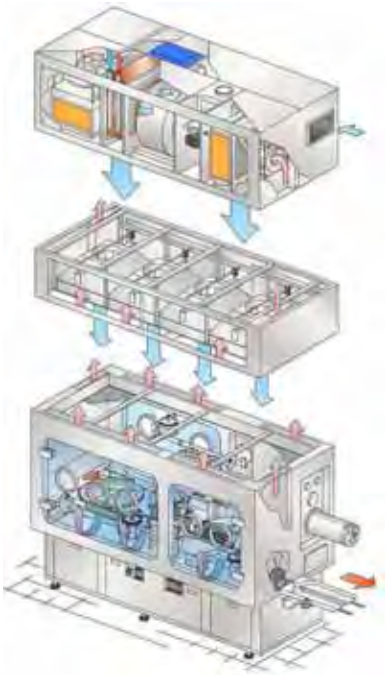
Application Note

Vaporised Hydrogen Peroxide for Bio-decontamination

Introduction

In the year 1994 Dräger introduced the first electrochemical hydrogen peroxide (H2O2) sensor for monitoring low concentrations of vaporized hydrogen peroxide (VHP).
Vaporized hydrogen peroxide became the preferred substance for decontamination 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 heating ventilation air conditioning systems HVAC
- decontamination of freeze dryers

Description

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

But VHP is also rated as a hazardous substance for humans with a defined workplace limit value. Thus personnel outside the fumigated equipment have to be protected against inadvertently released H2O2 vapours. After the decontamination cycle the decline of H2O2 concentration by aeration and purging has to be monitored to release the fumigated volume to allow people to safely enter or new sensitive material brought in for processing.

The mobile VHP generator, providing the vapour for the decontamination, also could cause a hazard to personnel. Therefore H2O2 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 measures, relevant personnel protective equipment to be used and actions to be taken in case of a hazard.

Safety targets are:

Workplace safety
Leak detection
Release for safe entry and access
Cycle parameter control
Emission monitoring after filter and scrubber

For these safety tasks Dräger offers different H_2O_2 detecting products:

One time spot measurement with Dräger-Tubes,
Continuous personal exposure monitoring with portable gas detectors,
Point and area monitors with stationary gas detectors for low and high concentrations.

Duct attached remote sensor

Challenge

Properties of VHP

VHP is a vapour and not a gas. That means the concentration in air can never be more than the vapour-pressure at a certain temperature. If the relative concentration reaches saturation (dew point) H2O2 vapour starts to condense as an aerosol or on any surface.

H2O2 is completely soluble in water. For this application solutions of 30% to 35 % H2O2 are in common. Because the evaporation of water is 15 times more effective than H2O2, the solution has to be actively evaporated e.g. on a heat-plate, to get the H2O2 into the air.

If H2O2 vapour hits condensed water it goes into solution. The VHP concentration in the surrounding air will decline.

H2O2 is not a stable substance. It decomposes into oxygen and water, hence there is always a continuous loss of H2O2 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.

H2O2 is a “sticky” substance. 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 measurement is affected showing smaller readings. This is important to be considered in pumped systems where the tubing will absorb some H2O2 before it hits the sensing device.
Dräger measures H2O2 vapour as a volume concentration (ppmv 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 decomposing under the specified environmental conditions and the intended use. For excessive VHP exposure only the sensor mouth should be exposed to the gas. Any use outside the specified conditions and intended use has to be verified by the user of the equipment.

Calibration

Due to unpredictable drift and loss of sensitivity over time a measuring system needs regular calibration. Because of the above mentioned physicochemical properties of it is not easy to perform a calibration with hydrogen peroxide vapour. VHP has to be generated with tools under laboratory conditions and verified with analytical equipment. This can not be performed in the field.
Dräger provides factory-precalibrated new sensors having the calibration stored in the sensor memory. For recalibration the sensor can be taken out of the transmitter and can be shipped to a Dräger service station for calibration with H_2O_2. In the meantime a replacement sensor can take over the measuring task. Sensors are returned with a calibration certificate stating the reading before and after calibration.
Drägersensors for VHP have an accidental cross-sensitivity on sulphur dioxide. The empirical ratio between SO_2 and H_2O_2 called relative sensitivity has a timely unpredictable 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. Further performance specifications can be found in the sensor datasheets.

Dräger Solution

Workplace safety and leak detection

A portable device carried at the body will protect and warn from exposure where ever people move and what they breeze.
A stationary device will monitor an entire area. It is essential to position the stationary equipment in the right locations to alert the gas presence fast and reliable. For that the gas distribution and convection has to be investigated and taken into account.
Air flow pattern and streams can be made visible with help of the Dräger Flow Check to verify the assumptions.

