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Hydrogen Peroxide Vapor sterilization of respirator masks for reuse

General

The recent SARS-CoV-2 outbreak an dits rapid speard around the globe requires social distancing to delay the spread of the pandemic virus throughout the world population.

Respirator and medical masks are being advocated as the most basic infection control measure. More specifically the N95 FFRs (filtering facepiece respirators) and its equivalents across in other countries (e.g., FFP2, KN95, DS/DL2, KF94) are the leading personal protective equipment (PPE) recommended by the Centers for Disease Control and Prevention (CDC); therefore, playing a crucial role at maintaining the health of medical staff treating corona patients worldwide, as well as for public health needs, keeping the epidemic from spreading.

This led directly to a shortage in the supply of sterile N95 FFRs, seeking governments and medical institutions for a safe, easy and accessible sterilization solution.

What is Hydrogen peroxide sterilization

Low temperature sterilization is a sterilization process best used for heat-sensitive devices that may be damaged by the conditions of a steam sterilization cycle.

Hydrogen peroxide sterilization, also known as hydrogen peroxide gas sterilization, is a low temperature sterilization process commonly used to sterilize heat-sensitive devices.

A hydrogen peroxide sterilization process involves filling the sterilizer chamber with H_2O_2 vapor. Once the sterilization cycle is complete, the vapor is vacuumed from the chamber and converted to water and oxygen.

Examples of Current Clinical Validations of Masks Sterilization

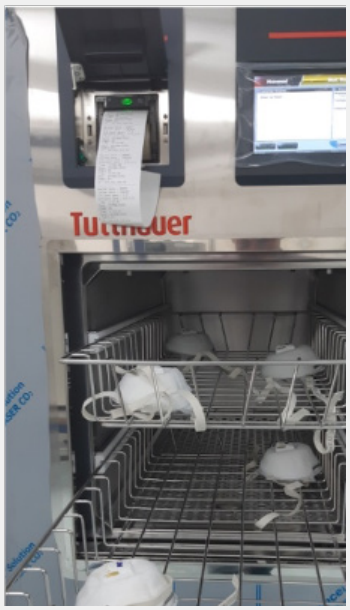
There are a few companies and clinical evidence validating the sterilization of FFR masks using Hydrogen peroxide sterilization.

The U.S. Food and Drug (FDA) recently granted the Battelle Critical Care Decontamination System (CCDS Columbus, OH, USA) Emergency Use Authorization (EUA) for large-scale and repeat (up to 20 cycles) PPE decontamination of N95 masks. The vapor phase hydrogen peroxide (VPHP) method exposes protective equipment to concentrated hydrogen peroxide vapors, in a 2.5-hour treatment cycle, destroying bacteria, viruses and other contaminants, including the novel coronoavirus SARS-CoV-2. Feasibility testing of the system demonstrated a 6-log reduction in G. stearothermophilus counts, without jeopardizing N95 respirator filter performance over multiple treatment cycles[1].

The Dutch National Institute for Public Health and Environment (RIVM) reported on similar results following exploratory FFP2 face mask reprocessing using hydrogen peroxide sterilization[2]. Unused FFP2 masks were reprocessed in up to four VPHP treatment cycles, which was previously shown to inactivate viruses. Reprocessed masks passed a standard fit test, with masks showing retained barrier efficiency, for up to two treatment cycles. Preliminary data suggest that the method is applicable for cellulose-containing masks as well.

Tuttnauer Study Report

Tuttenauer, a world-leading firm providing infection control solutions since 1925, manufactures a similar VPHP platform, which has been tested on the valved 3M Welding Fume Respirator 9925. The target of following reported study was to demonstrate the ability to sterilize FFRs by cold sterilization without affecting their performance.



