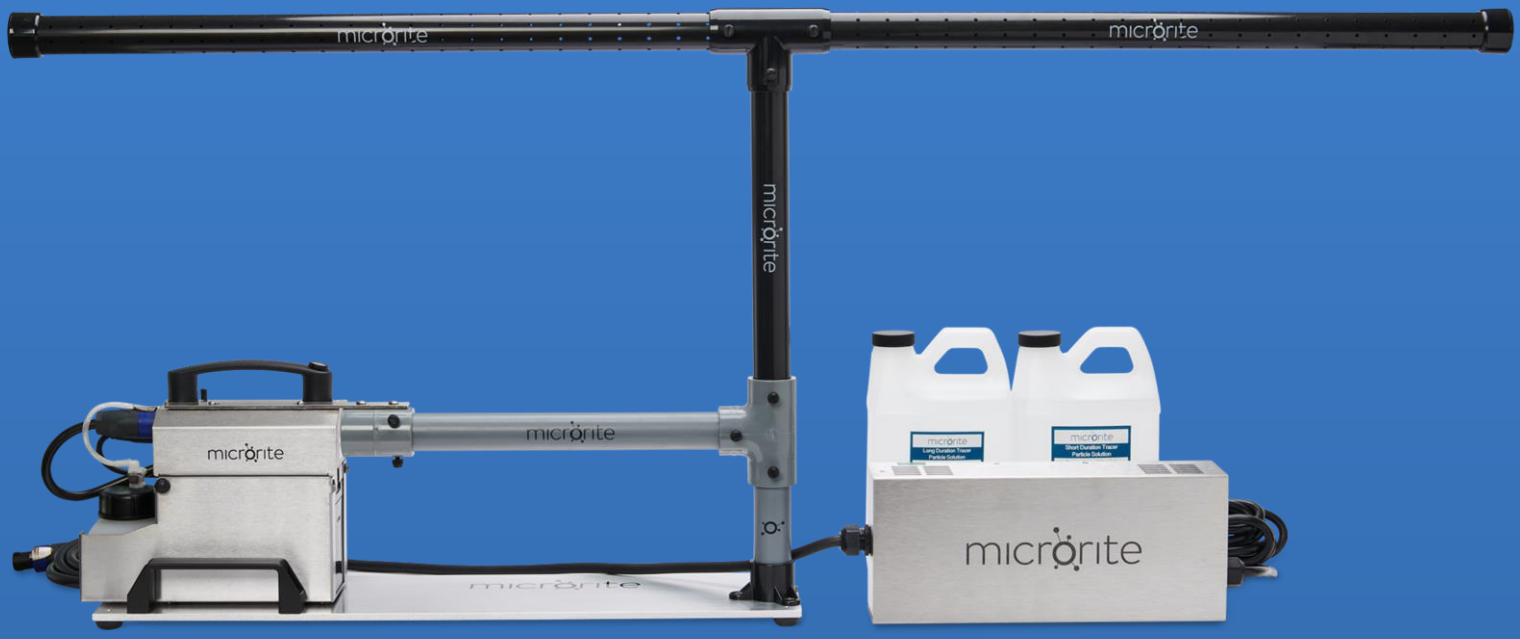
CALIBRATED SYSTEM FOR SMOKE STUDIES & RECOVERY STUDIES

Tracer Particle Generator System TPG-M1

The calibrated Tracer Particle Generator system produces Neutrally Buoyant, long lasting, submicron Tracer Particles for accurate airflow visualization in cleanrooms and controlled environments.



The TPG-M1 includes

1. **A high output Cleanroom Vaporizer which creates a sterile vapor with no combustion by-products**
2. **Extremely low vapor pressure Tracer Particle Solution for a long lasting visible fog**
3. **A fully configurable Diffuser Manifold System that converts the vapor into a stable tracer particle at atmospheric temperature and pressure**

NEUTRALLY BUOYANT TRACER PARTICLES

Cleanroom and controlled environments require clean air flow (typically produced by HEPA or ULPA filtration). Because clean air flow is critical to contamination control, understanding, characterizing or mapping air patterns in cleanrooms or contolled environments is an important part of contamination control.

