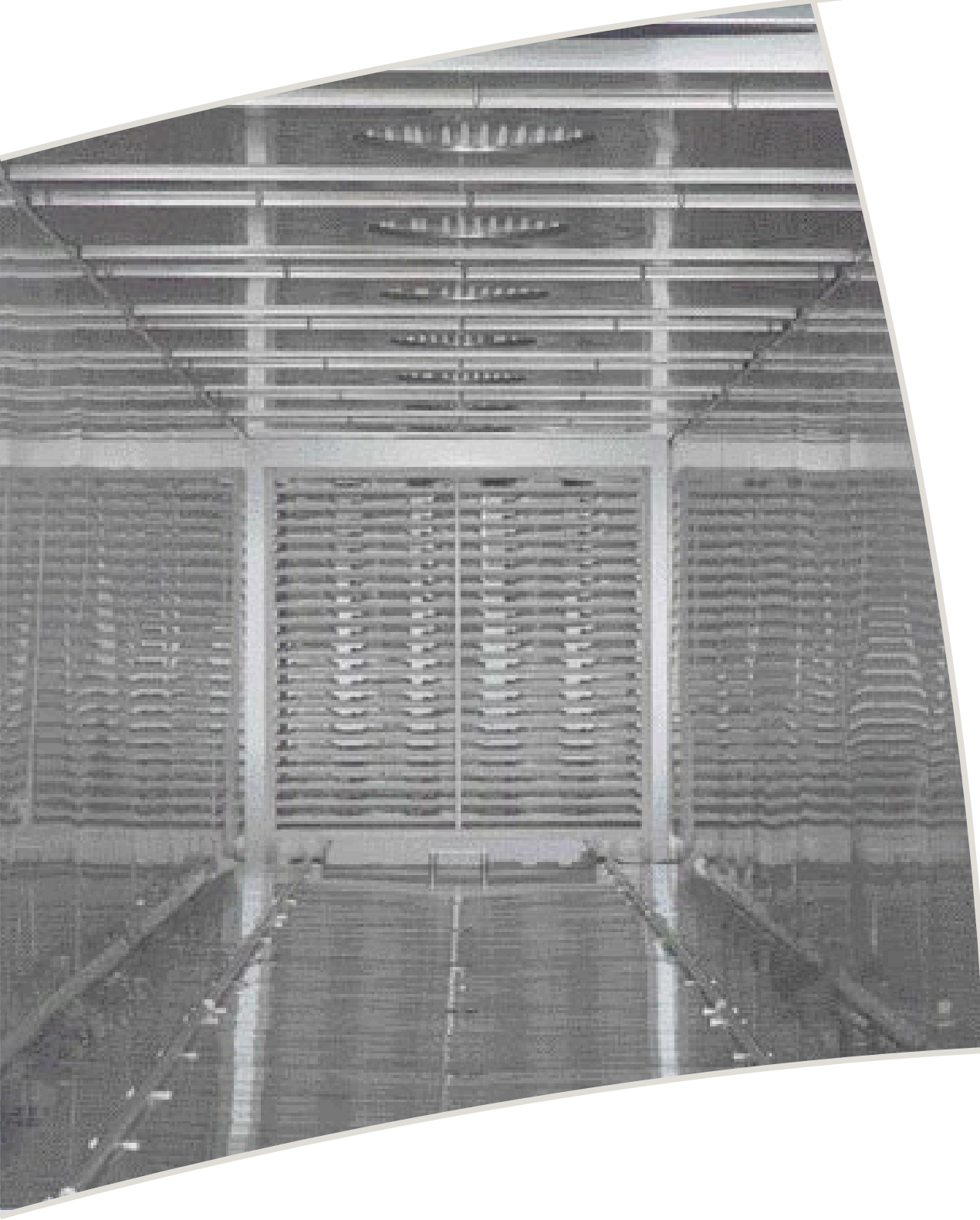


GETINGE

GETINGE TERMINAL STERILIZERS
SECURING OPTIMAL PROCESSING OF
PACKAGED PHARMACEUTICALS





FROM CONCEPT TO COMPLIANCE

Pharmaceutical production puts stringent demands on sterile processing equipment in terms of maximum uptime, high performance and optimal production capacity. And, of course, proper safeguards that exceed industry standard practice should minimize microbial and particulate contamination.

As a world leader in the field of washing and sterilization, Getinge draws from over 100 years of accumulated knowledge to provide the advanced equipment, application skills, documentation, regulatory know-how and support services you can depend on from “concept to compliance”.

Pharmaceutical competence

Our long-term involvement with washing and sterilization procedures has made us intimately familiar with pharmaceutical production methods. Therefore, we are well aware of the challenges associated with the sterile treatment of liquids, solids and the numerous types of delivery systems available today.

The complete production chain

Getinge can take care of virtually all your needs in the sterile processing of pharmaceuticals.

