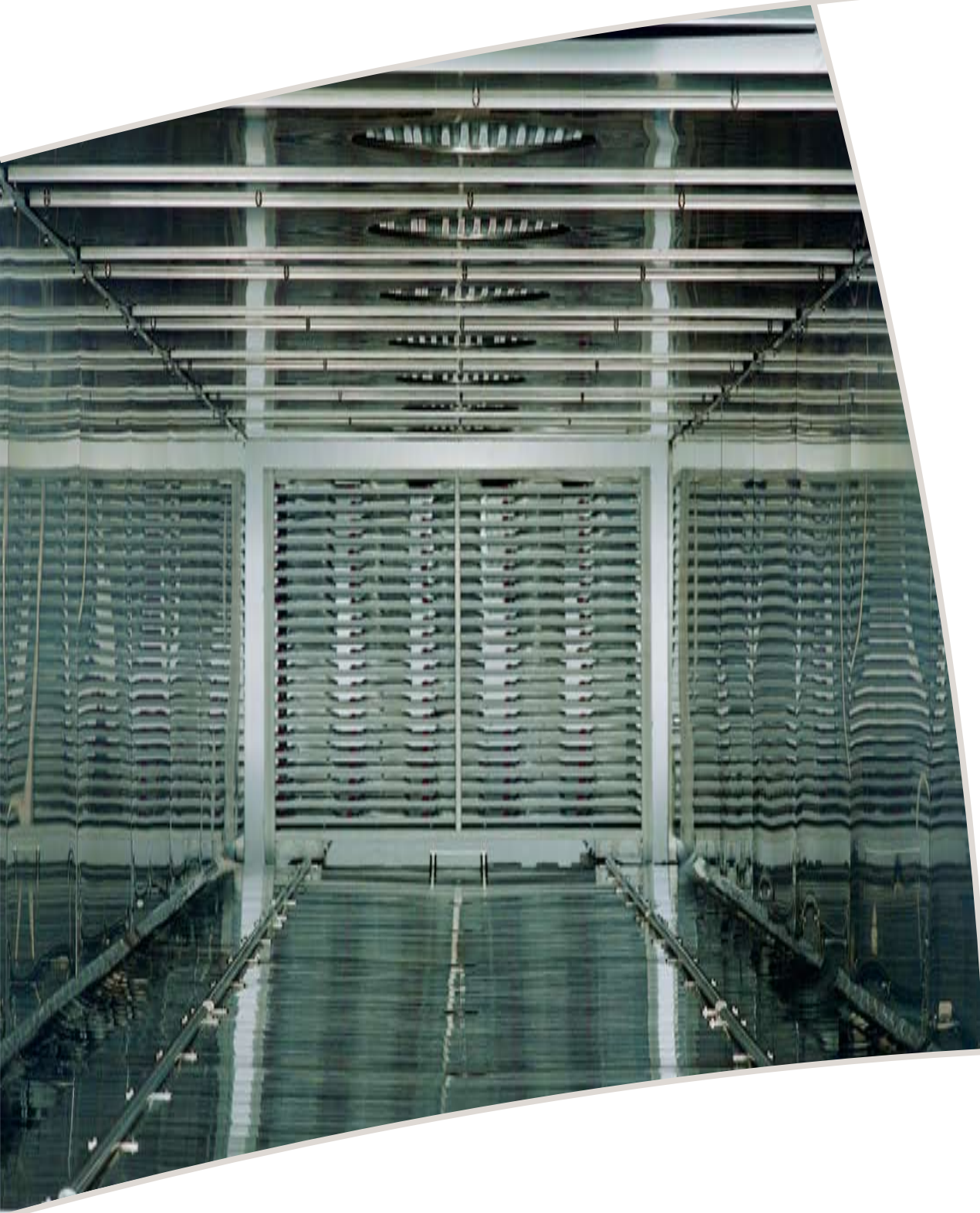


GETINGE

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 maximal 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
- Isolators for sterility testing and processing
- Installation design support services
- Testing, commissioning and qualification (FAT/SAT, IQ/OQ)
- Training and after-sales support

