

GMP-compliant large chamber cleaning system for individual applications



PH 880.2

Cleaning system for containers, drums and other large components in pharmaceutical production



Installation with two PH 880.2 cleaning units set up as mirror images

Innovation and experience as a basis

As one of the leading groups of companies in the life science sector, Belimed Life Science develops, produces and distributes innovative cleaning, disinfection and sterilization systems in the medical, pharmaceutical and laboratory sectors with over 40 years of experience.

Through constant new and further development based on customer needs and the latest guidelines, Belimed Life Science meets the ever-increasing demands on reprocessing processes – and thus guarantees the future-proofing of its products.

Cleaning processes are a fundamental part of the processes in pharmaceutical research and production, which are characterized by the highest demands on validation, reliability and effectiveness. All parts that come into contact with the product, such as containers, trays, drums, vessels, cans, funnels, and hoses, as well as pump parts, fittings, and components of filling systems, must be validated to be free of adhering product residues in compliance with the strictest quality requirements.

With the newly developed pharmaceutical series, Belimed Life Science has set new standards for the automated cleaning process in terms of pharmaceutical engineering, modularity and quality. Thanks to consistent implementation of GMP, GAMP and FDA requirements and a large number of innovative technical solutions, Belimed Life Science systems represent the future-proof standard in the pharmaceutical industry. Intelligent design measures ensure perfect self-cleaning of the systems. This prevents any product carryover. In addition, Belimed Life Science's own regionally organized service department offers all the services required to ensure a high level of system availability, such as inspection and maintenance, retrofit, spare parts and qualification.



The right solution for every application

Designed as a cleaning system for containers, drums, pallets and other large pharmaceutical-specific equipment, the PH 880.2 is part of a series of systems (PH 820.2, PH 840.2, PH 860.2) that is optimally matched to the rational functional sequence in a professional pharmaceutical process.

Based on a uniform technical concept, which is based on Belimed Life Science's many years of experience in mechanical cleaning, and largely identical design features, the system series covers a wide range of different cleaning scales. The PH 880.2 combines the highest possible standardization of components with the necessary flexibility in design to achieve the greatest possible adaptation of the system to the requirements of the production process.

Field of application

- For cleaning and drying of:
- Containers
- Barrels
- Containers
- Drums
- Trolleys
- Pallets
- Machine parts
- ... and much more

Design options

- Flexible chamber sizes
- 1 or 2 door
- non-floor loading
- floor level loading
- automatic loading and unloading by means of transport system
- Internal cleaning system via connection coupling
- Container interior cleaning system
- Chamber with rails for loading carriers or with set-down points for forklift loading
- Racks specific to the wash load
- Variable tank equipment
- Installation in clean rooms with gas-tight partition wall
- Cleaning Systems with special dimensions



GMP-compliant transport system with stainless steel chains for the flexible transport of containers, pallets and other large-volume wash goods

Flexible loading systems

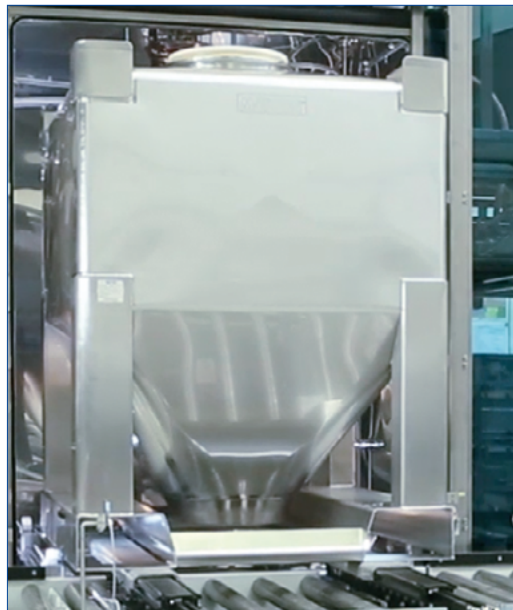
Depending on the process requirements and the type of wash ware, various loading and unloading options for the cleaning chamber are supported. Individual spatial and technical customer requirements can be taken into account.

