



THERMAL SYSTEMS

Process Engineering for your processes optimisation needs

Engineering under high pressure
Made in Germany



ZIRBUS
TECHNOLOGY

ZIRBUS TECHNOLOGY GMBH

Since its founding in 1984, ZIRBUS technology GmbH, as a German manufacturer, has gained an outstanding reputation on the international market. We manufacture not only freeze dryers and autoclaves but also focus on process technology. A steadily increasing number of customers is putting their trust in Zirbus brand autoclaves and lyophilizers.



Our customers' satisfaction is our top priority...



TOGETHER WITH OUR CUSTOMERS, WE CONTINUALLY DEVELOP NEW SOLUTIONS FOR VARIOUS AREAS OF APPLICATION



WE TAKE ADVANTAGE OF EVERY POSSIBLE OPPORTUNITY FOR IMPROVEMENT



PERFECTION IN SERVICE IS WHAT DRIVES US



EFFICIENT AND RELIABLE TECHNOLOGY



A PERFECT COMBINATION OF SOFTWARE AND HARDWARE



TECHNICALLY PERFECTED AND VALIDATABLE PROCESS ENGINEERING

CERTIFIED QUALITY

ASME certified

Modul H certified

EN ISO 9001 certified

The quality management (QM) system according to DIN EN ISO 9001 implemented and practiced at ZIRBUS technology GmbH provides the framework for our quality- and cost-oriented activities.

In addition, a risk management system is a component of the QM system.



COMPACT DESIGN, THEREFORE LESS SPACE REQUIRED AT THE INSTALLATION



PRESSURE VESSEL DESIGN UP TO 8 BAR, OPTIONALLY UP TO 20 BAR



HEATABLE FEED WATER TANK TO REDUCE INERT GASES



SHORT HEATING-UP TIMES

Technical data	Steamboy 9	Steamboy 18	Steamboy 22	Steamboy 30	Steamboy 37	Steamboy 50	Steamboy 65	Steamboy 80	Steamboy 120
Dimensions in (W x H x D) mm	400 x 724 x 553	504 x 724 x 853		685 x 1237 x 867			800 x 1725 x 1180		1045 x 1080 x 1845
Electric power kW	9	18	23	30	38	50	60	78	114
Steam performance kg / h	12	24	30	39	49	65	85	102	150
Operating pressure bar (G)	4,5 (optionally up to 20 bar)								
Permissible operating temperature	155 ° C								

The Steamboy steam generator

Our compact, Steamboy series electric steam generators are available in sizes ranging from 9-120 kW (12-150 kg/h of steam).

Maximum permissible operating temperature for standard generators is 155° C at an operating pressure of 4.5 bar. Pressure may also be elevated to a maximum of 20 bar (optional).

The pressure vessel is made entirely of AISI 316L (1.4404) stainless steel. Highly efficient insulation keeps heat dissipation to a minimum. The housing and supporting frame are made of finely brushed AISI 304 (1.4301) stainless steel.

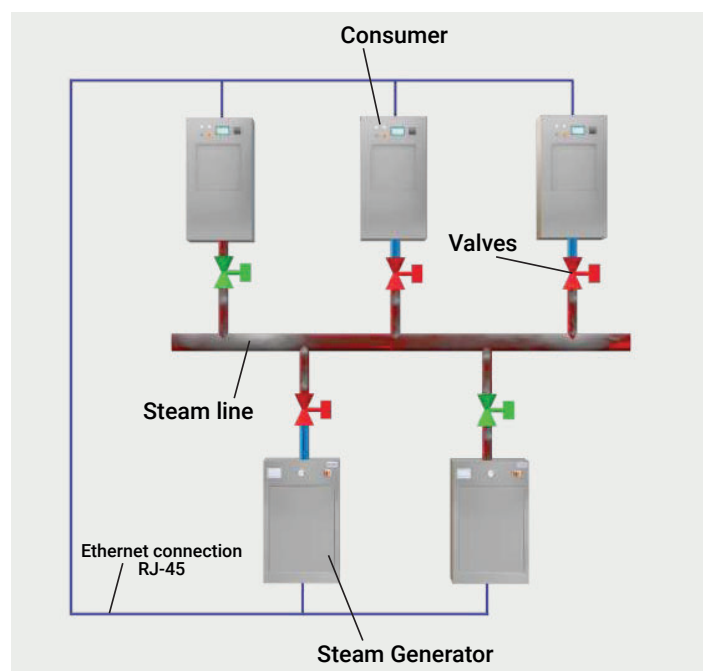


Ultrapure steam model

- ▶ All steam-conducting valves and pipes are made of AISI 316L (1.4435) stainless steel with orbital welds.
- ▶ The piping system is designed without dead space.
- ▶ Sterilising steam to meet the most sophisticated demands.
- ▶ Bacterial endotoxins < 0.25 EU/ml.

