



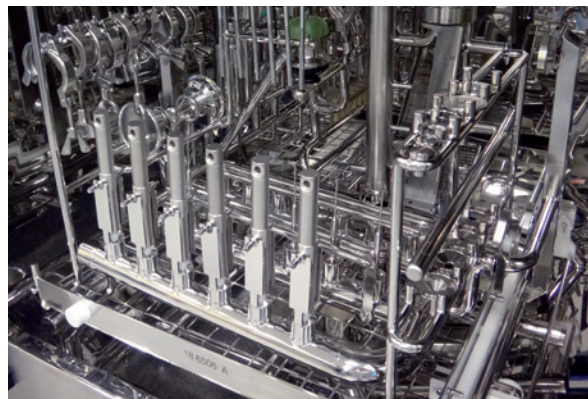
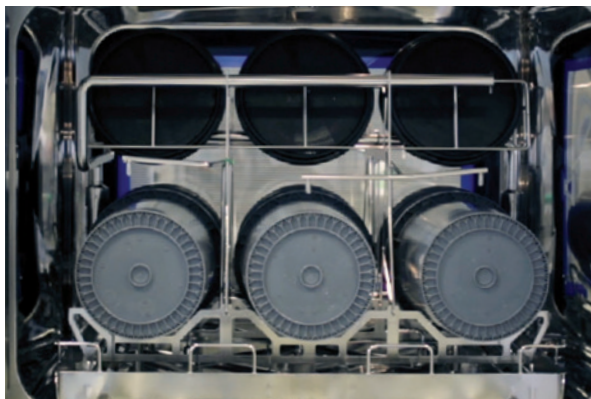
Hamo PG-800

Hamo PG-1300

**cGMP, FDA and EHEG Compliant
Cleaning Equipment (Pharma Grade)**

Consequent Professional Solutions

Hamo Cleaning equipment for industrial, life sciences and pharma fields are special cleaning equipment designed to process critical components such as, fermentation containers, big bottles, glassware, components of liquid- and powder-filling and packing-machines, mixers, tubes, cones, palettes, boxes, tableting-tools, and other parts from pharmaceutical, diagnostic and biotech industries.



Maximum Flexibility

Hamo Cleaning equipment are available in two sizes, to accommodate many different sizes of goods:

Hamo PG-800

Chamber usable dimensions W x D x H, mm (inches): 800 x 800 x 1000 (31,5 x 31,5 x 39,4)

Hamo PG-1300

Chamber usable dimensions W x D x H, mm (inches): 1300 x 1300 x 1000 (51,2 x 51,2 x 39,4)

Extended height execution PG-1300
1300 x 1300 x 1300 (51,2 x 51,2 x 51,2)
allows cleaning of containers of a height of up to 1250mm.

Chamber

The polished chamber (with only three openings) and tubing are designed to fully drain. The chamber and the tubings are designed with slopes to achieve a quick and full emptying.

The chamber is equipped with internal lighting, to be able to monitor the process during cleaning.

Glass-Doors

The units are executed in a single door-version, or as double-door if wash load shall be introduced through the machine into a higher classified room («Bio-Seal» room separation).

The doors are made out of two hardened glass, with surrounding inflatable seals in silicon or EPDM.

Load- and Unloading

By means of an external transport trolleys the machines are loaded and unloaded. Automated systems with feed- in and feed-out roller conveyors are also available.

Dosing Pumps

Up to four detergents or additives are dosed (dosing volume set-values are part of the wash-cycle setting) into the machine. The pumps are integrated in the machine, or can optionally also be installed externally of the machine.

Drying

The drying air is pre-filtered F8 and is, pressurized by a side-channel-blower and heated in a double wall heat exchanger – just before entering the chamber and the wash-system- again filtered via a filter HEPA H13 (incl. Filter-monitoring system).

Utilities

All media-supplies (except drain) are from above:

- The electrical and pneumatic supply
- Up to 3 separate water supplies
- Up to 4 additives/detergents
- Clean-air supply (eg for blow out of water inlet piping, hollow wash goods or pre-dry of brushes)
- Supply- and exhaust air (Drying)

Maintenance and Calibration-Friendliness

Machines working in a qualified environment have to be maintained and calibrated on a regular base.

The components in HAMO machines allow easy maintenance and quick calibration in accordance with the latest regulations. The machine concept allow easy access through doors to the control cabinet, to the dosing systems, the sensors.

