

Hydrogen peroxide decontamination in practice

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Technical Customer Support



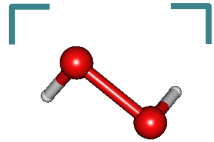
Agenda

Recap

Practical case study

Q&A session

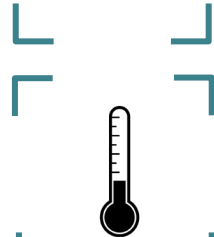
Typical process conditions



400 –1500 ppm H_2O_2 vapor during decontamination



$\leq 5 - 90$ % Humidity



$\leq 25^\circ\text{C}$ Temperature during the process



20 min – 1,5 hours Total cycle time

An effective H₂O₂ decontamination: how?



Appropriate
biocide
concentration

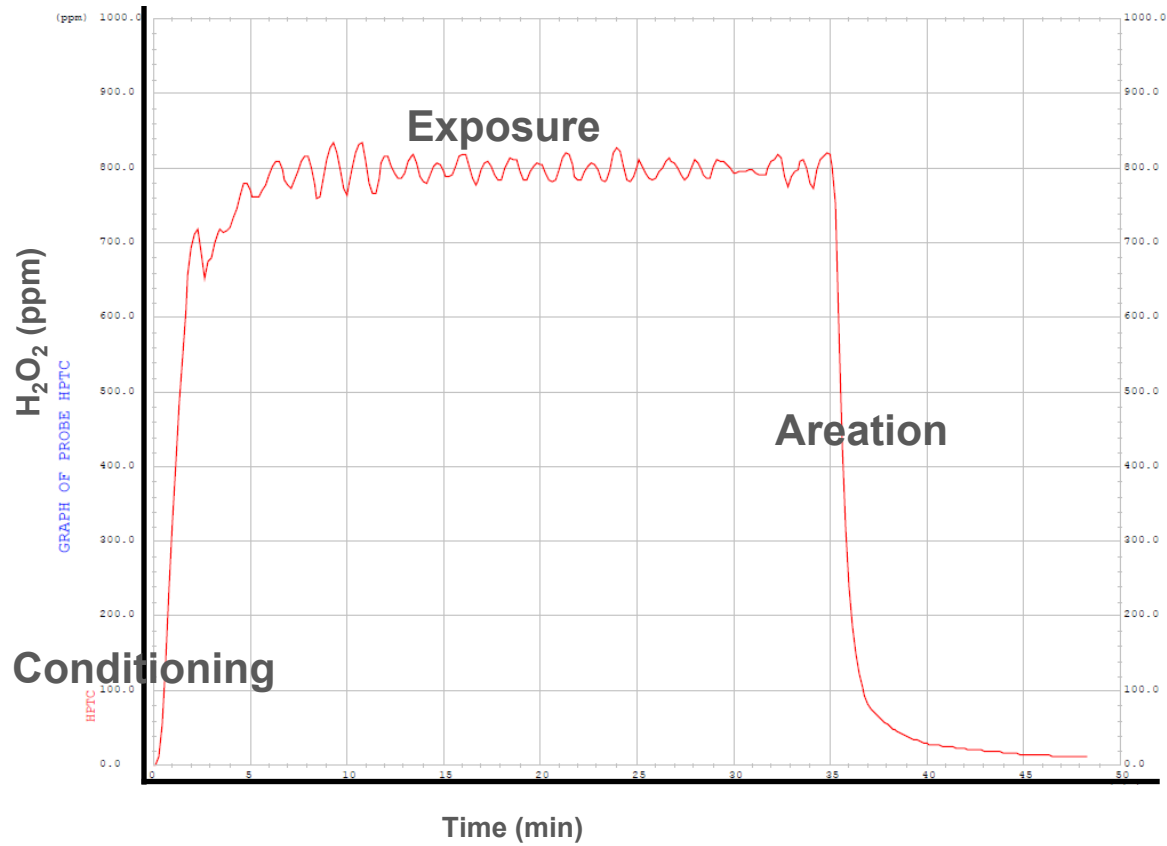


Temperature



Relative
humidity

Decontamination cycle



Typical process conditions

Fedegari Thema4 Process Controller is responsible for the control of machine hardware and cycles.

