



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 13, 2020

Carrie Daniels
Authorized Representative
TOMI Environmental Solutions, Inc.
8430 Spires Way, Suite N
Frederick MD 21701

Subject: PRIA Label Amendment – Application to Add Emerging Viral Pathogens Claims to the Product Label.
Product Name: “Binary Ionization Technology (BIT) Solution”
EPA Registration Number: 90150-2
Application Date: January 29, 2020
Decision Number: 559855

Dear Ms. Daniels:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 90150-2
Decision No. 559855

with FIFRA section 6. If you have any questions, please contact Michael Varco by phone at 703-347-0403, or via email at Varco.Michael@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "John Hebert", with a stylized flourish extending from the end of the name.

John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

[Language in brackets are notes to reviewer]

(Language in parenthesis are optional and may or may not appear on the final label)

Binary Ionization Technology® (BIT™) Solution

(Alternate Brand Names:

SteraMist™ BIT™ Solution

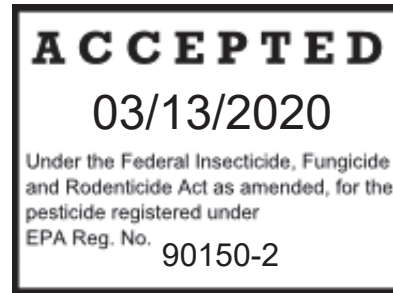
Binary Ionization Technology (BIT™) Plus

Binary Ionization Technology

BIT™

BIT™ Solution Ready-To-Use Hydrogen Peroxide

SteraMist™ BIT™)



{Begin Optional Front Panel Claims}

For use as a Healthcare-Hospital Disinfectant

(For use as a (Healthcare-Hospital) (Hospital-Healthcare) Disinfectant and (General Use)

(Multiple Use) (Disinfectant))

SteraMist™ Surface Unit:

(Bactericide¹

¹*Staphylococcus aureus* (Staphylococcus) (Staph) (ATCC #6538), *Pseudomonas aeruginosa* (Pseudomonas) (ATCC #15442), Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC #33592), and *Salmonella enterica* (Salmonella) (ATCC #10708)

Virucide²

²Influenza A virus (H1N1) (ATCC #VR-1469))

(Disinfects against *Staphylococcus aureus* (Staphylococcus) (Staph) (ATCC #6538),

Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442), Methicillin Resistant

Staphylococcus aureus (MRSA) (ATCC #33592), *Salmonella enterica* (Salmonella) (ATCC

#10708), and *Influenza A virus* (H1N1) (ATCC #VR-1469))

(For use in mold and mildew control and remediation for aesthetic purposes only)

SteraMist™ Environment System:

(Bactericide³

³*Staphylococcus aureus* (Staphylococcus) (Staph) (ATCC #6538), *Pseudomonas aeruginosa* (Pseudomonas) (ATCC #15442), *Salmonella enterica* (Salmonella) (ATCC #10708) and *Clostridium difficile* spores (C. diff) (ATCC #43598)

Virucide⁴

⁴Norovirus (Feline Calicivirus) (FCV) (ATCC #VR-782)

(Disinfects against *Staphylococcus aureus* (Staphylococcus) (Staph) (ATCC #6538),

Pseudomonas aeruginosa (Pseudomonas) (ATCC #15442), *Salmonella enterica* (Salmonella)

(ATCC #10708), *Clostridium difficile* spores (C. diff) (ATCC #43598), and *Norovirus* (Feline

Calicivirus) (FCV) (ATCC #VR-782))

{End Optional Front Panel Claims}

Active Ingredient:

Hydrogen peroxide 7.8%

Inert Ingredients 92.2%

total 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

FIRST AID	
If in Eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.
If on Skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment.	
For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center (1-800-222-1222).	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

See (back) (side) (right) (left) panel for additional precautionary statements
Net Contents: [as indicated on container]

EPA Reg. No. 90150-2 EPA Est. No. 72038-DE-001
(See (bottom) (side) (back) for Lot No./ Data Code, Product No., Expiration Date)

Questions? Comments? (symbol of telephone) Please Call: (1-800-525-1698)
Proudly Made in the USA

Contact TOMI™ at: +1.800.525.1698

Distributed by: TOMI™ Environmental Solutions, Inc., 5111 Pegasus Court, Suite A, Frederick, MD 21704 (or an authorized TOMI™ Environmental Solutions, Inc. distributor (insert name))

OR

Manufactured (for)(by): TOMI Environmental Solutions, Inc., 5111 Pegasus Court, Suite A, Frederick, MD 21704 (Available via Authorized TOMI Environmental Solutions, Inc. Distributor (insert name))

Binary Ionization Technology® (BIT™) is a licensed trademark of TOMI™ Environmental Solutions, Inc. USA

[Company logo] (Innovating for a Safer World)

(Use product only with SteraMist™ application equipment including the SteraMist™ Environment System and SteraMist™ Surface Unit equipment following detailed instructions provided in the SteraMist™ Binary Ionization Technology® (BIT™) User Manual.)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Liquid causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, or on clothing. Avoid contact with skin. Wear appropriate protective eyewear such as goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

For applicators and handlers of the SteraMist™ Surface Unit Hand Held equipment and for early re-entry for the SteraMist™ Environment System, the following PPE must be worn:

- Protective eyewear such as goggles or face shield, or safety glasses
- R95 or N95 Respirator (depending on environment) with Activated Charcoal Filter, Powered Air Purifying Respirator with organic vapor filter, or equivalent
- Gloves, long sleeves, and long pants.

Final selection of additional PPE must be done in accordance with hospital/site guidelines and take into consideration the use of the product as well as any infection or exposure hazards related to the environment to be disinfected.

PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with strong oxidizing and reducing agents.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Shade from radiant heat and direct sunlight. Stow away from powdered metals and permanganates. This product is for use in SteraMist™ application equipment only, including SteraMist Environment System or SteraMist™ Surface Unit, and by personnel trained by TOMI Environmental Solutions, Inc. Read and follow the Binary Ionization Technology® (BIT™) Solution (package insert) (and) (label) (and) (user manual(s)) for complete directions on pre-cleaning, sealing and use of Binary Ionization Technology® (BIT™) Solution in monitored and non-monitored applications. See SteraMist™ Binary Ionization Technology® (BIT™) User Manual for operating procedures of the SteraMist™ Environment System or SteraMist™ Surface Unit application equipment. Do not use this product without development of an appropriate fogging disinfectant plan as described in detail (in the attached package insert) (on the label). Do not deviate from standard cleaning procedures when using SteraMist™ application equipment. Binary Ionization Technology® (BIT™) Solution (fogging) (/) (misting) (/) (aerosolized spray) is designed to be the final step in standard cleaning procedures. Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices.

Microbial Disinfection

For use as a microbial disinfectant (fogging) (/) (misting) (/) (aerosolized spray) solution for disinfection of all dry, pre-cleaned, hard, non-porous, non-food contact surfaces in spaces and rooms. Do not deviate from standard cleaning protocols when using Binary Ionization Technology® (BIT™) Solution. Use product only with SteraMist™ application equipment such as SteraMist Environment System or SteraMist™ Surface Unit equipment following detailed instructions provided in the SteraMist™ Binary Ionization Technology® (BIT™) User Manual. Read and follow the directions (in the attached package insert) (on the label) on room

preparation, room set-up, treatment procedures, and equipment operating procedures for the specific SteraMist™ Environment System fogging/misting machine or SteraMist™ Surface Unit (aerosolized Spray) (application) equipment

Binary Ionization Technology® (BIT™) Solution should be used as part of a Hospital Disinfectant Plan. For complete guidelines on developing a Hospital Disinfectant Plan/General Disinfectant Plan/Mold Remediation Plan, refer to the (attached) (Package Insert) (label) (insert) or equipment User Manual.