We supply:

- Water pretreatment systems
- Water distillation systems
- Steam generators
- Component and equipment washers
- Component and equipment sterilizers
- Closure processing systems
- Terminal sterilizers
- Systems for sterility testing
- Process control and management systems
- Installation design support services

- Testing, commissioning and qualification
- Training and after-sales support

Optimizing economy

As Getinge supplies nearly everything from concept to compliance, we can optimize the lifecycle economy for your sterile processing equipment. Dealing with just one complete company will save you time, effort and cost.

Since all our equipment is compatible and has common documentation, rapid system integration and installation is assured. That equipment is built to meet the world's highest standards of quality and safety means maximum uptime and a safer working environment.

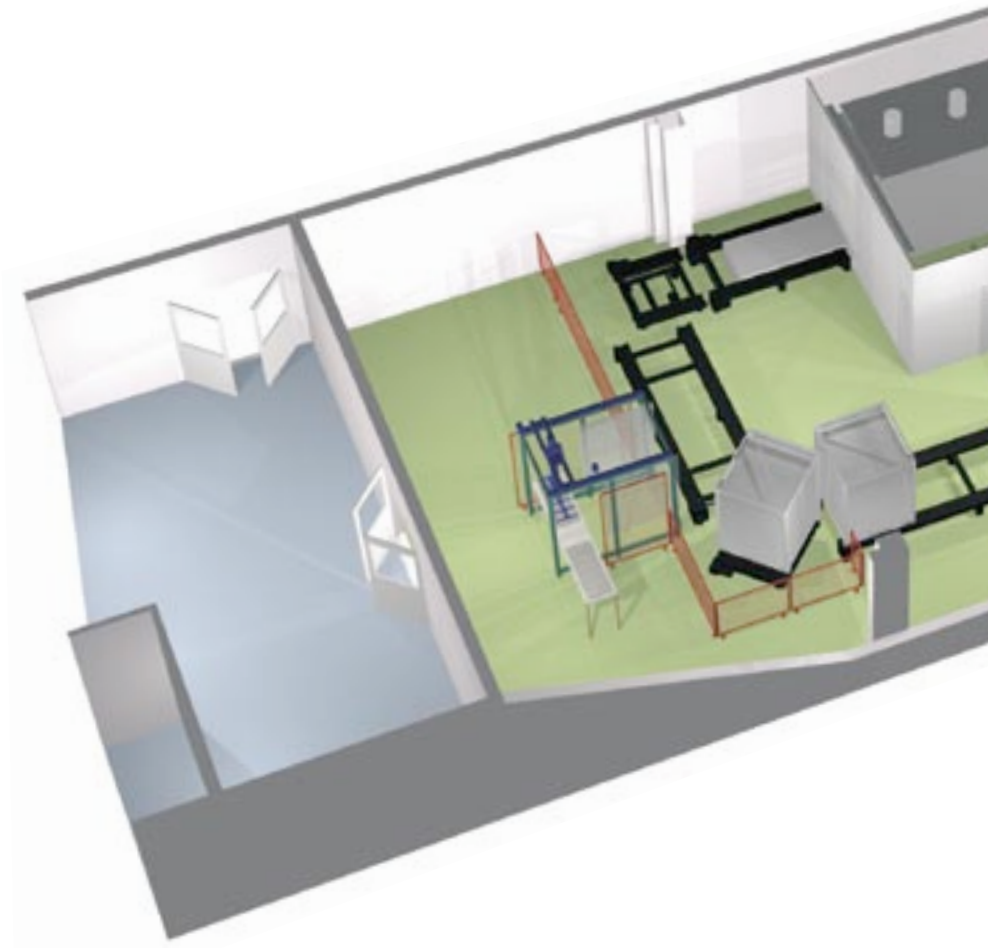


GENTLE BUT EFFECTIVE PRODUCT STERILIZATION

Getinge develops, manufactures and supplies completely integrated washing and sterilization systems for use within the life sciences.

Getinge GEV and GEC sterilizers kills the toughest microbes but are gentle enough to protect the integrity of components, products and packaging. A wide range of sterilization cycles increases their application versatility.

Getinge GE Steam Sterilizers can also be used to sterilize products in ampoules or vials.

