PROHS Equipamento Hospitalar
e Serviços Associados, S.A.

Rua do Castanhal, 316
Z. Industrial Maia I Sector II
Apartado 6019 EC Outeiro
4476-908 **Maia – Portugal**

| T | +351 229 059 170
| F | +351 229 015 900
| E | prohs@prohs.pt
| W | www.prohs.pt

Horizontal Sterilizer PN

PROHS®

Technical Characteristics Manual

Horizontal Steam Sterilizer

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 and for the ISO 13485:2003 - Quality Management System for medical devices manufacturers, working according to the finest rules of Hygiene and safety at work.

The sterilizers manufactured by PROHS have CE mark granted by SGS UK (CE 0120) under the directive 93/42/EEC- Medical Devices. As the sterilizer is an equipment under pressure, its covered by the Directive 97/23/CE – Pressure Equipment, having been granted with CE mark by SGS Portugal (CE 1155).

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.

Available Models

Available Capacities

PROHS Horizontal Sterilizers are available on the capacities shown below.

	Capacity (litres)	height x width x depth (cm)	height x width x depth (cm)
BRAND	**Model**	**Useful Dimensions**	**Exterior Dimensions**
PROHS	70L	32x32x70	170x77x92
	110L	40x40x70	180x84x96
	175L	50x50x70	180x94x96
	250L	50x50x100	180x94x127
	340L	70x70x70	195x116x96
	360L	60x60x100	180x106x127
	490L	70x70x100	195x116x127
	640L	70x70x130	195x116x157
	780L	70x70x160	195x116x187
	930L	70x70x190	195x116x206

If another size is requested, please consult us.

Available Options

The following options are available:

- One or two vertical sliding doors;
- With or without built-in steam generator;
- All or a part of pipes in stainless steel;

Accessories

The sterilizer can be supplied with following accessories:

- Load/ Unload car in stainless steel;
- Load/ Unload platform in stainless steel;
- Stainless steel sterilization baskets;
- Air compressor;
- Water softener;
- Recorder;
- Color Touch Screen on unloading area.
- SD Card

Sterilizer Front

Sterilizer Back

Loading Car and Platform

Technical Data

Construction Characteristics

Chamber

• The rectangular chamber is totally made in AISI 316L stainless steel, a material with high resistance to corrosion. Our chamber is equipped with a full jacket, during the production process is used an automatic robot for the welding process, complying with the Directive 97/23/CE, the CE mark is granted by SGS Portugal (CE 1155).

Sterilization Vessel

• Thermal Isolation of the chamber is achieved through the use of mineral wool, coated with an external protection in aluminum.

• The surface of the sterilizer chamber and door receives a special treatment for a better cleaning. The sterilizer is available with one or two vertical sliding doors, with a safety system, preventing the door opening during the cycle.

• The door gasket is made of rubber based on silicon (especially designed for high temperatures), being easy to replace.

• The overpressure is released by opening a safety valve, with proper dimension and calibration.

Doors and Safety

The autoclave doors are equipped with safety devices avoiding their opening if some conditions occur.

The following safety devices are available:

• Safety that stops the ascending movement of the door if there is an object interposition;

Door Security Detail

• Mechanical door lock when in closed position (high), the position control is made by micro switch.

• Additional safety features, when the sterilizer is in operation:

•The sterilization cycle does not start if the doors are open;

•The doors do not open simultaneously;

•The doors do not open if the sterilizer is under pressure;

• There is possibility to open the door in the discharge zone, after it has been closed. Useful, when the door has been closed without the platform;

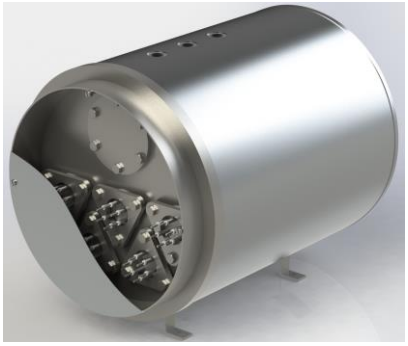
• The sterilizer's body is sustained by a heavy structure in stainless steel AISI304.

Steam Generator

The sterilizer can be supplied with or without built-in steam generator. The steam production is performed by electrical immersed heaters.
The sterilizer can be prepared to work with steam from the hospital net, or an external/built-in steam generator. The operator can define which steam (from the steam generator or the hospital net), supplies the sterilizer, by a simple touch in the screen. The steam generator vessel is made of AISI 316L stainless steel, welded in accordance with the Directive 97/23/CE.

