7MINUTES **PLASMA** STERILIZER

PLASMAPP

(저온플라즈마 7분멸균기)

Low_Temperature_PLASMA_Sterilizer

50 Countries – 1500 References

FPS-15s Plus(14L)

MINI(7L)

Plasmapp Sterilization Product Catalog

Fast Low-Temperature Plasma Sterilizer – 55°C

STERLINK®

Chamber : **14** Liter
3 Cycles Mode - Pouch : **7** min
- Pouch+ : **14** min
- Full Load : **36** min
Class IIb, CE Certified

STERLINK® Mini

Chamber : **7** Liter
2 Cycles Mode - Pouch : **7** min
- Full Load : **18** min

Class IIb, CE Certified

Specifications

Model	Dimensions [mm]			Weight [kg]	Chamber [liter]	Cassette (Sterilization cycle time)		
	Width	Depth	Height			STERPACK®	STERPACK® Plus	STERLOAD®
STERLINK®	433	614	437	67	14	O (7 min)	O (14 min)	O (36 min)
STERLINK® Mini	270	450	330	18	7	O (7 min)	X	O (18 min)

PLASMAPP
(LOW_TEMPERATURE_STERILIZER)

(세계최초 직분사방식 특허기술 적용,
안전멸균율 : $SAL\,10^{-6}$ 사전검증)

빠른멸균
저온멸균
깨끗한 멸균
안전멸균율(SAL:99.9999%)

저온 7분멸균
컴팩트한 디자인
원터치 운전
실시간 모니터링

적용분야
& 잠재고객

실험실, 연구소, 대학교, 바이오메디컬 산업분야, 제약회사,
종합병원(안과, 치과 제외)카지노, 수의과, 동물병원 등

1. FPS-15s Plus 사양

분 류	내 용			단 위
치 수	433 (W) x 614 (D) x 437 (H)			mm
챔버 용량	14			L
안전장치	물 리 적	도어센서 및 진공에 의한 열림 방지		
	전 기 적	과전류 방지용 정격 퓨즈 삽입		
공정변수	최대온도	60 미만		℃
	압력범위	0 – 760		torr
	과산화수소 주입 직전 압력	3.0 이하		torr
	확산압력	20 이상, 80 이하		torr
	공정확인	Chemical indicator (CI)	Class 4 (Compliance: ISO 11140-1)	
진 공	최저압력	3 이하		torr
	압력변화율	60 초 동안 6 torr 이하의 압력변화를 확인		
준비공정성능 (Smart Ready™ Process)	바코드	자동 바코드 인식 및 MODE 선택		
	건조성능	최저압력	3.0 이하	torr
		최저 상대습도	5 이하	%
멸 균	멸균성능	Biological indicator (BI)	SCBI (Compliance: ISO 11138)	
		LUMEN (Single-channel SUS)	Dia: 0.7, Length: 500	mm
		LUMEN (Single-channel SUS)	Dia: 2.0, Length: 1,500	mm
		LUMEN (Single-channel PTFE)	Dia: 1.0, Length: 2,000	mm
	멸균시간	POUCH	4	min
		POUCH PLUS	8	
		CHAMBER	15	
	Full cycle 소요시간 (기본 사양)	POUCH	7 ± 1 이내	
		POUCH PLUS	14 ± 1 이내	
		CHAMBER	36 ± 1 이내	
	Full cycle 소요시간 (최대 적재)	POUCH	10 ± 1 이내	
		POUCH PLUS	18 ± 1 이내	
멸균제	과산화수소수 (H_2O_2 58 – 59.5%)			
정화방식	플라즈마 방전 처리 (Low frequency DBD)			
Display	치 수	153.1 (W) x 85.6 (H)		mm
	해 상 도	800 x 480		pixels
포트	IEC-320 C14, USB type B, RS-232, RJ-45			
전기적 특성	정격전원	220-240 (10 A)		VAC
	정격주파수	50/60		Hz

2. STERLINK MINI 사양

분 류	내 용			단 위
치 수	본체: 270 (W) x 450 (D) x 330 (H) 펌프 유닛: 270 (W) x 450 (D) x 330 (H)			mm
챔버 용량	7			L
안전장치	물 리 적	도어센서 및 진공에 의한 열림 방지		
	전 기 적	과전류 방지용 정격 퓨즈 삽입		
공정변수	최대온도	60 이하		℃
	압력범위	0 – 760		torr
	과산화수소 주입 직전 압력	3.0 이하		torr
	확산압력	20 이상, 80 이하		torr
	공정확인	Chemical indicator (CI)	Class 4 (Compliance: ISO 11140-1)	
진 공	최저압력	3.0 이하		torr
	압력변화율	0.1 이하		$torr \cdot s^{-1}$
멸균공정 (Sterilization) ,60Hz	멸균성능	LUMEN (Single-channel Stainless Steel)	Dia: 0.7, Length: 500 Dia: 2.0, Length: 1,500	mm
		LUMEN (Single-channel PTFE)	Dia: 1.0, Length: 2,000	mm
	멸균시간	POUCH	4	분
		CHAMBER	8	
순환시간 (Cycle time) ,60Hz	반주기 공정 (Half cycle)	POUCH	5	분
		CHAMBER	13	
	전주기 공정 (Full cycle)	POUCH	7	분
		CHAMBER	18	
멸균제	과산화수소수 (H_2O_2 58 – 59.5%)			
정화방식	플라즈마 방전 처리 (Low frequency)			
Display	치 수	153.1 (W) x 85.6 (H)		mm
	해 상 도	800 x 480		pixels
포트	IEC-320 C14, RJ-45, USB type A, USB type B, cable connetor			

YOU TUBE :

1. What is the Plasmapp ? :

   https://youtu.be/NpcH8QGYUc4

2. Plasmapp_Low temperature Plasma Sterilizer_FPS-15s :

   https://youtu.be/OfAMkMkI7Xk

   (New)Plasmapp_Low temperature Plasma Sterilizer_FPS-15s :

   https://youtu.be/-mZC3OVOR9A

3. Sterlink :

   https://youtu.be/fk3tF7WTt9I

4. Introduction Plasmapp :

   https://youtu.be/sQeYH0u1w40

TEST-INSPECTION REPORT

Mask Sterilization Test

Manufacturer Name: Plasmapp Co., Ltd.
Representative: You Bong, LIM
Location: 83 Jukdong-ro, Yuseong-gu, Daejeon 34127, Republic of Korea

Product Name: Low temperature plasma sterilizer
Brand Name: STERLINK®
Model Name: STERLINK MINI
Serial Number: M07BUG042A

Test-Inspection Item: Mask Sterilization Test
Testing Laboratory: Plasmapp Research Institute
Location: 327 Dongbu-daero, Osan-si, Gyeonggi-do 18151, Republic of Korea (South Korea)

Decision: Pass

Tested until: 27 Apr. 2020 **Issued Date:** 29 Apr. 2020

Tested by: 전현정 Hyun Jeong, JEON, Process Inspector

Approved by: 이승헌 Seung Hun, LEE, General Director of R&D

Plasmapp Research Institute

Mask Sterilization Test

1. Test schedule

1.1 Date of test beginning: 14 Apr. 2020

1.2 Date of test completion: 27 Apr. 2020

2. Test article

Low temperature plasma sterilizer (STERLINK® MINI, S/N: M07BUG042A)

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 Masks

Type	Product	Model	Type	Manufacturer	Expiration date
KF94	All guard basic dust mask	-	KF94	All guard	Mar. 2023
N95	Particulate Respirator N95	8110S	N95	3M	Dec. 2024

3.2.2 Bacteria spore suspension

Item	Details
Model	Spore suspension
Manufacturer	MesaLabs
Lot Number	SSS-847
Expiration date	25 Oct. 2021
Comments	1.3×10^6 *Geobacillus stearothermophilus* spores (ATCC Cell Line 7953) / 0.1 ml complying with ISO 11138

*Figures of the masks and inoculated position were referred to the Appendix 1.

