

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<sup>+</sup>) and STERPACK™ plus

**Serial Number:** P152BWM004A and SX21B001X

**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:** 11 Feb. 2022      **Issued Date:** 16 Feb. 2022

**Tested by:** 김재근      **Approved by:** 이) 2-6호  
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Assistant Research Engineer      General Director of R&D

Plasmapp Research Institute



## Lumen Sterilization Test

### 1. Test schedule

1.1 Date of test beginning: 04 Nov. 2021

1.2 Date of test completion: 11 Feb. 2022

### 2. Test article

Low temperature plasma sterilizer (FPS-15s Plus, S/N: P152BWM004A)

Sterilant (STERPACK™ plus, Lot No.: SX21B001X)

### 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)	1.6	200

3.2.2 Validation load\*

Test sample	Validation load	
	Medical devices	Total weight [lbs]
Three lumens	Stainless steel scissors	1

3.2.3 Self-contained biological indicator (SCBI)

Item	Details
Product	Super Rapid Readout Biological Indicators
Model	BT96
Manufacturer	Terragene S.A.
Lot Number	A10539
D-value	80 sec (2.0 mg·L <sup>-1</sup> VH <sub>2</sub> O <sub>2</sub> , 50°C)
Survival time / Kill time	5.3 min / 13.3 min
Expiration date	Oct. 2023
Comments	1.0 × 10 <sup>6</sup> <i>Geobacillus stearothermophilus</i> 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

<b>Brand</b>	STERMATE™
<b>Model</b>	STERPACK™ plus
<b>Lot Number</b>	SX21B001X
<b>Expiration date</b>	Feb. 2022
<b>Manufacturer</b>	Plasmapp Co., Ltd.
<b>Comments</b>	Sterilant cassette for STERLINK™

### 3.2.5 Measuring instrument

<b>Equipment</b>	<b>Manufacturer</b>	<b>Model</b>	<b>Internal S/N</b>	<b>Calibration date</b>
High temperature data logger	MADGETECH	HiTemp140	PO-C-025	16 Feb. 2021
Pressure data logger	MADGETECH	PR140	PQ-C-031	10 Feb. 2021

### 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  $0.1 \text{ Torr} \cdot \text{s}^{-1}$ .)
- (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) Three prepared lumens and validation loads were inserted in Tyvek® and sealed. The prepared Tyvek pouch was inserted in the STEERPACK™ plus 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 pouch plus 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 at 60°C for 7 days.
- (6) After incubation, the results were reported as positive (change from purple to yellow) or negative (no change).

(7) 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 <sup>-1</sup> ] Criterion: < 0.1 Torr·s <sup>-1</sup>		
	Lumen #1	Lumen #2	Lumen #3
1	0.076	0.012	0.013
2	0.032	0.007	0.007
3	0.006	0.007	0.019
w/o rubber	Open	Open	Open

##### 4.2 Results of sterilization efficacy test

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

##### 4.3. Pressure parameter data during sterilization process [Torr]

Test number	Sterilization phase 1		Sterilization phase 2		Purification
	Base <sup>a</sup> (< 3 Torr)	Diffusion <sup>b</sup> (20 - 100 Torr)	Base <sup>a</sup> (< 3 Torr)	Diffusion <sup>b</sup> (20 - 100 Torr)	Final base <sup>c</sup> (< 3 Torr)
1	0.54	22.8	-	-	0.70
2	1.44	34.5	-	-	0.03
3	0.83	25.8	-	-	0.36

\*\*The related figures were referred to the Appendix 3 and 4. The time evolution of pressure and temperature inside the STERPACK™ plus during lumen sterilization test was described in the Appendix 5, as well.

<sup>a</sup>The base pressure just before injection of the sterilant.

<sup>b</sup>The diffusion pressure after diffusion of the sterilant which is complete.

<sup>c</sup>The base pressure after injection and purification.

<sup>d</sup>The load temperature is measured by the temperature data logger described in 3.2.5.

<sup>e</sup>The chamber temperature is controlled by K-type thermocouple.

