Humidity Measurement in H_2O_2 Bio-Decontamination

– Relative Saturation as the Key

Meet the Presenters

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

Piritta Maunu
Life Science Regulatory and Industry Expert at Vaisala with over 15 years of experience in biotechnology and life science applications.

Agenda

- Basics of bio-decontamination with vaporized H_2O_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 H_2O_2

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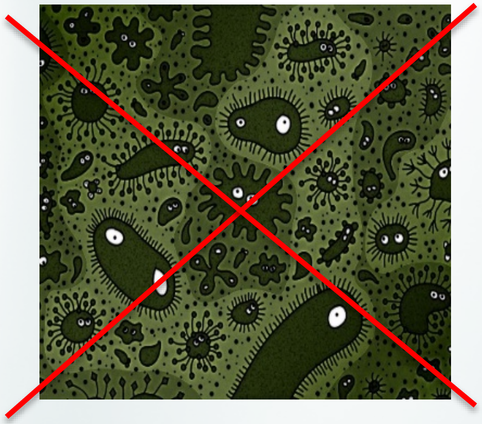
Why Use H_2O_2 for Bio-Decontamination

- 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

- H_2O_2, 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

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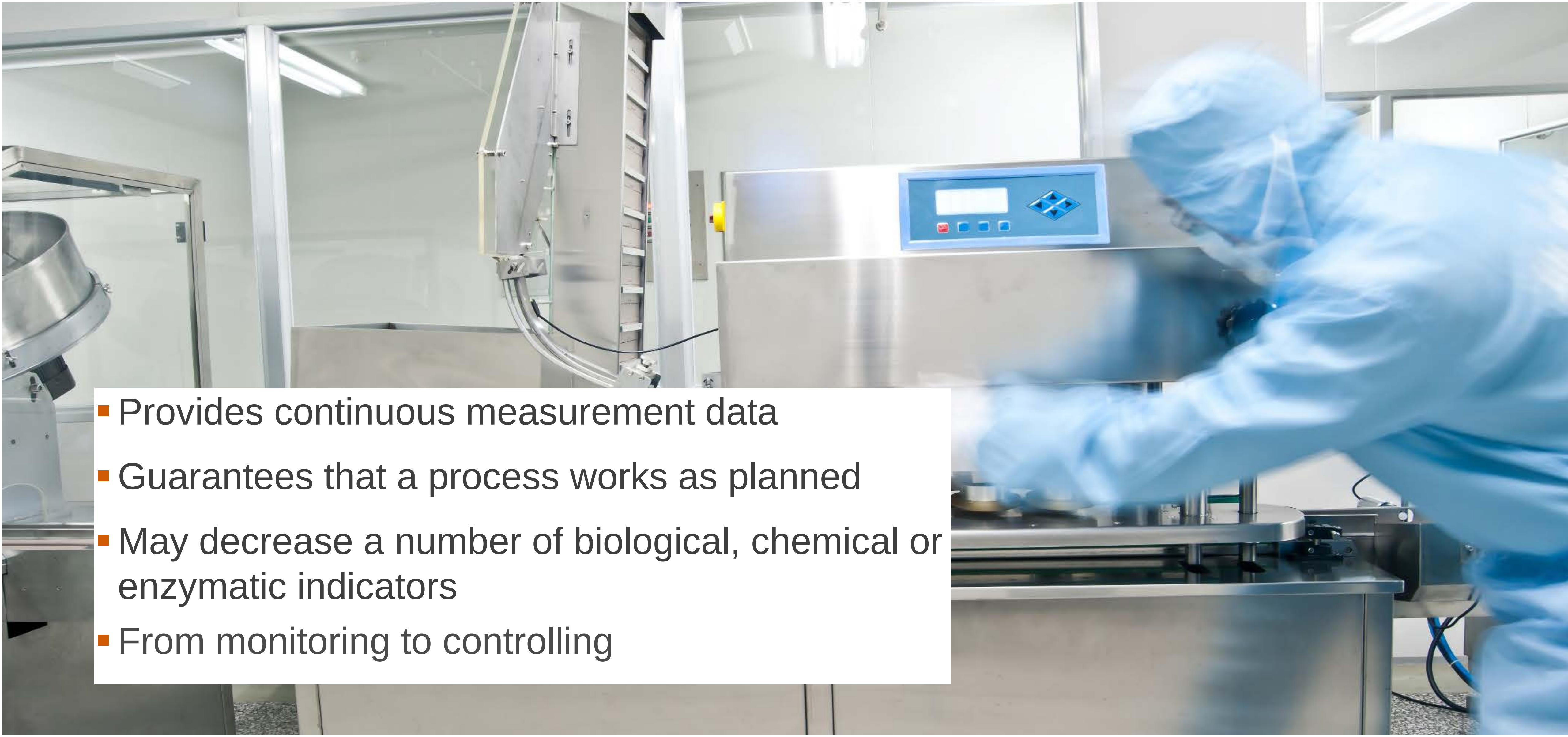
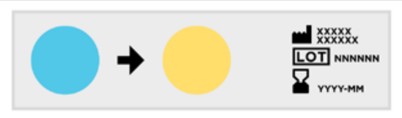
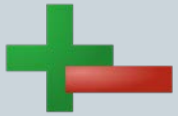
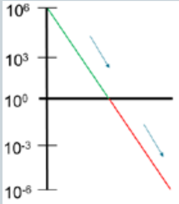
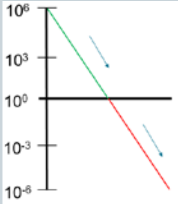
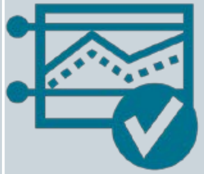
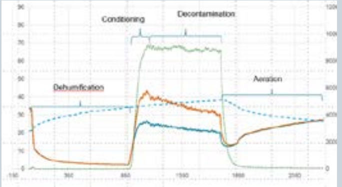
Why Repeatable Online Measurements?

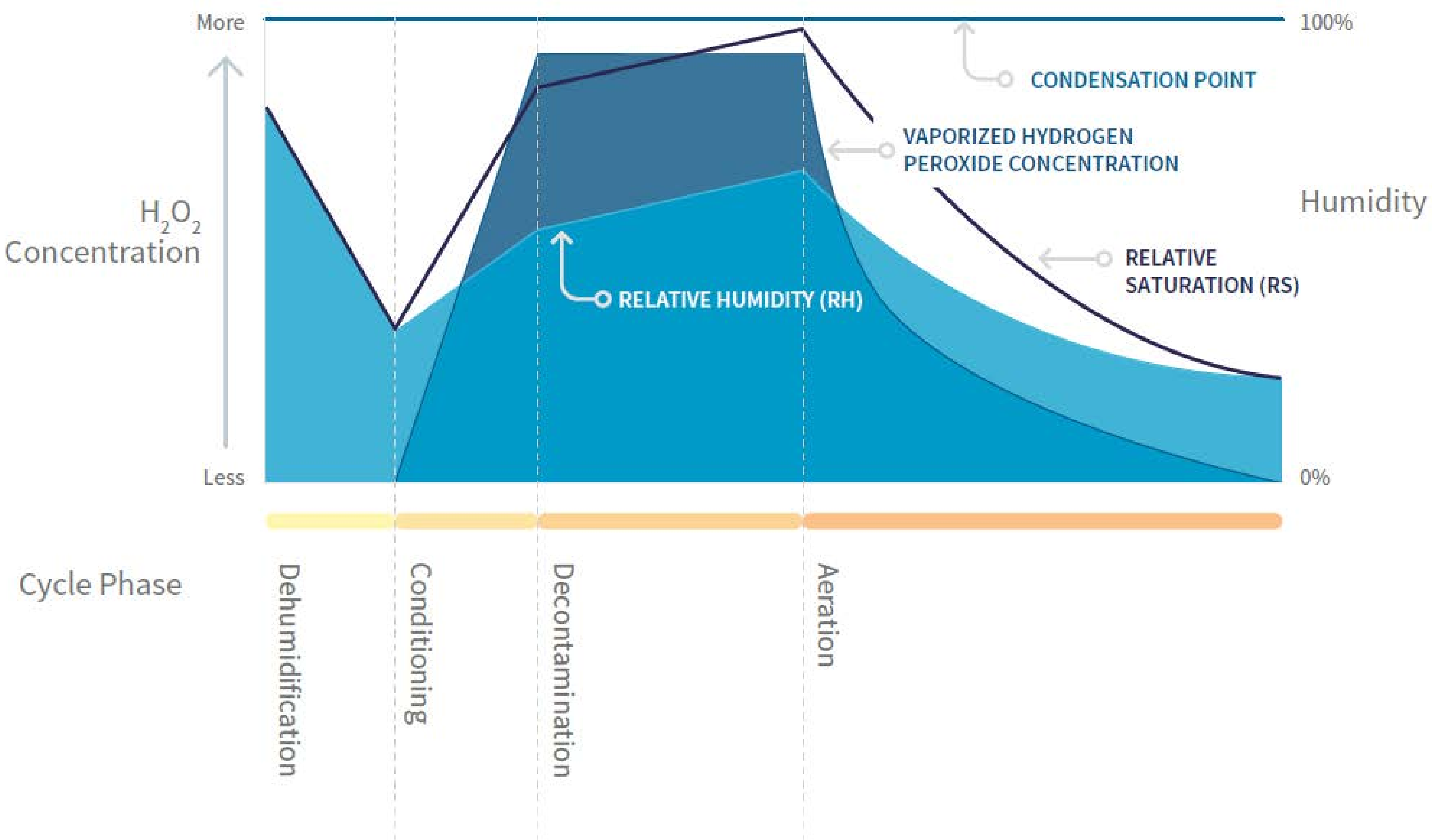


- Provides continuous measurement data
- Guarantees that a process works as planned
- May decrease a number of biological, chemical or enzymatic indicators
- From monitoring to controlling

Indicators vs. Online Measurements

	Chemical indicators (CI)	Biological indicators (BI)	Enzymatic indicators (EI)	Measurement sensor; Vaisala HPP272
What the product looks like?		 		
PROS	Inexpensive Easy to use	Quantitative results	Quantitative results Instantaneous reaction	**Continuous, stable and repeatable measurement**
CONS	Tells only "±" result Not quantitative results	Takes 7 days to get results Needs qualified personnel and laboratory premises	Manual work needed Doesn't give continuous measurement data	Doesn't tell if micro-organisms are dead; combine with BIs/EIs
What does this product measure?	Change in color; H_2O_2 concentration	Reduction of micro-organisms (SAL min. 10^{-6})	Reduction of micro-organisms (SAL min. 10^{-6})	**H_2O_2 ppm concentration, RH/RS and temperature**
				 

Example Bio-Decontamination Cycle



Typical non-condensing bio-decontamination process in isolators

Patented PEROXCAP® Technology

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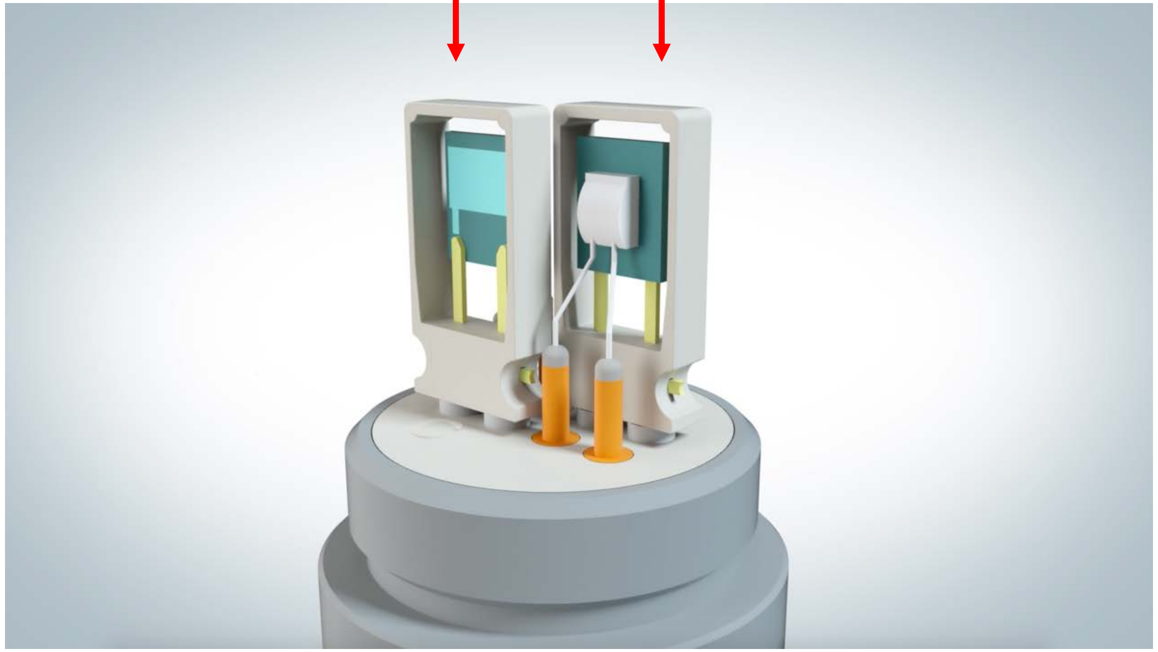
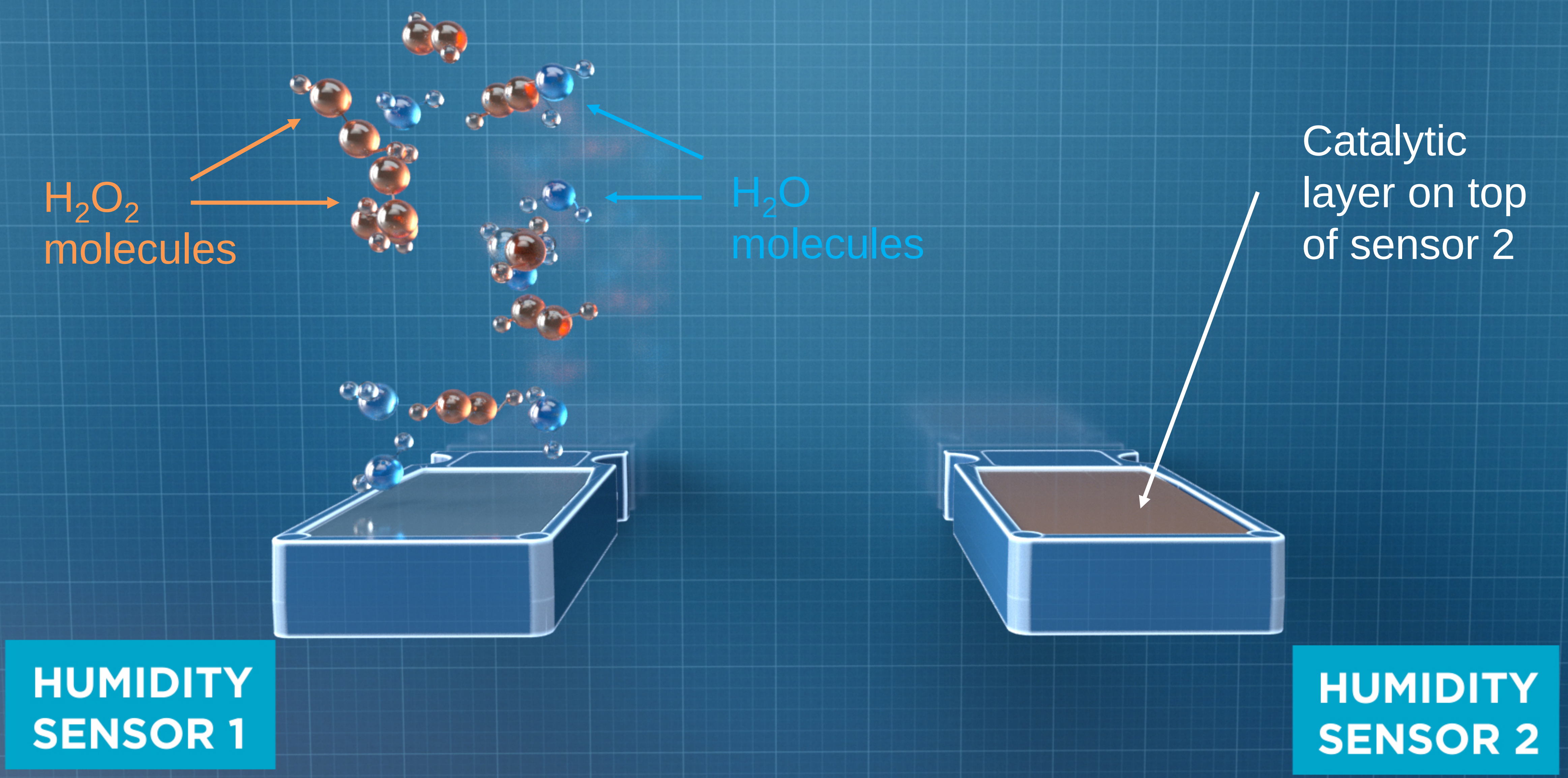
New Measurement Technology; PEROXCAP®

