

GETINGE

GETINGE GE STEAM STERILIZERS
SECURING HIGH PERFORMANCE
FOR THE LIFE SCIENCES



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.

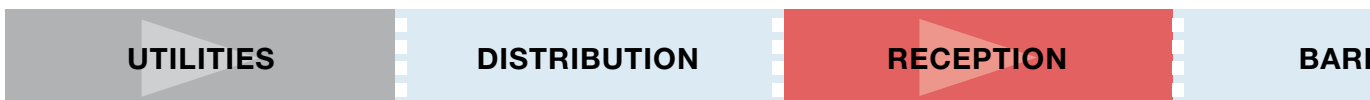
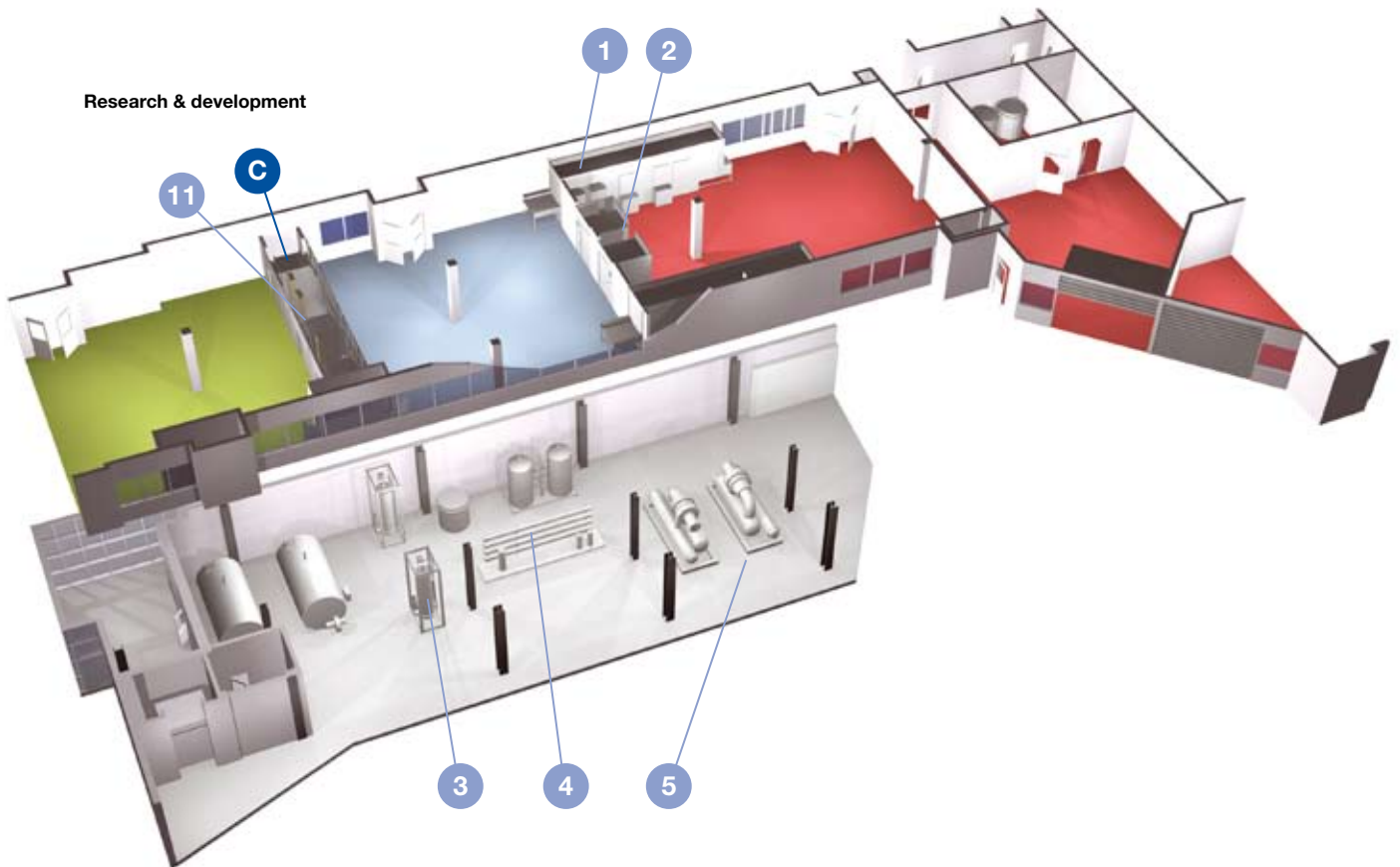
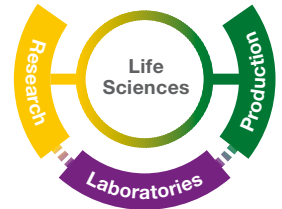
Because Getinge is a global company, we have the resources to take care of your service, maintenance and other support needs wherever you are. And our Getinge Academy offers numerous courses on the safe and efficient handling of equipment for sterile processing.

