Sterilizers for the Pharmaceutical Industry: Individual Total Solutions for Every Task

GMP-compliant steam, steam-air mixture and
hot-water shower sterilizers: PST 6050/6060/6080

Belimed
Infection Control

Sterilization – crucial in pharmaceutical production

The production steps in the pharmaceutical industry are aimed at maximum safety, top quality and high economy. This applies in particular to the sterilization processes. As the technology leader for over 40 years, Belimed has been offering unique flexibility in the engineering and manufacturing of tailor-made solutions.

Experience and know-how

Several thousand systems installed worldwide in leading pharmaceutical and biotech companies speak for themselves. Belimed is familiar with the requirements of the pharmaceutical industry and for decades has been a reliable and competent partner to this industry.

Excerpt from the extensive Belimed range of services

- Consultancy and planning
- Project management
- Engineering
- Production
- Installation and commissioning
- Tests, validation and qualification
- Documentation
- Maintenance and servicing

Maximum safety

One important prerequisite for the safety of a drug or medicine is the quality. The design of Belimed pharmaceutical sterilizers (PST) is consistent with the most current recommendations and guidelines (GMP, GAMP and FDA etc.). Belimed assists its customers in complying with the stringent requirements of the pharmaceutical production process and ensures smooth qualification and validation.

Customer-specific solutions

Flexibility is our strength. In addition to various standard solutions, we offer individual systems, tailored to the needs of the customer, which feature an extremely wide variety of chamber sizes and sterilization methods. Our product line ranges from laboratory sterilizers with an effective volume of a few hundred litres to large-scale sterilization systems with an effective volume of up to 60 m^3.

Extensive diversity of methodologies

The diversity of the materials to be sterilized requires adaptation of the ideal sterilization methods for the task. Belimed offers the right methods and programs for every application field, and they can also be combined freely. They all have one thing in common: safe treatment of the materials to be sterilized. We optimise the methods used depending on the requirements with regard to batch times, drying and temperature distribution.

Perfect quality

Maximum reliability and system safety are the focus at Belimed. This is shown by the durable construction, the first-rate manufacturing quality and the exclusive use of high-quality materials and components. One example of this is the robust doors made of stainless steel. The claw profiles fitted on all sides optimally absorb the pressure and distribute it uniformly. This prolongs the service life of the chamber and guarantees maximum safety. The same applies to the innovative door system. The Belimed sealing frame is made of solid stainless steel. Thanks to the precision-milled door seal slot, the solid silicone seal has a service life six times longer than that of comparable systems.

Easy maintenance

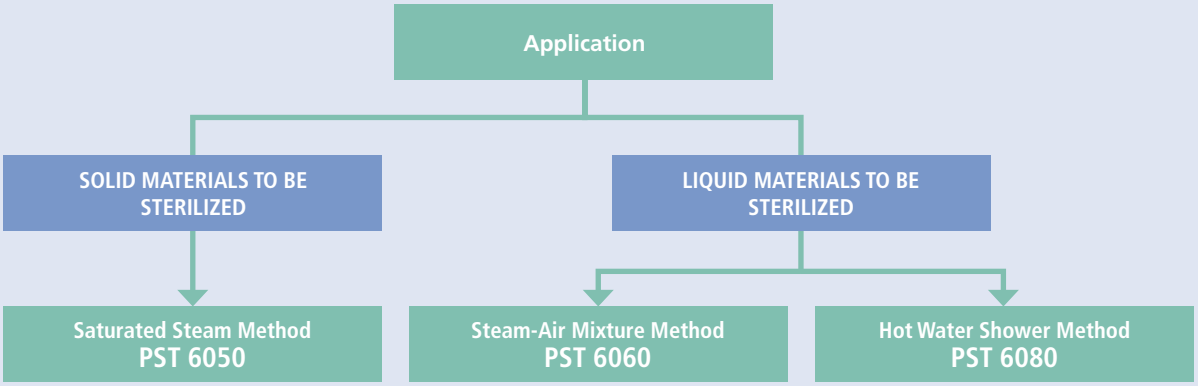
The Belimed PST sterilizers are designed for easy maintenance and servicing. All of the assemblies and the control system are secured in a separate maintenance compartment, which is easily accessible. This is an important aspect for shorter maintenance and servicing times.

