“FORMALDEHYDE LOW TEMPERATURE STERILIZER”

Hospital & Laboratory Application

cisa

Infection Control System

cisa Infection Control System

“THE CISA GROUP COMPANY”

COMPANY PROFILE

CISA has been manufacturing and selling sterilization systems for over 60 years for both hospitals and industrial applications for all sterilization needs.

CISA is an Industrial Group which manufactures hospital and industrial machinery having integrated technological production systems with factories in different continents and its headquarters in Lucca, Italy.

Distributor coordination and technical service centres are managed through CISA branches, located in Joinville (Brazil) for Brazil and Latin America, in Amman (Jordan) for Middle East area, and Singapore for Asia, as well as distributors and sales offices worldwide to ensure a constant presence and complete service in all countries in which CISA operates.

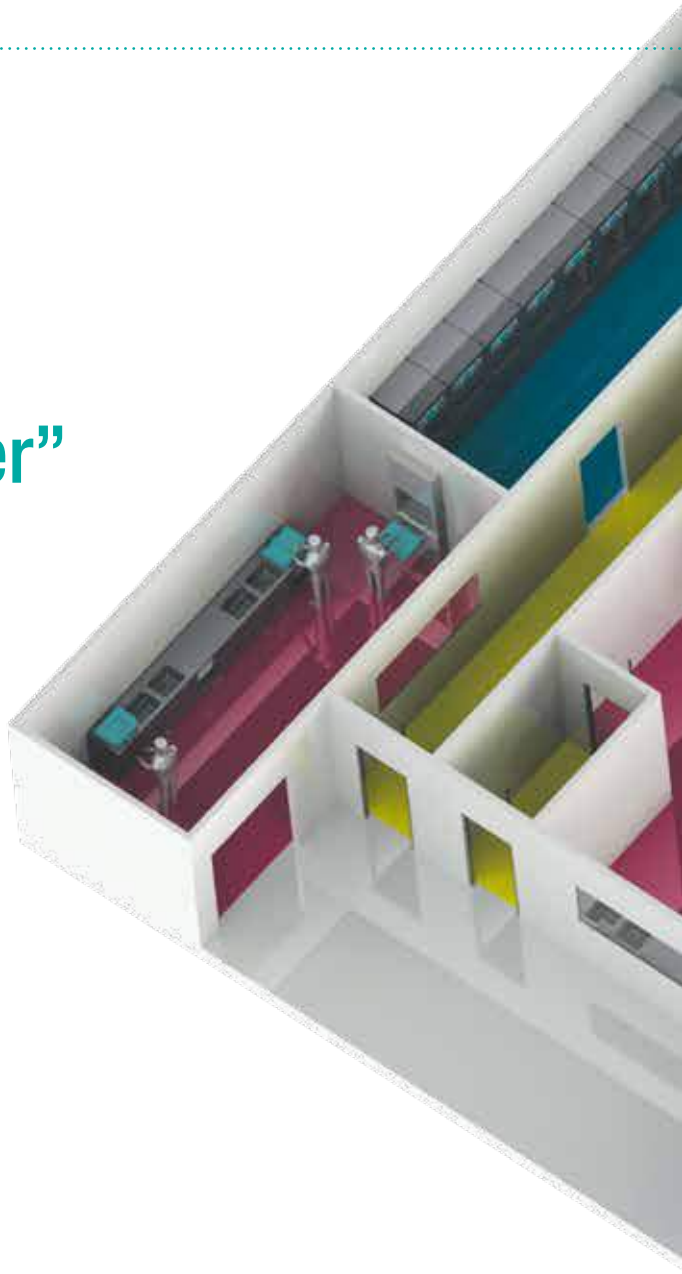
CISA takes part in a very important field, **sterilization**, that is in continuous development. For this reason it has focused its activity on a line of products that includes: infection control solutions, machinery for washing and disinfecting, machinery for high and low temperature sterilization, software systems for management control and medical waste treatments. All the products in the different lines are “made in CISA” from design to manufacture.

