

GETINGE
GETINGE GROUP

**GETINGE GEV TS SERIES
OPTIMIZED TERMINAL STERILIZATION**



Always with you

TERMINAL STERILIZATION: NEW CHALLENGES

The principle that Terminal Sterilization provides a higher degree of sterility assurance than aseptic processing is well understood and leads regulatory agencies around the world to require that if a product may be terminally sterilized, it must be.

Product packaging and commercial issues may not be provided as reasons for not performing a final sterilization step in the production of a sterile drug product, if the product itself can be sterilized. Similar principles apply for sterile ophthalmic products and medical devices.

As packaging and delivery systems become more sophisticated in the continuous effort to ease drug administration and improve patient safety, so the challenges to perform terminal sterilization grow: prefilled syringes, blister packaging and new plastic materials with intricate shapes require new and more sophisticated sterilization process control.

The drive to continuously reduce healthcare costs requires that more efficient production methods must be used: increased automation, larger batch sizes, more efficient production flow must be studied and incorporated in the logistic system.

Pharmaceutical competence

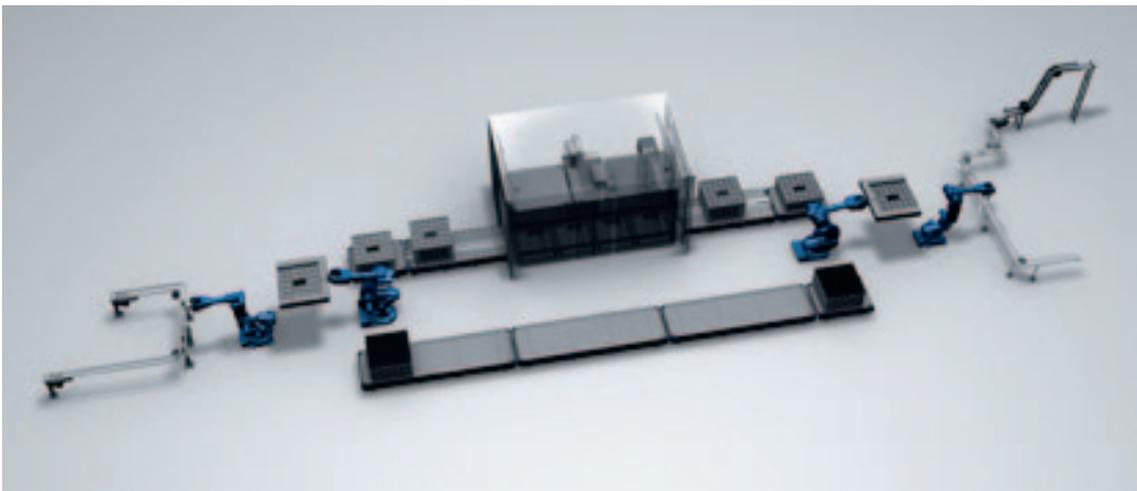
Getinge has a long history with the Pharmaceutical Industry and we are well aware of the issues and challenges faced by our clients.

We introduced the GEV Steam & Air mixture sterilizer to the industry more than 30 years ago, and since then it has been used extensively to sterilize many types of parenteral and ophthalmic products and medical devices.

The latest evolution, the GEV TS Series, builds on this experience while adding new process controls to allow processing of even the most delicate items.

Beyond the machine

We recognise that these machines are an integral part of an industrial production process handling tons of product. The GEV TS Series includes purpose designed rack and conveyor handling systems to ease the production flow and provide a complete solution for our customers' needs.

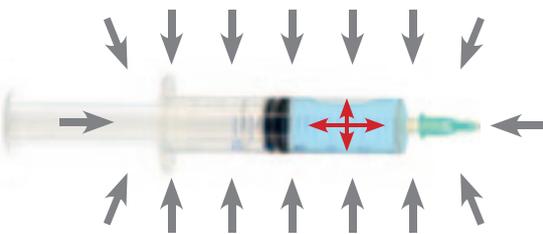


GENTLE BUT EFFECTIVE PRODUCT STERILIZATION

The Basic Process

To understand the process and features of the Getinge GEV TS Series sterilizers, it is necessary to understand the sterilization process for pharmaceutical products. Thermal sterilization of liquids in sealed containers such as vials, syringes, plastic bags and bottles requires consideration of the physical processes that occur during heating and cooling. When heating such a container, the following occurs (assuming an aqueous product):

- a The vapour pressure of the liquid increases (according to the Pressure-Temperature curve for water)
 - b The air in the container pressurises according to the Ideal Gas law (linear)
 - c The container expands (increasing volume and reducing pressure)
 - d The liquid expands (reducing volume and increasing pressure)
 - e Dissolved gases may evolve from the fluid
- Generally, for most common products and containers **(c)**, **(d)** and **(e)** may be disregarded. They may have some impact (e.g. in case of a 100% fill / zero headspace) but in practice, **(a)** and **(b)** predominantly contribute to the pressure inside the sealed container. According to Dalton's law, these partial pressures are additive – See chart A. This internal pressure will be generated in any sealed container that is heated, and must be



Balance Pressure must equal Internal Pressure to avoid closure and container disruption.

