Sterilization Systems

Feel the innovation

Plasma Sterilizers
Hospital application
Low Temperature Plasma Sterilizers
Advanced technology for safe low-temperature sterilization

Plasma Sterilizers

Feel the innovation
Plasma Technology

Plasma Sterilization is one of the latest low temperature techniques for sterilization. The CISA system for generating Plasma (an atmosphere constituted of ionized gas conditions of high vacuum) is based on a technology that has been developed to be ideal for sterilization of reusable medical devices. The medical community agrees that plasma is an ideal sterilization technology.

The CISA Plasma sterilizer has been designed with the most sophisticated features for safety control and is in compliance with the EU Medical Devices Directive 93/42. As with all CISA sterilizers, the plasma sterilizer has been designed energy saving, without affecting performance, thanks to advanced engineering solutions that make optimum use of power and energy consumption.

In addition, there is no risk from hazardous residues remaining on the sterilized devices or getting into the air of the working environment.

CISA Plasma sterilization advantages

The CISA Plasma sterilizers offer optimum sterilization results for a large range of medical devices.

- Low Temperature Sterilization (45-50 °C)
- Better penetration and efficiency
- Better heat distribution
- No toxic residuals
- Safe and full sterilization
- No connection for lumens
- Lower running costs
- Lower maintenance costs
- Improved load humidity management
- Specially designed to be installed in a CSSD
- Better control of dosing of Plasma
- Better cycle efficiency testing with Helix Test
- Large chamber size with a choice of “two” sizes
- Better versatility for different loads
- High volume load (SPS6464)
- High sterilization capacity and flexibility (SPS4270)
- Large coloured multi language touch screen for constant critical multi-parameter monitoring
Plasma Sterilization cycles and process
The materials to be sterilized are wrapped and placed on the shelves in the chamber and processed through a sterilization cycle (Fig.1).
Plasma sterilization equipment guarantees optimum sterilization results for lumened material and for linear surfaces as well.

Lumened material cycle diagram

![Lumened material cycle phases](image)
1- Pre Vacuum
2- Deep Vacuum
3- Sterilization
4- Vacuum
5- Sterilization
6- Vacuum
7- Sterilization
8- Vacuum
9- Aeration

Non-lumened material cycle diagram

Fig.1

After loading, the pressure is reduced and then plasma generated.
The Plasma is created by Direct Current pulses which cause ionization, excitation and photoionization of the sterilizer atmosphere under high vacuum.
Pressure is continually reduced by means of a special vacuum pump. The Plasma is present throughout the sterilization phase.
The plasma heat output (around 45°C) intensifies the action of the chemicals, also ensuring that no toxic residuals remain on the sterilized materials.
The combined action of a high vacuum, plasma and the sterilizing mixture ensures sterilization of the load.
During the flushing phase, filtered air is introduced into the chamber and quickly removed.
The process is then complete for non-lumened materials, but repeated again for lumened materials.
Plasma sterilization offers a short cycle time and with low temperatures (under 50°C), preserves heat sensitive medical devices.
Thanks to the Plasma it is also possible to remove the sterilizing agent from the surface of the medical devices, permitting their immediate use.
Plasma excitation is a simple process and independent of the make-up of the load material (e.g. metal, ceramic, glass or plastic).
The whole process is simpler and less expensive than with other low temperature sterilization, offering high flexibility and capacity to health care facilities.
**Microbiological test results**
The destruction of microorganisms occurs as the result of the oxidizing action of ions and free radicals which attack the cells’ walls and the inner part of the nucleus. Using a biological indicator with a population of $10^6$ spores, we can certify the effective reduction of the bio-burden and the achievement of the sterile status of the load, since the test load has a spore population higher than normal medical device loads. The sterile status of the loads are protected by packaging materials validated within the SPS sterilization process.

Efficacy tests were performed with a standard kit of spores of Geobacillus Stearothermophilus ATCC 7953, on strips populated with $10^6$ spores.

**Welcome to the SPS 4270**
The SPS420 is the new CISA Plasma sterilizer that offers the high quality performance of the SPS6464, but in a smaller size. The general functionality is the same as the SPS6464, but, thanks to some technical improvements, SPS4270 can guarantee the same optimum results in an even shorter cycle time. Sterilization using the new CISA Plasma technology is guaranteed even in 1500mm long narrow (2mm) close-ended lumens and catheters without the use of boosters and adaptors. Operating, maintenance and consumables costs are even lower with the new CISA SPS4270.
Application
The CISA Plasma sterilizers provide a quick and easy means to sterilize heat and moisture sensitive medical and hospital devices, thereby increasing their life. The machine can be installed in a CSSD or in any sterilization room, alongside similar equipment operating at higher temperatures.