Sensor 1 Sensor 2

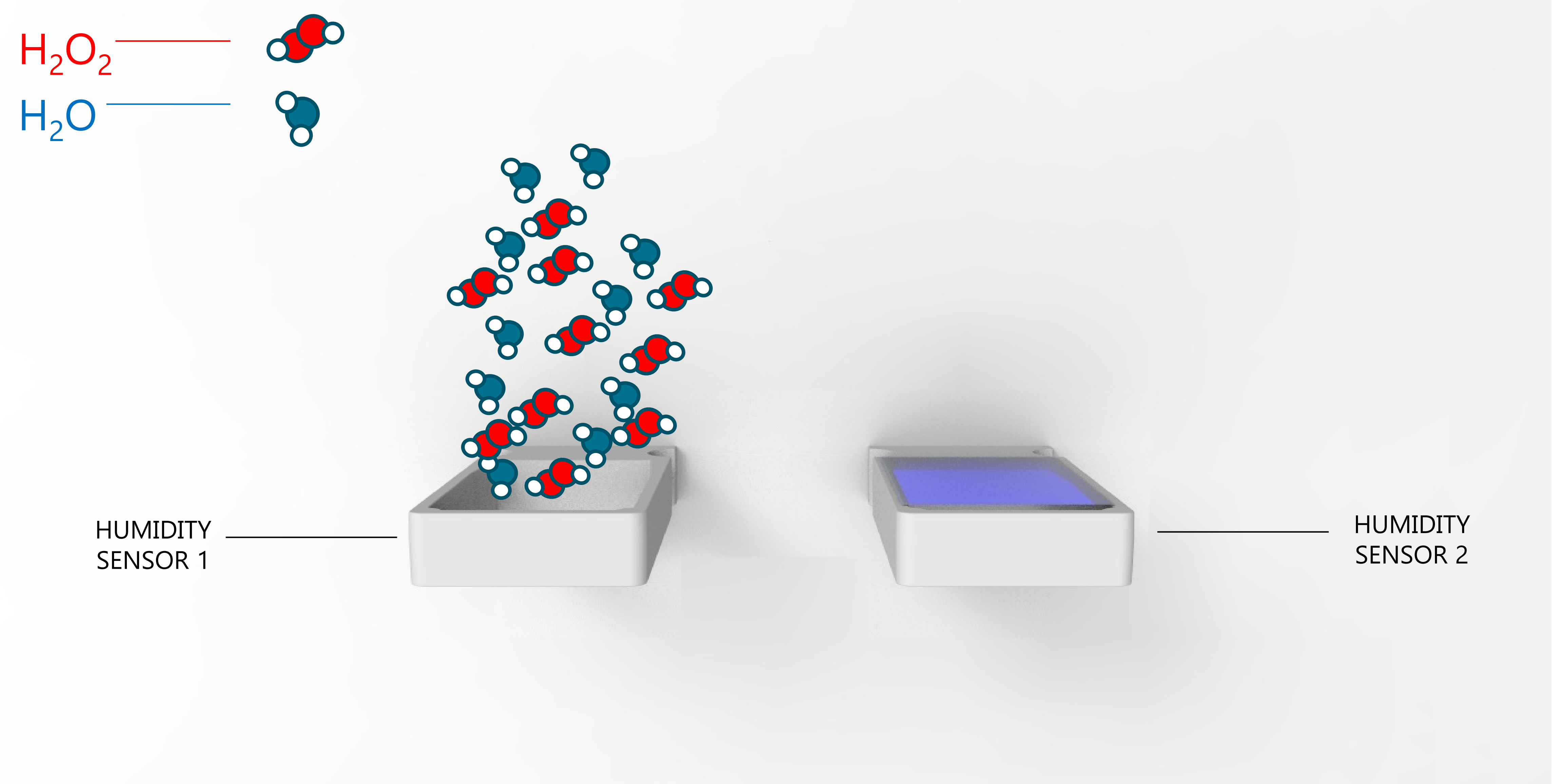


The Vaisala PEROXCAP® sensor technology is based on two capacitive thin-film polymer sensors, building on the reliable HUMICAP® technology.

New Measurement Technology; PEROXCAP®



New Measurement Technology; PEROXCAP®



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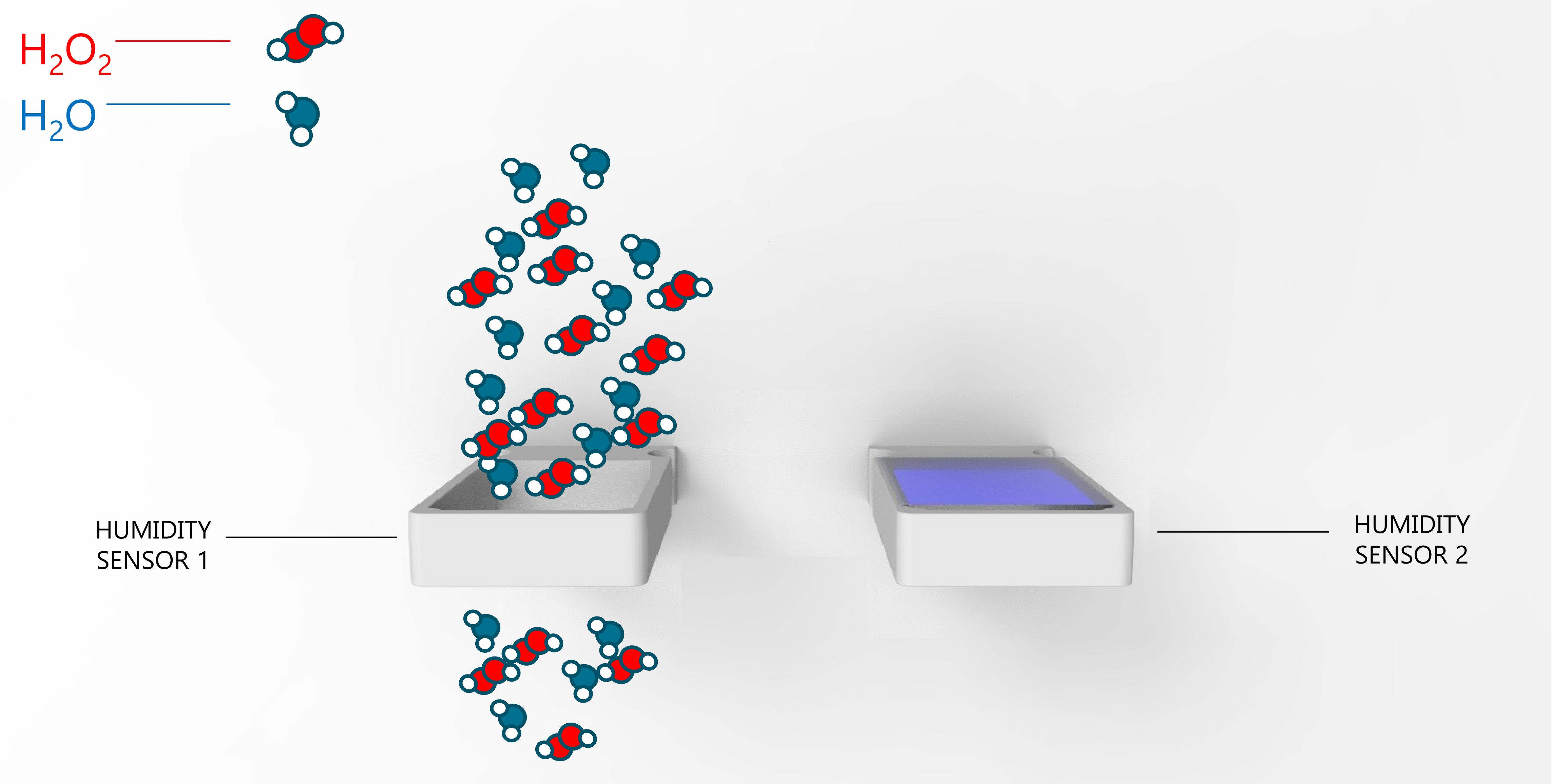
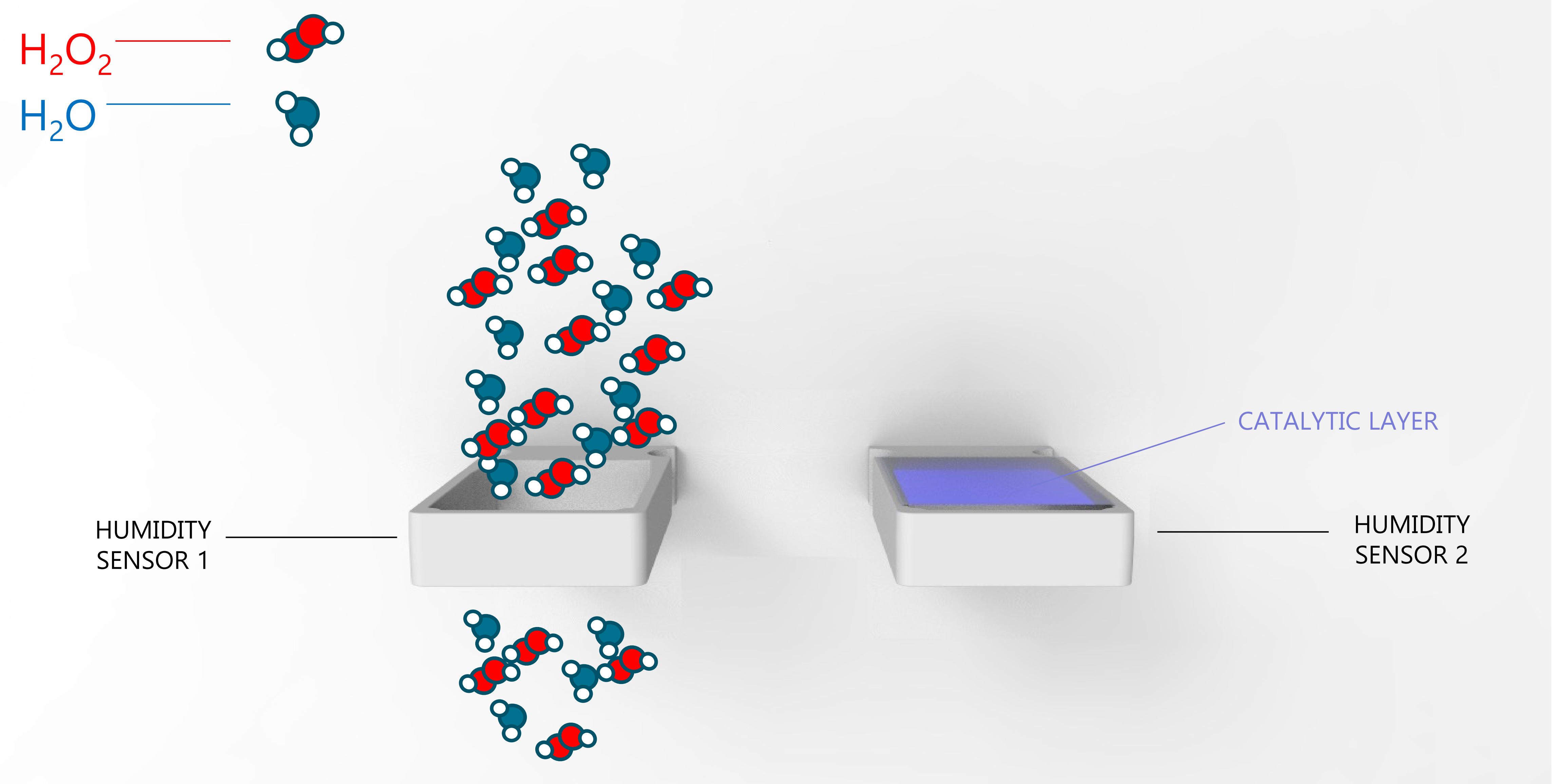
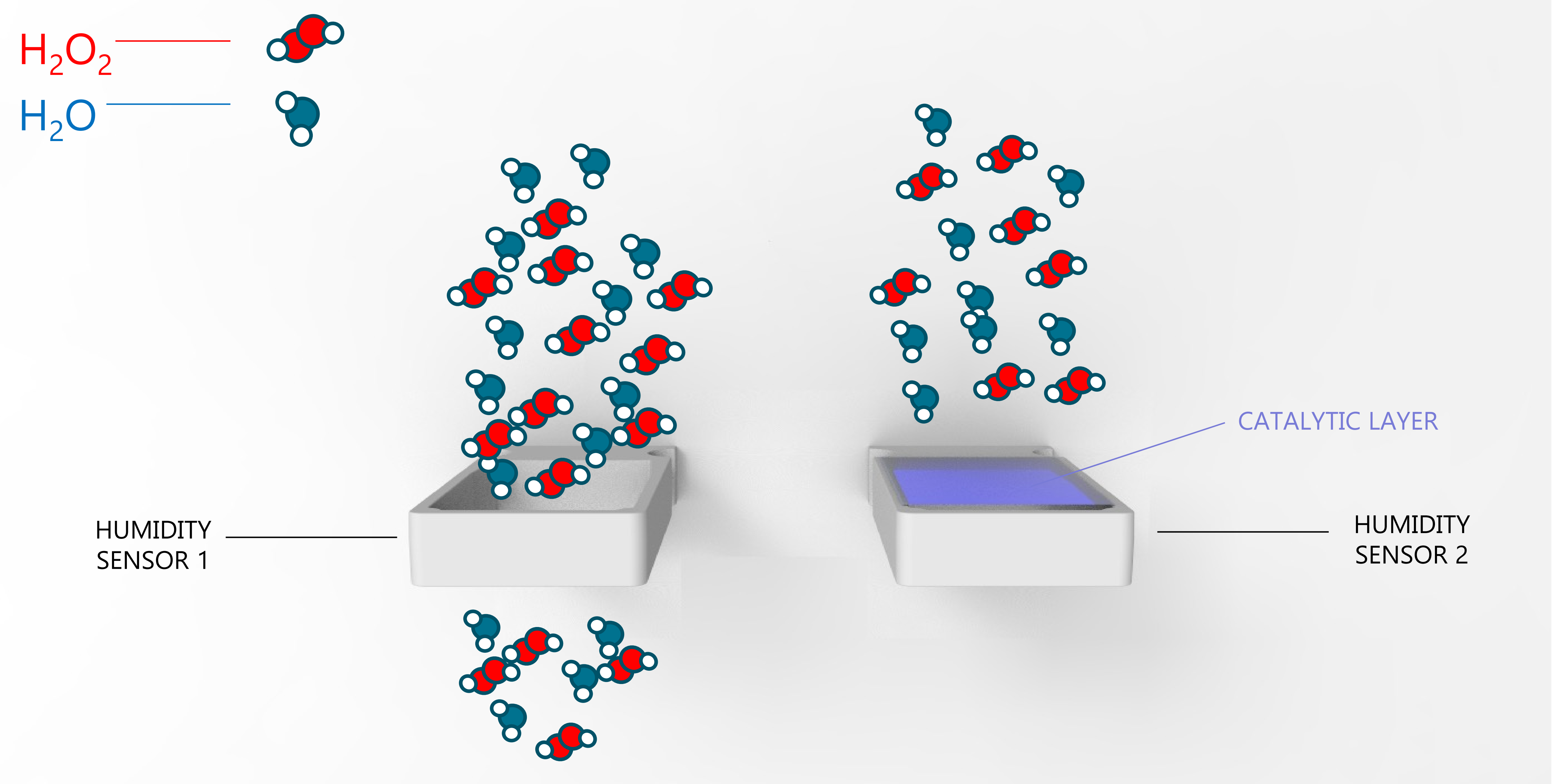


