

# Azteca AC Series

High-Tech in Sterilization



\*Cabinet mounted

**celitron**

medical technologies

**WE DO IT RIGHT!**

# Round Chamber Large Steam Sterilizer



## ■ MICROPROCESSOR CONTROLLED STEAM STERILIZER

The Azteca AC Sterilizer uses 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 ranging from 105°C to 138°C. The Sterilizer has an operating range of up to 2.5 Bar / 138°C.

The Azteca AC Sterilizer is a pre-vacuum/gravity sterilizer designed to cover a large field of applications for hospitals and medical centers.

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 AC 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.

## ■ CHAMBER

The Vessel is double-wall constructed with a round chamber, made of corrosion-resistant electro-polished Stainless Steel 1.4571 (V4A) AISI 316 Ti, and is thus easy to clean. The Sterilizer's framework and housing are also made of Stainless Steel. The highly efficient, high-quality Hanno-Tech insulation material releases no particles; thus, the Azteca AC Sterilizer can be used under clean room conditions.

## ■ DOOR (S)

The Sterilizer is supplied with either 1 or 2 hinged door(s) with an automatic door-locking device. Special safety features prevent the operator from opening the door when the chamber is pressurized or when the temperature is high.

## ■ GASKET

The sealing of the chamber is made by utilizing a heat-resistant silicone rubber gasket.





# HIGH-TECH IN STE

## ■ CYCLE DOCUMENTATION

For a clear and concise documentation of processes, the control unit is provided with a 24 character per line printer, connected to the processing Sterilizer. This releases a hard copy printing of the relevant information regarding 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 the cycle failure and the cause of the failure. RS485/RS232 PC communication port is available for full documentation and optional advanced Windows based software is available for monitoring, logging and control. A circular or strip temperature and pressure chart recorder can be supplied upon request.



## ■ STEAM GENERATOR

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



## ■ AIR COMPRESSOR

An electrically operated air compressor is provided in order to prevent a lack of available compressed air. The air is used to operate the Sterilizer's ball valves and/or power door.

## ■ COMMUNICATION SYSTEM

### PC Software

PC Software is available in order to collect and document the sterilization programs. The connection is done through RS232, USB or RS485.

### Data Collection

Sterilization cycles' data can be collected online on a SD card through a SD card slot, and can be downloaded into a computer equipped with proprietary PC Software. 1 Gigabyte SD card can collect up to 20 years logging data which includes: the selected cycle, start time, cycle stages, temperature/pressure, end time, cycle graph, cycle status (pass/ fail), etc. All collected data can be printed via PC.



### SD card & reader

1 SD card and 1 card reader are included.



# STERILIZATION



## ■ OPTIONS

### Option 1 → 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.

### Option 2 → 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 Sterilizer. A metal flange is welded around the Sterilizer's jacket, to completely separate between sides.

### Option 3 → LOADING EQUIPMENT

Each Sterilizer can be supplied with Stainless Steel shelves or a Stainless Steel loading cart and carriage.

### Option 4 → REVERSE-OSMOSIS

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 Sterilizer'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 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 + 99% of all bacteria.

### Option 5 → CHART RECORDER

A compact Dual Channel Programmable Strip Chart Recorder, with a digital display, can record the temperature and pressure during the cycle.

### Option 6 → SUPERVISOR

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 sensors 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.

### Option 7 → MONITORING & DOCUMENTATION SOFTWARE

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

### Option 8 → WATER SAVING SYSTEM

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

### Option 9 → BIO-HAZARD

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.

# 10 Reasons to choose Azteca AC Large Steam Sterilizer



## 1 High Quality Components

The chamber is built of Stainless Steel 316 Ti. All components have been purchased meeting the highest quality standards requirements from known leading companies around the world.

## 2 High Reliability

Behind the success of the company is a team of high-skilled professionals, including multi-disciplinary engineers, who develop sterilization equipment on OEM basis for leading manufacturers in the world, for more than 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 to Celitron Medical Technologies' success.

## 3 Outstanding Performances

- **Vacuum System** - Air removal via a powerful vacuum system, using a liquid ring vacuum pump and a condenser.
- **Large capacity** - Models from 90 to 200 liters fits 1 STU (except the 65 liter model), as well as varied chamber dimensions according to specific demands.

## 4 Modern Design

A combination of simple lines, modern colors and state of the art technology.

## 5 High Technology

- **Simple operation** using a high-tech computerized control system.
- Optional **powerful PC Windows based Software** is available for monitoring, logging, control and service.
- **A Graphic Display** and an ergonomic User Interface.
- Sterilization cycles' data collected online on a **SD card**.
- **The most advanced interface connections:** Ethernet, USB, RS232 and RS485.

