# Azteca A-501 Product Specification

## Product Description

Azteca A-501 is a fully automatic high-speed pre & post vacuum steam sterilizer.
This model is an electrically heated sterilizer, which operates with saturated steam as a sterilizing agent, and has a temperature between 121°C (250°F) and 134°C (273°F) and pressure up to 2.5 bars (36.3 psi).
The autoclave is classified as Class IIb according to MDD 93/42/EEC. The autoclave is designed as a Large Steam Sterilizer in accordance with EN285 and as Class I in accordance with EN60601-1, continuously operated, ordinary equipment without applied parts and without signal input-output parts. The device is not intended for use in the presence of flammable mixtures.

The sterilizer includes the following features:

- Large capacity sterilization chamber
- Vacuum pump for evacuation of the chamber
- Fully automatic door locking system – activated with one button on the display or with foot pedal
- Water reservoir for process and used water retention
- Water pump for water circulation
- Condenser and collector for condensation and collection of water
- Temperature sensors and a pressure transducer to monitor both vacuum and pressurized states
- Control valves operating at programmed intervals

*Illustration only

## Application

The unit is designed to cover a large field of applications for hospital CSSDs, pharmaceutical and biotechnological applications.

## Dimensions

| | |
|---|---|
| Inner chamber dimensions W x H x D: | 500 x 500 x 1035 mm |
| Chamber volume: | 255 Litres |
| External dimensions W x H x D: | 970 x 1810 x 1305 mm |

## Configuration and Options

| **Model** | **Heating** | **Door** |
|---|---|---|
| Azteca A-501 | Electric, 380-400V | Single or double |

**Available Options and Accessories:**

**Standard:**
□ Integrated ink printer
□ RS 232 communication port

**Optional:**
□ Built-in steam generator (27 kW)
□ Electropolished chamber
□ Biohazard cycle
□ 10″ LCD Display option
□ Stainless steel valves
□ Thermal printer
□ SD card slot with 2 GB SD card & reader
□ Reverse-Osmosis system (100 GPD)
□ Air compressor
□ HMI PC software
□ Side panels
□ Loading/unloading shelf rack
□ Loading/unloading trolley
□ Wire baskets and containers

## Languages

The operator panel is set up with following standard languages (maximum 8 languages per sterilizer, more option available upon request):

□ English □ Spanish □ French □ Hungarian □ Russian
□ Romanian □ Bulgarian □ Lithuanian □ Finnish □ Czech

## Standards

Azteca A-501 complies with following standards and codes:

*General Applicable Directives:*

Medical Device Directive- MDD 93/42/EEC on Medical devices Annex II excluding (4) as amended (2007/47/EEC);
Pressure Equipment Directive- PED 2014/68/EU
EMC Directive 2004/108/EC Article 7 (1)
RoHS II Directive 2011/65/EU

*Standards:*

47CFR part 15: 2004, subpart B, Class A;
EN 61326: 1997 + A1(98) + A2(01) Industrial locations equipment, Class A;
EN 60601 1:2006+AC:2010, EN 60601-1-2:2007+AC:2010, EN 60601-1-6:2010,
EN 62366:2008, EN ISO 10993-1:2009; EN 1041:2008, EN ISO 15223-1:2012
UL 61010-1:2004, EN/IEC 61010-1:2010;
EN 61010-2-040:05, UL 61010A-24-1:2002 edition 1997-05:2004;
EN 285:2006+A2:2009 - Large Steam Sterilizers

*The company's quality management system meets the following quality standards:*

- ISO 9001 – Quality Management Systems-Requirements.
- ISO 13485 – Quality systems - Medical devices - Particular requirements for the application of ISO 9001.
- EN ISO 14971 – Risk Management for Medical device.

# Azteca A-501 Product Specification

## Standard features

- **PRE- AND POST-VACUUM STERILIZER -** Using steam under pressure as the sterilizing agent for wrapped or unwrapped materials such as fabrics, surgical instruments, utensils, and other heat and moisture stable materials at temperatures from 121°C to 134°C. The A-501 sterilizer is a pre-and post-vacuum sterilizer designed to cover a large field of applications for hospitals, pharmaceutical and bio-technological applications.

- **DESIGN AND CONSTRUCTION –** The Azteca A-501 sterilizer has a floor standing design with the combination of stainless steel and glass. The sterilizer's framework, front panel and piping are made of stainless steel. The highly efficient, high-quality Hanno-Tech insulation material releases no particles; thus, the Azteca A-501 can be used under clean room conditions. The unit can come with or without stainless steel side panels, depends on customer's needs. The autoclave meets the highest standards requirements for quality, safety and operation.

