Humidity Measurement in H$_2$O$_2$
Bio-Decontamination
– Relative Saturation as the Key
Meet the Presenters

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Product Manager at Vaisala with 20 years of experience in life science applications and wide product management experience from leading international high tech companies.

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Life Science Regulatory and Industry Expert at Vaisala with over 15 years of experience in biotechnology and life science applications.
Basics of bio-decontamination with vaporized $\text{H}_2\text{O}_2$

The importance of continuous measurement during bio-decontamination

Patented PEROXCAP® technology

The difference between Relative Humidity (RH%) and Relative Saturation (RS%)

Five most typical pitfalls in humidity measurement during bio-decontamination

Q&A session
Basics of Bio-Decontamination with Vaporized H₂O₂
Why Use $\text{H}_2\text{O}_2$ for Bio-Decontamination

- Easy to use
- Destroys all biological contaminants
- Works in low temperature processes
- Processes can be validated
- Compatible with a wide variety of materials
- Environmentally friendly process
- Leaves no real residues – only water vapor and oxygen
Isolators, RABS

- Pharma / Manufacturing of pharmaceuticals:
  - Aseptic filling
  - Sterility testing
  - Freeze dryers
- Pharmacy compounding
- Blood and tissue banks

Transfer hatches, chambers

- Hospitals
- Pharma / Manufacturing of pharmaceuticals
- Cleanrooms
- Animal trials (food and supplies)
- Army
- Blood and tissue banks
- Pharmacy compounding

Vapor generators

- Clenrooms
- Healthcare (like hospitals)
- Animal trials (GLP)
- Service providers
- HVAC
- Transportation
  - Ambulance, airplane, cruisers, trucks
- Army
- Farming / Animal husbandry
- Construction

Incubators

- Pharma / GLP, GCP
- Blood and tissue banks
- Scientific research

Production lines

- Processing plants
- Filling lines
- Milking machines
Bio-Decontamination Measurements

- \( \text{H}_2\text{O}_2, \ \text{ppm} \)
- Humidity
- Temperature

Our main topic today

Potential other parameters:
- Time
- Pressure (P) and differential pressure (dP)
- Airflow and velocity
- Airborne particles
The Importance of Continuous Measurement During Bio-Decontamination
Why Repeatable Online Measurements?

- Provides continuous measurement data
- Guarantees that a process works as planned
- May decrease a number of biological, chemical or enzymatic indicators
- From monitoring to controlling
# Indicators vs. Online Measurements

<table>
<thead>
<tr>
<th>What the product looks like?</th>
<th>Chemical indicators (CI)</th>
<th>Biological indicators (BI)</th>
<th>Enzymatic indicators (EI)</th>
<th>Measurement sensor; Vaisala HPP272</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROS</td>
<td>Inexpensive</td>
<td>Quantitative results</td>
<td>Quantitative results</td>
<td>Continuous, stable and repeatable measurement</td>
</tr>
<tr>
<td></td>
<td>Easy to use</td>
<td></td>
<td>Instantaneous reaction</td>
<td></td>
</tr>
<tr>
<td>CONS</td>
<td>Tells only &quot;±&quot; result</td>
<td>Takes 7 days to get results</td>
<td>Manual work needed</td>
<td>Doesn’t tell if micro-organisms are dead; combine with BIs/EIs</td>
</tr>
<tr>
<td></td>
<td>Not quantitative results</td>
<td>Needs qualified personnel and laboratory premises</td>
<td>Doesn’t give continuous measurement data</td>
<td></td>
</tr>
<tr>
<td>What does this product measure?</td>
<td>Change in color; H₂O₂ concentration</td>
<td>Reduction of micro-organisms (SAL min. 10⁻⁶)</td>
<td>Reduction of micro-organisms (SAL min. 10⁻⁶)</td>
<td>H₂O₂ ppm concentration, RH/RS and temperature</td>
</tr>
</tbody>
</table>
Example Bio-Decontamination Cycle

Typical non-condensing bio-decontamination process in isolators
Patented PEROXCAP® Technology
The Vaisala PEROXCAP® sensor technology is based on two capacitive thin-film polymer sensors, building on the reliable HUMICAP® technology.
New Measurement Technology; PEROXCAP®

