

Specifications



Steam Sterilizers AMARO 5000 & STERI 21

A.J. COSTA (IRMÃOS), LDA
since 1953





1. GENERAL INFORMATION

1. 1 TECHNICAL INTRODUCTION

A. J. Costa (Irmãos), Lda. steam sterilizers are designed to cover a large field of applications for hospitals and medical centers as well as pharmaceutical and biotechnological industries and research laboratories. They meet the latest features in state-of-the-art sterilization technology.

A. J. Costa (Irmãos), Lda. sterilizers are available as multi-functional steam sterilizer with pre-vacuum and post-vacuum technology for healthcare facilities applications and gravity capabilities as laboratory liquids steam sterilizer.

All sterilizers are available for installation, either recessed through wall or as freestanding models. As buyer's option freestanding sterilizers are cabinet mounted, with stainless steel cover panels.

AJC 50x50(cm) & 70x70(cm) cross-section sterilizers have automatic vertical sliding power doors. Larger units AJC 70x112(cm) cross-section sterilizers are equipped with power automatic horizontal sliding doors.

A. J. Costa (Irmãos), Lda. sterilizers feature a Logic Controller (PLC) control system with a color touch screen display interface and a digital printer. The PLC controls the steam sterilizers with a pulsing, pressure/vacuum, air removal system. Visual indicators monitor all cycle phases with audible and visual cycle completion indicators. It is designed for efficient sterilization of heat and moisture-stable wrapped or unwrapped instruments and materials, textiles, heat sensitive materials, instruments in containers, dry goods, laboratory glassware, flask liquids and laboratory contaminated waste goods.

To meet the most demanding requirements, the sterilizers can be programmed with a huge diversity of cycles that have pulsed phases with vacuum and/or supra-atmospheric pressure, both in the pre-treatment phase and in the post-treatment phase (drying), gravity cycles, liquid cycles, decontamination cycles, vacuum test cycle, Bowie & Dick (air removal) test cycle.



1.2. CONSTRUCTION SPECIFICATIONS

1.2.1. Frame

The sterilizer pressure vessel and components are secured to a welded structural frame. The frame is constructed in stainless steel. It is mounted on threaded leveling screws with supplemental stainless steel weight distribution footpads. The frame is mechanically rectified by a CNC precision-machine, for perfect alignment of all mounted devices.

1.2.2 Sterilizer Pressure Vessel

The steam sterilizer is prepared to operate with saturated steam as sterilizing agent, condensate free, 97% to 100% steam quality and working at a temperature range from 105° C of up to 137° C.

The pressure vessel is a shell parallelepiped shape composed by the sterilization chamber and a full integral surrounding jacket.

According to the requirements of the EN 285 standard the sterilizer pressure vessel has two test connections ports to allow the introduction of sensors for validation purpose.

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1.2.2.1. Chamber

The chamber is made of AISI 316L stainless steel with an internal high finish luster obtained by mechanical polishing. It is constructed with 2 sheet-metal U-shaped. Chamber is of entirely welded construction with interior, longitudinal corners that are radiused. The chamber is fully jacketed. Steam baffles are positioned in the chamber to minimize wetting by condensate and insure proper steam distribution and equal load surface heating. The chamber drain system is on the center of the chamber, designed to dispose condensate to waste and equipped with safety systems to prevent sterilizer effluent from entering the sterilization chamber.

An automatic steam condenser exhaust system reduces temperature of exhaust steam flowing to the drain.



The automatic condensing system, consisting of a stainless-steel heat exchanger, converts chamber steam to condensate and disposes condensate to waste. Cooling water flow is regulated by the waste line temperature control system to minimize water usage.

On double door units the end frame bulkhead of the chamber are constructed of solid AISI 316L stainless steel and entirely welded on the pressure vessel.

On single door units, back of chamber is fitted with welded, 316L stainless-steel head.

The complete pressure vessel is then mechanically rectified and all mechanical dimensions are controlled by a CNC precision-machine.

