STERILIZATION OF OBJECTS USING H_2O_2

Bob Dotterer, VP of Engineering; Alan Campbell, VP of Marketing

Abstract

Caron's patented "dry" vaporized hydrogen peroxide system can be validated to sterilize large volumes of even thermally sensitive items that aren't compatible with traditional high heat sterilization.

Introduction

The recent COVID-19 crisis has highlighted the need to be able to decontaminate mass quantities of a wide range of reusable user-contact products, such as face shields, masks, and other personal protective equipment, for emergency use. Most of these products incorporate synthetic materials that are not suitable for repeated heat-based decontamination or sterilization. There is also a need to decontaminate or sterilize other types of heat-sensitive employee or user-contact products, such as filled sample vials. While low temperature decontamination technologies such as Ethylene Oxide (EtO), Peracetic Acid and Paraformaldehyde exist to fill this need, they have long-term toxicity issues that have limited their use, mostly to specialized offsite facilities. Hydrogen Peroxide (H_2O_2) is another low-temperature option. This powerful oxidizer has well documented and accepted anti-microbial properties, permitting a true Sterilization claim. Since it is fast-acting and catalyzes quickly, it offers short cycle times. Without the need to heat a chamber up to a high temperature, it also minimizes stress on unit components, sensors, and electronics. Unlike previous generations of low temperature gas sterilants, H_2O_2 decomposes into oxygen and water vapor after use, producing no lingering toxic chemicals or byproducts. As a result, H_2O_2 has become a major contamination elimination technology in both clinical sterile processing departments and life science research.

Caron has advanced the application of vaporized H_2O_2 sterilization technology by making it much simpler to use, and available within a large volume enclosure. Caron's gFog™ H_2O_2 technology pairs reduced user involvement with the shortest cycle duration. Caron integrates a dehumidification process into the cycle conditioning phase (US patent number 10,738,271). Unlike simple "wet" H_2O_2 vapor cycles, which saturate the chamber with an H_2O_2 mist, creating sterilant condensation and resulting sticky residue, Caron's dry process injects hydrogen peroxide vapor into the airstream in a controlled method, keeping the

amount of H_2O_2 and water vapor below saturation point, usually around 90% RH. A humidity sensor is used to monitor the amount of H_2O_2 in the air, and electronic control systems throttle vapor injection and maintain it at a constant level. By keeping the humidity below saturation point, no condensation forms anywhere within the chamber. Instead of a process that requires interior disassembly, drying, and reassembly after use, Caron's dry vapor cycle process permits immediate unit use post-cycle, minimizing both downtime and effort.

Background

Caron's cycle was designed to sterilize non-porous chamber surfaces, with sufficient capacity and duration to also decontaminate or sterilize high volumes of customer-provided porous or non-porous product within the chamber.

Caron's H_2O_2 process consists of three phases:

- Temperature (dehumidification)/ H_2O_2 increase to necessary levels (conditioning)
- Hold Temperature & H_2O_2 levels (kill phase)
- H_2O_2 removal (inactivation)

Sterilant volume and cycle duration parameters were determined through both theoretical and empirical test data:

- A 35% H_2O_2 concentration was selected for two reasons:
    - A higher concentration sterilant solution decreases the total volume of liquid that must be injected into the chamber and reduces potential for condensation.
    - It is the highest commonly used & commercially available concentration that is still under the US Department of Transportation threshold for passenger, cargo air freight, and rail shipment.
- H_2O_2 exposure D-value for chamber surfaces was established during an initial round of development and testing. Refer to "Sterilization of Reach-In Incubators Using H_2O_2" for specific details.
- Injecting H_2O_2 during the conditioning phase is critical to achieving a rapid sterilization cycle. 20% of the sterilization exposure is achieved during the conditioning phase, shortening the sterilization phase. (patented)
- Additionally, the inactivation phase begins with an existing high level of H_2O_2 concentration in the chamber. As this H_2O_2 level decreases over the 60 min time duration to a safe level, the H_2O_2 continues to act as a sterilant and provide further margin of product exposure.
- Bacillus stearothermophilus is the most prevalent Biological Indicator (BI) organism for validating H_2O_2 because it is one of the most resistant to hydrogen peroxide.

Caron assumes a unit temperature start value of 25°C prior to cycle start:

- If the chamber has been 'off' for hours, the internal temperature will be ambient, typically 18°C-22°C. In this case, 25°C is also a conservative cycle start value number.
- If the chamber had run through a cycle recently, the walls may be above 25°C, but the air temperature will be near room temperature, because the doors must be opened to load customer product and initiate the test.

Prior testing with BI's proved that a chamber cycle could achieve a complete 12-log reduction of all BI's by ramping from 25°C back up to 37°C and holding that temperature for 18 minutes while injecting H_2O_2 to 90% RH. Caron's Decontamination Chamber features a 45°C cycle, to further reduce cycle duration.

Caron's H_2O_2 injection takes place via a durable heated probe, which penetrates a disposable container, contacting the liquid sterilant within. The probe vaporizes H_2O_2, which is then drawn into the blower fan and circulated through the chamber via a pressurized back duct and uniform horizontal airflow across each shelf. H_2O_2 injection can only be initiated through the designated process, which includes an electronic door lock function, eliminating the potential for H_2O_2 release outside of the sealed chamber environment.

Caron uses a large volume activated charcoal filter to catalyze H_2O_2 into H_2O and O_2. This long-life filter is designed for continuous unit operation. It has been determined that a process inactivation step of 60 minutes will lower the H_2O_2 to a safe level.

