

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 STERPACK™ plus

Serial Number: P15RGA1J and SX22B006

Test·Inspection Item: Hydrogen Peroxide Gas Detection

Testing Laboratory:

Human & Environment Research Lab.  (주)사람과 환경 연구소
Human & Environment Research Lab.
92, Jomaru-ro 385 beon-gil, Bucheon-si, Gyeonggi-do, 14558, Republic of Korea

Decision: Pass

Plasmapp Research Institute



Hydrogen Peroxide Gas Detection (TWA)

1. Test schedule

1.1 Date of test beginning: 16 Mar. 2022

1.2 Date of test completion: 28 Mar. 2022

2. Test article

Low temperature plasma sterilizer (STERLINK™ FPS-15s Plus, S/N: P15RGA1J)

Sterilant (STERPACK™ plus, Lot No.: SX22B006)

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 Air Sampling Pump
Model	GILIAN-BDX II
Manufacturer	SENSIDYNE

3.2.2 Spectroscopy*

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

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

3.2.3 Sterilant

Brand	STERMATE™
Model	STERPACK™ plus
Lot Number	SX22B006
Expiration date	Feb. 2023
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	18 Feb. 2022
Pressure data logger	MADGETECH	PR140	PO-C-035	18 Jan. 2022

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·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 25°C 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 fifteen times of pouch plus 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 15 cm from the outlet 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	0.0036	< 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	0.57	33.7	0.54	34.3	0.26
2	0.31	32.2	0.48	31.1	0.29
3	1.21	34.2	0.93	32.6	0.14
4	0.29	22.6	0.62	27.7	0.07
5	0.66	38.9	0.04	38.8	0.31
6	0.60	30.8	0.32	34.7	0.32
7	0.72	29.1	0.69	34.5	0.13
8	0.37	33.2	0.20	35.6	0.59
9	0.45	36.4	0.88	38.5	0.59
10	0.41	34.8	0.47	41.4	0.02
11	0.42	21.0	0.24	24.3	0.47
12	0.42	26.3	0.70	30.0	0.75
13	0.41	30.4	0.32	31.2	0.32
14	0.46	29.1	0.24	34.3	0.88
15	0.63	28.8	0.46	30.7	0.66

**The time evolution of pressure and temperature inside the STERPACK™ plus during the sterilization process were described in the Appendix 3, as well.

^aThe base pressure just before injection of the sterilant.

^bThe diffusion pressure after diffusion of the sterilant which is complete.

^cThe base pressure after injection and purification.

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

Cycle 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	47.4 - 58.7	57.8 - 58.9	117 - 121	50.0 - 58.1	57.8 - 58.5	119 - 121
2	48.2 - 58.7	58.2 - 59.2	119 - 121	48.6 - 59.1	58.6 - 59.0	117 - 119
3	48.3 - 57.0	57.7 - 58.6	119 - 121	50.1 - 56.5	57.5 - 58.1	118 - 120
4	45.9 - 58.3	56.9 - 58.5	117 - 118	47.8 - 59.4	56.9 - 57.9	118 - 121
5	46.6 - 58.2	56.5 - 59.0	119 - 120	48.2 - 59.7	56.6 - 58.6	115 - 121
6	47.1 - 53.2	58.5 - 59.8	119 - 122	49.5 - 59.3	58.8 - 59.4	117 - 121
7	45.5 - 57.3	57.9 - 58.9	119 - 121	47.6 - 59.8	59.3 - 59.6	119 - 121
8	47.3 - 57.8	56.2 - 57.5	114 - 120	47.4 - 58.9	55.9 - 56.7	118 - 121
9	49.2 - 59.1	57.3 - 58.7	119 - 121	50.6 - 59.6	57.0 - 57.8	119 - 122
10	48.8 - 55.4	58.8 - 59.5	120 - 121	49.5 - 59.7	57.7 - 58.5	119 - 121
11	49.5 - 57.0	58.0 - 59.0	116 - 120	51.7 - 59.6	57.6 - 58.3	115 - 119
12	43.9 - 56.9	57.0 - 58.8	119 - 120	48.8 - 58.9	57.3 - 57.9	119 - 120
13	46.0 - 58.1	56.3 - 57.4	118 - 119	48.6 - 58.3	56.4 - 57.2	119 - 121
14	47.7 - 58.3	57.8 - 58.8	119 - 121	48.9 - 59.1	57.4 - 58.1	116 - 121
15	46.4 - 58.8	56.5 - 57.8	120 - 121	48.5 - 57.3	56.4 - 57.1	117 - 118

^dThe load temperature is measured by the temperature data logger described in 3.2.4.

