GMP-compliant washing in the narrowest space and without compromises

PH 810

Washing system for pharmaceutical production,
for research laboratories and pharmacies

Belimed
Life Science

Core competencies for successful cooperation

Washer and sterilizers
- Washer and sterilizers developed and built according to customer requirements
- highest process, user and environmental safety
- high machine reliability and plant availability through proven product design
- continuous development to increase usability and connectivity

Application technology competence
- Customized quality solutions – that is our guiding principle. Highest flexibility, low risk of change and fast realization are our strengths.
- Competent field experts will be happy to advise you and offer you a tailor-made solution that is perfectly suited to your application
- The machines are adapted to your specific local conditions and comply with worldwide specifications

Project Management
Our modern project management can be described in three words:
- Pragmatism – single-minded and focused
- Proximity – always in contact and at the pulse of the customer
- Commitment – we give our best so that your goals are achieved

Qualification services
- experienced full-service provider including qualification and validation
- consistently professional risk management and a conclusive clear workflow
- extensive product competence for optimized functionality and cost efficiency
- comprehensive documentation, solid data integrity and full compliance with legal requirements

Life-Cycle-Management
- Full life cycle management from the initial concept idea through production, qualification, maintenance and service to retrofit – everything from one source
- local service network to guarantee you the highest machine uptime

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
- Tabletting Tools
- Lyo Plates
- ... and much more

Description	Data
Usable chamber dimensions H × W × D (mm)	670 × 610 × 750
Installation outer dimensions H × W × 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 or 2

PH 810 cleaning system; only 100 cm wide

Economic operation

Thanks to permanent further development and superior technology, Belimed Life Science 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

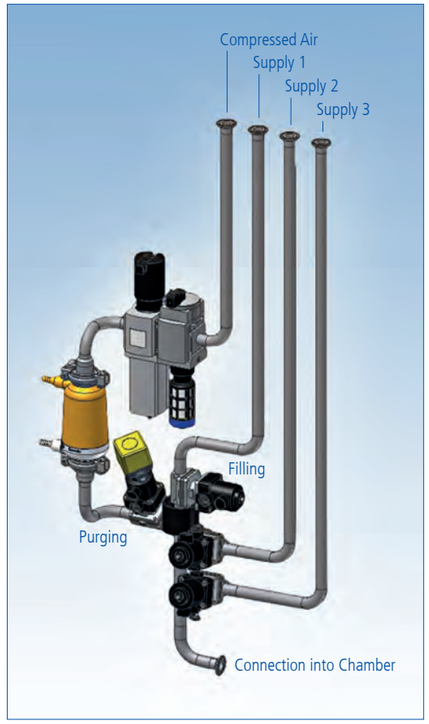
The device is equipped with a GMP pulsation rinsing system. This minimizes the consumption of expensive ultrapure water and can be implemented independently of the loop performance. The water-conducting pipelines are alternately filled with water and blown out with process air. The water is sprayed over the washing items with the aid of the process air.

High-precision dosing

Belimed Life Science'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 Life Science 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.

Characteristics – external

- Available for installation as either a single door, freestanding model or a double door pass through machine, with option of a gas tight installation between rooms of different classifications.
- Vertical sliding glass door(s) opening downwards with hollow-section profile seal
- Machine cabinets are finished with oil-smoothed stainless steel panels.

Characteristics – 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 "direct fresh-water rinsing procedure" (dF), i.e. coarse contaminations can already be discharged from the chamber in the pre-rinsing step via the dF 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.

A new standard of safety and quality

Secure process guidance and reliability of the systems are Belimed Life Science'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 Life Science 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 Life Science's technical documentation is comprehensive and well-structured and can be directly used for the qualification process. It is structured as follows:

Belimed Life Science-Standard:

- Standard pharma documentation
- Operating manual
- Technical datasheet
- Belimed Life Science 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

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-certifi ed EPDM

Innovative dosing system

Belimed Life Science'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 µm particle retention size).

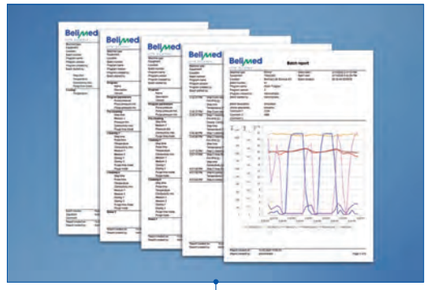
Accommodation of 2 10l containers below the machine. The containers can be separately removed, enabling highly ergonomic replacement.

Convenient and transparent user guidance

Intuitive operation

The modern, with a touch screen equipped graphical user interface (colour display 5.7") offers a simple and clear operation. All process relevant parameters are displayed. Both control and operation are carried out via the Siemens Nano Panel PC. The modern Siemens Nano Panel PC is based on Windows 10 and offers a wide range of interfaces and high robustness for maintenance-free continuous operation.

