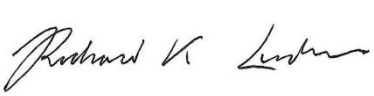
ASHRAE 241-2023 Standard Safety Analysis of the CASPR Medik X In-Duct Advanced Photocatalytic Device

Client: CASPR

ARE Project#: 10926.20.2.2

REPORT APPROVAL

Author: W. Andrew Dexter Title: Research Scientist	Signature:  Date: October 4th
Reviewed By: Richard Ludwick Title: Study Director	Signature:  Date: October 4th

ASHRAE 241-2023 Standard Safety Analysis of the CASPR Medik X In-Duct Advanced Photocatalytic Device

W. Andrew Dexter [a], *Richard Ludwick* [a], *Jamie Balarashti* [a]

[a] **Aerosol Research and Engineering Laboratories Inc. Overland Park, KS**

www.arelabs.com
(p) 913-850-6630 (f) 913-850-6635

Project # 10926.20.2.2

10/5/2023

CASPR™ TECHNOLOGIES

ASHRAE 241-2023 Standard Safety Analysis of the CASPR Medik X In-Duct Advanced Photocatalytic Device

W. Andrew Dexter [a], Richard Ludwick [a], Jamie Balarashti [a]
[a] Aerosol Research and Engineering Laboratories Inc. Olathe KS

Report Info

Submitter:
CASPR Technologies
1343 W Causeway Approach
Mandeville LA 70471

Testing Lab:
Aerosol Research and Engineering Laboratories, Inc.
12880 Metcalf Ave
Overland Park, KS 66213

Report History:
CASPR: Medik X
Safety Monitoring
Project Number: 10926.20.2.2
Submitted:

Associated Report:
CASPR: Medik X
Bioaerosol Efficacy Against MS2
Project Number: 10926.20.2.1
Submitted: 10/03/2023

Keywords:
· *CASPR Medik X*
· *Safety Analysis*
· *ASHRAE 241-2023*

ASHRAE 241-2023 Compliance:
This study was conducted in compliance with ASHRAE 241 and AHAM AC-5 along with Good Laboratory Practices (GLP) as defined in 21 CFR, Part 58,

Conflict of Interest:
Aerosol Research and Engineering Laboratories, Inc. have no affiliations with, or involvement in any capacity, with CASPR's financial interests such as membership, employment, stock ownership, or other equity interest.

ABSTRACT

Purpose:
The purpose of this in-vitro study was to measure four specific safety related items, per ASHRAE 241-2023, of the CASPR Medik X device while it was in normal operation. The four items that were measured were for the potential:
1) particulate generation from the device,
2) ozone production from the unit itself,
3) formaldehyde production rate, and
4) the level of sound that the unit produces while in operation (exempt for in-duct systems).

Background:
The Medik X device is classified as a medical grade HVAC device that utilizes a cell made up of a cold plasma bulb and proprietary catalytic coated honeycomb. It is designed to be installed in the HVAC ductwork such that the cell is inserted into the air flow. The catalyst generates gaseous hydrogen peroxide for decontaminating both air and surfaces.

All testing was conducted in a 30m³ bioaerosol test chamber which housed the partial HVAC system that the devices were installed in. The safety testing included analysis of particulate generation, ozone, and formaldehyde production and well as the sound level generated by the device. This study utilizes ASHRAE 241 testing parameters to determine safety.

Methods:
A partial HVAC system was constructed with installation points for the CASPR Medik X with a blower rate set at 5 air changes per hour (5 ACH). The Medik X was installed into the system, then the unit and blower were switched on, and measurements were taken for:
1) particulate generation using a TSI Aerodynamic Particle Sizer (APS) Model 3321,
2) ozone production using a Teledyne Model 456L ozone monitor,
3) formaldehyde production using an Interscan 4160, and
4) noise generated by the device

Each safety item was tested individually, and the data was logged over the 4-hour test period while the device was in operation. Control trials (background) were performed to establish the background levels of particulates, ozone, formaldehyde, and sound. The background was subtracted from the test data to yield a net value for each of the parameters that were monitored.

Results:

The CASPR Medik X passed the particulate and formaldehyde generation safety tests per the ASHRAE 241 guidelines. For particulate testing, the Medik X did not exceed the ISO Class 6 chamber particulate level. The formaldehyde generation emission rate averaged 38.23 ug/hr, which is under the 50 ug/hr threshold dictated by ASHRAE 241 guidelines.

Both the ozone and noise production were not tested. Instead, the manufacturer has a UL test certificate (Appendix C) that certifies the device does not exceed 0.005 ppm as tested by UL 867. Additionally, the device is an in-duct design and is therefore exempt from noise testing per section A 1.4.1.1 of ASHRAE Standard 241.

