HONG KONG
ASIAWORLD-EXPO
亞洲國際博覽館

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DECEMBER
2025

香港在通过科学方法控制湿包方面的经验

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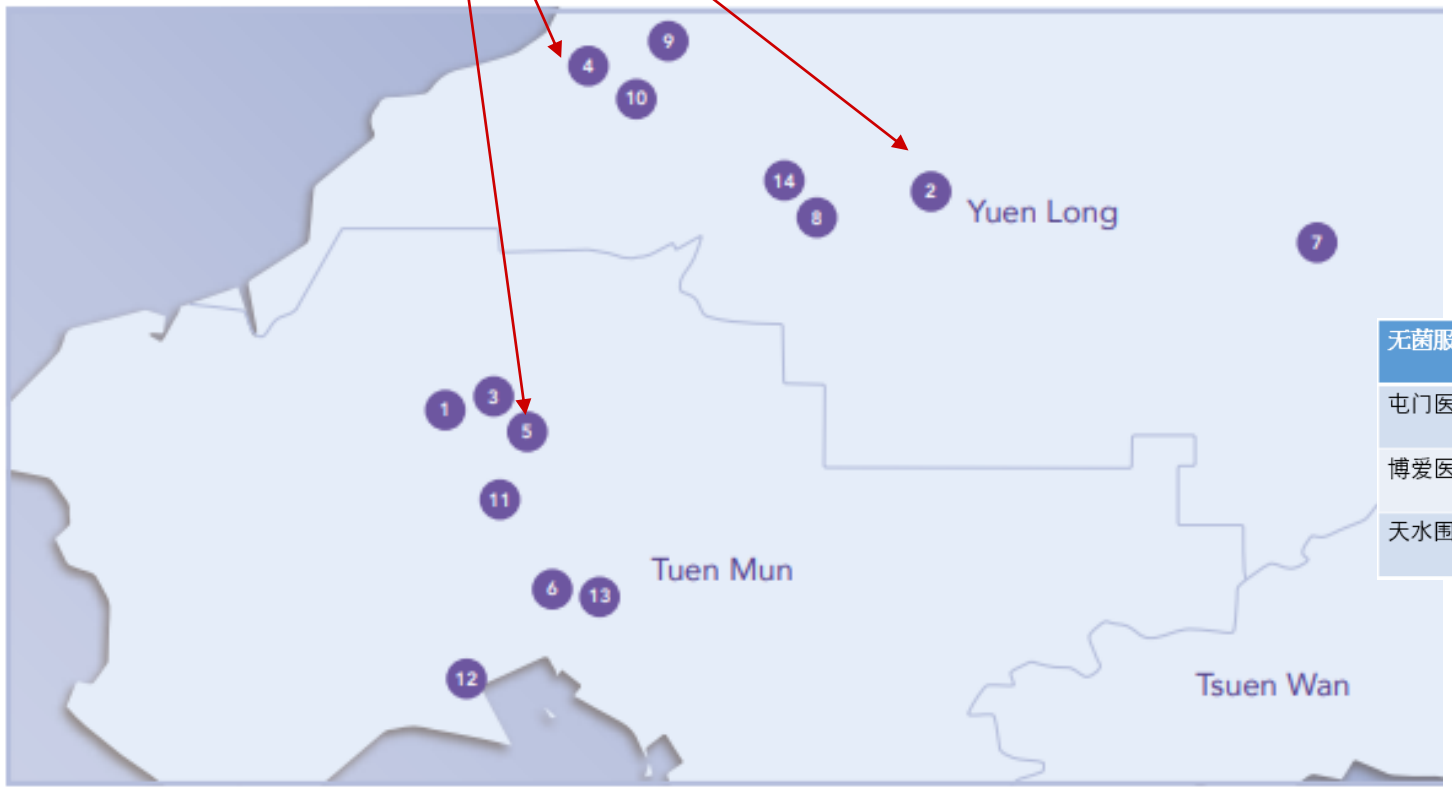
内容目录

- 介绍
- 湿包的常见原因
- 蒸汽灭菌的物理原理
- 湿包应对策略
- 湿包预防的管理层面

新界西·醫院聯網
New Territories West Cluster

醫院管理局
HOSPITAL AUTHORITY

截至2021年3月31日		醫院/醫療機構	專科門診診所	普通科門診診所
1	青山醫院	✓	✓	
2	博愛醫院 ✚	✓	✓	
3	小欖醫院	✓		
4	天水圍醫院 ✚	✓	✓	
5	屯門醫院 ✚	✓	✓	
6	屯門眼科中心		✓	
7	錦田診所			✓
8	容鳳書健康中心			✓
9	天水圍（天業路）社區健康中心			✓
10	天水圍健康中心（天瑞路）			✓
11	屯門診所			✓
12	屯門湖康診所			✓
13	仁愛普通科門診診所			✓
14	元朗賽馬會健康院			✓



无菌服务部的医院分布	手术室数量	医院床位	器械再处理月均量（每套）	备注
屯门医院	22	2100	7100	2个精神科（约1600张床位）
博爱医院	10	800	4500	
天水围医院	4+3	300	2600	3个远程手术室 + 9个门诊部

A. 介绍

- 湿包的定义因湿气出现的位置而异。

- 即使外包装在检查时未见潮湿，只要负载中存在水分，也可能污染包装，使其对微生物穿透变得透明。

《HTM 01-01，第C部分》指出：

- 湿包可能为微生物进入刚灭菌的包提供路径。

- 这是湿包的潜在威胁。

B. 湿包的常见原因

1. 蒸汽含水量过高（湿蒸汽）
2. 真空泵故障
3. 蒸汽疏水阀故障
4. 应正确使用并维护蒸汽疏水阀的位置
5. 蒸汽管道绝热不充分
6. 包装配置不良
7. 灭菌包重量过重
8. 灭菌包装载过多

