



Validation of the Envetec Generations system for treatment of
biohazardous waste

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Overall Status:

Envetec Generations Disinfection

- Utilizes peracetic acid as the primary disinfectant
- Concentration range 1500-4500 mg/L
- Synergistic activity with hydrogen peroxide
- pH 2.8

Overall Status:

Formation of peracetic acid



This equilibrium reaction ensures more PAA is formed as it is used up by reduction with organic matter

Continuous formation of PAA ensures that the original concentration is maintained

Overall Status:

Peracetic acid as a disinfectant

- Powerful oxidizing disinfectant
- Broad spectrum of activity
- Widely used in food and water industries
- Used for disinfection of endoscopes

Overall Status:

Typical concentrations used

- Sewage effluent 1-3 ppm
- Fruit and vegetables 60 ppm
- Meat up to 400 ppm
- Poultry up to 2000 ppm
- Endoscopes up to 10,000 ppm
- Envetec Generations 45,000 ppm

Overall Status:

STAATT and the indicator concept

- Validation of any disinfection process should use inactivation of spores to act as indicators for pathogens
- For routine laboratory waste, inactivation of 10^4 spores is required (STAATT level 3)
- For waste containing more dangerous pathogens, 10^6 inactivation is recommended (STAATT level 4)

Overall Status:

Efficacy of Envetec Generations

- Designed to achieve 6 log inactivation of *Geobacillus stearothermophilus* spores
- Contact time 12 minutes
- Temperature range 2-30°C

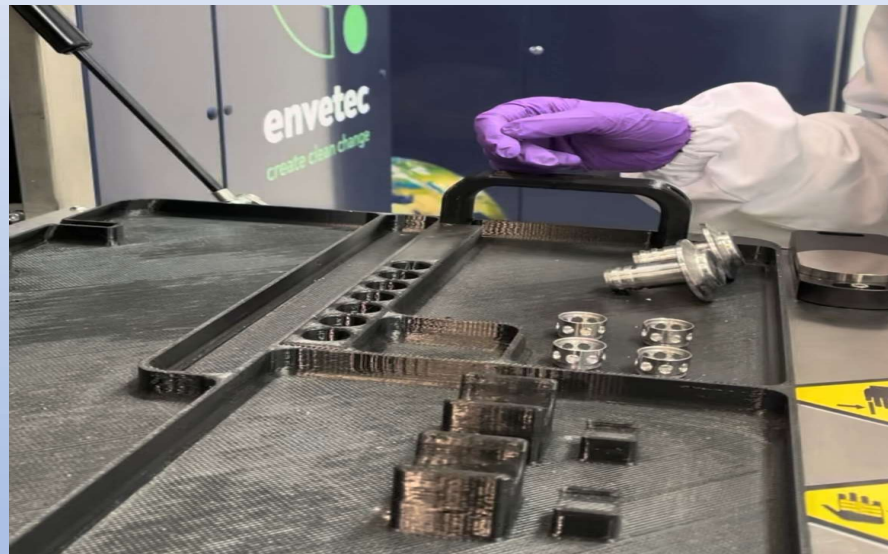
Overall Status:

Determination of efficacy (validation)

- Spores are immobilized on metal or paper discs $\geq 10^6$
- Placed into specifically designed, permeable holders
- Inserted into the machine receiver (spore discs are immersed into the disinfectant/waste mixture)
- Full cycle run, with “typical” waste
- Spore discs removed and cultured

Overall Status:

Determination of efficacy (validation)



