



Using Vaporized Hydrogen Peroxide for Bio-Decontamination

D-111046-2013

In 1994, Dräger introduced the first electrochemical hydrogen peroxide (H_2O_2) sensor for monitoring low concentrations of vaporized hydrogen peroxide (VHP). VHP became the preferred substance for decontamination due to its bioactive effect of killing bacteria. Today it is used in filling machines, barrier isolators, glove boxes, workbenches, and entire rooms.

Introduction

Vaporized hydrogen peroxide (VHP) is generated by actively vaporizing an aqueous hydrogen peroxide (H_2O_2) solution and injecting it into a room. Achieving a high level of microorganism bio-decontamination requires a defined high VHP concentration and exposure time. VHP is rated harmful to humans. As a result, many countries have imposed an occupational exposure limit value. Values in the United States for both 1993-1994 ACGIH TLV and current OSHA PEL are 1 ppm (1.4 mg/m^3) TWA. Staff outside a fumigated room or facility must be protected from accidental contact with H_2O_2 vapor. At the end of a sterilization cycle, the room or volume is rinsed with fresh air. An air analysis is necessary before it is safe for staff to enter the room or bring in new, sensitive material for a production stage. The concentration of H_2O_2 must be reduced through ventilation to non-hazardous levels, usually less than 1 ppm.

The generator that creates the H_2O_2 vapor for sterilization can also pose a risk to staff, which is why the generator's environment and connecting hoses need to be monitored for H_2O_2 gas leakage.

A risk analysis is necessary to satisfy regulatory guidelines. The purpose of the analysis is to identify all potential sources of risk, and to define measures to control exposure using gas measurement instruments, personal protection equipment, and operating instructions.

INDUSTRIAL APPLICATIONS:

- Pharmaceutical and chemical
- Healthcare and hospitals
- Food and beverage
- Laboratories, cleanrooms and material locks
- Animal farming
- Decontamination of heating ventilation air conditioning systems HVAC
- Decontamination of freeze dryers



Challenges

Properties of VHP

VHP is a vapor – not a gas. This means that the H_2O_2 concentration in the air never exceeds the vapor pressure at the corresponding temperature (and pressure). Above the saturation point (dew point), H_2O_2 vapor starts to condense as an aerosol or on surfaces.

H_2O_2 is completely soluble in water. Solutions of 30% to 35% H_2O_2 are common for applying VHP. As vaporization of water is 15 times more effective than that of H_2O_2 , the aqueous solution has to be actively vaporized, such as on a hot plate. When H_2O_2 is exposed to condensed water, the solution absorbs H_2O_2 and the VHP concentration in the ambient air diminishes.

H_2O_2 is an unstable compound. It decomposes to form oxygen and water. Thus, the concentration of H_2O_2 is constantly decreasing, which is why stabilizing chemicals are added to the aqueous solution. During active vaporization, these chemicals enter the fumigated room, and may condense on surfaces.

H_2O_2 is highly absorbent. A loss of concentration through absorption by the surrounding air and on surfaces can be observed. To saturate a surface requires a certain quantity of VHP. Thus, smaller concentrations are more heavily influenced than high concentrations. In pumped systems, the hoses adsorb H_2O_2 on their surfaces before it reaches the sensor and can be indicated. This loss and the accompanying delay in measurement must be taken into account. When rinsing with air, this effect extends the rinsing times of H_2O_2 outgassing from the surfaces. DrägerSensors® measure H_2O_2 vapor as a volume concentration (ppm).

Material compatibility

H_2O_2 is a chemically aggressive compound. Dräger transmitters and sensors are made from a chemical-resistant plastic (polyamide 12 blend). If high VHP exposure will be frequent, the transmitter should be installed outside the VHP atmosphere in a way that only the sensor extends into the measurement room (remote sensing). Any use that deviates from specified conditions must be verified by users on their own authority.