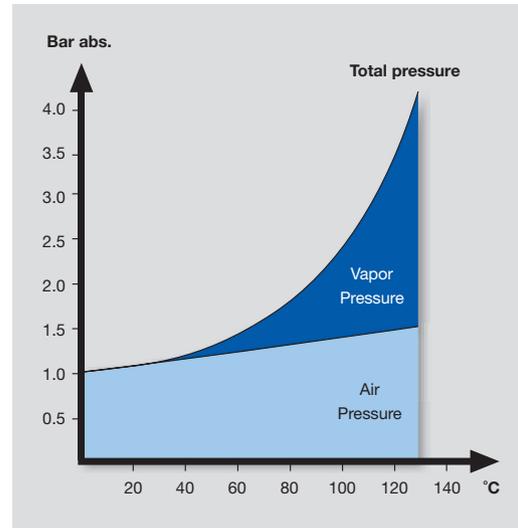


Chart A: Partial pressures of air and steam add up to the total pressure in a sealed container.

considered when evaluating the choice of thermal sterilization process. Rigid containers with a mechanically restrained closure (such as a glass vial with crimp seal) can withstand this internal pressure even if the external pressure is reduced, as is the case with a standard steam sterilization method utilizing vacuum air removal.

For other, less robust packaging (such as plastic containers or prefilled syringes), the internal pressure must be balanced such that there is no net pressure differential across the container and/or closure (or there is a risk of compromising the container and/or disrupting the closure (e.g. excessive stopper movement in a prefilled syringe)).

The Getinge GEV TS is designed as a such a system, using sterile compressed air as a "support" pressure to balance the pressure in the autoclave chamber with the internal pressure generated as the container and contents are heated using steam.

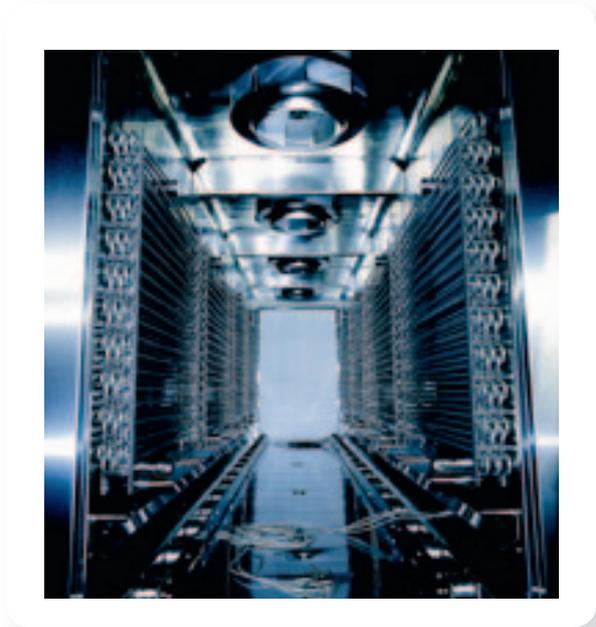
More Physics

Steam and air have different densities and will “stratify” if not mechanically mixed (i.e. the heavier air will sink to the bottom). Consequently a fan and ducting is used to create a circulation pattern and maintain a homogeneous environment.

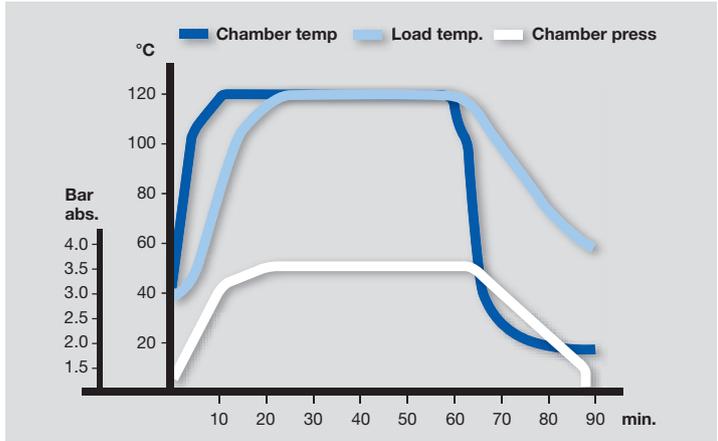
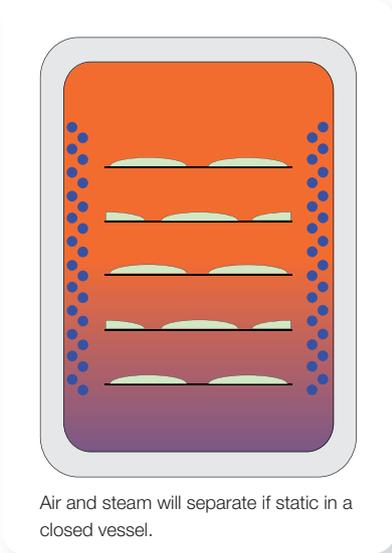
This system provides both uniform heating of the product and a pressure balance system, and is the basis of most steam-air mixture sterilizers, both from Getinge and (in various ways) our competitors.

Cooling

Having heated the product using steam, it is necessary to remove the energy during the cooling phase. To achieve this as quickly and efficiently as possible, Getinge use batteries of heat exchangers placed in the path of the circulating steam-air mix. The heat exchangers are cooled using (preferably chilled) cooling water. As the product temperature decreases, so the pressure is reduced to maintain the balance with the internal load pressure and avoid compression-distortion of the container. The result of this process is that the product



emerges sterile, cool, dry and ready for downstream processing. The pressure balance system prevents damage to the container, assuring that the product is not compromised.



