

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: STERLINK mini and STERLOAD™ mini

Serial Number: M07BUG037A and SM20E008

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 mini, S/N: M07BUG037A)

Sterilant (STERLOAD™ mini, Lot No.: SM20E008)

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™ mini
Lot Number	SM20E008
Expiration date	May. 2021
Manufacturer	Plasmapp Co., Ltd.
Comments	Sterilant cassette for STERLINK mini

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·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 sterilizer (STERLINK mini) was measured for 6 hours. The STERLINK mini performed eleven 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	0.0093	< 1	Pass
Respiratory area	0.0122	< 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	0.01	47.3	0.89	51.9	1.09
2	0.27	44.0	1.29	50.8	1.29
3	0.50	47.4	0.98	49.2	1.09
4	0.19	50.1	0.78	55.2	0.70
5	0.50	47.6	1.17	52.0	1.40
6	0.58	50.5	2.19	53.1	2.08
7	0.01	47.6	0.89	53.3	0.89
8	0.08	35.6	1.09	40.7	1.68
9	0.21	47.7	1.48	51.1	1.40
10	0.19	47.6	0.78	52.1	1.17
11	0.12	34.9	0.70	32.1	0.27

**The time evolution of pressure and temperature inside the chamber 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	46.1-56.1	56.1-59.5	115-121	46.7-58.2	55.5-59.8	114 – 121
2	43.5-54.4	55.7-59.1	115-123	42.5-52.7	55.4-56.1	115 – 124
3	49.0-57.3	55.2-58.5	120-122	50.0-59.1	56.2-58.9	118 – 120
4	44.2-57.1	55.7-59.5	114-124	45.1-57.8	57.8-59.2	112 – 124
5	49.9-57.1	55.6-59.8	115-121	52.1-58.8	57.5-59.0	116 – 123
6	43.8-58.0	55.2-57.0	114-123	47.2-58.9	55.6-58.8	115 – 119
7	48.4-53.3	56.1-57.9	112-120	53.3-55.5	57.8-59.3	112 – 120
8	40.9-55.9	55.3-58.1	117-124	41.3-58.6	55.5-59.3	115 – 121
9	43.3-57.9	57.1-59.7	112-121	45.8-59.3	56.4-59.9	118 – 123
10	46.7-57.1	57.3-58.9	114-123	48.1-59.4	57.5-59.1	119 – 121
11	40.1-50.6	57.9-59.6	116-121	40.4-48.9	57.4-59.5	117 - 122

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
4	300	300
5	300	300
6	300	300
7	300	300
8	300	300
9	300	300
10	300	300
11	300	300

^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.

5. Conclusions

The TWA of hydrogen peroxide exhausted from the STERLINK mini 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

