plasmapp

PLA-TIR-I-2021-M013-00

TEST·INSPECTION REPORT

Residual Sterilant on Tyvek® Validation

Manufacturer Name: Plasmapp Co., Ltd.

Representative: Youbong, LIM

Location: BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon, 34141, Republic of Korea

Product Name: Low temperature plasma sterilizer and sterilant

Brand Name: STERLINK™ and STERMATE™

Model Name: STERLINK mini and STERLOAD™ mini

Serial Number: M07BUH027A and SM21J002

Test·Inspection Item: Residual Sterilant on Tyvek® Validation

Testing Laboratory: Plasmapp Research Institute

Location: 372, Dongbu-daero, Osan-si, Gyeonggi-do, 18151, Republic of Korea

Tested until: 13 Oct. 2021 **Issued Date:** 15 Oct. 2021

Test manager: 전 현 정 **Approver:**

Hyun Jeong, JEON
Senior researcher

Youbong, LIM
Chief Executive Officer

Plasmapp Research Institute

Residual Sterilant on Tyvek® Validation

1. Test schedule

1.1 Date of test beginning: 06 Oct. 2021

1.2 Date of test completion: 13 Oct. 2021

2. Test article

Low temperature plasma sterilizer (STERLINK mini, S/N: M07BUH027A)

Sterilant (STERLOAD™ mini, Lot No.: SM21J002)

3. Test guideline

3.1 The tests were performed in accordance with the internal test standard.

3.2 Information of testing materials

3.2.1 Test sample

Product	Sterilization Roll Made with Tyvek®
Manufacturer	SIGMA Medical Supplies Corp.
Lot Number	912A
Expiration date	Jan. 2023
Comments	The sterilization wrap which has sterilization process indicator.

3.2.2 Validation load*

Test sample (Width × Length, cm)	**Validation load**	
	Medical devices	**Total weight [lbs]**
Six sealed test sample (10 × 10)	Stainless steel scissors	1.54

3.2.3 Hydrogen peroxide test strip

Item	**Details**
Product	WaterWorks™ Low Range Peroxide Check
Manufacturer	Industrial Test Systems, Inc.
Lot Number	060321H
Expiration date	May. 2023
Comments	It can detect the hydrogen peroxide from 0.05-4.0 ppm. (0.05, 0.3, 0.5, 1.0, 2.0, 4.0 ppm)

*Figure of the validation load was referred to the Appendix 1.

3.2.4 Sterilant

Brand	STERMATE™
Model	STERLOAD™ mini
Lot Number	SM21J002
Expiration date	Sep. 2022
Manufacturer	Plasmapp Co., Ltd.
Comments	Sterilant cassette for STERLINK mini

3.2.5 Measuring instrument

Equipment	Manufacturer	Model	Internal S/N	Calibration date
High temperature data logger	MADGETECH	HiTemp140	PO-C-025	16 Feb. 2021
Pressure data logger	MADGETECH	PR140	PQ-C-031	10 Feb. 2021

3.3 Test methods

(1) The sterilization roll was cut into 6 pieces each 10 × 10 (Width × Length, cm) size and sealed as test samples.

(2) The validation load was placed in the chamber as shown Figure 1.1 (a) of Appendix 1.

(3) Six sealed test samples were put on the validation load in the chamber.

(4) The prepared validation load and the test samples were processed with full cycle sterilization of the chamber mode. The temperature and pressure during the sterilization process was measured.

(5) After sterilization cycle, each test sample was left in the chamber with the chamber lid open for 0, 10, 30, 60, 120 and 300 seconds, and then removed from the chamber and put in each bottle which has 250 ml distilled water.

(6) The bottle was shaken for 10 seconds to elute the hydrogen peroxide remaining in test sample.

(7) One hydrogen peroxide test strip was dipped into the water sample in the bottle and shaken gently back and forth for 5 seconds.

(8) The test strip removed from the water sample and shaken once briskly to remove excess water.

(9) After 30 seconds, the color of the test strip was match to the color chart, and the hydrogen peroxide concentration was recorded.

(10) For the negative control, the test strip which was dipped in the distilled water in the bottle without test sample was used.

(11) The validation test except the negative control test was repeated three times.

