



**HONG KONG  
ASIAWORLD-EXPO  
亞洲國際博覽館**

**3<sup>RD</sup> TO 6<sup>TH</sup>  
DECEMBER  
2025**



**中山大學  
腫瘤防治中心  
SUN YAT-SEN UNIVERSITY CANCER CENTER**

# **The Effects of Load Mass on the Physical Parameters during Low-temperature Vaporized Hydrogen Peroxide (VHP) Sterilization Processes**

**Aiqin Chen / Xu Ju**

**Affiliation: CSSD / Department of Infection Control**

**Sun Yat-Sen University Cancer Center**

**Email: [chenaq@sysucc.org.cn](mailto:chenaq@sysucc.org.cn)**





# CONTENT



中山大學  
腫瘤防治中心  
SUN YAT-SEN UNIVERSITY CANCER CENTER

1. Research Background
2. Method
3. Result
4. Discussion and Conclusion
5. Further Research
6. Research Basis



# 1. Research Background

## 1.1 Low-temperature vaporized hydrogen peroxide (VHP) sterilizer

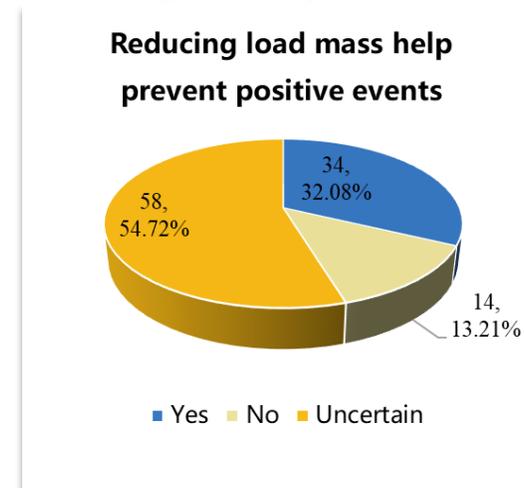
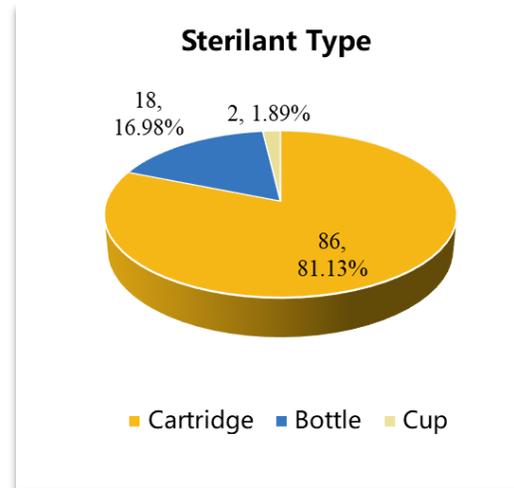
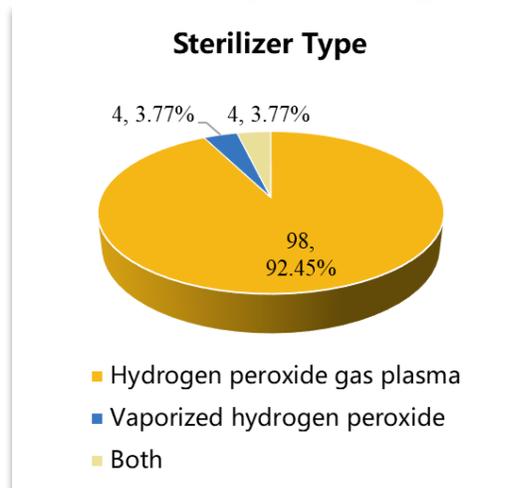
### 1 Variation in VHP sterilizer performance

- Multiple Manufacturers and models
- Wide variation in performance

### 2 Variation in load weight requirements

- Standard: Manufacturers **specify load mass limits**
- Manuals of some brands: **Lack the information**
- In practice: Users may **overload**
- Overloading → **Higher BI positivity**

### A Survey among 106 hospitals in southern China (Apr – May 2023)



# 1. Research Background

## 1.1 Low-temperature vaporized hydrogen peroxide (VHP) sterilizer

Example of sterilization practice:



Load mass limits in user manual

Cycle Type	Max. load mass (Kg)	Shelves
STANDARD	9.7	1 or 2
FLEX	9.7	1 or 2
DUO	6	1 or 2
EXPRESS	4.9	Bottom shelf only

Actual load mass (STANDARD cycle)