3.3 Test methods

3.3.1 Half cycle sterilization test

(1) The *Geobacillus stearothermophilus* spore suspension was inoculated to the specified area of each mask as shown in the Appendix 1 and dried. Before the inoculation, the spore suspension for inoculation was diluted by serial 10-fole dilution method and they were inoculated in tryptic soy agar as triplicate plates for each dilution to confirm the number of the spores. The inoculated plates were incubated at 58°C for 48 hours. The prepared spore suspension for the inoculation should have greater than 1.0×10^6 colony forming unit (CFU).

(2) Each mask with spores was inserted in Tyvek® pouch and sealed. **For the worst-case condition, the masks were positioned as far as possible from the sterilant injection nozzle.**

(3) The prepared pouch was processed with half cycle sterilization of chamber mode.

(4) For the control, inoculated mask which was left on the room temperature without sterilization process was used.

(5) After sterilization cycle, the inoculated area on the mask was cut by a flame-sterilized scissor and placed in the tryptic soy broth of 5 ml.

(6) All test and control sample were incubated at 58°C for 7 days. After incubation, all samples were mixed by a vortex mixer and the turbidity change of media was inspected. The results were reported as positive (growth) or negative (no growth).

(7) The mask sterilization test except control was performed in three consecutive half sterilization cycles.

4. Test results**

4.1 The number of the spores for inoculation

Number of recovered spores (10^6 CFU)	
#1	1.17 ± 0.08

4.2 Results of the mask sterilization test

Mask type	Condition	Number of positive/Number of tested			Sterilization Results
		#1	#2	#3	
KF94	Control		1/1		-
	Test	0/1	0/1	0/1	Pass
N95	Control		1/1		-
	Test	0/1	0/1	0/1	Pass

5. Conclusions

(1) The number of spores used for inoculation was above 1.0×10^6 CFU.

(2) After three consecutive mask sterilization tests, all the incubation results were negative except control.

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

**The related figures were referred to the Appendix 2. The time evolution of pressures inside the chamber were described in the Appendix 3, as well.

Appendix 1

1. Masks

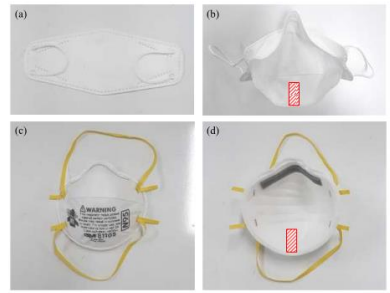

Figure 1.1 (a, c) The outside and (b, d) the inside for KF94 and N95, respectively. The area of inoculation was indicated as the square filled with diagonal line.

2. Half cycle of chamber mode for the sterilization test

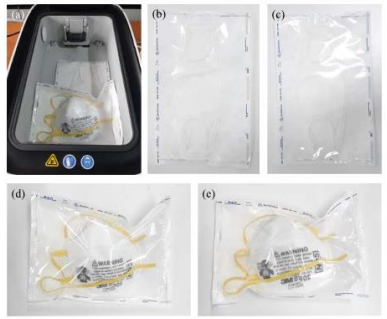

Figure 1.2 (a) The position of the inoculated masks sealed by Tyvek® pouch. The figure of (b, d) before and (c, e) after the sterilization for KF94 and N95, respectively.

Appendix 2

1. The number of the spores for the mask inoculation

Figure 2.1 Incubation results of 10^{-4} dilution samples of the spore suspension for inoculation.

2. Results of the mask sterilization test

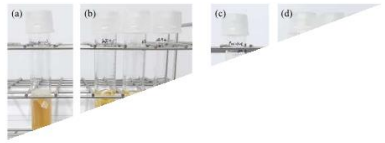

Figure 2.2 The incubation results for mask sterilization test. (a, c) The control and (b, d) three consecutive mask sterilization tests for KF94 and N95 type masks, respectively. The turbidity can be determined by black lines behind the tubes.

Appendix 3

1. Pressure curves of the mask sterilization test

Figure. 3.1 (a) The whole plot of pressure curve during the half cycle and (b) magnified plot of diffusion phase for each consecutive trial

BEYOND ASIAN HUB, TOWARD GLOBAL WORLD

TEST REPORT

98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, 13810, Korea TEL 82-2-2164-0011 FAX 82-2-2634-1008

Report No : MSK-2020-000694
Representative : Youbong Lim
Company name : Plasmapp.co., Ltd.
Address : 1F, 3F #301, 83 Jukdong-ro, Yuseong-gu, Daejeon 34127

Receipt Date : 2020.03.18.
Test Completion Date : 2020.04.20.

Sample name : Sterilizer, plasma, low temperature(Serial No. P15BUB015A)

Test Results

TEST ITEM	UNIT	SAMPLE	RESULT	TEST METHOD
Virucidal test(Human Influenza A (H1N1))	Log reduction	PPS-15s Plus	)3.38	By the client (Annex#1)

* Test conditions
- See the report

** Test virus
- Human Influenza A (H1N1) (Strain: KUMC-76), KBPV-VR-76

*** Host cells
- MDCK (NBL-2), ATCC CCl.-34

**** Log reduction (LR)
- LR = LU - LT
- LU = The titer recovered from the virus control specimen (untreated)
- LT = The titer recovered from virucidal test specimen (treated)

***** Interpretation of the results
- log reduction) 1:) 90 %
- log reduction) 2:) 99 %
- log reduction) 3:) 99.9 %
- log reduction) 4:) 99.99 %
- log reduction) 5:) 99.999 %

- Test period : Mar.18,2020 ~ Apr.20,2020

Annex#1 : By the client - The test methods
Annex#2 : Picture of appearance or shape
Attachment : Test Report

- Next Page -

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2020.04.20.

Korea Testing & Research Institute

President Kwon Oh-jung

QR Code for forgery

KTR KOREA TESTING & RESEARCH INSTITUTE

BEYOND ASIAN HUB, TOWARD GLOBAL WORLD

TEST REPORT

98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, 13810, Korea TEL 82-2-2164-0011 FAX 82-2-2634-1008

Report No : MSK-2020-000694
Representative : Youbong Lim
Company name : Plasmapp.co., Ltd.
Address : 1F, 3F #301, 83 Jukdong-ro, Yuseong-gu, Daejeon 34127

Receipt Date : 2020.03.18.
Test Completion Date : 2020.04.20.

Sample name : Sterilizer, plasma, low temperature(Serial No. P15BUB015A)

Test Results

TEST ITEM	UNIT	SAMPLE	RESULT	TEST METHOD

- Usage of Report : QUALITY CONTROL

NOTE : 1. The test results of this test report are only limited in to the samples and sample names provided by the client and do not guarantee the quality of all products of the client. You Can check website (www.ktr.or.kr) or QR code to verify the authenticity of the certificate.
2. This test report shall be used only within the purpose of its defined usage and shall not be used to public relation, advertisement and lawsuit.
3. This test report is only valid when printed on KTR original report paper with hologram and when re-issued by KTR. The copy and the electronic file of the test report are only for reference.