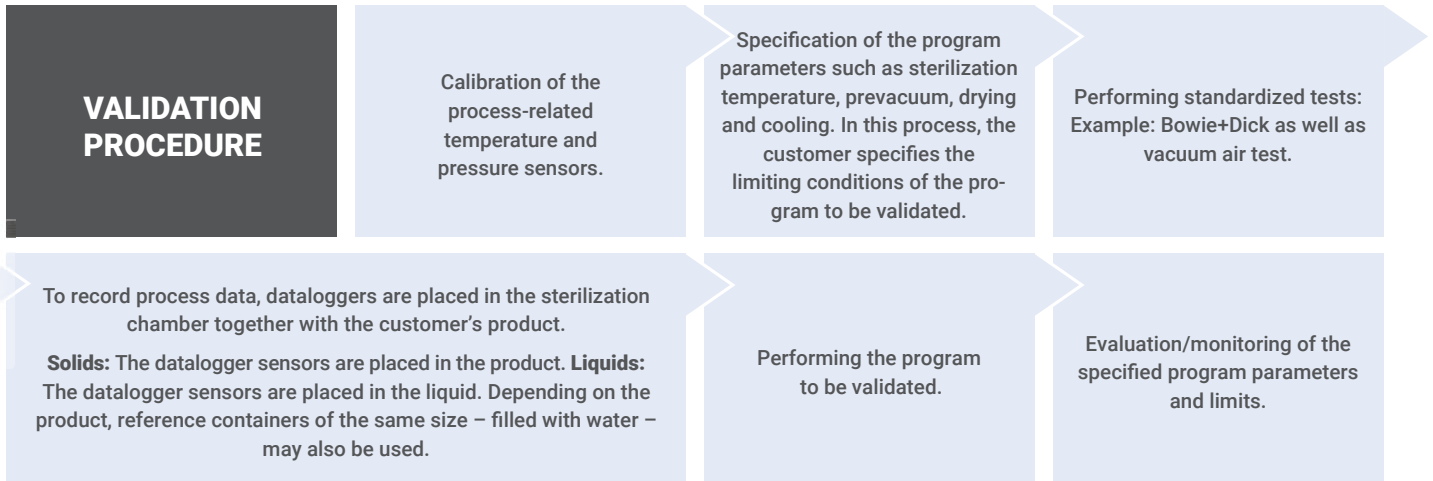
Steam management system

- ▶ Fully automated microprocessor control unit with touch panel for easy Operation.
- ▶ Operating pressure may be varied between 2,000 mbar and 4,500 mbar (optional: 20 bar).
- ▶ Pressure sensor for infinitely variable pressure measurement.
- ▶ Adjustable output levels.
- ▶ Two steam generators operating in parallel within a network, incl. output adjustment and offtake control.
- ▶ Additional steam reservoir to cover peak with drawal



To provide reproducible results, the thermal systems 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.



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 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.

<p>DESIGN-QUALIFICATION (DQ)</p>	<p>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).</p>
<p>INSTALLATION QUALIFICATION (IQ)</p>	<p>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.</p> <ul style="list-style-type: none"> · Material documentation · Calibration · Review of the piping plan
<p>OPERATION QUALIFICATION (OQ)</p>	<p>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.</p>
<p>PERFORMANCE QUALIFICATION (PQ)</p>	<p>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.</p>
<p>FACTORY ACCEPTANCE TEST (FAT)</p>	<p>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.</p>
<p>SYSTEM ACCEPTANCE TEST (SAT)</p>	<p>The SAT includes the implementation of the IQ and OQ at the customer's final installation location. A Zirus 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.</p>
<p>REQUALIFICATION</p>	<p>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.</p>
<p>CONFIGURATION SPECIFICATION</p>	<p>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:</p> <ul style="list-style-type: none"> · Hardware components and versions · Firmware versions · Software versions · Description of the sensors · Description of the performance parameters · User profiles
<p>FUNCTIONAL DESIGN SPECIFICATION (FDS)</p>	<p>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.</p>

Available in five 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

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
Qualification 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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