Instruments	Mass (Kg)	Total (Kg)
1 ultrasound probe package	5	12.5
1 3D scope package	4.5	
4 optical scope packages	3	

Loading mass and method seemed appropriate

Actually: load mass exceeded the manual limit

**All physical parameters, Chemical indicators, Biological Indicators were qualified!**

**About 30% Overweight !**



# 1. Research Background

## 1.2 Research basis

### Requirements for load mass in VHP sterilization in current international and national standards

#### ISO 22441-2022<sup>1</sup>

##### 6.2 Process characterization

6.2.1 The process parameters, together with their tolerances, shall be specified. These tolerances shall be based upon knowledge of the combination of process parameters yielding acceptable microbicidal effectiveness. Processing at such process parameters shall routinely yield a safe and functional product.

6.2.2 Process characterization, at a minimum, shall include:

- a) identification of phases necessary for a VH202 sterilization process;
- b) specification of defined process variables and corresponding parameters for each phase of the sterilization operation;
- c) any restriction of the items and load configuration for a given operating cycle such as mass, geometry and materials.

#### GB 27955 -2020<sup>2</sup>

##### 6 使用注意事项

- 6.1 在装载入灭菌设备前,灭菌物品应进行有效、正确的清洗和干燥处理。
- 6.2 包装材料应采用专用包装袋或医用无纺布。
- 6.3 灭菌物品的装载应严格按照灭菌器说明书要求进行,避免因装载不正确影响灭菌效果。
- 6.4 高浓度的过氧化氢会灼伤皮肤,正确操作灭菌设备同时采取个人防护措施。
- 6.5 使用灭菌剂过氧化氢的浓度及剂量与灭菌器说明书规定的要求一致。
- 6.6 应严格按照灭菌器说明书要求进行设备保养和维护。

**6.3 The load configuration shall strictly follow the user manual of the sterilizer to avoid improper loading that may affect sterilization efficacy.**

[1] ISO. Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices. International Organization for Standardization

[2] National Standards. Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer. State Administration for Market Regulation, Standardization Administration of China



# 1. Research Background

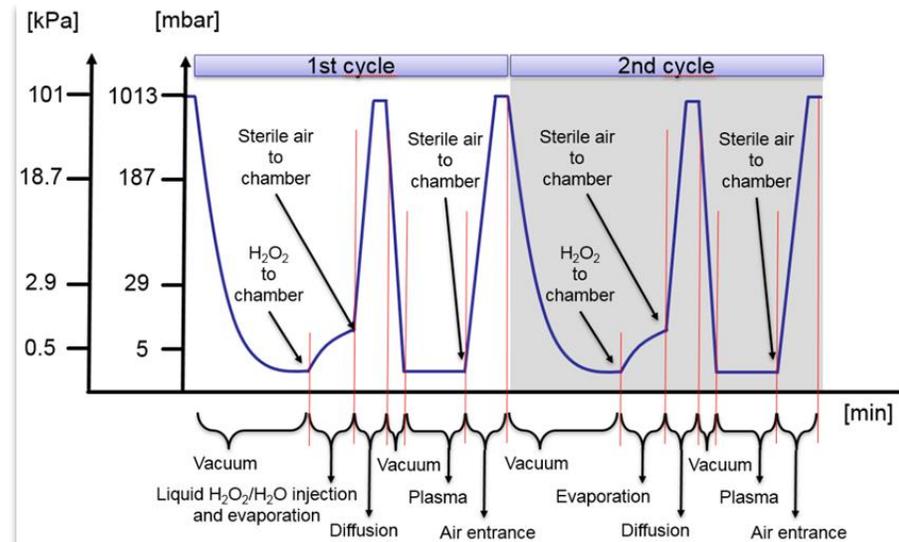
## 1.3 Objectives and significance

### Objectives

- To investigate the effect of load mass on physical parameters during VHP sterilization
  - ✓ To examine the variations in in-pack physical parameters under different load masses, including overweight conditions, across various types and models of VHP sterilizers
- To highlight the importance for CSSD to adhere to load mass limits during VHP sterilization

### Significance

- A basis for developing or revising SOPs



# 2. Method

## 2.1 Selection of sterilizers and physical parameters

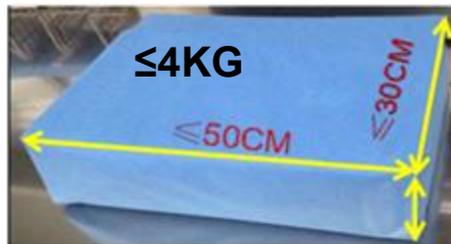
### Sterilizer: VHP-plasma

- Study site: CSSD of a cancer center
- Study period: Oct. 2024 – Feb. 2025
- 3 sterilizers: 2 brands / 2 models (A & B)
- IFU: All specify load mass limits

