



## ASHRAE STANDARD 241-2023 SAFETY TESTING OF THE GPS AIR 2400

### **PROJECT: GPS AIR 2400 – ASHRAE STANDARD 241 SAFETY TESTING**

TECHNOLOGY: Needlepoint Bipolar Ionization (NPBI™)

DEVICE: GPS-2400-12A

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

### **CHALLENGE ORGANISM:**

Not Applicable

### **STUDY COMPLETION DATE:**

07/17/2024

### **Medical Director**

Dana Yee, M.D.

### **Testing Facility**

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### **Laboratory Project Number**

1412A

### **Test Standard**

ASHRAE 241-2023 Safety



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## Efficacy Study Summary

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Study Title</b>          | ASHRAE STANDARD 241-2023 SAFETY TESTING OF THE GPS AIR 2400                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Laboratory Project #</b> | 1412                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guidelines:</b>          | ASHRAE Standard 241-2023, GCLP, and BSL-3 standards were used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Testing Facility</b>     | Innovative Bioanalysis, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>GLP Compliance</b>       | All internal SOPs and processes follow GCLP guidelines and recommendations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Description</b>          | <p>Per the manufacturer, the GPS-2400-12A ionization module is the core technology powering GPS Air's NPBI ionization systems. Testing was conducted in a chamber with the device installed in an external ductwork system to evaluate three specific safety-related items, per ASHRAE Standard 241-2023, of the GPS Air 2400 for particle generation, ozone production, and formaldehyde production rate.</p>                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Test Conditions</b>      | <p>Testing was conducted in a 22' x 11' x 8' chamber following BSL standards with an external 10 in. round ductwork system with a total duct volume of ~40 ft<sup>3</sup>, making the chamber's volume plus ductwork 1,976 ft<sup>3</sup>. The duct system fan produced an average of 478 fpm of air velocity measured in the supply ductwork 6 feet in front of the device location. Ion concentrations were measured at 12 chamber locations in a grid pattern with an average ion concentration of 10,300 negative ions/cc. The temperature during testing was approximately 71 ±2°F, with a relative humidity of 51 ±1%. Per the ASHRAE Standard 241-2023, each analyte was measured in separate safety tests and compared to the target levels defined in Table A-1, Required Analytes for Safety Testing (Table 5).</p> |
| <b>Control</b>              | <p>The control runs were conducted without the device operating to establish the background chamber levels of the three analytes (particulates, ozone, and formaldehyde). Control measurements without the device operating allowed for net value calculations for each analyte.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Test Results</b>         | <p>The results show the formaldehyde emission rate did not exceed 2 µg/h in the chamber for any of the experiment or control runs resulting in a calculated emission rate less than ASHRAE Standard 241's target rate of 50 µg/hr.</p> <p>Ozone testing measured less than the target of 5 ppb for the duration of all testing.</p> <p>Particle matter count concentration did not exceed one cleanliness class greater than the empty chamber as described in ISO 14644-14.</p>                                                                                                                                                                                                                                                                                                                                              |
| <b>Conclusion</b>           | <p>The GPS AIR 2400-12A safety test data measured below the target limits as stated in the ASHRAE 241-2023 test standard Table A-1. Therefore, the GPS Air's 2400 device meets the safety testing requirements per the standard for particle generation, ozone production, and formaldehyde production rate.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



## Study Report

**Study Title:** ASHRAE STANDARD 241-2023 SAFETY TESTING OF THE GPS AIR 2400

**Sponsor:** Global Plasma Solutions (dba GPS Air), 3101 Yorkmont Road Suite 1500. Charlotte, NC 28208

**Test Facility:** Innovative Bioanalysis, Inc., 3188 Airway Ave Suite D, Costa Mesa, CA 92626

**Technology Tested:** NPBI™

**Device Testing:** GPS Air 2400-12A

**Study Dates:**

**Study Report Date:** 07/19/2024

**Experimental Start Date:** 03/06/2024

**Experimental End Date:** 07/17/2024

**Study Completion Date:** 07/17/2024

### Study Objective:

The GPS AIR 2400-12A incorporating GPS's NPBI™ technology was provided by Global Plasma Solutions (dba GPS Air) for safety testing per ASHRAE Standard 241-2023. The study was conducted to evaluate the GPS Air 2400-12A device for three specific safety required parameters including particle generation, ozone production, and formaldehyde production rate.

The ASHRAE Standard 241-2023 was published in July 2023 to establish minimum requirements for the control of infectious aerosols to reduce the risk of disease transmission in the occupiable space in new buildings, existing buildings, and major renovations to existing buildings, including requirements for both outdoor air system and air cleaning system design, installation, commissioning, operation, and maintenance. The standard includes effectiveness and safety testing requirements for air cleaning systems. Testing was conducted in a chamber with the GPS Air 2400-12A device installed in an external ductwork system to evaluate three specific safety-related items: particle generation, ozone production, and formaldehyde production rate. The effectiveness testing was not completed as part of this safety study.

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## Study Materials and Equipment:

### Equipment Overview:

The GPS AIR 2400-12A incorporating GPS's NPBI™ technology (Fig. 1) arrived at the laboratory pre-assembled from the manufacturer and was inspected for damage upon arrival. Due to the closed design, no assessment was conducted on the inner components of the ionizer. Before testing, the test device was powered on and operated for three 10-minute periods (dry runs) to confirm ion concentrations in the chamber and correct operation. Alpha Lab AIC2 ion polarity meters were used at 12 locations in a grid in the chamber before testing, as shown in Figure 3, with an average ion concentration across those 12 locations of 10,300 negative ions/cc. It should be noted that due to the nature of ions, there were fluctuations in concentrations around the chamber.

