TOMI ENVIRONMENTAL SOLUTIONS | STERAMIST DISINFECTION & DECONTAMINATION iHP® | ionized HYDROGEN PEROXIDE

SIX 99.9999% LOG

EPA REG

ONE TECHNOLOGY, ENDLESS APPLICATIONS.

Patented iHP® Disinfection & Decontamination

DECON THAT DOES IT ALL.

- ✓ Six-Log Broad Spectrum Reductions
- ✓ Powered by Cold Plasma Science
- ✓ 4x Faster than Competitors
- ✓ Superior Material Compatibility
- ✓ No Mixing, Wiping, or Residue

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TCA | Total Clean Air

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ABOUT **TOTAL CLEAN AIR**

With over 30 years of experience in cleanroom design and construction, Total Clean Air is one of only two UKAS 17025-accredited cleanroom contractors in the UK, building cleanrooms to ISO 14644, EU GMP Annex 1, and all major international standards.

Provided services include initial feasibility and cleanroom consultancy through design, construction, IQ/OQ/PQ commissioning, validation, and ongoing maintenance and servicing.

Our technical authority is independently recognized. We are CPD-certified training providers, and our Technical Director sits on the British Standards Committee for ISO 14644. We also offer comprehensive environmental monitoring, EMS and BMS solutions, active air sampling, settle plates, and full laboratory analysis via ISO 17025-accredited partner Charles River.

Presented by

PHILLIP GODDEN

With a rich career spanning over thirty years in the pharmaceutical, healthcare, and defense sectors, Phillip serves as the Founder and CEO of Total Clean Air, where he channels his extensive experience into leading his enterprise to the forefront of the cleanroom and containment industry. Total Clean Air is renowned for its pioneering solutions, trusted by the world's most prestigious pharmaceutical and healthcare institutions.

ORIGINS OF iHP® AT **DARPA**

SteraMist® iHP® technology began as a project funded by the U.S. Defense Advanced Research Projects Agency (DARPA) in 2004 as a U.S. military defense response to the 2001 anthrax (Amerithrax) attacks. Highly promising results lead to the successful deployment of SteraMist® technology against biological warfare agents.

These initial findings revealed application potential beyond combating BWA/CWA, including applications ideal for the decontamination of biosafety cabinets and other controlled environments.

HIGH EFFICACY	RAPID ACTION	OPTIMAL SCIENCE	HVAC ENVIRONS	MATERIAL COMPATIBILITY
>7–9 log reduction against Bacillus spore surrogates.	Reduction occurred during exposure to spray within seconds/minutes.	Ionized mist exhibited higher ROS availability correlating with log reduction.	Achieved ~7-log reductions in moving-air tests.	Low H_2O_2 exposure estimate and minimal material change under extreme testing.

EPA REGISTRATION **MILESTONE**

After the anthrax attacks, SteraMist® embraced mainstream availability as the very first EPA-registered solution and technology combination. As a Hospital-Healthcare disinfectant, SteraMist® has continuously validated with the EPA to expand its application potential while also consistently validating performance with third-party laboratories.

SteraMist® is also validated against *Geobacillus stearothermophilus* with a six-log (or greater) reduction.

EPA LIST	ORGANISM
LIST G	Norovirus
LIST H	MRSA
LIST K	*C. difficile/C. auris*
LIST L	Ebola
LIST M	H1N1
LIST N	SARS-CoV-2
LIST Q	Emerging Viral Pathogens

STERAMIST® **BINARY IONIZATION TECHNOLOGY (BIT®)**

STERAMIST® TECHNOLOGY
Proprietary components exclusively for use with and optimized for BIT® Solution.

BIT® SOLUTION
7.8% hydrogen peroxide sole-active ingredient exclusively for use with SteraMist® technology.