Gabriele Pacini
CEO
Cisa - Infection Control System

“WITHIN THE CSSD”
WHERE YOU CAN FIND ME

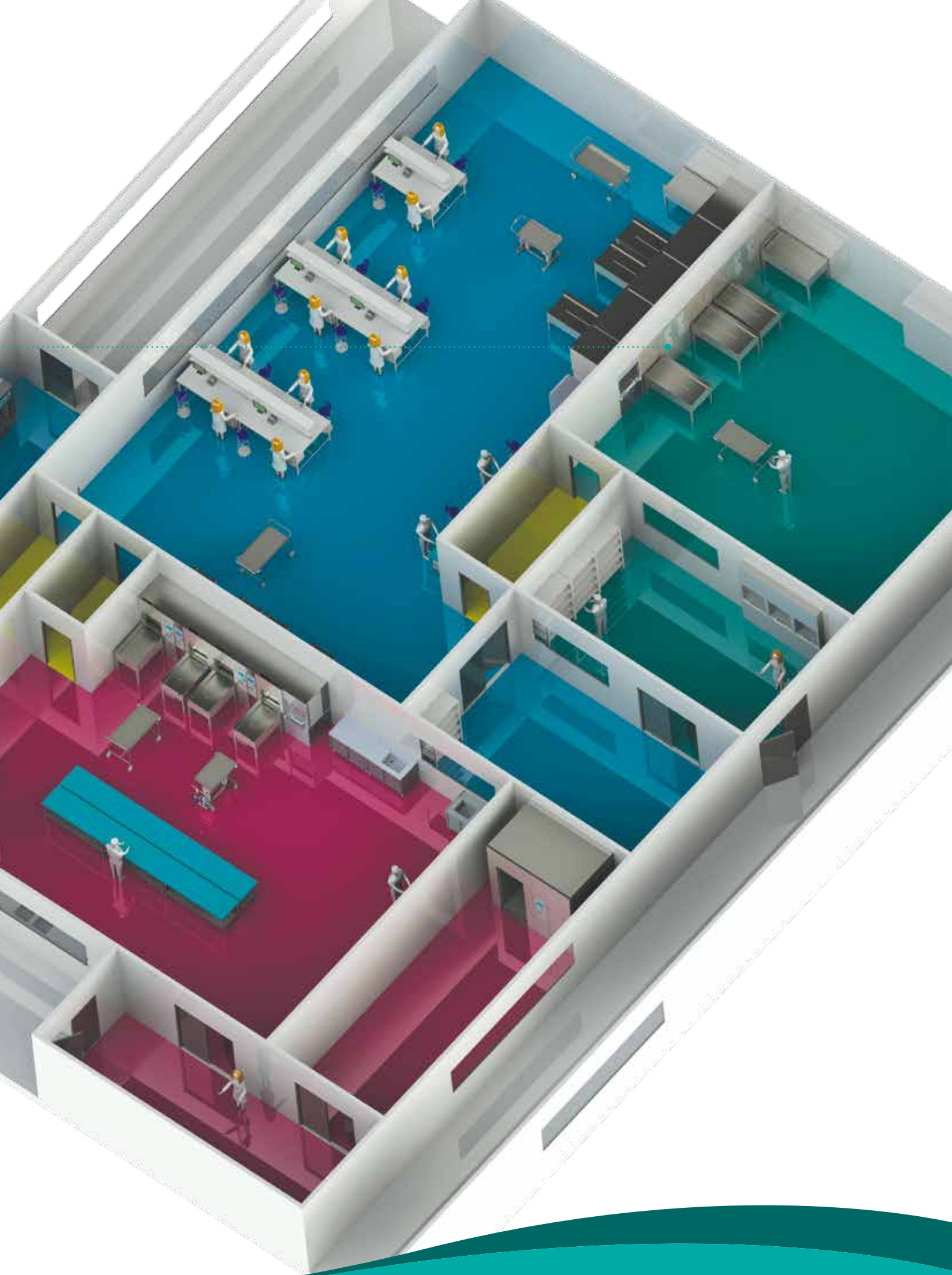
The Sterile Processing Department (Central Supply, or Sterile Supply as it is also known), comprises that service within the hospital in which medical/surgical supplies and equipment, both sterile and non-sterile, are cleaned, prepared, processed, stored, and issued for patient care.
The Formaldehyde - Low Temperature Sterilizer, Hospital and Laboratory Application (as shown on the legend) according the regulations of the CSSD is installed in the clean area with a pass through access of sterile area.

