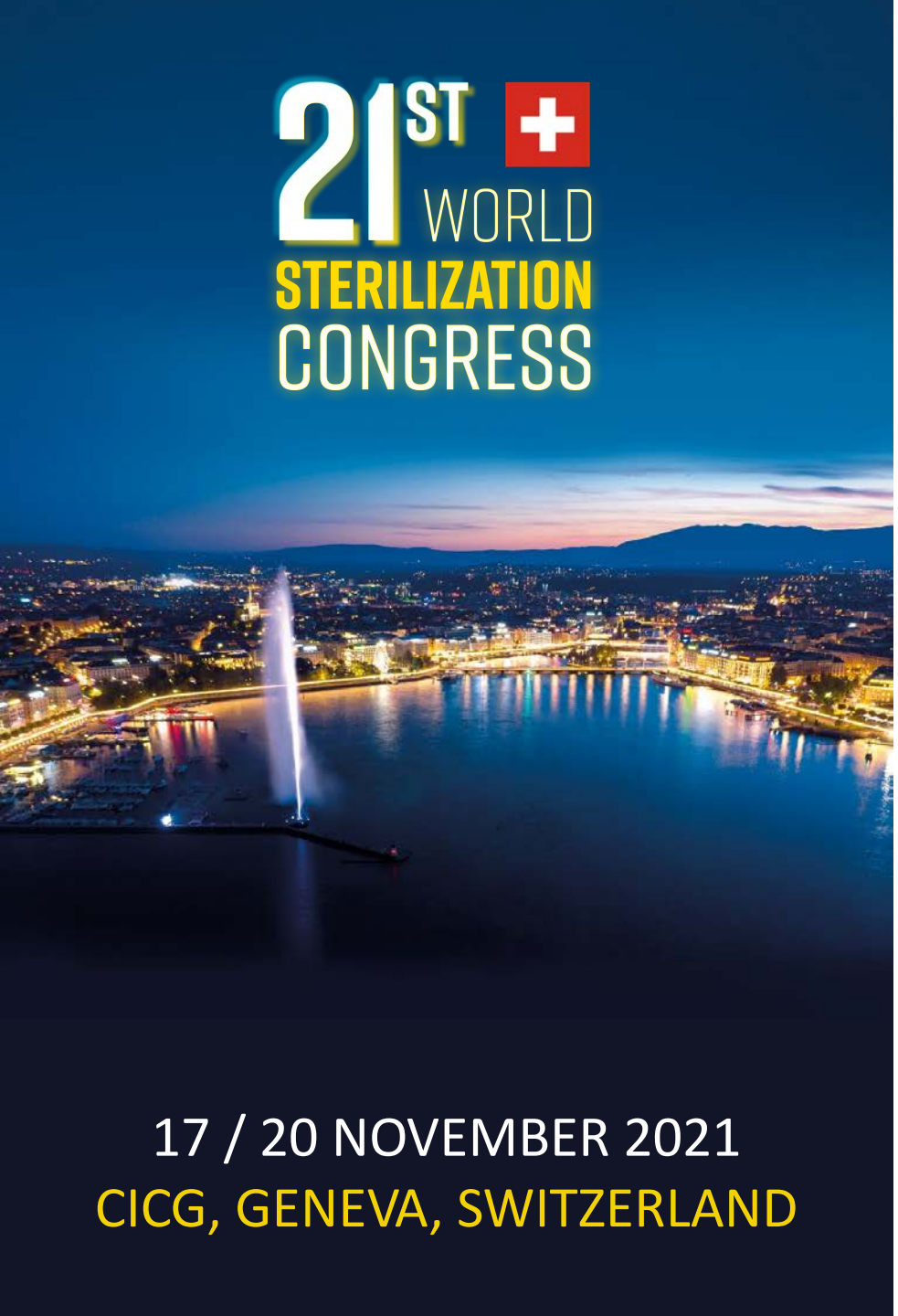


World Federation for Hospital Sterilisation Sciences

SGSV SSSH SSSO
Schweizerische Gesellschaft für Sterilgutversorgung
Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

Can Hydrogen Peroxide Sterilization Chemical Indicators be used to estimate the sterilant dose delivered to instrument sets?

Preliminary Findings

Name:

Dr Brian Kirk

Affiliation:

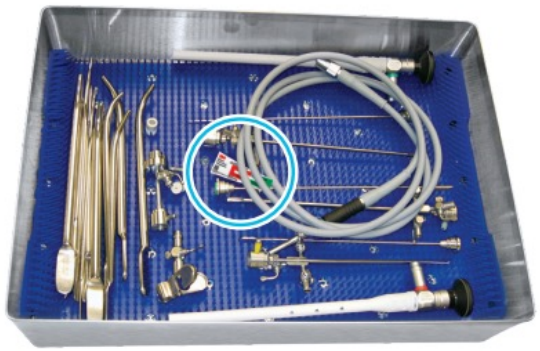
Brian Kirk Sterilization Consultancy Group Ltd UK

Contents

The many available Sterilization processes for Medical Devices

- Sterilization Processes
  - Mechanical Removal (Filtration)
  - **Physical**
    - **Hot**
      - Moist Heat (Steam)
      - Dry Heat
    - **Cold**
      - UV Light
      - Ionising radiation
        - Gamma
        - e- Beam
  - **Chemical**
    - Oxidising Agents
      - H_2O_2 Vapour
      - H_2O_2 Vapour (with Plasma)
      - H_2O_2 Vapour (with Ozone)
      - Chlorine Dioxide
      - Per Acetic Acid Vap (with Plasma)
      - Ozone Gas
    - Alkylating Agents
      - Ethylene Oxide
      - LTS with Formaldehyde
      - Glutaraldehyde

In Hospitals Steam is the most prevalent >95% of processes but LTS is required



LTS Utilisation in Health Care

Ethylene Oxide –

- Utilisation in hospitals country specific – Southern Europe high use.
- Many hospitals use contractors such as Anderson Caledonian or Isotron/Synergy/Steris (User remains responsible).

LTSF

- Once virtually every department had an LTS/LTSF sterilizer now hardly any.

Hydrogen Peroxide (VHP)

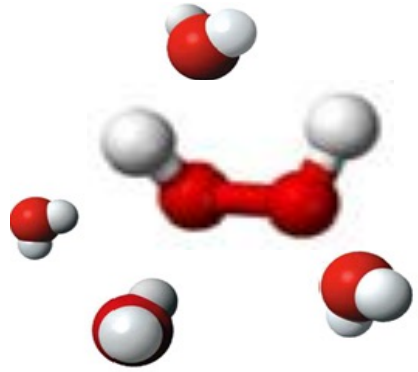
- "The growing technology"
- Many hospitals now using VHP processes
- Growing application area – endoscopy
- "*As the field of endoscopy develops there will be a greater need for sterile endoscopes*"
    - (paraphrased from Prof Tony Young's talks at IDSc 2010 conference)

Vaporized Hydrogen Peroxide Sterilization

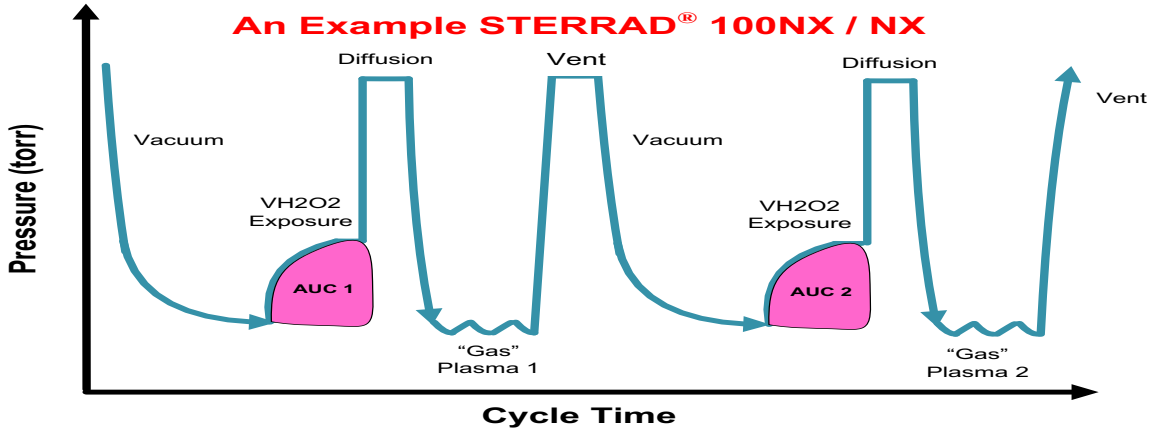
Process Temp: 30-50°C
Process Time: 30 to 100 min

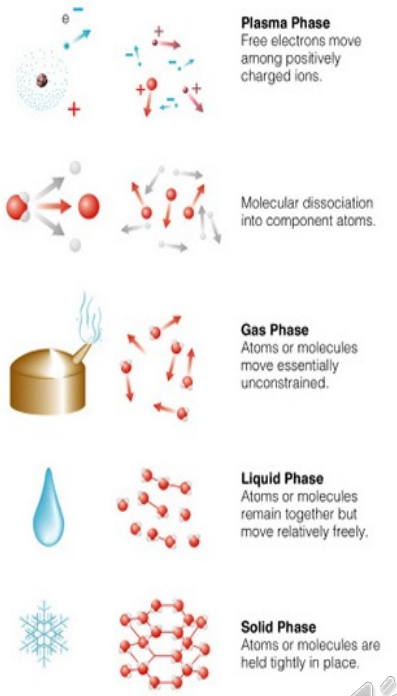
- H_2O_2 Vapour
- H_2O_2 Vapour (with Plasma)
- H_2O_2 Vapour (with Ozone)