H₂O₂ molecules

H₂O molecules

Catalytic layer on top of sensor 2

HUMIDITY SENSOR 1

HUMIDITY SENSOR 2
New Measurement Technology; PEROXCAP®

H$_2$O$_2$  H$_2$O

HUMIDITY SENSOR 1  HUMIDITY SENSOR 2
New Measurement Technology; PEROXCAP®

H₂O₂ — H₂O

HUMIDITY SENSOR 1

HUMIDITY SENSOR 2

Humidity Measurement in H₂O₂ Bio-Decontamination - Relative Saturation as the Key
New Measurement Technology; PEROXCAP®

H₂O₂

H₂O

HUMIDITY SENSOR 1

CATALYTIC LAYER

HUMIDITY SENSOR 2
New Measurement Technology; PEROXCAP®

H<sub>2</sub>O<sub>2</sub>       H<sub>2</sub>O

HUMIDITY SENSOR 1       CATALYTIC LAYER

HUMIDITY SENSOR 2
New Measurement Technology; PEROXCAP®

H₂O₂
H₂O

HUMIDITY SENSOR 1

CATALYTIC LAYER

HUMIDITY SENSOR 2
New Measurement Technology; PEROXCAP®

H$_2$O$_2$

H$_2$O

HUMIDITY SENSOR 1

HUMIDITY SENSOR 2

RELATIVE HUMIDITY, RH%

ALGORITHMS

CATALYTIC LAYER

Humidity Measurement in H2O2 Bio-Decontamination - Relative Saturation as the Key
New Measurement Technology; PEROXCAP®
New Measurement Technology; PEROXCAP®

H₂O₂
H₂O

H₂O₂ CONCENTRATION, ppm
RELATIVE SATURATION, RS%
RELATIVE HUMIDITY, RH%
ALGORITHMS
CATALYTIC LAYER
HUMIDITY SENSOR 1
HUMIDITY SENSOR 2

Humidity Measurement in H₂O₂ Bio-Decontamination - Relative Saturation as the Key
The Difference Between Relative Humidity (RH%) and Relative Saturation (RS%)
Relative Saturation vs. Relative Humidity

Only H₂O vapor present

H₂O and H₂O₂ vapor present
RS% value is the only parameter for controlling condensation when H$_2$O$_2$ vapor is present.
Maximum %RH

At every point RS = 100% RS
Maximum %RH

At every point RS = 100% RS
Maximum %RH is Dependent on Temperature

At every point RS = 100% RS

H2O2 concentration (ppm)

Temperature (°C)

Temperature (°C)

H2O2 concentration (ppm)

~ 53% RH

~ 72% RH

RS = 100% RS

Maximum %RH is Dependent on Temperature

At every point RS = 100% RS
Maximum %RH is Dependent on Temperature

At every point RS = 100% RS

Rule:

Higher the °C

Higher the max. RH%
Maximum %RH is Dependent on ppm Concentration

At every point RS = 100% RS
Maximum %RH is Dependent on ppm Concentration

At every point RS = 100% RS

**Rule:**

Higher the ppm

Lower the max. RH%

Bigger the difference RH% vs. RS%

**Table:**

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>H2O2 concentration (ppm)</th>
<th>RH%</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>600</td>
<td>~40%</td>
</tr>
<tr>
<td>20</td>
<td>400</td>
<td>~53%</td>
</tr>
<tr>
<td>30</td>
<td>200</td>
<td></td>
</tr>
</tbody>
</table>
H$_2$O$_2$ ppm as a Function of RS/RH Sensor Readings at 20.0°C
H₂O₂ ppm as a Function of RS/RH Sensor Readings at 20.0°C
$\text{H}_2\text{O}_2$ ppm as a Function of RS/RH Sensor Readings at 20.0°C

Approximately 53% RH
H$_2$O$_2$ ppm as a Function of RS/RH Sensor Readings at 20.0°C

~ 53% RH
$H_2O_2$ ppm as a Function of RS/RH Sensor Readings at 5°C

$H_2O_2$ ppm as a function of RS/RH sensor readings at $T=5.0 \, ^\circ C$

RH%  

RS%  

$H_2O_2$ ppm
**H₂O₂ ppm as a Function of RS/RH Sensor Readings at 5°C**

H₂O₂ ppm as a function of RS/RH sensor readings at T=5.0 °C

**Rule:**

At 5°C

Max.

