Best practice is to use new protective masks. Decontamination does not solve the PPE shortage crisis, and is an emergency practice to be considered during the COVID-19 pandemic. Safety of masks decontamination and reuse has not been fully characterized.

WHITE PAPER

Ozone process for protective masks decontamination and reuse

SteriLux is commercializing a sterilization device relying on the use of ultraviolet radiation to generate ozone inside an airtight container. In the context of the COVID-19 pandemic, SteriLux adapted its device to decontaminate protective masks. Ozone has proven to not only inactivate SARS-CoV-2 but has also been shown to be effective against other nosocomial pathogens and threat agents. The process enables at least 3 reuses without degrading filter performance and anatomical fit to help address the protective masks shortage during the COVID-19 pandemic.

Overview

The novel coronavirus (SARS-CoV-2) that causes Coronavirus disease 2019 (COVID-19) has led to a global shortage of protective masks. SteriLux process was adapted for the purpose of bulk decontamination of protective masks with the goal of increasing the useful lifetime of masks during the COVID-19 pandemic. Effective decontamination requires inactivation of the SARS-CoV-2 virus and maintenance of both the filter and fit performance of the masks.

Ozone is the most powerful oxidative agent that occurs naturally. Its anti-viral and anti- microbial properties have been well proven and documented. Ozone has a number of advantages over other decontaminating applications. The natural compound is easily generated from air by the appropriate ultraviolet wavelength irradiation, and it naturally breaks back down to oxygen, leaving no toxic fumes or by-products. As a gas it can penetrate everywhere, including through the multiple layers of FFP masks.

Mode of action

The SteriLux process involves a build-up phase to increase ozone gas concentration and humidity in the container; a disinfection phase during which high gas concentration and humidity are maintained; a purification phase to transform the remaining ozone back into oxygen.

The precise mechanism of action of ozone against viruses is highly complex and not thoroughly understood; however, the broad oxidizing activity against many macromolecules suggests that viral membranes, protein coats and nucleic acids are all vulnerable to ozone. For optimal efficacy, high relative humidity (>90%) is required, thus indicating that hydroxyl radical and additional water-derived radicals are involved in the oxidizing process.

Feasibility study

To assess the feasibility of decontaminating protective masks for reuse, two different masks were studied, type IIR and FFP2.

Phase I of the study was to establish the parameters of the ozone decontamination cycle to ensure complete inactivation of microorganisms by exposing the masks to various ozone doses. Decontamination efficacy was demonstrated by treating type IIR and FFP2 masks after wearing them for 4 and 8 hours respectively. All samples exposed to an ozone dose of at least 350 ppm.h were negative (i.e. sterile), while all control samples were positive (i.e. bacterial growth). This confirms that the ozone treatment is effective to decontaminate type IIR and FFP2 masks.

Phase II of the study focused on quantifying the impact of repeated decontamination cycles on the functional performance of FFP2. FFP2 performance was quantified by evaluating the filtration efficiency and facial fit after three consecutive cycles. FFP2 maintained >99% filtration efficiency with no degradation to head strap elasticity nor deformation for at least three consecutive cycles.

About SteriLux device

SteriLux device has the capacity to hold up to 50 masks per decontamination cycle. When the decontamination process is complete, the masks can be reused right away as the remaining ozone has been converted back to oxygen, leaving no toxic residues or by-products.

The process achieves high-level exposure that is significantly higher than previous research has shown to be effective against other similar viruses. The device monitors every critical parameters to verify effective decontamination and allow the safe release of the load at the end of each cycle.

COM-0011_200504_V01

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