Life Science Sterilizers

SERIES S100 I (SMALL SIZE)

OFFER NUM: ..... REFERENCE .....

DATE ..... SALES RESPONSIBLE .....

01 PRODUCT SPECIFICATIONS

PRODUCT

The line of steam sterilizers S100I series Matachana brand, have been designed to cover a wide range of applications for laboratories in research centers and institutes, universities, where they can develop research projects and / or teaching tasks, also for industries such as pharmaceutical, medical, food and biotechnology.

The entire line of sterilizers operates completely automatically and may be equipped with 1 or 2 manual vertical sliding doors, controlled by a PLC (Programmable Logic Controller), with operator-selectable parameters and cycles.

The sterilizer's front panels are made of AISI 304 stainless steel (EN 1.4301). The installation of the unit on the floor and its levelling are done using adjustable legs.

Several loading systems can be used to load this model of sterilizer, as well as shelves (fixed and/or removable). It is also possible to use internal chassis complemented with external trolleys of fixed height for the transfer and transport of the same to the interior of the chamber or vice versa.

APPLICATIONS

Steam sterilizers for laboratories and industry have very specific specifications and requirements. The choice of the right steam sterilizer depends on different factors: the diversity of the load, the frequency of use, the services available and the volumes of the different loads. The line of S100 I series sterilizers has been designed to provide maximum service to the highest quality in this type of centers and environments. Its processes cover a wide spectrum of applications with programs for processing porous loads, liquids, culture media, plastics, pipette tips, biological waste, contaminated materials and other laboratory articles. The temperature range is from 115 °C (239 °F) to 135 °C (275 °F) (processes for solid materials) and from 105 °C (221 °F) to 135 °C (275 °F) (processes for liquids).

CONFIGURING THE UNIT

Use the steps described in the following pages to customize the design of your sterilizer, selecting the configuration boxes and options required for your project. Once you have filled out the configuration, send the document to the sales department of MATACHANA, its distributor, or its representative to receive a quote.

02 MAIN FEATURES

STANDARD CHAMBER SIZES

Following to the next table of standard camera sizes, select the desired option:

MODEL	CHAMBER SIZE (Width x High x Deep)	CHAMBER VOLUME (Nominal Internal)
☐ S101V-1I	13 x 13 x 25 in 340 x 340 x 645 mm	4 ft3 108 l
☐ S101E-1I	13 x 13 x 25 in 340 x 340 x 645 mm	4 ft3 108 l
☐ S101V-2I	13 x 13 x 27 in 340 x 340 x 675 mm	3 ft3 98 l
☐ S101E-2I	13 x 13 x 27 in 340 x 340 x 675 mm	3 ft3 98 l

Remarks: The calculation of other specific (special) chamber sizes requires a specific analysis and study of the sterilizer in order for our technical/sales department to prepare the quote/project, which may result in longer delivery times if the order is formalized with the customer.

03 PROGRAM SETS

The S100 I Series has several preset programs that cover a wide range of sterilization processes. This section describes the standard and specific program sets, as well as the options that can be incorporated into them. Optionally and upon request, up to 99 additional programs can be added, which can be adjusted to suit the specific needs of the customer or site. The sterilizers have two types of programs:

- Pre-heating and test programs to verify proper sterilizer function.
- Production programs for the sterilization of solid and liquid materials.

04 TEST PROGRAMS

The test programs allow the operator to verify certain aspects of the correct operation of the sterilizer or the sterilization process. Used as both routine (daily) tests as well as when necessary, for example after carrying out maintenance tasks or if malfunctions are suspected.

- Bowie & Dick test (B&D Test).
- Vacuum Test.
- Pre-heating program.

05 SELECTING PROGRAM SETS

Following, you can find several standard and specific program sets, as well as its possible options:

☐ **SET A1:** Production programs for industry and laboratories (to process solid materials with pre-vacuum and drying).

☐ **SET A2:** Production programs for industry and laboratories (to process solid materials and liquid materials in open containers).

☐ **SET A5:** Programs of solid materials, with specific profiles for the sterilization of substrates (earth). This type of programs will eliminate weeds, viruses, pathogenic organisms and other living beings that could be very harmful in the cultivation and development of plants.

☐ **SET A7:** Programs for the treatment of special biosanitary residues in sterilizers of saturated steam its main objective is to covert waste into non-infectious waste, that is to say, to eliminate its potential capacity to transmit or cause diseases.

☐ **SET A8:** Programs for biological containment laboratories (BSL3) with potentially contaminated solid and liquid materials (with air and condensate treatment in chamber). For example, utensils, glass, textiles, plastics, petri dishes and open liquids.

☐ **SET A9:** Programs for biological containment laboratories (BSL1/BSL2) with potentially contaminated solid and liquid materials (with condensate treatment in chamber). For example, utensils, glass, textiles, plastics, petri dishes and open liquids.

Important note: For more details on the processes, consult sections defining standard and optional SETS and programs.

CONFIGURATION FOR OPEN LIQUID PROCESSES

The open liquid processes include a forced natural cooling system as a standard feature. With this cooling system, an approximate loss of liquid of 5 % may be expected due to the cooling generated by evaporation; other options can be incorporated if smaller losses of liquids are desired.

☐ **Program for the sterilization of liquids in containers NOT hermetically sealed, with parameters adjustable by the user. This option includes triple product probe.** This program is included in the SETS of A2, A8 and A9 programs.

☐ **Sterile air backpressure for open liquid processes with forced cooling.**

☐ **Sterile air backpressure for open liquid processes with natural cooling.**

☐ **Switch with key lock for selection of solid and liquid programs.** Located on the front panel beside the main display

☐ **An additional product triple Pt-100 for solid or liquid processes** with multi-probe adapter to put in the chamber.
Remarks: This option only allows up to a maximum of 4 product probes and a probe-holder for the requested number of probes will be installed inside the chamber.
Quantity: _____

☐ **Probe-fastenerto protect the probes during the loading and unloading** of the sterilizer. It will be located on the outer front part of the sterilizer. In double-door sterilizers, one will be installed on each side.

General Remarks: In the liquids processes, the product temperature probe and a minimum cooling time preset and controlled in the sterilizer software, guarantee the safe opening of the doors, which cannot be opened until the liquids have cooled to a temperature of below 80 °C (configurable).

COUNTERPRESSURE SETTINGS. CENTERS WITHOUT STERILE AIR

☐ **0.22 µm sterile filter for air back pressure in the chamber** with a filter encapsulated in a plastic housing with tri-clamp connections.

☐ **Sterile filter of 0.22 µm for the air counterpressure in chamber** in 316L stainless steel

☐ **Double function of the sterile filter,** for use for equalizing air inlet and for back pressure in chamber for liquid processes with back pressure cooling system.

Sterile membrane filter with sanitary housing

CONFIGURATION OF OPTIONAL PROGRAMS

☐ **Gravity Program.** This is a program especially indicated for the sterilization of materials for which an initial pre-vacuum is not recommended. This program is included as a standard feature for the USA.

☐ **Low-temperature program between 98 °C and 104 °C. (208 - 219 °F).** Suitable for disinfecting solid materials with water steam, provided that they can withstand the maximum temperature of 104 °C (219 °F).

☐ **Auto-Start Programmed self-start program.** For sterilizers S100 I with B&R control. Operator can confige time and program foar a automatic start up for each day of the week.

General remarks: The low-temperature programs are NOT sterilization processes and when they are selected, the screen will display a warning message that must be confirmed, before the process is activated. The proper use of this process must be established.

FILTER FOR EQUALIZATION OF THE CHAMBER PRESSURE

The equalization air inlatetake filter is used to break the vacuum at the end of a cycle, before the doors are opened. The bacteriological filter (sterileabsolute) that is installed on this model of sterilizer by default is a 0.22 µm hydrophobic filter.

In the standard arrangement, this sterileabsolute air filter is mounted on the outside of the chamber so it can be replaced easily. In addition, the user can check the replacement frequency in the user manual.

CONFIGURATIONS FOR THE EQUALIZATION FILTER

☐ **Substitution of the conventional 0.22 µm** sterile filter for equalization of the air in the chamber with a filter encapsulated in a plastic housing.

☐ **Substitution of the conventional 0.22 µm** sterile filter for equalization of the air in the chamber with a sterile filter with a PTFE hydrophobic membrane encapsulated in a sanitary housing made of high-grade stainless steel, EN 1.4404 / AISI 316L.