- The SteraMist Surface Unit should be used when disinfecting (specific objects) ((and) (or)) (selected surfaces) with a directed, aerosolized spray from a distance of no more than 20 - 24 inches from the target surface.
- The SteraMist Environment System should be used when (all room surfaces) (the whole room) need(s) to be disinfected.

SteraMist™ Surface Unit Hand Held (Aerosolized Spray) (Application) Directions:

Use the SteraMist™ Surface Unit exclusively in conjunction with the Binary Ionization Technology® (BIT™) Solution. For use in pre-cleaned enclosures and on pre-cleaned equipment. Remove any visible gross filth from surfaces and objects before application. The product must be used as packaged and not diluted in any way. To be used only on hard, non-porous surfaces.

For use on surfaces in industrial, commercial, and institutional settings (see label for list of specific Healthcare Use Sites and Other Use Sites lists). Apply at a maximum distance of 20-24 inches for a minimum of 5 seconds over a contiguous 1 square foot treatment area. Allow a minimum contact time of 7 minutes for the surface to dry. Refer to the attached Binary Ionization Technology® (BIT™) Solution (Package Insert) (label) for complete application instructions.

SteraMist™ Environment System Room Fogging/Misting Directions:

Use the SteraMist™ Environment System exclusively with Binary Ionization Technology® (BIT™) Solution. For use in pre-cleaned enclosures and on pre-cleaned equipment. Remove any visible gross filth from surfaces and equipment before application. The product must be used as packaged and not diluted in any way. To be used only on hard, non-porous surfaces.

For use in sealed rooms in industrial, commercial, and institutional settings (see label for list of specific Healthcare Use Sites and Other Use Sites lists). The use rate to achieve a minimum airborne concentration of 150 ppm (parts per million) hydrogen peroxide is approximately 0.5 milliliters (ml) of product per cubic foot (ft³) of enclosure (room) volume. The application time needed to achieve the required concentration will vary depending upon the room size. Once the 150 ppm dose concentration is achieved, contact time must be maintained for a minimum of 15 minutes before initiating aeration of the room. Treatment area must remain unoccupied until a Drager, PortaSens or other monitoring device registers hydrogen peroxide levels at <0.2 ppm. Refer to the attached Binary Ionization Technology® (BIT™) Solution (Package Insert) (label) for complete application instructions.

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

- Personal Protection: Refer to label PPE requirements.
- Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection, by application with a clean cloth, mop, and/or sponge saturated with an EPA-registered sporicidal product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces.
- Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

For Mold Control and Mold Inhibition

Use only with SteraMist™ Surface Unit hand-held (aerosolized spray) application equipment. For use as a mold control and mold inhibitor during remediation of sealed, dry pre-cleaned hard non-porous surfaces located in industrial, commercial and institutional settings (Including production operations in pharmaceutical manufacturing such as clean rooms, laboratories, animal research facilities, hotel rooms, offices, cruise ships, and recreational facilities) [OR] (see (label) (above) for list of specific Healthcare Use Sites and Other Use Sites lists). This product is not intended for use on or to control mold on textiles or hard porous surfaces. This product is used to treat wood, wallboard, concrete, and masonry (cinder) block building materials which have been painted, coated or sealed. This product is intended to control and inhibit mold and mildew for aesthetic purposes only. Before applying this product, visible mold growth must be removed, and conditions favorable to mold growth must be identified and corrected.

Remedial Mold Treatment

This product must be used as part of a comprehensive mold remediation or water damage restoration program, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected surfaces to below 20% moisture content

For use on pre-cleaned hard non-porous surfaces. Apply at a maximum distance of 18 inches for a minimum of 30 seconds over a 1 square foot treatment area. Allow a minimum contact time of 5 minutes. The product is to be used as packaged and is not to be diluted in any way. Refer to the Binary Ionization Technology® (BIT™) Solution (package insert) (label) or equipment User Manual for complete application instructions.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Keep out of direct sunlight and away from heat. Do not freeze. Store in original closed dark plastic container in cool, dry area, at average/normal room temperature, away from small children and pets.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site

or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration. If product is leaking or spills should occur, please dilute with water and dry with absorbent material, or dilute with water as it is flushed into waste water drain.

EMERGING VIRAL PATHOGENS CLAIMS – Hard, non-porous surface

This product qualifies for off-label emerging viral pathogen claims as outlined in the EPA Emerging Viral Pathogen Guidance for Antimicrobial Pesticides when used in accordance with the appropriate use directions.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories: Enveloped viruses and Large Non-enveloped viruses. The use directions for which this claim is appropriate is against Norovirus (Feline calicivirus) (FCN) (ATCC # VR-782).

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Norovirus (Feline calicivirus) (FCN) (ATCC # VR-782)
Large, non-enveloped virus	Norovirus (Feline calicivirus) (FCN) (ATCC # VR-782)

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

Optional Marketing Claims: (note that these claims may or may not appear on the commercial label; in addition, the claims may be used as bullet points or in a paragraph format)

MISCELLANEOUS CLAIMS

Environment System and Surface Unit Claims

Easily incorporated into (current) cleaning procedures
Lightweight, easy to transport, and capable of achieving reliable disinfection
Self-contained, allowing for reliable disinfection
Easy to transport and can be configured to treat multiple spaces simultaneously
Scalable technology - able to use multiple units/applicators
Economical, (non-corrosive), and easy to apply
Disinfection efficacy against bacteria^{1,3}
Healthcare disinfectant
Hospital disinfectant
(General Use) (Multi Use) Disinfectant
Ready-to-use (formula), (no mixing required)
Go (Goes) above, beyond, under and around disinfecting sprays and wipes
Disinfects hard to reach hard non-porous surfaces in treated room
Disinfects high touch hard non-porous surfaces (in treated room)
Patented Technology
No Wipe, No rinse
Leaves no residues (no wiping necessary)
No wipe, no rinse, leaves no residues
This product contains the sole active ingredient hydrogen peroxide
Sole Active Ingredient is Hydrogen Peroxide
Sole active ingredient is low concentration hydrogen peroxide
(Economical and) easy to apply
Bleach (Chlorine) (Bleach and Chlorine) free (disinfection) (disinfecting) (disinfectant) (formula)
(Bleach and Chlorine) (Formaldehyde) (Glutaraldehyde) (Titanium dioxide) (Peracetic acid), free disinfecting formula
Silver ion free (disinfection) (disinfecting) (disinfectant) formula
Easy, Effective
Frequent (daily) use formula
Everyday formula
Great (suitable) for frequent (daily) use
Leaves (room) surfaces disinfected
No (mixing) (or) (dilution) (diluting) required
Patented (iHP) (Activated) (Ionized Hydrogen Peroxide) (AIHP) technology
When you re-enter the room, you can "smell the clean"
Deodorizing by (killing)(eliminating)(destroying) odor-causing bacteria^{1,3} at their source
No wiping, no mess
A powerful technology in fighting (and) (reducing) the spread of bacteria^{1,3} on treated surfaces
Does not contain particulate (heavy metals) (minerals) (dyes) (fragrances)
Saves time and labor
Fragrance free (no additives)
Scalable for multiple (zones), (rooms), (bays), (suites), (areas), (space), (nooks)
Steramist Surface Unit requires no room preconditioning after pre-clean
Does not require adjustment to (modification of) (specific) room temperature or humidity before

use (application)
Mobile (portable) for rapid deployment throughout a facility
Low operating and maintenance costs
The ultimate tool for elimination of bacteria^{1,3} in the (hospital) (lab) environment
Touchless (application) disinfecting solution
(Bactericidal^{1,3}) (Virucidal^{2,4})
Ideal for pandemic preparedness for listed organisms
A (preventative) (proactive) action reduces exposure to bacteria^{1,3} on treated surfaces
Does not contaminate the environment with any toxic by-products
Leaves environment with only oxygen and water (humidity)
Does not leave silver ions on surfaces or equipment
Reduces colonization of bacteria^{1,3} on treated surfaces
Disinfection for (unoccupied) (public) (common) spaces.
Optional Applicators for whole (complete) Room Disinfection or (Partial) Surface Disinfection.
Ideal for complete disinfection of (material) (and) (equipment) transfer between (barrier points)
(clean spaces) (clean areas)