Optimizing economy

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

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

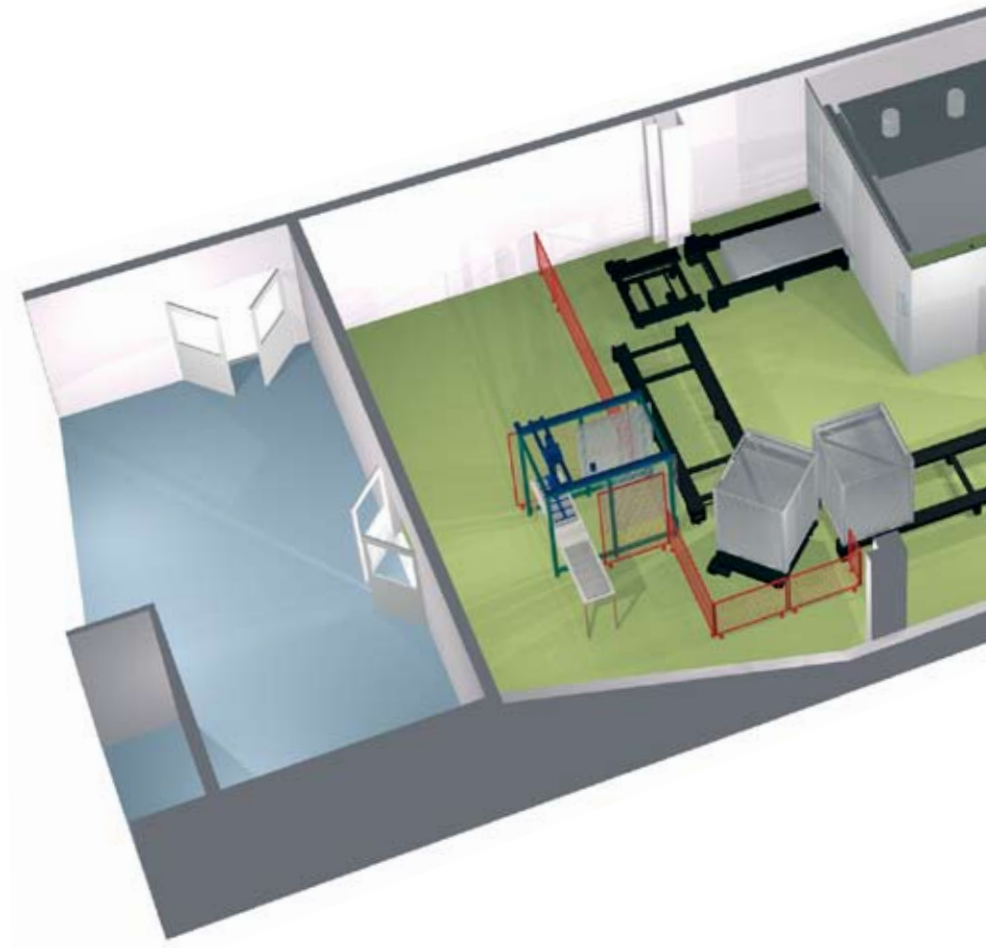


GENTLE BUT EFFECTIVE PRODUCT STERILIZATION

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

GEV/GEC sterilization kills the toughest microbes but is 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.