MANUFACTURER: GPS Air

MODEL: GPS-2400-12A

TECHNOLOGY: GPS NPBI™



Figure 1. GPS Air 2400-12A device tested.

### Testing Layout:

Testing was conducted in a sealed 22' x 11' x 8' chamber (Fig. 2) per Biosafety Level 3 (BSL3) standards. The room had a displacement volume of 1,936 ft<sup>3</sup> (54,821.42 L) of air. Ductwork external to the chamber was used for the study as shown in Figure 2. The total volume of the ductwork system was ~40 ft<sup>3</sup> making the volume of the chamber plus ductwork 1,976 ft<sup>3</sup>. Ductwork consisted of 20.83 ft of 10-inch round supply and return ductwork with five 90-degree elbows. In addition, a 28 in x 22 in x 72 simulated HVAC box was located between the supply and return ductwork. A supply diffuser and return grill were part of the system into and out of the chamber. The variable speed fan in the ductwork system was measured to an average of 478 fpm at the GPS AIR 2400-12A mounting location. See Figure 2 for a schematic of the chamber setup. The chamber remained closed during testing, with no air entering or leaving the room or ductwork system. A nebulizing port connected to a programmable compressor system was in the center of the 22 ft wall. At each chamber corner, low-volume mixing fans (approx. 30 cfm each) were positioned at 45-degree angles to ensure homogenous mixing of bioaerosol concentrations when nebulized into the chamber. The room was equipped with ozone, formaldehyde, and particle sensors for safety testing measurements. The device was mounted in the supply duct. The chamber was visually inspected, and pressure tested. All internal lab systems and equipment were reviewed before testing.

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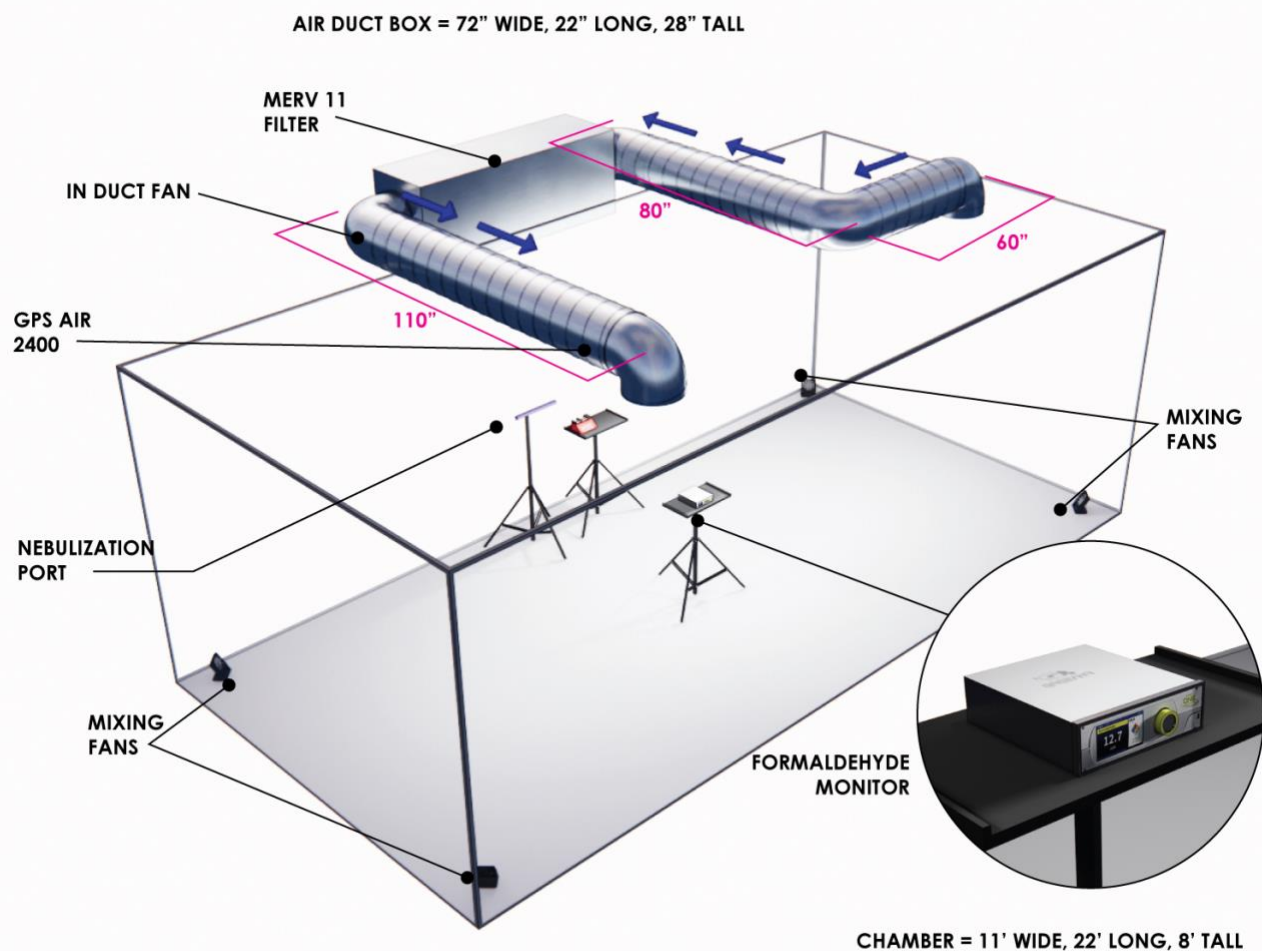


Figure 2. Chamber layout for control and experimental safety testing.