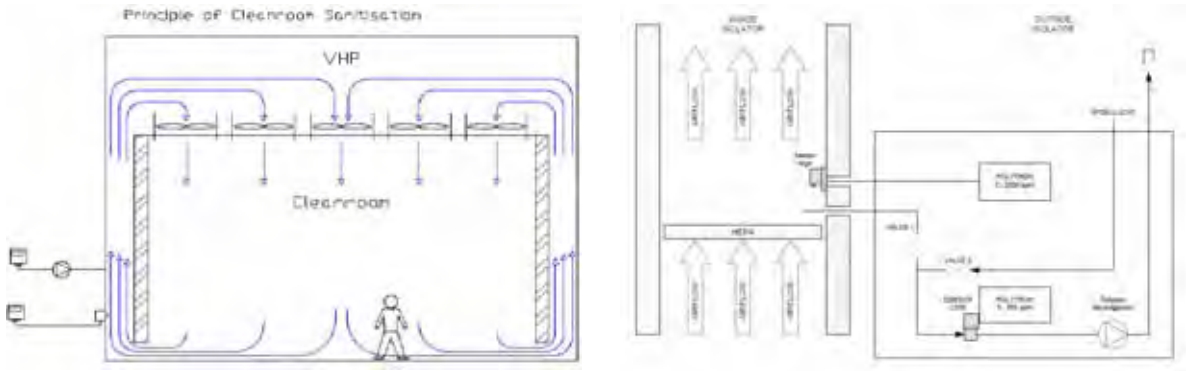

Check of air flow pattern.

Cycle parameter control and Safe Entry Measurement

A decontamination cycle for an isolators or clean room is divided in up to four phases. Dehumidification is the first phase in the fumigation cycle. During this phase air is circulated from the room through the dehumidifier to reduce the present humidity. This phase takes approximately 20 min. In the conditioning or 'gassing' phase VHP is actively injected into the room at a preset injection rate. This allows the concentration of VHP to be rapidly increased within the room to a predefined level. This phase normally takes 30 min. Decontamination sometimes is 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 and for a predetermined time. During this phase the predefined process parameter have to be applied to achieve the proven microbiological kill rate. Aeration is the longest phase in the cycle (approximately 5 h). The injection of VHP into the room is stopped, and air is circulated through a scrubber or filter or replaced by fresh air to bring down the VHP concentration below predetermined thresholds.

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

For safe access to the fumigated space at the end of the aeration phase both DrägerSensors HC and LC are applied. The LC sensor is to be protected by a controlled sampling system



Layout schematic for a safe entry or access measurement in clean-rooms and isolators

against the high concentration during the decontamination phase. The DrägerSensor HC can be used to monitor the high concentration cycle and control the start of the sampling system for the low concentration. In addition the HC sensor can show and monitor the fumigation curve.

Sensors should not be exposed beyond the max measuring range of the sensor. That would lead to prolonged recovery time.

The Dräger gas monitoring system must not be used for active control of the fumigation process!

Dräger products

Dräger Polytron 7000

Transmitter for stationary, continuous monitoring of gas concentrations in ambient air, with plug-in DrägerSensor.
Polytron 7000 o□ers following options:

- internal pump,
- internal relay module,
- dongles for extended software features like device diagnostics and data logging,
- di□erent digital interfaces like 4..20 mA, HART, LON Pro□bus, Fieldbus,
- remote sensor with up to 30m cable

DrägerSensor LC for low H_2O_2 concentrations
DrägerSensor HC for high H_2O_2 concentrations

Electrochemical di□usion sensor for stationary Dräger transmitters for continuous monitoring of the hydrogen peroxide (H_2O_2) concentration in ambient air.

DrägerSensor H_2O_2 LC; detection range 0,1 ppm to max 300 ppm	6809705
DrägerSensor H_2O_2 HC; detection range 100 ppm to max 7000 ppm	6809675

Dräger Pac III with electrochemical sensor for low H_2O_2 concentrations

Pac III is a portable gas monitor for continuous monitoring of toxic gases in the ambient air at the workplace.
Pac III S or H with

DrägerSensor XS EC H_2O_2; detection range 0,1 to max 20 ppm	6809170

Dräger detector tube H_2O_2 for low concentrations

Detector tube for pre-calibrated one-time spot check

Dräger-Tube hydrogen peroxide; detection range 0,1 to 3 ppm	8101041

Dräger Flow Check

Dräger Flow Check is an air □ow indicator designed to indicate air □ow in non-explosive areas.

Dräger Flow Check air □ow indicator	64 00761

Dräger Advantage

- selective real time monitoring of H2O2 vapour
- with H2O2 target gas pre-calibrated DrägerSensors
- onsite bump test or surrogate calibration with surrogate gas SO2
- □exible measuring range for low and high concentrations
- fast and stable gas response
- target gas calibration service