



Hamo P 640

*cGMP and FDA conform Cleaning Equipment
for Pharma, Medical and Life Sciences*

Unique solutions for your critical Cleaning Process

Hamo cleaning equipment has been designed for specific applications in the life science industries. These are used for the cleaning of critical components such as tableting-tools, components of liquid- and powder-filling and packaging machines, medical implants and other items from the production of food, medical devices, pharmaceutical, diagnostic and cosmetic.

The cleaning equipment is designed, produced and documented according to the latest cGMP guidelines.

Cleaning Equipment with maximum Flexibility

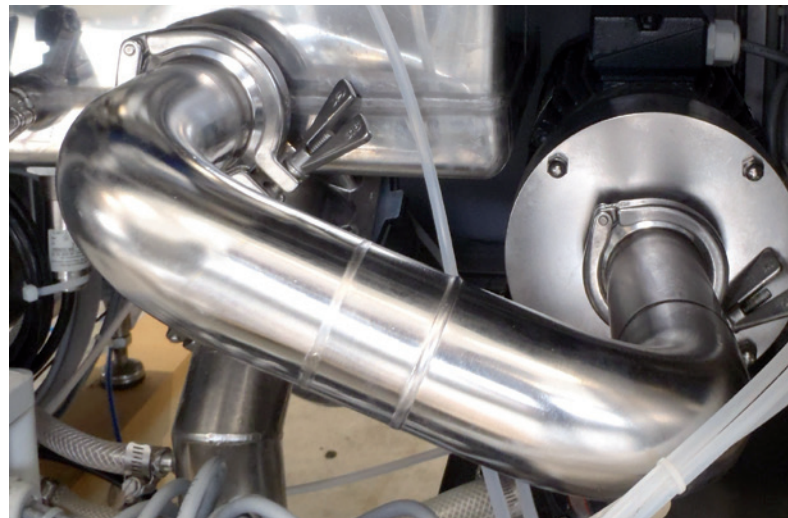
Chamber

The chamber is designed to fully drain. The cleaning chamber is designed with slopes to achieve a quick and full emptying.

The chamber is produced of 316L (1.4404) with surface quality $Ra \leq 0.8\mu m$ and is equipped with an internal lighting, to monitor the process during cleaning.

Piping

All piping and rotating arms are made of 316L (1.4404) with surface quality $Ra \leq 0.8\mu m$ according Sanitary design. The entire piping is equipped with TRI-Clamp connections



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.

The doors are made of double-walled hardened glass, with surrounding Silicon-seals.

Load-and Unloading

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

Dosing Pumps

Up to four detergents or additives are dosed by pumps into the machine (dosing volume set-values are part of the wash-cycle setting).



Drying

The drying air is sucked through a H8 pre-filter and finally filtered by a H13 filter, installed after the fan and electric heater, before entering the wash-system.

Utilities

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

- The electrical and pneumatic supply
- Up to three separate water supplies
- Up to 4 additives/detergents
- Optional clean-air supply (eg for blow-out or blow-off of wash-loads)

Service Friendliness

The machine concept allow easy access through doors to the control cabinet, to the dosing systems, the sensors, and the water-sample-probes.

Energy Efficiency

Hamo machines are built according the latest technologies to reduce the loss of energy and the use of resources. The insulation is asbestos and chloride free and 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.