1.2.2.2. Jacket

The continuous jacket is constructed of AISI 316L stainless steel. It is constructed with 2 sheet-metal U-shaped parts. Directly on those 2 sheet-metal, strength points are mechanical shaped and the jacket is of entirely welded, mounted and welded to the chamber, giving reinforcement according to the cross- section of the chamber. The jacket along with the chamber is designed, to avoid generating high tensions in any point of the structure, do to cyclic pressure and temperature variations. The jacket is designed to achieve uniform distribution of steam, and enables the stabilization of temperature around the chamber, thereby giving excellent performance during the drying process and reducing the time required to bring the chamber up to sterilization temperatures. This provides superior temperature distribution and prevents the formation of condensation on the chamber walls.

As buyer's option in Laboratory field work, pharmaceutical or food industry or other special cycle applications, the jacket can be assisted via cold water and air ballast support pressure for cooling proposes. At the end of the sterilization stage of the cycle a special temperature controlled recirculating system introduced cold water into the jacket using the chamber walls as a heat exchanger, reducing the chamber temperature and resulting in improved load cooling rate. The recirculating system with independent water tank assures that the cold filling water is never in direct contact with the jacket preventing possible pressure back-flow or contamination in case of malfunction. The temperature controlled operation, automatically controls the cooling rate of the load according to its specific needs. This way, as the jacket acts as a very efficient heat exchanger, the chamber/load pressure reduction can be controlled reducing the possibility of fluid loss.



The pressure vessel is constructed in accordance with PED 2014/68/EU and the European Standard EN 13445, for unfired pressure vessels.

1.2.3. Doors

Doors are constructed of AISI 316L stainless steel and reinforced, mechanically rectified by a CNC precision-machine which provides uniform quality of inner surface and precise mechanical dimensions.

Doors are insulated with Rockwool fiber insulation and covered with a finish stainless steel panel.

The steam sterilizer is equipped with one or two vertical or horizontal sliding doors, depending on the model.

Vertical or horizontal sliding door

AJC 70x70 and AJC 70x112 models have automatic operation, and each door is operated by one pneumatic cylinder mounted at the central inner part of the door. The operation of the cylinder is performed by air pressure and acts as a speed and motion control system. An adjustable restrictor controls the flow of compressed air, controlling the speed movement of the door. Door motion is controlled from the touch screen display. Horizontal door models are available with doors that slide from left-to-right, or right-to-left.

Doors are equipped with a sensor safety guard system, which automatically stops and reverses the doors motion if any obstruction is detected, throughout the entire door movement.

The end frames of the chamber are constructed of solid AISI 316L stainless steel and entirely welded on the pressure vessel. The complete pressure vessel is then mechanically rectified and all mechanical dimensions are controlled by a CNC precision-machine. On the chamber end frame, the gasket ring slot is open, calibrated and polished by the CNC, conferring superior work surface for the recessed silicon gasket.

The silicon gasket, seals the door operated by steam and will maintain a secure seal even in the event of a total utility loss. The gasket is retracted under vacuum when the sterilize cycle is complete.

The gaskets are easy to replace and do not require special tools or lubrication. The lifecycle of the door gasket is 1000 cycles.



Double door configurations are supplied with controls and security systems at both ends of the sterilizer to prevent the possibility of cross-contamination. As a single door steam sterilizer, equipment can be mounted as a freestanding unit with covering panel frame (OPTIONAL) or recessed on wall.

The single door steam sterilizer will produce loads from and to the same area. Provisions must be taken to have clear identified circuits for load the goods to sterilize and unload sterile materials for storage and distribution.

Double door steam sterilizer is mounted through a recessed wall. The two doors are located in two separate rooms. The front load door, on the side of the master control panel is facing the preparation area of the sterilization department, from where the steam sterilizer is operated and serves for loading the material into the sterilization chamber. This area is known as the "non-sterile side". The other door is located on the "sterile side" and serves for unloading the sterilized material from the steam sterilizer chamber. The sterile side of the steam sterilizer is equipped with a secondary control panel.

The silicon gasket, seals the doors operated by steam and will maintain a secure seal even in the event of a total utility loss. The gasket is retracted under vacuum when the sterilize cycle is complete.

