



GMP Washers for Parts and Containers

Biopharmaceutical and Pharmaceutical Industry



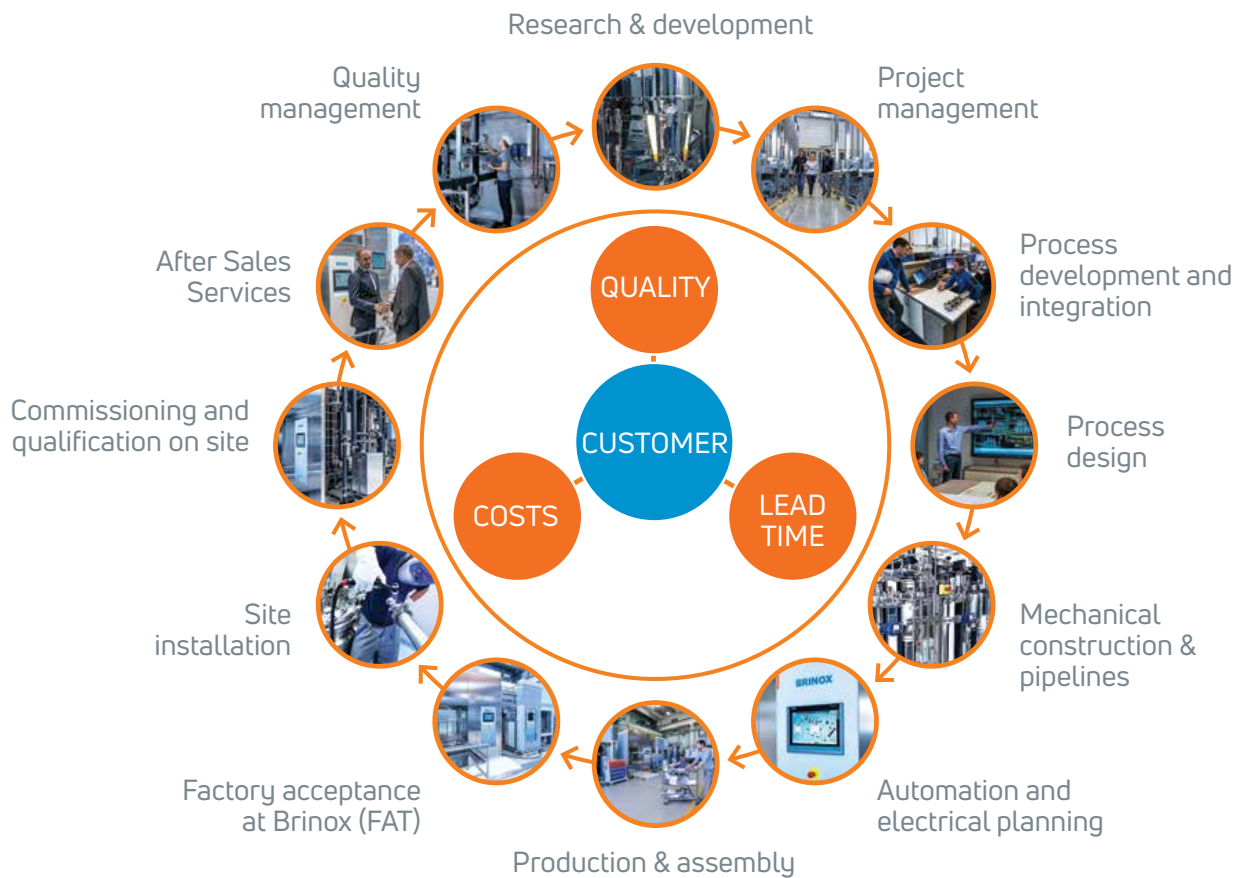
Technology that delivers



BRINOX



"One-Stop-Shop" - Brinox Integrated Turn-Key Approach



Our Experience is Your Advantage

With over 40 years of experience, the Brinox team excels in designing and manufacturing equipment for the biopharmaceutical, pharmaceutical, food & beverage, and chemical industries. Brinox Cleaning Systems are meticulously designed and constructed as customized system units, and completed as fully automated solutions. Our systems ensure optimal cleaning of various equipment integral to pharmaceutical processes and applications. Each Brinox Cleaning System embodies our commitment to quality, versatility, and innovation, meeting the diverse and evolving needs of our industry clients.