INTRODUCTION

On June 24th, 2023, the new ASHRAE 241-2023 guidelines were released to establish a more uniform testing protocol for all air purification devices. The protocol standardizes the safety testing for in-duct and standalone devices. This report presents the safety testing results for the CASPR Medik X tested per ASHRAE 241 guidance document requirements.

The ASHRAE standard includes guidelines for particulate, ozone, formaldehyde, and noise production limits. With these new guidelines, testing must be done on all air purification devices that adhere to these ASHRAE 241 standards.

The test plan incorporated testing the CASPR Medik X per the ASHRAE 241 safety requirements in a 30 m³ test chamber to evaluate the safety of the CAPSR Medik X device. The Medix X is pictured in **Figures 1** and **2** on the following page.

The Medik X device is designed to be installed into the ductwork of an already functioning HVAC system. It utilizes a UV-C light bulb to deactivate airborne pathogens. A

photocatalytic housing surrounds the bulb, producing dry hydrogen peroxide vapor to reduce both airborne and surface contamination.

STUDY OVERVIEW

The CASPR Medik X was evaluated for four potential safety risks: particulate, ozone, formaldehyde, and noise production. This study was performed in accordance with ASHRAE 241-2023 guidelines. This report presents the results of that testing.

This is one of two reports that detail the test results for the ASHRAE 241 and AHAM AC-5 testing of the Medik X. This report contains the safety testing data and results. The other report details the bioaerosol testing by ASHRAE 241 and AHAM testing guidelines. A test matrix outlining the safety testing can be found in **Figure 3** below.

PRODUCT DESCRIPTION

The CASPR Medik X is a medical-grade air purifier and surface decontamination device. This model houses a 14" UV-C bulb. Radiation from the bulb irradiates bacteria and viruses and also produces a photocatalytic effect with its catalytic housing to generate hydrogen peroxide, further reducing microbes both airborne and on surfaces. The device is designed to be retrofitted into existing HVAC systems in hospitals, businesses, or residential homes. The ability of the CASPR Medik X to utilize an already established HVAC system, with a fan and filter, dramatically reduces the initial cost of implementing one of these systems.

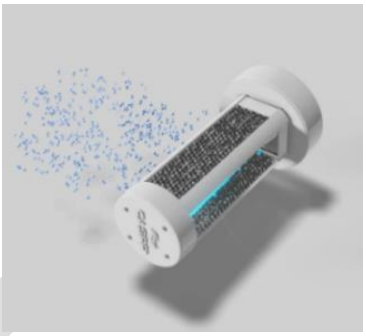


Figure 1: CASPR Medik X.

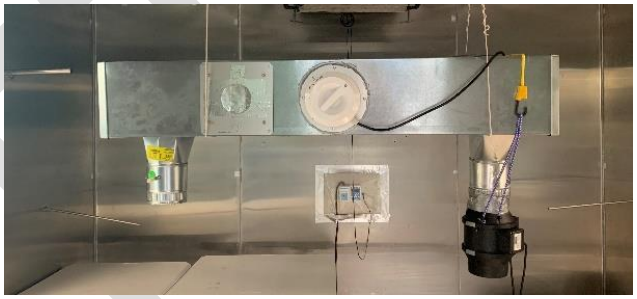


Figure 2: CASPR Medik X – Installed in partial HVAC duct used for testing in the bioaerosol test chamber.

Trial	Run	Device	Device Fan Speed (ft^3/min)	Test Species	Abbreviation	Chamber Size (m^3)	Detection Limit	Trial Time (hr)	Sampling Devices
1	Control	NA	NA	Ozone	O_3	30	0 ppb	4	Teledyne 465L
2	Control								
3	Challenge	CASPR Medik X	5 ACH						
4	Challenge								
5	Challenge								
6	Challenge								
7	Control	NA	NA	Particulate	Particles greater than 0.3 µm	30	1 pt/L	4	TSI 3321 APS
8	Control								
9	Challenge	CASPR Medik X	5 ACH						
10	Challenge								
11	Challenge								
12	Challenge								
13	Control	NA	NA	Formaldehyde	HCHO	30	0.2 ppb	4	Interscan 4160-1999b
14	Control								
15	Challenge	CASPR Medik X	5 ACH						
16	Challenge								
17	Challenge								
18	Challenge								

Figure 3: **Test Matrix.**

PARTICULATE SAFETY TESTING

Particulate Monitoring Equipment

A TSI model 3321 Aerodynamic Particle Sizer (APS) (TSI Inc., Shoreview, MN) was used to measure aerosol concentrations and the particle size distribution within the chamber during the test trials. The APS provided real-time aerodynamic particle characterization with a size range from 0.54-20.0 µm with 52 size bins of resolution. Sampling is continuous with a data export interval of 1 second. The APS has a continuous flow rate of 5 liters per minute (LPM). A picture of the APS is shown in **Figure 4** below.

Figure 4. TSI Aerodynamic Particle Sizer (APS) model 3321 was used to measure the challenge bioaerosol's total particle concentration and particle size distribution. It has a 0.54-20.0 µm aerodynamic diameter range, with 1 particle/L detection limits.

