

 NDDB	STANDARD OPERATING PROCEDURE Fumigation Vapour Hydrogen Peroxide -H₂O₂ (VHP)	Document No.	NDDB/F/01
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Scope and Objective:

The control of microbial load on surfaces of production rooms/area, storage rooms, research, Biosafety labs and Clean rooms is an everyday challenge. Surface sanitization or disinfection of production equipment's and rooms by wiping with chemicals not only is a time-consuming procedure, but also its efficacy and validation is very intricate. Alternatively, fumigation allows overcoming many critical aspects of wiping in both procedure and validation. The fumigation process mainly depends on the concentration of chemical, degradation, temperature, humidity, dimension of the target area and substrate to be decontaminated etc. Optimization, Standardization and strict control of these parameters should be considered when developing a robust protocol to be applied in effective fumigation process. This SOP covers the fumigation process and equipment's used for fumigation and the focus is set to the proper and simplified process.

Fumigation with Hydrogen Peroxide (H₂O₂)

Hydrogen peroxide is a clear, colorless liquid, and more viscous than water. It is most commonly available as a solution in water.

Prerequisites:

1. Hydrogen peroxide (HP) is a surface decontaminant and may not penetrate dirt and detritus. Heavily soiled surfaces should be cleaned prior to decontamination with VHP.
2. Remove all personnel from area to be contaminated as well as any equipment and materials that are not compatible with VHP and high levels of moisture. Trash/waste receptacle contents must be bagged, sealed and left in place for surface decontamination prior to being removed from the room.
3. Open all cabinet doors, drawers, and doors to suites and minimize occluded/covered surfaces to facilitate penetration of VHP.
4. Shut off HVAC of area to be decontaminated when possible.
5. While absorbable materials can remain in the room during bio-decontamination (e.g., paper, clothing, fabrics, etc.) the presence of a large quantity of absorbable material will extend gassing time and aeration time to account for peroxide absorbed.
6. Turn off equipment that may operate above or below ambient room temperature (e.g., autoclaves, incubators, refrigerators, and cold rooms) and allow them to return to ambient room temperature prior to cycle initiation to ensure VHP distribution.
7. Smoke detector disengagement responsibilities and sealing of space.

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Equipment's:

Portable 4-Direction Fogger/ Fogger/Mobile fogger. Selection of fogger mainly depends on area and dimension of the room.

Instructions:

A. Portable 4-Direction Fogger with compressed air (Figure 1)

1. Test the equipment with water only prior to any chemical use.
2. Place the chemical into a container of water for testing.
3. Open main supply air valve and adjust each nozzle valve to optimize to be fine fog.
4. Now ready for chemical fogging.
5. Run fogging as the controlling time.
6. When finished fogging, deactivate the air supply.
7. Follow other specific recommendation by the suppliers.

Operation:

1. Connect air supply and at the bottom of stand.
2. Put the chemical tube into the chemical tank.
3. Preferable height shall be adjusted by using L –knobs and tightens the L-knobs to secure.



Fogger with compressed air (Figure 1)

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B. Fogger (Electric motor Operated-(Fig 2-4))

1. With its powerful electric motor, fogger distributes the fine droplets evenly over the affected area and delivers a particle size between 5 to 40 microns. The needle dosage control knob allows a liquid output flow from a lowest output of 10 ml/min in the range to a maximum of 170ml/min to create heavy mist depending on the viscosity of the liquid to be fogged.
2. The only maintenance required is an occasional cleaning of the liquid filter (20) and the PP filter (29). Remove the filter and rinse it with running water to remove the clinging particles.
3. Avoid contamination when changing chemicals: Fogging with clean water (or appropriate solvent) through unit and rinse tank thoroughly.
4. Periodically check the cleanliness of the air filter (11). If the motor does breathe a sufficient quantity of clean air, the fogging operation will be inefficient and the motor could be overheated.
5. Check seal, gasket, tube and hose for leakage. Replace if necessary. Make sure the all the filters and solution filter are clean.

