

**GE STEAM STERILIZERS
FOR PHARMACEUTICAL PRODUCTION**



Always with you

LIGHTS ON FOR THE NEW GENERATION STERILIZERS

The new Getinge GE Steam Sterilizers is a range of the new breed of state-of-the-art sterilizers from the world's leading brand in infection control. Sterilizers that further perfect the efficient performance and superior throughput you can always expect from Getinge. You recognize them by their clear, light and characteristic touch-screen panels, easily readable from a distance. As well as by their thought-through and user-friendly design, making them easier to operate than ever.



Ergonomic and user-friendly

The clear and intuitive interface of the new touch-screen panels is only one of many examples of how we ensure that Getinge sterilizers are easier to operate and more ergonomic. Read more about the new touch-screens on page 6.



The difference is in the details

Many steam sterilizers look alike from the outside - a grey stainless steel box. The difference is what is inside the box. Getinge has many years of experience of manufacturing steam sterilizers for GMP applications, and that practical experience, expertise and knowledge cannot be imitated.

GETINGE
GETINGE GROUP





FROM CONCEPT TO COMPLIANCE

When it comes to complete sterile systems, Getinge is with you all the way. The earlier we are involved in the planning process for your new or replacement system, the more we can offer you. Our knowledge and application expertise are drawn from over 100 years of dedication to washing and sterilization within healthcare and the life sciences.

We can support you with initial advice, system design, steam generation and water distillation equipment, extensive ranges of washer-disinfectors and sterilizers, closure processing systems, accessories, installation design, validation support and maintenance. Dealing with just one competent company will save you a lot of time, effort and costs. Getinge can satisfy virtually all your sterile processing needs from “concept to compliance”.

Optimal lifecycle economy

Our systems are based on compatible modular units that can be rapidly integrated and installed to form complete customized solutions based solely on your needs. The high quality and performance that have made Getinge a world leader in washing and sterilization ensure optimal lifecycle economy.

The Getinge GE Steam Sterilizers offers:

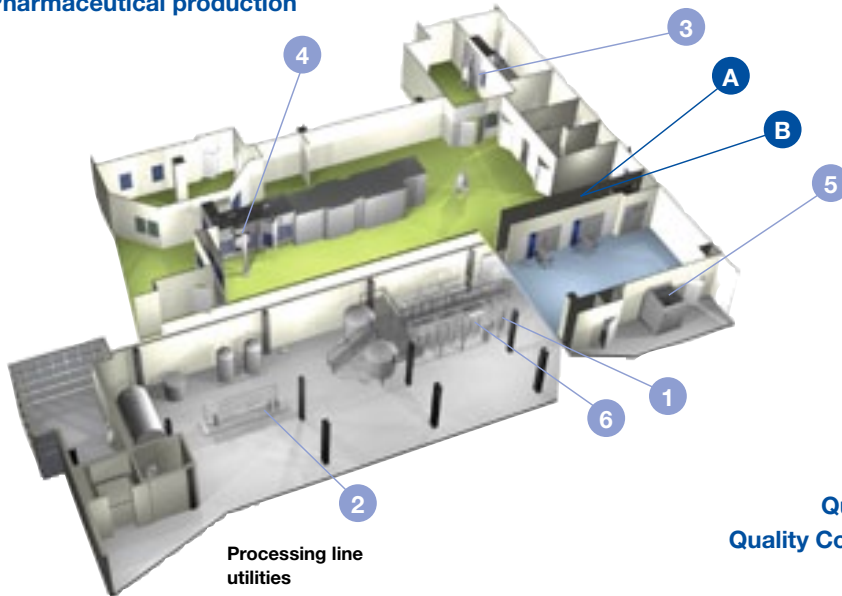
- Widest range of chamber sizes
- Leading-edge construction
- Strong on safety
- Outstanding flexibility and numerous design options



COMPLETE STERILE PROCESSING SYSTEMS

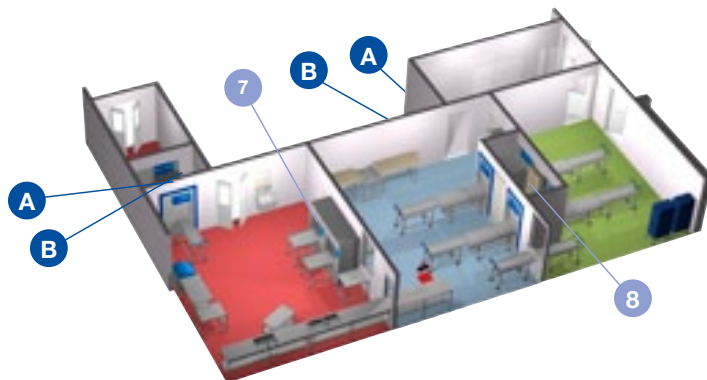
Getinge develops, manufactures and supplies completely integrated cleaning and sterilization systems for use within the pharmaceutical industry. Two typical installation examples for applications in bio-pharmaceutical production and quality assurance laboratories are shown below.

