DATASHEET

P150 plasma sterilizer



External dimensions	
- height	1745 mm
- width	860 mm
- depth	1060 mm
Sterilization chamber dimensions	
- height	400 mm
- width	450 mm
- depth	750 mm
Chamber volume	
- total	134 l
- usable	103 l
Sterilization baskets	
- dimensions	680 x 395 x 150 mm
- quantity	2
Sterilizing agent - H_2O_2 *(hydrogen peroxide)*	58 – 60%
Sterilization temperature	50–55°C
Electrical power supply	3N~ 400V, 50 Hz
Power	4 kW
Weight	390 kg

SMS P150 is a plasma sterilizer used to sterilize medical equipment and instruments made of heat-sensitive materials such as: products of synthetic and polymer materials, medical optical systems, medical electric instruments and electrical power cables, rigid endoscopes, ultrasonic medical devices, sensors, medical devices including ultrasound devices, medical implant tools installation.

It is a low temperature plasma sterilizer with a 103 liters chamber volume.

Plasma sterilizers are perfect for central sterilizing supply departments (CSSDs), outpatient clinics, operation theaters, respiratory and gastroenterology endoscopy clinics.

Specification

The chamber

The sterilizer's chamber is made of high quality aluminum with a polished and anodized surface. Silicone heaters are used to pre-heat the chamber to 50-55 °C. To minimize energy loss and maximize the efficiency of the sterilizer the chamber is insulated.

Chamber door

The chamber door is made of high quality aluminum with a polished and anodized surface. Silicone heaters are used to pre-heat the door to 50–55 °C. To minimize energy loss and maximize the efficiency of the sterilizer the chamber door is insulated.

Piping

- Pipes and other connection /support assemblies made of stainless steel.
- Tri-clamps are made of stainless steel and aluminum.

Housing

The sterilizer's housing is made of stainless steel for easy maintenance.

Sealing gasket

The P150 plasma sterilizer has a sealing gasket inserted into a special groove in the front face of the chamber. The door closing motion is designed to push the door against the gasket compressing it and sealing the chamber. At the beginning of every cycle the vacuum pressure further compresses the gasket producing an airtight seal.

Valves

Electromechanical valves are used to precisely control the flow of liquids and gases into and out of the chamber.

LCD touch screen

Our plasma sterilizers are equipped with an easy to read 9,7" LCD touch screen with an intuitive and user friendly interface.

Air intake filter

Sterilization cycles that end with a aeration phase require ambient air. To make sure this air is sterile our plasma sterilizers are equipped with an intake filter (sterile air filter). It removes 99,999% of particulates that have a size equal to or greater than 0,2 µm.

Vacuum system

The P150 used an efficient vacuum pump to remove air from the chamber. The produced vacuum has a pressure of 30–70 Pa (almost absolute vacuum).

Vibration reducing supports are used to prolong life span of the vacuum pump and lower noise levels.

Moisture detection system

During the sterilization process this system checks if moisture is present in the chamber. If the moisture level is too high, which could impede the sterilization process, the cycle is terminated and an error message is displayed on the screen, accompanied by an auditory alarm.

H_2O_2 dosing system

Depending on the load type and size different sterilization parameters are necessary, including the H_2O_2 dosage. The dosing system allows authorized personnel to change the H_2O_2 dose for each program. To achieve optimal sterilization results parameters recommended by the manufacturer, for each load type and size, should be used.

H_2O_2 monitoring system

The H_2O_2 monitoring system keeps track of environmental parameters inside the chamber to determine H_2O_2 concentration. If any of the parameters exceed operating values the cycle is aborted and an error message is displayed on the screen, accompanied by an auditory alarm.

Remote access and monitoring

The P50 is equipped with a remote access and monitoring system. When connected over a LAN/WAN the user can see the control panel as if standing in front of the sterilizer. Every function available from the sterilizer's control panel can be performed from the connected device.