Maximum accessibility

Designed for the pharmaceutical industry, the engineering and the quality of the materials and components used meet the most stringent demands with regard to reliability and long service life. The goal is to always ensure maximum system accessibility while constantly complying with all required specifications.

Increased ecology

As an innovative company, Belimed sets standards regarding ecological issues. When manufacturing our systems, our production technology attaches particular importance to the conservative use of resources associated with a low noise and pollutant emission. Wherever possible, environmental-friendly materials are used, which can be easily recycled or disposed of in compliance with environmental needs.



Belimed offers the right solution for every application.

PST 6050: Sterilization of solids using the saturated-steam method

The PST 6050 sterilizers are designed for the sterilization of solid and porous products, in addition to products from which air cannot easily be removed through the use of saturated steam and vacuum.

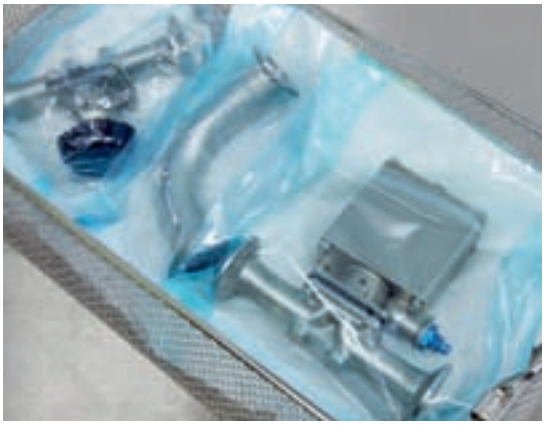
Extreme process reliability

High-quality materials, first-rate components from renowned manufacturers, a GMP-compliant design and production guarantee processes which are reliable and reproducible. Monitoring and control of pressure and temperature are performed via independent measuring and control loops. In the sterilization phase, the saturated steam ratio (pressure/temperature) is constantly monitored and a high degree of process reliability is guaranteed.

The sterile filters are sterilized as part of the process, in order to avoid cross-contamination. An automated integrity test monitors that the filters are operating correctly.

Flexible methods

All parameters, such as sterilization time, sterilization temperature, drying time, vacuum pulses, pulse amplitudes, pressure change rates and tolerance bands, are adjusted to the sterilization task. This flexibility is the prerequisite for perfect compliance with the various customer requirements.



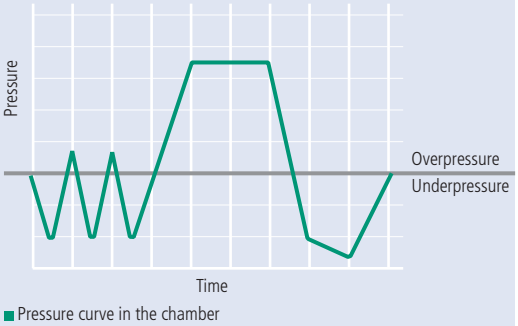
Efficient drying

The high-performance vacuum system meets the extremely stringent demands with regard to drying efficiency, with minimal consumption of water. The use of an air heater reduces condensate formation during heating and supports the vacuum-drying efficiency.

Example applications

- Machine and system components
- Tools
- Filters
- Empty containers made of glass, plastic or metal
- Textiles and clothing
- Rubber stoppers