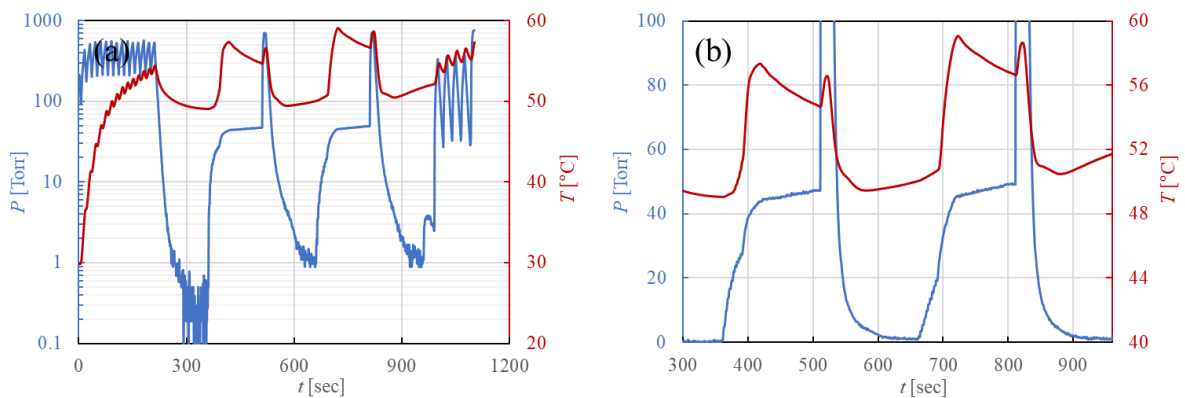
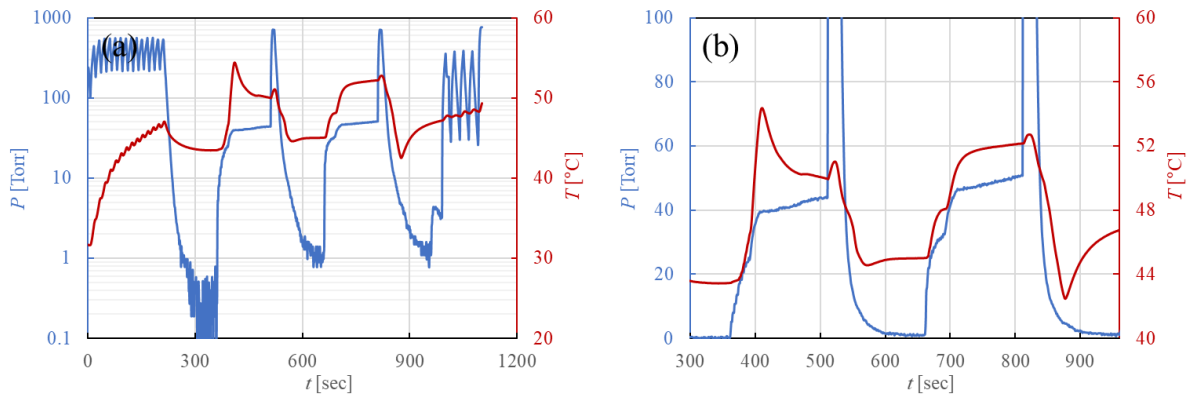
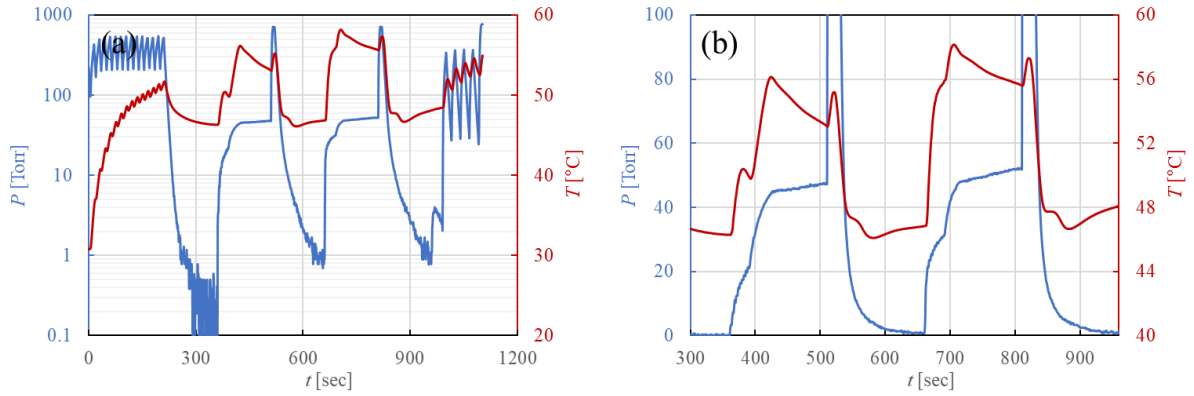
1. Position of collectors



Figure 2.1 Position of the air sample collectors.