**A**  
Cycle load  
limit

Cycle Type	Max. load mass (Kg)	Shelves
STANDARD	9.7	1 or 2
FLEX	9.7	1 or 2
DUO	6	1 or 2
EXPRESS	4.9	Bottom shelf only

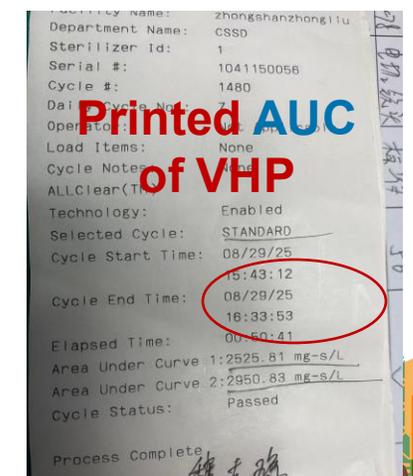
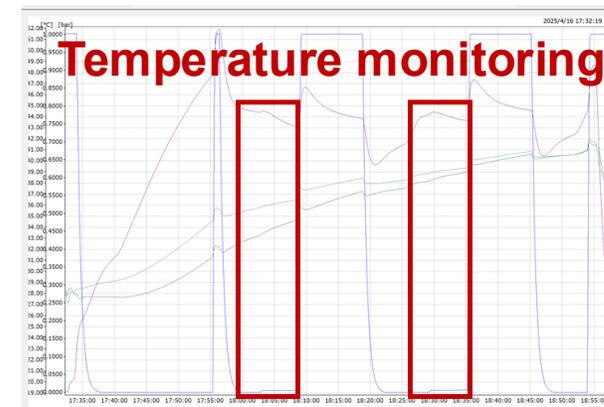
**B**  
Package load  
limit



### Measurements

- Load mass: Actual load (normal & overload)
- Temperature in the chamber:
  - ✓  $T_{min} / T_{mean} / T_{max}$
  - ✓ Two injection stages
- AUC (Area under the concentration-time curve) of VHP:

Built-in sensor **Brand A**

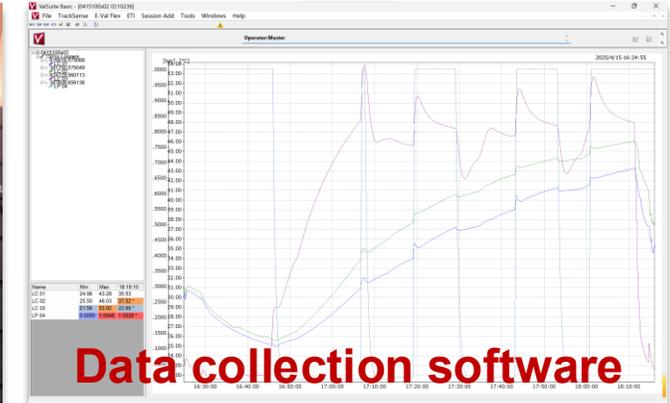


# 2. Method

## 2.1 Selection of sterilizers and physical parameters

### Data collection equipment:

- Thermobarograph:
  - ✓ 3 temp. probes + 1 pressure probe
  - ✓ Calibrated, within valid period
- Data collection software:
  - ✓ In conjunction with the thermobarograph



### Locations for temperature probes:

- Basis: ISO 22441:2022<sup>1</sup>
  - ✓ Geometric center, top / bottom shelves
  - ✓ Near the chamber door (Not placed in this study)

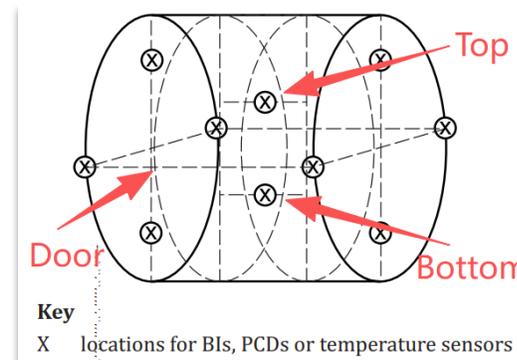


Table H.1 — Recommended minimum number of temperature sensors

Volume (L)	Number for OQ	Number for PQ
	Usable chamber space	Product load volume
<100	3	3
100 to 1 000	12	12
>1 000	12	24

