

H2O2 Low Temperature Plasma Sterilizer

PS-100X/XP/200X/XP

Technical Description and Configuration



PS-100XP



PS-100X



PS-200X



PS-40X

Shinva Medical Instrument Co., Ltd

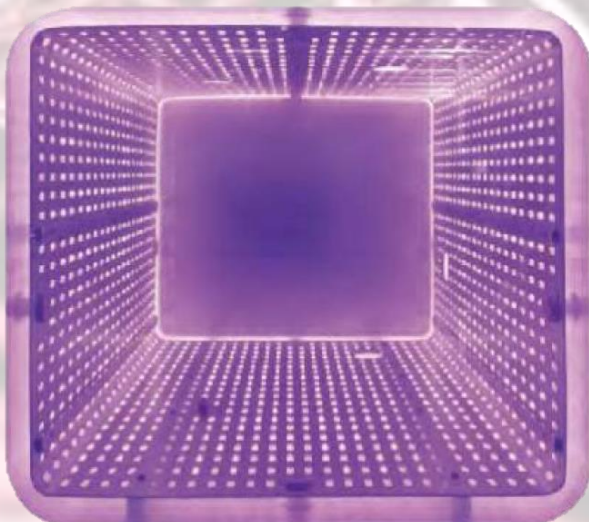
I Product introduction

Plasma refers to a highly ionized gas cloud, which is generated by the ionization of gases under the action of heating or strong electromagnetic force, mainly including electrons, ions, atoms, molecules, active free radicals and rays. Among them, active free radicals and rays, such as ultraviolet, have a strong killing effect on microorganisms. Plasma is the fourth form in nature in addition to solid, gas and liquid. Because the total number of positive and negative charges is always numerically equal, it is called plasma.

The SHINVA Plasma sterilizer utilizes hydrogen peroxide (H_2O_2) as its sterilizing agent, transforming it into a plasmatic state through an electromagnetic field at low temperatures. This innovative process combines both gaseous and plasmatic forms of H_2O_2 to thoroughly sterilize items within the chamber. Following sterilization, residual H_2O_2 is decomposed, leaving behind only water and oxygen at the conclusion of the cycle

II Product structure

The equipment is composed of the following parts:



1. Square sterilization chamber, including sterilization outer chamber, mesh electrode, container and heater, etc.
2. The chamber and mesh electrode are aluminum alloy, welded on both sides, and the service life of the chamber can reach more than 10 years.
3. Vacuum-pumping system, including vacuum pump, pressure transmitter, vacuum valve and controller.
4. Hydrogen peroxide injection system, including cassette feeding mechanism, cassette piercing mechanism, purifier, solenoid valve, etc.
5. Automatic control part, including electric control box, touch screen and other components.



III Product features

1. Exclusive use of the top rod driven electric lift door, easy to operate, no noise, improve the airtight sterilization chamber, improve the automation of the whole machine. A security system is installed on the door to ensure equipment and personal safety.
2. The sterilization chamber is made of aeronautic aluminum alloy material, which has excellent thermal conductivity and more balanced temperature to ensure that hydrogen peroxide remains 100% gaseous, so that the sterilization performance is more stable. The sterilization chamber adopts rectangular structure, and the effective volume.
3. The pipes and fittings linking the high-efficiency vacuum pump to crucial pressure-sensitive components are constructed from stainless steel 304 and 316L.
4. With hydrogen peroxide purification function, ensure that the hydrogen peroxide injected into the sterilization room diffuses more evenly, and will not occupy the surface of items due to moisture, affecting the sterilization effect.
5. Air-intake is also equipped with HEPA filter according to ISO 29463
6. Hydrogen peroxide is encapsulated in an independent sealed capsule case, which is accurate in filling and has a long validity period, safe and reliable, no leakage hazard, safe and convenient in operation and transportation.
7. PS-100X/100XP: Each cassette contains 12 capsules, which can run 6 full cycles or 12 flash cycles. Each capsule stores 5ml hydrogen peroxide.
8. PS-200X/200XP: Each cassette contains 12 capsules, which can run 3 full cycles or 6 flash cycles. Each capsule stores 4ml hydrogen peroxide.



9. Full automatic loading and puncturing of H₂O₂ cassette to ensure that workers do not contact hydrogen peroxide.

10. Passed multiple authoritative test reports.

Certificate	Testing institutions
CE	TUV

11. The size of the equipment is small, doesn't require any special facilities like water or aeration, easy to install and move using the wheels.



12. Equipped with hydrogen peroxide filter, so that the hydrogen peroxide gas is fully absorbed and decomposed in the process of evacuation, to ensure that there is no hydrogen peroxide pollution indoors.

13. Integrated electric constant temperature incubator is optional. The electric temperature incubator is integrated with the equipment, which can realize the rapid and convenient cultivation of biological indicators after sterilization. With independent control system, it can operate independently when the equipment is shut down, saving energy and improving the life of the equipment. Its culture temperature is constant, special for this equipment, and can be cultured in multiple groups at the same time,

with timing display, easy to operate.