Environment System Claims Only

For use in SteraMist™ equipment (technology) including (Binary Ionization Technology® (BIT™)) (fogging) (Environment System) (equipment) (by a trained technician or trained client)
For use in SteraMist™ (Binary Ionization Technology® (BIT™) (Environment System) (room) (fogger (s) (instruments) (device (s)) (fogger (s) system(s)
Room is safe to enter once hydrogen peroxide is below 0.2 ppm.
Effective whole (complete) room treatment (in just under 45 minutes for a room (18'8" x 16'8" x 11'9")/(3,663.7 ft³)/(104 m³) (including application time and contact time. Aeration time varies by environmental factors), (less time is typically needed for smaller size rooms))
Allows for complete room (disinfection) (and) (quick turnover)
Whole (complete) Room Disinfection (Disinfecting) (Disinfectant) (System)
Makes whole room disinfecting easier
Disinfect a typical two bed hospital room in just over 75 minutes, where a typical two-bed hospital room is (18'8" x 16'8" x 11'9")/(3,663.7 ft³)/(104 m³), (less time is typically needed for smaller size space)
(Whole) (complete) room disinfection
[Note to reviewer: where room dimensions are stated, one of the three dimensions will be used]

Surface Unit Claims Only

For use in SteraMist™ equipment (technology) including (Binary Ionization Technology® (BIT™)) (aerosolized spray) (application) (Surface Unit) (equipment) (by a trained technician or trained client)
For use in SteraMist™ (Binary Ionization Technology® (BIT™) (handheld) (Surface Unit) (aerosolized spray) (application) (instruments) (device (s)) (system(s)
(Allows for) quick⁵ room turnover
Efficient treatment time allows for quick⁵ room turnover
⁵Disinfection of high touch surfaces in a hospital room in just over 10 minutes, including application and contact time
Not dependent on the positioning of core equipment for effective disinfection
Surfaces in terminal clean rooms may be treated in (just) 15 minutes, for an average hospital room [Note to reviewer: one of the three dimensions will be used]
Mold (control) (and) remediation for aesthetic purposes only
SteraMist™ Surface Unit disinfects treated hard non-porous surfaces on high touch equipment
SteraMist™ Surface Unit disinfects hard non-porous high touch surfaces

SteraMist™ Surface Unit provides a fully portable, hand-held, point and spray application
SteraMist™ Surface Unit is applied in five seconds per square foot with a seven-minute contact time to disinfect

5-second direct application over contiguous surface (per square foot)/(1 ml per ft²) with the SteraMist™ Surface Unit [Note to reviewer: one of two application rate units will be used]

Surface Unit applications - simply spray surfaces for 5 seconds per ft² for disinfection

A powerful technology in fighting (reducing) exposure to bacteria¹ and viruses² on treated surfaces

Multiple Surface Units can reduce terminal clean rooms to (less than) 10 minutes

A (preventative) (proactive) action reduces exposure to bacteria¹ and viruses² on treated surfaces

GENERAL PRODUCT PERFORMANCE/USAGE CLAIMS

Environment System and Surface Unit Claims

Patented formula kills the bacterial cellular wall (to destroy) (which destroys) (destroying) the bacteria^{1,3}

Kills bacteria^{1,3} which may reduce your risk of exposure to bacteria on treated surfaces

Kills bacteria^{1,3} which may reduce the risk of potential exposure in treated (rooms) (space)

(Non vapor), (non vaporized) application

Application is not a vapor

Aerosolized application spreads like a gas

Aerosolized microns spread like a gas

Fully validated to comply with GMP (Good Manufacturing Practice) Standards

Product performance is supported by GLP efficacy data

(Low) (Limited) exposure (bottle) (cartridge) loading mechanism

Converts a liquid (solution) into a reactive oxygen species after passing through an atmospheric cold plasma arc

H₂O₂ converted by plasma science

Renders bacterial^{1,3} cells dead

Physical kill by destroying bacterial cell (C. diff spore) wall

(Covers) (Disinfects) (Treats) (Clings to) (Attaches to) the surface it touches

Uniform disinfection of all hard non-porous surfaces without corroding or oxidizing

Disinfection efficacy against bacteria^{1,3}

Effectively eliminates (pathogens^{1,3}) (bacteria^{1,3}) from hard, nonporous surfaces

Effective disinfectant against Salmonella enterica (Salmonella)

Effective disinfectant against gram positive and negative bacteria^{1,3} ((such as) (including)

(Staphylococcus aureus), (Salmonella enterica), (Pseudomonas aeruginosa)) (Methicillin resistant Staphylococcus aureus))

Effective broad-spectrum surface disinfectant

Intended for use in all (medical), (healthcare,) (clinical), (semi-critical care) and (long term care) facilities

Gets everywhere, disinfects pre-cleaned, hard, non-porous room surfaces

Reaches surfaces that regular disinfectants can't

Reduce(s) risk of cross contamination between treated surfaces

Reduce(s) labor costs

(Multi-purpose), (Multi-room), (Multi-surface) (Daily) (Disinfectant)

Kills pathogenic bacteria^{1,3}

Controls odor causing bacteria

Deodorizes by killing odor causing bacteria

Eliminates (Removes) odor causing bacteria
Gets rid of odors by killing the (bacteria) (that cause them)
Helps prevent the build-up of odors by killing odor-causing bacteria (on hard; pre-cleaned, non-porous surfaces)
Disinfects hard pre-cleaned, non-porous, (non-food) contact surfaces in: (see use sites) (Option to include sites from the Optional list of specific Healthcare Use Sites or Other Use Sites lists)
Disinfects hard pre-cleaned, non-porous, (non-food) contact surfaces in use sites listed below.
For (hospital) (healthcare) (medical) (semi-critical care) (long term care) facilities as a disinfectant
For use in (circulation cleaning) and (institutional) (industrial) disinfecting of previously cleaned non-porous food contact surfaces and equipment, such as (pipelines)(tanks)(vats)(fillers)(evaporators)(pasteurizers)
(Now) highly recommended for (see food handling use sites)
For use on hard, pre-cleaned, non-porous surfaces located in: (see use sites) (Option to include sites from the Optional list of specific Healthcare Use Sites or Other Use Sites lists)
For use on hard, pre-cleaned, non-porous surfaces located in use sites listed below.
Use this product in (see use sites) [OR] (Option to include sites from the Optional list of specific Healthcare Use Sites or Other Use Sites lists)
Kills (eliminates) 99.99% of *Pseudomonas aeruginosa* (pseudomonas) (ATCC #15442)
Kills (eliminates) 99.99% of *Staphylococcus aureus* (staphylococcus) (Staph) (ATCC #6538)
Reduces (avoids) risk of cross contamination between treated surfaces associated with wipes (sponges) (rags) (cloths)
Does not require additional aeration (scrubbing) time or waiting time after H₂O₂ is below 0.2 PPM
Full efficacy with SteraMist equipment can only be achieved by using SteraMist BIT Solution.
The only EPA Registered Solution + Equipment combination that provides the unique technology of hydrogen peroxide ionization for Hospital-Healthcare disinfecting
EPA Registered Equipment + Solution combination for Hospital-Healthcare disinfecting
Is a disinfectant for cleanroom and laboratory areas to disinfect washable, hard, non-porous, non-food contact surfaces, laminar-airflow equipment, and BioSafety cabinet work surfaces and exterior surfaces of the following: carts, trolleys, tables, casters, countertops, sinks, plumbing fixture surfaces, incubators, refrigerators, and centrifuge surfaces of metal, stainless steel, glass, plastic (such as polystyrene or polypropylene), Formica[®], and vinyl

