HYPER

VPHP GENERATOR



HYPER® is a Vapour Phase Hydrogen Peroxide (VPHP) generator specifically designed to perform bio-decontamination processes of clean, dry, isolators used in medical, pharmaceutical and biological applications.

The machine is intended for use in the pharmaceutical and radio-pharmaceutical industry.

It is used to guarantee the asepticity of processes such as: transfer of instruments and preparations, handling and production of drugs and performance of sterility tests.
Processes can be validated using biological indicators Geobacillus stearothermophilus to constantly achieve a 6-log sporicidal reduction.

HYPER works in single pass (open loop) configuration to achieve very fast bio-decontamination cycles.
It is controlled by a Siemens PLC to ensure a safe control process and generate a complete bio-decontamination cycle report.
HYPER can be either integrated with the isolator structure or remoted into an external cabinet made of stainless steel AISI 304.
To minimize operators' exposure to the liquid hydrogen peroxide during handling of bulk product, HYPER uses specially designed disposable containers containing 3.000 ml of 35% Hydrogen Peroxide (H_2O_2).

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CYCLE DESCRIPTION

The bio-decontamination process is a dry process resulting in no condensation of VPHP on treated surfaces.

HYPER® provides a low temperature bio-decontamination method, in which an aqueous solution of 35% H_2O_2 is flash vapourized into a pre-heated air stream, which enters the enclosure enriched with VPHP.

The cycle can be divided into four main phases:

DEHUMIDIFICATION

Dry HEPA (High Efficiency Particulate Air) filtered air is sent inside the isolator to decrease the relative humidity accordinig to customers recipe.

RISING

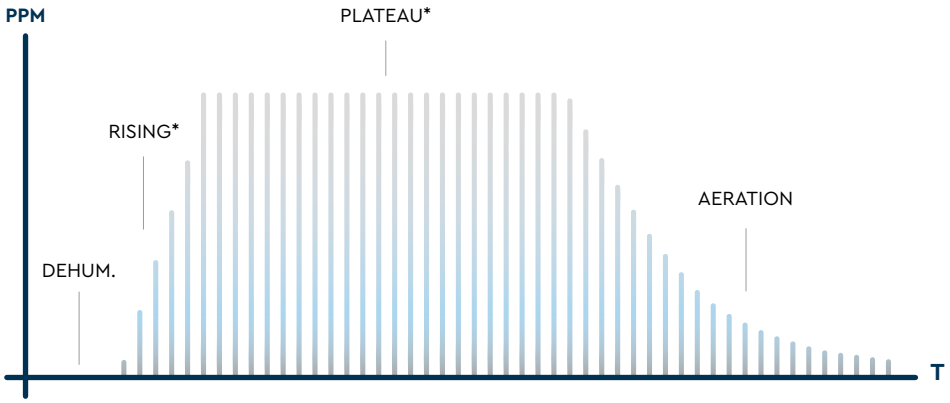
The flow of dry HEPA filtered air continues while H_2O_2 is injected into the air stream. The injection rate is controllable in the 0.0 to 30.0 grams per minute range, allowing to reach the target VPHP concentration in the fastest way possible.

PLATEAU

The target VPHP concentration, reached at the end of the rising phase, is maintained for a specific time throughout the enclosure.

AERATION

VPHP injection is stopped and the flow of dry HEPA filtered air is sent inside the isolator to reduce the concentration of H_2O_2.
Once the mayority of H_2O_2 is extracted, the ventilation system of the isolator completes the reduction of the VPHP concentration to a safe level (≤1ppm).



*The time is affected by injection rate, airflow rate, isolator volume, isolator load and temperature.



REV. 00_23



OPTIONS:

- Catalyst Group
- Dräger High-Low Concentration Sensors

MACHINE INFORMATION

Description	Value
Weight	115 kg
Dimensions (H x W x D)	1705 x 600 x 402 mm
Mains voltage	200-240VAC
Mains frequency	50/60 Hz
Rated current	15 A
Noise emission*	Lp A < 75 dB

*The noise emission test of the machine was performed with reference to UNI EN ISO 3746:2011.

PROCESS INFORMATION

Description	Value
VPHP (concentration VHP)	> 800 ppm
Microbial charge reduction	> 6 Log (99.9999%)
MAX injection rate	30 g/min
MAX air flow	75 m3/h

The company Tema Sinergie S.p.A. has a Quality Management System certified by Kiwa Cermet Italia S.p.A. according to the ISO9001:2015 (since 2000) and ISO13485:2016 (since 2013) regulations.