B.湿包的常见原因（续）

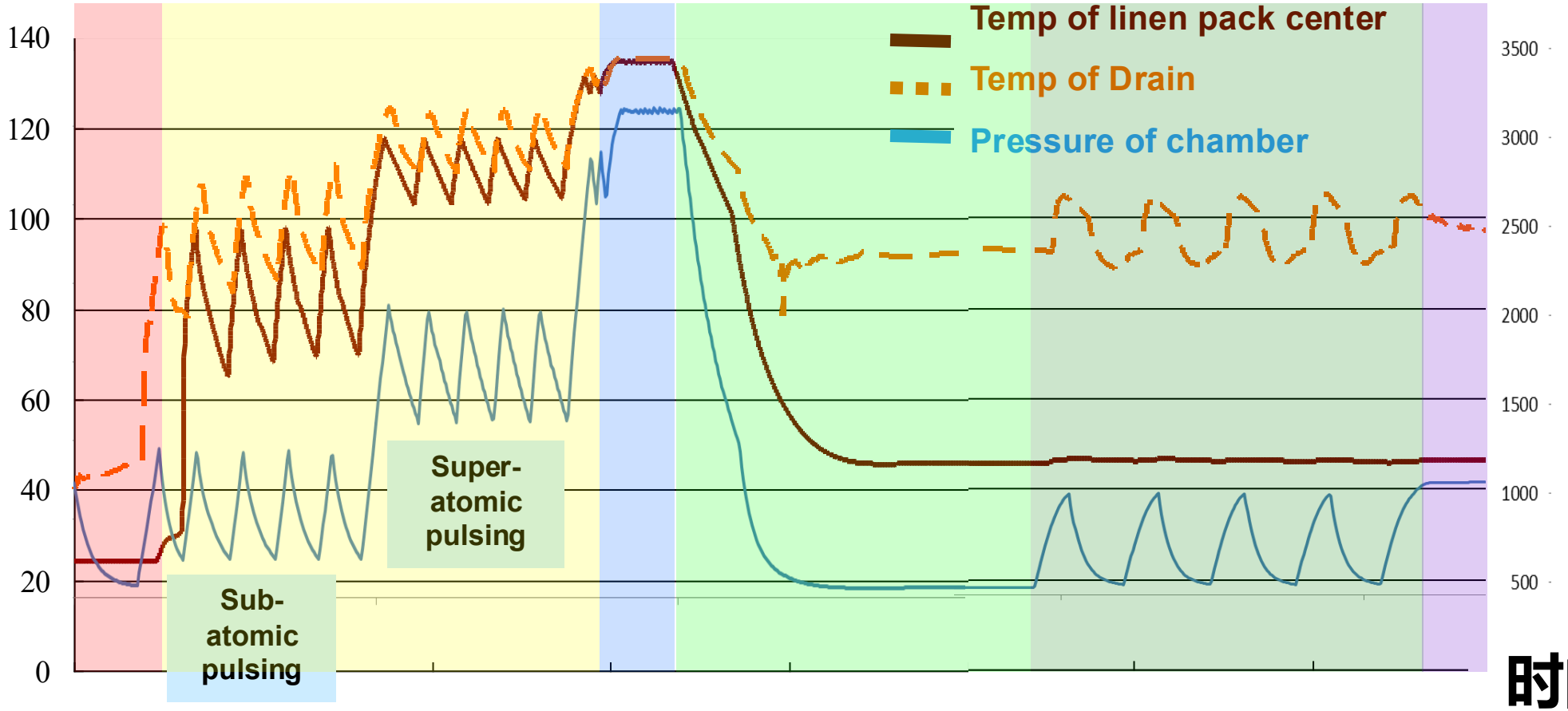
9. 灭菌车装载不当 - 冷凝水会流向下层的包
10. 灭菌后冷却不当
11. 混合负载
12. 冷凝水在包内某一位置积聚
13. 热能保存不足，导致干燥效果差
14. 干燥时间不足
15. 真空泵冷却水的温度超过 **EN 285 标准建议的 15 °C。**

C. 蒸汽灭菌的物理原理

灭菌周期

温度(°C)

压力 (mbar)