- **CHAMBER -** The vessel is a double full jacketed square chamber, made of corrosion-resistant sandblasted stainless steel 316L, which conforms to the Pressure Equipment Directive (PED). The inner shell, door and jacket are designed for a maximum working pressure of 2.5 bar and full vacuum.

- **DOOR** – The door system is automatic and the sterilizer is equipped with one or two vertical sliding door(s), provided with a pneumatic locking mechanism, activated by an air- operated valve, and safety pin preventing the opening of the door when the chamber is pressurized.

- **VACUUM SYSTEM** – Equipped with a Liquid ring vacuum pump, combined with a heat exchanger, and is a pre- and post-vacuum sterilizer having the following features:
  - An air removal stage (pre-vacuum), before starting the sterilizing stage.
  - A post-sterilization drying phase, based on the combined operation of heat and vacuum with air inlet pulses.

  In order to improve the efficiency of the vacuum pump – capability and speed– a heat exchanger is installed on the outlet piping of the chamber.
  The advantages of the pre-vacuum sterilizer are as follows:
  - Removal of air pockets from packs and porous load and most kinds of hoses (rubber, plastic etc.) by vacuum at the first stage of the cycle.
  - Better steam penetration into the load; resulting in effective sterilization.
  - Better temperature uniformity.
  - Better drying of materials due to the vacuum achieved in the chamber at the end of the sterilization cycle.

- **WATER SYSTEM** – The sterilizer is equipped with a water reservoir for the drain water and liquid ring vacuum pump. For units with built-in steam generator, a Reverse-Osmosis water purification system is available in order to improve the quality of water used to generate steam and if no central purified water at site. All autoclaves are standard supplied with a water saving system to reduce the amount of water during the sterilization cycles.

- **CONTROL SYSTEM** – A microprocessor based control system automatically controls all cycles. The system includes a 5.7" digital touch-screen LCD display (for double door units in both sides), communication, self and remote diagnosis and PC connection for external documentation and printing. The displayed information is available for users in a variety of languages. During the sterilization cycle the control system measures, controls and shows in digital display: the time, chamber temperature, chamber and jacket pressure and sterilization status. While the power is off, the non-volatile memory keeps the status of the Sterilizer, and the real-time clock, driven by its own back-up battery, keeps running the date and time. The control system ensures high reliability, simplicity, safety of operation and automatic process cycles.

- **SAFETY FEATURES & ALARMS** – The sterilizer has numerous safety features including: a safety valve, thermostat, temperature sensors, a water detection


electrode in the steam generator, pressure sensors, a door locking device and software safety features.
The controller is capable of providing an audio alarm, as well as displaying and/or printing several alarms, including:
□ Door Unlock □ Temperature/Pressure Error □ Low/High Temperature □ Low/High Pressure □ Low Vacuum and more.

- **ENERGY SAVING MODE** – The sterilizer is equipped with an energy saving mode which is activated when the unit is not used after a certain period of time. This mode reduces power consumption by approximately 12% to 30% and is thus environmental friendly.

- **OPERATION** – Easy to use: close the door, select the cycle on the touch-screen panel, and press the 'Start' key. The cycle will run automatically. At the end of the cycle, by pressing the 'Open Door' button, the door will automatically open.

# Azteca A-501 Product Specification

## Options and Accessories

## STANDARD

- **BUILT-IN INK PRINTER**

The unit supplied with an integrated ink printer. Each cycle can be documented by the printer which records the preset and actual parameters of the cycle: the selected cycle, cycle parameters, date, time, temperature, pressure, errors, etc. The last 60 cycles' data is automatically stored in memory, and can be re-printed.

- **RS232 Communication Port**

RS232 communication port is standard supplied for all sterilizers in order to connect them to PC.

## OPTIONAL

- **STEAM GENERATOR**

The Azteca A-501 can be equipped with a built-in electrical steam generator (27 kW). The steam generator, made of stainless steel, enables steam to always be ready for operation, and thus contributes to very fast cycles with low energy consumption. It takes place in a vessel which is completely separated from the sterilization chamber (no heating elements in the chamber itself).

- **ELECTROPOLISHED CHAMBER**

The sterilizer's chamber comes with sand-blasted finish, at the time of order electropolished finishing can be requested.

- **BIOHAZARD CYCLE**

This option is used to verify that no unsterilized materials will be taken out of the sterilizer. In order to implement this verification, the sterilizer is equipped with a special biohazard door safety system and other biohazard features: a bio filter and a water sensor electrode. Condense is collected in the chamber and removed to the drain, after being sterilized. In case a cycle fails, there is a risk of contaminant and biohazard, therefore opening the door is not allowed. In order to open the door, water shall be removed from the chamber by pressing the 'FLUSH' key.