<sup>f</sup>The vaporizer temperature is controlled by K-type thermocouple.

#### 4.4. Temperature parameter data during sterilization process [°C]

Test number	Sterilization phase 1			Sterilization phase 2		
	Load <sup>d</sup> (40-60°C)	Chamber <sup>e</sup> (55-60°C)	Vaporizer <sup>f</sup> (110-130°C)	Load <sup>d</sup> (40-60°C)	Chamber <sup>e</sup> (55-60°C)	Vaporizer <sup>f</sup> (110-130°C)
1	42.5 – 44.6	55.6 – 57.6	116 – 120	-	-	-
2	44.8 – 58.0	56.1 – 58.3	117 – 121	-	-	-
3	44.7 – 52.7	56.2 – 59.3	118 – 120	-	-	-

#### 4.5. Time parameter data during sterilization process [s]

Test number	Sterilization phase 1	Sterilization phase 2
	(250 ± 1 s)	(250 ± 1 s)
1	250	-
2	250	-
3	250	-

## 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.

## Appendix 1

### 1. Shape of lumen

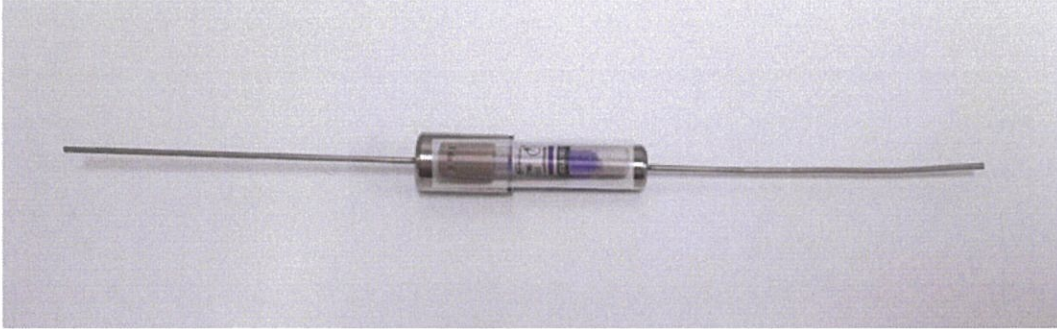


Figure 1.1 The inserted area of SCBI in lumen.

