TEST·INSPECTION REPORT

Hydrogen Peroxide Gas Detection (TWA)

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: P15RIA1R and SL20F009

Test·Inspection Item: Hydrogen Peroxide Gas Detection

Testing Laboratory:

Human & Environment Research Lab. (주)사람과 환경 연구소 Human & Environment Research Lab.
397, Seokcheon-ro, Bucheon-si, Gyeonggi-do, 14449, Republic of Korea

Decision: Pass

Plasmapp Research Institute

Hydrogen Peroxide Gas Detection (TWA)

1. Test schedule

1.1 Date of test beginning: 14 Jul. 2020

1.2 Date of test completion: 25 Aug. 2020

2. Test article

Low temperature plasma sterilizer (STERLINK® FPS-15s Plus, S/N: P15RIA1R)

Sterilant (STERLOAD®, Lot No.: SL20F009)

3. Test guideline

3.1 The tests were performed in accordance with the standard of Occupational Safety and Health Administration.

3.2 Information of testing materials

3.2.1 Air Sample Collector*

Item	Details
Product	Personal Sampling Pumps
Model	TUFF™
Manufacturer	CASELLA CEL

3.2.2 Spectroscopy*

Item	Details
Product	UV-vis Spectrophotometer
Model	UV-1280
Manufacturer	Shimadzu

*Figure of the equipment was referred to the Appendix 1.

3.2.3 Sterilant

Brand	STERMATE®
Model	STERLOAD®
Lot Number	SL20F009
Expiration date	Jun. 2021
Manufacturer	Plasmapp Co., Ltd.
Comments	Sterilant cassette for STERLINK®

3.2.4 Measuring instrument

Equipment	Manufacturer	Model	Internal S/N	Calibration date
High temperature data logger	MADGETECH	HiTemp140	PO-C-025	27 Sep. 2019
Pressure data logger	MADGETECH	PR140	PQ-C-014	23 Jun. 2020

3.3 Test methods

A quartz filter (25 mm, Titanium oxysulfate hydrate coated) was mounted on a personal air sample collector and the air had been collected with a pump flow rate of 1 $L \cdot min^{-1}$. After pretreatment of the collected sample, the concentration was calculated by the following equation after quantitative analysis with a UV-vis spectrophotometer. The evaluation of the results was made through comparison in accordance with permissible exposure limits (PEL) of occupational safety and health administration (OSHA).

$$C = \frac{(W - B)}{V} \times \frac{24.45}{MW}$$

C: Concentration of the subject substance [ppm]

W: Amount of collected sample [μg]

B: Amount of control (not exposed sample) [μg]

V: Total collected air [L]

24.45: Volume of the air of 1 mol at 25ºC and 1 atm [L]

MW: Molecular weight

Hydrogen peroxide exhausted from the low-temperature plasma sterilizers (FPS-15s Plus was measured for 6 hours. The FPS-15s Plus performed six times of chamber mode sterilization cycles, and the temperature and pressure during the sterilization process were measured. Measurements of the hydrogen peroxide are based on the time weighted average (TWA) for one working day at the outlet and proposed respiratory area (1 - 1.5 m within the radius of the main user) as described in Figure 2.1.

4. Test results**

4.1 Results of the hydrogen peroxide gas detection test

Position	Result [ppm]	Criterion [ppm]	Decision
Gas outlet	0.0149	< 1	Pass
Respiratory area	0.0022	< 1	Pass

4.2. Pressure parameter data during sterilization process [Torr]

Cycle 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	0.2	38.4	0.3	36.2	0.4
2	0.2	35.7	0.4	34.7	0.5
3	0.1	39.1	0.4	36.5	0.3
4	0.2	36.1	0.2	36.9	0.2
5	0.4	32.7	0.6	36.9	0.5
6	0.01	37.8	0.5	37.6	0.7