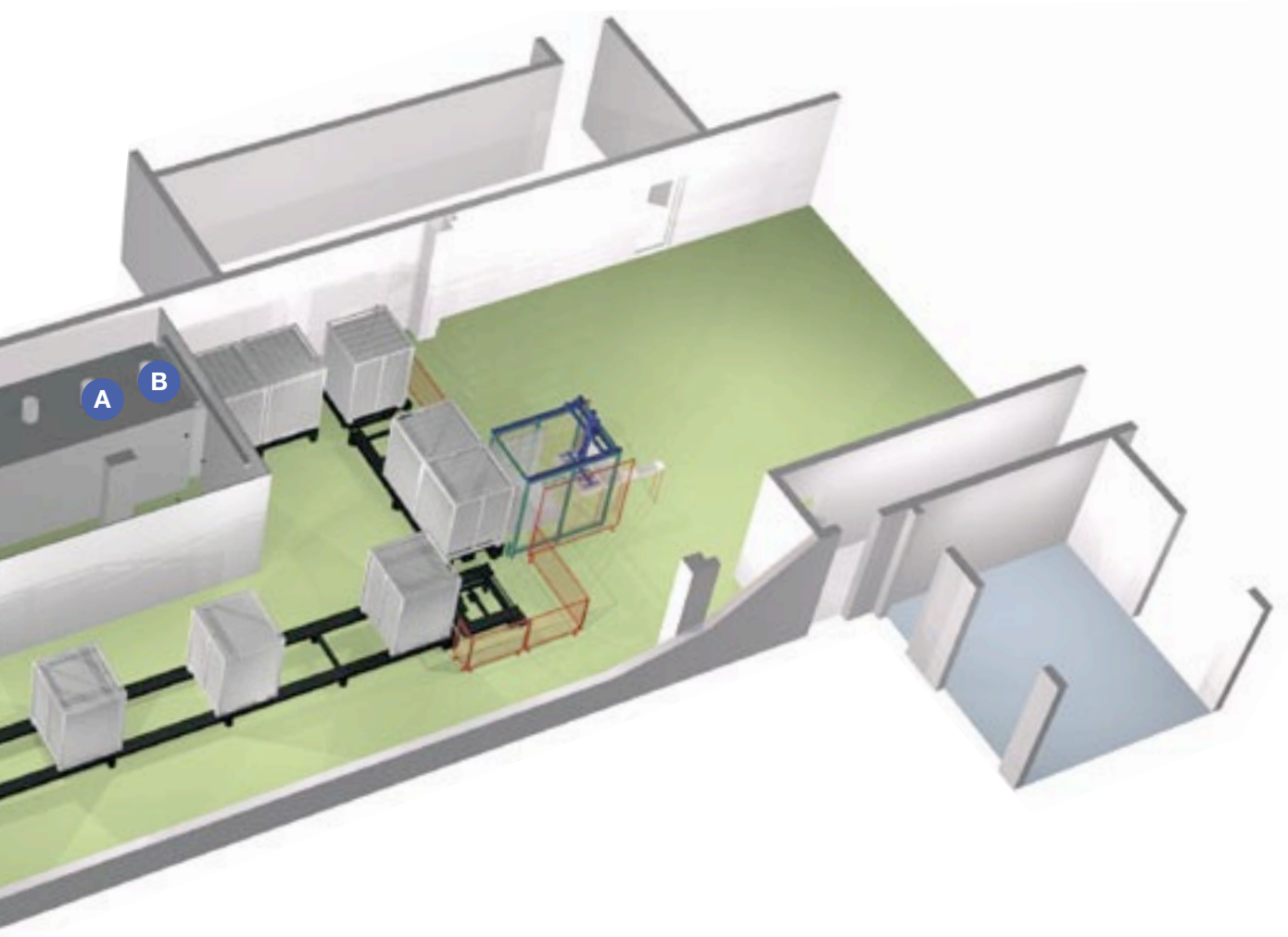


UTILITIES


DISTRIBUTION

RECEPTION

BAR




A **GEV**



Getinge Ventilator Terminal Sterilizers (GEVs)* are designed primarily for sterilizing products that must be dry and ready for further handling immediately after the cooling phase.

Standard chamber volume:
16 to 357 ft³ (0.5 to 10.1 m³).

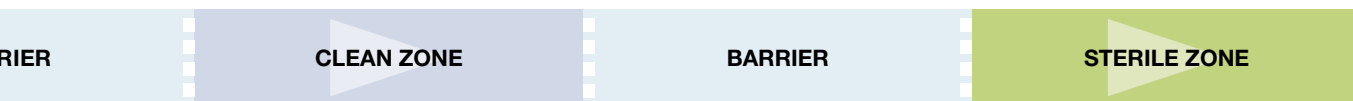
B **GEC**



Getinge Circulating Water Terminal Sterilizers (GECs) are primarily intended for sterilizing large volumes of liquids in sealed glass or plastic containers.

Standard chamber volume:
16 to 706 ft³ (0.5 to 20.0 m³).

* GEV Terminal Sterilizers use steam/air mixtures for sterilization.



SAFEGUARDING YOUR INVESTMENT



Robotic welding is used wherever possible to provide a high level of consistency and accuracy.



Getinge sterilizers are built in state-of-the-art production facilities.

A sterilization system represents a large capital investment. Therefore Getinge takes measures to ensure that our GEV/GEC Terminal Sterilizers provide true value with regard to design, performance and lifecycle economy.

Strong on safety

Getinge sterilizers are designed and built to meet the world's highest standards of quality and safety. Production facilities are ISO 9001-certified and all appropriate international regulations for safety, pressure vessels and the environment are rigorously followed. A risk assessment is performed on all products, focusing on personnel safety.

