

PROHS®

# Technical Characteristics Manual

## Vertical Steriliser PL

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e Serviços Associados, S.A.

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The PROHS steam sterilizers have as basis of their function the control of the parameters Temperature and Pressure seeking the complete elimination of all living microorganisms.

Through a fast and uniform heat transfer, the PROHS sterilizer is an indispensable tool in places where high levels of sterilization are required.

The sterilization through saturated steam performed by the PROHS sterilizer is the sterilization method by excellence, as it is the most safe and well-known process. Indeed, is the most economic sterilization system and the most used in hospitals.

Our products are manufactured in accordance with the standards of safety and quality control by certified and qualified technicians. Throughout the various stages of production, all products are submitted to rigorous tests and essays in

accordance with the European norms and directives, to ensure high quality and reliability.

The selection of certified components of high quality, allow us a significant reduction of the cost along the useful life time of the equipment as well as its easy substitution in any brand agent. PROHS is a certified company for the ISO 9001:2000 - Management System of Company Organization, working according to the finest rules of Hygiene and safety at work.

The sterilizers manufactured by PROHS have CE mark.

Aware that the production of a medical device requires an attentive position regarding the evolution of technology and production processes, PROHS invests heavily in R&D, either internally or by academic cooperation, so that has established a partnership with one of the leading technology institutions - *University of Minho* - in order to optimize the production process and the medical devices, both in sterilization and disinfection.

**We leave nothing to chance.**

### Product Description

The **PROHS** sterilizers have as basis of its function the control of the parameters Temperature and Pressure seeking the complete elimination of all living microorganisms.

The **PROHS** sterilizer is a post-vacuum/gravity sterilizer designed to cover a large field of applications for hospitals and laboratories, as well as pharmaceutical and bio-technological industries. Through a fast and uniform heat transfer, the **PROHS** sterilizers are an indispensable tool in places where high levels of sterilization are required.

Using steam under pressure as the sterilizing agent for wrapped or unwrapped goods such as fabrics, surgical instruments, utensils, but also liquids and other heat and moisture stable materials at temperatures from 105°C to 136°C. The sterilization by saturated water steam made by the **PROHS** sterilizers is the method of sterilization for excellence, as is the most secure and better known system, and indeed, the more economic sterilization.



Semi-automatic



Program Laboratory

## Available Models

### Available Capacities

The Vertical Sterilizers **PROHS** are available in 3 capacities: 75L, 100L and 150L

Brand		PROHS		
Model		75 L	100 L	150 L
Capacity (litres)	Total	75	100	150
	Useful	60	80	120
Useful dimensions (cm)		Ø 40x60	Ø 40x80	Ø 50x80
Exterior dimensions (height x length x with) (mm)		940x660x717	1035x660x717	1035x760x810
Power		7500 w	9000 w	9000 w
Power Supply (V/Hz)		3~ 400V / 50Hz		
Water Supply (Inches)		1/2"		
Sewer – Temperature Resistant		3/4"		
Approximate Weight (kg)		130	140	150

### Available Configurations

Configurations are available:

- SA – Semi-automatic
- PL – Laboratory Program

### Available Options

The following options are available:

- Printer
- Register
- Vacuum Pump to: (pre-sterilization and after-sterilization);

### Accessories

The sterilizer is supplied with

- Stainless steel baskets

## Features

- Cap and sterilization chamber totally stainless steel made AISI 316 L, material with high resistance to corrosion, meets the highest standards requirements for quality, safety and operation.
- The Vessels conforms to the Pressure Equipment Directive (PED), are designed for a maximum working pressure of 2.6 bar and full vacuum.
- Thermal Isolation – Chamber thermally isolated through the use of mineral coated wool.
- The Sterilizer's framework and housing are also made of Stainless Steel AISI 304.
- Equipped with damping door, working by pressure, through 9 fast squeeze cramps.
- The door sealing gasket is massive rubber-based silicon (special for high temperatures) of easy replacement.
- All the set that forms the sterilizer is mounted on a stainless steel structure AISI 304.
- The exterior shield of the sterilizer is stainless steel made AISI 304.
- The sterilizer is equipped with visualization instruments for water steam pressure and vacuum (Gauges).
- The condensed steam coming from the sterilization chamber before heading out to the line of sewage, passes through a cooling system consisting of a condenser mixed with cold water, in order to avoid that there is damage to the installation.
- The overpressure, happening, is compensated by the opening of a safety valve properly sized and calibrated.
- The heating and steam production inside the chamber are performed by electrical armored immersion resistances.
- Safety device that protects the resistances in water failures, it powers off the resistances not allowing an excessive temperature.
- Electric valves acting automatically in the cold water and condensed circuits.
- The air entrance for the equalization of the pressures in the Sterilizer is done through an adequate filter with characteristics to retain microorganisms, particles, etc.
- To automatically eliminate all the condensed air inside the sterilizer chamber, an automatic purger is used.
- End of Cycle acoustic signal.