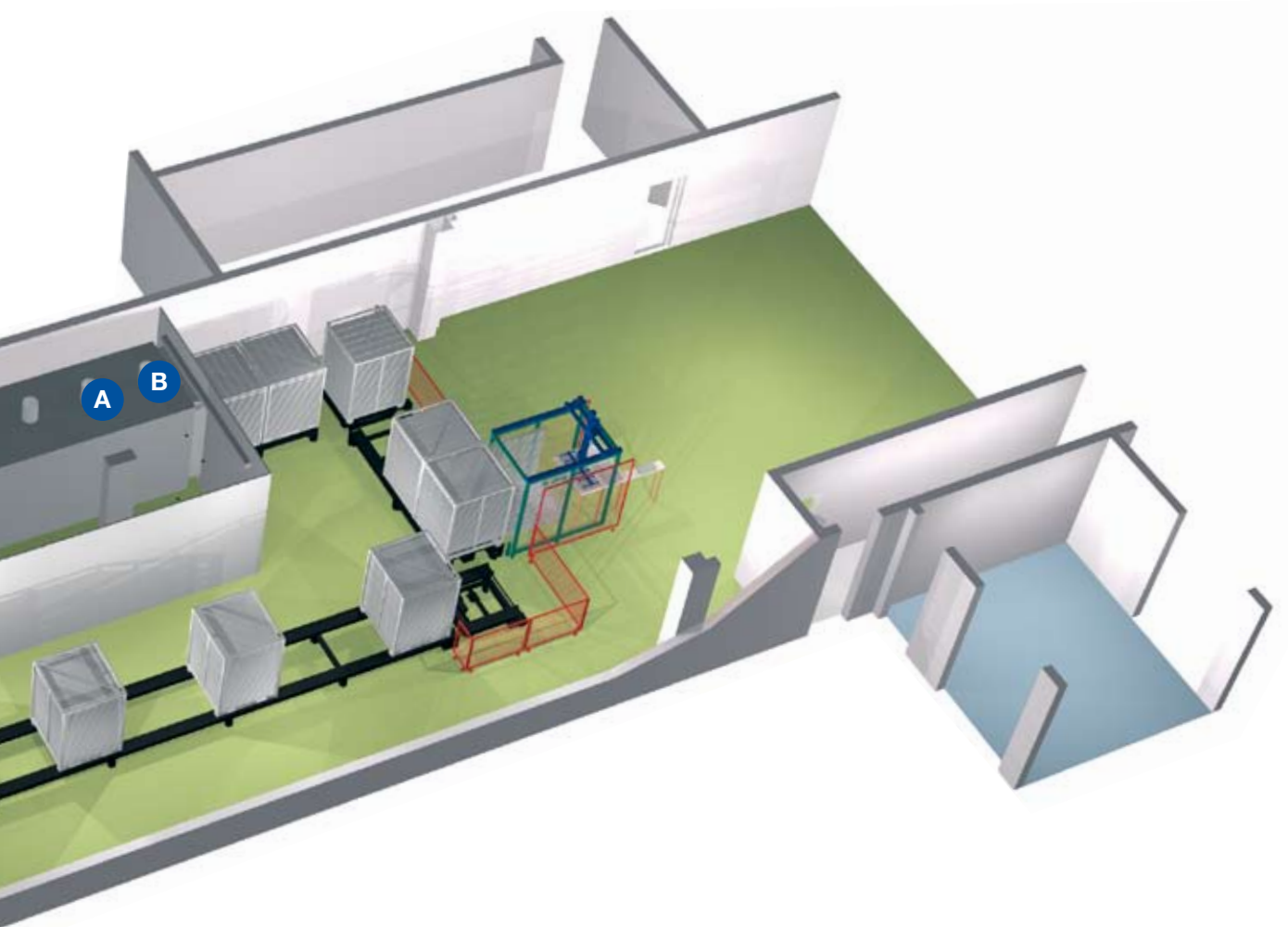


UTILITIES


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: 0.5 to 10.1 m³.

