TEST·INSPECTION REPORT

Lumen Sterilization Test

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/Lot Number: P15BTL046A and SL20G002

Test·Inspection Item: Lumen Sterilization Test

Testing Laboratory: Plasmapp Research Institute

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

Decision: Pass

Tested until: 25 Jun. 2021 **Issued Date:** 28 Jun. 2021

Tested by: 전현정

Hyun Jeong, JEON
Process Inspector

Approved by: 이승헌

Seung Hun, LEE
General Director of R&D

Plasmapp Research Institute

Lumen Sterilization Test

1. Test schedule

1.1 Date of test beginning: 23 Jun. 2021

1.2 Date of test completion: 25 Jun. 2021

2. Test article

Low temperature plasma sterilizer (STERLINK® FPS-15s Plus, S/N: P15BTL046A)

Sterilant (STERLOAD®, Lot No.: SL20G002)

3. Test guideline

3.1 The tests were performed in accordance with the standard of ISO 14937:2009.

3.2 Information of testing materials

3.2.1 Lumen*

Lumen type	Inner diameter [mm]	Length [mm]
Single-channel stainless steel lumen (Both side open)	2.4	280

3.2.2 Validation load*

Test sample	Validation load	
	Medical devices	Total weight [lbs]
Five lumens	Stainless steel scissors	3.97

3.2.3 Self-contained biological indicator (SCBI)

Item	Details
Product	Super Rapid Readout Biological Indicators
Model	BT96
Manufacturer	Terragene S.A.
Lot Number	RHI042022
D-value	11 sec (2.0 mg·L^{-1} VH_2O_2, 50ºC)
Survival time / Kill time	44 sec / 108 sec
Expiration date	Apr. 2022
Comments	1.2×10^6 *Geobacillus stearothermophilus* spores per vial (ATCC Cell Line 7953) complying with ISO 11138-1

*Figure of the lumen and validation loads were referred to the Appendix 1.

3.2.4 Sterilant

Brand	STERMATE®
Model	STERLOAD®
Lot Number	SL20G002
Expiration date	Jul. 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

3.3.1 Lumen leakage validation

(1) One side of lumen was directly connected to the test chamber which is connected to a vacuum pump (VP) via solenoid valve (SV) as depicted in Figure 2.1. Another side of lumen was blocked.

(2) The pressure data logger (PG) was located inside the test chamber.

(3) After sufficient pumping, the solenoid valve was closed in order to isolate the lumen and chamber system.

(4) If the lumen is leak-tight, the pressure raising rate after closing the valve is almost zero.

(5) The time evolutions of the pressure were recorded. (The criterion is less than 0.1 $Torr \cdot s^{-1}$.)

(6) Same tests without blocking one side of the lumen were conducted to clarify that there is no blockage in the lumen channel as described in Figure 2.2.

(7) All the data were recorded and plotted in Figure 3.1 and Figure 3.2.

3.3.2 Lumen sterilization test

(1) The SCBIs were inserted in the single-channel stainless steel lumens for each.

(2) The prepared lumens and dried validation loads were inserted in Tyvek® and sealed. **For the worst-case condition, the sterilant which has a short expiration date was used.**

(3) The prepared pouch was processed with half cycle sterilization of chamber mode and the temperature and pressure during the sterilization process were measured.

(4) After sterilization cycle, the SCBIs were immediately removed from the lumens. The internal ampoules of SCBIs were broken and shaken sufficiently so that the media be spread uniformly.

(5) All the exposed SCBIs and the positive control (unexposed to sterilant) were incubated in IC10/20FR (Auto-reader for biological indicators, Terragene S.A) at 60°C for 30 minutes or until sterilization result is obtained by print of IC10/20FR.

(6) The lumen sterilization tests except the positive control test were performed in three consecutive half sterilization cycles.

