

## STERILISERS

High temperature steam autoclave for hospital application







#### Cisa Group is a global supplier of infection control systems with production plants in Italy and Brazil.

Founded in 1947, Cisa Group, together with Cisa America and Cisa Brasile, forms an international group that is one of the world's leading manufacturers of washing, disinfection and sterilization technology for infection control for the healthcare and life sciences industries.







Creating safer environments in hospitals, healthcare facilities and laboratory applications is a fundamental priority for the well-being of humans worldwide.

This is the commitment that drives Cisa to its claim:

### We care about life

Cisa Group is part of Faper Group, leading Italian supplier of world-class, innovative engineering solutions.

The Group is inspired by its founder, Fabio Perini, and has based its success on the ability to combine invention and simplicity.

Faper Group was established in 2001 as a holding company dedicated to innovation in the fields of tissue paper converting, healthcare and real estate management.

#### DIRECTIVES

93/42/ EC 2007/47/EC 2006/42/EC 2014/30/UE 2014/35/UE PED 2014/68/UE

#### PRODUCT STANDARDS

EN 61010-1 EN 61010-2-040 EN 60204-1 EN 61326-1 EN 13445 EN 285 EN ISO 15883-1,-2,-6

#### QUALITY SYSTEM

UNI EN ISO 9001 UNI CEI EN ISO 13485





MORE INFO ON THE FAPER GROUP WEBSITE



# Technology





Cisa Group develops advanced infection control technologies for the safeguard of healthcare workers and the health of patients.

Complete central sterilizing service departments for hospitals (CSSD) Sterilization for healthcare applications and clinics of all sizes

Disinfection and washing technologies for different operational requirements

Cisa Group is the technology partner for scientists, researchers and engineers who develop life-enhancing products every day.



Washing and sterilization technologies for laboratories and research centres

Sterilization for pharmaceutical production







Cisa Group, with 15 years of experience in the treatment of infectious waste, provides ground breaking solutions safe, economical and carbon friendly. Cisa Group is leading the field with the invention of its Waste Sterilization Department (WSD<sup>®</sup>).

WSD®. Complete waste treatment department

WSM. Mobile WSD® Plug and Play Sterili-Station

Over the years it has developed unique proprietary IT and energy saving systems.



Tracecare<sup>®</sup> .Traceability of the sterilization process for the reconditioning of surgical kits in CSSDs

TraceWaste. Traceability of the sterilization process for the treatment of infectious waste using Cisa WSD Waste sterilization departments



### High temperature steam steriliser

Cisa's technology ensures high quality equipment for hospital applications and patient safety, with optimum results at low running costs.



### Within the CSSD

Central Sterilizing Service Department comprises that service within the hospital in which medical/surgical supplies and equipment, both sterile and non-sterile, are cleaned, prepared, processed, stored, and issued for patient care. Cisa's High Temperature Steam Steriliser is installed, following CSSD regulations, inside the clean area (as shown in the caption), with pass-through access to the sterile area.



# Why use a Cisa hospital steam steriliser

The machine is designed with PLC industrial grade microprocessor control for higher safety and guaranteed reliability; Cisa's R&D engineers have used advanced design to optimize the machine for hospital use by working, on quality, safety and ergonomy.

The machine is built with the highest quality components for perfect hygiene, perfect operation, high durability and maximum safety.

Stainless steel of the highest quality is used for assembling the machine. The machine frame and front panels are manufactured using stainless steel 304. The hydraulic plant and pipes are manufactured using stainless steel 316L.

The pressure vessel and steam generator as well as all steam pipes are insulated using high efficiency insulation material that reduces heat loss and stabilizes the temperature inside the pressure vessel to improve the quality of the sterilisation cycles.

They are designed with a simple user system for operators and in full compliance with environmental requirements and low noise emissions. Machine installation and maintenance are easy and on most of the models, maintenance can be performed directly from the frontal side of the machine itself. Compact architecture and high reliability are the core features of all our models.

### Chamber

#### **Sterilisation Chamber**

The chamber is made of AISI 316L with the possibility of upgrade to AISI 316Ti covered with non-toxic, fire resistant insulation foam, with extremely low thermal conductivity and no release of particles.

The chamber is electrically polished up to Ra of less than 0.2 micron (mirror finish electrolytic polishing treatment).

All welding of the pressure vessel is controlled and



checked, thus ensuring homogeneity by using advanced control methods.

The chamber is designed to withstand pressure, from absolute vacuum up to 3.5 bar maximum relative pressure, factory tested at 5.8 bar relative pressure.

#### **Jacket**

A full stainless steel jacket made of AISI 316L surrounds the chamber.