Manual loading and unloading

- via forklift etc.
- with transfer car and separate rack

Automatic loading and unloading

- via loading and unloading tables with telescopic drive for moving the wash load in and out via racks
- via loading and unloading tables with roller conveyor
- with congestion stretches
- via rotating loading tables for changing the transport direction
- with automated guided vehicles (AGVs)
- via a modular flexible transport system with stainless steel chains
- with automatic recognition of the wash goods and load status monitoring
- with automatic opening of containers above as well as below



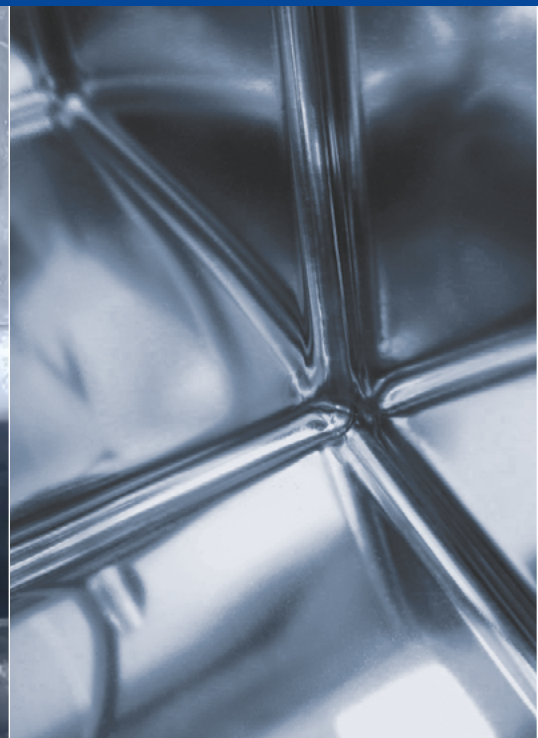
GMP-compliant cleaning of containers, drums and other large pieces of equipment



Patented, pneumatic connection coupling



Internal cleaning via rotation-monitored high-performance spray head
> Watch video on youtube.com