Allows the user to define cycle parameters:

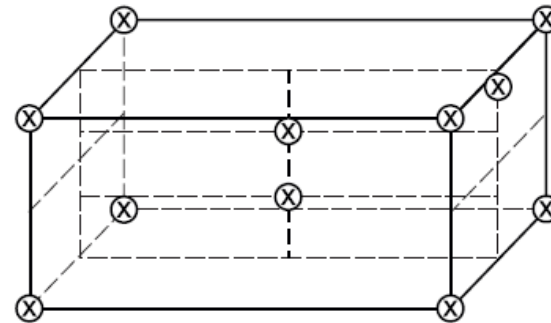
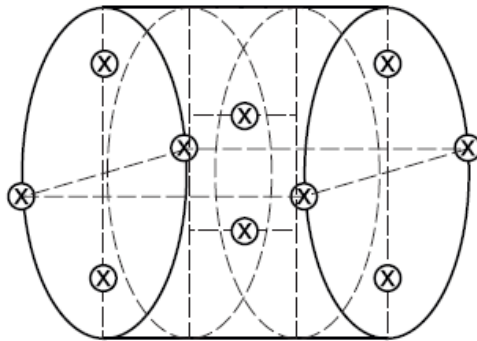
- Relative Humidity (RH) Set Point
- Temperature Set Point
- Decontamination Time
- H₂O₂ Concentration

Cycle Reproducibility: critical issues

- Cycle profile
- Biocide distribution
- Biological effectiveness

BIs & Validation

The BIs should be evenly distributed throughout the chamber and the load



Key

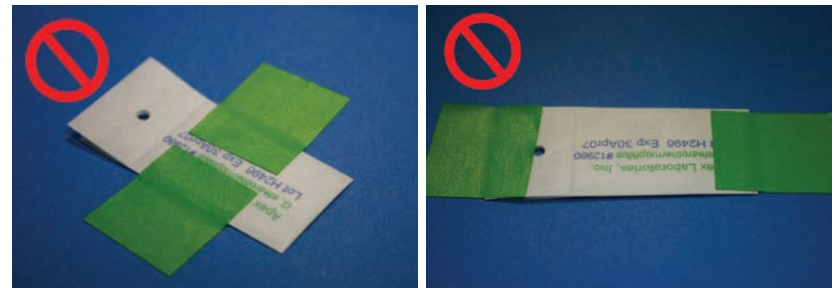
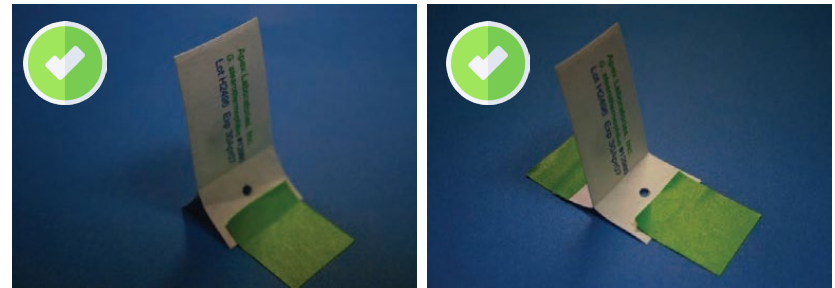
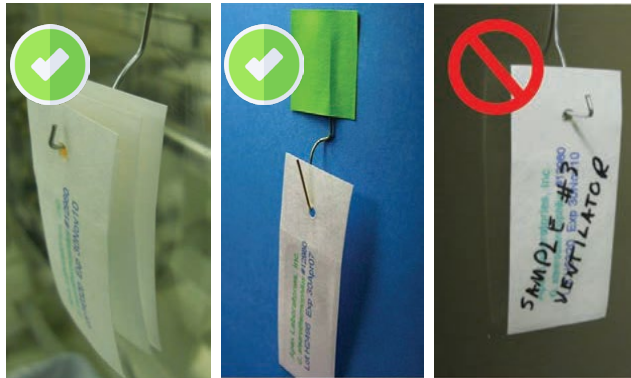
X locations for BIs, PCDs or temperature sensors

