GMP-Compliant Cleaning – Outstanding Results with Smallest Footprint



PH 810: cleaning system for pharmaceutical production, research laboratories and pharmacies





High-end GMP-compliant cleaning

Cleaning processes play an essential role in pharmaceutical research and production industries. All product-contacting parts must be cleansed of adherent product residues, if observing the most stringent quality requirements. The highest standards with regard to validation, reliability and effectiveness must be met.

Experience and know-how

The production processes in pharmaceutical research and production are designed for maximum security, top quality and high cost-effectiveness. This applies also to cleaning processes in particular. As technology leader, Belimed has for over 40 years continually developed innovations and ever more sophisticated product versions on the basis of customers' needs.

Customer-oriented solutions

The GMP-compliant cleaning system PH 810 is the newest example of how Belimed executes the practical implementation of customer requirements. It is the most compact pharmaceutical cleaning system on the market and is especially suitable both for pharmaceutical research and production and for pharmacies and laboratories with stringent quality requirements regarding the cleaning result.



That's true greatness. Often concentrated in the smallest of spaces.

Minimized installation dimensions – maximized chamber volume

The space available is more often than not limited by the building situation, or by the predetermined installation site in the case of replacement acquisitions. At a width of only 100 cm, a total height of 210 cm and sliding glass doors that open downwards, the PH 810 cleaning system features an excellent ratio of payload space to room space required. This makes transfer of the machine to the installation site and installation easy and uncomplicated.

Field of application

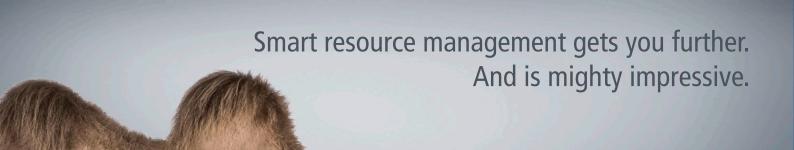
For cleaning and drying of

- bottles/ glassware/ pipettes
- infusion and injection bottles
- containers/ cans/ filter casings
- funnels
- machine change parts
- hoses/ tubes
- fittings
- rack shields
- ...and much more

Description	Data
Usable chamber dimensions H × W × D (mm)	670 × 610 × 750
Installation outer dimensions $H \times W \times D$ (mm)	2100 × 1000 × 980
Chamber volume (liters)	307
Loading height (mm)	870
Door design	Sliding glass door
Door opening	vertical
Number of doors	1 oder 2



PH 810 cleaning system; only 100 cm wide



Economic operation

Thanks to permanent further development and superior technology, Belimed systems set the standard for economic use of resources such as water, cleaning agents and energy. This saves costs and spares the environment.

Saving utilities through GMP pulsation rinsing

The device is equipped with a GMP pulsation rinsing system. This minimizes the consumption of expensive ultrapure water and relativizes the required connection value. The water-conducting pipelines are alternately filled with water and blown out with process air. The water is sprayed over the washing items with the aid of the process air.

High-precision dosing

Belimed's gravimetric dosing system (GDS) allows for further potential resource savings, as the process chemicals are added with a 2% dosing precision.

Over- or underdosing is thereby ruled out.





Wash goods-dependent level control – up to 20% resource savings per cycle

With the wash goods-dependent level control of the detergent solution, Belimed is making an active contribution to achieving a high level of economy and environmental protection. The required water volume or the filling amount is permanently allocated to each program or to the washing items. If the load is small, consumption of water, energy and cleaning agents is automatically reduced.

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 810 model.

Specifications - external

- Flexible utilization as 1- or 2-door model, standing model by the wall, installed as room divider also available with gas-proof wall.
- Vertical sliding glass door(s) opening downwards with hollow-section profile seal
- Machine cabinets are finished with oil-smoothed stainless steel panels.

Specifications - internal

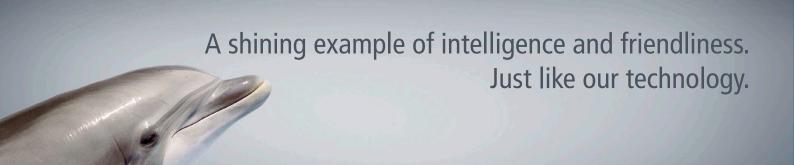
- Wash chamber and inside of tanks are made of mirrorfinished special sheet metal and feature generously rounded corners (radius ≤ R20). All chamber welding seams are ground and polished to a stringent standard (Ra ≤ 0.8 µm) – for efficient prevention of cross-contamination.
- High standard all surfaces that come in contact with the processed products (i.e. chamber ceiling, chamber floor and piping) are manufactured with specified slopes.
- No dead legs, crevice-free no protective panels in the chamber
- Tri-clamp connections according to DIN 32676 for sensors and pipe connections (safety clamps)
- Complete system equipped with rigid piping
- Efficient recirculation pump
- Controlled tank heating system featuring electric heating or steam heat exchanger in pharmaceutical design
- Sampling valve on machine sump

Cleaning system

- All water connections (up to 3 types of water) featuring dF procedure, i.e. coarse contaminations can already be discharged from the chamber in the pre-rinsing step via the "direct fresh-water rinsing procedure", thus optimizing the cleaning result while at the same time reducing cycle processing times.
- External cleaning by means of rotating spray arms of the rack mounted at the top and the bottom respectively
- Internal cleaning of hollow bodies is accomplished by means of direct injection systems on the rack. A highly efficient patented connection coupling featuring a special sealing mechanism ensures leak-free supply of the rack with consistent pressure.



