WP# 31; Fugitive Emissions of CD Gas from Corrugated Cardboard Rev. A

1. Summary

On July 28, 2021 ClorDiSys Solutions, Inc (CSI) performed testing with chlorine dioxide (CD) gas in a one pallet sterilizer (100 ft^3, 2.83m^3) to determine the whether CD gas exhibits fugitive emissions off cardboard at the end of a CD gas sterilization cycle. The sterilizer was loaded with 27.2 lbs (12.34 kg) of empty cardboard boxes.

For the test run, a gas concentration level of 3.5 mg/L (1260 ppm) and a target dosage of 3900 ppm-hrs was used, mimicking a currently used and validated medical device sterilization cycle. Off gassing was measured at 1 minute, 15 minutes, 30 minutes, and 60 minutes post-aeration with the chamber door closed. At all intervals, no detectable levels of CD gas (0.0 ppm) were measured. Once the chamber door was opened, no odor was detected and the chamber interior was measured at 0.0 ppm. The interior of multiple closed boxes were also measured with the ATI sensor as well, with no detectable levels of CD gas found.

It was found that when a thorough aeration is completed there is NO fugitive emissions of CD gas from corrugated cardboard boxes. Measurements taken prove that there is no CD gas off gassing that will be a safety hazard for workers unloading product into chlorine dioxide gas sterilizers.

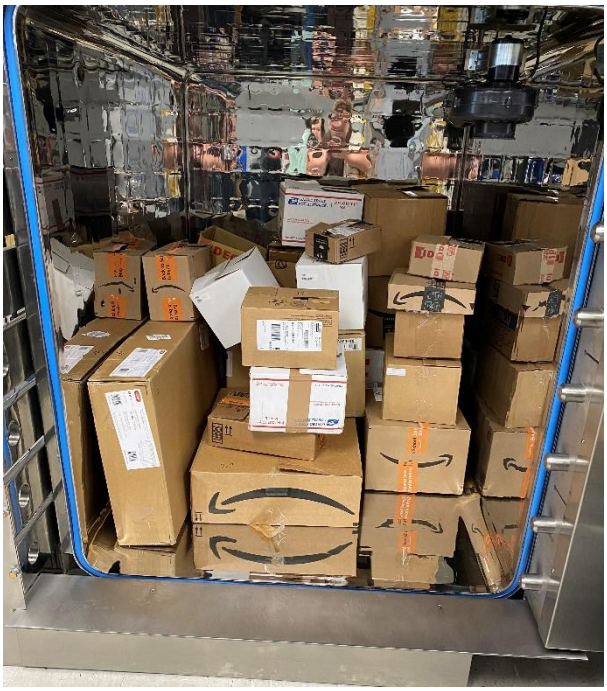

Figure 1: Pallet sterilizer filled with 27.2lbs (12.34kg) of various corrugated cardboard boxes.

2. Introduction

The chlorine dioxide sterilization process consists of the following steps; humidification to soften bacterial spore walls, the introduction of chlorine dioxide (CD) gas to reach the desired concentration (charge), a dwell period called exposure where the gas sits for a period of time in order to obtain the desired kill level, and finally, aeration to remove the gas.

The humidification range to soften the spore walls is 60% or higher with an optimal level of 65 – 75%. The exposure level and time that ClorDiSys targets to obtain a 6-log sporicidal reduction under ambient pressure conditions is 1 mg/liter (360ppm) for 2 hours. This equates to 720 ppm-hours of exposure (360 ppm x 2 hours). At the end of exposure, the gas is aerated until the concentration drops to 0.1 ppm, this is the 8-hour safety level as well as the odor threshold level. Concentrations and dosages vary with sterilizer cycles due to different loads patterns and load makeup.

The CD concentration is monitored throughout the process via the Steridox-VP Sampling system, which is located outside of the vacuum chamber. Sample tubing is run inside the chamber allowing a continuous sample to be pulled from the chamber so that the gas concentration is monitored and controlled at all times. This ensures a successful cycle each time and it assures that people are alerted if the desired gas concentration was not reached and therefore complete deactivation of spores did not occur. Aeration is completed by bringing the chamber pressure up to 85 KPa when exposure is completed. Once this is accomplished, the pressure is typically lowered to 20-40 KPa (25 KPa was used for this test). When the pressure reaches this set point the chamber is then

brought to 85 KPa again. These vacuum/break cycles are continued until the CD gas concentration is at or below 0.5mg/L. Once this is done a fixed number of vacuum/break cycles (8 was used for this test) is completed and the chamber is considered aerated and the cycle is completed.