Options and accessories

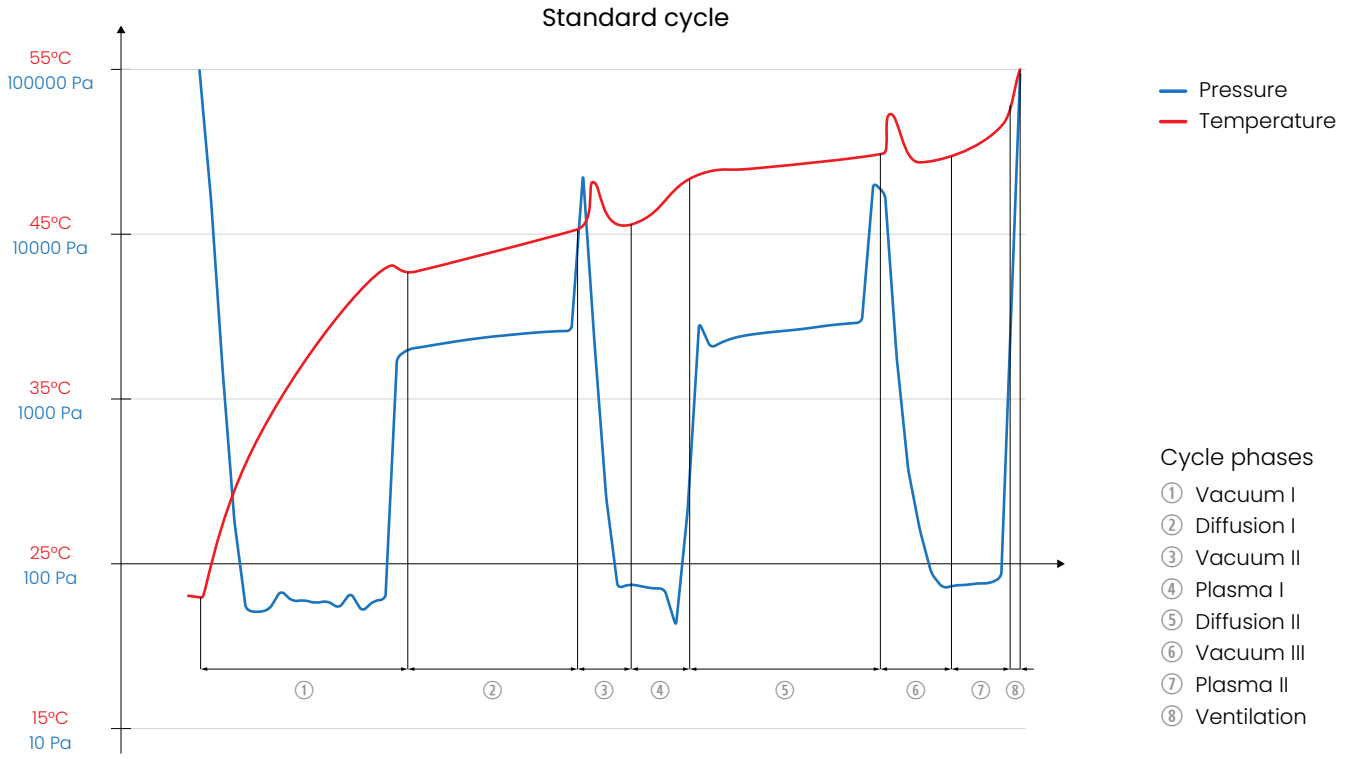
- biological barrier
- sterilization baskets

Cycles and cycle phases

The P150 has three cycles suited for different types of instruments and equipment. Each of these cycles consists of a different set of cycle phases, some of which occur more than once as shown in the table below.

Short cycle	Standard cycle	Advanced cycle
Vacuum I	Vacuum I	Vacuum I
Diffusion	Diffusion I	Purge I
Vacuum II	Vacuum II	Diffusion I
Plasma	Plasma I	Vacuum II
Ventilation	Diffusion II	Plasma I
	Vacuum III	Purge II
	Plasma II	Diffusion II
	Ventilation	Vacuum III
		Plasma II
		Ventilation

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Vacuum

During this stage the vacuum pump removes air from the chamber (vacuum pressure of 50–65 Pa). After reaching the requires vacuum pressure, high voltage is applied to the chamber to ionize the remaining air.

Residual moisture that could remain on the sterilized material and in its cavities is evaporated and removed by the vacuum pump.

Purification (purge)

The purification stage is only used in the Advanced (Long) cycle. It guarantees that moisture has been removed from instruments with long tubular cavities.

Diffusion

The diffusion phase is a sterilization stage and begins after the vacuum phase (or in case of Long cycle after the Purification phase). When the vacuum pressure reaches values between 50 and 65 Pa, hydrogen peroxide is heated and its vapors are transferred to the sterilizing chamber. This causes the pressure in the chamber to increase to 2100 – 2300 Pa for short and standard cycle, and to 1200 – 1600 Pa for long cycle.

This phase (each time it is run) uses 2,2ml of hydrogen peroxide in the short and standard cycles, and 3ml in the long cycle.