All use a mixture of H_2O and H_2O_2

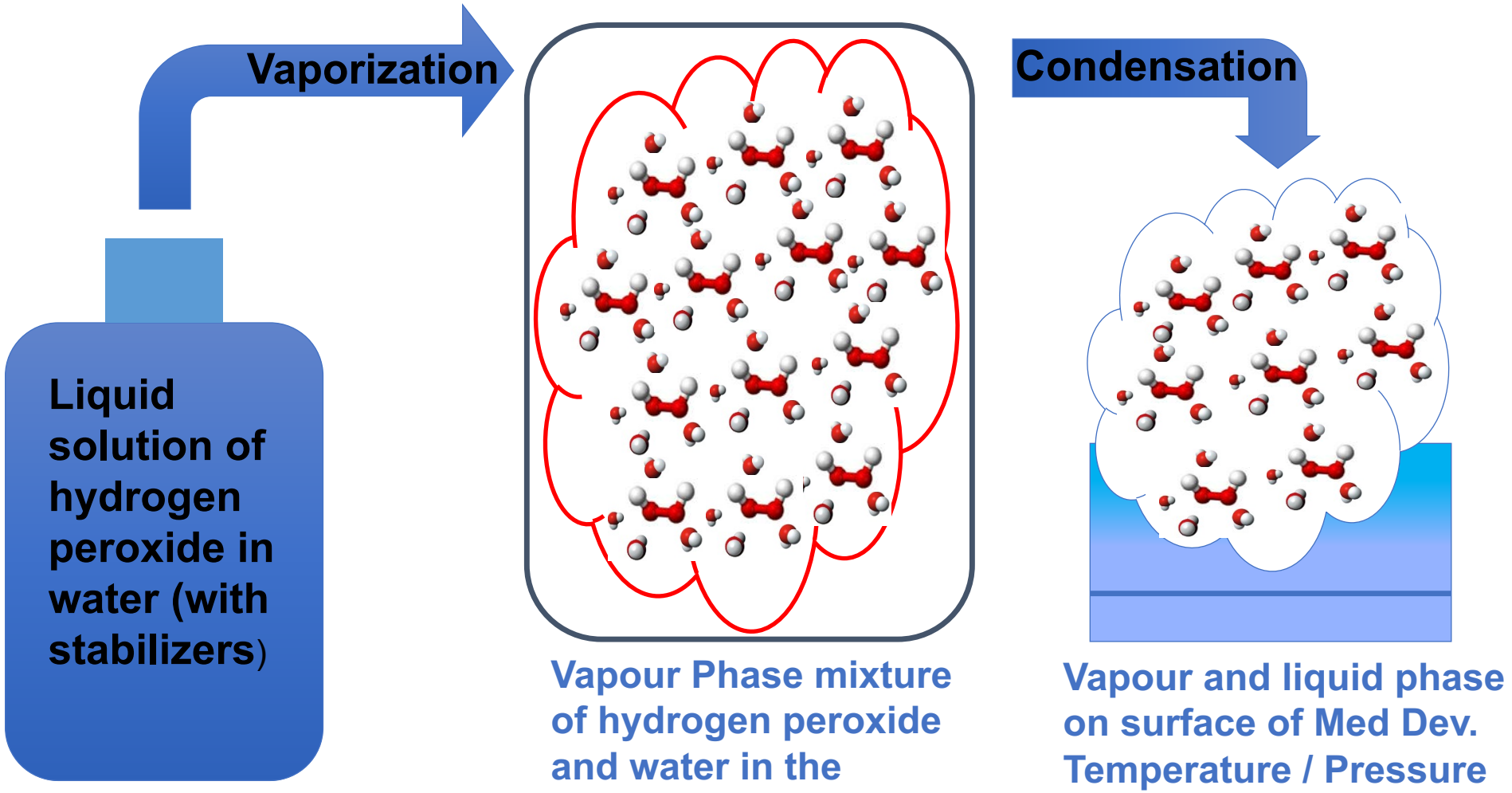


Process Limitations:
Restricted Lumen Length
No Paper Material
Corrosion

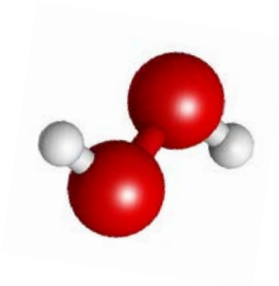




How does a vH2O2 process work - Surface Effects



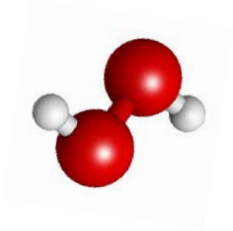
What do we need to monitor to ensure efficacy & how?



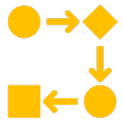
VH2O2 Sterilization Process Variables

- Time
- Temperature
- vH_2O_2 [c] / Dose (AuC)
- Moisture

UV Source



UV Detector



?

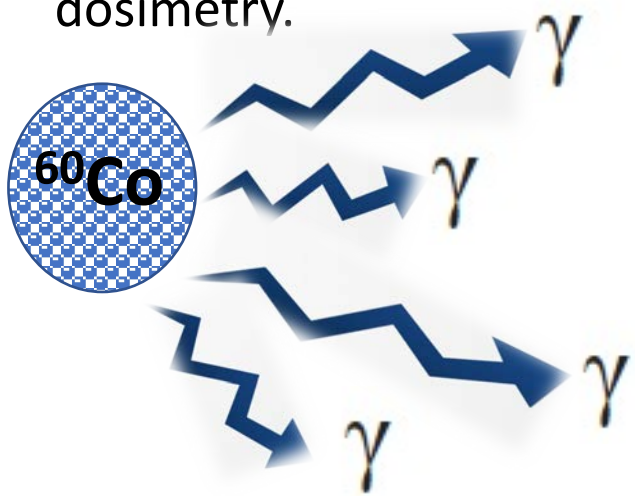
H_2O_2 vapour is produced from an aqueous solution so water is present during processing. The importance of its presence is debated.

In a recent publication data was presented to show the influence of the ratio of vH_2O_2 and vH_2O on microbial kill rate (D value) suggesting a 1.4 order of reaction.

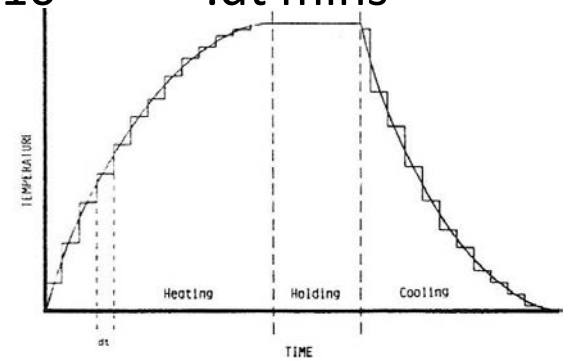
Zentrl Sterilization 2021:29(4):222-230

Time and Intensity vs “Dose”

- **Irradiation**
- **Absorbed Dose** -> An integral of radiation intensity and time of exposure.
- Measured in kGy representing energy absorbed per unit mass
- Traditionally 25kGy considered a sterilizing dose.
- Delivered dose estimated by dosimetry.

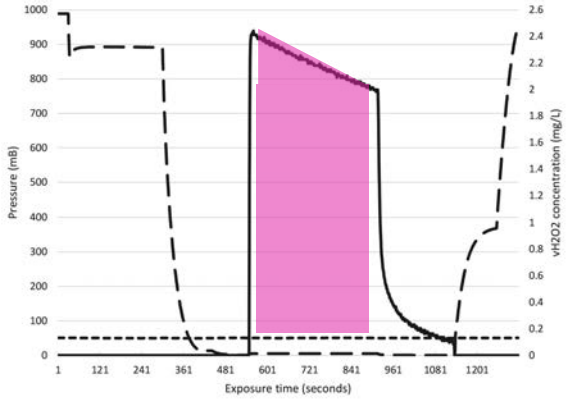


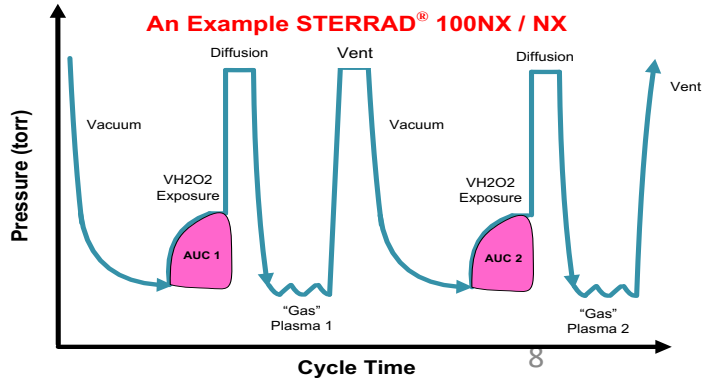
- **Moist Heat**
- Traditionally a series of **time-temp combinations**
- 121/15mins (F_o = 15 min)
- 134/ 3 mins (F_o = 60 mins)
- 132 / 4 mins (F_o = 50 mins)
- In contained product sterilization **equivalent time at a reference temperature** can be calculated by **integrating** the area under the T-t curve. **This is the dose of moist heat**.
- $F_o = \sum 10^{(T-121/z)}.dt$ mins



VH2O2

Many sterilizers calculate the area beneath the exposure curve as mg.s/L annotated AuC or “Dose”





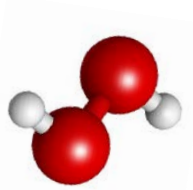
What do we need to monitor to ensure efficacy and how?