"Brinox Cleaning Systems", a trusted brand for an array of washing machines and automated cleaning solutions, caters to a broad spectrum of wash items:

- Intermediate Bulk Containers (IBC) in all shapes and sizes
- Stainless steel and plastic barrels
- Various types of vessels
- Transport pallets
- A comprehensive range of devices, tools, machine and format parts for pharmaceutical manufacturing including tableting, liquid filling machines, and packaging lines.
- Weighing tools and devices for use in weighing areas, filling lines, development labs, etc.
- Flexible pipes and hoses
- And many other specialized items

Advantages and Competencies

Brinox's own R&D department ensures adherence to cGMP, FDA, EMA and GAMP guidelines. The GMP washers are produced using state-of-the-art manufacturing machines.

Brinox Cleaning Systems (BCS) provide pre-cleaning, washing, rinsing, drying, and cooling steps. The cleaning of IBC containers and other washing items, and the washing system itself, is achieved through efficient water spraying, the use of various cleaning agents, the right temperatures, and optimum durations for each process step of the automated programs.

Brinox Cleaning Systems are characterized by high-quality manufacturing, cutting-edge hygienic design, optimum use of water, cleaning agents and energy media, and short cleaning times. The system is rounded off with the simple and user-optimized control by means of a touchscreen (HMI). Individual customer wishes and requirements are the basis for the final design of the machine.

A modern control system and a dedicated software give the user an array of options to create their own individual cleaning programs. After installation at the customer's site, the BCS is qualified with the support from Brinox. The cleaning system is then ready for use and guarantees a consistent quality and repeatability of the cleaning programs.

Brinox develops, produces and tests custom-made racks for various washing items, also for non-Brinox washers.

A link between BCSs and the customer's IT system (MES) ensures effective supervision, monitoring and archiving of all cleaning procedures and report parameters. Brinox BCSs support the use of electronic signatures per FDA 21 CFR Part 11.

Our comprehensive customer service ensures a high level of customer satisfaction, even after commissioning, and ensures high availability of the BCSs. As a competent full-service provider, Brinox also provides qualification and validation services.



Different Models of GMP Washers

BWS 707 • BWS 710 • BWS 810 • BWS 910
BWS 912 • BWS 1212

For cleaning of format parts of filling lines, different parts of tableting and capsule-filling machines, punches and dies, instruments and machine parts, bottles, stainless steel barrels, plastic vessels, funnels and flexible hoses.

- Single-chamber machine with single or double door execution and with vertical or horizontal sliding glass doors
- Electric, steam or combined media heating
- Technical compartment can be integrated on the left or right side
- BWS 710/810/910B/912B can be designed with an extended chamber height/depth





BWS 1018 • BWS 1318 • BWS 1322 • BWS 1622

For cleaning of IBCs, stainless steel barrels, boxes, pallets, and large machine parts.

- Single or multi-chamber machines with different chamber sizes
- Machines with single or double door execution
- The machines are built flush with the floor or installed in a pit
- Machines with additional buffer tanks
- for faster cycle times
- Transport systems for automated loading/unloading of the chambers, solutions for automatic opening of covers, flaps and split butterfly valves (SBV)
- With integrated cleaning of the interior/exterior and drying

Development and Manufacturing Process of Washing Racks

The use of washing racks is very important for the efficient cleaning, as they ensure the correct, repeatable and stable placement of all wash items. Based on our long experience and our flexibility in the development and production process, we are able to manufacture racks even for washers from other manufacturers, within a very short period of time.

Detailed design and manufacturing process:

- Scanning of all washing items at customer site
- Creation of the List of Washing Items (LWI)
- Creation of a 3D presentation of the rack loading
- DQ of the loading by the customer
- Final design and manufacturing of washing racks
- Riboflavin test and final inspection of the pipework
- Electro polishing
- Handover of the documentation to the customer



Advanced Customized Rack Design

Brinox has a track record of tackling even the most complex cleaning challenges. Our reputation has led us to receiving orders for rack designs even for non-Brinox washers.