4. Test results**

4.1 Results of the validation test

Test number	Aeration time [s]	Hydrogen peroxide concentration [ppm, $mg \cdot L^{-1}$]
Negative control		< 0.05
1	0	< 0.3
	10	< 0.3
	30	≤ 0.05
	60	≤ 0.05
	120	< 0.05
	300	< 0.05
2	0	≤ 0.3
	10	≤ 0.3
	30	< 0.3
	60	< 0.3
	120	≤ 0.05
	300	≤ 0.05
3	0	≤ 0.3
	10	< 0.3
	30	< 0.3
	60	< 0.3
	120	≤ 0.05
	300	< 0.05

4.2. Pressure parameter data during sterilization process [Torr]

Test number	Sterilization phase 1		Sterilization phase 2		Purification
	Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Final base[c] (< 3 Torr)
1	0.78	43.7	0.89	46.5	0.58
2	0.58	46.7	0.78	50.2	0.70
3	0.69	47.6	1.17	46.5	1.23

**The related figures were referred to the Appendix 2. The time evolution of pressures and temperature during sterilization process inside the chamber were described in the Appendix 3, as well.

[a]The base pressure just before injection of the sterilant.

[b]The diffusion pressure after diffusion of the sterilant which is complete.

[c]The base pressure after injection and purification.

4.3. Temperature parameter data during sterilization process [°C]

Test number	Sterilization phase 1			Sterilization phase 2		
	Load[d] (40-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)	Load[d] (40-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)
1	49.6 – 58.2	56.1 – 57.7	112 – 124	52.7 – 59.1	57.6 – 59.3	113 – 124
2	45.8 – 56.8	57.2 – 58.6	115 – 122	48.2 – 58.7	57.2 – 58.4	116 – 127
3	47.3 – 57.2	57.3 – 58.2	119 – 123	48.8 – 59.2	56.9 – 59.1	115 - 121

4.4. Time parameter data during sterilization process [s]

Test number	Sterilization phase 1 (300 ± 1 s)	Sterilization phase 2 (300 ± 1 s)
1	300	300
2	300	300
3	300	300

5. Conclusions

(1) As a result of the validation test, when the aeration time was 2 min or more, the concentration of hydrogen peroxide remaining in the test sample was detected as 0.05 ppm or less.

(2) According to the test results, the aeration time required after the chamber mode sterilization process is at least 2 min.

[d]The load temperature is measured by the temperature data logger described in 3.2.5.
[e]The chamber temperature is controlled by K-type thermocouple.
[f]The vaporizer temperature is controlled by K-type thermocouple.