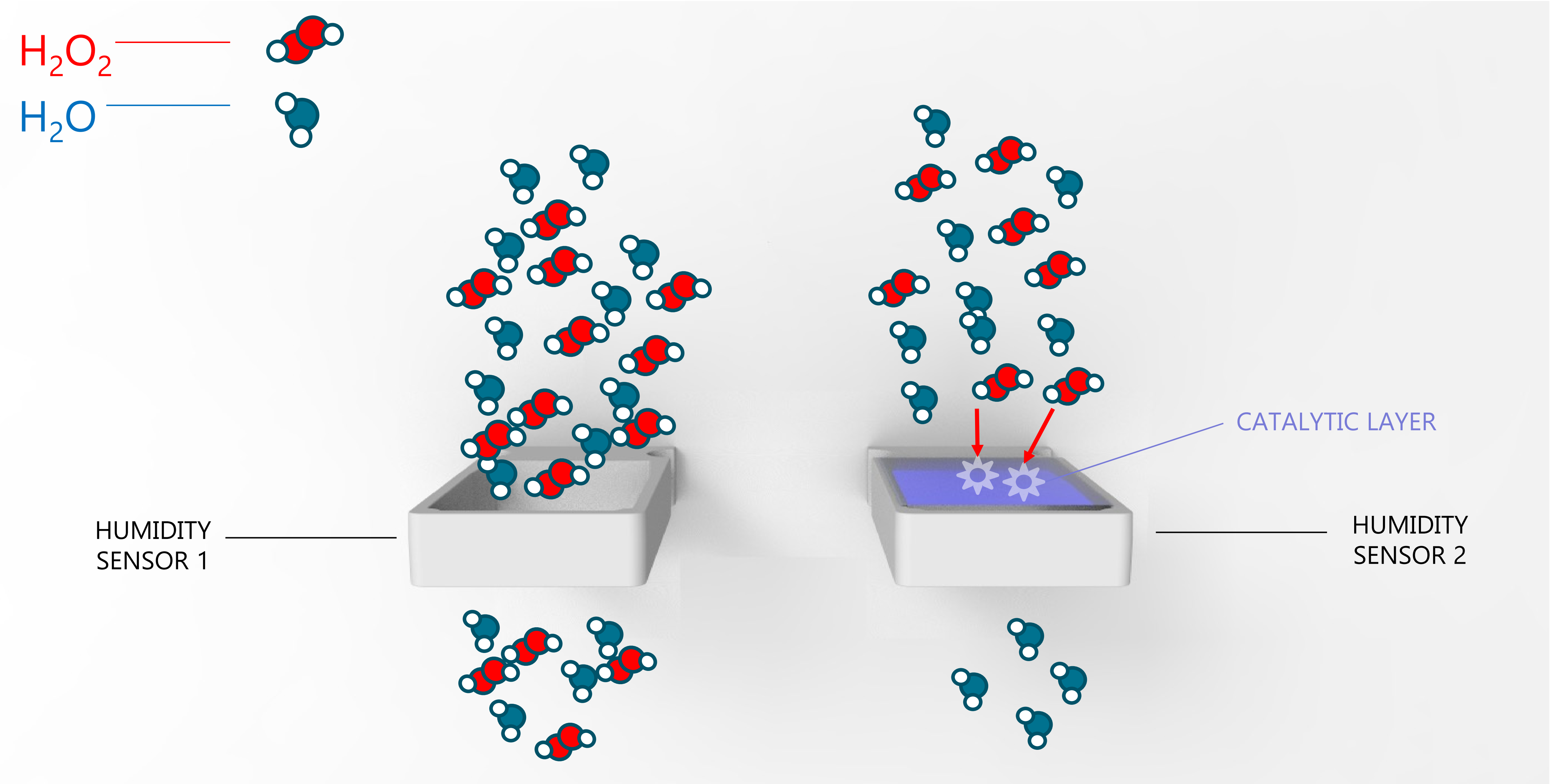
New Measurement Technology; PEROXCAP®



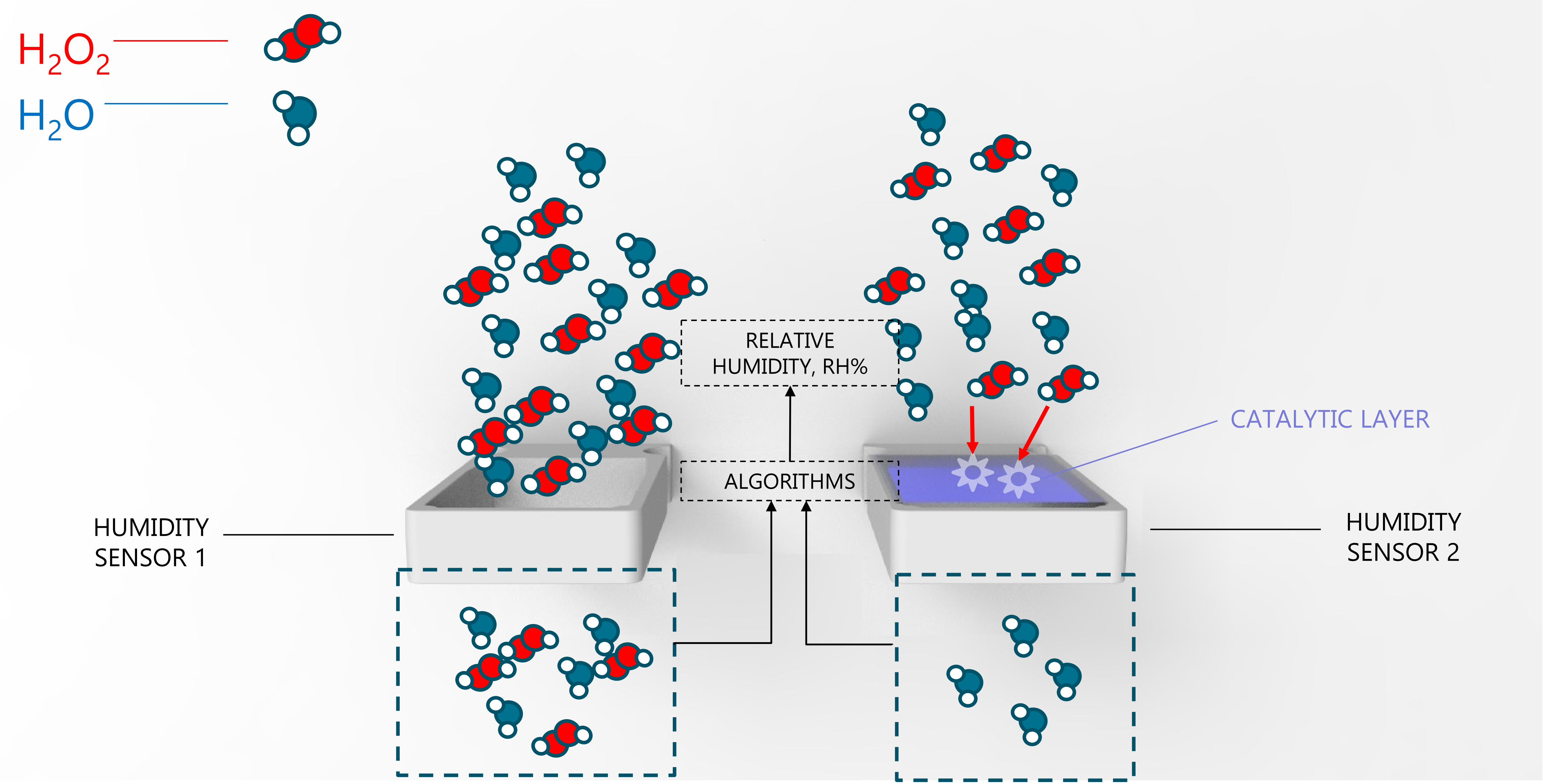
New Measurement Technology; PEROXCAP®



New Measurement Technology; PEROXCAP®



New Measurement Technology; PEROXCAP®



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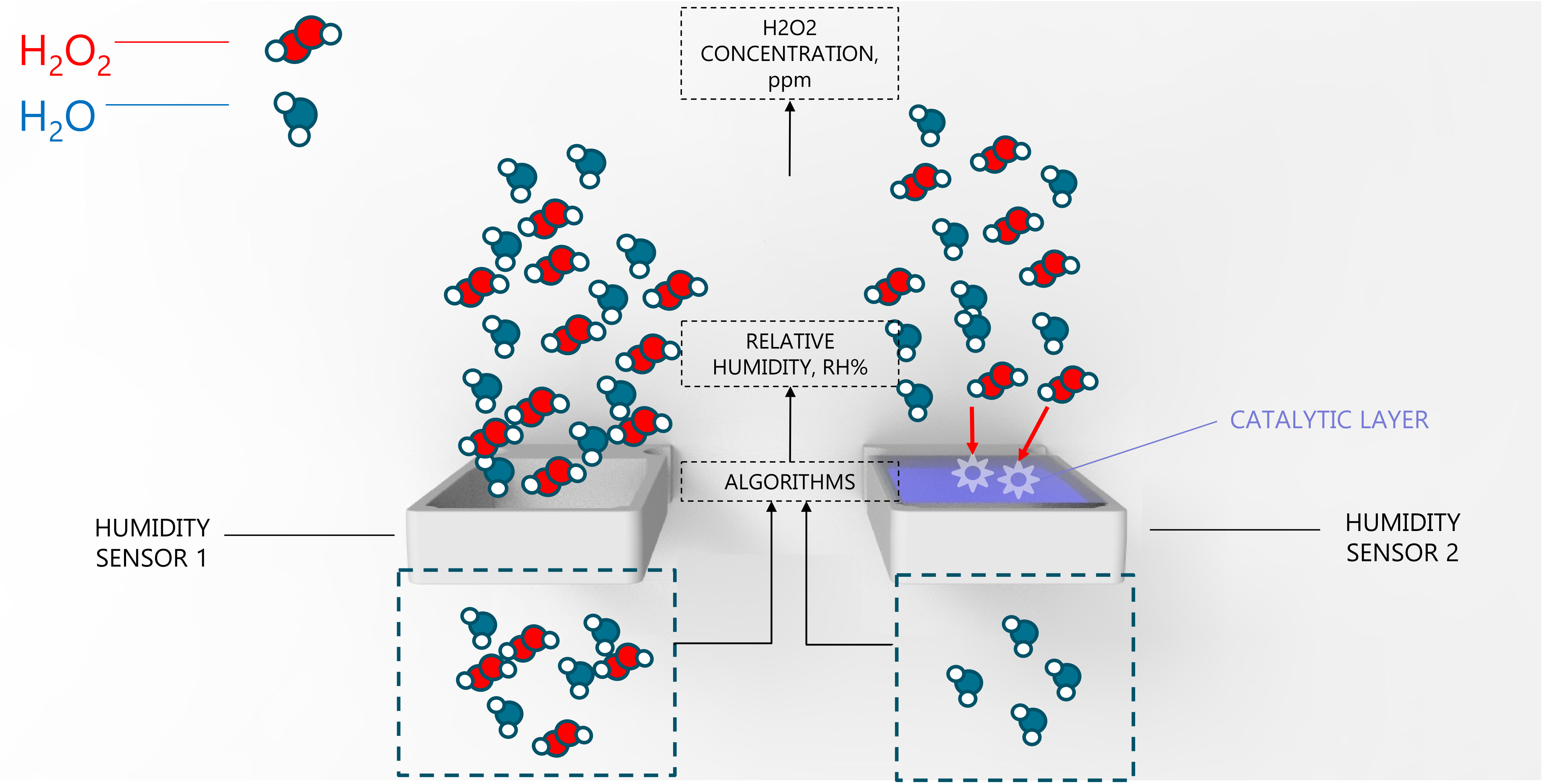
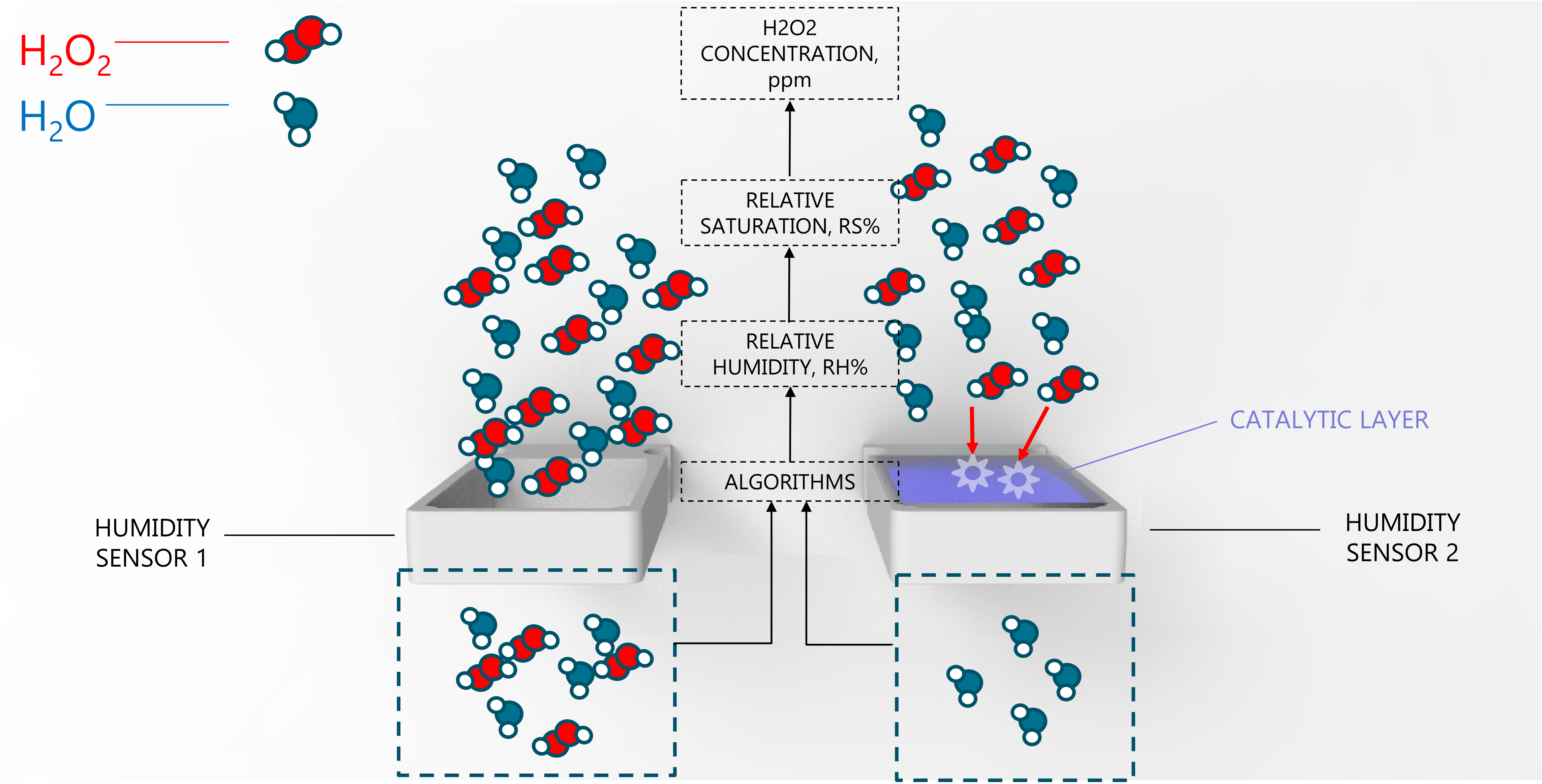
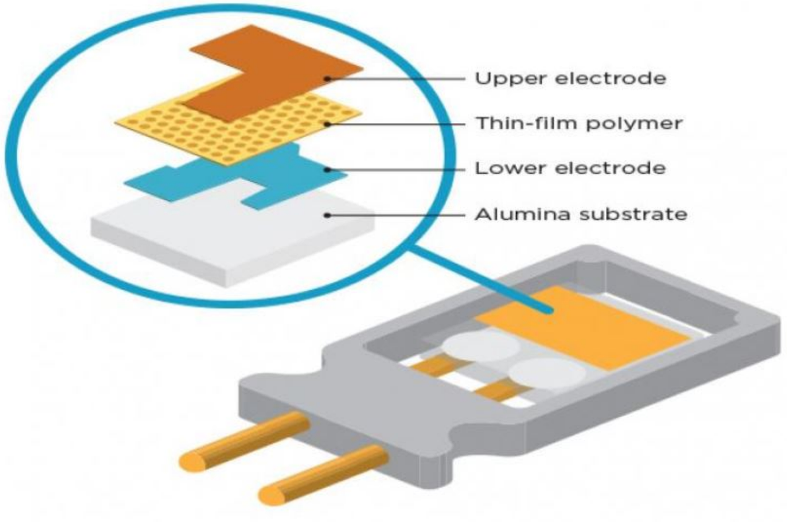
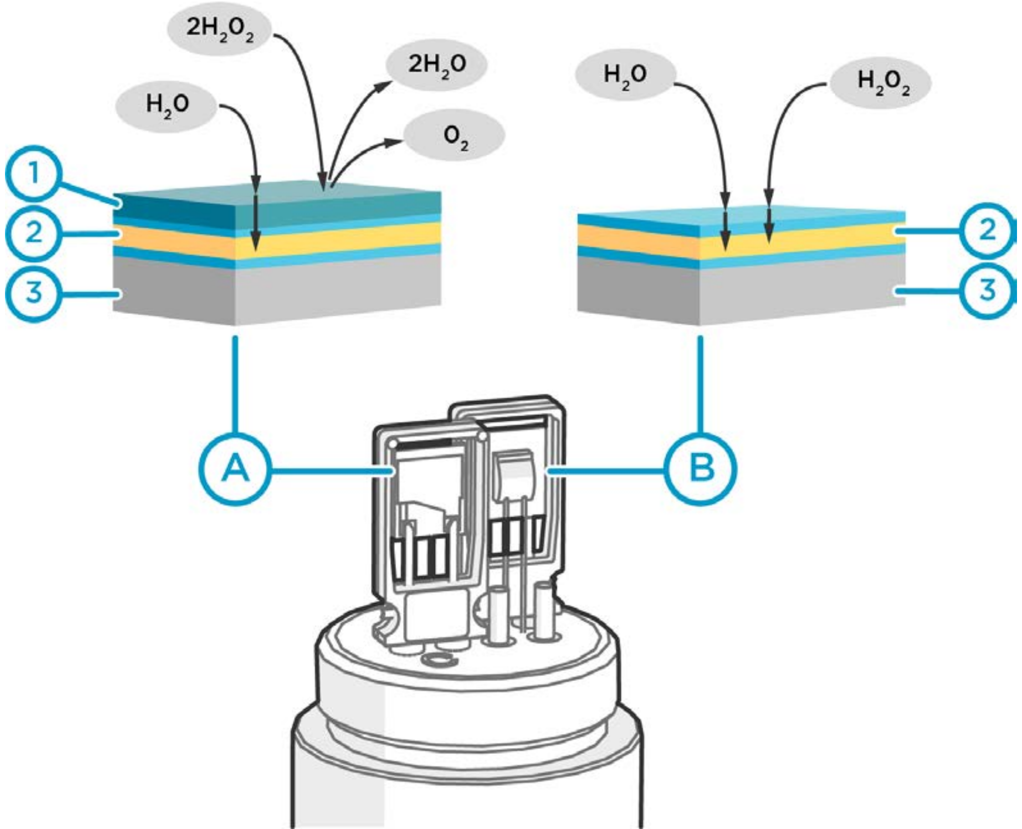