Operation:

• The generator's operation is autonomous and independent from the PLC.
• Equipped with electronic water relay, high and low water limiter and a safety alarm when there is water lack.
• Equipped with a pressure switch and a certified safety valve.
• It has a drain system for maintenance and cleaning.
• Internal system to save water and energy. In standby, the steam consumption is null.
• Water supplied to the steam generator passes through a water pump to increase the pressure.



Steam Generator

Vacuum Pump

The required vacuum production for a complete cycle (pre-vacuum, pulses and drying) is reached through a liquid ring vacuum pump, reducing the cycle time and increasing its performance.

The water used by the vacuum pump recirculates in a deposit to reduce the water consumption during the cycle.
To achieve the correct water temperature to feed the pump, it's used a temperature control system.
Best vacuum obtained: 33 mbar.

Fluid Circuits

All pipes and connections used to distribute the steam through the sterilizer are made in copper and brass. As an option, they can be provided in stainless steel.
The pneumatic valves are controlled by an electrovalves group.
During the maintenance process, the pneumatic valves can be easily controlled on the touch screen of the diagram menu or manually operated through the inputs/outputs.
The condensates pass through a cooling system before being sent to the drain, avoiding any damage on the installation.
Pipes are coated with thermo resistant material.
The condensates circuit allows:

- Automatic and permanent condensates drainage from the sterilizer (chamber, jacket and gaskets).
- Relief of the pressure in the chamber at the end of the sterilization cycle.
- Reutilized the vacuum pump water.

External Panels

- The external shield of the sterilizer is made in AISI 304 stainless steel.
- The temperature on the surface of the external panels and doors never exceeds 45 ºC at a room temperature of 23 ºC.
- The access to the electrical box and other components, normally on the right side, is protected by panels connected together.
- Those panels can be equipped with lock and key, to restrain the access to the components.

Components Characteristics

PLC - (Programmable Logic Controller)

The sterilizer is equipped with an automatic control, whose inputs/outputs (analogical and digital) can centralize all operations.

- Reliable, with high capacity and large memory.
- Bus protocol for communication Ethernet &Internet.
- RS-232 or RS-485 speed (56k) for PC & Network.
- The system manages and controls the operation process of the machine, with auto-test System.
- Total number of sterilizations counter (till 99,999,999 cycles), and a partial counter for Bowie & Dick a nd air leakage tests;
- Huge list of errors related to eventual specific failures of the cycle;
- Double PLC (Master & Slave), available as option;

Monitor

Intuitive and user friendly interface, through a color touch screen 5,7".
Having several menus that guide you through the sterilizer operations:

- Cycles selection;
- Doors (open/ close);
- Alarms (visual and audible);
- Visualize the cycle progress and its parameters (graphics, temperature, pressure, time, etc.);
- Access to several menus such as, technical maintenance, calibration, configuration, alarms storage, etc...;
- Several languages are available;

Fluid Circuits

Fluid Circuits

Gauges

Pneumatic Valve Control

Electric Box

Monitor (Touch-Sreen)

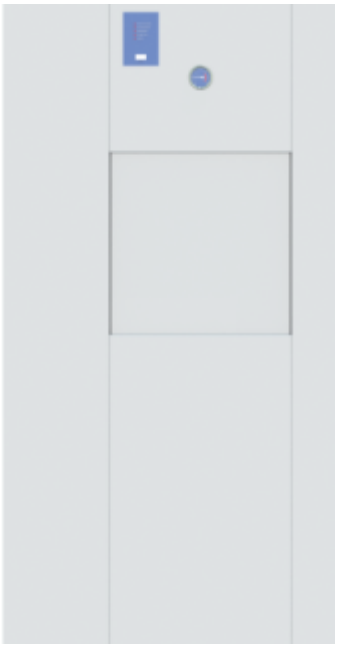
Printer

On/Off Button

Emergency Stop

Possibility to hide fields, if desired.

Possibility to print multiple copies of the last cycle. Useful when the paper runs out in the middle of the printing process, or when more than one copy of the cycle is needed.



Unload View

Panel Components

The Front Panel is constituted by the following components:

• Color Touch Screen 5,7" – Allows the visualization of all stages of the Sterilization Process, all operative commands are easily controlled through a simple touch in the screen.

• Power switch, to turn On and Off the Sterilizer.

• Emergency Stop – Immediately stops the Sterilizer.

