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: FPS-15s Plus (FPS-15s^{+}) and STERLOAD®

Serial Number: P15RFA1I and SL20K009

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:	26 Feb. 2021	**Issued Date:**	04 Mar. 2021
Tested by:	전현정	**Approved by:**	이승헌
	Hyun Jeong, JEON Process Inspector		Seung Hun, LEE General Director of R&D

Plasmapp Research Institute

Residual Sterilant on Tyvek® Validation

1. Test schedule

1.1 Date of test beginning: 24 Feb. 2021

1.2 Date of test completion: 26 Feb. 2021

2. Test article

Low temperature plasma sterilizer (STERLINK® FPS-15s Plus, S/N: P15RFA1I)

Sterilant (STERLOAD®, Lot No.: SL20K009)

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, mm)	**Validation load**	
	Medical devices	**Total weight [lbs]**
Six sealed test sample (10 × 10)	Stainless steel scissors	3.97

3.2.3 Hydrogen peroxide test strip

Item	**Details**
Product	WaterWorks™ Low Range Peroxide Check
Manufacturer	Industrial Test Systems, Inc.
Lot Number	030819H
Expiration date	Feb. 2021
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 loads was referred to the Appendix 1.

3.2.4 Sterilant

Brand	STERMATE®
Model	STERLOAD®
Lot Number	SL20K009
Expiration date	Nov. 2021
Manufacturer	Plasmapp Co., Ltd.
Comments	Sterilant cassette for STERLINK®

3.2.5 Measuring instrument

Equipment	Manufacturer	Model	Internal S/N	Calibration date
High temperature data logger	MADGETECH	HiTemp140	PO-C-020	27 Oct. 2020
Pressure data logger	MADGETECH	PR140	PO-C-018	26 Oct. 2020

3.3 Test methods

(1) The sterilization roll was cut into 6 pieces each 10 × 10 (Width × Length, mm) 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 aeration time validation test except the negative control test was repeated three times.

4. Test results**

4.1 Results of the aeration time validation test

Test number	Aeration time [s]	Hydrogen peroxide concentration [ppm, mg·L^{-1}]
Negative control		< 0.05
1	0	0.5 – 1.0
	10	0.3 - 0.5
	30	0.3 – 0.5
	60	0.05 - 0.3
	120	≤ 0.05
	300	< 0.05
2	0	0.3 - 0.5
	10	0.05 – 0.3
	30	0.05 - 0.3
	60	0.05 – 0.3
	120	≤ 0.05
	300	< 0.05
3	0	0.3 - 0.5
	10	0.3 - 0.5
	30	0.3 - 0.5
	60	0.05 - 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	0.10	34.8	0.92	33.6	0.49
2	1.20	32.8	0.01	33.6	0.92
3	0.30	28.2	0.98	30.2	1.73

**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] (50-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)	Load[d] (50-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)
1	53.4 – 57.8	55.4 - 57.2	117 - 123	53.8 – 58.1	56.4 - 58.0	118 - 124
2	52.0 – 56.4	55.7 – 58.2	112 - 121	53.1 – 57.2	55.9 – 58.3	115 - 126
3	51.6 – 56.5	55.4 – 56.8	113 - 123	52.0 – 56.8	55.7 – 58.9	119 - 125

4.4. Time parameter data during sterilization process [s]

Test number	Sterilization phase 1 (450 ± 1 s)	Sterilization phase 2 (450 ± 1 s)
1	450	450
2	450	450
3	450	450

5. Conclusions

(1) As a result of the aeration validation time 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. Aeration time validation test