### 2. Pouch plus mode test

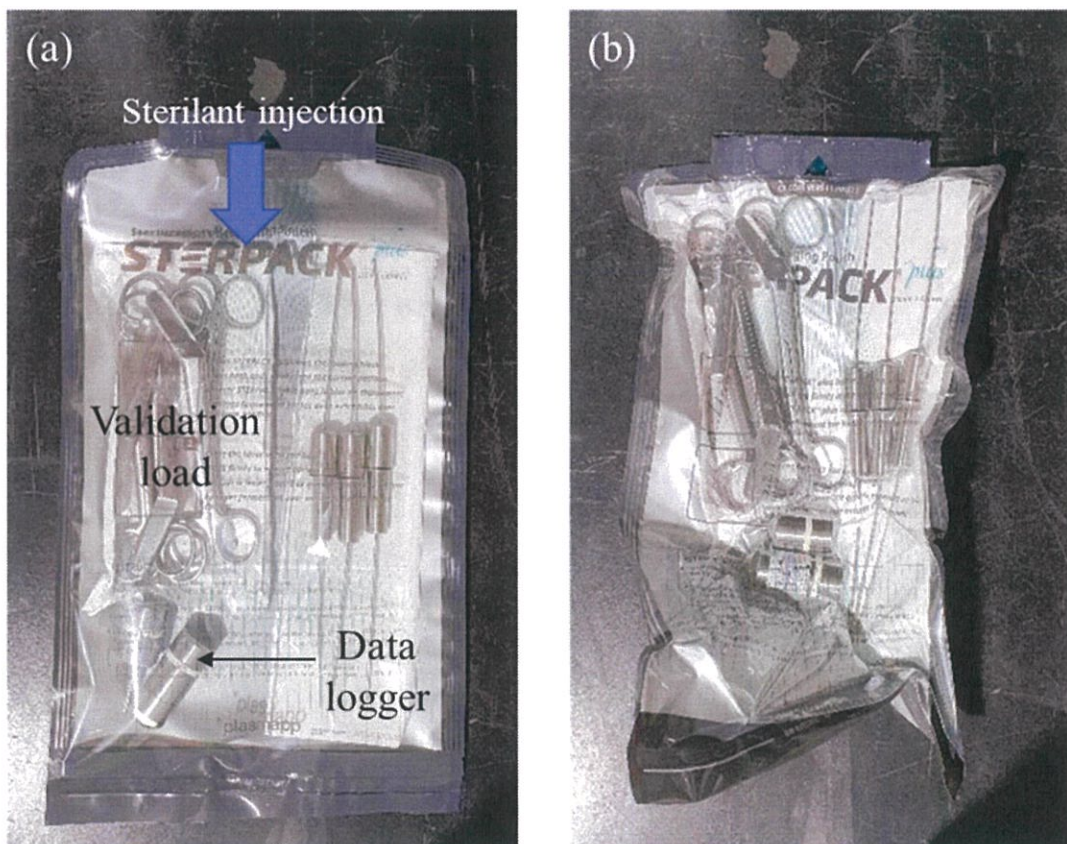


Figure 1.2 The validation load and lumens inserted SCBI sealed by STERPACK™ plus (b) before and (c) after the sterilization.