Heating and cooling rates can be adjusted to optimize the process cycle for the best production economy/utility consumption.

THE GEV TS AND GEV TS TURBO NEW FEATURES FOR THE ULTIMATE IN PROCESS CONTROL

The basic principles described on the previous page are applicable to most commercially available steam-air mixture sterilizers.

The Getinge GEV TS Series is designed as a range of competitive steam-air mixture sterilizers, with an outstanding performance, similar to that of previous Getinge GEV models.

The features of the Getinge GEV TS series are described in detail overleaf but include:

- Modular chamber design, with product zones
- Single speed fan per zone
- Two banks of efficient heat exchangers per zone
- Steam entry and drain connection per zone

A natural effect of a unidirectional flow of the steam/air mixture is that a temperature gradient is created in the direction of the flow. As the steam is carried with the airflow, it heats the product at the

bottom of the chamber first and loses energy as it rises towards the fan inlet.

The result is that during the heating process, a temperature differential is created from the top to the bottom of the load. See Diagram A.

Conversely during cooling, energy is removed from the environment rapidly as it is forced into contact with the efficient heat exchangers, resulting in more rapid cooling of the bottom load units and a temperature differential from bottom to top. See Diagram B.

Consequently, the total heating effect (or F_0) is uniform throughout the product, even if there is a temperature differential throughout the load at any instant during heating and cooling. (Note that the temperature during the sterilization phase is uniform throughout the load and better than the required $\pm 0.5^\circ\text{C}$.)



Diagram A – Heating.



Diagram B – Cooling.



Introducing the Getinge GEV TS Turbo

An issue with the temperature differential profile of steam-air mixture sterilizers is the balance pressure.

This may not be a problem for the majority of products, but may be catastrophic for other, more delicate loads.

Controlling balance pressure according to the load temperature at the top of the chamber may cause closure or container issues at the bottom and vice versa.

The GEV TS Turbo Series is designed to avoid these issues by reducing temperature differential within the load during heating and cooling. It does so by allowing the environment to move laterally through the load, by careful design of the loading rack coupled with adjustable slots in the liner / ducting. Getinge has designed racks for common load types including:

- Syringes – nested and bulk / individual
- Blister packed products
- Plastic containers such as BFS products and bags

In addition, modulating valves are used extensively to carefully control temperature and pressure to minimize damaging fluctuations and assure smooth transitions.

Optimized Cooling - RADICOOOL

To optimize cooling at the top layers or product, additional Radicool™ heat exchangers are placed radially around each centrifugal fan, cooling the air immediately as it exits.

Cooling efficiency is a factor of (assuming good GMP design and use of acceptable materials):

- Total heat exchange surface area
- Air path over the surface of the heat exchangers
- Air flow rate, a factor of fan design and rotation speed
- Cooling water temperature
- Nature of container and product

In the GEV TS Turbo, the process parameters and loading system design are optimized to provide the most effective cooling and optimal process time with minimal utilities.

- Centrifugal stainless steel fan driven by a powerful electric motor via a hygienic mechanical seal.
The motor of the GEV TS Turbo is >2.5x more powerful than that of the GEV TS model.
- Dual steam inlets (one each side of the fan, per zone) provide faster, more uniform heating.
- Dense batteries of stainless steel heat exchangers behind the ducting provide a torturous path for the circulating environment
- The inner liner design assures maximum flow of the air over the heat exchanger batteries.
- A variable frequency drive uses minimal power for homogenisation during heating and sterilization and maximum/controllable airflow during cooling
- Proportional valve(s) on cooling water supply allows controllable ramping of cooling rate for optimal protection of the load. Similarly proportional valve(s) on the steam inlet provide control over heating rate.

ENABLING YOU TO ACHIEVE OPTIMAL PROCESSING



The Getinge GEV TS Series is designed specifically for Terminal Sterilization of all kinds of parenteral products but specifically for products with delicate packaging and closure systems.

For the development of the new Getinge GEV TS Series sterilizers we have focused on our customers' needs and the requirements of the various products to be processed.

For the basic GEV TS Series we have focused on life cycle economy, with features for processing most sterile pharmaceutical products, including but not limited to:

- Large volume parenterals in glass or plastic containers
- Vials*, ampoules
- Ophthalmic items such as contact lenses in blisters

* As previously noted, vials may be processed in a normal vacuum steam sterilizer. However, the load emerges hot and water may be retained under the flip-cap/crimp seal.

More delicate items such as:

- Prefilled syringes (in nests or single in bulk)
- Blister packed items may require the additional features of the GEV TS Turbo.

To determine the optimal process conditions for a particular product, Getinge provides testing and process development services in our Customer Application Development Center in Sweden and Sterilization Technology Centers, which are located in Japan, USA and UK. Each center is equipped with a specially designed sterilizer that allows programming of a wide range of process cycles with complete control of all process parameters.

Conduct your own test runs

These centers are 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. We are licenced to hold certain drug products, although most can be simulated with water.

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. Furthermore, excellent pressure control is provided by accurately linking any change in pressure closely to product temperature throughout the complete process.

Unique Process Flexibility

The steam-air mix process of the GEV TS Series is one of the most versatile sterilization processes available.

In addition to the capabilities for pressure balance described earlier, a variety of additional process options are available to cope with the challenges presented by the many products and packaging styles used in the bio-pharmaceutical industry.