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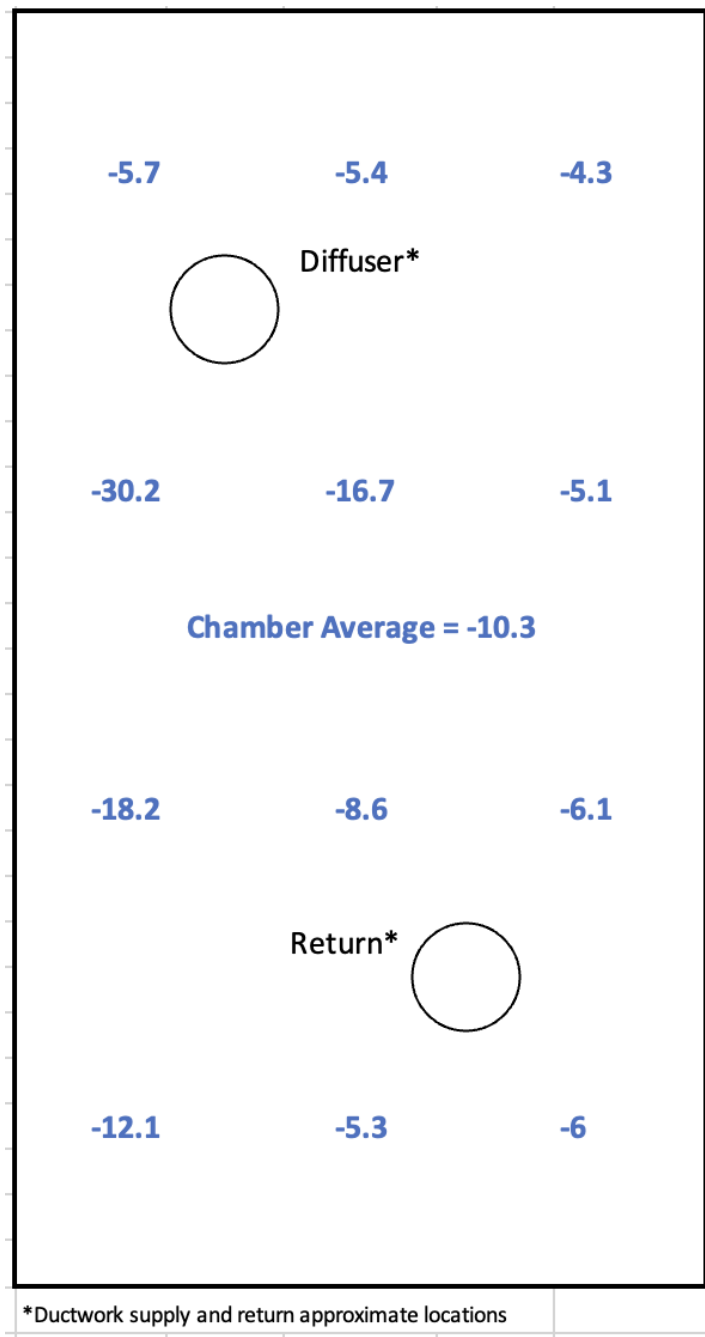


Figure 3. Negative ion concentration measurements from three dry runs across 12 locations in the chamber. (Measurements shown are in thousands. i.e. -10.3 = 10,300 negative ions/cc).

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## Test Equipment:

### Exposure Conditions and Equipment:

1. The temperature during all test runs was approximately  $71 \pm 2^\circ\text{F}$ , with a relative humidity of  $51 \pm 1\%$ .
  - a. ASHRAE Standard 241 requires the chamber's temperature to be  $73^\circ\text{F} \pm 5^\circ\text{F}$  ( $23^\circ\text{C} \pm 3^\circ\text{C}$ ).
  - b. ASHRAE Standard 241 requires the chamber's relative humidity to be  $50\% \pm 10\%$ .

2. Ion Alpha Lab AIC2 ion polarity meters were used at 12 locations in a grid in the chamber before testing, as shown in Figure 3, with an average ion concentration across those 12 locations of 10,300 ions/cc.

1. Alpha Lab's Air Ion Counter Model AIC2 meters
  - i. Range/Resolution: 2 million / 10 (ions/cc)
  - ii. Accuracy: 2 million / 10 (ions/cc), 200 million / 1000 (ions/cc)



3. TSi Aerodynamic Particle Sizer® (APS™) 3321 spectrometer
  - a. Real-time aerodynamic measurements of particles from 0.5 to 20 microns
  - b. High size resolution – 52 size channels
  - c. Continuous flow rate of ~5 liters per minute



4. Formaldehyde Sensor, Gasera One Formaldehyde Monitor
  - a. Ultra-sensitive cantilever enhanced photoacoustic detection technology with Quantum Cascade Laser source operating at a Mid-IR fundamental spectral absorption line of formaldehyde.
  - b. Principle of operation: photoacoustic infrared spectroscopy.
  - c. Monitoring of formaldehyde with below 1 ppb detection limit.
  - d. Accuracy: Better than 5% at the calibration concentration.
  - e. Standards: Complies with the Low Voltage Directive 2014/35/EU, EMC Directive 2004/108/EC and ROHS 2 directive 2011/65/EU.



