Use of an automated decontamination process in conventional isolators within the aseptic facility at Wrexham Maelor Hospital

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Introduction

With the introduction of the revised Annex 1[1], there is a requirement for Vaporized Hydrogen Peroxide (VHP) for sterilisation within Aseptic facilities. For many NHS facilities, the replacement of currently owned conventional isolators with brand new VHP isolators is not only impractical but financially impossible. As such alternative solutions are required, this poster looks at the one potential solution, the Devea Philleas Genius VHP module. A successful validation of this module was presented at QATS last year by Brian McBride [2]. On the back of this work, BCU Technical Services loaned the Phileas Genius from AB Scientific during Spring 2024 to explore the day to day usability and practicality of this solution.

Why?

The Aseptic Manufacturing Units across Betsi Cadwaladr University Health Board comprise of a wide range of conventional positive pressure isolators, this is typical of other manufacturing units in Health Boards and Trusts across the UK. Many of these isolators have been manufactured with traditional decontamination strategies in mind (spray and wipe) and as such contain many design features and unique features not seen in typical H_2O_2 isolators.

Aims and Objectives

During the loan period the aim was to determine the practicality of using the Phileas Genius within the manufacturing environment and, if suitable, validate an overnight gassing cycle in both a:

1. Atlas positive pressure isolator.
2. Envair Pharm-Assist positive pressure isolator.

The objective of this poster is to share the experience had by BCUHB Technical Services during the loan period of this portable H_2O_2 gassing system, and highlight points for other units to consider when implementing these technologies themselves.

Method

During the loan period, the Phileas Genius used the programme given in Figure 1 to deliver the gassing cycle.

The methodologies used for the validation of this cycle in 2 different isolators are detailed below.

1. Atlas Isolator: 6 Spore Log Reduction (SLR) Biological Indicators (BI) placed in 17 positions (figure 2). 1 BI per location and 3 separate cycles carried out.
2. Envair Isolator: : 6 SLR Biological Indicators (BI) placed in 17 positions. 3 BIs per location, only 1 cycle carried out.

During these cycles, H_2O_2 chemical testing strips were placed next to the BIs to determine whether the H_2O_2 was reaching the positions in acceptable concentrations.

A H_2O_2 sensor was also placed in the room outside of the isolators to determine the external H_2O_2 concentrations.

Parameter	Setting
Volume	0.67 m^3
Spraying Dose	12 mL/ m^3
Number of Cycles	5
Delay Time	0h 01s
Contact Time	Overnight (12 h)

Figure 1: Gassing cycle parameters

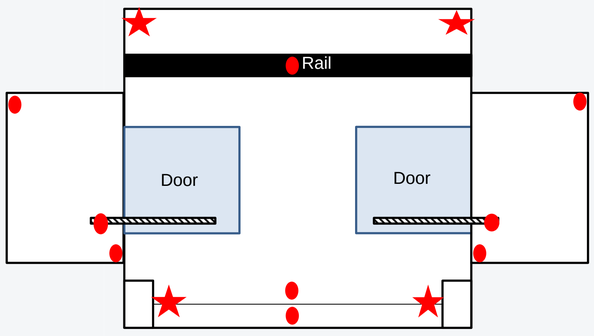

Figure 2: Locations of BIs and H_2O_2 chemical strips

Outcome

Figure 3: Setup for gassing cycle in Atlas Isolator

Figure 4: 'under workspace' position in Atlas Isolator

Atlas Positive Pressure Isolator

The validation programme outlined in the method section was successful and an overnight (12 hour) cleaning cycle was validated within the Atlas Isolator. This was achieved using 6 SLR BIs in the hatches and workspace, and 4 SLR BIs in the 'under workspace' (see troubleshooting below). In addition to the negative BI results, all chemical testing strips placed in the isolator returned positive, demonstrating there were no occluded areas in this design of isolator. The electronic H_2O_2 detector indicated a safe working concentration in the main isolator room at all times during the cycle and during the aeration period. The isolator workspace took ~ 25 minutes to return to a safe working concentration. This suggests that other isolators in the same room can be used whilst the Phileas Genius is undertaking a gassing cycle.