Pre-Heating

Heating a product with steam is rapid due to the unique process in which steam deposits energy: condensation. However, while efficient at heating, the resulting water can be problematical for downstream processing.

The rapid flow of air and design of the heat exchangers does remove much of the water, but drying can be improved by “pre-heating”.

In this process, the circulating air is heated prior to steam injection, and this heats the load. As a result, when steam is injected, less energy is required to raise the load to

sterilization temperature and thus, less condensate is produced, resulting in a dryer load.

Vacuum System

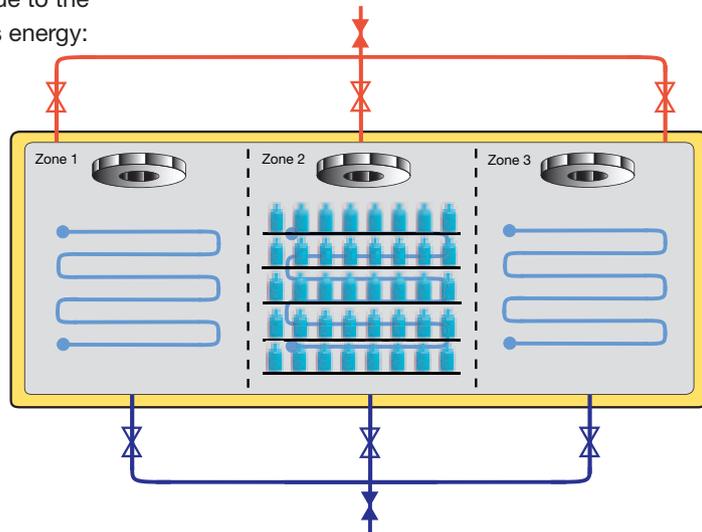
For some products it is beneficial to remove air from the chamber prior to the heating and sterilization phase, even if the subsequent process is a steam/air mixture process.

In other cases, the Terminal Sterilizer may be used for other processes - for example for component and equipment preparation and infeed to the production area.

In these cases, it is necessary to have a vacuum air removal system incorporated in the sterilizer. This comprises a water ring vacuum pump (a high performance model in case of the GEV TS Turbo) with a condenser to remove steam and heat exchanger for water conservation.

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).



BASIC DESIGN FEATURES

Both the GEV TS and GEV TS Turbo are based on the same basic design with a number of common core features:

- A rectangular solid stainless steel chamber with horizontal sliding door(s), polished internally and insulated externally, with a rigid Aluminum casing. Rectangular chambers require up to 30% less production floor area than a cylindrical equivalent.
- A stainless steel liner forms ducting to efficiently direct airflow in a circulatory pattern and maintain a homogeneous environment. The sectional liner is easily removed for maintenance and cleaning.
- The environment is recirculated using stainless steel centrifugal fans, driven externally by a powerful electric motor via a purpose designed, mechanical seal. This arrangement assures optimal flow.
- A heat exchanger, fabricated from sealed stainless steel tubing (assuring no leakage of coolant) is placed between the liner and chamber wall, providing a tortuous path for the chamber environment and providing maximum heat exchange efficiency. The design provides about 15% more heat exchange area than jacket cooling and a significantly improved heat exchange due to the tortuous path of air through it. The heat exchanger is also used for pre-heating, which is significantly more efficient in time and energy than systems which use the jacket for this process phase.
- Irrespective of chamber cross section, the chamber is designed in segments or “Zones”, each 1260 mm deep. Each zone contains a liner, fan, heat exchanger battery, steam entry and drain connection. Each zone accommodates one rack of product. Getinge’s patented “Zone Control™” feature allows a multi-zone sterilizer to be validated to process individual racks, allowing part loads to be processed.

High Performance Model: GEV TS Turbo

In addition to the basic features outlined above, the high performance GEV TS Turbo model includes the following:

- For processing of more delicate products, a lateral airflow is required. This is achieved using slots in the liner system.
- To assure uniform cooling, additional Radicool™ heat exchangers are placed radially around the fan. This adds an additional 30% heat exchange capacity to the basic system and a massive 65% more than a system using jacket cooling alone.
- The additional heat exchanger makes the process faster and enables lateral air flow when required.
- To allow optimum control of the airflow, the fan is controlled by a variable frequency drive, allowing a low rotation rate for maintaining homogeneity in heating and sterilization and maximum airflow during cooling.

These core features and other optional details are described in the “Configuration” table on page 13 overleaf.



A strong focus is placed on serviceability and life-cycle economy.



The GEV TS uses the autoclave process in combination with smart functional design of the loading rack for optimal processing.

1. Batteries of dense heat exchangers fabricated from sealed stainless-steel tubing power the GEV's rapid cooling. GMP compliant with no connections inside the chamber.

2. In the Zone: Sectional internal liners control GEV airflow and consequently temperature distribution. Each section / zone is equipped with fan, heat exchanger and piping. Liner is provided with adjustable slots on GEV TS Turbo models to allow lateral airflow.

3. A custom designed stainless steel centrifugal fan delivers high GEV airflow rates. Driven via a mechanical seal by a powerful electric motor.