New Measurement Technology; PEROXCAP®



The Difference Between Relative Humidity (RH%) and Relative Saturation (RS%)





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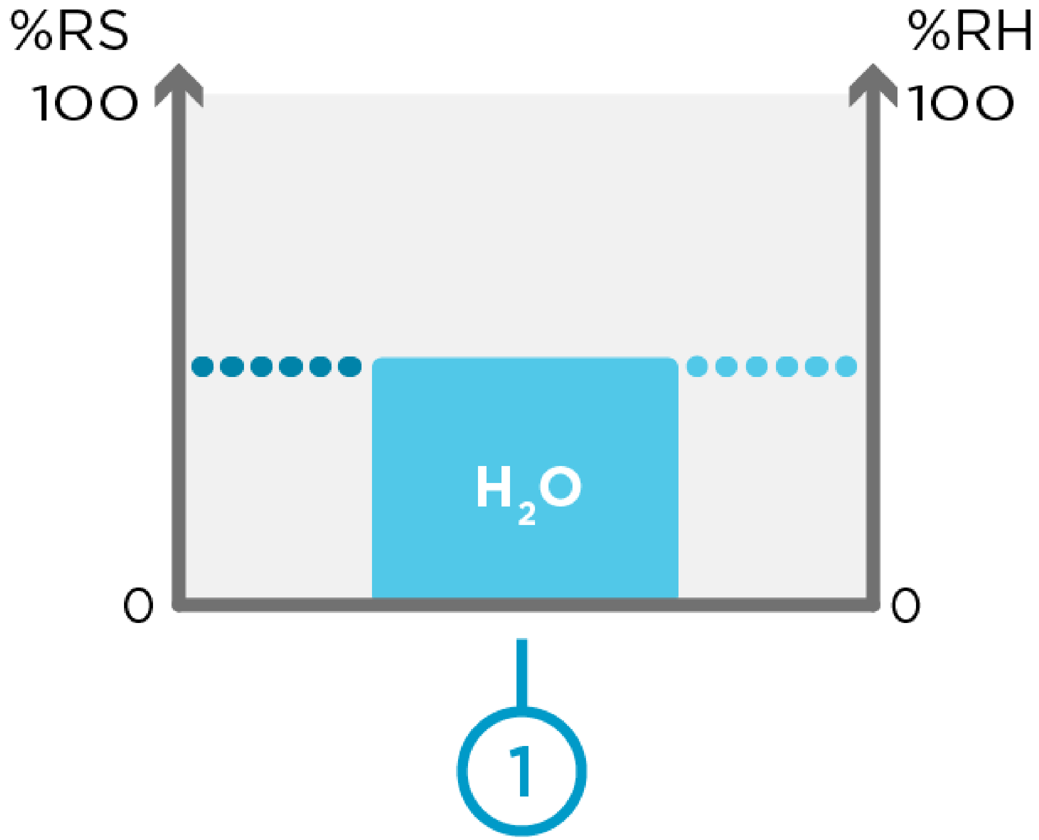
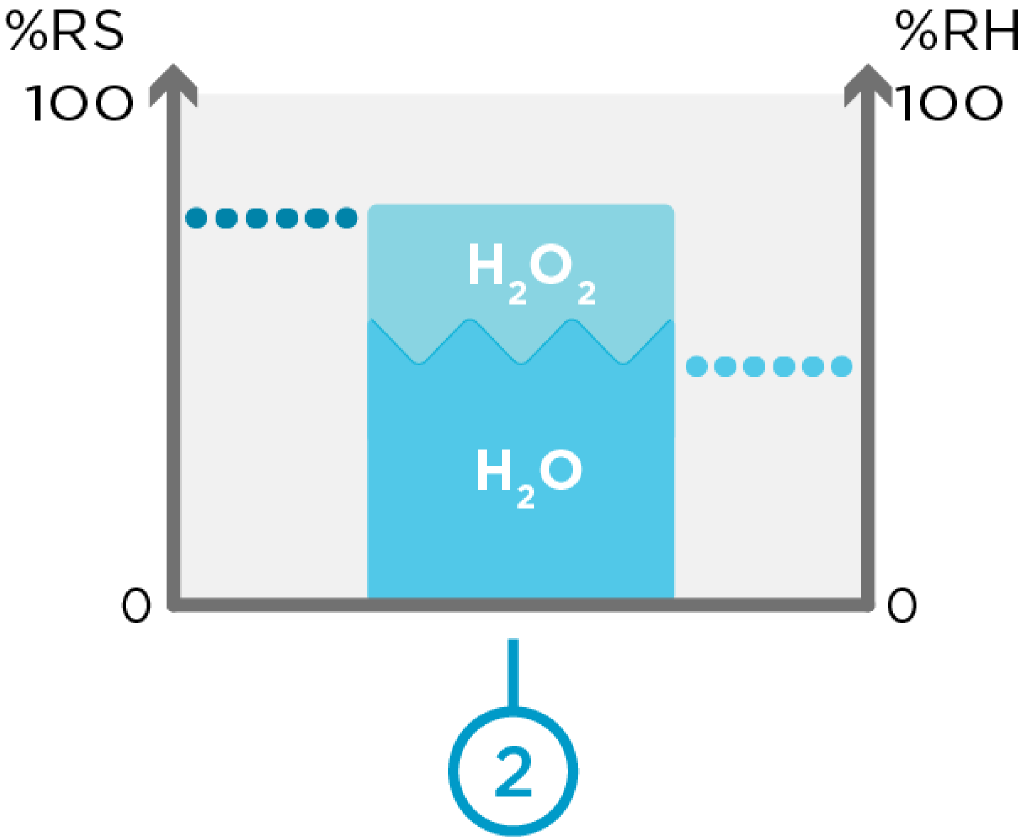
Relative Saturation vs. Relative Humidity

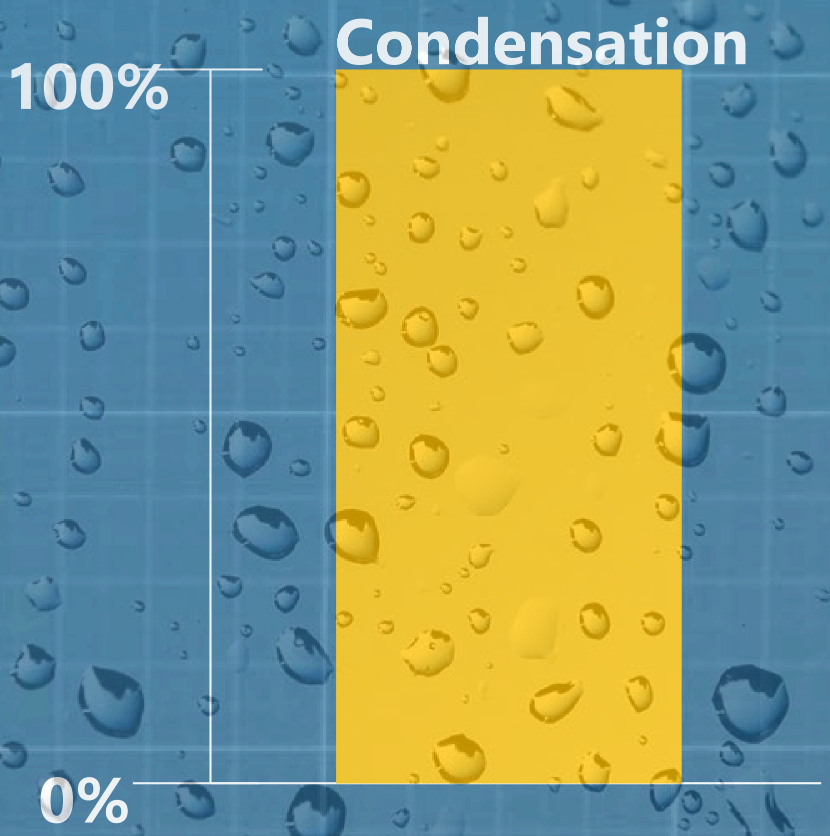


Only H_2O vapor present



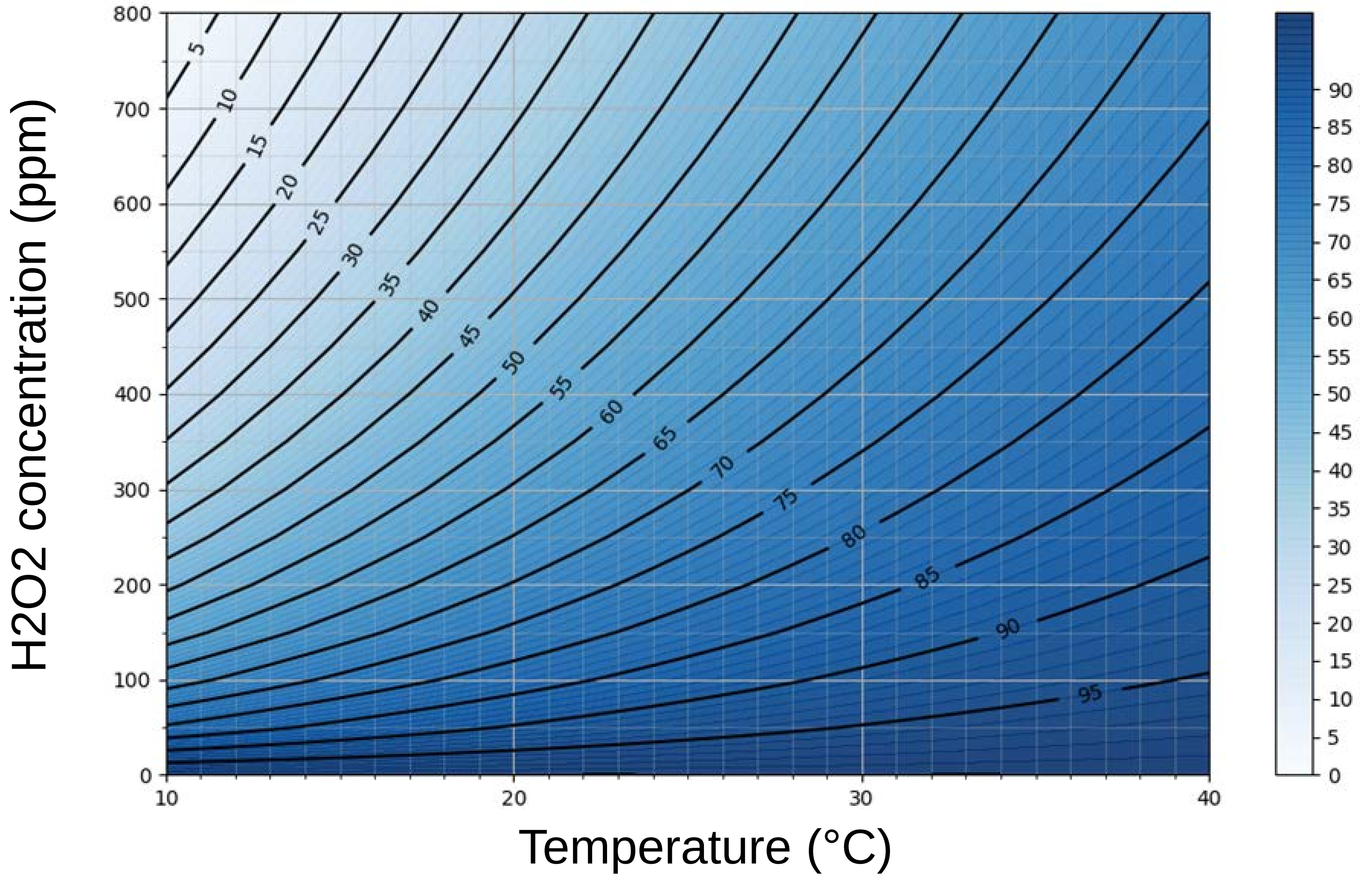
H_2O and H_2O_2 vapor present

RELATIVE SATURATION %



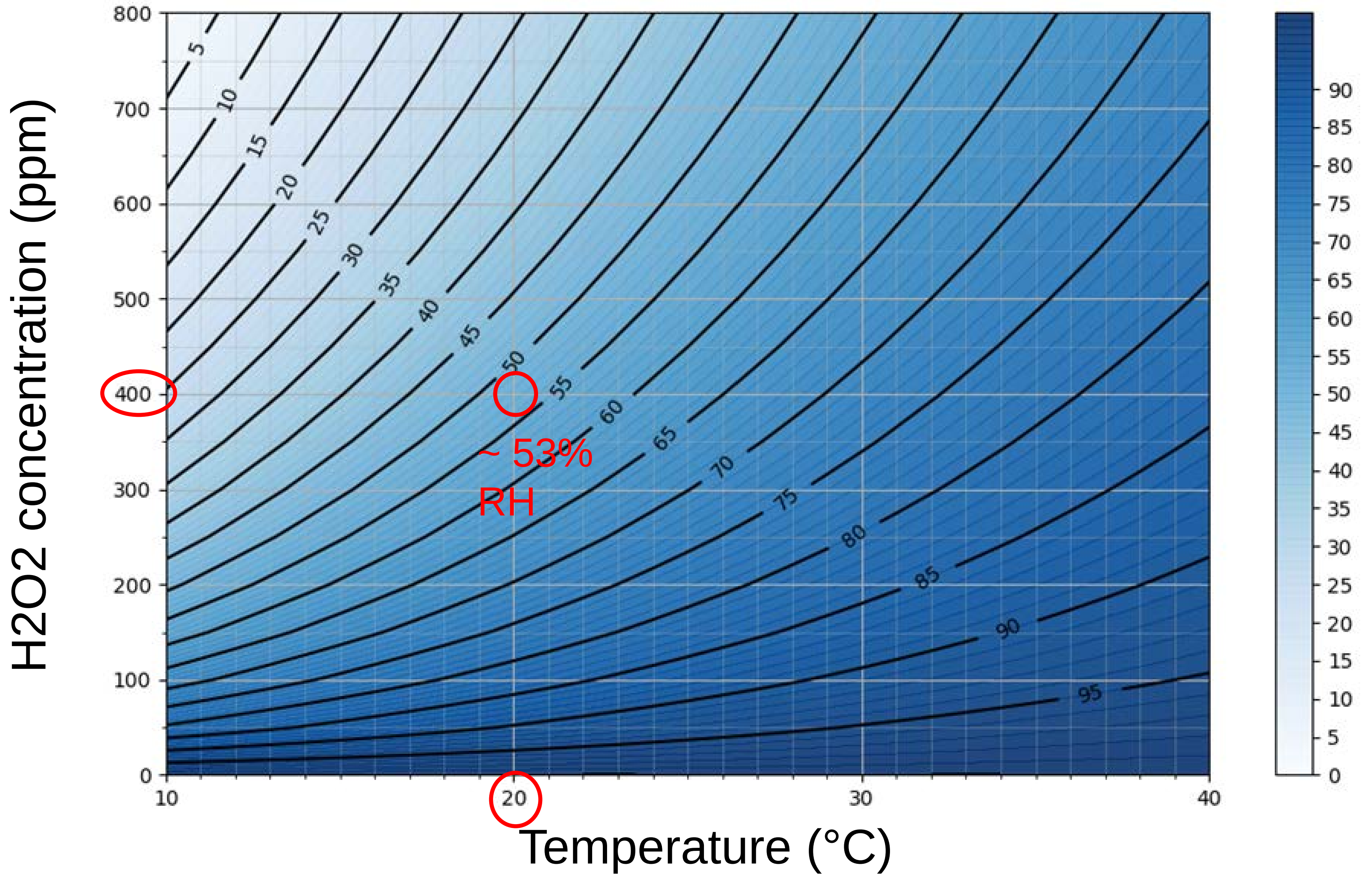
RS% value is the only parameter for controlling condensation when H_2O_2 vapor is present.