5. Ozone Sensor, 2.B Tech Model 211 Ozone Monitor
  - a. Dual beam, long path (30 cm) optical bench with high precision ( $< 0.5$  ppb)
  - b. NIST Traceable Calibration
  - c. EPA Federal Equivalent Method (FEM) for compliance monitoring





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## Test Method:

### Experimental Procedure:

1. Before the initial control test and following each safety test, the chamber was decontaminated and prepped per internal procedures.
2. Ion concentration dry-run testing measured average ion levels expected during the safety testing.
3. Each safety test was run as a separate 4-hour test for increased accuracy and repeatability.

### Formaldehyde Testing Procedure:

1. The Gasera One Formaldehyde Monitor was set up on a table in the chamber's center.
2. A single-pulse injection of limonene was nebulized into the chamber resulting in approximately 25 µg/m<sup>3</sup> (4.5 ppb<sub>v</sub>) initial gas concentration upon the start of each test.
3. Pulse nebulization occurred using a Blaustein Atomizing Module (BLAM), as shown in Figure 4, with a pre-set PSI and computer-controlled liquid delivery system.
4. Samples were taken every 30 seconds for the duration of the 4-hour tests.



Figure 4: BLAM Nebulizer

### Particle Testing Procedure:

1. The TSi Aerodynamic Particle Sizer® (APS™) 3321 spectrometer was set up on a table in the center of the chamber.
2. Samples were taken every 2 min for the duration of the 4-hour tests.

### Ozone Testing Procedure:

1. The 2.B Tech Model 211 Ozone Monitor was set up on a table in the center of the chamber.
2. Samples were taken every minute for the duration of the 4-hour tests.

### Post Decontamination (Particle and ozone tests):

After each particle and ozone test, the air filtration system underwent a 90+ minute air purge.

### Post Decontamination (Formaldehyde test only):

After each formaldehyde test the UV system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV exposure, the air filtration system underwent a 30-minute air purge. All test equipment was cleaned with a 70% isopropyl alcohol solution at the end of each day. The nebulizer was decontaminated with hydrogen peroxide mixtures.

## Control Protocol:

Duplicate control testing was conducted with the device off to evaluate the GPS Air 2400-12A incorporating GPS's NPBI™ technology. The samples were measured in the same manner and set up as the corresponding safety testing trials to serve as a comparative background baseline to calculate net results when the device was operating. Each control was run as a separate test run for increased accuracy and repeatability.



## Study Results:

### Formaldehyde Testing Results:

The results are shown below (Table 1) for Formaldehyde measurements at the start and finish of each test and control run. Emission Rate is shown as calculated from the concentration measurements. The emission rate for the GPS Air 2400 was calculated to be below the ASHRAE Standard 241-2023 requirement of 50 µg/hr.

Table 1: Duplicate Formaldehyde measurement results and emission rate calculations with and without the GPS Air 2400 device operating

| Test Run     | T0 - Start                | T- 4 hours                 | Emission Rate |
|--------------|---------------------------|----------------------------|---------------|
|              | HCOC (µg/m <sup>3</sup> ) | HCOC (µg /m <sup>3</sup> ) | (µg /hr)      |
| Control 1    | 10.11                     | 14.31                      | 1.05          |
| Control 2    | 17.21                     | 19                         | 0.4475        |
| Experiment 1 | 13.71                     | 16.71                      | 0.75          |
| Experiment 2 | 16.01                     | 15.04                      | -0.2425       |

### Particle Testing Results:

The results are shown below (Tables 2 & 3) for particle measurements at the start (T0) and finish (T-4 hours) of each test and control run. The ISO Clean Room class for the start and finish of each particle test is listed per ISO 14644-14. The particle data shows the GPS Air 2400 and control testing starting as ISO Class 5 and finishing as ISO Class 6 which passes the ASHRAE Standard 241-2023 criteria of not increasing the ISO classification level beyond the next highest level.

Table 2: Duplicate particle measurement results with the GPS Air 2400 device operating

|                      | Exp 1 - start                 | Exp 1 – end (4h)              | Exp 2 - start                 | Exp 2 – end (4h)              |
|----------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Size (greater than)  | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) |
| 0.3 µm               | 3213                          | 35944                         | 3219                          | 46586                         |
| 0.5 µm               | 1807                          | 13655                         | 1036                          | 15270                         |
| 1 µm                 | 201                           | 1004                          | 0                             | 1205                          |
| 5 µm                 | 0                             | 0                             | 0                             | 0                             |
| ISO Clean Room Class | 5                             | 6                             | 5                             | 6                             |

Table 3: Control duplicate particle measurement results without the GPS Air 2400 device operating

|                      | Control 1 - start             | Control 1 – end (4h)          | Control 2 - start             | Control 2 – end (4h)          |
|----------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Size (greater than)  | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) | particles (#/m <sup>3</sup> ) |
| 0.3 µm               | 2008                          | 58233                         | 3614                          | 38632                         |
| 0.5 µm               | 1004                          | 23494                         | 1004                          | 13481                         |
| 1 µm                 | 0                             | 602                           | 0                             | 1006                          |
| 5 µm                 | 0                             | 0                             | 0                             | 0                             |
| ISO Clean Room Class | 5                             | 6                             | 5                             | 6                             |



### Ozone Testing Results:

The results are shown below (Table 4) for average ozone measurements for each test and control run. The ozone measurements for the GPS Air 2400 were all below the ASHRAE Standard 241-2023 target requirement (< 5 ppb).

