

GETINGE GEW WASHER/DRYERS SECURING CRITICAL CLEANING IN THE MANUFACTURING ENVIRONMENT



COMPLETE STERILE PROCESSING SYSTEMS

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



PURPOSE DESIGNED FOR THE APPLICATION

Getinge GEW washer/dryers have been designed "from the ground up" to meet the needs of the Bio-Pharmaceutical Industry. Working in cooperation with users and engineers, our equipment has been developed to satisfy the unique demands and stringent regulations of the industry. The

GEW 888

Compact washer for cleaning glassware and various parts in the biotech manufacturing and quality control areas.

Automatic vertical sliding door for better ergo-

nomics and space saving. Highly sanitary construction thanks to 3D dead leas design.

Chamber Capacity: 500 I. (132 gal) Internal dimension: 805x770x805 mm (31^{3/4}x30^{3/8}x31^{3/4}")

2 independent wash levels

GEW 9109

Multipurpose washer for cleaning glassware, filling lines and equipment parts in the Bio-Pharmaceutical manufacturing area and Quality assurance / Quality control laboratory. Single or double door models. Horizontal sliding door and ultra-low water consumptions.



Chamber capacity: 800 l. (211.3 gal.) Internal dimensions:

900 x 1000 x 900 mm (351/2 x 393/8 x 351/2")

GEW 101210 & GEW 131313

For cleaning of IBC's, carboys, equipment parts in the Bio-Pharmaceutical manufacturing area and bulk chemical / API production. Single or double door models. Vertical hinged for ergonomic operation.

Chamber capacity:

GEW 101210: 1250 l. (330.2 gal.) GEW 131313: 2200 l. (581.2 gal.)

Internal dimensions: GEW 101210: 1005x1200x1005 mm (40x47x40"), GEW 131313: 1300x1300x1300 mm (51x51x51")

GEW 131820

For cleaning of IBC's, vessels, carboys, machine parts in the Bio-Pharmaceutical manufacturing area and bulk chemical / API production. Single or double door models. Sliding door for ergonomic operation. **Chamber capacity:** 4700 l. (1241.6 gal.)



Internal dimensions: 1300x1800x2000 mm (51x71x79")

GEW Series of cGMP washer/dryers constitute the most comprehensive range on the market today.

The versatility of GEW cGMP washer/dryers

The GEW Series washer/dryers are suitable for many common applications within Bio-Pharmaceutical production, and are equipped with appropriate features and options for demanding processes within production and the QA-QC Laboratory environments.

Two configurations are available for specified applications, with a range of configurable options:

GEW P Series

Configured to meet the most demanding requirements for pharmaceutical manufacturing. This series, together with purpose-designed inventory systems, is designed for critical cleaning of equipment, parts and components. Full traceability (ASME BPE) and documentation package are included.

GEW Pro Series*

Value engineered, this series is configured to meet cGMP cleaning, validation and repeatability in domains and application where budget constraints are to be considered. It has the same construction platform and accessories set as the unsurpassed P series.

* Not applicable to GEW 131820 model.



EXPERIENCE TO RELY ON

Getinge has an unique capability to provide you with complete sterile process systems. The earlier we are involved in the planning process for your new or replacement system, the more cost-effective solutions we can deliver.

Our knowledge and application expertise are drawn from over 100 years of dedication to cleaning and sterilization equipment within Healthcare and Life Sciences.

From concept to compliance

We can support you with initial advice, system design, extensive ranges of washer/dryers and sterilizers, closure processing systems, barrier isolation technology, installation, validation, support and maintenance. Dealing with just one competent company saves you time, effort and money. Getinge can satisfy all your sterile processing needs – from "concept to compliance".

Optimal lifecycle economy

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

Because Getinge is a worldwide company, we have the resources to meet your service, maintenance and other support needs wherever you are. And our Getinge Academy offers thorough training to assure the proper and efficient handling of equipment for sterile processing. You are in safe hands with Getinge.







SAFEGUARDING YOUR INVESTMENT

A production system represents a major capital investment in your future revenue stream. Getinge works hard to ensure that our GEW washer/dryers provide true value in design, performance, reliability and lifecycle economy.

State-of-the-art production

Getinge continually invests in state-of-the-art factories, production equipment and process development for one reason – to ensure that we can continue to provide our clients with the best equipment available. We believe we offer true value for money. This is reflected in our impressive client base – the world's leading Bio-pharmaceutical companies rely on Getinge.