4. Test results**

4.1 Results of lumen leakage validation

Test number	Pressure raising rate [Torr·s^{-1}] Criterion: < 0.1 Torr·s^{-1}				
	Lumen #1	**Lumen #2**	**Lumen #3**	**Lumen #4**	**Lumen #5**
1	0.078	0.027	0.086	0.066	0.088
2	0.068	0.031	0.090	0.065	0.072
3	0.086	0.042	0.094	0.072	0.076
w/o rubber	Open	Open	Open	Open	Open

4.2 Results of lumen sterilization test

Test type	Test number	Number of positive/Number of tested
Positive control		1/1
Three consecutive tests	1	0/5
	2	0/5
	3	0/5

4.3. 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	1.52	28.6	-	-	1.52
2	0.66	21.3	-	-	1.17
3	0.47	30.8	-	-	0.91

**The related figures were referred to the Appendix 3 and 4. The time evolution of pressure and temperature inside the chamber during lumen sterilization test were described in the Appendix 5, 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.

4.4. 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	51.5 – 55.7	55.7 – 58.9	111-122	-	-	-
2	52.0 – 57.3	56.2 – 57.8	116 – 124	-	-	-
3	52.6 – 57.2	56.1 – 57.0	118- 123	-	-	-

4.5. Time parameter data during sterilization process [s]

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

5. Conclusions

(1) The results of lumen leakage validation were confirmed that the lumens using in this test do not have the leakage.

(2) The results of three consecutive lumen sterilization tests were shown as all negative except control.

(3) According to the test results, lumen sterilization test is completely successful.

[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. Shape of lumen

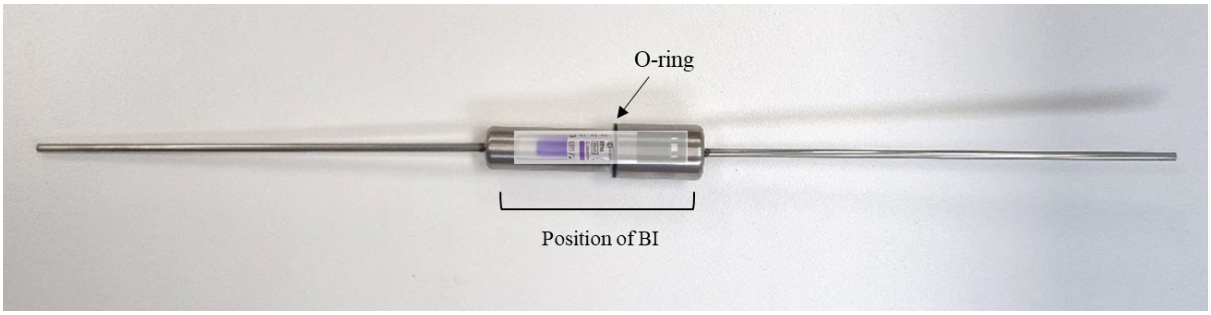


Figure 1.1 The inserted area of SCBI in lumen.