• Conventional gauges for easy visualization of the working pressure within the chamber, jacket and steam generator. (shown in the previous page)

• The double door version of the sterilizer has a panel that allows the visualization of the sterilization cycle's current stage.

• Printer – Dot-matrix or thermal (width 5.6 cm), fast printer with graphical records for conclusive results in real time.

Electrical Box

• Consists of control and power components, from reliable brands (e.g. Siemens, Omron);

All components are identified for an easy recognition.

As shown in the previous page figure – electrical box.

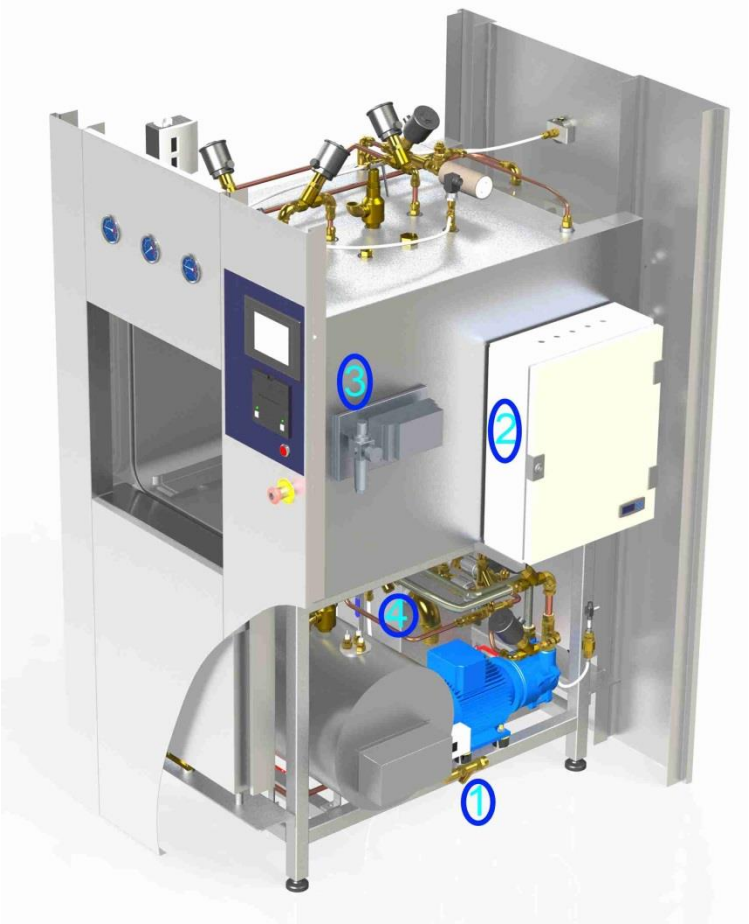
Other Components

• For a correct cycle control, the sterilizer is equipped with two pressure sensors (chamber and jacket) and two temperature sensor PT100 class A, installed in the chamber.

• The air entrance for the required equalization of the pressures in the Sterilizer is achieved through an adequate bacteriological filter which retains microorganisms, particles, etc (effectiveness ≥ to 99,995% for particules larger than 0,2 µm);

• An automatic steam trap to eliminate the condensate air inside the sterilizer chamber.

Installation Requirements



Compressed Air Installation (3)

The sterilizer needs a connection to compressed air with a cut-off valve pipe DN 3/8”, 5 to7 x10^5 Pa;

Installation Requirements

For a correct installation of the Horizontal Sterilizer, the following aspects must be taken in to attention:

· Must be placed in a flat 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 place where the sterilizer is installed must be well ventilated (4 to 6 renewals / hour);

· It must not be installed in places where explosive gases can be released.

· Care should be taken when handling liquids that may damage the sterilizer external panels.

Cold Water Installation (1)

The water feed must fulfill the following requirements:

· Cold water supply (DN 1/2” , 4 to 6 x10^5 Pa and hardness around 7 °F);

· It important to comply with the above water parameters requested by EN 285, Annex B. Otherwise, the correct operation of the machine can be affected.

Power Supply Installation (2)

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

· The electrical characteristics required on the technical chart, must be confirmed;

· The sterilizer must be connected to a net protected by an earth connection, according to the local law and norms.