Process Control System/
Ethernet (OPC-Tags)
21 CFR Part 11 / GAMP 5



Batch data with all sensor-detected process data

Servicing access

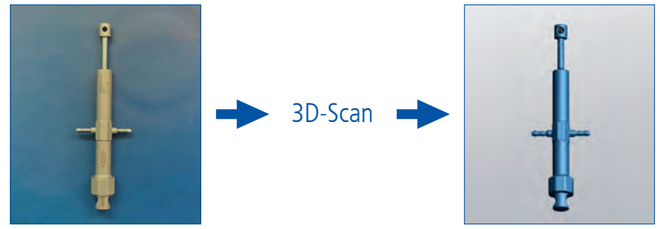
Water management

The Heart of the washing process – The Wash Rack

A perfect cleaning result is the result of a reliable washing system, a validated washing process and the correct positioning of the items to be washed on the rack. In many cases, the analysis of the flow of goods and the design of the rack takes more time, than the selection of the washer. Belimed Life Science supports you in creating an optimal design of the rack, so that your washing goods are efficiently and reproducibly clean.

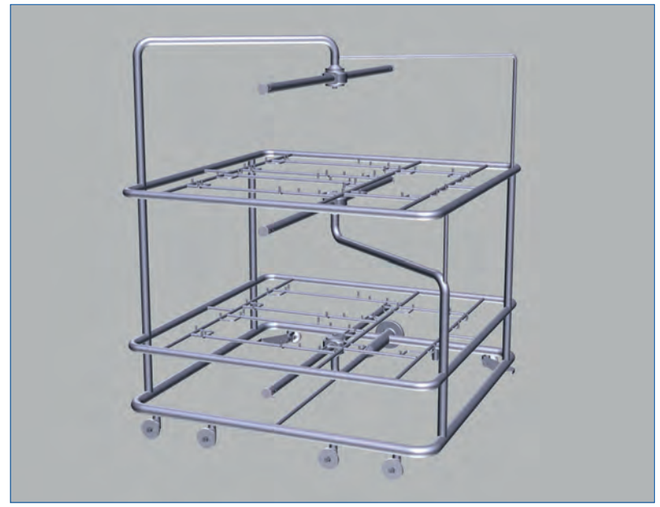
For the perfect design the rack Belimed Life Science adheres to the principles of "Quality by Design". We consistently use 3D models of the wash items so we can use the available space on the rack as efficiently as possible and position the wash items optimally for washing. If these models are not yet available, we measure the wash items on site using the latest 3D scanner technology.

For production release, you will receive the CAD drawings with the exact position of the items to be washed. This enables you to create clear loading SOPs very easily.



Original

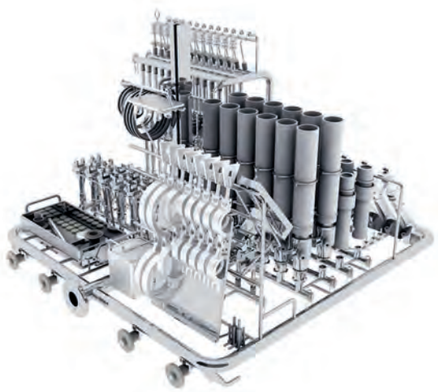
CAD



Display of a wash rack

Belimed Life Science Exchange Systems – Space-saving storage for flexible wash item loading

Defined positions of the wash items are required for reproducible washing. For this purpose, a lot of special holders are attached to the rack, whereby flexibility is often lost. In addition, such racks require a lot of storage space in controlled areas when not in use.



Belimed Life Science offers the ideal solution with its Exchange systems:

- defined positions for each wash item on compact Exchange system racks.
- identical water consumption for each Exchange system allows to validate the loads in different combinations
- only one basic system, the universal base can be stored in a space-saving manner
- High flexibility for changing washing goods

Each Exchange system is inserted into the universal rack system with a few simple steps and can also be loaded in advance. This saves time and at the same time prevents unnecessary mistakes from being made. An internal O-ring seal ensures loss-free transfer of the washing liquid to the attached nozzles.

Belimed Prevent™ – because caution is better than leniency

Belimed Prevent Services™ offer a comprehensive portfolio of services covering preventive maintenance, operational services and life cycle management. These services are designed to improve the performance of your Belimed Life Science equipment, reduce downtime and improve the performance of your Belimed Life Science PH washer.

The main advantages

✓ **Comprehensive service packages**

Belimed Prevent Services™ offers a comprehensive portfolio of services covering preventive maintenance, operational services and life cycle management. These services are designed to improve the performance of your machine, reduce downtime and create real value throughout the entire life cycle of your machine – allowing you to focus on your core business.