VH2O2 Sterilization Process Variables

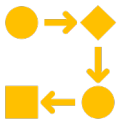
How to Monitor

Physical Measurements

UV Source

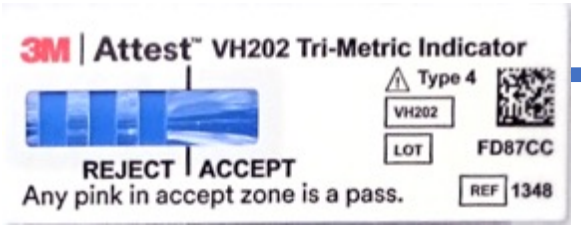


UV Detector



Biological Indicators

Chemical Indicators



Physical Measurements

- **time,**
- **Temperature**
- **VH2O2 [c]**

Biological Indicators:

- **React to all process variables**

Chemical Indicators

- **React to a specified range of process variables. The manufacturer states the Stated Values (SV) for these**

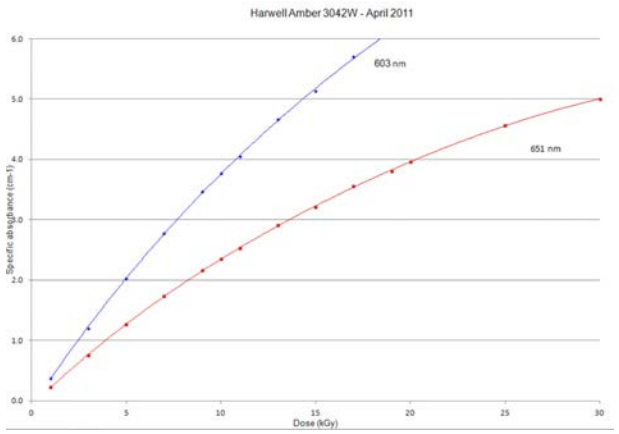
Chemical Indicators – Types - EN ISO 11140-1

- Type 1 – Process / Exposure Indicators (eg IndicatingTapes, Labels)
- Type 2 – Specific Test Indicators (e.g. BDT)
- Type 3 – Single variable indicators
  - Respond to a single variable in the process e.g. temperature
- Type 4 – Multivariable Indicators
  - Respond to two or more variables in the process
- Type 5 – Integrating Indicators
  - Respond in a way which mimics the response of a BI if used in the same process
- Type 6 – Emulating Indicators
  - Respond to all critical variables of the process at levels associated with acceptable sterilizing conditions e.g. 134 for 3 minutes

Majority of VH2O2 CIs are either type 1 or 4

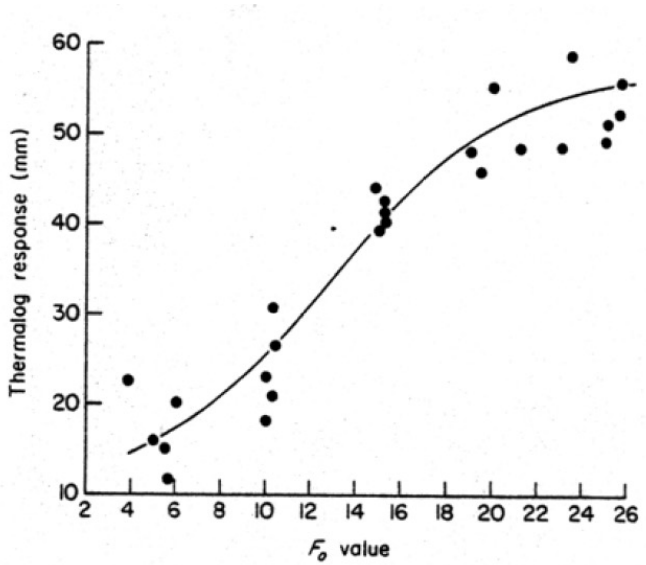
Chemical Indicator Dosimeters

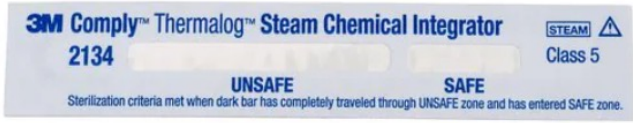
- Irradiation
- Polymethylmethacrylate (pmma) tokens respond in a calibratable manner to allow dose at point of placement to be estimated (Harwell Amber Dosimeters).



- With thank to Harwell Dosimeters

- Moist Heat
- Type 5 moving front chemical indicators respond in a calibratable manner to allow Fo to be estimated in contained product moist heat sterilization
- *(Bunn and Sykes, J Appl Bact 1981,51,143-147)*





Can VH2O2 CIs also be used as dosimeters ?

Research Question

- **Can VH2O2 CIs perform as dosimeters?**
- Study Plan:
- Using data from previously published data can;

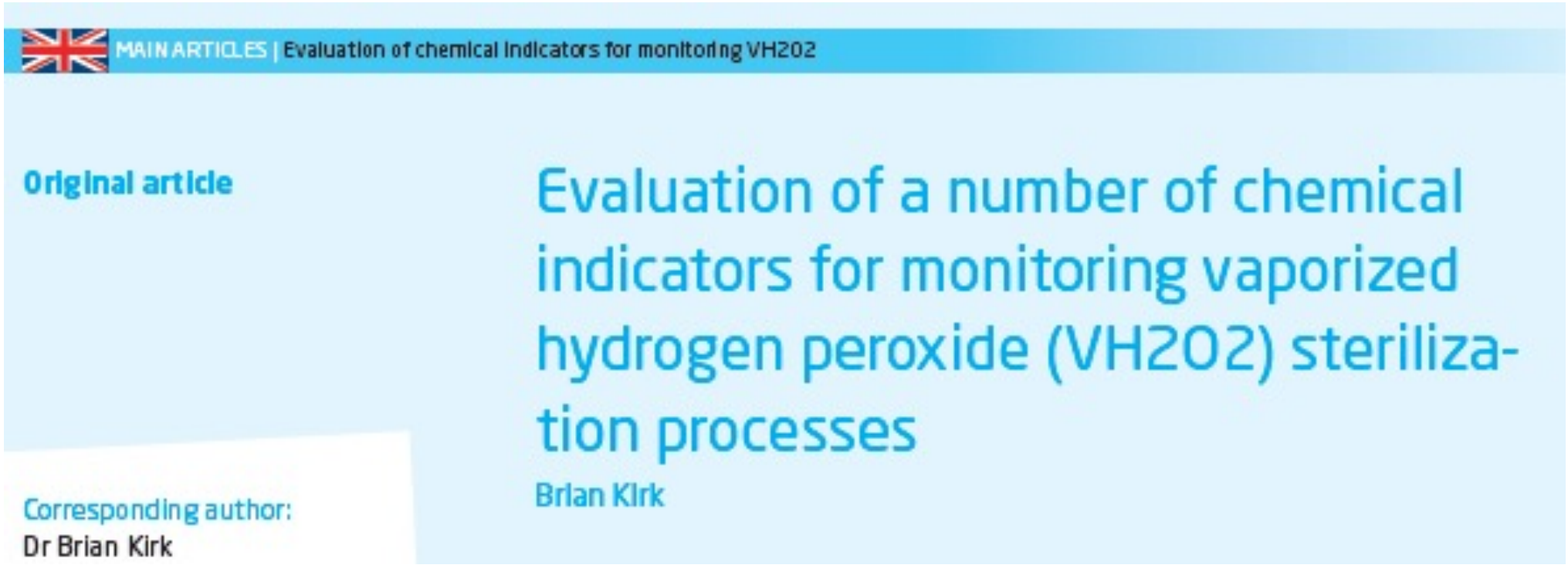
1. the response of type 1 and 4 CIs be calibrated to give dose (mg.s/L) of VH2O2 to which exposed

2. the calibrated CI's provide an estimate of the dose of VH2O2 delivered during a production sterilization cycle when placed within model medical device instrument sets.

