Application note: N°F024 March 2013

Humidity measurements in H_2O_2

The use of resistant relative humidity sensors in hydrogen peroxide sterilisation chambers.

Hydrogen peroxide sterilisation chamber

Discussed in this edition:

Sterilisation with hydrogen peroxide:

Sterilisation methods used around the world are changing. Hot steam morpholine or formaldehyde processes are being replaced by hydrogen peroxide sterilisation techniques.

New methods such as the Dry Sterilisation Process (DSP) and Vaporised Hydrogen Peroxide (VHP) offer district advantages over the previously mentioned methods.

The advantages are:

- Hydrogen peroxide is an effective sterilising agent due to its highly toxic effect on bacteria and fungal spores. By combining the highly reactive hydroxyl and hydroxyl radicals from the hydrogen peroxide with the cellular components of these microorganisms, they are reliably eliminated.
- Contamination of the sterilised products is virtually impossible.
- Compared to other sterilisation methods, hydrogen peroxide decomposes into water and oxygen, leaving no toxic residues.
- Low process costs.
- Precise process monitoring ensures reliable sterilisation results.
- The cycle times are short, the process is safe and environmentally friendly.
- Due to the above advantages, these dry aseptic sterilisation processes are now used in the pharmaceutical, biotechnology, cosmetic and biomedical industries as well as in the food industry for the sterilisation of surfaces and products.
- For example, it is used in the cold aseptic filling of beverages such as UHT milk and fruit juices in PET or HDPE plastic containers.

A typical sterilisation cycle with four phases:

Phase 1: Vacuum phase (conditioning)

Reduction of the chamber pressure to about 0.4 bar. This results in a reduction of the relative humidity of the atmosphere contained in the chamber.

Phase 2: Injection phase (H_2O_2 evaporation)

Depending on the desired concentration of H_2O_2 a 30 - 55% hydrogen peroxide solution is used.

A mixture of hydrogen peroxide gas and water steam is introduced into the chamber insulator until the desired concentration level of H_2O_2 is obtained. The atmosphere in the chamber will become more and more humid - the condensation point will almost be reached.

Phase 3: Diffusion phase (distribution and exposure to the sterilisation)

For a predetermined time period, the H_2O_2 concentration is maintained in the sterilising chamber. The desired aseptic results can be calculated by multiplying the H_2O_2 concentration by the time.

During the DSP technique, an intermediate step is added as detailed below.

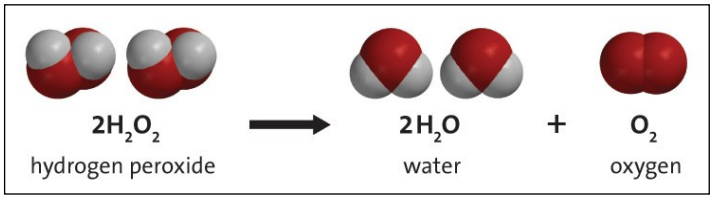
The diffusion phase progresses directly to the desired H_2O_2 concentration in the plasma phase.

High frequency (MHz range) radiation is used to convert the hydrogen peroxide into the plasma phase.

Phase 4: Aeration phase (Removal of H_2O_2 from the sterilisation chamber)

After removal of the gas, the pressure is reduced by the evaporation of the H_2O_2, The sterilisation chamber is then aerated with sterile air.

This process step results in a good and complete drying of the sterilisation chamber and a complete removal of the toxic hydrogen peroxide. The chamber can be opened and emptied as soon as it has a pressure corresponding to that of the environment.



Hydrogen peroxide decomposition

Why the need for humidity measurement?

For the described method of sterilisation using hydrogen peroxide, validation of the efficiency of the sterilisation process, based on the H_2O_2 concentration of the amount of liquid evaporated is not reliable enough.

For critical applications, such as in biomedicine, the control of the sterilisation process is achieved with chemical and biological indicators used in several places in the chamber insulator. As can be seen from the process description, relative humidity is a key parameter requiring measurement. The design specification, testing and evaluation of each individual chamber insulator and sterilisation cycle is crucial for assessing the effectiveness of the whole process.