~ 550 ppm

**H₂O₂ ppm**

RH%

RS%
H$_2$O$_2$ ppm as a Function of RS/RH Sensor Readings at 50°C

H$_2$O$_2$ ppm as a function of RS/RH sensor readings at $T=50.0$ °C

H$_2$O$_2$ ppm

RH%

RS%
H₂O₂ ppm as a Function of RS/RH Sensor Readings at 50°C

Rule:

At 50°C

Max.

~12500 ppm H₂O₂
Five Most Typical Pitfalls in Humidity Measurement During Bio-Decontamination
Five Most Typical Pitfalls in Humidity Measurement During Bio-Decontamination

1. Understand how temperature affects RS%
2. Find out the correct measurement point
3. Control condensation with RS%
4. Select correct materials
5. Carefully plan onsite calibration
Pitfall 1: Understand How Temperature Affects RS%

1. T = 22 °C
   RS = 89.5 %RS

2. T = 21.5 °C
   RS = 94.5 %RS

3. T = 21 °C
   RS = 100 %RS
Pitfall 2: Find out the Correct Measurement Point

- **Location:**
  - Inside a chamber
  - Based on BI/EI/CI testing
  - Worst case location
  - In inlet
  - In outlet

- **Method:**
  - In situ
  - Pump & tubing & sample cell

- **Airflows:**
  - Does a sensor stand for airflows?
Pitfall 3: Control Condensation with RS%

- RH not enough for condensation control
- RH value varies with temperature and ppmH2O2
- RS shows 100 %RS when the air mixture starts to condense

At every point
RS = 100% RS
Pitfall 3: Control Condensation with RS%

Humidity, RH% or RS% vs Time

- Water vapor only
- Water and hydrogen peroxide vapor
- NO CONDENSE: Relative saturation ~ 60 %RS
- RH readings of other brands' sensors without catalytic filters
- HPP272 RS readings
- RH readings of HPP272 and other brands' sensors with catalytic filters

4xHPP272 and several other brand's sensors tested
Pitfall 4: Select Correct Materials

- Material effects:
  - Absorption
  - Decomposition
  - Desorption or out-gassing

- Good results with:
  - PTFE
  - LCP
  - 316L (stainless steel)
  - Pure aluminium
Pitfall 4: Select Correct Materials

- Long out-gassing times with wrongly selected materials.

<table>
<thead>
<tr>
<th>Material</th>
<th>Desorption maximum [ppm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTFE</td>
<td>1.3</td>
</tr>
<tr>
<td>PFA</td>
<td>1.3</td>
</tr>
<tr>
<td>LCP</td>
<td>3.0</td>
</tr>
<tr>
<td>PPS</td>
<td>28.5</td>
</tr>
<tr>
<td>PC</td>
<td>57.2</td>
</tr>
<tr>
<td>PBT</td>
<td>67.2</td>
</tr>
<tr>
<td>ABS</td>
<td>74.2</td>
</tr>
<tr>
<td>Ixef</td>
<td>82.3</td>
</tr>
</tbody>
</table>

Material desorption of various plastics

![Graph showing material desorption of various plastics](image-url)
Pitfall 5: Carefully Plan On-site Calibration

- Challenge with H$_2$O$_2$ vapor
  - Difficult to achieve stable conditions

- Solution with PEROXCAP sensors
  - Based on humidity sensors
  - On-site calibration is easy to do with any humidity chamber

- For best measurement performance
  - **Traceable** H$_2$O$_2$ factory calibration available at Vaisala Service center
  - With both humidity and H$_2$O$_2$ vapor
Conclusion

- Basics of bio-decontamination with vaporized H$_2$O$_2$
- The importance of continuous measurement during bio-decontamination
- Patented PEROXCAP® technology
- The difference between Relative Humidity (RH%) and Relative Saturation (RS%)
- Five most typical pitfalls in humidity measurement during bio-decontamination
- Q&A session
Q&A Session