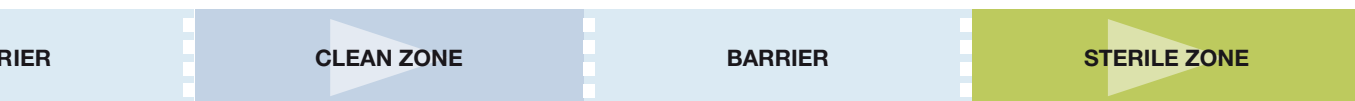
B **GEC**



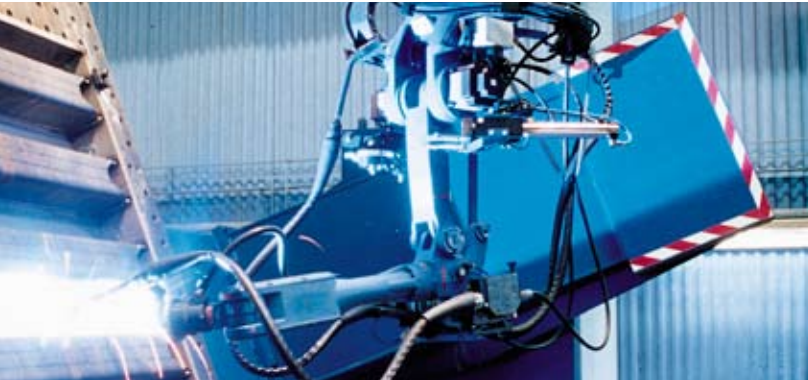
Getinge Circulating Water Terminal Sterilizers (GECs) are primarily intended for sterilizing large volumes of liquids in sealed glass or plastic containers.

Standard chamber volume: 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 0.5 to 20 m³. Customized chamber sizes are available on request.

Regulatory issues

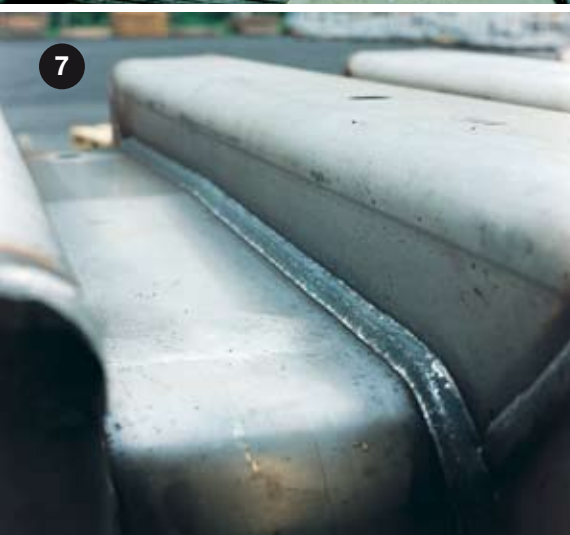
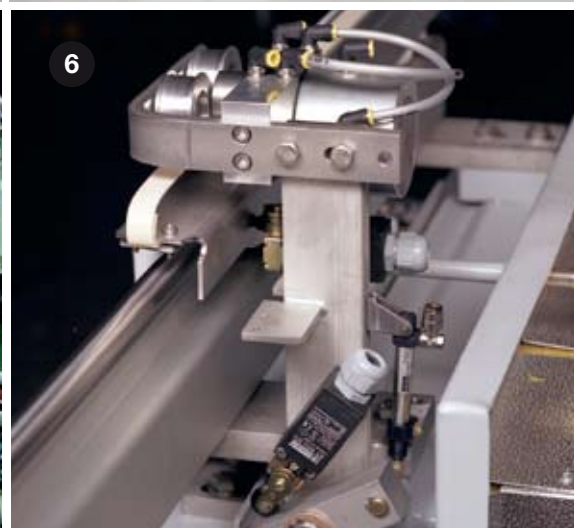
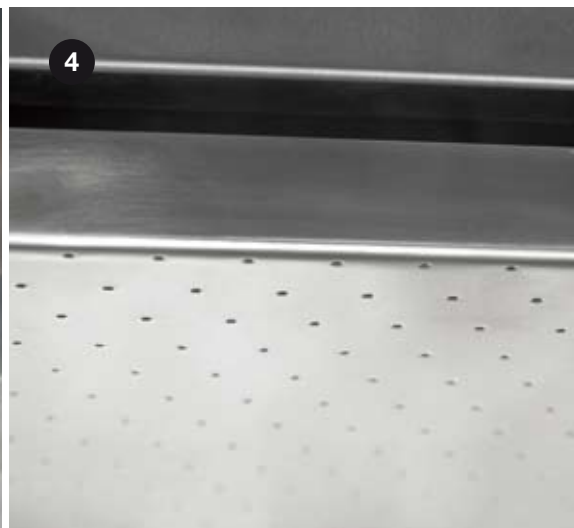
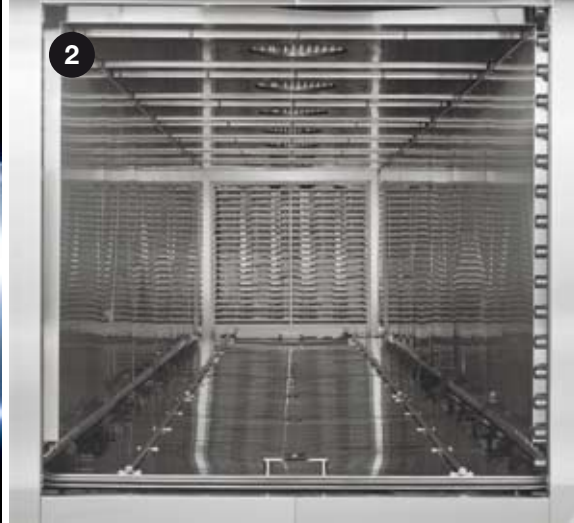
Getinge closely follows industry trends, practices, guidelines and regulatory requirements. Additionally we actively participate in working groups and committees working to refine these requirements.