Leading-edge construction

The production of Getinge sterilizers involves leading-edge construction techniques and use of the highest-grade materials. Accurate laser cutting minimizes the number of construction welds. Robotic welding provides a level of weld consistency superior to manual techniques and eliminates defects in welded seams. Robotic grinding systems reduce sites of potential corrosion and allow easy cleaning. And the unique sectional jacket design provides rigidity, allows visual inspection of all welds and reduces weight.

Advantages of sliding doors

The sliding doors of GEV/GEC Terminal Sterilizers offer a number of advantages over hinged doors. They are cleaner, safer and simpler. Hinges require grease which can collect dirt. Sliding doors are safe since the hot inner

surface is not exposed when the door is open. Space is maximized as the door does not swing outward, and there is free access to the chamber for loading/unloading.

Widest range of chamber sizes

Getinge has the widest range of chamber sizes available from any manufacturer to meet the needs of all common applications. Standard chamber sizes range from 16 to 706 ft³ (0.5 to 20.0 m³). Customized chamber sizes are available on request.

Regulatory issues

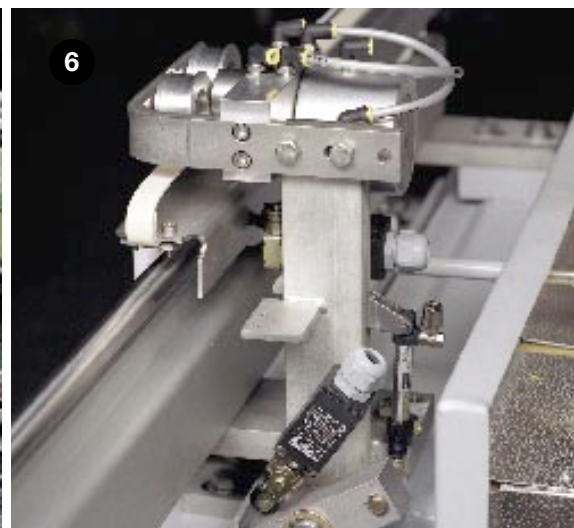
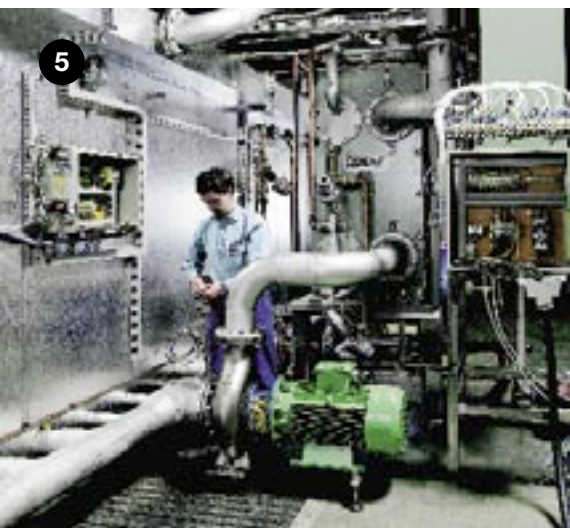
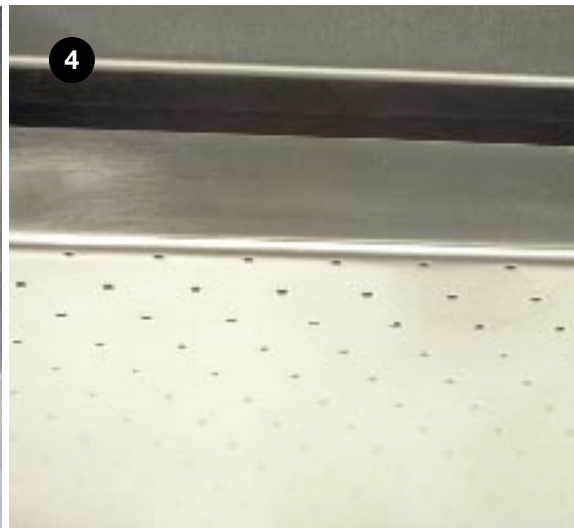
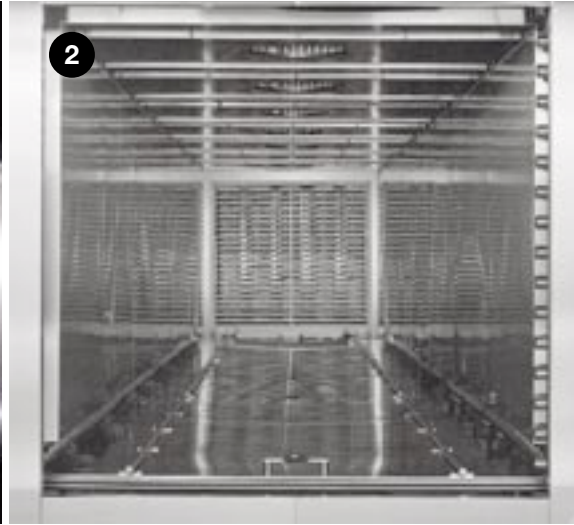
Getinge closely follows industry trends, practices, guidelines and regulatory requirements. Additionally we actively participate in working groups and committees working to refine these requirements.