Particulate Monitoring Test Methodology

The chamber was first measured for aerosolized particulate concentrations to establish the chamber particulate background level. The background control test was run for 4 hours, the same as the test trials. The chamber cannot exceed the ISO 5 Cleanliness Class based on Table 1 of ISO 14644-14 shown in **Figure 6** below.

The device was placed into the test chamber, switched on, and monitored for 4 hours. The particulate test data was then compared to the control data to determine the net production rate of particulates generated by the device.

ASHRAE 241 Particulate Requirements

As stated in the ASHRAE 241 guidelines, the level of particulates produced by the device *"shall not exceed one cleanliness class greater than the empty test chamber or test duct as described in ISO 14644-14, Table 1."*

Particulate Test Results

Mean Particle Concentration (pt/m^3)

Particle Size Range	Control 1	Control 2	Medik X
≥0.3µm	9804.4	9481.2	28072.1
≥0.5µm	109.5	110.1	19882.3
≥ 1.0µm	7.6	7.0	2097.6
≥ 5.0µm	0	0	5
ISO Classification	**5**	**5**	**6**

Figure 5. APS particulate data for the Medik X.

Particulate Test Conclusion

ASHRAE guidelines state that the chamber cannot exceed the ISO Class 5 limit and that the tested device cannot exceed ISO Class 6, or one class above the maximum control class. The control concentration level was classified as an ISO Class 4 to 5 chamber. The APS data shows that the device raised the ISO Class to 6, but did not exceed that class 6 ISO rating. The Medik X, therefore, passes the particulate portion of the safety testing.

ISO Class Number		Maximum allowable concentrations (particles/m3) for particles equal to and greater than the considered size					
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
Cleanest	1	10					
	2	100	24	10			
	3	1,000	237	102	35		
	4	10,000	2,370	1,020	352	83	
(Class 100)	5	100,000	23,700	10,200	3,520	832	
(Class 1,000)	6	1,000,000	237,000	102,000	35,200	8,320	293
(Class 10,000)	7				352,000	83,200	2,930
(Class 100,000)	8				3,520,000	832,000	29,300
	9				35,200,000	8,320,000	293,000

ISO CLEANROOM

Figure 6. Particulate ISO classification particulate levels by particle size.

OZONE SAFETY TESTING

Ozone Monitoring Equipment

A Model 465L Ozone Monitor was used to measure the test chamber ozone concentrations during the Medik X ozone safety test trials. Real-time ozone concentrations were monitored and recorded automatically every 20 seconds, using data logging software to capture the output readings. The model 465L has a continuous flow rate of 0.8 liters per minute (LPM). A picture of the 465L Ozone Monitor is shown in **Figure 7** below.

Figure 7. The Teledyne Model 465L UV Photometric Ozone Monitor. This Ozone monitor can detect ozone levels as low as 0 ppb and up to 500 ppm while sampling at 0.8 L/min

Ozone Monitoring Test Methodology

To assess the Medik X's ozone production accurately, the chamber, with no device present, was first measured for background ozone levels. This data established a background ozone level that was subsequently subtracted from the test data to determine the ozone contribution of the Medik X test device. Both the control and test trials were run for four hours. The ASHRAE 241 standard does not mention a background ozone concentration limit.

The device was placed into the test chamber and was subsequently turned on and monitored for four hours. This data was then compared to the control data to determine the net production rate of ozone by the device.

ASHRAE 241 Ozone Production Guidelines

The ASHRAE 241 requirements limit ozone production for the tested device to an average of 50 micrograms/hr over a four-hour test period.

Ozone Production Test Conclusion

The CASPR Medik X has a UL2998 certification stating that its ozone generation rate is within the limit provided by the ASHRAE 241 standard. This certification is in Appendix C of this document.

FORMALDEHYDE SAFETY TESTING

Formaldehyde Monitoring Equipment

The Interscan 4160-1999b Formaldehyde Gas Detector is a portable sampling unit that provides a real-time digital readout of formaldehyde concentrations in parts per billion. It is highly sensitive and capable of reading formaldehyde at concentrations as low as 0 ppb and up to 1999 ppb. This data was stored on a data logger and exported to an Excel file for further data analysis. A picture of the Interscan 4160-1999b Portable Formaldehyde Gas Detector is shown in **Figure 8** below.

Figure 8. The Interscan 4160-1999b Portable Formaldehyde Gas Detector. It has a 0-1999 ppb range with a 0.2 ppb resolution.

Formaldehyde Monitoring Test Methodology

To accurately assess the device's formaldehyde production rate, the chamber was first monitored to establish the background formaldehyde concentration. The control trial data was subtracted from the test trial data to calculate the net formaldehyde production rate. Both the control and test trials were run for four hours.

