



Product Specifications

Serie H

Hospital application steam sterilizers

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CISA reserves its right to correct clerical errors or change the technical specifications of the equipment without forewarning. We remind the readers that any picture and/or illustration contained herein is provided by way of example and may not represent the final product.

Intended Use

CISA steam sterilizers are used to achieve purposes of sterilization of medical devices generically adopted in the healthcare facilities.

The sterilizer uses saturated steam at an operative temperature range from 105°C up to 140°C and operative pressure up to 2.6 Bar, adopted in various sterilization programs for wrapped and unwrapped, porous, and nonporous heat and moisture stable materials like surgical instruments, textiles, linens, rubber and in general all materials resistant to heat.

The equipment is fully automatic and does not require specific technical knowledge from users; it is supplied configured with factory validated cycles dedicated to the common uses in healthcare field. The cycles foreseen automatic mechanical air extraction from sterilization chamber by vacuum, granting the sterilization process to be achieved in a saturated steam environment.

The shape and volume of the sterilization chamber is designed to be loaded manually or assisted with racks and trolleys, and it is conceived to easily contain modular baskets in metallic mesh and modular medical containers conform to ISO standard.

The access to the sterilization chamber is achieved by means of one or two automatic doors (pass-through).

Standards

CISA Sterilizers are built in accordance with standards: UNI EN 285:2016, UNI EN ISO 17665-1:2007, CEI EN 61010-1:2010 AMD1:2016 COR1:2019, CEI EN 61010-2-040:2015, IEC 60204-1:2016, and with European Directives: Low Voltage 2014/35/EU, Electromagnetic Compatibility 2014/30/EU, Machinery Directive 2006/42/EC, Pressure Equipment Directive 2014/68/EU. Provided of CE mark according to European Medical Device Regulation 2017/745/EU.

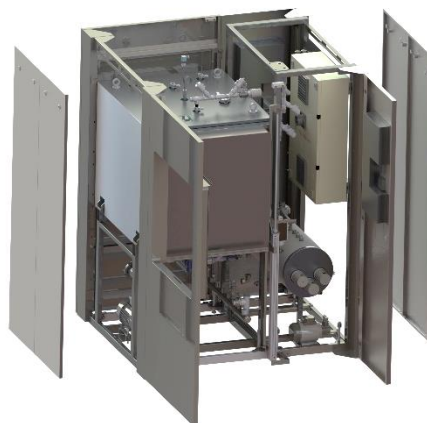
Product are realized within quality system UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2016.

Installation

The sterilizer is free-standing and has a cabinet-shape, which permits installation in open space or recessed in walls both in case of a single door or a double door system.

Maintenance Access

The front and back panels of the sterilizer are openable, granting access to the plant. Depending on the model selected, the equipment can be serviced from the front of the machine, from the side or from both.

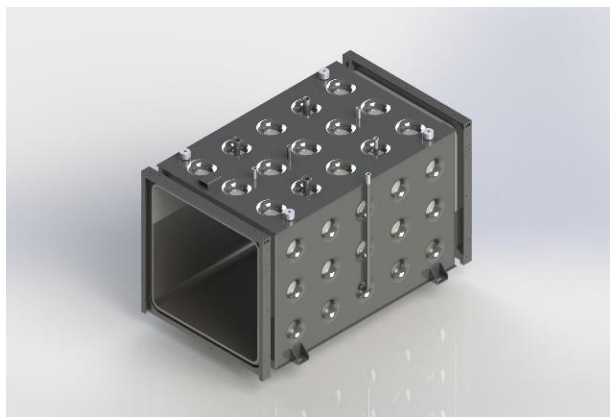


Mechanical Construction

The core of the sterilizer consists of a certified pressure vessel composed of three parts: a sterilization chamber, a jacket which surrounds the chamber, and one or two doors which provide access to the sterilization chamber and seal it from the external environment during the process.

Sterilization Chamber

The pressure vessel core part consists of a round-edges quadrangular section sterilization chamber, made of polished stainless steel AISI 316L (W.Nr.1.4404).



To preserve hygiene and extend its lifespan, the chamber is conceived with clean and essential shape, without encumbering rails, granting a high loading capacity and at the same time a low unused volume and subsequently a minor demand of energy respect to a generic sterilizer of the same useful capacity.

The chamber has a main exhaust drain (or two depending on the model) equipped of a removable and cleanable strainer filter to protect drain from accidental fall of debris.

The bottom of the chamber is shaped to allow condensates to be drained.

Full Jacket

The steam jacket consists of deep-drawn stainless steel AISI 316L (W.Nr.1.4404) sheets. It is welded around the sterilisation chamber and envelops it completely (full jacketed chamber). Its shape contributes to increase pressure vessel resistance to thermo-mechanical stress while guaranteeing a large heat exchange surface.

Doors

The door is made of stainless steel AISI 316L (W.Nr.1.4404). It features a protective outer sheathing made of Scotch-Brite® type satin finished stainless steel AISI 304 (W.Nr.1.4301) which encloses an expanded melamine foam mattress that guarantees a surface temperature under 45°C.

Validation Connections

The chamber features two entry ports for validation purposes, one for sampling pressure and another for temperature.

Closure of Doors

The door slides vertically or horizontally (depending on the model) through C-shaped frame embedded in the pressure vessel. Door frame is integral part of the chamber and is obtained from a unique raw piece worked with computer numerical control milling machine. The unique-piece door frame provides an unsurpassed level of mechanical safety as the door, when closed, is held on four sides from the very chamber structure, preventing accidental opening in case of overpressure.

The door closes automatically by acting on the buttons positioned on equipment control panel. The door is driven by an automatic system that makes it to slide, opening or closing access to sterilization chamber.



Chamber Sealing

The air-tight sealing of the chamber from external environment is guaranteed by introducing steam in the gasket seat and pushing the gasket toward the door. At the end of the cycle, a vacuum stage provides to bring the gasket back on its initial position inside its seat. Throughout the process, the sterilizer controls that gasket is pushed by the correct pressure by means of a safety pressure switch, which generates an alarm in case the pushing pressure detected would result not enough to guarantee the correct sealing and safety.

The silicone gasket fits perfectly into its seat, thereby preventing dirt from slipping inside and does require little to no maintenance except surface cleaning.

Vessel Finishing

The inner surface of the chamber has rounded and perfectly finished corners. The internal surfaces of the chamber and the doors are subjected to a progressively finer mechanical brushing to obtain a mirror-like finish compact surface, with high resistance to corrosion and a roughness (Ra) $<0.2 \mu\text{m}$.



Vessel Insulation

The pressure vessel is covered with extra-thick insulating material that limits heat dissipation and reduces condensation. The pressure vessel is insulated with 30-50 mm expanded melamine foam pads encased in an aluminium sheathing, rigid and removable for inspection.