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2020.04.20.

Korea Testing & Research Institute

President Kwon Oh-jung

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KTR KOREA TESTING & RESEARCH INSTITUTE

Annex#1 : By the client – The test methods

1. Test name

Virucidal test

2. Test article

Product name: Low temperature plasma sterilizer
Brand name: STERLINK®
Model name: FPS-15s Plus ("FPS-15s")
Consumable (Pouch with sterilant): STERPACK®

3. Virus used for test

Influenza A H1N1

4. Test methods

1) The virus was inoculated to the sterilized glass petri dish (6cm diameter) and dried.
2) The sterilized glass petri dish with virus was inserted in the STERPACK® and sealed.
3) The prepared STERPACK® was installed to the loading block of FPS-15s Plus and processed with half cycle sterilization of pouch mode.
4) After the sterilization, the virus inoculated on the sterilized glass petri dish was recovered and inoculated to the host cell to confirm the virus titer.
5) For the control, the sterilized glass petri dish with virus was inserted in the STERPACK®, sealed, and left on the room temperature without sterilization process during the sterilization time.
6) The log reduction was calculated by comparing the test results of the test and control sample. According to the test results, the virucidal performance of the FPS-15 Plus was confirmed.

Annex#2 : Picture of appearance or shape

KTR

Test Report

MSK-2020-000694

Low temperature plasma sterilizer

Virucidal test

President of KTR

Test outline

Study title : **Virucidal test**

Study number : MSK-2020-000694

Sponsor

Name : Plasmapp Co., Ltd.
Address : 83 Jukdong-ro, Yuseong-gu, Daejeon 34127, Republic of Korea
Representative : You Bong, LIM

Test facility

Name : Korea Testing And Research Institute
Address : 98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, Korea

Hyun Ho Kim — 2020.04.20.

Hyun Ho Kim, Ph.D. — Date
Study Director
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Cho Jin Sik — 2020.04.20.

Cho, Jin-Sik, M.S. — Date
Technical Manager
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This report is presented for the article that was submitted by the sponsor.

April 20, 2020

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1. Summary

This test was performed to assess the virucidal activity of the test article provided by the sponsor [Low temperature plasma sterilizer (Model: FPS-15s Plus)] according to By the client. The Human Influenza A (H1N1) requested by the sponsor were used as test viruses in the test. The virus suspension was dried on an inanimate, nonporous surface. After placing the viral film inside the test Pouch requested by the sponsor and operating the article, and then the eluates are assayed for infectivity. The activity of the virus was quantified by tissue culture 50 % infectious dose assay ($log_{10}TCID_{50}$) after infecting the host cells with the virus.

Under the test conditions, the log reduction of the Influenza A (H1N1) in the test article [Low temperature plasma sterilizer] was found to be >3.38 after operation of the test article.

1.1. Test Schedule

Total test period : March 18, 2020 to April 20 2020

1.2. Picture of the Test Article

MSK-2020-000694

2. Equipments & materials

2.1. Test Equipments

Biosafety cabinet class II	(Cryste, Republic of Korea)
Autoclave	(Coretech, Republic of Korea)
Dry oven	(Jisico, Republic of Korea)
Water bath	(Fisher, USA)
CO_2 Incubator	(Thermo, USA)
Centrifuge	(Hanil, Republic of Korea)
Deep freezer	(Thermo, USA)
Microscopy	(Leica, USA)
pH meter	(Thermo Orion, USA)
Vortex mixer	(Thermolyne, USA)
Haemacytometer	(Marienfeld, Germany)
75-cm^2 flask	(Falcon, USA)
150-cm^2 flask	(Falcon, USA)
Test tube	(Falcon, USA)
Serological pipette	(Falcon, USA)
96 well plate	(Falcon, USA)
Cell scraper	(Falcon, USA)
0.45 ㎛ filter	(Advantec, USA)

2.2. Test Article

Low temperature plasma sterilizer, Model: FPS-15s Plus, Serial No.: P15BUB015A (provided by the client)
Pouch, Model: STERPACK®, Serial No.: SP20C002 (provided by the client)
Glass petri dish, Model: -, Lot No.: - (provided by the client)

2.3. Test Materials

2.3.1. Virus

Human influenza A (H1N1) (Strain: KUMC-76)	(KBPV-VR-76)

2.3.2. Host Cells

MDCK (NBL-2)	(ATCC CCL-34)

2.3.3. Media and Reagents

Minimal Essential Media (MEM)	(GIBCO, USA)
Phosphate Buffered Saline (PBS)	(GIBCO, USA)
Fetal Bovine Serum (FBS)	(GIBCO, USA)
Bovine Serum Albumin (BSA)	(Sigma, USA)
Penicillin-Streptomycin (PS)	(GIBCO, USA)
Trypsin-EDTA	(GIBCO, USA)
TPCK-treated Trypsin	(Sigma, USA)
Crystal Violet	(Sigma, USA)
Methyl Alcohol	(Sigma, USA)

2.3.4. Cell Culture Medium
MEM + 10 % FBS

2.3.5. Virus culture medium
MEM + 0.3 % BSA + 1 ㎍/mL TPCK-treated trypsin

3. Test method

3.1. Host Cell Culture

MDCK cells were cultured by using a cell culture medium under the conditions of 5 % CO_2 and (36 ± 2) ℃.

3.2. Viral Culture

3.2.1. Influenza A (H1N1) Culture

MDCK cells monolayer-cultured in a 75-cm^2 flask were washed with PBS, and then infected with 3 mL of Influenza A (H1N1) diluent. After infection with the virus as described in section 3.2.2, the virus was cultured for 3 to 5 days until more than 90 % of host cells showed a cytopathic effect by adding virus culture medium. Subsequently, the culture supernatant was centrifuged at 2000 rpm for 10 minutes and the supernatant was filtered with a 0.45 ㎛ filter to isolate the virus.

3.2.2. Virus treatment conditions

Virus	CO_2 concentration	Temperature	Infection time
Influenza A (H1N1)	5 %	(33 ± 2) ℃	(60 ~ 90) minutes

3.3. Viral Film Formation

After adding 0.2 mL of the test virus to the sterilized glass petri dish, the viral film was formed by drying for 30 minutes in the ambient conditions of the laminar flow BSC with the petri dish cover removed.

3.4. Virucidal Test

3.4.1. Cytotoxicity Test

As in Section 3.3., 0.2 mL of the virus culture medium was placed on the inside bottom surface of a glass petri dish to form a film. The film was placed inside the test pouch requested by the client and sealed, and the test article was operated in a HALF CYCLE(operation time: about 6 minutes). After overlaying 2 mL of the virus culture medium, the film was resuspended by scraping the surface of the glass petri dish using a cell scraper(be considered the 10^{-1} dilution, hereinafter the same). And then the mixture was serially diluted with the virus culture medium by a factor of 10. The diluted solutions were treated with the host cells at (36 ± 1) ℃ for (30 ~ 60) minutes, and the cytotoxicity effect was observed by using a microscope.

3.4.2. Cell Culture Control

The MDCK cells were treated with the virus culture medium, which was used as the cell culture control.