Pic. 1: N95 FFR masks positioning in Tuttnauer's 160L PlazMax sterilization chamber

Material & Methods

N95 FFR sterilization process

Six (6) N95 FFR masks, type - 3M™ Welding Fume Respirator, FFP2, Valved, 9925, were placed in a Tuttnauer 160-liter PLazMax chamber, as demonstrated in Pic. 1. The masks where divided into 3 groups.
One (1) mask serve as a control, i.e., did not undergo any sterilization cycle.
Three (3) masks undergoing 3 sterilization cycles, and two (2) masks undergoing 5 sterilization cycles. The Sterilizer was then run on "Normal" program.

Vaporized hydrogen peroxide (VHP) sterilization process

Vaporized hydrogen peroxide sterilization process is constructed of four (4) main stages,

1. Sterilization chamber pressure is reduced to a very high vacuum
2. Liquid H_2O_2 gets converted into vapor
3. Under the high vacuum the vapors fill the chamber, contacting all surfaces and penetrating lumens.
4. After sterilization, the vapor is vacuumed from the chamber and converted into water and oxygen.

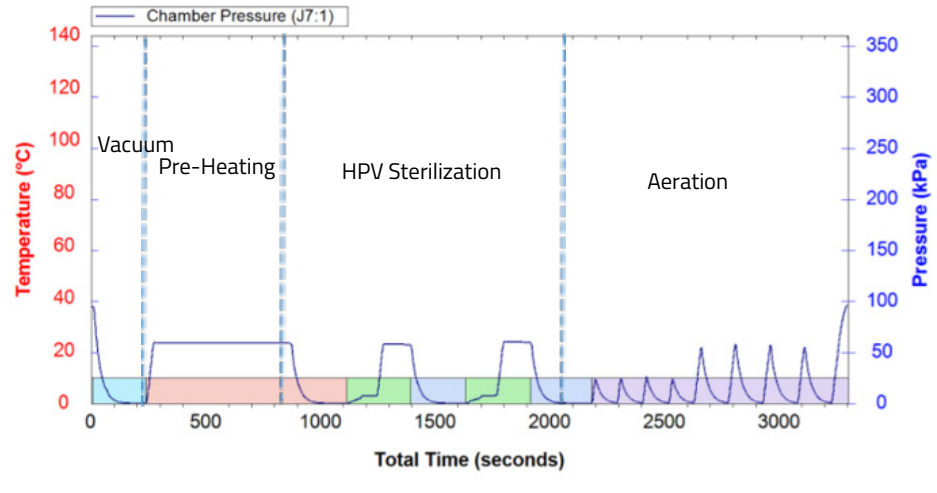


Diagram 1: PlazMax four (4) sterilization stages at 55°C

Diagram 1 presents the four stages of VHP sterilization process carried out on the PlazMax VHP sterilizer in the presence of the FFR masks. The process is carried out under constant temperature of 55°C.

Air flow Measurements through sterilized FFR masks

The air flow passing through the tested FFR masks (sterilized and non-sterilized) was carried out using the FX *3300 Air Permeability Tester III*, by TEXTEST Instruments as presented in picture 2 , following WSP 70.

1 standard, for Non-Woven application.

The system measures air flow under constant air pressure

Results are measured as $Feet^3$/min. – cfm.

Testing conditions: Tested area - 20cm2; Pressure – 125Pa;

The masks were cut into half and around the monodirectional filter, in order to fit into the test equipment.

Pic. 2: FX 3300 Air Permeability Tester III, by TEXTEST Instruments

Results & Discussion

Table 1 demonstrates the air flow (cfm) through the tested masks.

Mask #	Air Flow [cfm] No Ster.	Air Flow [cfm] 3 Ster. cycles	Air Flow [cfm] 5 Ster. cycles
1	39.5	37.9	37.6
	39.6	35	30.2
2		36.6	48
		30.6	51.2
Avg. air flow	39.55	35.03	41.75
.std. Div	0.07	3.18	9.64
[%] air flow Change		-11%	+6 %

Table 1: air flow measurements through sterilized FFR mask

It can be seen that avg. air flow has been slightly reduced after 3 sterilization cycles (11% reduction in air flow) while after 5 sterilization cycle the air flow remained more or less the same (6% increase). Although the test group is small, and taking into consideration the measuring unit limitations and inherent deviations in the product, it can be seen that there are no significant changes in the air flow through the masks that can demonstrate no effect on the non-woven material.