Typical pressure curve using the saturated-steam method

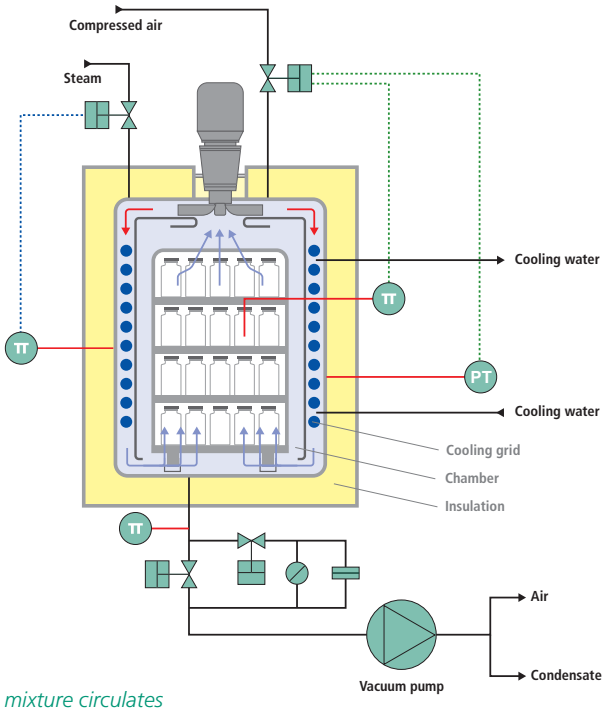


Air is removed from the chamber with one or several vacuum pulses. Heating and sterilization are performed by saturated steam, and drying is performed with one or several vacuum pulses. The process parameters can be adjusted to the requirements.

Stainless-steel piping with NEUMO BioConnect flange connections.

PST 6060: Sterilization of liquids with the steam-air mixture methods

The PST 6060 sterilizers were developed to sterilize liquids in closed or open containers with a mixture of steam and air. The mixture is vertically or horizontally circulated in the chamber using fans. This guarantees quick heating and cooling, and optimum temperature distribution.



The steam-air mixture circulates in the chamber and ensures fast heating and cooling and optimum temperature distribution.

Gentle treatment

An intelligent control system constantly adapts the pressure in the chamber to the pressure in the containers. This protects sensitive material to be sterilized against deformation.

Homogeneous temperature distribution and short cooling times thanks to an optimal ventilation concept

The manner of ventilation in the chamber has crucial significance with regard to the sterilization process. The selection of vertical or horizontal ventilation, or the combination of the two, depends on the material to be sterilized, and the nature of the load. Belimed offers the ideal solution for every application.

Drying cycle

The material is cooled and, at the same time, dried with sterile air at the end of the sterilization process. The batch is then ready for further processing.

Thanks to the precision-milled door seal slot, the solid silicone seal has a service life six times longer than that of comparable systems.

Combined solutions with the method 6050

The combination of method 6060 with method 6050 is possible depending on the application. For example, heating and sterilization are performed with saturated steam, while cooling is performed with a mixture of steam and air. The flexibility of the programs makes your investment even more valuable.

F_0 value sterilization: Optimum parameters for heat-sensitive materials

Sterilization on the basis of the F_0 value allows optimum adjustment of the sterilization time and sterilization temperature to the material in question. This even allows safe sterilization of heat-sensitive materials.

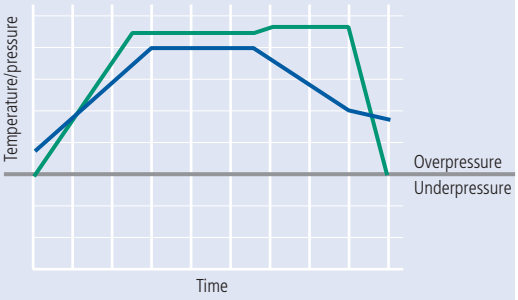
Hermetically sealed

The fan incorporated in the sterilizer is practically maintenance-free. It is hermetically sealed by the slide-ring unit, or optionally with a magnetic coupling.

Example applications

- Glass bottles
- Bags
- Ready-to-use syringes
- Ampoules
- Vials

Typical temperature and pressure curve using the steam-air mixture method



The steam-air mixture method is ideally suited to sterilizing pressure-sensitive materials.

High-quality materials and precise workmanship assure reliable operation.