The insulation material ensures the surface temperature of the sterilizer under 45°C . The insulation material is chloride-free, non-toxic, resistant to fire, with an exceptionally low thermal conductivity ($<0.035\text{W/m}^{\circ}\text{K}$) and does not decay while ageing.



Machine Frame

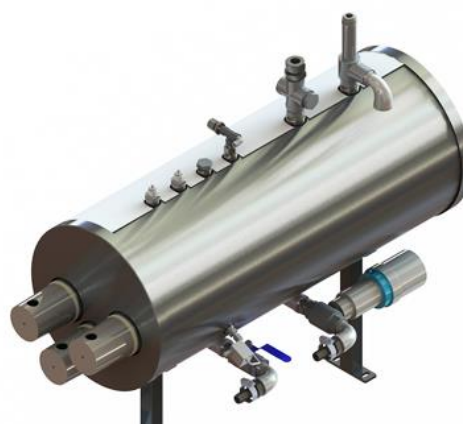
The sterilizer stands on a supporting frame made of 2mm thick square-section stainless steel tube AISI 304 (W.Nr.1.4301) which

sustain the sterilisation chamber and contains all the hydraulic components of the sterilizer.

Outer Panels

The front and side panels of the sterilizer are made of Scotch-Brite® satin finish stainless steel AISI 304 (W.Nr.1.4301) thickness 15/10.

Steam Generation



The equipment sterilizes by means of saturated steam. The steam may be supplied to the sterilizer from an external source or produced internally. All the available standard methods of steam supply are described below.

V mode (building steam)

The sterilizer uses steam originating from a central steam supply. To protect the sterilizer from scaling and corrosion wear, to assure the goodness of the sterilization cycle and to preserve the instruments and the goods to be processed, it is requested a clean steam quality according annex B of EN 285 Tab.4.

Depending on the model, the sterilizer is equipped of a suitable steam filtering element $5\mu\text{m}$, encased in a stainless steel AISI 304 (W.Nr.1.4301) housing.

E mode (electric steam generator)

Autonomous production of steam by means of a built-in electrically operated steam generator. It consists of a boiler made of stainless steel AISI 304 (W.Nr.1.4301) (AISI 316L optional). It is separated from chamber and connected to jacket by pipe intercepted by pneumatic valve.

The steam generator is equipped of multiple heating elements, water level sensors, control pressure switch, safety thermostat, overpressure safety valve, steam sampling valve and is insulated with 15 mm thick fiberglass pad, removable for inspection.

The steam generator water refill is achieved by means of a feeding pump with stainless steel AISI 316 (W.Nr.1.4401) impeller. The refill intervals are controlled by the control unit of the sterilizer. Steam generator includes manual and automatic time/volume descaling exhaust procedure.

EV mode (steam generator and building steam)

This mode embeds both E and V functionalities, switchable on user desire via the equipment user interface.

SV mode (steam-to-steam converter)

The SV mode permits the autonomous production of clean steam suitable for sterilization purposes by means of indirect heating of treated water using sterilization-unsuitable steam received from building source.

The system features an internal steam boiler loaded with treated water, that permits the indirect vaporization of the water by means of a high-efficiency steam-to-steam exchanger, fed with dirty steam.

The steam boiler is made in stainless steel AISI 316L (W.Nr.1.4404), and it is provided of water level sensors, control pressure switch, safety thermostat, overpressure safety valve, steam sampling valve and is insulated with 15 mm thick fiberglass pad, removable for inspection. Steam boiler includes manual and automatic time/volume descaling exhaust procedure.

The steam boiler water refill is achieved by means feeding pump with stainless steel AISI 316 (W.Nr.1.4401) impeller. The refill intervals are controlled by the control unit of the sterilizer.

ESV mode (steam generator and steam converter)

This version embeds both E and SV functionalities, switchable on user desire via the equipment user interface.

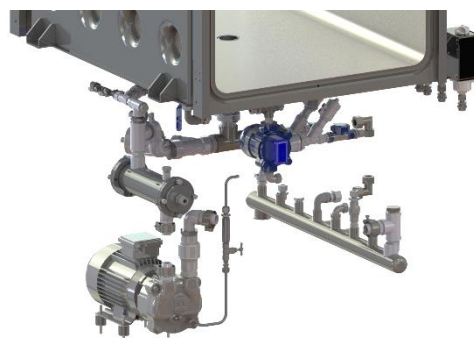
Piping System

Hydraulic system

The hydraulic plant consists of pipes and components entirely made of stainless steel AISI 316 (W.Nr.1.4401) and AISI 316L (W.Nr.1.4404). The fluids are intercepted by pneumatically-operated valves made of stainless steel AISI 316L (W.Nr.1.4404). The plant features tri-clover coupled sections to ease maintenance.

The steam enters in the sterilization chamber from the jacket via pipe intercepted by a pneumatic valve and subsequently distributed evenly inside by means of one or more steam baffles.

Condensates are discharged from chamber and jacket by means of steam traps, of thermostatic type for the chamber and floating type for the jacket. All the exhausts are collected in a unique stainless steel drain manifold.



All the components of the plant are marked, which reference can be found in the hydraulic and pneumatic schematics supplied with the equipment.

Piping insulation

All the pipes carrying hot fluids are insulated with a silicone foam sheathing with a Kevlar inner core, chloride-free, non-toxic, resistant to fire and to decay. It reduces condensation, thermal dispersion in the environment and protects service staff from accidental burns.

Pneumatic system

The machine requires compressed air from an external source, mainly to activate the pneumatic valves. The compressed air is connected to a pressure reducing group included of manometer

and filter and directed to solenoid pilot valves groups. Those solenoid pilot valves are commanded by the control unit and carry compressed air to the pneumatic actuator of the hydraulic valves to obtain their activation. The equipment is conceived with normally-closed pneumatic valves to guarantee safety in case of compressed air supply failure.

All the pneumatic components are interconnected by means of Teflon hoses of variable diameter between 4 and 6mm that run throughout the equipment enclosed in cable ducts to leave technical compartment neat and tidy.

Vacuum system

The equipment features a mechanical air extraction system consisting of a liquid-ring vacuum pump which ensures a rapid extraction of the air during the conditioning stages and an efficient drying during the post-sterilization stage. The vacuum pump is mounted on vibration isolators that prevents noise and vibrations on the equipment structure, granting quiet operation.

The hot exhausts of the chamber are cooled by means of a stainless steel AISI 304 (W.Nr.1.4301) tube-nest heat exchanger before reaching the vacuum pump. This cooling system, fed by cold water, protects the vacuum pump from excessive temperatures.



Air Filter

To restore atmospheric pressure inside the sterilization chamber after the final vacuum, the sterilizer is equipped of a replaceable absolute HEPA filter efficiency 99,995%.

Electric System

The sterilizer has an electric system which provides commands to the various components. The electric plant consists of a power electric section for motors and other high-absorption devices, and an electronic system for command and control.