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

Cycle 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	55.6 - 56.4	112 - 124	54.0 - 58.3	55.7 - 56.5	115 - 125
2	53.1 - 57.5	55.4 - 56.7	114 - 121	53.7 - 57.9	55.2 - 56.6	114 - 126
3	54.3 - 58.4	55.5 - 56.6	115 - 122	54.8 - 58.9	55.3 - 56.4	112 - 123
4	53.6 - 58.2	55.7 - 56.5	112 - 123	54.2 - 58.7	55.5 - 56.3	117 - 124
5	53.4 - 57.6	55.4 - 56.4	117 - 125	53.9 - 58.1	55.4 - 56.5	112 - 122
6	52.9 - 57.8	55.2 - 56.4	115 - 125	53.6 - 58.4	55.5 - 56.6	115 - 127

**The time evolution of pressure and temperature inside the chamber during the sterilization process 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.

[d]The load temperature is measured by the temperature data logger described in 3.2.4.

[e]The chamber temperature is controlled by K-type thermocouple.

[f]The vaporizer temperature is controlled by K-type thermocouple.

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
4	450	450
5	450	450
6	450	450

5. Conclusions

The TWA of hydrogen peroxide exhausted from the FPS-15s Plus sterilizer was measured in accordance with OSHA's methods, and the results were less than 1 ppm. Accordingly, it was determined that the concentration of hydrogen peroxide exhausted from the subject device met the OSHA's PEL standard.

Appendix 1

1. Equipment

Figure 1.1 Air sample collector

Figure 1.2 UV-vis spectrophotometer

Appendix 2

1. Position of collectors

Figure 2.1 Position of the air sample collectors.

Appendix 3

1. Pressure and temperature curves during sterilization process

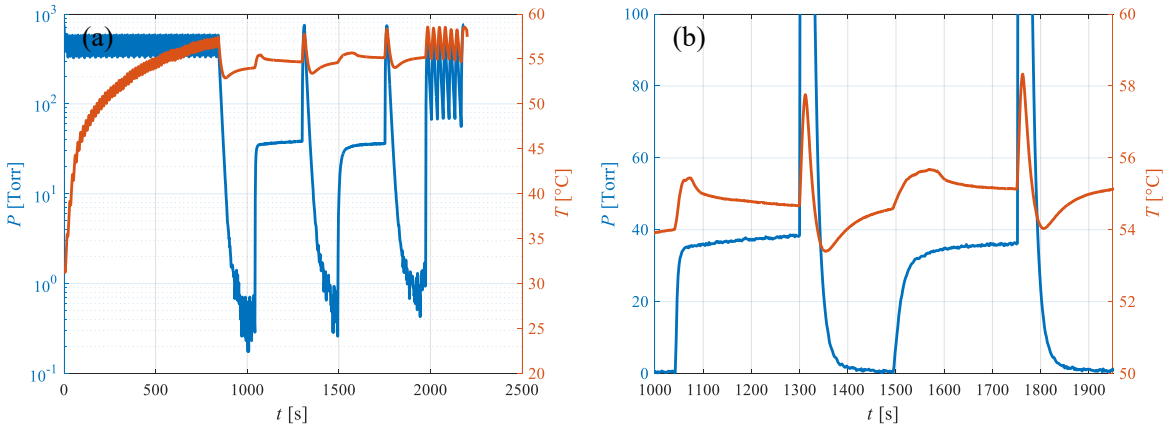

Figure 5.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 1.

