10/13/2020	7:19:44 PM	39.45	58.4
10/13/2020	7:24:44 PM	39.53	58.6
10/13/2020	7:29:44 PM	39.62	58.8
10/13/2020	7:34:44 PM	39.71	59
10/13/2020	7:39:44 PM	39.79	59.2
10/13/2020	7:44:44 PM	39.87	59.3
10/13/2020	7:49:44 PM	39.96	59.4
10/13/2020	7:54:44 PM	40.04	59.5
10/13/2020	7:59:44 PM	40.12	59.7
10/13/2020	8:04:44 PM	40.2	59.8
10/13/2020	8:09:44 PM	40.28	59.9
10/13/2020	8:14:44 PM	40.36	59.9
10/13/2020	8:19:44 PM	40.43	60
10/13/2020	8:24:44 PM	40.51	60.1

10/13/2020	8:29:44 PM	40.58	60.2
10/13/2020	8:34:44 PM	40.65	60.2
10/13/2020	8:39:44 PM	40.72	60.3
10/13/2020	8:44:44 PM	40.79	60.4
10/13/2020	8:49:44 PM	40.86	60.5
10/13/2020	8:54:44 PM	40.92	60.6
10/13/2020	8:59:44 PM	40.99	60.7
10/13/2020	9:04:44 PM	41.05	60.8
10/13/2020	9:09:44 PM	41.11	60.8
10/13/2020	9:14:44 PM	41.18	60.9
10/13/2020	9:19:44 PM	41.23	61
10/13/2020	9:24:44 PM	41.28	61.1
10/13/2020	9:29:44 PM	41.34	61.2
10/13/2020	9:34:44 PM	41.39	61.3
10/13/2020	9:39:44 PM	41.44	61.4
10/13/2020	9:44:44 PM	41.49	61.5
10/13/2020	9:49:44 PM	41.54	61.6
10/13/2020	9:54:44 PM	41.59	61.7
10/13/2020	9:59:44 PM	41.63	61.7
10/13/2020	10:04:44 PM	41.68	61.8
10/13/2020	10:09:44 PM	41.72	61.9
10/13/2020	10:14:44 PM	41.76	61.9
10/13/2020	10:19:44 PM	41.8	62
10/13/2020	10:24:44 PM	41.84	62.1
10/13/2020	10:29:44 PM	41.87	62.2
10/13/2020	10:34:44 PM	41.91	62.3
10/13/2020	10:39:44 PM	41.94	62.4
10/13/2020	10:44:44 PM	41.97	62.4
10/13/2020	10:49:44 PM	42	62.5
10/13/2020	10:54:44 PM	42.03	62.6
10/13/2020	10:59:44 PM	42.06	62.7
10/13/2020	11:04:44 PM	42.09	62.8
10/13/2020	11:09:44 PM	42.11	62.8
10/13/2020	11:14:44 PM	42.14	62.9
10/13/2020	11:19:44 PM	42.16	63
10/13/2020	11:24:44 PM	42.18	63
10/13/2020	11:29:44 PM	42.21	63.1
10/13/2020	11:34:44 PM	42.23	63.2
10/13/2020	11:39:44 PM	42.25	63.3
10/13/2020	11:44:44 PM	42.27	63.4
10/13/2020	11:49:44 PM	42.29	63.4
10/13/2020	11:54:44 PM	42.31	63.5
10/13/2020	11:59:44 PM	42.33	63.6
10/14/2020	12:04:44 AM	42.35	63.6
10/14/2020	12:09:44 AM	42.37	63.7
10/14/2020	12:14:44 AM	42.39	63.8
10/14/2020	12:19:44 AM	42.41	63.8
10/14/2020	12:24:44 AM	42.42	63.9
10/14/2020	12:29:44 AM	42.44	64
10/14/2020	12:34:44 AM	42.45	64
10/14/2020	12:39:44 AM	42.47	64.1
10/14/2020	12:44:44 AM	42.48	64.1
10/14/2020	12:49:44 AM	42.49	64.2
10/14/2020	12:54:44 AM	42.51	64.2
10/14/2020	12:59:44 AM	42.51	64.3
10/14/2020	1:04:44 AM	42.52	64.4
10/14/2020	1:09:44 AM	42.54	64.4
10/14/2020	1:14:44 AM	42.54	64.5
10/14/2020	1:19:44 AM	42.55	64.5
10/14/2020	1:24:44 AM	42.56	64.6
10/14/2020	1:29:44 AM	42.56	64.6
10/14/2020	1:34:44 AM	42.57	64.7
10/14/2020	1:39:44 AM	42.57	64.8
10/14/2020	1:44:44 AM	42.58	64.8
10/14/2020	1:49:44 AM	42.59	64.9
10/14/2020	1:54:44 AM	42.59	64.9
10/14/2020	1:59:44 AM	42.6	65
10/14/2020	2:04:44 AM	42.6	65
10/14/2020	2:09:44 AM	42.61	65.1
10/14/2020	2:14:44 AM	42.62	65.1
10/14/2020	2:19:44 AM	42.63	65.1
10/14/2020	2:24:44 AM	42.64	65.2
10/14/2020	2:29:44 AM	42.65	65.2
10/14/2020	2:34:44 AM	42.67	65.3