Stage 1 – The evaluation of a number of type 1 and 4 vH2O2 CIs

The following results are presented from a paper published in Central Service Journal,

Zentr Steril. 2020, 28(4),208-217



MAIN ARTICLES | Evaluation of chemical indicators for monitoring VH2O2

Original article

Evaluation of a number of chemical indicators for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes

Brian Kirk

Corresponding author:
Dr Brian Kirk

Products Tested

Method – exposure apparatus

Placed in the centre of the chamber 100mm above the vaporizer inlet port

Mounted on a pre cut acetate sample holder using vH2O2 indicator tape

sterilucent™
scientific sterilization solutions

PSD-85 Sterilizer

Sterilucent™ PSD-85 Hydrogen Peroxide Sterilizer

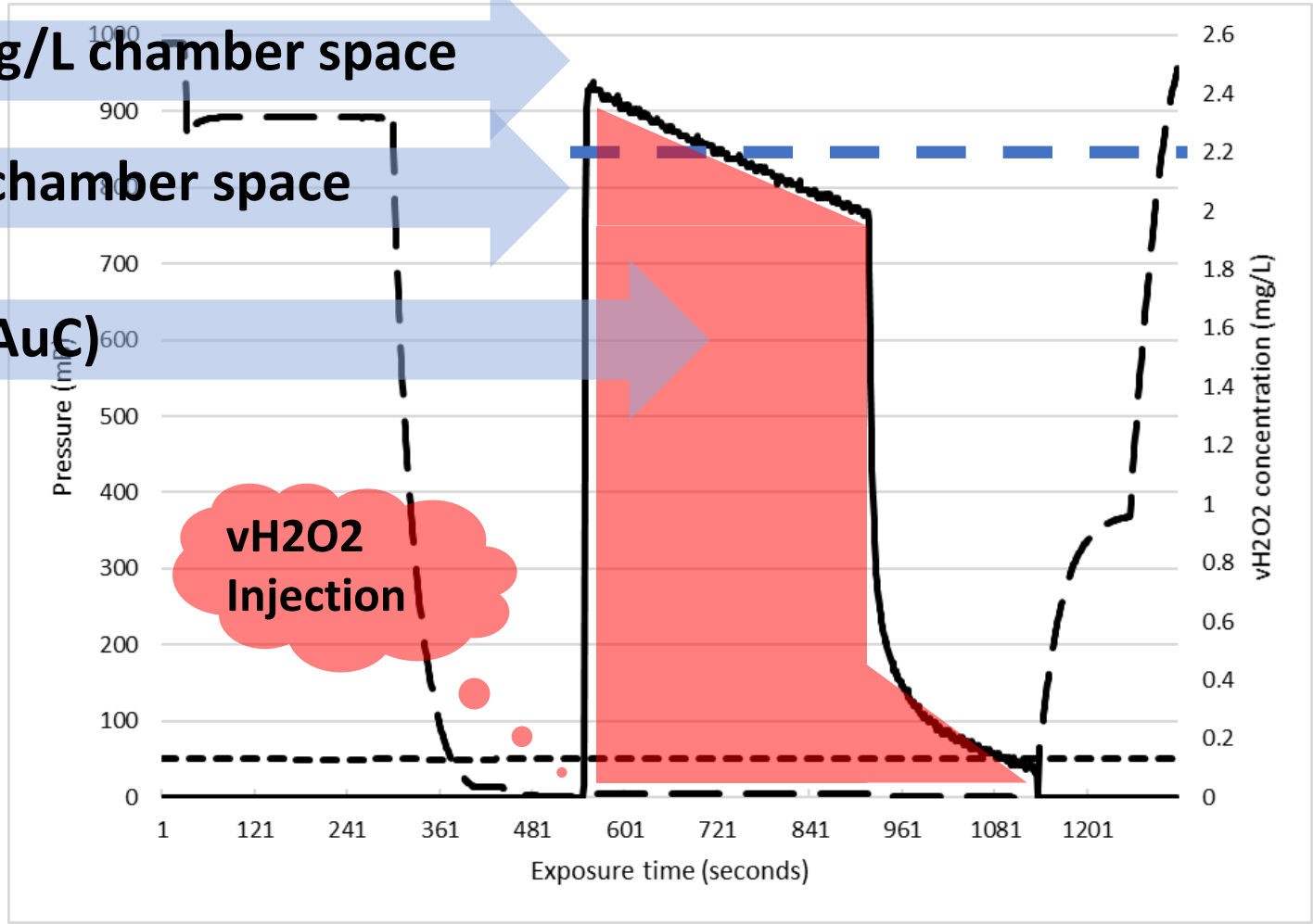
Measurement of Exposure to VH2O2

Measurement of concentration and dose (area under the curve mg.s/L)

Target Peak Concentration vH2O2 mg/L chamber space

Average Concentration vH2O2 mg/L chamber space

Dose vH2O2 mg.s/L chamber space (AuC)



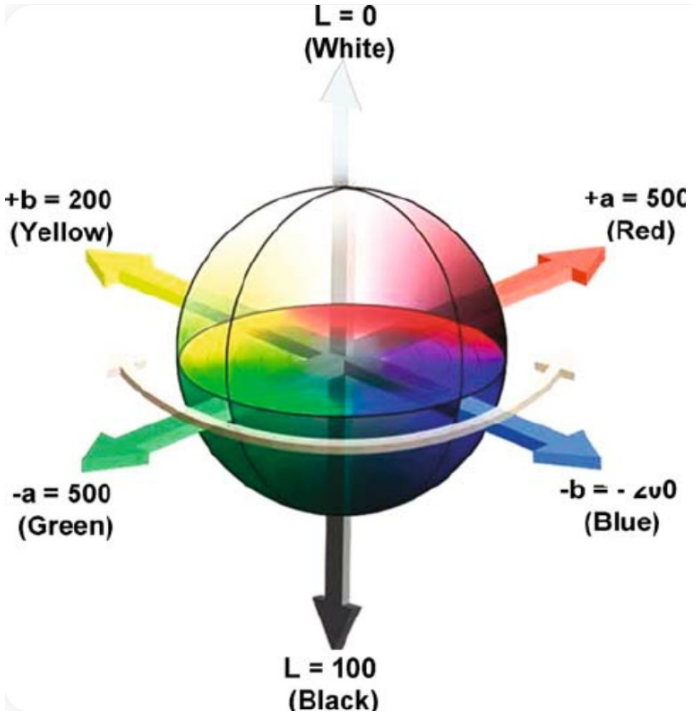
Short dotted line – temp °C
Long dotted line – pressure mB
Solid line = vH2O2 concentration mg/L

Measurement of colour change

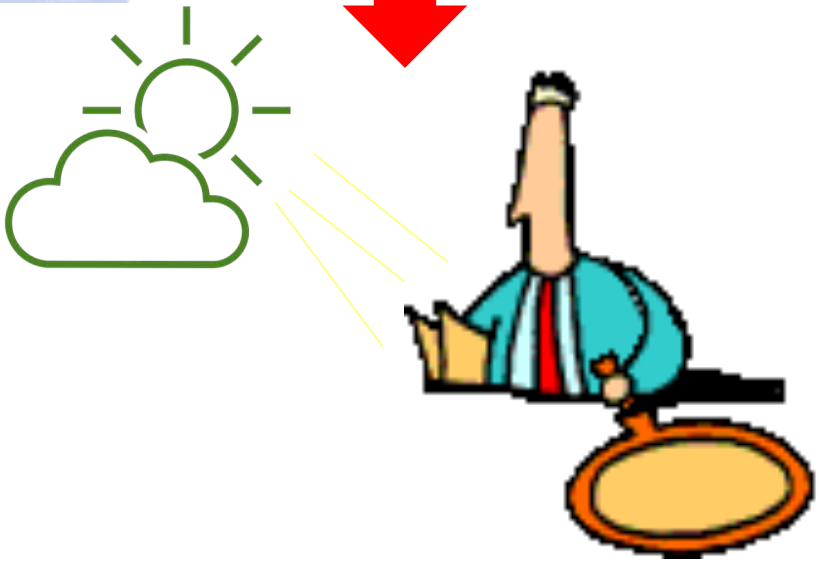
Colourimetry :