Electric Cabinet

All the electric and electronic components are enclosed in an IP55 protection rate cabinet. The electric cabinet is installed inside the sterilizer and accessible for maintenance. It features a power disconnecter switch and a locking key to allow safe access by authorised technicians. All electric and electronic components are installed on DIN rails to provide easy replacement. The electric cabinet is equipped of a fan to circulate fresh air inside.



All wires that connect the various components are of suitable section calculated on the power and voltage applied to the equipment. All wires inside the electric cabinet and inside the equipment runs enclosed in cable ducts to leave electric cabinet and technical compartment neat and tidy and to protect wires from heat and accidental cleaves.

All wires and electric components are numbered with permanent marks which reference is inside wiring schematics accompanying the documentation.

Control System

The sterilizer is completely automatic, run by an electronic system, and is operated by means of an interactive user interface, through which the user provides commands and receive information.

Human-Machine Interface

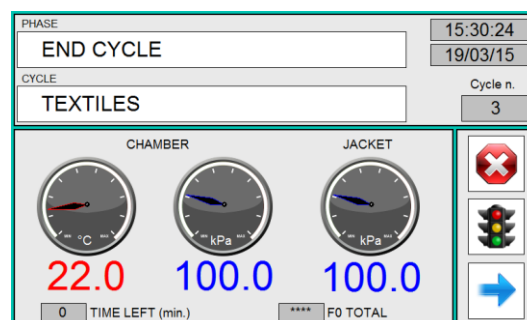
The equipment interface consists of a 7" industrial high-visibility color touchscreen. The touchscreen provides visual aid to the user and permits to give instruction to the equipment, launch sterilization cycles, check physical values in real-time, etc.

The touchscreen displays information with extended messages expressed in a comprehensible language. Software or technical expertise are not required to run the sterilizer, and any class of operator can be assigned to use the equipment simply following the step-by-step instructions displayed on the screen. The software of the equipment guides the user providing him logical path made of choices, thus reducing human error.



The user can navigate freely through the standard menus, except for the section reserved to maintenance personnel which requires a password. There are various menus accessible including:

- cycle library containing default factory validated cycles
- cycle real-time phase status, measured temperature and pressure values, set-point values
- real-time diagram of the process
- synoptic diagram
- scheduled maintenance intervals status
- alarms, warnings, and alarm log
- calendar control, cycle progressive counter
- real-time F0 value
- visualization of cycles archive in storage memory
- programming new sterilization cycles
- miscellaneous indication (door status, self-diagnosis, etc.)



Main Control System

The sterilizer is commanded by a microprocessor-based programmable logic controller (PLC), which acquires physical values, receives information from sensors and manages the activation of the various components.

The PLC is of industrial type (non-proprietary) with large availability on market, high reliability, and provided of CISA software installed on a non-volatile memory. This device is installed protected inside the electric cabinet and provided of a ten-years life granted battery.

Independent Monitoring System (IMS)

The equipment is equipped of an independent monitoring system which consists of an additional programmable logic controller (PLC) of the same type of the main control unit. This device determines in real time if the appropriate sterilization parameters (temperature / time / pressure) have been met throughout the sterilization process.

This is achieved by real-time comparison of the values coming from the main control system with those detected from the independent monitoring system, which has its own duplicate independent set of sensors. The comparison provides an immediate fail/success parametric response: detection of discrepancy between sensors results in alarms or warnings, providing superior compliance to EN 285 par.6.2.1 and 6.3.1.

The independent monitoring system is also in charge of real-time printing of sterilization report receipt, providing user the possibility of further assurance by manual check of the sterilization process detected values.

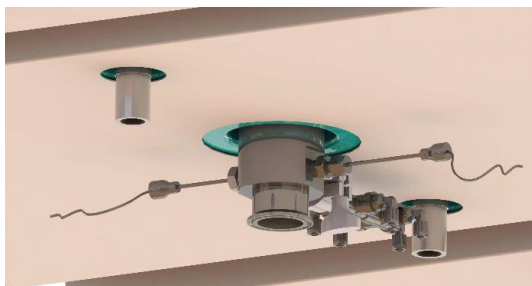
Temperature and Pressure Sensors

The sterilizer is equipped of sensors for measuring the temperature and pressure inside the pressure vessel, The following sensors are available in the sterilizer:

- Chamber drain temperature sensor (2)
- Chamber pressure sensor (2)
- Jacket pressure/temperature sensor (1)

Sterilization chamber temperature sensors consist of PT100 class A in-process accuracy $\pm 0,1^{\circ}\text{C}$ installed in the chamber drain (coldest point).

Chamber and jacket pressure sensors consists of pressure transducers, in-process accuracy $\pm 0.1\text{KPa}$.



Commanding Panel

The sterilizer features a control panel installed on the front of the sterilizer (and in the rear in case of double door pass-through system), it holds all the control elements of the sterilizer (HMI, printer, command buttons). The compartment protection rate is IP22 internally and IP54 externally.

The main commanding panel on the front side consist of:

- Main Touchscreen interface
- alphanumeric dot-matrix panel printer
- emergency cut-off button
- equipment on/off button
- door closing commands
- chamber pressure-vacuum gauge -1/0/5 bar
- jacket/steam generator pressure gauge -1/5 bar
- USB female port for cycle data download

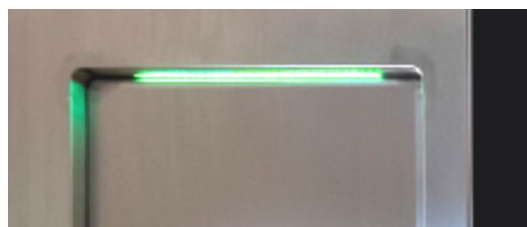


The commanding panel on the rear, in case of double door sterilizer, consists of:

- (option) Secondary Touchscreen interface
- emergency cut-off button
- indication LEDs for cycle in course, cycle end, alarm
- two door closing buttons
- chamber pressure-vacuum gauge -1/0/5bar

Chromatic Indicator

The front panels of the sterilizer are equipped with a 4-colour signaling bar which has the function of providing immediate evidence to the user the status of the sterilizer even from a distance.



Password and Level of Access

The sterilizer has a system to prevent intentional or accidental access to sensible functions to unauthorized personnel, by mean of a combined system of password and level of access. The

sterilizer can recognize up to 70 users and provide each of individual password and level of access.

The equipment has by default several levels of access to its functions, from minimum 1 (basic functions), to maximum level 9 (administrator). It is possible to customize the actions available to each level of access.

Languages

The touchscreen can be shown in several languages. The user can select the desired language amongst the packages already installed inside the sterilizer including, but not limited to: english, italian, french, german, spanish, russian, arabic, turkish, finnish, polish, romanian, korean, greek and others.