Pharmaceutical production



Processing line utilities

Quality Assurance / Quality Control laboratories





A. Small GE Steam Sterilizers

600 Series. Fully automatic high-pressure steam sterilizers with a single vertical sliding door, or two vertical sliding doors for pass-through operation.

Standard chamber volume: 10 to 28 ft³ (0.3 to 0.8 m³)



B. Medium-size GE Steam Sterilizers

900 Series. Similar to the small sterilizers but with larger chamber sizes and automatic horizontal sliding door(s).

Standard chamber volume: 21 to 39 ft³ (0.6 to 1.1 m³)



C. Large GE Steam Sterilizers

1400 and 2200 Series. Sterilizers with automatic horizontal sliding door(s) for large-scale applications. They can be pit-mounted for convenient floor loading.

Standard chamber volume: 49 to 600 ft³ (1.4 to 17 m³)

1-8 Other products

- | | |
|---------------------------|---|
| 1. Steam generators | 7. Glassware washers |
| 2. Water pretreatment | 8. Integral clean steam generator |
| 3. CPS System-WSSD, MPV | Other equipment from Getinge |
| 4. CPS Discharge System | includes terminal sterilization systems, isolators for formulation & filling, isolators for sterility testing |
| 5. Component washers | |
| 6. WFI generation/storage | |

The versatility of GE Steam Sterilizers.

Getinge GE Steam Sterilizers kill the toughest microbes but are gentle enough to protect the integrity of the components, products and packaging.

The GE Series sterilizers are suitable for many common applications within bio-pharmaceutical production, and are equipped with appropriate features, options and processes for the demanding applications within production and the QA-QC Laboratory environments.

Smorgasbord or the chef's special?

The complete GE Series of steam sterilizers is comprised of more than 280 models (24 chamber sizes and multiple program combinations) plus more than 80 standard options. For more simple selection, and using our experience and application knowledge, Getinge has pre-configured two variants, the "GE P" for production and the "GE Q" for the QA laboratory. Of course, additional options may be added according to application and customer needs.

GE SERIES Options (sample)	Production	QA Lab
• Cross Contamination Seal	○	●
• cGMP Features	●	●
• Sanitary Process Piping	●	●
• Drain Line Scavenger System		
• Self Cleaning Drain Strainer		
• In-place Filter Sterilization	●	●
• In-place Filter Integrity Test	○	
• Multiflow - Dual Control		
• Laser Color Printer		
• Pre-Qualification	○	○
• Functional Specification (FS)	●	●
• Software Design Specification	●	●
• Hardware Design Specification	●	●
• Vendor Data Sheet Package	●	●
• Sanitary Piping Documentation	●	●
• Videoboroscopy And Report	○	
• P 3100 Program Combination	●	
• P 3220 Program Combination		
• L 3200 Program Combination		●

● = Standard feature
○ = Common Option

SAFEGUARDING YOUR INVESTMENT

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

Strong on safety

Getinge steam 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

virtually 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 GE Steam Sterilizers offer a number of advantages over traditional 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 optimized as the door does not swing outward, and there is free access to the chamber for loading/unloading.



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.

FEATURES THAT SATISFY YOUR PROCESSING NEEDS

The features built into Getinge GE Steam Sterilizers involve two prime considerations – sterilizer customization and high performance in everyday use. The extensive range of features offered ensures a high degree of customization, and the most appropriate program combination and goods handling accessories facilitate smooth everyday operation.

Getinge’s modular approach assures the most cost-effective solution for your processing needs.

