PL 130

Low-Temperature Hydrogen Peroxide Sterilizer

PL 130 Low-Temperature Sterilization System using SteelcoPro PL sterilant is designed for use in the terminal sterilisation of moist and heat-sensitive medical re-usable devices properly prepared (cleaned, rinsed and dried) packed in suitable sterile barrier systems.

It is suitable for surgical instruments in metal, alloys and non-metal, delicate microsurgical instruments. Instruments with lumen with length up to 2200 mm and diameter equal or greater than 0,5 mm, until three channels.

The steriliser operates at low pressure and temperature and is characterised by high process efficiency and the speed of execution of the sterilisation cycles. The device is safe for instruments, the operators, and the environment as the residues released at the end of the sterilisation cycle are only oxygen and water vapour.

PL 130 steriliser features a PLC digital microprocessor with an independent recording system. The user interface is a 10" colour touch-screen control panel – alarms, alerts and status are clearly displayed colour-coded. A 10" colour touch-screen control panel is installed on both loading and unloading sides.

Other features include software with five predefined and validated programs, plus the validated vacuum test and five half-cycles for validation procedures (PQ).

The steriliser is designed and manufactured in Italy, according to the standards listed later.

The sterilisation chamber and door/s system are guaranteed against corrosion, cracking, deformation.

Sterilizers are designed for installation on the finished floor level. Loading and unloading operations can be done at an ergonomic height. The loading height is ergonomically placed at **920mm.**

Versions and Dimensions

PL 130/1 *(single door)*

External W x D x H:
770mm x 1040mm x 1685mm
30.32” x 40.94” x 66.34”

Chamber W x D x H:
450mm x 795mm x 400mm
17.72” x 31.30” x 15.75”

Chamber capacity:
143.1 L (5.05 cubic feet)

PL 130/2 *(double door)*

External W x D x H:
770mm x 1070mm x 1685mm
30.32” x 42.13” x 66.34”

Chamber W x D x H:
450mm x 820mm x 400mm
17.72” x 32.30” x 15.75”

Chamber capacity:
147.6 L (5.21 cubic feet)

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General description

Capacity

- Usable chamber volume: 140 L (4.94 cubic feet)
- 2 shelves (both sliding and one completely removable)

Standard Compliances

Steelco low temperature PL series sterilizers meet the applicable requirements of the following standards:

- European Directive for Medical Devices:
  93/42/EEC and its revised versions
- Machinery Directive
  2006/42/EC and its revised versions
- Technical norms and standards:
  - EN ISO 14937 (ANSI/AAMI)
  - EN ISO 14971
  - IEC EN 61010-1
  - IEC EN 61010-2-040
  - IEC EN 61326-1

Classified CE Medical Device (Community rule 93/42/CEE) code nr. 0051

Sound level

< 60 dBA

Standard features

Mainframe

- The sterilizer is provided with a heavy-duty AISI 304 stainless steel frame supporting the chamber and allowing a balanced distribution of weight on 4 wheels equipped with adjustable locking system (N.4 lockable wheels each with brake).

Technical Area

- Access to the service area is mainly through the front opening of the front and rear doors (in the case of double door unit). The doors can be completely opened using the dedicated key supplied. The equipment can be easily moved from its location using the 4 lockable wheels to facilitate maintenance operations.
- Pipes, valves, electrical components, and wiring are also easily accessible by opening panels on the unit's left and/or right side.

Sterilization Chamber

- Rectangular section with rounded corners, made of 6 mm thick AISI 316L stainless steel, satin finish. The stainless steel chamber is resistant to chemicals and ensures ease of cleaning as well as a long life/warranty.
- The external insulation of the chamber is realized with non-toxic fibre. The covering reduces heat loss and noise level.
- The operating pressure is 0-1 bar (0 - 1000 hPa) absolute pressure.
- Chamber pressure is electronically controlled by No.4 redundant pressure transducers that control the chamber's pressure in real-time (control and registration), ensuring extreme precision and safety.
- The system allows dual recording of pressure and temperature during the cycle. An additional alarm is activated if the value of a control probe differs from the reference probe beyond the specified tolerance limit.
- The redundant and independent control system of the main parameters of the cycle allows the parametric release.