Environment System Claims Only

Precise measurement of H₂O₂ dispensed – SteraMist Environment System
External aeration options to reduce cycle times
Environment System – fully automated cycles
Fast cycles (application) – minimal down time
Room fogger works to disinfect microorganisms³ in even the most hard-to-reach areas
Great (suitable) for whole (complete) room (disinfecting) (disinfection)
Multiple treatment applicators per unit (three trigger or non-trigger or combination applicators)
Super bugs require a super solution * * *Clostridium difficile* spores (C. diff), and *Pseudomonas aeruginosa* (Pseudomonas) (ATCC #15442).
Designed for killing ((*Clostridium difficile*)³ (C. difficile³) (C. diff³)) spores on pre-cleaned, hard non-porous surfaces in hospitals
Use on hard to reach areas (behind objects) (and)/(or) (around corners)
Not affected by (corners or shadows) (and/or) (line of sight)
Reaches around corners
Effect not diminished by (corners) (difficult to reach areas) (line of sight issues)

Surface Unit Claims Only

5 second per ft² disinfectant application for the SteraMist™ Surface Unit

Inactivates viral² cells

Surface Unit – single person (technician) (staff) application

Use in Mold Remediation on Hard, Non-Porous Surfaces for aesthetic purposes only

Kills bacteria¹ and inactivates viruses² which may reduce your risk of exposure from those pathogens¹ on treated surfaces

Kills bacteria¹ and inactivates viruses² which may reduce the risk of potential exposure in treated (rooms) (space) (surfaces).

Super bugs require a super solution * *Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC #33592) and *Pseudomonas aeruginosa* (pseudomonas) (ATCC #15442)

Handheld application method gives users the freedom to easily manipulate and treat all sides of desired objects.

SPECIFIC DISINFECTING CLAIMS

Environment System and Surface Unit Claims

Effective against Bacteria^{1,3}

Disinfection of all hard non- porous surfaces in a hospital (patient) room

Kills (eliminates) 99.99% of *Pseudomonas aeruginosa* (pseudomonas) (ATCC #15442)

Kills (eliminates) 99.99% of *Staphylococcus aureus* (staphylococcus) (Staph) (ATCC #6538)

An effective disinfectant (formula) (product) for use in healthcare facilities

An effective disinfectant (solution) (formula) (product) for use in (hospitals) (healthcare) (medical) (semi-critical care) (long term care) facilities

Effective against bacteria^{1,3}

Kills (eliminates) (destroys) (bacteria^{1,3}) on hard, non-porous surfaces

Kills (eliminates) bacteria^{1,3} (odors) and deodorizes

Kills the viruses^{2,4} associated with the flu and the common cold

(Bacteria^{1,3}) (Virus^{2,4}) (killer)(destroyer)(eliminator)

Kills antibiotic resistant bacteria^{1,3} (Methicillin Resistant) (*Staphylococcus aureus*) (MRSA)

On hard, pre-cleaned, non-porous, non-food contact surfaces this product kills (eliminates) bacteria^{1,3}

Surface Disinfectant

This product reduces the risk of cross contamination of bacteria^{1,3} on treated hard, pre-cleaned, non-porous surfaces

This product (helps) (aids) in the reduction of cross contamination of bacteria^{1,3} on treated hard, pre-cleaned, nonporous surfaces

Eliminates (bacteria^{1,3})(viruses^{2,4})(and)(odors) on hard non-porous surfaces that you (and)(your family)(your children) come into contact with everyday

Use this product in places that are difficult to (disinfect) (reach)

(This product) kills the bacteria that cause (bad) odors

(This product) kills bacteria^{1,3} on hard non porous, nonfood contact surfaces in public places

(This product) kills bacteria^{1,3} on commonly touched on hard non-porous, non-food contact surfaces (in non-residential public places) (in hotel rooms) (in medical facilities).

Environment System Claims Only

SteraMist™ Environment System (kills) (eliminates) 99.9999% of *Clostridium difficile* spores (*C. diff*)

Kills (eliminates) 99.99% of *Salmonella enterica* (Salmonella) (ATCC #10708)
Steramist™ Environment System (inactivates) (eliminates) 99.9% *Norovirus* (Feline Calicivirus) (FCV) (ATCC #VR-782)
(Disinfectant) (Disinfecting) fogging (formula) (product) for (whole) (complete) room surface (disinfection) (disinfecting)
An effective disinfectant (formula) (product) for use in healthcare facilities for (whole) (complete) room surface (disinfection) (disinfecting)
An effective disinfectant (solution) (formula) (product) for use in (hospitals) (healthcare) (medical) (semi-critical care) (long term care) facilities for whole (complete) room surface disinfection (disinfecting)
Whole (Complete) Room Surface Disinfectant.

Surface Unit Claims Only

For use in (controlling) (inhibiting) (mold) (and) (mildew) for aesthetic purposes only
Kills (eliminates) 99.99% of *Salmonella enterica* (Salmonella) (ATCC #10708)
Steramist™ Surface Unit (kills) (eliminates) 99.99% of Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC #33592)
Steramist™ Surface Unit (inactivates) (eliminates) 99.99% of Influenza A (H1N1) virus.

Steramist™ Surface Unit is effective against the following bacteria and the following virus:

¹*Staphylococcus aureus* (*Staphylococcus*) (*Staph*) (ATCC # 6538), *Pseudomonas aeruginosa* (*Pseudomonas*) (ATCC # 15442), Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC #33592), and *Salmonella enterica* (Salmonella) (ATCC #10708)

²Influenza A virus (H1N1)(ATCC#VR-1469))

Steramist™ Environment System is effective against the following bacteria and the following virus:

³*Staphylococcus aureus* (*Staphylococcus*) (*Staph*) (ATCC # 6538), *Pseudomonas aeruginosa* (*Pseudomonas*) (ATCC # 15442), *Salmonella enterica* (Salmonella) (ATCC #10708), and *Clostridium difficile* spores (*C. diff*)

⁴*Norovirus* (Feline Calicivirus) (FCV) (ATCC #VR-782)

Healthcare Use Sites:

(This product) (product name) is designed specifically as a (hospital) (healthcare) (hospital-healthcare) (ready-to-use) disinfectant (disinfecting) (fogging) (/) (aerosolized spray) (formula) (product) for use in the following settings:

Including but not limited to:

Ambulatory Surgical Centers (ASC)
Anesthesia Rooms or Areas
Assisted Living or Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms or Areas
Critical Care Units or CCUs
Dental Operatories
Dentist office
Elevators
Examination Room(s)
Dialysis Clinics (Facilities)
Donation Centers (blood) (plasma) (semen) (milk) (apheresis)
Emergency Rooms or ERs
Eye Surgical Centers
Health Care Settings or Facilities
(Hospital) Kitchens (non-food contact surfaces)
Hospices
Intensive Care Units ICU(s) (areas)
Isolation Areas
Laundry Rooms
Laboratories
Long Term Care Facilities
MRI Rooms
Medical Facilities
Newborn or Neonatal (Nurseries) (Intensive Care) Units
(NICU) Nursing or Nursing Stations
Operating Rooms or ORs
Ophthalmic Offices
Orthopedics
Out Patient (Surgical Centers (OPSC)) (Clinics)
(Facilities) Patient Areas
Patient Restrooms
(Pediatric) Examination Rooms or Areas
Pediatric Intensive Care Units (PICU)
Pharmacies
Physical Therapy Rooms or Areas
Psychiatric Facilities
Public (Care) Areas
Radiology or X-Ray Rooms or Areas
Recovery Rooms
Rehabilitation Centers
Respiratory Therapy Rooms or Areas
Restrooms

Surgery Rooms or Operating Rooms or ORs
Waiting Rooms or Areas

Other Use Sites: Animal Industry, Bio-Safety labs, Biotech Industry, Commercial, Education, Entertainment, Government, Historic Buildings, Homeland Defense, Hospitality, Industrial, Institutional, Multi-family housing, Military, Pharmaceutical, Recreational, Entertainment and Residential Settings and Assets, Senior Living, Tissue banks, Transportation (public and private), Worship Facilities.