TREATMENT FOR PROCESSES WITH CONTAMINATED HAZARDOUS AGENTS

The most important principles taken into account in the design of the sterilizers with the system for the treatment of materials potentially contaminated with hazardous agents in Sterile and containment areas are the following:

- One of the principles established in steam sterilization requires the elimination of air in the preliminary phase before steam is injected. The air that comes into contact with the materials in this phase is therefore potentially contaminated and cannot be removed from the chamber without being treated.

- The other principle is physical and is due to the fact that steam condenses when it comes into contact with colder surfaces, which means that the condensate that is produced when the steam heats up the contaminated materials, before sterilization conditions are achieved, is potentially contaminated, and cannot be removed from the chamber to the building's drainage system without prior heat treatment.

AIR AND EFFLUENT TREATMENT IN PROCESSES CONTAMINATED WITH HAZARDOUS AGENTS

There are several options available for treating the air and condensate extracted from the chamber and they can be applied based on the needs and design of the installation.

When the sterilizer requires the execution of this type of program, there are different solutions for treating the contaminated air and condensate.

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These processes prevent the risk of contamination to the outside, eliminating the air in the pre-vacuum phase through an sterile filter (PTFE) with a hydrophobic membrane, encapsulated in a sanitary housing made of high-grade stainless steel EN 1.4404 / AISI 316L and the chamber fluids that come into contact with the steam and condensate load generated during the process are heat treated with steam directly in the chamber during the sterilization cycle, before being discharged to the drainage network.

OPTIONS AND CONFIGURATIONS FOR AIR AND EFFLUENT TREATMENT

- ☐ **SIMPLE treatment L3.** Simplified programs to process contaminated materials (L3 filter located at the top). With this treatment system only sterilization processes for materials with risk agents can be carried out.
- ☐ **MIXED treatment system** (L3 filter located in the upper of the chamber), which allows conventional sterilization processes and sterilization processes for materials contaminated with risk agents.
  Remarks: This option is not recommended for contaminated areas due to the contamination risk when accidentally selecting the program without condensates/air treatment. with hazardous agents. (Filter L3 in the upper part of the chamber)
- ☐ **Sterilisation program (SIP) of the sterile filter** for the elimination of biocontaminated air in the chamber.
- ☐ **System for treatment of contaminated condensates inside the chamber.** For use in BSL1 and BSL2 laboratories, for environmental reasons.
- ☐ **A differential pressure switch will be installed on the housing of the sterile filter,** to filter contaminated air, to verify and monitor its degree of fouling; a fouled filter alarm message will be displayed on the control screen so that it can be replaced.

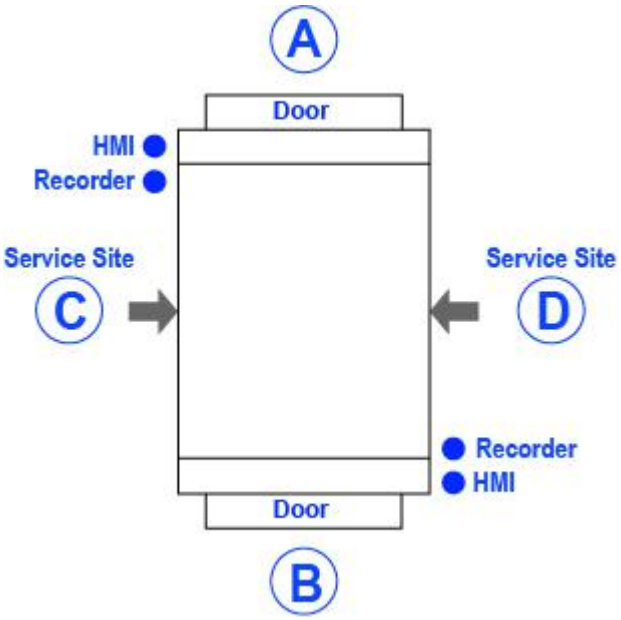
06 DEFINITION OF TERMINOLOGY FOR AREAS

"Loading zone or non-sterile" / "Unloading zone or sterile".

In this specification, the expression **"Unloading zone or sterile"** and **"Loading zone or non-sterile"** are used to define the areas and the direction of the workflow in the sterilizer.

The **Unloading zone** or sterile is any area or installation whose levels of air purity, differential pressure, temperature, and other climate variables must be kept within a series of specific limits. Therefore, the **"Loading zone or non-sterile"** is the area that is on the opposite side, where the main control display is located.

07 DIAGRAM OF EQUIPMENT CONFIGURATION



Following schema, select desired option:

	A	B	C	D
Loading area (Door)	☐	☐		
Service Site			☐	☐
HMI main control screen	☐	☐		
Printer	☐	☐		
Recorder	☐	☐	☐	☐

INSTALLATION CONFIGURATION

- ☐ Left maintenance for S100 series "V" models sterilizers (without steam generator)
- ☐ Left maintenance for S100 series "E" models sterilizers (with steam generator)
- ☐ Recessed with the wall on the NON-sterile side (Loading). Option suitable for 1 and 2 door sterilizers.
- ☐ Recessed with the wall on the sterile side (Unloading). Option for models with 1 and 2 doors.
- ☐ Recessed both side with the walls (double door).
- ☐ Adjustment of the sterilizer to the installation for the building's seismic restrictions. (Anchors)
  Indicate country and standards in force _____

General remarks: The sterilizers of this series incorporate as standard the set of side panels.

FRONT PANEL CONFIGURATION

- ☐ ZNE stainless steel front panels Auts. S100.
- ☐ ZE stainless steel front panels. Auts. S100.
- ☐ Left opening of maintenance doors ZNE S100.
- ☐ Right opening of maintenance doors ZN S100.

CONFIGURATION STAINLESS STEEL FINISH PANELS

- ☐ Standard upper and lower lintel, loading/non-sterile zone side, for finishing the unit with masonry.
- ☐ Standard set of jambs and lintels, unloading/classified side, for finishing the unit with masonry.
- ☐ Set of jambs and lintels to be remedied in the installation

Remarks: The pricing of the stainless steel finish panels of the sterilizer/s with the works will depend on the final configuration and measurements of the installation.

Door additional maintenance, to be installed between the equipments by the Load/No Sterile Zone according to the width of the door. Select option below:

Right opening	☐ 650 mm	☐ 700 mm	☐ 800 mm	☐ 820 mm
Left opening	☐ 650 mm	☐ 700 mm	☐ 800 mm	☐ 820 mm

CONFIGURATION ADDITIONAL OPTIONS

- ☐ Drainage pump for evacuating water at heights up to 900 mm. This option is necessary when there is no floor drain and the sterilizer water must be evacuated at a height of no more than 900 mm. Included are pump, tank and level sensors.
- ☐ Supply alarm with monitoring in the PLC. The alarm is activated when power or another supply (water, air, steam) is cut off.
- ☐ Remote alarm signal with activation of a relay with a voltage-free contact for functioning of visual/acoustic signals.
- ☐ Equipment en progress signal (through relay with contact free of tension)
- ☐ Signal open doors through relay with contact free of tension
- ☐ Uninterruptible power supply (UPS) only for control system; activated if power is cut off for 30 minutes.

POWER SUPPLY VOLTAGES AND FREQUENCIES

- ☐ 380/400V, 3 phase, 50 Hz
- ☐ 220/230V, 3 phase, 50 Hz
- ☐ 220/380-400V, 3 phase, 60 Hz
- ☐ 208/220/240V, 3 phase, 60 Hz
- ☐ 460/480V, 3 phase, 60 Hz
- ☐ 208V, 3 phase, 60 Hz.
- ☐ 480V, 3 phase, 60 Hz.
- ☐ Other supply voltages and frequencies

Please indicate other voltages and frequencies below in order to consult MATACHANA's Technical Commercial Department.

08 MECHANICAL CHARACTERISTICS

CHAMBER SET

The main component of each sterilizer is the chamber where the different products will be processed. One of the main characteristics of this family of S100 series sterilizers is that the loading mouth of the chamber is quadrangular and the body of the pressure vessel is cylindrical. The inner part of this container, is provided with a double aluminum structure, which converts its cabin into a completely rectangular space, this inner aluminum structure apart from being beneficial for drying the products is where they support the different loading systems. Both the chamber and the container doors are made of high quality stainless steel EN 1.4404/AISI 316L. To facilitate chamber cleaning, the cabin has rounded edges and its surfaces are perfectly polished.