Satisfying your needs

GEW Series washer/dryers, products of many years of practical experience, are designed to handle the toughest applications. We reckon that most applications are unique, so we offer custom designed racks and handling systems, as well as an extensive choice of standard accessories for common applications. Single door and double door models are available to suit your building layout and workflow.



Ergonomic design

Our load handling systems are developed for user-friendliness. Hinged and sliding doors provide with easy and safe access during loading and unloading, while a range of trolleys and other accessories enable easy transport of racks and articles to and from the work area.

Wide selection of chamber configurations

The Getinge GEW Series consists of a range of chamber sizes that offer optimal handling of common loads. Five standard models, in two configurations with a wide variety of options allows us to provide a custom configured washer/dryer to meet specific needs.

Regulatory issues

Getinge actively participates in the groups and committees that establish and update the industry practices, guidelines and regulatory requirements.

All of our washer/dryers are manufactured in accordance with the guidelines or standards relating to the intended applications and the country of installation.

> GAMP 5* • EU & US cGMP • ASME BPE Standard • ISPE'S Baseline[®] Guides • ISO 9001 & 14001 • 21 CFR Part 11

> > *except PACS 3500 System

Protecting the environment

The GEW Series washer/dryers are specifically designed to optimize utility and chemical usage, while providing the highest quality wash.

A COMPREHENSIVE RANGE

GEW 888

Very compact washer and the ideal solution for small premises dealing with space constraints. Its vertical sliding down door enhances ergonomics and compactness. From 50-liters Nalgene bottles to vials and small glassware items, this washer has been designed to provide you with flexibility and increased throughput thanks to its two independent wash levels.

GEW 888 can be fitted with CCB (option) and service access can be provided from front or side depending on the wash room configuration.

Outstanding low environmental impact thanks to its reduced water consumption; only 40 liters per fill.

GEW 9109

GEW 9109 is an ideal washer for multipurpose applications as its 810-liters chamber allows for washing on two levels with ultra low water consumption. In addition to low cycle costs and high productivity, the automatic sliding doors allow for good ergonomics. A cross contamination barrier (option) physically helps separate the loading from the unloading side, a needed feature in today's Bio-Pharmaceutical manufacturing area. As for all Getinge GMP washers, it is provided with a full traceability and validation package (P version).

GEW 101210 & GEW 131313

The medium sized GEW 101210 and GEW 131313 washers are designed primarily for the manufacturing area. The base model of each reference includes many features necessary for GMP compliance as standard. A wide range of optional features are also available to make them adaptable to a variety of applications.

The chambers are equipped with one or two vertical hinged glass doors for single ended use or pass through operation. The hinged door optimizes space and minimizes the footprint on these models.

The loading height is 710 mm (28"). A variety of standard racks and an ergonomic transport trolley are available for common applications. Custom racks may also be designed and provided.

GEW 131820

The largest washer in the series. It is designed for pit mounting in a 320 mm (12.6") deep pit, allowing direct floor loading of large, heavy or bulky items. Where pit mounting is not possible, the machine may be floor mounted with a loading height of just 320 mm (12.6").

This unit is intended for Bio-Pharmaceutical manufacturing operations, including cleaning of bulk chemical containers, vessels and machine parts. Racks are designed according to the application, based on our extensive experience.



GEW 888



GEW 9109



GEW 101210



GEW 131313



GEW 131820

FEATURES TO SATISFY YOUR PROCESSING NEEDS AND SUPPORT TO SATISFY YOUR GLOBAL PLANS

The Getinge GEW Series pedigree

The GEW cGMP washer/dryers have been developed using the knowledge and experience gained over many years. These industry leading washers are manufactured in Getinge's Center of Excellence for Life Science washers: Getinge Lancer factory in Toulouse, France. This factory has been a part of the Getinge Group since the inception of parametrically controlled cleaning for the Bio-Pharmaceutical industry in the early 1990's.

Formerly known as the Getinge-Lancer "PCM" range, the features of these washer/dryers have been finetuned using a process of technological development coupled with the experience of working with a very wide variety of applications on behalf of our clients from the pharmaceutical, the biotechnology and the cosmetics industries.

Today, the Getinge-Lancer factory is equipped with the latest technology and fabrication equipment for design and assembly of these washer/dryers. The equipment is distributed and supported through the Getinge organization, which comprises more than 32 Getinge sales companies serving all major markets, and more than 70 authorized distributors. We can provide a truly global service to support you wherever you choose to manufacture.