Load Grids

- The chamber is equipped with two shelves made of stainless steel. Both shelves are installed on rails : the lower shelf is partially extractable to facilitate the loading, the upper shelf is completely removable to allow the loading of bulky objects.
- Shelves with an ergonomic "U" shape, error-proof, to facilitate loading/unloading operations and prevent any procedural errors.
- Useful height of the shelves is 175mm. The useful height of the lower shelf reaches 360 mm in case of removal of the top shelf.
- Additional baskets and inserts for pouches, with different measures, can be optionally configured.

Sterilization Chamber Heating

- The chamber and door are surrounded by electric heating elements for an even distribution of heat and reduction of potential condensation areas.

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- A dedicated redundant PT 1000 probe (double probe) electronically controls the temperature of the sterilization chamber.
- Chamber, high chamber, low chamber and door temperatures can be monitored in real-time via HMI.

Door System

- The vertical sliding door is made of 12mm thick stainless steel AISI 316L without any welding.
- The door is equipped with an electrical heating system to prevent potential condensation areas. The heat insulation ensures that the outside temperature does not exceed 40°C.
- The doors are fitted with an innovative and high sensibility safety bumper to guarantee the safety of the operator/load. The bumper prevents the door to close in case of obstacle presence.
- The vertical movement is activated through a toothed belt motorized system to guarantee silence and precision during the phases of opening and closing.

- Door/s opening can be easily actuated by the dedicated foot pedal (positioned on both loading and unloading side) as well as from the touch screen control panel. Possibility of ergonomic hands-free loading/unloading via foot pedal.
- Possibility of programming the automatic closing of the door after unloading. Programmable open door alert.

Door Seals

- The chamber tightness is ensured by a special silicone gasket disposed along the perimeter of the door hatchway.
- The seal is guaranteed by the mechanical pressure of the door mechanism on the gasket. Pressure is kept until the end of the sterilization process.

Thermal Insulation

- The insulation is made of melamine and guarantees a temperature of lower external surfaces to 40°C.

Vacuum Pump

- Dual-stage oil sealed high power vacuum pump.
- Produces vacuum pulses that remove air and moisture from the chamber, alleviating moisture sensitivity.
- During the cycle, the system reaches the vacuum value of 0.20 hPa.
- The vacuum pump is combined with an oil filtration- and an oil recovery system that drastically reduces the oil consumption and significantly extends the maintenance intervals.
- The direct-drive rotary vane pump is quiet (<60 dBA) with low vibration.
- The system also consists of pressure transducers and pneumatic valves.
- Pump oil change every four years or 4800 cycles.

Hydrogen Peroxide Neutralization System

- Plasma generation system: the transformation of the H2O2 gas in the plasma status occurs through the generator; a high voltage electric arc in contact with the gas creates the plasma cloud.
- After the gas passage to the status of plasma and the consequent breakdown of the molecule of hydrogen peroxide, the drain of the sterilizer is filtered by a platinum catalyst filter to guarantee that no residual hydrogen peroxide is released.
- A further passage through an activated carbon filter further guarantees the elimination of any residue (triple action for the reduction of H2O2 residues).
- Ambient concentration of H2O2 vapors (PELTWA) less than 0.007ppm:
  - OSHA Method 1019: < **0.007 ppm** (0.010 mg / m ^ 3)
  - EC data log: 0 ppm
    to guarantee the total safety of workers and the environment

Catalytic Converter

- Platinum catalytic converter receives the outflow from the sterilization chamber and converts H2O2 into water and oxygen

Air filtration

- Vacuum breaker with filtration 99.995% test according to DOP

External panels

- The sterilizer panelling is made of stainless steel AISI 304 panels, Scotch Brite finish.