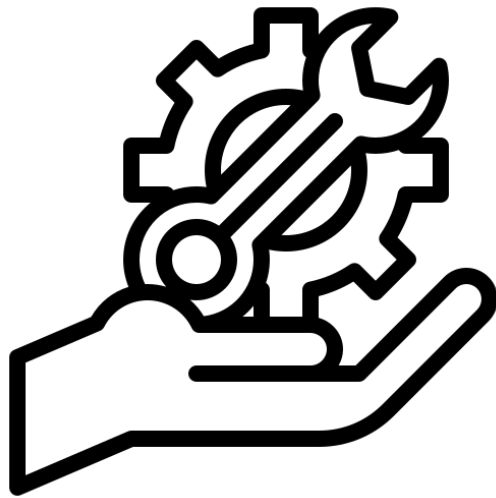
NOTE The diagram shows examples for locations in typical chamber usable space. Different chamber sizes can require more or fewer locations however a similar distribution pattern can be used.

ISO 22442:2022 – Annex K (informative) Recommended validation test procedures

BI placement & handling

Proper BI Placement During VHP Decontamination Cycles - Kurt McCauley Spore News MesaLabs Volume 9, No. 5





PRACTICAL CASE STUDY

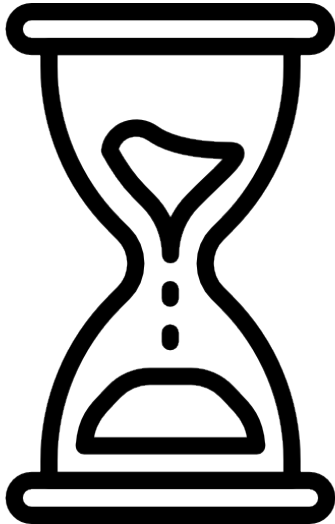
Simulation of a

Passbox reduced load

qualification



1. **Chamber loading** according to the layout
2. **BIs & CIs placement**
3. **H₂O₂ residual** concentration measurement
(LC Draeger sensor & Peroxide strips)



