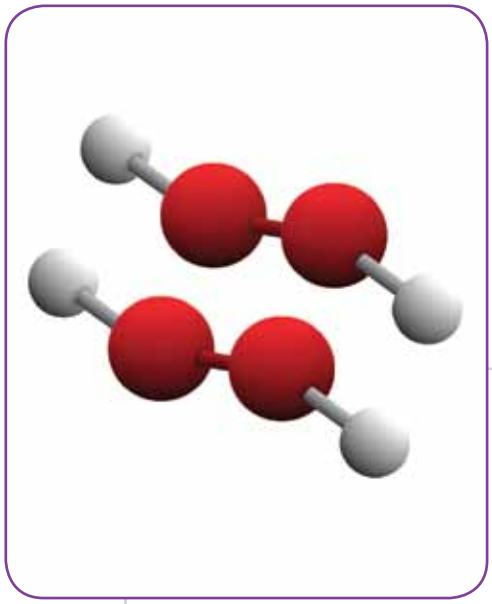

Bio-decontamination with Bioquell HPV

Technology built on a robust scientific foundation

- **Hydrogen peroxide vapour (HPV) surface sterilisation**
  ensuring elimination of biological contamination verified by a 6-log (99.9999%) reduction in bioburden
- **Safe, rapid, repeatable and residue-free**
  providing an effective treatment against a wide variety of microorganisms including fungi, bacteria and viruses
- **Compatible with a wide range of laboratory materials**
  including sensitive electronics

bioquell

Effective bio-decontamination to eradicate environmental microbiological contaminants

The eradication and risk management of microbiological contamination, comprising bacteria, viruses and fungi, are key drivers at many research sites and manufacturing plants operating in the life sciences industry. Whether in response to a contamination incident, or to help minimise the risk of a contamination event occurring, large and small organisations are turning to Bioquell to provide cleanroom and facility-wide hydrogen peroxide vapour (HPV) bio-decontamination solutions. These solutions work across a range of production environments including isolators, freeze dryers, biological safety cabinets, laboratory rooms and whole production/ research facilities.