For optimal process design, it is important to know the relative humidity at each of the phases, with precise measurement and humidity control.

There is a high demand for low drift hydrogen peroxide resistant relative humidity sensors.

The HygroMer HH-1 humidity sensor:

The new Rotronic cleanroom was utilised for the development of the HygroMer HH-1 sensor and this is where it is now being manufactured. The HygroMer HH-1 was designed to be compliant with the technical requirements of hydrogen peroxide sterilisation chambers and hydrogen peroxide environments.

The combination of the custom developed polymer material in conjunction with the specially developed sensor legs results in exceptional performance in everyday use.

Rotronic AirChip3000 technology together with selected HygroClip2 temperature and humidity probes provide a perfect combination for the new HygroMer HH-1 sensor. Either the HC2-S or HC2-S3 probe with the HygroMer HH-1 sensor fitted can be used directly with a transmitter, logger or a handheld instrument without any adjustment being required. The probe can be installed in any H_2O_2 environment.

With the freely scalable analogue output signals and the digital UART interface, HygroClip2 probes interface well with OEM and specialised applications. The perfect customer solution.

HygroMer HH1 Sensor

Test results in a harsh industrial application:

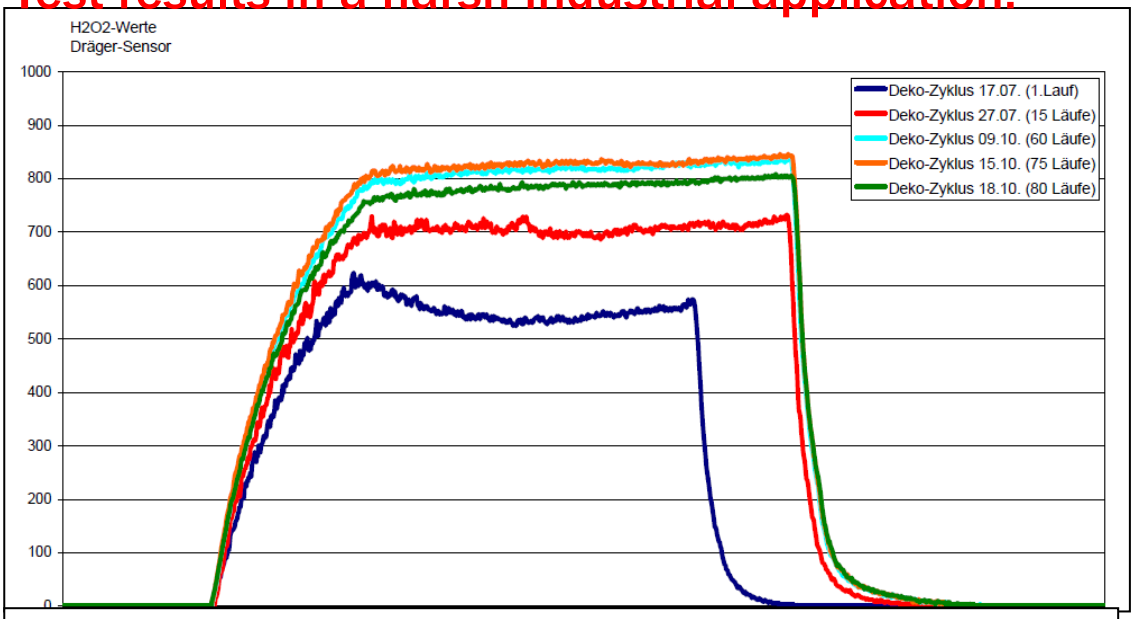
The performance of the HygroMer HH-1 sensor in H_2O_2 sterilisation applications was evaluated in a real life test. The test produced the following results:

The sensors were exposed to a mean H_2O_2 concentration of 800 ppm. At 80 cycles of 5 runs: the sensor was subjected to 400 hours of testing: exposed to H_2O_2 at ambient temperatures (maximum 38°C)

The HygroMer HH-1 sensor performed as specified and was unchanged. It showed no drift in humidity measurement during or following the H_2O_2 sterilisation cycles.

