Dräger

Vaporized Hydrogen Peroxide for Bio-decontamination

Application Note

Introduction

Dräger introduced the first electrochemical hydrogen peroxide (H_2O_2) sensor for monitoring low concentrations of vaporized hydrogen peroxide (VHP) in 1994. Vaporized hydrogen peroxide is the preferred substance for decontamination of a variety of products due to its bioactive effect of killing bacteria spores and other microorganisms. VHP is being used in filling machines, barrier isolators, glove box work benches and for entire rooms.

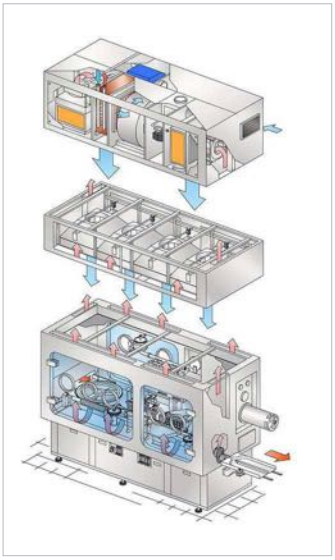
Market Segments

Pharmaceutical industry
Healthcare and hospitals
Food and beverage industry
Labs and clean rooms
Animal farming
Decontamination of HVAC systems
Decontamination of freeze dryers

Description of the Challenge

VHP is generated by actively evaporating liquid hydrogen peroxide solution. The vapor then is released or injected into a confined space. A high concentration is needed to generate a high decontamination and kill rate of microorganisms.

But VHP is also rated as a hazardous substance for humans with a defined workplace limit value (OSHA PEL 1 ppm). Thus personnel outside the fumigated equipment have to be protected against inadvertent leaks of H_2O_2 vapors. After the decontamination cycle the reduction of H_2O_2 concentration in the space by aeration and purging has to be monitored to clear the fumigated volume to allow people to safely enter or to enable new sensitive material to be brought in for processing.



The mobile VHP generator, providing the vapor for the decontamination, also could cause a hazard to personnel. Therefore H_2O_2 is to be monitored for unwanted leaks close to or around the generators and the connecting hoses. Complying with GMP requirements, a risk assessment has to be performed for the installation identifying all potential hazards and defining exposure control measuresas well as relevant personnel protection actions to be taken in case of a hazard. Some of the safety targets are monitoring workplace levels, leak detection, verifying purge for safe entry and to access cycle parameter control and potential emission monitoring after the system filter and scrubber.

The Process

VHP is a vapor and not a gas. This means the concentration in air can never be more than the vapor-pressure at a certain temperature. If the relative concentration reaches saturation (dew point) H_2O_2 vapor starts to condense as an aerosol or adheres to surfaces. H_2O_2 is completely soluble in water. For the VHP application, solutions of 30% to 35% H_2O_2 are common. Because the evaporation of water is 15 times more effective than H_2O_2, the solution has to be actively evaporated to get the H_2O_2 into the air. If H_2O_2 vapor hits condensed water it goes into solution. The VHP concentration in the surrounding air will decline.

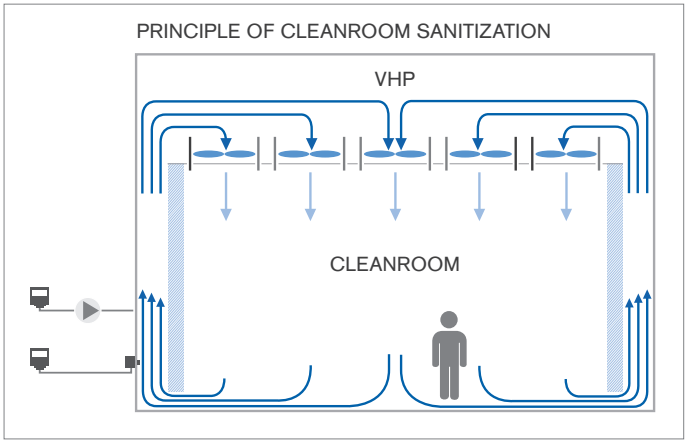
H_2O_2 is not a stable substance. It decomposes into oxygen and water, hence there is always a continuous loss of H_2O_2 concentration. In the liquid solution stabilizing chemicals are added to keep the concentration stable. Due to active evaporation these stabilizers are also distributed into the fumigated volume.