Table 4: Average Ozone measurement results with the GPS Air 2400 device operating versus baseline control

| Test               | Ozone Measurements (average) |
|--------------------|------------------------------|
|                    | ppb                          |
| Control            | 0.14                         |
| Experiment (4-hrs) | 1.22                         |
| Net Increase       | 1.09                         |

### Conclusion:

The GPS AIR 2400 safety test results measured below the target limits as stated in the ASHRAE 241-2023 test Standard Table A-1 (Table 5). Therefore, the GPS Air's 2400 device meets the safety testing requirements per the Standard for particle generation, ozone production, and formaldehyde production rate.

Table 5: Analyte target levels from ASHRAE Standard 241-2023, Table A-1

| Analyte of Concern                                         | Abbreviation                  | Test Method                                                                                                                                                                                                                                                                                             | Target                                                                                                                                                                                           |
|------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Formaldehyde                                               | HCHO                          | Formaldehyde shall be measured using any method described in ASTM D8407 <sup>23</sup> that has a detection limit better than 0.5 ppb <sub>v</sub> (0.6 µg/m <sup>3</sup> ) for a 1-minute sample.<br><br>Air change must be low enough to detect target emission rate with instrument detection limits. | Emission rate less than 50 µg/h                                                                                                                                                                  |
| Ozone                                                      | O <sub>3</sub>                | UL 2998-2020 or equivalent                                                                                                                                                                                                                                                                              | <5 ppb                                                                                                                                                                                           |
| Particulate matter count concentration (#/m <sup>3</sup> ) | Particles greater than 0.3 µm | ISO 14644-14 <sup>24</sup> (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. |



## References:

1. *ASHRAE Standard 241, 2023. Control of Infection Aerosols. American Society of Heating, Refrigerating, and Air Conditioning Engineers.*
2. *ASTM D8407, 2021. Standard Guide for Measurement Techniques of Formaldehyde in Air. West Conshohocken, PA: ASTM International.*
3. *ISO 14644-14, 2016. Cleanrooms and associated controlled environments—Part 14: Assessment of suitability for use of equipment by airborne particle concentration. Geneva, Switzerland: International Organization for Standardization.*
4. *Stephens, B., E.T. Gall, M. Heidarinejad, and D.K. Farmer. 2022. Interpreting air cleaner performance data. ASHRAE Journal 64(3):20–30.*
5. *UL 2998, 2020. Environmental Claim Validation Procedure (ECVP) for Zero Ozone Emissions from Air Cleaners. Northbrook, IL: Underwriters Laboratories, LLC.*

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**Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.**

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**Sam Kabbani, MS, BS, MT(ASCP), CLS**

**Date**

**Chief Scientific Officer, Innovative Bioanalysis, Inc.**

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**Albert Brockman**

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## Disclaimer

The Innovative Bioanalysis, Inc. ("Innovative Bioanalysis") laboratory is not certified or licensed by the United States Environmental Protection Agency and makes no equipment emissions claims pertaining to ozone or byproducts of any device. Innovative Bioanalysis, Inc. makes no claims to the overall efficacy of any device. The experiment results are solely applicable to the device used in the trial. The results are only representative of the experiment design described in this report. Innovative Bioanalysis, Inc. makes no claims as to the reproducibility of the experiment results given the possible variation of experiment results even with the identical test environment, viral strain, collection method, inoculation, nebulization, viral media, cell type, and culture procedure. Innovative Bioanalysis, Inc. makes no claims to third parties and takes no responsibility for any consequences arising out of the use of, or reliance on, the experiment results by third parties.

## Funding / Conflict of Interest Statement

The study was funded by GPS Air. Innovative Bioanalysis certifies that it has no affiliations with or involvement in any capacity with GPS Air's financial interests such as honoraria, grants, employment, stock ownership, or other equity interest.



## APPENDIX A: Glossary of Terms

**ASHRAE:** ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers). ASHRAE's goal is to serve as a source of technical standards and guidelines.

**ASHRAE Standard 241-2023:** The purpose of this standard is to establish minimum requirements for the control of infectious aerosols to reduce the risk of disease transmission in the occupiable space in new buildings, existing buildings, and major renovations to existing buildings, including requirements for both outdoor air system and air cleaning system design, installation, commissioning, operation, and maintenance. Where the effectiveness and/or safety performance of an air cleaning system is not covered by any of the above consensus standards then Normative Appendix A can be used to determine air cleaning system effectiveness and safety.

**CAP:** The College of American Pathologists (CAP), the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. A laboratory can pursue a higher level of quality by becoming accredited by The College of American Pathologists (CAP).

**CLIA:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are federal regulations for the United States-based clinical laboratories to provide industry standards for testing human samples for diagnostic purposes.

**Equivalent Clean Airflow:** The theoretical flow rate of pathogen-free air that, if distributed uniformly within the breathing zone, would have the same effect on infectious aerosol concentration as the sum of actual outdoor airflow, filtered airflow, and inactivation of infectious aerosols.