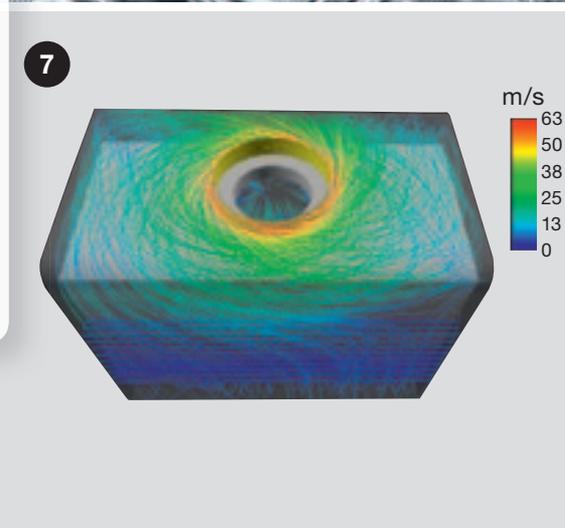
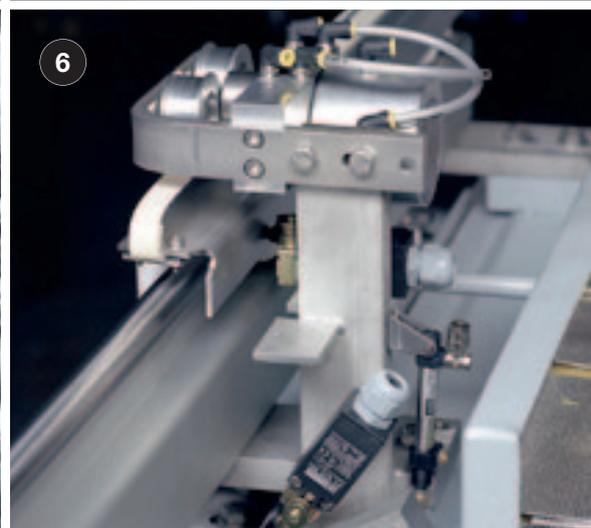
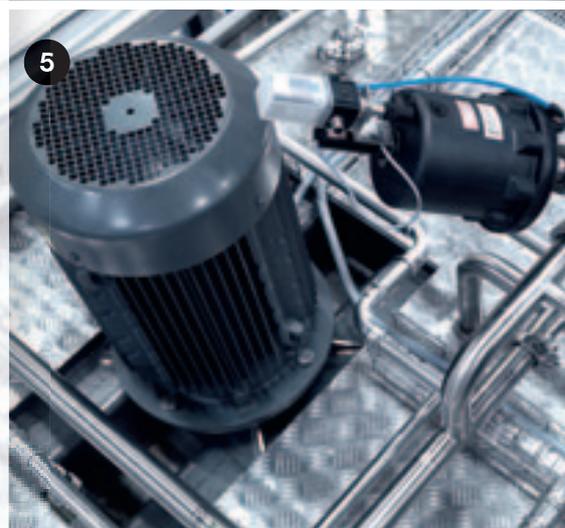
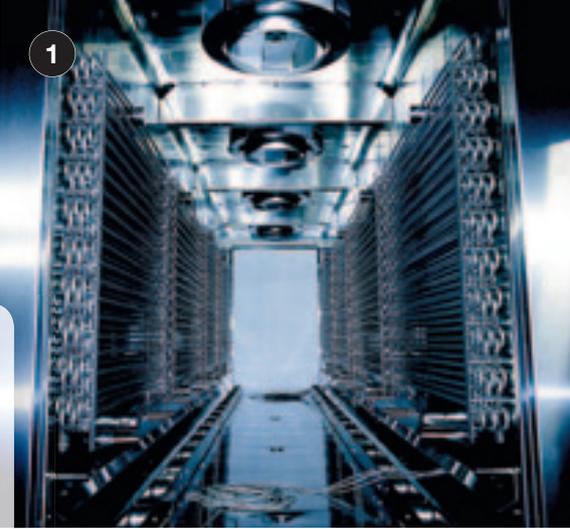
4. Radicool™ radial heat exchangers in the GEVTS Turbo model allows cooling of upper levels of product at an equal rate to lower levels, assuring more uniform temperature distribution and optimized pressure balancing. One steam inlet each side of the fan assure rapid heating and equal distribution to both sides.

5. A powerful electric motor drives the centrifugal fan via a hygienic mechanical seal. Typical power transmission is 3 to 11 kW (depending on model – motor power on the GEV TS Turbo is approximately 2.5x that of the GEV TS). Provided with a variable frequency drive system on the Getinge GEV TS Turbo models for efficient and controllable flow within the sterilizer chamber.

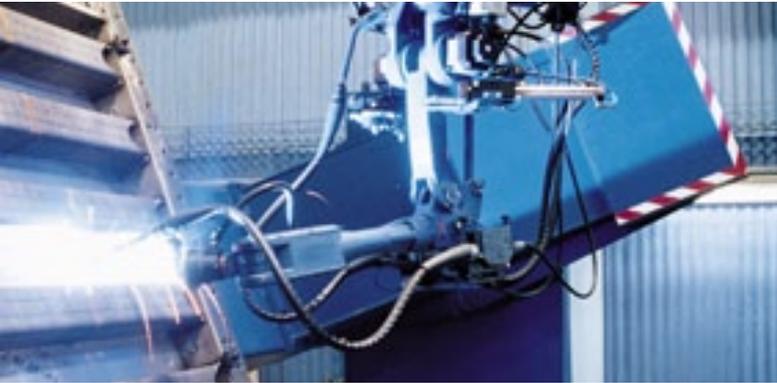
6. The doors of Getinge sterilizers are the cleanest, safest and simplest on the market.