Operation:

1. Make sure the plug (3) is disconnected from the power socket.
2. When you use the appliance for the first time or if you have not used it for a while, remove the closure ring (5) and check the tank (6) is clean.
3. Replace the power head (7), making sure the tank gasket (4) is in place and return the closure ring (5) to its position.
4. Pour the solution into the tank (6) then close the filling cap (8), make sure the O-ring (9) is in position.
5. Before connecting the power cord (3) to a power socket, make sure that
 - flow control knob (2) on close position
 - Switch (1) is set to the off position.
6. Aim the nozzle in the required direction and switch on the appliance.
7. Adjust to flow control knob for the quantity of product to be distributed.
8. When using solution which creates foam, to keep foam from penetrating into the power head (7) to damage the motor (1), in any case, the foam level should be kept lower than the PE filter (29).
9. Plan your job in such a way that the appliance draws in as little fog as possible.
10. Work so that you leave the treated areas through untreated areas in the exit direction.
11. Once fogging is complete, close the control knob before switching off the appliance.
12. Remove residues of solution and empty tank, fog using warm water.



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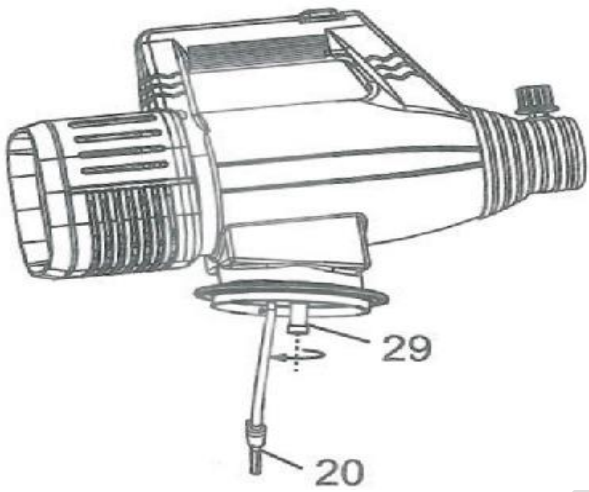