Estimation of colour change by measuring L*,a*,b*

From which E was calculated; E= L*+a*+b*



Visual Examination



Calibration Curves – AuC (Dose) vs a*, b* or E

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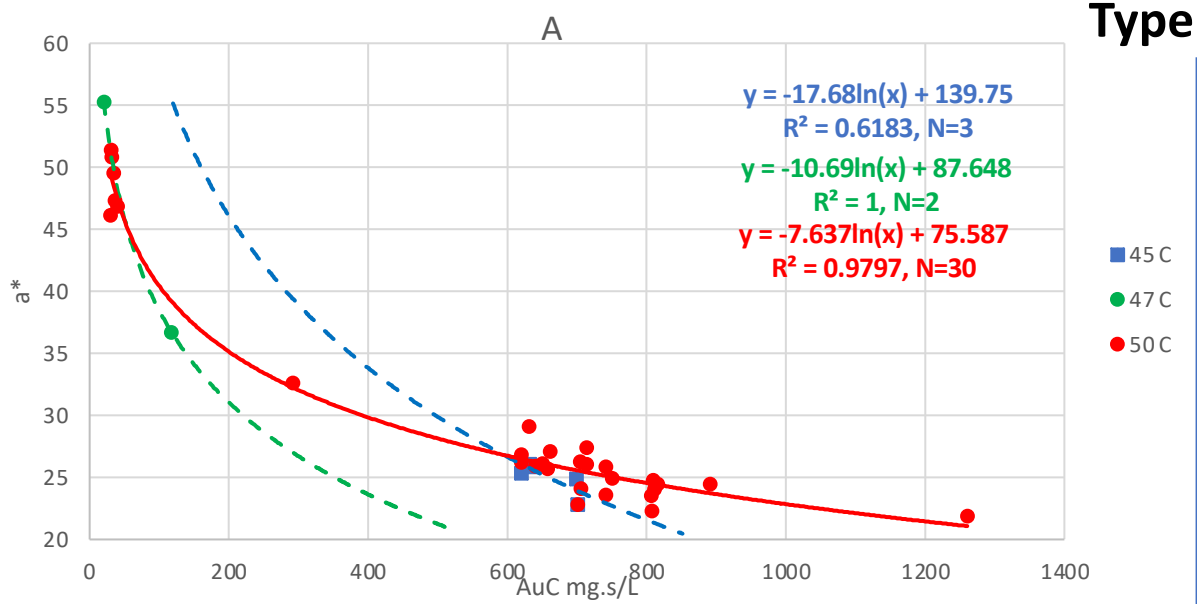
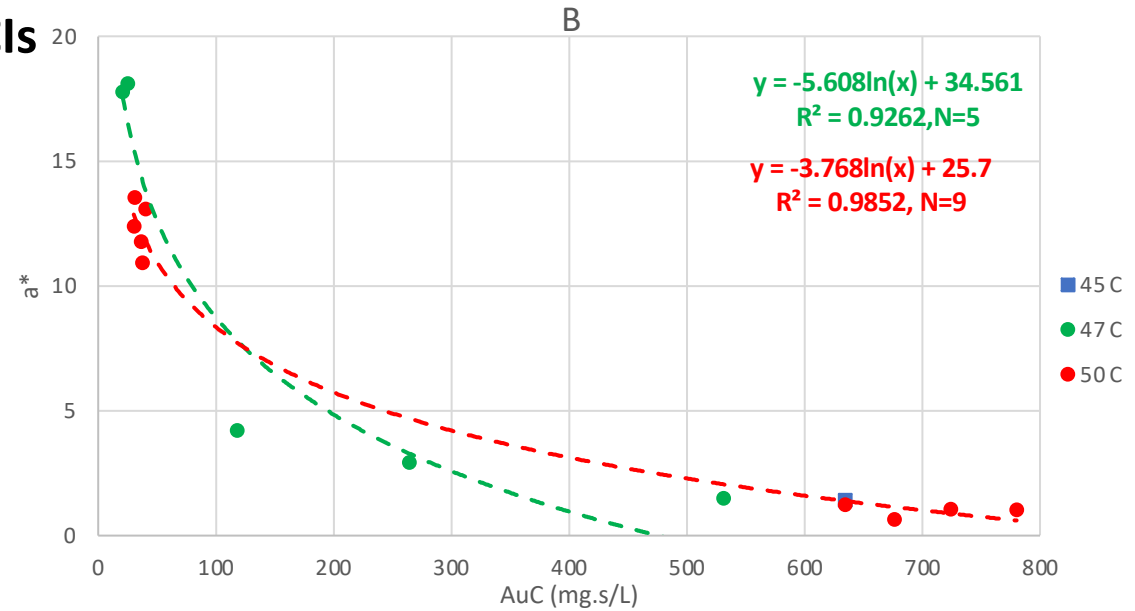
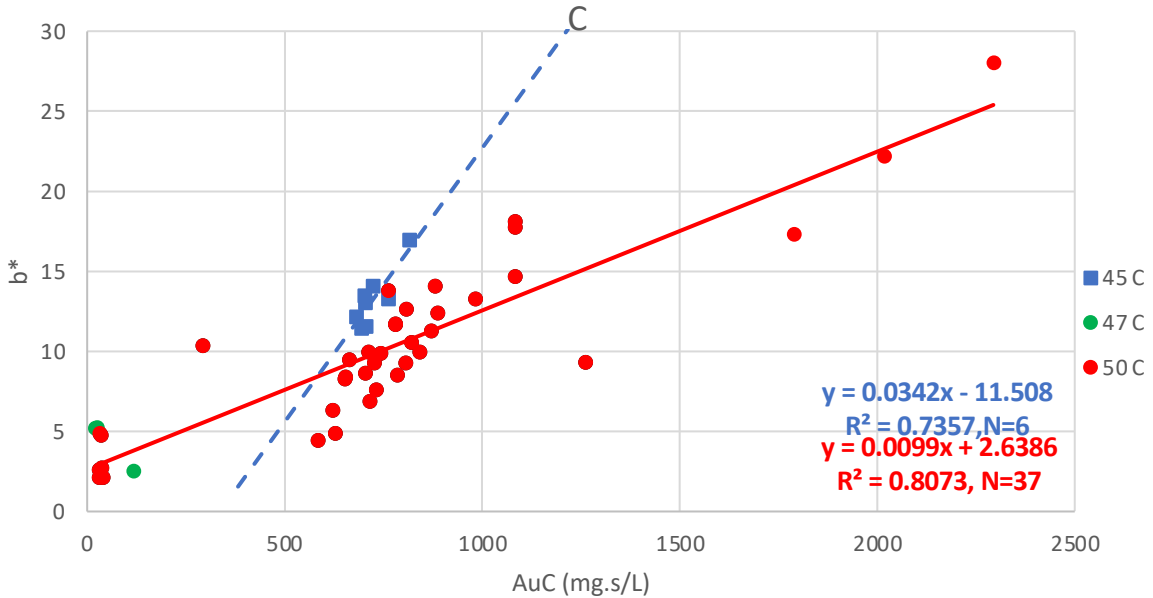
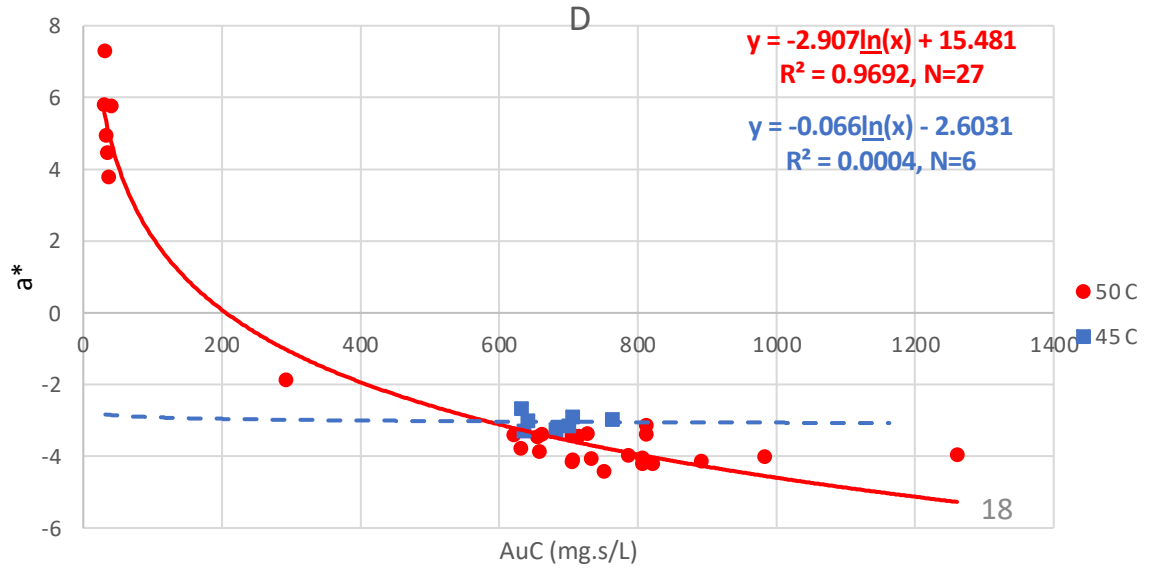
Società Svizzera di Sterilizzazione Ospedaliera