Sewer Installation (4)

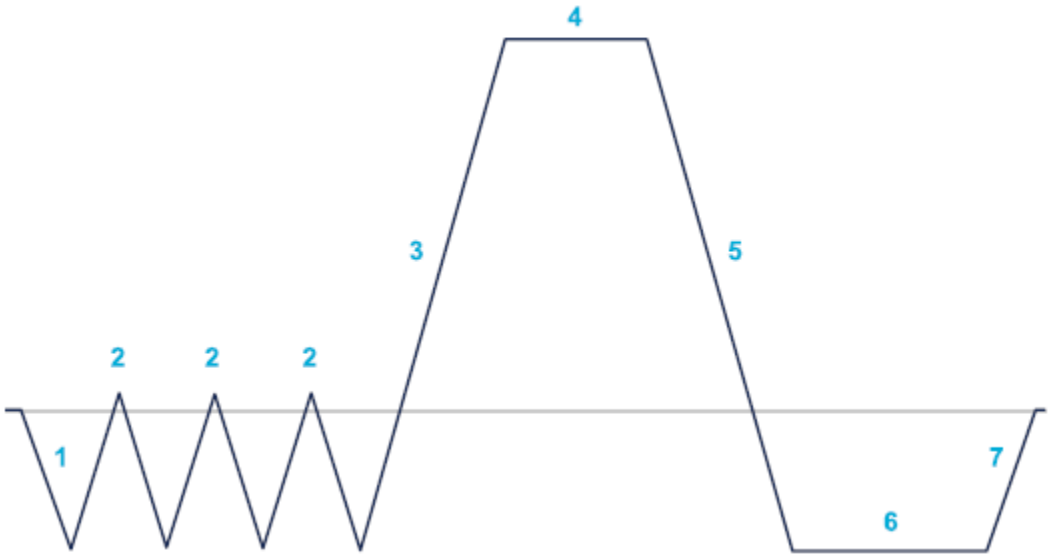
The sewer must comply with the following requirements:

· Heat resistant material, preferably alloy (DN50);

Notes:

Please request installation drawing. For any additional clarification, please contact us.

Horizontal Sterilizer (Program Normal)



Standard Program (Porous Load)

• Validated standard sterilization cycles specific for hospitals (134ºC Normal, 134ºC Instruments, 134ºC Containers, 134ºC Prions and 121ºC Rubbers);

• Drying methods (Vacuum, air pulses, steam pulses);

Only vacuum - appropriate for porous material (textiles);
Vacuum with air pulses – appropriate for instruments and rubbers;
Vacuum with steam pulses – appropriate for metallic containers with instruments.

• Preheating cycle (to preheat the sterilizer before performing the Bowie & Dick Test);
• A Flash cycle is available to be used when an urgent sterilization is required.
• The sterilizer can be also supplied with an open liquids cycle, upon request.

Test Cycles

In accordance to the EN 285 and CE mark, PROHS Horizontal Sterilizer is supplied with two Test cycles (Air Leakage and Bowie & Dick tests);

Configurable Programs

Up to a hundred new and fully configurable sterilization programs can be created:

• Program name;

• Number of pulses (0, 1, 2 or 3);

• Sterilization temperature (from 105.0 ºC to 136.0ºC, adjusted to the tenth of degree);

• Sterilization time (up to 99 minutes, adjusted to the second);

• Drying time (up to 99 minutes, adjusted to the second);

• Drying available (only vacuum, air pulses, steam pulses);

Program Description

• Vacuum production and steam injection through pulses, at least three, to achieve a complete elimination of the air inside the chamber.(PRETREATMENT - **1**, PULSES - **2**);

• Steam injection until the corresponding values of pressure and temperature required for the sterilization stage. (STEAM CHAMBER - **3**);

• (STERILIZATION – **4**). This stage maintains the parameters reached on stage 3, according to the cycle time selected, to achieve the death of all living microorganisms;

• Steam flows out of the chamber. (**5** - DECOMPRESSION);

• Coinciding with the adequate values of vacuum, time period and drying type (only vacuum or with injection of air pulses), so that the processed material be free from all moistness residues. (**6** – DRYING);

• The Pressures equalization is achieved through the entrance of sterile air in the chamber (AIR ENTRANCE– **7**), passing through a bacteriological filter.