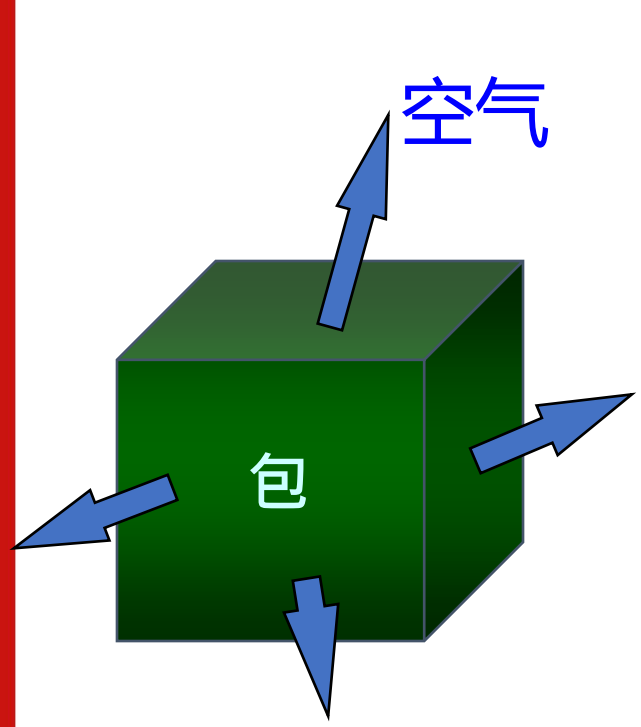


时间

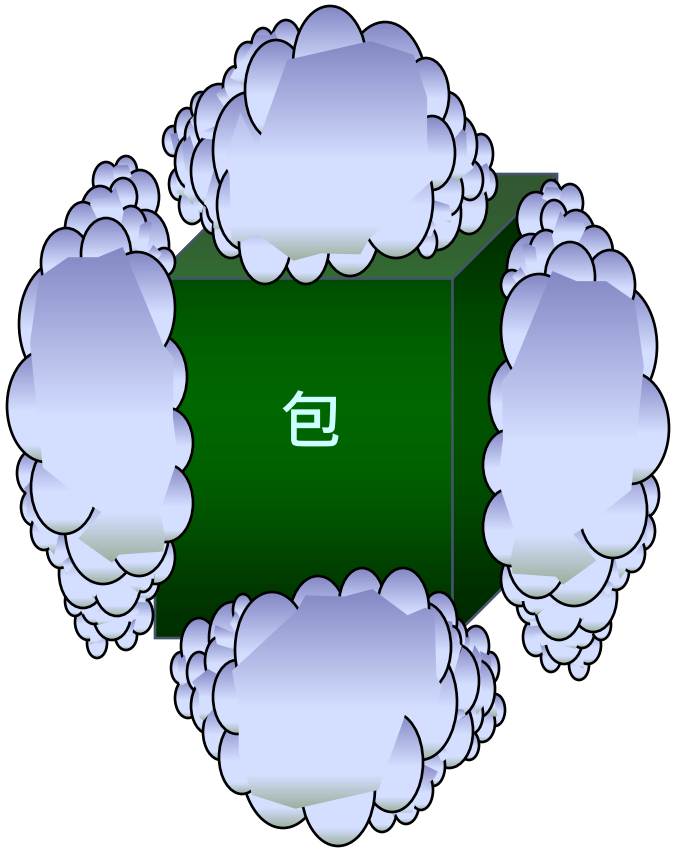
预真空	脉冲式/蒸汽渗透	灭菌	干燥	空气脉冲	回气

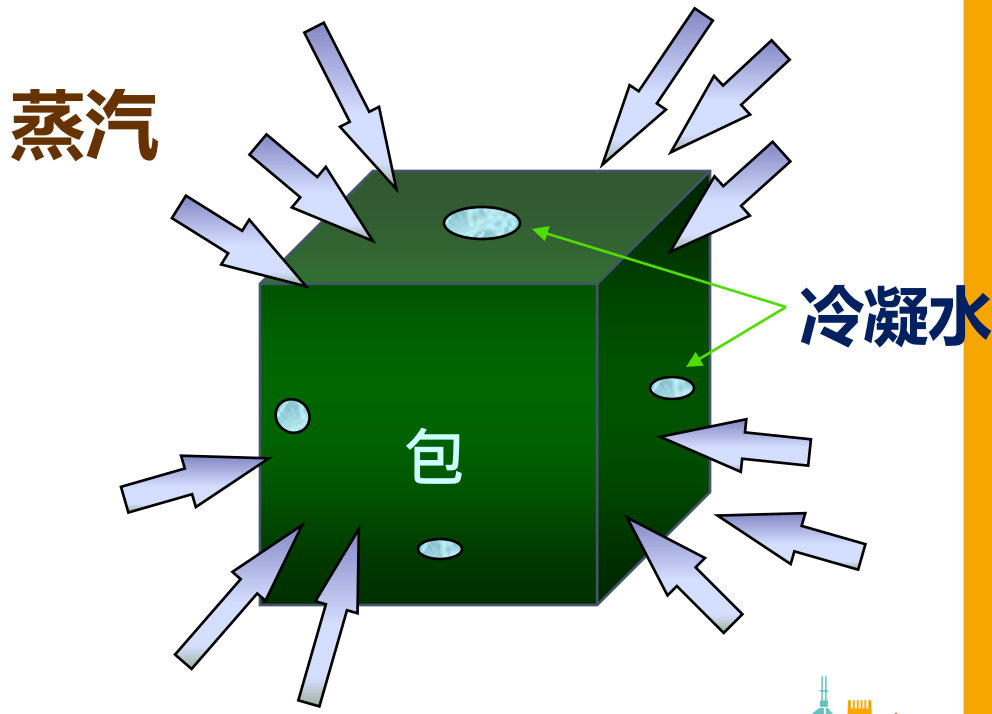
脉冲阶段

抽真空

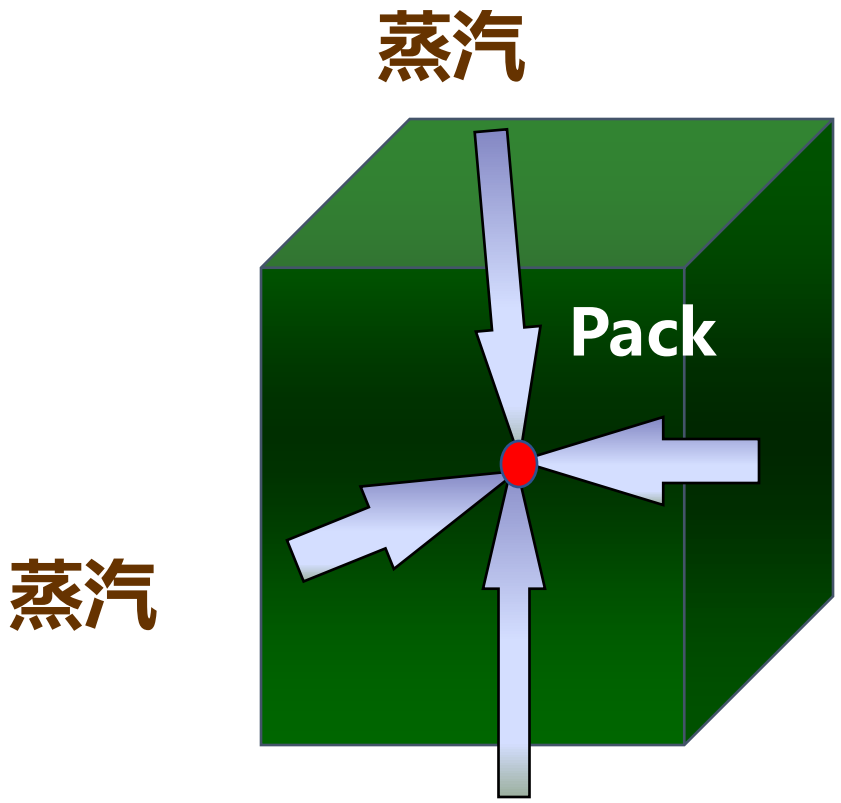


蒸汽進入