Cutting-edge Hygienic Washing Chamber Design



- Interior of the chamber and tank made of mirror-polished 3mm sheet metal with round corners R20
- Extruded chamber inlets with radius
- No dead legs and dead spaces
- No screw connections and no protective plates
- All wetted surfaces have an incline, such as the chamber floor / ceiling, pipes, etc.
- Welds smoothed and polished, no visible weld spots in the chamber
- No heating element in the chamber
- Surface roughness:
Chamber surface $Ra \leq 0.8 \mu m$
Welds $Ra \leq 0.8 \mu m$
- Material: 316L - 1.4404/1.4435
- All plastic parts have FDA certificates
- Tank level monitoring (min./ max./ safety) via frequency fork switch
- Electropolished chamber (optional)

Innovative Docking System for Washing Racks



- Patent-pending solution by Brinox
- 100% sealing, even with low water pressure of less than 0.5 bar
- Water-driven mechanism, no compressed air support required
- Transfer of high water pressure, max. 4 bar
- No dead space, 100% cleanable and drainable



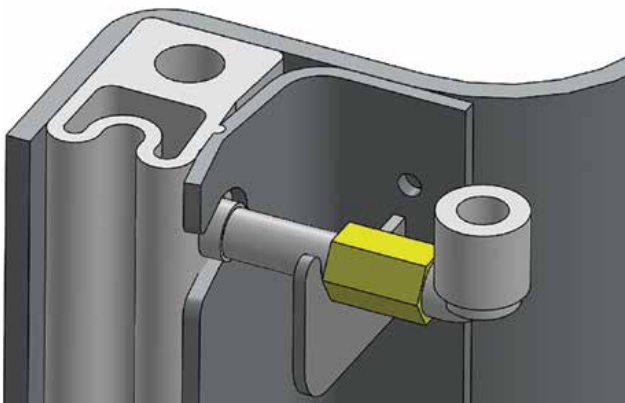


Sanitary Water Heating System

- Electrically or steam-heated double tube sheet heat exchangers (DTS) manufactured by Brinox for water heating
- Material: 316L - 1.4404/1.4435, $R_a \leq 0.8\mu\text{m}$
- Temperature control and regulation via PT-100 sensor

Safe Door Design and Sealing

- Vertical sliding doors BWS707/710/810
- Horizontal sliding doors BWS910/912/1018/1318/1322/1622
- Made with safety glass
- Integrated protection safety bar, $\leq 150\text{ N}$
- Inflatable seal with pressure monitoring
- Maintenance-free seal for easy replacement in the event of repairs without glue
- Interlock between loading and unloading door
- Gas-tight wall for separation of cleanroom zones



Final Rinse

Various final rinse approaches allow selection of the most efficient solution for each customer application.

In a recirculation process:

Final rinse with the washing pump for rinsing water circulation. Draining of the tank after each rinsing step.

- Low connection value (20 L/min) required, high efficiency grade, low water consumption (< 100 L)

Single-Pass directly into the drain:

WFI is used directly from the loop for rinsing. The rinsing water is not circulated through the washing pump.

- High connection value (150- 200 L/min) required, small efficiency grade, high water consumption (300- 500 L)

Single-pass directly into drain using pulsation technique:

The inlet pipe is filled with rinsing water and then purged with sterile compressed air. Recipe set-up for alternating pulsation sequences of water/ compressed air/ water/ compressed air etc.

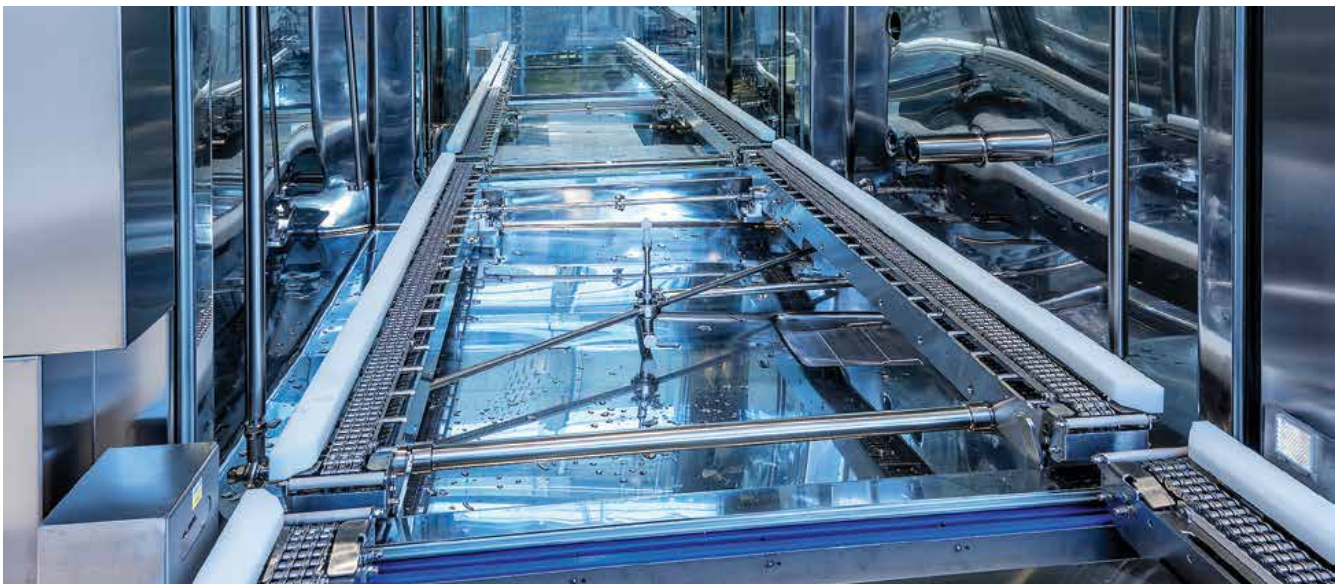
- Low connection value (20-50 L/min) required, improved efficiency grade, low water consumption (80 L)