Numerous design options

Design options that reflect Getinge’s reputation as a flexible and innovative supplier include:

- Chamber capacities ranging from 10 to 600 ft3 (0.3 to 17 m3)
- 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
- Integral clean steam generators
- Sterilizer mounted in either a cabinet, recessed between two walls, or recessed in a cabinet within one wall
- Cross-contamination wall seals to prevent airflow between areas served
- Models that can be installed directly on a floor for loading with carts or transfer trolleys, or pit-mounted models for convenient roll-in, roll-out load handling

	Hard goods			Porous goods					Liquids		Maintenance			
	Utensils	Empty glassware	Machine Parts	Textiles	Filters / Filtered Vessels	Rubber stoppers	Ampoules / vials	Machine parts (wrapped)	Glassware (wrapped)	Liquids - open	Liquids - sealed	Automatic leak test	Filter sterilization	Filter Integrity Test (WIT)
P310X	●		●	●	●	●	●	●				●	●	○
P320X	●		●	●	●	●	●	●		●		●	●	○
L320X	●	●		●	●	●	●		●	●	●	●	●	○
L330X	●	●		●	●	●	●		●	●	●	●	●	○

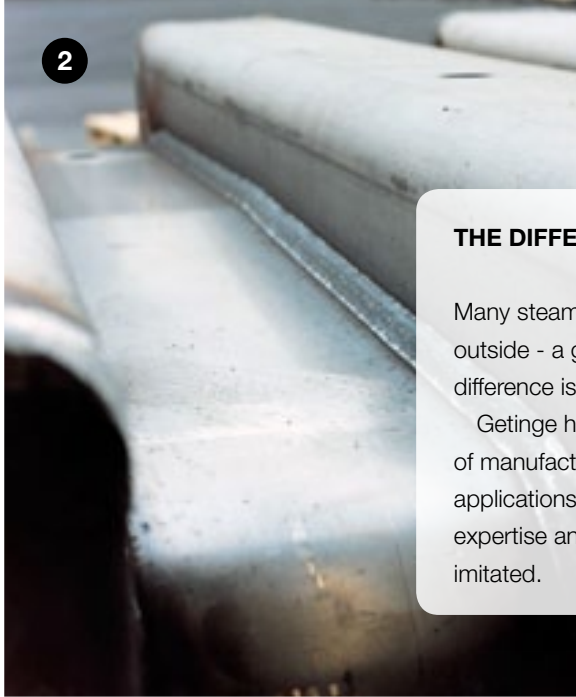
Last Digit = 0 : Standard six program combination
 Last Digit = 1 : Limited Combination for ease of validation

■ Production ■ QA/QC Laboratories ● Standard ○ Option



A large number of standard and tailored process combinations match Getinge's decades of application expertise to your particular processing needs.

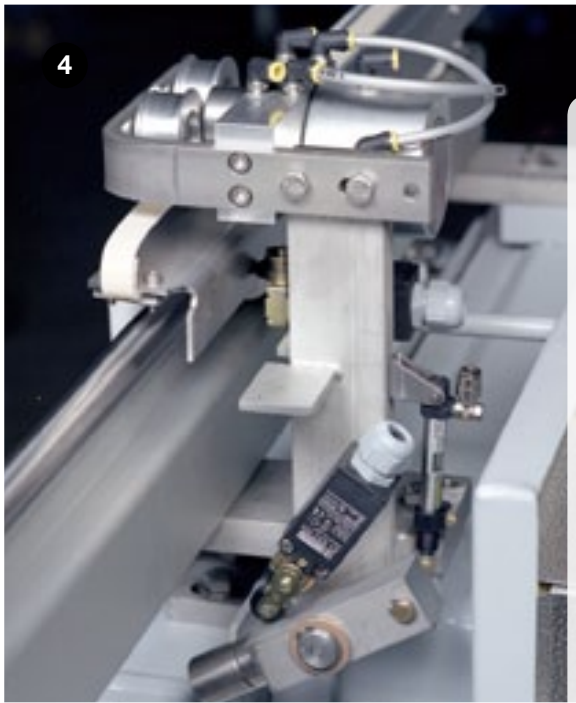
You can select the program combination best suited to your particular applications.



THE DIFFERENCE IS IN THE DETAILS

Many steam sterilizers look alike from the outside - a grey stainless steel box. The difference is what is inside the box.

Getinge has many years of experience of manufacturing steam sterilizers for GMP applications, and that practical experience, expertise and knowledge cannot be imitated.



1. Easy accessibility for maintenance is a key consideration in the design and assembly of Getinge sterilizers.

2. The unique sectional jacket adds strength and rigidity to the chamber, and robotic welding virtually eliminates defects. The resulting construction ensures a long lifetime with even the most rigorous use to safeguard your capital investment.

3. A wide range of loading accessories is available for diverse applications.

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

5. Getinge has the widest range of sterilizer capacities available from a single supplier.

6. Top-quality piping and components are assembled to the highest standards. A variety of piping and documentation options are available.