The language of the printed report receipt is restricted to Latin alphabet languages.

Stand-by and Automatic Start-up

The sterilizer has a built-in standby and wake up functions which permit to reduce the energy consumption and optimizing waiting time due to self-heating at the beginning of the working shift.

It is possible to program the sterilizer to stop self-heating and enter in a standby mode after being idle for a certain specified time. The sterilizer awakes and restart on user explicit command.

As the sterilizer has also a wake-up feature which can be programmed at a specific hour of the day, in order to start up automatically and heating itself before beginning of working shift. The sterilizer can be programmed to automatically start the daily pre-heating sterilization cycle at empty chamber, the vacuum test, and the Bowie-Dick test (if provided of automatic loading device). The wake-up feature can be set disabled during weekends.

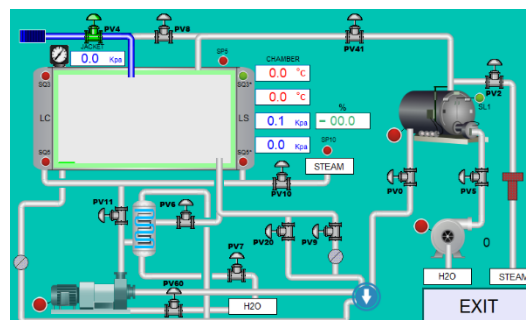
Scheduled Maintenance

The sterilizer is capable to notify the maintenance intervals of the sterilizer by calculating the actual working hours of components. This permits to optimize periodic maintenance interventions and replacement of the consumable parts (filters, gaskets, etc.)

Synoptic Diagram

The sterilizer is provided of a synoptic screen on the touch screen: a schematic reproduction of the piping diagram, where the service

staff can check the status of activation of all components of the sterilizer.



Service personnel has access to advanced function of the synoptic, where it is possible to activate all the components shown on the diagram, as a facility to check the output signals from the main control unit.

Safety Systems

The sterilizer is fitted with several mechanical and electronic devices that guarantees safety of the user and the integrity of the sterilization cycle. When a safety device intervenes, an alarm indication is shown on the touchscreen.

Overall Safety Systems

Following the list of the safety measures of the sterilizer, which provides safety of the user and the working environment:

- Protection against pressure vessel overpressure: safety valve.
- Protection against door opening in condition of pressure.
- Device to prevent and reverse door closure in case of obstacles.
- Device to prevent injection of steam inside the chamber if door is open or non-completely closed.
- Device to prevent simultaneous opening of the doors (interlock: only double door models).
- Protection against jacket overpressure.
- Device to coerce user in using both hands while closing door procedure.
- Device to prevent accidental injuries from electricity: mechanical power cut-off breaker.
- Protection for pumps overload (working without feed water)

Process Safety systems

Following the list of the safety measures adopted on the sterilizer, which guarantees safety of the process:

- Device to guarantee door sealing
- Device to detect temperature within sterilization range
- Device to detect failure of the temperature/pressure sensors
- Device to detect correct calibration of sensors

Additional safety systems when provided of steam generator:

- Device of protection against overtemperature of steam generator heating elements.
- Device for inhibiting activation of steam generator heating elements in absence of water refill.

Alarms

There are various alarms that intervenes when a safety system is being activated. All alarms and warnings are signaled in audible and visible mode to attract attention of the user: by means of a loud buzzer, messages on the video and on chromatic bar. The alarms messages are expressed with comprehensible language and provide immediate indication about the nature of the failure.



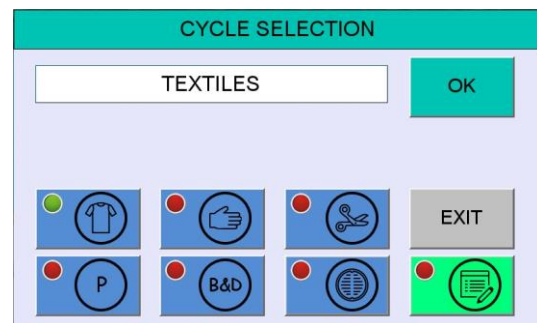
The alarm messages are as well printed on the sterilization cycle report slip. Additionally dedicated page showing alarms historical log is available.

There are two categories of alarm, as follows:

- Warnings: does not intervenes on the cycle progress.
- Critical alarms: intervenes in case of serious faults which aborts the cycle in course.

Sterilization Cycles

The sterilizer comes with a set of default cycles programmed and factory validated, adapt for use in healthcare field. The cycles are configured as a sequence of various phases: stepping to one phase to another is subject to achievement of the conditions of temperature and pressure set points.



The sterilization cycles are kept in permanent memory of the control unit and cannot be deleted or modified without factory administrator access level. Cycles can be selected on the touchscreen by accessing the cycles library page. The buttons shown on the page present a typical icon and the cycle name: pressing the relative button the cycle begins.

All default programs include a pre-vacuum conditioning step. By using steam/vacuum sequential pulses during the conditioning stage, the air is removed to ensure penetrability of the steam inside the load.

The sterilizer is capable of processing unwrapped and wrapped loads with any kind of packaging currently available on the market: wrapping in medical grade crepe paper or sealable plastic bags conform to ISO 11607-1, or reusable containers in stainless steel or aluminium conform to EN 868-8 standard.

Standard sterilization process

Sterilization cycles consists of a predefined sequence of the following phases:

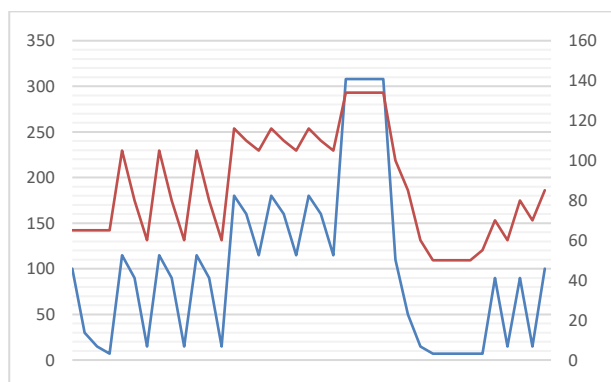
1. Initial vacuum until pre-set pressure value and hold for a pre-set time.
2. Conditioning: injection of steam alternate to exhaust and vacuum phases.

3. Heating: injection of steam in the chamber up to sterilization temperature.
4. Sterilization: (plateau) maintaining the temperature for the pre-set time.
5. Drying: vacuum step alternate to sterile air admission and injection of steam in jacket to dry the goods.
6. Aeration: chamber atmospheric conditions restoration by admission of sterile air through HEPA filter.