10/14/2020	2:39:44 AM	42.69	65.3
10/14/2020	2:44:44 AM	42.7	65.3
10/14/2020	2:49:44 AM	42.72	65.4
10/14/2020	2:54:44 AM	42.74	65.4
10/14/2020	2:59:44 AM	42.76	65.4
10/14/2020	3:04:44 AM	42.78	65.4
10/14/2020	3:09:44 AM	42.8	65.4
10/14/2020	3:14:44 AM	42.82	65.4
10/14/2020	3:19:44 AM	42.85	65.4
10/14/2020	3:24:44 AM	42.87	65.4
10/14/2020	3:29:44 AM	42.88	65.4
10/14/2020	3:34:44 AM	42.91	65.4
10/14/2020	3:39:44 AM	42.93	65.4
10/14/2020	3:44:44 AM	42.95	65.4
10/14/2020	3:49:44 AM	42.97	65.4
10/14/2020	3:54:44 AM	42.99	65.4
10/14/2020	3:59:44 AM	43.01	65.4
10/14/2020	4:04:44 AM	43.03	65.4
10/14/2020	4:09:44 AM	43.05	65.4
10/14/2020	4:14:44 AM	43.06	65.4
10/14/2020	4:19:44 AM	43.08	65.4
10/14/2020	4:24:44 AM	43.09	65.5
10/14/2020	4:29:44 AM	43.11	65.5
10/14/2020	4:34:44 AM	43.12	65.5
10/14/2020	4:39:44 AM	43.13	65.5
10/14/2020	4:44:44 AM	43.14	65.5
10/14/2020	4:49:44 AM	43.15	65.5
10/14/2020	4:54:44 AM	43.17	65.5
10/14/2020	4:59:44 AM	43.18	65.5
10/14/2020	5:04:44 AM	43.2	65.6
10/14/2020	5:09:44 AM	43.22	65.6
10/14/2020	5:14:44 AM	43.22	65.6
10/14/2020	5:19:44 AM	43.24	65.6
10/14/2020	5:24:44 AM	43.25	65.6
10/14/2020	5:29:44 AM	43.26	65.6
10/14/2020	5:34:44 AM	43.26	65.6
10/14/2020	5:39:44 AM	43.27	65.7
10/14/2020	5:44:44 AM	43.28	65.7
10/14/2020	5:49:44 AM	43.29	65.7
10/14/2020	5:54:44 AM	43.3	65.7
10/14/2020	5:59:44 AM	43.3	65.7
10/14/2020	6:04:44 AM	43.3	65.8
10/14/2020	6:09:44 AM	43.31	65.8
10/14/2020	6:14:44 AM	43.31	65.8
10/14/2020	6:19:44 AM	43.32	65.8
10/14/2020	6:24:44 AM	43.32	65.8
10/14/2020	6:29:44 AM	43.33	65.8
10/14/2020	6:34:44 AM	43.33	65.9
10/14/2020	6:39:44 AM	43.34	65.9
10/14/2020	6:44:44 AM	43.34	65.9
10/14/2020	6:49:44 AM	43.34	66
10/14/2020	6:54:44 AM	43.34	66
10/14/2020	6:59:44 AM	43.34	66
10/14/2020	7:04:44 AM	43.35	66
10/14/2020	7:09:44 AM	43.35	66
10/14/2020	7:14:44 AM	43.35	66
10/14/2020	7:19:44 AM	43.35	66.1
10/14/2020	7:24:44 AM	43.36	66.1
10/14/2020	7:29:44 AM	43.37	66.1
10/14/2020	7:34:44 AM	43.37	66.1
10/14/2020	7:39:44 AM	43.38	66.1
10/14/2020	7:44:44 AM	43.38	66.1
10/14/2020	7:49:44 AM	43.39	66.1
10/14/2020	7:54:44 AM	43.4	66.1
10/14/2020	7:59:44 AM	43.4	66.2
10/14/2020	8:04:44 AM	43.41	66.2
10/14/2020	8:09:44 AM	43.42	66.2
10/14/2020	8:14:44 AM	43.42	66.2
10/14/2020	8:19:44 AM	43.42	66.2
10/14/2020	8:24:44 AM	43.43	66.2
10/14/2020	8:29:44 AM	43.44	66.2
10/14/2020	8:34:44 AM	43.44	66.2
10/14/2020	8:39:44 AM	43.45	66.2
10/14/2020	8:44:44 AM	43.45	66.2