Design & Installation
The different sizes belong to the same design standards with free standing or pass through walls. The CISA SPS sterilizers have been designed and manufactured in compliance with relevant International and European directives and safety, product, and process standards, including EN 14937. The CISA SPS sterilizers are equipped with two PLC controllers with microprocessor for independent control, as well as two parallel pressure sensors to guarantee optimum performance and reliability. The construction of the machine is from the highest quality materials for perfect hygienic functionality and durability. The equipment is designed with a user friendly system for the operators, and is in full compliance with environmental requirements. The installation and maintenance of the machine are described in smooth and clear steps, offering effortless installation with ease of positioning and connection to the main utilities. The compact architecture is such that the overall dimensions are always relative to the machine's capacity. Valves are pneumatic for reliability and they are manufactured in stainless steel for a long service life.

Construction
The materials used in the construction of the machine are top of the range with high quality AISI 316Ti (chrome-nickel-molybdenum-titanium) stainless steel for the chamber including with internal shelving, jacket, and door, to guarantee a high performance and durability of the pressure vessel. The frame and external panels of the machine are also manufactured using stainless steel. All components inside the hydraulic plant, piping and valves are manufactured using 316L stainless steel. The machines’ construction reflects the experience of CISA in the field of decontamination equipment and represents a benchmark for the industry. The chamber is manufactured in a single piece with electric polishing up to an Ra less than 0.2 micron (mirror finish electrolytic polishing treatment) and is manufactured to a thickness of 6-8 mm. The jacket is created by robotic welding to guarantee the structure. The chamber is designed to withstand pressure from absolute vacuum up to +3.5 bars and factory tested up to 6.4 bars.
Control Panel
The control panel is based on a modern design with a smooth surface for hygiene and for easy cleaning, and is installed on the load side. The control panel comes with a large 8” touch screen, built-in printer, optional chart recorder, emergency stop button, and other control buttons including On/Off.
The control panel is also equipped with pressure gauges to monitor the process.
The control panel is installed at eye level to enable easy reading and control.
The control panel displays the cycle status, any alarms, a pressure gauge for chamber pressure, emergency button, and control buttons for door closure. Another optional touch screen or printer can be installed on the unloading side if required.

- Audio visual alarms display with alarm history
- Maintenance program for preventive maintenance
- Operators access level control
- Calibration and technical pages (password protected)
- Programming new cycles or modifying standard cycle (password protected)

Touch Screen cycle phases

Touch Screen start

Touch Screen operator code

Touch Screen
The touch screen allows the operator to monitor:

- Phase
- Pressure
- Temperature
- Time
- Cycle Selected
- Date and time
- A menu to lead to other monitoring and control pages
- Option for manual interaction
- Set point follow up

Multi language touch screen
Most major languages are pre-installed in the machine: users can easily choose English, Italian, French, Spanish, Arabic, Russian, Portuguese, German, Turkish, Polish, Chinese, Greek, Romanian, Korean, Bulgarian, and others.

Operator access level control
Every operator has his/her own identity using the CISA Password controlled pre-defined access level system: different levels can be set for each operator with multiple functions for each. The operator name is stored in the system and on the print out.

Alarms
Audio Visual Alarms are provided: the alarms list includes multi level alarms with clear message notification; alarm levels are configured based on the level of gravity to stop the machine or stop the cycle or just warn without affecting the running of the cycle.
Alarm lists are comprehensive for the safe and ideal operation for both operator and machine, including:

- Cartridge alarm
- Door lock alarm
- Max phase time
- Vacuum and Pressure alarm
- Power failure
- Air shortage alarm
- Low Internal battery
- Low/high temperature range

Any alarm occurring is printed out during the cycle and an alarm history is available
Alarms are also indicated on the unloading side in the double door pass-through version. An End of cycle alert is included to advice the user to start the unloading process.
A chart recorder is available as an option for viewing the output from the independent sensors with validation and comparison between printed and recorded data.
Service and maintenance programme
The touch screen has pages covering periodic preventive maintenance, ensuring safe functioning of the machine. The technical pages also cover calibration and parameter control. The maintenance and technical pages are password protected: only authorized personnel have access to them.

Printer & chart recorder
The built-in printer for cycle documentation includes on the print out: date and time, hospital name, cycle number, operator name, selected cycle, parameter values at different cycle stages (programmable to customer requirements), phase completion timings, total cycle time, and validity of the completed cycle. In case of an alarm occurring during a cycle, the details are registered and printed. All the pre-programmed cycles have been validated to the ISO14937 standard and can be executed by the operator.