Energy Efficiency

Hamo machines are built according the latest technologies to reduce the loss of energy and the use of resources. The double walled chamber are asbestos and chlorine free insulated, which reduces the heat loss to a minimum. The innovative pump and spray system reduces the use of water to an absolute minimum.

Safety

The machines are built to the latest safety guidelines: Main switch and safety circuits, pressure monitoring of the pneumatic supply, door-opening only if chamber temperature is below safety level, dripping pan with alarm, etc.



Process-Safety / Control System

Control

The machine is controlled via a modern Control-system (Siemens S7 1500) which stands for reliability and flexibility; it is designed and built according the latest regulations and complies with GAMP.

The visualization runs on a touch screen (HMI TP 1200); optional barcode-reader or other interfaces are available.

Software

The software (Siemens TIA portal including audit trail) complies with FDA Title 21 CFR Part 11 and GAMP

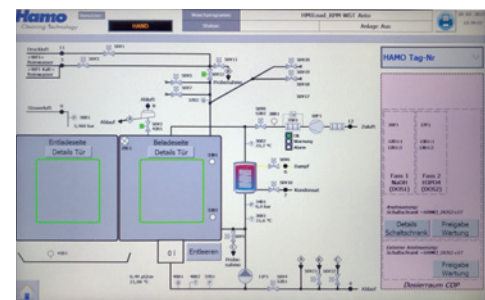
The cleaning cycles are individually configured to be adapted to the soiling and the specific requirements of the wash-load.

The integrated user management on the software allows easy configuration of the access-levels of 5 user-group. Specific user-group have different access-rights; therefore configuration or changes on cleaning-processes can only be made by authorized personal.

Job-Report / Load-Documentation

cGMP and state of the art quality methods request the documentation of the cleaning processes and their critical parameter.

The job-report and /or the load-documentation can therefore be printed by a local printer or saved as PDF-file.



Integration in Customer Networks

Integration into customer networks can be executed in different ways; possible interfaces are Siemens Profibus, Siemens Profinet, Ethernet and USB:

MES System-connection (manufacturing execution system), via a customer-side **DCS System (distributed control system)**, eg for sending or receiving the cleaning recipes.

MES System-connection via **SCADA-functionality (Supervisory control and data acquisition)** by software Siemens PM Quality and/or PM Control.

Document-network for data-storage on a fileserver with active directory for machine-generated pdf.

PAN-connection (Personal area network), for time-synchronisation, user-log-in and machine generated protocols; OPC (OLE for process control).

Electric Cabinet / Components

As standard the electric cabinet, executed according latest standards (CE/IP65) is integrated in the machine; the analogue-digital-signal-box is IP 65; all cables halogen-free and individually tagged. Used drives, sensors and measuring components (pressure, temperature, conductivity etc.) are selected based on highest expectation of the high-end customer base.

Execution PG (Pharma Grade)

Technical Execution / Tubing / Components

The machine are designed, built and documented according the latest requirements of the pharmaceutical industry, such as EHEDG, FDA, cGMP and GAMP.

As for example:

- Chamber and welding surface quality $RA \leq 0,8 \text{ mm}$; all radius minimal 30 mm polished
- All piping sanitary/aseptic execution (Tri-Clamps) according ISO 11864-3
- All membrane valves without dead legs; membranes made out PTFE/EPDM



Regulation / Quality Assurance

Design and manufacturing are by a quality system ISO 9001 / 13485 and a team with high quality experience. The manufacturing process o is guidelined by reviews and milestones which guarantee the requirements of FDA, cGMP as well as GAMP.

During factory acceptance test, based on the standard FAT protocols the machines are checked on conformity according the URS/FS. Trained Hamo personal set up, install, start-up, calibrate the equipment; also they can execute installation qualification (IQ) and operational qualification (OQ) as well they can support any performance qualification (PQ).

Special Options

In cooperation with customers or market partners, Hamo equipment is offered in many special versions (or with special options).



High Containment Solutions

Adapted process-control with highest safety for personnel; with integrated gloves which allow manipulation of wash-load in hermetically closed wash-chamber.



Sample port externally of machine-body

Release of sample-taking via log-in at HMI; activation via push-button.

