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Exploration of Most Difficult-to-Sterilize Location in Pulse Vacuum Sterilizers

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ABSTRACT: Objective The present study aims to explore the most difficult-to-sterilize location within the chamber of pulse vacuum sterilizers, providing a reference for the placement of biological monitoring packs during routine operation. **Method** Using temperature and pressure detectors, temperature testing was conducted on 16 identical models of pulse vacuum sterilizers in four Grade III-A hospitals under different loading conditions, including no-load, instrument load, and dressing load. The location of the slowest heating point within the sterilizer chamber was determined. **Result** Statistics from 43 batches, totaling 258 data points show that the slowest heating point appeared most frequently at the lower level of the sterilizing rack, near the loading door, occurring 29 times, accounting for 67.44%; the location at the upper level of the sterilizing rack near the loading door occurred 14 times, accounting for 32.56%. **Conclusion** The most difficult-to-sterilize locations for this model of pulse vacuum sterilizer were near the loading side door, with the highest probability at the lower-level location near the door. Therefore, it is recommended to place the biological monitoring pack at the lower level of the sterilizing rack, near the loading side door, during routine biological monitoring.

KEY WORDS: Pulse vacuum sterilizer; Most difficult-to-sterilize location; Biological monitoring

Introduction

Steam sterilizers are allowed to be used after verified their sterilization efficacy by passing biological indicator challenge tests and Bowie-Dick test (B-D test)[1]. According to the requirements of Appendix A2 Monitoring Method, *Central sterile supply department (CSSD)-Part 3: Surveillance standard for cleaning. disinfection and sterilization* (WS 310.3—2016), when performing biological monitoring of sterilizers, "the standard biological monitoring pack or biological PCD should be placed above the sterilizer exhaust port or at the location within the sterilizer suggested by the manufacturer as the most difficult to sterilize"[2]. Two issues encountered in daily operation are to be addressed, including whether the "most difficult-to-sterilize location" for different brands and models of sterilizers is always "above the sterilizer exhaust port" and how exactly the "most difficult-to-sterilize location" should be identified. Therefore, the temperature and pressure detectors were used to conduct no-load heat distribution tests, full-load instrument heat distribution tests, and full-load dressing heat penetration tests on 16 pulse vacuum sterilizers of identical brand and model in four Grade III-A hospitals. The aim was to determine the "most difficult-to-sterilize location" within the sterilizer chamber. The methods and results are summarized below.

1 Materials and methods

1.1 Materials

1.1.1 Sterilizer

A pulse vacuum sterilizer (Belimed MST

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9618HS2) was used in this study. The sterilization programs used for testing included the P1 Instrument Sterilization Program and the P2 Dressing Sterilization Program. The preset parameters involved a sterilization temperature of 134℃ and a sterilization time of 5 minutes.

1.1.2 Temperature and pressure detector

EBRO 9 and Testo-100, both from Germany and metrologically certified, were adopted as two temperature and pressure testers. Each test applied seven temperature probes and one pressure probe.

1.1.3 Sterilizing rack

The sterilizing rack is made of stainless steel and divided into upper, middle, and lower levels. Each level can hold six standard sterilization baskets sized 30*30*60 cm. The maximum load capacity reaches 18 standard baskets.

1.1.4 Self-made instrument pack

M16100 stainless steel bolts, as commonly used stainless steel instruments, were used to maintain loading consistency. A total of 32 bolts were laid flat in an instrument basket sized at 60*28*8 cm for packing. According to the manufacturer's instructions, each instrument pack weighed 7.5 kg. A total of 18 instrument packs were used, evenly filling the three levels of the sterilizing rack during tests.

1.1.5 Self-made dressing pack

The common dressing pack was used with external dimensions of approximately 30*30*50 cm and a weight of 5.0 kg. A total of 18 dressing packs were used, evenly filling the three levels of the sterilizing rack during tests.

1.2 Methods

1.2.1 Routine test

The leak test and B-D test were run daily first, and the results shall be qualified.

1.2.2 No-load heat distribution test

1.2.2.1 Six temperature probes were placed at locations A, B, C, D, E, and F on the sterilizing rack (Figure 1). The sensing part of the probes should not contact the rack. Another temperature probe was placed at location G in the chamber drain port (Figure 2) as a reference measurement point. The reference measurement point is generally located below the sterilizer chamber exhaust port[3].