“Formaldehyde Low Temperature Sterilizer”
Hospital & Laboratory Application



Legend:

- DIRTY AREA
- CLEAN AREA
- STERILE AREA



“DESIGN & INSTALLATION”
THE POWER OF CUSTOMIZATION

CISA steam/formaldehyde sterilizers for Hospital application are customizable in terms of functions and design;

CISA is able to satisfy all the customer needs with multiple machine configurations:

- Single - or double - door application; automatic or manual, vertical or horizontal movement door.
- Automatic Loading/Unloading.
- Stainless steel panel closures
- Rectangular or rounded chambers
- Human interface on load/ unload or both sides
- Several types of steam production or utilization. From integrated steam generator, integrated clean steam generator to the use of the centralised steam of the facility where the machine is installed.

“The machine is designed with PLC industrial grade microprocessor control for higher safety and guaranteed reliability; CISA R&D engineers have used advanced design to optimize the machine for the use in hospitals, by working on quality, safety and ergonomy.
The machine is built with highest quality components for perfect hygiene, perfect operation, high durability and maximum safety. They are designed with a simple user system for operators and in full compliance with environmental requirements and low noise emissions. The Installation and the maintenance of the machines are easy and for the most of the models is possible to be done from the frontal side of the machine itself. Compact architecture and high reliability, are the core features of all our models.”

2 IN 1 COMBO STEAM & STEAM-FORMALDEHYDE STERILIZER

This machine allows both High & Low temperature sterilization cycles using steam (for standard surgical instruments) or steam-formaldehyde (for thermo-sensitive material devices) with low operating costs, high levels of safety and the complete flexibility to have 1 machine instead of 2.

LOW-TEMPERATURE FORMALDEHYDE / HIGH-TEMPERATURE STEAM STERILIZER

Sterilizer for Hospital and laboratory application using combined technology that enables low-temperature and high-temperature sterilization, in full safety.

SAFE LOW-TEMPERATURE STERILIZER

The formaldehyde is activated as a sterilizing agent using steam, and the quality of gas diffusion is assisted by steam. Formaldehyde is introduced into the machine by a pouch which needs to be inserted into the compartment for liquid. The lower end is simply connected to a flexible tube and a rupture valve enables the liquid passage of the formaldehyde. The safety of gas leak is guaranteed by a self-monitoring vacuum leak test before the start of the cycle. Thanks to the multi-washing phases at the end of the cycle, using steam and air to guarantee no dangerous formaldehyde residues, the sterile load is safe and does not require aeration of the installation room. Materials are ready for use immediately after the end of the cycle. At the end of the cycle the bag is completely emptied from the machine, and by this may be removed by the operator in full safety and replaced by a new one for the next cycle.

TECHNOLOGY

The technology of CISA is based on accumulated experience through the years, investments and innovative R&D office introducing continuous updates, as well as efficient and powerful team in the field of the solution healthcare field.

“POWERFUL VACUUM SYSTEM”
LIQUID RING VACUUM PUMP

Using a multi-stage water ring vacuum pump, the sterilizer features 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 the water consumption.

“ENERGY SAVING SYSTEM”
HIGHEST PROTECTION

The sterilizers CISA are designed to reach high level of energy saving, where at the same time, without affecting the performance of the cycle, are using optimized power and are energy saving , which guarantees full respect of the environment, using different solutions for thermal, noise, drainage and air outlets protection as well as low electromagnetic emissions.

“COST SAVING MACHINE”
NO MAINTENANCE COST

CISA machines are leading product in terms of cost saving. They are manufactured to have very low running and maintenance costs.

“EXCELLENT INSULATION”
NO HEAT LOSS

The pressure vessel is covered by high thick material, for insulation which prevents heat loss. The perfect insulation increases the quality of the sterilization cycle, reducing potential temperature drops. The quality of the insulation material absolve also the safety requirements for the operators, never exceeding 45 degrees during sterilization phase.

“PRE VACUUM PHASE”
AIR REMOVAL

This phase is characterised by using alternate Vacuum/Steam pulsation, which guarantees a good steam penetration inside the load. The type and the quantity of pulsations depend on load and packing material. This phase is common for both, high temperature sterilization when used Steam as well as for a low temperature when using steam-formaldehyde.

“CONDITIONING”
HEATING UP

In this phase the temperature inside the autoclave increases up to reach that sterilization point. In steam mode - high temperature, in the sterilizer are alternating vacuum and pressure pulsations in order to properly distribute steam inside the chamber. Instead, in the formaldehyde cycle, at this stage the chamber is constantly under vacuum and, by means of pulsations, the liquid formaldehyde, is sucked and injected into the chamber after being vaporized.