### Steam

#### **Steam Generator**

The standard equipment features a steam generator is manufactured in stainless steel AISI AISI 316/316L with powerful heating elements, stainless steel water pump and optional break tanks (Air Gap). The steam generator is equipped with auto draining system for high reliability and better functionality in its lifetime.

The machine can be configured for steam generation using one of the following solutions:

- (E): Built-in steam generator with electric heating
- (V): External steam supply from hospital steam network (domestic steam).
- (EV): Combination between (E) & (V) which enables the user to select the type of heating from the touch screen as internal (E): or external (V).
- (SV): Steam to steam converter to generate medical quality steam from black steam using a built-in heat exchanger.
- (ESV): Combination between (E) & (SV) with automatic selection by touch screen.

### Doors

#### Automatic sliding doors

Automatic sliding doors enable safe & smooth door opening/ closure using a pneumatic or electrical system depending on the model. The sliding movement of the door can be vertical or horizontal, depending on the model.

#### **Gasket and seal**

The sealing of the door is guaranteed by the dynamic movement of the gasket obtained through introduction of steam in the gasket seat. The perfectly rounded corners prevent wear and tear on the gasket itself. Vacuum is performed at the end of the cycle to obtain the separation of the gasket from the door, for an easy opening of the latter avoiding damage to the gasket itself; this system does not need maintenance and lubrication.



#### Door(s) safety closure & interlock safety

The machine can be manufactured with a single door (1P) or pass-through double doors (2P). The machine is provided with high safety features for the door(s), including the following:

- Both doors (in case of double doors execution) cannot open at the same time, as the interlock safety device prevents cross contamination
- The safety lock does not enable door opening if a cycle is running or if the chamber is pressurized
- There is no cycle start or steam inlet until the door(s) have been checked and are tightly closed
- For operator safety: door closure is stopped if an obstacle is found on the way of the closure.

### Control system

#### **Control panel**

The human interface is based on a modern industrial grade component designed with a smooth surface for hygiene and easy cleaning. The control panel is provided with standard 7" HMI touch screen upgradable to 10", built-in 2" dot matrix printer, (optional chart recorder) emergency button(s), door control buttons, pressure gauges for chamber, jacket or the steam generator. Touch screen is mounted at an ergonomic level position to enable good view and easy control.

#### **Printer**

On the panel there is a built-in impact printer for cycle documentation which includes: printout of date and time with hospital name, lot number, operator name, selected cycle, parameter values for different cycle phases, phase by phase display, total cycle time and cycle results (valid or invalid) as well as printing alarms during cycle execution.



#### **User interface**

The touch screen allows to control the following functions:

- Selecting cycle and packing type
- Self-check display before starting the cycle and confirmation of the selected page
- Display of status cycle and parameters (temperature, pressure and time)
- Pages for set-point cycle follow up and real time diagram display
- Audio/visual alarms display with alarm history
- F0 Calculation
- Visualization of the last 80 cycles- graphical or value parameters
- Possibility of downloading the cycles on an external USB drive for storage and PC visualization
- Maintenance program for preventive maintenance
- Operator access level control (password protected)
- · Calibration & technical pages (password protected)
- Programming of new cycles or modifying standard cycles (password protected)
- Type of steam heating selection
- Programmable automatic start up and shut off time
- Alarm messages in clear text
- Door opening/closing management
- Troubleshooting pages

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• Stand-by mode for energy saving

#### **Operator access level control**

Cisa systems allow every operator to have its own identity code by using the predefined password and access level to which it belongs. The levels can be customized for each operator with access to multiple functions. The operator name will be printed and kept in the system for external storage, or transferred to the external supervision/traceability system software.





#### Alarms

Audio and visual alarms are defined for operator warning; the alarms list includes multilevel alarms with clear message notifications; alarm levels are configured, according to the level of importance, to stop the machine or the cycle, or to issue a warning notification without affecting the running cycle.

The alarm lists are complete for safe and perfect operation for the operators and the machines. The alarms history can display all the alarms that occurred in the last 90 days. Alarms are also displayed on the unloading side in case of double doors models. The end of cycle alert is included for alerting the user of the finished cycle and unloading process.

#### Service & maintenance

The touch screen is equipped with software pages for periodic preventive maintenance, enabling a safe operation of the machine, and a self-maintenance program for steam generator discharge with user acceptance. There are technical pages for calibration and parameter control. Easy and friendly troubleshooting pages are added for easy maintenance and service.

#### Maintenance

Most of the Sterilisers are designed to enable front-side maintenance access. The components inside are collected inside an electrical panel in a way to guarantee to protect them from involuntary contact with fluids and to guarantee greater safety for operators, easy maintenence and more efficient durability of the components.