## APPENDIX B: Calculation Equation(s)

### **Average Emission Rate for Formaldehyde:**

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

$E$  = emission rate,  $\mu\text{g/h}$

$V$  = volume of the chamber,  $\text{m}^3$

$L_{off}$  = first order loss rate for the chemical that includes both air change and surface losses (see Stephens et. al)

$C_{t=\Delta t}$  = concentration at the end of the test period,  $\mu\text{g}/\text{m}^3$

$C_{t=0}$  = concentration at the beginning of the test,  $\mu\text{g}/\text{m}^3$

$\Delta t$  = total length of test in h; minimum = 4

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## APPENDIX C: Equipment Calibrations

### 2B Technologies Model 211-G Ozone Monitor™

#### Calibration Certificate

|                                                      |                                                  |        |
|------------------------------------------------------|--------------------------------------------------|--------|
| <b>Calibration Description:</b>                      | NIST Traceable Calibration of Ozone Monitors     |        |
| <b>Calibration ID number:</b>                        | 211_1019_071223                                  |        |
| <b>Location:</b>                                     | 2B Tech, 6800 W. 117th Ave. Broomfield, CO 80020 |        |
| <b>Calibration Lab Conditions</b>                    | 21.6 °C                                          | 20 %RH |
| <b>Instrument Model:</b>                             | 211-G                                            |        |
| <b>Instrument s/n:</b>                               | 1019G                                            |        |
| <b>Slope (S):</b>                                    | 1.060                                            |        |
| <b>Offset, ppbv (Z):</b>                             | 0.0                                              |        |
| <b>Measurement Uncertainty (ppbv)<sup>1,2</sup>:</b> | 0.7                                              |        |
| <b>2B Spec, accuracy:</b>                            | greater of 1.0 ppbv or 2% of reading             |        |
| <b>2B Spec, precision:</b>                           | greater of 0.5 ppbv or 1% of reading             |        |
| <b>Overall Pass/Fail:</b>                            | PASS                                             |        |
| <b>205 2B Working Standard s/n:</b>                  | 283                                              |        |
| <b>Transfer Standard Calibration Date:</b>           | 08-Feb-22                                        |        |
| <b>Working Standard Calibration Date:</b>            | 06-Jan-23                                        |        |
| <b>Date of Calibration:</b>                          | 11-Dec-23                                        |        |
| <b>Cal Expiration Date:</b>                          | 09-Dec-24                                        |        |

Based on the following calibration provided by the U.S. National Institute of Standards and Technology (NIST), 2B Technologies designates the calibration of all Ozone Monitors™ to be NIST traceable through an unbroken chain of comparisons. The transfer standard is used to calibrate the working standard, which in turn is used to calibrate the customer's instrument. Each step in the chain is fully documented.

**Transfer standard.** Our transfer standard is a Thermo Electron O3 Calibration Primary Standard, model 49i-PS, serial number 0726724741. The transfer standard was calibrated by NIST against their Standard Reference Photometer, serial number 0, in Gaithersburg, MD on the date above. Measurements were collected of ten concentrations (25 to 1000 ppbv) and two zero concentrations. A linear regression was fit to the data and calibration factors were determined for the transfer standard.

**Working standard.** Our working standard is a 2B Technologies Model 205 Ozone Monitor. The working standard was calibrated by 2B Technologies by comparison to our transfer standard. Measurements were collected of six concentrations (50 to 300 ppbv) and one zero concentration. A linear regression was fit to the data and calibration factors were determined for the working standard.

**Customer's instrument.** The instrument was calibrated against the working standard. Ozone was generated by photolysis of oxygen followed by dilution in a flow of ozone-free air. The gas mixture was sampled by both instruments through a sampling tee. Measurements were collected from each instrument at six different concentrations (50 to 300 ppbv) and one zero concentration. A linear regression was fit to the data, and calibration factors were determined, applied and tested at zero and six concentrations of ozone.

**Cal performed by:** WESSLEY KING

**Signature:** 

**calibration date:**

11-Dec-23

1. N=2; 95% confidence

2. references: NIST Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results 1994 ed.  
Taylor, John. *An Introduction to Error Analysis*, 2nd ed. Univ. Science Books: Sausalito, 1997.

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## 2B Technologies Model 211-G Ozone Monitor™ Post Calibration Data

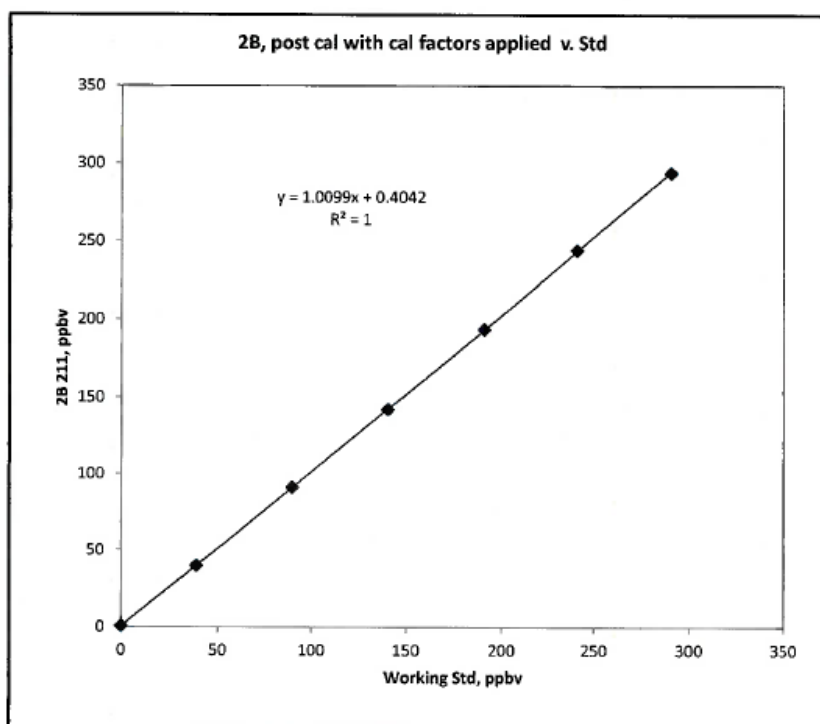
Serial Number: 1019G

Date: 11-Dec-23

cal factors applied z= 0.0

s= 1.060

| Std   | 2B    | deviation | % deviation | STD | pass/fail |
|-------|-------|-----------|-------------|-----|-----------|
| 290.8 | 293.6 | 2.8       | 1.0         | 0.5 | PASS      |
| 240.9 | 244.1 | 3.2       | 1.3         | 0.4 | PASS      |
| 190.9 | 193.5 | 2.6       | 1.4         | 0.4 | PASS      |
| 140.6 | 142.1 | 1.5       | 1.1         | 0.5 | PASS      |
| 89.6  | 91.0  | 1.4       | 1.6         | 0.4 | PASS      |
| 39.0  | 39.6  | 0.6       | 1.6         | 0.4 | PASS      |
| 0.0   | 0.4   | 0.4       | n/a         | 0.4 | PASS      |



