



PROCESSES

Sterilization
Washing
Chemical
bio-decontamination
Contamination
control
Dense-phase fluids plants

SPECIAL APPLICATIONS

Rotating sterilizers
Pharmaceutical closures
processing

COMPONENTS

Pressure vessels
Doors
Piping
Process controller
Wireless sensors

ACCESSORIES

Un/loading conveyors
Customized racks

FCTS- Fedegari Sterility Test Isolator with built-in Hydrogen Peroxide Vaporizer

Innovation in a commodity market?

When creativity is in your blood you cannot settle for basic innovation but you will explore new paths for revolutionary solutions. This was our goal when we started designing our first isolator.

Process control

Given Fedegari's experience in different contamination control processes, our first priority was to assure the highest reliability of the process. We investigated various alternative solutions only to discover repeatability of performances – as it is normally expected in thermal sterilization – was a little more than a dream.

System reliability

Only experience – practical field experience – provides the highest degree of reliability because the single subsystems and solutions in general have already been tested under real operating conditions. In Fedegari when we design a new machine we assemble in a different form several in-house engineered solutions which have already been used in other machines before, thus reducing to a minimum the new developments which have to be validated by the time. Unhappy with the performances and the reliability of third-party H_2O_2 – vaporizers, we have installed the same solutions that we have standardized for our bio-decontamination machines that does not require any proprietary consumables. This innovative design provides real time biocide concentration control (over traditional estimated calculations) and is managed by the very same Thema4 which is today's reference standard for all contamination control machines where process failure is not an alternative. Through the H_2O_2 sensors and other devices, Thema4 assures that vapor concentration remains extremely stable (within ± 15 ppm) thus making process repeatability the obvious consequence.

Efficient bio-decontamination

The unit transfer hatch is equipped with a magnetic-driven fan in the ceiling. This innovative design for homogenizing the H_2O_2 - air mixture allows a uniform distribution of the vapor and avoids any possible leak. Moreover, an UDAF that creates a piston effect, guarantees the correct biocide distribution.



Sterility Test Isolator

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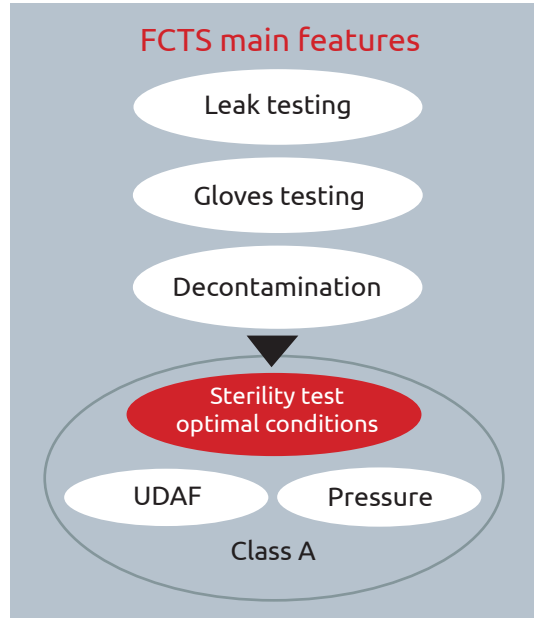
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FHPV

Fedegari Hydrogen Peroxide Vaporizer

The dosage is performed by the process controller and the consumption is measured and indicated on each batch report. The process does not start if there is not enough H_2O_2 liquid into the buffer tank. An H_2O_2 level sensor fixed on the buffer tank restore the liquid H_2O_2 level from the customer H_2O_2 tank. The metering system checks the amount of H_2O_2 left into the buffer tank, pumps the liquid through the tubing system and meters the specific amount of liquid biocide to be delivered to the vaporizer unit.

Design features

Compliant to cGMP guidelines, the working chamber has non-directional BA surface finishing ($Ra \leq 0.4 \mu m$). Air-tightness is 100% guaranteed by ultra-safe doors. Two sensors monitor the amount of H_2O_2 in a fixed sampling point of the chamber. The first H_2O_2 sensor (150-1500 ppm) measures the concentration to control the process. The second H_2O_2 sensor (0-300 ppm) is installed for safety (TLV<1ppm). The isolator can be equipped with sterility test suits from different makes.



H_2O_2

Thema 4
Process controller

Measurement

+

Control

Key-benefits

- Feedback control for superior process repeatability even if load patterns change
- Fixed concentration profile with no impact of H_2O_2 degradation on the process
- Drastically reduced validation time for cycle and load
- Material routing optimization
- Gloves and leak testing totally managed by Thema4 process controller
- Silicon self-retractable gaskets for 100% air tightness on all doors
- Significantly reduced operational costs with non-proprietary consumables
- Thema4: easy integration with other Fedegari machines and customers' SCADA systems
- Cost-effectiveness: time and cost-savings on training and maintenance due to standardization of components, procedures and process controller
- Bespoke racking and storage
- Controlled means for loading and removing the processed loads and waste materials