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When open, doors are totally out of the chamber and sealing gaskets, allowing safe and complete access to them.

The doors are designed to prevent opening while under pressure or in case of electrical power failure, by a safety lock mechanism, with proper device for manual operation in case of power failure.

Doors motion and operation have special interlock systems and are based on the following conditions:

- A cycle cannot be started if the doors are not properly closed and lock control system is safely actuated.
- A door cannot be opened while the automatic cycle operation of the steam sterilizer is in progress.
- A door cannot be opened if the chamber is under pressure.
- Both doors cannot be opened at the same time. Opening of one door automatically locks the other.
- After opening the door on the unsterile side, even after closing it and it being locked and sealed, the door on the clean side can be opened only after performing a complete sterilization cycle.



- If a cycle fails, only the non-sterile side door can be opened and operated.
- After a test cycle, only the non-sterile side door can be opened and operated.
- A door cannot be opened at the end of the cycle if the chamber temperature is higher than the preset final temperature.

Double door configurations are supplied with controls and security systems at both ends of the sterilizer to prevent the possibility of cross-contamination.

1.2.4. Insulation

Superior heat loss reduction to the surrounding environment and heat conservation is achieved with rigid Rockwool fiber insulation, overlaid with AISI 304L stainless steel sheet-metal. The sheet-metal is formed, overlapped, and riveted along the pressure vessel. The stainless-steel sheet, covered with EPDM material, makes the insulation system impervious to water, thus eliminating wet condensation. The exterior surface of the sterilizer will irradiate a maximum temperature of 40°C.

1.2.5. Piping

All piping components delivering steam or sterile air to the load are AISI 316L stainless steel threaded. All piping connections terminate within the confines of the sterilizer and are accessible as standard, from front and right side of sterilizer.

As buyers option the piping components delivering steam can be insulated with EPDM material.

All major piping, pneumatic and electrical components are tagged and numbered to match the diagrams. Threaded stainless steel is available as a customer option.

Steam traps are thermostatic, non-proprietary, and NTS (nearly to steam) industrial grade. They are positioned and sized for maximum efficiency. Steam traps are used for the removal of air and condensate from the system.

Control valves are non-proprietary, industrial grade, brass or stainless steel. They are actuated by electric solenoids for air pressure 24V DC. Pneumatic valves for steam, exhaust and sterile air, have special



connectors to simplify sterilizer piping, and can be serviced individually. Water control valves are 24V DC operated. Safety valves are approved, stamped, and sized for the vessel design pressure.

As buyer's option the steam sterilizer can be equipped with an Automatic Self-Cleaning Drain Strainer which is commonly designed for Animal Care applications. Water is back flushed through the main drain strainer circuit. This feature does not eliminate the need to perform the cleaning of the chamber.

1.2.6. Vacuum System

Rapid evacuation of chamber air and moisture is achieved with a liquid ring vacuum pump. The vacuum pump reduces the chamber pressure during pre-vacuum and post-drying phases. A water conservation system is used to limit the consumption of the potable water during the process and to guarantee maximum efficiency of the vacuum pump.

The liquid ring vacuum pump, works in a self-recirculated circuit, reducing water consumption. Effluent discharge temperature is further reduced by a dual pass, coil bundle, heat exchanger before entering the vacuum pump. In special cases the discharge temperature is further reduced by cool water at the floor drain. Cooling water flow is regulated by the waste line temperature controller to minimize water usage. The system is designed to work with cold water up to 15° C. The vacuum pump can be removed for easy cleaning and maintenance by unscrewing the bottom plate supports.

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Following the drying phase, chamber vacuum is relieved to atmospheric pressure by an air inlet bacteria-retentive filter. With an absolute rated membrane, efficiently remove all particles down to 0.01 micron, thus removing airborne bacteria, viruses and bacteriophage. It is easily accessible for maintenance purposes.

1.2.7. Steam Source

The steam source requires clean house steam and the sterilizers are piped, valved and trapped to receive building supplied steam.

Steam must be supplied with particles removed and be suitably line trapped to ensure that it is dry and supplied at 3.0 to 3.5 bar dynamic.