Tuttnauer Validation Summary

A study, targeted to demonstrate the ability to sterilize FFRs by cold sterilization, with Tuttnauer HPV PlazMax, without affecting their performance, has been conducted.

The results, although based on a small test group, showed no significant changes in the air flow through the masks even after 5 sterilization cycles.

How to operate - Tuttnauer Recommended Cycle

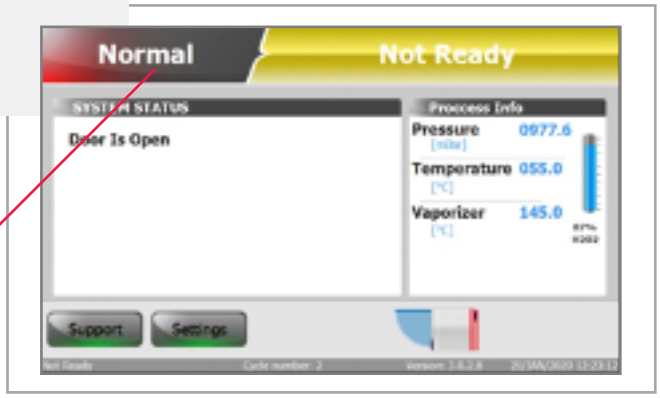
For easy sterilization and reuse of the single use masks (including N95 FFRs filtering facepiece respirators) simply choose the "normal" cycle program in Tuttnauer PlazMax machine.

Take the following steps:

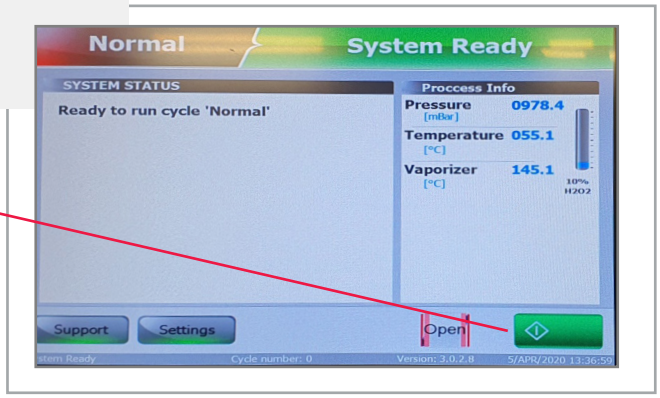
- Switch on the machine.
- The first screen to appear is the main home screen (verify that the door is open to allow choosing the right program).

Note: If the machine is already pre-set for "Normal" program, place your masks in the chamber and press start to run the cycle.

In case a different program appears, click on the "Red Button" to change to the program to "Normal".



Then click on the start icon.



- Total Masks capacity per one load is up to 120.
  To maximize your load you can place the masks on top of each other.
- If local policy calls for a single packaging of the masks, please place the packaged masks on top of each other. Make sure not to exceed the basket's dimensions.
- Normal cycle run for 45 min. thereafter the masks are sterilize and ready to be used again.
- No need for extra aeration post cycle. New cycle can be immediately operated.

Commercially Used References

This sterilization technique is commercially approved an used around the globe.

Coronavirus In Ohio: Battelle Pioneers Technology To Clean And Reuse PPE

https://radio.wosu.org/post/coronavirus-ohio-battelle-pioneers-technology-clean-and-reuse-ppe#stream/0

FDA lifts restrictions on Ohio-based Battelle's mask-sterilizing technology amid coronavirus shortages

https://www.usatoday.com/story/news/nation/2020/03/29/coronavirus-fda-eases-restrictions-mask-sterilization-technology/2936670001/

References:

1. **Ref: N95 FFR Decontamination for Reuse Final Report July 22, 2016**
2. **Ref: Hergebruik mondkapjes March 18, 2020**

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