Standard Cycles Library

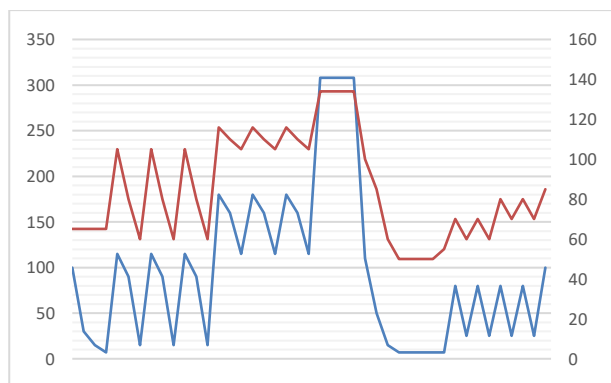
The sterilizer comes provided with 4 validated sterilization cycles for healthcare use:

1) Sterilization cycle at 134°C (Porous)



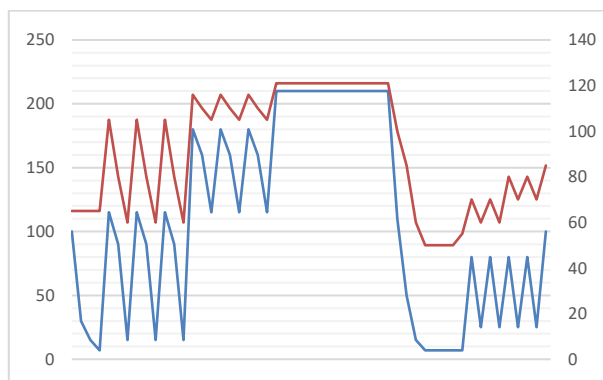
it is suitable for textiles, linen, porous materials and in general for any type of solid and porous loads resistant to temperatures up to 134°C.

2) Sterilisation cycle at 134°C (Instruments)



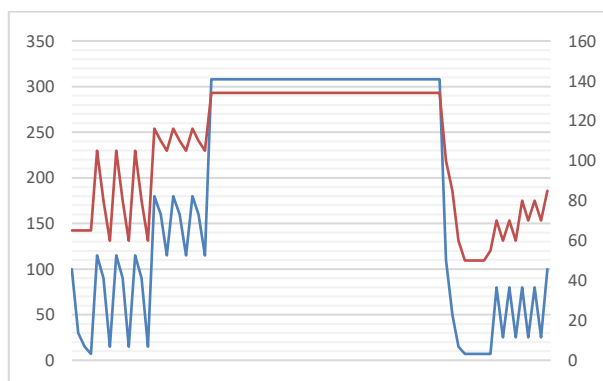
specific for solids and surgical instruments, empty glassware and in general for any type of solid and porous load resistant to temperature up to 134°C and requiring enhanced drying.

3) Sterilization cycle at 121°C (Plastic)



adapt to gloves, catheters and plastic or rubber materials and in general, for any kind of heat-sensitive load resistant up to 121°C.

4) Sterilisation cycle at 134°C (Prions)



adapt for porous and solid loads suspect of Creutzfeldt-Jakob or Anthrax disease.

Test programs

The equipment features two default test programs: the Vacuum Leak Test to verify the leak proofness of the chamber and the Bowie-Dick test to verify the efficiency of the air remotion and consequently of the steam penetration.

5) Vacuum leak test cycle (Vacuum Test)

Chamber vacuum leakage test cycle according EN 285 standard. Max accepted leak rate 0.13 kPa/min.

6) Steam penetration test cycle (Bowie-Dick)

Steam penetration test cycle according EN 285 standard, usable in combination with test packs or sheets conform to ISO 11140-4 and Helix test conform ISO 11140-1.

7) Programmable cycles (up to 60)

This category of programs can be freely programmed by the user through the touch screen interface, following a procedure described inside the user manual and accessible from users of an appropriate level of access.

Once a cycle is programmed, it can be run automatically as a normal cycle and remains available for further uses. Up to 60 cycles can be programmed, and each one can be identified by an individual name and an icon.

User can validate a custom cycle by using the chamber validation ports available together with appropriate sampling tools (excluded) and proceeding to validate the process according ISO 17665-1 standard.

F0 function

The control system includes the calculation of F0 to alert the user who programs a new cycle if the data inserted are sufficient for a correct sterilization process. The sterilizer automatically advises when the resulting F0 value is satisfied.

For all cycles, the progressive F0 value detected by the sterilizer is displayed, printed for each phase of the cycle and the final value is reported in the printed receipt.

Traceability and Data Reports

Printer

The sterilizer has by default a 24 dot-matrix characters alphanumeric printer (thermal printer as option) which prints data relative to the sterilization cycle in course. The data indicated are referred to the set-point value and actual value of temperature and pressure for each phase of the cycle, besides the date, time, operator name and code, batch number, cycle number, F0 value, cycle outcome, etc. as well as the graphic diagram indicating the pressure and temperature trend.

By effect of the independent monitoring system, the printout at the end of the process contains the unambiguous certification “cycle regular” or “cycle irregular”.

Cycle Internal Memory

The sterilizer is capable to store the last 80 cycles processed inside its internal memory. Those cycle are permanently stored in

a FIFO (first-in first-out) manner and resides inside the sterilizer memory until intentionally cancelled or automatically replaced from newest processes. The sterilizer provides to notify the need of downloading stored cycles. The stored cycles in memory can be displayed on the screen in graphic and numeric form.

USB download and CISA Data Viewer

The equipment is supplied in standard of an USB female port, embedded in the load side control panel. Connecting a USB key permits to retrieve and visualize the cycles downloaded on it, increasing the cycle memory to 2000 cycles for GByte capacity of the USB card connected to the equipment. The cycles stored in the internal memory are in CSV format.

CISA Data Viewer optional software can be supplied as a high-level interface to browse through downloaded cycles displaying those files in a graphic and numerical form, printable. The software runs on windows OS provided of a token license and does not require a direct connection with equipment.

Data Interfaces

The sterilizer is provided of an RJ45 connection port to transmit data to external tracking system or to CISA proprietary track and trace software TRACECARE®. Optionally it can be equipped of n.1 RS232 and n.1 RS485 additional ports.

Documentation

Accompanying documents

Equipment comes provided with complete set of documents:

- Installation manual.
- Quick-guide user manual.
- Service and maintenance instruction manual.
- Electric, pneumatic, and hydraulic schematics.
- EC conformity declaration.
- PED conformity declaration.
- Safety valve certificates.
- Temperature and pressure sensor certificates.
- Software release with equipment passwords.

Additional copies of the whole documentation can be supplied while ordering or later necessity.

Capacity and Dimensions

All models are available in single and double door.