2. Chamber mode test

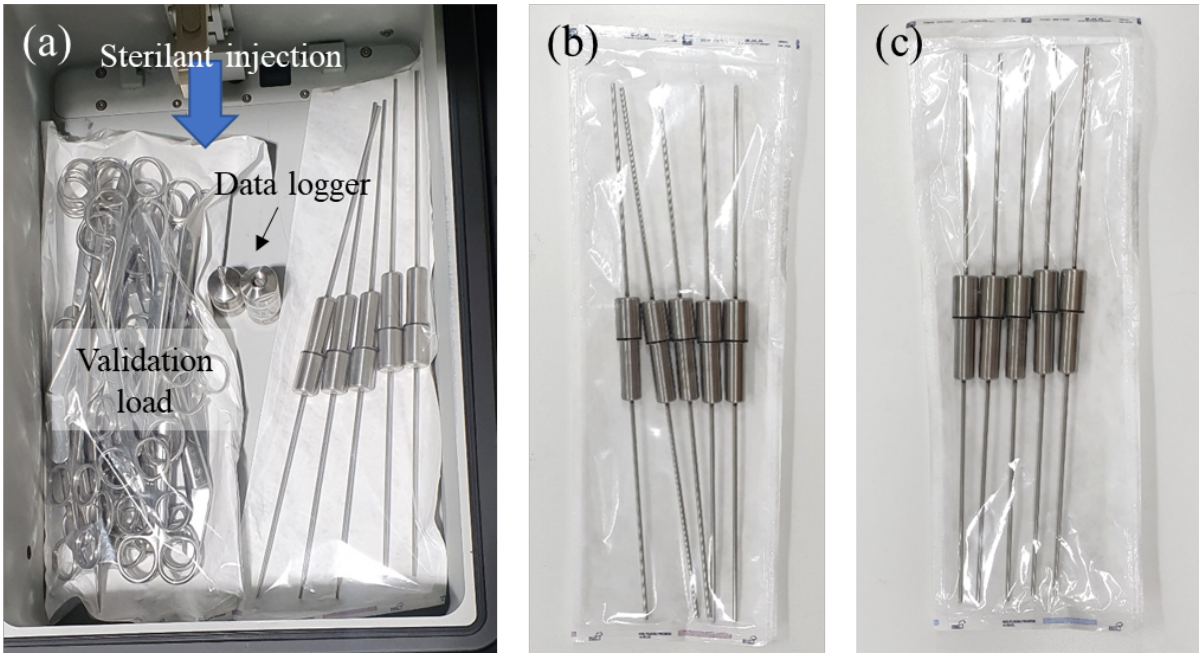


Figure 1.2 (a) The position of validation load and lumens inserted SCBI sealed by Tyvek® pouch. The lumens are described in (b) before and (c) after the sterilization.