Programs	Type of Material
Preheating	Should not be used to sterilize material
121ºC Normal	Thermo-sensitive materials (rubbers, Glasses, etc.)
134ºC Normal	Textiles (Hollow Load)
134ºC Instruments	Wrapped Instruments
134ºC Containers	Metallic containers with instruments
134ºC Prions	Material contaminated with Prions
134ºC Fast	Unwrapped materials
Bowie Dick	Specific Test (Leakage Test)

Programs	Preheating	134ºC Normal	121ºC Normal	134ºC Instruments	134ºC Containers	134ºC Prions	134ºC Fast	Bowie & Dick
N.º of Pulses *	-	3	3	3	3	3	1	3
Sterilization Temperature (ºC)	134	134	121	134	134	134	134	134
Sterilization Time (min)	3	4	16	4	4	18	3	3:30
Drying / Vacuum (min)	1	5	-	-	-	10	5	5
Drying with air Pulses (min)	-	-	20	20	-	-	-	-
Drying with Steam Pulses (min)	-	-	-	-	20	-	-	-

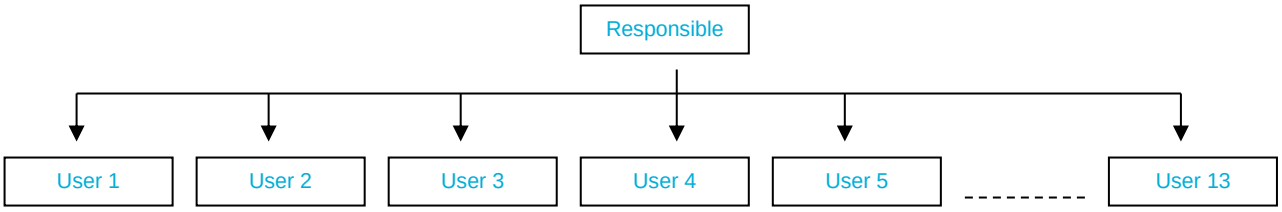
*- Our standard cycle can have up to 5 pulses.

Access Codes

• It uses access codes, optional, associated to the user's names.

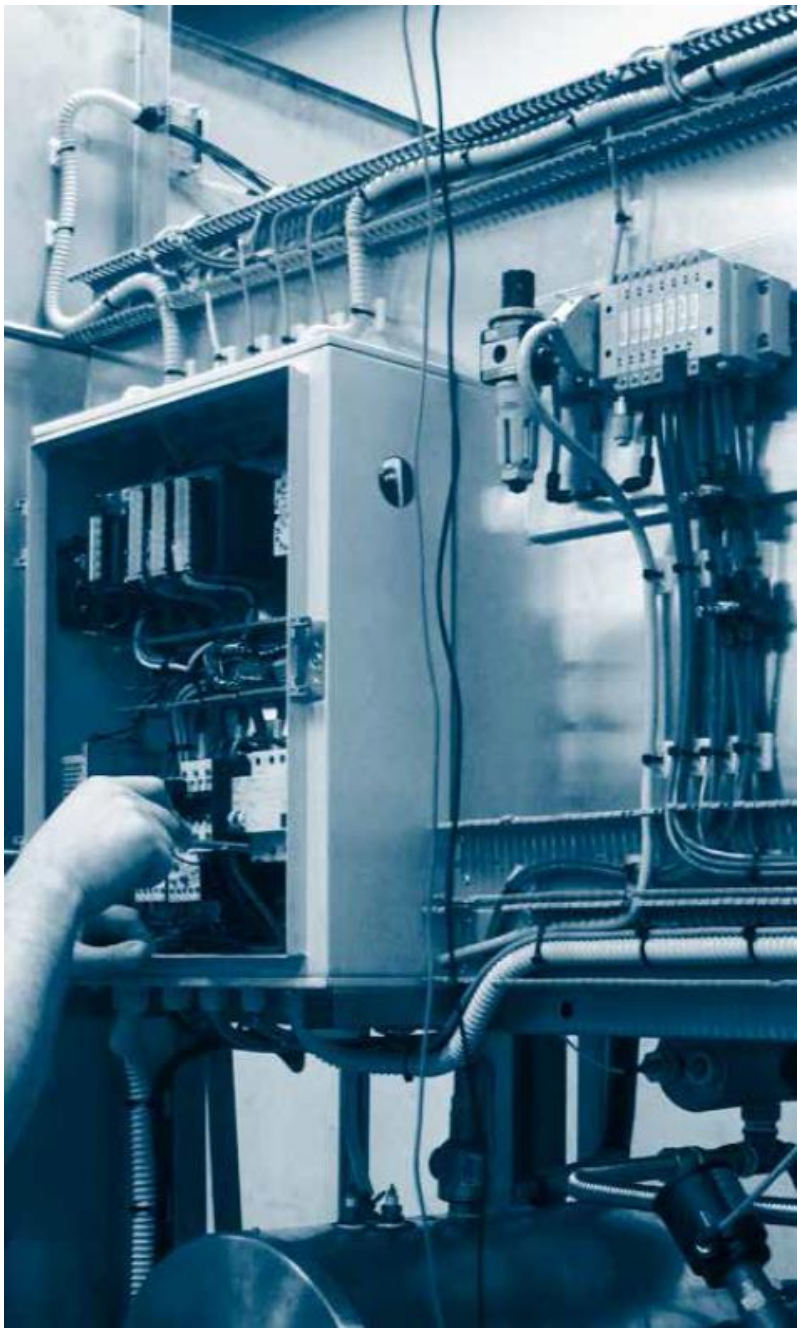
It has a simple 2 level hierarchy.