KEY FEATURES

- Hinged and sliding glass door(s)
 - Designed to optimize installation footprint
 - Heat and noise insulated glass allows for visual monitoring of cleaning process
- Single or double door models
- Cross Contamination Barrier to prevent clean area from contamination and excessive air transfer
- · Fully drainable, sanitary design
 - Maximized use of orbital welding
 - Chamber and piping slopes >2%
- ASME BPE compliant design (P version)
- HEPA filtered dual path drying system
 - Independent channels for chamber and load
- · Lowest utility and water consumption on the market
 - Most powerful recirculation pumps versus competitors for cleaning efficacy
- · Selection of automation systems
 - Rockwell Allen Bradley (Compact Logix as standard)
 - Siemens (Simatic S7 platform)
 - Getinge PACS 3500 platform
- GAMP 5 compliant documentation and programming*
- Highest level of parametrically controlled cleaning
 to meet the demands of the Bio-Pharmaceutical industry

* Not available on PACS 3500 systems





INTELLIGENT FUNCTION AND DESIGN

1. Efficient drying

Two separate drying systems (one for the chamber and one for the process path and racks) provide once-through HEPA filtered air for maximum drying efficiency. Ceramic heating elements (steam heating is an option) allow variable drying temperature control for different materials. All components are upstream of the final HEPA filters. Air is exhausted to a vent connection on the washer.

2. Filter monitoring

DOP ports and differential pressure transmitters are standard features, providing essential routine monitoring capability of the HEPA filters. Magnhelics[®] differential pressure gauges are available for visual verification of filter loading.

3. Fully automated

The Getinge GEW Washer/Dryer is equipped with a GAMP 5 (except PACS system) compliant, 21CFR Part 11 capable, state-of-the-art modular PLC system. Getinge offers

Siemens interface

a choice of our own PACS 3500 system or a selection of Allen Bradley or Siemens platforms, all with equal functionality and documentation.

4. Robust and sanitary construction

Sanitary main recirculation pump with vertical outlet. Sloped (min 2%) design, and smooth (Ra<0,6 mm/25 mm), crevice-free construction of chamber, piping and racks eliminates water retention and sites for biofilm or corrosion. 316L stainless steel is used throughout, with EPDM, PTFE or other FDA (21CFR part 177) and USP class VI approved gaskets. Globally available components, e.g. GEMU process valves, are standard. Orbital welding is used wherever possible and extensive documentation is provided.

5. Washing configurations

Integral chamber spray system with wash rack interface provides multi-level washing that optimizes load configuration and minimizes processing time.

Water is heated using a sanitary steam-water heat exchanger in the sump of the chamber (electrical heating is optional) for efficient and effective heating.



SINGLE DOOR MODELS		CHAMBER SIZE (Nominal internal) W x H x D	OVERALL SIZE W x H x D
GEW 888-1	mm	805 x 770 x 805	2043 x 2211 x 1101
	inch	31 ^{3/4} x 30 ^{3/8} x 31 ^{3/4}	80 ^{1/2} x 87 x 43 ^{3/8}
GEW 9109-1	mm	900 x 1000 x 900	2395 x 2275 x 1220
	inch	35 ^{1/2} x 39 ^{3/8} x 35 ^{1/2}	94 ^{1/4} x 89 ^{1/2} x 48
GEW 101210-1	mm	1005 x 1200 x 1005	2234 x 2515 x 1230
	inch	39 ^{1/2} x 47 ^{1/4} x 39 ^{1/2}	88 x 99 x 48 ^{3/8}
GEW 131313-1	mm	1300 x 1300 x 1300	2480 x 2600 x 1530
	inch	51 x 51 x 51	97 ^{5/8} x 102 ^{3/8} x 60 ^{1/4}
GEW 131820-1	mm	1300 x 1800 x 2000	3250 x 2850 x 2300
	inch	51 x 71 x 79	128 x 112 x 90



DOUBLE DOOR CHAMBER SIZE **OVERALL SIZE** MODELS (Nominal internal) WxHxD $W \times H \times D$ 805 x 770 x 805 2043 x 2211 x 1222 mm GEW 888-2 inch 313/4 x 303/8 x 313/4 80^{1/2} x 87 x 48 900 x 1000 x 900 2395 x 2275 x 1395 mm GEW 9109-2 35^{1/2} x 39^{3/8} x 35^{1/2} 94^{1/4} x 89^{1/2} x 54^{7/8} inch 1005 x 1200 x 1005 2234 x 2515 x 1265 mm GEW 101210-2 inch 39^{1/2} x 47^{1/4} x 39^{1/2} 88 x 99 x 497/8 mm 1300 x 1300 x 1300 2480 x 2600 x 1565 GEW 131313-2 975/8 x 1023/8 x 615/8 inch 51 x 51 x 51 1300 x 1800 x 2000 3250 x 2850 x 2600 mm GEW 131820-2 51 x 71 x 79 128 x 112 x 102 inch

6. Installation

All models are provided with brush finish stainless steel fascia panels for recessed installation, with additional side panels to form a cabinet as an option. Single or dual cross contamination barriers to maintain clean area classification and facilitate room air balancing. (Available on larger models.)