Figure 2

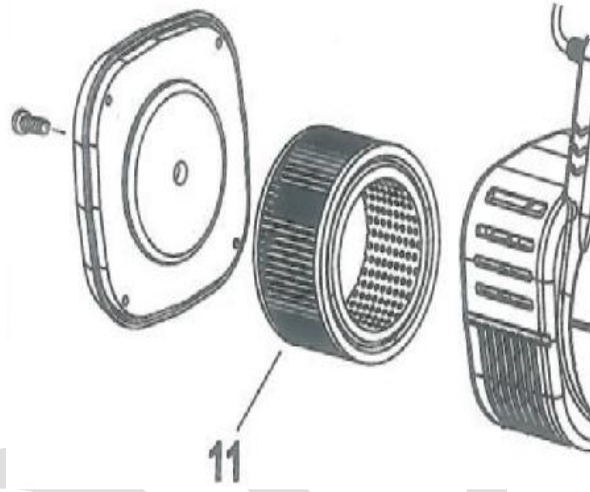


Figure 3

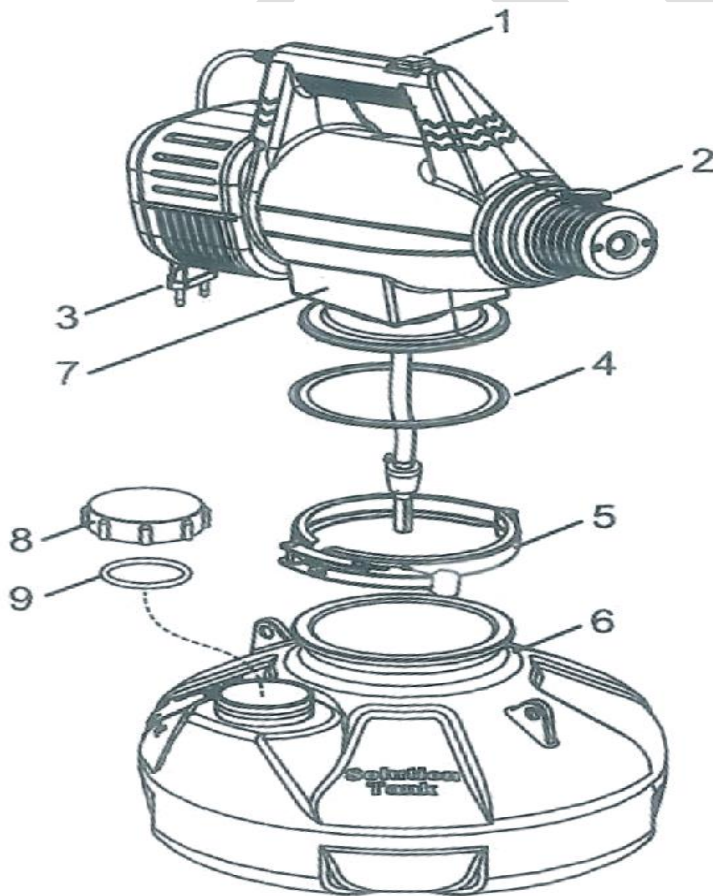


Figure 4

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Decontamination Procedure:

1. Fumigation with hydrogen peroxide first requires a procedure to dehumidify the area to prevent condensation or proper humidification needs to be maintained.
2. Once the humidity and temperature levels are stabilized, a 35% / 59% hydrogen peroxide solution is vaporized via a generator (fogger) and released into the room/area.
3. Place the Fogger/generator in the center of room for even VHP distribution (as per equipment operating instructions).
4. To get the sporicidal activity concentration shall be of 0.5-3 mg/L at 25°C Vaporized hydrogen peroxide.
5. During the inactivation phase, the hydrogen peroxide concentration is maintained at a maximum concentration level.
6. The percentage of hydrogen peroxide that is consumed by absorption or decomposition is resupplied to the system.
7. The overall fumigation time is shall be based on the area of fumigation/suppliers recommendation.
8. In Aseptic filling area (56m³/1977ft³) following condition may be considered for fumigation.

Condition	Airflow: 34m ³ /hr H ₂ O ₂ injection:10g/min Time : 40 min
Sterilize	Airflow: 32m ³ /hr H ₂ O ₂ injection:6g/min Time : 80 min
Aerate	Airflow: 38m ³ /hr Time : 4h Or AHU may be used

9. Aeration is necessary to remove the H₂O₂ by using AHU or natural aeration time.
10. Residual H₂O₂ shall be monitored by sensors (should be <1ppm).
11. Enter room adhering to appropriate practices to prevent re-contamination of the area.
12. Wearing gloves retrieve all Chemical indicators (CIs).
13. Inspect CIs to ensure adequate color change and validate the process.

Health and Safety

1. Hydrogen peroxide (HP) is a strong oxidizer and is irritating to the eyes, skin, and mucous membranes. It is imperative that all personnel using HP wear the appropriate personal protection equipment.

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- a. Protective eyewear (e.g., goggles or face shield) must be worn when performing procedures that could result in HP coming in contact with the eyes.
 - b. Protective eyewear, impervious sleeves and gloves (e.g., neoprene or vinyl) are required when handling concentrated HP solutions (i.e., changing or filling bottles).
 - c. Wash hands after handling HP.
 - d. Flush skin/eyes with water if come in contact with HP.
 - e. HP spills should be cleaned-up with water.
2. If you must enter an area briefly during or immediately after fogging with HP, coverall with hood and boots (or long sleeves, long pants, hair cover and shoe covers), gloves, snug-fitting goggles, and half-face respirator with organic vapour filters and a particulate filter are required.
 3. HP should be stored in the dark at ambient room temperature.

Effectiveness

The chemical indicators (CI) may be used for check the proper decontamination /fumigation process. (CI will change color and fades from blue towards white when exposed to the parameters i.e., time, concentration and micro-condensation of the VHP surface decontamination) process.

Ease of Use

The key advantages of this technology are in its ease of use. As vaporized hydrogen peroxide decomposes over a short period it allows shorter aeration time. Typically rooms can be completely decontaminated in less than 120 minutes, and whole buildings can be decontaminated within a day. After completion, it takes typically only 2 hours before the rooms are clean, safe and ready to be used again.