HORIZONTAL- FLOOR- STANDING AUTOCLAVES **WITH ROUND CHAMBER** 295 - 825 Liter

ZIRBUS TECHNOLOGY

COST EFFECTIVE ALTERNATIVE TO THE ANGULAR CHAMBER

LOW LOADING HEIGHT

LOW MEDIA REQUIREMENTS

SHORT PROCESS TIMES

Technical data	LabStar 330	LabStar 475	LabStar 560	LabStar 825
Dimensions in mm (W x H x D)	950 x 1750 x 1168	950 x 1750 x 1468	950 x 1750 x 1768	950 x 1750 x 2368
Chamber capacity in Liters	330	475	560	825
Free usable space in mm (Ø x D)	750 x 670	750 x 1070	750 x 1270	750 x 1870

DESCRIPTION OF THE **INDIVIDUAL COMPONENTS**

ZIRBUS TECHNOLOGY

CONNECTION TO A CENTRAL STEAM SUPPLY

Alternatively or in addition, the autoclave can be connected to a central steam supply. Design includes all necessary fittings.

GASTIGHT PARTITION (BIOSEAL) FOR PASS-THROUGH VERSION

This (gas)tight partition is required when the autoclave is installed between two rooms with different pressure and safety classes. This ensures that there is no air exchange (diffusion) between the rooms.

WATER-SAVING FEATURE FOR MANTLE COOLING SYSTEM AND VACUUM PUMP

To save cold water, the active cooling and the vacuum pump can be connected to an in-house cooling water circuit. This results in a reduction in water use by up to 95 percent.

STEAM/AIR MIXTURE METHOD (DLGV)

Thermolabile and pressure-sensitive packaging, e.g. blister packaging and closed bottles, can be gently sterilized using this method.

SPRAY COOLING

The sterilization material to be cooled is cooled down very quickly and evenly to the set removal temperature. Cooling takes place by directly spraying the product with cold water, including support pressure regulation.

HOT WATER IRRIGATION METHOD (HWBV)

Instead of steam, the product is irrigated and sterilized with hot water. This is performed via spray nozzles in the chamber. The method is especially suitable for steril-izing closed containers and large quantities of liquid.

STERILIZABLE INTAKE AIR FILTER

The filter element is mounted in a stainless steel housing and is automatically sterilized inline with each sterilization cycle. An additional Class A PT100 temperature sensor monitors the temperature during this process.
The autoclave display shows the intervals for replacing the filter element.

SPECIAL PROGRAMS

We create customer-specific special programs ourselves through our own software development department. These include, for example:

- ISO - 4802
- ATF filter program
- Durham program

AUTOMATIC FILTER INTEGRITY TEST (WIT TEST)

This test is recommended to ensure increased safety. In addition, it is used to check the function of the supply air or exhaust air filter. The review of the intervals can be defined through the software. This is a validated method.

CONTROL VALVES FOR RAMP FUNCTION

This yields additional adjustment options in the program control:

- Evacuation speed using vacuum pump adjustable in mbar/min
- Heating speed adjustable in °C/min
- Pressure release speed adjustable in mbar/min

The values can be individually adjusted for each program.

VALIDATION

To provide reproducible results, the autoclave processes are individually validated according to DIN EN 17665. The validation is the inspection of the device with regard to its proper functioning. This is performed under real-life conditions with the customer's product in order to check the process parameters.
In doing so, the temperature distribution in the sterilization chamber at various measurement points plays a crucial role. The process requirements are met if the temperature differences are the same as or less than the temperature range specified by the customer.

VALIDATION PROCEDURE

Calibration of the process-related temperature and pressure sensors.

Specification of the program parameters such as sterilization temperature, prevacuum, drying and cooling. In this process, the customer specifies the limiting conditions of the program to be validated.

Performing standardized tests: Example: Bowie+Dick as well as vacuum air test.

To record process data, dataloggers are placed in the sterilization chamber together with the customer's product.

Solids: The datalogger sensors are placed in the product. **Liquids:** The datalogger sensors are placed in the liquid. Depending on the product, reference containers of the same size – filled with water – may also be used.

Performing the program to be validated.

Evaluation/monitoring of the specified program parameters and limits.

INDUSTRY PC – IPC DOCUMENTATION SOFTWARE

The IPC is a add-on module of the standard touch screen. With this add-on, additional comprehensive functions are available to the user. In this way, we achieve the best possible combination of software and hardware for you for controlling and monitoring your processes.