Formaldehyde safety testing also included an additional control test with limonene. Limonene is a chemical commonly found in many household products, including cleaning solutions and beauty products. Limonene is known to produce formaldehyde if exposed to ozone. Limonene was aerosolized inside the chamber at a concentration of 25 µg/m^3, or 4.5 ppb$_v$, as a chemical input for potential formaldehyde production per ASHRAE 241 guidelines. The chamber was then monitored for potential formaldehyde conversion caused by the basal ozone level in the chamber.

The concentration of limonene used for the control test (25 µg/m^3 or 4.5 ppb$_v$) was volatilized in the chamber containing the device. The device was then turned on and

monitored for four hours. This data was then compared to the control data to determine the net production of ozone attributed to the device.

ASHRAE 241 Formaldehyde Guidelines

The ASHRAE 241 requirements for formaldehyde production are very low, only allowing the tested device a formaldehyde emission rate of 50 µg/hr over the four hours of testing.

Emission rates are determined by the following equation provided by the ASHRAE Standard:

$$E = V\left(L_{off}C_{t=\Delta t} + \frac{C_{t=\Delta t} - C_{t=0}}{\Delta t}\right)$$

Where:
E= Emission rate, µg/hr
V= Volume of the Chamber in m^3
L_{off}= the first order loss rate for the chemical (which is 0 for formaldehyde)
$C_{t=\Delta t}$ = Concentration at the end of the trial in µg/m^3
$C_{t=0}$ = Concentration at the beginning of the trial in µg/m^3
Δt= total duration of the trial

Using this equation, the emission rate of formaldehyde was calculated.

Formaldehyde Test Results

CASPR Medik X

Trial ID	Limonene Starting Concentration (ug/m^3)	Testing Duration (hours)	HCHO Emission Rate (ug/hr)
Control 1	25	4	5.53
Control 2	25	4	4.61
Trial 1	25	4	39.61
Trial 2	25	4	36.85
Net Emisson Rate Average			38.23

Figure 9. Formaldehyde test results obtained for the control and Medik X device trials.

Formaldehyde Test Conclusion

The ASHRAE 241 standard provides a limit for formaldehyde generation. The CASPR Medik X is within the formaldehyde generation limits, producing an average of 38.23 net ug/hr of formaldehyde, which is below the threshold of 50ug/hr. This data indicates that the Medik X formaldehyde generation rate is within safety limits.

NOISE LEVEL SAFETY TESTING

Noise Monitoring Equipment

The Aoputtriver is a digital sound level meter designed to measure the decibel level of various environments. IT has a 30-130 dB range with an accuracy of ± 1.5 dB with a resolution of 0.1 dB making it highly accurate. It has a sampling frequency of 2 times each second. A picture of the Aoputtriver AP-882A is shown in **Figure 10** below.

Figure 10. The Aoputtriver AP-882A is a digital sound meter with an accuracy of ±1.5 dB with sampling 2 times every second.

Noise Level Measurement Methodology

A background reading of the ambient noise level in the test room was taken. The tests were performed outside the testing chamber to prevent wall reverberation. These readings were then used as a baseline to determine the noise level attributed to the device.

The test device was placed in the same room used for control testing, switched on, and analyzed in the same way that the control test was performed in approximately the same area. The ASHRAE 241 guidelines state that readings must be taken approximately 1 meter (3.3 ft) from the tested device. This was done at various points around the unit, approximately every 45 degrees.

ASHRAE 241 Noise Guidelines

The ASHRAE 241 guidelines do not state a specific limits for sound production for any device. The guidance document just states that sound levels must be taken and reported.

Noise Level Results and Conclusion

The CASPR Medik X is exempt from noise testing per section A 1.4.1.1 of ASHRAE Standard 241.

Analyte of Concern	Abbreviation	Test Method	Target	Results	Pass/Fail
Formaldehyde	HCHO	Formaldehyde shall be measured using any method described in ASTM D8407 [23] that has a detection limit better than 0.5 ppb_v (0.6 µg/ m^3) for a 1-minute sample. Air change must be low enough to detect target emission rate with instrument detection limits.	Emission rate less than 50 µg/hr	Average formaldehyde generation was 152.91 ug/m^3 over the course of 4 hours. The final emission rate was 38.23 ug/hr.	Pass
Ozone	O3	UL 2998-2020 or equivalent	<5 ppb	State UL Certification	Pass
Particulate matter count concentration (#/m3)	Particles greater than 0.3 µm	ISO 14644-14 [24] (duct testing requires isokinetic sampling)	Test results shall not exceed one cleanliness class greater than the empty test chamber or test duct as described in ISO 14644-14, Table 1. Empty chamber shall not measure higher than Class 5.	Device did not exceed ISO Class 6	Pass

Figure 11 Executive Summary.

Summary of Results

A total of two different tests were performed, the formaldehyde and particulate matter generation tests, in duplicate. The device passed both the formaldehyde and particle generation tests. The results are summarized in Figure 11 above.