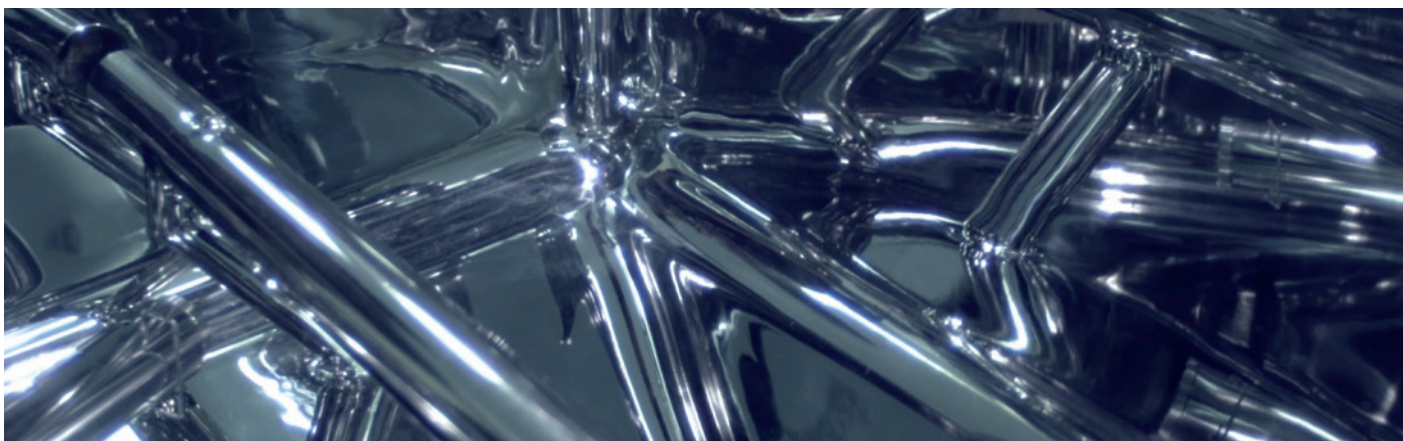
Machine Documentation

The machine is shipped with a detailed machine documentation according CE, containing eg: Manual, spare part list, layout, P&ID-plans, data-sheets, CE-conformity declaration, electrical-diagram, pneumatic-diagram etc.

Qualification-Support-Documentation (QSD)

Hamo simplifies the qualification and validation process with extensive, professional support documentation.

As an experienced manufacturer of cGMP pharmaceutical cleaning machines, Hamo Cleaning Technology supplies the „as-built“ qualification documentation adapted to the respective cleaning machine and supports you with many years of experience and know-how during implementation.



Commissioning, IQ/OQ and FAT/SAT

The cleaning machines are completed in the factory, installed on the in-house test bench, started up and calibrated by Hamo specialists. As part of the internal factory test (pre-commissioning), the conformity of the machine is demonstrated in documented way.

During a factory acceptance test (FAT), the cleaning machine can be checked and accepted. The commissioning on site as well as the training of the operating and maintenance personnel is carried out by qualified Hamo specialists.

Installation and Operational Qualification (IQ / OQ) and also Performance Qualification (PQ) support can be provided based on defined test specifications.

Independent Direct Rinse System (IDRS)

When required, a direct final rinse system can be installed; using directly supplied water for rinsing without using the tank or the pump; it can also be used to blow off with clean air.

Process-Safety / Reproducibility

Control

The machine is controlled via a modern Siemens Control-system which stands for reliability, flexibility and worldwide support. The visualization (HMI) runs on a Siemens TP Comfort Panel. The cleaning cycles are individually configured to be adapted to the soiling and the specific requirements of the wash-load.

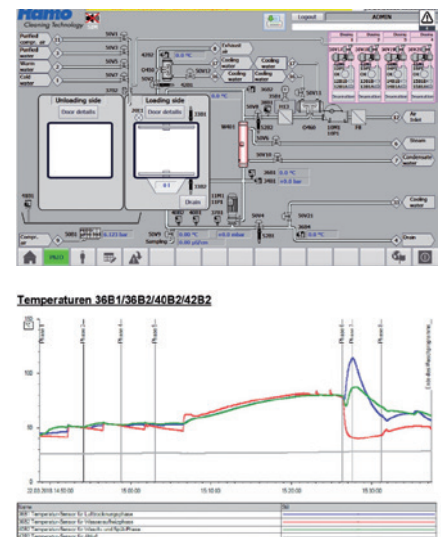
The integrated user management on the software allows easy configuration of the access-levels of each user-group. Specific user-group have different access-rights; therefore configuration or changes on cleaning-processes can only be made by authorized personal.

Process data monitoring and trending of relevant parameters is available in the control concept and can be set individually, depending on the washing recipe.

Integration in Customer Networks

Integration into customer networks can be executed in different ways; possible interfaces are 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).





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.

Calibration

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.

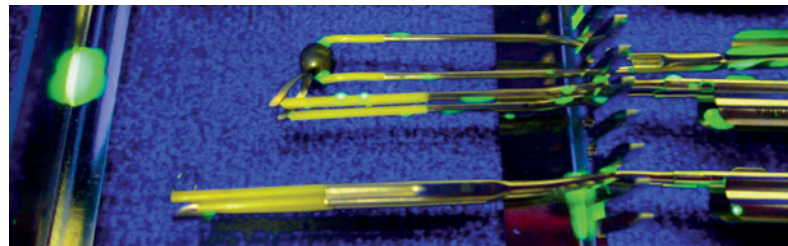
Regulation / Quality Assurance

Design and manufacturing are by a quality system ISO 9001/ISO 13485 and a team with high quality experience.