3. Method

3.1. Material and Equipment

3.1.1. Steridox-VP 100 ft^3 / 2.83 m^3 (serial #: SVP-05A-2021)

3.1.2. CSI CD Cartridges (Lot #: 07142021A)

3.1.3. ATI C-16 PortaSens III Gas Detector – chlorine dioxide (Serial #: H10-12-0756-00 & H10-12-0961-00) see calibration sheets attached.

3.1.4. WeighMax Shipping Scale (Serial #: S140236907)

3.1.5. Boxes 27.2 lbs. (12.34kg) of corrugated cardboard, (see figure 1)

Figure 2: Measurement of CD off gassing 30 minutes post aeration with chamber door closed and NO exhaust on. 0.0 PPM was measured using both sensors.

3.2. Procedure and Results

3.2.1. **Procedure**

Test Run: Boxes were assembled, weighed and placed inside the sterilizer (see figure 1). After boxes were placed inside the one pallet sized sterilizer the door was closed and the cycle started. The RH SP was 75%, Concentration SP was 3.5mg/L (1260 ppm) and the dosage set for 3900 ppm-hrs. Aeration vacuum break cycles was set to 8 cycles after concentration is below 0.5mg/L. See attachment 3 for all cycle parameters. After the cycle completed aeration (final dosage of 3944 ppm-hrs), the side chamber cam-lock fitting was removed and 2 separate ATI PortaSens III sensors measured cardboard box off gassing at three time points.

- At 1 minute post exposure 0.0 ppm was measured on 2 ATI sensors.
- At 15-minute post exposure 0.0 ppm was measured on 2 ATI sensors.
- At 30-minute post exposure 0.0 ppm was measured on 2 ATI sensors.
- At 60-minute post exposure 0.0 ppm was measured on 2 ATI sensors.

Figure 3: Measurement of CD off gassing inside chamber after opening the door (left) and also inside 1 box (right). 0.0PPM was measured on both locations.

After 60 minutes post exposure the chamber was opened and CD gas was again sensed at 0.0 PPM and there was no residual odor detected. Additionally, a box was tested by inserting the ATI PortaSens tip into the

box to measure any off-gassing inside the box and 0.0 PPM was measured. Actual run data can be seen in below attachments.

4. Conclusion

Corrugated cardboard boxes adsorb chlorine dioxide gas. A test run was performed at ClorDiSys Solutions, Inc's facility in Branchburg NJ to test for the fugitive emission of CD gas from corrugated cardboard after a sterilization cycle. It was found that when a thorough aeration is completed, there are no fugitive emissions of CD gas from corrugated cardboard boxes. No measurable levels of CD gas were detected up to 1 hour after aeration within the closed sterilizer chamber or within the cardboard boxes.

5. Approvals

Final Report Approvals			
Name	**Title**	**Signature**	**Date**
Mark Czarneski	Director of Technology		7-29-2021

Attachment 1 – Calibration sheets for Porta-Sens Low Level Sensors

Document #: PR-012
Issue #: 10
ATTACHMENT V

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ClorDiSys

ATI Porta-Sens Calibration Certificate

Customer Name: ClorDiSys	Customer Facility Location: Branchburg NJ
Procedure / Document Used: PR-012	Serial #: H10-12-0756
Procedure Performed by: Nick Smith	Date Performed: 26 Jan 2021
Start Time: 10:12 AM	End Time: 10:27 AM

Reference Sensor Information

Manufacturer	ATI	Part Number	00-1005
Serial Number	H10-12-0921	Next Calibration Date	13 Jan 2022

Sensor Information

Manufacturer	ATI	Part Number	00-1005
Serial Number	H10-12-0756	Next Calibration Date	1/2022

Chamber Calibration Information

Low Concentration Verification	***ppm***
Reference Sensor	0
Sensor Before	0
Sensor After	0
High Concentration Verification	***ppm***
Reference Sensor	202
Sensor Before	234
Sensor After	202