### Advantages

#### **Pre-vacuum phase**

This phase is characterised by use of alternating Vacuum/Steam pulsations, which guarantees a good steam penetration inside the load. The type and the quantity of pulsations they have been defined in the type tests and optimized for the type of cycle validated.

#### **Sterilisation phase (plateau)**

This is the main phase of the process in which steam is maintained inside the chamber at a constant temperature and pressure, depending on the selected cycle.

#### Post-vacuum phase

Cisa technology uses a powerful vacuum pump that has high vacuum values with less time needed for drying which is one of the most important issues in terms of sterilisation.

#### Powerful vacuum system

Using a powerful water ring vacuum pump, the steriliser features a deep and stable vacuum which guarantees excellent air removal in pre-vacuum and excellent drying in post-vacuum phase. The vacuum pump is mounted on a vibration-damping frame to reduce noise. A water recovery system can be added as an option to reduce water consumption.

#### Start up time & stand by

The machine can be programmed an early start up and warming as well as an auto vacuum leak test cycle before early morning staff arrival. It is also possible to program an early morning B&D test cycle if automatic loading is available.

#### **Sterilisation cycles**

All pre-programmed cycles are validated as per UNI EN 285 standards.

The autoclave has different programmed cycles, depending on its application.

The default programmed cycles are:

- Sterilisation cycle at 134°C for general porous load
- Sterilisation cycle at 134°C for general solid load
- Sterilisation cycle at 121°C for general porous load
- Steam penetration test cycle (Bowie & Dick)
- Vacuum leak test
- Sterilisation cycle at 134°C (Prions, Creutzfeldt-Jacob)
- Flash cycle at 134°C
- Open programmable cycles (from 01 to 60 programmable cycles must be validated; password protected)

#### **Energy saving system**

The Cisa sterilisers are designed to reach a high level of energy saving, using optimized power and energy conservation at the same time, without affecting the performance of the cycle, and with full respect for the environment; they also use different solutions for thermal, noise, drainage and air outlets protection as well as low electromagnetic emissions.

#### **Excellent insulation**

The pressure vessel is covered with high-thickness material for insulation, which prevents heat loss. The perfect insulation increases the quality of the sterilisation cycle, reducing potential temperature drops.

The quality of the insulation material also meets the safety requirements for the parts in contact with operators, never exceeding 45 degrees during the sterilisation phase.

#### **Sterile air**

At the end of the cycle, sterile air is injected inside the chamber to obtain uniform pressure, using an HEPA H14 air filter.



#### **Quality and features**

The machine is designed according to European directives and construction rules and international standards.



### Optional

#### **Remote maintenance**

The machine, through the Touch Screen, is equipped with a remote access system that allows to be connected to the Cisa customer service by means of a simple Ethernet connection with internet access. This represents the fastest way for a Cisa technician verify a problem and reduce downtime.

#### Vacuum pump system with Aquazero®

This Cisa technology for the steam sterilisation, with low water consumption, energy savings, cost savings and a high-efficency process.

Aquazero® by Cisa is a patented system to produce vacuum that does not require water to perform the vacuum conditions, in a sterilisation cycle.

Compared to traditional methods with liquid ring pumps it presents considerable advantages, including: no water consumption for the production of vacuum and less equipment downtime for the not ordinary maintenance, because the liquid ring vacuum pump, is often subject to hard water aggression and to its replacement.

#### Additional touchscreen

An additional touch-screen can be installed upon request on the unloading side (steriliser with two doors-2P).

#### Comfort touchscreen 10"

Cisa sterilisers can be equipped on the loading side - or, as an optional, on the unloading side - with a larger, 10" touch screen interface, for a better view of the display commands and consequently for greater usability.

#### **Drain cooling device**

All discharges (vacuum pump, cooling device, chamber and jacket condensation) are conveyed into a stainless steel tank with a temperature control before the exhaust in the pipeline.

The device measures the discharge temperature and if necessary adds service water to cool it down. The drain will be maintained at less than 60°C and it is adjustable for better management of service water consumption.

#### Liquid cycle (Natural Cooling)

The steriliser can be equipped with an additional flexible product probe inside the sterilisation chamber to be used as a sampling point of reference for liquids in bottles. The equipment will be provided with an additional cycle in the main menu to carry out liquid cycles with natural cooling.

#### Water recovery device

The water used by the liquid-ring vacuum pump is collected in a break tank, where it is cooled by adding fresh water coming from the supply line and fed back into the circulation line of the pump itself.

This system saves up to 60% (depending on the temperature of the water adducted) of the service water used by the liquid-ring vacuum pump, thus optimizing management costs.





#### Water storage tank with air gap system

The system is designed to disconnect the demi water in order to protect the functionality of the surge pressure from the water supply. This system carries the water to an open break tank and brings it back to an atmospheric pressure, to avoid back-flow into the supply line.