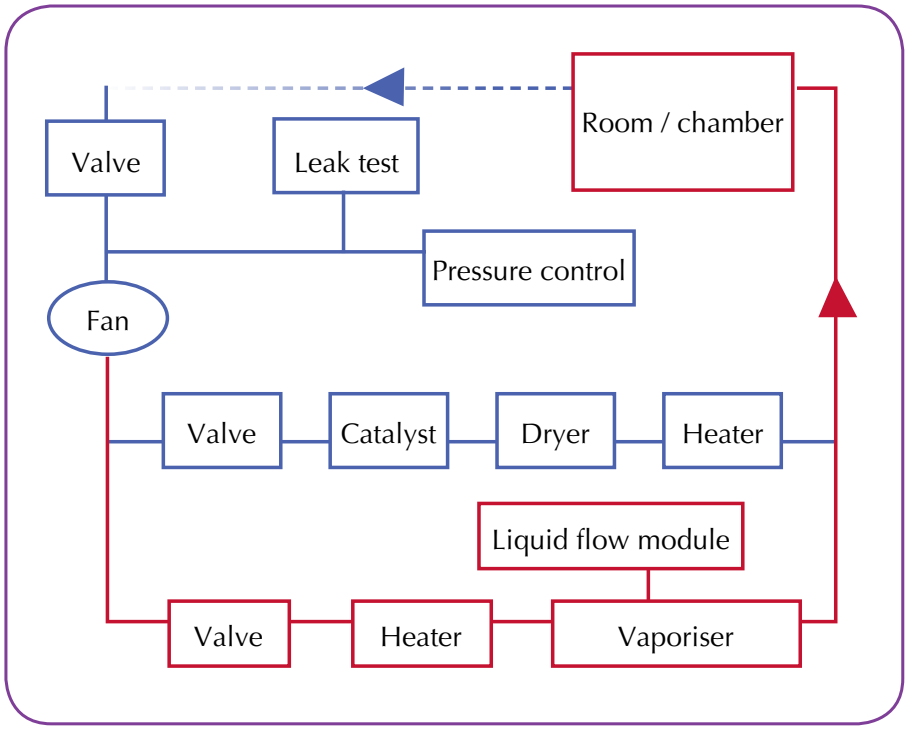

Figure 1. 'Dual circuit' technology

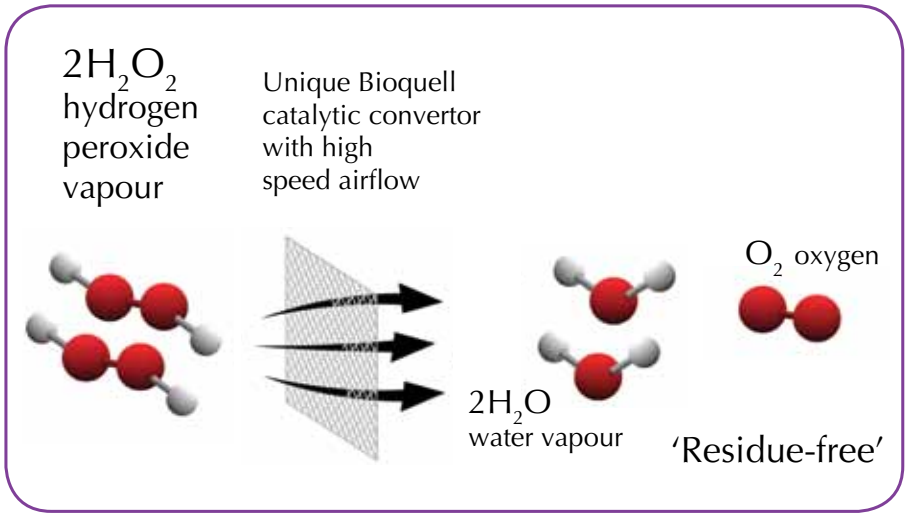

Figure 2. Residue-free nature of the Bioquell process

Technology description

Bioquell HPV technology utilises a modern vapour-phase method of decontamination. Bioquell systems are operated at ambient room temperature and relative humidity. The process leaves only oxygen and a harmless residue-free water vapour after the bio-decontamination cycle. This means that no further wiping down of surfaces is required upon completion of the bio-decontamination cycle.

The Bioquell system has been designed so that all surfaces, including the particles in the air, come into contact with the active sterilant. Bioquell HPV generators produce the vapour by flash-evaporating high quality 30-35% w/w aqueous hydrogen peroxide solution. This vapour is then distributed homogenously throughout the target area using purpose-designed nozzles supported by on-board and/or stand-alone distribution fans. Advanced computational fluid dynamics (CFD) modelling was used during the design of these nozzles and fan units to achieve a fast and homogenous distribution. When a generator is placed outside of the target area, pipe work is required in order to transfer the vapour to the injection nozzle. This pipe work is provided with insulated supply paths and/or trace heating. This ensures that the vapour is delivered at an elevated temperature and does not condense before reaching the target area.

During the bio-decontamination cycle, on-board sensors provide a controller with measurements of the HPV concentration, temperature and relative humidity within the target space. To help minimise the amount of aqueous hydrogen peroxide required for each target area, the PLC controls a unique and patented 'dual circuit' technology system (see Figure 1). Hand held hydrogen peroxide devices can be used outside the target area to accurately detect any leaks of very low-level concentrations of HPV.

At the end of each bio-decontamination cycle, the HPV is catalysed into a harmless oxygen and water vapour. This can be achieved via the generator itself, or with additional Bioquell aeration units assisting the breakdown and in some applications, by venting directly to atmosphere.

Bioquell HPV technology has been demonstrated in scientific literature to inactivate a wide range of microorganisms. It is safe to use in pharmaceutical, biological and food processing plants and is compatible with sensitive electronics.

The HPV bio-decontamination cycle

After equipment set-up, the bio-decontamination cycle (Figure 3) commences with the heating of the HPV generator vaporiser. This is described as the conditioning stage. Once the operating temperature has been reached, the gassing stage commences (1). Here, aqueous hydrogen peroxide is injected on to the vaporiser bar and the resultant HPV introduced directly into the target space at an elevated temperature. As more and more HPV is introduced, the air becomes saturated. When the air cannot hold any more HPV, dew point has been reached (2). At this stage, aqueous hydrogen peroxide will begin to condense as an even layer on all exposed surfaces. This is clearly identified when the rising hydrogen peroxide concentration curve starts to plateau over time (3).

The concentration of hydrogen peroxide on the surfaces is at a much higher level than in the air, thus creating a powerful and uniform decontamination agent. Deposited in a layer only 2-6µm deep, which is typically invisible to the naked eye, it is this micro-condensate that provides fast oxidisation and the release of free radicals leading to massive cellular destruction. Extensive research and development has demonstrated that this micro-layer is critical for repeatable inactivation of microorganisms and rapid D-values (the time taken for a 1-log or 90% inactivation of a specific microorganism).