Mod	Volume	Chamber dimensions mm			Version	HMI	Overall dimensions mm				Service access
	Litri/SU	Width	Height	Depth			Width	Height V	Height E	Depth	
P-3270	71 1 SU	322	322	720	Standard	Top	700	1850	1850	998/1028	Front
P-3290	101 1,5 SU	322	322	1000	Standard	Top	700	1850	1850	1278/1308	Front
P-3670	157 2 SU	333	666	720	Standard	Side	903	1850	1850	998/1028	Front
P-3690	218 3 SU	333	666	1000	Standard	Side	903	1850	1850	1278/1308	Front
P-4270	144 2 SU*	452	452	720	Standard	Side	903	1850	1850	998/1028	Side
P-4210	199 3 SU*	452	452	1000	Standard	Side	903	1850	1850	1278/1308	Side
P-4212	255 4 SU*	452	452	1280	Standard	Side	903	1850	1850	1558/1588	Side
P-6464	313 4 SU	660	660	720	Standard	Side	1424	1850	1850	998/1028	Front
					Medium	Side	1175	1850	2450		Side
					Slim	Top	903	1850	2450		
P-6410	434 6 SU	660	660	1000	Standard	Side	1424	1850	1850	1278/1308	Front
					Medium	Side	1175	1850	1850		Side
					Slim	Top	903	1850	2450		
P-6412	556 8 SU	660	660	1280	Standard	Side	1424	1850	1850	1558/1588	Front
					Medium	Side	1175	1850	1850		Side
					Slim	Top	903	1850	2450		
P-6415	695 10 SU	660	660	1600	Standard	Side	1424	1850	1850	1878/1908	Front
					Medium	Side	1175	1850	1850		Side
					Slim	Top	903	1850	2450		
P-6420	868 12 SU	660	660	2000	Standard	Side	1424	1850	1850	2278/2308	Front
					Medium	Side	1175	1850	2450		Side
					Slim	Top	903	1850	2450		

Note: the overall dimensions of the sterilizer depend on the model and configuration and all the possible variants are not fully listed here.

US = 300x600x300h mm

*ISO 400x600x200h mm

Standard Equipment Configuration

The sterilizer is supplied in standard with the following listed features:

- Chamber, jacket, doors in stainless steel AISI 316L
- Internal finishing of chamber and doors Ra <0.2µm
- Frame and front panels in AISI 304 stainless steel
- Side panels in AISI 304 stainless steel
- Pipes in AISI 316 and AISI 316L stainless steel
- Pneumatic valves in AISI 316L stainless steel
- Liquid ring vacuum pump
- IP55 electric cabinet
- Signaling chromatic bar
- Double chamber temperature probe with automatic redundancy control
- Double chamber pressure sensor with automatic redundancy control
- Jacket temperature/pressure sensor
- 7" Touchscreen interface
- Double PLC (control + independent monitoring)
- Right-hand command panel or on top of chamber (depending on model)
- Manometers for chamber and jacket pressure
- Load-side dot-matrix panel printer
- Interface for traceability
- Stand-by function and automatic start
- 4 cycles validated for medical use
- Vacuum leak test
- Bowie & Dick and Helix test
- 60 programmable cycles
- Manuals, technical documentation, and certificates
- Assembled shipping in wooden box

Options and Accessories Available

Depending on the model chosen, the sterilizer can be supplied with following options:

- Chamber, jacket, doors in stainless steel AISI 316Ti
- Medium version: width 1175 mm
- Slim version: width 906 mm
- Left-hand command panel (reverse version)
- Aquazero waterless vacuum system
- Vacuum pump water recovery system
- Vacuum pump water storage tank
- Steam generator treated water storage tank
- Degassing system
- Discharge cooling device
- Steam generator power upgrade
- Jacket condensate separation for recovery
- Sight-glass generator water level
- Additional certified safety valve
- EN285 steam sampling elbow
- Secondary touchscreen HMI
- Comfort 10" touchscreen HMI
- Thermal printer
- Cycle for liquids with natural cooling
- UPS automatic voltage regulator
- Remote maintenance system
- Physical air detector
- Internal trolleys and external carriages
- Automatic loading and/or unloading systems
- Finishing wall closure frames
- Custom cycles programming (validation excluded)
- Additional documentation copies
- Disassembled shipment

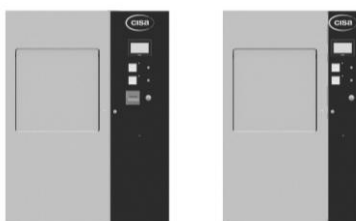
Structural Options Description

AISI 316Ti pressure vessel

On request the equipment can be supplied with chamber in stainless steel AISI 316Ti (W.Nr.1.4571). [MODELS P-640]

Medium Version

The sterilizer overall width reduced to 1175 mm. This version limits the number of options that can be installed within. [MODELS P-640]



Slim Version

The sterilizer overall width reduced to 906 mm, control panel on top of the chamber. This version limits the number of additional options that can be installed. This version requires maintenance access from the side. [MODELS P-640]



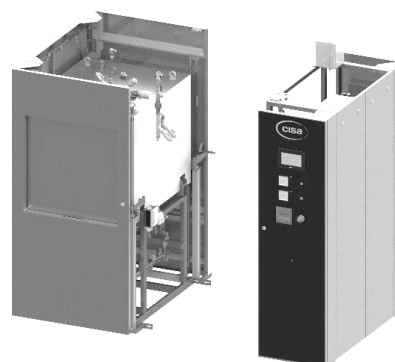
Reverse Version (left-hand command)

Depending on installation needs, the equipment can be supplied with reversed chamber configuration. In such case, the chamber is placed on the right and the control panel on the left, looking from loading side (left-hand command). [ALL MODELS]



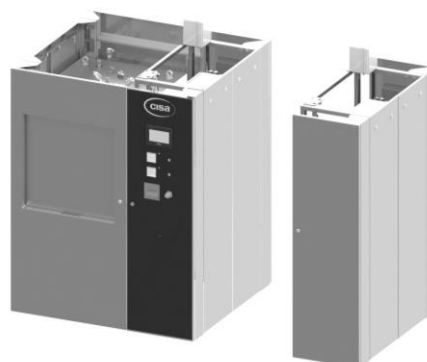
Disassembled Shipment

Depending on the model selected, to facilitate transportation through narrow places or doorways to the final installation place, the sterilizer can be delivered with frame divided in two sections that can be reassembled afterward. [MODELS P-3600, P-640]



Additional Module

Depending on the model selected, some optional configurations require additional space by requiring the installation of an extension (additional module), thus increasing the overall dimensions of the sterilizer. The additional module can be shipped separated and subsequently reassembled. [ALL MODELS]



Hydraulic Options Description

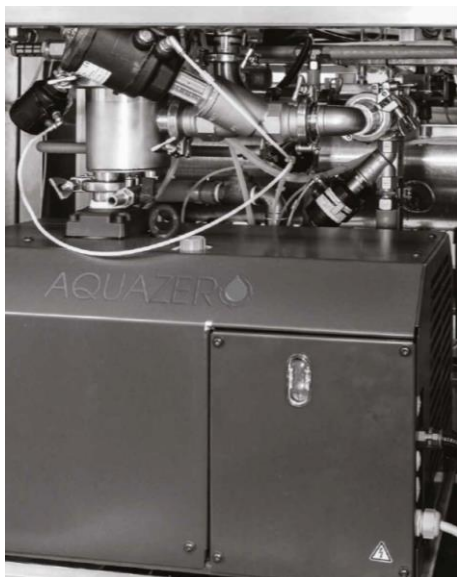
AQUAZERO® waterless vacuum system

The innovative process designed by CISA (Patent EP1696969BI) consists of a device that does not require water to obtain vacuum in the sterilization chamber. This vacuum system permits extraction of the air through a dry pump with an effective suction power of 80m³/h.