#### **Degassing system**

The degasser is a technology that allows the removal of non-condensable gas from the feed water: the water supply of the electrical steam generator is accumulated in a tank and is heated up to allow the release of the gas dissolved in the water. This ensures a better quality of saturation of the steam generated from the machine.

Degassing system required water storage tank.

#### Air detector

The machine can be equipped with an air detector system to check the presence of noncondensable gases inside the chamber. The system has a calibration system to check its integrity.

#### Steam generator upgrade

Cisa provides the customer with the possibility to increase the electrical power in steam generator in order to shorten cycle times. This system makes it possible to save about 15% of the total cycle time.

The power of the generator varies depending on the model of the steriliser.

#### **Mirror reverse machine**

The equipment can be configured in a standard or inverted module. In the first case, the chamber is placed on the left (looking from the loading side) and the technical module to the right, and in the second case the chamber is placed on the right side and the technical module is placed on the left.



#### **UPS backup control system**

The UPS backup system is connected to the PLC and the touchscreen and allows to bring the cycle to completion in case of sudden surges or power failure. The cycle remains valid as long as the conditions that ensure the cycle performances have not been compromised.

#### **LED Light**

This option allows for the operators of the machine to recognize the status of the machine even when the operators are far from the machine.

The light are LED with different colors.

The LED light is applicable either to a single door and double door machine.

### Accessories

#### System for automatic autoclave loading/ unloading

The system automatizes equipment loading/unloading operations allowing the steam steriliser to be loaded or unloaded automatically.

Each individual system consists of a device placed in front of each machine, detecting sensors and coupling devices for trolley, manual bypass mode and safety devices.

#### Loading accessories

Accessories for assisted loading and unloading are available for each model, and include: internal trolley (shelving unit), external trolley (loading/unloading transfer carriages) in fixed or electrical height-adjustment configuration.

Loading devices are manufactured in stainless steel with a configurable position of the shelves and designed to optimize the chamber volume.



LED LIGHT

White: machine ready to be loaded
Blue: machine is running a cycle
Green: the cycle is ended regularly
Red: the cycle is stopped or ended irregularly due to alarms





### Our product range

All of the sizes and measurements below can be modified according to the different configurations and applications of the machines. All measures are expressed in mm (W  $\times$  H  $\times$  D).



CISA P-H SERIES MEDICAL DEVICE CLASS IIB 93/42/ EC

Series	Models	Vol. L	US/ SU	Chamber Dimension	Dimensions 1P e 2P (LxAxP)**		
P-3000H	P-3270 H Mini	89	1	<b>Ø</b> 432x610	783	1600 (solo E)	790
	P-3270 H	71	1	322x322x720	700	1850 (V-E-EV)	998/1028
P-3600H	P-3670 H	157	2	333x666x720	903	1850 (V-E-EV)	998/1028
	P-3690 H	218	3	333x666x1000	903	1850 (V-E-EV)	1278/1308
P-420H	P-4212 H	255	4* ISO	452x452x1280	903	1850 (V-E-EV)	1558/1588
P-640H	P-6464 H Large	313	4	660x660x720	1424	1850 (V-E-EV)	998/1028
	P-6410 H	434	6	660x660x1000	1175	1850 (V-E-EV-SV-ESV)	1278/1308 1278/1308
	P-6410 H Slim				903	1850 (V) 2450 (E-EV)	
	P-6412 H	556	8	660x660x1280	1175	1850 (V-E-EV-SV-ESV)	1558/1588 1558/1588
	P-6412 H Slim				903	1850 (V) 2450 (E-EV)	
	P-6415 H	695	10	660x660x1600	1175	1850 (V-E-EV-SV-ESV)	- 1878/1908
	P-6415 H Slim				903	1850 (V) 2450 (E-EV)	
	P-6420 H	868	12	660x660x2000	1175	1850 (V) 2450 (E-EV)	2278/2308
	P-6420 H Slim				903	1850(V) 2450 (E-EV)	
P-1000H	P-1113H	961	12	660x1120x1300	2000	2100 (V-E-EV-SV-ESV)	1740-1770
	P-1115H	1182	15	660x1120x1600	2000	2100 (V-E-EV-SV-ESV)	2040-2070
	P-1120H	1478	18	660x1120x2000	2000	2100 (V-E-EV-SV-ESV)	2440-2470

#### Slim (E-EV)



SU/US sterilization unit = 300x600x300h mm

\*ISO-Norm (ISO) sterilization unit = 400x600x200h mm

\*\*The overall dimensions are determined from the choice of heating modes.





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Company with a certified quality management system

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