Maintenance
The sterilizer is designed to enable maintenance access from the front through a hinged door with key lock. The components are installed inside in such a way as to guarantee easy access and an ergonomic engineering layout for better performance. The electrical components are installed in a sliding controls box which is sealed to IP55 protection level to guarantee better component protection as compared with open plan electric circuitry. With the preventive maintenance programme and trouble shooting system, maintenance is trouble-free using CISA systems.

Automatic sliding door(s)
Automatic Sliding doors enable safe and smooth door open/closure through the use of a pneumatic system. The doors have a window for process and load monitoring.

Door options
The machine can be supplied as single door (1P) or as double door pass through (2P).
CISA sterilization units conform to the requirements of the International and European standard ISO EN 14937 and to the different Standards it refers to, amongst which are ISO61010-1, ISO61010-2-040, ISO60204-1. The machines are also CE marked according to the EU Medical Devices Directive 93/42.

**Gasket**
The self-lubricating gasket has been certified for sterilization processes, and, due to the quality of the machined seating, does not need maintenance.

**Seal**
The gasket seal seat, on the frame of the unit is specially created with a CNC machine tool. The internal surface of the seat is ground to an N6 level to provide perfect adherence of the gasket. The perfectly rounded corners avoid wear and tear on the gasket itself.

**Door safety closure & interlock safety**
The machine is provided with high level safety features including for the door(s) the following:
- In the double door version, both doors cannot be open at the same time due to an interlock safety device to prevent cross contamination.
- A Safety lock prevents door opening if a cycle is running.
- A cycle will not start until the system has checked that the door(s) are tightly closed.
- For operator safety: door closure is stopped if an obstacle is found in the way of the closing door.

**Safety features**
The machine features safety programmes to international and European standards with a self test for automatic checking.

**Networking and Management software**
The CISA Plasma machine can be connected to a computerized management system and/or sterilizer control system. Our proprietary external supervision and networking system, NCS, can be added for the sterilizer for central data monitoring, archiving, and reporting using an ETHERNET connection with real time data transfer.

**NCS:** System for central data monitoring, archiving and reporting using a real time data interface.

**ITINERIS:** system for CSSD management and instrument tracking system.

**RMS:** Remote maintenance system for external maintenance. Check and interface.

**Black Box**
The Black Box is a device that can be installed in the sterilizer as a communication distribution device, and as a data storage system. The Black Box enables different communication facilities as the recovering system.
Accessories and Optional Extras

**Stainless steel fascia**
A stainless steel fascia can be added to introduce stainless steel panels between sterilizers for easy cleaning of the surface and for a safe environment. The machines can be installed as standard or as mirror images of each other for better control with a stainless steel enclosure between them.

**Air compressors**
Compressed air is needed for the pneumatic valves and for door operation. If compressed air is not available, we can supply electric silent air compressors with electric feed from the sterilizer power outlet point, or a separate power supply. The quality, pressure, and flow rate of compressed air from these compressors is consistent with the machines’ requirements.

**Baskets/Containers/Trays**
A wide range of basket types in all sizes is available.

**Tyvek® type packing**
Choosing the proper packaging material for a medical device requires careful consideration of the nature of the device, the sterilization process, and the packaging material’s characteristics. Low temperature sterilization methods require that the packaging includes a porous component. Tyvek®, with its porous nature and high moisture-vapour transmission, is the most widely used for plasma sterilization.

**Sterilizing Agent**
The sterilizing agent is a chemical solution based on hydrogen peroxide and is contained in a special cartridge, which is suitable for the application. The cartridge is inserted into a cassette to make its handling, shipping, and introduction inside the injection port easier. All the phases of transport inside the injection port (including the suction of the chemical solution) are completely automatic.
## Plasma Sterilizers HOSPITAL APPLICATION

<table>
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<tr>
<th>Version</th>
<th>Power supply</th>
<th>Door closing</th>
<th>Leak</th>
<th>Pushed gasket</th>
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<tbody>
<tr>
<td>• Hospital (H)</td>
<td>• Electrical</td>
<td>• Vertical</td>
<td>•</td>
<td></td>
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<tr>
<td>• 1 Door (1P) • 2 Doors (2P)</td>
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<tr>
<td>• Programmable logic controller &amp; touch screen (TS)</td>
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### SERIES SPS

<table>
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<tr>
<th></th>
<th>CISA 6464 SPS/1P</th>
<th>CISA 6464 SPS/2P</th>
<th>CISA 4270 SPS/1P</th>
<th>CISA 4270 SPS/2P</th>
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<tr>
<td>Chamber Dimensions (LxHxD) (mm)</td>
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<td>Chamber volume (l)</td>
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<td>Load capacity S.U.</td>
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<td>6 (1/2 S.U.)</td>
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<td>Overall dimensions (WxHxD) mm</td>
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<td>Heat loss (W)</td>
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