In order to eliminate condensate and improve the drying of the equipment, in the external and lower part of the chamber, a stainless steel coil is added through which steam circulates in the drying phases as a bedroom.

To facilitate the levelling of the chamber assembly there are four adjustment feet resistant to high loads.

The connections of the chamber with the different circuits and validation sockets are made by means of threaded connections. In order to save energy and minimise heat radiation, the entire perimeter of the chamber is perfectly insulated with environmentally friendly insulating material.

The pressure vessel is designed for a relative excess pressure of at least 3.5 bar (EU, PED).

The drain inside the chamber has a mesh filter made of high-grade stainless steel EN 1.4404 / AISI 316L, to prevent possible obstructions of the discharge point and the conduits that may be caused by the inherent wastes contained in the loads.

MATACHANA designs and produces all of its pressure vessels for sterilizers in its own production factories.

CHAMBER CONFIGURATIONS

- ☐ The chamber floor slopes towards the drain (self-draining).
- ☐ Chamber built of stainless steel EN 1.4571 / AISI 316Ti.
- ☐ Chamber and doors polished to an average finish roughness of Ra 0.8 µm.
- ☐ Chamber and doors polished to an average finish roughness of Ra 0.6 µm.
- ☐ Chamber and doors polished to an average finish roughness of Ra 0.4 µm.
- ☐ Chamber and doors with electro-polished surface finish.
- ☐ Passivation of all internal surfaces, doors, process piping and process valves.

(*) Ra ("Arithmetic Average Roughness")

DOORS AND BLOCKING SYSTEM

The opening and closing of all the doors of the S100 I series sterilizers is manual and with vertical movement. The operation is carried out by means of an ergonomic handle with a new quality design through guides located on both sides that are fixed to the chamber structure.

The door functions are triggered by the control system and with specific buttons. These buttons are clearly indicated on the operator display and are located on the front panels of the unit.

All doors are equipped with safety systems and mechanical and electrical interlocking (sensors, position switches, and

blocks) that are managed by the sterilizer's own software. This prevents incorrect operation and prevents the doors from being opened while the unit is in operation, performing a process under pressure inside the chamber.

Once the doors are closed, they are hermetically sealed with the chamber by a dynamic inflatable silicone gasket, which is activated by compressed air. This air-based operation has a very significant advantage over sterilizers whose door seals are steam activated. This is mainly due to the fact that the compressed air extends the life span of the seal, due to the lower thermal load generated on it. When the door-open button is pressed, a vacuum is generated inside the seal housing allowing it to withdraw to its original position and facilitate the movement of the door.

Remarks: The life span of air-driven door seals is guaranteed for one year.

ADDITIONAL PROTECTIVE MEASURES FOR THE OPERATOR

In addition to the door's safety systems, the chamber has specific monitoring of the pressure, to ensure that there is no residual pressure inside it, before allowing the doors to open. As an "intrinsic safety" feature, while the door is still in the closed and mechanically locked position, when the button is pressed to open it, the door seal is withdrawn and the chamber pressure is fully equalized to atmospheric pressure.

PROGRAMMING OF DOORS OPENING

The programming of the control system prevents both doors from opening at the same time, and ensures that one or both doors gaskets are always under pressure, thus guaranteeing airtightness between the areas through the sterilizer chamber.

Depending on the customer's needs and installation, the opening and closing of doors can be adjusted in the controller, so that the sterilizer lock functions can be performed in the most appropriate way for the proper operation of the centre.

The control system and its simple configuration allow for flexible parameter settings and for doors to open according to the user's needs.

PROGRAMMING DOORS OPERATION

ONE-DOOR VERSIONS (STANDARD)

In these sterilizer models, the door can be opened or closed at any time, provided that the unit has power and the necessary supplies, and there is no cycle in progress.

TWO-DOOR VERSIONS (STANDARD)

Circulation of materials in standard sterilizers is directional, from the **Non-sterile/loading** side to the **Sterile side** (unloading **door**). The main control panel is located on the front panel of the door on the **Non-sterile/loading side.** In this case, doors may only be opened and closed if the unit has power, has the necessary supplies and has previously completed any processes that were underway. The two doors are interlocked, so that they can never be open at the same time, to minimize the risk of cross contamination between the zones. This means that to open each of the doors, certain conditions must be met, depending on the configuration of the sterilizer, whether the last program carried out was sterilization or a test, and whether or not it finished with failures.

From the operator contro panel located at the **Unloading** or **Sterile** area, sterilization processes can be programmed to be sselected and triggered started from the operator control panel.

09 DOOR HANDLING CONFIGURATIONS

DEFINITION OF WORK AREAS

- ☐ ANNEX 20: Conditions for single door sterilizers for industrial, laboratory, Vivarium and biological containment applications with loading and unloading through the same door
- ☐ ANNEX 21: Two doors sterilizers for Industry and Laboratory applications with unidirectional workflow to the unloading/sterile zone.

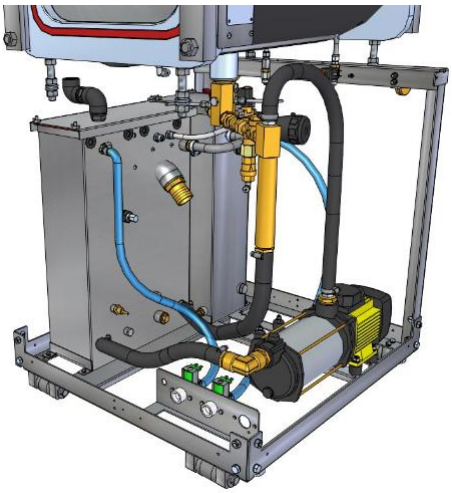
Important note: For more details on the operation of doors and workflows, see annexes.

10 VACUUM SYSTEMS

S100 I sterilizers may be standard-equipped with a Venturi ejector vacuum system.

EJECTOR VACUUM SYSTEM

This vacuum system works by means of a "water ejector"; it is highly efficient and requires minimal maintenance. The vacuum system (ejector+pressure pump) is more silent, faster and consumes less power than the traditional liquid ring vacuum pump. The combination of the ejector technology and automation allow more efficient vacuum processes to eliminate incondensable gases and air from the inside of the chamber.



The water ejector vacuum system in sterilizers is used specifically in processes to remove air, to evaporate, dry, etc. This type of device is designed to optimize energy efficiency and conserve the environment, offering significant economic and environmental benefits.

Ejectors are oil-free so they do not send any contaminants to the recirculation water. They are very resistant to high temperatures and have high steam condensation tolerance. Another important aspect, since there are no moving parts, is that in the vacuum process, evaporation takes place continuously and is balanced, reducing process times. In general, the MATACHANA system provides better performance and efficiency in terms of work costs, energy, and total process time.

WATER EFFICIENCY

The performance of the ejector depends mainly on the supply and temperature of the recirculation or cooling water.

At Matachana Group, we believe that water is a scarce resource, so its usage must be adequately planned. For this reason, the vacuum circuits have been designed and developed to limit water usage and at the same time guarantee maximum efficiency of the vacuum system during the processes.

- ☐ **Connection of the water tank of the vacuum system to the closed external refrigeration circuit** (chiller or chiller owned by the customer).

Remarks: The chiller is a unit that generates chilled water that can work at temperatures between 4 and 8 °C. Connect the steriliser to the customer's external cooling system, with a cooled water recirculation system, can reduce consumption of tap water by up to 80 % and electricity consumption in the vacuum phases. All of this reduces energy and water consumption and increases efficiency, providing maximum performance of the vacuum systems and shortening cycle times.