Standard sterilizer steam piping is constructed of stainless steel and includes a shutoff valve and a steam trap.



As buyer's option the steam sterilizer can be equipped with an electrical heated built-in stainless steel AISI 316L steam generator.

Depending on the option, the built-in steam generator can act as a standby unit if building steam is not available for the sterilization process or can be the main source of saturated steam for the sterilization process.

If the steam sterilizer has a DUAL OPTION for steam source, the steam sterilizer is built to receive two steam supply sources, namely from the building, or from the internal built-in steam generator. There is a selector function on the user interface to choose the steam source. Before selecting the built-in generator as steam source, check if the steam generator is connected to the electrical supply and it is working properly.

Built-in steam generator main features are:

- **Water level control system** – Consists of three capacitive level sensors mounted on an external water level sight pipe, heat and pressure resistant, that allows constant observation of water level while the steam generator is in operation. Water level sensors are not influenced by water resistivity, ensuring work capability with low water conductivity as reverse osmosis water quality. Water level is automatically controlled maintaining the proper working level and shuts of the heating elements when water supply drops below a safe operating level.
- **Heating elements** – Long life heavy duty stainless steel AISI 316 heating elements, welded on an AISI 316 stainless steel flange for added strength and safety.
- **Water pressurizing pump** – The water pump supplies distilled mineral-free water to the steam generator. The water pump ensures that water inlet pressure to the steam generator is not dependent of the facility's water inlet pressure.
- **Operating pressure control** – Operates automatically to maintain steam pressure at working defined range.
- **Steam pressure safety valve** – Certified pressure relief valve that automatically opens to reduce pressure whenever excessive steam causes pressure build-up.
- **Blowdown/drain valve** – Facilitates emptying the steam generator during blowdown/drain sequence. Automatic blowdown system as OPTION.
- **Steam pressure gauge** – Positioned at service area allows visual observation of steam pressure over full range.



1.2.8. Control System

The gauges, touchscreen and printer are mounted in the stainless-steel panel.

The electronic control system and software monitors and controls all sterilizer operations and functions and are designed to operate up to 25 different factory-programmed standard sterilization and test programs.

The control system of the sterilizer is based on PLC technology, ensuring a highly reliable and safe operation. The computerized control unit ensures a fully automatic operation through the entire process; hence, after setting the pre-selected parameters and starting the operation, no further operator intervention is required.

Factory pre-set programs are intended for instruments in containers, single or double wrapped instruments and packs, wrapped fabrics, heat and moisture sensitive materials, prions cycle, slow exhaust pressure cycles for sterilizing liquids in borosilicate containers with vented closures and warm-up cycle. In addition, there are two test programs: Bowie & Dick Test and the Vacuum Leak Test. Special propose sterilizers for biosafety P3 type laboratories have cycles for contaminated waste material in bags or special containers.

Special propose sterilizers for biosafety P3 type laboratories may be provided with dual control capabilities, allowing for each cycle to program the opening sequence of the doors according to the needs defined by the user. Allows you to program loading and unloading through the same door or opening the doors to load on one side and unload on the opposite side. The biosafety P3 type cycles include a filter integrity test.

In order to prevent unwanted operation of the sterilizer, this programming is protected by the use of a security password of the appropriate level.

The sterilizers AJC are equipped with laboratory work cycles, standardly programmed. In order to perform the laboratory work cycles, the sterilizer should also be supplied with an additional accessory, a product probe to accurately measure the temperature inside the liquid to be sterilized.

The laboratory work cycles include cycles for liquids in open containers. The operator is able to choose if the process of initial evacuation is assisted by vacuum or not, as well as whether it is a fast or slow exhaustion process. The laboratory work cycles also enable the selection of temperature, the contact time for sterilization and the possibility of controlling the process by F0 function.



In addition to laboratory work cycles, the sterilizers AJC are also programmed with test work cycles, Bowie & Dick and vacuum cycles, along with sterilization cycles for glassware and wrapped or unwrapped instruments for immediate use, with drying phase assisted by vacuum.