**GAMP | cGMP | BPE2005 | MCA | ISPE BASELINE GUIDES
FDA | EN46002 | 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.

The patented GEV “Zone Control™” feature allows validated processing of part batches, allowing production flexibility while reducing validation effort.

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 RAT 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 and trays
- Stackable shelves
- Various rail systems
- Loading trolleys
- Roller conveyors

Handling and movement of heavy production loads can be difficult and hazardous. Getinge can provide complete production logistics systems, assisted by our specialist partner, Compliant Logistics. See page 14 for more details.

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

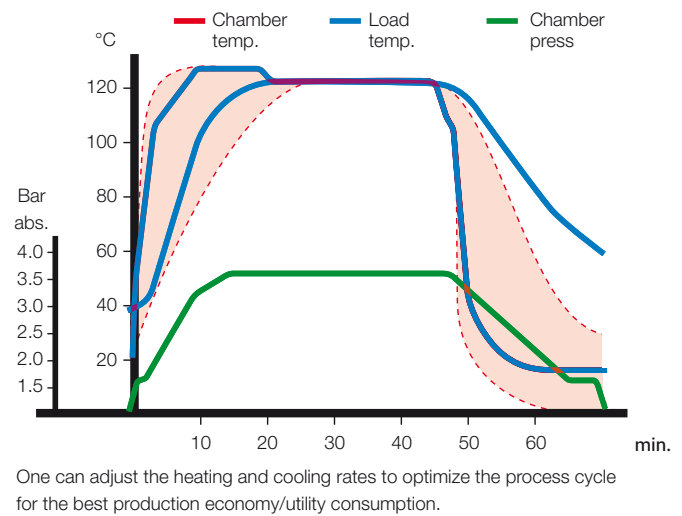
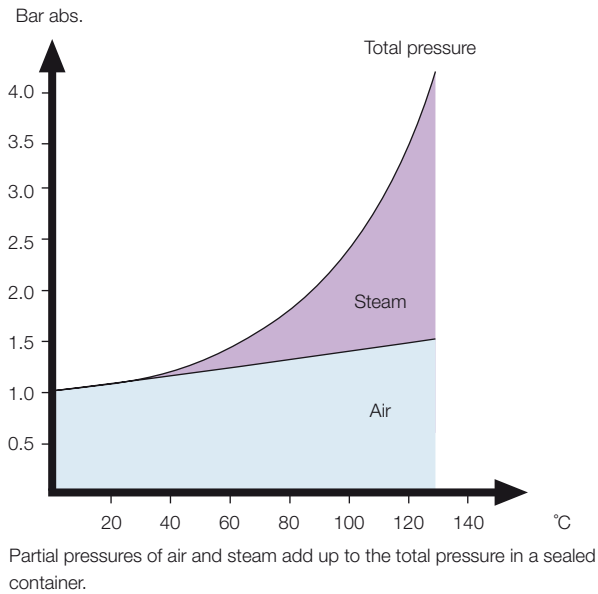
The Sterilization Technology Center is the place to come and discuss your application challenges with our experienced personnel. You can conduct test runs on your own products and packaging to define the