A:152L; B:135L





# 2. Method

## 2.3 Statistical analysis

### Descriptive analysis:

- Mean  $\pm$  Standard deviation

### Multiple linear regression:

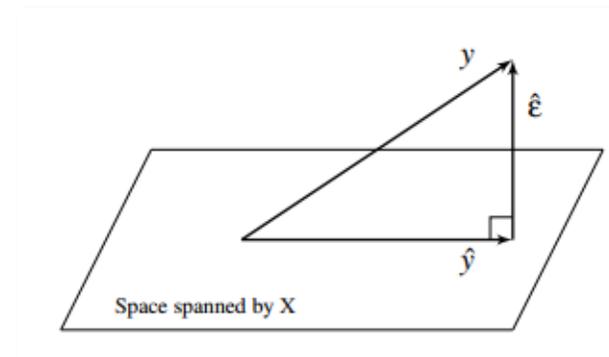
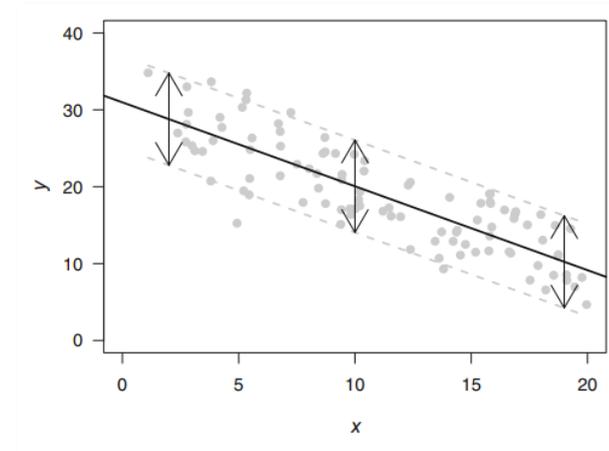
- Investigate associations:
  - ✓  $T_{\min}$  /  $T_{\text{mean}}$  /  $T_{\max}$  & load mass
  - ✓ AUC (Area under the concentration-time curve) of VHP & load mass

### Adjustment for covariates

- Sterilizer brand / Injection stage / Probe location

### Stratified analysis

- Stepwise regression: interaction terms
- ANOVA (Analysis of Variance) : model comparison
- Stratified analysis



# 3. Result

## 3.1 Descriptive analysis

Expressed as mean  $\pm$  standard deviation

Brand	Load mass (Kg)	Injection Stage	Location	Temperature (°C)			AUC of VHP (mg·s/L)
				Minimum	Maximum	Average	
A	11.06 $\pm$ 2.68	Stage 1	Top	31.52 $\pm$ 3.66	33.60 $\pm$ 3.09	32.86 $\pm$ 3.16	2269.44 $\pm$ 734.89
			Bottom	30.72 $\pm$ 3.18	32.50 $\pm$ 2.86	31.80 $\pm$ 2.90	
		Stage 2	Top	37.16 $\pm$ 3.15	39.23 $\pm$ 3.08	38.36 $\pm$ 3.03	3355.47 $\pm$ 1006.49
			Bottom	35.93 $\pm$ 3.18	37.99 $\pm$ 3.25	37.17 $\pm$ 3.15	
B	9.27 $\pm$ 1.48	Stage 1	Top	34.06 $\pm$ 4.64	36.93 $\pm$ 4.26	35.72 $\pm$ 4.15	/
			Bottom	30.93 $\pm$ 3.75	32.94 $\pm$ 3.38	32.11 $\pm$ 3.39	
		Stage 2	Top	39.94 $\pm$ 3.58	41.74 $\pm$ 3.15	40.88 $\pm$ 3.27	/
			Bottom	36.22 $\pm$ 3.57	38.20 $\pm$ 3.18	37.33 $\pm$ 3.20	

### Load mass:

- Brand A > Brand B

### Temperature in the chamber:

- Top > Bottom
- The 2<sup>nd</sup> injection stage > The 1<sup>st</sup> injection stage