PST 6080: Sterilization of liquids using the hot-water shower method

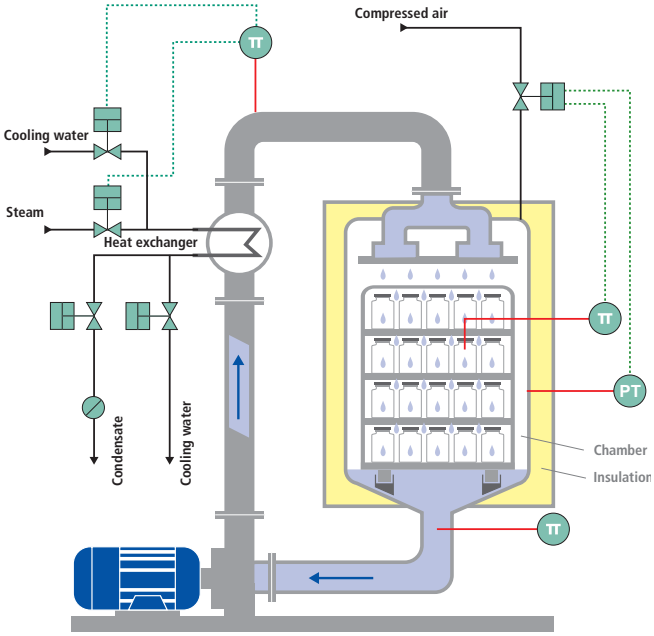
The PST 6080 sterilizers sterilize using the hot-water shower method, ideal for large-volume liquids in sealed containers. A sealed water system heats, sterilizes and cools.

Safe and simple process control

The high-volume water-circulation rate and the two-stage water-distribution system ensure accurate and homogenous temperature distribution in the material to be sterilized. The pressure in the chamber is continuously adapted to the internal pressure of the containers. The entire process can be controlled easily and accurately.

Short batch times

Efficient heat transfer between the material to be sterilized and the sterilization medium, as well as the high-performance heat exchanger and circulation pumps, ensure short batch times.

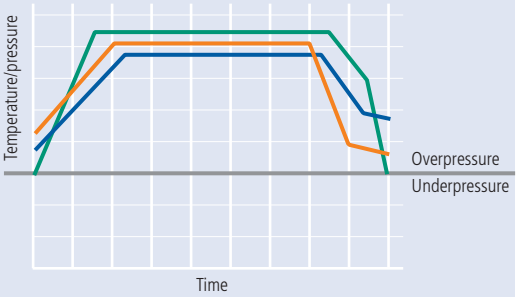


A two-stage water distribution system ensures precise and homogenous temperature distribution in the material to be sterilized.

Example applications

- Glass bottles
- Plastic bottles
- Bags
- Vials
- Ampoules

Typical temperature and pressure curve using the hot-water shower method



The hot-water shower method ensures a homogenous temperature distribution with very short batch times and high production capacity.

Sterilizer PST 6068: The combined solution

All methods can be combined as required thanks to the modular structure of the system, for test systems in research and development, for example. This means that both porous materials (using the saturated steam method) and liquids (using the steam-air mixture and hot-water shower methods) can be sterilized in the same sterilizer.

Tailor-made solutions

As a company specializing in the field of sterilization, Belimed offers a broad range of standard equipment. However, each product has its own requirements. Belimed understands these requirements and can implement them as individualized solutions.

Safe process control by movement of the materials to be sterilized

Rotating sterilizer: Rotation of the batch during sterilization ensures a homogenous temperature distribution. This is particularly important if multi-component parenterals with differing specific gravity (emulsions) are to be sterilized reliably. Despite the complex and sophisticated technology, the Belimed rotating sterilizer can be operated easily. Thus, the system can be equipped with an automatic feeding system.

The immobilisation of the load in the rotating basket is completely automated and involves a special pneumatic system. The single- or dual-door systems can be used with all sterilization processes. Thanks to a variable speed control, the process can be adapted easily to the material to be sterilized. Process safety is enhanced still further with load temperature measurement.

Shaking sterilizer: In this unit, the material to be sterilized is thoroughly mixed by uniform movement back and forth during the entire process. Even here, Belimed attaches a great deal of significance to ease of operation and increased process safety. Even heavy, large-volume loads can be handled thanks to the unique asynchro shaking system.

Easy to load

Belimed offers a broad range of automatic loading systems for its sterilizers. Depending on whether the materials to be sterilized are packed on trolleys or pallets, and depending on the size and weight of the load, the system can be equipped with a sliding transport system, a chain transport system or a roller transport system. If space is at premium, or in the case of other difficult installation situations, a cross-push or lifting system may be required. One of Belimed's additional core expertises is the automatic pallet loading system including a pick-up and delivery shuttle . All moving parts are arranged outside the chamber. This ensures maximum freedom from particles, and the system is particularly maintenance-friendly.

Motivated people stand behind every Belimed sterilizer.

The user-friendly Touch Operating Panel (TOP) is suited to the needs of the customer and features many advantages.

