

Azteca A-446 Product Specification

Product Description

Azteca A-446 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

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: 406 x 406 x 670 mm
 Chamber volume: 110 Litres
 External dimensions W x H x D: 660 x 1900 x 910 mm

Configuration and Options

Model	Heating	Door
Azteca A-446	Electric, 380-400V	Single

Available Options and Accessories:

Standard:

- Built-in steam generator (12 kW)
- Integrated thermal printer
- RS 232 communication port
- Stainless steel internal shelves

Optional:

- Electropolished chamber
- Biohazard cycle
- Stainless steel valves
- 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



*Illustration only

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-446 complies with following directives and standards:

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.

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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-446 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-446 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-446 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 vertical sliding door, 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, 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.

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Options and Accessories

STANDARD

- **STEAM GENERATOR**

The Azteca A-446 sterilizer is equipped with a built-in electrical steam generator (12 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).

- **PRINTER**

The unit supplied with an integrated thermal 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.

- **INTERNAL SHELVES**

2 stainless steel internal shelves are standard included for easy loading.



OPTIONAL

- **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.

- **STAINLESS STEEL VALVES**

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

- **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.



- **SIDE PANELS**

The Azteca A-446 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.



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- **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.



- **WIRE BASKETS AND ALUMINUM CONTAINERS**

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



Distributor:



DELTA PLUS (PVT) LTD.

H # 220, STREET # 13

Khayaban-E-Kashmir

G-15/4, Islamabad , Pakistan

TEL+92(51)2160155-6

FAX: +92(51)2160157

info@deltapluspvt.com

URL: www.deltapluspvt.com

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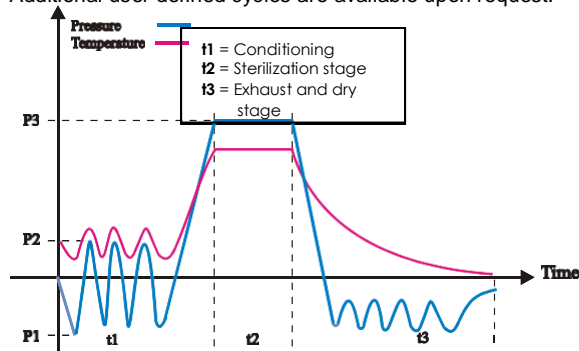
Cycle descriptions

Azteca A-446 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 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 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 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 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 8 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.)

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Technical Data	Azteca A-446
Chamber volume, net.	110 litres (29.06 gal)
Inner chamber dimensions, W x H x D	406 x 406 x 670 mm (16.0 x 16.0 x 26.4 inch)
Chamber shape, type	Square, stainless steel 316L, welded, sandblasted
Jacket	Double full jacket
Door	Fully automatic, vertical sliding, pneumatic door locking device with safety pin
External dimensions W x H x D	660 x 1900 x 910 mm (26.0 x 74.8 x 35.8 inch)
Approximate weight	350 kg (771.6 lb.)
Shipping dimensions W x H x D	810 x 2100 x 1400 mm (31.9 x 82.7 x 47.2 inch)
Approximate shipping weight	510 kg (1124.3 lb.) (depends on ordered accessories)
Average water consumption during the cycle	120 litres (31.7 gal) (depends on load and selected cycle)
Mineral free water reservoir volume	8.5 liters (2.25 gal)
Max. water temperature at the reservoir	65°C (149°F)
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 with steam generator	14 kW, 3 phase, 380-400V – 3 x 25A, 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	Thermal 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 20 kg (44.0 lb.) (10 kg/Tray)
Max. recommended textile load	7.5 kg (16.5 lb.) / 1STU or 8 kg (17.6 lb.) (4 kg/Tray)
Appearance of face	Stainless Steel and glass