^eThe chamber temperature is controlled by K-type thermocouple.

^fThe vaporizer temperature is controlled by K-type thermocouple.

4.4. Time parameter data during sterilization process [s]

Test number	Sterilization phase 1 (250 ± 1 s)	Sterilization phase 2 (250 ± 1 s)
1	250	250
2	250	250
3	250	250
4	250	250
5	250	250
6	250	250
7	250	250
8	250	250
9	250	250
10	250	250
11	250	250
12	250	250
13	250	250
14	250	250
15	250	250

5. Conclusions

The TWA of hydrogen peroxide exhausted from the FPS-15s Plus sterilizer during the pouch plus mode 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 during the pouch plus mode met the OSHA's PEL standard.

Appendix 1

1. Equipment



Figure 1.1 Air sample collector

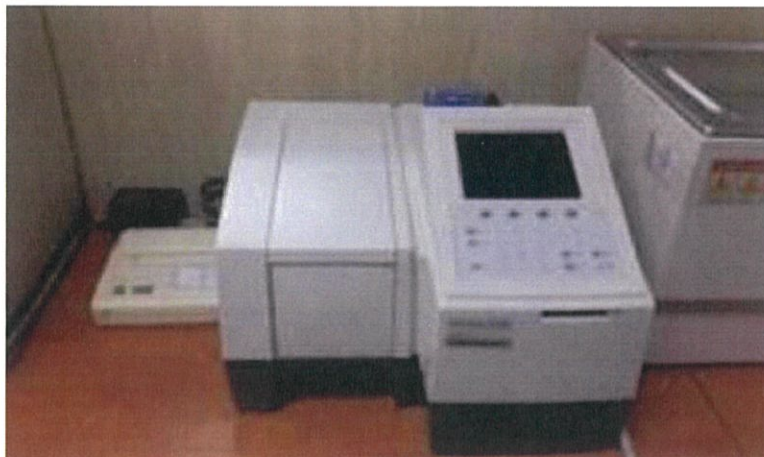


Figure 1.2 UV-vis spectrophotometer

Appendix 2

1. Position of collectors



Figure 2.1 Position of the air sample collector.

Appendix 3

1. Pressure and temperature curves during sterilization process

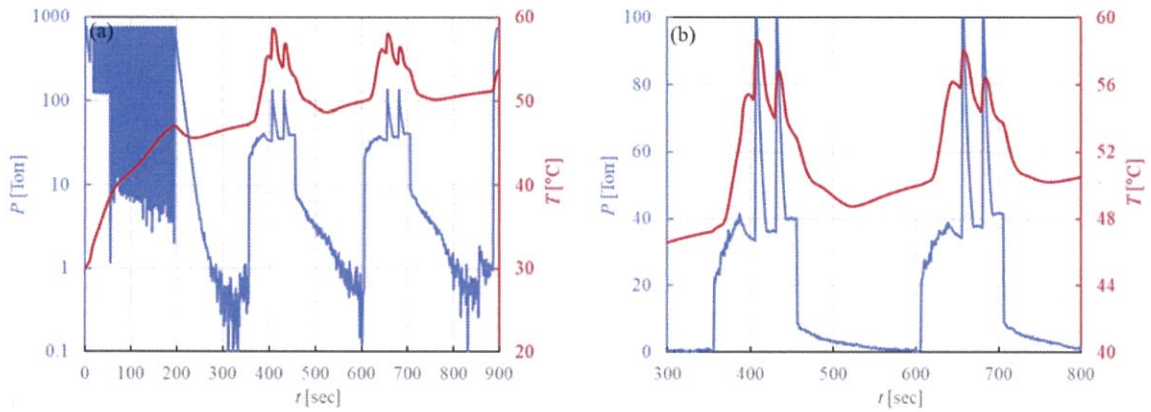


Figure 3.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 1.