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# INNOVATIVE BIOANALYSIS

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|                                |                   |
|--------------------------------|-------------------|
| Instrument Serial Number       | 1019G             |
| Calibration Date               | 11-Dec-23         |
| Slope (S)                      | 1.060             |
| Offset (Z), ppbv               | 0.0               |
| Precision, ppbv                | 0.5               |
| Flow Rate A, cc/min volumetric | 1045              |
| Flow Rate B, cc/min volumetric | 920               |
| Photodiode Voltage A           | 0.94              |
| Photodiode Voltage B           | 0.97              |
| Flow Rate Cal Factor A         | 1.00              |
| Flow Rate Cal Factor B         | 0.84              |
| Solenoid Valve                 | Pneutronics (NPB) |
| Air Pump                       | KNF               |
| Ozone Scrubber                 | Heated Graphite   |
| PCB Version                    | 1.3               |
| Firmware Version               | 20A               |
| Current, Amp                   | 0.50              |
| Power at 12 V, Watt            | 6.00              |

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# INNOVATIVE BIOANALYSIS

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TSI PM 2007157



## CERTIFICATE OF AS LEFT CALIBRATION

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126, USA.  
Tel: 1-800-874-2811 Fax: 1-654-490-3824 <http://www.tsi.com>

TSI Incorporated does hereby certify that the below described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self-calibration techniques. TSI is registered to ISO-9001:2015. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the TSI calibration service department issuing this report.

| Unit Under Test (APS) |          |
|-----------------------|----------|
| Manufacturer          | TSI Inc. |
| Model                 | 332100   |
| Serial Number         | 72215008 |

| Environmental Conditions |       |     |
|--------------------------|-------|-----|
| Temperature              | 23.2  | °C  |
| Relative Humidity        | 39.3  | %   |
| Ambient Pressure         | 966.5 | hPa |

|   |                  |
|---|------------------|
| X | In Tolerance     |
|   | Out of Tolerance |

| Reference Equipment       |           |            |            |
|---------------------------|-----------|------------|------------|
| Reference Device          | System ID | Last Cal   | Cal Due    |
| Gilibrator                | E002211   | 11/29/2021 | 11/30/2022 |
| Multimeter                | E001315   | 12/07/2020 | 6/30/2022  |
| CPC standard              | E010340   | 05/12/2021 | 5/31/2022  |
| TSI 3080 Classifier       | E003653   | 01/24/2022 | 1/31/2023  |
| Oscilloscope              | E001650   | 04/28/2021 | 10/31/2022 |
| Barometric Pressure Meter | E010476   | 07/29/2021 | 7/31/2022  |
| Ambient Temp/RH Probe     | E010477   | 06/29/2021 | 6/30/2022  |

| Flow Verification, Unit: L/min |       |                 |              |
|--------------------------------|-------|-----------------|--------------|
| Parameter                      | Value | Allowable Range | Pass or Fail |
| Sheath Flow Rate               | 4.000 | 3.95 ~ 4.05     | PASS         |
| Aerosol Flow Rate              | 1.018 | 0.95 ~ 1.05     | PASS         |

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# INNOVATIVE BIOANALYSIS

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159 PIN 2000157

| Calibration Material | Manuf. | Nominal Size [µm] | Label Size [µm] | Lot Number | Traceability | Expiry Date |
|----------------------|--------|-------------------|-----------------|------------|--------------|-------------|
| PSL                  | duke   | 0.350             | 0.345           | 241164     | NIST         | 6/30/2024   |
| PSL                  | duke   | 0.400             | 0.400           | 230332     | NIST         | 8/31/2023   |
| PSL                  | duke   | 0.500             | 0.500           | 240944     | NIST         | 5/1/2024    |
| PSL                  | duke   | 0.700             | 0.702           | 245567     | NIST         | 10/31/2024  |
| PSL                  | duke   | 1.00              | 1.000           | 229294     | NIST         | 8/1/2023    |
| PSL                  | duke   | 2.00              | 2.000           | 237967     | NIST         | 3/1/2024    |
| PSL                  | duke   | 5.00              | 5.008           | 231705     | NIST         | 9/30/2023   |
| PSL                  | duke   | 7.00              | 6.976           | 212685     | NIST         | 6/30/2022   |
| PSL                  | duke   | 10.0              | 10.02           | 233796     | NIST         | 12/31/2023  |
| PSL                  | duke   | 15.0              | 14.97           | 219894     | NIST         | 12/31/2022  |
| PSL                  | duke   | 20.0              | 20.00           | 237865     | NIST         | 3/31/2024   |