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- The front panel (and also the rear in the case of double door configuration) is laterally hinged and can be totally opened for access to the machine's technical compartment. In case of free installation, the sterilizer is supplied with removable side panels. The door panels integrate the HMI and all the technical equipment for the device's control and safety.
- System to ensure low noise levels is integrated with the panels

Electrical Panel and System

- The electrical panel includes:
  - CPU Cards and control system
  - Additional command and control cards
  - Relay with indicator lights
  - EMC filter (EMC protection)
  - Contactors and motor protection circuit
  - Fuses
  - Clamps
  - Circuit Breakers
- All the electric wires are individually marked, and the components are identified as well. The reference number is printed on the electrical and hydraulic diagrams supplied together with the equipment.
- The machine is provided with an Ethernet port for service purpose.
- The machine is provided with a USB port. The USB port allows software upgrades and BACK-UP.
- The machine is provided with a LAN connection which allows connecting to a traceability system.
- The machine is equipped with an SD card that can be used to perform a back-up of the machine, save the cycles, and transfer the programs screen, data, and images.

Control System and Sensors

- The control system consists of an industrial PLC with a 10" colour touch-screen resistive type panel with Input / Output modules and a printer. In the double door configuration, an additional 10" control panel is placed on the unloading side.
- The verification of the sterilisation process is carried out simultaneously by the PLC and an independent system, which guarantees a double-check of the sterilisation cycles' information.
- The system allows dual control and recording of chamber pressure and temperature. It activates an alarm if the value of a control probe differs from the reference probe beyond the specified tolerance limit. Control of the H2O2 concentration for the whole duration of the cycle through the redundant control of the pressure in the chamber.
- The control system includes five validated sterilisation process cycles, 1 test cycle and 50 places for customised cycles.
- Any new programme loaded into the steriliser has to be validated. The parameters of each cycle are programmed to run through each phase automatically.
- The control system also includes five half-cycles for validation procedures.

Printer

- The thermal printer is located on the front of the sterilisation unit. It provides an easy to read record of the sterilisation cycle that includes the graph. It is possible to configure the position of the printer according to the requests at the moment of the order (ex: printer in the unloading side).

Compressed Air Circuit

- Compressed air circuit with a built-in air compressor to activate pneumatic valves installed with mechanical seal fittings.

User Access

- The operator can access the normal use of the steriliser by entering the code and the related password. Access to the operation of the machine is protected with multiple levels of users (five levels)
- Password protection forbids any unauthorized user from accessing critical functions and/or commands.
- For safety reasons, some machine parameters and/or functions are accessible only by entering the relative password.
- The security password levels are:
  1. Operator Level
  2. Department Head level
  3. Maintenance level
  4. Supervisor level
  5. Manufacturer level

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- All-access are recorded; the system stores all access by describing the actions and events that have occurred.
- The simplified user interface warns the operator about the possible operations also if an alarm occurs (the procedure is guided). The following programs, "Cycle Selection and Execution", "door open and close", "Alarm settings", cycle "Cancellation", are performed by touching the touch screen of the sterilizer. Alarms, alerts and status are clearly displayed colour-coded. The alarms are audible and visual.
- Dedicated screens allow the service technicians to access the calibration and operational verification of the components.
- Dedicated screens allow the operators responsible for the maintenance to set up the machine easily.
- During the cycle, the temperature and the pressure values are recorded at time intervals of 1 second.
- Printout of the cycle report. At the end of the cycle, the printer prints the report of the executed cycle. The printout also shows the switch-on and the switch-off time and the graph, besides the values of process parameters and all the machine data, as well as all the data and parameters of the cycle.
- Memory storage of up to 1.000 executed cycles data

Technical Data

- The PLC includes an Ethernet port to connect the sterilizer to a data mass storage device. The port can also be used to connect the system to a system of traceability and process control.
- The interface of the system, the printouts and the instruction manuals are available in different languages upon customer request.
- The redundant (double) PT1000 temperature probe installed in the sterilizer allows the control and recording system to monitor the correct temperature parameters.
- The N.4 pressure sensors use a 0-10 V signal. These electrical signals are read by the control system and provide accurate redundant control of pressures during the entire sterilization cycle.
- A moisture detection sensor (as standard) in the sterilization chamber checks, at the beginning of the cycle, in real-time, if the load's moisture level exceeds the defined limit and eventually stops the cycle before proceeding with sterilant agent injection. The humidity value is available via HMI. The initialization phase automatically removes residual moisture in all available validated cycles.