You're in safe hands with Getinge.

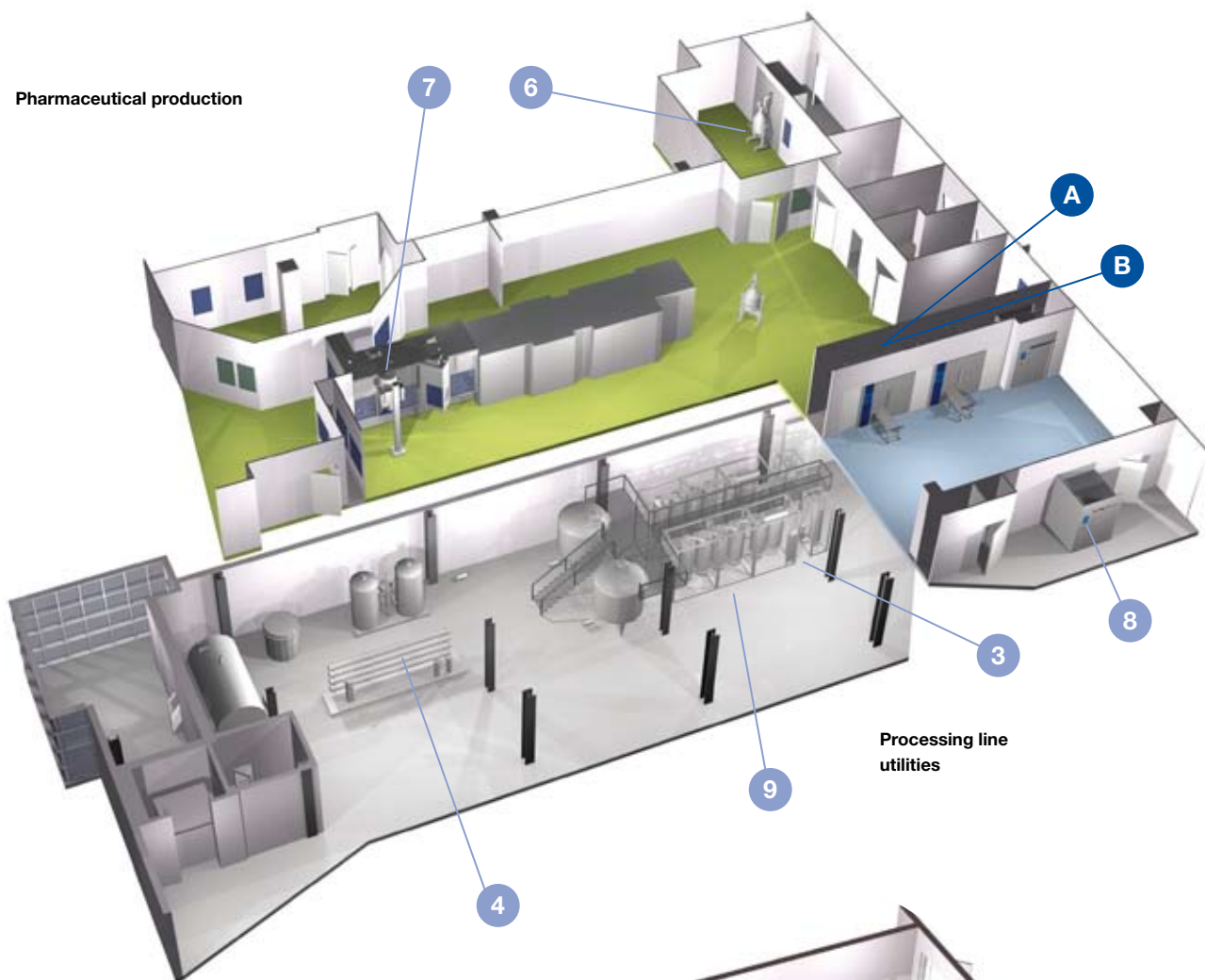


COMPLETE STERILE PROCESSING SYSTEMS

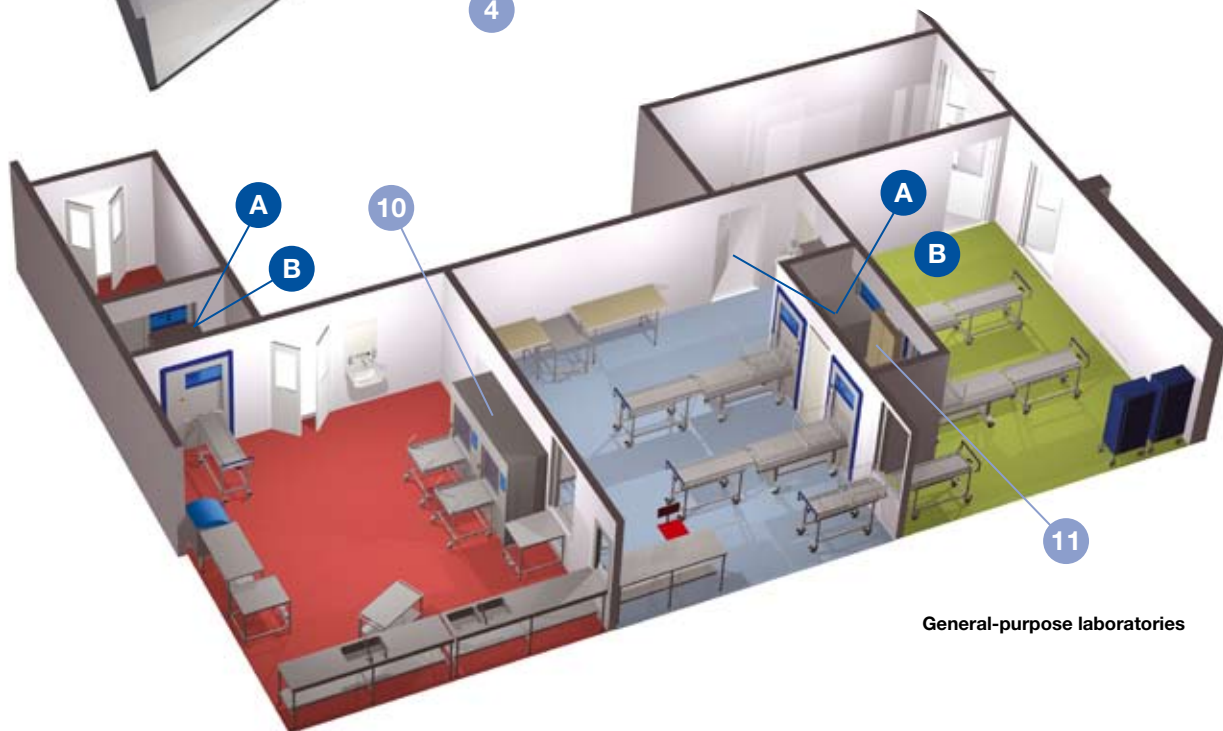
Getinge develops, manufactures and supplies completely integrated washing and sterilization systems for use within the life sciences (the branches of science concerned with living organisms). Three typical installations for applications in research facilities, pharmaceutical and biotech production, and general-purpose laboratories are shown below.



Pharmaceutical production



Processing line utilities



General-purpose laboratories



The versatility of GE Steam Sterilizers. GE Steam Sterilizers kill the toughest microbes but are gentle enough to protect the integrity of components, products and packaging. A wide range of sterilization cycles increases their application versatility.

The types of Getinge GE Steam Sterilizer best suited to the installations shown are presented below. General information is provided in this brochure. Please refer to individual product specifications for additional details.