In medical product cleanrooms, the FDA, PIC/S, EMA, WHO require [1]In situ Air Pattern Analysis (Smoke Studies or Air Flow Visualization) of cleanrooms and barrier systems that are expertly reviewed with written conclusions. Additionally, the studies are to be captured on video for review. [2] International cleanroom standards, cGMP guidance and [3]cleanroom testing practices indicate "Neutrally Buoyant Tracer Particles" for Air Flow Visualization. The Tracer Particle Injection Method as defined in ISO 14644-3:2019 requires the tracer particles are not be so large that gravity causes them to diverge from following the actual air flow being observed.

Microrite's Tracer Particle Generator system provides a cloud of Tracer Particles that are submicron (<1.0 micrometer/micron) in size and are Neutrally Buoyant. These long lasting, Neutrally Buoyant Tracer Particles are ideal for getting a visual representation of air flow patterns in cleanrooms, barrier systems and the interfaces between areas of different classifications (e.g., Grade A/ISO Class 5 and Grade B/ISO Class 7 areas).

The Tracer Particles used by Microrite, Inc. are **NOT SMOKE PARTICLES**. When properly diffused, a Neutrally Buoyant cloud-like fog of Tracer Particles sized between 0.3µM and 0.5µM is released into the cleanroom environment. These sterile particles are comprised of USP Grade Materials Such as Triethylene Glycol, Monopropylene Glycol, Dipropylene Glycol and purified water. The cloud of Tracer Particles is oil and glycerin free, non-condensing, FDA GRAS approved and is non-toxic. For typical Air Flow Visualization Studies, this fog does not condense and pool up on cleanroom surfaces or cleanroom equipment.

The Tracer Particle Solution is vaporized at ~320˚C creating a sterile and hot vapor that exits from the cleanroom vaporizer into an expansion chamber, mixing with inlet air and traveling via a high temperature silicone tube to the Diffuser System. The Diffuser System/Manifold releases a cloud of very small Tracer Particles that cool when exiting the diffuser becoming Neutrally Buoyant when entering the air stream. Neutrally Buoyant Tracer Particles are not affected by gravity and will accurately follow the air currents and identify turbulence, dead spaces and eddy currents.

Long Lasting Neutrally Buoyant Tracer Particles Visualize Air Mixing

Tracer Particles should remain visible from where they are diffused into the clean air system being tested all the way to the air return. This allows for the visualization of air flow directions and air mixing in both unidirectional and non-unidirectional air flow cleanrooms. Microrite Tracer Particles have an extremely low vapor pressure, creating Tracer Particles that take up to 20 minutes to evaporate making the TPG suitable for cleanroom recovery studies as well.

More importantly it allows for visualization of Combination-Flow cleanrooms and the interface between unidirectional and non-unidirectional air flows. This is extremely important in aseptic manufacturing where visualizing air flow in conjunction with operator movement at the interface between Grade A and Grade B is critical to the evaluation, qualification and regulatory review of aseptic operations.

Diffuser System

A Diffuser Manifold is required to properly introduce the Tracer Particles into a cleanroom. Inside the manifold the vapor cools and mixes with air forming a cloud of tracer particles at ambient temperature and pressure while avoiding fully condensing back into a fluid. This removes the jetting effect of shooting the Tracer Particles in a single direction (Often Downward) that may falsely demonstrate unidirectional airflow when dead spaces and eddy currents are apparent. In addition, excess condensation of the Tracer Particles on surfaces in the cleanroom is avoided since the fog exits the manifold at the same temperature and pressure as the cleanroom environment. [3]Water, CO2 or Nitrogen Based "Cleanroom Fogging Systems" Tracer Particles are NOT Neutrally Buoyant and cannot visualize dead spaces or areas where there is no air flow.