In addition to eliminating the consumption of water to produce vacuum, this system permits to reduce maintenance costs and the typical downtime of liquid ring vacuum pumps and ejector systems due to the calcareous deposit effect of the feed water.

[MODELS P-4212, P-6410/12/15/20]

[WITH ADDITIONAL MODULE: ALL MODELS]



Service water saving system (recycling & airgap)

The water used by the vacuum pump liquid-ring instead of being disposed in the drain, is collected in a tank, and cooled by adding fresh water. The water in the tank is thus circulating in a loop and reintroduced inside the vacuum pump liquid ring. During the vacuum phase, the water in the loop will progressively accumulate heat: a thermostat placed inside the tank detects the heating and, upon a certain range, activates a valve to refill with fresh water; the hot water in suspension is discharged toward the drain through an overflow.

This system permits to save up to 50% of the usual amount of water used from a liquid-ring vacuum pump connected to the water supply (saving depends on water supply temperature).

The tank act as protection of the equipment against sudden pressure drops of the water supply and as airgap system to prevent backflow on supply line. Tank is provided of level sensors. [MODELS P-3600, P-420, P-640]



Network water storage tank (storage & airgap)

Accumulation storage tank for the service water used from the sterilizer for supplying vacuum pump liquid ring. The accumulation tank act as protection of the equipment against sudden pressure drops of the water supply and as an airgap system to prevent backflow on the water supply. The tank is provided of water level sensors. [MODELS P-3600, P-420, P-640]

Treated water storage tank (storage & airgap)

Accumulation storage tank for the treated water used from the sterilizer for the generation of steam. The accumulation tank act as protection of the equipment against sudden pressure drops of the water supply and as an airgap system to prevent backflow on the water supply. The tank is provided of water level sensors. [MODELS P-4210/12, P-640]

Water degassing system

The degassing system permits to remove non-condensable gases from the water used to produce steam. By heating the treated water storage tank dedicated to the steam generator up to 70°C,

it allows the liberation of the gases dissolved in the water into the air. This grants a higher saturation quality of the steam that comes into contact with the material. The introduction of this device is subject to the installation of the treated water accumulation system. [MODELS P-4210/12, P-640]

Discharges cooling device

All the exhausts (vacuum pump, tube-nest cooler, tanks overflows, chamber and jacketed condensates) are conveyed into a stainless-steel dump tank used to collect and control discharge drain temperature. The dump tank is provided of a thermostat adjustable at the desired temperature (factory set point 60°C). Fresh water is added in the tank when the exhausts temperature is being detected higher than the set-point, to reduce the final discharge temperature in the main drain. [ALL MODELS]



Steam generator power upgrade

Increases the electric power installed on the built-in steam generator of the sterilizer to shorten cycle times. This system allows to save up to 10% of the total cycle time at the expense of a greater power consumption. The power upgrade of the generator varies depending on the model selected. For certain configurations this may require an additional space on the side or in the top of the equipment. [MODELS P-6410/12/15/20]

Condense Recovery

On request jacket condensate discharge can be supplied separated for connection to a building condensate recovery line. [ALL MODELS]

Sight-glass water level

On request the steam generator can be supplied with additional sight-glass water level. [ALL MODELS]

Additional Safety Valve

On request, the equipment can be supplied with an additional certified safety valve positioned at choice on the chamber, jacket, or steam generator. [ALL MODELS]

EN285 Steam Sampling Tube

On request, the equipment can be supplied with a steam sampling tube built according to indication on EN285 standard. [ALL MODELS]

Process Options Description

Secondary touchscreen

An additional touch screen is installed on the unload side of double door sterilizers. The secondary touchscreen can act as primary or secondary and has all the function of the main touchscreen. [ALL MODELS]

Comfort touchscreen

Expands the touchscreen of loading or unloading side to a 10" diagonal dimension for a better view of the display commands and consequently for a better comfort while operating the equipment. [ALL MODELS]

Thermal Printer

On request, the panel printer can be supplied of thermal transfer type. [ALL MODELS]

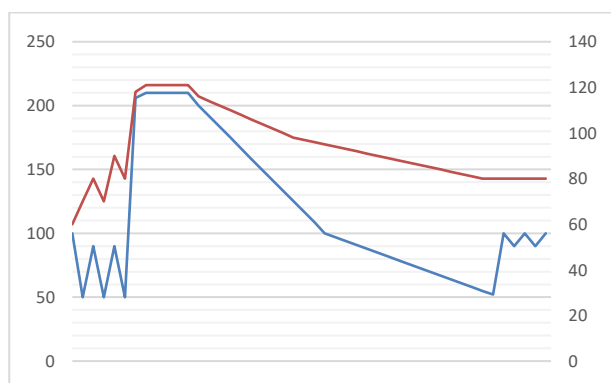
Control system backup UPS

The backup UPS system is connected to the PLC and the touch screen and allows the continuation of the cycle in the event of sudden changes in voltage or even power shortages, as long as the cycle integrity conditions at the restoration of the power will result still valid. This system exploits its maximum benefit when the sterilizer is connected to power supplies subject to voltage fluctuation and instability, thus guaranteeing protection to the sterilizer control unit. [ALL MODELS]

Liquid cycle (Natural Cooling)

The sterilizer is being equipped of an additional armored flexible product probe inside the sterilization chamber to be used as a sampling point of reference liquid bottle. The equipment is provided of an additional cycle in the main menu to carry out cycles for liquid loads:

8) Sterilization cycle at 121°C (Liquids Natural Cooling)



adapt to process liquids in open, sealed, or non-hermetically sealed containers, featuring natural cooling. [ALL MODELS]

Liquid cycle consists of a sequence of following phases:

1. Sequence of light vacuums for air extraction.
2. Heating: injection of steam in the chamber up to pre-set sterilization temperature.
3. Sterilization: sterilisation hold up time for a pre-set time (sterilization plateau).
4. Cooling: shutting-off steam injection and keeping chamber in a quiescence state until liquids naturally cool to a predetermined set-point (factory set-point 80°C).
5. Sequence of light vacuums until set
6. Aeration: chamber atmospheric conditions restoration by admission of sterile air through HEPA filter.

