

GMP Compliant Cleaning Encompassing High Level Efficiency and Flexibility



PH 820.2 / PH 840.2 / PH 860.2:
Cleaning machinery, designed for pharmaceutical research and production



*Installation of six
cleaning systems PH 840.2*

Based on innovation and experience

As one of the leading companies operating in the area of decontamination and infection control, Belimed has been developing, producing and marketing innovative cleaning, disinfection and sterilization systems in the sectors of healthcare, pharmaceutical industry and laboratories for over 30 years now.

By an ongoing process in developing their products and the further development on the basis of customer needs, in line with the most recent guidelines and directives, Belimed has ensured that their products meet current and future market requirements, thus meeting the ever-more stringent demands applicable to cleaning efficacy processes.

Cleaning methods are an essential process component in pharmaceutical research and production industries. This is typically shown by the high level requirements of sanitization and validation, to ensure repeatability of the process at any time. The operational target of completely removing any product contamination from all components must be accomplished by adhering to an extremely stringent validated procedure. These stringent demands encompass all machinery parts that may come into contact with the processed products, i.e. glassware, production change parts, filter housings, containers, kegs hoses, pumps and filling line components.

With its newly developed PH range of GMP washers for the pharmaceutical industry, Belimed has set a new standard in engineering in automated cleaning process machinery. Modular design and top level quality are at the heart of these products. Implementation of GMP, GAMP and FDA requirements plus a large number of innovative technical solutions are the keys for Belimed's future in the pharmaceutical industry. The intelligent design of the PH range ensures self cleaning of the machine chamber and pipework at each process stage, thus avoiding the risk of cross contamination.

Belimed has placed a high priority not only on the build quality of its product, but also the after sales support. With regionally based engineering support for installation, planned preventative maintenance, plus its support service offices for spare parts, documentation and validation, Belimed can provide all its customers with after sales back up throughout any of its products' life cycle.

The right solution for all fields of application

With the PH 8xx.2 series, Belimed offers a range of cleaning systems that have been specifically designed for pharmaceutical process environments.

Based on standardized technical concepts that have evolved from years of Belimed's experience in mechanical cleaning, the PH washer range covers a wide spectrum of cleaning requirements and features harmonized construction characteristics throughout the various models. The model range PH 8xx.2 represents greater flexibility in machinery layout, thus enabling easy adaptation to individual process requirements.

Models PH 820.2, PH 840.2 and PH 860.2 are largely similar in their function and construction design. They do vary in terms of their chamber volume and thus in their wash goods loading capacity per batch. The PH 820.2 and PH 840.2 feature a rotating wash arm under the chamber ceiling and above the chamber floor respectively. Due to their greater length, the PH 860.2 is equipped with two corresponding wash arms, top and bottom. The overlapping rotation ensures gap-free rotational spray coverage.

Layout options

- 5 chamber sizes
- Single or double door operation
- Service compartment on right or left side
- Application-specific product wash racks
- Integration into barrier technology featuring gas-tight divider walls
- Custom dimension installations on request

Scope

For cleaning and drying of

- Bottles (e.g. Schott)
- Rack shields
- Filling equipment
- Machine change parts
- Hoses/tubes
- Fittings
- Containers
- and many more (e.g. filter housings, filter plates, valves)

The vertical sliding glass door of the PH 820.2 features a unique drive system which leads to significant space saving.

Due to the horizontal opening door design, the PH 840.2 and PH 860.2 have a particular benefit for areas that have height restrictions.



The patented connection coupling with its special sealing mechanism guarantees leak-free supply to the cleaning system at a constant pressure, thus providing shorter cleaning times at higher wash jet pressure.



Pharma-adapted design

Design that incorporates customer requirements and at the same time meets the latest FDA, GMP and GAMP guidelines represents the main focus in the development of the PH 8xx.2 model range.

Of particular significance here is the dead-leg- and crevice-free wash chamber design with rounded corners: Soil deposits in the machine arising from the cleaning processes have been prevented from the outset and allow a contamination-free cleaning.