Walk in VHP bio-decontamination chamber

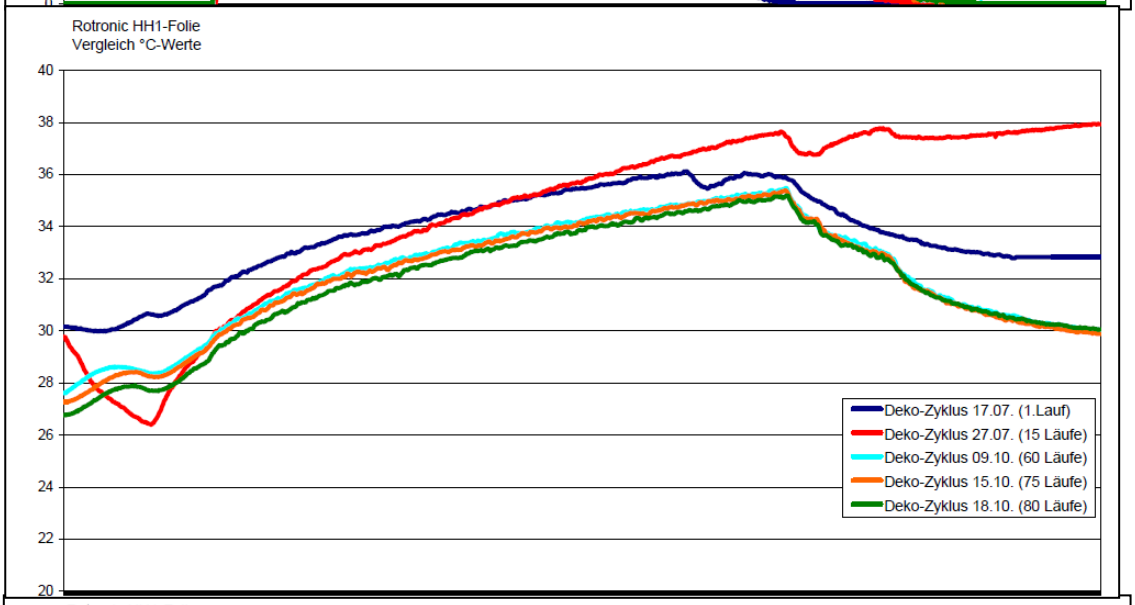
Test results in a harsh industrial application:



The H_2O_2 profile during the test cycles:

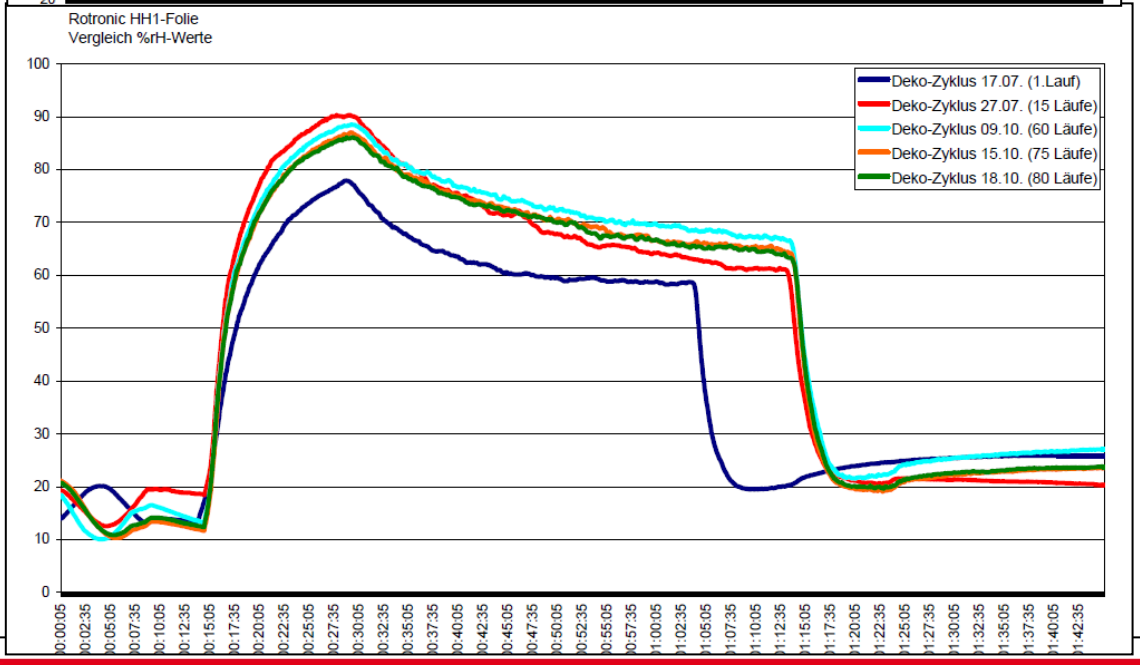
- Dark blue: 1 cycle
- Red: 15 cycles
- Light blue: 60 cycles
- Orange: 75 cycles
- Green: 80 cycles