Safety Devices

- PL 130 sterilizers are equipped with a locking system that prevents the starting of a cycle if the door is not properly closed.
- The automatic sliding door is kept locked during the sterilization cycle and cannot be opened until the operator's safety conditions are met (pressure, potential presence of H2O2).
- The doors are fitted with an innovative and high sensibility safety bumper to guarantee the safety of the operator. The bumper prevents the door to close in case of obstacle presence.
- Doors in the double door version are interlocked to prevent their simultaneous opening.
- Access to the cartridge of the sterilizing agent is denied during the entire execution of the cycle.
- The machine is equipped with piezoresistive transducers, overtemperature devices, devices against the door opening in case of the potential presence of hydrogen peroxide, short circuit and overheating protection.
- A main switch is placed on the power supply panel.
- An emergency button is available on both loading and unloading sides (in case of two-door system).

Sterilant Agent

- Cartridge: hydrogen peroxide in aqueous solution at 58% contained in a disposable cartridge (single shot) with a capacity of 12 ml (boxes of 10 and 20 cartridges per box).
- The single shot cartridge avoids any waste due to the short expiry time of the sterilant after loading in the machine and guarantees the same quality of sterilant at each cycle.
- The cartridge is equipped with an RFID identifier to prevent reuse, incorrect re-filling or use after the expiry date.
- The RFID system provides information on product code, production batch, expiry date and H2O2 quantity.
- The equipment automatically unloads the used cartridge at the end of the cycle, releasing it completely empty and free of residues. The replacement of the cartridge takes place without the possibility of error thanks to the poka-yoke system with which it is equipped. After use, empty cartridges can be disposed of with normal waste.

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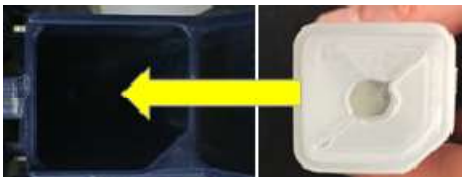
- Cartridge expiration: 12 months (stored at 5-25°C).
- The cartridge loader opening is automatically actuated, the system is equipped with a safety device. The cartridge compartment is locked during the entire execution of the cycles.
- Hydrogen peroxide dosing quantity is electronically controlled.

Injection of the Sterilizing Agent

- The injection of the sterilising agent is dosed and controlled by an advanced control system. The system controls the dosage of hydrogen peroxide in each sterilisation phase and throughout the process by monitoring the pressure values redundantly checked (through 4 transducers).
- The sterilising agent is nebulised by an electrically heated vaporiser and suctioned in the chamber by the vacuum status of the same.



- A dedicated PT 1000 double probe electronically controls the temperature of the vaporiser.
- The sterilising agent's injection into the sterilisation chamber takes place from a side opening of the same.

Programming and Cycle Operation

Working programmes are factory programmed and validated; they are available for the operator selection in the control panel.

The low-temperature hydrogen peroxide steriliser is designed to sterilise moist and heat-sensitive medical devices packed in suitable sterile barrier systems.