MATERIAL COMPATIBILITY TESTING

As an EPA-registered disinfectant, SteraMist is subjected to many material compatibility tests. While a standard iHP® cycle consists an injection phase (seconds to minutes), a short dwell phase, and an aeration phase, testing included a full 10-day submersion in BIT® Solution. SteraMist contains no dyes, fragrances, chlorine, ammonium, bleach, or silver ions, resulting in gentle applications that achieve reductions and expand equipment lifespans.

FABRICS	METALS	CLEANROOM
During a 10-day study, common fabrics found in healthcare environments were immersed in standing liquid BIT® Solution consisting of 7.8% hydrogen peroxide per inactivated gallon. Standard protocol is to spray for seconds or minutes, not to immerse in BIT® solution for 10 days.	A similar 10-day study submerged 33 different metals and 6 non-metals commonly used in aerospace industries, with each sample was pulled at 24-hour intervals for observation before being returned to the BIT® solution. TOMI protocol is to spray for seconds or minutes, not for any metals or materials to be immersed for 10 days in our solution.	A final test simulated a cleanroom containing PVC, doorknobs, light switches, and hanging material samples. The area was subjected to 160 hours and 1000 cycles of injection - an amount far in excess of the scope of recommended SteraMist treatment intervals. TOMI protocol is to spray for seconds or minutes, not for 160 hours of injection.
After the 10-day immersion test, the results indicated insignificant changes to mass, color, and texture over the duration of the test.	Even after 10 days of immersion in BIT® solution, brass, nickel, copper, and stainless steels indicated only a negligible change in mass, with some having as little as a 0.1% reduction in weight.	After 1000 uninterrupted cycles, results consistently indicated only negligible, primarily visual damage (white powdery film).