Cutout wash chamber – round corners

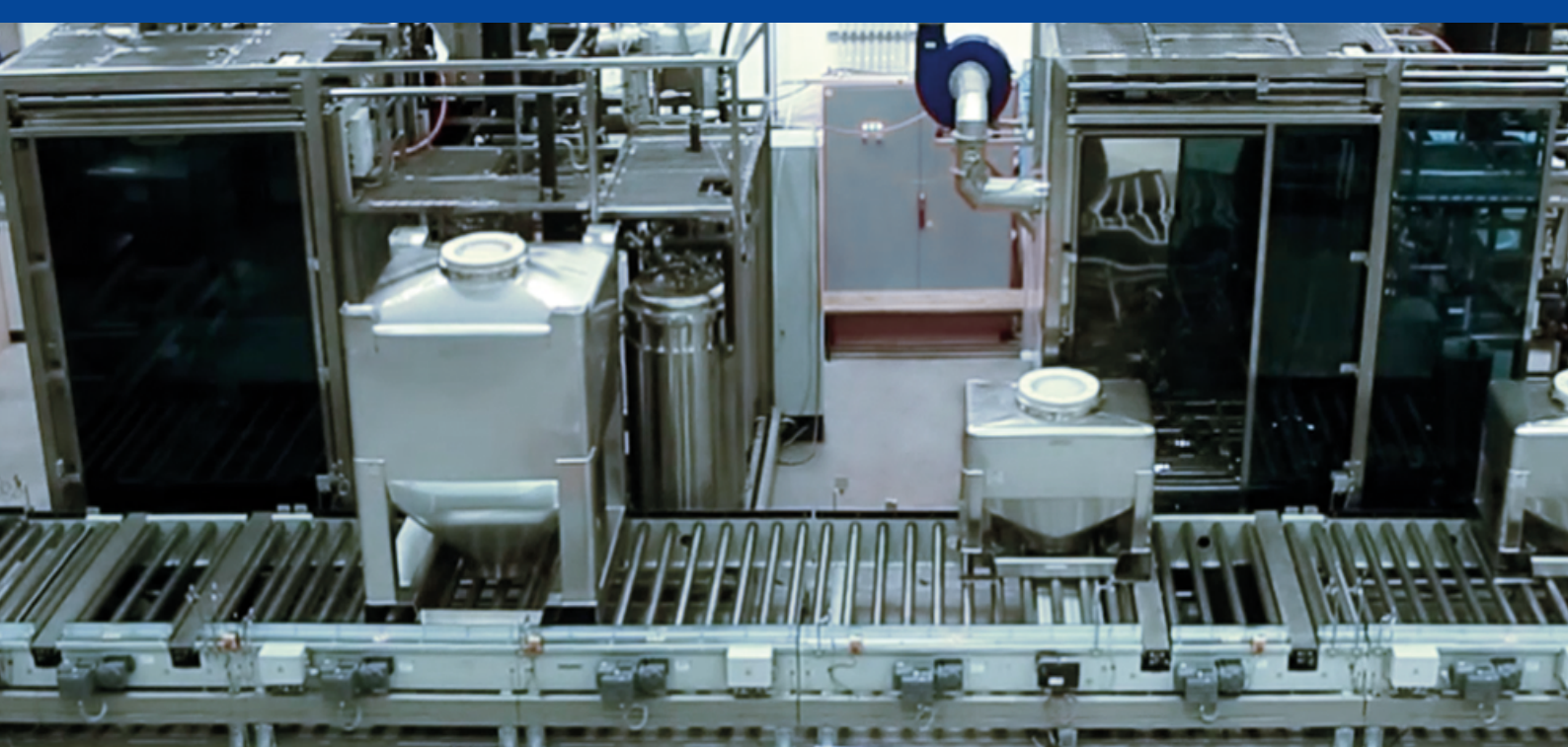
Pharmaceutical grade design

Design requirements arising both from customer needs in pharmaceutical applications and from the latest FDA, GMP and GAMP guidelines were consistently implemented in the development of the PH 880.2.

Of particular importance here is the washing chamber design with round corners, which is free of gaps and dead space: it efficiently prevents the problem of cross-contamination. Contamination and deposits in the machine caused by the cleaning process are avoided right from the start.

Execution

- The maintenance-friendly, integrated technical and service room allows not only machine aggregates but also all media connections and cleaning containers to be stored.
- Machine cladding made of very smooth, oil-impregnated stainless steel sheets
- Horizontal sliding glass doors with inflatable seals and a contamination-free electric belt drive allow visual control of the washing process and represent an optimum in terms of tightness and ease of maintenance.
- Hygienically optimal sump tank integrated into the wash chamber
- Wash chamber and tank interior in mirror plate design with round corners (radius R20) and ground and polished chamber weld seams ($Ra \leq 0.8\mu m$)
- All surfaces in contact with the product with inclination (chamber roof, chamber floor, piping)
- Free of dead space and gaps, no screw connections and protective plates in the chamber
- Drives for automatic loading and unloading outside the chamber
- Pipe connections with clamp connections according to DIN 32676 offer the highest possible safety within the piping; clamp secured with two screws.
- Completely self-draining circulation pump in 3A2s-standard; 5.5 kW
- Regulated tank heating by means of steam heat exchanger in pharmaceutical design ($Ra \leq 0.8\mu m$)
- Pneumatically driven diaphragm valves



PH 880.2 Multi-chamber system with fully automatic transport system that can be adapted to the items to be washed.

Cleaning system

In view of the sensitive items to be washed and the high demands on the degree of cleaning to be achieved, particular attention was paid during development to the coordination of washing solution pressure and flow rate distribution between external and internal cleaning.

- Exterior cleaning via rotating spray arms. These are located one each in the chamber floor, two on the side walls, and one on the roof. These are permanently monitored by magnetic proximity initiators, which are located outside the chamber, permanently. For this purpose, the rotary blades are equipped with hermetically sealed magnets at the ends.
- Container interior cleaning with recoil-driven high-performance rotary spray head that can be moved into the container for effective removal of product residues on the inside of the container.
- The internal cleaning of hollow bodies (e.g. drums) is carried out via a direct injection system on the rack. A perfectly sealing, patented connection coupling with a special sealing mechanism ensures a constant pressure, leak-free supply of the cleaning system and thus shorter cleaning times at higher washing nozzle pressure.
- Different modules can be used, e.g. for opening container lids, to create a fully automated process.

Materials and components

Without exception, the materials and components used from renowned manufacturers meet the highest standards of quality and durability.

- Media-carrying parts such as chamber, tank, piping and pumps are made of AISI 316L.
- Frame and external cladding in AISI 304
- Components with FDA approval
- EPDM gaskets
- Optional material certificates 3.1

Specific material requirements can be accommodated through a variety of options.