3.4.3. Virus Susceptibility Control

The test virus was mixed at 1:9 ratio in virus culture medium, and diluted stepwise by a factor of 10 in the virus culture medium. Each diluent was infected into the host cells to measure the viral titer of the test virus(Initial).

After forming the viral film as in Section 3.3., it was sealed in a test Pouch requested by the sponsor and allowed to stand at (22 ± 2) ℃ for 6 minutes. Thereafter, 2 mL of the virus culture medium as added, and then the virus film was recovered by scraping the surface of the glass petri dish using a cell scraper, and then diluted 10 times in the virus culture medium. Each diluent was infected into the host cells to measure the viral titer of the control group(After 6 minutes).

3.4.4. Virus Test

After forming the viral film as in Section 3.3., it was sealed in a test Pouch requested by the sponsor, and the test article was operated in a HALF CYCLE(operation time: about 6 minutes). Subsequently, the viral titer of the test group(After operation) was measured in the same manner as in Section 3.4.3.(the viral titer of the control group).

3.5. Validation Test

The solution recovered as in the cytotoxicity test(Section 3.4.1.) was used as the test solution, and used for the validation test (below).

3.5.1. Sub-cytotoxicity Test

The test solution for each concentration not exhibiting cytotoxicity was treated with the host cells for 30 minutes, and then the cell monolayer was washed with PBS. Subsequently, the cells were infected with the test virus dilution as described in section 3.2.2, and cultured as described in section 3.6.1..

3.5.2. Neutralization control

The neutralized test solution was mixed with the same amount of the test virus dilution, and the mixture was kept for (10 ~ 20) minutes for reaction. Subsequently, the cells were infected with the mixture as described in section 3.2.2., and cultured as described in section 3.6.1..

3.6. Virus Recovery

After the reaction, each solution was serially diluted 10-fold, and 100 ㎕ of each diluted solution treated in 8 wells (8 replicates) of the cells prepared in advance in 96 well plates. Then, the cells were incubated as described in section 3.2.2., and cultured as described in section 3.6.1..

3.6.1. Culture Conditions

Virus	CO_2 concentration	Temperature	Culture time
Influenza A (H1N1)	5 %	(33 ± 2) ℃	(3 ~ 5) days

3.6.2. Staining Conditions

The cells were stained with 25 % Methyl alcohol (v/v), 0.5 % crystal violet (w/v) staining solution for 10 minutes at (22 ± 2) ℃.

3.6.3. Result observation

The number of stained wells was counted and the titer was calculated by the Spearman-Karber method. The virus titer was determined according to [Equation 1] of section 3.7.1., and the log reduction was determined by using [Equation 2] of section 3.7.2..

3.7. Calculation of Results

3.7.1. Virus titer calculation [Equation 1]

$L = X_0 - (\frac{d}{2}) + d \times \sum \frac{r_i}{n_i}$

L : $\text{Log}_{10}\text{TCID}_{50}$ titer

X_0 : Log_{10} of the reciprocal of the lowest dilution at which all test inocula are positive

d : Log_{10} of the dilution factor (that is, the difference between the log dilution intervals)

n_i : Number of test inocula used at each individual dilution

r_i : Number of positive test inocula (out of n_i)

$\sum \frac{r_i}{n_i}$: Sum of the proportion of positive tests beginning at the lowest dilution showing 100 % positive result

3.7.2. Log reduction (LR) [Equation 2]

$LR = L_U - L_T$

L_U = The titer recovered from the virus control specimen (untreated)

L_T = The titer recovered from virucidal test specimen (treated)

A log values are rounded up to the two decimal place.

3.8. Test requirements

3.8.1. Cytotoxicity control

If the cytotoxicity of the host cell by the test solution is not reduced only by dilution, it should be neutralized using a gel-filtration column according to the ASTM E1482-12 method.

3.8.2. Sub-cytotoxicity control

Even if cytotoxicity caused by the test article is not visually observed, sub-cytotoxicity shall be verified because the test article may increase or decrease the viral infectivity. If the virus titer is lower than that of the control group by (45 ± 5) % or more, the diluted solution should be excluded from the calculation of the log reduction.

3.8.3. Neutralization control

The neutralization should be validated after neutralizing the test article at the time point when the reaction between the test article and the virus is completed. If the virus recovery rate is found to be less than that of the control group by (80 ± 5) % or more, the neutralization is not sufficient. Therefore, an appropriate neutralization step should be taken by using a gel-filtration column or by employing any other methods.

4. Results

4.1. Cytotoxicity of the Test Solution

As a result of confirming the cytotoxicity of the test solution after operation of the test article, cytotoxicity was observed at 10^{-1} dilution.

Table 1. Results of the Cytotoxicity Test

Host cells	Maximum dilution factor which does not show cytotoxicity
MDCK cells	10^{-2}

4.2. Results of Virucidal Test

The viral titer of the test virus(Initial) was 6.63 $\log_{10}\text{TCID}_{50}$/mL, that of the control group(After 6 minutes) was 5.88 $\log_{10}\text{TCID}_{50}$/mL, and that of the test group(After operation) was <2.50 $\log_{10}\text{TCID}_{50}$/mL.

Therefore, the reduction rate(Log Reduction) was found to be >3.38 after operation of the test article.

Table 2. Results of Influenza A (H1N1)

Cell Culture Control		Dilution	Test virus (Initial)		Control Group (After 6 minutes)		Test Group (After operation)	
Positive	Negative		Positive	Negative	Positive	Negative	Positive	Negative
0	8	10^{-1}	8	0	8	0	–	–
		10^{-2}	8	0	8	0	0	8
		10^{-3}	8	0	8	0	0	8
		10^{-4}	8	0	8	0	0	8
		10^{-5}	6	2	3	5	0	8
		10^{-6}	3	5	3	5	0	8
		10^{-7}	0	8	0	8	0	8
		10^{-8}	0	8	0	8	0	8

Table 3. Results of Calculation (Unit : $\log_{10}\text{TCID}_{50}$/mL)

Virus	Test virus (Initial)	Control Group (After 6 minutes)	Test Group (After operation)
Influenza A (H1N1)	6.63	5.88	<2.50

Table 4. Results of Log Reduction

Virus	After operation LR[1)]
Influenza A (H1N1)	>3.38

*LR: log reduction

$LR = L_U - L_T$

L_U = The titer recovered from the virus control specimen (untreated)

L_T = The titer recovered from virucidal test specimen (treated)

[1)] Interpretation of the results

Log reduction	Percent (%) reduction
1 or higher	90% or higher
2 or higher	99% or higher
3 or higher	99.9% or higher
4 or higher	99.99% or higher
5 or higher	99.999% or higher

4.3. Results of Validation Test

No cytopathic effect were found in the cell culture control, cytotoxicity and sub-cytotoxicity of the test solution was not observed, and neutralization of the sample was confirmed in the neutralization control, thus proving the validity of the test.

Table 5. Results of the Sub-cytotoxicity and Neutralization Test

Dilution	Influenza A (H1N1)	
	Sub-cytotoxicity Test	Neutralization Test
Ctrl	+ + + +	+ + + +
10^{-1}	T T T T	T T T T
10^{-2}	+ + + +	+ + + +
10^{-3}	+ + + +	+ + + +
10^{-4}	+ + + +	+ + + +
10^{-5}	+ + + +	+ + + +
10^{-6}	+ + + +	+ + + +
10^{-7}	+ + + +	+ + + +
10^{-8}	+ + + +	+ + + +
Determination	Lack of interference	Successful neutralization

T = toxic to cell line; + = virus recovered; 0 = no virus recovered

5. Conclusion

Under the test conditions, the log reduction of the Influenza A (H1N1) in the test article [Low temperature plasma sterilizer] was found to be >3.38 after operation of the test article.

