PHARMA & BIOTECH

OSMOTRON® PRO

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Professional Process Management for your Production

For You and Planet Blue.



With the launch of OSMOTRON[®] in 1996 BWT Pharma & Biotech offered the first skid-mounted system for the production of pharmaceutical water. At present more than 1000 systems are in use across the world. OSMOTRON[®] PRO is the completely reengineered product line which was developed to ensure ergonomic, economic and environmental qualities.

The unique design that along with many other advantages makes this system distinctive ensures that OSMOTRON® PRO, with its many technical innovations, is the most attractive Purified Water system of all times. Various additionally available options offer advanced possibilities and make the system operation safer, more energy-efficient and easier.

OSMOTRON[®] PRO processes involve pretreatment via softening and microfiltration stage followed by a reverse osmosis stage and a final demineralization via the patented SEPTRON[®] EDI module. This process technology meets current USP and European Pharmacopoeia requirements in a safe and reliable way. Each system is pre-qualified before shipment and undergoes a full functional FAT test at our factory.

OSMOTRON[®] PRO is available in various standardized versions with nominal outputs from 500 l/h to 9,000 l/h. Larger capacities or customer specific requirements for specific projects can also be accommodated.



OSMOTRON® PRO – Standardized Types for Every Application

OSMOTRON® PRO PW

for production of Purified Water includes following process steps: Backwash filter, Serial working softener, 5µm-security filter, Reverse Osmosis, SEPTRON® EDI-Technology

OSMOTRON® PRO HPW

for production of Highly Purified Water with SEPTRON®-BioSafe EDI-Technology with integrated Ultrafiltration-membrane unit

OSMOTRON [®] PRO Standardized Types	Execution	Sanitization Softener	Sanitization RO/EDI
OSMOTRON [®] PRO PW-Basic OSMOTRON [®] PRO HPW-Basic	Basic version in plastic, Stainless Steel after EDI Regular Grade of Automation	Chemical / SANISAL P	Chemical
OSMOTRON [®] PRO PW OSMOTRON [®] PRO HPW	Softener in plastic, RO/EDI in Stainless Steel Highest Grade of Automation	Chemical / SANISAL P	Chemical
OSMOTRON [®] PRO PW-S OSMOTRON [®] PRO HPW-S	Softener in plastic, RO/EDI in Stainless Steel Highest Grade of Automation	Chemical / SANISAL P	Hot water
OSMOTRON [®] PRO PW-2S OSMOTRON [®] PRO HPW-2S	Completely in Stainless Steel Highest Grade of Automation	Hot water	Hot water

OSMOTRON® PRO – Many Innovations giving you a lot of Advantages

OSMOTRON[®] PRO was developed to ensure optimal ergonomics and optimal energy efficiency.

Highlights

- Compact, standardized, prefabricated system, fully tested and prequalified before delivery.
- All process steps arranged on one skid, including pretreatment, softening, filtration, membrane stage and final demineralization via the patented SEPTRON[®] EDI module and control cabinet.
- SEPTRON[®] pharmaceutical grade EDI technology for PW production, optional as SEPTRON[®] BioSafe with integrated membrane stage and highest microbiological safety for HPW production.
- Advanced AQU@VIEW automation solutions with validated and user friendly AQU@VIEW software in combination with all visualization systems (Siemens, Rockwell etc.). Additional options like data archiving, audit trail, data exchange or remote control can be added easily.

Ergonomics and Design

- All parts and sampling points of OSMOTRON[®] PRO ensure optimum access, which facilitates maintenance and sampling.
- Functional, clear and orderly design with integration of cable ducts and sewage drains in the frame.
- Easy sampling: all quality relevant samplings are integrated on a central panel.
- Easiest handling via PC panel and user friendly AQU@VIEW-Software.



Easiest sampling of all quality relevant sampling points due to the central panel.

The sewage drains are integrated into the frame allowing for clear design and less pipework.