11 STEAM SUPPLY FROM MAINS MODELS "V".

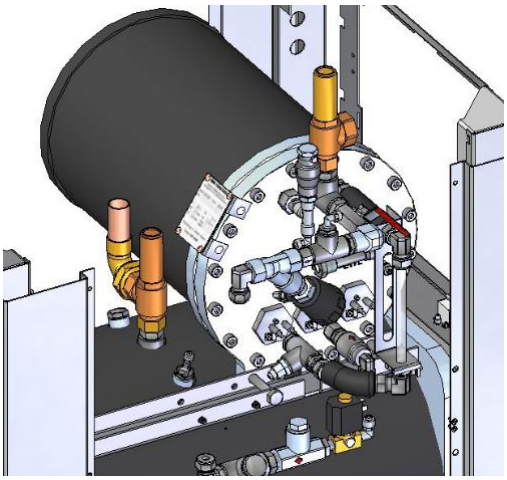
As standard, model "V" sterilizers will be supplied for connection to the building's steam network and internally will have steam chamber circuits and lower coil. The circuits will have independent pneumatic valves and are connected to a single steam inlet of the building network.

NETWORK STEAM CONFIGURATIONS

- ☐ **Carbon steel steam reducer, made up of the following elements:** Reducer valve + high-pressure gauge, safety valve, condensate separator, purge valve, and observation opening, filter and cutoff valves.
  Remarks: This option will always be installed outside of the technical zone of the sterilizer in the area or on the wall that is most convenient for the installation.
- ☐ **Stainless steel steam reducer in AISI 316L, made up of the following elements:** Reducer valve + high-pressure gauge, safety valve, condensate separator, purge valve, and observation opening, filter and cutoff valves.
  Remarks: This option will always be installed outside of the technical zone of the sterilizer in the area or on the wall that is most convenient for the installation.
- ☐ **Sintered filter with stainless steel casing for the input of the network steam ster. SC500**

12 INTEGRATED STEAM GENERATORS FOR MODELS"E"

The electrical steam generators manufactured by MATACHANA are the product of extensive construction experience and constant improvement of the product, adjusting the size to the needs of each sterilizer. The design is aimed at providing flexible operation, thanks to scaling of power levels and constant balancing of the water intake to the boiler, promoting optimum exchange and maximum performance, which gives the unit unbeatable thermal efficiency.



The generators are made of high-grade stainless steel EN 1.4404/AISI 316L, to generate clean steam, and they are standard equipped with a water supply pump with a PPS technical plastic body with high mechanical strength and resistance to temperatures of 140 °C - 284 °F.

Remarks: These generator models must work using treated water (osmosis, deionized or similar), which has a conductivity between 1 and 5 microSiemens / cm (µS / cm) and depending on the application.

STEAM GENERATOR CONFIGURATIONS

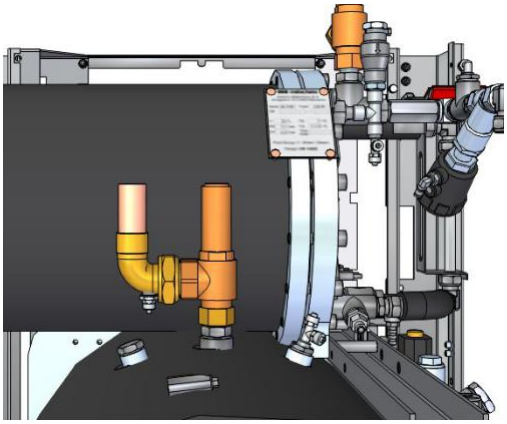
- ☐ **Manual steam by-pass for selecting the unit's steam generator or the general network.** The sterilizer will be equipped with a steam by-pass with the elements needed to function interchangeably with the unit's own steam generator or from the general network. It includes 2 manual valves to open/close the different circuits, as well as the selection on the display of the unit's own steam generator or the building's steam network.
- ☐ **Automatic emptying system of the steam generator** to remove the suspended solids and residues from the bottom part of the generator. This option includes a pneumatic valve to have a controlled water discharge, connected to the bottom part of the steam generator. The activation of this valve is controlled directly from the touch panel of the sterilizer having the possibility to modify the frequency (number of cycles) and activation time

13 OTHERS MECHANICAL CONFIGURATIONS

SAFETY VALVES

The sterilizer's pressure vessel (chamber unit), is equipped with safety and relief valves that have CE certification for the Europeanother markets, which guarantees that our products are designed in accordance with the standards and procedures of this certification for pressure vessels.

The relief valves that are included in the pressure vessels of our sterilizers protect against excess pressure in both the chamber and steam generator.



- ☐ **The discharge points of the relief valves are aimed at the floor.**
- ☐ **The discharge points of the relief valves are specifically directed towards the drain.** With specific pipes.
- ☐ **The discharge port points of the chamber and jacket relief valves are directed to the exterior,** from a specific point in the technical area of the sterilizer; the continuation from this point of the unit to the exterior will be done by the customer.

DRAIN WATER COOLING

- ☐ Drainage cooling system. Cooling system for discharge water from the drain. This option incorporates an intrinsic safety system that prevents all effluents from leaving the general drain at temperatures ≤ 45 - 60 °C / 140 °F.

Remarks: Slightly higher temperature peaks may occur for short periods of time, less than 30 seconds.

PRESSURE GAUGES

By default, sterilizers of one and two doors integrate in the front panel of the **Loading Area/non-sterile** two pressure gauges to check the chamber pressure and the steam supply. Optionally, one more can be installed to display the air supply pressure.

Also, two doors sterilizers, include in the **Unloading/Sterile Area** an extra pressure gauge to check the chamber pressure from this side.

Remarks: Analogic pressure gauges above mentioned, are only to facilitate visual information. The control system includes other specific digital elements to visualize and check processes pressures and temperatures.

OPTIONS MANOMETERS

- ☐ **Add two pressure gauges on the front loading side to check the pressure of the mains air supply.** In this option, the 3 gauges are aligned vertically.
- ☐ **Reading of pressure gauges in MPal Megapascal.**

BACKLIT INFORMATION PANELS

The backlit information panel on the front of the unit displays a series of icon indicators that indicate the sterilizer status at all times, along with the process status, warnings, dangers, etc. Some of these symbols may be turned off depending on the current status of the sterilizer, turning on when necessary. When the sterilizer is disconnected, all of these symbols will be turned off.

CONNECTION PORTS AND VALIDATION OPTIONS

The standard chamber is equipped with two welded 1" screwed connection ports, to connect test validation instruments in the chamber and to measure pressure, temperature, and for thermometric validation of temperature distribution in the chamber.

14 CONFIGURATION OF SENSORS AND CIRCUITS

TEMPERATURE AND PRESSURE SENSORS

The control software incorporates displays for individual adjustment of each of the temperature or pressure sensors connected to the controller. Optionally, each transmitter and sensor can be supplied calibrated according to UNE-EN ISO/IEC 17025 with the date of manufacture and measured values.

As standard, the sterilizer is equipped with the following pressure and temperature sensors:

- Sensors in the drain for control and monitoring the chamber temperature.
- Sensors for chamber pressure control.
- Product temperature probes in the chamber for liquid process control (this probe is standard when the sterilizer is equipped with the liquids option).

Remarks: Pt100 temperature sensors are manufactured in accordance with IEC 60751, with an accuracy of ± 0.1 °C. The pressure sensors are equipped with temperature-compensated adjustment. The accuracy is 1 % over the range of 0 to 4 bar.

VALVES AND COMPONENTS

The sterilizer's process valves are pneumatic piston valves made of high-grade stainless steel EN 1.4404 / AISI 316L. This type of valve complies with all of the relevant requirements and can work under difficult operating conditions, with proven effectiveness. All of this makes it possible to obtain better watertightness of processes, as well as reducing maintenance and extending the life span of the component.

The rest of the oscillating check valves, cutoff valves, couplings and other components involved in the processes are also made of high-grade stainless steel EN 1.4404 / AISI 316L, or materials that are compatible with the utility of their service.

CLEAN MEDIA PIPING AND FITTINGS (STANDARD)

All the steam pipes and fittings to the chamber that are involved in the sterilization process, including all the valves, fittings, etc., and all the pipes connected to the chamber up to the first cutoff valve, will be built of high quality stainless steel. 1.4404 / AISI 316L. The valves and the main components of the sterilizer will have terminations for connection to screwed type pipes and fittings.

NON-CLEAN MEDIA PIPES AND FITTINGS (STANDARD)

All the pipes non-clean media NOT involved pipes in the sterilization process, including all valves, fittings, etc. are made either of brass, teflon, or silicone, depending on the needs of the circuit. The connections of the components with the pipes may be threaded, flanged, welded, as applies to the circuit.

The rest of the pipes of the sterilizer are also made of stainless steel, but their connections may be welded, flanged or threaded, depending on the case.