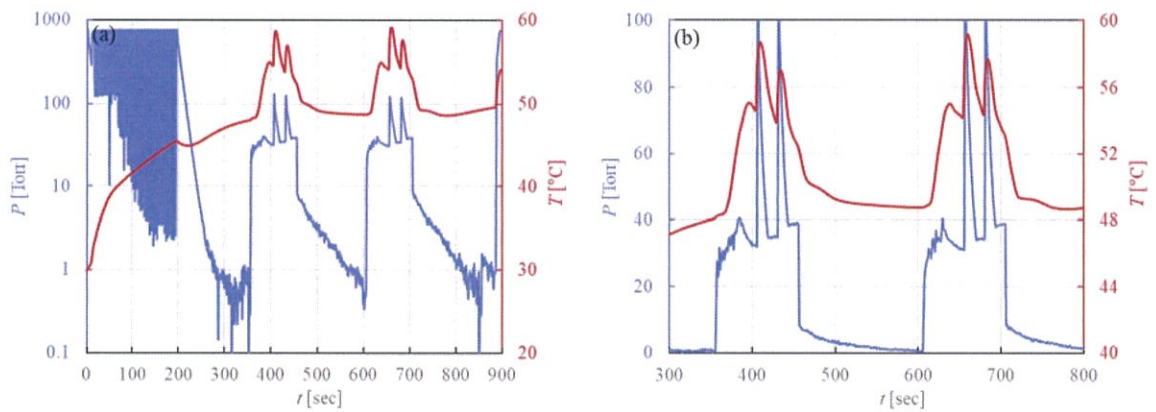


Figure 3.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 2.

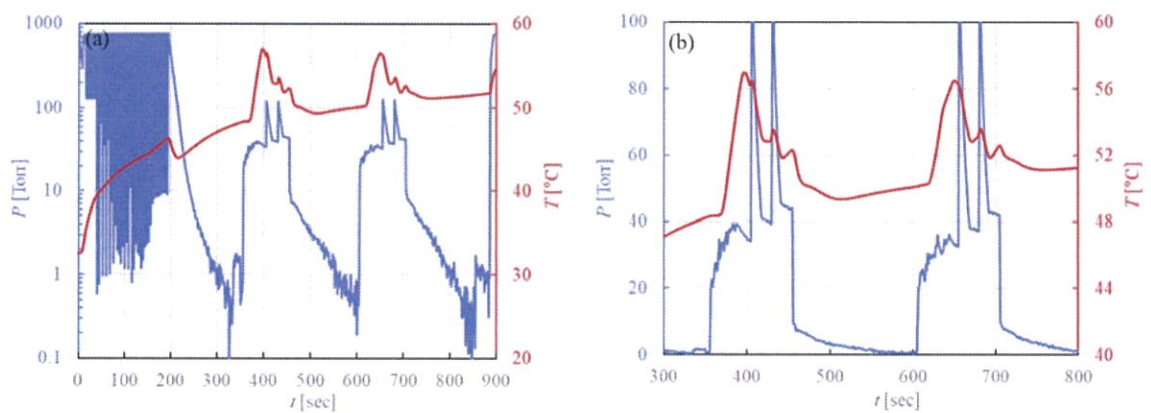


Figure 3.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 3.

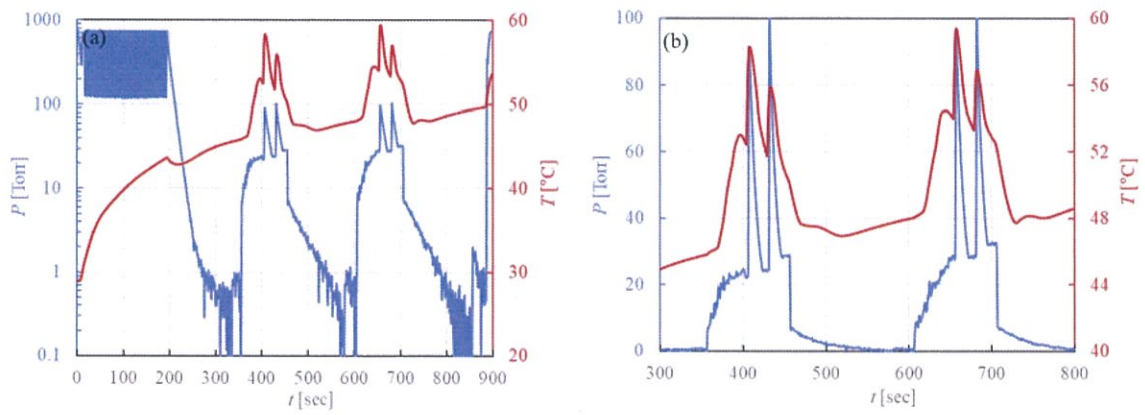


Figure 3.4 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 4.