10/14/2020	8:49:44 AM	43.46	66.2
10/14/2020	8:54:44 AM	43.46	66.3
10/14/2020	8:59:44 AM	43.47	66.3
10/14/2020	9:04:44 AM	43.47	66.3
10/14/2020	9:09:44 AM	43.48	66.3
10/14/2020	9:14:44 AM	43.49	66.3
10/14/2020	9:19:44 AM	43.49	66.3
10/14/2020	9:24:44 AM	43.5	66.3
10/14/2020	9:29:44 AM	43.51	66.3
10/14/2020	9:34:44 AM	43.51	66.3
10/14/2020	9:39:44 AM	43.52	66.3
10/14/2020	9:44:44 AM	43.52	66.3

10/14/2020	9:49:44 AM	43.54	66.3
10/14/2020	9:54:44 AM	43.54	66.3
10/14/2020	9:59:44 AM	43.55	66.3
10/14/2020	10:04:44 AM	43.56	66.3
10/14/2020	10:09:44 AM	43.57	66.3
10/14/2020	10:14:44 AM	43.57	66.3
10/14/2020	10:19:44 AM	43.57	66.2
10/14/2020	10:24:44 AM	43.55	66.1
10/14/2020	10:29:44 AM	43.48	65.8
10/14/2020	10:34:44 AM	43.4	65.9
10/14/2020	10:39:44 AM	43.31	66
10/14/2020	10:44:44 AM	43.21	66.1
10/14/2020	10:49:44 AM	43.11	66.3
10/14/2020	10:54:44 AM	43.02	66.3
10/14/2020	10:59:44 AM	42.94	66.3
10/14/2020	11:04:44 AM	42.88	66.4
10/14/2020	11:09:44 AM	42.81	66.5
10/14/2020	11:14:44 AM	42.75	66.5
10/14/2020	11:19:44 AM	42.7	66.5
10/14/2020	11:24:44 AM	42.66	66.5
10/14/2020	11:29:44 AM	42.62	66.5
10/14/2020	11:34:44 AM	42.58	66.5
10/14/2020	11:39:44 AM	42.55	66.4
10/14/2020	11:44:44 AM	42.52	66.4
10/14/2020	11:49:44 AM	42.5	66.5
10/14/2020	11:54:44 AM	42.47	66.4
10/14/2020	11:59:44 AM	42.45	66.3
10/14/2020	12:04:44 PM	42.43	66.2
10/14/2020	12:09:44 PM	42.41	66.3
10/14/2020	12:14:44 PM	42.39	66.2
10/14/2020	12:19:44 PM	42.38	66.1
10/14/2020	12:24:44 PM	42.37	66.1
10/14/2020	12:29:44 PM	42.35	66.1
10/14/2020	12:34:44 PM	42.34	66
10/14/2020	12:39:44 PM	42.33	65.9
10/14/2020	12:44:44 PM	42.32	65.8
10/14/2020	12:49:44 PM	42.3	65.8
10/14/2020	12:54:44 PM	42.29	65.7
10/14/2020	12:59:44 PM	42.29	65.6
10/14/2020	1:04:44 PM	42.27	65.6
10/14/2020	1:09:44 PM	42.26	65.6
10/14/2020	1:14:44 PM	42.25	65.4
10/14/2020	1:19:44 PM	42.26	65.4
10/14/2020	1:24:44 PM	42.24	64.7
10/14/2020	1:29:44 PM	42.24	64.7
10/14/2020	1:34:44 PM	42.25	64.8
10/14/2020	1:39:44 PM	42.24	64.8
10/14/2020	1:44:44 PM	42.23	64.8
10/14/2020	1:49:44 PM	42.22	64.7
10/14/2020	1:54:44 PM	42.23	64.6
10/14/2020	1:59:44 PM	42.23	64.6
10/14/2020	2:04:44 PM	42.22	64.6
10/14/2020	2:09:44 PM	42.22	64.4
10/14/2020	2:14:44 PM	42.23	64.4
10/14/2020	2:19:44 PM	42.22	64.3
10/14/2020	2:24:44 PM	42.22	64.6
10/14/2020	2:29:44 PM	42.15	57.3
		40.92510563	62.92077465