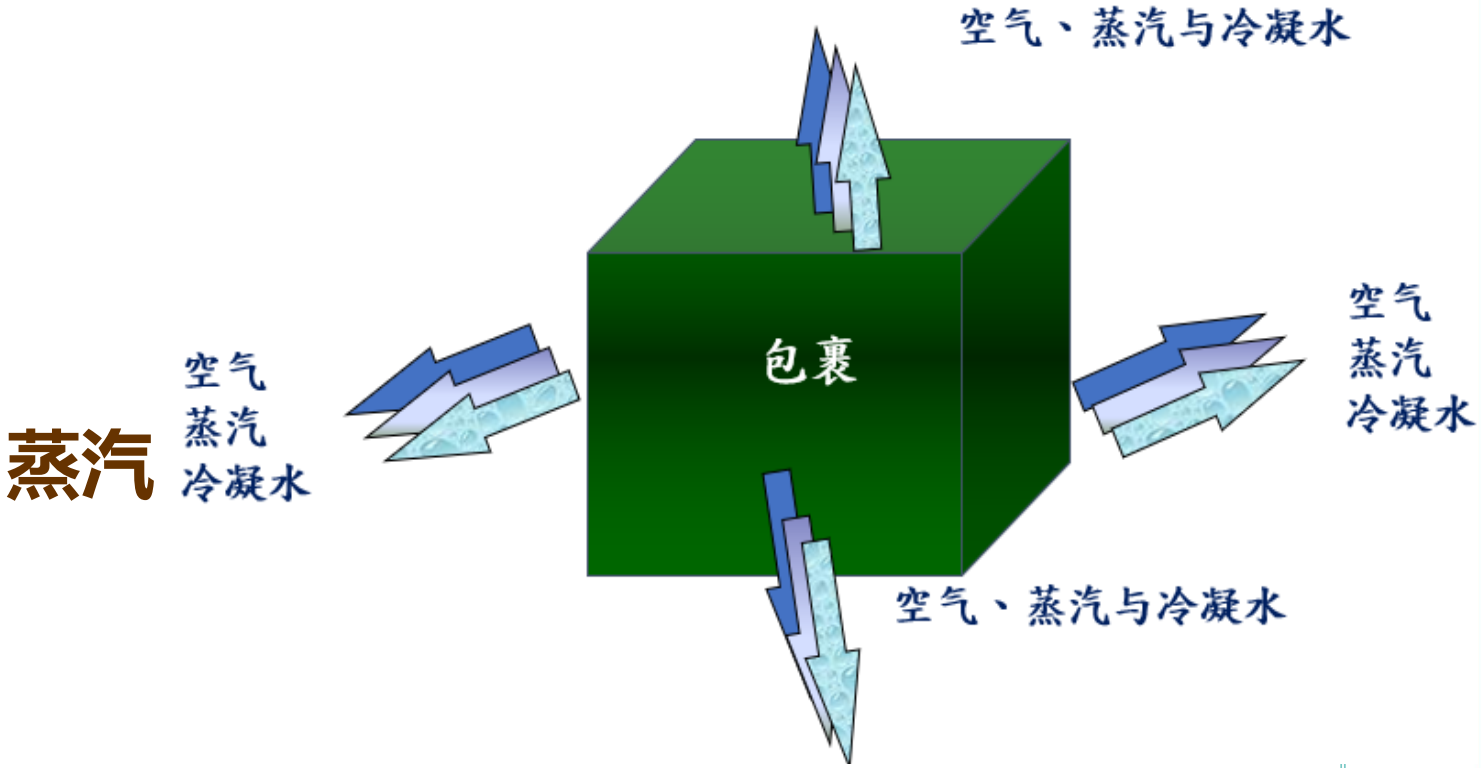




灭菌



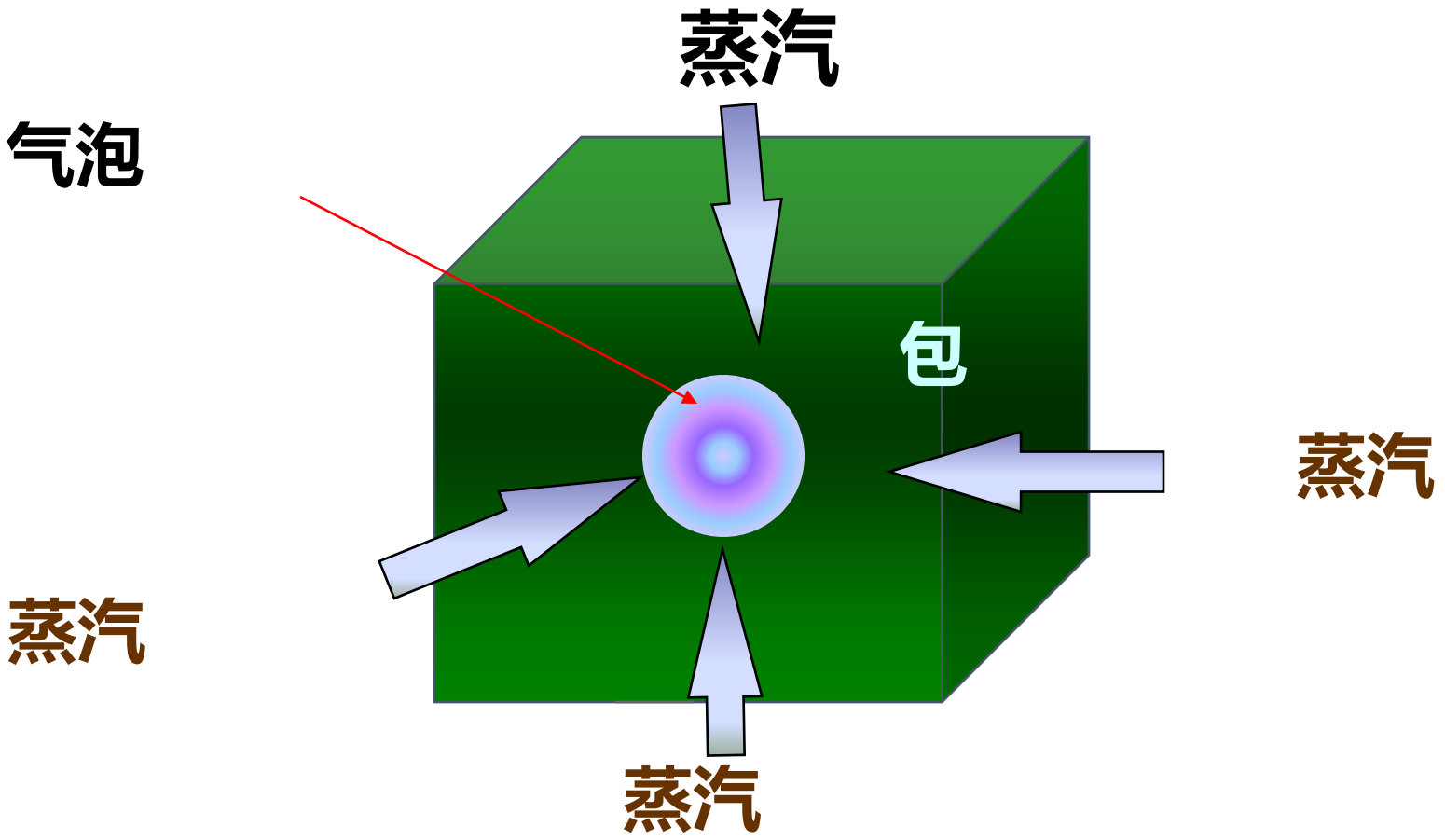
烘干



- 空气含量低于3.5%
  (EN285 2015 13.3.1)

蒸汽灭菌循环 - 失败

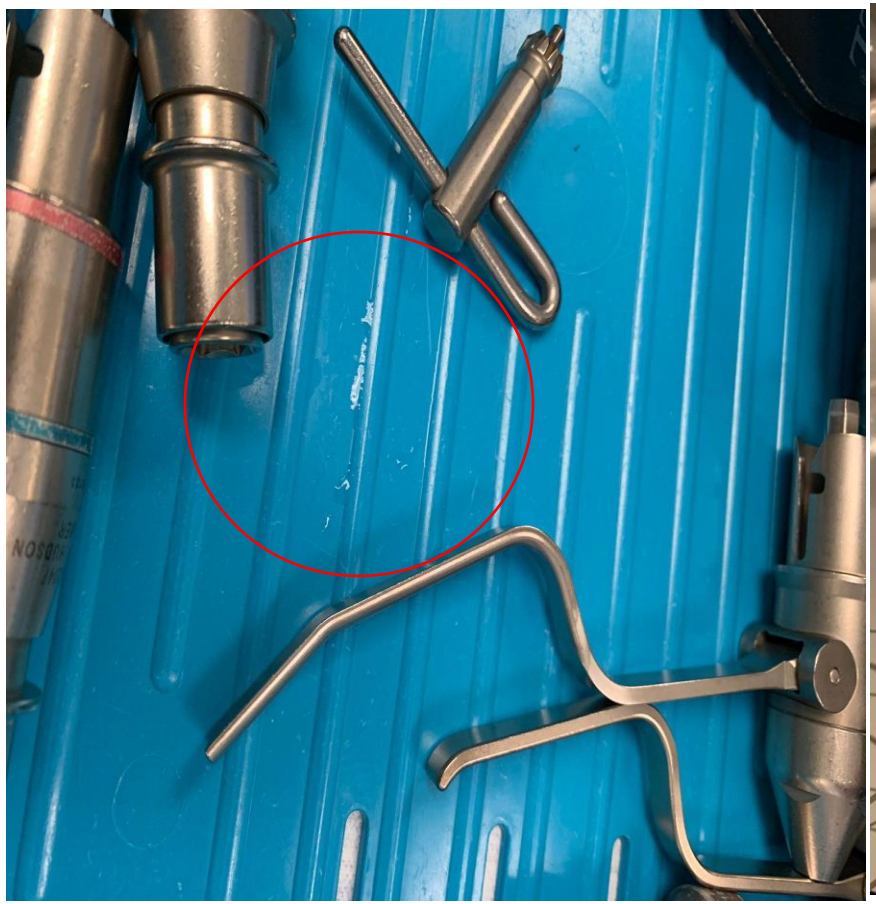
- 灭菌器蒸汽质量差或漏气导致空气排出不充分。
- 包装中心可能残留空气，阻碍灭菌过程。