NON-CLEAN MEDIA PIPES AND FITTINGS MADE OF STAINLESS STEEL

- ☐ All of the NON-processnon-clean media pipes will be made of stainless steel, including all of the valves, fittings, etc. These stainless steel pipes are constructed with threaded and / or compression fittings. Piping of the purges to the drain will be made of teflon or silicone, as is applicable.

MONITORING DEVICES IN PROCESS

- ☐ Manual device for testing Air Detector in S100 series sterilizers

PIPE INSULATION

All steam pipes distributed throughout the sterilizer are insulated with shells for thermal insulation. This prevents the temperature from exceeding 60 °C - 140 °F, avoiding burns, preventing risk of condensation, and ensuring the energy efficiency of the equipment.

OTHER PIPE INSULATION OPTIONS

- ☐ Insulation of the cold-water inlet pipes. The pipes will be insulated with thermal insulation claddings so that they do not affect the latent heat of the sterilizer and thus avoid condensation, guaranteeing the energy efficiency of the units.

15 NOTIFICATION, ERROR AND ALARM MESSAGES

When a condition appears that generates an alarm, notification or error message, a continuous acoustic signal will be generated, and the "message window" will appear on the HMI control display.

Errors: These appear when the equipment operator carries out an incorrect action, such as attempting to open the door when this is not allowed for safety reasons. This type of message does not reset the cycle in progress.

Warnings: Warnings appear when there is an equipment malfunction, but the existing failure does not cause the reset of the current cycle. The cycle will continue to completion, generating the cycle correct indication and allowing the load to be unloaded. However, a new cycle cannot be started if the condition that generated the warning is still present.

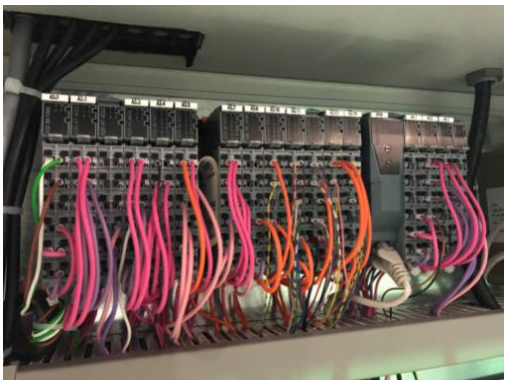
Alarms: They are generated by equipment malfunctions that prevent the cycle from being completed satisfactorily. This type of message triggers an automatic reset of the cycle, which means that the execution of the process that is underway running will be cancelled. While the recovery program is carried out, the process reset phase will be displayed on the control display. The unit will then execute the process phases that are strictly necessary to reach the end of the cycle and to allow the door of the unit to be opened safely to remove the load from the loading side.

The following alarms, among others, will be displayed: Power failure, chamber and jacket pressure too high, temperature sensor failure, doors open, vacuum pump failure, low seal gasket pressure, etc.

Remarks: Whenever an alarm occurs, the current process is considered INCORRECT and, therefore, the load should always be considered to be NON-sterile. After an incorrect cycle, only the door to the **Non-sterile/loading zone** will be able to be opened.

16 CONTROL SYSTEMS

The PLC (Programmable Logic Controller) is the system that manages all the functions of the unit. It could be said that the PLC is the "brain" of the sterilizer that controls , all the states, processes and sequences in each of the sterilization cycles in real time. The sensors and analogue and digital signals connected to the controller are the ones that constantly provide the information on the unit's actual status (temperature, pressure, water level, etc.). These also control the actions that are preset in the software on the actuators, valves, pumps, and contactors that are required to execute and control the processes. Redundant sensors and the monitoring of important operating parameters provide the highest possible process reliability.



The standard control system (PLCs and touch screens), used by MATACHANA is manufactured by B&R Industrial Automation GmbH. This equipment combines control and visualization technology, offering the user complete smart solutions with immense resources that allow extremely flexible and dynamic configurations. The standard configuration of our equipment includes two CPUs, one is for control and the second, which acts independently, used for logging.

TOUCH-SENSITIVE OPERATOR SCREENS

The standard sterilizer is equipped with a 5.7" multi-touch screen and an operator panel in the unloading area, depending on the model and user needs.

The touch screens incorporated into the units have been designed for use in difficult environments and ensure the highest level of operational comfort, which provides the user with a human-machine interface that is easy, direct and intuitive to operate. They also facilitate critical or potentially dangerous operations, providing the operator with an effective way to avoid unintentional errors. Touch screen on the unloading or Sterile side, the same size as the one selected for the loading/non-sterile side.

The programming of the operator's screens is provided with the appropriate elements for the control, display and printing of the process parameters. The following function, among others, can be carried out from the touch screen:

- Door opening/closing, start, restart of the operation cycle.
- Display of temperatures, pressures, phase time and estimated time to the end of the cycle.
- Indication of the status of the doors, alarms, operation and phase of the current cycle.

☐ **Connection to the sterilizer via the WiFi network.** The standard ethernet connection is via cable with RJ45 connector.

☐ **OPC UA server real-time communication protocol** for SCADA (Supervisory Control and Data Acquisition) solutions.

☐ **Communication for SCADA solutions by Profibus or Modbus protocol.** Indicate whether the connection is Master.

☐ **Communication for SCADA solutions by Profibus or Modbus protocol.** Indicate whether the connection is Slave.

☐ **Connection to remote maintenance for remote interaction, with monitoring and supervision systems** (For maintenance tasks by MATACHANA's Technical Assistance Service).
Remarks: In this option control system and screens will be changed to Siemens.

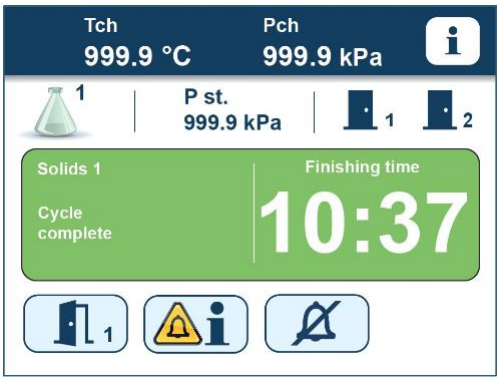
☐ **USB port located on the front panel** for downloading processes. Main display side.

17 EXAMPLES OF HMI DISPLAY

Process selection screen

Process status screen

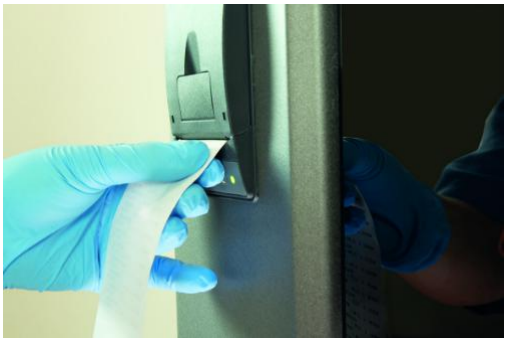
Cycle complete no incidents screen



General Settings Screen

PROCESS DATA PRINTER

All sterilizers include an alphanumeric thermal printer as standard feature, a video recorder as an option, integrated into the front of the sterilizer (located in the Non-sterile/loading area). The data printer allows the log of the completed cycle to be printed. The printer report contains the most relevant information on the completed cycle.



- ☐ Automatic paper rewinder for sterilizers S101
- ☐ **Change printer position to unloading or dessigned area.**
- ☐ **Connection to DIN A4 printer,** connected to the ethernet network. You will need the IP address of the printer to enter it into the sterilizer and this option does not include the printer.
- ☐ **Data printer DIN A4 format.** The standard thermal printer is NOT included in this option.
- ☐ **Video-recorderup to 3 channels.**
- ☐ **Video-recorder up to 9 channels.**
- ☐ **Video-recorder in unloading area.**

Remarks: The video-recorders generate a graphic log of the chamber pressures and temperatures during the process. With the video-recorder software, the files can be viewed and transferred to a PC.

18 QUALITY STANDARDS

MAXIMUM QUALITY AND RELIABILITY

MATACHANA's sterilizers include, in their technical design, the latest developments in safety and efficacy, ensuring full control of all processes. Our units are manufactured in accordance with the guidelines of the DIN EN ISO 9001:2015 quality standard, certified by the control entity Lloyd's Register Ltd., which ensures our commitment to constant innovation in the technology of our equipment and systems, always guided by a single idea: The benefit of this technology for the user.