1) **FDA Guidance for Industry: Sterile Drug Products Produced By Aseptic Processing - Current Good Manufacturing Practice, September 2004**

2) **ISO 14644-3:2019 Cleanrooms and associated controlled environments- Part 3:Test Methods:**
- **B.3.3.2 Tracer injection method**
- **C.4.4.3 Fog generator, to generate aerosols (mists). A thermally produced aerosol of DI water/glycols/alcohols**
"Apparatus such as a tracer particle generator"
"The test is carried out by observation or imaging of the behaviour of tracer particles"

3) **CETA Certification Guide for Sterile Compounding Facilities CAG-003-2006 -13 Revised May 20, 2015**

SPECIFICATIONS

Tracer Particle Generator/Cleanroom Vaporizer (Microprocessor Controlled)	**Two Modes of Operation:** Attached Battery or External Power Supply For Uninterrupted Operation
NIST Calibration (with Diffuser Manifold)	Particle Size Ratio 0.3µM / 1.0µM >20:1
Material	Stainless Steel
Operating Voltage	12 VDC, 400 Watt output
Warm-up Time	1 Second
Fluid Reservoir	250 mL
Fluid Consumption	10 mL/minute at maximum setting
Control	Start Button or Radio Remote (Included)
Dimensions (CRV-M1)	8.7" X 3.9" X 8.27" (22.3 cm X 10 cm X 21cm)
Weight (CRV-M1) (with Battery)	12.4 lbs (5.6 kg)
Battery: Non-Spillable Valve Regulated Lead-Acid: Trickle Charger Included Meets Transportation regulations via truck, rail, ocean & air transportation • DOT requirements: 49 CFR 173.159 (d) • IATA, ICAO requirements Special Provision "A67" for air transportation	**Fully Charged Battery Operation** • Approximately 100 vapor emissions of 4-5 seconds. • Approximately 10 minute vapor emission continuously Battery Re-Charging Time: Approximately 13 Hours (Based upon fully discharged battery)
Universal Power Supply **Material** **Input Voltage** **Output Voltage**	Uninterrupted Continuous Operation Stainless Steel Enclosure 100-240 VAC 50/60 HZ 12 VDC @ 20 amp
Dimensions	12" X 5" X 2.75" (30.4 CM X 12.7 CM X 6.9 CM)
Weight	9.6 lbs (4.35 kg)
Diffuser System	**Connection Via High Temperature Silicone Hose**
Flexible, Adaptable, Configurable Manifold System	Professional Manifold Available
Tracer Particle Solution	**USP Grade:** Triethylene Glycol, Monopropylene Glycol, Dipropylene Glycol and Purified Water
Long Duration Tracer Particle Solution	For non-unidirectional flow cleanrooms and larger areas **(Required for Recovery Studies)**
Short Duration Tracer Particle Solution	For small spaces, Isolators, RABS, BSCs, laboratories **(Do Not use for Recovery Studies)**

WHAT IS INCLUDED

- Cleanroom Vaporizer
- Diffuser Manifold (2 Ft)
- Silicone Hose
- Battery Base
- 4 Liters of TPG Solution (2L Long Duration & 2L Short Duration)
- Battery Charger
- Remote Control (Receiver and Transmitter)
- Flight case
- Universal AC Power Supply (100-240VAC 50/60Hz)

OPTIONS

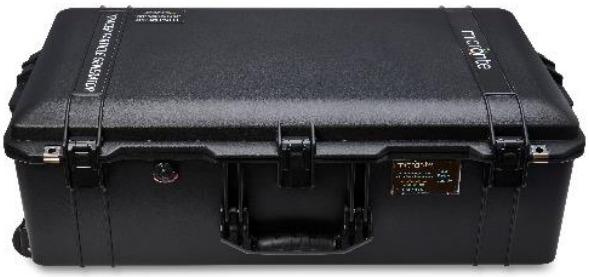
Spare Battery: Non-Spillable Valve Regulated Lead-Acid:

- Meets Transportation regulations via truck, rail, ocean & air transportation
- DOT requirements: 49 CFR 173.159 (d)
- IATA, ICAO requirements Special Provision “A67”
- Approximately 100 vapor emissions of 4-5 seconds/Charge or 10 minutes of vapor emission at continuous operation.
- Battery requires approximately 13 hours to fully charge.