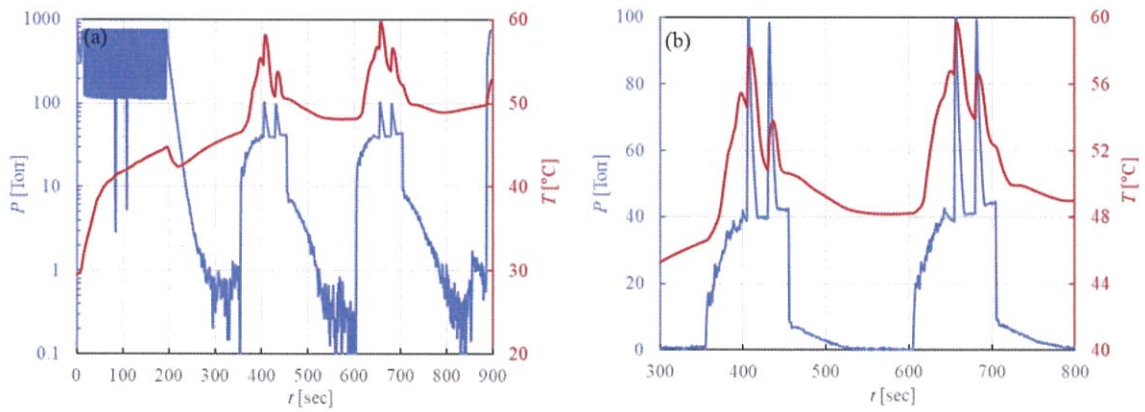


Figure 3.5 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 5.

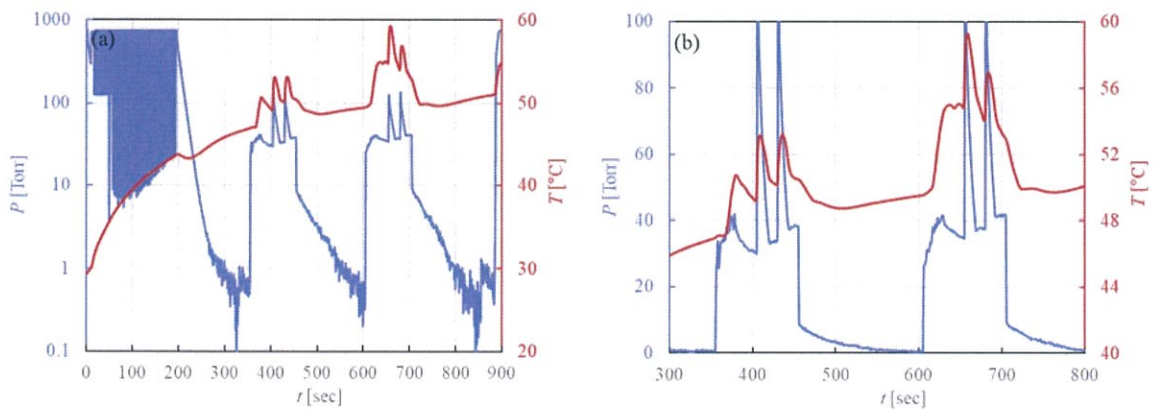


Figure 3.6 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 6.

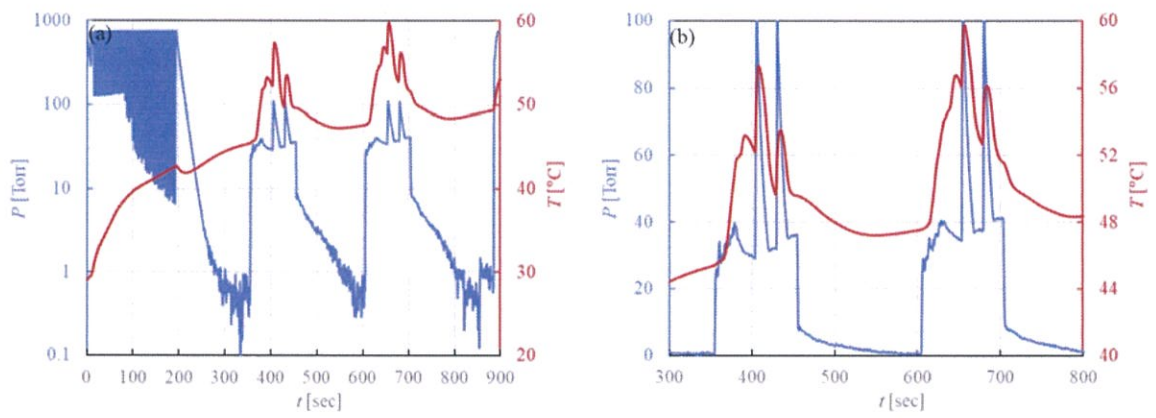


Figure 3.7 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 7.