✓ **Total Cost of Ownership**

One of our main goals at Belimed Life Science is to support our customers throughout the entire life cycle of their equipment and to promote the benefits of technology and total cost of ownership (TCO). To measure the performance of equipment and reduce operational and financial risks, customers of Belimed Life Science are more and more interested in long-term service contracts nowadays.

✓ **A global network of experts**

Our worldwide service network of regional subsidiaries and authorized partners ensures that our trained and certified service technicians react quickly to your requirements and provide spare parts at your location. In addition, our global support team is available to assist you with technical questions – whenever and wherever necessary.

Maintenance packages

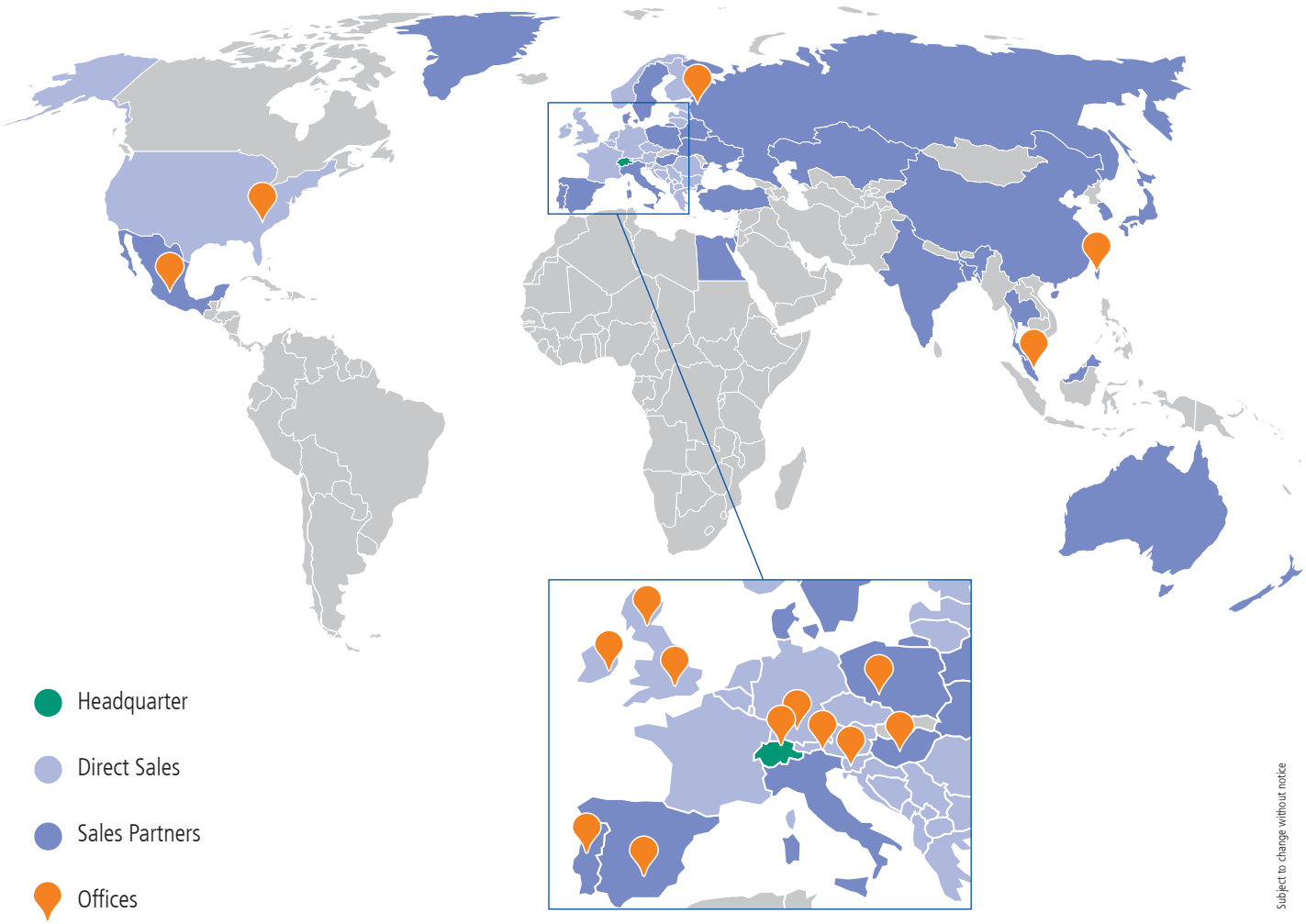
Belimed Life Science has developed a range of flexible service plans to keep your equipment running. From preventive maintenance and repair work to comprehensive all-inclusive packages.

Lifecycle Services

Extended warranty contracts ensure cost transparency for Belimed Life Science machines over longer periods (2-10 years). In addition, our retrofit packages prevent the equipment from becoming obsolete and avoid expensive downtimes.

Operating services

Consultancy services to help optimise equipment performance and ensure compliance with specifications and latest regulatory requirements is guaranteed.



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