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The Institute of Healthcare Engineering and Estate Management

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# Reprocessing of Personal Protective Equipment (PPE) - An IHEEM Factsheet (1)

## Background

The Food and Drug Administration in the USA have given Emergency Use Authorisations[1] pertaining to the use of vaporised hydrogen peroxide (VH2O2) sterilizers for disinfecting type N95 and similar respirators against the Covid-19 Coronavirus. The purpose of this factsheet is to provide an overview of this information. The information contained within highlights the current situation, some basic considerations and regulatory authority positions. It will be updated as and when new information becomes available.

VH2O2 sterilizers sold in the USA are regulated by the FDA as medical devices. They must be cleared by the FDA before a manufacturer can bring such devices to market. As part of this clearance process (known as an FDA 510(k)), the manufacturer must provide evidence of utility for the purposes claimed and this will include the types of devices which can be sterilized and how they should be presented to the sterilizer including any limitations on loading configurations and compatibility of materials.

The USA legal process has a mechanism for issuing Emergency Use Authorisations which allow, under national emergencies, the extension of use of devices for a limited time to deal with a situation which is deemed critical. UK legislation has no such provision but clearly the government and parliament have the ability to modify national laws and regulation.

## UK situation

Some UK Sterile Service Departments (SSDs) have free standing VH2O2 sterilizers in use within their departments. Two manufacturer's products are predominantly found within UK SSDs, these being the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and the STERIS V-PRO Sterilization Systems. There are other manufacturers products in use, but these contribute only a small proportion of machines in use. Both the ASP STERRAD[2] and STERIS V-PRO[3] sterilizers have been granted FDA EUAs for use as disinfectors for respirators typically of the type N95 (and other models of similar construction).

Under current UK Department of Health operating policies, UK SSDs can be registered as medical device manufacturers and the legislation relating to such registration is the Medical Device Directive and the body of legislation empowering such into UK law. The mechanism for registration includes development of a documented quality system including operational procedures which are audited by a Notified Body and overseen by the national Competent Authority which in the UK is the Medicines and Healthcare products Regulatory Agency (MHRA).

## Key Issues

There are a number of technical and regulatory issues which must be considered regarding reprocessing respirators in UK SSDs.

## Workflow

The SSDs have a carefully defined workflow in which soiled surgical instruments and other reusable medical devices carrying residual body tissue, blood, and microbiological contamination, some of which may be pathogenic, enter the workflow and undergo a manual cleaning process. After this stage, the items are passed through an automated washer-disinfector in which detergents and high temperature water are employed to remove residual soil and microbiological contamination to a very low level. After this stage, devices are inspected, packaged in a sterile barrier system, and then sterilized in a validated sterilization process, usually by steam but also low temperature methods such as VH2O2. The introduction of contaminated PPE would be at the final stage of the workflow and would involve presenting to the sterilizer, individually packaged respirators, which are potentially contaminated with the wearer's spittle and spittle and sputum expelled from infected patients during treatment. This then means that the respirator has not gone through the normal decontamination processes leading to sterilization and this then presents a risk of contamination of the areas within the department normally protected by the initial manual cleaning followed by automated washing and disinfection. The dirty to clean process flow would be disrupted.

## Regulatory Considerations

The reprocessing of single use medical devices is forbidden within the UK NHS. PPE is not categorised as a medical device and therefore fall outside of the scope of the MDD/MDR and the procedures and registrations which govern the operation of an SSD. PPE requirements are regulated in UK by the Health and Safety Executive (HSE). The implications of an SSD agreeing to reprocess contaminated PPE, in particular respirators, would need to be carefully considered by Trust management. Disruption of the normal workflow of an SSD would be unacceptable since the capability to supply sterile supplies must continue even within the current crisis. As of today, the MHRA nor any other UK regulatory body have issued an exemption to the Regulations for single-use medical devices or PPE to be reprocessed. Relocation of the VH2O2 equipment away from the normal operations of the SSD might be considered since such sterilizers are largely free-standing machines.

## Technical Considerations

In general PPE and in particular respirators are single use items. There are a number of implications which must be considered should it be decided to reprocess such devices.

1. **Material compatibility** - The compatibility of the materials exposed to a VH2O2 process must be considered (e.g. cellulose cannot be sterilized in such processes).
2. **Respirator fit** - Reprocessing can damage the shape, fit and elasticated attachment of respirators. The capability to retain fit seals must be proven to remain effective after reprocessing.
3. **Filtration efficiency** - Reprocessing can damage the materials of the respirator, in particular the structure and electrostatic attraction properties of the filtration system making them less effective.
4. **Physical damage** - Removal of respirators may result in physical damage creating holes in the fabric or damage to the materials employed to ensure a good fit. Careful inspection before reuse would need to be carried out to ensure no such physical damage had occurred.
5. **Hydrogen peroxide residuals** - The consequences of sterilant residuals on the safety of reprocessed respirator wearers must be considered. Hydrogen peroxide is a potential skin and respiratory tract irritant.
6. **Viral inactivation -** After use, a respirator may contain coronavirus contamination embedded within a matrix of spittle and sputum. Salts from perspiration of the wearer may also be present. It is known that such biocontamination can protect against viral inactivation. Any validation study establishing the effectiveness of a respirator decontamination process against Coronavirus must consider the issues of residual soil.

A recently published technical bulletin[4] discusses studies which have addressed some of these concerns.

## Personnel Hygiene

Respirators cannot be cleaned as this may affect the respirator fit and filtration efficiency. The proposed vH2O2 disinfection processes have no cleaning capability therefore for hygienic reasons respirators would need to be individually identified and returned to the same user after disinfection. A suitable workflow would need to be established.

## Current Guidance

Current Department of Health, MHRA and HSE guidance does not recognise or recommend the reprocessing of single use respirators. It is understood that DHSC and NHSC are considering evidence for methods of decontamination. The HSE has issued new guidance suggesting PPE may be reused[5]. This guidance does not cover reprocessing.

## References

[1] FDA. (2020). *Emergency Use Authorization (EUA) information, and list of all current EUAs.* Available: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe. Last accessed 22/04/2020.

[2] FDA. (2020). *ASP STERRAD FDA EUA.* Available: https://www.fda.gov/media/136884/download. Last accessed 22/04/2020.

[3] STERIS V-PRO FDA EUA https://www.fda.gov/media/136843/download

[4] 3M. (2020). *Decontamination Methods for 3M N95 Respirators.* Available: https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwi9sM30nvnoAhVHZcAKHVmTBOUQFjAAegQIAhAB&url=https%3A%2F%2Fmultimedia.3m.com%2Fmws%2Fmedia%2F1824869O%2Fdecontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf&usg=AOvVaw2BQprRKM0QwK9D6MsJWYjA . Last accessed 22/04/2020.

[5] Public Health England. (2020). *Considerations for acute personal protective equipment (PPE) shortages.* Available: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/managing-shortages-in-personal-protective-equipment-ppe. Last accessed 22/04/2020.