Ozone testing was performed and passed at another facility that issued a state UL certification; that certificate is in Appendix C of this report. Since the device is designed for an in-duct installation, it is exempt from noise testing per section A 1.4.1.1 of ASHRAE Standard 241.

Conclusion

The Medik X passed all safety testing requirements outlined in the ASHRAE 241-2023 Standard.

REFERENCES

AHAM. (2023). AHAM AC-5: Performance Evaluation of Room Air Cleaners. Association of Home Appliance Manufacturers.

ASHRAE 241. (July 2023). Control of Infection Aerosols. American Society of Heating, Refrigerating, and Air Conditioning Engineers.

Ding and Wing. (2001). Effects of Sampling Time on the Total Recovery Rate of AGI-30 Impingers for E. coli. Aerosol and Air Quality Research, Vol. 1, No. 1, pp. 31-36.

Feller, W. (1950). An Introduction to Probability Theory and Its Applications. Wiley.

T. Reponen, K. Willeke, V. Ulevicius et al. (1997). Techniques of Dispersion of Microorganisms in Air. Aerosol Science and Technology, 27, pp. 405-421.

U.S. Department of Health and Human Services Food and Drug Administration. (March 2009). Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff.

Dietrich, Watts L., et al. (2020). Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol — November 2020. Morbidity and Mortality Weekly Report, 69(46), pp. 1744-1750.

Analytical Testing Facility

Aerosol Research and Engineering Labs, Inc.
12880 Metcalf Ave
Overland Park, KS 66213

Project

10926.20.1.2

Study Director

Richard Ludwick
Aerosol Research and Engineering Laboratories

GLP Statement

We, the undersigned, hereby certify that the work described herein was conducted by Aerosol Research and Engineering Laboratories in compliance with ASHRAE 241, AHAM AC-5, and Good Laboratory Practices (GLP) as defined in 21 CFR, Part 58.

Conflict of Interest Statement

Aerosol Research and Engineering Laboratories, Inc. have no affiliations with, or involvement in any capacity, with CASPR's financial interests such as membership, employment, stock ownership, or other equity interest.

Study Director:

Richard Ludwick
Study Director
ARE Labs, Inc.

10/03/2023
Date

Principal Investigator:

W. Andrew Dexter M.S.
Staff Research Scientist
ARE Labs, Inc.

10/03/2023
Date

APPENDIX A:
Equipment Calibration Certificates

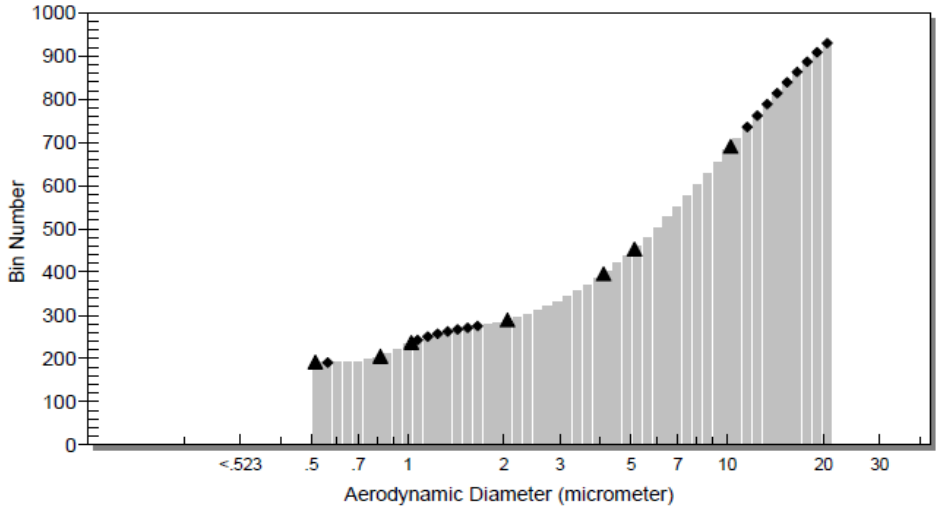
TSI
Particle Instrument Division
Mailing Address: P.O. Box 64394 St.Paul, MN 55164 USA
Shipping Address: 500 Cardigan Road Shoreview, MN 55126 USA
Phone: 1-800-677-2708 or (651)490-2833 FAX:(651)490-3860

Certificate of Calibration

TSI model 3321

Date of Calibration: August 01, 2023
Serial Number: 71043195

	Geometric Diameter (µm)	Accumulator Median Bin	Particle Density (g/ml)
Particle #1	0.5	192	1.05
Particle #2	0.8	205	1.05
Particle #3	1.0	237	1.05
Particle #4	2.0	289	1.05
Particle #5	4.0	396	1.05
Particle #6	5.0	453	1.05
Particle #7	10	691	1.05



TSI Incorporated does hereby certify that all materials, components, and workmanship used in the manufacture of this equipment are in strict accordance with the applicable specifications agreed upon by TSI and the customer and with all published specifications. All performance and acceptance tests were successfully conducted according to required specifications. TSI Incorporated certifies that the instruments used to calibrate this instrument are traceable to the National Institute of Standards and Technology (NIST), where applicable, and internal TSI calibration standards where NIST standards do not exist.