Plasma

When the vacuum pressure reaches values between 65 and 70 Pa a high voltage with a high frequency is applied to the hydrogen peroxide vapor creating a low-temperature plasma. During this process hydrogen peroxide is decomposed to oxygen and water vapor.

Water and oxygen are removed from the chamber by the vacuum pump.

Ventilation

The last stage of each cycle is the ventilation phase. During this phase the chamber is aerated.

After the ventilation phase ends, the sterilizer gives an audible signal to indicate the end of the cycle. A report about the finished cycle both on the LCD screen and in the form of a printout.

Safety features

Door safety systems

- the chamber door cannot be opened when a cycle is active
- if the door is open H_2O_2 will not flow into the chamber
- a cycle cannot be activated if the door is open or not locked properly
- an interlocking door system (double door models only), that does not allow both doors to be opened at the same time, which prevents crosscontamination between the sterile and clean side
- Each sliding door is equipped with pressure-sensitive edge that stops the doors movement if an obstacle is encountered.

Control system

The control system manages all the system functions, monitors system operations and warns the user about any malfunctions.

Control system has the following features:

- 6 analogue inputs
  - 3 PT100 sensors (temperature)
  - 3 analog inputs (pressure)
- digital inputs and outputs for sterilizer control
- chamber pressure and temperature measurement
- real-time component monitoring system
- user access levels
- cycle phase monitoring
- languages (multiple languages)

User interface

The graphic user interface allows the user to monitor and control the plasma sterilizer. It is designed to be user friendly and easy to use. Here is a quick overview of the main sections of this interface.

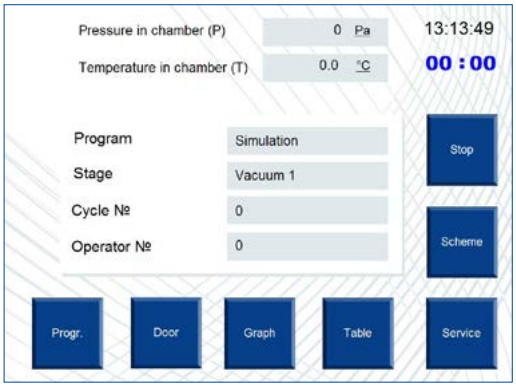
Welcome screen

After the control system is initiated the screen will display a welcome message.



Overview and main menu

This screen displays an overview of the current sterilizer parameters (chamber pressure, chamber temperature, selected program, cycle phase etc.) and the main menu. This menu is used to navigate to other sections of the user interface. The program start/stop button is located on this screen - "start" when there is program selected and "stop" if there is a program running.

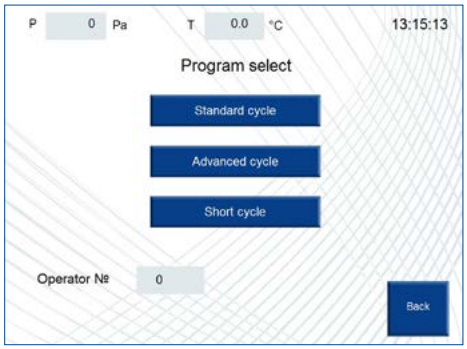


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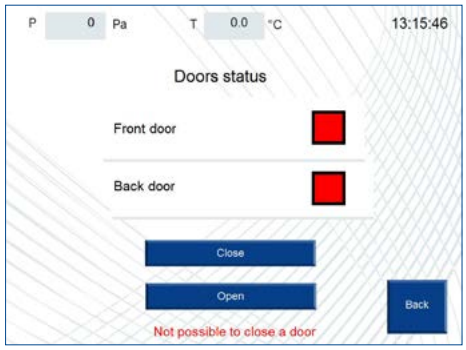
Programs

All the available programs are listed on this screen. The user can choose a program from this list and enter his/her ID.



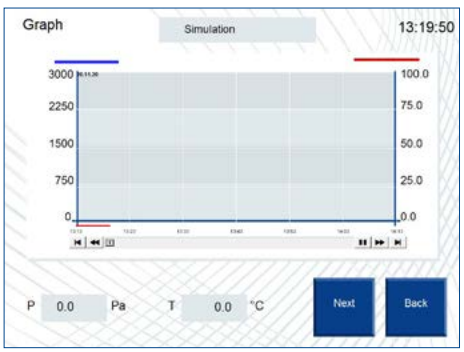
Doors

Users can operate the door on the loading side and check the state of the door on the unloading side. The door on the unloading side can only be opened and closed from the unloading side. For safety reasons and to eliminate cross contamination between the unclean and clean sides both doors cannot be opened simultaneously.



