

# Azteca Series

High-Tech in sterilization





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### ■ HIGHLIGHTS

- Models, from 90 to 200 Liters (fits 1STU), as well as varied chamber dimensions according to the specific demands.
- Simple operation using high tech computerized control system.
- Air removal based on a powerful vacuum system, using Liquid Ring Vacuum Pump and Condenser.
- Modern design, graphic display and ergonomic user interface. Simplified automatic and manual control, based on computerized controller.
- Most advanced interface connection: Ethernet, USB, RS 232 and RS 485.
- Data Collection: Possibility to collect data via SD card
- Special door safety mechanisms, closing and opening are done manually.
- Meets highest standards requirements for Quality, Safety and Operation.
- 10 sterilization cycles and two test cycles, Bowie & Dick and Leak test.
- High speed, integrated steam generator and steam heated jacket.
- The Azteca Sterilizers performs approved, validated processes for all types of materials and loads.
- Easy to operate; minimizes risk of wrong operation.
- Easy to maintain.

# Large Steam Sterilizer



## ■ MICROPROCESSOR CONTROLLED STEAM STERILIZER

Using steam under pressure as the sterilizing agent for wrapped or unwrapped goods such as fabrics, surgical instruments, utensils, and other heat and moisture stable materials at temperatures from 100°C to 138°C.

The Azteca sterilizer is a pre-vacuum/gravity sterilizer designed to cover a large field of applications for hospitals and laboratories, as well as pharmaceutical and biotechnological industries.

The sterilizer operates with saturated steam as a sterilizing agent and has an operating range of up to 2.5 Bars / 138°C.

Within the health services, sterilization of medical supplies is an essential issue in the battle against the advance of many infectious diseases. In order to improve the quality of sterile supply, international standards which specify the requirements for the equipment and procedures in the sterilization departments in health facilities have been developed.

## ■ DESIGN AND CONSTRUCTION

Azteca Sterilizer meets the highest standards requirements for quality, safety and operation. Stainless Steel Pressure Vessels, 316 Ti, conforms to the Pressure Equipment Directive (PED). The inner shell, door(s) and jacket are designed for a maximum working pressure of 2.5 bar and full vacuum.

The sterilizer is made of 316L stainless steel and is heated by saturated steam supplied by a central building source or a stand-alone electric steam generator.

## ■ CHAMBER

The Vessel is double wall constructed with a round chamber.

Model A-470 to A-5100- the round pressure vessel is made of corrosion-resistant electro-polished stainless steel 1.4571 (V4A) AISI 316 Ti and is thus easy to clean.

The autoclave framework and housing are also made of stainless steel.

The highly efficient, high-quality Hanno-Tech insulation material releases no particles; thus, the A-470 to A-5100-Series can be used under clean room conditions. The pressure vessel complies with applicable requirements of the PED (Pressure Equipment Directive).

## ■ DOOR (S)

The sterilizer is supplied with either 1 or 2 manual doors.

Special safety features prevent the operator from opening the door in the following instances: When the chamber is pressurized or has high temperature.

## ■ GASKET

Sealing of the chamber is made by utilizing a heat resistant silicone rubber gasket.



## ■ MOUNTING FRAME

A galvanized steel frame with rustproof painted finish and height adjustable leveling bolts shall support the sterilizing chamber, piping and cabinet. The front of the sterilizer includes a service door (to provide access to the piping components) and a storage compartment for manuals.

## ■ CONTROL SYSTEM

Microprocessor control system, state of the art "Freescale" technology automatically controls all programs including sterilization cycle, graphic display, communication, self and remote diagnosis, PC-connection for external documentation and printing. It ensures reliable, safe and user friendly operation.

During the sterilization cycle, it measures, controls and shows in digital display: the time, chamber temperature, chamber pressure and sterilizer status.

While the power is off, the non volatile memory will keep the status of the sterilizer, and the real time clock driven by its own back-up battery keeps running the date and time.

## ■ SLEEP MODE: SAFETY AND ENERGY CONSERVATION

Azteca Autoclave is equipped with a Sleep Mode which is activated when the unit is not used after a certain period of time. This Mode will save energy and will insure safety of operation.