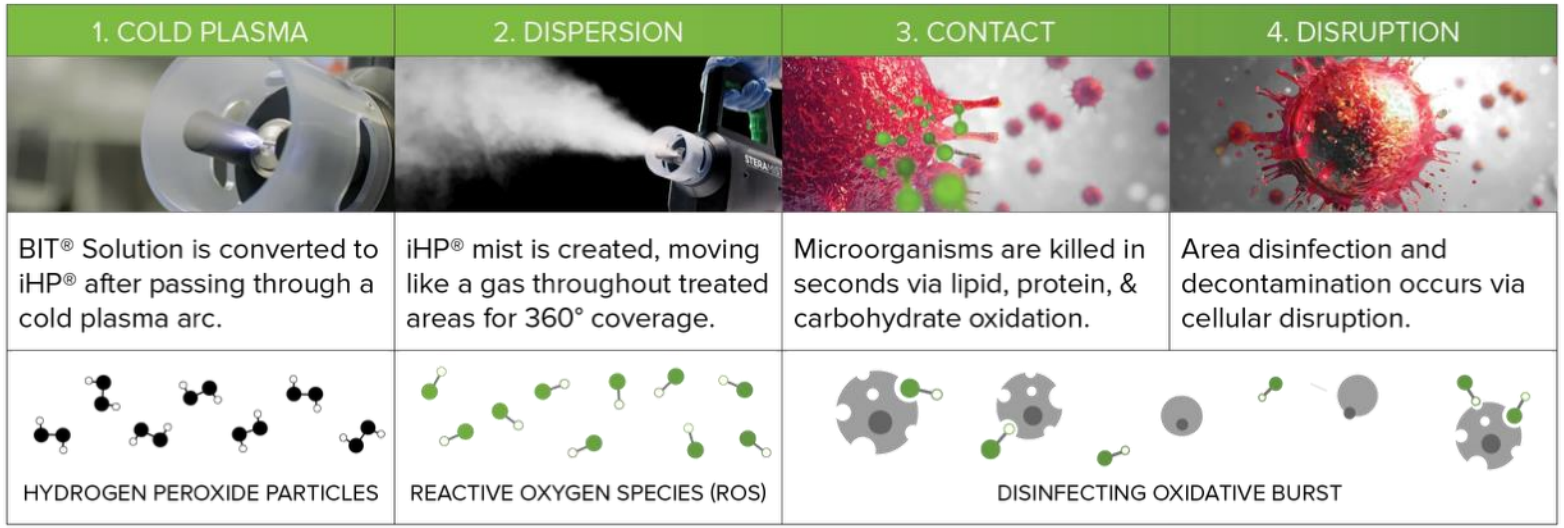
THE **SCIENCE** OF iHP®

Unlike other cleanroom decontamination methods, SteraMist® avoids the corrosion often associated with high concentrations of hydrogen peroxide or abrasive additives. This is made possible through the ionization of proprietary 7.8% hydrogen peroxide BIT® Solution using cold plasma Binary Ionization Technology (BIT®).

Cold plasma ionization via applicator arc creates an optimal amount of reactive oxygen species (ROS) for any given space with the added benefit of efficacy without raising ambient temperatures in any environment – critical for maintaining delicate cleanroom and testing space conditions.

SUBMICRON PARTICLES

iHP® cold plasma science ionized a lightweight mist, providing a charge to particles as small as 30-40 nanometers. This microscopic size and maneuverability leads to the even treatment of workspaces and filtration systems.



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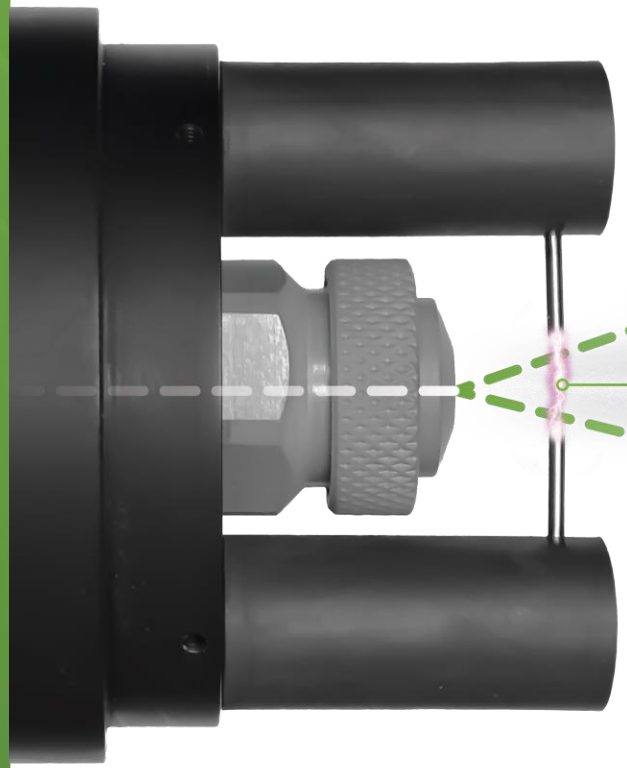
7.8% Hydrogen Peroxide Sole-Active Ingredient BIT® Solution **(Pre-Ionized)**	**iHP® is *not* simply heated H_2O_2 vapor.** The cold plasma arc on the applicator level is *non-thermal*, ionizing the 7.8% BIT® Solution to create a fine, dry mist of ROS.	Rather than rely on simple H_2O_2, iHP® ROS mist disperses evenly, **destroying microbes nearly on contact via organic oxidation.**



Gentle, non-corrosive mist of ionized particles **maintains the lifespan of aseptic enclosures.**

Cold Plasma Arc

Broken H_2O_2 bonds form hydroxyl radicals **with particle sizes as low as 30-40 nanometers**

METHOD COMPARISON

While hydrogen peroxide is already a common component of most biosafety cabinets, vaporized hydrogen peroxide is counted among modern cleanroom standards. However, ionized Hydrogen Peroxide (iHP®) stands out in critical ways. From simpler solution composition, less active ingredient, reduced size, and improved cycle speeds, SteraMist® offers notable benefits that can exceed those of hydrogen peroxide vapor, chlorine dioxide, and formaldehyde.