The manufacturing process is guided by reviews and milestones which guarantee the requirements of FDA and cGMP.

Qualification

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



Application Laboratory



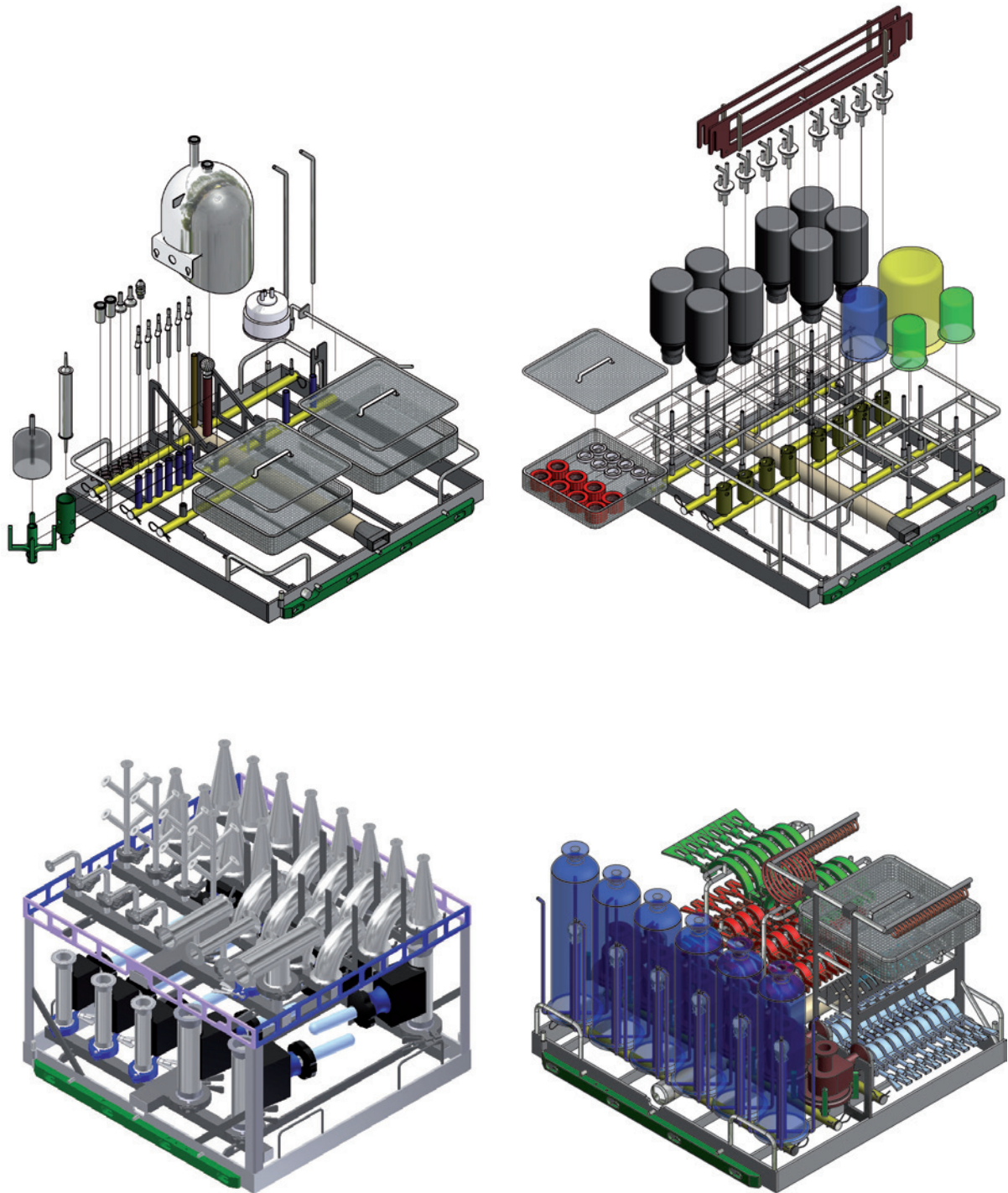
New cleaning cycles are developed and validated in the application laboratory. Customized cleaning processes will be (on request together with the customer) tested and documented.

Customized Racks

Hamo have specialized personnel with long experience in Life Science and medical cleaning capable of developing customized racks.

This experience paired with intense cooperation with our customers, allow innovative and creative solutions.