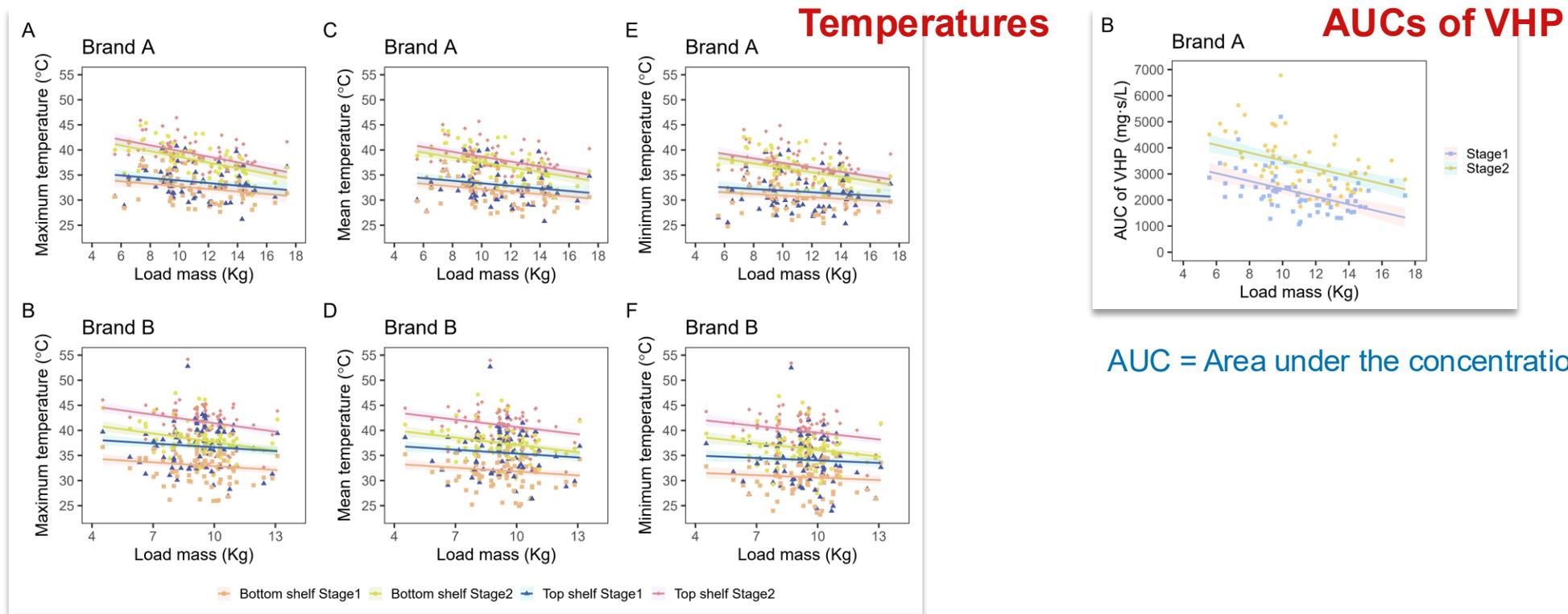
### AUC (Area under the concentration-time curve) of VHP:

- The 2<sup>nd</sup> injection stage > The 1<sup>st</sup> injection stage



# 3. Result

## 3.2 Linear trends between load mass and physical parameters in the chamber during injection stages



Physical parameters during the injection stages **negatively associated** with load mass

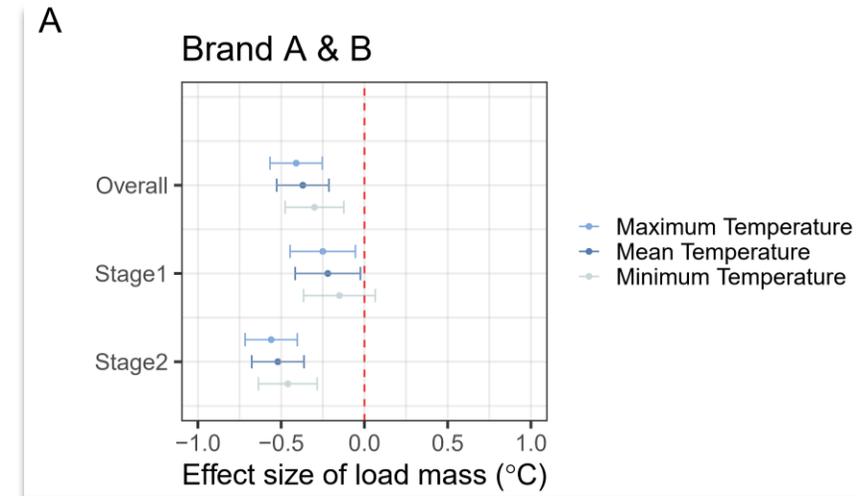


# 3. Result

## 3.3 Effects of load mass on physical parameters in the chamber during injection stages (Quantification)

Parameters	Effect size (95%CI)	Unit	P-value	Note
Min. Temperature	-0.30 (-0.48, -0.13)	°C	< 0.001	/
Mean Temperature	-0.37 (-0.53, -0.21)	°C	< 0.001	/
Max. Temperature	-0.41 (-0.57, -0.25)	°C	< 0.001	/
AUC of VHP	-149.16 (-200.55, -97.77)	mg·s/L	< 0.001	Brand/Model A