Calibrated by: _____

Figure 1A: APS calibration certificate.

CERTIFICATION OF CALIBRATION

This instrument has been calibrated using standards maintained at Teledyne API (9970 Carroll Canyon Raod, San Diego, CA 92131, USA), which are traceable to the United States National Institute of Standards and Technology. This calibration was performed to Teledyne API specifications and to the requirements of ISO 9001:2015. Supporting documentation relative to traceability is on file at this office, and is available for examination at Teledyne API upon request.

CERTIFICATION OF:

Model: 465L Rack MKS 6 Channel
Part Number: 060680500 Firmware Rev: B6
Serial Number: 2271

CAL DATE: 8/31/2018

CERTIFICATION LEVEL
RESTRICTED ☐ (see below)
INTERIM ☐
FINAL ☑

SALES ORDER NUMBER: 309035

CALIBRATION JOB INSTRUCTION NO:

AS RECEIVED CONDITION:

☑ Initial Calibration ☐ Item received in calibration ☐ Item is out of calibration

As found condition (test data): **INITIAL CALIBRATION**

CALIBRATION DATA: This certifies that the above referenced instrument meets or exceeds all design specifications. Testing has been performed using instruments calibrated by an independent party using a NIST-traceable SRP ozone analyzer for the assay of ozone as described in *40CFR50, Appendix D*. It is maintained as a certified transfer standard according to the guidelines described in EPA's Technical Assistance Documents: *Transfer Standards for the Calibration of Air Monitoring Analyzers for Ozone (EPA-600/4-79-056), September 1979, and Technical Assistance Document for the Calibration of Ambient Ozone Monitors (EPA-600/4-79-057), September 1979* for concentrations at or below 1 ppm. Instrument readings in excess of 1 ppm are extrapolated. This transfer standard is periodically verified against an NIST Standard Reference Photometer. Specific data are available upon request.

Environmental Conditions At Time Of Calibration: 65-75 °F, RH = 20-80%
If calibration is restricted, specify restriction: NO RESTRICTION

TEST DATA

Input (PPM)	Measured (PPM)	% Deviation
0.00	0.00	0.00%
0.25	0.25	-0.11%
0.50	0.50	0.02%
0.90	0.90	0.16%

TEST AND MEASUREMENT EQUIPMENT USED:

Model Number	Serial Number/Asset Number		Calibration Date	Calibretion Due
703E	SN: 225	EL#: 447	7/27/2018	7/27/2019

PERFORMED BY: 133 **DATE** 8/31/2018

APPROVED BY: Quality Representative **DATE** 8/31/18

06575G (DCN 7947) **7/2/18**

Figure 2A: Teledyne 465L factory calibration certificate.

IE MONITORING INSTRUMENTS
Industrial Environmental Monitoring Instruments, Inc.
7410 Worthington-Galena Rd
Worthington, OH 43085
Phone: (614) 436-4933
Website: www.ierents.com

Formaldehyde Monitor Calibration

Instrument: Interscan 4160 HCHO
Serial #: 22526
Date: 8/25/2023
Technician: Sam Shults

Calibration Data

	Standard	Reading
Zero Gas	Charcoal Filter	0 +/- 3 ppb
Span	682 ppb	683 ppb

Accuracy = +/- 5%

Calibration Standards

Standard	Serial#	Expires	Manufacturer
4348 ng/min HCHO Perm Tube	65536	3/21/2024	Kin-Tek
Bios ML-500 Calibrator	206586	9/29/2023	Bios International

Instrument must be calibrated and operated according to manufacturers specifications

Figure 3A: Interscan calibration certificate.

APPENDIX B:
Test Chamber Validation

INTRODUCTION

Validating a bioaerosol chamber is a crucial process to ensure its accuracy and reliability in maintaining controlled experiments. This involves thorough assessments to confirm that the chamber met the strict standards for conducting bioaerosol studies. Factors such as chamber homogeneity, ionization assessment, air exchange rates, and control stability are rigorously tested to ensure consistent and accurate results. Validation assures researchers that the chamber functions properly, enabling them to conduct reliable bioaerosol studies that contribute to informed decision-making in areas like indoor air quality and infectious disease research.

EQUIPMENT

Testing Chamber

The test chamber, **Figures 1 and 2**, is the main component in bioaerosol testing used for controlled manipulation and testing of microorganisms. It allows for the introduction, sampling, and secure confinement of microorganisms, thus contributing to the precision and reproducibility of testing outcomes. ARE Lab's 30m^3 test chamber adheres to the stringent guidelines in AHAM AC-5 and aligns with both AHAM and ASHRAE 241 criteria.