R17768 MultiChannel 170E21
70
60
50
40
30
20
10
0
Value
10/13/2020 9:36:00 AM
10/13/2020 2:24:00 PM
10/13/2020 7:12:00 PM
10/14/2020 12:00:00 AM
10/14/2020 4:48:00 AM
10/14/2020 9:36:00 AM
10/14/2020 2:24:00 PM
Date & Time
R17768 - Temperature (°C)
R17768 - Humidity (% RH)

Device Name:	**RHTemp1000IS**	**RHTemp1000IS**
Device Description:	**Intrinsically Safe Temperature and Humidity Data Logger**	**Intrinsically Safe Temperature and Humidity Data Logger**
Serial Number:	**R17768**	**R17768**
Device ID:	**MultiChannel**	**MultiChannel**

Date	Time	Channel 1 Temperature (°C)	Channel 2 Humidity (% RH)
10/13/2020	2:54:43 PM	24.87	63.2
10/13/2020	2:59:43 PM	25.35	64.7
10/13/2020	3:04:43 PM	26.23	64.3
10/13/2020	3:09:43 PM	27.41	61.3
10/13/2020	3:14:43 PM	28.79	59.1
10/13/2020	3:19:43 PM	30.31	57.2
10/13/2020	3:24:43 PM	31.88	55.3
10/13/2020	3:29:43 PM	33.43	53.7
10/13/2020	3:34:43 PM	34.93	52.3
10/13/2020	3:39:43 PM	36.37	51.2
10/13/2020	3:44:43 PM	37.73	50.2
10/13/2020	3:49:43 PM	39.03	49.3
10/13/2020	3:54:43 PM	40.24	48.5
10/13/2020	3:59:43 PM	41.37	47.9
10/13/2020	4:04:43 PM	42.42	47.4
10/13/2020	4:09:43 PM	43.37	46.9
10/13/2020	4:14:43 PM	44.26	46.7
10/13/2020	4:19:43 PM	45.07	46.4
10/13/2020	4:24:43 PM	45.8	46.3
10/13/2020	4:29:43 PM	46.47	46.2
10/13/2020	4:34:43 PM	47.07	46.2
10/13/2020	4:39:43 PM	47.6	46.3
10/13/2020	4:44:43 PM	48.09	46.4
10/13/2020	4:49:43 PM	48.52	46.6
10/13/2020	4:54:43 PM	48.9	46.9
10/13/2020	4:59:43 PM	49.25	47.1
10/13/2020	5:04:43 PM	49.56	47.4
10/13/2020	5:09:43 PM	49.84	47.8
10/13/2020	5:14:43 PM	50.1	48.2
10/13/2020	5:19:43 PM	50.33	48.6
10/13/2020	5:24:43 PM	50.53	49
10/13/2020	5:29:43 PM	50.71	49.4
10/13/2020	5:34:43 PM	50.87	49.9
10/13/2020	5:39:43 PM	51.02	50.4
10/13/2020	5:44:43 PM	51.15	51
10/13/2020	5:49:43 PM	51.28	51.9
10/13/2020	5:54:43 PM	51.4	52.8
10/13/2020	5:59:43 PM	51.51	53.6
10/13/2020	6:04:43 PM	51.61	54.3
10/13/2020	6:09:43 PM	51.69	54.9
10/13/2020	6:14:43 PM	51.77	55.4
10/13/2020	6:19:43 PM	51.84	55.9
10/13/2020	6:24:43 PM	51.9	56.2
10/13/2020	6:29:43 PM	51.96	56.6
10/13/2020	6:34:43 PM	52.01	56.9
10/13/2020	6:39:43 PM	52.06	57.2
10/13/2020	6:44:43 PM	52.1	57.6
10/13/2020	6:49:43 PM	52.13	57.9
10/13/2020	6:54:43 PM	52.16	58.2
10/13/2020	6:59:43 PM	52.19	58.4
10/13/2020	7:04:43 PM	52.21	58.5
10/13/2020	7:09:43 PM	52.24	58.7
10/13/2020	7:14:43 PM	52.27	58.9
10/13/2020	7:19:43 PM	52.28	59.1
10/13/2020	7:24:43 PM	52.3	59.3
10/13/2020	7:29:43 PM	52.32	59.5
10/13/2020	7:34:43 PM	52.33	59.6
10/13/2020	7:39:43 PM	52.34	59.8
10/13/2020	7:44:43 PM	52.36	59.9
10/13/2020	7:49:43 PM	52.37	60.2
10/13/2020	7:54:43 PM	52.38	60.3
10/13/2020	7:59:43 PM	52.38	60.5
10/13/2020	8:04:43 PM	52.39	60.6