Appendix 3

1. Pressure and temperature curves during sterilization process



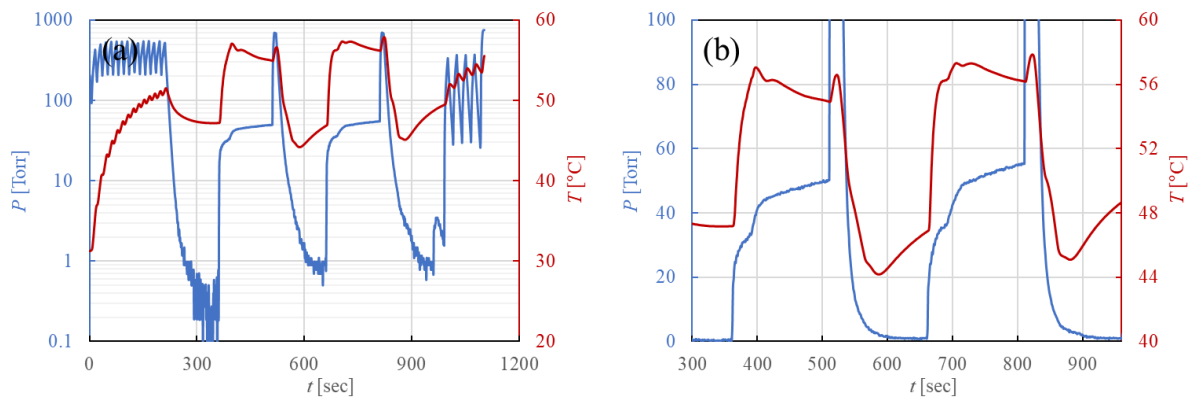


Figure 3.4 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 4.

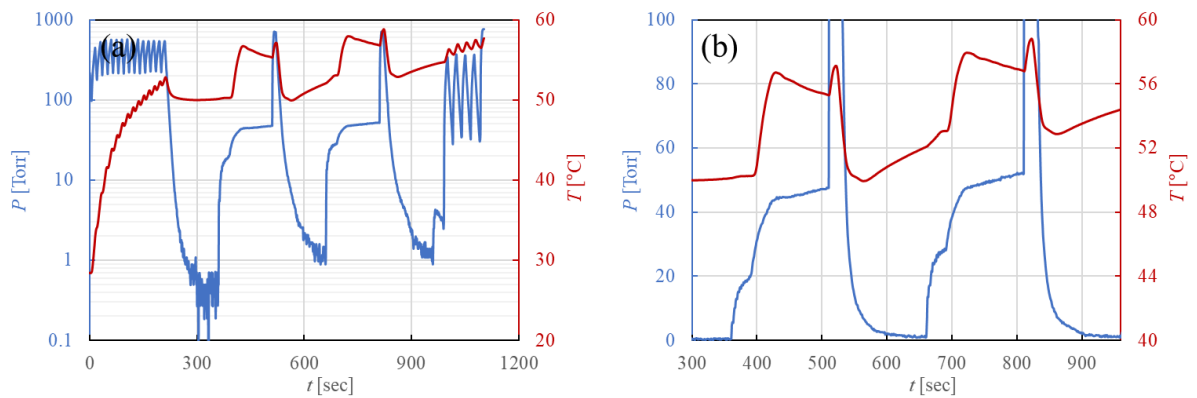


Figure 3.5 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 5.

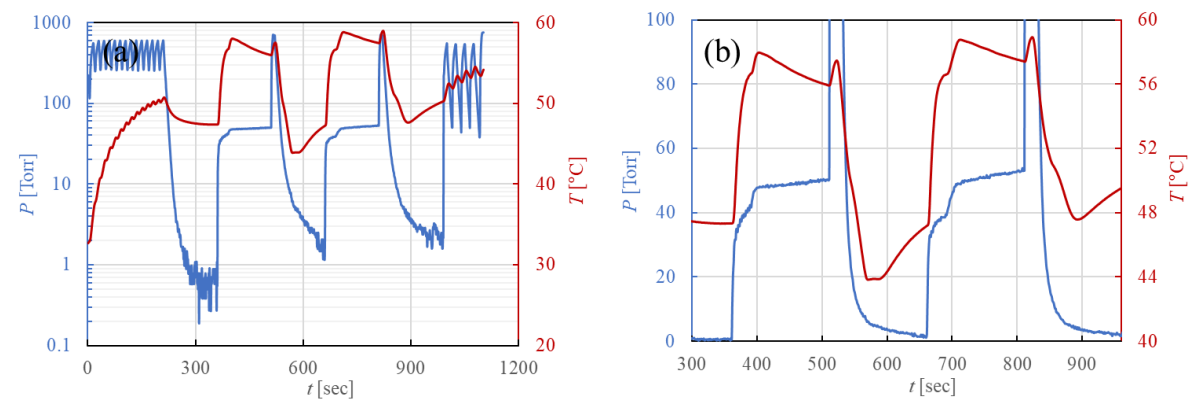


Figure 3.6 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 6.