➤ **Effect size:** The average change in physical parameters for every 1 kg increase in load mass



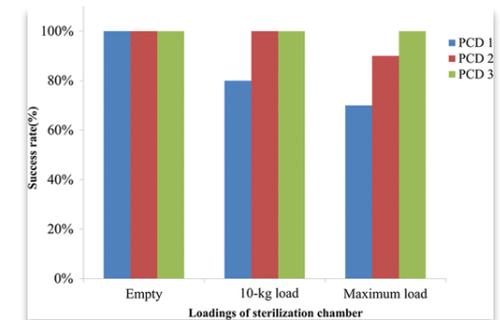
- **Effect of load mass on temperatures:**
  - ✓ More significant in the 2<sup>nd</sup> injection stage
- **P-values for interaction:**
  - ✓ 0.032 ( $T_{min}$ ); 0.052 ( $T_{mean}$ ); 0.064 ( $T_{max}$ )



# 4. Discussion and Conclusion

## 4.1 Findings and Interpretation

- **Finding 1: The AUC of VHP was negatively correlated with load mass during VHP sterilization**
  - ✓ Injection stage: hydrogen peroxide injected → vaporized and diffused → inactivates microorganisms
  - ✓ Insufficient VHP in chamber → cannot fully cover all load surfaces → more difficult to penetrate complex lumens
- **Finding 2: Chamber temperature was negatively correlated with load mass during VHP sterilization**
  - ✓ Heat radiation: heavier load → absorbs more heat<sup>1,2</sup> → lower chamber temperature
  - ✓ At lower temperatures: VHP tends to condense on surfaces or in gas<sup>3,4</sup> → incomplete vaporization → lower VHP concentration (**underlying mechanisms**)
- **Implication: Increased load mass may reduce VHP sterilization effectiveness**
  - ✓ Similar research:  
VHP Sterilization success rate decreased as load mass increased<sup>5</sup>



[1] Tessarolo F et al. Monitoring Steam Penetration in Channeled Instruments: An Evidence-Based Worst-Case for Practical Situations. *Front Med Technol*

[2] Lau WL et al. Heat and mass transfer model to predict the operational performance of a steam sterilisation autoclave including products. *International Journal of Heat and Mass Transfer*

[3] Yuan Y et al. Effect of initial temperature and relative humidity on VHP penetration during HEPA in-situ fumigation disinfection. *Energy and Built Environment*

[4] Karimi Estahbanati MR. Advances in Vaporized Hydrogen Peroxide Reusable Medical Device Sterilization Cycle Development: Technology Review and Patent Trends. *Microorganisms*

[5] Noh MS et al. Evaluation of Sterilization Performance for Vaporized-Hydrogen-Peroxide-Based Sterilizer with Diverse Controlled Parameters. *ACS Omega*



# 4. Discussion and Conclusion

## 4.1 Findings and Interpretation

- Negative correlation between AUC of VHP and load mass → **overload may lead to VHP sterilization failure** → higher patient infection risk
- **Collaboration between manufacturers and healthcare institutions needed** to reduce potential risks
- **Recommendations:**
  1. **For manufacturers**
    - ✓ Some can not provide load mass limits
    - ✓ Before market release: conduct thorough testing and specify load limits under different conditions (e.g., instrument material, size)
  2. **For healthcare institutions / CSSDs**
    - ✓ Develop SOPs based on manufacturer-specified load limits
    - ✓ Strictly enforce SOPs each cycle; never skip weighing load mass
  3. **Enhance monitoring**
    - ✓ Use physical indicators and ISO 11140-1<sup>1</sup> Type 4 chemical indicators each cycle
    - ✓ Balance economic sustainability with sterilization failure risk: increasing biological monitoring frequency

**Biological monitoring frequency:**

**GB 27955<sup>3</sup>:**

Low-temperature VHP sterilization: once daily

[1] ISO. Sterilization of health care products — Chemical indicators. Part 1: General requirements. International Organization for Standardization

[2] AAMI. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. The Association for the Advancement of Medical Instrumentation

[3] National Standards. Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer. State Administration for Market Regulation, Standardization Administration of China