As optional, the sterilizer can be equipped with sterilization work cycles specially designed for animal cages. These cycles enable the operator to program different process parameters, including temperature, contact time of sterilization and drying time. The process of air exhaustion is automatically controlled and implemented through an HEPA filter sterilized by steam, allowing the operator to control efficiently the process of sterilization of contaminated materials.

As optional, the sterilizer can also be equipped with two sterilization work cycles for pet food diet. These cycles allow the operator to program different process parameters, including the temperature, contact time for sterilization, selection of initial air removal stage and final stage of drying by vacuum assisted. It is also possible to set the drying time, vacuum control and the possibility of drying control assisted by residual humidity.

The sterilizer AJC has 9 standard factory set cycles that are intended to answer all foreseeable needs in CSSD steam sterilization processes. The 3 first cycles are test cycles and the others 6 cycles are working cycles. The working cycles are completely customizable according to customer needs, since it is possible to program 25 different sterilization cycles.

- Cycle 1 HEAT ING UP 121°C
- Cycle 2 BOWIE & DICK TEST
- Cycle 3 VACUUM TEST
- Cycle 4 INSTRUMENTS 134°C
- Cycle 5 TEXTILES 134°C
- Cycle 6 CONTAINERS 134°C
- Cycle 7 PRIONS 134°C
- Cycle 8 SENSITIVE MAT 121°C
- Cycle 9 RAPID CYCLE 134°C

A list of real-time process critical values, the selected program, the main phases of the cycle, temperature, pressure and the status of the machine are controlled and displayed on a 7" LCD color touchscreen digital display with graphical display (Plot Graph). For process documentation, all the relevant information concerning operation is printed. As buyer's option the LCD color touch screen can have 10.4".



The touchscreen allows the user to operate and program the steam sterilizer control by touching (pressing) the appropriate touch-sensitive areas on the display. On each screen, all rectangular- outlined boxes are touch-sensitive areas, referred to as buttons.

The color touchscreen display and keyboards located on both the non-sterile and sterile panels enables, including but not limited to, the operator to select a sterilization program, start/stop a cycle, and close or open a door.

A programming mode, which can be accessed by a code from the unsterile panel display only, enables technicians to set up the system, set and change a number of additional parameters and operational modes and perform calibration. Language can be set in one of the five available options: Portuguese, Spanish, English, French or Romanian.

As default, the user has access to cycle selection, cycle start and door control. Users can only run factory-set cycles and test cycles. Access to other functions, such as, setting parameters, calibration, service and maintenance procedures is controlled using pre-defined access levels and passwords preventing unauthorized access.

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Each cycle is adjustable to meet specific processing requirements. All user-accessible control functions can be changed using the touch screen control. Cycle parameters are retained in control memory for repeated use. Once cycle is started, cycles and cycle values cannot be changed until cycle is complete. The system features a comprehensive alarm/alert system, with automatic triggering of pre- programmable information alerts. The self-diagnostic program monitors the sterilizer performance automatically and process check-up and failure corrections.

In case of a malfunction during the sterilization cycle, the process enters in an emergency alarm phase, which safely will end the process automatically.

Audio/visual alarms range includes:

- Temperature, pressure sensor and analogue input failure
- Power failure
- Door failure
- Gasket and chamber sealing failure
- Phase Timeout



- Doors safety interlock failure
- Water supply failure
- Steam failure
- Compressed air failure
- Vacuum Pump failure
- PLC failure

The bar Graph screen displays the chamber temperature and pressure as a bar graph and also shows a digital time representing the time remaining in the cycle. The Plot Graph screen displays the chamber temperature and pressure as a trend curve using a graphic display.

A process data record printer and a graphic recorder (as OPTIONAL) are mounted at the "non -sterile side", to record all relevant process information like: program cycle steps, time, temperature, pressure, date, cycle start time, both sterilizer and daily cycle number, total cycle count, fault conditions, user verification and signature and load information.

As buyer option the steam sterilizer can be equipped with AJC Vision MAP software, a built-in PC and a Printer in A4 format. The AJC VISION MAP software allow the collection in digital format all cycle data (information and graphics) and can be connected to a PC, SERVER and external printer to print cycle reports and history in A4 format.