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: 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: 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: 1.4 to 17 m³

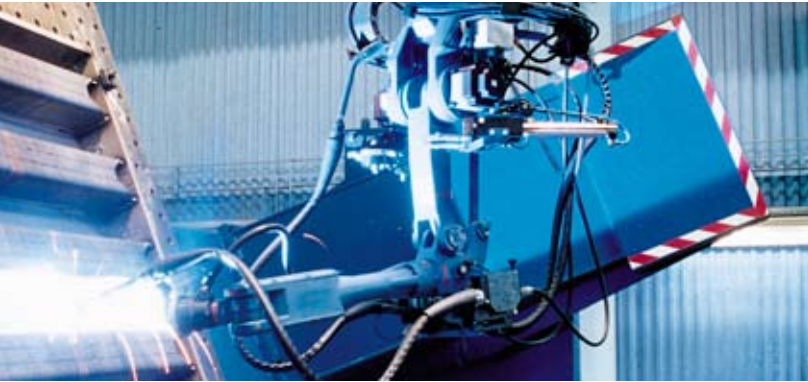
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Other products

- | | |
|-------------------------|------------------------------------|
| 1. Tunnel washers | 7. CPS Discharge System/ LTS, RTP |
| 2. Cage washers | 8. Component washers |
| 3. Steam generators | 9. WFI generation/storage |
| 4. Water pretreatment | 10. Glassware washers |
| 5. Vacuum system | 11. Integral clean steam generator |
| 6. CPS System-WSSD, MPV | |



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 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 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 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 0.3 to 17 m³. Customized chamber sizes are available on request.

Regulatory issues

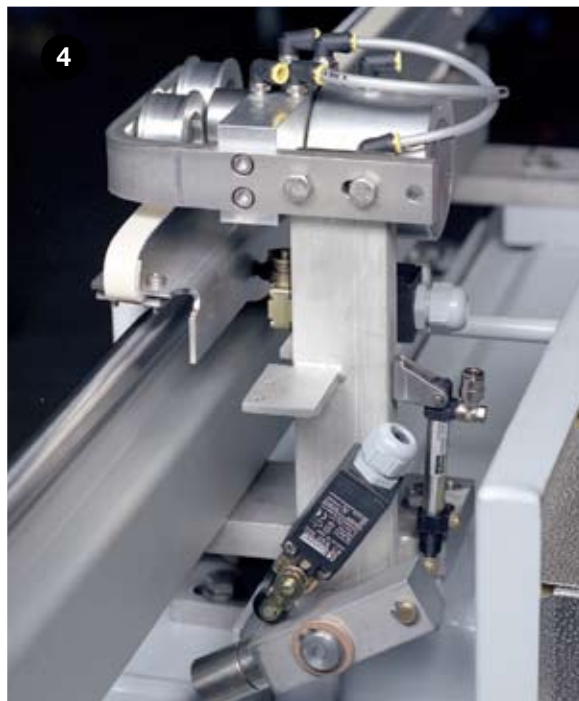
Getinge closely follows industry trends, practices, guidelines and regulatory requirements. Additionally we actively participate in working groups and committees working to refine these requirements.

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

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

Protecting the environment

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



1. 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 eliminates defects. The resulting construction ensures a long product lifecycle 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.

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 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 electric or clean steam generators.
- Sterilizer mounted in either a cabinet, recessed between two walls, or recessed in a cabinet within one wall.
- Cross-contamination (hermetic)/biological seals.
- 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.

Program combinations

The ongoing development of new pharmaceutical products and delivery devices, together with new laboratory techniques, research in genomics and infectious diseases has resulted in demand for more advanced steam sterilization methods. Getinge offers these advances to provide combinations that optimize your processing needs.

For ease of operation and validation, each standard model is provided with a combination of programs appropriate for the specified application. There are four general classes of materials:

- Hard goods
- Porous loads/wrapped goods
- Liquids in open containers
- Liquids in sealed containers

Moreover, additional processes are available, e.g. for decontaminating hazardous /pathogenic materials. Special processes can be developed on request.

Practical accessories

To complement our GE Steam Sterilizers, we offer a wide range of accessories that cover:

- Goods handling – shelf racks, loading trolleys and automated product handling.
- Media supply – different types of steam generators, compressed air supply systems and water treatment systems.