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 creates 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 process 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, including vacuum cycles can also be incorporated in GEV Terminal Sterilizers, making the GEV a uniquely flexible sterilizer. Programs may include:

- Liquids in glass or plastic containers and open vessels
- Products in blister packs
- Textiles, glassware, utensils, filters, rubber stoppers

Excellent heat transfer

During heat up and sterilization and air 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.

Optimized cooling

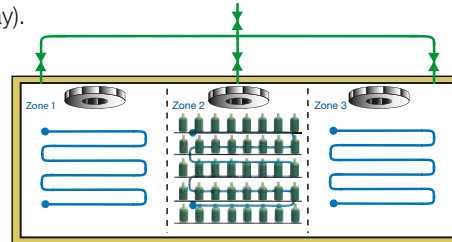
Steam is condensed immediately after the sterilization phase and replaced by sterile filtered air which is cooled by internal heat exchangers fabricated from seamless tubing. After cooling, the dry product may be unloaded and moved immediately to the downstream process.



Rapid cooling and drying is achieved by powerful centrifugal fans and internal water cooled heat exchangers.

Zone Control

This patented system allows the zones of a multi-rack sterilizer to be independently controlled, allowing a single process to be validated for either full or part batches. This valuable feature is designed to save time during validation while providing production managers with flexible equipment utilization (e.g. part load at the end of the day).



GEV model	6610	6613	6913	6915	91413	91425	91637	91650
CHAMBER VOLUME m ³	0.5	0.6	1.0	1.2	2.3	4.3	7.6	10.1
*CHAMBER WIDTH, mm	600		660		900		950	
*CHAMBER HEIGHT, mm	600		990		1450		1600	
*CHAMBER DEPTH, mm	1000	1300	1350	1540	1350	2500	3750	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.

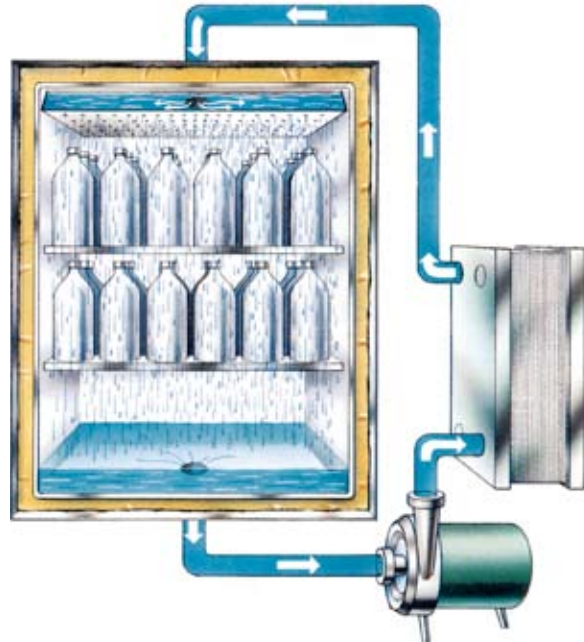
A closed system

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 m ³	0.5	0.6	0.8	1.1	1.8	3.3	6.4	20.0
CHAMBER WIDTH, mm	660			870			920	1270
CHAMBER HEIGHT, mm	600		850		1400		1750	1550
CHAMBER DEPTH, mm	1000	1300	1350	1700	1350	2500	3750	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