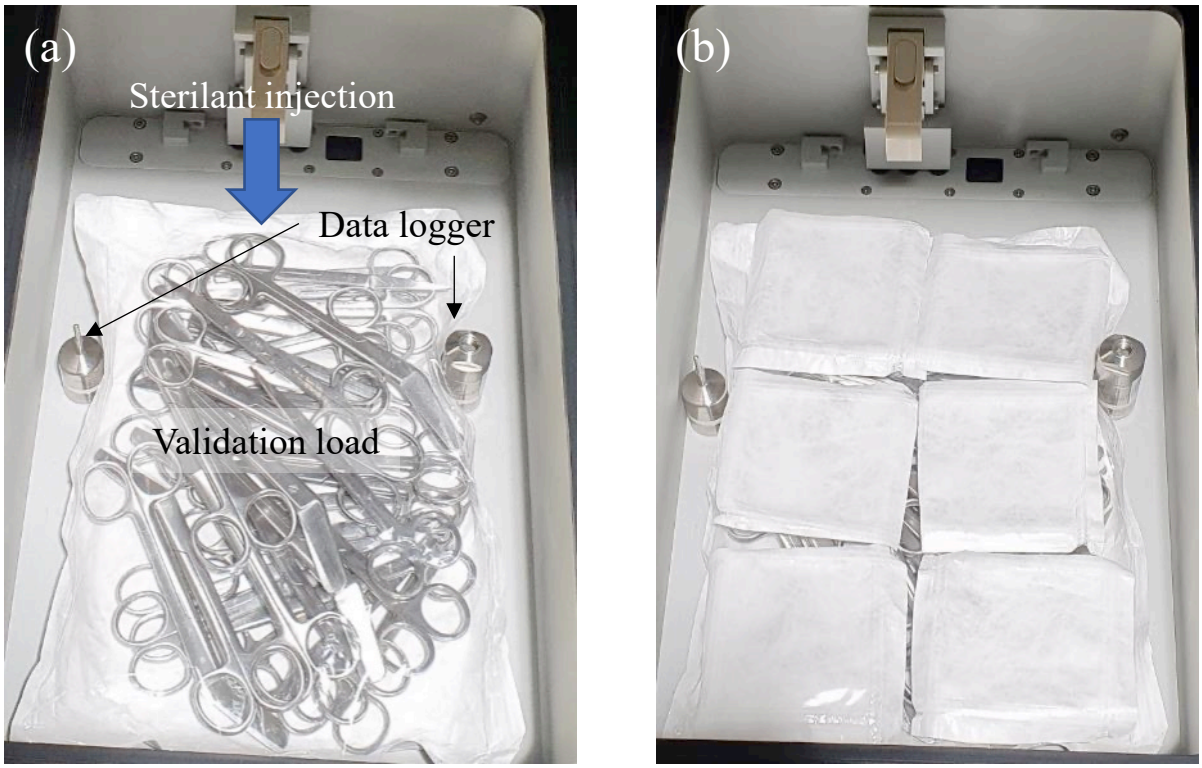

Figure 1.1 (a) The position of validation load and data loggers in the chamber and (b) the test samples were placed on the validation load.

Appendix 2

1. Results of the aeration time validation test

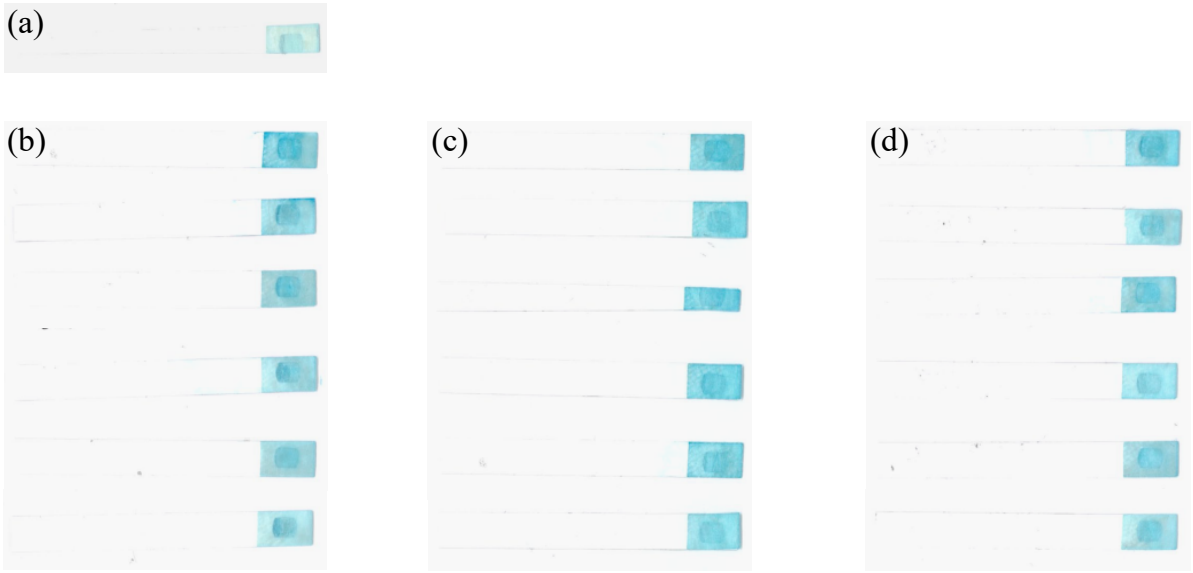

Figure 2.1 Color change result of hydrogen peroxide strip in (a) negative control and (b-d) three validation tests. It is a test sample aeration for 0, 10, 30, 60, 120, and 300 seconds in order from the top in each validation test figure.