- **10˝ LCD DISPLAY OPTION**

The sterilizer standard supplied with LCD 5.7˝ color graphic touch-screen display. In case bigger display is needed the 10˝ LCD display option is available.

- **STAINLESS STEEL VALVES**

This option contains stainless steel 316L process valves, solenoid, air operated.

- **BUILT-IN THERMAL PRINTER**

For inkless cycle recording, instead of the standard supplied built-in ink printer, thermal printer can be supplied upon request. It has the same features, printing of the relevant information regarding operation during the cycle, such as temperature, pressure, vacuum, sterilization and drying time, number of cycles, etc.

- **SD CARD OPTION**

For paperless recording sterilization cycles' data can be also collected on a SD card through an optional SD card slot. Collected data can be downloaded into a computer equipped with proprietary PC Software (HMI Light). 2 GB SD card collects up to 40 years logging data, including: the selected cycle, start time, cycle stages, temperature / pressure, end time, cycle status (pass / fail), etc. All collected data can be printed via PC.

- **REVERSE-OSMOSIS (water softener)**

A Reverse-Osmosis system shall 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's 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. It is capable of removing over 96% of total dissolved solids +99% of all organics +99% of all bacteria.

- **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 valves and the automatic door.

- **HMI PC SOFTWARE (Monitoring and Documentation Software)**

Powerful PC Windows based software is available for monitoring, logging control and service. The software enables complete control over the sterilizer, including data receiving, creating graphs, parameter tables with the option of printing either graphs or texts.

# Azteca A-501 Product Specification

- **SIDE PANELS**

The Azteca A-501 sterilizer can be purchased as a standalone unit for free standing installation with stainless steel side panels, which cover the sides of the unit in order to protect the sterilizer's components from the dust.

- **LOADING/UNLOADING SHELF RACK**

Loading/unloading shelf rack is available to placing the instruments inside the chamber. The shelf rack has 1 fixed shelf on the bottom and 1 shelf, which can be placed in 2 levels.

- **LOADING/UNLOADING CART**

Loading/unloading cart is necessary for placing the shelf rack into the sterilizer's chamber. The cart comes with locking system to the chamber for easier loading and unloading and breakable wheels. For double door models 2 carts are suggested.

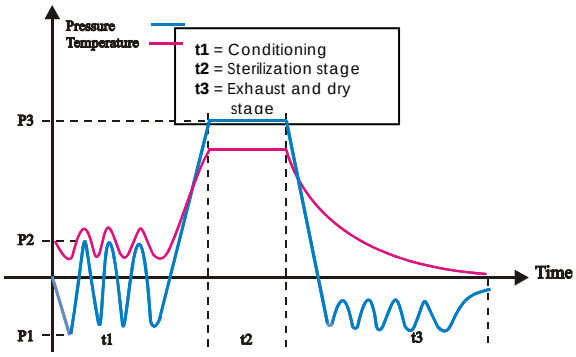
- **WIRE BASKETS AND ALUMINUM CONTAINERS**

Stainless steel wire baskets or aluminum containers in different sizes are available upon request.

# Azteca A-501 Product Specification

## Cycle descriptions

Azteca A-501 offers 7 different cycles: 5 sterilization cycles, and 2 test cycles.
5 preprogrammed sterilization cycles: flash cycle, cycles for wrapped and unwrapped materials, prion and porous cycles.
The two available test programs are the Vacuum Test for checking the integrity of the chamber and piping system and the Bowie & Dick test which checks the efficiency of the sterilization process.
Additional user defined cycles are available upon request.




### 1 - Flash 134°C /3 min (Warm Up).

Sterilizing unwrapped instruments. Without drying stage.
Load weight <10 kg/1STU or <20 kg/Tray.

- ☑ Sterilization temperature: 134°C, –0°C +3°C.
- ☑ Sterilization time: 3 minutes.
- ☑ Vacuum pulses: 4.
- ☑ Average cycle time: 20 minutes.

### 2 - Unwrapped 134°C /3 min, 2 min dry (Dynamic sterilizer chamber pressure).

Sterilizing unwrapped instruments. With drying stage.
Load weight <10 kg/1STU or <20 kg/Tray.

- ☑ Sterilization temperature: 134°C, –0°C +3°C.
- ☑ Sterilization time: 3 minutes.
- ☑ Dry Time: 2 minutes.
- ☑ Vacuum pulses: 4
- ☑ Average cycle time: 21 minutes.

### 3 - Wrapped 134°C /3.5 min, 15 min dry

Sterilizing wrapped instruments. With drying stage.
Load weight <10 kg/1STU or <20 kg/Tray.