6. References

6.1. ASTM E1052-11, Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension

6.2. ASTM E1053-11, Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces

6.3. ASTM E1482-12, Standard Practice for Use of Gel Filtration Columns for Cytotoxicity Reduction and Neutralization

6.4. ASTM E2197-11, Standard Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporicidal Activities of Chemicals

6.5. ASTM E2720-10, Standard Test Method for Evaluation of Effectiveness of Decontamination Procedures for Air-Permeable Materials when Callenged with Biological Aerosols Containing Human Pathogenic Viruses

6.6. ASTM E2721-10, Standard Test Method for Evaluation of Effectiveness of Decontamination Procedures for Surfaces When Challenged with Droplets Containing Human pathogenic viruses

6.7. ASTM E2756-10, Terminology Relating to Antimicrobial and Antiviral Agents

6.8. Schmidt, N. J. *et. al.*, Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections, 7th Edition, Am. Pub. Hlth. Assoc., Washington, DC, 1995.

6.9. BS EN 14476:2013+A1:2015, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1)

6.10. US EPA OCSPP 810.2000, General considerations for testing public health antimicrobial pesticides

6.11. US EPA OCSPP 810.2200, Disinfectants for use on environmental surfaces

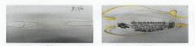
경북테크노파크 GYEONGBUK TECHNOPARK

시험성적서 (Certificate of Laboratory Testing)

성적서 번호(Certificate No.) : 20-0151 페이지(page) : (1) of 총 (1)

1. 의뢰자(Client)
기관명(Name) : Plasmapp Co., Ltd.
주소(Address) : 83, Jukdong-ro, Yuseong-gu, Daejeon 34127, Republic of Korea
의뢰일자(Request Date) : 2020.4.23

2. 제조사 (Manufacturer)
기관명(Name) : -
주소(Address) : -

3. 시험개요 (Test Outline)
시험대상(Test Sample) :  KF94 N95
시험기간(Date of Test) : 접수일자(Date of Receipt) : 2020.04.23 완료일자(Date of Completion) : 2020.05.11
시험항목(Items of Test) : Particulate filtration efficiency (sodium chloride, Paraffin oil)
■고정시험실(Permanent Testing Lab)
*주소(Address) :
시험장소(Location of Test) : 18, Solgubul-gil, Wachon-myeon, Gyeongsan-si, Gyeongsangbuk-do, Republic of Korea
□현장시험(On Site Testing)
시험방법(Test method used) : Apply in Guidline for Health Mask in MFDS (NaCl Aerosol average particle size 0.6 μm, 95 LPM)

4. 시험결과 (Result of Test) :

Test sample	Particulate filtration efficiency(sodium chloride)(%)	Particulate filtration efficiency(Paraffin oil)(%)
KF94	99 / 99 / 99	99 / 99 / 99
KF94 Chamber mode 20회	99 / 99 / 99	99 / 99 / 99
KF94 Chamber mode 50회	99 / 98 / 99	99 / 99 / 99
N95	99 / 99 / 99	99 / 99 / 98
N95 Chamber mode 20회	98 / 98 / 98	96 / 96 / 97
N95 Chamber mode 50회	99 / 99 / 99	98 / 98 / 98

※ This report are for the samples of filter media provided by the customer. The test results do not guarantee the quality of final products and do not mean a certification of KF mask.

5. 시험성적서 용도(usage of Test Report) : -

6. 확인 (Affirmation)
작성자(Test performed by) 성명(Name) : Lee Kyoungmin (sign)
기술책임자/승인자(Approved by) 성명(Name) : Kim Eunmi (sign)

※당 기관의 직인이 없는 경우 및 사본의 효력이 없습니다. If you do not have a seal of our organization and a copy, it is not valid.
※이 시험성적서의 내용은 의뢰인이 제공한 시료 및 시료명으로 시험한 결과로서, 판매 제품에 대한 품질을 보증하지는 않습니다. (The test results on this report are for the samples and sample names provided by the customer and they do not guarantee the quality of all products of the customer.)
※이 시험성적서는 당 기관의 사전 서면 동의없이 홍보·선전·광고 및 소송용으로 사용될 수 없으며, 용도 이외의 사용을 금합니다. (This test report shall not be used for public relation, advertisement, lawsuit and any other purpose outside the scope of its defined usage.)
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※이 시험결과는 KS Q ISO/IEC 17025 와 KOLAS 인정과 관련없음.(해당시 기재)(This test report is not valid without an official seal.)

May. 12th. 2020
GYEONGBUK TECHNOPARK (signature)

(주소, Address) 38542 경북 경산시 삼동로 27(477, Sampung-Ro, Gyeongsan City, Gyeongbuk, KOREA, 38542) (전화, Tel) +82-53-819-0000 (팩스, Fax) +82-53-819-0009

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Test·Inspection Report

Bacteriostasis Test for Mask

Manufacturer Name: Plasmapp Co., Ltd.

Representative: You Bong, LIM

Location: 83 Jukdong-ro, Yuseong-gu, Daejeon 34127, Republic of Korea (South Korea)

Product Name: Low temperature plasma sterilizer

Brand Name: STERLINK®

Model Name: STERLINK MINI

Serial Number: M07BUG042A

Test·Inspection Item: Bacteriostasis Test for Mask

Testing Laboratory: Plasmapp Research Institute

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

Decision: Pass

Tested until: 24 Apr. 2020 **Issued Date:** 29 Apr. 2020

Tested by: 전현정 Hyun Jeong, JEON, Process Inspector

Approved by: 이승헌 Seung Hun, LEE, General Director of R&D

Plasmapp Research Institute

Bacteriostasis Test for Mask

1. Test schedule

1.1 Date of test beginning: 20 Apr. 2020

1.2 Date of test completion: 24 Apr. 2020

2. Test article

Low temperature plasma sterilizer (STERLINK® MINI, S/N: M07BUG042A)

3. Test guideline

3.1 The tests were performed in accordance with the internal test standard of the manufacturer.

3.2 Information of testing materials

3.2.1 Masks

Type	Product	Model	Type	Manufacturer	Expiration date
KF94	All guard basic dust mask	-	KF94	All guard	Mar. 2023
N95	Particulate Respirator N95	8110S	N95	3M	Dec. 2024

3.2.2 Bacteria spore suspension

Item	Details
Model	Spore suspension
Manufacturer	MesaLabs
Lot Number	SSS-847
Expiration date	25 Oct. 2021
Commments	1.3×10^6 *Geobacillus stearothermophilus* spores (ATCC Cell Line 7953) / 0.1 ml complying with ISO 11138

*Figures of the masks were referred to the Appendix 1.

3.3 Test methods

(1) The masks were prepared for each.

(2) Each mask was inserted in Tyvek® pouch and sealed.

(3) **For the worst-case condition, the prepared pouches were processed with three consecutive full cycle sterilization of chamber mode.**

(4) After sterilization cycle, each mask was cut into two rectangular shape, approximately 25 mm length and 10 mm width using sterilized scissor.

(5) The spore suspension of 0.1 ml consisting of approximately 90 colony forming units (CFU) of the *Geobacillus stearothermophilus* spores prepared by serial 10-fold dilution method as shown in Appendix 2 was inoculated on a mask of rectangular piece for each mask type, and dried.