Performed By: Nick Smith	Date: 26 Jan 2021
Signature: Nick Smith	

Analytical Technology, Inc.
6 Iron Bridge Drive, Collegeville PA 19426
Tel: 1-800-959-0299 • Fax: 610-917-0992
Email: sales @analyticaltechnology.com
ISO9001:2015 registered company

Gas Detector Calibration Certificate

ATI Order No. 176611
Certification ID 50001

Customer	ClorDiSys Solutions, Inc.
Product	Chlorine Dioxide Smart Sensor Module
Part No.	00-1005
Model No.	H10
Gas No.	12
Gas Source	ACD Cal 2000 Generator
Cylinder/Reference	Chlorine Dioxide Cell 20-31003623
Gas Supplier	ACD Generator
Traceability	Gas Supplier
Accuracy	±5%
Gas Concentration	2.00 PPM
Gas Flowrate	500 CC/MIN
Issue Date	28-Jun-21
Next Cal Date	28-Jun-22
Technician	Tech 27

Notes
1. Traceability other than NIST indicates that NIST or NMI standard does not exist.
2. Calibration method and results meet the specifications of Analytical Technology, Inc (ATI).
3. Environmental conditions at time of calibration: 65-75 °F, 20-80 %RH

Certified Items

Unit/Sensor Serial Number(s)	Zero as Found *	Zero as Left	Span as Found *	Span as Left
H10-12-0960		0.00 PPM		2.00 PPM
H10-12-0961		0.00 PPM		2.00 PPM
H10-12-0962		0.00 PPM		2.00 PPM

* As found data not applicable to new or replacement items.

Monday, June 28, 2021

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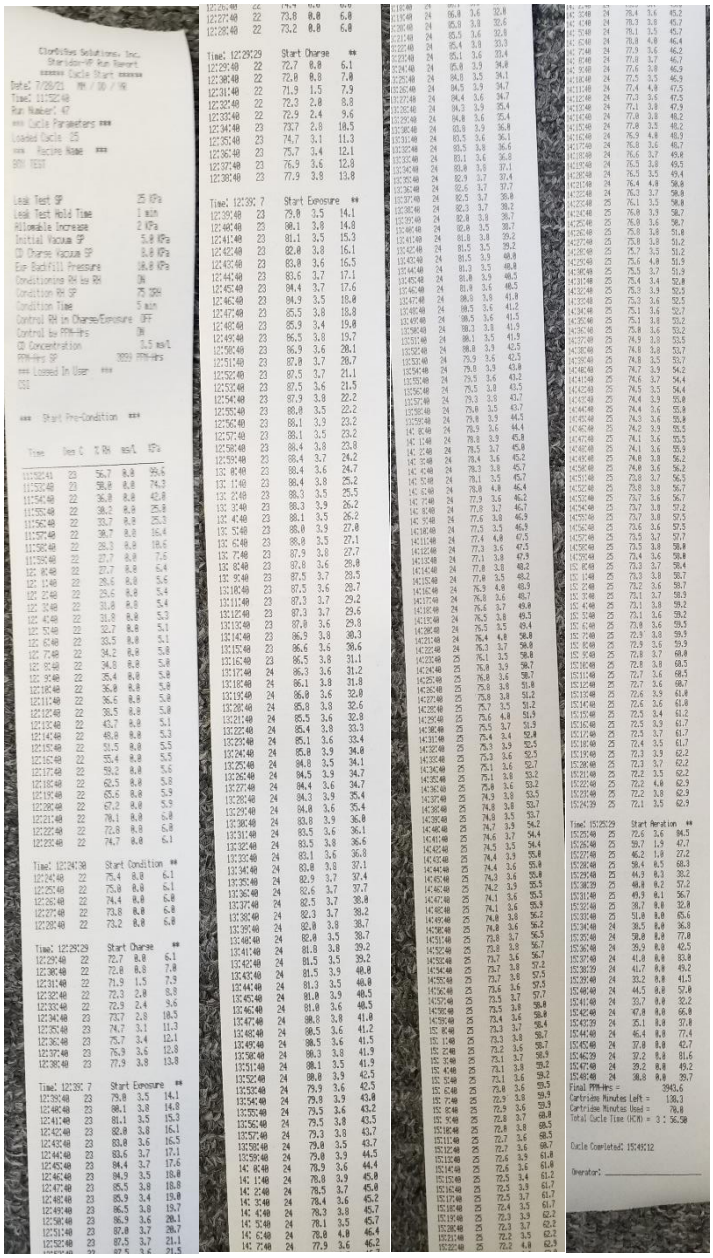
Attachment 2 – Sterilization Cycle Printout Run Reports