# 4. Discussion and Conclusion

## 4.2 Limitations and prospects

### ➤ Generalizability

- ✓ Single hospital, 2 brands, 2 models
- ✓ **Findings still credible**: one of the largest oncology center in South China & VHP sterilizers commonly used both domestically and internationally

### ➤ Investigation of the correlation between load mass and sterilization success directly was not validated

- ✓ **Results suggest risk of sterilization failure may increase without controlling load mass**

### ➤ Limited consideration of factors affecting VHP sterilization success

- ✓ Load material, load shape, packaging material, baseline physical parameters, etc.
- ✓ **Study identifies overall trends between load mass and physical parameters**

### ➤ Future research can further investigate these aspects



# 4. Discussion and Conclusion

## 4.3 Conclusion

### Conclusion 1:

- **Physical parameters during VHP sterilization negatively correlated with load mass**
  - ✓ Chamber temperature decreased as load mass increased during VHP sterilization
  - ✓ In Brand A sterilizers, AUC of VHP decreased with increasing load mass
  - ✓ Reduced AUC of VHP may compromise sterilization efficacy

### Conclusion 2:

- **Manufacturers and CSSDs should collaborate to ensure VHP sterilization quality**
  - ✓ Manufacturers: specify load mass limit per sterilization cycle for each sterilizer model
  - ✓ CSSD staff: follow the user manual and pay attention to load mass in sterilization practice



# 5. Further Research

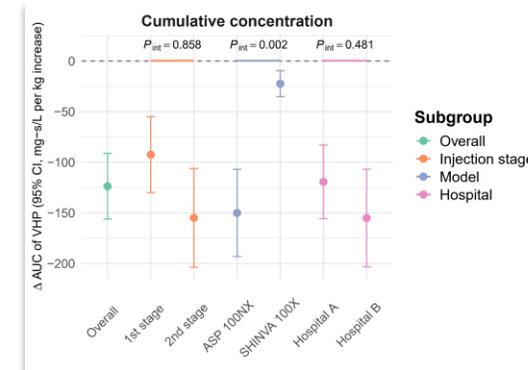
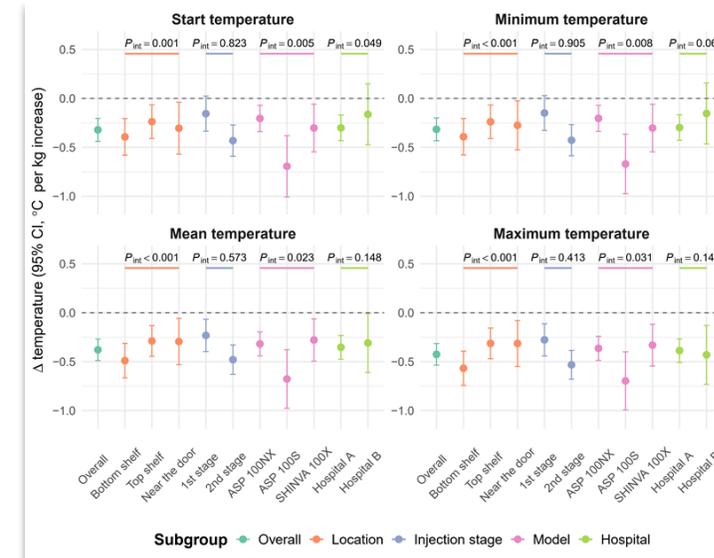
## Effect of load mass on Temp. & Pressure & AUC of VHP

Measurements	$\beta$	Standard error	95% CI	P value
Start temperature	-0.32	0.06	(-0.44, -0.20)	< 0.001
Minimum temperature	-0.32	0.06	(-0.43, -0.20)	< 0.001
Mean temperature	-0.38	0.06	(-0.49, -0.27)	< 0.001
Maximum temperature	-0.43	0.06	(-0.54, -0.32)	< 0.001
Start pressure	-0.13	1.36	(-2.80, 2.53)	0.921
Minimum pressure	0.05	1.33	(-2.57, 2.66)	0.973
Mean pressure	-18.98	4.86	(-28.51, -9.45)	< 0.001
Maximum pressure	-192.55	59.44	(-309.06, -76.05)	0.001
AUC of VHP	-123.72	16.55	(-156.17, -91.28)	< 0.001