The maximum concentration of H_2O_2 is 850ppm.



The temperature profile during the test cycles:

The maximum temperature was 38°C, the minimum was 26°C.



The relative humidity profile during the test cycles:

The maximum relative humidity was just over 90%rh.

What solutions can Rotronic offer?

The measurement of relative humidity is not an easy task in the sterilisation chambers due to:

The ***relative humidity being very high*** during the diffusion phase process.

Additionally, ***the H_2O_2 entering*** into the chamber.

The result of the stress that both of these factors place on the humidity sensor is drift! The sensor will drift much faster than expected!

All manufacturers' relative humidity sensors will drift when placed in such an environment, the HygroMer HH-1 sensor is much more resistant for this application and has significantly lower drift with a longer life.

In order to maintain the perfect conditions in the chamber, Rotronic offers a range of products that will control and monitor the system.

HF5 transmitter with a HC2-S-HH probe

Rotronic products:

Humidity and temperature probes:

- ***HC2-S-HH***
  H_2O_2 resistant humidity sensor,
  -50...100°C,
  0…100%rh,
  ±0.8%rh and ±0.1K at 23°C…

Handheld:

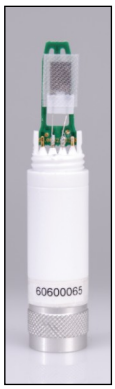
- ***HP23-A***
  2 probe inputs
  Digital or analogue inputs
  10,000 point memory
  All psychrometric calculations
  Real time clock

Transmitters:

- ***HF5 series***
  For interchangeable probes,
  2 or 3/4 wire configuration,
  Various analogue and digital outputs, Display,
  All psychrometic calculations available…

Data loggers:

- ***HL-NT range***
  For interchangeable probes (up to 7 probes with docking station)
  32MB flash card,
  Display, Conforms to FDA 21CFR Part 11 and GAMP4…
- ***LOG-HC2-RC***
  For interchangeable probes
  Secure wireless technology
  500,000 point memory
  433 or 915 MHz transmission
  Conform to FDA21 CFR Part 11 and GAMP4…



HC2-S3-HH

HL-NT data logger

Customer benefits:

H_2O_2 resistance:

Sensor manufacturers have issues when placing their sensors into H_2O_2 environments. Rotronic has developed a solution for these applications which also prolongs the life span of the sensor.

The significant advantage is that the sensor can remain in the application for a longer period of time without the need for frequent calibration, adjustment or replacement.

Calibration and adjustment:

Calibration and adjustment (if necessary) is very easy with the latest Rotronic HygroClip2 product range. Since the communication is digital, the calibration procedure can be achieved via a PC, or directly on the device with the use of Rotronic humidity standards. A calibration can be ordered if required with a certificate.

For H_2O_2 applications, there will be a need for periodic calibrations to check sensor performance

Rotronic offers a fast and effective method of calibrating sensors across the product range

Interchangeability:

Hot swapping is a fast and simple procedure for most Rotronic products. Should the probe fail just replace the probe, there is no need to replace the logger, transmitter or handheld. No adjustment is required.