RMS Remote Maintenance System

The Remote Maintenance system (RMS) is a feature developed to provide remote maintenance to the equipment. By connecting the equipment to an Ethernet network with access to the Internet, RMS permits to CISA service authorized staff to:

- display remotely the touchscreen of the equipment, having access to all its functions, cycle and alarms history, cycle on

course etc. and gives service staff possibility to intervene remotely providing real-time diagnosis of the problem, thus reducing sterilizer downtimes.

- remotely update the touchscreen interface software.
- remotely update the equipment Programmable Logic Controller (PLC) software.

The service interventions are subject to the subscription of a remote service contract. [ALL MODELS]

Physical air detector (Air-Check)

The Air-Check device calculates in real time the presence of residual non-condensable gases inside the chamber before the sterilization stage: a sample of steam taken from chamber discharge allows an analysis of non-condensable gases coming from the steam itself and/or due to leakages of the chamber.

The working principle of this device is about the relationship between pressure and temperature of the saturated steam, which is established in a physical manner. This volumetric system works with dedicated temperature and pressure probes by injecting the steam inside a container of calculated volume and subsequently, facilitating the process of condensation, provides the calculation of the amount of residual gases in relation to the pressure/temperature values detected. The system can be regulated using a calibrated leakage device. [ALL MODELS]

Factory Custom Cycle Programming

On request, it is possible to provide custom cycle programming in factory. The custom cycles are programmed on customer specification. Validation of programmed cycles is excluded and must be carried out from customer before use. [ALL MODELS]

Finishing wall closure frames

On request finishing frames are available for closing the gap between the sterilizer and boundary walls. [ALL MODELS]

Loading Systems Option Description

The sterilizer is conceived to be loaded with baskets in metallic mesh and modular medical containers. The sterilizer can be loaded manually, however, a range of loading accessories to assist loading of material to be processed inside the sterilization chamber is available:

Internal Trolley



Loading carriage, made in stainless steel AISI 304 (W.Nr.1.4301), consisting in one fixed base and one intermediate removable and adjustable shelf. The shelves are made of welded mesh to reduce condensation and better distribution of steam inside the goods. The introduction inside the sterilization chamber occurs through a set of temperature-proof polymeric bearing wheels. The trolley does not require rails to slide inside. [ALL MODELS]

External Trolley/Carriage



Permits transportation of the internal trolley and, by means of a suitable coupling device, it can be hooked to the sterilizer fronts to

allow the insertion of the internal trolley inside the sterilization chamber. Entirely made in stainless steel AISI 304 (W.Nr.1.4301), it consists in a heavy-duty structure, provided of four castors, two of them provided of stop-brake. [ALL MODELS]

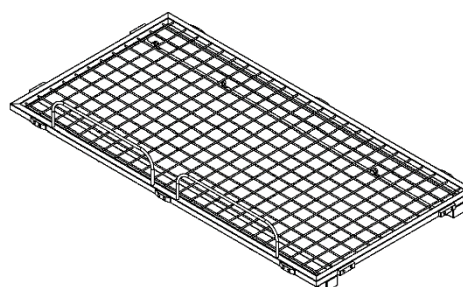
Height-adjustable external trolleys/carriage



Permits transportation of the internal trolley and, by means of a suitable coupling device, it can be hooked to the sterilizer fronts to allow the insertion of the internal trolley inside the sterilization chamber. Entirely made in stainless steel AISI 304 (W.Nr.1.4301), it consists in a heavy-duty structure easily cleanable, provided of four castors, two of them provided of stop-brake.

Provided of vertically extending electro-mechanical pistons with maximum thrust capacity of kg. 400 and a console with buttons control for lifting and lowering the loading platform, with manual and programmable adjustment. [MODELS P-640]

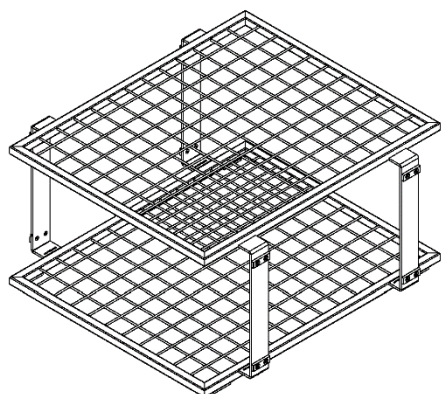
Platform Internal Trolley



Loading platform, entirely made in stainless steel AISI 304 (W.Nr.1.4301). The base shelf is made of welded mesh to reduce condensation and better distribution of steam. The introduction

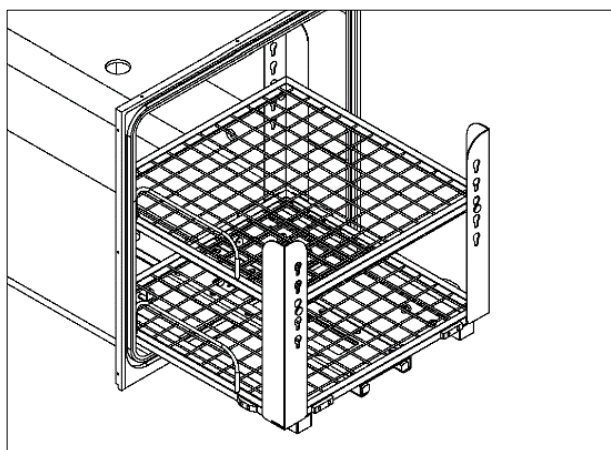
inside the chamber happens through a set of temperature-proof polymeric bearing wheels. The platform trolley does not require rails to slide inside. [MODELS P-420, P-640]

Internal Rack



Internal rack double shelf, entirely made in stainless steel AISI 304 (W.Nr.1.4301) to permit manual loading of baskets, containers, or loose packaged material. The shelves are made of welded mesh to reduce condensation and better distribution of steam. It is conceived to reside permanently inside the sterilization chamber during general working operation but can be removed for cleaning purposes. [ALL MODELS]

Slide-out Trolley



Loading rack conceived for assist loading and unloading maneuvers where the use of external trolley is not possible for space restrictions. It is entirely made in stainless steel AISI 304 (W.Nr.1.4301) and can slide outside from the chamber by up to 2/3 of its length, on both sides in case of a double door sterilizer.

Consists of one fixed base and one intermediate removable and adjustable shelf. The shelves are made of welded mesh to reduce condensation and better distribution of steam. It is conceived to reside permanently inside the sterilization chamber during general working operation but can be removed for cleaning purposes. [ALL MODELS]

Automatic loading and unloading Systems

The automatic loading and unloading devices are conceived to automate the operations of loading and unloading of the material: this device allows loading and unloading the sterilizer automatically, without intervention of the user. Each individual system is composed of a platform placed in the loading and/or unloading side of each equipment. [MODELS P-640]