Data is automatically printed at the beginning and at the end of each cycle with all transition point's information and summary verification of time at selected temperature/pressure (min/max values) performed during cycle operation.

The PLC stores the cycle data and in case of printer failure during the cycle or on demand, the user can reprint the last cycle.

As buyer's option the steam sterilizer can be equipped with one or more load temperature probes inside the sterilization chamber and perform sterilization based F0 control. The control system allows control of liquid sterilization by F0 value rather than time and temperature. This mode of control may optionally be used for heat sensitive liquids.



Before operating the sterilizer, it is important to become familiar with the location and function of all major components and controls.

As OPTIONAL the record system can be mounted on the “sterile side”.

The steam sterilizer has an automatic shutdown system. If no operation is performed after an adjustable time, it will go into an energy conservation mode. Sterilizer utilities can be restarted as soon the user starts or selects a new cycle.

1.2.9. Steam Sterilizer Independent Monitoring System

As buyers option an independent monitoring system (IMS) is available.

The IMS is an individual electronic independent system, built in the sterilizer, equipped with a secondary controller, totally independent from the sterilizer main automatic process controller, equipped with backup redundant sensors to monitor and record temperatures, pressures, time and process stages, in order to provide independent confirmation that process sterilization specifications were achieved, according to the limits and tolerances defined in EN285.

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The IMS is equipped with a network communication port that ensure constant accurate transfer of machine process data to a PC provided with an appropriate software that collects and digital records the information of each individual machine, enabling documentary proof of the sterilization processes.

The IMS software is an electronic paperless data process recording and documentation system that holds all of the data locally and has the ability to transfer information across an existing network to an appropriate server. The data can then be accessed in real time or historically and printed graphically or in simple list format. Sterilizer data can be displayed graphically in real time.

The IMS independent controller and sensors system compares the parameters monitored by the main automated sterilization process controller with the parameters monitored and recorded by its own. The system indicates and records if there is a fault report within the equipment main control, and performs a cross checking of the timing, stages, cycle relevant temperatures and pressures, and automatically have the ability to give a pass or fail reading for every cycle that is carried out, triggering alarms if the limits are not achieved. User is password protected and as the ability for final acceptance and parametric release of the cycle load, and that is permanently recorded on the IMS software.



1.2.10. Temperature and Pressure Sensors and Gauges

The system is equipped with up to four temperature sensors, two absolute pressure transducers, four pressure gauges, and safety devices having the following functions:

The temperature sensors:

- In the drain - control of heat exchanger, drain and liquid ring vacuum pump water temperature.
- In the chamber condensate line (double independent PT100 probe) - control, monitoring, and printout of sterilization process temperature.
- Inside the chamber (flexible PT100 probe, as OPTIONAL for liquids) - control monitoring and printout of load sterilization process temperature.

The absolute pressure transducers:

- Chamber pressure - control, display, monitoring and printout.
- Jacket pressure - control, display, monitoring and printout

The pressure gauges

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Front Panel:

- Steam source pressure (built-in steam generator or building steam supply).
- Chamber pressure.
- Jacket pressure.

Service Area:

- Steam source pressure (built-in steam generator and/or building's steam supply).

The safety devices

Pressure Safety Valves:

- Built-in steam generator certified pre-set pressure calibrated for 3,6 bar gauge.
- Chamber certified pre-set pressure calibrated for 2,6 bar gauge.
- Jacket certified pre-set pressure calibrated for 2,6 bar gauge.

Door end switch:

- Open and close position, prevents the inlet of steam pressure to the chamber and to the door gasket if the door is not closed.

**Door safety lock:**

- Safety lock mechanism, with proper device for manual operation, preventing door opening in case of power failure or compressed air failure.

Door safety sensors:

- Two sensors for safety guard system on each door, which automatically stop and reverse the movement of the door if any obstruction is detected along its entire path, preventing the door from trapping any object when closing.

Emergency Stop push-buttons:

- Mounted on both the unsterile and sterile panel. This feature is designed to prevent human hazards, accidents or equipment breakdown in compliance with the European Standards EN-285 requirements.