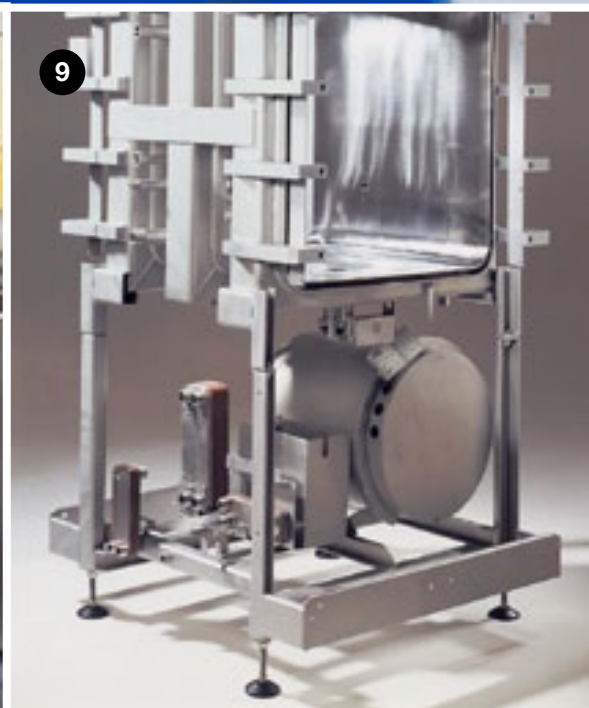
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8



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7. State-of-the-art control systems.

8. CFC-free insulation enclosed in corrosion-proof aluminium.

9. Robust stainless steel jacket and frame on the outside, cleanable polished surfaces for cleanability on the inside.

10. In process inspection and testing is performed throughout the manufacturing process. Comprehensive documentation is delivered with every sterilizer.

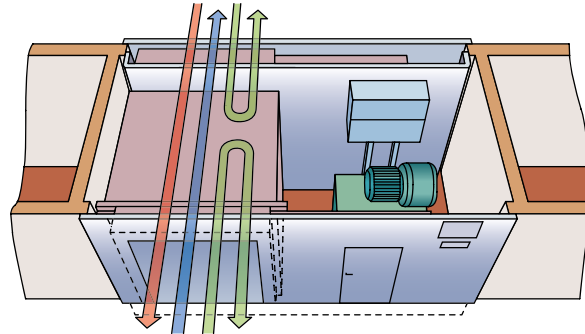
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GE STEAM STERILIZER SELECTION GUIDE P & Q CONFIGURATIONS

Getinge GE Steam Sterilizers in P and Q configuration incorporate all the features needed for bio-pharmaceutical production and the related Quality Assurance laboratory. The table below lists the core features found in the two ranges of GE Steam Sterilizers, as well as those of particular interest to each specific application.



Double-door sterilizers may be equipped for 'Multiflow' operation to optimize operational efficiency while protecting the areas served.

CORE FEATURES, GE Steam Sterilizers for Pharmaceutical Production & QA/QC

- Solid stainless steel chamber, jacket & frame
- Unique sectional jacket design with efficient insulation encased in Aluminum.
- Robotically welded & polished chamber (Ra < 0.63µm / 25µinch)
- Clean, safe and simple automatic sliding door(s)
- Pneumatically operated process valves
- Fully automatic leak rate test
- 0.2µm membrane type sterilizing grade air admission filter in stainless steel housing
- In-situ steam sterilization of air filter (maintenance programme)
- cGMP features including:
 - Secondary (independent) temperature sensor in chamber drain
 - Level sensor (and alarm) in chamber drain
 - Membrane isolated pressure gauges
- Sanitary stainless steel chamber piping (media to chamber / product contact media)
- Stainless steel media-to-jacket piping
- Getinge PACS 3500 Purpose designed control system with OP30 HMI
- Choice of convenient loading systems. Removable rails for easy cleaning
- Hinged front fascia for easy service access
- Validation Support Documentation incl. Functional, Hardware and Software Design Specifications, Vendor Data Sheets and Extended Sanitary Piping Documentation.
- Optional controls above door or beside door (Small GE Steam sterilizers)
- Ergonomic loading height
 - Small GE Steam Sterilizers - 32" (800 mm) loading height
 - Medium-size GE Steam Sterilizers - 24" (600 mm) loading height
 - Large GE Steam Sterilizers - 12" (300 mm) loading height, or pit-mounted for direct floor loading

