

# AZTECA A-6612 610 LITRE STERILISER

## Azteca A-6612 Product Specification

### Product Description

Azteca A-6612 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 range of up to 137°C (279°F) and pressure up to 2.3 bars (34 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
- Water reservoirs 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

### Application

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

### Dimensions

Inner Chamber dimensions W x H x D: 700 x 700 x 1250 mm  
Chamber volume, net.: 610 Litres (8 STU)  
External W x H x D: 1116 x 1950 x 1520 mm

### Configuration and Options

Model	Heating	Doors
<input type="checkbox"/> Azteca A-6612	<input type="checkbox"/> Electric, 400V, AC	<input type="checkbox"/> Single or Double

#### Available Accessories

- Impact Printer
- RS 232 Communication port
- SD Card & Reader
- HMI PC Software
- IQ, PQ, OQ
- SES 285 Sterilizer Evaluation System
- Reverse-Osmosis System
- Built-in Steam Generator
- Bio Shield
- Biohazard filter
- Side panels/Cabinet
- Shelf rack
- Loading/Unloading cart
- ISO Baskets
- Water recycling system
- Silent Air compressor



### Languages

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

- English     Romanian     Russian     French

### Standards

Azteca A-6612 complies with following standards and codes:

- CE 0473 Approved by the British Notified body Intertek – AMTAC.
- EN 285:2006 – Large Steam Sterilizers.
- Medical Device Directive (MDD) 93/42/EEC.
- EN 61010-1:01 – Safety of electrical equipment – General Requirements.
- EN 61010-2-040:05 Safety requirements for electrical equipment for measurement, control and laboratory use.
- EN 61326 (Directive 89/336/EE) – (EMC) Emission compatibility.
- EN 61000-6-2; EN 61000-6-4 Electromagnetic compatibility (EMC)-Generic standards- Emission and Immunity for industrial environments.
- Pressure Equipment Directives (PED) 97/23/EC Essential safety requirements.
- ISO 17665-1:2006 – Sterilization of health care products Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Quality Management System Standards:
- ISO 9001: 2008 – Quality Management Systems-Requirements.
- ISO 13485:2003 – Quality systems - Medical devices - Particular requirements for the application of ISO 9001.
- EN ISO 14971 –Risk Management for Medical device.

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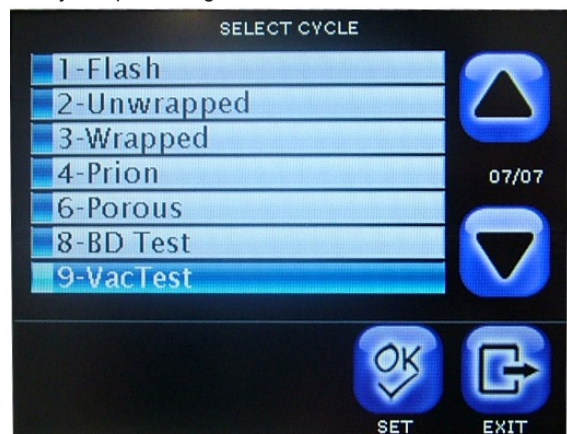
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### Standard features

- **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 121°C to 134°C. The A-6612 sterilizer is a pre-and post-vacuum sterilizer designed to cover a large field of applications for hospitals, laboratories, pharmaceutical and bio-technological industries. Within the health care 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 care facilities, have been developed.
- **Design and Construction** - The Azteca A-6612 sterilizer meets the highest standards requirements for quality, safety and operation. The sterilizer's framework, piping and housing are also made of stainless steel. The highly efficient, high-quality Hanno-Tech insulation material releases no particles; thus, the Azteca A-6612 can be used under clean room conditions.
- **Chamber** - The vessel, with a double full jacketed square chamber, is made of corrosion-resistant sandblasted stainless steel 316 L, and is thus easy to clean. Stainless steel pressure vessels 316 L conforms to the Pressure Equipment Directive (PED). The inner shell, door(s) and jacket are designed for a maximum working pressure of 2.76 bar and full vacuum.
- **Exterior** – Stainless steel cover with or without stainless steel side panels.
- **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.
- **Safety Devices**  
Numerous safety features including: a safety valve, thermostat, a temperature sensor, a water detection electrode in the steam generator, pressure sensors, a door locking device and software safety features.
- **Alarms** – Depending on the state of the input and of the installed accessories, 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.
- **Door locking mechanism** – The door system is automatic and the sterilizer is equipped with one or two vertical sliding doors, 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.
- **Water system** – The sterilizers are equipped with 2 Water Reservoirs: one for the drain water and liquid ring vacuum pump and one for the mineral free water for saturated steam.
- **Energy saving mode** - The Sterilizers are 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.
- **Control system / Touch screen panel** – A microprocessor based control system, state of the art "Free scale" technology, automatically controls all programs including the sterilization cycle. The system includes a 5.7" digital touch-screen graphic display (for double door units 2 displays), communication, self and remote diagnosis and PC connection for external documentation and printing. It ensures a reliable, safe and user-friendly operation. 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 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.



- **Operation** – Operating is simple: 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 on the Touch-Screen Panel, the door will automatically open.

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- **Printer** – The unit supplied with an integrated impact 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.



### Options and Accessories

- **Data collection** – Sterilization cycles' data can be collected online through standard RS232 connection, enables connecting the computer and the Sterilizer using the PC Software (optional).

Sterilization cycles' data can be also collected online on a SD Card through an optional SD Card Slot. Collected data can be downloaded into a computer equipped with proprietary PC Software. 2 Gigabyte 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. An optional Ethernet Connection enables controlling, monitoring and connecting your Azteca A-6612 sterilizer with no need of additional software.