“STERILIZATION PHASE (PLATEAU)”
HIGH TEMPERATURE STEAMING

This is the main phase of the process in which, for the High Temperature Cycles, steam is maintained inside the chamber at a constant temperature and pressure, depending of the selected cycle. Instead, in case of formaldehyde sterilization cycles, temperature is maintained at a low level with small vapour pulses.

“WASHING”
FORMALDEHYDE REMOVAL

After the sterilization phase, the residues remained of formaldehyde, in the sterilization chamber, are removed by washing with use of vacuum. At the same time it is also completely emptied the formaldehyde bag so that the operator can pull it out from the machine without any liquid residues inside.

“POST VACUUM PHASE”
DRYING PHASE QUALITY

CISA technology is using 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 sterilization.

“CONSTRUCTION”
HIGHEST QUALITY

For the construction of the machine is used the highest quality of stainless steel. The internal chamber and jacket are manufactured in AISI 316L with the possibility of upgrade in AISI 316 Ti (chrome-nickel-molybdenum-titanium). The frame and front panels of the machines are manufactured using stainless steel 304L. The hydraulic plant and pipes are manufactured using stainless steel 316L.
The pressure vessel and steam generator as well all steam pipes are insulated using insulation material with high efficiency that reduces heat loss and stabilizes the temperature inside the pressure vessel to improve the quality of the sterilization cycles.

“CONTROL PANEL”
CLEAR IMAGE

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

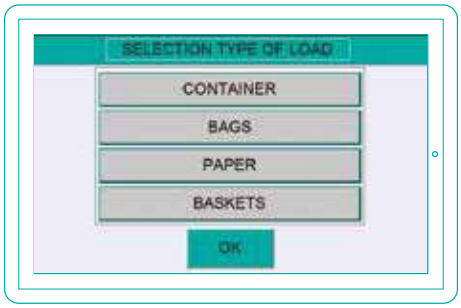
CONTROL SYSTEM & USER INTERFACE

The touch screen gives control to the following functions:

- Selecting cycle and packing type
- Self-check display before starting the cycle and confirmation of the page chosen
- Display of status cycle, 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 50 cycles, graphical or value parameters
- Possibility of downloading the cycles on a external USB drive for storage and PC visualization

Maintenance program for preventative maintenance:

- Operators access level control (password protected)
- Calibration & technical pages (password protected)
- Programming of new cycles or modifying standard cycle (password protected)
- Type of steam heating selection
- Programmable automatic start up and shut off time
- Alarm Messages in clear text
- Door open/closure management
- Troubleshooting pages
- Stand by



OPERATORS ACCESS LEVEL CONTROL

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

ALARMS

Audio and visual alarms are defined for operator warning; the alarms list includes multi-level alarms with clear message notification; alarm levels are configured based on the level of importance to stop the machine or the cycle as well as just 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 last 90 days. Alarms are also indicated on unloading side in case of double doors execution. The end of cycle alert is included for alerting the user for the finished cycle and unloading process.

"TOUCH SCREEN"
MULTI LANGUAGE

Most world languages are pre-installed in the machine. Users can easily choose them from the touch screen, including: English, Italian, French, Spanish, Arabic, Russian, Portuguese, German, Turkish, Polish, Chinese, Greek, Romanian, Korean, Bulgarian and others.

"PROGRAM"
SERVICE & MAINTENANCE

The touch screen is equipped with software pages for periodic preventive maintenance, enabling a safe functioning of the machine, and auto 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.
The maintenance and technical pages are protected with password where only authorized technicians have access.

“REMOTE MAINTENANCE”
CONNECTED TO CISA

The machine, through the Touch Screen, is equipped with an remote access system that allows to be connected to the CISA customer service by a simple Ethernet connection. This represent the fastest way for a CISA technician to do a check up of the problem and reduce the down time.

“START UP TIME & STAND BY”
ADVANCED PROGRAMS

The machine can be programmed for early start up and warming as well as an auto vacuum leak test cycle before early morning staff arrival. There is also the possibility to program an early morning B&D test cycle only if automatic loading is provided. As an advance it is considered the option for stand by and automatic shut off which can be programmed and no operator presence is necessary.