Appendix 1

1. Residual sterilant on Tyvek® validation test

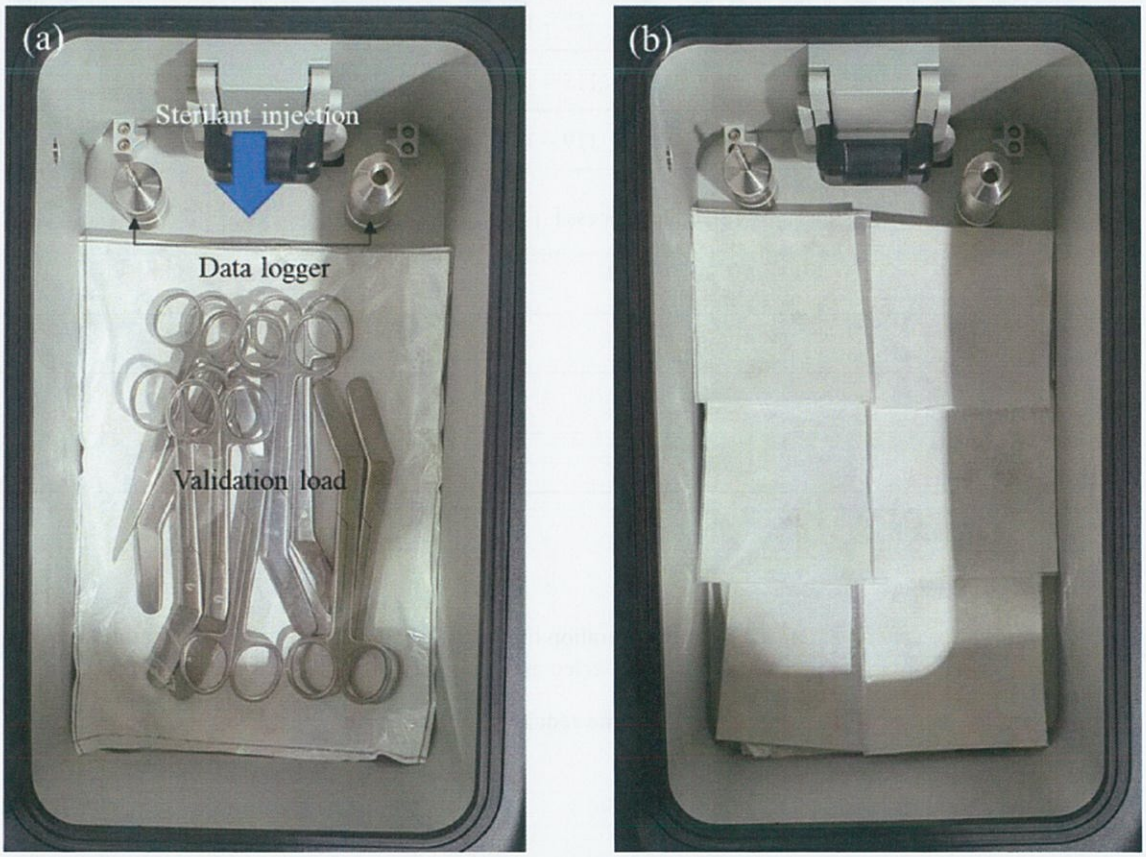

Figure 1.1 (a) The position of validation load and data loggers in the chamber and (b) the test samples were placed on the validation load.

Appendix 2

1. Results of the residual sterilant on Tyvek® validation test

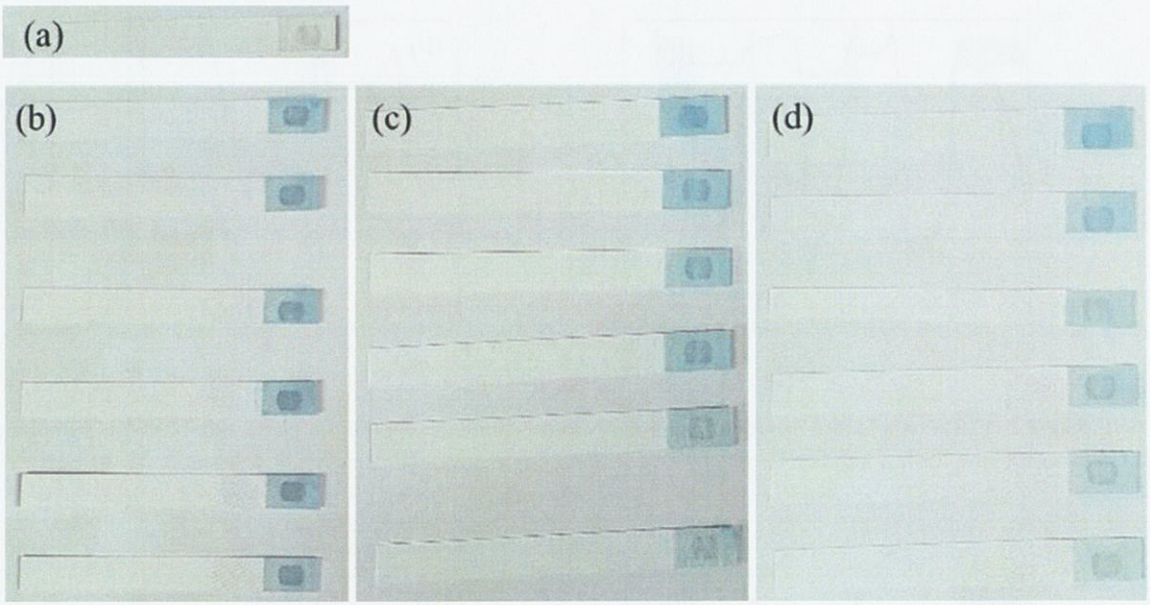

Figure 2.1 Color change result of hydrogen peroxide strip in (a) negative control and (b-d) three validation tests. It is a test sample aeration for 0, 10, 30, 60, 120, and 300 seconds in order from the top in each validation test figure.