Attachment 3 – Sterilization Cycle Run Reports

ClorDiSys — Steridox-VP Cycle Run Report (Page 1 of 3) — Run Number 47

Cycle Start Date (MM / DD / YY): 07 / 28 / 21 | User: CSI | Alarm Status: Cycle Successful No Abort Alarms Occurred

Cycle Parameters

BOX TEST	Recipe Name
25	Loaded Recipe
25	Leak Test SP (K Pa)
2	Allow Press Inc (K Pa)
1.0	Hold Time (min)
5.0	Initial Vacuum SP (K Pa)
8.0	CD Charge Vacuum SP (K Pa)
10.0	Exposure Backfill Pressure (KPa)
Off	RH / Pressure Conditioning
Off	Control RH In Exposure
75	RH SP for Condition (%)
75	RH SP for Charge / Exposure (%)
5	Condition Time (min)
3.5	CD Charge Conc. (mg/L)
3900	PPM-Hrs
On	Control by PPM-Hrs

Cycle Run Step Data

	Time H : M : S	Temperature (Deg C)	RH (%)	Conc. (mg/L)	Pressure (KPa)
Cycle Start	11 : 52 : 40	23.1	57	0.0	99.7
At Vacuum Pull	11 : 56 : 48	22.6	34	0.0	25.4
Start Condition	12 : 24 : 29	22.8	75	0.0	6.2
Start Charge	12 : 29 : 29	22.9	73	0.0	6.1
Reading Before Backfill	12 : 39 : 07	23.0	78	3.8	14.0
Start Exposure	12 : 39 : 07	23.0	78	3.8	14.0
Start Aeration	15 : 25 : 29	25.4	72	3.8	63.2
Cycle Completed	15 : 49 : 12	24.4	47	0.0	93.1

Condition Phase

	Minimum	Maximum
Temperature (deg C)	22.8	22.9
RH (%)	73	75

Exposure Phase

	Minimum	Maximum
Concentration (mg/L)	3.4	4.1
Temperature (deg C)	23.0	25.5
RH (%)	72	88

Time & Consummable Usage

	H : M		Remain	Used
Total Cycle Time	03 : 56.5	Cartridge Minutes	138.3	70.0
Final Dosage (PPM-Hrs)	3943	Cartridge Expiration Date	07 / 22	
Chlorine PSI Used	442	Cartridge Lot Number	07142021A	

Software Versions

HMI V 3.00 | PLC V 3.00 | Print V 1.01

Chamber Serial #: SVP-05A-2021

Operator: _____ (Print) _____ (Signature) Date: _____ Mgmt Initials: _____

ClorDiSys — Steridox-VP Config Parameters Report (Page 2 of 3) — Run Number 47

Cycle Start Date (MM / DD / YY): 07 / 28 / 21 | User: CSI | BOX TEST | Recipe Name 25 Loaded Recipe | Chamber Serial # SVP-05A-2021