Customized Racks / Wash-load baskets

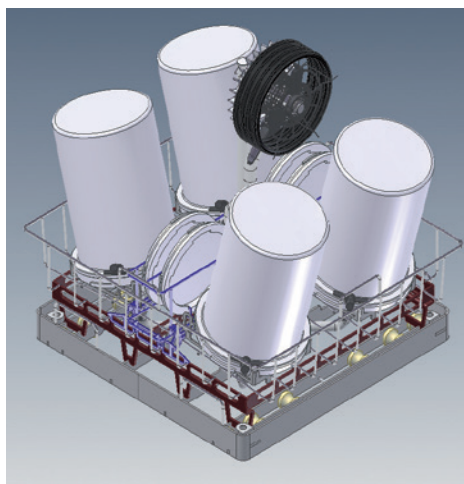
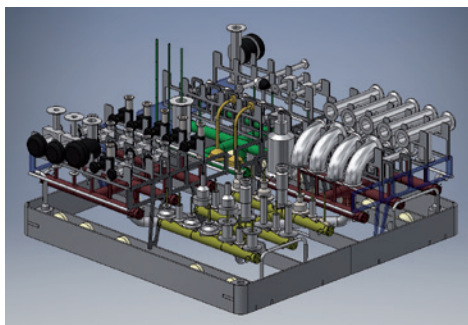
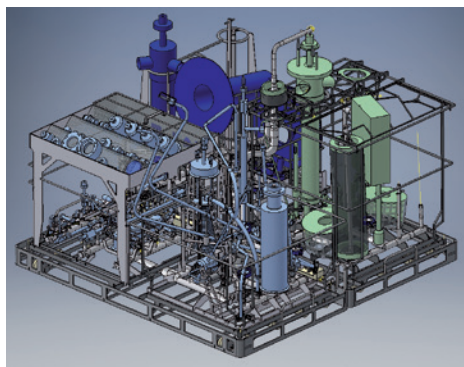
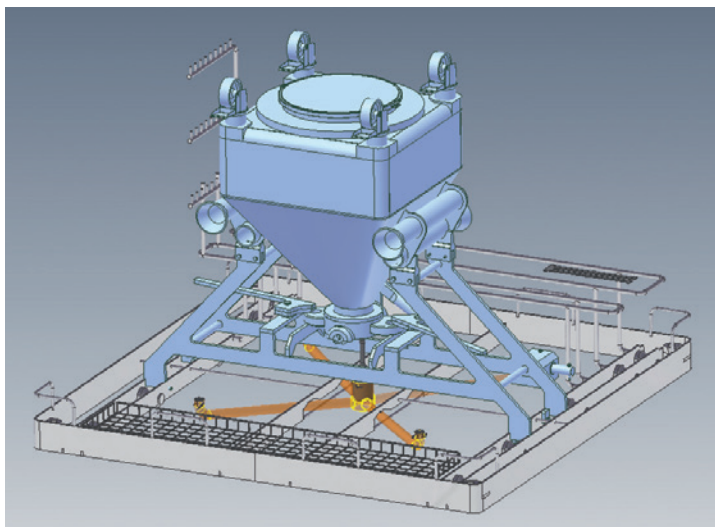
Racks / Washload-Documentation / Engineering (Lay-out) / Manufacturing / Documentation

Hamo have specialized personnel with long experience in pharmaceutical cleaning capable of developing customized racks.

The process includes the inventorying (digitalizing) of the wash-load, the lay-out-engineering (including analysing the spray-pictures), the manufacturing (316L) and the documentation (incl. certificates) of the racks.; this work is done in close cooperation with the customer.

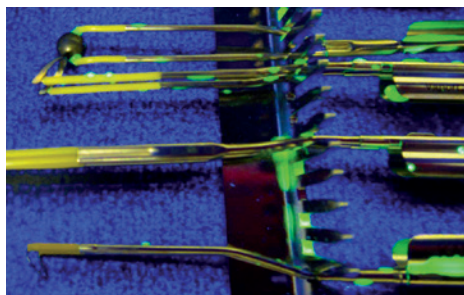
Examples

Racks for brushes for various blister-lines, rack for tubes in various diameters and lengths; Rack for change-parts of filling- and packing-lines, rack for bioreactors (with automatic clapped-opening for high-containment-applications) as well as rack for general change-parts.