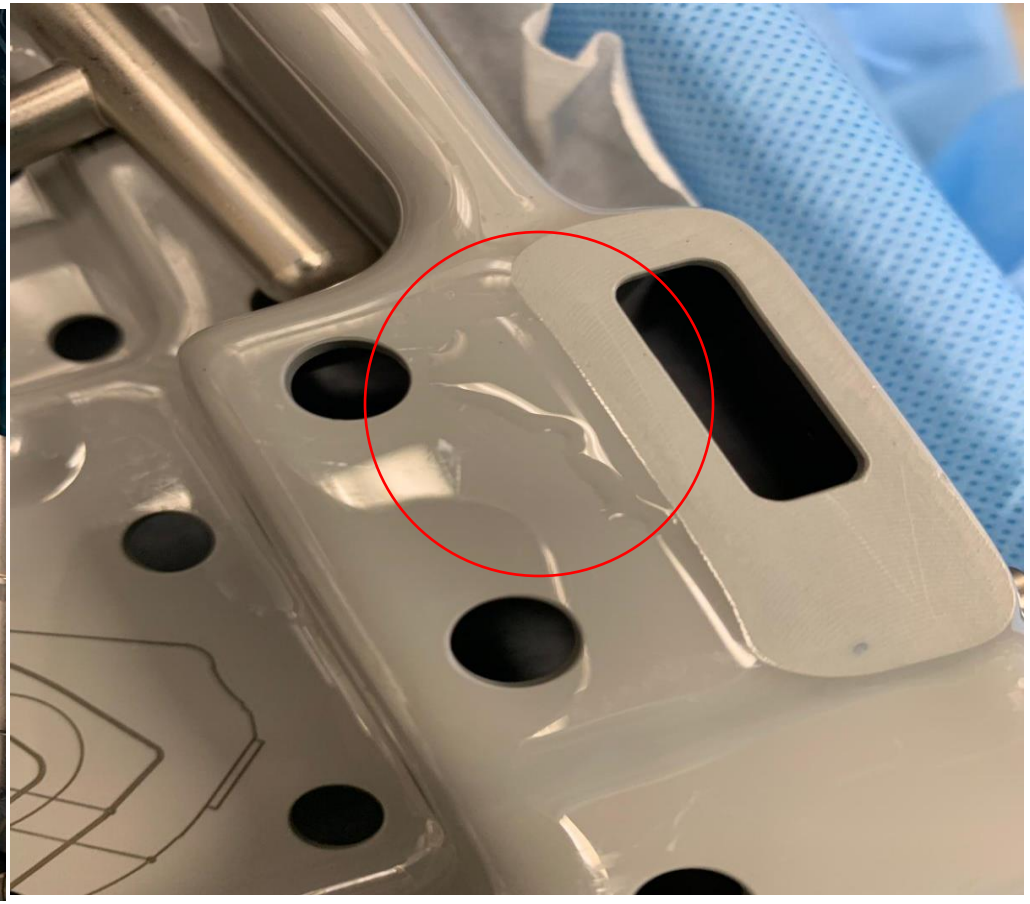


预防湿包

不要将无菌物品停留于炉腔内烘干

保留热能以实现干燥效果

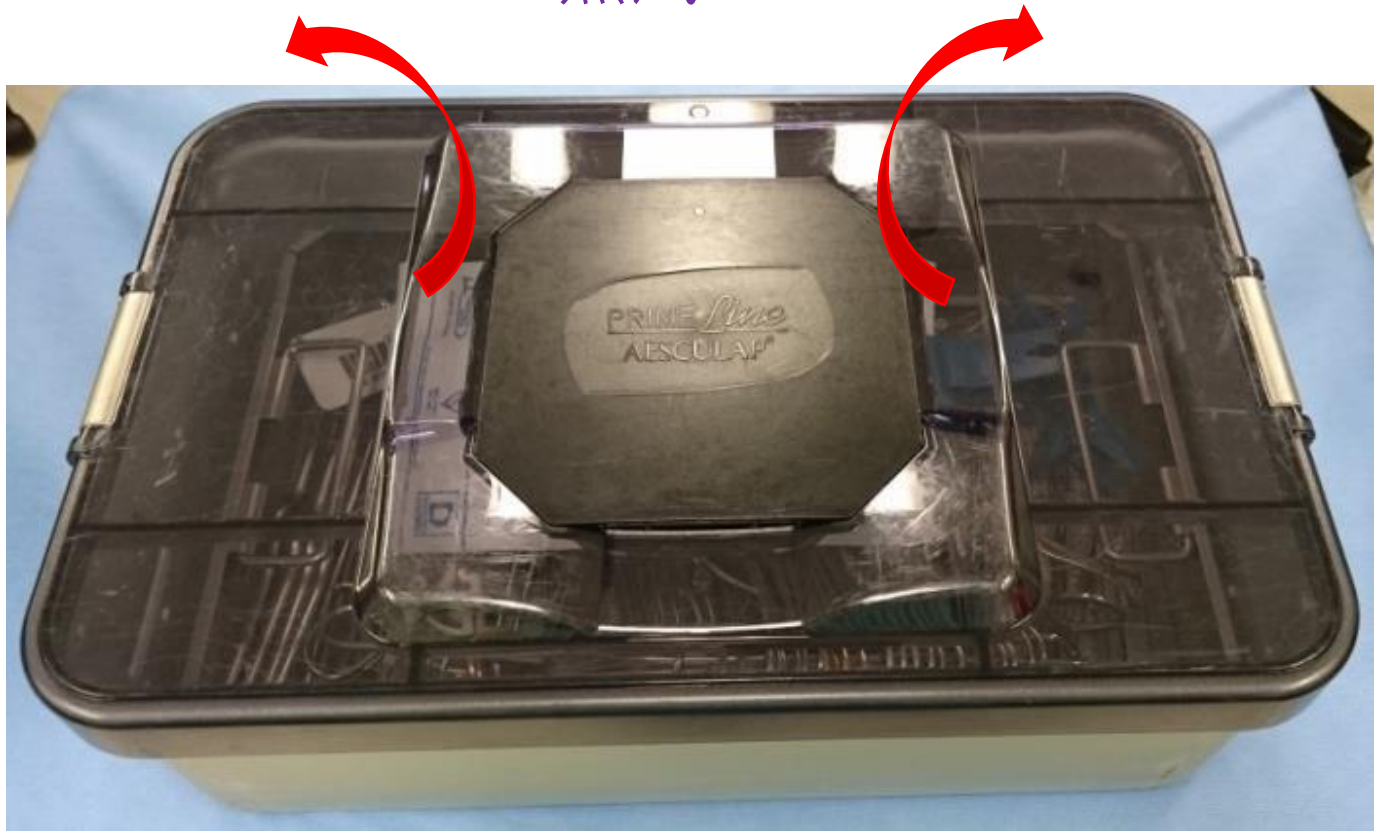




塑料底部几乎没有热能，无法将冷凝水转化为蒸汽

保留热能以实现干燥效果 (续)

- 在干燥阶段，冷凝水积聚在热金属表面会被蒸发成蒸汽，其体积膨胀比为 1:1694 (在 1 bar 压力下)