## Appendix 2

### 1. Lumen leak-tight validation

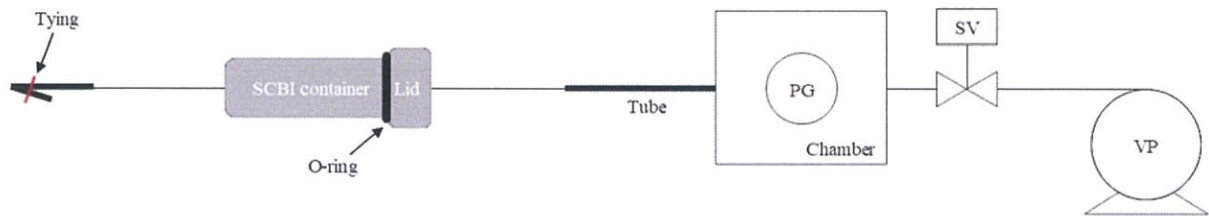


Figure 2.1 Apparatus of lumen leak-tight test for the lumen

### 2. Lumen open test

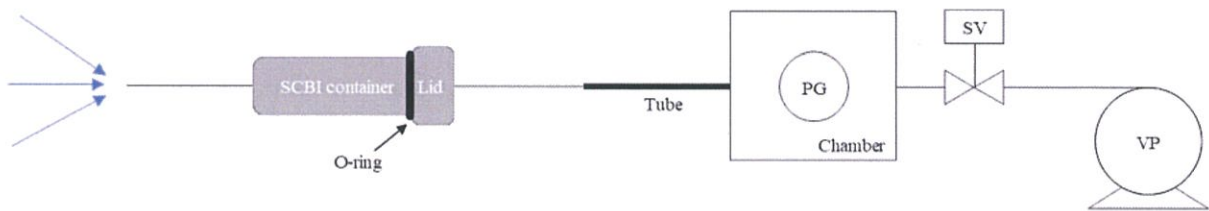


Figure 2.2 Apparatus of lumen open test without blocking

## Appendix 3

### 1. Result of lumen leak-tight validation

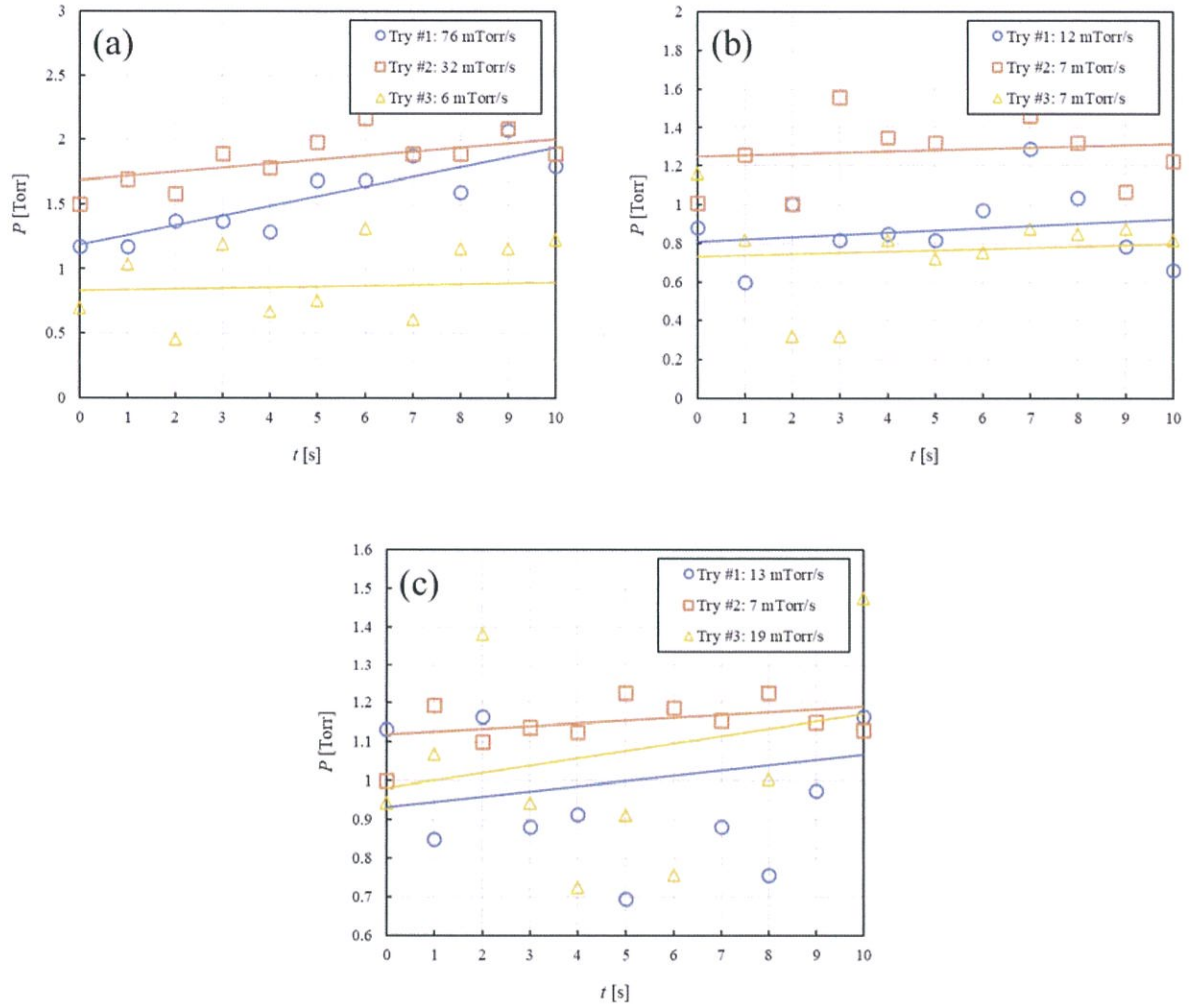


Figure 3.1 Pressure rising after closing the solenoid valve (SV) for (a) Lumen #1, (b) Lumen #2, and (c) Lumen #3.