	Hard goods			Porous goods					Liquids		Automatic leak test	Filter sterilization	Filter wit
	Utensils	Empty glassware	Animal cages	Textiles	Filters	Rubber stoppers	Ampoules/Vials	Animal bedding	Animal feed	Liquids - open			
P322X	•	•	•	•	•	•	•	•	•	•	•	•	•
P310X	•	•	•	•	•	•	•	•	•	•	•	•	•
P320X	•	•	•	•	•	•	•	•	•	•	•	•	•
L320X	•	•	•	•	•	•	•	•	•	•	•	•	•
L330X	•	•	•	•	•	•	•	•	•	•	•	•	•

↑ Last Digit = 0 : Standard six program combination
 Last Digit = 1, 3 : Limited Combination for ease of validation
 Last Digit = 2 : Effluent Retention for processing pathogenic material
■ Research ■ Production ■ Laboratories ● Option

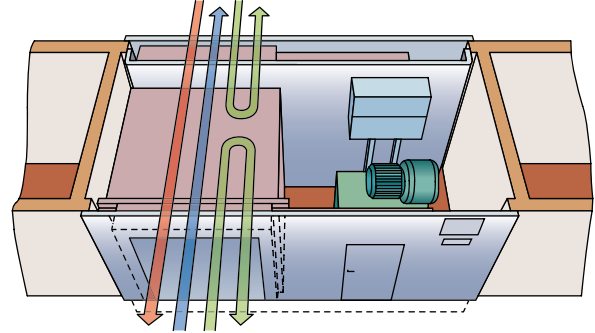


A large number of standard and tailored process combinations match Getinge’s decades of application expertise to your particular processing needs.

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

GE STEAM STERILIZER SELECTION GUIDE

Getinge GE Steam Sterilizers incorporate all the features needed for research and development departments, pharmaceutical production, and different laboratories. The table below lists the core features found in the three sizes 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	RESEARCH	PRODUCTION	LABORATORIES
Large GE Steam Sterilizers	Small GE Steam Sterilizers	<ul style="list-style-type: none"> Optional controls above door or beside door Ergonomic 800 mm loading height 			
	Medium-size GE Steam Sterilizers	<ul style="list-style-type: none"> Solid stainless steel chamber, jacket & frame Unique sectional jacket design Robotically welded & polished chamber Clean, safe and simple automatic sliding door(s) Pneumatic process valves Fully automatic leak rate test Bacteria-retentive air admission filter Highly polished chamber for easy cleaning Flexible loading options Removable rails for easy cleaning Aluminum-encapsulated insulation for low heat emission Hinged front for easy service access Optional integral steam generators (electrical unit alt. for small sterilizers) 	<ul style="list-style-type: none"> Self-cleaning drain strainer Stainless steel piping "Multiflow" door sequencing Cross contamination seal Specific Pathogen Free seal (SPF seal) Water conservation system Biohazard process 	<ul style="list-style-type: none"> Integral pure steam generator Filter sterilization & Water Intrusion Test (WIT) cGMP features Sanitary stainless steel piping "Multiflow" door sequencing Cross contamination seal Fan-assisted cooling (GEL process) 	<ul style="list-style-type: none"> Integral clean steam generator Jacket cooling Fan-assisted cooling (GEL process) Water conservation system Biohazard process Biological seal
	Large GE Steam Sterilizers		<ul style="list-style-type: none"> Ergonomic 600 mm loading height Rub rails to prevent damage to chamber walls Ergonomic 300 mm loading height, or pit-mounted for direct floor loading Optional matt internal chamber surface finish 		



State-of-the-art control systems.

Robust stainless steel on the outside, cleanable polished surfaces for cleanability on the inside.

CFC-free insulation enclosed in corrosion-proof aluminum.

Wide variety of loading accessories; withdrawable shelves.

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 simple laboratory use to cGMP 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.

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 800mm. 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, and extendable/withdrawable shelves.



600 Series	666	6610	6613	6617
Chamber volume m ³	0.3	0.45	0.6	0.8
Chamber depth, mm	660	1000	1300	1700
Chamber height, mm	672			
Chamber width, mm	672			

Smaller GE models are available for use in laboratories.

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 600 mm.

Like our small GE Steam Sterilizers with jacket cooling, the GEL option further enhances the cooling rate of GE Steam Sterilizers by accelerating the airflow with a magnetically driven fan.