Appendix 3

1. Pressure and temperature curves of the aeration time validation test

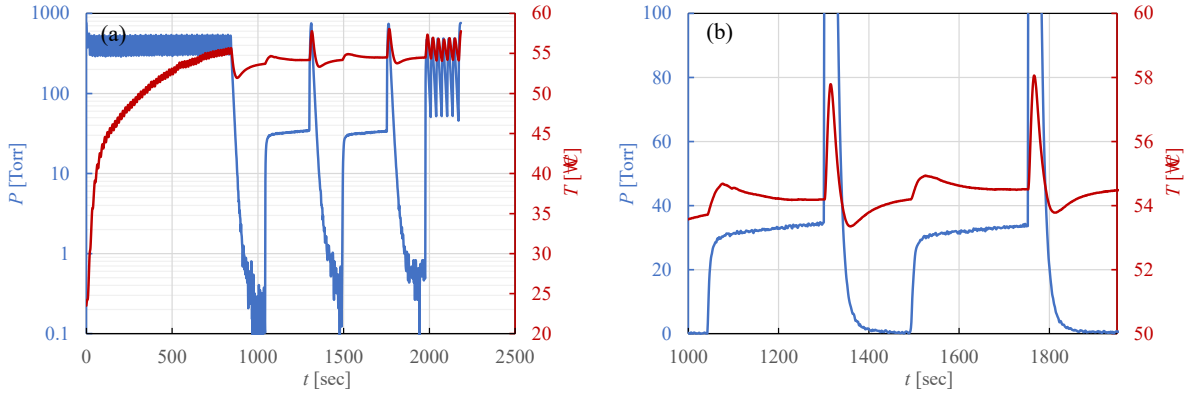

Figure 3.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 1.

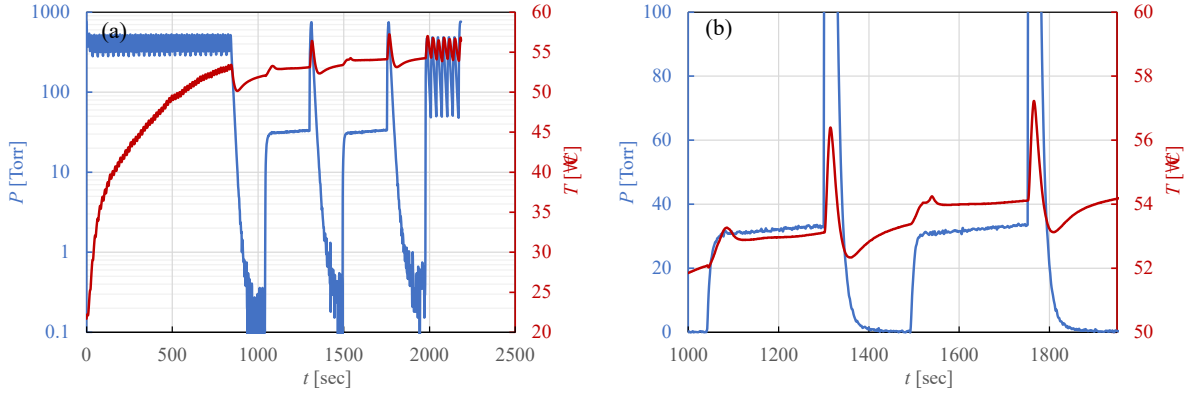

Figure 3.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 2.

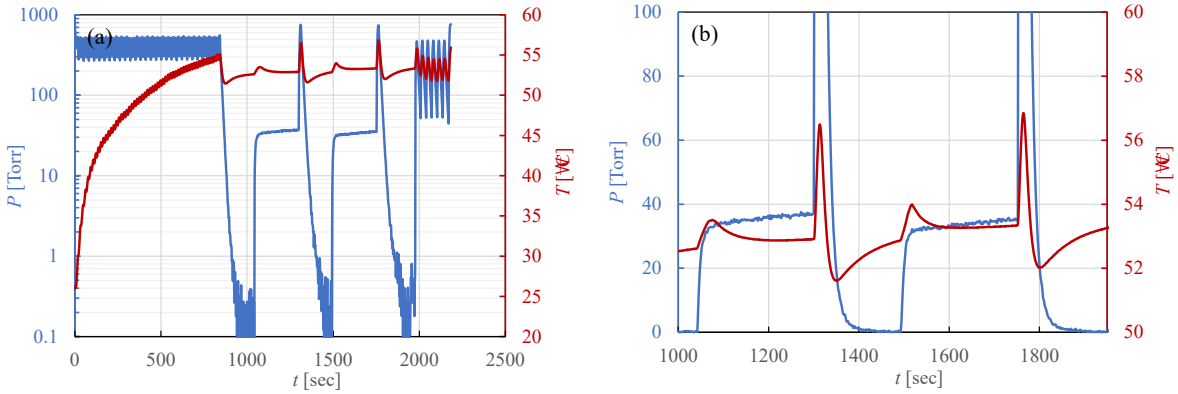

Figure 3.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for test number 3.