Note:
A. Directly above the drain port on the bottom level of the sterilizer rack
B. Geometric center of the sterilizing rack
C. Upper level of the sterilizing rack near the loading side door
D. Upper level of the sterilizing rack near the unloading side door
E. Lower level of the sterilizing rack near the loading side door
F. Lower level of the sterilizing rack near the unloading side door
G. Reference measurement point (see Figure 2)

Figure 1 Schematic diagram of temperature probe placement for no-load test

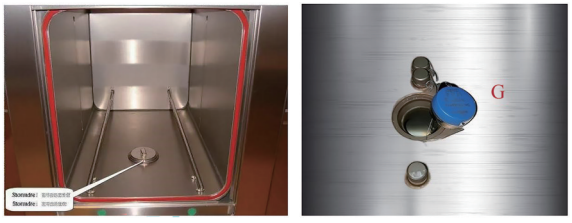

Figure 2 Reference measurement point G, sterilizing chamber exhaust port

1.2.2.2 No-load heat distribution test

The no-load heat distribution test ran the P2 Dressing Sterilization Program. The sequence in which temperature probes at different locations reached the sterilization temperature was compared to analyze the slowest heating point. Temperature data are shown in Table 1.

According to the data of the full-load instrument heat distribution test, the slowest heating point was point E (lower level of sterilizing rack near loading door location), with △T of −31 seconds (at first test), −33 seconds (second test), and −40 seconds (third test).

1.2.3 Full-load instrument heat distribution test

1.2.3.1 Temperature probe placement

The temperature probe placement of the full-load dressing heat penetration test is shown in Figure 3. A

Table 1 Time data for each point reaching sterilization temperature in the no-load heat distribution test

Location	First test		Second test		Third test	
	T	△T	T	△T	T	△T
A	14:07:43	−44 s	15:13:31	−45 s	16:16:35	−53 s
B	14:07:34	−53 s	15:13:32	−44 s	16:16:39	−49 s
C	14:07:44	−43 s	15:13:31	−45 s	16:16:39	−49 s
D	14:07:40	−47 s	15:13:32	−44 s	16:16:36	−52 s
E	14:07:56	−31 s	15:13:43	−33 s	16:16:48	−40 s
F	14:07:44	−43 s	15:13:37	−39 s	16:16:45	−43 s
G	14:08:27	0 s	15:14:16	0 s	16:17:28	0 s

Note: T refers to the time point when each test point reached sterilization temperature; △T refers to the time difference between each test point and reference measurement point G reaching sterilization temperature; "−" indicates reaching sterilization temperature earlier than the reference point; and "+" indicates later than the reference point.

total of 18 self-made instrument packs were placed evenly on the three levels of the sterilizing rack. Six temperature probes were placed inside the instrument packs; then the instrument packs containing temperature probes were placed at locations A, B, C, D, E, and F. The sensing part of the probes should not contact instruments or the stainless-steel mesh basket. Another temperature probe at location G was placed inside the chamber drain port, as shown in Figure 2.

1.2.3.2 Full-load instrument heat distribution test

The full-load instrument heat distribution test was applied to investigate the sequence in which the medium inside instrument packs at different locations reached sterilization temperature under full instrument load and to analyze the slowest heating point. The P1 Instrument Sterilization Program was run for testing. Test data are shown in Table 2.

Table 2 Time data for each point reaching sterilization temperature in the full-load instrument heat distribution test

Location	First test		Second test		Third test	
	T	△T	T	△T	T	△T
A	11:09:16	−1 s	13:03:54	0 s	16:04:40	0 s
B	11:09:16	−1 s	13:03:54	0 s	16:04:39	−1 s
C	11:09:17	0 s	13:03:55	1 s	16:04:44	4 s
D	11:09:17	0 s	13:03:54	0 s	16:04:40	0 s
E	11:09:21	4 s	13:03:54	0 s	16:04:40	0 s
F	11:09:17	0 s	13:03:54	0 s	16:04:40	0 s
G	11:07:17	0 s	13:03:54	0 s	16:04:40	0 s

According to the data of the full-load instrument heat distribution test, point C was the slowest heating point twice (1 second and 4 seconds), and point E was the slowest heating point once (4 seconds).

1.2.4 Full-load dressing heat penetration test

1.2.4.1 Temperature probe placement

The temperature probe placement of the full-load dressing heat penetration test is shown in Figure 3. Six temperature probes were placed at the geometric center of six dressing packs, respectively, close to the dressing surface; then the dressing packs containing temperature probes were placed at locations A, B, C, D, E, and F.

1.2.4.2 Test data

The full-load dressing heat penetration test data are shown in Table 3.

According to the data of the full-load dressing heat penetration test, point E was the slowest heating point twice (1 second and 2 seconds), and point C was the slowest heating point once (7 seconds).