ISO 9001

MATACHANA's constant efforts help it to fulfil the needs of its clients and also to comply with the highest quality standards, backed by the approvals and certification of our products in terms of development, manufacturing, delivery, installation, and marketing of the product, technological solutions, and post-sale service. Successfully creating reliable and practical solutions in sterilization technology, time and again.

COMPANY STANDARDS

- ISO 9001 Quality management.
- ISO 14001 Environment management.
- ISO 50001 Energy management.

ENVIRONMENTAL MANAGEMENT

Our constant quest for technological innovation aimed at the sustainability and improvement of our products, leads us to carefully control the life cycle of our equipment and its environmental impact. This control has allowed us to improve the manufacturing of our equipment by gaining substantial energy savings with respect to previous series.

19 STERILIZERS STANDARDS AND CODES

The sterilizers manufactured by MATACHANA are designed and manufactured in accordance with the latest standards for Europe, the US, and international standards, and they conform to the standards described below:

- UL 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements.
- UL 61010-2-040: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials.
- ASME Boiler & Pressure Vessel, Section VIII, Division 1, 2017 U-Stamp.
- Seismic Pre-approval R-0272 and R-0275, California Administrative Code for Seismic Stress Calculations.
- ASTM C-795 & ASTM C-871. Specification for thermal insulation for use in contact with austenitic stainless steel.
- IEC 60204-1 [EN 60204-1] Safety of machinery -Electrical equipment of machines - Part 1: General requirements.
- IEC 61310-1 [EN 61310-1] Safety of machinery - Indication, marking and actuation - Part 1: Requirement for visual, auditory and tactile signals.
- IEC 61326-1 [EN 61326-1:] Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.
- IEC 61000-3-2 [EN 61000-3-2] Harmonics, Electro-magnetic compatibility - limitations of voltage changes.
- IEC 61000-6-2 [EN 61000-6-2] Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity for industrial environments.
- IEC 61000-6-4 [EN 61000-6-4] Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments.
- CE Compliance.
- PED -Pressure Equipment Directive.
- Directive 2006/42/EC on machines (MD).
- Directive 2014/35/EU on low voltage (LVD).
- Directive 2014/30/EU on electromagnetic compatibility (EMCD).
- Directive 2011/65/EU Restriction of the use of certain hazardous Substances in Electrical and electronic Equipment (RoHS).
- EN 285: 2006 + A2: Steam sterilizers, Large Sterilizers.
- EN 61140 + A1: Protection against electric shock - Common aspects for installation and equipment.
- EN 13445-1: Unfired pressure vessels - Part 1 Generala.
- EN ISO 4126-1: Safety devices for protection against excessive pressure. - Part 1 Safety valves.
- EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk.
- EN 12347 Biotechnology. Performance criteria for steam sterilizers and autoclaves.

20 COMPETENCE CENTER (PROJECTS)

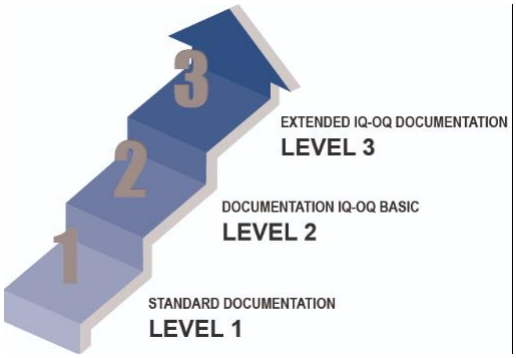
The MATACHANA's Competence Center, located in Barcelona (Spain), develops solutions in which every detail counts. The department is responsible for all technical requests from customers, taking into account their requirements in terms of capacity, productivity, efficiency, and safety, guaranteeing correct compliance with local regulations.

Equipped with the latest planning and design technology, our technical project office proposes and studies technical solutions for each customer, which are later presented using advanced 3D technologies.

The result: an installation designed according to their specific needs and supported by complete technical documentation to ensure correct application and installation at the site.

21 DOCUMENTATION

Quality as a general principle of MATACHANA is an intrinsic characteristic of all our products, in which all the processes and manufacturing guidelines of the equipment are followed and controlled in a very specific way. Including from the design specifications to component selection, manufacture, assembly, and factory testing. All of the aspects of the manufacturing process are examined and documented to guarantee and demonstrate that the product has been built and tested in accordance with the specifications and operating requirements requested by the customer.



STANDARD LEVEL 1 DOCUMENTATION

One copy of the following documentation are delivered as standard with each sterilizer:

- **User & MaintenanceInstruction manual** (User manual, data sheet, quick guide etc.)
- **Certifications** (Declaration of conformity, certificates of safety valves, etc.)
- **Technical information and drawingsplans** (Technical data sheet, electrical schematics, P&ID-Piping and Instrumentation Diagram, installation plans, sort testing, safety, and standard test bench calibration protocol and technical service network).

☐ **Delivery to the customer of the complete standard test bench protocol (Testing, safety and calibration)**
Observations: Test Protocols, safety and test bench calibration are stored in our factory facilities for the life of the sterilizer.

☐ **Delivery of additional standard documents before delivery of standard form (paper format).**

In addition to the standard accompanying documentation, additional copies may be supplied in paper format.
Quantity sets of documentation: _____

☐ **Delivery of pressure vessel quality documentation,** which includes the following: EC certificate of conformity; Calculations of vessels, chamber and generator; Non-destructive controls chamber and generator; Certificate of conformity and Safety valves; Certificates for materials and insulation; Construction plans of the vessels.

☐ **Set of technical data sheets of the main components of the sterilizer (to be attached to the standard documentation).** Together with the standard documentation, the technical data sheets of the main components of the equipment are delivered.

☐ **Standard Acceptance Test WITH 1 DAY STAY - 1 CUSTOMER (factory equipment inspecction without specific requirements) .**
This test will consist only of equipment inspection at the factory by the customer, without it having submitted or having specific documentary requirements. In the STANDARD acceptance test, the most important points of the equipment will be analyzed with the customer in a generic way and will be delivered to the standard protocol of testing, safety and calibration, generated and completed by the factory verification team test bench. Once the equipment has been inspected with the client, a summary document signed by both parties will be issued.
Remarks: The expenses for lodgingaccomodation, travel allowances, and travel for 1 day, for the inspection of the unit in the factory, of the personnel assigned by the customer, will be paid by the customernot included.

- **Installation and start up.** MATACHANA's technical service carries out a series of BASIC acceptance tests as a standard service. These consist of the inspection of the installation and performing an installation and commissioning protocol that includes the following points:

- Verification of the positioning of the unit (according to the installation plansdrawings).
- Startup verification (according to the instructions in the equipment manual).
- Verification of alarm functioning (one of each type).
- Verification of test and production cycles.
-Verification of quality of water, steam, air, electricity, drainage, ventilation supplies, etc.
- Training of the centre's maintenance team and users.
- Evaluation of the customer's level of satisfaction (in regard to the installation and commissioning).

DOCUMENTATION IQ-OQ BASIC LEVEL 2

Factory Acceptance Testing (FAT) will be carried out in accordance with the test procedures established in our standard quality protocols, which include basic IQ-OQ

documentation with the tests to be carried out, together with installation plans, electrical diagrams, Piping and Instrumentation Diagram (P&ID), documentation of the pressure vessel and calibration certificates of the instrumentation used for the tests. These documents will be validated in conjunction with the Engineering Department and are intended to support subsequent qualification procedures, saving considerable time and effort.

☐ **Level 2 documentary set (basic IQ-OQ documentation).** The purpose of the Factory Acceptance Test (FAT) is to inspect equipment at our facilities in accordance with previously defined FAT protocols. During FAT, the sterilizer hardware and software are thoroughly checked according to a checklist of functionality, performance and quality parameters. FAT tests are generally carried out in conjunction with the customer, giving him first-hand characteristics and the operation of the equipment.