(6) A remain mask of rectangular piece for each mask type was left in the room temperature as negative control samples.

(7) After dried, each rectangular mask piece was placed in the tryptic soy broth of 5 ml.

(8) The spore suspension of 0.1 ml consisting of approximately 90 CFU of the *Geobacillus stearothermophilus* spores was inoculated in tryptic soy broth of 5 ml as a positive control sample.

(9) All samples were incubated at 58°C for 24 hours. After incubation, all samples were mixed by a vortex mixer and the turbidity change of media was inspected. The results were reported as positive (growth) or negative (no growth).

4. Test results**

4.1 Results of bacteriostasis test

Mask type	Test	Number of positive/Number of tested
Positive control		1/1
KF94	Negative control	0/1
	Test sample	1/1
N95	Negative control	0/1
	Test sample	1/1

**The related figures were referred to the Appendix 3. The time evolution of pressures inside the chamber were described in the Appendix 4, as well.

5. Conclusions

(1) The results of bacteriostasis tests were shown as all positive except negative controls.

(2) According to the bacteriostasis test results, the growth of *Geobacillus stearothermophilus* spore inoculated on the mask were not inhibited by three consecutive full sterilization cycle of chamber mode.

Appendix 1

1. Masks

Figure 1.1 (a, c) The outside and (b, d) the inside for KF94 and N95, respectively. The area of inoculation was indicated as the square filled with diagonal line.

2. Chamber mode for the bacteriostasis test

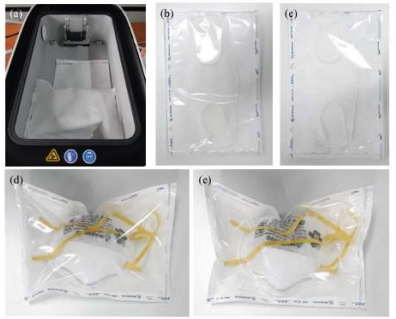

Figure 1.2 (a) The position of the masks sealed by Tyvek® pouch. The figure of (b, d) before and (c, e) after the sterilization for KF94 and N95, respectively.

Appendix 2

1. The number of the spores in spore suspension prepared for inoculation.

Figure 2.1 The incubation results of 0.1 ml spore suspension prepared for bacteriostasis test. They were incubated at 58 °C for 24 hours.

Appendix 3

1. Results of the bacteriostasis test

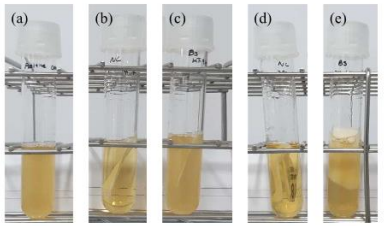

Figure 3.1 The incubation results for bacteriostasis test. (a) The positive control. (b) The negative control and (c) test sample of the KF94 type mask. (d) The negative control and (e) test sample of the N95 type mask. The turbidity can be determined by black lines behind the tubes.

Appendix 4

1. Pressure curves of the bacteriostasis test

Figure 4.1 (a) The whole plot of pressure curve during the full cycle and (b) magnified plot of diffusion phase for each consecutive trial