冷凝水蒸发与膨胀过程

最小尺寸的容器示意图（附图）

- 尺寸： 254 毫米 × 258 毫米 × 75 毫米
- 体积 = 4914.9 立方厘米
- 冷凝水转化为蒸汽的体积膨胀比为 1:1694（在 1 bar， 100°C 条件下）
- 假设所有冷凝水都蒸发： 4914.9 ÷ 1694 = 2.9 cm^3 冷凝水

饱和蒸汽的物理性质

绝对压力	沸点	比容（蒸汽）	密度（蒸汽）	液态水的比焓（显热）	蒸汽比焓（总热量）	汽化潜热
(bar)	(°C)	(m^3/kg)	(kg/m^3)	(kJ/kg)	(kJ/kg)	(kJ/kg)
0.02	17.51	67.006	0.015	73.45	2533.64	2460.19
0.1	45.83	14.675	0.068	191.84	2584.78	2392.94
0.2	60.09	7.65	0.131	251.46	2609.86	2358.4
0.3	69.13	5.229	0.191	289.31	2625.43	2336.13
1[1)]	99.63	1.694	0.59	417.51	2675.43	2257.92
2	120.23	0.885	1.129	504.71	2706.29	2201.59
3	133.54	0.606	1.651	561.44	2724.66	2163.22
3.5	138.87	0.524	1.908	584.28	2731.63	2147.35
5	151.85	0.375	2.669	640.12	2747.54	2107.42

1) = 1 bar 绝对压力 = 0 bar 压力錶 = 100 kPa 绝对压力 = 一个大气压

冷凝水蒸发与扩散（续）

- 在 60°C 条件下，冷凝水转化为蒸汽的体积膨胀比为 1:7650
- 假设所有冷凝水都蒸发：4914.9 cm^3 ÷ 7650 = 0.64 cm^3 冷凝水
- 在 100°C 条件下，2.9 cm^3 冷凝水 = 97%–100% 相对湿度
- 在 60°C 条件下，0.64 cm^3 冷凝水 = 0.64 ÷ 2.9 = 22% 相对湿度
- 应考虑在灭菌周期结束时，过滤空气的相对湿度，以平衡压力