Validated cycles configuration

- **Fast Cycle** - Duration about 27 min + 3 min of initialization (30 min)

  For sterilizing generic reusable medical devices, rigid scopes without lumen and micro-surgery kits, with the exclusion of hollow instruments (surface sterilization).
  Max load: 19.5 Kg
- **Flex Cycle** - Duration about 37 min + 3 min of initialization (40 min)

  For sterilising single and dual-channel flexible lumens. Up to n.2 dual channel flexible endoscopes with 1mm diameter and length up to 1050 mm (first channel) + 1mm diameter and length up to 1000 mm (second channel); or up to 2 single-channel flexible endoscopes with a diameter of 1 mm and length up to 1050 mm.

  Max load: two flexible dual channel endoscopes as above or 2 daVinci endoscopes (Intuitive Surgical).

  Max load: 10.5 Kg.

  Up to 6 lumens
- **Standard Cycle** - Duration about 48 min + 4 min of initialization (52 min)

  For sterilizing hollow rigid, semi-rigid and flexible instruments until three channels with diameter from 0,7 mm and length up to 750 mm (depends on the type of load).
  Max load: 10.3 Kg.

  Until 22 lumens.
- **Intensive cycle** - Duration about 60 min + 4 min of initialization (64 min)

  For sterilizing hollow instrumentation single channel, dual channel and triple channel with diameter from 0,5 mm and length up to 2200 mm (depends on the load).
  Max load: 6.5 Kg

  Lumens: from 3 to 22
- **Superfast Cycle (Optional)** - Duration about 20 min + 2 min of initialization (22 min)

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For sterilizing generic reusable medical devices (surface sterilization).
Max load: 5.5 Kg

Sterilization temperature between 50°C and 55°C.

Cycle Description

Once a program is started, the sterilizer automatically processes the load through a predefined combination of the standard phases below mentioned.

The cycles are factory programmed and validated, cannot be modified by the operator and include the following typical treatments:

- **Preparation** – This phase is executed to reach the optimal conditions needed for a sterilization cycle as well as for a testing cycle.

  The system checks in real time the moisture level of the load in the chamber and eventually stops the cycle before the injection of the sterilant if the level of moisture is not within the safety parameters of sterilization (saving the use of cartridge)
- **Initializing** – This phase generates a fractional vacuum, further heats the load to remove residual moisture and maintains the chamber at a predefined absolute pressure before injection (conditioning phase to remove any residual moisture). The system checks the humidity level in the chamber in real time through a dedicated sensor which detects and displays the value via HMI. The system automatically stops the cycle before the sterilant is injected if the humidity level does not fall within the sterilization safety parameters (pre-cycle diagnostic system).
- **Sterilization** – Injection of a quantity of 2.5 ml of hydrogen peroxide (per chamber vacuum). The dosing system in the sterilisation chamber by an advanced injection system is equipped with a pre-set syringe and automatically controlled.

  The chamber's temperature and the pressure are kept constant for a variable duration in minutes depending on the cycle, subsequent partial vacuum brake of filtered air and maintaining the chamber to the new pressure condition for a variable duration in minutes depending on the cycle. Vacuum step and neutralisation of the residual hydrogen peroxide per suction and simultaneous activation of the plasma generator. The subsequent passage of the residual hydrogen peroxide through the platinum catalyst and through the activated carbon filter (triple action to eliminate H2O2 residues in the environment).
  The described sterilisation phase above is repeated 4 times. The last two repetitions are implemented to obtain the "overkill" effect.
- **Cycle completion (Aeration)** – Through fractionated vacuum in the chamber for a predetermined time, the end of which the atmospheric pressure is re-established pressure inside the chamber.

  The steriliser drain is treated with a plasma generator, a platinum catalyst filter and an activated carbon filter to guarantee no hydrogen peroxide residue is released. In the event of the operator voluntarily stopping the cycle or generating an alarm, the cartridge is emptied of any unused hydrogen peroxide residue before being automatically released. Unused hydrogen peroxide passes through the plasma generator and then through the catalyst and the activated carbon filter, guaranteeing the total absence of residues in the cartridge used or emissions into the environment. If the cycle is voluntarily stopped by the operator before the phase that foresees the suction of H2O2, it will be possible to reuse the cartridge already loaded.