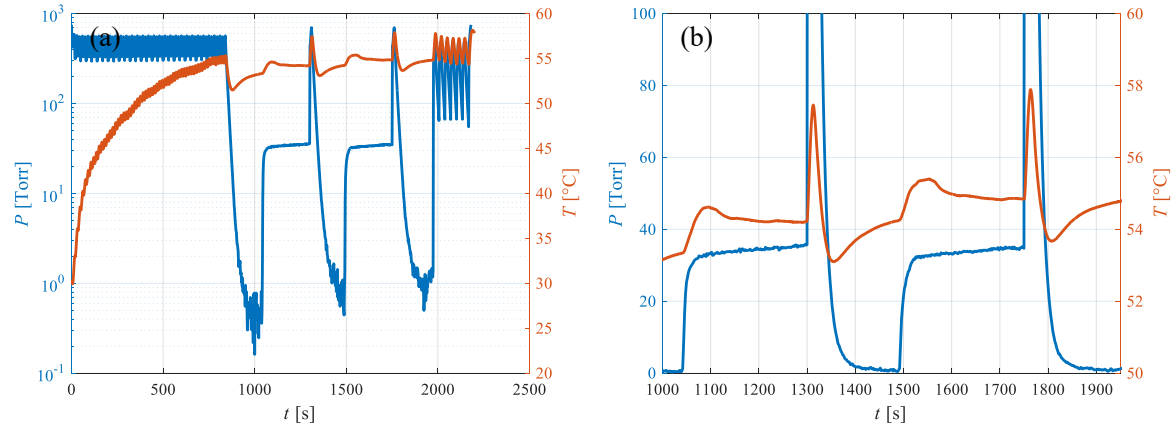

Figure 5.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 2.

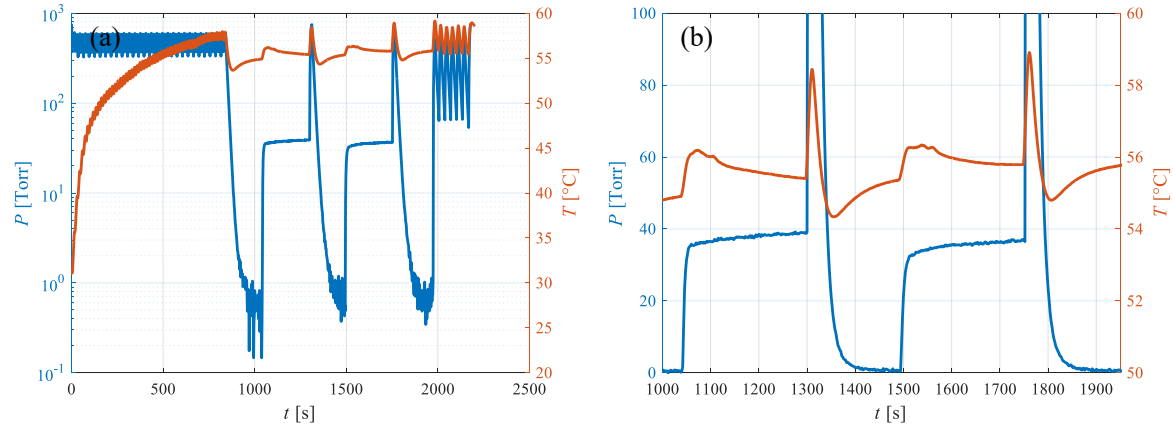

Figure 5.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 3.

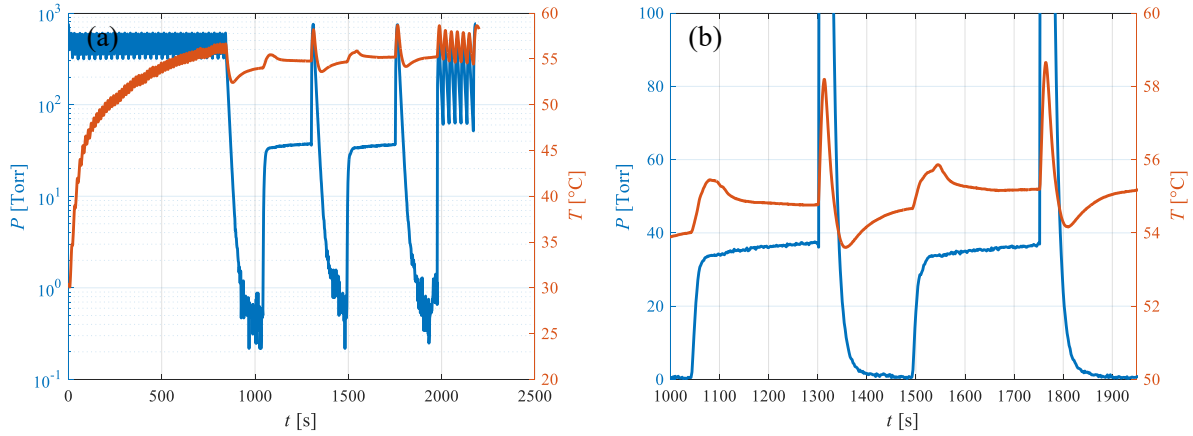

Figure 5.4 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 4.