7. Computational Fluid Dynamics (CFD) calculations were studied to optimize the design of the fan and liner system.

8. Top quality piping and components assembled to the highest standards.



SAFEGUARDING YOUR INVESTMENT



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

A sterilization system represents a large capital investment. Therefore Getinge takes measures to ensure that our GEV TS Series 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 stiffener design provides rigidity, allows visual inspection of all welds and reduces weight, thereby saving utilities.



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

Advantages of sliding doors

The sliding doors of GEV TS Series 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.

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 | MCA | ISPE BASELINE GUIDES FDA | EN ISO 13488 | ISO9000 | 21CFR Part 11

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

CONFIGURATIONS

CORE FEATURES

- Footprint efficient, rectangular, 316L stainless steel chamber
- Robotically welded & polished chamber
- 316L Stainless steel internal liner (ductwork) for control of steam and airflow within chamber
- Internal heat exchangers fabricated from stainless steel tubing providing efficient heating and cooling of circulating air within chamber. Two batteries per Zone. No connections to media within chamber
- Unique sectional design with efficient insulation encased in rigid Aluminum
- 304 Stainless steel fascia around door aperture, brush finish for easy cleaning
- Clean, safe and simple automatic horizontal sliding door(s)
- Stainless steel process piping (media to chamber / product contact media)
- 0.2µm membrane type sterilizing grade air filter in stainless steel housing
- In-situ steam sterilization of air filter & sterile air piping (maintenance programme)
- Pneumatically operated process valves
- Modulating valve on water inlet for smooth, accurate control of cooling phase
- cGMP features including:
 - Independent temperature sensor in chamber drain
 - Level sensor (and alarm) in chamber drain
 - Membrane isolated pressure gauges
- Zone Control™ system for validated processing of part loads
- GAMP compliant automation system (see "Control System")
- Comprehensive Validation Support Documentation including
 - Functional Specification
 - Hardware Design Specification
 - Software Design Specification
 - Vendor Data Sheets
 - Extended Sanitary Process Piping Documentation incl.
 - Weld procedure specifications
 - Weld Log
 - Heat and material certificates of welded components
 - Isometric drawings of sanitary piping system, identifying welded joints

GEW TS

- Fan driven by powerful single speed motor via a hygienic mechanical seal
- Additional fascia panels
- Clean room integration panels
- Cross contamination seal
- In Situ Filter Integrity Test (WIT)
- Sanitary stainless steel process piping system
- Stainless steel non-process piping
- Passivation of chamber & process piping system
- Chamber & process system surface finish, Ra< 0.8µm (30µinch)
- Chamber & process system surface finish, Ra< 0.5µm (20µinch)
- Modulating valve for steam inlet for accurate control of heating rate
- Vacuum system (see description)
- Preheating system (see description)
- Choice of automation systems and HMI panels
- Choice of printers or recorder for process documentation
- PACS Supervisor for independent process monitoring (with Getinge PACS 3500 automation system)
- Wireless temperature sensor system, with PLC, transmitter and 2 wireless sensors
- Additional wireless sensor
- Fan surveillance sensors monitoring correct fan rotation
- Videoboroscope inspection and report of sanitary piping system
- Cleaning & surface finish documentation
- Pre-Qualification during FAT (saves time and expense during site validation)

GEW TS Turbo

- Fan driven by powerful motor controlled by a variable frequency drive via a hygienic mechanical seal
- Slotted chamber liner to allow lateral flow of steam / air environment for processing of delicate loads.
- Additional Radicool™ radial batteries of sealed stainless steel heat exchanger for each fan
- Additional fascia panels
- Clean room integration panels
- Cross contamination seal
- In Situ Filter Integrity Test (WIT)
- Sanitary stainless steel process piping system
- Stainless steel non-process piping
- Passivation of chamber & process piping system
- Chamber & process system surface finish, Ra< 0.8µm (30µinch)
- Chamber & process system surface finish, Ra< 0.5µm (20µinch)
- Modulating valve for steam inlet for accurate control of heating rate
- High Performance vacuum system (see description)
- Preheating system (see description)
- Choice of automation systems and HMI panels
- Choice of printers or recorder for process documentation
- PACS Supervisor for independent process monitoring (with Getinge PACS 3500 automation system)
- Wireless temperature sensor system, with PLC, transmitter and 2 wireless sensors
- Additional wireless sensor
- Fan surveillance sensors monitoring correct fan rotation
- Videoboroscope inspection and report of sanitary piping system
- Cleaning & surface finish documentation
- Pre-Qualification during FAT (saves time and expense during site validation)

• = Standard Feature ○ = Optional Feature

		GEV MODEL						
	Units	111212	111225	121625	121637	141837	141850	141863
No. of Zones		1	2	2	3	3	4	5
Chamber volume	m ³	1.68	3.35	5.07	7.60	9.79	13.05	16.31
Chamber width	mm	1100	1100	1250	1250	1400	1400	1400
Chamber height	mm	1200	1200	1600	1600	1840	1840	1840
Chamber depth	mm	1260	2520	2520	3780	3780	5040	6300

The above dimensions are for models selected from a much wider range. Any cross section may be configured with up to 5 Zones (or more). * Width and Height figures are rounded down and are "nominal". Usable volume is nominal for the GEV TS Turbo model. Usable height for the GEV TS model is approximately 20mm more than for the GEV TS. Corresponding usable volume is fractionally higher.