- ☑ Sterilization temperature: 134°C, –0°C +3°C.
- ☑ Sterilization time: 3.5 minutes.
- ☑ Dry Time: 15 minutes.
- ☑ Vacuum pulses: 4.
- ☑ Average cycle time: 35 minutes.

### 4 - Prion 134°C /18 min, 20 min dry

Sterilizing wrapped instruments. With drying stage.
Load weight <10 kg/1STU or <20 kg/Tray.

- ☑ Sterilization temperature: 134°C, –0°C +3°C.
- ☑ Sterilization time: 18 minutes.
- ☑ Dry Time: 20 minutes.
- ☑ Vacuum pulses: 4.
- ☑ Average cycle time: 55 minutes.

### 6– Porous 121°C /20 min, 20 min dry

Sterilizing of heat sensitive materials and textiles. With drying stage.
Load weight <7.5 kg/1STU but maximum 10 kg.

- ☑ Sterilization temperature: 121°C, –0°C +3°C.
- ☑ Sterilization time: 20 minutes.
- ☑ Dry Time: 20 minutes.
- ☑ Vacuum pulses: 4.
- ☑ Average cycle time: 55 minutes.

### 8 – Bowie and Dick Test 134°C /3.5 min, 1 min dry (Hollow load A)

This is a test program, with fixed sterilization parameters of 134°C and 3.5 min., drying time of 1 min., which cannot be modified by the operator.

- ☑ Sterilization temperature: 134°C, –0°C +3°C.
- ☑ Sterilization time: 3.5 minutes.
- ☑ Dry Time: 1 minute.
- ☑ Vacuum pulses: 4.
- ☑ Average cycle time: 21 minutes.

### 9 – Leak Test (Vacuum test)

The vacuum pump is activated until the pressure reaches a level of at least 15 kPa, all the valves and pump shut down. The following 5 min. is for the stabilization condition of the chamber. From now on along the next 10 min. the allowable decrease of pressure is 0.13 kPa / min. (or 1.3 kPa for 10 min.)

## Azteca A-501 Product Specification

| Technical Data | Azteca A-501 |
|---|---|
| Chamber volume, net. | 255 litres (67,3 gal) |
| Inner chamber dimensions, W x H x D | 500 x 500 x 1035 mm (19.7 x 19.7 x 40,7 inch) |
| Chamber shape, type | Square, stainless steel 316L, welded, sandblasted |
| Jacket | Double full jacket |
| Door(s) | Fully automatic, vertical sliding, pneumatic door locking device with safety pin |
| External dimensions W x H x D | 970 x 1810 x 1305 mm (38 x 70.9 x 51.3 inch) |
| Approximate weight | 750 kg (1654 lb.) |
| Shipping dimensions W x H x D | 1140 x 2010 x 1475 mm (44.8 x 79.1 x 58 inch) |
| Approximate shipping weight | 850 kg (1874.0 lb.) (depends on ordered accessories) |
| Average water consumption during the cycle | 180 litres (47.55 gal) (depends on load and selected cycle) |
| Mineral free water reservoir volume | 8.5 liters (2.25 gal) |
| Max. water temperature at the reservoir | 65ºC (149ºF) |
| Max. working pressure | 2.5 bar (36.3 psi) |
| Min. working pressure | -0.9 bar (-13.5 psi) |
| Air removal | Fractionated vacuum |
| Drying system | Vacuum |
| Energy saving mode | Stand-by mode |
| Automatic water filling | Standard |
| Automatic water draining | Standard |
| Max. electric power without steam generator | 2 kW, 3 phase, 380-400V – 3 x 16A, 50/60 Hz |
| Max. electric power with steam generator | 27 kW, 3 phase, 380-400V – 3 x 63A, 50/60 Hz |
| Voltage fluctuation | ±10% |
| Peak sound level | < 70 dB |
| Operation | Electronic with microprocessor |
| Controls | Digital |
| Display | 5.7″ LCD color display, resistive touch-screen |
| Integrated printer | Ink printer (standard) |
| Connection to PC | RS232 (standard) |
| Number of sterilization cycles | 5 cycles - Flash 134 °C / Unwrapped 134 °C / Wrapped 134 °C / Prion 134 °C / Porous 121 °C |
| Average cycle time | Flash – 20 min / Unwrapped – 21 min / Wrapped – 35 min / Prion and Porous – 55 min |
| Sterilization temperatures | 121°C and 134°C |
| Number of test cycles | 2 cycles - Bowie & Dick test and Vacuum test |
| Max. recommended solid load | 10 kg (22.0 lb.) / 1STU or 40 kg (88.2 lb.) (20 kg/Tray) |
| Max. recommended textile load | 7.5 kg (16.5 lb.) / 1STU or 10 kg (22.0 lb.) (5 kg/Tray) |
| Appearance of face | Stainless Steel and glass |