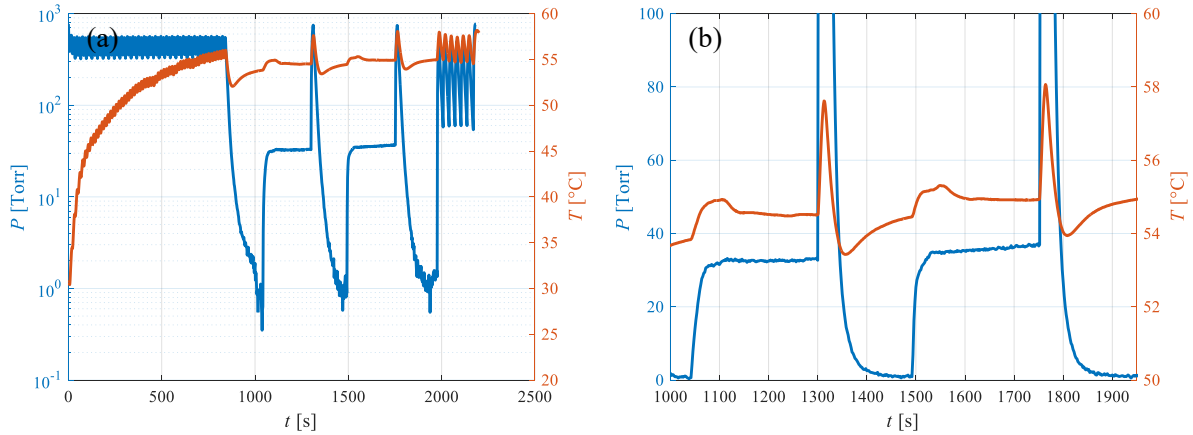

Figure 5.5 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 5.

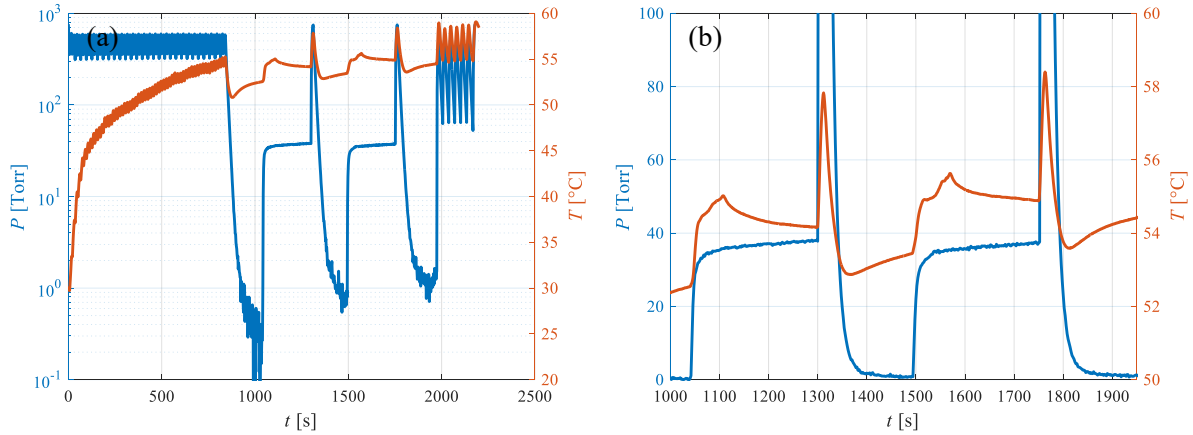

Figure 5.6 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 6.