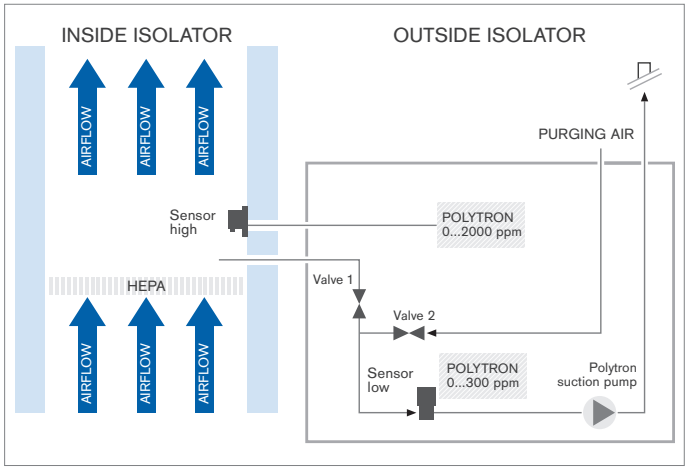
H_2O_2 is a sticky vapor. One can observe a loss of concentration due to absorption and adsorption on surfaces. Saturating a surface with a small VHP concentration takes much longer than with a high one. The concentration is affected, resulting in lower readings. It is important to consider this in pumped systems where the tubing will absorb some H_2O_2 before it hits the sensing device. Dräger measures H_2O_2 vapor as a volume concentration (ppmv, for short ppm).

Material compatibility

VHP is a chemically aggressive substance. Dräger transmitters and sensor are made of PA12 (polyamide 12 blend) which is a chemically resistive plastic, showing no decomposition under the specified VHP environmental conditions and the intended use. For excessive VHP exposure, only the sensor opening should be exposed to the vapor. Any use outside the specified conditions and intended use has to be verified by the operator/owner of the equipment.

Cycle Parameter Control and Safe Entry Measurement





The decontamination cycle for an isolator or clean room is divided into as many as four phases. Dehumidification is the first phase in the fumigation cycle. During this phase, air from the room is circulated through the dehumidifier to reduce the humidity level. This phase takes approximately 20 minutes. In the conditioning or gasing phase, VHP is actively released into the room at a preset injection rate. This allows the concentration of VHP to be rapidly increased in the room to a predefined level. This phase normally takes 30 minutes. Decontamination is sometimes referred to as the 'dwell' phase. During this phase, a constant flow of VHP is maintained at a specific injection rate to ensure a constant concentration over a predetermined time. During this phase, the previously defined process parameters have to be applied to achieve the required microbiological kill rate. Aeration is the longest phase in the cycle, taking approximately 5 hours. The injection of VHP into the room is stopped, and air is circulated through a scrubber or filter, and/or replaced by fresh air to bring the VHP concentration down below predetermined safe thresholds.

The entire fumigation cycle has to be qualified and validated during the equipment commissioning by means of chemical (CI) and biological indicators (BI), complying with GMP regulations. The time frame and injection rate are monitored parameters of the validated customized cycle.

For safe access to the fumigated space at the end of the aeration phase, both the H_2O_2 LC and HC DrägerSensors® should be protected by a controlled sampling system from the high concentration used during the decontamination phase. The HC DrägerSensor can be used to monitor the high concentration decontamination cycle and control the start of the sampling system for the low concentration. In addition, the H_2O_2 HC sensor can show and monitor the fumigation curve using the Regard 7000 Controller and graphics software.

Sensors should not be exposed beyond the maximum measuring range of the sensor. That will result in a prolonged recovery time. The Dräger gas monitoring system must not be used for active control of the fumigation process!