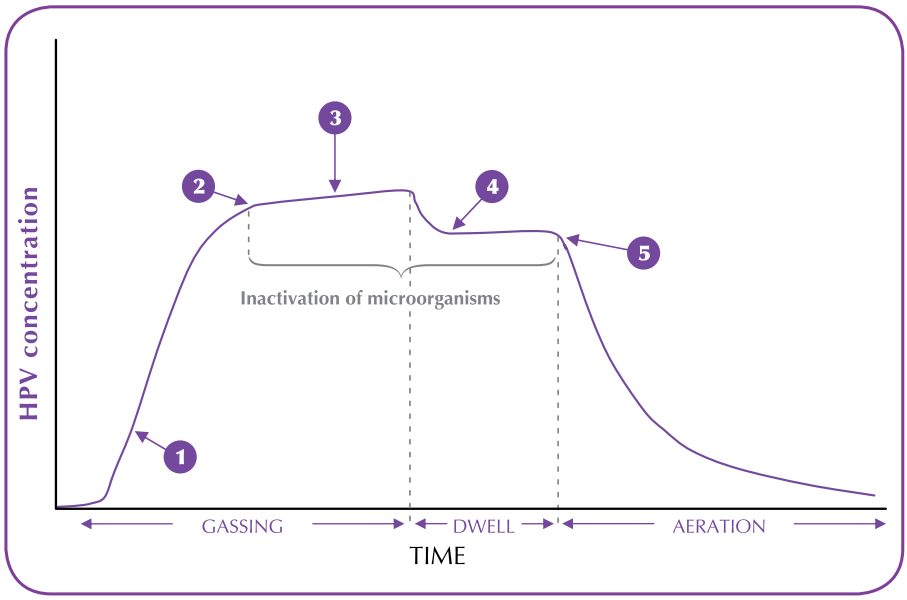

Figure 3. HPV cycle schematic

Once the optimised micro-condensation level has been reached, the HPV bio-decontamination cycle enters the dwell stage (4). Here the hydrogen peroxide concentration is maintained at a controlled and stabilised level to allow a defined contact time with the exposed surfaces. This time is critical as it ensures the safe and reliable inactivation of the environmental bioburden/biological contaminant.

Once the dwell phase has passed, the final aeration phase is initiated (5). Here powerful fans help to revaporise the hydrogen peroxide from the surfaces back into the air and force it through catalytic filters designed to break down the HPV into water and oxygen. In some instances, the room or enclosure air handling system can also be used to help speed up the aeration process. In this situation, HPV is vented to the outside environment, where it will dilute and naturally catalyses to oxygen and water. This leaves no adverse impact on the environment.

The Bioquell HPV bio-decontamination cycle is completed when a target levels of <1ppm hydrogen peroxide air concentration is achieved - the official maximum operator exposure limit (OEL).

Material compatibility

Bioquell's HPV technology has been used extensively in life science research facilities, processing/manufacturing plants and hospitals around the world. HPV applications have included the decontamination of highly sensitive electronic equipment without damage or malfunction. Additionally, extensive material and equipment testing has been conducted by Bioquell to simulate a lifetime of exposure to repeated HPV cycles. This advice is regularly published and is readily available.

Microbiological efficacy and mode of action

Bioquell HPV technology achieves a significantly higher level of bio-decontamination than manual cleaning with bleach, formaldehyde and other aerosol/nebuliser-based delivery systems. It has been scientifically proven to eliminate pathogens from the environment with the inactivation verified/validated using 6-log *Geobacillus stearothermophilus* biological indicators – the same standard used to validate steam sterilisers/autoclaves.

Unlike the manual application of liquid disinfectants and formaldehyde, Bioquell's automated process eliminates operator error whilst achieving a homogenous mix of HPV, distributed evenly within the target zone. Bioquell HPV technology ensures the optimised active sterilant contact time is achieved in order to provide repeatable biological decontamination. Real-time cycle monitoring is also provided ensuring repeatability and safety.

Hydroxyl radicals are released during the decomposition of the hydrogen peroxide. This powerful oxidising agent damages microbial cell wall/ membrane components (such as transmembrane lipids and porin proteins), cytoplasmic constituents (such as enzymes and ribosomes) and the cellular nucleic acid/DNA. The exact mechanism of action varies according to the microorganism. This multi-faceted mode of action means that microbial resistance to HPV treatment is unlikely to develop.

The process is effective for the elimination of various biological contaminants including *E. coli, Aspergillus, Enterobacter, Streptococcus, Legionella, Mycobacterium tuberculosis* and even anthrax. Additionally, because the Bioquell HPV system uses 30-35% w/w hydrogen peroxide solution, it is able to deactivate spore formers and catalase-positive nosocomial pathogens (e.g. MRSA, Gram-negatives).

Suggested further reading:

The Influence of Humidity, Hydrogen Peroxide Concentration and Condensation on the Inactivation of *Geobacillus stearothermophilus* Spores with Hydrogen Peroxide Vapour.

Beatriz *et al. J Pharm Innov* 2008; 3:123-133.

Abstract The study presented here examined the factors influencing the effectiveness of surface decontamination with hydrogen peroxide vapor. The impact of relative humidity and hydrogen peroxide gas concentrations was investigated and compared to a dew point analysis of these various sterilant atmospheres. For this purpose, a series of different H_2O_2 decontamination cycles were developed and tested for antimicrobial effectiveness using biological indicators inoculated with greater than 10^6 spores of *Geobacillus stearothermophilus*. The results indicate that an increasing concentration of hydrogen peroxide in the gas phase and higher humidity levels result in a faster inactivation of the test organisms. The higher the H_2O_2 gas phase concentration was, the more independent the inactivation effect from the humidity level. At lower H_2O_2 concentrations, the same kill was achieved with higher humidity. Subvisible condensation was found to be necessary for short inactivation times, but condensation in the visible range did not further enhance the sporicidal activity. The molecular deposition of water and hydrogen peroxide on the target surface represents the determining factor for microbial inactivation, whereas the hydrogen peroxide concentration in the gas phase is of secondary importance.

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