11	1 Leak Test Pause (sec)	95.0	23 High Vacuum SP (KPa)	2.0	43 Exposure CD Alm SP-X (mg/L)
150	2 Heat Up Time (sec)	10.0	24 Stop Pull Vacuum (P23-24)	300	44 Aeration Fault Timer (sec)
10	3 Condition Add to SP-X (%RH)	On	28 S90 Inj RH to SP	15	45 Cycle Hi RH SP (%RH)
30	4 Pause for RH Settle (sec)	On	29 S1040 Inj RH to SP	95	46 Hi Hi RH Alarm SP (%RH)
10	5 At Condition SP for X (sec)	On	30 S2020 Inj CD to SP	2.0	47 Hi CD Con SP+X (mg/L)
2.0	6 RH Burst Time (sec)	On	31 S2060 Inject CD to SP	15	48 Low Temp Alarm SP (Deg C)
60	8 Stm Inj Cool Down Time (sec)	On	32 S3020 Inject CD to SP	40	49 Hi Temperature Alarm SP (Deg C)
120	9 Heat Up Stm Inj if Cool (sec)	30.0	33 CD at SP for X (sec)	30	51 Vacuum Pull Fault (Min)
10	10 Ht Up Stm Inj is Not CI (sec)	Off	34 Charge Exposure PR	30	52 Vacuum Break Fault (Min)
5	11 Gen PR Time (sec)	300	35 Ch Pressure Alarm Time (sec)	30.0	61 2nd Aeration Vacuum SP (S4080)
10	12 Charge Pause (sec)	1800	36 Hum Excessive Time (sec)	2.0	62 Add more RH SP-X
3.0	13 CD Charge Minimum Inject	5	37 Condition RH Alarm SP-X	5.0	63 Pause RH timer at SP-X
5.0	15 CD Expose Inject Time (sec)	2	38 Excessvie Cond Time Multiply	1.0	64 Keep RH on for X sec
25.0	17 Initial Aeratain Vacuum SP	4	39 Slow Charge Time X/Y	2.0	65 Adjust CD Exposure
0.5	19 CD Reduce SP (mg/L)	10	40 Slow Charge Concentration	0.0	66 Exposure at SP-X Pause Timer
85.0	20 Aer Vac Break SP (KPa)	30	41 Excessive Charge Time	8	67 Vacuum Break cycles
95.0	21 S4120 Vac Brk SP (KPa)	3	42 Excessive Exposure Time		

Operator: _____ (Print) _____ (Signature) Date: _____ Mgmt Initials: _____

ClorDiSys — Steridox-VP Global Parameter Set Report (Page 3 of 3) — Run Number 47

Cycle Start Date (MM / DD / YY): 07 / 28 / 21 | User: CSI | BOX TEST | Recipe Name 25 Loaded Recipe | Chamber Serial # SVP-05A-2021

300	60 Cartridge Maximum (Min)	On	85 Use CSI Steam Generator	A	100 Use CD A/B sensor
20	61 Gen Chlorine Flow Rate (LPM)	60.0	86 PT-3 Maximum Scale (PSI)	A	101 Use RH A/B sensor
1.0	62 Gen Pressure Relief SP (PSI)	10.0	87 Gen Pres Low / Loss Flt (PT3<X) (PSI)	A	102 Use TT A/B sensor
103.4	66 Vac Sen (PT-4A) Max (KPa)	17.0	88 CSI Steam Gen Heat Up Time (Min)	A	103 Use PT-4 A/B sensor
20	67 Reg Pressure Low Fault (PSI)	300	89 System Inactivity, Auto-Log Off (Min)		
35	68 Reg Pressure Hi Fault (PSI)	Off	90 Use Oil Vacuum Pump		
-40.0	69 Temp Lower Scale (Deg C)	10.0	91 RH Difference Alert (%RH)		
180.0	70 Temp Upper Scale (Deg C)	10.0	92 Temperature Difference Alert (Deg C)		
10	76 Gen Pressure Alarm (PSI)	10.0	93 Chamber Pressure Difference		
0.2	77 Adjust CD Exp Conc (mg/L)	3.0	94 CD Difference Alert (mg/L)		
0.0	78 Exposure at SP (mg/L)	0	95 Vacuum Break cycles		
5	79 Cart Max Add (P60+X) Stop	On	96 Use Automatic Doors		
50	80 Step 10 Vacuum SP (KPa)	103.4	97 Vac Sen (PT-4B) Max (KPa)		
80	81 Break Vacuum SP (KPa)	10.0	98 Automatic Door Gasket Deflate Time (sec)		
30	82 Vacuum Pull SP (KPa)	0.0	99 Vacuum Valve Delay Timer (sec)		
8	83 Vacuum / Break Cycles				
100	84 Chamber Volume (Cu Ft)				

Note: Parameters 80-83 are used for chlorine and cartridge changeout

Operator: _____ (Print) _____ (Signature) Date: _____ Mgmt Initials: _____

Attachment 4 – Sterilization Cycle Data