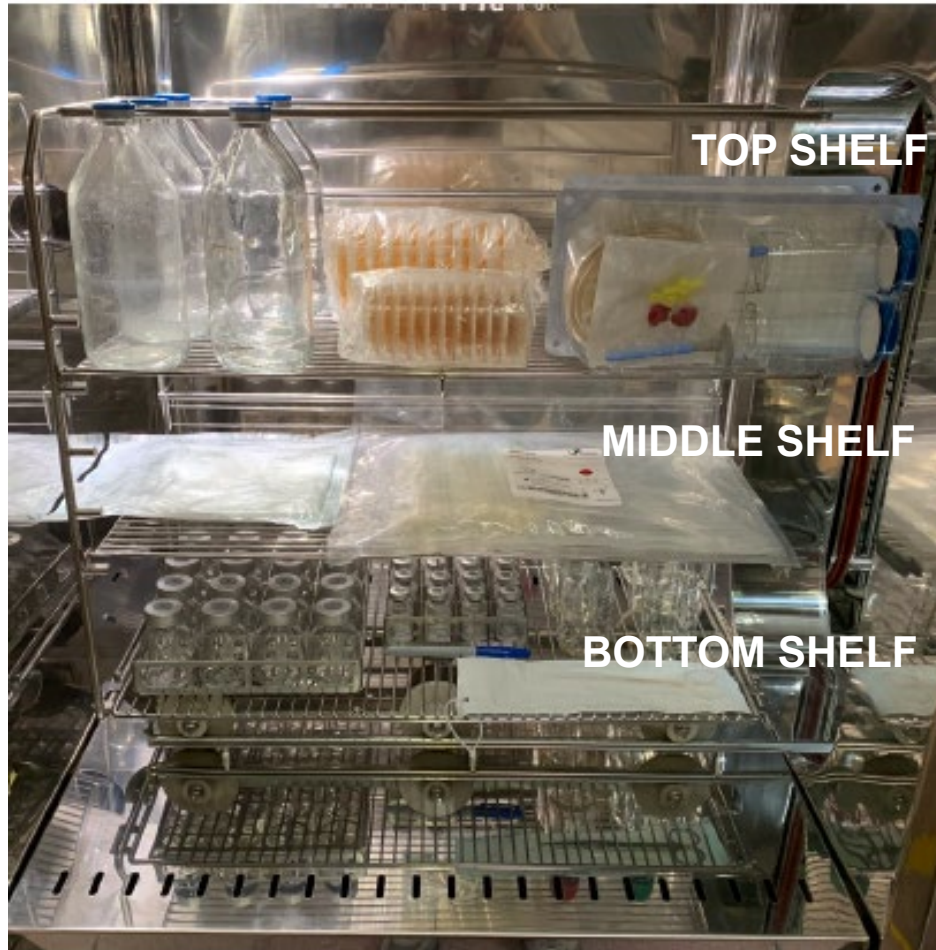
KEEP CALM
and wait for ...
...1 ppm!

Practical case study: Passbox qualification



1. **Reproducibility** of the decontamination process with 3 runs
(3 BIs at each defined position)
2. **Homogeneity** of the H₂O₂ vapor distribution
(1 CI at each defined position)
3. H₂O₂ **residual** concentration into the chamber
(LC Draeger sensor)

Load description



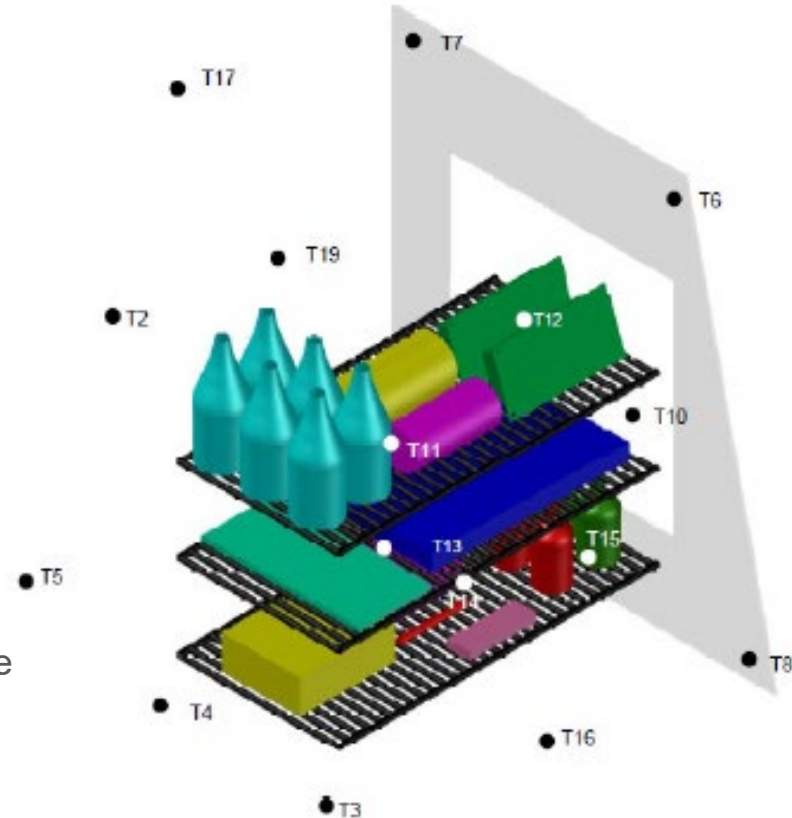
6X Washing solution bottle
1X TSA Petri pocket (90mm dishes)
1X Rodac Petri pocket (60mm dishes)
2X Canister