Appendix 3

1. Pressure and temperature curves of the residual sterilant on Tyvek® validation test

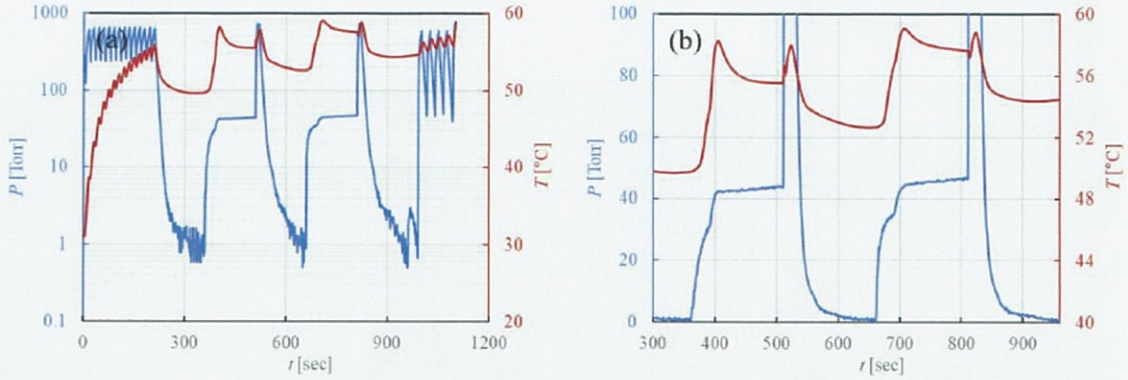

Figure 3.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 1.

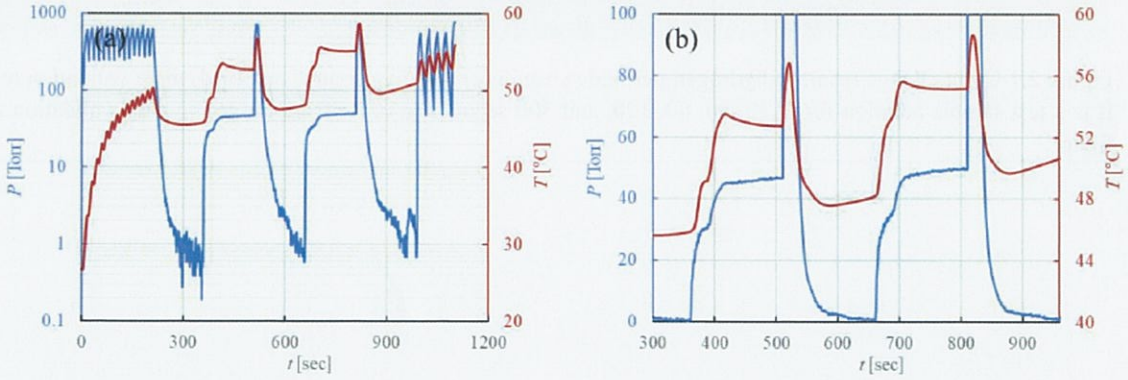

Figure 3.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 2.

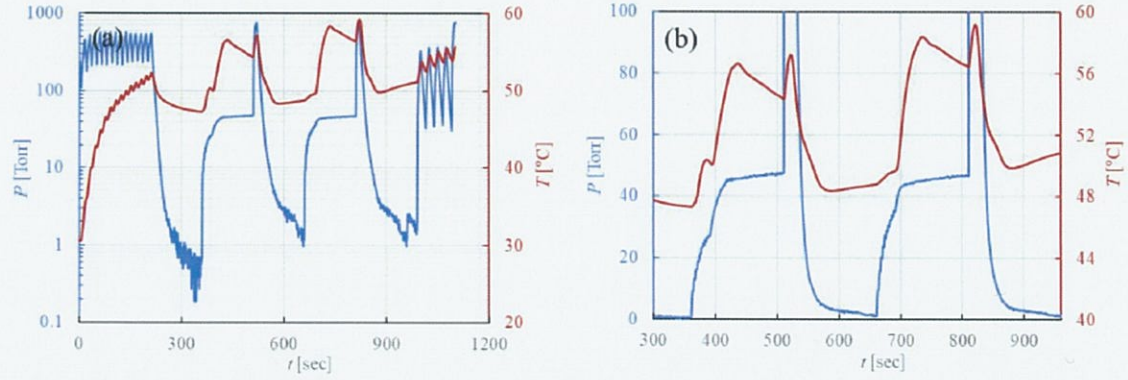

Figure 3.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 3.