	FUNCTION	COMPATIBILITY
STERAMIST® iHP®	**Decon, Sterilize**	**Does not damage surfaces.**
Vaporized Hydrogen Peroxide	Decon, Sterilize	Repeated use damages plastics/rubbers.
Chlorine Dioxide (ClO_2)	Decon, Sterilize	Corrosive to electronics & materials.
Formaldehyde	Sterilize	Highly corrosive.

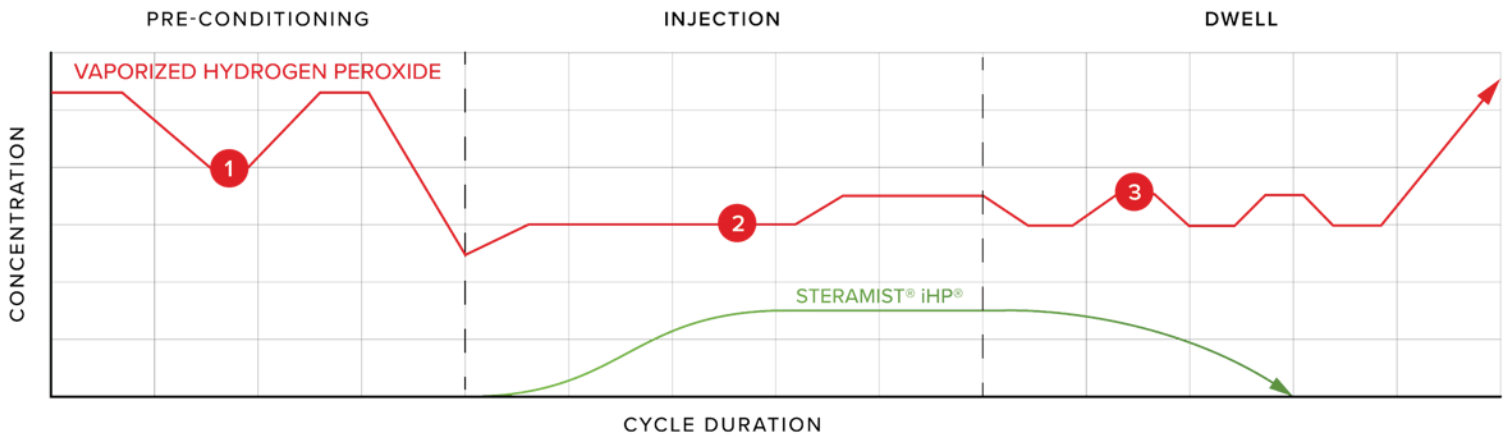
	High Log Efficacy	Electronic Compatibility	No-Touch Disinfection	No Mixing	No Bleach/ Acid/Chlorine	Even Dispersion	Submicron Size	Quick Application	No Residue
STERAMIST®	■	■	■	■	■	■	■	■	■
Hydrogen Peroxide Vapor	■	■	■	■		■	■	■	■
Chlorine Dioxide (ClO_2)	■		■			■			
Formaldehyde	■		■		■	■			

iHP® vs VHP

While many confuse ionized Hydrogen Peroxide (iHP®) with vaporized hydrogen peroxide, the differences between both are distinct.

While vaporization is achieved via heating, ionization is achieved by cold plasma. Vaporized hydrogen peroxide requires the maintenance of specific conditions to exist and treat spaces.

Many cabinets with existing fittings designed for vaporized hydrogen peroxide easily accommodate iHP® hardware.