1.3 CHARGING SYSTEM

The charging system is composed by stainless steel platforms specifically conceived to load and unload the sterilization chamber. The charging system provides support and enables the placement of the load (wrapped instruments, unwrapped instruments, containers...etc) inside the sterilization chamber.

For Amaro 5000 and Steri 21 models, there are five charging system options available:

Option 1) One level loading car/ Transfer carriage – The internal loading car with one level is placed inside the sterilization chamber and provides support to the stainless steel baskets containing the load to be sterilized; The transfer carriage is an external trolley that helps removing the internal loading car from inside the sterilization chamber and transfer the load to a transport trolley;

Option 2) Two level loading car/ Transfer carriage – The internal loading car with two levels is placed inside the sterilization chamber and provides support to the stainless steel baskets containing the load to be sterilized; The transfer carriage is an external trolley that helps removing the internal loading car from inside the sterilization chamber and transfer the load to a transport trolley;



Option 3) Removable intermediate shelf/Bottom shelf – Internal removable shelves that are available in two configurations, single shelf or a double shelves, are placed inside the sterilization chamber and provide support to the stainless steel baskets containing the load to be sterilized. They are manually removable.

Option 4) Sliding loading platform

Option 5) Multilevel loading car / Automatic Loading and Unloading - The internal multilevel loading car is placed inside the sterilization chamber and provides support to the stainless steel baskets containing the load to be sterilized; The automatic loading/unloading is an external fixed trolley that automatically loads/unloads the multilevel loading car to/from inside the sterilization chamber.

For Amaro 5000 models: each loading basket has 30x30x60 cm (1 STU/STE).

- Amaro 5000 707070-1D/2D has a chamber capacity of 4 STU – 4 baskets
- Amaro 5000 7070100-1D/2D has a chamber capacity of 6 STU – 6 baskets
- Amaro 5000 7070130-1D/2D has a chamber capacity of 8 STU – 8 baskets
- Amaro 5000 7070160-1D/2D has a chamber capacity of 10 STU – 10 baskets
- Amaro 5000 7070190-1D/2D has a chamber capacity of 12 STU – 12 baskets

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For Steri 21 models: the maximum of baskets that fit the sterilization chamber are (please note that these are not STU baskets)

- Steri 21 404066-1D/2D can have a maximum of 2 baskets;
- Steri 21 505066-1D/2D can have a maximum of 3 baskets;
- Steri 21 5050100-1D/2D can have a maximum of 4 baskets;

1.4 WATER TREATMENT SYSTEM

As buyer's option the sterilizer can have Prefiltration, RO system or Water Softener System. The steam generator should always receive treated water, in order to ensure a good quality of the produced steam. The RO System is recommended, since it is in compliance with the CE directive EN 285, because not only the water is fully deionized, softened as well this system is able to destroy bacteria and other microorganisms present in the water.

AJC Built-in Reverse Osmoses system includes a built-in water tank manufactured in stainless steel AISI 316L which deposit the reverse osmoses water produced along the process.



The built-in water tank includes an independent stainless-steel coil in order to circulate and cool the condensates coming from the jacket (reducing inlet water required for the cooling phase).

This process will also allow the preheating of the osmoses water (reducing electrical power required for producing the steam) and eliminate the non-condensable gases (increasing the steam quality for the sterilization process).

At the end the cycle time is reduced significantly.

The higher capacity models also include a built-in water boost pump.

1.5 ELECTRICAL FEATURES

Standard Electrical Connection is 400V Tryphase 50 Hz. As buyer's option, we can offer special connection for 220 V - III - 60 Hz.



APPLICABLE STANDARDS AND DIRECTIVES

- EN 285:2016+A1:2021 Sterilization - Steam sterilizers - Large sterilizers
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
- EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices
- EN ISO 20417:2021 Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 60601-1-6:2010+A2:2021 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 61010-1:2010+A1:2019 Safety Requirements for electrical equipment for measurement, control and laboratory use: General requirements
- EN 61010-2-040:2015 Requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for sterilizers and washer disinfectors used to treat medical materials
- EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
- EN ISO 9001:2015 Quality Management Systems;
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018;



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