10/13/2020	8:09:43 PM	52.39	60.7
10/13/2020	8:14:43 PM	52.4	60.9
10/13/2020	8:19:43 PM	52.4	61
10/13/2020	8:24:43 PM	52.4	61.1
10/13/2020	8:29:43 PM	52.4	61.2
10/13/2020	8:34:43 PM	52.4	61.4
10/13/2020	8:39:43 PM	52.4	61.6
10/13/2020	8:44:43 PM	52.4	61.8
10/13/2020	8:49:43 PM	52.39	61.9
10/13/2020	8:54:43 PM	52.39	61.9
10/13/2020	8:59:43 PM	52.39	62
10/13/2020	9:04:43 PM	52.39	62
10/13/2020	9:09:43 PM	52.39	62.1
10/13/2020	9:14:43 PM	52.4	62.1
10/13/2020	9:19:43 PM	52.39	62.2
10/13/2020	9:24:43 PM	52.39	62.3
10/13/2020	9:29:43 PM	52.38	62.5
10/13/2020	9:34:43 PM	52.37	62.6
10/13/2020	9:39:43 PM	52.37	62.6
10/13/2020	9:44:43 PM	52.37	62.7
10/13/2020	9:49:43 PM	52.37	62.8
10/13/2020	9:54:43 PM	52.36	62.8
10/13/2020	9:59:43 PM	52.36	62.8
10/13/2020	10:04:43 PM	52.36	62.9
10/13/2020	10:09:43 PM	52.36	62.9
10/13/2020	10:14:43 PM	52.35	62.9
10/13/2020	10:19:43 PM	52.34	62.9
10/13/2020	10:24:43 PM	52.34	63
10/13/2020	10:29:43 PM	52.34	63
10/13/2020	10:34:43 PM	52.33	63
10/13/2020	10:39:43 PM	52.33	63.1
10/13/2020	10:44:43 PM	52.33	63.1
10/13/2020	10:49:43 PM	52.32	63.2
10/13/2020	10:54:43 PM	52.32	63.2
10/13/2020	10:59:43 PM	52.31	63.3
10/13/2020	11:04:43 PM	52.3	63.3
10/13/2020	11:09:43 PM	52.3	63.4
10/13/2020	11:14:43 PM	52.3	63.4
10/13/2020	11:19:43 PM	52.29	63.4
10/13/2020	11:24:43 PM	52.29	63.4
10/13/2020	11:29:43 PM	52.28	63.4
10/13/2020	11:34:43 PM	52.28	63.5
10/13/2020	11:39:43 PM	52.27	63.5
10/13/2020	11:44:43 PM	52.27	63.5
10/13/2020	11:49:43 PM	52.26	63.5
10/13/2020	11:54:43 PM	52.26	63.5
10/13/2020	11:59:43 PM	52.26	63.5
10/14/2020	12:04:43 AM	52.26	63.5
10/14/2020	12:09:43 AM	52.26	63.5
10/14/2020	12:14:43 AM	52.25	63.5
10/14/2020	12:19:43 AM	52.24	63.5
10/14/2020	12:24:43 AM	52.24	63.5
10/14/2020	12:29:43 AM	52.23	63.5
10/14/2020	12:34:43 AM	52.23	63.6
10/14/2020	12:39:43 AM	52.22	63.6
10/14/2020	12:44:43 AM	52.22	63.5
10/14/2020	12:49:43 AM	52.22	63.6
10/14/2020	12:54:43 AM	52.22	63.6
10/14/2020	12:59:43 AM	52.22	63.6
10/14/2020	1:04:43 AM	52.22	63.6
10/14/2020	1:09:43 AM	52.21	63.6
10/14/2020	1:14:43 AM	52.21	63.7
10/14/2020	1:19:43 AM	52.2	63.7
10/14/2020	1:24:43 AM	52.2	63.7
10/14/2020	1:29:43 AM	52.19	63.7
10/14/2020	1:34:43 AM	52.19	63.7
10/14/2020	1:39:43 AM	52.19	63.7
10/14/2020	1:44:43 AM	52.19	63.7
10/14/2020	1:49:43 AM	52.19	63.7
10/14/2020	1:54:43 AM	52.18	63.7