Characteristics

- The maintenance-friendly, integrated technical and service compartment not only houses the machine unit, but also provides space for all media connections as well as storage of additive containers.
- Machine cabinets are finished with oil-smoothed stainless steel panels.
- Vertical or horizontal sliding glass doors with (leak-proof) inflatable seals and soil-proof electric linear or friction wheel drives enable visual checks of the washing process, thus attaining an optimal level in ease of maintenance and operational safety.
- Wash chamber and inside of tanks are produced from mirror finish special sheet metal and feature generously rounded corners (radius R20). All chamber welding seams are grounded and polished to exacting standard ($Ra \leq 0.8 \mu m$).

- All surfaces that come in contact with the processed products (i.e. chamber ceiling, chamber floor and piping) are manufactured with a specified slope.
- No dead legs, crevice-free, no screw and bolt connections inside the chamber.
- High-level safety within the piping system is provided by application of Neumo-Sterile flanges (authorized application e.g. for caustic soda or acetic acid).
- Complete self-draining, vertically oriented Hilge recirculation pump in 3A2 standard; max. 4 kW
- Controlled tank heating system featuring electric heater or steam heat exchanger in pharmaceutical design ($Ra \leq 0.8 \mu m$)
- Pneumatic actuated membrane valves

Cleaning system

With consideration to the delicate wash goods and the required high degree of cleaning efficiency, special attention was given to optimize wash liquid pressure and solution distribution between inner and outer product cleaning.

- External cleaning by means of rotating wash arms, both from the top and the bottom with permanent rotation monitoring
- Internal cleaning of hollow bodies is accomplished by direct injection on the load rack. A high efficiency, patented connection coupling enables leak-free and constant pressure supply of the cleaning system. This results in higher wash jet pressure and thus shorter wash cycles.



Rounded corners, free of gaps and dead legs: Clever wash chamber design prevents soil deposits.

The maximum operational reliability of the Belimed cleaning systems is based on the utilisation of high quality materials and components backed up by Belimed's own stringent quality assurance testing procedures.

Materials/Components

The selected materials and major brand components meet even the highest requirements in terms of quality and longevity.

- Wetted components such as chamber, tank, piping and pumps are manufactured from 316L stainless steel.
- Frame and panels are manufactured from 304 quality stainless steel.
- Components are FDA certified.
- Seals are made of EPDM.
- Optional material certification 3.1

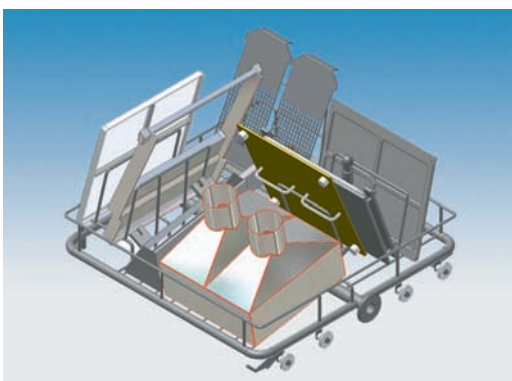
Customer specific material requirements may be accommodated by means of a wide range of available options.

GMP Rinsing/Drying

Cleaning, rinsing and drying are accomplished by means of a single pipework system. As an option, the final rinse may be supplied by direct intake from the supply line (GMP Final Rinse). A powerful high capacity dryer unit, combined with the tight connection coupling enables optimal drying performance even without the option of compressed air blow drying. The system consists of pre-filter, fan, heater and a HEPA filter H13 as the final element in the air stream. The access opening for qualification of the filter integrity (DEHS Challenge Test) has been designed for easy access.