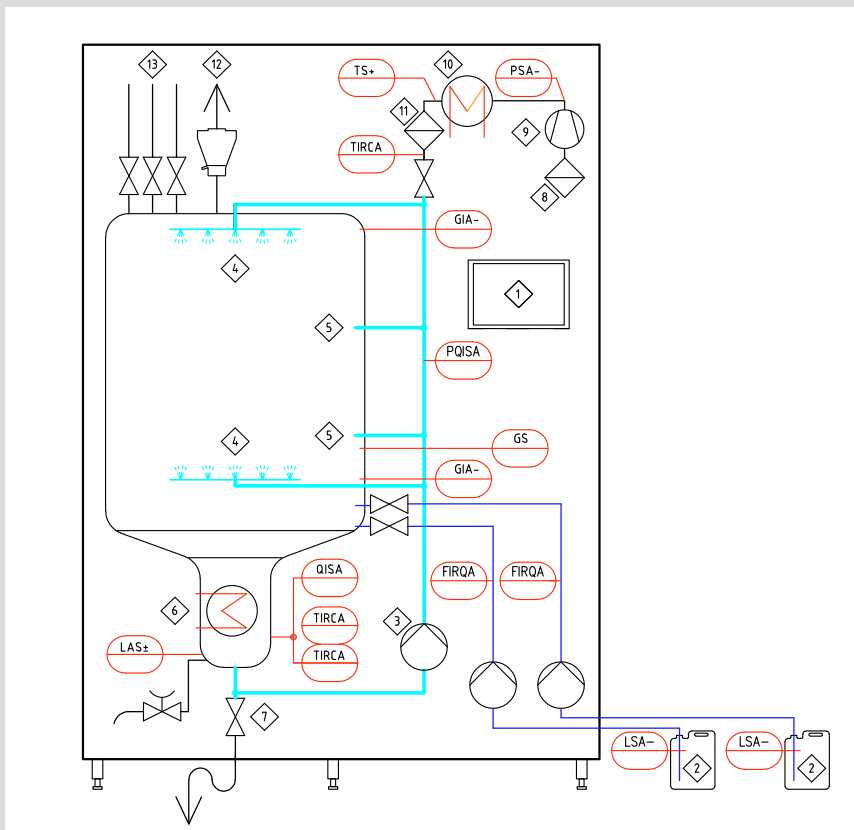
In Pharma execution all racks are completely in stainless steel 316L (1.4404), electro polished and are delivered with the requested documentation and the necessary certificates.



Technical Data

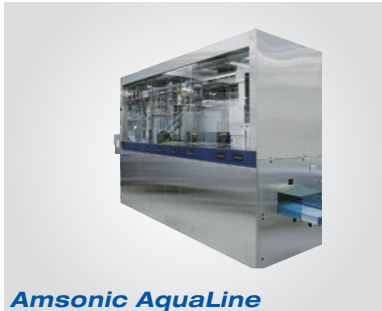
HAMO	P 640
External Dimensions (mm)	
Width	1200
Height	1800
Height with open door	2650
Depth	900
Usable Dimensions W x D x H (mm)	
	640 x 640 x 640
Regulations	
	CE / FDA 21 CFR part 11: Electronic records
Documentation/Certificates	
	QSD / Qualification documentation and certificates (GMP/FDA) optional
Material	
	Stainless steel in contact with wash media AISI 316L polished; others stainless steel AISI 304
Electric	
	3 x 400V, 50 Hz and special executions
Water	
	Three different water (eg Tap-water, demineralized- and WFI)
Pneumatic	
	(Optional) 2-6 bar, dry oil-free
Drain	
	50 l/min gravity

Machine Concept



- 1 Control (HMI)
- 2 Container for cleaning additives
- 3 Circulating pump
- 4 Rotating spray arms (2)
- 5 Contact coupler (2) for internal washing/rinsing
- 6 Water heater
- 7 Drain valve
- 8 Pre Filter air
- 9 Ventilator dryer
- 10 Air heater dryer
- 11 Air Filter H13
- 12 Air extraction
- 13 Water supplies (3)

Your center of competence for medical, pharmaceutical and industrial precision cleaning



Amsonic AquaLine

Water-Based Precision Cleaning Equipment (Ultrasonic)

Amsonic AquaLine / ModuLine

High performance-Ultrasonic-Precision-Cleaning equipment



Hamo P 640

Pharma-Conform Spray Cleaning systems (cGMP)

Hamo P 640

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



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 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



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