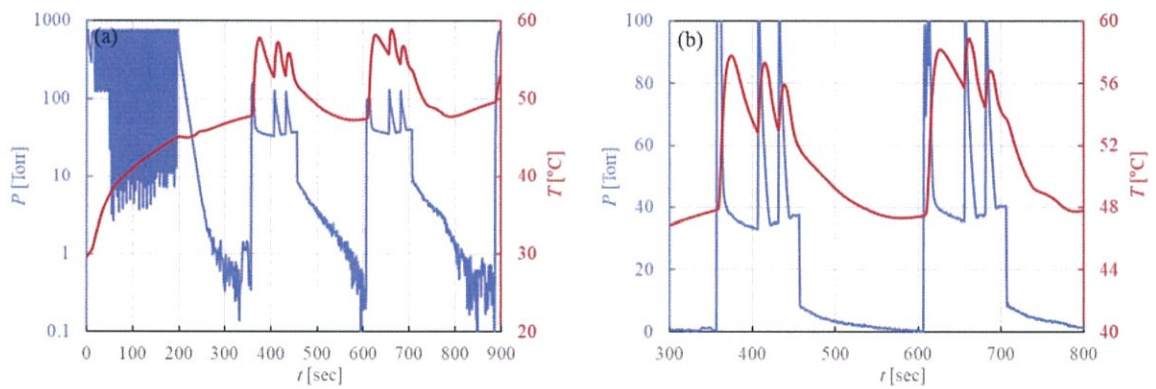


Figure 3.8 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 8.

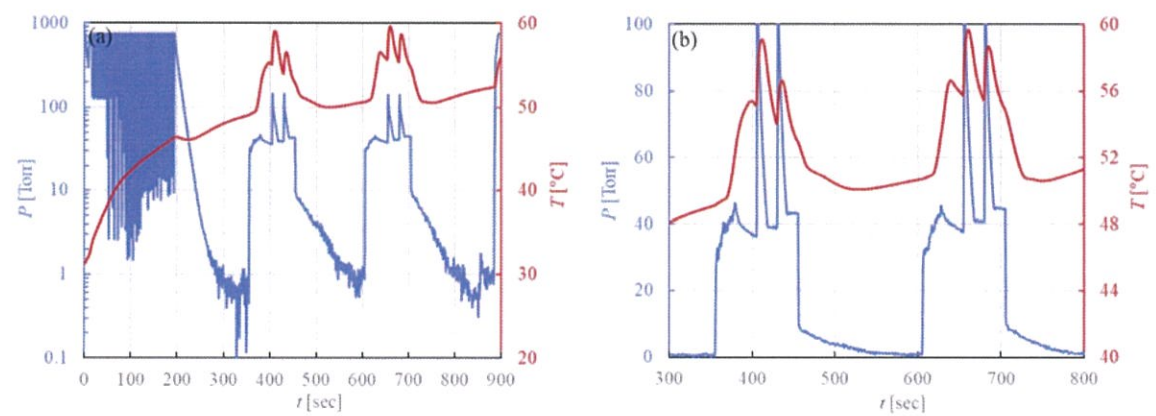


Figure 3.9 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 9.