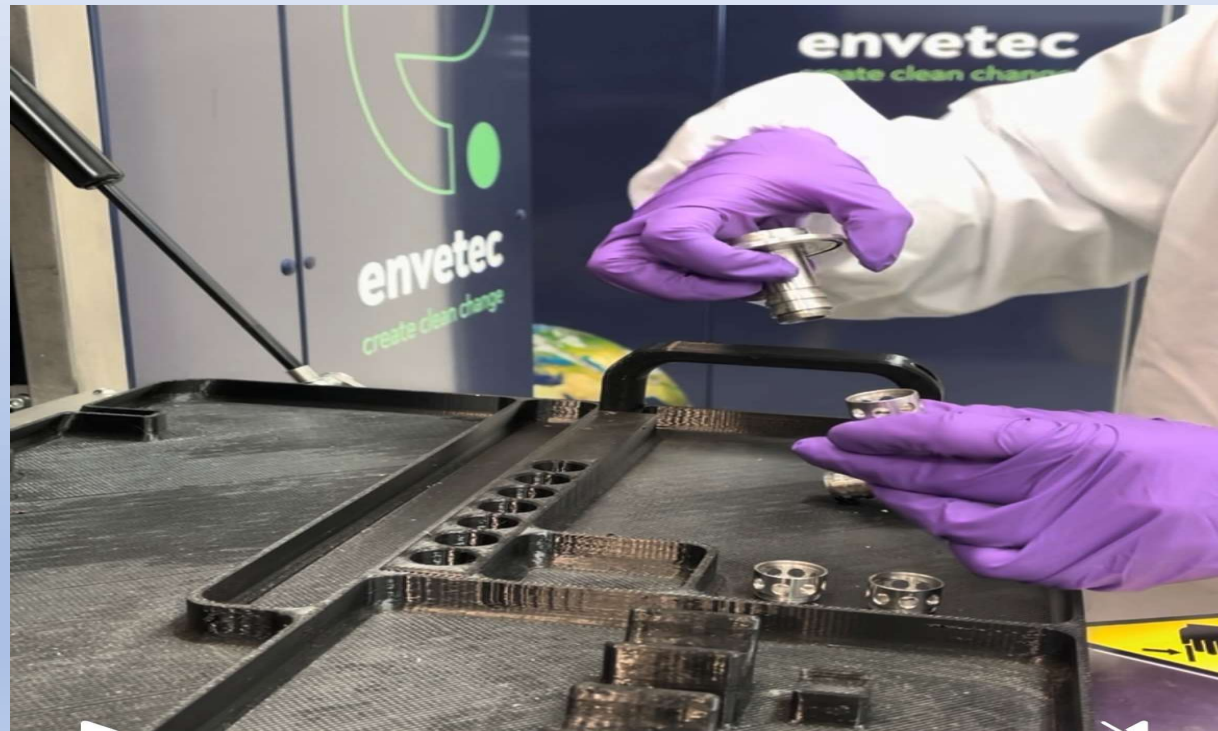
Overall Status:

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Determination of efficacy (validation)



Overall Status:

Standard culture of *Geobacillus* spore discs

- After treatment discs are placed into 50 ml TSB with thiosulphate and pH indicator
- Incubated at 55°C for seven days
- Examined daily for turbidity and acid production
- Growth of spores indicated by turbidity (precipitate) and color change

Overall Status:

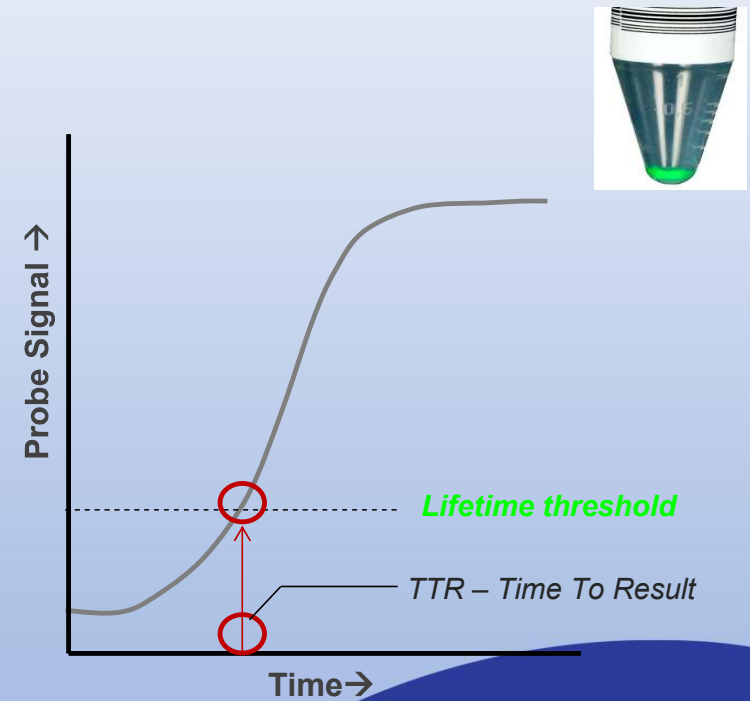
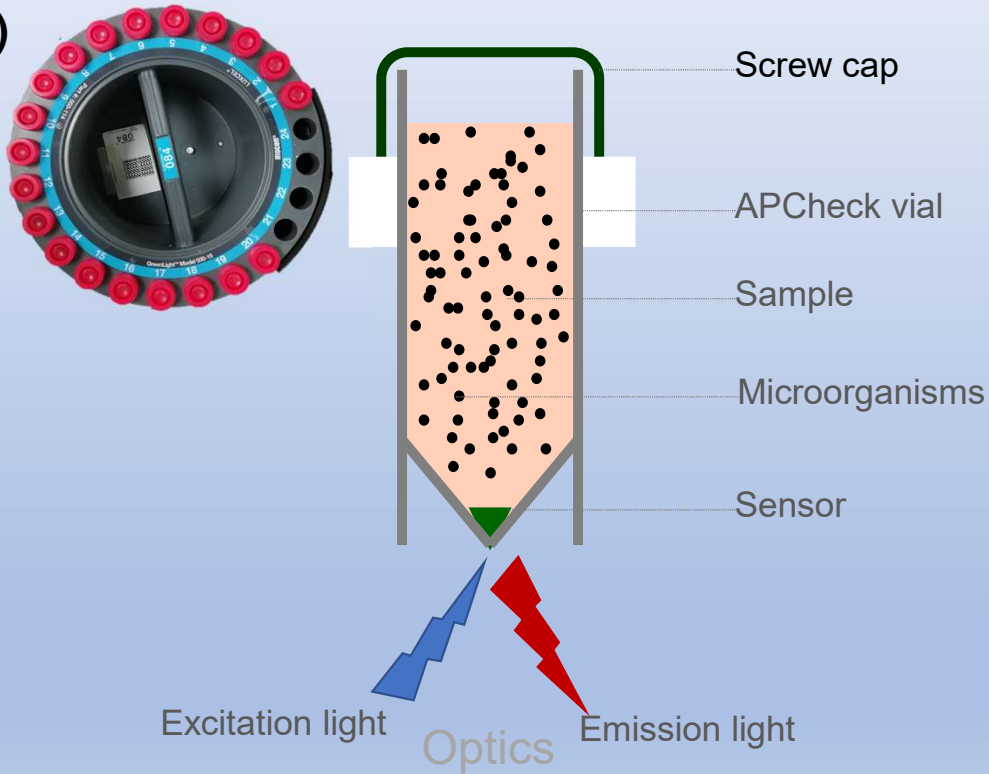
Envetec's rapid culture of *Geobacillus* spores