## ■ ALARMS

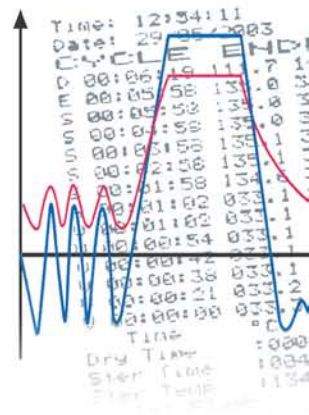
Depending on the state of the input, and of the installed accessories, the controller is capable of displaying and/or printing several alarms including:

- Door Unlock
- Temperature/ Pressure Error
- Low/High Temperature
- Low/High Pressure
- Low Vacuum
- And more

## ■ STERILIZATION AND TEST CYCLES

Twelve standard sterilization programs are available between 105°C and 138°C; four (4) for unwrapped instruments, four (4) for wrapped instruments and packages, and two (2) for liquids.

Two test programs are also standard, the Leak Test checks the integrity of the chamber and piping system and the Bowie & Dick test checks the efficiency of the sterilization process.



## ■ CYCLE DOCUMENTATION

For a clear and concise documentation of process, the control unit is provided with a 24 character per line printer, connected to the processing unit. This releases a hard copy printing of the relevant information concerning operation during the cycle such as temperature, pressure, vacuum, sterilization and drying time, number of cycles, etc. In case of an uncompleted cycle, the print-out indicates cycle failure and the cause of the failure. RS485/ RS232 PC communication port is available for full documentation and Optional Advanced PC windows based software is available for monitoring, logging and control. A circular or strip chart temperature and pressure recorder can be supplied on request.



## ■ STEAM GENERATOR

Integrated separate steam generator (no heating elements in sterilization chamber)

Steam generation takes place in a vessel that is completely separated from the sterilization chamber (i.e. no heating elements in the chamber itself). The steam generator is built-in into the autoclave housing. As the generator is separated from the chamber, it needs not be cooled during the cool-down-phase

## ■ COMMUNICATION SYSTEM

### PC software

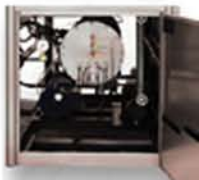
PC software is available in order to collect and document the sterilization programs. The connection is done through RS 232, USB or RS 485.

### Data Collection

Sterilization cycles data can be collected on line on a SD Card through a SD Card Slot. Collected data can be downloaded into a computer equipped with proprietary PC Software. 1 Gigabyte SD card may collect up to 20 years logging data which includes: selected cycle, start time, cycle stages, temperature / pressure, end time, cycle status (pass / fail), etc.

### SD card / Card Reader

1 SD card and 1 Card reader are included.



## ■ OPTIONS

### OPI- CABINET

The sterilizers can be either cabinet or recess mounted. A cabinet mounted sterilizer has stainless steel side panels for free standing installation. A recess-mounted sterilizer is installed through either one or two walls.

A double door sterilizer recessed through one wall will include stainless steel panels for flush mounting.



### OP2- BIO-SHIELD

The bio-shield is used as a seal to prevent any cross contamination passing from the dirty side to the clean side of the room. The bio- shield is assembled only in a 2 doors autoclave. A metal flange is welded around the autoclave jacket, which separates completely between sides.



### OP3- LOADING EQUIPMENT

Each autoclave can be supplied with stainless steel shelves or stainless steel loading cart and carriage.

### OP4- AIR COMPRESSOR

An electrically operated air compressor can be provided if there is a lack of available compressed air. The air is used to operate the unit's ball valves and/ or power door.



#### **OP5- REVERSE-OSMOSIS**

A Reverse-Osmosis system must be used to improve the quality of the water used to generate steam in the electric steam generator. The use of mineral-free water will contribute to better performance and longer life of the autoclave chamber. The water purification system uses a high quality booster pump which can provide 6.8 bar water pressure to pass through the membrane even under low water pressure area. The booster pump prevents damage and prolongs the life of the membrane and improves the TDS rejection of 26.4 or 52.8 liter per day. It is capable of removing over 96% of total dissolved solids +99% of all organics and +99% of all bacteria.

#### **OP6- CHART RECORDER**

Compact Dual Channel programmable Strip Chart Recorder with a digital display will record the temperature and pressure during the cycle.