  If the operator voluntarily stops the cycle before the phase that foresees the suction of H2O2, it will be possible to reuse the cartridge already loaded for the cycle.

  At the end of the cycle, used cartridges are automatically returned by the machine completely empty and free of residues and can be disposed of with normal waste (according to internal regulations).

  The single-dose cartridges guarantee maximum user safety.

  At the end of the cycle, the load does not have any residue, does not require ventilation and can be used immediately.

Testing Programmes

- **Vacuum Leak Test:** this cycle is used to check the sterilizer vacuum integrity (tightness of all components on the vacuum line). It is also possible to program it automatically at the most suitable time for the work of the sterilization department. The Test issues a print-out containing all the parametric data and the cycle graph, as well as the information of "Cycle completed OK" (no anomaly detected) or "Cycle completed Not OK" (in case of any anomaly verification). The information contained on the touch panel guides the user in resolving any alarms.

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Validation Programmes

- Five half-cycles (4+1 optional), protected by password, are available for validation procedures (EN ISO 14937 (ANSI/AAMI))

Construction

- Frame made of stainless steel AISI 304 (DIN 1.4301)
- External panels made of stainless steel AISI 304 (DIN 1.4301) scotch brite finish
- Vertical sliding door/s made of stainless steel AISI 316L (DIN 1.4404) without any welding.
- Sterilization rectangular chamber made of stainless steel AISI 316L (DIN 1.4404) satin finish.
- Silicone door seals
- Fine satin finishing (2 µm) for process pipes
- High quality thermal insulation to minimize energy consumption

Option Features

Electrical Connections

- As per the requirements of the installation site

Set of Spare Parts

- For two years of activity

Barcode Reader

- System identification (hand scanner) for the recognition of the load and operator

RFID reader

- RFID gun system for the recognition of load and operator

Free Contacts

- For critical alarms: these relay contacts (also called "dry contacts") are used to signal alarms or to provide information on the cycle status

SteelcoData Live

- Centralized cycle traceability software for Steelco devices.

UPS

- Uninterruptible Power Supply for the temporary power supply of the PLC control system

Floor anchorage

- Floor anchorage

Racks and Carts

A large variety of accessories for the load's optimal arrangement into the sterilizer (insert for pouches and baskets) is available.

Consumables

A large selection of chemical and biological process indicators as well as incubators is available.

Validation Support Documentation and Services

Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) testing available upon request

Required Utilities

For connection details please refer to installation drawing of the selected model/version.

Electrical requirements

Standard configuration for European power supply voltage 400V/3~+N/50 Hz.
Other voltages are available on request.

Documentation Provided

- Declaration of conformity
- Wiring diagram
- P&ID
- GA
- User Manual
- Vacuum pump documents

Preventive Maintenance

Customers are invited to contact STEELCO for annual maintenance.

The activities of preventive maintenance, along with the calibration and replacement of the worn parts, ensure the equipment's best performances and help minimise sudden and costly downtimes.

STEELCO has a worldwide staff of qualified and skilled technicians who can provide these services and carry out on-site installation, training, and repairs. Please contact STEELCO for further details.

NOTES

1. Customer must ensure that the sterilizer stands on a levelled floor suitable for sustaining the load of the device. The supply lines and the drain of the various process fluids have to meet

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the pressure and flow rates specific for the sterilizer. In case of “special” installations (e.g. equipment installed in a pre-existing technical compartment, recessed, paired with other equipment), all the internal parts of the machine have to be protected in order to avoid that unskilled personnel can have a direct access to them (inspection doors equipped with a key or any other locking system that does not allow a direct access). Check the installation diagram and if necessary please contact STEELCO for further information

2. 2. STEELCO recommends that the disconnect switches (with lock in OFF position; not provided by STEELCO) for the electrical supply line are installed in close proximity of the unit
3. 3. STEELCO recommends a proper and adequate lighting of the area close to the technical area and (if possible) the provision of a power supply in case of maintenance service

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