Real-time optimisation of vapour phase hydrogen peroxide bio-decontamination cycles using a new combined sensor

Tim Coles and Sanna Lehtinen

Abstract

Bio-decontamination cycles using hydrogen peroxide vapour are currently controlled parametrically. A new hydrogen peroxide sensor introduced by Vaisala gives real-time values for both peroxide concentration and relative saturation (the point at which water and hydrogen peroxide vapour condense simultaneously). This offers the opportunity to control gassing cycles directly, and thus the potential to develop more precise cycles with faster turn-around, and reduced de-gassing effects.

Introduction

Until recently, vapour phase hydrogen peroxide (VPHP) bio-decontamination cycles have been parametrically controlled, in most cases. The critical control parameters are the air/vapour flow rate, and the peroxide solution delivery rate to the evaporator, whilst the initial humidity has also to be established. These parameters are set during the gassing cycle development procedure, which is currently applied universally to new isolator systems. The parameters are monitored during the cycle, but they take no active part in the control of the cycle, the values being simply recorded. Given this scenario, most users opt for setting parameters that give the biggest "hit" of hydrogen peroxide vapour, with high ppm levels. Such users are keen to establish log 6 reduction in the shortest possible time, taking little account of any potential for developing a more optimised cycle. Whilst this approach has perhaps satisfied the regulators so far, the lack of sophistication is becoming more obvious.

To assist readers, and for clarity, the four phases of the hydrogen peroxide vapour bio-decontamination cycle as well as the recommended terminology are described in the box.

Active cycle control

The active control of the VPHP cycle parameters, on a feedback loop system, offers major advantages. Unfortunately, this has not been possible until recently because the available sensors needed to deliver control feedback have had too greater time constant, and have relatively poor repeatability. However, the advent of the Vaisala combined vaporized hydrogen peroxide and humidity sensor has opened up new horizons. This instrument can provide a real-time signal for both the ppm level of vaporized hydrogen peroxide, and a measure of what Vaisala term "Relative Saturation".[1, 2] As described in this paper, at 100% Relative Saturation, (RS) both hydrogen peroxide and water vapour condense at the same time, forming the frank, visible condensation that should generally be avoided in VPHP bio-decontamination cycles.[3, 4]

Using this new instrument, it is possible to provide active control through the gassing cycle, of both the ppm level of hydrogen peroxide, and the RS. In this way, the RS can be held just short of frank condensation, while the

The phases of the hydrogen peroxide vapour bio-decontamination cycle

Whichever type of vapour generator is used, the hydrogen peroxide vapour bio-decontamination cycle is generally considered to consist of four distinct phases. These phases have been variously named by the manufacturers, but unfortunately some are confusing and, arguably, inaccurate. The main issue lies with the use of the word "conditioning" for the second phase of the cycle. The word "conditioning", in the context of air handling means primarily cooling, but also dehumidification or re-humidification. Therefore, using that word to describe the gas build-up phase, after the actual dehumidification phase, is bound to cause confusion.

The four phases of the VPHP bio-decontamination cycle are best described as follows:

1. Dehumidification:
The humidity of the air in the complete system is reduced to a known level, below 50%. Note that the humidity is reduced, and not taken down to near zero, which is not required for a valid cycle.

2. Gas build-Up:
The concentration of vapour in the system is increased to a known level. It is desirable to achieve the target level as quickly as possible

3. Dwell:
The concentration of vapour is held constant at the target level, for a period of time. That time is determined during gassing cycle development, and will generally be that which achieves a demonstrated log 6 reduction of the chosen BI, plus a chosen safety margin, e.g. 50%.

4. Aeration:
The concentration of vapour is bought down to the 8-hour OEL level of 1 ppm, or less. Again, most operators will seek to achieve a vapour concentration under 1 ppm as quickly as possible, in order to start process work. Note that following aeration, the ventilation of the aseptic chamber (e.g. an isolator) must be kept running to avoid vapour concentration rising once again, due to de-gassing of the various surfaces.