“STERILIZATION CYCLES”

THINK DIFFERENT

All pre-programmed cycles are validated as per EN285 standards. The customer can also run validation using the included validation ports for customer cycles according UNI EN ISO 17665-1.
The autoclave has programmed different cycles, depending on its application.
The cycles are as follows:

1	Sterilization cycle at 134°C for general porous load, empty glass ware and generally all load that is temperature-proof
2	Sterilization cycle at 134°C for general solid load, specifically for surgical instruments, empty glass ware and generally all load that is temperature-proof.
3	Sterilization cycle at 121°C for general porous load, empty glassware and generally all load that is temperature-proof
4	Flash cycle at 134°C

LIQUID FORMALDEHYDE CYCLES

5	Low temperature steam-formaldehyde sterilization cycle at 65°C

COMMON CYCLES

6	Steam penetration test cycle (Bowie & Dick)
7	Vacuum leak test
8	Open cycle (from 01 to 60 programmable cycles; must be validated; password protected)

Additional cycle can be added and or validated upon requested.

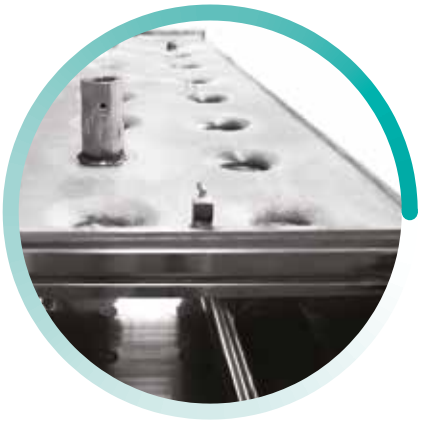
“CHAMBER”
HIGHEST QUALITY

The chamber is made of AISI 316L 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 robot controlled and checked which guarantees to be homogeneous using advanced control methods.
The chamber is designed to withstand pressure, from absolute vacuum up to +3.5 bar relative pressure; factory tested at 5.80 bar, relative pressure.

“JACKET”
TESTED FINELY

A full stainless steel jacket surrounds the chamber made of AISI 316L. The jacket is tested at 6.8 bar relative pressure to withstand pressure.



“STEAM GENERATOR”
DIFFERENT SOLUTIONS

The Steam generator is manufactured in stainless steel AISI 316 L with powerful stainless steel elements, and stainless steel water pump and optional break tanks.

The machine can be configured using one of the following solutions concerning steam generator:

(E): Built-in steam generator electric heating.
(V): External steam supply from hospital steam network (domestic steam).
(EV): Combination between (E) & (V) which enable the user to select type of heating from touch screen as internal (E) or external (V) without hardware interface.
(SV): Steam to steam converter to generate medical quality of steam from service steam using the built-in heat exchanging facility.
(ESV): Combination between (E) & (SV) with same selection method as explained above.

The steam generator is equipped with auto cleaning and flushing for high reliability and better functionality.
Steam generator, converter and steam pipes are insulated using thermal insulation material for controlling heat loss.

“MAINTENANCE”
EASY ACCESS

Most of the Sterilizers are designed to enable frontal side maintenance access. The components inside are installed in a way to guarantee easy access for maintenance and are represented with a good engineering layout for better performance.
Electric components are installed in a sealed electric box protection level IP55 to guarantee higher safety for the operators and longer lasting working efficiency of the components.
For external connection, software upgrade, are installed: RS232 and RJ45.

“BUILT-IN PRINTER & CHART RECORDER”
CLEAR INFORMATION

On the panel there is a built-in printer for cycle documentation which includes: print out of the date and time with hospital name, lot number , operator name, selected cycle, parameters values in different cycle phases that can be programmed as per customer requirements, phase by phase display, total cycle time and cycle results (valid or invalid) as well as printing alarms during cycle execution. A chart recorder is optionally added with independent sensors with validation and comparison between printed and recorded data.

“AUTOMATIC SLIDING DOOR(S)”
SAFE & SMOOTH

Automatic Sliding doors enable safe & smooth door opening/closure using a pneumatic or electrical system depending from the model.
The movement can be: (SV): vertical sliding door(s) (SO): horizontal sliding door(s).

“GASKET AND SEAL”
LITTLE BIG DETAILS

The sealing of the door is guaranteed by dynamic movement of the gasket obtained through introduction of steam in the seat of the gasket.
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 same avoiding damage to the gasket itself and 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 including the following, for the door(s):

- 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.

“STERILE AIR”
BEST QUALITY FILTER

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

“SAFETY FEATURES”
SELF TEST

According to international and European standards, the machine features a high safety program with a self test for auto check.