Appendix 2

1. Lumen leak-tight validation

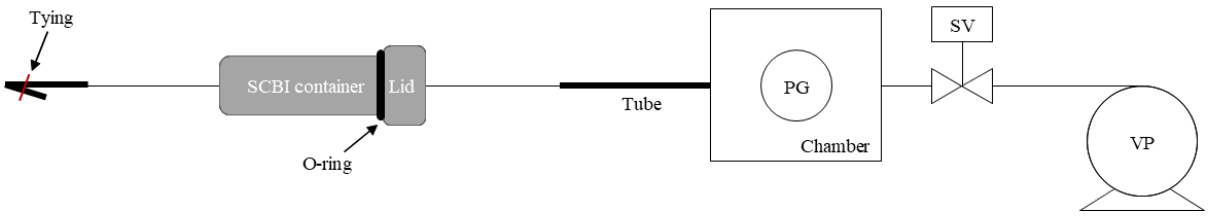


Figure 2.1 Apparatus of lumen leak-tight test for the lumen

2. Lumen open test

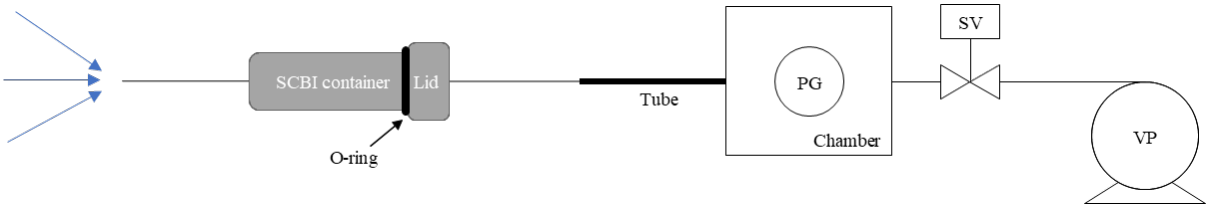


Figure 2.2 Apparatus of lumen open test without blocking

Appendix 3

1. Result of lumen leak-tight validation

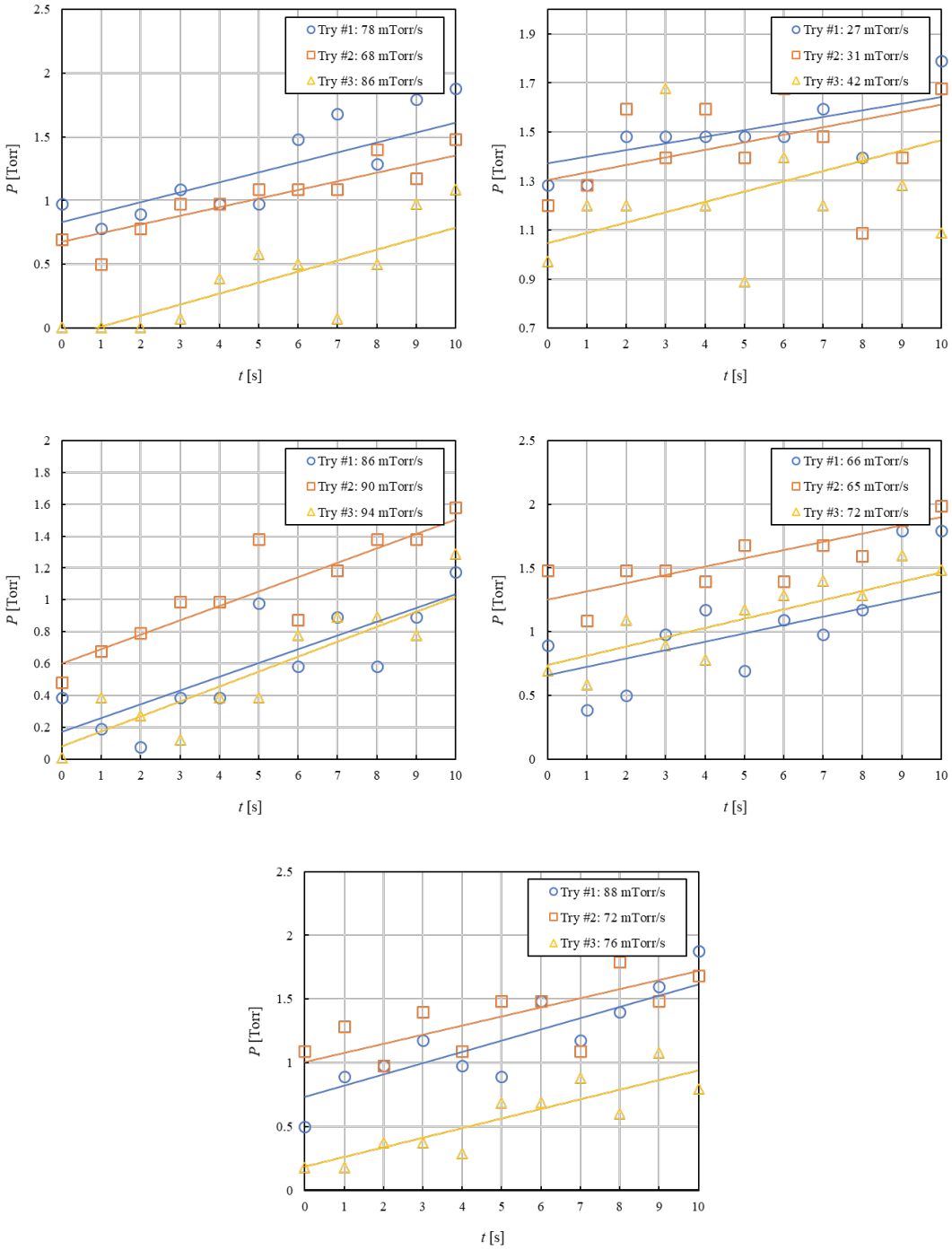


Figure 3.1 Pressure rising after closing the solenoid valve (SV) for (a) Lumen #1, (b) Lumen #2, (c) Lumen #3, (d) Lumen #4, and (e) Lumen #5.