### Improvements:

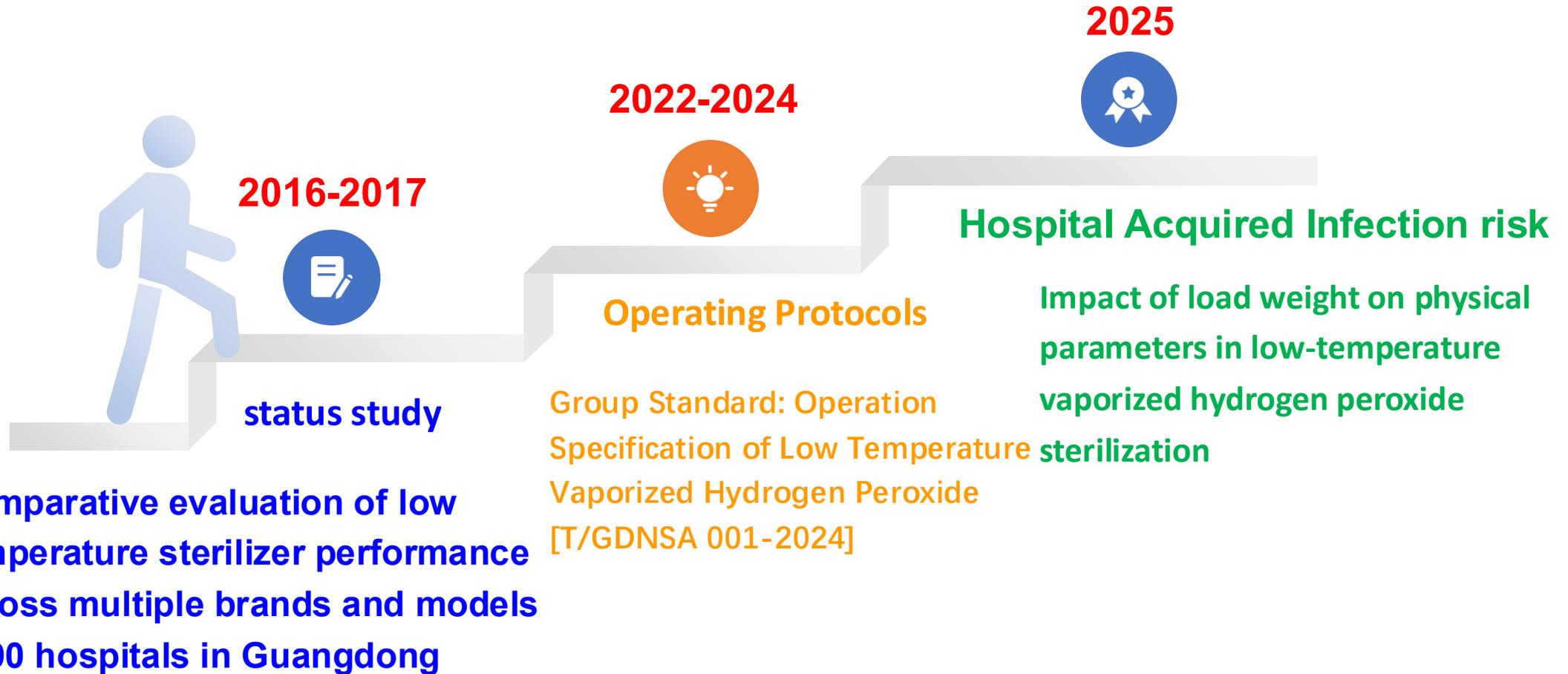
- Dual-center study (2 brands, 3 models)
- Baseline physical parameters adjusted
- Association between chamber pressure and load mass

**Robust and consistent results !**



# 6. Research Basis

Guangdong CSSD team: over 10 years of continuous research





# Acknowledgements



## **Funding:**

Guangdong Nurse Association Evidence-based Nursing Practice Program  
[Grant No. gdnurse2024xz03]

## **Technology:**

Guo Chengzhi. Mingzhou Sirui Medical Products (Shanghai) Co., Ltd





中山大學  
 腫瘤防治中心  
 SUN YAT-SEN UNIVERSITY CANCER CENTER

**Thank you for your attention**

**26<sup>TH</sup> WORLD STERILIZATION CONGRESS**

BRING THE STERILIZATION SCIENCE TO THE NEXT LEVEL  
 將滅菌科學提升到新水平

3<sup>RD</sup> TO 6<sup>TH</sup> DECEMBER 2025

**HONG KONG ASIAWORLD-EXPO**  
 亞洲國際博覽館

Supported by:  
 HONG KONG TOURISM BOARD  
 香港旅遊發展局

政府總局  
 Government General Secretariat  
 2025