Specific Areas of use include; Airplane, **Ambulance**⁺, **Automobile**⁺, Barrier isolator, Biological Decontamination Chamber, Biological Safety Cabinet, Blood Bank, Boat, Bowling Alley, Bus, Cargo Planes, Campground Facility, Church (Temple) (Mosque) (House of worship), Clean Room (Electronic) (Pharmaceutical) (Tissue Bank), Clinic (Medical), College or University Facility, Commercial Building, Correctional Facility, Cruise Ship, Day Care Center, Dorm, Factory, Fire House, Gymnasium, Health Club (Spa), Home, Hospital, Hotel, Industrial Facility, Infirmary, Institutional Facility, Laundromat (Institutional), Locker Room, Manufacturing Plant (non-food), Massage Therapy Facility, Military (Installation) (Vessel) (Aircraft) (**Vehicle**⁺) (Asset), Mobile Home, Motel, Nursing Home, Office (Medical, Dental, Physician's, Commercial, Correctional, Sheriff), Pharmaceutical Test and Manufacturing Facility, Pharmacy, Indoor Playground, Police Department, Public Facilities, Public Restroom, Recreational Center, Rental Facility, Residential Facility, Retail Facility, Recreational Vehicle, School Bus, Schools, Shelter, Sports Arena, Submarine, Theaters, Tissue Bank, Train, Veterinary Clinic, Vivarium, and Warehouse. ⁺ **Only for application with the SteraMist™ Surface Unit.**

Food Handling Use Sites (includes Storage, Preparation, Processing, and Serving):

Food Manufacturing Plant, Food Handling Establishments, Food Warehouses, Cafeteria, Farmer's Market, Food Service Establishment, Food Processing, Packing Plants, Restaurant, Fast Food Restaurant, Supermarket or Grocery Store

FOOD AREAS: In establishments where food and food products are held, prepared, processed and served, application may be made only when the facility is not in operation provided exposed food is covered or removed from the area being treated prior to application. Food contact surfaces must be rinsed with potable water after use of the product. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage, enclosed processing systems (mills, dairies, edible oils, syrups), serving areas (where prepared foods are served, such as dining rooms).

NON-FOOD AREAS: This product may be used to treat nonfood areas in food handling use sites. Nonfood areas include garbage rooms, lavatories, entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling).

[Package Insert or Additional Label Language for

Binary Ionization Technology® (BIT™) Solution

EPA Reg. No. 90150-2]

Binary Ionization Technology® (BIT™) Solution

(Alternate Brand Names:

SteraMist™ BIT™ Solution

Binary Ionization Technology (BIT™) Plus

Binary Ionization Technology

BIT™

BIT™ Solution Ready-To-Use Hydrogen Peroxide

SteraMist™ BIT™)

STERAMISTTM
POWERED BY BINARY IONIZATION TECHNOLOGY

Healthcare-Hospital Disinfectant (and General Use Disinfectant) (and/or Mold Remediation)

[Inclusion of the Table of Contents is optional]

(TABLE OF CONTENTS)

- 1. GENERAL INFORMATION - Binary Ionization Technology® (BIT™) Solution..... 2
- 2. Binary Ionization Technology® (BIT™) SOLUTION Application Process 2
- 3. USER SAFETY REQUIREMENTS 3
- 4. Hospital Disinfectant PLAN (HDP)/General Disinfectant Plan (GDP)/Mold Remediation Plan (RMP).... 3
- 5. SteraMist™ Environment system USE INSTRUCTIONS..... 5
 - 5.1 Room Preparation..... 5
 - 5.2 Treatment Protocol 7
 - 5.3 Routine System Maintenance, Calibration Procedures, and Troubleshooting 9
 - 5.4 Storage and Shipping 10
 - 5.5 Annual Recalibration and Recertification 10
- 6. STERAMIST™ SURFACE UNIT USE INSTRUCTIONS..... 10
 - 6.1 Preparation 10
 - 6.2 Treatment Protocol 11
 - 6.3 Routine System Maintenance and Calibration Procedures, and Troubleshooting..... 12
 - 6.4 Storage and Shipping 12
 - 6.5 Annual Recalibration and Recertification.....12

1. GENERAL INFORMATION - BINARY IONIZATION TECHNOLOGY® (BIT™) SOLUTION

The Binary Ionization Technology® (BIT™) Solution is for use exclusively with the SteraMist™ application equipment including the SteraMist™ Environment System and the SteraMist™ Surface Unit for (hospital) disinfection of rooms and/or mold control and remediation for aesthetic purposes only. Review the SteraMist™ User Manuals for proper instructions on how to operate the SteraMist™ Environment System and SteraMist™ Surface Unit prior to utilizing the equipment for disinfecting areas and/or remediating mold. SteraMist™ Binary Ionization Technology® (BIT™) Solution should be applied by properly trained personnel who are thoroughly trained in the use, safety, and operation of the SteraMist™ Environment System and SteraMist™ Surface Unit and Binary Ionization Technology® (BIT™) Solution Application Process, exclusively using Binary Ionization Technology® (BIT™) Solution and who have received a Certificate of Completion of the SteraMist™ Technician Training course from TOMI™ Environmental Solutions.

Binary Ionization Technology® (BIT™) Solution is for use as a hospital disinfectant and/or general disinfectant and/or for mold control and remediation on hard non-porous surfaces, and is not for use on textiles or hard porous surfaces. Binary Ionization Technology® (BIT™) Solution has been registered with TOMI™ Environmental Solutions, Inc. in accordance with Federal Regulations for the specific uses described on the product label, in this package insert, and the SteraMist™ User Manuals. Uses other than what is specified and described in these materials are not permitted.

The instructions that follow explain how to define appropriate use conditions for use in dry, pre-cleaned spaces. Using the SteraMist™ Environment System, this includes sealed enclosures in industrial, commercial, and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, laboratories, animal research facilities, hotel rooms, offices, cruise ships and recreational facilities, and all other use sites as detailed in the SteraMist™ Environment System User Manual). Using the SteraMist™ Surface Unit, all use site surfaces may be treated without isolation/sealed enclosures.

Effective application of Binary Ionization Technology® (BIT™) Solution requires adequate Activated Ionized Hydrogen Peroxide (AIHP) concentration and exposure time. The process parameters are controlled through the use of appropriate monitoring instruments. See the SteraMist™ User Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process. For additional guidance, in-service, and training on how to develop and monitor custom cycles, contact TOMI™ Environmental Solutions, Inc.

2. BINARY IONIZATION TECHNOLOGY® (BIT™) SOLUTION APPLICATION PROCESS

The SteraMist™ Binary Ionization Technology® (BIT™) Solution is applied through the SteraMist™ application equipment including the SteraMist™ Environment System or the SteraMist™ Surface Unit (SteraMist™) for the required time to maintain the

desired concentration of Activated Ionized Hydrogen Peroxide (AIHP). The Binary Ionization Technology® (BIT™) Solution fog quickly is broken down into water (humidity) and oxygen.