Single-pass directly into drain using additional buffer tank:

A buffer tank is filled and then pumping the rinsing water into the spray system without recirculation.

A heated buffer tank is available.

- Low connection value (10 L/min) required, improved efficiency grade, low water consumption (100 L)



Washing and Rinsing System

The external surfaces of IBCs and vessels and the items on the washing rack are cleaned and rinsed using self-rotating washing heads and rotors. These are installed on the walls, ceiling, and bottom of the chamber.

Brinox's patented non-round spray nozzle design maximizes the mechanical cleaning effect. It helps reduce wash times and detergent/ water consumption.

Internal cleaning of IBCs is performed by a 360° rotating nozzle, which moves vertically into the IBC for cleaning. Both the up/down lifting movement and the rotational movement are monitored. In case of a failure, an alarm message will be triggered.

The connecting flange on the side of the washing rack is automatically connected with the chamber connection and guarantees a constant supply of the cleaning medium.



Piping, Valves and Pumps

- Single-pipe system for washing, rinsing, drying
- Completely self-draining, with a 2% slope
- No dead ends, compliant to 3D rule
- Complete piping system made of 316L stainless steel - 1.4404/1.4435, $R_a \leq 0.8 \mu\text{m}$
- Pneumatically operated aseptic diaphragm valves from GEMÜ
- Standard compressed hot air purging of the pipe system for better drying
- Standard Tri-Clamp connections; Bioconnect® flanges (optional)
- Orbitally welded piping whenever possible
- Hot pipes are thermally insulated with Armaflex HT, temperature max. 150°C, fire class B2, CFC and PVC-free
- Reduced delta ferrite <3% (optional)
- Electropolished piping (optional)
- Passivation of the pipework
- Standard version with frequency-controlled pump
- Pump housing without dead legs
- Gap-free sealing surfaces
- Cavitation-free operation up to +85°C; optionally up to +93°C
- Fully self-draining
- Pump pressure: up to 4.0 bar
- Pump capacity: between 360 L / min - 830 L / min

Sensors

- GMP-compliant positioning of E&H sensors:
 - Tank level sensor
 - Pump pressure sensor
 - Conductivity measurement for dosing cleaning agents and final rinse
- Washing and rinsing temperature
- Drying temperature
- No dead volumes or gaps due to the flush wall installation
- Conductivity sensor installed without protective pipe
- EHEDG (Hygienic Design)-compliant
- Installation with gapfree flanges or NeumoBioControl® sterile process connections
- TOC measurement of final rinse (optional)

Conductivity Measurement of Final Rinse Water

- Conductivity probe inside the washing chamber
- Conductivity probe in the circulation line
- Conductivity probe in the drain

The final rinse water is filled into the chamber and the conductivity of the water is measured during rinsing. At the end of the final rinse the max. conductivity is measured. The conductivity target value or the number of final rinse cycle repetitions is defined in the program recipe.

The conductivity probe can be installed in the washing chamber or in the circulation loop, depending on the customer's validation standards.

During the single-pass final rinse, the rinse water flows continuously from the loop line of the building or from the water tank directly into the drain.

A conductivity sensor is installed in the drain line of the machine in a bypass, measuring the maximum conductivity value.