Efficiency and Sustainability

- Thanks to its efficient rinsing method applied during production and in idle time for EDI and RO stage the recovery of OSMOTRON[®] PRO exceeds 70% in the basic version.
- With additional concentrate processing stage total recovery can be increased to 90%. As a result, due to reduced feed water and waste water levels, operational costs are even lower.
- One of the available options includes performance regulation via tank volume. This allows to operate the system using the optimum performance mode of 70 to 100% and thus ensures continuous production as far as possible. As a result operational costs are additionally optimized thanks to reduced feed water and waste water level and low energy consumption.
- On an optional basis the softeners can be equipped with the new developed MULTIJOINT block valves which allow alternating operation of the working and safety filter. This reduces regeneration cycles and leads to savings in regeneration salt, feed water and waste water.

Modularity and Flexibility

- The modular concept ensures easy adjustment to customer's specifications.
- Various options can be added easily as required.
- The modular design allows easy capacity expansion within the standardized sizes of 500 - 1,500l/h, 3,000l/h - 6,000 and 8,000 - 9,000l/h. The system can be easily adopted to an increased water demand.
- Units for larger capacities or customer specific requirements are designed on a project basis.
- The construction can follow country specific requirements (e.g. ASME standards).



The MULTIJOINT block valves provide deadleg-free construction and highest microbiological safety.

Safety

- The system adjusts automatically to the variable raw water conditions (e.g. pressure, temperature and conductivity).
- OSMOTRON® PRO offers intelligent and simplified process management with the shortest possible distance between water input and output, water is continuously flowing through all pipes in contact with water both during normal operation and during recirculation, giving the highest microbiological safety (see diagrams 1 and 2 below).
- The MULTIJOINT block valves in 316L stainless steel substitute 8 single valves, which reduces deadlegs, facilitates emptying process, improves flow and minimizes piping.



Diagram 1: Normal operation - Filling the storage tank



Diagram 2: Recirculation – Storage tank full

Your benefits with OSMOTRON® PRO

- The highest possible operational safety
- Facilitated handling due to advanced automation and easier solutions
- Low operational costs
- Short lead times due to standardized, prefabricated units
- Modular expandability
- Simplified acceptance by authorities and straightforward auditing



All aggregates and components are perfectly accessible for maintenance work.



Heart of the System – The Unique SEPTRON® Module

SEPTRON[®] is a patented EDI module, manufactured exclusively by BWT Pharma & Biotech. SEPTRON[®] is the only spiralwound EDI module manufactured in Europe and is a high quality Swiss product. It has been specifically developed for generation of pharmaceutical Purified and Highly Purified Water.

Various sizes of the SEPTRON® modules ranging from 150 to 4,000 l/h ensure optimal system configuration.

In addition to the excellent water quality the SEPTRON® module offers further advantages:

- Significant reduction of CO₂ and SiO₂ levels
- Excellent TOC reduction = compliance with the USP limits, also with high TOC content in raw water
- High degree of regeneration thanks to the homogeneous electric field = the highest possible water quality
- Low voltage (< 100 V) = more safety</p>
- Space saving, compact design
- 316L stainless steel housing
- Seal-free, spiral-wound technology
- 100% factory tested and certified





OSMOTRON® PRO HPW with SEPTRON® BioSafe – For Best Water Quality

With SEPTRON[®] BioSafe, BWT Pharma & Biotech offers the first electrodeionisation module with an integrated ultrafiltration membrane stage in the world. Based on our proven and patented SEPTRON[®] module, it has been completed with a ultrafiltration membrane unit for particulate and germ removal as well as pyrogen reduction.