	VAPORIZED HYDROGEN PEROXIDE	IONIZED HYDROGEN PEROXIDE
1	**Air/humidity must be removed** via vacuum to enable VHP injection without condensation.	iHP® does not require pre-conditioning. **No vacuums. No pre-treating. No condensation.**
2	**35% H_2O_2 is vaporized at 100°C** and injected into the space to reach 1-2mg/L.	The dry mist of iHP® is injected to quickly fill enclosures **below saturation without over-wetting**.
3	**Vapor is continuously pulsed** into the space with air or steam maintaining the vacuum.	iHP® is dissipated, exhausted into duct, or circulated to treat filters. **No lengthy, complicated pulsing.**

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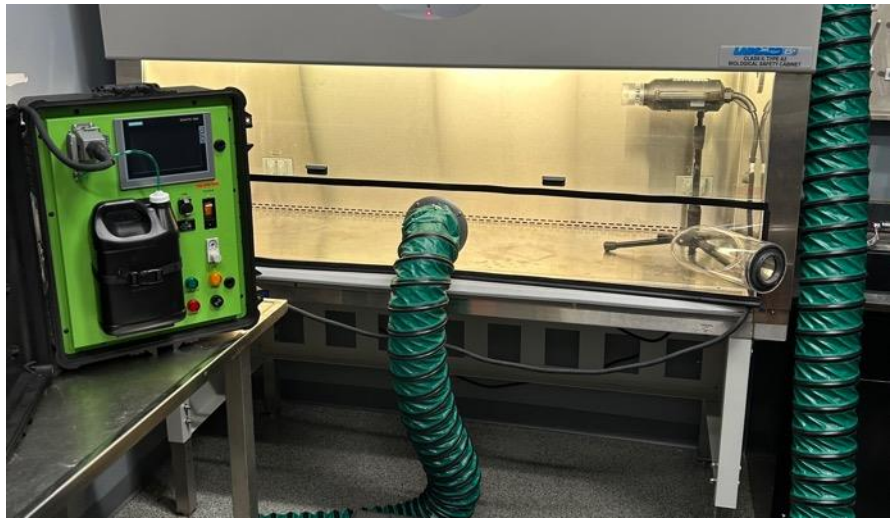
BIOSAFETY CABINET **VIABILITY**

SteraMist® iHP® technology remains chemically and conceptually unchanged since its early stages of research and development, meaning use in all Class II biosafety cabinet types (A1, A2, B1, and B2) is still entirely viable.

Whether permanently integrated or disinfected via external generator, SteraMist® has successfully been deployed to treat cabinets of every category, from biosafety cabinets and barrier systems to sterilization chambers and material transfer hatches.