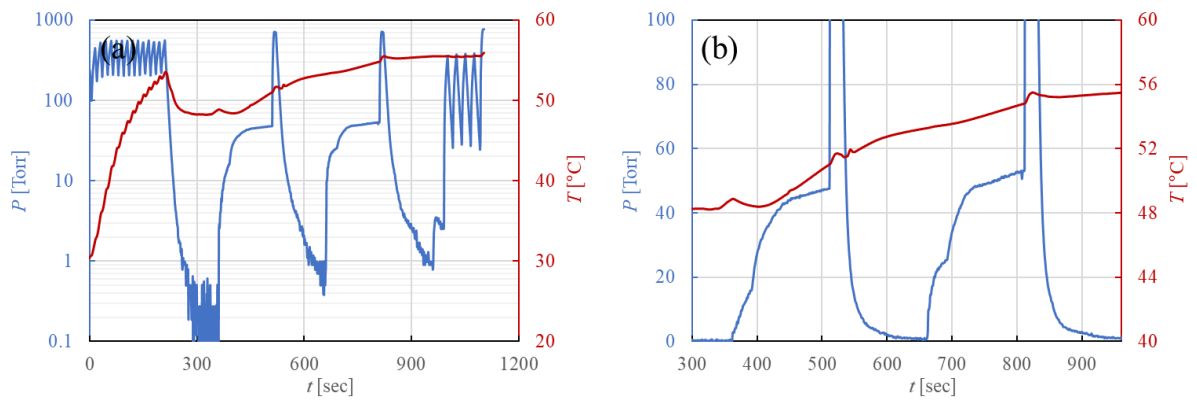


Figure 3.7 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 7.

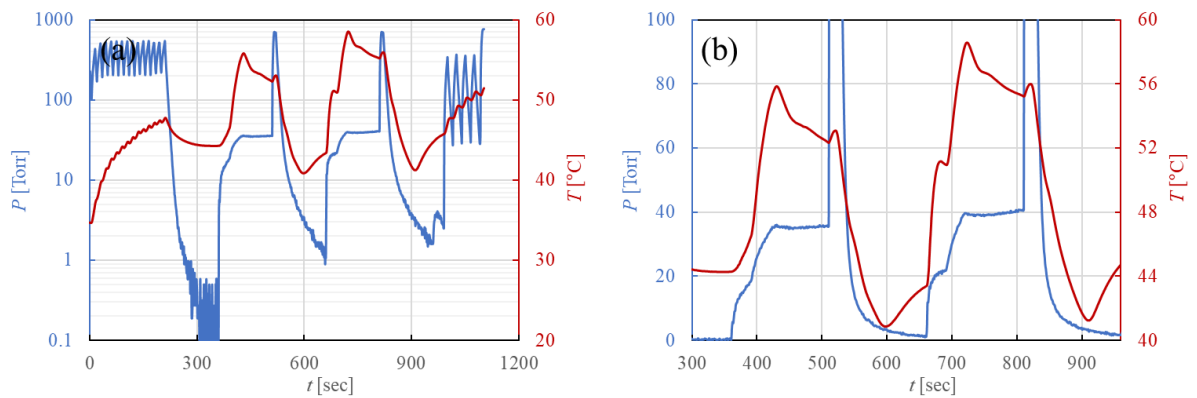


Figure 3.8 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 8.