Wireless LOG-HC2-RC

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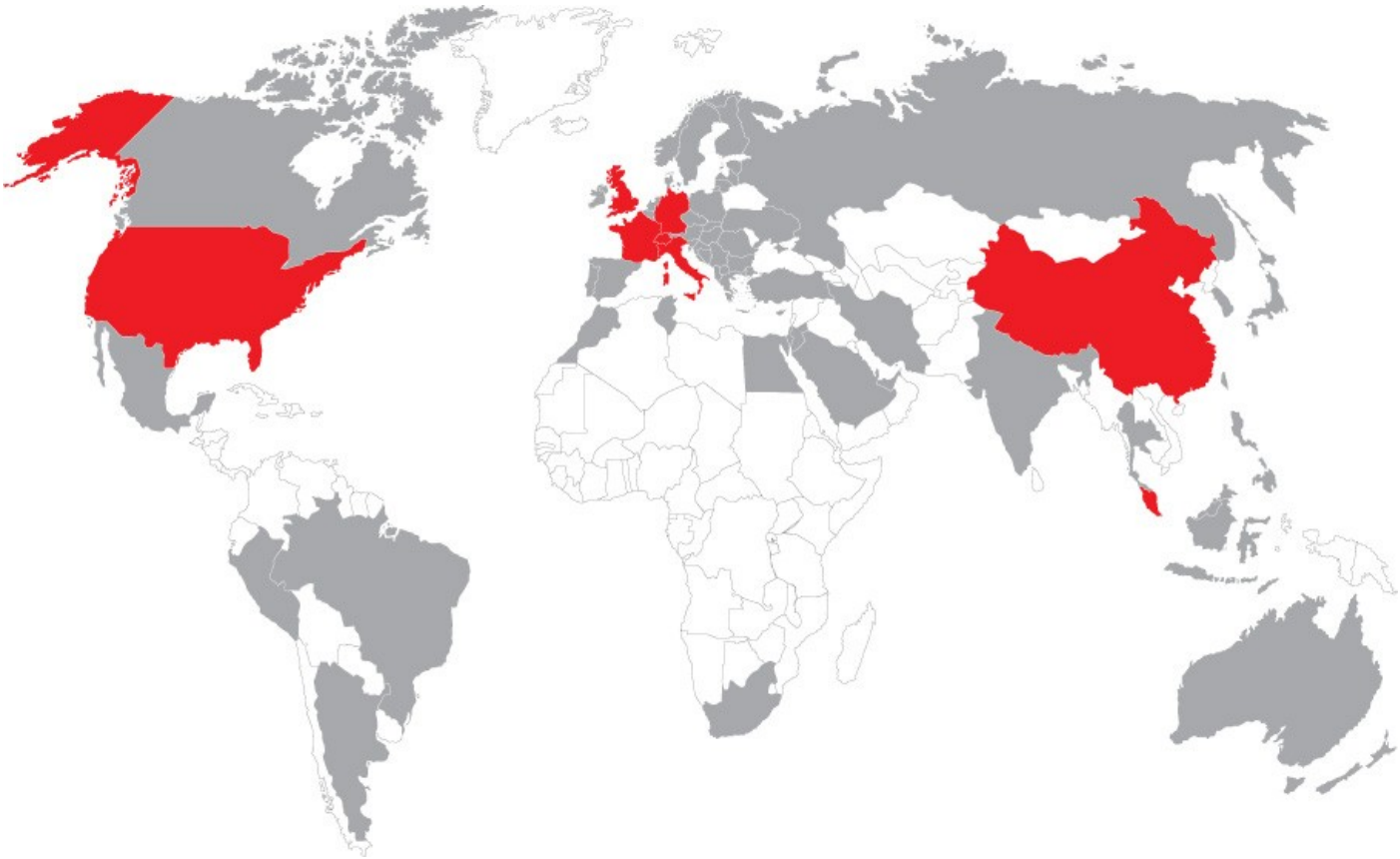
Contact us:

Rotronic is represented in over 40 countries around the world. An up to date list of all our partners is available on our website: www.rotronic.com



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