Dräger Solutions

Workplace safety and leak detection for H_2O_2

Stationary gas detection devices can monitor the working area for H_2O_2 leaks. It is essential to position the stationary equipment in the right locations to quickly and reliably alert workers when the gas is present. For optimal response the likely gas leak points, distribution and convection have to be identified and taken into account. Gas mapping programs can prove invaluable in saving lives and money by optimizing coverage.

Detection of hydrogen peroxide in disinfecting processes

Dräger Polytron® 7000 or 8100 are universal transmitters that accept any DrägerSensor by downloading sensor-specific information from the embedded EEPROM sensor. The sensor has an internal temperature element that compensates for temperature variations between -40 to +149°F. The Polytron 7000 can accommodate an internal pump and data logger, while the Polytron 8100 comes standard with a 30,000 event data logger. All units are available with optional relays. Communication options include 4-20 mA, HART, Modbus, Foundation Fieldbus and more.

Sensors for personnel and TLV-level leak detection applications

- H_2O_2 LC DrägerSensor: detection range 0 to 1 ppm min up to 300 ppm max, 0.1 ppm resolution.
- Electrochemical diffusion sensor: for stationary Dräger transmitters for continuous monitoring of low levels of H_2O_2 concentration in ambient air.

Sensors for monitoring disinfection levels of chambers/ rooms applications

- H_2O_2 HC DrägerSensor: detection range 0 to 100 ppm min to 7000 ppm max, 10 ppm resolution.
- Electrochemical diffusion sensor: for stationary Dräger transmitters for continuous monitoring of high levels of H_2O_2 concentration in ambient atmosphere of disinfection chambers/rooms.

Complementary solutions

- Diagnostic dongles for the Polytron 7000 and 8100 enable extended software features such as sensor diagnostics to provide sensor vitality data for warning that a sensor is nearing end-of-life to allow preventive maintenance.

- The Regard 7000 Controller is designed specifically for safety systems and is SIL 2 rated. It can record and display current conditions of the connected devices and provide detailed diagnostic, preventive maintenance and configuration capability on its connected devices using a master-less system. It can also differentiate spurious signals from actual gas excursions, dramatically reducing the potential for false alarms.

Advantages of Dräger Solutions

- Selective real-time monitoring of H_2O_2 vapor
- H_2O_2 target gas pre-calibrated DrägerSensors
- Onsite bump test and/or surrogate calibration with SO_2 surrogate gas
- Specialized measuring ranges for low and high concentration applications
- Fast and stable gas response
- Target gas calibration service

Comments

Calibration

Due to drift and loss of sensitivity over time, a measuring system needs regular calibration. Because of the above mentioned physicochemical properties of hydrogen peroxide, it is not easy to perform a calibration with hydrogen peroxide vapor. VHP has to be generated with tools under laboratory conditions and verified with analytical equipment. This cannot be performed easily in the field.

Dräger provides new, factory pre-calibrated sensors with calibration data stored in the sensor EEPROM memory. For recalibrating the sensor, the user can select the new Dräger H_2O_2 Sensor Exchange Program. On an agreed upon schedule, a recalibrated sensor is sent to the user and the old sensor can be taken out of the transmitter and shipped to a Dräger Service Center. In the meantime, the replacement sensor takes over the measuring task. Sensors are sent with a calibration certificate stating the reading before and after calibration.

DrägerSensors for VHP have a cross-sensitivity to sulfur dioxide. The empirical ratio between SO_2 and H_2O_2, called relative sensitivity, has a time-based tolerance. For new sensors the tolerance is ±10%. For safety and liability reasons, a target gas calibration with H_2O_2 must be given preference over a surrogate calibration with SO_2, but the surrogate calibration may suffice in many instances. Further performance specifications can be found in the sensor datasheets.

Expert Technical Support

Gas detection can be complicated and specific needs can vary from plant to plant. Dräger gas detection experts have extensive experience and can recommend the best solution for each facility. Dräger customers can take advantage of Dräger's ~~unmatched~~ technical support to discuss their application in detail and create an optimal gas detection solution.

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