COMMON OPTIONS, PRODUCTION

- Integral pharmaceutical grade steam generator
- In Situ Filter Integrity Test (WIT)
- "Multiflow" door sequencing
- Cross contamination seal
- Jacket cooling
- Fan-assisted jacket cooling (L3300 program combination)
- Biohazard process (decontamination - vaccines production)
- PLC Control System (Allen Bradley Compact Logix with PanelView Plus HMI)
- Choice of printers or recorder for process / batch documentation
- PACS Supervisor for independent process monitoring
- Pre-Qualification during FAT (saves time and expense during site validation)

Common Options, QA / QC Laboratory

- Integral clean steam generator
- In Situ Filter Integrity Test (WIT)
- Jacket cooling
- Fan-assisted jacket cooling (L3300 program combination)
- PLC Control System (Allen Bradley Compact Logix with PanelView Plus HMI)
- Choice of printers or recorder for process documentation
- PACS Supervisor for independent process monitoring
- Pre-Qualification during FAT (saves time and expense during site validation)

SMALL GE STEAM STERILIZERS

The modular design of Getinge small GE Steam Sterilizers allows them to be used for a broad range of applications – from QA laboratory use to small scale pharmaceutical production. The base specification includes a comprehensive variety of core features designed to provide intrinsic safety, functionality, reliability and longevity. A range of optional features facilitates customization according to the customer’s application.

Vertical sliding doors

These fully automatic high-pressure steam sterilizers are available with a single vertical sliding door, or two sliding doors for pass-through operation. The loading height is 32” (800 mm). Control panels may be on one or both sides (see also Multiflow operation). The small GE Steam Sterilizers can be connected to a central steam supply or equipped with an integral electrical or steam-heated steam generator.

Typical loading equipment consists of a shelf rack, trolley, or extendable / sliding shelves.



600 Series	666	6610	6613	6617
Chamber volume ft ³ /m ³	10.6 / 0.3	16 / 0.45	21 / 0.6	28 / 0.8
Chamber depth, in/mm	26 / 660	39 / 1000	51 / 1300	67 / 1700
Chamber height, in/mm	26 / 672			
Chamber width, in/mm	26 / 672			

Smaller GE models are available in P & Q Configuration

MEDIUM-SIZE GE STEAM STERILIZERS

Getinge medium-size GE Steam Sterilizers are similar to the small sterilizers with the exception of larger chamber sizes and automatic horizontal sliding door(s). The loading height is 24” (600mm).

As with our small GE Steam Sterilizers L3300 program combination further enhances the cooling rate of GE Steam Sterilizers by accelerating the airflow with a centrifugal fan, bringing more air into contact with the chamber wall (externally cooled by water in the jacket).

For high-capacity production, the Getinge GEV model with mechanically driven fan and internal heat exchangers for rapid cooling and drying is recommended.

Typical loading equipment consists of a shelf, rack and trolley.



900 Series	6910	6913	6915	6917
Chamber volume ft ³ / m ³	21 / 0.6	28 / 0.8	33 / 0.95	39 / 1.1
Chamber depth, in / mm	39 / 1000	53 / 1350	60 / 1540	67 / 1700
Chamber height, in / mm	36 / 920			
Chamber width, in / mm	26 / 672			

LARGE GE STEAM STERILIZERS



This range of sterilizers covers large-scale production applications in the pharmaceutical industry.

Program combinations are available for sterilization of items such as vessels, textiles, rubber stoppers and filters as well as machine parts, tanks, carboys, etc. And there are cycles for cooling vented liquids and effluent sterilization (which may be used for decontamination of materials in vaccines production).

Large GE Steam Sterilizers incorporate a program for the slow cooling of liquids in vented rigid containers. To prevent liquid boiling or loss, or the rupture of containers, an option is available which incorporates assisted cooling with air overpressure. For higher capacity liquid production, Getinge recommends the GEV process.

Typical loading equipment consists of a loading trolley and a shelf rack. On pit mounted units, a shelf trolley may be used for direct floor loading.

Four main functions

Getinge large GE Steam Sterilizers, with automatic horizontal sliding door(s) provide four main functions:

- Sterilization of material entering a sterile zone
- Sterilization of product or used items and waste from a sterile/containment zone
- A pass-through barrier between a sterile/containment zone and the outside world
- Stand-alone sterilization capacity

Installation alternatives

Large GE Steam Sterilizers are either floor-mounted or pit-mounted. When pit mounted, the sterilizer floor is flush with the facility floor allowing trolleys/ racks to roll easily in and out of the chamber. A pit depth of only 10 to 12" (250 to 300 mm) facilitates building work and sterilizer installation.