Figure 5: Setup for gassing cycle in Envair Isolator

Figure 6: Hatch positions in Atlas Isolator

Envair Pharm-Assist Positive Pressure Isolator

The validation programme outlined in the method section was unsuccessful and we were unable to validate an overnight (12 hour) cleaning cycle within the Envair Isolator. The reasons behind this are discussed further in the troubleshooting section below. Similar to the Atlas Isolator, the electronic H_2O_2 detector indicated a safe working concentration in the main isolator room at all times during the cycle and during the aeration period. The isolator workspace took ~ 25 minutes to return to a safe working concentration.

Troubleshooting

In this section we will outline several learning points that were taken away during our time with the portable device and common points of interest discussed with other interested parties in the aftermath.

1. **The isolator undergoing sterilisation must be turned off for gassing and contact stages of the cycle**. This is an important consideration, as within Wrexham Maelor Hospital, a shared exhaust system is used for the negative pressure isolators, therefore, if one of these isolators is off, the others cannot be used.
2. **Understanding your isolators is key.** We were unable to validate a cycle in the Envair isolator as the staff user profiles d not allow for both internal hatch doors to be opened at the same time. This should be considered in more modern isolator systems which use electronic locking mechanisms as in this instance it could not be remedied during the loan period.
3. **What constitutes your critical area?** One position failed during the 6 SLR BI validation in the Atlas isolator. This position lay beneath the workspace and several support blocks, as seen in figures 3 and 4. 4 SLR BIs were used and the location passed the validation. 4 SLR was deemed adequate as this provided a better SLR than the current spray/ wipe technique and the area is non-product contact.
4. **Correct positioning is important.** In the Envair isolator there is a Perspex screen that designates the critical area, as seen in figure 5. During the gassing cycle, significant condensation was observed on the screen due to the placement of the device. The device was moved forward and this eliminated the condensation problem, however, the effectiveness of the cycle was reduced.
5. **Validation protocol.** During the loan, 2 types of validation protocol were used. Before starting, the protocol used should be assessed for your needs, and the pros and cons of each considered. 3 cycles using 1 BI per location mitigates the cost of failure, however, is more susceptible to incidents such as 'clumping' of the BIs.
6. **What do you want the device to do?** Establishing the role you expect the device to carry out in your facility is imperative. It was initially considered that the device could be used for the transfer of goods into the isolator, however, due to the size of the isolators in YMW this was not practical and it was found to be much better suited to a cleaning role.

Conclusion

The results obtained above have helped determine that there is a use for these technologies within Technical Services at BCUHB, particularly in a cleaning role. Whereby it can offer efficiency savings, freeing up additional operator and isolator capacity. This is of particular importance as many Technical Services units around the UK have highlighted these as significant issues.

A familiarity with H_2O_2 gassing systems and a good knowledge of the isolators you wish to implement the device in, is imperative for the optimal implementation of these new technologies. It is hoped that the findings outlined in this poster aid other facilities in both their decision making and implementation processes for these devices.

Further work

During the loan period, only an overnight contact time was investigated using 7.4% H_2O_2. Further work could be carried out into:

1. Repeat the validation in the Envair Pharm-Assist isolator
2. Shorter contact time – a 3 or 4 hour contact time would enable sterilisation to occur during the working day and so the device could be used for inter-sessional cleans.
3. 30% H_2O_2 – a stronger concentration could enable shorter contact times and determining how this would effect the aeration time of the gassing cycle

References

1. Brian Mcbride, EJPPS, 274 (2022), https://doi.org/10.37521/ejpps.27404
2. The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 1, e05af55b-38e9-42bf-8495-194bbf0b9262_en (europa.eu)

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