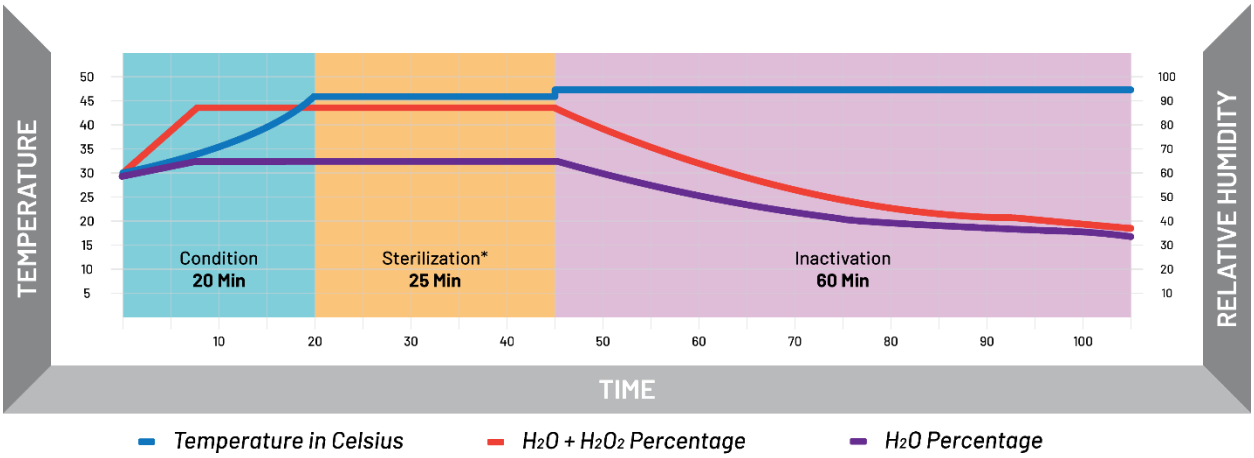
Materials and Methods

Given the varied materials, quantities, and sample construction techniques possible for products being sterilized, standard BI's may not be appropriate. Porous materials, such as textiles or paper, and samples incorporating narrow crevices or interior surfaces will require longer exposure and greater sterilant volume within the cycle to produce the desired result. It is possible that certain material volumes or configurations may not be sterilizable within the standard unit cycle. Consult with a recognized third-party test laboratory, such as Mesa Laboratories (Bozeman, MT), to determine whether a standard test coupon is available for your application, or if a material or configuration specific to your application should be used. Typically, the latter option would involve sending a defined sample to the test lab for inoculation, after which validation would proceed in a similar way to that of standard BI's.

* 7800-25, Decontamination Chamber
* STER309 or STER310, 35% Hydrogen Peroxide, container of 56ml (10x or 50x)
* Either standard Biological Indicator (BI) (reference Apex Discs, Geobacillus stearothermophilus spores, Catalog number APEX-456, by Mesa Labs or samples of target product load type(s), as determined in consultation with a 3rd party test laboratory.
* Standard Chemical Indicator (CI) strips, 3M Comply Hydrogen Peroxide, Catalog number 1248
* Data logger, Keysight model 34972A LXI
* Basic refrigerator, maintain temperature 2-8°C

BI Test Locations Within the Chamber

Summary of H_2O_2 Cycle Steps



** Pre-validated for chamber surfaces, owner validation required for product load.*

Stage	Time	Temperature	Humidity (H_2O_2 + H_2O)
Conditioning	20 minutes	25°C to 45°C	Ambient to 90%
Sterilization*	25 minutes	45°C	90%
Inactivation	60 minutes	46°C**	90% to ambient

* *Pre-validated for chamber surfaces, owner validation required for product load*

** *Novel inactivation process patent pending*

Validation Test Procedure

1. Remove all contents from chamber.
2. Open unit door.
3. Position BI's in representative locations within the chamber, typically back-left of the top shelf, front-right of the bottom shelf, and left center and right center of the middle shelf.
4. Attach a control BI to the exterior wall of the chamber.
5. Attach a CI to the clip located on the right-hand side of the integral H_2O_2 module.
6. Install 35% H_2O_2 canister within the integral H_2O_2 module, and close module door.
7. Close the unit door.
8. Initiate a cycle from the unit touchscreen controller.
9. Verify unit is performing properly throughout the sterilization cycle.
10. When the cycle is complete, confirm H_2O_2 exposure by examining the CI, and then remove all BI's & store in refrigerator at 5°C.
11. Send all exposed BI's to third-party test facility (in this case, MesaLab) for overnight processing.

The no-touch H_2O_2 canister does not require measuring or pouring and can be disposed of after use. Estimated cumulative user time to initiate and conclude a cycle is less than 5 minutes.

BI Processing

12. Per protocol and third-party test lab's internal procedures

Validation Results for Growth

Negative growth results will indicate successful inactivation of that test coupon. The outside control coupon, however, should test positive for growth. If the test coupon fails to test positive, re-run the validation process until a positive result is achieved.

Conclusions

Caron's gFog H_2O_2 cycle achieves fast, documented, and highly reproducible low temperature chemical decontamination for large reach-in chambers. This cycle was developed using established and recognized methods and test materials and employs Caron's uniform directed airflow to ensure consistent heat, humidity, and H_2O_2 distribution throughout the chamber.

With the proper validation testing, consistent sterilization of chamber loads can also be established, even in large quantities, and with porous materials. While this might not apply to every product type, vaporized H_2O_2's ability to rapidly sterilize surfaces and materials make it an ideal choice for many sample types and applications.

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CARON PRODUCTS & SERVICES, INC. PO Box 715 / Marietta OH 45750 / PHONE 740 373 6809 / 800 648 3042 / FAX 740 374 3760