Qualification (Riboflavin)

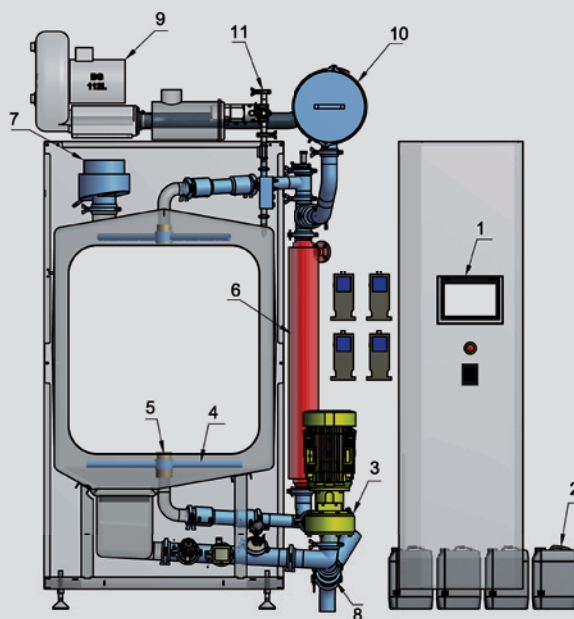
On request Machine and/or racks can be qualified by a documented Ribovlavin-test by our specialists.



Technical Data

HAMO	PG-800	PG-1300
External Dimension mm (inches)		
Width	1800 (70,9)	2300 (90,6)
Height	2950 (116,2)	2950 (116,2) / *3550 (139,8)
Depth	1300 (51,2)	1700 (66,9)
Usable Dimension mm	800 x 800 x 1000	1300 x 1300 x 1000 / *1300
W x D x H inches	31,5 x 31,5 x 39,4	51,2 x 51,2 x 39,4/ *51,2
Regulations	CE FDA 21 CFR part 110: Food / FDA 21 CFR part 210/211: Pharma FDA 21 CFR part 177: non ss-parts FDA 21 CFR part 11: Electronic records	
Material	Stainless steel in contact with wash media AISI 316L polished	
Electric	3x 400V, 50 Hz ,or special voltage	
Water	3 different water (eg Tap water, Demi, Osmose, WFI etc)	
Pneumatic	6-8 bar, oil free	
Steam	Saturated steam 2-8 bar	
Drain	min 50 l/min gravity	
Supply- and Exhaust air (Drying)	400 m3/h	

- 1 Control (HMI)
- 2 Containers (4) for detergents and additives, incl. level sensors
- 3 Circulating pump
- 4 Spray arms (2)
- 5 contact coupler for internal washing/rinsing
- 6 Water- and air heater
- 7 Air extraction
- 8 Drain valve
- 9 Drying system
- 10 Drying air filter H13 HEPA
- 11 Medium manifold for water and detergents



Qualification Support Package (QSD)

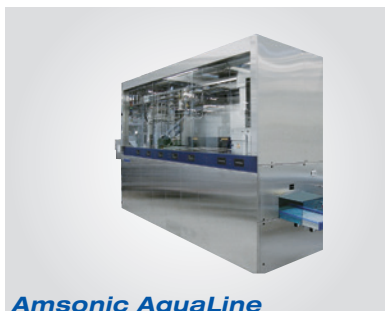
In addition to the detailed machine documentation according CE Hamo can offer the customer a full qualification support package in the form of extensive professional support-documentation; this results in a massive reduction of time and cost for IQ, OQ and PQ.

Based on specific requirements the following documentation is available:

- Material certificates 3.1 FDA compliant; Calibration certificates; weld-log etc
- FS/FDS/HDS&SDS : FAT/SAT ;IQ & OQ documents.



Your centre of competence for precision cleaning



Amsonic AquaLine

Hamo/Amsonic offers a wide range of water-based and closed circuit A3 solvent based cleaning units that provide thorough cleaning processes for various industrial sectors:

Water-Based Precision Cleaning Equipment (Ultrasonic)

Amsonic AquaLine / ModuLine

High performance-Ultrasonic-Precision-Cleaning equipment



Hamo 210

Water-Based Spray Cleaning systems

Hamo 210 / 420 / 840

Spray-cleaning and drying equipment for life sciences- and medical-devices applications



Hamo PG 800

Pharma-Conform Spray Cleaning systems (cGMP)

Hamo PG 800 / 1300

Pharma-Conform (cGMP) Cleaning equipment in single or double door execution (Bio Seal)

Amsonic Hamo HPM

High pressure cleaning systems (>80 bar) for pharmaceutical application



Amsonic 400 R

Solvent-Based Precision Cleaning Equipment

Amsonic 400 R Serie

Solvent-based Ultrasonic equipment (Class A3) Cleaning under vacuum, above or below flash point

Detergents / Additives

Amsonic PreciClean / Hamo liquid

Water based detergents



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