OPTIMAL HANDLING AND PROCESSING

Rack Design

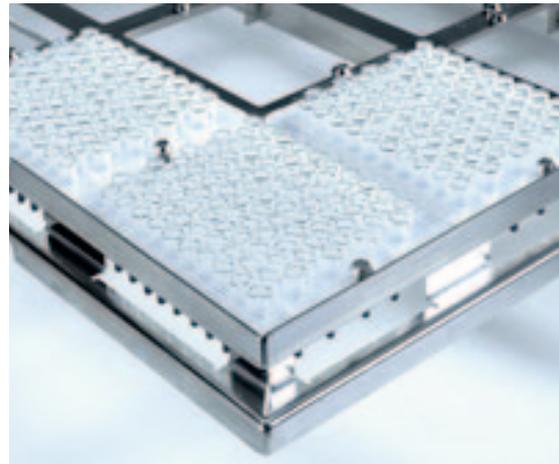
Protection of the product and process efficacy are highly dependent on the shelf and rack design. They must allow adequate and uniform flow of the sterilizing media, while supporting the product to prevent damage or deformation.

At the same time the shelves and racks must be designed for easy loading and handling. Getinge

has experience of many 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.



Simple loading and machine operation. Wireless sensors aid the loading process.



Syringes loaded on trays in nests.



Single syringes loaded in bulk. Shelves leave no scratches on barrel surface.

SMOOTHER LOADING AND UNLOADING

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, FlexLink, 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.

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



The GEV TS Series is more than a sterilizer: Getinge delivers a complete solution for the production logistics.



Modular conveyors may be combined to provide a recirculatory system for racks and stacking shelves.



Automation systems for product batching and stacking are available.

FlexLink

FlexLink offer production logistics solutions for the Medical Device & Pharmaceutical Industry; our solutions manage the flow of materials, products and information in production facilities. FlexLink provide material management and assembly systems solutions based upon a modular hardware platform, robotics and an integrated MES/EBR software application. We integrate unit operations as well as vertically in the IT system, eg. ERP systems. The software optimizes production flow, manage deviations, complies with CFR 21 Part 11 and has been developed and qualified according to GAMP.

www.flexlink.com

INSPECTION, TESTING AND CONTROL SYSTEMS

Reproducibility and reliability of process control is crucial in life science applications.

To achieve this and minimize human error, Getinge supplies PLC based automation systems designed for the challenging environments typically found in life science applications, and programmed using a wealth of experience gained since Getinge introduced the first PACS computer controlled sterilizers in the mid 1980's.

Getinge offers a choice of hardware platforms, each with the same fundamental equipment functionality and programming methodology.

- Rockwell – Allen Bradley (Logix Platform)
- Siemens – Simatic (S7 Based platform)
- Getinge – PACS 3500

All systems accurately handle tasks such as parameter setting, recipe handling, sequence control, and data processing, presentation and storage.

Versatile features

The features included in our automation systems are:

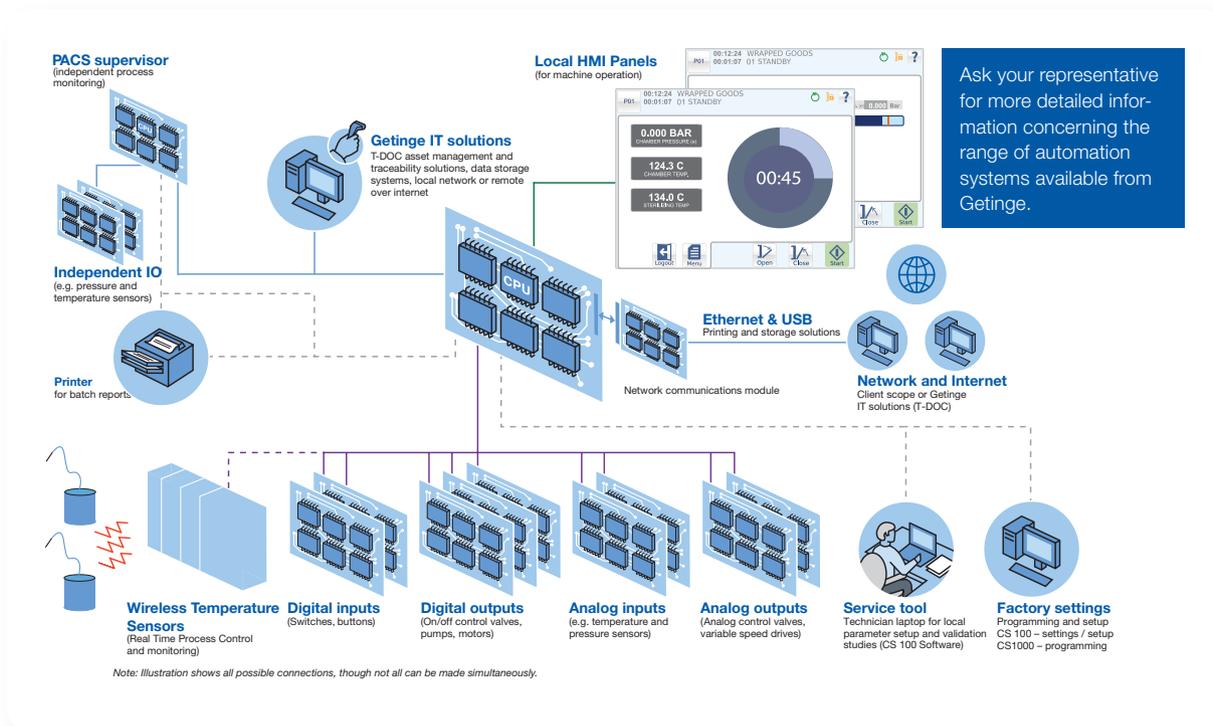
- User friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multi-level password protection