Dosing System for Cleaning Agents

- Dosing of detergent directly into the circulation line for homogeneous distribution
- Direct dosing is recommended for the first circulation of the washing solution with cleaning or anti-corrosion agent:
 - when cleaning hydrophobic contaminations
 - to prevent corrosion of tableting tools through contact with pure PW or WFI water
- Up to 4 dosing pumps with cleaning agent monitored via integrated volume flow meter
- Dosing from canisters, separate dosing station or loop possible
- Suction lance on the container with low and empty level indicator
- Cleaning agent pipework made of stainless steel
- Mass flow meter for precise dosing
- Easy calibration via the HMI



Media Sampling

PW/WFI sampling from the inlet line:

- Sampling through the pneumatic valve in the technical area
- Sequence of the water sampling (pipe cleaning, sampling, purging with compressed air)
- User friendly sampling box in the front panel of the washer on the loading side (optional)

Wash solution sampling from the recirculation line:

- Sampling point in the machine's technical area
- Ergonomic height position of the sampling valve

Taking samples of single-pass final rinsing water:

- Sampling point at the bottom of the tank
- Accessible from loading side

Compact Drying System

- Integrated drying and cooling (in bypass, optional) unit with fan
- Air intake from technical area, from HVAC system, or from outside
- Pre-filter G4 and HEPA filter H13 (standard, 99.95% retention) according to EN 1822:2009
- Heating with electricity or steam
- Material: 316L – 1.4404/1.4435
- Temperature range: 80 - 120°C
- Temperature probe PT100, 4 leads
- Differential pressure monitoring and connections for DOP / DEHS test of the HEPA filter
- Air volume: between 250 m³/h - 1200 m³/h
- 100 % flap cleaning during the cleaning process
- Heating of the compressed air for purging pipes and washing items such as hoses
- Considerable batch time reduction by active cooling of wash items (optional)



Operation & Control

- There is a touchscreen HMI 15" with industrial PC on the loading side and a touchscreen HMI 7" on the unloading side
- In addition, the system status is indicated by means of a clearly visible coloured light strip
- The machine is controlled by a PLC controller produced by Siemens type S7-1500 PLC
- Allen Bradley PLC and HMI (optional)
- The main control cabinet is located in the technical area of the machine next to the control panel
- The switch boxes with the ET 200 SP I / O module are integrated into the technical area of the system
- Through an ethernet, the control system can be connected to the central archiving and data processing system in compliance with FDA 21 CFR Part 11



Cleaning Recipes

The individual cleaning recipe parameters such as type of water used, process temperatures, duration, pump pressure, type of detergent, detergent concentration and conductivity thresholds can be defined individually for each process step and can be chosen freely.

The Individual Program Steps

- Pre-cleaning
- Washing
- Rinsing
- Purging
- Drying
- Cooling

Can be combined with each other as required in a recipe.

Our process specialists will support in creating a recipe with optimum cleaning efficiency.

Process Control and Documentation



The process control system is based on an open SCADA/PLC platform with GE iFix SCADA. All directives and norms as well as the state-of-the-art are the basis:

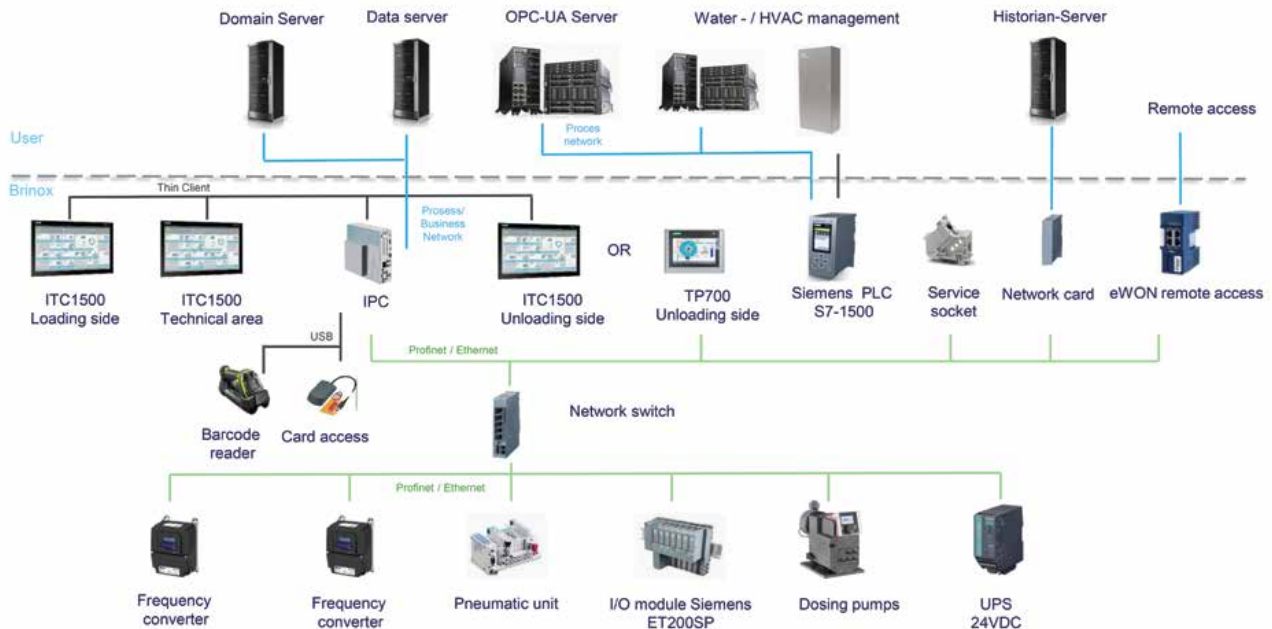
The automation system provides:

Advanced SCADA visualisation and manual intervention for individual component control: Every controlled valve / motor can be manually controlled from the SCADA level. For testing purposes and in cases of production issues sensor values can also be forced.

- The following process parameters are monitored and controlled:
 - Temperature probe, PT-100 class A
 - Water pressure in all washing steps
 - Detergent concentration
 - Washing solution conductivity (optional)
 - Water conductivity in final rinse step
 - Pressure drop on HEPA filter
 - Rotation of spray arms/ nozzle of cleaning lance
- HEPA Filter differential pressure control
- The recipe management system provides high flexibility when creating recipes, and this allows for optimized cleaning sequences for many different applications
- The use of a SQL-database is the foundation for a virtually unlimited number of recipes. The recipes are subject to a pre-defined approval process with E-signatures and automated versioning. Recipes can be activated or inactivated.
- Electronic batch reporting and the audit-trail system provide complete batch reports in electronic or printed form
- FDA 21 CFR Part 11 compliance with access control based on Windows security.

Interface to other systems:

- Domain server
- PW/WFI water system supply
- Control system interfaces with site utilities like water, HVAC, power
- Data server/ central SQL Database
- Historian server
- Integration in distributed control system (DCS) or Emerson's DeltaV™ Automation Platform
- Automated recipe selection based on product information transmitted directly from the building MES
- Allen Bradley PLC and HMI (optional)



Brinox washing machines can be connected to an MES system. Three types of interfaces are supported – OPC or database interface, or fully adapted. The recipe selection is predefined by the MES system based on a barcode. The barcode is mounted on the washing rack and will be scanned automatically or captured manually by the operator. A fully automated workflow is achieved in this way, eliminating possible operator errors.