- Relies on detection of growth based upon oxygen depletion
- Uses an oxygen sensor that responds to changes in oxygen concentration
- Sensor emission “lifetime” increases with decreasing oxygen concentration
- Growth detected in ≤ 48 hours

930 series[®] : Technology Principle

Overall Status:

(a)



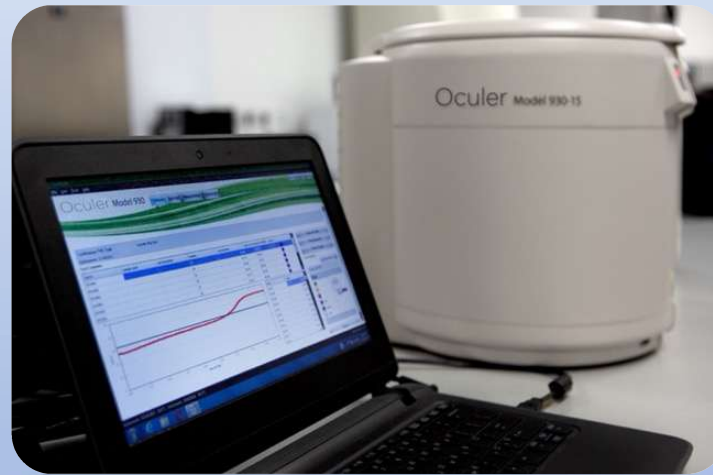
Overall Status:

Benefits of Envetec's rapid culture of *Geobacillus* spores

- Results available in real time
- Conclusive results within 48 hours
- No subjectivity, automated reading
- No false positive results
- Self-contained incubator/reader

Overall Status:

The Envetec “Oculer” instrument



Overall Status:

Efficacy testing

- All validation tests performed in the presence of routine laboratory waste
- Additional challenges include the addition of 25% milk or bovine blood
- Blood poses the greatest challenge because of the presence of intracellular catalase

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Efficacy testing

- All validation tests performed in the presence of routine laboratory waste
- Additional challenges include the addition of 25% milk or bovine blood
- Blood poses the greatest challenge because of the presence of intracellular catalase (peroxide degradation)

Overall Status:

Efficacy testing results

- In challenge tests, with or without the addition of high levels of organic material, the disinfection system achieved six log inactivation of spores
- Comparison of the sensitivity of *G. stearothermophilus* and *B. atrophaeus* showed that *Geobacillus* had the highest resistance
- D values of *Geobacillus* a minimum of one minute higher than those of *Bacillus*

Overall Status:

The challenge of GMOs

- For infectious waste, 6 log inactivation of spores is deemed to be sufficient to destroy pathogens
- Spores are orders of magnitude more resistant to disinfection than vegetative cells
- Legislation prevents the release of uncontrolled release of GMOs into the environment
- Validation for GMOs involves more stringent testing

Overall Status:

The challenge of GMOs

- No data available on the application of the STAATT indicator system to the inactivation of GMO vectors
- Studies undertaken by Envetec involved challenging the system with 10^{12} cfu of *E. coli*, *Saccharomyces* and *Geobacillus*
- Broth cultures typically contain 2×10^8 cfu/ml (5 litres required)
- Organisms presented (separately) in broth or on agar plates
- No organisms detected in the solid waste or the effluent

Overall Status:

Summary

- Envetec Generations effectively inactivates, spores and vegetative cells
- High CT 90,000 mg/minutes is higher than any other application
- Neutralization of the effluent within the machine ensures environmental compliance