IMPORTANT: Depending on the needs and availability of the customer, these acceptance tests may be performed with or without the customer's presence. For this reason, one of the following options should be selected:

☐ **FAT acceptance test (basic - level 2) with customer support. 1 DAY - 1 CLIENT for factory equipment inspection without specific documentary requirements.** This qualification shall consist of a 1 day factory inspection by a person assigned by the customer. This basic FAT will be completed and delivered to the customer along with the rest of the documentation. During the visit the following objectives will be fulfilled:
- To visit the production centre and to see in a generic way how the manufacture of its equipment has been carried out.
- Verify/analyze the standard tests carried out by the Test Bench personnel on the equipment.
- The specific tests previously determined by the client and/or proposed by our Engineering Department will be carried out. The client must indicate with sufficient time the required tests, bearing in mind that only 1 day is available to carry out this acceptance test.

Observations: The expenses resulting from the accommodation, per diems and travel of 1 day, for the inspection of the equipment in the factory, of the personnel assigned by the client, will be at the client's expense.

☐ **FAT acceptance test (basic - level 2) without customer assistance to be completed by factory personnel without specific documentary requirements.** This qualification without specific documentary requirements will be carried out by factory personnel from the test bench with the collaboration of the engineering department. This basic FAT will be completed and delivered to the customer together with the standard protocol of testing, safety and calibration, generated and completed by the verification team of the factory test bench.

IMPORTANT: Neither of the two basic FAT acceptance testing options (level 2), with or without customer visit, include load testing, NOR temperature distribution testing or thermal mapping.

Site Acceptance Test (SAT). MATACHANA's technical service carries out a series of BASIC acceptance tests at the installation as a standard service. These consist of the inspection of the installation and performing an installation and commissioning protocol that includes the following points:

- Verification of the positioning of the unit (according to the installation plans).
- Startup verification (according to the equipment manual).
- Verification of alarm functioning (one of each type).
- Verification of test and production cycles (according to the equipment manual).
- Verification of quality of water, steam, air, electricity, drainage, ventilation supplies, etc.
- Training of the users and maintenance team at the centre.
- Evaluation of the customer's level of satisfaction (in regard to the installation and commissioning).

The purpose of the acceptance tests in the installation (SAT) is to inspect the sterilizer at its final location and to guarantee a start-up of the sterilizer without problems, verifying that it complies with the performance and expected performance requirements. The SAT, like the FAT, is performed jointly with the MATACHANA client and engineers, and will be carried out with the test procedures defined in the IQ-OQ protocols. The completion of the standard or basic protocols will be carried out at the point of installation of the equipment, after completing the installation process completely.

Remarks: In order to carry out the Performance Qualification (PQ) and validation services, consult the Technical Assistance Service of the Matachana Group.

☐ **Set of certificates of materials and calibration of critical instrumentation (max. 6 instruments).** This SET includes material and calibration certificates for up to 6 critical instruments (probes and transmitters) in contact with the process. These certificates will show that these instruments will perform the measurement in an optimal state of use, in order to know if they really meet the requirements requested by the customer. The calibration certificates consist of documenting the comparison of the values obtained by the measuring instrument against the values obtained by a standard equipment, which has also been compared with another standard of a higher metrological hierarchy.

EXTENDED IQ-OQ DOCUMENTATION (LEVEL 3)

☐ **Level 3 documentary set (Extended IQ-OQ)** . Description of the documentation for specific qualifications. Current Good Manufacturing Practices and National and International Quality Standards describe the design, manufacture, installation and operation of the equipment. This implies that they are routinely calibrated, inspected or verified in accordance with a written programme designed to ensure the proper functioning of the equipment. The verifications and tests carried out on the equipment are as follows:
- DQ Design Qualification.
- Installation Qualification (IQ Instalation Qualification).
- OQ Operation Qualification.
- **(Optional)** Performance Qualification (PQ). This qualification wil be valued by our validations service.

Extended documentation includes the DQ and IQ-OQ documentary sets for FAT and SAT (Factory and Site Acceptance Test).The functional specifications of the DS equipment will be included in section DQ.

DQ (Design Qualification) document set

Verification protocol that ensures that the design proposed by the equipment manufacturer conforms to the legal safety standards and requirements, in addition to conforming to the operational user requirements defined by the customer, and for the purpose for which it was designed. This documentation includes the documents described below:

DQ Documentacion in the design/approval phase

- (SDS)-(HDS) documentation with functional specifications, and software and hardware design specifications. Choose this option in the section on Complementary Documentation.
- P&ID diagrams of the equipment with piping and instrumentation. (Fluid schematic and materials list)
- Installation plan for the unit. (with dimensions, weights and connections, water, air, steam, drain, electricity, etc..).

DQ Documentation to be delivered in the final phase

- Certificate of construction materials.
- Calibration certificates of the machine's instruments.
- Calibration certificates of the patterns used.
- Maintenance and user training program.
- Construction plans for the pressure vessels andchamber-jacket unit the following documentation: Weldding dossier for the pressure vessels; Weldding inspection report; PAMS (welding procedures).
- Safety valve certificates.
- List of critical components.
- Set of fluid and electrical schematics

☐ **IQ-OQ acceptance test (Extended FAT - LEVEL 3) UP TO 3 DAY - 3 CUSTOMERS for factory equipment inspection WITH SPECIFIC REQUIREMENTS).** IQ-OQ Acceptance Test (For Extended FAT of LEVEL 3). (FAT-Factory Acceptance Test). This qualification shall consist of factory inspection for a maximum of 3 days and 3 persons assigned by the customer. The "Qualification" of the equipment will be carried out with the test procedures defined in the IQ OQ protocols, in order to verify that the equipment functions as described in the equipment design specifications.
Compliance with this protocol will take place at the point of manufacture of the equipment, after complete completion of the manufacturing process, including the final tests implicit in the production of the sterilizer. This protocol will provide evidence that the sterilizer and all its components, including control systems, function and react in a reproducible manner. It will also show that the programs, times, pre-programmed cycle profiles, alarms, security features and inputs/outputs guarantee a perfect operation of the equipment. All tests are performed with the sterilizer chamber empty. All procedures, acceptance criteria, expected responses and documentation of actual responses are defined in the protocol.

Acceptance Test IQ-OQ (standard - LEVEL 3) (SAT - Site Acceptance Test). This qualification will consist of an inspection at the installation for a maximum of 3 days with the people assigned by the customer. The "Qualification" of the unit will be carried out with the test procedures defined in the IQ-OQ protocols, with the aim to inspect the sterilizers in its final location and to guarantee its start up without problems, verifying that the unit functions as described in its design specifications.

Remarks:

- The IQ-OQ acceptance test for the factory inspection of a maximum of 3 days and 3 persons assigned by the customer is included in the documentary SET of LEVEL 3 (extended documentation). This article is only to confirm the attendance of the 3 customers.
- The expenses resulting from the Lodging, diets and displacements of 3 days, for the inspection of the equipment in factory, of the personnel assigned by the client, will be in charge of this one.

LEVEL 3 SUPPLEMENTARY DOCUMENTATION

☐ **Material certified SETS 3.1.** In this documentary SET, will be included certificates of construction materials 3.1, in contact with process steam, according to EN 10204. This includes pressure vessels, process valves up to the first cut, instrumentation, etc....
Important remark: In this SET the connections for the interconnection of the valves are NOT included, neither the accessories of load, that in the case that they are wanted to include, they will have to be requested of independent form.
The material certificates of the pressure vessels are included in the documentary SET of the DQ of the Extended documentation of LEVEL 3.

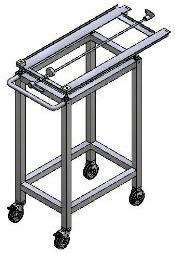
COMPLEMENTARY DOCUMENTATION (LEVELS 2 AND 3)

☐ **Temperature distribution test or thermal mapping** for a maximum of 3 cycles. This test is associated with the subsequent delivery of documentation, as well as the location of cold and hot spots. If this option is selected, the temperature distribution test or thermal mapping will take place at the FAT (OQ) and the following processes will be performed:
- (1) Test Program.
- (1) Solids Program.
- (1) Open Liquids Program.

22 LOADING ACCESSORIES SERIE S100 I

MATACHANA designs all of the loading systems and accessories always keeping in mind that they are very important for the entire sterilization process. In addition to this, ergonomics and the type of process to be serviced are also taken into account in development, and they are designed to be safe, simple and comfortable for the user. Based on our experience, we can offer a wide range of loading accessories to cover different applications, always keeping in mind that each application may have different operational, functional, and design characteristics.