Control systems

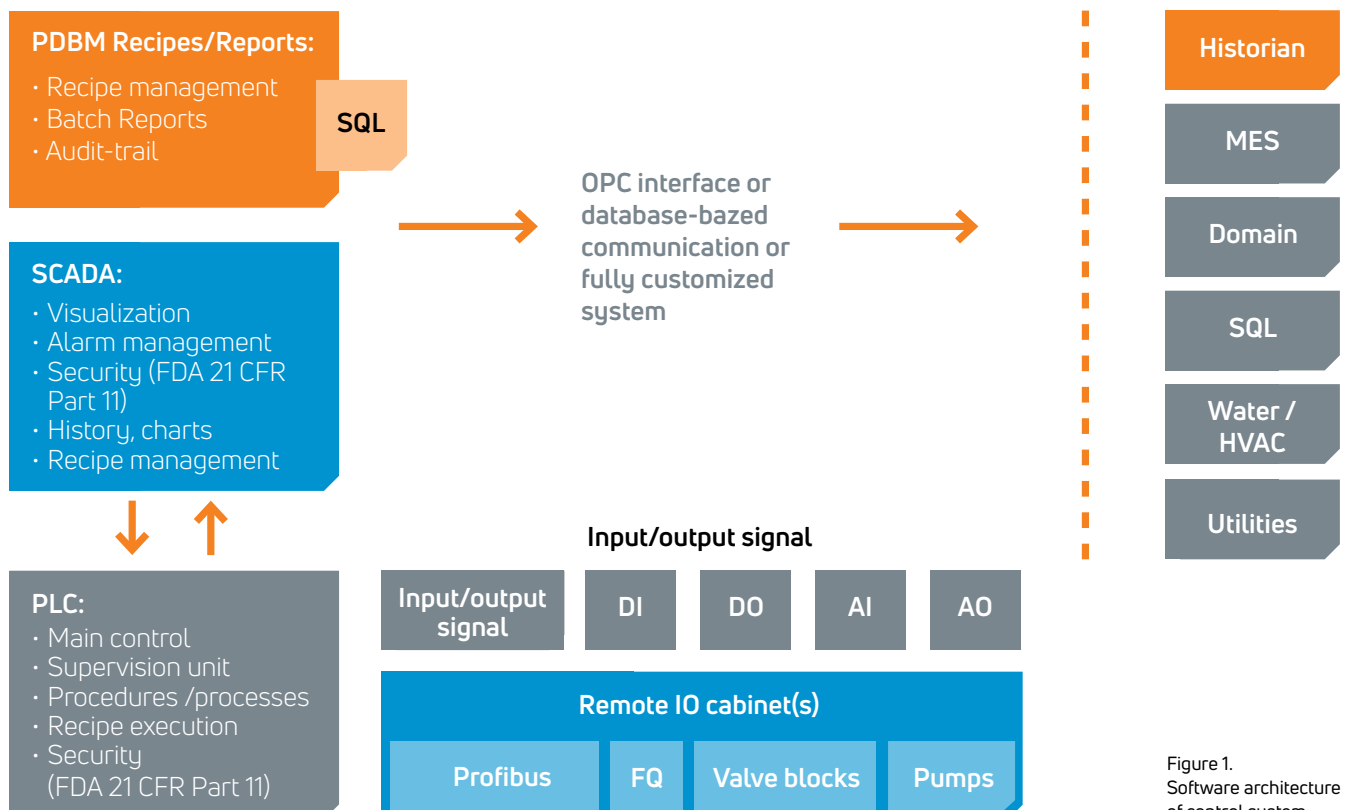


Figure 1.
Software architecture
of control system

Documentation

Qualification documents

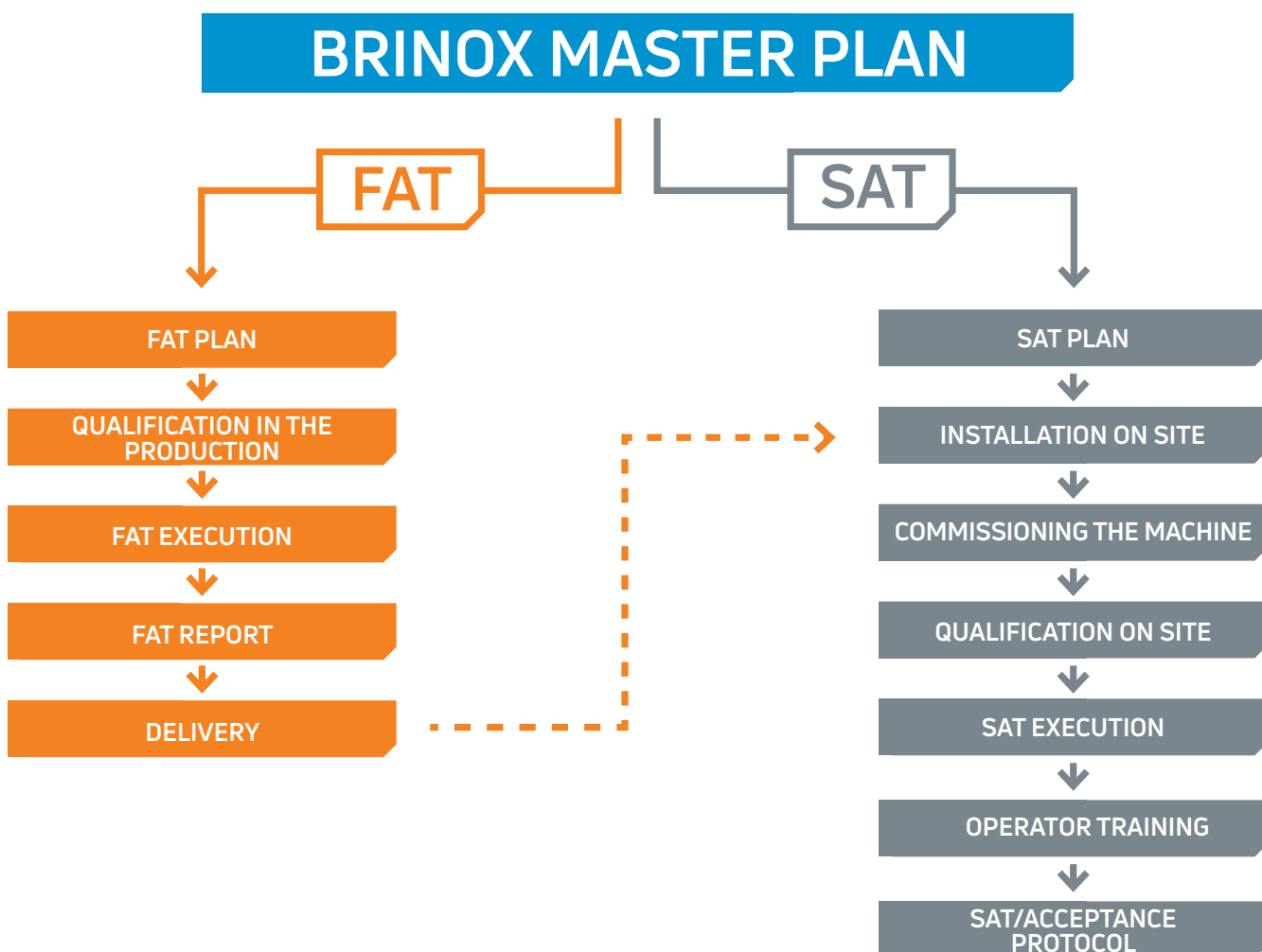
- Qualification master plan
- DQ - Design Qualification (Layout, P&I diagram, electrical diagram, FDS, HDS, SDS, etc.)
- FAT/SAT documents
- IQ – documentation
- OQ – documentation