PROFESSIONAL MANIFOLD SYSTEM

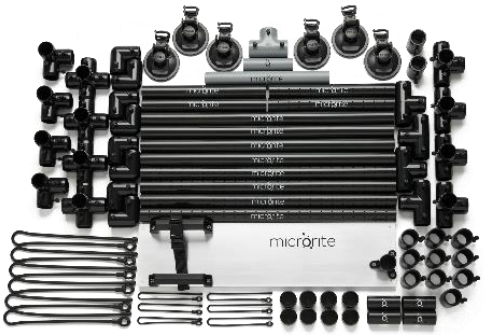
Professional Manifold System:

Configurable Manifold System for RABS, Isolators, Flow Hoods, Lyophilization Loading Areas, Pass-Throughs, Doors and Mobile HEPA Carts

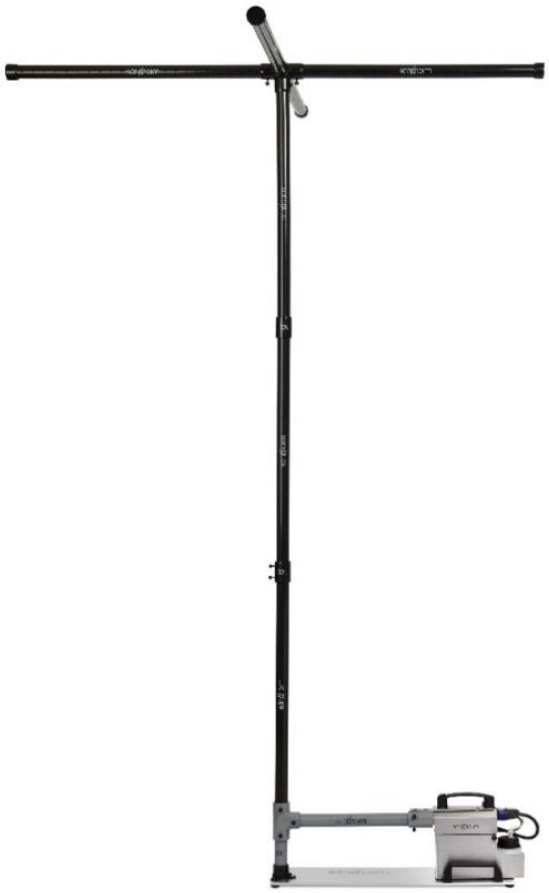


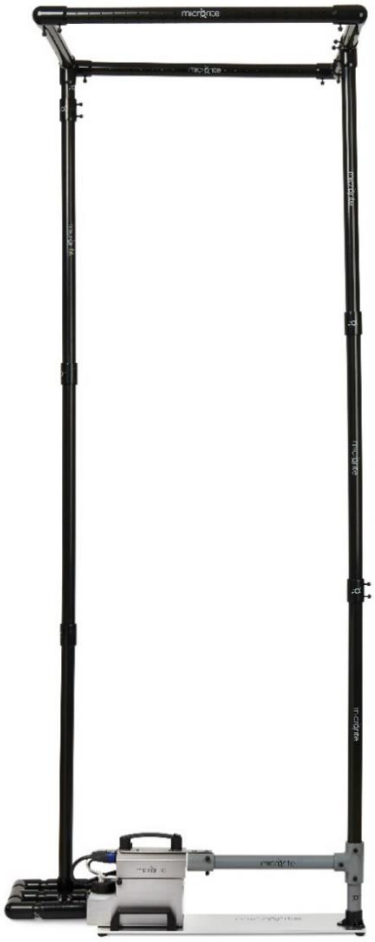
Includes:

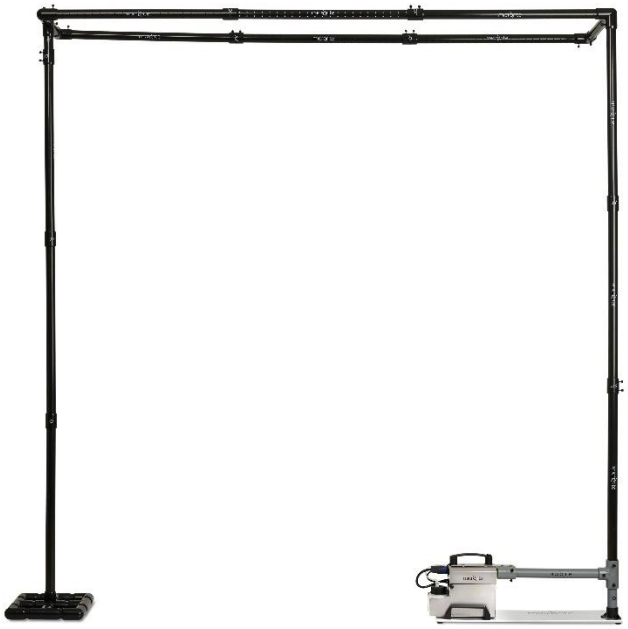
(1) Base Plate Stand I (2) 3” Diffusers
(6) Suction Cups I (4) 24” Blanks
(6) 24” Gear Ties I (2) 12” Diffusers
(6) 12” Gear Ties I (2) 12” Blanks
(4) 24” Diffusers I (2) 3” Blanks
(6) Diffuser Couplings with Locking Screws I (4) Three Way Couplings
(6) Couplings with Locking Screws I (4) Four Way Couplings
(4) Tee Fittings I (4) 5 Way Couplings
(8) Elbows I (8) End Caps

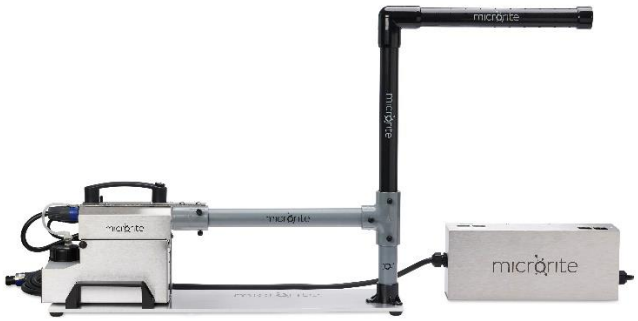


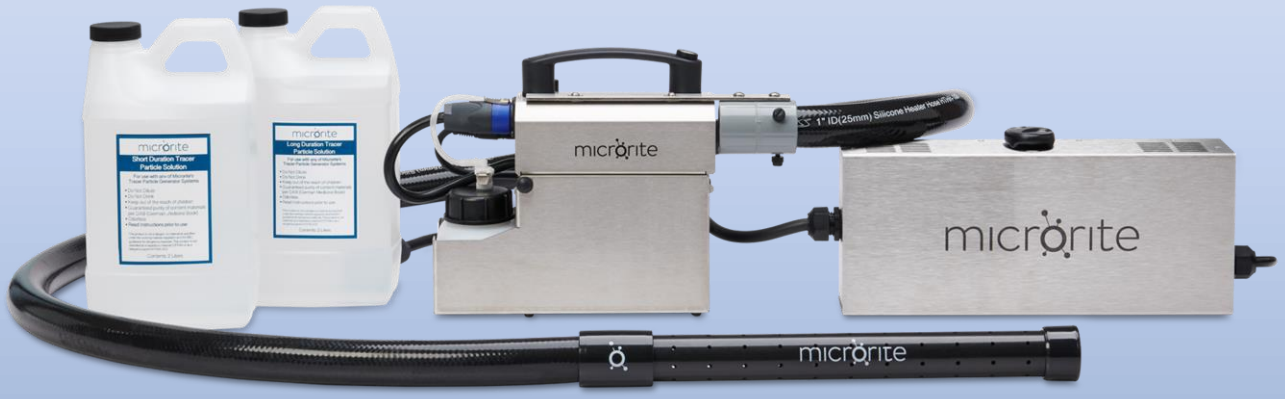
EXAMPLE MANIFOLD CONFIGURATIONS











microrite
Cleanroom Solutions

T: 833-TPG-SYS1 or 833-874-7971
E: support@microrite.com
www.tracerparticlegenerator.com

Download our whitepaper