Type 1 CIs



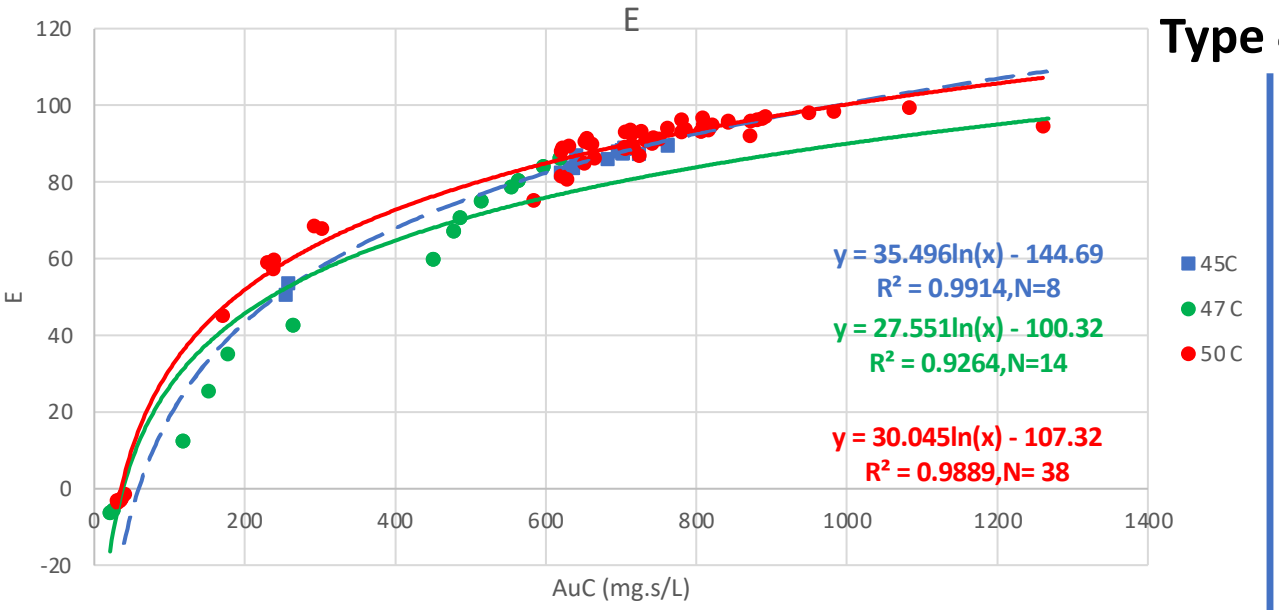


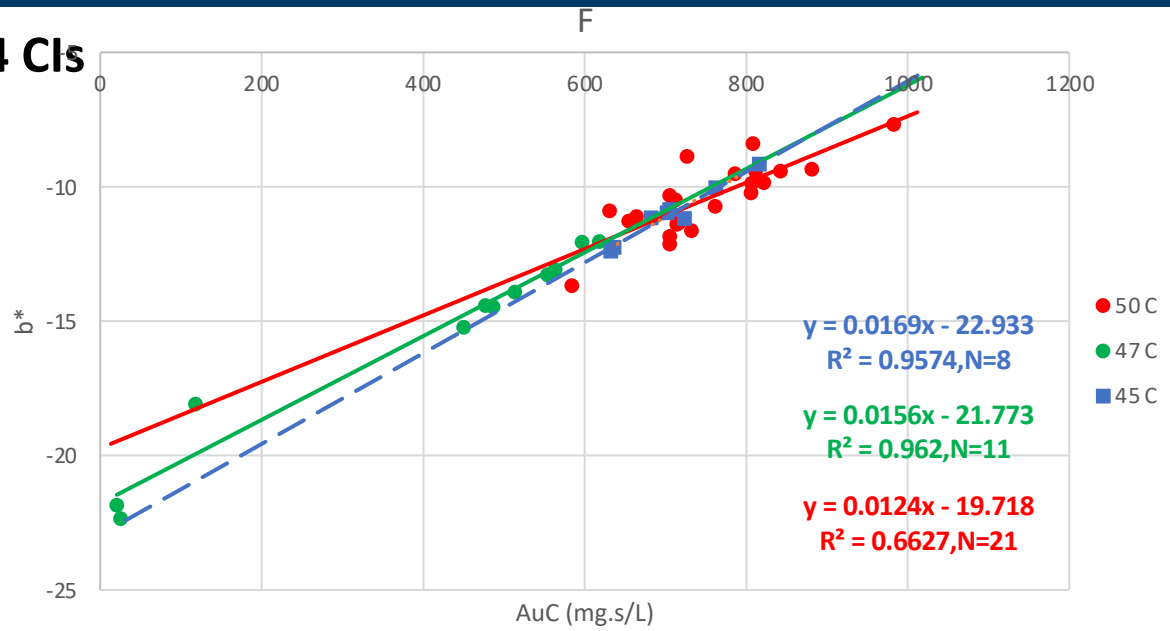


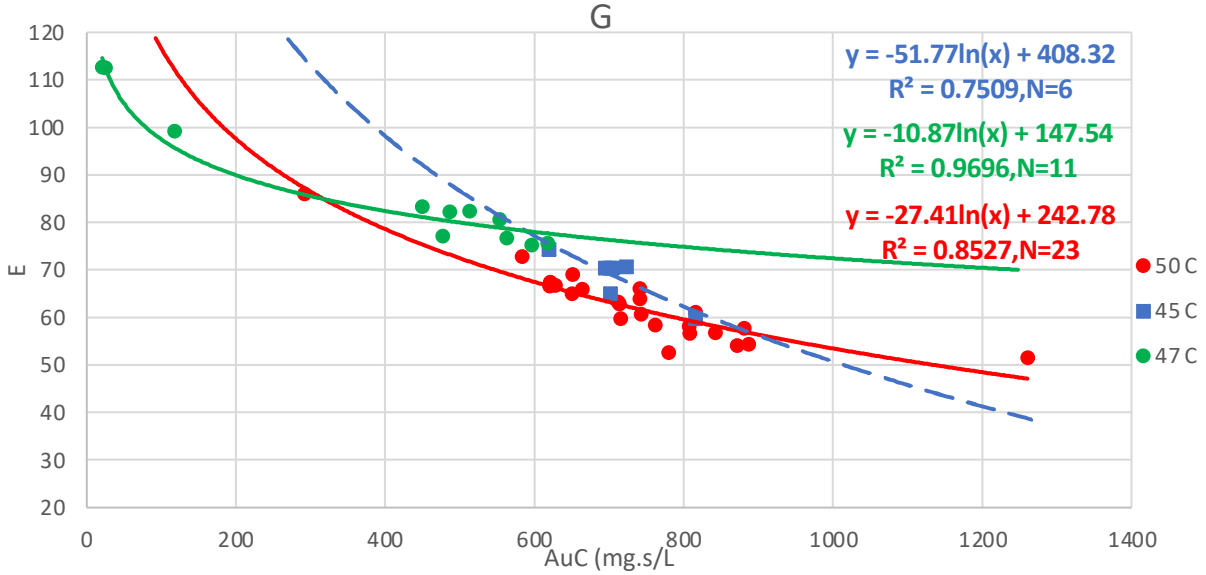


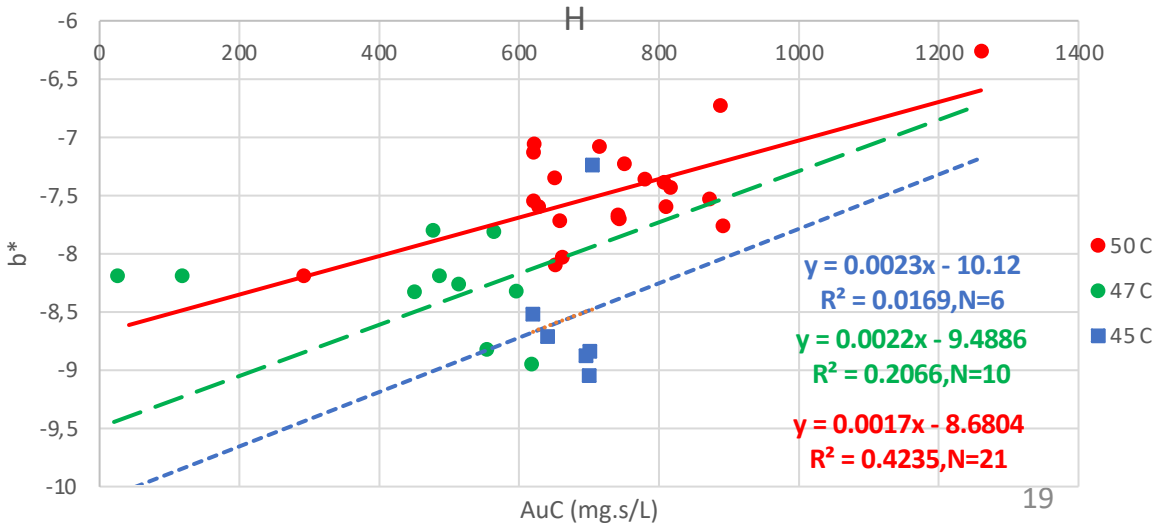
Calibration Curves – AuC (Dose) vs E,a*or b*

Type 4 CIs





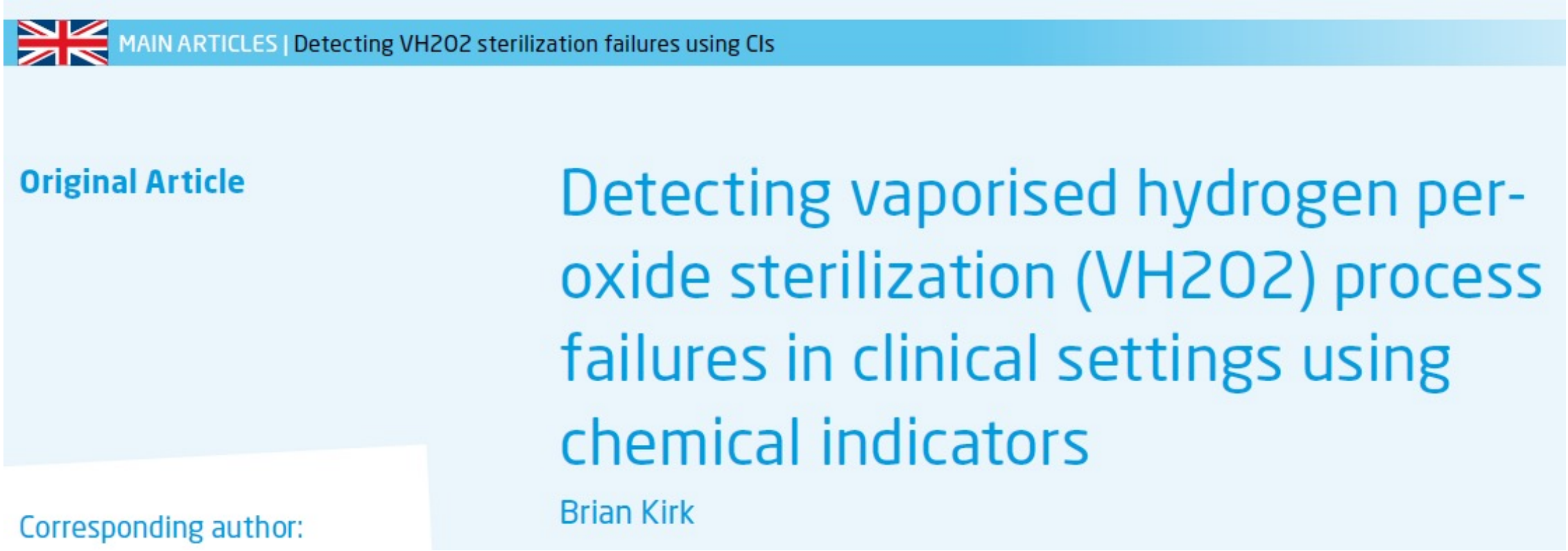




Stage 2 - Clinical Case Study

The following results are presented from a paper published in Central Service Journal,