System documentation

- Material certificates 2.1, 2.2 or 3.1
- FDA certificates of conformity for non-metal parts
- Welding documentation
- Video endoscopy

User documentation

- Operating and maintenance instructions
- Alarm list
- Spare parts list
- Trouble shooting list
- Warranty certificate and compliance statement



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Combined Cleaning System

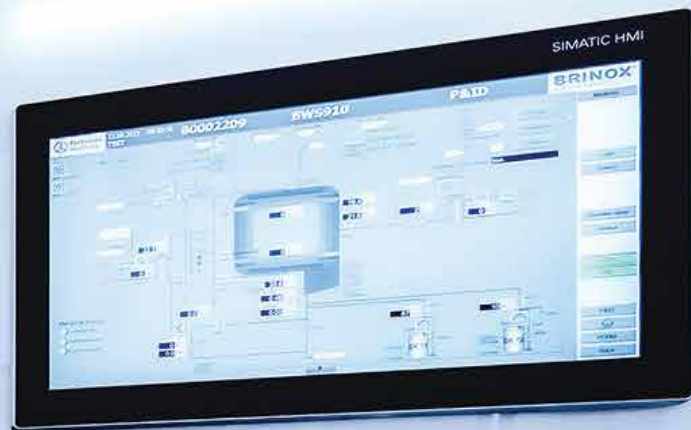


BWS 912 B / 1212

- Cleaning system for parts/components with additional external cleaning system for an independent cleaning of mobile vessels and containers
 - Increased cleaning throughput due to the parallel, autonomous cleaning and drying of the
- two cleaning systems (chamber + external)
 - External cleaning system incl. the dosing of cleaning agents, pump pressure monitoring, conductivity measurement, water heating and drying
 - Validatable process



BRINOX



Technical specifications are subject to change without notice.

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BRINOX®
process systems

Brinox Innovations AG

Poststrasse 14
6300 Zug
Switzerland
T: +41 41 727 81 50
info@brinox-innovations.ch

Brinox d.o.o.

Sora 21
1215 Medvode
Slovenia
T: +386 1 361 97 30
info@brinox.eu

Brinox USA, Inc.

101 S. Tryon St.
Charlotte, NC 28280
United States of America
T: +1 704 898 3698
info@brinox-usa.com

Brinox Deutschland GmbH

Maria-und-Georg-Dietrich Str. 2
77652 Offenburg
Germany
T: +49 781 970 678 10
info@brinox.de