2 Results

2.1 After conducting a total of 43 batches of tests

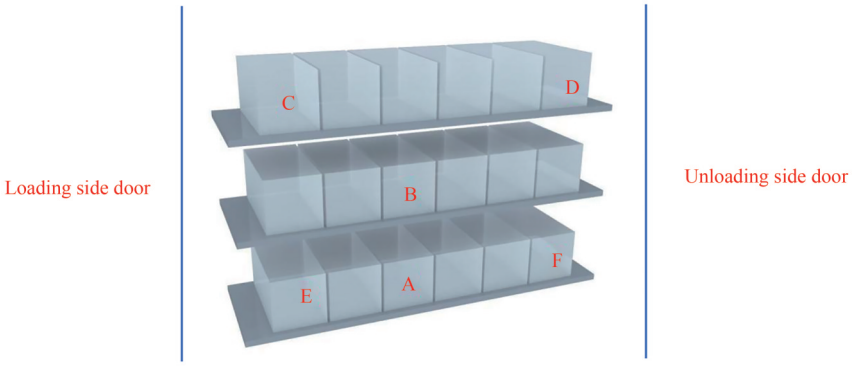

Figure 3 Schematic diagram of temperature probe placement for the loaded test

Table 3 Time data for each point reaching sterilization temperature in the full-load dressing heat penetration test

Location	First test		Second test		Third test	
	T	△T	T	△T	T	△T
A	11:09:57	−9 s	13:21:43	2 s	15:29:06	−6 s
B	11:09:58	−8 s	13:21:38	1 s	15:29:06	−6 s
C	11:10:04	−2 s	13:21:48	7 s	15:29:12	0 s
D	11:10:04	−2 s	13:21:43	2 s	15:29:06	−6 s
E	11:10:05	−1 s	13:21:42	1 s	15:29:14	2 s
F	11:10:04	−2 s	13:21:43	2 s	15:29:06	−6 s
G	11:10:06	0 s	13:21:41	0 s	15:29:12	0 s

on 16 pulse vacuum sterilizers of identical brand and model, the statistics for the slowest heating point at different locations within the sterilizer chamber are shown in Table 4.

Table 4 Statistics of the slowest heating point locations within the sterilizer chamber in 43 batches

Location	A	B	C	D	E	F	G
No-load			1		7		
Instrument load			2		1		
Dressing load			11		21		
Total			14		29		
Percentage (%)			32. 56		67. 44		

Note: G is the reference measurement point.

2.2 For the Belimed MST 9618HS2 pulse vacuum sterilizer, the most difficult-to-sterilize locations were near the loading side door on the sterilizing rack. Among them, the slowest heating point occurred 14 times on the upper level of the sterilizing rack and 29 times on the lower level. This indicates that the location near the loading door on the sterilizing rack has the highest probability of being the slowest heating point, and the lower level has a higher probability than the upper level.

3 Discussion

3.1 The pressure steam sterilization can sterilize items rapidly and reliably using saturated steam[3-5]. When the sterilization pressure remains stable, the key to maintaining the quality of pressure steam sterilization lies in the sterilization temperature and time within the pack[6-7].

3.2 This study is based on the description in the *PDA Technical Report No. 1, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control* where Section 5.0 stipulates that "The appropriate location for physical evaluation and biological indicator challenge testing can be determined by appropriate chamber and load heat distribution studies"; for tests on surface temperature of different loads, Section 5.2.2.2, Qualification of Porous/Hard Goods Sterilization Cycles, states that "Place the BI challenge system at the slowest heating item location, which is generally considered the most difficult location to sterilize". The primary purpose of sterilizer heat distribution validation is to demonstrate the uniformity of heating medium distribution throughout the load zone. By testing and analyzing two performance parameters of the sterilizer, including temperature and time, any deviation from the original design may be determined, and whether the equipment performance meets process requirements can be judged[8]. This study conducted heat distribution tests under no-load and full-load instrument conditions, comparing the sequence in which temperature probes at different locations reached the sterilization temperature and analyzing the slowest heating point. The dressing heat penetration test was applied to verify the conclusion of the slowest heating point drawn from the heat distribution test and to validate the sterilization performance under full dressing load conditions[9].

3.3 Understanding and discussion of "most difficult-to-sterilize location"

The "most difficult-to-sterilize location" can be defined as a certain volume of sterilization space. For example, the fully loaded sterilizing rack of this model can be considered as having a space volume equivalent to 18 standard baskets. This study has preliminarily identified the most difficult-to-sterilize location within the sterilization chamber, where the probability of sterilization failure is highest. Therefore, during installation and commissioning, before the equipment is put into use, no-load and load temperature tests can be conducted to analyze the slowest heating point of the sterilizer, determine the most difficult-to-sterilize location, and confirm steriliza-

tion performance. However, it should be noted that changes in loaded items, packaging materials, or loading methods may cause the location of the slowest heating point to fluctuate. Sterilization temperature is a critical parameter of sterilizer performance. Using a temperature and pressure detector to test the sterilization parameters of a sterilizer can objectively reflect its operational status[10]. Regular testing of sterilization parameters has already played an important role in monitoring in CSSD[11].

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