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 m ³	0.6	0.8	0.95	1.1
Chamber depth, mm	1000	1350	1540	1700
Chamber height, mm	920			
Chamber width, mm	672			

LARGE GE STEAM STERILIZERS



This range of sterilizers covers large-scale applications in the pharmaceutical industry, general-purpose laboratories and research facilities. Programs allow sterilization of items such as utensils, textiles, rubber stoppers and filters. Machine parts, tanks, carboys, etc., can also be processed. And there are cycles for cooling vented liquids and effluent sterilization.

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, certain models may also incorporate assisted cooling with air overpressure.

Program combinations for research facilities are suitable for sterilizing animal feed, cage racks and bedding.

Typical loading equipment consists of customers' own racks, a shelf trolley and a shelf rack.

Four main functions

Getting large GE Steam Sterilizers, with automatic horizontal sliding door(s) and a loading height of 0 to 300 mm provide four main functions:

- Sterilization of material entering a sterile/containment zone.
- Sterilization of 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. With the latter, 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 250 to 300 mm facilitates building work and sterilizer installation.

1400 and 2200 series	71413	91413	91425	121422	92222	122222	152222	182222
Chamber volume m ³	1.4	1.7	3.3	4.0	4.5	6.0	7.5	9.0
Chamber depth, mm	1350		2500	2200				
Chamber height, mm	1450				2200			
Chamber width, mm	700	900	1250	900	1250	1550	1830	

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

CONTROL SYSTEMS

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

Versatile features

The major features included in PACS 3000 are:

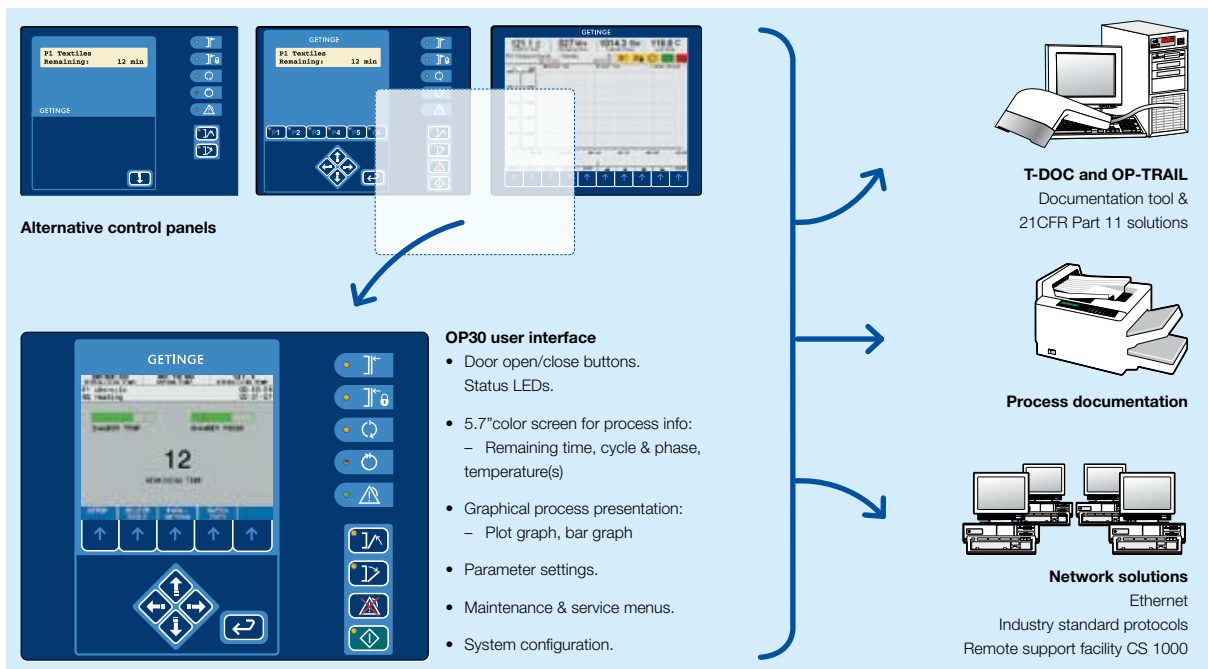
- A user-friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multilevel password protection
- Multilanguage display
- PACS Supervisor independent monitoring system

Regulatory compliance

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

Standard PLC Systems

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





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

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