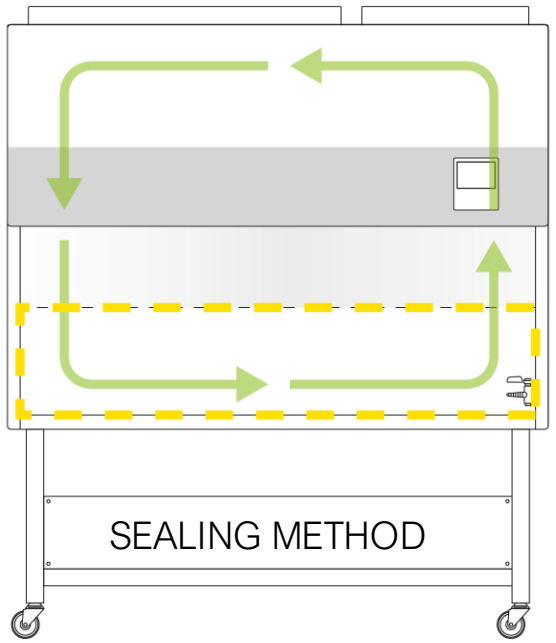


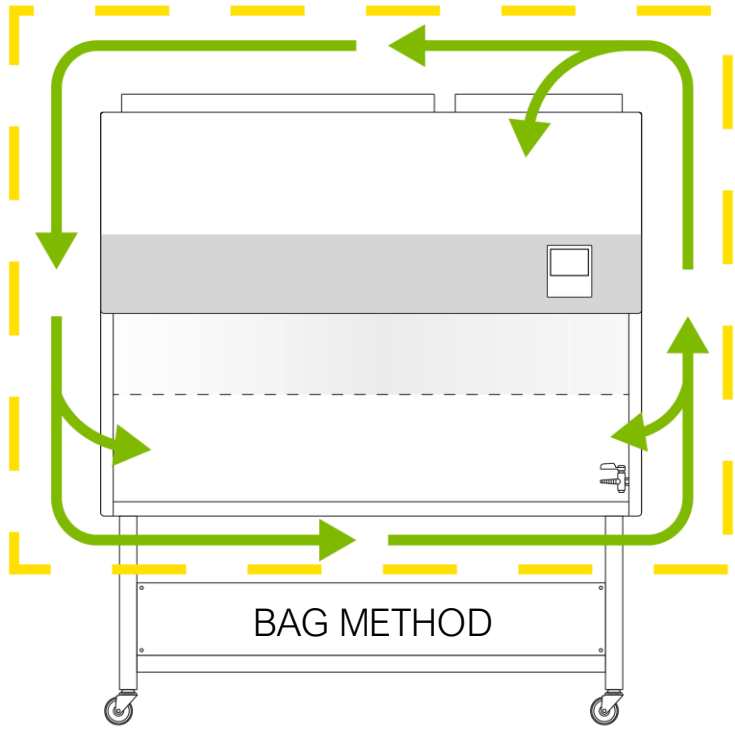
PROTOCOL **PARAMETERS**

PARAMETER	VALUE
BIT® Solution Volume	**6ft. Workspace:** 12 mL/ft³ of volume (w/ 10% worst-case reduction to 10.8 ml/ft³ for validation testing). **Workplace & Plenum:** 6 mL/ft³ of entire cabinet volume
H_2O_2 Concentration	7.8% BIT® Solution (EPA-Registered).
Monitoring	H_2O_2 probe within cabinet - readings every 10 minutes throughout application phase.
Blower Operation	BSC Internal Blower Paused During Cycle; External Blower Parameters (CFM) documented where used.
Aeration Threshold	H_2O_2 must reach ≤1.0 ppm before cabinet may be opened.
Dwell Time Safety Factor	10% reduction in dwell time compared to final published instructions (for validation worst-case scenario).

DECONTAMINATION METHODS

While sealed workspace depressurization is required during injection, SteraMist® treatment into controlled cabinets does not require active fan systems for aeration. The submicron particles of iHP® can easily reach and treat defined filter-facing and plenum locations without relying on active airflow.