## 2. Result of lumen open test

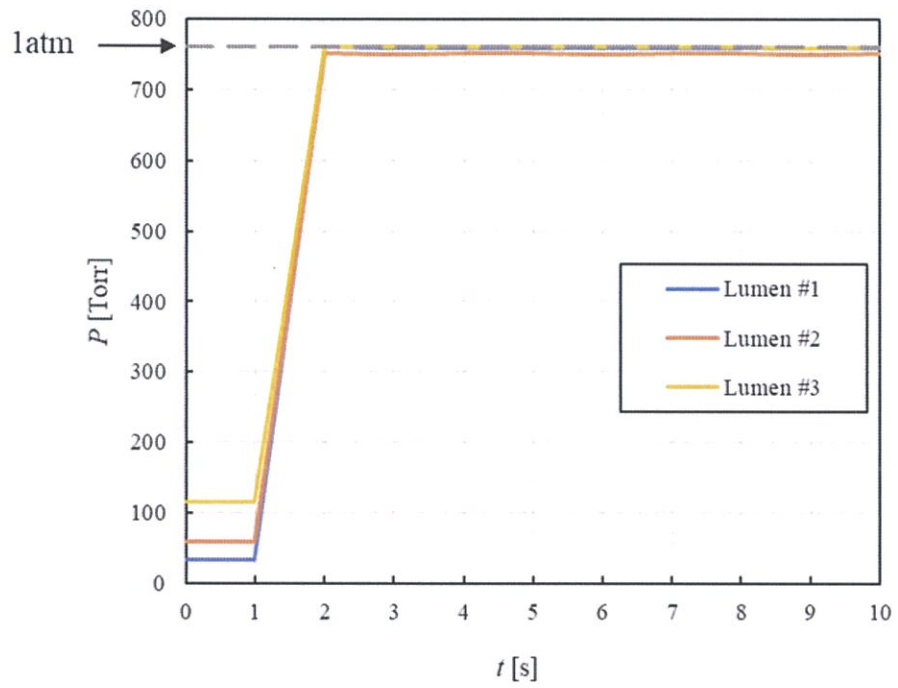


Figure 3.2 After the solenoid valve (SV) closed, the pressure reached atmospheric pressure. Accordingly, it is clarified that the SCBI container is properly connected to the vacuum pump.

## Appendix 4

### 1. Results of the lumen sterilization test

#### 1.1 Positive control



Figure 4.1 The incubation results of the positive control

#### 1.2 Three consecutive half sterilization tests

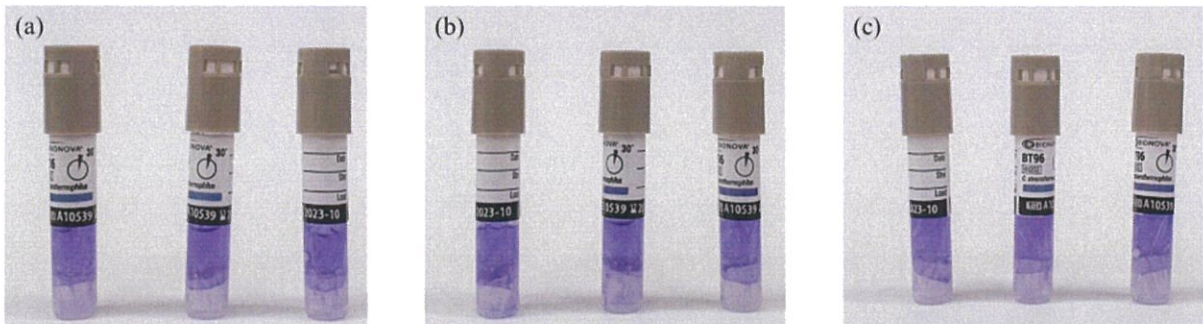


Figure 4.2 The incubation results of three consecutive half sterilization cycles.