Intelligent control systems

The control systems of the PST sterilizers meet the most current GAMP standards. The application software was developed by Belimed and has been validated. We guarantee operating convenience, process reliability and reproducibility, safety and maximum accessibility.

Maximum flexibility

The heart of the control systems is a programmable logic controller (PLC), as manufactured by Siemens, SAIA or Allen Bradley for example, which controls, regulates and monitors the entire process sequence. The modular system offers maximum flexibility.

High degree of functionality and user-friendliness

We offer various user interfaces, suited to customer needs. These Touch Operating Panels (TOPs) feature the following characteristics:

- Clear, graphic operator interface
- Logical process visualization
- Flexible parameter assignment for the cycles
- Individualized language selection
- Integrated help function
- Automatic service notification
- Graphical and numerical batch reports
- Easy, automatic measuring-sensor calibration
- Potential operation from the loading or unloading side

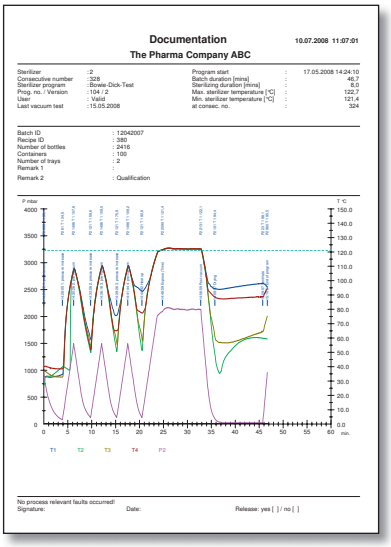
Compliance with FDA 21 CFR part 11

The intelligent user management system controls access rights and password management for all users. By means of an audit trail, all user activities, including data modification, are logged. The database offers virtually unlimited storage options for process data and batch reports. Consequently, this guarantees full traceability at all times. Electronic signatures are used for batch release.

Networking capability

The control systems can be networked via Ethernet (TCP/IP) and PROFIBUS with SCADA systems, based on WinCC, DeltaV, iFix etc. The data range to be transmitted can be defined flexibly. Remote maintenance via modem adds to the system's high accessibility.

Clearly structured cycle documentation.



Documentation

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The Pharma Company ABC

Project and quality management

Belimed offers system planning, implementation, qualification and validation in a single package. Our professional project management team ensures individual support by our project managers over the course of the project, from the order specification through to final acceptance.

Individually optimised solutions

We work closely with our customers starting with the planning and development phases. We incorporate specific needs and requirements (URSs) into the solution right from the very start, and record them in process-oriented, GMP-compliant user product briefs. This guarantees you full compliance with both your own as well as the regulatory requirements, which allows the system to fit seamlessly in your production plant.