## 6 Reliable Service

Azteca AC Sterilizers are easy to maintain thanks to the design of all internal and external components. The component selection and position is designed to make it easy to reach and easy to service. The access to the unit is easy from both front and side. The service technician can monitor all service processes via PC. Celitron's After-Sale Service Department maintains a network of competent technicians who can assist all over the world.

## 7 Easy to use

- **A fully automatic door-locking device.** Opening and closing of the door by pressing only one button.
- **A RO water purification system** is available in order to improve the quality of the water used to generate steam in the electric steam generator.
- **A friendly Graphic User Interface**, available for users in a variety of languages.

## 8 Environmental Friendly

- **Energy saving mode** reduces power consumption and is thus environmental friendly.
- **The water saving system** is available to reduce the amount of water used during the sterilization (pre-vacuum, sterilization and exhaust) cycles. This is accomplished by utilization of a heat exchanger.
- **Paperless recording** using a SD card.

## 9 Highest Standards

- Meets the highest standards requirements for quality and safety, complies with EN 285 (Large Steam Sterilizers Standard).
- Stainless Steel Pressure Vessels 316 Ti conforms to the Pressure Equipment Directive (PED).
- Safety Standards: EN 60601-1, EN 61010-1 and EN 61326.
- CE 0473 approved by the British notified body Intertek-AMTAC.

## 10 We do it right!

Celitron Medical Technologies is committed to the continuous improvement of our products, while keeping up to date with the most advanced technologies, regulation requirements and keeping our customers satisfied.



## ■ TECHNICAL SPECIFICATIONS

MODEL AZTECA SERIES		AC-450	AC-470	AC-550	AC-575	AC-5100
Chamber Size (mm)	Diam	400	400	500	500	500
	D	500	700	500	700	1000
Load Capacity (596x275x270 mm)		-	1	-	1	1
Chamber Volume (total/nominal) (Liter)		70 / 65	95 / 90	110 / 100	160 / 150	210 / 200
Overall Size (mm)	W	750	750	850	850	850
	H	630	630	730	730	730
	D	770	970	810	1050	1300
Weight (Kg)		100	145	150	190	210
Door	Automatic 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					
Power including Steam Generator (kW)	10	10	10	10	10	10





# Azteca AC Series

## Large Steam Sterilizer

### ■ Company Profile

**Celitron Medical Technologies Kft. is a developer and manufacturer of high quality Sterilizers** (Bench-Top and Large Steam Sterilizers, Plasma Sterilizers, HMI, Sterilizer Evaluation System) that meets stringent requirements which are secured in a Quality Management System in accordance with International Standards. The company controls, measures and analyzes all processes and implements any action for achieving the required output.

With selected and tailor made models for OEM partners and distributors in these markets, Celitron is aiming to secure a stronghold in the European market in the long term by means of high service quality and strong delivery capacity, and to enter attractive markets such as Asia and America with an expanding sales team.

Celitron intends to grow globally by developing new solutions for the Medical, Dental and Laboratory markets of tomorrow. Celitron's strong innovative drive is based on close relationships with partners and the know-how of the research and development team as well as the quality manufacturing of the Hungarian team.

#### **Celitron's products comply with the following international standards and directive guidelines:**

CE 0473 Approved by the British Notified body Intertek- AMTAC.

**EN 285-** Large Steam Sterilizers; **Medical Device Directive** (MDD) 93/42/EEC; **Pressure Equipment Directive** (PED) 97/23/EC; **ISO 17665-1:2006.**

#### **Safety and EMC Standards:**

**EN 60601-1+ A1:93 + A2:95-** Medical Electrical Equipment- General Requirements for Safety; **EN 61010-1-** Safety Electrical Equipment for Laboratory Use; **EN 61010-2-040:05-** Safety requirements for electrical equipment for measurement, control and laboratory use- Particular requirements for sterilizers and washer-disinfectors used to treat medical materials; **EN 60601-1-2:01-** Medical electrical equipment- General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests (EMC);

**EN 61326:** 1997 + A1:98 + A2:01+ A3:03 Electrical equipment for measurement, control and laboratory use- EMC-requirements; **EMC Directive** 89/336/EEC Article 7 (1).

#### **Quality Management System Standards:**

**ISO 9001: 2000-** Quality Management Systems- Requirements; **ISO 13485:2003-** Medical devices - Quality management systems- Requirements for regulatory purposes; **EN ISO 14971 –** Risk Management for Medical device.



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