## Appendix 5

### 1. Pressure and temperature curves of the lumen sterilization test

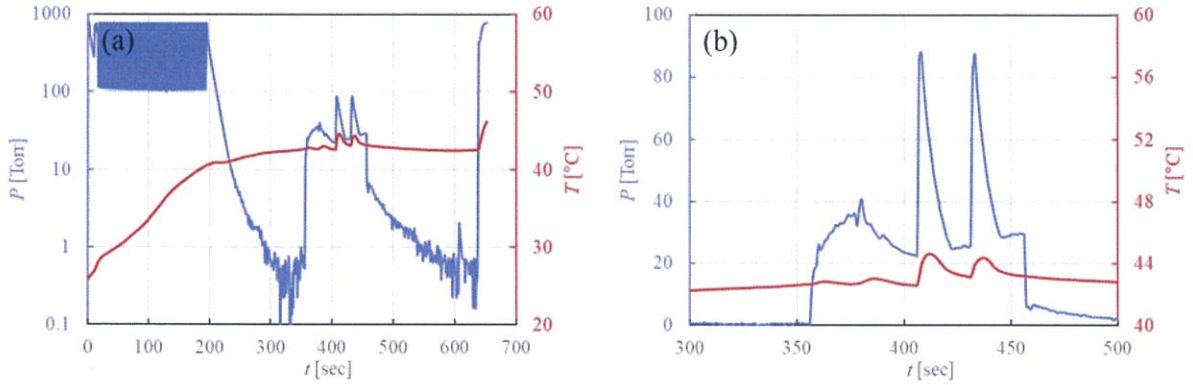


Figure 5.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for sterilization cycle 1.

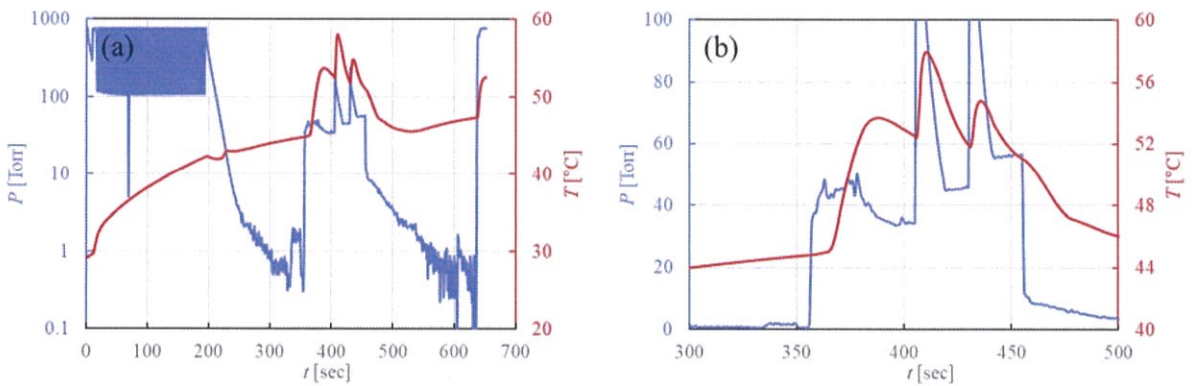


Figure 5.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for sterilization cycle 2.

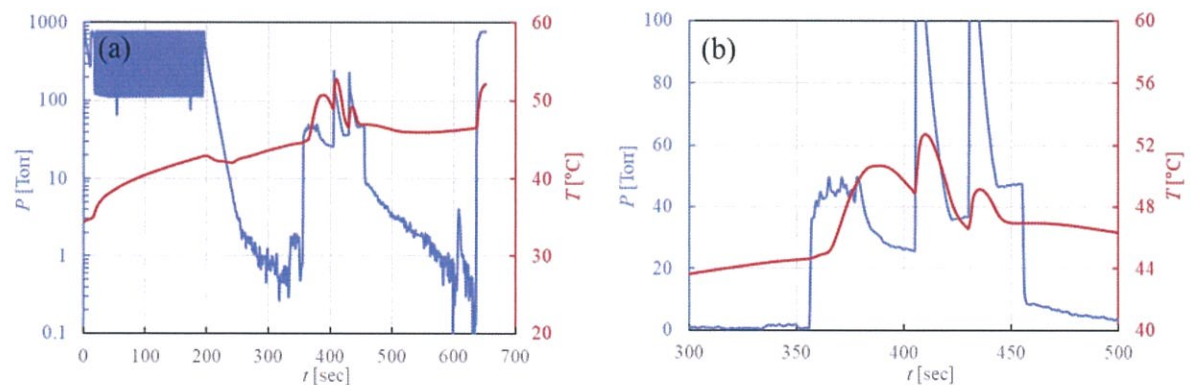


Figure 5.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for sterilization cycle 3.