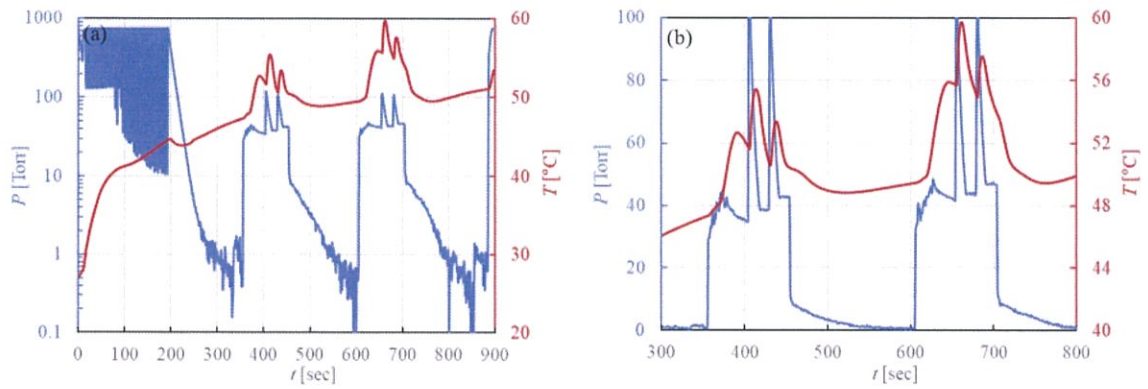


Figure 3.10 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 10.

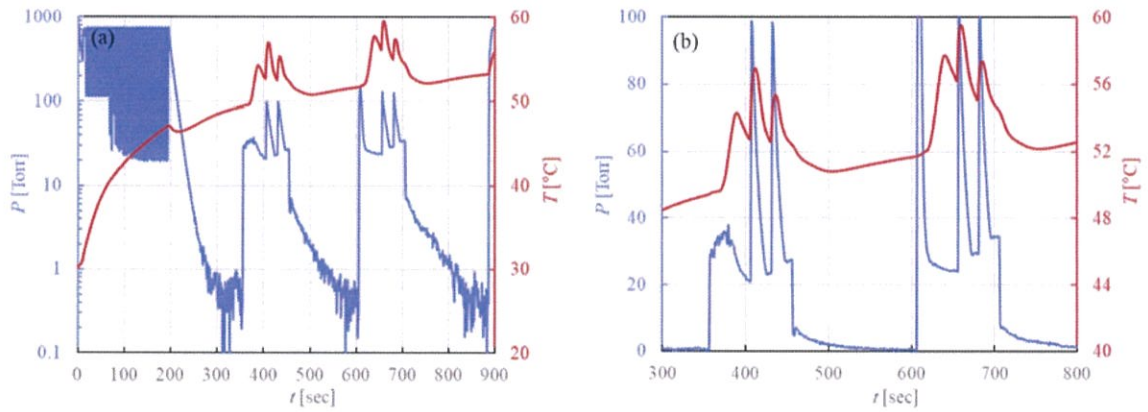


Figure 3.11 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 11.

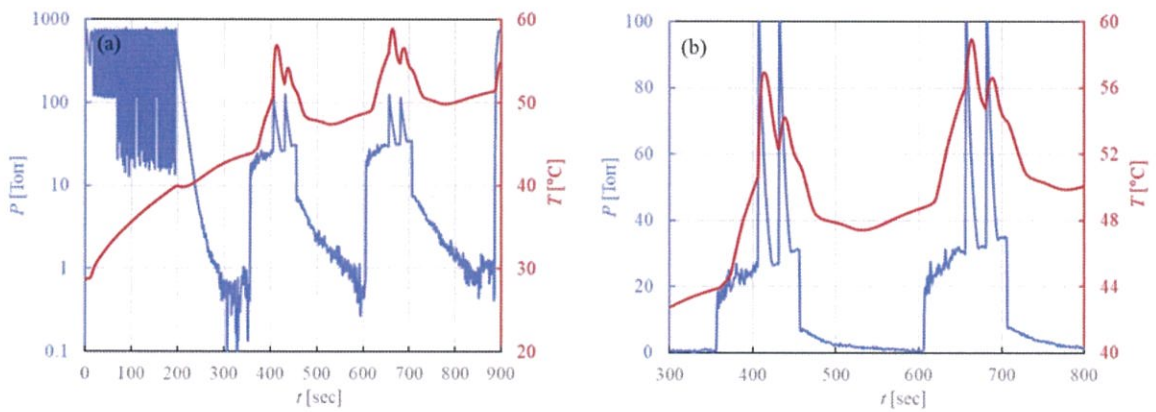


Figure 3.12 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 12.