Zentr Steril. 2020, 28(6),334-343



MAIN ARTICLES | Detecting VH2O2 sterilization failures using CIs

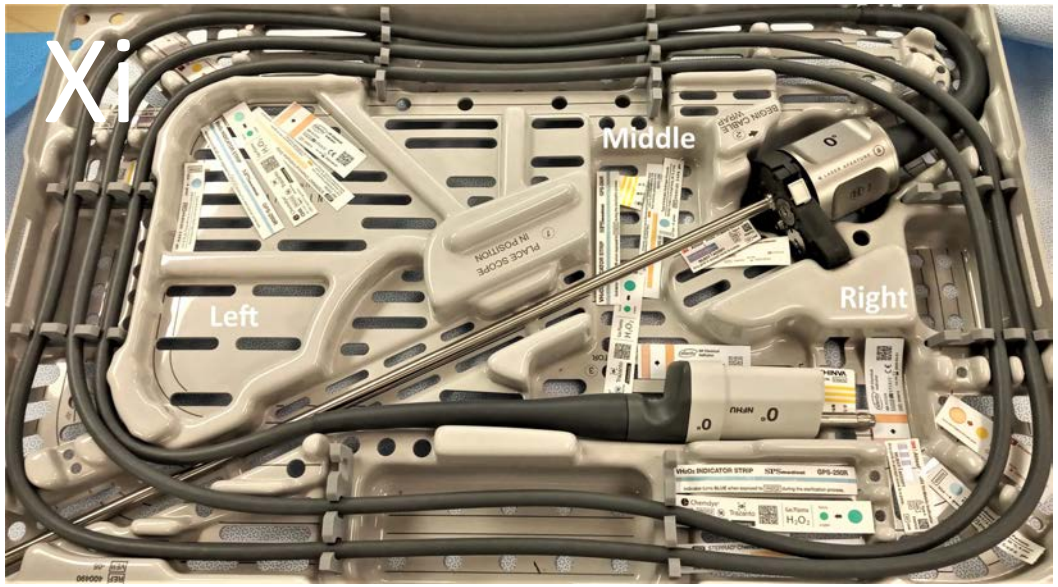
Original Article

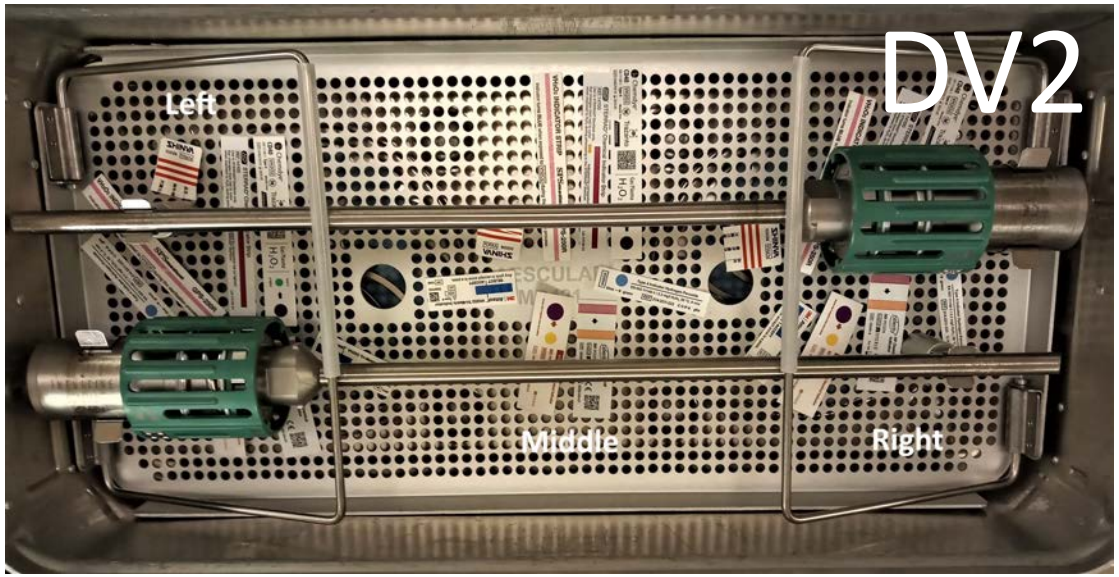
Detecting vaporised hydrogen peroxide sterilization (VH2O2) process failures in clinical settings using chemical indicators

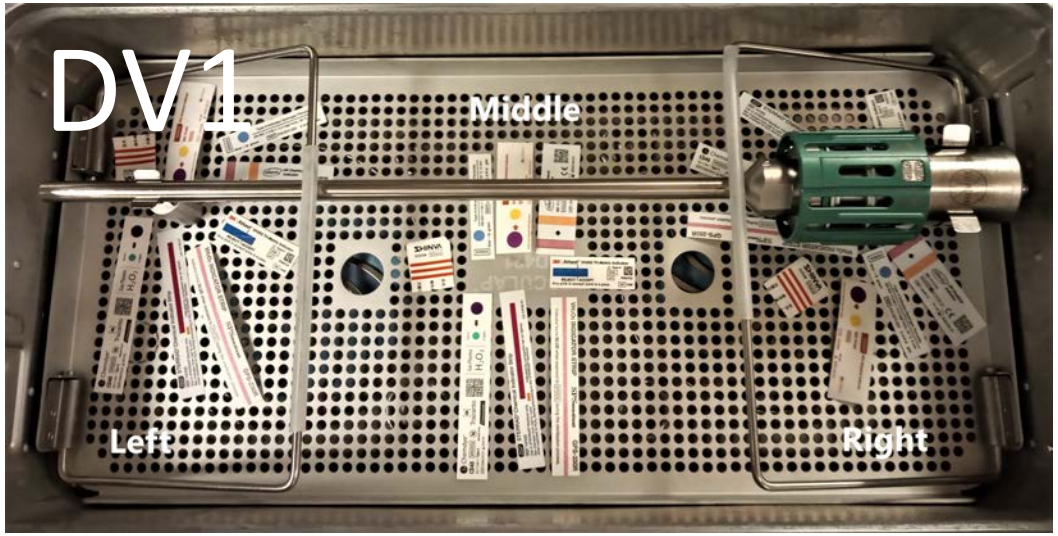
Brian Kirk

Corresponding author:

Method – model loads tested and placement of CIs



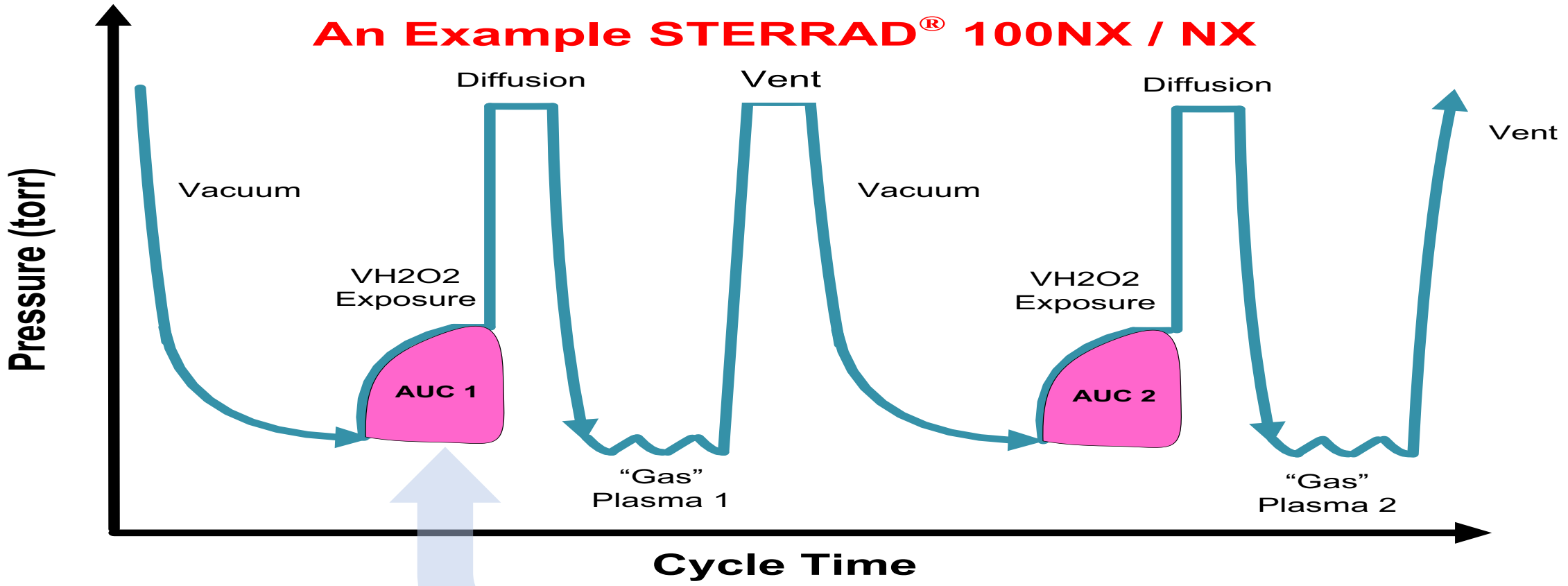




Method – sterilizer used including recommended loads

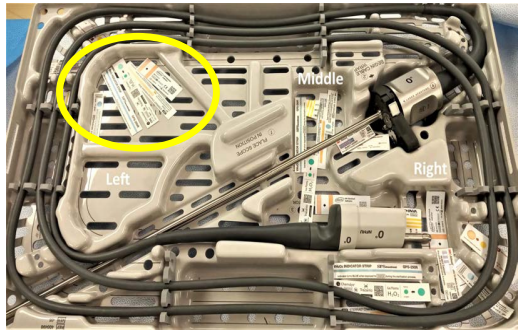
- Tests were carried out in ASP® STERRAD® NX100® VH2O2 sterilizers (https://www.asp.com/product/terminal-sterilization/STERRAD-100nx)
- EXPRESS cycle - maximum loading weight 4.85 kg /10.7lb or
- STANDARD cycle – maximum loading weight 9.7kg/21.4lb
- Two different sterilization processing departments in hospitals in the USA.
- **Ten** replicate cycles for each load configuration / processing cycle was used