- **Monitoring and Documentation Software (HMI Software)** – Powerful PC Windows based software is available for monitoring, logging control and service.
- **Sterilizer Evaluation System (SES 285)** – A 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 sensor system. The "SUPERVISOR" performs a cross checking of the timing/stages/cycles of the sterilization according to the limits and tolerances defined in EN285, and sends it to the user alarms in case the parameters are not accepted. The "SUPERVISOR" is connected to a printer which registers all parameters and provides documentary proof of the sterilization processes.
- **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. The booster pump prevents damage, prolongs the life of the membrane and improves solids +99% of all organics +99% of all bacteria.
- **Steam generator** – The Azteca A-6612 sterilizer can be equipped with a built-in 54 kW steam generator, when central steam source is not available. The steam generator is made of stainless steel 316 L. The large capacity of the heaters enables steam to always be ready for operation, and thus contributes to a very fast cycle.

- **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's jacket, to completely separate between sides.
- **Biohazard filter** – 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 bio-hazard door safety system and other bio-hazard features: a bio-hazard 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 bio-hazard, 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.
- **Side panels / cabinet** – The Azteca A-6612 sterilizer can be purchased as a standalone unit with stainless steel side panels.
- **Shelf rack** – Stainless steel shelf rack with 2 shelves.
- **Loading/Unloading cart** – Stainless steel loading / unloading cart is available. For double door unit two carts are suggested.
- **ISO Baskets** – Stainless steel wire baskets are available upon request (size: 300\*300\*600 mm).
- **Water recycling system** – The water saving system is supplied to reduce the amount of water used during the sterilization (pre vacuum, sterilization, exhaust and drying) cycle.
- **Silent 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 power door.

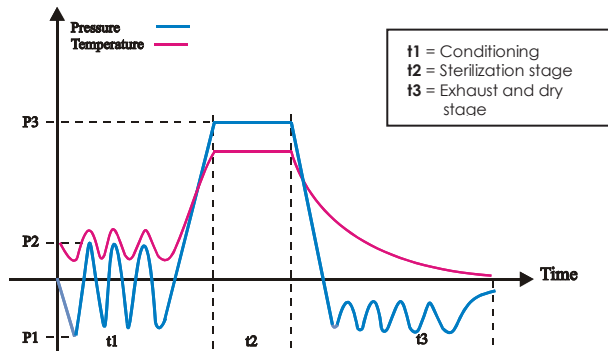


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## Azteca A-6612 Product Specification

### Cycle descriptions

Azteca A-6612 offers 7 different cycles: 5 sterilization cycles, and 2 test cycles. Additional cycles are available upon request. 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.



#### 1 - Flash 134°C /3 min (Warm Up).



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

- ☑ 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.  
Load weight <10 kg/1STU. With drying stage.

- ☑ 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.  
Load weight <10 kg/1STU. With drying stage.

- ☑ 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.  
Load weight <10 kg/1STU. With drying stage.

- ☑ 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.  
Load weight <7.5 kg/1STU. With drying stage.

- ☑ 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.)

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Technical Data	Azteca A-6612
Cycle type (according to EN 285)	B
External dimensions W x H x D	1116 x 1950 x 1520 mm (43.9 x 76.8 x 59.8 inch)
Chamber volume, net.	610 Litres. (161.1 gal) (8 STU)
Chamber shape, type	Square 316L, welded, sandblasted
Inner Chamber Dimensions, W x H x D	700 x 700 x 1250 mm (27.6 x 27.6 x 49.2 inch)
Approximate Weight	1000 kg (2204.6 lb)
Approximate Shipping weight	1240 kg (2733.7 lb)
Shipping dimensions W x H x D	1370 x 2210 x 1600 mm (53.9 x 87.0 x 63.0 inch)
Mineral free water reservoir volume	8,5 Litres (2.25 gal)
Average water consumption during the cycle	225 Litres (59.4 gal) (depends on load and selected cycle)
Max. Water temp. at the reservoirs	65°C (149°F)
Max. Working pressure	2.76 bar (40 psi)
Min. Working pressure	-0.9 bar (-13.5 psi)
Jacket	Double full jacket
Peak sound level	< 70 dB
Max electric power without steam generator	2 kW, 3 phase, 400V – 3 x 16A, 50/60 Hz
Max electric power with steam generator	56 kW, 3 phase, 400V – 3x 100A, 50/60 Hz
Voltage fluctuation	±10%
Operation	Electronic with microprocessor
Controls	Digital
Display	LCD Color Display, Resistive Touch Screen
Integrated printer	Yes -(Standard)
Connection to PC	Standard RS232, USB connection for service technicians and Ethernet connection as an option
Maximum recommended solid load	10 kg (22.0 lb) / 1STU
Maximum recommended textile load	7.5 kg (16.5 lb) / 1STU
Number of Cycles	7 cycles - 5 sterilization cycles and 2 test cycles
Cycle type (stated load types)	Wrapped or non-wrapped, solid, hollow load products Type A and porous products.
Sterilization temperatures	134° - 121° C
Special / Test Cycles	Bowie & Dick test and Vacuum test
Air removal	Fractionated vacuum
Drying system	Vacuum
Suggested Cycle time (minutes)	Total time: Flash134-(20 min) unwrapped +hollow134 (21 min) , prion, porous 134 (55 min), wrapped 134-(35 min)
Stand-by	Yes
Appearance of Face	Stainless Steel
Automatic water filling	Standard
Automatic water draining	Standard
Door locking device	Fully automatic, pneumatic door locking device with safety pin