10/14/2020	1:59:43 AM	52.19	63.7
10/14/2020	2:04:43 AM	52.18	63.7
10/14/2020	2:09:43 AM	52.17	63.7
10/14/2020	2:14:43 AM	52.17	63.7
10/14/2020	2:19:43 AM	52.17	63.7
10/14/2020	2:24:43 AM	52.17	63.6
10/14/2020	2:29:43 AM	52.17	63.6
10/14/2020	2:34:43 AM	52.17	63.6
10/14/2020	2:39:43 AM	52.17	63.6
10/14/2020	2:44:43 AM	52.17	63.6
10/14/2020	2:49:43 AM	52.17	63.6
10/14/2020	2:54:43 AM	52.17	63.6
10/14/2020	2:59:43 AM	52.16	63.6
10/14/2020	3:04:43 AM	52.17	63.6
10/14/2020	3:09:43 AM	52.16	63.6
10/14/2020	3:14:43 AM	52.16	63.6
10/14/2020	3:19:43 AM	52.15	63.6
10/14/2020	3:24:43 AM	52.15	63.6
10/14/2020	3:29:43 AM	52.15	63.6
10/14/2020	3:34:43 AM	52.14	63.6
10/14/2020	3:39:43 AM	52.15	63.6
10/14/2020	3:44:43 AM	52.15	63.6
10/14/2020	3:49:43 AM	52.15	63.6
10/14/2020	3:54:43 AM	52.15	63.6
10/14/2020	3:59:43 AM	52.15	63.6
10/14/2020	4:04:43 AM	52.15	63.6
10/14/2020	4:09:43 AM	52.15	63.6
10/14/2020	4:14:43 AM	52.14	63.6
10/14/2020	4:19:43 AM	52.14	63.6
10/14/2020	4:24:43 AM	52.13	63.6
10/14/2020	4:29:43 AM	52.12	63.7
10/14/2020	4:34:43 AM	52.12	63.7
10/14/2020	4:39:43 AM	52.11	63.7
10/14/2020	4:44:43 AM	52.11	63.6
10/14/2020	4:49:43 AM	52.12	63.6
10/14/2020	4:54:43 AM	52.12	63.6
10/14/2020	4:59:43 AM	52.12	63.6
10/14/2020	5:04:43 AM	52.12	63.6
10/14/2020	5:09:43 AM	52.12	63.6
10/14/2020	5:14:43 AM	52.11	63.6
10/14/2020	5:19:43 AM	52.11	63.6
10/14/2020	5:24:43 AM	52.11	63.6
10/14/2020	5:29:43 AM	52.1	63.6
10/14/2020	5:34:43 AM	52.1	63.6
10/14/2020	5:39:43 AM	52.09	63.6
10/14/2020	5:44:43 AM	52.09	63.6
10/14/2020	5:49:43 AM	52.08	63.6
10/14/2020	5:54:43 AM	52.07	63.6
10/14/2020	5:59:43 AM	52.07	63.6
10/14/2020	6:04:43 AM	52.06	63.6
10/14/2020	6:09:43 AM	52.06	63.5
10/14/2020	6:14:43 AM	52.05	63.5
10/14/2020	6:19:43 AM	52.05	63.5
10/14/2020	6:24:43 AM	52.05	63.5
10/14/2020	6:29:43 AM	52.04	63.5
10/14/2020	6:34:43 AM	52.04	63.5
10/14/2020	6:39:43 AM	52.03	63.5
10/14/2020	6:44:43 AM	52.03	63.5
10/14/2020	6:49:43 AM	52.02	63.5
10/14/2020	6:54:43 AM	52.02	63.5
10/14/2020	6:59:43 AM	52.02	63.5
10/14/2020	7:04:43 AM	52.01	63.6
10/14/2020	7:09:43 AM	52.01	63.6
10/14/2020	7:14:43 AM	52.01	63.6
10/14/2020	7:19:43 AM	52.01	63.6
10/14/2020	7:24:43 AM	52	63.6
10/14/2020	7:29:43 AM	52	63.5
10/14/2020	7:34:43 AM	52	63.5
10/14/2020	7:39:43 AM	52	63.5
10/14/2020	7:44:43 AM	52	63.5