Maximum %RH



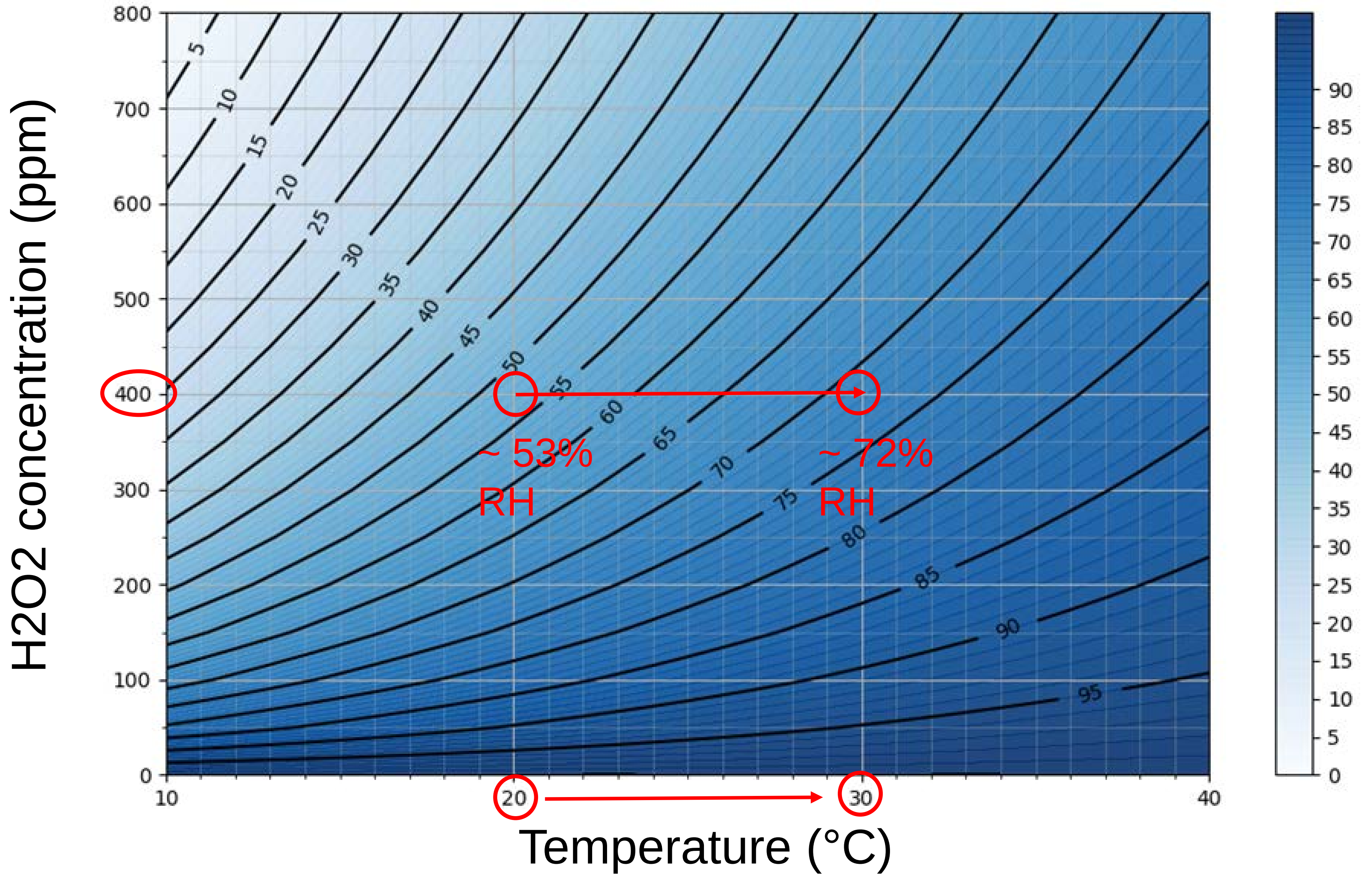
At every point
RS = 100% RS

Maximum %RH



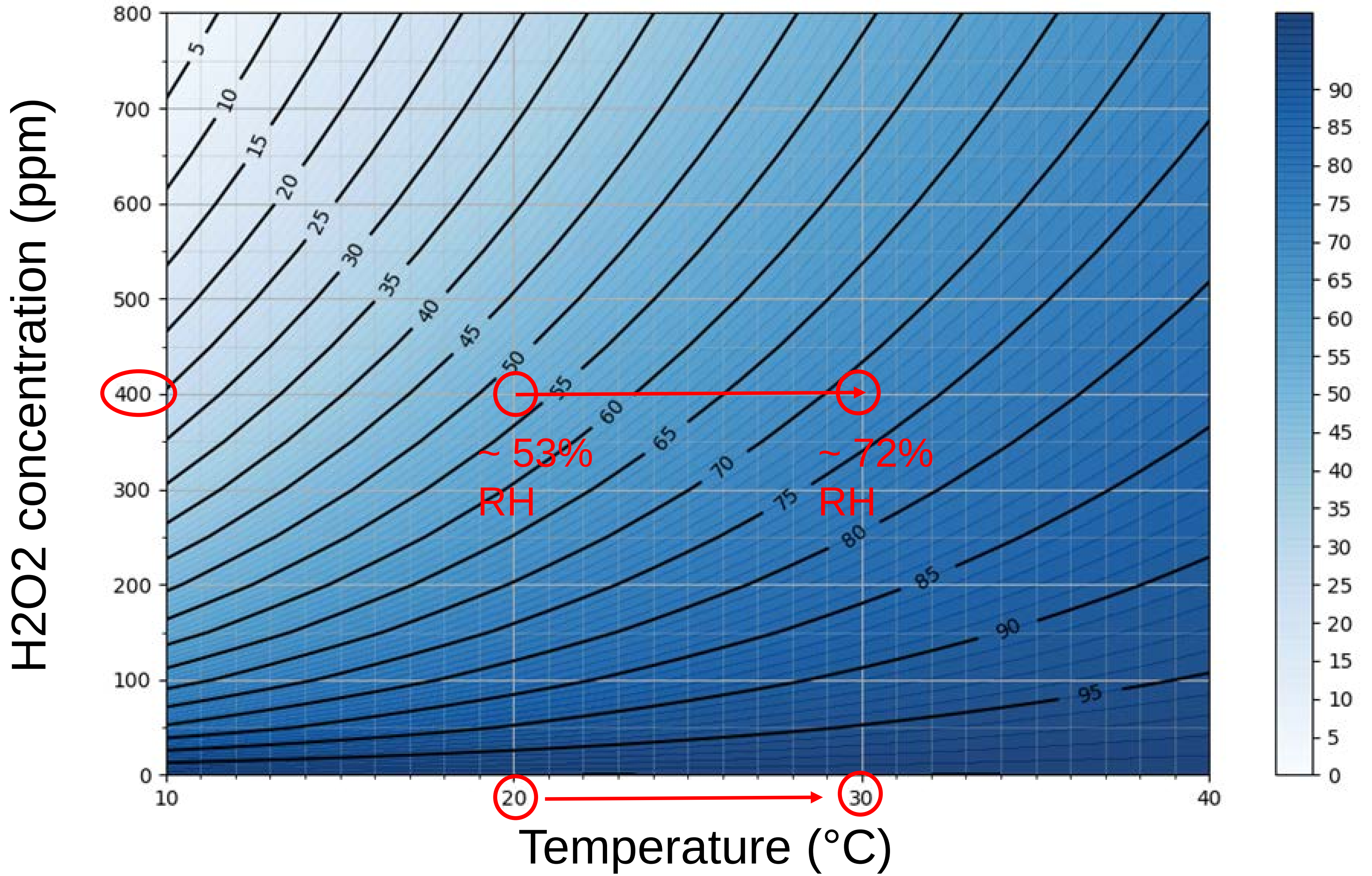
At every point
RS = 100% RS

Maximum %RH is Dependent on Temperature



At every point
RS = 100% RS

Maximum %RH is Dependent on Temperature



At every point RS = 100% RS

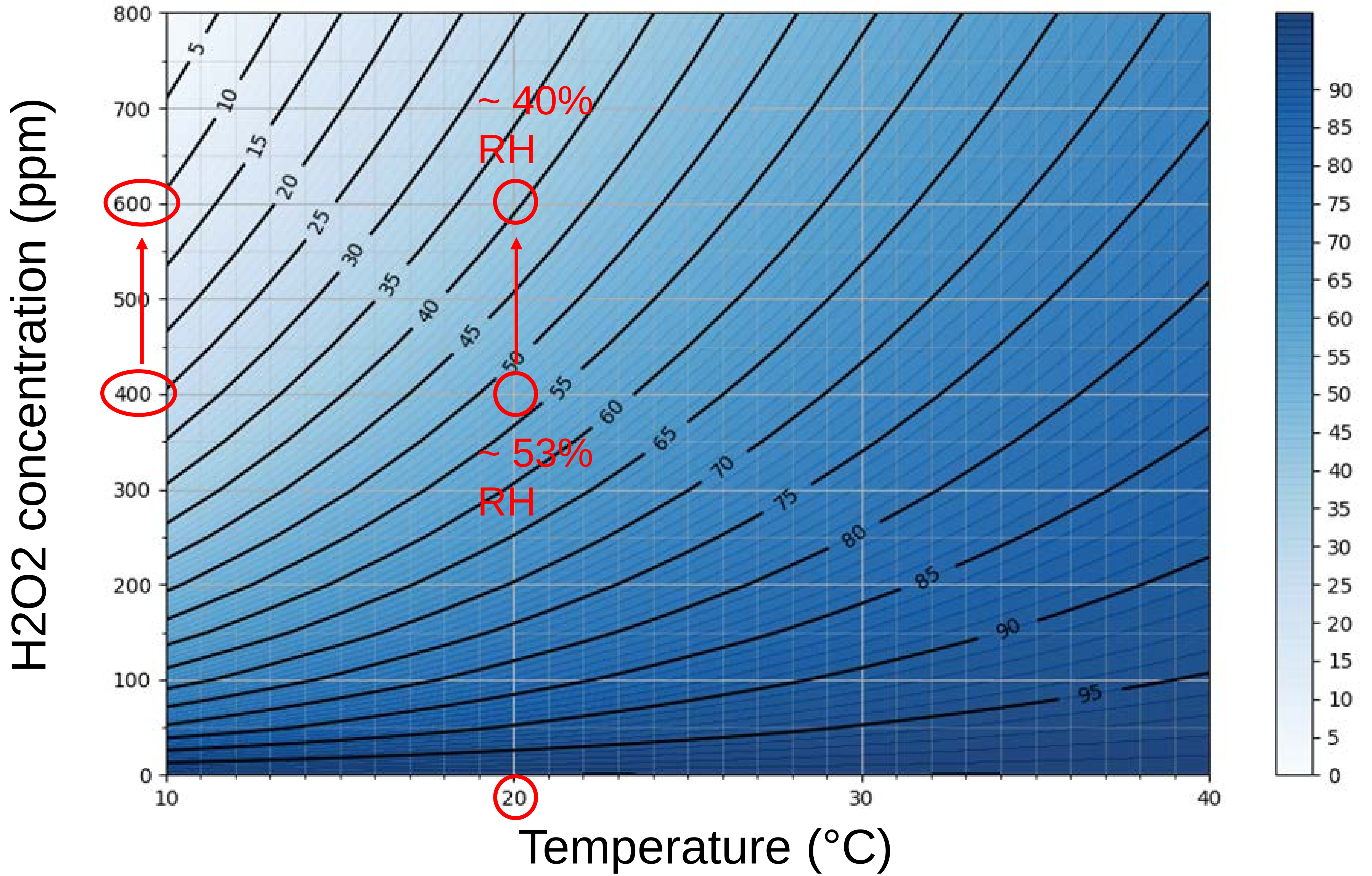
Rule:

Higher the °C

↓

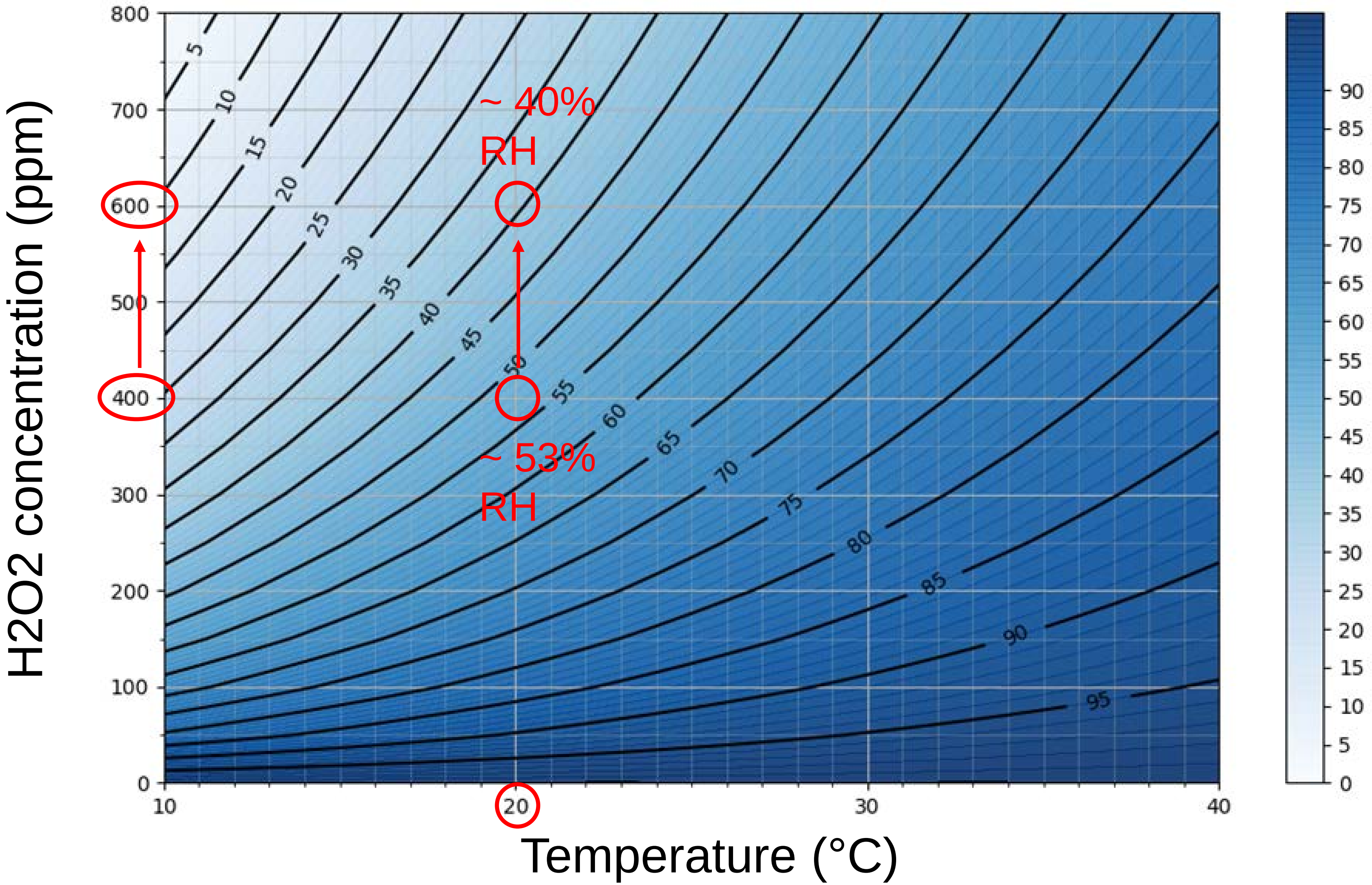
Higher the max. RH%

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

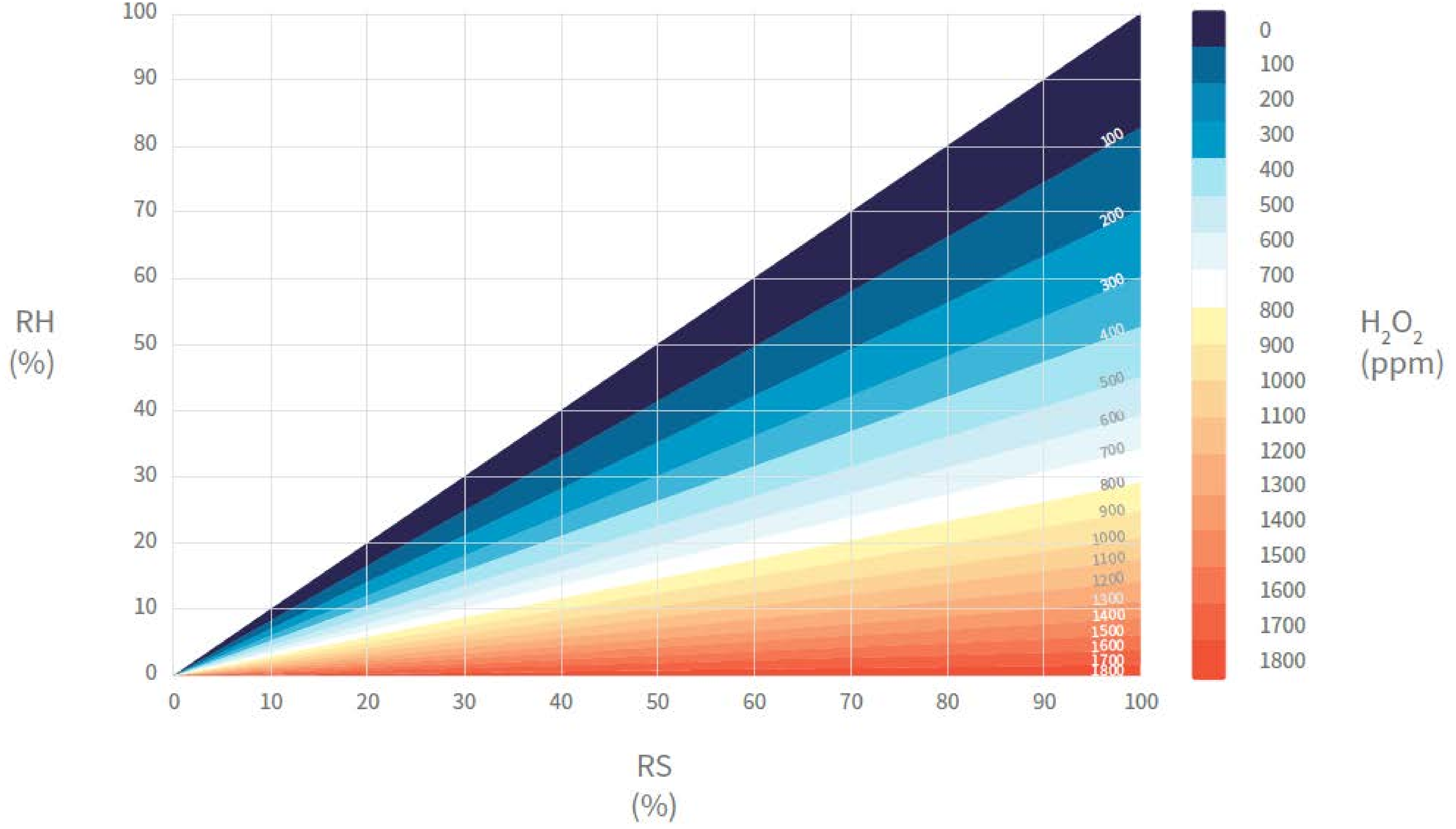
↓

Lower the max. RH%

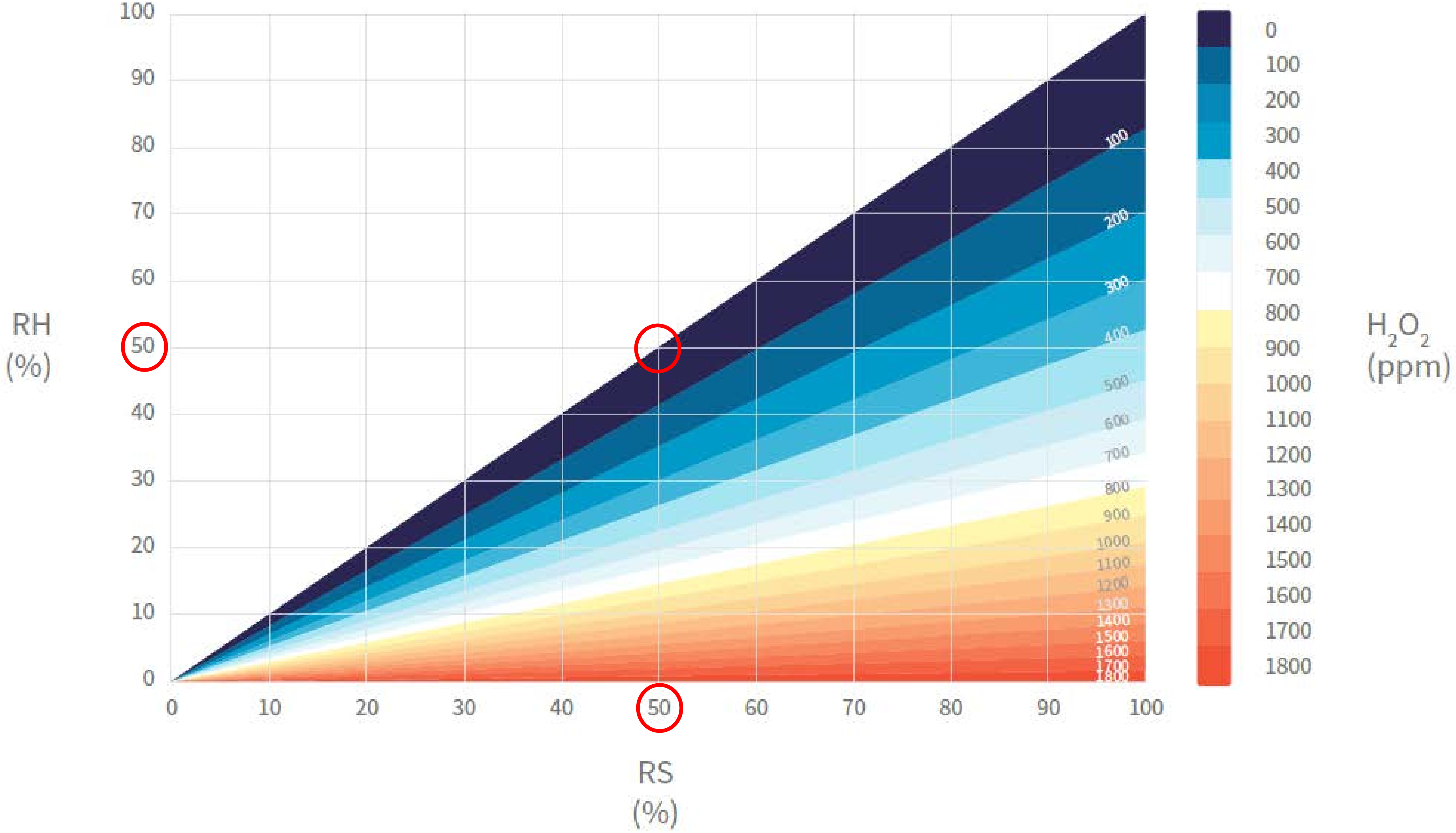
↓

Bigger the difference RH% vs. RS%

H_2O_2 ppm as a Function of RS/RH Sensor Readings at 20.0˚C



H_2O_2 ppm as a Function of RS/RH Sensor Readings at 20.0˚C



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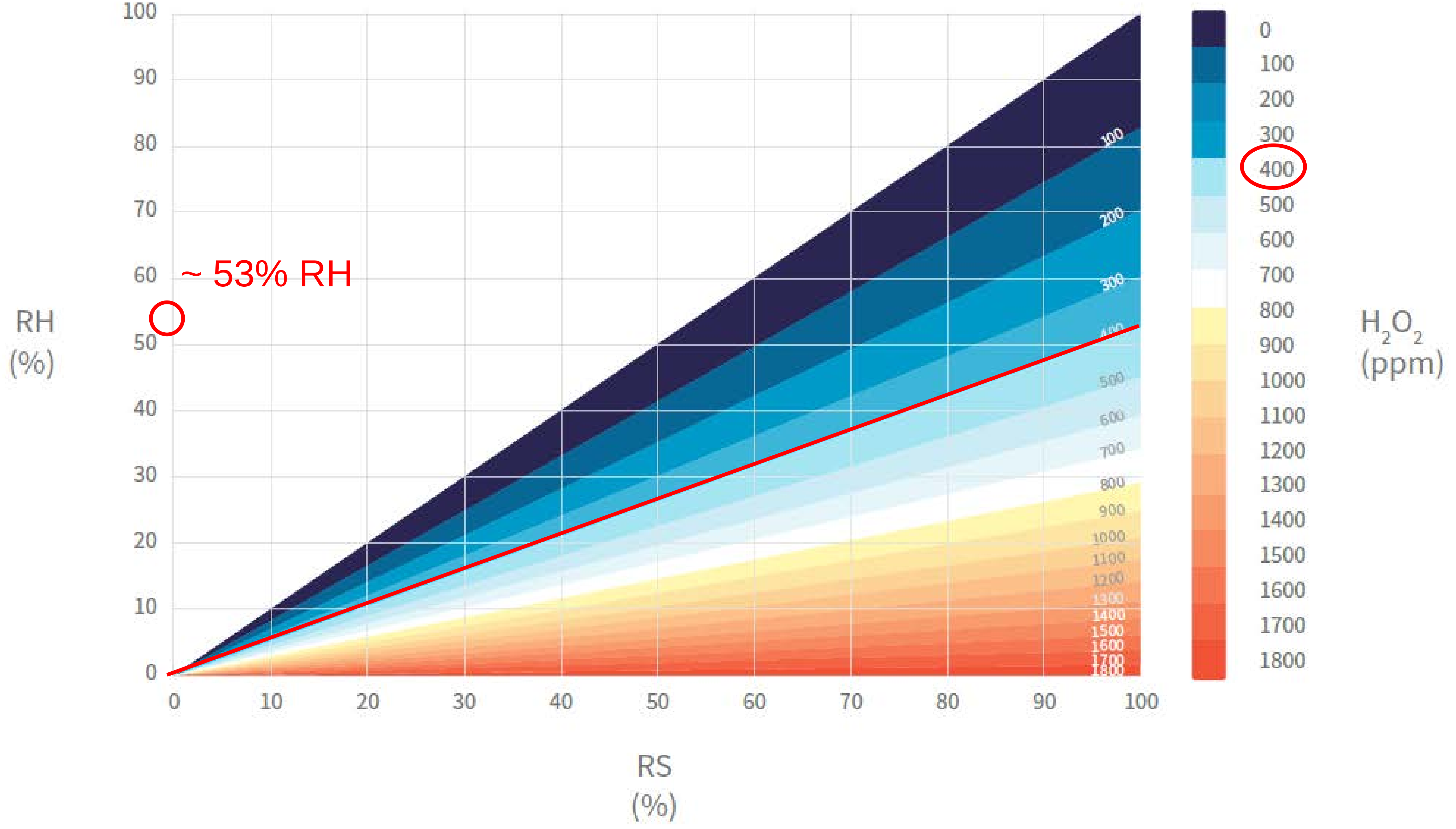
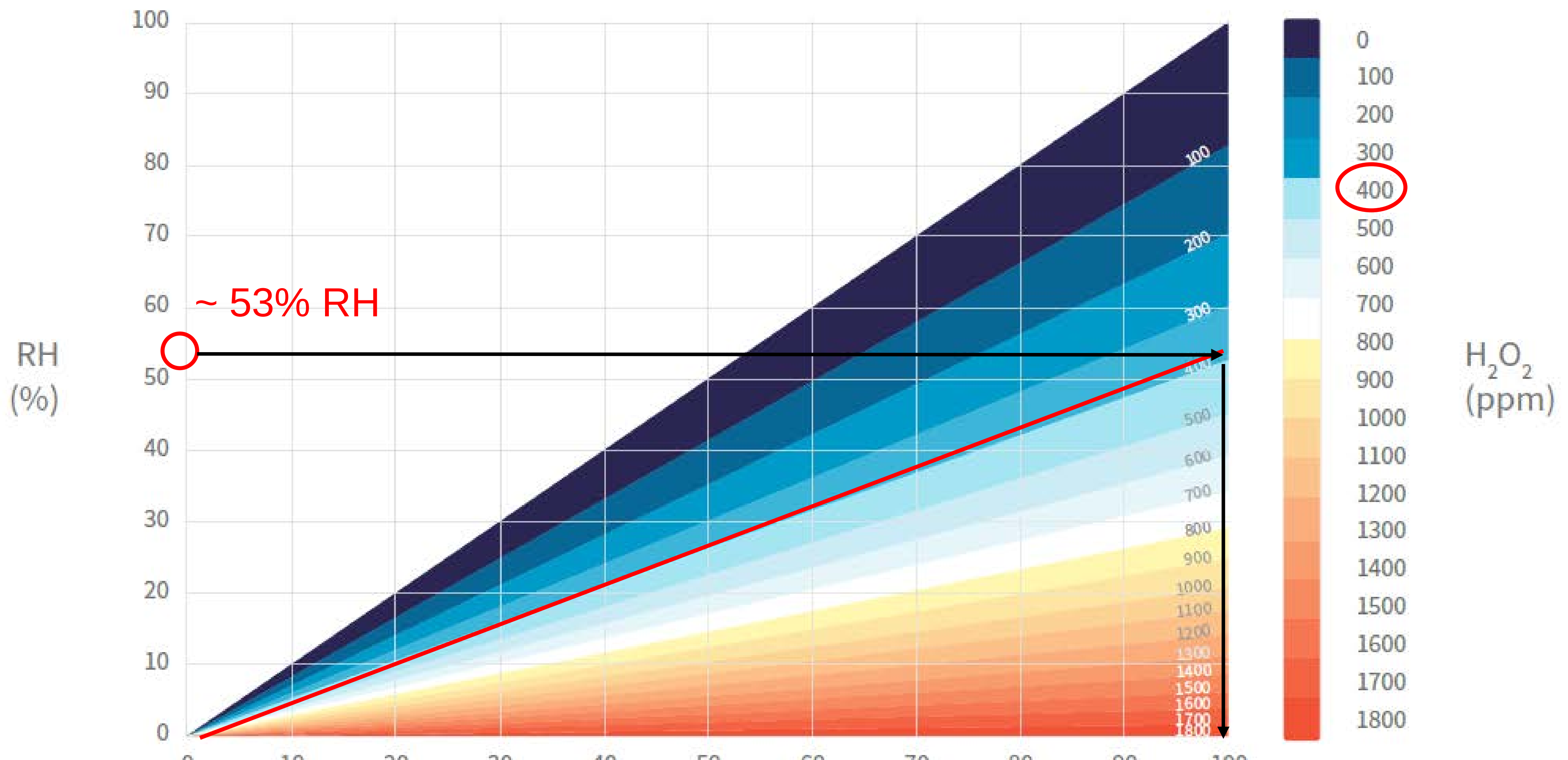
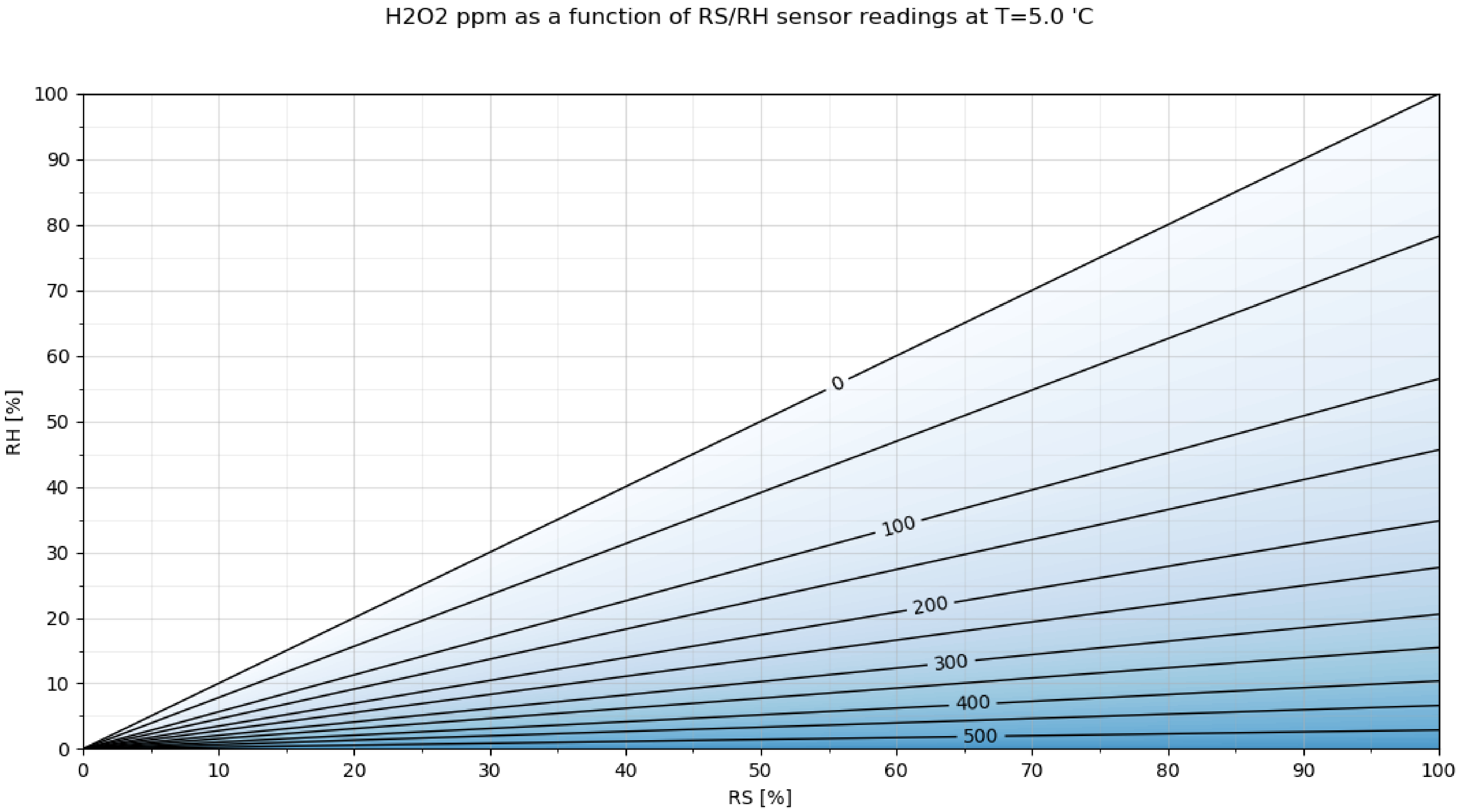