**GAMP | cGMP | BPE2002 | MHRA | ISPE BASELINE GUIDES
FDA | EN ISO 13488 | ISO9000 | 21CFR Part 11**

All sterilizers are manufactured according to the guidelines or standards relating to the intended applications and the country of installation.

Protecting the environment

Special processes have been developed for safe disposal of discarded waste for environmental protection. Options are also available to reduce cooling water consumption by up to 75%.



1. Batteries of dense heat exchangers fabricated from seamless stainless-steel tubing power the GEV's rapid cooling. GMP compliant with no connections inside the chamber.
2. Sectional internal liners control GEV airflow and consequently temperature distribution. Each zone is equipped with fan, heat exchanger and piping.
3. A custom designed stainless steel centrifugal fan delivers high GEV airflow rates. Driven via a unique mechanical seal by an electric motor.
4. Unique distribution plate of the GEC ensures constant and uniform water cascade over the product for uniform heating and cooling.
5. A powerful sanitary centrifugal pump delivers massive flow rates to the GEC cascade system. Efficient plate heat exchangers heat and cool the circulating water.
6. The doors of Getinge sterilizers are the cleanest, safest and simplest on the market.
7. The unique sectional jacket adds strength and rigidity to the chamber, and robotic welding eliminates defects. The resulting construction ensures a long product lifecycle to safeguard your capital investment.
8. Top-quality piping and components are assembled to the highest standards.

FEATURES THAT SATISFY YOUR PROCESSING NEEDS

The features built into Getinge GEV/GEC Terminal Sterilizers allow the user to define and program the processing parameters best suited to particular types of packaged pharmaceuticals. Steam/air mixtures in the GEV Terminal Sterilizer are used to sterilize products that need to be dry after the cooling cycle, whereas cascading water in the GEC Terminal Sterilizer is used for the rapid sterilization of bulk liquids.

Versatile programs

Program combinations are designed to suit particular applications of GEV or GEC models, whether for sterilizing different types of product or performing single-product sterilization cycles. Sterilizers that incorporate a vacuum pump provide even more versatile operation.

With GEV models, the products in the chamber may be heated with hot air at the start of a cycle before steam is used in order to minimize condensation and shorten the drying phase.

With GEC models, temperature overdrive is used at the start of a cycle to shorten both the heating phase and the total process cycle.

Numerous design options

Just a few design options that reflect Getinge's reputation as a flexible and innovative supplier are:

- A wide range of chamber capacities.
- Single-door or double-door, pass-through models.
- Dual sequencing controls at both ends of a pass-through model with master control panels if required.
- Service area on either side of the chamber.
- Clean steam supply from a built-in generator and/or external source.
- Sterilizer mounted in either a cabinet, recessed between two walls, or recessed in a cabinet within one wall.

- A range of loading systems, e.g. powered roller conveyors, trolleys, pallet trucks and the Getinge Robotic Automatic Transporter system.
- Models that can be installed directly on a floor for loading with racks and transfer trolleys, or pit-mounted models for convenient roll-in, roll-out load handling.

Complete loading/unloading solutions

Getinge's extensive choice of high-grade stainless steel loading systems range from basic product handling items such as sliding shelves to highly automated loading/unloading units. These are ergonomically designed for safe, simple and smooth product handling. Both standard and custom-built systems are provided to meet the demands of diverse material-handling challenges. The wide variety of loading/unloading equipment includes:

- Shelf racks
- Shelf trays
- Stackable shelves
- Various rail systems
- Loading trolleys
- Roller conveyors

GEV processing results in dry cool products. It suits containers with closures not mechanically held in place and blister packs.



ENABLING YOU TO ACHIEVE OPTIMAL PROCESSING



GEC processing enables high-volume throughput of bulk liquids and does not deform flexible plastic containers.

In keeping with Getinge's policy of continuous product and application development, a Sterilization Technology Center is available for customers who need to define the correct processing conditions for particular products.

Sterilization Technology Centers are located in Japan, Sweden, the USA and the UK. Each center is equipped with specially designed sterilizers that allow programming of a wide range of process cycles and printout of relevant documentation.