SEPTRON[®] BioSafe can be used together with reverse osmosis integrated upstream to achieve Highly Purified Water quality (HPW) with germ counts of \leq 10 CFU/ 100 ml. In contrast to traditional HPW treatment systems, cold and hot water SEPTRON[®] BioSafe modules have the advantage of achieving a high pure water quality at low investment, operational and energy costs in combination with a space-saving, compact design. SEPTRON® BioSafe is particularly suitable for pharmaceutical applications where efficiency and low effort are important. An upgrade is possible easily. The membrane stage is exchanged by our technicians in the scope of routine maintenance of the high-purity water system to ensure long-term freeness of germs. The unit is replaced without being touched, using a special replacement system; GMPcompliant operation is thus always ensured. The user does not have to perform any work at the system.



SEPTRON® BioSafe is used by default in the OSMOTRON® PRO HPW for the production of Highly Purified Water.



Flexible Sanitization Concepts for your Quality Demands

BWT Pharma & Biotech offers various solutions for the sanitization of system components.



SANISAL P tabs – for the simultaneous sanitization and regeneration of the softener.

Chemical sanitization

In the type OSMOTRON[®] PRO PW-Basic and OSMOTRON[®] PRO PW all process stages can be sanitized with chemicals.

The flexible sanitization concept allows individual sanitization of the softener and RO/EDI depending on the microbiological situation.

SANISAL P - combined safety for your softener system

A softener system that is controlled microbiologically prevents microbial contamination at subsequent stages of the process.

The chemical sanitization with SANISAL P provides increased operational and production safety.

SANISAL P is the first regeneration agent with 2 in 1 functionality for regeneration and sanitization in one go.

It is a perfect alternative to hot water sanitization. Contrary to this method SANISAL P can be applied in existing systems without the necessity to modify them.

SANISAL P offers the following advantages:

- The easiest possible application (like a regular softener salt)
- Automatic sanitization during each regeneration
- Integrated protection of the brine tank
- Perfect alternative to more expensive thermal or chemical sanitization methods
- Increased operational and production safety
- Low investment and energy costs
- Also applicable in existing systems



Hot water sanitization

Hot water sanitization of water treatment systems has several advantages compared with chemical sanitization:

- The process can be simply monitored with the aid of an integrated temperature measurement. This allows fully automated operation.
- Hot water reliably prevents the development of biofilms
- No need to rinse out chemical agents
- Simple and reliable process validation

BWT Pharma & Biotech offers various hot water sanitization options:

- OSMOTRON® PRO PW-S comprises hot water sanitization at > 80°C of the demineralization stages of reverse osmosis and electrodeionization (as well as of the UF stage of the OSMOTRON® PRO HPW)
- OSMOTRON[®] PRO PW-2S also includes a softener stage in hot water sanitization version at > 80 °C

As microbiological situation between the process stages is different, the process stages can be sanitized independently. The flexible sanitization concept allows individual sanitization of the softener, RO and EDI.



Efficient Options for highest Efficiency, Safety and Operation Comfort

Output and WCF regulation

Output regulation allows to run the OSMOTRON® PRO system at minimum capacity in recirculation mode with full tank. Furthermore, the OSMOTRON® PRO system can be operated by means of a variable Water Conversion Factor (WCF) thanks to the availability of the WCF regulation function. It reduces water consumption during recirculation by approx. 75% and lowers electrical power consumption by approx. 40%, due to reduced capacity and increased WCF in recirculation mode.

Performance regulation via tank level

One of the available options includes performance regulation via tank volume. This allows the system to operate using the optimum performance mode of which ensures continuous production as far as possible. As a result operational costs are further reduced thanks to low waste water level and low energy consumption.

ECOSALT C hardness monitor

ECOSALT C is a online measuring system with a continuous measurement cycle every 30 seconds. Contrary to the regular residual hardness measuring devices ECOSALT C does not use up indicators and monitors its own measuring functionality, thereby ensuring an absolutely reliable monitoring of the softener function.

ECOSALT C prevents damages to the subsequent membrane stages due to reliable and permanent control of the softener.