“QUALITY & SAFETY”
OUR CERTIFICATES

The formaldehyde sterilizer CISA P-HF complies with the directive for Medical Devices Directive 93/42 / EEC, according 2007/47 / EC, and with the requirements of UNI EN 14180: 2009, related to the sterilization of formaldehyde. These machines also comply with the directives 2004/108 / EC (EMC) and 2006/95 / EC (LVD) and the norms IEC 61010-1: 2013, IEC 61010-2040: 2005, IEC 60204-1 : 2010.

“OPTIONALS”
SOMETHING FOR EVERYONE

ADDITIONAL TOUCH-SCREEN

An additional touch-screen can be installed upon request on the unloading side (sterilizer with two doors-2P)
The dual touch-screen can customize the settings for the control of the machine; one of the two sides of commands can act as a main one.

TOUCH SCREEN 10”

CISA sterilizers can be equipped on the load side - or, as an optional, on the unloading side - with a bigger touch-screen 10 Inch 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 condenses) are conveyed in a container of stainless steel with thermostat to control the temperature before the exhaust in the pipeline.
The device measures the discharge temperature and is adding service water. The water will be maintained at less than 60°C and will thus be suitable for every supply line as well as adjustable for better management of the consumption of service water.

AIR GAP SYSTEM

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

AIR DETECTOR

The machine can be equipped with an air detector as an optional feature. This will improve the functionality of the machine using guaranteed steam concentration with less air bubbles.

DEGASSER

The degasser is a technology that allows the removeal of presence of non-condensable gas in the steam released into the sterilization chamber; the water supply of the electrical steam generator is accumulated in a tank and is heated up to 70° C to allow the liberation of the gas dissolved in the water.
This ensures a higher quality of saturation of the steam that comes into contact with the material needed for sterilization.
The introduction of this technology is subject to the installation of an air gap system in the treated water supply.

STEAM GENERATOR UPGRADE

CISA provides the customer with the possibility of choosing electric power of steam generator in order to shorten the cycle times, especially in the preheating phase.
This system makes it possible to save about 15% of the total cycle time at the expense of greater power consumption.
The power of the generator varies depending on the model of the sterilizer.

MIRROR REVERSE MACHINE

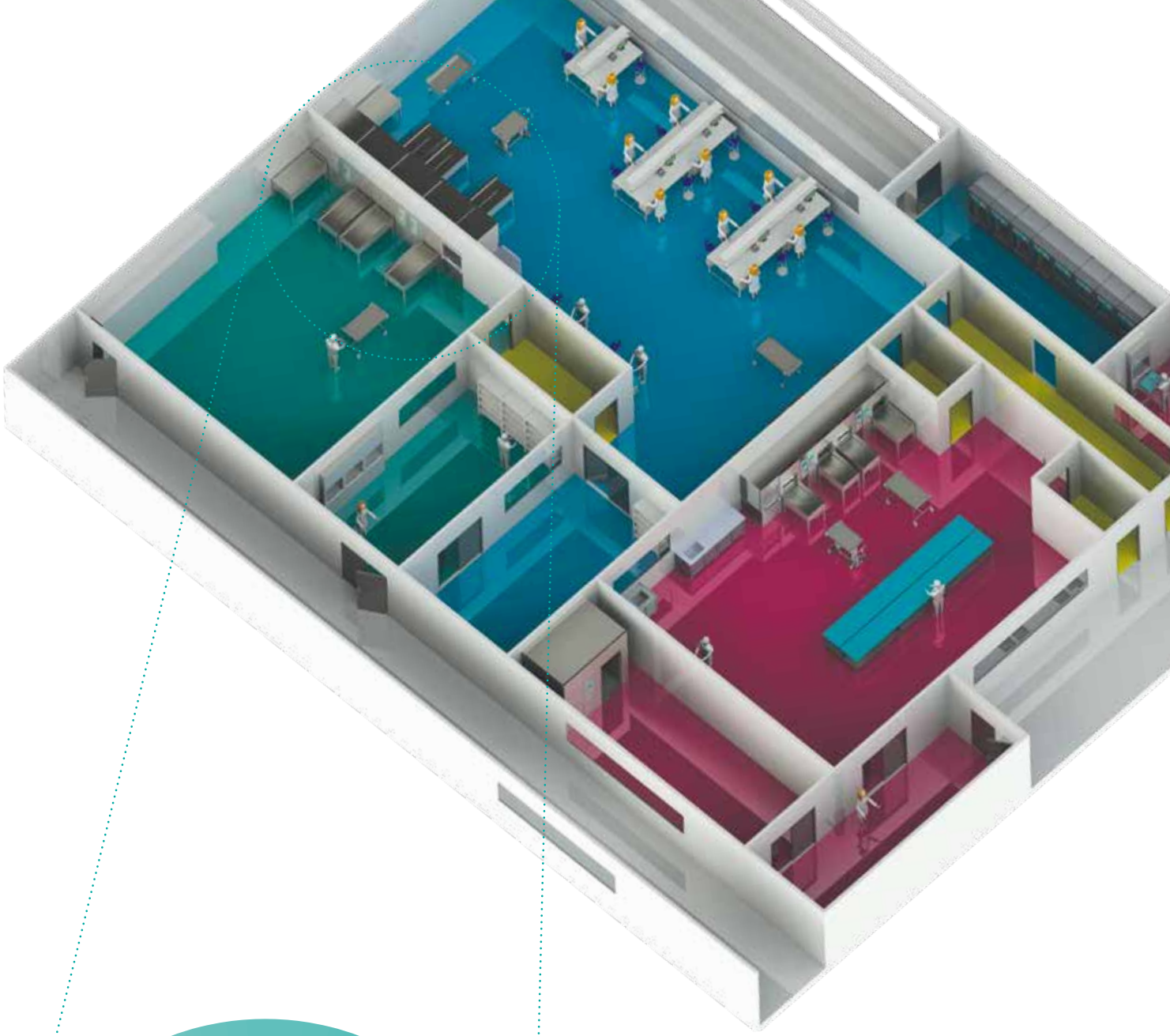
Depending on installation needs and to facilitate the operations of ordinary and extraordinary maintenance, the equipment can be configured in a standard or inverted module.
In the first case the chamber is placed at the left (looking from the loading side) and the technical module to the right, and in the second case the chamber is placed on the right side and the technical module is placed on the left. This optional varies from the request of the client.