Conduct your own test runs

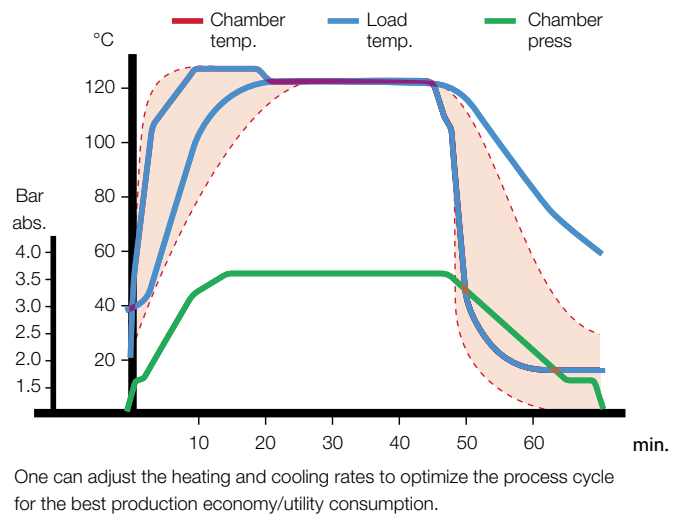
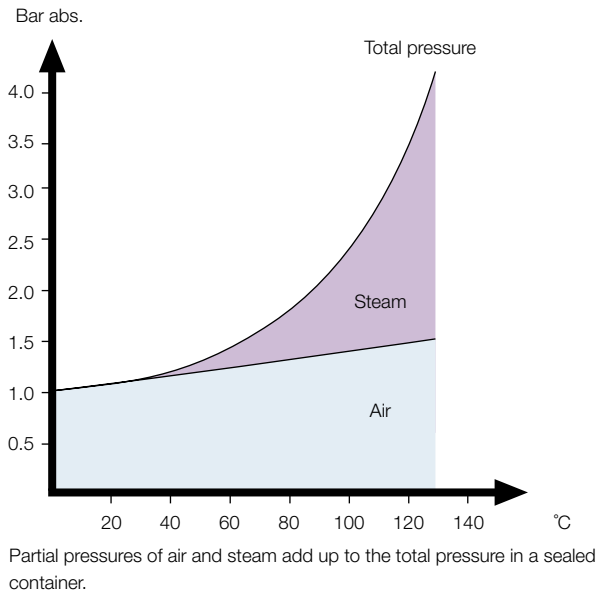
The Sterilization Technology Center is the place to come and discuss your application challenges with our experienced personnel. You can conduct test runs on your own products and packaging to define the

sterilization parameters best suited to them. Scale-up runs can also be carried out to test the suitability of selected cycles prior to final decision-making.

Customer programming via the control system interface also makes it possible for you to make changes to each phase of the process cycle after a sterilizer has been installed in your production facilities.

Preventing deformation

GEC Sterilizers provide two ways of preventing deformation of plastic containers: the use of air overpressure, independently controlled during the heating and cooling phases, and, when required, the use of special loading trays developed by Getinge. GEV Terminal Sterilizers are gentler on products and



packaging that tend to be pressure-sensitive. Air overpressure is used during the heating and cooling phases, but only to prevent plastic containers from deforming or closures from being displaced.

The GEV sterilizer incorporates programs that ensure PVC containers are clear at the end of the cooling cycle.

Accurate pressure-temperature link

The liquid being sterilized, fill volume, container material style, and the type of closure all determine the correct temperature and pressure to be used during the process cycle. These parameters are independently controlled in GEV/GEC units so it is easier to achieve the required processing conditions. Furthermore, excellent pressure control is provided by accurately linking any change in

pressure closely to product temperature throughout the complete process cycle.

A combination of good heat transfer and optimized cooling for different packaging offered by GEV/GEC Terminal Sterilizers enables rapid processing to be defined for a wide range of products.

Own design team

We have our own team of design and planning experts that develops installation drawings for individual machines as well for complete washing and sterilization systems, along with utilities that match process and production needs. So once you have chosen the sterilizer or system that satisfies your production needs, we can help you to get it up and running as soon as possible.

STERILE DRY GOODS READY FOR HANDLING

Dry products from Getinge GEV Terminal Sterilizers are ready for immediate handling and further processing such as inspection, labeling, packing, etc. GEV Product Sterilizers are also ideal for products, e.g. blister-packed products and sophisticated delivery devices, that can be distorted or damaged by standard steam processes.

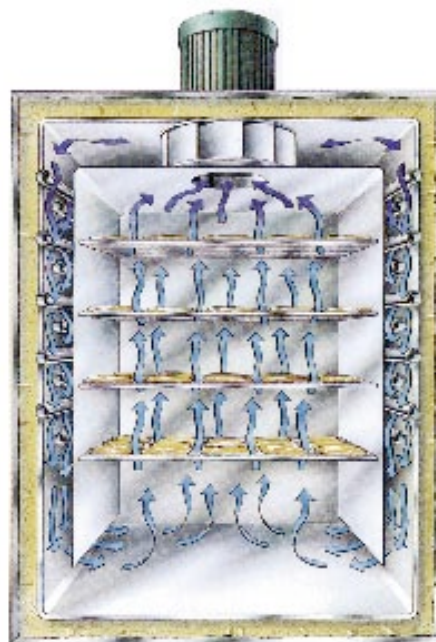
Moisture-sensitive materials also benefit from GEV sterilization, and the variable and independent regulation of air overpressure makes it possible to design sterilization programs for a range of pressure-sensitive products.