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Low Temperature Plasma Sterilizer
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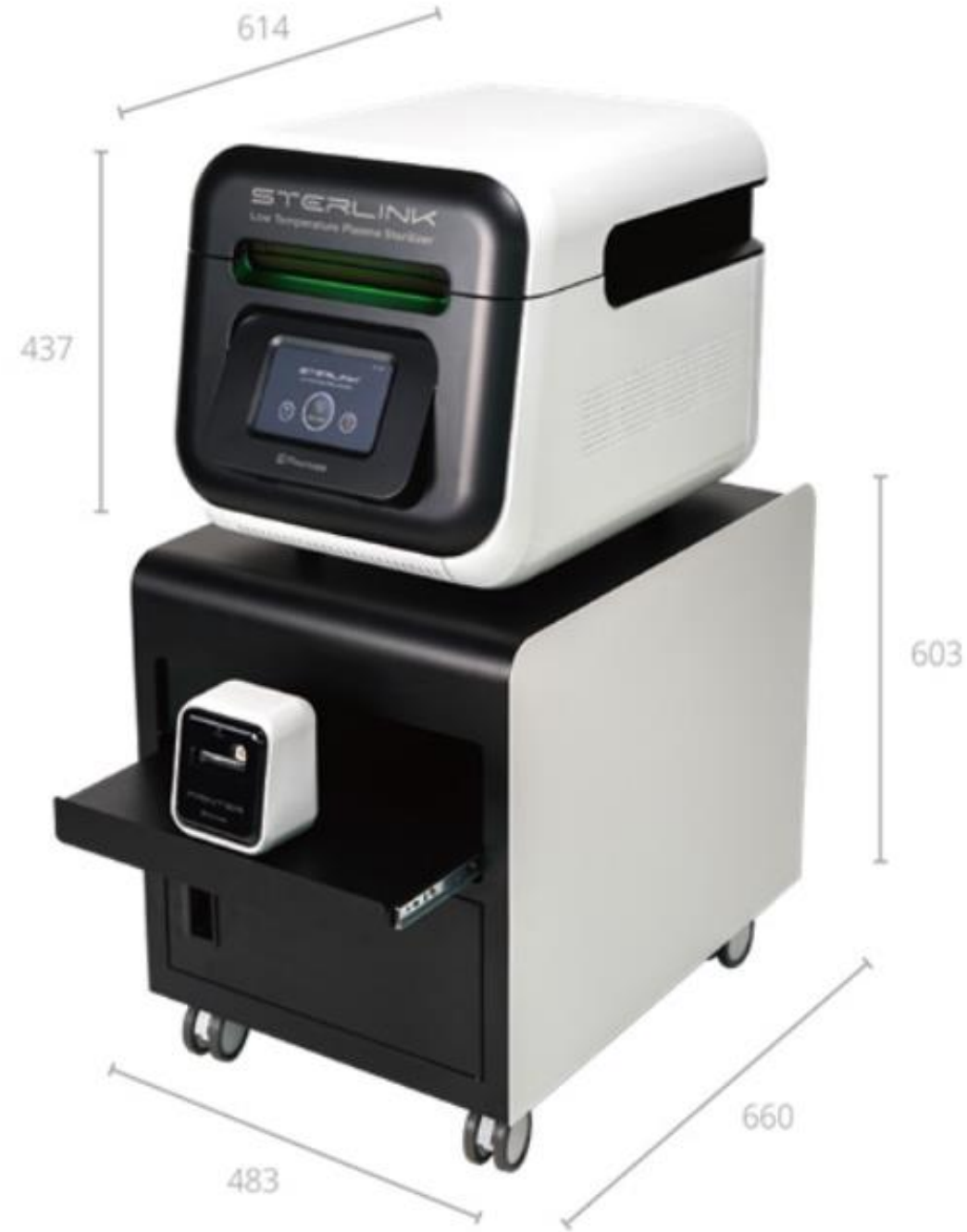
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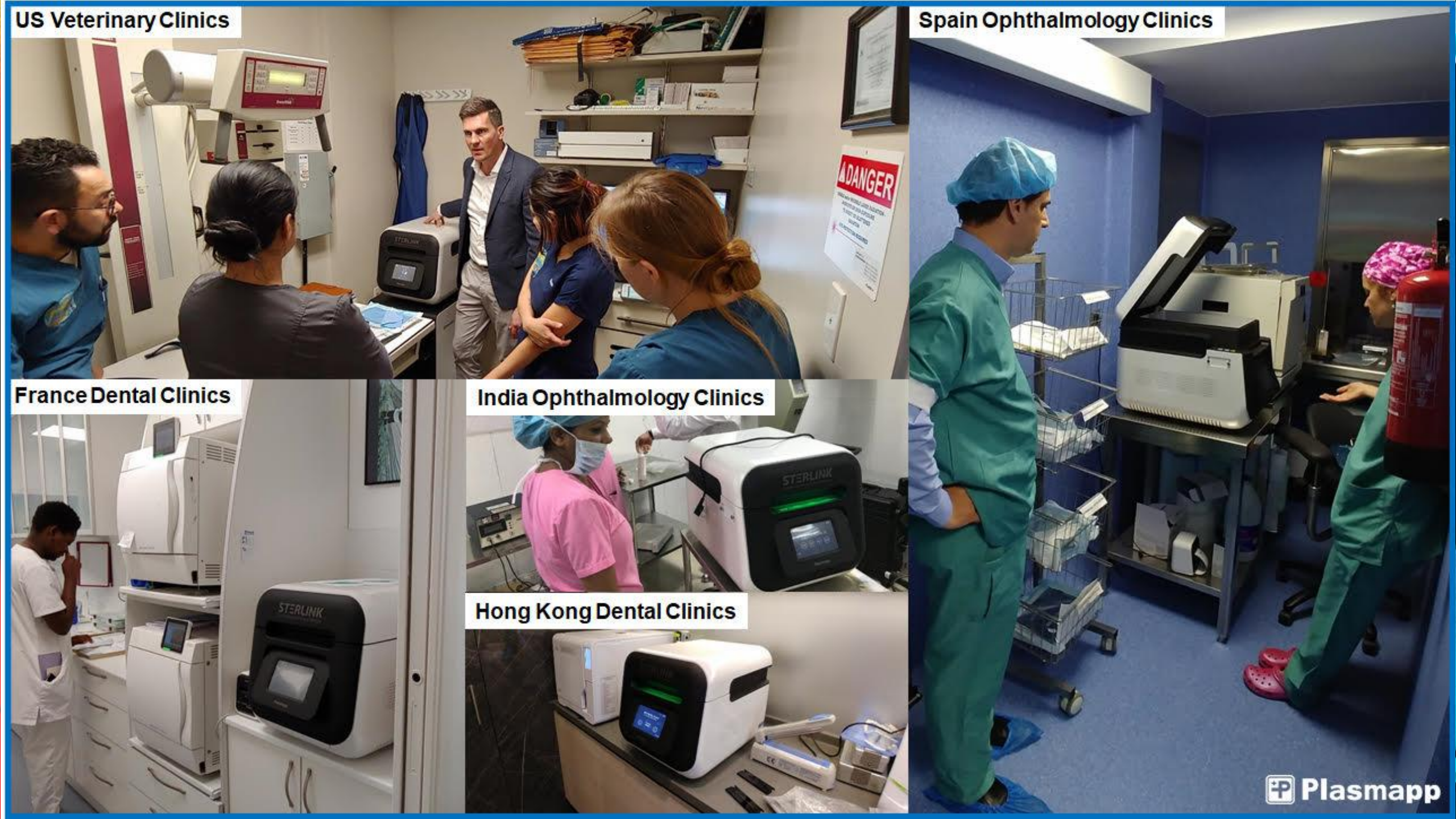
STERLINK MINI
Low Temperature Plasma Sterilizer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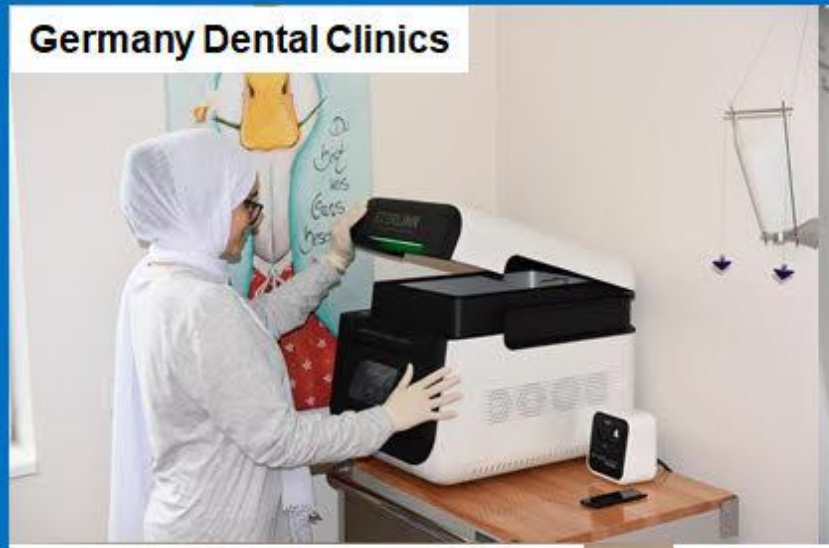
STERLINK
Hong Kong Dental Clinics
Plasmapp

Germany Dental Clinics



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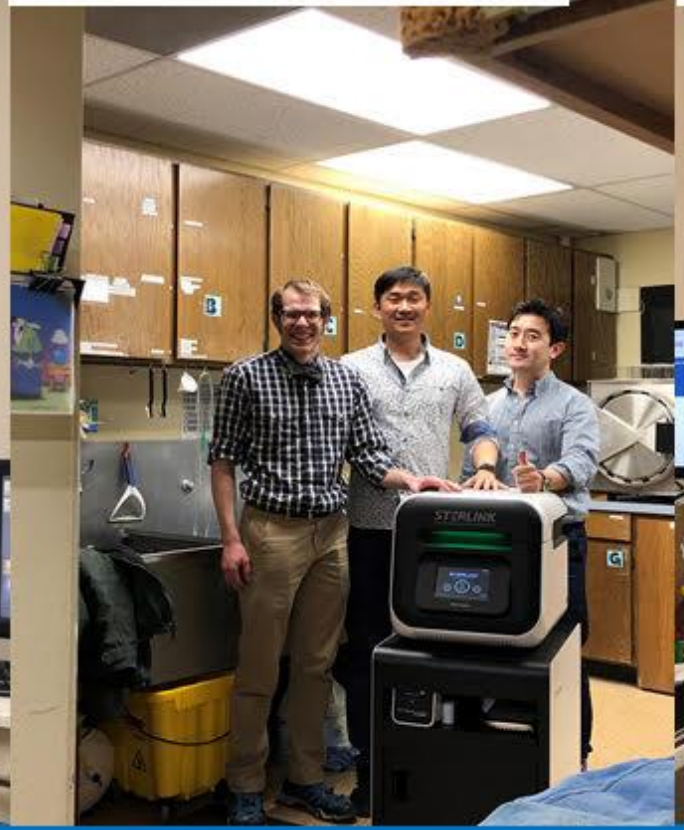
USA Vet Hospital – Sierra, NV