UPS BACKUP CONTROL SYSTEM

The UPS backup system is connected to the PLC and the touch-screen and allows you to accomplish the cycle in case of sudden surges or power failure. The cycle remains valid as long as the conditions that guarantee the cycle performances have not been compromised.

LOADING ACCESSORIES

Accessories for loading and unloading are available for each model with the selection of: internal trolley (shelving unit/transfer carriage), external trolley (loading/unloading), automatic loading device automatic unloading device, electric height-adjustable loading/unloading trolley.
Loading devices are manufactured in stainless steel with sizes and loading mechanisms that enable full use of chamber and smooth operation with less personnel activity. Chamber rails can be added as an optional.



SYSTEM FOR AUTOCLAVE AUTOMATIC LOADING / UNLOADING

The system facilitates material loading/unloading operations. In fact this device allows the autoclave to be loaded or unloaded without a presence of an operator.
Each individual system consists of a device placed in front of each machine, detecting sensors and coupling devices external trolley, push-button actuation and safety devices.
The pneumatic mechanism and the electronic control by PLC guarantee a high reliability of the system.
This group is entirely controlled by the PLC installed in the autoclave. A series of electronic devices prevents jams that may occur or any injuries to personnel working in close proximity.

“MODELS”
OUR PRODUCT RANGE

All of the sizes and measurements below can be changed according to the different configurations and applications of the machines.

*U.S. 600x300x300mm
**U.S. 600x400x200
The measures are expressed in mm.

	SERIES	CHAMBER DIM	DIMENSIONS 1P-2P	LT - U.S.*
P-3600	P-3670 HF	336x666x720	903x1850x998-1028	157 - 2
	P-3690 HF	336x666x1000	903x1850x1278-1308	218 - 3
P-420	P-4270 HF	452x452x720	903x1850x998-1028	144 - 2**
	P-4210 HF	452x452x1000	903x1850x1278-1308	199 - 3**
	P-4212 HF	452x452x1280	903x1850x1558-1588	255 - 4**
P-640	P-6464 HF	660x660x720	1424x1850x998-1028	313 - 4
	P-6410 HF	660x660x1000	1424x1850x1278-1308	434 - 6
	P-6412 HF	660x660x1280	1424x1850x1558-1588	556 - 8
	P-6415 HF	660x660x1600	1424x1850x1878-1908	695 - 10
	P-6420 HF	660x660x2000	1424x1850x2278-2308	868 - 12

Infection Control System

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