7. Chemical addition

The washer can be fitted with up to 5 peristaltic dosing pumps (according to application) for cleaning and neutralization agents to aid the mechanical cleaning process. Sanitary dosing valves are uniquely welded directly to the chamber wall to ensure proper rinsing. Pump pressure is monitored and a conductivity sensor is available to confirm proper additive dosing.

8. Final rinse with WFI

The sump is filled with WFI and recirculated throughout the hydraulic circuit to provide a single fluid path design ensuring complete rinsing of the entire system. The process continues for a time interval (determined by conductivity and/or TOC during process development studies).



TOC option

Optional conductivity and/or online TOC monitors are available to confirm that all cleaning agents and soil have been removed. This process minimizes WFI consumption and provides a validatable, repeatable result.

9. Door configurations

Each model is available in single door or double door configuration. Doors are equipped with interlocks to prevent opening during washer operation and simultaneous opening of the dual door units.

10. Environmental efficiency

The Getinge GEW washer/dryers combine unsurpassed chamber volume with a small environmental footprint. They operate on remarkably low water volumes and as a result, detergent dosage and energy consumption are minimized without compromising cleaning efficiency.



Sanitary spray systems in the chamber in combination with injection outlets on racks ensure complete and uniform coverage of both internal and external surfaces of processed items. Optional detection sensors for spray arms proper rotation confirm correct operation.



Chambers are made of 316L stainless steel and fully welded (no crevices). All welds are polished and passivated. All models feature rounded corners (>12 mm radius) with minimum slopes (min 2 %) to ensure complete drainage. Chamber fixtures are sanitary and all non-stainless steel materials are FDA approved and USP Class VI.



A sanitary steam heating coil in the sump rapidly heats circulating water and controls the temperature with accuracy. If steam is not available, electrical heaters may be provided at the same location.



CAD is used extensively in the design phase. Our customization and 3D modeling service is used to help design inventory systems for cleaning of specific components.



Exclusive twin channel drying system. Each channel includes a high capacity blower powered by a brushless motor, a heating system (electrically heated ceramic element as standard, steam heating as option) and a HEPA filter (in that sequence). One channel is used to dry the chamber and external surfaces of the load while the other ensures fast drying of the hydraulic circuit, rack and internal surfaces of the load.



Automatically sliding or hinged doors provide with convenient and ergonomic loading while optimizing space usage (overall footprint). All doors are made up with two sheets of toughened tempered glass with an air gap providing heat and noise insulation. The full-view glass door allows for visual monitoring of the cleaning action – e.g. spray arm rotation. Optional chamber light is available.

GETINGE GEW P- & PRO SERIES	Ρ	PRO
CHAMBER		
316L stainless steel contruction/FDA (USP class VI) approved elastomeric seals / 0,6 micron (24 Ra) surface finish or better. Radius-corner chamber (>12mm (1/2") and fully drainable hydraulic circuit	•	•
Chamber welds ground flushed	•	0
Chamber welds polished	•	
Chamber light for load viewing/vehication of water distribution	0	U
DOOR		
Glass door for load viewing, double pane insulated safety glass for verification of water distribution	•	•
PROCESS PIPING AND VALVES		
Fully drainable hydraulic circuit	•	•
Croitally welded, chamber piping slope > 2 % Forged sanitary diaphragm valves		ŏ
Hygienic angle seat valves	N/A	ĕ
ASME BPE 2009 compliant	•	Ŏ
PUMP		
Sanitary recirculation pump	•	•
Recirculation pump pressure monitoring with vertical pump outlet	•	•
WATER INLETS		
Quantity of water inlets Additional water inlets (up to 3 total)		
Water distribution loop piloting	0	0
	Ŭ	Ŭ
CHEMICAL DOSING SYSTEM		
Quantity of dosing pump Additional dosing pump (up to 5 total)	1	
Chemical pump pressure monitoring		
Conductivity monitoring-final rinse phase	ě	ŏ
Conductivity monitoring-final rinse phase and wash phase	0	Ō
AUTOMATION SYSTEM		
Getinge PACS	•	•
Allen Bradley/Siemens PLC	0	0
I nermal printer	•	
	0	U
Side (GEW 888, GEW 9109, GEW 101210, GEW 131313 and GEW 131820) access for easy maintenance Single (GEW 888 and GEW 9109) or dual cross-contamination barrier (GEW 101210, GEW 131313 and GEW 131820)	Ŏ	
Flush brush finish stainless steel front panels/easy cleaning/washdown capable	ĕ	ĕ
DOCUMENTATION		
Weld numbering weld mapping and weld boroscopic report		Ŏ
Full material traceability (3.1 certificates)	ě	ŏ
TESTING AND QUALIFICATION	\circ	0
	0	0
ACCESSORIES		
Range of standard modular racks (basic rack, jet rack)	0	0
ousiom made racks-e.g. glassware, ming line, noses, IBU's, Carboys Transfer trolleys for racks	0	0
	0	U
• = Standard O = Option N/A = Not applicable		