Graph (graph)

To aid in monitoring the ongoing sterilization process users can view a real-time graph of the temperature and pressure in the chamber. Additionally this screen displays the current cycle phase and time. The “Next” button displays the same data but in the form of a table, also in real-time.



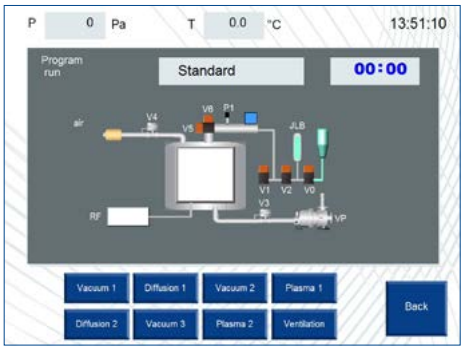
Progress (table)

The progress screen shows the current program settings, the progress of the sterilization cycle and the elapsed time since the beginning of the sterilization cycle.



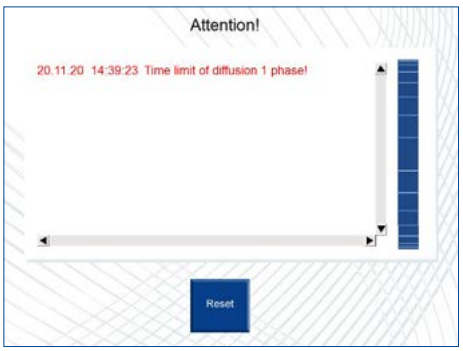
Sterilizer diagram (scheme)

This screen allows the user to check the status of all the main components of the sterilizer (valves, pumps, sensors) in real-time. Additionally staff can monitor the current chamber pressure, chamber temperature, cycle phase and time.



Alerts

This screen will pop-up, regardless of the screen the user is on, and show an alert accompanied by an alert sound.



Cycle documentation

SMS P150 plasma sterilizers have a printer installed loading side to print cycle documentation.

Standard printouts contain the following information:

- date and time the cycle began
- sterilization cycle number
- operator ID
- sterilization program name and set parameters
- sterilizer serial number
- name and start time of the cycle phase
- temperature and pressure in the chamber at set intervals
- cycle end time, temperature and pressure
- actual times of individual phases
- minimum and maximum temperatures reached during the cycle
- outcome of the sterilization cycle or vacuum leak test

Programs

Our plasma sterilizers have three programs suited for different types of instruments and a vacuum leak test.

Short

Surface cleaning, items that do not have cavity

Sterilization temperature: 48–55°C

Cycle time: 28–30 min

H_2O_2 usage: 2.2 ml

Standard

Most surgical instruments

Sterilization temperature: 50–55°C

Cycle time: 60–65 min

H_2O_2 usage: 2 x 2.2 ml

Advanced

Long flexible endoscopes and complicated items

Sterilization temperature: 50–55°C

Cycle time: 65–75 min

H_2O_2 usage: 2 x 3 ml

If there are special needs for the sterilized loads cycle parameters can be changed. Please contact your distributer for further information and technical support.

Vacuum leak test

This program enable the user to check if the sterilizer chamber is properly sealed, without leakage and holds the appropriate vacuum pressure.

Environmental impact

The sterilizer is composed of 60% stainless steel, 35% of aluminum (Anodized) and 5% of other materials (PTFE, viton, silicone,) which – after dismantling the unit by an authorized person – may be recycled.

Packaging for shipment

To prevent damage during shipping/transportation SMS sterilizers are packed into specially designed wooden creates.

Standards and directives

SMS Plasma sterilizers meet all necessary standards and directives, not less than listed below.

Europe

- ISO 9001:2015 – Quality Management Systems
- EN ISO 13485:2016 – Medical Devices - Quality management systems / requirements for regulatory purposes
- EN ISO 14971:2013 – Medical Devices - Application of risk management to medical device

Safety and EMC Standards

- EN 61010-1:2011 Safety requirements for electrical equipment for measurement, control and laboratory use
- EN 61010-2-040:2015 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- EN 61326-1:2013
- Class B Medical Devices (CISPR 11 / EN 55011)

Directives

- 93/42/EEC Directive – Medical Device
- EU Directive 2006/95/EC – Low Voltage Directive
- EU Directive 2004/108/EC – Electromagnetic Compatibility
- EU Directive 2006/42/EC – Machinery

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