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KFDA

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GMP
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- 7min Fast 7 min Sterilization
- Compact Design
- One-touch Operation
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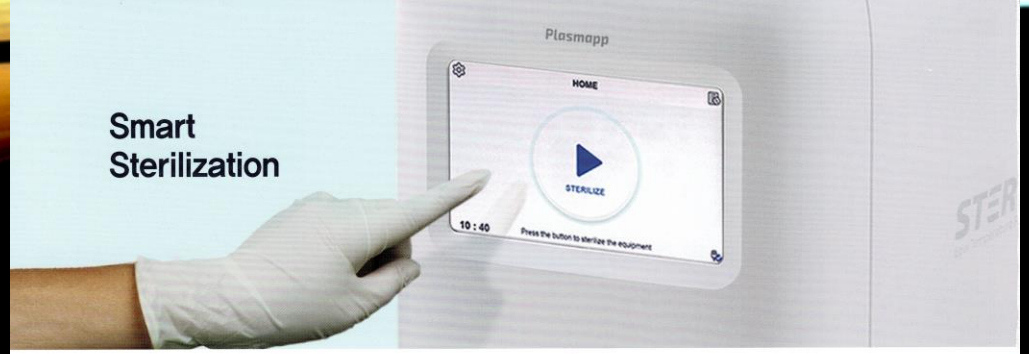
STERLINK® FPS-15s Plus 14L | STERLINK® MINI 7L

A low-temperature plasma sterilizer
Sterilization of a wide range of medical devices

The world's first direct injection pouch-type
patented sterilization technology has been applied.
SAL of 10^{-6} is validated to ensure sterilization stability of medical devices.

(SAL: Sterility Assurance Level, 99.9999%)



Smart Sterilization

Sterilant Cassettes, Consumables and Accessories

※ Sterilant cassettes

STERPACK®
- Size : 135×280mm
- 50ea / Box

STERPACK® Plus
- Size : 240×410mm
- 30ea / Box

STERLOAD®
- 30ea / Box

STERLOAD® MINI
- 30ea / Box

※ Consumables

Tyvek® 100
- Size : 100×400mm
- 120ea / Box

Tyvek® 200
- Size : 200×400mm
- 90ea / Box

Tyvek® 300
- Size : 300×400mm
- 60ea / Box

Sterilization wrap
- Size : 60×60cm
- 50ea / Box

Accessories

STERSEAL®
- Size : 505×255×145mm
- Weight : 12kg
- Temperature : 135℃ / 150℃

Cart
- Size : 483×660×603mm
- Weight : 37kg

Label printer
- Size : 120×102×146mm
- Weight : 0.5kg

Label sticker roll
- Width : 52 × 110mm
- Label counts : 49ea

※ Accessories

CI tape
- Width : 20mm
- Length : 50m

CI strip
- Size : 18×105mm
- 250ea / Box

BI
- Time : 30 min
- 50ea / Box

Tray

STERPACK® Tray
- Size : 195×80×30mm

STERPACK® Plus Tray
- Size : 260×160×50mm

※ Single Use Only

※ Tyvek® is a Dupont™ registered trademark.

STERPACK® STERLOAD®

The world's first direct injection pouch with patented sterilization technology

Vacuum sealing pouch enables to check immediate sterilization conditions

Using safe disposable sterilant cassettes

STERPACK® Specification

Cassette	Mode	Sterilant	Cycle time	Capacity
STERPACK®	Pouch Mode	H_2O_2 58%–59.5% (0.1 cc/cell)	7min	1L
STERPACK® Plus	Pouch Plus Mode	H_2O_2 58%–59.5% (0.3 cc/cell)	14min	4L

STERLOAD® Specification

Cassette	Mode	Sterilant	Cycle time	Capacity
STERLOAD®	Chamber Mode	H_2O_2 58%–59.5% (0.9 cc/cell) (0.7cc/cell)	36min	14L
STERLOAD® MINI			18min	7L

※ STERPACK® Plus, STERLOAD® : Compatible with STERLINK® FPS-15s Plus only
※ STERLOAD® MINI : Compatible with STERLINK® MINI only

Using Tyvek® pouch

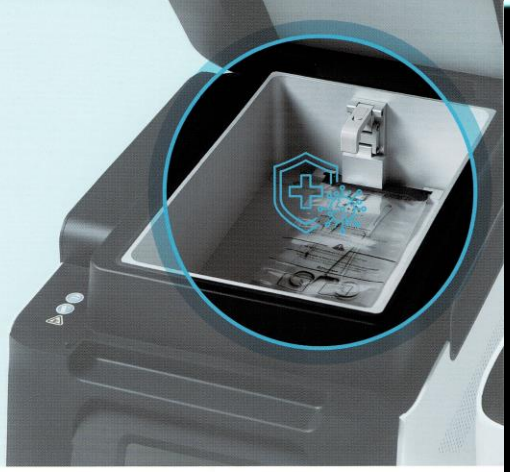
Using in chamber mode

Sterilization Performance

STERLINK® verifies sterilization performance through the following lumen tests

Lumen claims for STERLINK®

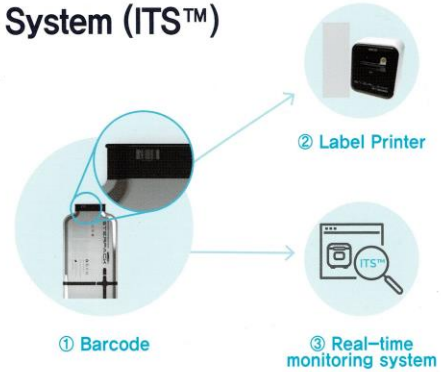
- 0.7ø x 500 mm Stainless
- 2.0ø x 1500 mm Stainless
- 1.0ø x 2000 mm PTFE



Instrument Tracking System (ITS™)

Equipment tracking using barcode

- Real-time monitoring to check the STERLINK®
- Provide the latest software updates remotely



Comparison Chart

Sterilizer	Temperature	Cycle Time	Sterilant	Feature
Autoclave	Up to 134℃	60min + 1 hour cooldown	Hot steam	• Cloth sterilization • Long cycle time • Risk of burn • Damage of medical instruments
E.O. Gas	Up to 60℃	Over 120min + 12 hour ventilation	E.O. gas	• Highly dangerous toxic gas • Long cycle time
Plasma Sterilizer	Up to 60℃	70min	H_2O_2	• High cost • Large volume • Additional ventilation • Very low efficiency
STERLINK®	Up to 60℃	Pouch Mode : 7min Pouch Plus Mode : 14min Chamber Mode : 36min	H_2O_2 direct injection	• Fast sterilization cycle • Economic cost • Compact size • Ergonomic design • Easy maintenance • ITS™ system • Eco-friendly • Safeness of heat sensitive instrument

STERLINK®

Specification

Model	STERLINK® FPS-15s Plus	STERLINK® MINI
Size (W×D×H)	433 × 614 × 437 mm	275 × 440 × 330 mm
Chamber (W×D×H)	264 × 410 × 125 mm (14L)	206 × 346 × 113 mm (7L)
Diagonal length (Chamber)	47cm	36cm
Vacuum Pump	Pump built-in type	Pump stand-alone type
Weight	67kg	20kg (Pump module : 21kg)
Cycle time	STERPACK® : 7min STERPACK® Plus : 14min STERLOAD® : 36min	STERPACK® : 7min STERLOAD® MINI : 18min

Applications & potential customers

Laboratory, Research Center, University, Bio Medical Industries, Pharmaceutical Company, General Hospital (except Ophthalmology/Dental clinic), Casino,

Veterinary medicine, Animal Hospital etc.,

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