H_2O_2 ppm as a Function of RS/RH Sensor Readings at 20.0˚C



%RS ~ 100%

H_2O_2 ppm as a Function of RS/RH Sensor Readings at 5˚C



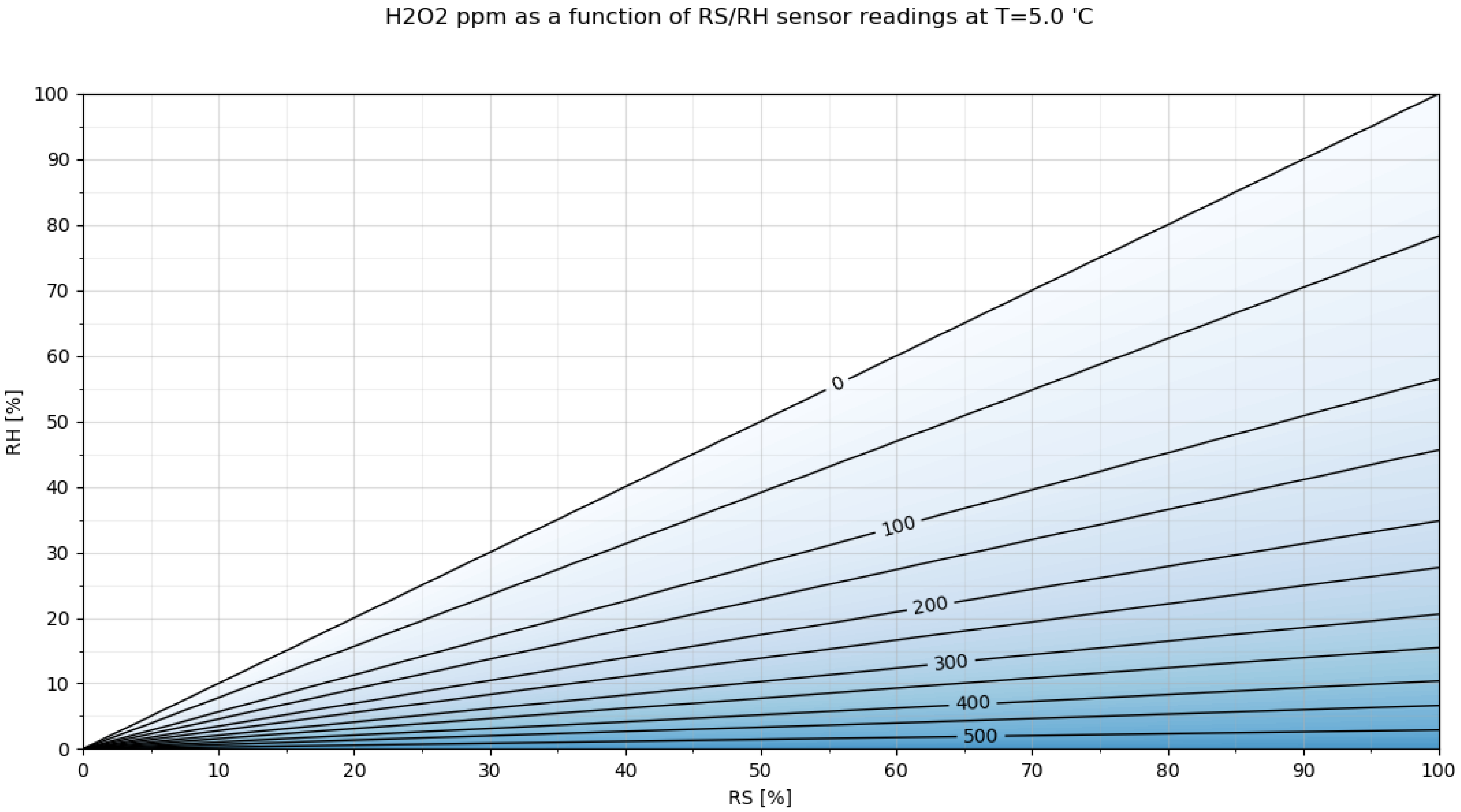
H_2O_2 ppm

RH%

RS%

H_2O_2 ppm as a Function of RS/RH Sensor Readings at 5˚C

RH%



RS%

H_2O_2 ppm

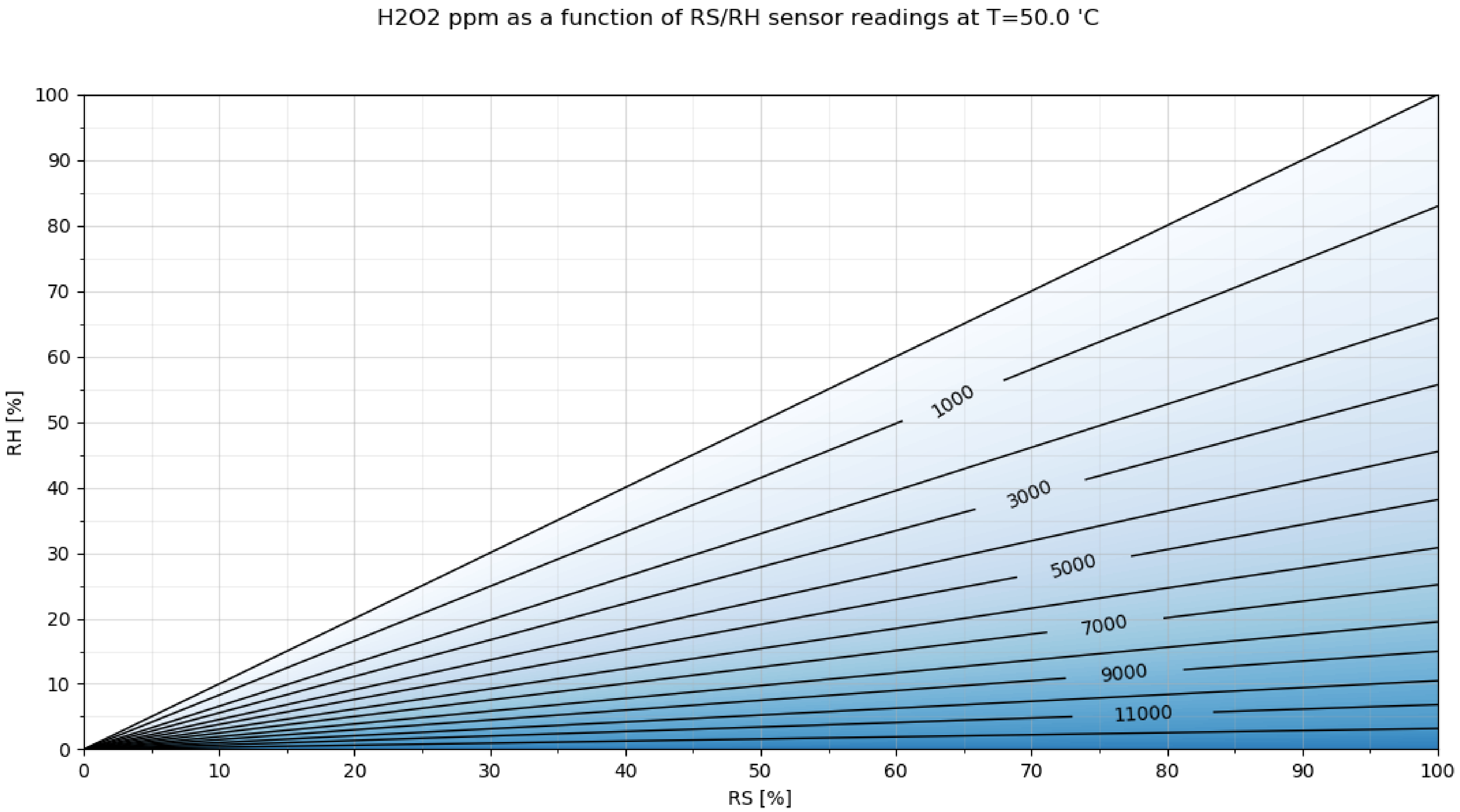
Rule:

At 5°C

↓

Max.
~ 550 ppm
H_2O_2

H_2O_2 ppm as a Function of RS/RH Sensor Readings at 50˚C

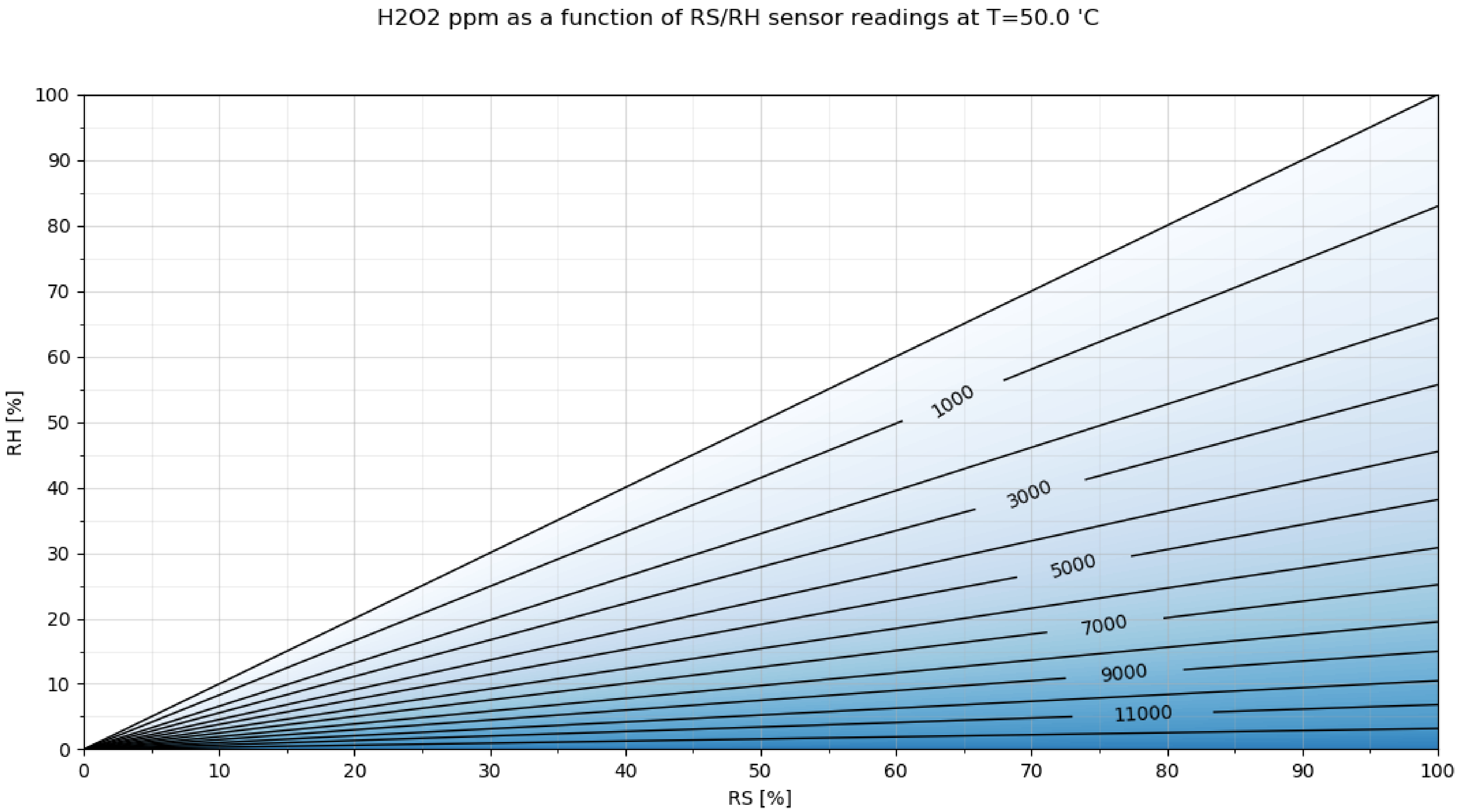


H_2O_2 ppm

RH%

RS%

H_2O_2 ppm as a Function of RS/RH Sensor Readings at 50˚C



RH%

RS%

H_2O_2 ppm

Rule:

At 50°C

↓

Max. ~12500 ppm H_2O_2

Five Most Typical Pitfalls in Humidity Measurement During Bio-Decontamination

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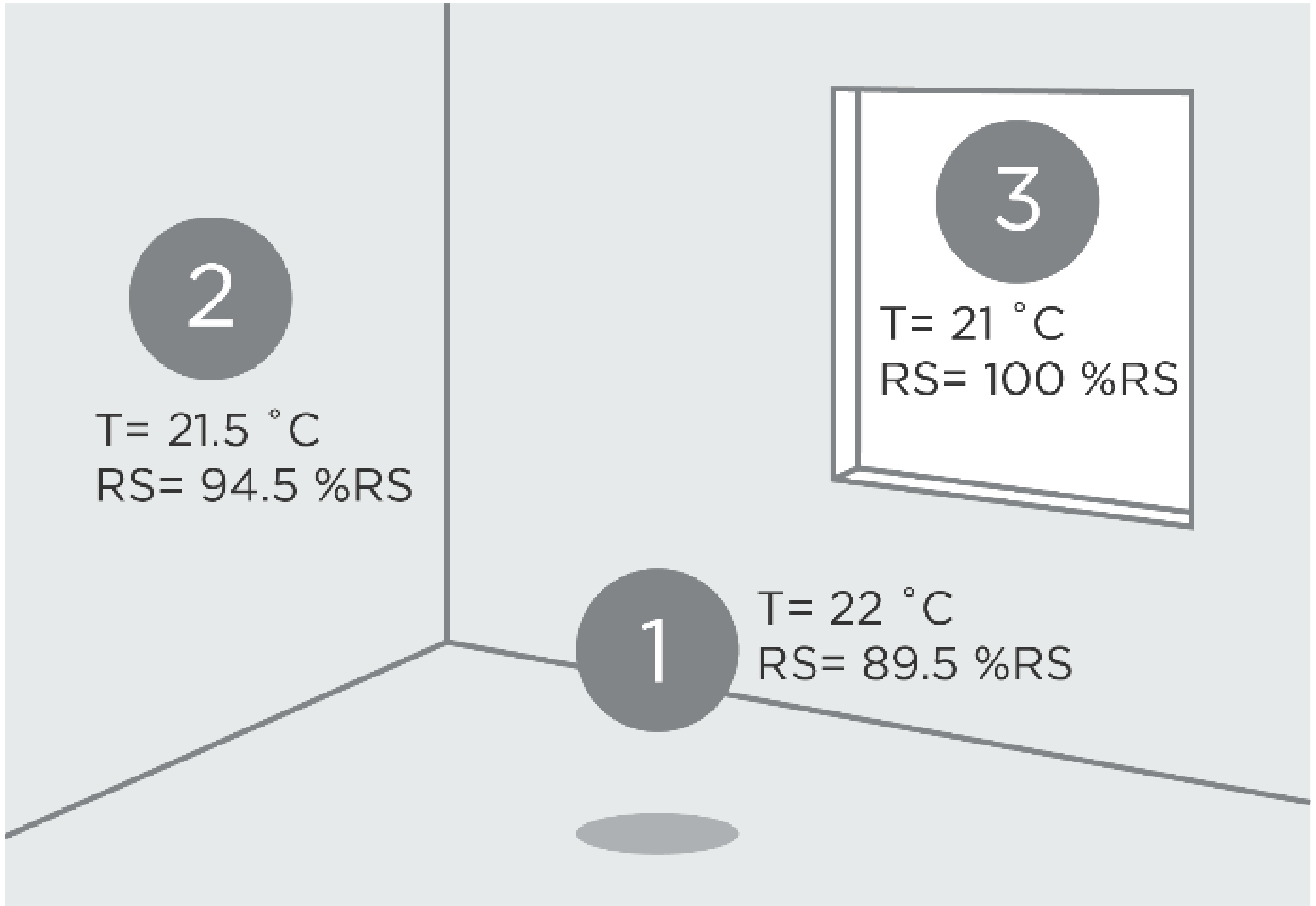
Five Most Typical Pitfalls in Humidity Measurement During Bio-Decontamination