The BIT™ process consists of four phases:

- A. PREPARATION PHASE – Develop Hospital Disinfectant Plan and/or General Disinfectant Plan and/or Mold Remediation Plan reviewing the user safety requirements and PPE on the label and using guidance in Section 4. Make sure areas to be treated are pre-cleaned and are dry and free of visible biofilm. When using the SteraMist™ Environment System, sealing the space will allow for a faster concentration of AIHP.
- B. APPLICATION PHASE - The Binary Ionization Technology® (BIT™) Solution will flow through the Atmospheric Cold Plasma Arc in the nozzle, convert into AIHP, and is introduced into the air stream. The APPLICATION phase facilitates concentration of AIHP in the treatment area. APPLICATION time will be determined by the number of application nozzles used, enclosure materials, environmental conditions, and treatment volume/area.
- C. CONTACT PHASE - Application time will provide adequate AIHP and hydrogen peroxide levels in the treatment area. After application is complete, sufficient AIHP will be present to provide disinfection of application area through CONTACT. The CONTACT time is specified below for each application method.
- D. AERATION PHASE –Once the Binary Ionization Technology® (BIT™) Solution application is complete and contact time has concluded, the enclosure is aerated and/or scrubbed to reduce the AIHP and hydrogen peroxide levels within the enclosure to less than or equal to a 0.2 ppm level prior to reentry into the enclosure by trained personnel.

3. USER SAFETY REQUIREMENTS

Refer to the product label for user safety requirements and PPE.

4. HOSPITAL DISINFECTANT PLAN (HDP) AND/OR GENERAL DISINFECTANT PLAN (GDP) AND/OR MOLD REMEDIATION PLAN (MRP)

GENERAL GUIDANCE FOR PREPARATION OF A HOSPITAL DISINFECTION/ GENERAL DISINFECTANT AND/OR MOLD REMEDIATION PLAN

A Hospital Disinfection Plan (HDP) and/or General Disinfectant Plan (GDP) and/or Mold Remediation Plan (MRP) is an organized, written description of the required steps involved to help ensure an effective disinfection and/or mold remediation. It will also assist in complying with pesticide product label requirements. The guidance that follows is designed to assist in addressing all the necessary factors involved in preparing for and treating a structure and/or area.

This guidance is intended to assist in the planning of any disinfection that may be performed PRIOR TO ACTUAL TREATMENT. It is meant to be somewhat prescriptive, yet flexible enough to allow the experience and expertise of the user to make changes based on circumstances that may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, an effective disinfection can be performed.

Before any disinfection and/or mold remediation begins, carefully read and review the label and the SteraMistTM User Manuals. This information must also be given to the appropriate company officials (supervisors, foreman, safety officer, etc.) in charge of the structure and/or area. Preparation is the key to any successful disinfection. Finally, before any disinfection and/or mold remediation begins you must be familiar with and comply with all applicable local and state laws. The success of the disinfection and/or mold remediation is not only dependent on your ability to do your job but also upon carefully following all rules, regulations, and procedures required by governmental agencies.

SITE-SPECIFIC GUIDANCE FOR PREPARATION OF A HOSPITAL DISINFECTANT PLAN AND/OR GENERAL DISINFECTANT PLAN AND/OR MOLD REMEDIATION PLAN

The TOMITM Environmental Solutions, Inc. trained personnel are responsible for working with the owners and/or the responsible employees and/or the trained client of the site that is undergoing Binary Ionization Technology[®] (BITTM) Solution treatment to develop a site-specific Hospital Disinfectant Plan (HDP) and/or General Disinfectant Plan (GDP) and/or Mold Remediation Plan (MRP) for each site that will be treated with Binary Ionization Technology[®] (BITTM) Solution. Trained persons are responsible for all tasks of the disinfection and/or mold remediation processes unless otherwise noted in the respective plan and must be on site for the entire disinfection and/or mold remediation treatment process. The plan must address characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

- A. Inspect the structure and or area to determine its suitability for disinfection and/or mold remediation.
- B. When sealing is required, consult previous records for any changes to the structure, seal leaks, and monitor any occupied adjacent rooms and/or buildings to ensure safety.
- C. Prior to each disinfection and/or mold remediation, review any existing HDMP, SDS, SteraMistTM User Manual, and other relevant safety procedures with company officials and appropriate employees.
- D. Develop procedures and appropriate safety measures for nearby persons who will be in and around the area during application and aeration including posting signs “treatment in place”.
- E. Develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application, disinfection, and aeration. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.

- F. Develop procedures for local authorities to notify nearby residents in the event of an emergency.
- G. Confirm the placement of placards to secure entrance into any area under disinfection as needed.
- H. Confirm the required safety equipment is in place and the necessary manpower is available to complete disinfection.

These factors must be considered in putting a plan together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area.

In addition to the plan, the trained person or persons must read the entire label (and this package insert), and the SteraMistTM User Manual and follow all directions carefully. If the trained person or persons have any questions about the development of a plan, contact TOMITM Environmental Solutions, Inc. for further assistance. A HDMP must be developed for each treated site. In the event of an emergency application, a generic plan may be used and updated after disinfection and/or mold remediation. TOMITM Environmental Solutions, Inc. trained person or persons must sign the plan indicating it was followed. The signed plan and related documentation, including monitoring records, must be maintained by the applicator for a minimum of 2 years and a copy provided to the owner of the treated site.

[Note to Reviewer: Use Instructions for the SteraMistTM Surface Unit may appear before the Use Instructions for the SteraMistTM Environment System in the Package Insert]

5. STERAMISTTM ENVIRONMENT SYSTEM ROOM FOGGING USE INSTRUCTIONS

5.1 Room Preparation

- A. Review existing product label, treatment plan, hospital/company specific PPE protocols, and SteraMistTM Environment System User Manual.
- B. Survey the room taking note of the following:
 - a. Dimensions of the room (in feet): length, width, and height.
 - b. Location of supply and return vents and any other air entry or egress paths, door jambs, windows, bathroom vents, hoods, etc.
 - c. Position and type of equipment and furniture.
 - d. Proximity to staff and general public.
- C. Room isolation:
 - a. Determine room isolation approach and perform isolation. Isolation is preformed to speed concentration of the AIHP to the required dose level of 150 ppm.
 - b. The SteraMistTM Environment System must not be used without disabling HVAC and other ventilation systems. If ventilation systems must remain operational, controls must

be put in place to prevent dilution of the fog through ventilation and unintentional personnel exposures.

- c. Isolation may also be achieved by sealing with tape and plastic sheeting or other means.
- D. Determine aeration approach: Venting to atmosphere is the preferred method. Alternatively, scrubbing may be performed by using a scrubbing device in the room or by placing activated carbon filters over ventilation returns. Dehumidifiers are also effective in removing airborne hydrogen peroxide.
- E. Expose all surface areas requiring disinfection and/or mold remediation. Open all drawers, cabinet doors, and bathroom doors.
- F. Cleaning: Remove gross filth and visible soil prior to application. All areas must be completely dry and free of visible biofilm before application.
- G. Secure the enclosure.
 - a. Remove all animals, open beverages, medications, and food (plants may remain in area).
 - b. Place “Steramist™ in Use” placards outside all room entrances to ensure no one enters during treatment without wearing appropriate PPE.
 - c. Placards may be removed once the space being treated has aerated and monitors (such as a Drager or PortaSens) register the hydrogen peroxide levels at/below 0.2 ppm.
- H. Set up hydrogen peroxide monitoring, for safety purposes and for process verification. This must be done to verify the fogging concentrations have reached the desired level and to indicate when it is safe to re-enter. Two devices are recommended for measuring airborne hydrogen peroxide:
 - a. A monitor (such as a Drager) with H₂O₂ sensor has a dynamic range of 0-20 ppm. This H₂O₂ sensor is intended to be used outside the treatment area for low level leak detection and containment verification.
 - b. A monitor (such as a PortaSens) can be equipped with a hydrogen peroxide sensor with a dynamic range of 0-200 ppm or 0-2000 ppm.
 - i. When equipped with the 0-200 ppm sensor, this unit can be used in place of the Drager unit for containment verification. It is outfitted with a sample tube, which can be fitted under the door and used to monitor the treatment room concentrations of hydrogen peroxide. It can also be taken into the treatment room by the operator to verify purge is complete.
 - ii. When equipped with the 0-2000 ppm sensor, the PortaSens unit is used to monitor treatment room concentrations during fogging operations where hydrogen peroxide concentrations exceed 150 ppm.
 - c. Limitations of electrochemical sensors (such as Drager and PortaSens):
 - i. Sensors saturate and have inaccurate readings when the relative humidity exceeds 90%.
 - ii. Sensors may respond to other chemicals, in this case the isopropyl alcohol in the BIT™ Solution and the ozone produced by the high-energy electrical arc could give a false higher reading.