10/14/2020	7:49:43 AM	52	63.5
10/14/2020	7:54:43 AM	52	63.5
10/14/2020	7:59:43 AM	52	63.5
10/14/2020	8:04:43 AM	52	63.5
10/14/2020	8:09:43 AM	52	63.5
10/14/2020	8:14:43 AM	52	63.5
10/14/2020	8:19:43 AM	52	63.5
10/14/2020	8:24:43 AM	52	63.5
10/14/2020	8:29:43 AM	52	63.4
10/14/2020	8:34:43 AM	52	63.4
10/14/2020	8:39:43 AM	52	63.4
10/14/2020	8:44:43 AM	52	63.4
10/14/2020	8:49:43 AM	52	63.4
10/14/2020	8:54:43 AM	51.99	63.4
10/14/2020	8:59:43 AM	51.99	63.3
10/14/2020	9:04:43 AM	51.99	63.3
10/14/2020	9:09:43 AM	51.99	63.3
10/14/2020	9:14:43 AM	51.99	63.3
10/14/2020	9:19:43 AM	51.99	63.3
10/14/2020	9:24:43 AM	51.99	63.2
10/14/2020	9:29:43 AM	52	63.2
10/14/2020	9:34:43 AM	52	63.2
10/14/2020	9:39:43 AM	52	63.1
10/14/2020	9:44:43 AM	52.01	63.1

10/14/2020	9:49:43 AM	52.01	63.1
10/14/2020	9:54:43 AM	52.01	63.1
10/14/2020	9:59:43 AM	52.01	63.1
10/14/2020	10:04:43 AM	52.01	63.1
10/14/2020	10:09:43 AM	52.01	63.1
10/14/2020	10:14:43 AM	52	63.1
10/14/2020	10:19:43 AM	52	63.1
10/14/2020	10:24:43 AM	51.95	61.8
10/14/2020	10:29:43 AM	51.78	51.2
10/14/2020	10:34:43 AM	51.7	44.9
10/14/2020	10:39:43 AM	51.67	43.1
10/14/2020	10:44:43 AM	51.7	41.8
10/14/2020	10:49:43 AM	51.76	39.4
10/14/2020	10:54:43 AM	51.84	38.2
10/14/2020	10:59:43 AM	51.93	37.5
10/14/2020	11:04:43 AM	52.02	36.8
10/14/2020	11:09:43 AM	52.1	36.1
10/14/2020	11:14:43 AM	52.18	35.6
10/14/2020	11:19:43 AM	52.24	35.3
10/14/2020	11:24:43 AM	52.3	34.8
10/14/2020	11:29:43 AM	52.35	34.4
10/14/2020	11:34:43 AM	52.39	33.9
10/14/2020	11:39:43 AM	52.43	33.9
10/14/2020	11:44:43 AM	52.46	33.5
10/14/2020	11:49:43 AM	52.49	32.9
10/14/2020	11:54:43 AM	52.52	32.6
10/14/2020	11:59:43 AM	52.54	32.3
10/14/2020	12:04:43 PM	52.56	31.9
10/14/2020	12:09:43 PM	52.58	31.5
10/14/2020	12:14:43 PM	52.59	31.1
10/14/2020	12:19:43 PM	52.6	31.1
10/14/2020	12:24:43 PM	52.6	30.8
10/14/2020	12:29:43 PM	52.61	30.4
10/14/2020	12:34:43 PM	52.62	30.2
10/14/2020	12:39:43 PM	52.62	30
10/14/2020	12:44:43 PM	52.63	29.7
10/14/2020	12:49:43 PM	52.64	29.5
10/14/2020	12:54:43 PM	52.65	29.1
10/14/2020	12:59:43 PM	52.66	29
10/14/2020	1:04:43 PM	52.66	28.9
10/14/2020	1:09:43 PM	52.66	28.7
10/14/2020	1:14:43 PM	52.66	28.4
10/14/2020	1:19:43 PM	52.66	28.3
10/14/2020	1:24:43 PM	52.66	28.9
10/14/2020	1:29:43 PM	52.66	28.4
10/14/2020	1:34:43 PM	52.66	28.4
10/14/2020	1:39:43 PM	52.67	28.1
10/14/2020	1:44:43 PM	52.67	27.7
10/14/2020	1:49:43 PM	52.67	27.4
10/14/2020	1:54:43 PM	52.67	27.3
10/14/2020	1:59:43 PM	52.66	27.2
10/14/2020	2:04:43 PM	52.67	27
10/14/2020	2:09:43 PM	52.66	26.9
10/14/2020	2:14:43 PM	52.67	26.7
10/14/2020	2:19:43 PM	52.68	26.4
10/14/2020	2:24:43 PM	52.68	25.6
10/14/2020	2:29:43 PM	52.59	24.8
		50.94647887	55.7778169