GMP rinsing and drying

Cleaning, rinsing and drying are performed via a single-pipe system. Optionally, final rinsing can be performed directly from the supply line (GMP Final Rinse). Strong high-performance drying and the tight connection coupling ensure optimum drying results even without the optional pressurized air blow-out. The system consists of a pre-filter, fan, heater and HEPA filter H13 as the last element in the air stream. The access opening for qualification of filter integrity (DEHS Challenge Test) is ergonomically placed.



B-Touch – visibly and noticeably more operating safety

User interface

The B-Touch user interface is intuitive to operate and all routine operations can be reached with just a few clicks. This not only makes work easier, but also reduces operator errors and increases productivity.

Application control

The B-Touch system control system is based on current Siemens or Rockwell PLC systems. An industrial PC serves as HMI, which enables all necessary functions for connection to process control systems. The HMI was created with VisiWin, which reduces additional license fees.

Software

The B-Touch software was created and tested according to the GAMP5 standards for software validation. The corresponding documents are included in the system documentation. All technical requirements for use according to 21 CFR Part 11 or Annex 11 are available for audit trail, electronic signatures and data security according to the ALCOA Plus principle.





Rotation-monitored high-performance spray head
> [Watch video on youtube.com](#)

Safe process control

The high operational reliability of Belimed Life Science cleaning systems is based on the exclusive use of materials and components of the highest quality and years of experience.

Process control

The reproducibility of the cleaning result is ensured by the permanent monitoring of all relevant process parameters. For this purpose, a comprehensive sensor system is available for measuring the cycle data:

- Detergent concentration with flow and conductivity measurement
- Pressure monitoring of all cleaning and rinsing cycles
- Temperature control with PT-100 sensor, class A
- Conductivity monitoring of the final rinse

Qualification

Belimed Life Science's optional technical documentation includes a comprehensive and overviewable collection of documents that can be used directly for qualification:

- Documentation (DQ, IQ, OQ, FAT, SAT)
- Welding book
- Video endoscope examination of the piping
- Purification test with riboflavin



Technical data and capacities

Type	PH 880.2S	PH 880.2M	PH 880.2MH	PH 880.2L
Usable chamber mass H x B x T (mm)	1800 x 1000 x 1700	1800 x 1300 x 1700	2100 x 1300 x 1700	2100 x 1600 x 2000
Plant external dimensions without container cleaning H x B x T (mm)	2700 x 3100 x 2360	2700 x 3400 x 2360	3000 x 3400 x 2360	3000 x 3700 x 2660
Plant external dimensions with container cleaning H x B x T (mm)	4500 x 3100 x 2360	4500 x 3400 x 2360	2550 x 3400 x 2360	5000 x 3700 x 2660
Chamber volume (liters)	3060	3978	4640	6720
Loading height (mm)	500 / floor level	500 / floor level	500 / floor level	500 / floor level
Door version	Sliding glass door	Sliding glass door	Sliding glass door	Sliding glass door
Door opening	horizontal	horizontal	horizontal	horizontal
Number of doors	1 or 2	1 or 2	1 or 2	1 or 2
Plinth height (mm)	100	100	100	100
Floor pit depth for floor-level loading (mm)	450	450	450	450
Water connections cold water hot water Deionized water (AP) WFI water Outlet	DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 70	DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 70	DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 70	DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 25 2–3 bar DN 70
Electrical connection	400 V / 50 Hz 480 V / 60 Hz	400 V / 50 Hz 480 V / 60 Hz	400 V / 50 Hz 480 V / 60 Hz	400 V / 50 Hz 480 V / 60 Hz
Exhaust air connection	DN 200	DN 200	DN 200	DN 200
Steam connection	Saturated steam DN 40, 2,5 bar	Saturated steam DN 40, 2,5 bar	Saturated steam DN 40, 2,5 bar	Saturated steam DN 40, 2,5 bar

Subject to change without notice



- Belimed Life Science AG Sales
- Belimed Life Science Inc.
- Belimed Life Science AG – Services
- Belimed Life Science AG – Local Partner

Belimed Life Science AG

Zelgstr. 8
8583 Sulgen
Switzerland
Tel. +41 71 49 94 000
info@belimed-lifescience.com

www.belimed-ls.com

Belimed
Life Science