5.2 Treatment Protocol

Once the room has been prepared by exposing and cleaning the surfaces, isolating the room, and setting up the monitoring, the SteraMist™ Environment System can be set-up and treatment can be initiated.

- A. Position applicators.
 - a. The remote applicator is outfitted with a three-point connector on the unit. Align the three-point connector (electrical, air, and liquid) to the respective three-point receptor. Firmly, press the connector plugs into their receptors until they bottom out. Slide the locking mechanism of the electrical receptor all the way to the right.
 - b. Depending on number of pods in the room, place the pods in a manner that allows for a vortex to be formed.
 - c. Environmental variables that should be taken into consideration during application are room air movement or wind and, to a lesser extent, temperature and humidity. 50% relative humidity is optimal.
- B. Put on appropriate PPE and respiratory protection as stipulated in your training or hospital/company specific Respirator Protection Program.
- C. Connecting the Binary Ionization Technology (BIT™) Solution Cartridge:

Install the 1-gallon Binary Ionization Technology (BIT™) Solution Cartridge. To install the cartridge, first remove the screw cap from the cartridge. Save it to reuse later in capping any remaining Binary Ionization Technology (BIT™) Solution. The rigid tube is inserted into the underside of the application cap and the flexible tube into the topside of the application cap. Ensure that both tubes are fully seated into the fittings on either side of the application cap. Fully seat the other end of the flexible tube into the tube fitting on the Binary Ionization Technology (BIT™) Solution input. Binary Ionization Technology (BIT™) Solution is to be used exclusively with SteraMist™ Environment System or the SteraMist™ Surface Unit equipment. Use of any other solutions or liquids may damage the equipment, void the warranty, or cause operator injury.

 - a. Insert Tube into Fitting - Push the tubing through the collet and dual O-rings until it bottoms out against the tube stop. The collet holds the tube in place and the dual O-rings provide a leak resistant seal.
 - b. Test and Inspect - Push and pull the tubing toward and away from the fitting to ensure that it has been installed properly. Test and inspect the installation for any leaks.
 - c. Tube Removal - Push uniformly around the collet flange against the fitting body while pulling the tubing away from the fitting to release it.
- D. Plug the air scrubber into fogger three prong outlet. Use of the scrubber will shorten aeration time.
- E. The system is labled for the voltage to be used. Plug the system into a standard electrical 110v-120V or 220v-240v wall outlet using the cord provided. Press the switch to the ON (–) position, the switch is located next to where the power cord connects to the unit.
- F. The touch screen will boot up and the “RUN screen” will appear. Press “Run”. The “Select Number of Rooms for Treatment” screen will appear. One to three rooms may be selected.

Press the appropriate button (i.e., One, Two, or Three). The “Room A Injection Volume” screen will appear.

- a. Room Dimensions. In series, select each of the number fields (initially defaulted to “0”) to the left of the words: Length, Width, and Height in feet. Enter the associated room dimension.
- b. Dose Concentration.
 - i. Select the number field (initially defaulted to “0.00”) to the left of the words “ml /per cubic ft.” Dose concentration must be calculated at rate of 0.5 ml/ft³.
 - ii. Press “Calculate”.
 - iii. Alternatively, you may directly enter the dose (in ml) by pressing the button to the right of “Calculate”. (This button appears as “0 TOTAL ml” by default.) The minimum dose rate must be 0.5 ml/ ft³.
- c. Select pods.
 - i. From the buttons to the right side of the screen, select pod or pods to be used in selected room A. Pods can only be selected if they are detected. Pods can only be detected if they are connected.
 - ii. Press: “Next”
 - iii. If multiple rooms are selected on the “Select Number of Rooms for Treatment” screen (step 4.7), “Room B Injection Volume” and “Room C Injection Volume” screens will appear. Repeat the above steps a) through e) for additional rooms. Then press “Next”. Please note, that if decontaminating 3 rooms simultaneously, a pod must be assigned to each room. A pod cannot be assigned to more than one room at a time. However, if programming one or two rooms, you may use multiple pods in each room. **The system will always assign the first room as Room A, the second room as Room B, and the third room as Room C. Always assign the largest room as room A to ensure correct initiation of dwell count down and subsequent scrubber initiation.**
- d. The “Setup Scrubber” screen will appear.
 - i. Enter: Contact time (in minutes). The minimum contact time is 15 min.
 - ii. Enter: Scrub time (in minutes). (Dependent on room size, environmental conditions and scrubbers)
 - iii. Press: “Next”.
- e. The “Startup Options” screen will appear. Select “Remote” or “Manual” as appropriate.
 - i. If remote start was selected, it will start immediately. Start the fogger by pressing the button on the remote.
 - ii. If you select “Manual”, the “Setup Delay” screen will prompt the operator to enter a delay time (in seconds). The minimum manual start time is 10 seconds. Once a delay time is entered, press: “Start”. The “Warning” Screen will appear and begin countdown to startup.
- f. While wearing proper PPE, in either Remote Mode or Manual Mode, wait to assure that all the programmed pods are functioning (fog and high energy electrical arc have

started). If not, then press “stop” on the screen and check pod connections. You must repeat the program sequence from step 4.7. If pods still do not function properly, check that the dip tube is reaching the bottom of the cartridge and that you have enough solution in the cartridge. Also, check that you have created a circular flow in the room. You may adjust the pods to achieve correct vortex without stopping while the SteraMist™ is in operation. Exit room and seal door to complete room isolation.

- g. When starting operation, the device will cycle through three phases: 1) air flow 2) liquid flow (may take up to 30 seconds before mist is visible) and 3) high energy electrical arc. Decontamination activity has begun once a steady fog and the high- energy electrical arc are observed.
- h. Monitor for hydrogen peroxide with a monitor (such as a Drager Monitor or PortaSens Monitor) outside the room being treated. If hydrogen peroxide concentrations exceed 0.2 ppm outside the treatment room, seal leaks as necessary. Applicators sealing the leak must wear appropriate PPE. If a leak occurs, general personnel must leave the adjacent area and may not return until concentrations are below 0.2 ppm.
- i. In the event of poor room isolation, pushing the button on the remote control or touching the stop button on the touch screen will shut down the fogger.
- j. Scrubbing. If applicable, the scrubber will turn on automatically after the contact period has ended. Scrubbing is typically performed until a concentration of <0.2 ppm H₂O₂ is achieved.
- k. Cycle end. When the decontamination cycle is complete, the “Process Data” touch screen will continue to be displayed. This screen displays the actual amount of solution dispersed into each room. It will also display the Contact Time and Scrub Time. This is the minimum data that should be recorded along with date, time, and room number.
- l. To deactivate the SteraMist™ Environment System while running a cycle, press the remote button or stop button on touch screen. The device will cycle off in the following order: 1) high energy electrical arc, 2) liquid flow, and 3) air flow. You may now press “exit” and disassemble the unit until next use.
- m. To turn off the SteraMist™ Environment System, switch the power to the OFF (“0”) position. Unplug the power cord from the electrical outlet and the generator.
- n. After each use:
 - i. Ensure the SteraMist™ equipment is unplugged from the power source, and, using isopropyl alcohol, clean all residues present from the nozzle tip guard, electrodes, electrode posts, spray nozzle, air cap, and retaining ring.
 - ii. At the end of each shift, prior to storage or shipment, flush solution.
- o. Remove “SteraMist in Use” placards, PPE, and store appropriately. Make notes of any HDMP recommendations for future use and complete required paperwork.