The word "sterilisation" should not be applied to the VPHP cycle which is a highly effective process when carried out correctly on clean surfaces, but cannot technically be considered as anything more than bio-decontamination.

ppm concentration is maintained at a level optimised during the gassing cycle development (GCD) exercise. This method automatically decreases the variability of conditions from batch to batch and leads to more stable ppm levels during repeated gassing cycles. The instrument can, of course, provide not only the cycle control, but also a readout of the ppm level and the RS to deliver positive documentary confirmation of each cycle.

Gassing cycle optimisation

The target of the majority of gassing cycle developments is generally the demonstration of log 6 reduction in the shortest possible time, as mentioned above. The intuitive approach to this has generally led to high ppm levels of peroxide during the biodecontamination phase of the cycle, sometimes even with values in excess of 1,000 ppm. However, users have reported relatively fast log 6 reduction with much lower concentrations, down into the low hundreds. These apparently disparate results derive from the nature of the VPHP process, specifically the micro-condensation which has been extensively described elsewhere.[3, 4]

The use of lower hydrogen peroxide concentrations is attractive for a number of reasons. It may for instance offer:

- Reduced aeration times
- Reduced gas build-up time
- Reduced overall cycle time
- Fewer issues with post-cycle degassing
- Less peroxide used
- Lower risk of damage to delicate equipment
- Lower risk to personnel

It would therefore seem reasonable to suggest that gassing cycles should not simply seek log 6 reduction, but should also seek to optimise the cycle to a relatively low ppm concentration. With the use of the real-time data that the Vaisala instrument can provide, this exercise is potentially fairly easy to carry out.

Proposal for research – gassing cycle optimisation

Neither of the authors has the facility to carry out the research and development work needed to demonstrate the methodology for cycle optimisation. Such work would require a small isolator, a VPHP generator, and a Vaisala peroxide instrument, together with microbiological capability to incubate BIs. Only a few BI sites would be needed in the isolator, and multiple cycles could be run back-to-back with for example, varied gas build-up times. The use of enzyme indicators would speed the process but would add to the costs. This exercise would be well suited to a university higher degree course.

Proposal for research – gassing cycle active control

Again, neither of the authors has the facilities to develop a VPHP generator with active control, but this should be well within the capability of any gas generator manufacturer. In essence, it is suggested that the ppm level feedback from the Vaisala instrument would actively drive the delivery of hydrogen peroxide solution to the vaporiser. The ppm level during the gas dwell phase would thus be maintained at a value set by the operator, within limits that would become apparent as the work proceeds.

At the same time, feedback of the RS from the Vaisala instrument might be linked to the air / gas delivery rate, in order to hold the RS just short of frank condensation. There is an interaction between the ppm level, the RS and the air / gas circulation rate that would need to be explored.

We understand that the Finnish company Cleamix has already incorporated this technology into a new range of hydrogen peroxide vapour generators. They use the measured ppm to maintain the desired ppm level, and the RS to control the humidity to avoid frank condensation.

Conclusion

The Vaisala peroxide instrument offers the potential to control VPHP bio-decontamination systems actively, giving more precise cycle control than the current practice of parametric methods. It also produces a real-time record of the cycle, ideal for documentary support, and validation.

The instrument could also make the optimisation of VPHP cycles a regular feature, with faster cycle times, reduced aeration times and fewer de-gassing issues.

References

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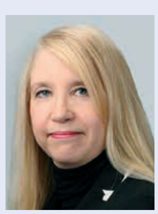
Tim Coles, BSc (Hons), M.Phil., Technical Director, Pharminox Isolation Ltd., has worked in the field of isolator technology for over twenty years. He was a founding member of the UK Pharmaceutical Isolator Working Party that produced *Pharmaceutical Isolators*, Pharmaceutical Press, 2004, and more recently of the PDA committee that produced Technical Report No 51: *Biological Indicators for Gas and Vapour Phase Decontamination Processes* [for the validation of isolator sanitisation]. His book Isolation Technology – a Practical Guide, CRC Press Inc. 2004, is now in its second edition.



Sanna Lehtinen is a Product Manager at Vaisala. She has worked as an electronics designer and with life science product management in leading international high tech companies for 20 years. At Vaisala, Sanna ensures product quality and road mapping, gathers industry insight, develops leading products for demanding customer needs and produces relevant customer-facing material. Sanna holds an MSc in Biomedical Engineering from Tampere University of Technology and an MSc in Economics from Helsinki School of Economics.