Washing tank made of mirror-finished sheet metal with installed heating elements and fine screen in the pump suction pipe. Sieve tray mounted above the washing tank as fall protection



A new standard of safety and quality

Secure process guidance and reliability of the systems are Belimed's central focus. Besides the first class manufacturing quality, this is also demonstrated by the process monitoring, the intuitive operation and the well-structured documentation.

Process monitoring

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

- Cleaning additive concentration by means of gravimetric dosing system (GDS), with conductivity measurement
- Pressure monitoring covering all cleaning and rinsing cycles
- Temperature monitoring by means of PT-100 sensors, class A
- Conductivity monitoring of final rinse
- Permanent monitoring of spray arm rotation
- Air stream monitoring of drying system
- Differential pressure monitoring of HEPA H13 filter
- Validation connector for independent monitoring system

Documentation

Belimed's technical documentation is comprehensive and well-structured and can be directly used for the qualification process. It is structured as follows:

Belimed standard:

- Standard pharma documentation
- Operating manual
- Technical datasheet
- Belimed commissioning checklist

Options:

- IQ/ OQ/ FAT/ SAT documents
- Manufacturer certificate 2.1 according to EN 10204
- Welding certificate and acceptance test certificate 3.1 according to EN 10204
- Video endoscope examination of the welding seams of the washing and rinsing system piping





Accommodation of 2 10l containers below the

machine. The containers can be separately

Wash chamber is made of mirror-finished special sheet metal and features rounded corners – for efficient prevention of cross-contamination

Materials / components

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

- All product-contacting component parts of the circulation and filling system are made of 1.4435/ 1.4404 (AISI 316L) stainless steel/ Ra ≤ 0.8 µm
- Machine paneling made of 1.4301 (AISI 304) stainless steel
- Seals, door seals and valve membranes made of FDA-certified EPDM

Innovative dosing system

Belimed's new gravimetric dosing system (GDS) operates by the principles of weighing technology and replaces the use of flow meters. The added value for the user in this context becomes apparent in view of the dosing precision — over- or underdosing is ruled out. Dosing precision is not affected even by high fluctuations of viscosity.

- Up to 4 dosing connections possible (2 or 4)
- It is additionally possible to monitor the conductivity of the washing liquid

Efficient drying

A powerful high-capacity drying unit combined with the

tight connection coupling ensure fast and complete

drying of the washed items. The system consists of H13 pre-filter, fan, heater and an H13 HEPA filter as the final element in the air stream. The access opening for qualification of filter integrity (DEHS Challenge Test) has been designed for easy, ergonomically optimized access. For cleaning long hoses and machine components with small boreholes, it is recommended to use the optionally available compressed air blow-out

function of the washing and rinsing system (autoclavable sterile-filter with $0.003 \mu m$ particle retention size).

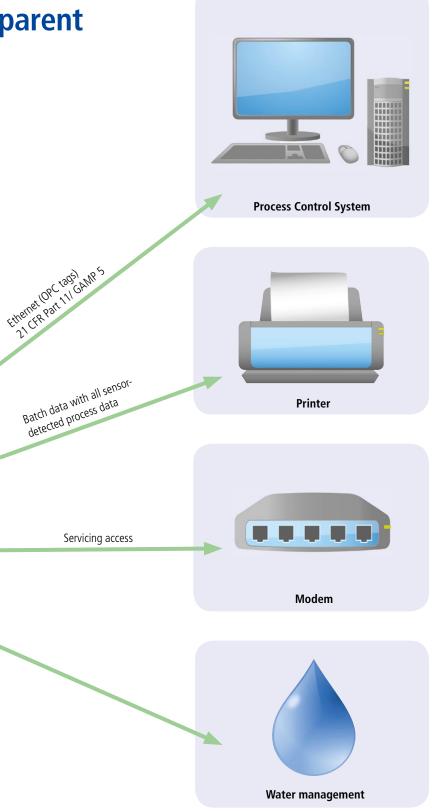


Convenient and transparent user guidance

Intuitive operation

The modern, touch screen-equipped graphic control panel (5.7" color display) allows for clear and easy operation. All process-relevant parameters are displayed. The system is both controlled and operated via the B&R Power Panel 65. The system can optionally be controlled either via the Siemens or the Rockwell Allen-Bradley PLC control unit.







Great to be so flexible. But in more ways than the choice of color.