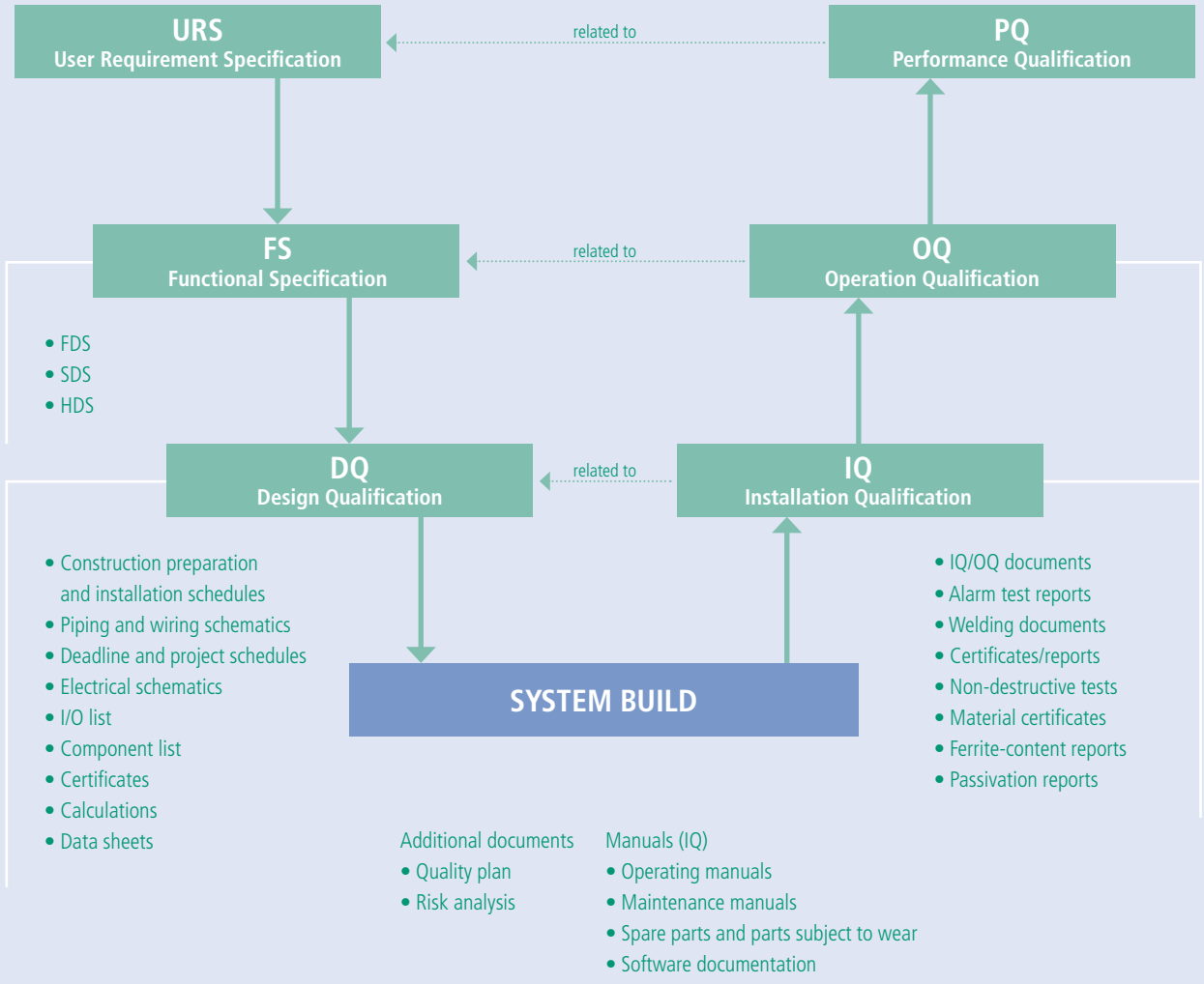
Certified quality

Excellently trained, motivated staff forms the basis for the implementation of the most ambitious customer projects. Combined with the use of high-quality materials and ultra-modern production technologies, we guarantee an excellent level of quality in our systems. The PST sterilizers feature longevity, economy and maximum availability. We comply with all significant specifications such as ISO 9001:2000, ASME, the Pressurized Equipment Directive (PED) and we operate in compliance with the current standards (EU standards, US standards, GMP and GAMP etc.).

The systematic, clearly structured sequence of every project ensures strict compliance with agreed deadlines and costs.

As a competent partner to the pharmaceutical industry, Belimed is aware of the significant importance of a systematic procedure for project implementation. The tried-and-tested V-model in compliance with GAMP serves as the basis for this. This includes, among other things, extensive, project-specific documentation. Certified application of the V-model significantly simplifies our customer's qualification tasks (IQ, OQ and PQ).

V-model



Close to you throughout the world: Service and support

The tailor-made service and maintenance package is just as unique as your own sterilization solution. We commit ourselves to the maximum operating safety for your systems: from preventive maintenance within the framework of defined contracts through support services such as telephone consultancy or remote maintenance via modem up to the deployment of our servicing technicians on site.

Professional services

We build on long-term partnerships to increase the productivity of our customers in a sustainable manner. We achieve this by an integrated service and maintenance package. Competent consultancy, individually matched training, installation and commissioning, regular qualifications and both maintenance and support are important components of the Belimed quality management system.

Personalised and close

The branch offices and authorised partners of Belimed's worldwide network are never very far from you. Our customers benefit from short response times, immediate availability of spare parts and personnel, and expert on-site support strategy. Our primary goal is to achieve maximum productivity and system accessibility.