Alternative cycles, such as for porous textile loads, filled ampoules and dry empty glassware, can also be incorporated in GEV Terminal Sterilizers. GEV units with a vacuum cycle provide sterilization cycles for:

- Liquids in sealed glass containers and open vessels
- Liquids in sealed plastic containers
- Products in blister packs
- Textiles, glassware and utensils
- Filters
- Rubber stoppers

Excellent heat transfer

During heat up and sterilization, either steam, air, or steam/air mixtures are forcefully recirculated throughout the products in the chamber by one or more high-power fans. This provides excellent heat transfer during the heating phase and uniform temperature distribution during the sterilization phase.



Rapid drying is achieved by powerful centrifugal fans and internal water cooled heat exchangers to create a homogenous environment and uniform heat distribution.

Optimized cooling

Steam is condensed immediately after the sterilization phase and replaced by filtered air (through a bacteria-retentive filter) which is subsequently cooled by internal heat exchangers fabricated from seamless tubing. When the product has been cooled to the required temperature and dried, any remaining pressurized air is vented before unloading.

Any concerns regarding leakage from heat exchangers are alleviated; all connections are external to the chamber and an optional automatic leak test confirms heat-exchanger integrity during each processing cycle.

GEV model	6610	6613	6913	6915	91413	91425	91637	91650
CHAMBER VOLUME ft ³ /m ³	16/0.5	21/0.6	36/1.0	41/1.2	82/2.3	151/4.3	267/7.6	357/10.1
*CHAMBER WIDTH, in/mm	24/600		26/660		35/900		37/950	
*CHAMBER HEIGHT, in/mm	24/600		39/990		57/1450		63/1600	
*CHAMBER DEPTH, in/mm	39/1000	51/1300	53/1350	61/1540	53/1350	98/2500	148/3750	197/5000

The above dimensions are for models selected from a much wider range.

Models GEV 6610 and 6613 incorporate vertical sliding doors, whereas other models have horizontal sliding doors.

* Usable dimensions

RAPID, EFFICIENT STERILIZATION OF BULK LIQUIDS

Using hot water recirculated by a high-capacity pump, Getinge GEC Terminal Sterilizers provide efficient utilization with high product throughput. Alternative cycles, such as for porous textile loads, filled ampoules and dry empty glassware, can also be incorporated in GEC models.

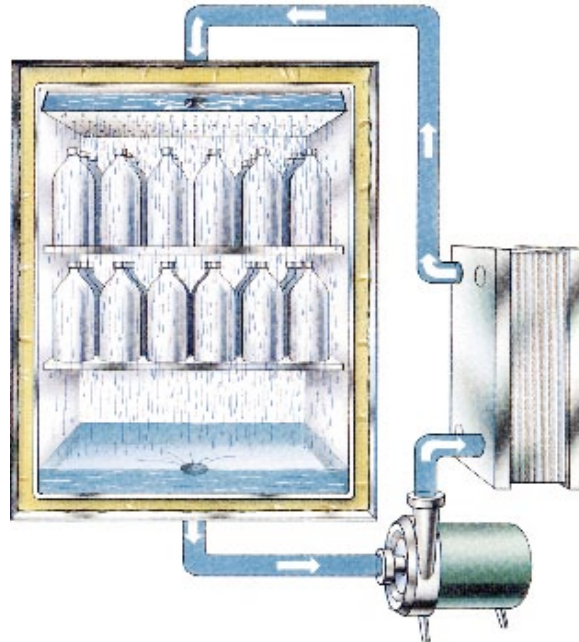
A closed system

The GEC sterilization process utilizes a closed loop water system for rapid heating and cooling. Another main benefit of using water as the heat transfer medium is that the process sterilizes the water along with the product and therefore presents no hazard to the product. Any suitable type of water may be used, including de-mineralized, distilled, purified or WFI. Selection of appropriate process water is determined by the product material and closure integrity, as well as a client's process requirements. As an option, water may be stored in an integral sump for reuse.

External heat exchangers are used to indirectly cool the circulating water after completion of the sterilization phase.

Uniform temperature

Water cascades from a perforated tray at the top of the chamber to create a uniform temperature. High water flow rates also ensure that uniform temperature distribution is maintained throughout the chamber during the sterilization phase. Distortion or damage to flexible containers is prevented by controlling filtered (through a bacteria-retentive filter) air over-pressure during the process.



The closed system conserves heat and sterilizes the heating/cooling water to minimize the risk of contamination.

Precise control of cooling

External heat exchangers are used to indirectly cool the circulating water after completion of the sterilization phase. Precise control of the cooling rate and the safe handling temperature necessary for the product is easily achieved using the GEC system (generally more rapidly than the corresponding GEV or GE cycles).