EO Gas Release Information							
Tote #	Gas Pre-Weight (g)	Gas Post-Weight (g)	Net Weight Release (g)	Tote #	Gas Pre-Weight (g)	Gas Post-Weight (g)	Net Weight Release (g)
Tote #1	104.98	76.09	28.89	Tote #19			
Tote #2	106.81	75.45	31.36	Tote #20			
Tote #3	101.68	76.00	25.68	Tote #21			
Tote #4	102.59	75.79	26.80	Tote #22			
Tote #5	102.33	76.42	25.91	Tote #23			
Tote #6	102.88	75.85	27.03	Tote #24			
Tote #7	103.32	75.97	27.35	Tote #25			
Tote #8	104.00	75.93	28.07	Tote #26			
Tote #9	105.40	75.91	29.49	Tote #27			
Tote #10	106.10	75.63	30.47	Tote #28			
Tote #11	105.89	75.68	30.21	Tote #29			
Tote #12	104.59	75.78	28.81	Tote #30			
Tote #13	105.16	76.19	28.97	Tote #31			
Tote #14	104.86	76.12	28.74	Tote #32			
Tote #15	102.99	75.98	27.01	Tote #33			
Tote #16	102.46	76.03	26.43	Tote #34			
Tote #17	104.57	75.91	28.66	Tote #35			
Tote #18	104.28	75.83	28.45	Tote #36			

N/A
ER 13OCT2020

All EO Gas Post Weights Pass (22 g – 45 g) ☑ Yes ☐ No (If no, notify Supervisor)

Operator Signature/Date: Manuela Beltran 14OCT2020 **Checked By/Date:** Ben Tidwell 16 OCT 2020

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60 CM Reg Run #: 360E21

Pre E

001:N + 104.988 g
002:N + 106.819 g
003:N + 101.682 g
004:N + 102.596 g
005:N + 102.331 g
006:N + 102.881 g
007:N + 103.321 g
008:N + 104.007 g
009:N + 105.404 g
010:N + 106.107 g
011:N + 105.894 g
012:N + 104.593 g
013:N + 105.164 g
014:N + 104.864 g
015:N + 102.995 g
016:N + 102.462 g
017:N + 104.575 g
018:N + 104.283 g

Post E

021:N + 76.097 g
022:N + 75.458 g
023:N + 76.000 g
024:N + 75.797 g
025:N + 76.426 g
026:N + 75.855 g
027:N + 75.975 g
028:N + 75.933 g
029:N + 75.910 g
030:N + 75.631 g
031:N + 75.688 g
032:N + 75.780 g
033:N + 76.191 g
034:N + 76.126 g
035:N + 75.989 g
036:N + 76.036 g
037:N + 75.911 g
038:N + 75.839 g

Operation 6 – Dosimeter Check					
Tote #	**Dosimeter Travel Length**		**Tote #**	**Dosimeter Travel Length**	
Tote #1		Pass Fail	Tote # 19		Pass Fail
Tote # 2		Pass Fail	Tote # 20		Pass Fail
Tote # 3		Pass Fail	Tote # 21		Pass Fail
Tote # 4		Pass Fail	Tote # 22		Pass Fail
Tote # 5		Pass Fail	Tote # 23		Pass Fail
Tote # 6		Pass Fail	Tote # 24		Pass Fail
Tote # 7		Pass Fail	Tote # 25		Pass Fail
Tote # 8		Pass Fail	Tote # 26		Pass Fail
Tote # 9		Pass Fail	Tote # 27		Pass Fail
Tote # 10		Pass Fail	Tote # 28		Pass Fail
Tote # 11		Pass Fail	Tote # 29		Pass Fail
Tote # 12		Pass Fail	Tote # 30		Pass Fail
Tote # 13		Pass Fail	Tote # 31		Pass Fail
Tote # 14		Pass Fail	Tote # 32		Pass Fail
Tote # 15		Pass Fail	Tote # 33		Pass Fail
Tote # 16		Pass Fail	Tote # 34		Pass Fail
Tote # 17		Pass Fail	Tote # 35		Pass Fail
Tote # 18		Pass Fail	Tote # 36		Pass Fail
Operator Signature/Date	Manuela Beltran 16OCT2020		Checked By/Date	Ben Tisdall 16 OCT 2020	

N/A ER 13OCT2020

Printed By/Date: ER 13OCT2020 Lot: 040482-R5/039482-R3/0085-F2 60CM Reg Run #: 360E21