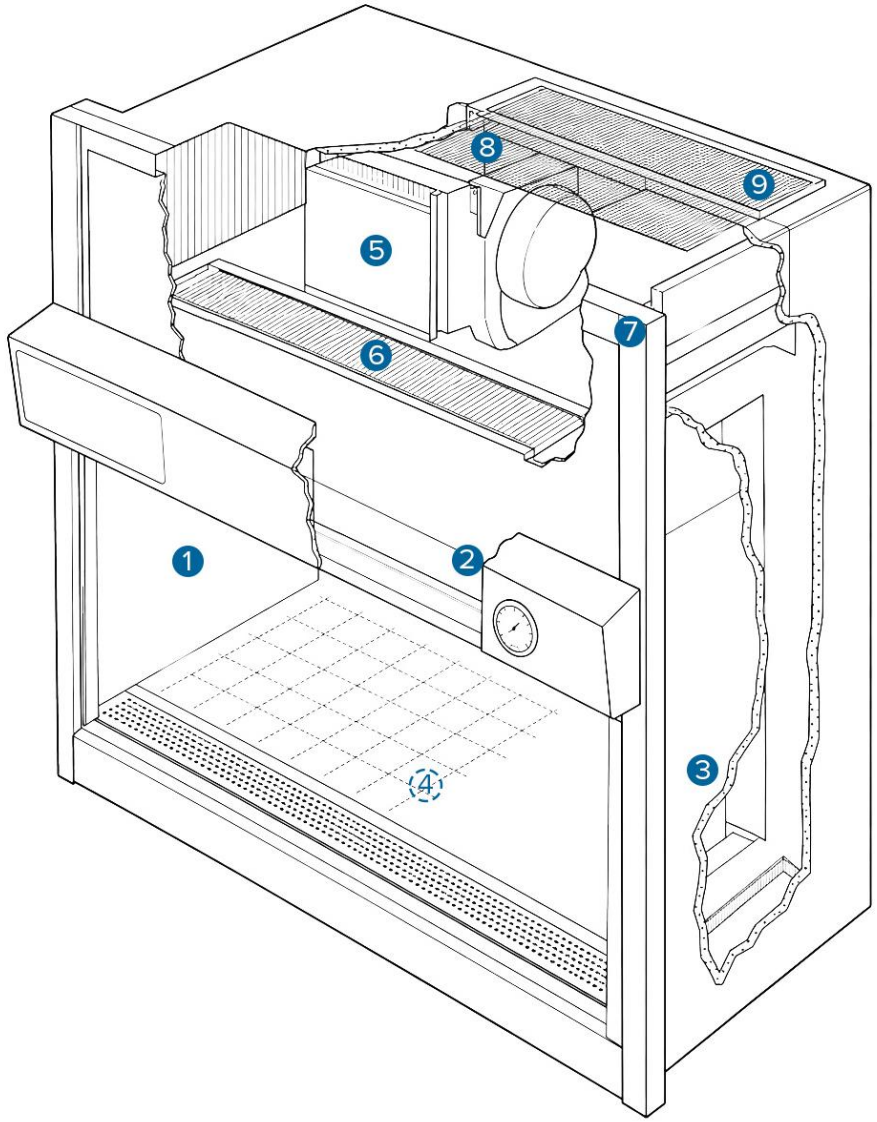
VALIDATION METHOD

Biological Indicators (BIs) will be used to verify the decontamination process. BIs to be used are 6-log *Geobacillus stearothermophilus* on a stainless-steel coupon. All BIs obtained for this testing will be from the same lot.

A minimum of nine (9) triplicate pairs of BIs and one CI for each triplicate shall be placed within the cabinet (BSC).

3x BIs & 1 CI WILL BE PLACED:

- 3x on the Left/Rear, Right Wall of Workspace
- 1x Beneath Workspace Surface
- 1x Within the HEPA Fan
- 1x on Plenum Floor
- 1x on Recirculated Air Filter
- 2x on Exhaust Filter



STANDARD OPERATING **PROCEDURE**

1. Purpose
To define the standardised method for delivering ionised hydrogen peroxide (iHP) decontamination of biosafety cabinets in full alignment with NSF protocol and TCA quality standards.

2. Scope
Applies to all TCA engineers performing iHP decontamination of biosafety cabinets under NSF-aligned validation and operational deployment.

3. Responsibilities
Engineers: Execute SOP and record data accurately.
Verifier: Independently check all recorded data.
Technical Manager: Final review and approval.

4. Pre-Deployment Checks
- ✓ Confirm cabinet type and condition
- ✓ Confirm decontamination scope
- ✓ Verify calibration of all instruments
- ✓ Confirm availability of BIs and consumables

5. Cabinet Preparation
- Calculate Internal Volume
- Install Indicators (Biological/Chemical) as Per Protocol
- Install Monitoring Probes
- Seal Cabinet and Exhaust Paths

6. iHP System Setup
- Confirm BIT Solution Concentration
- Verify System Integrity and Connect
- Set Parameters In Line with Protocol

7. Execution
- Initiate Cycle
- Monitor H_2O_2 Concentration Every 10 Minutes
- Monitor for External Leakage
- Record All Parameters in Real Time

8. Aeration & Safe Entry
- Continue Aeration Until ≤1 ppm
- Confirm Safe Access Before Opening

9. Post-Process
- Remove Indicators Aseptically
- Label and Record All Samples
- Transfer for Incubation or External Lab

10. Data Recording
- Record All Data Contemporaneously
- Ensure Dual Sign-off on All Entries

11. Deviation Management
- Record Any Deviation
- Escalate to Technical Manager
- Repeat Test (If Required)

12. Completion
- Confirm All Documentation Complete
- Submit for Review and Approval

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STANDARD **CYCLE**

Based on initial viability testing.