1X Pocket sterile wipes
1X Pocket swabs (10 pieces each)

2X Sample cart
3X TSB bottle
3X FTM bottle
1X Scissors
1X Pencil

BIs & CIs Layout

- T1 Left corner of the sealing front side
- T2 Left corner of the sealing backside
- T3 Left corner of the bottom front side
- T4 Left corner of the bottom backside
- T5 Middle of the left wall
- T6 Right corner of the sealing front side
- T7 Right corner of the sealing backside
- T8 Right corner of the bottom front side
- T9 Right corner of the bottom backside
- T10 Middle of the right wall
- T11 Between the bottle and Petri package - top shelf
- T12 Between the canisters - top shelf
- T13 Middle of the middle shelf
- T14 Middle of the bottom shelf
- T15 Between the bottle of the bottom shelf, the left side
- T16 Middle of the bench
- T17 Middle of the ceiling
- T18 Middle of the front wall (transfer unit door)
- T19 Middle of the back wall



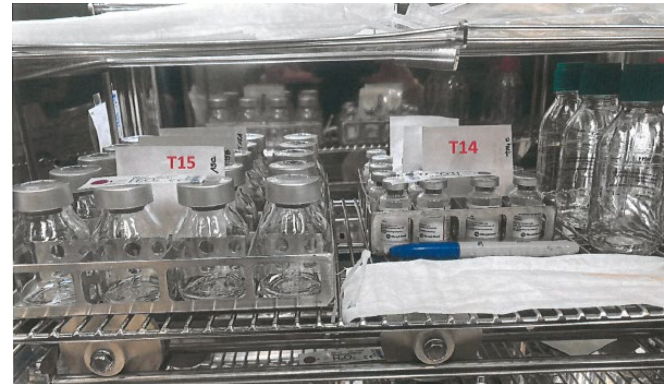
BIs & CIs Mapping

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BIs & CIs Mapping

3 BIs and 1 CI at each chosen position



CIs Result

Not exposed



Exposed



BIs Results



+ = Growth
- = No growth

Chamber H₂O₂ residual concentration

Measuring the H₂O₂ concentration during the aeration phase



Dräger Electrochemical *Low Concentration* (LC) sensor

THEMA 4



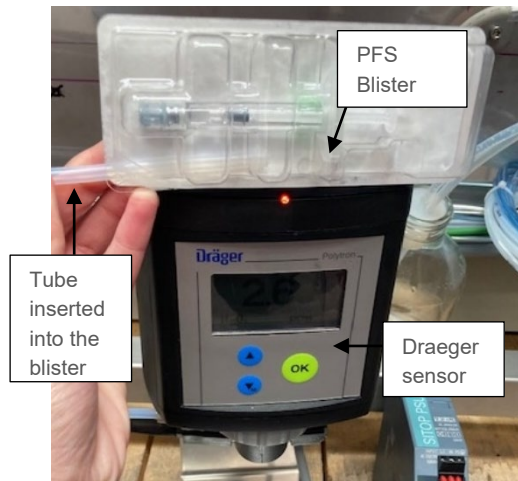
Process controller for



Only when the H₂O₂ concentration is under the required level (e.g. 1 ppm) is possible to open the door

Product H₂O₂ residual concentration

Measuring the H₂O₂ concentration into the product



Into the blisters
Draeger sensor



Inside the product
Test Peroxydes strips



It is the responsibility of the operator to verify that containers, media, and supplies are unaffected by the decontamination process

Thank you for your attention