GEC model	6610	6613	6913	6917	91413	91425	91837	131682
CHAMBER VOLUME ft ³ /m ³	16/0.5	21/0.6	30/0.8	37/1.1	63/1.8	115/3.3	227/6.4	706/20.0
CHAMBER WIDTH, in/mm	26/660			34/870		36/920	50/2770	
CHAMBER HEIGHT, in/mm	24/600		33/850		55/1400		69/1750	61/1550
CHAMBER DEPTH, in/mm	39/1000	51/1300	53/1350	67/1700	53/1350	98/2500	148/3750	323/8200

The above dimensions are for models selected from a much wider range.

Models GEC 6610 and 6613 incorporate vertical sliding doors, whereas other models have horizontal sliding doors.

* Usable dimensions

SMOOTHER LOADING AND UNLOADING



Automated shelf rack handling system



Driven roller conveyor system



Loading trolley

OPTIMAL HANDLING AND PROCESSING



- 1. Shelf rack with adjustable shelves
- 2. Shelf rack with slidable shelves
- 3. Stackable shelves

The systems shown on this page are just a few examples of the many accessories available from Getinge.

CONTROL SYSTEMS

Reproducibility of sterilization cycles is crucial in life science applications. To achieve this and minimize human error, Getinge supplies the PACS 3000 Control System for use with its GEV/GEC Production Sterilizers. PACS 3000 accurately handles tasks such as parameter setting, sterilizer operations, system programming via CS 1000 software, and data processing, presentation and storage.

Versatile features

The major features included in PACS 3000 are:

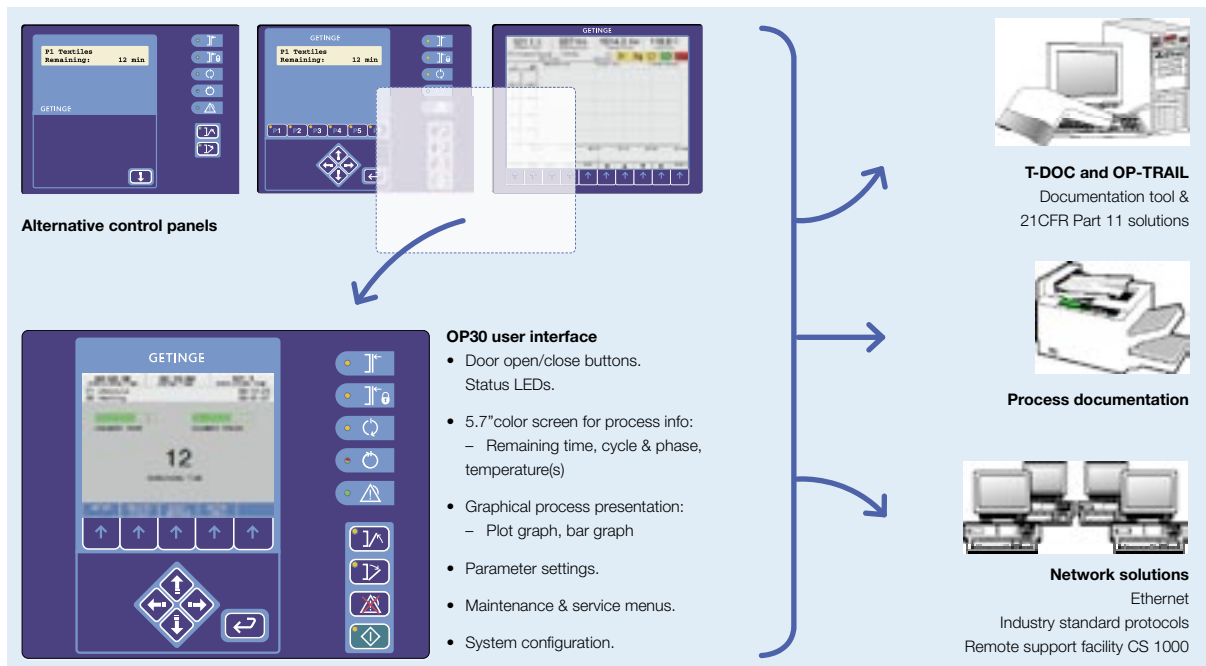
- A user-friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multilevel password protection
- Multilanguage display
- PACS Supervisor independent monitoring system

Regulatory compliance

The entire PACS 3000 is developed according to stringent GAMP (Good Automated Manufacturing Practice) guidelines of the pharmaceutical industry, and is FDA 21 CFR part 11-capable. Every system is supported with comprehensive system documentation.

Standard PLC Systems

The PACS 3000 is designed for use with sterile processing systems. Many thousands of PACS systems are in operation around the world in validated production facilities. However, if a customer prefers, standard PLC systems are available based on Allen-Bradley hardware platforms. These PLCs can be provided as standard options with similar functionality and documentation to the Getinge PACS 3000.





Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

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GETINGE

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