5.3 Routine System Maintenance, Calibration Procedures, and Troubleshooting

Refer to the SteraMist™ Environment System User Manual for instructions regarding routine system maintenance, calibration procedures, and troubleshooting guidance.

5.4 Storage and Shipping

If the SteraMist™ Environment System™ will be unused for more than 2 days, the system must be flushed of all Binary Ionization Technology (BIT™) Solution using only deionized (DI) water. Please see SteraMist™ Environment System User Manual for detailed instructions on flushing the system. Never store or ship the SteraMist™ Environment System without fully flushing the system.

5.5 Annual Recalibration and Recertification

The SteraMist™ Environment System must be recalibrated™ and recertified annually by a certified SteraMist™ Service Technician. Contact your certified SteraMist™ Service Technician at 1.800.525.1698 to schedule onsite calibration or to arrange for shipping of your SteraMist™ to a TOMI™ location for calibration.

6. STERAMIST™ SURFACE UNIT HAND HELD USE INSTRUCTIONS

6.1 Preparation

- A. Review the product label, existing HDMP for the location to be treated, use your training PPE protocol or hospital/company specific PPE protocols, and SteraMist™ Surface User Manual.
- B. Survey the area to be treated, taking note of the following:
 - a. Position of equipment and furniture.
 - b. Proximity to other room occupants.
 - c. Application goal, i.e., total room (disinfection)(remediation) or only high touch surface (disinfection) (remediation).
- C. Venting to the atmosphere is the preferred aeration method. However, the SteraMist™ Surface Unit may be used effectively without disabling HVAC and other ventilation systems. Alternatively, scrubbing may be performed by placing an air scrubber in the room or by placing carbon filters over ventilation returns. Dehumidifiers are also effective in removing airborne hydrogen peroxide.
- D. Cleaning: Remove gross filth and visible soil prior to application. All areas must be completely dry and free of visible biofilm before application.
- E. Secure the enclosure. Remove all plants, animals, open beverages and food.
- F. Place “SteraMist in Use” placards outside all area entrances to ensure no one enters during treatment without appropriate PPE. Placard may be removed once the space being treated has aerated and a monitor (such as Drager or PortaSens) register the hydrogen peroxide levels at/below 0.2 ppm.

6.2 Treatment Protocol

Once the room has been prepared by exposing and cleaning the surfaces, isolating the room, and setting up the monitoring, the SteraMist™ Surface Unit can be set-up and treatment can be initiated.

- A. Put on appropriate PPE as described in the product label.
- B. To install the Binary Ionization Technology (BIT™) Solution cartridge, first remove the screw cap. Save it to reuse later in recapping any remaining Binary Ionization Technology (BIT™) Solution. Place the dip tube into the Binary Ionization Technology (BIT™) Solution Cartridge and firmly screw on the cap. Insert the Binary Ionization Technology (BIT™) Solution Cartridge into the solution compartment. The measurement window on the bottle must be facing out in order for the unit to work properly. Binary Ionization Technology (BIT™) Solution is to be used exclusively with SteraMist™ Environment System or the SteraMist™ Surface Unit equipment. Use of any other solutions or liquids may damage the equipment, void the warranty, or cause operator injury.
- C. Setting up the SteraMist™ Surface Unit
 - a. Plug the power cord into a standard 120V electrical outlet. To turn on the SteraMist™ Surface Unit, switch the power, located on the side of the body, to the ON (–) position.
 - b. The handheld applicator comes fully connected to the generator. Please refer to the SteraMist™ Surface Unit User Manual for applicator connection instructions.
- D. Operating the SteraMist™ Surface Unit:
 - a. Prime the handheld applicator by setting the rocker switch to the “Prime” position and engaging the trigger on the handheld applicator until a steady stream of Binary Ionization Technology (BIT™) Solution is consistent. Then disengage the trigger.
 - b. Set rocker switch to “Spray”.
 - c. In order to close the generator door in preparation for application, align and insert the multi conductor cable strain relief in the cabinet slot and close and latch the cabinet door.
 - d. When activating the handheld applicator in “spray” mode, the device will cycle through three phases: 1) air flow, 2) mist flow, and 3) atmospheric cold plasma arc. Disinfection and/or Remediation activity can begin once a steady fog and the atmospheric cold plasma arc are observed. Remember; always keep the nozzle of the applicator pointed away from you and others at all times and never operate the handheld applicator while pointed upward.
- E. Application:
 - a. Apply in broad even strokes, ensuring that there is a consistent even mist with no drips, runs, or missed areas. Do not over saturate.
 - b. For Microbial Disinfection: Binary Ionization Technology (BIT™) Solution must be administered a maximum of 2 feet from the surface being disinfected/remediated, at a coverage rate of 1 ml/ft.² for 5 seconds. Allow product to contact surface for a minimum of 7 minutes.

- c. To Kill Mold: Binary Ionization Technology (BITTM) Solution must be administered a maximum of 18 inches from the surface being disinfected, at a coverage rate of 1 ml/ft.² for 30 seconds. Allow product to contact surface for a minimum of 5 minutes.
 - d. The application rate is practiced and assessed during training and can be visually confirmed by the technician or a third party outside the area by timing coverage strokes.
 - e. Environmental variables that should be taken into consideration during application are room air movement or wind, and to a lesser extent temperature and humidity.
 - f. Biological Indicators can be used to confirm coverage.
- F. To deactivate the handheld applicator, release the button. The device will cycle off in the following order: 1) atmospheric cold plasma arc, 2) mist flow, and 3) air flow.
- G. To turn off the SteraMistTM Surface Unit, switch the power, located on the side of the generator, to the OFF (0) position. Unplug the power cord from the electrical outlet and the generator.
- H. Monitoring: Once a monitor (such as a Drager or PortaSens) show hydrogen peroxide levels in the treatment area of 0.2 ppm or less, remove 'SteraMist in Use' sign and replace in cabinet for future use.
- I. After each use: ensure the SteraMistTM is unplugged from the power source and wipe the applicator nozzle with an alcohol prep pad to remove any dirt or debris. USE ALCOHOL PREP PADS ONLY.
- J. It is recommended that the SteraMistTM Surface Unit should be flushed once a day with deionized (DI) water while on the "Prime" setting to keep the lines clean. Please see SteraMistTM Surface Unit User Manual for detailed instructions on flushing the system. Never store or ship the SteraMistTM Surface Unit without fully flushing the system.

6.3 Routine System Maintenance and Calibration Procedures, and Troubleshooting

Refer to the SteraMistTM Surface Unit User Manual for instructions regarding routine system maintenance, calibration procedures, and troubleshooting.

6.4 Storage and Shipping

It is recommended that the SteraMistTM Surface Unit should be flushed once a day with deionized (DI) water while on the "Prime" setting to keep the lines clean. Please see SteraMistTM Surface Unit User Manual for detailed instructions on flushing the system.

Never store or ship the SteraMistTM Surface Unit without fully flushing the system.

To store the applicator and multi-conductor cable, open the case, remove the cord strain relief, and coil the multi-conductor cable around the multi-conductor retaining hooks in the door. The applicator is stored in the mesh pouch.

6.5 Annual Recalibration and Recertification

The SteraMistTM Surface Unit must be recalibrated and recertified annually by a certified SteraMistTM Service Technician. Contact your certified SteraMistTM Service Technician at 1.800.525.1698 to schedule onsite calibration or to arrange for shipping of your SteraMistTM to a TOMITM location for calibration.