Structurally, the chamber has dimensions of 30 $\pm$ 1.5 cubic meters, or approximately 1060 ft^3, with the width deliberately maintained within 85 to 100% of its length. This dimensional consistency ensures a uniform testing space, which allows for reliable experimentation.

Constructed from a non-porous material, the chamber's walls exhibit notable qualities. Beyond its physical attributes, this material emits minimal volatile organic compounds (VOCs), is non-reactive, non-reflective, and has a non-ionizing quenching nature. This creates an environment conducive to reliable and repeatable testing conditions.

Airtight integrity is monitored and controlled, within the chamber achieving a controlled air change rate (ACH) below 0.05, as per the benchmark set by ASTME 741. This characteristic provides the operator with the ability to isolate the testing environment, thus enhancing result reliability.

The chamber is designed to prevent external microbial contamination while maintaining internal atmospheric conditions. These features include an aseptic maintenance system, HEPA filtration, cross-contamination-free item transfer mechanisms, external power control, real-time observation facilitated by multiple viewing windows, and the capability to produce and evenly disperse aerosolized microbes.

Sampling ports, positioned approximately 48 inches from the floor and 12 inches from the walls, ensure optimal sample collection while maintaining prescribed device separation. The chamber's temperature and humidity are maintained, within ASHRAE 241 limits, with a programmable controller.

The incorporation of negative pressure airflow allows for controlled purging, and a HEPA filter adds an additional layer of protection, inhibiting potential contamination. The 30m^3 testing chamber at ARE Labs fulfills both AHSRAE 241 and AHAM AC-5 requirements.

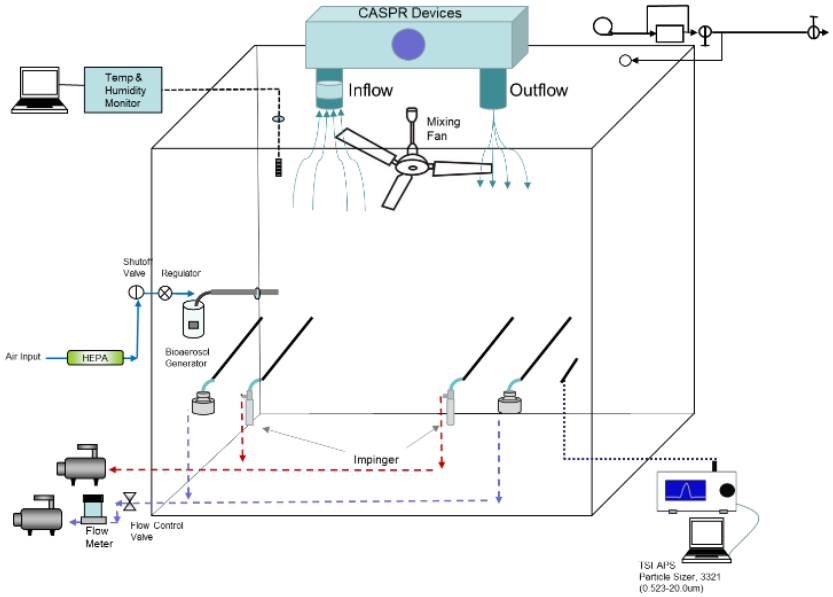


Figure 1: 30m^3 Environmental Test Chamber Flow Diagram. Chamber includes bioaerosol induction, multiple bioaerosol sampling ports, particle size monitoring, internal mixing fans, and temperature and humidity controls. Main system HEPA evacuation system not pictured.

Shown below in **Figure 2**, the bioaerosol chamber used for all testing in this study. A Magnehelic gauge (Dwyer instruments, Michigan City IN), with a range of -0.5 to 0.5 inches of H_2O, is used to monitor and balance the system pressure during aerosol generation, aerosol purge, and testing cycles. A general flow diagram of the aerosol test system is shown in **Figure 1** on the previous page.

Figure 2: The 30 m³ bioaerosol testing chamber at ARE Labs adheres to AHAM AC-5 standards and ASHRAE 241 criteria. The chamber is equipped with HEPA filtered air in/out, multiple bio aerosol sampling ports, decontamination, and pressure balance.

Temperature and Humidity Monitor/Controller

The temperature and humidity within the chamber are monitored and controlled with an AC Infinity Controller 69. This controller allows for real-time monitoring and control of the temperature in the 30m³ bioaerosol chamber used for testing. Temperature and humidity control is essential for the stability of aerosolized micro-organisms during testing.

ASHRAE 241 and AHAM AC-5 both have temperature and humidity requirements for temperature and humidity inside of the bioaerosol chamber during testing. The required range for humidity is 50% ± 10% while the temperature range is 73°F + 5° (23°C + 3°C). A picture of the controller is shown in **Figure 6** on the following page.

Figure 3: AC Infinity Controller 69 Temperature and Humidity Controller.