Alternate Local HMI Panel

Regulatory compliance

Getinge's automation systems are developed according to stringent GAMP (Good Automated Manufacturing Practice) guidelines of the pharmaceutical industry, and are FDA 21 CFR part 11 capable. Every system is supported with comprehensive documentation.



INSPECTION, TESTING AND DOCUMENTATION

As a general principle, Getinge follows ISPE GAMP guidelines in respect of project execution and provision of documentation to support our clients' qualification of sterile process equipment.

Quality is an intrinsic feature of every Getinge product. From the design specification, through component selection, fabrication, assembly and factory testing, every aspect of the manufacturing process is examined and documented to ensure and prove that the product is designed, built and tested according to the customer specifications and performance requirements.

Our objective is to demonstrate and document that we adhere to a cohesive quality control program in accordance with Good Engineering Practice.

Comprehensive validation support documentation

During the manufacturing process, in-process checking is performed to ensure compliance with specifications, and documentation is maintained as confirmation.

After manufacture, every unit undergoes comprehensive and rigorous Factory Acceptance Testing (FAT), again accompanied by detailed documentation. A complete package comprising these, together with installation, user and technical

manuals, is provided with the equipment. These documents are intended to support your subsequent qualification procedures, thus saving considerable time, effort and expense on site.

Optionally, we can also provide a "Pre-Qualification" of the system, carrying out the same test procedures as defined in the IQ-OQ protocols, which will later be performed on site as part of the validation exercise. This exhaustive procedure identifies the inevitable minor issues with equipment and documentation and ensures a trouble free start-up and site acceptance testing later on.

Deliverable documentation packages include:

- Submittals (design documentation)
- Construction
- Automation
- Testing & Qualification
- Installation Manual
- User Manual
- Technical Manual



Every GEV TS Series undergoes rigorous factory acceptance testing in a dedicated test bay with facilities to support our clients during the inspection and test of their equipment.

TRAINING, ACCESSORIES, CONTINUOUS SUPPORT AND SERVICE

Our core business idea could be summarized in one sentence: To keep our clients safe and operationally effective. We spare no effort to obtain this. Everything we do must be related to this aspect of our customer relationship. Integrated solutions, continuous assessments and upgrades, well-defined quality systems and efficient service programs are some pillars of this philosophy. Rapid system integration, a high degree of technical compatibility and swift spare part delivery are others

Our Philosophy

Getinge's aim is not only to provide high quality, industry leading, reliable equipment, our objective is to be your chosen partner within specific application areas of Infection and Contamination control.

Our products and services are available globally, provided and supported by 27 Getinge sales and service companies and a network of more than 65 authorized distributors. We presently distribute and support our products locally in more than 100 countries.

Our Scope Services

We can also provide:

- Installation, commissioning and qualification services
- Routine maintenance and periodic validation
- Training, carried out by our professional Academy
- Spare parts, from our regional distribution centers



Installation, commissioning and qualification services are provided by our global network of sales and service support companies and representatives



Training is provided by the Getinge Academy, an organisation with regional centers, run and staffed by professional trainers

OTHER GETINGE PRODUCTS FOR TERMINAL STERILIZATION

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

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

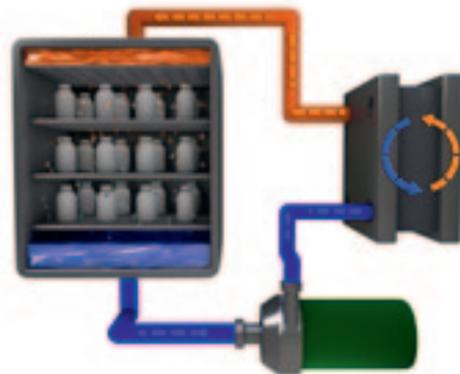
The GEC sterilization process utilizes a closed loop water system for rapid heating and cooling. Another main benefit of using water as the heat transfer medium is that the process sterilizes the water along with the product and therefore presents no hazard to the product. Any suitable type of water 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.

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).



A rapid and reliable alternative for the sterilization of parenterals: the Getinge GEC Series circulating water sterilizers.



COMPLETE SOLUTIONS FOR CONTAMINATION PREVENTION

Getinge is the world's leading provider of solutions for effective cleaning, disinfection and sterilization in the healthcare and life science sectors. We are dedicated to helping our customers provide maximum productivity in the most cost-efficient way. We do this by offering well thought through and customized solutions. This means that we are with our customers all the way from architectural planning and education to traceability and support – with complete solutions, long-term commitment and global presence. Getinge – Always with you.

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GETINGE

GETINGE GROUP

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GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. **ArjoHuntleigh** focuses on patient mobility and wound management solutions. **GETINGE** provides solutions for infection control within healthcare and contamination prevention within life sciences. **MAQUET** specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.