• Possibility to configure an outside technician, who has complete access to the technical options of the sterilizer;



Options	User	Hospital Responsible	Technician
Execute a cycle (Programs)	●	●	●
Execute the Bowie Dick test	●	●	●
Execute the air leakage test	●	●	●
Execute a configurable program	●	●	●
Execute the Sterilizer cleaning (Open doors)	●	●	●
Print last cycle	●	●	●
Set date and time	X	●	●
Execute the program 134ºC Fast	X	●	●
Adjust the brightness and contrast	X	●	●
Manage the fields Client and Sterilizer	X	●	●
Manage the name and codes of the users	X	●	●
Manage sound options, end of cycle and alarm	X	●	●
See Inputs / See Outputs	X	X	●
See the errors report in the "Touch Screen"	X	X	●
See the counters	X	X	●
Advance manually the cycles stages	X	X	●
Access to Options during the execution of the Safety Program	X	X	●

Quality and Security



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 and for the ISO 13485:2003 - Quality Management System for medical devices manufacturers, working according to the finest rules of Hygiene and safety at work.

Throughout its production and before being shipped from the factory, PROHS Horizontal Sterilizer is submitted to several tests according to the safety standards (EN 285: 2006).

It's given a special attention to functional aspects, such as:

- The sterilization cycle does not start if the doors are open;
- The doors do not open simultaneously;
- The doors do not open if the sterilizer is under pressure;
- The safety system in case of overheating
- The safety system in case of power failure or water lack;
- The safety valve;
- The audible and visual error messages;
- The cycle parameters control (temperature, pressure, time);

Technical Characteristics

Brand	Model	Useful Dimensions	Exterior Dimensions	Energy (3 ~ 400V - 50/60Hz)		Water Consumption	Weight	Useful Space
		/litres capacity	/cm height x width x length	/cm height x width x length	/WITH steam generator	/WITHOUT steam generator	/litres	/Kg (approximate, with steam generator)	/stu
PROHS	70L	32x32x70	170x77x92	26kW	3,6kW	110	260	1
	110L	40x40x70	180x84x96	26kW	3,6kW	120	495	1
	175L	50x50x70	180x94x96	26kW	3,6kW	130	570	1
	250L	50x50x100	180x94x127	26kW	3,6kW	145	685	1
	340L	70x70x70	195x116x96	32kW	3,6kW	170	750	4
	360L	60x60x100	180x106x127	32kW	3,6kW	170	800	1
	490L	70x70x100	195x116x127	32kW	3,6kW	200	830	6
	640L	70x70x130	195x116x157	47kW	3,6kW	225	1000	8
	780L	70x70x160	195x116x187	47kW	3,6kW	225	1200	10
	930L	70x70x190	195x116x206	60kW	3,6kW	225	1400	12

OPTIONS

- The Sterilizer is available with **one** or **two doors**;
- **Car** and **Loading Platform** in stainless steel;
- **Sterilization Baskets** in stainless steel
- **Independent Data Recorder**
- **Process Software** (stores the cycle's data);
- **Steam Generator** (integrated or external);
- Silent **Air Compressor**;
- **Water Softener**;
- **Color Touch Screen** in Unloading Area.

Programs*	Sterilization Duration (minutes)
Heating Program	—
134 ºC Normal (textiles)	4m
121ºC (rubbers)	16m
134ºC Fast	3m
134ºC Instruments	4m
134ºC Containers	4m
134ºC Prions	18m
Bowie Dick Test	3m30s
Air Leakage Test	—

Possibility to create up to a 100 new programs

* all cycles can be adjusted or removed according to costumer demand

Types of Drying

High Vacuum Drying

High Vacuum and Air Pulses Drying (Instruments)

High Vacuum and Steam Pulses Drying (Containers)