Method – sterilization process employed



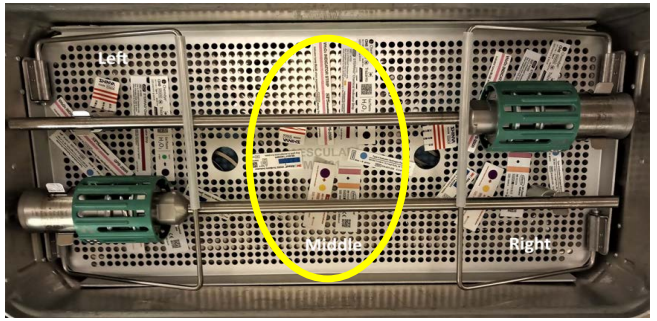
Dose vH2O2 mg-s/L chamber space (AuC)

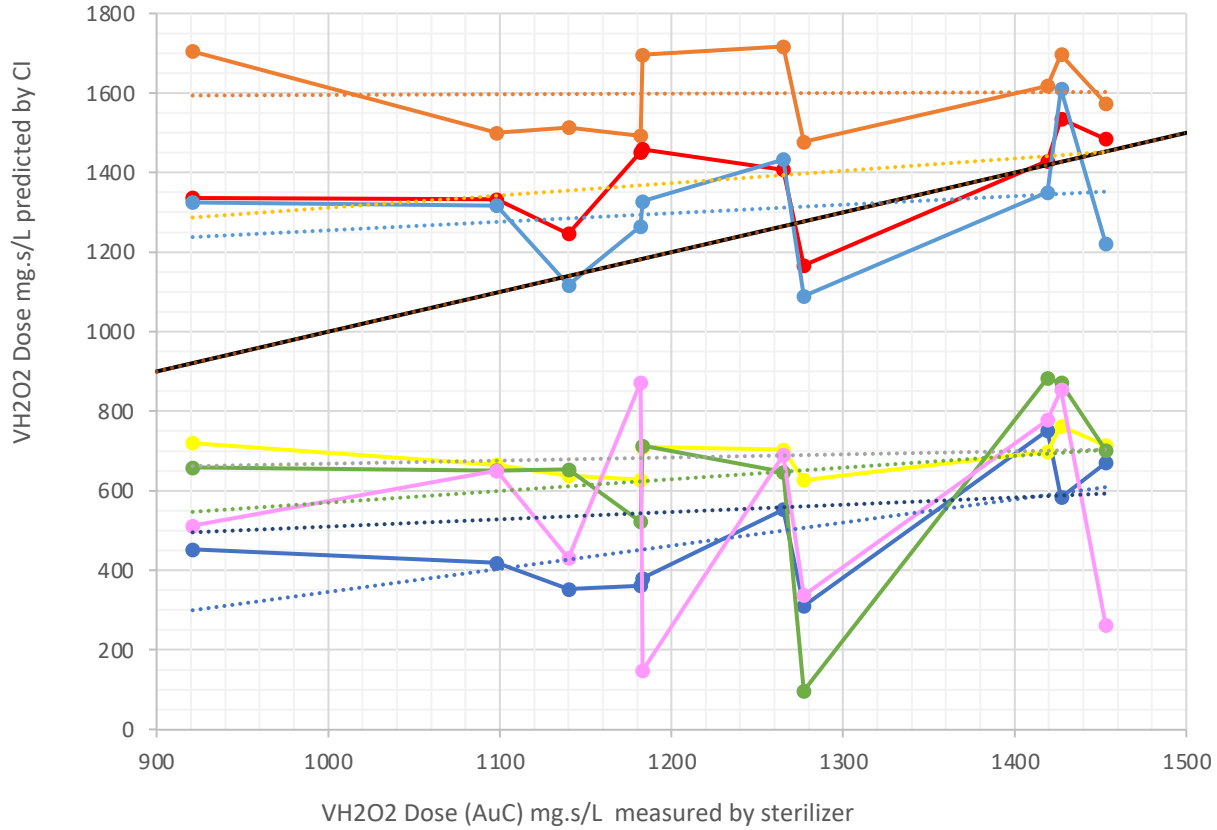
Clinical Studies – Predicted vs Measured VH2O2 [c]

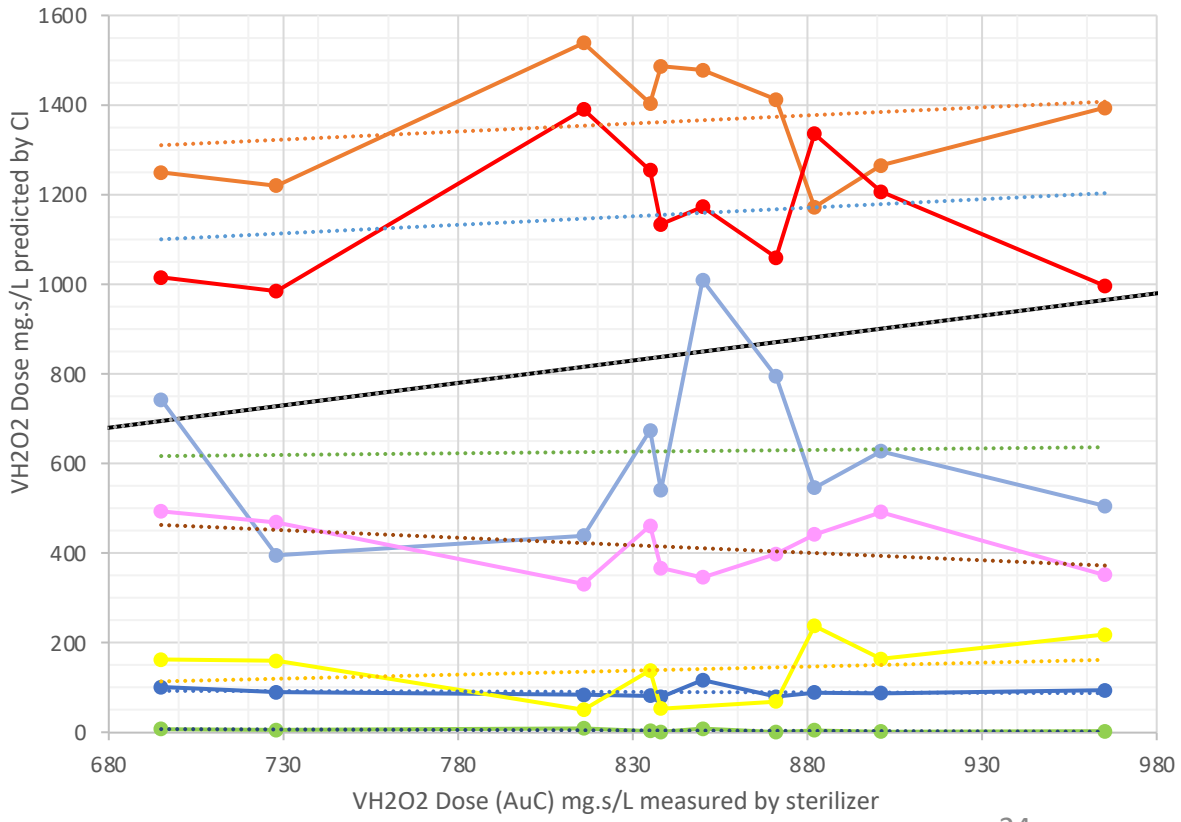


Key to the colours:

Orange = A	Blue = E
Yellow = B	Purple = F
Red = C	Light Blue = G
Green = D	







Conclusion 1: Calibrating CIs to Dose

- Preliminary data suggests that the colour change of **some** chemical indicators is quantitatively related to the dose of hydrogen peroxide vapour to which they are exposed at a specified temperature.
- Calibration curves of a colour change attribute (E, a* or b*) vs exposure dose (AuC, mg.s/L) can be created with high correlations.
- Further data is required across a wider range of exposure doses to confirm these correlations.
- ISO TC 198 wg6 could consider developing a type 5 integrating indicator category based on dose (mg.s/L) response rather than simple colour change.

Conclusion 2: Use in a clinical setting

- Since some CIs were shown earlier to change colour in a predictable way towards changing VH2O2 dose;
- The CI curves should overlay the black line
- Even if offset the CI curves should run parallel to the black curve
- The sterilizer measured VH2O2 dose shows great process variability
- Some CIs predict higher values of VH2O2 dose and others lower
- The predicted VH2O2 dose varies greatly with no overall predictable trend.
- Is this due to CI variability (no) or process variability (yes) due to fluctuating conditions of VH2O2 [c] and Temp at point of placement?
- More experimentation is needed