最小尺寸容器（如图所示）

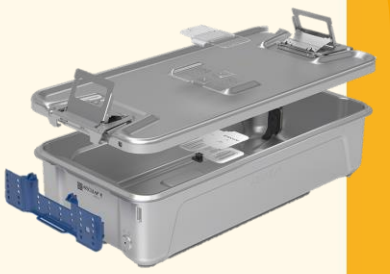
D. 湿包应对策略

1) 记录与分析（如发现湿包则重新包装）

记录湿载位置和参数

2)内容整理

A. 更换容器



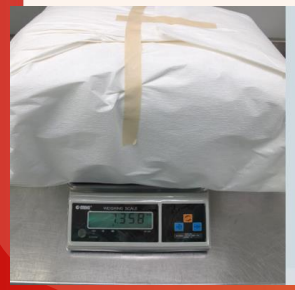
B. 移除低热能容量物品

C. 控制重量

≤15KG

D. 最小化图形托盘

3)负载干燥度测试



$$\Delta m = \frac{(m_2 - m_1)}{m_1} \times 100\%$$

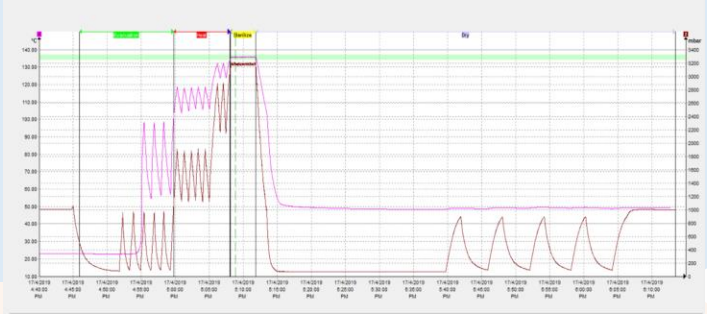
Weight Comparison

EN285

D.湿包应对策略

4.优化干燥阶段

- 延长干燥时间（例如 >20分钟）
- 在正常灭菌流程后进行空气冲洗



5. 真空压力性能监测

比较干燥阶段的真空压力，以确保真空泵的效能

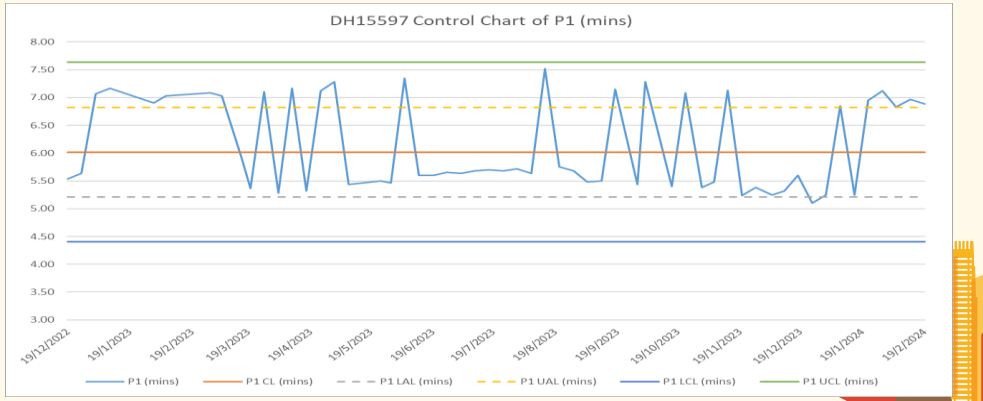
Loggers in process

#19720237 Calibration date 02/11/2023 15:37:21

Overall result

Passed

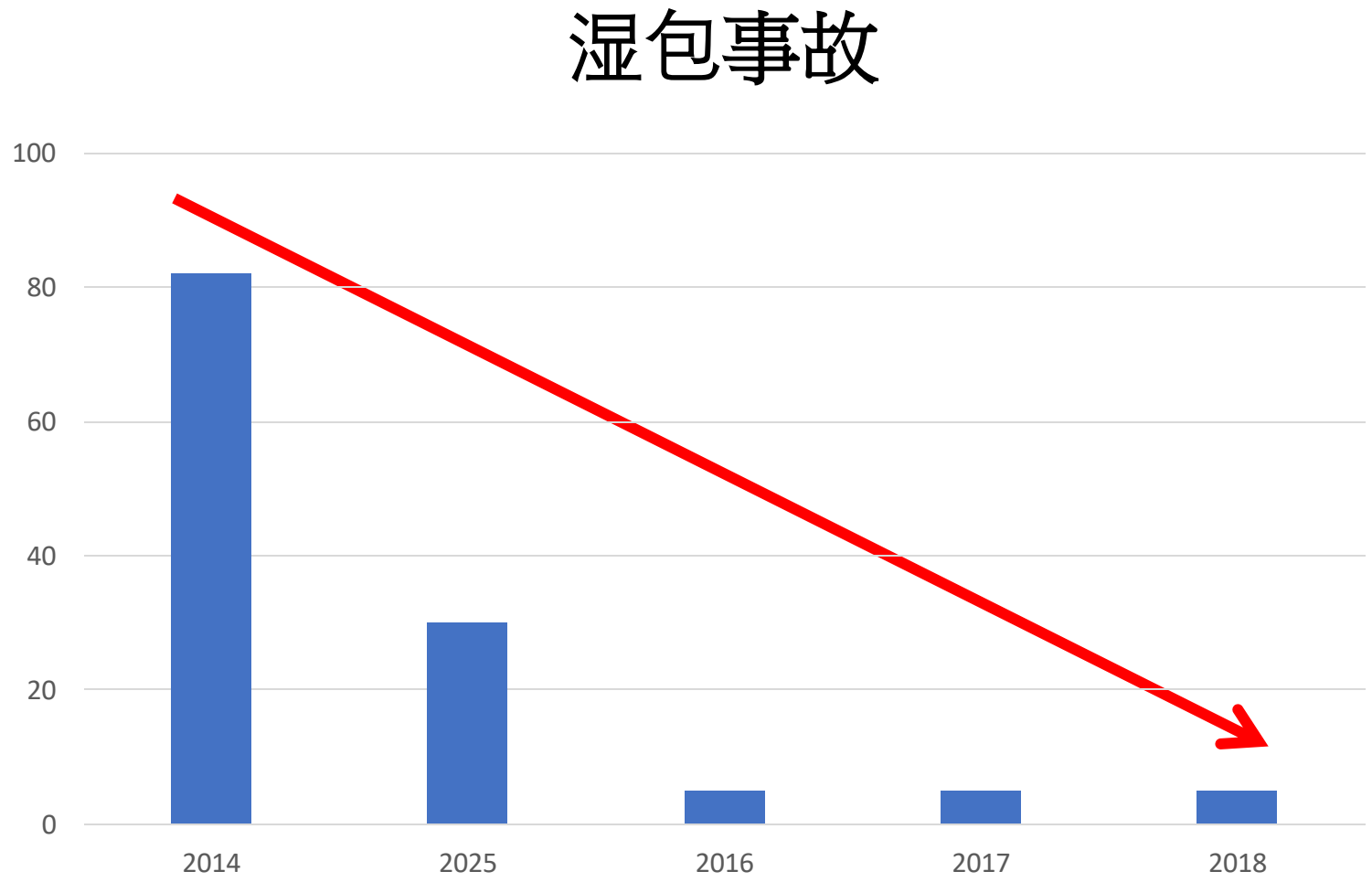
Detailed results	Nominal	Actual
2. Pulsing 1		
Duration	>= 00:04:07 ; <= 00:07:30	00:06:38
Limits [Pressure]	>= 0.00 mbar	107.00 ... 987.00 mbar
3. Pulsing 2		
Duration	>= 00:03:30 ; <= 00:05:23	00:04:54
Limits [Pressure]	>= 0.00 mbar	1117.00 ... 1912.00 mbar
4. Pulsing 3		
Duration	>= 00:00:00	00:01:36
Limits [Pressure]	>= 0.00 mbar	2130.00 ... 2893.00 mbar
5. Steam Admission Stage		
Limits [Temperature]	>= 0.00 °C	122.55 ... 134.66 °C
Duration	>= 00:00:00	00:00:33
Limits [Pressure]	>= 0.00 mbar	2165.00 ... 3093.00 mbar
6. Sterilization Stage		
Limits [Pressure]	>= 3042.00 mbar	3090.00 ... 3149.00 mbar
Limits [Temperature]	>= 134.00 ; <= 137.00 °C	134.51 ... 135.29 °C
Duration	>= 00:03:30	00:03:30
7. Drying Stage		
Limits [Pressure]	>= 0.00 mbar	49.00 ... 76.00 mbar
Duration	>= 00:24:13 ; <= 00:24:50	00:24:36
8. Air Flush Stage		
Duration	>= 00:19:52 ; <= 00:31:13	00:22:49
Total process		
Duration	>= 00:00:00	01:16:30



6. 使用吸水衬垫

- 增加冷凝水的表面积，便于吸收能量
- 掩盖湿包问题（但不是解决湿包的好方法）

湿包发生率显著降低



E. 管理策略 – 1）持续员工培训的整合

- 集中培训实践
- 改革岗位职能培训
- 传承实践经验
- 以知识为导向的技能传授
- 团队建设

2) 系统性事件记录

由无菌供应部门报告

客户报告

NTWC Sterile Services Department	文件號碼:	NTWCSSD-C-NM-003-V13
	版本:	13
Quality Improvement on Reporting Nearly Missed Case in NTWC SSD	生效日期:	01 - 04 - 2024
	下次修定:	01 - 04 - 2027
	頁數:	頁 1

Quality Improvement on Reporting Nearly Missed Case in NTWC SSD

All Nearly Missed Case should be reported through email within 48 hours.

Severity Grade	→	Nearly Missed belongs to group 3 & 4 should report to DOM verbally in advance
1. Low risk	→	Nearly Missed happens within SSD.
2. Moderate risk	→	Nearly Missed is related to customers and is related to product's non-conformity.
3. Moderate high risk	→	Nearly Missed is related to expensive instruments / potential complaint.
4. High risk	→	Nearly Missed may affect patient safety or clinical service.

Non-conforming product

Hospital Code for reporting & statistics	TMH: T	POH: P	TSWH: W

Follow up action	TMH	POH	TSWH
Internal training	W C LAW & All PCAI		
Staff interview	Cherry CHAN	Martin TANG	Edward YIP
System review	Leo YEUNG	S M KO	S M KO / Ben LAI
Wet load follow up	Ken YIP	Johnson WAN	Ben LAI

Management review	Frequency
Nearly Missed Case Statistics	Monthly
Review in SSD Management meeting	Quarterly
Nearly Missed Case Review Training	Weekly

IOD / OSH Incident

Immediate action	Duty i/c
Follow up action by Department Safety Officer	
TMH DSO	Cherry CHAN
POH DSO	Priscilla LAW
TSWH DSO	Ben LAI

Non-OT Related

Fault of machine or facility
Shortage of supply
Environmental defect

Immediate action	Duty i/c
Follow up action by SSD i/c	
TMH	Leo YEUNG
POH	S M KO
TSWH	S M KO/ Ben LAI

Wet Load

Report by SSD staff:	Record by Wet load form
Report by customers:	Nearly missed report

Author : Chu Yee Man Rank : EOII Date : 01/04/2024

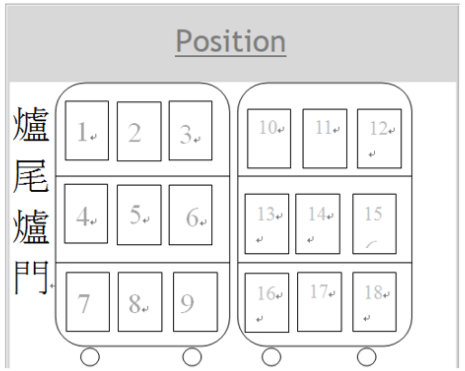
Approved by : Ko Shui Mei Rank : WM Date : 01/04/2024