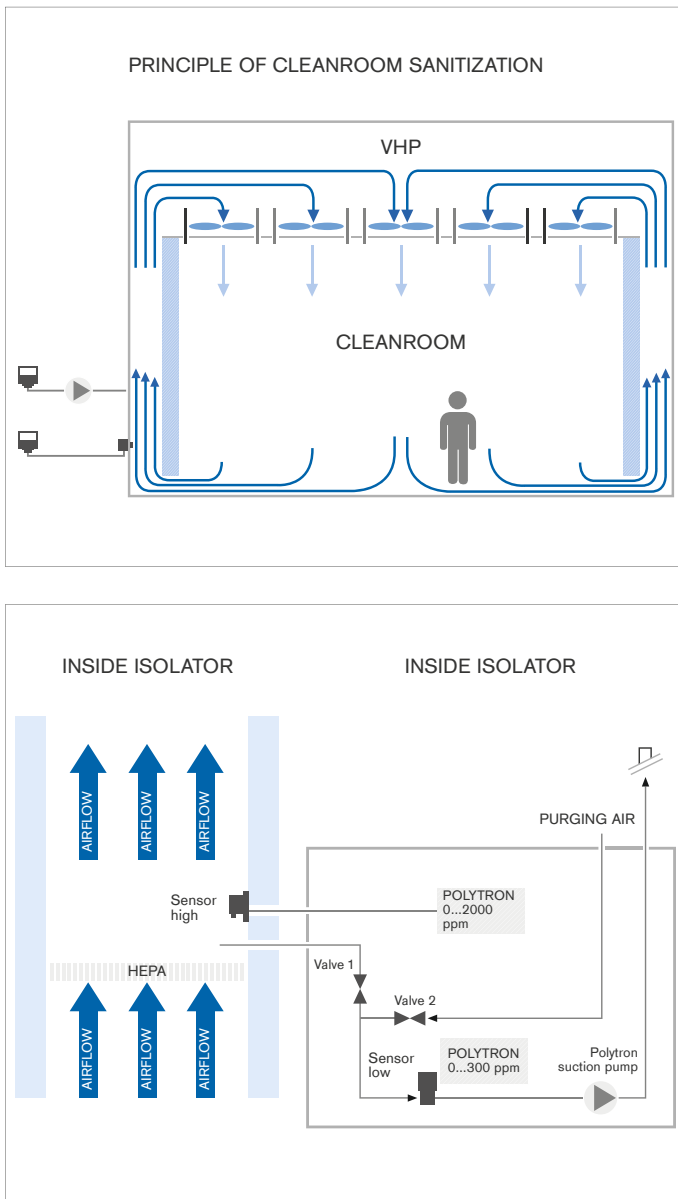
DL-9283-2014

PROTECTIVE GOALS:

- Workplace monitoring
- Leakage detection
- Release for safe entry and access
- Cycle parameter checks
- Emission control behind filters and scrubbers

FOR THESE GOALS, DRÄGER PROVIDES A NUMBER OF SOLUTIONS TO MONITOR H_2O_2 :

- Short time measurement with Dräger-Tubes®
- Ongoing personal measurement with portable gas detectors
- Point and area monitoring with stationary gas detectors for high and low concentrations



Graphic 1 and 2:
Layout schematic for a safe entry or access measurement in clean-rooms and isolators

Calibration

Because of the physical and chemical properties described above, calibration with hydrogen peroxide is not easy to perform. VHP has to be generated with resources under laboratory conditions, and the

concentration verified with an analytical device. This is not possible in the field.

Dräger offers factory-calibrated sensors. The calibration information is stored in the sensor. For recalibration, the sensor can be removed from the transmitter and sent to a Dräger Service station for H₂O₂ calibration. A spare sensor continues to measure in the interim. Sensors are supplied with a calibration certificate, which documents the measurement values before and after calibration. DrägerSensors for H₂O₂ have a cross sensitivity to sulfur dioxide (SO₂). The empirical ratio of sensitivity between SO₂ and H₂O₂ is known as relative sensitivity. This value has a statistical spread and does not have a guaranteed constant time. The tolerance for new sensors is ±10%. For reasons of accuracy and reliability, it is therefore preferable to calibrate with the H₂O₂ target gas instead of a substitute calibration with SO₂. Other performance specifications are available in the datasheet.