Transfer trolleys



Loading carts

GENERAL CHARACTERISTICS

All external carts and loading accessories are made of quality stainless steel (EN 1.4301 / AISI 304). The interior loading framesloading carts, as standard, have 2 load levels with 1 height-adjustable shelf, according to the needs and load types (in addition to the frames, more adjustable shelves can be added to provide more load levels). All frame modelsThe loading carts have rotating or fixed wheels (depending on the model) that are resistant to steam and temperatures up to 140 °C (284 ° F).

GENERAL DIMENSIONS OF CARTS AND FRAMES

Selection of different loading systems for S100 I sterilizers. In the following points, select the loading systems required by the customer based on their needs and the type of loads.

It is important to take into account that the interior loading frames may have two types of shelves depending on the types of loads; mark how they should be built, with reinforced perforated sheet metal or a rod structure, both of which are made of AISI 304 stainless steel. In the attached table, select the type of shelf and then mark the interior loading frame box.

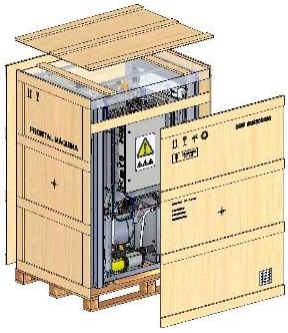
SELECTION OF LOADING SYSTEMS BASED ON NEEDS

	☐ Chamber guides S100 for external trolley Quantity: _____
	☐ External trolley for loading and unloading sterilizers model S101. Quantity: _____
	☐ Internal loading shelf rack for sterilizers model 101. Manufactured in AISI 316 stainless steel. Quantity: _____
	☐ Removable loading platform with fixing at the base of the chamber for sterilizers Mod. S101. Quantity: _____
	☐ Jeu de guides latéraux caméra pour stérilisateurs à étagères intermédiaires S101.
	☐ Loading rack for S101 sterilizers. Fully built in AISI 316L stainless steel. Quantity: _____
	☐ Lower shelf, made of AISI 304 grade stainless steel rod. With 4 support points in the chamber.

Remarks: For other requirements, needs, or details for the loading systems, exterior carts, and interior loading frames for series S100 I sterilizers, consult MATACHANA's technical sales department.

23 PACKING SYSTEMS

Devices and equipment that are extremely heavy or fragile, such as the S100 I sterilizers, require specific packaging depending on the distance and means of transport, in order to guarantee the delivery of the contents in a safe way, without suffering any kind of mishaps.



On the packaging of each item separately, fragile items are kept as far apart as possible from each other, and from the corners and sides of the box, to reduce the likelihood that they will break or be damaged, using different types of materials for cushioning and protection. Different types of materials are used to cushion and protect, including: bubble wrap, moulded foam (a foam that compresses and forms protective moulds around the contents), corrugated cardboard partitions, and strong packaging paper or corrugated paper.

MATACHANA has the certificates that demonstrate that the packaging is made with heat-treated wood in accordance with the FAO ISPM regulations. The different packages will be marked according to the specifications in the standard UNE-EN ISO 780:2000.

All of the sterilizers manufactured by MATACHANA are always delivered in accordance with the internal guidelines for conditioning for transport, depending on the destination and the method of transport, with the following types of packaging:

1. Packaging in a COMBINATION BOX
2. Packaging in a PLYWOOD BOX.
3. Packaging in a PLYWOOD BOX WITH ALUMINIUM FOR MOISTURE PROTECTION.

All sterilizers will be secured to pallets made of boards arranged next to each other that will allow water and condensation to drain off. The following standard packaging is used for land transport, air or sea transport (in a container):

- **Packaging in a combination box:** The sides and top of the box will be made of sheets of heavy-duty cardboard with four wooden reinforcements at the bottom, middle, and top, which will be secured to the pallet and to each other. A protective cover sheet of polyethylene will be placed on top of the box and the top cover will later be secured on top of it.
- **Packaging in plywood box:** The sides and top will be covered with a sheet of plywood with four wooden reinforcements that will be secured to the pallet and to each other. A protective cover sheet of polyethylene will be placed on top of the box and the top cover will later be secured on top of it. All plywood boxes will have ventilation holes, in order to prevent condensation inside.

☐ **Packaging in plywood box and aluminium moisture protection.** The unit will be delivered wrapped in an aluminium sheet with Aircup bubble film on the base. Before wrapping, desiccant clay (250gr/m^3) will be placed inside and when the packaging process has been completed, a vacuum will be applied to reduce the amount of air inside the unit. After the moisture barrier has been sealed, the unit will be packaged in the standard plywood box.

Remarks: The desiccant clay used for this type of packaging is NOT deliquescent OR corrosive, and is also totally chemically neutral.

☐ **Preparation of the sterilizer for packaging, transport and storage in extreme cold conditions.**

24 EQUIPMENT GUARANTEE

Antonio Matachana, S.A. guarantees its equipment against all manufacturing or functional defects for a period of 12 months following the installation of the unit, or 15 months from the date of shipment (whichever comes first), in accordance with the conditions defined below:

1. Replacement free of charge of any part that is observed to have manufacturing defects during the guarantee period, including spare parts, labour to carry out the replacement, and shipping costs. Defective parts must be replaced by Antonio Matachana, S.A. or by an authorised distributor, based on the information sent in writing by the customer. The replaced parts will become the property of the supplier.
2. The replacement of parts during the guarantee period shall not extend the duration of the guarantee; nevertheless, the guarantee may be extended for the amount of time that the operation of the equipment was interrupted due to the defect and its repair.
3. This guarantee does not cover malfunctions that are the result of deterioration or accidents caused due to negligence, lack of attention or maintenance, or use not in accordance with the user manual, or the use of consumables that do not comply with the specifications determined by Antonio Matachana, S.A. Inadequate or improper maintenance is also understood to include failure to observe the intervals for preventive maintenance, or preventive maintenance carried out by persons not expressly authorised by Antonio Matachana, S.A.
4. The guarantee does not cover the consumable parts and products required for the correct functioning of the sterilizer, such as, printer paper, grease and lubricants, sterile air filter and water filters, seals (door seals, clamps, pneumatic cylinder seals, O-rings, flat seals, etc.) and membranes, as well as batteries, fuses, bulbs, and lamps.
5. The guarantee shall be void if modifications are made to the original parts, or in the case of repairs done with parts other than those supplied by Antonio Matachana, S.A. manufactured by unauthorised third parties.

6. The guarantee shall also not cover interventions in which the reported defect is not detected, nor shall it cover defects caused by force majeure, such as atmospheric and geological phenomena, water, fire, etc.
7. In all cases, the customer's right to file claims regarding damages caused by the deficiencies shall expire after 6 months.
8. This guarantee does not apply to repairs. These shall be subject to their own conditions.

The pressure vessels of the sterilizer manufactured by MATACHANA are guaranteed against material and labour defects under normal operation for ten years (PED) provided that the sterilizer is maintained continuously under the MATACHANA service contract.

25 TECHNICAL ASSISTANCE SERVICE

Matachana Group's Technical Assistance Service is made up of highly qualified professionals who are constantly updating their training, and its aim is to guarantee the quality of MATACHANA's equipment and ensure the satisfaction of our customers.

Through the Helpdesk, Matachana Portal, and Matachana Online Technical Service, the extensive network of National TAS branch offices in Spain, France, Germany, Malaysia, and Argentina, along with the team of specialized engineers who provide direct assistance to the network of distributors of the International TAS, we offer the necessary technical support, Logistics of original spare parts, and MAINTENANCE, ensuring high quality and operation of equipment over the course of its life span, anywhere in the world.

26 INTELLECTUAL PROPERTY

27 CONTENTS

Because our products are constantly being improved, the contents of this document may be revised or modified without prior notice. Some elements and/or instructions may vary depending on the equipment and the available options. In this case, the user will find an attached document with the necessary technical specifications.

28 ADDITIONAL INFORMATION

If you do not find an option that you require to fulfil the specifications or requirements of your project in this information, contact our sales department, or a MATACHANA distributor or representative so that we can give you additional information and assistance. You can also fill in the following form with the observations you consider appropriate.

General remarks about the product

Observations on the programmes

Mechanical remarks

Control system remarks

Remarks on loading systems

Remarks regarding optional equipment

29 CONTACT

matachana

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