INVENTORY SYSTEMS: EFFICIENCY, ERGONOMY AND EFFICACY

Smooth, uninterrupted production requires that the right tools and equipment are available and ready for use when you need them. Equally important is the ability to move heavy or awkward articles to where they're needed, safely and efficiently.

Getinge's inventory management and handling accessories are specifically designed to meet these needs. Working in cooperation with our customers – and, where necessary, manufacturers of production equipment – we optimize washer/dryer accessories to assure a safe, ergonomic system that keeps you up and running.

Equally important to production efficiency is cleanliness: elimination of the possibility of cross-contamination with residues or dirt from previous use. Getinge uses CAD systems with 3D modeling to ensure that every corner and cavity of the article being processed is thoroughly washed. After washing, the same injection porting is used to convey hot sterile filtered air inside for drying.

The pictures on this page show examples of the many customized systems Getinge has supplied. A wide variety of standard racks are available for the more common applications.



Valve bodies, mounted on a customized manifold fitted to an otherwise standard rack, ensure 100% coverage of all product contact parts, as well as the exterior surfaces.



Glassware racks can be provided with a variety of holders and nozzles to ensure optimal cleaning without risk of damage.



Injection rack; designed and fabricated using a wealth of experience.



Machine parts are frequently sent to Getinge for modelling/rack design.



3D CAD modeling is used to design tailor-made racks for different applications, usually in cooperation with the user or equipment supplier.



Injection nozzles, designed for effective cleaning and drying may themselves be disassembled for cleaning and maintenance.



Loading trolleys can be provided to efficiently move materials to and from the washer/ dryers.



Special rack/basket for cleaning and drying silicon and metal tubing together with their tri-clamp fittings.

INSPECTION, TESTING AND DOCUMENTATION

As a general principle, Getinge follow ISPE's Baseline[®] and GAMP 5 Guides in respect of project execution and documentation to support our clients' qualification of sterile process equipment.



Every GEW washer/dryer undergoes rigorous factory acceptance testing in a dedicated test bay with facilities to support our clients during the inspection and testing their equipment.

Quality is inherent to 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 manufacturing, 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.

We can also provide a "Pre-Qualification" of the system upon request, 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 any 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



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.

TOC (Total Organic Carbon) monitoring option is also available on every Getinge GMP washer. With this option, you will be able to self-run controls on level of endotoxines and microbes at the end of your cycle – a key element to track the efficiency of your cleaning process. TOC option saves time and money by providing direct result of your cleaning process, no need to wait for external results – reactivity improved.

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

Regulatory compliance

Getinge's automation systems are developed according to stringent GAMP 5* (Good Automated Manufacturing Practice) guidelines of the pharmaceutical industry, and are FDA 21 CFR part 11 capable. Every system is supported with comprehensive documentation.

*except PACS 3500 System

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Alternate Local HMI Panel



FROM INSPIRATION TO INSTALLATION

Getinge specializes in early planning consultation and smart contamination prevention solutions for bio-pharmaceutical production, biomedical research, medical device manufacturing, laboratories and highly contaminated environments. Backed by more than 100 years of experience, global reach and the largest installed base for many equipment areas, we help our customers plan for maximum productivity in the most cost-efficient way. From logistics planning and premium equipment to un matched service and training, count on **Getinge – right from the start.**

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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.