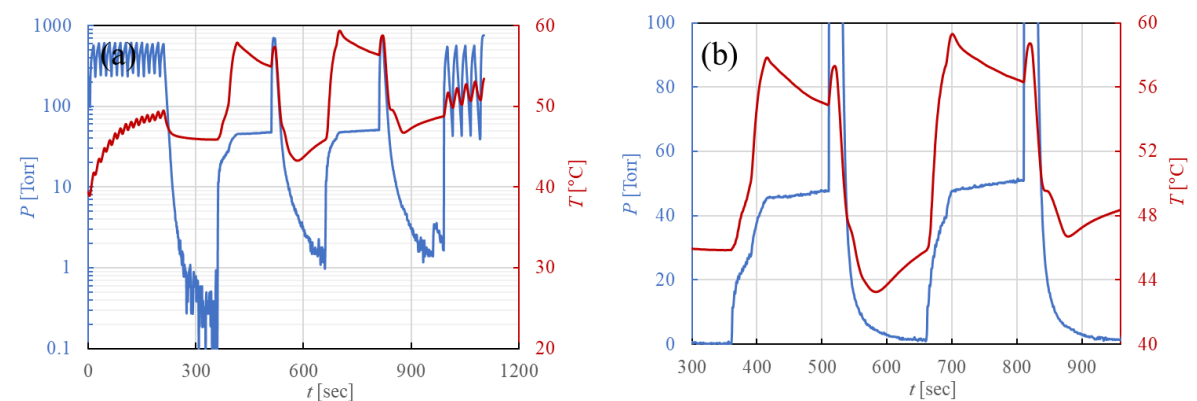


Figure 3.9 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 9.

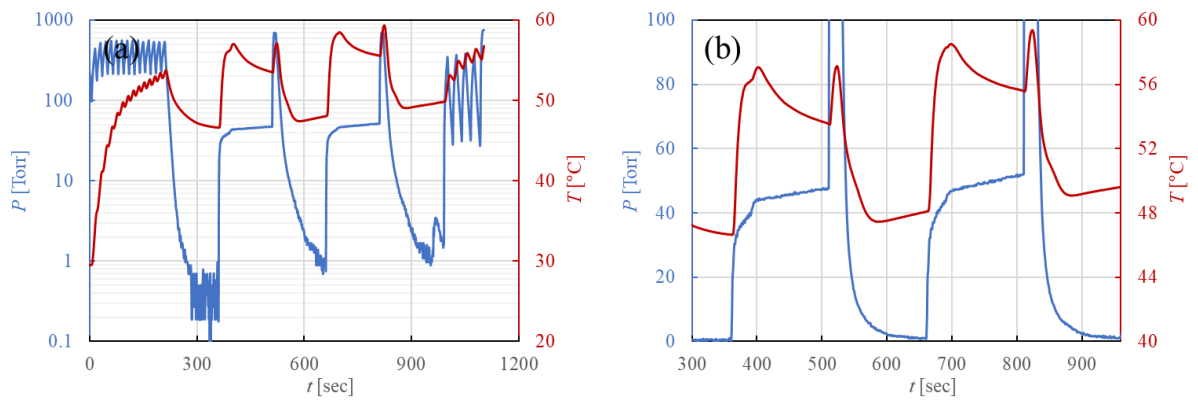


Figure 3.10 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 10.

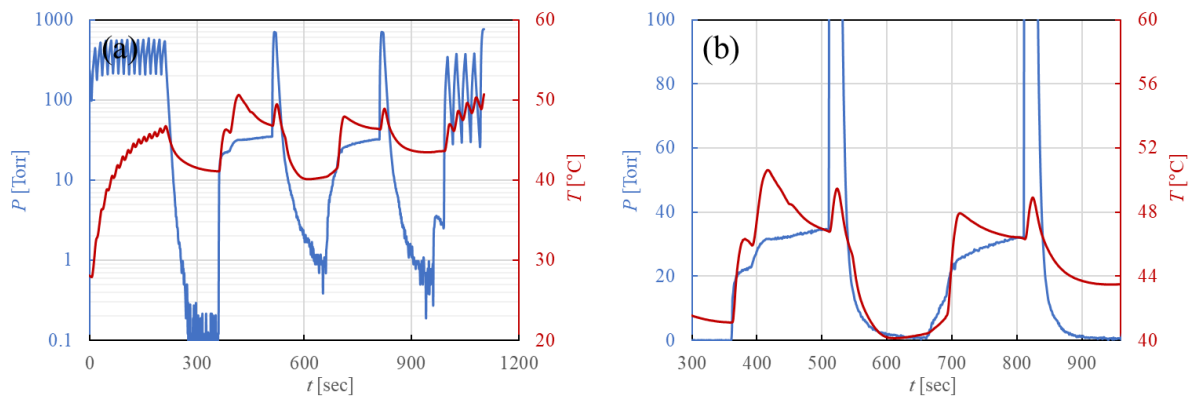


Figure 3.11 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for cycle 11.