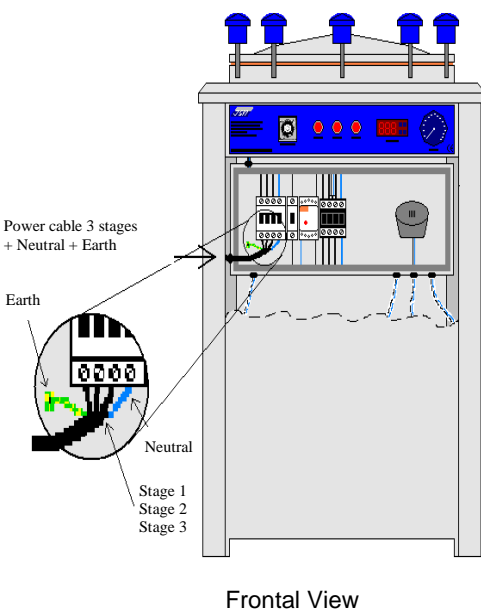
## Installation Requirements

For a correct installation the following aspects must be taken in to attention:

- Must be placed in a plain and leveled surface;
- Laterally, a free space of approximately 40 cm must be kept. This is an essential space for a correct access for maintenance;
- The installation place must be well ventilated (4 to 6 renewals / hour);
- It must not be installed in places where the possibility to release gases with explosive characteristics to the environment exists. Care must be taken in handling liquids that might damage the exterior plating.

## Installation of the Power Supply

Once placed in a proper place, following the previous conditions, the installation of the power supply, must fulfill the following requirements:



- Make sure the power supply characteristics comply with:
  - 75L model: 3x380V; 50Hz; 16A; 7,5 kW
  - 100L model: 3x380V; 50Hz; 16A; 7,5 kW
  - 150L model: 3x380V; 50Hz; 20A; 9 kW
- The sterilizer must be connected to a net protected by an earth connection, as the applicable norms.

## Installation of Cold Water & Sewer



### Sewer

- The sewer must comply with the following requirements:
  - Sewer in DN 3/4",
  - Heat resistant material, preferably alloy (DN40);
  - Placed at 85mm from the ground, in the right lateral;

### Water

- Fulfill the following requirements to feed the water:
  - General cold water supply (DN 1/2", 4 to 6x10<sup>5</sup> Pa and hardness around 7 °F);
  - Placed at 85mm from the ground, in the left lateral;
  - It's possible to have until three diferents conections of water:
    - Osmose => Chamber (steam);
    - Decalcify => Drying system;
    - Normal => Cooling system;

### Notes:

For any additional clarifications, please consult us.

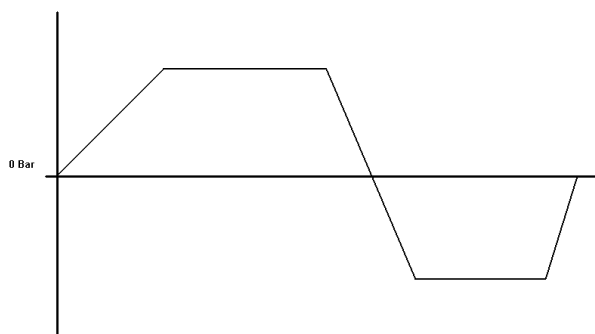
### Functioning Characteristics

#### Vertical Sterilizer S.A. (Semi-automatic)



- All the control is done by the operator,
- Temperature and time of sterilization cycle needs to be introduced,
- Easy visualization of the work pressure and temperature, through a manometer and controller term,
- Drying is performed by a water coil for cooling, in the bottom and over all chamber height, thus obtaining a perfect drying,

- Graphic of a cycle



- Description of the stages of a sterilization cycle:
  - **Heating**, heating of the water until the steam production. Increasing the pressure and the temperature in the chamber;
  - **Sterilization**, maintenance of the water steam pressure at the sterilization temperature;
  - **Discharge**, Exit of the water steam from the sterilizer chamber;
  - **Drying**, vacuum production in the sterilizer chamber;
  - **Airing**, air entrance in the sterilizer chamber;



### Vertical Sterilizer P.L. (Program Laboratory)



- All the control is made from the PLC (Programmable Logic Controller). During the sterilization cycle the control system measures, controls and shows in digital display: (time, temperature and chamber pressure, sterilization status and errors). While the power is off, own back-up battery keeps the status of the sterilizer, date and time.
- Display, allowing a simple and intuitive interface with the sterilizer.
- Equipped with two sensor of temperature. One for control of the chamber and another one that allows to be placed in the liquid, to guarantee a differential of  $\pm 1^{\circ}\text{C}$  between the two temperatures.
- Drying is performed by a water coil for cooling, in the bottom and over all chamber height, thus obtaining a perfect drying.

- For a clear and concise documentation of processes, the control unit is provided with a thermal printer, option, connected to the PLC. With all relevant information regarding operation during the cycle. In case of an uncompleted cycle, the print-out indicates the cycle failure and the cause of the failure.
- Executes the following programs:

Parameters	Cycles			
	Solids 1	Solids 2	Liquids L	Liquids C
Sterilization Temperature ( $^{\circ}\text{C}$ )	100.0 $^{\circ}\text{C}$ to 136.0 $^{\circ}\text{C}$			
Sterilization Time (min)	1 minute to 90 minutes			
Drying (min)	1 to 90 min	1 to 90 min	Does not have	
Total Time (min)	Variable (depends on the parameters)			
Kind of Material	Solid Material Clean Material	Decontamination and Media Culture	Liquid Media Culture/Liquids (control by the <b>liquids</b> temperature sensor)	Liquid Media Culture/Liquids (control by the <b>chamber</b> temperature sensor)

**Note:** We can add new programs under requested.

### Standards

Our sterilizers comply with the following international standards and directive guidelines:

- Directive (PED) 97/23/EC
- Quality Management System Standards:
  1. ISO 9001:2000 - Quality Management Systems-Requirements;