2. Result of lumen open test

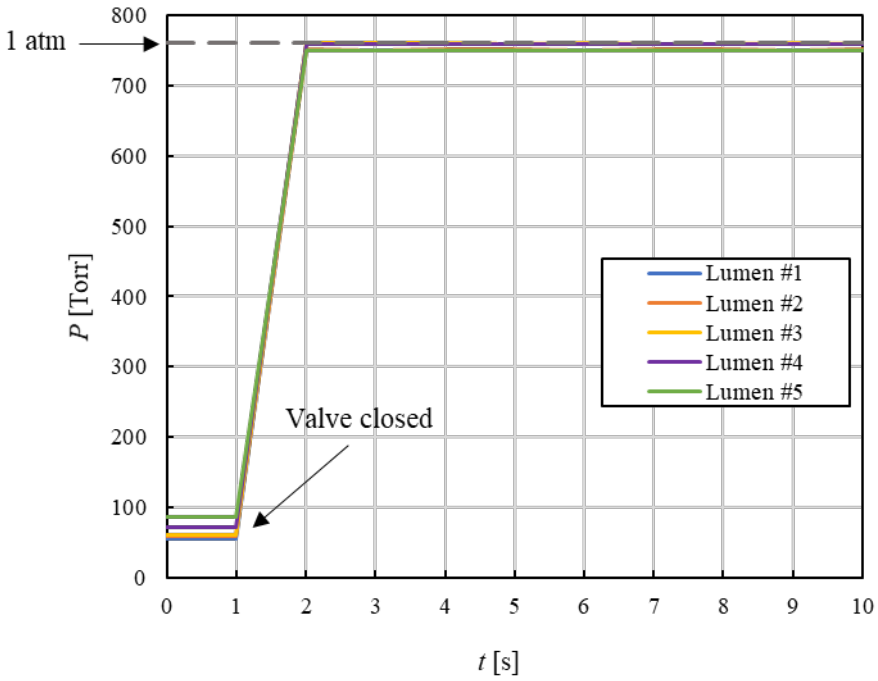
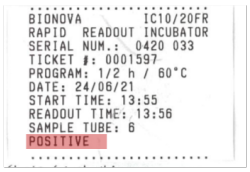


Figure 3.2 After the solenoid valve (SV) closed, the pressure reached atmospheric pressure. Accordingly, it is clarified that the SCBI container is properly connected to the vacuum pump.

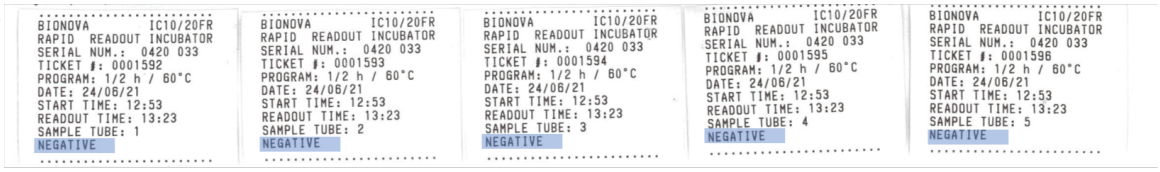
Appendix 4

1. Results of the lumen sterilization test

(a)



(b)



(c)

(d)

Figure 4.1 The incubation results of (a) the control and (b-d) three consecutive lumen sterilization tests for chamber mode sterilization. The negative result implies complete sterilization.