#### **OP7- SUPERVISOR**

Totally independent monitoring and documenting system, the "SUPERVISOR" compares the parameters recorded by the basic automated sterilization process control system with the parameters recorded by its own completely independent sensors system. The "SUPERVISOR" perform a cross checking of the timing /stages/ cycles of the sterilization according to the limits and tolerances defined in EN285 and EN554 standards and sends it to the user alarms in case the parameters are not respected. The "SUPERVISOR" is connected to a printer which registers all parameters and provides documentary proof of the sterilization processes.

#### **OP8- MONITOR AND DOCUMENTATION SOFTWARE**

Powerful PC windows based software is available for monitoring, logging control and service.

#### **OP9- COOLING SYSTEM**

Allows fast cooling of the chamber for liquid programs. The autoclave can be equipped with 2 different cooling systems:

##### **OP9-1- Jacket Cooling System**

The cooling procedure reduces the jacket temperature rapidly. During this stage, compressed air is inserted into the chamber, maintaining the pressure of the chamber to prevent liquid overflow or container damage.

##### **OP9-2- Spray Cooling System**

Circulation pump pushes sterile water through heat exchanger and sprinklers, Cold water is being used in order to cool the heat exchanger. During the whole process, the Pressure inside the autoclave is maintained by using compressed air. As a result, the water temperature quickly drops, and the cooling is produced in the fastest way without damaging the content of the bottles.

#### **OP10- WATER SAVING SYSTEM**

The water saving system is supplied to reduce the amount of water used during a sterilizing (pre-vacuum, sterilization, and exhaust) cycle. This is accomplished by utilization of a heat exchanger.



## ■ MAINTENANCE AND AFTER-SALE SERVICE

High standards and reliable components, high quality constructions combined with service minded design make the Azteca sterilizer easy to maintain.

The access to the unit is easy from both front and side. The components selection and position designed to make it easy to reach and easy to service.

Because professionalism is not something that can be improvised, our After-sale service department maintains a network of competent technicians who can intervene all over the world. Maintenance, consultation, evaluation, prevention and training constitute the excellence of our services. Hospitals, clinics, laboratories: we share the same requirement which is keeping a perfect equation between your needs and our capacity to satisfy you.

## ■ TECHNICAL SPECIFICATIONS

MODEL AZTECA SERIES		A-470	A-570	A-5100
Chamber size mm	Diam	400	500	500
	D	700	700	1000
Stu Basket (600x300x300 mm)			1	1
Chamber volume	Ltr	90	140	200
Overall Size mm	W	750	1130	1130
	H	1670	1670	1670
	D	980	980	1140
Weight	Kg	150	300	350
Door		Manual Door		
Sterilization Temperature		105 - 138°C		
Vacuum System		Liquid Ring Pump		
Steam Source		Saturated Steam		
Pressure		3.5 - 5 BAR		
Compressed Air		5 - 7 BAR		
Water Source		Filtered Tap Water of 25°C Max.		
Pressure		1.0 - 6.0BAR		
Power Source		3-Ph.380 V, 50/60 Hz		
Without Generator (Kw)		1	1	1
With Generator (Kw)		10	10	19
External steam Generator				
Kw		9	9	18

## ■ COMPANY PROFILE

Celitron Medical Technologies Kft. is a dynamic company, developing and manufacturing infection control equipment and accessories.

Behind the success of this company is a team of multi-disciplinary engineers who developed sterilization equipment on OEM basis for leading manufacturers in the world, for the last 20 years. The fusion between the know-how of the research and development team and the quality manufacturing of the Hungarian team is the key of success of Celitron Medical Technologies Kft. The company is flexible, adapting itself to the modern hospital requirements, and is able to provide solutions to the most stringent demands of the infection control market.

## ■ STANDARDS

Medical Device Directive-93/42/EEC (MDD); Pressure Equipment Directive-97/23/EC (PED).  
 Safety and EMC Standards: EN 60601-1 + A1:93 + A2:95 + A13:96; EN 61010-2-040:05 (Safety);  
 EN 60601-1-2:01 (EMC); EN 285:06-Large Steam Sterilizers; EN 554:94-Sterilization & Validation.  
 Quality Management System Standards: ISO 9001:2000; ISO 13485:2003; ISO 14971  
 (Risk Management).



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