3D view of a loading rack

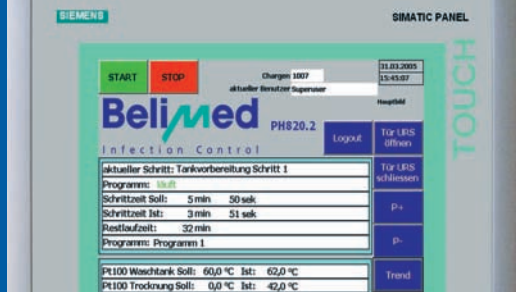


Loading rack for processing containers



Neumo-Sterile flange





Reliable process guidance

Intuitive Operation

The modern, touch screen equipped graphic control panel (Siemens MP 277, 10,4" Color or Allen-Bradley PanelView Plus 1000) enables simple and concise operation. All essential process data are on display.

The machine control unit is either a Siemens S7-300 or a Rockwell Allen-Bradley CompactLogix PLC. As an option, both control systems may be linked to a higher level management system via Profibus or Ethernet (standard with the Allen-Bradley) for further data processing. The 21 CFR Part 11 compliance is reached by the Siemens Audit Trail Option.

The software is in compliance with the guidelines under GAMP4.

For greater operational safety, control and power sections are strictly segregated and housed in separate control cabinets. For ease of service and maintenance, the control section is located in the access door to the technical compartment.

Process Monitoring

Reproducibility of cleaning results is assured by permanent monitoring of all process relevant parameters. For this purpose, Belimed has a number of sensor packages:

- Cleaning additive concentration, featuring flow and conductivity metering
- Pressure monitoring covering all cleaning and rinsing cycles
- Temperature monitoring by means of PT-100 sensors, class A
- Conductivity monitoring of final rinse
- Drying with air stream monitoring
- Differential pressure monitoring of the sterile filter
- Validation connector for independent monitoring system

Batch Documentation

A batch protocol containing all sensor detected process data may be printed or transmitted in data format to an external PC or network.

Qualification

The optional technical documentation available from Belimed contains comprehensive and concise information that may be directly applied for the qualification process:

- Documentation (DQ, IQ, OQ, FAT, SAT)
- Manufacturer certificate (2.1 / 2.2 / 3.1)
- Welding certificate
- Video endoscope examination of the piping system
- X-ray testing of welding seams
- Dye penetrant testing of welding seams
- Cleaning test using Riboflavin

The documentation is also available according to the ISPE baseline Volume 5 (IT, FT, FAT, FCT).



Integrated technical and service compartment that also houses the machine utilities and pipework connections as well as storage of additives containers.

Technical data

| Type | PH 820.2 | PH 820.2H | PH 840.2 | PH 860.2 PH 860.2L |
|---|---------------------------------|---|---|---|
| Usable chamber dimensions H x W x D (mm) | 670 x 610 x 750 | 1100 x 610 x 750 | 990 x 830 x 830 | 1200 x 830 x 1250 1200 x 830 x 1500 |
| Installation outer dimensions H x W x D (mm) | 2080 x 1500 x 1020 | 2510 x 1500 x 1020 | 2080 x 2300 x 1320 | 2340 x 2300 x 1740 2340 x 2300 x 1990 |
| Installation height with open door (mm) | 2360 | 3220 | – | – |
| Chamber volume (liter) | 307 | 503 | 682 | 1245 1494 |
| Loading height (mm) | 800 | 800 | 800 | 800 |
| Door design | sliding glass door | sliding glass door | sliding glass door | sliding glass door |
| Door opening | vertical | vertical | horizontal | horizontal |
| Number of doors | 1 or 2 | 1 or 2 | 1 or 2 | 1 or 2 |
| Pedestal height (mm) | 100 | 100 | 100 | 100 |
| Water connection | CW WW DI (AP) WFI A | DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 70 | DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 70 | DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 20 2–3 bar DN 70 |
| Electro connection | E | 3N 400 V 50 Hz, P 35 kW | 3N 400 V 50 Hz, P 35 kW | 3N 400 V 50 Hz, P 36 kW |
| Exhaust air connection | AL | DN 100 | DN 100 | DN 150 |
| Steam connection | FD | saturated steam DN 20 2,5 bar | saturated steam DN 20 2,5 bar | saturated steam DN 20 2,5 bar |

Subject to modification

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