Wetload_nav

Wetload Record — Edit | Export to Excel | Close Form

Wetload

Date	Hospital	Sterilizer No	Cycle	Program	Drying time	Air flush time	Position	Wetload was found	Set Template	Set ID	Weight of set
8/4/2024	TMH	DH15472	3325	3	28:50	19:10	8	蓋內	TMH.T10048	TMH.T10048.05	6.9
8/4/2024	TMH	DH15472	3329	3	28:19	19:14	8	蓋內	TMH.T20069	TMH.T20069.08	6.79



Nearly Missed Incident Edit Menu — Form Profile: GrpWet

Incident Code	240913T00302	Incident Date	13/9/2024 17:35:00	Incident Closed	13/9/2024 11:44:20
Hospital	TMH	Reported by		Follow Up By*	EO I
Category	Non-Conforming product	Latest Update	13/9/2024 11:44:23	Severity*	Moderate risk
Sub-Category	Wet Pack	Updated by		Feedback By*	OT/ TMEC

Feedback to User ☐ For Training ☑ Reported to AIRS ☐ Incident Closed ☑

Incident Heading* (Characters Left 61): Wet Load observed in TMH.N20051.01 KNEE PROSTALAC(L)(S.O.4)

Incident Details* (Characters Left 1836): On 12/9/2024 17:35 , OT WM inform SSD that water droplet was encountered on one of the L Size of KNEE PROSTALAC inTMH.N20051.01 KNEE PROSTALAC(L)(S.O.4).

Root Cause (Characters Left 798): Owing to material of instrument, the absorbed heat capacity was not sufficient to vaporize the condensate after sterilization. The loading configuration could not facilitate the drainage of condensate.

Immediate Action (Characters Left 787): SSD I/C was informed. The problematic instrument was not used in operation. OT performed usage area check out on 2024-09-12 21:16 and received by SSD on 2024-09-13 08:25 for operation on 13/9/2024 pm.

Recommendation (Characters Left 854): The concerned staff should be alerted the case. Designated loading configuration with slope was recommended to lower the chance of water droplet.

Follow Up(1000) (Characters Left 918): Concerned staff was interviewed. To share the case on 20/09/2024 weekly training.

Staff Involve ☐ Uncertain Staf | Staff Role

PCA II Packer

C II Checker

Photos — Add File | Save As

\\pohnas001\pohcssd\CSSDQMS\Frontend_Phot

\\pohnas001\pohcssd\CSSDQMS\Frontend_Phot

\\pohnas001\pohcssd\CSSDQMS\Frontend_Phot

Files

3) 多学科方法


使用者
维护服务供应商
验证服务供应商
无菌服务部，器械接收员(外借器械)
无菌服务部，监督员，追溯记录员
无菌服务部，器械包装员
无菌服务部，灭菌器操作员

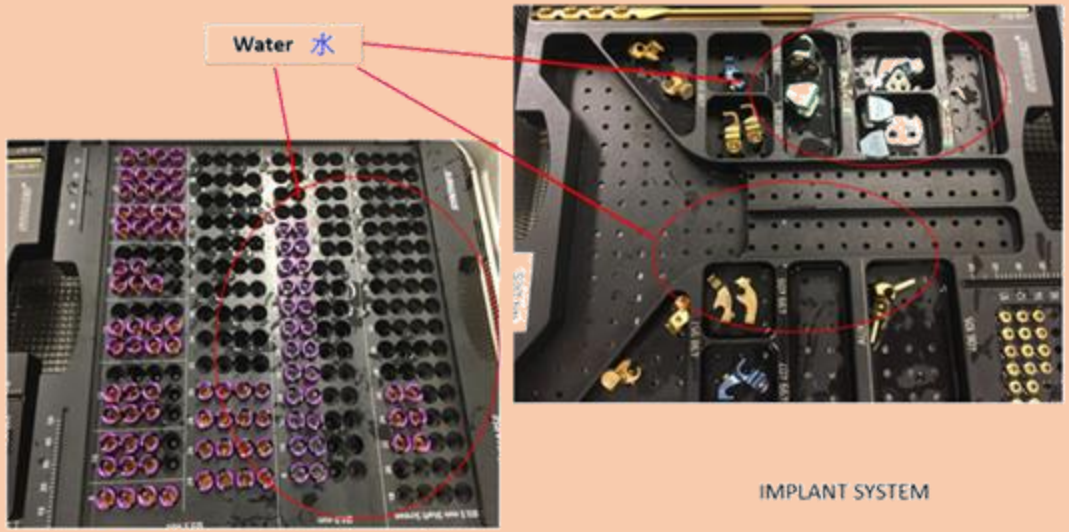
4) 前线员工参与

在屯门医院 CSSD 进行的测试

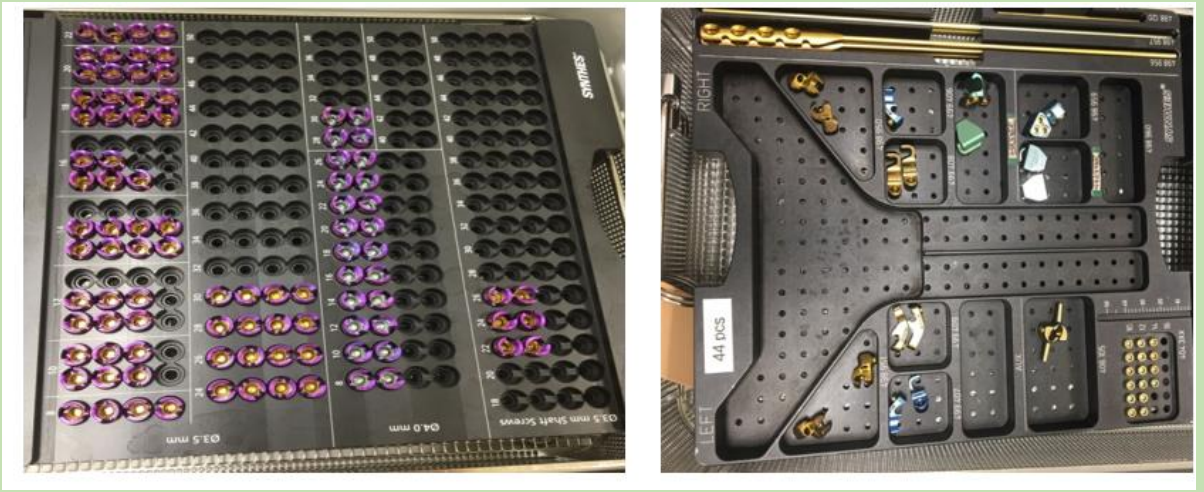
将1小杯无菌水（少于50毫升）随机倒入器械中以模拟极端情况/最坏情况。

- 测试的物品组经过正常的蒸汽灭菌周期

➢灭菌前



➢灭菌后



感谢您的关注


26TH WORLD STERILIZATION CONGRESS
BRING THE STERILIZATION SCIENCE TO THE NEXT LEVEL
將滅菌科學提升到新水平
3RD TO 6TH DECEMBER 2025
HONG KONG
ASIAWORLD-EXPO
亞洲國際博覽館
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