EXPANDED OPTIONS

- Independent documentation (analog values) of temperature and pressure
- Batch documentation as PDF and CSV file
- Automatic printout of batch documentation after the end of the program
- Expandable storage module to file the batch logs
- 99 formulations can be defined as desired
- Integration in the network and thus possible remote maintenance of the entire system
- Optional user management to set up different user groups

The batch documentation consists of a graphic representation of the temperature and pressure gradients. On the second page of the documentation, the individual program steps are listed in table form. If a value should be outside of the target value, this is automatically marked in red. Included in the batch log is also a personalized signature field for acknowledging batches.

QUALIFICATION

Qualification serves as proof that the manufactured system meets the requirements agreed on and that the performance characteristics as well as the versions are compliant. The qualification is performed according to DIN EN 58950-3 and GMP guidelines.

DESIGN-QUALIFICATION (DQ)	Specification of the requirements for the system in the form of a DQ plan/specifications. Comparison of the requirements by means of DQ report/specifications, alternative offer (SDS, FDS, HDS).
INSTALLATION QUALIFICATION (IQ)	During the IQ, it is documented that the system, as it is installed, matches the information in the specifications and the requirements from the DQ. · Material documentation · Calibration · Review of the piping plan
OPERATION QUALIFICATION (OQ)	During the OQ , it is documented that the system is fully functional. This includes tests to be performed which are as realistic as possible or which are to be performed under routine manufacturing conditions.
PERFORMANCE QUALIFICATION (PQ)	Within the PQ, the validation report is generated with the customer's product and proof is provided that the system meets the targeted performance parameters.
FACTORY ACCEPTANCE TEST (FAT)	Acceptance of the system in the manufacturing factory according to the FAT protocol. Here the proper functioning and design of the system are reviewed together with the customer.
SYSTEM ACCEPTANCE TEST (SAT)	The SAT includes the implementation of the IQ and OQ at the customer's final installation location. A Zirbus employee qualified to perform this task conducts the qualification of the system on site together with the customer. In this process, he/she verifies the proper functioning according to the requirements specified by the customer.
REQUALIFICATION	During requalification, it is ensured that the system is still in a qualified condition following changes. Quality-related system parameters are assessed and evaluated. In general, the requalification consists of the same tests which were already performed during the initial qualification.
CONFIGURATION SPECIFICATION	The configuration specification has replaced the earlier customary documents of the hardware design specification (HDS) and software design specification (SDS). The following parameters are described here, as a matter of priority: • Hardware components and versions • Firmware versions • Software versions • Description of the sensors • Description of the performance parameters • User profiles
FUNCTIONAL DESIGN SPECIFICATION (FDS)	In the case of the FDS, the system manufacturer confirms the correct execution of the system according to the customer's specifications. The features of the system are described and performance parameters as well as components used are defined and documented.

DOCUMENTATION

Available in six versions to fit your needs.

BATCH PRINTER

Generates an informative paper printout with all relevant data at the end of the process.

STERILOG

BATCH DOCUMENTATION SOFTWARE

Windows-based software automatically reads the process data from the autoclave and processes these data into a graphic and numeric PDF log (direct coupling with the Ethernet interface RJ45).

USB MEMORY CARD

To record process data on a USB stick at an integrated USB port of the autoclave; includes “SteriLog” evaluation software.

INDEPENDENT DOCUMENTATION

The measured values for temperature and pressure for batch documentation are recorded independently of the SPS control according to DIN EN 285. This enables independent recording of three temperature sensors and a pressure sensor.

10-CHANNEL SCREEN PRINTER

GMP-COMPLIANT

To ensure GMP-compliant documentation, this must be performed according to
FDA 21 CFR Part 11 and GMP.
It must be ensured that the documented process data cannot be manipulated in any way. The system must be protected from unauthorized access and monitored with the aid of audit trails. Any user activities are documented and recorded. Electronic signatures can be used to confirm formulations.

SERVICE & QUALIFICATION

SERVICE

We offer you outstanding service. Our employees regularly take part in training sessions to make high-quality service possible.

HOTLINE

Our technical hotline will assist you regarding operation and if you are having system- or process-related problems.
If you need us, we can get to you within 24 hours.

REPLACEMENT PARTS

We process spare parts deliveries immediately. Delivery is generally made the same day.

CONSULTATION

We can provide you with advice regarding your project and draw on our experience to assist you.
Sample sterilizations can also be carried out in our application laboratory.

OUR SERVICES INCLUDE:

- Delivery, installation and training
- Maintenance and Service
- Calibration with DKD (German Calibration Service)-tested measuring instruments
- Validation according to recognized guidelines
- Quali ication DQ / IQ / FDS, SDS, HDS /OQ / PQ according to GMP guidelines
- Customized process development and optimization
- Sterilization and drying on a contract basis in our own application laboratory

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