1400 and 2200 series	71413	91413	91425	121422	92222	122222	152222	182222
Chamber volume ft ³ / m ³	19 / 1.4	60 / 1.7	116 / 3.3	140 / 4.0	160 / 4.5	212 / 6.0	265 / 7.5	318 / 9.0
Chamber depth, in/mm	53 / 1350		98 / 2500	86 / 2200				
Chamber height, in/mm	57 / 1450				86 / 2200			
Chamber width, in/mm	27 / 700	35 / 900		49 / 1250	35 / 900	49 / 1250	61 / 1550	72 / 1830

The above dimensions are for models selected from a much wider range of standard chambers. Non standard chambers are available on request.



DESIGNED WITH ENVIRONMENTAL ASPECTS IN MIND

At Getinge, we are committed to contribute to a sustainable society. We work purposefully to optimize our use of energy and natural resources, minimize our emissions to air and reduce the environmental impact of our waste management.

The environmental engagement of Getinge does not cease with product delivery but include the complete product life cycle. To gain maximum eco-effectiveness, we consider the environmental aspects of the entire life cycle including stages as product development, operational factory administration, production processes, distribution, intended use of the product and, finally, scrapping of the product.

Main focus: energy efficiency

Our overriding environmental objective is optimizing energy consumption and thus reducing the impact on the climate.

Thanks to Getinge's design concept, the process times are among the shortest on the market. This means that sterilization of the goods will require less energy consumption.

A loading system for every need

A new sterilizer represents a large capital investment. Therefore Getinge ensures that our sterilizers provide true value with regard to design, performance and life cycle economy. This includes the loading system and accessories which are an integral part of the complete system, and the part that the operator comes into contact mostly during the routine operation of the equipment.

For each application, Getinge offers a variety of loading alternatives, from simple sliding shelves to completely automated systems.

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 GE Steam Sterilizer undergoes rigorous factory acceptance testing in a dedicated test bay with facilities to support our clients during the inspection and test of their equipment.

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:

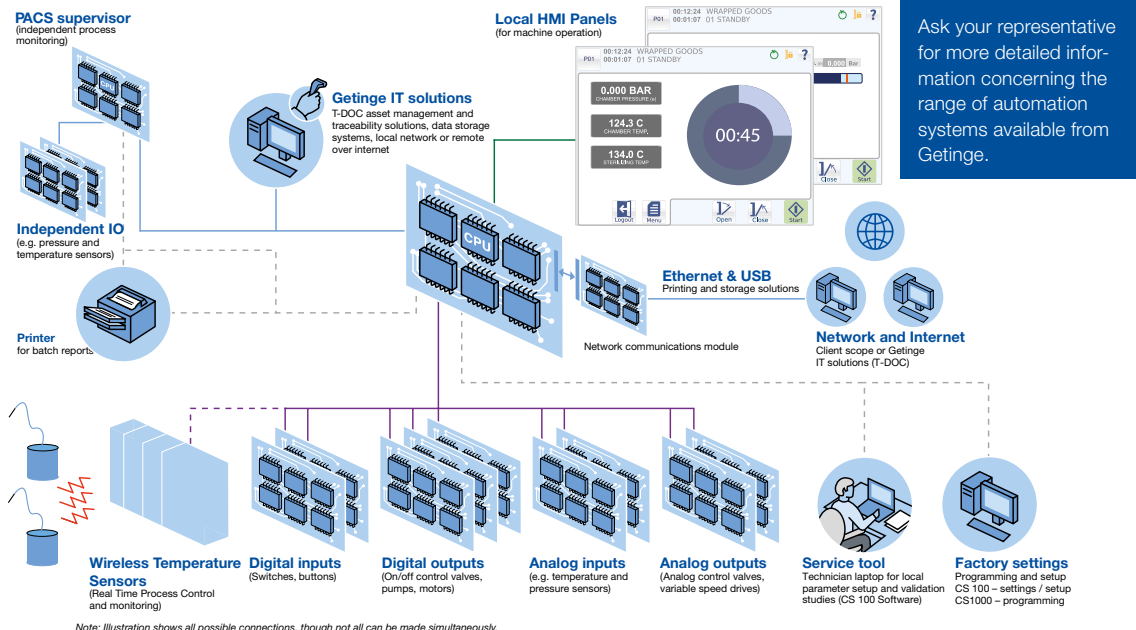
- User friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multi-level password protection



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.





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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