| Label Size [µm] | Aero. Size* [µm] | Bin Number | Reference CPC Counts | Measured Counts | Detection Efficiency* | Allowable Range | Pass or Fail |
|-----------------|------------------|------------|----------------------|-----------------|-----------------------|-----------------|--------------|
| 0.345           | 0.354            | 166.7      | 122382               | 53532           | 0.44                  | 0.40 ~ 1.05     | PASS         |
| 0.400           | 0.410            | 169.2      | 14004                | 10573           | 0.75                  | 0.70 ~ 1.05     | PASS         |
| 0.500           | 0.512            | 175        | 38129                | 38953           | 1.02                  | 0.85 ~ 1.05     | PASS         |
| 0.702           | 0.719            | 186        | 39022                | 39895           | 1.02                  | 0.95 ~ 1.05     | PASS         |
| 1.000           | 1.025            | 201        |                      |                 |                       |                 |              |
| 2.000           | 2.049            | 250        |                      |                 |                       |                 |              |
| 5.008           | 5.132            | 422.3      |                      |                 |                       |                 |              |
| 6.976           | 7.148            | 503.6      |                      |                 |                       |                 |              |
| 10.02           | 10.27            | 607.3      |                      |                 |                       |                 |              |
| 14.97           | 15.34            | 791.6      |                      |                 |                       |                 |              |
| 20.00           | 20.49            | 975.3      |                      |                 |                       |                 |              |

\* Aero. Size stands for aerodynamic diameter.  $Dp_{geo} = Dp_{aero} / \sqrt{RT(pp)}$

\* Detection Efficiency = Measured Counts / Reference CPC Counts

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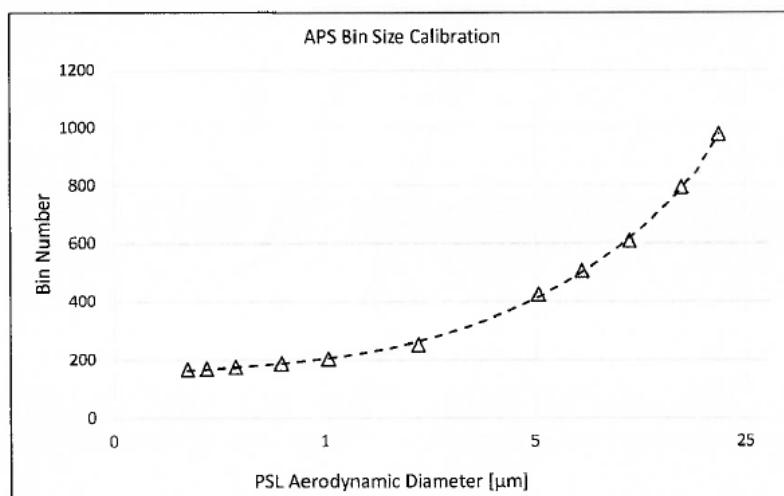
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# INNOVATIVE BIOANALYSIS

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TSI PN 2000157



\*Spline fitting of the calibration points is saved in the APS firmware for calculating the aerodynamic diameters reported by the instrument.

Reference Calibration Document: TSI Doc. No. 10000046885, Rev. A

Calibrated by: Lynn Anderson  
Service Technician

Signature:

*Lynn Anderson*

Date of Calibration: 4/13/2022

Reviewed by: Annette DeWitt

Signature:

*Annette DeWitt*

Date of Review: 4/13/2022

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Test sheet

TEST SHEET

Product:      GASERA ONE FORMALDEHYDE

Serial number: 040033

Date: 2024-05-30

Initials:            IP

Parameters

| Channel | CIT, Channel integration time [s] | CIT multiplier |
|---------|-----------------------------------|----------------|
| HCHO    | 0.5                               | 12             |

Target pressure200 mbar

Detection limits and repeatability

| Gas  | Detection limit* [ppb] | Repeatability** |
|------|------------------------|-----------------|
| HCHO | 0.74                   | 0.6%            |

\*Method: 2 times standard deviation of 10 consecutive measurement points in zero gas measurement, scaled to 60 s response time  
\*\*Method: Ratio of standard deviation to the average of 10 consecutive measurement points in the highest concentration in the linearity test

Span gas test

| Gas  | Sample concentration [ppb] | Measured concentration* [ppb] | Relative error -% |
|------|----------------------------|-------------------------------|-------------------|
| HCHO | 394                        | 392.8                         | -0.29             |

\*Method: Average of 10 consecutive measurement results

Measurement response time

Average 40 seconds with default gas exchange cycles, channel integration times (CIT) according to "Parameters" table above.

Calibration gases and concentrations

| Gas           | Concentration                                         | Accuracy*         |
|---------------|-------------------------------------------------------|-------------------|
| Synthetic air | 100%                                                  | Purity: grade 5.5 |
| HCHO*         | 394 ppb                                               | ± 5%              |
| H2O**         | Multipoint:<br>24000ppm, 20000ppm,<br>10000ppm, 0 ppm | ± 2%              |

\*Defined by the gas vendor  
\*\*Accuracy by Gasera sample generation system

# INNOVATIVE BIOANALYSIS

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Maintenance sheet

## MAINTENANCE SHEET

Product: GASERA ONE  
Serial number: 040033

Date: 2024-06-04  
Initials: IP

Customer reference:  
Gasera reference: G-RMA-00267

### Maintenance request

Scheduled maintenance.

### Maintenance actions

- Particle filters changed
- SMARC battery changed
- New wedge windows
- Leak test
- Re-calibration
- Performance tests
- Updated Test Sheet

Gasera Ltd | Lemminkäisenkatu 59, 20520 Turku, FINLAND | [www.gasera.fi](http://www.gasera.fi) | [contact@gasera.fi](mailto:contact@gasera.fi) | Business ID : 1930453-0