14. The sterilizer's body is crafted from carbon steel, featuring powdered painted panels that offer exceptional resistance to scratches.
15. With kick type quick door opening. Only by gently kicking the foot switch of the equipment, the sealed door can be opened or closed, freeing the hands of the operator.
16. Module with vacuum drying function (optional). The vacuum drying module can perfectly combine the plasma sterilizer with the vacuum drying cabinet to thoroughly dry the lumen instruments and ensure the sterilization quality. Completely replace the vacuum drying cabinet. After cleaning, the pre-blown or pre-dried instruments are put into the sterilization room. At a low temperature of 50~60°C, the boiling point of water decreases with the decrease of air pressure. After vacuum drying for 10~60min, the moisture inside the lumen instruments will be thoroughly dried.
17. Real-time monitoring function of plasma power supply. Real-time detection display plasma power supply and record the critical value of the printing stage. The system will automatically judge the abnormal fault of the power supply, give an alarm and automatically cut off the output.
18. Optional hardware module available for remote monitoring via Ethernet of the real-time working processes, alarm, error codes reading on the sterilizer.
19. With STANDARD, FLEXIBLE, RAPID and CASSETTE RELAY sterilization programs, can meet the requirements of different items, different sterilization time. RAPID cycle sterilization time can be as short as 26 minutes.

Program Name	Sterilization Range	Running Time
STANDARD	For sterilization of luminal and non-luminal instruments	55min
FLEXIBLE	For 2 PCS of flexible endoscope	45min
RAPID	For surface sterilization of small quantities of articles	26min

VACUUM DRY (optional)	For drying lumen apparatus	15min
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Lumen Dimension			
PS-100X/100XP			
Material	Inner Diameter	Length	Loading capacity
Stainless steel lumen	≥1mm	≤500mm	10 pcs
Teflon or polyethylene lumen	≥1mm	≤2000mm	10 pcs
PS-200X/200XP			
Material	Inner Diameter	Length	Loading capacity
Stainless steel lumen	≥0.8mm	≤3000mm	10 pcs
Teflon or polyethylene lumen	≥1mm	≤1000mm	10 pcs

20. With system automatic detection function, real-time monitoring of the sterilization process, if there is any abnormality, the system will automatically alarm, and display the cause of the fault on the big 10-inch touchscreen display
21. With the function of humidity detection of sterilized articles, if the articles are dried unqualified, it will alarm to remind users of the sterilization after the articles are dried again;
22. With multiple sterilization information viewing function. In the process of sterilization, the color touch screen can display the sterilization stage, sterilization time, sterilization

pressure, sterilization temperature and other sterilization information in real time. Thermal printer can automatically print sterilization records which can be stored for more than 3 years; Computer monitoring system is optional to realize real-time monitoring of sterilization data and permanent storage of historical operation records. Internal memory capable of storing history for 15000 cycles, also USB port is available for flash disk storage and PC connectivity.

23. Optional application of traceability system; It can realize the traceability of the whole work flow, such as the recovery, washing, sterilization and distribution of instruments.
24. With key components maintenance intelligent reminder function, such as vacuum pump oil change, which can effectively guarantee the service life of components; Comprehensive training materials are available to ensure that operators are skilled in operating the equipment.
25. The Siemens S7-1200 system PLC from Germany's Siemens manufacturer- boosts stable and reliable performance alongside powerful functionality
26. The pressure transmitters from Germany's WIKA and Japan's SMC offer excellent precision, high reliability, and stable output, ensuring dependable performance in various applications.
27. Optional double door with separation wall construction. Double door structure, front and back door interlock, with isolation wall, can effectively realize sterile area isolation, avoid the re-contamination of sterilized goods.
28. The manufacturer can provide: 56%-60% hydrogen peroxide cassette, chemical indicator card, indicator label, multi-specification non-woven fabric, multi-specification packaging pouch, multi-specification instrument container, self-contained biological indicator, vacuum pump oil, long-acting printer paper, etc..

IV Technical Parameter

Model	PS-100X	PS-100XP	PS-200X	PS200XP
Technical parameter				
Number of doors	1	2	1	2
Chamber dimension (LxWxH) mm	750x450x400		1250x450x400	
Volume(L)	135		225	
Overall dimension (LxWxH) mm	1030x760x1760		1510x760x1760	
Weight (Kg)	400		500	
STANDARD cycle time (Mins)	55		60	
Sterilization Temperature (°C)	50±5			
Sterilizing agent	56%-60%H2O2			
Power supply	380V 50Hz			
Total power (KW)	3.8		4.7	
Installation ambient temperature	10~40°C			
Distance between the operating end and obstacles (mm)	>1000		>1500	
Minimum maintenance distance	1 meter on each side			

V Auxiliary Device



- a) Electric constant temperature incubator
Temperature: 56 (°C) Incubation time: 48 hours
- b) Biological indicator (self-contained) Strain: *Adipobacter thermophilus* Quantity: $1 \sim 5 \times 10^6$
- c) Chemical indicator card:
Put in the pouch and indicate whether the hydrogen peroxide is evenly diffused.
- d) Chemical indication label:

After packaging, attach the chemical indicating label to the transparent side and non-woven material of the sealing pouch. Chemical indicator band discolours after exposure to hydrogen peroxide. The function of the label is to encapsulate the non-woven fabric package, record the relevant information of the package, and indicate whether the package has been sterilized.

e) Packaging pouch (sealed sterilized articles)

f) Material: the front layer is polypropylene, the back layer is high-density polyethylene synthetic transparent paper;

Packaging temperature: 120 (°C) ~ 125 (°C) is recommended.

Size (100m per roll): width 75mm, 100mm, 150mm, 250mm, 300mm

g) Sterilization agent

Name: Hydrogen peroxide (H_2O_2)

Concentration: 56%-60% ;

Specification: 12x5ml/capsule (PS-100X/100XP)

12x4ml/capsule (PS-200X/200XP)

Storage: Keep out of light at room temperature

h) Non-woven cloth (used for wrapping instruments such as plates)

Size: 500mm×500mm; 800mm×800mm; 1200mm×1200mm

i) Metal sterilization container

See sample instrument loading basket for detailed information.

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MEDICAL DEVICES TÜV SÜD PRODUCT SERVICE GMBH