Dräger H₂O₂ Monitoring Solutions

Workplace monitoring and leakage detection

For personal protection, workers should wear a portable gas detection device that alerts them to exposure wherever they are. For area monitoring, a stationary gas detector monitors a defined area. It is important that stationary gas detectors be placed in an ideal location to detect gas quickly and reliably. To ensure this, it is necessary to inspect and consider gas dispersion and airflow.

Cycle parameter control and safe entry measurement

A sterilization cycle for isolators or cleanrooms can be divided into four phases. The first phase in a fumigation cycle is dehumidification. During this phase, air from the target room is cycled through a dehumidifier to reduce air humidity. This takes about 20 minutes, depending on the volume of the room. In the conditioning or fumigation phase, hydrogen peroxide is actively vaporized at a pre-set injection rate and fed into the room. This takes about 30 minutes. Sterilization is sometimes also called the "dwell" phase. The VHP concentration is kept constant for a predefined duration of exposure. Pre-configured process parameters are applied during this phase.



The parameters have been determined in the application validation for the required microbiological extermination rate.

Ventilation is the longest phase in the cycle (up to 5 hours). VHP is no longer pumped into the room. The air is fed through a catalytic scrubber or replaced with fresh air to lower the concentration of H_2O_2 to a pre-defined threshold value. The fumigation cycle, specific to each device, must be qualified and validated in compliance with Good Manufacturing Practice (GMP) rules during consignment. Chemical (CI) and biological indicators (BI) in the device or room measure the extermination rate. The programmed process parameters for VHP fumigation are derived from this.

DRÄGER POLYTRON® 7000:

Transmitter for stationary, permanent monitoring of gas concentration in the ambient air with a plug-in DrägerSensor. Polytron 7000 includes:

- An internal pump
- An internal relay module
- Dongles for software extensions such as device diagnostics and data logging
- Various digital interfaces such as 4 to 20 mA, HART, Profibus, Fieldbus, and Modbus
- A remote sensor with up to 100 ft/30 m cable

DrägerSensor LC for low, and DrägerSensor HC for high H_2O_2 concentrations: Electrochemical diffusion sensors for stationary Dräger transmitters that permanently monitor the concentration of hydrogen peroxide in ambient air.

DrägerSensor H_2O_2 LC: measurement range 0.1 ppm to max. 300 ppm PN: **68 09 705**

DrägerSensor H_2O_2 HC: measurement range 100 ppm to max. 7,000 ppm PN: **68 09 675**

Dräger X-am® 5100 with an electrochemical sensor for low H_2O_2 concentrations: This is a portable gas detector for continuously monitors toxic gases in the ambient air at the workplace.

Dräger X-am 5100-s with DrägerSensor XS EC H_2O_2 : portable gas detector with a measurement range 0.1 to max. 20 ppm PN: **68 09 170**

Dräger Tube H_2O_2 for low concentrations: pre-calibrated tube for one-time spot check Dräger Tube hydrogen peroxide; measurement range 0.1 to max. 3 ppm PN: **81 01 041**

Dräger PAS® Colt: emergency escape breathing apparatus that combines a full face mask with a 5- or 10-minute air cylinder.

The measurement of H_2O_2 with an HC DrägerSensor can be used to check and record the concentration profile. Both HC and LC DrägerSensors are used to ensure safe conditions at the end of the ventilation phase. A controlled intake circuit protects the LC sensor from the high concentration present during the sterilization phase. The DrägerSensor HC can start the intake circuit for low concentrations by itself. The sensors should not be gassed with H_2O_2 beyond the maximum measurement range. To do so would result in extended recovery time. The Dräger gas detector system is not suitable for regulating the fumigation process.

ADVANTAGES OF DRÄGER GAS MONITORING TECHNOLOGY

- Selective real-time monitoring of H_2O_2 vapor
- DrägerSensors pre-calibrated with H_2O_2 target gas
- On-site bump test or surrogate calibration with SO_2 as a substitute gas
- Flexible measurement ranges for low and high concentration
- Fast and stable gas response
- H_2O_2 target gas calibration

Examples presented are illustrative, and actual conditions may vary due to many factors. Contact Dräger to determine what equipment is best to suit your facility needs.



D-111840-2013

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