Flexible accessories

Flexibility is our strength. We offer a comprehensive range of accessories that is customized to meet our customers' individual needs. In addition to the standard assortment listed, we offer customer-specific solutions for production equipment, format components, tableting equipment etc. Belimed pays special attention to the development of the racks with regard to the sensitive wash items and to stringent requirements with regard to the degree of cleaning to be achieved.



Basic rack, 1-level	
For loading of: Washing items that do not require direct injection. Compatible for loading e.g. 2 open baskets (art. No. 769 075) W X D X H = 570 X 340 X 185 mm Usable height 570 mm	Equipped with: 1 spray arm below 1 removable spray arm above Pipe ends designed as cleaning apertures
Art. No.	825 031



Basic rack, 2-level	
For loading of: • Washing items that do not require direct injection. Usable height • Lower level = 270 mm • Upper level =: 270 mm	Equipped with: • 2 rod supports • 1 spray arm below • 1 spray arm between the levels • 1 spray arm above • Pipe ends designed as cleaning apertures
Art. No.	825 028



Rack for laboratory glass bottles	
For loading of: 4 laboratory bottles (GL45), 2000 mL 3 laboratory bottles (GL45), 5000 mL 2 laboratory bottles (GL45), 10L – 20L 9 screw caps (GL45, blue or red) or 4 laboratory bottles (GL45), 10L – 20L	Equipped with: 1 1 direct injection nozzles 9 bottle retainers 2 bottle holders 1 spray arm below 1 spray arm above Pipe ends designed as cleaning apertures
Art. No.	825 036



Universal 1-level rack – for 4 exchange systems

For loading of:

• 4 different washing items on exchange systems

Equipped with:

- 4 plug-in connections for exchange systems
- 1 spray arm below
- 1 spray arm above
- Pipe ends designed as cleaning apertures

Art. No. 825 125



Exchange system for laboratory bottles compatible with racks 825 125 / 825 126

For loading of:

• 6 laboratory bottles (GL45), 100 – 1000 mL

Equipped with:

- 6 direct injection nozzles designed as bottle retainers
- Pipe ends designed as cleaning apertures

Art. No. 825 131



Exchange system for laboratory bottles compatible with racks 825 125 / 825 126

For loading of:

- 4 laboratory bottles (GL45), 1000 2000 mL
- or
- 3 laboratory bottles (GL45), 2000 mL
- 1 laboratory bottle (GL45), 5000 mL

Art. No.

Equipped with:

- 4 direct injection nozzles designed as bottle retainers
- Pipe ends designed as cleaning apertures

825 136



Exchange system for laboratory bottles compatible with racks 825 125 / 825 126

For loading of:

• 1 laboratory bottle (GL45), 1000 mL - 20L

Equipped with:

• 1 direct injection nozzle designed as bottle holder/retainer

Art. No. 825 138



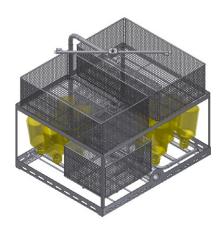
Exchange system for open basket compatible with racks 825 125 / 825 126

Washing items that do not require direct injection

Support for 1 open basket, W × D = 340 × 285 mm (art. No. 820 306)

Equipped with:

Art. No. 825 150



Universal 2-level rack – for 4 exchange systems

For loading of:

Lower level

• Various washing items on exchange systems (see exchange system rack, art. No. 825 125)

Upper level

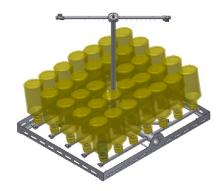
• Washing items that do not require direct injection

Equipped with:

- 4 plug-in connections for exchange systems, lower level

 1 rod support, upper level
- 1 spray arm below
- 1 spray arm between the levels
- 1 spray arm above
- Pipe ends designed as cleaning apertures

Art. No. 825 126



Rack for laboratory glass bottles

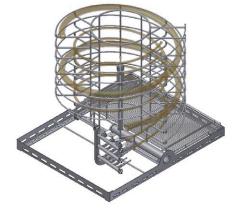
For loading of:

• 34 laboratory bottles (GL45), 100 – 1000 mL

Equipped with:

- 34 direct injection nozzles designed as bottle retainers
- 1 spray arm below
- 1 spray arm above
- Pipe ends designed as cleaning apertures

Art. No. 825 027



Rack for laboratory glass bottles

For loading of:

- 10 hoses, Ø up to 13 mm, length up to 3.5 m
- 3 hoses, Ø up to 20 mm, length up to 3.5 m

- **Equipped with:** 1 rotating nozzle
- 1 sieve support
- 13 hose nozzles
- 1 spray arm below
- Pipe ends designed as cleaning apertures

Art. No. 825 039



Transfer cart

For loading of:

- Up to 2 racks on 2 levels
- Loading height = 870 mm

Art. No.

Equipped with:

- Removable drip tray
- Easy-running swivel wheels with locking brake
- Securing device for racks

870 032

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