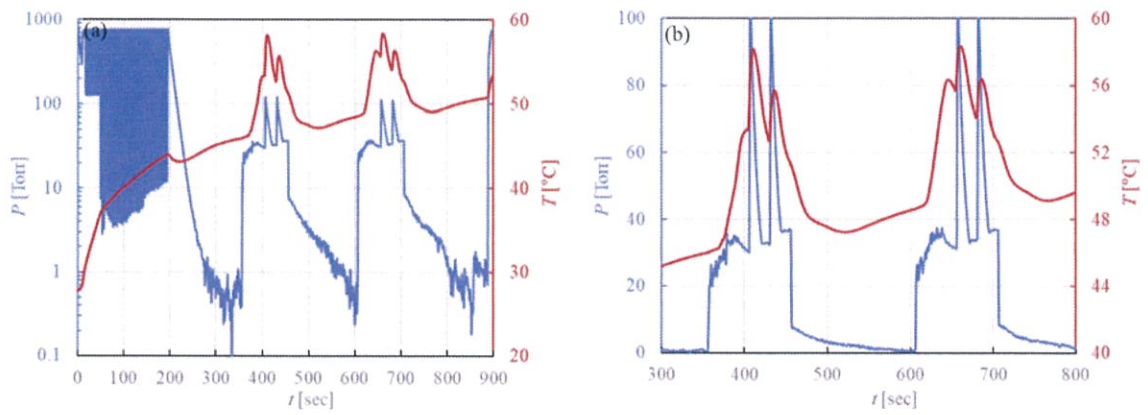


Figure 3.13 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 13.

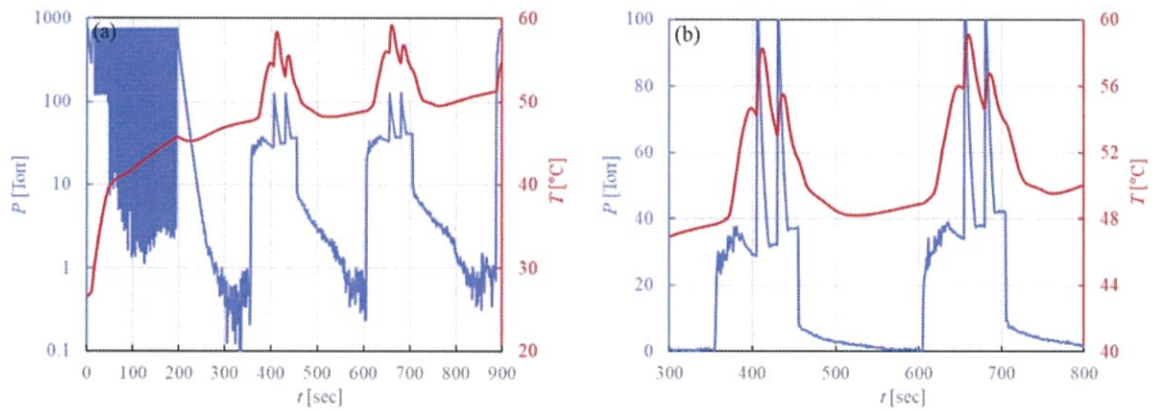


Figure 3.14 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 14.

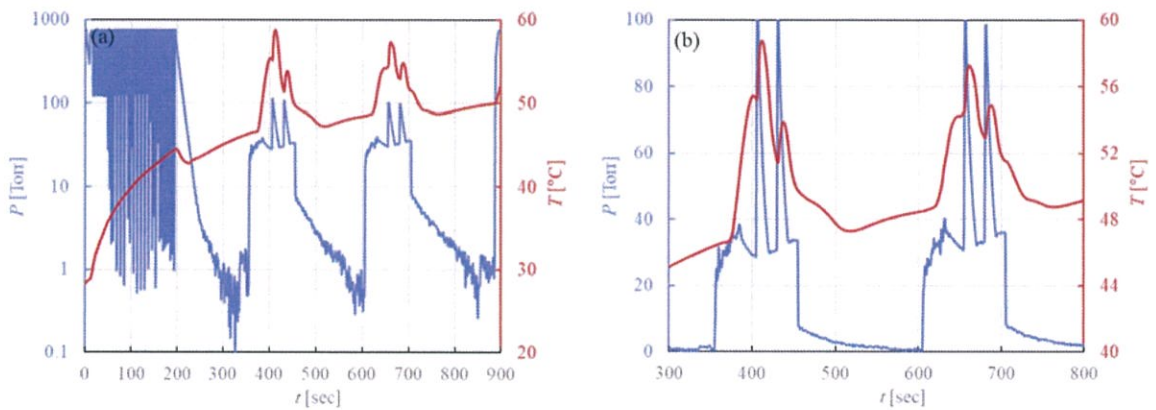


Figure 3.15 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 15.