MULTIJOINT block valves

The standard version of the OSMOTRON[®] PRO is equipped with MULTIJOINT block valves, in 316L stainless steel for the final process steps.

On an optional basis the softeners can also be equipped with MULTIJOINT block valves in polypropylene for enhanced reduction of deadlegs, improved flow, reliable operation and reduced operation cost due to reduced regeneration cycles for the softener.

AQU@VIEW automation solutions

AQU@VIEW automation solutions include additional options like data archiving, audit trail, data exchange or remote control which can be added easily as required.



With the AQU@VIEW software all process conditions can be easily monitored and registered.



An optional membrane degassing stage removes high CO₂ concentrations.

Innovative Technology Combined with Comprehensive Services for Successful Projects

Innovative technology is one key to success, but experience and services are the others. BWT Pharma & Biotech has the expertise and specialists to deliver you a successful project.

Engineering and Project Execution

From concept studies to planning and dimensioning to detail engineering and project execution.

The specialists and experts of BWT Pharma & Biotech cover all fields of engineering. Process engineers, automation engineers, mechanical engineers, validation engineers, project managers among others take care of our customers projects and bring them to a successful conclusion.

Documentation and Validation

Consistent documentation and compliance with the regulations and guidelines like cGMP, GAMP, USP and Eur. Ph. Requirements, ISPE Engineering Baseline Guide, Vol. 4 "Water and Steam Systems". We create the conditions to make sure you experience a successful inspection of your system.

Qualification of each project follows the "V-model", from URS to the final FAT/SAT which is carried out before the system is finally handed over to the customer.

Full Production Facilities and Quality Assurance

All factories of BWT Pharma & Biotech use the latest technology for production of the systems. The final assembly of the systems in the factory, including commissioning and the FAT, results in pre-qualified complete systems.

In combination with our Quality Assurance System we can ensure the highest quality is delivered for our customers satisfaction.

IQ/OQ, SAT and Training

The on-site services include commissioning, start up, IQ/ OQ, SAT execution and training.

Training of the operating personnel by experienced service engineers is one key to ensure reliable and trouble-free operation.

Even after handover of the system BWT Pharma & Biotech remains your reliable partner for various service and maintenance packages with individual levels of support, based on your needs.





BWT – the Company

Best Water Technology Group (BWT) is Europe's leading water technology company. Our water partner network comprises the group's 3,300 employees and thousands of plumbers, planners, architects and hygiene experts. Our Research & Development teams, using state-of-the-art methods, work on new processes and materials to create products that are both ecological and economical. Looking ahead, a key development issue is a reduction in the products' use of operating resources and energy consumption and the resulting minimisation of CO_2 emissions.

Whether at the place where the water pipe enters the building ('point of entry') or at the tapping point ('point of use'), BWT's trend-setting 'Made in Europe' products have proved their quality millions of times over in the treatment of: drinking water, mineral water and ultrapure water for the pharmaceutical industry; water for swimming pools; heating and process water; boiler and cooling water; and water for air-conditioning. BWT's wide-ranging innovations guarantee maximum safety, hygiene and health in the daily use of water - that precious elixir of life. These innovations, among others, include: SEPTRON®, the world's first electrodeionisation module (EDI) with spiral wrap; manganese oxide activation (MDA) – a method for effective manganese removal; AQA total bipolar technology for chemical-free limescale protection; SANISAL – the world's first regeneration salt for softening water systems, which also works as a disinfectant; and the new, revolutionary Mg^{2+} technology

that improves the taste of filtered water, coffee and tea. Through its unique, high efficiency membranes for fuel cells and batteries, BWT is creating a cleaner, more sustainable energy supply for the 21st century.

BWT – For You and Planet Blue

signifies that our mission is to take ecological, economical and s ocial responsibility, to provide our customers and partners with the best products, systems, technologies and services in all areas of water treatment and, at the same time, to make a valuable contribution to preserving the global resources of our blue planet.



Find us on www.bwt-pharma.com