Overall Injection: 300mL
Overall Duration: 120 mins.

1. Deactivate Blower/Heater.
2. (Workspace Only) Inject 8mL/min for 37.5 minutes, activating Blower/Heater 2.5 minutes into injection.
3. Blower/Heater remains ON for an additional 82.5 minutes after injection completion.
4. Deactivate Blower/Heater and collect indicators after aeration.

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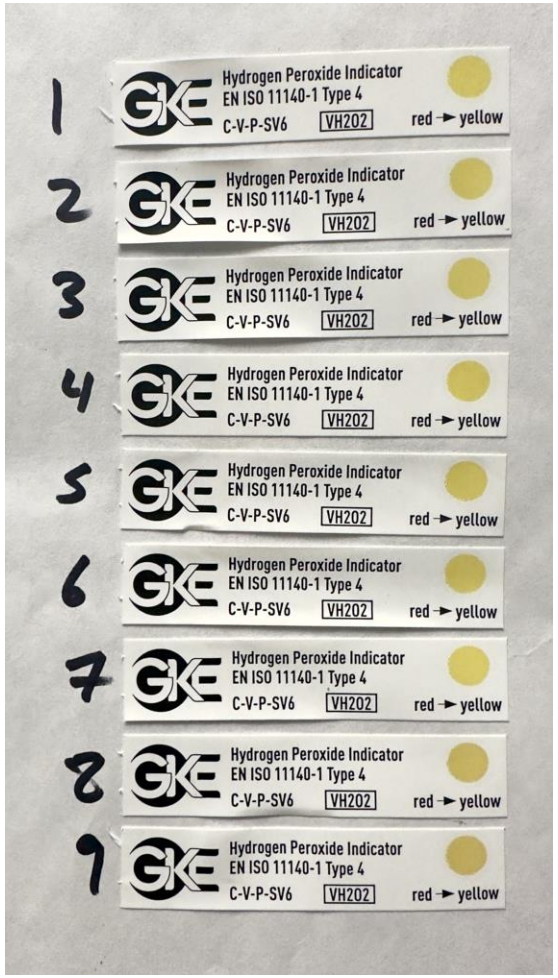
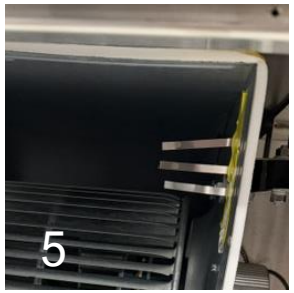
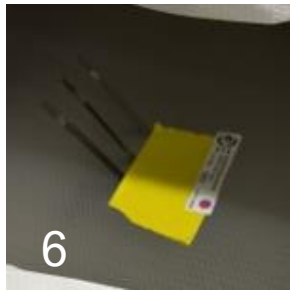
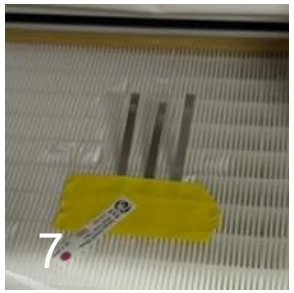
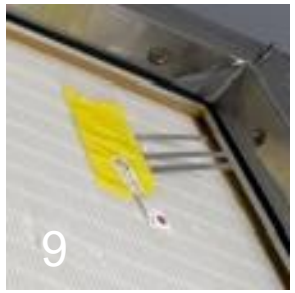
PLACEMENT & PROOF OF CONCEPT











THANK YOU

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