Ion Monitor

The COM 3200 Pro II ion meter, **Figure 7** below, measures ion concentrations in real time and was used during testing to ensure the ion concentrations were consistent inside the chamber. The ion meter measures ions using the Gerdien capacitor method and can detect positive and negative ions down to 10 per cubic centimeter. This was only used for the chamber validation aspect of the testing and not used during any portion of the safety testing as required for ASHRAE 241.

Figure 4: COM 3200 Pro II ion meter used for ion measurements of the PA663 ionizer.

CHAMBER VALIDATION TESTING

Bio-homogeneity – Impinger Tests

One key component of the chamber validation process is the bioaerosol homogeneity test. This test validates the homogeneity of the chamber, making sure that the atmosphere within the chamber is well mixed.

Six AGI-30 impingers were used for this chamber validation. The impingers were systematically rotated through all four impinger ports to generate a matrix of impinger tests against all ports. Each port was tested with each impinger a minimum of two times during this validation.

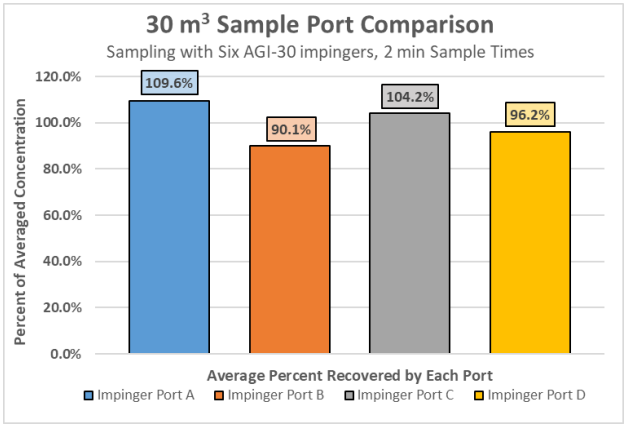


Figure 5: Impinger port-to-port comparison. Percent averages are calculated by taking the count for each port divided by the average plate count for the four ports.

These impinger samples were plated in triplicate by two technicians to reduce plating discrepancies. Each set of plate counts generated by each technician were compared to one another and a port-to-port comparison was created. This showed that each port of the 30m³ chamber produced a similar result to one another validating the chamber homogeneity during trials. A graphical representation of the average measured for each port is shown in **Figure 8**. While these results do not show gaseous homogeneity specifically, the homogeneity of a gas should be far more homogenous due to the much higher diffusion rate that gases have over aerosolized biologics.

Ionization Homogeneity Validation

To measure the baseline concentration of ions present in the sealed 30 m³ chamber over 4 hours, a COM 3200 Pro II ion meter was used. The chamber had an average net ion concentration of -143.39 +/- 55.64 ions per cubic centimeter. Testing shows that the net ion concentration is essentially neutral in regard to the charge within the chamber. See the ion data graph from the ion test trial in **Figure 10**. The total production of ions naturally occurring in the chamber is nominal.

These control tests implement the ANSI/AHMA AC-5 2022 guidelines, ensuring a thorough and precise assessment of air cleaner performance in reducing airborne microbes. The methodical approach, from preparation to measurement and analysis, underscores the importance of consistent and accurate testing procedures.

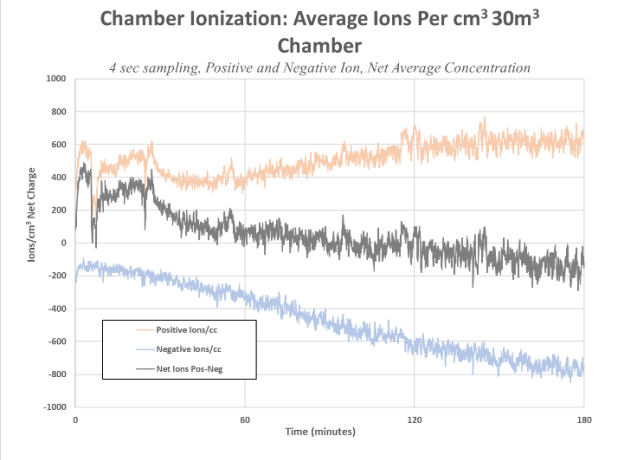


Figure 7. Total baseline level of ions present in the 30m³ chamber.

APPENDIX C:
CASPR Provided Ozone State UL Certification

ENVIRONMENTAL CLAIM VALIDATION SUMMARY

CASPR Group

CASPR MEDIK X

Report Number:

252601-4180

Validation Period:

19 Oct 2021 - 19 Oct 2024

Claim:

Zero Ozone Emissions – Measured Ozone Emissions from CASPR MEDIK X during use phase does not exceed 0.005 ppm as tested by UL 867.

Method:

ECVP 2998 Zero Ozone Emissions from Air Cleaners, Third Edition - 2020

Facility:

Gray