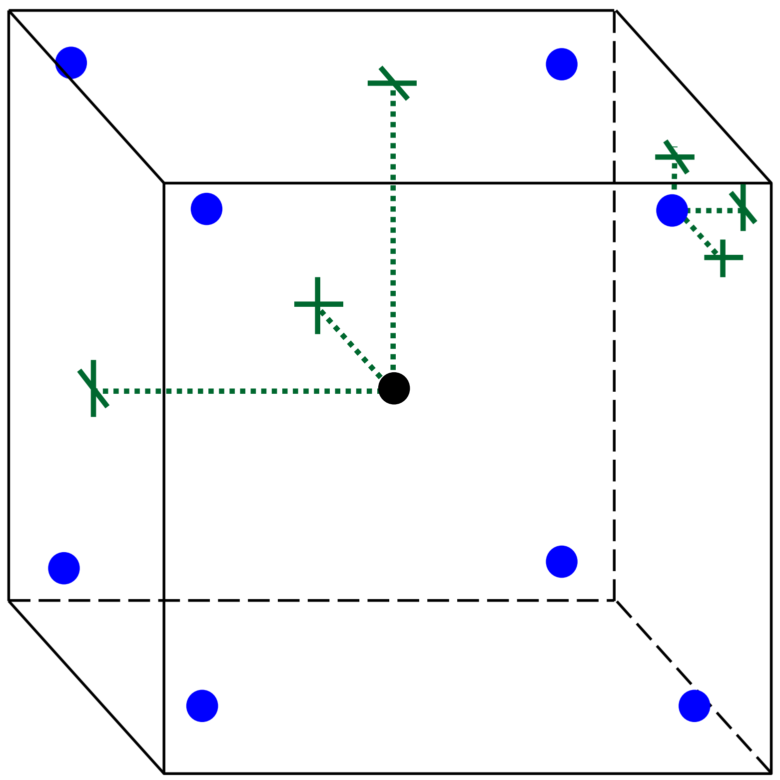
1. Understand how temperature affects RS%
2. Find out the correct measurement point
3. Control condensation with RS%
4. Select correct materials
5. Carefully plan onsite calibration

Pitfall 1: Understand How Temperature Affects RS%



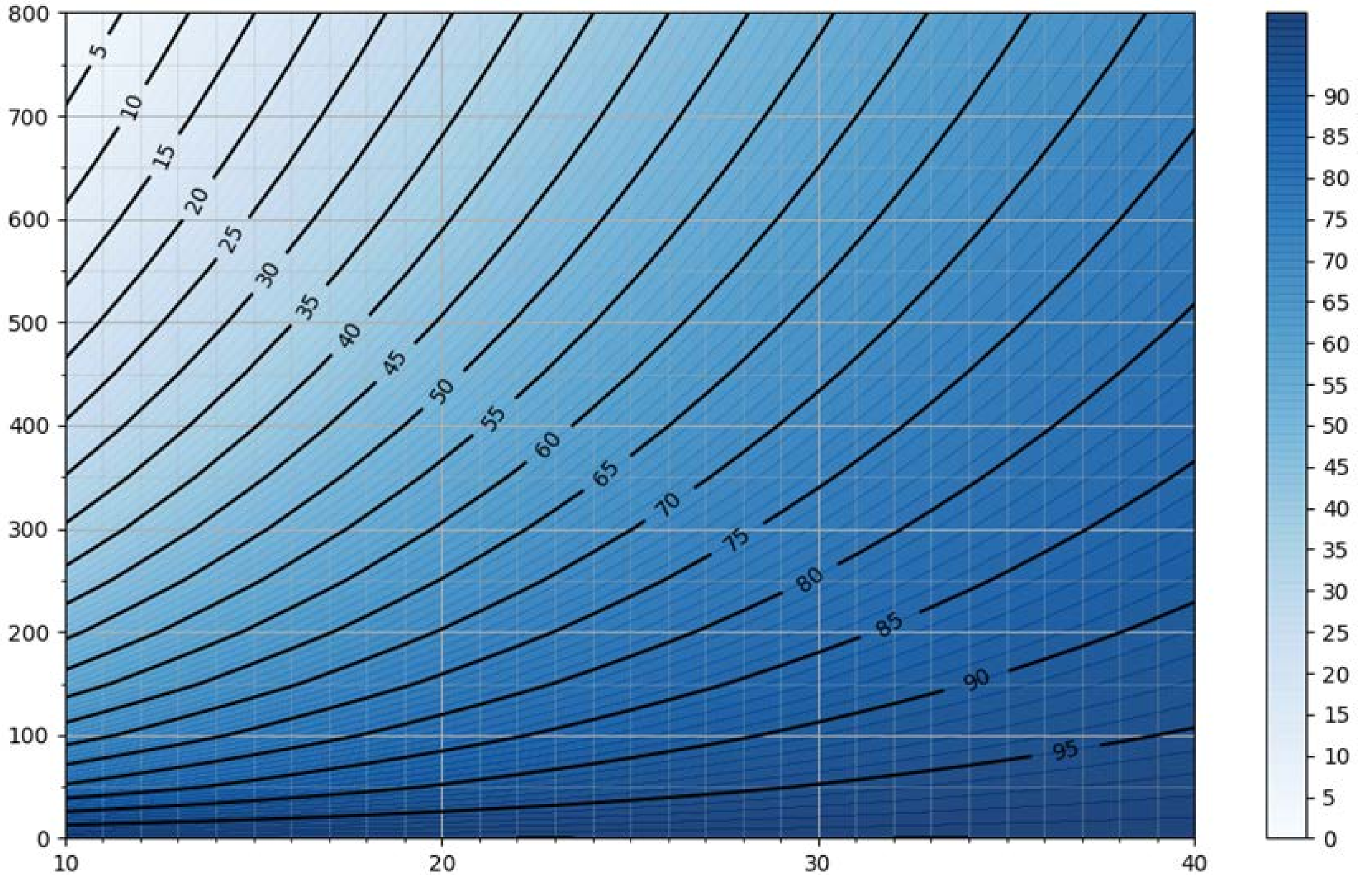
Pitfall 2: Find out the Correct Measurement Point

- 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?



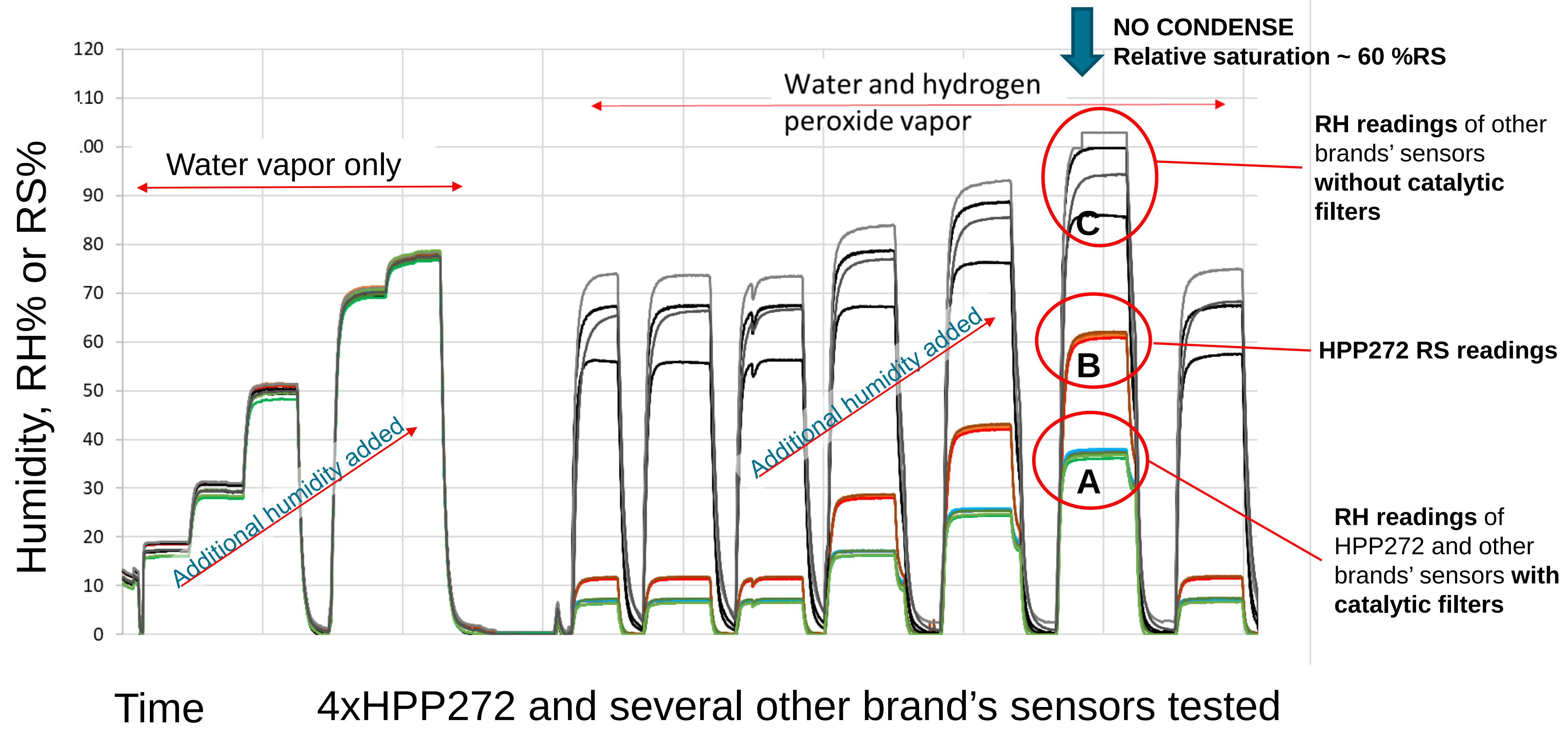
Pitfall 3: Control Condensation with RS%

- 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%

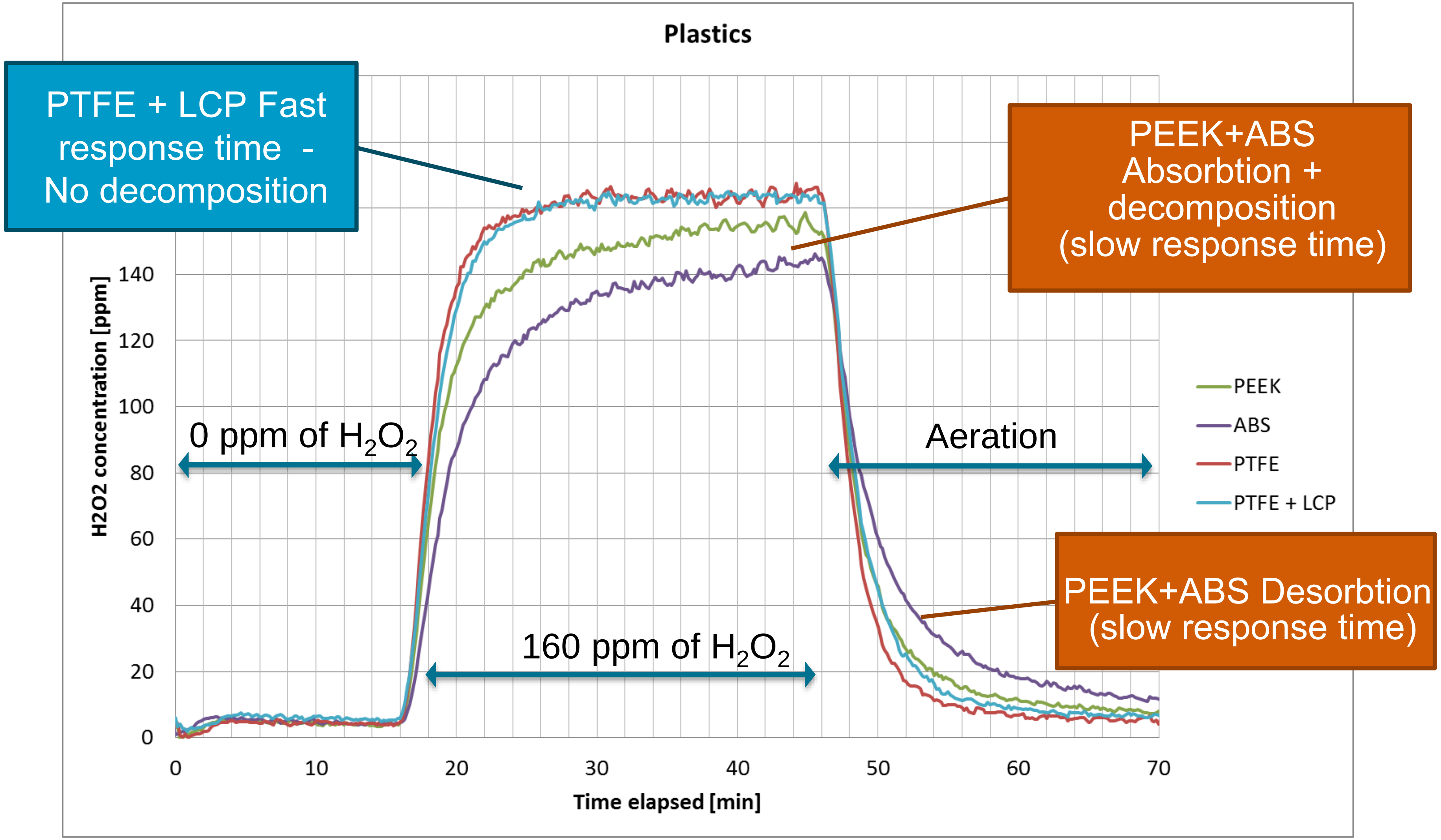


4xHPP272 and several other brand's sensors tested

Pitfall 4: Select Correct Materials

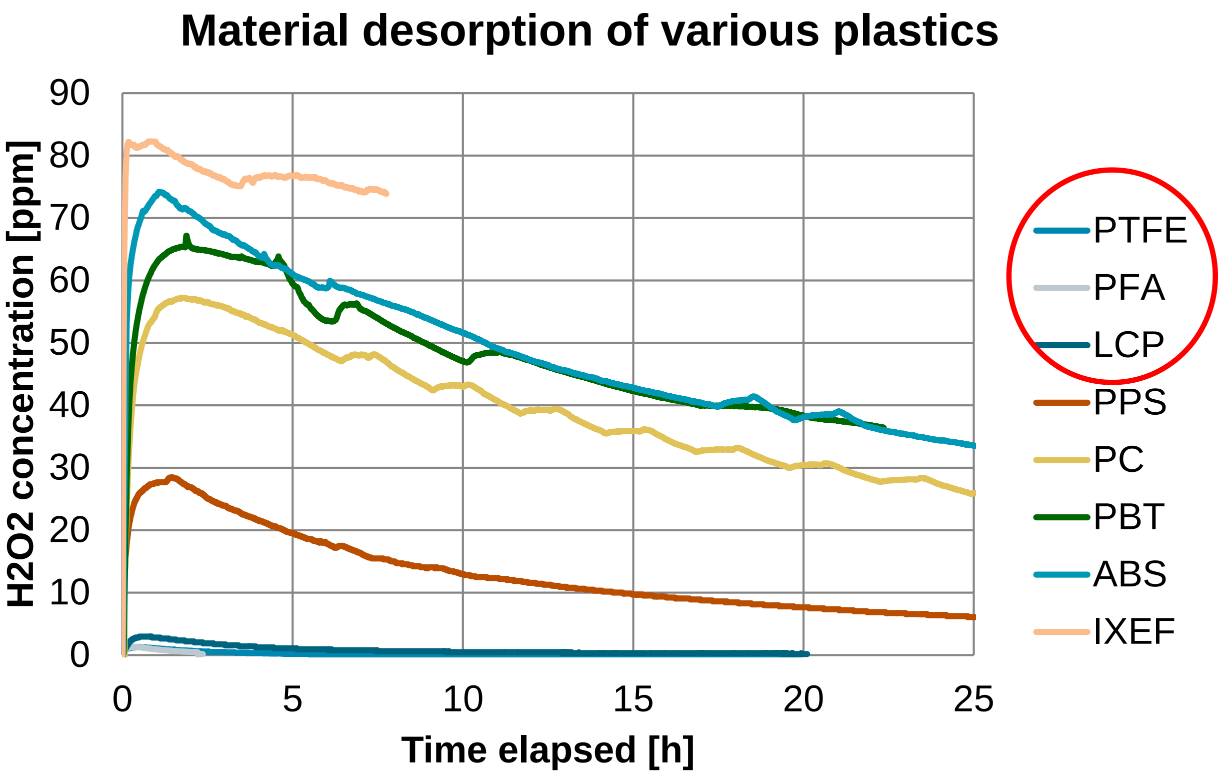
- Material effects:
  - Absorbtion
  - Decomposition
  - Desorbtion or out-gassing

- Good results with:
  - PTFE
  - LCP
  - 316L (stainless steel)
  - Pure aluminium



Pitfall 4: Select Correct Materials

- Long out-gassing times with wrongly selected materials.



Material	Desorption maximum [ppm]
PTFE	1.3
PFA	1.3
LCP	3.0
PPS	28.5
PC	57.2
PBT	67.2
ABS	74.2
IXEF	82.3

Pitfall 5: Carefully Plan On-site Calibration

- Challenge with H_2O_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_2O_2 factory calibration available at Vaisala Service center
  - With both humidity and H_2O_2 vapor

Conclusion

- Basics of bio-decontamination with vaporized H_2O_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-decontamintion
- Q&A session

Q&A Session

Thank You for Attending!

- PEROXCAP® calibration technical note
- HPP270 Series data sheet
- Learn more about Bio-decontamination
  - Blogs
  - Videos
  - Application Notes