Appendix 5

1. Pressure and temperature curves of the lumen sterilization test

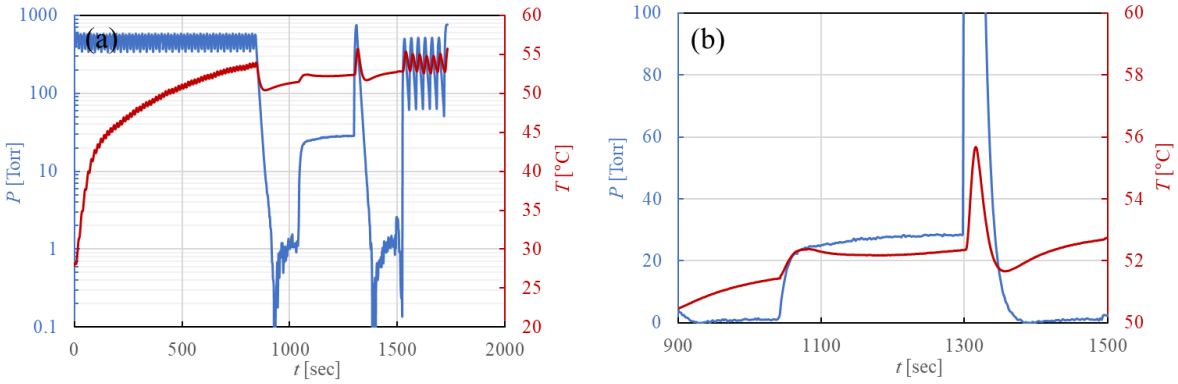


Figure 5.1 (a) The whole plot of pressure and temperature curve during the half cycle and (b) magnified plot of diffusion phase for test number 1.

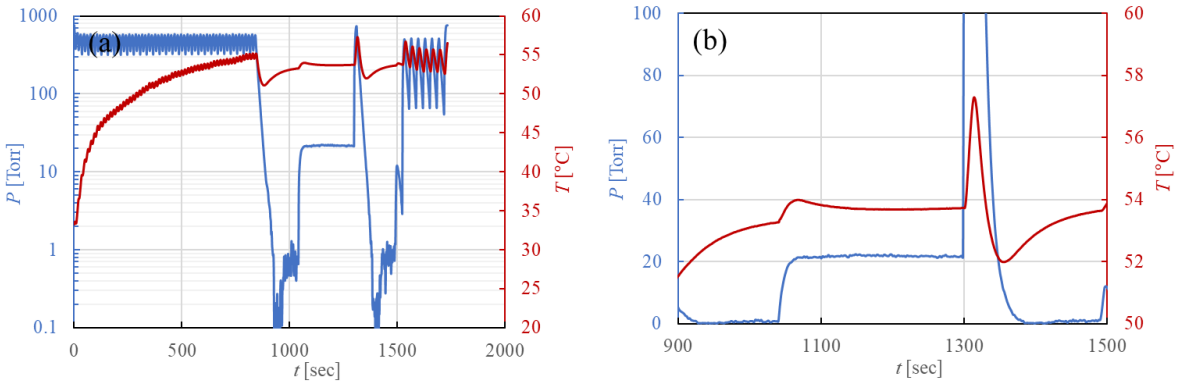


Figure 5.2 (a) The whole plot of pressure and temperature curve during the half cycle and (b) magnified plot of diffusion phase for test number 2.

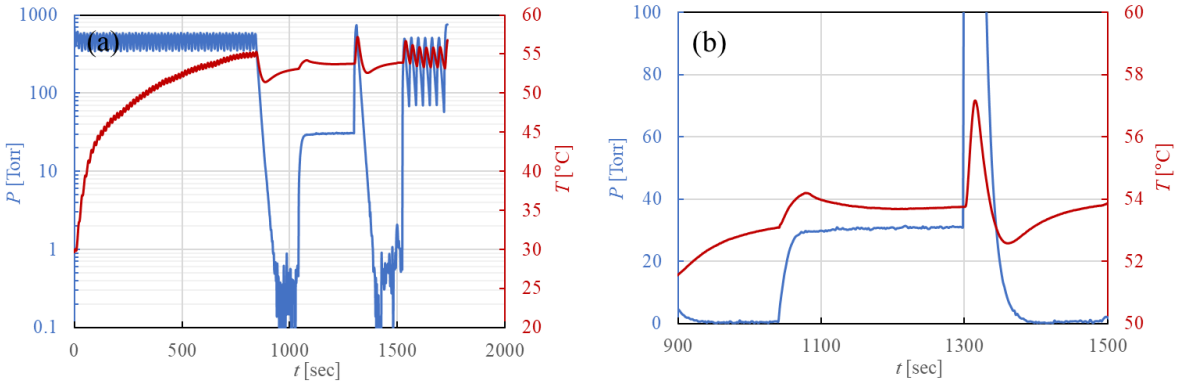


Figure 5.3 (a) The whole plot of pressure and temperature curve during the half cycle and (b) magnified plot of diffusion phase for test number 3.