COMPLETE LOGISTIC SOLUTIONS



Production Logistics. In a busy production environment, transporting product to and from a sterilization chamber is a logistical exercise.

Loads are often heavy (a rack of liquid product can weigh more than 1000 kg) and are difficult and potentially unsafe to handle manually.

Getinge recommends the use of automated load handling systems for large loads and offer a variety of alternatives to suit your product and installation requirements.

Together with our global partner, Compliant Logistics, we can provide conveyor systems that integrate with the sterilizer and circulate the loading racks. These systems designed to combine heavy industrial manipulation with the GMP production environment.

Compliant Logistics can also provide robotic solutions for automatic loading and unloading of shelves and racks if required.

Rack Design

Protection of the product and process efficacy are key to the rack design. Racks and shelves must allow adequate and uniform flow of the sterilizing media, while supporting the product to prevent deformation. Getinge has experience of all types of packaging and can recommend suitable shelving systems.

We also offer a test and prototyping service to assist in the design of shelving and process development for new packaging styles.

COMPLIANT LOGISTICS

Compliant Logistics AB offer production logistics solutions for the Medical Device & Pharmaceutical Industry; our solutions manage the flow of materials, products and information through a production facility. Compliant Logistics provide material management and assembly systems solution based upon a modular hardware platform and an integrated MES/SCADA software application. The system allows for integration with other unit operation as well as vertically in the IT system, eg ERP systems. The software optimizes production flow and manage variants and has been developed and qualified according to GAMP.

www.compliantlogistics.com

GETINGE CONTROL SYSTEMS

Reproducibility of sterilization cycles is crucial in life science applications. To achieve this and minimize human error, Getinge supplies the PACS 3500 Control System for use with its GEV/GEC Production Sterilizers. PACS 3500 accurately handles tasks such as parameter setting, sterilizer operations, system programming and data processing, presentation and storage.

Versatile features

The major features included in PACS 3500 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 3500 is developed according to stringent GAMP4 (Good Automated Manufacturing Practice) guidelines of the pharmaceutical industry. Every system is supported with comprehensive system documentation.

Standard PLC Systems

The PACS 3500 is designed for use with sterile processing systems. Many thousands of PACS systems are in operation around the world in validated production facilities.

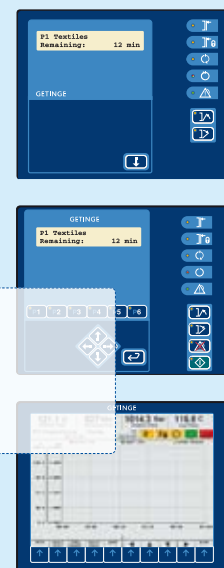
However, if a customer prefers, standard PLC systems are available based on Allen-Bradley or Siemens hardware platforms. These PLCs can be provided as standard options with similar functionality and documentation to the Getinge PACS 3500.



OP30 user interface

- Door open/close buttons. Status LEDs.
- 5.7" color screen for process info:
 - Remaining time, cycle & phase, temperature(s)
- Graphical process presentation:
 - Plot graph, bar graph
- Parameter settings.
- Maintenance & service menus.
- System configuration.

Alternative control panels





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

THE GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. Equipment, services and technologies are supplied under the brands **ARJO** for patient hygiene, patient handling and wound care, **GETINGE** for infection control and prevention within healthcare and life science and **MAQUET** for surgical workplaces, cardiopulmonary and critical care.