- Belimed companies
- Authorised partners and representatives

Dimensions for dual-door standard systems with method 6050

Standard models	Clear dimensions of sealing frame in mm			Overall system dimensions in mm			Chamber volume
	Height	Width	Depth	Height	Width	Depth	Litres
6-6-6	750	660	740	2000	2000	1000	370
6-6-9	750	660	1040	2000	2000	1300	520
6-6-12	750	660	1400	2000	2000	1660	700
9-6-9	1080	660	1040	2000	2150	1300	750
9-6-12	1080	660	1400	2000	2150	1660	1010
9-9-9	1030	960	1100	2000	2800	1600	1250
9-9-12	1030	960	1400	2000	2800	1900	1590
11-6-9	1230	660	1090	2250	2390	1600	1055
11-6-12	1230	660	1400	2250	2390	1900	1345
15-6-9	1600	660	1100	2750	2390	1600	1350
15-6-12	1600	660	1400	2750	2390	1900	1765
12-8-12	1350	900	1400	2500	2500	1900	1990
14-8-12	1500	900	1400	2750	2500	1900	2150
17-9-14	1800	950	1540	3000	2500	2040	2950
18-10-15	1900	1100	1700	3000	2800	2300	3960

All models are also available as single-door versions. The dimensions may vary dependent on the method. Chamber sizes are available by agreement.

	6050	6060	6080
METHODS			
Saturated-steam method	■	■	O
Gravity method	■	■	O
Steam-air mixture method DLGV by fans (horizontal, vertical ventilation)	–	■	–
Hot-water shower method DHBV	O	–	■
F_0 sterilization	■	■	■
Supported pressure	■	■	■
Rapid cooling by flooding the twin jacket	O	O	–
Temperature measurement in the containers	■	■	■
Vacuum pulse	■	■	O
Direct cold-water cooling	O	O	–
Pulsed vacuum drying FVT	■	■	O
Rotation of the material to be sterilized during the sterilization cycle	O	O	O
Shaking of the material to be sterilized during the sterilization cycle	O	O	O
P & ID			
Inline filter sterilization of the intake air filter	O	O	O
Filter in vacuum line and condensate sterilization	O	O	–
Air heater for air intake	O	O	O
Pipes, ground and electropolished	O	O	O
Integration of vacuum system in customer's cooling conduit	O	O	O
External installation of the vacuum system	O	O	O
Direct or indirect connection of the cooling grids to the cooling water conduit	O	O	O
Automated integrity test, WIT of the filter	O	O	O
Air detector	O	O	–
PID control	O	O	O
CONTROL / OPERATOR CONTROL			
Colour touch operating panel TOP 7000	■	■	■
Colour touch operating panel TOP 7700 (Siemens TP370)	O	O	O
Colour touch operating panel TOP 9000 (Industrial PC)	O	O	O
Colour touch operating panel TOP 7500 (Allen Bradley)	O	O	O
Operating side 2: basic function / process displays	■	■	■
Operating side 2: extended functionality	O	O	O
SAIA PLC	■	■	■
Siemens PLC	O	O	O
Allen Bradley PLC	O	O	O
Interconnection with SCADA system	O	O	O
MECHANICAL CONSTRUCTION			
Single or dual door	■	■	■
Door drive with linear drive	O	O	O
Sterilization chamber and jacket made of 1.4404 (316L)	■	■	■
Surface of the chamber, ground and electropolished	O	O	O
Sterilization chamber, "left"	O	O	O
Low-ferrite welds for parts coming into contact with product	O	O	O
Rack and frame made of 1.4301 (304)	O	O	O
Floor-mounted	O	O	O
Batch and transport trolley	O	O	O
Loading and unloading systems	O	O	O
Electrical steam generator or steam-to-steam converter	O	O	O
Fans for method 6060 with magnetic coupling	–	■	–
Sump base	O	O	O
Gastight partition wall, on one or both sides (Bioseal)	O	O	O
DOCUMENTATION/MISCELLANEOUS			
DQ documentation	■	■	■
FS (FDS, SDS and HDS)	O	O	O
IQ/OQ test plans	O	O	O
Operator manual and maintenance instructions	■	■	■
SERVICES			
Additional documentation	O	O	O
FAT	■	■	■
Installation/commissioning	O	O	O
Performing SAT (IQ/OQ)	O	O	O

■ = Standard, O = Optional, – = Not available
Subject to modification

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